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Korean Medical Consultation With Open-Weight Large Language Models: Pilot Comparative Evaluation of Retrieval-Augmented Generation With Metadata Filtering

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Abstract

Background: This study develops an open-source large language model–based chatbot tailored for Korean health consultations. The chatbot was implemented using the retrieval-augmented generation (RAG) technique alongside metadata filtering to enhance its performance.

Objective: This study aims to analyze and compare the performance of a RAG-based chatbot with other leading language models in the context of Korean health consultations.

Methods: A 10.4 GB Korean medical document corpus (487,277 segments) was constructed from official websites of major Korean hospitals, public health sources, and medical textbooks. This study quantitatively compared 5 open-source large language models (Qwen3:4B, Mistral:7B, Llama-3.1:8B, Gpt-Oss:20B, and Gemma3:27B) in 3 configurations: baseline (model only), RAG-only, and RAG with metadata filtering. The RAG system used a specialized Korean embedding model (upskyy/bge-m3-korean) and an Elasticsearch store. Performance was assessed by an emergency medicine specialist using a validation set of 226 questions across 7 common diseases and scoring responses based on accuracy, safety, and helpfulness.

Results: The application of RAG alone failed to yield statistically significant performance improvements and, in some cases (Llama 3.1: 8B and Gemma 3: 27B), resulted in decreased scores. However, the combination of RAG with metadata filtering yielded statistically significant (P<.05) performance increases in most models. Notably, the average score for Mistral:7B increased from 3.79, SD 0.08, to 4.10, SD 0.10, and Gpt-Oss:20B increased from 4.43, SD 0.05, to 4.51, SD 0.04, with the latter achieving the highest safety score (4.61, SD 0.03). The Gemma3:27B model, which possessed a high baseline performance (4.42, SD 0.03), was an exception, exhibiting no significant improvement (P=.14) even with filtering.

Conclusions: The effectiveness of RAG for specialized domains such as Korean medical consultation is highly dependent on a metadata filtering process that controls the quality of retrieved information; simple information augmentation is insufficient. Furthermore, the benefit of RAG is limited when a model's intrinsic knowledge (eg, Gemma3:27B) already meets or exceeds the quality of the external knowledge base. This finding indicates that performance enhancement strategies must account for both the retrieval mechanism's quality and the model's preexisting capabilities.

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KEYWORDS

large language model; LLM; retrieval-augmented generation; RAG; metadata filtering; health chatbot; Korean health care

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Introduction

Background

With the rapid advancement of artificial intelligence (AI), medical chatbots are playing an increasingly pivotal role in providing personalized health care consultations and managing patient data [1,2]. However, despite the overall progress of large language models (LLMs), a performance gap between English and Korean persists, as technical breakthroughs in high-resource languages do not inherently transfer to midresource languages such as Korean [3,4]. These limitations act as structural constraints when directly applying general-purpose LLMs to the Korean health care environment, particularly in their failure to sufficiently reflect local medical systems, legal regulations, and ethical standards [5,6].

Concurrently, South Korea's medical ethics, guidelines, and legal norms are closely integrated with highly standardized prescription and treatment protocols, which are intrinsically linked to the National Health Insurance reimbursement system, licensing requirements, and clinical guidelines from professional societies [7,8]. Consequently, standardized procedures and criteria often carry more weight than individual clinical discretion [9]. As a result, recommendations from general-purpose GPT-based models—primarily trained on United States or European guidelines—may conflict with Korean regulations, potentially suggesting interventions that are prohibited, not covered by insurance, or legally sensitive [10-12]. Such discrepancies pose significant risks, including information errors, misdiagnosis, and institutional misalignment, thereby compromising both patient safety and legal liability [13,14]. This misalignment represents a substantial barrier, revealing the structural limitations of applying general LLMs directly to the Korean health care context.

Furthermore, Korean medical inquiries are characterized by patients describing their symptoms, progress, and concerns in detailed narrative forms [15,16]. A primary challenge for medical chatbots is accurately extracting clinically essential information from such verbose text and matching it with the appropriate Korean medical guideline documents [17,18]. Specifically, as Korean is an agglutinative language with high morphological complexity—where medical vocabulary consists of a mixture of Hanja, loanwords, and native Korean terms—specialized text processing and retrieval technologies optimized for the Korean language are required [19,20].

Current LLM-based medical chatbots, including commercial models, primarily rely on pretrained internal knowledge. This often leads to "hallucinations"—generating factually incorrect information—and a failure to ensure reliability based on the latest domain-specific evidence [21,22]. Specifically, when consultation content pertains directly to a specific country's insurance standards, local medical systems, or locally used products and ingredients, simple learning-based response mechanisms struggle to guarantee the precision and up-to-dateness required for medical safety [10]. To address these limitations, the ecosystem has recently shifted toward state-of-the-art open-source LLMs such as Llama 3 (Meta), Mistral (Mistral AI), and Gemma (Google LLC), which allow for higher levels of customization, including on-premises deployment, domain-specific fine-tuning, and enhanced data privacy [23]. Nevertheless, even high-performance open-source models require architectural reinforcement, such as systematic integration with external knowledge, to ensure accuracy and safety in the medical domain. In this context, retrieval-augmented generation (RAG) is emerging as a promising solution [24]. By using dense retrieval techniques and Korean-specific embedding models, RAG enables chatbots to access refined medical databases, allowing this study to focus on generating fact-based responses grounded in prevalidated medical literature, guidelines, and local regulations [25].

However, RAG alone faces limitations in sufficiently processing the unique characteristics of Korean medical inquiries. As these inquiries are often long and narrative, with the patient's core intent frequently obscured by peripheral context (such as emotions or treatment experiences), simple vector similarity-based retrieval often fails to select the most appropriate evidence documents [26]. As a sophisticated enhancement to overcome this, metadata filtering has been proposed. This approach involves the LLM extracting structured metadata—such as clinical department, disease category, age group, and specific drugs or procedures—from the query and filtering the database accordingly before the retrieval stage, thereby narrowing the search space [27]. This ensures that the system performs retrieval and generation only on the most relevant subsets of documents, which significantly improves response accuracy and consistency, especially for complex, multistep medical questions [28]. Despite these developments, there is a lack of empirical research systematically comparing and evaluating the performance of various open-source LLM architectures that combine RAG with metadata filtering within the Korean medical context [29]. Furthermore, benchmarks and evaluation frameworks that reflect the unique characteristics of Korean medical inquiries are not yet sufficiently established [30]. We identified a research gap that necessitates an empirical validation of open-source LLM-based architectures integrating RAG and metadata filtering to design safe and reliable medical chatbots tailored to the Korean health care environment.

Objectives

Therefore, we aimed to develop and comparatively evaluate a Korean medical consultation chatbot architecture that integrates RAG with LLM-based metadata filtering to better align responses with Korean clinical information needs and locally grounded evidence. We constructed a Korean medical document corpus (10.4 GB; 487,277 segments) and implemented an RAG pipeline using a Korean-specialized embedding model with an Elasticsearch-based retriever, augmented by metadata filtering that extracts structured clinical cues (eg, disease-, symptom-, or drug-related signals) to narrow the retrieval space before generation. We then compared 5 open-weight LLM backbones (Qwen3:4B, Mistral:7B, Llama-3.1:8B, Gpt-Oss:20B, and Gemma3:27B) under 3 configurations—baseline (no retrieval), RAG-only, and RAG plus metadata filtering—to determine when retrieval and filtering improve Korean health consultation responses. Performance was validated on 226 Korean consultation questions spanning 7 common disease categories, with an emergency medicine specialist rating each response for

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accuracy, safety, and helpfulness using a predefined scoring protocol.

Methods

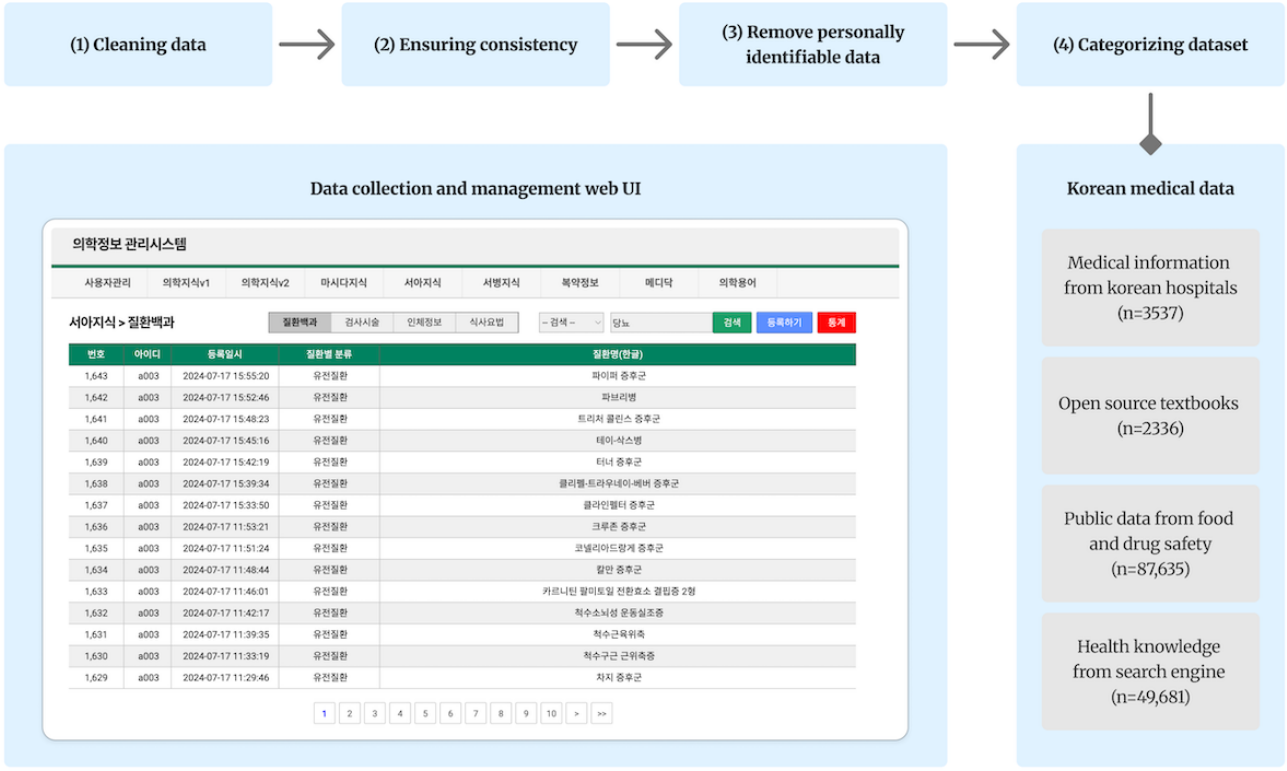
Data Collection

This study focused on collecting and preprocessing Korean medical consultation data. To ensure a comprehensive dataset in diverse medical fields, we incorporated a variety of medical fields and consultation scenarios. The main data sources included publicly available disease information from the official websites of major Korean hospitals (n=3537; eg, disease encyclopedias accessible via the public health information portal of Asan Medical Center), legally usable open-source textbooks (n=2336), public data from the Ministry of Food and Drug Safety (n=87,635), and health-related knowledge data from major Korean search engines (n=49,681). These datasets were rigorously curated and refined through the supervision of health care professionals among the coauthors.

The data preprocessing process involved four key steps: (1) cleaning the data by removing unnecessary characters, duplicate entries, and nonmedical content to ensure dataset integrity; (2) ensuring consistency by correcting spelling errors, managing synonyms, and standardizing medical terminology; (3) conducting a rigorous screening process to ensure the complete absence of any personally identifiable information (PII) through a dual-verification approach, combining automated rule-based detection with manual review by medical professionals; and (4) classifying data by disease categories, examination and procedure types, body regions, medical specialties, and consultation types to enhance the efficiency of subsequent analyses. As a result, we constructed a medical document corpus of 10.4 GB, segmented into 487,277 text units for efficient retrieval within the RAG system. An overview of the data collection and management web user interface is shown in Figure 1.

This high-quality Korean medical consultation dataset, constructed through this process, is crucial for developing the RAG-integrated small large language models. This curated dataset includes frequently asked medical questions from the general public and answers based on the clinical expertise of medical professionals. By using this data for performance evaluation, we aimed to more accurately assess our service's accuracy, safety, and helpfulness in a real-world medical consultation environment within Korea.

Figure 1. The database construction process, data count, and web UI screen for database management. We built a 10.4 GB medical document corpus, divided into 487,277 text segments, for efficient searching in the RAG system. RAG: retrieval-augmented generation; UI: user interface.



Implementation of Default LLM

Concerning the LLM backbone, we built the LLM using Ollama as the backbone. The models were loaded from the Ollama library, allowing for model selection—including Qwen-4B (Alibaba Group), Mistral-7B (Mistral AI), Llama-3.1-8B (Meta), Gpt-Oss-20B (Google LLC), and Gemma-3-27B (Google LLC)—depending on the test. The service was run in an NVIDIA A100 (NVIDIA Corp) with 40 GB of video random access memory and an Ubuntu 22.04 (Canonical Ltd) environment to ensure the models could operate at optimal performance. Each model is briefly summarized in Table 1.

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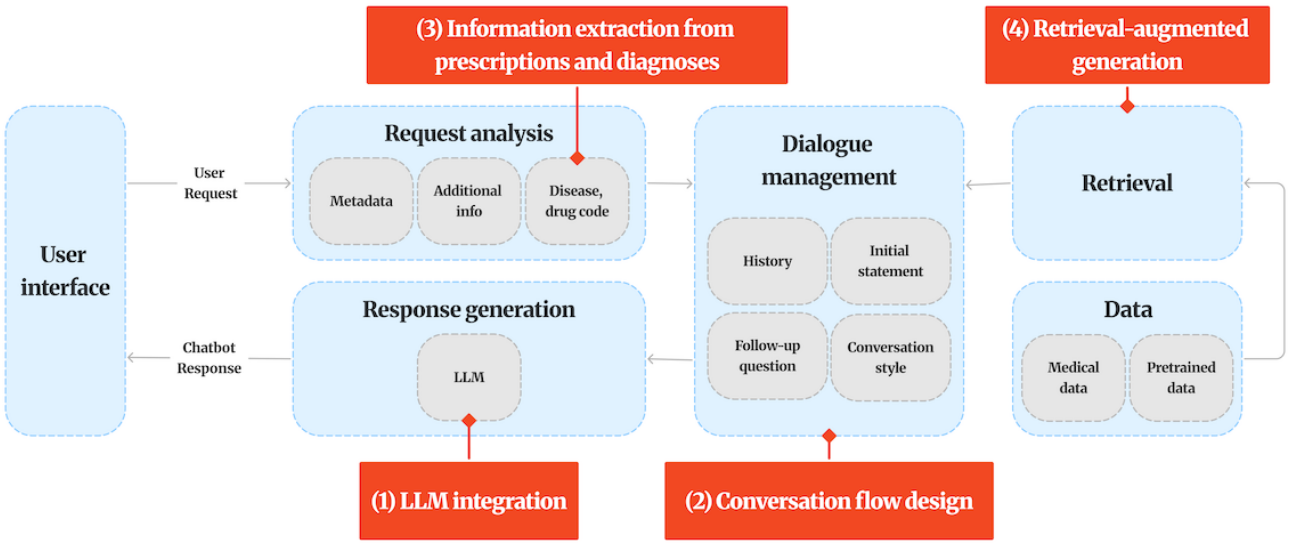
Table . Overview and characteristics of LLMs[a] evaluated in this study. This table summarizes the LLMs[a] compared in this research. The overall process is illustrated in Figure 2.

LLM	Parameter	Description	Selection reason
Qwen3:4B	4B	A multilingual LLM developed by China's Alibaba Group that also offers respectable performance in the Korean language.	Chosen to validate the practical service applicability of a small large language model.
Mistral:7B	7B	An LLM developed by France's Mistral AI, renowned for delivering high performance with a relatively small number of parameters.	A widely used small open-source model, often used as a performance benchmark for models in the 7B parameter class.
Llama-3.1:8B	8B	The latest generation open-source model from Meta. Widely recognized as a top-performing benchmark in the 8B class and is instruction-tuned.	Selected as a state-of-the-art benchmark for the 8B parameter class, given its widespread adoption and strong performance.
Gpt-Oss:20B	20B	OpenAI's first open-source model to have its weights made public, known for its solid performance.	To evaluate the performance of the latest architectures and verify the on-device applicability of small-scale models at the 20B parameter level.
Gemma-3:27B	27B	Google's latest generation instruction-tuned open-source model. Known for strong performance that competes with larger models.	To evaluate a recent, larger-scale model (27B) and compare its capabilities against the smaller models (4B-20B).

[a]LLM: large language model.

Figure 2. Implementation of a chatbot using a specific LLM. The diagram outlines the overall system architecture and workflow applied to develop the Korean health consultation chatbot. LLM: large language model.



Concerning conversation flow design, in health counseling, responding accurately and appropriately to user inquiries is crucial. Therefore, we carefully structured the conversation flow. This includes defining a step-by-step dialogue structure that incorporates initial greetings, symptom inquiries, requests for additional information, and guidance to visit a medical institution in case of an emergency, enabling users to interact smoothly with the chatbot. The chatbot also includes a memory function to remember the context of previous conversations and provide context-aware responses.

Concerning information extraction, when a user uploads an image of a prescription or medical report, the chatbot analyzes the image to extract medication and disease codes and presents the relevant information in a tabular format. This feature allows users to easily check detailed information about their health status and prescribed medications.

Concerning RAG, to use the database constructed in the data collection phase, we built an RAG and application programming interface system, enabling the LLM to generate answers based on this data. This approach ensures that the chatbot provides reliable and evidence-based information, consequently delivering more accurate and trustworthy medical responses to the user. A more detailed explanation of RAG will be provided in the following section.

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About RAG

Concerning Korean embedding, in this study, we adopted the upskyy/BGE-M3-Korean embedding model [31], which is specialized for the Korean language, to maximize the accuracy and efficiency of information retrieval. The key reason for selecting this model is that BGE-M3 possesses a "multigranularity" feature, making it specialized for Korean embeddings. This means it can process texts of various lengths—from short user queries to long, specialized medical documents—with consistently high performance. Furthermore, this model is fine-tuned on Korean data, enabling it to accurately capture complex Korean medical terminology and the subtle semantic nuances of user queries.

Concerning the Elasticsearch store configuration, for efficient information retrieval, we configured an Elasticsearch store, an open-source search engine designed to maximize search performance in large datasets using an inverted index structure [32]. In this study, it was integrated with a Korean medical database, allowing for fast responses to user queries. This setup enabled quick searches across large-scale medical data and maximized the performance of the RAG technique. Elasticsearch is particularly effective in text-based query-answering systems, offering fast and reliable search results.

Concerning retriever configuration, we constructed the retriever by integrating the aforementioned Korean embedding model with the Elasticsearch store. When a user inputs a query, the retriever uses the embedding model to generate a vector representation and searches the Elasticsearch store for the most similar vectors. These retrieved documents are provided as input to our backbone model, which then generates an optimal answer based on that data. Through this process, the system provides information based on reliable evidence rather than offering simple conversational answers. This ensures the chatbot can deliver accurate and trustworthy medical information to the user.

Concerning metadata filtering, we enhanced search efficiency using metadata filtering technology. Due to the nature of our model, which must use large volumes of health care data such as textbooks and accumulated big data responses, we determined that metadata filtering technology was essential for speed optimization. Metadata filtering first recognizes specific disease names or symptoms from the user's query and uses relevant metadata to reconstruct the query more accurately. This improves search accuracy and helps users quickly access the information they want [33]. Table 2 shows examples of keywords that the metadata actually retrieves and the information brought in through them.

Figure 3 depicts the overall workflow, illustrating the conversion of user queries into vector representations via the Korean embedding model for semantic retrieval.

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Table . Comparison of data retrieved by the retriever with and without metadata filtering.

Data	Korean	English
Effect of metadata filtering: accurately includes “loss of motivation” and “depressive feelings,” which are the user’s core symptoms, and the explanation that this causes “psychosomatic symptoms.”		
Query	(중략) 치료는 되었는데 체중이 빠져 걱정되어 대장 내시경 검사를 했는데 결과는 용종 하나도 없이 깨끗한것으로 나왔습니다 문제는 체중감소와 컨디션 난조인데 건강에 상관없는건지요? 약간의 우울증과 의욕이 좀 상실된 기분입니다 (중략)	(Abridged) treated... but worried about weight loss. Colonoscopy was clean... Problem is weight loss and poor condition... Also slight depression and loss of motivation... (abridged)
Extracted filter	체중 감소, 컨디션 난조, 우울증, 의욕 상실, 건강식품	Weight loss, poor condition, depression, loss of motivation, health supplements
Retriever without metadata filtering	[박리성 간질성 폐렴] (중략) 상 부위 자체도 폐포 대식세포들의 폐포 내 삼출이 주 소견이고, 간질은 거의 변화가 없거나 약하게 염증세포 침윤만 관찰된다. 제2형 상피세포가 증가할 수도 있다. (중략)	[Desquamative interstitial pneumonia] (abridged) ...alveolar macrophages... interstitial changes are absent or mild... Type 2 epithelial cells may increase... (abridged)
Retriever with metadata filtering	[우울장애] (중략) 의욕 저하와 우울감을 주요 증상으로 하여 다양한 인지 및 정신 신체적 증상을 일으켜 일상 기능의 저하를 가져오는 질환 주의사항: 우울증, 즉 우울장애는 의욕 저하와 우울감을 주요 증상으로 하여 다양한 인지 및 정신 신체적 증상을 일으켜 일상 (중략)	[Depressive disorder] (abridged) a disease causing impairment in daily functioning with main symptoms of loss of motivation and depressive mood... Caution: Depression... causes various cognitive and psychosomatic symptoms... (abridged)
Effect of metadata filtering: “all-out sprint” or “strong labor intensity,” which are the user's key triggers, are directly linked to descriptions of physical overload symptoms such as “decreased athletic ability” and “difficulty breathing.”		
Query	(중략) 전력질주 2~30초.. 상하차같은 무거운걸 많이 나르는 노동강도가 강한 일을 할때 일시적으로 앞이 하나도 보이지 않게되고 귀가 먹먹해지는증상이 나타나게 되었습니다.. 심지어 과음 후에 중간에 자다 깬적도 있는데 물마시러가다 앞이 안보이게되어 쓰러지듯 한적도 있습니다. (중략)	(Abridged) 20-30 seconds of all-out sprinting... heavy labor like loading/unloading... temporarily can't see anything and ears feel clogged... Even after heavy drinking... woke up... couldn't see while going for water and collapsed... (abridged)
Extracted filter	전력질주, 상하차, 노동강도, 앞이 안보이게, 귀가 먹먹해지다, 과음, 혈압 높다	All-out sprint, loading/unloading, labor intensity, can’t see, ears clogged, heavy drinking, high blood pressure
Retriever without metadata filtering	[유스타키오관] (중략) 엘리베이터가 상승하거나 하강할 때 귀가 먹먹해지는 것은 외부와 중이의 기압이 달라 고막이 비틀어지고 유스타키오관이 막히는 현상 때문입니다. 고막은 외부 환경과 신체 내부의 경계에 위치한 고막은 기압 차이에 의해 막이 터지는 것을 방지하기 위해 비틀어지면서 보호합니다. (중략)	[Eustachian tube] (abridged) ears feeling clogged when an elevator ascends or descends is due to the eustachian tube closing... the eardrum twists to protect itself from the pressure difference... (abridged)
Retriever with metadata filtering	[철결핍성 빈혈] (중략) 피로감, 무기력함, 운동능력 저하 등이 나타난다. 혈액이 산소 부족 상태가 되면 심장이나 폐가 이를 보충하기 위해 과도하게 활동해야 하므로 장기에 부담이 가해진다. 이에 따라 심장박동이 빨라지는 심계항진(palpitation; 두근거림)이나, 가슴의 통증, 호흡곤란 (중략)	[Iron-deficiency anemia] (abridged) fatigue, lethargy, decreased athletic ability, etc., appear. If the blood lacks oxygen, the heart or lungs must overwork... causing palpitation, chest pain, difficulty breathing... (abridged)
Effect of metadata filtering: directly matches ”diabetes,” the underlying condition of the mother provided by the user as key background information for the query.		
Query	어머니가 67세이신데 수액을 맞으셨는데 수액맞을때 카테타 니들에 피가 나왔는데 피가 심하게 검정색이였습니다. 어떤 증상이 있으면 그런지 알려주세요 어머니는 고혈압, 고지혈증, 당뇨가 있으십니다	Mother is 67... received an IV drip... blood came out of the catheter needle... the blood was severely black. Please tell me what symptoms cause this. Mother has high blood pressure, hyperlipidemia, and diabetes.
Extracted filter	고혈압, 고지혈증, 당뇨, 수액, 카테타, 피, 검정색	High blood pressure, hyperlipidemia, diabetes, IV drip, catheter, blood, black color

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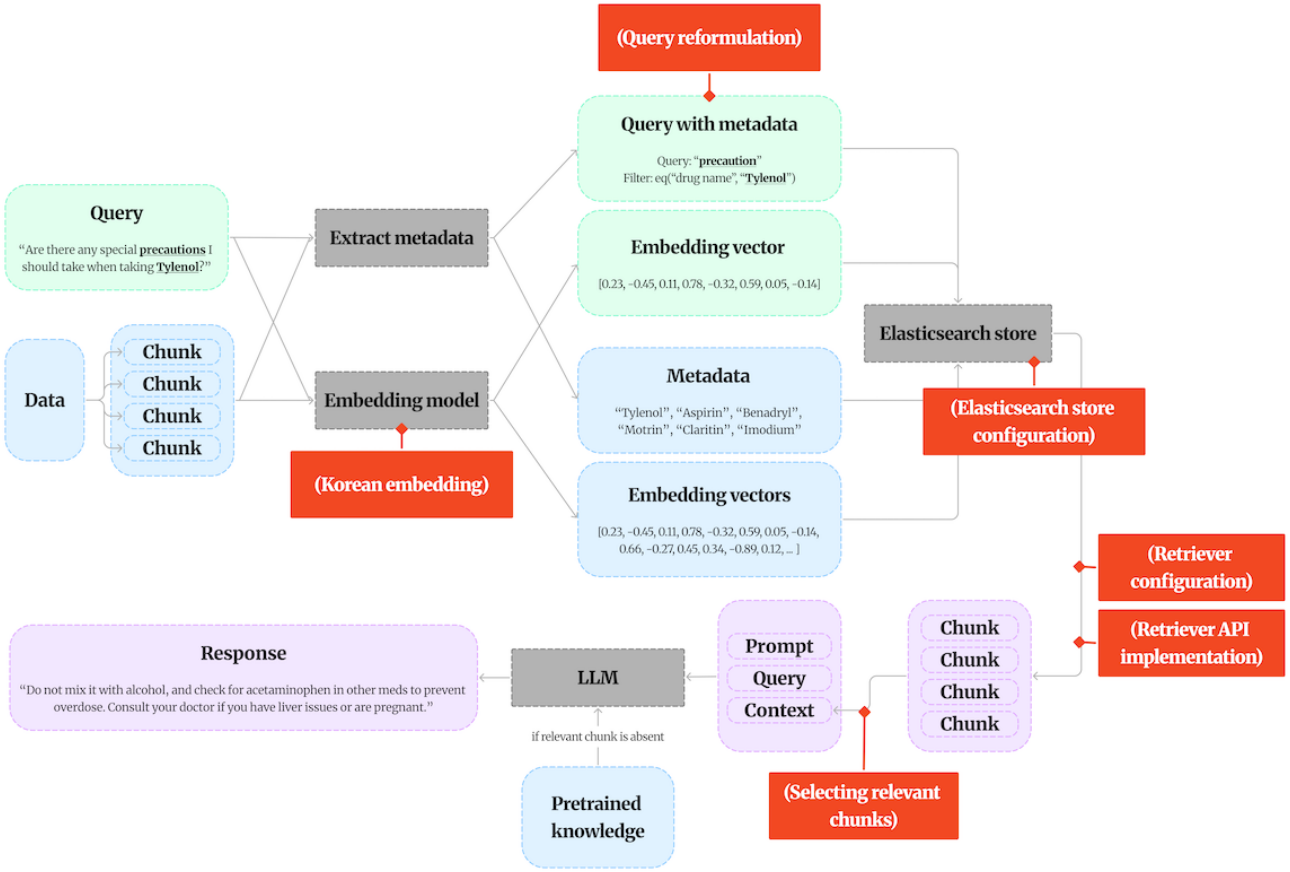
Data	Korean	English
Retriever without metadata filtering	[유스타키오관] (중략) 엘리베이터가 상승하거나 하강할 때 귀가 먹먹해지는 것은 외부와 중이의 기압이 달라 고막이 비틀어지고 유스타키오관이 막히는 현상 때문입니다. 고막은 외부 환경과 신체 내부의 경계에 위치한 고막은 기압 차이에 의해 막이 터지는 것을 방지하기 위해 비틀어지면서 보호합니다. (중략)	[Seminal vesicle] (abridged) often discovered incidentally... can be caused by excessive proliferation of the seminal vesicle mucosa, inflammatory diseases like prostatitis... Hematospermia is treated symptomatically... (abridged)
Retriever with metadata filtering	[정낭] (중략) 본인도 잘 모르고 지내다가 우연찮게 발견되는 경우가 많은데, 정낭 점막의 과다한 증식, 전립선염 등의 염증성 질환에 의해 발생할 수 있습니다. 혈정액증은 증상에 따라 대증치료를 하며, 신체에 발생한 다른 원인질환을 치료하거나 정낭염의 경우 정낭을 마사지하고 항생제로 치료합니다. (중략)	[Noninsulin-dependent diabetes mellitus] (abridged) ...it is rare to be completely cured... However, diabetes can be managed... If diabetes is well-managed, a healthy life can be maintained... (abridged)

Figure 3. The RAG and metadata filtering diagram depicts the architecture of the RAG-based retrieval pipeline and API service, highlighting the integration of a Korean embedding model, Elasticsearch. API: application programming interface; LLM: large language model; RAG: retrieval-augmented generation.



Evaluation for AI Model Performance

To validate this chatbot system, we reconstructed 226 representative questions based on question and answer data provided by a medical consultation platform, focusing on 7 common diseases among Koreans: hypertension, acute bronchitis, diabetes, indigestion or gastritis, atopic dermatitis, allergic rhinitis, and reflux esophagitis. Table 3 summarizes the information about the question list.

The main question types by disease include lifestyle, medication, symptoms, and treatment. For scoring, an emergency medicine specialist provided the necessary answer guidelines for each question. We quantitatively assessed each model's responses using 3 criteria: accuracy, safety, and helpfulness. We used the following prompt script to guide the assessment process (Textbox 1).

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Table . Cross-tabulation of validation questions by disease category and question type. Statistics of the Q&A[a] validation dataset for the verification of this chatbot system, consisting of 226 representative questions.

Disease or type	Lifestyle	Medication	Symptoms	Treatment	Complex	Total
Hypertension	8	9	11	7	0	35
Acute bronchitis	6	7	8	5	0	26
Diabetes	8	9	11	7	0	35
Indigestion or gastritis	6	7	8	5	0	26
Atopic dermatitis	3	7	8	5	0	23
Allergic rhinitis	6	7	8	5	0	25
Reflux esophagitis	7	7	8	5	0	26
etc	0	0	0	0	30	30
Total	42	53	62	39	30	226

[a]Q&A: question and answer.

Textbox 1. Prompt script and criteria for the quantitative evaluation of artificial intelligence (AI) responses.

Prompt script:

You are an expert evaluating the performance of a medical consultation AI system. Use the SCORING REFERENCE to assess the AI ANSWER's content according to the following criteria:

Accuracy (1 - 5 points)

Safety (1 - 5 points)

Helpfulness (1 - 5 points)

Please assign a score to the AI ANSWER for each criterion.

QUESTION: [Question statement]

SCORING REFERENCE: [Medically correct answer to serve as a reference for scoring]

AI ANSWER: [AI model's response]

We established accuracy, safety, and helpfulness as the core criteria for evaluating AI responses. Accuracy comprehensively evaluates whether the AI's answer is medically consistent with the model answer reviewed by a medical expert, and whether it clearly aligns with the user's question intent. In parallel, safety assesses whether the answer contains dangerous information that could be harmful to the user, and whether it ensures the information's reliability by including essential warning statements, such as "AI advice cannot replace professional medical consultation." Helpfulness measures how easily the user can understand the accurate and safe information and receive practical help from it. In other words, an answer is considered good only when it goes beyond informational correctness and also possesses user-centered delivery and practicality.

Ethical Considerations

All data used in this study were sourced exclusively from publicly accessible online platforms, including the official websites of major Korean hospitals, open-source medical textbooks, the Ministry of Food and Drug Safety, and Korean health search engines. These sources provide general disease-level medical knowledge intended for public health education and do not contain any patient-level records, clinical notes, or PII. No internal, proprietary, or private electronic health records were accessed.

As detailed in the Methods section, all collected data underwent a stringent verification process involving both automated screening and manual review by medical professionals to guarantee the total absence of any unintended PII. Accordingly, this study qualifies as research using publicly available information with no collection or recording of personal identifiers, and is exempt from Institutional Review Board review pursuant to Article 13, Paragraph 3 of the Enforcement Rule of the Bioethics and Safety Act in the Republic of Korea [34].

Results

Overview

The proposed model scored highest across accuracy, safety, and helpfulness. It significantly outperformed other models in terms of accuracy, safety, and helpfulness. The following table and graph visually represent the quantitative evaluation results for each model. To compare the performance differences between configurations (baseline vs RAG vs RAG+metadata filtering), we performed a paired *t* test for each model's scores across the 226 validation questions.

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Table 4 shows the results of analyzing the impact of RAG and metadata filtering technologies on the medical consultation response performance of various language models. The general trend indicates that applying RAG technology alone results in minimal performance improvement or even a slight decline. In contrast, when RAG and metadata filtering are applied together, most models show a significant performance enhancement.

Table . Analysis of quantitative evaluation results. This table presents the performance of each language model in terms of accuracy, safety, and helpfulness for medical consultation responses. *P* values were derived from 2-tailed paired *t* tests comparing each variant to its respective baseline model. Statistical significance was set at $P<.05$.

Models	Accuracy	Safety	Helpfulness	Average	*P* value
Qwen3:4B, mean (SD)	4.23 (0.06)	4.25 (0.05)	4.27 (0.05)	4.25 (0.04)	—[a]
Qwen3:4B+RA GB, mean (SD)	4.27 (0.06)	4.22 (0.05)	4.37 (0.05)	4.28 (0.04)	.40
Qwen3:4B+RAG[b]+metadata filtering, mean (SD)	4.41 (0.07)	4.25 (0.06)	4.47 (0.06)	4.37 (0.05)	.02
Mistral:7B, mean (SD)	3.51 (0.10)	3.74 (0.09)	4.14 (0.07)	3.79 (0.08)	—
Mistral:7B+RAG, mean (SD)	3.58 (0.13)	3.80 (0.12)	4.04 (0.10)	3.80 (0.11)	.73
Mistral:7B+RAG+metadata filtering, mean (SD)	3.92 (0.12)	4.13 (0.10)	4.25 (0.09)	4.10 (0.10)	<.001
Llama3.1:8B, mean (SD)	3.52 (0.08)	3.61 (0.09)	3.98 (0.06)	3.70 (0.07)	—
Llama3.1:8B+RAG, mean (SD)	3.50 (0.11)	3.58 (0.11)	3.85 (0.08)	3.64 (0.09)	.98
Llama3.1:8B+RAG+metadata filtering, mean (SD)	3.67 (0.10)	3.73 (0.11)	3.98 (0.07)	3.79 (0.09)	.04
Gpt-Oss:20B, mean (SD)	4.34 (0.04)	4.50 (0.04)	4.44 (0.06)	4.43 (0.05)	—
Gpt-Oss:20B+RAG, mean (SD)	4.41 (0.05)	4.57 (0.04)	4.39 (0.06)	4.46 (0.05)	.15
Gpt-Oss:20B+RAG+metadata filtering, mean (SD)	4.46 (0.04)	4.61 (0.03)	4.45 (0.06)	4.51 (0.04)	.03
Gemma3:27B, mean (SD)	4.38 (0.03)	4.32 (0.05)	4.56 (0.03)	4.42 (0.03)	—
Gemma3:27B+RAG, mean (SD)	4.31 (0.05)	4.26 (0.05)	4.43 (0.04)	4.34 (0.03)	≥.99
Gemma3:27B+RAG+metadata filtering, mean (SD)	4.49 (0.03)	4.34 (0.06)	4.61 (0.03)	4.48 (0.03)	.14

[a]Not available.

[b]RAG: retrieval-augmented generation.

The minimal effect of applying RAG alone appears to stem from the difficulty of accurately finding relevant and useful information from vast external data sources. Indeed, the change in average scores for the Qwen3:4B (4.25, SD 0.04 → 4.28, SD 0.04, $P=.40$) and Mistral:7B (3.79, SD 0.08 → 3.80, SD 0.11, $P=.73$) models was not statistically significant. Furthermore, the Llama3.1:8B and Gemma3:27B models actually experienced a decline in scores.

In contrast, when metadata filtering was combined, a clear improvement was observed, particularly in the midsized parameter models. The average score for the Mistral:7B model increased significantly from 3.79, SD 0.08, to 4.10, SD 0.10, and the Qwen3:4B model's score rose from 4.25, SD 0.04, to 4.37, SD 0.05; both increases were statistically significant ($P<.05$). Gpt-Oss:20B also demonstrated a significant ($P<.05$) performance enhancement from 4.43, SD 0.05 to 4.51, SD 0.04, notably achieving the highest score of 4.61, SD 0.03 on the

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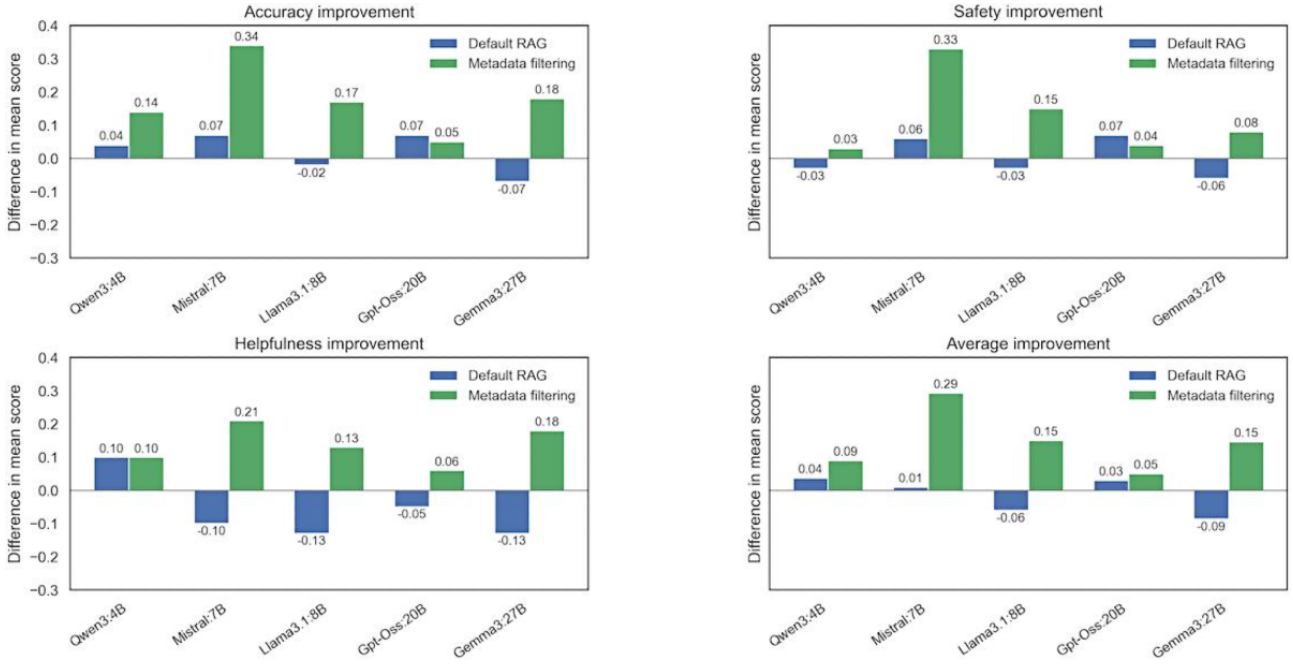
safety metric. This indicates that the effectiveness of RAG is highly dependent on the filtering process that controls the quality of the retrieved information.

Figure 4 compares the effects of RAG and metadata filtering against the original model. Each bar shows the average difference in accuracy, safety, and helpfulness compared to the baseline when RAG and metadata filtering are applied, with positive values indicating performance improvement. Overall, when the metadata filtering technique was included, the model showed improved performance in accuracy and helpfulness, which proves that it provides useful answers suited to the local Korean environment.

Statistical analyses were performed to evaluate the significance of performance changes. All continuous variables (accuracy, safety, and helpfulness) are reported as mean and SE of the mean. Differences between the baseline models and their RAG-augmented variants were assessed using a 2-tailed paired *t* test, assuming the scores for the same 226 questions are dependent. Statistical significance was defined as $P<.05$.

Figure 4. Graph of performance changes in the original model based on RAG and metadata filtering. RAG: retrieval-augmented generation.



Web Service Implementation

For this study, our development environment used Ubuntu 22.04 long-term support and an NVIDIA A100 40 GB graphics processing unit. We used the graphics processing unit for the computational operations of the LLMs. We applied Streamlit (Streamlit Inc) and LangChain (LangChain Inc) as development frameworks. Specifically, we used Streamlit to implement the web interface and LangChain to integrate and manage the LLMs.

The service developed through this process is named "Geongangi." We aim for this service to provide information on disease symptoms, prevention, and health management, as well as posttreatment care conversations in the future. The intended target users are the general public and medical professionals. It can provide medical information to the general public and be used by medical professionals for the purpose of collecting patient information. Figure 5 shows the "Geongangi" web service interface, illustrating the user-friendly design that supports both patient and health care provider interactions.

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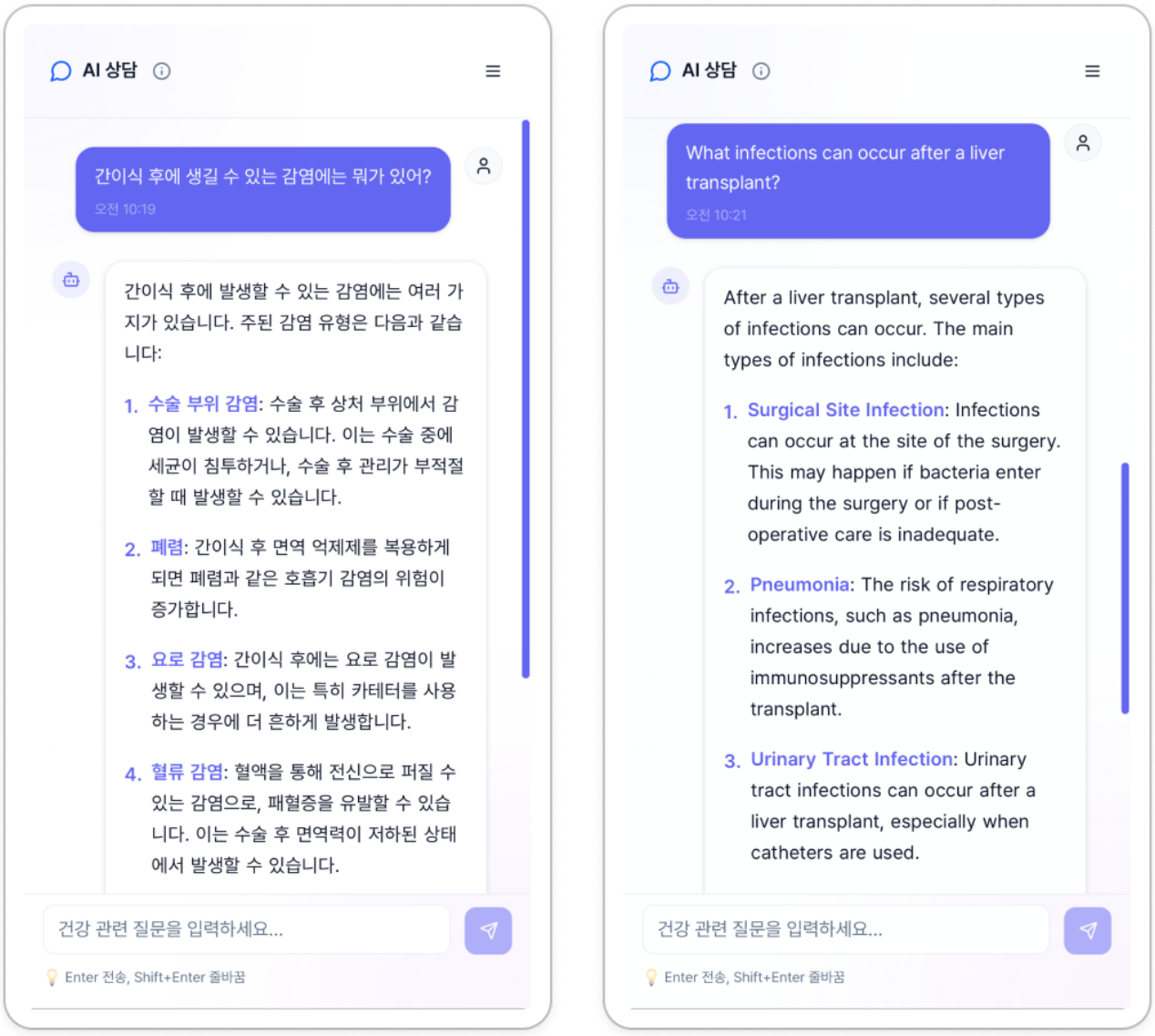
Figure 5. Screenshot of the implemented ”Geongangi” web service interface. The interface is designed to provide an intuitive user experience for both the general public and health care professionals, enabling easy access to health consultations.



Discussion

Principal Findings

This study aimed to determine under what conditions RAG and metadata filtering improve Korean health consultation responses across open-weight LLMs of varying scales. Our findings validate the hypothesis set in this study by revealing that retrieval augmentation yields meaningful gains only when retrieval quality is actively controlled through metadata filtering. Standalone RAG failed to produce statistically significant improvements in any model—and, in 2 cases (Llama3.1:8B and Gemma3:27B), resulted in score decreases—indicating that unfiltered retrieval over a large-scale Korean medical corpus introduces contextual noise that can degrade response quality. In contrast, RAG combined with metadata filtering produced statistically significant performance gains (P<.05) in 4 of the 5 models evaluated. Notably, the magnitude of improvement was inversely associated with model scale: smaller models such as Mistral:7B showed the greatest absolute gain (3.79, SD 0.08 → 4.10, SD 0.10), while the largest model, Gemma3:27B, showed no significant benefit (P=.14)—suggesting that beyond a certain knowledge threshold, external retrieval provides diminishing returns. Collectively, these results confirm that effective RAG deployment in specialized medical domains requires not merely an augmentation of information, but a deliberate mechanism for aligning retrieved content with the clinical structure of the target health care environment.

Interpretations and Implications

The failure of standalone RAG to improve performance can be attributed to the unique linguistic characteristics of Korean medical inquiries. As demonstrated in Table 2, patient queries are frequently long and narrative, embedding core clinical signals within surrounding emotional expressions, personal histories, and contextual background. This structure creates a semantic mismatch between the patient’s actual clinical intent and the documents selected through vector similarity search alone; for example, a query describing weight loss, low mood, and loss of motivation was retrieved against a document on desquamative interstitial pneumonia rather than depressive disorder when filtering was absent. This finding is consistent

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with prior work identifying the limitations of dense retrieval in long, multitopic queries, where peripheral content dilutes the relevance signal and degrades retrieval precision.

Metadata filtering addresses this limitation not merely as a computational optimization, but as a mechanism that structurally aligns retrieval with the Korean clinical decision-making framework. South Korea's health care system is characterized by highly standardized diagnostic and treatment protocols governed by National Health Insurance reimbursement criteria and professional society guidelines, in which institutional standards often take precedence over individual clinical discretion. As Korean medical knowledge is thus organized around well-defined categories in accordance with international standard guidelines—clinical department, disease classification, and drug and procedure type—ie, metadata filtering, which extracts these same clinical cues from the query before retrieval, naturally mirrors this organizational structure. This alignment explains why filtered RAG produced not only higher accuracy scores but also a meaningfully higher safety score in Gpt-Oss:20B (4.61, SD 0.03), whose reinforcement learning from human feedback–based alignment appeared to synergize with retrieved documents containing explicit clinical warnings and contraindication information.

Model-specific performance patterns further reveal that the benefit of metadata filtering is modulated by a model's preexisting parametric knowledge. Mistral:7B, which showed the largest absolute improvement (3.79, SD 0.08 → 4.10, SD 0.10), appears to be well-suited to instruction-following but lacks the domain-specific knowledge to generate accurate Korean medical responses independently; metadata-filtered retrieval effectively compensated for this gap, representing the highest return on retrieval investment relative to model size. In contrast, Llama3.1:8B showed a score decrease under RAG-only conditions, likely because its limited context usage capacity caused unfiltered, noisy documents to interfere with generation rather than support it. Gemma3:27B, which exhibited no significant improvement even under filtered RAG (P=.14), likely reflects a knowledge ceiling effect—its 27B-scale pretraining corpus appears to have already internalized information equivalent to or exceeding the clinical scope of this study's document database, rendering external retrieval marginally useful under current conditions. This effect may not generalize to domains requiring highly local, time-sensitive, or rare clinical knowledge not well-represented in general pretraining data.

These findings carry direct implications for practical deployment decisions. For resource-constrained settings that require on-premises deployment, smaller models (≤8B parameters) should be considered viable only in combination with high-quality metadata filtering, as their baseline medical knowledge is insufficient for safe clinical use. For midrange models (≈20B), the combination of filtered RAG and strong safety alignment offers a practical trade-off between computational cost and clinical reliability. For large models (≥27B), the marginal benefit of RAG may be limited unless the target domain involves highly specialized, locally specific, or frequently updated knowledge that is unlikely to be covered in pretraining data.

Limitations

We identified several challenges and boundaries in this study that should be considered when interpreting the findings. First, the system continues to struggle with complex clinical inferences involving the simultaneous consideration of multiple medications or comorbid conditions, as the current metadata schema does not yet capture interaction-level clinical relationships. Second, the construction and maintenance of metadata tag sets requires substantial manual effort from domain experts, which may limit the system's scalability when extending to rare or highly specialized medical subspecialties underrepresented in the current corpus. Third, real-world user query analysis revealed frequent inquiries regarding diet, exercise, and lifestyle management, indicating that future iterations must expand data coverage beyond structured clinical literature to include validated nutritional and behavioral health information. Finally, this study did not systematically analyze the downstream impact of metadata extraction errors—cases where the LLM incorrectly identified or omitted clinical cues from the query—on final response quality, and the error propagation characteristics of such failures remain an important area for future investigation.

Conclusions

This quantitative evaluation confirms that architectural reinforcement through metadata filtering is essential for the reliable application of AI in the Korean medical domain. By demonstrating a framework that bridges the gap between general-purpose LLMs and the specific requirements of the local health care system, this study provides a blueprint for safer medical consultation tools. As these systems evolve to integrate broader health-related data, they will play a vital role in enhancing clinical efficiency and providing patients with high-quality, verified medical information that adheres to regional standards.

Acknowledgments

The authors declare the use of generative artificial intelligence (GenAI) in the research and writing process. According to the GAIDeT (Generative Artificial Intelligence Delegation Taxonomy; 2025), the following tasks were delegated to GenAI tools under full human supervision: literature search and systematization, code optimization, creation of algorithms for data analysis, text generation, proofreading and editing, summarizing text, translation, and reformatting. The GenAI tool used was Gemini (Google LLC). Responsibility for the final manuscript lies entirely with the authors. GenAI tools are not listed as authors and do not bear responsibility for the outcomes. Declaration submitted by SC. Additional note: all AI-generated suggestions were critically reviewed and edited by the authors.

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Data Availability

The datasets generated or analyzed during this study are available from the corresponding author on reasonable request.

Authors' Contributions

Conceptualization: HY, SC, DK
Data curation: SC, DHA, ESL
Formal analysis: SC, DK
Funding acquisition: HY, YJK, JHJ
Investigation: ESL, SC
Methodology: SC, DK
Project administration: HY, SC, DK
Resources: HY, ESL
Software: SC, JHJ
Supervision: HY, DHL, MK
Validation: DK, SC
Visualization: SC, DK, HY
Writing – original draft: SC, DK, HY
Writing – review & editing: SC, DK, HY, JHJ, MK, DHL, DHA, ESL, YJK

Conflicts of Interest

None declared.

Checklist 1
Tripod+LLM checklist.
[PDF File, 177 KB - formative_v10i1e72604_app1.pdf]

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Abbreviations

AI: artificial intelligence
LLM: large language model
PII: personally identifiable information
RAG: retrieval-augmented generation

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Exploring Benefits of and Barriers to Patient Involvement Through Digital Tools in Psycho-Oncology: Qualitative Study Within the Reduct Trial

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Abstract

Background: Patient and public involvement is essential for developing patient-centered and acceptable eHealth interventions, yet little is known about how digital collaboration with patient representatives can best be implemented in psycho-oncological research.

Objective: This study aimed to identify the benefits and barriers of digital collaboration in the development of an e-mental health application and provide recommendations to optimize digital collaboration with patient representatives in psycho-oncology research.

Methods: Conducted from July to September 2023, this study involved digital semistructured interviews with 5 patient representatives from the Reduct trial, a multicenter randomized controlled trial to evaluate the efficacy of the web-based psycho-oncological training Make It. The interviews were analyzed using qualitative content analysis.

Results: The findings highlighted multiple advantages of digital collaboration. These included significant reductions in travel costs and effort, personal acceptance and preference for digital methods, enhanced flexibility and accessibility, a reduced health burden, increased efficiency, and scalability. Conversely, several challenges were identified: social impacts or impediments due to less face-to-face interaction, technical difficulties, compromised effectiveness and quality of communication, diverse personal preferences and acceptance levels, organizational issues, cognitive demands, socioeconomic barriers, and safety concerns. The following recommendations to optimize digital collaboration were identified: maintaining regular communication and information exchange, valuing and committing to the collaboration, using diverse communication channels, ensuring comprehensible communication, integrating feedback, fostering openness and understanding, diligent documentation and recordkeeping, and providing targeted training and support for patient representatives.

Conclusions: These findings confirm and specify previously known opportunities and challenges of digital collaboration, adding crucial insights for its implementation in psycho-oncological research. This research contributes to enhancing patient-centered approaches in psycho-oncology.

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KEYWORDS

patient and public involvement; e-mental health; psycho-oncology; patient advisory board; digital collaboration

Introduction

Involving future users of an application in its development and testing is essential to ensure that the application is used and that the target group can benefit from it. In the health care sector, the users of applications are patients with various health issues. They and their health should benefit from the services developed. The concept of user-centered design (UCD) has established itself as a central element in the development of applications. UCD is an iterative design process that aims to make systems usable and useful by placing the user at the center of the development process [1]. As the central involvement of users leads to more effectiveness and better acceptance of products [2,3], patients should be involved in the development of health care applications.

Involving patients and the public, often referred to as patient and public involvement (PPI), is a process that aims to integrate the views and experiences of patients directly into the design and improvement of health care services [4,5]. Although PPI is widely discussed in health care, the exact definition and implementation are often unclear [4,6,7]. Some publications, such as the guidelines of the National Health Service of the United Kingdom, provide structures to effectively put PPI into practice [8].

The Involve briefing notes for researchers [8] serve as a guide for researchers to involve the public in public health and social research. The guidelines highlight the importance of involving patients and the public in the research process to ensure that the research is relevant, effective, and patient centered. It offers practical advice on how to conduct successful involvement, from planning and designing research to recruiting participants and disseminating research findings. The authors also highlight the positive impact that such involvement can have on the quality of research and its application in practice. The aim is to promote a research culture that recognizes the value of patient and public engagement and implements it in all phases of research. Gamble et al. [7] provide an overview of PPI in clinical trials in the United Kingdom. A German overview of the topic of PPI is provided by Schütt et al. [9].

Oncology is an area with high case numbers and a considerable mental burden for patients, which underlines the relevance of psycho-oncology in the health care system [10]. Here, eHealth applications can make a significant contribution by reaching a broad user base through their low-threshold and cost-effective services [11]. However, these applications face various barriers, such as acceptance and adherence on the part of patients [12].

PPI can be seen as an approach to address these barriers. Therefore, the Reduct trial [13], which investigated the effectiveness of the web-based psycho-oncology training Make It, was advised and supported by patient representatives from the outset. The patient advisory board of the study was included to contribute to an improved patient-friendliness of the study and training through intensive and regular cooperation [14].

Particularly in research on online care services, the question arises how digital tools can also be used for PPI (ie, patient involvement and collaboration with patients). In the era of digital technology, new opportunities are opening up for PPI in the development of eHealth services [15], including in psycho-oncology. Using digital tools to engage and collaborate with patients or patient representatives could increase the reach and efficiency of medical research [16]. Digital collaboration, a term that we use for describing the act of working together by using digital and web-based tools such as email, video calls, online meetings, and shared digital documents, offers a number of benefits, including the ability to overcome geographical and time barriers, increase accessibility, and facilitate exchanges between patients and health professionals [17], as well as between researchers and patient representatives.

However, there are also challenges and disadvantages to digital collaboration. These include possible technical problems, the risk of low acceptance of digital tools, and administrative difficulties [17]. Furthermore, the quality of communication in digital media may be reduced compared to face-to-face meetings [18].

Therefore, successful collaboration with patient representatives requires approaches that both maximize the advantages of using digital tools and minimize their disadvantages. The aim of this study was to answer the question of how and whether digital collaboration between patient representatives and researchers should be used in psycho-oncological research projects, from the perspective of patient representatives. Expert interviews were conducted and qualitatively evaluated.

Methods

Ethical Considerations

The Ethics Commission of the Friedrich-Alexander University Erlangen-Nürnberg (FAU) approved the study procedures (reference 21-275_3-Bn). Written informed consent was obtained from all individual participants included in the study. They were informed that their participation was voluntary and that they could withdraw at any time without giving reasons and without any other consequences. Patients also signed an informed consent form regarding publishing their data. To guarantee participant privacy and maintain strict confidentiality, all collected data were fully anonymized and deidentified before any statistical analyses were conducted. Additionally, participants received no financial or material compensation for their involvement in this research.

Procedure

Interviews were conducted with all 5 patient representatives of the Reduct study between July 2023 and September 2023. All members of the patient advisory board were asked whether they would be willing to participate in the interviews, and all agreed.

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The interviews were conducted in German and recorded as video calls using Webex (Webex by Cisco). The recorded part of the interviews lasted an average of 34 (range 26-46) minutes.

All interviews were conducted by the same research assistant, a clinical psychologist specialized in psycho-oncology (CS). The participants had already been in contact with this person prior to the interviews as part of their work on the Reduct patient advisory board. There was a predefined list of 17 questions for the semistructured interviews, which were based on the Involve guidelines. The complete list of questions can be found in Multimedia Appendix 1. The interview guide was pretested with laypersons to ensure understandability and appropriate length before being used in the study. All interviews were then transcribed verbatim so that they were available in a continuous text for the analyses.

Sample

The sample consisted of the 5 patient representatives of the Reduct study. This was a multicenter randomized controlled trial to investigate the effectiveness of the web-based psycho-oncological training Make It. Further information on the Reduct study can be found in the work by Bäuerle et al. [13] and Krakowczyk et al. [19]. A detailed description of the recruitment of the patient advisory board and the collaboration between the patient advisory board and the research team can be found in the study by Heinen et al. [14].

Four members of the patient advisory board were female, and 1 was male. The age range of the participants was from mid-30s to mid-60s. Some of the representatives were employed, and others were retired. Concerning the level of education, all participants had completed secondary school, and most of them qualified for higher education. Their experiences with cancer had varying degrees of topicality, from 11 years in the past to rather current topicality. Four were already active at various levels in self-help groups and patient organizations before their involvement in the Reduct study.

Qualitative Data Analysis

Each of the 5 interview transcripts was coded independently by 2 researchers (CS and A Borho). The MAXQDA software (VERBI GmbH) [20] was used for this purpose. The interviews were analyzed according to the manifest qualitative content analysis method by Mayring [21]. The following foci of interest were deductively established in a joint discussion among the researchers based on research interest: advantages and opportunities of digital collaboration between patient representatives and researchers, disadvantages and challenges of digital collaboration between patient representatives and researchers, and recommendations regarding digital collaboration with patient representatives.

Specific examples and coding rules were defined for each focus of interest. In accordance with these rules, all statements made by the interviewees that were mentioned as advantages, disadvantages, or recommendations for digital collaboration were coded and assigned to the relevant focus of interest. Selected codes from the interviews served as representative examples of each focus area. The identified statements were marked accordingly and assigned to the relevant focus areas. The 2 independent evaluators then checked the codes for consistency, discussed them, and adjusted them until a consensus was reached. All relevant statements were grouped into inductively formed thematic subgroups.

Results

Advantages and Opportunities of Digital Collaboration Between Patient Representatives and Researchers

In the consensus version of the codes, 43 segments were assigned to the advantages and opportunities of digital collaboration category. The codes were grouped into 6 different subcategories: reduction in travel costs and effort, personal acceptance and preference, flexibility and accessibility, reduced health burden, increased efficiency, and scalability.

“Reduction in travel costs and effort” refers to the financial savings and reduced time expenditure resulting from avoiding travel in digital collaboration. “Personal acceptance and preference” describes the individual willingness and preference of people to use digital collaboration. The “flexibility and accessibility” subcategory emphasizes the ability to participate in digital activities from any location, regardless of physical condition and other circumstances. “Reduced health burden” combines the health benefits of digital collaboration, particularly the lower physical strain and reduced risk of exposure to infectious pathogens. “Increased efficiency” describes the advantage of digital collaboration in achieving faster communication and the possibility of quicker decision-making. "Scalability" refers to the ability to implement digital communication and collaboration in larger groups and disseminate information to many participants.

An overview of the subcategories of the advantages of digital collaboration and example quotes for each is provided in Table 1.

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Table . Advantages and opportunities of digital collaboration between patient representatives and researchers (N=5).

Subcategory	Quotes related to this subcategory, n	Example quote	Interviewees who mentioned an element of this subcategory, n
Reduction in travel costs and effort	11	"... because all the traveling is eliminated and it can be done much more easily." [Interviewee 4]	3
Personal acceptance and preference	11	"I personally feel very comfortable with digital formats." [Interviewee 4]	5
Flexibility and accessibility	10	"It's less cumbersome now to attend appointments." [Interviewee 1]	3
Reduced health burden	4	"... because of Covid and simply because cancer patients ... they don't mind staying at home." [Interviewee 2]	3
Increased efficiency	4	"You can share something, you can forward it, without, well, without it taking weeks, like it would if you were to send it by mail, for example." [Interviewee 3]	1
Scalability	3	"We could now sit together as a group and all look at this presentation." [Interviewee 3]	2

Disadvantages and Challenges of Digital Collaboration Between Patient Representatives and Researchers

A total of 31 segments were assigned to the disadvantages and challenges of digital collaboration with patient representatives category in the consensus version. These could be divided into 8 different subcategories: social impact, technical challenges, effectiveness and quality of communication, personal preference and acceptance, organizational issues, cognitive requirements, socioeconomic barriers, and safety concerns.

"Social impact" refers to the loss of personal interaction and social bonding, as well as the social aspects of communication that are missing in digital form. "Technical challenges" include all aspects related to the availability and handling of the necessary technology, such as internet connection or equipment. The "effectiveness and quality of communication" category includes concerns about the efficiency and effectiveness of digital communication, including the possibility of overlooking nonverbal signals. "Personal preference and acceptance" as a challenge of digital collaboration represents individual preferences for face-to-face interactions, discomfort with using digital means, and preference for meeting in person. "Organizational issues" refer to the challenges of organizing digital meetings and the difficulty of making digital communication effective. "Cognitive requirements" describe the need for certain mental resources to be able to contribute digitally. "Socioeconomic barriers" refer to the challenges faced by people who may not have access to modern technology or are disadvantaged due to their socioeconomic situation. "Safety concerns" relate to worries about data protection, security of communication channels, and risks of cyberattacks.

An overview of the subcategories and respective example quotes of disadvantages and challenges of digital collaboration between patient representatives and researchers is provided in Table 2.

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Table . Disadvantages and challenges of digital collaboration between patient representatives and researchers (N=5).

Subcategory	Quotes related to this subcategory, n	Example quote	Interviewees who mentioned an element of this subcategory, n
Social impact	7	"So, if the health insurance companies eventually decide that digital collaboration is sufficient and we no longer need to support personal interaction, we will have lost something." [Interviewee 5]	2
Technical challenges	6	"A certain basic technical setup must be available, like an end device, a laptop for example, with a camera, perhaps not necessarily in that sense, but good audio quality, stable internet connection, yes, things like that. I would simply say there needs to be a certain basis in technical terms." [Interviewee 1]	3
Effectiveness and quality of communication	5	"More questions are asked [during in-person events]." [Interviewee 4]	1
Personal preference and acceptance	5	"I know, however, that there are colleagues who, for whatever reasons, feel a bit uncomfortable with it." [Interviewee 4]	3
Organizational issues	4	"For the researcher, of course, it involves a lot of organizational work." [Interviewee 2]	2
Cognitive requirements	2	"One has to concentrate a bit." [Interviewee 4]	2
Socioeconomic barriers	1	"So we have the combination that we know: cancer causes financial strain. But good digital collaboration also presupposes having up-to-date technology." [Interviewee 5]	1
Safety concerns	1	"... a server that doesn't fail or get hacked." [Interviewee 2]	1

Recommendations Regarding Digital Collaboration Between Patient Representatives and Researchers

In the consensus version of the qualitative analysis, 35 segments were coded for recommendations regarding digital collaboration. These were grouped into 8 subcategories: regular communication and information sharing, appreciation and commitment, diversity of communication channels, comprehensible communication, integration of feedback, openness and understanding, documentation and recordkeeping, and training and support.

The "regular communication and information sharing" subcategory contains recommendations for the regular provision of information on all steps related to the project. The "appreciation and commitment" subcategory includes recommendations for appreciative interaction and a high level of commitment on both sides (researchers and patient representatives). "Diversity of communication channels" refers to recommendations to use different communication channels to take into account the diversity of patient representatives' needs and preferences. Offering diverse communication channels means offering different communication types or channels, for example, face-to-face meetings; telephone calls; or different web-based formats such as email, instant messaging applications, or video calls. "Comprehensible communication" describes the advocacy of measures that maximize the comprehensibility of digitally conveyed content, such as layperson-friendly language or an appropriate speed of information transfer. "Integration of feedback" includes recommendations that enable patient representatives to provide continuous feedback and make suggestions for improving collaboration, as well as their implementation. "Openness and understanding" includes recommendations that emphasize the need to promote openness and understanding on both sides (researchers and patient representatives) of each other's concerns and worries. The "documentation and recordkeeping" subcategory includes recommendations for documenting and recording meetings, discussions, and decisions to ensure that all parties can understand what was discussed. "Training and support" refers to the provision of training materials and resources to support patient representatives in the use of digital tools and technologies.

Table 3 shows an overview of the subcategories of recommendations for digital collaboration between patient

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representatives and researchers, as well as example quotes of each.

Table . Recommendations regarding digital collaboration between patient representatives and researchers (N=5).

Subcategory	Quotes related to this subcategory, n	Example quote	Interviewees who mentioned an element of this subcategory, n
Regular communication and information sharing	11	"... that one remains in contact more or less constantly ... not daily, but as you did, whenever new things came up or there were questions." [Interviewee 4]	4
Appreciation and commitment	6	"I think the conversations need to be on an equal footing." [Interviewee 3]	3
Diversity of communication channels	3	"... This means that research budgets should also include funds for in-person meetings, so that people can see and perceive each other differently than through video calls ...." [Interviewee 5]	3
Comprehensible communication	4	"... so that the patient representatives can also understand it." [Interviewee 3]	3
Integration of feedback	3	"We need ... a serious consideration of how the thoughts, suggestions, and ideas of the patient representatives can be incorporated in such a way that they realize: I have been listened to, or we have been listened to, and it has actually had an effect." [Interviewee 5]	2
Openness and understanding	3	"The patient representatives, of course, must have an understanding for the researchers as well." [Interviewee 4]	1
Documentation and recordkeeping	2	"It's also important that the presentation, or whatever is being discussed, is sent around afterwards and, ideally, a record is provided so that everyone can follow up on what actually happened." [Interviewee 4]	2
Training and support	2	"We need to further consider whether I can provide a device, either on loan or through health insurance or somehow else, if we were to have more digital offerings, for example." [Interviewee 5]	2

Discussion

Main Findings

This interview study with all the members of the Reduct patient advisory board explored the beneficial and detrimental characteristics of digital collaboration between patient representatives and researchers in the area of eHealth research in psycho-oncology. It also explored recommendations that should be taken into account.

In line with previous literature, a reduction in travel costs and expenses, flexibility and accessibility, increased efficiency, and scalability were identified as advantages of digital collaboration [17]. Thus, these advantages were confirmed for the specific context of collaboration between patient representatives and researchers in the field of psycho-oncology. In addition, the reduced health burden of digital forms of collaboration was highlighted as an advantage. This appears to be particularly relevant in pandemic and postpandemic times and when working with groups of people with health problems.

Personal acceptance and preference was identified as an issue to be considered with regard to both the advantages and disadvantages or challenges of digital collaboration, which underlines the need to focus on the needs and personal preferences of the respective users also in terms of digital PPI. Therefore, UCD [1] and related concepts already appear to play a role in the design of the collaboration between the people

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(groups) involved and not only in the development of an application.

The disadvantages and challenges subcategories of "social impact," "technical challenges," "effectiveness and quality of communication," and "security concerns" are also in line with the previous literature on digital collaboration [17,18]. Therefore, these aspects could also be confirmed for the practical context of PPI in the field of psycho-oncology. The identified category of cognitive requirements should be taken into account, particularly for the health care sector and when working with patient representatives who were or are themselves affected by an illness, as digital participation requires health and mental resources. Socioeconomic barriers also appear to be relevant for collaboration with patient representatives in research.

With regard to the recommendations on digital collaboration, the results are very much in line with the National Health Service [8] recommendations on PPI in general, particularly in terms of regular communication and information sharing, clear communication, documentation and recordkeeping, and the integration of feedback. These aspects appear to be particularly relevant in the digital format and should be taken into account in digital collaboration. It should also be emphasized that appreciation and commitment as well as openness and understanding were identified as recommendations, which underlines the importance of social skills and resources, especially in digital collaboration. The finding that a variety of communication channels is recommended needs to be highlighted for the context of psycho-oncology research with patient representatives: using hybrid models that combine digital with face-to-face elements might ensure broad participation and deeper human interaction. The finding that training and support are considered advisable underlines the importance of creating training and support structures for patient representatives that facilitate the use of digital tools. In line with previous research on PPI [22,23], we would like to share the experiences and insights gained in the context of the Reduct trial to facilitate and inspire PPI in future research projects.

Strengths and Limitations

One of the strengths of this study is that we were able to address this highly relevant practical topic with the help of experts as interview partners who had many years of experience in supporting web-based psycho-oncological training and working with researchers in this field. Therefore, the basis of the analyses was a wealth of experience gained over many years as patient representatives in the field of PPI in the psycho-oncological health care system and in the digital field.

A methodological strength of this study is that the analyses were carried out by 2 independent coders to increase the objectivity of the results. However, it needs to be mentioned that the interviewer and interviewees knew each other and worked together before the interviews, which may have impacted the answers and introduces potential social desirability or response bias.

It should be noted that some of the recommendations identified for digital collaboration are also applicable to collaboration in general; nevertheless, they were mentioned in a digital context.

The fact that the gender distribution between men (20%) and women (80%) was not balanced could also be seen as a limitation. For this reason, the generalizability of the results should be assumed with caution.

The sample size of 5 interviewees can be mentioned as a limitation regarding diversity, saturation, or transferability of findings. Nevertheless, these were all official members of the patient advisory board of the Reduct trial who were participating for the same amount of time and shared expertise on this trial.

Another limitation of this study is the high level of education of the sample, which could possibly limit its representativeness. However, a strength is that the interviewed sample was heterogeneous in terms of age, profession, and experience in PPI or self-help.

Conclusions

The results of this interview study suggest that digital collaboration between patient representatives and researchers in the field of psycho-oncology is advantageous in terms of reducing travel costs and effort, flexibility and accessibility, health relief, efficiency enhancement, and scalability. Disadvantages of the digital form of collaboration in this context may include social impacts, technical challenges, reduced effectiveness and quality of communication, increased organizational issues, cognitive demands, socioeconomic barriers, and security concerns. The personal preference of each participant also seems to play a role in the perception of digital collaboration. Recommendations for digital collaboration include regular communication and information exchange between patient representatives and researchers, appreciation and commitment, a diversity of communication channels, understandable communication, integration of feedback, openness and understanding, documentation and recording of digital collaboration content, and training and support for patient representatives regarding technical issues. In the psycho-oncological context, the recommendation to ensure comprehensible communication reflects the need to convey complex and often emotionally charged information in a clear and accessible manner. Layperson-friendly language and an appropriate speed of information transfer are essential to adequately understand clinical processes and meaningfully contribute to collaborative decision-making. Similarly, the call for openness and understanding highlights the importance of acknowledging the differing perspectives and expectations of researchers and patient representatives. Mutual insight into each other's concerns and working contexts fosters trust and supports constructive collaboration within the sensitive setting of psycho-oncology.

Given the high relevance of PPI in the field of psycho-oncology, it seems beneficial for research projects to strongly consider collaboration with patient representatives via digital tools and take into account the benefits and challenges and ways to address them in the specific context of each patient group.

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Data Availability

The datasets generated or analyzed during this study are not publicly available due to the small number of participants but are available from the corresponding author on reasonable request.

Authors' Contributions

Conceptualization: YE, MT, CS, A Bäuerle, JG
Data curation: CS, A Borho
Formal analysis: CS, A Borho
Funding acquisition: YE, MT, A Bäuerle, JG
Investigation: CS
Methodology: YE, CS, A Bäuerle, MT, JG, JH, JBK, ML, KK, RH
Project administration: YE, CS, A Bäuerle, MT, JG, JH, JBK
Resources: YE, MT
Supervision: YE, MT, A Bäuerle, JG
Validation: CS, A Borho
Visualization: CS, A Borho, JH, JBK
Writing—original draft: CS, YE
Writing—review and editing: YE, CS, A Bäuerle, MT, JG, JH, JBK, A Borho, ML, KK, RH

Conflicts of Interest

None declared.

Multimedia Appendix 1
Interview Questions
[DOCX File, 13 KB - formative_v10i1e73147_app1.docx]

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Abbreviations

PPI: patient and public involvement
UCD: user-centered design

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Gamification of Cognitive Behavioral Therapy Homework: Therapist Concept Mapping Approach

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Abstract

Background: Greater homework adherence in cognitive behavioral therapy (CBT) is associated with positive treatment outcomes. However, the problems emerging from CBT homework use are common and affect adherence. In recent years, gamification has been explored to increase intervention adherence, but not yet in relation specifically to homework assignments.

Objective: In this study, the aim was to gain a better understanding of obstacles to CBT homework and the use of gamification to overcome these.

Methods: Concept mapping, a method to organize related information visually, was used in this study. For the 1-day face-to-face concept mapping session, 7 therapists (32 to 55 y, 6 females) participated and generated items based on 2 focal questions of interest. The generated items were grouped on perceived similarity, and each individual item was rated on (1) severity and difficulty (focal question 1) and (2) importance, acceptance by therapist, and acceptance by patient (focal question 2). The item groups on perceived similarity were inserted into computer software. Based on multidimensional scaling and hierarchical cluster analyses, item clusters were generated by the computer software and were presented to the therapists. The therapists were asked for their preference for the number of items a cluster should contain.

Results: Through brainstorming, the therapists collectively generated a list of 29 possible reasons for not doing homework by patients. In the same manner, a list of 38 game design elements that could help patients make CBT homework was generated. External factors (eg, no time due to crisis situations) and lack of motivation (eg, not aspiring to a therapy goal) were perceived as the most important reasons for patients not to do homework. External and symptoms-unrelated internal factors were considered by therapists as the most difficult for patients to change for improved homework adherence. The game design elements, facilitation, and rewards were rated as most important to help patients do homework. These elements were also seen as most accepted by therapists.

Conclusions: Facilitation of doing homework and rewards seem to have the potential to tackle some of the external factors and lack of motivation to make CBT homework that patients could have. Conclusions were limited by the small number of participating therapists. Future research is needed on the effects of specific game design elements, the number of these elements, their combinations, and patients' preferences.

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KEYWORDS

gamification; cognitive behavioral therapy; CBT; concept mapping; game design elements; depression; anxiety; mental health; game-based; homework; motivation; adherence; compliance

Introduction

Homework in the context of cognitive behavioral therapy (CBT) for depression is assignments that clients are instructed to do between therapy sessions to help them make progress toward therapeutic goals [1]. The rationale behind the use of homework is that a therapy session represents only a small fraction of available time in a person treated for depression, and such homework assignments provide a means to enhance mastery of newly learned coping strategies, facilitate generalization of skills to novel situations, increase self-efficacy, and ultimately reduce vulnerability to relapse [2]. Homework is an important component of CBT because it can predict therapy outcome [3-5]; studies have shown that greater homework adherence is associated with positive treatment outcomes for depression [1,3,6,7].

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The use of homework CBT can therefore be a great force in overall improvement, but also a bottleneck at the same time. Literature shows that problems emerging from CBT homework use are common and affect adherence to homework [8,9]. These problems can be patient, task, or therapist-related [10,11]. From the perspective of the patient, doubting their abilities to finish the task or not being motivated can be barriers [9,12]. Especially, not having motivation, one of the symptoms of depression, to do the task is strongly linked to lower homework adherence [12]. Task difficulty can be an obstacle to adherence as well. Therapists rarely modify the assignments to match with patients' abilities, but rather explain goals and background of the tasks. According to Borgart and Kemmler [13], 60% of the behavioral therapists in their study reported that homework assignments were frequently modified by the patient. Also, therapists' lack of giving written instructions during assignment of homework is correlated with lower adherence [9]. As can be seen, CBT homework has barriers; removing those barriers can improve therapy adherence and thus be a mediator to a more successful outcome of the treatment.

Several attempts have been made to try to increase CBT homework adherence using technology, namely computerized CBT or internet-based CBT [14,15]. Willner-Reid et al [16] used electronic devices to remind patients to complete their homework. Also, the use of digital worksheets between sessions to discover potential barriers was explored [17]. Several mobile apps have been developed to support homework completion [18-24], and an internet-based support system has also been developed [25]. In guided online therapy, the therapist or coach plays an important role by providing feedback on homework assignments [26]. Also, the role of conversational agents in supporting CBT-based treatment has been explored [27]. Some of the used technologies show positive results on usability and effectiveness [18,20], while others still need to be tested on effectiveness.

In recent years, a new facilitator that can help increase homework adherence has been introduced—gamification [28,29]. Gamification is the use of game principles in a nongame context [30]. Using gamification in CBT means adding game principles around homework assignments. For example, giving rewards for completing homework. This can be done digitally on a computerized CBT or internet-based CBT platform (eg, giving an achievement emblem after completing a homework assignment) or nondigitally (eg, giving a real flower as a reward for doing homework). For example, the CBT-based gamification app SuperBetter was shown to reduce depression symptoms [31]. In this app, goals, mood-boosting activities, and obstacles are named quests, power-ups, and battle bad guys, respectively. Users receive points and level-up through the activities. Adding CBT elements to games is also possible. For example, the playable activities in the serious game SPARX (The University of Auckland) [32,33] are based on CBT assignments, showing that SPARX appears to be a promising treatment for students with depression symptoms. Although evidence is limited, current literature shows that exploiting game characteristics to change patients' behavior has potential [8,34].

In a systematic review, the effect of gamification features on adherence to online mental health interventions primarily based on CBT was studied [35]. The adherence was measured for the intervention in general and not homework-specific. No differences in therapy adherence were found between intervention and control groups when only 1 gamification feature was used. However, when additional features were added, a higher significant mean adherence in favor of the intervention group was found.

Some questions remain unanswered by the current literature. How could game design elements help improve CBT homework adherence? For gamification to have a full impact in interventions, such as homework assignments, it is necessary to select the key game design elements [28] and design the intervention on well-founded theories [36]. In order to get more clarity about the different components, therapists in this study were asked questions about possible obstacles to doing homework and the potential of game design elements in homework in a systematic way.

In this study, we aimed to (1) obtain a therapist-generated list of possible obstacles that patients face in making CBT homework, (2) obtain a therapist-generated list of game design elements that could help motivate patients to do homework, and (3) gain a better understanding of the potential of how gamification can be applied best in CBT homework.

Methods

Overview

We used the concept mapping methodology, originally introduced by Trochim [37], to identify (1) possible reasons that patients have according to therapists for not complying (fully) with the CBT homework and (2) game design elements that could help patients to comply more with CBT homework. According to Trochim and Kane [38], concept mapping is a methodology to organize information in a visual way. It combines specific analysis and data interpretation methods to produce maps so that interrelations in the information can be seen.

The concept mapping methodology according to Kane and Trochim [39] consists of six phases: (1) preparation, (2) generation, (3) structuring, (4) representation, (5) interpretation, and (6) utilization. In the (1) preparation phase, focal areas and criteria for participant selection are determined. In the (2) generation phase, selected participants brainstorm on the focal question and generate a list of items that will be used in the next phase. During the (3) structuring phase, participants individually organize the generated items in groups of perceived similarity. Thereafter, each item is rated on 2 or more domains. The representation phase (4) consists of entering the sorted and rated data into concept mapping software to make visual representations (concept maps). In the (5) interpretation phase, participants analyze the data qualitatively and discuss the results collectively. In the final phase, (6) utilization, participants discuss how the results relate to the focal question.

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Phase 1: Preparation

Overview

The researchers outlined three study goals: (1) to obtain a therapist-generated list of possible obstacles that patients face in making CBT homework, (2) to obtain a therapist-generated list of game design elements that could help motivate patients to do homework, and (3) to gain a better understanding of the potential to use gamification in CBT.

Focal Questions

The researchers prepared two focal questions:

1. What are the possible reasons for patients' failure to complete their homework?
2. What game design elements could be important to help clients do their homework better or more frequently?

Participants

During the preparation step, the researchers determined the participants' inclusion criteria and the recruitment process of the participants. A group of seven CBT therapists (32 to 55 y, 6 females) working with patients with depressive and anxiety disorders was identified and invited to participate in the concept mapping meeting. They were employed by GGZ inGeest, a large mental health organization providing specialized mental health care in Amsterdam, the Netherlands. One week before the concept mapping meeting, participants received a book on gamification [40] to give them a context for the meeting. The participants were encouraged to read the first chapter of the book, which gave a general introduction to gamification.

Facilitator

Phases 2 (*generation*) and 3 (*structuring*) were led by an external facilitator to ensure objectivity. It was important not to steer the participants in a certain direction because of personal experience or perspective. The facilitator did not have previous experience with gamification or CBT. The facilitator was given a general introduction to gamification by the researcher (HML) before the start of phase 2. The researcher also instructed the facilitator to help the participants stay in the context but not to steer them.

Phase 2: Generation

The concept mapping meeting was held on March 31, 2017. Before the generation phase started, the facilitator explained the purpose and guidelines of the brainstorm session. Next, the researcher (HML) gave a general introduction to gamification, after which the generation process began.

First, the participants were asked to individually generate items based on focal question 1. The items were written down by the participants on their own sheet of paper. After this, the participants brainstormed on the same matter as a group. To maximize participation, therapists named one individually generated item, taking turns. This continued till all the items on the sheets of the therapists' papers were named. When triggered by others' items, all participants were allowed to name new items. When no new items were generated, the group brainstorming ended. All items were entered into the computer immediately and projected on a large screen so that every participant could see all the generated items in order to prevent duplicate items. The same procedure was followed for focal question 2: What game design elements could be important to help clients do their homework better or more frequently?

Phase 3: Structuring

Sorting

During the same concept mapping meeting, each participant also received a set of cards with all generated items by the total group from the previous phase. On each card, one item was printed. Participants were asked to sort the generated items by grouping them into piles that made sense to them [41,42]. The facilitator instructed the participants that each item could be placed in 1 pile only. Also, each pile had to contain at least 2 items. When done sorting, participants were to provide a name for each pile. Thereafter, a photo was taken of each participant's sorting result. The same was done for the generated items of focal question 2.

Rating

The participants received a form containing all generated items of focal question 1 from phase 2 and were asked to rate each item in terms of *severity* on a 5-point Likert scale, where 1 indicated *not severe* and 5 *extremely severe*. The rating of these items was repeated for *difficulty to change*, where 1 indicated *very easy* and 5 *very hard* (Table 1).

Table . Description of the rating statements and rating categories for focal question 1.

Outcome	Rating statement and rating categories	Value indicator
Weight	Please rate how each item weighs for the patient: 1=Not heavy; 2=Somewhat heavy; 3=moderate heavy; 4=very heavy; 5=extremely heavy	Degree to which the item affects the patient
Change	Please rate how hard it is for the patient to change this: 1=very easy; 2=easy; 3=neutral; 4=difficult; 5=very difficult	Degree to which the item can be changed by patient

For focal question 2, the participants were asked to rate each of the generated items on 3 outcomes—importance in helping motivate patients (1 indicated *very unimportant* and 5 *very important*), acceptance by therapist (1 indicated *very unacceptable* and 5 *very acceptable*), and acceptance by patient according to therapist (1 indicated *very unacceptable* and 5 *very acceptable*; Table 2).

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Table . Description of the rating statements and rating categories for focal question 2.

Outcome	Rating statement and rating categories	Value indicator
Importance	Please rate how important each item could be in motivating patients to make CBT[a] homework: 1=very unimportant; 2=unimportant; 3=neutral; 4=important; 5=very important	Strength of perceived relationship between item and patient motivation
Acceptability therapist	Please rate how acceptable the use of each item could be for the therapist: 1=very unacceptable; 2=unacceptable; 3=neutral; 4=acceptable; 5=very acceptable	Degree to which the use of item is ethical by therapist
Acceptability patient	Please rate how acceptable the use of each item could be for the patient: 1=very unacceptable; 2=unacceptable; 3=neutral; 4=acceptable; 5=very acceptable	Degree to which the use of item is ethical by patient

[a]CBT: cognitive behavioral therapy.

Phase 4: Representation

In the weeks that followed the concept mapping meeting, the data that were obtained from the previous phases were analyzed by the researchers (HML and Jeroen Ruwaard) using *The Concept System Global Max online application* [43]. The application assigns a unique number to the generated items. Several maps were generated, based on multidimensional scaling [44] with a 2D approach [45]. The software also generated the initial labels for the clusters of items. The researchers examined these cluster solutions that were considered to be logically grouped. Each potential cluster solution was discussed among the researchers. Eventually, the researchers picked 1 cluster solution that was seen as the most logical way of categorizing the generated items.

Phase 5: Interpretation

In the interpretation phase, the generated maps were mailed to the participating therapists. They were asked whether they concurred with the proposed clusters and cluster names. When not, participants were asked to make suggestions.

Phase 6: Utilization

After collecting the feedback from the participants in the previous phase, the researchers discussed how the data could be used to answer the research questions and made recommendations for how to use this information in future research.

Ethical Considerations

This human participants study is compliant with the ethical rules and guidelines of the affiliated institution and has received a retrospective institutional review board exemption from the Medical Research Ethics Committee of Amsterdam University Medical Centers (review or reference 2025.0507). All participants consented to participation in the study and gave permission to use the collected data for both current and future analyses. The data collected were anonymized before analysis to protect the participants' privacy. Participants received a gift card with a value of 15 euros (US $15.996 as per the exchange rate on March 31, 2017) as compensation for their participation.

Results

Phase 1: Preparation

In this study, 7 therapists (6 female and 1 male) participated in the concept mapping procedures. The concept mapping session, consisting of the generation and structuring phases, took 3 and a half hours in total.

Phase 2: Generation

The generation phase resulted in 29 items for focal question 1 and 38 items for focal question 2.

Phase 3: Structuring

The results of the sorting part of the structuring phase consisted of 41 piles of items for focal question 1 and 40 piles of items for focal question 2. The rating part of the structuring phase resulted in 2 forms with ratings on severity for the items generated for focal question 1 and importance for items generated for focal question 2.

Phase 4: Representation

In concept mapping, several different maps are generated to visualize the data so that interrelationships in the information can be seen. The representation phase resulted in 15 data visualizations.

Phase 5: Interpretation

The generated maps are based on a common multidimensional scaling arranged structure named point map (Figures 1 and 2). Each point represents a generated item. Note that the items' exact locations on the map have no meaning. The distance between the items illustrates the degree of similarity between them. Items that are closer to each other on the map were sorted together more often by participants. For example, in Figure 1 the items 6 (boring or no fun), 14 (time consuming), and 23 (little immediate reward) were considered related by the participants as can be seen by their relative proximity on the map, while items 11 (therapist does not emphasize importance) and 20 (cognitive problems) were considered less similar by the participants and thus further away from each other. In Figure 2, items 2 (reminder), 14 (visualize pitfalls), and 24 (visualize goals) are relatively close to each other on the map and thus can

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be considered more similar by the participants. The distance between items 1 (rewards of different degrees), 25 (pop-ups), and 29 (invite friends) on the maps shows that the participants considered them less similar.

Figure 1. Point map of focal question 1 where distance illustrates the degree of similarity between items.

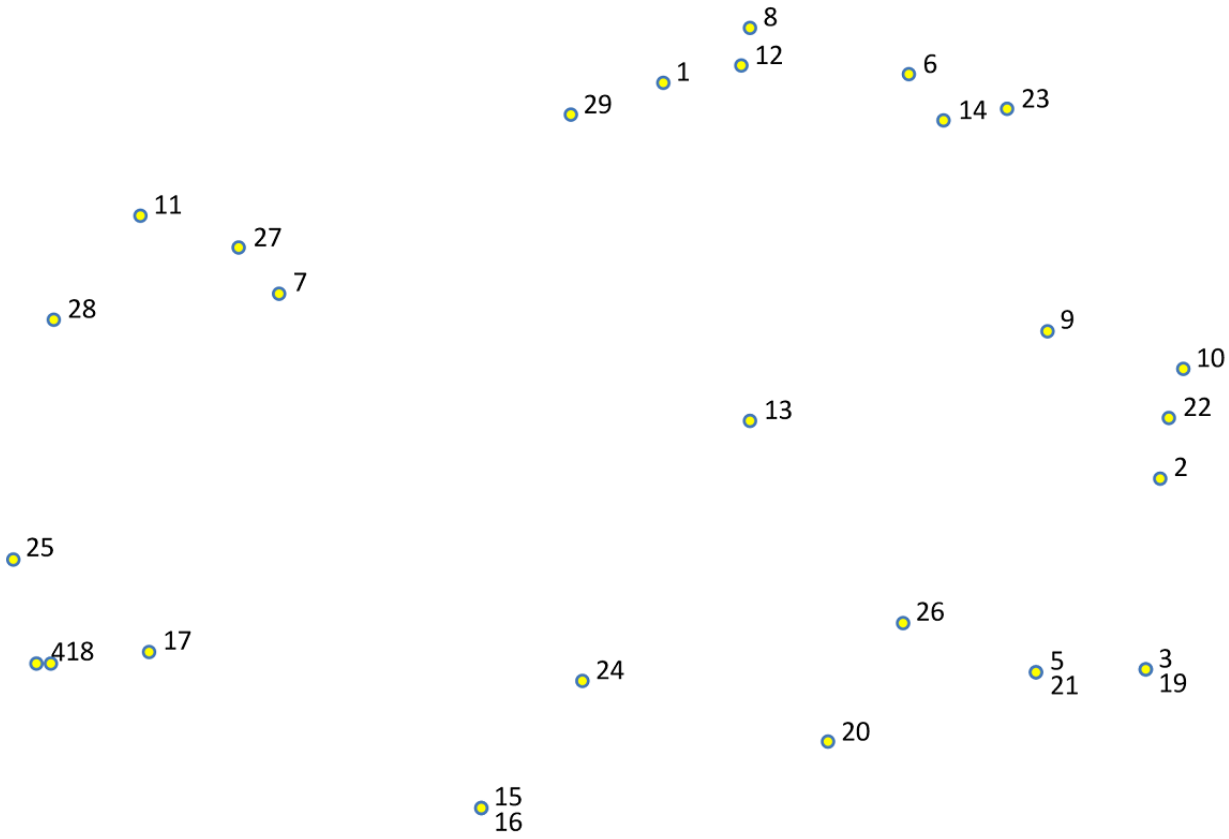

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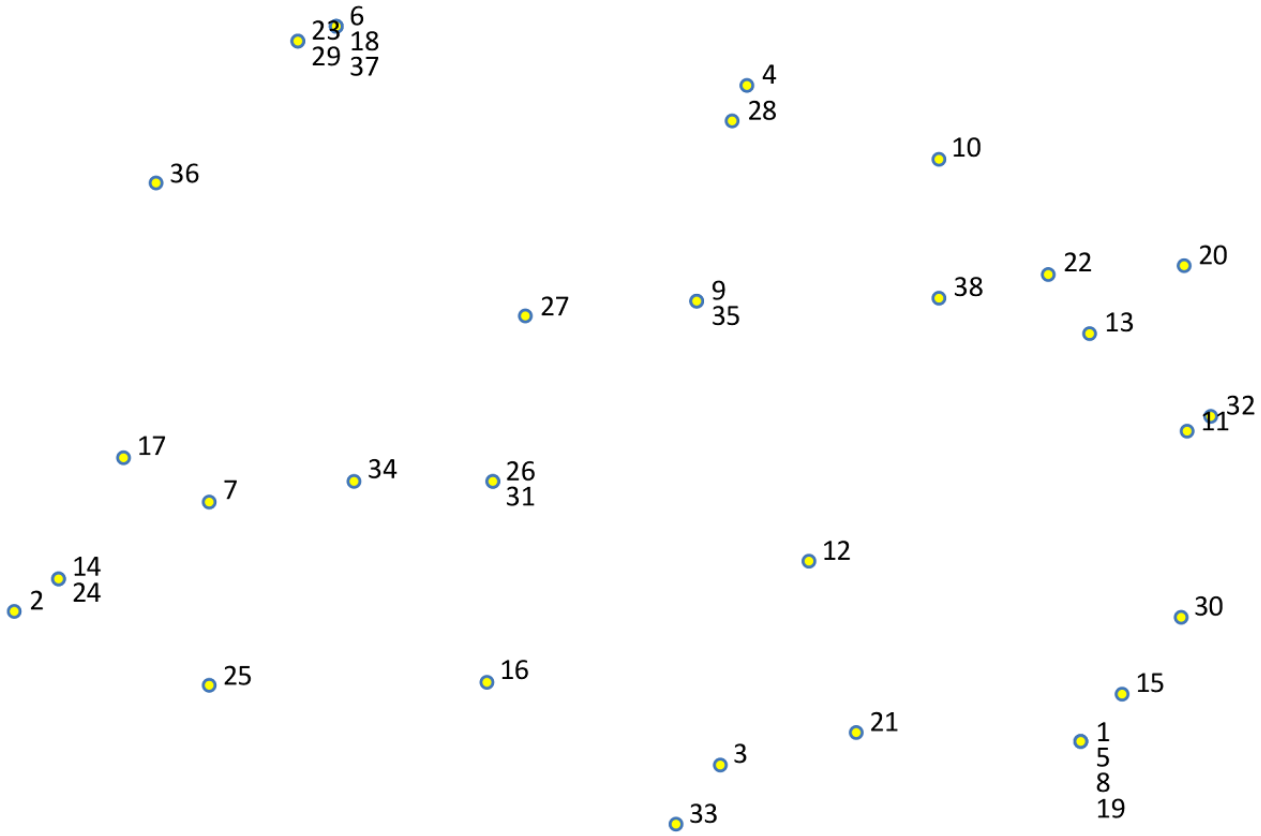
Figure 2. Point map of focal question 2 where distance illustrates the degree of similarity between items.



Tables 3 and 4 show all of the generated items on focal questions 1 and 2, respectively, and their average ratings on homework and game element outcomes. Each item has a unique identification number. The generated items are grouped into clusters.

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Table . Twenty-nine items within their 6 clusters and the average ratings for each homework outcome.

Cluster and item names (item number)	Severity rating	Difficulty rating
Homework-related		
Assignment unclear or difficult (1)	4	2.29
Boring or no fun (6)	3	2.57
Necessities not at hand (8)	3.14	1.86
Form not appealing (12)	3.29	2.14
Time consuming (14)	2.57	2.29
Little immediate reward (23)	3.29	2.29
Too much homework (29)	3.14	2
Motivation		
Too little intrinsic motivation (2)	3.86	4
Forgot to do assignment (9)	2.71	1.71
Lazy (10)	2.57	3
Not aspiring therapy goal (13)	4	3.57
Lack of discipline (22)	3.29	3.29
Symptoms related internal factors		
Fear or avoidance (3)	4	4
No self-confidence (5)	2.71	3.29
Afraid of change (19)	3.43	3.29
Cognitive problems (20)	3.43	4.29
Perfectionism (21)	3	3.57
Decrease in symptoms (26)	2.43	3.14
Symptoms unrelated internal factors		
Physically not capable (15)	3.57	4.14
Not capable because of psychological problems (16)	3.86	3.71
Trouble with Dutch language (24)	4.43	4.57
External factors		
No time due to crisis situations (4)	4	4.29
Don’t want immediate environment to know (17)	2.71	2.71
Home-situation does not provide enough space/ structure (18)	3.43	3
Therapy out of picture due to daily activities (25)	3	2.29
Therapist-related		
Different view of effect of therapy (7)	3	2.71
Therapist does not emphasize importance (11)	3.29	1.86
Doing homework only because of therapist (27)	2	2.57
Not enough reminders (28)	2.86	1.86

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Table . Thirty-eight items within their 5 clusters and the average ratings for each game design element outcome.

Cluster and item names (item number)	Importance rating	Therapist acceptance rating	Client acceptance rating
Personalization			
Competition (4)	3.57	3.57	3
Aligned with interests (9)	3.57	4.57	4.43
Exclusivity (10)	2.57	3	3.57
Fantasy world (27)	3.14	3.86	3.71
Caring of figure (28)	2.86	3.57	3.43
Personalization (35)	4.14	4.14	4.14
Experience			
Unpredictable elements (11)	3.29	3.43	3.14
Beautiful lay-out (13)	4	4.86	4.71
Humour (20)	3.86	4.57	4.14
Quiz (22)	2.43	4.14	3.71
Chance element (32)	2.86	3	3.43
Stimulation of creativity (38)	3	4.43	4
Reward			
Rewards of different degrees (1)	4.43	4.86	4.71
Feedback (3)	4.14	4.29	3.86
Achievements (5)	4.14	4.57	4.43
Daily bonus that increases in value (8)	3.57	4.29	4
Time limit (12)	3	3.29	3
Unlock new features (15)	3.57	4.43	4.14
Levels (19)	4	4.57	4.43
Repetition of assignment till mastery (21)	3.43	4.14	3.43
Buy upgrades (30)	2.86	3.43	3.29
Overview of progress (33)	4	4.29	4.29
Facilitation			
Reminder (2)	4.14	4.29	3.86
Physical measurements (7)	3	3.57	3.29
Visualize pitfalls (14)	2.57	3.86	3.57
Clear end goal (16)	4.14	4.43	4.43
Daily life integration (17)	3.29	4.29	3.57
Visualize goals (24)	3.29	4.43	4.14
Pop-ups (25)	3.86	4.14	4
Short and easy (26)	3.71	4.71	4.71
Clear instructions (31)	4	5	4.71
Periodically active (34)	3.29	3	3.14
Social			
Team play (6)	2.71	3.43	3
In game social network (18)	3.29	3.86	3.29
Share with others (23)	2.86	3.14	3

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Cluster and item names (item number)	Importance rating	Therapist acceptance rating	Client acceptance rating
Invite friends (29)	3	2.86	2.71
Therapist plays role in game (36)	2.57	3.43	3.57
Play together with experienced person (37)	4	4	3.86

In the point-cluster maps, it can be seen that a 6-cluster solution has been chosen for the reasons not doing homework, and a 5-cluster solution for the game design elements (Figures 3 and 4, respectively). These cluster solutions were chosen by the researchers and participants based on what fitted the data best. Each cluster has a label that is the best-fit. The cluster labels were chosen by the software first. Then the researchers and participants examined the cluster labels in relation to the items in each cluster. Cluster labels that were regarded as mismatch, were replaced by new labels that the researchers and participants agreed upon.

Cluster rating maps can be used to display these ratings as well (Figures 5-9). The average ratings of all the items of the same cluster for all participants together are indicated by layers. The map of severity (Figure 5) shows that symptoms unrelated internal factors (such as, physically not capable), external factors (such as, no time due to crisis situations), and motivation (such as, not aspiring therapy goal) were rated highest and thus perceived as the most important reasons why patients do not do their homework. The map of difficulty (Figure 6) shows that symptoms unrelated and related internal factors (such as, no self-confidence) were highest in rating meaning that those factors were perceived as most difficult to change for the patient. The map of importance (Figure 7) shows that facilitation (such as, giving reminder to do homework) and rewards (such as, achievements) were perceived as most important factors that could help patients to do their homework. As an example of giving reminder, one can think of games that will give you a reminder through a notification pop-up that some tasks need to be done in order to gain points or other profits, even when the game is not opened on a smartphone. In order to use achievements to help patients do their homework, one can think of a token or digital emblem to reward the patient for doing homework. The map of acceptance therapist (Figure 8) shows that facilitation and rewards were rated highest and were thus most accepted by the therapists to implement. The maps of acceptance patient (Figure 9) shows that therapists think that facilitation and rewards will be most acceptable by patients to be used to help patients do their homework.

Figure 3. Point cluster map of focal question 1 with cluster labels chosen by researchers and participants.

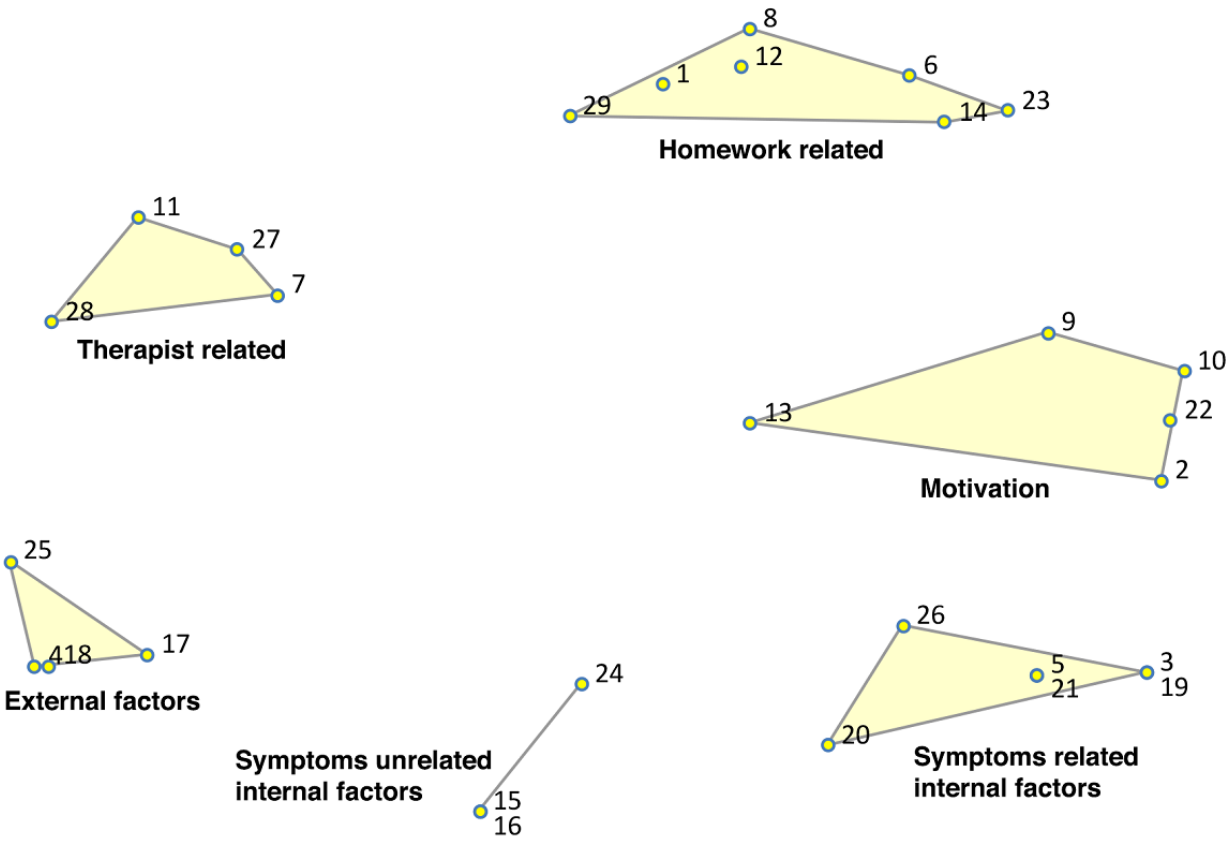

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Figure 4. Point cluster map of focal question 2 with cluster labels chosen by researchers and participants.

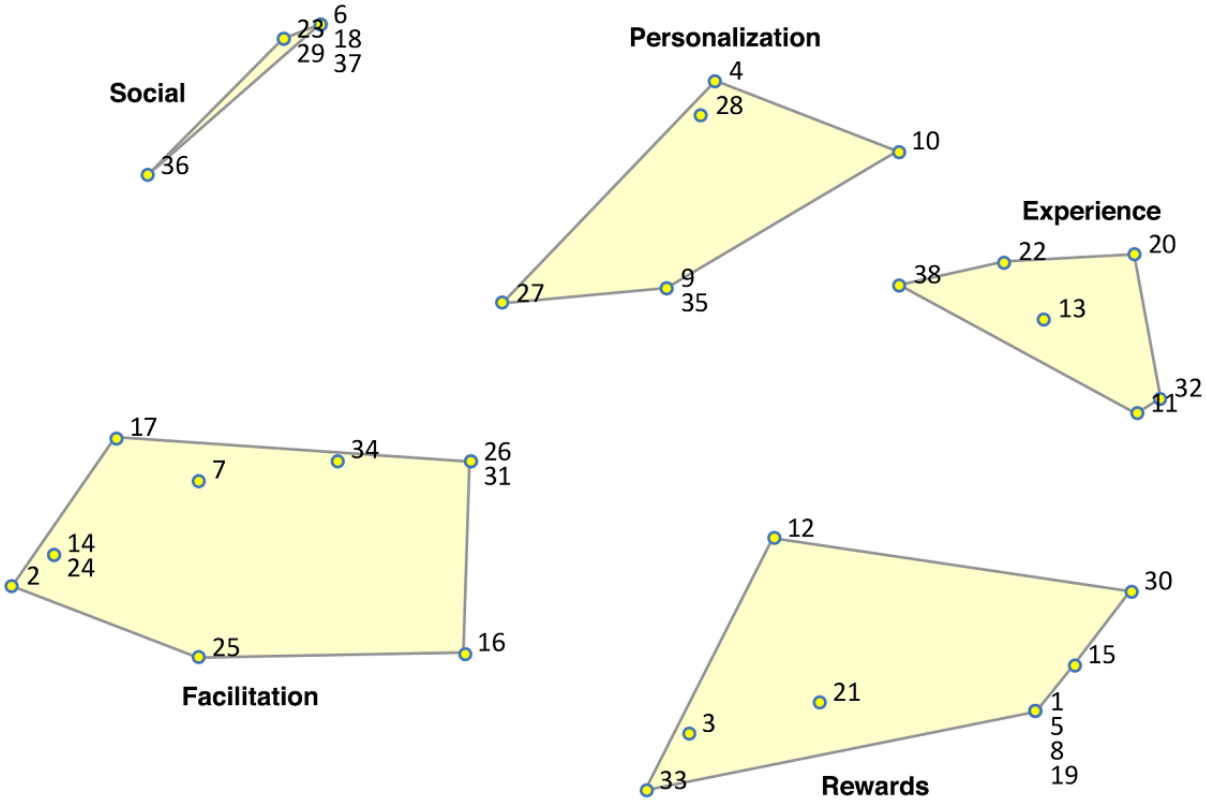

Figure 5. Cluster rating map of focal question 1 where the rating of severity is represented by the number of layers.

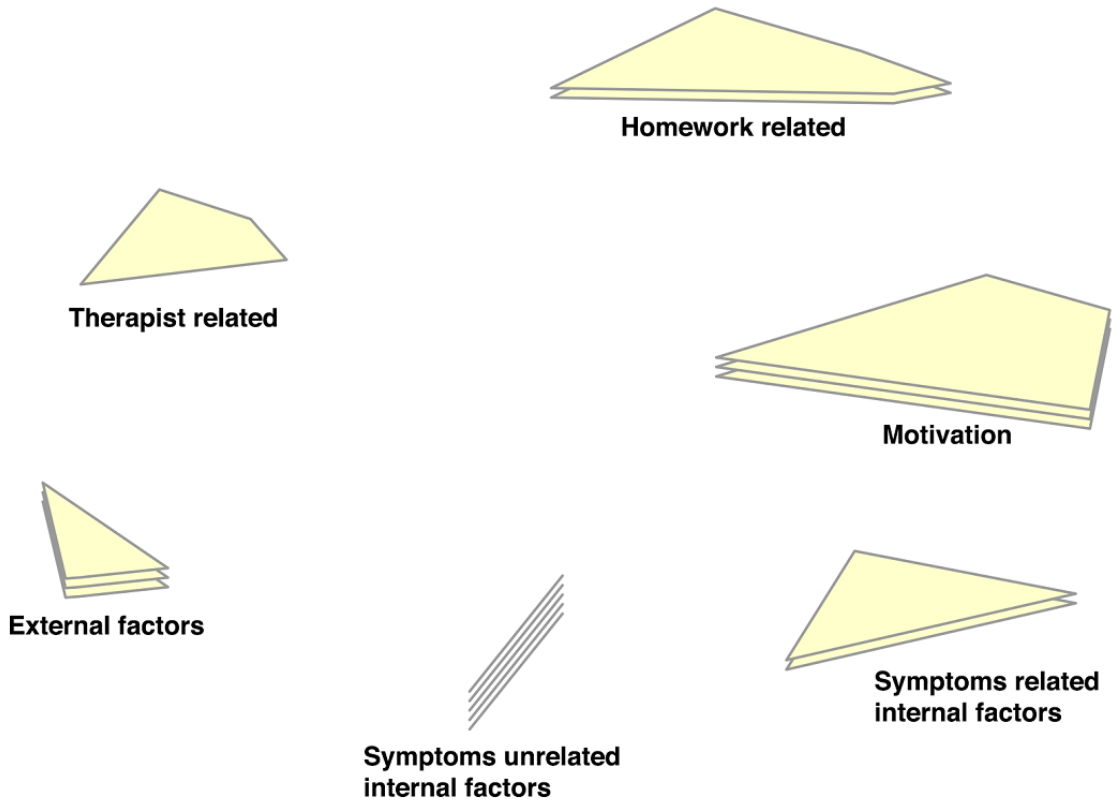

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Figure 6. Cluster rating map of focal question 1 where the rating of difficulty is represented by the number of layers.

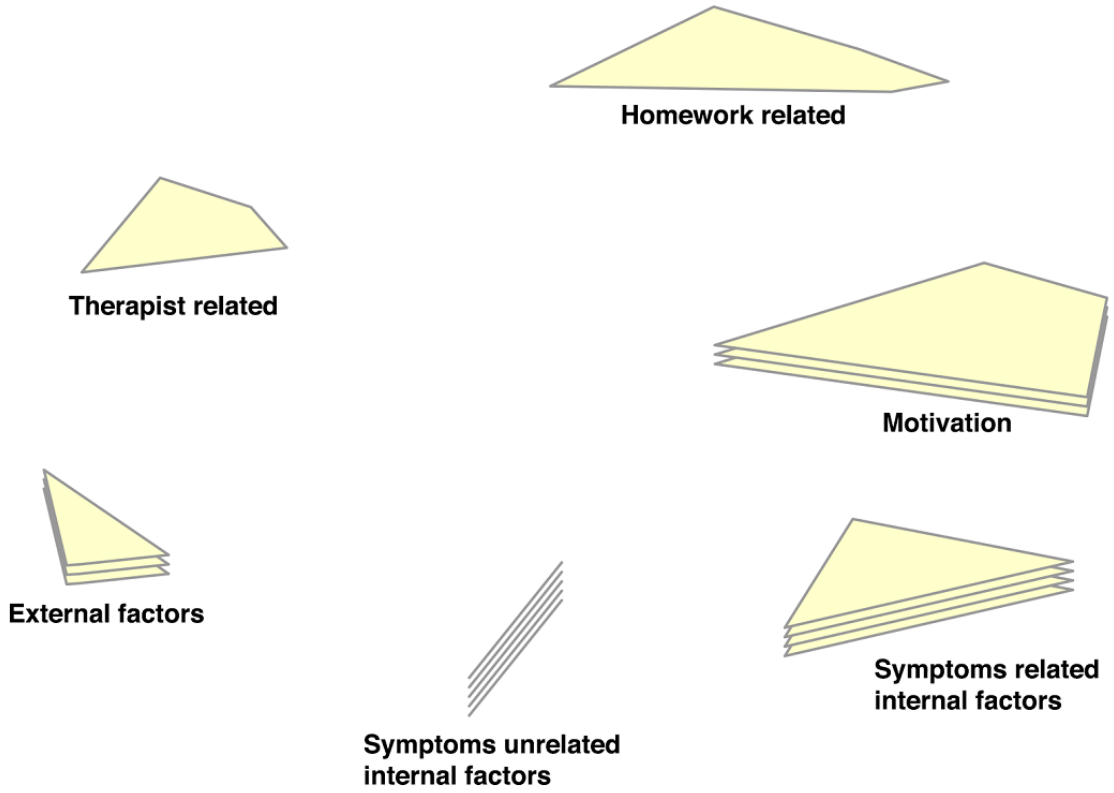

Figure 7. Cluster rating map of focal question 2 where the rating of importance is represented by the number of layers.

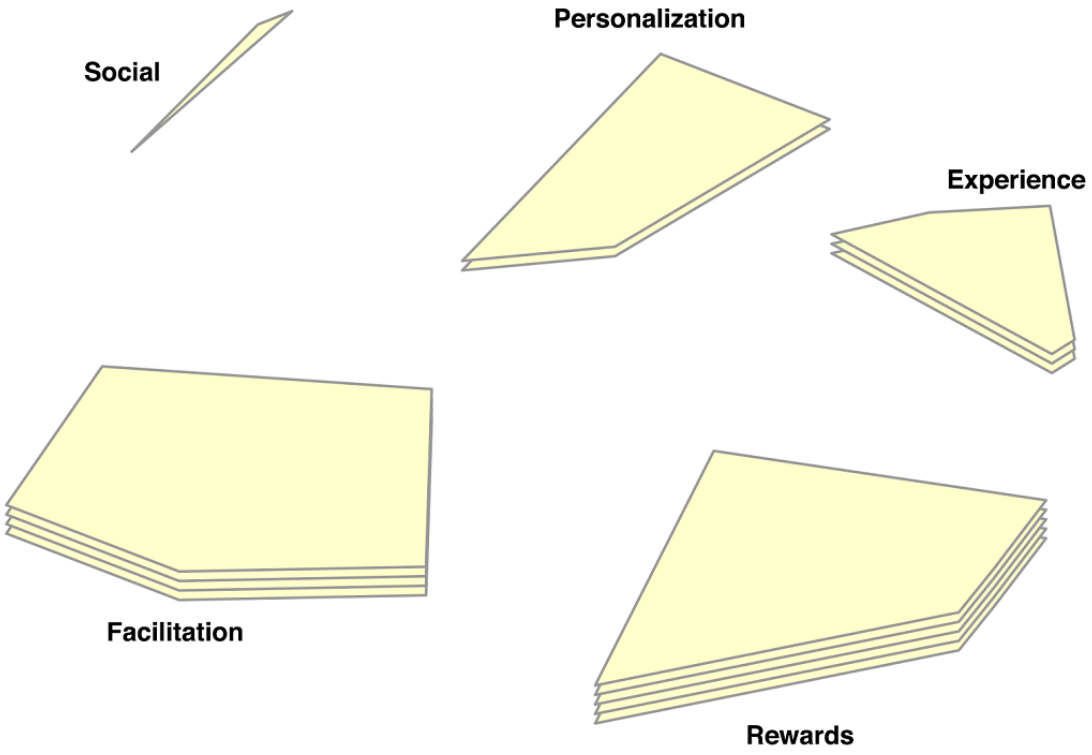

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Figure 8. Cluster rating map of focal question 2 where the rating of acceptance by the therapist is represented by the number of layers.

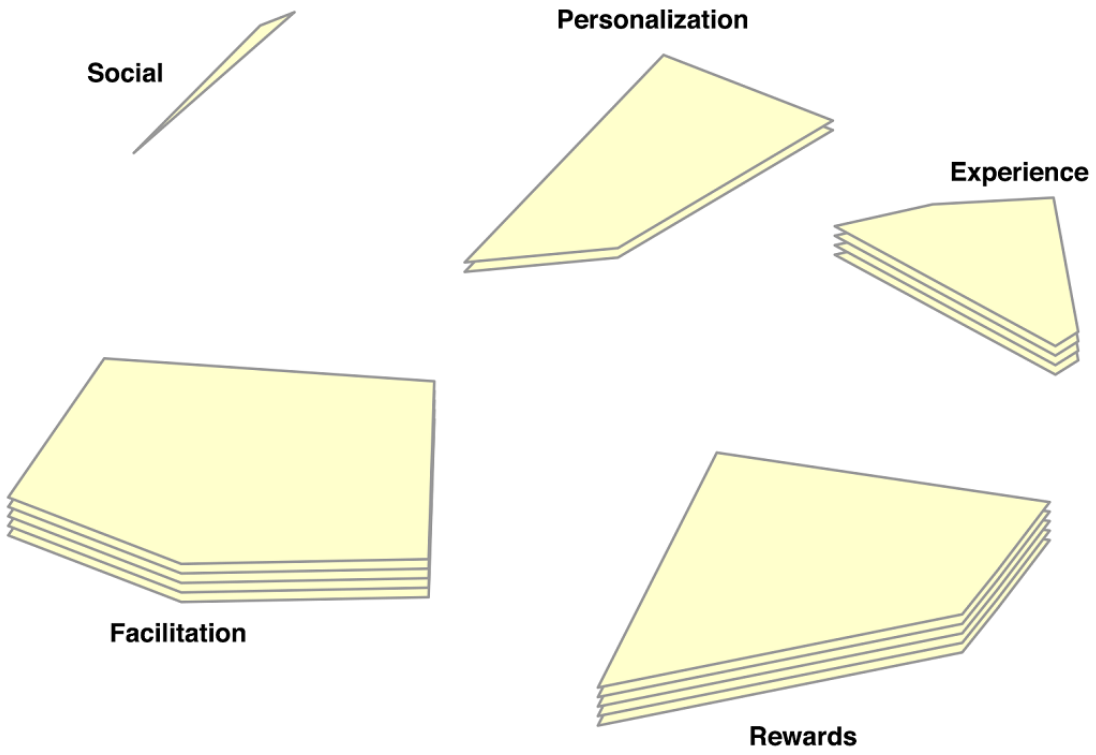
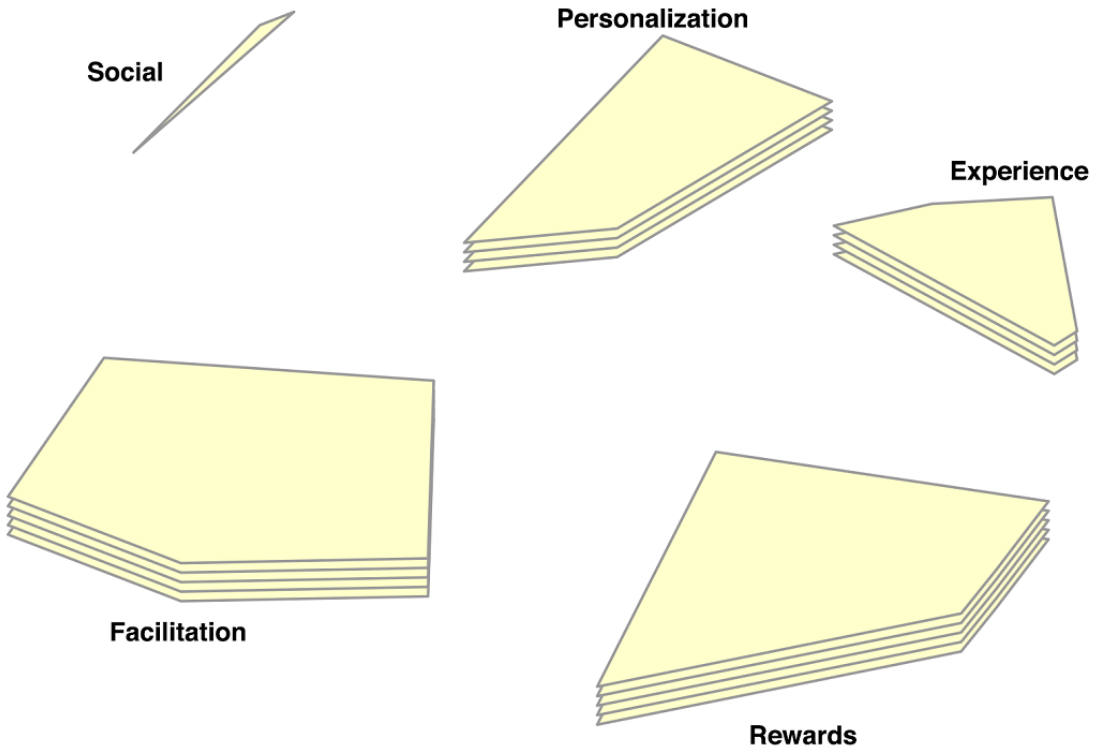


Figure 9. Cluster rating map of focal question 2 where the rating of acceptance by the patient is represented by the number of layers.



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In pattern matching, patterns of variables are compared, as illustrated in Figures 10-12. The relationship between severity and difficulty is presented in Figure 10. Again, symptoms unrelated to internal factors (eg, physically not capable) were seen as most important for patients not to do homework. At the same time, these "symptoms unrelated to internal factors" (Figure 10) were regarded as hardest for patients to change. Homework-related reasons (eg, homework necessities not at hand) were perceived as relatively easy to change by patients. In Figure 11, the relationship between importance and acceptability of the therapist is shown. Rewards are seen as both important and acceptable by therapists. Social elements, such as inviting friends to join or an in-game social network, were perceived as not important and not acceptable by therapists due to privacy and confidentiality issues. Although facilitation and fun were acceptable to therapists, their importance was comparatively low. Figure 12 shows the relationship between importance and acceptability of the patient. The results are similar to the previous figure.

Figure 10. Pattern match of focal question 1 showing the relationship between severity and difficulty.

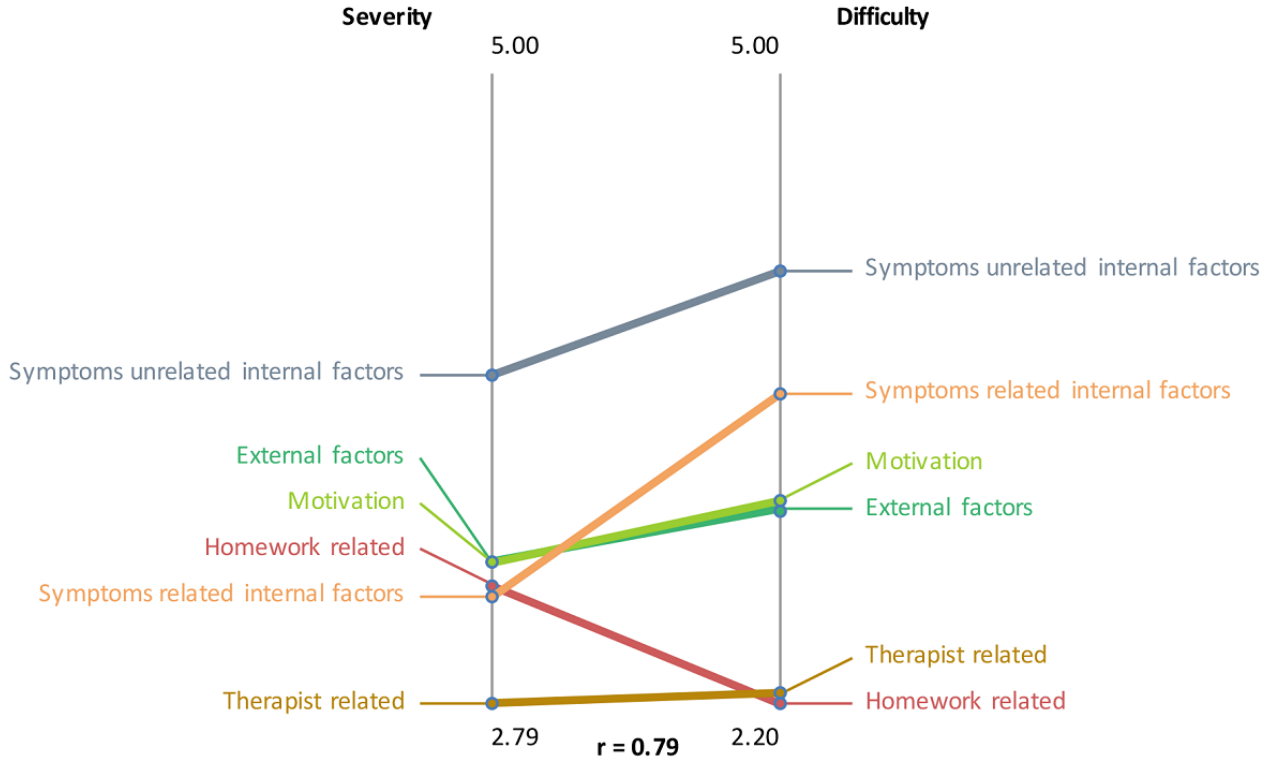

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Figure 11. Pattern match of focal question 2 showing the relationship between importance and therapist acceptance.

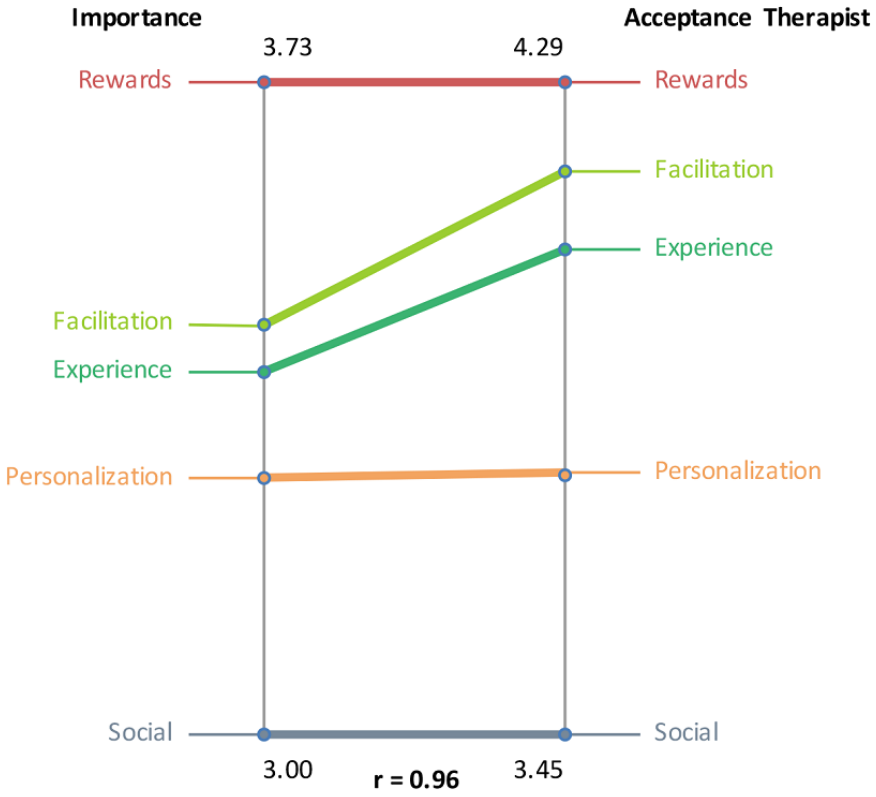
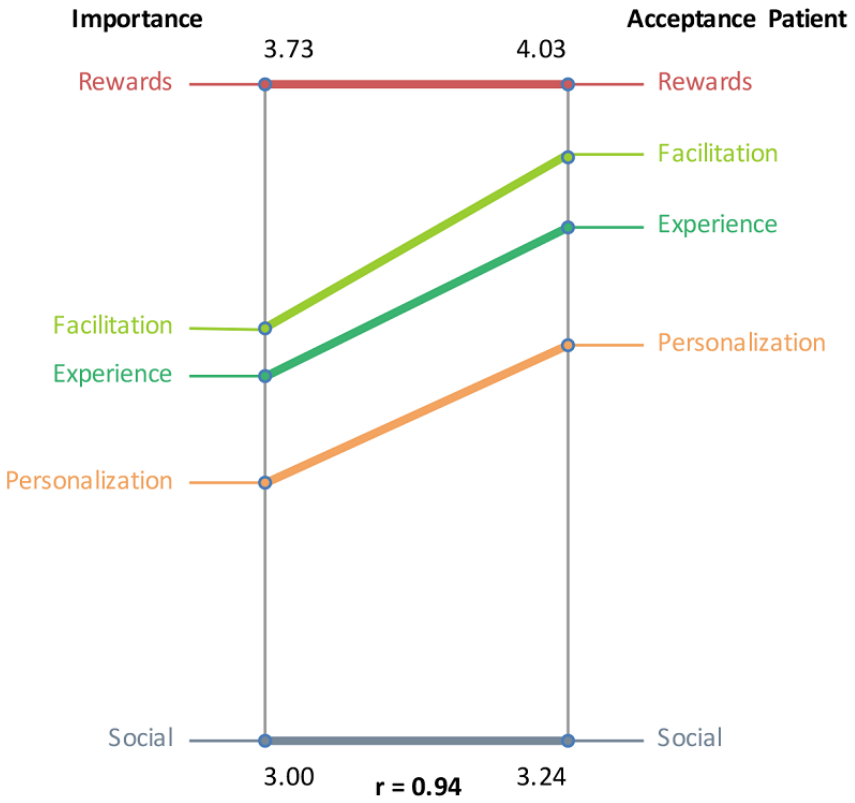


Figure 12. Pattern match of focal question 2 showing the relationship between importance and patient acceptance.



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The variables severity and difficulty were plotted against one another to explore their relationship (Figure 13). The analysis showed that item number 24 (troubles with Dutch language) was seen as most severe and most difficult to change. The variables importance and acceptance by the therapist were plotted against one another to examine their relationship, as illustrated in Figure 14. The plot shows that game design element 1 (rewards of different degrees) was seen as the most important and one of the most accepted by therapists to implement. The variables importance and acceptance by the patient (according to the therapists) were plotted against one another to examine their relationship, as can be seen in Figure 15. The analysis showed that game design element 1 (rewards of different degrees) was seen as the most important and one of the most accepted by patients (from the therapist's perception) to implement.

Figure 13. Bivariate plot of severity versus difficulty showing their relationship.

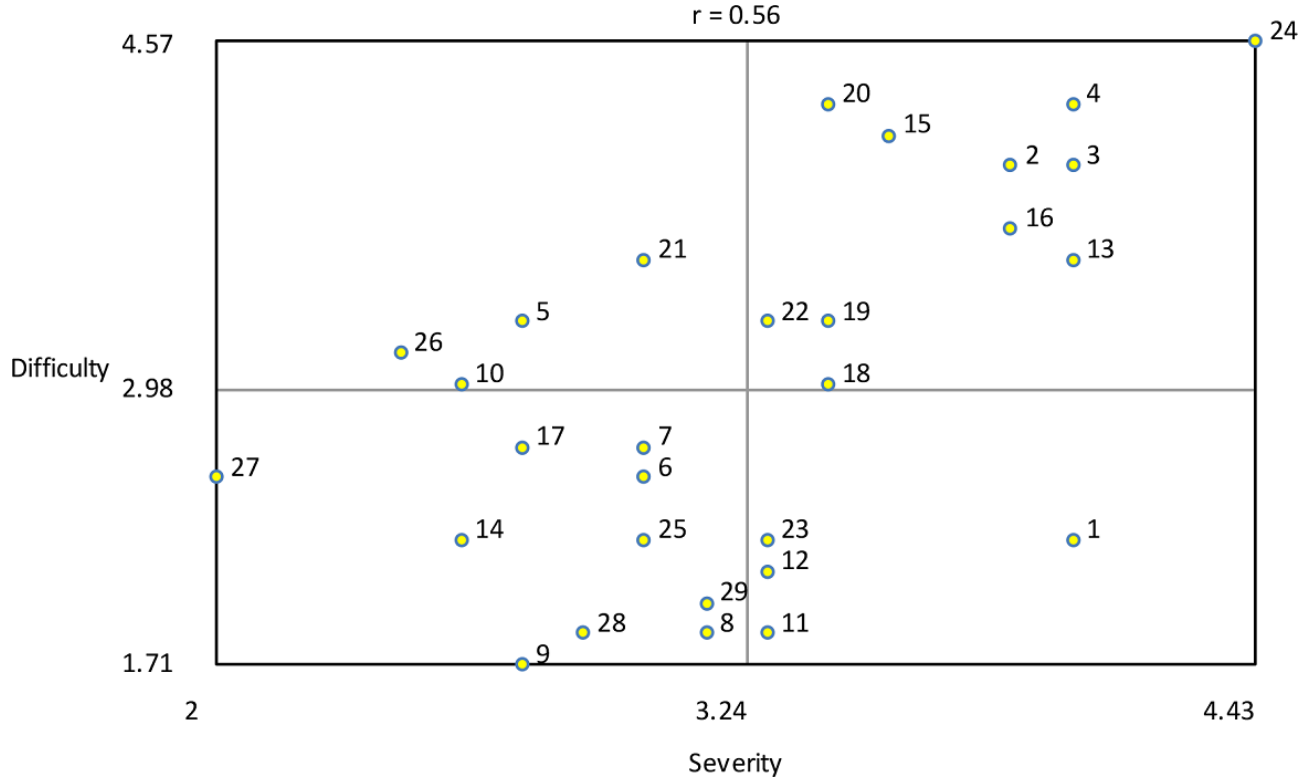

Figure 14. Bivariate plot of importance versus therapist acceptance showing their relationship.

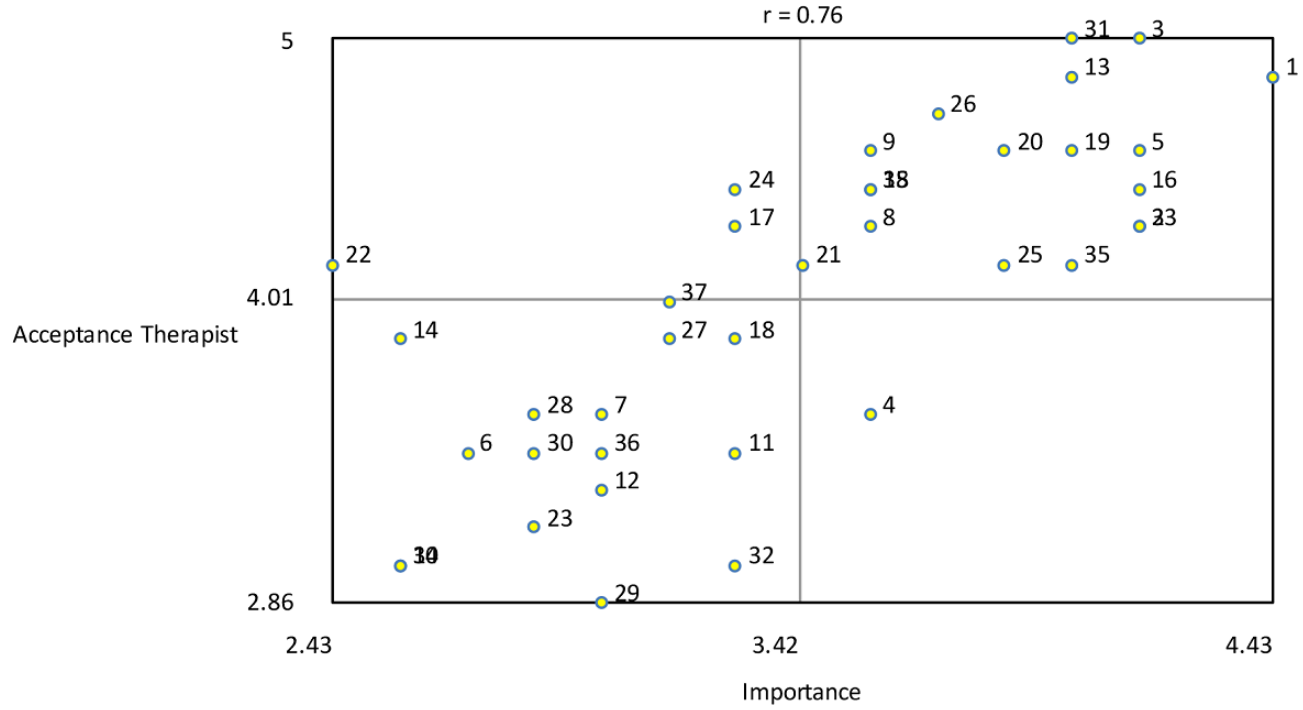

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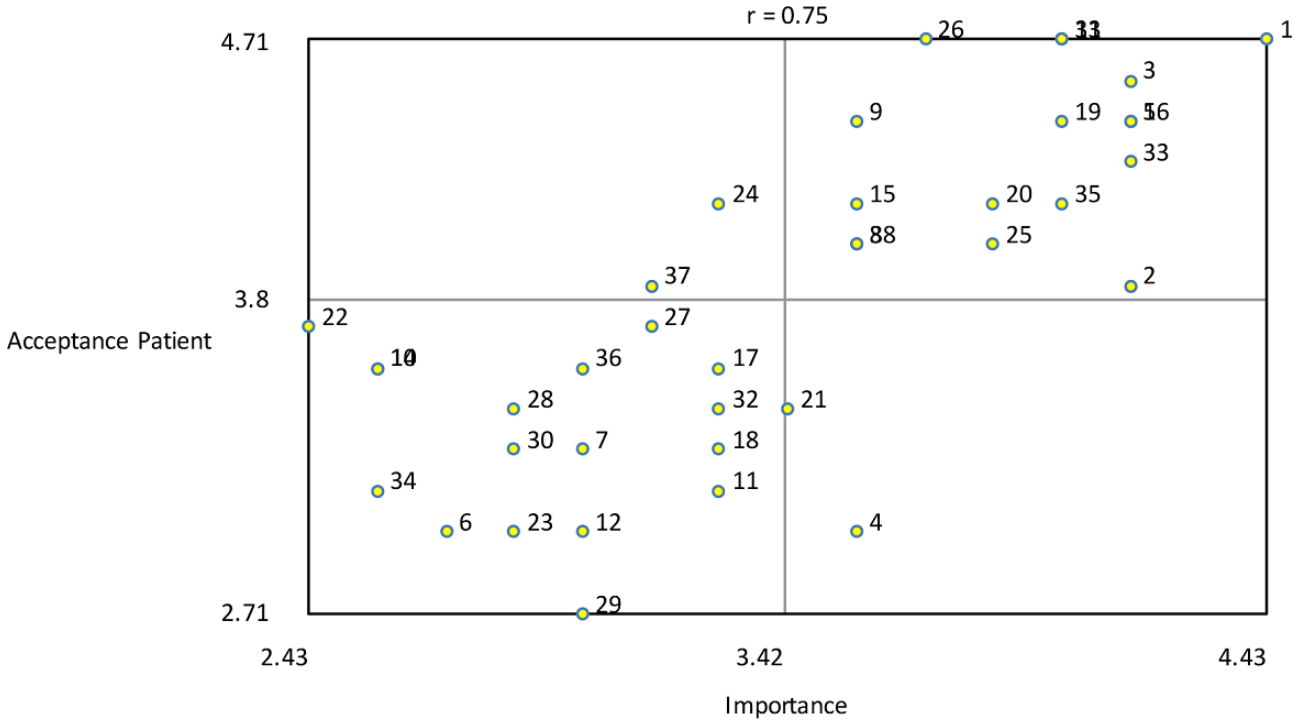
Figure 15. Bivariate plot of importance versus patient acceptance showing their relationship.



Phase 6: Utilization

The utilization phase resulted in a summary of results, limitations, and conclusions.

Discussion

Summary of Results

This study aimed to gain a better understanding of the potential of using game design elements in CBT homework to boost adherence. A total of 7 behavioral therapists participated in the concept mapping session. Symptoms unrelated to internal factors (such as physical incapability) were perceived as the most important reasons for patients not to do homework. These factors were perceived as difficult to change and might not be the responsibility of the therapist. However, next to these, external factors (no time due to crisis situations, do not want immediate environment to know, home-situation does not provide enough space or structure, and therapy out of picture due to daily activities) and motivation (such as too little intrinsic motivation, forgot to do the assignment, and being lazy) were perceived as relatively important reasons that cause patients not to do assignments. These barriers are similar to the findings of Bunnell and colleagues [46]. Homework-related characteristics, although not the most important, were seen as fairly easy to change. Facilitation (such as reminders, clear end goal, daily life integration, visualize goals, pop-ups, short, and easy and clear instructions) and reward (rewards of different degrees, feedback, achievements, daily bonus that increases in value, time limit, unlock new features, levels, repetition of assignment till mastery, buy upgrades, and overview of progress) were perceived as the most important gamification clusters that could help patients do their homework. Therapists think that facilitation and rewards will be most acceptable to be used in CBT homework and also to be most accepted by patients as well.

The result of this study, the perception of therapists that the game design element facilitation, such as reminders, can help patients make CBT homework, fits nicely with earlier findings that homework adherence is higher when less time passes after the assignment of homework [10]. Giving reminders soon after the assignment of homework can thus contribute to a higher homework adherence. Also similar to earlier research, facilitation such as giving clear instructions to patients is an important component of homework adherence [47,48]. In gamified form, it could mean a tutorial or explanation of the homework with immediate rewards. In many mobile games (such as FarmVille 3 [Zynga Inc] or TopHeroes [River Game HK Limited]), the onboarding tutorial often gives immediate rewards. In the same way, using rewards, such as achievements, seems compatible with existing literature suggesting that patients' motivation is strongly linked to homework adherence [9,12]. Earlier studies also show that using rewards in internet interventions can boost adherence, although not specifically focusing on CBT homework [35]. Although gamification seems to have potential to tackle some of the obstacles that patients could have to make CBT homework, it should be acknowledged that technology like gamification cannot solve all of these obstacles.

Limitations

One of our limitations is the small sample size of the concept mapping. One of our limitations is the small sample size of the concept mapping, although there are no fixed rules for the sample size to be applied. Adequate sample sizes are influenced by the complexity and interactions between concepts, among others. Another limitation is the heterogeneity of the group as most of the therapists in our study were female (6 out of 7) even though it is a good representation of the field. Furthermore, no patients participated in this study; thus, the perception of what

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is acceptable or seen as important to implement in order to help patients do homework better cannot be confirmed.

Conclusion

For future research, it would be interesting to study the effects of (combinations of) specific game design elements, not just the overall category or cluster. Also, there are combinations of game design elements that could cancel each other's effects. Furthermore, the minimum number of game design elements of the same category to be used in order to be effective should also be investigated. The distinction between serving game design elements online or traditionally (nondigitally) is another intriguing aspect. Furthermore, research on patients' preferences on to be implemented game design elements is needed. All these could contribute to the future of using gamification to help patients do their CBT homework better and thus improve therapy outcomes.

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Data Availability

The datasets generated during and/or analyzed during this study are available from the corresponding author on reasonable request.

Conflicts of Interest

None declared.

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Abbreviations

CBT: cognitive behavioral therapy

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Evaluating Biomedical Feature Fusion on Machine Learning's Predictability and Interpretability of COVID-19 Severity Types: Model Development, Interpretation, and Validation

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Abstract

Background: Accurately differentiating severe from nonsevere COVID-19 clinical types is critical for the health care system to optimize workflow. Current techniques lack the ability to accurately classify COVID-19 clinical types in patients, especially as SARS-CoV-2 continues to mutate.

Objective: We explore the predictability and interpretability of multiple state-of-the-art machine learning (ML) techniques trained and tested under different biomedical data types and SARS-CoV-2 variants.

Methods: Comprehensive patient-level data were collected from 362 patients (severe COVID-19: n=148; nonsevere COVID-19: n=214) infected with the original SARS-CoV-2 strain in 2020 and 1000 patients (severe COVID-19: n=500; nonsevere COVID-19: n=500) infected with the Omicron variant in 2022 - 2023. The data included 26 biochemical features from blood testing and 26 clinical features from patients' clinical characteristics and medical history. Different ML techniques, including penalized logistic regression, random forest, *k*-nearest neighbors, and support vector machines, were applied to build predictive classification models based on each data modality separately and together for each variant. Fifty randomized train-test splits were conducted per scenario, and performance results were recorded.

Results: The fusion (hybrid) characteristic modality yielded the highest mean area under the curve (AUC) in this study, achieving 0.915, while the biochemical and clinical modalities had AUCs of 0.862 and 0.818, respectively. All ML models performed similarly under different testing scenarios and were consistent when cross-tested with data of patients infected with the original strain and those infected with the Omicron variant. Our models ranked elevated d-dimer (biochemical), elevated high sensitivity troponin I (biochemical), and age greater than 55 years (clinical) as the most positively predictive features of severe COVID-19.

Conclusions: These results are compatible with the hypothesis that ML is a useful tool for predicting severe COVID-19 based on comprehensive individual patient–level data. Further, ML models trained on the biochemical and clinical modalities together show patterns consistent with enhanced predictive performance. The improved performance observed with Omicron variant data agrees with the hypothesis that ML approaches may retain utility across variants in this study setting, although further validation is required before clinical application. Future work using larger datasets with more ethnic variation and investigating unbiased ML interpretation methods may be able to provide further validation.

(JMIR Form Res 2026;10:e76542) doi:10.2196/76542

KEYWORDS

machine learning prediction; data-driven; COVID-19; clinical types; clinical decision support

Introduction

The COVID-19 pandemic caused by SARS-CoV-2 has impacted health care systems everywhere. Since 2019, several major SARS-CoV-2 variants and subvariants have manifested, with the Omicron variant being the most persistent since November 2021 [1]. A critical effect of the pandemic has been the sudden increased burden on health care facilities, mostly hospitals. The influx of patients with severe COVID-19 overwhelms intensive care units, which results in increased mortality [2], especially in regions with fewer health resources [3,4].

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In current clinical practice, patients with COVID-19 are typically classified as having severe disease by features such as shortness of breath, low oxygen saturation, and low partial pressure of oxygen in arterial blood/fraction of inspired oxygen. However, these few features cannot sufficiently distinguish between patients with severe and those with nonsevere COVID-19, as some patients with severe COVID-19 may lack these or any symptoms upon admission [5]. Without suitable medical intervention, these patients may progress quickly to a critical condition, resulting in a high risk of mortality [6]. This uncertainty motivates a predictive method of classifying patient types, which is reliable and efficient, while also making use of alternative features. Early determination of patient types may enable health care professionals to improve their treatment plans and optimize facility resources.

The interest in integrating machine learning (ML) into general clinical practice has grown rapidly in recent years [7]. Particularly, studies on the implementation of ML as a method for clinical decision support systems (CDSSs) are ongoing. While these studies have shown great potential, their greatest limitation is a lack of interpretability [7]. Given the weight of their decisions, clinicians are hesitant to rely on "black-box" systems. In response, the subfield of explainable artificial intelligence has emerged to provide clinicians with more transparent ML models [8]. This direction of work seeks to incorporate mechanisms within ML pipelines that output both reliable classification predictions and understandable decision processes. Early detection of COVID-19 severity in patients, using ML, is often studied using a singular ML technique or data modality [9,10]. Among the studies using multiple data types or ML techniques [11], many only used data from the early waves of infection. Some attempts to provide interpretable models were found [11], but many lacked this feature.

In this study, we investigated the performance and feature importance of various ML techniques for COVID-19 severity classification prediction, and then we evaluated feature modalities that provide the most predictive and consistent results. We trained ML models using different techniques with patient-level biochemical and clinical feature modalities, both separately and together as a fusion modality. We applied logistic regression (LR), decision tree–based random forest (RF), *k*-nearest neighbors (kNN), and support vector machines (SVM), and we evaluated their abilities to predict severe COVID-19. We developed these ML models from data collected from patients infected with the original strain and Omicron variant to investigate model consistency across different variants within this study.

Methods

Data Collection

Our study uses two distinct datasets covering two time periods with distinct dominant viral variants. All patients were confirmed to be positive for COVID-19 by two independent quantitative reverse transcriptase–polymerase chain reaction (qRT-PCR) tests before inclusion in this study. The first set includes 362 patients infected with the original SARS-CoV-2 strain upon admission to Wuhan Union Hospital in China from January to March 2020. This dataset was previously described and analyzed by Chen et al [5] and serves as a comparative baseline in this study. Among these 362 patients, 148 had severe COVID-19 according to the guidelines established by the National Health Commission of China and the American Thoracic Society [12,13], while the remaining 214 were designated as having the nonsevere type. Patients were categorized as having severe COVID-19 based on at least one of the following criteria: (1) respiratory rate of >30 breaths per minute, (2) oxygen saturation of <93% at rest, or (3) partial pressure of oxygen in arterial blood/fraction of inspired oxygen of <300 mm Hg (40 kPa). As this dataset contains data from patients infected by the original SARS-CoV-2 strain, this set is referred to as "original" hereinafter. The second dataset consists of 1000 patients admitted to Wuhan Union Hospital in China from December 2022 to January 2023, during which time patients were diagnosed with the SARS-CoV-2 Omicron variant. Based on the same guidelines outlined earlier, 500 of these patients were classified as having severe COVID-19, while the other 500 were classified as having nonsevere COVID-19.

In our study, the input data were complete and without any missing feature data. The deidentified patient information comprised two main modalities of biomedical features. The first feature modality had 26 distinct laboratory testing features from blood tests, most of which were continuous values of the readings. The specifics of these tests are reported in detail in our prior study [5]. We refer to this feature modality as "biochemical" hereinafter. The second is a total of 26 features of one-hot encoded binary values indicating the presence of preexisting conditions, comorbidities, symptoms, and other key risk factors such as demographic information. This modality is referred to as "clinical" features hereinafter. A complete description of these features across the two modalities is presented in the supplementary materials of our prior study [5]. Together, features from both modalities were appended into a single corpus of deidentified patient data with 52 multimodal features. This was referred to as the "fusion" set, as it fused across the continuous, real-valued biochemical and binary clinical feature modalities. We note that the specific features of respiratory rate, oxygen saturation, and fraction of inspired oxygen were excluded from our predictive feature list, as they were the original clinical standard to determine COVID-19 severity.

ML Pipeline Development, Validation, and Interpretation

We developed, evaluated, and compared the performance of several state-of-the-art ML classification techniques, including RF, kNN, and SVM. All ML techniques were implemented as supervised binary classification problems. To acknowledge LR's popularity in the field [11,14-19], we included it as a benchmark method. LR is generally sensitive to highly correlated variables, also known as multicollinearity, making predictions less precise [20]. This technique is also rather susceptible to overfitting; hence, it may be less capable of generalizing to unseen prediction sets. A powerful method of reducing overfitting is through regularization or penalization of regression. When LR is penalized (usually using l1 or l2 norms), the multicollinearity issue can be reduced [16].

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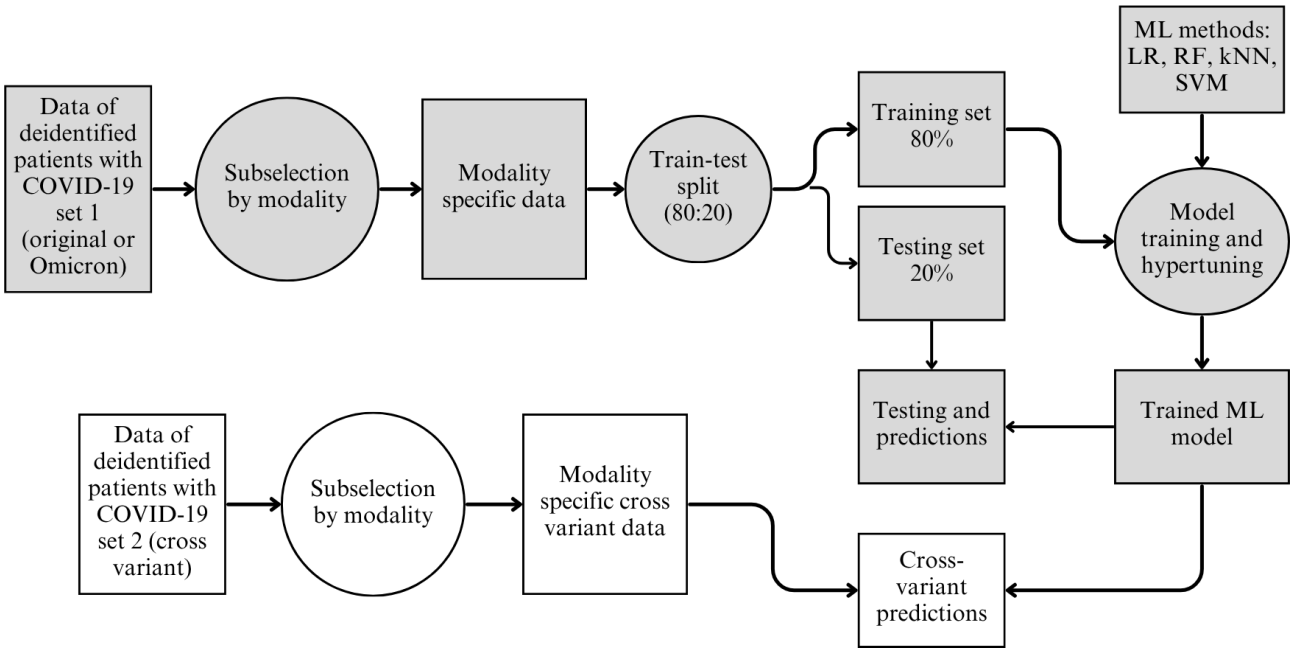
To contrast with LR, we evaluated RF, kNN, and SVM. RF is an ensemble learning algorithm that adapts to nonlinearities within the data [21]. Within the "forest," each individual binary decision tree is built by recursively partitioning subsets of the training data according to the features that yield the most information gain. Like LR, RF is interpretable after training and is a frequent choice for CDSS tasks. The kNN classifier assigns samples to their predicted classes with which they share the most similarities, as determined by a chosen distance function [22]. This technique's performance depends on the choice of number of "neighbors" to the sample that the algorithm consults when predicting a class. We included kNN, since it is a popular classifier due to its ease of use and effectiveness when dealing with larger datasets [23]. Lastly, SVMs are classifiers trained to create boundaries between classes in the high-dimensional feature space. SVM aims to maximize the distance between samples of different classes. This decision boundary is referred to as a hyperplane, and its geometry allows for application to both linear and nonlinear problems. SVM is also a frequent choice of classification algorithm for CDSS tasks [24,25].

Using Python 3.10 and a variety of ML-related libraries from scikit-learn [26], we developed an end-to-end ML framework for each of the four classifiers to predict COVID-19 severity types from patients' clinical, biochemical, and fusion feature modalities. A full list of packages is included in Multimedia Appendix 1. The nonsevere and severe COVID-19 types were labeled as 0 and 1, respectively. Each classifier was constructed to predict the outcome (0 or 1) based on the input features provided. We provide a graphical display of this pipeline in Figure 1.

Figure 1. Machine learning (ML) model pipeline design. Deidentified patient biomedical data were collected from Wuhan Union Hospital from January to March 2020 (patients infected with the original SARS-CoV-2 strain: n=362) and December 2022 to January 2023 (patients infected with the Omicron variant: n=1000). The data were grouped by their feature modality: biochemical, clinical, or fusion. An 80:20 split was performed to generate training and testing sets, respectively. Four classifiers were developed and evaluated for their performance: logistic regression (LR), random forest (RF), *k*-nearest neighbors (kNN), and support vector machine (SVM). Upon hyperparameter tuning, each classifier was validated with the same-variant hold-out set and the preprocessed cross-variant set.



For a given dataset, the corpus was first randomly partitioned into training and hold-out testing sets by an 80% to 20% split, respectively. Each feature type—biochemical, clinical and fusion—was then preprocessed by a standard scaler separately prior to training to ensure consistency across different features. Following the scaling step, a grid search method of hyperparameter tuning was used during training to maximize the ML model's performance. The resulting optimal hyperparameters for each classifier are detailed in Multimedia Appendix 1. Upon completion, the model with trained hyperparameters was then applied to the 20% hold-out data for testing. This process was repeated 50 times to generate different random training-testing splits and hyperparameter searches, each resulting in an independent model. To summarize, each model only witnessed 80% of a given dataset for training and was evaluated for its performance on the remaining 20% of unseen data. This process was conducted to avoid overfitting [27] and establish an average performance for each setting.

ML classifiers' performances were evaluated by the receiver operating characteristic (ROC) curve and computing the area under the curve (AUC) of ROC. In this study, AUC was selected as the main performance metric (as opposed to the F-measure or accuracy) because AUC has been shown to be more reliable than the other metrics [28]. For both the original strain and Omicron variant datasets, we evaluated ML classifier performance of training and testing on each modality separately and fused.

Each dataset (the binary clinical feature modality alone, the continuous biochemical feature modality alone, and a fusion modality that incorporates both feature modalities) underwent the pipeline defined earlier. To evaluate the consistency of the developed ML classifiers, we swapped and cross-tested with

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testing data from the other variant. For example, models trained on the original SARS-CoV-2 strain data were also tested with Omicron variant data, and vice versa: this process was mirrored for classifiers trained on Omicron variant data. For cross-testing, the testing data were standardized according to the scaling scheme from the classifier's training data. During cross-testing, the entire corpus was used as a hold-out testing set, since the classifiers were only trained with one variant and never trained with the other variant's data. The cross-set testing was evaluated for its performance exactly as the same-set testing.

One of the advantages of certain ML classification techniques is their interpretability in addition to performance. Of the classifiers developed in this study, we gathered insights from LR and RF classifiers. The resulting feature coefficient vector obtained from training LR indicated what the classifier "learned" from the data. This appears as the largest absolute coefficient corresponding to the most influencing feature in predicting the severe COVID-19 type [29]. For RF, feature importance was quantified and ranked by the feature's mean decrease in Gini impurity [30], which is commonly used in feature selection tasks [31]. During RF's training, these feature importances were computed using scikit-learn's feature_importances_ package [30]. By averaging the feature rankings (ie, importance in predicting the severe COVID-19 type) over 50 runs, we compared feature importance identified by LR versus that identified by RF, as well as different feature importances between the original strain and Omicron variant data. These comprehensive investigations enabled us to validate findings from the ML classifiers by cross-checking results with other studies performing traditional statistical studies aimed at identifying predictive features of the severe COVID-19 type.

Ethical Considerations

All patients were comprehensively evaluated before being admitted to the hospitals. Their fully deidentified, anonymous biomedical data were extracted from the electronic health record system. All participants were informed about the study, agreed to participate, and provided written informed consent. An institutional review board (IRB) application was submitted and approved by the Wuhan Union Hospital, Tongji College of Medicine, Huazhong University of Science and Technology (IRB approval #IEC-J-345), where the data were collected.

Results

ML Classifiers' Performance

Upon running each ML classifier pipeline for 50 independent repetitions, the average AUC value was calculated (Table 1). We validated that the computed average AUC was equal to the AUC of the composite ROC curve; hence, there is no need for their distinction. These values were tabulated according to which SARS-CoV-2 variant dataset and modality were used for training each ML classifier. The SDs of the AUC did not exceed 0.06 across all testing scenarios. A summary of the SDs is provided in Multimedia Appendix 1.

Table . Areas under the receiver operating characteristic curve.

Modality and testing sets	Training sets							
	Logistic regression		Random forest		*k*-Nearest neighbors		Support vector machine	
	Original	Omicron	Original	Omicron	Original	Omicron	Original	Omicron
Biochemical								
Original	0.667	0.681	0.678	0.739	0.608	0.664	0.671	0.676
Omicron	0.746	0.849	0.777	0.862	0.690	0.800	0.740	0.853
Clinical								
Original	0.720	0.768	0.708	0.757	0.668	0.735	0.728	0.769
Omicron	0.754	0.818	0.746	0.792	0.724	0.789	0.782	0.808
Fusion								
Original	0.749	0.754	0.697	0.763	0.692	0.733	0.739	0.749
Omicron	0.798	0.915	0.809	0.893	0.791	0.858	0.827	0.908

Our tuned ML classifiers demonstrated overall high AUCs in predicting patients with severe COVID-19 in this study setting. In our study, ML models trained from Omicron variant data performed the best across all scenarios in our design. The highest AUC among classifiers trained on Omicron data was 0.915, compared to the original strain data's highest AUC at 0.827 (Table 1). Performance of different ML classifiers trained on the same dataset showed minor differences. All ML classifiers developed from either original or Omicron data performed similarly when tested on the Omicron data.

For each ML classifier, ROC plots were generated for the same-variant and cross-variant testings, yielding a total of 4 training-testing combinations (original-original, Omicron-Omicron, original-Omicron, and Omicron-original, where the latter two were cross-variant testings). Each ROC plot visualizes comparisons among the three feature modalities (clinical alone, biochemical alone, and fusion). All 16 plots are presented in Multimedia Appendix 1. For brevity, we discuss four graphs from RF in Figures 2A-2D. Each graph shows the composite ROC plot over 50 independent repetitions for each modality. The shaded regions denote 1 SD from the mean of

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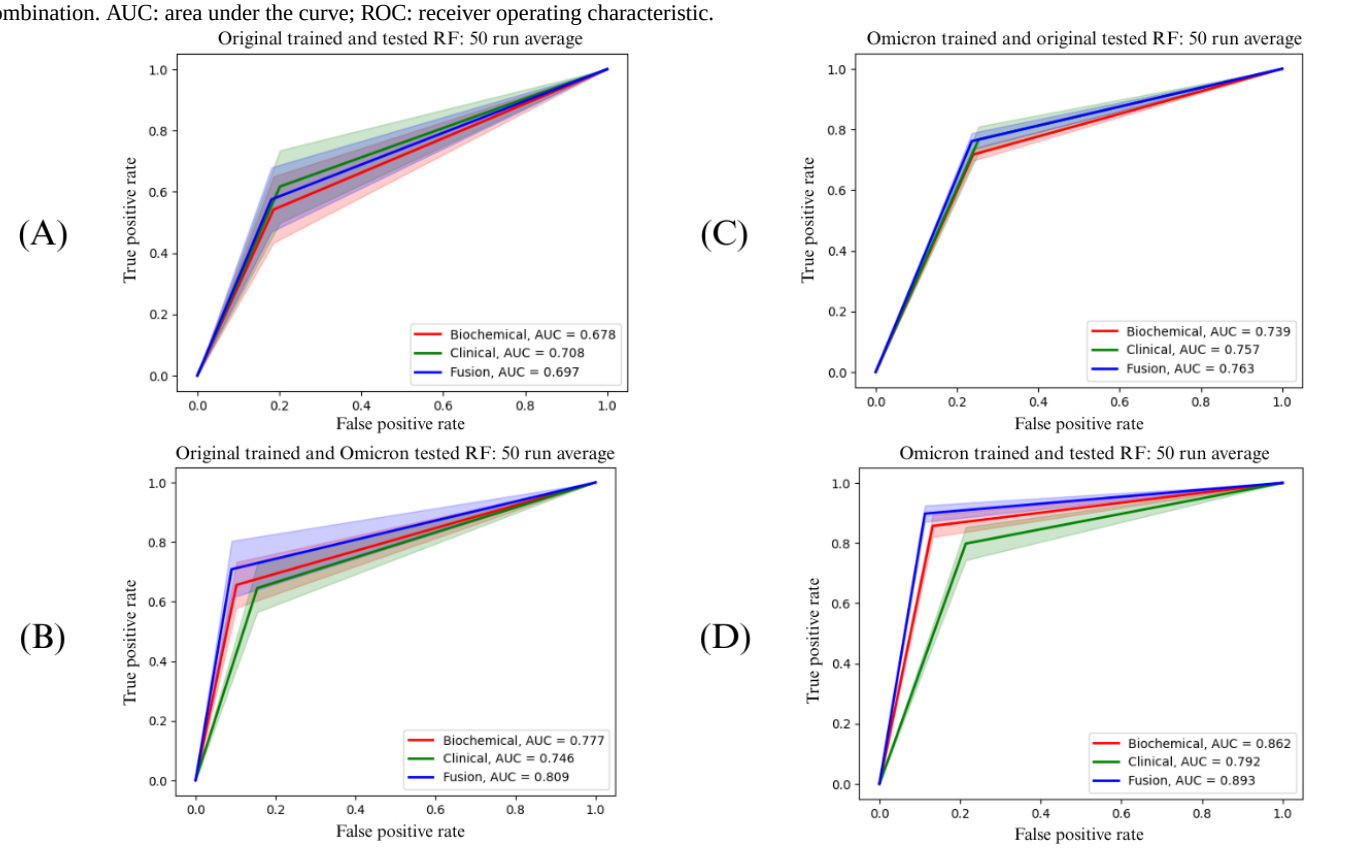
the true positive rate. The red, green, and blue lines represent the performance of models with biochemical, clinical, and fusion feature modalities, respectively.

Classifiers trained with the fusion feature modality generally demonstrated relatively higher predictive power than either biochemical or clinical feature modality alone within this study. The clinical feature modality performed slightly worse than the fusion modality, while the biochemical feature modality alone had the relative least predictive power. Regardless of ML classification technique, models trained and tested with original strain data experienced the largest variation in their performance. We note that this combination also had the lowest performance of the four training-testing combinations. Classifiers trained with original strain data had improved performance when cross-testing with Omicron data.

This table displays the mean AUC values of each ML classification technique when applied to various training and testing combinations over 50 random independent splits. For each classifier, a model was developed, trained, and tuned with either data of patients infected with the original strain or Omicron variant. The developed classifier was tested on hold-out data from both the same variant and the cross-variant data. Values are separated by training-testing combinations, as well as feature modality for training.

Figure 2. ROC curve plots for random forest (RF). This figure shows the mean ROC curves plotted for each of the four training-testing combinations. Each figure contains the ROC curve of each data modality (biochemical: red, clinical: green, and fusion: blue). Panel (A) plots the curve of classifiers trained and tested on original strain data only (ie, original-original combination). Panel (B) plots the curve of classifiers of the original-Omicron combination. Panel (C) plots the curve of classifiers of the Omicron-original combination. Panel (D) plots the curve of classifiers of the Omicron-Omicron combination. AUC: area under the curve; ROC: receiver operating characteristic.



Feature Importance Ranking

During each replication of the ML classifier, the feature coefficient vectors from the tuned LR classifier and the mean decrease of Gini impurity score vectors from the RF classifier were recorded and averaged after 50 replications. The averaged coefficients were then used to identify potential key features that differentiate severe from nonsevere COVID-19 and to evaluate how different training data (original strain or Omicron variant) and feature modalities influence the feature rankings. Note that LR's associated coefficient vector has real values, while RF's reduction of Gini importance is interpreted as probabilities in [0, 1].

Feature importances were determined by the fusion modality, as feature fusion demonstrated the relative highest predictive power for severe COVID-19 within this study. These feature importances are displayed in Figure 3. Regardless of ML classifiers (LR and RF) or SARS-CoV-2 variant, features such as d-dimer (biochemical modality), high sensitivity troponin I (hsTNI; biochemical), and age of >55 years (clinical modality) were consistently ranked in the top five most predictive features for COVID-19 severity. Features that often appeared among the top ten also include high-sensitivity C-reactive protein (hsCRP; biochemical) and hypertension (clinical).

There were also some disagreements in feature rankings between the two techniques. For instance, LR suggested a history of chronic obstructive pulmonary disease (COPD; clinical) as an important predictive feature of the severe COVID-19 type when trained on both the original strain and Omicron variant data, but COPD was not identified as a top feature in RF. Conversely,

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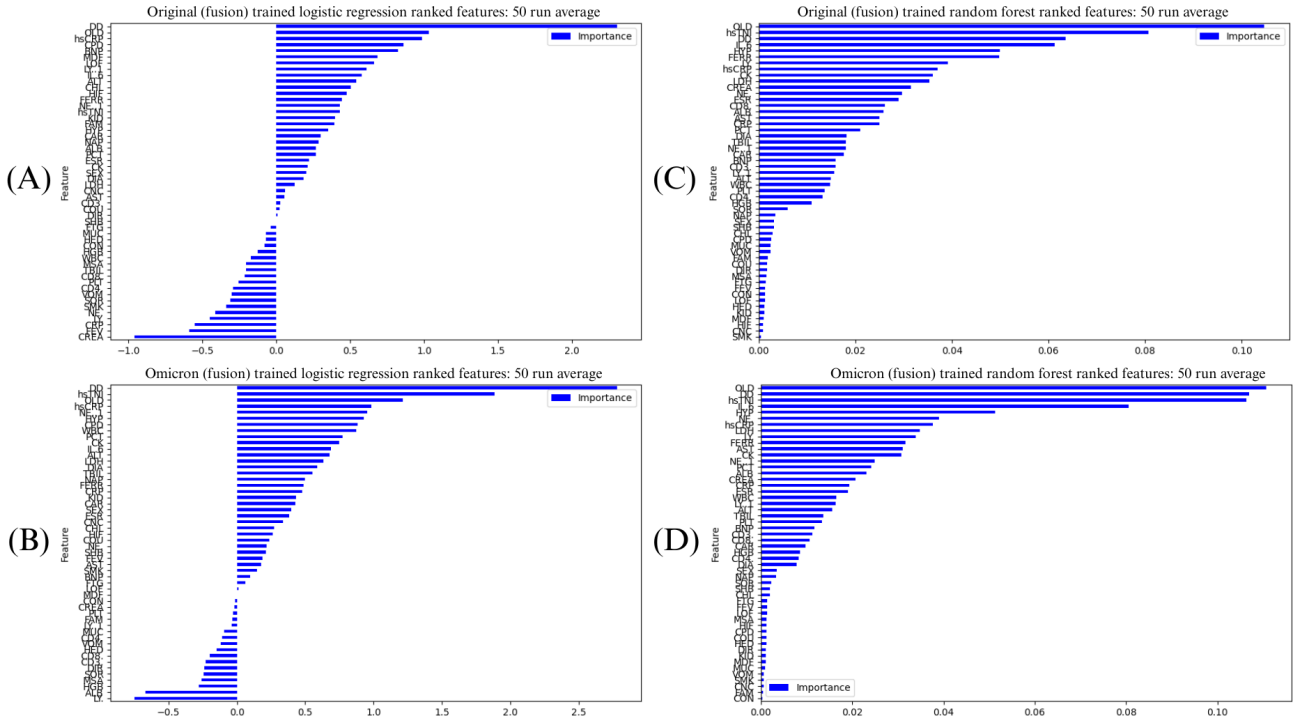
only RF identified elevated lymphocytes (biochemical), ferritin (biochemical), and interleukin-6 (biochemical) as important features regardless of SARS-CoV-2 variants.

By comparing the feature rankings across variants, LR trained on the original strain data identified low-, mid-, and high-grade fever (clinical) all among the top ten most predictive features, while its counterpart trained on Omicron variant data identified elevated procalcitonin (biochemical), neutrophil percentage (biochemical), and white blood cell count (biochemical) as the most predictive features. Such discrepancies in feature rankings were not observed in results from RF classifiers trained on different variants' datasets.

Lastly, there were some slight differences in the range of feature importance (quantified by coefficients in LR and Gini impurity scores in RF) across the two variants. LR's feature coefficients on average fell in the range of −0.95 to 2.30 for the original strain, whereas the range was −0.70 to 2.85 for the Omicron variant. Mean decreases of Gini impurity were in the range of 0-0.10 and 0-0.12 for the original strain and Omicron variant, respectively.

Figure 3. Feature rankings. This figure displays the mean feature rankings from logistic regression (LR) classifiers trained on (A) the original strain dataset and (B) on the Omicron variant, and from random forest (RF) on (C) the original strain and (D) the Omicron variant. Feature rankings are determined by the coefficients of the feature weight vector in LR, and Gini impurity scores in RF.



Discussion

ML Performance and Interpretability

In this study, we evaluated the predictive power of multiple ML techniques when using different feature modalities. We found differences in model performance and interpretations across different SARS-CoV-2 variants. Overall, our results are compatible with the hypothesis that ML is a useful tool for predicting severe COVID-19 based on comprehensive individual patient–level data. More importantly, we found evidence that fusion of the biochemical and clinical modalities showed a pattern of enhanced predictive power of all ML models evaluated in this study. Models trained on multiple feature modalities have yielded the relative best performance in many metrics across all testing sets. This pattern is worthy of further investigation, as these multimodal features are accessible by health care systems, especially with wide adoption of electronic health record systems. Results can be obtained efficiently from these systems, allowing the predictive ML classification model to be a fast and reliable CDSS tool to identify patients at high risk of severe COVID-19 [32].

The similarity of performance among the four ML techniques evaluated in this study suggests that the specific choice of modeling technique is not important for the task of classifying severe from nonsevere COVID-19 types. In general, LR, RF, and SVMs all showed relatively similar performance with their highest AUC scores being 0.915, 0.893, and 0.908, respectively. The kNN model exhibits the weakest performance of the methods considered in this study, with its highest AUC being 0.858. This may be due to the relatively small size of the datasets, requiring further investigation with more samples [23]. Since model interpretability is important to the integrability of these ML models into CDSSs [7], LR and RF should be considered. The LR model offers the analyst information on which features are positively and negatively associated with the risk of severe COVID-19. However, LR is susceptible to multicollinearity between different features [20]. The RF model, on the other hand, is more resilient to the multicollinearity issue in the input data [21]. The RF model's performance in this study is consistent that reported in other similar studies [5,11].

Upon validation, this study was among the first to use ML to propose potential critical biomedical features with the most predictive power of differentiating patients with severe

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COVID-19 across different dominant variant phases. The feature rankings provided by LR and RF may be important for clinical decision-making and provide insights into COVID-19 pathology with further clinical investigations. Our study postulates that elevated biomarkers such as D-dimer for coagulation, as well as hsTNI and hsCRP as indicators for cardiac damage, are positively associated with severe COVID-19 within this study. This finding is compatible with those of other studies that have shown that cardiovascular injury due to COVID-19 is highly associated with severe disease and adverse patient outcomes [33]. Other studies suggest that higher D-dimer is associated with higher risk of progressing to a severe stage [34]. Our findings also suggest that patients' clinical information, such as being 55 years or older or having preexisting conditions such as hypertension and COPD, could increase the risk of progression to severe COVID-19. Other studies also agree that age and hypertension are major risk factors for severe COVID-19 [35-37]. The identifications fit well within the work toward constructing explainable ML pipelines as they provide clinicians with the machine's decision-making process [7].

By identifying potential key risk factors associated with severe illness before its onset, ML may be able to give clinicians augmented views of patient information and the possibility of personalized treatment [38]. Throughout the COVID-19 pandemic, patients with COVID-19 in China were triaged based on their severity, in which patients with severe COVID-19 were treated at separate facilities compared to patients with nonsevere COVID-19 [39]. The designated hospitals for patients with severe disease were part of a coordinated emergency response to the surge of infections. It was reported that these response measures and designated facilities resulted in improved recovery rates for patients with severe disease [40]. These improved patient outcomes were made possible by accurate differentiation of patients types throughout the epidemic.

When comparing important features between patients infected by the original strain and those infected with the Omicron variant, we have identified a slight increase in the feature weight vector and Gini impurity values, which have not been reported before. This finding might suggest that COVID-19 severity could have become more predictable in more recent variants. This potentially explains the higher variability and lower performance of models trained and tested on the data of patients infected with the original SARS-CoV-2 strain. However, this claim requires significant further research with larger datasets over more detailed timelines. We also speculate that patient-level data may have higher quality in the Omicron wave than in that with the original strain. We pose a potential explanation for this difference in data quality.

As previously mentioned, our data originate from Wuhan Union Hospital in China in January to March 2020 and December 2022 to January 2023. Throughout the epidemic, government responses to disease prevention and control, medical care protocols, and national guidelines changed regularly [39]. In particular, the pathology, clinical manifestation, and diagnosis of SARS-CoV-2 evolved over this time frame [41]. According to one study detailing the timeline of such changes, clinical treatment protocols changed five times between January and March 2020 [41]. This same study reports only one change during the window of December 2022 to January 2023. The number of changes may be reflected in our data, as we found higher variability in the models trained on the data collected early during the epidemic.

Limitations and Future Work

This study has a variety of limitations. One hindrance to the generalizability of this ML framework for clinical decision support is the lack of variation in the study data samples. Due to the emergency of COVID-19, all biomedical data in this study were taken at the individual's time of admission to one health care facility, and most patients were of Han Chinese ethnicity. The limited ethnicity coverage could result in a potential sampling bias, and the conclusions from this study might only apply to specific demographic groups. While this study builds an ML framework and demonstrates its feasibility in COVID-19 CDSSs, it is necessary to further validate the findings (eg, key influential clinical and biomedical features) with larger scale multicenter studies across different regions and different phases of the pandemic to increase patient representativeness [42]. We plan to identify additional studies and/or collect new data when possible to enhance data representation, especially across more demographic groups. Findings from these future studies could further evaluate the consistency of the ML workflow (eg, whether there are further variations in influential feature sets), and lead to new clinical studies and insights on the pathological mechanisms of COVID-19 prognosis in different demographic groups.

Furthermore, the generalizability of this study's findings is limited by the differences in datasets. Our results revealed differences in performance between the two sets, resulting in the speculation that patient-level data may have higher quality in the Omicron wave than in that with the original strain. It is also possible that the difference in cohort sizes and prevalence of severe cases influenced the models' performance metrics. Nevertheless, the two cohorts were obtained from the same hospital, and we had carefully designed the inclusion criteria to make the two cohorts as comparable as possible, especially with regard to key risk factors such as gender and age. Future research could improve this limitation by analyzing datasets with fewer differences in size and prevalence.

Another limitation is that we were not able to evaluate ML model predictability for other major SARS-CoV-2 variants, such as Alpha and Delta. Retrospective studies are needed to comprehensively evaluate the consistency of the developed ML models across different phases of the COVID-19 pandemic with different dominant variants and subvariants. These evaluations may be able to support or provide alternative hypotheses for the higher variation in predictability in the earlier data as it was previously discussed.

Considering the importance of interpretability in ML for clinical decision support, we acknowledge a limitation in our interpretation methods. For the RF models, we calculated feature importance using the mean decrease in Gini impurity. Gini impurity measures have been shown to be biased toward features with a high number of possible split points [43]. This can often result in continuous features to be favored over binary features when ranking their importance using an impurity measure. We

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acknowledge that this may have introduced bias to RF feature rankings of the fusion models, as the biochemical features were continuously valued whereas the clinical features were binary. This potential favoritism of the biochemical features over the clinical features in our fusion models limits the clinical interpretation of our feature ranking results.

Future research could overcome the abovementioned limitation by using another method of feature ranking. One potential method proposes an alternative way of constructing decision trees during the training phase [44]. In this study, statistical methods are used to preselect the most informative and unbiased features for constructing the trees. This results in more accurate decision trees and a reduction in the dimensionality of training data. Exploring these and other methods for debiasing feature rankings from RF classifiers would provide an opportunity to improve on this limitation.

There are a variety of future research directions suggested by this study. Notwithstanding improvements made on the limitations previously discussed, we acknowledge the existence of other emerging ML techniques worthy of investigation. Considering the desire for explainable ML models, techniques with an easily understandable decision processes would be of the highest interest. Additionally, given the tentative promise of LR as a classification tool for COVID-19 CDSSs, other regression techniques such as Lasso or Ridge regressions may be useful. Since Lasso and Ridge regressions are also interpretable, an analysis of the performance and feature importances of these techniques may provide even more insight.

While we found evidence supporting the hypothesis that individual ML techniques are a useful tool in predicting severe COVID-19, and investigating the power of advanced ensemble techniques may facilitate new analyses. Explorations of ensemble techniques involving LR, RF, kNN, and SVM are showing signs of predictive power for cardiovascular diseases using similar underlying datasets to this study [45,46]. These studies using ensemble techniques suggest that predictive power may be enhanced even when individual classifiers are not as robust [45,46]. Our study may find improved predictive power of severe COVID-19 by using more advanced ensemble methods beyond RF.

Further studies with a focus beyond COVID-19 may provide insights into the predictive power of ML classification techniques from individual-level data collected from patients with other respiratory illnesses. This is especially useful to health care systems inundated with patients infected with various influenza strains or the respiratory syncytial virus. Using similar ML techniques and leveraging the power of transfer learning, our developed ML pipeline can be further applied to studying other diseases with similar underlying datasets (eg, clinical and biochemical).

Another potential direction is the incorporation of more data modalities, such as patient-level medical imaging (including x-ray and computed tomographic scans) and multiomics data. Due to the higher dimensionality of imaging modalities in relation to biochemical and clinical modalities, more advanced ML techniques such as a deep convolutional neural network would need to be applied to handle such modalities.

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Data Availability

An institutional review board (IRB) application was submitted and approved by the Wuhan Union Hospital, Tongji College of Medicine, Huazhong University of Science and Technology (IRB approval #IEC-J-345), where the data were collected. These data and the code created for this study are available by visiting the GitHub repository [47].

Authors' Contributions

Conceptualization: SC
Data curation: SC
Formal analysis: HWN-P
Funding acquisition: SC
Investigation: HWN-P
Methodology: HL, HNW-P, IO, KM, SC
Project administration: SC
Resources: SC
Software: HWN-P

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Supervision: SC
Validation: HL, IO, KM
Writing–original draft: HWN-P
Writing–review and editing: HL, HWN-P, IO, KM, SC

Conflicts of Interest

None declared.

Multimedia Appendix 1
Additional tables and figures.
[DOCX File, 1329 KB - formative_v10i1e76542_app1.docx]

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Abbreviations

AUC: area under the curve
CDSS: clinical decision support system
COPD: chronic obstructive pulmonary disease
hsCRP: high sensitivity C-reactive protein
hsTNI: high sensitivity troponin I
IRB: Institutional Review Board
kNN: *k*-nearest neighbors
LR: logistic regression
ML: machine learning
qRT-PCR: reverse transcriptase–polymerase chain reaction
RF: random forest
ROC: receiver operating characteristic
SVM: support vector machine

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Sexual Assault Prevention via Bystander Intervention Using Instagram Reels as a Communication Channel: Experimental Design Study

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Abstract

Background: Bystander intervention is one of the most commonly used methods to curb the sexual violence crisis on college campuses. Most universities conduct training among their student bodies to ensure students are familiar with the procedure. However, it is necessary to remind and repeat messages to audiences to underscore their importance and solidify that knowledge among populations.

Objective: In this study, the author developed Instagram-type reel messages that consider multiple frameworks used to develop bystander training and programs, such as the social norms approach and bystander barriers.

Methods: These messages were tested via a 4×1 experimental design study with college students at a large public university (N=157). The conditions were messages that emphasize norms (norm reinforcement condition, based on the social norms approach; n=39), messages that emphasize behavior (norm readjustment condition, based on bystander barriers; n=39), messages that underscore the discrepancy between perceived peer norm and actual behavior (combination condition, based on both the social norms approach and bystander barriers; n=39), and a control condition (n=40).

Results: ANOVA analysis revealed that the norms reinforcement condition and the combination condition seemed to have the greatest impact on participants' perceived norms and behavioral intentions. In particular, when assessing norms as the dependent variable, the reinforcement group was significantly different from the readjustment group (Δmean 0.682, SD 0.160; $P<.001$), the combination group (Δmean 0.675, SD 0.160; $P<.001$), and the control group (Δmean 0.432, SD 0.159; $P=.04$). For behavioral intentions to engage in bystander intervention, the reinforcement group was significantly different from the control group (Δmean 0.217, SD 0.073; $P=.02$), and the combination group was significantly different from the control group as well (Δmean 0.221, SD 0.073; $P=.02$).

Conclusions: The findings indicate that these messages could work in conjunction with training as a way to underscore the importance of bystander intervention behavior. It also highlights the role that Instagram reels can play in the prevention of sexual violence on college campuses.

(JMIR Form Res 2026;10:e86512) doi:10.2196/86512

KEYWORDS

bystander intervention; message evaluation; sexual violence prevention; social media; college students

Introduction

Background

The issue of sexual assault on college campuses in the United States is well documented [1,2]. Traditional training procedures have been used to address this concern, most prominently bystander intervention training efforts [3]. These trainings are often delivered in person or online [4]. However, considering the social media usage among college-aged adults being high (particularly Instagram at 78%) [5], it is necessary to explore mobile health (mHealth) efforts as a complementary way to enhance these trainings.

mHealth can be defined as "a medical and public health practice supported by mobile devices, such as mobile phones, patient monitoring devices, personal digital assistants, and other wireless devices" [6]. The success of mHealth strategies varies depending on the subject matter of the intervention and how the success was measured [7,8]. They can also vary based on the delivery mode, such as text messages and gamification efforts [7]. Considering this context, using social media platforms to share prosocial behavior messaging tailored for a specific population can fall under the mHealth umbrella, particularly if the social media effort does not exist in a vacuum and is combined with existing training on college campuses.

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The first step to develop a proper message to be shared on social media, particularly on platforms such as Instagram and its reels, is a strong tailoring effort in terms of the message [9]. In Couto [10], potential messages were piloted and assessed as Instagram reels addressing engagement in bystander intervention behavior using a social norms approach [11] in combination with Burn's [12] bystander intervention barriers, specifically the barrier that refers to failure to take responsibility. As defined in Burn [12], the failure to take responsibility barrier refers to people's reluctance to engage in bystander intervention because of the belief that others will do so instead. Conversely, the social norms approach suggests that people are likely to engage in a behavior if others are doing so as well [11]. Using those 2 approaches to develop 3 different messages, Couto [10] explored the feasibility and credibility of these initial messages, which were subsequently adapted for this study, as described in the *Methods* section.

However, as this study evaluates the effects of these messages, we must not rely solely on the frameworks used to develop the messages but also consider how prosocial behavior can be propagated. An often-used theoretical approach to predict prosocial behavior is the integrative model of behavioral prediction [13], which is an expansion of the theory of planned behavior [14] that includes factors that can influence not only the intentions to engage in a behavior but also environmental factors, such as media consumption [15]. Instagram reels exposure, thus, can be considered one of these background factors. The theory of planned behavior strictly suggests that the attitudes, norms, and efficacy constructs described in the framework refer to the behavior they are predicting specifically [14], whereas the integrative model of behavioral prediction allows for more flexibility [13].

Many studies have explored how to increase bystander intervention among different programs (eg, [16,17]), and a number of them use the integrative model of behavioral prediction or the theory of planned behavior to explain how people come to the decision to engage in bystander intervention (eg, [18,19]), as these theories focus on attitudes toward the behavior, norms in relation to the behavior, and efficacy in engaging in the behavior. However, this study focuses on the novelty of Instagram reels as a tool not commonly used for mHealth efforts, particularly in bystander intervention campaigns, while also considering Burn's [12] bystander barriers. It is important to note that Burn [12] refers specifically to barriers associated with the steps of the bystander intervention process, rather than to broader systemic barriers such as gender norms [20].

Instagram is a global social media platform widely used among college-aged individuals [21]. Instagram reels, in particular, are short videos that can be scrolled through or shared via Instagram stories. Instagram reels have increasingly been used by health care professionals, particularly in efforts to improve health literacy [22,23]. However, there is a gap between content created by health care professionals and content developed in alignment with a broader prevention approach, such as those implemented by universities in the United States to address sexual violence on their campuses.

Current Study

In this study, Instagram reel-type messages were tested in terms of incentivizing bystander intervention among college students. These messages have been extensively piloted [10] and were tested in a 4×1 experimental design, where each condition represents one of the main frameworks used to study bystander intervention behavior: the social norms approach [24], bystander intervention barriers [12], a combination of both, and a control. The study seeks to explore which of these conditions increases perceived norms, efficacy, attitudes, intentions to intervene, and intentions to take responsibility.

The following hypotheses were developed based on the literature discussed here and the theoretical frameworks used:

- H1: Participants in the norm readjustment condition will have higher intentions to take responsibility than those in the norm reinforcement condition.
- H2: Both norm readjustment and norm reinforcement conditions score higher regarding the intention to take responsibility, perceived peer norm, attitudes, efficacy, and intentions to engage in bystander intervention when compared to the control condition.

The following research question (RQ) was developed in consideration of the lack of evidence regarding the possible effects of combining the bystander barriers and social norms approaches to develop a bystander intervention message, and how it would perform compared to single-theory approaches:

- RQ1: Will the norm readjustment condition significantly differ from the norm reinforcement condition in (1) perceived peer norms, (2) self-efficacy, (3) attitudes, and (4) intentions?

Considering that the combination condition is theoretically exploratory, the following RQs were developed:

- RQ2: Does combining readjustment and reinforcement messages improve participants' intentions to engage in bystander behavior?
- RQ3: Are (1) perceived peer norms, (2) self-efficacy, (3) attitudes, and (4) intentions higher in the combination condition than in the other experimental conditions?

Methods

Procedures and Participants

Participants were recruited by requesting a list of student emails from the Registrar's Office of the university where the study took place, targeting a group of 2000 undergraduate students, 500 from each class standing (ie, first-year students, sophomores, juniors, and seniors). The request was made on September 22, 2023. The 2000 students were emailed, and a total of 157 participants responded, resulting in a 7.5% response rate. In the sample, 61.3% (n=68) of the participants identified as women, 94.5% (n=104) identified as cisgender, and 69.1% (n=76) identified as heterosexual. In terms of race and ethnicity, 73% (n=81) identified as White, followed by 10.8% (n=12) as Asian American and 5.6% (n=6) as a race not listed in the options; 60% (n=66) indicated that they are not Hispanic/Latino/a. The participants were also predominantly

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middle class in terms of socioeconomic status (n=81, 73%), and the plurality of the participants were first-year students (n=39, 35.1%). The age range was 18 to 29 years (mean 19.97, SD 1.81 years). Considering that normative messaging is tailored to specific groups in mind, the sample is appropriate as the recruitment strategy of requesting emails from the Registrar's Office can yield a sample that reflects the student body, even though it is a convenient sample. For a full breakdown of the demographic characteristics, see Multimedia Appendix 1.

Participants received an email with a link to the study. They first had to respond to screeners concerning whether they were university students currently in the United States; were between the ages of 18 and 29 years; and consent to participate in the study by signing the consent form, which is the first material they saw when they are redirected from their emails.

The study design is a posttest-only four (norm readjustment, norm reinforcement, norm readjustment and reinforcement, and control) by one experiment showing variations of an Instagram reel that is 20 seconds long concerning bystander intervention behavior. This Instagram reel effort has been rigorously tested quantitatively and qualitatively in terms of credibility, reliability, validity, and perceived message effect with a different sample with similar characteristics [10]. Table 1 shows a breakdown of each condition, its theoretical framework, and an example message. Messages were developed using data from the population (different sample) that focused on normative behavior. The visuals included a party video, and the audio featured uplifting music. The messages are slightly different from the ones tested in Couto [10] to account for the feedback participants shared on credibility. Participants responded to close-ended survey items about the message's production and credibility, as well as open-ended items. Multimedia Appendix 1 provides a list of links to examples of the messages tested in this study.

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Table . Description of conditions, theoretical frameworks, and example messages of study investigating the effect of different messaging in the format of Instagram reels on college students' intentions to engage in bystander intervention behavior in 4×1 experimental design study.

Condition	Theory	Example message

Readjustment	Barriers	• BE AN ACTIVE BYSTANDER
		  • Only 48% of (students) have told someone that their drink had been drugged (based on the response of 249 university students in Spring 2023)
		• IT'S ON YOU!
		  • Be part of the group that helps!

Reinforcement	Social norms	• BE AN ACTIVE BYSTANDER
		  • More than 97% of (students) believe that their friends would make sure another friend was ok if they seem to be in an uncomfortable situation at a party (based on the response of 249 university students in Spring 2023)
		• IT'S ON YOU!
		  • Be part of the group that helps!

Combination	Barriers + social norms	• BE AN ACTIVE BYSTANDER
		  • More than 95% of (students) believe that their friends would discourage a friend from getting someone drunk to have sex with them, but only 55% of (students) have done so (based on the response of 249 university students in Spring 2023)
		• IT'S ON YOU!
		  • Be part of the group that helps!

Control	N/A[a]	• BE SAFE AT YOUR NEXT PARTY!
		  • At parties, make sure you know where the nearest exit is in case of an emergency. You never know when you might have to bounce!
		• PLAN AHEAD!
		  • Safe partying is more fun!

[a]N/A: not applicable.

Ethical Considerations

The institutional review board that granted approval to this study deemed the study exempt from further review (20080 - 001). The institutional review board is housed at Washington State University. Participants received an online informed consent form before completing the study and had to agree to its terms before participating in the study. Participants had the choice to provide their email in a Qualtrics form unlinked from the study questionnaire to enter a draw for the chance to win 1 of 4 US $20 Walmart gift cards or one $100 Tango gift card for their vendor of choice. The data were collected anonymously, and it was not possible to link the email data used for incentive distribution to the study data.

Measures

Bystander Intervention Barriers: Failure to Take Responsibility

Burn [12] developed bystander intervention barrier items that are widely used in the field. Participants were asked to indicate how much they disagree (1) or agree (5) with these items on a Likert-type scale. Example items include "I am less likely to intervene to reduce a person's risk of sexual assault if I think she/he made choices that increased their risk" and "If a person is dressed provocatively, or acts provocatively, I feel less responsible for preventing others from taking sexual advantage of them." This is a subscale from a scale with 5 factors that reflect the 5 types of bystander intervention barriers identified by Burn [12]. This subscale has 8 items (Cronbach α=0.85). In its original study [12], the Cronbach α was 0.85.

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Bystander Intervention Efficacy

To address bystander intervention efficacy, the items that the University of New Hampshire adapted from Banyard [25] in short form [26] were used. The scale, originally called the Bystander Efficacy Scale, contained 4 items preceded by the following statement: "Please read each of the following behaviors. Indicate in the column Confidence how confident you are that you could do them. Rate your degree of confidence by recording a whole number from 0 to 100 using the scale given below," with a scale ranging from 0 (cannot do) to 100 (very certain). Example items include "Get help and resources for a friend who tells me they have been raped" and "Do something if I see a woman surrounded by a group of men at a party who looks very uncomfortable" (Cronbach α=0.74). In the original study [25], the Cronbach α was 0.87.

Bystander Intervention Attitudes

An adapted version of McMahon's [27] bystander intervention attitude scale was used, called the Bystander Attitude Scale, Revised, which was adapted from Banyard [25]. Participants were presented with items such as "Say something to my friend who is taking a drunk person back to his/her room at a party" and asked to answer how much they agree (5) or disagree (1) that the actions described in the items are appropriate (Cronbach α=0.80). Cronbach α for the scale was not reported in McMahon [27].

Bystander Intervention Perceived Norms

Three items were adapted from Hust et al [28]. Participants were asked to indicate how much they agree (5) or disagree (1) with statements related to perceived norms. Items include the stem "most students at my university would," followed by items such as "make sure their friend is ok if they see him/her in an uncomfortable sexual situation at a party" and "discourage a friend who said they planned to get someone drunk to have sex" (Cronbach α=0.79). In Hust et al [28], the Cronbach α was 0.69.

Intentions to Intervene in an Alcohol-Involved Sexual Assault Situation

Three items were adapted from Hust et al [28]. Participants were asked to indicate how much they agree (5) or disagree (1) with statements related to intentions. Items include the stem "I would" followed by items such as "make sure their friend is ok if they see him/her in an uncomfortable sexual situation at a party" and "discourage a friend who said they planned to get someone drunk to have sex" (Cronbach α=0.78). In Hust et al [28], the Cronbach α was 0.75.

Results

Statistical Analysis

Power Analysis

To define the size of the sample necessary to conduct the analyses described below, a power analysis was conducted using a medium-to-large effect size (0.15 for a regression, 0.3 for an ANOVA [29], a power of 0.8, and a significance level of .05). The power analysis indicated that for a 4×1 ANOVA, a sample of 128 participants (32 people per group) is necessary. Therefore, the current sample size is appropriate.

One-Way ANOVA

In an ANOVA, there are three assumptions: (1) data normality, which can be checked by investigating whether kurtosis and skewness fall within the range of [−2,2], as well as ensuring there are more than 30 individuals per group; (2) the independence of the sample, which is verified via data collection; and (3) the homogeneity of the samples, which can be ensured by having evenly sized groups or by using the Levene test [30]. Considering all groups are generally equal, all assumptions have been met.

Missing Data Analysis

To check the type of missing data in the dataset, Little's [31] MCAR (missing completely at random) analysis was conducted. Little's MCAR analysis indicated that the data are not MCAR. In this event, an expectation-maximization imputation method was used to fill in the missing data by considering other variable values when creating values for the missing data. This method is more sophisticated than mean imputation [32], making the sample more robust.

Hypothesis and Research Questions Testing

Hypothesis 1 suggested that participants in the norm readjustment condition would have higher intentions to take responsibility than those in the norm reinforcement condition. This hypothesis was rejected as the ANOVA test indicated that there were no differences between the 4 experimental groups ($F_{3,153}$=0.506; P=.68).

The second hypothesis purported that both the readjustment and reinforcement conditions would score higher in terms of the intention to take responsibility, perceived peer norms, attitudes, efficacy, and intentions to engage in bystander intervention when compared to the control condition. This hypothesis was partially supported. Post hoc results indicated that participants in the reinforcement condition indicated higher perceived peer norms (Δmean 0.432, SD 0.159; P=.04) and intentions (Δmean 0.217, SD 0.073; P=.02) compared to participants in the control condition. Participants in the readjustment condition did not indicate significantly higher means for norms (Δmean 0.250, SD 0.159; P=.40), attitudes (Δmean 0.183, SD 0.083; P=.13), efficacy (Δmean 0.059, SD 0.123; P=.96), intention to take responsibility (Δmean 0.120, SD 0.160; P=.88), or intentions to intervene (Δmean 0.164, SD 0.073; P=.11) compared to the control.

RQ 1 explored the differences between the readjustment and reinforcement conditions in terms of norms, efficacy, attitudes, and intentions to intervene. The ANOVA omnibus test indicated that there was a difference between all 4 conditions in terms of norms ($F_{3,153}$=7.965; P<.001) and intentions ($F_{3,153}$=4.095; P=.008). The post hoc Tukey honestly significant difference (HSD) test indicated that the significant difference in norms came from participants in the reinforcement condition, indicating higher perceived peer norms than participants in the readjustment (Δmean 0.682, SD 0.160; P<.001), combination (Δmean 0.675, SD 0.160; P<.001), and control conditions

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(Δmean 0.432, SD 0.159; *P*=.04). In terms of intentions to intervene, the post hoc Tukey HSD test revealed that participants in the reinforcement condition indicated higher intentions to intervene compared to participants in the control condition (Δmean .217, SD=.073; *P*=.02), but there was no statistically significant difference from the readjustment condition (Δmean 0.053, SD 0.073; *P*=.89).

The second RQ considers if combining the information from the reinforcement and readjustment conditions (the combination condition) would improve intentions to intervene compared to the other conditions. As mentioned earlier, the ANOVA omnibus test revealed that there are significant differences between the 4 groups in terms of intentions to intervene. The post hoc Tukey HSD test shows that the combination condition has a significantly higher intentions to intervene mean compared to the control group (Δmean 0.221, SD=0.073; *P*=.02). However, this is also true for the reinforcement conditions, and there are no significant differences between the reinforcement and combination conditions (Δmean 0.004, SD 0.073; *P*>.99). Thus, there seems to be no clear improvement when comparing the combination condition to other conditions in terms of intentions to intervene.

The final RQ inquired if the combination condition would be higher in terms of intentions, attitudes, efficacy, and norms than the other conditions. From previous ANOVA results discussed here, it is known that there is a difference between conditions only in terms of norms and intentions. The post hoc Tukey HSD test shows that the combination condition shows a significant improvement on the control condition in terms of intention, but it is significantly lower than the reinforcement condition in terms of norms (Δmean 0.675, SD 0.160; *P*<.001). Tables 2-4 provide the descriptive information for each condition and each outcome, a summary of the ANOVA results, and a summary of the post hoc Tukey HSD test results, respectively.

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Table . Descriptives from each ANOVA condition in the study investigating the effect of different messaging in the format of Instagram reels on college students' intentions to engage in bystander intervention behavior in 4×1 experimental design study.

Dependent variable and condition	Participants, n	Mean (SD)	SE
Norm			
Reinforcement	39	4.5354 (0.54484)	0.08724
Readjustment	39	3.8535 (0.76213)	0.12204
Combination	39	3.8602 (0.79889)	0.12793
Control	40	4.1036 (0.70049)	0.11076
Total	157	4.0882 (0.75416)	0.06019
Attitudes			
Reinforcement	39	4.4892 (0.29431)	0.04713
Readjustment	39	4.5203 (0.34800)	0.05572
Combination	39	4.5128 (0.33215)	0.05319
Control	40	4.3371 (0.47873)	0.07569
Total	157	4.4640 (0.37476)	0.02991
Efficacy			
Reinforcement	39	4.4377 (0.52525)	0.08411
Readjustment	39	4.4186 (0.46870)	0.07505
Combination	39	4.1344 (0.66494)	0.10648
Control	40	4.3594 (0.51387)	0.08125
Total	157	4.3377 (0.55590)	0.04437
Barrier			
Reinforcement	39	1.9418 (0.64281)	0.10293
Readjustment	39	1.9969 (0.77568)	0.12421
Combination	39	2.0882 (0.66285)	0.10614
Control	40	2.1166 (0.75949)	0.12009
Total	157	2.0364 (0.70950)	0.05662
Intentions			
Reinforcement	39	4.9594 (0.08613)	0.01379
Readjustment	39	4.9067 (0.24222)	0.03879
Combination	39	4.9631 (0.16172)	0.02590
Control	40	4.7424 (0.56404)	0.08918
Total	157	4.8919 (0.33196)	0.02649

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Table . ANOVA results in the study investigating the effect of different messaging in the format of Instagram reels on college students' intentions to engage in bystander intervention behavior in 4×1 experimental design study.

Outcomes	SS[a]	*df*	MS[b]	*F* test (*df*)	ω^2	*P* value
Norm						
Between groups	11.985	3	3.995	7.965 (3, 153)	0.117	<.001
Within groups	76.742	153	0.502	__[c]	—	—
Total	88.727	156	—	—	—	—
Attitudes						
Between groups	0.885	3	0.295	2.148 (3, 153)	0.021	.097
Within groups	21.024	153	0.137	—	—	—
Total	21.909	156	—	—	—	—
Efficacy						
Between groups	2.276	3	0.759	2.528 (3, 153)	0.028	.06
Within groups	45.931	153	0.300	—	—	—
Total	48.208	156	—	—	—	—
Barrier						
Between groups	0.772	3	0.257	0.506 (3, 153)	−0.010	.68
Within groups	77.758	153	0.508	—	—	—
Total	78.530	156	—	—	—	—
Intentions						
Between groups	1.278	3	0.426	4.095 (3, 153)	0.056	.008
Within groups	15.913	153	0.104	—	—	—
Total	17.190	156	—	—	—	—

[a]SS: sum of squares.

[b]MS: mean square.

[c]Not applicable.

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Table . Post hoc Tukey honestly significant difference (HSD) results of ANOVA in the study investigating the effect of different messaging in the format of Instagram reels on college students' intentions to engage in bystander intervention behavior in 4×1 experimental design study.

Dependent variable	(A) Condition	(B) Conditions	ΔMean (A–B)	SE	*P* value
Norm	Reinforcement	Readjustment[a]	0.68193	0.16038	<.001
		Combination[a]	0.67521	0.16038	<.001
		Control[a]	0.43183	0.15938	.04
	Readjustment	Reinforcement[a]	−0.68193	0.16038	<.001
		Combination	−0.00672	0.16038	>.99
		Control	−0.25010	0.15938	.40
	Combination	Reinforcement[a]	−0.67521	0.16038	<.001
		Readjustment	0.00672	0.16038	>.99
		Control	−0.24338	0.15938	.42
Attitudes	Reinforcement	Readjustment	−0.03111	0.08394	.98
		Combination	−0.02368	0.08394	.99
		Control	0.15207	0.08342	.27
	Readjustment	Reinforcement	0.03111	0.08394	.98
		Combination	0.00742	0.08394	>.99
		Control	0.18318	0.08342	.13
	Combination	Reinforcement	0.02368	0.08394	.99
		Readjustment	−0.00742	0.08394	>.99
		Control	0.17575	0.08342	.16
Efficacy	Reinforcement	Readjustment	0.01909	0.12408	.99
		Combination	0.30332	0.12408	.07
		Control	0.07829	0.12330	.92
	Readjustment	Reinforcement	−0.01909	0.12408	.99
		Combination	0.28423	0.12408	.11
		Control	0.05920	0.12330	.96
	Combination	Reinforcement	−0.30332	0.12408	.07
		Readjustment	−0.28423	0.12408	.11
		Control	−0.22503	0.12330	.27
Barrier	Reinforcement	Readjustment	−0.05509	0.16144	.99
		Combination	−0.14640	0.16144	.80
		Control	−0.17479	0.16043	.70
	Readjustment	Reinforcement	0.05509	0.16144	.99
		Combination	−0.09131	0.16144	.94
		Control	−0.11970	0.16043	.88
	Combination	Reinforcement	0.14640	0.16144	.80
		Readjustment	0.09131	0.16144	.94
		Control	−0.02839	0.16043	.998

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Dependent variable	(A) Condition	(B) Conditions	ΔMean (A–B)	SE	*P* value
Intentions	Reinforcement	Readjustment	0.05270	0.07303	.89
		Combination	−0.00364	0.07303	>.99
		Control[a]	0.21700	0.07257	.02
	Readjustment	Reinforcement	−0.05270	0.07303	.89
		Combination	−0.05634	0.07303	.87
		Control	0.16430	0.07257	.11
	Combination	Reinforcement	0.00364	0.07303	>.99
		Readjustment	0.05634	0.07303	.87
		Control[a]	0.22064	0.07257	.02

[a]$P \leq .05$.

Discussion

Principal Findings

The results indicated that the reinforcement condition seemed to have the greatest impact on the outcome variables compared to all other 3 conditions. Perceived peer norms were significantly higher among participants who were exposed to the reinforcement condition compared to all 3 conditions, and they were significantly higher in terms of intentions to intervene when compared to the control. The only other condition to show significant results was the combination condition, in which intentions to intervene were significantly higher compared to participants in the control group.

This study underscores the importance of the social norms approach when properly researched and applied. The social norms approach is commonly used as a framework for the study of reducing sexual violence on college campuses [24]. Although bystander intervention behavior exists in a different context from other prosocial behaviors that are practiced to decrease sexual violence, the importance of norms remains.

Given the lack of effect on the failure-to-take-responsibility barrier and the extremely low mean scores indicating that participants did not perceive this barrier as applicable to them, the way this barrier is conceptualized should be reconsidered. Failure to take responsibility is one of 5 barriers to engaging in bystander intervention [12]. However, it seems that these barriers are studied and considered in a linear manner, as if overcoming the first barrier opens the doors for the next step, and so on. The findings of this study challenge this assumption. Failure to take responsibility appears to be disapproved of by this population, and it was an overall nonfactor in terms of being affected by the conditions. One should consider the possibility of social desirability, but considering the responses of participants, it may reflect a reluctance to take responsibility, but rather a lack of efficacy. Further investigation is needed to determine the extent to which failure to take responsibility translates into a lack of efficacy to perform what the participants perceive as the appropriate action. Failure to take responsibility may be more closely related to a bystander's comfort level than to the belief that it is not their problem and, therefore, they will not intervene.

The conditions did not have an effect on efficacy. However, considering the size of the sample and the significance level of the omnibus test on efficacy, it is possible a larger sample would show significant effects. Although promising, efficacy is difficult to communicate in such short messages. Even in the presence of significant results, it would be inappropriate to expect college students to develop self-efficacy skills in relation to bystander intervention with only exposure to a message. Indeed, the goal of this study is not to provide a "magic bullet" but to create a tool that can be used in conjunction with the many trainings offered on college campuses across the United States [33].

In terms of theory, the findings build upon the social norms approach by showing that pluralistic ignorance can be addressed with normative messaging [24]. However, much of this study focused on establishing that bystander intervention is a unique behavior, in that pluralistic ignorance could be detrimental given the presence of the failure-to-take-responsibility barrier. Norms, however, appeared to play a greater role than the barrier, suggesting that the traditional approach to social normative messaging development may apply to bystander intervention behavior. In fact, the underwhelming role of the barrier could explain why the combination condition affected only the intentions condition. Although this was the case, the result was still noteworthy. It shows that in other paradoxical behaviors—such as bystander intervention—where perceived norms can be a detractor instead of stimulus and normative-only messaging is not enough, combining the 2 approaches could be beneficial. There is a need to explore other behaviors that function in a similar way.

This need also extends to existing studies that explore ways to promote bystander intervention behavior among college students. Although there are many studies that explore the effects of and on norms of bystander intervention trainings (eg, [11,34]), this study appears to be the first study to examine norms directly related to bystander intervention, rather than relying on proxies such as rape myth acceptance [34]. Additionally, this study is, to the author's knowledge, one of the first attempts to understand the bystander barriers empirically. Much of Burn's [12] work is based on a collective understanding of the bystander intervention literature. However, once it is established that these barriers exist when examining

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other studies, it is necessary to examine them in the context of how these barriers present themselves in messaging tailored to address bystander intervention behavior.

Furthermore, one major aspect of this study is assessing the feasibility of Instagram reels as a way to support sexual violence prevention campaigns on college campuses. As mentioned, health care workers are already using such platforms to create health-related content [22]. Incorporating tailored messaging into a new channel through a holistic health campaign appears to be the next step in meeting audiences where they are for health literacy efforts.

With these results in mind, it is also necessary to consider next steps to expand this effort. Replication studies are needed to ensure the effect is consistent. Replication should occur not only within the same population over longitudinal waves but also across different populations (in this case, college campuses). Thus, the replication effort has two components: one addressing the depth of the message (longitudinal effort) and the other addressing the breadth of the message (multiple college campuses efforts).

There is also a need for field experiments. Although results are promising, it is not possible to determine how this message would perform if it organically appeared as an advertisement on Instagram reels. A study is needed in which participants are allowed to view the content organically in a laboratory setting, followed by an assessment of how the broader college population perceives the message on their actual Instagram accounts. In a similar vein, it is necessary to test the message in different contexts and assess if this alters its effects. This can be conducted both in a replication study and in laboratory settings, focusing on trust and credibility concerns.

Finally, the results suggest that the operationalization of failure to take responsibility may be too complex to be captured in studies as it is right now. Further research is needed to investigate the underlying causes of reluctance to help others. This research would benefit particularly from qualitative efforts.

Limitations

Although many steps were taken to mitigate the limitations of this study, there are still limitations to be considered. First, the study was not conducted in a laboratory setting. This was a calculated risk to increase external validity. However, it is necessary to consider that some participants may not have watched the messages as attentively as they would have in a laboratory setting. In contrast, one element of external validity that could be improved is the inclusion of visual cues that indicate this is supposed to be an Instagram reel. Although the portrait orientation video is one possible cue, there are other elements that could have been included.

Another limitation is that, although experimental, this was a cross-sectional, posttest-only study. The results may be promising, but it is necessary to also assess longitudinal designs. Thus, no long-term effects can be established for this message intervention, and considering that the intent is multiple exposures to the message when presented organically on social media, an assessment of multiple exposure effects is also necessary.

Finally, the power analysis conducted for this study considered a medium-to-large effect size. However, it is possible that larger sample sizes could have detected more minute relationships with smaller effect sizes. More investigation is needed with larger samples. This can also be affected by the relatively high proportion of data (approximately 30%); therefore, the results should be interpreted cautiously since expectation-maximization imputation was used.

Conclusions

In this study, different theoretical frameworks that can be used individually or in combination to develop messages that encourage bystander intervention behavior in sexual violence situations on college environments were explored. The messages were designed with the intent to be an Instagram reel message, as this platform is popular within the intended audience of young adult college students [35,36], leading to a wide reach. Additionally, it is worth noting that this message would work in conjunction with other university efforts to address sexual violence prevention and bystander intervention behavior. Many universities across the United States have required bystander intervention training for first-year students (. Green Dot, in particular, is used in more than 500 universities in the United States [33].

In this study, the author explored the role of dual-theory message design in addressing bystander intervention on one specific college campus. The results underscore the importance of fully researched and tested normative messaging. There are many research implications, from the role of dual-theory approaches in the message development of health communication messages to the importance of mixed methods as a methodology. Although some limitations exist, future research focusing on the breadth and depth of the messages may address many of these limitations.

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Data Availability

Data from this study can be made available upon request at the discretion of the author.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Link to video of message example.
[DOCX File, 13 KB - formative_v10i1e86512_app1.docx]

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Abbreviations

HSD: honestly significant difference
MCAR: missing completely at random
mHealth: mobile health
RQ: research question

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A Formative Evaluation of Parental Perceptions Related to Acceptability, Appropriateness, Feasibility, and Reported Use of an e-Learning Resource Targeting Diet in the First 1000 Days: Survey Study

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Abstract

Background: In October 2022, the Nutrition Now (NN) e-learning resource was implemented within Maternal and Child Healthcare centers and Early Childhood Education and Care centers of a southern Norwegian municipality. The e-learning resource targets expectant parents, parents of children aged 0 - 2 years, and Early Childhood Education and Care staff, aiming to promote healthy dietary behaviors during the first 1000 days of life.

Objective: This study aimed to explore parental perceptions related to the acceptability, appropriateness, feasibility, and reported use of the NN e-learning resource among parents.

Methods: From October 2022 to May 2023, expecting parents and parents of children aged 0 - 2 years were recruited from 2 Norwegian municipalities, one intervention group receiving access to the NN e-learning resource, and one control. Participants in the intervention group received a web-based follow-up questionnaire 7 months after gaining access to the NN e-learning resource. Data were analyzed using descriptive statistics.

Results: Of the 179 participants in the NN study intervention group, 48 completed the web-based follow-up questionnaire administered 7 months after enrollment. Parents rated the e-learning resource positively on items assessing whether they liked and appreciated the resource, perceived it as an appropriate source of information, and found it doable and easy to use. Most respondents reported visiting the resource (38/48, 79%), although only 21% (10/48) reported frequent visits. Less than half of the participants answering the web-based follow-up questionnaire reported having watched the theme films (20/48, 42%), the recipe films (17/48, 35%), or making food using recipes provided in the e-learning resource (20/48, 42%).

Conclusions: Parents rated the NN e-learning resource positively but reported limited use. These findings point to the need for strategies that enhance engagement with self-guided digital interventions among expectant parents and parents of young children. Future efforts should focus on identifying how to maximize potential adoption of the e-learning resource and evaluate its impact to promote healthy dietary behaviors during the first 1000 days of life.

Trial Registration: ISRCTN Registry ISRCTN10694967; https://www.isrctn.com/ISRCTN10694967

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KEYWORDS

digital health; e-learning resource; digital intervention; diet intervention; Acceptability of Intervention Measure; AIM; Intervention Appropriateness Measure; IAM; Feasibility of Intervention Measure; FIM; first 1000 days

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Introduction

A balanced diet in early life is important for children's current and future health [1-3], with parents serving as the primary influences on their dietary behaviors. Digital health resources may have the potential to provide parents with accessible tools to support healthy diets within families [4,5]. Systematic reviews evaluating parent-focused digital and mobile health (mHealth) interventions suggest that some interventions may improve selected dietary behaviors, such as fruit and vegetable intake or reduced sugar-sweetened beverage consumption, while others show no significant effect [4,6]. Furthermore, few of these interventions target pregnant women or children younger than 2 years of age. The period from conception to a child's second birthday, commonly referred to as "the first 1000 days," represents a critical window during which the foundations for healthy dietary habits are established [7,8]. Developing and evaluating digital interventions targeting this early-life period could therefore be important for both research and public health.

To promote healthy dietary behaviors in expecting parents and families with infants and toddlers, the Nutrition Now (NN) e-learning resource was developed and made available through Maternal and Child Healthcare (MCH) and Early Childhood Education and Care (ECEC) centers in a southern Norwegian municipality [9]. The e-learning resource combines content from 4 dietary interventions with existing evidence of effectiveness [10-14] into a single comprehensive web-based platform, targeting different early-life transitions from pregnancy to the age of 2 years. In 2 of the interventions underpinning the NN e-learning resource, parents were involved in the development of intervention content by providing feedback on intervention materials and participating in surveys and qualitative interviews about their preference for content and experiences with the interventions [15,16]. Insights from these evaluations informed the tailoring of the NN e-learning resource. The content of the NN e-learning resource was primarily designed for parents and ECEC staff but was also accessible for MCH staff. The part of the e-learning resource targeting parents was organized into four stages, including (1) pregnancy, (2) newborn, (3) infants aged 5 - 12 months, and (4) toddlers aged 1 - 2 years. The e-learning resource provided content tailored to these stages, presented through (1) short thematic films and texts covering topics such as diet during pregnancy, the introduction of solid foods, and the development of healthy eating habits; (2) cooking videos; and (3) age-appropriate recipes. Screenshots from the e-learning resource are presented in Multimedia Appendix 1. A detailed description of the NN e-learning resource and its components is provided in the study protocol [9].

Although digital health interventions have shown potential to improve dietary behaviors, much of the existing evidence is derived from controlled research trials, and there remains a limited understanding of how such interventions perform under real-world settings. Evaluating implementation outcomes is therefore important for identifying facilitators and barriers for effective implementation, and subsequently, intervention effectiveness [17]. In the context of digital health interventions, assessing outcomes such as acceptability, appropriateness, and feasibility may provide important insights into how interventions are received and whether they are likely to be adopted and sustained in practice [18]. In a systematic review by Bonvicini et al [6], assessing the effectiveness of mHealth interventions targeting parents to prevent and treat childhood obesity, the authors report that all studies (n=20) evaluated usability, acceptability, and feasibility of their interventions. However, there remain inconsistencies in how these outcomes are defined and measured across studies within digital health. Using standardized definitions and evaluation criteria to assess these outcomes may help in faster translation of how digital health interventions succeed or fail in their effectiveness to change behavior [18,19]. Implementation science offers several frameworks for the evaluation of implementation outcomes, including the framework by Proctor et al [17], proposing 8 key outcomes: acceptability, appropriateness, adoption, feasibility, fidelity, penetration, cost, and sustainability [20]. Acceptability, appropriateness, and feasibility are commonly explored during the earlier stages of implementation [21,22] and can help tailor interventions and implementation strategies to user needs and preferences, potentially enhancing intervention adoption and impact [17,23]. According to the implementation outcomes framework of Proctor et al [17], acceptability is the perception among users that an intervention is agreeable, palatable, or satisfactory. Appropriateness is defined as the perceived fit, relevance, or compatibility of the intervention for a given person and/or the perceived fit of the intervention to address a particular issue or problem [17]. Feasibility is the extent to which an intervention can be successfully used or carried out within a given setting and reflects actual fit or suitability for everyday use [17]. Although these outcomes are conceptually similar, they capture different dimensions of early implementation [17]. An intervention may be perceived as appropriate but not feasible, or acceptable but not appropriate, underscoring the importance of assessing these outcomes separately [23].

Furthermore, it is important to examine intervention use to identify features that are most or least engaging. Intervention use is often described in the context of engagement, which is conceptualized in a variety of ways within digital intervention research [24]. Perski et al [25] have proposed a 2-part definition of engagement, where the two key components are (1) extent of use and (2) subjective experience. According to Perski, the extent of use is determined by the length of intervention contact, time exposed to the intervention, frequency of contact, and variety of content used. Together, acceptability, appropriateness, feasibility, and intervention use capture complementary aspects important to understand early implementation processes. Acceptability, appropriateness, and feasibility reflect users' perceptions about an intervention and may influence intentions to adopt and extent of use [23]. On the other hand, extent of use and experience with an intervention may shape perceptions of fit or relevance [26]. Evaluating both perceived implementation outcomes and aspects of actual use thus offers important insight into factors potentially influencing intervention effectiveness.

Finally, when evaluating digital health interventions, it is relevant to explore the characteristics of the user to determine if the intended user groups are being reached [27].

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The aim of this study was to conduct a formative evaluation exploring parental perceptions related to acceptability, appropriateness, feasibility, and reported use of the NN e-learning resource among expectant parents and parents of children aged 0 - 2 years.

Methods

Study Setting, Participant Recruitment, and Data Collection

The NN project is a hybrid type 1 implementation-effectiveness trial, using a quasi-experimental, nonrandomized design. One Norwegian municipality received access to the NN e-learning resource, while a control municipality was not given access and received usual care [9]. The NN project comprises 2 phases, with the first phase encompassing implementation within a municipality setting before scale-up to county settings (phase 2) [9]. This study reports descriptive findings from a formative evaluation conducted during the first phase of the NN project, focusing on parents in the intervention municipality who were invited to use the NN e-learning resource. The findings were intended to inform refinement of the resource and its implementation strategies before upscaling in phase 2. All expectant parents and parents of children aged 0 - 2 years were eligible to participate. This study adhered to the CHERRIES (Checklist for Reporting Results of Internet E-Surveys) [28], and the completed checklist is available in Checklist 1.

Recruitment occurred between October 2022 and May 2023 through MCH centers, ECEC centers, municipal websites, and social media. Eligible participants completed a web-based baseline questionnaire providing written informed consent and data on sociodemographic characteristics. Once enrolled, parents in the intervention municipality gained free access to the full e-learning resource. The e-learning resource was designed for the general population of expectant parents and parents of children aged 0 - 2 years, and its universal design aimed to make it accessible to families across socioeconomic positions and ethnic backgrounds.

The parent modules within the e-learning resource were self-guided and designed to be independent of human support [29,30]. Content was available in Norwegian, English, and Arabic. To encourage engagement, participants received email newsletters linking directly to the NN e-learning resource, with pregnancy-specific content for those enrolled during pregnancy and age-appropriate content for those with children. In total, 4 newsletters were sent during pregnancy, 1 at birth, 8 sent monthly from 4 to 12 months, and 12 sent biweekly from 12 to 24 months. These newsletters were automatically distributed based on the due date or the child's birthdate provided at baseline. Although newsletters provided links to age-relevant content based on due date or child's age, parents were free to navigate and use any part of the resource.

Seven months after enrollment, participants were invited by email to complete a web-based follow-up questionnaire on implementation-related outcomes and e-learning resource use. Participants who did not respond to the initial invitation received 3 additional email reminders. As the e-learning resource was self-guided and the fact that parents were unrestricted in the content they accessed, responses to the follow-up questionnaire reflect parents' perceptions based on the components they chose to engage with.

All data were collected using digital questionnaires created in the survey tool Nettskjema (University of Oslo), integrated with Services for Sensitive Data (TSD, University of Oslo), ensuring secure collection, storage, and analysis of sensitive research data. Data were pseudonymized using numerical identifiers, and access to identifiable information was restricted to members of the research team.

Variables and Assessment

The survey questions used in this study are available in Tables S1 and S2 in Multimedia Appendix 2. Information on sociodemographic characteristics was obtained through 9 questions in the web-based baseline questionnaire, which included queries about parental gender, country of birth, employment status, urban or rural residence, civil status, household size, household income, and educational level.

For this study, items informed by the Acceptability of Intervention Measure (AIM), Intervention Appropriateness Measure (IAM), and Feasibility of Intervention Measure (FIM), developed by Weiner et al [23], were used to describe parental perceptions of the e-learning resource. The original measures contained 4 items, each rated on a 5-point Likert scale from 1=completely disagree to 5=completely agree, with higher scores indicating greater acceptability, appropriateness, or feasibility. These measures were selected because they provide brief instruments specifically developed to assess implementation outcomes aligned with the framework proposed by Proctor et al [17,23]. Although several other measurement instruments exist to assess implementation outcomes, the AIM, IAM, and FIM are among the measures with the fewest items for assessing these early-implementation outcomes [31]. Additionally, they are not restricted to a particular intervention type or context [23]. For these reasons, they were considered the most appropriate starting point for developing a tailored questionnaire for parents having access to the NN e-learning resource.

In this study, unpublished Norwegian translations of the AIM, IAM, and FIM measures were used. During questionnaire development, the research team found several items to be difficult to understand in Norwegian, both in terms of wording and conceptual clarity. It was considered likely that our target group (expectant parents and parents of children aged 0 - 2 years) could encounter similar challenges. To reduce redundancy and improve clarity, multiple items were excluded after thorough discussion within the team. The final version used for this study retained only the third and fourth items from the original AIM and FIM, and the first item of the IAM, and was rephrased for clarity. While these changes may have affected the measures' validity, they were necessary to improve clarity and reduce respondent burden. Given the reduction and rephrasing of items, the adapted questions used in this study no longer reflect the original multi-item measures. For this reason, responses are analyzed and presented at the item level and interpreted as parents' ratings of whether they liked the e-learning resource, appreciated it as a new resource, believed it was appropriate as

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a source of information regarding meals, found it doable, and found it easy to use.

In line with the definition of engagement of Perski et al [25], with distinctions between subjective experience and extent of use, this study focuses on the latter, with emphasis on frequency (ie, how often contact is made with the intervention over time) and depth (ie, variety of content used). Although objective platform analytics (eg, number of logins and time spent on specific pages) were available for the NN e-learning resource, these data could not be linked to individual participants. Use was therefore assessed through self-report measures. Specifically, to evaluate use of the e-learning resource, parents were asked whether they had visited it, with response options including "Yes, quite a lot," "Yes, a bit," or "No." These options were designed to capture participants' self-perceived use without imposing specific frequency thresholds, aiming to reflect broad individual use patterns. Participants answering "Yes, a bit" or "No" were asked a follow-up question about why they had not visited the NN e-learning resource or used it sparingly. Response options included "Didn't have time," "Had technical problems," "Lost interest," and "Other," with the latter option allowing participants to provide a written explanation. Additionally, parents were asked whether they had watched the thematic films or recipe films and whether they had used any of the recipes provided in the e-learning resource, with response options including "Yes," "No," and "Don't know."

Data Analysis

Descriptive statistics (frequencies with percentages, means with SDs, and medians with IQRs) were used to summarize data related to demographic characteristics; responses to the individual acceptability-, appropriateness-, and feasibility-related items; and reported use of the e-learning resource. Internal consistency of the adapted 2-item AIM and FIM measures was assessed using the Cronbach α coefficient. Construct validity of the IAM item was examined using Spearman ρ correlation with the mean scores of the adapted AIM and FIM measures. The results are presented in Table S1 in Multimedia Appendix 3.

Since many participants were lost to follow-up, differences in demographic characteristics were assessed between participants answering the follow-up administered 7 months after enrollment and participants lost to follow-up. This was done using the chi-square test and Fisher exact test due to indications of nonnormality.

All statistical procedures were performed with SPSS (version 29; IBM Corp).

Ethical Considerations

This study is part of the NN project, approved by the regional committees for Medical Research Ethics South East Norway (reference: 32248), the University of Agder's Faculty Ethical Committee, and the Norwegian Data Protection Service (reference: 847590). All participants who wished to take part in the NN study were directed to the study's registration website, where participants were informed about the study's aim and their participation rights, including their right to withdraw from the study at any time. Participation was voluntary, and electronic informed consent was obtained when participants chose to sign up for the study. Participants could withdraw from the study at any time. To protect participant privacy, all data were pseudonymized using unique numerical identifiers, and directly identifiable information was accessible only to authorized members of the research team. No personally identifiable information is presented in the paper. Participants in the intervention municipality did not receive compensation for participation in the study or for completing the questionnaire administered 7 months after enrollment.

Results

In total, 179 participants enrolled in the NN study, of whom 48 (27%) responded to the web-based follow-up questionnaire administered 7 months after enrollment, and 131 (73%) were lost to follow-up. An overview of their characteristics is presented in Table 1. Most participants were Norwegian-born women working or on leave of absence and residing in urban areas. The majority were cohabiting or married, living in 3-person households, with annual household incomes between US $91,726 and US $123.478. A difference in educational attainment was observed between those who completed the web-based follow-up questionnaire and those who did not respond. A higher proportion of follow-up respondents reported that either they or their partner had higher education compared to nonresponders (44/48, 92% vs 93/131, 71%), suggesting differential attrition by educational level.

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Table . Baseline characteristics for participants in the Nutrition Now study intervention group, including those answering a web-based follow-up questionnaire administered 7 months after enrollment and those lost to follow-up.

Baseline characteristics	Total (N=179)[a], n (%)	Participants at follow-up (n=48)[b], n (%)	Participants lost to follow-up (n=131)[c], n (%)	*P* value
Gender				.99[d]
Women	157 (88)	42 (88)	115 (88)	
Men	15 (8)	4 (8)	11 (8)	
Missing	7 (4)	2 (4)	5 (4)	
Country of birth				.09[d]
Norway	141 (79)	42 (88)	99 (76)	
Other	31 (17)	4 (8)	27 (21)	
Missing	7 (4)	2 (4)	5 (4)	
Employment status				.57[e]
Working	76 (43)	18 (38)	58 (44)	
Student	10 (6)	2 (4)	8 (6)	
Leave of absence	62 (35)	17 (35)	45 (34)	
Other	24 (13)	9 (19)	15 (12)	
Missing	7 (4)	2 (4)	5 (4)	
Residential area				.99[d]
Urban living	139 (78)	37 (77)	102 (78)	
Rural living	33 (18)	9 (19)	24 (18)	
Missing	7 (4)	2 (4)	5 (4)	
Civil status				.79[e]
In relationship	2 (1)	—[f]	2 (2)	
Cohabitant	88 (49)	24 (50)	64 (49)	
Married	78 (44)	22 (46)	56 (43)	
Other	4 (2)	—	4 (3)	
Missing	7 (4)	2 (4)	5 (4)	
Number of people in household				.97[e]
1	2 (1)	—	2 (2)	
2	25 (14)	6 (13)	19 (15)	
3	81 (45)	21 (44)	60 (46)	
4	44 (25)	13 (27)	31 (24)	
≥5	20 (11)	6 (13)	14 (11)	
Missing	7 (4)	2 (4)	5 (4)	
Household income (EUR)[g]				.17[e]
<€52,000	24 (13)	3 (6)	21 (16)	
€52,000 - €78,000	40 (22)	9 (19)	31 (24)	
€78,000 - €105,000	60 (34)	22 (46)	38 (29)	
>€105,000	45 (25)	11 (23)	34 (26)	
Do not want to answer	3 (2)	1 (2)	2 (2)	
Missing	7 (4)	2 (4)	5 (4)	
Educational level[h]				.007[e]

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Baseline characteristics	Total (N=179)[a], n (%)	Participants at follow-up (n=48)[b], n (%)	Participants lost to follow-up (n=131)[c], n (%)	*P* value
University or college over 4 years	83 (46)	25 (52)	58 (44)	
University or college up to 4 years	54 (30)	19 (40)	35 (27)	
Upper secondary school	33 (18)	2 (4)	31 (24)	
Primary and lower secondary school	2 (1)	—	2 (2)	
Missing	7 (4)	2 (4)	5 (4)	

[a]In total, 179 participants from the intervention municipality enrolled in the Nutrition Now study and received access to the Nutrition Now e-learning resource. All intervention participants were eligible to receive the web-based follow-up questionnaire administered 7 months after enrollment. Data on sociodemographic characteristics is lacking for 7 (4%) participants at baseline.

[b]Participants at follow-up are defined as expectant parents and parents of children aged 0 - 2 years enrolling in the study and answering the follow-up questionnaire administered 7 months after enrollment. Within the participant in the follow-up group, there are missing values on all variables for 2 (4%) participants at baseline.

[c]Participants lost to follow-up are defined as expectant parents and parents of children aged 0 - 2 years enrolling in the study and not answering the follow-up questionnaire administered 7 months after enrollment. Within the participant lost to follow-up group, there are missing values on all variables for 5 (4%) participants at baseline.

[d]Chi-square test with Yates continuity correction.

[e]Fisher exact test.

[f]Not applicable.

[g]Household income is calculated from Norwegian Kroners (NOK) to EUR using an exchange rate of 11.46 as of July 2, 2024. Income figures have been rounded up to the nearest thousand. A currency exchange rate of €1=US $1.18 is applicable.

[h]Educational level represents the highest attained educational level of at least 1 parent or caregiver.

The median rating for the individual items assessing whether participants liked and appreciated the resource, perceived it as appropriate, and found it doable and easy to use was 4 (IQR 3-4; Table S2 in Multimedia Appendix 3), indicating that respondents generally agreed with the statements about the e-learning resource. The proportion of responses to all items is presented in Figure 1.

Table 2 presents participants' use of the NN e-learning resource after 7 months of access, including whether they reported visiting the resource, reasons for not visiting, and whether they watched theme films, recipe films or used the provided recipes.

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Figure 1. The proportion of responses to individual items informed by the AIM, IAM, and FIM among participants at follow-up. AIM item 3 refers to the statement "I like the Nutrition Now e-learning resource." AIM item 4 refers to the statement "I appreciate Nutrition Now as a new resource." IAM item 1 refers to the statement "Nutrition Now seems appropriate as a source of information regarding meals for my family." FIM item 3 refers to the statement "The Nutrition Now resource seems doable." FIM item 4 refers to the statement "The Nutrition Now resource seems easy to use." (A) Proportion of responses from all participants. (B) Proportion of responses among participants visiting the e-learning resource "quite a lot." (C) Proportion of responses among participants visiting the e-learning resource "a bit." (D) Proportion of responses among participants not visiting the e-learning resource. AIM: Acceptability of Intervention Measure; FIM: Feasibility of Intervention Measure; IAM: Intervention Appropriateness Measure.

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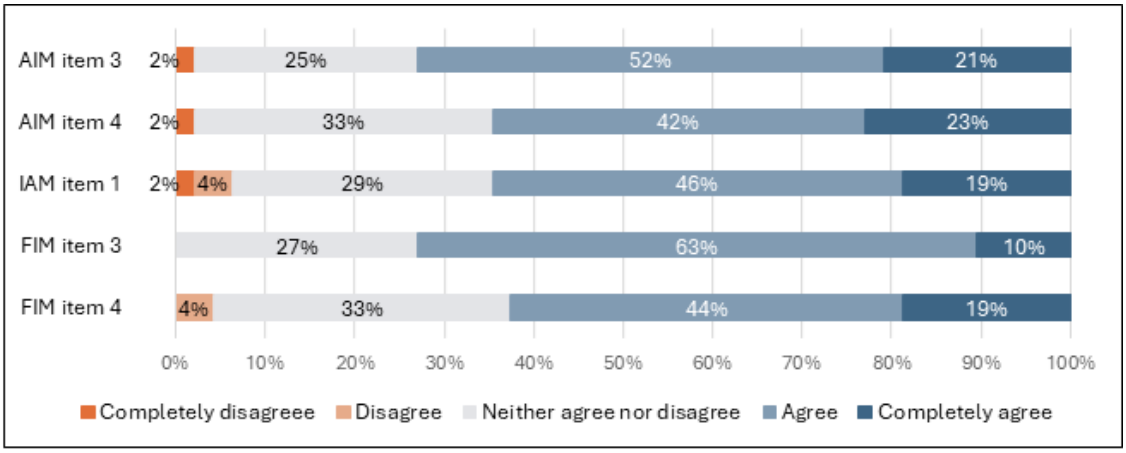
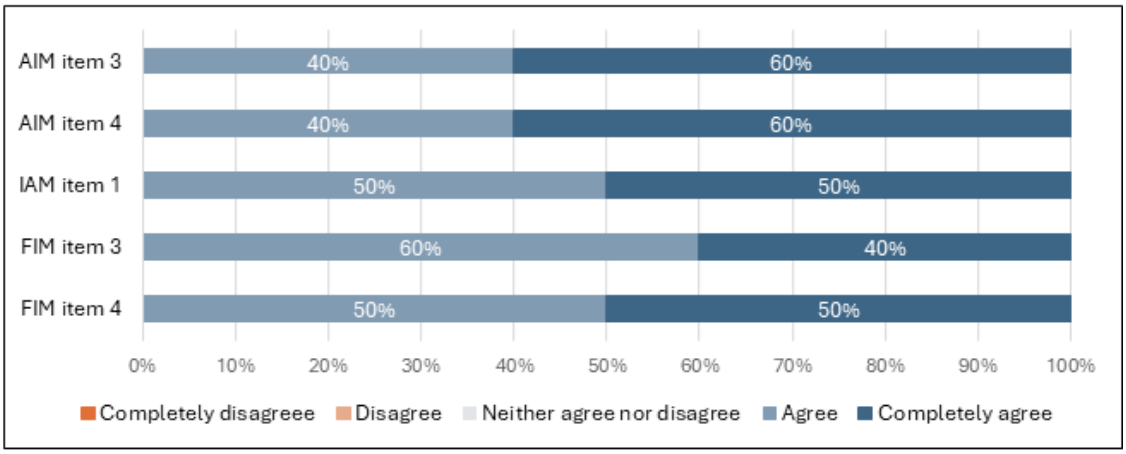
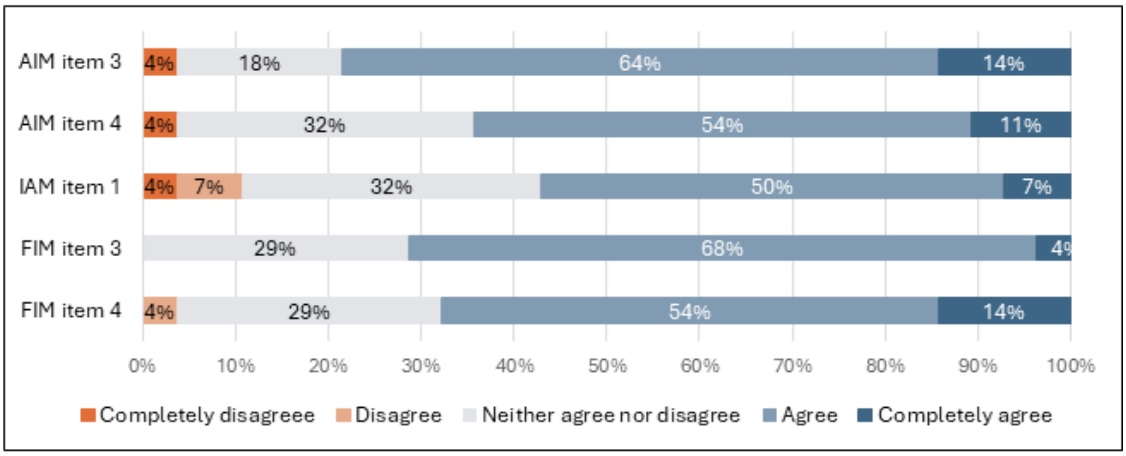
(A) All participants at follow-up, n=48



(B) Visited the resource "quite a lot", n=10



(C) Visited the resource "a bit", n=28



(D) Did not visit the resource, n=10

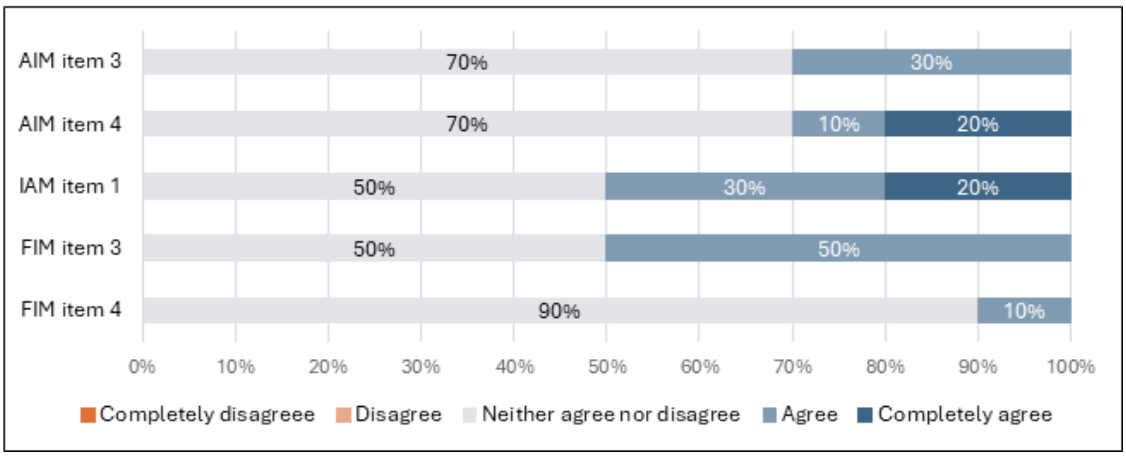


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Table . Use of the Nutrition Now (NN) e-learning resource among participants answering a web-based follow-up questionnaire administered 7 months after enrollment.

Variables	Values (n=48), n (%)
Visited the resource	
Yes, quite a lot	10 (21)
Yes, a bit	28 (58)
No	10 (21)
Reasons for not visiting the resource[a]	
Did not have time	14 (29)
Had technical problems	2 (4)
Lost interest	6 (13)
Other[b]	16 (33)
Watched theme films	20 (42)
Watched recipe films	17 (35)
Made food using NN recipes	20 (42)

[a]Follow-up question provided to those answering "yes, a bit" or "no" to whether they had visited the resource.

[b]Participants answering "other" could provide a written response if they pleased. In total, 9 participants provided a response. Cited reasons among participants included forgetting about the resource, finding information elsewhere, not taking the time to visit, and finding it cumbersome to navigate.

Discussion

Principal Findings

The results show that participants receiving access to the NN e-learning resource and responding to the follow-up survey reported positive ratings regarding liking the e-learning resource, appreciating it as a new resource, finding it appropriate as a source of information regarding meals for their family, and finding it doable and easy to use. However, despite the positive ratings, the extent of self-reported use was limited. The majority of respondents (38/48, 79%) reported visiting the resource, but only 21% (10/48) reported frequent visits. Less than half reported watching the films (theme films: 20/48, 42% and recipe films: 17/48, 35%) or using the recipes provided in the e-learning resource (20/48, 42%). Given the low follow-up rate, small sample, and higher educational attainment among respondents, the findings should be interpreted with caution.

Our findings are consistent with previous studies on parent-focused digital health interventions to promote healthy diets. For example, Vázquez-Paz et al [32] reported that parents found the PersuHabit app, designed to promote healthy eating in children, to be likeable, useful, and easy to use. Similarly, Bonvicini et al [6] found that mHealth interventions targeting childhood obesity were generally well-received among parents across multiple studies. However, although digital interventions targeting parents and their children are positively perceived, maintaining engagement may be more difficult to achieve. In this study, although most parents reported visiting the NN e-learning resource, use of its components was limited. Only 21% (10/48) of respondents reported visiting the e-learning resource "a lot," and less than half engaged with the theme films, recipe films, or used the provided recipes. These results contrast with those of the Early Food for Future Health study by Helle et al [11], where 85% of participants watched most of the videos, and 66% engaged with the cooking videos. Instead, our findings are more in line with the Food4Toddlers study by Røed et al [33], where participants completed only 8 of 22 lessons, with less than half trying 1 - 5 recipes, and one-third using none.

Participants cited time constraints, loss of interest, and forgetfulness as reasons for limited use of the e-learning resource. These reasons may reflect broader contextual factors shaping parents' capacity to engage with digital interventions during early parenthood. This life stage may be characterized by new routines and shifting priorities, which may reduce parents' willingness or ability to explore an e-learning resource. In a previous qualitative evaluation of staff experiences with implementing and informing parents about the NN intervention, staff described parents of young children as navigating a hectic period, perhaps preferring faster or more immediately accessible formats of health information (eg, apps) rather than exploring a resource [34]. Another factor may be the wide availability of other digital platforms in recent years. In the qualitative evaluation from our research group, staff reported that parents now access dietary information from multiple sources, including government-supported websites, commercial apps, and social media platforms [34]. The competing availability of these alternative platforms may reduce engagement with NN's website format, even though it was positively rated.

Similar to the results of this study, Borghouts et al [35] identified time limitations, forgetfulness, and difficulties in integrating digital health tools into daily routines as barriers to engagement in their review of digital mental health interventions. They noted that participants in self-guided interventions often struggle with engagement, suggesting that structured user guidance could be beneficial [35]. Given these challenges, self-guided e-learning resources like NN might benefit from more structured use instructions. Clearer, organized guidance might enhance user

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engagement, helping users better integrate the e-learning resource into their daily lives.

Moreover, reviews on engagement strategies for digital mental health interventions have suggested features such as gamification and prompts as measures that may help promote engagement [36,37]. Gamification may include features such as progress bars, streak counters, or achievement badges [38]. For the NN e-learning intervention, gamification features could include tracking streaks showing the number of times or days the user has visited the resource or progress bars showing the number of thematic films completed and perhaps influence interest and motivation to engage with the resource. In addition, participants in this study received email newsletters containing content from the e-learning intervention to encourage engagement. In a mixed methods study evaluating engagement with a digital health intervention focused on type 2 diabetes management, Alkhaldi et al [39] reported that email prompts were significantly associated with visits to the digital health intervention, whereas text messaging was not. Participants in their study preferred short and clear prompts, with one noting that clear descriptions of the linked content would be a useful feature [39]. In the NN intervention, the email newsletters were designed to be brief and clear. However, including information on the estimated time required to view a video or read a text might help parents consider using the resource despite time constraints.

Nevertheless, engaging participants in digital health interventions remains challenging. A narrative review proposed human support as a program feature that may influence engagement with digital mental health interventions [36]. However, the optimal type of support and participants most likely to benefit remain unclear. In real-world settings, a multipronged approach may be effective. Within the NN intervention, human support may be a feasible and appropriate strategy, as the e-learning resource is delivered through MCHs and ECECs. Ensuring that these professionals are familiar with the intervention and equipped to deliver nutritional guidance and support may enhance the perceived relevance and usefulness of the intervention among parental users. However, further efforts are needed to understand facilitators and barriers of use and engagement with digital food and nutrition interventions. Qualitative methods could provide deeper insights into parents' motivations for engaging with such interventions [40], as well as reasons for nonparticipation [41]. It could also provide greater insight into features needed to promote the use, acceptability, feasibility, and appropriateness of digital nutrition resources. Another strategy could have been to involve parents in the development process. Co-design approaches involve engaging end users and key stakeholders early in intervention development to embed their needs and values into the intervention within the design while identifying and addressing potential barriers for adoption [42]. Although parents and health care nurses were involved during development for some of the original interventions underpinning NN, a more explicit cocreation design process could have included parents with diverse socioeconomic and cultural backgrounds to inform decisions about content and modes of delivery in the NN intervention, with the aim of improving fit across the full target population. Such an approach could have helped ensure that the intervention was fully aligned with what parents find realistic and useful in everyday life.

Strengths and Limitations

A key strength of this study is its real-world setting, where participants had free access to the NN e-learning resource and could engage with it at their discretion. This approach provides a more authentic reflection of how such resources are accessed and used in everyday contexts compared to controlled trial settings.

This study also has some limitations. The proportion of participants who responded to the follow-up questionnaire was low (48/179, 27%). Those who did respond had a higher educational level than those lost to follow-up, raising concern about self-selection bias, potentially making the results more reflective of individuals with higher educational attainment. We originally intended to examine differences in implementation and use outcomes by sociodemographic characteristics, but the small, homogeneous sample made this analysis unfeasible. Additionally, it is important to acknowledge that a large proportion of participants did not complete the follow-up questionnaire, resulting in limited insights into their experiences with the resource and uncertainty regarding overall use and acceptance. The high loss to follow-up should also be interpreted, considering the study design. The use of a hybrid implementation-effectiveness design allowed the intervention to be accessed under real-world conditions, in which participation was voluntary, and follow-up was digital through email prompts. Nevertheless, relying solely on digital modalities for follow-up may have contributed to lower retention and completion of follow-up surveys. Alternative designs, such as feasibility studies, could have helped identify and address retention challenges before moving forward with implementation.

Another limitation that may have influenced findings on resource use is that participants in NN were recruited at any time between early pregnancy and child age 2 years. Although participants had 7 months of access to the resource at the time of the survey, the number and type of newsletters they received during that period differed according to the status of pregnancy or parent at enrollment. As the newsletters contained links to the resource, this variation may have influenced how often participants were prompted to visit the resource. Furthermore, the original AIM, IAM, and FIM measures were modified for this study, including removal and rewording of items, which limits content validity and direct comparison with other studies using the fully validated instruments. Although validated measures exist for related constructs such as usability, user experiences, or technology acceptance, there are few brief, validated instruments that assess acceptability, appropriateness, and feasibility as defined within the implementation outcomes framework by Proctor et al [17]. Nevertheless, using alternative validated measures such as the user version of the Mobile Application Rating Scale [43], or the System Usability Scale [44], could have provided more valuable insights into aspects of intervention engagement, functionality, or perceived usability, particularly to inform refinements of the NN intervention prior to potential scale-up.

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Future research should explore different approaches to assess these constructs among users of digital health interventions.

Conclusions

The NN e-learning resource was rated positively among those who responded to the survey, on items assessing perceived resource liking, appreciation, appropriateness, and whether it seemed doable and easy to use. Among respondents, access and use of the resource were limited, highlighting challenges of engaging expectant parents and parents of infants and toddlers with self-guided interventions in real-world settings.

Future research should examine the effectiveness of digital interventions in improving healthy eating behaviors during the first 1000 days, assess strategies needed to engage users with such interventions, and refine approaches to assessing early-phase implementation outcomes, including the measurements of acceptability, feasibility, and appropriateness, and their potential overlap.

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Data Availability

All data generated and analyzed during this study are included in this paper and the appendices. An anonymized version of the dataset for this study is available from the corresponding author upon reasonable request.

Authors' Contributions

NCØ, ERH, FNV, and ACM contributed to the conception of the Nutrition Now project. NCØ is the principal investigator of the project, with ACM, ERH, and FNV as co-principal investigators. NCØ, ERH, FNV, ACM, NGO, CH, SHH, PL, MHA, AKW, HR, and TB contributed to the design of the Nutrition Now study. SHH, CH, and ERH contributed substantially to the development of the Nutrition Now resource, led by NCØ. NGO, FNV, ERH, NCØ, ACM, and CH were involved in the development of questionnaires. NGO conducted the analyses and led the drafting of this manuscript. All authors contributed substantially to reviewing and editing the manuscript and approved the final version.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Screenshots from the Nutrition Now e-learning resource.
[PPTX File, 2701 KB - formative_v10i1e84277_app1.pptx]

Multimedia Appendix 2
Survey questions included in this study.
[DOCX File, 40 KB - formative_v10i1e84277_app2.docx]

Multimedia Appendix 3
Internal consistency, correlations, and median participant ratings for adapted items from the Acceptability of Intervention Measure, Feasibility of Intervention Measure, and Intervention Appropriateness Measure in the Nutrition Now study.
[DOCX File, 29 KB - formative_v10i1e84277_app3.docx]

Checklist 1
CHERRIES checklist.
[DOCX File, 27 KB - formative_v10i1e84277_app4.docx]

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Abbreviations

AIM: Acceptability of Intervention Measure
CHERRIES: Checklist for Reporting Results of Internet E-Surveys
ECEC: Early Childhood Education and Care
FIM: Feasibility of Intervention Measure
IAM: Intervention Appropriateness Measure
MCH: Maternal and Child Health
mHealth: mobile health
NN: Nutrition Now

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Optimizing Navigation and Text Messaging Interventions to Promote Participation in a Food Is Medicine Program Among People Participating in Cardiac Rehabilitation: Human-Centered Design Study

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Abstract

Background: Food Is Medicine (FIM) programs integrate interventions such as medically tailored meals or produce prescriptions into clinical care. However, there is limited evidence on how to design these programs to be responsive to the lived experiences of participants to optimize initiation, engagement, and long-term retention.

Objective: The objective of the study was to develop interventions to promote initiation, engagement, and retention in FIM programs that are responsive to the lived experiences of participants.

Methods: We used a human-centered design approach to engage current and former cardiac rehabilitation participants in the development of interventions to promote participation and engagement in a FIM program. We recruited participants through invitations sent via electronic health record messages. We interviewed participants about their experiences, preferences, and unmet needs related to healthy eating and program design. Additionally, we elicited participant feedback on draft versions of patient navigator scripts and text messages promoting healthy eating habits.

Results: A total of six participants identified themes across Theory of Planned Behavior constructs and emergent themes, including the cost of healthy food, cultural appropriateness, clear and timely communication, transportation, local food access, scheduling flexibility, the ability to provide feedback to the program, and personalized support for navigating food resources. Participants described financial strain as a key barrier to healthy eating and noted that social influence often shaped eating behaviors. Feedback on navigator scripts led to revisions clarifying program logistics, addressing barriers such as language and cultural dietary restrictions, and tailoring positive endorsements to individual health goals. Based on participant feedback, text messages were made more concise, reframed positively (eg, humor and gratitude), and encouraged to be warmer, with respectful language that is easy to understand, while avoiding stigmatizing or overly clinical phrasing. Participants also suggested that messages should reflect empathy and offer actionable information to increase trust and engagement with the program. Trust in the health care system and a sense of dignity in receiving food support emerged as critical themes influencing overall satisfaction and retention. Participants emphasized that endorsement from their health care team and cardiologist was important for building trust in the program. Communication between health care navigators and FIM navigators could help reduce the burden placed on patients to navigate food resources.

Conclusions: Using a human-centered design approach, we gained insights about participant-identified needs for navigation scripts and text messages that are culturally sensitive and personalized to promote optimal participation in a FIM program.

(JMIR Form Res 2026;10:e85650) doi:10.2196/85650

KEYWORDS

Food Is Medicine; human-centered design; cardiovascular disease; nutrition intervention; health equity

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Introduction

Healthy eating prevents cardiovascular (CV) events [1-4]. However, many individuals with CV conditions lack the time or resources to maintain a healthy diet. Food Is Medicine (FIM) programs can help address barriers to healthy eating. FIM interventions include providing medically tailored meals (MTMs), medically tailored groceries (MTGs), and nutritious food referrals for individuals with specific medical conditions [2,5]. These interventions can improve quality of life, improve CV risk factors, reduce hospitalizations, and reduce health care costs [2,5-9]. More specifically, MTMs improve health outcomes for those with CV conditions, especially those with barriers to planning, shopping for, or preparing healthy food. Studies of MTMs show improvements in health-related quality of life, diet quality, self-efficacy, food security, and CV risk factors (eg, blood pressure and cholesterol) [7,10,11]. MTG and healthy food referrals help support individuals who can prepare their own meals and can increase diet quality and reduce food insecurity [9,12].

Despite the benefits of FIM programs, questions remain about optimal approaches for referral, initiation, engagement, and retention in FIM programs to improve participation, engagement, and, ultimately, health outcomes [2]. Cardiac rehabilitation (CR) is a 12-week multidisciplinary program for people with heart conditions and includes counseling on nutrition and establishing long-term health habits [13,14]. CR patients are actively engaging in behavior change to prevent recurrence of future CV events; therefore, their participation in CR represents an opportune time to connect patients with FIM programs [15]. However, the best strategies for promoting the enrollment of CR patients in FIM programs are not known.

Our objective was to develop interventions to promote initiation, engagement, and retention in FIM programs that are responsive to the lived experiences of participants. We conducted human-centered design (HCD) sessions with CR patients to design 2 behavioral science–based support interventions to promote participation in a FIM program: navigation and text messaging. Navigation was adapted from approaches known for enhancing enrollment and participation in CR [16]. Text messages were based on behavioral science principles to promote initiation and engagement and were adapted from previously studied text message libraries [17,18]. These interventions are now being tested in a randomized trial for comparing the efficacy of navigation and text messaging interventions for increasing participation in FIM programs (NCT06500962).

Methods

Study Design

We conducted HCD sessions with individuals enrolled in CR at the University of California, San Francisco. During these HCD sessions, we collected qualitative data from participants to develop and iteratively refine the interventions through 4 phases: discover, define, develop, and deliver [19-21]. Our use of HCD is consistent with the broad principles of ISO 9241‐210, which defines HCD as an approach that centers users' needs and requirements throughout an iterative design process. Specifically, our approach satisfied core HCD principles, including explicit understanding of users, tasks, and context (Session 1); active user involvement throughout the design process; and iterative refinement of interventions based on user-centered feedback (Sessions 2‐3). This structured, user-centered approach helps ensure that interventions are systematically refined, grounded in the lived experiences of patients, and ultimately more likely to be effective in practice. This checklist can be found in Checklist 1.

Recruitment

We recruited a convenience sample of participants who were at least 18 years of age and participating in CR at University of California, San Francisco, an urban academic medical center. Invitations were sent via electronic health record messages. Participants were asked to provide information on gender, race or ethnicity, age, health literacy [22], and perceived social status [23]. Quantitative data were collected and managed using REDCap (Research Electronic Data Capture) electronic data capture tools.

HCD Sessions

HCD sessions were conducted by trained facilitators over Zoom, with each session lasting 90 to 120 minutes. For each session, we held 2 groups with 2 to 4 participants each. Sessions took place between April 2024 and June 2024.

In Session 1, our aim was to understand participants' perceptions, thoughts, and behaviors about FIM in the context of the Theory of Planned Behavior [24]. We used a template that integrated themes from the Theory of Planned Behavior to do so. This template can be found in Multimedia Appendix 1. We then took participants through a "User Journey" depicting the steps that a patient would take to participate in a FIM program called Project Open Hand. This instrument can be found in Multimedia Appendix 2. As we went through each step, we asked participants for feedback about what they would like to hear and see at each step of the journey. Based on participant responses, we developed our navigation scripts and text message library. These interventions can be found in Multimedia Appendix 3 and Multimedia Appendix 4, respectively.

Session 2 reviewed the navigation scripts and text message library with participants. Participants provided feedback on each section of the navigation script, as well as the content, length, grammar, and language of the text messages. These materials were revised based on participant feedback.

Session 3 focused on reviewing the refined navigation scripts and text messaging libraries. Additional minor revisions were made based on participant feedback.

Each session was conducted virtually using Zoom and was hosted on 2 different dates to accommodate participant scheduling needs. One primary facilitator (RDO) led each session and interviewed participants using interview guides that were drafted prior to the start of the study. The interview guides can be found in Multimedia Appendix 5. Additional members of the research team (LC and AN) were present to observe and

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document participant reactions and responses and to prompt further input when appropriate. The investigators did not have prior relationships with any research participants.

Interventions

Navigation

We structured navigation scripts using a similar process to what is recommended for encouraging patients to enroll in CR: (1) explain the program, (2) explain the benefits, (3) provide positive endorsement, (4) describe the process to enroll, (5) welcome questions, (6) address barriers to attendance, and (7) provide follow-up information [25]. We adapted this structured approach to develop scripts for navigators to help guide CR patients through the process of enrolling and participating in a FIM program. Before enrolling in the FIM program (ie, completing their intake call with Project Open Hand staff and scheduling their first meal service), the participant will receive navigation from a health system–based navigator. After enrolling in the FIM program, the participant will receive navigation from a FIM program–based navigator.

Text Messaging

We developed a library of text messages to (1) promote healthy eating, (2) encourage enrollment in a FIM program, and (3) encourage adherence to a FIM program once enrolled. Text messages were designed to address behavioral science constructs using behavior change techniques [18]. Messages were 160 characters or fewer, with some including web links to relevant American Heart Association resources.

Analysis

HCD sessions were audio-recorded and transcribed. Audio recordings were not returned to participants for comment or correction. We qualitatively described participant responses using a rapid analysis template based on the Theory of Planned Behavior and emergent themes [24]: (1) attitudes or beliefs about FIM (thoughts or feelings about FIM and the acceptance of statements as truths or facts), (2) social influence regarding FIM (perception that an important person supports a behavior), and (3) perceived behavioral control. The template we used to analyze participant responses can be found in Multimedia Appendix 1. Three study staff members (AN, LC, and RDO) coded responses individually to extract themes and representative quotations from each transcript before meeting to achieve consensus. Analyses were completed concurrently with data collection. We calculated descriptive statistics (eg, mean and SD) for participant demographic information using STATA version 18 (StataCorp LLC).

Ethical Considerations

This study was approved by the WCG Institutional Review Board (1370693), and procedures were followed in accordance with WCG Institutional Review Board and institutional guidelines. Prior to the start of the first session, participants provided written informed consent. They also provided verbal consent for audio recording prior to the beginning of each session. To protect participant confidentiality and to minimize the possibility of sharing information that could be used for potential reidentification, session transcripts will not be available; however, analysis files may be obtained from the corresponding author upon reasonable request. Participants were compensated US $200 per HCD session for their time and participation.

Results

Overview

Twenty-two people were invited to participate in the study: 6 consented and participated, 1 consented but did not participate in any study activities after providing consent, 3 were found to be ineligible, 1 explicitly declined, and 11 did not respond. We enrolled 6 participants, of whom 4 were female and 2 were male, 2 self-identified as Black or African American and 4 as White. All participants spoke English. Participants ranged in decade of age from their 40s to their 80s. Mean perceived social status was 6 (SD 2.6; scale from 1 lowest to 10 highest). Mean health literacy was 2.8 (SD 1; scale from 0 to “Not at all confident filling out medical forms” to 4 “Extremely confident”).

Qualitative Findings

In addition to prespecified themes from the Theory of Planned Behavior, which are (1) attitudes or beliefs about FIM, (2) social influence regarding FIM, and (3) perceived behavioral control, we also identified emergent themes: (4) cost of shopping for healthy foods, (5) culturally appropriate food, (6) local food options, (7) flexibility with FIM programs, (8) ability to give feedback to FIM programs, and (9) personalization. Qualitative themes are described in additional detail below.

Theme 1: Attitudes and Beliefs About FIM

There was an overall understanding among participants that eating healthy foods is important, particularly for maintaining one’s health. Participants preferred to make healthier choices and believed that FIM programs can improve eating habits and instill the confidence needed to eat and cook healthier foods.

> *If I have a little more vegetables in my daily diet, I think it will make me feel a little better on the inside.* [P5]

> *This program [FIM] will help with your recovery, because the food is more based on what you need to eat.* [P4]

> *[The FIM program] is helping you to change your way of eating… to keep your heart healthy.* [P4]

Theme 2: Social Influence Regarding FIM

There was a general understanding among participants that different individuals will influence eating habits in various ways, thus impacting the ability to adhere to diets recommended by FIM programs. Some of these individuals were family members, friends, and the participant’s clinical team (doctors, dietitians, etc). Regardless of who they are, participants agreed that eating habits are influenced by the people one eats with, whether negatively or positively.

General

> *I mean when I’m at a table of six or eight people, and everybody has dessert but me? Well, I don’t want to get left out, so I’m more likely to have dessert.* [P3]

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> *I think normally we have sort of a social norm of, you know, three meals a day. It's gonna be balanced. It's gonna be complex a little, and if you're with other people or something like that, it's gonna be nicer. You're not just gonna be like, you know, okay here's a bowl of mashed potatoes and nothing to go with them.* [P6]

Family

> *Some of the stuff that I would cook and prepare, that I was raised on, [my children] don't eat, so I had to start cookin' stuff that they would eat, so that kind of changed my eating habits. So my menu mostly revolves around what they would eat.* [P5]

> *If you're working with someone who is cooking for others, children, whoever is in their household, if they are eating different foods from the family, it would be a family affair…. if the family's eating habits don't change, that would be a big barrier to maintaining change achieved through Project Open Hand.* [P3]

The Clinical Team

> *Somebody to just give you guidance and not wait until we have these heart conditions to do so.* [P4]

> *The only person who wants me to eat healthy are my doctor, my cardiologist, and people in the health field. And myself.* [P4]

Theme 3: Perceived Behavioral Control

Participants generally seemed motivated to eat healthier and agreed that they had all developed different habits unique to their current situations. While there is a consensus that individuals would like to eat healthier, the challenge often lies in having the energy and knowledge to prepare nutritious meals.

Individuals explained habits that they have developed around cooking and eating food based on their current situations and perceived ability to make certain foods.

> *I'm in super bachelor mode… often I'll just fix one item and just eat that… often that's about as much as I can do sometimes. Since I'm not really sharing it with anyone… it is just getting food in.* [P6]

> *I love eating, but I'm also lazy… I'm not gonna get up and make, you know, a 7-vegetable omelet.* [P1]

> *Even with your friends…The bottom line comes to us. Taking control over what we put in our bodies.* [P4]

Furthermore, participants shared that part of the barrier to eating healthy lies in shopping for healthier foods and groceries. These barriers are often out of one's control. There are multiple factors that individuals must consider when grocery shopping, including cost, current living situation, and shelf life.

> *[Finding healthy food to eat] is also the combination of like, you know, not only is this, is this good? Is this healthy? But then you know the price and when you have your budget in one eye and doing calculations in the other eye… can be stressful on its own frankly.* [P6]

> *I will make compromises, and I will hit the pasta aisle, and I will hit the ramen aisle and all of the things that last forever.* [P6]

> *I think [the senior living center] buys a hundred pounds of whatever vegetable they're having. So we get the same vegetables. I love broccoli, but you know by the seventh day in a row I'd rather have something else.* [P3]

Theme 4: Cost

Participants expressed a strong desire to eat healthy but acknowledged that this lifestyle can be prohibitively expensive. They also highlighted the stress of budgeting and calculating what they can afford. As a result, many end up eating only what fits their budget, even if it is not healthy.

> *Money restrictions create a lot of bad health food choices, or bad food choices, I think.* [P6]

> *I'll be looking at things just like, oh I really want that, but I can't afford it. So therefore I don't get it. So I wind up getting something else. I shop a lot of sales.* [P4]

> *Often, it comes down to 'How many pennies per calorie is this' rather than price per ounce or gram… 'Okay how long can I live off of this stuff?'* [P6]

Theme 5: Cultural Appropriateness

Cultural appropriateness refers to the idea that there is a match between the foods provided and the cultural food traditions of the patient. Participants cited that the cultural appropriateness of foods is a factor that impacts their eating habits. Therefore, it can be understood that cultural appropriateness is particularly crucial in the context of FIM programs, as it affects the patient's ability to adhere to the meal plans or cook with the groceries provided.

> *I'm a country girl, we like ham, hogs, mustard greens, collard greens, pinto beans, black-eyed peas… we like that good Southern cookin,' but when I came up here to California, all that stuff I see back home, they don't sell up here. So I have to make my menu list different* [P5]

Theme 6: Local Food Options

Many individuals expressed a strong desire to obtain fresh groceries and support local farmers' markets, as they believe these items are inherently healthier. However, they find farmers' markets challenging to access due to high prices.

> *It's the priciness of it, I would totally support the local farmers over anybody else.* [P4]

> *The Farmers' Market is like goin' out there and pickin' it yourself. So you know it is fresher, and like I say, fresher is better.* [P5]

Theme 7: Flexibility of FIM Programs

Regarding FIM programs, there was widespread consensus that the program needs to be flexible (ie, with scheduling food services, switching between MTM and MTGs), as patients will have other commitments such as rehabilitation sessions or

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doctor's appointments and may desire having meals or groceries delivered depending on their current situation.

> *Showcasing your flexibility here and there. So many of these programs are basically like 'Do this or you're disqualified.' That adds a lot of stress.* [P6]

Theme 8: Feedback

Individuals also emphasized that FIM programs should create space for feedback as it empowers patients to be active participants in the program and helps ensure the program remains responsive and adaptable to their needs.

> *Lack of ability to express feedback may be a barrier. If after a month you're getting bored with it, and you can't express that boredom, you might give up.* [P2]

> *Let people know they can say "Hey I prefer this type of food over this.* [P2]

Theme 9: Personalization

Participants also stressed the need for personalizing the FIM program to each individual. When implementing and explaining the program, they suggested that explanations should be related back to the patient's unique circumstances. This approach will clarify how the program will impact them personally and will likely increase their motivation and engagement.

> *It will give you tools to learn how to eat appropriately for your body and health concerns.* [P1]

> *Why is this here? What is this gonna do for me?* [P6]

These representative quotes, as well as some others, are listed below in Table 1.

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Table . Representative quotes from participants regarding Theory of Planned Behavior constructs and emergent themes.

Theme	Representative quotes
Theory of Planned Behavior themes	
Attitudes and beliefs about FIM[a]	• *"If I have a little more vegetables in my daily diet, I think it will make me feel a little better on the inside."* (P5) • *"This program will help with your recovery, because the food is more based on what you need to eat."* (P4) • *"[The FIM program] is helping you to change your way of eating… to keep your heart healthy."* (P4)

Social influence regarding FIM	• General
	  • *"I mean when I when I'm at a table, of six or eight people, and everybody has dessert but me? Well, I don't wanna get left out, so I'm more likely to have dessert."* (P3)
	  • *"I think normally, we have sort of a social norm of, you know, 3 meals a day. It's gonna be balanced. It's gonna be complex a little, and if you're with other people or something like that, it's gonna be nicer. You're not just gonna be like, you know. Okay, here's a bowl of mashed potatoes and nothing to go with them."* (P6)
	• Family
	  • *"Some of the stuff that I would cook and prepare, that I was raised on, [my children] don't eat, so I had to start cookin' stuff that they would eat, so that kind of changed my eating habits. So my menu mostly revolves around what they would eat."* (P5)
	  • *"If you're working with someone who is cooking for others, children, whoever is in their household, if they are eating different foods from the family, it would be a family affair... if the family's eating habits don't change, that would be a big barrier to maintaining change achieved through Project Open Hand."* (P3)
	• The Clinical Team
	  • *"Somebody to just give you guidance and not wait until we have these heart conditions to do so."* (P4)
	  • *"The only person who wants me to eat healthy are my doctor, my cardiologist, and people in the health field. And myself."* (P4)

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Theme	Representative quotes

Perceived behavioral control	• General
	  • *"I'm kind of in super bachelor mode... often I'll just fix one item and just eat that... often that's about as much as I can do sometimes. Since I'm not really sharing it with anyone... it is just getting food in."* (P6)
	  • *"Just getting nutrition in front of me for the most part would be preferable."* (P6)
	  • *"Even with your friends...The bottom line comes to us. Taking control over what we put in our bodies."* (P4)
	  • *"You have to be your own cheerleader... when it comes to your health."* (P4)
	• Buying Food/Groceries
	  • *"I will make compromises, and I will hit the pasta aisle, and I will hit the ramen aisle and all of the things that last forever*. (P6)
	  • *"[Finding healthy food to eat] is also the combination of like, you know, not only is this, is this good? Is this healthy? But then you know the price and when you have your budget in one eye and doing the calculations in the other eye… can be stressful on its own frankly."* (P6)
	• Cooking/Preparation
	  • *"I [freeze my food] because I'm afraid that I might run out of money and I'm afraid that I don't wanna run out of food. So I try to stretch what I get."* (P4)
	  • *"I love eating, but I'm also lazy… I'm not gonna get up and make, you know, a 7-vegetable omelet."* (P1)
	• Eating
	  • *"Although there will be days of scarfing pasta and mashed potatoes and things like that."* (P6)
	  • *"I think [the senior living center] buys a hundred pounds of whatever vegetable they're having. So we get the same vegetables. I love broccoli, but you know by the seventh day in a row I'd rather have something else."* (P3)
	  • *"I'm a foodie person, so I'd like to make different things, and I get bored if I eat the same thing over."* (P4)

Emergent themes	

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Theme	Representative quotes
Cost	• *"Money restrictions create a lot of bad health food choices, or bad food choices, I think."* (P6) • *"I'll be looking at things just like, oh I really want that, but I can't afford it. So therefore I don't get it. So I wind up getting something else. I shop a lot of sales."* (P4) • *"Often it comes down to 'how many pennies per calorie is this' rather than price per ounce or gram... ok how long can I live off of this stuff."* (P6)
Cultural appropriateness	• *"I'm a country girl, we like ham, hogs, mustard greens, collard greens, pinto beans, black-eyed peas... we like that good Southern cookin,' but when I came up here to California, all that stuff I see back home, they don't sell up here. So I have to make my menu list different."* (P5)
Local food options	• *"It's the priciness of it, I would totally support the local farmers over anybody else."* (P4) • *"The Farmers' Market is like goin' out there and pickin' it yourself. So you know it is fresher, and like I say, fresher is better."* (P5)
Flexibility	• *"Showcasing your flexibility here and there. So many of these programs are basically like 'Do this or you're disqualified.' That adds a lot of stress."* (P6)
Feedback	• *"Lack of ability to express feedback may be a barrier. If after a month you're getting bored with it, and you can't express that boredom, you might give up."* (P2) • *"Let people know they can say 'Hey I prefer this type of food over this."* (P2)
Personalization	• *"It will give you tools to learn how to eat appropriately for your body and health concerns."* (P1) • *"Why is this here? What is this gonna do for me?"* (P6)

[a]FIM: Food Is Medicine.

Intervention Feedback

Navigation Scripts

Overall, participants recommended that navigators take the time to thoroughly learn about each participant by asking in-depth and detailed questions in each section of the script. This will help personalize the intake process as much as possible.

Examples of the feedback received in response to the navigation script are listed in Table 2.

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Table . Description of feedback and modifications for navigation scripts.

Section	Feedback
Explain what FIM[a] is	• Differentiate between a nutritionist and a dietitian. If the program is using a dietitian, then the word "nutritionist" should be replaced with "dietitian" as a dietitian is perceived to provide a higher level of care due to differences in training. • Clarify whether the program is just for the participant, or if it includes the participant's entire family. • Instead of presumptuous statements, such as "I will also learn more about you," use "I hope to learn more about you and how we can help you learn about eating healthier."
Benefits	• Indicate that the program is "Integrating care together" (ie, FIM works with the clinical team to provide care). • *"Lay out the cause and effect... here is [the program's] medicinal value."*
Positive endorsement	• Indicate "demonstrable effects" - *"Why would someone want this and need this—what's it gonna do for them?"* • Behavior modification: "*The food is designed for you to start looking at food differently for your heart health*." • Individually tailor reasons as to why FIM would be beneficial for the participant.
Process to enroll	• It is unclear who is calling whom, make the process clearer. Indicate when the participant is talking to the health system navigator and the FIM navigator. • The part that states "We will send in an enrollment form to Project Open Hand" is not clear. Who is sending the form to whom? How are you sending it? • Overall, participants liked that the health system navigator is communicating with the FIM navigator. One participant remarked that it "*allows the person to take the stress out of the food situation*" and is "*part of the healing*."
Discuss any barriers	Participants gave examples of barriers to discuss: • Language • Cultural or dietary restrictions • Lack or loss of interest in the program (due to multiple reasons: they don't like it, they don't see positive results, etc) • Lack of ability to give feedback to the program (creating space to allow participants to express feedback so that the program can better suit their needs)

[a]FIM: Food Is Medicine.

Text Messages

General Comments

We received both general suggestions and detailed edits for our text messages. Overall, participants preferred messages with positive affect (eg, gratitude, humor). They also recommended framing messages to incentivize positive behavior change and incorporating language around harm reduction rather than instructing patients to completely avoid certain foods. Concise text messages with examples of recommended foods and changes were preferred. Participants also expressed a desire for 2-way text messaging with the ability to have a conversation with a health professional such as a dietitian.

Length

We received mixed feedback regarding the length of text messages. Some participants recommended making messages longer to justify our recommendations, whereas others preferred the messages to be concise. To incorporate both sides of the feedback, we shortened some messages while including external links that participants could access to learn more.

Grammar

Participants found some text messages confusing and provided feedback regarding clarifying the language and prose.

Behavior Modification and Encouragement

The importance of positively reframing messages to encourage behavior change was also stressed. Furthermore, participants suggested that providing clear and concrete examples when suggesting actions can serve as an additional incentive for individuals to follow through.

Providing Resources

There was a consensus that any text messages recommending an action, such as enrolling or calling the FIM program, should include a phone number for contacting the FIM program.

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Examples of how text messages were modified in response to participant feedback are shown in Table 3.

Table . Text message modifications.

Feedback	Original	Modification
Short messages with links to learn more		
	Avoid nighttime eating! There is nothing wrong with a healthy snack after dinner, but avoid large amounts of food high in calories or fat.	Avoid nighttime eating! If you are going to eat, choose a fruit or vegetable. Click to learn more!
	Remove temptation by getting rid of all the convenient, unhealthy snacks.	Remove temptation by getting rid of all the convenient, unhealthy snacks. Click to learn what is considered an unhealthy snack.
Easy to read		
	Learning how to read food labels can help you make healthier choices. Choose lower sodium, saturated fat and added sugars.	Reading food labels can help you make healthier choices. Choose low sodium, low saturated fat, and low added sugars. Click to learn more!
	Eating whole-grain foods can help lower your cholesterol. Oatmeal, whole-grain cereals, brown rice, whole-wheat bread, and rye bread are all whole-grain foods.	Oatmeal, whole-grain cereals, and brown rice are some whole-grain foods that will help lower your cholesterol. Click to learn more!
Behavior modification and encouragement		
	Eating too fast or when you're distracted may lead to consuming too many calories—slow down!	Savor the flavor! Eating too fast or when you're distracted may lead to consuming too many calories. Click to learn more!
	Almost done with Project Open Hand? Don't give up on all your healthy choices—create a plan to keep yourself going.	Almost done with Project Open Hand? Create a plan to keep yourself going—start by writing down your favorite foods from Project Open Hand.
	Feeling tired? Eating healthy foods can help give you more energy. Project Open Hand can help!	Feeling tired? Join Project Open Hand to eat heart-healthy foods and gain more energy! Call now at 415-447-2326!
Providing resources		
	Want to take a positive step toward a healthier life? Sign up for Project Open Hand today!	Want to take a positive step toward a healthier life? Sign up for Project Open Hand today by calling 415-447-2326.
	Make a plan for when you will sign up for Project Open Hand.	Make a plan and set some time aside for when you will sign up for Project Open Hand. Call now at 415-447-2326!

Discussion

Principal Results

Using HCD principles, we worked with people participating in CR to develop 2 interventions to promote enrollment and engagement in a FIM program: navigation and text messaging. Our findings suggest that, overall, participants held positive beliefs about the impact of FIM programs and understood the importance of having a healthy diet. Despite this understanding, there were numerous factors impacting individuals' eating habits, such as personal beliefs about healthy eating, social influences on the eating habits, cost, and availability of healthy foods. Furthermore, participants emphasized that FIM program design features, such as flexibility, ability to offer feedback, and personalization were important for remaining engaged.

Other barriers, such as financial feasibility and access to healthier foods, were also discussed. Fresh produce is often more expensive and not as readily available locally, and this may impose a financial burden on individuals who come from low-income backgrounds [26]. This leads to unequal access to a healthier diet, further exacerbating the disproportionate burdens and impacts of cardiac illnesses in these populations [27]. Understanding healthy eating within the context of these financial strains is crucial for developing interventions that enhance the effectiveness of FIM programs.

Participants noted that their cardiologist and health care team are key figures in encouraging healthy behaviors. Thus, they emphasized that partnership between these providers and the FIM program is important—not only to monitor the FIM program's impact on their CV health but also to improve access to these programs, since physicians can often play a central role in initiating referrals. Other studies have similarly found that a strong partnership between health care providers and food pantries, along with a consistent availability of healthy food resources, is vital in ensuring the effectiveness of food prescription programs. For example, one study employed clinic-based interventions in coordination with local food banks

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and showed measurable improvements in patient outcomes, such as improved blood sugar and blood pressure control [27]. Another qualitative study in Houston revealed that program success relies on clear workflows between clinicians and food pantry staff and the integration of food prescriptions into routine health care [28].

The use of HCD to engage people with lived experiences in the development of an intervention may improve the relevance and acceptability of health behavior interventions. The feedback provided by participants encouraged positive framing, the offering of examples, and practical actions rather than the presentation of information about health consequences. The feedback provided to us demonstrated similar themes consistent with findings from other studies that have used HCD sessions for text messaging. For example, in a study that focused on developing text messages for the prevention of CV disease in people with HIV, participants similarly preferred messages that were short, clear, and actionable. They emphasized the importance of a positive tone over judgmental language and valued advice that was culturally relevant [16]. These patterns, similar to those found in our study, suggest that text message–based interventions are most effective when they deliver brief, actionable, and supportive messages that align with the contextual realities of patients. This approach, if used in future text-based interventions, may enhance engagement, promote behavior change, and ultimately reduce disparities in health outcomes.

Personalizing FIM programs to align with individuals' unique health goals and nutrition literacy is important for maximizing their effectiveness. Research shows that when nutrition interventions are tailored to an individual's knowledge level and perceived self-efficacy in making dietary changes, they are more likely to adopt and sustain healthy behaviors [29]. This encourages individuals to make better dietary choices, leading to increased fruit and vegetable intake and a greater ability to manage decisions related to food. As a result, individualized approaches not only allow for greater access to healthier foods but also allow for the development of the skills and confidence required to use them effectively.

Limitations

Despite having many strengths, our study has limitations that should be acknowledged. Our HCD sessions were conducted with a small number of participants, with each session consisting of only 3 to 4 participants. While a sample of 6 participants is appropriate for our study design, our sample included only participants who identified as Black or African American and White. This may limit the generalizability of our study's findings. Future research should prioritize replicating the findings of this study with larger and more racially and ethnically diverse samples to reach data saturation and ensure that FIM program interventions are generalizable and culturally responsive across populations. Furthermore, our study was conducted at a single urban academic medical center CR program, which may also limit the generalizability of our findings for individuals with other chronic conditions and those who may benefit from FIM. Individuals who do not live in urban areas, are enrolled in other rehabilitation programs, or have other chronic conditions not related to cardiac health may offer different perspectives and feedback regarding their unique experiences with healthy eating and the impact of FIM programs. Additionally, the virtual format of our HCD sessions may have impacted the quality of discussion. While conducting the sessions over Zoom ensured that all participants could attend, it may have influenced the way in which participants engaged in discussions. Furthermore, HCD ideally incorporates direct observation of participants engaging with the intervention being developed, a method that was not feasible with the virtual format of our sessions. This may have limited our ability to capture feedback on real-world usability and real-time behavioral and nonverbal responses to our interventions. Future research should incorporate field observation to further refine these interventions. The interventions developed in our study may need to be adapted for use in other settings.

Connecting CR and FIM programs offers a scalable opportunity to improve healthy eating and health outcomes in people with heart conditions. HCD and behavioral science approaches are promising in the development and execution of effective, coordinated nutrition care for these individuals. This research will inform future studies testing the feasibility and efficacy of navigation and/or text messaging to improve participation in FIM among patients with heart disease.

Acknowledgments

Generative artificial intelligence was used to edit the phrasing and wording in some portions of the manuscript.

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Data Availability

The datasets generated or analyzed during this study are available from the corresponding author on reasonable request.

Authors' Contributions

Conceptualization: AB (lead)
Data curation: AN (equal), RDO (equal), LC (equal)

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Formal analysis: AB (equal), RDO (equal), AN (equal), LC (equal)
Funding acquisition: AB
Investigation: AB (equal), RDO (equal), AN (equal), LC (equal)
Methodology: AB
Project administration: AB (lead), LC (supporting), RDO (supporting), AN (supporting)
Resources: AB (lead), ET (equal)
Supervision: AB
Validation: RDO (equal), AN (equal), LC (equal)
Visualization: AN (lead), AB (supporting)
Writing – original draft: AN (lead), AB (supporting)
Writing – review & editing: AN (lead), AB (supporting), RDO (supporting), LC (supporting), ET (supporting)

Conflicts of Interest

Erika Tribett is an employee of Project Open Hand, a non-profit organization that provides Food Is Medicine services. No other disclosures related to this research.

Multimedia Appendix 1
Rapid analysis template.
[DOCX File, 14 KB - formative_v10i1e85650_app1.docx]

Multimedia Appendix 2
Participant user journey.
[DOCX File, 1757 KB - formative_v10i1e85650_app2.docx]

Multimedia Appendix 3
Test message library.
[DOCX File, 20 KB - formative_v10i1e85650_app3.docx]

Multimedia Appendix 4
Health system navigator script and Food Is Medicine navigator script.
[DOCX File, 20 KB - formative_v10i1e85650_app4.docx]

Multimedia Appendix 5
Participant interview guides.
[DOCX File, 19 KB - formative_v10i1e85650_app5.docx]

Checklist 1
COREQ 32-item checklist.
[DOCX File, 19 KB - formative_v10i1e85650_app6.docx]

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Abbreviations

COREQ: Consolidated Criteria for Reporting Qualitative Studies
CR: cardiac rehabilitation
CV: cardiovascular
FIM: Food Is Medicine
HCD: human-centered design
MTGs: medically tailored groceries
MTM: medically tailored meal
REDCap: Research Electronic Data Capture

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Effect of a WeChat Intervention Based on the Common-Sense Model on Breast Cancer–Related Lymphedema Preventive Behaviors: Quasi-Experimental Study

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Abstract

Background: Breast cancer–related lymphedema is the most prevalent postoperative complication among breast cancer survivors. Although mobile health tools are increasingly used for patient education, evidence supporting their efficacy in lymphedema prevention remains limited.

Objective: This study aimed to evaluate the effectiveness of a WeChat-based intervention grounded in the common-sense model (CSM) in improving preventive behaviors, modifying illness perceptions, and reducing lymphedema incidence among breast cancer survivors and to validate the targets of the intervention.

Methods: This study used a quasi-experimental design. Participants (N=192) were recruited from the breast cancer department of a cancer hospital in Guangzhou, China. The control group (n=98) received routine care. The intervention group (n=94) participated in a 3-month CSM-guided WeChat mini-program (“Nantian e-Care”) delivering tailored educational articles, exercise tutorials, arm circumference monitoring, and real-time nurse consultations. Outcomes, including preventive behaviors, illness perceptions, and lymphedema incidence, were assessed 1, 3, and 6 months post surgery. Generalized estimating equations were used for the analysis.

Results: The intervention group exhibited significant improvements in lifestyle adjustments (Wald χ^2_2=6.9, *P*=.03) and physical exercise adherence (Wald χ^2_2=6.9, *P*=.03) compared with the control group. Illness perception, including identity (Wald χ^2_3=8.1, *P*=.04), timeline cyclical (Wald χ^2_3=8.5, *P*=.04), personal control (Wald χ^2_3=9.3, *P*=.03), illness coherence (Wald χ^2_3=29.8, *P*<.001), and behavioral (Wald χ^2_3=19.5, *P*<.001) and physical factors (Wald χ^2_3=24.1, *P*<.001) were markedly enhanced. Mechanistically, skin care improvements were driven by intervention effects, personal control, illness coherence, and behavioral attribution. Lifestyle changes were correlated with intervention and illness coherence. Adherence to physical exercise was not statistically significantly affected by the intervention, although a trend was observed. Critically, the intervention group demonstrated a lower incidence of lymphedema at 6 months (7.50% vs 16.48%, χ^2_1=3.9, *P*=.048).

Conclusions: The CSM-guided WeChat intervention effectively promoted preventive behaviors, optimized illness perceptions, and reduced lymphedema risk. These findings underscore the value of integrating theory-driven mobile health tools into postoperative care and highlight scalable strategies for chronic disease management in resource-limited settings.

Trial Registration: Chinese Clinical Trial Registry ChiCTR2100048798; https://www.chictr.org.cn/showprojEN.html?proj=130038

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KEYWORDS

breast cancer–related lymphedema; common-sense model; illness perception; preventive behaviors; WeChat

Introduction

Breast cancer–related lymphedema (BCRL) is a chronic and debilitating condition affecting >20% of survivors [1]. BCRL arises from surgical- or radiotherapy-induced lymphatic damage, leading to chronic tissue swelling, fibrosis, and functional impairment. Patients require long-term or lifelong control and management [2,3], which markedly affects their physical and mental health and quality of life [4]. The currently available

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treatment methods can only relieve symptoms rather than cure BCRL, underscoring the importance of primary prevention.

Prevention of BCRL focuses on the management of risk factors. It is difficult for patients to change the risk factors related to cancer treatment (eg, lymph node resection and radiotherapy). Nevertheless, risk factors related to personal behaviors (eg, overweight or excessive weight fluctuation, injury, and infection) can be controlled and avoided through self-management strategies [5]. BCRL preventive behaviors refer to recommendations and precautions that target the aforementioned avoidable factors, including skin care, avoidance of compression and injury, lifestyle, and functional exercise [6,7]. Previous studies have confirmed that early preventive behaviors can effectively prevent BCRL [8]. However, adherence to recommended behaviors is suboptimal (<50%) [9], highlighting the need for innovative interventions.

The common-sense model (CSM) of self-regulation provides a theoretical framework for understanding how individuals perceive, interpret, and respond to health threats [10]. At its core, the CSM emphasizes the role of illness perceptions (cognitive and emotional representations of a health condition) in shaping coping strategies and health behaviors. Key dimensions of illness perception include identity (symptoms attributed to the illness), timeline (expected duration), consequences, personal and treatment control, illness coherence (understanding of the condition), and emotional representation. CSM has been extensively applied in chronic disease management, where interventions designed to modify illness perceptions, such as providing structured information, correcting misconceptions, and enhancing personal control beliefs, have demonstrated positive effects on health behaviors and clinical outcomes [11-13]. For example, among patients with myocardial infarction, an illness perception–focused intervention significantly improved lifestyle adherence and reduced cardiac risk factors [13], underscoring the potential of illness perception as a modifiable target for behavior change.

In the context of BCRL, patients' perceptions of the condition, such as beliefs about its causes, controllability, and potential consequences, may significantly influence their engagement in preventive behaviors [14-16]. Our prior longitudinal study supports this proposition, showing that baseline illness perceptions, particularly personal control and causal attributions, predict both initial levels and trajectories of preventive behaviors in breast cancer survivors [17]. Individuals with inaccurate or incomplete perceptions of BCRL often exhibit reduced preventive awareness and adherence. Therefore, a CSM-guided intervention that systematically targets these perceptions holds promise for improving BCRL prevention. Despite this rationale, no study has explored the effects of CSM-based interventions on BCRL-preventive behaviors among breast cancer survivors.

Traditional education methods are challenging in terms of patient accessibility and engagement. In recent years, the development and popularization of mobile technology have provided new ideas for health education. Mobile health–based self-management interventions (eg, webpages, applications, and social media software) have been proven to effectively promote the education and management of patients with breast cancer and reduce the burden on medical staff [18]. However, these studies have mainly focused on lifestyle improvements [19] or symptom management of BCRL [20], and few studies have targeted BCRL prevention. Considering cost-effectiveness, WeChat mini-programs stand out among various mobile health intervention tools [21]. Therefore, on the basis of the CSM and previous research, our group developed a WeChat mini-program named "Nantian e-Care" to deliver tailored and interactive content, facilitate continuous monitoring, and provide timely feedback, potentially enhancing patient engagement and behavior change [22]. This study aimed to evaluate the effectiveness of this CSM-based WeChat intervention in improving BCRL preventive behaviors, modifying illness perception, and reducing the incidence of BCRL among breast cancer survivors.

Methods

Design

This study adopted a quasi-experimental design and was prospectively registered in the Chinese Clinical Trial Registry (ChiCTR2100048798). The study followed the TREND statement checklist (Checklist 1) for the reporting of nonrandomized evaluations. A quasi-experimental sequential cohort design was adopted primarily due to pragmatic constraints in implementing a randomized controlled trial within the clinical workflow, aiming to minimize intergroup contamination of the digital intervention. We acknowledge that this design choice introduces potential threats to internal validity from historical changes or maturation between the recruitment periods. To mitigate these threats, all institutional protocols for routine BCRL education were kept consistent throughout the study duration.

Study Setting and Sampling

Patients who had undergone surgery for breast cancer were recruited by convenience sampling from the breast cancer department of a cancer hospital in Guangzhou, China, between June 2023 and June 2024. The inclusion criteria were as follows: age ≥18 years, diagnosis of primary breast cancer (stages I-III), first unilateral axillary lymph node dissection, primary school educational level or higher, daily WeChat use, and voluntary participation in the study. The exclusion criteria were as follows: cognitive impairment, other types of cancer, bilateral breast cancer, distant metastasis or recurrence, upper limb disability, and other edema symptoms. Participants who read <50% of the articles or incorrectly answered the quality control items of the questionnaires were excluded from analysis.

Considering the risk of intergroup contamination and the required sample size, patients who underwent breast cancer surgery between June and August 2023 were included in the control group. After the 6-month follow-up of the control group, patients who underwent surgery between April and June 2024 were enrolled in the intervention group.

Sample Size Calculation

The sample size was estimated a priori on the basis of the primary behavioral outcome. For pragmatic planning, the sample size was calculated using the formula for comparing 2

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independent means using a *t* test, which provides a conservative estimate for the subsequent longitudinal analysis [23]: $n_1=n_2=(1+1k)[(t1-\alpha/2+t1-\beta)\ \sigma\delta]2$. In this formula, k denotes the allocation ratio, defined as n1/n2; $t_{1-\alpha/2}$ denotes the 2-sided critical value from the standard normal distribution for a given significance level α; $t_{1-\beta}$ denotes the one-sided critical value from the standard normal distribution for the desired power (1−β); σ denotes the assumed common standard deviation of the outcome variable in both groups; and δ denotes the clinically meaningful difference between the 2 group means. Based on the study by Li et al [24], the mean total scores for BCRL preventive behaviors were 53.45 (SD 7.64) in the control group and 58.92 (SD 8.20) in the intervention group, indicating a mean difference of 5.47 points. this difference represents an approximate improvement of 9% on the total scale score, which is considered a clinically relevant shift in self-reported preventive practices. Setting α=.05 (2-sided) and power (1 – β)=.90, the initial calculation yielded 46 patients per group. Accounting for an estimated attrition rate of ≤20%, the final target was set at a minimum of 58 patients per group. The final analyzed sample size exceeded the minimum target due to successful recruitment within the study periods. This increased the statistical power of the study beyond the initial 90% target.

Interventions

The control group received routine nursing care, including perioperative nursing, early postoperative functional exercise, and discharge guidance. Education related to BCRL prevention included prevention instructions combined with oral and written education, as well as an explanation and demonstration of the methods of and precautions to be taken during a 3-stage functional exercise (stage 1, from the first postoperative day to the day of drainage tube removal; stage 2, from the day of drainage tube removal to the day of stitch removal; and stage 3, after the removal of stitches). At the end of the follow-up period, the control group received all the resources similar to the intervention group.

The intervention group received a 3-month Nantian e-Care mini-program intervention (Figure S1 in Multimedia Appendix 1) in addition to routine nursing. This intervention was designed to support patients across key postoperative phases to foster the adoption and maintenance of preventive behaviors. In the immediate postoperative phase (first month), the focus was on establishing foundational knowledge, such as BCRL symptoms and early-stage exercises, and initiating self-monitoring routines. During the subsequent, intermediate phase (months 2 - 3), the content reinforced behavioral risk factor management and prepared patients for long-term self-care, aiming to translate knowledge into sustained practice during the critical prevention window. The intervention components included the following: (1) delivery of BCRL-related educational articles (covering definition, causes, symptoms, course, recurrence, prognosis, treatment, and prevention); (2) provision of functional exercise videos corresponding to 3 postoperative stages, equipped with follow-along, timing, and logging features; (3) regular reminders for arm circumference measurement and data upload; and (4) a consultation channel for patient inquiries (Table S1 in Multimedia Appendix 1). The detailed intervention protocol has been described in a prior publication [22]. The main implementation process was as follows:

1. Evaluation: two to three days after surgery, the researchers explained the purpose and significance of the study to eligible patients, obtained informed consent, added patients' WeChat accounts, guided them to access the Nantian e-Care mini-program, and collected baseline data on illness perception.
2. Planning: the Nantian e-Care automatically planned the routine reminders of the education articles according to the surgery date of each patient and decided whether to intensify the reminders according to the baseline illness perception. The logic of tailoring was based on the revised Illness Perception Questionnaire (IPQ-R). Patients scoring below or above the predetermined thresholds on key CSM dimensions triggered an intensified intervention protocol. This intensification included an increased frequency of reminders and the delivery of additional, targeted educational content focused on the specific perception domains where scores were suboptimal at baseline. In contrast, the routine reminders included the standardized, automated delivery of all educational articles, scheduled based on the patient's surgery date (Table S1 in Multimedia Appendix 1).
3. Service: according to the plan, the mini-program automatically delivers articles and functional exercise videos. Patients could also read articles and watch videos in the knowledge module. They were required to perform functional exercises for ≥30 minutes daily. The functional exercise video page was automatically timed after entry, and a cumulative exercise of 30 minutes daily was automatically clocked in. Patients were able to modify their exercise duration according to their actual exercise. An instructional video of arm circumference measurements was also available. Patients were required to measure their arm circumference before discharge and at 1, 3, and 6 months after surgery or when they felt unwell.
4. Evaluation and feedback: one or two quizzes were attached at the end of the article, through which patients could evaluate their learning. Follow-up data on preventive behaviors and illness perception were collected at 1, 3, and 6 months after surgery, and scores and suggestions were automatically generated. Participants could then receive timely feedback. For example, patients should ideally be able to correctly identify all 8 symptoms. If the identity dimension was <8 points, BCRL symptoms were displayed on the feedback interface to help users further consolidate relevant knowledge.
5. Coordination and referral: patients could ask questions at any time in the consultation module. Breast cancer surgeons or nurses and lymphedema specialist nurses served as study consultants to answer questions (eg, breast cancer treatment and side effects, care of surgical wounds or drains, and diagnosis of BCRL). If the patient required treatment or professional assistance, they were advised to visit the relevant clinic.

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Measurements

The general information questionnaire included sociodemographic information (eg, age, body mass index, educational level, and residence) and disease- or treatment-related information (eg, pathological diagnosis, tumor stage, number of lymph node resections, adjuvant therapy, and dominance of the affected arm).

Primary Outcome Measures

The implementation of BCRL preventive behaviors in breast cancer survivors for nearly 1 month was assessed using the Lymphedema Risk-Management Behaviors Questionnaire [14]. The questionnaire included 4 dimensions— skin care, avoidance of compression and injury, lifestyle, and other matters requiring attention—with a total of 18 items. A 5-point Likert scale was used. The reliability and validity of the questionnaire were good (Cronbach α=0.79; content validity index=0.87). Functional exercise after breast cancer surgery is essential for BCRL prevention, and the above questionnaire includes only 1 item for exercise. Therefore, adherence to the functional exercise was assessed using the physical exercise adherence dimension of the Functional Exercise Adherence Scale [25]. This dimension was scored on a 4-point Likert scale, where higher scores indicated better adherence to physical exercise. The Cronbach α for the physical exercise adherence dimension was 0.90. Although the mini-program offered a clocking feature to aid self-tracking, it was not used as the primary outcome measure because follow-up indicated that patients often exercised independently without activating the timer, after becoming familiar with the routines. Therefore, the self-report scale was used to obtain a standardized measure of overall adherence.

Secondary Outcome Measures

Illness perception of BCRL among breast cancer survivors was measured using the IPQ-R [26], which includes 3 parts and 9 dimensions. Part 1 was the identity dimension, which covered 8 basic symptoms and signs of BCRL. The number of symptoms that patients considered to be related to BCRL was the identity dimension score. A higher score indicated more comprehensive knowledge of BCRL symptoms. Part 2 consisted of 7 dimensions scored on a 5-point Likert scale. Higher scores on the timeline acute/chronic, timeline cyclical, consequence, and emotional representation dimensions indicated a more negative attitude toward the course, recurrence, prognosis, and risk of BCRL. Higher scores on the personal control and treatment control dimensions indicated greater confidence in the prevention and control of BCRL through patients' own efforts or medical means. Higher scores on the illness coherence dimension indicated a more comprehensive understanding of BCRL. Part 3 was the causes dimension, which included 5 factors: tumor and treatment, psychological, behavioral, physical, and uncontrollable. The scoring method was the same as for part 2. Higher scores indicated a higher likelihood that the patient thought that the occurrence and development of BCRL were related to this factor. The scale had good reliability and validity. The content validity index values for the identity and causes dimensions were 0.92 and 0.81, respectively; and the Cronbach α for the other 7 dimensions ranged from 0.61 to 0.92 [27].

At 3 and 6 months after surgery, the circumference of both upper limbs was measured at the metacarpophalangeal joints, wrist creases, 10 cm above and below the lateral epicondyle, elbow creases, and armpits. BCRL was defined as the affected side measuring >2 cm larger than the unaffected side at any measurement point (2 - 3 cm, 3 - 5 cm, and >5 cm indicated mild, moderate, and severe BCRL, respectively), a diagnostic threshold consistent with established guidelines for postoperative monitoring [28].

Investigators added participants' WeChat accounts after enrollment and reminded them to complete the follow-up questionnaires at 1, 3, and 6 months after surgery. The control group completed electronic or paper-based questionnaires based on their preferences. The intervention group completed the follow-up questionnaires on the WeChat mini-program.

Data Analysis

SPSS Software (version 25.0; IBM Corp) and R for Windows (version 4.3.1; R Foundation for Statistical Computing) were used for statistical analyses. Statistical significance was set at $P \leq .05$. An intention-to-treat analysis was performed. Statistical descriptions were performed using the mean, SD, median, IQR, frequency, and composition ratio. A 2-tailed Student *t* test, ANOVA, χ^2 test, and rank-sum test were used for comparisons between 2 groups. The generalized estimating equation method was used to analyze the effects of the intervention on BCRL preventive behaviors and illness perception. The models included data from all assessment time points: baseline and 1 month, 3 months, and 6 months post surgery. The scores for each dimension were used as dependent variables, and group, time, and the group × time interaction term were included in the model as independent variables. The statistical significance of the group × time interaction effect indicated that the variable scores of the 2 groups changed differently over time, indicating that the intervention was effective [29].

Intervention targets were verified according to the causal step model proposed by Baron and Kenny [30]. Initially, the effects of the interventions on preventive behaviors and illness perception were examined separately. Subsequently, the effects of the intervention and illness perception on preventive behaviors were simultaneously considered. The group, time, and group × time terms and illness perception dimensions (measured at the same follow-up time points as the preventive behaviors) were used as predictive variables, and each dimension of preventive behaviors was used as an outcome variable for the generalized estimating equation analysis, respectively. The statistically nonsignificant effect of illness perception on preventive behaviors indicated that the effect of the intervention on preventive behaviors was unrelated to illness perception. A statistically significant effect of illness perception and a statistically nonsignificant intervention effect on preventive behaviors indicated that the effect of the intervention was mainly caused by changes in illness perception. The statistically significant effects of both intervention and illness perception on preventive behaviors indicated that the effect of the intervention on preventive behaviors was caused by both intervention and illness perception.

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Ethical Considerations

This study was approved by the ethics committee of the Sixth Affiliated Hospital of Sun Yat-sen University (no. L2019ZSLYEC-001). This study was performed in line with the principles of the Declaration of Helsinki and followed the principles of voluntary participation, confidentiality, and no harm. Participants were informed that their participation was entirely voluntary and that they had the right to withdraw from the study at any time without providing a reason and without any negative consequences for their future care or their relationship with the hospital. All participants provided oral or written informed consent for participation and the publication of their anonymized data. At the end of follow-up, the participants received a compensation of ¥30 to ¥50 (US $4.39-7.32) based on their compliance.

JY is the creator and owner of the mini-program and authorizes the use of images in the manuscript.

Results

Characteristics of the Sample

Patient attrition resulted from loss of contact, lack of time or energy, unwillingness to continue participation, or meeting the elimination criteria. The loss-to-follow-up rates were 5.78% ([6 + 4 + 7]/[98 × 3]) in the control group and 7.45% ([3 + 4 + 14]/[94 × 3]) in the intervention group. Following the intention-to-treat principle, all initially allocated participants (N=192; 98 in the control group and 94 in the intervention group) were included in the final analysis, as illustrated in the participant flow diagram (Figure 1).

A total of 192 breast cancer survivors aged 27 to 75 years were analyzed. All participants were women, except for 1 man in the intervention group (Table 1). The baseline characteristics between the 2 groups were not significantly different ($P>.05$; the exact P values are reported in Table 1).

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Table . Baseline characteristics of the 2 groups.

Variable	Control group (n=98)	Intervention group (n=94)	*t* test/chi-square/z score
Age (years), mean (SD)	47.47 (10.54)	46.56 (9.53)	0.624[a] (*df*[b]=190, *P*=.53); –0.479[c] (*P*=.63)
<45, n (%)	43 (43.9)	43 (45.7)	
45 - 59, n (%)	41 (41.8)	41 (43.6)	
≥60, n (%)	14 (14.3)	10 (10.7)	
BMI (kg/m^2), mean (SD)	22.85 (3.06)	22.86 (3.11)	0.660[a] (*df*=190, *P*=.98); –0.575[c] (*P*=.56)
<18.5, n (%)	5 (5.1)	9 (9.6)	
18.5 - 24.0, n (%)	63 (64.3)	49 (52.1)	
≥24.0, n (%)	30 (30.6)	36 (38.3)	
Educational level, n (%)			–0.324[c] (*P*=.75)
Primary school	14 (14.3)	8 (8.5)	
Junior high school	17 (17.3)	25 (26.6)	
Senior high school	32 (32.7)	24 (25.5)	
Bachelor's degree or higher	35 (35.7)	37 (39.4)	
Residence, n (%)			
Urban	66 (67.3)	59 (62.8)	0.4[d] (*df*=1, *P*=.51)
Rural	32 (32.7)	35 (37.2)	
Tumor stage, n (%)			
I	13 (13.3)	13 (13.8)	–0.007[c] (*P*=.99)
II	52 (53.0)	49 (52.2)	
III	33 (33.7)	32 (34.0)	
Number of lymph nodes removed, mean (SD)	15.93 (7.65)	16.68 (8.97)	–0.256[a] (*df*=190, *P*=.53)
Adjuvant therapy received, n (%)			
Chemotherapy	85 (86.7)	77 (81.9)	0.8[d] (*df*=1, *P*=.36)
Radiotherapy	53 (54.1)	62 (66.0)	2.8[d] (*df*=1, *P*=.09)
Endocrine therapy	51 (52.0)	40 (42.6)	1.7[d] (*df*=1, *P*=.19)
Targeted therapy	30 (30.6)	27 (28.7)	0.08[d] (*df*=1, *P*=.78)
Affected arm that was dominant, n (%)	53 (54.1)	44 (46.8)	1.0[d] (*df*=1, *P*=.31)
Family history of breast cancer, n (%)	6 (6.1)	4 (4.3)	0.07[e] (*P*=.80)

[a]*t* test.

[b]df: degrees of freedom.

[c]Mann-Whitney *U* test.

[d]Pearson χ^2 test.

[e]Continuity correction of χ^2 test.

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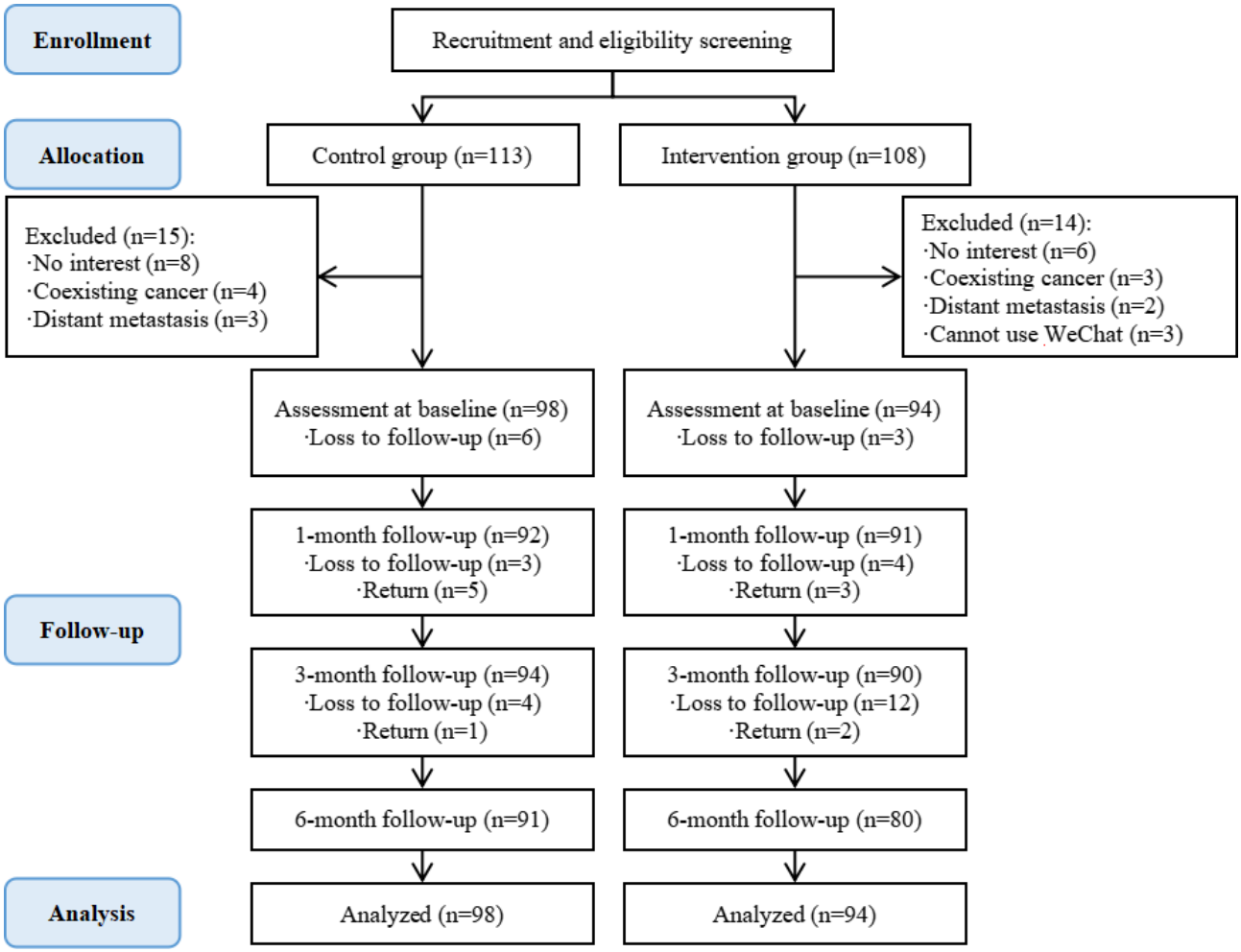
Figure 1. Flow diagram of the participants. "Return" indicates participants who were temporarily lost to follow-up at the previous time point but returned to the study at the current follow-up.



Effect of Intervention on Preventive Behaviors

The results of the generalized estimating equation analysis showed that the group effects of skin care (Wald χ^2_1=5.5, *P*=.02), avoidance of compression and injury (Wald χ^2_1=4.6, *P*=.03), lifestyle (Wald χ^2_1=6.3, *P*=.01), other matters requiring attention (Wald χ^2_1=8.8, *P*=.003), and physical exercise adherence (Wald χ^2_1=9.1, *P*=.003) between the 2 groups were statistically significant. The time effects of skin care (Wald χ^2_2=43.0, *P*<.001), avoidance of compression and injury (Wald χ^2_2=11.0, *P*=.004), lifestyle (Wald χ^2_2=38.6, *P*<.001), and other matters requiring attention (Wald χ^2_2=18.0, *P*<.001) were also statistically significant. Furthermore, the interaction effects of group and time on lifestyle (Wald χ^2_2=6.9, *P*=.03) and physical exercise adherence (Wald χ^2_2=6.9, *P*=.03) between the 2 groups were statistically significant. Figure 2 illustrates the changes in the scores for each dimension of preventive behaviors over time in the 2 groups.

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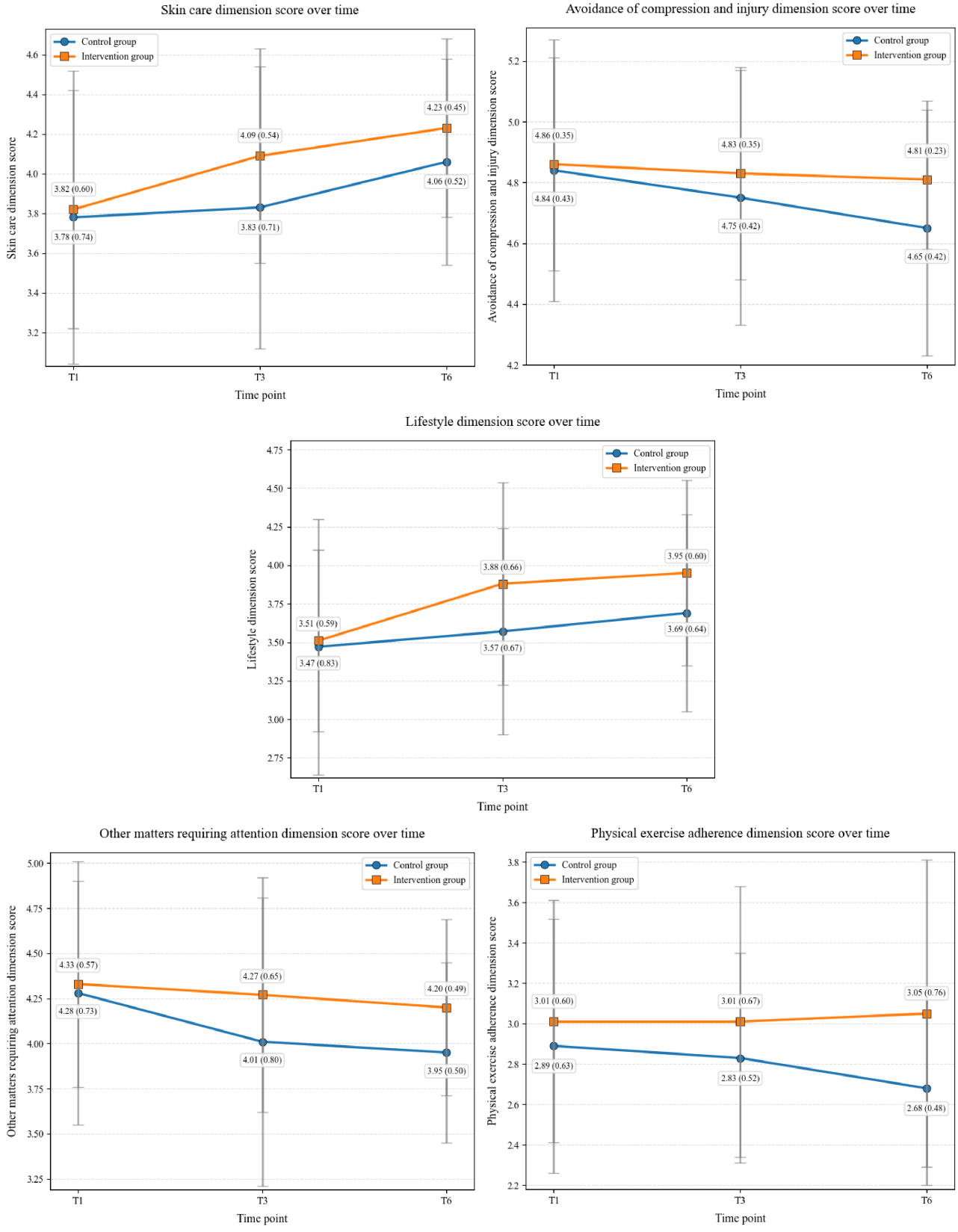
Figure 2. Mean (SD) scores for each dimension of preventive behaviors over time. T1, 1 month after surgery; T3, 3 months after surgery; T6: 6 months after surgery.



Effect of Intervention on Illness Perception

The results of the generalized estimating equation analysis showed that the group effects of identity (Wald χ^2_1=4.331, P=.04), timeline acute/chronic (Wald χ^2_1=9.9, P=.002), personal control (Wald χ^2_1=4.0, P=.04), illness coherence (Wald χ^2_1=20.9, P<.001) in the 2 groups were statistically significant.

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The time effects of identity (Wald χ^2_3=25.0, *P*<.001), timeline acute/chronic (Wald χ^2_3=25.6, *P*<.001), timeline cyclical (Wald χ^2_3=22.2, *P*<.001), personal control (Wald χ^2_3=23.3, *P*<.001), treatment control (Wald χ^2_3=34.7, *P*<.001), illness coherence (Wald χ^2_3=136.8, *P*<.001), and behavioral factors (Wald χ^2_3=45.5, *P*<.001) and physical factors (Wald χ^2_3=37.4, *P*<.001) of the causes dimension were statistically significant. The interaction effects of group and time on identity (Wald χ^2_3=8.1, *P*=.04), timeline cyclical (Wald χ^2_3=8.5, *P*=.04), personal control (Wald χ^2_3=9.3, *P*=.03), illness coherence (Wald χ^2_3=29.8, *P*<.001), and behavioral factors (Wald χ^2_3=19.5, *P*<.001) and physical factors (Wald χ^2_3=24.1, *P*<.001) of the causes dimension were also statistically significant. Figure S2 in Multimedia Appendix 1 shows the changes in the scores for each dimension of illness perception over time between the 2 groups.

Effect of Intervention on the Incidence of Lymphedema

In the control group, 8 of 94 patients (8.51%) and 15 of 91 patients (16.48%) were diagnosed with mild BCRL at 3 and 6 months postoperatively, respectively. In the intervention group, 6 of 90 patients (6.67%) and 6 of 80 patients (7.50%) were diagnosed with mild BCRL at 3 and 6 months post surgery, respectively. The χ^2 test revealed a statistically significant difference in the incidence of BCRL between the 2 groups at 6 months after surgery (χ^2_1=3.9, *P*=.048).

Verification of Intervention Targets

As shown in Table 2, the intervention (group × time, Wald χ^2_3=6.7, *P*=.04) and personal control (Wald χ^2_1=4.5, *P*=.03), illness coherence (Wald χ^2_1=10.5, *P*=.001), and behavioral factors (Wald χ^2_1=4.2, *P*=.04) exerted statistically significant effects on the skin care dimension. These findings indicated that the improvement in skin care–related behaviors was caused by a combination of the intervention and changes in personal control beliefs, illness coherence, and behavioral attribution. The effects of the intervention (group × time, Wald χ^2_3=6.3, *P*=.04) and illness coherence (Wald χ^2_1=5.5, *P*=.02) on the lifestyle dimension were statistically significant, indicating that the improvement in lifestyle-related behaviors was driven by both the intervention and illness coherence. Although not statistically significant, a trend was observed suggesting that improvements in physical exercise adherence may be attributable to both the intervention (group × time, Wald χ^2_3=5.7, *P*=.06) and personal control (Wald χ^2_1=3.8, *P*=.053).

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Table . Generalized estimating equation models for the validation of intervention targets.

Variable	Lymphedema Risk-Management Behaviors Questionnaire								Functional Exercise Adherence Scale	
	Skincare		Avoidance of compression and injury		Lifestyle		Other matters requiring attention		Physical exercise adherence	
	Wald chi-square	*P* value	Wald chi-square	*P* value	Wald chi-square	*P* value	Wald chi-square	*P* value	Wald chi-square	*P* value
Group (*df*[a]=1)	1.6	.20	1.7	.19	4.1	.04	6.2	.01	4.5	.03
Time (*df*=3)	34.6	<.001	12.9	.002	25.7	<.001	13.0	.002	3.6	.17
Group × time (*df*=3)	6.7	.04	1.4	.49	6.3	.04	3.1	.21	5.7	.06
Illness perception										
Identity (*df*=1)	1.5	.22	0.8	.36	0.9	.35	0.3	.56	0.5	.50
Timeline acute/chronic (*df*=1)	0.3	.58	0.03	.87	0.5	.47	0.09	.77	0.6	.45
Timeline cyclical (*df*=1)	1.1	.30	2.0	.15	2.0	.16	2.13	.14	2.1	.15
Consequence (*df*=1)	1.5	.23	0.5	.50	0.1	.72	0.4	.53	3.1	.08
Personal control (*df*=1)	4.5	.03	0.3	.58	1.6	.20	0.35	.55	3.8	.053
Treatment control (*df*=1)	0.7	.40	0.5	.50	0.8	.38	0.08	.77	0.3	.58
Illness coherence (*df*=1)	10.5	<.001	3.4	.07	5.5	.02	0.18	.67	3.0	.09
Emotional representation (*df*=1)	0.006	.94	0.1	.75	0.8	.37	1.6	.20	0.08	.78
Causes										
Cancer and treatment factors (*df*=1)	0.05	.83	0.08	.77	0.04	.85	0.9	.34	0.3	.57
Psychological factors (*df*=1)	0.9	.34	0.2	.68	0.1	.73	1.4	.24	0.005	.94
Behavioral factors (*df*=1)	4.3	.04	0.06	.80	2.6	.11	3.6	.06	0.02	.88
Physical factors (*df*=1)	0.4	.52	2.1	.15	1.7	.19	0.03	.86	0.007	.93
Uncontrollable factors (*df*=1)	1.1	.30	0.1	.75	0.5	.48	0.4	.54	0.02	.90

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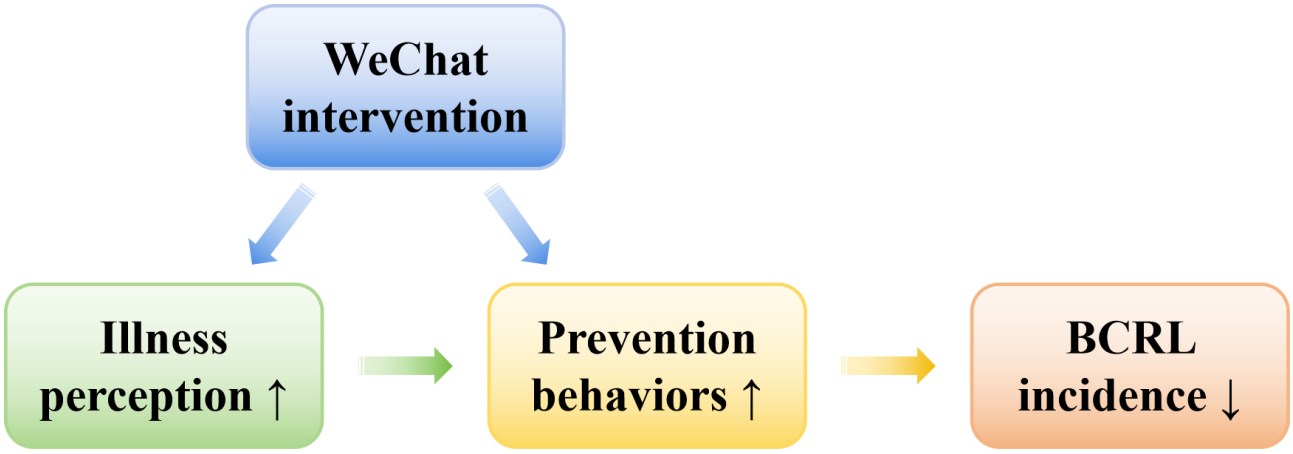
[a]*df*: degrees of freedom.

Exploratory generalized estimating equation analyses suggested that improvements in the skin care dimension were associated with the intervention and with concurrent changes in personal control beliefs, illness coherence, and behavioral attribution (see Table 2). Improvements in lifestyle were associated with the intervention and illness coherence, while improvements in physical exercise adherence were marginally associated with the intervention and personal control. These correlational findings suggest that illness perception may be one pathway for behavior change and warrant formal testing in future studies with dedicated designs. These findings align with the CSM proposition that modifying illness perceptions can facilitate health behavior change.

Figure 3 presents the conceptual framework of the intervention based on the CSM. The WeChat-based intervention aims to reduce the incidence of BCRL by directly promoting preventive behaviors and/or indirectly improving such behaviors through the modification of illness perceptions.

Figure 3. Conceptual framework of the WeChat intervention based on the common-sense model. BCRL: breast cancer–related lymphedema.



Intervention Fidelity and Participant Engagement

Engagement data for the WeChat mini-program are shown in Table S2 in Multimedia Appendix 1. Participants had a median number of logins of 26.5 (IQR 19.0-46.0) and read a median of 40 (IQR 25.8-50.5) articles, exceeding protocol targets. The number of arm circumference measurements (median 3.5, IQR 2.0-5.0) met requirements. However, adherence to daily functional exercise was low (median 2 [IQR 2.0-4.0], 3 [IQR 1.0-10.0], and 4 [IQR 1.0-17.8] days for the 3 phases, respectively) despite the achievement of near-target durations (eg, 30 minutes/day) on days with exercise.

Discussion

This study demonstrated that the CSM-based WeChat intervention was effective in improving BCRL preventive behaviors and illness perception, as well as in reducing the incidence of BCRL among breast cancer survivors.

Effects of Intervention on Preventive Behaviors

Consistent with previous results [24], the present findings showed that CSM-based interventions could significantly improve the lifestyle of breast cancer survivors. Taking "maintaining an ideal weight" as an example, patients who underwent surgery might think that the operation was a major trauma and the body required nutritional supplementation, thus taking in excessive energy [31]. During the intervention, the causes of BCRL were presented to patients to raise their awareness regarding the association of overweight or obesity with BCRL risk [32] so that the patients adjusted their diet accordingly.

However, there was no effect of the intervention on behaviors related to skin care, avoidance of compression and injury, or other matters requiring attention. For skin care, the scores showed an upward trend in both groups. Patients could slowly recover their past habits with the gradual healing of the surgical wound and recovery of function of the affected limb even without intervention because these behaviors were consistent with their own habits [33]. However, Li et al [24] showed that a management model based on a smart medical system could effectively improve skin care–related behaviors of breast cancer survivors. The observed difference might be attributed to the differences in the participants included in the 2 studies. Taking "applying lotion" as an example, most patients in this study resided in the Guangdong province or surrounding areas characterized by a humid climate; thus, most of them did not have the habit of applying lotion. However, Li et al [24] recruited participants from northern regions, where the climate is relatively dry; hence, those participants might have had the habit of applying a lotion prior to the disease. It may be more difficult to develop a new habit than to restore an existing habit.

For avoiding compression and injury and other matters requiring attention, scores in both groups showed a downward trend. This is possibly because in the early postoperative period, patients paid more attention to protecting the affected side due to pain caused by the surgical wound. With the healing of the wound and improvement in physical condition, patients might pay less attention in this regard [34], particularly in cases where the behaviors differed from their past habits. In the case of "mopping the floor," if the affected arm was dominant, the patient was likely to gradually return to previous activity habits [16].

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The intervention had an effect on maintenance of patient adherence to functional exercises. In the control group, adherence to functional exercise showed a decreasing trend over time, consistent with the findings reported by Zhang et al [35]. However, there was no significant difference between the scores at the 3 time points in the intervention group. This may be because the articles related to functional exercise in Nantian e-Care made patients more aware of the importance of consistent exercise for BCRL prevention. In addition, the follow-along, timing, and logging features of functional exercises may play a motivating role [36].

Effects of the Intervention on Illness Perception

The intervention in this study was effective in improving patients' perceptions of the symptoms and recurrence of BCRL, personal control beliefs, illness coherence, and behavioral and physical attributes. Patients who received education on BCRL prevention were confident that they could prevent BCRL. However, as patients learn more about BCRL, particularly its recurrence and treatment limitations, their confidence may decrease [37]. In this study, personal control beliefs did not improve, possibly because of a ceiling effect [38]. Nonetheless, even though the intervention did not improve patients' confidence in preventing BCRL, it helped maintain that confidence without a significant decline. Although awareness of BCRL increased over time in both groups, patients in the intervention group received more information, which improved their understanding of BCRL earlier and faster. In addition, the intervention significantly improved the behavioral and physical attributes of BCRL. This may be because the introduction of knowledge about the causes of BCRL provided patients with a deeper understanding of the effects of behavioral and physical factors.

This study found that CSM-based health education could improve the perception of BCRL in breast cancer survivors, consistent with previous studies on patients with chronic diseases [39,40]. Specifically, patients demonstrated increased scores on dimensions such as personal control and illness coherence, reflecting greater confidence in BCRL management and a clearer understanding of BCRL, and reported decreased scores on dimensions such as timeline cyclical and emotional representation, indicating reduced perceptions of recurrence risk and emotional distress. This study suggests that, compared with traditional face-to-face or paper-based education, the intervention combined with WeChat could more effectively improve the delivery of information and patients' illness perception of BCRL. Li et al [24] also found that afamily nursing network could effectively improve patients' perceived mastery of their disease knowledge. Patients could effectively obtain information using fragmented time and improve their awareness of breast cancer and BCRL. The integrated management model through a mobile application or WeChat could effectively improve the cognition of patients with breast cancer regarding the causes, symptoms, treatment, and prevention of BCRL [24].

Effect of Intervention on the Incidence of Lymphedema

In this study, the incidence of BCRL was lower in the intervention group at 6 months after surgery. These results indicated that the postoperative, time-structured intervention could potentially reduce the risk of initial BCRL, consistent with previous studies [24,41]. Notably, in this study, the observed BCRL was mild, and the overall incidence was substantially lower than that reported in previous studies. BCRL is multifactorial and has a low incidence. Therefore, it is unclear whether the effect of our intervention on the risk of BCRL was greater than that reported previously. The risk of developing BCRL increases over time. Further investigation of its occurrence 1 year or more after surgery is warranted to explore the long-term effects of the intervention.

Verification of Intervention Targets

This study found that some dimensions of illness perception can be identified as intervention targets. In other words, the implementation of preventive behaviors among breast cancer survivors could be improved by increasing their awareness of BCRL, personal control beliefs, and attribution of behavioral factors. This further validates the notion that illness perception influences coping behavior in CSM and provides an evidence-based foundation for future clinical interventions.

Regarding the intervention's feasibility and acceptability, informal feedback from participants during follow-up indicated that the WeChat mini-program was generally perceived as convenient and user-friendly. Participants appreciated the structured information, the ability to revisit exercise videos, and the timely access to nurse consultations. However, some reported challenges in consistently logging exercise sessions within the app after becoming familiar with the routines, as noted in the engagement data. A systematic qualitative evaluation of user experience, including barriers and facilitators to engagement, is an important next step to optimize the intervention and its implementation in routine care.

Limitations

This study had some limitations. First, the use of a nonrandomized, sequential cohort design constitutes a major limitation. Although baseline characteristics were balanced and routine care protocols remained consistent, unmeasured historical confounding cannot be ruled out. This could include subtle, undocumented shifts in nursing practices, variations in the emphasis of standard patient education by different staff, or broader institutional changes. While there is no direct evidence that such changes occurred, their potential influence on outcomes remains a possibility. Therefore, the observed effects should be interpreted as preliminary evidence of association and feasibility, and causal attribution requires confirmation in a future randomized controlled trial. Furthermore, the correlational design and multiple statistical tests limit causal inference and increase the risk of type I error. Future research should use targeted, hypothesis-driven designs (eg, with staggered measurement of mediators and outcomes) and more robust statistical methods (eg, path analysis with bootstrapping) to formally test the mediating role of specific illness perception dimensions. Second, the primary outcomes of preventive behaviors were assessed via self-report, which carries the risk of recall and social desirability biases. Although the use of validated scales and consistent measurement time points across both groups aimed to mitigate this risk, the more intensive

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interaction with the intervention platform may have differentially heightened awareness in the intervention group. Future studies would benefit from objective behavioral data (eg, sensor-based activity tracking) where feasible. Third, this study was conducted at a single cancer center in southern China, and all participants were required to be daily WeChat users to engage with the intervention. This sampling strategy, while necessary for the trial's feasibility, may limit the generalizability of the findings. It potentially excludes individuals who are older or have lower digital literacy. Future research should aim to include more diverse clinical settings and develop alternative delivery strategies to reach non-WeChat users and ensure equitable access to BCRL prevention programs. Fourth, this study included a follow-up period of only 6 months after surgery, which may be insufficient to demonstrate the effect of the intervention on the BCRL incidence. In future, a longer follow-up period should be considered to investigate the long-term effects of the intervention. Finally, BCRL was assessed via circumferential measurement, which, while clinically valid and guideline-recommended, is less sensitive than volumetric or bioimpedance-based assessments. This may have influenced the recorded incidence rates.

Conclusions

The CSM-based WeChat intervention program for the prevention of BCRL could directly improve the preventive behaviors and illness perception of breast cancer survivors to a certain extent and reduce the risk of BCRL. Preventive behaviors can also be indirectly improved by changing illness perception (ie, by introducing BCRL-related knowledge and improving personal control beliefs). Interventions based on illness perception allow for more precise targeting of underlying cognitive and emotional factors. In future clinical education, WeChat interventions based on illness perception should be considered to assist breast cancer survivors in preventing BCRL.

Acknowledgments

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Data Availability

The datasets are available from the corresponding author upon reasonable request.

Authors' Contributions

Conception: Xia Luo, JY; Design: Xia Luo, JY; Supervision: JY; Materials: JC, ML, Xinyi Li; Funding acquisition: JY; Data collection and/or processing: Xia Luo, JC, ML; Analysis and/or interpretation: Xia Luo, ML; Literature review: Xia Luo, ML, Xinyi Li; Writing: Xia Luo, JY; Critical Review: Xia Luo. All authors have read and approved the final manuscript. All authors participated sufficiently in the work and agreed to be accountable for all aspects of the work.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Supplemetary material including a figure depicting user interfaces in the WeChat mini-program "Nantian e-Care", a table providing a description of the intervention program for preventing breast cancer–related lymphedema, graphs depicting the scores for each dimension of illness perception over time, and a table showing the WeChat mini-program engagement metrics.
[DOCX File, 968 KB - formative_v10i1e77255_app1.docx]

Checklist 1
TREND statement checklist.
[PDF File, 160 KB - formative_v10i1e77255_app2.pdf]

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Abbreviations

BCRL: breast cancer–related lymphedema
CSM: common-sense model
IPQ-R: revised Illness Perception Questionnaire

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Digital Phenotyping via Passive Network Traffic Monitoring: Prospective Observational Study in University Students

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Abstract

Background: Digital behaviors such as sleep, social interactions, and productivity reflect how individuals structure their daily lives. Among university students, online activity patterns mirror academic schedules, social rhythms, and lifestyle habits, with disruptions linked to sleep, stress, and well-being. Existing approaches—including wearables, apps, and surveys—depend on self-report or active participation, limiting long-term adherence. Passive sensing of network traffic offers a scalable alternative for the unobtrusive capture of smartphone usage patterns that preserves privacy.

Objective: This study evaluated the degree to which encrypted smartphone network traffic, collected via a standard virtual private network (VPN), can capture patterns of digital behavior. We assessed feasibility (sustained data capture) and acceptability (usability, burden, and privacy perceptions) and examined how traffic-derived features reveal aspects of digital behavior—including timing, intensity, and regularity—relevant to health and daily functioning.

Methods: We conducted a 2-week prospective observational study at New York University. Participants installed the WireGuard VPN client on personal smartphones, enabling passive capture of encrypted network traffic. Feasibility was assessed using a mixed methods approach combining quantitative measures of user retention and data coverage with qualitative analysis of semistructured exit interviews. Acceptability was evaluated using the System Usability Scale, NASA Task Load Index, and qualitative interview analysis. Exploratory analyses visualized traffic-derived features in relation to digital activity patterns.

Results: Thirty-eight students consented, of whom 29 (76.3%) contributed valid network traffic data and formed the analytic cohort. Within this cohort, 93% of participants (27/29; Wilson 95% CI 78% - 98%) contributed at least 5 days of monitoring, corresponding to 71% retention relative to all consented participants (27/38; Wilson 95% CI 55% - 83%). The mean data coverage within the analytic cohort (n=24) was 74.1% (SD 19.3%; median 77.1%, IQR 63.6%-90.0%; bootstrap 95% CI 66.3% - 81.4%). These participants contributed an average of 311.6 (~13 d, SD 3.5) hours of monitored traffic, ranging from 121 to 496 hours. Acceptability outcomes were evaluated among participants completing the exit survey and interview. Usability ratings were high (System Usability Scale score: mean 78, SD 14.96), and perceived workload was low (NASA Task Load Index scores were minimal). Participants described the system as easy to install, unobtrusive, and generally trustworthy, although some reported temporarily disabling the VPN during activities they considered private. No inferential statistical tests were conducted; analyses

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were descriptive. Exploratory analyses indicated that traffic-derived features reflected daily digital activity rhythms and revealed distinctive lifestyle patterns, including gaming and irregular late-night food delivery use.

Conclusions: VPN-based monitoring of encrypted smartphone traffic was feasible and acceptable, enabling sustained passive data collection with minimal burden. This approach shows promise as a scalable, device-agnostic method for digital phenotyping that captures fine-grained behavioral rhythms while preserving privacy. With broader validation, this technique could expand the toolkit for studying health and well-being in everyday life.

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KEYWORDS

passive sensing; digital phenotyping; encrypted network traffic; remote monitoring; digital behavior

Introduction

Background

Many changes relevant to health and well-being manifest as gradual shifts in the timing and regularity of everyday activities, rather than as isolated events captured at a single point in time [1-4]. Consequently, commonly used episodic assessments—such as surveys, retrospective self-reports, or infrequent evaluations—often miss subtle but meaningful changes in daily behavior that precede or accompany shifts in health and functioning [5]. Prior work has consistently linked disruptions in behavioral rhythms—such as sleep disturbance and irregular daily routines—to psychiatric and cognitive conditions. This highlights the potential for these everyday behavioral patterns to be early indicators of changes in well-being [6-42]. Notably, many such behavioral alterations are detectable well before clinical diagnosis, underscoring the potential value of passively collected digital behaviors as low-burden, noninvasive markers of emerging health risk [2,3,43-47].

Digital behaviors—defined by how people interact with devices and digital platforms—offer a practical window into changes in daily routines, social engagement, and rest-activity organizations as they unfold over time [48-58]. Among university students, digital behaviors mirror academic, social, and lifestyle demands, and irregularities have been tied to stress and poorer health [59-66]. Although much of the existing evidence comes from clinical contexts, it reflects a broader principle: health-relevant behavioral change is often expressed in the timing, regularity, and structure of everyday activities. When captured passively through digital traces, these behavioral rhythms can serve as low-burden markers of changes in well-being, even in nonclinical populations.

Yet, capturing such behaviors in real-world contexts remains constrained by the limitations of current measurement approaches. For example, polysomnography is the gold standard for quantifying sleep architecture and fragmentation, but it is expensive, invasive, and typically limited to single-night laboratory assessments [67,68]. Wearable and sensor-based systems offer the possibility of extending monitoring into daily life [69-72], although their adoption is often limited by the psychological burden of continuous device use, adherence challenges, battery consumption, restricted coverage, and behavioral changes they impose [39,68,73-81]. These limitations have motivated researchers to seek more naturalistic, low-burden sources of behavioral data, most notably smartphones [82-84].

Deeply embedded in the daily routines of young adults, smartphones generate continuous digital traces that reflect a wide range of everyday rhythms, including social interaction, online engagement, mobility, and rest-activity cycles [82,85]. Prior work has shown that messaging activity patterns can reveal diurnal rhythms [86,87], while periods without device use can approximate disengagement, such as sleep or downtime [88,89]. While such signals cannot capture fine-grained quality measures, they provide scalable proxies for broader temporal patterns of behavior. In our study, we leverage passive digital traces—captured through encrypted network traffic—from everyday smartphone use to estimate key behavioral regularities, such as activity onset and offset, usage intensity, and daily rhythm stability, without relying on self-reports, surveys, or other active input from users.

Prior Work

Translating digital traces into meaningful behavioral indicators requires methods that are scalable, minimally burdensome, and privacy-preserving. Achieving this balance remains challenging under current mobile operating system constraints. iOS and Android restrict continuous background monitoring by third-party sensing apps, while built-in analytics tools such as Apple's Screen Time and Android's Digital Wellbeing provide only coarse-grained summaries (eg, daily or weekly app totals) without fine-grained temporal context [90-94]. More intrusive approaches—including rooting, jailbreaking, or continuous screen capture—impose substantial participant burden and raise privacy concerns, limiting their suitability for long-term, real-world deployment [88,95,96].

Despite these constraints, prior work has demonstrated that digital behaviors carry meaningful behavioral signals. In young adults, late-night and irregular device use has been associated with disrupted sleep and depressive symptoms [97-99], while broader patterns of messaging, app engagement, and disengagement have been linked to mood, social well-being, and cognitive function [89,100-104]. These findings underscore the promise of digital behavior as a scalable proxy for well-being, even as existing sensing approaches remain technically and ethically constrained.

Current approaches reflect a trade-off between burden and precision. Self-report instruments are easy to deploy but suffer from recall errors, social desirability bias, and participant fatigue when repeated frequently [5,105-107]. Higher-resolution

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approaches, including custom tracking apps, offer greater accuracy but demand intrusive permissions and elevated privileges [75,79,108,109]. Mobile sensing platforms such as the Effortless Assessment of Risk States and Beiwe have been widely deployed in behavioral health research [110-116], yet they depend on operating system (OS)–level application programming interfaces (APIs; eg, iOS Screen Time), participant-mediated configuration (eg, whitelisting), sustained device permissions, which can substantially limit data yield: in a large-scale deployment of the Effortless Assessment of Risk States involving 4754 adolescents, fewer than half (n=1463, 30.8%) contributed analyzable data [117]. Screenomics [118] provides fine-grained, content-level capture via frequent screenshots [119], but at the cost of substantial intrusiveness, privacy concerns, and limited scalability for long-term use [117,120,121].

These limitations highlight the need for methods that balance resolution, scalability, and privacy while reducing participant burden. Network-level approaches offer one promising direction, as encrypted traffic metadata can capture the *timing*, *regularity*, and *intensity* of digital engagement—behavioral dimensions that prior work has linked to sleep, mood, and cognitive functioning [122-125]—without accessing content or requiring elevated permissions. Prior studies have shown that such metadata can reveal coarse app categories [126] and device-level behaviors [127-129], although evaluations have typically been limited in scope or deployment setting. Our study extends this line of work by evaluating a VPN-based, metadata-only sensing framework in a real-world deployment and assessing the ability of network traffic–derived features to recover health-relevant behavioral rhythms under constraints of feasibility and acceptability relevant to longitudinal use. A broader contextual comparison with prior mobile sensing approaches is provided in the *Relation to Prior Work* section.

Goal of This Study

The goal of this study was to evaluate the feasibility and acceptability of a VPN-based, network-level sensing approach and to assess the ability of network traffic–derived features to capture daily behavioral patterns relevant to health and well-being. Specifically, we characterized network traffic–derived features as markers of daily behavioral patterns—including activity onset and offset, usage regularity, and the stability of daily routines—in a real-world university deployment.

Unlike many existing tools, this approach requires no app whitelisting or custom keyboards, imposes negligible battery overhead, and avoids intrusive permissions, making it suitable for longitudinal deployments in everyday settings. The network traffic data we collected mirror what internet service providers or mobile carriers routinely observe, but with stronger safeguards: all traffic is anonymized and never shared with third parties [130]. By enabling continuous, low-burden observation of everyday digital behavior, this approach provides a foundation for studying how patterns of screen use, sleep timing, and daily behavioral rhythms relate to health and well-being over time.

Building on this rationale, we structured the study around the following aims:

- Aim 1 (feasibility): to evaluate the feasibility of continuous, passive capture of encrypted network traffic on participants' devices for supporting app usage inference
- Aim 2 (acceptability): to evaluate participants' perceptions of the monitoring method, with emphasis on usability, privacy, and burden
- Exploratory aim: to explore the ability of network traffic–derived features to capture health-relevant daily behavioral patterns, including sleep-wake cycles, usage regularity, and activity rhythms

Together, these aims position our approach as a scalable, privacy-preserving foundation for longitudinal research on digital behavioral rhythms with implications for health outcomes. Given the single-site university setting and the high baseline digital literacy of the study cohort, the feasibility and acceptability observed here should be interpreted as an upper bound relative to what may be achievable in more diverse or older populations.

Methods

Study Tools

We conducted a 2-week observational study with university students at New York University (NYU) to evaluate the feasibility and acceptability of passive digital phenotyping using VPN-based smartphone network traffic. Participants installed the WireGuard VPN app [131] on their personal smartphones, enabling continuous collection of encrypted network traffic metadata. Feasibility and acceptability were assessed using a mixed methods approach combining quantitative measures with standardized usability instruments—the System Usability Scale (SUS) [132] and the NASA Task Load Index (NASA-TLX) [117]—and semistructured exit interviews. In addition to feasibility and acceptability, we conducted exploratory analyses to investigate traffic-derived features as markers of broad daily behavioral patterns.

Participants and Recruitment

Participants were recruited through academic advisors across multiple NYU schools and departments who distributed study invitations via internal mailing lists. Recruitment began in April 2025 and targeted university students who were willing to participate in a 2-week passive monitoring study. Interested students received a consent packet describing study procedures and privacy considerations before enrolling.

As this was a feasibility pilot, no predetermined sample size was specified; recruitment continued on a best-effort basis within the study time frame. As shown in the CONSORT (Consolidated Standards of Reporting Trials) diagram (Figure 1), the final cohort reflects the number of participants who were successfully recruited and onboarded during the study period. Detailed demographic characteristics are reported in Multimedia Appendix 1. Additional details regarding recruitment rationale, outreach procedures, and onboarding workflow are provided in Multimedia Appendix 2.

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Figure 1. CONSORT (Consolidated Standards of Reporting Trials)–style participant flow diagram, showing progression from initial recruitment through study completion. VPN: virtual private network.

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Study Instrument: WireGuard VPN for Passive Monitoring

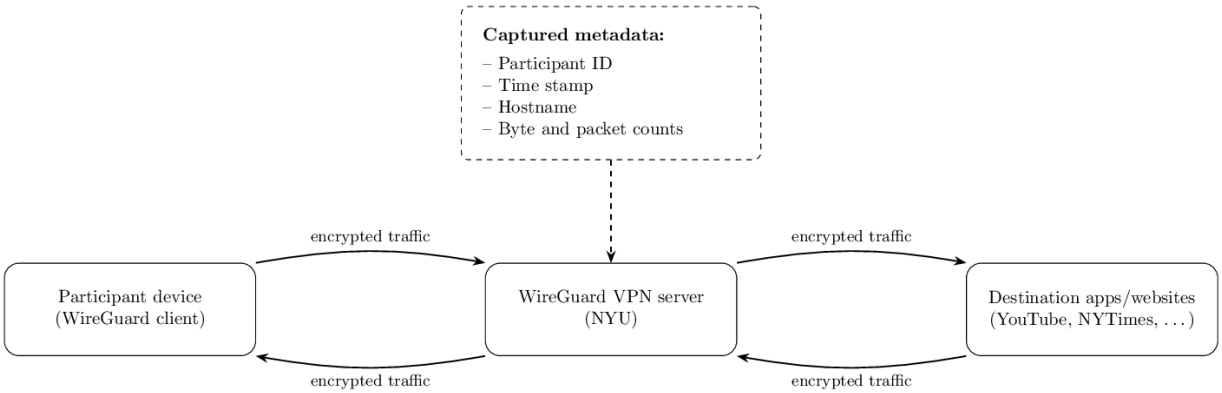
A central challenge in mobile behavioral research is capturing objective measures of smartphone use without modifying the OS, requesting intrusive permissions, or imposing sustained battery and attention costs. Existing approaches—such as platform-specific monitoring apps or rooted devices—are challenging to scale, fragile to OS updates, and raise privacy concerns.

To address these limitations, we used a virtual private network (VPN) [133] to passively capture encrypted network traffic metadata. When active, the VPN routes all device-to-internet traffic through a study-managed server, allowing the observation of high-level metadata such as destination hostnames, packet counts, and byte volumes, while leaving all packet contents end-to-end encrypted. This approach is device agnostic and OS agnostic, requires no app-level permissions or whitelisting, and preserves content privacy by design.

We implemented this approach using the WireGuard VPN protocol, selected for its cross-platform availability and robustness in continuous operation. Participants installed the official WireGuard client and connected via a personalized configuration, after which traffic metadata were passively logged in fixed time windows for analysis (Figure 2). In laboratory testing, the VPN imposed negligible battery overhead (<1% over 24 h), enabling sustained, unobtrusive monitoring.

Additional technical details regarding VPN configuration, server infrastructure, and data aggregation are provided in Multimedia Appendix 3.

Figure 2. System architecture. All device-to-internet traffic is routed through a New York University (NYU)–hosted WireGuard virtual private network (VPN) server. Although packet contents remain end-to-end encrypted, the server captures metadata (eg, hostnames and traffic volumes), enabling passive behavioral analysis without accessing message content.



Field Study

Onboarding Process

After enrollment, participants completed setup through a secure web portal that generated a personalized VPN configuration, which they installed using the official WireGuard app. The installation status was verified prior to the start of data collection. Full onboarding procedures and portal design details are provided in Multimedia Appendix 4.

Data Collection

Once the WireGuard VPN was activated on a participant's device, it remained active by default and routed all device-to-internet traffic through the study server unless it was explicitly disabled or interrupted (eg, by a device reboot). During active periods, the server captured encrypted traffic metadata aggregated in 10-second windows [134]. Packet contents were never collected.

This design allowed us to observe *when* and *how intensively* apps were used without access to content. For example, when a participant streamed YouTube, we could observe traffic exchanged with services such as *youtube.com* and the corresponding traffic volume, but not which specific video was viewed. The same principle applied to news sites, banking portals, and messaging apps: we captured only high-level traffic characteristics, never sensitive user content.

Participants could manually disable the VPN, and unintentional downtime could also occur (eg, following device reboot). Visibility of VPN status varied across devices: older iPhones display a persistent VPN icon in the status bar, newer iPhones with a notch, and most Android devices omit such an indicator. As a result, participants may be unaware when the VPN is inactive.

To mitigate data gaps and support adherence, the study protocol incorporated reminder emails sent every 2 to 3 days, directing participants to a study portal where they could verify connection status.

The portal provided real-time feedback on cumulative active study days and compensation earned (Figure D.1 in Multimedia Appendix 5), serving both as a technical safeguard against accidental disengagement and as a behavioral nudge to maintain adherence. Beyond payment tracking, the portal also provided a transparency dashboard that allowed participants to see the types of hostnames and apps being observed and to visualize their activity patterns over time (Figures 3 and 4). These views were designed to contextualize participants' own digital behavior

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while reinforcing transparency regarding the scope of data collection (Figure 4).

Implementation parameters, storage formats, aggregation settings, and compensation thresholds are documented in Multimedia Appendix 5.

Figure 3. Hostname → app → category pipeline. Domains observed in network traffic are matched against Apple's App Privacy Report (APR) to recover the generating app (via bundle ID), which is then linked to its primary genre using the iTunes Search API. This process yields higher-level behavioral categories that complement app-level mappings. API: application programming interfaces.

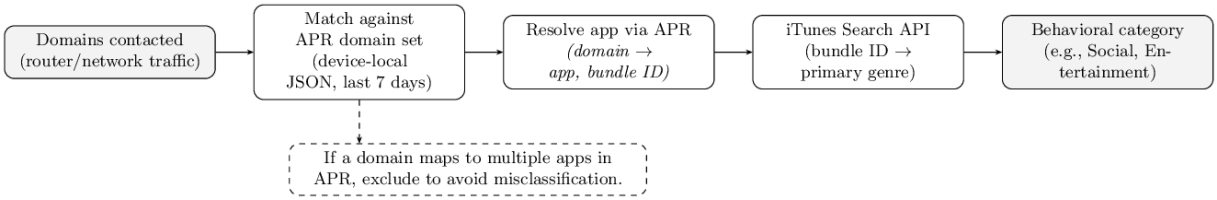
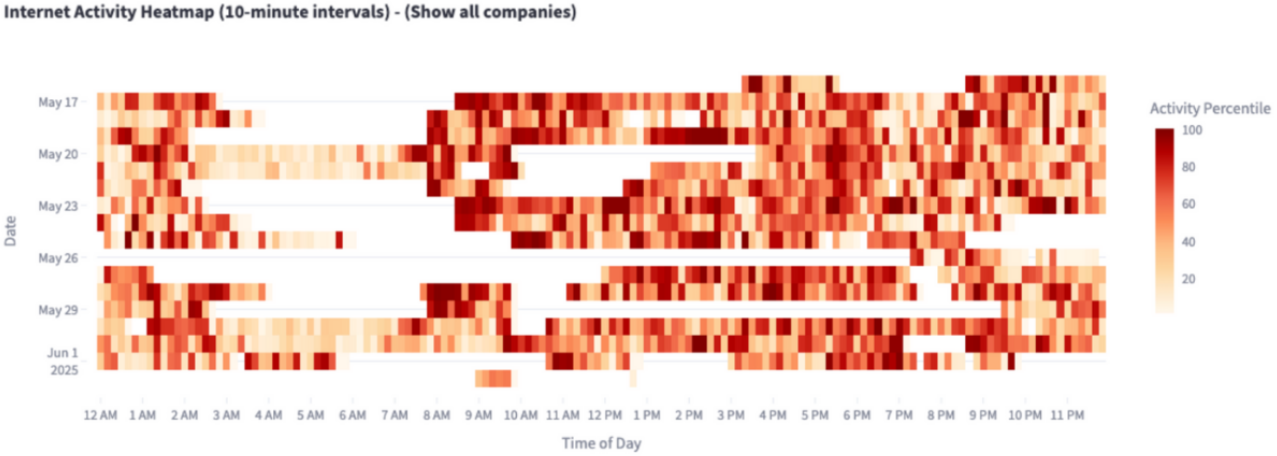


Figure 4. Internet activity heatmap aggregated in 10-min intervals over 24 h. Rows represent study days, and columns represent time of day; color intensity indicates the percentile of observed activity.



Privacy Model

To prevent linkage between digital behaviors and real-world identities, each participant created a random participant ID (PID) during onboarding; no mapping between PIDs and personal information was stored, and participants could regenerate a new PID at any time. The VPN server logs *metadata only*—PID, time stamp, destination hostname, and byte or packet counts; packet contents are never collected. Data were stored on NYU-managed infrastructure with encryption and restricted access to authorized study personnel. Before enrollment, participants received a plain-language briefing (slides, video, and live demonstration) describing the privacy model and risks and provided informed consent.

Exit Surveys and Interviews

At the conclusion of the study, participants were invited to complete a short exit survey. The survey collected free-text entries for the top 10 apps used during the study period, along with standardized usability assessments: the NASA-TLX and the SUS.

Participants were also invited to a semistructured follow-up interview conducted via Zoom (Zoom Video Communications, Inc. [135]) to reflect on their experience with VPN-based monitoring. Interview prompts focused on VPN usage, engagement with the study portal, perceived burden, and willingness to extend participation beyond the 2-week study period. The interview format prioritized participant-led discussion, allowing concerns and observations to surface organically. A complete set of interview questions is provided in Multimedia Appendix 6.

To preserve anonymity while enabling compensation, study completion and payment were decoupled from collected metadata. The study portal generated a completion code encoding the participant's compensation amount without linking it to their participant identifier (PID). Participants presented this code during the interview to confirm eligibility for payment without revealing their study identity. Additional details on interview scheduling and compensation verification are described in Multimedia Appendix 7.

As an optional step, participants using iPhones could choose to share their Apple App Privacy Report (APR), an Apple-generated summary of recent app activity (described in the section *Data Analysis*). Participants were briefed on the scope and limitations of this report, which indicates app usage timing but not accessed content. Shared reports served only as a complementary reference for app usage, augmenting the network metadata collected through the VPN.

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Data Analysis

To evaluate feasibility, acceptability, and the potential of passive traffic data to capture everyday activity patterns, we combined qualitative insights from participant interviews with quantitative analysis of network traffic metadata.

Qualitative Analysis: Interviews

Two authors independently reviewed interview transcripts [136] and conducted an inductive thematic analysis [137-140], generating an initial set of 127 codes. Through iterative axial coding, the code set was refined by merging overlapping categories, revising definitions, and removing redundancies. Themes were developed through consensus-based synthesis to capture recurring patterns in participants' experiences related to feasibility, acceptability, and trust. This approach was selected to allow themes to emerge directly from participants' accounts while maintaining analytic transparency and reproducibility. The complete qualitative codebook, including first-cycle codes and axial groupings, is provided in Multimedia Appendix 8.

Quantitative Analysis: Feasibility

We evaluated feasibility across 2 domains, that is, user retention and data coverage, following conventions in digital phenotyping and mobile sensing research.

User Retention

User retention was defined as the proportion of participants who contributed at least 5 days of traffic out of all participants who contributed any traffic. This threshold ensured that estimates were based on individuals with a meaningful amount of monitoring.

Data Coverage

Data coverage was defined as the proportion of 60-minute intervals (hours) within each participant's monitoring window (from their first observed active hour to their last) that contained valid VPN traffic. An hour was considered "active" if at least one byte of data was observed during that interval. For example, if a participant's monitoring window spanned 120 hours, but traffic was observed in only 100 of those hours, and their coverage rate was 83%. This definition captures transient lapses (eg, when the phone was rebooted or the VPN was manually disabled) while aligning with conventions in digital phenotyping, where adherence is measured as the percentage of expected intervals containing data [141-144].

At the day level, coverage was summarized using a complementary metric: a "valid day," defined as any calendar day containing at least one active hour of VPN traffic. Whereas hour-level coverage quantifies the continuity of monitoring within a participant's observed window, valid days capture the temporal span over which participants contributed data. Coverage was further examined across time-of-day and weekday and weekend strata to assess systematic gaps (see Multimedia Appendix 9 for stratification definitions).

Exploratory Analysis: Network Traffic

Inferring Behavioral Rhythms

To extract behavioral structure from encrypted network flows (ie, sequences of packets sharing a common source, destination, and time window), we treated traffic volume as a proxy for smartphone activity. Internet communication involves both downloads, which largely reflect content delivery (eg, high-volume video streams vs smaller text loads), and uploads, which more directly capture user-initiated actions such as taps, clicks, or navigation. Although exceptions exist—such as high upload traffic during calls or background updates—the relative balance between uploads and downloads provides a useful signal of interaction intensity. As phones are never completely silent, with low-level background exchanges for notifications and maintenance, we interpret higher-volume deviations above this baseline as more indicative of active user engagement.

To assess the validity of this assumption, we conducted an empirical evaluation using annotated sleep-wake periods on researcher devices, which showed systematically lower upload activity during sleep than wake periods (Multimedia Appendix 9).

In particular, we focus on percentile-normalized upload traffic as a heuristic proxy for user-initiated interaction because many common actions (eg, sending messages, posting, or searching) generate outbound requests. Raw byte counts were aggregated into contiguous, nonoverlapping 10-minute bins, a resolution that suppresses transient bursts while preserving diurnal dynamics. For each participant, this yielded a 24-hour activity vector per day. To account for differences in overall smartphone usage—arising from individual habits, app patterns, and device capabilities—we applied a rank-based, within-day percentile normalization. Specifically, for each day d, the traffic volume in bin t was replaced by its empirical percentile relative to the distribution $\{x_{d,1},\ldots,x_{d,T}\}$, where T denotes the number of bins in that day. This transformation is invariant to monotonic scaling and preserves intraday temporal structure, enabling direct cross-participant comparison of diurnal phase and amplitude while suppressing between-subject variance in absolute throughput.

We then visualized and analyzed normalized time series in 2 complementary ways. First, we projected daily activity onto a radial heatmap (Figure 5), where angular position denotes clock time (0 - 24 h), concentric rings denote successive days, and color denotes normalized traffic intensity (red=high percentile and blue=low percentile). This polar representation highlights rest-activity cycles, phase shifts, and fragmentation of daily usage patterns. Nighttime intervals (8 PM to 8 AM) were shaded, and weekends were highlighted in green to facilitate alignment with social schedules.

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Figure 5. Temporal dynamics of overall and category-specific upload traffic for 2 representative participants. Each radial heatmap shows 24 h (angular axis) across successive days (concentric rings). Color indicates normalized traffic intensity, with red denoting higher device usage and blue denoting lower usage. Nighttime hours (8 PM to 8 AM) and weekends (green rings) are marked to facilitate alignment with social schedules.

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To isolate context-specific rhythms, each network flow was enriched by mapping hostnames to high-level app categories (eg, social, entertainment, games, business, education, and food and drink). Mappings were derived from Apple's APR (see section *Inferring Apps From Hostnames*), supplemented by manual verification and aggregation to category-level taxonomies. For each participant, we generated a set of paired radial visualizations: one depicting aggregate device activity and additional plots for each activity category of interest (Figure 5). This design enabled structured comparison between global digital behavioral rhythms and the distinct temporal patterns associated with multiple behavioral categories.

The result is a device-agnostic framework that combines upload-sensitive traffic features, percentile normalization, radial time encoding, and app-level categorization to detect time-of-day and behavioral regularities in digital behavior while preserving privacy. While some background traffic may still be misclassified as user activity and the precise boundary between passive and active phone use remains unresolved, we could still infer broad patterns of usage. More specifically, the approach identified meaningful diurnal and behavioral regularities inferred from encrypted network traffic alone, offering a scalable path for digital phenotyping without OS-level instrumentation.

Inferring Apps From Hostnames

Overview

Encrypted network traffic captured by our VPN consists of destination hostnames associated with network flows. While these hostnames provide a high-level view of device communication, they do not directly identify the apps responsible for generating traffic. In some cases, attribution is straightforward—for example, traffic to youtube.com almost certainly reflects YouTube usage. In many others, however, hostnames correspond to shared infrastructure such as content delivery networks, analytics services, or platform-level end points (eg, cloudflare.com and akamai.net), which are used by many unrelated apps. As a result, naïvely attributing hostnames to apps risks substantial misclassification.

Accurate app inference from network traffic, therefore, requires an external source of app-domain ground truth and a conservative strategy for handling ambiguity. In this study, our goal is not to exhaustively attribute all traffic to specific apps but rather to recover a reliable lower bound on app presence and timing that can support descriptive and exploratory behavioral analyses. To this end, we combine participant-collected and scripted app-domain observations and conservatively consider only domains that uniquely identify a single app.

The following subsections describe the data sources, filtering steps, and validation procedures used to construct this conservative app-domain mapping.

Data Sources: APR

To identify apps from observed hostnames, we leveraged Apple's APR, an opt-in iOS feature that logs, at the app level, the set of hostnames contacted by each app over a rolling 7-day window. The APR is stored locally on the phone as a JSON file and provides a direct mapping between hostnames and the apps responsible for generating them.

APR data were collected from two complementary sources:

1. Participant-collected APRs. A subset of study participants elected to share their APR data. In total, APRs were collected from 15 participant devices, yielding app-domain observations spanning 247 distinct apps. These APRs reflect domains observed during naturalistic, real-world app use ("deep-state" usage).
2. Scripted APRs from controlled app interactions. To expand coverage beyond participant-reported apps and ensure representation of commonly used apps, we additionally collected APRs from controlled scripted interactions on research devices operated by the study team. On these devices, the study team manually interacted with 313 apps for approximately 1 minute per app, restricted to publicly accessible features and without creating user accounts for apps requiring authentication. Of these, 288 apps generated usable APR data and were included in the scripted APR corpus. App selection was informed by two sources: (1) 55 apps reported by participants in exit surveys and interviews and (2) top-ranked apps from the Apple App Store across multiple categories.

Together, participant-collected APRs (247 apps) and scripted APRs (288 apps) yielded a global union corpus spanning 424 distinct apps, with 111 apps observed in both datasets and comprising a total of 3788 registered domains. This unfiltered union corpus served as the starting point for the domain normalization and app-domain disambiguation procedures described below. To support higher-level behavioral analysis, apps identified via APR were mapped to functional categories using Apple's iTunes Search API [145], which returns each app's primary genre (eg, social, entertainment, and productivity). This yields a hierarchical mapping from hostname → app → behavioral category, illustrated in Figure 3.

Domain Normalization and Filtering

Raw hostnames recorded in APRs include a mixture of externally routable domains, local network identifiers, and nonroutable destinations such as IP literals. As only externally routable domains can be meaningfully associated with app backends or third-party services, we first filtered out local and nonroutable hostnames and then normalized the remaining hostnames to their externally routable registered (base) domains [146]. Full procedural details of domain filtering, normalization rules, and resulting domain counts are provided in Appendix I.1 in Multimedia Appendix 10.

This normalization step operates exclusively at the domain-entry level: individual hostname observations may be removed, but apps are not excluded at this stage. App-level exclusion occurs only during subsequent global app-domain disambiguation, where domains shared across multiple apps are conservatively removed to ensure unambiguous attribution (described below).

Global App-Domain Disambiguation

After domain normalization, many registered domains remained associated with multiple apps, typically reflecting shared infrastructure, such as content delivery networks, analytics

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services, advertising platforms, or OS-level services. As these domains cannot be reliably attributed to a single app, their inclusion would introduce ambiguity into app-level inference.

To ensure unambiguous attribution, we applied a conservative global app-domain disambiguation strategy over the union of participant-collected and scripted APR data. Only domains that uniquely mapped to a single app across the entire union corpus were retained; domains shared across multiple apps were excluded. For example, requests to youtube.com were retained because they appeared exclusively in association with the YouTube app, whereas domains such as cdn.apple.com or app-measurement.com, which appeared across many unrelated apps, were excluded. Under this global criterion, approximately two-thirds of registered domains (67.7%) were uniquely attributable to a single app, while the remaining domains (32.3%) reflected shared infrastructure and were conservatively excluded to avoid ambiguous attribution.

This conservative disambiguation substantially limits byte-level attribution, as shared infrastructure dominates overall traffic volume. Consistent with this expectation, only 1.47% of total upload bytes were attributable to app-unique domains. However, when evaluated temporally, 98.7% of 10-minute bins contained at least one app-attributable domain, indicating that app presence and activity timing are preserved across nearly all observation windows.

We therefore interpret app-level traffic attribution as a conservative lower bound on app usage volume. By prioritizing precision over coverage, this union-level procedure yields a reliable characterization of app presence suitable for feasibility assessment and exploratory behavioral rhythm analysis without relying on ambiguous infrastructure domains. Full disambiguation procedures and coverage statistics are provided in Appendix I.2 in Multimedia Appendix 10.

Scripted Versus Participant ("Deep-State") Comparison

Brief scripted app interactions may not capture all domains that arise during prolonged or authenticated ("deep-state") app use, raising concerns that scripted APRs could underrepresent app-identifying domains. To assess the impact of this limitation on app identification in our study, we compared domains observed during brief scripted launches with those observed during participant-collected, real-world usage of the same apps.

Despite differences in interaction depth, brief scripted launches recovered app-identifying domains for nearly the same set of apps as prolonged naturalistic use. Within the shared cohort, 30 of 47 apps were semantically identifiable based on domains observed during scripted interactions. Participant-collected ("deep-state") usage identified only one additional app (31 in total), as domains observed during sustained or authenticated use offered limited incremental benefit and more often reflected shared infrastructure or generic services rather than app-specific signals.

These results indicate that, for the feasibility-oriented aims of this study, brief scripted interactions are sufficient to recover the app-identifying domains needed to infer app presence and activity timing. Full validation details—including app overlap criteria, semantic identifiability rules, and quantitative overlap statistics—are provided in Appendix I.3 in Multimedia Appendix 10.

Ethical Considerations

This study was approved by the NYU Institutional Review Board (IRB-FY2025-9589) and conducted in accordance with the Belmont Report and the Declaration of Helsinki. All participants were adults and provided electronic informed consent prior to enrollment. No personally identifiable information or content data were collected; participants were assigned random identifiers, and traffic metadata were stored on secure, access-restricted university servers. Participants were compensated under an institutional review board–approved tiered schedule based on VPN connection duration, with payments issued via anonymized completion codes. No vulnerable populations were enrolled.

Results

Outcome 1: Feasibility

Feasibility was assessed using a mixed methods approach that combined quantitative measures of retention and data continuity with qualitative analysis of exit interviews. In this study, feasibility refers to participants' ability to sustain passive VPN-based monitoring over time, as well as the operational conditions under which data collection was interrupted or discontinued.

Quantitative Feasibility: Retention and Data Coverage

User Retention

User retention was quantified as progression along the study pipeline (Figure 1). Specifically, we tracked the proportion of students advancing from initial eligibility screening through consent, onboarding, VPN activation, and study completion. This mirrors conventions in digital health feasibility studies, where recruitment yield and retention are reported alongside data completeness [147,148].

Recruitment outreach reached 100 students, of whom 38 provided informed consent. Of these, 32 completed the onboarding survey, 29 provided valid network traffic data, and 27 remained active for more than 5 days. At study completion, 26 participants completed the exit survey, and 25 completed the exit interview.

Overall, this corresponds to 93% retention among participants who contributed any valid network traffic data to the analysis stage (27/29; Wilson 95% CI 78% - 98%) and 66% completion from consent through the exit interview (25/38; Wilson 95% CI 50% - 79%). Comparisons between students who consented but did not continue and those who completed the study revealed no systematic differences in department, major, or university role, suggesting minimal self-selection bias that might confound usage patterns.

Data Coverage

Feasibility was also evaluated using data coverage, defined as the proportion of expected monitoring intervals with valid VPN traffic. As onboarding was staggered and the study ended on a fixed date, not all participants contributed a full 14 days of data.

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Feasibility was therefore defined relative to each individual's observed monitoring window (from first to last active day), consistent with digital phenotyping conventions that measure adherence based on monitoring opportunity [149,150].

To ensure comparability of temporal rhythms, we restricted coverage analyses to the 24 participants who remained in a consistent time zone (ie, not traveling during the study period). Across these participants, the mean feasibility was 74.1% (median 77.1%; bootstrap 95% CI 66.3% - 81.4%), with coverage ranging from 21% to 100%. This variability reflects heterogeneous adherence, with some participants maintaining near-continuous VPN connectivity and others exhibiting intermittent gaps. On average, participants contributed 311.6 (~13 d, SD 3.5) hours of monitored traffic, with individual totals spanning 121 to 496 hours. In addition to overall coverage, we examined the temporal distribution of VPN off periods. Across all 24 participants, the median gap in coverage was 7.5 (IQR 2.8 - 23.8) hours, with most interruptions being relatively short (ie, <24 h). However, occasional extended lapses occurred, with the maximum gap reaching 304 hours (~12.5 d). This extreme case (participant P05) showed nearly 13 days of continuous activity, followed by approximately 12.5 days of inactivity, before briefly reenabling the VPN at the study's end.

Stratification confirmed that coverage was consistent across daily rhythms and calendar cycles (Table 1). The mean coverage was stable across mornings (71.1%), afternoons (75.9%), evenings (77.6%), and nights (71.9%), as well as between weekdays (74.2%) and weekends (74.0%). Aggregate analysis pooling bins across all participants yielded similar estimates (69.7% - 76.2% across strata;), underscoring that passive VPN sensing did not systematically fail during specific daily routines or social contexts. On average, participants contributed 16.2 (SD 3.8, range 10 - 23) valid days—defined as calendar days with at least one active hour of VPN traffic—reflecting the calendar span of participation across staggered onboarding and study completion.

Complementary visualizations illustrate continuity and adherence patterns. The calendar-aligned timeline (Figure G.1 in Multimedia Appendix 9) highlights deployment feasibility under staggered onboarding, while the Day-0–aligned timeline (Figure G.2 in Multimedia Appendix 9) normalizes trajectories to participants' start dates, revealing heterogeneity in adherence and lapse patterns.

Table . Participant-level data coverage (mean and median across individuals), reported overall and stratified by time of day and weekday and weekend cycles.

Scope	Mean (%)	Median (IQR), (%)	95% CI (%)
Overall	74.1	77.1 (63.6-90)	62.7 - 78.8
Morning	71.1	75.0 (57.9-88.6)	67.4 - 83.3
Afternoon	75.9	79.0 (69.1-90.3)	70.1 - 84.7
Evening	77.6	82.8 (67.1-92.4)	63.4 - 79.7
Night	71.9	75.5 (56.8-85.8)	66.7 - 81.7
Weekday	74.2	79.5 (63.5-86.6)	64.8 - 83.2
Weekend	74	76.4 (61.2-99.4)	66.3 - 81.4

Qualitative Feasibility Findings

Participants' accounts from the exit interviews provide a detailed picture of how the VPN-based monitoring system functioned in everyday use and why interruptions occurred. Across interviews, feasibility was most often described in practical terms—how easy the system was to set up, how much attention it required over time, and what happened when routine phone use or technical events disrupted monitoring. These findings reflect patterns that emerged across multiple rounds of independent coding and iterative synthesis, with themes developed to capture both facilitating and constraining conditions for feasibility.

Many participants began by describing onboarding as simpler than they had anticipated. Several entered the study expecting a technically demanding setup, only to find the process straightforward and clearly guided. As one participant reflected, "I thought this was going to be a lot more work, but it was really easy to participate in. I had no problems at all" (participant 24). Others emphasized the clarity of the instructions and the minimal learning required: "It was very clearly organized, so that made it effortless to set up" (participant 6) and "It's just tapping one button—that's it" (participant 10). For these participants, ease of setup shaped early expectations that participation would be manageable alongside academic and personal routines.

Once installed, participants consistently described the system as requiring little to no ongoing effort. Rather than needing active maintenance or frequent checking, the VPN was described as something that simply "ran" while participants went about their normal activities. One participant explained, "There was nothing too complex. It wasn't something I had to maintain or keep monitoring" (participant 7), while another noted, "It was very little effort—pretty invisible" (participant 22). This low operational demand appeared central to sustained participation. Several participants linked their continued enrollment to the fact that the system did not demand much ongoing effort: "At first I thought it would be more hands-on, but in the end I didn't really have to do much" (participant 18).

For some participants, the system's unobtrusiveness was so pronounced that it faded entirely from awareness. Multiple interviewees described forgetting about the VPN altogether after initial setup. As one participant put it, "I set it up and then

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just forgot about it, basically" (participant P3). Another participant echoed this sentiment: "It was one of those things where you forget about it" (participant 12). In several cases, this invisibility led participants to continue running the VPN beyond the planned 14-day study period simply because there was no reason to turn it off. These accounts align with objective data showing that some participants contributed more than 2 weeks of valid recordings without deliberate effort to sustain participation.

Participants also emphasized that the system did not interfere with daily life. Many described being able to use their phones normally, without changes to work, study, or leisure activities. One participant stated plainly, "It didn't interfere at all with anything" (participant P6), while another explained, "I could still use my phone the way I was used to—I didn't really notice it throughout the day" (participant 14). For these participants, feasibility was closely tied to the system's ability to blend into existing routines rather than impose new ones.

At the same time, this same invisibility contributed to several of the feasibility breakdowns observed in the quantitative data. As the VPN demanded so little attention, participants often failed to notice when monitoring stopped. The most common scenario involved phones powering off, batteries dying, or devices restarting. Several participants described realizing only later that data had not been collected during these periods. One recalled, "My phone died and I didn't realize the VPN turned off. It took almost a day before I noticed" (participant 6). Another participant explained, "I didn't know that once my phone died I would have to manually turn it back on" (participant 7).

Importantly, participants were clear that these interruptions were not intentional. When asked directly, several stated that they had never deliberately disabled the VPN: "No, I never turned it off intentionally at all" (participant 24). Instead, lapses were described as the result of forgetting that the VPN required manual reactivation after device-level events. In this sense, the same low-maintenance design that supported feasibility also reduced participants' awareness of the system state.

A smaller number of participants described intentional pauses in monitoring due to perceived technical side effects. These included concerns about battery drain during long days away from charging or frustration with occasional network slowdowns. One participant explained, "When videos took a long time to load, I'd get frustrated and turn off the VPN for a bit" (participant 10), while another participant noted, "I noticed my battery draining really fast" (participant 7). Although these cases were relatively uncommon, they tended to correspond to longer gaps in data coverage. Importantly, independent laboratory measurements indicated that the VPN consumed less than 1% battery over a 24-hour period, suggesting that these interruptions were driven less by objective resource usage than by participants' perceptions of device performance.

Finally, interviews revealed that participants' perceptions of their own adherence did not always align with recorded data. Some participants overestimated how long the VPN had been active, while others underestimated it. As one participant reflected uncertainly, "I want to say it was like two and a half weeks..." (participant 2). These discrepancies highlight the limits of self-report for assessing feasibility and reinforce the value of passive logging in understanding real-world use.

Outcome 2: Acceptability

Acceptability was evaluated using a mixed methods approach combining standardized workload and usability instruments with in-depth qualitative analysis of exit interviews. In this study, *acceptability* refers not only to whether participants were willing to tolerate the system but also to their perceptions of its appropriateness, trustworthiness, and value for sustained use in everyday life.

Quantitative Acceptability: Workload and Usability

To evaluate the acceptability of our system in naturalistic daily use, we administered adapted versions of the NASA-TLX [117] and the SUS [132] during the exit survey. These instruments quantify, respectively, the perceived workload associated with system use and the overall usability of the interface and interaction design.

As shown in Figure G.3 in Multimedia Appendix 9, NASA-TLX ratings indicated consistently low levels of burden across all 6 dimensions: mental demand (mean 2.69, SD 3.27), physical demand (mean 1.54, SD 1.79), temporal demand (mean 2.92, SD 4.09), performance (mean 4.08, SD 4.18), effort (mean 3.85, SD 4.31), and frustration (mean 2.88, SD 3.78). The boxplots display the distribution of responses, with medians (horizontal lines) often below the mean values (black dots), reflecting skewness due to a small number of outliers (open circles). Although the NASA-TLX does not prescribe thresholds for "acceptable" workload, the uniformly low scores suggest that participants experienced minimal cognitive, physical, or temporal strain.

For context, prior digital health deployments have reported substantially higher NASA-TLX scores—for example, a COVID-19 exposure notification app showed a mean mental demand of approximately 29 out of 100 and overall workload of 25 to 35 out of 100 [106]. In contrast, our participants' scores corresponded to approximately 10 to 20 out of 100, indicating that the VPN-based system operated unobtrusively with minimal daily burden.

Additionally, SUS results reinforced this conclusion. The mean SUS score was 78.08 (SD 14.96), ranging from 52.5 to 100. According to established SUS benchmarks [151], scores above 68 are interpreted as reflecting good usability, positioning our passive monitoring system well above the benchmark for acceptability.

Qualitative Acceptability in Everyday Use

Participants' interview accounts provide deeper insight into how these low workload and high usability scores translated into lived experience. Across interviews, acceptability was often articulated in practical terms, including the degree of perceived intrusiveness, alignment with participants' expectations around privacy and control, and the perceived value of the system beyond data collection.

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Many participants framed their acceptance of the system around its minimal impact on daily life. The VPN was frequently described as something that "just ran" without requiring attention or disrupting routines. As one participant noted, "It was very little effort. Pretty invisible" (participant 22). Another participant explained, "It didn't interfere at all with anything" (participant 6). For these participants, acceptability was closely tied to the absence of friction: the system did not ask them to change how they used their phones or manage new tasks.

Trust and institutional context also played a central role in acceptability. Several participants described feeling comfortable with passive monitoring because they trusted the research team and the university affiliation. Clear explanations during onboarding about what data were collected, how they were handled, and how anonymity was preserved helped establish this trust. As 1 participant reflected, "You explained it pretty well—what you were doing, how you were capturing the data, how you were making sure it wasn't attached to my name" (participant 14). This transparency appeared to reduce anxiety and supported continued participation even when monitoring was largely invisible.

At the same time, acceptability was not unconditional. A subset of participants expressed ongoing discomfort during specific activities, particularly those involving financial or sensitive personal information. Three participants described feeling uneasy during banking or similar tasks, and 7 participants reported occasionally disabling the VPN in such contexts. One participant explained simply, "Sometimes I turn it off when I'm using my banking apps" (participant 20). These behaviors illustrate that acceptability was negotiated dynamically: participants balanced trust in the system with situational judgments about privacy and control.

Importantly, these selective interruptions did not reflect wholesale rejection of the system. Rather, they demonstrate how participants exercised agency to manage perceived risk while remaining broadly willing to participate. For most participants, the ability to turn the VPN off when desired appeared to *increase* acceptability by preserving a sense of control.

Acceptability also extended beyond tolerance to perceived benefit for some participants. Several described the dashboard and visualizations as prompting reflection on their own digital behaviors. Twelve participants reported increased awareness of smartphone usage patterns, with a subset noting intentional behavior changes as a result. One participant observed, "Seeing the patterns in my phone usage on the heat map was interesting. It made me more aware of how much I use my phone, and sometimes I felt like I might need to tone it down" (participant 11). Another described realizing how quickly time passed during app use: "It made me notice just how quickly 40 minutes can disappear" (participant 2). In some cases, this awareness motivated short-term changes, such as reducing social media use: "Once I saw it was tracking my activity, I actually took a break from Instagram for a week" (participant 13).

These perceived benefits contributed to the willingness to continue. Nineteen participants expressed interest in using the system beyond the 14-day study period, describing it as unobtrusive and easy to live with. Four others expressed a neutral but permissive stance—"no reason to stop using it"—reflecting that the system imposed little cost even if it did not actively engage them. Others indicated that continued use would depend on resolving specific reliability concerns, particularly around unexpected VPN shutdowns.

Outcome 3 (Exploratory): Capturing Behavioral Rhythms From Network-Derived Features

To explore patterns of daily structure in passive network traffic relevant to behavioral rhythms, we conducted an exploratory, cohort-level analysis using interpretable, participant-level traffic-derived rhythm metrics, as described below.

Cohort-Level Rhythm Metrics

For each participant, we derived 2 complementary metrics that summarize daily activity patterns from upload network traffic after within-day rank (percentile) normalization: (1) day-to-day stability, computed as the mean correlation between consecutive daily activity profiles, following prior work on cross-day behavioral regularity [152]; and (2) circadian power ratio, defined as the proportion of spectral power concentrated at the 24-hour frequency and serves as a standard spectral measure of circadian rhythmicity [153,154].

Figure 6 shows the joint distribution of these metrics across all participants. Together, these metrics capture complementary aspects of behavioral regularity: consistency across days (day-to-day stability) and strength of circadian rhythmicity (circadian power ratio). To identify dominant behavioral patterns across participants without imposing predefined thresholds, we applied unsupervised clustering in the joint space of these 2 metrics. Specifically, we performed k-means (k=2) clustering on z score–standardized values of day-to-day stability and circadian power ratio to ensure comparable scaling across metrics. We selected 2 clusters as a minimal and interpretable partition aligned with the dominant structure observed in the joint metric space, separating participants with relatively more routine versus more fragmented activity rhythms. This analysis revealed 2 broad, data-driven groupings corresponding to relatively more routine versus more fragmented activity rhythms across participants.

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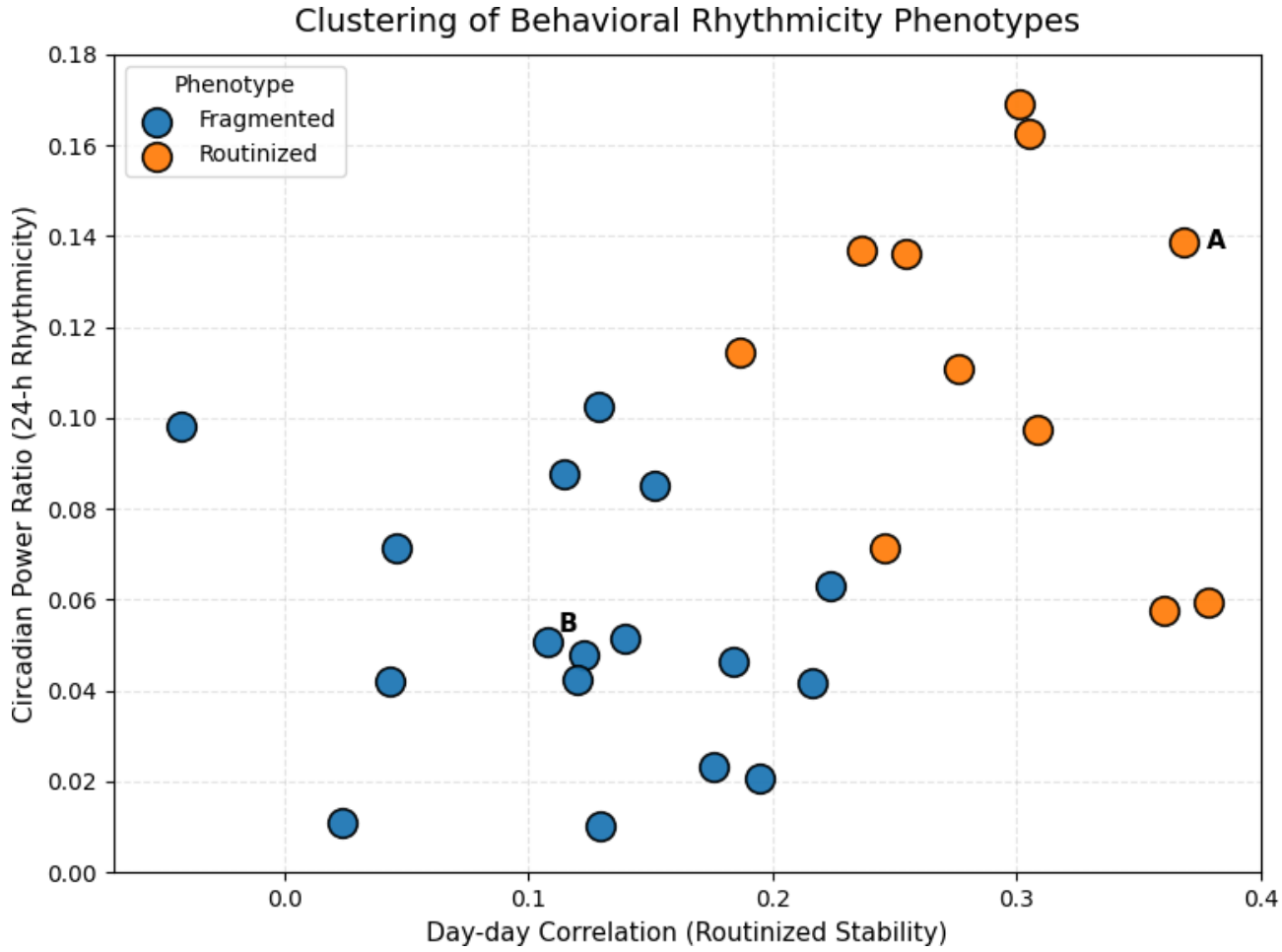
Figure 6. Cohort-level behavioral rhythm structure derived from passive network traffic. Each point represents 1 participant, plotted by day-to-day activity stability and circadian power ratio. Colors indicate unsupervised clustering performed for descriptive purposes. Participants A and B are annotated to illustrate how exemplar temporal profiles (Figure 5) relate to cohort-level structure.



Illustrative Participant-Level Temporal Patterns

Two participants (A and B) are annotated in Figure 6 as occupying distinct regions of the cohort-level rhythm space, reflecting contrasting patterns of behavioral regularity and fragmentation. To illustrate how these cohort-level differences manifest in individual behavior, Figure 5 presents detailed temporal visualizations for these participants.

Participant A exhibited a highly regular daily pattern, with activity concentrated during daytime hours and minimal activity overnight. The radial plots show a strong and stable day-night rhythm across days, with social media activity closely mirroring overall traffic. Category-specific views further indicate consistent engagement with gaming and business-related apps, alongside limited interaction with food delivery services.

In contrast, participant B displayed a more fragmented and irregular activity profile. Although some day-night structure was present, social media activity appeared at variable and atypical hours, including late night and early morning. Category-level traces showed comparatively greater reliance on food-related services and minimal engagement with gaming or business apps.

Figure 6 shows cohort-level variation in behavioral regularity alongside participant-level temporal patterns derived from encrypted network traffic. The 2 participants are presented as illustrative examples situated within the broader cohort-level structure, rather than as representative or diagnostic cases. This analysis is explicitly exploratory and descriptive and does not claim inferential separation or validated behavioral phenotypes; instead, it is intended to demonstrate the feasibility of deriving interpretable rhythm features from passive network data.

Discussion

Principal Results

This study examines encrypted smartphone network traffic as a means of longitudinally characterizing the temporal organization of everyday digital activity under real-world conditions. Rather than inferring specific behaviors or clinical states, we focus on how passive network metadata captures interpretable temporal patterns in digital activity, including periods of sustained activity, relative inactivity, and variability in daily engagement. Such temporal structure has been widely studied in health and behavioral research as a marker of routine organization and change but is difficult to observe continuously without intrusive or burdensome sensing approaches [155,156]. Accordingly, we interpret our findings in terms of their implications for measuring behavioral rhythms at scale, rather than for identifying specific health conditions or outcomes.

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Empirically, we observe that encrypted network traffic exhibits interpretable temporal structure within individuals, characterized by recurring patterns of activity and inactivity over time. While the degree of regularity varied across participants, these temporal patterns could be recovered without inspecting content or requiring intrusive sensing. Using a VPN-based monitoring system, we sustained continuous data capture for nearly 2 weeks on average, with minimal participant effort, demonstrating that longitudinal observation of everyday digital activity is feasible in naturalistic settings without intrusive sensing or content inspection.

From the perspective of studying behavioral organization over time, sustained feasibility is critical, as changes in routine structure and engagement often unfold over weeks rather than days [1-3,157]. In descriptive comparison with prior remote digital health studies reporting median retention of approximately 5.5 days or completion rates near 50% [147,158], our 93% retention among contributing participants (27/29, 93.1%) lies at the upper end of reported values, suggesting that network-level monitoring can sustain multiweek observation windows sufficient to capture day-to-day variability and gradual change.

Beyond retention, participant accounts indicate that feasibility depended on a balance between minimal operational burden and low system salience—conditions that are essential for observing naturalistic patterns of everyday behavior. Participants consistently described the system as lightweight and unobtrusive, with SUS scores well above standard usability benchmarks, and interview accounts highlighting its “invisible” operation in daily life. This low level of disruption is particularly important for studies aimed at characterizing routine organization and temporal regularity, as more intrusive monitoring can itself alter behavior. Coverage gaps arose primarily from device-level interruptions, benign senescent forgetfulness [159], or occasional technical frictions rather than resistance to participation or perceived burden.

Acceptability was shaped not only by low operational burden but also by privacy, trust, and perceived control. Most participants expressed confidence in the research team and institutional safeguards; when concerns arose, they were typically addressed through selective, temporary disabling of the VPN during sensitive activities rather than disengagement from the study. Importantly, this pattern suggests that acceptability was not passive but actively negotiated over time, with user control enabling continued participation even in the presence of situational discomfort.

For behavioral and health-oriented research, this capacity for negotiation is consequential: rigid, always-on sensing can provoke disengagement, whereas approaches that allow situational control may better support long-term observation of everyday routines. Participants’ qualitative accounts aligned closely with quantitative indicators of low workload and high usability, reinforcing that acceptability was actively maintained throughout the deployment.

Exploratory analyses further indicated that traffic-derived features captured coherent daily patterns of digital activity rhythms, with systematic variation across participants in temporal regularity and routine structure. Specifically, individuals differed in the consistency, concentration, and fragmentation of activity over the course of the day, reflecting variation in how daily routines were organized. While this study does not assess specific behaviors or health outcomes, the ability to recover stable, individual-level differences in behavioral regularity demonstrates that encrypted network traffic can serve as a viable proxy for longitudinal study of everyday behavioral organization. Such dimensions of behavioral organization have been widely studied in health and behavioral research as early indicators of changes in mental and cognitive health, even before clinical diagnosis [100-104].

Limitations and Future Work

Several limitations constrain interpretation and generalizability. Network traffic alone cannot reliably distinguish foreground user interaction from background processes, as updates, notifications, and keep-alive signals may generate activity without active use. Although percentile normalization reduces some noise, it remains a coarse proxy for engagement rather than a definitive separation of foreground and background states.

As illustrated in Figure 7 and supported by the empirical evaluation in Multimedia Appendix 9, sleep periods exhibited lower percentile-normalized upload traffic than awake periods, with sharp peaks more likely reflecting user-driven activity. However, background processes can occasionally mimic bursty patterns, and these distinctions should therefore be interpreted as heuristic approximations. Additionally, not all behaviors generate network traces. Fully offline actions—such as composing notes without iCloud sync or using local-only apps—cannot be observed through this approach. While this limits the ability to attribute activity to specific behaviors, it also serves as a privacy safeguard by reducing the risk of overidentification while still capturing meaningful behavioral rhythms.

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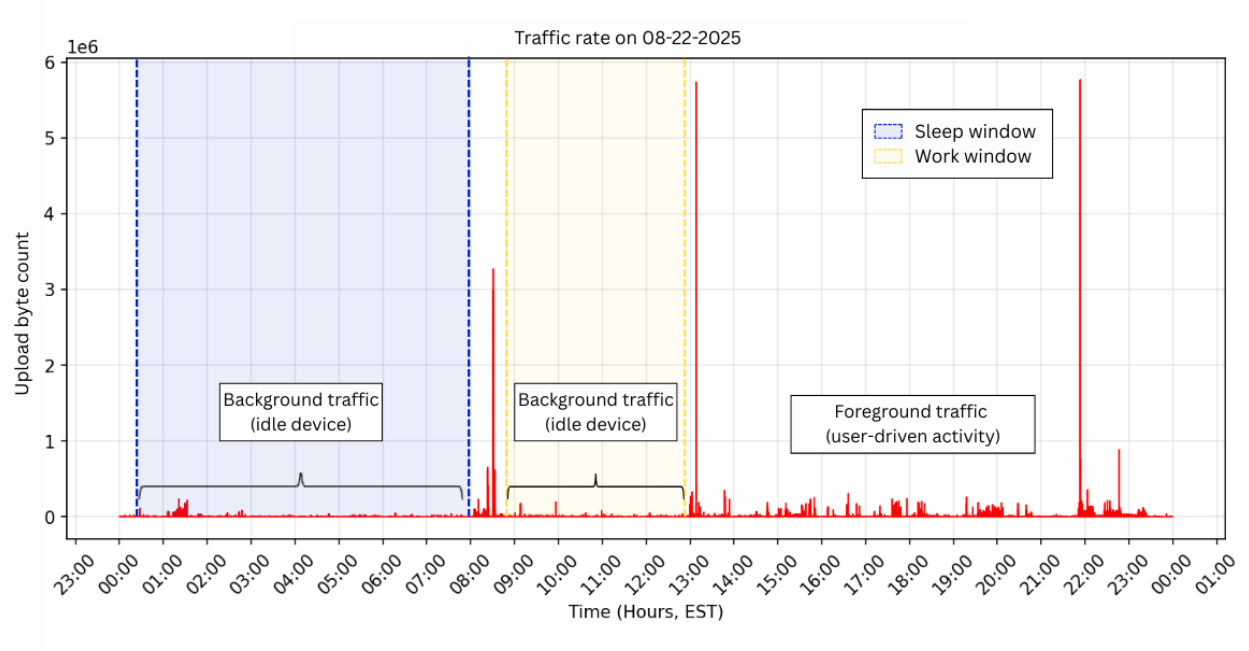
Figure 7. Daily upload traffic from a researcher's device on August 22, 2025. Background periods (eg, sleep and work windows) are shaded, with bursts of foreground activity visible as spikes in upload volume.



Another limitation concerns the temporal and platform stability of app-domain mappings derived from Apple's APR, which exposes app-domain associations over a rolling 7-day window, whereas our monitoring period extended to approximately 2 weeks. Our analyses, therefore, assume that app-identifying domains remain sufficiently stable over short deployments. Although we did not explicitly measure temporal drift, the consistency of domains recovered across participant-collected APRs and controlled scripted interactions suggests that the retained mappings reflect persistent backend infrastructure rather than transient connections. Over longer deployments, however, app updates or changes in third-party services may necessitate periodic reestimation. Moreover, APR is currently limited to iOS; extending this approach to Android will require alternative strategies such as controlled app interaction experiments, longitudinal aggregation, or hybrid labeling pipelines.

From a systems perspective, data gaps following phone restarts occasionally led to extended lapses in monitoring. These gaps highlight the need for stronger reliability safeguards. Future iterations should prioritize automated VPN reactivation and user-facing notifications when connectivity lapses occur, ensuring continuous coverage without manual intervention.

Beyond technical considerations, awareness of being monitored may introduce reactivity effects. While several participants reported forgetting about the system entirely, others used the feedback productively to reflect on their digital habits. Future work should distinguish between distortion of natural behavior and constructive self-awareness, clarifying when monitoring alters behavior in ways that undermine inference versus when it provides meaningful benefit.

Generalizability is also limited by the demographic composition of our sample, which consisted of university students from a single elite US institution—a group likely to be more familiar with VPNs and digital privacy trade-offs. Although technology adoption among older adults is increasing [160-167], comfort with passive monitoring and mental models of digital surveillance may differ substantially across populations. Broader recruitment will be essential for evaluating feasibility and acceptability in more diverse and representative cohorts.

Looking ahead, an important direction for future research is to evaluate the utility of network-derived behavioral rhythms in populations at elevated risk for cognitive and neuropsychiatric disorders. Prior work has shown that disruptions in sleep-wake cycles and daily behavioral regularity often precede clinical diagnosis of conditions such as depression, Alzheimer disease, and Parkinson disease. While this study was not designed to assess clinical outcomes, its contribution lies in establishing a low-burden, scalable method for measuring the longitudinal behavioral patterns that such studies aim to track in aging or clinical populations.

Equally important is validation against independent ground truth. Combining network traffic–derived rhythms with complementary data sources—such as accelerometer signals, wearable-derived sleep measures, location context, or experience sampling—would enable stronger links between digital activity patterns and behavioral or psychological states. Cross-device monitoring represents another promising extension. As WireGuard is compatible with all major operating systems, expanding monitoring to laptops and tablets could provide a more holistic view of how individuals transition between contexts throughout the day.

Finally, methodological refinements will be necessary to capture finer-grained app usage. Preliminary experiments suggest that different functionalities (eg, text messaging vs video calls) produce distinct network signatures. Systematic labeling in controlled settings, paired with user-reported logs, could enable classifiers to infer more specific behaviors at scale. Together, these extensions—broader populations, cross-device integration, multimodal validation, and analytic refinement—would move the system beyond feasibility and acceptability toward a robust,

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generalizable platform for longitudinal behavioral monitoring, with apps ranging from circadian rhythm research to cognitive health.

Relation to Prior Work

Our method occupies a distinct space between high-burden active sensing and coarse, platform-restricted analytics. Existing approaches—including self-reports, OS-level logs, and custom sensing apps—face challenges such as recall bias, declining adherence, battery overhead, and restrictive platform permissions, limiting their ability to support longitudinal observation in naturalistic settings.

We address these limitations in 3 ways. First, the system is OS-agnostic: operating at the network layer via a standard VPN profile, it functions across iOS, Android, laptops, and other devices without rooting or platform-specific APIs. Second, it preserves privacy by capturing only metadata (eg, timestamps and encrypted flows) rather than message content or typed input. Third, it incorporates participant-facing dashboards that enhance transparency and support informed participation.

Together, this combination of precision, privacy preservation, and scalability differentiates our method from prior sensing paradigms and establishes it as a flexible foundation for behavioral research in naturalistic, longitudinal settings.

Conclusions

Our study demonstrates the feasibility and acceptability of a passive monitoring system for encrypted network traffic that can be mapped into interpretable activity patterns. By sustaining unobtrusive capture over extended periods, the approach yields rhythms aligned with circadian structure and digital routines while minimizing participant burden. Limitations in app-level inference, demographic scope, and device coverage define clear avenues for refinement. With broader recruitment, multidevice integration, and validation against ground truth, this system could expand the digital phenotyping toolkit for investigating sleep, mental health, and cognitive change across the lifespan at scale.

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Generative artificial intelligence (AI) tools (GPT-4o and GPT-5.1) were used under full human supervision for limited tasks classified under the Generative Artificial Intelligence Delegation Taxonomy (GAIDeT, 2025), specifically for proofreading, editing, and summarizing author-written text. These tools were used solely to refine language and condense content drafted by the authors. No scientific content, analyses, methodological decisions, or interpretations were generated by AI. All AI-assisted content was reviewed and verified by the authors, who retain full responsibility for the final manuscript. Participant quotations were lightly edited for clarity and privacy while preserving meaning.

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Conflicts of Interest

ZB and JK have a financial interest in Life Analytics Inc, a company that may have a commercial interest in the results of this research and technology. This potential conflict of interest has been reviewed and is managed by Oregon Health & Science University.

Multimedia Appendix 1
Demographic characteristics of the final analytic sample.
[DOCX File, 16 KB - formative_v10i1e84618_app1.docx]

Multimedia Appendix 2
Recruitment and onboarding procedures.
[DOCX File, 15 KB - formative_v10i1e84618_app2.docx]

Multimedia Appendix 3
VPN implementation and data collection details.
[DOCX File, 15 KB - formative_v10i1e84618_app3.docx]

Multimedia Appendix 4
Participant onboarding and study portal.
[DOCX File, 293 KB - formative_v10i1e84618_app4.docx]

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Multimedia Appendix 5
Data capture and participant portal specifications.
[DOCX File, 303 KB - formative_v10i1e84618_app5.docx]

Multimedia Appendix 6
Semistructured interview questions.
[DOCX File, 14 KB - formative_v10i1e84618_app6.docx]

Multimedia Appendix 7
Exit survey administration and interview procedures.
[DOCX File, 14 KB - formative_v10i1e84618_app7.docx]

Multimedia Appendix 8
Qualitative codebook summarizing themes, subthemes, and original codes derived from exit interview transcripts.
[DOCX File, 29 KB - formative_v10i1e84618_app8.docx]

Multimedia Appendix 9
Coverage stratification and aggregate feasibility.
[DOCX File, 595 KB - formative_v10i1e84618_app9.docx]

Multimedia Appendix 10
App-domain inference pipeline and validation.
[DOCX File, 18 KB - formative_v10i1e84618_app10.docx]

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Abbreviations

AI: artificial intelligence
API: application programming interface
APR: App Privacy Report
CONSORT: Consolidated Standards of Reporting Trials
GAIDeT: Generative Artificial Intelligence Delegation Taxonomy
NYU: New York University
OS: operating system
SUS: System Usability Scale
VPN: virtual private network

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Integrating Virtual Reality Simulation, Online Learning, and Group Reflection to Strengthen Dementia Care in Nursing Homes: Mixed Methods Pilot Study

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Abstract

Background: Long-term care facilities are increasingly caring for persons living with dementia as this population grows. Frontline care workers provide most hands-on support, yet they often have limited access to formal dementia education and training. Traditional training formats frequently fail to support experiential learning or accommodate the linguistic, cultural, and demographic diversity of the long-term care workforce.

Objective: This mixed methods pilot study examined the effects of the combined use of online learning, immersive virtual reality (VR) simulation, and facilitated group discussions on the training and preferred learning formats. In particular, this study tested whether training based on relationship-centered care (eg, emphasizing the importance of mutual respect, empathy, and shared humanity) in care relationships embodied in the immersive VR simulation allows staff to experience dementia-related cognitive and sensory changes from the perspective of persons living with dementia.

Methods: A total of 21 certified nursing assistants from 1 US nursing home participated in a 3-month mixed methods intervention. Empathy and knowledge were measured using pre- and postintervention standardized tests; qualitative feedback was collected through open-ended surveys and group discussions.

Results: Participants were predominantly female, Black certified nursing assistants with approximately 68% reporting 8 years or more of care experience. Among the 76.2% (16/21) of the participants who completed the pre- and postintervention surveys, empathy scores increased from pretest (mean 5.31, SD 0.74) to posttest (mean 5.51, SD 0.61). The mean difference of 0.20 (SD 0.43) did not reach statistical significance (t_{15}=1.88; P=.08), but the effect size was moderate (Cohen d_z=0.47, 95% CI −0.03 to 0.43). Dementia knowledge scores also increased from pretest (mean 5.50, SD 2.37) to posttest (mean 5.94, SD 2.11), with a mean difference of 0.44 (SD 1.63), which was not statistically significant (t_{15}=1.07; P=.30), and demonstrated a small effect size (Cohen d_z=0.27, 95% CI −0.43 to 1.31). Qualitative findings revealed that participants perceived the VR training as engaging and emotionally impactful. Participants described reframing their understanding of dementia, reporting reduced stigma and increased empathy toward persons living with dementia. Many noted that experiencing dementia-related symptoms through VR helped them better understand residents' behaviors and respond with greater compassion. Participants expressed a strong preference for immersive VR and facilitated group discussions over online modules, and cultural differences in the VR scenarios were not perceived as barriers to learning.

Conclusions: While preliminary, these findings suggest that combining relationship-centered care with immersive VR may enhance empathy and engagement among staff, particularly when paired with facilitated discussion and plain language explanations. This multimodal model appears particularly valuable for supporting empathic learning within diverse and experienced workforces. Larger, multisite studies with sustained follow-up are needed to determine long-term effects and optimize training for linguistically and culturally diverse workforces.

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KEYWORDS

AD/ADRD; relationship-centered care; extended reality; empathy; workforce; long-term care; Alzheimer disease

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Introduction

Dementia is one of the most pressing global public health issues, affecting an estimated 55.2 million people worldwide [1]. Impaired cognitive functioning is one of the major contributing factors leading to nursing home placement among older adults worldwide [2], and the prevalence rate of persons with cognitive impairment in nursing homes was 21.2% in 2022 [3]. In the United States alone, this translates to approximately 3 million persons living with dementia currently residing in nursing homes, a number expected to increase with population aging and rise in dementia prevalence [4].

The quality of care is contingent upon the direct care staff. This was underscored by the Biden administration's passage of a law in 2022 to improve nursing home care by increasing staffing levels [5], although the policy was repealed under the Trump administration in 2025 [6]. While the direct relationship between staffing levels and a nursing home's quality of care is under-studied [7], existing evidence constantly demonstrates that nursing staff are critical to the delivery of high-quality care [8]. Specifically with care for persons living with dementia, the skills and attitudes of direct care staff are central to maintaining their quality of life [9,10]. Recent work by Mukamel et al [4] further suggests that nursing homes with specialized care in dementia provide better care for their residents living with dementia, highlighting that targeted resources and staffing focused on dementia care are effective.

Despite their central role, the vast majority of nursing home staff work under challenging conditions in which they navigate communication barriers, behavioral and psychological symptoms of dementia (BPSD), and the emotional demands of providing care [11]. These stressors contribute to staff stress and burnout [11-15] and are among the leading causes of high turnover rates in nursing homes [16,17]. Workforce instability, in turn, undermines continuity of care and limits opportunities for skill training and development.

A recent study on staff in dementia care facilities reported that in-service training focusing on capacity building has been shown to improve staff attitudes, knowledge, and competence while potentially mitigating job stress [18]. Evidence on BPSD-specific training has demonstrated the value of structured, skill-based approaches that can be integrated into demanding work routines [19]. However, high-quality dementia care extends beyond task competence. It requires the ability to connect, communicate, and build relationships grounded in empathy and trust [20,21]. Traditional dementia training, whether it is delivered in classrooms, via printed materials, or through online modules, often falls short in fostering such relational and empathetic skills [22]. Moreover, existing trainings have often been found to have limited impact on relational skills and sustained behavior change [23,24]. Other common limitations of traditional training include a lack of immersive, experiential learning; minimal adaptation to linguistic and cultural diversity; and insufficient reinforcement for long-term knowledge retention [24-27].

In response to the need for more empathic approaches to care, the health care field has increasingly adopted relationship-centered care. This approach grew out of a research program and agenda to encourage the development or expansion of educational programs that reflect an integrated biomedical-psychosocial perspective—an integrated approach to patient care [28]. Research has shown that empathy among medical students and residents often declines over time as they progress through medical training, particularly in the context of time pressure, heavy workloads, and emotional fatigue [29]. Relationship-centered care was introduced as a corrective framework that builds on understanding the centrality of relationships, recognizing that both patients and physicians in the care relationship matter. In dementia care, relationship-centered care emphasizes the importance of building long-lasting strong, trusting relationships between persons living with dementia and care workers. These personal connections allow residents to feel more valued and understood, which can significantly enhance their emotional well-being and overall satisfaction with care [30].

Relationship-centered care is conceptually distinct from the well-known concept of person-centered care because person-centered care does not always emphasize the importance of human connection and personhood in relationships [29]. Training in relationship-centered care positions empathy, trust, and nuanced moment-to-moment communication as central to dementia care training, such as through eye contact, appropriate touch, and adaptive speech. Training in empathy and empathetic communication has been shown to significantly improve participant empathy, attitudes toward patients with dementia, and certain verbal and nonverbal communication skills [31]. There is also strong evidence that empathetic communication training led staff to have enhanced positive behavior and satisfying interactions with persons living with dementia [32].

Furthermore, there is growing evidence suggesting that multimodal training aligned with relationship-centered care principles can enhance care processes, suggesting that experiential and skill-focused education is an important complement to didactic content [33]. In particular, training with in-person feedback and guided reflection have enhanced the attained skills [32]. Debriefing sessions in simulated training for health care professionals have proved effective in both technical and nontechnical skills [34]. Guided group discussions after training for medical trainees have been found to form professional identity and create professional socialization [35].

Simulation-based education is widely recognized for improving communication and empathy in health care [36]. Virtual reality (VR), in particular, allows learners to "step into the shoes" of persons living with dementia and experience their cognitive, sensory, and emotional challenges. Research suggests that VR can enhance empathy, dementia knowledge, and reflective practice [37,38], although its effectiveness may vary by staff characteristics such as age and primary language [39]. Despite its promise, most VR interventions have been implemented with students or informal caregivers, not with nursing home direct care staff, who provide most hands-on dementia care. Barriers such as cost, equipment needs, and staffing constraints have limited access to such training in long-term care settings [40,41].

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Recent advances have strengthened the feasibility of VR simulation-based learning, which immerses participants in the lived experience of persons living with dementia. A dementia-focused review by Huang et al [37] found that VR can improve empathy, knowledge, and reflective practice, although challenges such as simulation sickness and equipment comfort must be addressed in nursing home contexts. A broader meta-analysis in health care education indicates that VR can outperform non-VR methods in improving knowledge, skills, and learner satisfaction [38]. Microlearning formats, which are short, focused VR modules, have been linked to higher engagement and retention [42]. Similarly, just-in-time simulation supports targeted learning refreshers close to the point of care [43], aligning with this study's monthly VR-plus-discussion structure.

Despite growing interest in the use of VR in dementia care training, several critical gaps exist in the literature. First, prior VR-based dementia training studies have mostly focused on students, family caregivers, or health care professionals outside of long-term care, with limited attention given to direct care staff [37]. This omission is clearly consequential, as direct care staff in nursing homes are the ones who deliver most hands-on support to residents living with dementia. By focusing on this workforce, this study addresses a critical gap in the literature and responds to a population with unique training needs and operational constraints. Moreover, their training opportunities are restricted by time, staffing shortages, deprioritization of dementia education, and chronic underfunding for direct care staff, underscoring the need for empirically tested, accessible, and practice-relevant interventions that meet the needs of this workforce.

Second, few prior interventions have taken a fully integrated approach to learning. There are studies that have offered online education or stand-alone VR experiences, but few studies have examined the effects of VR when embedded into comprehensive training that integrates cognitive learning with simulated experience and reflective processing [42,43]. The absence of such a learning model limits the understanding of how VR can impact direct care workers' approach to care for persons living with dementia. Specifically, there is a lack of data on how VR effects changes in knowledge acquisition on dementia care, promotes empathy, and encourages translation of relationship-centered care skills into daily practice.

Third, while empathy is often discussed as a key outcome of dementia training, it is not consistently measured alongside factual knowledge gains. Many studies assess empathy or attitudes in isolation, making it difficult to determine whether VR-based training simultaneously strengthens affective capacities (eg, empathic perspective taking) and cognitive competencies (eg, understanding effective communication approaches for persons living with dementia). This lack of dual-outcome assessment constrains conclusions about the comprehensive educational value of VR interventions [24,27,37,38].

To address these gaps, this study aimed to evaluate a multimodal dementia care training that integrated relationship-centered care–based online modules, immersive VR simulations, and facilitated group reflection specifically targeting direct care workers in nursing homes. This study tested whether VR-enhanced training produced improvements in primary outcomes—empathy and communication knowledge. This design allows for hypothesis-driven examination of VR's potential role as a mechanism for increasing empathic understanding and strengthening dementia-specific communication knowledge among direct care staff working with persons living with dementia. The paucity of reporting guidelines on VR led us to use the reporting guidelines by Vlake et al [44] on early clinical evaluation on the use of extended reality, which encompasses VR, mixed reality, and augmented reality, to report our study (Multimedia Appendix 1).

Methods

Overview

This mixed methods pilot study used a pretest-posttest design to evaluate a 3-month dementia training program for nursing home direct care staff. The quantitative component measured changes in empathy and dementia communication knowledge before and after the intervention. The qualitative component consisted of focus group interviews conducted at posttest to explore participants' perceptions of the program's content, delivery, and relevance to their work.

Recruitment

The study was conducted in a nursing home located in northern Virginia. Conducting studies in nursing homes, especially the entry phase of recruitment, has been documented as difficult due to organizational, administrative, and staff barriers [45]. Specifically, clear support from top management, ability to coordinate shifts with colleagues, and maneuvering high workload and turnover rates have been reported as important conditions for successful research [46]. Hence, this study used a nonprobability, convenience sampling approach. Recruitment was conducted through public posting and distribution of flyers that included the study description and inclusion criteria. Eligible participants were staff who (1) worked in direct care roles, (2) could communicate in English, and (3) were willing to complete all components of the training and data collection. There were no formal screening procedures used. With permission from the nursing home administrative team, flyers created by the investigators were distributed to the nursing home's direct care staff. Interested staff members volunteered to participate in the study. Administrative staff also helped with recruitment by speaking directly to care staff and encouraging participation. Recruitment was coordinated through facility administrators. In particular, developing a trusting personal contact with one of the key administrators was very helpful to manage the recruitment process [45].

Intervention

The training program was conducted by the principal investigator and coinvestigator once a month over the course of 3 months from March to May 2025 using a combination of the 3 complementary learning formats described below. This multimodal approach was designed to layer conceptual

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understanding (online module), experiential insight (VR), and application (group discussion).

Online Module (Monthly)

Three online modules were created by the investigators using Microsoft PowerPoint slides and narrated and recorded using Zoom (Zoom Video Communications). These videos were then uploaded to the YouTube channel. They were made available through a handout with QR codes linked to the YouTube videos. Self-paced content covered relationship-centered care principles, effective communication strategies (eg, posture, eye contact, touch, and adapted speech), and approaches to BPSD management.

VR Simulation (Monthly)

The simulation was delivered during in-person sessions using Jolly Good Inc's dementia care VR platform [47]. Our VR content focused on the use of real actors, whereas many of the VR simulation trainings in dementia use avatars. Past research findings suggest that older adults are less likely to connect with avatars, thus making their VR experience less effective [48,49]. The VR videos were recorded in Japan using Japanese actors. Three scenarios placed participants in the perspective of a person living with dementia. The first scenario simulated visual hallucinations, a symptom observed in persons with moderate to severe Lewy body dementia. The second simulated paranoia and object misrecognition, symptoms observed in persons with moderate to severe dementia. In the final scenario, the VR video alternated between 2 perspectives: an aide providing care and a resident living with dementia who was experiencing confusion. It highlighted how the same interaction can feel from each viewpoint.

Facilitated 60-Minute Group Discussion (Monthly)

Immediately following each VR session, the principal investigator guided debriefing on the VR experience, checked for cybersickness, encouraged peer sharing of strategies, and linked learning to everyday practice.

Measures

Pre- and posttest outcomes were measured using 2 standardized tests. Empathy was assessed using the 10-item Jefferson Scale of Empathy–Healthcare Provider Version [50], which uses a 7-point Likert scale (1="strongly disagree"; 7="strongly agree"). Items reflecting a lack of empathy were reverse scored. Higher scores indicated greater empathy. Dementia communication knowledge [51] was measured using a 10-item multiple-choice test focusing on effective communication techniques with persons living with dementia. Scores reflected the number of correct responses. We also collected participants' demographics, including age, gender, race and ethnicity, language spoken at home, years of experience in direct care, work status, and personal experiences with persons living with dementia. Additionally, we conducted focus group interviews with open-ended questions exploring learning experiences, perceived applicability, and perceived changes in attitudes or behaviors. Three open-ended questions were posed: (1) "How was the overall training?" (2) "What did you think about the VR experience?" (3) "What did you think about the online videos?"

Procedures

Baseline surveys were conducted in February 2025. Training sessions took place monthly from March 2025 to May 2025, with each month's in-person session including VR and discussion. Postintervention surveys and focus groups were completed in May 2025. These sessions were all conducted before or after the participants' work shifts. Jolly Good Inc provided the VR headsets, software, and on-site technical support.

Ethical Considerations

The study protocol was determined to be exempt from in George Mason University's Institutional Review Board (STUDY00000298). However, we collected informed consent from our participants, which delineated their rights to terminate participation at any time and to be protected in terms of privacy and confidentiality. Participation was voluntary, and all data were deidentified prior to analysis. All participants received a US $100 addition to their salaries at the start of the training and a US $100 gift card upon completion of the training.

Analysis

Quantitative analyses were performed in the SPSS statistical software (IBM Corp). Paired-sample 2-tailed *t* tests were conducted to compare pre- and postintervention empathy and knowledge scores for participants who completed both assessments. Effect sizes were calculated using the Cohen *d*.

After the intervention, qualitative focus group interviews were conducted, videotaped, transcribed verbatim, and analyzed using thematic analysis to identify patterns related to perceived learning, feasibility, and practical application. The initial analysis was conducted by the principal investigator, and the results were then discussed and validated by the team of investigators through team discussion meetings. Data from both strands of the study were integrated during interpretation to provide a comprehensive understanding of program outcomes.

Results

Descriptive Results: Demographics

A detailed demographic profile of the participants is provided in Table 1. The study included 21 participants, with 76.2% (16/21) completing both pre- and postassessments. Participants' mean age was 45.8 (SD 15.0) years for the full sample and 45.7 (SD 16.3) years for the complete-case subset. Most participants were female (19/21, 90.5% in the full sample; 15/16, 93.8% in the complete-case subset) and identified as Black or African American (20/21, 95.2% in the full sample; 15/16, 93.8% in the complete-case subset). Nearly half (10/21, 47.6%) of the full sample reported more than 16 years of experience in dementia care, with a similar distribution in the matched subset (7/16, 43.8%). Informal or on-the-job dementia training was the most common form of prior training (15/21, 71.4% in the full sample; 11/16, 68.8% in the complete-case subset). Primary work shifts were split between day (8/21, 38.1%) and evening (13/21, 61.9%) in the full sample, whereas the complete-case subset predominantly worked day shifts (11/16, 68.8%). Regarding the number of residents living with dementia in their care, the

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full sample reported that 28.6% (6/21) cared for 1 to 3 residents, 14.3% (3/21) cared for 4 to 6 residents, 52.4% (11/21) cared for 7 to 10 residents, and 4.8% (1/21) cared for more than 10 residents. The complete-case subset had a similar distribution. Most participants (18/21, 85.7% in the full sample; 14/16, 87.5% in the complete-case subset) spoke English at home, but it was an African dialect, not American English. Over one-third (7/21, 33.3% in the full sample; 5/16, 31.3% in the complete-case subset) reported a personal connection to dementia.

Table . Demographic profile of the participants who responded to the preintervention survey (entire sample) and both the pre- and postintervention surveys (paired sample=37).

Characteristic	Entire sample (n=21)	Paired sample (n=16)
Age (years), mean (SD)	45.8 (14.98)	45.67 (16.33)
Gender, n (%)		
Women	19 (90.5)	15 (93.8)
Men	2 (9.5)	1 (6.3)
Race, n (%)		
Black or African American	20 (95.2)	15 (93.8)
Hispanic or Latinx	1 (4.8)	1 (6.3)
Experience (years), n (%)		
1-3	3 (14.3)	3 (18.8)
4-7	2 (9.5)	2 (12.5)
8-15	6 (28.6)	4 (25.0)
≥16	10 (47.6)	7 (43.8)
Previous dementia training, n (%)		
Formal	3 (14.3)	2 (12.5)
Informal	15 (71.4)	11 (68.8)
None	3 (14.3)	3 (18.8)
Primary shift, n (%)		
Day	8 (38.1)	11 (68.8)
Evening	13 (61.9)	5 (31.3)
Residents with dementia in their care per shift, n (%)		
1-3	6 (28.6)	5 (31.3)
4-6	3 (14.3)	2 (12.5)
7-10	11 (52.4)	8 (50.0)
>10	1 (4.8)	1 (6.3)
Primary language spoken at home, n (%)		
English	18 (85.7)	14 (87.5)
Spanish	1 (4.8)	1 (6.3)
Other	2 (9.5)	1 (6.3)
Personal connection to dementia, n (%)		
Yes	7 (33.3)	5 (31.3)
No	14 (66.7)	11 (68.8)

Bivariate Results

Table 2 reports the standardized test scores. For the paired-sample *t* tests, 16 participants who completed both the pre- and postassessments were included. Empathy was assessed using a 10-item composite scale, including 4 reverse-scored items with higher values indicating greater empathy. The results showed a slight increase in empathy from pretest (mean 5.31, SD 0.74) to posttest (mean 5.51, SD 0.61). The mean difference was 0.20 (SD 0.43) points, with a 95% CI for the mean difference of −0.03 to 0.43. This change did not reach statistical significance (t_{15}=1.88; *P*=.08), although the corresponding effect size was in the small to moderate range (Cohen *d*=0.47).

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Table . Empathy and dementia knowledge test results of the paired sample of participants (n=16)[a].

Measure	Before, mean (SD)	After, mean (SD)	*t* test (*df*)	*P* value	Cohen *d*
Empathy (1-7)	5.31 (0.74)	5.51 (0.61)	1.88 (15)	.08	0.47
Knowledge (1-10)	5.50 (2.37)	5.94 (2.11)	1.07 (15)	.30	0.27

[a]*P* values are 2 tailed. Cohen *d* values for paired-sample *t* tests are calculated using the SD of the pretest scores. “Paired” refers to participants who completed both the pre- and posttests.

Dementia knowledge was assessed using 10 items, with correct responses scored as 1 and incorrect responses scored as 0, yielding a total score ranging from 0 to 10. Knowledge scores increased from pretest (mean 5.50, SD 2.37) to posttest (mean 5.94, SD 2.11). The mean difference of 0.44 (SD 1.63) points, with a 95% CI of −0.43 to 1.31, was not statistically significant (t_{15}=1.07; *P*=.30). The associated effect size was small (Cohen *d*=0.27).

Qualitative Results

Thematic analysis identified three main themes: (1) reframing dementia, (2) growing empathy and understanding, and (3) preferred training formats.

Reframing Dementia

Participants described a shift in how they perceived dementia, moving away from viewing it as a problem or a source of shame toward a more compassionate perspective. For some, this shift involved recognizing that dementia is not a personal failing but a condition requiring understanding:

> *This training let me see a more positive and compassionate attitude towards persons with dementia. It reduced the stigma [of dementia]...like something to look down upon. I have more empathy [after the training].*

Others noted that the training challenged their assumptions and helped normalize dementia as part of aging rather than something to be feared or hidden.

Growing Empathy and Understanding

The VR experience prompted participants to think differently about their residents, fostering a deeper sense of empathy. Some reflected on how the training helped them better understand the behaviors of persons living with dementia:

> *I always wanted persons with dementia to be a little bit nice to me. But now I know why they are who they are.... I think about them more.*

One participant summed up their overall experience:

> *We learned a lot from it. I see everything good, I understand everything good.*

Preferred Training Formats

Although most participants admitted that they did not watch the online modules as requested, they expressed a clear preference for training that included immersive VR and facilitated group discussions. They emphasized that the in-person, experiential format was more engaging and memorable than the online content alone.

Interestingly, despite the VR videos being dramatized in Japanese settings, participants reported that the cultural context did not limit their learning. The symptoms and scenarios depicted were perceived as universally relevant:

> *I see the same symptoms and problems.*

Discussion

Principal Findings

This pilot study explored the effect of the integration of relationship-centered care training with immersive learning on direct care staff’s empathy and dementia knowledge. The study participants were predominantly female, Black care workers with over 16 years of experience in the field. Many learned about dementia primarily through informal, on-the-job training. They cared for multiple persons living with dementia per shift, reflecting the high emotional and physical demands typical of their roles.

As a pilot study, this investigation was designed to assess feasibility and generate preliminary estimates of intervention effects rather than test definitive hypotheses. Accordingly, the sample size (n=16) provided sufficient power to detect only large within-person effects, and the absence of statistically significant changes in empathy and dementia knowledge outcomes was anticipated. Therefore, emphasis is placed on effect size estimation and CIs to inform the design of a future adequately powered study.

While the overall changes in empathy and knowledge did not reach statistical significance, both moved in the expected positive direction. The small to moderate effect size for empathy (Cohen *d*=0.47) suggests that there may be meaningful benefits even within the short time frame of this intervention. This aligns with findings from relationship-centered care programs that foster personhood and potentially boost self-efficacy [52,53].

The qualitative findings complement the quantitative results by providing context for the small but positive changes observed in empathy and knowledge scores. Participants described the VR training as reframing their perceptions of dementia; reducing stigma; and prompting more compassionate, person-centered perspectives. Many favored interactive, immersive formats over online modules. Emotional learning appeared to be a particular strength of the VR component even though the scenarios were set in an Asian cultural context.

The knowledge effect (Cohen *d*=0.27) was more modest, which mirrored the observation by Stafford et al [54] that VR can be engaging but not always more effective than traditional dementia training. Given that most participants spoke African dialects of English and had limited baseline knowledge of dementia,

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traditional mainstream, web-based training methods or handouts and content written or explained in formal English may be less effective. A combination of visual learning using VR and more time spent on explaining dementia knowledge in simple English during group sessions may improve comprehension and retention.

The modest improvement observed in dementia communication knowledge (Cohen *d*=0.27) should also be interpreted in light of the qualitative findings. Several participants reported that they did not complete the online modules as intended and, instead, relied primarily on the in-person VR and facilitated discussion sessions. Therefore, limited engagement with the asynchronous modules may partially explain the small knowledge effect size observed in the quantitative analysis. This finding highlights an important structural challenge in dementia workforce training. Although online modules are often used to increase accessibility, direct care staff in long-term care settings often have limited time during work hours to access and complete them as intended. Participants indicated that training was most feasible when administrators allowed them to attend sessions during paid work time. Taken together, these mixed methods findings suggest that while immersive VR and facilitated discussion may promote emotional learning and engagement, knowledge acquisition through online modules may require stronger organizational support and protected training time to ensure consistent participation and successful attainment of training objectives.

The findings also speak about broader workforce development needs. This was an experienced, committed workforce, yet access to formal training opportunities remained limited. For certified nurse assistants, training was often feasible if administrators freed them from floor duties during work hours. Appropriate time and space for structured, evidence-based education can strengthen both empathy and knowledge outcomes. Past literature also points to stronger benefits when coupled with sustained practice and reinforcement [55]. Future programs might consider extending the duration, incorporating booster sessions, and embedding other scenarios.

Limitations

There are several study limitations. First, the training was implemented in 1 setting with a fairly homogenous workforce, which limits generalizability. Second, due to the small sample size, statistical power was limited. Participation may have been hindered by the nursing home's initial decision not to offer direct incentives; recruitment improved once gift cards were introduced. More visible and systemic incentives should be adopted to encourage participation in training for direct care staff. Third, given that many participants began the training with relatively high empathy scores, the potential for a ceiling effect should be considered. The smaller gains in dementia knowledge may be due to the variability in baseline knowledge and the need for repeated reinforcement to consolidate new information. Nevertheless, the positive direction of change and the strong engagement from participants point to the promise of this approach.

Conclusions

Although this was a small pilot study, the combination of immersive VR and relationship-centered care content shows potential as part of a larger, sustained training strategy. Future work should address VR accessibility and affordability for direct care staff training for those who will benefit the most. Larger studies with more diverse samples and longer follow-up periods are needed to see whether these early gains translate into lasting changes in attitudes, communication, and care practices.

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Data Availability

The datasets generated or analyzed during this study are available from the corresponding author on reasonable request.

Authors' Contributions

LMC conceptualized the study, secured institutional approvals, designed the intervention, and led data collection. LMC also conducted the quantitative and qualitative analyses, interpreted the findings, and drafted the original manuscript. MI contributed to intervention implementation, supported participant recruitment and data collection, and provided substantive input on the interpretation of the results. Both authors contributed to manuscript revisions, approved the final version, and agree to be accountable for all aspects of the work.

Conflicts of Interest

None declared.

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Multimedia Appendix 1
RATE-XR (Reporting for the Early-Phase Clinical Evaluation of Applications Using Extended Reality) checklist.
[DOCX File, 24 KB - formative_v10i1e86672_app1.docx]

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Abbreviations

BPSD: behavioral and psychological symptoms of dementia
VR: virtual reality

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Comparing Perceptions of ChatGPT Use in Health Attitude Contexts Among Users and Nonusers: Cross-Sectional Study

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Abstract

Background: In light of the growing use of artificial intelligence (AI) in health care, individuals' access to and use of health information are transforming. ChatGPT, an AI chatbot, provides immediate responses to health queries, with the potential to influence health-related attitudes, thereby raising concerns related to privacy, reliability, and security.

Objective: This study aimed to investigate the perceived usefulness, risks, anxiety, and social influence of ChatGPT on health attitudes among users and nonusers in Saudi Arabia.

Methods: A cross-sectional study was conducted using an online survey based on a validated tool. In total, 337 participants aged 18 years and older responded to questions assessing their perceptions of ChatGPT on health-related attitudes.

Results: Data showed that 76.1% (194/255) of the respondents used ChatGPT, with the majority being younger and more highly educated. The main uses for health-related purposes were health education (43/194, 22.2%) and physical activity guidance (31/194, 16%). The analysis showed that users considered ChatGPT useful for health-related decisions, with 45.9% (89/194) finding it easy to learn and use, but concerns about privacy (106/194, 54.7%) and reliability (87/194, 44.9%) remained. Among nonusers, security risks (39/61, 63.9%) were the major barrier to using AI-based tools for health purposes, and 68.9% (42/61) found such tools attractive and engaging. There were no statistically significant differences between users and nonusers across all examined sociodemographic characteristics (P>.05).

Conclusions: The study established the potential of ChatGPT in improving health decision-making and revealed cultural, privacy, and trust issues that may affect its implementation. These findings underscore the importance of strengthening the security of AI-based applications to enhance public acceptability of related health policies and to support the safe integration of tools such as ChatGPT into the health care system.

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KEYWORDS

artificial intelligence; AI; ChatGPT; health attitude; health informatics; Saudi Arabia

Introduction

Over recent years, artificial intelligence (AI) has revealed significant potential in health care, particularly in education, research, decision-making, and teleconsultation [1,2]. The paradigm shift associated with this technology suggests that AI can address highly challenging problems and draw from enormous volumes of health-related information [3]. There have been affirmative advancements in interventions, public health screening, and program design, enhancing its use and promising to lead to more efficient health care systems [4,5].

One advanced AI tool is ChatGPT, a conversational agent developed by OpenAI, designed using natural language processing to deliver human-like conversational responses [6]. After its launch in late 2022, ChatGPT has been widely used, with 1 million users in the first week and 100 million in January 2023 [7]. The use of ChatGPT in health care practice has revealed approximately 70% clinical decision-making accuracy [8,9]. ChatGPT supports symptom screening, health optimization, resource use, and reduction of the load on the health care workforce [6,10].

Previous investigations have demonstrated that AI-generated tools can shape health behaviors and health care services [1]. According to a study conducted in the United Arab Emirates, positive attitudes toward ChatGPT were linked with lower perceived risks, lower anxiety, and higher scores in attitudes

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toward technology and social influence. Furthermore, a positive attitude was associated with Arab nationality and male sex [11]. Nonetheless, in Taiwan, use of ChatGPT was lower among individuals without prior experience with an AI tool but higher among male participants and those with higher educational attainment [12]. However, in Jordan, the investigation highlighted the need to consider perceptions of risk, usefulness, ease of use, and attitudes toward technology [13].

More than 23 million people across Europe use technology to make health-related decisions, and most use health applications [14]. In Saudi Arabia, AI implementation in health care, used through telemedicine and other online health applications, reveals a new trend toward the use of technology within the Saudi health system [15,16].

Although the adaptation of clinical procedures and productivity may benefit from the use of ChatGPT [6,17], additional research is required to investigate the health attitudes across Saudi Arabia to capture the cultural, linguistic, and privacy-related concerns [18,19].

The aim of this study was to compare perceptions of ChatGPT use by examining its perceived usefulness, associated risks, anxiety levels, and social influence on health attitudes among users and nonusers.

Methods

Research Design and Setting

This analytical cross-sectional study was conducted in Saudi Arabia to compare perceptions of ChatGPT, including perceived usefulness, perceived risk, anxiety, and social influence, on health attitudes among ChatGPT users and nonusers.

Study Population and Sample Size Calculation

In total, 337 participants aged 18 years or older, residing in Saudi Arabia and having internet access, were recruited through an online survey. The single-population proportion formula was used to determine the required sample size, with a 95% CI (Z) and a 5% margin of error (E). After reviewing the existing literature to determine the smallest sample size (p), we found a study that reported a positive health care–related view of ChatGPT prevalence of approximately 70% [20]. Using the following formula, the minimum required sample size was calculated to be 323:

$$n = (Z^2) \times p \times (1 - p)$$

$$E^2 = (1.96)^2 \times 0.70 \times (1-0.70)(0.05)^2 \approx 323.$$

The sample size was chosen to estimate the overall prevalence and characteristics of ChatGPT use within the target population, rather than to aim for an equal number of users and nonusers. In this study, the participants were classified into two groups: (1) ChatGPT users, defined as respondents who reported having used ChatGPT, and (2) ChatGPT nonusers, defined as respondents who had not used ChatGPT but were aware of and familiar with it (eg, through media exposure, discussions in academic classes, or peers). This approach ensured that all participants included in the analysis had sufficient awareness of ChatGPT to provide meaningful responses.

The inclusion criteria were participants aged 18 years or older, living in Saudi Arabia, and having access to the internet. Participants who reported no awareness or familiarity with ChatGPT were excluded from the analysis. This classification resulted in an analytic sample of 255 participants (n=194, 76.1% users and n=61, 23.9% nonusers).

Study Instruments

The questionnaire used in this study was adapted from a previously validated instrument based on a modified TAME-ChatGPT (Technology Acceptance Model Edited to Assess ChatGPT Adoption), which demonstrated acceptable reliability in prior studies (Cronbach $\alpha \geq 0.71$) [21]. In this study, the adapted questionnaire was pilot-tested to assess clarity and comprehension before deployment, as shown in Multimedia Appendix 1.

The survey measured ChatGPT perception on four constructs that corresponded to the research aim: (1) perceived usefulness, which reflects participants' beliefs that ChatGPT is useful for accessing and supporting health-related information; (2) perceived risk, which includes threats related to privacy, security, and reliability when accessing and supporting health-related information; (3) anxiety, which refers to fear or worry about using ChatGPT for health-related purposes; and (4) social influence, which captures the perceived influence of peers or family on participants' readiness or recommendation to use the tool.

All items were evaluated using a 5-point Likert scale (from "strongly disagree" to "strongly agree"), with higher summed scores of relevant items indicating greater support for the construct.

Sociodemographic information and health-related characteristics were also collected in the questionnaire, considering the status of ChatGPT users and nonusers who were aware of ChatGPT but had not used it. This method enabled comparison of perceptions and attitudes toward ChatGPT between user and nonuser groups in the context of health-related decision-making.

Study Techniques, Duration, and Setting

Data collection was conducted from mid-November 2023 to February 2024 using a convenience sampling technique. Participants were recruited via official university email systems and social media platforms. Email invitations were distributed across Imam Abdulrahman bin Faisal University (Eastern province), Umm Al-Qura University (Makkah province), Shaqra University, and Prince Sultan University (Riyadh province) to capture diverse geographic locations and perspectives. Additional invitations were shared via Telegram (12.6.2) and WhatsApp (version ; Meta Platforms Inc) groups.

Statistical Analysis

In this study, SPSS (version 23.0; IBM Corp) was used for all data analysis. Descriptive statistics, including frequencies, percentages, means, and SD, were used to summarize the characteristics of participants and the overall scores of perception. Additionally, the χ^2 test was used to evaluate relationships between ChatGPT use status (users vs nonusers) and sociodemographic variables. Furthermore, factor scores

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were summarized using descriptive statistics, including means (SDs), medians (IQRs), and ranges, to describe the central tendency and dispersion of responses, as the primary goal was to characterize the distribution of perceptions across factors. Both mean (SD) and median (IQR) were reported for all perception factor scores to consistently summarize central tendency and dispersion and to provide a complete description of their distribution, regardless of normal distribution. The level of statistical significance was set at $P \leq .05$.

Ethical Considerations

The institutional review board of Imam Abdulrahman bin Faisal University granted ethics approval (IRB-HAP-05-D-003) for this study. All participants provided informal consent before completing the survey. Participant privacy and confidentiality were maintained, with all data anonymized and access restricted to the research team. No financial compensation was provided to participants.

Results

Among the analytic sample of 255 participants, 194 (76.1%) were ChatGPT users and 61 (23.9%) were nonusers who were familiar with ChatGPT. Participant sociodemographic characteristics are presented in Table 1. Overall, 89.8% (n=229) were Saudi nationals, and 53.7% (n=137) had a bachelor's degree. The participants' family income varied; approximately half (n=125, 49%) reported earning ≥15,000 SAR 3.75 (US $1.00). Among the participants, 63.5% (n=162) were single, 35.3% (n=90) were married, and 1.2% (n=3) were divorced or widowed. In terms of regions, the majority of participants (n=119, 46.7%) were in the central region, followed by the western (n=65, 25.5%) and eastern regions (n=48, 18.8%), with no substantial difference between the southern (n=11, 4.3%) and the northern (n=12, 4.7%) regions.

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Table . Sociodemographic characteristics of the participants (N=255).

Sociodemographic characteristics	Participants, n (%)
Sex	
Female	166 (65.1)
Male	89 (34.9)
Age group (years)	
18-24	112 (43.9)
25-34	67 (26.3)
35-44	55 (21.6)
≥45	21 (8.2)
Nationality	
Saudi	229 (89.8)
Non-Saudi	26 (10.2)
Educational level	
Elementary and secondary	28 (11.0)
Bachelor’s degree	137 (53.7)
Master’s degree	55 (21.6)
Doctorate	35 (13.7)
Family income (SAR; US $1.00=SAR 3.75)	
<1000	13 (5.1)
1000-2999	11 (4.3)
3000-5999	17 (6.7)
6000-8999	27 (10.6)
9000-11,999	34 (13.3)
12,000-14,999	28 (11.0)
≥15,000	125 (49.0)
Marital status	
Single	162 (63.5)
Married	90 (35.3)
Divorced or widowed	3 (1.2)
Region	
Central	119 (46.7)
Western	65 (25.5)
Eastern	48 (18.8)
Southern	11 (4.3)
Northern	12 (4.7)
Have you used ChatGPT?	
Yes	194 (76.1)
No	61 (23.9)

In total, 194 (76%) participants reported using ChatGPT. When participants were asked about their sources of health information, the majority (n=69, 27%) reported health authorities, whereas only 4% (n=10) reported AI-based sources. Furthermore, personal experience, scientific sources, and medical guidance were reported by 10% (n=36) to 20% (n=48) of participants as sources of health information (Figure 1).

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Figure 1. Source of clinical information.

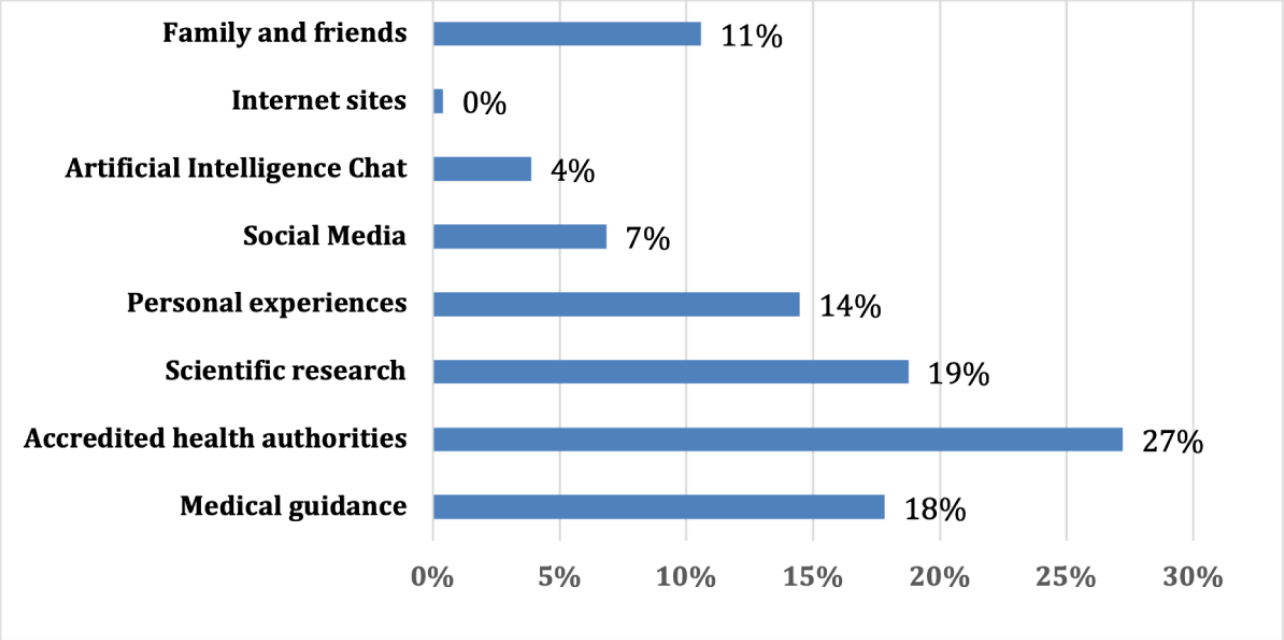
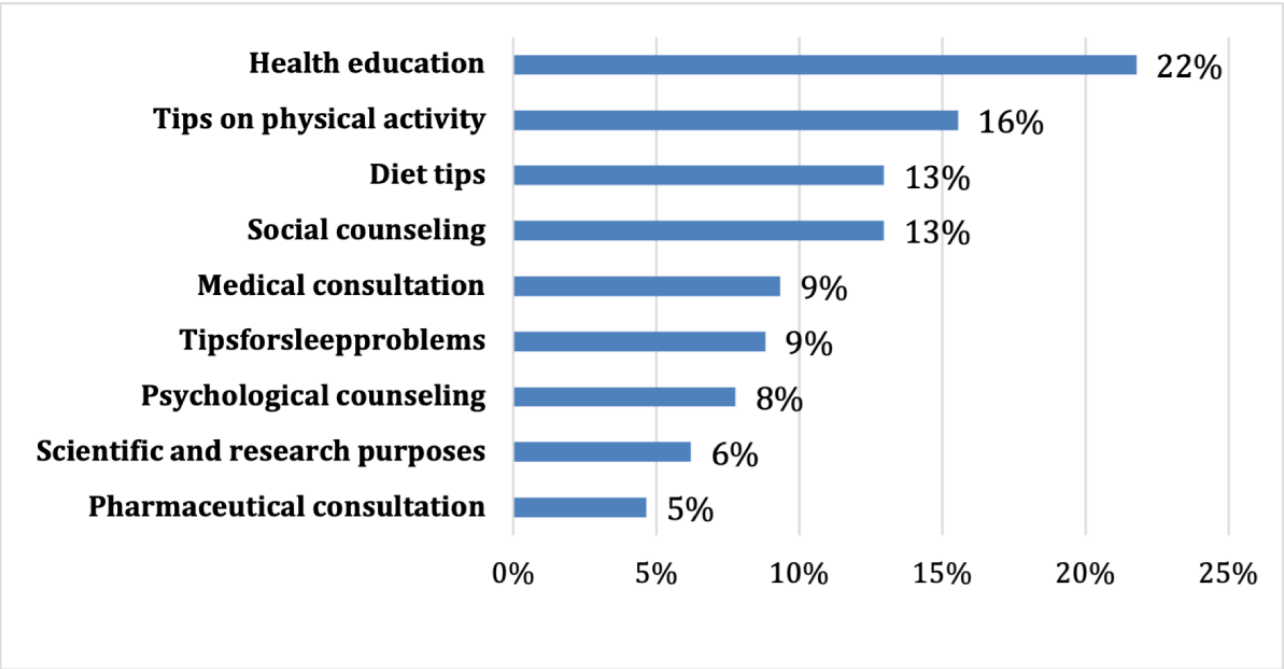


Figure 2 shows that 22.2% (43/194) of ChatGPT users reported using it for health education, followed by 16% (n=31) using it for tips on physical activity. However, use for scientific and research purposes, psychological counseling, tips for sleep problems, and medical consultation ranged from 5% (n=10) to 10% (n=17), while use for diet tips and social counseling ranged from 10% (n=25) to 15% (n=31).

Figure 2. Percentage of ChatGPT users by main health-related purpose.



Female participants represented a higher percentage of ChatGPT users than male participants (127/194, 65.5% vs 67/194, 34.5%, respectively), and participants aged <24 years had the highest use rate (87/194, 44.8%) compared to other age groups (Table 2). Respondents with bachelor's degrees (98/194, 50.5%) reported using ChatGPT more than other degree holders. Moreover, those who were single reported higher use of ChatGPT than those who were married, divorced, or widowed (124/194, 63.9%; 68/194, 35.1%; and 2/194, 1%, respectively). In contrast, unemployed participants (105/194, 54.1%) reported higher use of ChatGPT than employed participants (89/194, 45.9%). However, there were no significant associations between socioeconomic variables and ChatGPT use.

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Table . Comparison of sociodemographic characteristics between ChatGPT users and nonusers (N=255).

Characteristics	User, n (%)	Nonuser, n (%)	χ^2 (*df*)	*P* value
Sex			0.048 (1)	.83
Female	127 (65.5)	39 (63.9)		
Male	67 (34.5)	22 (36.1)		
Age group (years)			0.487 (3)	.92
18-24	87 (44.85)	25 (40.98)		
25-34	50 (25.77)	17 (27.87)		
35-44	42 (21.65)	13 (21.31)		
≥45	15 (7.73)	6 (9.84)		
Educational level			4.355 (3)	.23
Elementary and secondary	21 (10.82)	7 (11.48)		
Bachelor's degree	98 (50.52)	39 (63.93)		
Master's degree	45 (23.20)	10 (16.39)		
Doctorate	30 (15.46)	5 (8.20)		
Marital status			0.179 (2)	.91[a]
Single	124 (63.92)	38 (62.30)		
Married	68 (35.05)	22 (36.06)		
Divorced or widowed	2 (1.03)	1 (1.64)		
Employment status			0.455 (1)	.50
Not employed	105 (54.12)	30 (49.18)		
Employed	89 (45.88)	31 (50.82)		
Family income (Saudi Riyal)			4.309 (6)	.64[a]
<1000	11 (5.67)	2 (3.28)		
1000-2999	8 (4.12)	3 (4.92)		
3000-5999	15 (7.73)	2 (3.28)		
6000-8999	21 (10.83)	6 (9.84)		
9000-11,999	25 (12.89)	9 (14.75)		
12,000-14,999	18 (9.28)	10 (16.39)		
≥15,000	96 (49.48)	29 (47.54)		

[a]Significance level set at $P \leq .05$.

Table 3 shows users' perspectives on using ChatGPT. In total, 83.5% (162/194) of participants reported favorable responses, 11.9% (23/194) reported neutral responses, and 4.6% (9/194) reported unfavorable responses, indicating that ChatGPT is perceived as quick and easy to learn. Furthermore, the results indicate 45.9% (89/194) favorable responses, 30.9% (60/194) neutral responses, and 23.2% (45/194) unfavorable responses, illustrating that a higher proportion believed that ChatGPT is helpful for saving time when searching for health information. In contrast, when recommending ChatGPT to family and colleagues for accessing health information, 26.3% (51/194) of participants reported favorable responses, 27.8% (54/194) reported neutral responses, and 45.9% (89/194) reported unfavorable responses. Moreover, only 20.6% (40/194) favorable responses (50/194, 25.8% neutral and 104/194, 53.6% unfavorable responses) reflect that ChatGPT was perceived as more beneficial than other health information sources. A notable proportion of participants reflected on the accuracy and reliability of the health information provided by ChatGPT, with 25.2% (49/194) reporting favorable responses, 29.9% (58/194) reporting neutral responses, and 44.9% (87/194) reporting unfavorable responses. Nonetheless, participants agreed that security risks (109/194, 56.2% favorable; 33/194, 17% neutral; and 2/194, 26.8% unfavorable responses) and privacy risks were concerns when using ChatGPT (106/194, 54.7% favorable; 44/194, 22.7% neutral; and 44/194, 22.7% unfavorable responses). Furthermore, a certain proportion believed that it could lead to misinformation (68/194, 35.1% favorable; 85/194, 43.8% neutral; and 41/194, 21.2% unfavorable responses), and most users did not automatically use it for medical decisions (32/194, 16.5% favorable; 39/194, 20.1% neutral; and 123/194, 63.4% unfavorable responses). However, most believed that

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ChatGPT cannot reduce their visits to a physician (39/194, 20.1% favorable; 29/194, 14.9% neutral; and 126/194, 65% unfavorable responses).

Table . ChatGPT users' perspective on health-related attitudes[a].

Statements	Strongly disagree, n (%)	Disagree, n (%)	Neutral, n (%)	Agree, n (%)	Strongly agree, n (%)
ChatGPT helps me save time when searching for health information.	19 (9.8)	26 (13.4)	60 (30.9)	51 (26.3)	38 (19.6)
I recommend ChatGPT to my family and colleagues to access health information.	32 (16.5)	57 (29.4)	54 (27.8)	32 (16.5)	19 (9.8)
ChatGPT is more useful than other health information sources I have previously used.	44 (22.7)	60 (30.9)	50 (25.8)	27 (13.9)	13 (6.7)
I appreciate the accuracy and reliability of health information provided by ChatGPT.	36 (18.6)	51 (26.3)	58 (29.9)	42 (21.6)	7 (3.6)
I believe that using ChatGPT can help save the time and effort required to make health decisions.	30 (15.5)	36 (18.6)	48 (24.7)	57 (29.4)	23 (11.9)
I have used tools or techniques similar to ChatGPT in the past.	20 (10.3)	54 (27.8)	29 (14.9)	62 (32.0)	29 (14.9)
I automatically find myself using ChatGPT when I need information to make a health decision.	52 (26.8)	71 (36.6)	39 (20.1)	23 (11.9)	9 (4.6)
I often use ChatGPT as a source of health information.	64 (33.0)	71 (36.6)	27 (13.9)	23 (11.9)	9 (4.6)
Using ChatGPT leads to misleading information.	4 (2.1)	37 (19.1)	85 (43.8)	56 (28.9)	12 (6.2)
I am concerned about the potential security risks of using ChatGPT.	11 (5.7)	41 (21.1)	33 (17.0)	64 (33.0)	45 (23.2)
I believe that relying on technology such as ChatGPT can reduce my visits to a physician.	56 (28.9)	70 (36.1)	29 (14.9)	28 (14.4)	11 (5.7)
It takes a short time to learn how to use ChatGPT.	3 (1.5)	6 (3.1)	23 (11.9)	73 (37.6)	89 (45.9)
There are potential privacy risks associated with using ChatGPT.	8 (4.1)	36 (18.6)	44 (22.7)	70 (36.1)	36 (18.6)

[a]Unfavorable (strongly disagree+disagree), neutral, and favorable (agree+strongly agree) categories are presented for descriptive purposes. Percentages indicate trends and do not imply statistical significance.

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Table 4 presents the perspectives of nonusers on ChatGPT. Concerns included lack of confidence in information reliability (11/61, 18.1% favorable; 23/61, 37.7% neutral; and 27/61, 44.3% unfavorable responses), security risks (39/61, 64% favorable; 14/61, 23% neutral; and 8/61, 13.1% unfavorable responses), privacy risks (36/61, 59% favorable; 19/61, 31.1% neutral; and 6/61, 9.8% unfavorable responses), and misinformation (24/61, 39.4% favorable; 29/61, 47.5% neutral; and 8/61, 13.1% unfavorable responses). Similar to the users, nonusers believed that ChatGPT could not reduce physician visits (23/61, 37.7% favorable; 6/61, 9.8% neutral; and 32/61, 52.4% unfavorable responses) and should not be relied on for making health decisions (11/61, 18% favorable; 8/61, 13.1% neutral; and 42/61, 68.8% unfavorable responses). However, nonusers expressed interest in using ChatGPT to search for health information (30/61, 49.2% favorable; 13/61, 21.3% neutral; and 18/61, 29.5% unfavorable responses) and recognized it as an important tool for accessing such information (23/61, 37.7% favorable; 20/61, 32.8% neutral; and 18/61, 29.5% unfavorable responses). Additionally, they believed that technologies such as ChatGPT are attractive and fun (42/61, 68.9% favorable; 14/61, 23% neutral; and 5/61, 8.2% unfavorable responses) and were willing to learn how to use it (36/61, 59% favorable; 19/61, 31.1% neutral; and 6/61, 9.8% unfavorable responses). Trust in the opinions of family and colleagues plays a role in participants' willingness to adopt ChatGPT, with 44.2% (27/194) reporting favorable responses, 39.3% (24/194) reporting neutral responses, and 16.4% (10/194) reporting unfavorable responses.

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Table . Non-ChatGPT users' perspectives on ChatGPT for health-related attitudes[a].

Statements	Strongly disagree, n (%)	Disagree, n (%)	Neutral, n (%)	Agree, n (%)	Strongly agree, n (%)
I am confident about the reliability of the health information provided by ChatGPT.	13 (21.3)	14 (23)	23 (37.7)	9 (14.8)	2 (3.3)
Using ChatGPT leads to misleading information.	0 (0)	8 (13.1)	29 (47.5)	17 (27.9)	7 (11.5)
There are potential security risks associated with using ChatGPT.	0 (0)	8 (13.1)	14 (23)	30 (49.2)	9 (14.8)
There are potential privacy risks associated with using ChatGPT.	0 (0)	6 (9.8)	19 (31.1)	19 (31.1)	17 (27.9)
Relying on technology such as ChatGPT can reduce my visits to a physician.	13 (21.3)	19 (31.1)	6 (9.8)	19 (31.1)	4 (6.6)
I may rely entirely on technology such as ChatGPT to make my health decisions.	19 (31.1)	23 (37.7)	8 (13.1)	8 (13.1)	3 (4.9)
I am passionate about using technology such as ChatGPT to learn and search for health information.	3 (4.9)	15 (24.6)	13 (21.3)	27 (44.3)	3 (4.9)
I believe that technology such as ChatGPT is an important tool for accessing health information.	7 (11.5)	11 (18)	20 (32.8)	20 (32.8)	3 (4.9)
I think that technology such as ChatGPT is attractive and fun to use.	0 (0)	5 (8.2)	14 (23.0)	35 (57.4)	7 (11.5)
I am always keen to learn about new technologies such as ChatGPT.	0 (0)	6 (9.8)	19 (31.1)	29 (47.5)	7 11.5
I trust the opinions of my family or colleagues about using ChatGPT.	1 (1.6)	9 (14.8)	24 (39.3)	21 (34.4)	6 (9.8)

[a]Unfavorable (strongly disagree+disagree), neutral, and favorable (agree+strongly agree) categories are presented for descriptive purposes. Percentages indicate trends and do not imply statistical significance.

Table 5 presents participants' perceptions regarding ChatGPT use across the main constructs. ChatGPT users (n=194) reported their scores on perceived usefulness, behavioral cognitive aspects, perceived risk of use, and perceived ease of use. The levels of perceived risk, anxiety, and technology or social influence were reported in nonusers who were knowledgeable about ChatGPT (n=61). Overall, participants reported moderate perceived usefulness (mean 7.2, SD 3.9), indicating general agreement that the technology is beneficial. However, ease of use was rated lower (mean 5.3, SD 1.5), suggesting that while some found the system accessible, others faced usability challenges. Perceived risk was notably high (mean 8.4, SD 3.0), and anxiety associated with ChatGPT use was also present (mean 2.9, SD 2.1), indicating potential hesitancy or concerns regarding the technology. Interestingly, responses from participants who reported unfamiliarity with ChatGPT (n=61) showed an even higher perceived risk (mean 9.4, SD 2.1), reinforcing the idea that unfamiliarity contributes to skepticism. The role of technology and social influence emerged as a positive factor (mean 11.9, SD 3.2), suggesting that external influences, such as peer recommendations or societal trends, play a significant role in shaping perceptions toward ChatGPT.

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Similarly, behavioral cognitive factors showed moderate endorsement (mean 4.6, SD 2.6), indicating variability in participants' attitudes toward adoption.

Table . Participants' perceptions regarding the use of ChatGPT across various factors[a].

Measures	Users				Nonusers		
	Perceived usefulness	Behavioral cognitive factor	Perceived risk of use	Perceived ease of use	Perceived risk	Anxiety	Technology or social influence
Mean (SD)	7.2 (3.9)	4.6 (2.6)	8.4 (3.0)	5.3 (1.5)	9.4 (2.1)	2.9 (2.1)	11.9 (3.2)
Median (IQR)	7.5 (4-10)	5.0 (3-6)	8.0 (6-10)	5.0 (4-6)	9.0 (8-11)	3.0 (1-4)	12.0 (10-14)
Range	0-16	0-12	2-16	0-8	3-14	0-8	2-20

[a]Factor scores were calculated by summing participants' responses to all items within each factor. Items were rated on a 5-point Likert scale (0=strongly disagree to 4=strongly agree). Total scores for each factor were then used to compute descriptive statistics, including mean (SD), median (IQR), and range. Sample sizes were n=194 for users and n=61 for nonusers of ChatGPT.

Discussion

Principal Findings

This study analyzed views on ChatGPT as a health information–seeking tool among users and nonusers in Saudi Arabia. The findings indicate that most participants reported traditional health authorities as their most frequently cited sources of health information. The use of ChatGPT differed across participants, with some reporting its use for health education and others for physical activity. Fewer participants reported using it for psychological counseling, sleep-related problems, and medical consultation. Although this has recently become a topic of discussion, research indicates progress in this area [22]. However, nutrition advice and social counseling were found to be more effective. This aligns with studies suggesting that AI-powered chatbots can significantly improve dietary guidance [23]. These results indicate that ChatGPT might not yet be a substitute for traditional health information sources but rather an additional source of health-related information.

It has been noted that the use of ChatGPT was common across different sociodemographic groups, and differences between users and nonusers were not found to be significant. Younger participants (age ≤24 years) and those with doctoral degrees were slightly more likely to be using ChatGPT; however, these differences were not statistically significant. According to previous research, higher educational and socioeconomic levels may also affect the use of AI-based applications such as ChatGPT [24-26]. Although age has been reported to influence willingness to embrace AI technologies [27], this effect was not observed in this study. ChatGPT was used for health education and instructions on physical activity; however, the study did not evaluate whether the information prompted actual behavior change.

Prior research investigating perceptions of usefulness, ease of use, risk, and psychosocial issues has indicated a generally positive attitude toward ChatGPT [28]. Other studies involving health care professionals and students have yielded similar results, with perceived usefulness moderated by reliability and perceived risks [12,29]. These results are consistent with this study, in which respondents reported moderate perceived usefulness of ChatGPT and concerns about privacy, security, and misinformation. Although prior studies indicated that social and age-related variables could contribute to the adoption of AI technologies [30,31], the data in this study did not show statistically significant relationships between age and ChatGPT use.

In this study, a large number of ChatGPT users found it useful and relatively easy to use, but very few said that they used it when making health-related decisions. There were also concerns regarding the accuracy, privacy, and security of information, especially among nonusers. These issues align with previous studies showing that users remain skeptical about trusting AI-generated information and about using it in medical practice [32,33].

Even though numerous participants were interested in technologies such as ChatGPT and reported positive expectations of its usefulness, the findings should be interpreted in light of the descriptive nature of the data. Perceived usefulness was more likely to be accentuated among users, whereas perceived risk was more relevant among nonusers.

This study has a number of limitations. First, the cross-sectional design does not permit any causal inference. Second, the use of convenience sampling can introduce selection bias and reduce the representativeness of the sample. Third, the study used self-reported data, which could be affected by recall bias, reporting bias, and social desirability bias.

Despite these limitations, this study provides insight into people's perception of ChatGPT as a health information–seeking tool. Although the participants were aware of its potential usefulness, concerns regarding privacy, security, and information reliability remained important considerations. Future studies should consider using more diverse and representative samples and investigating how perceptions of AI-based health information tools change over time.

Conclusions

The study investigated perceptions of ChatGPT as a health information–seeking tool among users and nonusers in Saudi Arabia. ChatGPT was viewed as a convenient and accessible source of health-related information, especially for health education and assistance with physical activity. However, concerns regarding privacy, security, and reliability of information were raised by both users and nonusers. These findings indicate that interest in AI-based tools such as ChatGPT

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exists, but issues related to trust, data privacy, and information quality can arise when they are used to seek health-related information.

There is a need for further investigation into AI-driven health care decision-making, particularly regarding privacy, trust, and long-term adoption patterns. Policymakers should focus on enhancing security measures, ensuring accuracy, and fostering trust to facilitate the responsible use of AI tools in the health care system.

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Data Availability

The datasets generated and analyzed during this study are available from the corresponding author on reasonable request.

Authors' Contributions

Conceptualization: HS
Data curation: HS
Formal analysis: AA
Methodology: HS
Project administration: HS
Validation: AA
Writing—original draft: HS
Writing—review and editing: AA, KK, SR
Interpretation of results: AA
Contributed to discussion, conclusion: SR
Interpretation of results, corresponding author: KK
All authors have read and agreed to the published version of the manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Questionnaire items.
[DOCX File, 26 KB - formative_v10i1e79276_app1.docx]

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Abbreviations

AI: artificial intelligence
TAME-ChatGPT: Technology Acceptance Model Edited to Assess ChatGPT Adoption

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Enhancing Sleep and Mental Health: Longitudinal, Observational, Real-World Study From a Digital Mental Health Platform

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Abstract

Background: Poor sleep is closely linked to mental health challenges and workplace burnout. Mental health and workplace stressors can impair sleep, while good sleep quality supports cognitive and emotional resources to cope with daily challenges. Despite positive outcomes of maintaining good sleep, many people struggle to get enough restorative sleep at night. Given the bidirectional relationship between sleep and mental health, evidence-based digital mental health solutions may offer an accessible and scalable approach to improving sleep quality.

Objective: This study examines whether engagement with an employer-sponsored, multimodal digital mental health platform is associated with improvements in sleep quality over time, and whether changes in sleep quality are associated with concurrent changes in mental health and burnout outcomes.

Methods: This 12-month prospective, observational study followed working adults who were newly registered to an employer-sponsored digital mental health platform (Modern Health). The platform leveraged technology (mobile and web) to connect employees with comprehensive provider-led and self-guided care through therapy, coaching, on-demand digital resources, and group psychoeducational sessions. Participants [N=578; 61.1% (n=353) women; mean age 33.88, SD 8.73 years; 40.3% (n=233) people of color] completed measures of self-rated sleep quality, depression, anxiety, and burnout (exhaustion, cynicism, and professional efficacy) at baseline and after 3 and 12 months of accessing the platform. Upon registering for the platform, participants were given an initial care recommendation, but could flexibly engage in any combination of services. Participants in this study engaged with at least one care modality, including therapy, coaching, psychoeducation sessions, and self-guided mental health resources. We examined perceived sleep quality and associations with other study variables at baseline, changes in perceived sleep quality over time, and whether changes in sleep quality correlated with concurrent changes in mental health and burnout.

Results: At baseline, 42% (243/578) reported poor sleep quality and were more likely to have higher levels of depression, anxiety, and burnout. A generalized linear mixed-effects model showed that each additional month of platform access was related to an increased odds of having good sleep quality by 3.7% (P=.02). Linear mixed-effects models found that higher sleep quality over time was associated with lower depression, anxiety, exhaustion, cynicism, and efficacy (all P<.001). Among participants reporting poor sleep quality at baseline, 44% (62/141) reported good sleep quality at 12 months. Within this subgroup, paired sample t tests showed significant reductions in depression (−48.3%) and anxiety (−38.3%), and increased cynicism, burnout, though cynicism levels remained below the cutoff for high burnout (23.9%; all P <.01).

Conclusions: Use of an employer-sponsored digital mental health platform was associated with meaningful improvements in self-reported sleep quality over 12 months. These gains were associated with significant reductions in depression, anxiety, and burnout symptoms, highlighting broader well-being benefits of comprehensive mental health care.

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KEYWORDS

sleep; mental health; burnout; longitudinal; observational; real world; digital health; platform; workplace; employees; depression; anxiety; exhaustion; cynicism; efficacy; prospective; therapy; coaching; psychoeducation; well-being

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Introduction

Sleep is a fundamental process for regulating our overall health and well-being [1-3]. Consequences of poor sleep include daytime impairment [4], diminished ability to manage challenges effectively [5], and negative impacts on mental health [6]. As such, poor sleep is commonly linked to a range of mental health challenges [7,8] and is often noted as a prominent, distressing symptom of conditions like anxiety and depression [8,9].

Poor sleep quality and mental health concerns share a bidirectional relationship. For instance, getting poor sleep due to a variety of environmental, situational, social, and psychological factors [10-12] can negatively impact mood and increase worry the following day [13,14]. Additionally, it can impair attention, decision-making, and concentration, all of which are essential for navigating daily challenges [15]. Consequently, poor sleep quality can reduce one's capacity to effectively cope with stressors [5,16] and regulate the negative emotions that may result from impaired coping [17,18]. At the same time, individuals with elevated mental health symptoms tend to experience racing thoughts that can disrupt their sleep [19-23]. This bidirectional cycle can contribute to the development or exacerbation of mental health challenges [24].

Poor sleep quality not only impacts mental health, but the impact also extends to well-being in the workplace. Sleep supports the restoration of cognitive and emotional resources that are essential for tackling workplace challenges [15,17,25]. Consequently, poor sleep quality is linked to greater workplace stress across a range of occupations [26]. When workplace stress is not adequately managed, it can intensify to burnout [25]. Burnout encompasses a range of symptoms including emotional exhaustion, detachment from one's work, and a diminished sense of accomplishment [27]. Improving sleep quality can help individuals to better manage their workplace stress and protect against feelings of burnout [28].

As sleep is interconnected with mental health and burnout, addressing either part of this relationship may help to effectively break the harmful cycle. For example, when people feel more mentally well and engaged at work, their sleep quality may improve, and when they achieve better quality sleep, they may better regulate their mood and contribute to productive and meaningful work. Mental health interventions such as cognitive behavioral therapy [29] and mindfulness-based therapies [30] have shown promise in improving sleep quality, even when sleep was not the primary focus of treatment. However, only around a quarter of adults in the United States receive the necessary treatment for a mental health condition [31].

Digital mental health solutions offer a promising approach to increasing access to evidence-based interventions to improve sleep quality. Digital mental health is an umbrella of services, such as telehealth, digital therapeutics, online group therapy, chat-based care, and digital self-guided content, that are delivered through online platforms, mobile apps, or wearables [32-35]. There are currently several digital health solutions available specifically for sleep, such as digital cognitive behavioral therapy for those with clinical insomnia (d-CBTi) [36]. However, many individuals experience subclinical sleep issues, and even the mere perception that our sleep quality is poor can have a significant negative effect on emotional well-being and daily functioning [37-39]. Therefore, solutions beyond d-CBTi that effectively improve sleep may have broader public health implications.

Digital health platforms that offer comprehensive mental health services and are multimodal (eg, offer services across multiple care modalities) may improve sleep outcomes by addressing the underlying mental health factors that can affect sleep. For instance, one study found that adolescents receiving nonsleep-related digital mental health services experienced improvements in sleep quality as their mental health symptoms improved [40]. This evidence is promising, but more research is needed to evaluate the broader impact among the general population. Additionally, it is essential to examine digital mental health platforms that take a holistic care approach, expanding the range of services and care modalities to support users with varying health and well-being needs.

This study addresses a significant gap in the literature by examining the influence of engagement in multimodal employer-sponsored digital mental health services on sleep quality and associated mental health and burnout outcomes over time. The platform uses technology and a stratified care model that takes into account employees' clinical needs and preferences and connects them with the right level of care. This care includes a global network of licensed clinicians and certified coaches delivering one-on-one telemental health care, support, and group psychoeducation sessions, and an extensive on-demand library of digital resources. All care modalities are evidence-based, culturally centered, and focus on five domains of health and well-being: emotional, physical, social, professional, and financial health. Evaluating the impact of a platform that addresses multiple dimensions of well-being through scalable, evidence-based multimodal care could provide insights for population-level sleep solutions.

In this study, we investigated how changes in sleep quality after engagement with a comprehensive digital mental health platform for 3- and 12-month periods were associated with changes in mental health concerns (depression and anxiety). Additionally, we investigated how changes in sleep quality across these timepoints influenced aspects of organizational burnout, including exhaustion, cynicism, and professional efficacy.

Our first aim was to analyze baseline associations between sleep quality, mental health, and workplace burnout among employees newly registered for the platform to understand the risk factors and correlates of poor sleep. Given the bidirectional relationships among these variables, we hypothesized that poor sleep quality would be associated with worse depression and anxiety symptoms, and higher levels of burnout. Our second aim was to examine longitudinal changes in sleep quality over time among employees engaging with the digital mental health platform across 3 and 12 months. We hypothesized that individuals would improve their sleep quality after engaging with the platform. Our third aim was to explore whether changes in sleep quality over time were associated with concurrent changes in mental health symptoms and workplace burnout. We hypothesized that as an individual's sleep quality improved,

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they would also experience improvements in their depression and anxiety symptoms and reduce their feelings of burnout.

Methods

Study Design

This was a 12-month prospective, observational study of adults from multiple workplace organizations who had newly registered for an employer-sponsored digital mental health benefits platform (Modern Health). Participants were eligible if they (1) were 18 years or older; (2) had access to a smartphone, tablet, or computer; (3) were employed by companies partnered with the mental health platform; and (4) had indicated they were planning to start care (by either matching with a therapist or coach, or engaging with one piece of digital content). Data were collected at 3 timepoints: baseline (after registration) and at 3 and 12 months following registration. Data were collected between September 2021 and March 2023.

Ethical Considerations

The study was conducted in accordance with the Declaration of Helsinki and approved by the Western Clinical Group Institutional Review Board (protocol code 1316167) on August 20, 2021. All participants provided informed consent to participate in the study. Participant privacy was protected by deidentifying all data collected. Data were securely stored on secure, encrypted servers via Box that were only accessible by the researchers. Participants were offered a US $25 digital gift card as compensation for completing each survey (up to US $75 total for completing surveys at all 3 timepoints).

Procedure

Eligible individuals registered for an account with the platform via a mobile app or website. During the onboarding process, users completed clinical assessments using validated measures such as the 9-item Patient Health Questionnaire (PHQ-9) and the 7-item Generalized Anxiety Disorder scale (GAD-7) to determine clinical need. Users also specified their preferred care delivery method, such as “on my own,” “one-on-one,” or “unsure,” and selected their desired area of focus from the following domains: emotions, physical well-being, professional life, relationships, and finance. From these selections, a proprietary algorithm provided them with an initial care recommendation (eg, to start with coaching for a member with mild clinical need who preferred one-on-one support). After onboarding to the platform, users could begin using the digital mental health services. Individuals were able to engage in services based on their care recommendation, or they could self-refer and use any combination of multimodal care, including one-on-one care, group psychoeducation, and self-guided resources as they desired. Upon completing the onboarding process, individuals who met the specified inclusion criteria were invited by email to fill out a screening questionnaire. This questionnaire gathered additional demographic information to ensure a balanced sample that was representative of the broader US population and the commercial population who had access to this employer-sponsored benefit. Those who successfully completed the screening were subsequently directed to a consent form. Participants who provided their informed consent to join the study received a baseline survey via email, which took approximately 30 - 45 minutes to complete. Throughout the study period, participants engaged with the digital mental health services and received two follow-up surveys at 3 and 12 months via email. All questionnaires and surveys were conducted using Qualtrics’ online survey platform. The study procedure is depicted in Figure 1.

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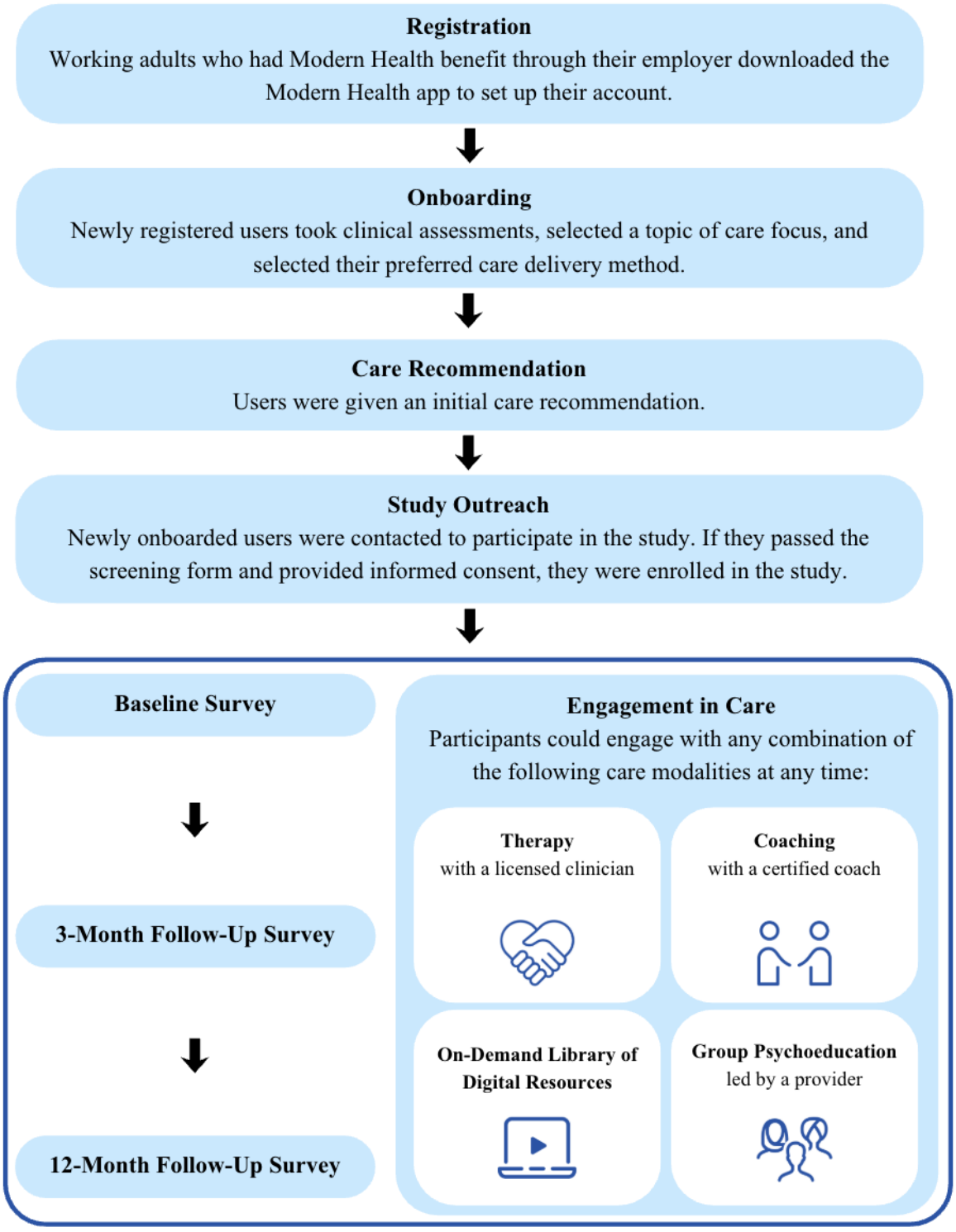
Figure 1. Flowchart of study intervention. Working adults who were newly registered and onboarded to the platform and met eligibility criteria were outreached for participation in the study. The baseline survey was sent to participants when they first initiated care, and after 3 and 12 months of using the platform services.



Digital Mental Health Services

Overview

The digital mental health platform is an employer-sponsored mental health benefit, offering employees no-cost access to a range of mental health services such as one-on-one care with a therapist or coach, group psychoeducation sessions, and self-guided digital resources. For eligibility in this study, all participants accessed at least one therapy or coaching session, or engaged with at least one piece of digital content.

Therapy and Coaching

Participants had access to 50-minute one-on-one therapy sessions provided in person or via Zoom by licensed therapists holding advanced psychology or related degrees (eg, PhD, PsyD,

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LCSW, LMFT, or LPC). Additionally, participants had access to 30-minute coaching sessions provided via Zoom by International Coaching Federation–certified coaches [41]. All coaches had at least 100 hours of coaching experience plus at least 6 additional hours of training from the digital mental health company on topics of culturally centered care and identifying high-risk situations that may require crisis or higher-level support. All therapists and coaches were vetted carefully for offering evidence-based practices such as motivational interviewing, cognitive behavioral therapy, acceptance and commitment therapy, and dialectical behavior therapy. Ongoing provider quality monitoring was conducted by a team of legal, compliance, provider operations, and clinical experts to ensure rigorous clinical standards were upheld.

Participants were recommended to these one-on-one services after their initial intake assessment, or they could opt to self-refer. In both cases, a proprietary algorithm matched participants with a list of providers who were most relevant to their clinical needs, spoke their desired language, and had session availability within a few days. The matching algorithm also took into account provider specializations in the participant's domain of focus. For example, if a participant wanted to work on their physical well-being and sleep quality, they were provided a list of therapists or coaches who specialized in sleep-related issues and could provide personalized strategies and support to help improve sleep habits. In this health domain, providers have the opportunity for individualized care, in which they could provide psychoeducation around how sleep and mental health are related, build routines around sleep hygiene and rest, implement techniques for cognitive restructuring to disrupt worrying and maladaptive thoughts at bedtime, and use motivational interviewing to support behavior changes necessary for sleep and mental health improvement. The amount and frequency of sessions that participants attended depended on their personal preferences, employer coverage, and individual needs.

Self-Guided Digital Resources and Group Psychoeducational Sessions

Participants had unrestricted access to an on-demand digital library featuring mental health programs and resources available to them. These included brief daily exercises, interactive programs, educational podcasts, mindfulness practices, and self-paced educational courses designed with the support of mental health experts including an in-house team of clinical psychologists, covering topics like emotions, relationships, and professional life. In addition to ample content aimed at improving mental health, the digital library also contained several resources specific to sleep. These included a self-paced, structured 6-session course called "Tools for Better Sleep, Rest, and Movement Throughout Your Day" and a 6-episode podcast covering elements of cognitive behavioral therapy for those with clinical insomnia (CBTi) including sleep hygiene, bedtime stimulus control, relaxation techniques, sleep restriction, and cognitive restructuring. There were also guided meditations, body scans, progressive muscle relaxations, breathing exercises, and calming sounds designed to help with sleep. Providers could recommend self-guided resources that were relevant to participants' concerns or goals. Participant use of self-guided resources was recorded; however, specific content selection was not.

Finally, participants could join live group psychoeducation sessions led by therapists and coaches. Sessions covered topics such as dealing with challenges in the workplace, processing stressful world events, and building emotional resilience. Several regularly featured sessions were specific to improving sleep quality (eg, "Sleep: A Beginner's Guide" and "Sleep: A Deep Dive," both 1-hour-long sessions). Group sessions were provided in a variety of formats, such as webinar-style learning, skill-building workshops, and informal discussions to support different user preferences. Participation in the group sessions was anonymous.

Measures

Demographics

Participants provided information on their age (by typing a number in years in an open-text box) and selected their gender identity, race/ethnic identity, and level of education from preset dropdown menus, which also had the option to include another category.

Sleep Quality

Perceived sleep quality was measured by a single item ("During the past month, how would you rate your sleep quality overall?") from the Pittsburgh Sleep Quality Index [42]. Participants could choose 1 of 4 response options: (3) "very good," (2) "fairly good," (1) "fairly bad," or (0) "very bad." A binary variable was created, such that "very bad" or "fairly bad" responses were categorized as "poor sleep," while "fairly good" or "very good" responses were categorized as "good sleep." We defined improvement in sleep quality as a participant being categorized as having "poor sleep" at baseline and "good sleep" at a follow-up timepoint. Single-item self-rated health measures are increasingly being used in clinical practice and health research due to their feasibility and strong predictive validity [43,44]. In real-world settings, lengthy questionnaires are not always practical, especially when examined at multiple timepoints. As such, this single-item measure of sleep quality was chosen to capture a relatively accurate perception of one's sleep. Single-item sleep quality measures have been used in previous studies [20,45,46], and research suggests that one's perception of their sleep quality can be more predictive of well-being and daytime functioning than objective measures [37-39].

Depression

Depression severity was measured by the PHQ-9 [47]. Participants reported how often they were bothered by a number of depression symptoms over the past 2 weeks, on a 4-point scale ("0=not at all" to "3=nearly every day"), with higher total scores indicating greater symptomatology. A positive screen for depression symptoms was indicated by a score of ≥10 [47].

Anxiety

Anxiety severity was measured by the GAD-7 [48]. Participants reported how often they were bothered by a number of anxiety symptoms over the past 2 weeks, on a 4-point scale ("0=not at all" to "3=nearly every day"), with higher total scores indicating

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greater symptomatology. A positive screen for anxiety symptoms was indicated by a score of ≥8 [49].

Workplace Burnout

Burnout was measured by the 16-item Maslach Burnout Inventory (MBI-GS-16) [50], which examines 3 different subscales of burnout (exhaustion, cynicism, and professional efficacy). Participants reported how often they experienced a number of feelings about their job on a 7-point scale ("0=never" to "6=every day"). An average was taken from the total score of each subscale. Higher average scores on the exhaustion subscale indicate greater feelings of fatigue and emotional exhaustion from work. Higher average scores on the cynicism subscale indicate greater indifference toward one's work. Higher average scores on the efficacy subscale indicate greater feelings of competence and achievement in one's work; thus, lower scores on this subscale indicate higher burnout. Higher levels of burnout were categorized by a frequency of "once a week" or more for exhaustion and cynicism subscales (≥4), and a frequency of "a few times per month" or less for the efficacy subscale (≤3).

Platform Engagement

To assess engagement in the platform, we reported average utilization for coaching, therapy, and self-guided digital resources. We included participants in this study who had used at least one service during the study timeframe. We did not have access to data on group psychoeducation sessions engagement as participation was anonymous.

Statistical Analyses

All analyses were conducted using R software (version 4.4.1; R Foundation for Statistical Computing). We conducted descriptive statistics for demographic variables, baseline sleep quality, mental health, and burnout. We also calculated the percent of participants categorized as having "poor sleep" or "good sleep" at baseline, as well as those screening positive for depression symptoms, anxiety symptoms, or high levels of burnout in the overall sample.

Our first aim was to evaluate whether baseline sleep quality was associated with mental health (depression and anxiety) and workplace burnout (exhaustion, cynicism, and professional efficacy). For this aim, chi-square tests examined whether there were differences in the proportions of positive screens for depression, anxiety, or high burnout between participants with poor sleep quality versus those with good sleep quality.

Our second aim was to evaluate longitudinal changes in sleep quality among employees engaging with the digital mental health platform across 3 and 12 months. First, we descriptively report the proportion of participants whose sleep quality improved (went from poor to good), maintained the same sleep quality, or worsened (went from good to poor) from baseline to follow-up timepoints.

Second, a generalized linear mixed-effects model with a logit link was conducted using the *lme4* package [51] to assess if time since registering for the mental health platform predicted the odds of reporting good sleep quality.

$$\log P(Yit=1)(Yit=0) = \beta 0+\beta 1(Timeij)+Subjecti$$

In this model, the outcome variable was sleep quality (coded as binary: 0=poor sleep and 1=good sleep). The model included a fixed-effect for time since registering for the mental health platform (baseline=0, 3-month follow-up=3, and 12-month follow-up=12) and a random intercept for participants to account for different baseline sleep quality levels. Overdispersion was assessed with Pearson residuals, with no evidence of overdispersion observed (dispersion ratio=0.46). Mixed-effects models were selected for our longitudinal analyses in aims 2 and 3 to examine changes across the 3 timepoints while accounting for repeated measures within participants and accounting for data missing to follow-up using maximum likelihood estimation, which assumes data are missing at random.

Our third aim was to evaluate whether changes in sleep quality over time (between baseline, 3-month follow-up, and 12-month follow-up) were associated with concurrent changes in mental health symptoms and burnout. First, we conducted a series of linear mixed-effects models with the overall sample to examine the relationship between sleep quality and outcomes over the course of accessing the digital mental health services. Five models were constructed, one for each of the 5 mental health and burnout outcomes, all of which were continuous.

$$Yit=\beta 0+\beta 1Timeit+\beta 2SleepQualityit+Subjecti+ it$$

The models included fixed effects for time since registering for the mental health platform (baseline=0, 3-month follow-up=3, and 12-month follow-up=12) and sleep quality (coded as binary: 0=poor sleep and 1=good sleep). Random intercepts for time were included at the participant level to account for individual differences in baseline mental health or burnout levels. Diagnostics confirmed that model assumptions were adequately met. Quantile-quantile plots showed approximate normality of residuals and random effects, with only minor deviations at the tails. Residual plots showed no evidence of heteroscedasticity, with residuals evenly distributed across fitted values and no systematic patterns. Finally, models converged without warning. For the second part of aim 3, as an exploratory, descriptive analysis, we conducted paired samples *t* tests among participants who reported poor sleep quality at baseline and good sleep quality at the 3- or 12-month follow-ups, with the aim of describing symptom trajectories among individuals whose sleep improved. These subgroup analyses were intended to complement the full-sample longitudinal analyses. We calculated percent change scores in mean symptoms of depression, anxiety, and burnout between study timepoints using the formula: [(follow-up mean – baseline mean)/baseline mean] × 100.

Results

Study Participants and Baseline Descriptive Data

We outreached to 8786 users who were initially eligible for the study, of which 2032 completed the screening form, and 950 agreed to participate and provided their informed consent. Of the 950 who consented and completed the baseline survey, 734 completed at least one follow-up survey, 724 provided sleep data for at least one follow-up survey, and of those, 578 engaged

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with at least one service between their baseline and 12-month survey timepoints. Participants were, on average, 33.88 (SD 8.73) years old, 61.1% (353/578) identified as women, and 40.3% (233/578) identified as a person of color (see Table 1 for sample demographics and characteristics). The full analytic sample (N=578) was used in our baseline descriptive and cross-sectional analyses, as well as longitudinal analyses with mixed-effects models, to maximize use of available data across timepoints. Of this group, 527 participants engaged with the platform between baseline and 3-month follow-up and provided data at 3 months; this sample was used in the analyses reporting the descriptive proportions of change and paired *t* tests examining change from baseline to 3 months. Similarly, 343 participants engaged between baseline and 12-month follow-up and provided data at 12 months; this sample was used in analyses reporting the descriptive proportions of change and paired *t* tests examining change from baseline to 12 months.

Table . Baseline demographic characteristics and descriptive statistics in the overall sample and by baseline sleep quality.

Demographic characteristic	Overall sample (N=578)	Poor sleepers (n=243)	Good sleepers (n=335)
Age, mean (SD)	33.88 (8.73)	33.95 (8.36)	33.82 (9.0)
Gender identity, n (%)			
Woman	353 (61.1)	160 (65.8)	194 (57.9)
Man	197 (34.1)	74 (30.5)	124 (37.0)
Gender nonbinary	28 (4.8)	9 (3.7)	17 (5.1)
Race and ethnicity, n (%)			
Asian or Asian American	109 (18.9)	45 (18.5)	64 (19.1)
Black or African American	36 (6.2)	20 (8.2)	16 (4.8)
Hispanic, Latino, or Spanish Origin	47 (8.1)	20 (8.2)	27 (8.1)
Non-Hispanic White	345 (59.7)	138 (56.8)	207 (61.8)
More than 1 race/ethnicity	39 (6.7)	19 (7.8)	20 (6.0)
Education[a], n (%)			
<Bachelors	72 (12.5)	40 (16.5)	32 (9.6)
Bachelors	348 (60.2)	141 (58.0)	207 (61.8)
>Bachelors	158 (27.3)	62 (25.5)	96 (28.7)
Platform engagement over 12 months, mean (SD)			
Therapy sessions	6.25 (5.42)	5.60 (4.37)	6.79 (6.15)
Coaching sessions	3.39 (3.10)	3.48 (3.32)	3.32 (2.96)
Digital resources	10.94 (18.40)	10.21 (13.78)	11.47 (21.14)

[a]Difference is statistically significant (P<.05).

At baseline, 42% (243/578) of participants indicated their sleep quality over the past month was either “very bad” (n=24) or “fairly bad” (n=219), categorizing them as baseline “poor sleepers.” The remaining 58% (335/578) of participants indicated their sleep quality as either “fairly good” (n=289) or “very good” (n=46), categorizing them as baseline “good sleepers.”

For mental health symptoms at baseline, average depression (mean 8.35, SD 5.63) and anxiety scores (mean 7.63, SD 5.37) were below the clinical cutoffs of ≥10 for the PHQ-9 and ≥8 for the GAD-7. Additionally, 36.9% (213/578) of participants had a positive baseline screen for depression symptoms, and 42.9% (248/578) of participants had a positive baseline screen for anxiety symptoms.

For burnout symptoms at baseline, average exhaustion (mean 2.08, SD 1.67) and cynicism (mean 2.03, SD 1.59) were below the high burnout cutoffs of ≥4 for high exhaustion and cynicism on the MBI-GS-16. Average professional efficacy (mean 4.58, SD 1.05) was above the high burnout cutoff of ≤3 for low professional efficacy. Additionally, 26.9% (155/576) of participants were above the cutoff indicating high exhaustion, 16.1% (93/577) of participants were above the cutoff indicating high cynicism, and 8.7% (50/575) of participants were below the cutoff indicating low professional efficacy.

Regarding platform engagement during the 12-month study period, 42.9% (147/343) used therapy, attending an average of 6.25 virtual therapy sessions, 63.6% (218/343) used coaching, attending an average of 3.39 virtual sessions, and 77.3% (265/343) accessed self-guided digital content, engaging with an average of 10.94 resources. The majority of participants (221/343, 64.4%) used at least 2 modalities of care, and 19.2% (66/343) used all 3 modalities of care at least once.

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Baseline Associations Between Sleep Quality, Mental Health, and Burnout

Average depression and anxiety scores were below clinical cutoffs for those with good sleep quality (depression: mean 6.18, SD 4.73; anxiety: mean 6.03, SD 4.62) and above clinical cutoffs for those with poor sleep quality (depression: mean 11.30, SD 5.41; anxiety: mean 9.82, SD 5.57). Chi-squares indicated a higher proportion of participants with poor sleep at baseline screened positive for depression [χ^2_1(N=578)=102.47, P<.001, φ=0.42] and anxiety [χ^2_1(N=578)=61.97, P<.001, φ=0.33] than those with good sleep at baseline (see Table 2). For example, 60.9% (148/243) of poor sleepers screened positive for depression at baseline versus 19.4% (65/335) of good sleepers.

Table . Positive screens for mental health and high burnout in the overall sample and by baseline sleep quality[a].

	Overall sample (N=578)	Poor sleepers (n=243)	Good sleepers (n=335)
Mental health symptoms			
Depression screen[b], n (%)			
Negative screen	365 (63.2)	95 (39.1)	270 (80.6)
Positive screen	213 (36.9)	148 (60.9)	65 (19.4)
Anxiety screen[b], n (%)			
Negative screen	330 (57.1)	92 (37.9)	238 (71.0)
Positive screen	248 (42.9)	151 (62.1)	97 (29.0)
Burnout symptoms			
High exhaustion[b], n (%)			
Negative screen	421 (73.1)	151 (62.4)	270 (80.8)
Positive screen	155 (26.9)	91 (37.6)	64 (19.2)
High cynicism[b], n (%)			
Negative screen	484 (83.9)	191 (78.6)	293 (87.7)
Positive screen	93 (16.1)	52 (21.4)	41 (12.3)
Low professional efficacy[b], n (%)			
Negative screen	525 (91.3)	212 (87.2)	313 (94.3)
Positive screen	50 (8.7)	31 (12.8)	19 (5.7)

[a]A positive screen for depression or anxiety was defined as baseline depression or anxiety scores above the clinical cutoff (≥10 for depression, ≥8 for anxiety). High burnout was defined as exhaustion and cynicism scores ≥4, and professional efficacy scores ≤3.

[b]The difference is statistically significant (P<.05).

Average burnout exhaustion and cynicism were below the high burnout thresholds for both individuals with both good sleep quality (exhaustion: mean 2.49, SD 1.59; cynicism: mean 1.84, SD 1.50) and poor sleep quality (exhaustion: mean 3.23, SD 1.69; cynicism: mean 2.28, SD 1.68). Additionally, average professional efficacy was above the low professional efficacy threshold for individuals with both good sleep quality (mean 4.72, SD 0.99) and poor sleep quality (mean 4.4, SD 1.1). However, chi-squares indicated a higher proportion of participants with poor sleep at baseline had high burnout for exhaustion [χ^2_1(n=576)=23.34, P<.001, φ=0.2], cynicism [χ^2_1(n=577)=8, P=.005, φ=0.12], and low professional efficacy [χ^2_1(n=575)=7.88, P=.005, φ=0.12] than those with good sleep at baseline (see Table 2). For example, 37.6% (91/242) of poor sleepers were classified as having high exhaustion at baseline versus 19.2% (64/334) of good sleepers.

Longitudinal Changes in Sleep Quality

Descriptively, the proportion of participants categorized as poor sleepers was the following at each timepoint: 42% (243/578) at baseline, 38.1% (201/527) at 3 months, and 35.9% (123/343) at 12 months. From baseline to 3 months, 81.8% (248/303) of participants who reported good sleep at baseline maintained good sleep quality at 3 months, while 18.2% (55/303) worsened and reported poor sleep quality at follow-up. Additionally, 65.2% (146/224) of participants who reported poor sleep at baseline maintained poor sleep quality at 3 months, while 34.8% (78/224) improved and reported good sleep quality at follow-up. From baseline to 12 months, 78.2% (158/202) of participants who reported good sleep at baseline maintained good sleep quality at 12 months, while 21.8% (44/202) worsened and reported poor sleep quality at follow-up. Additionally, 56% (79/141) of participants who reported poor sleep at baseline maintained poor sleep quality at 12 months, while 44% (62/141) improved and reported good sleep quality at follow-up.

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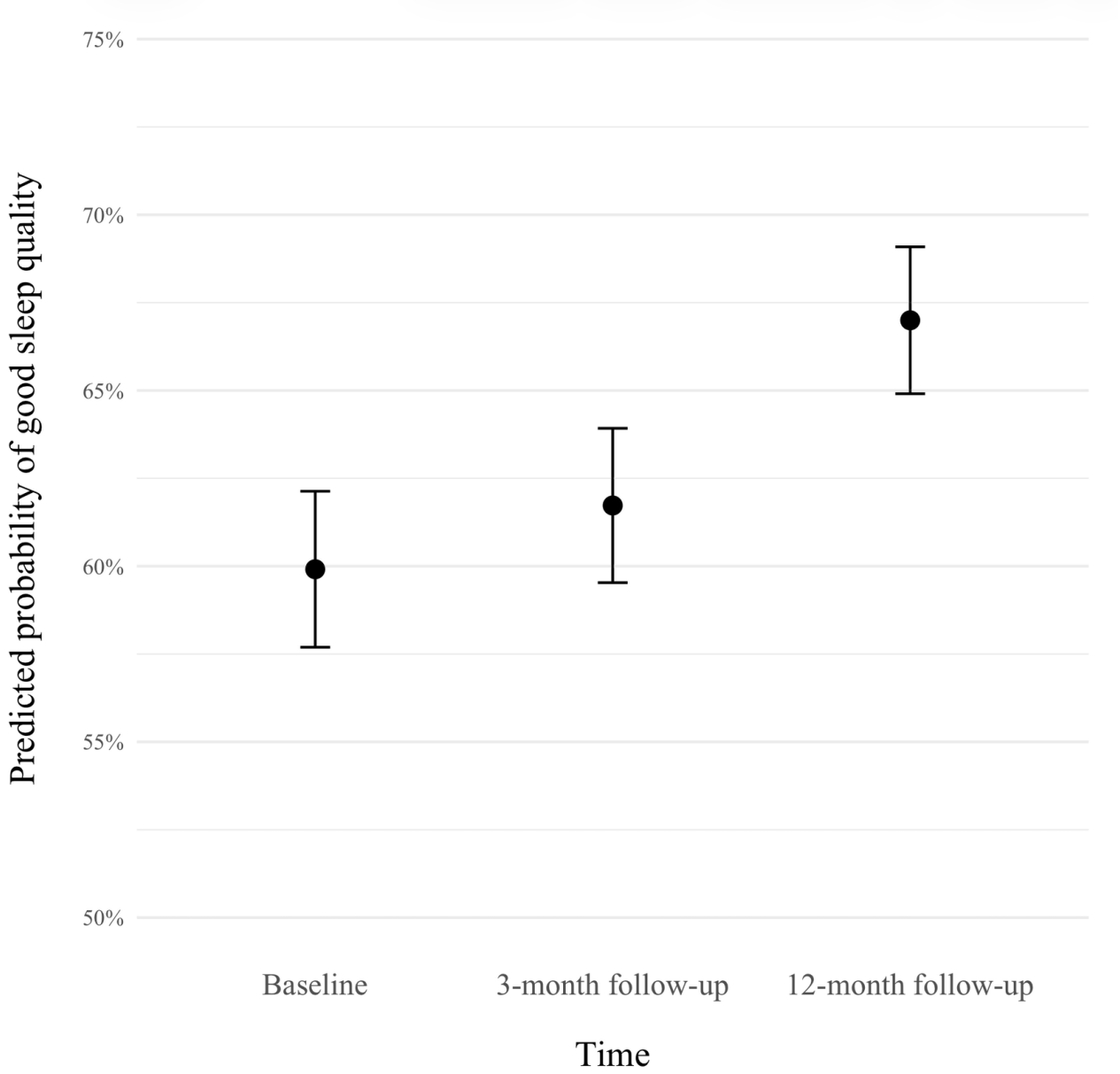
A generalized linear mixed-effects model was constructed to predict the odds of good sleep quality over time (see Figure 2). The model included a fixed effect of time and random intercept for participants. The model indicated that time since registering for the mental health platform had a small but statistically significant association with sleep quality (β=0.04, SE=0.02; *z*=2.29, two-tailed; *P*=.02). The β of 0.037 for time translates to an odds ratio of 1.037 (95% CI 1.006-1.071), indicating that for each additional month of platform access, the predicted odds of having good sleep quality increased by 3.7%. The model predicted that compared to baseline, the odds of having good sleep quality were 11.6% higher at 3 months and 55.1% higher at 12 months. Based on this model, Figure 2 depicts the predicted probability of having good sleep quality at each timepoint.

Figure 2. Predicted probability of good sleep quality by timepoint. The predicted probability of good sleep quality is 59.9% at baseline, 61.7% at 3-month follow-up, and 67% at 12-month follow-up. Error bars represent 95% CIs.



Relationships Between Sleep Quality, Mental Health, and Burnout Over Time

A series of linear mixed-effects models (see Table 3) were constructed to examine the impact of time since initiation of platform services and sleep quality on 5 mental health and burnout outcomes across the 3 study timepoints. In the model predicting depression, time since registering for the platform was significantly associated with depression symptom reduction (β=−0.16, *P*<.001). Sleep quality significantly predicted depression symptoms when controlling for time (β=−3.7, *P*<.001), such that a 1 unit increase in sleep quality (moving from poor sleep to good sleep) was associated with a 3.7 point reduction in depression scores. Given the intercept was 9.81 (close to the cutoff of ≥10 for a positive depression screen), a 3.7 point reduction associated with improved sleep quality indicates that average depression scores reduced to 6.11, which are approaching the mild range (<5). Similarly, for anxiety, time since registering for the platform was significantly associated with anxiety symptom reduction (β=−0.12, *P*<.001). Sleep

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quality significantly predicted anxiety symptoms when controlling for time (β=−2.9, *P*<.001), such that a 1 unit increase in sleep quality was associated with a 2.9 point reduction in anxiety scores. The intercept in this model was 8.89 (above the cutoff of ≥8 for a positive anxiety screen); thus, a 2.9 point reduction associated with improved sleep quality indicates average anxiety scores reduced to 5.99, which are approaching the mild range (<5).

Table . Fixed effects estimates of time and sleep quality on mental health and burnout outcomes[a].

Outcome variable and predictor	β	SE	*t* test[b] (*df*)	*P* value
Mental health				
Depression				
(Intercept)	9.81	0.22	43.88 (1159.75)	<.001
Time	–0.16	0.02	–7.72 (980.77)	<.001
Sleep quality	–3.70	0.25	–15.07 (1467.82)	<.001
Anxiety				
(Intercept)	8.89	0.23	37.87 (1149.47)	<.001
Time	–0.12	0.02	–5.71 (967.75)	<.001
Sleep quality	–2.90	0.25	–11.54 (1467.06)	<.001
Burnout				
Exhaustion				
(Intercept)	3.07	0.08	39.11 (1063.65)	<.001
Time	0.04	0.01	6.74 (924.95)	<.001
Sleep quality	–0.50	0.08	–6.60 (1326.02)	<.001
Cynicism				
(Intercept)	2.23	0.08	28.40 (1109.20)	<.001
Time	0.07	0.01	11.09 (941.18)	<.001
Sleep quality	–0.30	0.08	–3.70 (1400.73)	<.001
Professional efficacy				
(Intercept)	4.43	0.05	85.99 (1122.00)	<.001
Time	–0.01	0.00	–3.19 (948.96)	.002
Sleep quality	0.22	0.05	4.11 (1417.82)	<.001

[a]Time is coded as 0 for baseline, 3 for 3-month follow-up, and 12 for 12-month follow-up. Sleep quality is coded as 0 for "poor sleep" and 1 for "good sleep."

[b]All tests are 2-tailed.

In the model predicting burnout exhaustion, time since registering for the platform was significantly associated with an exhaustion score increase (β=0.04, *P*<.001). Sleep quality significantly predicted exhaustion when controlling for time (β=−0.5, *P*<.001), such that a 1 unit increase in sleep quality was associated with a 0.5 point reduction in exhaustion scores. For cynicism, time since registering for the platform was significantly associated with a cynicism score increase (β=0.07, *P*<.001). Sleep quality significantly predicted cynicism when controlling for time (β=−0.3, *P*<.001), such that a 1 unit increase in sleep quality was associated with a 0.3 point reduction in cynicism scores. For professional efficacy, time since registration for the platform was significantly associated with an efficacy score decrease (β=−0.01, *P*=.002). Sleep quality significantly predicted professional efficacy when controlling for time (β=0.22, *P*<.001), such that a 1 unit increase in sleep quality was associated with a 0.22 increase in professional efficacy scores.

Next, we conducted paired sample *t* tests within the subset of participants who improved their sleep from baseline to 3- or 12-month follow-ups (Table 4) to better understand how mental health symptoms and burnout changed between the study timepoints (from baseline to 3-month, or from baseline to 12-month). Participants with poor sleep at baseline who reported good sleep at 3-month follow-up (n=78) showed significant reductions in depression (−42.8%) and anxiety (−30.5%; all *P*<.001) between baseline and 3-month follow-up. Participants with poor sleep at baseline who reported good sleep at 12-month follow-up (n=62) showed significant reductions in depression (−48.3%) and anxiety (−38.3%; all *P*<.001) at 12-month follow-up. None of the 3 burnout domains changed over 3 or 12 months in the samples of participants who improved their sleep quality at 3- or 12-month follow-up, with the exception

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of a significant increase in cynicism at 12-month follow-up (23.9%, $P<.01$), though it remained below the cutoff for high burnout.

Table . Paired sample *t* tests of outcomes among participants who improved their sleep from baseline to follow-up timepoints.

Variable	n	Range	Baseline, mean (SD)	Follow-up, mean (SD)	*t* test[a] (*df*)	*P* value	Cohen *d*
Baseline to 3-month follow-up							
Depression	78	0 - 27	10.17 (5.29)	5.82 (4.10)	–7.05 (77)	<.001	0.80
Anxiety	78	0 - 21	8.94 (5.94)	6.21 (4.70)	–4.86 (77)	<.001	0.55
Exhaustion	78	0 - 6	2.93 (1.75)	2.85 (1.79)	–0.51 (77)	.61	0.06
Cynicism	78	0 - 6	2.17 (1.61)	2.33 (1.77)	1.14 (77)	.26	0.13
Efficacy	78	0 - 6	4.53 (1.11)	4.54 (1.06)	0.05 (77)	.96	0.01
Baseline to 12-month follow-up							
Depression	62	0 - 27	11.40 (5.96)	5.90 (4.21)	–7.35 (61)	<.001	0.93
Anxiety	62	0 - 21	9.60 (5.92)	5.92 (4.91)	–5.55 (61)	<.001	0.70
Exhaustion	58	0 - 6	3.26 (1.70)	3.06 (1.46)	–0.54 (57)	.59	0.07
Cynicism	59	0 - 6	2.38 (1.74)	2.95 (1.64)	2.55 (58)	.01	0.33
Efficacy	59	0 - 6	4.39 (1.03)	4.40 (1.05)	0.28 (58)	.78	0.04

[a]All tests are 2-tailed.

Discussion

Main Findings

To date, sleep research has primarily focused on the treatment of insomnia instead of taking a broader public health perspective to sleep treatment. Given the impact of sleep perception on mental health and well-being outcomes, a broader focus on sleep among the general population may offer critical insights into public health interventions to address sleep. We evaluated the real-world effectiveness of an employer-sponsored digital mental health platform for improving sleep quality and also evaluated whether improved sleep quality was associated with changes in mental health and burnout. As predicted, we found that engagement with the mental health platform was associated with improved sleep quality. Additionally, when sleep quality was higher, individuals tended to show reduced mental health and burnout symptoms. This study is important as it assessed the impact of a multimodal mental health platform within a broad population.

The large percentage of participants who registered for the mental health platform who reported poor sleep quality at baseline (243/578, 42%) supports a plethora of research showing that many people struggle to achieve restful and restorative sleep at night. This finding mirrors an American Psychological Association statistic from 2013, where 42% of adults reported fair or poor quality sleep [20]. For such individuals, especially those who experience sleep issues but do not reach the threshold for a sleep disorder diagnosis, there is a clear need for services that can help to improve sleep problems. Our findings suggest that multimodal digital mental health platforms, though not explicitly a sleep intervention, can offer support beyond just mental health, playing a valuable role in other health behaviors and domains of well-being known to influence mental health.

When examining correlates of poor sleep before starting care, we found that individuals with poor sleep quality at baseline were more likely to report higher depression and anxiety symptoms, greater exhaustion and cynicism at work, and lower professional efficacy for their job. These associations align with past research showing that maintaining quality sleep is crucial for sustaining the cognitive resources needed to tackle daily challenges [15,17] and managing negative emotional experiences [5,18]. As such, sleep disturbances may make it difficult to manage and recover from daily challenges, leading to exhaustion, feelings of burnout, and greater mental health symptoms. Given the bidirectional relationship between these variables, the opposite may also be true. Experiencing greater mental health and workplace concerns could lead to greater sleep disturbances. Individuals may lie awake at night with intrusive thoughts or worry about work-related challenges [20-22]. Additionally, the body's physiological response to stressors, such as greater cortisol in the body, can disrupt the wake-sleep cycle [52]. While this study cannot determine the directionality of these baseline relationships, our findings strongly underscore the complex interplay between these variables. Given that the population studied here was seeking mental health support from a digital platform, these baseline findings highlight the range of health and well-being needs of these individuals beyond care for depression or anxiety.

Although the services in the digital mental health platform primarily focused on emotional health, the platform also leveraged multiple modalities of care (therapy, coaching, and self-guided resources) to support people with their physical well-being and sleep habits. Thus, for aim 2, we explored

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whether sleep quality improved over the course of using digital mental health services. We found that 34.8% (78/224) of participants who initially reported poor sleep at baseline improved to good sleep by the 3-month follow-up, and 44% (62/141) improved to good sleep by the 12-month follow-up. Additionally, our model examining change in sleep quality across all 3 timepoints, while accounting for repeated measurement within participants and missing data, predicted that the odds of reporting good sleep quality consistently increased over time. Specifically, the odds of experiencing good sleep quality rose by 3.7% for each month of platform access, indicating a 55.1% increased odds of good sleep after 12 months. While not everyone experienced sleep improvements, and some individuals experienced worsening sleep symptoms over time, sleep issues can be difficult to change for some individuals. Future research may explore which individuals are less likely to experience sleep improvement and the factors underlying this resistance to change. Nonetheless, the overall findings are promising for this type of innovative intervention, and in line with previous research showing that mental health treatment can also lead to welcomed improvement in sleep quality [29,30,40].

The improvement in sleep quality observed in our study underscores the potential for digital mental health interventions to support sleep-related concerns. These platforms provide a unique opportunity to reach individuals with subclinical sleep issues or those who may not present or have access to sleep treatments like CBTi. Given the high rate of sleep concerns in the general public, sleep problems have become somewhat normalized. As a result, many individuals may overlook these concerns, fail to seek support for their sleep outside of the traditional medical system, or face barriers when they do [53]. Additionally, gold standard interventions like CBTi can be time intensive, and research on these interventions has focused primarily on clinical populations. This leaves a gap in our understanding of the impact of less intensive, but still evidence-grounded, interventions that could have broad public health implications. Digital mental health platforms can serve as an accessible entry point for sleep support, offering an alternative to standard treatments for sleep that may be less accessible, limited in availability, or not well-known. As services for these mental health platforms are carefully developed, they may consider taking a holistic care approach to support the diverse and interconnected health and well-being needs of their users.

Given the strong link between sleep quality, mental health, and burnout, for aim 3, we explored whether changes in sleep quality over time were associated with changes in depression, anxiety, and all 3 domains of burnout. Between our 2 analyses, we found that improved sleep quality was associated with improved mental health symptoms and, to some extent, workplace burnout. Examining mental health across time, our regression models predicted a significant reduction in depression and anxiety symptoms. Additionally, when one's sleep quality was good, depression and anxiety were significantly lower by 3.7 points and 2.9 points, respectively. These models showed that at baseline, depression and anxiety were close to or above the cutoffs for a positive screen and moderate symptoms, and that when sleep quality improved, average scores dropped to around 6, which is closer to mild levels of symptoms.

In our second analysis for this aim, we found that among participants who reported poor sleep at baseline and improved to good sleep by the 3-month follow-up, their average depression scores statistically significantly improved by 42.8%. This change of 4.35 points was also close to the threshold to be considered clinically significant change, which is a 5-point reduction in depression [54]. At 12 months, people who improved their sleep quality reported a 48.3% improvement in depression and a clinically significant point reduction of 5.5 points, on average. Regarding anxiety, those who improved their sleep quality by 3 months reported a 30.5% improvement at the 3-month follow-up, and those who improved their sleep quality by 12 months reported a 38.3% improvement in symptoms at the 12-month follow-up. It is possible that mental health improvements directly contributed to individuals experiencing better sleep quality. Alternatively, as the relationship between sleep and mental health is bidirectional [55], improvements in sleep quality may have had positive downstream effects on mental health. The digital mental health platform provided comprehensive services aimed at enhancing overall well-being, including physical health, with some resources specific to sleep hygiene and psychoeducation. Improvement in either sleep quality or mental health likely contributed to positive change in the other.

Regarding the association between changes in sleep quality and changes in the 3 domains of burnout, we first found that over time, exhaustion and cynicism significantly increased while professional efficacy decreased. However, burnout scores were already low at baseline, and this amount of change was not enough to move scores over the threshold to be considered high burnout at any timepoint. Sleep quality seemed to act as a kind of buffer against these increases. When one's sleep quality was good, exhaustion and cynicism were statistically significantly lower by 0.5 points and 0.3 points, respectively, and professional efficacy was higher by 0.22 points. These point reductions in exhaustion and cynicism and increase in efficacy associated with good sleep quality across study timepoints put participants' burnout scores even further into the category of lower burnout.

The buffering impact of good sleep quality was also partially supported by our exploratory paired sample *t* test analyses. While the regression analyses showed that burnout slightly increased over time, our *t* tests indicated that the subsample of participants who improved their sleep quality from baseline to either follow-up timepoint maintained their low levels of burnout. Directionally, exhaustion scores were lower at follow-up (though not statistically significant), cynicism scores were higher at follow-up (and significantly so at 12 months, but remained below the high burnout cutoff), and professional efficacy did not change (directionally or statistically). Because burnout was low at baseline, and remained below cutoffs throughout the study, there was limited room for further reduction. The slight increase in cynicism between baseline and 12 months may reflect a floor effect. However, the overall observed maintenance of low burnout over time, especially for those with good and improving sleep quality, is a positive outcome.

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The study findings related to burnout may reflect additional contributing factors. Burnout may be attributed to aspects of organizational culture, job demands, and workplace policies [56,57] that remain unchanged despite individual improvements in sleep and mental health. This could account for the fact that burnout slightly declined over time, yet sleep quality and mental health tended to improve. It is also possible that burnout has a larger influence on sleep quality than the reverse. Individuals experiencing burnout may be facing work-related stressors such as working long hours and dealing with emotional exhaustion, which can disrupt their ability to maintain a consistent bedtime routine or mentally wind down before bed [25]. As burnout decreases, sleep quality may improve from the reduced stress and demands. Of note, only a small portion of participants had elevated burnout at baseline, and we did not stratify the sample by baseline burnout severity. It is possible that individuals with higher initial burnout experienced improvements in sleep quality as their burnout decreased. For the majority of participants who started out with low levels of burnout, their treatment goal may have been to maintain their lower levels, a pattern that aligns with the study findings.

Improvements in sleep alone may not address the organizational factors that likely have a more significant impact on burnout. The complex nature of burnout may require more targeted interventions, starting in the workplace itself with strategies such as systemic improvements, to see significant changes. However, improving sleep quality may still have a positive impact. Overall, burnout tended to be lower at time points when individuals reported good sleep quality. When sleep improved from poor to good, burnout levels remained low. Improving sleep through mental health interventions may help to buffer against the exacerbation of workplace stress and burnout. Therefore, it is worth investing in solutions that target sleep and mental health, as they can also affect how someone shows up at work, even when burnout may be increasing due to other organizational factors; improved sleep may attenuate this increase.

Limitations

There are several notable limitations of the study. First, this was an observational study of real-world data collected between 2021 and 2023. As the study examined an existing digital mental health benefit, the study did not include a control group for comparison. Therefore, we are unable to make causal claims that the digital mental health platform caused the observed changes in sleep quality or mental health. Additionally, the aim 3 exploratory subgroup analysis focused on individuals whose sleep improved and was not designed to infer causality or compare outcomes with those whose sleep did not improve. Observed changes of these variables over time may have been related to a number of alternative factors, such as world events like the COVID-19 pandemic, life events, other temporal factors, or even regression to the mean due to the multiple time points accessed. However, several studies have demonstrated improvements in mental health following use of this digital mental health platform [58-60], and there is mounting evidence that individuals often experience enhanced sleep quality following improvements in their mental health [29,30,40]. Nonetheless, future studies could incorporate a comparison group in their design to further validate the effectiveness of digital mental health services in improving sleep.

Participants were eligible for the study if they attended at least one therapy or coaching session, or engaged with at least one self-guided digital resource. Many of our participants used a combination of one-on-one care and self-guided resources. Therefore, we were unable to stratify sleep quality improvements by care modality. Additionally, detailed information regarding the specific timing and duration of platform engagement was not available to the researchers. Future studies may explore how factors such as service type, content, level of engagement, and timing of engagement may influence the magnitude of sleep quality improvement. Future research may also consider using clustering approaches to identify distinct patterns of multimodal engagement across care types and examine how these patterns relate to mental health and sleep outcomes. This could help determine the most effective strategies for improving sleep quality with digital mental health services.

All participants were employees of organizations sponsoring the digital mental health platform. Therefore, the results of the study may not generalize to nonworking adults or employees that were not represented on the platform. For instance, factors such as job-related workload or financial stress may have impacted sleep quality, and these particular stressors may vary in other populations.

Finally, all data collected in this study were self-reported by participants, and individuals may not have accurately evaluated themselves or remembered their experiences. Furthermore, we used a single item to measure sleep quality perception. We did not assess objective measures of sleep quality, such as actual sleep duration, latency, and efficiency. However, research has shown that one's perception of their sleep quality can strongly influence emotional well-being and cognitive performance, sometimes even more so than objective sleep metrics [37-39].

Conclusions

This study examined how the use of an employer-sponsored digital mental health platform impacted perceived sleep quality and correlates of poor sleep over time. At baseline, poor sleep was related to higher symptoms of depression, anxiety, and burnout, highlighting the multifaceted nature of challenges experienced by a sample of participants motivated to engage in mental health care and support. Results suggest that digital mental health solutions offering a comprehensive, holistic approach to well-being can support sleep improvement. Sleep quality improved while participants engaged with services, and this improvement in sleep was associated with improvements in mental health symptoms and maintenance of burnout below cutoff levels. Given the strong connection between sleep and emotional well-being, the study demonstrates that sleep and mental health can be addressed simultaneously with digital mental health services, with improvements supporting other positive outcomes such as management of workplace burnout.

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Data Availability

Individual deidentified data that underlie the results reported in this manuscript can be shared privately for research purposes upon receipt of a methodologically sound proposal, and whose proposed use of the data from the study related to this article are approved by the authors. To gain access, requesters will need to submit a proposal to the corresponding author and sign a data access agreement that includes a commitment (1) to using the data only for research purposes; (2) to not attempt to, or actually, reidentify any individual; (3) to securing the data using appropriate safeguards; and (4) to destroying or returning the data after analyses are completed.

Conflicts of Interest

KK, BH, NC, JRW, and SJSH are employed by and receive income from Modern Health and have been granted equity in Modern Health. Modern Health provided support to the University of North Carolina at Charlotte to support KMVS. SML has no financial disclosures.

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Abbreviations

CBTi: cognitive behavioral therapy for those with clinical insomnia
d-CBTi: digital cognitive behavioral therapy for those with clinical insomnia
GAD-7: 7-item Generalized Anxiety Disorder scale
MBI-GS-16: 16-item Maslach Burnout Inventory
PHQ-9: 9-item Patient Health Questionnaire

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Frugal-Oriented Information and Communication Technology for Development Framework Toward Low-Cost Digital Maternal Health in Low- and Middle-Income Countries: Quantitative Descriptive Study

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Abstract

Background: The Sustainable Development Goals (SDGs) aim to eradicate poverty and inequality while ensuring that all individuals enjoy good health. Among these, target 3.1 seeks to reduce the global maternal mortality ratio to less than 70 per 100,000 live births. However, progress toward this target has been limited, particularly in low- and middle-income countries (LMICs), where health care delivery remains constrained by limited resources. While digital innovations have increasingly been adopted to improve health care access and service delivery, a significant proportion of populations in LMICs continues to experience inadequate access to essential maternal health services. This gap underscores the need for affordable, sustainable, and contextually appropriate strategies that are cost-effective in improving maternal health outcomes in underserved communities.

Objective: This study leverages the principles of frugal innovation and information and communication technologies for development (ICT4D) to propose a frugal-oriented ICT4D framework to deliver low-cost digital maternal health solutions in LMIC settings. The framework seeks to optimize the use of available resources, foster equitable access to maternal health care, and contribute toward achieving SDG 3, particularly target 3.1.

Methods: The study was conducted in both rural and urban-poor settings in Kenya using a 2-phased quantitative approach. In phase 1, eight theoretical themes relevant to maternal health uptake were explored. These themes were represented on color-coded sorting cards, which participants ranked according to perceived importance. Phase 2 involved administering structured survey questionnaires to collect empirical data. The study included a total of 32 participants, whose insights provided a foundation for analyzing the significance of contextual factors influencing maternal health service utilization.

Results: The weighted scores for 3 of the 8 predetermined theoretical themes—such as resources, information services, and social support programs—emerged as the most influential factors shaping maternal health promotion (N=32). Resources ranked highest (n=6, 18.81%), followed by information services (n=6, 17.99%), while social support programs accounted for 9.64% (n=3) of the overall influence. These findings highlight critical enablers and barriers within the maternal health care landscape and provide a nuanced understanding of contextual dynamics that affect the uptake of maternal health services. The results informed the design of a frugal-oriented ICT4D framework that prioritizes low-cost digital interventions tailored to resource-limited settings.

Conclusions: Despite increasing recognition of digital innovations as tools for health care transformation in LMICs, adoption of existing capital-intensive solutions remains low due to financial and infrastructural constraints. This study emphasizes the importance of adopting frugal innovation and ICT4D principles in designing low-cost, scalable digital health interventions to improve access to maternal health care. Implementing such approaches can address resource limitations, enhance maternal health outcomes, and support progress toward SDG 3, particularly target 3.1. The proposed framework provides a foundation for future research and practical interventions aimed at sustainable, equitable maternal health service delivery in LMIC contexts.

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KEYWORDS

digital health innovation; maternal health promotion; underserved populations; sub-Saharan Africa; innovative methods and strategies

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Introduction

The Context of Maternal Mortality and Sustainable Development Goals

The overall aim of the Sustainable Development Goals (SDGs) agenda is to transform our world; hence, it is a call to action to end poverty and inequality, protect the planet, and above all, ensure that all people enjoy good health [1]. Unfortunately, the world faces myriad threats, including conflict, climate change, and the aftermath of the COVID-19 pandemic, which are devastatingly impacting the progress made so far in reducing poverty toward achieving the SDGs [2]. This has led to an increase in the number of people and households living in extreme poverty, thus causing the most significant rise in between-country inequality. There is a wide disparity between high-income countries and low- and middle-income countries (LMICs), leading to inequitable global development. LMICs have continued to lag in fiscal and overall capacity relative to their high-income country counterparts, due to more significant vulnerabilities among LMIC communities [3].

Notably, a significant portion of the global population, including women and children, lacks access to essential health care services, leading to poor health outcomes. Over 287,000 women died in 2020 due to pregnancy and childbirth-related complications [4], which translates to about 800 women dying every day during the same period [2]. In addition, millions of children have been killed globally from preventable causes, including poverty, disease, and hunger [5]. On a global scale, an estimated 774 million children live in multidimensional poverty, while at the same time, 100 million people are pushed into poverty annually due to high health care costs. As a result, childhood vaccinations have declined substantially over the past 3 decades, whereas deaths from tuberculosis and malaria have increased since the COVID-19 pandemic [2].

Unfavorable socioeconomic conditions, including income levels, employment status, gender, education, and ethnicity, influence the situation. These factors push individuals to lower socioeconomic status, thus exposing them to a higher risk of poor health [6]. Therefore, it is against this background that target 3.1, whose objective is ‘‘to reduce the global maternal mortality ratio to less than 70 per 100,000 live births,” was established. The SDG agenda commits to reducing maternal mortality to achieve universal health coverage (UHC) by 2030 [2]. There is a need to address setbacks through greater innovation and investment to build resilient health systems to withstand future health threats, including pandemics like COVID-19. This could be achieved by leveraging relevant innovative approaches and information and communication technologies (ICTs) to enable social and economic development toward achieving the SDGs.

ICTs for Development (ICT4D) and Frugal Innovation in Health Care

ICT4D refers to using ICT in various domains, including socioeconomic development, international development, and human rights, to bridge the digital divide and improve the lives of the underserved in LMICs [7]. ICT4D in health care, therefore, entails the use of ICTs to collect, store, retrieve, and exchange health care information to facilitate efficient, effective, and patient-centered care [8-11] to enhance socioeconomic development. However, the application of ICT4D in Kenya’s health sector is not exceptional in the face of earlier barriers, particularly inadequate health infrastructure, leading to high-cost health care ICT innovations [12]. There is a lack of funding to provide sufficient health ITs, including computer hardware and software, skilled personnel [10,13], and an appropriate policy framework to facilitate the optimum utilization of ICTs in health care delivery [14-16]. To address these challenges adequately, the principles of ICT4D (digital development) and frugal innovation (FI) should be leveraged. ICT4D principles include designing with the user; understanding the ecosystem; designing for scalability; building for sustainability; data-driven solutions; using open standards, open data, open source, and open innovation; reusing and improving ICT tools; and addressing privacy and security concerns while strengthening collaboration among key stakeholders [7,17].

Frugality is one way to produce effective and affordable health care innovations using fewer resources to deliver services to marginalized populations [18]. FI is a strategy about ‘‘how to do more with less’’ to overcome resource constraints and develop novel and locally relevant solutions to address local problems [19,20]. It refers to products, services, and systems that can be redesigned and re-engineered for underserved users to facilitate access to basic services and infrastructure [16]. The concept of FI entails the application of the principles of simplicity, affordability, and sustainability in the design and implementation of digital technologies, which has potential to strengthen health systems for better health care delivery and management in LMICs, such as sub-Saharan Africa (SSA) [21-23]. The benefits of ICT4D can therefore be leveraged through combining business, IT systems, and social innovation through redesigning or re-engineering business processes and products (hardware and software) with new features in digital applications using minimal resources. These resources can be easily recycled for increased value addition, with a focus on cofunctionalities (simplicity), cost-effectiveness (affordability), and maintainability (sustainability) to mitigate resource constraints in providing digital services to the public [24-26] to make them more readily accessible. A perfect example of FI in the context of ICT4D in Africa is the high mobile penetration, which helps bridge the digital divide by providing consumers with access to services. Notably, the simplicity and affordability of mobile phones have led to increased adoption rates of mobile financial services, such as M-PESA, in Kenya and within SSA countries [27,28].

ICT4D solutions can help address local health concerns and promote long-term values for communities. Therefore, ICT4D encompasses the use of ICT across the fields of socioeconomic development, international development, and human rights [7]. It is a form of digital development that uses and applies digital tools and solutions to address social, economic, and environmental challenges [29,30]. The significance and potential of ICT4D lie in its focus on aiding underserved and impoverished populations by empowering them with access to information, services, opportunities, and rights. Increased ICT

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access and use have significant potential to accelerate the attainment of the SDGs, as highlighted in recent analyses of the ICT4D value chain [31,32].

Study Aims and Research Questions

To establish sustainable health care systems in LMIC settings, it is necessary to embrace frugal ICT4D innovations in the health sector. The concept of FI should be adopted to strip down, simplify, and create efficient digital health innovations to increase access to health services for marginalized and underserved groups [14,33-35]. This calls for resource-constrained approaches to innovation, such as frugal digital innovation (FDI) in LMIC settings. The paper aims to leverage the principles of FI and ICT4D to propose a novel frugal-oriented ICT4D innovation framework to guide the development of low-cost digital innovations for underserved communities in Kenya. Specifically, the study seeks to explore contextual factors influencing maternal health in underserved contexts, such as Africa, to inform the proposed solution. This will help to increase access to health care, with a focus on maternal health in SSA toward achieving SDG 3.1 [24,34]. The research questions to be answered by the study include the following:

- What contextual factors influence the utilization of digital maternal health services among underserved communities in LMIC settings?
- How could low-cost digital maternal health interventions be developed to promote maternal health among underserved communities in LMICs?

Methods

The study, conducted between March and July 2023 in 2 contextual sites, rural and urban-poor settlements, in Kenya, is significant as it focuses on the uptake of maternal health in LMICs, a crucial aspect of public health. The main target was maternal health stakeholders in the public health sector, including pregnant women and health care practitioners.

Study Design

Overview of the study

A quantitative approach was used because of its immense benefits in improving the validity of research. This included its ability for objectivity in measurement and data collection, use of standardized instruments to reduce researcher bias, identification of trends and patterns, generalizability of findings, empirical evidence to support decisions, as well as the replication and comparison of findings [36-38]. Despite the limitations of quantitative research approaches in capturing the uncertainty of complex relationships and interactions among research phenomena, the study used theoretical themes to supplement the surveys.

Sampling Procedure

A total of 32 participants were recruited for the study, comprising 2 main groups: 15 pregnant women and 17 professional stakeholders. Participants were drawn from the designated study sites, namely rural Kitui County and the urban-poor Kibra informal settlements in Nairobi.

Pregnant women were recruited based on their willingness to participate, age eligibility, and residency within the selected study locations. Professional participants, including community health providers (CHPs), were nominated from various stakeholder groups operating within the study sites. A snowball sampling technique was employed to identify additional eligible participants [39,40].

The inclusion criteria for professional stakeholders included age eligibility, relevant educational qualifications (minimum of postsecondary education), employment in a maternal health–related role (eg, CHPs, health policy experts, or ICT specialists), and work experience. Participants were also required to be affiliated with a facility or organization serving the study communities during the research period. These criteria were clearly communicated to initial key informants and applied consistently throughout the snowball sampling process. Detailed inclusion and exclusion criteria for each stakeholder group are provided in Table 1.

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Table . Detailed inclusion criteria by stakeholder category[a].

Stakeholder category	Inclusion criteria
Pregnant women (service users)	• Age: above 18 years • Residency: residing in either a rural setup within Kitui County or a poor-urban setup within Nairobi's Kibra Slums during the study period • Consent: willingness to participate in the study
Health professionals (nurses, clinical officers, medical officers, and midwives)	• Age: above 18 years • Educational qualifications: have a minimum of a postsecondary qualification (diploma or higher) in nursing, midwifery, medicine, or a related health discipline • Role: employed as a health care worker providing maternal health services • Experience: have a minimum of 3 years of work experience in the current or a related role • Affiliation: should be working in a health facility or organization serving the study communities
CHPs[b]	• Age: above 18 years • Education: have at least a secondary school level education • Role: be accredited CHPs actively serving in the catchment communities for ≥1 year • Recruitment: be identified and nominated via snowball sampling techniques • Experience: have a minimum of 1 year of active engagement in maternal health–related community support
Health policy and ICT[c] specialists (technical)	• Age: above 18 years • Educational qualifications: have a minimum of a postsecondary qualification (diploma or higher) in a relevant field (either in public health or health management and IT/ICT or computer science), respectively • Role (health policymakers): be a specialist in maternal health policy, occupy a supervisory/managerial role (eg, county health management team member or facility in charge), and in a related field • Role (ICT specialists): be supporting health-related ICT systems/programs • Experience: have a minimum of 3 years in a professional role in a relevant field

[a]The table outlines the eligibility and inclusion criteria used to purposively select study participants across stakeholder categories involved in maternal health service delivery, community support, and health policy and ICT systems.

[b]CHPs: community health providers.

[c]ICT: information and communication technology.

Execution of the Study

The study was conducted in two phases: (1) an exploration of 8 predetermined theoretical themes as potential contextual factors for maternal health in LMICs and (2) quantitative survey research.

Exploration of Theoretical Themes

Stage 1 of the study was based on theoretical themes identified as potential individual and contextual factors influencing the uptake and utilization of maternal health services in an African context, including education, poverty, population density, media exposure, autonomy, empowerment, and access to health care services [41,42]. Against this background, 8 themes were derived from the literature and explored to guide the study. They include information, resources, social support, technical competency, personal development, power, interest, and influence. Using a toolkit of sorting cards to represent the various themes in different colors as shown in Figure 1, the researchers selected 13 out of the 32 participants randomly to rank the factors (1-8) according to the individual order of preference. This would assist researchers in identifying potential priority areas in enhancing the utilization of maternal health services to guide the study.

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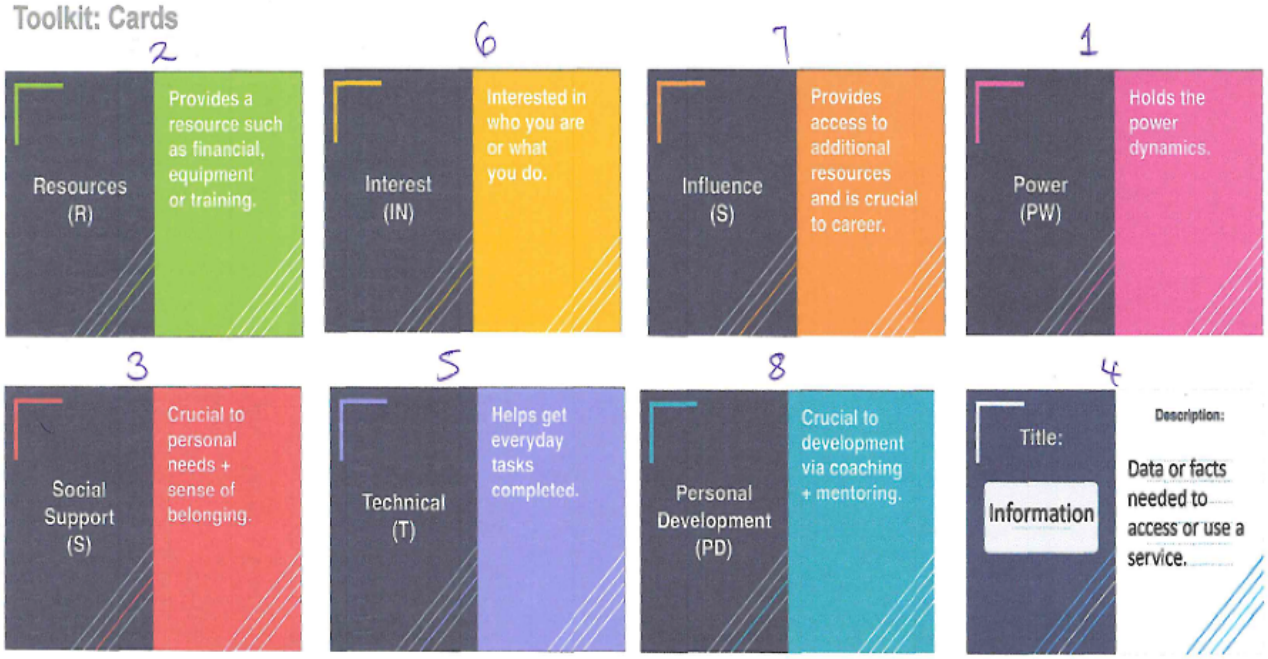
Figure 1. Illustration of participants ranking sorting cards representing contextual factors influencing maternal health in low- and middle-income countries (LMICs), arranged according to individual preferences.



Quantitative Survey Study

The design and development of survey questionnaires were tailored to the various participant groups in the study, based on the most significant factors influencing maternal health utilization in the study context. This was achieved through the sorting cards ranking exercise. Questionnaires were developed with closed-ended questions and administered to all participant groups, that is, pregnant women, health professionals, health policymakers, CHPs, and ICT experts.

Data Analysis and Interpretation

Sorting Cards

The sorting of the card data was analyzed based on individual stakeholder participants' ranked order of the 8 contextual factors perceived to influence the utilization of digital maternal health services, as per the card-sorting grid presented in Table 2.

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Table . Ranked card-sorting results showing participants' prioritization of contextual factors influencing digital maternal health utilization from highest to lowest.

Participant	1	2	3	4	5	6	7	8
NCW1	Information	Resources	Power	Technical competency	Interest	Influence	Personal development	Social support
NCW2	Information	Resources	Interest	Influence	Power	Technical competency	Social support	Personal development
NHP 1	Resources	Power	Technical competency	Interest	Information	Influence	Personal development	Social support
NHP 2	Resources	Information	Personal development	Interest	Influence	Technical competency	Social support	Power
KHP 1	Information	Resources	Social support	Personal development	Interest	Technical competency	Influence	Power
KHP 2	Resources	Information	Interest	Personal development	Information	Social support	Influence	Power
KHP 3	Resources	Technical competency	Interest	Information	Social support	Personal development	Influence	Power
KCW1	Power	Resources	Social support	Information	Technical competency	Interest	Influence	Personal development
KCW2	Power	Resources	Social support	Personal development	Information	Influence	Technical competency	Interest
PMSP1	Information	Technical competency	Resources	Power	Interest	Influence	Personal development	Social support
PMSP2	Information	Technical competency	Resources	Interest	Influence	Personal development	Social support	Power
PM1	Technical competency	Social support	Influence	Personal development	Interest	Power	Resources	Information
HP1	Information	Resources	Personal development	Technical competency	Social support	Interest	Influence	Power

Ranking and Selection of Important Factors

Participants' rankings placed resources and information as the top 2 contextual factors, followed by technical competency, interest, power, social support, and personal development (see Table 3). These results informed the selection of resources, information services, and social support programs as the focal dimensions for the survey.

Table . Weighted importance of factors influencing the utilization of maternal health services[a].

Factor	Weighted score, %
Resources	18.81
Information	17.99
Technical competency	12.85
Interest	11.99
Power	10.06
Personal development	9.85
Social Support	9.64
Influence	8.78

[a]Percentage values were calculated by dividing each factor's weighted score by the total score (467) and expressing the result as a proportion of 100%.

The various contextual factors were ranked and prioritized in terms of their respective scores as represented in Table 3. The subsequent quantitative survey, however, focused on 3 out of the 8 contextual factors, that is, resources, information services, and social support programs, respectively. Resources and information were selected because they received the highest overall rankings (positions 1 and 2) in the card-sorting exercise and therefore represented priority structural determinants of digital maternal health utilization in this setting. Social support programs, although ranked seventh, were included because they were found to be consistent with empirical evidence that low social support during pregnancy is associated with poorer mental

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health and adverse outcomes. For example, the Bedaso et al's systematic review and meta-analysis report that low social support is significantly associated with antenatal depression and anxiety among pregnant women. Participants' responses also emphasized the importance of social protection mechanisms, including cash transfers, health insurance, and other support services, in enabling pregnant women to access and sustain maternal health service utilization. Together, these 3 dimensions offered a conceptually coherent and contextually grounded set of priorities to guide the design of the survey instrument and subsequent analysis.

Quantitative Survey

Survey Instrument Development and Administration

Survey questions were based on the 3 selected factors to guide the study: resources, information services, and social support programs. The data were analyzed and presented using descriptive statistics, including percentages and tabulations. Data analysis was based on the 3 factors, as illustrated in subsequent sections.

Resources

.Among the 15 pregnant women surveyed (N=15), the utilization of maternal and child health services was distributed across multiple service areas. Antenatal care, child immunization, general medical care, and nutrition services were the most frequently accessed, each reported by 2 (13.3%) respondents, as shown in Table 4. In contrast, postnatal care, baby delivery, medical laboratory, pharmacy, health education, family planning, and child welfare services were each accessed by 1 (6.7%) respondent.

Table . Distribution of maternal health services[a].

Maternal health service(s)	Values, n (%)
ANC[b]	2 (13.3)
PNC[c]	1 (6.7)
Baby delivery	1 (6.7)
Child immunization	2 (13.3)
General medical care	2 (13.3)
Medical laboratory	1 (6.7)
Pharmacy	1 (6.7)
Nutrition	2 (13.3)
Health education	1 (6.7)
Family planning	1 (6.7)
Child welfare	1 (6.7)

[a]Percentages were calculated based on 15 respondents and redistributed proportionally to total 100%.

[b]ANC: antenatal care.

[c]PNC: postnatal care.

Overall, the findings indicate a relatively even distribution of service utilization, with no single service overwhelmingly dominant. This pattern suggests that pregnant women attending public community health facilities engage with a broad range of maternal and child health services, reflecting the multifaceted nature of care-seeking during pregnancy.

Information Services

The study examined 2 key components within the maternal information dimension: "information needs" and "information sources."

Information Needs

With respect to information needs (N=15), 4 major elements were identified: diet and nutrition, pregnancy-related complications, causes of miscarriage, and physical fitness and exercise. Diet and nutrition and pregnancy-related complications emerged as the leading areas of concern, each accounting for 28% (n=4) of responses. These were followed by causes of miscarriage and physical fitness and exercise (n=3 each), while other categories were minimally reported at 2% (n=1) (see Table 5).

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Table . Distribution of maternal health information needs for pregnant women[a].

Type of information need	Percentage score, %
Diet and nutrition	28
Pregnancy-related complications	28
Physical fitness and exercise	24
Causes of miscarriage	18
Others	2

[a]Percentage scores represent the proportion of respondents reporting each category as a key maternal health information need.

These findings indicate that information related to diet and nutrition, as well as pregnancy-related complications, represents the most critical knowledge areas for supporting preventive maternal health care among pregnant women. The prominence of these needs underscores the importance of implementing more targeted and effective interventions, particularly digital information services, to facilitate faster, secure, and timely dissemination of maternal health information among relevant stakeholders.

The majority of respondents (11/15, 80%) reported that they received relevant information, while 20% (3/15) indicated that they only occasionally received the required information. However, when assessing the adequacy of the information received, 27% (4/15) of women reported that their information needs were only partially met, and 13% (2/15) indicated that their needs were not met at all. These findings suggest that although access to information is relatively high, gaps remain in ensuring that maternal health information is sufficiently comprehensive and responsive to women's specific needs.

Information Sources

A total of 32 participants reported that information services supporting maternal health promotion programs were derived predominantly from human sources (n=21, 67%), including health professionals, CHPs, and family members. In contrast, nonhuman sources, such as books, magazines, and the internet (n=2, 6%), accounted for a smaller proportion of information channels. Notably, health IT tools were not reported as a source of maternal health information (n=0, 0%) as shown in Table 6.

Table . Distribution of sources of maternal health information for expectant mothers in the community[a].

Source of information	Percentage score, %
Health professionals	25
CHPs[b]	19
Family and friends	23
Mass media	17
Books, magazines, and pamphlets	10
Internet	6
Health IT tools	0

[a]Percentages represent the proportion of respondents reporting each source as a channel for receiving maternal health information.

[b]CHPs: community health providers.

According to the study findings, 94% of maternal health information was primarily accessed through traditional sources, including paper-based books and magazines, verbal communication among patients, health professionals, CHPs, and family members, as well as mass media (Table 5). In contrast, internet-based sources accounted for only 6% of responses, while health IT tools were not utilized at all (0%). These findings indicate minimal adoption of digital health technologies or the nonexistence of the relevant infrastructure within the study setting.

With regard to the use of ICT for accessing, sharing, and communicating maternal health information, respondents (N=14) reported varying levels of computer literacy: 67% (n=9) indicated being computer literate, 13% (n=2) reported partial computer literacy, and 20% (n=3) were computer illiterate. The most commonly used digital devices and platforms included mobile phones (n=4, 31.9%), SMS text messaging intervention services (n=3, 23.4%), and television and radio (n=3, 19.4%). Email and social media accounted for 10.6% (n=1) of usage, whereas desktop computers and laptops were least utilized (n=0, 2.1%). These findings suggest that although basic digital literacy is relatively high, the use of advanced digital health tools remains limited, with mobile-based technologies serving as the primary medium for digital communication.

Social Protection and Support Services

The findings illustrate the distribution of social protection services available to pregnant women and children within the study context as shown in Table 7. Food relief and health insurance constituted the most prominent forms of support, followed by cash assistance, security services, and children's assistance. Subsidized housing represented the least provided

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social protection service among those assessed, as shown in the table.

Table . Distribution of primary social protection services offered to pregnant women[a].

Social protection service	Percentage of responses, %
Cash assistance	19
Food relief	22
Subsidized housing	5
Health insurance	21
Security	17
Children assistance	16

[a]Field survey data on primary social protection services offered to pregnant women and children in the study area.

The findings indicate that social protection efforts mainly prioritize immediate needs, particularly food security and health insurance, reflecting a focus on short-term welfare and protection against health-related financial risks. However, lower provision of subsidized housing and moderate levels of cash, security, and child assistance suggest gaps in addressing structural determinants of maternal and child well-being. Strengthening integrated, long-term social protection strategies is necessary to enhance economic stability, safe living conditions, and sustainable health outcomes.

Ethical Considerations

The study received ethical approval (reference: MEEC21-029) from the University of Leeds Research Ethics Review Committee in the United Kingdom on November 14, 2022, prior to its commencement. All relevant ethical considerations concerning key stakeholders, including the researcher, research participants, and the sponsoring organization, were carefully addressed, and the study strictly adhered to these guidelines to ensure compliance and integrity throughout the research process. In addition, informed consent was obtained from all participants before participation, and their confidentiality and privacy were safeguarded through the coding of responses to conceal their identities. Participants were also compensated for their time and any inconvenience or expenses incurred during the study period, including transport and airtime costs.

Results

Key Contextual Factors Influencing Maternal Health Service Utilization

This study highlights the complex contextual factors influencing pregnant women's access to and utilization of digital maternal health services in public community health facilities within underserved LMIC settings. Using weighted scores derived from sorting cards across predetermined theoretical themes, the analysis identified resources (18.81%), information services (17.99%), and social support programs (6.64%) as the most salient dimensions. These findings provide a blueprint for designing frugal ICT4D solutions aimed at promoting equitable access to maternal health care. Participants ranked resources and information as the most significant constraints on service utilization, ranking them first and second, respectively (see Table 3). Although social support was ranked seventh, it was deliberately retained for 2 reasons. First, its theoretical importance is well established, as prior studies indicate that social support strongly influences maternal and perinatal health outcomes as well as care-seeking behavior in LMICs [43,44]. Second, its contextual relevance is supported by stakeholder feedback, which highlights the critical role of social protection programs, such as cash transfers, food relief, and health insurance, in mitigating poverty-related barriers to health care access in Kenya.

We therefore selected resources, information, and social support as the focal dimensions for the survey because they combine high empirical salience with strong theoretical and contextual relevance for maternal health promotion in underserved Kenyan settings. By integrating these structural and social dimensions, the study provides a comprehensive understanding of the multifaceted challenges shaping maternal health service utilization in underserved LMIC contexts.

Resources

The study observed that the dimension of "resources" was critical and a strong influencer of the utilization of maternal digital health services in the study setting. Despite the crucial role of digital technologies in promoting maternal health services to women during the pregnancy period, it greatly depended on the availability of necessary resources. These included the physical infrastructure itself, as well as equipment, devices, and services needed for health facilities and households to operate efficiently. Notably, the needed internet infrastructure and access to and affordability of computing equipment and devices, such as smartphones, laptops, and desktop computers, played a key role toward the utilization of digital maternal health services by stakeholders. Particularly, digital access to such services, including health insurance, recommended nutritional guidelines, and general health education programs, was equally important as far as maternal health promotion was concerned. For instance, out of 14 women, only 10.6% (n=2) of them had access to email and social media, whereas 2.1% (n=0) owned a desktop/laptop, and 31.9% (n=5) had access to a smartphone. Furthermore, the majority of women were not covered by the National Health Insurance Fund to access maternal health services in government health facilities, hence a lack of UHC. Therefore, in underserved LMIC settings, new strategies should be developed to address resource scarcity and promote equitable access to maternal digital technologies, thereby enhancing health care delivery.

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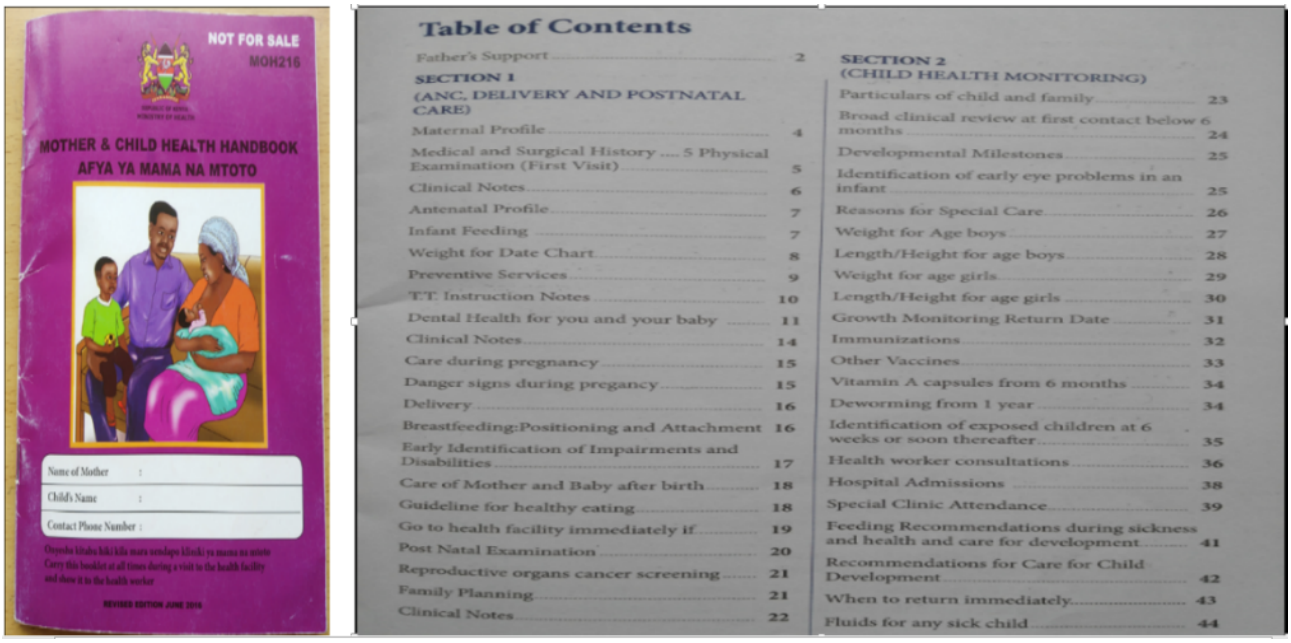
Information Services

The study observed 2 significant categories of information services provided by the government to promote and utilize maternal health services/programs. These include maternal health information through the Ministry of Health and information on existing social protection services through the Directorate of Social Protection. These categories of information were considered vital for promoting and utilizing maternal health programs among pregnant women, underscoring the importance of the findings. The study noted that the nature of the information services offered by the 2 government departments was mainly paper-based/manual, with a smaller percentage in digital form. Paper-based information services were prone to faster deterioration and destruction, thus losing vital patient health data/information. Women participants expressed frustration regarding the mother and child booklet (shown in Figure 2), the only government-approved standard document containing the individual maternal profile.

Figure 2. Antenatal care (ANC) booklet with maternal profile contents.



The booklet was used to manage and share maternal health information, including recording clinical notes and serving as a reference for clients and health professionals during antenatal visits and at the point of care. However, the booklet was prone to loss or destruction by natural causes, such as fire outbreaks [14]. Generally, paper-based information services and sources were the order of the day as shown in Figure 3. The major limitation of manual records is that they are prone to faster deterioration by agents of destruction, leading to the loss of vital patient information and fragmentation of health information records and systems.

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Figure 3. Pregnant women attending an antenatal care (ANC) health education session at a local community health facility.

Social Support Services

To alleviate the vulnerability of pregnant women/mothers and children from poor households, the government initiated social protection programs/services to supplement maternal health promotion services, including the Nutrition Improvements through Cash and Health Education initiative program. The program provided cash assistance and transfers to enable pregnant women and nursing mothers to access basic needs, such as food and health care.

Discussion

Digital Solutions to Address Resource Limitations

Our study findings confirm the existence of resource-limitation challenges arising from inadequate digital health care infrastructure, which is insufficient to meet the needs of women and children [14]. Long queues at health facilities indicate an acute shortage of both health infrastructure and personnel to address the demand for maternal health services. Therefore, there is a critical need to provide affordable, cost-effective, timely, secure, and efficient digital information services to promote maternal health.

Affordable digital solutions have the potential to significantly enhance access to maternal health promotion services, including health education and telemedicine. Such interventions can facilitate lower-cost consultations and support better personal care decisions, ultimately improving health outcomes for pregnant women and children in marginalized communities within LMICs. These improvements can be realized through the 3 key dimensions of maternal health promotion: resources, information, and social support services.

Resources

Among the reasons for partial or incomplete access to services are long patient queues in public facilities, long geographical distances between the area of residence and the health facility, poor or lack of transport infrastructure, and the unaffordability of health services for women [14,45]. The majority of the women were merely homemakers, and therefore, their low economic status meant that most of them could only afford health services to a limited extent. The situation calls for finding ways to address resource constraints and enable equitable access and utilization of maternal health services toward enhancing UHC [3].

Information Services

The findings confirm a lack of integration and collaboration among different stakeholders and thus information silos, making sharing and communication of health information difficult [46,47]. This situation underscores the need for digital maternal health information services, rather than traditional forms, to better address fragmentation. The dimensions of information

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needs and information sources played a critical role in determining the nature of information services provided, whether manual or digital.

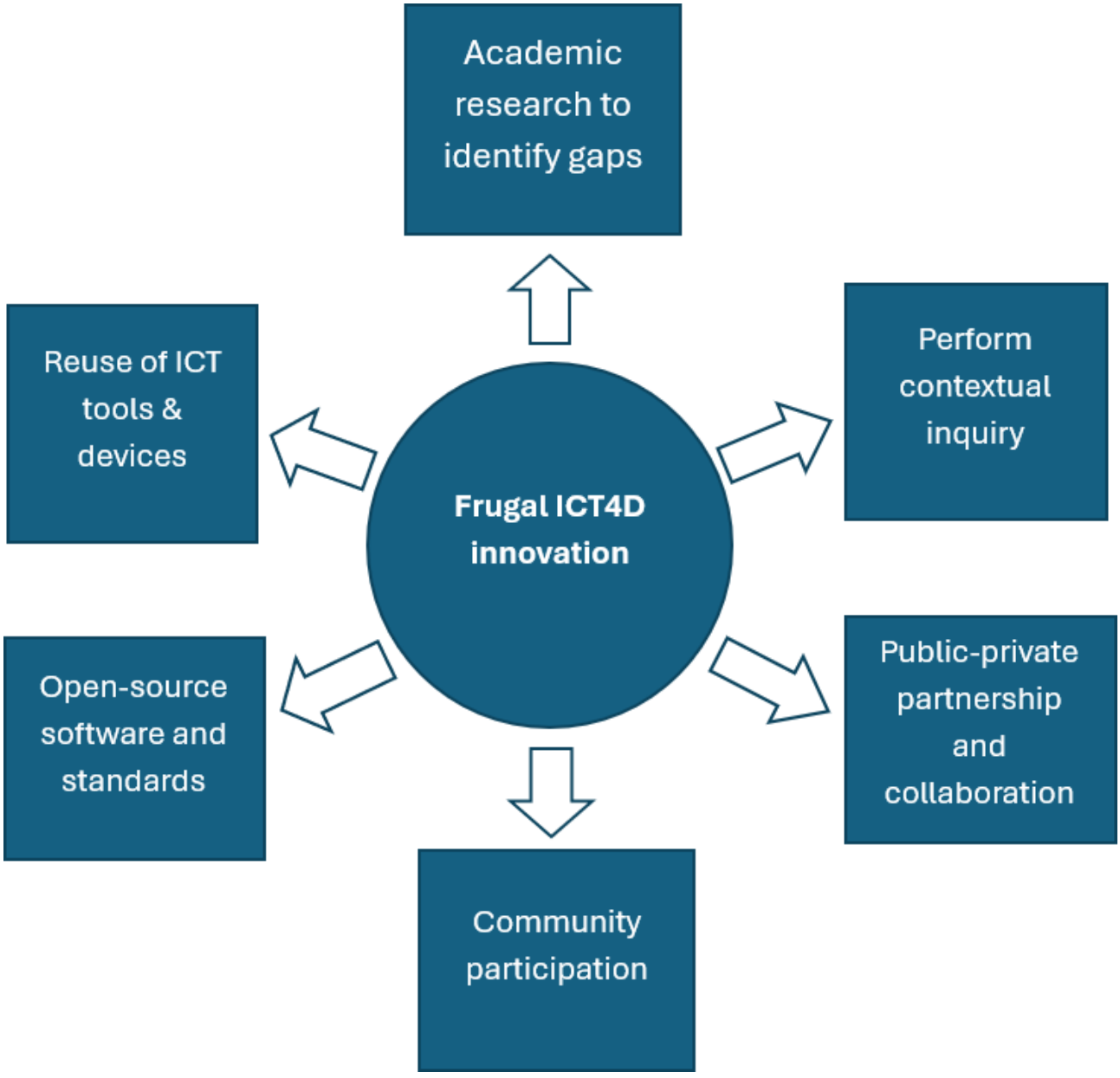
Social Support Services

According to the findings, such programs, including relief food, health insurance, and cash transfer services, were most needed, suggesting high levels of poverty in many households. This situation increases vulnerability to poverty, hence exposing pregnant women and children to the risk of poor health care during pregnancy and postnatal care. Understanding the importance of these social support services will help you empathize with pregnant women's challenges.

Proposed Research Framework

Based on the study findings, the proposed solution (frugal-oriented ICT4D innovation framework) comprises six dimensions, namely (1) academic research and development (R&D), (2) contextual inquiry, (3) public-private partnership (PPP) and collaboration, (4) community participation, (5) open-source software and standards, and (6) reuse of ICT tools and devices as shown in Figure 4. The conceptual model is aligned with the principles of FI and ICT4D to create sustainable, low-cost digital innovations that promote the delivery of maternal health services to underserved populations in LMIC settings.

Figure 4. Frugal-oriented information and communication technologies (ICTs) for development (ICT4D) innovation framework.



Academic R&D

R&D is a critical requirement for innovation toward economic development [48]. Academic research should be leveraged to identify gaps in ICT4D for health, tap students' skills and staff expertise to deliver sustainable, low-cost digital health interventions in frugal settings, and promote maternal health. IT/information systems research projects, community ICT4D initiatives, and industrial attachments for graduate and undergraduate students should be leveraged under the

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supervision of senior academic staff to deliver affordable digital innovations. This will help lower the costs of developing or acquiring digital health solutions for the purpose of affordability [35] rather than hiring full-time personnel. Frugal ICT4D innovation emphasizes the need to build intersections between technical, social, and institutional innovations, particularly on how their material properties enable the FDI processes [49].

Contextual Inquiry

ICT4D research studies should be contextualized to deliver context-specific innovations that maximize impact in the context of use [50]. This enables the use of what is locally available and takes into consideration critical contextual factors, including people's culture, socioeconomic situation, technological infrastructure, etc, which facilitate considerable savings [49], while at the same time creating meaningful ICT4D innovations that are responsive and fit into existing work practices and social context.

PPP and Stakeholder Collaboration

A PPP and health stakeholder collaboration with clear business obligations between public and private partners should be set out under constitutional and contractual terms to raise the necessary resources to develop products and services [21,51]. It involves working collaboratively among different stakeholders and partners (individuals, groups, and organizations) who may have specific interests in the project [52]. Particularly, internal stakeholders (health professionals and providers/hospitals) and external stakeholders (government, patients, and community workers) should be engaged to alleviate predominant resource constraints by contributing, in the form of sharing, their inputs in terms of knowledge, skills, and resources [53]. This will involve industry-academia and community collaborations focusing on underserved population groups and communities in LMICs to achieve sustainable community development through ICT4D innovations [54]. Collaboration enables open innovation for the public sector, which requires governments to listen more closely to citizens and other end users of digital innovations who are the beneficiaries of new public services. This helps overcome barriers to open innovation, such as immature methods for participation, inadequate understanding of how to formulate appropriate strategies for developing public sector innovations, institutional barriers to innovation and collaboration, weak innovation culture, poor funding, and a technology-deterministic approach to innovation [49].

Community Participation

The involvement of community members is critical for planning, decision-making, implementation, and monitoring of health projects that directly affect their health and well-being [8]. The approach enables context-specific initiatives by empowering local people and ensuring that development efforts are tailored to the community's local needs and priorities, including positive health outcomes [41]. Through community participation, members build relationships with public institutions and individuals, giving their community access to valuable external resources, such as funding and social support, thereby strengthening social capital.

Open-Source Software and Standards

Given the underserved nature of communities in LMIC settings, with predominant resource constraints, free, that is, open-source, software tools should be optimized, such as Ushahidi crowdsourcing, which allows users to collect, analyze, and visualize information at a lower cost [47,55]. Open-source tools and standards are attractive to FDI because they are free to download and use, can be optimized, and significantly reduce software development and acquisition costs to address resource limitations, thereby positively impacting the community. Moreover, the open-source software easily conforms to open standards and is thus universal, unlike proprietary software [34,49].

Reuse of ICT Tools and Devices

According to Peyal et al [33], FDI implies a scenario in which innovators harness the power of readily available digital technologies to develop new products and services that use fewer resources to deliver greater value. This entails using ICT tools and devices with frugal characteristics to make them inexpensive [49], which involves reusing what is available to minimize wastage to ensure resource efficiency. ICT adoption significantly influences FI, such that greater levels of frugality in ICT4D innovations increase user satisfaction [56]. To reduce the cost of development or acquisition, there is a need to reuse, combine, and recombine computing resources (software, hardware, and networks) to create new products and services. This fosters affordability and accessibility of digital health services within contextual constraints, delivering economic and social values [49,57].

Study Limitations and Future Research

The selection of the key informants was mainly performed purposefully, based on the role(s) of each participant in the research context, including health care policymakers, pregnant women/mothers, health professionals, CHPs, and ICT experts. Other essential criteria might not have been considered. Furthermore, the study was mainly conducted in government health facilities and thus excluded the private sector, where some of the participants received health care services. This may have otherwise provided good responses and insights into the study, enabling comparison and improving the validity of the findings. In addition, it is essential to note that the study findings were based on stakeholders' responses on maternal health from the perspectives of resources, information, and social protection services in health facilities in Nairobi and Kitui counties. To validate the findings outside the study contexts, future studies should cover a broader geographical scope by extending the study to more counties and including both public and private facilities. The relevance of these study findings outside the original context is not guaranteed; hence, there is a need to verify them empirically across various underserved settings in LMICs.

Conclusion

Underserved communities from LMIC settings, such as SSA, live in abject poverty, a scenario that consequently denies the majority of individuals and households a chance to access basic health care, including pregnant women and children. This is

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attributable to the inability to afford health care services, which compromises health and well-being and places marginalized communities at higher risk of poor health outcomes. Despite efforts to create digital innovations to enable health promotion toward achieving SDG 3, little progress has been made, particularly in maternal health. An estimated 800 women die globally every day from pregnancy and childbirth-related complications, some of which cases are preventable. There is low adoption of existing expensive digital health innovations, and thus, they lack cost-effectiveness in an LMIC context. Therefore, these calls for adopting cost-effective approaches, such as FI and ICT4D, to redesign and create sustainable, low-cost digital innovations to mitigate resource constraints and deliver greater value. The proposed research framework can serve as a blueprint to guide the design and implementation of sustainable low-cost ICT4D innovations to increase access to and promote health, including maternal health, for the underserved in LMICs toward achieving SDG 3.

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Data Availability

The data supporting this study are available in Multimedia Appendix 1.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Data presenting the diet sheet, suggested stakeholders to be involved in proper maternal health care, and stakeholder mapping exercise.
[XLSX File, 72 KB - formative_v10i1e77330_app1.xlsx]

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Abbreviations

CHPs: community health providers
FDI: frugal digital innovation
FI: frugal innovation
ICT: information and communication technology
ICT4D: information and communication technology for development
LMICs: low- and middle-income countries
PPP: public-private partnership
R&D: research and development
SDGs: Sustainable Development Goals
SSA: sub-Saharan Africa
UHC: universal health coverage

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Surgeons' Perceptions on the Utility of a Conceptual Novel Force Sensor at the Surgeon-Tool Interface: Formative Interview Study

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Abstract

Background: Real-time force feedback is essential in many surgical specialties. While previous research has focused on force measured at the tool-tissue interface, little work has explored the benefits, limitations, or opportunities of measuring force at the surgeon-tool interface.

Objective: This study aims to explore scenarios in which surgeons from different medical specialties and experience levels could benefit from receiving feedback on the force exerted at the surgeon-tool (or surgeon-tissue) interface.

Methods: Exploratory qualitative research was conducted through interviews with medical practitioners (N=15). This study explored perceptions of a conceptual novel force-sensing surgical glove that could provide real-time feedback in terms of usability, utility, value, and limitations. Opportunities and barriers to implement a sensor of this type in clinical practice were also explored. Participants had experience in anesthetics, dental surgery, plastic and dermatological surgery, general surgery, and obstetrics and gynecology, as these surgical fields all require precise feedback on exerted forces.

Results: Participants identified two key areas where a force sensor could yield significant benefits: (1) it could enhance surgical training through objective skill assessment and quantifiable feedback, and (2) it could provide valuable insights into the forces applied during practice, particularly in scenarios where other sensory feedback is masked. Participants appreciated that a sensorized glove that can provide real-time force sensing at the surgeon-tool interface would allow for continued feedback irrespective of the instrument, and integrate seamlessly into their current surgical workflow. Furthermore, as surgeons in some specialisms, for example, dental or obstetrics and gynecology, perform manual tasks, having a sensorized glove would provide feedback in instances where they are physically manipulating tissue. However, participants expressed concerns about accurately defining safe force ranges due to the variability in patients' anatomical structures and the potential interference with tactile sensation.

Conclusions: Surgeons from various clinical practices agreed that force sensing at the surgeon-tool interface could be valuable and provide them with optimal versatility as to when they would adopt force sensing. A sensorized glove could improve decision-making and surgical outcomes when other sources of information guiding force exertion are masked. Conversely, it could be detrimental when the organic information to guide force exertion is distorted when using the sensor. While the choice between interaction modalities is dependent on the accessibility of different senses during surgery, design suggestions as to where sensors are best placed on a sensorized glove are dependent on the instrument used or the type of manual procedure conducted.

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KEYWORDS

haptics in surgery; force feedback; sensorized glove; user requirements; surgeon-tool interface

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Introduction

When treating medical disorders operatively, surgeons must apply physical force to manipulate human body tissue [1]. Applying an appropriate amount of force is pivotal to the success of surgeries since excessive or insufficient force application can damage bodily tissue or prevent task completion [2]. Nonetheless, applying appropriate force levels poses a significant challenge for novice and expert surgeons [3,4]. Thus, surgeons rely on real-time feedback to determine what force to exert depending on the type of surgery [5,6].

The importance of real-time force measurement in surgery has long been acknowledged and has been deemed desirable in many medical specialties, including plastic surgery [7], anesthetics [8], dentistry [9], and obstetrics and gynecology [10], demonstrating the importance of force sensing across medical specialties.

In recent years, scientists have investigated the usability of sensors attached to diverse surgical tools that quantify the pressure surgeons apply to their patients' tissues [2,3,11,12]. Such force-sensing devices' applicability is limited by issues around biocompatibility and sterilization, long-term stability, and adaptation to surgical tools [13]. In response, researchers have developed novel surgical tools with smart force-sensing abilities [14]. However, such force-sensing systems only enable force measurement for individual surgical instruments [15]. This presents high costs, and inconsistencies between instruments' force sensing could distract operators; for example, each instrument may use a different method of visualizing and reporting force measurements [13].

Layard Horsfall et al [16] developed a piezoresistive sensor that can be attached to the fingertips of surgical gloves, similar to that in Figure 1. They aim to address the limitations of existing intraoperative force measurement methods and enable a practical, effective, and affordable method to measure intraoperative forces [17]. Additionally, the glove is designed for sterility and provides real-time feedback of the force being applied to instruments. To evaluate the glove, Layard Horsfall et al [16] assessed expert and novice surgeons' force exertion during a grape dissection task, which is a common surrogate task performed by neurosurgeons. When mounted on a surgical glove, they found that the sensor could detect statistically significant differences in the amount of force expert and novice surgeons applied to a scalpel during the task, revealing significant potential for improvement in surgeons' application of intraoperative force. However, the magnitude of intraoperative forces required during surgery varies significantly between and within surgical specialties depending on the maneuver performed, the tissue manipulated, and the instrument used [1]. Therefore, for a novel sensor to be beneficial to specific surgical specialties, it is important to identify which procedures within those specialties force feedback would offer the most value. Based on this information, a sensor's feedback can be customized to account for the variations of intraoperative forces applied across and within surgical specialties.

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Figure 1. An example of a novel force sensor surgical glove prototype.

Existing literature proposes that measuring manually applied forces carries benefits across multiple areas, including surgical practice, training, and assessment of junior staff.

Most surgical procedures require the exertion of light touch. For example, the analysis of error types by Tang et al [18] made by surgical trainees during laparoscopic cholecystectomies revealed that more than 50% of errors emanated from participants exerting excessive force. These findings led several studies to investigate how real-time feedback on forces applied to human tissue affects force exertion. Golahmadi et al [1] conducted a systematic review of 6 studies that compared the amount of force applied when feedback was provided versus when no feedback was provided, concluding that forces decreased when feedback systems existed. These results also indicate that real-time feedback on exerted forces could improve surgery outcomes.

Besides direct benefits on surgical outcomes and patient safety, force sensing can substantially improve the training of novice

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surgeons who currently learn through subjective feedback from their mentors [19,20]. As tolerance for operating errors decreases, the demand for accurate force exertion training methods is growing [21]. Previously, real-time feedback systems for manual force were found to optimize novice surgeons' operating techniques. The impact of real-time force feedback during training on surgical trainees' tissue-handling learning curve was assessed [22]. In a randomized controlled trial, 72 medical students conducted 6 different suturing tasks under real-time force feedback, postprocessing force feedback, or no force feedback (control). Students significantly improved tissue-handling performance when force feedback was present.

In addition to its role in surgical training, force sensing could provide a quantitative metric of surgical skill for objective assessment of the outcome quality of surgical tasks [23,24]. Cundy et al [20] developed a force-sensing box trainer for laparoscopic surgery and validated different force variables as indicators of surgical skill for 5 curriculum tasks. The overall magnitude of the force exerted during the task indicated the participants' experience level, highlighting the suitability of force measurement as an assessment method.

For the force sensor to be applied during specific medical procedures, it must account for the variations of intraoperative forces between and within surgical specialties.

Golahmadi et al [1] reviewed studies conducted in various surgical specialties that measured forces exerted at the tool-tissue interface. They found significant differences in average and maximum forces applied between different surgical specialties when averaging across tasks and models. Average forces found in ophthalmology (0.04 N), neurosurgery (0.68 N), vascular surgery (0.07 N), and cardiothoracic surgery (1.47 N) were significantly smaller than those recorded in general surgery (4.67 N), ear, nose, and throat surgery (8.49 N), obstetrics and gynecology (8.69 N), and urology (9.79 N). These findings emphasize the need to investigate the potential value of a sensor glove in different surgical specialties.

The force applied during surgery largely depends on the specific maneuver medical practitioners perform. Sugiyama et al [25] investigated forces applied using bipolar forceps during frequently performed neurosurgical tasks to build a catalog of force profiles. They quantitatively compared forces exerted during different neurological tissues' coagulation, grip, division, and dissection and found that force measurements differed statistically significantly between selected maneuvers with bipolar forceps. These findings highlighted the need to determine safe force ranges for surgical maneuvers.

Across surgical specialties, forces applied differ significantly due to the various manipulated tissues. Golahmadi et al [1] compared the mean average and the mean maximum force applied to the 4 main tissue types (nervous: n=17; epithelial: n=18; muscle: n=3; connective: n=10) and discovered significant differences between the intraoperative forces applied. Nervous tissue received the smallest mean average (0.4 N) and mean maximum (1.7 N) intraoperative force, followed by epithelial and muscle tissue (mean average: 3.8 N, 4.1 N; mean maximum: 9.7 N, 6.7 N), and connective tissue received the highest mean average (45.8 N) and mean maximum force (347.9 N). This variance of forces exerted across human body tissues highlighted the need to identify where the sensor could best be applied.

The forces required to manipulate human body tissue can also vastly differ inter- or intraindividually. Fernee et al [26] investigated the variation of dental tissues within and between 30 healthy individuals' first incisor and second premolar teeth using Bayesian multilevel modeling and revealed that dental tissues differed in volume and surface area at the individual and tooth levels. Furthermore, Di Stasio et al [27] investigated normal values of epithelial thickness for 6 different anatomic locations in the oral cavity using a sample of 28 healthy patients, discovering that the SD of mean thickness exceeded 10% of the mean value for 5 of 6 individual anatomic locations.

Each surgical instrument demands specific magnitudes of force since the instrument's handling and the force transfer to the tissue vary between tools. A review by Golahmadi et al [1] demonstrated that the intraoperative forces that surgeons apply differ according to how they use their instruments.

However, beyond the tool-tissue interface, there is also the surgeon-tool interface, where the sensor is placed on the surgeon to measure forces applied to the tool. Rosen et al [28] conducted a study exploring the forces applied at the surgeon-tool interface in teaching scenarios as an objective measurement of skill in minimally invasive surgery and found that experienced surgeons apply much less force and torque than novice surgeons, which was later corroborated by the study of Layard Horsfall et al [16]. Furthermore, Aggravi et al [29] compared intraoperative forces exerted at the surgeon-tool interface using bipolar forceps, a spatula, and a suction tool. They found that forces exerted by the thumb, index, and middle fingers differed for the different tasks conducted with the different instruments. These findings imply that the local spread of exerted force must be considered in creating real-time feedback for individual maneuvers. Nevertheless, some interventions, such as minimally invasive laparoscopic surgery, require force from surgeons in different ways than manual force [30]. However, few studies have explored force sensing at the surgeon-tool interface. Additionally, in some instances, surgeons may perform manual interactions with the patient, physically interacting with tissue, which is described as the surgeon-tissue interface. In this study, we are treating these as equivalent. Thus, from this point forward, when we discuss the surgeon-tool interface, we are also including the surgeon-tissue.

While most studies have investigated the use of intraoperative force through measurement at the tool-tissue interface, there is little work that has explored the benefits, limitations, or opportunities of measuring force at the surgeon-tool interface across and within different medical specialties. Thus, it is critical to investigate in which surgical scenarios operators from different medical specialties can benefit from real-time force measurement at the surgeon-tool interface.

This study aims to explore these scenarios in which surgeons from different medical specialties and experience levels could incorporate the use of a conceptual novel force sensor that would provide real-time feedback on the force exerted at the surgeon-tool interface.

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To address this issue, we conducted a series of semistructured interviews. Our approach consisted of showing participants a concept video of a novel force sensor and generating conversation as to how such a technology could be adopted into their clinical practice. This work is a formative, exploratory investigation intended to generate initial insights into an underresearched area and inform future research and design iterations.

Methods

This study comprised 30-minute-long semistructured interviews with surgeons from 5 different medical specialties. Semistructured interviews allowed us to elicit detailed narratives [31] and a succinct postinterview generalization of insights beyond the borders of surgical specializations.

Ethical Considerations

Ethics approval for this study was granted by the local ethics committee (reference UCLIC_2022_002_Costanza). Informed consent was obtained from all participants, who were provided with an information sheet, and all data were anonymized to maintain participant privacy. Additionally, each participant received approximately US $25 Love2Shop (the United Kingdom) or approximately US $26 Amazon (Germany) voucher for contributing to this research.

Participants

Through convenience sampling, 15 medical practitioners with operative expertise (male: n=9 and female: n=6) were recruited from specialties where force application is critical and varied (soft vs hard tissues and instrumental vs manual handling). Participants came from anesthetics (2/15, 13%), dental surgery (4/15, 27%), general surgery (3/15, 20%), plastic and dermatological surgery (3/15, 20%), and obstetrics and gynecology (3/15, 20%). At least 2 participants were sampled from each clinical background to ensure a balance between representing a broad range of medical specialties and enabling aggregation of interview results. Participants were recruited from Germany (9/15, 60%) and the United Kingdom (6/15, 40%). The only exclusion criterion was participants' clinical experience, which had to be at least 1 year in practice and not exceed 2 years out of practice (mean 16.5, SD 12.4 years). Experience was recorded for descriptive purposes only and was not used as a proxy for surgical skill. Table 1 presents an overview of the participants.

Table . Overview of participant characteristics including specialty, sex, country, and years of experience within their surgical specialty.

ID	Specialty	Sex	Country	Experience (years)
AN1	Anesthesia	Male	Germany	25
AN2	Anesthesia	Male	United Kingdom	6
DS1	Dental surgery	Male	Germany	30
DS2	Dental surgery	Male	Germany	35
DS3	Dental surgery	Male	Germany	30
DS4	Dental surgery	Male	Germany	39
GS1	General surgery	Male	Germany	19
GS2	General surgery	Male	Germany	15
GS3	General surgery	Female	Germany	2
PD1	Plastic surgery	Male	Germany	10
PD2	Dermatological surgery	Female	United Kingdom	4
PD3	Plastic surgery	Female	United Kingdom	6
OG1	Obstetrics and gynecology	Female	United Kingdom	7
OG2	Obstetrics and gynecology	Female	United Kingdom	14
OG3	Obstetrics and gynecology	Female	United Kingdom	5

Introductory Video for Concept Familiarization

Participants did not interact with a physical prototype during the interview, as each surgical group would have required a different prototype relevant to their specialism, and this formative study sought to better understand user requirements for such prototypes. Therefore, feedback was based on a conceptual video demonstration of the novel force sensor. Each interview was introduced by showing a 2-minute video (Multimedia Appendix 1) to provide participants with a shared understanding of the concept rather than influence attitudes toward a specific implementation. The video contained spoken information on the sensor's background, aim, functionality, and use in a clinical context and contained footage of the sensor applied to a surgical glove being used by neuroscientists in a grape dissection task provided by Layard Horsfall et al [16]. The video also showed moving images of the sensor being pressed alongside a real-time visualization of the force feedback (Figure 2). Two video versions were created, one with German and one with English audio, depending on the participant's first language. After reviewing the video, participants were invited to pose questions about the functionality or use of the sensor glove.

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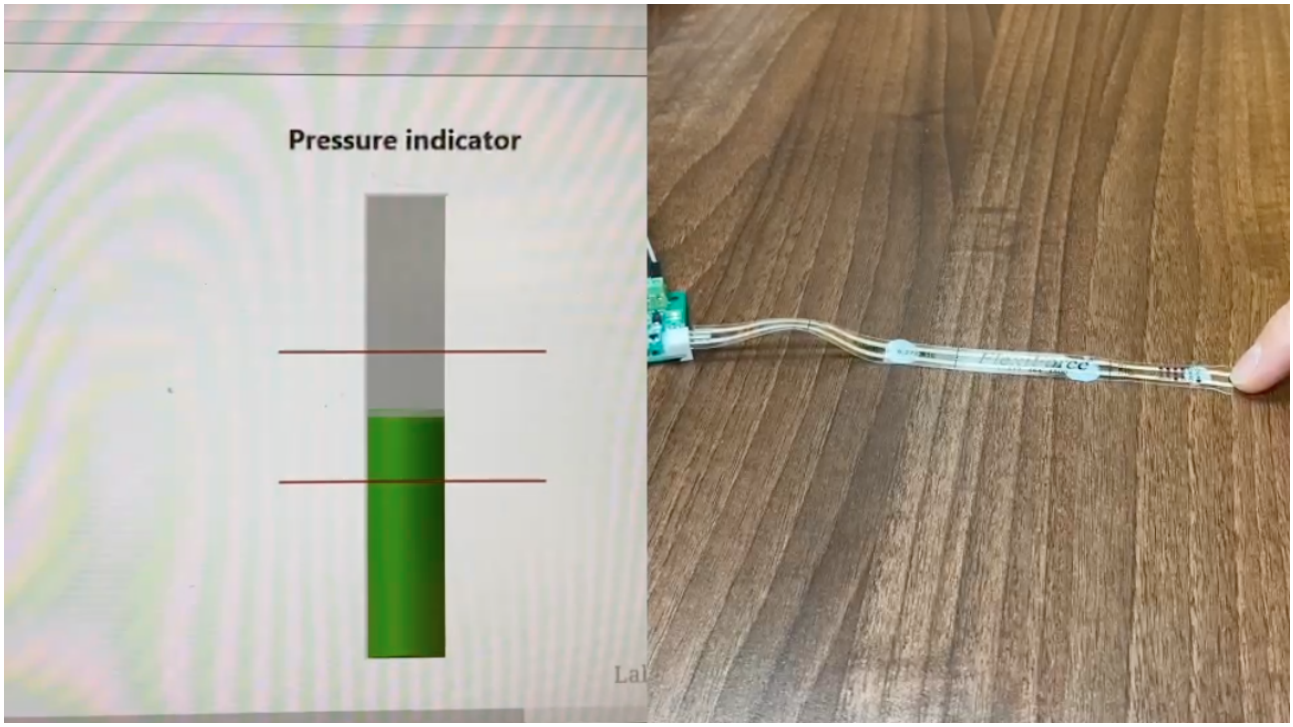
Figure 2. Video excerpt showing real-time feedback visual.



Study Design

The first 9 participants were asked to provide a detailed description of their most performed operative procedure prior to the interview to help the interviewer prepare. However, three of the first six participants did not provide this information, and requesting the information led to loss of contact with three further prospective participants, so this phase of the study was subsequently removed. The interviewer (who was not a medical professional) took steps to familiarize themselves with the relevant surgical procedures in preparation for each interview. For later participants, instead of discussing a predetermined procedure, they were asked to identify maneuvers in which applying appropriate force is crucial. This change did not appear to impact the results, as participants were still asked to discuss the potential use of the sensor within their daily practice, and it allowed participants to steer the discussion toward use cases they wanted to propose.

At the start of the interviews, surgeons participating online received an information sheet to read via email and a link to a digital consent form hosted on REDCap (Research Electronic Data Capture; Vanderbilt University) [32]. Those participating in person received a printed information sheet and signed their informed consent through REDCap on the interviewer's laptop. Subsequently, participants were briefly reminded of the research goal and invited to ask questions about the study. All interviews were recorded using Microsoft Teams.

The semistructured interviews were conducted in person (n=1) or online using Microsoft Teams (n=14), depending on the participant's preference, and lasted approximately 30 minutes to facilitate the recruitment of time-poor experts. As this was an exploratory study, no predefined end points were set; instead, interviews were designed to elicit broad insights into usability, opportunities, and barriers. In addition, as a formative investigation, no prototype was available for direct observation or usability testing. A semistructured interview guide (Multimedia Appendix 2) was used, containing open-ended and probing follow-up questions to gain in-depth insight into the medical practitioners' perspectives on the potential use of a novel sensor. The interview comprised three phases: previous experience with force-sensing mechanisms, pressure-sensitive maneuvers, and potential benefits and limitations of a force sensor glove.

To begin, participants were asked to disclose their operative expertise and describe any experience with force-sensing mechanisms. Participants were then encouraged to identify challenges they faced during their work related to the exertion of manually applied forces. These questions aimed to help participants think about scenarios in which a novel force sensor could help them apply appropriate intraoperative force. The central part of the interview focused on pressure-sensitive maneuvers that they had identified before or during the opening phase of the interview. The interviewer prompted participants to think about how they might apply a novel sensor in their existing workflow and describe how it would affect their practice and added probing questions to understand participants' motivation to use or not use a force sensor. Finally, participants were asked to consider the surgical glove's benefits and limitations in the context of surgical training and assessment to determine whether a force sensor might have value in training junior surgeons. Additionally, participants were asked to consider the benefits and drawbacks of attaching a force sensor to the hand instead of having a sensor on the instrument and to debate the installation of different feedback modalities. Before finishing the interview, participants had the opportunity to make final remarks and ask any remaining questions.

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Data Analysis

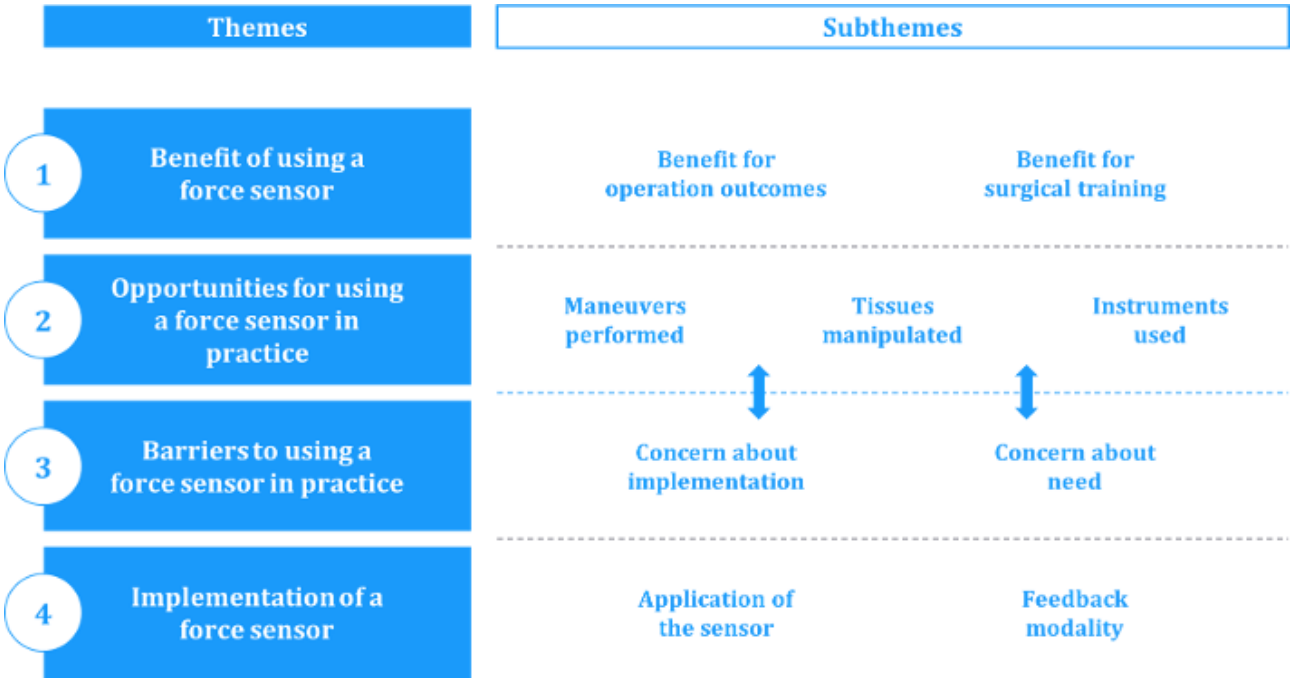
The first author (BM) transcribed each interview using Microsoft Word and manually translated the transcripts of interviews held in German to allow for their analysis in English and better comparison across the dataset. The first author conducted a thematic analysis of the transcripts using NVivo (version 14.23.0; Lumivero). Initially, the transcripts were reviewed to establish a comprehensive understanding of their content. Initial codes were generated inductively, wherein meaningful segments relevant to the research aim were identified and labeled. These codes were then compared, grouped, and refined using affinity mapping to identify potential themes from the data. Subsequently, the identified themes were iteratively reviewed and validated with the original interview data to ensure their accuracy and relevance. Finally, the themes were refined. and named to create a comprehensive representation of the surgeons' perceptions of usability requirements for a novel sensor. The analysis was inductive; thus, no predefined codes were used, and measures such as theoretical saturation, which presuppose a postpositivist approach to analysis, are inappropriate [33,34].

Results

Overview

In total, four top-level themes were identified: benefits, opportunities, barriers, and deployment of a force sensor (Figure 3).

Figure 3. Overview of themes and subthemes.



Theme 1: Benefits of Using a Force Sensor

All participants identified a range of ways in which a novel force sensor could benefit their work. The main anticipated benefits were its improvement of operative outcomes and the training of prospective surgeons.

Benefit for Operation Outcomes

Participants across different medical specialties expected that a novel sensor would enhance operative outcomes by offering real-time feedback on the surgeons' exerted force. All participants identified scenarios within their disciplines where the application of inappropriate force causes harm to patients or prevents task completion. Therefore, all participants predicted that real-time feedback about their exerted force could increase patient safety within their operating environment: "I think if you know exactly how much force you're applying, that may make you rethink what manoeuvres you're doing to deliver that baby" (OG2).

Participants agreed that providing real-time feedback on exerted force using a sensor could positively affect patients' health. Beyond patient safety, several participants indicated that the provision of force feedback could enhance their operation speed. During specific procedures, practitioners must carefully approach the correct magnitude of force; suitable force feedback would enable them to skip time-expensive approaches to reach adequate force levels. This would improve efficiency and effectiveness and could also create financial gains:

> *I have to decide whether I can sit down and work on it very slowly and carefully for half an hour, which is of course completely uneconomical. Or I just apply the appropriate force and it goes faster.* [DS2]

While the feedback could increase surgeons' effectiveness and efficiency, it could also create a psychological benefit, which enhances their operations' outcomes. For example, many surgeons reported that receiving information about how much force they are applying would boost their comfort and provide assurance about their performance: "It is a problem in today's increasingly justiciable times that we still rely on feelings" (AN1). Furthermore, participants reported that their increased confidence could impact their operative performance positively. Finally, the indirect force feedback could also benefit operative

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outcomes in terms of patients' psychological well-being during surgery. That is, feedback on the surgeons' exerted force was proposed to comfort patients who are not under anesthesia: "It can be a tool for trust building in scenarios where women have been previously sexually assaulted or had very traumatic internal examinations" (OG3).

In summary, the interviews demonstrated that surgeons could profit from using a novel force sensor during practice to apply appropriate magnitudes of force, which could enhance operative effectiveness and efficiency.

Benefit for Surgical Training

Offering real-time feedback on surgeons' exerted force through the use of a novel sensor was identified to benefit the training of junior doctors, as existing medical training methods are inappropriate and unstructured. Participants reported that, in most cases, junior doctors learn to perform surgery through "learning by doing" (GS1). Unsurprisingly, the current shortcomings of surgical training for junior doctors were judged problematic by participants who feared the outcomes of untrained surgeons' mistakes:

> *And of course, you don't want to endanger a patient just so that the new generation learns something. [...] but that's the truth [...] at the moment.* [GS2]

Furthermore, the interviewees criticized that, where surgical trainees are learning in practice, the present teaching style is dominated by the apprentice model, whereby senior surgeons instruct junior surgeons through qualitative feedback, which is exceptionally challenging for trainees due to individual differences between trainers and trainees. Most participants agreed that there is a demand for objective feedback about their exerted force. Thus, the prospect of a force sensor that generates real-time feedback on forces elicited enthusiasm for its implementation in training inside operating theaters:

> *That's where I see the advantage because they are still a bit lost, they don't really have any benchmarks and they have to gain experience, which may be unnecessary, and patients have to suffer. So yes, maybe you can improve that with such a pressure sensor.* [DS3]

While many participants acknowledged the benefit of the sensor in practical training, others proposed that the sensor could be used in simulation training. According to the interviewees, existing methods and models for simulation training are unavailable, unsuitable, or unaffordable. Two-thirds of all participants expressed that a novel force sensor could demonstrate high usability in simulation training outside the operating theater. The main benefit would be that junior surgeons could develop their tactile senses and learn how much force is appropriate in specific situations before applying their skills to actual patients: "I think it would be an absolutely incredible tool because that way you could practice as much as you want before you apply it to a human being and potentially sever that facial nerve" (PD2).

Altogether, the interviews demonstrated that junior practitioners could profit most from a novel force sensor as a source of objective feedback on how much force they are and should be applying. Thus, they could use it to refine their skills outside and to guide their forces inside the operating theater.

Theme 2: Opportunities for Using a Force Sensor in Practice

The second theme describes the opportunities to use a force sensor in practice. Participants rated the application of the sensor glove as meaningful depending on the characteristics of their maneuvers performed, tissues manipulated, or instruments used.

Maneuvers Performed

Across all medical specialties and experience levels, participants could imagine using a force sensor to assist them in various maneuvers in their work and identified maneuver-specific characteristics. Almost all participants expressed that they would appreciate an additional source of feedback in procedures where there is no external indication of how much force they are applying; thus, they must rely on their experience to determine appropriate magnitudes of pressure: "From my experience, it's just based on what you've experienced previously because it's a blind procedure, you can't see what you're doing" (OG1).

The interviews uncovered different reasons for surgeons' limited awareness of their exerted force. For example, visual feedback from the surgical site can be obstructed or masked where sensitive tissue is hidden through other tissue or blood flow at the operating site: "They're bleeding, and you can't see whether you're in the axial direction of the root" (DS4).

In some procedures, surgeons may be reliant on auditory feedback from patients to determine whether the force applied is appropriate. However, the use of anesthesia may result in application of inappropriate force not being apparent until after the anesthesia has worn off: "I can only say that if I don't have any complications postoperatively, then obviously the procedure was fine, there's not much more feedback there really" (DS3).

Thus, there is a significant opportunity to apply a force sensor during maneuvers where surgeons are unaware of their exerted force due to the absence of alternative sensory input such as direct visual or auditory patient feedback.

Tissues Manipulated

Procedures that require force sensing to avoid harm to the patient are usually defined by the practitioners' interaction with particular bodily tissue. Participants frequently referenced the opportunity to apply a novel force sensor when dealing with tissue sensitive to excessive intraoperative force: "With nerves and vessels, you obviously have to be extremely careful because it depends on the size, but they're usually quite delicate" (PD3).

Although most participants named fine, delicate tissues among those most sensitive to excessive pressure, one participant added: "When you're required to apply quite larger forces for certain things, then it becomes quite important to know exactly how much" (PD3). The most force-sensitive tissue types are not necessarily the most delicate ones. Instead, participants labeled tissue as sensitive to pressure based on its importance for bodily functioning. The tissue types most frequently classified as critical for bodily functioning by participants across all disciplines were blood vessels and nerves:

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> *The effect on damaging a nerve on the head and neck is quite profound. You're talking about not being able to lift your eye [...] not being able to smile properly.* [PD2]

Additionally, participants pronounced that tissue types are sensitive to the amount of force applied when they have poor healing abilities. In that context, bones were frequently mentioned by general surgeons:

> *The thing with skin is [...], it will heal. But if you break a bone, it is a big deal.* [PD3]

Meanwhile, in dental surgery, connective tissue, which supplies other structures with blood, is deemed poorly healing: "If unnecessary pressure is applied to an instrument, this can lead to tissue tears, which are then difficult to manage" (DS1). Thus, the sensor was also considered to be useful when practitioners handle coarse tissue.

Instruments Used

In addition to force-sensitive tissues, those procedures that require force sensing to avoid causing harm to the patient are usually defined by the surgeons' use of specific instruments: those that are susceptible to transmitting excessive force. Across medical specialties, participants reported using a variety of instruments that, when applied inappropriately, can cause significant harm to their patients and thus could benefit from real-time feedback: "If you clamp an artery too much, it's broken" (GS2). However, one participant remarked that the potential to cause harm to the patient is not evident for all tools:

> *I think that only with some devices could you even achieve these consequences if you're doing it wrong. And that's why I don't think it would make sense to put it on all the devices, because it would probably be a waste of money if you don't really need it in that area.* [GS3]

The interviews have shown that one thing instruments that can apply excessive force to human body tissue have in common is that the force needed to reach the operative goal is specified, but the mechanics of the instrument do not define practitioners' force application: "With most of the devices that we use for suturing and such things, the pressure is already predefined by the mechanics" (PD1).

Thus, many surgical instruments are designed in a way that prevents the application of excessive forces. Examples of such instruments were electrocautery scissors, forceps, and saws:

> *But whether you use the saw more or less depends on the saw. You just have to operate it.* [GS1]

Theme 3: Barriers to Using a Force Sensor in Practice

Despite defining the opportunities to use a novel force sensor across surgical disciplines, participants also discussed factors that could prevent the use of a force sensor inside the operating theater.

Concerns About Implementation

Even with acknowledging the potential benefit of real-time feedback on exerted forces, many participants doubted the successful definition of specific safe force ranges to provide them with informative real-time feedback on the force they exert on their patients. Some participants argued that, despite their extensive experience, they do not know what the right or wrong amount of force to be applied is during specific procedures: "Although I have been doing this for many years, I wouldn't know at what pressure a problem for the bone occurs" (DS4). Furthermore, participants struggled to imagine how such force ranges would be determined while considering all variables that determine appropriate forces: "I would probably find it difficult because there are so many factors that are variable due to the different instruments and different tissues that I can't standardise" (PD1).

Participants doubted the establishment of safe force ranges for pressure measured by a novel sensor because they reported exerting a complex composite of forces on their instruments. For instance, some participants remarked that they apply pressure with multiple areas on the hand during instrumental work. Others mentioned also applying pulls and torques during procedures with significant physical components:

> *So, with forceps we are not using the palms of our hands that much really. We're using more traction and our fingers and actually in reality probably our biceps.* [OG2]

While the componential exertion of force makes it difficult to determine how much force is adequate when measured at the sensor, most participants also raised concerns about the vast inter- and intraindividual differences between patients' tissues. Most participants feared that these differences in tissue quality would prevent the definition of force ranges calibrated to patient needs:

> *From patient to patient? They are infinite. So, it's actually different for everyone. So, also for me the question is really how can you manage that in the end?* [DS2]

Nonetheless, some interviewees mentioned that individual differences could be predicted using advanced imaging methods or accounted for by creating force ranges for standardized patient groups: "If you have a bell curve for different types of people you could sort of establish a range of forces that could potentially show the doctors where it gets critical" (PD3). However, this approach cannot account for intraindividual tissue differences such as the effects of scarring from earlier operations. Consequently, the tissue properties' unpredictability could limit the feedback's informativeness. Overall, participants identified several issues that could complicate establishing safe force ranges adapted to the specific procedure and patient.

Concerns About Need

Many participants were doubtful about the need for a sensor and the feedback it generates and posited different reasons surgeons might not need a sensor implemented in their work. First, force feedback was voted redundant whenever surgeons could rely on other sources of information to determine how much pressure they should apply. For some participants, their years of clinical experience were sufficient information: "I think once you've done a couple of thousand, you don't necessarily

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need a quantitative measure because your experience and your sense of feel is used to it" (AN2).

In addition to relying on their experience, several participants explained that, in most procedures, visual or tactile feedback is available at the operating site, making the additional force feedback redundant:

> *You usually feel a bit of a give and then you see a literal white tissue. When you get to that plane, you don't go any deeper and then you cut away your specimen.* [PD2]

While sensory information might make force feedback from a novel sensor redundant, participants found scenarios in which any information about their exerted force is unnecessary. Whenever the potential to cause harm is very slight, participants claimed no need for feedback on their exerted forces. This was often the case in coarse procedures where the required force is unconstrained:

> *In trauma surgery, I think it's probably more difficult to integrate such a sensor, because there's a lot of force involved. [...] Theoretically you can't use too much force.* [GS3]

Although some participants judged the force feedback unnecessary for their work, others questioned the costs relative to the benefits: "I'm not sure how useful this would be only because you've got to think whether it's worth paying for something like that when actually removing something on the abdomen or the leg is a pretty easy procedure in the first place" (PD2).

While these comments referred to preoperative costs, other participants expected adverse operative outcomes. Some participants were worried about the negative impact on their tactile senses from wearing the sensor: "Surgeons work a lot with the tactility of the fingertip and if there's something in front of it, then that can also be a disadvantage" (GS2). Additionally, some participants were cautious about the impact the interpretation of the real-time feedback would have on their performance: "I would like to be looking at the lesion not at something else to look at pressure" (PD2). Furthermore, experienced surgeons were worried about junior surgeons' neglect of organic information: "The disadvantage of technology is sometimes that young anaesthetists no longer look at people" (AN1). Further, some medical practitioners who regularly interact with their patients during surgery explained that real-time feedback could stress the patients. Therefore, the interviews revealed a series of procedure- and practitioner-specific factors that limit the value of real-time feedback on surgeons' intraoperative forces.

Theme 4: Implementation of a Force Sensor

The final recurrent theme from participant interviews covers participants' accounts of the implementation of a force sensor. Having been introduced to the concept of a novel force sensor, practitioners frequently discussed how the sensor and the real-time feedback should be implemented to generate the most significant benefit for them.

Application of the Sensor

While existing force-sensing systems applied in medicine are predominantly applied to surgical tools, a novel force sensor was developed to be applied to surgical gloves. Many surgeons appreciated the prospective benefits of wearing a sensor on their surgical gloves during instrumental surgery. DS1 proposed implementation of a force sensor on the glove when operators expect to use many instruments in quick succession: "In order to be able to keep up with the speed, I would suggest to rather have it on your finger." Other proposed advantages of wearing the sensor on the glove were the relative ease of installation and use:

> *Presumably it would be a bit of faff having a long wire draping out of the syringe, you're waggling around someone's back. With Scrubs, it would just reach through your scrub and up your sleeve and down.* [AN2]

Looking ahead, an advanced, wireless force sensor would allow for effortless installation and use at both the tool-tissue interface and the surgeon-tool interface. However, in addition to its implementation during instrument use, many participants suggested the application of the sensor to the glove for manual examinations, particularly during diagnostic maneuvers:

> *This examination includes an examination of the chewing muscles and also of the temporal lobe up here. And I could also imagine that this pressure sensor would be used to know how hard you have to press.* [DS3]

During instrumental and manual manipulation, surgeons expressed various preferences regarding a sensor's local application on a glove. Participants' preference for where a sensor should be applied depended on the instruments used during the respective maneuver. However, different operators also described having personal preferences regarding using certain instruments: "This is a bit specific, because different people will use the syringe in different ways" (AN1). While in most cases, a sensor's application on a glove was voted preferable by the participants, some interviewees voiced their preference for force measurement at the instrument to know the magnitude of the force exerted at the tool-tissue interface rather than the surgeon-tool interface:

> *The interesting thing is the pressure that ultimately acts on the tip of the forceps. Not the one I apply, but the one that acts on the tip.* [PD1]

The interviews demonstrated that force measurement conducted at the tool-tissue interface was generally more requested when the forces exerted by the surgeons were complex composites of different hand areas:

> *I guess then you can then maybe have the sum of the two forces. Whereas if it's on the finger, you'd have to choose in terms of whether it's on the thumb or the hand that's pressing the thing or both.* [OG3]

Feedback Modality

Many participants expressed their opinion regarding the feedback modality when considering the reception of real-time

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feedback during interventions, which were mostly based on a prototype used in the opening video (Multimedia Appendix 1): "But I think if you were to devise an instrument and it had a red bar on it and my force was going towards the red bar or the higher end of the red bar, then I would start paying attention to that" (OG2).

However, most participants who discussed the impact of the visual feedback criticized that the visual feedback could distract surgeons from the operating site: "But a display means that you have to look at it again, and of course you don't look away when you're operating" (GS2). Instead, those participants were pleading for visual feedback "where you don't have to widen your field of vision" (GS3).

Auditory feedback was initially considered to be inappropriate by the developers of the sensor due to the existing audible alarms in the operating theater. This view was confirmed by those participants who reported working in a noisy environment and supported by those working in particularly stressful conditions, where audible feedback was thought to stress the surgeons and the patients:

> *I spend my life trying to make stressful situations as calm as possible. The last thing I want to do is make it more stressful.* [OG2]

Nonetheless, many interviewees suggested auditory feedback as a viable alternative to visual feedback. The primary benefit of auditory feedback is that it can quickly catch the surgeons' attention: "The one that we use more is the sound because as soon as it starts to go off the radar with the beeping, you kind of know that that's the area that you're interested in" (PD3).

Other participants, who criticized auditory and visual feedback, suggested administering tactile feedback: "I suppose something a bit like the electric toothbrushes, if you're pressing too hard it will vibrate" (AN2). However, other participants contradicted this again since: "if your fingertips vibrate all of a sudden, it might be strange" (GS3). Altogether, the interviews revealed that surgeons must choose whatever feedback works best for them, depending on which senses are occupied by environmental stimuli and which are available.

Discussion

Principal Findings

Our research has shown how a novel force sensor could be valuable in clinical practice, specifically at the surgeon-tool interface. All conclusions are formative, as they reflect perspectives from a small but highly relevant sample and do not account for the full complexity of real-world surgical scenarios. In total, four themes with specific implications were distilled based on their relevance to the research objectives (Table 2). In particular, the findings propose the application of the sensor when performing procedures where other sources of information guiding force exertion are masked, manipulating tissues that are susceptible to excessive force due to their importance for bodily functioning, or using instruments that are prone to cause harm to the tissue due to their mechanical design. However, participants questioned the value of the sensor when performing maneuvers where individual tissue differences are significant, force compositions are complex, or there is enough explicit and tacit knowledge on which surgeons can base their force judgment. Finally, the findings highlighted the need for domain-specific determination of appropriate places to apply the sensor and an appropriate feedback modality.

Table . Key implications of the present findings.

Themes	Implications for application
Theme 1: Using a novel force sensor could ...	• Help practitioners apply adequate force magnitudes during surgery • Provide objective surgical skill training and quantifiable assessment
Theme 2: A novel sensor should be applied for ...	• Maneuvers where other sources of information guiding force exertion are masked • Tissues susceptible to excessive force due to their importance for bodily functioning • Instruments prone to cause harm to the tissue due to their mechanical design
Theme 3: A novel sensor should not be applied in ...	• Procedures with large individual tissue differences and complex force compositions • Procedures with enough explicit and tacit knowledge to base force judgment on
Theme 4: A novel sensor could be implemented ...	• At various hand areas to measure force during instrumental and manual procedures • At the instrument when the force is a complex composite from multiple hand areas • With feedback depending on the accessibility of the visual, auditory, and tactile senses

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Limitations

This study explored 15 surgeons' views on the sensor glove's usability. As a formative study, the sample size aimed to ensure comprehensiveness across relevant contexts while avoiding placing excessive demands on busy health professionals. While these participants came from various medical specialties to ensure a balance between representing a broad range of medical specialties and allowing for aggregation of interview results, the sample does not represent the entire surgeon population or all surgical specialties across the medical landscape. Thus, the results presented here might not generalize to the perspectives of practitioners from other specialties. By conducting this study's interviews primarily online, there was reduced rapport between the interviewer and the interviewee, which could have reduced participant engagement.

Finally, the interviewer's lack of medical training could have adversely affected the interviews, though they took steps to familiarize themselves with the specifics of the different procedures performed by participants; conversely, the interviewer was not involved in the development of the sensorized glove and was not biased by being trained in one of the medical specialisms included in the study, thereby removing many other sources of bias.

Participants noted ethical and ergonomic challenges such as sterilization, tactile interference, and data privacy, but these fall outside the scope of this formative study and will be addressed in future design and validation phases.

Comparison With Prior Work

Benefit of Using the Sensor

Using the sensor could benefit surgeons in two ways: by enhancing the operative outcomes of interventions and improving the training of junior surgeons. We found that participants expected that wearing the sensor during surgery could enhance operative outcomes, reinforcing the notion that real-time feedback on exerted forces can improve the quality of surgery [1,18,35]. Nonetheless, like Ebrahimi et al [35], most existing research has only assessed the impact of feedback on the exertion of intraoperative force measured at the tool-tissue interface. Our findings extend this knowledge by suggesting that feedback on exerted forces could also enhance operative outcomes when measured outside the patient's body at the surgeon-tool interface.

Most participants agreed that the sensor could help junior surgeons develop a feeling for adequate intraoperative forces, overcoming the difficulties of learning from qualitative feedback described in the scientific literature [2,22]. We found that a novel force sensor could be used for training purposes both in and out of the operating theater. This supports Rhienmora et al [36], who suggested that the feedback serves to develop a feel for adequate forces and can be interpreted for assessment purposes. Thus, the sensor could accelerate surgical skill acquisition through objective feedback in real time and serve as a novel quantifiable metric.

Opportunities for Using a Force Sensor in Practice

First, our results revealed that surgeons should use a force sensor when performing maneuvers where other sources of information on intraoperative forces are masked. These results corroborate existing studies that have attributed poor surgical outcomes to errors of perception rather than poor motor skills [37,38] and initially inspired researchers to test the provision of feedback on exerted forces during surgery [39]. Because organic force feedback is often masked in standard open surgeries, we propose that feedback on exerted forces from a novel sensor should be provided in those scenarios.

Second, our results demonstrated that a force sensor should be applied when tissues are susceptible to inappropriate force due to their relative importance for bodily functioning. This finding supports previous research that has highlighted the importance of force sensing when surgeons deal with delicate structures in retinal or nervous tissue, as they require minimal force [11,12,25]. Our findings extend this view, as they propose that a particular tissue's importance for bodily functioning does not just depend on its delicacy but also on that tissue's healing qualities. The current results demonstrate that a sensor could also have high applicability when dealing with more coarse tissue with poor healing abilities, such as bone tissue.

The application of a novel sensor when dealing with instruments prone to cause harm to the patient was also identified as an opportunity, as previous research has indicated that the design of interactive medical devices can provoke user error [40]. Our study supports these findings since it revealed that where the exertion of intraoperative force is not predefined by the instrument's mechanics, the chance to harm patient tissue is high (in contrast to instruments where the mechanics define the exertion of force). Although our interviews revealed some examples of the latter (eg, electrocautery scissors, forceps, and saws), this has not been reported in prior literature.

Barriers to Using a Force Sensor in Practice

The implementation of accurate force ranges is challenged by vast individual differences between patients' tissues. This finding is supported by previous studies that identified significant differences in tissue qualities between individuals [26] and within individuals [27]. Building on the findings by Jacquet et al [41], which demonstrate that significant variability in skin mechanical properties persists even after controlling for sex, age, and BMI, our findings suggest that fixed force ranges for real-time feedback may be insufficiently informative for patients whose tissue qualities deviate from the norm. Thus, the sensor should be applied in cases where inter- and intraindividual differences are minor or predictable.

Additionally, implementing force ranges is challenged by the multimodality of the forces that surgeons use to manipulate their patients. Apart from the linear manual pressure applied on the fingertip, which the sensor can achieve, intraoperative forces can be complemented by torques or pulls, which are activated by different parts of the surgeon's body, such as the wrist or the biceps [42]. Therefore, this sensor should only be applied in scenarios where the exertion of intraoperative force is less complex.

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Finally, surgeons' ability to rely on their experience and other information sources challenges the need for real-time feedback on exerted forces to be displayed. Our findings support existing conceptions of direct visual and tactile feedback's impact on the operator's judgment [43]. During surgical manipulation of human tissue, visuotactile neurons in the human brain allow surgeons to combine visual and haptic information into one judgment [44]. Our study supports the existing conception that surgeons judge their exerted force by relying on their experience and that surgical clinical judgment necessitates decisions blending explicit knowledge derived from evidence with tacit knowledge drawn from experience [45]. Thus, the sensor might be redundant when surgeons have enough explicit and tacit knowledge to base their judgment on. However, in high-risk situations or low-visibility scenarios, the sensor may still be of use to experienced surgeons.

Implementation of a Force Sensor

Although participants did not interact with a physical prototype, their feedback highlights key design considerations for future iterations and provides an initial framework for usability testing in subsequent studies. Importantly, these design considerations need to be adapted for different surgical specialties. For example, dentists may require sensor placement optimized for fine instrument handling, whereas obstetricians may need configurations suited for manual examinations. Opie et al [46] explored the use of a sensorized glove in a usability study to assist with vaginal examinations during childbirth. It consisted of 18 participants either specializing in childbirth or with the intent to work in women's health. That study involved creating a realistic environment where the usability of the device could be assessed in a safe and effective manner. Participant feedback from that study had a direct influence on the design of the sensorized glove for future iterations.

We identified that a novel force sensor and the associated real-time feedback should be implemented in multiple areas of the hand depending on the instrument. Additionally, by measuring intraoperative force at the surgeon-tool interface, a novel force sensor could also be used for manual treatments and diagnostic procedures to improve surgeons' application of adequate forces during manual procedures as previously suggested in physiotherapy where they showed a temporary performance improvement when provided with force feedback [47,48].

When the force exerted onto tissue is a complex composite of forces applied by the hand, the sensor should be at the instrument tip. Aggravi et al [29] measured the contact forces exerted on three surgical tools and discovered a significant difference in forces applied by the thumb and index finger. Although these findings imply that a glove could have multiple force sensors, interpreting the different feedback strands could be challenging. This was supported by our participants, who suggested that measuring force at the tooltip to receive information on the sum of the force applied by different hand parts was more practical.

Finally, the indirect force feedback modality should depend on the accessibility of the visual, auditory, and tactile senses. Previous research discussed the benefits and drawbacks of providing visual, auditory, and tactile feedback in clinical settings [49-52], leading to the conclusion that the choice of feedback modality cannot be generalized. These findings were confirmed by a recent survey among health care professionals who stressed the importance of predetermining the best procedure-specific feedback modality based on the load on different senses in the operating environment [53]. Ultimately, it might come down to creating custom configurations of more than one feedback modality, as introduced by Tajadura-Jiménez et al [54], who introduced multisensory integration processes used to alter the perceived materiality of a touched surface to shape people's touch behavior.

Conclusions

This study explored the usability of a conceptual novel sensor for measuring intraoperative force at the surgeon-tool interface. Insights were gathered from semistructured interviews with 15 surgeons from different medical disciplines and experience levels who evaluated the concept of a force sensor provided by a video showcasing a conceptual force sensor. This formative study found that wearing a force sensor could enhance surgical outcomes by aiding surgeons in applying appropriate force levels and facilitate training for aspiring surgeons by providing an objective metric of force. Practical applications of the new sensor include maneuvers with little feedback on exerted forces from organic sources, where the tissues manipulated are vital for bodily functioning and have poor healing qualities, and where the instruments used are prone to inflict harm because of their mechanical design. However, the sensor's usability is limited, where establishing safe force ranges is complicated by significant individual differences in tissue qualities and complex force compositions, and where experienced surgeons do not need the sensor due to sufficient explicit and tacit knowledge of their exerted force. The implementation of the sensor at various hand locations is feasible. However, its placement on the instrument is preferred when exerted forces are complex composites from multiple areas on the hand. Finally, the feedback modality should be tailored to specific maneuvers. While substantial benefits, opportunities, and potential for using a sensor at the surgeon-tool interface exist, future research should address barriers and optimize its implementation to realize its benefits.

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Conflicts of Interest

None declared.

Multimedia Appendix 1
Video used in the study to introduce an exemplar novel force sensor.
[MP4 File, 31793 KB - formative_v10i1e78845_app1.mp4]

Multimedia Appendix 2
The semistructured interview guide used in the study.
[PDF File, 243 KB - formative_v10i1e78845_app2.pdf]

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Abbreviations

REDCap: Research Electronic Data Capture

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The Power of Multimodality in Multimodal Large Language Models, Unimodal ChatGPT 5.0, and Human Clinical Experts on a Wound Care Certification Examination: Cross-Sectional Comparative Study

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Abstract

Background: Multimodal large language models (MLLMs) capable of integrating visual and textual information represent a promising advancement for clinical applications requiring image interpretation. Wound care assessment, which demands simultaneous analysis of wound photographs and clinical data, provides an ideal domain to evaluate multimodal vs unimodal artificial intelligence capabilities against human expertise.

Objective: This study aims to compare the performance of MLLMs, unimodal ChatGPT 5.0, and human clinical experts on a standardized wound care certification examination.

Methods: This cross-sectional comparative study evaluated 3 participant groups on a 25-question wound care certification examination spanning 4 clinical domains (Diagnosis, Treatment, Complication Management, and Wound Subtype Knowledge). Participants included 3 MLLMs (Med-PaLM 2, LLaVA-Med, and BioGPT), 1 unimodal large language model (ChatGPT 5.0), and 4 human clinical experts (general surgeon, wound care nurse, and 2 internal medicine physicians). Statistical analyses included one-way ANOVA with Tukey post hoc tests and domain-specific Kruskal-Wallis comparisons.

Results: Human experts achieved the highest accuracy (mean 86%, SD 9.1%), followed by MLLMs (mean 78.7%, SD 12.2%), while ChatGPT 5.0 achieved 64% accuracy, failing the 70% certification threshold. Significant overall group differences were observed ($F_{2,5}$=8.42, P=.02, η^2=0.74). MLLMs significantly outperformed ChatGPT 5.0 (difference=14.7 percentage points, P=.03, Cohen d=1.38), with the multimodal advantage most pronounced in visually dependent domains: Diagnosis (81% vs 43%, P=.008) and Complication Management (72% vs 50%, P=.03). No multimodal advantage was observed for text-based Wound Subtype Knowledge (both 67%). Med-PaLM 2 achieved 92% accuracy, matching that of the wound care nurse, while the general surgeon achieved the highest overall performance (96%).

Conclusions: MLLMs demonstrate significant performance advantages over unimodal artificial intelligence in wound care assessment, particularly for visually dependent clinical tasks. While human experts with specialized wound care experience maintain overall superiority, the point estimate of the top-performing MLLM (Med-PaLM 2, 92%) fell within the observed range of human scores; however, the underpowered comparison (power=0.52) and wide CIs preclude definitive conclusions regarding noninferiority or equivalence to human experts. These findings support the potential role of MLLMs as clinical decision-support tools, warranting further adequately powered validation studies.

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KEYWORDS

multimodal large language models; wound care; artificial intelligence; clinical decision support; certification examination; ChatGPT; Med-PaLM 2

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Introduction

The progression of artificial intelligence (AI) within the health care sector has advanced from rule-based expert systems to sophisticated deep learning models capable of analyzing complex medical data. A notable advancement is the development of multimodal large language models (MLLMs) that simultaneously analyze textual descriptions and clinical images, reflecting the integrative reasoning approach used by human clinicians [1,2].

Wound care exemplifies a clinical domain in which multimodal capabilities may offer substantial benefits. Accurate wound assessment necessitates the integration of visual pattern recognition (such as wound bed characteristics, tissue types, and staging), clinical history documented in text, and adherence to evidence-based protocols [3]. In dermatology, a 2025 narrative review of large language model applications noted that while models such as ChatGPT 5.0 demonstrate impressive textual reasoning, they remain constrained in capturing the image-based, context-specific subtleties necessary for complex dermatologic assessment [4].

Recent multimodal models have been developed to overcome these limitations. Google's Med-PaLM 2 combines medical imaging interpretation with clinical text comprehension, attaining expert-level performance in medical licensing examinations [5]. Microsoft Research's LLaVA-Med extends the Large Language-and-Vision Assistant framework specifically for biomedical applications, trained on over 15 million biomedical image-text pairs [6]. BioGPT incorporates biomedical entity recognition and relationship extraction, thereby enhancing clinical reasoning [7].

ChatGPT 5.0, launched in early 2025, signifies OpenAI's most advanced text-based language model, featuring enhanced reasoning skills, improved encoding of medical knowledge, and superior contextual understanding [8]. Despite these advancements, it remains fundamentally a unimodal system that processes only textual input, prompting inquiries regarding whether multimodal integration yields measurable advantages in clinical subspecialty assessments.

This study aimed to conduct a comparative analysis involving 3 groups: MLLMs, the cutting-edge unimodal ChatGPT 5.0, and human clinical experts, all pertaining to wound care certification examination questions. The hypotheses posited were as follows: (1) MLLMs would surpass ChatGPT 5.0, especially in domains heavily reliant on visual information; (2) human experts would outperform both AI groups; and (3) the highest-performing MLLMs would approach the accuracy levels of human experts.

Methods

Study Design

This cross-sectional comparative study evaluated the performance of 3 participant groups on a standardized 25-question wound care certification examination: (1) MLLMs (n=3), (2) unimodal large language model (n=1), and (3) human clinical experts (n=4). The study was conducted at Etimesgut Şehit Sait Ertürk State Hospital, Ankara, Turkey, between January and March 2025. This study was designed and reported in accordance with the Standards for Reporting of Diagnostic Accuracy Studies—Artificial Intelligence extension and the COSMIN (Consensus-Based Standards for the Selection of Health Measurement Instruments) guideline [9,10].

Examination Development and Question Sources

Twenty-five multiple-choice questions were systematically compiled from established wound care certification examination resources and clinical practice guidelines. Primary sources included the National Alliance of Wound Care and Ostomy WCC Practice Examination Bank (2024); the American Board of Wound Medicine Certified Wound Specialist Examination Preparation Guide (2023 - 2024); the Wound, Ostomy, and Continence Nursing Certification Board Certification Content Outline (2024); the National Pressure Injury Advisory Panel Clinical Practice Guideline (2019); the Wound Healing Society Diabetic Foot Guidelines (2023); and the International Wound Infection Institute Consensus Document (2022). Question distribution across clinical domains is presented in Table 1 [11-16].

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Table . Distribution and content of examination questions by clinical domain (N=25).

Domain	Questions, n	Sources	Question topics
Diagnosis	7	NAWCO[a] (3), NPIAP[b] (2), ABWM[c] (2)	PI[d] staging (III vs IV), Wagner classification, venous vs arterial differentiation, unstageable PI, TIME[e] framework, DTPI[f] recognition, Marjolin's ulcer
Treatment	6	ABWM (2), WHS[g] (2), WOCNCB[h] (2)	NPWT[i] indications, compression therapy, debridement selection, moist wound dressings, DFU[j] offloading, antimicrobial selection
Complication Management	6	IWII[k] (3), ABWM (2), NAWCO (1)	Infection vs colonization, biofilm management, osteomyelitis screening, periwound maceration, dehiscence risk, contact dermatitis
Wound Subtype Knowledge	6	WHS (2), WOCNCB (2), NPIAP (2)	DFU prognosis, ABI[l] interpretation, PI prevention, mixed etiology management, revascularization criteria, CDC wound classification

[a]NAWCO: National Alliance of Wound Care and Ostomy.

[b]NPIAP: National Pressure Injury Advisory Panel.

[c]ABWM: American Board of Wound Medicine.

[d]PI: pressure injury.

[e]TIME: Tissue management, Infection or inflammation control, Moisture balance, and Edge of wound advancement.

[f]DTPI: deep tissue pressure injury.

[g]WHS: Wound Healing Society.

[h]WOCNCB: Wound Ostomy Continence Nursing Certification Board.

[i]NPWT: negative pressure wound therapy.

[j]DFU: diabetic foot ulcer.

[k]IWII: International Wound Infection Institute.

[l]ABI: Ankle-Brachial Index.

Multimodal Large Language Models

Architecture Overview

MLLMs integrate visual and textual information through specialized neural network architectures containing vision encoders, projection layers, and cross-modal attention mechanisms (Figure 1). This enables simultaneous processing of clinical wound images and textual patient data.

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Figure 1. Multimodal vs unimodal large language model (LLM) architecture for clinical wound assessment. Left: Multimodal pipeline with vision encoder and cross-modal attention. Right: Unimodal text-only pipeline. Adapted from Singhal et al [5] and Gao et al [6]. Schematic representation of the study methodology comparing MLLMs, a unimodal LLM, and human clinical experts on a standardized wound care certification examination. (A) MLLMs process clinical wound images through vision encoders (Vision Transformer) and integrate visual features with text via cross-modal attention mechanisms. (B) Unimodal LLM (ChatGPT 5.0) receives only textual descriptions without direct image access. (C) Human experts perform visual inspection combined with clinical expertise. The 25-question examination comprised 4 domains: diagnosis (n=7), treatment (n=6), complication management (n=6), and wound subtype knowledge (n=6). AI: artificial intelligence; MLLM: multimodal large language model.

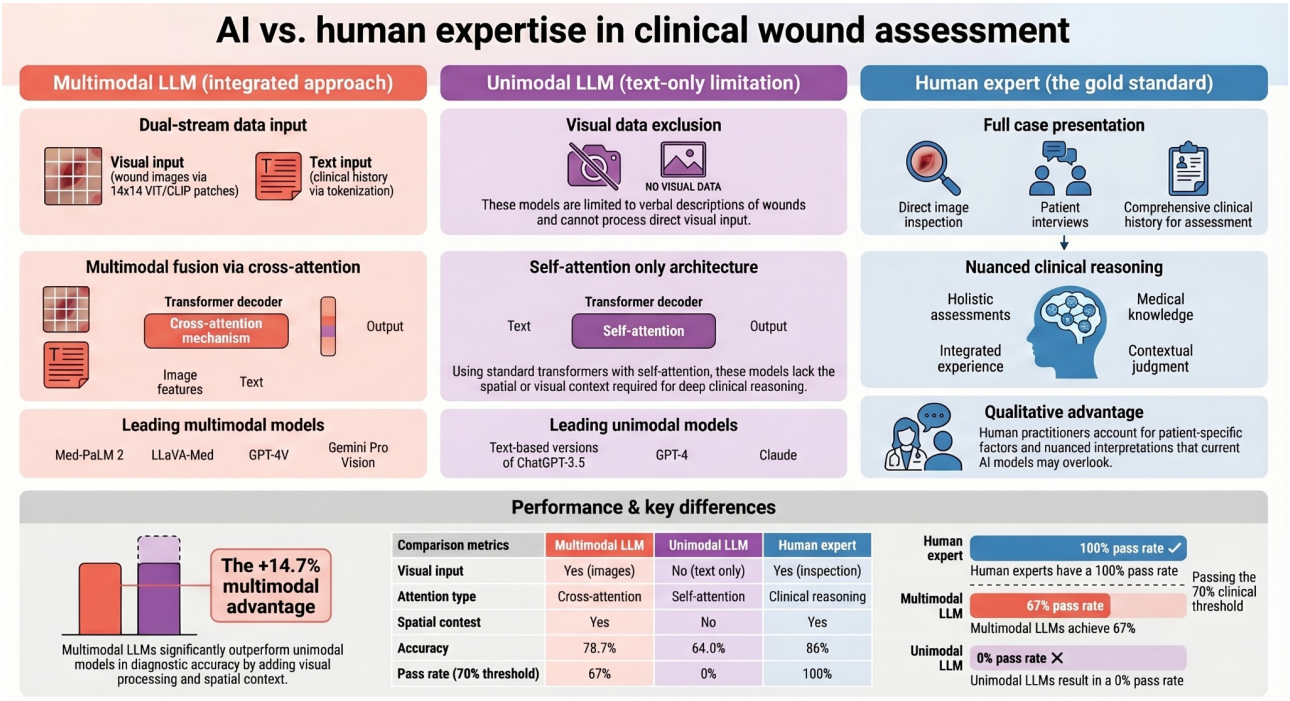

Image Processing Pipeline

The visual processing pathway consists of 4 stages:

- Stage 1—Preprocessing: clinical images resized to 336×336 pixels, normalized using ImageNet statistics (mean 0.485, SD 0.229; mean 0.456, SD 0.224; and mean 0.406, SD 0.225).
- Stage 2—Patch embedding: images divided into 14×14 pixel patches (576 tokens). Each patch linearly projected into a 768-dimensional embedding space with [CLS] token prepended.
- Stage 3—Positional encoding: learnable positional embeddings added to preserve spatial relationships between wound regions.
- Stage 4—Transformer encoding: patch embeddings processed through 12 to 24 transformer layers with multihead self-attention.

Cross-Modal Attention

Cross-modal attention enables the integration of visual and textual modalities:

$$\text{Attention}(Q, K, V) = \text{softmax}(QKT/d) \times V,$$

where Q derives from text embeddings and K and V from image features. This allows selective attention to relevant wound regions when processing clinical queries.

Models Evaluated

Med-PaLM 2 (Google Health) is a late fusion architecture combining the Vision Transformer-G/14 vision encoder with the PaLM 2-L language model, which is trained on medical images, clinical notes, radiology reports, and medical literature. This is accessed via the Google Cloud Healthcare API (medpalm-2-vision-preview, temperature=0).

LLaVA-Med (Microsoft Research) is an early fusion architecture with a Contrastive Language-Image Pretraining Vision Transformer-L/14 encoder and a Mistral-7B backbone, which is fine-tuned on PMC-15M (15 million biomedical image-text pairs from PubMed Central) and deployed using llava-med-v1.5-mistral-7b (temperature=0).

BioGPT (Microsoft Research) is a text-focused 1.5B parameter model trained on 15 million PubMed abstracts. This features enhanced biomedical entity recognition for processing detailed verbal wound descriptions and is accessed via the Azure API (biogpt-large, temperature=0).

Multimodal Prompt Protocol

The multimodal prompt protocol is presented in Textbox 1 (Multimedia Appendix 1).

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Textbox 1. Multimodal prompt protocol.

System prompt:

You are an expert wound care specialist with access to both clinical wound images and patient history. Analyze visual and textual information to select the single best answer.

Examine the wound image for: tissue types, wound bed characteristics, edges, periwound skin, exudate, depth, and infection signs.

Integrate visual findings with clinical history.

Respond with only the letter of the correct answer (A, B, C, D, or E).

Question template:

[IMAGE]

{wound_photograph.jpg}

[PATIENT]

Age: {age} | Sex: {sex} | Diagnosis: {diagnosis}

[HISTORY]

{clinical_history}

[WOUND]

Location: {location}

Duration: {duration}

Characteristics: {wound_description}

[QUESTION]

{question_stem}

1. {option_a}
2. {option_b}
3. {option_c}
4. {option_d}
5. {option_e}

Answer:

Example (Diagnosis domain—question 3):

[IMAGE]

sacral_wound_003.jpg

[PATIENT]

Age: 78 years | Sex: Female | Diagnosis: Stroke with hemiplegia

[HISTORY]

Long-term care admission 6 weeks post-hemorrhagic stroke. Bedbound.

T2DM (HbA1c 8.2%), PVD, CKD stage 3. Albumin: 2.8 g/dL. BMI: 18.5.

[WOUND]

Location: Sacral region

Duration: 3 weeks

Characteristics: Full-thickness tissue loss, subcutaneous fat visible, no bone/tendon exposed. 60% granulation, 40% slough. Moderate serous exudate. Distinct edges. Periwound erythema 1 cm. Size: 5 × 4 × 1.5 cm.

[QUESTION]

Based on NPIAP classification, what is the correct staging?

1. Stage 2 Pressure Injury
2. Stage 3 Pressure Injury
3. Stage 4 Pressure Injury

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4. Unstageable Pressure Injury
5. Deep Tissue Pressure Injury

Answer:

Unimodal Large Language Model

Model Description

ChatGPT 5.0 (OpenAI) was released on January 2025, representing state-of-the-art text-based AI. This features a 128,000-token context window, enhanced reasoning, and improved medical knowledge encoding and is accessed via API (gpt-5.0-2025-01-15, temperature=0).

Architectural Limitations

ChatGPT 5.0 cannot process images. Visual wound characteristics must be conveyed verbally, introducing the following:

- Information loss during verbal translation
- Absence of spatial context processing
- Observer-dependent description variability

ChatGPT 5.0 Prompt Protocol

The ChatGPT 5.0 prompt protocol is presented in Textbox 2.

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Textbox 2. ChatGPT 5.0 prompt protocol.

System prompt:

You are an expert wound care specialist. You will receive detailed verbal wound descriptions with patient history. You have NO image access.

Base assessment entirely on textual information provided.

Analyze wound description for: tissue types, depth, exudate, edges, periwound condition, and infection signs.

Respond with ONLY the letter of the correct answer (A, B, C, D, or E).

Question template (expanded verbal description):

[PATIENT]

Age: {age} | Sex: {sex} | Diagnosis: {diagnosis}

[HISTORY]

{clinical_history}

[WOUND DESCRIPTION - VERBAL]

Location: {location}

Duration: {duration}

Detailed characteristics:

- Tissue Loss Depth: {depth_description}
- Wound Bed Composition: {tissue_percentages}
- Exudate: {exudate_type_amount}
- Wound Edges: {edge_characteristics}
- Wound Size: {dimensions}
- Periwound Skin: {periwound_description}
- Infection Signs: {infection_assessment}
- Additional Findings: {other_observations}

[QUESTION]

{question_stem}

1. {option_a}
2. {option_b}
3. {option_c}
4. {option_d}
5. {option_e}

Answer:

Example (same question 3):

[PATIENT]

Age: 78 years | Sex: Female | Diagnosis: Stroke with hemiplegia

[HISTORY]

Long-term care admission 6 weeks post-hemorrhagic stroke. Bedbound.

T2DM (HbA_{1c} 8.2%), PVD, CKD stage 3. Albumin: 2.8 g/dL. BMI: 18.5.

[WOUND DESCRIPTION - VERBAL]

Location: Sacral region over sacral prominence

Duration: 3 weeks

Detailed characteristics:

- Tissue Loss Depth: Full-thickness extending through dermis into subcutaneous fat. Fat visible in wound base. No bone, tendon, muscle, or fascia exposed or palpable.

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- Wound Bed Composition: 60% beefy red granulation tissue (moist, friable); 40% adherent yellow fibrinous slough (central).
- Exudate: Moderate serous, pale yellow, no purulence.
- Wound Edges: Distinct, well-demarcated, not rolled or undermined, no epithelialization visible.
- Wound Size: 5 cm × 4 cm × 1.5 cm depth.
- Periwound Skin: Mild erythema 1 cm from margins, intact, no maceration, induration, or warmth.
- Infection Signs: None (no purulence, warmth, advancing erythema).
- Additional Findings: No tunneling or undermining. Pain 3/10 with dressing changes.

[QUESTION]

Based on NPIAP classification, what is the correct staging?

1. Stage 2 Pressure Injury
2. Stage 3 Pressure Injury
3. Stage 4 Pressure Injury
4. Unstageable Pressure Injury
5. Deep Tissue Pressure Injury

Answer:

Human Clinical Experts

Four clinical experts representing diverse wound care backgrounds participated in this study: a board-certified general surgeon (GS) with 10 years of wound care experience specializing in debridement, negative pressure wound therapy, grafting, and flap reconstruction; a certified wound care nurse (WCN) with 8 years of experience in assessment, dressing selection, and compression therapy; and 2 internal medicine physicians with palliative care experience (IM-1: 5 y; IM-2: 3 y) focusing on wound management in chronic disease and comfort-oriented care settings. All 4 experts completed the examination simultaneously in the same room under standardized proctored conditions on February 15, 2025 (14:00-15:30) at Conference Room B-204, Etimesgut Şehit Sait Ertürk State Hospital, with desks arranged at 2-m intervals with privacy dividers, standardized lighting (500 lux), and temperature control (22 °C). Two independent proctors supervised throughout: Proctor 1 (front) managed timing and instructions, while Proctor 2 (rear) monitored for communication; duties included identity verification, electronic device collection, simultaneous sealed packet distribution, continuous monitoring, time announcements (15-min and 5-min warnings), and sealed answer sheet collection at 90 minutes. Each participant received identical sealed packets containing instruction sheets, blinded answer sheets (codes WC-A through WC-D), question booklets (25 multiple-choice questions), high-resolution wound photographs (10×10 cm, 300 DPI, color calibrated), and clinical history sheets, with written instructions prohibiting reference materials, electronic devices, and interparticipant communication. Completion times were 67 minutes (GS), 72 minutes (WCN), 81 minutes (IM-1), and 85 minutes (IM-2).

Statistical Analysis

Group differences in overall accuracy were assessed using one-way ANOVA with Tukey honestly significant difference post hoc tests for pairwise comparisons. Effect sizes were calculated using eta-squared (η^2) for ANOVA and Cohen *d* for pairwise comparisons. Domain-specific analyses employed the Kruskal-Wallis *H* test. Pairwise comparisons used Fisher exact test with Bonferroni correction. Performance correlations with clinical experience and specialization were assessed using Pearson correlation coefficient (*r*). All statistical analyses were performed using R version 4.3.2 (R Foundation for Statistical Computing), with statistical significance set at $P<.05$.

Ethical Considerations

This study was approved by the Ankara Provincial Directorate of Health Non-Interventional Ethics Committee (decision number 2025-10-3; October 24, 2025). As this study used anonymized examination data and involved no direct patient intervention, individual informed consent was not required per applicable institutional guidelines.

Results

Overall Performance Comparison

Three distinct participant groups were evaluated on a standardized 25-question wound care certification examination designed to assess competency across 4 clinical domains: Diagnosis, Treatment, Complication Management, and Wound Subtype Knowledge. The participant groups included MLLMs (n=3 models: Med-PaLM 2, LLaVA-Med, and BioGPT), a unimodal large language model (ChatGPT 5.0; n=1 model), and human clinical experts (n=4 participants: GS, WCN, IM-1, and IM-2). Substantial and statistically significant performance differences were observed across groups, with a clear hierarchical pattern emerging that reflects the fundamental importance of visual processing capabilities for clinical wound assessment (Figure 2).

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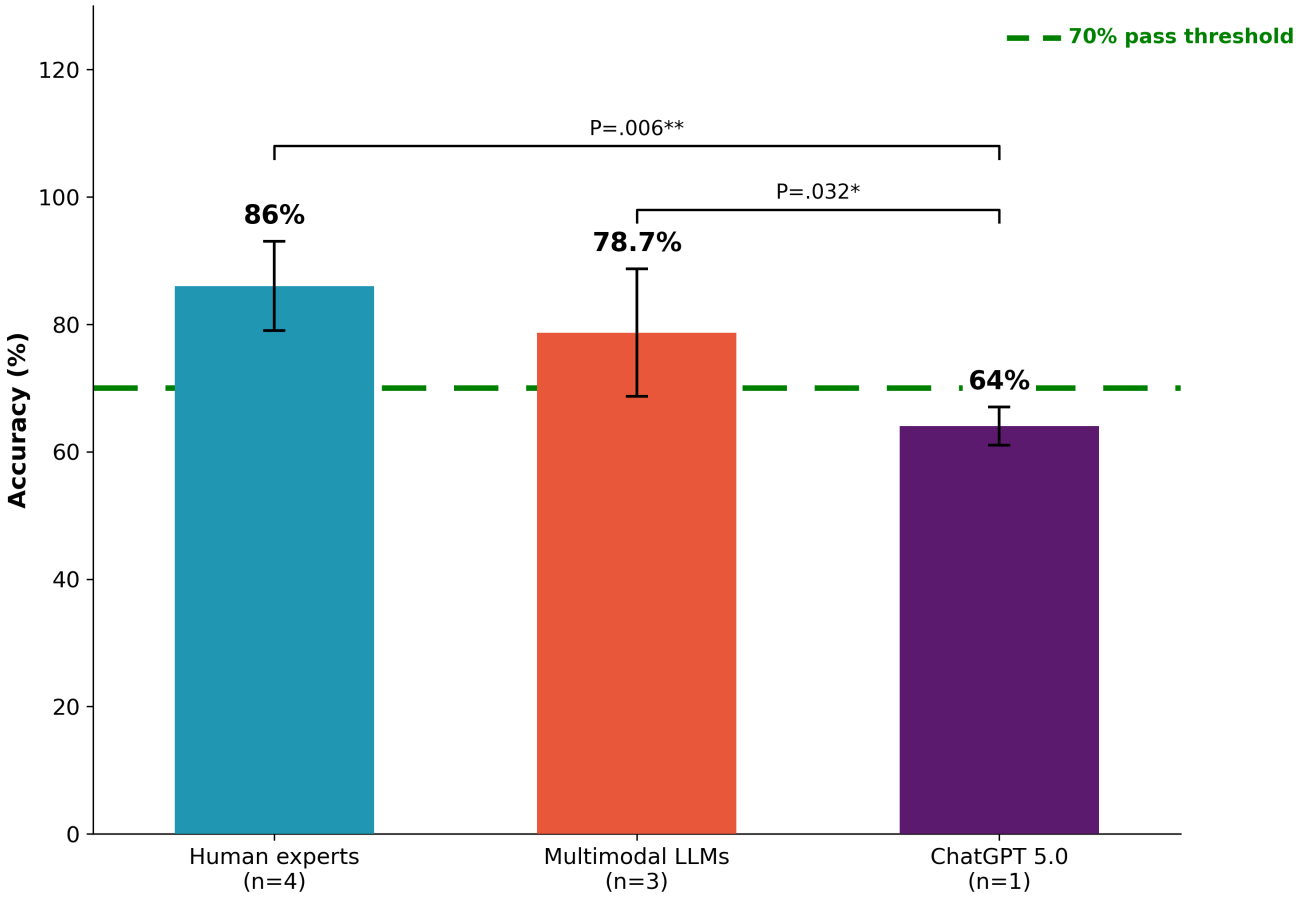
Figure 2. Overall performance comparison by participant group. Bar chart depicting mean examination accuracy (%) with SD error bars. Human clinical experts (n=4) achieved 86% (SD 9.1%), the multimodal large language model (LLMs; n=3) achieved 78.7% (SD 12.2%), and ChatGPT 5.0 (n=1) achieved 64%. The dashed green line indicates the 70% certification threshold. Statistical analysis revealed significant differences between groups (ANOVA: $F_{2,5}$=8.42, P=.018, η^2=0.74). Human experts significantly outperformed ChatGPT 5.0 (P=.006, Cohen d=2.12), and multimodal LLMs also outperformed ChatGPT 5.0 (P=.032, d=1.38). *P<.05, **P<.01.



Human clinical experts achieved the highest aggregate performance with a mean accuracy of 86% (SD 9.1%), corresponding to 21.5 out of 25 questions answered correctly on average. Individual human expert scores ranged from 76% to 96%, with a 95% CI for the group mean of 71.5% to 100.5%. The coefficient of variation within the human expert group was 10.6%, indicating moderate within-group heterogeneity attributable to differences in specialized training and clinical experience. All 4 human experts (100%) exceeded the 70% certification passing threshold, demonstrating consistent competency across the group despite varying levels of wound care specialization.

MLLMs achieved the second-highest aggregate performance with a mean accuracy of 78.7% (SD 12.2%), corresponding to 19.7 out of 25 questions answered correctly on average. Individual MLLM scores demonstrated substantial variability, ranging from 68% (BioGPT) to 92% (Med-PaLM 2), with a 95% CI for the group mean of 48.4% to 109%. The coefficient of variation within the MLLM group was 15.5%, higher than that observed for human experts, reflecting considerable heterogeneity in model architecture, training data, and multimodal fusion strategies. Two of the 3 MLLMs (66.7%) exceeded the 70% certification threshold: Med-PaLM 2 at 92% and LLaVA-Med at 76%, while BioGPT narrowly failed at 68%.

The unimodal ChatGPT 5.0 achieved the lowest performance at 64% accuracy, correctly answering 16 of 25 questions. As a single-model comparator, no within-group variability statistics are applicable; however, the model's performance fell 6 percentage points below the 70% certification threshold, representing a clinically meaningful failure to demonstrate wound care competency. Despite representing the state of the art in text-based AI with enhanced medical knowledge encoding and sophisticated reasoning capabilities, ChatGPT 5.0's text-only architecture proved insufficient for certification-level performance in this visually dependent clinical domain.

One-way ANOVA revealed statistically significant overall differences among the 3 groups ($F_{2,5}$=8.42, P=.018). The effect size was large (η^2=0.74), indicating that group membership—reflecting the presence or absence of multimodal processing capabilities and human expertise—explained approximately 74% of the total variance in examination performance. This finding demonstrates that architectural differences in information processing have profound implications for clinical decision-making accuracy in wound care assessment, with visual processing capabilities representing a critical determinant of performance.

Post hoc pairwise comparisons using Tukey Honestly Significant Difference test revealed the specific nature of between-group differences. Human clinical experts significantly outperformed

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ChatGPT 5.0 with a mean difference of 22 percentage points (95% CI 8.4% - 35.6%; *P*=.006), representing the largest between-group difference observed and a very large effect size (Cohen *d*=2.12). This 22-percentage-point advantage for human experts over the most advanced unimodal AI system underscores the continued importance of human clinical judgment for tasks requiring the integration of visual assessment with experiential pattern recognition.

MLLMs significantly outperformed ChatGPT 5.0 with a mean difference of 14.7 percentage points (95% CI 2.3% - 27.1%; *P*=.03) and a large effect size (Cohen *d*=1.38). This finding provides direct evidence that multimodal processing capabilities—specifically, the architectural ability to directly analyze clinical images rather than relying on verbal descriptions—confer substantial and statistically significant advantages for wound care decision-making. The multimodal advantage translates to approximately 3.7 additional correct answers per 25-question examination, representing a clinically meaningful improvement in diagnostic accuracy.

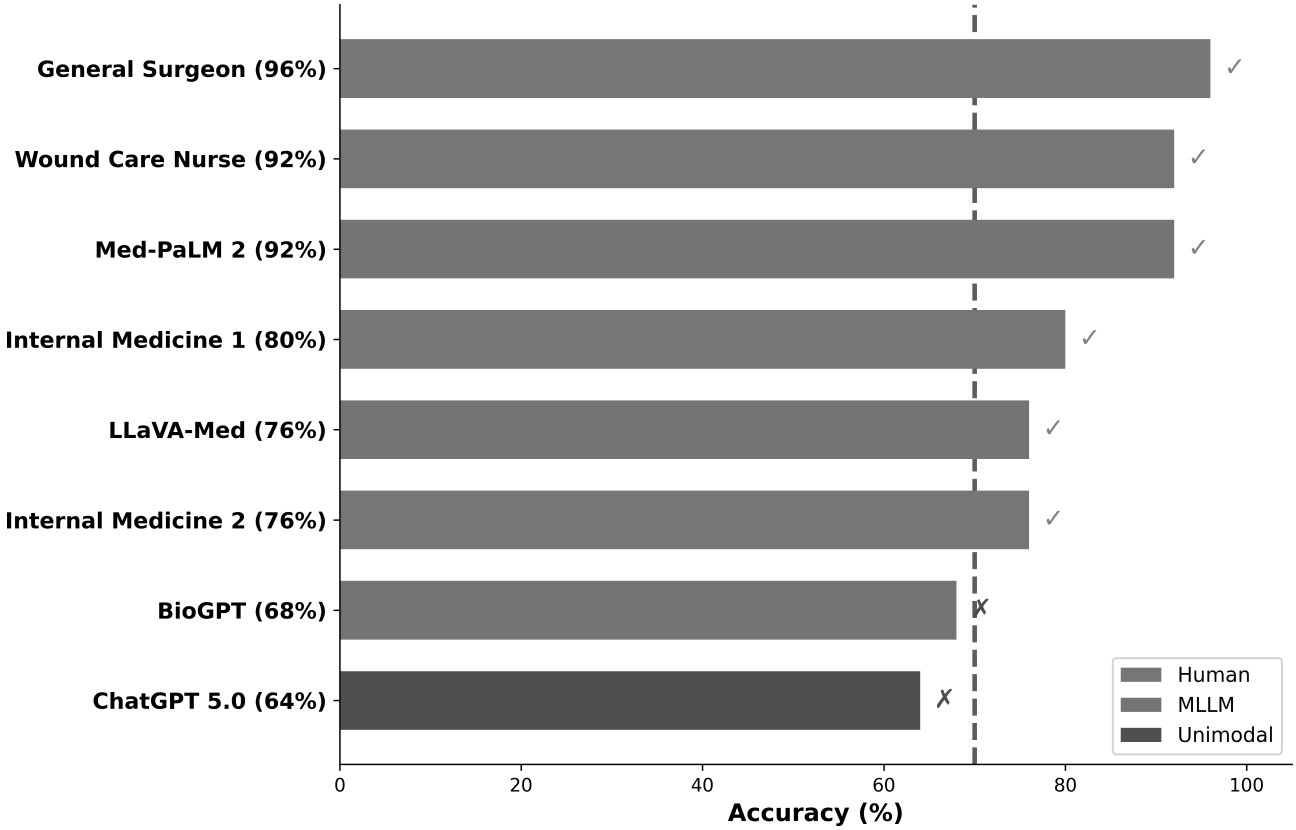
Human clinical experts demonstrated a trend toward higher accuracy compared to MLLMs, with a mean difference of 7.3 percentage points (95% CI −2.1% to 16.7%; *P*=.09) and a medium effect size (Cohen *d*=0.68). Although this difference did not achieve statistical significance at the conventional α=.05 threshold, the substantially underpowered nature of this comparison (post hoc power=0.52) and the wide CIs spanning zero preclude definitive conclusions regarding either superiority or equivalence. Thus, while the direction of the effect favors human experts, adequately powered studies are necessary to confirm this trend.

Individual Performance Analysis and Subtype Comparisons

Overview of Individual Performance Variability

Analysis of individual participant performance revealed substantial within-group variability, which provides important context for interpreting aggregate differences and understanding factors contributing to successful wound care decision-making. Individual performance ranged from 64% (ChatGPT 5.0) to 96% (GS), a 32-percentage-point spread reflecting the combined influence of visual processing capabilities, specialized training, and clinical experience (Figure 3).

Figure 3. Individual participant performance ranked by accuracy. Horizontal bar chart displaying examination accuracy for all 8 participants ranked in descending order. Colors indicate participant category: blue (human experts), orange (multimodal large language model), and purple (unimodal large language model). The general surgeon achieved the highest score (96%), followed by the wound care nurse and Med-PaLM 2 (both 92%). BioGPT (68%) and ChatGPT 5.0 (64%) scored below the 70% certification threshold (dashed green line). Pass rates differed across groups: human experts 100% (4/4), multimodal large language models 67% (2/3), and unimodal large language model 0% (0/1). Checkmarks (✓) indicate passing scores; crosses (✗) indicate failing scores. MLLM: multimodal large language model.



Human Expert Subtype Analysis

Within the human expert group, performance demonstrated a clear gradient related to specialized wound care training and dedicated clinical experience. Participants with specialized wound care credentials achieved substantially higher accuracy than internal medicine physicians with general palliative care backgrounds. The GS, possessing 10 years of dedicated wound care experience encompassing complex debridement, negative pressure wound therapy, skin grafting, and reconstructive flap

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procedures, achieved the highest accuracy among all participants at 96% (24/25 correct, 95% CI 79.6% - 99.9%). This performance significantly exceeded ChatGPT 5.0 (P=.003, Fisher exact test, OR 13.5, 95% CI 1.58 - 115.2) and was numerically, though not statistically, higher than all other participants.

The WCN, holding certified WCN credentials from the Wound, Ostomy and Continence Nursing Certification Board with 8 years of specialized practice in wound assessment, evidence-based dressing selection, and compression therapy management, achieved 92% accuracy (23/25 correct, 95% CI 73.9% - 99%). This performance was statistically equivalent to Med-PaLM 2 (92% vs 92%; P>.99) and significantly exceeded ChatGPT 5.0 (P=.008, OR 6.44, 95% CI 1.42 - 29.2). The equivalence between the specialized WCN and the best-performing MLLM suggests that current AI technology can approach, but not exceed, the performance of dedicated wound care specialists.

IM-1, with 5 years of palliative care experience managing wounds in patients with advanced chronic diseases but without specialized wound care certification, achieved 80% accuracy (20/25 correct, 95% CI 59.3% - 93.2%). While this performance exceeded the 70% certification threshold, it was significantly lower than that of the specialized experts (GS and WCN combined: 94% vs 80%; P=.04). IM-2, with 3 years of palliative care experience focusing on comfort-oriented wound management, achieved 76% accuracy (19/25 correct, 95% CI 54.9% - 90.6%), the lowest among human experts but still exceeding the certification threshold. Performance differences between IM-1 and IM-2 were not statistically significant (P=.50), but both performed significantly below-the specialized experts (P<.05).

Statistical analysis confirmed strong associations between performance and expertise indicators. Examination accuracy correlated significantly with years of dedicated wound care experience (Pearson r=0.78, 95% CI 0.24 - 0.95; P=.01), indicating that each additional year of specialized experience was associated with approximately 2.3 percentage points of improved accuracy. Performance also correlated with possession of specialized wound care credentials (point-biserial r=0.84; P=.008), with credentialed experts (GS and WCN) achieving a combined mean of 94% vs 78% for noncredentialed physicians (IM-1 and IM-2)—a 16-percentage-point difference (95% CI 4.2% - 27.8%; P=.02) that exceeds the 14.7-percentage-point multimodal advantage over ChatGPT 5.0.

AI Model Subtype Analysis

Within the AI participant group, substantial performance heterogeneity was observed despite all multimodal models possessing visual processing capabilities. This variability reflects differences in model architecture, training data composition, multimodal fusion strategies, and domain-specific fine-tuning approaches. The range of AI performance (64%-92%) exceeded that of human experts (76%-96%), indicating that current AI systems demonstrate greater inconsistency in wound care competency than human clinicians.

Med-PaLM 2 (Google Health) achieved the highest AI accuracy at 92% (23/25 correct), matching the WCN and ranking tied for second among all participants. Med-PaLM 2 significantly outperformed ChatGPT 5.0 (92% vs 64%, difference=28 percentage points, P=.008, OR 6.44, 95% CI 1.42 - 29.2), LLaVA-Med (92% vs 76%, difference=16 percentage points, P=.04, OR 3.64), and BioGPT (92% vs 68%, difference=24 percentage points, P=.02, OR 5.41). Med-PaLM 2's superior performance likely reflects its late fusion architecture with bidirectional cross-attention, extensive training on expert-curated medical datasets including clinical images with quality-controlled annotations, and substantial model scale (540B parameters). While the point estimate for Med-PaLM 2 (92%) was numerically close to the human expert mean (86%, P=.41), this comparison was substantially underpowered (power=0.52), and the wide CIs preclude a definitive conclusion regarding noninferiority or equivalence to human experts. Med-PaLM 2 exceeded 2 individual human experts (IM-1: 80%; IM-2: 76%), suggesting that optimally designed multimodal AI may approach, though not demonstrably match, specialized human performance.

LLaVA-Med (Microsoft Research) achieved 76% accuracy (19/25 correct), marginally exceeding the 70% certification threshold and ranking tied for fifth with IM-2. LLaVA-Med's performance did not significantly differ from ChatGPT 5.0 (76% vs 64%, difference=12 percentage points, P=.12, OR 1.78, 95% CI 0.57 - 5.54), although the direction favored LLaVA-Med. The model's moderate performance, despite training on PMC-15M (15 million biomedical image-text pairs), suggests that early fusion architecture with simple feature concatenation may be less effective than late fusion approaches with cross-attention for clinical tasks requiring nuanced visual-textual integration. Additionally, the automated extraction of training pairs from PubMed Central, without expert curation, may introduce noise that limits clinical accuracy.

BioGPT (Microsoft Research) achieved 68% accuracy (17/25 correct), narrowly failing the 70% certification threshold and ranking seventh among 8 participants. BioGPT's performance did not significantly differ from ChatGPT 5.0 (68% vs 64%, difference=4 percentage points, P=.38, OR 1.20, 95% CI 0.40 - 3.63). As a primarily text-focused model without native image processing, BioGPT processed detailed verbal wound descriptions rather than directly analyzing images, representing a hybrid approach that provides limited multimodal advantage. The minimal performance difference between BioGPT and ChatGPT 5.0 (both text-dependent) compared to the substantial advantages demonstrated by true multimodal models (Med-PaLM 2, LLaVA-Med) confirms that visual processing capability, rather than biomedical text specialization alone, drives performance improvements in wound care assessment.

ChatGPT 5.0 (OpenAI) achieved 64% accuracy (16/25 correct), ranking last among all participants and failing the certification threshold by 6 percentage points. Despite representing the state of the art in unimodal text-based AI with enhanced medical knowledge encoding, a 128,000-token context window, and sophisticated reasoning capabilities, ChatGPT 5.0's text-only architecture proved fundamentally inadequate for wound care certification. ChatGPT 5.0 was significantly outperformed by

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4 participants: GS (*P*=.003), WCN (*P*=.008), Med-PaLM 2 (*P*=.008), and IM-1 (*P*=.048). Performance differences from LLaVA-Med (*P*=.12), IM-2 (*P*=.12), and BioGPT (*P*=.38) did not reach statistical significance but consistently favored the comparators.

Cross-Subtype Performance Comparisons

Direct comparisons between specific human experts and AI models revealed important patterns regarding the relative capabilities of specialized expertise vs AI (Table 2). The GS (96%) significantly outperformed all AI models, including Med-PaLM 2 (96% vs 92%, difference=4 percentage points, *P*=.50, ns), LLaVA-Med (*P*=.02), BioGPT (*P*=.006), and ChatGPT 5.0 (*P*=.003). This finding indicates that highly specialized human experts currently exceed even the best-performing AI systems, although the difference from Med-PaLM 2 was small and not statistically significant.

The WCN (92%) demonstrated performance equivalent to Med-PaLM 2 (92% vs 92%, identical scores) and significantly exceeded LLaVA-Med (*P*=.04), BioGPT (*P*=.02), and ChatGPT 5.0 (*P*=.008). This equivalence between a specialized human expert and a top-tier multimodal AI suggests that current technology has achieved parity with dedicated wound care professionals, though not with the most experienced surgical specialists.

IM-1 (80%) was not significantly different from Med-PaLM 2 (80% vs 92%, difference=12 percentage points, *P*=.16), LLaVA-Med (80% vs 76%; *P*=.50), BioGPT (80% vs 68%; *P*=.22), or ChatGPT 5.0 (80% vs 64%; *P*=.048—marginally significant). This pattern indicates that AI performance spans the range of nonspecialized human clinicians, with top AI models exceeding and bottom AI models falling below typical internal medicine performance.

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Table . Individual question performance: multimodal large language models vs ChatGPT 5.0 vs human experts (N=25).

Q#	Question topic	MLLMs			Unimodal	Human experts			
		Med-PaLM2	LLaVA-Med	BioGPT	GPT-5.0[a]	GS[b]	WCN[c]	IM-1[d]	IM-2[e]
D1[f]	Pressure injury Stage III vs IV differentiation	✓[g]	✓	✓	✗[h]	✓	✓	✓	✓
D2	Diabetic foot ulcer Wagner classification	✓	✓	✗	✗	✓	✓	✓	✗
D3	Venous vs arterial ulcer clinical features	✓	✓	✓	✓	✓	✓	✓	✓
D4	NPUAP unstageable wound identification	✓	✓	✗	✗	✓	✓	✗	✗
D5	TIME framework wound bed assessment	✓	✓	✓	✗	✓	✓	✓	✓
D6	Deep tissue pressure injury recognition	✓	✓	✓	✓	✓	✓	✓	✓
D7	Marjolin's ulcer malignant transformation	✓	✗	✗	✗	✓	✓	✗	✗
T1[i]	NPWT indications and contraindications	✓	✓	✓	✓	✓	✓	✓	✓
T2	Compression therapy for venous ulcers	✓	✓	✓	✗	✓	✓	✓	✗
T3	Debridement method selection algorithm	✓	✓	✗	✗	✓	✓	✓	✓
T4	Moist wound healing dressing selection	✓	✓	✓	✓	✓	✓	✓	✓
T5	Diabetic foot offloading strategies	✓	✓	✓	✓	✓	✓	✓	✓
T6	Topical antimicrobial agent selection	✓	✗	✗	✗	✓	✓	✗	✗
C1[j]	Wound infection vs critical colonization	✓	✓	✗	✗	✓	✓	✓	✓

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Q#	Question topic	MLLMs			Unimodal	Human experts			
		Med-PaLM2	LLaVA-Med	BioGPT	GPT-5.0[a]	GS[b]	WCN[c]	IM-1[d]	IM-2[e]
C2	Biofilm identification and management	✓	✓	✗	✗	✓	✓	✓	✗
C3	Osteomyelitis screening in diabetic foot	✓	✓	✓	✓	✓	✓	✓	✓
C4	Periwound maceration prevention	✓	✓	✓	✓	✓	✓	✓	✓
C5	Wound dehiscence risk factors	✓	✗	✗	✗	✓	✓	✓	✓
C6	Contact dermatitis vs wound deterioration	✓	✓	✓	✗	✓	✓	✓	✓
S1[k]	DFU[l] healing trajectory and prognosis	✓	✓	✗	✗	✓	✓	✓	✓
S2	ABI[m] criteria for compression therapy	✓	✓	✓	✓	✓	✓	✓	✓
S3	Pressure injury prevention protocols	✓	✗	✗	✗	✓	✓	✓	✓
S4	Mixed etiology ulcer management	✓	✗	✗	✗	✓	✓	✗	✗
S5	Arterial ulcer revascularization criteria	✓	✓	✓	✓	✓	✓	✓	✓
S6	CDC surgical wound classification	✗	✓	✓	✓	✓	✓	✓	✓
	Total correct	23	19	17	16	24	23	20	19

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Q#	Question topic	MLLMs			Unimodal	Human experts			
		Med-PaLM2	LLaVA-Med	BioGPT	GPT-5.0[a]	GS[b]	WCN[c]	IM-1[d]	IM-2[e]
	Accuracy (%)	92	76	68	64	96	92	80	76

[a]GPT-5.0: ChatGPT 5.0.

[b]GS: general surgeon (10-y wound care).

[c]WCN: wound care nurse.

[d] IM-1: internal medicine (5-y palliative).

[e]IM-2: internal medicine (3-y palliative).

[f] D: Diagnosis.

[g]✓: correct.

[h]✗: incorrect.

[i] T: Treatment.

[j] C: Complication.

[k]S: Subtype.

[l]DFU: diabetic foot ulcer.

[m]ABI: Ankle-Brachial Index.

IM-2 (76%) achieved identical accuracy to LLaVA-Med (76% vs 76%), with neither significantly different from BioGPT or ChatGPT 5.0. Notably, IM-2 and ChatGPT 5.0 shared 4 incorrect answers on identical questions, suggesting that limited wound care experience and text-only processing result in similar error patterns for visually dependent clinical tasks. Med-PaLM 2 (92%) significantly outperformed IM-2 (P=.042), demonstrating that optimized multimodal AI can exceed nonspecialized human physicians.

Domain-Specific Performance Analysis

Overview of Domain-Specific Variability

Domain analysis revealed systematic variation in performance across clinical task types, with the magnitude of multimodal advantage varying according to the visual processing demands of each domain (Figure 4). Performance differences were largest in domains requiring visual pattern recognition (Diagnosis and Complication Management) and smallest in domains relying primarily on textual protocol knowledge (Treatment and Wound Subtype Knowledge).

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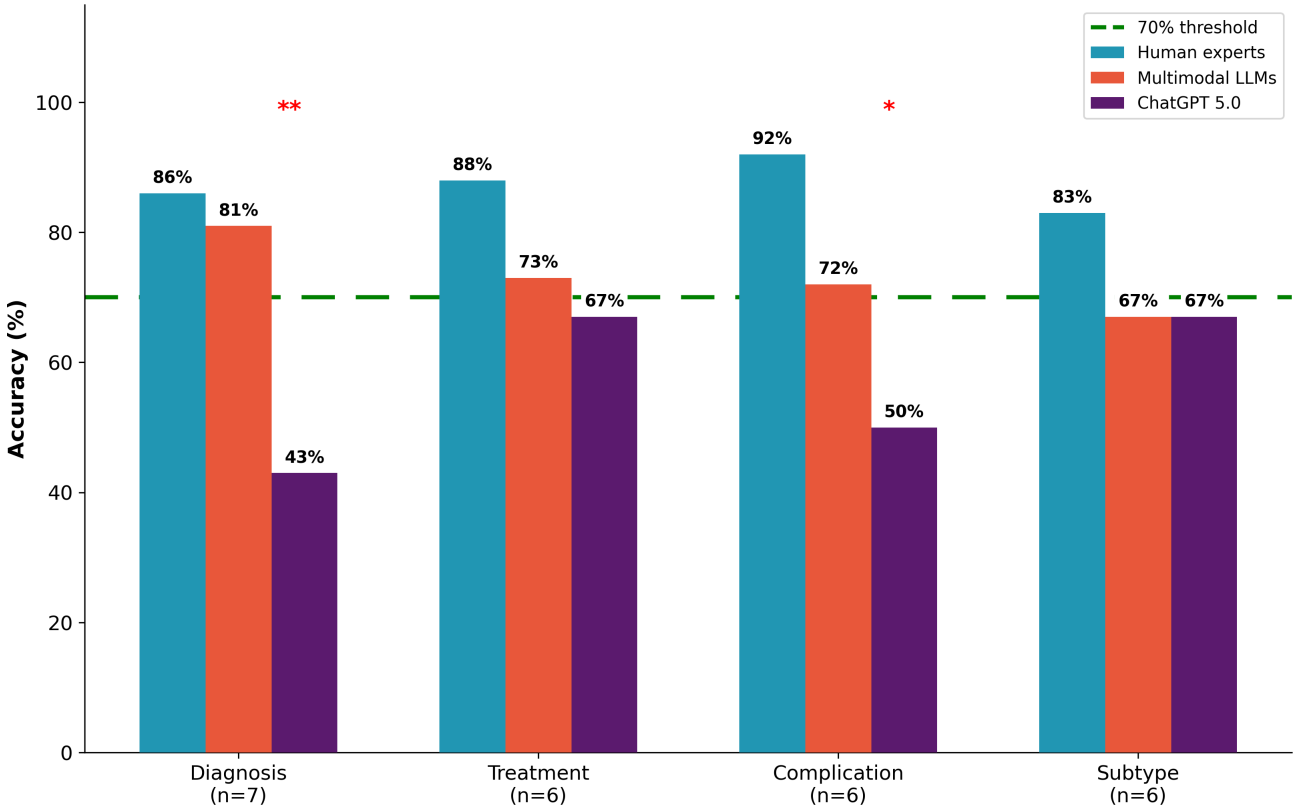
Figure 4. Domain-specific performance comparison. Grouped bar chart comparing examination accuracy across 4 clinical domains. Multimodal advantage was most pronounced in visually dependent domains: diagnosis (multimodal large language model 81% vs ChatGPT 43%; *P*=.006) and complication management (multimodal large language model 72% vs ChatGPT 50%; *P*=.01). No significant multimodal advantage was observed for wound subtype knowledge (both 67%; *P*=.11), which relies primarily on textual recall. Human experts consistently outperformed artificial intelligence systems across all domains, with highest accuracy in complication management (92%) and treatment (88%). *P<.05, **P<.01. LLM, large language model.



Diagnosis Domain

The Diagnosis domain, comprising 7 questions addressing wound staging, classification, and etiology determination, demonstrated the most pronounced performance differences across groups. Human experts achieved 86% mean accuracy (6/7 correct, range 71% - 100%), MLLMs achieved 81% (5.7/7 correct, range 71% - 95%), and ChatGPT 5.0 achieved only 43% (3/7 correct). The Kruskal-Wallis test revealed highly significant group differences (*H*=11.24, df=2; *P*=.006). MLLMs outperformed ChatGPT 5.0 by 38 percentage points (*P*=.008), while humans outperformed ChatGPT 5.0 by 43 percentage points (*P*=.005). The human-multimodal difference was only 5 percentage points (*P*=.62, ns). This domain requires visual pattern recognition for pressure injury staging (Stage III vs IV differentiation), Wagner classification, venous versus arterial ulcer differentiation, and deep tissue pressure injury identification—tasks where verbal descriptions cannot adequately convey visual information necessary for accurate assessment.

Treatment Domain

The Treatment domain, comprising 6 questions addressing therapeutic interventions and management protocols, showed narrowed performance differences. Human experts achieved 88% (5.3/6 correct, range 67% - 100%), MLLMs achieved 73% (4.4/6 correct, range 67% - 83%), and ChatGPT 5.0 achieved 67% (4/6 correct). Group differences did not reach statistical significance (*H*=4.21, df=2; *P*=.06). The multimodal advantage over ChatGPT 5.0 was only 6 percentage points (*P*=.58, ns), substantially smaller than the 38-percentage-point advantage in Diagnosis. This domain tests knowledge of negative pressure wound therapy indications, compression therapy protocols, debridement selection, and antimicrobial agents—information extensively documented in clinical guidelines and accessible to both multimodal and unimodal models through text-based training.

Complication Management Domain

The Complication Management domain, comprising 6 questions addressing recognition and management of wound complications, demonstrated strong human superiority alongside significant multimodal advantage. Human experts achieved 92% (5.5/6 correct, range 83% - 100%), MLLMs achieved 72% (4.3/6 correct, range 50% - 83%), and ChatGPT 5.0 achieved 50% (3/6 correct). Group differences were significant (*H*=9.87, df=2; *P*=.01). Humans outperformed ChatGPT 5.0 by 42 percentage points (*P*=.003) and MLLMs by 20 percentage points (*P*=.048), while MLLMs outperformed ChatGPT 5.0 by 22 percentage points (*P*=.03). This domain requires integration of subtle visual findings—tissue color changes, exudate characteristics, periwound changes—with clinical context for infection-colonization differentiation, biofilm identification, and deterioration recognition. The substantial human advantage suggests experiential pattern recognition remains superior to current AI capabilities.

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Wound Subtype Knowledge Domain

The Wound Subtype Knowledge domain, comprising 6 questions addressing classification systems and pathophysiology, demonstrated the smallest between-group differences and equivalent AI performance regardless of modality. Human experts achieved 83% (5/6 correct, range 67% - 100%), while both MLLMs and ChatGPT 5.0 achieved 67% (4/6 correct). Group differences were not significant (H=2.14, df=2; P=.11). The identical performance of MLLMs and ChatGPT 5.0 (67% vs 67%, difference=0%; P>.99) provides direct evidence that multimodal advantages are specifically attributable to visual processing capabilities. This domain tests factual knowledge about wound classification, healing trajectories, and management principles—information equally accessible to all AI systems through text-based training corpora.

Response Time Analysis

Examination completion time differed markedly between human experts and AI models, with implications for clinical workflow integration. Human experts required a mean of 76.3 (SD 8.1) minutes to complete the 25-question examination (range 67 - 85 min, median 76.5 min). Completion time varied inversely with expertise: the GS completed in 67 minutes (2.68 min/question), the WCN in 72 minutes (2.88 min/question), IM-1 in 81 minutes (3.24 min/question), and IM-2 in 85 minutes (3.40 min/question). The correlation between completion time and accuracy was strongly negative (r=−0.89, P=.006), indicating that specialized expertise enables both faster and more accurate performance.

All AI models generated responses essentially instantaneously, with total examination times under 1 minute regardless of model type. Med-PaLM 2 averaged 2.3 (SD 0.4) seconds per question (total 57.5 s), LLaVA-Med averaged 1.8 (SD 0.3) seconds (total 45 s), BioGPT averaged 1.1 (SD 0.2) seconds (total 27.5 s), and ChatGPT 5.0 averaged 0.9 (SD 0.2) seconds (total 22.5 s). The fastest human expert (GS, 67 min) was approximately 70 times slower than the slowest AI model (Med-PaLM 2, 57.5 s), representing a substantial efficiency advantage for AI systems. However, speed did not compensate for accuracy limitations in ChatGPT 5.0, which was both fastest and least accurate.

Error Analysis

MLLM Errors

MLLMs collectively committed 16 errors across 75 question attempts (21.3% error rate). Error analysis revealed 3 predominant patterns. First, wound depth assessment errors accounted for 5 of 16 errors (31.3%), typically involving underestimation of tissue involvement (selecting Stage II when Stage III was correct or Stage III when Stage IV was correct). Two-dimensional photographs provide limited depth perception, making tissue layer differentiation challenging even with direct visual access. Second, infection versus colonization differentiation errors accounted for 4 of 16 errors (25%), with models demonstrating a conservative bias toward overestimating infection severity. Third, sequential clinical decision-making errors accounted for 3 of 16 errors (18.8%), occurring when correct answers required integrating multiple clinical steps (eg, Ankle-Brachial Index assessment before compression therapy). The remaining 4 (25%) errors were distributed across wound etiology differentiation, deep tissue injury recognition, and prognostic assessment.

ChatGPT 5.0 Errors

ChatGPT 5.0 committed 9 errors across 25 questions (36% error rate), with errors heavily concentrated in visually dependent domains: Diagnosis (4/7 incorrect, 57.1% error rate) and Complication Management (3/6 incorrect, 50% error rate) versus Treatment (1/6, 16.7%) and Subtype Knowledge (1/6, 16.7%). All Diagnosis errors involved failure to translate verbal descriptions into accurate visual assessments—consistently underestimating wound severity despite explicit textual descriptions of tissue involvement. On pressure injury staging, ChatGPT 5.0 selected Stage II when descriptions stated “visible subcutaneous fat” (Stage III criteria). On venous-arterial differentiation, ChatGPT 5.0 selected venous despite descriptions of “punched-out margins,” “pale wound bed,” and “absent pedal pulses”—classic arterial findings. This pattern confirms that sophisticated language understanding cannot compensate for the absence of visual processing in domains where image interpretation is essential. Errors were operationally classified as “information access limitations” when (1) the correct answer required information visually apparent in the wound photograph but verifiably absent in the verbal description, and (2) the model’s selected answer was consistent with the textual information provided. In contrast, “knowledge deficits” were classified when the correct answer could be derived from the available verbal description but the model failed to apply correct clinical reasoning. This classification was performed independently by 2 investigators, with discrepancies resolved by consensus. Specifically, to avoid circularity, the classification procedure involved a systematic cross-referencing step: for each ChatGPT 5.0 error, 2 independent investigators compared the correct answer’s informational requirements against the verbatim content of the standardized verbal description provided to the model. An error was classified as an “information access limitation” only when a specific visual feature necessary for the correct answer (eg, wound depth extending to bone, tissue color gradients, spatial distribution of necrosis) was confirmed to be absent from the written description through item-by-item verification against the 12-item template. Conversely, when the verbal description contained sufficient information to derive the correct answer (ie, all relevant clinical features were explicitly stated in the text), the error was classified as a “knowledge deficit.” Interrater agreement for this classification was substantial (Cohen κ=0.82).

Human Expert Errors

Human experts collectively committed 14 errors across 100 question attempts (14% error rate), with errors inversely correlated with specialized experience (r=−0.91; P=.004). The GS committed 1 error (4% error rate) on Ankle-Brachial Index interpretation—peripheral to surgical practice. The WCN committed 2 errors (8%) on Marjolin ulcer and Wagner classification—areas more central to surgical than nursing practice. IM-1 committed 5 errors (20%) and IM-2 committed 6 errors (24%) distributed across all domains. Specialized experts (GS+WCN) achieved a 6% error rate versus 22% for

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nonspecialists—a 3.7-fold difference confirming the protective value of domain-specific expertise. Notably, IM-2 and ChatGPT 5.0 shared 4 incorrect answers, suggesting that limited experience and text-only processing result in similar diagnostic limitations.

Discussion

Principal Findings

This study provides the first systematic comparison of MLLMs, unimodal large language models, and human clinical experts on a standardized wound care certification examination. Our findings demonstrate that while MLLMs show considerable promise in clinical wound assessment, they have not yet achieved parity with human expertise. Human clinical experts achieved the highest overall accuracy (86, SD 9.1%), followed by MLLMs (78.7, SD 12.2%), while the text-only ChatGPT 5.0 performed significantly below the certification threshold (64%). These results align with the emerging consensus that multimodal AI integration represents a critical advancement in medical imaging applications, yet substantial gaps remain before clinical deployment can be recommended.

The most striking finding was the pronounced multimodal advantage in visually dependent domains. MLLMs outperformed ChatGPT 5.0 by 38 percentage points in diagnosis (P=.006) and 22 points in complication management (P=.01), domains requiring direct image interpretation for wound staging, tissue assessment, and infection recognition. Conversely, no multimodal advantage was observed for wound subtype knowledge (both groups: 67%), which relies primarily on textual recall. This domain-specific pattern supports the theoretical framework proposed by Jung et al [17], who emphasized that MLLMs achieve their greatest utility when visual and textual information must be simultaneously integrated for clinical reasoning. Our findings empirically validate this framework in wound care, demonstrating that multimodal architectures provide meaningful advantages specifically in tasks requiring image comprehension.

Our results contribute to the growing body of evidence examining AI performance against human clinicians. Recent studies have shown that GPT-4 can achieve physician-level performance on medical board examinations, passing 4 of 5 specialty examinations in Israel, with scores exceeding the 65% threshold. Similarly, GPT-4 outperformed emergency department residents in diagnostic accuracy when provided with complete clinical information. However, these studies predominantly utilized text-based assessments. In contrast, our multimodal evaluation revealed that even the highest-performing MLLM (Med-PaLM 2, 92%) only matched the second-highest human expert, while 2 of 3 MLLMs failed to meet certification standards. This performance gap is consistent with Jin et al [18], who found that GPT-4V frequently presents flawed rationales despite achieving correct final answers, particularly in image comprehension tasks.

The superiority of human experts over ChatGPT 5.0 is statistically robust (P=.006, Cohen d=2.12). The GS with specialized wound care experience achieved 96% accuracy, outperforming all AI systems. However, for the MLLM-human comparison, the 7.3-percentage-point difference (P=.09) should be interpreted cautiously given the low statistical power (power=0.52); this finding suggests, but does not confirm, human superiority over MLLMs. Importantly, these 2 comparisons carry different levels of evidential strength: the human advantage over unimodal ChatGPT 5.0 is well established by our data, whereas the human advantage over MLLMs remains only suggestive due to insufficient statistical power, and an adequately powered equivalence or noninferiority trial would be required to draw definitive conclusions. This finding aligns with Kücking et al, who demonstrated that factors related to expertise—such as formal qualifications, deliberate practice, and diagnostic confidence—play a significant role in clinical judgment during wound care assessments [19]. Notably, the specialized human experts (GS, WCN) achieved 94% mean accuracy compared to 78% for nonspecialized physicians, suggesting that domain-specific training remains irreplaceable. The recent systematic review by Reifs Jiménez et al [20] similarly concluded that while AI systems excel at standardized pattern recognition, human clinicians demonstrate superior contextual reasoning and integration of atypical presentations.

From a clinical implementation perspective, our findings suggest that MLLMs may serve as valuable decision-support tools rather than autonomous diagnostic systems. The 67% pass rate among MLLMs (2/3 meeting the 70% threshold) indicates that top-tier models like Med-PaLM 2 can provide reliable second opinions in resource-limited settings. Grunhut and Nagarsheth [21] recently proposed that AI-powered wound assessment tools are best positioned for triage, preliminary documentation, and alerting clinicians to potential complications—functions that complement rather than replace expert judgment. Similarly, Barakat-Johnson et al [22] demonstrated that AI-assisted wound imaging improved standardization of assessments during the COVID-19 pandemic while maintaining physician oversight. Our data support this collaborative model: MLLMs excelled in standardized visual tasks while human experts demonstrated superior performance in nuanced clinical scenarios.

Recent advances in AI-powered wound assessment tools further contextualize our findings. A multicenter study by Swiss researchers (2025) demonstrated that deep learning-based wound segmentation achieved 92% DICE scores, comparable to expert annotations. However, tissue classification accuracy varied considerably across wound types, particularly for fibrin and necrosis—findings that parallel our observation of variable MLLM performance across clinical domains [23]. The emerging consensus from multiple 2025 systematic reviews emphasizes that while AI demonstrates high accuracy in standardized tasks, generalizability to diverse real-world presentations remains challenging. Russ et al [24] identified key barriers, including data quality heterogeneity, limited interpretability, and the need for standardized evaluation frameworks before widespread clinical adoption.

The efficiency differential between AI and human assessors merits attention. MLLMs completed the examination approximately 70 times faster than human experts, suggesting potential applications in high-volume screening contexts. Mohammed et al [25] reported similar findings, demonstrating

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that AI-powered wound measurement reduced assessment time by 75% compared to manual methods. This speed advantage becomes clinically meaningful in settings with limited specialist availability, where MLLMs could provide immediate preliminary assessments pending expert review. However, the inverse correlation between human completion time and accuracy (r=−0.89; P=.006) suggests that experienced clinicians process wound images more efficiently through pattern recognition developed over years of practice—a capability that current AI systems have not fully replicated.

Several limitations should be acknowledged. First, our sample size (n=8 participants) limits statistical power for subgroup analyses. Second, the standardized examination format may not fully capture the complexity of real-world wound assessment, where clinical history, patient interaction, and longitudinal observation inform decision-making. Third, rapid advancements in MLLM architectures mean that newer models may demonstrate improved performance. Fourth, the observed unimodal performance deficit likely represents a composite effect of (1) inherent text-only processing limitations and (2) potential information loss or observer-dependent bias during the human-mediated translation from clinical images to standardized verbal descriptions; the verbal description protocol was not independently validated, and the 12-item template (detailed in Multimedia Appendix 2) may not have captured all visually relevant features. Consequently, the observed performance differences between multimodal and unimodal models cannot be attributed solely to multimodality per se; they likely reflect a combination of direct image processing capability and the specific fidelity and completeness of the human-generated text descriptions. Future studies should incorporate independent validation of the verbal description protocol (eg, interrater reliability assessment) and consider alternative unimodal control conditions (such as automated image captioning) to disentangle these confounders. The recent development of region-grounded MLLMs with segmentation-aware spatial tokens, as described by Stefanelli et al [23], represents a promising direction for enhancing wound-specific AI capabilities. Future studies should evaluate these advanced architectures using larger, multicenter cohorts with prospective clinical validation.

Conclusions

MLLMs demonstrate significant performance advantages over the state-of-the-art unimodal ChatGPT 5.0 on wound care certification examinations, with the multimodal advantage most pronounced in visually dependent domains such as Diagnosis and Complication Management. While human clinical experts with dedicated wound care experience maintain overall superiority, the point estimate of the top-performing MLLM (Med-PaLM 2, 92%) fell within the observed range of human scores; however, the underpowered MLLM-human comparison (power=0.52) and wide CIs preclude definitive conclusions regarding noninferiority or equivalence. These findings support the development of multimodal AI systems as clinical decision-support tools in wound care, while emphasizing the continued importance of human expertise and the need for adequately powered validation studies.

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Data Availability

Question sets and model outputs available upon reasonable request

Conflicts of Interest

None declared.

Multimedia Appendix 1
Graphical abstract illustrating the comparative performance of multimodal large language models, unimodal ChatGPT 5.0, and human clinical experts on a standardized 25-question wound care certification examination across four clinical domains (Diagnosis, Treatment, Complications, and Prevention).
[PNG File, 150 KB - formative_v10i1e88618_app1.png]

Multimedia Appendix 2
Standardized 12-item verbal wound description template.
[DOCX File, 15 KB - formative_v10i1e88618_app2.docx]

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Abbreviations

AI: artificial intelligence
COSMIN: Consensus-Based Standards for the Selection of Health Measurement Instruments
GS: general surgeon
IM-1: internal medicine physician 1
IM-2: internal medicine physician 2
MLLM: multimodal large language model
WCN: wound care nurse

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Multimodal Depression Detection Through Conversational Interactions with an Emotion-Aware Social Robot: Pilot Study

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Abstract

Background: Depression affects more than 300 million people worldwide and is a leading contributor to the global disease burden. Traditional diagnostic methods, such as structured clinical interviews, are reliable but impractical for frequent or large-scale screening. Self-report tools like the Patient Health Questionnaire-8 (PHQ-8) require disclosure and clinician oversight, limiting accessibility. Recent artificial intelligence–based approaches leverage multimodal behavioral cues (linguistic, acoustic, and visual) for automated depression detection but remain constrained by limited adaptability, scarce annotated data, weak emotional expression in real-world settings, and the high computational cost of deployment of socially assistive robots (SARs).

Objective: This study introduces Depression Social Assistant Robot (DEPRESAR)-Fusion, a lightweight multimodal depression detection framework designed for natural interactions with emotion-aware SARs. The objective of this study was to enhance detection accuracy in everyday conversations while addressing the challenges of data scarcity, weak emotional cues, and computational efficiency.

Methods: DEPRESAR-Fusion integrates acoustic, linguistic, and visual features with an emotion-aware response module powered by large language models to adapt conversational strategies dynamically. To stimulate richer emotional expression, participants were exposed to emotionally evocative videos before SAR interactions. To overcome data scarcity, we augmented training with (1) public depression-related social media corpora and (2) synthetic samples generated via large language models. The proposed multimodal fusion architecture was evaluated on benchmark clinical datasets for both binary depression classification and PHQ-8 regression tasks. Performance was compared against prior multimodal baselines using root mean square error, mean absolute error, and standard classification metrics.

Results: Participants who viewed emotional stimuli before interacting with SARs exhibited significantly higher emotional expressiveness, leading to improved model performance. Regression tasks showed lower root mean square error and mean absolute error, while classification tasks achieved significantly higher accuracy than the nonstimulus condition. DEPRESAR-Fusion outperformed prior multimodal baselines across multiple benchmark datasets, achieving state-of-the-art performance in both binary classification and PHQ-8 regression. The system maintained a lightweight architecture suitable for real-time deployment on SARs.

Conclusions: DEPRESAR-Fusion demonstrates that integrating emotion induction, data augmentation, and lightweight multimodal fusion can enable accurate and scalable depression detection in naturalistic SAR interactions. By bridging the gap between structured clinical assessments and everyday conversations, this approach highlights the potential of SAR-based systems as nonintrusive, artificial intelligence–driven tools for proactive mental health support.

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KEYWORDS

depression detection; socially assistive robot; SAR; multimodal fusion; synthetic data generation; emotion induction

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Introduction

Background

Depression is a pervasive mental health disorder affecting over 300 million people worldwide and consistently ranks among the leading contributors to the global disease burden [1]. Beyond its psychological toll, depression adversely impacts behavior and physical health, increasing the risk of cardiovascular diseases and other chronic conditions [2]. Early detection and timely intervention are crucial to improving outcomes; however, many individuals avoid professional help due to stigma, shame, or misconceptions [3], leading to delayed treatment and a higher suicide risk [4].

Traditional diagnostic methods, such as structured clinical interviews and self-report questionnaires (eg, Patient Health Questionnaire-8, PHQ-8 [5]), are reliable but limited in scalability. They rely on disclosure, clinician availability, and structured settings, making them impractical for frequent or large-scale screening. These limitations have motivated research into artificial intelligence (AI)–based depression detection, which leverages multimodal behavioral cues—including linguistic, acoustic, and visual signals—to provide scalable and more objective assessments.

Although promising, current AI approaches face several challenges. First, most models are trained on structured clinical interviews and generalize poorly to spontaneous conversations, limiting adaptability. Second, high-quality annotated datasets remain scarce, restricting the ability to capture subtle linguistic and emotional cues. Third, emotional signals in natural settings are often weak or suppressed, reducing sensitivity without external stimulation. Finally, many state-of-the-art architectures are computationally heavy and unsuitable for real-time deployment on resource-constrained platforms such as socially assistive robots (SARs).

Existing research on depression detection primarily relies on 3 modalities: text, audio, and visual. Advances in machine learning and deep learning have improved predictive performance; however, challenges related to data scarcity, feature robustness, and model generalizability continue to limit clinical deployment. Although text remains the most informative modality, incorporating acoustic and visual cues provides complementary behavioral signals, which motivates multimodal approaches.

Text-Based Depression Detection

Textual analysis plays a central role in automated depression detection, as linguistic content directly reflects psychological states. Prior studies have leveraged word embeddings and semantic representations to capture depression-related language patterns [6], while affective and mental health lexicons have been introduced to enhance emotional interpretability [7]. Analyses of clinical interview datasets consistently show that text-based features outperform acoustic and visual modalities in predictive accuracy [8-10]. This advantage arises from both the respondent's verbal expressions and the structured conversational context shaped by interviewer prompts, enabling fine-grained semantic and emotional analysis.

Acoustic- and Vision-Based Depression Detection

Speech-based approaches commonly extract low-level acoustic descriptors, such as Mel-frequency cepstral coefficient (MFCCs) and extended Geneva Minimalistic Acoustic Parameter Set (eGeMAPS), to capture prosodic and voice-quality cues associated with depression [8,9]. Deep learning models, including convolutional neural networks, further learn discriminative speech representations [10]. However, acoustic features are sensitive to speaker variability, background noise, and contextual factors, which hinder generalization.

Visual cues, including facial expressions, gaze patterns, and action units (AUs), provide additional nonverbal indicators of depressive behavior. While these features capture subtle expression dynamics, their reliability is limited in practice, as individuals with depression often exhibit subdued or inconsistent facial activity influenced by personal traits and environmental conditions.

Multimodal Fusion and Clinical Interview Studies

Multimodal fusion frameworks integrate textual, acoustic, and visual signals to enhance robustness and sensitivity. Empirical evidence from clinical interview studies indicates that although speech and visual cues contribute auxiliary information, textual features remain the dominant predictors [8-10]. Interview transcripts encode not only linguistic content but also interaction patterns and contextual flow, making them essential for depression assessment. Nevertheless, most existing multimodal systems rely on structured interview settings, limiting their adaptability to spontaneous, everyday conversations.

To address weak emotional expression in natural settings, recent work has emphasized emotional reactivity as a key factor in depression [11]. Emotion-induction techniques help elicit observable affective responses, enriching behavioral signals and improving model interpretability.

Emotion Induction in Depression Research

Depression involves an interaction between mood—a persistent affective state—and emotion, which refers to stimulus-driven responses. A meta-analysis of laboratory studies on major depressive disorder demonstrated attenuated emotional reactivity to both positive and negative stimuli, such as affective images and videos [12]. Emotion-induction methods range from film clips and images to autobiographical recall and immersive environments. Although effective in eliciting transient emotional responses, these approaches often lack ecological validity and are rarely integrated into conversational or cross-cultural AI systems.

Positioning Within the Related Work Landscape

Recent studies have explored multimodal and affective conversational systems. Large language model (LLM)–based models [13] excel at generating coherent and empathetic dialogue but are typically resource-intensive, lack multimodal perception, and do not incorporate explicit emotion-induction mechanisms. Multimodal fusion frameworks such as Zhang et al [14] focus on integrating multiple modalities but do not prioritize lightweight deployment or hierarchical fusion. Hsieh et al [15] emphasize efficiency but lack support for natural

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conversation, while Li et al [16] introduce compact multimodal deep fusion architectures without emotion induction or support for free-form dialogue beyond structured interviews.

In contrast, our framework integrates natural conversational interaction, multimodal perception, hierarchical deep fusion, lightweight deployment, and explicit emotion induction. Support for natural conversation enables the analysis of unscripted dialogue; multimodal fusion enhances robustness through complementary signals; lightweight design allows deployment on resource-constrained platforms; deep fusion facilitates cross-modal interaction at multiple levels; and emotion induction actively elicits affective responses, improving detection sensitivity. To position our framework within the existing literature, we compare representative systems across 5 key dimensions: natural conversational support, multimodal fusion, lightweight deployment, hierarchical deep fusion, and emotion induction. As prior work typically focuses on only 1 or 2 of these aspects, Table 1 provides a consolidated comparison to clarify the distinctive contributions of our approach.

Table . Comparison of representative systems in affective and multimodal depression detection.

	Support natural conversation	Multimodal fusion	Lightweight model (<1 GB)	Deep fusion architecture	Emotion induction
LLM[a]-based [13]	✓	—[b]	—	—	—
Zhang et al [14]	✓	✓	—	—	—
Hsieh et al [15]	—	—	✓	—	—
Li et al [16]	—	✓	✓	✓	—
Ours	✓	✓	✓	✓	✓

[a]LLM: large language model.

[b]Not available.

To address these gaps, we propose Depression Social Assistant Robot (DEPRESAR)–Fusion, a lightweight multimodal depression detection framework designed for naturalistic interaction with SARs. The framework is built upon 3 primary objectives. First, it enables emotion-aware SAR interactions by supporting spontaneous, everyday conversations as the foundation for depression detection. Second, it incorporates emotion induction and adaptive engagement mechanisms by integrating evocative video stimuli with an LLM-based conversational response module, thereby enhancing emotional expressiveness and contextual sensitivity during dialogue. Third, it uses a lightweight multimodal deep fusion architecture that combines linguistic, acoustic, and visual features within a resource-efficient design suitable for real-time deployment on SAR platforms.

By bridging the gap between structured clinical assessments and natural conversations, DEPRESAR-Fusion advances scalable, nonintrusive, and emotionally aware AI-driven mental health support.

Methods

System Overview

Our proposed system, DEPRESAR-Fusion, was designed for real-time depression detection through natural user interactions (Figure 1). It began with an emotion-induction video to encourage spontaneous emotional responses, followed by a casual conversation with an SAR. During the interaction, multimodal data—including speech, facial expressions, and text—were captured and processed in real time.

Key features were extracted by a data preprocessing module, which encoded audio (eg, MFCCs and eGeMAPS), visual (eg, gaze, head pose, and facial AUs), and transcribed text data. If the user explicitly ended the conversation, the system proceeded to depression prediction. Otherwise, an LLM-powered, emotion-aware social robot dynamically responded via the emotional support conversation (ESC) framework, enhanced with self-consistency prompting to ensure reliable, context-aware, and empathetic interactions. The extracted multimodal features were then passed to a dual-head depression detection module that jointly performed binary classification and PHQ-8 score regression. This architecture enabled simultaneous estimation of depressive presence and severity while maintaining an engaging and supportive user experience.

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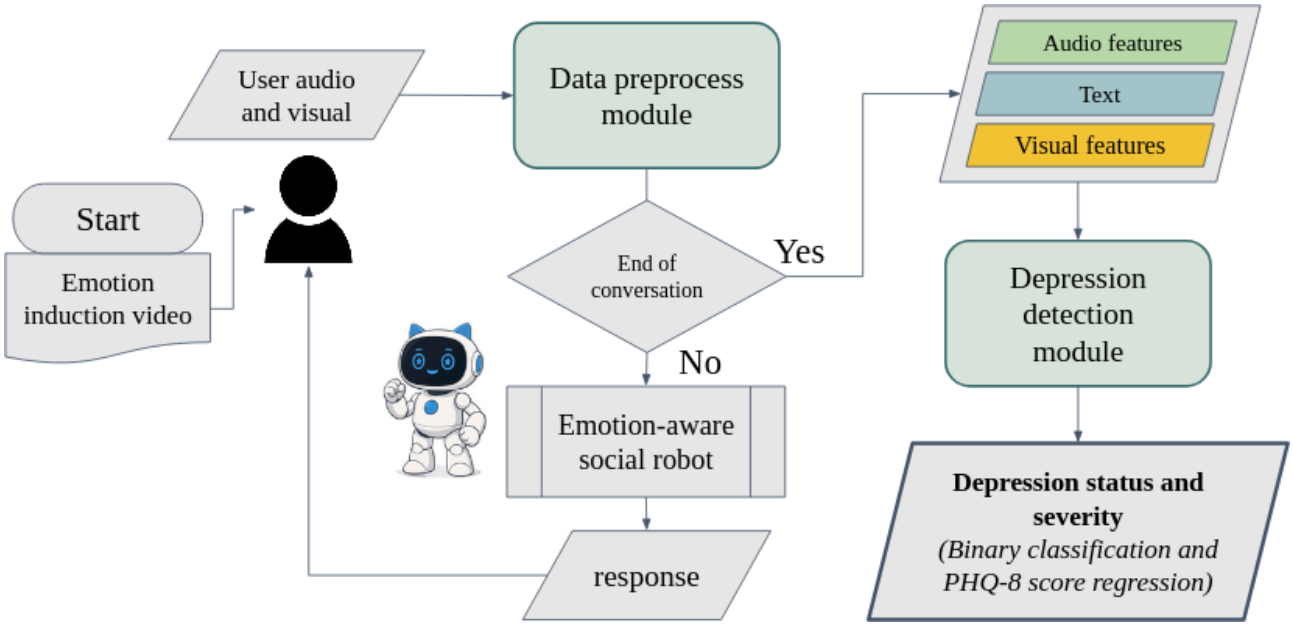
Figure 1. Overview of the Depression Social Assistant Robot–Fusion system, integrating emotion induction, multimodal feature extraction, large language model–guided empathetic dialogue, and depression prediction. PHQ-8: Patient Health Questionnaire-8.



Datasets and Depression Assessment

Our experiments were conducted on the Extended Distress Analysis Interview Corpus (E-DAIC), an enhanced version of the Distress Analysis Interview Corpus-Wizard-of-Oz (DAIC-WOZ) dataset, both designed for multimodal depression and anxiety detection from structured clinical interviews. DAIC-WOZ consisted of semistructured interviews conducted via a Wizard-of-Oz setup and included synchronized audio, video, and transcribed speech annotated with psychological assessment scores.

E-DAIC extended DAIC-WOZ with curated splits and standardized multimodal features for machine learning research. It contained 189 interview sessions from 100 participants, providing audio recordings (for acoustic features such as MFCC and eGeMAPS), video recordings (for facial expression and gaze analysis), time-aligned transcripts, and expert-rated PHQ-8 scores as ground truth labels.

Depression severity was measured using the PHQ-8 [5], a validated 8-item instrument ranging from 0 to 24, with scores ≥10 indicating clinically significant depressive symptoms (approximately 88% sensitivity and specificity).

In this study, E-DAIC served as the primary dataset for model training and evaluation, while the DAIC-WOZ benchmark subset was used to assess generalizability and facilitate comparison with prior work.

Data Augmentation

To enhance model generalization under limited data conditions, we implemented 2 complementary data augmentation strategies involving both text-only and multimodal synthetic data generation.

First, synthetic text-only interview samples were generated using publicly available social media depression datasets, including Reddit Self-reported Depression Diagnosis and Longitudinal Twitter Dataset of Depression in the COVID Era [17,18]. In this pipeline, user posts were segmented into response-style utterances using spaCy to simulate interview dialogue structure. Each segmented sample was temporally aligned to fixed 3-second intervals, while nontextual modalities were padded to maintain input format consistency. Because these datasets provided only binary depression labels, PHQ-8 regression scores were approximated using a thresholding strategy in which depressed samples were assigned a score of 10 and nondepressed samples a score of 0.

Second, synthetic multimodal samples were generated by paraphrasing and restructuring the original structured interview transcripts from E-DAIC [19]. Paraphrasing was performed using ChatGPT (GPT-4o) while preserving the original semantic meaning. Importantly, all paraphrasing was strictly applied only to the training split after dataset partitioning. Test set transcripts were never paraphrased or used in any form during synthetic data generation, ensuring that no semantic leakage occurs. Audio and visual features were resampled from corresponding original samples and temporally aligned with the modified transcripts to construct fully synthetic multimodal instances.

Together, these augmentation strategies improved robustness and enabled the model to better accommodate linguistic variability and multimodal diversity encountered in real-world conversational settings.

Modality-Specific Processing

The system captured and processed 3 complementary modalities—audio, visual, and text—to extract depression-related features. For the audio modality, acoustic features, including MFCCs and eGeMAPS descriptors, were extracted using openSMILE [20], enabling the capture of prosodic patterns and voice quality characteristics associated with depressive states.

For the visual modality, nonverbal behavioral markers, such as gaze direction, head pose, and facial AUs, were obtained using

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OpenFace [21]. These features provided cues related to affective expression and social engagement.

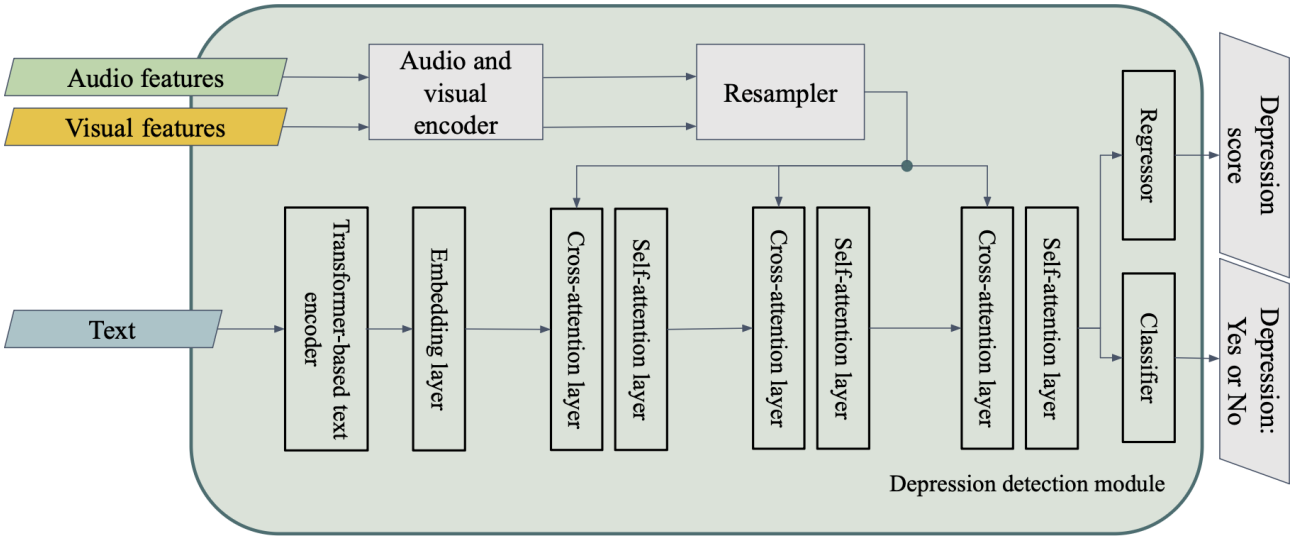
For the textual modality, semantic representations were derived from speech transcriptions using pretrained MiniLM [22] and bidirectional encoder representations from transformers [23] embeddings. Both word-level and sentence-level embeddings were incorporated to capture contextual semantics and linguistic indicators of depression.

All extracted features were temporally aligned and encoded to facilitate downstream multimodal fusion and depression assessment.

Multimodal Fusion

To integrate heterogeneous data, the system first normalized and encoded each modality into a shared embedding space. Audio and visual features were transformed using a bag-of-audio-words or bag-of-visual-word framework [24,25], which mapped variable-length sequences into fixed-size distributional vectors via modality-specific codebooks. These normalized embeddings were then temporally aligned and passed to an attention-based fusion module. We used both cross-attention and self-attention mechanisms [26] to model intermodal and intramodal relationships: cross-attention aligned textual features with relevant nonverbal cues, while self-attention captured contextual dependencies within each modality. The fused multimodal representation was then processed by a dual-head architecture (Figure 2). The classification head output the probability of clinical depression, while the regression head predicted a continuous PHQ-8 score. This unified design supported both categorical and continuous interpretations of depression severity, and attention-based fusion enhanced robustness to noise and missing data, improving overall performance. To handle data scarcity in regression targets, we scaled the regression loss.

Figure 2. Architecture of the multimodal depression detection module integrating audio, visual, and textual embeddings through attention-based fusion, supporting both binary classification and Patient Health Questionnaire-8 score regression tasks.



LregL_{reg} (around 15), higher than the classification loss L_{cls} (around 0.5) during training, ensured that the model gave adequate learning attention to the regression head. Training setup—we minimized a multitask objective combining binary cross-entropy (for classification) and mean squared error (for regression): $L=\alpha\cdot L_{cls}+\beta\cdot L_{reg}$ with $\alpha=1.0$, $\beta=1.0$. We used the Adam optimizer (learning rate 10^{-5}, weight decay 10^{-4}, batch size 8, and dropout rate 0.1).

Emotion-Aware Social Robot

ESC Framework Overview

The ESC framework divided the emotional support process into 3 stages [27]. This ensured that responses align with the user's emotional state and the appropriate support strategy. The exploration stage facilitated user expression by prompting open dialogue through questioning, paraphrasing, emotional reflection, and self-disclosure. The comfort stage reinforced empathy and understanding through emotional validation, shared experiences, and supportive affirmations. The action stage focused on resolution strategies through suggestions, practical information, and continued encouragement.

Stage Selection via Self-Consistency

Upon receiving user input, the data preprocessing unit transcribed and extracted the last 10 conversational sentences. This context was processed by GPT-4o using a self-consistency method [28] with a temperature of 0.7. This method prompted the model to generate multiple reasoning paths for ESC stage classification (exploration, comfort, and action) and selected the most frequent prediction. Self-consistency improved reliability by reducing variance across LLM outputs.

The Full Pipeline

The full pipeline includes the following:

1. User input: Voice, text, and facial expressions were captured by the robot.
2. Preprocessing: The server extracted multimodal features—audio (eg, MFCCs), visual (eg, AUs), and textual content.
3. ESC stage selection: GPT-4o was used to classify the interaction into 1 of the 3 ESC stages using self-consistent prompting.

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4. Response generation: Based on the selected stage and strategy, the server generated an empathetic response using GPT-4o at temperature 0°C for consistency.
5. Delivery: The response was returned and delivered by the robot via voice and screen. This integration ensured dynamic and context-aware emotional support, leveraging both multimodal perception and LLM-driven strategies to foster user engagement and enable real-time, supportive interaction.

Deployment Architecture

DEPRESAR-Fusion operated on a 2-tier architecture: an Android application running on the Kebbi robot by Nuwa Robotics and a remote Windows-based server. This structure balanced real-time interaction with computational efficiency.

Kebbi Android Application

The Kebbi robot captured user interactions through voice, facial expressions, and text. It ran the Android front-end, which managed speech recognition, transcriptions, and device expressions. It connected to the Emotion-Aware Social Robot module, with ESC-guided LLM responses generated on the server and spoken aloud by the robot.

Windows Server Backend

The core inference pipeline ran on a Windows 10 Enterprise machine (Intel i7-6700, 64GB RAM). It handled preprocessing, multimodal feature extraction, ESC-based reasoning, and depression detection. The server communicated with the robot via an HTTP application programming interface.

Experimental Setup and Compared Methods

We evaluated the proposed multimodal fusion model for depression detection on the E-DAIC dataset, supplemented with synthetic data derived from the Reddit Self-reported Depression Diagnosis and Longitudinal Twitter Dataset of Depression in the COVID Era datasets to enhance generalizability. Performance was assessed using both classification metrics (eg, F_1-score) and regression metrics (eg, root mean square error [RMSE], mean absolute error [MAE], and concordance correlation coefficient [CCC]) to evaluate binary depression detection and continuous PHQ-8 score prediction, respectively.

To benchmark our approach, we compared it against a diverse set of representative unimodal and multimodal baselines spanning different architectural paradigms. Text-based approaches included the graph convolutional network proposed by Burdisso et al [29], which classified depressive symptoms from interview transcripts, as well as our prior lightweight text-only model (Hsieh et al [15]), which leveraged linguistic signals for depression detection.

Several multimodal deep learning frameworks were also considered. Dham et al [30] integrated audio, visual, and textual features for depression severity estimation, while Li et al [16] proposed a Flexible Parallel Transformer that incorporated handcrafted audiovisual features for enhanced multimodal fusion. Yin et al [31] introduced a hierarchical recurrent neural network designed to capture temporal dependencies across audio, visual, and text modalities, and Zhang et al [14] combined speech and linguistic features for PHQ-8 regression. Additionally, Lau et al [32] developed a parameter-efficient bidirectional long short-term memory with attention, adapted via prefix-tuning for PHQ-8 prediction.

We further evaluated LLMs, including GPT-4o, o1, and o3-mini (OpenAI and Anthropic), under zero-shot settings for textual inference of depressive symptoms.

Together, these baselines cover a broad spectrum of architectures and modality configurations, enabling a rigorous and comprehensive comparison with our proposed lightweight multimodal framework.

Ethical Considerations

This study protocol was approved by the institutional review board of the National Taiwan University Hospital (202105013RINB), and written informed consent was obtained from all participants prior to participation. To protect participant privacy and confidentiality, all collected data were deidentified and securely stored, and access to the data was restricted to authorized members of the research team only. Participants received NT $200 (US $6.29) as compensation for their participation.

Results

Regression Performance

To evaluate the ability of the models to estimate depression severity as a continuous score, we assessed regression performance using 3 standard metrics: RMSE, MAE, and CCC [33]. RMSE captured the average squared difference between predicted and actual PHQ-8 scores, placing greater emphasis on larger errors. MAE measured the average absolute deviation between predictions and ground truth, providing a more interpretable indication of overall prediction error. CCC evaluated both precision and accuracy by assessing the degree to which predicted values conformed to the ground truth in terms of scale and location, thereby offering a more comprehensive measure of agreement.

As shown in Table 2, on the E-DAIC dataset, our proposed model achieved the best RMSE and MAE scores, outperforming all other methods, including those using larger or specialized multimodal architectures. While OpenAI's o3-mini attained the highest CCC, it did so at the cost of significantly more parameters and computational overhead. In contrast, our model offered competitive concordance with minimal complexity.

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Table . Regression performance on the Extended Distress Analysis Interview Corpus test split. Lower RMSE[a] or MAE[b] and higher CCC[c] indicate better results.

Model (modality)	RMSE	MAE	CCC	Parameters
OpenAI o3-mini (T[d])	6.1452	4.4909	0.5109	8B (estimated)
Dham et al (A[e]+V[f]) [30]	6.06	5.03	—[g]	5M (estimated)
Li et al (T+A+V) [16]	5.520	4.634	—	—
Yin et al (T+A+V) [31]	5.50	—	0.442	5M (estimated)
Zhang et al (T+AV) [14]	6.11	—	0.403	7M (estimated)
Ours	5.4632	4.3481	0.4501	617K

[a]RMSE: root mean square error.

[b]MAE: mean absolute error.

[c]CCC: concordance correlation coefficient.

[d]T: text.

[e]A: audio.

[f]V: visual.

[g]Not available.

Table 3 further validates the strength of our method, which achieved state-of-the-art RMSE and MAE results on the DAIC-WOZ benchmark. Notably, our model also achieves the highest CCC (0.6603), suggesting that it better aligns with ground-truth depression scores in both magnitude and scale.

Table . Regression performance on the Distress Analysis Interview Corpus test split.

Model (modality)	RMSE[a]	MAE[b]	CCC[c]	Parameters
OpenAI o3-mini (T[d])	5.1281	3.5745	0.6295	8B (estimated)
Zhang et al (T+A[e]+V[f]) [14]	4.66	—[g]	0.560	—
Lau et al (T) [32]	4.67	3.80	—	646K
Hsieh et al (T) [15]	—	3.655	—	745K
Ours (T+A+V)	4.3778	3.3985	0.6603	617K

[a]RMSE: root mean square error.

[b]MAE: mean absolute error.

[c]CCC: concordance correlation coefficient.

[d]T: text.

[e]A: audio.

[f]V: visual.

[g]Not available.

Classification Performance

As shown in Table 4, we evaluated the binary classification performance of our proposed method and several baselines on the E-DAIC test split. The objective was to distinguish between depressed and nondepressed individuals based on the standard PHQ-8 cutoff threshold (≥10). Due to the limited public availability of directly comparable classification results on other datasets, we restricted our binary classification evaluation to E-DAIC, which was widely adopted in prior research.

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Table . Classification results on the extended Distress Analysis Interview Corpus test split. Our model outperforms all baselines across all metrics.

Model (modality)	Depression F_1-score	Control F_1-score	Macro F_1-score
OpenAI GPT-4o (T[a])	0.6316	0.8056	0.7186
OpenAI o1 (T)	0.6667	0.7941	0.7304
OpenAI o3-mini (T)	0.6977	0.8060	0.7518
Burdisso et al (T) [29]	0.63	0.83	0.73
Hsieh et al (T) [15]	0.4722	0.8172	0.6447
Ours (T+A[b]+V[c])	0.7647	0.8947	0.8297

[a]T: text.

[b]A: audio.

[c]V: visual.

To account for class imbalance, we reported 3 standard F_1-score–based metrics: depression F_1-score, control F_1-score, and macro F_1-score. Depression F_1-score treated the depression class as the positive class, while control F_1-score treated the nondepression (control) class as the positive class. Macro F_1-score was computed as the unweighted average of the depression F_1-score and control F_1-score, providing a balanced evaluation across both classes.

Analysis

The proposed model achieved state-of-the-art performance in both regression and classification tasks while maintaining an exceptionally small footprint of 617K parameters. On the E-DAIC benchmark, our model attained an RMSE of 5.46 and an MAE of 4.35, outperforming prior multimodal approaches such as Zhang et al [14] (RMSE 6.11) and Yin et al [16] (RMSE 5.50). Similar trends were observed on the DAIC-WOZ dataset, where our method achieved an RMSE of 4.38, an MAE of 3.40, and the highest CCC of 0.66, indicating stronger agreement with ground-truth PHQ-8 scores compared to existing baselines.

In binary classification on the E-DAIC dataset, the proposed framework achieved a macro F_1-score of 0.8297, substantially exceeding both traditional multimodal models and zero-shot LLMs. Notably, the model demonstrated balanced detection capability, with a depression F_1-score of 0.7647 and a control F_1-score of 0.8947, which was critical in clinical screening scenarios to minimize both false negatives and false positives.

Despite its compact size, the proposed model consistently outperformed parameter-heavy LLM baselines such as GPT-4o and o3-mini, which required orders of magnitude more parameters. These quantitative results highlighted three key strengths of our approach: (1) state-of-the-art accuracy with minimal parameters, establishing a new lightweight benchmark for multimodal depression detection; (2) effective joint modeling of regression and classification through a simple multitask 2-head architecture; and (3) robust generalization across both DAIC and E-DAIC datasets, supporting deployment on resource-constrained platforms such as SARs.

Ablation Study

To quantify the contribution of each modality in our multimodal framework, we performed an ablation study by selectively disabling feature groups during both training and testing. Each ablated modality was replaced with random noise, ensuring that the architecture and learning dynamics remained consistent across settings.

Experimental Conditions

We evaluated 5 experimental configurations to analyze the contribution of each modality within the proposed framework. The original configuration activated all modalities, including sentence-level embeddings, word-level embeddings, audio features, and facial features.

In the No SentEmb configuration, sentence-level embeddings were replaced with random noise to remove high-level semantic structure while preserving the remaining modalities. In the No WordEmb setting, word-level embeddings were replaced with noise to eliminate low-level linguistic information.

The No Audio configuration excluded acoustic features, thereby removing prosodic cues such as tone and pitch, which were associated with depressive speech patterns. Similarly, the No Facial configuration omitted visual features, eliminating facial AUs and gaze information that provided nonverbal affective signals.

This ablation design enabled a systematic examination of the relative contributions of semantic, acoustic, and visual modalities to overall depression detection performance.

Ablation Study of Modality Configurations

As shown in Figure 3, removing word embeddings (No WordEmb) resulted in a substantial degradation in the depression F_1-score, underscoring the essential role of token-level linguistic cues in depression detection. Sentence-level embeddings (No SentEmb) also had a substantial impact, confirming the importance of capturing semantic context. In contrast, removing acoustic (No Audio) or visual (No Facial) features led to moderate declines in overall performance. These findings suggested that while linguistic features were the primary drivers of detection accuracy, audio and visual modalities contributed to supplementary signals that improved robustness. Our results aligned with prior work [34,35], demonstrating the dominant predictive power of text in affective computing tasks. This analysis validated the

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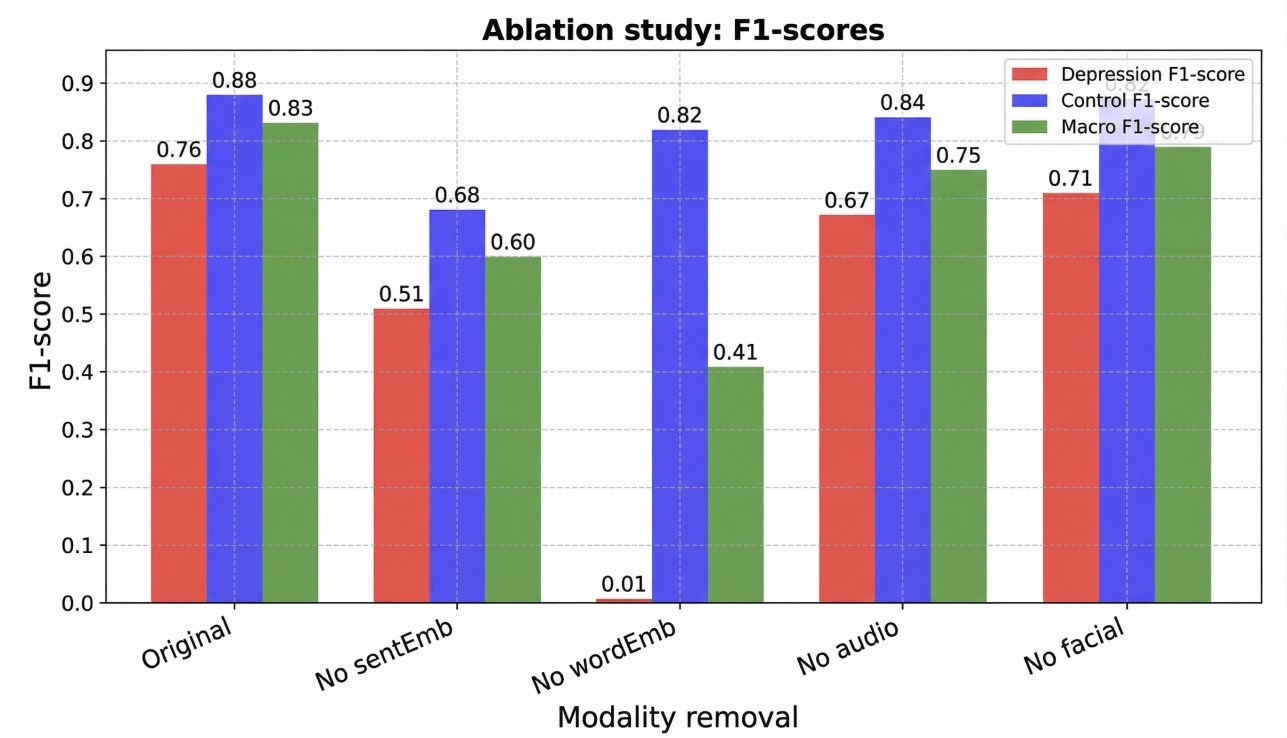
effectiveness of our multimodal fusion strategy and highlighted the complementary roles of each modality.

Figure 3. Ablation results across modality configurations. Word-level embeddings show the largest contribution, followed by sentence-level semantics. Audio and visual cues provide additive but less critical information.



Real-World Evaluation

Robot Platform

For the real-world evaluation, the proposed DEPRESAR-Fusion framework was deployed on a commercially available SAR, the Kebbi robot. This robot is equipped with a microphone array for audio capture, an RGB camera for visual input, a display screen for visual feedback, and onboard speech synthesis for spoken responses. Multimodal inputs, including user voice and facial expressions, were captured by the robot and transmitted to a connected server for real-time feature extraction and inference. The Kebbi platform served as the interactive interface through which users engaged naturally with the system.

Deployment Setup

To examine the feasibility of real-time deployment, we conducted a pilot user study involving 22 adult participants recruited through the Department of Psychology at National Taiwan University. Participants ranged in age from 19 to 55 years, with the majority between 19 and 25 years old. The gender distribution was balanced (n=11 male participants and n=11 female participants). All participants provided informed consent prior to participation.

Each participant interacted naturally with the Kebbi robot in a spoken dialogue consisting of at least 10 user-generated utterances. Following the interaction, participants completed the PHQ-8, which served as the ground truth measure of depressive symptom severity.

Participants were randomly assigned to 1 of 2 conditions. The emotion-induced group (n=11) viewed a targeted emotion-induction video designed to elicit affective expression prior to the interaction, whereas the control group (n=11) proceeded directly to the robot interaction without priming.

This deployment was designed as a feasibility pilot study to evaluate real-time integration and interaction robustness, rather than to provide statistically powered clinical validation.

Statistical Consistency with Benchmark Dataset

To validate the external validity of our deployment, we compared PHQ-8 statistics between the DAIC-WOZ test split and our real-world sample. The class distribution (depressed vs nondepressed) and score statistics (mean and SD) show strong alignment between the 2 datasets (Tables 5 and 6).

Table . Number of participants with depression and participants without depression.

	DAIC-WOZ[a] test split	Real-world data
Participants without depression	33	14
Participants with depression	14	8

[a]DAIC-WOZ: Distress Analysis Interview Corpus-Wizard-of-Oz.

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Table . PHQ-8[a] score statistics.

Statistics	DAIC-WOZ[b] test split, mean (SD)	Real-world data, mean (SD)
Average PHQ-8 score	6.98 (6.47)	7.45 (6.40)
Average score (nondepressed)	3.36 (3.04)	3.50 (2.71)
Average score (depressed)	15.50 (3.76)	14.38 (4.44)

[a]PHQ-8: Patient Health Questionnaire-8.

[b]DAIC-WOZ: Distress Analysis Interview Corpus-Wizard-of-Oz.

The average PHQ-8 score and SD in both datasets were nearly identical, indicating that our field data were statistically comparable to the DAIC-WOZ benchmark and suitable for generalization assessment.

Model Performance in the Wild

We evaluated the model's classification and regression performance in a real-world setting and compared it to its performance on the DAIC-WOZ test set. The classification model generalizes well to real-world conversations, achieving slightly improved F_1-scores and recall scores, despite a minor drop in overall accuracy to 0.7895 (statistically significant at paired *t* test, P=.02). In contrast, regression accuracy drops more noticeably, indicating that real-world data introduce greater variability in symptom expression than observed during training (Tables 7-9).

Table . Classification task performance.

Classification task	Precision	Recall	F_1-score	Accuracy
DAIC[a] test split	0.6667	0.8571	0.7500	0.8300
Real-world data	0.7000	0.8750	0.7778	0.7895

[a]DAIC: Distress Analysis Interview Corpus.

Table . Regression task performance.

Real-world data	RMSE[a]	MAE[b]
DAIC[c] test split	4.3778	3.3985
Real-world data	6.5252	4.7217

[a]RMSE: root mean square error.

[b]MAE: mean absolute error.

[c]DAIC: Distress Analysis Interview Corpus.

Table . Real-world performance with and without emotion induction.

Metric	With emotion induction	Without emotion induction
Regression task		
RMSE[a]	5.0868	7.7650
MAE[b]	3.8653	5.4853
Classification task		
Precision	0.6000	0.6667
Recall	1.0000	0.8000
F_1-score	0.7500	0.7273
Accuracy	0.8182	0.7273
P value (Binomial test)	.03	.11

[a]RMSE: root mean square error.

[b]MAE: mean absolute error.

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Impact of Emotion Induction

We further examined the influence of emotion induction on model performance by comparing results across the emotion-induced and control groups. Participants exposed to emotional stimuli before the interaction exhibited improved regression accuracy (significantly lower RMSE and MAE) and stronger classification performance. This improvement reflects the effectiveness of the proposed emotion-induction procedure as a whole, rather than isolating emotion-specific causal effects. Although the observed difference reached statistical significance (P=.033), this result should be interpreted with caution given the small sample size. The finding was intended to highlight a preliminary trend rather than to establish a definitive causal conclusion.

User Feedback

We conducted a postinteraction survey with 12 Likert-scale questions (6 positive and 6 negative) to assess user experience (Table 10). Figure S1 in Multimedia Appendix 1 summarizes mean ratings across participants, with error bars indicating the SEM. Positive items (Q1-Q6) received generally higher scores than negative ones (Q7-Q12), indicating favorable perceptions of the agent's understanding, empathy, and clarity—especially Q3 ("I can understand what the robot says") and Q1 (perceived understanding). Negative items, particularly Q9 and Q10, scored low, reflecting disagreement with negative experiences. The paired positive or negative results confirm effective communication and emotional responsiveness. However, lower scores on Q5 and Q6 (emotional comfort or support) indicated a discrepancy between perceived understanding and perceived emotional comfort. This discrepancy was not unexpected in human-robot interaction settings. While the ESC framework guided the agent to adopt appropriate high-level empathetic strategies, perceived emotional comfort was also strongly influenced by factors such as vocal prosody, response timing, and nonverbal cues. These aspects were only partially addressed in the implementation, which may explain the observed gap between perceived understanding and emotional comfort.

Table . User feedback questionnaire items.

ID	Question (translated from Chinese)
Q1	I feel the robot understands what I say.
Q2	I feel the robot understands my emotional state.
Q3	I can understand what the robot says.
Q4	I feel the robot shows empathy.
Q5	I feel the robot comforts me.
Q6	I feel the robot fulfills my emotional support needs.
Q7	I feel the robot does not understand what I want to express.
Q8	I feel the robot cannot understand my emotional state.
Q9	I cannot understand what the robot is trying to express.
Q10	I feel the robot lacks empathy.
Q11	I feel the robot does not comfort me.
Q12	I feel the robot cannot fulfill my emotional support needs.

This user feedback provided empirical evidence that our emotion-aware agent not only achieved effective basic communication but also demonstrated empathetic engagement, a critical factor in human-robot interaction. Unlike prior work that often focused solely on task performance, our results emphasized the agent's ability to foster emotional rapport, which was essential for applications in mental health support. The identified gaps in emotional comfort indicated promising directions for refining conversational tone to enhance user trust and acceptance, advancing the design of socially intelligent agents.

Discussion

Principal Findings

This study introduces DEPRESAR-Fusion, a lightweight multimodal depression detection framework designed for naturalistic interaction with SARs. Across both regression and classification tasks, the proposed model demonstrated strong predictive performance while maintaining an exceptionally compact architecture (617K parameters).

On PHQ-8 regression tasks, the model achieved the lowest RMSE and MAE on the E-DAIC dataset and state-of-the-art performance on the DAIC-WOZ benchmark, while maintaining competitive CCC values. These results indicate that the proposed dual-head architecture can effectively estimate both depressive severity and categorical status within a unified framework.

In binary classification, the model achieved a macro F_1-score of 0.8297 on E-DAIC, demonstrating balanced performance across depressed and nondepressed classes. Importantly, the system maintained stable performance during real-world deployment on a commercial SAR platform, suggesting practical feasibility beyond controlled benchmark settings.

The ablation study revealed that linguistic features—particularly word-level embeddings—contribute the most substantial predictive signal. Acoustic and visual modalities provided complementary improvements, enhancing robustness without

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dominating the predictive process. Furthermore, the pilot deployment indicated that emotion induction may increase expressive signal strength and improve downstream detection performance, suggesting the practical value of integrating affect elicitation into conversational AI systems.

Comparison with Prior Work

Our findings are consistent with prior research demonstrating the dominant predictive role of textual features in depression detection. Studies based on clinical interview transcripts have shown that linguistic content often outperforms acoustic and visual modalities in predictive accuracy [8-10,34,35]. Our ablation results support this observation, as removing word-level embeddings resulted in the largest degradation in performance.

Compared with multimodal architectures, such as Yin et al [31], Zhang et al [14], and Li et al [16], our model achieves lower RMSE and MAE while maintaining a substantially smaller parameter footprint. While transformer-based or hierarchical recurrent frameworks emphasize deep cross-modal modeling, our attention-based fusion module demonstrates that efficient structured integration can achieve competitive or superior results with significantly reduced computational cost.

Relative to parameter-efficient text-only approaches such as Lau et al [32], our multimodal framework provides improved regression consistency, suggesting that incorporating behavioral cues beyond text enhances severity estimation. Additionally, compared with zero-shot LLMs (eg, GPT-4o, o3-mini), our model achieves stronger classification performance despite operating at a fraction of the parameter scale, highlighting the value of task-specific multimodal design over parameter scaling alone.

Finally, while psychological literature has established altered emotional reactivity in depression [11,12], few computational systems explicitly integrate emotion induction into multimodal detection pipelines. Our pilot findings suggest that embedding affect elicitation within conversational interaction may enhance behavioral signal salience in naturalistic settings.

Limitation

This study has several limitations that warrant careful consideration. The real-world deployment involved a relatively small sample size (n=22), which constrains statistical power and limits the precision of effect size estimation. Although certain differences—particularly in the emotion-induction condition—reached statistical significance, the modest sample increases uncertainty regarding robustness and reproducibility. Larger-scale studies are necessary to confirm stability across broader populations.

Participants were primarily young adults affiliated with a university setting, resulting in a relatively homogeneous demographic profile. Such sampling may introduce selection bias and restrict external validity. Depression presentation varies across age groups, socioeconomic contexts, and cultural backgrounds. The generalizability of the current findings to older adults, clinical psychiatric populations, or cross-cultural environments, therefore, remains to be established.

PHQ-8 was used as the sole ground truth indicator of depressive symptom severity. While widely validated and frequently adopted in computational depression research, PHQ-8 is a self-report instrument rather than a clinician-administered diagnostic interview. Self-reported measures may be influenced by reporting bias, transient emotional states, or social desirability effects. Incorporating structured diagnostic interviews or multimethod assessment frameworks would strengthen clinical validity.

The emotion-induction protocol relied on a fixed set of emotionally evocative video stimuli. Emotional reactivity varies across individuals, and standardized stimuli may not elicit comparable affective responses in all participants. Although improved predictive performance was observed following induction, the study design does not fully disentangle whether the performance gain reflects increased emotional expressiveness, cognitive priming, or heightened engagement. More controlled experimental paradigms—including neutral baseline conditions or counterbalanced stimulus designs—would allow for clearer causal interpretation.

The data augmentation strategy also introduces considerations. Synthetic text samples were generated exclusively from training data to prevent information leakage; however, approximating PHQ-8 regression targets through threshold-based assignment reduces label granularity. This simplification may limit the precision of severity calibration. In addition, paraphrased transcripts, while semantically constrained, may differ distributionally from naturally occurring spontaneous conversations, potentially affecting generalization.

The evaluation framework focuses on cross-sectional assessment rather than longitudinal monitoring. Depression is dynamic and episodic, and a single interaction may not capture temporal symptom fluctuations. Long-term validation is needed to determine sensitivity to clinical change and suitability for continuous monitoring scenarios.

Finally, while attention mechanisms provide partial insight into modality weighting, the interpretability of specific multimodal feature contributions remains limited. Greater integration of explainability tools and clinician-in-the-loop evaluation would be necessary before large-scale clinical deployment.

Future Directions

Future research should explore cross-cultural and multilingual generalization to broaden applicability across diverse populations. The emotion-induction mechanism may be further optimized through adaptive or reinforcement-based strategies to enhance user engagement.

In addition, incorporating continual and personalized learning mechanisms could support longitudinal adaptation without full retraining. Future work should also integrate explainability tools and conduct systematic failure case analyses to improve robustness and clinical interpretability. Finally, more controlled experimental designs, such as neutral-video conditions, are needed to better isolate emotion-specific induction effects.

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Conclusions

DEPRESAR-Fusion demonstrates that compact multimodal architectures can achieve state-of-the-art depression detection performance while remaining suitable for real-time SAR deployment. By integrating multimodal perception, lightweight deep fusion, and emotion-aware interaction mechanisms, this work advances practical, scalable, and field-validated approaches to AI-driven mental health support.

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The authors disclose the use of generative artificial intelligence (AI) tools during the manuscript preparation process. According to the Generative AI Delegation taxonomy (2025), generative AI was used under full human supervision to assist with language drafting, proofreading and editing, language tone refinement, translation, and reformatting.

The generative AI tool used was ChatGPT-4o (OpenAI). The AI tool was not involved in the study design, data collection, data analysis, interpretation of results, or any scientific or clinical decision-making. Responsibility for the final manuscript lies entirely with the authors. Generative AI tools are not listed as authors and do not bear responsibility for the final outcomes.

Declaration submitted by: PYL, YQS.

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Conflicts of Interest

The authors declare no conflicts of interest. The authors were involved in the design and development of the system described and evaluated in this study as part of the research process. No commercial products were developed or marketed as part of this work, and the authors received no financial benefit related to the outcomes of this study.

Multimedia Appendix 1
Mean user ratings on a 5-point Likert scale.
[DOCX File, 53 KB - formative_v10i1e84110_app1.docx]

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Abbreviations

AI: artificial intelligence
AU: action unit
CCC: concordance correlation coefficient
DAIC-WOZ: Distress Analysis Interview Corpus-Wizard-of-Oz
DEPRESAR: Depression Social Assistant Robot
E-DAIC: Extended Distress Analysis Interview Corpus
eGeMAPS: extended Geneva Minimalistic Acoustic Parameter Set
ESC: emotional support conversation
LLM: large language model
MAE: mean absolute error
MFCC: Mel-frequency cepstral coefficient
PHQ-8: Patient Health Questionnaire-8
RMSE: root mean square error
SAR: socially assistive robot

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Counterclockwise Virtual Reality–Based Embodiment of a Younger Self and Revisit of a Past Iconic Event in Older Adults: Between-Groups Study of Cognitive and Physical Performance

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Abstract

Background: The original counterclockwise study carried out in the late 1970s provided an extreme example of "reminiscence therapy," reporting improvements in older adults' cognitive and physical functioning after they had lived for 5 days in a house set up as if decades earlier (the 1950s). We tested a virtual reality (VR) analog of this approach, enhanced by embodying participants in a virtual body that looked like themselves at the corresponding younger age.

Objective: This study aimed to examine whether brief VR exposures combining (1) embodiment in a virtual body as one's younger self and (2) immersion in an iconic past event improve age-related subjective and performance outcomes compared with a current-self VR control condition.

Methods: We carried out a between-groups study with 23 healthy older adults (aged 65 - 85 years; mean age 71.2, SD 4.03 years). Participants were randomly allocated to either a Young Self condition (n=11; mean 72.3, SD 4.17), where they were embodied in a virtual body that looked like themselves from the 1960s, or in a Current Self control condition (n=12; mean 70.1, SD 3.75), where participants were embodied in their current body. There were 5 sessions. In Session 1, participants completed a baseline assessment. There were then 2 VR exposures, approximately 1 week apart (Sessions 2 - 3), and follow-ups at 1 week (Session 4) and approximately 2 weeks (Session 5) after the final VR exposure. Outcomes included subjective age, awareness of age-related change, World Health Organization–Five Well-Being Index, Trail Making Test performance, and physical functioning (eg, grip strength).

Results: A hierarchical Bayesian analysis revealed that 1 week after the final VR exposure, those in the Young Self condition demonstrated lower subjective age than those in the Current Self condition (prob=.95). They had higher awareness of positive age-related change (prob=.89) and a higher score on the World Health Organization–Five Well-Being Index (prob=.84). Moreover, with respect to performance variables, they took less time to trace a trail (prob≥.99), made fewer mistakes in doing so (prob=.89), had greater right-hand (prob=.85) and left-hand (prob≥.99) grip strength. However, 2 weeks after their final VR exposure, these differences diminished apart from positive awareness of age-related change (prob=.82), trail-making mistakes (prob=.83), and left-hand grip strength (prob≥.99). Here, "prob" refers to posterior probability.

Conclusions: The results demonstrate that even 2 short VR exposures, where people were embodied in their younger body and immersed in an iconic event from more than 50 years earlier, resulted in improvement in some age-related responses. This is encouraging for further research with more extensive VR experiences over a longer time period.

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KEYWORDS

counterclockwise; aging; virtual reality; reminiscence therapy; embodiment; body ownership

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Introduction

In the classic "Counterclockwise" study carried out in 1979, Langer [1] placed a group of 8 older men in a house for 5 days where everything was designed to be like the year 1959. The idea was that this backward time travel might lead to improvements in their mental and physical capabilities. The house was decorated to match the 1950s era, including furniture, types of lighting, and interior design. Newspapers and magazines from 1959 were also present. Even the television (TV) was from that time, playing black-and-white shows, and the radio played only 1959 programs, including the popular music of the time. The residents were encouraged to discuss issues current in 1959, such as the Cuban Revolution, the presidency of Dwight D Eisenhower, and popular sporting events, as if they were happening at that time. The residents brought photographs from the 1950s and were told to refer to themselves in those photos in the present tense. Moreover, they were required to wear 1950s-style clothing. There were no mirrors to show how they actually looked in the late 1970s, and no other modern objects were present. After the 5 days, the residents showed measurable improvements in physical strength, joint flexibility, posture, vision, hearing, and cognitive performance. Anecdotally, others judged them to look younger. When they first arrived at the house, the participants had trouble carrying their luggage; in contrast, when they finally left, they effortlessly carried their luggage to the waiting transport. Pagnini et al [2] carried out a quite faithful replication of the original study, but at the time of writing, the results did not appear to be available.

Counterclockwise was an early, intense, and immersive version of what today is referred to as reminiscence therapy (RT). RT involves encouraging older adults to recall and relive past experiences, often triggered by photographs and other objects from that time. It is often stated that it originated with Butler [3]; however, he discussed rather the "life review," a condition where older adults reminisce (often quite negatively) about their past as death approaches, a behavior often viewed derogatorily by younger people and considered to have no beneficial effects. Butler did not explicitly propose this as a form of therapy, but rather described it as a phenomenon to be studied as something that occurs in later life and should be understood. He described it as a spontaneous phenomenon, possibly acting as an adaptive function for coping with old age. Nevertheless, these observations may be seen as foundational for the use of explicit reminiscence as a therapy. Indeed, Lewis and Butler [4] went on to develop "life review therapy" to enhance the spontaneous review to make it "more conscious, deliberate, and efficient." Their method involved (1) requesting that the patient create autobiographies, (2) "pilgrimages" back to the places of birth and young adult life, (3) reunions with people from those times, (4) genealogical research to look into the lives of their forebears, (5) finding and looking at photo albums and scrapbooks, (6) summation of their life's work, especially for those whose work was important to them, and (7) resurrecting their ethnic identity where this had been ignored or forgotten. It was suggested that the effectiveness of life review therapy depended on how well the process could help people resolve persistent feelings of resentment, guilt, bitterness, mistrust, and a sense of meaninglessness. As such, this type of life-review therapy was not aimed at improving cognitive or physical prowess, but rather to help people come to terms with the process of aging.

An early experimental study based on these ideas was carried out by Goldwasser et al [5], who treated older adults with dementia and compared group RT with supportive group therapy and a no-treatment group. The goal was to assess the effects on affective, cognitive, and behavioral functioning. The RT was carried out verbally by asking participants questions that evoked particular memories (eg, what they were doing during the war). They found positive effects on depression and affect in the RT group compared with the other 2 groups, but no other changes. Although the results were limited, the importance of this study was its formal between-groups experimental design and that it explicitly considered cognitive and behavioral functioning. While Goldwasser et al [5] (also refer to [6]) used verbal means to evoke memories, Yamagami et al [7] used "activity reminiscence therapy," which requires participants to carry out activities in an old-fashioned way, such as cooking rice, including teaching it to younger adults or other members of the therapy group. They found some improvements in memory and indications of improvements in communication, interaction, and behavior 3 months posttreatment compared to 3 months pretreatment.

Such early examples of RT relied mainly on verbal recall of events through questioning and group discussion. However, studies such as [8,9] used photographs and other media. More recently, more technologically based methods have been used—for example, [10] discusses how to source items from the internet for personalized RT, and a systematic review can be found in [11]. Saragih et al [12] provide a meta-analysis of RT for people with dementia. Han et al [13] provide a systematic review and meta-analysis in general, concluding that RT has positive effects on cognition and that there is potential for further improvements, including the possible use of virtual reality (VR).

VR is increasingly used to deliver reminiscence-based interventions by immersing older adults in scenes from the past rather than relying solely on photographs or verbal recall. A recent review by Mao et al [14] concludes that VR-based RT is generally feasible and acceptable for older adults, with promising effects on emotional outcomes and some aspects of cognition, although heterogeneity in intervention content and outcome measures limits firm conclusions about effect size and durability. Randomized and longitudinal studies likewise suggest potential benefits for psychological well-being and cognitive functioning, sometimes exceeding those of traditional reminiscence approaches, but with mixed evidence for sustained cognitive change across follow-up [15]. In parallel, broader work on immersive VR with older adults emphasizes both the opportunity for ecologically rich interventions and the importance of designing for age-related sensory, motor, and novelty-related constraints [16].

In the outline of previous work above, we have seen that the approaches exposing participants to their past included talking, photographs, carrying out an activity, or being immersed in VR. These methods might be characterized as "exogenous" in the sense that the participant is always outside looking in or acting

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like something in the past. This leaves open a mechanistic question central to the counterclockwise premise: whether changing the self-perception of one's age-related appearance, rather than only triggering autobiographical memory, is necessary to obtain measurable changes in age-related cognition and physical functioning. In this paper, we introduce a different paradigm, a VR version of counterclockwise. Many of the aspects of that original study were reproduced. The study was carried out in Barcelona, Spain, where participants were placed in a virtual room reminiscent of a living room in 1968, with decoration and furniture of that time. A black-and-white TV was playing the Eurovision Song Contest 1968, which took place at the Royal Albert Hall in London, where Massiel represented Spain and won the competition. This remains an iconic, highly memorable event for older adults today. Participants were then transported to the audience at the Royal Albert Hall, in a reproduction of the event, including the orchestra and backing singers, with the original soundtrack from the performance.

In VR, a person's body can be visually substituted by a life-sized virtual body seen from a first-person perspective (1PP) [17,18]. Based on body tracking, the virtual body can be programmed to move synchronously with real body movements. When the body is seen from a 1PP and moves synchronously with actual body movements (visuomotor synchrony), evidence suggests that participants experience a strong illusion of "body ownership," that is, the feeling that the virtual body is their body, even though they know that it is not. This was first shown by Petkova and Ehrsson [17], who used cameras mounted on top of a manikin looking down toward its body, and the video was streamed to a head-mounted display (HMD) worn by the participant. The manikin's body and the corresponding areas of the real body were stroked by the experimenter, so that as the participant looked down, they would see the manikin's body substituting their own, and the stroking on the manikin's body would be felt synchronously on their real body. This led to body ownership over the manikin's body, indicated by a questionnaire and a physiological arousal response when the manikin's body was seen to be threatened by a knife. This method of inducing body ownership used visuotactile synchrony, inspired by the rubber hand illusion [19], rather than visuomotor synchrony, but the principle is the same—multisensory integration, including a 1PP view over the virtual body, leads to the body ownership illusion. Embodiment based on visuomotor synchrony has been demonstrated many times, for the hand [20,21] and for the full body [18,22-26], with some evidence that visuomotor may be more powerful than visuotactile [27].

Embodiment affords a fundamental difference from the original counterclockwise study: participants were embodied in a virtual body that looked like their younger selves from approximately that time. In the study reported in [1], the residents could not see themselves due to the absence of mirrors. In contrast, in our study, the participants were encouraged to spend some time looking at themselves in a virtual mirror and moving so that the mirror reflection moved synchronously and corresponded with their actual movements, thus supporting an illusion of ownership over their virtual body. We aimed to test whether a VR-based counterclockwise analog that combines (1) immersion in a salient autobiographical past context and (2) embodiment in a younger-looking virtual body produces measurable improvements relative to a current-self VR control condition. We hypothesized that participants who experienced their younger body and were transported to the immersive simulation of the Eurovision Song Contest 1968 performance by Massiel at the Royal Albert Hall would show greater improvement linked to shifts in subjective age and in measures of well-being, cognitive performance [28], and physical functioning than the control group, who were embodied in a virtual copy of their current body and transported to a recent performance of the same song by Massiel, as she looks today. Outcomes were assessed at baseline, after 2 VR exposures, and at follow-ups approximately 1 week and 2 weeks after the second exposure.

Methods

Experimental Design

The experiment followed a between-groups design with 1 factor with 2 levels: Current Self and Young Self. In the Current Self condition, participants were embodied in a virtual body that looked like their current appearance, in a modern living room (Figure 1). In the Young Self condition, participants saw themselves in their younger body in VR, located in a living room decorated as if it were in their youth (Figure 2). In each case, there was a TV in the room playing adverts and excerpts from programs of the time, followed by the start of a program about the Eurovision Song Contest 1968. In the Current Self condition, participants were then transported to a theater where they saw the present-day appearance of the singer Massiel performing the same song that won the Eurovision Contest in 1968 ("La la la"), celebrating the 50th anniversary, displayed in the VR environment on a large screen at the front of the theater (Figure 3A-3B). In the Young Self condition, participants were transported to a virtual Royal Albert Hall in 1968 and experienced attending the concert performance with the singer Massiel, her backing group, and the orchestra performing at the Eurovision Contest (Figure 3C-3D). In all cases, participants were embodied in their current or younger self virtual bodies from a 1PP (refer to Procedures). Hence, participants saw their virtual body both by looking down toward themselves directly and also as reflected in a virtual mirror. Participants' real body movements were also mapped to their virtual bodies in real time using VR tracking devices. Participants were randomly allocated to either the Current Self or Young Self condition, and they completed 5 experimental sessions. Further details are given in the Procedures subheading and Table 1.

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Figure 1. The Current Self virtual body and living room. (A and B) Participants see their virtual body by looking directly down at themselves and also in the mirror. As they move their upper body, the virtual body moves correspondingly and synchronously. (C) The living room view to the right of the participant, with the modern television (TV) showing the orchestra leader of the 1968 Massiel concert. (D) The room with the participant looking further to the right. The room is decorated in a modern style.

Figure 2. The Young Self virtual body and living room. (A-B) Participants see their young virtual body by looking down at themselves and also in the mirror. As they move their upper body, the virtual body moves correspondingly and synchronously. (C) The living room view to the right of the participant, with the monochrome television (TV) showing the orchestra leader of the 1968 Massiel concert. (D) The room with the participant looking further to the right. The room is decorated in a 1960s style.

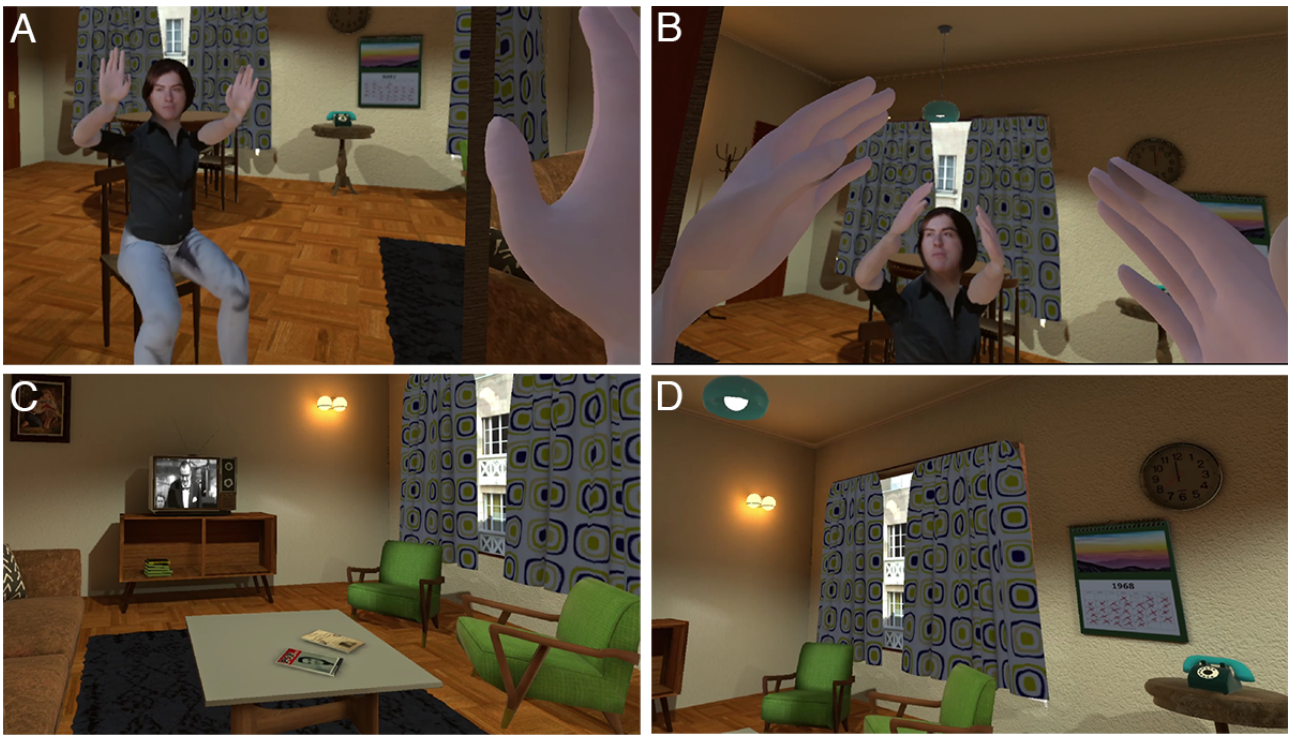

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Figure 3. The concerts with the participant in the audience. (A) The 50th-anniversary concert shows the present-day appearance of Massiel on a large screen in a theater. (B) Toward the end of the performance of the song, the participant is clapping. (C) The 1968 performance at the Eurovision Song Contest, showing Massiel on stage, the backing singers, and the orchestra. (D) Toward the end of the concert, the participant is clapping.

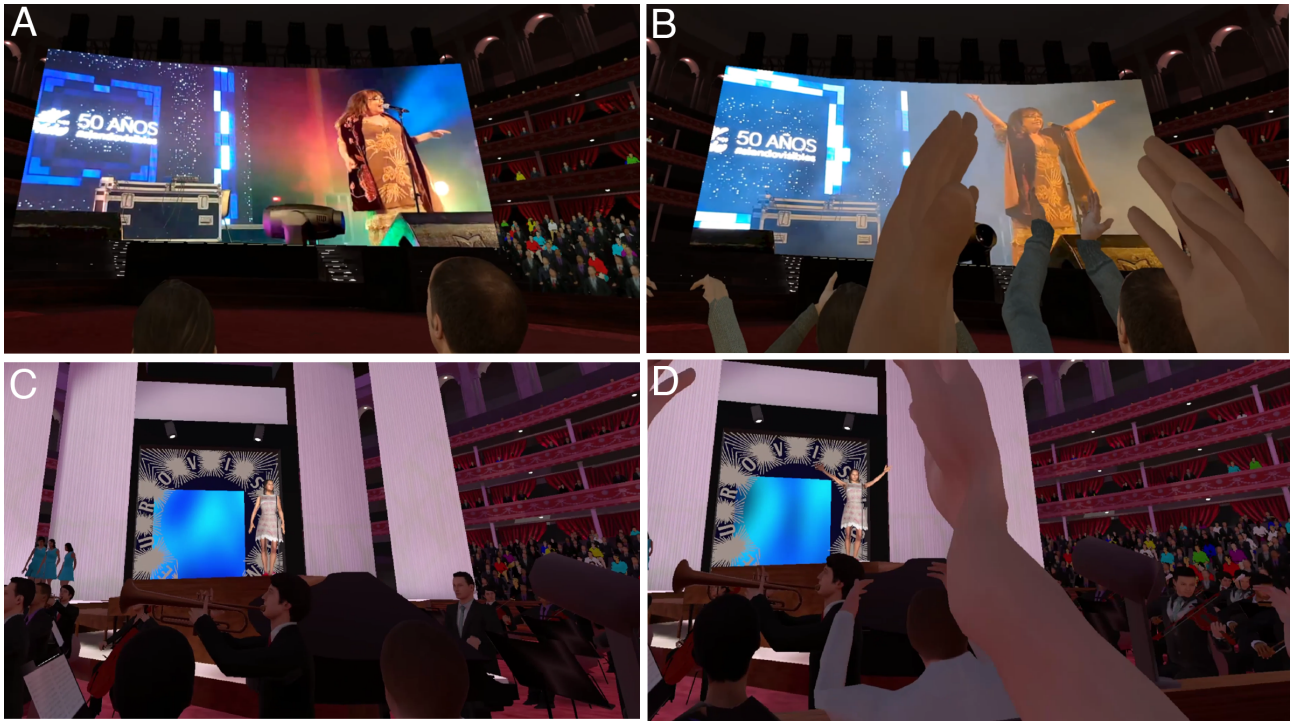

Table . Overview of the experimental sessions.

Session	Label	Timing	Description
1	Baseline	First visit	Consent + data protection forms; questionnaires; physical/performance measures: handgrip strength, walking speed, and balance.
2	VR[a] Exposure 1	Approximately 1 week after Session 1 (on average)	VR: living room scene only; postsession questionnaires; handgrip strength, walking speed, and balance
3	VR Exposure 2	Approximately 1 week after Session 2 (on average)	VR: living room scene, then Royal Albert Hall with Massiel performing the winning song; postsession questionnaires; handgrip strength, walking speed, balance.
4	Follow-up 1	Approximately 1 week after Session 3	Questionnaires; handgrip strength, walking speed, and balance.
5	Follow-up 2	Approximately 2 weeks after Session 4	Questionnaires; handgrip strength, walking speed, and balance.

[a]VR: virtual reality.

Participants

Thirty participants were recruited from the Department of Medicine (Faculty of Medicine and Health Sciences, University of Barcelona) among those attending cognitive assessments as part of a follow-up study on determinants of healthy aging. There were 7 dropouts: 5 for reasons unknown, 1 because of cardiology advice, and 1 due to the bereavement of a close family member. Finally, there were complete data on 23 participants (11 in the Young Self condition and 12 in the Current Self condition). The resulting distribution of participants by condition and sex is shown in Table 2. All participants were healthy Caucasian women and men aged 65-85 years and were not affected by any illness that prevented regular daily activity such as walking. All were retired.

Additional inclusion criteria included the following: no consumption of alcohol on the day of the experiment (before participation), no use of psychoactive medication, no existing conditions that caused dizziness, no strong susceptibility to motion sickness (eg, while traveling by car, boat, or airplane), no history of epilepsy, no cognitive impairment as assessed with the Mini-Mental State Examination (MMSE) [29-31], no major disabilities (such as requiring a wheelchair or assistive devices), no traumatic events during the age at which they would embody

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their younger self, and no history of neurological or major neuropsychiatric diagnoses (as determined by their physician). All participants were compensated for their participation with a payment of €100 (€20 for each session; conversion rate: approximately US $104). Multimedia Appendix 1 provides a summary of each demographic, background, and basic health variables and MMSE score for participants across conditions.

Table . Participant characteristics by condition, showing age and sex.

Condition	Male, n; mean (SD)	Female, n; mean (SD)	Total, n; mean (SD)
Current Self	4; 72.2 (4.19)	8; 68.9 (3.13)	12; 70.1 (3.75)
Young Self	6; 71.0 (4.15)	5; 73.8 (4.09)	11; 72.3 (4.17)
Total	10; 71.5 (3.98)	13; 70.9 (4.23)	23; 71.2 (4.03)

Equipment

The study was carried out at Hospital Clinic, University of Barcelona. The VR experience was presented via the Meta Quest 2 HMD. The device has a display resolution of 1832×1920 pixels per eye and is powered by a Qualcomm Snapdragon XR2 processor with 6 GB of RAM, ensuring smooth performance. The headset displays at a 90-Hz refresh rate for fluid motion and reduced motion blur. It has built-in spatial audio and integrated tracking sensors. The HMD was attached to an MSI Katana laptop (Intel Core i7, RTX3060, and 16 GB of RAM) from which the program was executed. The Quest also has 2 handheld controllers. Both the head and hands are tracked in 6 degrees of freedom. Using this tracking, the motions of the upper virtual body could be matched to the movements of the real body using inverse kinematics, as described by Oliva et al [32].

Procedures

Participants attended the 5 sessions described earlier in Table 1, with 2 VR exposures spaced approximately 1 week apart. Participants attended the experiment at prearranged times and were randomly allocated to the experimental or control condition. An overview of each session is described next, and a summary is given in Table 1.

Session 1: Baseline

Participants were provided with both verbal and written information about the experiment. They were required to complete and sign informed consent and data protection forms. Additionally, they were asked to complete a demographic questionnaire (ie, age, occupation, and so on) and a standardized screening questionnaire (MMSE) [29-31], to check cognitive functioning, as well as a single-item self-assessment of health question (“In general, how would you rate your health: excellent, very good, good, regular, or bad?”), which is a strong and consistent predictor of health outcomes.

They then completed a series of questionnaires that served as the pre-exposure assessments, including the Philadelphia Geriatric Center Morale Scale [33], the World Health Organization–Five Well-Being Index (WHO-5) [34,35], the Trail Making Test (TMT) [36,37], and underwent assessments for grip strength, walking speed [38], and balance [39] (refer to “Response Variables” subheading). All questionnaires were given on paper. Participants took short breaks between the various assessments or whenever requested. Before departing, a frontal photograph of the participant’s current appearance was taken to be used for the Current Self condition to produce their current body (Figures 1A and 1B), and they supplied a frontal photograph from their youth to be used for the Young Self condition (Figures 2A and 2B). The whole procedure lasted approximately 45 minutes.

Sessions 2 and 3: VR Exposure 1 to VR Exposure 2

Upon arriving at the laboratory for the first VR exposure, participants were introduced to the VR equipment, and the procedures were explained again. They were told that they could withdraw at any time without giving reasons and without any loss to themselves. Next, they were seated on a chair, put on the HMD, and were asked to hold the controllers. Participants remained seated throughout the VR exposure and were asked to only move their upper body, including their arms, hands, torso, and head, and to look around.

Once inside the virtual environment, participants found themselves seated in the virtual living room and were free to look around naturally. For the Current Self condition, the living room is shown in Figure 1C-1D, and for the Young Self condition in Figures 2C and 2D. A series of instructions was then given to them through audio guidance. Initially, participants were guided through a series of body movement exercises to explore the capabilities and real-time motion of their virtual bodies, including arm and head movements. Next, they were asked to look around in all directions and describe their surroundings. Following this orientation phase, they were instructed to focus on a TV located in the living room and observe its content. After a few advertisements, the TV started to show the Eurovision Song Contest 1968 performance by Massiel, after which the display gradually faded to black, marking the end of the VR exposure. Participants were then asked to complete the postexposure questionnaires and tasks. The session lasted approximately 45 minutes.

Approximately 1 week later, participants returned to the laboratory and were once again equipped with the VR headset and controllers. When the VR experience began, it started in the same living room as during the previous exposure. For those in the Current Self condition, where their virtual body was their current appearance, the TV showed a program about Massiel’s win more than 50 years earlier, and participants were transported to a modern theater where they watched a present-day performance of the same song by Massiel, shown on a large screen in front of the theater (Figures 3A and 3B). In other words, they saw Massiel as she looks today. For those in the Young Self condition, the TV program featured the opening of

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the Eurovision Song Contest 1968, announcing Spain as the winner, with Massiel's performance of "La, la, la" (Figures 3C and 3D), as she looked at that time. As the scene transitioned, participants in the Young Self condition were transported to the audience at the Royal Albert Hall in London, where the event originally took place. Both groups experienced Massiel's entire performance. The scenarios are provided in Movie S1 in Multimedia Appendix 2, and the concerts are illustrated in Figure 3. Participants were then asked to complete the postexposure questionnaires and tasks. The session lasted approximately 45 minutes.

Session 4: Follow-Up 1

Approximately 1 week after their second VR exposure, participants returned to the laboratory for the postintervention assessment (Session 4). They completed the grip strength, balance, and walking speed tasks, as well as the postexposure questionnaires. The session lasted approximately 30 minutes.

Session 5: Follow-Up 2

Approximately 2 weeks later, participants returned to the laboratory for the second postintervention assessment (Session 5) and repeated the tasks and questionnaires to assess changes over time. The session lasted approximately 30 minutes.

Response Variables

VR-Related Variables

There were 2 types of response variables: the first type assessed the responses of participants to the VR experience. These are shown in Table 3 and include measures of presence, recognition of their virtual body, body ownership, and agency. We did not make inferences about these responses to the broader population; however, the extent of body ownership and agency was critical for the success of the method. Therefore, we present the results of these variables only descriptively.

Table . Response variables in relation to the virtual reality (VR) experience.

Variable	Interpretation
Presence and copresence	
there	Please rate your sense of being in the virtual environment on the following scale from 1 to 7, where 7 represents your normal experience of being in a place. Scale: 1 "Not at all" to 7 "Very Much"
real	To what extent were there times during the experience when the virtual environment was the reality for you? Scale: 1 "At no time" to 7 "Almost all the time"
visited	When you think back about your experience, do you think of the virtual environment more as images that you saw or more as somewhere that you visited? Scale: 1 "Images that I saw" to 7 "Somewhere that I visited"
beingin	During the time of the experience, which was strongest on the whole, your sense of being in the virtual environment or of being elsewhere? Scale: 1 "Being elsewhere" to 7 "Being in the virtual environment"
others	How much did you have a sense of being in the same space with other people? Scale: 1 "Not at all" to 7 "Very much so"
Recognition, body ownership, and agency	
recognized	How much did you recognize yourself when you saw your virtual body in the mirror? Scale: 1 "Not at all" to 7 "Very much so"
mybody	When you looked down toward yourself in the virtual reality, how much did the body you saw feel like your body (ignoring how much it looked like your body)? Scale: 1 "Not at all" to 7 "Very much so"
mirror	When you looked at yourself in the mirror, how much did the body you saw feel like your body (ignoring how much it looked like your body)? Scale: 1 "Not at all" to 7 "Very much so"
mymovements	How much were the movements of the virtual body your movements? Scale: 1 "Not at all" to 7 "Very much so"
Simulator sickness	
dizzy	How much dizziness or nausea did you feel while in the virtual reality? Scale: 1 "Not at all" to 7 "Very much so"

Age-Related Variables

The second type included age-related variables, comprising subjective measures (based on questionnaires) and performance-based measures, which assessed how a particular act—such as grip strength—was carried out. These are shown in Table 4.

The prespecified primary outcomes were subjective age (dlogage), WHO-5 well-being, TMT performance (Parts A and B: time and errors), and grip strength (left and right). Secondary

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outcomes included awareness of age-related change (AARC Positive and AARC Negative), morale (Philadelphia Morale Scale), balance, walking speed, and descriptive VR experience measures (presence, recognition, ownership, agency, and simulator sickness). Outcomes were assessed at baseline (Session 1), immediately following VR exposures (Sessions 2 and 3), and at follow-ups (Sessions 4 and 5).

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Table . Response variables in relation to performance.

Variable	Interpretation	Rationale
Subjective variables		
subjectiveage	Participants were asked to assess their subjective age: "How old do you feel?" The response variable is measured as: dlogage=log(subjectiveage/age).	An indicator of subjective aging and aging identity that may be sensitive to embodiment. Beyond chronological age, it has been linked to important outcomes in older adulthood [28].
philadelphiatotal	Philadelphia Morale Scale—typically consists of 17 items, and the scoring range can vary depending on the format used. Each item is scored as either 0 (negative response) or 1 (positive response), making the total score range from 0 to 17.	Widely used measure of older adults' morale/psychological well-being, capturing key dimensions such as agitation, attitude toward one's own aging, and loneliness dissatisfaction [40], constructs that may plausibly shift with immersive or embodiment-related manipulations.
AARC[a] Negative and AARC Positive	AARC[a]: items are scored on a 1 (strongly disagree) to 5 (strongly agree) Likert scale, where respondents rate their agreement or the extent to which they have experienced certain changes (eg, "With my increasing age, I realize that I have become wiser," "With my increasing age, I realize that I am more prone to illness," and so on); AARC[a] Negative: higher scores mean the person perceives more negative changes with age. This may include a decline in health, memory, and physical ability, as well as social losses and reduced opportunities, and lower scores suggest fewer perceived downsides of aging; and AARC Positive: higher scores indicate that the person perceives more positive changes with age. Examples include increased wisdom, emotional regulation, deeper relationships, greater self-acceptance, or feeling more selective and purposeful in life. Lower scores suggest fewer perceived benefits of aging.	Widely used measure to understand how individuals perceive and react to the aging process, which can influence their overall well-being and behavior across both positive changes (eg, increased wisdom and improved emotional regulation) and negative changes (eg, physical decline and cognitive deterioration) [41]. It can help situate VR[b] embodiment effects within a core aspect of aging identity, specifically how people notice and interpret age-related change.
wellbeingscale	WHO-5[c] – scores / 100, where greater scores indicate greater well-being.	Brief measure of current subjective well-being in older adults, capturing positive mood and functioning over the past 2 weeks (eg, vitality, energy, relaxation, and interest in daily life). Because VR embodiment may influence affective state and self-related evaluations, the WHO-5 provides a concise, sensitive outcome for detecting short-term changes in overall emotional well-being [42].
Performance variables		
TMTAtime	Trail Making Test (TMT) Part A: participants connect a series of numbered circles (1-25) in ascending order as quickly as possible. This measures processing speed and visual-motor coordination. Time (in seconds) to complete the test.	Objective measure of visual scanning/visual search and processing speed with a clear visual–motor (psychomotor) tracking component, making it well-suited for quantifying performance in tasks that depend on fast visuomotor responding. It is widely used in aging research because it shows reliable age-related slowing and has normative data in older adult samples, supporting interpretation of performance differences in later life [43].
TMTBtime	TMT Part B: participants alternate between connecting numbered circles and lettered circles (eg, 1-A-2-B-3-C) in ascending order. This assesses cognitive flexibility, executive functioning, and the ability to switch between tasks. Time (in seconds) to complete the test.	Objective measure of visual scanning/visual search and processing speed with a clear visual–motor (psychomotor) tracking component, making it well-suited for quantifying performance in tasks that depend on fast visuomotor responding. It is widely used in aging research because it shows reliable age-related slowing and has normative data in older adult samples, supporting interpretation of performance differences in later life [43].

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Variable	Interpretation	Rationale
TMTAmistakes	TMT Part A: number of mistakes during the test (data for this measure were lost).	Objective measure of visual scanning/visual search and processing speed with a clear visual–motor (psychomotor) tracking component, making it well-suited for quantifying performance in tasks that depend on fast visuomotor responding. It is widely used in aging research because it shows reliable age-related slowing and has normative data in older adult samples, supporting interpretation of performance differences in later life [43].
TMTBmistakes	TMT Part B: number of mistakes during the test	Objective measure of visual scanning/visual search and processing speed with a clear visual–motor (psychomotor) tracking component, making it well-suited for quantifying performance in tasks that depend on fast visuomotor responding. It is widely used in aging research because it shows reliable age-related slowing and has normative data in older adult samples, supporting interpretation of performance differences in later life [43].
gripstrengthRmean	Grip Strength Test: right-hand force (kg), mean score.	Brief, objective indicator of overall muscle strength and physical capability in older adults. It is sensitive to age-related decline and is widely used as a marker of frailty/functional risk [44]. Lower grip strength is consistently linked to higher risk of disability and cardiovascular mortality in large-scale observational evidence and meta-analyses [45].
gripstrengthLmean	Grip Strength Test: left-hand force (kg), mean score; valid values were those >0 kg and <100 kg; and values were recorded as missing if the measurement differed by >20 kg for the same hand.	Brief, objective indicator of overall muscle strength and physical capability in older adults. It is sensitive to age-related decline and is widely used as a marker of frailty/functional risk [44]. Lower grip strength is consistently linked to higher risk of disability and cardiovascular mortality in large-scale observational evidence and meta-analyses [45].
balancemean	4-Stage Balance Test: mean score (in seconds); 0=lowest; 10=highest; and greater times are better (better balance).	Brief, objective measure of static postural control in older adults. Balance impairment is common with aging and is clinically important because poorer performance on this test is used in fall-risk screening and is associated with increased risk of future falls [46].
walktime	10-Meter Walk Test: comfortable walking time for a 10-meter distance (seconds).	Usual walking speed is a valid, reliable, and sensitive marker of functional status in older adults, and slower gait is associated with worse health outcomes [47]. It can be used to test the idea that if gait improves, embodiment transfers to functional motor behavior.

[a]AARC: awareness of age-related change.

[b]VR: virtual reality.

[c]WHO-5: World Health Organization–Five Well-Being Index.

Implementation

Creating the Characters

The virtual bodies of the 3 backup singers, the conductor, and Massiel, the main singer, were created using the automatic 3D avatar generation system described in [48]. For the audience, high-resolution virtual humans were used within a 3.5-m radius from the participant, and these were programmed to look toward the participant at random intervals occasionally. Some of these characters were created using the same generation method [48], while others were adapted from the Microsoft Rocketbox Avatar Library [49]. For characters positioned between 3.5 m and 10 m away, an optimized per-joint impostor technique was applied to ensure rendering efficiency while maintaining visual fidelity [50]. Beyond 10 m, image-based crowd rendering was used to represent distant audience members [51]. In the Current Self condition, the audience consisted of virtual humans with an older appearance, whereas in the Young Self condition, the audience consisted of virtual humans with a youthful

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appearance. The animations of Massiel, the conductor, and the 3 backup singers were recorded using an OptiTrack motion capture system, and these recorded animations were applied to their corresponding avatars within the virtual scene.

Creating the Theaters

For the Young Self condition, the Royal Albert Hall was manually modeled in Blender (Blender Foundation) based on the official blueprints, comprising approximately 2900 seats, including 384 central audience seats and 48 orchestra seats. Each element, including stage layout, seating arrangement, and decorative structures, was modeled to match the proportions and architectural details of the original venue as accurately as possible.

Software and Implementation

These VR applications were developed using QuickVR [32]. QuickVR's Avatar Tracking system synchronizes the movements of participants with their avatar using inverse kinematics to estimate and replicate the participant's posture in real time. All 3D models, including the concert hall, stage, and environmental elements, were created using Blender. The overall application was implemented in Unity (Unity Technologies).

Statistical Model and Analysis

Throughout, we used Bayesian statistical analysis, which is especially appropriate for the exploratory nature of this research. Rather than reaching conclusions (ie, via hypothesis testing), we present probabilities. A particular advantage is that we have many response variables, and with frequentist statistics, every additional statistical test further invalidates the meaning of the "significance level." We would then have to resort to ad hoc methods such as Bonferroni corrections. In the Bayesian method, all response variables can be treated simultaneously in 1 overall model, and we can derive as many probability statements of interest as needed without impacting their validity. Moreover, unlike simply quoting results such as "t=3.2 and P<.05," we explicitly state all assumptions and provide the source code online so that anyone can repeat the analysis, change prior distributions or the likelihood function, and examine the responses.

We report posterior means and 95% highest density intervals (HDIs), which can be interpreted as the range within which the true parameter value lies with 95% probability, given the data and model assumptions. In the Bayesian framework, before using the data, parameter values have prior probability distributions, reflecting the current state of knowledge. These distributions are updated by the data to yield the posterior distributions. The HDIs computed from the posterior distributions can be compared to the prior HDIs, and they typically focus on a much narrower range of values. Similarly, we can compute the posterior probability that a parameter is positive (or negative), indicating the probability that it is positively (or negatively) associated with the response variable.

We describe each component of the overall model together with the analysis of each response variable.

The linear predictor for any response variable refers to the right-hand side expression in the statistical model for that variable. For all of our response variables, the linear predictor is of the form:

$$\text{individual}+\text{condition}+\text{session}+(\text{session}\times\text{condition})$$

where individual represents the participant, condition is the main factor (Current Self=0 and Young Self=1), and session is (1,2,…,5). The last term is the interaction between condition and session.

The factors are represented by the following parameters:

u_j is the random effect term of the jth participant (j=1,2,…,n=23)

α_j is the main effect of the jth Session (j=1,2,…,5)

β_k is the effect of the kth condition k (k=1,2), where k=1,2 represent the Current Self and Young Self levels.

γ_{jk},j = 1,2; k = 1,2,…,5,is the interaction effect between session and condition, representing the additional effects of Young Self over the sessions.

For model identifiability, we set:

$$u_1=\alpha_1=\beta_1=\gamma_{1k}=\gamma_{j1}=0$$

j = 1,2; k = 1,2,…5

Hence, parameters are interpreted as offsets from the first participant (an arbitrary reference), the Current Self condition, and Session 1.

The statistical model is equivalent to a 2-way ANOVA model with random effects for participants. Here, the u_j account for the effects of the individuals, and the α_j,j=2,…,5 account for the change from Session 1 to Sessions 2 - 5 under the Current Self condition. The parameter β_2 reflects the difference between Young Self and Current Self at Session 1. The γ_{jk} allow for interaction between the condition and session; that is, they provide the additional effect of Young Self compared with Current Self in Sessions 2 - 5, beyond the effect given by β_2.

Hence, β_2 represents the initial difference between Young Self and Current Self in Session 1 (ie, before any intervention). The γ_{2k},k=2,3,…,5 represent the additional effects of being in the Young Self condition across sessions.

As explained at the start of this section, the Bayesian framework assigns prior probability distributions to the parameters, which are then updated by the data to produce posterior distributions:

$$\text{posterior distribution} \propto \text{likelihood} \times \text{prior distribution}$$

The likelihood is the distribution of the response variable conditional on the parameters.

Traditional ANOVA assumes a normal distribution for the likelihood. However, Figure S1 in Multimedia Appendix 3 shows the histograms of the subjective variables by condition (Current Self and Young Self), and Figure S2 likewise shows the distributions for the performance measures. In the case of the subjective variables, most of the distributions are skewed, and therefore, skew-normal distributions were used for the likelihoods. Skew-normal distributions have an additional parameter (in addition to the mean and SD) controlling skewness, and when this parameter is 0, the normal distribution is recovered. Therefore, in any case, the normal distribution is a special case of the skew-normal distribution. With respect to

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the performance variables, these are time or strength measures, which are nonnegative and typically follow a Gamma distribution. The alternative to using these likelihoods would be to attempt ad hoc transformations of the response variables to find one that transforms them to normality, which is, in general, not recommended [52]. We only used a log transformation log(subjectiveage/age) to ensure that this variable was based on a difference rather than a division, thereby reducing outliers and bringing its distribution into line with the other subjective variables. The full statistical models, including prior distributions, are given in Multimedia Appendix 4.

For analysis of the parameters, we concentrate on the HDIs of their posterior distributions. The HDI is analogous to a traditional CI, but it is an interval with a posterior probability. The 95% HDI is the smallest interval that contains 95% of the posterior distribution of the parameter. This is in contrast to a CI in frequentist statistics, which is such that if there were a large number of identical repetitions of the experiment, then 95% of the computed CIs would contain the true value of the parameter. However, any specific computed CI (ie, the one based on the actual available data) does not have 95% probability of containing the true value. In the frequentist interpretation, this specific computed interval either contains the population value of the parameter or does not; hence, only a probability of 0 or 1 could be assigned. Additionally, for each parameter, we provide the probability that it is positive or negative (ie, positively or negatively associated with the response variable).

All these results are provided in Tables S1 and S2 in Multimedia Appendix 5, which give summaries of the posterior distributions of all the parameters. Here, we present a graphical summary for each response variable, including box plots of the raw data by session and condition, and HDIs represented as horizontal line segments (Figures 4 and 5). At the end of each line segment representing the HDI, the probability of the parameter being positive is shown.

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Figure 4. Box plots for presence- and body-related variables showing the medians and IQRs for variables listed in Table 3. (A) The variables related to presence, and (B) the virtual body–related variables.

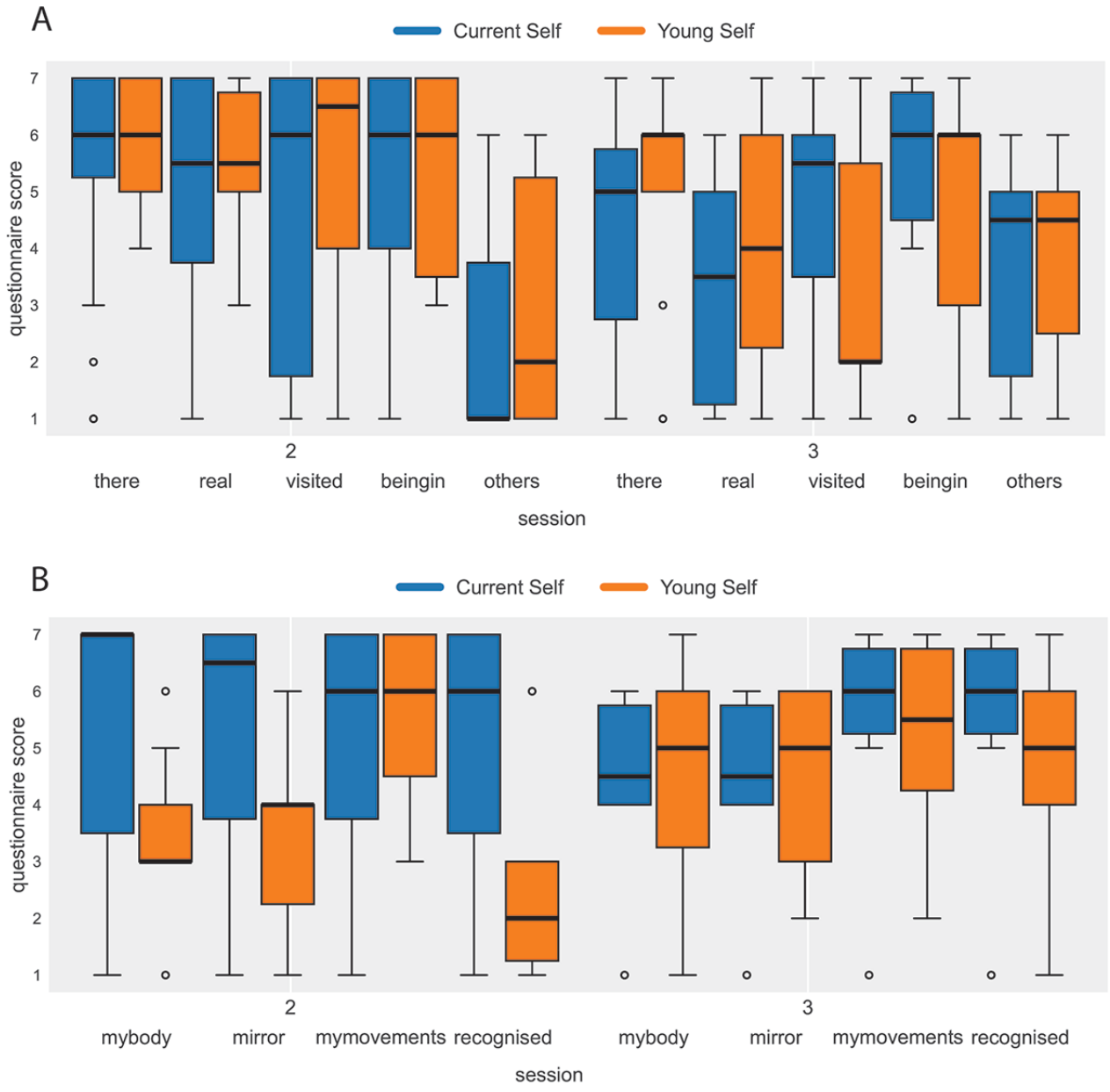

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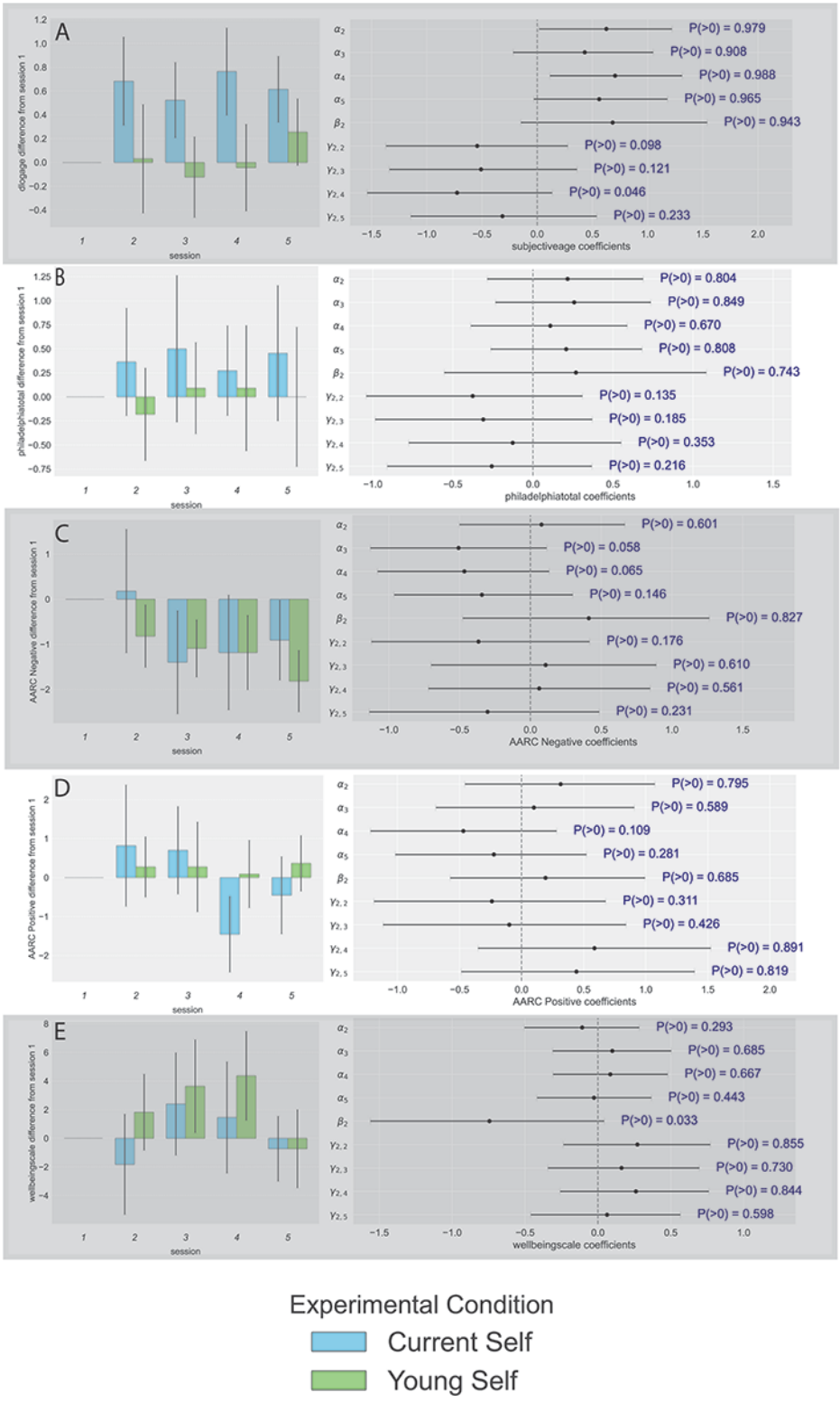
Figure 5. Bar charts of the subjective variables by session and condition (left) and 95% highest density intervals for the parameters of the model (right). (A) log(subjectiveage/age), (B) philadelphiatotal, (C) awareness of age-related change (AARC) Negative, (D) AARC Positive, and (E) wellbeingscale. *P*>0 is the probability that the corresponding parameter is positive.



Ethical Considerations

The experiment was approved by the University of Barcelona Bioethics Commission (Comissió Bioètica of Universitat de Barcelona) and conducted in accordance with institutional ethical guidelines and international standards for the protection of human participants. Ethical measures included obtaining written informed consent, ensuring the right to withdraw at any point during or after the experiment, and maintaining confidentiality. Participants were informed that their data were strictly private and that the researchers would only access an anonymous ID number rather than any identifying information. After the final phase of the experiment, participants were debriefed about the purpose of the study. Because the intervention involved viewing and embodying a

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self-representation at a different life stage, participants were screened for factors that could increase distress (including major neuropsychiatric diagnoses and traumatic experiences during the target age period). Participants were reminded that they could pause or discontinue the VR exposure at any time without penalty.

Results

Baseline Characteristics

Table 5 summarizes participants' demographic characteristics, background, and basic health variables, including ratings of subjective age and cognitive impairment. Overall, the groups were comparable, with no notable differences observed. Participants generally rated their health as good, and MMSE scores were above the standard 23/24 cutoff (overall mean 28.7, SD 0.78), indicating normal cognitive functioning [53].

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Table . Summary of each demographic, background, and basic health variable.

Variable and meaning	Current	Young	Overall
Studies, n			
0=primary	3	—[a]	3
1=secondary	1	1	2
2=professional	2	4	6
3=university	5	6	11
StudyCompletionAge, mean (SD)			
At what age did you finish your studies?	19.8 (4.02)	21.4 (5.59)	20.6 (4.82)
Computing, median (IQR)			
Level of knowledge in information technologies (1=lowest and 7=highest)	5 (4-6)	4 (4-5)	4.5 (4-5)
Programming, median (IQR)			
Level of experience in programming (1=lowest [beginner] and 7=highest [expert])	1 (1-2)	1 (1-2)	1 (1-2)
VR[b], median (IQR)			
How frequently has the participant had VR experiences (1=lowest [never] and 7=highest [a lot of times])	1 (1-5)	2 (1-5)	1.5 (1-5)
Gamesyear, median (IQR)			
How many times have you played video games during the last year? (0=0, 1=1 - 5, 2=6 - 10, 3=11 - 15, 4=16 - 20, 5=21 - 25, and 6= ≥25)	0 (0-1)	0 (0-1)	0 (0-1)
Gamesweek, median (IQR)			
How many hours a week do you play video games? (0=0, 1=1, 2=2 - 3, 3=3 - 5, 4=5 - 7, 5=7 - 9, and 6= ≥9)	0 (0-0)	0 (0-0)	0 (0-0)
SubjectiveHealth, median (IQR)			
How would you rate your health in general? (0=excellent, 1=very good, 2=good, 3=regular, and 4=bad)	2 (1-2)	2 (2-2)	2 (2-2)
MMSETotal, mean (SD)			
Mini-Mental State Examination (total score; 0=lowest and 30=highest)	28.9 (0.70)	28.5 (0.82)	28.7 (0.78)

[a]Not available.

[b]VR: virtual reality.

Presence and Embodiment

Figure 4A shows the box plots for the presence variables. There appears to be no difference in presence scores between the conditions, except for the variable “visited” in Session 3. In Session 2, the scores for “others” are low, whereas in Session 3, they are high. This is because there were no others in Session 2; thus, these data are consistent.

Figure 4B shows the results for the recognition, body ownership, and agency variables shown in Table 3. While in Session 2, people recognized their current selves, they did not recognize their younger selves. However, this was rectified in Session 3. For the Young Self condition, the body ownership scores for the variables mybody and mirror were low in Session 2, but this was rectified in Session 3. Agency-related scores

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(mymovements) were high in all conditions and sessions, reflecting the operation of the tracking system and the program.

This experiment was not about body ownership as such, and therefore, we do not make inferences about these variables to the broader population. Rather, we report them as manipulation checks. Participants' self-reported ownership and agency ratings were generally consistent with the intended embodiment manipulation, particularly by the second VR exposure (Session 3), when recognition of the younger avatar improved.

Simulator Sickness

The questionnaire included the following question: "How much dizziness or nausea did you feel while in the virtual reality?" on a 7-point scale ranging from 1 ("Not at all") to 7 ("Very much so"). For both sessions and conditions, the median score was 1, with the IQR of 0. There were 2 outliers, a score of 7 in Session 2 (the first VR exposure) and a score of 3 in Session 3.

Subjective Response Variables

Subjective Age

Here, we are interested in the difference between the person's real age and their subjective age, that is, the age that they feel themselves to be. Figure 5A (left) shows the bar charts for the differences dlogage=log(subjectiveage/age), offset from Session 1 (ie, each value compared with the Session before any VR exposure). In each case, the mean dlogage in the Young Self condition is always lower than in the Current Self condition. However, the SEs are quite large. Figure 5A (right) shows the HDIs for each parameter in the statistical model fit for the response variable dlogage. The $\alpha j,j=2,...,5$ show that the Current Self results in high scores. Although the HDIs include 0, they are mostly to the right of the 0 line, and all the probabilities are greater than 0.908. The parameter $\beta 2$ again shows that at Session 1, the Current Self score is greatest (prob=.94). However, considering the γjk in Session 2, the Young Self condition has a strong probability of subjective age being less than that of the Current Self condition (prob=1–.10=.99), a moderate probability at Session 3 (prob=1–.12=.88), and a strong probability in Session 4 (prob=1–.046=.954), but the advantage is lost by Session 5. Hence, overall, the subjective age from Sessions 2 - 4 has a moderate to high probability of being less in the Young Self condition compared with the Current Self condition, but this effect is not maintained by Session 5.

Morale (Philadelphia Morale Scale)

In Figure 5B (left), we can see that the means are higher for the Current Self than for the Young Self condition, although the SEs are very high. Figure 5B (right) shows no effect of condition (Current Self vs Young Self) on this response variable. All the HDIs are wide and include 0, and none of the probabilities are salient.

AARC Negative

The bar charts for AARC Negative in Figure 5C (left) show that in both conditions, the negative evaluations decreased similarly over the sessions. The HDIs show more clearly that in the Current Self condition (αj) there is a decrease in the response in Sessions 3, 4, and 5, but that these are offset by moderate-probability increases in the corresponding Young Self condition. Overall, we conclude that there was no impact of the condition on AARC Negative.

AARC Positive

Figure 5D (left) suggests that in Sessions 2 and 3, there is little difference between the conditions. However, in Sessions 4 and 5, the Current Self means are lower than the Young Self means, although with large SEs. Figure 5D (right) suggests that the Young Self condition in Session 4 has greater scores than the Current Self condition (prob=.89) and similarly in Session 5 with a moderate probability of .82.

Well-Being (WHO-5)

Figure 5E (left) shows that the Young Self score is always at least as great as the Current Self score, with the most pronounced difference in Session 4. However, all the SEs are large. Figure 5E suggests that in Sessions 2 and 4, the Young Self scores are greater than the Current Self scores, with moderate probabilities of .86 and .84, respectively.

Performance Variables

TMT Part A Completion Time

From Figure 6A (left), we can see that in both conditions, there is evidence of a reduction in completion time (tmtatime). In Session 2, the Young Self condition is lower than the Current Self (prob=1–.05=.95) and in Session 4 (prob≥.99; Figure 6A, right). However, by Session 5, there is no difference.

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Figure 6. Bar charts of the performance variables by session and condition (left) and 95% highest density intervals for the parameters of the model (right). (A) tmtatime, (B) tmtbtime, (C) tmtbmistakes, (D) gripstrengthRmean, (E) gripstrengthLmean, (F) balancemean, and (G) walktime. *P(*>0) is the probability that the corresponding parameter is positive.

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TMT Part B Completion Time

The bar charts in Figure 6B (left) do not show any marked difference between the conditions, and this is confirmed by the HDIs of the posterior distributions of the parameters (Figure 6B, right).

TMT Part B Errors

The bar charts in Figure 6C (left) indicate that the mean number of mistakes was always lower for the Young Self condition, and the HDIs and the probabilities moderately support this for Session 2 (prob=1–.17=.83), Session 4 (prob=1–.11=.89), and Session 5 (prob=1–.16=.84).

Grip Strength (Right Hand)

Figure 6D (left) shows a higher mean strength in the Young Self condition in Session 4, though with large SEs. This is moderately supported by the HDI and probability (prob=.85) for Session 4 (Figure 6D, right).

Grip Strength (Left Hand)

Figure 6E (left) shows a very clear advantage of the Young Self condition for all sessions, and this is backed up by the very high probabilities for the interaction terms (the minimum probability that Young Self is greater than Current Self is .95).

Balance (4-Stage Balance Test)

From Figure 6F (left), we can see that empirically, the balance mean score (in seconds; balancemean) is mostly greater for the Young Self condition; however, this is not supported by the statistical model (Figure 6F, right).

Gait Speed

Figure 6G (left) indicates that gait speed (walktime) is empirically greater for the Young Self condition for Sessions 2 - 4, though with very large SEs. However, the statistical model shows no differences between the Current Self and Young Self conditions (Figure 6G, right).

Summary

With moderate to high probabilities over the sessions, those in the Young Self condition reported lower subjective age than those in the Current Self condition. With moderate probabilities, the Young Self group had greater AARC Positive scores than the Current Self group in Sessions 4 - 5. This means that they tended to perceive more positive changes with age. With moderate probabilities, the Young Self group had greater well-being scale scores than the Current Self group in Sessions 2 and 4. This scale indicates a greater sense of well-being. In Sessions 2 and 4, the Young Self group had lower TMT Part A times than the Current Self group, with high probability. This refers to the time required to complete the TMT. The number of mistakes made in the TMT Part B was lower in the Young Self than in the Current Self condition in Sessions 2 and 4, with moderate probabilities. The right-hand grip strength measured for the Young Self group was higher in Session 4 than that of the Current Self group, with moderate probability. The left-hand grip strength was greater in the Young Self group overall, with high probabilities.

The statistical analysis did not find any salient differences between the groups for Philadelphia total (a measure of morale), AARC Negative (reporting more negative changes with age), TMT Part B time (the time to complete a TMT), and balancemean (time standing on 1 leg).

It is interesting to see that differences between the 2 groups were most often found in Sessions 2 (the first VR session) and 4 (1 week after the VR exposures). However, it is important to note that all of the effects had vanished by Session 5, except for AARC Positive (with moderate probability), TMT Part B errors (with moderate probability), and left-hand grip strength (with high probabilities).

Discussion

Principal Findings

This study tested whether a VR analog of the counterclockwise paradigm, combining immersion in an autobiographical past context with embodiment in a younger-looking virtual body, produces measurable improvements in age-related subjective and performance outcomes relative to a Current Self VR control. We conducted a between-groups experiment in which a group of older adults was embodied in a virtual body that either resembled themselves as they are today (Current Self) or as they were in their teenage years or early 20s (Young Self). The Current Self group spent time in a modern virtual living room, where they saw their virtual body when looking down at themselves and when it was reflected in a mirror, and which moved synchronously with their own movements. They were then transported to the audience of a concert, where the modern-day Massiel performed the song that won her the Eurovision Song Contest in 1968. The Young Self group followed the same procedures, except they were embodied in their young body, in a 1960s living room, and were transported into the audience of a VR depiction of the original 1968 Massiel performance. Hence, they were either transported back in time with respect to their appearance and location (Young Self) or remained as they are now with respect to their appearance and the setting (Current Self). The experiment was conducted over 5 sessions (1: initial contact, 2: first VR exposure, 3: second VR exposure, 4: one week later, and 5: about two weeks later) with a number of subjective response measures and performance measures on each occasion.

Relative to the control, the Young Self condition showed the clearest evidence of benefit for subjective age and well-being, alongside improved TMT performance and higher grip strength, with effects most evident at Session 2 and at 1-week follow-up (Session 4). Several outcomes showed little evidence of between-group differences (eg, Philadelphia morale, AARC Negative, TMT Part B completion time, and balance), and most effects diminished by Session 5, but with persistent results observed for AARC Positive, TMT errors, and left-hand grip strength.

Comparison With Prior Work

VR offers a potentially powerful method for delivering RT. Rather than looking at old photographs, newsreels, or home movies, participants can be directly immersed in scenes from

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the past. The systematic review of 22 studies by Ng et al [54] shows, most importantly, that across a wide range of interventions, there was little evidence of contraindications such as simulator sickness, and some positive outcomes for cognition. For example, Niki et al [55] carried out a study in Japan where VR was used among 10 participants aged at least 75 years who either saw scenes captured from a 360-degree camera ("live action") or computer graphics–generated scenes themed from 1955 to 1980. They found that the method reduced anxiety and that there was some preference for the live action method, without contraindications such as simulator sickness. Likewise, a scoping review by Restout et al [56] found that participants positively appraised the use of 360-degree videos in this domain. Tominari et al [57] conducted a study in which 52 individuals with mild cognitive impairment participated in 8 weeks of RT, using either tablet-based panoramas (ie, nonimmersive) or conventional photos. Both groups demonstrated significant improvements in cognitive functions, with the tablet group showing higher morale. Similarly, Huang and Yang [58] carried out a pilot study involving 20 participants with dementia, where VR RT sessions—featuring scenes such as historical residences, music, and photographs—were held twice weekly for 3 months. While the VR intervention did not lead to significant cognitive changes immediately after the treatment, it did result in improvements in depressive symptoms, with evidence of decline over the next 6 months.

Khirallah Abd El Fatah et al [15] used personalized immersive VR reminiscence scenarios created using participants' photo albums and videos, along with background information such as songs and friends gathered during interviews. These scenarios were compared with traditional RT and a control group that received standard care in older adult homes. While both the traditional and VR RT enhanced cognitive function and psychological well-being, the VR approach demonstrated greater efficacy.

While much RT research is mainly empirical, Lau et al [59] introduced a conceptual model (Immersion, Interaction, Imagination, and Impression) to help choose the content suitable for VR RT scenarios. This involved carrying out a survey conducted to identify suitable reminiscence materials for different age groups in Hong Kong, followed by the development of a prototype application. The prototype was then tested in a pilot study with occupational therapists, who provided positive feedback on its potential to offer a more engaging therapeutic experience compared to traditional methods. They noted that it helped elicit positive attitudes and motivation among older adults with dementia and improve their condition. The content was chosen to represent culturally significant scenes from various periods of Hong Kong's past, tailored to specific age groups.

The most important aspect of our paradigm is that we do not use VR only to reproduce the appearance of the past, but we also change the body of the participant to represent the corresponding younger age. This was impossible in the original counterclockwise study, but it is straightforward in VR. As we have seen, other uses of VR in RT immerse people in representations of the past, but the issue of how they themselves appear is not considered. In this sense, we have two findings: (1) that RT in VR can produce several indicators of at least short-term improvement, and (2) the young virtual body can play an important role. It could be argued that our control condition should instead have been a condition without any virtual body self-representation. However, the fact that we found, on some variables, a difference between the Young and Current Self representations addresses this objection, since we have shown that changing the body has an effect. A study without any virtual body representation would not add additional information.

It might be thought that age may impact the propensity of older adults to achieve body ownership; in particular, they might not tolerate the small differences between proprioception and the seen movements of the virtual body that are inevitable in a VR setup. However, Martinelli et al [60] found that as people age and their proprioceptive sense declines, they rely more on the visual sense, so that movements of the virtual body would override such inaccuracies.

In relation to the impact of the representation of people at a different age, Reinhard et al [61] studied the effect on walking speed of embodying younger adults in older bodies and found that the speed after embodiment was lower. However, we did not find the converse effect, that embodying older adults in their younger body would increase their walking speed.

Our findings on subjective age and handgrip strength are also consistent with experimental and observational work on subjective age and physical functioning. In an experimental study, Stephan et al [62] provided older adults with positive, age-referenced feedback after an initial handgrip test; those who were led to believe that their performance was good for their age subsequently reported a younger subjective age and showed stronger handgrip on a second trial compared with controls who did not receive such feedback. In a complementary experiment, Swift et al [63] showed that framing a handgrip test as a comparison with younger adults ("Are they half as strong as they used to be?") impaired older adults' handgrip strength and persistence relative to a neutral comparison condition, indicating that age-related social comparison cues can immediately weaken physical performance. However, our results suggest that the Young Self condition functioned as a positive prime, successfully counteracting typical age-related decline by supporting the perceived physical capability of the participants through their rejuvenated virtual identity as their younger self and through exposure to an event from their youth.

Beyond these lab manipulations, Wang et al [64] found that community-dwelling older adults who felt younger than their chronological age demonstrated better performance on several physical fitness indicators, including grip strength. In a geriatric outpatient sample from Northern India, Bhattarai et al [65] reported that each additional kilogram of handgrip strength was associated with a higher likelihood of feeling younger than one's peers. Large cross-sectional data from the Successful Aging Evaluation study similarly show that feeling younger than one's chronological age is associated with better physical and mental health across the adult lifespan [66]. Taken together, this literature suggests that subjective age is modifiable and closely linked to markers of physical functioning. Against this backdrop,

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the present results—in which older adults were embodied in a younger virtual body—tended to reduce subjective age and enhance left-hand (and to some extent right-hand) grip strength relative to the Current Self condition and can be interpreted as a proof of concept for the current intervention. We suggest that VR-based reminiscence and embodiment paradigms tap into similar subjective-age mechanisms that have been demonstrated in non-VR experimental and epidemiological work.

Although not in the context of RT, there is related work in which people were embodied in bodies of different ages. For example, Hershfield et al [67] embodied younger adults in older bodies, and this impacted their behavior with respect to saving behavior. Tammy and Wu [68] embodied older adults (aged at least 60 years) who did not engage in vigorous activity in younger virtual bodies, finding that this led to greater perceived exercise exertion. Vahle and Tomasik [69] carried out studies with young and older adults to examine the effect of embodiment in differently aged bodies on cognitive and physical functioning. They found that younger participants embodying older avatars experienced performance declines in both cognitive and physical tasks compared with those with younger avatars. However, and in contrast to some of our findings, they did not find any significant performance differences in physical or cognitive domains for older participants embodying younger avatars vs older avatars.

Limitations

The most important limitation of the study is the small sample size. This occurred for two reasons: (1) the difficulty in recruiting from this population, and (2) the relatively large drop-out rate due to illness or other factors more likely to occur among older participants. However, the Bayesian analysis is ideal for this. We start with prior distributions with high variance. Each additional data point updates the probability distributions of the parameters of the statistical model. Of course, the greater the number of participants, the narrower the posterior HDIs may become. If the data had no effect on the response variables, then the posterior distributions would not change much from the priors. However, in this experiment, if we compare the HDIs of the prior distributions (Table S2 in Multimedia Appendix 5) with the HDIs of the corresponding posterior distributions (Tables S1 and S2 in Multimedia Appendix 5; Figures 5 and 6), we can see that they are much narrower than the priors. Hence, clearly, the data had an important effect.

Beyond sampling limitations, other procedural factors may have further constrained the study's findings, and these should be addressed in future work. Due to technical limitations in the avatar reconstruction pipeline, the young avatars were often less realistic, having been derived from low-resolution, black-and-white historical photographs that remained suboptimal despite artificial intelligence (AI)–based enhancement. This discrepancy may have weakened participants' sense of body ownership and inadvertently confounded condition assignment with avatar quality. AI-based enhancement may also produce unintended perceptual effects, such as eliciting an uncanny valley response [70]. Although this is unlikely in our manipulation, since the virtual body representations were still far from photorealistic, such effects may become more relevant as future enhancements increase realism. Future studies should therefore treat AI enhancement as a perceptual manipulation that requires validation, for example, by conducting brief pilot tests that include ratings of avatar eeriness and likability.

Additional problems included the need for experimenter-prompted verbal guidance during some VR sessions. Since the tasks were audio-guided, participants frequently required additional assistance, leading to interruptions that may have reduced presence for some participants. Future setups should incorporate in-scene virtual agents capable of offering guidance and companionship within the virtual environment, thereby preserving presence while minimizing experimenter intervention.

Hardware constraints may have also affected participant experience. For example, the headsets tethered to the computer limited mobility, and battery depletion or incompatibility with corrective glasses likely reduced comfort and visual fidelity, particularly among participants with pre-existing vision impairments. Furthermore, extending the duration of VR exposure would give participants more opportunity to acclimate to both the virtual environment and their embodied avatars, mitigating the disorienting effects of technological novelty in this age group. Finally, repeated administration of certain neuropsychological tests may have introduced practice effects or ceiling limitations, obscuring potential improvements. Future protocols should diversify cognitive measures to ensure sensitivity to genuine change.

Although the present experiment was not designed to investigate body ownership as such, the intervention necessarily relies on inducing a degree of body ownership in a self-resembling virtual body, which raises ethical and safety considerations. For example, experimental work suggests that immersive VR can transiently increase dissociative experiences, including depersonalization and derealization (DPDR) symptoms, particularly among individuals with higher preexisting dissociation tendencies [71,72]. However, recent cross-sectional survey findings indicate that most current VR experiences are unlikely to cause long-term DPDR symptoms for the majority of users [73]. In addition, avatar-based exposures can influence self-perception and body image attitudes [74]. A recent systematic review highlights how digital bodies might expose users to privacy and identity issues [75]. To mitigate potential risks, our study design incorporated several procedural safeguards, including rigorous participant screening for neuropsychiatric diagnoses and prior trauma, time-limited exposures, and a controlled laboratory environment. However, since we did not use standardized assessments for DPDR or body image changes, we cannot exclude the possibility of subtle or transient altered self-experiences. Future research should integrate validated state measures of dissociation, monitor for adverse psychological reactions both immediately postexposure and during follow-up, and establish prespecified stopping rules and support pathways for participants in distress.

Furthermore, although we manipulated embodied age between groups, our study does not directly test whether switching from a younger to an older or current virtual self (or vice versa)

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produces asymmetric emotional responses. However, participants in the Young Self condition necessarily transitioned from viewing and moving as a younger-looking self in VR to re-encountering their current real body when the headset was removed. This "re-entry" could plausibly produce a contrast effect, heightening AARC in a manner analogous to temporal self-comparison processes often implicated in nostalgia-related reactions [76]. However, since many of the responses (especially the reduction in subjective age) lasted at least 1 week after the VR exposure, this was unlikely to have been a problem. Future research should examine whether effects differ depending on the direction of embodied-age change and test "re-entry" procedures (eg, a brief grounding and debriefing phase or a gradual transition back to a current-self representation) designed to minimize potential negative contrast effects [77].

Overall, our experimental study has shown that a VR version of counterclockwise, where people are placed back in the past with a virtual body that looks like their younger self, can have a number of positive effects on responses that indicate self-improvement to overcome some effects of aging. However, most of these effects do not last beyond about 3 weeks. In a way, this is not surprising, because in the original counterclockwise experiment, the participants spent almost an entire week in the house decorated to look like the 1950s, in their 1950s clothes and with 1950s TV and magazines, whereas in our experiment, there were just 2 short exposures. However, our results hold promise for future work with multiple exposures, each with a different scenario.

Apart from the audience in the theater, the participants were alone in the VR scenarios. In earlier pilot studies, some participants suggested that it would have been useful if they had been accompanied by virtual human characters representing people from their past (in the Young Self) and present (in the Current Self) scenarios. This is possible, in that we would require photographs of others to construct their virtual bodies. However, for the Young Self condition, there may be ethical or data protection problems, for example, in representing people who were no longer alive and therefore unable to give permission, and for older adults, it would be quite likely that significant others from their youth (such as parents) would no longer be living, although some might be (siblings and friends). This may further complicate the process of recruitment, since not only would we need to find participants, but also those who had significant others able to permit the use of their photographs at a younger age. While this would make recruitment more difficult, it is likely to be worthwhile.

Conclusions

More broadly, these findings suggest that VR-based interventions may be able to operationalize "age mindset" manipulations in a scalable and controllable way, allowing systematic testing of intervention "dose" (duration, repetition, and variety of scenarios) and mechanistic ingredients (past-context cues vs self-representation). If replicated in larger studies, this approach could provide a method for low-burden behavioral interventions targeting subjective age and related functional outcomes, with potential extensions to populations where reminiscence-based approaches are already used (eg, mild cognitive impairment or depressive symptoms), while maintaining careful attention to usability and safety in older adults.

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The authors disclose that no machine learning, artificial intelligence (AI), language models, and/or similar technologies or tools were used for purposes of information gathering, analysis, content creation, and/or paper writing and editing. AI tools were used to help search for Python libraries for statistical analysis.

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Data Availability

The datasets generated or analyzed during this study are available in the Kaggle repository [78].

Authors' Contributions

MS contributed to conceptualization, methodology, formal analysis, validation, resources, supervision, project administration, funding acquisition, writing the original draft, and reviewing and editing the paper. DB contributed to conceptualization, methodology, investigation, resources, software, writing the original draft, and reviewing and editing the paper. RI contributed to software, visualization, and reviewing and editing the paper. RM contributed to data curation, methodology, investigation, and reviewing and editing the paper. CPM contributed to data curation and reviewing and editing the paper. DBF, EB, and MM contributed to methodology, investigation, resources, and reviewing and editing the paper.

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Conflicts of Interest

MS is a founder of the company Virtual Bodyworks, which works in the area of using virtual reality for diversity, equity, and inclusion in companies. Virtual Bodyworks had no knowledge of or role in the study design, data collection, analysis, data interpretation, paper preparation, or the decision to publish.

Multimedia Appendix 1
Summary of each demographic, background, and basic health variable.
[DOCX File, 19 KB - formative_v10i1e88338_app1.docx]

Multimedia Appendix 2
Video of the virtual reality scenario.
[MOV File, 104563 KB - formative_v10i1e88338_app2.mov]

Multimedia Appendix 3
Histograms of the response variables.
[DOCX File, 659 KB - formative_v10i1e88338_app3.docx]

Multimedia Appendix 4
The overall statistical model.
[DOCX File, 28 KB - formative_v10i1e88338_app4.docx]

Multimedia Appendix 5
Summaries of the posterior distributions.
[DOCX File, 47 KB - formative_v10i1e88338_app5.docx]

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Abbreviations

1PP: first-person perspective
AI: artificial intelligence
DPDR: depersonalization and derealization
HDI: highest density interval
HMD: head-mounted display
MMSE: Mini-Mental State Examination
RT: reminiscence therapy
TMT: Trail Making Test
TV: television
VR: virtual reality
WHO-5: World Health Organization–Five Well-Being Index

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Exploring User Experiences of an Augmented Reality Smartphone App Prescribing Exercise for Children and Young People With Cancer: Results From a Qualitative Study

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Abstract

Background: Mobile health (mHealth), and specifically smartphone apps, have grown exponentially in both functionality and accessibility and are becoming an important component of health care. Research exploring the use of mHealth for managing or treating chronic diseases, such as cancer, has shown promising effects. Yet, comparatively little work has examined how such technologies can enhance exercise interventions for young people with cancer. To optimize the effectiveness of mHealth in these contexts, it is essential to build a stronger evidence base on user experience.

Objective: This study aimed to investigate how healthy children and young people engaged with an augmented reality (AR) app developed specifically for children and young people undergoing cancer treatment, and to identify design features that may support engagement and behavior change in the intended clinical population.

Methods: School and university students, aged 8 - 21 years, were eligible to participate in the study. Practical workshops allowed participants to engage with the AR exercise app before taking part in focus groups to explore user experiences. Data were analyzed using qualitative content analysis, which also involved a critical friend approach using 2 researchers (HM and KS). Suggested improvements were mapped against the motivational affordances' taxonomy.

Results: A total of 39 participants aged 8 - 21 years took part in the focus group study. Participants found the demonstrations and varied exercises useful but expressed some concerns regarding data safety and functionality of the novel AR avatar. It was proposed that additional educational components, challenges, and rewards, as well as a customizable avatar, social support features, and audio instructions for a more inclusive design would be desirable and could enhance user experience. When mapped against the motivational affordances taxonomy, the suggested improvements aligned primarily with mechanisms of user education, challenges, feedback, cooperation, and comparison.

Conclusions: This study provides an understanding of how apps that prescribe exercise can be optimized to enhance motivation and user experience. By assessing feedback and suggestions for improvements, the findings highlight key design features that may support engagement. While this initial work focused on healthy, age-matched participants, further evidence specifically in children and young people with a childhood cancer diagnosis is needed.

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KEYWORDS

mHealth; AR; qualitative research; physical activity; exercise; childhood cancer; mobile health; augmented reality; mobile phone

Introduction

Over the past 50 years, chronic health conditions among children and young people have risen on a global scale [1]. Conditions such as cancer, type 2 diabetes, obesity, and mental health disorders are increasingly prevalent in this population, resulting in a substantial burden on health care systems [2]. Addressing this issue requires a comprehensive, multidisciplinary approach, incorporating preventive public health measures, early and targeted interventions, and health care systems that cater to the

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physical and psychological dimensions of chronic illnesses in children and young people [3]. The use of technologies within health care may offer an important role in the management of long-term conditions in pediatric populations [4].

Specific research in patients with cancer has reported that digital interventions have elicited positive outcomes, including improving adherence to medication [5], symptom management [6], physical activity levels [7], and mental well-being [8]. Digital tools can empower young patients to take an active role in their health management [9], as well as having the potential to alleviate some of the pressures (eg, staff shortages, limited capacity of services and facilities, and increased demand) on health care systems by supporting disease management outside of traditional clinical settings.

Children and young people undergoing treatment for cancer have some unique barriers to physical activity. These include (1) treatment-related side effects, such as fatigue and pain; (2) psychological barriers, such as fear of injury and low mood; and (3) organizational barriers, such as limited clinical space and lack of sports equipment during home stays [10].

Addressing these barriers requires accessible, personalized solutions. Digital interventions have grown exponentially in both functionality and accessibility, emerging as an increasingly important component of health care delivery [11]. Interventional evidence suggests that using mobile health (mHealth) tools can benefit those managing chronic conditions, such as cancer, by offering a more personalized approach to real-time health management [12]. mHealth tools have been shown to provide a medium for personalized care, continuous monitoring, and patient engagement, therefore improving clinical outcomes and enhancing quality of life for patients [13,14]. mHealth has opened doors for the development of innovative smartphone apps tailored to meet the health needs of specific populations, such as pediatric patients with cancer [15].

More specifically, the integration of augmented reality (AR) in mHealth tools has gained traction in recent years [16]. AR technology overlays digital information on places or objects in the real world [17], as seen in apps, such as Pokémon Go (Niantic Inc). It is expected that incorporating AR within existing tools could enhance user satisfaction and facilitate long-term engagement by using more graphic-focused screen design and multimedia message presentation, as well as clear demonstrations and instructions by an AR avatar [18]. There is a previous systematic review [19] exploring the effectiveness of AR interventions for physical activity promotion and improving health outcomes. This evidence in children and young people reported that AR helped participants increase their physical activity levels as well as their engagement and motivation toward physical activity. Additionally, social interactions and psychological distress were also improved [19]. However, there is a lack of research on the user experience of AR apps specifically designed for promoting exercise participation during cancer rehabilitation.

Development and implementation of mHealth tools and specifically AR apps, in pediatric populations, especially for long-term, maintained engagement, presents significant challenges, emphasizing the need to use theoretical frameworks as well as evidence-based and user-centered approaches [20,21]. In recent years, there has been an increased acknowledgment of behavior change techniques, such as goal setting, motivational messaging, and outcome feedback, in the design of mHealth tools and programs [21]. Current guidance for designing and evaluating mHealth tools has specified that it is of particular importance that behavior change techniques are used as a basis for development to ensure content is theory-driven and follows evidence of best practice [22]. The app that was designed and evaluated as part of the research outlined here contains features based on behavior change techniques, such as feedback on behavior, instruction on how to perform the behavior, and demonstration of the behavior [23]. While these techniques are promising for integration in interventions promoting physical activity, there is limited evidence on their application in more complex mHealth tools, such as apps using AR. To address this gap, additional strategies, including motivational affordances, should be considered.

Motivational affordances are defined as design features, such as gamification and personalized feedback, that focus on increasing user engagement, distinguishing them from the internal cognitive processes emphasized in behavior change techniques [24,25]. The success of apps relies on user engagement, which is based on the user's motivation. Satisfaction, efficiency, and engagement define the overall user experience; however, apps do not always provide the expected results and rarely investigate user engagement [26]. For this purpose, the integration of disciplines of usability and motivational psychology could be achieved through research in motivational affordances [27]. Motivational affordance mechanisms and design elements could be used to satisfy the user's motivational requirements (ie, psychological, cognitive, social, and emotional); thus, there have been calls for motivational affordances to be applied in mHealth design. Theory-based approaches for the evaluation of apps are particularly useful due to their specific technology designs, which seek to tap into users' motivations, so they are captivated by them and really seek to use them [28]. However, there is a particular lack of evidence evaluating the usefulness of and user preferences for motivational affordances in exercise prescription apps for children and young people with cancer [29,30]. It is vital to specifically assess the potential for integrating motivational affordances in exercise prescription apps, since their adequacy and specificity are key in populations with chronic diseases [31].

Due to the novel nature of this app, there is a need for extensive evaluation of the app's functionality and usability, particularly regarding the navigation, layout, instructions, and AR demonstrations, before testing with children and young adults with cancer. The findings of this study provide valuable insights, which are more appropriately assessed in a more controlled setting, such as schools and healthy peers [32]. Participants of this study were age-matched to the target population for which the app was being developed.

Thus, the aim of this study was to explore the experiences of school pupils and university students of an AR smartphone app designed to prescribe exercise for children and young people with cancer. The study also aims to map participants'

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suggestions for improvement onto motivational affordance mechanisms and design elements. Understanding user preferences allows developers to refine features, improve accessibility, and create more engaging and effective mHealth tools for exercise prescription [32].

Methods

Overview

The methods (including app design, recruitment, data collection, and data analysis) have been comprehensively described in a previous publication [32]. In reporting of methods, the 32-item COREQ (Consolidated Criteria for Reporting Qualitative Research) checklist has been used (Checklist 1) [33].

AR App Development

The AR app was developed to support an individualized exercise program for children and young people undergoing cancer treatment, particularly when face-to-face provision was not possible, the child was at home, or they were immunocompromised. Its design was guided by an interdisciplinary team of software developers, digital health researchers, and pediatric oncology exercise professionals. Key features were implemented with the needs of children with cancer in mind, including professional input during onboarding to record diagnosis and contraindications, child-reported fatigue and activity levels, and a pre-session questionnaire to screen for new symptoms. The app offers upper body, lower body, and core exercises with seated and standing options, and a rate of perceived exertion scale that automatically adjusts exercise volume if intensity is inappropriate.

Recruitment and Setting

Participants were recruited through schools and universities. Eligibility criteria are presented in Textbox 1.

Textbox 1. Participant eligibility criteria.

Children and young people in

- Years 4, 5, 6, 7, 8, and 9 of primary school and secondary school, aged 8-14 years old
- Sixth form in secondary school, aged 16-18 years old
- University, aged 19-21 years old

Proficient in the English language

- Able to take part in a session up to 30 min of low-moderate intensity body weight exercises

Participants were recruited through convenience sampling of age-matched children and young people, representing a mix of rural and urban schools, along with 1 university group. During the recruitment of primary school children, the research team liaised with the school and its teachers, who passed on information about the study to potential participants and legal guardians. Participants were told why the research was being conducted and that the app had been developed for children with cancer in mind. For secondary school pupils, members of the team visited the school to explain the purpose of the study and outline what involvement in the workshops and focus groups would entail. For university students, the team provided details about the study by attending a selection of lectures.

Ethical Considerations

This research has received ethical approval from the Oxford Brookes University Faculty of Health and Life Sciences Research Ethics Committee (David E. Evans, Paul Hough, Robyn Curtis, and Jo Brett; approval 211547). Written informed consent and assent, including parental consent where applicable, were required to participate in the project in accordance with the project approvals granted by Oxford Brookes University Faculty of Health and Life Sciences Research Ethics Committee (registration 211547). All data were fully anonymized before analysis, with any identifying information removed to ensure participant confidentiality. Participation was voluntary, and individuals could withdraw at any time without penalty. Participants did not receive any compensation for their involvement.

Before the workshops, non–user-facing onboarding steps were completed to ensure that participants could access the main functions of the app, even though they did not have a cancer diagnosis. This setup involved selecting the following default options: all body areas were eligible for exercise, activities were not limited to seated movements, participants did not use a prosthetic limb, and they did not experience peripheral neuropathy. At the beginning of each workshop, participants were told why the research was being conducted and that the app had been developed for children with cancer in mind. None of the individuals invited to take part had used or interacted with the AR app.

Participants were given a phone and then progressed through the user-facing onboarding sequence. Once this was completed, participants completed an individualized exercise session, following the AR avatar demonstrations (Figure 1). Each workout consisted of 6 exercises, with the number of repetitions (1-6) and sets (1-3) automatically adjusted by the app's algorithm based on responses provided during the onboarding process. Following the session, participants completed a postsession questionnaire, which included a rating of perceived exertion measure (Figure 2).

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Figure 1. App screen during exercise.

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Figure 2. Rate of perceived exertion scale.

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Subsequently, participants took part in focus group discussions to explore the user experience of using the AR app and had the opportunity to share suggested improvements. For the focus groups, a semistructured interview guide was used (Table 1).

Table . Semistructured interview guide for focus groups.

Topic and guiding questions	Prompts
Smartphone app perceptions	
What are your thoughts on using a smartphone app to help you do exercise?	• What kind of app are you thinking of? • How have your thoughts changed from before the workshop to now? • How would you use an app to be more active and do exercise?
How do you feel about using an augmented reality app to support you to be more active?	• Why would you use one? Why would you not?
Which part of the app do you feel would help you the most in doing more exercise?	• Which features did you enjoy the most? • Which features do you think you wouldn't need?
Exercise selection and prescription	
Which exercises do you remember from the app?	—[a]
What did you think about the exercises that were selected for you?	• Did you find the exercises easy or difficult? • Have you done any of these exercises before?
What do you think children who are your age (or younger or older) would think about these exercises?	—
Augmented reality avatar experiences	
What did you think about the avatar?	• What did you like about the avatar? • What kind of avatar would you prefer?
How did you find the avatar's demonstrations?	• Were you able to follow the reps and rounds? Was this made clear enough on the screen?
Were there any problems with the avatar whilst you were using the app?	• Did the avatar appear properly on the screen? Was the avatar the wrong size? • Were there any problems with the avatar's demonstrations?
App usability	
How do you feel about the phone we gave you for using the app?	• Did you find it easy or difficult to use? • What do you think about the size and display? • How did you find pressing different buttons on the phone?
How did you find using the tripod that held the phone whilst you were exercising?	—
Do you feel that the equipment you were using affected your experience in any way?	• Did the phone make it easy or hard to follow the demonstrations? • Was the tripod getting in the way of how well you could follow the demonstrations? • What do you think about the space you used for doing the exercises?
How did you find answering the questionnaire questions on the phone?	• What do you think about the amount of questions? • What do you think about how the questions were worded? • What do you think about answering questions on an app, compared to, for example, a piece of paper?
Suggestions for improvement	
How do you think the app could be improved?	• What do you think would make the avatar more useful? • What do you feel we should change about the exercises?
How else do you think we could help you be more active and do more exercise?	• What other technologies or equipment would you find useful?

[a]Not applicable.

Workshops were conducted by KS (PhD, postdoctoral research assistant, female) and HM (MSc [Res], postgraduate research assistant, female), and SW (PhD, postdoctoral researcher and senior lecturer, male, qualitative research and technology

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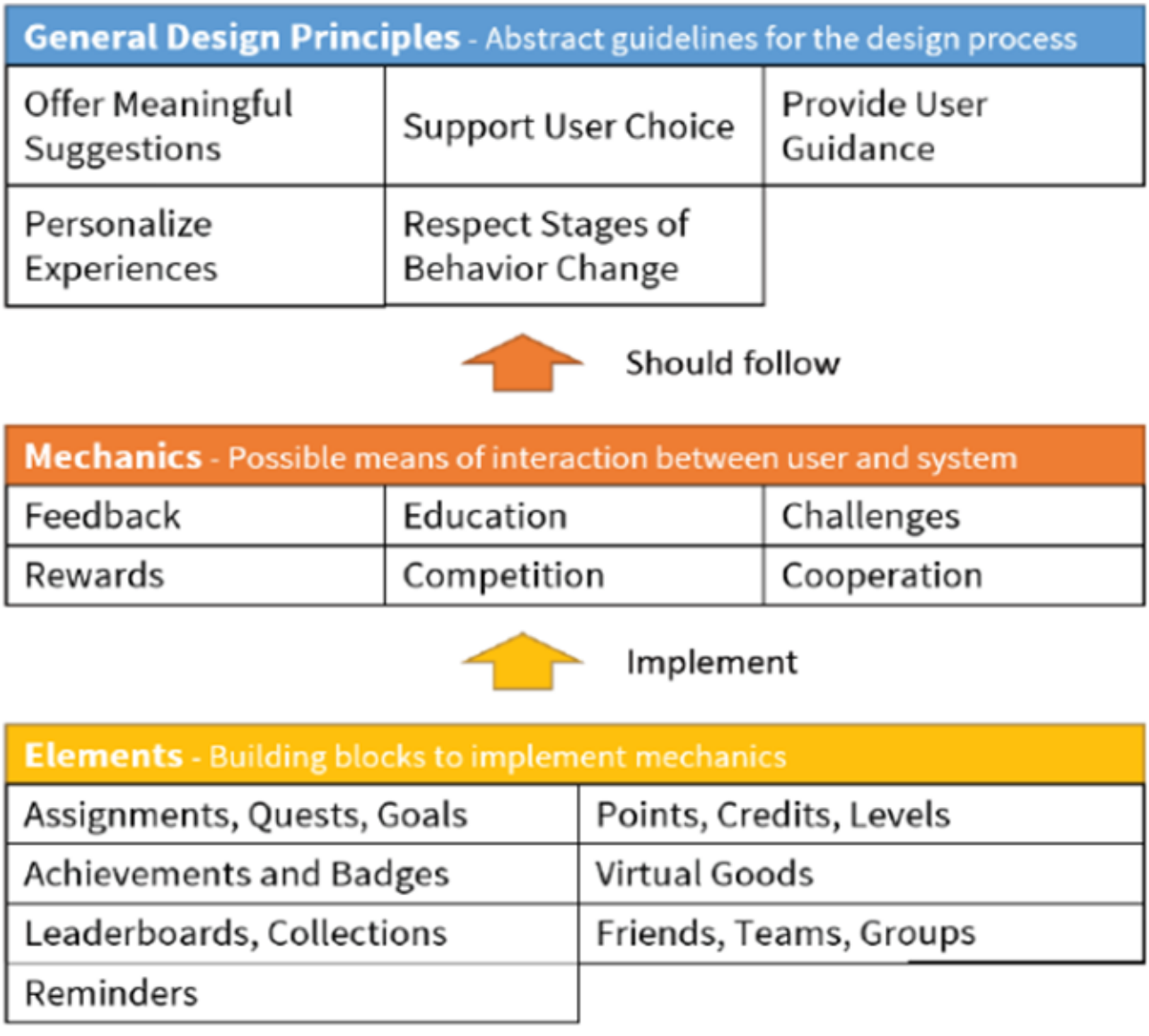
expert), and focus groups were conducted by KS and HM. The research team had previous experience in conducting mixed method and qualitative research and specific training as part of their academic qualifications. Focus groups were audio-recorded and transcribed.

Data Analysis

Edited transcriptions were printed and reviewed in paper format, with 3 researchers (KS, SW, and HM) collaboratively conducting a coding process. Analysis combined deductive and inductive approaches [34-36]. The deductive component applied a pre-established framework based on key topics—hardware user experience, app interface, app design, AR functionality, avatar design, and exercise prescription. User experiences and suggested improvements were considered separately. Any remaining data from the discussion were inductively coded through intercoder conversations [32].

Features mentioned as suggested improvements were mapped onto the mechanisms and design elements outlined in the taxonomy of motivational affordances (Figure 3) [24]. Applying the taxonomy ensured relevant features were mapped onto evidence-based strategies and a unified terminology was used, which will aid the development and evaluation of future tools.

Figure 3. Taxonomy of motivational affordances (reproduced from Weiser et al [24], which is published under Creative Commons Attribution-NonCommercial 4.0 International [CC BY-NC 4.0 37]).



Moreover, 2 coders (HM and KS) independently mapped the features to the taxonomy to enhance the validity of the coding process. Subsequently, "critical friend" discussions were held to explore the suitability of the respective selections and to encourage reflexivity and enhance the dependability and credibility of data [38]. This approach also encouraged KS and HM to reflect upon their coding and provided room for considering alternative interpretations [38].

Results

Overview

In total, 19 primary school pupils, 28 secondary school pupils, and 3 undergraduate (UG) university students took part in the practical workshops, with 39 providing consent to take part in the subsequent gender-mixed focus groups. These were conducted in the respective educational facilities (eg, school

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classroom). There were 8 focus groups in total—3 with primary school students, 4 with secondary school students, and 1 with university students. Workshops and focus groups were conducted between June and December 2021 at one primary school in Gloucestershire, one secondary school in Oxfordshire, and one university in Oxfordshire (United Kingdom). Participant ages and year groups are presented in Table 2.

Participants were able to test the app for 20 - 30 minutes before taking part in semistructured focus groups, which lasted between 16 and 28 minutes.

Table . Demographic characteristics of focus group participants.

Stages of education	Total participants, N	Sex, n
Primary school (year group 4-6, ages 8-11 y)	8	4 male, 4 female
Secondary school (year group 7-9, ages 12-14 y)	19	4 male, 15 female
Sixth form of secondary school (year group 12, ages 16-17 y)	9	6 male, 3 female
Undergraduate university students (ages 18-21 y)	3	2 male, 1 female
Total	39	16 male, 23 female

User Experience

Overview

Overall, most participants reported that they enjoyed using the app and described it as “fun” (Y9, UG). One participant explained they enjoyed using an app as it “was fun to do exercise that you don’t usually do” (Y9). They also mentioned they would likely use it if it were available and suitable for their needs. Moreover, they felt the app could be a useful tool for promoting physical activity more broadly, and most agreed that it would help users engage more specifically with exercise. In particular, participants pointed out that the app “could build confidence” and “basic strength” (UG) to enable users to subsequently engage in more comprehensive physical activity provisions (such as group exercise classes). When comparing face-to-face exercise provisions, a participant shared that

> *sometimes it’s nice to not have a scheduled time to go and see someone to do it in person. [...] If you feel insecure or feel weak, you can literally just set up the phone and do it alone [...]. It feels a lot easier.* [UG]

When asked about long-term use, some participants mentioned they would likely use it for a long time, whereas others stated they would likely use it for the shorter term only, with one describing they would engage with it for “two weeks and then get bored with it” (Y8). In contrast, other participants highlighted that the app could be helpful as a “prompt” to exercise, and it is “easy to follow and to pick up and make a habit of” (UG).

AR Functionality

During the focus groups, participants specifically discussed their experiences of using the app with regard to the AR functionality, app design, onboarding processes, accessibility, and safety. In addition to the iPhones (model 12, screen size 6.06 inches; Apple Inc), participants in this study were given a tripod to ensure they could execute the exercises without holding the phone. Participants generally found it useful to have a digital exercise demonstration, compared with paper-based drawings or text. Participants shared that using the AR app makes accessing exercise “quick” and “easy” (UG). Participants shared that the AR avatar felt like a “training partner” who provided a bit more motivation and “[made] the exercise more fun” and “might make […] someone feel like one of their friends is doing the same” (UG). Furthermore, participants felt that for clinical users who may wish to do activities without face-to-face supervision, the AR functionality could be useful to provide demonstrations and maintain a sense of personalization and care. Participants liked being able to watch the demonstration for as long as they needed to and “didn’t feel rushed” (UG), as there was no specific time allocation per exercise. Participants agreed that having a virtual exercise demonstration is useful, especially if users had insufficient knowledge to execute specific exercises.

In comparison, there was no consensus among participants with regard to the use of AR compared with more traditional (2D) video demonstrations. One participant mentioned that “there are more problems presented by the AR than solved by the AR” (Y12), hinting at technical difficulties that occurred when scanning the room to allow the avatar to appear. Participants mentioned that they had to scan the surroundings with the phone for the AR avatar to appear before each exercise, which some stated was “frustrating” (Y8, UG), and others felt like they should not have to physically move the phone each time to make the avatar appear. It should be noted that this was not an issue for everyone, with some participants saying that “it worked quite quickly” (Y8). It also transpired that at times, the avatar would appear in a different location to the one scanned, or appear too large or too small. Moreover, some participants mentioned that it was difficult to follow exercises that required them to be seated or lying down on the floor, as they could no longer see the phone screen. It was suggested that using videos would allow users to move the phone without impacting the exercise demonstration. On the other hand, some participants stated that the use of an avatar was unique to this app and generated a more enjoyable experience compared with traditional apps (ie, those using videos), as it made the exercises feel more like a game. One participant said that,

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> *[...] it was really fun and enjoyable because while I was doing it, I didn't really notice I was doing exercise.* [Y5/6]

App Design

Most participants stated that they merely focused on the avatar, without reading the other information presented on the screen, whereas some read the text before looking at the avatar. Among users who indicated they read the instructions, some found it difficult to decipher whether they were asked to perform 1 round, 1 set, or multiple sets. It was evident that text presented in bold was perceived as important and was prioritized by some participants before beginning the exercise.

Onboarding Process

Some participants questioned the relevance of some of the questions, for example, with regard to the ability to keep their balance on a slippery surface, and also mentioned that some of the questions felt repetitive. Others appreciated that the individual questions were needed for the subsequent exercise prescription, and older users mentioned they liked that there would be scope for progression.

Participants stated that an option to skip a question they felt uncomfortable answering would be beneficial as "someone might be worried that if [...] they find it hard to do something, they might not like people knowing that" (Y5/6). Participants appreciated that the questionnaires did not ask them for any input on their height and weight, as they perceived this may be potentially uncomfortable for some users. Moreover, questions that enabled more tailored exercises were welcomed as they would "feel more motivated because it's actually targeted [...] personally, instead of just a generic app" (UG).

Regarding the number of questions, there was no consensus among participants. Some felt the questionnaires were too long, and they would potentially skip questions, respond randomly, or cease use of the app. Others stated the questionnaires were "quite short" (Y4) and not "too long or bothersome" (UG). One participant appreciated that "[...] for the people who actually need it, [they] would pay attention to what is actually going on because they want to get better" (Y9), hinting that intended users (ie, children with cancer) would also be more likely to appreciate the need for onboarding questions.

It was also discussed that most felt the questions were easy to read; however, others stated they might need to be shortened for younger users. One participant (Y5/6) mentioned that the questions should be as specific as possible, as they struggled to select an answer when the question was not clear (eg, asking about their ability to carry a heavy book, with confusion on what "heavy" would entail).

In regard to the answer options, most participants felt that 5 options were sufficient, and the wording should be clearer to effectively distinguish between options (eg, "sometimes" vs "almost never").

Exercise Prescription

Most participants stated that the prescribed exercise intensity was achievable, although a few participants reported that some of the exercises were too easy. The selected exercises were deemed to be suitable, with a "good range" and appropriate provision of exercises done in a lying, sitting, and standing position. One participant felt this made it "interesting" and "fun" (Y9).

Participants felt that a gradual intensity progression is helpful in regard to a decrease or increase in intensity or repetitions based on previous performance or feedback input from users. The rate of perceived exertion scale (Figure 2) was well-received, and participants found it easy to select the relevant score.

Accessibility

Some participants stated that they found it beneficial not to need specific equipment (ie, other than a chair), whereas others mentioned they would prefer exercise sessions that require no equipment at all. One participant added that the app was also beneficial for those with limited access to appropriate outdoor space for exercising as "you don't need a big field to do exercise, so even if you live in a flat […] you can still do it" (Y5/6). It was also recognized that paying for exercise apps, such as this one, could be a barrier for some users, as expressed by one, "it's really good to have it free" (Y7).

Safety

A couple of participants also discussed their experiences with data and usage safety, including concerns regarding how much, and what type of information was collected, as well as how this would be shared. One participant hinted that the length of the onboarding questionnaires may "[make them] a bit suspicious of what is happening so [would] delete it" (Y9). One participant mentioned their parents may share these concerns and would encourage them not to provide personal information, such as their real age.

Avatar Design

Participants generally agreed that the avatar design was appropriate for a variety of ages, with no suggestions made on specific features that should be changed as a default. Participants commented that the avatar was "cute and funny" (Y9), and the design allowed for easy interpretation of the exercise demonstrations. Older participants highlighted that they appreciated the semirealistic design and felt that the avatar's body shape was helpful not to "feel pressure of 'you have to look like this'" (UG) but rather encouraged them to focus on being physically active for enjoyment.

Suggested Improvements

Throughout the focus groups, participants voiced suggestions for future improvements of the app. Table 3 contains an overview of suggested improvements linked to the following motivational affordance mechanisms: user education, challenges, feedback, cooperation, and comparison.

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Table . Summary of suggested improvements by motivational affordance mechanisms.

Category	Participant quote	Recommendation	Motivational affordance design elements
User education			
Exercise instructions	• "I think if it explains to you what it does or [help with], […] that would be more educational" (UG)[a] • "[...] I didn't actually know how long I was doing it for." (Y4) [b]"[...] It didn't [...] say per leg or all together." (Y12)[g] • "[...] It could say [...] you need a chair [...]." (Y12) • "[…] I would prefer more text or description of what we're going to do" (UG) • "I think it would definitely help especially when you are doing an exercise when you can't […] directly see the screen, the audio telling you the next exercise is about to start would definitely help someone notice when to move onto the next one" (Y12)	Provide detailed (written or audio) instructions explaining purpose, repetitions, and equipment	Assignments
Visual demonstration aids	• "It would be better if it had arrows of [...] where to move." (Y9)[f]	Implement additional visual guidance to support movement execution	Assignments
Duration	• "[...] there [could] be a timer in front of you so you could see [...] how long there is to do this exercise." (Y12) • "[...] There should maybe be an option to do a countdown [...]." (Y7)[d]	Consider use of countdowns or timers	Assignments and goals
Order	• "I would try [to] space out the chair exercises [...]. [...] So maybe do a sitting down one, a lying down [one] and then a standing up [one]." (Y5/6)[c]	Ensure sitting, lying, and standing exercises are included and interspersed	Assignments
Exercise type and variety	• "I guess it would be good to have more variety [...]" (Y12) • "[...] There should be options on what you want to work on, like if you want to work on your legs [...], on your arms, or you want to do your whole body." (Y9)	Give a variety of exercises and allow user choice for type of exercises (including strength and mobility)	Assignments, quests, and goals
Rest	• "I think [...] there should be a rest time." (Y9) • "[...] If it was as long as you like, then I would give up. I would lay down and forget about it." (Y9)	Implement specific durations for rest	Assignments
Equipment options	• "[...] You could do an option so people that aren't used to exercising [...] can have a chair with them [...]." (Y5/6)	Provide exercises using equipment to facilitate safe and appropriate exercise performance	Assignments and quests

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Category	Participant quote	Recommendation	Motivational affordance design elements
Challenges			
Setup	• "[...] There should be [...] a few different levels, so an easy, a medium and a hard [...]." (Y4) • "I think it would be nice [...] before you go to the exercise you can type in how much you want to do [...]." (Y12)	Provide different levels of intensity to account for previous experience and current capabilities and allow users to select their own	Levels, quests, and goals
Intensity progression	• "[...] It [should be] updated [...] every two weeks [...]. The exercise levels could change, [...] get harder." (Y8)[e] • "[…] If you found it too hard, it can make the exercises a bit easier next time" (Y9) • "[...] Whenever you finish an activity, you can write down what was easy or hard for you [...]." (Y7)	Allow intensity progression or regression and user input to gain feedback on perceived exercise intensity	Assignments, quests, goals, and levels
Progress overview	• "A form of motivation would be a progress bar, [...] and over time you can see [how] well you improve." (Y12)	Provide progress overview graphs, bars, or charts as motivational tool	Points, achievements, and badges
Feedback			
Compliance	• "[…] There could be a sensor, it could make sure, seeing what you are doing, like saying out of 10, it knows what you are doing" (Y5/6)	Consider sensor technology to track movements and give feedback on execution	Points and achievements
Encouragement	• "I thought it was a bit quiet, so "you can do this," or like "you've done great" or something" (Y9)	Provide audio encouragement during or between exercises	Achievements
Cooperation and comparison			

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Category	Participant quote	Recommendation	Motivational affordance design elements
Group exercise	• "Maybe you could choose how many people do the workout, so if you want to do it as a family then you could say partner round or how many people are playing with and then you could have three different avatars […]" (Y5/6) • "It would be a good idea if, […] you could FaceTime a friend whilst you're doing the exercise or you could have like a split screen thing where you both do it and you can see what each other are doing and like talk to them whilst doing it" (Y7)	Give options for group exercise with invited users	Friends, teams, and groups
Social support	• "Because your friends would probably encourage you if you say this is hard, they would encourage you" (Y7)	Allow users to interact with others via call or chat feature	Friends, teams, and groups
Performance comparison	• "Like a scoreboard with other people's scores on it." (Y5/6)	Allow comparison between users via visual aids	Leaderboards

[a]Undergraduate (UG) focus group.

[b]Y4: Year 4 focus group.

[c]Y5/6: Combined Year 5/6 focus group.

[d]Y7: Year 7 focus group.

[e]Y8: Year 8 focus group.

[f]Y9: Year 9 focus group.

[g]Y12: Year 12 focus group.

In addition to these improvements, participants discussed options for incorporating gamification within the app, which was mentioned to hold potential to attract users who usually do not enjoy exercise. One participant added that "[...] rather than playing games [...], [they] would be doing exercise" (Y7). They felt it could be useful to use young people's interest in computer gaming or other activities and amalgamate this with the exercise-related features of an app. Table 4 contains an overview of gamified features proposed by participants, linked to challenges and rewards as per the motivational affordance mechanisms.

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Table . Overview of suggested improvements for gamification by motivational affordance mechanisms.

Category	Participant quote	Recommendation	Motivational affordance design elements
Challenges			
Exercise tasks	• "[...] If you are jumping on the spot, [...] you can try and beat your high score [...]." (Y4)[a]	Give personalized activity tasks	Quests and challenges
Cognition	• "[...] You can add games that could teach them about Maths and English [...]." (Y7)[b] • "You could [...] match the [...] name of the exercise to the actual exercise." (Y8)[c]	Integrate games related to school subjects or logical thinking	Quests
Special interest	• "[...] It might be good to teach them activities, [like] how to shoot a basketball, how to dribble a football." (Y7) • "[...] There could be [...] vocal exercises for people who like singing." (Y7)	Incorporate activities to train special interests	Quests
Virtual world	• "[...] You could make the avatar do games, like football or basketball [...]." (Y4) • "[...] The avatar could do stuff at home, like as if it's them but in the game, [...] like going to school and things [...]." (Y7)	Create virtual world for the avatar to complete tasks	Quests
Rewards			
Virtual rewards	• "[...] If you reach your [...] target for one day of exercise you then [...] unlock the points and then you can get something to customize your avatar a bit more [...]." (Y9)[d] • "[...] At the start of the app you could have the yellow one and blue one but then when you complete [...] 10 exercises, you can unlock other [...] [colors]." (Y9) • "[...] If you do [the exercise] amazingly, you could get [...] stars and you could trade it in for [...] a little fun game play." (Y5/6)[e]	Provide rewards (eg, via avatar customization) for exercise achievements	Credits, achievements, and badges

[a]Y4: Year 4 pupils focus group.

[b]Y7: Year 7 focus group.

[c]Y8: Year 8 focus group.

[d]Y9: Year 9 focus group.

[e]Y5/6: Combined Year 5/6 pupils focus group.

In addition to the suggested improvements shown in Tables 3 and 4, and outside of the scope of features related to motivational affordances, participants highlighted that equipment for using the app should be user-friendly. For example, phone screens should be of sufficient size (>6 inches), and tripods should be sturdy and easy to adjust. Moreover, customization of the app interface (eg, by giving options to change background colors), or of the avatar (eg, by allowing users to change its features, such as age, gender, skin color, hair, body composition, and clothes, or giving nonhuman options, such as, animals or fantasy characters) would be useful and could enhance engagement with the exercise. It was also

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suggested that allowing users to play their own music or select from a choice of songs could be motivating.

Discussion

Principal Findings

This study explored user experiences of an AR exercise app and mapped users' suggested improvements against motivational affordance mechanisms and design elements [24]. Most participants reported that they enjoyed using the app. Participants found the demonstrations and varied exercises useful but expressed some concerns regarding data safety and functionality of the AR avatar. Suggestions included improvements, such as additional educational components, incorporating challenges and rewards, as well as a customizable avatar and a social support feature, such as the possibility of exercising with family or friends. Additionally, some suggestions, such as the integration of audio instructions for a greater inclusive design, were made. Finally, users also expressed concerns about personal data safety. When mapped against the motivational affordances taxonomy, the suggested improvements aligned with mechanisms of user education, challenges, feedback, cooperation, and comparison. This study underlines the importance of incorporating a variety of motivational affordances to account for different user needs and preferences.

Motivational Affordances

Within this study, participants' suggestions frequently mapped against the taxonomy of motivational affordances [24]. It is promising that motivational affordances incorporated within the current app, such as user education on how to perform exercise, seem to be particularly effective in improving physical activity levels among patients with cancer in other research [39]. Participants in our study also suggested new features, such as audio instructions, visual progress bars, and the ability to connect with other users, highlighting the need to further develop design features, such as achievements, credits, and friends [24].

While current studies may assess the general usefulness of mobile apps, a deeper exploration is needed to determine how specific features drive engagement and thus encourage long-term physical activity, especially in populations, such as pediatric oncology, which we know face additional barriers to exercise. Currently, we may only understand the usefulness of motivational affordances, and further research should delve deeper into the mechanisms through which the features work, for example, via belief in capabilities and intentions [40]. Investigating these underlying mechanisms could help optimize app design and ensure that interventions are effectively promoting behavior change, and not only short-term app use. Long-term engagement is particularly important for survivors of children with cancer as physical activity levels are often lower than noncancer controls [41], and observational studies have identified associations between sedentary behavior and adverse effects on cardiometabolic and bone health [42].

Gamification

For end users to use and positively benefit from an app, they must actively engage with it. Our findings indicated that incorporating challenges and rewards is preferred, which is in line with other app research [43]. However, it has to be considered that when using the app within clinical populations, there may be contraindications (eg, treatment-related side effects) that prohibit users from engaging with the app, or some of its features, for a period of time. When programming the app to provide challenges and rewards, such as continuous usage streaks or increases in exercise prescriptions, it is crucial to also incorporate rewards for the performance of tasks achievable by all users. Additionally, if participation is affected by a reason outside of the users' control (eg, treatment), they should not be negatively affected (eg, losing a daily streak or points). The approach of personalized gamification has been highlighted by Mahmoudi et al [44], with the addition of customization, where users can select elements they wish to use. Customization of the app interface and avatar was a frequent suggestion within this study. Avatar-based interventions, and specifically customizable avatars, have been shown to promote health-related behavior change, including exercise [45]. Within the motivational affordance taxonomy, there is no clearly defined mechanism dedicated to "customization" [24]. While customization as a reward or as a transactional element involving earned coins may be conceptually aligned with the motivational affordances design features of credits or achievements, there is no explicit mechanism pointing toward users customizing features (eg, interface or avatar) without first fulfilling certain criteria or earning that capability. While customization may be a popular demand, future research should explore whether being able to personalize apps is motivating in itself or whether the motivation is attached to the act of "earning" the reward in order to do so.

Social Support

The results showed that having a social support feature, such as being able to exercise with family members or friends, may be beneficial for app engagement and links well to friends, teams, and group mechanisms within the taxonomy of motivational affordances [24].

Family apps have been seen to have promising effects on physical activity levels and psychosocial outcomes by promoting child-parent exercise [46]. Including social features in exercise apps for children with cancer may enhance engagement and motivation. One study [47] found that physical and social activities merged when ambassadors (ie, peers or siblings) participated alongside survivors of childhood cancer, supporting enjoyment and adherence. Integrating peer interactions into digital platforms could replicate these benefits, promoting physical activity and well-being. While the current app does not have this feature due to the restrictions of data protection and safety, this concept may be of interest when considering the isolation and reduced opportunities for social interaction often experienced by children with cancer [48].

Interestingly, 1 participant revealed a different perspective and highlighted that the app could be a useful tool for those who do not have family members or friends who exercise. It was

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mentioned that the AR avatar could serve as a form of "digital friend" who could positively influence exercise participation, which was in line with findings from a study conducted by Thorsteinsson et al [47]. There is some initial research on a sense of belonging and digital support received from apps that can positively influence physical activity levels [49]; however, the findings of this study underline the importance of exploring this concept more comprehensively.

Accessibility

The results highlight a need to enhance accessibility within mHealth applications, particularly through the extension of existing motivational affordance mechanisms, such as assignments, to better accommodate diverse user needs and promote inclusive design. For instance, the inclusion of a text-to-speech function was recommended, which would provide meaningful support for users with reading difficulties or visual impairments. This recommendation aligns with existing research emphasizing the importance of designing inclusive digital experiences [50]. The evidence highlights the importance of accessibility features, such as voice control, voice over, color contrast, and easy access controls, to ensure apps are usable for individuals with disabilities [50]. These features are particularly relevant in physical activity apps, where ease of use and clear instructions are essential for safe engagement. For example, individuals with visual impairments may rely on voice commands and audio feedback to navigate exercise programs, while those with motor disabilities may benefit from customizable controls that allow for seamless interaction. Therefore, app developers should consider the inclusion of such features to ensure inclusivity and enhance user satisfaction across diverse populations.

Data Safety

Results highlight concerns regarding the appropriateness of the app collecting and potentially sharing personal data (eg, age). It is important to recognize that the use of an app that requires any user input should be accompanied by relevant training and information for users. It is expected that, by providing extensive information to users and their parents or guardians, concerns may be mitigated effectively, with users satisfied and subsequently willing to provide accurate information. It has been widely acknowledged that the increased volume of data available through the use of mHealth tools, such as apps, can indeed be used to provide better services if current data protection and sharing regulations are adhered to [22]. Looking ahead, due to the frequent multicomponent treatment approach for children and young people with cancer, it would be crucial to explore how user data within apps (eg, rate of perceived exertion and exercise duration and intensity) can be integrated within digital health records for a more comprehensive treatment approach. As part of such evaluations, specific mHealth reporting and assessment guidelines, such as the mHealth Evidence Reporting and Assessment checklist, should be used [51].

Strengths and Limitations

This study provides a rich and in-depth understanding of user experiences when using the app, allowing researchers to study potential unexpected patterns in how users interact with the different app features. Mapping results with motivational affordances allows for a better understanding of certain features that might be more motivating and support app engagement within this population. Our findings can inform the development of effective mHealth tools that support behavior change in the field of exercise and physical activity as well as guide future interventions, including more personalized, user-centered approaches to digital health technology.

Despite our study's strengths, it is important to acknowledge limitations. First, this study recruited healthy participants. While some perceptions of the app's functionality are expected to be comparable between patients with cancer and healthy age-matched peers, there may be differences in the usability of the app between these 2 populations. Some pediatric patients with cancer may have a unique motivation with regards to exercise and physical activity, as well as different physical and cognitive needs and preferences; user experiences of some features could differ. Currently, the AR app is at technology readiness level 5. Future studies with the intended clinical population would progress the app to technology readiness level 6.

Second, the study targeted a broad age range (8 - 21 y), while the app itself remained largely static across all ages. While differences in cognitive ability, physical capability, accessibility, and design preferences may mean that some features are less engaging for certain age groups, given the lack of existing AR apps for this population. This approach is also pragmatic, considering the high costs associated with technology development, allowing initial feedback to inform improvements before investing in age-specific customizations.

Third, this study focused on short-term app interaction. Given that the app is designed to support exercise prescriptions over several weeks, the brief duration prevented the assessment of features influencing longer-term adherence. Although the controlled setting allowed for the collection of immediate feedback, it did not capture the evolving experiences users may have during extended use. Future studies should incorporate longitudinal testing to better understand long-term engagement and identify which features support ongoing use.

Finally, there was also the potential of researcher bias in the study, as the investigators had a background in sport and exercise science, which may have influenced how data were interpreted or which themes were prioritized.

Despite these limitations, the study provides valuable foundational evidence to guide improvements to the app and inform future research on implementing mHealth tools within pediatric exercise interventions.

Conclusion

Theory-driven evidence for best practice on mHealth apps is often inconsistent or not focused on the overall user experience. This study explored young people's experiences of an AR exercise app and mapped suggested improvements onto the motivational affordance mechanisms and design elements. Users identified several ways the app could be strengthened, including the addition of educational content, challenges and rewards, a

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customizable avatar, and social features that enable exercising with family or friends. Suggestions also highlighted the need for greater inclusivity through features, such as audio instructions, and clear safeguards around the security of personal data. Mapping these recommendations onto the motivational affordance taxonomy revealed alignment with mechanisms, such as assignments, achievements, friends, groups, and credits, underscoring the diversity of motivational pathways that can support engagement. Further research directly involving children and young people with a childhood cancer diagnosis is planned to further explore the preferences of those facing unique barriers to physical activity and exercise. Such work will also be crucial for advancing the technology readiness level of the intervention by testing the app with the intended population in real-world settings.

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Data Availability

The data will be available from the corresponding author upon reasonable request.

Authors' Contributions

Conceptualization: HM, KS, SW, MAN, ED, JF, PW
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Investigation: HM, KS, ASS, SW, PW
Methodology: HM, KS, ASS, SW, MAN, ED, EW, JF, PW
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Supervision: EW, PW
Writing – original draft: HM, KS, ASS, EW, PW
Writing – review and editing: HM, KS, ASS, SW, MAN, ED, JF, EW, PW
Co-first authors – HM, KS

Conflicts of Interest

None declared.

Checklist 1
COREQ checklist.
[DOCX File, 3768 KB - formative_v10i1e76855_app1.docx]

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Abbreviations

AR: augmented reality
COREQ: Consolidated Criteria for Reporting Qualitative Research
mHealth : mobile health
UG: undergraduate

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Global Mapping of Telemedicine Regulation and Ethical Safeguards: Mixed Methods Exploratory Document Analysis

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Abstract

Background: Telemedicine has become central to digital health strategies, yet the regulatory environment that shapes ethical safeguards and equitable access remains uneven and incompletely assessed across countries. Legal and normative instruments matter because they define requirements for privacy, consent, accountability, professional readiness, and barrier reduction.

Objective: This study aimed to map the current global landscape of normative instruments related to telemedicine and identify which ethical and social safeguards are explicitly addressed, with particular attention to equity.

Methods: We conducted a document analysis guided by the READ (ready the materials, extract data, analyze data, and distill findings) framework. From February 2024 to February 2026, we conducted a structured web-based search across all World Health Organization (WHO) member states with no language restrictions, using official government sources, statutory professional regulators, and institutional publication channels. Retrieval combined internal site searches, direct navigation, external search engine queries, and targeted snowball sampling to identify currently in-force instruments. Two researchers independently extracted and coded data using a predefined codebook. We operationalized 10 binary items covering regulatory presence and scope (questions 1 and 2), safeguards for data protection (question 3), consent and disclosure (questions 4 and 5), prior in-person prerequisites (question 6), monitoring (question 7), training requirements (question 8), and equity (questions 9 and 10). We summarized frequencies overall and stratified by WHO region and World Bank income group and conducted a qualitative thematic analysis of included normative instruments.

Results: Of the 194 WHO member states, 81 (41.8%) had at least one current normative instrument related to telemedicine in force. Among these, 72.8% (59/81) defined telemedicine or telehealth. Data protection provisions were most common (73/81, 90.1%), followed by mandatory informed consent (n=71, 87.7%) and monitoring mechanisms (n=65, 80.2%). Fewer countries required disclosure of telemedicine limitations (n=36, 44.4%) or mandated telemedicine-specific training (n=26, 32.1%). Prior in-person consultation requirements were uncommon (n=8, 9.9%). Equity-related safeguards were uneven: 51.9% (n=42) referenced justice, equity, or nondiscrimination, whereas 30.9% (n=25) included concrete barrier reduction provisions (eg, digital inclusion or accommodations for people with disabilities and minors).

Conclusions: Telemedicine regulation is becoming more common, but both coverage and safeguarding content remain uneven. While privacy, consent, and monitoring are frequently addressed where regulation exists, disclosure, physician competency, and operational equity measures are less consistently specified. Strengthening telemedicine governance will require translating ethical commitments into enforceable standards that address digital determinants of access and protect groups at risk of exclusion.

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KEYWORDS

telemedicine; health equity; digital health; informed consent; privacy; bioethics

Introduction

Telemedicine is part of the World Health Organization's (WHO) global strategy on digital health for 2020 to 2025, which aims to improve access to health services [1] and achieve the goal of universal health care [2]. The expansion of telemedicine after the COVID-19 pandemic was not accompanied by universal health coverage, which stagnated between 2019 and 2021 [3].

One criterion for measuring telemedicine progress is the assessment of established legal frameworks [4]. Notably, the legal context for telemedicine activities has not been sufficiently assessed [5]. Previously, a 2016 WHO report stated that 67% of countries had no legislation or policy to define jurisdiction

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over eHealth actions [2]. Conceptually, telemedicine is commonly situated within telehealth, which, in turn, is part of broader digital health or eHealth. However, both scholarship and policy documents acknowledge that these labels are inconsistently used across settings, with eHealth often treated as an umbrella term that includes telehealth and telemedicine, among other subdomains [6]. In addition, definitions vary widely, with over 100 definitions recognized in the literature [7]. For the purposes of this study, "telemedicine" refers to the provision of clinical care or clinical support at a distance using information and communications technologies [4,8]. To maximize cross-country comparability when legal instruments used different labels, we treated "telemedicine" and "telehealth" as interchangeable terms for remote clinical care mediated by information and communications technologies.

Regulation is especially relevant because telemedicine depends on governance arrangements that define safeguards for privacy, consent, accountability, and equitable access. Recent work emphasizes that data governance regulations have often lagged digital health innovation and that many low- and middle-income countries (LMICs) lack digital data governance strategies [9]. This gap can undermine patient trust as concerns about privacy, security, and downstream uses of data may reduce willingness to share data and mishandling or reidentification can lead to stigmatizing harms in low-resource settings [9].

When dividing countries by income group, the statistics show a clear difference: 55% of the high-income group vs 5% of the low-income group report having defined policies or legislation addressing eHealth [2]. This characterization by income group is essential because the adoption of telemedicine services aims to improve health outcomes for the most disadvantaged populations, particularly in LMICs [10]. At the same time, evidence syntheses focused on low- and lower-middle–income contexts describe persistent constraints related to weak governance and the lack of legal and policy frameworks, as well as the role of poor or vague eHealth strategies as barriers to sustainable implementation [6].

Therefore, this study addressed the following research question: what is the current state of telemedicine legislation worldwide? Our study aimed to provide a global overview of the existing legal frameworks regarding telemedicine and identify the ethical and social concerns associated with implementing and practicing telemedicine within current norms, particularly in terms of equity.

Methods

Overview

We conducted a document analysis and followed the READ framework, which includes 4 steps: ready the materials, extract data, analyze data, and distill findings [11]. The unit of analysis was the country. Our objective was to map, for each WHO member state, whether any current telemedicine-related normative instrument existed and which ethical safeguards were explicitly addressed in those instruments.

Search Strategy and Data Sources

We performed a structured web-based document search from February 2024 to February 2026 with no language restrictions. Documents in English, Portuguese, Spanish, French, and Italian were reviewed in the original language. For other languages, machine translation (Google Translate) was used to translate documents into English for eligibility assessment and data extraction. For each WHO member state, we searched telemedicine-related normative instruments through three complementary routes: (1) official government sources, prioritizing ministries of health and other health authorities, national gazettes, and legislative repositories; (2) professional regulatory bodies such as medical councils or boards for binding rules, codes, or official guidance regulating telemedicine practice; and (3) institutional publication channels that compile or discuss telemedicine regulation, including reports from the WHO, International Bar Association [12], Inter-American Development Bank (IDB) [8], and the Organisation for Economic Co-operation and Development [13].

Core search terms included "telemedicine," "digital health," and "e-health" adapted to each jurisdiction's terminology. We also captured "telehealth" when it appeared in the title, text, indexing, or cross-referenced materials of retrieved instruments and in jurisdictions where "telehealth" was the locally preferred term. However, "telehealth" was not used as a uniform stand-alone core search term across all country searches. Retrieval used internal website search tools when available, direct navigation to legislation or regulation sections, and external search engine queries combining the country name and/or issuing authority with the core terms to identify documents not easily retrievable through site navigation. We also used targeted snowball sampling by following references within retrieved documents (eg, amendments, implementing decrees, and cross-referenced policies) to identify the most current and authoritative versions. Our primary focus was on national-level instruments applicable to clinical telemedicine practice; when subnational instruments (as in federations where regulation is enacted at the state or provincial level) were encountered, they were recorded but not used to define the presence of country-level regulation unless they were from the highest applicable authority in that jurisdiction.

Eligibility Criteria and Exclusions

We included normative instruments that (1) were issued by a government authority or a statutory regulatory body (including medical councils or boards), (2) explicitly addressed the provision of telemedicine or telehealth, and (3) were current and in force at the time of extraction. We considered regulation primarily as "a rule or order issued by an executive authority or regulatory agency of a government and having the force of law" [14]. However, we also included binding rules, codes, or official guidance issued by governments or medical boards when they contained normative requirements for telemedicine practice. We excluded nonofficial commentary; media reports; secondary analyses; documents that were not current or authoritative; and instruments that were explicitly labeled as drafts or in a planning phase, including proposed bills and planning stage strategies. When multiple versions existed, we

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retained the most recent version in force and documented the substituted instruments as background.

Constructing the Global Overview

We produced a global overview covering WHO member states and WHO regions classified by income level according to the World Bank [15]. WHO membership includes 194 countries divided into 6 regions. World Bank income groups are stratified as high income, upper-middle income, lower-middle income, and low income, with 1 country, Venezuela, listed as unclassified in the 2024 list. Niue and the Cook Islands are WHO member countries not included in the World Bank classification. For country-level mapping, the presence of any eligible in-force telemedicine-related instrument was coded as "regulatory mechanism present." The absence of an identified eligible document was recorded as "no instrument identified," which should not be interpreted as evidence that telemedicine activities do not occur in that setting.

Data Extraction and Development of Extraction Questions

In step 2 of the READ approach, we extracted data into spreadsheets organized by WHO region. Telemedicine was selected as the analytic focus because the extraction domains were anchored in the IDB framework for telemedicine regulation [8], which provides a structured, previously developed set of regulatory dimensions that can be operationalized consistently across countries.

The set of questions (Textbox 1) was defined by mapping the IDB framework maturity model [8] domains across their 7 questionnaires and adapting it to 2 analytic aims: first, to capture the presence and basic scope of telemedicine regulation (questions 1 and 2) and, second, to capture core ethical safeguards commonly addressed in telemedicine governance, including privacy and data protection (question 3) when present within telemedicine-related instruments (or when those instruments explicitly incorporated general privacy rules); informed consent and disclosure of the limits of telemedicine (questions 4 and 5); and an ethically dual-use prerequisite with implications for both continuity and access (question 6), that is, whether norms mandate a prior in-person consultation before telemedicine is permitted, as well as monitoring mechanisms (question 7) and professional competence requirements (question 8). Equity was treated as a core safeguard domain operationalized through 2 complementary items: question 9 captured whether norms explicitly referenced justice, equity, or nondiscrimination as a guiding principle, and question 10 captured whether norms included concrete barrier reduction provisions such as digital inclusion measures, accessibility accommodations for persons with disabilities, or specific safeguards for minors. Each question was operationalized as a binary variable with predefined criteria for what constituted an explicit normative statement. Full operational definitions and decision rules are provided in Multimedia Appendix 1. We piloted the extraction form on a purposive subset of countries across different WHO regions and income levels to refine definitions, clarify ambiguous items, and harmonize coding decisions before full extraction.

Textbox 1. Data extraction questions.

- Question 1: are there regulatory aspects in telemedicine?
- Question 2: do the norms define telemedicine?
- Question 3: are there concerns about the protection of personal data?
- Question 4: is informed consent mandatory?
- Question 5: do the norms require that patients be provided with information about the limits of telemedicine?
- Question 6: do the norms require prior in-person consultation?
- Question 7: is there a monitoring mechanism in place?
- Question 8: is it necessary to have any training in telemedicine to provide care in this modality?
- Question 9: do the norms mention the principle of justice in any way?
- Question 10: is there a guarantee for reducing access barriers (digital inclusion or accommodations for minors and people with disabilities)?

For each country, we downloaded all documents included in the study, and for each of the 10 questions, responses were coded as binary ("yes" or "no") and recorded in a Microsoft Excel spreadsheet available in the Figshare repository (Digital Science; see the Data Availability section). "Yes" required an explicit normative statement addressing the item. In instances in which a country possessed multiple eligible instruments, the item was designated as "yes" if any currently in-force instrument explicitly included a provision addressing the item. Ambiguous cases were deliberated and resolved through consensus.

Data Quality Assurance

All eligible documents were independently reviewed and coded by 2 researchers using the predefined codebook. For countries with multiple eligible instruments, coding decisions were based on review of all in-force documents identified for that jurisdiction. Discrepancies were resolved in consensus meetings with reference to the underlying document text and the operational definitions in the codebook. We also conducted peer debriefing to review the coherence of country-level coding and the interpretation of cross-country patterns.

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Quantitative and Qualitative Analysis

In step 3 of the READ approach, we analyzed data quantitatively using descriptive statistics. We calculated counts and proportions of countries meeting each item in Textbox 1 overall and stratified by WHO region and World Bank income group.

In parallel, we conducted a qualitative contextual review of the extracted text excerpts and relevant sections of the normative instruments. All eligible in-force instruments identified in countries with a regulatory mechanism present were included in this qualitative review. We read the full text of each included document and extracted passages relevant to the analytic domains. Qualitative analysis was primarily deductive, using the extraction domains to organize and compare material across jurisdictions. We then conducted a secondary interpretive pass to identify recurring regulatory framings, omissions, and equity-related concerns that were not fully captured by the binary items. These observations were discussed within the team and used to contextualize the quantitative patterns, with particular attention to ethical and social implications and equity-related safeguards. In step 4 of the READ approach, we distilled findings by integrating quantitative results and qualitative observations into a narrative synthesis of global regulatory coverage and gaps.

Ethical Considerations

Although this study did not constitute human subject research because it was limited to document analysis of publicly available sources, it was submitted to the Ethics Committee of the Faculty of Medicine of the University of Porto for confirmation and received administrative approval under the number 115/CEFMUP/2023. Informed consent was not applicable.

Results

Regulatory Concentration and Basic Scope (Questions 1 and 2)

Across the 194 WHO member states, 81 (41.8%) countries had at least one current telemedicine normative instrument in force (question 1). Of these 81 countries, 59 (72.8%) included an explicit definition of telemedicine or telehealth in the regulatory text (question 2). Table 1 provides a condensed overview of all items; fully stratified results for each question are provided in Multimedia Appendix 2.

Table . Condensed overview of telemedicine regulatory coverage and safeguards.

Domain and measure	Countries, n/N (%)
Regulatory presence and scope	
Any current in-force telemedicine-related normative instrument (question 1)	81/194 (41.8)
Explicit definition of telemedicine or telehealth (question 2)	59/81 (72.8)
Data protection	
Privacy or data protection provision (question 3)	73/81 (90.1)
Consent and disclosure	
Mandatory informed consent (question 4)	71/81 (87.7)
Disclosure of telemedicine limitations (question 5)	36/81 (44.4)
Access conditions	
Prior in-person consultation required (question 6)	8/81 (9.9)
Oversight	
Monitoring or oversight mechanism (question 7)	65/81 (80.2)
Professional readiness	
Telemedicine-specific training requirement (question 8)	26/81 (32.1)
Equity principles	
Justice, equity, or nondiscrimination referenced (question 9)	42/81 (51.9)
Barrier reduction	
Provision to reduce access barriers (question 10)	25/81 (30.9)

Data Protection (Question 3)

Protection of personal data was the most frequently addressed safeguard. Data protection or privacy-related provisions were identified in 90.1% (73/81) of the countries.

Informed Consent and Disclosure of the Limits of Telemedicine (Questions 4 and 5)

Mandatory informed consent for telemedicine was required in 87.7% (71/81) of the countries (question 4). In contrast, fewer than half (36/81, 44.4%) required that patients be informed about the limitations of telemedicine (question 5).

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Prior In-Person Consultation (Question 6)

Only 9.9% (8/81) of the countries mandated a prior in-person consultation before telemedicine was permitted.

Monitoring and Professional Competence Requirements (Questions 7 and 8)

Monitoring or oversight mechanisms relevant to telemedicine were present in 80.2% (65/81) of the countries (question 7). Specific telemedicine training requirements for providers were less common, appearing in 32.1% (26/81) of the countries (question 8).

Equity-Related Safeguards (Questions 9 and 10)

Equity was unevenly addressed. In total, 51.9% (42/81) of the countries referenced justice, equity, or nondiscrimination as a guiding principle within telemedicine norms (question 9). However, only 30.9% (25/81) of the countries included explicit provisions for reducing barriers, such as digital inclusion measures or accommodations for people with disabilities and minors (question 10).

Discussion

Despite the global increase in telemedicine regulations, a significant regulatory divide persists. High-income regions have established robust norms, whereas low-income countries lack specific frameworks, particularly for data protection, informed consent, professional accountability, and equity.

Regulatory Concentration and Global Inequity

Telemedicine regulation remains unevenly distributed worldwide, with substantial variation across regions and income groups. In our updated mapping, 81 countries had identifiable telemedicine regulations.

Compared with earlier WHO survey findings on telemedicine and eHealth [2], which reported that 33% of countries had some form of norms in this area, our mapping identified in-force telemedicine instruments in 41.8% (81/194) of WHO member states. Because the WHO survey relied on self-reported responses and used broader eHealth categories, these estimates are not directly comparable; however, the difference suggests that formal regulatory instruments are now identified in a larger share of countries than previously reported.

A central ethical implication is that the presence of telemedicine norms does not necessarily translate into improving access to health care [5]. When legal standards are absent, incomplete, or poorly specified, key ethical and equity-oriented safeguards become fragmented and are often delegated to institutional policies, private platforms, or professional discretion [16-18]. This governance structure can distribute protections and accountability unevenly across settings.

These dynamics matter because telemedicine is frequently promoted as a tool to expand access and advance universal health coverage [1-3,10]. It tends to benefit populations with greater connectivity, health literacy, and institutional coverage while leaving socioeconomically vulnerable groups with fewer protections and fewer pathways for redress when harm occurs [19-21].

If regulation is developed primarily in areas with already strong health care access, telemedicine may disproportionately benefit populations with greater connectivity, literacy, and institutional coverage unless safeguards for equity are operationalized [1-3,10]. Regulation, in this sense, becomes part of the distributive architecture of health systems, shaping who receives protection, under what standards, and with which mechanisms of accountability.

Data Protection and the Commodification of Health Data

The findings show that data protection was widely recognized in telemedicine norms, with most regulated countries addressing privacy and confidentiality. This is ethically significant because telemedicine intensifies data flows across platforms, providers, and institutions, increasing the risks of unauthorized access, secondary use, and informational harms [18,19,22,23]. In many jurisdictions, data protection requirements may be anchored in general frameworks such as the General Data Protection Regulation [24] or HIPAA (Health Insurance Portability and Accountability Act) [25], but the operational implications for telemedicine still depend on how specific telemedicine rules define responsibilities, data governance, and accountability mechanisms [18].

The Americas and Europe still lead in privacy protection, as the 2016 WHO report [2] indicates, which aligns with our findings. Despite 90.1% (73/81) of the countries demonstrating concern about data protection in their norms, only 3.7% (3/81) were low-income countries. However, privacy provisions by themselves do not ensure equity. As health data are increasingly treated as a commodity, governance structures must address power asymmetries in data collection and use [18].

A privacy clause can coexist with limited patient understanding, weak enforcement capacity, and platform-driven practices that disproportionately burden low-resource settings [18,19,22,23]. For regulations oriented toward equity, privacy protections should be paired with clear obligations regarding transparency, security standards, data sharing, and remedies for misuse, particularly when patients have limited bargaining power and few alternatives.

Informed Consent, Disclosure, and Telemedicine-Specific Understanding

A substantial proportion of telemedicine frameworks (71/81, 87.7%) required informed consent, indicating broad recognition that remote care entails clinical and informational risks [18,19,22,23]. However, consent requirements are ethically robust only when they are paired with adequate disclosure of telemedicine limitations. Among the 71 countries with consent requirements, 60.6% (43/71) were in Europe and the Americas versus 39.4% (28/71) elsewhere, and 95.8% (68/71) were in higher-income settings versus 4.2% (3/71) in low-income settings.

Although consent was highly valued in the norms, the obligation to address modality-specific constraints was not explicit, so it risks becoming a procedural formality rather than a meaningful safeguard [19,22]. Specific telemedicine consent should communicate what can and cannot be safely managed remotely;

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when escalation to in-person care is required; and how patient data are stored, shared, and protected [19,26].

Disclosure obligations are also equity relevant. Individuals may consent without meaningful alternatives, adequate understanding of technical limitations, or the connectivity needed to use telemedicine effectively [19,21-23]. When telemedicine is adopted as the default pathway, the ethical risk is a 2-tiered standard of explanation and care in which disadvantaged populations receive weaker disclosure and weaker protection [18]. Therefore, strengthening telemedicine-specific disclosure can protect autonomy while also reducing preventable harm among populations with lower health and digital literacy.

Prior In-Person Consultation and the Balancing of Equity

Requirements for prior in-person consultation illustrate how regulation can create equity concerns. While an initial face-to-face encounter may strengthen clinical accuracy and the therapeutic relationship [18,27], mandating in-person contact before telemedicine can create barriers for geographically isolated or economically constrained populations and may worsen inequities [28]. Although only 9.9% (8/81) of the norms mandated prior in-person consultation, 5 of those were from LMICs, which often face practical and clinical barriers.

A more equity-sensitive approach is to define clinical and risk-based criteria for when in-person evaluation is necessary while preserving patient choice and ensuring safe escalation pathways [28]. Such criteria-based regulation can support safety without embedding avoidable access barriers into law. It also aligns legal requirements with clinical realities, recognizing that appropriate use varies by condition, setting, and patient needs.

Monitoring and Professional Competence

As telemedicine expands, regulatory attention often turns to oversight and fraud prevention [29,30]. Monitoring mechanisms were present in 80.2% (65/81) of the identified frameworks, although oversight criteria were often described in broad terms [29,31]. Europe and the Americas accounted for 48.1% (39/81) of the countries with a monitoring mechanism in place, whereas only 3.7% (3/81) of low-income countries had one. There is consensus that monitoring can deter malpractice and protect populations, but given ongoing debates about telehealth fraud, oversight should be transparent and proportionate [29,31].

In parallel, training requirements are an important marker of professional readiness. Remote care requires specific competencies in communication, risk triage, documentation, privacy practices, and clinical escalation [5,7,22,32,33]. Among the analyzed norms, 67.9% (55/81) did not require any telemedicine training regardless of country region. All low-income countries in the sample fell within this “no training requirement” group. Where training is not expected, practice may become more variable, and clinicians may compensate for uncertainty through overtesting or overprescribing, increasing costs and potentially undermining quality [7,32,33]. Therefore, training standards can operate as both quality and equity safeguards by reducing avoidable variation across providers and settings and by supporting safer telemedicine use where specialist support is limited.

Since the WHO first documented it, there has been concern about the need for robust governance in the monitoring and evaluation of telemedicine, transforming the digital encounter from a private transaction into a transparent, auditable clinical act that protects both patient safety and the physician’s professional integrity [2,4].

From “Equity Language” to Enforceable Duties

The global overview indicated that justice is increasingly referenced in telemedicine norms (42/81, 51.9%). However, ethical language does not automatically translate into enforceable protections [19-21,34,35]. This gap matters because many determinants of effective telemedicine use are not clinical. They are conversion factors and digital determinants of health that ascertain whether formal availability translates into genuine access. This includes aspects such as connectivity, affordability, literacy, accessible design, language support, disability accommodations, and social protection [19,21,34,36]. The capabilities approach by Sen [37] helps clarify why access to technology alone does not guarantee substantive freedom to obtain care, particularly for disadvantaged groups whose autonomy and dignity are constrained.

In LMICs, socioeconomic conditions pose challenges to implementing telemedicine, and existing norms often fail to operationalize equitable access. Among the norms studied, justice was cited in only 2.4% (1/42) of those from low-income countries compared with 40.5% (17/42) of those from high-income countries. Higher-income patients often use telemedicine more than underserved populations [27], raising ethical concerns about prioritizing coverage for advantaged groups.

The presence of barrier reduction guarantees in a meaningful share of countries (25/81, 30.9%) is an important advance, but it also highlights whether equity is treated as an aspirational principle or as a compliance requirement [19-21,34,35]. Without enforceable duties, telemedicine may expand primarily among those already digitally connected, which conflicts with the “leave no one behind” principle [35].

This also creates a risk of equity washing; references to justice that are not linked to enforceable obligations can remain rhetorical rather than protective [38]. Through a capabilities and digital determinant lens, equity-oriented regulation requires duties that translate equity-relevant conversion factors into minimum standards and accountability expectations rather than relying solely on general commitments to justice [19-21,34].

Limitations and Implications

This study has limitations inherent to global document analysis. First, it depends on the availability and retrievability of official documents through web-based sources and may underrepresent jurisdictions where relevant norms exist but are not publicly accessible online. Second, written legal and regulatory texts do not necessarily reflect implementation, enforcement capacity, resource constraints, or routine practice. Third, definitional heterogeneity persists across jurisdictions; although we used an

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inclusive approach and triangulated sources, variation in what counts as "telemedicine regulation" remains. Fourth, our search strategy was adapted to each jurisdiction and captured "telehealth"-labeled instruments when identified through local terminology, indexing, or cross-references, but "telehealth" was not used as a uniform stand-alone core search term across all country searches. Accordingly, some instruments indexed exclusively under telehealth may have been missed. Fifth, our corpus focused on formal normative instruments (eg, laws, regulations, codes, and official guidance) and did not systematically include other sources that may shape governance in practice, such as case law, litigation trends, administrative decisions, contractual arrangements, or platform-level rules.

These limitations are important for interpreting the findings. The results are best understood as a map of the documented normative landscape rather than a direct measure of implementation or regulatory effectiveness. Future research should examine how regulatory provisions are implemented and enforced and whether they are associated with reduced barriers in practice. Additional work is also needed on how jurisdictions allocate rights and responsibilities over data generated through telemedicine, including data subject rights, secondary uses, and cross-border data transfers. Consumer-facing digital health use (eg, online health information seeking and conversational artificial intelligence tools) was outside the scope of this study and warrants separate analysis because it raises distinct regulatory questions.

Conclusions

Telemedicine regulation is present in a substantial share of WHO member states. However, significant gaps remain across countries in both coverage and content. Our mapping shows that telemedicine normative instruments are concentrated in higher-income settings and that key safeguards are implemented unevenly across jurisdictions, including data protection, informed consent, disclosure of telemedicine limitations, oversight mechanisms, provider competence requirements, and measures intended to reduce access barriers. These findings mainly impact governance. Legal texts indicate formal regulatory priorities but do not capture implementation, enforcement capacity, or outcomes. Nevertheless, identifying which safeguards are consistently addressed and which are frequently absent helps clarify where minimum protections are likely weak and where equity provisions remain underdeveloped. Future research should extend beyond cataloging laws to assess implementation and structural effectiveness, including whether regulatory choices translate into accountability, patient protection, and more equitable access in practice.

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Data Availability

The datasets generated or analyzed during this study are available in the Figshare repository [39].

Authors' Contributions

Conceptualization: RG
Data curation: RG, CASdS
Methodology: RG
Project administration: RG
Supervision: CASdS, ID, RN
Visualization: ID
Writing—original draft: RG
Writing—review and editing: CASdS, RN

Conflicts of Interest

None declared.

Multimedia Appendix 1
Codebook for telemedicine regulation mapping.
[PDF File, 95 KB - formative_v10i1e86613_app1.pdf]

Multimedia Appendix 2

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Stratified results and graphs.
[PDF File, 169 KB - formative_v10i1e86613_app2.pdf]

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Abbreviations

HIPAA: Health Insurance Portability and Accountability Act
IDB: Inter-American Development Bank
LMIC: low- and middle-income country
WHO: World Health Organization

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Access to Technology-Mediated Community Mental Health Care Among Low-Socioeconomic Status Consumers With Serious Mental Illness: Qualitative Study

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Abstract

Background: Access to mental health care is critical for the effective management of serious mental illness (SMI), but consumers with low socioeconomic status (SES) have lower rates of service usage and worse retention in care. Digital technologies are often lauded as a way to bridge access gaps; however, little is known about how technology-mediated care may influence care access among low-SES consumers and how consumers use technology in care access.

Objective: This study aimed to examine the applicability of Levesque et al's access framework to technology-mediated care for SMI and analyze how low-SES consumers use technology to facilitate care access. Furthermore, the study assesses whether and how technologies are involved in care access at multiple points within the process of accessing care.

Methods: This study used 2 qualitative methods: ethnographic observations at a mental health treatment court and interviews with low-SES consumers with SMI using community mental health care (n=14) and key informant interviews with health and service providers working with this population (n=14). Observations occurred from July 2022 through September 2023, and interviews occurred between January 2022 and May 2024. Data analysis involved both inductive and deductive coding approaches. Data from both the interviews and observations were analyzed in NVivo and further triangulated through analytic memos.

Results: Levesque et al's framework required several extensions to accommodate technology-mediated care related to SMI for low-SES consumers: (1) a cyclical rather than linear trajectory; (2) simultaneous care acquisition from multiple health and service providers; (3) staying in care long-term; (4) identification of both one-time and ongoing health needs; and (5) an emergency pathway for entering care. Consumers often faced challenges related to the varied digital requirements of each provider and a dearth of integrative, patient-facing tools like portals. Within this context, some consumers use mobile apps, communication, and telehealth technologies across various care access stages. Consumers used technology by figuring out how to navigate technology-mediated care, especially by leaning on others, such as case managers, for support. These others provided consumers with temporary technologies, showed them how to use technologies, and accompanied them through the process of using technology for accessing care.

Conclusions: This study highlights that accessing care is iterative and ongoing, involving multiple forms of co-occurring service provision. A theoretical contribution of this work is its extension of Levesque et al's care access framework to better reflect technology-mediated care for SMI among low-SES consumers. This work also underscores ongoing challenges for accessing technology-mediated care and the importance of human support in addressing access difficulties. Clinical implications include incorporating digital readiness assessments and providing comprehensive guidance on how consumers can effectively use technologies for care. Future work should investigate how technology-mediated care can make care access easier rather than harder.

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KEYWORDS

health care equity; access to care; telehealth; digital health; mental health

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Introduction

Serious mental illness (SMI)—a set of chronic conditions affecting 1 in 25 adults in the United States—significantly impacts individuals' abilities to function in their daily lives [1]. SMI care is truly a matter of life and death, as people with SMI are at an increased risk of suicide [2]. Moreover, people with SMI who are using mental health care have better health outcomes overall [3].

Nevertheless, the rate of mental health care use in people with SMI in the United States is insufficient to adequately manage their mental health [4]. Indeed, fewer than two-thirds of adults with SMI (henceforth, "consumers") in the United States received mental health treatment in the past year [5]. Moreover, a lack of retention in mental health care is common: up to one-third of those who have some contact with mental health services disengage from care [6]. For our purposes, nonretention in care is defined as disengaging from treatment without symptom improvement or not completing treatment for the recommended duration [7].

Care usage and retention among consumers are also differential; those with low socioeconomic status (SES)—"the socially derived economic factors that influence what positions individuals or groups hold within the multiple-stratified structure of a society" [8]—have the lowest mental health care usage rates [9]. Furthermore, consumers with low SES have higher rates of care dropout [10]. Barriers to care are also amplified and compounded among consumers with low SES, which impedes care retention [11]. Such barriers include the stress associated with multiple competing obligations, like changing work schedules, transportation precarity, and childcare needs [11]. Consumers who drop out of care are at greater risk of experiencing homelessness, hospitalization, and negative health outcomes such as suicide [3,12].

Furthermore, consumers with low SES who are not in care may have increased interactions with the criminal justice system, resulting in disproportionately high rates of imprisonment [13,14]. Racial discrimination that results in the overrepresentation of African American and Indigenous people in US prisons exacerbates the issue for low-SES consumers with SMI in these minoritized racial and ethnic groups [14,15].

Usage of mental health care first requires access to that care, which we define as "the opportunity to identify healthcare needs, to seek healthcare services, to reach, to obtain or use healthcare services, and to actually have the need for services fulfilled" [16]. Access is at least partly a result of how mental health care systems function, or their "arrangements." Notably, mental health care arrangements for consumers who have low SES often differ from those of their higher SES counterparts. Specifically, care for low-SES consumers is predominantly offered through a public, Medicaid-funded system [17], known as "community mental health care," rather than being funded out-of-pocket or through private health insurance. The American Psychological Association defines community mental health care (CMH) as "providing prevention, treatment, and rehabilitation mental health services, sometimes organized as a practical alternative to the largely custodial care given in mental hospitals" [18].

CMH services are offered through local entities that provide counseling, psychiatric care, and case management, while also facilitating access to critical social services for those with low-SES, such as affordable housing and food purchasing assistance. CMH services can successfully support low-SES consumers with SMI, resulting in greater acceptance of health care, fewer hospital admissions, cost reductions compared with hospital-based outpatient care, and fewer deaths by suicide [19]. CMH also provides specific services to consumers with criminal justice involvement, including re-entry programs for people who are on probation or leaving incarceration. Moreover, and critically for this research, CMH provides health care via specialized courts that divert people with SMI and criminal justice involvement away from prison. Such courts typically require that people with SMI use mental health care as a part of probation conditions, a structured mode of enhancing care access for consumers that provides a rich opportunity for investigating how access to care is accomplished in an increasingly technology-mediated care environment.

Of note, technology is often lauded as a way to enhance access to mental health care [20]. This study defines technology broadly as the "tools, techniques, crafts, systems, or methods of organization, to solve a problem or serve some purpose or end" [21]. While digital technologies are vital to modern care access, the expanded definition allows us to analyze different forms of technology (like pen and paper, physical calendars, calendaring apps, patient portals, etc) to understand their role in care access [21]. Digital health technologies can increase care access by facilitating remote care [22], enabling remote monitoring [23], and improving the referral process [24] while decreasing costs for low-SES consumers. Nevertheless, little is known about how care access processes may change in such an environment, and for low-SES consumers.

In theory, technologies could also facilitate retention in mental health care. Reminders like text messages and automated phone calls, for example, can help people remember scheduled appointments [25]. The use of communication technologies to provide health care remotely, called "telehealth" [26], also improves treatment retention in some, but not all, cases [27-30]. Retention outcomes for telehealth may be enhanced when providers establish care via in-person visits and then transition to telehealth [31]. However, few studies specifically examine care retention in CMH and criminal justice contexts. Moreover, there is a dearth of research characterizing how consumers with low SES use technology to enable access to and retention in mental health care. These issues are critical because low-SES consumers have lower device ownership and face more difficulties with using technologies [32-34].

Thus, this study seeks to understand the theoretical implications of technology-mediated CMH care to better understand its role in the process of accessing care.

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Methods

Overview

The study used two qualitative methods: (1) ethnographic observations and (2) semistructured interviews. Observations occurred at a Mental Health Treatment Court ("the court" or MHTC). The court links consumers with SMI who have experienced recent legal trouble—most of whom have low-SES—to health care specifically for their SMI instead of prison. Interviews were conducted with both low-SES consumers (C) with SMI (n=14) who had some form of prior criminal justice contact and health care and service providers (HSPs) working with this population (n=14) who served as key informants regarding study research questions. The methodologies were reported in accordance with the COREQ (Consolidated Criteria for Reporting Qualitative Research) checklist.

Ethical Considerations

The Institutional Review Board at the University of Michigan reviewed this study and determined that the studies (observations and service provider interview study HUM00205027; consumer interview study HUM00238889) were exempt from ongoing review based on minimal-risk research with adults. To protect confidentiality, participants were assigned a participant code. After reviewing the study information, all consumers and HSP participants provided verbal informed consent to participate in interviews. All HSP participants were offered a US $25 incentive for a 60-minute interview, and consumers a US $40 incentive for a 90-minute interview. This study was executed in accordance with the principles of the Declaration of Helsinki.

Conceptual Model: Access to Health Care

The present research is framed using the influential "Conceptual framework of access to health care" of Levesque et al [16] to conceptually outline the process of accessing mental health care. The general framework of Levesque et al [16], intended to apply across varied clinical contexts, establishes five stages of health care access: (1) perception or identification of health care needs, which is followed by (2) health care seeking, (3) health care reaching, (4) health care usage (primary and secondary access, which vary in type and intensity), and (5) health care consequences (economic, satisfaction, and health). At the same time, organizational and individual factors that enable access precede each access point. In the model, individual consumer characteristics also influence the process of health care access. Hence, this framework centers the process of accessing mental health care, which is well-suited to achieving study objectives. However, to extend the model to reflect the chronicity of SMI, the study includes retention in care as part of the guiding framework.

Beyond this, it is notable that the Levesque et al [16] model is for general health care, not mental health care, nor does it include necessary technological factors. It also does not consider how access to care may differ for those with low-SES. Therefore, by addressing the study's research questions, this study aims to enhance and extend the Levesque et al [16] model to suit empirical data as needed.

Using the Levesque et al [16] framework, with the addition of retention in care as an access stage, this study addresses the following research questions:

- RQ1. What changes, if any, are necessary to improve the applicability of the conceptual framework of access to health care related to SMI for low-SES consumers and technology-mediated care contexts?
- RQ2. How do low-SES consumers use technologies throughout the process of accessing health care related to their SMI?

Research Setting

This research was conducted in one Midwestern state from January 2022 through May 2024, involving ethnographic observations at one court in a Midwestern state. The court is a collaboration of multiple care and service providers that requires that consumers with SMI who participate, most of whom lack employment and have public insurance, stay in health care for their SMI for at least 12 months. Such requirements must be met, or a person with SMI could face incarceration or altered judicial supervision for the offenses that first brought them into contact with the criminal justice system.

Consumers at the MHTC primarily receive mental health care through a local CMH agency with additional support from local nonprofit agencies, but the court monitors their overall progress. MHTC review sessions occur at the court multiple times monthly with multiple staff HSPs from CMH, nonprofit organizations, and criminal justice sectors. Many HSPs interact with consumers remotely between review sessions via email, phone calls, and text messages. HSPs also contribute to regular, in-person court team meetings to monitor and assess participants' progress with health care for their SMI and related social services.

During the early COVID-19 pandemic, MHTC conducted review sessions remotely via videoconference, with in-person meetings resuming in late 2022. Since consumers enrolled in the court typically face multiple challenges in accessing and staying in mental health care, studying this setting offers a valuable opportunity for identifying how technology access may help or hinder access to SMI-related health care and related services among low-SES consumers.

Recruitment and Sampling

While the court review sessions were open to the public, the first author (AKS) secured support from stakeholders before the observational period. The first author was a volunteer with a mental health nonprofit that supported the MHTC participants, so they started discussing the proposed research with the nonprofit board of directors to get their feedback and ensure no conflicts of interest. After multiple discussions, the board of directors communicated its project support. Then, the first author obtained permission from the MHTC judge to observe the court. To do so, the first author presented the judge with the research protocol and Institutional Review Board information and held a web-based meeting to discuss the research aims before the onset of observations. Observations were conducted for the full length of most court review sessions from July 2022 through Sept 2023. AKS recruited HSPs linked to the MHTC via a

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purposive sampling approach to represent different consumer-facing roles [35]. Participants and stakeholders were made aware of AKS's presence as a researcher via an announcement from the judge, in which they described the research goals, interest in conducting said research, and rationale for the observations.

The first author recruited consumers in person at one MHTC (all receiving care through CMH) and consumers receiving CMH care with criminal justice histories through local mental health clubhouses. Starting with a referral-based strategy, a member of a mental health nonprofit provided the initial connection to a clubhouse member, who subsequently connected the first author with the staff leadership of that organization. After the first set of consumers and peer support specialists were interviewed from the clubhouses, the study used chain referral sampling to interview other members across the state.

Clubhouses are intentionally formed as nonclinical spaces for individuals with SMI to build community and support recovery [36]. Clubhouses adopt a psychosocial rehabilitation model prioritizing teamwork and a strengths-based focus for "members." Many clubhouses throughout the state, including the ones from which participants were recruited, require members to be consumers at their local CMH. Notably, some consumers play a dual role as formal peer support specialists. Services such as CMH typically use peer support specialists, and this group often bridges other mental health services, like these mental health clubhouses.

Data Collection

Observations of Court Review Sessions

The first author conducted ethnographic observations during biweekly court review sessions from July 2022 to September 2023, including the transition from video conferences due to the COVID-19 pandemic to in-person sessions. The observations averaged over 1 hour and 40 minutes per session. The lead author observed 23 of the 28 sessions from July 2022 through Sept 2023 (missing 5 sessions for personal or professional reasons). Observations were concluded when data saturation was reached, and no new insights were gleaned from the final 3 observation sessions [37]. AKS recorded jottings and later summarized them in field notes during observations [38]. A review of the field notes was conducted to confirm that no additional novel insights emerged in the final observations.

Observations focused on the technology used in the courtrooms that enabled or created barriers to access. Additionally, special attention was paid to both consumer-facing and provider-facing technologies that impacted each consumer's mental health care access and retention. This included "social services" and "other services" related to mental health recovery, including housing, substance use treatment, food benefits, vocational support, transportation, and educational services [39].

Interviews

AKS conducted semistructured interviews with consumers who were receiving care from CMH and with criminal justice histories (n=14) and health and service providers (HSPs) affiliated with the MHTC (n=14). Prior to conducting the first interview, AKS piloted the interview with a colleague to clarify language and estimate the timing of the interview, with consumer interviews taking 90 minutes and HSP interviews taking 60 minutes. Interviews were conducted using an interview guide. All providers were current or former employees or volunteers who worked with consumers in court. HSP interviews occurred between January 2022 and November 2023, and consumer interviews between October 2023 and May 2024. For all interviews, no one else was present besides the participants and AKS. AKS transcribed the interviews verbatim or summarized the interviews (upon participant request). Interviews for both consumers and providers continued until after the data were saturated and there were no new emergent themes [37]. Subsequently, the final 3 transcripts from both samples (consumers and HSPs) were reviewed to confirm that there were no new emergent findings and that no new inductive themes emerged from the data. No transcripts were returned to participants for comment or correction.

Demographic Surveys

Providers and consumers completed a demographic survey after the interviews, with the option to answer survey questions over the phone. Both groups were asked questions about sex, age, race/ethnicity, and the highest level of education. Consumer surveys also asked about patient health insurance and years of technology use.

Data Analysis

Qualitative Data Analysis

All qualitative coding was conducted using NVivo, and iterative review of the transcripts began when data collection started. The coding mixed deductive and inductive approaches. Deductively, AKS and TCV developed codes based on the Levesque et al [16] model, in which each process-oriented concept in the model became a process code. A round of coding was conducted to group various actions and processes across the Levesque framework, specifically coding interviews and transcripts into the following groups: (1) perception or identification of health care needs, (2) health care seeking, (3) health care reaching, (4) health care usage, and (5) health care consequences. While coding the access stages, AKS identified that "staying in care" was an additional stage not accounted for and subsequently added that code, reviewing all transcripts for this additional inductive code. An associated coding matrix can be found in Multimedia Appendix 1 [16]. Furthermore, inductive coding involved AKS and TCV, both researchers with mixed methods health informatics research experience, independently reading 3 randomly selected consumer interviews, 3 randomly selected provider interviews, and 5 randomly selected field notes to develop emergent codes via process coding [40]. To gain a nuanced understanding, AKS triangulated data across the sets of interviews and ethnographic field notes, applying the same codes to all data sources to enable comparison across sources. AKS subsequently developed analytical memos for individual codes to synthesize emergent results and map the inductive codes to the access model.

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Quantitative Data Analysis

AKS calculated descriptive statistics for demographic variables, including frequencies, means, and SDs.

Results

Participant Characteristics

Most consumers (C) interviewed were White and female (12/14, 85.7%), with a mean age of 51.2 years (Table 1). A total of 12 (85.7%) consumer participants had Medicaid or Medicare for health insurance, and 10 (71.4%) were college-educated. In regard to employment, 6 (42.9%) were working part-time, 3 (21.4%) were unemployed, 3 (21.4%) were beneficiaries of Social Security Disability Insurance, and 2 (14.3%) were employed full-time. These consumers were employed full-time and had private insurance due to their positions as peer support specialists at CMH while also receiving CMH care. One consumer currently participated in an MHTC, and 12 consumer interviewees were mental health clubhouse members. Of the clubhouse members, 2 were both consumers and peer support specialists. The HSP participants were primarily White (12/14, 85.7%) and female (10/14, 71.4%), with a mean age of 57.8 years. Service provider respondents held positions at the court, CMH, and housing agencies.

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Table . Demographics of the interview participants (N=28).

Demographics	Consumers (n=14)	Health care and social service providers (n=14)
Sex, n (%)		
Female	12 (85.7)	10 (71.4)
Male	2 (14.3)	4 (28.6)
Age (years), mean (SD)[a,b]	51.2 (12.2)	57.8 (18.7)
Race/Ethnicity, n (%)[a]		
White	12 (85.7)	12 (85.7)
African American	2 (14.3)	1 (7.1)
American Indian or Alaska Native	1 (7.1)	0 (0)
Hispanic	1 (7.1)	0 (0)
Asian	0 (0)	1 (7.1)
Highest level of education, n (%)[a]		
High school	3 (21.4)	0 (0)
Some college	1 (7.1)	0 (0)
Bachelor degree	3 (21.4)	3 (21.4)
Associate degree	6 (42.9)	0 (0)
Graduate degree	1 (7.1)	6 (42.9)
Professional degree	0 (0)	4 (28.6)
Employment		
Working full time	2 (14.3)[c]	—[d]
Working part time	6 (42.9)	—
Unemployed	3 (21.4)	—
Social Security Disability Insurance	3 (21.4)	—
Insurance[e], n (%)		
Commercial	2 (14.3)[c]	—
Medicare (Dual Eligible for Medicaid)	8 (57.1)	—
Medicare exclusively	1 (7.1)	—
Medicaid exclusively	2 (14.3)	—
Other[f]	1 (7.1)	—
Years of internet use[e], mean (SD)	18.1 (8.3)	—

[a]One service provider did not answer these questions.

[b]Two consumers did not answer this question.

[c]These were employed as peer support specialists at community mental health care (CMH) while also receiving CMH care.

[d]Not applicable.

[e]Only consumers were asked these questions.

[f]One consumer had “health care that you bought on health care insurance marketplace” but did not provide further details.

RQ1. What Changes, If Any, Are Necessary to Improve the Applicability of the Conceptual Framework of Access to Health Care Related to SMI For Low-SES Consumers and Technology-Mediated Care Contexts?

We have identified changes necessary to the Leveque et al [16] model and now discuss each stage within the revised model to reflect the empirical data (Figure 1).

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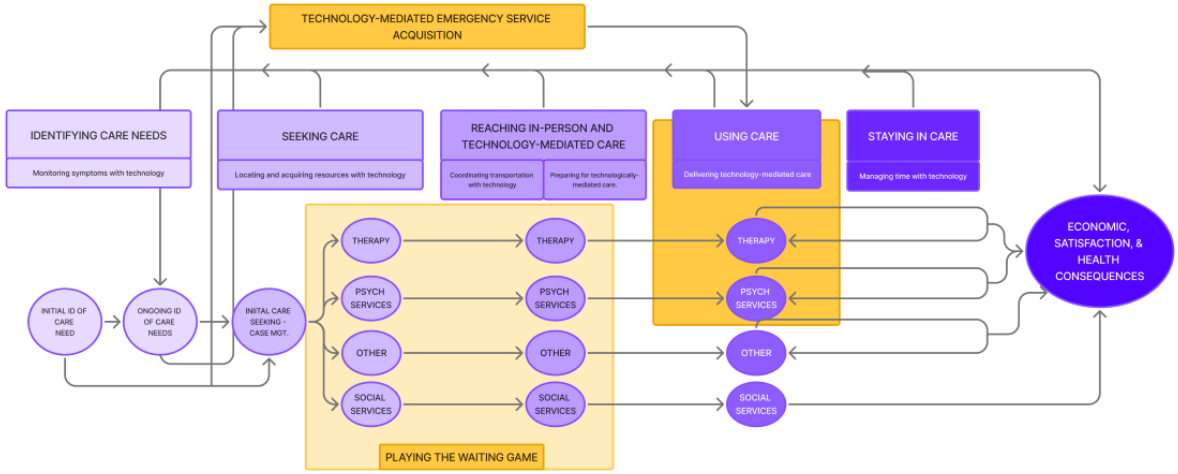
Figure 1. Technologically mediated care access cycle for people with serious mental illness.



Perceptions of Needs and Desire for Care

While the Levesque et al [16] model described the "Perceptions of needs and desire for care," all study participants had already been diagnosed with SMI and were largely using some form of mental health care. Thus, a more apt description of this stage for participants is "Identifying care needs." Additionally, unlike the Levesque et al [16] model, which categorizes identifying care needs as one discrete stage, there were two need identification stages for study participants. The first stage involved the initial identification of care needs, and the second stage involved the ongoing identification of care needs (Figure 1).

Within this sample, the first stage of initial identification of care needs often occurred decades prior, typically in young adulthood. As one consumer (C012) stated, "I've been getting help with mental health since I was younger…I didn't do that on my own." Others initially identified needs because of an acute mental health incident in adulthood. For example, C010 stated that "up until the time I cracked, I never needed any [mental health care]."

Some consumers pursued ongoing identification of care needs to become aware of any new or increased needs (Figure 1). Hence, monitoring symptoms with technology was a key part of this stage. For instance, 2 consumers used smartphone mobile apps and wearables in ways that identified symptom changes. As discussed below, technology-mediated communication with friends and family also served this purpose.

Health Care Seeking

For the "Health care seeking" stage of the Levesque et al [16] model, care seeking is depicted for only one care setting at once. However, low-SES consumers with SMI frequently sought several different sources of care—some of them related to recovery (eg, housing) but not necessarily providing treatment—often simultaneously. Hence, in Figure 1, we have changed this category to "Seeking Care." Specifically, for the population under study, this involved therapy and psychiatric services, as well as "other services" and "social services." Case managers also helped people connect with "other services" based on each consumer's needs, including substance use treatment, food access, educational services, vocational support, group therapies, and assisted living. This could involve legal services such as probation officers or MHTC staff, depending on the situation. For example, one MHTC participant describes:

> *I have a probation officer that really is more of a person that ties the threads between my caseworker [and] my progress in the treatment court. I meet with him every two weeks.* [C001]

The "social services" that consumers with SMI in this sample regularly sought included: (1) housing resources (ie, Section 8 vouchers or low-income housing), (2) health insurance if needed (eg, Medicaid/Medicare), (3) transportation supports (eg, free bus passes, medical transportation services), (4) assistance with job seeking (vocational support), and (5) food benefits. Typically, "other services" and "social services" were offered by CMH partner organizations. After being connected with these services, consumers could navigate them with varied levels of support. C008 uses CMH for therapy, psychiatry, and case management. Beyond that, he describes some of the different services that CMH helped coordinate, like "$300 towards fixing my car," securing a "housing voucher," and obtaining a federally subsidized "food card."

Another departure from the Levesque et al [16] model was an initial seeking care step: case management. Most consumers experienced this step when they enrolled as their local CMH. When this happened, they automatically received a case manager to facilitate their further care-seeking and linkage. As Figure 1 shows, case management initially facilitated access to psychotherapy, psychiatric services, and necessary "other services" and "social services" that support mental health recovery. CMH typically provides psychotherapy and psychiatric services directly. However, consumers sometimes sought therapists outside the CMH-provided options due to provider shortages, related wait times, and schedule limitations at CMH.

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An extension of the technology-mediated care context is locating and acquiring resources with technology. As mentioned, some consumers searched for potential therapists via web-based databases or web searches. Additionally, consumers made inquiries or completed web-based forms on their devices. One consumer described completing a web-based form for multiple resources:

> *For my DHHS [Department of Health and Human Services], I just filled out paperwork and then sent that in for my Medicaid and food stamps.* [C009]

An additional necessary modification of the seeking care stage is the addition of emergency service acquisition, as demonstrated in the revised model (Figure 1); emergency care-seeking circumvented several care access stages when required. This occurred when consumers arrived at psychiatric emergency services of their own volition (calling 911, going to the emergency room [ER]) or due to others in the community calling 911 if they believed that the consumer was a threat to themselves or others. Calling 911 due to a psychiatric emergency may have occurred at either the initial or ongoing needs identification stage. In recognition of the use of technology to acquire emergency services, the category of technology-mediated contact was added. Notably, through this emergency service acquisition, it is also possible that consumers will have contact with the criminal justice system. For example, C003 describes witnessing this experience by saying,

> *I have a friend… she gets really sick when she doesn't take her medicine and the police have to force her to go to the hospital and they have to put her in handcuffs and take her away.*

Calling the police works to keep CMH consumers safe while in crisis, but it often compensates for a lack of resources for low-SES CMH consumers.

> *Where there's a lack [of other crisis care] access, you call law enforcement.* [HSP07]

Depending on the situation, this step may also result in legal trouble that could lead to participation in the MHTC diversion court.

Starting at the care-seeking stage and continuing through reaching care, a new cross-stage category is needed: "playing the waiting game" (Figure 1). This was a common experience of low-SES consumers with SMI, who often faced prolonged waits for appointments, new provider assignments, housing acquisition, and medical transport. Waiting typically occurred with little guidance or communication of updates from HSPs. For example, a fieldnote from observations at court in April 2023 described the following scenario:

> *The judge asked about housing and how this person is doing with their housing situation. They said that it's not great, but they're getting by. Money is really difficult and they're on a waitlist for Section 8 housing.*

Notably, there was typically a lack of technological systems through which consumers could follow the status of applications for housing or other services. Instead, a consumer or case manager sought any updates via email or phone.

Health Care Reaching

For the health care reaching stage of Levesque et al [16], we again see low-SES consumers or the HSPs who work with them contacting multiple forms of care, often simultaneously. Furthermore, it is critical to note that the care that was reached was delivered either in-person or in a technology-mediated manner (ie, logging into a computer for a telehealth appointment). Hence, the name given to this stage of the model was altered to say, "Reaching in-person and technology-mediated care."

Although some care was delivered in person, coordinating transportation with technology for in-person visits was often necessary. Some consumers used transportation apps on a smartphone or booked nonemergency medical transportation. For instance, one consumer (C006) used a bus app to arrive at their appointments on time, stating, "I have maps on my phone, so I use that a lot to tell me when the bus is coming."

Preparing for technology-mediated care was necessary here as well. This involved consumers acquiring and maintaining technologies, often with the help of HSPs or clubhouse peers. It also consisted of following various procedures and using different technologies driven by those used by the HSP in question. Consumers constantly renegotiate reaching care, partly due to technology-related challenges related to having technology and adapting to various HSP systems. For example, even if a consumer knew how to use a platform (like Zoom), variable settings across providers created complexity.

> *With Zoom… sometimes there's a password and sometimes there's not a password… so that can get confusing…if you're not consistent with how you're using something and the rules are changing as you're getting to different parts of an app or whatnot, I just don't think it's fair to people.* [C004]

C005 also argued that HSPs make "too many assumptions that everyone should be using computers or have the knowledge or capabilities to access everything… one assumption that is that everyone must have patience and endurance to contend with computer glitches, free ups, correction to typos, tech compatibility, and trying to figure out how to use the different apps and how to use the different things accordingly."

Playing the waiting game also persisted into the health care reaching stage because consumers who lacked personal transportation had to plan their medical transportation far in advance. They also spent much time waiting for transportation providers to arrive. Another participant described how she used her phone to establish medical transportation:

> *I usually do it on the app [Access2Care] on my phone. Normally, you could set up transportation within a month in advance.* [C012]

On the day of the appointment, the transportation service provider often sends a digital notification or reminder:

> *When the day comes, I just lie in bed, wait for the ding to give you the text of the drivers on the way. Then, I head out when the driver arrives.* [C010]

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Health Care Usage

The Levesque et al [16] model maintains a singular box to represent "health care usage," with primary and secondary access subcategories. However, this distinction does not entirely fit SMI care for low-SES patients. Rather, here again, there is a need to maintain recognition of the use of multiple services simultaneously: therapy, psychiatric services, other services, and social services (Figure 1). These services were often provided via technology-mediated delivery, such as therapy appointments or court review sessions via telehealth. One benefit of this approach was that it reduced consumers' travel times by using telehealth calls, making it possible to fit more into their schedules, allowing for increased schedule flexibility. For example, service providers (eg, HSP03) identified such a benefit for MHTC participants ("other services" box in Figure 1), stating that Zoom is "easier for the participants as far as transportation and the ability to get to the court."

At this stage, there is also a need to recognize the continued pathway of emergency service acquisition. Such direct service occurs via the ER or inpatient care if the hospital admits a consumer. This typically resulted in hospitals discharging patients into CMH care. However, there were situations in which consumers could be court-ordered to adhere to treatment recommendations, often when they posed a risk to themselves or others or if their judgment was deemed to be impaired by their SMI. C003 described her experience with this:

> *One time I was in the hospital and they put me on a telehealth thing with a tablet to talk to a court… I was so sick and mentally ill in that hospital that I didn't know anything that was going on around me.* [C003]

This pathway primarily stabilized consumers so they could again engage in care through usual routes or make care engagement decisions with sound judgment.

Staying in Care (New Stage)

A "staying in care" stage was added to the original framework to accommodate SMI care's complex access cycle. The importance of this category of access was evident in the experiences of the study participants. Most study consumers received psychiatric services 2 - 24 times a year and received therapy as often as every week. The presence of staying in care is an explicit step in the framework to emphasize that consumers benefit from sustained service use and that retention helps produce favorable mental health outcomes from participants' perspectives. In Figure 1, arrows to the right of the use category indicate that consumers must keep using these services regularly, thus staying in care.

At this stage, managing time with technology is a key adaptation for a technology-mediated care context. This involved accomplishing time-sensitive activities such as scheduling, rescheduling, and remembering health care appointments using various technologies. For example, as discussed subsequently, many consumers used calendaring apps to keep track of their upcoming health care appointments and stay in care. Health care organizations also helped consumers stay in care through reminders in the form of automated phone calls, live calls, text messages, emails, or appointment cards.

Health Care Consequences

As for the health care consequences stage, the Levesque et al [16] model outlines the economic, satisfaction, and health-related consequences of health care access. While each of these was evident in study results, data concerning the experiences of low-SES consumers suggests the need to modify the framework to additionally reflect the psychosocial and emotional consequences as part of health consequences. Indeed, there were negative consequences in each category above for those who could not figure out how to access technology-mediated care. As we elaborate below, consequences included experiences of frustration, anger, and lowered self-efficacy, suggesting extensions to the existing model. For instance, C004 described how she felt when she could not get her telehealth video call working; she said, "Frustrated. We expect technology to work a hundred percent of the time."

RQ2. How Do Low-SES Consumers Use Technologies Throughout the Process of Accessing Health Care Related to Their SMI?

Overview

Consumer technology use falls into 3 emergent categories that recur across multiple stages of the access framework: keeping track, figuring it out, and leaning on others. In this study, keeping track entailed consumers monitoring their symptoms, mental health status, medications, schedules, and appointments. This allowed them to make necessary adjustments and clearly understand their present and future care needs. Figuring it out refers to the continuous, individualized efforts of low-SES consumers with SMI to comprehend and navigate their care across multiple services and amid complex and often unclear processes. This involved performing tasks to prevent care disruptions and adapting to new tools used for accessing care. As C006 noted, "Technology in some ways has been good, but it has also been very trying to figure it out." Leaning on others refers to the external support consumers seek or receive from friends, family, and peers with SMI or HSPs to facilitate access to technologically mediated health care. Consumers leaned on others routinely, such as regularly discussing new symptoms, or on an ad hoc basis, like when troubleshooting spotty Wi-Fi. Having introduced these categories, their presence in the context of each Levesque et al [16] model stage is now outlined.

Identifying Care Needs

As mentioned, most low-SES consumers with SMI were primarily engaged in the ongoing identification of care needs rather than in recognizing initial symptoms. At this stage, monitoring symptoms with technology was performed as part of consumers' larger practices of keeping track. Here, consumers were often leaning on others, particularly loved ones or peers, by digitally communicating their SMI symptoms, using tools to identify new or changing symptoms collaboratively. Consumers usually call or text friends and family to "check in" on their mental health. For some, technology-mediated "check-ins" with a loved one increased symptom awareness

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and allowed consumers to verify their own mental health self-assessments and determine the necessary next steps.

> *If I'm in crisis or something I'll usually reach out to my best friend or my mom or my dad and just check my own thinking on stuff and see how bad it is before I make decision to go to hospital or reach out to [my] case manager.* [C004]

Regular technology-mediated communication with friends also supported symptom monitoring, allowing individuals to lean on each other for awareness of mental health episodes.

> *I have a best friend that I talk to daily…We both notice in each other if we're having an episode, a bipolar episode.* [C014]

These mechanisms for technology-mediated communication supported consumers' needs identification while providing them with social support.

Two consumers also used smartphone mobile apps and wearables in ways that identify symptom changes. Specifically, C009 used mood-tracking features on the MyStrength mobile app designed to self-monitor her symptoms. C008 used a Fitbit wearable and its mobile app for biometric feedback, alerting her to changes in her stress and anxiety: "This Fitbit [that's] hooked up to my phone… it'll beep and say, 'okay, your stress level is at blah, blah, blah',…it'll buzz me." For C008, this app helped her identify her needs, adding that the app helped to make her "more aware."

Seeking Care

Consumers were sometimes proactive in seeking care by figuring out what services were available and how to access them with technological tools. We called this access process "locating and acquiring resources with technology" in the modified framework above. Figuring it out for some consumers involved searching for potential therapists via web-based databases, web search engines, or perusing service-related websites to locate resources. Web-based applications were typically necessary to acquire resources. Some consumers also independently contributed to figuring out how to apply for social services while using technology, such as housing or food stamps, and then did so. Nevertheless, many consumers faced obstacles when figuring out how to access services alone. For instance, issues with insurance compatibility and navigating these websites frequently complicate these processes. Such challenges led consumers towards leaning on others while seeking services, especially HSPs, who guided consumers through the technology-mediated process of applying for services. Importantly, case managers provided a second set of eyes on important paperwork before a consumer submitted it, as one consumer stated:

> *I filled out the paperwork and let [the case manager] look at it… Just to check for accuracy.* [C012]

Leaning on others when using technology to seek health care also included others submitting documents related to consumers' mental health needs. For example, C013 used resources at a mental health clubhouse to fill out and submit a housing application, stating, "The clubhouse staff, they would help me fax applications to different apartments or email them to print them off." Similarly, C009 stated, "I filled out my paperwork and I think [CLUBHOUSE STAFF] emailed it to the landlord." By leaning on case managers and clubhouse staff to review and send documents via technology, consumers could more confidently navigate the complex process of seeking social services in technology-mediated ways.

Sometimes, HSPs also offered in-person social support to those who struggled to navigate technology-mediated applications for social services. In turn, this assisted with understanding and emotional regulation.

> *I said, 'Oh, you have to fill out this form on the computer.' No, I'm not going to do that. I want to talk face-to-face with somebody because I don't understand all those forms.* [C005]

C005 described how in-person case manager support prevented her from becoming too emotionally overwhelmed at the computer: "In-person, if they say, 'Okay, can I save this? Can we break it down to doing it probably 20 minutes at a time.'" By transitioning from an independent digital submission to a supportive in-person approach, consumers found it easier to manage the lengthy and complex form submission processes in the care-seeking stage.

Reaching in-Person and Technology-Mediated Care

As mentioned, technology was involved in 2 parts of the reaching care stage: coordinating transportation with technology for in-person visits and preparing for technologically mediated care. For the former, consumers set up their medical transportation through mobile apps or phone calls before their appointment. For example, C006 described reaching in-person services, stating, "I've got my [TRANSIT] app and… you schedule rides there." For some, this coordination included medical transportation services (such as local ride-sharing services for people with disabilities) and ride-hailing services (such as Uber or Lyft).

Figuring out how to coordinate transportation meant that participants had to use various apps or platforms to get to in-person care. Consumers who lived near accessible public transportation often used apps on their cell phones to plan their travel and physically navigate their way to those appointments. For example, one consumer used a bus app to arrive at her appointments on time and also described how she used a website provided by her local transit:

> *So I was able to [use] [local bus] in [CITY1], [CITY2], I'm coming from [CITY2], and I take the bus.* [C003]

As for preparing for technologically mediated care, consumers spent time figuring it out in relation to having the necessary technology for visits. Indeed, consumers often faced financial challenges that restricted their ability to use telehealth as they balanced their health care needs with other expenses. To address this challenge, leaning on others was common. HSPs like case managers and clubhouse staff played a crucial role, providing the technology consumers needed to connect to technology-mediated care. They ensured that consumers had

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access to the right digital tools and often had private spaces appropriate for conducting telehealth calls.

> *I was fortunate. I had Clubhouse, and they were willing to let me be in a room by myself [for the visit] and help me with the Zoom [beforehand].* [C009]

Preparing for technology-mediated care also meant acquiring technology skills, another place in which consumers reported leaning on others. For instance, one consumer who had a peer support role at a Clubhouse also described her role in teaching her peers how to use novel technologies:

> *I did take a couple of tablets to specific members that did not have any technology experience. So I had to show them how to start it up, how to get to the program, how to connect with virtually… it was a training process.* [C008]

Furthermore, as mentioned, it was common for each consumer to have multiple providers with whom they interacted regularly. Often, the consumer had to figure it out in relation to interacting differently with each provider, either via different technologies or in person. Due to variable mechanisms for engaging with other HSPs, it was difficult for consumers to know what was appropriate and what was not, necessitating figuring it out. As one consumer described, mechanisms for accessing health information were not streamlined. This puts consumers in a position to try multiple digital methods (eg, calling and portal use) to change or reschedule an appointment. C006 explained how she would get a new appointment scheduled, expressing frustration with the process:

> *Probably I would try to call first, and then if I can't get through, then I would probably go on the portal and try to schedule an appointment. But again, if it's something new, [technology] takes me a while to learn.*

Leaning on others also taught consumers how to use technology-mediated communication to interact with service providers. A peer support specialist and consumer (C004) stated, "I can show people how to email their case manager or get on the phone and teach them proper etiquette." This effort needed to figure it out, which added complexity to reaching care.

Using Health Care

Health care typically involves some technology-mediated care delivery. For example, C012 described the range of services he used:

> *I go to therapy at least twice a month, and I have a case manager that I see once a month and a psychiatrist. I see him every three months, two to three months. And most of our appointments are in-person, but some of my therapy sessions are over Zoom or telehealth.*

Notably, for this consumer and others, the provider typically decided whether an appointment would be in-person or technologically mediated, often without much input from the consumer. When it came time for telehealth visits, consumers reported leaning on others, specifically clubhouse staff and members, to make visits work. In clubhouses, there was an environment in which learning to use or access technologies for care was a collaborative effort. One consumer shared her experience, stating:

> *It was a bit confusing to me because my phone does beat me up sometimes, and so I had to have [Clubhouse Staff] come in and help me go to my text messages, I think, and click on the [TELEHEALTH] link.* [C013]

At times, clubhouse members also walked other members through using a novel device to connect with care.

Keeping track of medications and appointments was a goal of some SMI consumers, and it was especially important for consumers involved in the MHTC since therapy was part of probation conditions. However, this was difficult for most consumers. Regardless of MHTC involvement, there was a lack of sufficient consumer-facing technologies. Indeed, most consumers in this study did not have patient portals for their CMH care. This stymied consumers. As C004 mentioned, "I use the patient portal for [HEALTHCARE SYSTEM], so I should probably use it for CMH too." Limited or no access to their records made it burdensome for consumers to obtain information about diagnoses, medications, and appointments. Hence, consumers were trying to figure out how to manage their medications without efficient technological systems for medication management and how to keep track of appointments without such technologies. Consumers saw a need for improved technological systems that would enable them to track and manage their care easily. C002 described the potential benefits of having an integrated portal:

> *Because then they can see [their medical information] in front of their face… instead of having to rely on memory or texts or phone calls and messages. It's right there in front of you… it's empowering just to have that access.*

As a result of inadequate access to personal health information, consumers often had to lean on others. Specifically, they relied on case managers as intermediaries to keep track of their appointments and medications. C002 explained how she would obtain her medication list:

> *I would start with my case manager. She probably would refer me to somebody in records... I might try saying, 'Hey [CASE MANAGER], can you have [PSYCHIATRIST] send a med list so you can send it to me?' I just want to see what's on my list.*

Staying in Care

A major part of staying in care is managing time effectively to remember and attend appointments. Service providers highlighted that some consumers face significant adjustments when beginning or reinitiating care. An MHTC HSP (HSP08) noted that consumers struggled to establish "an understanding of all that is expected to them and time management and being able to comply with [APPOINTMENTS]." Additionally, HSP04 stated:

> *Some of them…clearly haven't even had experience keeping a calendar before… that is often a big*

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> *adjustment time, that it's hard for them to pull it together.*

Thus, some consumers had to figure out how to manage time with technology to stay in care.

From those figuring it out to those who were more accustomed, consumers in the sample used calendaring apps to keep track of their upcoming health care appointments to stay in care. One consumer (C004) said, "I use the calendar app a lot because if I don't put it in there and get a reminder, I'll forget about." Knowing the different upcoming commitments ensured that they could attend and prepare themselves for these appointments. To keep track of her medications, one consumer (C008) also used a "reminder list on my phone that says, 'okay, take this medication with you today.'"

While digital calendars worked for some, other consumers used physical calendars to keep track of appointments and other commitments. Still, others used both digital and physical calendars to reinforce their memory by recording upcoming appointments in multiple places. When asked how she used her paper calendar, one consumer stated

> *[For] people's birthdays and my med reviews and doctor appointments with my primary care physician and stuff like that.* [C003]

Consumers with challenges attending appointments also used physical calendars to keep track, as indicated by this MHTC fieldnote:

> *The judge mentions that [CONSUMER] has missed a few meetings with CMH and asks him what is going on with that. He says not that he knows of. He doesn't think he has missed any therapy appointments… He mentioned that he bought a physical calendar because he's been having trouble keeping track of things. He mentioned he doesn't want to have to rely on his phone but it's a work in progress.*

This consumer was reticent to adopt a digital calendar but ended up incorporating both versions for keeping track.

Consumers reported leaning on others through digital and paper reminders provided by health care organizations and the court to help them stay in care. For instance, health care organizations help consumers stay in care through reminders in the form of automated phone calls, live calls, text messages, or emails. This resulted in consumers keeping track of appointments more easily. One consumer described her experience with phone call reminders:

> *They [CMH] still do old school automated phone reminders. So you answer and they say, 'Hello, you have an appointment with [NAME].' I go on whatever date at two o'clock.* [C002]

This kind of reminder from CMH helped jog consumers' memory, alerting them that they needed to attend an appointment—often the next day. Another consumer noted they are less likely to miss care when they receive reminders:

> *[CMH] sends me reminders about my appointment… that helps a lot because sometimes I wrote it down wrong on the calendar at home or I haven't wrote it down or something like that.* [C013]

In other settings, including the MHTC, consumers were also given a paper card or sheet indicating their upcoming appointments to help them keep track of appointments. This is analogous to paper reminder cards that consumers receive in person after health care appointments:

> *I do get a reminder card from them when I go, and most of the time I keep it in my wallet… if I'm not sure what time it is, I'll go back and look at the card though.* [C012]

One service provider also described how case managers often gave such physical reminders:

> *We're like, 'Hey, this is just as a reminder. So, you know, it's coming up, they might wanna put it out in their fridge or in their wallet or purse.'* [HSP02]

Consumers who could not figure it out with respect to managing time with technology risked missing care-related appointments, even if an MHTC mandated them. An example of this in the legal context can be seen in MHTC fieldnotes:

> *I observed an MHTC consumer struggling to try to connect to the court via Zoom at that moment and described how they missed an appointment because of phone issues, ' I know you're connected; I can see your screen, but something's wrong… ' said the judge, trying to figure out what was happening. The consumer lets the judge know that his phone went out; he can't see its screen, so it's hard to maneuver. He almost missed court because he couldn't get it to work; he missed another one of his appointments because his phone wasn't working right.*

Care Consequences

The original Levesque model highlights the economic consequences of care, which, for our purposes, encompasses the time and travel costs related to health care visits. For technology-mediated care, consumers highlighted positive impacts on time costs. C004 explained:

> *Even people that can't make it in for meetings, they're able to hop on Zoom and join meetings, which is so important for so many people.*

Reduced transportation challenges were also evident from consumers' perspectives. C014 said that technology-mediated connections remove additional time needed to get to care: "I don't even have to think about traveling or taking the bus, it's easier to do it virtually." HSPs identified a similar benefit for MHTC participants, stating that Zoom is:

> *Easier for the participants as far as transportation and the ability to get to the court.* [HSP03]

Satisfaction is also a health care consequence in the Levesque et al [16] model. Most consumers advocated for maintaining hybrid care options to increase access, recognizing both the benefits and trade-offs of technologically mediated care and improving overall satisfaction. Here, it was recognized that technology-mediated care could make people more comfortable

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as an aspect of satisfaction. For example, HSP05 mentioned that when conducting court sessions over Zoom, consumers are "more comfortable. It's not as intimidating." HSP02 also reflected this sentiment:

> *Telehealth allows [consumers] to be in the comfort of their own home and not have to navigate bus routes, making it much more comfortable for them.*

However, less-satisfied consumers and service providers raised concerns about negative impacts on social connectedness, with C003 stating, "It just kind of makes me feel lonely seeing people in a computer."

The Levesque et al [16] model also highlights the health consequences of care, including emotional and psychosocial health, for this study. Here, the impacts of technology-mediated care could be negative. Specifically, failing to figure out how to facilitate technology-mediated care delivery caused emotional distress, as one peer described:

> *Not knowing how to do something or not having the monies to afford a more expensive computer... adds to the whole self-blame.* [C005]

This may lead to frustration and anger, as a consumer noted:

> *If I don't succeed, I get very angry with myself.* [C006]

Discussion

Principal Findings

For low-SES consumers with SMI in the United States, the process of accessing care departs from the Levesque et al [16] model in several key ways. The revised model reworks the identification of care needs to include initial and ongoing stages. There were also 3 approaches to accessing care not outlined in the Levesque et al [16] model: emergency services, initial care access enabled through case management, and subsequent and often simultaneous care through various services (therapy, psychiatric services, other services, social services). For this study sample, reaching care also involved in-person and technology-mediated services. Moreover, the addition of staying in care was validated by empirical results. Care consequences also involved recognition of emotional and psychosocial health. The revised model incorporates roles for technology throughout the access stages indicated in the purple rectangle in Figure 1): monitoring symptoms with technology (identification of care needs); locating and acquiring resources with technology (seeking care), coordinating transportation with technology and preparing for technologically mediated care (reaching in-person and technology-mediated care), technology-mediated care delivery (using health care), and managing time with technology (staying in care). Technology-mediated contact was also present for emergency service acquisition.

Consumers' use of technologies thus influenced every stage of their access to health care. Key use categories included figuring it out, leaning on others, and keeping track. For leaning on others in technology use, consumers reported relying on friends and family to help monitor and track symptoms, apply for services, make telehealth visits work, and learn to connect digitally. This aligns with work that highlights how justice-involved individuals, such as those who were formerly incarcerated, often leverage offline networks to navigate an increasingly digital world [41]. Figuring it out involved learning to acquire services independently, coordinating transportation with technology, receiving care from HSPs across multiple platforms, and developing the ability to engage in managing time with technology. Together, these practices helped to ensure that consumers attended scheduled appointments, thus allowing them to stay in care over time.

Comparison With Prior Work

Previous studies have described numerous technologies designed to identify mental health care needs. For instance, prior literature outlines diagnostic tools, self-monitoring technologies for tracking symptoms, sensing technologies, and algorithmic detection [42-47]. However, while 2 participants engaged with apps for monitoring symptoms, more people in this study monitored symptoms via technology-mediated discussions with friends and family. Specifically, consumers called or texted their supportive loved ones and used these interpersonal relationships as barometers for evaluating their mental health status, either explicitly (asking a friend for advice) or through mutual passive monitoring. Therefore, the findings of this study uncovered new relational methods for self-monitoring symptoms with technology.

The need for multiple services and the lack of the service organization's clarity about how to pursue them often overwhelmed consumers. Participants frequently did not have adequate technology to submit service applications independently, nor did they know how to fill them out. Consequently, study consumers often needed the support of their case managers or peers to complete web-based applications for housing or disability benefits, such as those consumers receiving Social Security Disability Insurance. While prior work has identified the importance of case management in helping clients fill out applications for benefits [48], this work is novel in highlighting how this type of support may be particularly necessary with a shift to technology-mediated platforms. When technological literacy was a prerequisite for applying for public benefits and assistance, HSPs' roles evolved to encompass cofacilitating those applications.

Adding the emergency services acquisition model based on study results highlights direct, technologically mediated pathways to care acquisition. This aligns with other studies that identified that populations with low SES have increased rates of 911 calls and psychiatric ER use due to mental health emergencies. The observation of increased rates of ER use among low-SES populations compared with higher-SES populations is also found in other health conditions [49]. Emergency services sidestepped the other cycle stages while sometimes problematically engaging with law enforcement during entry to care. These data align with the findings of Wood et al [50] of the "gray zone" of policing, asserting that those with unmet mental health needs are "unengaged or under-engaged individuals who fall through service cracks." This aligns with findings around there being multiple points at the access continuum wherein consumers can drop out of care, thus not staying in care or being retained. While this safety net

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is helpful in emergencies, more work needs to be done to prevent the escalation of mental health concerns from reaching emergent levels. Investments in programs that provide ambulatory psychiatric assessments and care, such as mental health urgent care, may help to decrease the need for emergency services. One example that successfully leveraged technologies was the Veterans Health Administration's efficacious implementation of unscheduled emergency telehealth interventions within urgent care clinics [51]. This is increasingly important when considering the intersection of race, SES, and mental health status, as Black individuals with SMI are less likely to receive any mental health care [14] and face increased risks of lethal altercations with interactions with law enforcement [52].

This work also contributes novel findings that show that services such as mental health clubhouses can facilitate access to technology-mediated care. Specifically, members often act as "informal peers," stepping in to provide support as needed. The value of this type of technology-focused peer support has also been observed in other fields, such as oncology [53]. Relatedly, there has been an increasing investigation into "digital peer support," or the delivery of peer support via technology [54]; however, this work affirms that some consumers require in-person support [55]. Future work should investigate how best to arrange peer technology support services for diverse consumers and situations.

Theoretical Implications

One key contribution of this work is its extension of the health care access framework of Levesque et al [16] to better represent technologically mediated mental health care access for low-SES CMH consumers (Figure 1). By establishing the cyclical nature of mental health care access for low-SES consumers with SMI, this extends the original framework of Leveque et al [16] to encompass situations more likely to emerge with other chronic and complex conditions. For example, cyclical patterns in accessing care likely extend to other chronic conditions such as HIV, postural orthostatic tachycardia syndrome, or asthma, which share the need for ongoing and often lifelong management to maintain wellness [56-58].

The extended model also shows that health care often involves multiple forms of care at once. Hence, the care access stage for one service (eg, seeking stable housing outside a shelter) may be at an entirely different stage than that for another service (eg, obtaining biweekly therapy sessions from a CMH therapist). A consumer may thus experience multiple access stages simultaneously, as the stages are not mutually exclusive to one type of service. Moreover, consumers with SMI typically need long-term care to manage symptoms, and they may move in and out of care with different providers or perhaps cease some types of care altogether for a period of time or permanently.

This extended model also considers consumer retention in care as a vital yet often overlooked aspect of health care access. Staying in care can result in positive patient outcomes, leading to recovery or better symptom management. On the other hand, not staying in care or experiencing care attrition can lead to deteriorating health outcomes [59,60]. While staying in care is crucial for managing SMI, health care needs can change over time. For example, a person with a stable SMI and existing social services linkages might have monthly therapy appointments and biannual psychiatric appointments for medication management. In contrast, individuals who experience acute SMI symptoms may require more active symptom monitoring and additional services.

Another novel aspect of the extended model is the addition of roles for technology throughout each step in the process of access to care. Specifically, the purple box below the access cycle displays the role of technology throughout the different steps, including technology monitoring symptoms, locating and acquiring resources, preparing for telehealth and coordinating transport, delivering technology-mediated care, and supporting time management. This technology-enhanced process likely generalizes to chronic health conditions, as telehealth is increasingly available after COVID-19 care. Researchers must continue investigating hybrid and digital care models for low-SES populations beyond those with SMI [61].

The model visually displays the complexity of accessing care for SMI, laying out ongoing processes that must be managed simultaneously. Notably, technology-mediated care has largely added to this complexity for consumers. Together, these factors can challenge consumers, primarily when they are symptomatic. As such, this model illuminates the complicated patient journey through care and can equip consumers and HSPs with a blueprint for assessing where individual consumers may need additional support in the care access cycle. Ultimately, this revised framework can be used to map journeys for care access and highlight areas needing support. Specifically, service providers could use this tool to assess difficulties in journeys to health care access for individual patients. For example, for consumers who struggle with transportation, providers may be able to identify additional means to support them in reaching care, potentially preventing barriers before they arise.

Furthermore, the expanded framework could be used at the system level, unearthing issues such as prolonged wait times ("playing the waiting game") and stages at which consumers are likely to fall out of care in local care systems. For example, suppose consumers are largely able to stay in psychiatric care, but there are high rates of dropping out of therapy. In that case, interventions can be developed to target improvements within that specific stage (staying in care) for that particular service (therapy). By breaking down the concept of access into more granular stages, clinical care can more precisely allocate resources to access stages needing additional support.

Clinical Implications

This study affirms prior research indicating that the abrupt shift from primarily in-person services to telehealth services in the wake of the COVID-19 pandemic may have disproportionately negatively impacted care access for low-SES consumers [27,62-64], including preliminary related work [65]. In this study, those without technological resources and skills faced additional barriers to using technologies across access stages, which aligns with recent SAMHSA telehealth guidelines that detail usability and functionality barriers that impede care access [66]. Providers thus have an opportunity to better understand the digital connectedness of their consumers and work to accommodate them. To do so, health systems could conduct a

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digital readiness assessment upon intake to assess consumers' abilities to engage in technology-mediated care. To do so, providers may want to adopt tools such as the "Telehealth readiness assessment tool from the Maryland Health Care Commission" [67] or the "Digital Health Readiness Questionnaire" [68]. This would improve both awareness of individual consumer needs and organizational readiness for telehealth implementation, which has been identified as a major challenge by SAMHSA in the treatment of consumers with SMI [66]. In addition, the results of this study support the efforts of Bobert et al [69] to advocate for assessments that match the dynamic nature of technology-mediated care access. It is crucial to understand if consumers can access care digitally and what support they need, or provide alternative strategies for care access if consumers lack the ability or interest in technology-mediated care.

This work unearths the complicated nature of obtaining technology-mediated care, a significant issue. Clinical settings can address this by transparently guiding consumers on navigating care, potentially through support personnel such as digital navigators who provide digital access assistance. Digital navigator programs train staff to promote digital literacy skills in clinical settings, supporting consumers in learning the skills needed to navigate digital care access in culturally appropriate ways [70,71] While peer support specialists in this study started providing digital navigation services in an emergent way to meet the needs of their fellow consumers, expanding peer support specialists' roles to officially include technology instruction could enable peers to integrate these services into their formal responsibilities. This programming type should follow the principles set out by Wisniewski et al [72], such as core smartphone skills, technology troubleshooting, language specific to digital health, and approaches to support digital engagement. Furthermore, these peer technology specialists could provide both scheduled and on-demand support, helping consumers troubleshoot issues, set up initial accounts, practice using telehealth platforms before appointments, and gradually build consumers' independence through scaffolded learning experiences [72]. Checklists that outline care expectations provided digitally or in print, per the consumer's preference, would help create a more centralized approach to building consumers' understanding of digital care. In addition to social services, this checklist could also be generated for available providers such as therapists and psychiatrists.

Beyond peer support, accessible hybrid care involving both digital and face-to-face elements can potentially be enhanced through policy changes. Local and national policies should focus on developing policies that enable low-SES consumers to continue engaging in hybrid care with less emotional and financial strain. Furthermore, the CARES Act introduced temporary flexibilities for telehealth reimbursement, and while this provision was temporarily extended through September 2025 [73], this study provides evidence for the continuing need for telehealth reimbursement flexibilities, especially within a low-SES consumer population. There have been recent moves by the US Federal government to expand telehealth services for nonbehavioral health care [74], and such policies should begin to integrate behavioral health as well.

Limitations

There are several study limitations. The interviews and observations were conducted in one midwestern state within the United States, potentially reflecting local norms regarding care access. While this may impact generalizability, there was a diverse age range of consumers, although consumer participants did not reflect the broad racial diversity of CMH participants. While most consumers were on Medicaid and were not employed full-time, they were also highly college-educated, meaning they may have had more advantages than some low-SES consumers. With demographic differences in mind, there was little mention of the intersections between SES, race, and SMI within the interviews, which should be further researched. Additionally, consumers who can be interviewed may be more stable in their recovery, and further research is needed to understand whether consumers in less stable recovery use technologies differently. Service providers' perspectives on retention in care may be influenced by supporting MHTC consumers who may adhere to care to avoid judicial consequences; nevertheless, the consumer interviews provide insights into care retention for consumers not legally obligated to engage with care, providing a well-rounded consumer perspective. Furthermore, this study does not provide a quantitative validation of the framework extensions, which could be a focus of future work. Regarding qualitative data analysis, although there was dual code generation and regular meetings to discuss the coding approach, a formal assessment of interrater reliability was not conducted. Finally, most of the consumers in this study participated in their local clubhouse (n=12), which may account for the frequency with which peer support emerged as an important factor in CMH care access.

Conclusions

This study proposed a new model of a technology-mediated mental health care access cycle for low-SES CMH consumers that demonstrated the cyclical and ongoing nature of care access for this population. It also showed that retention, or staying in care, is critical to the access cycle. Technology use shapes access to mental health care for low-SES consumers with SMI, with roles for technology at every stage of care access. Findings highlighted consumers' ongoing struggles to figure it out despite navigating multiple services, and with a lack of technology-mediated tools like portals. Results also underscore the importance of social connections in enabling access to technology-mediated care, notably as case managers and peers give consumers someone "to lean on" when using technology. Future work should investigate the ways in which technology-mediated care can make care access easier rather than harder. As one study participant said, technology-mediated health care "should not be only available to people who can go through all those steps. It should be available to everybody."

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Data Availability

The qualitative data gathered during this study are not publicly available and cannot be shared due to confidentiality concerns. Furthermore, ethical restrictions imposed by the consent form signed by participants prevent data sharing and data requests. Any questions about this can be directed to the corresponding author.

Authors' Contributions

AKS contributed to conceptualization, data curation, formal analysis, investigation, methodology, project administration, provision of resources, and writing of the original draft, as well as reviewing and editing the manuscript. TCV contributed to conceptualization, investigation, methodology, provision of resources, supervision, validation, and reviewing and editing the manuscript.

Conflicts of Interest

AKS is a scientific editor at JMIR Publications. The work reported in this manuscript was completed prior to this role, during a previous affiliation. TCV has no conflicts to declare.

Multimedia Appendix 1
Coding matrix.
[DOCX File, 9 KB - formative_v10i1e79608_app1.docx]

Checklist 1
COREQ checklist.
[PDF File, 497 KB - formative_v10i1e79608_app2.pdf]

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Abbreviations

CMH: community mental health care
COREQ: Consolidated Criteria for Reporting Qualitative Research
ER: emergency room
HSP: health and service provider
MHTC: Mental Health Treatment Court
SES: socioeconomic status
SMI: serious mental illness

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Opportunities for Digital Health to Support Early Psychosis Care in Ghana: Qualitative Study Among Patients, Caregivers, and Clinicians

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Abstract

Background: Youth experiencing early psychosis in West Africa often face delays in accessing evidence-based treatment. Digital mental health interventions may offer an acceptable and scalable approach to improve access to early psychosis care in West Africa; however, few data exist on the experiences and perspectives of patients with early psychosis and their caregivers to inform digital intervention development.

Objective: This study aims to explore current experiences of early psychosis care, identify barriers and facilitators to in-person early psychosis care within health facilities, and identify opportunities for digital interventions to support patients with early psychosis and caregivers in Ghana.

Methods: We conducted qualitative focus group discussions among patients with early psychosis, their caregivers, and their mental health care providers recruited at Accra Psychiatric Hospital in Accra, Ghana. Trained qualitative researchers facilitated discussions using a structured qualitative interview guide, exploring current care practices for early psychosis in Ghana, barriers and facilitators to facility-based care, and perceptions of digital mental health interventions. Transcripts were translated, transcribed, and analyzed thematically using a hybrid inductive and deductive approach grounded in the theoretical framework of acceptability.

Results: Overall, we conducted 4 focus group discussions (N=31) among 7 patients with early psychosis (median age 28, IQR 21 - 41 years), 6 caregivers (median age 58, IQR 29 - 34 years), and 18 clinicians (median age 30, IQR 29 - 34 years). Participants described current early psychosis care practices in Ghana, including seeking spiritual and traditional healing, the dearth of information and resources about psychosis, and the integral role of caregivers in facilitating treatment engagement and continuation (often at the cost of caregiver mental distress and burnout). Common barriers to facility-based mental health care included stigma associated with mental illness, lack of prior knowledge about early psychosis and treatment options, and practical constraints (eg, financial, logistical, and health care system limitations). Motivating factors for facility-based care included success stories from community members and strong rapport and trust in mental health clinicians. Technology (eg, mobile phones, laptops, radio, and television) was commonly used among participants in typical daily tasks, health information seeking, and stress reduction. Participants expressed support for digital tools that could deliver psychoeducation about early psychosis, support treatment adherence, and extend patient-provider communication between clinic visits.

Conclusions: Digital mental health interventions have the potential to complement facility-based early psychosis services in Ghana by addressing misinformation, reducing access barriers, and supporting caregiver roles. These qualitative findings inform potential integration points, content, attributes, and strengths of digital modalities that could be leveraged to support patients with early psychosis and their caregivers in Ghana.

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KEYWORDS

early psychosis; digital health; technology serious mental illness; Ghana; West Africa; qualitative; patients; caregivers; clinicians

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Introduction

Mental health service coverage remains low across West Africa [1,2], where individuals with untreated serious mental illness face increased risk of poverty, exclusion, neglect, and abuse [3,4]. Early psychosis is defined as the period when a person first begins to experience hallucinations, delusions, or difficulty distinguishing reality [5]. This period represents a key window for intervention. Reducing the duration of untreated psychosis can alter the course of illness toward better psychiatric and social outcomes [5,6]. Evidence-based interventions such as antipsychotic medications and cognitive behavioral therapy for psychosis are most effective when introduced early, reducing symptom severity, risk of hospitalization, and functional impairment [7-9]. Strong community ties and family support systems are assets in low- and middle-income country (LMIC) settings; there is evidence that recovery outcomes following early psychosis treatment may be especially strong in LMICs [10]. Yet in West Africa, few youths with early psychosis receive these interventions since availability is scarce [11]. Systematic estimates of early psychosis care uptake are not available for this region; however, a cross-sectional survey in Ethiopia identified that 40% of people with psychosis received treatment for a current episode, and that more than 70% of them did not receive "minimally adequate care" (at least 4 follow-up care visits with medication monitoring) [12].

In many cases, people with early psychosis and their caregivers first seek care from religious or traditional healers, delaying access to psychiatric or psychological treatment [13,14]. Beliefs about the spiritual origin of symptoms—such as witchcraft or prophetic calling (the belief that psychotic symptoms are spiritual messages from a deity) [15]—alongside high levels of stigma and health care system barriers limit access to care in formal health care settings. Long distances to clinics, understaffed facilities, and extended wait times further discourage service use, extend the duration of untreated psychosis, and have made it difficult to integrate mental health care into primary care systems [16]. Even when individuals are diagnosed in a formal psychiatric setting, medication discontinuation and disengagement from care are common among patients with early psychosis globally [17]. The World Health Organization recommends family-inclusive models in LMICs [18] that align with local norms of reciprocal caregiving [19] and leverage the central role played by caregivers in the recovery and social integration of their loved ones with early psychosis [20]. In West Africa, however, families often have little access to information or support to fulfill this role [19].

Addressing unmet needs among individuals and families affected by early psychosis in West Africa requires novel approaches that overcome known care-seeking barriers [21,22]. Mobile and digital tools (eg, mobile- and internet-enabled tools such as SMS text messaging and smartphone apps) may offer one way to increase access to mental health support [21], particularly given the high levels of mobile phone ownership (>75%) reported across many countries in the region [23]. Ghana is increasingly recognized as a West African leader in digital innovation, particularly for improving health infrastructure [24]. Ghana also has an advanced telecommunications infrastructure and a longstanding, albeit underresourced, mental health care system. Digital tools for mental health can leverage widely available infrastructure—such as mobile phones and internet access—and may reduce barriers related to transportation, wait times, and concerns about privacy or stigma that impede access to evidence-based early psychosis psychological treatment.

Mobile health tools for psychological support have been shown in high-income settings to improve symptoms and reduce relapse for youth with early psychosis and to help families communicate about mental health [25-28]. Digital tools for behavioral health are expanding rapidly in African contexts, particularly in areas such as HIV care and maternal-child health [29]. Such tools offer scalable support for the treatment of early psychosis in low-resource settings by incorporating educational and caregiver-involvement features. Yet, there are currently no digital resources developed or adapted for people experiencing early psychosis and their caregivers in the African context, despite growing support from the World Health Organization for digital mental health interventions in LMICs [30].

To explore current care practices for early psychosis in Ghana, barriers and facilitators to mental health service use, and opportunities for digital approaches to address early psychosis, we conducted a qualitative study among people experiencing early psychosis, their caregivers, and mental health care providers.

Methods

Study Design, Participants, and Setting

To qualitatively understand experiences of those impacted by early psychosis, current care practices for early psychosis in Ghana, barriers and facilitators to accessing in-person early psychosis care in hospitals and clinics, and opportunities for digital mental health to address early psychosis, we conducted focus groups with patients with early psychosis, their caregivers, and mental health care providers at Accra Psychiatric Hospital (APH). This facility is Ghana's national psychiatric referral hospital. It provides services to 28,000 outpatients per year and serves up to 300 inpatients at a time, making it the largest psychiatric hospital in Ghana. Patients and their families often travel long distances within Ghana and the surrounding region to receive psychiatric services at APH. Ghana's mental health care system is situated within a multitiered public sector health care system comprised of community, district, regional, and national-level health facilities. Mental health care professionals are situated within each level, predominantly master's-level trained practitioners. Typical pharmacological treatments include injectable and oral first-generation antipsychotics. Psychotherapeutic modalities such as supportive counseling are provided, which sometimes includes manualized cognitive behavioral therapy. Ghana's National Health Insurance Scheme includes coverage for mental health services; however, implementation does not always consistently cover these services, leading to out-of-pocket expenses.

Study Procedures

We identified patient and caregiver participants for potential participation in focus group discussions through purposive

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sampling, contacting families participating in a pilot program at APH for early psychosis. This pilot program aimed to provide coordinated multispecialty and assertive community outreach services to individuals experiencing early psychosis. Early psychosis was characterized as the onset of psychotic symptoms within the previous 5 years, with no continuous pharmacological treatment of more than 3 consecutive months. To assess interest in study participation among patients with early psychosis and caregivers enrolled in the early psychosis pilot program, trained research staff (psychiatric residents training and practicing at APH) reached out to the caregivers of patients identified with early psychosis via telephone. All patients and caregivers enrolled in the pilot program at APH were contacted. Participation by patients and caregivers was independent, with no requirement that both be involved. We held 1 focus group for patients with early psychosis and 1 for caregivers. Focus groups were conducted at APH and lasted about 1 hour.

Mental health care providers were eligible for participation in focus group discussions if they were actively providing mental health care to individuals experiencing early psychosis at APH. We recruited providers by inviting all APH mental health clinicians providing early psychosis care (eg, clinical psychologists, psychiatrists, and psychiatric residents) to a seminar on opportunities for digital mental health to support early psychosis care. Providers interested in contributing provided contact information and were scheduled into 1 of 2 focus group discussions based on clinical schedule and workload. To accommodate interest and optimize inclusion of provider experiences, we held two 1-hour focus groups at APH for early psychosis clinicians. Focus group sessions were audio-recorded, translated (from a mix of English and Twi into English), and transcribed.

Data on demographic characteristics were collected for each participant using REDCap (Research Electronic Data Capture; Vanderbilt University) electronic questionnaires on tablets by trained data assessors. Qualitative researchers (DAA and AL) used a structured interview guide that was informed by the theoretical framework of acceptability [31] to inquire about the topics of interest (experiences of those impacted by early psychosis, current care practices for early psychosis in Ghana, barriers and facilitators to facility-based early psychosis care, and opportunities for digital mental health interventions). Focus group discussions were conducted in a private room away from clinical activity on the APH campus. Discussions were carried out in English with translation into Twi by translators (AFO and CAD) fluent in both languages. Accra-based researchers cofacilitated the discussions and reviewed the data to mitigate power imbalances and ensure culturally sensitive interpretations.

Qualitative Analysis

We conducted a thematic analysis of the focus group transcripts using a mixed inductive and deductive approach. Thematic analysis involves identifying, organizing, and interpreting patterns of meaning within qualitative data [32]. This flexible method follows a structured process, including data familiarization, coding, theme development, review, and refinement. We followed a mixed deductive (ie, predefined codes) and inductive (ie, codes emerging from data) approach to facilitate identification of themes emerging from participants' narratives while also attending to topics of interest informed by our interview guide and relevant literature [33].

Coding Process

Transcripts were first reviewed for accuracy and completeness following translation from Twi to English (AFO, MA, and DAA). A structured codebook was developed collaboratively by the 3-person coding team (AL, AB, and ED), all researchers from the University of Washington.

The coding team consisted of a Research Manager with a Master of Public Health degree and a background in global mental health (AB), a Research Coordinator with a Bachelor's degree in Psychology (ED), and a research faculty member with a doctoral degree in epidemiology and a background in global mental health (AL). Two team members (AB and AL) had 3 years of experience conducting research in Ghana's mental health care system; the other member (ED) did not have prior experience working in Ghana. Researchers from APH (JA and KO) and the University of Ghana (DAA and SA) reviewed and enhanced cultural understanding and contextual relevance of the codebook and later interpretation of the data, improving trustworthiness of the analysis [34]. The codebook drew on both the interview guide (deductive codes) and initial readings of the transcripts (inductive codes), with detailed definitions for each code and subcode to ensure consistent application across coders. To ensure the rigor of our analysis, we used multiple strategies, including maintaining an audit trail of coding decisions and codebook revisions, systematic double-coding of all transcripts, and regular team meetings to discuss emerging findings and resolve coding discrepancies. The structured codebook facilitated consistency in coding application across team members [34].

Coding was conducted systematically using Dedoose qualitative analysis software (version 10.0.34; SocioCultural Research Consultants, LLC). Two coders (AB and ED) independently coded 30% of the transcripts to pilot the code application. Coders met to discuss discrepancies in initial coding, clarify definitions, and agree on application protocols. Following this pilot coding, each transcript was independently coded using the structured codebook. The coding team met regularly to discuss code definitions, resolve discrepancies, and refine the codebook based on emerging patterns in the data. Disagreements between coders were resolved through discussion, with a third team member (AL) serving as an adjudicator when consensus could not be reached. This approach facilitated a robust and consistent method to ensure coding reliability and consistency across the dataset [35].

Theme Development

Following systematic coding, the team reviewed coded segments and grouped related codes into preliminary themes. These themes were iteratively reviewed, refined, and, where necessary, collapsed or expanded to ensure they were distinct, coherent, and well-supported by the data. Coding memos were used throughout the process to document the rationale for theme development and any changes made during the analytic process.

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Final themes were agreed upon by the full coding team and illustrated with representative quotations from the transcripts.

Ethical Considerations

Verbal consent was obtained from all individuals before participation, as this study was deemed sufficiently low risk to allow verbal consent. Study participants were compensated with 140 Ghanaian Cedis (~US $10)—an amount comparable to covering their transportation costs and time to and from the study setting. This amount did not represent undue influence in this economic and cultural context. Ethical approval for the study was granted by the University of Washington Institutional Review Board (STUDY00020314) and the Ethics Review Committee of APH (APH-ERC 00020/24). Participants were provided with a copy of the informed consent form, as desired, which made clear their right to withdraw from the study at any time. Privacy and confidentiality were protected for all study participants. Before study enrollment, team members clarified that participation was voluntary and unrelated to clinical services.

Results

Description of Populations

Overall, 31 participants engaged in focus group discussions to inform the development of a digital support tool for individuals impacted by early psychosis in Ghana. Seven patients with early psychosis, 6 of their caregivers, and 18 clinicians participated. Among patients with early psychosis, the median age was 28 (IQR 21 - 41) years (Table 1). Clinicians were slightly older, with a median age of 30 (IQR 29 - 34) years. Caregivers had a median age of 58 (IQR 54 - 68) years. A third of patients with early psychosis and their caregivers were female (patients: n=2, 29% and caregivers: n=2, 33%), while our sample of clinicians had an equal distribution of men and women.

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Table . Characteristics of focus group discussion participants impacted by early psychosis in Ghana.

Characteristic	Patients with early psychosis (n=7)	Early psychosis caregivers (n=6)	Clinicians (n=18)
Age (years), median (IQR)	28 (21-41)	58 (54-68)	30 (29-34)
Sex, n (%)			
Female	2 (29)	2 (33)	9 (50)
Male	5 (71)	4 (67)	9 (50)
Marital status, n (%)			
Married/cohabiting	1 (14)	5 (83)	8 (44)
Divorced	0 (0)	1 (17)	1 (6)
Never married	6 (86)	0 (0)	9 (50)
Highest educational attainment, n (%)			
Primary	1 (14)	1 (17)	0 (0)
Secondary	3 (43)	4 (67)	0 (0)
Tertiary	3 (43)	0 (0)	0 (0)
University	0 (0)	0 (0)	10 (56)
Graduate	0 (0)	0 (0)	8 (44)
Other (eg, below primary)	0 (0)	1 (17)	0 (0)
Literacy, n (%)			
English only	5 (71)	4 (67)	6 (33)
Twi only	0 (0)	1 (17)	0 (0)
Both	2 (29)	0 (0)	12 (67)
Neither	0 (0)	1 (17)	0 (0)
Religion, n (%)			
Christian	7 (100)	6 (100)	12 (67)
Islamic	0 (0)	0 (0)	6 (33)
Residential setting, n (%)			
Urban (city)	7 (100)	6 (100)	17 (94)
Peri-urban (town)	0 (0)	0 (0)	1 (6)
Regularly employed	1 (14)	5 (83)	18 (100)
Job position, n (%)			
Psychiatrist	—[a]	—	1 (6)
Clinical psychologist	—	—	1 (6)
Psychiatric resident	—	—	9 (50)
Medical officer/clinical psychology trainee	—	—	7 (39)
Travel time to Accra Psychiatric Hospital (minutes), median (IQR)	60 (60-120)	60 (45-120)	—

[a]Not applicable.

The most common role among clinician participants was Psychiatric Resident (n=9, 50%)—many of the clinicians providing direct care to patients with psychosis are Psychiatric Residents completing their training at APH. The second most common role was Medical Officer or Clinical Psychology trainee (n=7, 39%), indicating that our sample of clinicians represented relatively early-career professionals, which is well-aligned with the demographics of practicing clinicians within APH and the Ghana National Mental Health System.

Only 1 early psychosis patient was married (n=1, 14%), while caregivers were predominantly married (n=5, 83%), and nearly half of clinicians were married (n=8, 44%). The majority of patients with early psychosis had completed secondary or tertiary education (n=6, 86%), a lower proportion of caregivers had achieved more than primary education (n=4, 67%), and all

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clinicians had achieved university education or higher (n=18, 100%). Only 1 early psychosis patient was regularly employed (n=1, 14%), while most caregivers (n=5, 83%) were employed. Patients with early psychosis and their caregivers lived on average 1 hour away from APH. Demographic characteristics of these study participants are similar to those in a survey of 256 patients with early psychosis and their caregivers conducted by our team at APH, demonstrating that this sample is representative of this population visiting APH [36].

Current Care Practices for Early Psychosis in Ghana

During focus group discussions, participants described the current status of care practices for early psychosis in Ghana, including actions taken to address early psychosis, sources of early psychosis support and information, and how caregivers are involved in early psychosis care. Additional representative quotations regarding current care practices are provided in Table 2.

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Table . Illustrative quotations on current care practices for early psychosis in Ghana.

Category	Representative quotations
Actions taken to address early psychosis	
Consulting others	• "The next day, she got really aggressive and took her bag and said she was leaving. So I had people help me stop her. Her brother who was playing football in the neighborhood came home and suggested we take her to the Polyclinic but my sister insisted we bring her here because my daughter was too aggressive. By God's grace, we we're able to get her here safely." (Caregiver) • "I was there one day when a friend of mine told me he knew someone who struggled with similar issues and when the person was brought to this hospital, that person got better and is even married now. I then decided to discuss it with my child's mother so we get a solution. She also agreed and we brought the child to this hospital. We were so lucky it was Dr. [Name] we met when we came. Dr. [Name] saw the symptoms my son was experiencing." (Caregiver) • "For me, it was my pastor who helped me because the church was the first place I ran to when my child's condition worsened. He prayed for us but after three days his symptoms got worse again. I called him to inform him that was when he told me he'd seen my son around the church and then he cautioned me to get him to this hospital. My pastor is also a doctor. So I brought my son here. I see the improvements now. And it's all because of his help and that's of the staff in this facility." (Caregiver)
Religious, spiritual, and traditional approaches	• "So, if they manage to take the clients there, and then say, those that have suffered acute psychosis, and maybe, like, after a day or so, they see that they're improving, they'd rather take them into pastors or churches. They would take them to religious leaders or traditional things. They'd rather take them to those places." (Clinician) • "…when the child's condition first came about, his mother took him to some churches and prayer camps which didn't help. I didn't like those places because Some of the churches can deceive you and ask you to bring some money, buy all sorts of things which will result in no improvement in their health." (Caregiver) • "Mostly they are brought in by relatives and that's usually after they've sought help from other spiritual camps and you know some are attributed to witchcraft and all that. So I think most of the time they come in with family or they are referred err maybe they present to hospitals on account of different things then they refer to us. But it's very unusual for you to see a patient with psychosis come in voluntarily." (Clinician)
Facility-based care	• "At first uh my parents, they didn't believe what I was going through and uh I used force. I used to tell them anything with force before they told me to go to the hospital. So, I went to a clinic at my place called Zion. Zion Hospital. So they the doctor referred me to see a psychiatrist. So that's when I realized that I have to come to the parents and let them know where to go. So that's when we came to this place." (Patient) • "I also think that some of them also seek regular health care. They actually do often. I remember when I was doing my obstetric rotation, we had a patient come in complaining about, that was postpartum, so she had some form of postpartum psychosis. She actually walked in with her husband and talked about it. So we had, like, this whole session. And we had a couple of the women also opening up after that. So I think some of them also seek regular health care." (Clinician) • "She started hearing voices and cries of animals for four continuous days. She felt it was abnormal. So she informed her sister that 'what I'm hearing is not normal. I want to go to a general hospital.' So on their way, they brought her here. So she felt like they had betrayed her." (Clinician)
Sources of early psychosis support and information	

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Category	Representative quotations
Unhelpful advice or information	• "In my case, when the condition started, I went to my pastor to pray for me and he said she wasn't sick. My pastor said there was nothing wrong with her rather, she just enjoyed going out with her friends. And I told him I know my daughter. I can tell she's sick. So he prayed for her and said there was no need to take her to the hospital but when I saw where things were going, I brought her to the hospital." (Caregiver) • "You see uh, how do I put this, You get a lot of input from different people when something happens. What you hear is what causes you to make it move. You (claps) don't know what's happening. So the incident would have to first happen for you to know the steps you must take. For instance, you can get two or three great advises from about 10 people. That's how we roamed through different prayer camps before arriving at our last resort which is this hospital." (Caregiver)
Helpful advice or information	• "When the doctor diagnosed me that I had schizophrenia, I went to research about the sickness, schizophrenia. They said it's a mental illness caused during the adolescence age of a, of an individual. So, I had knowledge about the sickness. Even if it wasn't for the doctor, like I hadn't heard of that sickness before. And it has helped so, anytime I can see someone suffering from that, I can know. I'm not a doctor but I can also give the maybe the person is also suffering from schizophrenia." (Patient) • "So when you also inform them about some of the success stories with other clients who are engaged, like they are doing okay in their work, they are they get hopeful or they know that oh they can also do something about their lives and their life doesn't mean that once they get out of this illness, then they are not going to amount to erm anything. So I think that's when when they get resolution in their symptoms is also the success story." (Clinician)
Role and toll of caregivers in early psychosis care	

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Category	Representative quotations
Encouraging formal health system care and treatment adherence	• "In the year 2019 - 2020, I was with a friend and I involved myself into drug abuse, was into this codine, raffinol, so um during that period, I start to have dreams. Dreams and nightmares. My dreams was very rough. So I didn't understand myself. So it's something that I started to tell people about my story. Nobody could help me. So I came here with my dad. That's when they prescribed medicine for me." (Patient) • "As a parent, you would have to do everything possible to get your child the right treatment, even if you have to borrow money for it. You'll now have to make sure your child sees how much you love them so that their situation wouldn't get worse. Don't listen to what people will say about the whole thing, rather heed to the directions of the doctors and you'll get the results you desire." (Caregiver) • "The few issues we've had are the ones with very strong delusions, the systematized delusions, and those that poor insight is actually part of the diagnosis. You see that in some schizophrenics, that generally they have a very poor insight. So getting them to understand the condition and adherence on medication is a challenge. Like the…if the family members get to understand this and would help them to be taking their medications, providing them with the support to come for reviews, I mean eventually, we are yet to get there but eventually we will see a change in their conditions too." (Clinician)
Comforting, listening, talking, and strategizing	• "So when your child starts experiencing symptoms, truth be told, your neighbors will have different opinions about what is happening. Rumors ranging from drug abuse to thefts, your neighbors will say lots of different things. You, the parent, would now be the one to better explain the situation to the neighbors, well enough to keep your child safe and happy." (Caregiver) • "What helped us decide to take action was love. And a parent wouldn't just stand by while their child suffers so you'll have to act fast to get them the right care. Health care is what we're trying to get for our loved ones." (Caregiver)
Material support (housing, transportation, and financial)	• "Anytime the doctors call my mother that maybe we'll be having a review, maybe this date or a specific date, she comes to drop me before she goes to work. So as for that one, anytime we have an appointment here, she- makes she takes her time to drop me before she goes to work. So that's the support I receive for now." (Patient) • "This is the phone I use. Only this one. I can't go buy an expensive phone when my child has a mental health disorder. I spend Gh¢ 70 everyday, how can I spare money you buy a phone worth over Gh¢ 1500. I use this same phone to update two of my friends about my son's condition and ask them to help him find a job." (Caregiver) • "As for me… (03) when my child got sick, I used up most of my money. I sold my fridge, two TV sets, and the smaller TV set we were using broke about a week ago…It's just there. So the TV set we watch to get our mind off things is now broken. My son is now distraught about the TV. He keeps asking me to help him fix it and I can't. So all these are some of the problems." (Caregiver)
Mental stress, burnout, and burden on caregivers	

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Category	Representative quotations
	• "So if you don't have God to look up to (kisses teeth) you'd start hating the child. Because its embarrassing seeing your child walking about and picking up trash by the roadside. So you can only cope by the help of God and by prayers. Do you think you can get some sleep when your child leaves the house at 6PM and you can't find them until 3AM? You can't!" (Caregiver) • "And the parent also doesn't get it easy at all. You'll be worried and just be overthinking. Thinking about what the family needs and about providing food for them. And all that becomes extremely distressing when you also have yourself to take care of." (Caregiver) • "You see, when you see what your loved one is going through, you tend to question your abilities as a parent. You ask yourself if their situation is as a result of you not taking good care of them. I console myself with the fact that no parent in the whole world is perfect at parenting." (Caregiver) • "I was really distraught when my daughter was experiencing those symptoms because I thought I was going to lose her. I really cried. I cried a lot." (Caregiver) • "I've not gotten anyone saying why, but some people do say why me? Like why am I the only one in the situation? Like they feel like they're the only one in the situation but like they are not so." (Clinician)

Actions Taken to Address Early Psychosis

To address their own or their loved one's early psychosis, it was common for patients and caregivers to seek help through religious or traditional means. Participants described seeking counsel from church leaders, visiting traditional or faith healing prayer camps (locations where prophets or church leaders house and provide faith healing services to individuals with mental and/or physical ailments) within their communities, and initiating herbal remedies. These steps often served as the initial action taken, delaying initiation of treatment within the formal health care system. One caregiver described starting to take action toward early psychosis support, "…when the child's condition first came about, his mother took him to some churches and prayer camps which didn't help. I didn't like those places because some of the churches can deceive you and ask you to bring some money, buy all sorts of things which will result in no improvement in their health." Clinicians also described patients arriving at APH following engagement with spiritual healing approaches. One clinician said, "…but the first point of contact is either a religious leader or the herbalist. And then if that fails…if there is an acute or an overwhelming agitation that they cannot control, that's the time that they show up to us." People often consulted their immediate social networks for help. One caregiver said, "I was there one day with a friend of mine [who] told me he knew someone who struggled with similar issues and when the person was brought to this hospital [APH], that person got better and is even married now. I then decided to discuss it with my child's mother… She also agreed and we brought the child to this hospital."

Sources of Early Psychosis Support and Information

Patients and their caregivers described information and resources that were helpful in their journey to address early psychosis. Psychoeducation about psychosis and psychotic disorders, treatment options, and success stories was helpful to those impacted by early psychosis. One patient said, "I went to research about the sickness, schizophrenia…so I had knowledge about the sickness…And it has helped." A clinician described the usefulness of psychoeducation, "So with interacting with people, patients with early psychosis, one thing I noticed is that most of them are confused as to what they are experiencing. Because it's something new to them. So you have to take time to try to explain to them the symptoms and what they are going through."

Role of Caregivers in Early Psychosis Care

Caregivers of people with early psychosis play vital roles in encouraging their loved ones to engage in care from the formal health care system; providing comfort, listening to their loved ones' experiences, and strategizing about next steps; providing material support via housing, transportation, and financial support; and supporting medication adherence. Often, the extent and frequency of caregiver responsibilities associated with early psychosis care come at a cost to caregivers' mental health and can contribute to burnout. One caregiver described being spread thin before getting help: "So when he started experiencing symptoms…we did so many things. I did so many things, because of his condition…someone pointed out this place [APH], a mental hospital where we could get some help…truly, I have seen an improvement." Caregivers often provide medication adherence support. One clinician recounted, "…if the family members get to understand this and would help them to be taking their medications, providing them with the support to come for reviews, I mean eventually…we will see a change in their conditions."

Toll of Early Psychosis Caregiving on Caregivers

Providing comfort, listening, and strategizing about next steps for their loved ones' treatment was a key caregiver role described by participants. One caregiver said, "What helped us decide to take action was love. And a parent wouldn't just stand by while their child suffers." Participants consistently described caregivers providing vital material resources such as housing,

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transportation to mental health appointments, and financial support. Demonstrating the financial support required, one caregiver said, "This is the phone I use. Only this one. I can't go buy an expensive phone when my child has a mental disorder."

Actions taken to address early psychosis often take a toll on caregivers in the form of mental stress, burnout, and financial insecurity. One clinician described, "…some people do say 'why me?' Like 'why am I the only one in the situation?'" A caregiver described the hardships faced by parents of patients with early psychosis, "…the parent doesn't get it easy at all. You'll be worried and just be overthinking. Thinking about what the family needs and about providing food for them. And all that becomes extremely distressing when you also have yourself to take care of." Another caregiver said, "…you tend to question your abilities as a parent. You ask yourself if their situation is as a results or you not taking good care of them."

Barriers and Facilitators to Psychiatric Early Psychosis Care in Ghana

Focus group discussions with patients with early psychosis, caregivers, and clinicians illuminated several barriers that prevented families from seeking or achieving formal health care system–based early psychosis care. These discussions also highlighted motivating factors that facilitated facility-based care.

Barriers

Stigma related to receiving care at a psychiatric hospital was a commonly reported barrier to seeking care at APH or other formal health care facilities. Caregivers and patients described having to overcome their own negative beliefs about receiving care at APH. A caregiver said, "…my son after finding out I was bringing him here got aggressive and didn't want to come. He had to be boxed in in the taxi by three people...But after talking with the psychologist, he calmed down and admitted this wasn't a place for 'mad' people." Caregivers, while grateful for the care received at APH, expressed preference for the hospital to no longer be called a "psychiatric" hospital. One caregiver reported, "The name of this place, that's 'Psychiatric Hospital,' like a hospital for mentally ill persons. I think polishing or changing the name would be a good thing. Because there's a lot of stigma surrounding the psychiatric hospital."

Lack of prior knowledge about psychosis symptoms, mental health conditions, or APH often served as a barrier to seeking facility-based early psychosis care. One clinician said, "They don't believe this is what is going to work…they are skeptical because they don't believe…it's a medical problem." Another clinician reported, "…most of them are committed to superstitious things or religious-connected, religious problems, but not a mental health problem." Further, advice from within the community encouraging patients and caregivers to seek care from faith-based institutions also served as a barrier to facility-based care. This sometimes resulted in long delays before patients eventually sought care at APH. One caregiver recounted, "He experienced the symptoms for about two years before we brought him here. That was because people had convinced me to think it was a spiritual problem."

Practical limitations such as financial burden associated with medications and facility-based services, logistical factors, distance from the health facility, and lack of trust in the health care system capacity additionally served as barriers to facility-based early psychosis care. Patients expressed concern about their caregivers' ability to afford their treatment in the context of multiple financial obligations and limited finances. One patient reported, "If not for financial challenges I would've gotten help here way earlier than I did." Caregivers also expressed difficulty in financing transport and treatment for their loved ones. Clinicians described health care system resource limitations and their impact on patient experiences. One clinician said, "Sometimes you see a patient and you look at the progress you are making, you want to see the person probably the next week or the following week but then you…realize that the date you want to give them is fully booked …That kind of affects the efficacy of the therapy that we do for them."

Facilitators

Several factors motivated patients with early psychosis and their caregivers to seek facility-based early psychosis care. Prior knowledge or awareness about psychosis symptoms, mental health conditions, or APH sometimes encouraged facility-based care-seeking. One caregiver said, "We took him to church, and someone pointed out this place [APH]…saying he got the help he needed here, so he believed my son would also get help here…truly; I have seen an improvement." Clinicians described awareness-raising activities and familial experience with mental health as other avenues facilitating facility-based care. One clinician said, "During mental health awareness month, we see people trooping in. We ask them, 'How do you hear about our services?' And they would be like, 'I heard about you on the radio, I heard about it [APH] on TV.'"

Patients with early psychosis and caregivers who participated in focus group discussions expressed appreciation for the professional and competent care they received at APH, particularly emphasizing trust in their providers. One patient said, "…the doctors were ready to take care of me. Every time I call them, I get through to them, and they call me too to check up on me." Another patient said, "Okay, what made it easy was like this doctor, Dr. [name]. He was always at your beck and call…He was ready to listen, so I also told him a lot of things." As discussed in a prior section, caregivers were a leading facilitator for seeking and continuing facility-based services. Family members often heavily influence a loved one's initial care-seeking, financing, and logistical support, treatment adherence, and ultimately reintegration into the community.

Opportunities for Digital Health for Early Psychosis

We explored opportunities for enhancing early psychosis care by leveraging technology. Among patients with early psychosis, caregivers, and clinicians, we asked about their use of technology to support their typical daily activities, their use of technology to support psychoeducation or mental health, and their perceptions and feelings about the potential use of technology to support mental health. Common uses of technology in the daily lives of patients with early psychosis and caregivers included internet access for searching

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information, communicating with friends and family, and using social media. Extended and additional quotations about current care practices for early psychosis in Ghana are provided in Table 3.

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Table . Illustrative quotations about opportunities for digital mental health for early psychosis.

Unhelpful	Helpful
Typical interactions with technology in daily life	
(Patient) Uh once you even get the phone, you need money to maintain it you need money to maintain it and buy also data bundles or data plan that will allow you to surf the internet. So if you don't have it's like you're just holding a white elephant. It just (1:23:03, inaudible). You understand what I'm saying?	(Caregiver) .we use the phone for countless things. It's what the youth use to study. One of my sons in JHS 2 uses the phone for every school work, so the phone truly helps.
(Clinician) In addition to that, I've come to realize that some of the patients who experience especially insomnia, when you are trying to establish or come up with a sleep routine, just trying to understand their sleep behaviors, you notice that, they are up till like 2AM, 3AM What are you doing at that particular time? They will tell you mindless scrolling.	(Patient) For me, if I get a phone, I can use it to make phone calls and find a job. Things like that.
(Clinician) Because growing up, I mean, when you're always on your phone, your parents might scold why are you always on your phone? Come out, come and do this blah blah blah. So although genuinely you might be on the phone seeking help for whatever condition you are going through but you maybe misconstrued by your older caregivers. They might scold you for always being on your phone.	(Caregiver) I'm a seamstress so I use the phone to get dress inspirations online.I store client orders on the laptop. The TV is mounted in the shop so I watch some shows to release stress. I also what the news or movies or other TV shows.
(Patient) Yeah, sometimes the network is slow. Um it makes it difficult for you to access certain things on the internet.	(Patient) Through the phones, the phones and the you can you can acquire for scholarships for schools outside the country.
(Patient) Lack of financial support. People don't have the money or the resources to buy a mobile phone or a television or a laptop. They won't be updated on what is going on the internet.	(Caregiver) I use this same phone to update two of my friends about my son's condition and ask them to help him find a job. So if I have a phone, (1:11:35 - 1:11:44, inaudible). I use the phone for business. I'm a carpenter so I get booked over the phone. The phone helps with communication.
Experiences using technology to support mental health	
(Clinician) You know also I think that, that is the beauty of human, humanness. When it's totally technology it's almost robotic but then when you as a human or like professionals are able to consume that information and artistically tweak it to make it more relatable to the client. That's better than just consuming and then transferring robotic information.	(Caregiver) The little I'll add on is uh honestly, the phone really helps.It helps because when necessary, I can contact the doctor from the comfort of my home. The doctor will call me back if he's busy. The psychologist as well. So the phone is very necessary for communication And for things related to my child's mental health condition.
(Clinician) Male participant: So, sometimes I think they have their. they have their opinions, and they want them validated. So they, Uh, sort of Uh just pick out what will push what they want to say.	(Clinician) So with regards to the phones, I think some patients are able to contact me on the phone. And um sometimes they have complaints that ordinarily they wouldn't be able to come for reviews to you know talk about it. So we talk about it over the phone.
(Clinician) I think my reservation is the tendency it has to replace it [in-person mental health care] instead of complement it. So it's supposed to be a tool to complement our services, to complement our work. But it runs the risk of patients replacing it instead. .It's stands the risk of doing the opposite of what we intend it to do.	(Clinician) I think in the last couple of years, the advocacy around mental health has gone up a notch. So that helps as well. Because I remember back in medical school, a couple of colleagues and myself took it upon ourselves to do some kind of mental health awareness on social media, including YouTube.
(Clinician) One challenge that we particularly had to struggle with is internet connectivity. So the tool we are using is based on internet. In our part of the world, we don't have very fast internet. So there are so many interruptions.And then, also, even when the internet is available, it comes at a high cost.	(Patient) Female participant 1: As for me, I used the TV. Sometimes I watch Nigerian movies with moral lessons that make you calm and happy. So that's what I often use. Male translator: Do those movies include situations similar to your condition? Female participant 1: Yes. Sometimes, I see things that I've also experienced so when that happens, I pick a few things from the movie, which reduces overthinking.
Perceptions and feelings about digital mental health	
(Clinician) So usually they will attribute apps to being foreign.there are a lot of conspiracy theories about apps and you know downloading stuff on your phone.These are people who already have some delusions, some people, I mean those are some of the cultural things that are going to. play (out) when it comes to using apps.	(Patient) It can also help you get more information about your health or some remedies or care.
(Clinician) I was just worried of the legality, like legal issues when it comes to our digital care. Like, will the physician take that responsibility or duty of care? Because if the client should do something wrong from the app, what will be your responsibility (as a clinician)? Those are the things I'm also worried about.	(Caregiver) You guys can educate us on the drugs prescribed so that we can search and know exactly what the drug looks like before purchase.

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Unhelpful	Helpful
(Clinician) If I have to do reading everything, going through the menu, having to scroll through it and then download the documents and have to do everything all together, it's really very difficult for our clients to want to engage with such apps.	(Clinician) Personally, I think there are a lot of pitfalls in treatment and barriers we face .I think for me it's interesting to see the merge; how technology can bridge the gap in our treatment plans and help with like seeing patients and um trying to break the barrier basically.
(Clinician) And sometimes in that regard [using a phone for providing mental health care], it's hard to put certain boundaries. Maybe initially it helps. You're able to follow up, make sure the patient comes back for reviews. Then the patients, when it's time to go off that medium, they insist on still remaining there.	(Clinician) I just quite excited about the fact that it might make my clients' life easier in terms of having to come to the hospital every time they are feeling some distress or having to call somebody they might not reach. I just feel like digital mental health interventions would make their journey to recovery much easier and it'll also prevent a relapse like much better than if you keep coming and going.

Experiences Using Technology to Support Mental Health

Patients with early psychosis and caregivers found technology helpful in supporting their search for information about mental health conditions and communicating with care providers. Caregivers highlighted the convenience of using their phones to reach out to providers from their homes. This sentiment was supported by clinicians, who noted that technology helps caregivers share concerns or ask questions that otherwise might not be expressed. One clinician said, "…some patients are able to contact me on the phone... sometimes they have complaints that ordinarily they wouldn't be able to come for reviews [to address]." Participants also reported using technology to manage mental distress. One early psychosis patient said, "You also get some kind of reassurance when you listen to songs or sermons on the radio." Another patient said, "Sometimes I watch Nigerian movies with moral lessons that make you calm and happy…I see things that I've also experienced so when that happens, I pick a few things from the movie, which reduces overthinking."

Potential of Digital Health to Address Barriers

Generally, participants perceived that digital health for early psychosis could improve understanding of symptoms, enhance mental health support between facility-based visits, and encourage continuity of care. One caregiver noted that a digital support tool could reduce challenges with identifying authentic medications: "…you guys can educate us on the drugs prescribed so that we can search and know exactly what the drug looks like before purchase." One clinician felt that introducing a digital support tool could reduce cultural stigma around mental health: "…more advocacy for specific psychosis cases and creating awareness about what exactly goes into psychosis would be a very good start toward minimizing the stigma and then promoting people's health-seeking behaviors."

Concerns About Implementing Digital Mental Health

Early psychosis clinicians also expressed some negative perceptions about potential digital approaches. In contrast to the clinician who felt a digital tool could support continuity of care, another felt digital approaches could influence discontinuation of care. One clinician said, "Maybe initially it helps. You're able to follow up, make sure the patient comes back for reviews. Then the patients, when it's time to go off that medium [technology], they insist on still remaining there." Another clinician was concerned that digital tools could worsen delusional beliefs, "…there are a lot of conspiracy theories about apps and you know downloading stuff on your phone…These are people who already have some delusions…those are some of the cultural things that are going to… play (out) when it comes to using apps." Clinicians also emphasized the importance of a thoughtful introduction of a digital intervention for early psychosis by appropriate stakeholders to encourage trust and dispel perceptions of malintent: "It depends on who has accepted it and who is propagating it. If it's even a good intervention, but it's brought in by government that is leading it, it will typically be termed as 'oh, it is this political party and they are using it for this agenda to get votes.'"

Overall, participants remained hopeful about additional early psychosis support through a digital intervention. A caregiver said, "We will embrace knowledge or education on the use of technological devices."

Discussion

Principal Findings

In this qualitative study among patients with early psychosis, their caregivers, and their mental health care providers in Ghana, several themes emerged, exemplifying opportunities to enhance early psychosis care with digital mental health interventions (eg, smartphone-based apps, text-messaging interventions, telehealth interactions, and so on). Early psychosis care in the West African region is often delayed due to care-seeking from spiritual and traditional healing approaches and impeded or discontinued by practical barriers (eg, financial, logistical, real, or perceived health care system capacity limitations), as identified in other studies in Africa [37]. Substantial engagement by caregivers in early psychosis care is common in Ghana, which often vitally facilitates treatment yet imposes caregiver burnout and mental distress, as reported in other settings [38].

Youth experiencing their first episode of early psychosis in LMIC settings of West Africa represent a particularly vulnerable population. However, early intervention with effective treatment has the potential to improve their symptom trajectory, functioning dramatically, and ultimately integration in society [10,39]. Digital interventions to support early psychosis treatment are expanding globally, with demonstrated feasibility, acceptability, and preliminary efficacy to improve treatment outcomes [40], yet they do not currently exist in West Africa. Existing tools have strengths in leveraging evidence-based psychotherapies for early psychosis symptom management and treatment adherence promotion; however, they are not appropriate for West African contexts due to high literacy

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requirements and cultural irrelevance. Our study is one of the first to characterize patient, caregiver, and clinician perspectives about the use of digital interventions to address early psychosis in the African region. Focus on early intervention in psychosis programs in LMICs is generally low [41]. Our qualitative findings identify potential integration points, content, attributes, and unique strengths of digital modalities that could be leveraged to support patients with early psychosis and their caregivers in Ghana. Specifically, a tool that incorporates psychoeducation about early psychosis symptoms, effective treatment options, principles of evidence-based psychotherapies for self-management, and caregiver resources, integrated into in-person early psychosis care, could improve support for families in this context.

Digital Health Opportunities Within Current Early Psychosis Care Practices

In qualitative discussions, patients with early psychosis, caregivers, and clinicians illuminated persistent gaps in current early psychosis care in Ghana that could be alleviated with digital mental health interventions. Delays in seeking treatment were common, often shaped by a misunderstanding of symptoms and a lack of awareness of available mental health services. Overwhelmingly, participants described a dearth of information and resources within the community about mental health. Longer duration of untreated psychosis in LMICs compared to higher-income countries is well-documented [14,42]. Digital mental health awareness campaigns and media about the signs of early psychosis and available mental health services could be offered via frequented platforms such as WhatsApp (WhatsApp Inc), YouTube (YouTube LLC), and social media sites to normalize experiences and encourage earlier treatment engagement.

Participants discussed that psychoeducation at the point of first contact was especially important in improving their understanding of mental health conditions and justifying the importance of timely and consistent treatment. A digital platform offering early psychosis psychoeducation could reinforce information shared during clinical visits and provide patients and families with an accessible resource between appointments. Digital psychoeducation integrated into early psychosis care has been shown to enhance quality of care and support patient engagement and functional recovery in high-income settings [43]. Both patients and caregivers described challenges navigating and sustaining engagement with psychiatric services. Digital tools could be used in these settings to support mental health referral or appointment tracking, care navigation, treatment adherence support, and shared decision-making among families impacted by early psychosis, which could strengthen continuity of care. Digital care navigation is increasingly implemented globally to facilitate mental health care system engagement and retention [44].

The extensive role that caregivers play in facilitating early psychosis treatment in this setting suggests that digital interventions for early psychosis will be most effective if they integrate caregiver-specific content alongside patient-focused modules. In-person mental health services have strengths such as the ability to distribute medications, conduct necessary labs and symptom screenings, enable real-time clinical observation and risk assessment, and provide structure and social connection. Digital interventions integrated into routine care could leverage the strengths of in-person care while improving consistency and completeness of psychoeducation and therapeutic messages about early psychosis. Cultural values of family cohesion and community shared responsibility are assets in West Africa [45-47], contributing to high potential for early psychosis remission and functional recovery if caregivers are provided ample psychoeducation and resources in this setting. Caregivers in Ghana described significant emotional and financial stress, similar to other settings [38,45], underscoring the potential benefit of providing caregiver-specific content (eg, coping strategies, resources, and self-care approaches) via digital interventions to support the well-being of caregivers and their loved ones.

Our findings were specifically evaluated in the context of early psychosis, yet they likely have applicability to other mental health disorders. The first episode or early stage of psychosis is a crucial time for intervention with high potential to improve symptom trajectory. Thus, our findings about the potential for digital tools to fill current gaps in early intervention in Ghana are particularly salient for early psychosis. However, we note that findings about intervention content (psychoeducation, care navigation and tracking, and caregiver resources) and barriers to mental health care that could be overcome by digital tools likely apply to other mental health conditions (eg, depression, anxiety, bipolar disorder, and so on) in West Africa.

Digital Health Opportunities to Overcome Barriers and Leverage Facilitators of Facility-Based Early Psychosis Care

Participants described barriers to care-seeking and continuity within the mental health care system, including stigma around mental illness, spiritual or supernatural beliefs about symptoms, limited knowledge of psychosis and available care, financial and logistical challenges such as cost, distance, and long wait times, and lack of insight or reluctance to seek treatment. These findings are consistent with prior research in West Africa about barriers to mental health care [15,48,49]. Motivators for seeking or continuing care included positive experiences and trust in mental health care providers, success stories from community members, family support, and increased awareness of psychosis and treatment options.

Digital mental health interventions could supplement facility-based care, offering opportunities to overcome barriers while amplifying care facilitators. A commonly cited factor delaying facility-based early psychosis care was the attribution of psychosis symptoms to spiritual causes [15,48]. Digital interventions hold promise for counteracting misinformation about early psychosis in Ghana by integrating spiritual explanations for psychosis with messages that promote evidence-based etiologic understanding [21]. Further, participants expressed hesitancy to seek care at APH due to stigma historically associated with the institution as a former “lunatic asylum” under colonial rule [49]. Participants emphasized the importance of normalizing and destigmatizing mental health conditions in Ghana, which could be facilitated

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via digital content relevant to the cultural context. A recent meta-analysis demonstrated stigma-reduction effects of online interventions among people with mental health conditions [50]. Content delivered privately via digital modalities may reduce shame and foster acceptance. The on-demand and location-agnostic nature of digital interventions may circumvent common practical barriers to care, including transportation costs, long wait times, and extensive travel distances. Accessing psychoeducational materials in the privacy of one's home may encourage repeated engagement and deeper reflection, supporting the development of insight among patients with early psychosis.

Leveraging existing facilitators within the formal health care system–based care, digital interventions are an optimal modality to extend patient-provider communication and amplify trust-building. Expansion of telehealth in psychiatry accelerated during the COVID-19 pandemic to address barriers to in-person care, exemplifying the potential for digital approaches to improve patient-provider alliance [51]. Digital interventions could also include success stories as motivating examples, amplifying one of the approaches that clinicians voiced as effective in engaging and retaining families in treatment. Additionally, providing caregiver-focused content in a digital intervention could harness the integral influence of caregivers in facilitating early psychosis care, potentially expanding that influence and providing caregiver-specific well-being support.

Digital Health Opportunities Based on Participant Perceptions and Experiences

Focus groups with patients with early psychosis, caregivers, and clinicians concluded with discussions about their experiences with technology and perceptions of using technology to support early psychosis care. Our findings highlight the widespread use of phones for information seeking and communication—both to support typical daily tasks and specific mental health–related objectives. The ubiquity of mobile phone availability and the acceptability of digital mental health interventions for early psychosis were echoed in our team's survey results among more than 250 individuals affected by early psychosis in Ghana [36]. A digital early psychosis intervention could be embedded within this familiar hardware to improve uptake and usability. Participants also described seeking relaxation and stress reduction via digital content types (eg, radio sermons and television shows with moral messages). Digital tools could provide evidence-based psychoeducation and psychological skills tutorials relevant to early psychosis using culturally acceptable narrative storytelling formats [52]. Clinicians emphasized the importance of introducing a digital intervention via trustworthy, respected, and nonpartisan community leaders to optimize trust and uptake. Participants further emphasized that a digital intervention should be accessible offline in settings with low internet bandwidth and should use simple interfaces and limited written language to optimize equity.

Limitations

This qualitative study enrolled a small sample of patients with early psychosis, caregivers, and clinicians at APH. As such, participants were enrolled based on their care attendance at a single hospital in Accra, Ghana. Our findings may not be generalizable to patients not seeking facility-based care or those attending care in other facilities in the region. However, we intentionally situated our study at APH, the largest and most prominent psychiatric hospital in Ghana. Eligibility for patients with psychosis was based on receiving an initial psychosis diagnosis within the prior 5 years without continuous treatment exceeding 3 months. This definition aligned with that used by APH's early psychosis pilot program and reflects the long duration of untreated psychosis commonly observed in Ghana. This definition may be overly inclusive, such that it includes individuals who would not be considered "early psychosis" in other settings; however, our priority was alignment with the care context at APH. Since qualitative research was conducted via group discussions, our study may have been subject to social desirability bias, whereby participants tailored their responses to align with perceived expectations or desired responses, particularly given the sensitive and stigmatized nature of the topic. To counteract this potential bias, trained qualitative researchers opened each focus group by reinforcing the voluntary nature of study participation and the researchers' genuine interest in understanding participants' authentic experiences and perceptions.

Conclusions

Our qualitative study among those affected by early psychosis in Ghana highlights the potential for culturally grounded digital interventions to address acute gaps in early psychosis care in West Africa. By leveraging familiar technologies to disseminate psychoeducation, challenge stigmatizing beliefs, and support care continuity, digital tools may offer an acceptable and accessible complement to facility-based mental health services. Our findings suggest relevant content, design features, and contextual strengths that could be harnessed to develop a digital early psychosis intervention to support patients and their caregivers. Practical specifications such as offline-accessible, low-bandwidth, and low-literacy features are particularly relevant for digital mental health interventions in West African settings. As Ghana and other West African countries expand mental health service coverage, digital approaches represent a promising avenue to strengthen support for families affected by early psychosis. Overall, individuals affected by early psychosis in Ghana are open to digital interventions to enhance early psychosis treatment in West Africa. Future research should build on these findings to co-develop culturally relevant and evidence-based digital interventions for early psychosis in the region.

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Authors' Contributions

Conceptualization was carried out by AL, JA, and KO. Investigation was performed by AL, JA, DAA, KO, AOA, and DBZ. Methodology was developed by AL, JA, DAA, JT, BB, AB, SA, and KO. Project administration was overseen by AL, JA, AB, EQS, KO, and AOA. Resources were provided by KO, AOA, and DBZ. Data collection was conducted by AL, AB, EQS, DAA, AFO, MA, and CAD. The original draft of the manuscript was written by AL, AB, JA, JT, ED, and KO. Review and editing of the manuscript were carried out by AL, JA, AB, DAA, JT, SA, BB, EQS, ED, AFO, MA, CAD, AOA, DBZ, and KO.

Conflicts of Interest

DBZ has financial interests in Merlin LLC and Focus Technology. He has provided consultation services to Trusst Health, K Health, Boehringer Ingelheim, eQuility, Deep Valley Labs, Butler Hospital, and Otsuka Pharmaceuticals.

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Abbreviations

APH: Accra Psychiatric Hospital
LMIC: low- and middle-income country
REDCap: Research Electronic Data Capture

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Exploring Influencing Factors of Medication Adherence Among Chinese Patients With Alzheimer Disease: Delphi Study Informing Future Artificial Intelligence–Supported Interventions

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Abstract

Background: Alzheimer disease (AD) affects cognition, treatment adherence, family connections, and health care resource allocation. Most patients with AD have low adherence to medication therapy due to the limitations associated with cognitive impairment. Therefore, increasing the involvement of patients and their family members in medication management is important to improve treatment outcomes and reduce the burden of care.

Objective: This study explores the potential application of artificial intelligence (AI) in medication management for Chinese patients with early- to mid-stage AD focusing on enhancing medication adherence. The study first predicts and evaluates key factors through an online Delphi study, which provides a basis for their subsequent incorporation into the AI model as input variables to enable prediction of medication-taking behaviors. Since AI research in medication management for this population is still undeveloped, this paper further explores the multiple potentials of AI from a theoretical view, including drug dosage optimization, multidrug interaction detection, and family education support. It will provide a preliminary direction and theoretical basis for the development of an intelligent medication management system in the future.

Methods: The exploratory online Delphi study with no modification predicted the key factors influencing medication adherence. Based on the results, the study confirmed the potential of AI to improve adherence. Participation by 12 experts in 3 rounds systematically assessed the core elements influencing patients' adherence to their medication.

Results: Family care, social support, environmental factors, emotional support, and patient behaviors were identified as the primary factors influencing medication adherence among Chinese patients with AD. These factors were validated and ranked through iterative Delphi rounds, with family care and social support receiving the highest importance scores. The Wilcoxon signed-rank test indicated no significant difference between rounds (P=.06), supporting the stability of the consensus. These findings establish a foundational set of variables for AI systems that predict and enhance medication adherence.

Conclusions: This study highlights the critical factors affecting medication adherence by Chinese patients with AD. It was designed as an exploratory online Delphi study to identify and prioritize key influencing factors, rather than to validate a specific AI-based system, and the findings provide a theoretical foundation for future AI-informed interventions. The results also indicate theoretical potential roles for AI in supporting medication management, such as optimizing drug dosage, detecting multidrug interactions, and enhancing family education.

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KEYWORDS

artificial intelligence; medication adherence; adherence; Chinese health care system; online Delphi study; participatory design; design for health; AI-driven medication management

Introduction

Progression of the neurodegenerative disorder Alzheimer disease (AD) profoundly impairs cognitive performance and daily activities in older persons, and it has emerged as a critical public health issue due to the aging population worldwide [1,2]. Medication adherence is a critical factor influencing disease outcomes and quality of life in individuals with AD [3]. Nevertheless, deterioration of patients' cognitive abilities and memory significantly impedes their capacity to precisely and punctually administer medication, leading to poor adherence and suboptimal treatment effects [3-6]. In this context, medication management becomes highly dependent on the sustained involvement of family caregivers. Although family assistance is widely regarded as a key supportive strategy for improving medication adherence, this reliance also substantially

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increases the burden on family caregivers and does not consistently guarantee sustained and stable medication-taking behaviors [7].

Artificial intelligence (AI) technologies have recently been progressively used in health care, exhibiting significant potential for enhancing drug administration and adherence [8]. The advent of AI offers patients and their families innovative management options that enhance drug adherence and alleviate the stress on carers. Nonetheless, current research has concentrated on the overall patient demographic or the advancement of technology, while investigations into medication adherence to assist with medication management among Chinese patients with AD are scarce [5,6,9,10].

With disease progression and cognitive decline compromising patients' memory and capacity for independent medication management, family caregivers assume a central role in supporting medication management, underscoring the importance of understanding how caregivers can effectively assist patients in this process. Despite extensive research on medication adherence in AD, existing studies have predominantly focused on patients or formal health care systems, offering limited caregiver-centered insight into how medication management is enacted in everyday practice [11,12]. This is particularly evident in the Chinese context, where caregiving responsibilities are heavily family-based and differ substantially from the assumptions underlying many western health care models [13,14]. Moreover, although AI technologies have shown promise for supporting medication adherence, current research remains largely technology-driven, with insufficient attention to caregivers' real-world needs and decision-making processes, leaving the practical role of AI in supporting medication management inadequately defined [15]. Accordingly, this study focused on understanding how family caregivers support patients with medication management, with particular attention to how AI-related opportunities may align with caregivers' everyday knowledge, experiences, and decision-making, as highlighted in existing literature on medication adherence and user-centered health support.

Based on this, this study used an online Delphi study with no modification to assess and validate the key factors affecting medication adherence by Chinese patients with AD and core needs related to patient-centered medication management. In addition, this study aimed to explore the potential opportunities of AI for optimizing medication management and provide a scientific basis for enhancing therapeutic support for patients with AD.

The specific research questions (RQs) are as follows:

- RQ1: What are the influencing factors in medication adherence for Chinese patients with AD?
- RQ2: What is the relative importance of the factors influencing medication adherence by patients with AD?
- RQ3: What adherence factors can inform AI to improve adherence, and how can these factors be effectively used within AI systems?

Methods

Delphi Study

This study was designed as an exploratory online Delphi study to identify and prioritize key factors influencing medication use among Chinese patients with AD. The study was not intended to validate an AI-based system but to provide a theoretical foundation for future AI-informed interventions. This study was conducted and reported in accordance with the DelphiSTAR reporting guideline (Checklist 1) [16].

Medication adherence is affected by various intricate elements, including cognitive capacity, familial support, and cultural context [17-21]. This study incorporated professional insights from diverse fields such as gerontology, health, and design. The online Delphi study consensus from panelists incorporates multidisciplinary viewpoints via anonymity rounds, making it particularly suitable for cross-disciplinary research in health studies [22-24].

Research Framework

This research used a mixed methods approach using the online Delphi study to systematically investigate the primary factors influencing medication adherence by Chinese patients with AD. The study design incorporated qualitative and quantitative in 3 rounds. The rounds were designed to build a consensus of the data. Validity and reliability were confirmed through the data analysis.

The initial round gathered extensive expert opinions through semistructured interviews and developed a preliminary research framework. The data were analyzed using an inductive, bottom-up thematic analysis approach [25], allowing core themes to emerge from the data. This phase was qualitative and focused on identifying key themes. The study used Cohen kappa agreement to verify the credibility and reproducibility of the qualitative data [8]. In this study, interrater reliability was assessed based on 2 randomly selected respondents as an exploratory check of rating consistency. Given the limited sample size, this analysis was not intended to provide a definitive estimate of interrater agreement but rather to support the overall stability of the ratings. The small number of raters represents a limitation and should be considered when interpreting the results [26].

The second round synthesized and validated the outcomes of the first round. The final round amalgamated data from the preceding rounds to ascertain the weights of the factors and achieve consensus. The multiround feedback mechanism and anonymity significantly mitigate bias in group interactions, preserving the independence and impartiality of experts' viewpoints [27]. Due to the small sample and the fact that the sample did not satisfy a normal distribution, we used Wilcoxon tests [28] to test the differences between the results of round 2 and round 3. The number of Delphi rounds was predefined as three. The process was discontinued after the third round, as the comparison between rounds 2 and 3 showed no statistically significant differences, indicating stability in the expert ratings.

This study developed a theoretical framework for influencing elements in qualitative interviews. At the same time, the

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quantitative questionnaire empirically validated the real impact of these aspects through accurate measurements and statistical analysis, illustrating the complementary relationship between the two methodologies. Integrating qualitative and quantitative methodologies offers a comprehensive perspective on the subject while enhancing the scientific and practical significance of the findings.

Panelists

Participants were recruited through online advertisements posted on social media and professional networks from April 2023 to August 2023. The ethics approval and consent to participate subsection describe how informed consent was obtained. We selected 12 participants from an initial pool of 85 candidates who represented a range of professional fields related to AD. All candidates were screened according to predefined inclusion criteria to ensure relevance to the research aims. All 12 experts completed round 1, and the same panel participated in rounds 2 and 3, resulting in a 100% response rate across all rounds.

Specifically, participants were required to meet at least one of the following criteria: (1) having a professional background related to AD or health care practice (eg, clinicans or professionals); (2) possessing substantial practical experience in AD care, such as family or individuals involved in long-term patient support; (3) holding roles related to health policy, organizational decision-making, or service management; and (4) having interdisciplinary experience relevant to health technology, such as design or development of digital or smart health care solutions (including AI). In addition, participants with specific experience applying AI to medication management were given priority. However, due to the emerging nature of the field, no suitable candidates with such expertise were identified.

Notably, although the participants did not have direct practical experience with AI, it was spontaneously raised during discussions with smart packaging experts as a potential support tool. This led to actively and constructively exploring its future applications in health management and packaging interaction.

Table 1 shows the panelist selection.

Table . Criteria for selection of personnel for the panel of experts.

Filter criteria	Description	Status
Professional health care experience	Participants need to have a professional background related to Alzheimer disease (eg, neurologist).	✓
Practical experience	Candidates with extensive practical experience will be able to provide real-life examples and insights. Examples include patients' family members.	✓
Policy decision-makers	These include relevant organizational managers and policy decision-makers.	✓
Interdisciplinary experience	This criterion includes health technology (eg, AI[a] and smart packaging) designers.	✓
AI experience	Experience with practical applications of AI in medicine management is needed.	×
General AI knowledge	Understanding of fundamental concepts, capabilities, and limitations of AI, particularly in relation to health care applications, is needed.	✓

[a]AI: artificial intelligence.

The final panel consisted of 12 participants, including caregivers (n=7), organizational managers (n=1), neurologists (n=2), and designers or researchers with relevant experience (n=2). This composition ensured diverse perspectives on medication adherence, balancing clinical, practical, managerial, and design insights while remaining feasible in terms of temporal and geographical constraints. All interviews and questionnaires were conducted remotely via the internet, audio-recorded, and transcribed verbatim to ensure data accuracy and study efficiency [29]. The interviews were conducted via Zoom, and surveys were distributed through the Star Questionnaire on WeChat.

The selected panel size is consistent with methodological recommendations for Delphi studies, which generally suggest that expert panels of approximately 10 to 18 individuals can yield stable and meaningful consensus when participants possess relevant domain expertise [30,31]. Accordingly, the inclusion of 12 participants in this study falls within this recommended range and is considered sufficient to support a reliable and scientifically sound consensus process.

Round 1: Semistructured Interview

This study systematically examined the principal factors influencing medication adherence by patients with AD via semistructured interviews during the qualitative phase. Due to the inherent flexibility, semistructured interviews were suitable for eliciting comprehensive, context-dependent information from respondents regarding family roles, patient behavior patterns, and medication management [32].

The interview questions were developed based on a comprehensive literature review and were informed by theoretical perspectives on medication adherence and

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user-centered design. Questions assessing participants' understanding of AD and medications for its treatment (Q1) were included to evaluate caregivers' baseline health literacy, which is widely recognized as a key determinant of medication adherence in chronic and cognitive conditions [33]. Questions on family involvement (Q2, Q6) were grounded in research indicating that social and emotional support is critical for improving adherence among dementia patients [34,35]. Questions addressing patient behavior and treatment complexity (Q4, Q5) drew upon studies linking cognitive decline and polypharmacy to poor adherence [36,37]. Inquiries into patient experience and smart packaging (Q3, Q7, Q8) were inspired by emerging research on the role of assistive technologies and participatory design in health management [4,17]. A complete list of questions and their corresponding design rationale are provided in Multimedia Appendix 1.

In particular, the interviews included items exploring participants' experiences and perspectives regarding smart packaging. This focus aimed to understand how packaging design and usability factors might impact medication adherence behaviors among patients with AD and their caregivers.

Core themes were derived from interview data using a coding system and thematic analysis, with the researcher manually extracting codes to ensure depth and accuracy in the analysis. The study validated the interassessor coding consistency using Cohen kappa, an appropriate measure for assessing interassessor agreement while eliminating the influence of random consistency [8,38]. Following validation via this method, the study achieved a high degree of reliability in coding, thereby augmenting the credibility and reproducibility of the data. The detailed evaluation process is provided in Multimedia Appendix 2.

We identified and validated 20 major influences throughout the qualitative study phase, encompassing the primary domains of family roles, patient behavior patterns, and medication management. During the subsequent quantitative research phase, questionnaires were used further to assess the importance and influence of these identified elements.

Rounds 2 and 3: Questionnaire

This study evaluated the principal factors influencing medication adherence in patients with AD throughout the quantitative phase using two rounds of assessment using a Likert scale. The Likert scale spans from 1 to 5 and assesses the degree of participant influence on each component [39]. The first round of questionnaires collected participants' ratings for each factor from which we calculated a mean score. The second round of questionnaires provided feedback on the mean scores from the first round, allowing participants to confirm or adjust their ratings, thereby validating changes and monitoring the dynamics of cognitive processes [36,40]. This methodology integrates the exploratory characteristics of qualitative research with the validation aspects of quantitative research to augment the rigor of the findings. Figures 1 and 2 illustrate examples of the rating format used in Rounds 1 and 2, respectively. In both rounds, the same set of 20 factors corresponding to 20 questions was evaluated. The full list of evaluation factors is provided in Multimedia Appendix 3.

Figure 1. Example of the Likert scale in round 2.

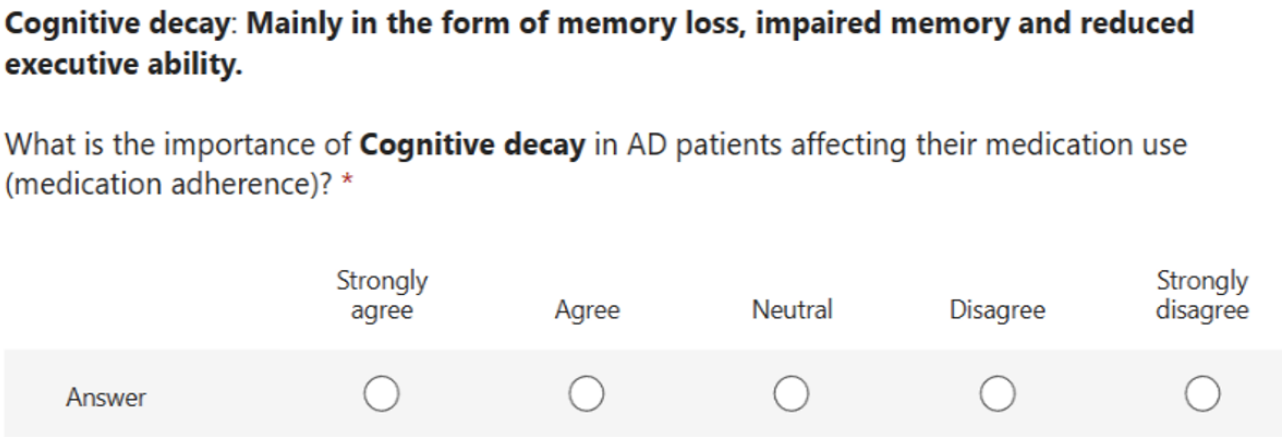

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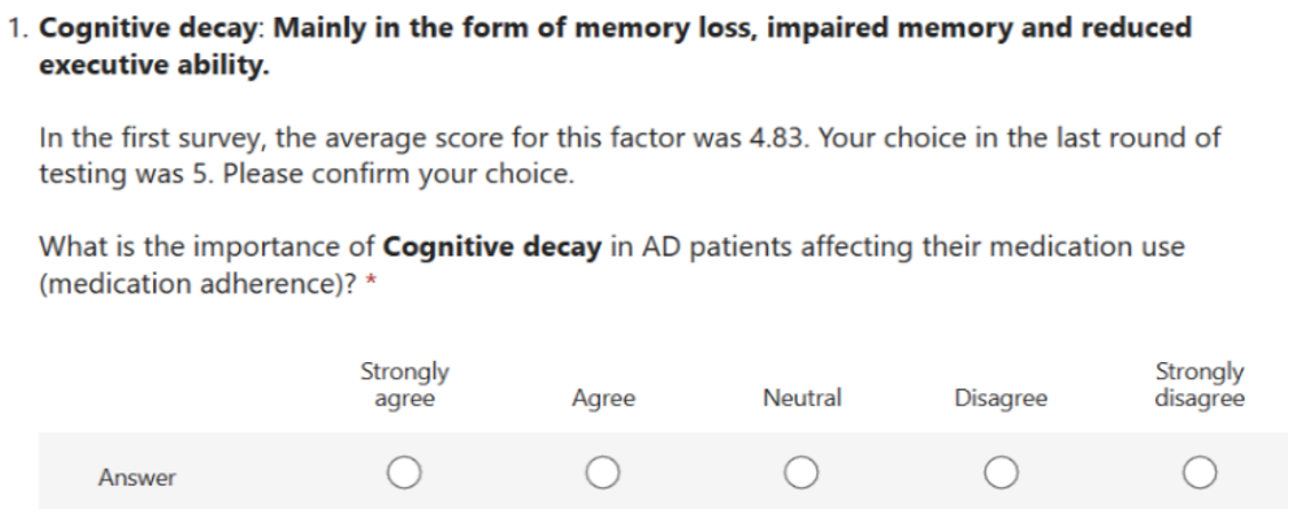
Figure 2. Example of the Likert scale in round 3.



We used the Wilcoxon test to evaluate score changes between the two rounds and to eliminate random variation. This nonparametric statistical technique is appropriate for comparing small samples and data that are not normally distributed [41]. The Wilcoxon test mitigates the influence of outliers on analytical outcomes by ordering the data, enhancing the results' robustness and reliability [42,43].

Ethical Considerations

This study was approved by the Ethics Committee of the University of Leeds (approval number: FAHC 22 - 002) and was conducted in accordance with the principles of the Declaration of Helsinki. All participants were provided with an information sheet outlining the study aims, procedures, voluntary nature of participation, and data protection measures. Written informed consent was obtained prior to participation through an opt-in procedure. Participants were informed of their right to withdraw at any time without penalty and the publication of their anonymized data.

Because the same individuals took part in both the questionnaire and interviews, the study data were treated as confidential rather than anonymous. The questionnaire collected personal data (name, email, profession, and expertise). Participants' identities were known to the researcher during data collection. Identifying information was removed from interview transcripts, and pseudonyms were used in all reporting. No compensation was offered. Data were stored securely on password-protected institutional devices in accordance with institutional data protection policies and UK GDPR [44].

Results

Round 1: Semistructured Interviews

This study examined the participation of family members of patients with AD in treatment, medication experiences, and patient behavior through remote semistructured interviews with 12 individuals. Each interview lasted 30 minutes to 45 minutes and was audio-recorded for later analysis. A categorical method was used to enhance the analysis of participants' perspectives and experiences [45]. Due to a small sample restriction, codes were manually derived from the semistructured interview data. Simultaneously, the integration of interviews with the literature analysis yielded 4 principal categories and 20 subcategories about medication adherence: familial and social support, patient self-management, health care service design, and problems in health care management. Table 2 illustrates the categories of the theme analysis, whereas Multimedia Appendix 2 presents the methodology for extracting the interview codes.

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Table . Theme analysis.

Themes and subthemes	Code
Family and social support	
Family and social support	Home care/daily care
Emotional support	Family companionship, treatment attitudes, emotional comprehension (eg, encouragement)
Therapeutic assistance	Family supervision, medication management, doctor-patient communication
Caregiver education	Nursing skills, effective communication, reduction of psychological burden, understanding of the condition
Family environment	Stability, motivation of family to cooperate with treatment, living alone, living situation
Patient self-management	
Cognitive decay	Disease progression, memory impairment, diminished executive ability, memory impairment
Treatment awareness	Resisting medication, lack of awareness
Complexity of medication regimens	Polypharmacy, dosing frequency, units per dose, and non-oral routes
Treatment motivation	Mental health, treatment beliefs and attitudes, treatment engagement
Habits and behavior	Smoking and drinking
Medical management challenge	
Progression of illness	Stage of illness, cognitive degeneration, aggravated, change of treatment program
Clinical progression	Therapeutic strategies: polypharmacy, drug type
Therapeutic effects	Drug side effects, drug effect, delayed drug effects, precise dosage
Doctor-patient communication	Communication clarity, information asymmetry, inconsistent medical advice, limited consultation time, caregiver involvement in decision-making, understanding of medication instructions
Financial factors	Treatment costs, financial burden
Medical service design	
Assistive tools	Application, pill box dividers, smart packaging
Technology and innovation	AI[a], AR[b], image processes, teletherapy, real-time monitoring
User demands and experience	Accessible design, information accessibility, messaging and understandability
Human-computer interaction	Drug packaging and labeling design, social support platform, health care accessibility and flexibility, medication management applications, supervise medication, filtering information
Cultural awareness	Weak culture awareness

[a]AI: artificial intelligence.

[b]AR: artificial reality.

Interrater Reliability: Calculation of Cohen Kappa Agreement

After concluding the first round of code analyses and assessments for this study, two questionnaire results (R1 and R2) were chosen randomly to test the consistency of scores. Banerjee et al [8] suggested that random sampling reduces bias and increases the sample's representativeness, which can increase the findings' credibility to some degree. Table 3 compares the code categories of participants R1 and R2 that are mapped to each other and correspond to the study's codes.

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Table . The comparison between the code categories of researcher R1 and R2.

Code categories	R2		
	0	1	Sum (%)
R1			
0	4	2	6 (0.25)
1	3	15	18 (0.75)
Sum (%)	7 (0.3)	17 (0.7)	24

In a binary system, “1” means agreeing with the initial code, and “0” means disagreeing with the initial code. Multimedia Appendix 2 displays the accord between the first and second evaluators regarding the initial codes. The analysis is shown in Table 3.

The observed rater agreement, Pa, is calculated first. This value may involve coincidence:

Pa=(N00+N11)/24

Pa=(4+15)/24=0.95

Multimedia Appendix 2 displays the likelihood that both raters will concur. The first opportunity is when they concur on the researcher’s initial code. This time, they record the same code (or a similar one). The second opportunity arises when respondents concur with one another but disagree with the researcher. The probability of coincidental agreement (Pe) is determined in the second stage. The following equation is used to calculate this probability:

$PE=(R1_0/6)\times(R2_0/7)+(R1_1/17)\times(R2_1/18)$

$Pe=0.25\times0.3+0.71\times0.75=0.6075\approx0.61$

where Pe is the probability of assuming chance agreement, $R1_0$represents the total codes where the first rater disagrees, $R1_1$ is the max number of codes the initial rater competes with, $R2_0$ is the number of codes the second rater disagrees with, and $R2_1$ is the number of codes the second rater accepted.

According to these equations, there is a 60% possibility that two raters will coincide by chance. The final Cohen kappa value was therefore: kappa=(Pa-Pe)/(1-Pe)=(0.95 - 0.61)/(1 - 0.61)=0.87≈0.9.

Cohen kappa ranges from 0 to 1, with 0 indicating no agreement and 1 indicating complete agreement. Based on this ratio, we found a value of 0.9. Raters agreed 90% of the time. Landis and Kock [46] calculated the kappa value to assess the Cohen value for data reliability. The “Strength of agreement” column in Table 4 shows that 0.9 represents almost flawless reliability. The protocol data analysis is in Table 4.

Table . Cohen kappa reliability and agreement values [46].

Value for reliability	Strength of agreement
<0.00	Poor
0.00 - 0.20	Slight
0.21 - 0.40	Fair
0.41 - 0.60	Moderate
0.61 - 0.80	Substantial
0.81 - 1.00	Almost perfect

Round 2: Questionnaire

The first Likert scale assessed 20 adherence variables for patients with AD. Using the Likert scale, the mean score for each question was calculated and ranked from highest to lowest to ascertain the significance of the factor. After the first round of quantitative evaluation, the mean score for each factor was determined, as shown in Table 5. The key factors were family care and social support, habits and behaviors, emotional support, home environment, treatment assistance, and doctor-patient communication.

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Table . Scale for assessing scores of influencing factors in Chinese patients with Alzheimer disease according to the Likert scale in round 2.

Number	Keywords	Score, mean
1	Family care and social support	4.83
2	Habits and behaviors	4.42
3	Emotional support	4.33
4	Family environment	4.33
5	Therapeutic assistance	4.25
6	Doctor-patient communication	4.17
7	Progression of illness	4.08
8	Cognitive decay	4.08
9	Treatment awareness	4.08
10	Financial factors	4
11	Complexity of medication regimens	4
12	Cultural awareness	3.92
13	Therapeutic effects	3.92
14	Caregiver education	3.75
15	Human-computer interaction	3.67
16	User demands and experience	3.67
17	Treatment motivation	3.58
18	Clinical progression	3.58
19	Assistive tools	3.08
20	Technology and innovation	2.92

Round 3: Questionnaire

We used the same scale for the third evaluation. It gave users the mean scores to evaluate the significance of each subcategory collected in the initial round. In addition, they could view the previous responses during the second round. The procedure was devised to allow panelists to review their answers from the previous round of testing and change their minds if necessary. By assessing adherence factors in patients with AD twice using a Likert scale, it was possible to assess the stability of relevant adherence influencing factors, to assess the efficacy and significance of the intervention, and to provide support for the individualization of the intervention and quality control of the study [39,47].

Evaluation of Test Results Using the Wilcoxon Test

We used the Wilcoxon test to compare arithmetic results between the second and third phases to assess consistency and inconsistency, facilitate the foundation of consensus, and exclude random variation, thereby enhancing the credibility of the study results [41,42]. Comparing the results of the two testing sessions revealed that the panelists altered their responses, resulting in changes in the SDs of some factors (Table 6) and demonstrating consensus among the panelists regarding the significance of each factor influencing adherence.

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Table . Standard deviation (SD) results of the second and third round tests.

Influencing factors	Round 2 SD	Round 3 SD
Family care and social support	0.37268	0.64010
Therapeutic assistance	0.55277	0.5
Caregiver education	1.01036	0.75920
Family environment	0.62361	0.89753
Emotional support	1.14261	0.43301
Cognitive decay	0.98601	0.49301
Treatment awareness	0.70711	0.70711
Complexity of medication regimens	0.70711	0.79931
Treatment motivation	1.11803	0.64010
Habits and behaviors	0.64010	0.68718
Progression of illness	0.62361	0.49301
Clinical progression	1.02740	0.79931
Therapeutic effects	1.18732	0.79931
Doctor-patient communication	0.98601	0.72169
Financial factors	1.29099	1.06719
Assistive tools	1.01036	1
Technology and innovation	0.75920	1.23322
User demands and experience	1.03749	0.86201
Human-computer interaction	0.74536	0.64010
Cultural awareness	0.86201	0.59512

Wilcoxon signed-rank tests were performed on the SDs from the second and third rounds to determine chance-excluded changes. The data in Table 5 were tested with SPSS (IBM Corp).

Of the values in Table 7, 14 had a negative ranking, indicating that the SD value in round 3 was less than in round 2. The 5 values that were ranked positively indicate that the SD increased in the second round. One of the values had a tied position, meaning that the second and third phases had the same value. The null hypothesis for this study's Wilcoxon test was "There is no change in standard deviation between the first and second rounds, and the difference between the first and second rounds follows a symmetric distribution around zero." The Wilcoxon signed-rank test results for *round 3 SD-round 2 SD* were z=–1.851 (P=.06) based on positive ranks.

Table . Statistics for the Wilcoxon signed-rank test.

Round 3 SD-round 2 SD	Results (n=20), n	Mean ranking	Sum of rankings
Negative rankings	14[a]	10.07	141.00
Positive rankings	5[b]	9.80	49.00
Ties	1[c]	—[d]	—

[a]Round 2 SD<round 1 SD.

[b]Round 2 SD>round 1 SD

[c]Round 2 SD=round 1 SD.

[d]Not applicable.

For all statistical analyses, a P value <.05 was considered statistically significant [48,49]. The Wilcoxon signed-rank test yielded a P value of .06, which exceeds the predefined significance threshold. The null hypothesis of no significant difference in SDs in rounds 2 and 3 cannot be rejected, indicating stability in the distribution of expert ratings across rounds. Therefore, the results remained consistent with those obtained in round 2 (more details in Table 5).

Discussion

Individual Perspectives: Medication Complexity and Individualized Needs

Pharmaceutical treatment of AD is notably complex, particularly with polypharmacy, where adherence poses a considerable challenge. Polypharmacy is a significant problem affecting drug

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adherence by patients with AD, as evidenced by the intricate nature of treatment regimens. Patients frequently need to administer numerous drugs, which imposes significant demands on the medication management capabilities of both patients and their families [34,37,50].

> *The timing and dosage of each medicine is different, and it takes much effort on my part to keep track and monitor, especially the measurement, timing, and temperature of the herbs.* [C5]

Moreover, drug-drug interactions exacerbate therapy uncertainty, especially for patients with AD who have various comorbidities [35]. Patients with comorbidities must manage both AD drugs and concurrent prescriptions for other diseases, such as antihypertensives or antidiabetics. This simultaneous treatment may result in pharmacokinetic and pharmacodynamic interactions that could provoke adverse reactions and heighten therapeutic risks [51].

> *My mother has diabetes and high blood pressure, and she needs so many different types of medication that I am concerned that they will conflict.* [C6]

Personal variations also substantially influence medication treatment. Hampel et al [52] observed that patients with mild and severe AD need distinct drug combinations owing to variations in phenotypic and underlying pathology. Nonetheless, the drug dose is frequently assessed in healthy older individuals during current drug development, a bias that overlooks patients' specific requirements [53]. Consequently, improving drug doses and treatment protocols to mitigate potential drug interactions and enhance the precision and customization of therapy has emerged as a research priority.

Family Perspectives: Caregiver Burden and Emotional Support

In the Chinese cultural framework, families significantly influence the care of patients with AD. Due to the traditional culture of "filial piety," family members frequently act as the principal carers for patients [54]. As the disease advances, the patient's self-care capacity diminishes [55], requiring more support from family carers, particularly for medication administration [56,57].

> *Our family lives in a rural area, and it's hard to follow the doctor's advice, especially since medication usage is often confusing.* [C2]

The family's emotional condition significantly influences the patient's motivation and adherence to medicine [58]. Emotional support alleviates patients' psychological distress and enhances their acceptance of and compliance with treatment [59]. Long-term care obligations impose significant psychological and physical strain on families, diminishing the efficacy of family oversight and potentially resulting in neglect of drug management. Furthermore, research indicates that the negative feelings of family members can elicit suspicion or resistance in patients, thereby impacting treatment outcomes [60].

> *Caring for patients requires so much time commitment that I have felt exhausted, and several times I have forgotten to remind my father to take his medication, which makes me crazy.* [C5]

Societal Perspective: Inadequate Resources and Cultural Influences

Elevated levels of social support have been demonstrated to markedly enhance patients' adherence to medicine [61]. The disproportionate allocation of health care resources and inadequate public awareness of AD in China's eastern and western regions substantially impact patient diagnosis and treatment rates [9,62].

> *Our family lives in a rural area, and it is hard to follow the doctor's advice, especially since medication usage is often confusing.* [C2]

Cultural influences are also major elements that affect drug adherence. Certain family members of patients reject western medication in favor of herbal remedies, citing worries regarding the adverse effects associated with western pharmaceuticals [63]. Moreover, families' inadequate comprehension of medical information and insufficient recognition of treatment significance undermine drug adherence [64]. This indicates that enhancing family members' awareness and acceptance of medication management through education and information is essential for addressing the issue [65].

Technological Perspective: Emerging Smart Technologies and the Potential of AI

Recent technological advancements have introduced new opportunities for enhancing medication adherence among patients with AD. Smart packaging, wearable monitoring devices, and mobile health apps have demonstrated potential for tracking medication-taking behaviors, sending reminders, and providing dynamic feedback to users [4,17]. These innovations allow for real-time behavioral data collection, offering the possibility of more timely and personalized adherence interventions.

> *I think if the medicine box could remind us automatically, it would be much easier. Sometimes we forget, and by the time we remember, it's already too late.* [C5]

Building upon these technological foundations, AI offers promising pathways to enhance medication management further [5,6]. By analyzing real-time adherence data captured through smart technologies, AI-driven systems could predict adherence risks, deliver customized reminders, optimize drug regimens (precision therapy), and provide tailored educational support to caregivers and patients [35,52,66,67]. This integration could significantly strengthen home-based care practices for AD management.

Opportunities and Challenges for AI

To address how the identified adherence-related factors may inform future AI-supported interventions, Figure 3 presents a conceptual map. Based on the identified adherence-related factors, two overarching opportunities for AI-supported intervention were identified: precision therapy and AI-enabled educational support. This framework does not represent an implemented technical system but rather illustrates how factors

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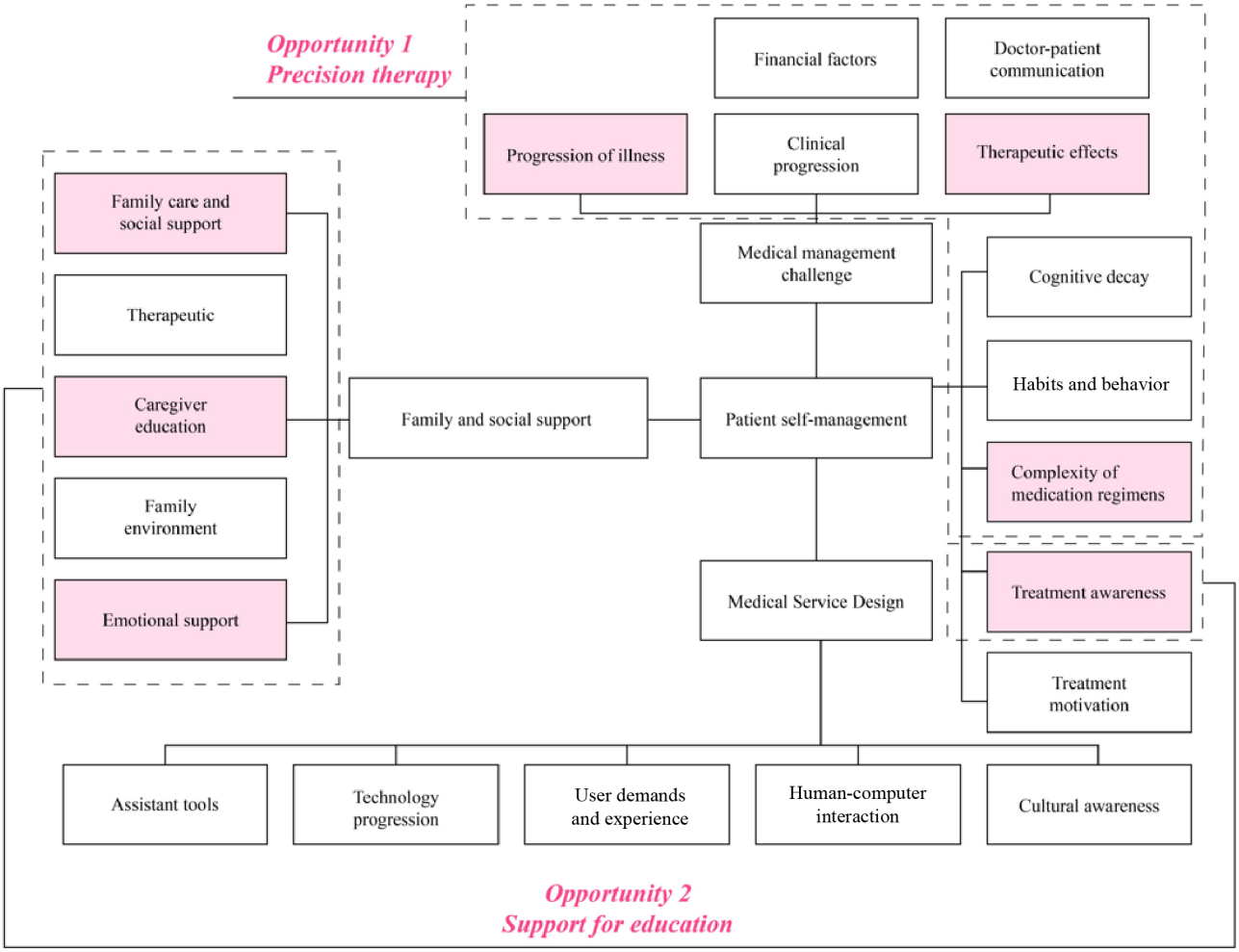
identified through the Delphi study could theoretically be operationalized within AI-assisted medication management.

Figure 3. Opportunities for artificial intelligence (AI) drug dose prediction using deep learning and machine learning to assist family members with medication management.



First, factors such as medication complexity, disease progression, and treatment variability highlight the potential role of precision therapy in supporting personalized medication management. These findings suggest that AI systems could, in principle, assist with dosage optimization and risk identification based on patient-specific characteristics [35,52,53,66,67].

Second, factors related to family support, treatment awareness, caregiver education, and emotional burden point to the potential value of AI-based educational and supportive functions. Such systems may support caregivers through tailored information delivery and decision support, thereby addressing gaps in knowledge and reducing caregiving burden [68,69].

It should be emphasized that these opportunities are conceptual rather than technical implementations. Practical challenges related to data availability and ethical considerations currently limit direct operationalization [70,71]. The proposed framework therefore serves as a theoretical foundation to inform future system design and empirical research.

Participants' insights into smart packaging revealed that such technologies could not only enhance medication adherence through design interventions but also serve as critical data collection touchpoints. Real-time tracking of medication behaviors through smart packaging can generate valuable adherence data, providing a foundation for developing future AI-driven systems.

Furthermore, participants' reflections highlighted that the requirements and barriers existing at the individual, family, and societal levels significantly influence medication management practices. These multilayered needs inform the design of AI applications, suggesting that future AI-driven interventions should focus on precision therapy and intelligent caregiving and incorporate educational support better to address the complex dynamics of AD care.

Precision Therapy

Deep learning (DL)–based drug dose prediction can introduce precision medicine to patient-centered drug management [72]. Precision medicine is the process of tailoring medicine to the health status of each patient in order to maximize the quality of health care [73,74].

The personalized treatment of AD via precision medicine has tremendous potential. First, precision medicine can more effectively address the challenges of polydrug management posed by the simultaneous administration of multiple medications [66,67,75]. In their study, Keine et al [35]

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hypothesized that polypharmacy would increase the risk of adverse drug reactions induced by drug interactions. The polypharmacy faced by older adults with AD is reflected in the multidrug treatment of AD and the need to take multiple medications to maintain life due to various underlying diseases. This emphasizes the imperative need for personalized drug management (ie, more precise drug dosage and drug action detection) to develop a more personalized and accurate drug management strategy. Second, individual differences are biased [52]. The concept of *precision medicine* proposed by Yiannopoulou and Papageorgiou [76] seeks to target the unique drug requirements of each patient to minimize the presence of risk factors and optimize the treatment of comorbidities. When developing drugs for AD, the dosage of drugs is frequently measured against the standard of healthy older adults. In his study, Xing [53] noted that the gender disparity among patients with AD will become an essential factor influencing precise and individualized treatment.

Precision treatment measurement management is inseparable from AI technologies for detection and prediction, such as machine learning (ML) and DL. In the field of patient medication management, AI presents numerous opportunities for the implementation of precision medicine. AI uses methods based on ML and DL to conduct simulation experiments with different concentrations to evaluate the effects of drugs on patients and detect differences in individual patient conditions [77,78]. Alternatively, ML classification methods can be used to screen and classify various drug collections and predict deleterious effects [79]. However, ethical considerations must be considered when using genetic or biomarker testing for early risk assessment and detection [80].

Precision medicine provides an important technological foundation and developmental direction for supporting family members when assisting with medication management. However, its current applications remain largely confined to clinical and research settings, with insufficient consideration of the roles and decision-making contexts of caregivers in everyday medication management.

Support for Education

AI-based educational support for AD can be helpful in several ways. Munteanu et al [68] pointed out that modern AI technology based on computer vision can provide personalized assistance to patients with AD. For example, Sharma and Rani [69] proposed a health internet framework based on DL to provide decision-making suggestions for patients with AD and their families. The framework integrates anomaly-tracking methods and Internet of Things–based assistance mechanisms to support patients with making correct decisions by informing them of incorrect decisions and providing reinforcement and supportive assistance.

AI-based educational support demonstrates clear potential to assist family caregivers by providing accessible information and decision-related guidance in the context of AD care. However, it is essential to note that, although AI plays a vital role in AD education and support, AI tools as supplementary tools cannot replace the role of doctors and professional medical teams [70,71]. This involves medical ethics responsibility.

Challenges

Although the development of AI in the medical field has excellent prospects, it still faces some challenges. First, the reliability of AI-based systems remains a key concern, particularly in medication management, where inaccurate predictions or system errors may lead to inappropriate dosing or missed medication [81,82].

Second, the effective use of AI technologies requires a level of digital literacy and sustained engagement that may not be readily achievable among family caregivers of people with AD in China. Many caregivers have limited experience with digital health technologies, which may reduce system adoption, increase cognitive burden, and compromise long-term usability [83].

In addition, the application of AI in medication management raises broader ethical and social concerns. These include questions surrounding responsibility and accountability when AI-generated recommendations are followed, as well as the risk of over-reliance on automated systems in situations that require human judgment and emotional sensitivity [84,85]. Such challenges highlight that AI-based solutions should function as supportive tools rather than replacements for human caregiving and their implementation must be carefully aligned with real-world caregiving practices and ethical considerations.

Future Studies

Future research should concentrate on integrating precision medicine principles with AI technologies to address the requirements of personalized drug management for AD patients. Priority must be given to optimizing drug dosage, modifying treatment protocols, and identifying multidrug interactions via AI while concurrently developing mobile apps and wearable technology integrated with the Internet of Things to facilitate effective medication management for family members. In addition, research needs to expand the focus on social communication and education; popularize AD information to enhance public awareness; and focus on cultural appropriateness, ethical issues, and technical dependability in technology diffusion to assure equity and sustainability.

Contribution and Limitations

Knowledge Contribution

The contributions of this study are primarily evident in two principal characteristics. First, this study systematically identified and synthesized key factors influencing medication adherence among Chinese patients with AD through an online Delphi study. By integrating multidisciplinary expert perspectives, the study provided an empirically grounded understanding of adherence-related challenges and established a conceptual foundation for future intervention development.

Second, this study focused on exploring the potential implications of these factors for future AI-supported medication management in a theoretical and exploratory manner rather than validating or implementing an AI-based system. By clarifying how adherence-related factors may inform the design of technology-assisted interventions, the study offers a preliminary framework to guide subsequent research aimed at supporting

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family caregivers and improving medication adherence among people with AD.

Research Limitations

This study elucidated the principal factors influencing medication adherence among Chinese patients with AD. It examined the prospective use of AI in medication management, establishing a theoretical basis for subsequent research in this domain. This study, however, possessed the following limitations. Owing to time limitations, only 12 participants completed the interviews, resulting in a limited sample size that may affect the generalizability of the findings. Second, the restricted representation of the core group, comprising 8 family members at various stages of the disease, may have complicated the data processing, potentially impacting the generalizability of the findings. Subsequent research should increase the sample size to better reflect family members and carers and refine the classification of patients by disease stage to augment the reliability and applicability of the results.

Moreover, although the panel size was sufficient for an exploratory Delphi study, there was a limited number of participants with direct AI implementation experience. Future studies should involve a broader range of specialists, such as neurologists, clinical pharmacists, and AI practitioners, to further validate and extend the findings. All of these will establish a more robust basis for an in-depth examination of the critical concerns in drug administration for people with AD.

Conclusion

This study thoroughly examined the factors impacting medication adherence and the demands of Chinese patients with AD from several viewpoints. It further examined the domain of AI, emphasizing the primary impacting elements and requirements, uncovering prospects in precision therapy and educational support. Precision therapy is anticipated to facilitate individualized drug management by using technologies like ML and DL. Furthermore, AI-driven educational assistance can furnish comprehensive information to patients' families and aid patients with making informed decisions. Although the potential applications of AI in medication management are vast, it is essential to address the issues of technological reliability, user experience, and ethical and societal ramifications.

Acknowledgments

We wish to express our deepest gratitude to all those who participated in planning and data collection as well as all participants of the study. The authors declare the use of generative artificial intelligence (GAI) in the research and writing process. According to the GAIDeT taxonomy (2025), the following tasks were delegated to GAI tools under full human supervision, such as proofreading and editing and some translation. The GAI tool used was Chat GPT5.2. Responsibility for the final manuscript lies entirely with the authors. GAI tools are not listed as authors and do not bear responsibility for the final outcomes.

Data Availability

The datasets generated and analyzed during this study are available from the corresponding author on reasonable request.

Authors' Contributions

Both authors contributed to the conception of the work. XZ designed the experiments, collected the data, and is the main author of this paper. RE guided and reviewed the paper.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Questions asked of reach respondent type.
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Multimedia Appendix 2
Kappa analysis process.
[DOCX File, 16 KB - formative_v10i1e89508_app2.docx]

Multimedia Appendix 3
Round 2 questionnaire.
[DOCX File, 52 KB - formative_v10i1e89508_app3.docx]

Checklist 1
Delphi studies in social and health sciences – recommendations for an interdisciplinary, standardized reporting (Delphi-STAR).
[DOCX File, 29 KB - formative_v10i1e89508_app4.docx]

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Abbreviations

AD: Alzheimer disease
AI: artificial intelligence
DL: deep learning
ML: machine learning
RQ: research question

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Designing Psychologically Grounded Artificial Intelligence for Supporting Bystander-Based Cyberaggression Intervention: Mixed Methods Exploratory Study

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Abstract

Background: Cyberaggression poses a growing threat to mental health, contributing to increased distress, reduced self-esteem, and other adverse psychosocial outcomes. Although bystander intervention can mitigate the escalation and impact of cyberaggression, individuals often lack the confidence, strategies, or language to respond effectively in these high-stakes online interactions. Advances in generative artificial intelligence (AI) present a novel opportunity to facilitate digital behavior change by assisting bystanders with contextually appropriate, theory-informed intervention messages that promote safer online environments and support mental well-being.

Objective: This mixed methods design study aimed to explore the feasibility of using generative AI to support bystander intervention in cyberaggression on social media. Specifically, we examined whether AI can generate effective responses aligned with established intervention strategies and how these responses are perceived in terms of their potential to de-escalate online harm and foster behavior change.

Methods: We collected 1000 real-world cyberaggression examples from public social media datasets and generated bystander intervention responses using 3 distinct prompt strategies: a generic policy reminder, a baseline GPT prompt, and a theory-driven GPT prompt (AllyGPT). To evaluate the responses, we conducted computational linguistic analyses to assess their psycholinguistic features and carried out a mixed methods evaluation. Three trained coders rated each message on favorability, conversational impact, and potential to change behavior and later participated in semistructured interviews to reflect on their evaluation process and perceptions of intervention effectiveness.

Results: Linguistic analyses revealed that baseline GPT responses exhibited more emotionally positive and authentic language compared to AllyGPT responses, which showed a more analytical and assertive tone. Policy reminder messages were linguistically rigid and lacked emotional nuance. Human evaluation results showed that AllyGPT responses received the highest effectiveness ratings for low-incivil cyberaggression cases in 2 dimensions (favorability and changing behavior), and baseline GPT works better for mid and high levels for all effectiveness dimensions. For medium- and high-incivility aggressions, baseline GPT responses received the highest ratings across all 3 dimensions of effectiveness (favorability, discussion-shifting potential, and likelihood of changing bullying behavior), followed by AllyGPT, with policy reminders rated lowest. Qualitative feedback further emphasized that baseline GPT responses were perceived as natural and inclusive, while AllyGPT responses, although grounded in psychological theory, were sometimes viewed as overly direct. Policy reminders were considered clear but lacked persuasive impact.

Conclusions: Our work showed that designing effective AI-generated bystander interventions requires a deep sensitivity to platform culture, social context, and user expectations. By combining psychological theory with adaptive, conversational design and ongoing feedback loops, future systems can better support bystanders, delivering interventions that are not only contextually appropriate but also socially resonant and behaviorally impactful. As such, this work serves as a foundation for scalable, human-centered AI systems that promote safer online spaces and users' mental well-being.

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KEYWORDS

cyberaggression; bystander intervention; generative artificial intelligence; AI; large language model; theory-driven intervention; digital well-being; mental health

Introduction

Background

In today's digitized world, cyberaggression has become a critical mental health concern, affecting individuals across age groups and platforms [1]. As an umbrella term encompassing behaviors such as cyberbullying, hate speech, and online harassment [2], cyberaggression carries substantial emotional and psychological weight [3]. Research consistently documents its adverse mental health impacts, including anxiety, depression, social withdrawal, and emotional dysregulation [4,5]. Meta-analyses further show that cybervictimization predicts depression, suicidal ideation, and suicide attempts among youth [6,7]. These harms extend beyond adolescence, with adults also facing targeted abuse that undermines dignity, safety, and civic participation [8-10]. Cyberaggression often co-occurs with offline aggression, amplifying psychological effects [11], and perpetrators themselves face risks such as low self-esteem, heightened aggression, and internalizing symptoms [12]. Moreover, studies indicate that vulnerable populations, such as those with existing emotional or social difficulties, may experience exacerbated distress when targeted online [13].

Recognizing these harms, scholars have examined strategies to prevent escalation and reduce impact [14-16]. One promising approach involves bystanders, witnesses to online harassment who can interrupt harmful interactions, defend victims, or report abuse [17]. Prior research has shown that online bystander intervention is often enacted through a range of behaviors beyond direct confrontation, including social norm signaling and emotional support for targets [18-21]. Research has highlighted that bystanders' active or passive involvement can substantially influence the course and outcomes of cyberaggression by enabling real-time de-escalation and reinforcing social norms without requiring formal moderation or punitive action [20,22,23]. Yet, many remain hesitant due to uncertainty, fear of retaliation, or lack of effective language [24,25]. This work focuses on reducing barriers to action, specifically, uncertainty about how to intervene and a lack of effective language, rather than directly addressing bystanders' underlying motivation or risk tolerance. Existing interventions often rely on static templates that fail to adapt to the nuances of diverse incidents [26]. Generative artificial intelligence (AI), particularly large language models (LLMs), offers new potential by producing scalable, human-like language for intervention [27]. However, few approaches are grounded in psychological theories of helping behavior, limiting their capacity to support intentional and effective action.

To address these gaps, this study introduces "AllyGPT," a theory-driven LLM designed to support online bystander interventions by scaffolding context-sensitive, psychologically grounded response strategies. By integrating psychologically grounded prompt design with the generative capacities of LLMs, we aim to produce context-sensitive, linguistically appropriate responses that empower bystanders to intervene effectively. This approach advances scalable, theory-informed support for safer digital spaces and improved mental well-being.

Related Work

The Role of Bystanders in Cyberaggression Intervention

Bystanders, those who witness but are not directly involved in cyberaggression, play a pivotal role in disrupting harmful dynamics [28]. Their responses vary in tone, target, and intention, ranging from aggressive actions (eg, threats and insults) to prosocial support [29,30]. Within cyberbullying, where victims often struggle to defend themselves, bystanders are particularly well studied [31]. Broadly, bystander interventions are categorized as aggressive, constructive, victim-focused, or constructive bullying-focused; aggressive strategies can escalate conflict [28,32], whereas constructive approaches, such as encouraging apologies, asking perpetrators to stop, or supporting victims with empathy or advice, are more effective in de-escalation [33-35]. Bystander interventions are uniquely embedded within ongoing interactions. Unlike post hoc moderation or long-term educational approaches, bystanders can intervene as harm emerges, offering immediate support to targets while signaling that aggressive behavior violates community norms [20,36]. This ability to reduce harm in real time and shape collective expectations makes bystander intervention a critical and complementary strategy, particularly in early-stage incidents where formal enforcement is yet to be enacted.

Large-scale discourse analyses reveal that bystanders use diverse strategies, including callouts, mocking, education, and moderation. For example, Ray et al [36] examined over 2 million Twitter and Reddit posts, finding that constructive approaches, such as educating perpetrators and mobilizing support, reduced hate speech and encouraged engagement, while mocking had little effect. Yet, intervention rates remained low, with bystanders active in only one of 6 Twitter threads and under 40% of Reddit discussions. These barriers highlight the need for scalable supports to help bystanders act effectively. Building on this, this study focuses on 5 constructive intervention subtypes, assessing both the linguistic quality (eg, tone and affect) and effectiveness (favorability, discussion shift, and behavior change) of LLM-generated responses.

The Potential of LLMs in Cyberaggression Bystander Intervention

LLMs have emerged as powerful tools for mitigating online harms, including cyberaggression [37,38]. Their capacity to understand and generate human-like language enables novel approaches to detecting harmful content, supporting victims, and fostering prosocial interactions [27]. For instance, Islam et al [37] proposed an LLM-based cyberbullying detection pipeline combining preprocessing, query generation, and classification for early intervention. Similarly, Vanpech et al [38] extended this approach using GPT-4 Vision to analyze images posted on

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Twitter and classify bullying content. These studies underscore LLMs' potential in detection-focused interventions. Beyond detection, LLMs have been applied to bystander support and education. For example, Hedderich et al [18] developed an LLM-based chatbot platform for K-12 classrooms, enabling educators to simulate social media interactions and teach bystander strategies. Similarly, Wu et al [39] generated personalized persuasive messages aligned with strategies such as comforting, evoking, and scaffolding, showing that LLMs can adapt interventions to users' contexts. Collectively, this work demonstrates growing interest in leveraging LLMs for intervention generation.

However, prior work has largely emphasized detection or educational use cases, leaving open questions about how LLMs can serve as in situ scaffolds for real-time bystander intervention during unfolding incidents of cyberaggression. In addition, prior studies emphasize technical alignment over psychological grounding [40]. Without integration of established bystander theories, LLM-generated interventions risk overlooking the cognitive and emotional processes driving real-world decisions. To address this gap, our study examines 5 intervention strategies rooted in bystander theory, using prompt engineering to generate responses that are linguistically appropriate, context aware, and psychologically informed. Therefore, we ask, "How can generative AI be designed to provide psychologically grounded, context-sensitive suggestions for bystanders intervening in cyberbullying scenarios?"

Study Purpose

The primary goal of this study was to explore the potential of generative AI to support scalable, psychologically grounded bystander intervention responses to cyberbullying. To meet this goal, this study aimed to address 3 objectives:

- To design prompt strategies informed by psychological theories of bystander behavior (eg, the 5 bystander intervention responses) for generating constructive, context-sensitive intervention messages using LLMs
- To evaluate the quality and effectiveness of AI-generated bystander intervention responses (eg, standard policy reminder, baseline GPT, and theory-driven GPT) across dimensions such as linguistic characteristics, favorability, potential for altering discussion and likelihood of changing aggressive behavior
- To generate design guidelines and theoretical insights for building safe, scalable, and psychologically informed AI systems that empower bystanders to intervene in harmful online interactions

We addressed the following research questions (RQs):

- RQ1: How do bystander intervention responses generated by (1) standard policy reminder, (2) baseline GPT, and (3) theory-driven AllyGPT differ in terms of psycholinguistic characteristics (eg, authoritative, emotional tone)?
- RQ2: How effective are bystander intervention responses generated by (1) standard policy reminder, (2) baseline GPT, and (3) theory-driven AllyGPT?

Methods

Study Overview

We collected publicly available datasets of real-world cyberaggression and developed 3 bystander intervention strategies reflecting varying levels of specificity and psychological framing. Using these strategies, we generated intervention responses. To address RQ1, we analyzed their linguistic and psychological characteristics with the Linguistic Inquiry and Word Count (LIWC) tool, assessing features such as tone, cognitive processes, emotionality, and authenticity. To address RQ2, we conducted a human-centered evaluation in which three trained external coders rated each response on (1) *perceived favorability*, (2) *potential to shift the discussion*, and (3) *likelihood of changing aggressive behavior*. Coders then participated in semistructured interviews to elaborate on their evaluation criteria, preferences, and reflections. Quantitative and qualitative analyses were conducted to compare psycholinguistic features and perceived effectiveness across strategies.

Ethical Considerations

The study was approved by Rutgers University's Institutional Review Board (Study ID: Pro2024001658). All coders provided informed consent prior to participation and were informed of their rights, including the ability to withdraw at any time without penalty. Given the potentially sensitive nature of the materials, coders were informed in advance about the content and provided with contact information for support resources if participation caused discomfort. Interview recordings and transcripts were deidentified prior to analysis, and all study data were stored on an institutional review board–approved, secure cloud server with access restricted to authorized research personnel only.

Data Collection

Cyberbullying Dataset

We collected 1000 cyberaggression examples from the 2 sources [41,42]. Of 1000 cyberaggression examples, 200 were collected from the dataset created by Huang et al [40], while 800 were collected from the dataset created by ElSherief et al [41].

Bystander Intervention Strategies

Overview

We had three bystander intervention strategies: (1) standard policy reminder, (2) baseline GPT, and (3) AllyGPT. Each condition supports different mechanisms that enable bystanders to progress toward intervention. Policy reminders act as normative interventions, signaling collective standards that legitimize action without direct confrontation [21]. Baseline GPT responses provide generic intervention scaffolds that reduce barriers to knowing how to act [24,43,44]. AllyGPT responses are theory-aligned, context-sensitive interventions that scaffold empathy, perspective-taking, or de-escalation to address cognitive and affective barriers to action [44-47]. Below, we explain how we designed our bystander intervention strategies.

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Strategy 1: Standard Policy Reminder

The following standard policy reminder was taken from the Reddit platform [48] , and the same reminder was applied as an intervention message to all cyberbullying examples:

> *We do not tolerate the harassment, threatening, or bullying of people on our site; nor do we tolerate communities dedicated to this behavior.*

Strategy 2: Baseline GPT

For the baseline GPT strategy, we used the following prompt to generate bystander intervention responses using the GPT-4o model. The same prompt was used to generate intervention responses for all cyberbullying examples: "Generate a bystander intervention response to the comment."

Strategy 3: AllyGPT

To tailor intervention messages to the specific context of each cyberaggression scenario, we designed a structured prompting framework in which GPT first assessed the level of incivility and direction of aggression. With the 2 dimensions, a decision tree (see below for details) was used to select the appropriate combination of bystander intervention strategies. The same prompt was used with GPT-4o to generate intervention responses for all cyberaggression examples. The full mapping between the aggression context and intervention strategy is detailed below.

The Theoretical Ground and Design of AllyGPT

The 5 Bystander Strategies Designed Based on Theories and/or Empirical Evidence in Psychology

We implemented 5 theoretically and empirically grounded strategies for prompting LLM-generated bystander intervention responses. Each strategy was derived from psychological literature and operationalized through specific prompts in the form of "dos and don'ts" to guide GPT responses. Table 1 presents a brief overview of the definition, psychological basis, and prompting guidelines for each bystander intervention (see Multimedia Appendix 1 for full details).

Table . Definition, psychological ground, and prompt of the 5 bystander intervention strategies.

Strategy	Definition	Psychological basis	Prompting guidelines
Calling out the aggressive behavior	Explicitly points out the harm or injustice in the aggressive behavior and may question or ask the perpetrator to stop.	Defended victims report higher self-esteem and less distress than those without defenders [49].	• *Do*: Focus on the content of the aggression. • *Don't*: Avoid swearing or personal insults.
Correcting misinformation	Offers factual corrections using evidence, statistics, or historical context to challenge harmful or misleading claims.	Educative interventions are shown to de-escalate online discourse and create long-term learning moments [36,50].	• *Do*: Focus on facts and the behavior, not the person. • *Don't*: Avoid engaging in back-and-forth debate.
Validating and expressing empathy	Acknowledges the victim's emotional experience and offers emotional support.	Empathic responses increase self-esteem and coping and mitigate the negative effects of aggression [51-53].	• *Do*: Validate the victim's specific statements and show care and understanding. • *Don't*: Avoid making assumptions or escalating the conflict.
Advising disengagement	Encourages the victim to leave the conversation or disengage from the harmful interaction to prioritize their well-being.	Supportive disengagement can improve emotional adjustment and empower the victim without implying blame [54,55].	• *Do*: Empower the victim to prioritize self-care and autonomy. • *Don't*: Avoid commands or framing exit as weakness.
5.Redirecting the discussion	Shifts the conversation away from the aggression topic to defuse tension and divert attention from the perpetrator.	Topic redirection minimizes exposure to harm and helps de-escalate aggression [56].	• *Do*: Introduce a new, unrelated topic to shift attention. • *Don't*: Avoid acknowledging or directly responding to the aggressive content.

Decision Tree for Selecting Strategies and Drafting Bystander Intervention Message

To generate bystander intervention responses, we prompted AllyGPT to first assess each aggressive message based on 2 dimensions: incivility level (low, moderate, or high) and direction (group targeted vs individual targeted). These dimensions are grounded in bystander intervention theory and empirical research on cyberaggression, which identifies severity appraisal and target identifiability as primary determinants of whether and how bystanders intervene. Bystander intervention theory conceptualizes intervention as a sequential process in which individuals must first interpret an event as sufficiently serious to warrant action and to assume responsibility [44], while empirical studies show that incident severity strongly predicts intervention likelihood and interacts with empathy and responsibility attribution [45]. Direction further shapes responses by influencing emotional salience, perceived responsibility, and social visibility: person-targeted aggression elicits clearer moral judgments and stronger empathic engagement, whereas group-targeted harm more often leads to diffusion of responsibility and reduced effectiveness of individualized

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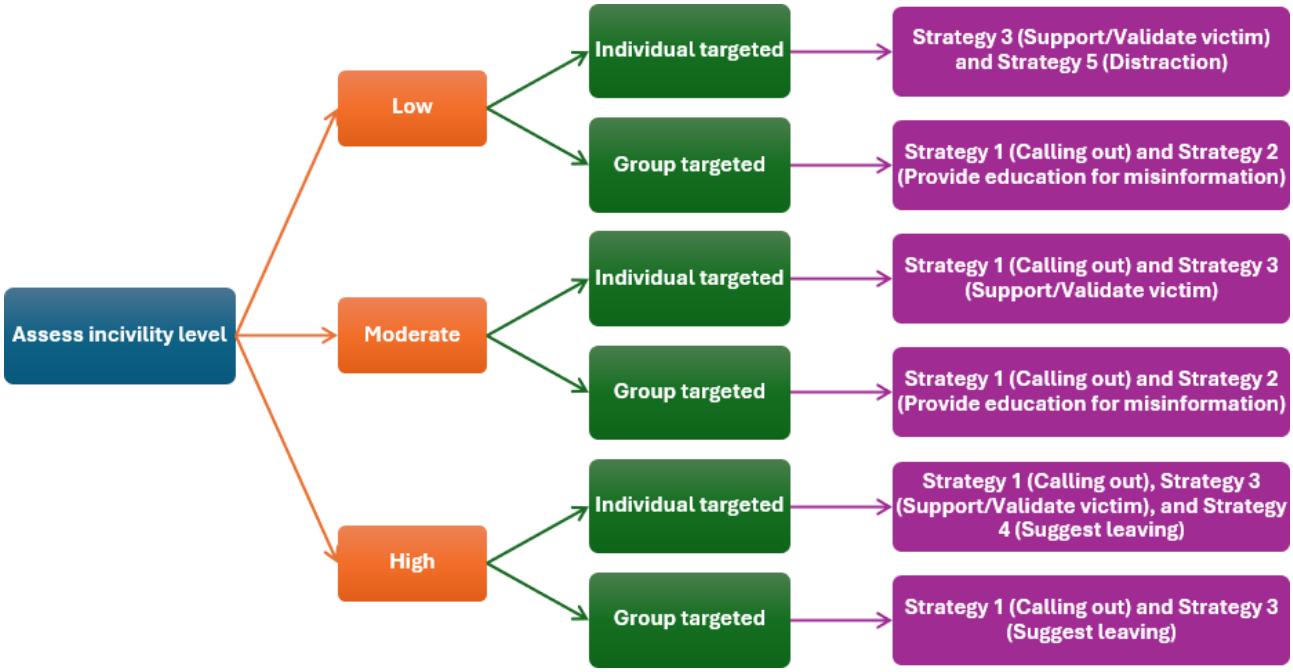
responses [46]. Prior work also suggests that empathy-focused strategies are more effective in lower-severity contexts, while assertive or confrontational approaches are more appropriate in higher-severity or public settings [47]. Together, these insights informed AllyGPT's selection and conditional combination of intervention strategies to generate context-sensitive bystander responses. Below, we present the prompt encoding this decision logic.

1. Assess the *incivility level* of the aggressive message:
   a. If the message does not contain profane language such as name-calling, swearing, or threatening content, then the incivility level of the message will be *low*.
   b. If the message contains name-calling, slang, or swearing content but does not include threats of violence or aggression, then the incivility level of the message will be *moderate*.
   c. If the message contains threats, violence, or aggression, then the incivility level of the message will be *high*.
2. Then assess the *direction* of the bullying:
   a. If the message is more general and not person-specific (eg, vague insults, general hateful comments, and directed at a group but not an individual), then the direction is *group targeted*.
   b. If the message is person-specific and targets an individual (eg, quoting a certain user's ID or name and personal attacks), then the direction is *individual targeted*.
3. Consider both the incivility level and direction to select and combine the most effective strategies, following the rationale that:
   a. If the message contains low to moderate incivility, consider educational approaches and distract attention; otherwise, prioritize removing the potential victim from further harm by suggesting leaving; and
   b. If aggression is person specific and targets an individual, prioritize emotional support for the victim and removing the victim from further harm by suggesting leaving; otherwise, focus on education for misinformation and distracting attention.
4. Refer to the following suggestion for bystander intervention is made for different types of cyberaggression statements (Figure 1).

Figure 1. Visualized decision tree to generate bystander intervention responses.



Through the above process, we generated 3 responses for each of the 1000 cyberaggression scenarios, resulting in a total of 3000 bystander responses (1000 per strategy) across the three intervention approaches: (1) standard policy reminder, (2) baseline GPT, and (3) AllyGPT.

Evaluation Metrics

Linguistic Differences

To evaluate the linguistic differences across bystander intervention responses generated by 3 different strategies, we used the LIWC [57] to extract several linguistic features from the bystander responses. The features we extracted in this study included word count (total number of words), words per sentence (average sentence length), analytical thinking (degree of logical and formal thinking), authenticity (extent of honest and genuine expression), positive tone (prevalence of positive emotional language), negative tone (prevalence of negative emotional language), and netspeak (use of internet-specific shorthand and casual online expressions, eg, "lol" and "brb").

Perceived Effectiveness Measures

The effectiveness of the bystander intervention messages was evaluated using three variables: (1) *perceived favorability*, (2) *discussion shift*, and (3) *behavior change*. Three trained coders independently rated each bystander intervention response on 3 effectiveness dimensions using a 5-point Likert-type scale (1=strongly disagree and 5=strongly agree). The first dimension,

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perceived favorability, assessed the extent to which a response would likely be viewed positively by other social media users (mean 3.88, SD 0.88). The second dimension, *discussion shift*, evaluated the potential for the response to redirect the conversation toward a more positive, objective, and/or less antagonistic tone (mean 3.95, SD 0.81). The third dimension, *behavior change*, measured the perceived likelihood of the response influencing the bully's or agitator's future online behavior (mean 3.45, SD 0.86).

Each coder was responsible for evaluating bystander intervention responses associated with all 1000 cyberaggression scenarios, ensuring exposure to all 3 intervention strategies. To achieve this, the intervention responses were divided into 3 batches so that each coder rated one-third of the responses from each strategy. For example, coder 1 evaluated strategy 1 responses from batch 1 (aggressive messages 1 - 333), strategy 2 responses from batch 2 (messages 334 - 666), and strategy 3 responses from batch 3 (messages 667 - 1000; Table 2). This approach ensured that each coder rated the effectiveness of intervention responses across all 3 strategies while covering the full set of 1000 cyberaggression examples. Table 3 presents the example aggressive messages, bystander responses generated from the 3 strategies, and coder ratings of the 3 effectiveness variables.

Table . Distribution of coding assignments across 1000 cyberaggression examples, ensuring each coder evaluated responses from all 3 bystander intervention strategies.

Batches	Bystander response strategy 1 (n=1000)	Bystander response strategy 2 (n=1000)	Bystander response strategy 3 (n=3000)
Batch 1: aggressive messages 1 - 333	Coder 1	Coder 3	Coder 2
Batch 2: aggressive messages 334 - 666	Coder 2	Coder 1	Coder 3
Batch 3: aggressive messages 667 - 1000	Coder 3	Coder 2	Coder 1

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Table . Example aggressive messages, bystander responses generated by the 3 intervention strategies, and the effectiveness scores rated by the coders (in the order of favorability or discussion shift and behavior change).

Aggressive message and intervention strategies	Bystander responses	Effectiveness scores
Why are black fathers and Shaq's free throw attempts the same? They're always missing		
Policy reminder	"We do not tolerate harassment, threatening, or bullying of people on our site; nor do we tolerate communities dedicated to this behavior."	4/4/3
Baseline GPT	"It's important to spread positivity and respect in our community. Racist or derogatory jokes are not only offensive but also foster a harmful environment. Let's aim for constructive and respectful interaction instead."	4/4/3
AllyGPT	"Such stereotyping is decidedly offensive and it's not okay to continue this conversation in a disrespectful manner. To the person affected by this, please know that your value is not determined by such uninformed comments. This conversation is becoming progressively more toxic, and it might be beneficial for you to step away for a while."	5/5/5
mim torse lottttttta ugly white people here . are you mad at the immigrants cuz they sexy		
Policy reminder	"We do not tolerate harassment, threatening, or bullying of people on our site; nor do we tolerate communities dedicated to this behavior."	4/4/3
Baseline GPT	"There's definitely room for diverse opinions here, but let's aim to maintain respect for all members and avoid generalizations. Beauty, like attractiveness, is subjective and varies greatly between individuals, cultures, and societies. Let's remember, every ethnicity has its own unique charm and attractiveness. Regarding the immigration issue, it's a complex topic and it's possible to have a meaningful discussion without degrading each other."	5/5/4
AllyGPT	"The comment you're making is disrespectful and propagates unfounded stereotypes. Instead of focusing on differences, let's embrace our shared humanity. Each person is unique, and beauty is subjective and multi-faceted. In regards to immigration, it's important to remember that people immigrate for diverse reasons, and making assumptions based on their appearance is unhelpful and can spread misinformation."	4/4/4

Three graduate students in psychology (2 doctoral and one master's) were trained as independent raters. Training involved a structured, multistep process combining group instruction, guided practice, and independent rating. Coders were first introduced to the study purpose, research questions, and their own experiences with social media and cyberaggression. They were then provided with a detailed coding manual containing sample scenarios, example ratings, and rationales for the 3 effectiveness dimensions (favorability, discussion shift, and behavior change).

As a group, coders practiced rating 3 scenarios, followed by discussion and feedback to build consensus. They next completed independent practice ratings on 3 additional scenarios, which were reviewed and discussed to refine consistency. Coders were also trained on the Qualtrics survey platform, including rating procedures and response scales. To establish intercoder reliability, each independently rated 25 additional scenarios; consensus agreement of 80% or greater was required before proceeding to the full study (1000 scenarios per coder and 3000 total).

A 1-hour booster session was conducted midway through coding to address procedural questions, clarify operational definitions, and review rating criteria. Coders jointly discussed 2 example responses, examining features linked to higher versus lower ratings across the dimensions. Intercoder agreement was computed using a group consensus method. Individual coder ratings for each of the 25 scenarios and the 3 effectiveness dimensions (perceived favorability, discussion shift, and behavior change) were compared to the group mean ratings. Agreement was considered achieved when coder ratings fell

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within one point of the group mean. For the 3 effectiveness dimensions, the Krippendorff α was 0.73 for favorability, 0.84 for discussion shift, and 0.89 for behavior change.

Semistructured Interview

After completing the survey, each coder participated in a separate semistructured exit interview conducted by 2 researchers. Through the interviews, we explored coders' views on the effectiveness of responses generated by the 3 strategies, their overall coding experience, and any questions about the study. To aid recall, coders were reminded of the rating scales and were shown their average scores across the 3 effectiveness dimensions. They also reviewed 2 example aggression scenarios with responses from all strategies: one where baseline GPT outperformed AllyGPT and another where AllyGPT outperformed baseline GPT across all dimensions. Examples were selected to ensure consistent trends across dimensions, randomly sampled from different coding batches, and paired with the corresponding policy reminder. Interviews lasted about 50 minutes, were audio recorded, transcribed, and deidentified. Coders received compensation for their participation.

Data Analysis Approach

For RQ1, we used a set of *t* tests to compare the linguistic characteristics of bystander intervention responses generated by baseline GPT and AllyGPT. An α of .05 was used to determine the statistical significance of the mean difference between the 2 intervention strategies. As all policy reminders consisted of identical messages across all cases, their linguistic features (eg, word count and positive words) exhibited zero variance, and they were excluded from statistical analyses comparing mean differences across strategies. Descriptive statistics for standard policy reminders are reported separately to provide a benchmark, while statistical comparisons were conducted between AllyGPT and baseline GPT, where variation in generated responses allowed for meaningful analysis.

To address RQ2, we used a set of ANOVA and *t* tests to compare the average perceived effectiveness rating across (1) 3 different bystander intervention strategies, (2) incivility level, and (3) the direction of aggression (individual vs group). An α of .05 was used to determine the statistical significance of the mean difference across the 3 intervention strategies. Next, we conducted a series of robust general linear models using heteroskedasticity-consistent SEs to examine the main and interaction effects of intervention strategy (policy reminder, baseline GPT, and AllyGPT), incivility level (low, moderate, and high), and direction of aggression (group targeted vs individual targeted) on the 3 outcome measures. Pairwise contrasts were conducted to compare strategy conditions, and significant interactions were further probed using simple effects analyses.

Finally, the interview data were qualitatively analyzed using a thematic analysis approach. A single researcher conducted the primary qualitative analysis using an inductive thematic approach. Transcripts were read iteratively to build familiarity, after which initial codes were generated to capture patterns in participants' reflections on response effectiveness, cross-strategy comparisons, and coding challenges. Codes were refined through constant comparison and analytic note-taking, then synthesized into higher-level themes. Identified codes and themes were reviewed with the other authors as an analytic quality check to assess coherence and clarify interpretations. As coding was not independently replicated, no formal intercoder disagreement resolution was used. We refer to individual coders using identifiers (eg, coder 1) when presenting quotes in the qualitative findings.

Results

Descriptive Statistics

The final dataset consisted of 996 cyberaggression scenarios and their corresponding bystander responses, all of which were evaluated by the 3 human coders. Four (0.04%) scenarios were excluded through listwise deletion due to missing values; given the small number of cases removed (<1% of the dataset), this exclusion is unlikely to have biased the results. Among the 996 cyberaggression scenarios, 4.6% (n=46) of the cases were classified as low incivility, 48.3% (n=481) were classified as moderate, and 47.1% (n=469) were classified as high. Regarding the target of bullying, 75.7% (n=754) of the cases were group targeted, while 24.3% (n=242) were individual targeted (Table 4). These distributions indicate that the majority of cyberaggression cases in the dataset involved moderate to high levels of incivility and were more often directed at groups rather than individuals. Example responses generated by the 3 bystander intervention strategies by the incivility level and the direction of aggression are shown in Multimedia Appendix 2.

Table . The distribution of the cyberbullying example dataset in terms of the level of incivility and the direction of incivility.

Level of incivility	Group targeted (n=754, 76%), n (%)	Individual targeted (n=242, 24%), n (%)	Total (N=996, 100%), n (%)
Low incivility	34 (3.4)	12 (1.2)	46 (4.6)
Medium incivility	341 (34.2)	140 (14.1)	481 (48.3)
High incivility	379 (38.1)	90 (9)	469 (47.1)

RQ1: Linguistic Differences Among the 3 Bystander Intervention Strategies

To assess linguistic differences across intervention strategies, we conducted independent samples *t* tests comparing messages generated by the baseline GPT and AllyGPT using LIWC 2022 variables. We used fixed-format policy reminders as a linguistic benchmark, which were excluded from *t* tests due to their lack of variability (Table 5).

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Table . Linguistic characteristics of bystander intervention messages generated by the 3 different strategies (policy reminder, baseline GPT, and AllyGPT).

Characteristics	Policy reminders, mean	Baseline GPT, mean (SD)	AllyGPT, mean (SD)	*t* test (df)	*P* value	Direction
WC[a]	25 (0)	65.56 (21.71)	46.61 (11.69)	24.29 (1532.06)	<.001	Policy<AllyG-PT<baseline GPT
WPS[b]	25 (0)	16.65 (4.12)	13.63 (2.91)	18.89 (1792.75)	<.001	Policy<AllyG-PT<baseline GPT
Analytic	28.63 (0)	37.43 (21.66)	44.41 (26.20)	−6.49 (1927.67)	<.001	Policy<baseline GPT<Ally GPT
Authentic	85.17 (0)	45.88 (27.81)	33.40 (27.55)	10.07 (1996)	<.001	AllyGPT<baseline GPT<policy
Negative	12 (0)	2.38 (2.34)	4.66 (3.53)	12.68 (1996)	<.001	Baseline GPT<AllyGPT<policy
Positive	0 (0)	6.55 (3.43)	4.65 (3.25)	−17.01 (1732.28)	<.001	Policy<AllyG-PT<baseline GPT
Netspeak	0 (0)	0.09 (0.51)	0.04 (0.44)	2.43 (1995.29)	.02	Policy<AllyG-PT<baseline GPT

[a]WC: word count.

[b]WPS: word per sentence.

All 996 messages produced using policy reminders were identical, yielding a fixed *word count* of 25 and *words per sentence* of 25, with no variability across messages. In contrast, messages generated by the 2 GPT-based strategies demonstrated significantly greater linguistic variation. An independent samples *t* test (Welch) comparing baseline GPT and AllyGPT revealed that bystander intervention responses generated by baseline GPT were significantly longer than those generated by AllyGPT. Similarly, baseline GPT produced messages with a greater mean words per sentence compared to those generated by AllyGPT. Overall, the policy reminder messages were uniform and minimal in length and complexity, while both GPT-based strategies generated more linguistically varied responses. Among the generative approaches, the baseline GPT produced messages that were longer and more syntactically complex than those generated by the AllyGPT strategy.

For the *analytic thinking* score, baseline GPT messages had significantly lower means compared to AllyGPT, with Welch correction for unequal variances. This means that AllyGPT-generated bystander intervention responses are in a more structured and logical language than the baseline GPT. Both GPT-generated strategies were more analytical than the policy reminders, which scored even lower, reflecting their templated and rigid format. In contrast, *authentic language* was more prevalent in baseline GPT than in AllyGPT responses, assuming equal variances, suggesting that the baseline GPT produced more personally expressive messages. Notably, policy reminders had the highest authenticity score among all strategies, reflecting their formalized stance and declarative tone.

For *positive emotional tone*, baseline GPT responses scored higher than those from our GPT. Policy reminders, in contrast, scored zero on positive emotion, reflecting their strictly normative stance. Conversely, *negative emotional tone* was more prominent in AllyGPT messages than in baseline GPT, with unequal variances assumed. The policy reminder messages showed the highest negative emotional tone, indicating elevated levels of negative emotion due to their emphasis on prohibition and sanctions. Policy reminders scored much lower, aligning with their strict and emotionally neutral or negative framing. Finally, the use of *netspeak* (eg, online slang) was significantly higher in baseline GPT than in AllyGPT. Policy reminders contained no netspeak, consistent with their formal and standardized tone.

Together, these findings highlight distinct linguistic signatures of each intervention strategy. Baseline GPT responses tended to be emotionally positive and authentic, while AllyGPT emphasized structured reasoning and a more assertive tone. The fixed policy reminders, although consistent and easily recognizable, lacked emotional nuance and personalization, underscoring the value of generative AI for producing more context-aware and psychologically resonant interventions. Table 5 presents the mean difference and the direction of the difference in psycholinguistic characteristics across the 3 bystander interventions.

RQ2: Perceived Effectiveness of Bystander Interventions

Quantitative Results

Main Effects of Intervention Strategies on Perceived Effectiveness

Perceived Favorability

A one-way Welch ANOVA was conducted to examine differences in perceived favorability across the 3 intervention strategies: standard policy reminders, baseline GPT-generated responses, and AllyGPT-generated responses. The analysis revealed a significant effect of intervention type on perceived favorability ($P<.001$). Post hoc Games-Howell comparisons indicated that all pairwise differences were statistically significant ($P<.005$). The mean favorability ratings were highest

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for the baseline GPT responses, followed by AllyGPT responses and standard policy reminders.

Potential for Altering the Discussion

A one-way Welch ANOVA revealed significant differences in how effective interventions were perceived at shifting discussions. Baseline GPT responses again received the highest ratings, followed by AllyGPT, with policy reminders receiving the lowest ratings (P<.001). Post hoc comparisons using the Games-Howell correction indicated all comparisons reached statistical significance (P<.005).

Likelihood of Changing Aggressive Behavior

A one-way Welch ANOVA indicated a statistically significant difference in perceived effectiveness in changing bullying behavior among the 3 intervention types: standard policy reminder, baseline GPT-generated responses, and AllyGPT-generated responses (P<.001). Post hoc Games-Howell tests revealed that all pairwise differences were statistically significant (P<.001). Table 6 summarizes the mean difference and the direction of difference.

Table . Three effectiveness variables across the 3 intervention strategies.

Variables	Policy reminder (n=996), mean (SD)	Baseline GPT (n=996), mean (SD)	AllyGPT (n=996), mean (SD)	Welch ANOVA		Post hoc test
				F test (df)	*P* value	
Favorability	3.50 (0.50)	4.14 (0.99)	3.98 (0.92)	219.28 (2, 1792.02)	<.001	Baseline GPT>AllyGPT>policy reminder
Altering discussion	3.81 (0.39)	4.16 (0.96)	3.89 (0.90)	58.30 (2, 1682.03)	<.001	Baseline GPT>AllyGPT>policy reminder
Changing behavior	3.06 (0.29)	3.83 (1.00)	3.45 (0.91)	328.77 (2, 1542.98)	.001	Baseline GPT>AllyGPT>policy reminder

Main Effects of the Aggression Context on Perceived Effectiveness

Incivility Level and the Perceived Effectiveness of Bystander Responses

A one-way ANOVA indicated that there was no statistically significant difference in mean values for perceived favorability, effectiveness in altering the discussion, and effectiveness in changing bullying behavior across intervention messages generated for high-level, medium-level, and low-level aggressive messages (Table 7).

Table . Three outcome variables by incivility level.

Variables	Low (n=138), mean (SD)	Moderate (n=1443), mean (SD)	High (n=1407), mean (SD)	ANOVA	
				F test (df)	*P* value
Favorability	3.88 (0.76)	3.88 (0.87)	3.86 (0.89)	0.202 (2, 2985)	.81
Altering discussion	3.94 (0.67)	3.96 (0.81)	3.95 (0.82)	0.09 (2, 2985)	.90
Changing behavior	3.46 (0.73)	3.44 (0.88)	3.45 (0.85)	0.06 (2, 2985)	.93

Direction of Aggression and the Perceived Effectiveness

Independent-samples t tests revealed significant differences in the perceived effectiveness of intervention messages depending on whether the aggression was group targeted or individual targeted. Responses addressing group-targeted aggression were rated as significantly more favorable than those addressing individual-targeted bullying (P<.001). Similarly, interventions for group-targeted bullying were seen as more effective in altering discussions than for individual-targeted bullying (P<.001). Finally, messages addressing group-targeted bullying were rated as more effective in changing bullying behavior than those addressing individual-targeted bullying (P=.001; Table 8).

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Table . Three outcome variables by direction of aggression.

Variables	Group (n=2262), mean (SD)	Individual (n=726), mean (SD)	*t* test (df)	*P* value
Favorability	3.92 (0.84)	3.74 (0.95)	4.46 (1115.39)	<.001
Altering discussion	3.99 (0.77)	3.85 (0.90)	3.56 (1090.78)	<.001
Changing behavior	3.48 (0.83)	3.35 (0.93)	3.20 (1115.36)	.001

Interaction Effects of Bystander Intervention and Aggression Context on Perceived Effectiveness

Interaction Effects of Bystander Strategy and Incivility Level on the Perceived Effectiveness

Overview

We conducted a series of robust general linear models with heteroskedasticity-consistent SEs to examine the main and interaction effects of strategy (standard policy reminder, baseline GPT, and AllyGPT) and incivility level (low, moderate, and high) on 3 outcome measures. Pairwise contrasts were used to compare strategy conditions, and significant interactions were further examined using simple effects analyses. Overall, strategy type mattered more than incivility level. Across all outcomes, GPT-generated responses (both baseline and AllyGPT) were consistently rated higher than policy reminders. Incivility level alone did not significantly influence ratings, and very few strategy ×incivility interactions emerged. The only notable exception was that baseline GPT responses were perceived as more effective in changing behavior when paired with moderately incivil messages.

Perceived Favorability

There was a significant main effect of strategy type, in which GPT-based responses were rated as more favorable than policy reminders. Incivility level and interaction effects were not significant (Table 9).

Table . General linear model results for the strategy and incivility level interaction.

Variables	Main effect of the strategy	Main effect of incivility	Interaction effect (*B*)	Key contrasts (*B*)
Favorability	GPTs>policy (*P*<.005)	—[a]	—	AllyGPT (+0.48), baseline GPT (+0.41) versus policy
Altering discussion	—	—	—	GPT responses are directionally higher
Changing behavior	GPTs>policy (*P*<.005)	—	Baseline GPT×moderate incivility (+0.30, *P*=.03)	AllyGPT (+0.61), baseline GPT (+0.52) versus Policy

[a]Nonsignificant.

Altering Discussion

No significant main or interaction effects were observed. Although GPT-based responses were directionally more positive, the differences were not statistically significant.

Behavior Change

Both baseline GPT and AllyGPT responses were rated as more effective than policy reminders. A small interaction was observed, with baseline GPT showing an added advantage under moderate incivility.

Figure 2 visualizes the interaction effects of strategy and incivility level on bystander intervention ratings across 3 outcome variables. Although the interaction effect was not statistically significant, exploratory pairwise comparisons indicated a pattern in which AllyGPT responses were rated more favorably and more effective for behavior change than baseline GPT responses at low levels of incivility. These differences were not observed at moderate or high levels of incivility.

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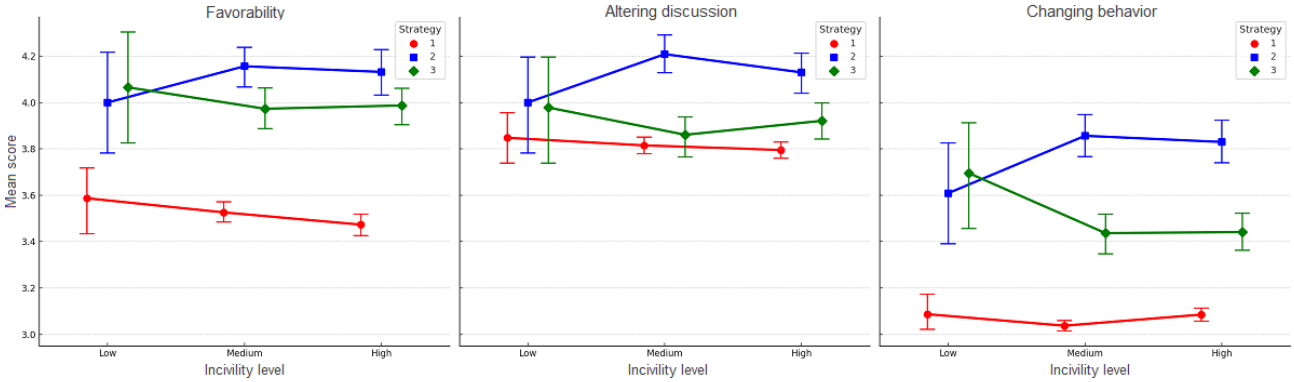
Figure 2. Interaction effects of strategy and incivility level on bystander intervention ratings across 3 outcome variables: favorability, altering discussion, and changing behavior. Mean scores and 95% CIs are plotted for each strategy (red=policy reminder, blue=baseline GPT, and green=AllyGPT) at each incivility level (low, medium, and high).



Interaction Effects of Intervention Strategy and Direction of Aggression

Perceived Favorability

GPT-based responses (both baseline and AllyGPT) were rated more favorably than policy reminders. Responses addressing person-targeted aggression were rated less favorably than those addressing group-targeted bullying. No significant interactions were observed (Table 10).

Table . General linear model results for the strategy and direction of aggression interaction.

Variables	Main effect of the strategy	Main effect of direction	Interaction effect (*B*)	Key contrasts (*B*)
Favorability	GPTs>policy (*P*<.001)	Person<group (*P*<.001)	—[a]	Baseline GPT (+0.63), AllyGPT (+0.51) versus policy
Altering discussion	GPTs>policy (*P*<.001)	—	—	Baseline GPT (+0.39), AllyGPT (+0.12) versus policy
Behavior change	GPTs>policy (*P*<.001)	—	AllyGPT×person targeted (−0.26, *P*=.001)	Baseline GPT (+0.79), AllyGPT (+0.45) versus policy

[a]Nonsignificant.

Altering Discussion

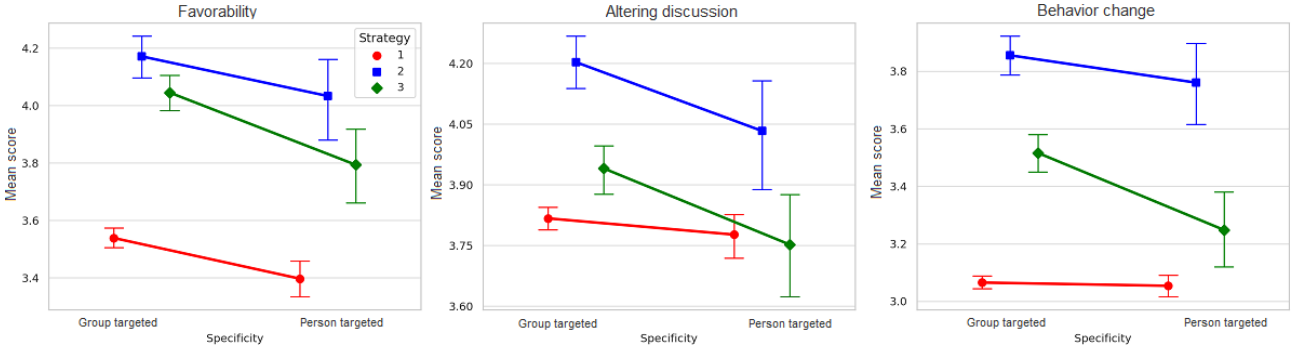
Baseline GPT responses were rated as most effective in shifting discussions, followed by AllyGPT, with policy reminders rated lowest. The direction of bullying did not significantly influence ratings. No interaction effect was found.

Changing Aggressive Behavior

Both baseline GPT and AllyGPT responses were perceived as more effective than policy reminders. A significant interaction emerged: AllyGPT responses were rated as less effective in changing behavior when applied to person-targeted bullying compared to group-targeted bullying. Other interactions were statistically not significant.

Figure 3 visualizes the interaction effects of strategy type and specificity on 3 outcome variables.

Figure 3. Interaction effects of strategy type (red=policy reminder, blue=baseline GPT, and green=AllyGPT) and direction (group targeted vs person targeted) on 3 perceived outcomes of bystander intervention messages: favorability, altering discussion, and behavior change, with error bars indicating 95% CIs.



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Qualitative Insights Into the Perceived Effectiveness of Intervention Strategies

Perceived Favorability of Intervention Strategies

The semistructured interviews with the coders provided nuanced perspectives on the perceived effectiveness of 3 different intervention strategies. First, the coders consistently described the standard policy reminder as robotic and impersonal. While these messages were generally viewed as inoffensive and safe, their lack of contextual adaptation made them feel generic. However, coders noted that this very standardization helped prevent the messages from seeming intrusive or out of place within online conversations: "It's robotic but doesn't feel like it's coming out of nowhere. It kind of works because it doesn't assume too much" (coder 1).

Baseline GPT responses were received more favorably than policy reminders due to their balance of specificity and neutrality. Coders noted that these responses avoided being too generic while also refraining from making direct or accusatory assumptions about the bully's intent: "*They don't first attack the bully. They kind of try to educate the bully. It's not a very aggressive message*" (coder 2). The tone of these responses was described as gentle, constructive, and inclusive. One coder appreciated the frequent use of collective language (eg, "we" and "let's"), which conveyed a shared commitment to respectful communication within online communities: "It's using a lot of 'we' language... and I find that more favorable for viewing" (coder 1).

Coders described the responses generated by the AllyGPT prompting as the most specific, often incorporating detailed psychological framing and references to the nature of the aggression. While this specificity occasionally added persuasive depth and a human-like tone, it also introduced potential drawbacks. In cases where the response identified specific problematic content or implied motive (eg, racial bias), coders noted that such directness might provoke further defensiveness or hostility from bullies: "It's kind of diving deeper and assuming the comment writer's thought processes... It feels like there's a little more of an argumentative tone" (coder 3). Although coders acknowledged that firmer messages could resonate in highly aggressive scenarios, they also emphasized that overt specificity or presumed interpretation could reduce the intervention's acceptability, especially when assumptions do not align with the aggressor's perceived intent.

Effectiveness of Altering the Discussion in More Positive Ways

Human coders widely agreed that the GPT-generated responses, particularly those from both baseline GPT and AllyGPT prompts, were generally more effective in shifting conversations toward a more positive and objective tone compared to the standardized policy reminders. While coders acknowledged that the standard policy reminder emphasized the importance of respectful communication, they felt this response "points out the need for more objectivity, but doesn't really lead to a positive direction" (coder 1). As a result, they did little to steer the conversation in a constructive direction.

In contrast, coders perceived the baseline GPT responses as more successful in nudging conversations toward civility. These responses not only emphasized objectivity and respectful tone but also offered an alternative path for engagement, such as refocusing the discussion on shared understanding or mutual respect. This dual approach, highlighting a problem while proposing a constructive next step, was particularly appreciated by the coders. They also emphasized that the emotionally neutral and nonconfrontational tone used in these responses helped defuse tension. This approach, in their view, increased the likelihood that others would respond positively.

> *It emphasizes that we're all different... it redirects the conversation in a more positive and objective way. [...] Generally, people are more receptive when things are not aggressive or sounding too emotional* [Coder 2]

Coders noted that the customized responses generated by the AllyGPT model often provided in-depth reasoning for why a comment was harmful while stressing the importance of respectful dialogue and the responsibility of maintaining safe social spaces. However, the more assertive tone and direct confrontation of aggressive behavior raised concerns among coders. Some felt that these responses, while well-intentioned, could come across as accusatory or argumentative, especially if they appeared to infer the perpetrator's motives.

> *There's an argumentative tone... you don't know how the perpetrator is going to respond. [Baseline GPT] feels more like, "let's just not talk about this," and that steers the conversation toward a more positive direction.* [Coder 3]

A critical insight raised by coders concerned the focus of the intervention. While AllyGPT responses often centered on validating the victim's experience, coders questioned the effectiveness of these responses when they failed to directly engage the perpetrator. One coder stated that, "It's taking the focus away from the perpetrator and onto the victim... the conversation can't go more positive if we're not addressing that person" (coder 3). In contrast, baseline GPT responses were seen as doing a better job of engaging the perpetrator without provoking defensiveness. These messages reminded the aggressor to be mindful of their language and consider its impact, without making them feel targeted.

Effectiveness of Changing Aggressive Behavior

Coders' perceptions of the effectiveness of each intervention strategy in changing aggressive behavior largely aligned with their earlier assessments of how well the responses altered the direction of the discussion. Across the board, coders emphasized that effective behavioral change requires directly, yet constructively, engaging the perpetrator in a way that encourages reflection and more respectful communication. Again, standard policy reminders were viewed as having a limited and neutral impact on changing aggressive behavior. While they did set a boundary and signal that harmful behavior was not tolerated, coders noted that these messages "didn't suggest a more helpful or adaptive way for the perpetrator to act or speak" (coder 1).

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Coders consistently perceived baseline GPT responses as striking an effective balance, being specific enough to address inappropriate behavior yet gentle enough to avoid provoking defensiveness. This balance, they felt, increased the likelihood that bullies would be receptive to the message and consider adjusting their behavior. One of the strengths of the baseline GPT responses, according to the coders, was the way they suggested alternative ways to engage in discussion, such as "Let's focus on discussing specific policy points or actions that spark our concern or approval" (coder 2), redirecting attention to a shared goal or more constructive conversation topics.

Coders acknowledged that the responses generated by the AllyGPT model were tailored and direct in highlighting the specific aspects of a comment that were problematic. This directness sometimes added clarity and educational value. However, coders also expressed concern that these responses occasionally made assumptions about the bully's intent or internal beliefs, such as labeling a comment as "discriminatory" or referring to an "insinuation," which could be perceived as confrontational and reduce the effectiveness of the intervention. Instead of encouraging reflection, such responses risked escalating the situation or causing the perpetrator to disengage.

> *People are more receptive when they're not directly attacked... we don't know how strong their belief is, maybe they just wanted to post a hateful joke.* [Coder 2]

Overall, coders emphasized that for an intervention to be effective in promoting behavior change, it should maintain a respectful and nonjudgmental tone, avoid strong assumptions about motivation, and provide a clear, constructive alternative to harmful behavior.

Strengths and Limitations of Current Interventions and Recommendations for Designing Effective Bystander Intervention Responses

Strengths of GPT-Generated Bystander Intervention Messages

Coders highlighted several strengths of GPT-generated responses compared to standard policy reminders. Most notably, they praised the model's ability to show context awareness and personalization. Rather than offering one-size-fits-all statements, the interventions often reflected the specifics of the bullying scenario. As one coder noted, "I was impressed with its ability to focus in on the specific details of what was being said" (coder 3).

Coders also emphasized the conversational and human-like tone. They appreciated language that felt natural and approachable, contrasting sharply with the robotic style of policy reminders: "How personable does it sound for that response? That was really important for me" (coder 3). Such qualities were seen as enhancing rapport and trust.

Finally, GPT responses were perceived as more engaging and persuasive, with greater potential to redirect conversations toward civility. Their contextual sensitivity, approachable tone, and constructive framing made them feel better positioned to encourage reflection and behavior change. Overall, coders viewed GPT-generated responses as more relatable and impactful than standardized policy reminders.

Limitations of GPT Responses and Challenges in Evaluation

Despite these strengths, coders also identified limitations. A key challenge was the subjectivity of evaluation, with judgments shaped by personal interpretation and uncertainty about real-world impact. To manage this ambiguity, some used policy reminders as a neutral reference point: "Policy reminder is also neutral it doesn't add much but sets a benchmark" (coder 1).

Coders also doubted the effectiveness of any response, AI-generated or otherwise, against deeply entrenched or hostile beliefs. As one put it, "There's not much that can be done to change someone making a hateful joke" (coder 2). Another added, "Some people are too inflexible... I don't think any sort of response will change them" (coder 3).

Finally, while GPT often produced contextually appropriate responses, occasional lapses occurred when it misinterpreted situations: "There were a few responses where ChatGPT was totally off the mark or got off task" (coder 3). These errors underscored the need for refinement to improve accuracy in sensitive contexts.

Recommendations for Designing Effective Bystander Intervention Responses

Coders offered thoughtful recommendations for enhancing the design of GPT-generated intervention messages. One key suggestion was to acknowledge both the perpetrator's and the victim's perspectives, particularly in messages that challenge inappropriate behavior. Coders noted that responses were more persuasive and less likely to provoke defensiveness when they began by validating the perpetrator's viewpoint before introducing critique.

Another recurring recommendation was to use a friendly, conversational tone rather than formal or emotionally charged language. Coders preferred responses that felt approachable and clear, avoiding complex vocabulary or accusatory phrasing: "I prefer more casual and natural language—nothing too serious or full of big words [...] Starting with friendly language, then pointing out the issue, and ending with a suggestion worked best" (coder 1). This approach was seen as helpful in reducing tension and guiding users toward reflection and behavioral change.

Finally, coders recommended balancing personalization with structural consistency. While they appreciated the human-like and tailored qualities of many GPT responses, they also valued a recognizable format that helped organize the message and ensure clarity. A common preference was for a response structure that included an opening statement, identification of the problematic issue, and a constructive suggestion for alternative behavior. As one coder put it, "The customized ones added a personal touch... but I appreciate the consistency of the standard responses too" (coder 3).

Together, our qualitative findings underscore the importance of bystander interventions that are empathetic, conversational, and contextually grounded. Coders consistently rated

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GPT-generated responses as more effective than policy reminders across all dimensions. Baseline GPT was praised for its balanced tone and gentle redirection, while AllyGPT stood out for clarity and victim-centered framing, although it was sometimes seen as overly direct or assumptive. In contrast, policy reminders were viewed as impersonal and unlikely to shape discussion or behavior. Overall, coders emphasized that effective interventions balance clarity with compassion, avoid excessive emotionality, and offer respectful alternatives (Table 11).

Table . Summary of comparative analysis of 3 bystander intervention strategies across key effectiveness dimensions.

Dimension	Policy reminder	Baseline GPT	AllyGPT
Perceived favorability	Impersonal, robotic tone; and neutral but not engaging	Balanced tone, human-like, inclusive ("we" language); and seen as most favorable	Highly specific and assertive; and sometimes too direct or assumptive for some users
Shifting discussion	Lacks specific direction; and points out the issue but does not offer alternatives	Suggests alternative directions; and redirects conversation constructively	Offers strong moral framing; and effective in serious cases but may feel argumentative
Changing behavior	Low likelihood of impact; and lacks personalized suggestions	Highlights inappropriate behavior gently; and offers behavioral alternatives	Directly addresses aggressors; and may be effective in some cases, but risks pushback

Discussion

Principal Findings

Taken together, our findings highlight clear distinctions in how AI-generated bystander strategies are perceived. Linguistic analyses showed that baseline GPT produced emotionally positive and authentic responses, closely mirroring natural online communication. AllyGPT, in contrast, adopted a more analytical and assertive tone, while policy reminders appeared rigid, impersonal, and lacking nuance. These linguistic styles aligned with evaluations: baseline GPT consistently received the highest ratings across favorability, discussion shift, and behavior change, followed by AllyGPT, with policy reminders rated lowest. Although GPT-based strategies generally outperformed policy reminders, interaction analyses revealed subtle patterns. Incivility level minimally moderated effectiveness; for example, AllyGPT was rated most effective in low-incivility cases for favorability and behavior change, whereas baseline GPT performed better across moderate- and high-incivility contexts. Qualitative insights reinforced these patterns, noting baseline GPT's balanced and inclusive tone, AllyGPT's psychological grounding but occasional bluntness, and policy reminders' lack of engagement or persuasiveness.

Context Matters: Aggression Direction, Level of Civility, and Response Alignment

Our findings underscore that while GPT-generated interventions generally outperform standard policy reminders, their effectiveness is highly context-dependent. Responses to individual-targeted bullying were rated differently across all outcome dimensions compared to group-targeted cases, although these main effects were less consistent when interaction terms were considered. This suggests that psychologically grounded interventions may be especially impactful in contexts requiring validation of victims or direct challenges to aggressors.

This context dependence aligns with the established bystander theory proposed by Latané and Darley [44] that frames intervention as a sequential process of noticing, interpreting, assuming responsibility, knowing how to act, and then intervening. Empirical work by Fredrick et al [19] supports this sequential model and highlights the role of empathy and psychological factors. Specifically, in cases of person-targeted bullying, the moral clarity and emotional salience of the situation may better enable bystanders to progress through these steps, particularly steps 2 through 4, leading to more effective intervention. Our results suggest that empathy- and perspective-taking-based responses, as used in AllyGPT, are particularly impactful when the victim is clearly identifiable, and harm is personal.

Conversely, group-targeted bullying often leads to diffusion of responsibility, whereby bystanders feel less personally obligated to intervene because they assume others will act [58]. As harm is spread across multiple individuals, it becomes less clear who to help, thereby reducing the urgency to respond [59]. Additionally, the reduced emotional immediacy in group harm diminishes moral clarity and empathetic motivation, weakening the impact of emotionally charged or individualized intervention messages [60]. Bystander intervention is more likely when victims are identifiable and emotionally salient, conditions often lacking in group-targeted bullying. Together, these factors reduce the effectiveness of personalized emotional appeals, pointing instead to approaches that emphasize collective responsibility. In these cases, coders favored responses that were casual, concise, and aligned with platform norms, traits more common in baseline GPT messages.

More broadly, our findings extend earlier work in online incivility and bystander behavior, which has emphasized the role of situational factors, such as severity of incivility, social context, and perceived responsibility in shaping intervention decisions [20,61]. Our results suggest that strategies optimized for one context (eg, group level and low incivility) may not generalize well to another (eg, person-specific high incivility). Thus, an effective AI-driven intervention system must be capable of dynamic adjustment, tailoring tone, content, and framing to the particular features of the incident.

Language Matters: Tone, Style, and Social Norm Alignment

Beyond content and strategy type, the linguistic style of intervention responses shaped their perceived effectiveness.

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Results from the LIWC analysis and coder feedback showed that tone, informality, emotional expression, and lexical choices played a decisive role in how responses were received. This underscores the need for AI-generated bystander responses to align with the communicative norms of fast-paced platforms such as Reddit or Twitter.

Baseline GPT responses often used informal, colloquial language, such as slang, abbreviations, or interjections (eg, "u," "lol," and "haha"). Although these responses were less grounded in psychological theory, coders described these as more natural and appropriate, suggesting that platform-congruent tone may foster receptivity and reduce defensiveness. This echoes prior work showing that benign, casual objections are often preferred regardless of offense severity [62]. As such, bystander responses generated in language that conforms to community or platform norms in a casual tone may help reduce the risk of dismissal or defensiveness.

In contrast, responses generated by AllyGPT used a more formal, structured, and logically reasoned tone, often referencing social norms or authoritative values (eg, "It's important to promote constructive discussion here"). While this approach was rooted in well-established psychological strategies (eg, validation, perspective-taking, and norm reinforcement), coders sometimes interpreted these messages as overly prescriptive or emotionally distant, particularly in group-targeted bullying scenarios. This suggests that overly formal or didactic language can undermine relatability and emotional resonance, particularly in community-based settings [63].

Interestingly, the LIWC results revealed that AllyGPT exhibited a higher level of negative emotional tone, primarily due to the use of empathic phrases (eg, "It's upsetting to see such comments"). These were designed to validate victims' emotional experiences, yet this empathetic tone may have inadvertently signaled greater emotional intensity or confrontation, especially when applied to group-level incidents with less obvious individual harm. This trade-off between emotional support and perceived harshness underscores the delicate balance required in bystander intervention design.

Additionally, contrary to our initial expectations, message length did not appear to drive perceived effectiveness. Although baseline GPT responses were longer on average, they were still rated more favorably. This suggests clarity, relevance, and stylistic attunement matter more than verbosity, offering a counterpoint to prior findings [64]. Taken together, these results highlight critical design implications: linguistic style must be adapted not only to the bullying content but also to the platform and social context in which interventions are deployed.

Designing Adaptive and Context-Aware LLM-Based Bystander Interventions

On the basis of our findings, we provide guidelines to design adaptive and context-aware LLM-based tools to generate bystander responses.

- *Adapt to platform and social contexts*: design interventions that fit the norms of each platform (eg, Reddit vs TikTok), account for different user roles (eg, bystander vs aggressor), and reflect community guidelines and expectations
- *Blend theory with natural language*: use psychologically grounded strategies (eg, validation and redirection) but express them in casual, conversational ways that feel authentic to users. Consider hybrid approaches where experts design the structure and AI fills in the style
- *Balance length and readability*: avoid overly short, templated responses that lack nuance and generate responses with sufficient length to convey empathy and guidance clearly without overwhelming users
- *Keep messages positive and relatable*: use friendly, familiar language with cues that feel personal and nonjudgmental (eg, "just a reminder" or "hey, let's keep it respectful"). Minimize negative emotional framing (eg, accusatory or punitive tones) that can escalate conflict
- *Learn and improve over time*: build in ways for users to react to or rate AI responses. Use this feedback to continuously refine tone, content, and delivery to match the evolving needs of different online communities

Taken together, these implications point to practical, deployable intervention designs within existing platforms. With refinements, AllyGPT can be implemented as an assistive layer, rather than a platform-level moderation system, that offers optional, context-sensitive bystander response suggestions at the point of interaction. Similar to AI-powered reply aids [65-67], it can be integrated directly into platforms (eg, reply scaffolds or pre-post nudges) or deployed via third-party tools such as browser extensions. With its lightweight decision logic and prompt conditioning, AllyGPT can run on existing LLM infrastructures. Future work can examine adoption, platform incentives, and governance considerations for responsible deployment.

Limitations and Future Work

We acknowledge several limitations that inform directions for future research. First, our dataset was drawn from a limited set of online communities and showed imbalances in incivility severity and bullying directionality. This may have constrained the generalizability of our findings. Future work should curate more diverse, representative examples across platforms and contexts, particularly those relevant to vulnerable populations. Second, while we implemented best practices in our coding protocol, each of the 3 raters evaluated 1000 responses, a scale that risks coder fatigue. Future studies should distribute tasks across larger rater pools and incorporate intentional overlap across coding subsets to support reliability calibration and detect potential coder drift or explore adaptive protocols to reduce cognitive burden.

Third, our evaluation did not include real-world social media users, leaving open questions about how digital bystanders themselves would perceive AI-generated interventions. Engaging users directly through experiments or field studies will be critical to assess both effectiveness and ethical acceptability. Future work might also explore hybrid approaches that combine theoretically grounded templates with dynamically generated content, balancing psychological rigor with personalization and safety. In addition, exploratory contrasts suggested AllyGPT may be more effective than baseline GPT in low-incivility contexts, especially for favorability and

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behavior change. Although not statistically significant, these patterns highlight promising avenues for further investigation with larger samples or more granular measures.

Finally, this work does not aim to directly address motivational barriers to bystander intervention, such as fear of retaliation or unwillingness to intervene. Instead, AllyGPT targets a complementary challenge: uncertainty about appropriate language and strategy once bystanders are inclined to act. While lowering cognitive and linguistic barriers may indirectly support action, future work should examine how AI-supported interventions can be combined with mechanisms that more directly address bystander motivation. Despite these limitations, this study presents an important step toward using generative AI to foster prosocial digital behavior. By grounding response generation in psychological theory and evaluating perceived effectiveness, we lay the foundation for future research on human-AI collaboration in digital mental health and online harm mitigation.

Conclusions

This study demonstrates the promise of leveraging generative AI to support bystander intervention in the cyberbullying context, an area closely tied to digital mental health. By systematically comparing baseline GPT responses, theory-informed prompts (AllyGPT), and standard policy reminders, we revealed key differences in perceived effectiveness, linguistic style, and user preferences. Through a mixed-method evaluation, we identified not only the strengths of AI-generated interventions but also their limitations in emotional nuance, contextual fit, and behavioral impact. Our work highlights the potential of psychologically grounded and contextually adaptive AI interventions to reduce the psychological harm associated with cyberbullying. By empowering bystanders to intervene more effectively, our work contributes to the design of scalable, human-centered AI tools that promote safer online environments and users' mental well-being.

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Conflicts of Interest

None declared.

Multimedia Appendix 1
Details of the 5 bystander intervention strategies grounded in psychological theories.
[DOCX File, 2198 KB - formative_v10i1e84391_app1.docx]

Multimedia Appendix 2
Example responses generated by the 3 bystander intervention strategies by incivility level and direction of aggression.
[DOCX File, 27 KB - formative_v10i1e84391_app2.docx]

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Abbreviations

AI: artificial intelligence
GAIDeT: Generative Artificial Intelligence Delegation Taxonomy
GenAI: generative artificial intelligence
HC3: heteroskedasticity-consistent standard errors
LIWC: Linguistic Inquiry and Word Count
LLM: large language model
RQ: research question

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Prediction of Relapse Using Digital Technology in People in Recovery From Substance Use Disorders: Early Economic Evaluation With a Case Study of the Subreal App

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Abstract

Background: Many people relapse after achieving abstinence in substance use disorders. Health care providers may scan the horizon for new technologies to predict response that allow interventions to be targeted rather than routine. Currently, no such predictive technologies are available in the United Kingdom. The Subreal app is available for use in research contexts, but no clinical data specific to the app are yet available. Early health economic modeling can use data from the literature to explore characteristics essential for the new technology to be cost-effective. This information can guide developers in setting performance targets and pricing and estimating potential cost savings and/or cost-effectiveness for health care providers.

Objective: This study was supported by a UK industry funding body to explore the potential of digital technologies such as the Subreal app to offer cost savings or cost-effectiveness for health care providers. We explored the threshold price and clinical effectiveness required to deliver cost savings and cost-effectiveness in 2 subpopulations with substance use disorders in a UK setting.

Methods: Deterministic models were used to estimate costs per relapse and quality-adjusted life years over 1-, 5-, and 20-year time horizons for people who have achieved abstinence after treatment for alcohol or opioid misuse. The intervention was a digital technology predicting relapse, provided—in addition to standard care—for 1 year post achievement of abstinence. In Subreal, biomarker data are collected daily through the app, and artificial intelligence–enhanced risk assessment flags patients who require additional support. The comparator was event-driven, reactive response to relapse. Costs and quality-of-life estimates were calculated using Markov models with data from existing published sources. The base-case estimate of 15% reduction in first-year relapse rates was based on a previous study on a similar but simpler digital technology.

Results: Digital technologies such as the Subreal app have the potential to be cost-saving from a UK health and social care perspective, especially when used over a longer time horizon. Assuming a reduction of 15% in first-year relapse rates, digital technologies have the potential to be cost-saving, provided that they do not cost more than £300 (US $400.09) and £460 (US $613.47) per patient per annum for alcohol and opioid use disorders, respectively. No cost was included for postalert care, as it was assumed that this could be met within existing resources. Cost savings would be achieved predominantly through a reduction in treatment requirements as fewer people relapse. Price thresholds would reduce correspondingly if a <15% reduction in relapse rates were achieved.

Conclusions: Developers of digital technologies that aim to reduce relapse need to focus on the generation of evidence of clinical effectiveness and develop a commercially sustainable pricing model that allows health care providers to benefit from cost savings.

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KEYWORDS

early economic evaluation; early health technology assessment; technology development; digital technology; substance use disorder; opioid use disorder; alcohol use disorder; prediction; relapse

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Introduction

Background

Between April 2023 and March 2024, nearly 311,000 adults were in contact with drug and alcohol treatment services in England [1]. This represents a 7% rise compared with the previous year, and it is the highest number of adults in treatment since 2009-2010 [1]. Alcohol and drug use disorders cause increased morbidity and mortality and place an economic burden on the health and welfare system and potentially on the criminal legal system [2-4]. Notably, 72% and 69% of people starting treatment for alcohol use disorder (AUD) and opioid use disorder (OUD), respectively, report having mental health needs [1]. Treatment for AUD is predominantly delivered in the community, with virtually all people receiving some form of psychosocial treatment and 18% also receiving pharmacological treatment [1]. Similarly, for OUD, 99% of people on treatment receive psychosocial treatment, but rates of pharmacological treatment (94%) are higher than those for AUD [1]. People receiving treatment for AUD tend to stay in treatment for approximately 6 months; in 2023 - 2024, 58% of people completed treatment and were free from dependence [1]. For OUD, people remain in treatment for much longer, with the average reported as 3.3 years in 2023 - 2024 and only 23% of people completing treatment.

Substance use disorders tend to have a relapsing nature. Of the 1.2 million people who were in contact with drug and alcohol services in the United Kingdom from 2005 - 2006 to 2023 - 2024, 31% had more than 4 treatment journeys, 26% had been in treatment continuously since their treatment started, and 71% had been in treatment for 5 years or more [1]. A 2007 US study reported that 36% of those achieving abstinence from alcohol sustained abstinence for 12 months, whereas 86% of those sustaining abstinence for 12 months remained abstinent at 5 years [5]. For opioids, another US study, from 1986, reported that 35% relapsed immediately after treatment, whereas 73% of those who sustained abstinence for 12 months remained abstinent at 42 months [6]. These data demonstrate the importance of supporting abstinence over the first 12 months posttreatment.

The UK government has published a 10-year health plan for England, aiming to transform the National Health Service (NHS) to be fit for the future [7]. The plan focuses on embracing digital technologies and on preventing illness (including secondary prevention). Therefore, a digital technology to prevent relapse from substance use disorders is strongly aligned with UK strategic health priorities. Additionally, NHS Core20PLUS5 is a national approach to inform action to reduce inequalities at the national and system levels [8]. It targets the most deprived 20% of the national population as well as people experiencing social exclusion, specifically people with drug and alcohol dependence.

About the Technology

The Subreal app integrates cutting-edge digital biomarkers (heart rate variability and pupillary light reflex) and artificial intelligence–enhanced predictive algorithms to enable the early detection of relapse risks, automated decision support systems for clinicians, and remote patient management that leverages real-time physiological and behavioral data. The technology is expected to drive a shift away from reactive, event-driven care to a more anticipatory and proactive continuous management approach, improving patient outcomes and reducing care costs. We anticipate that it will be useful for the care of people across a broad range of substance abuse disorders, including those who abuse a number of substances simultaneously. Predictive algorithms to detect high-relapse-risk episodes use smartphone-collected digital biomarker data and digital phenotyping techniques, including app use behavior and patterns in missing data. Physiological data are collected through the patient recording a short video and submitting it via the platform. Predictions are designed to be used as a clinical guideline for further intervention, where a clinician is notified through SMS text messaging, pager messaging, or other appropriate clinical management system about the increased relapse risk, which might incentivize patient-clinician contact and lead to the administration of a psychological or pharmacological intervention for relapse prevention. No detailed review of data by the clinician is required, as the prediction tool simply sends an alert to a designated person. The digital platform will allow for rapid scalability across different clinical settings, allowing for widespread uptake and improvement in patient care. The benefits are expected to be realized through reducing relapse rates, hospital admissions, and overall health care burden.

The app is currently at a preclinical stage (Technology Readiness Level 4 [TRL 4]) as an investigational medical device under the European Union medical device regulations. Similar predictive solutions for alcohol and opioids already exist on the wider European market, including Kontigo Care Previct Alcohol and Previct Drugs operating in Sweden in clinical practice. Subreal differs from Previct, as it uses physiological data captured via smartphone (Figure 1), whereas Previct uses a combination of breathalyzer data and self-reported patient data from questionnaires and journals [9].

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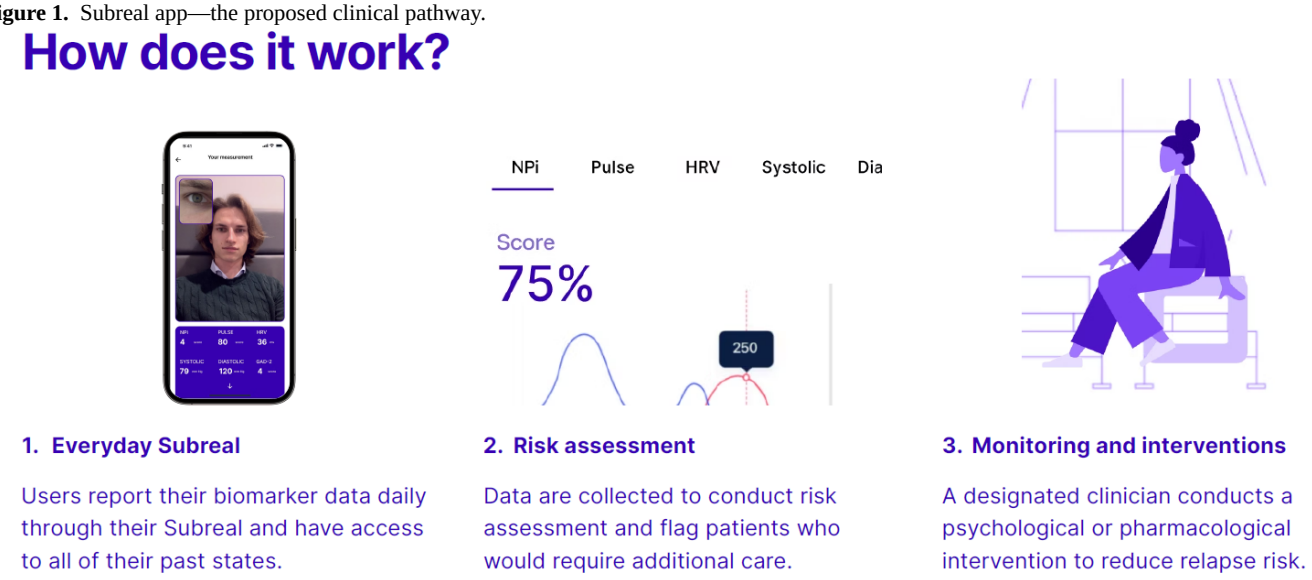
Figure 1. Subreal app—the proposed clinical pathway.



Early Exploratory Economic Evaluation

Economic evaluation is the comparative analysis of the costs and consequences of 2 or more possible options [10]. It is undertaken as part of technology adoption decision-making at many health technology assessment (HTA) bodies around the world. In the United Kingdom, cost-utility analysis is undertaken by the National Institute of Health and Care Excellence (NICE) to inform decisions about whether or not to adopt a technology in a given indication at a fixed price [11]. The economic evaluation approach used by NICE can be adapted to inform developers as part of what has become known as "early HTA" [11]. By definition, this analysis may be undertaken before clinical effectiveness evidence specific to the technology is available. The purpose of early HTA is to inform developers of health technologies and their funders and investors about the potential value of their technology in a particular context and to explore what characteristics are essential to realize that value [12,13]. Early HTA identifies target clinical effectiveness and price levels that would be acceptable to health care providers [13]. Publication of early analyses can also be useful for health care providers in horizon scanning for technologies to meet a clinical need and in deciding whether to support research efforts related to technologies in development. Research funders such as the National Institute for Health Research are increasingly asking for an early health economic evaluation to be undertaken as a requirement for funding.

Objectives of the Study

The objective of this study was to provide an estimate of potential cost-effectiveness or cost saving of introducing a digital technology that enables early detection of relapses (the Subreal app) to the clinical pathway in the first year of recovery for people with AUD or OUD. This will inform developers and investors about pricing policy and necessary performance of the technology at different price levels. It will also inform potential adopters and clinical research partners about the potential cost and health outcome implications of adopting a technology of this type.

Methods

Decision Problem

The first stage of an economic evaluation is to determine the scope of the decision problem. This is often done using the Population, Intervention, Comparator, and Outcome (PICO) framework. The PICO framework for this study is presented in Textbox 1.

Textbox 1. Population, Intervention, Comparator, and Outcome (PICO) for scope of the economic evaluation.

- Population (P):

1. people with moderate or severe alcohol use disorder who have successfully completed treatment but remain at risk of relapse
2. people with opioid use disorder who have successfully completed treatment but remain at risk of relapse

- Intervention (I): standard-of-care pathway including a digital technology, such as the Subreal app, for the first year of abstinence
- Comparator (C): standard of care
- Outcome (O): quality-adjusted life years (QALYs), costs per patient

People who have completed treatment and achieved abstinence for AUD and OUD were considered as 2 separate populations. These populations were chosen, as they are the largest patient groups in the UK substance abuse statistics—representing 44% and 30% of adults in treatment, respectively—in 2023 - 2024 [1]. In both cases, the intervention was the provision of the Subreal app for the first year of abstinence. In addition, health care providers would need to design some process to build the

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app into their standard of care (ie, monitoring and responding to alerts and reducing routine check-ins). As this was a preliminary economic evaluation and there could be significant variation in the approach taken by health care providers, we assumed that any changes in process could be achieved using existing resources. At a later stage in development, pathways including the Subreal app will be codeveloped with clinical partners. The comparator was usual treatment (also referred to as standard of care). The outcomes of interest for a cost-utility analysis were the costs and quality-adjusted life years (QALYs) associated with the full pathway of care. QALYs are a generic measure combining quality and length of life, where 1 year in perfect health is equivalent to 1 QALY [14]. This is a useful measure, as it allows interventions in different disease areas to be compared for value for money using a common denominator. We also included cost per relapse avoided, as it may be a useful indicator for health service decision makers.

Analytic Approach

The analysis was a cost-utility analysis comparing costs and QALYs. Costs per relapse were also calculated. A currency exchange rate of £1=US $1.33 is applicable. The estimates were used not only to estimate the potential impact on costs and QALYs separately but also to calculate the net monetary benefit (NMB). The NMB was calculated by multiplying the impact on QALYs by the UK willingness-to-pay threshold per QALY and then adjusting for the cost impact. Currently, the UK willingness-to-pay threshold per QALY is between £20,000 and £30,000; we used £20,000 in our calculations [15]. A positive NMB indicates that a technology is cost-effective. Markov models were used to model the impact of Subreal over 1-, 5-, and 20-year time horizons. This model structure is useful for relapsing conditions, as it permits people to move between disease, treatment, and disease-free states multiple times. The 1- and 5-year time horizons were selected because health care providers often want to understand whether a technology will deliver cost savings and/or be cost-effective in the short and medium term. The 20-year time horizon was included because both costs and health outcomes may continue to be impacted over a person's lifetime. Costs and outcomes were discounted at 3.5% per annum, in line with the NICE reference case [15]. A UK health and social care perspective was adopted, which means that only costs incurred by the health and social care systems were taken into account. This is a standard approach in the assessment of UK health technologies [15]. Impacts of reducing relapses may also reduce wider costs to society (eg, in the criminal justice system or welfare payments such as unemployment benefits). There may also be costs to the person such as out-of-pocket expenses for private care or loss of earnings due to treatment or morbidity. Including these costs is known as taking a societal perspective. There may be an opportunity during a subsequent clinical study to collect these cost data and present a societal perspective as a sensitivity analysis together with the health and social care perspective.

Model Structure

Figures 2 and 3 show the structure of the Markov models used in this study. People in the alcohol model start in the abstinence state. Death is possible from any health state. They can remain abstinent or relapse. From the relapse state, people can spontaneously recover, start treatment, or remain in the relapse state. From the treatment start state, people can continue their treatment or drop out. From treatment continuation, people can return to the abstinence state or relapse. The cycle length was set to 3 months, as it allows for some people to drop out of treatment after 3 months and for the start and continuation of treatment to roughly approximate the average length of treatment for AUD (6 months).

The opioid model was similar to the alcohol model, except that the treatment start and treatment continuation were renamed medically supervised withdrawal and medication for opioid use disorder (MOUD), respectively. People can complete medically supervised withdrawal and then relapse or can continue to MOUD. People cannot relapse from MOUD, but they can remain in MOUD indefinitely. Again, the cycles were 3 months long, reflecting that medically supervised withdrawal is generally approximately 12 weeks long and that MOUD can continue for long periods.

Both models were set up to allow for the Subreal app to impact relapse rates, treatment-seeking rates, and recovery rates. No impact was included in the base case for treatment-seeking rates and recovery rates. However, if it were to become apparent during evidence generation that there was impact in these areas, it could be incorporated at a later date.

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Figure 2. Structure of the alcohol Markov model. Letters A-J represent transition probabilities. A, relapse rate; B, treatment-seeking rate; C, treatment continuation rate; D, recovery rate on completion of treatment; E, spontaneous recovery rate; F, dropout rate (1 – treatment continuation rate); G, mortality rate from abstinence; H, mortality rate from treatment; I, mortality rate from relapse; J, nonrecovery rate (1 – recovery rate on completion of treatment). Death is an absorbing state. People can remain in abstinence and relapse states.

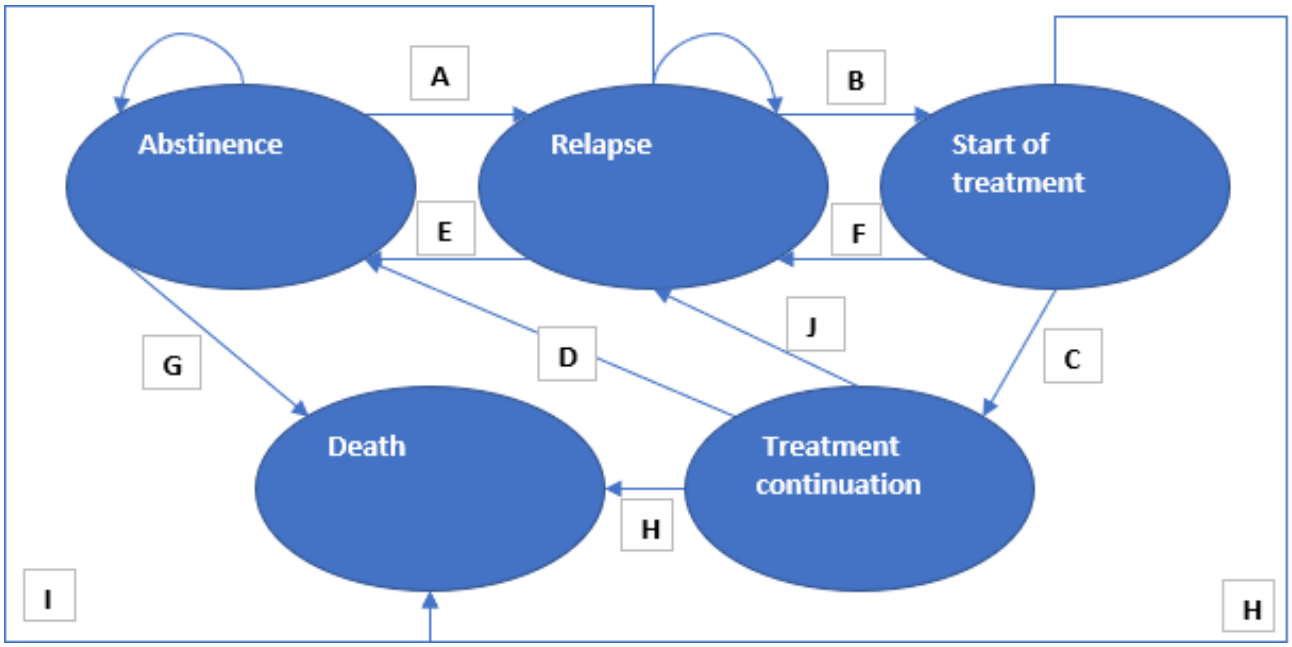
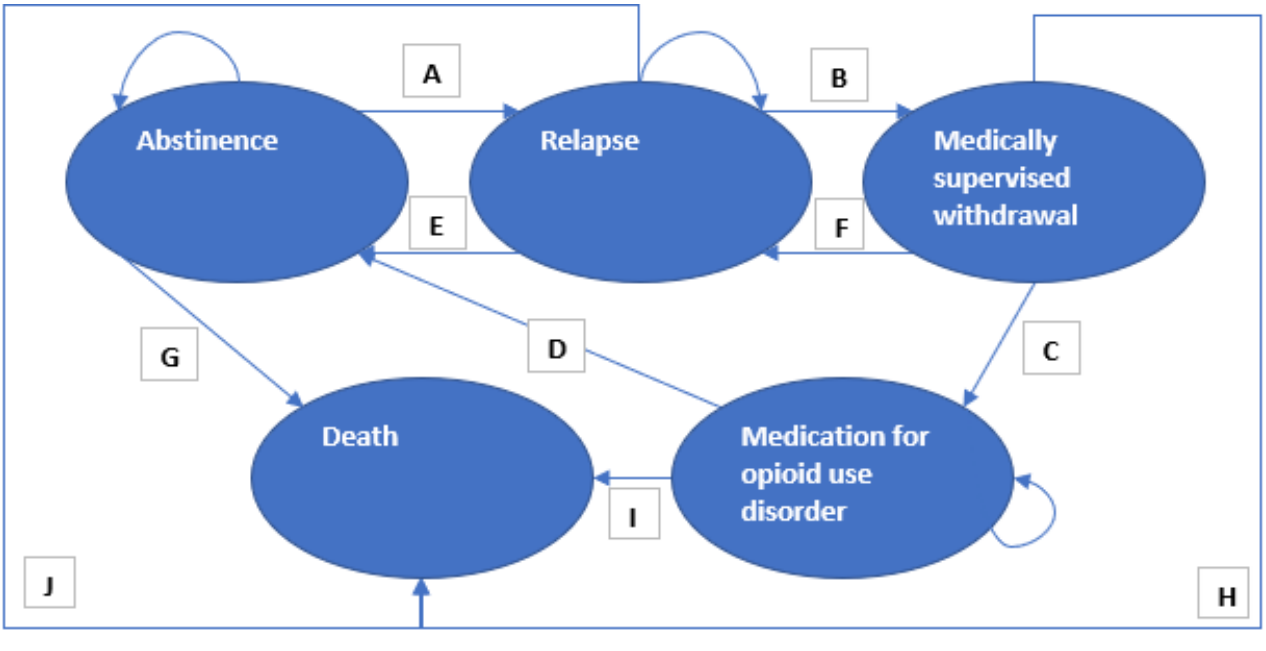


Figure 3. Structure of the opioid Markov model. Letters A-J represent transition probabilities. A, relapse rate; B, treatment-seeking rate; C, treatment continuation rate; D, recovery rate on completion of treatment; E, spontaneous recovery rate; F, dropout rate (1 – treatment continuation rate); G, mortality rate from abstinence; H, mortality rate from medically supervised withdrawal; I, mortality rate from medication for opioid use disorder (MOUD); J, mortality rate from relapse. Death is an absorbing state. People can remain in abstinence, relapse, and MOUD states.



Parameter Estimates

Tables 1 and 2 contain details of parameter estimates used to populate the models. The key parameters for the cost-effectiveness of any new health technology are the incremental cost of the technology and its clinical effectiveness. No clinical effectiveness data specific to the Subreal app are available, as this is an early economic evaluation. We assumed that the clinical effectiveness of the digital health technology is 15% in the base case, in line with that achieved in a published clinical study [9]. This was varied across a wide range in threshold analysis. We included £25 per 3-month cycle or £100 per annum for the incremental cost of the digital technology. This was based on an assumption and was varied in threshold analysis. For some parameters, the data provided in referenced papers were manipulated. Supporting calculations and comments on sources for these estimates are included in Multimedia Appendix 1.

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Table . Parameter estimates for the alcohol model (the base-case estimate and lower and upper limits for 1-way sensitivity analysis).

Parameter	Estimate	Lower limit	Upper limit	Source
Transition probability				
Relapse rate – year 1	0.13	0.11	0.16	Dennis et al [5]
Relapse rate – years 2 - 3	0.08	0.06	0.09	Dennis et al [5]
Relapse rate – year 4 onwards	0.03	0.03	0.04	Dennis et al [5]
Treatment-seeking rate	0.8	0.64	0.8	Assumption
Recovery rate after treatment	1	0.8	1	Assumption
Treatment continuation rate	0.58	0.46	0.7	Adult substance misuse treatment statistics 2003-2004 [1]
Spontaneous recovery rate	0.002	0.001	0.002	Mellor et al [16]
Relative mortality rate for abstainer vs occasional drinker	1.04	0.94	1.16	Zhao et al [17]
Relative mortality rate for high-volume drinker vs occasional drinker	1.24	1.07	1.44	Zhao et al [17]
Impact of Subreal app				
Impact on relapse rate	0.85	0.68	1.02	Wallden et al [9]
Impact on treatment-seeking rate	1	0.8	1.2	Assumption
Impact on recovery rate	1	0.8	1.2	Assumption
Costs[a], GBP[b]				
Cost in abstinence state	0	0	0	Assumption
Cost in treatment states	2086	1668	2503	See Multimedia Appendix 2
Cost in relapse state	1223	979	1468	See Multimedia Appendix 2
Cost of Subreal app (per patient per 3-month cycle for 1 year)	25	25	25	Assumption
Quality of life				
Utility in abstinence state (full-year utility)	0.67	0.53	0.8	UKATT[c] trial [18]
Utility in treatment (full-year utility)	0.62	0.5	0.74	UKATT trial [18]
Utility in relapse state (full-year utility)	0.57	0.46	0.69	UKATT trial [18]
Discount rates				
Discount rate for costs	0.035	0.01	0.05	NICE reference case [15]
Discount rate for outcomes	0.035	0.01	0.05	NICE reference case [15]
Proportion of male individuals in the population	0.74	0.59	0.89	UKATT trial [18]

[a]A currency exchange rate of £1=US $1.33 is applicable.

[b]GBP: Pound Sterling.

[c]UKATT: UK alcohol treatment trial.

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Table . Parameter estimates for opioid model (the base-case estimate and lower and upper limits for 1-way sensitivity analysis).

Parameter	Estimate	Lower limit	Upper limit	Source
Transition probability				
Relapse rate – cycle 1	0.35	0.28	0.42	Simpson and Marsh [6]
Relapse rate – cycles 2 - 4	0.06	0.05	0.08	Simpson and Marsh [6]
Relapse rate – cycles 5 - 8	0.04	0.03	0.05	Simpson and Marsh [6]
Relapse rate – cycle 9 onwards	0.02	0.02	0.02	Simpson and Marsh [6]
Treatment-seeking rate	0.9	0.72	0.8	Assumption
Recovery rate after treatment	0.02	0.01	0.02	Adult substance misuse treatment statistics 2023-2024 [1]
Treatment continuation rate	1	0.8	1	Assumption
Spontaneous recovery rate	0	0	0	Assumption
Relative mortality rate for medically supervised withdrawal state	6.04	4.83	7.25	Kelty et al [19]
Relative mortality rate for MOUD state	3.55	2.84	4.26	Kelty et al [19]
Relative mortality rate for relapse state (off treatment)	6.14	4.91	7.36	Kelty et al [19]
Impact of Subreal app				
Impact on relapse rate	0.85	0.68	1.02	Wallden et al [9]
Impact on treatment-seeking rate	1	0.8	1.2	Assumption
Impact on recovery rate	1	0.8	1.2	Assumption
Costs[a], GBP[b]				
Cost in abstinence state	0	0	0	Assumption
Cost in treatment states	2324	1959	2759	See Multimedia Appendix 2
Cost in relapse state	0	0	0	See Multimedia Appendix 2
Cost of Subreal app (per patient per 3-month cycle for 1 year)	25	25	25	Assumption—not varied in OWSA[d], varied in threshold analysis
Quality of life				
Utility in abstinence state (full-year utility)	0.9	0.72	1	UK population norm (Janssen et al [20])
Utility in treatment (full-year utility)	0.62	0.5	0.74	NICE[c] TAG[e]115 [21]
Utility in relapse state (full-year utility)	0.57	0.46	0.69	NICE TAG115 [21]
Discount rates				
Discount rate for costs	0.035	0.01	0.05	NICE reference case [15]
Discount rate for outcomes	0.035	0.01	0.05	NICE reference case [15]
Proportion of male individuals in the population	0.73	0.58	0.87	Adult substance misuse treatment statistics 2023-2024 [1]

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[a]A currency exchange rate of £1=US $1.33 is applicable.

[b]GBP: Pound Sterling.

[c]NICE: National Institute for Health and Care Excellence.

[d]OWSA: 1-way sensitivity analysis.

[e]TAG: technology appraisal guidance.

Dealing With Uncertainty

A deterministic approach was taken in the 2 models. This means that a single estimate was used for each parameter to populate the model. The NICE reference case [15] specifies that a probabilistic approach should be taken in a cost-utility analysis. Probabilistic sensitivity analysis uses a probability distribution for each parameter, which more accurately reflects the joint uncertainty in the cost and quality-of-life outcomes. This approach is believed to be inappropriate for an early exploratory health economic model, as it can lead to an impression of spurious accuracy when key clinical effectiveness data are missing [13]. This approach will be more appropriate following a clinical trial of the Subreal app. For this study, we used 1-way sensitivity analysis, which varies a single parameter at a time, thus showing the importance of individual estimates for the overall result. One-way sensitivity analysis varies parameters up and down by 20%. We also performed some specific threshold analyses to determine what the price needs to be at given effect sizes and what the effect size needs to be at given price levels. Due to data limitations, no subgroup analysis or characterization of distributional effects was planned.

Validation

The internal validity of the models was checked by using extreme values and review by a second health economist. Face validity was confirmed by clinician review and comparison to other long-term sources (eg, for long-term relapse rates and mortality). No other stakeholders were involved in the planning or validation of the study due to resource and time constraints.

Reporting

We used the revised CHEERS (Consolidated Health Economic Evaluation Reporting Standards) checklist [22] to ensure that our reporting was comprehensive. A completed questionnaire is provided as Checklist 1.

Preregistration

Our study protocol was not preregistered due to the exploratory nature of the analysis. For the same reason, no health economic analysis plan was developed.

Ethical Considerations

No ethics approval was needed for this study, as it relied solely on data from the published literature or other publicly available sources. No confidential patient data were used. The individual shown in Figure 1 provided consent for his image to be used.

Results

Base-Case Results

Tables 3 and 4 present the base-case results for the alcohol and opioid models, respectively.

The alcohol model estimated very small QALY gains over 1-, 5-, and 20-year time horizons and cost savings of £129, £256, and £256, respectively (Table 3). This resulted in an NMB of £163, £299, and £300, respectively. The majority of the benefit came from cost savings due to reduced cycles of treatment, as the number of relapses was lower with the use of the Subreal app.The savings made for each AUD relapse avoided were £1642 in the first year and higher in subsequent years, as the long-term implications of a relapse avoided were also included.

Similarly, the opioid model estimated very small QALY gains over 1-, 5-, and 20-year time horizons but larger cost savings of £261, £2747, and £2750, respectively (Table 4). This resulted in an NMB of £397, £3529, and £3757, respectively. Again, the majority of the benefit came from cost savings due to reduced cycles of treatment, as the number of relapses was lower with the use of the Subreal app. The NMB value in opioid model was higher than that in the alcohol model because OUD relapses are more frequent and more costly given long-term treatment and low recovery rates. The savings made for each OUD relapse avoided were £3884 in the first year and significantly higher in subsequent years, as the long-term implications of a relapse avoided were also included.

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Table . Base-case results for the alcohol model.

Alcohol model	Relapses	Savings per relapse avoided[a], GBP[b]	QALYs[c]	Costs[a], GBP	NMB[d], [a]GBP
1-year time horizon					
SOC[e] plus Subreal app	0.53	—[f]	0.6310	1561	—
SOC	0.61	—	0.6292	1690	—
Difference per patient	−0.08	1642	0.0017	−129	163
NMB for population[g]	—	—	—	—	6.2 m[h]
5-year time horizon					
SOC plus Subreal app	5.63	—	9.1316	16,075	—
SOC	5.72	—	9.1294	16,330	—
Difference per patient	−0.10	2669	0.002	−256	299
NMB for population	—	—	—	—	11.3 m
20-year time horizon					
SOC plus Subreal app	8.91	—	12.444	20,837	—
SOC	9.00	—	12.442	21,092	—
Difference per patient	−0.10	2669	0.002	−256	300
NMB for population	—	—	—	—	11.3 m

[a]A currency exchange rate of £1=US $1.33 is applicable.

[b]GBP: Pound Sterling.

[c]QALYs: quality-adjusted life years.

[d]NMB: net monetary benefit.

[e]SOC: standard of care.

[f]Not applicable.

[g]Population is % people successfully completing treatment multiplied by the number of people starting treatment, from the adult substance misuse treatment statistics 2023-2024 [1].

[h]m: million.

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Table . Base-case results for the opioid model.

Opioid model	Relapses	Savings per relapse avoided[a], GBP[b]	QALYs[c]	Costs[a], GBP	NMB[d], [a]GBP
1-year time horizon					
SOC[e] plus Subreal app	0.44	—[f]	0.8252	2240	—
SOC	0.51	—	0.8183	2501	—
Difference per patient	−0.07	3884	0.0068	−261	397
NMB for population[g]	—	—	—	—	1.3 m[h]
5-year time horizon					
SOC plus Subreal app	1.24	—	11.6571	59,104	—
SOC	1.27	—	11.6180	61,851	—
Difference per patient	−0.03	86,633	0.0391	−2747	3529
NMB for population	—	—	—	—	11.7 m
20-year time horizon					
SOC plus Subreal app	1.64	—	14.7428	74,027	—
SOC	1.67	—	14.6924	76,777	—
Difference per patient	−0.03	94,550	0.0504	−2750	3757
NMB for population	—	—	—	—	12.5 m

[a]A currency exchange rate of £1=US $1.33 is applicable.

[b]GBP: Pound Sterling.

[c]QALYs: quality-adjusted life years.

[d]NMB: net monetary benefit.

[e]SOC: standard of care.

[f]Not applicable.

[g]Population is % people successfully completing treatment multiplied by the number of people starting treatment, from the Adult substance misuse treatment statistics 2023-2024 [1].

[h]m: million.

Threshold Analysis

Tables 5 and 6 show the results of a 2-way threshold analysis, which explored the effects of various levels of impact on relapse rates alongside the effect of different price levels for the Subreal app. Table 5 shows that in a population with AUD, at £100 per annum (base case), the Subreal app would be cost-effective over a 1-year time horizon with a reduction in relapse rates of 10%. At £250 per annum, the reduction in relapses would need to be 15%, and at £350 per annum, it would need to be 20%. Table 6 shows that in a population with OUD, at £100 per annum (base case), the Subreal app is likely to be cost-effective if it achieves any reduction in relapse rates. At a price of £350 per annum, a reduction in relapse rates of 10%-15% is required for the Subreal app to be cost-effective. At a price of £700 per annum, the reduction in relapse rates would have to be greater than 20% for the app to be cost-effective.

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Table . Two-way threshold analysis of the effects of incremental cost and impact of the Subreal app on relapse rates on the net monetary benefit over a 1-year time horizon (all values in GBP)[a] in a population with alcohol use disorder.

Incremental cost of Subreal app per patient per annum	£100	£250	£350	£700
5% reduction in relapse rates	−11[c]	−156	−253	−591
10% reduction in relapse rates	76	−69	−166	−504
15% reduction in relapse rates	163[b]	19	−78	−416
20% reduction in relapse rates	253	108	11	−327

[a]A currency exchange rate of £1=US $1.33 is applicable.

[b]Base-case value.

[c]A negative net monetary benefit indicates that the app is not cost-effective.

Table . Two-way threshold analysis of the effects of incremental cost and impact of the Subreal app on relapse rates on the net monetary benefit over a 1-year time horizon (all values in GBP)[a] in a population with opioid use disorder.

Incremental cost of Subreal app per patient per annum	£100	£250	£350	£700
5% reduction in relapse rates	67	−78[c]	−175	−513
10% reduction in relapse rates	231	86	−10	−349
15% reduction in relapse rates	397[b]	252	155	−183
20% reduction in relapse rates	564	419	322	−16

[a]A currency exchange rate of £1=US $1.33 is applicable.

[b]Base-case value.

[c]A negative net monetary benefit indicates that the app is not cost-effective.

One-Way Sensitivity Analysis

Multimedia Appendices 2 and 3 illustrate the results of the 1-way sensitivity analysis for the alcohol and opioid models, respectively.

The most influential parameter was the impact of the digital technology on the relapse rate. This was the only parameter that had the potential to eliminate the base-case NMB when reduced by 20%. Most other parameters had limited impact, as they influenced both the standard of care pathway and the pathway including the digital technology. The cost of implementing the digital technology would also be highly influential; however, the cost of the technology was not included in this analysis, as it was explored in the 2-way threshold analysis.

As for the alcohol model, the most influential parameter in the opioid model was the impact of the digital technology on the relapse rate. The other parameters had less impact, as they affected the results for both treatment pathways. The cost of the technology is also influential and was explored in the 2-way threshold analysis.

Discussion

Findings of This Study

The early health economic models demonstrated that a digital health technology predicting relapse, such as the Subreal app, has the potential to be cost-effective and cost saving as part of the care pathways for people with AUD or OUD in the United Kingdom. The study identified the combinations of the impact on relapse rates and annual fees per patient that result in a technology that is cost-effective from a UK health and social care perspective. The model results indicate that the developers should focus on generating evidence on the impact of the Subreal app on relapse rates, as this was the parameter that most influenced the results of the health economic analysis. The study indicates that the potential for cost-effectiveness and cost saving increases as longer time horizons are explored but that there is potential for cost saving within a 1-year time horizon.

Comparison With Previous Economic Evaluations

We are not aware of any other economic evaluations of technologies to predict relapse in people with substance use disorder who have achieved abstinence. Economic evaluations in the area of AUD or OUD take a variety of analytical approaches and use different perspectives and time horizons. It

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is difficult to directly compare the results of these analyses with this study. However, they are useful in describing the range of costs that may be appropriate, with some studies including the costs to the criminal justice system [18,23,24]. Some studies have also provided quality-of-life estimates, which were useful to benchmark the utilities included in the models.

Strengths and Limitations

The models presented allow the developers of a digital technology designed to reduce relapse rates to explore the size of clinical effect that may be required to support different price levels. We are not aware of another decision model that has been designed to facilitate this. The models are available to other developers from the corresponding author upon request. The models have several limitations mainly arising from either a lack of available data in the literature or restrictions in the literature search due to resource constraints that are typical in early models [24]. We performed targeted literature searches to populate the models, rather than conducting any systematic reviews. Some of the data we used, particularly for relapse rates, are from the United States and are quite dated. Other sources were not ideally suited to our purpose; for example, the UK alcohol treatment trial (UKATT) [18] costs and quality-of-life estimates are for mixed groups of abstainers and individuals who continue to consume alcohol. We have also made a number of assumptions such as the proportion of people who would seek treatment after relapsing. The limitation of data sources is a frequent problem in early health economic modeling, where the methods adopted need to be tailored to the resources available for the analysis. This generally precludes significant data analysis elements or full-scale systematic reviews. However, as the sensitivity analysis demonstrated, the only influential parameters are the price of the technology and its clinical effectiveness. All other parameters are unlikely to influence the overall result because they impact both sides of the models. The models explored only 1 position in the AUD and OUD pathways, that is, people who have recently achieved abstinence. It is possible that the findingsare generalizable to other positions in the pathway where there is potential to increase support in order to prevent an adverse outcome (such as dropping out of treatment or relapsing while on MOUD). Clinical evidence would be required to support the size of the reduction in adverse events, but the economic argument is essentially the same. The models considered only AUD and OUD, but the population potentially served by the digital technology may be broader. For example, users of the Subreal app may have a combination of different substance use disorders—that is, polysubstance use disorder—which was not accounted for in the models. The key findings of the models would likely hold true regardless of the type of substance use disorder, provided that a reduction in relapses could be demonstrated in clinical studies. We adopted a health and social care perspective, although it is known that substance use disorders have wider societal costs. These wider costs could be considered at a later development stage, and their inclusion would likely increase the probability of cost-effectiveness, as relapse would have a higher associated cost. Although our analysis considered UK data, the results are likely to be generalizable in any health system that provides a similar level of care to people with substance use disorders.

Implications and Recommendations

The study suggests that digital technologies predicting relapse in people with AUD and OUD could be cost saving and cost-effective. Such technologies offer a potential commercial opportunity for developers, provided that the technology could be delivered for a cost, which would also allow for some of the cost to be retained by health care providers. It is vital that developers of digital technologies predicting relapse generate evidence of clinical effectiveness compared to standard of care in different populations of people who have achieved abstinence following treatment for substance use disorders. It should be noted that abstinence is not a goal for many people in treatment for OUD and the developers may wish to explore whether and how a digital technology could be useful as part of their care pathway. Health care providers may wish to consider whether this technology could be incorporated into care pathways, as it may offer cost savings over short and long time frames, as well as improving patient health (and therefore wider societal) outcomes. Practical problems to be resolved in collaboration with health care providers include how technology could be provided to allow equitable access and process redesign to incorporate the use of the app.

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Data Availability

All data used are publicly available with full references provided.

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Authors' Contributions

Conceptualization: JB, SB, MB
Data curation: JB
Formal analysis: JB, SB
Funding acquisition: MB
Investigation: JB, SB, MB
Methodology: JB, SB, MB
Project administration: SB, MB
Resources: JB, SB, MB
Software: JB
Supervision: SB, MB
Validation: JB, SB, MB
Visualization: JB
Writing – original draft: JB
Writing – review & editing: JB, SB, MB

Conflicts of Interest

MB is a director and shareholder of Subreal Limited, a company developing monitoring tools for substance use disorders. SB and JB declare no conflict of interest.

Multimedia Appendix 1
Additional detail on parameter estimates.
[PDF File, 104 KB - formative_v10i1e87186_app1.pdf]

Multimedia Appendix 2
Tornado diagram illustrating the results of the 1-way sensitivity analysis for the alcohol model (blue bars depict the lower limit, while red bars depict the higher limit). NMB, net monetary benefit.
[PNG File, 119 KB - formative_v10i1e87186_app2.png]

Multimedia Appendix 3
Tornado diagram illustrating the results of the 1-way sensitivity analysis for the opioid model (blue bars depict the lower limit, while red bars depict the higher limit). MSW, medically supervised withdrawal; MOUD, medication for opioid use disorder; NMB, net monetary benefit.
[PNG File, 132 KB - formative_v10i1e87186_app3.png]

Checklist 1
CHEERS checklist.
[PDF File, 176 KB - formative_v10i1e87186_app4.pdf]

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Abbreviations

AUD: alcohol use disorder
CHEERS: Consolidated Health Economic Evaluation Reporting Standards
HTA: health technology assessment
MOUD: medication for opioid use disorder
NHS: National Health Service
NICE: National Institute for Health and Care Excellence
NMB: net monetary benefit
OUD: opioid use disorder
PICO: Population, Intervention, Comparator, and Outcome
QALYs: quality-adjusted life years
TRL: Technology Readiness Level
UKATT: UK alcohol treatment trial

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Coverage, Traits, and Geographic Distribution of Online Surgeon Reviews: Large-Scale Cross-Sectional Analysis

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Abstract

Background: The use of online physician rating platforms has significantly increased and has been shown to influence physician selection. There are limited data on the use of these platforms for rating surgeons.

Objective: In this study, we sought to assess the geographic distribution of and patterns in rating scores of surgeons in the United States. Additionally, we examined rating volumes across different surgical specialties and the association between peer-nominated and patient-initiated ratings on online rating platforms in the United States.

Methods: We conducted a cross-sectional study by identifying 201,154 surgeons in the United States via the National Plan and Provider Enumeration System records and Doctors and Clinicians downloadable file. We assessed surgeon coverage on 3 online rating platforms and their geographic use patterns. We described the rating scores and volumes across different surgical specialties and assessed the relationship between rating platforms by comparing peer-nominated and patient-initiated online ratings.

Results: A total of 78.86% (158,630/201,154) of the surgeons had ratings on at least 1 of the 3 patient-initiated websites across 11 specialties. Plastic surgeons, neurosurgeons, and orthopedic surgeons had the highest mean number of patient-initiated ratings. Surgeons with "Top Doctor" recognition from peers (23,171/201,154, 11.52%) were associated with an increased median patient-initiated rating (Healthgrades: 4.36, IQR 3.88-4.71 vs 4.20, IQR 3.64-4.64, $P<.001$, and $r=0.09$; Vitals: 4.30, IQR 4.00-4.60 vs 4.20, IQR 3.80-4.50, $P<.001$, and $r=0.09$; RateMDs: 4.20, IQR 3.80-4.50 vs 3.80, IQR 3.60-4.60, $P<.001$, and $r=0.16$). Geographic analysis indicated that 91.06% (295,816,471/324,870,510) of the US population lives in a county with a surgeon rated 10 times or more.

Conclusions: Both patient-initiated and peer-nominated rating platforms have a comprehensive coverage of surgeons in the United States, but this coverage differs significantly between surgical specialties. Further work should assess how publicly available online ratings drive surgeon selection and their association with patient experience and postoperative outcomes.

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KEYWORDS

online ratings; surgeons; demographics; coverage; reviews

Introduction

The use of online physician rating platforms is steadily increasing and plays a critical role in patients' selection of health care providers. According to recent surveys, 86% of respondents reported reading online reviews before choosing a physician, and 73% indicated a preference for physicians with ratings of 4 out of 5 or higher [1,2] These figures underscore the substantial influence of such platforms (in addition to other factors such as insurance coverage and referral patterns) on patients' choices.

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These rating platforms encompass both peer-nominated ratings, which include physician-nominated lists that designate high-performing physicians as "Top Doctors," and patient-initiated ratings that collate patient-submitted reviews and ratings of their experiences with physicians. These platforms offer potential and current patients a wealth of information, including narrative reviews; numerical ratings for specific dimensions; and an overall rating of care, typically using a 5-point scale. The influence of online ratings may also extend to clinic volumes, with some surgeons raising concerns regarding the possible disproportionate use of these open-forum platforms to share complaints [3,4]. To evaluate whether online ratings reflect the quality of care delivered, prior work has reported no association between ratings and objective quality metrics or peer assessments of clinical performance [5]. Health care institutions have likewise become increasingly attentive to their online reputations with an increasing number of patients using these platforms [6,7].

In studies focusing specifically on surgical practices, factors associated with more favorable online ratings have included active X (formerly known as Twitter) use and shorter patient-reported clinic wait times among orthopedic surgeons [8], lower clinic volumes among urologists in California [9], and qualitative attributes (such as perceived trustworthiness, punctuality, and ease of scheduling) as strong predictors of higher ratings [10]. Disparities across geographic regions (eg, underserved or rural areas) and across surgical specialties with differing practice styles (such as variations in clinical acuity and patient volume) may further influence the likelihood of appearing on curated lists or receiving favorable ratings. However, the scope of prior investigations has been limited by the number of specialties examined and the geographic coverage of surgeons included on both patient-initiated and peer-nominated platforms.

To our knowledge, a large-scale study assessing the representation of the entire cohort of surgeons in the United States on physician rating platforms has not been performed. By creating a national surgeon directory from datasets published by the US Centers for Medicare and Medicaid Services (CMS), the country's largest health care payer, we sought to address this gap in the literature by quantifying surgeon representation on the predominant online rating platforms nationally, describing any geographic differences in online representation, comparing the representation of surgeons between patient-initiated and peer-nominated physician rating platforms, and assessing specialty-specific differences in surgeon representation among these platforms.

Our research questions are as follows:

1. What is the overall coverage of surgeons on the 3 major online physician rating platforms in the United States?
2. Are there county-level regional differences in surgeon representation on online rating platforms in the United States?
3. What is the relationship between overall rating and rating volume on patient-initiated rating platforms and peer-nominated "Top Doctor" status among surgeons in the United States?
4. How does surgeon visibility on these online patient-initiated and peer-nominated rating platforms differ across different subspecialties in the United States?
5. Are there differences in the demographics of highly reviewed surgeons?

Methods

This study followed the STROBE (Strengthening the Reporting of Observational Studies in Epidemiology) reporting guidelines [11].

Ethical Considerations

The data used to conduct this study are publicly available. No patient data were involved. The study was exempt from institutional review board approval and requirement for informed consent. Research data, including individual surgeon-level information, were deidentified. No compensation was provided for the publicly available data of the included surgeons.

Identification of Patient-Initiated and Peer-Nominated Physician Rating Platforms

We identified the most popular patient-initiated and peer-nominated rating platforms based on search traffic (via Semrush, which tracks the reach of a website by looking at the number of its backlinks) [12]. We identified 3 patient-initiated rating platforms (RateMDs, Vitals, and Healthgrades) and 1 peer-nominated "Top Doctor" rating platform (Castle Connolly [13]) that had the highest number of backlinks on Semrush and had the largest volume of recognized surgeons nationally. Castle Connolly is a private consumer research firm that distinguishes the nation's top 7% of physicians through a physician peer nomination process and awards "Top Doctor" status based on these nominations. These lists are prepared for each specialty and most subspecialties. As the largest physician-nominated "Top Doctor" publication, prior studies have used Castle Connolly to assess the validity and role of physician-nominated ratings [14].

Cohort Derivation: Surgeon Identification and Linkage to Patient-Initiated and Peer-Nominated Ratings

We began by identifying all currently practicing surgeons in the United States using 2 publicly available datasets maintained by the US CMS (step 1 of Figure 1). The National Plan and Provider Enumeration System is a mandatory national registry of licensed health care providers and includes a unique National Provider Identifier, self-reported specialty, and practice location [15]. To ensure active clinical practice and improve specialty verification, we linked National Plan and Provider Enumeration System records to the CMS Doctors and Clinicians downloadable file, which contains physicians actively enrolled in and billing Medicare services [16]. Together, these datasets enabled comprehensive nationwide identification and subspecialty stratification of practicing surgeons by providing us with their registered National Provider Identifier, name, primary practice location, and specialty.

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Figure 1. Methodology workflow. We created a surgeon directory using the National Plan and Provider Enumeration System (NPPES) and Doctors and Clinicians (DAC) surgeon directories from the Centers for Medicare and Medicaid Services (CMS). Next, we performed automated Google searches for each physician to find the rating platforms of interest. We then extracted the ratings from each rating website of interest and merged them with the "Top Doctors" list. NPI: National Provider Identifier.

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Extraction of Data

We performed web scraping by adapting Python scripts from the GitHub repository linked by Wang et al [17]. From our surgeon directory, we programmatically ran Google searches using name, location, and specialty (step 2 of Figure 1). Through recording the top Google search results, we could reliably find a website link to each surgeon's online patient-initiated rating profiles (Healthgrades, Vitals, and RateMDs). With a website link to each patient-initiated rating profile, we could then extract the total number of ratings and overall ratings on each surgeon profile (step 3 of Figure 1). An additional script was written to web scrape the peer-nominated rating platform (August 2022) and create a directory of listed physicians who were also recognized by Castle Connolly as "Top Doctors." Web scraping of the patient-initiated physician rating platforms was performed between November 2022 and January 2023. Subsequent data cleaning was performed in the Python programming language (version 3.9; Python Software Foundation) and R (version 4.2.2; R Foundation for Statistical Computing).

Outcomes

Descriptive statistics regarding the number of surgeons on at least one of these rating platforms; median number of ratings; and the proportions with at least one rating, 10 or more ratings, 25 or more ratings, 50 or more ratings, and 100 or more ratings stratified by specialty were reported. The number of ratings required to meet the top 1, 5, 10, 25, and 50 percentiles of surgeons across different specialties on patient-initiated rating platforms was reported. We reported the number of surgeons, stratified by specialty, who were given ratings of 4, 4 to 4.5, and 4.5 or above out of 5. We analyzed the use of different rating platforms by comparing the number of ratings across surgical specialties. To compare surgeon ratings, we computed a weighted average to create an aggregate rating across all 3 platforms by multiplying each platform's average rating by its number of reviews, summing these values, and dividing by the total number of reviews. Comparing a weighted average allowed us to normalize for differing rating volumes across platforms.

To ensure adequate review sampling, we restricted visualization to surgeons with 10 patient-initiated ratings or more (the median number of ratings) and mapped their geographic distribution. Mapping of the geographic distribution of surgeons with 10 or more ratings and "Top Doctor" status across counties (defined as the primary administrative division of a state in the United States) [18] in the continental United States was performed. The top 25 counties with the highest number of surgeons rated as "Top Doctors" and surgeons with 10 or more ratings were reported.

Comparisons of ratings across the 3 patient-initiated platforms were made by stratifying by "Top Doctor" status to understand the association between physician- and patient-initiated ratings.

Statistical Analysis

We analyzed the number of ratings and rating scores across specialties. Surgeon ratings were categorized into a 3-level classification based on prior research: low (<4.0), medium (4.0 - 4.49), and high (≥4.5) [19]. A weighted average was calculated by adding the product of the number of ratings and average rating on each platform and then dividing by the total number of ratings across all platforms. This calculation was done to account for a surgeon's variation in number of ratings across each patient-initiated rating platform. Geographic analysis was conducted to determine the geographic distribution of surgeons with patient-initiated ratings and "Top Doctor" designation. Specifically, we normalized the surgeon population using percentages of the total number of surgeons within a county. We linked zip codes to Federal Information Processing Standard codes that corresponded to a county. We explored the relationship between "Top Doctor" designation and patient-initiated ratings. We observed a left skew of the rating scores with clustering near the upper bound of the scale consistent with known ceiling effects in online physician ratings. We also observed a right skew of the number of ratings due to the large ranges encountered in the number of ratings across surgeon online profiles. Normality was assessed by plotting histograms for overall rating and number of ratings. We used nonparametric statistical tests as a result, and more specifically, we conducted comparisons between "Top Doctor" surgeons and non–"Top Doctor" surgeons using the Mann-Whitney *U* test. Across the 3 patient-initiated online rating platforms, the rating scores and number of ratings were compared after being stratified by "Top Doctor" status. Rank biserial correlation was used as the nonparametric metric of effect size for each Mann-Whitney comparison. It was derived by dividing the statistic from the Mann-Whitney *U* test by the square root of the sample size. Finally, we identified surgeons with the highest number of ratings (top 1%) to define the characteristics of this unique surgeon population. Data analysis and visualization were performed using R (version 4.2.2).

Results

Characteristics of Surgeons on Online Rating Platforms

Of the 201,154 unique surgeons identified, 189,463 (94.19%) had a profile on a patient-initiated rating platform, and 158,630 (78.86%) had at least one rating on a platform (Figure 1). Plastic surgery, colorectal surgery, and orthopedic surgery had the highest percentage of surgeons with at least one rating at 85.46% (6038/7065), 84.57% (1683/1990), and 84.01% (28,237/33,611), respectively (Table 1). General surgery and cardiothoracic surgery had the lowest percentage of surgeons with at least one rating at 67.96% (26,738/39,343) and 74.77% (4116/5505), respectively (Table 1). Among all surgeons with at least one rating, the mean and median number of ratings were 26.37 (SD 53.24) and 10 (IQR 1-32), respectively. Using the weighted average of the ratings across all 3 patient-initiated rating platforms, we found that the mean rating was 4.12 (SD 0.78) out of 5 and the median was 4.26 (IQR 3.71-4.70) out of 5 (Table S1 in Multimedia Appendix 1).

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Table . Descriptive information of surgeons in the United States across specialties on peer-nominated rating website recognition along with specialty-specific counts of total review thresholds (reviews aggregated across all patient-initiated rating platforms) in this cross-sectional study (N=201,154).

Specialty	"Top Doctor" designation, n (%)	Rating count, median (IQR)	Rating count, mean (SD)	Surgeons with an online profile on ≥1 patient-initiated review platform, n (%)	Surgeons with ≥1 total patient-initiated ratings, n (%)	Surgeons with ≥10 total patient-initiated ratings, n (%)
All	23,171 (11.52)	10 (1-32)	26.37 (53.24)	189,463 (94.19)	158,630 (78.86)	103,600 (51.50)
Cardiothoracic (n=5505)	867 (15.75)	6 (0-16)	12.33 (22.60)	5094 (92.53)	4116 (74.77)	2184 (39.67)
Colorectal (n=1990)	535 (26.88)	20 (4-45)	32.97 (48.44)	1850 (92.96)	1683 (84.57)	1280 (64.32)
General (n=39,343)	3028 (7.70)	4 (0-16)	13.46 (31.18)	36,190 (91.99)	26,738 (67.96)	13,598 (34.56)
Neurosurgery (n=7574)	965 (12.74)	18 (2-51)	38.14 (64.10)	7110 (93.87)	6179 (81.58)	4571 (60.35)
OB/GYN[a] (n=51,293)	3275 (6.38)	12 (2-34)	24.82 (39.64)	48,461 (94.48)	41,389 (80.69)	27,492 (53.60)
Ophthalmology (n=24,227)	3546 (14.64)	8 (1-24)	22.77 (63.30)	23,008 (94.97)	19,211 (79.30)	11,551 (47.68)
Orthopedic (n=33,611)	4396 (13.08)	21 (3-54)	42.91 (69.63)	31,986 (95.17)	28,237 (84.01)	21,500 (63.97)
Otolaryngology (n=13,394)	2549 (19.03)	13 (2-34)	28.92 (66.66)	12,710 (94.89)	10,912 (81.47)	7522 (56.16)
Plastic (n=7065)	1398 (19.79)	21 (4-50)	42.51 (77.86)	6686 (94.64)	6038 (85.46)	4617 (65.35)
Urology (n=13,552)	1982 (14.63)	14 (2-34)	25.35 (43.04)	12,930 (95.41)	11,243 (82.96)	7741 (57.12)
Vascular (n=3600)	630 (17.50)	7 (1-18)	15.12 (35.20)	3438 (95.50)	2884 (80.11)	1544 (42.89)

[a]OB/GYN: obstetrics and gynecology.

The number of ratings and overall ratings across different patient-initiated rating platforms is shown in Figure S1 in Multimedia Appendix 1. Across all specialties, a small number of surgeons received disproportionately high numbers of ratings, and the ratings were negatively skewed, with most aggregate ratings at around 4 out of 5, whereas relatively few were below 3 out of 5.

We identified 11.52% (23,171/201,154) of surgeons with "Top Doctor" status on the peer-nominated rating platform (Table 1). On the peer-nominated platform, the 3 surgical specialties with the highest proportion of surgeons recognized as "Top Doctors" were colorectal surgery (535/1990, 26.88%), plastic surgery (1398/7065, 19.79%), and otolaryngology (2549/13,394, 19.03%). The specialties with the lowest rates of recognition were obstetrics and gynecology (3275/51,293, 6.38%) and general surgery (3028/39,343, 7.70%; Table 1).

Geographic Distribution of Surgeons on Online Rating Platforms

The geographic distribution of surgeons with 10 or more patient-initiated ratings and "Top Doctor" status is shown in Figure 2. The practice locations of our surgeon cohort included 2199 US counties, which represents coverage for 94.9% of the US population (308,139,520 persons across all counties, with an estimated US population of 324,870,510) [9-11,13]. We found evidence of wide coverage across the United States of both the patient-initiated and peer-nominated platforms. A total of 85.18% (1873/2199) of the counties, covering 91.06% (295,816,471/324,870,510) of the population, had at least one surgeon with 10 or more ratings, and 48.93% (1076/2199) of the counties, covering 82.03% (266,475,236/324,870,510) of the population, had at least one surgeon with "Top Doctor" status (Figure 2). We found that Los Angeles, Cook, New York, Maricopa, Harris, Miami-Dade, Orange, San Diego, Nassau, and Dallas, in order from highest to lowest, were the counties with the highest number of surgeons with 10 or more patient-initiated ratings. We found a similar pattern of geographic distribution for surgeons recognized as "Top Doctors," with a higher presence in the US northeast.

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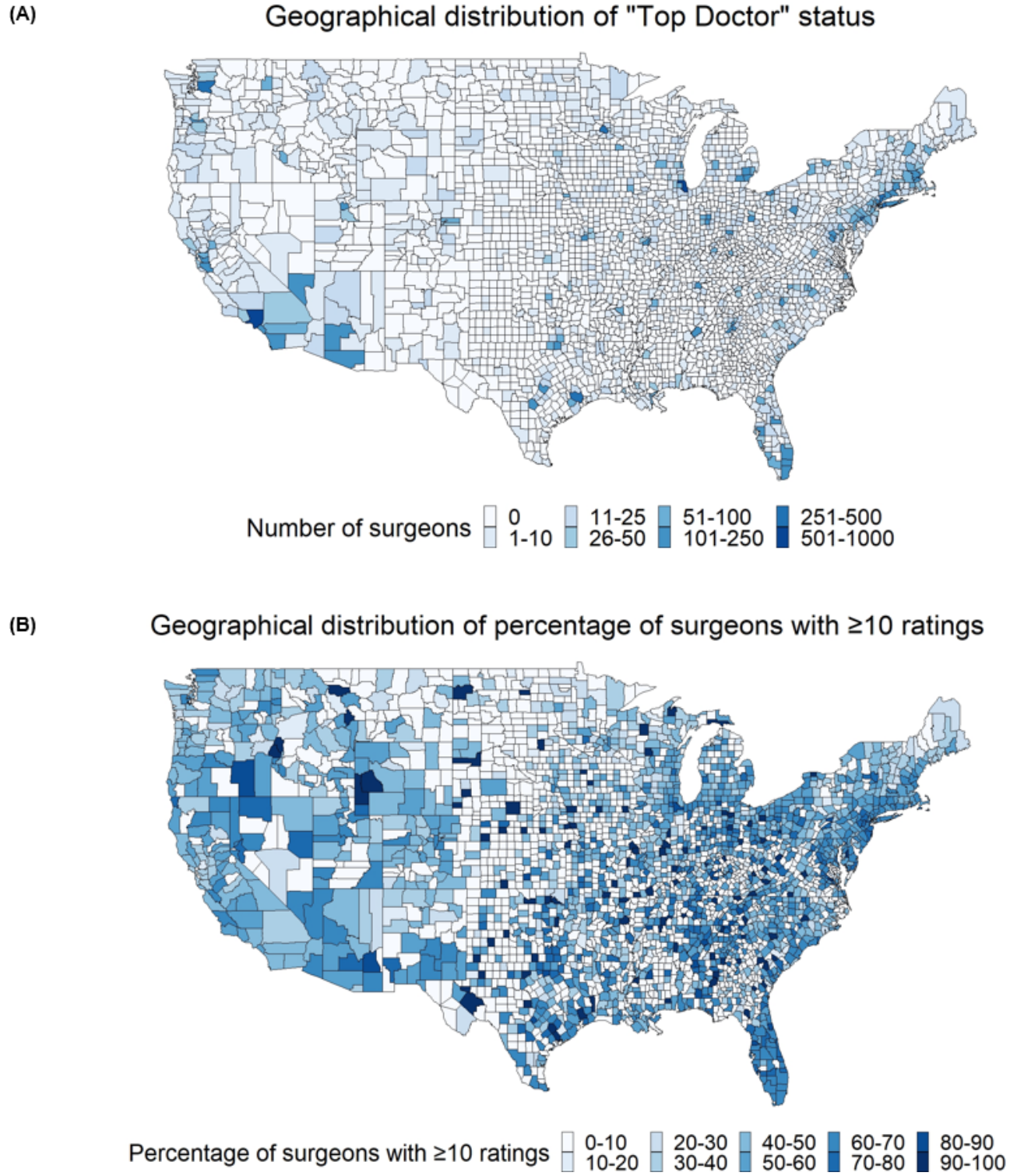
Figure 2. (A) Geographical distribution of Castle Connolly "Top Doctors" in the United States in this cross-sectional study. (B) Geographical distribution of surgeons with 10 or more ratings in the United States. We mapped the zip codes of each surgeon's primary practice location to their local county to generate a county-specific number of "Top Doctor" surgeons and the percentage of surgeons with 10 or more ratings for the contiguous United States (197,019/201,154, 97.94% of the total directory). Counties that had 0 surgeons were assigned a percentage of 0.



Relationship Between Rating Volume and Overall Rating Across Surgical Specialties

We examined differences in rating volume, stratifying surgeons by specialty and rating classification (<4, 4-4.5, and ≥4.5 out of 5; Table S2 in Multimedia Appendix 1). Among surgeons in the lowest and highest rating groups, there was a higher concentration of profiles with a low number (<10) of ratings, suggesting insufficient sampling. However, we also found that surgeons with high numbers of ratings (>100) were more likely to be in the highest (≥4.5) rating group (Figure S2 in Multimedia Appendix 1). Cardiothoracic surgery, plastic surgery, general surgery, and ophthalmology were the specialties with the highest proportion of surgeons with ratings of 4.5 or higher (Table S2 in Multimedia Appendix 1).

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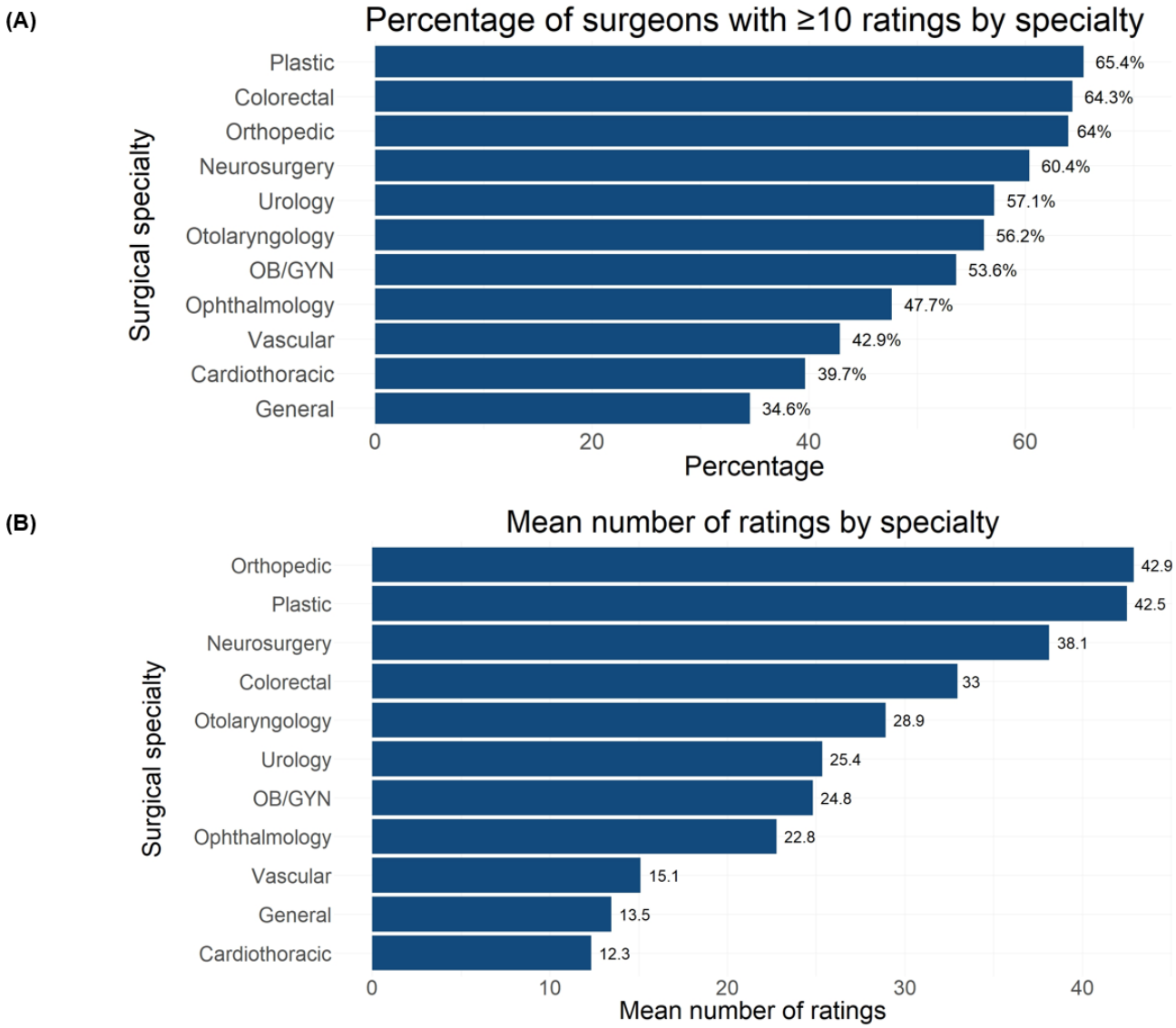
We identified substantial variation in the proportion of surgeons with 10 or more ratings across surgical specialties (Figure 3A). While specialties such as plastic surgery, colorectal surgery, orthopedic surgery, and neurosurgery had over 60% of surgeons with 10 or more ratings, specialties such as general surgery, cardiothoracic surgery, and vascular surgery had less than 45% of surgeons with 10 or more ratings. There was substantial variation in the mean number of ratings across specialties, with orthopedic and plastic surgery averaging over 40 ratings per surgeon, whereas general and cardiothoracic surgery averaged fewer than 15 ratings per surgeon (Figure 3B).

Figure 3. (A) Bar plot showing the percentage of surgeons in the United States with 10 or more ratings by each specialty in this cross-sectional study. (B) Bar plot showing the mean number of ratings for surgeons in the United States by each specialty in this cross-sectional study. OB/GYN: obstetrics and gynecology.



Relationship Between Peer-Nominated and Patient-Initiated Platforms

We explored the relationship between peer-nominated and patient-initiated rating platforms and found that surgeons recognized as "Top Doctors" had higher median ratings across all patient-initiated rating platforms compared to their non–"Top Doctor" counterparts (Healthgrades: 4.36, IQR 3.88-4.71 vs 4.20, IQR 3.64-4.64, P<.001, and r=0.09; Vitals: 4.30, IQR 4.00-4.60 vs 4.20, IQR 3.80-4.50, P<.001, and r=0.09; RateMDs: 4.20, IQR 3.8-4.5 vs 3.80, IQR 3.60-4.60, P<.001, and r=0.16; Figure 4A). Additionally, surgeons recognized as "Top Doctors" had a greater median number of ratings across all platforms (Healthgrades: 15, IQR 7-29 vs 6, IQR 1-16, P<.001, and r=0.23; Vitals: 17, IQR 9-32 vs 7, IQR 1-18, P<.001, and r=0.23; RateMDs: 2, IQR 0-7 vs 1, IQR 0-4, P<.001, and r=0.12; Figure 4B).

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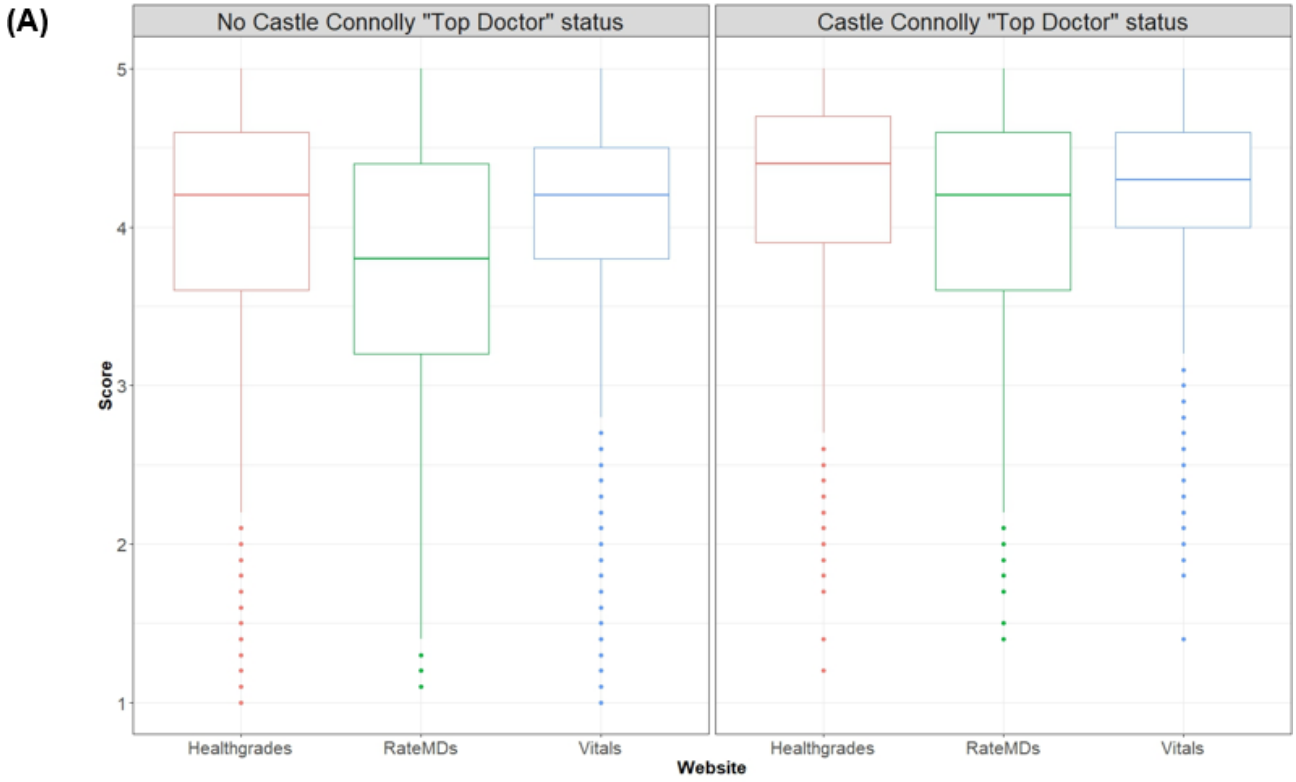
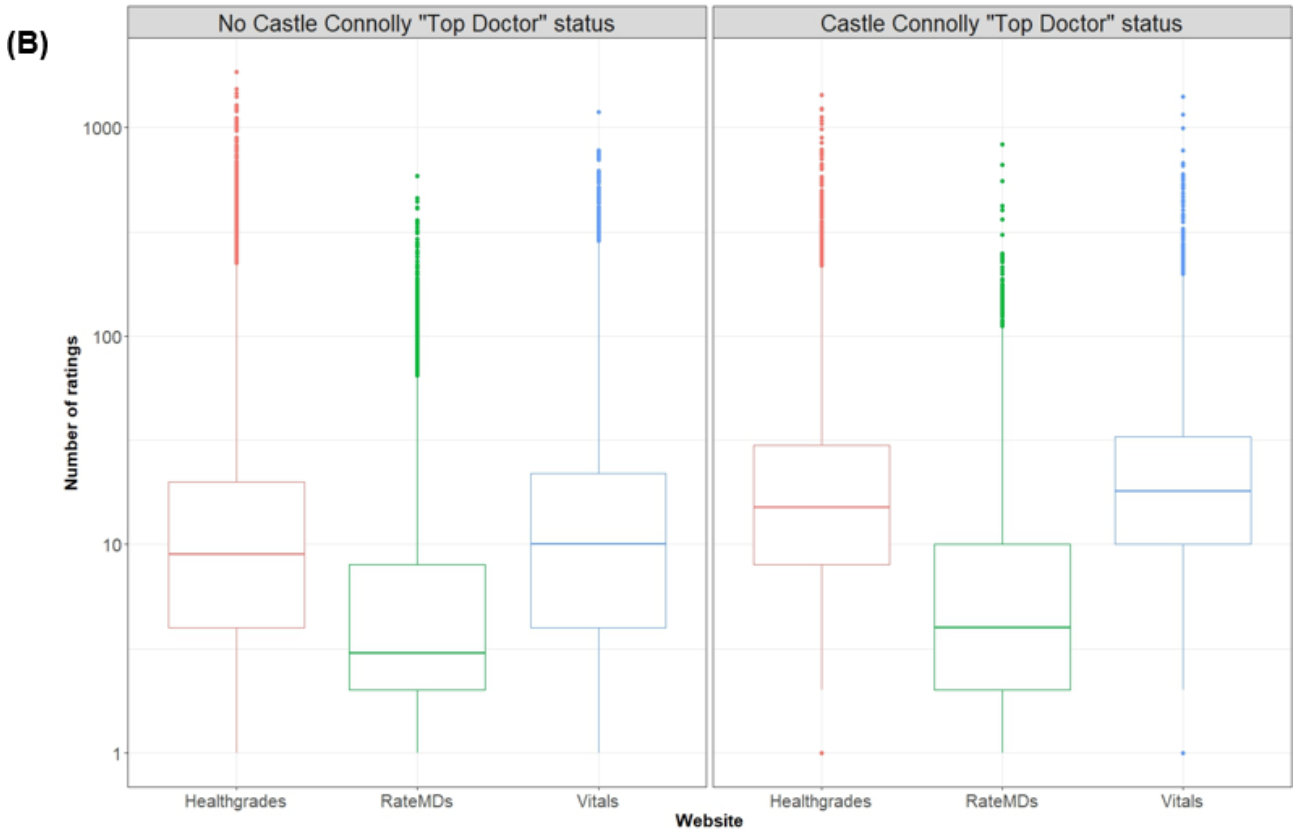
Figure 4. (A) Box plots of rating scores for surgeons in the United States with 10 or more ratings, stratified by peer-nominated “Top Doctor” status for each patient-initiated rating platform in this cross-sectional study. (B) Box plots of rating volume for surgeons in the United States with 10 or more ratings, stratified by peer-nominated “Top Doctor” status for each patient-initiated rating platform in this cross-sectional study.





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Characteristics of Surgeons With a High Number of Patient-Initiated Ratings

Finally, we explored specialty-specific patterns among surgeons with a high number of patient-initiated ratings. We found 133 individual surgeons with at least 500 ratings on 1 of the 3 platforms, with median ratings of 4.80 (IQR 4.70-4.90), 4.90 (IQR 4.90-5.00), and 4.85 (IQR 4.70-4.90) on Healthgrades, Vitals, and RateMDs, respectively. We also found considerable variation in the number of reviews required to be in the top 1 percentile across specialties, with cardiothoracic surgeons having 124 total ratings compared to plastic surgeons with 372 total ratings. At a specialty-specific level, surgeons in plastic surgery (372 ratings), orthopedic surgery (324 ratings), and neurosurgery (280 ratings) had the highest threshold for the number of ratings necessary to reach the top 1 percentile.

Discussion

Principal Findings

We found that 78.86% (158,630/201,154) of surgeons in the United States had at least one rating on a patient-initiated platform, and 11.52% (23,171/201,154) were recognized as "Top Doctors" by their peers. A total of 91.06% (295,816,471/324,870,510) of the population in the continental United States lives in a county with at least one surgeon with more than 10 reviews. Major metropolitan areas contained the highest frequency of surgeons with a high number of patient-initiated ratings, as well as those designated with a "Top Doctor" status. There was considerable variation in the number of highly rated surgeons on patient-initiated and peer-nominated platforms between specialties. Surgeons who had "Top Doctor" status were also more likely to receive a higher volume of ratings and overall ratings on patient-initiated rating platforms.

Comparison With Prior Work

Previous studies have largely examined physician rating websites that are patient-initiated within specific specialties and/or regional locations [9,10,20-29]. Our study included both patient-initiated and peer-nominated rating platforms across all surgical subspecialties with comprehensive coverage of surgeons across the United States. Compared to a recent study that showed that 51.5% of physicians have at least one rating across 5 different patient-initiated rating platforms, we found meaningfully higher representation among surgeons on 3 different platforms that we identified as having the highest online traffic volume [17]. While there is inconsistent evidence regarding associations between surgeons being recognized by their peers as "Top Doctors" and both the number of patient-initiated ratings and overall patient ratings [14,27], we found that the median number of patient-initiated ratings and median ratings across all 3 patient-initiated rating platforms was statistically significantly higher (P<.001) among surgeons recognized as "Top Doctors."

Our study focused specifically on the quantitative ratings on patient-initiated platforms. Prior studies of rating websites have noted that written reviews often describe characteristics aside from surgical outcomes, including bedside manner, wait times, communication with staff, and office environment [19,21,24,30-47]. We found that the rating scores of surgeons across all specialties were largely skewed toward a higher rating, and these findings suggest that patients use these platforms for positive feedback more commonly than for grievances, as feared by physicians. Prior studies have also reported similar findings based on quantitative and text analyses [48,49]. The extent to which these patient-initiated and peer-nominated websites capture patients' experience compared to other review systems (eg, Press Ganey surveys) remains to be elucidated. Thematic or qualitative analyses of free-text patient comments (eg, sentiment analysis) may offer additional insights into patient considerations in rating surgeons.

Limitations

Our study has limitations consistent with the study design. The rating websites used may have incorrect or outdated information and duplicate profiles. The data collected represent a snapshot of ratings, and changes over time to the ratings were not captured. Following the methods of Wang et al [17], much of the data were linked to the profiles found on Google search results and subsequently mapped to the name, specialty, and location in the surgeon directory. However, some ambiguities exist with common names or differences between nicknames found on online profiles and legal names used for official licensing. We programmatically resolved these by matching other factors such as location and specialty to further match profiles with different first names. The remaining cases that could not be programmatically resolved were addressed via manual review. Through automated Google searches to identify the profiles, there is the potential for profiles to be missing if they did not appear early (within the first 2 pages) in the search results. Google search results may return the profiles of related physicians in the same city or those with similar names. Our high rate of physician profile retrieval indicates that most profiles were captured, and subsequent data cleaning served to minimize errors.

Mixed Incentives and Biases of Online Surgeon Rating Platforms

Our findings underscore the ubiquity and accessibility of online surgeon ratings, with top online search results of surgeons consistently yielding online profiles on several physician rating platforms. This widespread visibility highlights the growing influence of these ratings on patient perceptions and surgeon selection; however, notable disparities exist across surgical specialties and geographic regions on these online rating platforms. Patient-initiated online ratings are not regulated (eg, lack of patient verification) and, thus, may allow for exceedingly positive or negative reviews, which are not reflective of the direct patient-surgeon experience [30-32,50]. However, we found in this study that most surgeons had aggregate ratings at 4 out of 5 stars or higher, suggesting that ratings are typically positive overall and concerns that rating platforms display disproportionately negative experiences may be unfounded. While these rating websites aim to provide reputable assessment of surgeons by physician peers and patients, the accuracy of these platforms may instead be affected by financial incentives to promote a favorable online presence. Some of these rating platforms sell marketing collateral and promotional products

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that are eligible for highly rated physicians. It is also possible that soliciting reviews from patients may lead to biased results; consistent with this, we observed that the cohort of 133 surgeons with 500 or more patient reviews on a single platform often had near-perfect ratings. Future efforts to improve the bias in these rating systems are needed, and comparison of the ratings on these online platforms to independent third-party surveys from verified patients (eg, the Hospital Consumer Assessment of Healthcare Providers and Systems by the CMS) may be warranted.

Conclusions

Surgeons across all specialties and locations are well represented on online rating platforms, with considerable variation in the volume of ratings between individual surgeons, across surgical specialties, and across a wide geographic distribution. The prevalence of these rating platforms justifies future work to understand the relationship between these ratings and how patients choose surgeons, as well as the association between ratings and objective measures of surgical outcomes.

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Disclaimer

Generative artificial intelligence was not used in the analysis or the drafting of this manuscript.

Data Availability

The datasets generated or analyzed during this study are available from the corresponding author on reasonable request.

Conflicts of Interest

YT receives funding from the National Institutes of Health National Institute on Aging (R01AG068633 and R01AG082991), National Institutes of Health National Institute on Minority Health and Health Disparities (R01MD013913), and GRoW @ Annenberg for other work not related to this study and serves on the board of directors of M3, Inc. These funders had no role in considering the study design or in the collection, analysis, and interpretation of the data; writing of the report; or decision to submit the article for publication. AJ has received a merit award from the Department of Anesthesiology and Pain Medicine, Temerty Faculty of Medicine, University of Toronto. All other authors declare no other conflicts of interest.

Multimedia Appendix 1
Additional information across surgical specialties and rating platforms.
[DOCX File, 702 KB - formative_v10i1e79427_app1.docx]

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Abbreviations

CMS: Centers for Medicare and Medicaid Services
STROBE: Strengthening the Reporting of Observational Studies in Epidemiology

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Development of Virtual Mental Health Stepped Care Service for a Heart Failure Remote Management Program: Qualitative Descriptive Study

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Abstract

Background: Depression is highly prevalent yet undertreated among people living with heart failure, indicating barriers to mental health services. Although various digital mental health interventions have been developed to detect, treat, and manage depression in this population, these interventions have seen limited integration into clinical care and a lack of implementation research. Stepped care is a service innovation that may promote the implementation of these technologies into clinical settings, but few studies have examined how these services are designed in clinical settings.

Objective: This study aimed to identify strategies to address health system barriers to accessing mental health care from the perspective of people living with heart failure, clinicians, and researchers, and to incorporate these strategies into the design of a virtual mental health stepped care service within a heart failure remote management program.

Methods: A qualitative description study was conducted using purposive recruitment of people living with heart failure, clinicians, and researchers from a heart failure remote patient management program. As part of a service design approach, semistructured interviews explored potential strategies to address barriers to accessing mental health services. Two researchers coded the data descriptively and constructed themes to guide the development of a virtual stepped care service.

Results: A total of 22 participants were interviewed, comprising 13 people living with heart failure and 9 clinicians and researchers. Six themes were identified, comprising 4 requirements and 2 foundational principles. The requirements were to (1) adopt a collective approach to identify distress across methods, people, and time points; (2) maintain a referral-based approach; (3) rely on existing mental health human resources; and (4) offer patient choice among various mental health care options. These requirements were supported by two principles: (1) building on organizational strengths and (2) reducing treatment burden. Based on these findings, a virtual stepped care service was developed, incorporating a depression screening module, referral-based workflows, and, where clinically appropriate, patient choice in treatment selection.

Conclusions: The stakeholder-informed design of this virtual stepped care service contributes to the limited literature on stepped care service design and demonstrates how such models can be tailored to their intended contexts. Although each component was designed to address health system barriers to mental health care for people living with heart failure, resource limitations may constrain the balance between feasibility and quality of care. Future research should evaluate the acceptability of this model among people living with heart failure and clinicians.

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KEYWORDS

telemedicine; e-counseling; patient care management; heart failure; digital health; telemonitoring; remote monitoring; depression

Introduction

Background

Despite the established impact of depression on heart failure outcomes, this prevalent comorbidity remains unaddressed or underaddressed in usual care [1,2]. Clinical practice guidelines, in addition to a growing body of research, have called for a more integrated approach to addressing depression, such as incorporating depression screening and diagnosis into heart failure care [1,3-5]. However, in prior qualitative research, our research team identified that this remains hindered by barriers at the health system and patient levels [6] and may contribute to the poor uptake of mental health services documented within this population [7-9].

In both the heart failure and mental health service literature, virtual technologies are seen as promising tools to enhance access to mental health services [1]. Virtual mental health, as defined by Jeunemaître, encompasses "technological applications used for mental health assessment, support, prevention, and treatment" [10]. Despite this potential and the effectiveness of virtual mental health interventions in controlled research settings for people living with complex chronic conditions, their uptake and integration into real-world clinical care have remained limited [11-13]. Scholars argue that closing this research-to-practice gap is a critical priority to improve population-level outcomes for those at heightened risk, such as people living with heart failure [11].

To foster the adoption of virtual mental health technologies into clinical care, scholars have pointed to a narrow and often simplistic view of what constitutes a virtual mental health intervention as a key barrier to their implementation [11]. In proposing three critical misconceptions facing the field of virtual mental health, Mohr et al [11] argue that the prevailing view of virtual mental health technologies as stand-alone products (ie, a focus exclusively on the technology itself) fails to account for the broader context in which these technologies are deployed. Instead, they suggest a move away from viewing these technologies as mere products toward viewing them as technology-enabled services, encompassing the people, workflow, and organizational contexts that shape their implementation. This recommendation has been echoed more broadly by virtual health scholars [11,14-16]. Taken together, the existing literature suggests that successful implementation of virtual mental health technologies requires not only product innovation, but also service innovation, with active engagement from stakeholders essential in designing both aspects [14-16]. Yet, while there is ample literature on virtual mental health product innovation, the literature on service innovation surrounding these technologies has been comparatively scarce [17].

Stepped care is an often-discussed service innovation to promote the implementation of virtual mental health technologies for those living with chronic conditions [12]. Traditionally, stepped care is defined by two core principles: (1) individuals should be given the least restrictive mental health service first, and (2) patients should "step up" to more intensive services as needed [18]. Since the emergence of stepped care, various architectures have been explored, often varying based on how treatment is allocated to the patient. For example, "stratified" or "matched" architectures determine treatment intensity by assessing the severity of the patient's symptoms [19]. In contrast, the Stepped Care 2.0 architecture has challenged this stratified approach, opting to move away from organizing interventions in a hierarchy [20,21]. Instead, Stepped Care 2.0 emphasizes a more patient-centered approach to care allocation, with less reliance on diagnostic assessment and greater inclusion of patient preference [20]. Although there has been growing interest in various types of stepped care models to implement virtual mental health technologies, how these models should be designed with the perspectives of diverse stakeholders in the implementation context remains unclear. This is particularly important as research has suggested that stepped care should be tailored to the local contexts and the available resources in these settings, though few studies have explicitly described the process of doing so for clinical settings outside postsecondary institutions [22].

Objective

The objectives of this study were twofold: (1) to explore strategies to address health system barriers to accessing mental health services for patients enrolled in a heart failure remote management program, and (2) to develop a virtual mental health service that implements these strategies to improve access to mental health care for people living with heart failure. The research question guiding this study was "How should a virtual mental health stepped care service be designed to improve access to mental health care for people living with heart failure based on the perspectives of individuals living with heart failure, clinicians, and researchers?"

Methods

Overview

A service design approach was used to develop the virtual stepped care service for people living with heart failure [15]. Service design is a "human-centered, collaborative, interdisciplinary, iterative approach which uses research, prototyping, and a set of easily understood activities and visualization tools to create and orchestrate experiences that meet the needs of the business, the user, and other stakeholders" [23]. Through understanding touchpoints (when an individual engages with the organization) and the journey (a series of touchpoints), service design endeavors to create services centered upon the experience of people who engage with them [23].

Objective 1 (Methods)

To address the first study objective of exploring strategies to overcome system-level barriers to accessing mental health services for people living with heart failure, qualitative

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interviews were conducted with stakeholders at the University Health Network, Toronto General Hospital, to identify key barriers (pain points) people living with heart failure face when seeking mental health services and to identify potential strategies to address these pain points. As the purpose of this study was to improve heart failure care through collecting rich descriptions of participant perspectives, this research was situated within a naturalistic approach, which assumes that reality is subjective and experienced differently by each individual (relativist ontology), and that knowledge is shaped by those experiences (subjectivist epistemology) [24,25]. A qualitative description methodology, as outlined by Sandelowski [25], was selected to understand stakeholder perspectives on the design of a virtual mental health stepped care service so that they could be incorporated into the design of a new service [26].

Qualitative description was chosen for its focus on staying close to the data when exploring practice- and policy-relevant questions. This approach aims to understand and ascribe meaning to the phenomenon (the design of a virtual mental health stepped care service for a heart failure remote management program) as closely as possible to the participants' perspectives to support descriptive and interpretive validity, respectively [25,27]. In the case of this research, a description of the requirements of a new service was desired to ensure that the needs of the stakeholders who would be using, involved with, and affected by the newly developed service delivery model were addressed. Moreover, the focus on understanding and interpreting phenomena as closely as possible to the study participants was especially valuable given the early stages of the service design process, wherein the goal is to prioritize the views and needs of participants in the design of virtual health services.

Theoretical Framework

To explore how a virtual mental health stepped care service could be designed to improve access to mental health care, we drew upon the patient-centered access to care framework proposed by Levesque et al. [28]. This framework was selected for its conceptualization of access as a journey, rather than a single event, composed of 5 stages: perceiving a need or desire for health care, seeking health care, reaching services, using those services, and experiencing consequences of health care services (positive or negative) [28]. Within each stage of this journey, factors at both the supply side (eg, health care system) and demand side (eg, patients and their support networks) may facilitate or prevent health care access. On the supply side, these include the approachability, acceptability, availability, accommodation, affordability, and appropriateness of health care services. These are complemented by factors on the demand side, namely, the ability of patients and their support networks to perceive a need for care, seek health care services, reach services, as well as pay for and engage with health care services.

In a previous study using this framework, our research team identified barriers faced by people living with heart failure when accessing mental health care in Ontario, Canada, using Levesque's framework [6]. Table 1 summarizes the domains of access at each stage of seeking health care, as well as the barriers found to prevent people living with heart failure from accessing mental health care identified in this previous investigation. The current study builds upon this previous research by describing the barriers experienced by people living with heart failure during their journey of accessing mental health services and applies Levesque's framework to inform the design of the virtual mental health stepped care service. Specifically, the framework was used to determine how each stage of access and associated health system barriers may be intentionally addressed by potential features of a virtual stepped care service [28].

Table . Health system barriers impacting access to mental health services for people living with heart failure.

Stage of access [28]	Health system factors impacting access [28]	Health system barriers faced by people living with heart failure [6]
Perceiving health needs and desire for care	Approachability	• Difficulties detecting mental health concerns • Unpreparedness for referral conversations
Seeking health care	Acceptability	—[a]
Reaching health care	Availability and accommodation	• Limited types of mental health services available • Inconsistent pathways to mental health services • Poorly timed mental health services
Using health care	Affordability	• Limited human resources due to underinsurance of mental health care
Health care consequences	Health care consequences	• An underresourced system does not allow for choice or finding a fit • Insufficiency of generic mental health services

[a]Not available.

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Setting

Individuals living with heart failure were recruited by phone from the Medly (University Health Network) program, which has been operational as standard of care at Toronto General Hospital, a large urban hospital in Ontario, Canada, since 2016. The Medly program is a smartphone-based heart failure remote patient management program that supports clinical care and patient self-management [29]. The Medly smartphone app is available on iOS and Android and prompts patients to enter their blood pressure, weight, heart rate, and symptoms regularly [29]. Depending on their entries, patients receive automatic self-care messages based on an alert system. Should patients score within a concerning range, their clinical care team is notified via email alerts and a clinician dashboard, who provide follow-up care based on the alerts, as well as the physiological and symptom data from the Medly system [29].

Participants

English-speaking individuals living with heart failure were eligible to participate if they were current patients of the Medly heart failure program at Toronto General Hospital. People living with heart failure were recruited across a range of demographic factors to ensure representation with respect to age, sex, ethnicity, place of birth, highest education received, place of residence, living arrangement, and income in Canadian dollars. Efforts were also made to ensure that participants with varying levels of comfort using smartphones were included, acknowledging that recruitment from a smartphone-based remote management program might result in participants who are more inclined to access health care virtually.

All 13 people living with heart failure approached for the study agreed to participate. No individuals refused to participate or withdrew from the study. Likewise, all clinicians of the Medly program were also invited via email to participate in the study. After these initial interviews with clinicians of the program, snowball sampling was used to recruit additional clinicians and researcher participants. A total of 10 clinicians and researchers were approached for the study, 9 of whom agreed to participate. One clinician declined participation in the study due to their high workload associated with the COVID-19 pandemic.

Consistent with guidelines regarding qualitative research, the number of participants recruited was determined based on the principle of data adequacy, which prioritizes the ability of the data collected to provide a nuanced and rich understanding of the topic of study [30]. Data collection occurred until data adequacy was achieved, which was achieved at 23 participants.

Data Collection

Author AS, who had no prior relationship with the study participants, conducted one-on-one semistructured interviews in English with all participants. All interviews were conducted over the phone due to public health restrictions associated with the COVID-19 pandemic at the time of interviews and the wide geographical distribution of participants in the Medly program. The interviewer conducted the phone interviews in a private space, and all individuals who participated also did so in a private space at their home or workplace. No participants reported the presence of additional individuals at the time of their interviews.

At the time of data collection, AS was a PhD candidate in Health Informatics Research with formal training in qualitative methods and prior experience conducting qualitative studies.

Participants were made aware of AS's role as a student. AS had previously worked in the community mental health sector, largely from a public health and patient-engagement perspective. These prior experiences with patient perspectives on mental health care and digital health research were important to consider when engaging with clinician participants in this study, whose perspectives were less familiar to AS. To determine how her experiences in community mental health and digital health research shaped the findings of the research, AS conducted memoing throughout the research process and engaged in discussions with the broader research team, which included clinicians from the disciplines of mental health nursing, psychology, and psychiatry.

Interviews ranged from 40 to 60 minutes in duration. Interview guides tailored to each participant type (people living with heart failure, clinicians, and researchers) were created with the research team. For people living with heart failure, the guide included open-ended questions and prompts inquiring about the mental health needs of participants based on their experiences living with heart failure and/or seeking mental health services (Multimedia Appendix 1). Participants were asked to share their perspective on current approaches to managing their mental health and their needs for new mental health service delivery models. Similarly, the clinician (Multimedia Appendix 2) and researcher (Multimedia Appendix 3) interview guides asked participants to draw upon their clinical or research experience when discussing their perspectives on current approaches to addressing the mental health challenges faced by people living with heart failure, difficulties with current approaches, and service delivery needs and requirements to address these challenges. Interviews were audio recorded, stripped of identifying details, and professionally transcribed verbatim. No repeat or follow-up interviews were conducted, nor were transcripts or analyses returned to participants for member checking purposes.

Data Analysis

Two study team members (AS and ASF) analyzed the data to offer different perspectives on the analysis. At the time of analysis, AS and ASF were both PhD candidates in Health Informatics with training and experience in qualitative research. AS came from a public health background, and ASF offered the perspective of a clinician as a nurse. First, both authors read and reread transcripts to gain an in-depth familiarity with the data. Second, each team member independently coded the data inductively and grouped them into initial categories and themes. NVivo (version 12; QSR International) was used to organize and code data. Third, following the development of the initial themes, AS and ASF met to discuss their codes and themes and to highlight where their analyses were similar and different. Where coding and themes differed, both team members discussed these differences to understand where each individual saw unique aspects of the analyses and their relevance to the

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research questions and phenomenon of study. These discussions were intended to deepen the analysis through the different perspectives and experiences of the authors rather than to achieve consensus on the coding and themes. Finally, both team members met to construct a final set of codes and themes based on their independent analyses. Both AS and ASF memoed throughout the analysis to reflect upon how their personal perspectives may have contributed to the analysis.

Objective 2 (Methods)

As part of the second study objective to develop a virtual mental health service for people living with heart failure, prototypes of the virtual stepped care service components were developed and visualized through design mockups and a service blueprint. Consistent with a service design approach, the design of the virtual stepped care service components was conducted iteratively. The initially visualized prototypes of the virtual stepped care model were presented to relevant stakeholders and refined based on expert feedback. These included experts in psychiatry, psychology, program administrators of existing virtual health services, digital product design, hospital legal services, and nursing staff from the Medly remote management program. For example, in designing the depression screening component of the model, a validated screening tool was initially selected based on the literature. However, iterative consultation with psychiatrists, administrators, and hospital legal services highlighted the need for specific design features for the remote administration of the screening tool at the hospital. This prompted specific language to be incorporated in the Medly app to ensure clinical safety. After multiple rounds of stakeholder engagement and refinement, a final prototype of the virtual stepped care service was reviewed and vetted by a core expert group that included psychiatric, psychological, nursing, and health informatics perspectives.

Ethical Considerations

This study was approved by the University Health Network Research Ethics Board (protocol nos 16‐5789 and 20‐6329) and the University of Toronto Research Ethics Board (protocol nos 40,274 and 41477). All participants provided written informed consent before study enrollment and were not provided with compensation for their participation in this study. Study findings are reported in alignment with the Standards for Reporting Qualitative Research [31].

Results

Participants

A total of 22 participants were interviewed, including 13 people living with heart failure and 9 clinicians and researchers specializing in mental health or heart failure care (Table 2).

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Table . Demographic characteristics of people living with heart failure interview participants (N=13).

Characteristic	Participant, n (%)
Age (years)	
21-30	2 (15)
31-40	1 (8)
41-50	0 (0)
51-60	2 (15)
61-70	4 (31)
71-80	2 (15)
81-90	2 (15)
Sex	
Male	7 (54)
Female	6 (46)
Ethnicity	
White (Caucasian)	8 (62)
Black	1 (8)
Filipino	1 (8)
South Asian	1 (8)
Chinese	1 (8)
Arab or West Asian	1 (8)
Place of birth	
Canada	8 (62)
Other	5 (38)
Highest education achieved	
High school	3 (23)
Trade or technical training	2 (15)
College or university	5 (38)
Postgraduate	3 (23)
Place of residence	
Urban	6 (46)
Suburban	4 (31)
Rural	2 (15)
Not declared	1 (8)
Living arrangement	
Living with family or partner	9 (69)
Living alone	3 (23)
Living with friends or roommates	1 (8)
Income (CAD $)	
<15,000 (US $10,935.67)	1 (8)
15,000-49,999 (US $10,935.67-US $36,451.52)	3 (23)
50,000-74,999 (US $36,452.25-US $54,677.65)	7 (54)
>75,000 (US $54,678.37)	1 (8)
Not declared	1 (8)
Comfort with smartphone	

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Characteristic	Participant, n (%)
Very comfortable	2 (15)
Comfortable	2 (15)
Somewhat comfortable	3 (23)
Not comfortable	2 (15)
Does not use a smartphone	3 (23)
Not declared	1 (8)

Objective 1: Strategies to Address Barriers to Accessing Mental Health Services for People Living With Heart Failure

The following section describes the themes and strategies to address health system barriers to mental health care access across each domain of Levesque's framework [28].

Approachability: Collective Action to Find Signals of a Range of Distress

In response to the barriers to detecting mental health concerns among people living with heart failure, clinicians highlighted the need to work together to detect a range of distress states. Participants posited that this would be best achieved by leveraging the unique and complementary strengths of each type of clinician. Psychiatrists recognized that patients had a strong therapeutic alliance with their chronic disease clinician, such as the close nurse-patient relationship facilitated through remote patient management. As such, this relationship was thought to provide another layer of detection of distress, potentially sooner. Likewise, cardiac clinicians noted that they could benefit immensely from the structured and detailed assessment skills of mental health clinicians, for which they did not feel fully prepared or trained.

> *We really rely on [non-psychiatric clinicians] to identify distress, to explain it to their patients. Because they really have the therapeutic alliance with their patients and can see it in action and can help us contextualize some of the nuances of what they're seeing. They are seeing things that may be signals of more distress that they need us to help them discern. So, what is the mental health literacy of our health care community that provides very specialized and medical, and surgical interventions? And what is holistic care?* [Clinician 1]

Clinician perspectives were complemented by patients who had an interest in holistic assessment of their health, recognizing that the current telemonitoring of their heart failure symptoms did not tell a full story of their health and sometimes painted a picture of well-being that they did not feel was accurate for their situation. More holistic and dynamic assessment of different aspects of health was not only seen as more accurate but also a way to humanize their care.

> *...statistically, I'm fantastic. And yet, I feel like a bag of sh*t, and I wish I wasn't here...And I know they try to measure how you're feeling, but if the measurement tools they're using aren't gaged to efficiently judge that, then what criteria are they using to determine whether or not you're having a good ride or not?* [Patient 1]

Availability and Accommodation: Capacity Building While Staying in Your Lane

While acknowledging the constraints of the mental health care system, participants emphasized the need to respond to a range of distress that is possible in the context of physical health conditions, including subclinical distress. This involved expanding the "helpers" in the space who could recognize and respond to mental health concerns, thereby ensuring that psychiatrists were not the only clinicians providing support for this aspect of health.

> *I think we've lost a little bit of that sense of the spectrum of who all of the helpers are in this space. No one thinks of your personal trainer as being a cardiac specialist prevention office. But effectively that's what they are right? You're going to the gym and your personal trainer to try and prevent this from becoming a disease. But it is not medicalised, right? Unless I have a cardiac event and then I go to cardiac rehab and I get the trainer because I've had an event. And then it's becoming medicalised. Because we know it's good but people aren't going to do it on their own. Or they can't afford to...I think that's the challenge—who are all of these helpers in this space? And which ones need to be medicalised within the program or not?* [Clinician 1]

Building the mental health literacy of both patients and clinicians was thought to facilitate a wider range of helpers to draw upon, instead of assuming that all had adequate mental health literacy at the start of seeking care. Participants noted that this education could include understanding the psychosocial aspects of heart failure, normalizing distress when living with heart failure, and knowing the mental health services available. In addition to these areas, the ability to discuss the intersections between mental and physical health was also noted as an especially important training area for all clinicians.

> *That [mental health] literacy, that education for patients and their families, their caregivers, and for the other health care professionals… All of that shared understanding of what this is in that space that you're trying to accomplish, and what's actually available. Some basic competencies and taking space for patients to engage in it. Whatever we decide that common understanding is.* [Clinician 1]

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In addition to improving mental health literacy among patients and non–mental health clinicians, improving the understanding of heart failure support, such as the Medly program, was also highlighted as an important training area for mental health care professionals, thereby fostering greater mutual understanding between physical and mental health clinicians.

Balanced with the need to expand participation from nonmental health clinicians was also the desire and need to "stay in your lane" or remain within one's areas of expertise. While patients and clinicians believed that integration of mental and physical health care was needed, some level of separation of each type of care was also valued. For clinicians, this meant clear clinical pathways and a preference for applying a referral-based approach to mental health concerns, whereby heart failure clinicians could refer out mental health concerns among their patients and were not deeply involved in the ongoing mental health care of their patients.

> *Cardiologists are not going to want to be dealing with mental health issues in terms of management. Identification? Absolutely. Appropriate referral? Hell yes. Management? No way.* [Clinician 2]

For patients, maintaining a level of separation between their mental and physical health care meant a desire to keep the details of their mental health care separate from their heart failure clinicians, while still ensuring that clinicians were broadly aware of any care received that might affect their cardiac care.

> *I think all your health care providers should be on top of you in the metaphoric sense that they need to know what's going on in your life at all times. Because if there's something that is off and my GP hasn't noticed, well, I feel like my cardiologist should or my endocrinologist should. There should be some level of collective communication going on behind me that, OK, they can access it and they have some idea that this is what's going on…I would want [my cardiologist] to be [aware of my mental health]. And if they're not, I would call them myself and tell them.* [Patient 2]

Affordability: Working With the Underinsurance of Mental Health Care

A central element of the model of care noted by participants was to work within the limited mental health resources and supports available to reserve publicly funded psychiatric services for the most complex and severe cases. Recognizing these constraints, 1 clinician discussed the benefits and challenges of proactive (engaging mental health supports early to reduce risk) and reactive (awaiting mental health concerns to be referred to a mental health clinician) models of care. Leveraging existing mental health services and supports as much as possible, instead of developing new ones, was considered the most feasible mode of care.

> *...there are so many gaps in mental health care. And not an organized system provincially. So trying to do what we can, but also knowing that we can't boil the ocean, right? There's just so much need, and being able to draw some of the boundaries in that is going to be a bit of a challenge for us. So we're trying to be careful not over-promising what we can deliver to patients and their families.* [Clinician 1]

Appropriateness: Personalization, Choice, and Quality Connections

Patients desired a quality connection to mental health care services tailored to their individual needs, preferences, and readiness. Inherent to finding such connections was the ability to have various options to choose from and to create opportunities for patient choice. Despite the desire for choice, patients noted that the current health care system did not allow for such an approach. One patient described their ideal system, which would offer the mental health care they were seeking.

> *...health professionals would address you as if you were a real person with a real life and they had some idea of what that life was, what their job was, and what they were protecting when they were looking after you.* [Patient 3]

Foundational to a quality connection was the existence of mental health service options to choose from, as well as different delivery method options for each service that went beyond the in-person and virtual dichotomy (in-person, phone, videoconferencing, and asynchronous). This was echoed by clinicians, who noted that a multipronged approach was needed for quality mental health support among those living with heart failure, such as a combination of psychotherapy and medication.

> *I think truly the answer is to have a suite of opportunities that are therefore suited to each patient on a more individual basis as opposed to sending everybody for one plan.* [Clinician 2]

> *...you can't just give a drug. You've got to counsel as well. You've got to advise about self-care. You've got to link them up with other people. So it's a multi-pronged approach where you're talking about the complex clinical level patient.* [Clinician 3]

Once options were presented to patients, they desired to participate in the selection of the appropriate service for them in partnership with their clinician, as well as having an option to withdraw from mental health care at any time. When selecting the right service, patients considered their personal technology use and digital barriers, stage in chronic disease course, and prior experiences with mental health care through themselves or a loved one. In addition, mental health clinician factors, such as age and gender, were also important to them. Patients highlighted that recognizing the uniqueness of each individual's situation was an important goal when seeking mental health care, even among those experiencing similar health circumstances.

> *It's not textbook either. So, you can have five [people like me] in a row. We all have similarities, but we're all very different. And we have different needs for tools...it's leaving it up to the individual where their boundaries lie…you can pick and choose what tools apply to you.* [Patient 4]

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Foundation Principle 1: Reducing Treatment Burden

A central theme raised by all participants was the importance of reducing the burden of treatment on clinicians and patients. For clinicians, this arose through the emphasis on managing the workload of nurses. While leveraging the strong nurse-patient relationship established through remote management was considered a valuable opportunity to detect and respond to mental health concerns, there were simultaneous concerns that increasing engagement with mental health would contribute to nurse burnout. To address this, engaging nurses with clear expectations and workflows was strongly recommended by nurse and cardiologist participants.

Similar to the nurses, cardiologists expressed interest in their patients' mental health needs, but noted a need for a narrow role in the care model due to their limited capacity and time. Applying a referral-based approach or automatic enrollment to virtual mental health supports to reduce the reliance on cardiac clinicians for patient access to mental health care was one strategy proposed to improve the feasibility and acceptability of the care model. Similarly, patients interviewed saw this approach as making mental health care more approachable and less intimidating.

> *...maybe patients could access it themselves… I wonder if it was like something that they said "you can check out this extra thing if you want, on your own time." Something that is a little bit more passive rather than me directing them to it.* [Clinician 4]

Likewise, patients expressed motivations to reduce the work associated with managing their conditions and were keen to understand the clear benefits of mental health support before adopting further treatments. When discussing potential mental health screening approaches, patients described a desire to avoid unnecessary work by completing readings only when they were struggling.

> *I think it could be optional because basically when I'm fine I don't really want to spend time filling out extra stuff around my mental health. But you know I want the option where I can click 'not applicable' or something.* [Patient 5]

Contrary to common notions that self-guided supports are lower intensity, some patients perceived mental health supports that involved heavy amounts of reading as more work-intensive than those relying on video or speaking to someone.

> *...giving them something to read is a lot of time and commitment toward something, or if you're making them read it then make it short and that people's attention spans are very short these days.* [Patient 6]

Foundational Principle 2: Building Upon Organizational and Programmatic Strengths

Building upon organizational strengths was thought to be an important approach to improve access to mental health care. At the hospital, the organization had several strengths that promoted interest and buy-in for an initiative focused on improving access to mental health care for people living with heart failure, including a corporate strategy outlining integration of mental and physical health care as a priority, as well as examples of chronic disease clinics that provided strong mental health support (eg, cancer care). These were noted as strengths for the organization to build upon, generating enthusiasm and interest in expanding further within heart failure care. In addition to broader organizational strategies, participants noted opportunities to build upon the strengths of the heart failure telemonitoring program itself, namely its symptom monitoring, communication to the patient's care team, strong nurse-patient relationship, and already high use of the Medly app by patients. Leveraging the Medly app in new ways was thought to promote trust in addressing the new topic of mental health, which could potentially spill over into other virtual mental health interventions that patients are connected to as a result of the model of care.

> *I feel that patients trust Medly a lot. So maybe having mental health support within it, being accessible from it, might be an added element of trust to it.* [Clinician 4]

Objective 2: Virtual Mental Health Service Design for a Heart Failure Remote Management Program

Based on the strategies identified through qualitative interviews, the following section addresses the second objective of describing the design of a virtual mental health service for a heart failure remote management program. Table 3 summarizes how the service design components were tailored directly to the strategies identified for Objective 1.

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Table . Strategies and features of the virtual mental health stepped care model to address barriers faced by people living with heart failure when accessing mental health services.

Domain of access	Health system barriers [6]	Strategies	Virtual mental health stepped care features
Approachability	Difficulties detecting mental health concerns; unpreparedness for referral conversations; and denial, stoicism, and self-reliant coping methods.	Collective action to find signals of a range of distress	Integrating mental health into virtual chronic condition management programs.
Availability and accommodation	Inconsistent pathways to mental health services and the inconvenience of in-person delivery.	Capacity building while staying in your lane	Referral-based approach; clear workflows; preserving separation of mental health care pathways from heart failure; and virtual care delivery.
Affordability	Limited human resources due to underinsurance of mental health care, lack of full insurance coverage, and high cost of psychological services.	Working with the underinsurance of mental health care	Integration of existing mental health services and use of no-cost mental health services.
Appropriateness	Insufficiency of generic mental health services.	Personalization, choice, and quality connections	A suite of mental health service options, choice at certain stages of the stepped care model, and tailored mental health supports for heart failure.
Foundational principle 1: reducing treatment burden	—[a]	—	—
Foundational principle 2: building upon organizational and programmatic strengths	—	—	—

[a]Not available.

Approachability: Medly Mental Health Module

Although several heart failure guidelines recommend the regular screening of depression, this practice has not yet been conducted within heart failure care at Toronto General Hospital [1,3-5]. To promote the approachability of mental health services, screening for depressive symptoms via the 9-item Patient Health Questionnaire (PHQ-9) was integrated into the existing Medly telemonitoring smartphone app (Figure 1A), which requires patients to report their weight, blood pressure, heart rate, and symptoms daily [29].

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Figure 1. Design of the depression screening module for the Medly smartphone app for heart failure remote management.

The PHQ-9 is a commonly used questionnaire to screen for symptoms of depression, with each item corresponding to a criterion for depression as outlined in the *DSM-IV* (*Diagnostic and Statistical Manual of Mental Disorders* (Fourth Edition) [32]. Scores on the PHQ-9 can range from 0 to 27, with specific score ranges corresponding to mild (5-9), moderate (10-14), moderately severe (15-19), and severe (20-27) depressive symptoms [32]. Prior research has validated the use of the PHQ-9 among people living with heart failure [33]. Meta-analytic research has identified a cutoff score of ≥10 to diagnose clinically significant symptoms of depression with high sensitivity (80%) and specificity (92%) in medical settings, including cardiology [34].

In an effort to preserve patient choice, the PHQ-9 screening module was intentionally made optional, allowing patients to decline to participate in a screening, described as a "mental health check-in" in the app (Figure 1B). As the heart failure portion of the Medly app is intended for daily use and the PHQ-9 inquires about the depressive symptoms experienced over the past 14 days, the PHQ-9 screening module was set to prompt patients to complete screening every 14 days from their last reading, with the option available for patients to engage in more frequent screening through an "add mental health check-in" option (Figure 1C).

Once PHQ-9 screening is completed by the patient, the module was designed to provide patients with an automated alert based on the PHQ-9 score range. This approach, involving self-report screening followed by an algorithm-based interpretation and alert, aligns with the existing app design for heart failure previously described in the "Methods" section [29]. To coordinate alerts between mental health and physical health and to reduce confusion for patients, a "single severity system" was developed, which assigns and presents a single alert to the patient's state based on heart failure, mental health, or both symptoms. Alert states are visible immediately to the patient after completing their reading, as well as to the clinician via email and the clinician's dashboard for notification and review.

In addition to an alert state, self-care messages are automatically provided to the patient based on their PHQ-9 score. Each automated message notifies patients of their score, provides the interpretation of their score (eg, mild, moderate, severe depressive symptoms, self-reported thoughts of harm to self or others), and suggests next steps based on their score (eg, call your Medly nurse). Importantly, as the ninth item of the PHQ-9 pertains to suicidal ideation, language for this self-care message was taken from institutional guidance on the remote administration of the PHQ-9 and provides crisis resources and information in a "Learn More" section of the Medly app. A suicide risk management protocol was also developed for instances where a patient self-reports thoughts of harm to self or others on the PHQ-9, which outlined how to connect patients to an on-call psychiatrist.

Availability and Accommodation: Referral-Based Workflows and Virtual Delivery

Upon screening for depressive symptoms, a workflow for clinicians to follow up with patients for clinically significant symptoms of depression (PHQ-9≥10) was identified. A service blueprint was created to visualize the pathways between screening and various care options. After an alert, patients who report clinically significant symptoms of depression are referred

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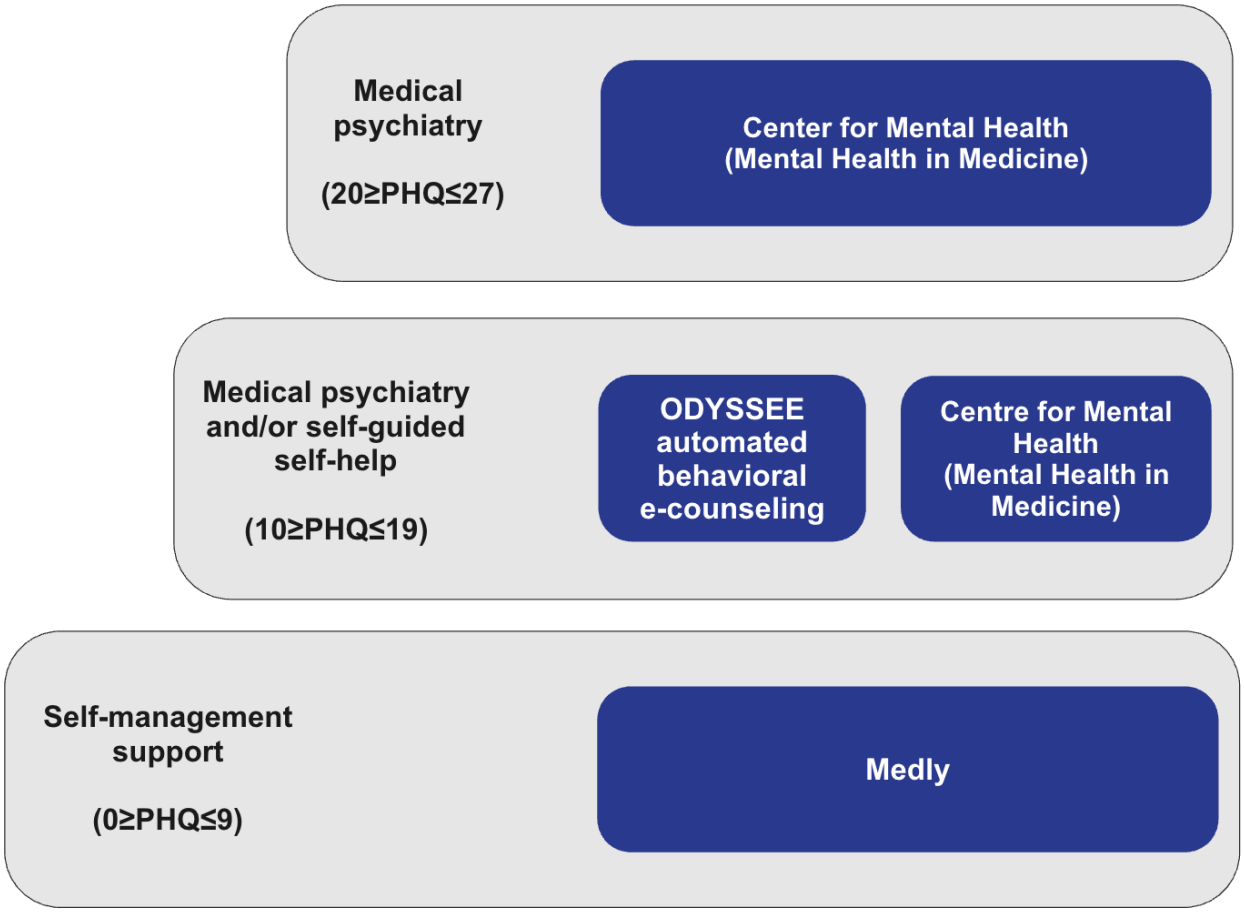
to a mental health nurse practitioner at a specialized medical psychiatry clinic called the University Health Network Mental Health in Medicine Clinic, where they receive further assessment to determine whether psychiatric care is needed [35]. Should the mental health nurse identify no need for psychiatric care (moderate depressive symptoms and no suicidal ideation), patients are provided with the option to choose from 2 existing mental health services: virtual mental health care via the ODYSSEE automatic behavioral e-counseling platform (Behavioural Cardiology Research Unit, University Health Network) [36] and usual care at the Mental Health in Medicine Clinic (Figure 2) [35]. Patients with nonclinically significant symptoms of depression on the PHQ-9 (score between 0 and 9) are not provided with additional interventions and are advised to continue using the Medly remote monitoring app to self-manage their condition.

Figure 2. Virtual mental health stepped care model for the Medly heart failure remote management program. PHQ: Patient Health Questionnaire.



In drafting the service blueprint with stakeholders from the ODYSSEE team and the Mental Health in Medicine Clinic, the registration or referral processes required to access these services were considered to ensure the patient experience was intentionally understood, and potential pain points were identified and minimized, where possible. Through this service design approach, the different systems used by each of the care options were identified as a potential pain point, as they would require patients to create multiple account logins to proceed with a referral. For example, in the Medly program, patients are given account credentials to log into their Medly app. Should a patient in the model of care choose to access the ODYSSEE automated behavioral e-counseling, they would need to create separate account credentials to access this care option. While it was not feasible to reconcile this into a single login at the time of service design, the service design process helped identify this as a pain point to potentially address in the future.

Affordability: Use of Existing Mental Health Services

Clinical champions of each service (ODYSSEE and the Mental Health in Medicine Clinic) who shared clinical and research interests in improving access to mental health care for people living with heart failure were identified for this project. ODYSSEE and the Mental Health in Medicine Clinic were selected to be included in the model of care as they already existed within Toronto General Hospital and offered content or care that was tailored to the journey of living with heart failure, which was among the factors that people living with heart failure previously had identified as important to quality mental health care [6]. Importantly, both care options are available free of charge to the patient, allowing patients to select mental health services without restrictions based on income or private insurance coverage. Services at the Mental Health in Medicine Clinic are covered under the universal provincial insurance plan, while the ODYSSEE program was covered through research funding at the time of the research. The inclusion of ODYSSEE

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was considered to be especially important to promote the affordability of mental health services, as it provides psychoeducational content based on principles of cognitive behavioral therapy. As access to publicly funded psychological services is highly limited in Canada, the introduction of ODYSSEE into the service delivery model served to make psychological services and content more readily available to people living with heart failure.

Appropriateness: Patient Choice

Should patients' PHQ-9 score range fall within 10 - 19, and they are not found to require psychiatric care based on the assessment by the mental health nurse practitioner at the Center for Mental Health, the model encourages patient choice by allowing them to choose from the ODYSSEE automated behavioral e-counseling program or standard care from the Mental Health in Medicine Clinic. The element of patient choice at this stage was intended to allow patient preferences surrounding mental health care to be integrated into the model of care, where possible. Patients with a PHQ-9 score between 20 and 27 are not offered choice in their intervention and are guided to care as usual via the Mental Health in Medicine Clinic.

Discussion

Principal Findings

In this study, we describe the design of a virtual mental health stepped care service for people living with heart failure enrolled in a heart failure remote management program in Ontario, Canada. Building upon previous research that documented barriers to accessing mental health services for this population, we explored strategies to mitigate these barriers and incorporated them into a new clinical service [6]. The contributions of this study lie not only in the design of the virtual stepped care model, but also in how stakeholders and existing clinical resources in the implementation context were engaged to conceive this new service.

Through a design process involving the perspectives of people living with heart failure, clinicians, and researchers, the resultant virtual mental health service includes a depression screening module within the existing Medly smartphone-based heart failure telemonitoring app to improve detection of depressive symptoms. Following screening, referral-based pathways were defined to replace previously inconsistent patient pathways to mental health services. To mitigate affordability barriers, existing mental health services available within the implementation context were selected to allow people living with heart failure to access mental health care without incurring out-of-pocket costs. For those found to be experiencing moderate scores of depressive symptoms, the stepped care service offers people living with heart failure the ability to choose between automated behavioral e-counseling and usual care through the hospital's medical psychiatry clinic [37]. The goal of this newly created intervention is to provide more holistic heart failure care that addresses both patients' physical and mental health needs to improve the person-centeredness of heart failure care and, consequently, the quality of care received.

An emerging yet growing body of research has argued that stepped care models should be context-specific and designed based on principles, rather than seeking to apply a standardized model across settings with different mental health resources [22,38]. Our study aligns with this notion and offers an example of how stepped care services can leverage existing mental health resources within an organizational context that were not initially designed for integration, which is most often the case in real-world settings. While we anticipate that the context-informed design approach used will promote the feasibility of implementation of the model in subsequent phases, applying such an approach also presents limitations in this research. Specifically, while attuning to the needs and existing capacities of the implementation context when designing the service delivery model may promote its feasibility of implementation, it may also prevent a more comprehensive approach to care that requires more intensive services to meet the wide range of needs of the intended population. For example, despite the intention and desire for more person-centered approaches to mental health service delivery for the heart failure program, stakeholders engaged in this study called for a more traditional, referral-based model of stepped care instead of more contemporary and flexible versions such as Stepped Care 2.0 [20,21]. This design decision reflects the trade-offs between designing theoretically robust interventions and those that are practically implementable based on the readiness and capacities of an organization.

In addition to the practical design of the virtual stepped care service, our findings offer conceptual contributions to the growing stepped care literature that can help inform similar undertakings in other contexts. Recently, stepped care scholars have proposed that "patient readiness to engage in care" is a key principle underlying treatment allocation within person-centered variations of stepped care (eg, Stepped Care 2.0) [20,38]. While participants in this study affirmed the importance of considering their readiness to access mental health care (eg, desire to revisit potentially difficult emotions and experiences, their comfort engaging with long-term mental health care), they also highlighted a nuance not yet discussed in the stepped care literature. Participants considered the work and burden of engaging in mental health care in their decisions to access mental health services, especially in light of their treatment for heart failure and other chronic conditions they were already engaging in (eg, tests, medications, hospitalizations, medical appointments, and complex self-care behaviors). The impact of such "illness work" on the patient, per sociological perspectives from Corbin and Strauss [39,40], is known as treatment burden. Emerging research indicates that digital health interventions may also affect treatment burden, both positively and negatively, by at times introducing illness work [41]. In this study, this was evident as people living with heart failure viewed commonly regarded "low intensity interventions," such as educational modules, as "too much work" when education was delivered in a traditional text-based format. These findings suggest that the work of digital mental health interventions must be considered in the stepped care allocation process, especially those intended for people living with heart failure. Stepped care models may find it fruitful to encourage patients to not only connect with the intervention that aligns

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with their readiness but also consider the amount of illness work they can adopt, given their total workload. Further research is needed to investigate the concept of treatment burden as a principle guiding treatment allocations within stepped care.

While this study focused on barriers at the health system level, it is important to note that our research team previously documented barriers at the patient level, including low mental health literacy, stigma, difficulties attending services in person, and lack of insurance coverage to pay for psychological services [6]. Although the intervention components described in this study may also reduce patient-level barriers, more substantial efforts may be needed to fully address these barriers. For example, we anticipate that the inclusion of screening in the virtual stepped care service will not only improve the approachability of the health system but also enhance patients' ability to perceive their mental health needs. Moreover, the focus on using existing mental health services as part of the intervention, instead of creating new ones, was to improve the affordability of mental health services, which may also circumvent insurance barriers at the patient level. Future studies should explore, incorporate, and evaluate complementary interventional strategies to address patient-level barriers to accessing mental health care alongside the health system–level strategies identified in the current research.

Comparison With Prior Research

While the exploration of virtual stepped care services in heart failure care is limited, studies in other clinical areas offer examples of how these interventions have been designed. Indeed, previous studies describing the creation of virtual stepped care services for other health areas appear to suggest that the engagement of interdisciplinary stakeholders, such as clinicians, patients, researchers, and technology developers, is critical to the design of these interventions and the evaluation of these service delivery models [42-48]. In this study, our team adopted a service design approach combining interviews and iterative feedback cycles, whereas other studies have commonly used design workshops [43,45,48] or focus groups [47]. While these exploratory qualitative approaches used in previous studies to empathize with the end users' needs mirror those used in this study, some studies followed the design with user testing to further identify pain points and refine the intervention before implementation [43]. As user testing was not conducted during this study, usability challenges may impact the acceptance and use of the stepped care model and warrant consideration in the future.

A related strand of the literature has focused less on user-centered design and more on the practical realities of designing stepped care models in real-world settings [46,48]. These studies describe the organizational work required to establish partnerships, create shared platforms, map existing services, define levels of care and patient pathways, and deliver the intervention under a unified brand by forming advisory or working groups composed of interdisciplinary stakeholders [46]. Both the findings of this study and previous studies highlight the need to balance organizational collaboration with patient engagement activities to align various stakeholder interests with a clear goal of defining an improved patient journey.

Limitations

The study findings should be interpreted in light of the following limitations. First, participants were recruited and interviewed when COVID-19 physical distancing and stay-at-home orders were implemented. The strategies integrated into the virtual stepped care model may therefore represent a period when virtual care was more strongly preferred and used. Further research is needed to explore the acceptability of this service delivery model when COVID-19 measures are no longer in place [49]. Second, while participants were purposively recruited across a range of demographic factors, the sample interviewed was English-speaking people living with heart failure with access to a heart failure remote management program through a large urban academic hospital. As such, the strategies to improve access outlined in this study may not represent the full range of ways to address barriers faced by people living with heart failure and may be most transferable to people living with heart failure with higher levels of health care access. Future research is needed to determine appropriate strategies for people living with heart failure with lower levels of health care access and English proficiency. Health service designers, researchers, and policymakers seeking to improve access to mental health services for people living with heart failure may find it valuable to engage in a similar process of engaging diverse stakeholders to define strategies most suitable for their local context.

Conclusion

Amid growing interest in stepped care models to implement virtual mental health technologies, this study outlines how virtual stepped care services can be designed and tailored to their intended implementation context to address health system barriers to mental health care. In addition to identifying strategies that heart failure remote management programs may integrate to improve access to mental health care for people living with heart failure, the findings of this study offer a practical approach to designing virtual stepped care models in partnership with local stakeholders that is both theoretically informed and rooted in the needs and capacities of the implementation context. Through this process, two key principles were identified for virtual stepped care services designed to suit their local contexts: (1) building upon organizational and programmatic strengths, and (2) reducing treatment burden. While the specific components of the virtual stepped care service may be most applicable to similar settings in urban, high-resource environments, the theory- and context-informed service design approach can serve as a process for future initiatives to improve access to mental health care for people living with heart failure. Future research should explore the feasibility of applying this design approach in different settings, as well as investigate the applicability of treatment burden and building upon contextual strengths as broader principles guiding virtual stepped care models.

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Data Availability

The datasets generated or analyzed during this study are not publicly available because participants did not provide explicit consent for their data to be shared publicly.

Conflicts of Interest

ES is considered the inventor of the Medly system under the intellectual property policies of University Health Network (UHN) and may benefit from future commercialization of the technology by UHN.

Multimedia Appendix 1
People living with heart failure interview guide.
[PDF File, 94 KB - formative_v10i1e82139_app1.pdf]

Multimedia Appendix 2
Clinician interview guide.
[PDF File, 90 KB - formative_v10i1e82139_app2.pdf]

Multimedia Appendix 3
Researcher interview guide.
[PDF File, 79 KB - formative_v10i1e82139_app3.pdf]

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Abbreviations

***DSM-IV*:** *Diagnostic and Statistical Manual of Mental Disorders* (Fourth Edition)
PHQ-9: 9-item Patient Health Questionnaire

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User Experience and Early Clinical Outcomes of a Mental Wellness Chatbot for Depression and Anxiety: Pilot Evaluation Mixed Methods Study

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Abstract

Background: Artificial intelligence–powered conversational agents (ie, chatbots) are increasingly popular outlets for users seeking psychological support, yet little is known about how users experience early-stage prototypes or which therapeutic processes contribute to clinical improvement. A transparent evaluation of emerging chatbot prototypes is needed to clarify if, how, and why artificial intelligence companions work and to guide their continued development.

Objective: This mixed methods pilot study evaluated user experience, acceptability, and preliminary clinical signals for an early-stage mental wellness chatbot. We also examined whether baseline symptom severity moderated clinical improvement.

Methods: Three sequential cohorts (n=125) completed a 2-week, incentivized chatbot exposure (approximately 60 min per week). Participants provided first-impression ratings, qualitative feedback, and pre–post assessments of depressive symptoms (PHQ-8 [Patient Health Questionnaire-8]), anxiety symptoms (GAD-7 [Generalized Anxiety Disorder-7]), psychological distress, well-being, and loneliness. Statistical models estimated symptom change and tested interactions with baseline symptom severity. Mixed methods analysis integrated quantitative outcomes with large language model–assisted qualitative content analysis of open-ended responses.

Results: Participants described the chatbot as accessible, easy to use, and emotionally validating, while citing limitations in personalization and conversational depth. Qualitative responses consistently highlighted early therapeutic processes such as emotional validation, goal setting, and perceived attunement. Regression models showed significant pre–post reductions in depressive (Hedges g=–0.32) and anxiety (g=–0.32) symptoms, alongside modest improvements in distress and well-being. Baseline severity moderated improvement, with marginal effects indicating larger predicted reductions at higher PHQ-8 and GAD-7 baseline scores (eg, PHQ-8=15: g=–0.84; GAD-7=15: g=–0.62).

Conclusions: This pilot provides a comprehensive view of early chatbot development and suggests promising user experiences and preliminary symptom improvements under structured pilot conditions. By integrating experiential and exploratory clinical data, the study identifies candidate process targets to inform ongoing refinement. Findings support continued development and demonstrate procedural feasibility for progression to larger, longer-term trials evaluating engagement and clinical outcomes under more naturalistic conditions.

(JMIR Form Res 2026;10:e90644) doi:10.2196/90644

KEYWORDS

digital health; artificial intelligence; large language models; therapeutic alliance; mental health.

Introduction

Background

Mental health conditions such as depression and anxiety remain among the leading causes of disability worldwide, yet access to timely, evidence-based care continues to fall short of population need [1]. Structural barriers such as high costs, shortages of trained clinicians, long waitlists, geographic disparities, and perceived stigma limit the reach of traditional psychotherapy and contribute to persistent treatment gaps [2,3]. As a result, scalable digital solutions have become a major focus for innovation, with particular attention to platforms that can deliver immediate, flexible, and low-threshold support outside of, or as a supplement to, formal clinical settings.

Large language model (LLM)–based chatbots are rapidly evolving in the digital mental health space [4]. As reviewed in

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recent narrative and systematic syntheses of artificial intelligence (AI) mental health chatbots [5,6], these chatbots offer the possibility of responsive, personalized conversational support delivered at scale, with emerging studies suggesting they may help reduce mental health symptoms, increase engagement, and broaden access to care [7-13]. Yet, some researchers have been critical of diving straight into clinical trials [14], as the development of these products has largely outpaced the empirical evidence base, with key questions remaining about how therapeutic processes unfold within chatbot interactions, how users perceive safety and trust, and whether these tools function best as stand-alone interventions or complements to clinician-delivered care [15,16].

To date, studies assessing chatbots as mental health tools provide limited transparency into how prototypes were designed, refined, and evaluated for safety. As a result, little is known about how users actually experience early-stage chatbots, such as how safe, helpful, or trustworthy they feel, what facilitates or impedes engagement, and how these factors affect the impact of the chatbot. This gap is consequential, as understanding users' initial experiences with mental wellness chatbot prototypes is essential for responsible development and real-world effectiveness. Indeed, prior research on digital mental health interventions shows that early impressions such as perceived safety, personalization, and feeling understood are strongly associated with subsequent engagement, adherence, and indicators of therapeutic response [17,18]. These experiential factors also shape trust and therapeutic alliance, which are central determinants of whether users continue to engage long enough to experience meaningful benefits [19,20]. However, recent theoretical work suggests that alliance and other change processes in chatbot-based interventions may not operate identically to those in human psychotherapy, given that chatbots lack human therapists' ontological and sociocultural status [21]. This further highlights the need to empirically examine how users experience and interpret interactions with early-stage mental wellness chatbots.

Whereas several recent studies have focused on symptom outcomes in randomized trials [5] or evaluated chatbot performance in controlled vignette-based simulations [22], fewer investigations have examined early-stage prototype development using mixed methods approaches that integrate user experience, safety workflows, and preliminary clinical signals. As a result, there remains limited visibility into how conversational design choices, early user impressions, and structured protocols shape engagement and short-term outcomes. Because complex, multidimensional user experiences are best captured using human-centered, mixed methods that combine quantitative usability and symptom metrics with qualitative insight into how users interpret and experience emerging AI tools [23], early-stage evaluations benefit from integrating both forms of evidence. This study provides a comprehensive assessment of an early-stage chatbot prototype, explicitly linking user experience and exploratory clinical outcomes to inform responsible refinement and progression to larger trials.

This Study

Situated within digital mental health evaluation research, this pilot study used mixed methods to evaluate an early-stage LLM–based mental wellness chatbot designed to support adults experiencing at least mild anxiety or depression. Across 3 successive cohorts, participants interacted with the chatbot over a 2-week period, providing both quantitative and qualitative feedback on usability, acceptability, and perceived therapeutic value. We also explored pre-post changes in mental health symptoms as a preliminary gauge for a potential therapeutic signal. In the absence of randomization or a comparison arm, early clinical signals from chatbot prototypes should be interpreted as exploratory rather than as evidence of efficacy [24]. By integrating experiential and early clinical outcome data within a structured pilot framework, this study contributes prototype-stage evidence to inform responsible refinement, optimization, and future controlled evaluation of mental wellness chatbots. Accordingly, the aim of this study was to conduct a comprehensive mixed methods evaluation of a generative LLM–based mental wellness chatbot, examining user experience, safety monitoring feasibility, and exploratory clinical signal to inform responsible prototype refinement and future controlled trials.

Methods

Overview of the AI Chatbot

The LLM–powered mental wellness chatbot evaluated in this study was developed to provide brief emotional support for adults experiencing mild to moderate anxiety or depressive symptoms. Responses were guided by evidence-based principles drawn from supportive and cognitive-behavioral therapy frameworks, enabling the chatbot to respond empathically to user input while encouraging adaptive coping and reflection.

Rather than delivering a structured, manualized treatment protocol, the chatbot facilitates supportive mental wellness conversations informed by evidence-based common factors, including emotional validation and reflective listening, collaborative clarification of goals, and brief coping or activation prompts (eg, grounding or perspective-taking exercises) [25]. These processes were intentionally scaffolded through system-level instructions emphasizing emotional safety, nondirectiveness, and avoidance of clinical diagnosis or prescriptive advice. The app functioned as a stand-alone iOS application with a cloud-based backend hosted by Amazon Web Services. Additional details regarding the therapeutic framework, AI architecture, and real-time safety classifier are provided in the Multimedia Appendix 1 [26-37].

Study Procedures

The study was conducted from September to November 2025. Participants were recruited through dscout (dscout Inc), a web-based research platform with a large opt-in panel of adults across the United States that is focused on user experience research. Eligible participants were aged ≥21 years who reported at least mild symptoms of anxiety or depression at the time of screening. Individuals who endorsed suicidal or self-harm thoughts in the past 2 weeks (ie, score of ≥1 on the ninth item

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of the Patient Health Questionnaire-9 [PHQ-9]) or serious mental illness, as well as those currently receiving psychotherapy, were excluded from this early-stage pilot test of an app that has not yet been evaluated for individuals with complex clinical needs. Additional screening and demographic balance procedures are described in the Multimedia Appendix 1 [26-37]. Enrollment occurred in 3 successive cohorts to allow iterative refinement of the chatbot prototype between cohorts. After completing eligibility screening, participants were invited to complete a baseline survey assessing demographics, clinical symptomatology (eg, depressive and anxiety symptoms), and attitudes toward mental health therapy and chatbots for emotional support. After baseline, participants were instructed to download the prototype application via TestFlight—Apple's official beta-testing platform for iOS. Participants were instructed to use the chatbot for at least 60 minutes per week during the 2-week study period. The first use of the chatbot triggered a first impressions survey and open-ended qualitative prompts focused on initial user experience feedback. One week following the app download, participants completed a brief follow-up survey and qualitative prompts focused on usability and acceptability. Finally, the 2-week follow-up survey reassessed the clinical metrics and attitudes toward mental wellness chatbots originally assessed at baseline. All survey instruments/measures and interview materials are described in the Multimedia Appendix 1 [26-37].

Chatbot interactions were continuously monitored in real-time by an automated, transcript-based safety classifier that was calibrated to high sensitivity due to the early stage of chatbot testing. The classifier detects participant responses indicating potential harm to self, to others, or from others (Multimedia Appendix 1 [26-37] provides details). All flagged responses triggered a real-time alert to the study clinicians, who reviewed each flagged transcript within 2 hours to determine whether phone-based outreach for a safety check or emergency intervention was warranted.

Participants

The screening survey was hosted on dscout and distributed to their active panel of participants. As required by dscout, the study description made clear that this was a 2-week digital mental health and well-being study involving the use of a mobile app. The screener stopped participants as soon as they failed an eligibility criterion to reduce the burden of continuing to ask unnecessary items once ineligibility was established. Because exclusions occurred dynamically throughout the screener, precise counts for every individual exclusion step cannot be calculated.

A detailed description of eligibility screening and a participant flow diagram is provided in Figure S2 in Multimedia Appendix 1 [26-37]. In short, 3406 individuals completed the screening, and 184 (5.4%) were eligible, with the most common exclusions being living in an ineligible state, not meeting the minimum symptom severity threshold (PHQ-2 or Generalized Anxiety Disorder-2 [GAD-2] score ≥3), or being currently engaged in some form of mental health care. Of the eligible pool, 125 were ultimately enrolled. Consistent with the aims of pilot-stage testing, this sample was not designed to represent individuals with acute or high-risk clinical presentations. The final sample represented 32 different US states, ranging in age from 21 to 67 (mean 34.6, SD 9.9) years, and 80 (64%) identified as women. While most reported being White (74/125, 59.2%), 19 (15.2%) were Black or African American, 13 (10.4%) were Asian or Asian American, 10 (8%) were multiple races, and 9 (7.2%) reported another race or preferred not to answer. Regarding ethnicity, 13 (10.4%) were Hispanic/Latinx. Most were employed (91/125, 72.8%), while 17 (13.6%) listed their employment status as currently a student, and 17 (13.6%) were not employed. More than half (70/125, 56%) reported some form of prior mental health care. While 89 (74.2%) had previously used an AI chatbot, only 30 (25.2%) had used one for mental health support or information.

Ethical Considerations

This study was approved by Pearl IRB (Indianapolis, IN; Study# 2025 - 0463), an independent institutional review board. All procedures were conducted in accordance with the ethical standards of the 1964 Helsinki Declaration and its later amendments. Consent was obtained electronically from all participants prior to participation. Usage was incentivized at US $50 per week for those who met the 60-minute threshold and US $30 for those who exceeded 30 minutes but did not reach 60 minutes. Including compensation for survey and interview completion, participants could earn up to US $275 in total. All quantitative and qualitative data were deidentified prior to analysis and stored on secure, access-restricted servers. The secure LLM (GPT-4o-mini) instance used for qualitative analysis did not retain participant data or use it for model training. Only authorized members of the research team had access to study data.

Qualitative Analytic Approach

Open-ended written responses and transcribed video responses were analyzed using a structured, LLM-assisted qualitative content analysis approach designed to characterize recurring feedback patterns within qualitative data. LLM-assisted content analysis is an emergent qualitative technique that leverages LLMs' strengths in pattern recognition and linguistic synthesis [38]. An inductive approach was appropriate given that our goal for this analysis was purely descriptive: that is, we aimed to characterize emergent themes rather than to apply prespecified theories or codes to the data [39]. The LLM was prompted to extract candidate themes related to user experience (both positive and negative) and to provide illustrative quotes directly drawn from participant responses. Themes were generated separately for each cohort to explore potential shifts as the chatbot prototype evolved across iterative refinements.

In keeping with qualitative rigor standards [40], several strategies were used to enhance trustworthiness. A reflexive approach was adopted to account for potential bias arising from the nonneutrality of the LLM and the researchers' positionality as employees of the company developing the chatbot. To increase dependability, the analytic procedure was repeated independently 3 times using identical prompts, and theme labels and descriptions were compared across runs to assess stability and consistency in structure. To enhance credibility [40], the researchers reviewed LLM-generated themes and quotations to

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ensure that quotes were coherent, nonredundant, and accurately reflected the described pattern. To ensure confirmability, we retained only themes that were consistently reproduced across model runs and deemed coherent in relation to the dataset as a whole. Transferability was supported by a detailed description of the study context, participant characteristics, and prototype-stage setting, allowing readers to evaluate applicability to similar contexts.

Statistical Analyses

The goal of this user experience pilot trial was to recruit a sufficiently large sample to characterize usability and acceptability, gather rich user feedback, and obtain preliminary estimates of symptom change to inform the design and justification of future full-scale trials; accordingly, it was not statistically powered to detect clinical effects. First, descriptive statistics were used to summarize responses to the first-impression survey and 1-week follow-up surveys, including items assessing perceived emotional safety, trust, sense of being understood, professionalism, personalization, acceptability, and perceived advantages relative to a human therapist. Mean item ratings and stacked bar distributions were calculated using all available data.

The PHQ-8 and GAD-7 were analyzed separately to capture domain-specific symptom change and also combined into a Patient Health Questionnaire Anxiety and Depression Scale (PHQ-ADS) composite representing overall symptom burden [26], as this is a common metric used in digital mental health studies [41,42]. The composite was included to facilitate interpretation of global symptom change rather than to introduce a distinct confirmatory endpoint. Consistent with the developmental aims of this pilot, all symptom outcomes were interpreted as exploratory indicators to inform future trial design.

Clinical outcome analyses were restricted to participants with at least mild symptoms at baseline for the given outcome. For depressive symptoms, models included only participants with PHQ-8 scores ≥5 at baseline; for anxiety symptoms, only those with baseline GAD-7 scores ≥5 were included. Models estimating total symptoms (PHQ-ADS) and secondary outcomes were estimated among participants who had either PHQ-8 or GAD-7 ≥5 at baseline (not necessarily both). Changes in clinical outcomes from baseline to the 2-week follow-up were estimated using linear mixed-effects models with a random intercept for participant, with time (follow-up vs baseline) as the main predictor and demographic covariates and cohort indicators included as fixed effects. Exploratory regression models tested whether first-impression ratings of the chatbot predicted 1-week therapeutic alliance and acceptability scores, adjusting for covariates and cohort. Finally, Pearson correlations examined associations between each first-impression rating and residualized symptom change scores (ie, calculated by regressing follow-up symptom scores on baseline severity and using the residuals as indices of symptom change independent of baseline levels), providing preliminary evidence for experiential predictors of improvement.

This study was reported in accordance with the CONSORT (Consolidated Standards of Reporting Trials) extension for pilot and feasibility trials (Checklist 1).

Results

Study Protocol Feasibility Metrics

Overview

The following metrics describe the feasibility of the structured, incentivized study protocol rather than naturalistic engagement patterns. Because app use was incentivized to encourage adequate prototype evaluation, retention, and usage statistics should be interpreted as indicators of procedural feasibility informing next-stage trials, not as estimates of voluntary real-world uptake. Retention was strong under the incentivized, time-limited study protocol (96% at 1 week; 95% at 2 weeks). We nevertheless examined correlates of attrition using logistic regression and found that dropout was unrelated to age, gender, education, employment, household income, baseline symptom levels, or baseline attitudes toward mental wellness chatbots. Across the 3 enrollment cohorts, there were no significant baseline differences in clinical severity.

Over the 2-week intervention period (defined as the first 16 days following activation to accommodate minor variation in start timing), participants completed a median of 7 sessions, with 79.6% completing at least 5 sessions and 30.1% completing at least 10 sessions. Participants used the chatbot on 7.4 distinct days, on average (SD 2.8), indicating that engagement was generally distributed across the exposure period rather than all at once. Across sessions, participants generated a median of 157 talk-turns (ie, message exchanges), indicating sustained conversational engagement with the chatbot. Adherence to the study protocol was high, with 75.2% of participants reaching the recommended exposure (≥120 total minutes of use) and 87.6% completing at least 90 minutes (median 141.9 minutes). Older age was significantly associated with greater total minutes of app use; no other baseline demographic or attitudinal variables were related to minutes of use or total talk turns with the chatbot. Notably, household income was not significantly associated with total minutes of use (Spearman $\rho=-0.06$, $P=.57$) or with likelihood of reaching the incentivized exposure threshold (odds ratio 1.00, 95% CI 1.00-1.00; $P=.91$).

Safety Monitoring

During the 2-week exposure period, 10 (8.0%) participants triggered a real-time safety alert (no participants triggered more than one). Of these 10 alerts, 5 were flagged for potential risk of harm to self, 2 for harm to others, and 3 for harm from others. All transcripts flagged by the real-time safety classifier were reviewed by a study clinician within 2 hours, and none met the study threshold for phone-based safety outreach (eg, indicators of acute or imminent risk). The “harm to self” alerts referenced concerns about death in other contexts (eg, panic attacks, loved ones) or risk factors (eg, feeling like a burden), but no suicidal thoughts. “Harm to others” alerts reflected third-party nonviolent contextual behaviors or hypothetical situations, and “harm from others” alerts reflected general interpersonal conflict or precautionary safety concerns.

Qualitative User Experience Findings

Consistent with the early-stage, developmental focus of this pilot, qualitative analyses were exploratory and used primarily

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to identify actionable areas for product refinement. Across the 3 cohorts, participants described the chatbot as accessible, easy to use, and nonjudgmental, but limited by repetitive and impersonal responses. Qualitative content analysis identified three primary domains of experience: (1) accessibility and usability, (2) emotional validation and reflection, and (3) limitations in personalization and conversational depth.

Participants across all cohorts described the chatbot as a convenient outlet for emotional expression and appreciated being able to engage at any time and fit sessions flexibly into their routines. As one participant explained, “The chatbot was able to express my feelings without any judgment, and it’s there whenever I needed to talk.” [Cohort 1]. Others highlighted the app’s intuitive interface and customizable sessions, calling it “super easy to use. To set up... super easy. It may be the simplest app I’ve ever used to actually get in and do that.” [Cohort 2] and appreciating that “it was handy. I could use it at any point in time 24/7.” [Cohort 3]. These qualities made the chatbot particularly appealing as a low-barrier, on-demand support tool.

Across cohorts, participants also valued the chatbot’s ability to validate emotions and encourage self-reflection. Many described feeling heard and supported when the chatbot acknowledged their emotions, with one noting that it “did a good job validating my feelings and helping me remember that others feel the same way” [Cohort 1]. Later users reported that it facilitated goal setting and simple coping strategies, such as reminders to take breaks or practice breathing exercises: “It helped me set a goal, did a grounding exercise, and gave me tools to get started” [Cohort 3]. These elements contributed to perceptions of the chatbot as supportive, though somewhat limited in depth.

Despite these strengths, the chatbot’s repetitiveness and lack of personalization emerged as key pain points. Participants frequently described conversations as “robotic” or “circular,” with limited responsiveness to context. One Cohort 1 user noted, “It just kept asking the same questions and using the same exact language,” while a Cohort 2 participant remarked, “Every response was starting with my name... it seems very unnatural and stiff.” Others lamented that the chatbot failed to pivot or offer specific advice: “It kept asking me the same questions... whereas a human could pivot the conversation” [Cohort 3]. Feedback on session structure also shifted across cohorts. Cohort 1 users requested more guidance around session length, which informed the introduction of timed sessions; however, Cohorts 2 and 3 reported occasional frustration when session cut-offs truncated ongoing discussion.

Across cohorts, core themes were consistent: participants valued accessibility and emotional validation but critiqued repetitive and impersonal responses. Cohort-level differences primarily reflected emphasis on emotional safety in Cohort 1, usability and goal-setting in Cohort 2, and coping tools and session design in Cohort 3. As the prototype evolved across cohorts, feedback appeared to shift from general impressions to more specific critiques of functionality and conversational adaptability. Overall, participants saw clear potential in the chatbot while emphasizing that improvements in personalization, conversational nuance, and responsiveness will be essential for enhancing its value.

Usability of the Chatbot App

Usability, assessed using an adapted Intervention Usability Scale (IUS) [27] specific to the mental wellness chatbot (0 - 100 scale), was generally favorable. Participants reported a mean IUS score of 75.0 (SD 13.6). Although the IUS does not have established percentile norms, scores in the mid-70s are interpreted as “good” usability on the original System Usability Scale [43]. For context, the mean usability rating in this study was higher than that reported for the motivational interviewing intervention in the original IUS validation paper (68.7), suggesting that the chatbot app was, on the whole, experienced as usable by participants. Household income was not correlated with usability scores (r=0.07, P=.47).

User Experience and Acceptability Ratings

Participants generally reported moderately positive first impressions of the chatbot’s emotional safety, trustworthiness, sense of being heard and understood, and professionalism, with mean ratings hovering slightly above the scale midpoint on most items (Figure 1A). However, a substantial minority of participants endorsed neutral or negative response options, particularly for items related to feeling deeply understood (≈40%) and perceived personalization of responses (≈65%), indicating focal opportunities for improvement. At the 1-week follow-up, perceptions of emotional safety, comfort, and professionalism were generally stable (Figure 1B), although ratings of response personalization declined relative to first impressions.

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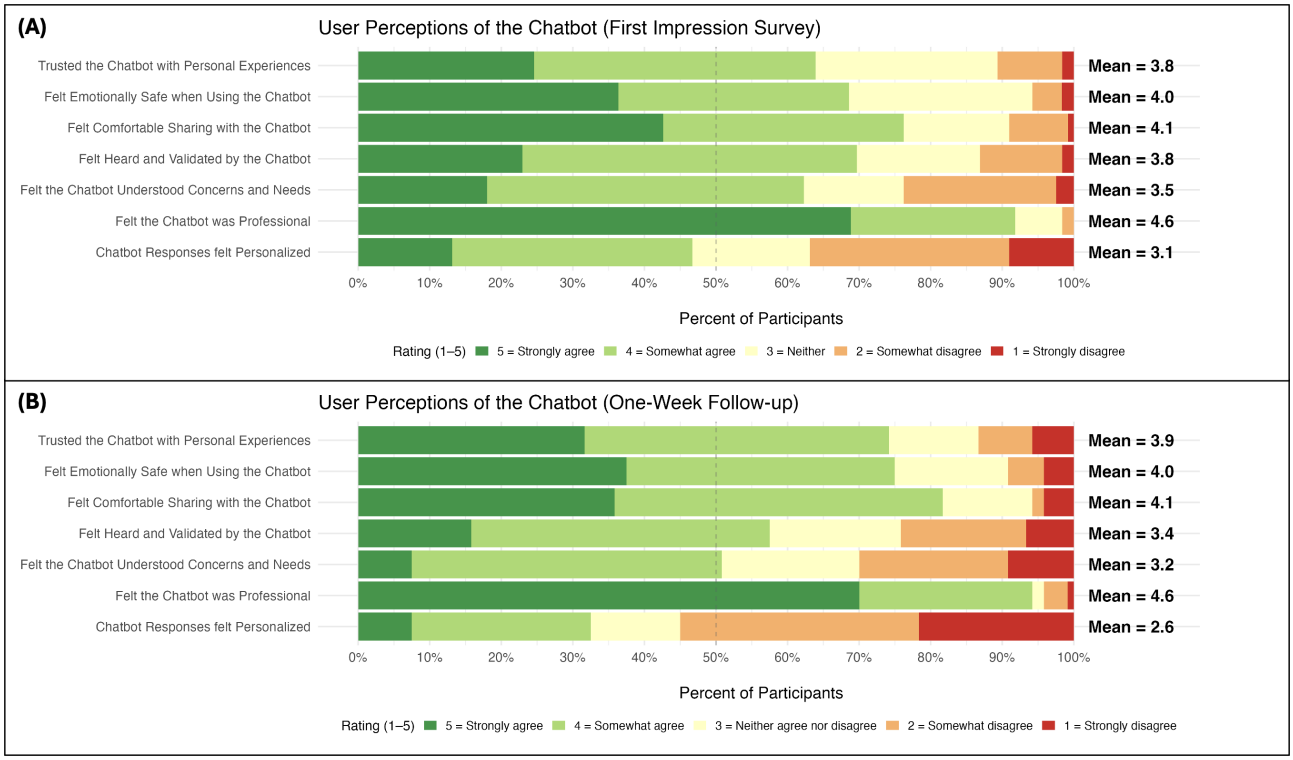
Figure 1. Panel (A) displays ratings from the first-impression survey completed immediately after initial interaction with the chatbot; Panel (B) displays ratings from the 1-week follow-up survey.



Acceptability ratings at one week reflected a similar pattern of mixed strengths and areas to improve upon (Figure 2A). Most participants agreed or strongly agreed that they trusted the chatbot to respond appropriately and understood how the app was intended to help. However, broader indicators of acceptability were notably lower. Fewer than 10% strongly agreed that they liked interacting with the app, and fewer than half agreed or strongly agreed overall. Perceived helpfulness was also modest, with only ≈40% agreeing that the chatbot's responses were helpful for their mental health. Ratings of self-efficacy also highlight an area for improvement, with fewer than half agreeing that they were able to use the app consistently and correctly. Household income was not related to first impression ratings (r=0.05, P=.59) or overall acceptability (r=–0.09, P=.37).

Therapeutic alliance ratings at 1-week follow-up were moderate across bond, task agreement, and goal agreement subdimensions, with mean item scores just narrowly above the scale midpoint (Figure S3 in Multimedia Appendix 1 [26-37]). Compared with human therapists, participants generally viewed the chatbot as more accessible, less stigmatizing, and easier to open up to and be honest with (Figure 2B). Taken together, these findings indicate that while the chatbot was generally viewed as safe, respectful, and understandable, with some key advantages over traditional therapy settings, participants' experiences of enjoyment, perceived helpfulness, confidence in use, and personalization were more variable and less positive, on average. Household income was not related to perceived therapeutic alliance (r=−0.11, P=.28).

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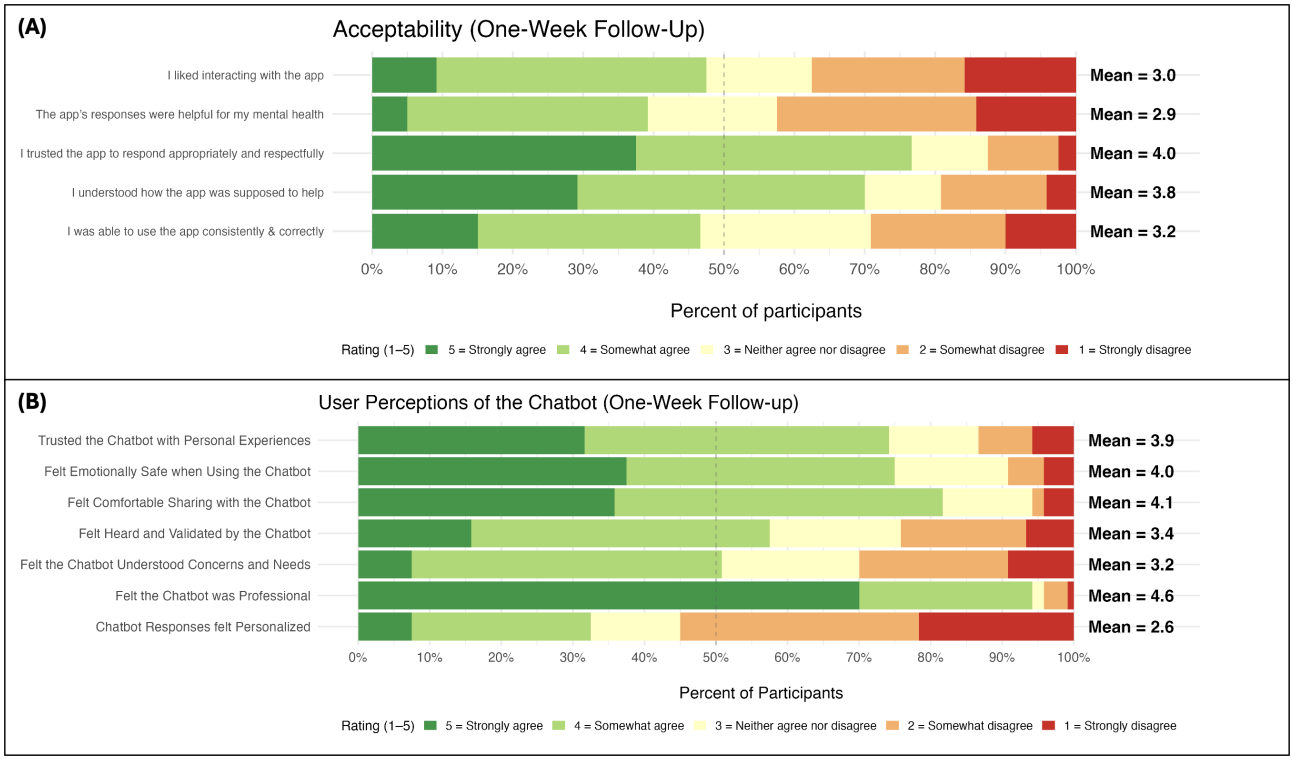
Figure 2. Panel (A) displays acceptability ratings of the chatbot; Panel (B) displays ratings of perceived advantages of the chatbot relative to traditional, human therapy.



Clinical Outcomes

Overview

Descriptive estimates of clinical outcomes at baseline and 2-week follow-up are shown in Table 1, and regression model results are shown in Table 2. Mixed-effects models showed a significant reduction in depressive symptoms from baseline to 2-week follow-up, corresponding to a small-to-moderate standardized effect size (Hedges *g*, computed using the baseline SD/Glass's Δ=–0.32, 95% CI –0.52 to –0.11). Anxiety symptoms also decreased significantly, with a similar standardized effect magnitude (*g*=–0.32, 95% CI–0.50 to –0.14). Total-symptom models, including all participants with either PHQ-8 or GAD-7 scores >4, indicated significant overall improvement across the 2-week period (*g*=–0.26, 95% CI –0.42 to –0.09). Household income was not correlated with residualized change in total symptoms (*r*=–0.14, *P*=.16).

Table . Descriptive statistics for clinical outcomes at baseline and follow-up. The analytic sample for assessing depressive and anxiety symptoms included those with baseline patient health questionnaire (PHQ) or generalized anxiety disorder (GAD) scores >4, respectively. All other outcomes included participants with either PHQ or GAD >4 at baseline.

Measure/scale	Baseline		Two-week follow-up	
	N	Mean (SD)	N	Mean (SD)
Depressive symptoms (PHQ-8)	96	10.14 (4.10)	92	8.84 (4.39)
Anxiety symptoms (GAD-7)	107	10.38 (4.10)	102	9.18 (4.73)
Total symptoms (PHQ+GAD)	116	18.85 (7.77)	111	16.94 (8.24)
Well-being (WHO-5)[a]	116	9.43 (4.34)	110	10.26 (4.82)
Psychological distress (K6)	116	7.38 (3.68)	110	6.59 (3.85)
Loneliness (UCLA-3)[b]	114	2.30 (1.72)	109	2.15 (1.99)
Chatbot attitudes (APOI[c])	116	49.38 (9.34)	111	48.54 (11.02)

[a]WHO-5: World Health Organization-5 Well-Being Index.

[b]UCLA-3: University of California, Los Angeles 3-Item Loneliness Scale.

[c]APOI: Attitudes Towards Psychological Online Interventions.

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Table . Longitudinal mixed-effects models predicting depressive, anxiety, and total symptom scores by time (baseline vs 2-week follow-up).

Covariate	Depressive symptoms (PHQ-8)[a] (n=96)			Anxiety symptoms (GAD-7)[b] (n=107)			Total symptoms (PHQ-ADS)[c,d] (n=116)		
	β	SE	*P* value	β	SE	*P* value	β	SE	*P* value
Time (follow-up vs baseline)	−1.30[e]	0.44[e]	.003[e]	−1.31[e]	0.38[e]	.001[e]	−2.01[e]	0.67[e]	.003[e]
Cohort 2 (vs cohort 1)	0.34	0.93	.718	−0.25	0.96	.79	−0.23	1.66	.89
Cohort 3 (vs cohort 1)	−0.31	0.89	.73	−1.1	0.93	.24	−2.11	1.61	.19
Age	0.00	0.04	.95	0.05	0.05	.29	0.05	0.07	.51
Woman (vs man)	−0.50	0.78	.52	0.11	0.82	.90	−0.93	1.43	.52
College degree (vs no degree)	−1.04	0.97	.28	0.3	1.01	.76	−1.52	1.77	.39
Postgraduate degree (vs no degree)	−1.82	1.08	.09	−1.92	1.11	.08	−4.25[e]	1.95[e]	.0[e]3
Unemployed (vs employed)	1.32	1.09	.22	-1.69	1.13	.14	−1.31	1.94	.50
Current student (vs employed)	−1.07	1.31	.41	-0.01	1.28	>.99	−1.32	2.14	.54
Asian/Asian American (vs White)	−1.09	1.19	.36	0.85	1.25	.50	0.04	2.14	.99
Black/African American (vs White)	2.30	1.28	.07	0.09	1.33	.94	1.75	2.17	.42
Multiple races (vs White)	1.68	1.78	.35	2.43	1.77	.17	6.22[e]	3.12[e]	.047[e]
Another race (vs White)	5.22	3.14	.10	2.75	3.29	.40	8.30	5.78	.15
Hispanic (vs Non-Hispanic)	4.79	2.74	.08	4.02	2.89	.16	9.88	5.18	.056
Interaction models[f]									
Time × baseline symptom Levels	−0.64[e]	0.17[e]	<.001[e]	−0.27[e]	0.09[e]	.001[e]	−0.35[e]	0.08[e]	<.001[e]

[a]Participants in the depressive symptoms model had to have a baseline PHQ score >4.

[b]Participants in the anxiety symptoms model had to have a baseline GAD score >4.

[c]Participants in the total symptoms model had to have either PHQ or GAD score >4 at baseline.

[d]PHQ-ADS: Patient Health Questionnaire Anxiety and Depression Scale.

[e]Statistically significant estimates.

[f]Interaction models were each tested separately, controlling for the same covariates as the main effects models above. Inverse interaction coefficients indicate that participants with higher baseline symptoms showed greater reductions from baseline to follow-up (ie, larger improvements).

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Baseline Symptomatology as a Moderator

Across outcomes, participants with higher baseline symptom severity demonstrated larger improvements over the 2-week period, reflected by significant baseline-severity×time interactions (Table 2). To probe these interactions, we estimated the marginal intervention effect across a continuum of plausible baseline values. These estimates are model-based and reflect greater statistical uncertainty at the upper end of the baseline severity distribution, where observations were relatively sparse and should be interpreted cautiously.

For depressive symptoms, the magnitude of improvement increased steadily as baseline PHQ-8 severity increased (Figure 3A). At a baseline PHQ-8 score of 10, the predicted effect size was *g*=–0.29, consistent with a modest reduction. At baseline scores of 12.5 (*g*=–0.57) and 15 (*g*=–0.84), the corresponding predicted effects indicate medium to large improvements. At higher baseline severity (PHQ-8=17.5), the estimated improvement was *g*=–1.12, reflecting a very large effect. A similar pattern emerged for anxiety symptoms (Figure 3B). At a baseline GAD-7 score of 10, the predicted effect size was *g*=–0.29. This effect size increased at baseline scores of 12.5 (*g*=–0.46) and 15 (*g*=–0.62). At higher baseline severity (GAD-7=17.5), the model predicted a larger improvement (g=–0.78).

These marginal-effect curves show that while effect size magnitudes were modest at lower baseline symptom levels, participants with moderate to severe depressive or anxiety symptoms demonstrated substantially greater reductions over the 2-week exposure period. These results indicate that baseline severity meaningfully moderated clinical change, with higher-severity individuals showing the largest predicted reductions.

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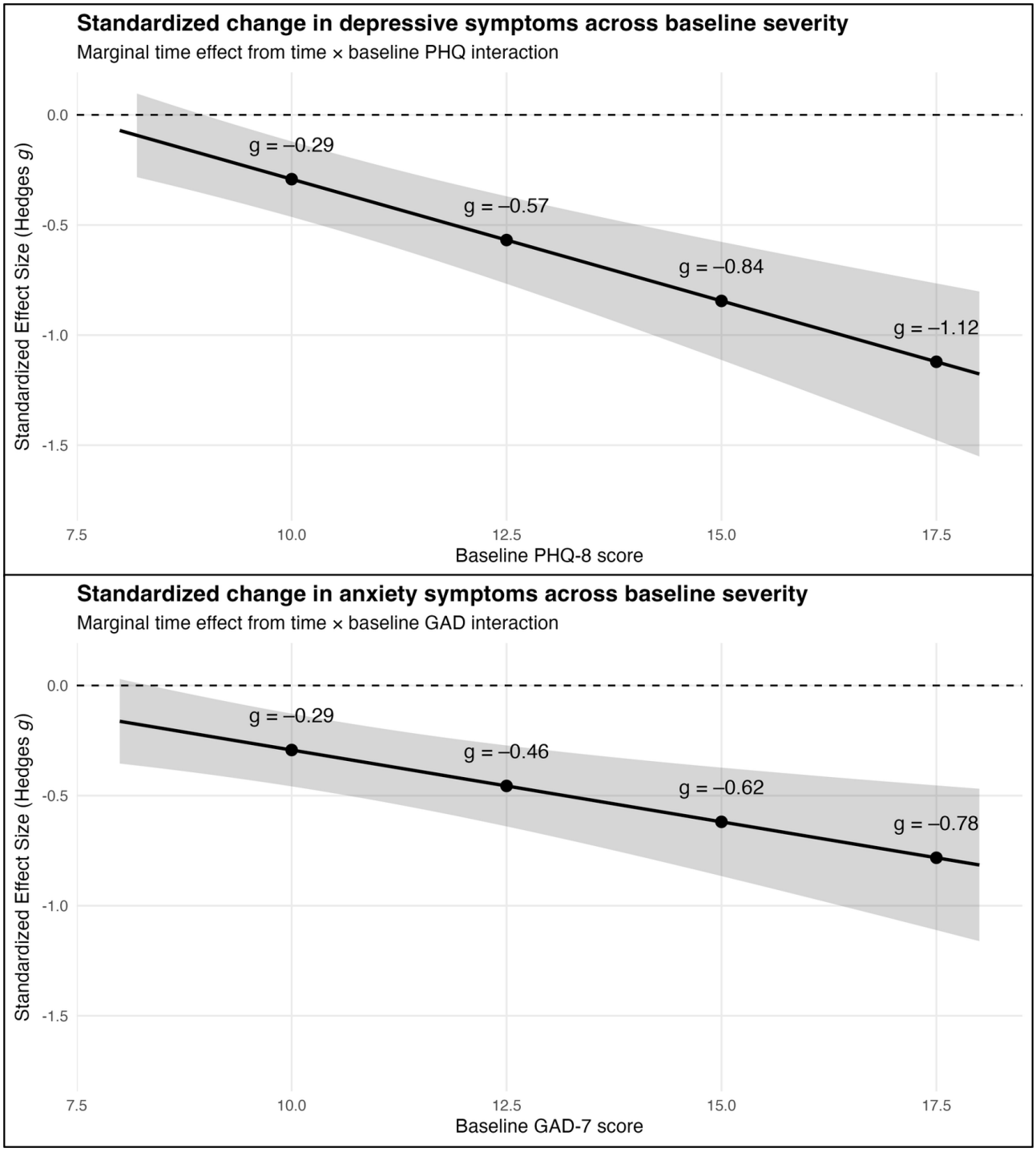
Figure 3. Curves show the model-estimated marginal effect of time (follow-up vs baseline) from mixed-effects models with a time× baseline interaction. Shaded regions indicate 95% CIs based on the delta method. GAD: generalized anxiety disorder; PHQ: patient health questionnaire.



Secondary Clinical Outcomes

For secondary outcomes (Table 3), well-being increased (*g*=0.19, 95% CI 0.03-0.36) and psychological distress decreased (*g*=–0.21, 95% CI –0.38 to –0.04), with both effect sizes in the small-to-moderate range. Loneliness showed a small, nonsignificant reduction (*g*=–0.11, 95% CI –0.26 to 0.04). Attitudes toward mental wellness chatbots did not shift significantly across the exposure period, although the direction of change suggested slightly less favorable attitudes at follow-up (*g*=–0.09, 95% CI –0.24 to 0.05).

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Table . Longitudinal mixed-effects models predicting secondary clinical outcomes by time (baseline vs 2-week follow-up). Participants in these models had to have either a patient health questionnaire (PHQ) or generalized anxiety disorder (GAD) score >4 at baseline.

Covariate	Wellbeing (WHO-5) (n=116)			Psychological distress (K6) (n=116)			Loneliness (UCLA-3)[a] (n=116)			APOI[b] – Therapy Chatbot (n=116)		
	β	SE	*P* value	β	SE	*P* value	β	SE	*P* value	β	SE	*P* value
Time (follow-up vs baseline)	0.85[c]	0.37[c]	.02[c]	−0.77[c]	0.32[c]	.02[c]	−0.19	0.13	.15	−0.88	0.68	.19
Cohort 2 (vs cohort 1)	−0.19	0.99	.84	−0.37	0.78	.64	−0.29	0.39	.46	3.32	2.18	.13
Cohort 3 (vs cohort 1)	0.31	0.96	.74	−0.25	0.76	.74	−0.55	0.38	.15	0.67	2.11	.75
Age	−0.04	0.04	.31	0.00	0.03	.89	0.01	0.02	.42	0.02	0.10	.82
Woman (vs man)	−1.07	0.85	.21	−1.17	0.67	.08	−0.27	0.34	.42	−0.17	1.88	.93
College degree (vs no degree)	−0.25	1.06	.81	−0.86	0.83	.30	−0.26	0.42	.54	−0.95	2.33	.68
Postgraduate degree (vs no degree)	0.79	1.16	.50	−1.80[c]	0.92[c]	.049[c]	−0.51	0.46	.27	−5.00	2.56	.05
Unemployed (vs employed)	−0.85	1.16	.46	−0.94	0.91	.31	0.10	0.45	.83	−0.38	2.54	.88
Current student (vs employed)	−1.00	1.27	.43	−0.35	1.00	.73	0.67	0.50	.18	−1.97	2.80	.48
Asian/Asian American (vs White)	0.33	1.27	.79	0.97	1.01	.33	0.64	0.50	.21	−0.31	2.81	.91
Black/African American (vs White)	0.47	1.29	.72	0.11	1.02	.91	1.13[c]	0.51[c]	.03[c]	1.86	2.84	.51
Multiple races (vs White)	−1.29	1.86	.49	2.39	1.47	.10	0.20	0.74	.79	−2.83	4.07	.49
Another race (vs White)	2.29	3.45	.51	4.85	2.72	.07	0.09	1.36	.95	9.29	7.57	.22
Hispanic (vs Non-Hispanic)	0.79	3.08	.80	5.21[c]	2.43[c]	.03[c]	1.12	1.22	.36	2.39	6.78	.72

[a]UCLA-3: University of California, Los Angeles 3-Item Loneliness Scale.

[b]APOI: Attitudes Towards Psychological Online Interventions.

[c]Statistically significant estimates.

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Associations Between Usage and Symptom Change

Using residualized change scores adjusted for baseline symptom severity, Pearson correlations indicated that associations between chatbot usage metrics and total symptom change (PHQ-ADS) were small and not statistically significant (r=–0.13 to –0.08; Figure S4 in Multimedia Appendix 1 [26-37]). However, all correlations trended in the expected direction: participants who used the app more (more minutes, sessions, talk-turns, or days active) tended to show slightly greater symptom improvement. Given the structured, incentivized exposure window, variability in usage was intentionally constrained, limiting the ability to observe naturalistic dose–response associations.

Associations Between First Impressions and Symptom Change

Pearson correlations between first-impression ratings and residualized symptom change scores showed that 3 early experiential perceptions were significantly associated with greater improvement in total symptoms (PHQ-ADS; Figure S5 in Multimedia Appendix 1 [26-37]): feeling that the chatbot understood participants' concerns and needs (r=–0.22, 95% CI –0.39 to −0.04), perceiving the chatbot as professional (r=–0.25, 95% CI –0.42 to –0.07), and rating the chatbot's responses as personalized (r=–0.29, 95% CI –0.45 to –0.10). Correlations with emotional safety, trust, comfort sharing, and feeling heard or validated were small and nonsignificant.

Experiential Predictors of Therapeutic Alliance and Acceptability

Exploratory models examined which specific experiences, assessed at the 1-week follow-up, were associated with therapeutic alliance and acceptability (Table 4). Although the trust item was removed due to multicollinearity issues (ie, Variance Inflation Factor >4), several experiences emerged as relevant correlates. Participants who felt more emotionally safe, heard/validated, and understood by the chatbot reported significantly higher therapeutic alliance scores and greater overall acceptability. Additionally, perceived personalization of the chatbot was significantly related to therapeutic alliance and acceptability, though with a slightly smaller effect. Taken together, participants' sense of emotional safety and validation from the chatbot were the strongest experiential correlates of therapeutic alliance and acceptability.

These models also revealed notable demographic patterns. Relative to White participants, those identifying as Black, Hispanic, or multiracial/another race reported significantly higher acceptability, and Black participants also reported higher alliance. Additionally, participants in Cohort 2 (and for alliance, Cohort 3) reported higher ratings than those in Cohort 1, possibly reflecting iterations made to the chatbot based on the first cohort's feedback.

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Table . Experiential predictors of therapeutic alliance and acceptability scores. Participants in these models had to have either a patient health questionnaire (PHQ) or generalized anxiety disorder (GAD) score >4 at baseline. These 2 outcomes, therapeutic alliance and acceptability scores, are correlated r=0.81, P<.001.

Covariate	Therapeutic alliance			Acceptability scores		
	β	SE	*P* value	β	SE	*P* value
Felt emotionally safe using the chatbot	0.46[a]	0.18[a]	.01[a]	0.19[a]	0.08[a]	.02[a]
Felt comfortable sharing with the chatbot	−0.33	0.20	.10	0.00	0.09	.96
Felt heard and validated by the chatbot	0.64[a]	0.16[a]	<.001[a]	0.17[a]	0.07[a]	.02[a]
Felt the chatbot understood concerns and needs	0.38[a]	0.16[a]	.02[a]	0.29[a]	0.07[a]	<.001[a]
Felt the chatbot was professional	0.30	0.21	.15	0.08	0.09	.37
Felt the chatbot responses were personalized	0.26[a]	0.13[a]	.04[a]	0.12[a]	0.05[a]	.03[a]
Cohort 2 (vs cohort 1)	0.99[a]	0.31[a]	.002[a]	0.36[a]	0.14[a]	.009[a]
Cohort 3 (vs cohort 1)	0.97[a]	0.31[a]	.002[a]	0.21	0.13	.12
Age	0.00	0.01	.89	0.00	0.01	.53
Woman (vs man)	0.37	0.27	.16	0.03	0.12	.79
College degree (vs no degree)	−0.63	0.33	.06	−0.21	0.15	.14
Postgraduate degree (vs no degree)	−0.12	0.37	.75	−0.18	0.16	.26
Unemployed (vs employed)	0.48	0.37	.20	0.41[a]	0.16[a]	.01[a]
Current student (vs employed)	−0.77	0.43	.08	−0.20	0.19	.29
Asian/Asian American (vs White)	0.63	0.42	.13	0.16	0.18	.38
Black/African American (vs White)	1.20[a]	0.40[a]	.004[a]	0.44[a]	0.18[a]	.01[a]
Multiple races (vs White)	1.05	0.57	.07	0.54[a]	0.25[a]	.03[a]
Another race (vs White)	1.52	1.05	.15	1.00[a]	0.46[a]	.03[a]
Hispanic (vs Non-Hispanic)	1.21	0.93	.20	1.09[a]	0.41[a]	.009[a]

[a]Statistically significant estimates.

Discussion

Summary of Findings

This mixed methods pilot evaluated (1) user experience and acceptability, (2) feasibility of safety monitoring, and (3) an exploratory clinical signal for an early-stage generative AI mental wellness chatbot. Under an incentivized, time-limited protocol, participants reported the chatbot as accessible and emotionally validating while noting limitations in personalization and conversational depth. Safety workflows were feasible: 8% of participants triggered an automated safety alert, all were reviewed within 2 hours, and none required

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outreach under prespecified criteria. Models showed small-to-moderate pre–post reductions in depressive and anxiety symptoms, with larger predicted improvements among participants with higher baseline severity, though model-predicted effects at the upper end should be interpreted cautiously given sparser data among those with elevated baseline symptoms. Together, findings support procedural feasibility and identify candidate therapeutic targets to inform ongoing refinement and future controlled trials.

Interpretation and Comparison With Prior Work

Clinical Signal

Participants demonstrated measurable improvements in depressive and anxiety symptoms over the 2-week exposure period, despite the brief, incentivized format and the early developmental stage of the prototype. Small-to-moderate reductions were also observed for psychological distress and well-being, suggesting that even limited engagement with the chatbot produced detectable short-term clinical benefits. These findings are notable given the relatively mild symptom severity of the enrolled sample and the modest exposure (≈60 min per week).

Baseline symptomatology moderation analyses provide critical context for understanding these effects in comparison to other recently published chatbot studies. Participants with more severe baseline symptoms experienced substantially greater improvement, with standardized effect sizes increasing sharply with more elevated baseline severity. This pattern indicates that the chatbot prototype's clinical impact is not uniform but may vary as a function of initial symptom burden; however, given the restricted risk profile of this pilot sample, moderation patterns should be interpreted cautiously, especially at the higher end, given sparse data and wider CIs. Indeed, the modest average effects observed in the full sample are partly a function of the sample's relatively low baseline severity, not necessarily a limitation of the chatbot itself.

This has direct relevance for interpreting our findings within the burgeoning literature on mental wellness chatbots. Recent trials of more mature systems, such as Therabot [9] and Ash [44], have reported larger effect sizes than the main effects estimated herein. However, these trials deliberately recruited participants with moderate to severe symptoms, required higher-frequency, longer-duration exposure, and used different statistical modeling approaches to estimate effect sizes. Because symptom severity is a strong determinant of effect magnitude, studies that enroll more symptomatic participants naturally provide more opportunity for measurable change [45]. Our moderation results reinforce this point as higher baseline symptoms were associated with substantially larger predicted improvements. Thus, while direct comparisons to more established chatbots are not yet appropriate given differences in product maturity, engagement requirements, and sample symptom levels, our findings suggest that this early-stage prototype has the potential to produce clinically meaningful effects when used by individuals with greater initial symptom severity. We interpret this evidence as proof of concept, clarifying both the potential of the nascent system and the likely improvement as the product becomes more refined and is tested in samples with higher baseline symptomatology.

User Experience and Design Considerations

The convergent quantitative and qualitative findings highlight both the prototype's strengths and the most critical areas for refinement. Participants frequently characterized the chatbot as accessible, nonjudgmental, and easy to use. These positive qualities strongly aligned with the goal of AI-supported mental health tools to lower barriers to care [46]. Users' impressions also aligned with high usability ratings and moderate therapeutic alliance scores, indicating that participants were able to form a basic sense of responsiveness and support with the tool. Importantly, alliance in AI-mediated interactions is conceptually distinct from the relational bond cultivated with human therapists and should not be interpreted using the same benchmarks [47]. As others in this area have argued [48], alliance plays a more modest and indirect mechanistic role in digital interventions. In this context, the moderate alliance observed presently likely represents a realistic upper bound for early-stage prototypes, but is nevertheless a key focus for forthcoming product development.

A core design tradeoff in AI tools is that stronger safety and content-guardrail constraints often limit the natural fluidity of conversation, shaping how users experience and evaluate the system. Integration of the qualitative and quantitative findings revealed consistent limitations in personalization, conversational depth, and perceived helpfulness. Some participants described the interaction pattern as repetitive, formulaic, or context-insensitive, which directly aligns with lower quantitative ratings on items related to personalization and understanding. Acceptability ratings also revealed mixed experiences: trust and perceived appropriateness were strong, whereas enjoyment, perceived helpfulness, and self-efficacy in using the chatbot correctly were more variable. Notably, attitudes toward mental wellness chatbots overall became slightly less favorable from baseline to follow-up, suggesting that initial optimism or curiosity may have surpassed the practical realities of interacting with an early-stage prototype, which is a pattern frequently reported in digital mental health when user expectations exceed current product capabilities [49,50].

Participants often expressed expecting immediate advice capable of resolving distress within a single interaction. Although understandable, such expectations run counter to core therapeutic principles. Evidence-based psychotherapy discourages providing directive advice at the outset of treatment, before adequate case understanding has been established [51], and even the most effective interventions require ongoing practice and reflection rather than instant resolution. The present mental wellness chatbot emphasizes clarifying questions and reflective prompts that can feel repetitive or circular but are designed to mirror therapy processes [25]. In contrast, general-purpose AI systems (ie, ChatGPT) often provide rapid, directive answers that may feel more responsive yet do not align with therapeutic process fidelity. When user expectations for immediate relief exceed what a clinically guided system can reasonably provide, perceived helpfulness may decline,

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emphasizing the need to set clear expectations about the capabilities and purpose of early-stage mental wellness chatbots.

Unexpectedly, demographic patterns also offer important implications for chatbot-based mental well-being tools. Black, Hispanic, and multiracial participants reported higher acceptability and alliance than White participants. These findings are exploratory and should be interpreted cautiously, particularly given sample size considerations and the structured, incentivized design of the study. While chatbot-based interactions may represent a potentially lower-barrier modality for some groups who face disproportionate barriers in traditional mental health systems, further investigation in larger and more diverse samples under naturalistic conditions is required before drawing conclusions regarding equity implications.

Therapeutic Signal and Early Mechanisms of Change

Consistent with theory on early therapeutic processes, several first-impression ratings, including feeling understood, perceiving professionalism, and experiencing personalization, were significantly associated with greater symptom improvement. These associations are consistent with participant narratives describing moments of emotional validation and goal-setting support. Importantly, these associations emerged despite the prototype's limited personalization, suggesting that even brief experiences of attunement or perceived competence may exert disproportionate influence on therapeutic expectancies and engagement.

Conversely, the absence of dose–response relationships between usage metrics and symptom change is likely attributable to the structure of the pilot study itself. Engagement was incentivized, compressed, and highly uniform across participants, limiting the natural variability needed to detect behavioral predictors of improvement. Qualitative reports were consistent with this interpretation: while some participants sought emotional support, others acknowledged using the app primarily to meet compensation thresholds. Longer, more naturalistic trials (ie, flexible use) are likely to provide a more accurate test of organic engagement–outcome relationships.

Safety Monitoring

Finally, the safety monitoring procedures tested in this pilot support the feasibility of this clinician-supervised mental wellness chatbot. In this study, 8% of participants triggered at least one automated safety alert, and all alerts were promptly reviewed by a clinician. Consistent with the deliberately high-sensitivity safety classifier and nonacute sample, none met the prespecified threshold for phone-based outreach (eg, acute or imminent risk). This pattern suggests that real-time safety guardrails can successfully surface potentially concerning content while keeping the volume of urgent follow-ups manageable, which is encouraging for larger human-in-the-loop trials. Nonetheless, further testing among higher-risk samples with longer exposure periods is needed to determine how the workload associated with safety monitoring would differ when higher-risk users (eg, those with suicidal thinking) are not excluded.

Implications for Early-Stage Development of Mental Well-Being Chatbots

Collectively, these mixed methods findings suggest that even a minimally refined generative AI–based chatbot can deliver a safe and accessible user experience that may be associated with modest short-term improvements in mental health symptoms under pilot conditions. The iterative cohort design highlights the value of rapid user feedback loops for refining conversational flow, session pacing, and safety monitoring protocols. As LLM-based systems continue to evolve, improvements in contextual coherence, personalization, and adaptive responsiveness may strengthen user experience and engagement, but these possibilities require evaluation under more rigorous, controlled conditions.

As chatbot systems are iteratively refined, tracking theory-consistent mediators, such as experiential and behavioral change processes, across product versions will be critical to determining whether design modifications meaningfully enhance user experience and clinical signal. Longer-term randomized studies under more naturalistic conditions are also needed to evaluate durability and to examine how chatbots may operate within integrated care pathways; for example, as a pretherapy intake tool, a between-session reinforcement, a maintenance tool following treatment, or a monitored entry point that escalates to human clinicians when symptom trajectories fail to improve or deteriorate [52]. Finally, future work should continue to explore the balance between usability and therapeutic rigor, as highly engaging conversational interfaces must also preserve core therapeutic processes that may not always prioritize immediate gratification.

Limitations

Regarding limitations, the brief, 2-week exposure period limits conclusions about durability, particularly because outcomes were measured during or immediately after active use. Such designs may capture proximal engagement effects rather than sustained change [14]. However, this timeframe was appropriate for a pilot focused on usability, acceptability, and early clinical signals, and it enabled rapid prototype iteration. The single-arm pre–post design also raises the possibility of regression to the mean. In the absence of a randomized comparison group, improvements cannot be attributed definitively to the chatbot intervention, yet the magnitude of observed improvements—especially at higher baseline severity—appears larger than short-term changes typically reported in waitlist-controlled meta-analyses [53,54]

Participants were recruited from a convenience panel familiar with providing user-experience feedback on digital apps (dscout), which may limit generalizability, but provided high compliance and rich qualitative feedback appropriate for early-stage evaluation. Relatedly, pilot sampling purposefully excluded individuals with acute risk and those currently in treatment, consistent with the nascent state of this chatbot app. Engagement during this pilot was supported by usage-contingent incentives to ensure adequate exposure for prototype evaluation. This structure was appropriate for assessing usability, safety monitoring procedures, and early experiential processes, but engagement metrics should be interpreted as reflecting the

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feasibility of the study protocol rather than voluntary real-world uptake. While such incentives are common in early prototyping research, future effectiveness trials should evaluate voluntary, real-world engagement. Moreover, incentive structures may have influenced not only engagement patterns but also self-reported experiential and clinical outcomes, introducing potential response bias and limiting the internal validity of these self-reported measures. Although exploratory analyses did not detect significant associations between household income and self-reported experiential or clinical outcomes, income data were missing for 13.6% of participants, which may introduce selection bias if nonresponse was systematic.

Finally, the qualitative aspects relied on LLM-assisted content analysis to identify recurring experiential patterns rather than on researcher-led reflexive thematic analysis. Although theme stability was assessed across multiple independent model runs and outputs were reviewed for coherence, this approach did not incorporate traditional qualitative features such as prolonged coding immersion, formal reflexivity procedures, or independent human coding. Accordingly, qualitative findings should be interpreted as descriptive and exploratory, appropriate to the formative aims of this pilot study.

Conclusions

This pilot user experience study establishes critical feasibility and proof of concept for an early-stage mental well-being chatbot that can deliver meaningful and safe usability and measurable short-term symptom improvement, even in a mildly symptomatic sample. Transparent documentation of iterative development, combined with mixed methods insights and severity-based marginal effects, highlights both promising preliminary findings and the design targets most likely to enhance future engagement and clinical impact. These findings guide continued refinement and set the stage for rigorous, longer-term trials evaluating sustained engagement, clinical durability, and performance in more symptomatic samples.

Beyond this prototype, the study demonstrates a practical evaluation template for early-stage LLM mental health tools that combines user experience, safety workflow feasibility, and exploratory clinical outcomes with explicit caution about efficacy inference. As mental wellness chatbots continue to develop, transparent reporting of design constraints, safety monitoring, and user-perceived therapeutic processes will be critical for responsible iteration and for interpreting early clinical signals prior to larger randomized trials and real-world deployment.

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Data Availability

Deidentified quantitative data in their final form used for analyses will only be made available on reasonable request based upon compliance with legal, regulatory, confidentiality, and patient privacy requirements. Transcript and qualitative data will not be publicly available.

Authors' Contributions

SG contributed to conceptualization, methodology, formal analysis, and writing of the original draft, as well as reviewing and editing the manuscript. EJW contributed to methodology, formal analysis, and reviewing and editing the manuscript. GB and ERD contributed to project administration, investigation, and reviewing and editing the manuscript. KHB contributed to the investigation and writing of the original draft, as well as reviewing and editing the manuscript. MB and AC contributed to conceptualization, supervision, and reviewing and editing the manuscript. MH contributed to conceptualization, methodology, supervision, writing of the original draft, and reviewing and editing the manuscript.

Conflicts of Interest

SG, MH, EJW, GB, ERD, KHB, MB, and AC reported being employed by and holding equity in Spring Care Inc outside the submitted work. In addition, AC reported being the lead inventor on 3 patent submissions relating to treatment for major depressive disorder (US Patent and Trademark Office number Y0087.70116US00 and provisional application numbers 62/491 660 and 62/629 041) outside the submitted work. Finally, AC reported holding equity in Carbon Health Technologies Inc, Wheel Health Inc, Parallel Technologies Inc, Healthie Inc, and UnitedHealthcare; and providing unpaid advisory services to health care technology startups outside the submitted work.

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Multimedia Appendix 1
Additional figures and information.
[DOCX File, 4095 KB - formative_v10i1e90644_app1.docx]

Checklist 1
CONSORT checklist.
[DOCX File, 27 KB - formative_v10i1e90644_app2.docx]

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Abbreviations

AI: artificial intelligence
CONSORT: Consolidated Standards of Reporting Trials
GAD: generalized anxiety disorder
IUS: Intervention Usability Scale
LLM: large language model
PHQ: patient health questionnaire
PHQ-ADS: Patient Health Questionnaire Anxiety and Depression Scale

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Fact-Checking Large Language Model Responses to a Health Care Prompt: Comparative Study

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Abstract

Background: Large language models use machine learning to produce natural language. These models have a range of potential applications in health care, such as patient education and diagnosis. However, evaluations of large language models in health care are still scarce.

Objective: This study aimed to (1) evaluate the accuracy and efficiency of automated fact-checking by 2 large language models and (2) illustrate a process through which a large language model might support a patient in redrafting a prompt to include key information needed for patient safety.

Methods: A parallel comparison of 2 large language models and 3 human experts was conducted. A clinical scenario was devised in which a woman aged 23 years questions the safety of retinoid treatment for acne by sending prompts to 2 large language models (GPT-4o and OpenBioLLM-70B). GPT-4o and OpenBioLLM-70B were asked to suggest improvements to the patient's initial prompt to elicit key information for clinical decision-making. After the patient sent the revised prompt to the large language models, the models were then asked to fact-check the final response. To test the generalizability of automated fact-checking, a set of 20 clinical statements on disparate topics, mostly related to drug indications, contraindications, and side effects, was developed. The large language models also fact-checked these 20 medical statements. The results were compared against the evaluations of 3 clinical experts. The outcome measures were as follows: (1) percentage of accuracy of automated fact-checking, (2) time to complete fact-checking, and (3) a binary outcome for prompt redrafting (advising the patient to revise her prompt by naming her acne medication to address safety concerns).

Results: For the scenario of a patient with acne, GPT-4o and OpenBioLLM-70B both had 86% agreement with the clinical experts' fact-checking. The large language models did not consistently convey the urgency of discontinuing isotretinoin treatment when pregnancy is suspected. In addition, the models did not adequately convey the importance of folic acid supplementation during pregnancy. For the set of 20 medical claims, GPT-4o fact-checking had 100% agreement with that of human experts, whereas OpenBioLLM-70B had 95% agreement. OpenBioLLM-70B diverged from human experts and GPT-4o on 1 question related to pediatric use of antihistamines. The expert fact-checks took a mean time of 18 (SD 3.74) minutes, GPT-4o took 42 seconds, and OpenBioLLM-70B took 33 minutes. The GPT-4o responses for the acne scenario had some inconsistencies but zero fabrication and no obvious omissions. In contrast, OpenBioLLM-70B omitted 1 key information item needed for patient safety.

Conclusions: GPT-4o can interact with patients to improve the quality and comprehensiveness of the information contained in health-related prompts. GPT-4o and OpenBioLLM-70B can conduct efficient fact-checking that is close to the level of accuracy of human experts. Human experts need to perform additional checks for accuracy and safety.

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KEYWORDS

machine learning; artificial intelligence; AI; deep learning; patient medication knowledge; patient participation; shared decision-making

Introduction

Generative artificial intelligence (GenAI) is a form of artificial intelligence that can generate text, images, or other data types. Tools such as ChatGPT and Gemini offer a new opportunity for patients and clinicians to access health information [1].

There is evidence that patients are willing to use ChatGPT for self-diagnosis [2]. Clinicians are willing to use ChatGPT for

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various tasks in practice [3,4]. In some cases, GenAI has suggested diagnoses that have eluded clinicians [5]. However, GenAI can provide misleading and factually incorrect information authoritatively without indicating that it is unreliable [6,7].

Clinicians might be able to distinguish factually correct from incorrect GenAI responses in their areas of expertise but not in topics in which they only have general knowledge, whereas patients will always need support to fact-check GenAI responses. There is a need for improved tools to support clinicians and patients in this process.

The role of GenAI may extend beyond answering users' health care prompts. GenAI may also have a role to play in the subsequent fact-checking of these responses. This additional layer of "self-checking" may bolster the accuracy of responses. There is scant evidence on the ability of GenAI to perform this function. There is also scant literature describing the manner in which a patient might interact with GenAI to accomplish this in a real-world context.

Ni et al [8] evaluated the accuracy of large language models (LLMs), a prominent form of GenAI, in fact-checking public health statements. They found that the accuracy ranged from 66% to 90% depending on the type of prompt and the incorporation of relevant documents into the LLM system.

Zarharan et al [9] compared the accuracy of a number of LLMs for fact-checking public health statements. When zero-shot prompting was used, the most accurate model was GPT-4. Zero-shot prompting means that the user does not input any relevant examples from which the LLM could learn what constitutes a satisfactory response. In contrast, when the user provided one or more examples from which the model could learn (known as single- or few-shot prompting), open-source models achieved a level of accuracy that was comparable to that of the proprietary GPT-4 model. The highest accuracy was achieved by Vicuna-13B and Mistral-7B after undergoing fine-tuning, a process that adjusts some of the LLM's weights for improved performance in a specific task. These models achieved 68.5% and 72.0% F_1-scores, respectively.

LLMs may also have a role to play in patient portals. A patient portal is a mechanism whereby patients can communicate with health care providers via the electronic health record. Chen et al [10] used an LLM to draft responses to simulated patient messages (N=156) in a patient portal in a radiation oncology service at a tertiary care hospital. The LLMs' responses were compared to responses generated by human experts. The human responses were shorter (34 vs 169 words). The LLM drafts posed a risk of severe harm in 7.1% of responses and a risk of death in 0.6% of responses. These risks were generally due to underestimating or failing to convey the acuity of a clinical scenario.

An advanced form of LLM is known as a reasoning model. Reasoning models break a prompt into smaller tasks and incrementally derive a conclusion. Vladika et al [11] used a reasoning model to verify medical statements. For each statement, an LLM generated up to 5 new questions in response. These questions were then answered using the model's internal knowledge combined with a web search. Subsequently, another LLM integrated the responses to these questions and used this information to fact-check the original statement.

This study had 2 aims. The first was to evaluate the accuracy and efficiency of automated fact-checking by 2 LLMs. We compared the LLMs' responses to those of human experts who searched for evidence sources. The second aim was to illustrate a process through which a patient might interact with an LLM to craft a prompt with appropriate information to support patient safety. We chose to use the following LLMs: GPT-4o (OpenAI), a commonly used framework, and OpenBioLLM-70B, an open-source model that performs strongly on biomedical benchmarks [12].

Methods

Patient Involvement

To ensure realism and relevance for patients, we adopted a patient-centered research approach. Our patient coauthor experienced acne in her late 20s and was prescribed treatments. She was involved in developing the clinical scenario and the initial prompt that was the basis for the evaluation.

Ethical Considerations

No ethics approval was required for this work as it did not involve data obtained from human participants, in accordance with the policies of the Dartmouth Health Institutional Review Board.

Scenario

On the basis of our patient author's experience, we proposed a query from a hypothetical patient, equivalent to a "prompt" to be given to LLMs. A hypothetical patient aged 23 years is taking isotretinoin to treat her acne. She is concerned she might be pregnant but has not had a pregnancy test. She asks an LLM for advice. Her first prompt (Textbox 1) does not specify isotretinoin. This is the first step in the process in Figure 1. This scenario contributes to both aims of this study. The LLMs generate responses that can serve as material for fact-checking (aim 1), whereas the scenario also illustrates a realistic manner in which a patient might interact with LLMs (aim 2).

Textbox 1. Initial large language model prompt from a hypothetical patient requesting guidance on acne treatment in the context of possible pregnancy.

"I'm a 23-year-old woman. I think I might be pregnant. I'm pretty healthy, I just take acne capsules, otherwise I'm not on any medicines. What should I do?"

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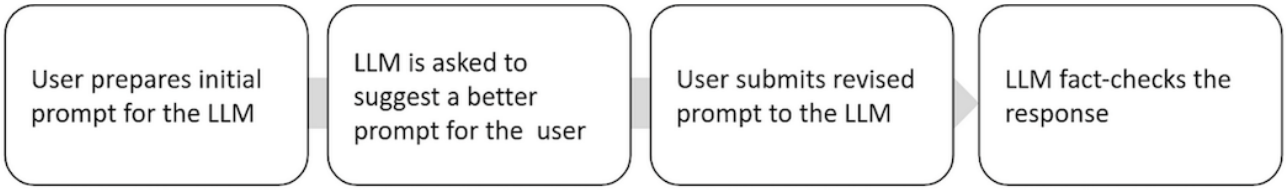
Figure 1. Prompt improvement and fact-checking process that can be undertaken by a patient using a large language model (LLM).



Automated Prompt Improvement and Fact-Checking Process

When patients craft a prompt for an LLM, they may fail to convey critical aspects of their condition or medical history, leading to suboptimal or even harmful responses from an LLM. To address this, we developed a redrafting prompt (Textbox 2) asking the LLMs to suggest ways to improve the patient's initial prompt, such as by including details of medication or symptoms. This is step 2 of the process shown in Figure 1. The LLM then suggests ways to refine the patient's initial prompt. The redrafting prompt can constrain the length of the LLM's response to avoid overwhelming the user, for example, "Please list the three most important items of information" to include. In our approach, we did not constrain the LLM. The LLM persona for the redrafting prompt ("You're a medical expert") was informed by a research study by Pal et al [13].

Textbox 2. Redrafting prompt: hypothetical patient requests guidance from a large language model to refine her original prompt regarding acne treatment in the context of possible pregnancy.

"You're a medical expert. Consider the statement below from a patient. Please state what additional information you would want from the patient in order to make a good decision."

As part of this process, a patient author (OD) reviewed the LLM responses. The patient author flagged the potential harm of drug treatment as concerning; hence, our hypothetical patient added the name of her acne treatment to her revised prompt but did not make any further changes (step 3 in Figure 1).

Two LLMs, GPT-4o and OpenBioLLM-70B, generated responses for each prompt. GPT-4o was accessed via the ChatGPT web portal. OpenBioLLM-70B was deployed on Google Colab using an NVIDIA A100 graphics processing unit. The automated prompt improvement and fact-checking process is summarized in Figure 1. The prompts and the exact responses were dated and stored so that we could apply and compare the 2 fact-checking methods. The prompts were sent to GPT-4o and OpenBioLLM-70B on September 16, 2024, and January 6, 2025, respectively.

LLM Fact-Checking

As part of this scenario, we imagined that the patient also wanted to fact-check the response to the revised prompt but was unsure about how to accomplish this task. We outlined a process through which the patient can prompt an LLM to conduct an automated fact-check of the previous response. This is compared against a manual method that we designed, which, although unlikely to be routinely used by patients or clinicians, provides a benchmark against which to compare GenAI fact-checking.

The LLM fact-check involves 2 separate prompts. The first prompt checks factuality, whereas the second prompt asks the LLM to identify inconsistencies and contradictions. These prompts are complementary. These 2 automated fact-checking prompts are shown in Textbox 3. The phrasing of the fact-checking prompt was informed by the research by Zhang et al [14].

Textbox 3. Prompts for fact-check and consistency check: hypothetical patient asks a large language model to check the factuality and consistency of its previous responses.

Fact-check

"You're a medical expert. Evaluate the truthfulness of the statement below. Consider your sources, context and date while assessing. To answer return 'Final Answer: {verdict}, {reason}.' You must respond with a valid verdict: ('false,' 'mostly-false,' 'half-true,' or 'true') or 'uncertain,' providing reasoning and citing sources by providing the domain of pertinent search results. Here is the statement to check:"

Consistency check

"You're a medical expert. Please identify any inconsistencies or contradictions in the following statement:"

"Gold-Standard" Comparator: Fact-Checking by Human Experts

The manual fact-checking process consisted of 6 steps. To remove potential bias, one judge (author PR) completed manual fact-checking before the LLM fact-checking. The other 2 judges did not have access to the LLMs' fact-checking responses. All 3 judges are pharmacists, and all conducted fact-checking independently. The fact-checking process steps were as follows:

- Step 1—identify information claims in the response. A claim is a discrete phrase containing relevant information. Each claim was tabulated (Multimedia Appendix 1). A sentence might contain multiple claims. For example, the response to the initial prompt referred to "blood tests, urine tests, and possibly an ultrasound." These 3 tests were classified as 3 separate claims.
- Step 2—determine the accuracy of each claim. This can be done in several ways; for example, a simple binary

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classification (true or false) can be used. We adapted the approach by Quelle and Bovet [15] and used 5 categories: true, mostly true, mostly false, false, and uncertain.
- Step 3—identify contradictory or inconsistent claims.
- Step 4—identify claims that may pose clinical risk. This may comprise ambiguous, misleading, or omitted information relevant to patient safety.
- Step 5—assess the quality of the evidence that supports the response claims. This involved online searches using Google and PubMed to check the veracity of each claim. Online information sources were considered eligible if the source was judged to be credible and evidence-based. This assessment was based on the experts' pharmacology training and interpretation of medical evidence using criteria such as sample size and study design [16].
- Step 6—assess comprehensiveness by reviewing cited sources and determining whether critical pieces of information were omitted.

Evaluating the Generalizability of LLM Fact-Checking

As part of aim 1, we evaluated the generalizability of LLMs' ability to fact-check health care claims. The 2 LLMs assessed the factuality of 20 clinical claims. Independently, the 3 expert reviewers assessed the same claims.

The 20 claims are shown in Multimedia Appendix 1. To achieve a balanced dataset, 10 claims were considered to be true by the human judges, and 10 were false. A blend of true and false claims enabled the calculation of a true positive rate and a true negative rate. For example, a true claim was "Mercaptopurine is indicated for maintenance of remission of Crohn's Disease." A false claim was "Trifluoperazine is safe in patients with phaeochromocytoma." The claims addressed a variety of topics: clinical indications, contraindications, treatment duration, side effects of treatment, and drug interactions.

We used the following prompt for the LLMs:

> *You're a medical expert. Please assess the strength of evidence for the health claim below. Consider your sources, context and date while assessing. To answer return "Final Answer: {verdict}, {reason}." You must respond with a valid verdict: ("True," "False"). Here is the claim to check:*

This prompt was administered to both LLMs for each of the 20 claims.

GenAI Research

A methodological checklist for GenAI research has been developed by Sallam et al [17]. This checklist can be found in Multimedia Appendix 2.

Results

The first task for the LLMs was to offer guidance to help redraft the user's initial prompt (second step of Figure 1). ChatGPT's guidance for redrafting (Multimedia Appendix 1) addressed 7 topics. Crucially, GPT-4o requested more specific details on the patient's acne medication in light of the potential harm during pregnancy. In general, GPT-4o adopted a patient-centered approach, requesting information on the user's support system and lifestyle factors. GPT-4o's response was extensive and could have led to a major revision of the prompt. However, the prime concern of the patient was the potential harm from acne medication, so she revised her prompt by naming the medication.

The revised prompt submitted to the LLMs was as follows:

> *I'm a 23-year-old woman. I think I might be pregnant. I'm pretty healthy, I just take isotretinoin for acne otherwise I'm not on any medicines. What should I do?*

In contrast, OpenBioLLM-70B's response to the redrafting prompt is shown in Multimedia Appendix 1. This response was shorter than the GPT-4o response (75 vs 279 words, respectively). OpenBioLLM-70B mentioned 6 topics, such as a missed period, home pregnancy test, and contraceptive use. However, OpenBioLLM-70B did not mention the risk of acne medication during pregnancy and did not ask the patient to provide more information on her medication. Hence, in this redrafting task, GPT-4o was superior to OpenBioLLM-70B in terms of patient safety.

After the prompt redrafting step, the revised prompt was submitted to the 2 LLMs. The LLMs both generated a response to the revised prompt. The LLMs were then prompted to fact-check the GPT-4o response as this contained more detail on the safe use of acne medication.

Table 1 shows the results of comparing human expert and automated fact-checking. The complete assessment is provided in Table S1 in Multimedia Appendix 1. The experts followed the manual fact-checking process and identified 16 claims to verify. Of the 16 claims, the experts deemed 13 (81.3%) to be true, and 3 (18.8%) were classified as mostly true. This manual process (including the search for sources and specifying citations in the table of claims) took 18 minutes (full results are shown in Multimedia Appendix 1).

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Table . Results of fact-checking by GPT-4o, OpenBioLLM-70B, and human experts for isotretinoin treatment of acne in the context of possible pregnancy.

	Human experts[a]	GPT-4o	OpenBioLLM-70B
Number of claims identified	16	13	13
Number of true claims	13	13	13
Number of mostly true claims	3	0	0
Number of false claims	0	0	0
Number of uncertain claims	0	0	0
Time taken to review (mean and SD shown for the 3 expert reviewers)	18 (3.74) min	42 s	33 min, 21 s

[a]The following information sources were used as references in the manual search by the human experts: the National Health Service, the Centers for Disease Control and Prevention, the Health Service Executive, the National Institutes of Health, the Mayo Clinic, *PLOS One*, the National Organization for Rare Disorders, the American Pregnancy Association, and the American College of Obstetricians and Gynecologists.

By comparison, GPT-4o identified 13 claims to verify and deemed all these claims to be true. This process took 42 seconds. The experts disagreed with the LLM classification of the claim about the use of folic acid because the response understated the importance of taking folic acid during pregnancy. Disagreement about the discontinuation of isotretinoin occurred for this response. The experts believed that isotretinoin treatment should be paused immediately without waiting for the results of a pregnancy test or a clinical visit given the risk involved. The response from the LLM was inconsistent; a section early in the response recommended stopping isotretinoin after a positive pregnancy test, whereas the conclusion recommended immediate cessation of isotretinoin. This inconsistency was not detected by the consistency check (Textbox 3).

Multimedia Appendix 1 shows ChatGPT's response to the fact-check for consistency. The LLM suggested 4 improvements: the use of more sensitive pregnancy tests, safer treatments for acne, mental health support, and follow-up monitoring for maternal and fetal health. In contrast, the experts focused primarily on the urgency of discontinuing isotretinoin treatment and seeking advice from a clinician who could devise a comprehensive care plan in cooperation with the patient.

As part of aim 1, our study also tested the generalizability of LLMs' fact-checking capability. The 20 medical statements under scrutiny are shown in Table S2 in Multimedia Appendix 1. GPT-4o had 100% agreement with human experts (Table S3 in Multimedia Appendix 1), whereas OpenBioLLM-70B had 95% agreement (Table S4 in Multimedia Appendix 1). For example, both LLMs found the following statement to be true:

> *Combined hormonal contraceptives should not be used in patients with acute porphyrias or gallstones.*

Both LLMs correctly deemed the following statement to be false:

> *Sumatriptan is used to treat dizziness and drowsiness.*

One question related to chlorphenamine, an antihistamine drug. In its response, OpenBioLLM-70B incorrectly stated the following:

> *False, The evidence does not support the claim that chlorphenamine can relieve the symptoms of allergy in children as young as 1 month.*

In contrast, GPT-4o and the 3 human experts asserted that there was evidence to support the use of chlorphenamine in this age group. GPT-4o mentioned the following:

> *According to reputable sources, including the British National Formulary for Children (BNFc), chlorphenamine can be used in infants as young as 1 month old, albeit with adjusted dosing and under medical supervision. Its use in this age group is typically reserved for specific indications due to concerns about sedation and anticholinergic side effects. Still, the evidence supports its effectiveness and safety when properly dosed and monitored.*

The complete LLM responses to fact-checking of these 20 medical statements can be found in Tables S3 and S4 in Multimedia Appendix 1.

Discussion

Principal Findings

This scenario-based study demonstrates that an LLM can become a valuable source of evidence-based information by being prompted to undertake self-checking processes. The responses were checked by 3 experts and found to be fact-based; there was no fabrication or essential omissions. However, the LLMs did not consistently recommend immediately stopping isotretinoin or sufficiently guide the patient to take folic acid. A clinician could have corrected these errors, but a patient could have been misled.

By using methods in which LLMs are asked to revise the quality of prompts and undertake fact-checking for truthfulness and consistency, we showed that LLM responses could be improved to the point where the results showed an 86% agreement with those of experts undertaking verification. There are efficiency implications as the GPT-4o process was 24 times faster than the check conducted by the experts. Such capability and speed are superior by far to those of a nonexpert. The use of OpenBioLLM-70B was slower than that of the human experts, but the use of infrastructure on Google Colab was not optimized for quick model serving. OpenBioLLM-70B deployment could, in principle, be accelerated to match the latency of GPT-4o.

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Results in the Context of Similar Studies

Our study aligns with recent evidence that LLMs can play a helpful role in fact-checking in various domains [18]. LLMs are more accurate on health-related questions when scientific consensus exists but are less able to respond when the evidence is controversial, ambiguous, or recently published [19]. Kusunose et al [20] found that GPT-3.5 achieved 80% accuracy for questions about hypertension guidelines, but the accuracy dropped to 36% when the evidence was weaker. LLMs can support shared decision-making by highlighting for clinicians the questions that patients are most likely to ask and providing written information in accessible ways to patients [21]. Standardized datasets have been developed to measure the factuality of LLMs in domains such as health care [22]. However, expert-crafted questions may differ significantly from patients' questions in terms of clarity and inclusion of relevant information. Thus, it is important to involve patients in this process of LLM validation.

Unanswered Questions and Future Research

Despite our results, we do not recommend using LLMs in routine clinical practice without clinician verification. However, as patients will inevitably use LLMs and find flawed information that will be misinterpreted [23], clinicians must find methods to adapt to LLMs. Future research needs to further evaluate the capability of LLMs to self-improve and self-check comparing the responses to realistic benchmarks. As LLMs are based on stochastic algorithms, future research can investigate mechanisms to integrate LLMs with rule-based logic systems to mitigate inaccuracy and improve fact-checking. Bangerter et al [24] found that a hybrid approach to fact-checking combining LLMs and fuzzy logic increased reliability, but this was not applied to health care claims.

Further research is also needed on the use of LLM agents. Agents can engage in back-and-forth with patients to ensure an appropriate level of detail for evidence-based decision-making. Agents can then craft an optimal prompt and deliver this to a subject matter expert LLM. Research is also needed into optimal methods of keeping LLMs up-to-date with new evidence. This could be a blend of fine-tuning some parameters of the LLM and giving the LLM access to new documents in a technique known as retrieval-augmented generation. Another fruitful area for research is likely to be multimodal artificial intelligence models, for example, integrating medical imaging, data tables (eg, trends of blood pressure and cholesterol measurements), and natural language input.

A multidisciplinary approach is needed to ensure the safe use of LLMs. Haltaufderheide and Ranisch [25] argue that the degree of acceptable human oversight for LLMs in health care varies depending on the potential for harm. Han et al [26] found that subtle modification of approximately 1% of an LLM's parameters can cause it to learn incorrect biomedical facts. There is a risk of malicious actors exploiting this vulnerability.

Strengths and Weaknesses of This Method

A strength of this study was the use of an actual clinical question: a concerning situation for many who have acne and are sexually active. The clinical scenario was co-designed with our patient coauthor, who also guided the development of our methods and interpretations of the responses. All prompts and LLM responses were dated and archived to ensure transparency and reproducibility. We demonstrated how to increase the ability of LLMs to rapidly deliver high-quality information by prompting GenAI systems to self-improve and self-evaluate. This mimics a process whereby a clinician asks a patient to provide additional information. Given the inevitable use of LLMs as a source of health care information, these prompt revision and fact-checking methods are relevant to a wide audience. We used a panel of 3 judges to bolster the validity of the evaluation. We tested the generalizability of fact-checking by using 20 claims on disparate health care topics (Multimedia Appendix 1).

Our study has a number of limitations. Only 1 detailed clinical scenario was developed related to acne management. Many other clinical scenarios should be evaluated to improve our understanding of the capabilities of LLMs. Our study used 2 LLMs for fact-checking, but new LLMs are being developed that may improve the accuracy of fact-checking. There may be scope to improve performance by using a specialized LLM for fact-checking and another LLM to respond directly to patients' prompts. A rigorous comparison of prompt engineering techniques for fact-checking was not conducted in our study. Furthermore, although our patient author (OD) improved the realism of our scenario, there may have been some Hawthorne effect, whereby behavior changes when a person knows they are under observation. Patients may interact differently with LLMs in a natural setting. Finally, fact-checking, even by experts, is imperfect. Clinical guidelines and high-quality scientific literature reviews often have inconsistencies, and interpretations of evidence may differ [27,28]. This was mitigated by the use of 3 human experts for fact-checking, but there is still potential for inaccuracy.

Broader Implications

Scientific processes rely on self-correction, such as peer review, which, although fallible, over time serves to separate fact from fiction. Given that patients will turn to LLMs, regulators could set accuracy thresholds for GenAI [29]. It may be feasible to build in prompt improvement and fact-checking when health care questions are submitted and withhold responses if questions are unclear [30] or if there is insufficient scientific consensus.

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No funding was received for this study.

Data Availability

All data generated or analyzed during this study are included in this published article (and its supplementary information files). Python code is available from the corresponding author on reasonable request.

Authors' Contributions

PR and GE conceptualized the study, conducted the analysis, and wrote the manuscript. OD was involved in developing the clinical scenario and prompts, editing the manuscript, and agreeing on the final version.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Prompts and large language model responses.
[DOC File, 1489 KB - formative_v10i1e68223_app1.doc]

Multimedia Appendix 2
Methodological checklist.
[DOC File, 35 KB - formative_v10i1e68223_app2.doc]

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Abbreviations:

GenAI: generative artificial intelligence
LLM: large language model

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Development of iGET Living, a Digital Graded Exposure Intervention for Youth With Chronic Pain: Multiphase User-Centered Design and Pilot Study

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Abstract

Background: Pediatric chronic pain affects up to one-third of youth and is associated with significant disruptions in social, emotional, and behavioral functioning. Although behavioral treatments are effective, access remains limited due to geographic, financial, and systemic barriers. Digital behavioral health interventions offer a promising solution, but many lack user-centered design, iterative refinement, and implementation-informed development strategies that support usability and scalability.

Objective: This study aimed to develop and iteratively refine iGET Living, a digital graded exposure intervention for youth with chronic pain, using a combined user-centered and implementation-informed framework, and to evaluate its preliminary acceptability, feasibility, and user-perceived success.

Methods: Guided by the Consolidated Framework for Implementation Research (CFIR) and the mHealth (mobile health) Agile Development and Lifecycle model, intervention development proceeded through 3 phases. Phase 0 translated an evidence-based in-person graded exposure treatment (GET Living) into an initial digital prototype. Phase 1 involved iterative user-centered refinement across 3 cycles of qualitative development sessions with youth with chronic pain (n=15), incorporating think-aloud usability testing, Likert-rated feedback, and rapid qualitative analysis mapped to CFIR constructs to guide real-time modifications to content, design, and functionality. Phase 2 piloted the refined intervention with a new sample of youth (n=38, n=30 completers) recruited from a tertiary pediatric pain clinic to evaluate feasibility, acceptability, treatment credibility and expectancy, and user-perceived functional improvements. Quantitative outcomes were summarized descriptively, and qualitative exit interview data were analyzed using rapid qualitative analysis.

Results: Across development cycles, youth feedback informed substantive refinements to the intervention, including reducing text density, incorporating animated educational videos, enhancing interactive features, and improving navigation and layout. These changes resulted in progressive improvements in clarity, satisfaction, and acceptability across prototypes. In the Phase 2 pilot study, participants reported moderate-to-high treatment credibility (mean of 19.71 out of 30) and expectancy (mean of 17.96 out of 30), as well as high satisfaction (mean of 46.12 out of 60). Acceptability ratings across domains of the Theoretical Framework of Acceptability were favorable. Qualitative exit interviews highlighted the interventions' perceived role in helping youth re-engage in valued activities.

Conclusions: Using a combined CFIR and agile development approach, iGET Living emerged as a feasible, acceptable, engaging digital graded exposure intervention for youth with chronic pain. These findings highlight the value of integrating implementation frameworks and participatory design early in digital intervention development and support further evaluation in a preliminary efficacy trial.

Trial Registration: ClinicalTrials.gov NCT05079984; https://clinicaltrials.gov/study/NCT05079984

International Registered Report Identifier (IRRID): RR2-10.1136/bmjopen-2022-065997

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KEYWORDS

Pediatric pain; exposure treatment; digital intervention; implementation; user-centered design

Introduction

Pediatric chronic pain is a significant health problem, affecting 20% - 35% of children and adolescents worldwide [1-3], with many experiencing significant disruptions to multiple domains of functioning (eg, social, emotional, and behavioral) [4-6]. Despite robust evidence for behavioral health interventions targeting youth with chronic pain [7], access-to-care barriers (eg, shortage of services outside of urban areas, high treatment-related costs, long provider waitlists) significantly limit accessibility [8,9]. Digital behavioral health interventions offer solutions to these barriers, with existing research supporting their effectiveness, scalability, and capacity to increase access to evidence-based treatment [10-14]. Notably, however, despite great potential and the proliferation of research [13,15-24], only 28% of internet or smartphone app tools are disseminated adequately or in a timely manner, often due to limited sustainability planning, lack of user-centered refinement, and technical constraints [25].

Recent meta-analyses and scoping reviews underscore the growing evidence base and ongoing challenges in developing, evaluating, and implementing sustainable digital interventions for chronic pain [26-28]. Digital interventions developed within academia are often theoretically rigorous but may lack user-centered design features, agile iteration, and technical robustness, limiting uptake and sustainability [10,29]. Another challenge is the limited application of product design and software development principles to digital health research [30]. For example, academic digital interventions often rely on static, text-heavy content, limited interactivity, and minimal iterative usability testing, reflecting constraints in technical expertise, funding, and access to dedicated development teams [10,29].

To bridge the gap between intervention development and sustainable clinical use, recent studies emphasize the need for frameworks that integrate implementation science with user-centered digital development [27,31,32]. The Consolidated Framework for Implementation Research (CFIR) [33] provides a structured approach for identifying multilevel determinants that influence the adoption, implementation, and maintenance of interventions. In parallel, the mHealth (mobile health) Agile Development and Lifecycle model [34] emphasizes iterative, user-centered design, rapid prototyping, and mixed method evaluation. Although independent frameworks, they are complementary: CFIR highlights determinants of implementation (ie, intervention characteristics, outer setting, inner setting, individual characteristics, and implementation processes) that guide intervention development and identification of barriers and facilitators to adoption [27,31,32], while the mHealth Agile model provides practical strategies for digital intervention design and refinement [34]. In this study, CFIR was used to guide the identification and organization of implementation-relevant determinants, including intervention characteristics and end user perceptions that informed design decisions, whereas the mHealth Agile Development and Lifecycle model structured the timing and process of iterative development, testing, and refinement across phases. Together, they offer a comprehensive approach for developing interventions that are evidence-based and implementation-ready.

Despite the growing interest in digital behavioral interventions for chronic pain, relatively few studies have described structured, implementation-informed approaches to intervention development. The objective of this study was to develop and iteratively refine iGET Living, a digital graded exposure intervention for youth with chronic pain, using a combined user-centered and implementation-informed framework, and to evaluate its preliminary feasibility, acceptability, and user-perceived success [35]. The development included 3 phases (Figure 1): project identification and initial prototype development (phase 0), iterative user-centered refinement of the prototype (phase 1), and pilot testing of iGET Living (phase 2). We hypothesized that iterative refinement across phases would result in progressive improvements in clarity, satisfaction, and acceptance of iGET Living, leading to a finalized version of the intervention that was suitable for evaluation in a preliminary efficacy trial.

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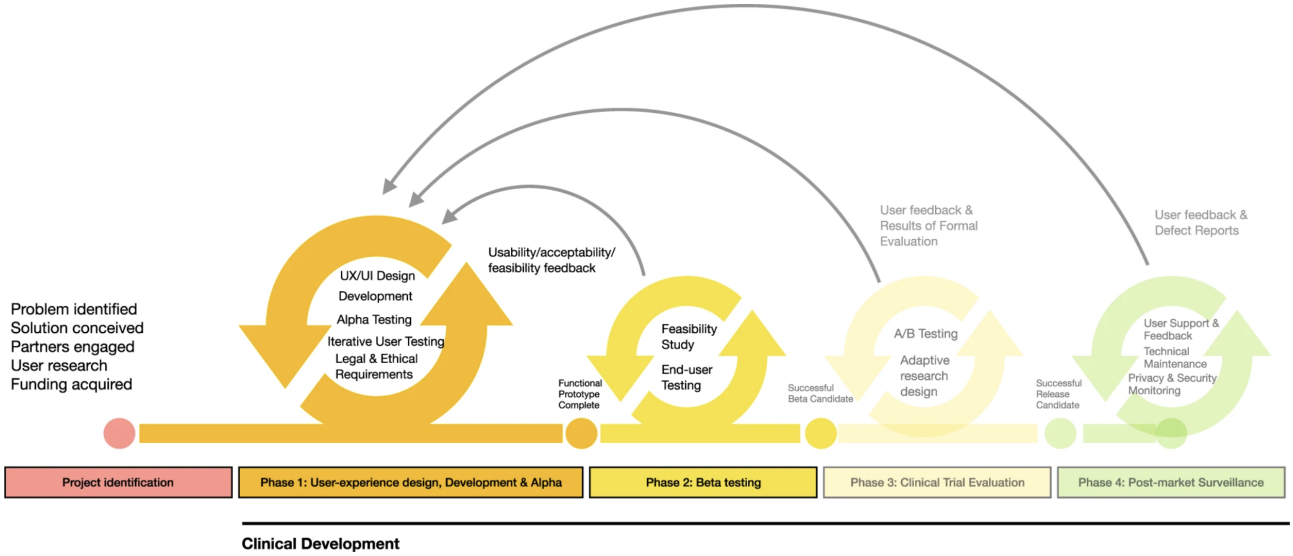
Figure 1. The mHealth (mobile health) agile development and lifecycle model. Reproduced from Harrison et al [35], published under CC BY-NC 4.0.



Methods

Study Design

This study is part of a larger, multi-phase project focused on the development, refinement, and pilot testing of iGET Living (NCT05079984). The overall project was guided by 2 complementary frameworks: the mHealth Agile Development and Lifecycle model, which emphasizes rapid, iterative development grounded in user feedback, and the CFIR [33], which provides a structured approach to identify key determinants of successful implementation. The development of iGET Living was reported in alignment with the Guidance for the Reporting of Intervention Development (GUIDED) checklist [36] and the Template for Intervention Description and Replication checklist [37] (Checklist 1).

Ethical Considerations

All procedures were approved by the Institutional Review Board at Stanford University (Protocol #53323). Informed consent and assent were obtained through a secure, web-based application (REDCap [Research Electronic Data Capture]). All data were collected via REDCap, deidentified, and stored on a secure, cloud-based server. Youth participants in phase 1 received a US $30 Amazon gift code for up to 3 hours of qualitative data collection (user feedback interviews). Youth participants in phase 2 received US $30 gift codes at baseline, discharge, and US $50 gift codes at 3-month follow-up.

Phase 0: Project Identification and Prototype Development

Phase 0 on translating the core principles of the in-person intervention into a digital prototype. Guided by the principles of agile development, this phase included envisioning a digital solution to overcome access barriers in pediatric pain care, identifying end users, and assembling the multidisciplinary expertise and infrastructure required for digital intervention development. Strategic and operational goals were outlined, and funding was secured to support an iterative design and testing. A microlearning approach was applied to restructure the in-person intervention content into a brief, scalable, digital format. Core components from graded exposure treatment (GET) Living were translated from paper-based worksheets and session activities into digital modules. Content was reorganized for short daily use and supplemented with animated videos and interactive exercises to support engagement in a digital format of the intervention.

Phase 1: User-Centered Refinement of the iGET Living Prototype

Overview

Phase 1 focused on iterative, user-centered refinement of iGET Living. Across 3 cycles of user testing sessions, quantitative and qualitative data on treatment content, clarity, acceptability, layout, and overall engagement were collected. Each cycle informed real-time refinement of modules, navigation structure, and visual presentation.

Participants

Participants were recruited from the Pediatric Pain Management Clinic at Stanford Medicine, Children's Health. To be eligible, youth (1) were between ages 10 and 18 years old, (2) had a diagnosis of chronic (>3 mo) pain, (3) were English literate, and (4) had access to a computer, smartphone, or tablet with internet connection. Review of the literature and previously conducted usability testing studies indicates that prototype refinement is typically achieved within 2 - 3 cycles of testing, with ≈5 participants in each cycle [38,39]. Given this, we aimed to enroll 5 youth per interview cycle, with a total of 3 cycles, resulting in a final sample of 15 youth.

Procedures

Eligible participants were provided a link to a secure web-based screening form via REDCap, where they left contact information and expressed interest in participation. A research assistant (RA) followed up with a phone call to confirm eligibility, and once confirmed, the RA scheduled a user development session. Consent, assent, and demographic information were obtained via REDCap prior to the user development session. User development sessions were 2 hours long and conducted via Zoom by an RA. During the development session, participants

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were given access to the digital prototype and were able to view content and pilot features. The development sessions also followed a semistructured interview guide containing Likert-rated and open-ended questions guided by the CFIR Intervention Characteristics domain [33]. Participants were also encouraged to think aloud about likes, dislikes, and difficulties with understanding the content or navigating the prototype. All user development sessions were audio-recorded and stored on a secure cloud-based platform. Data were collected following engagement with each module, as well as at the conclusion of viewing all the content in the prototype. Modules were refined based on quantitative ratings and qualitative data during a series of 3 iterative cycles.

Data Analysis

Sample characteristics were examined using descriptive statistics. To facilitate intervention refinement, qualitative data from user development sessions were analyzed using rapid qualitative analysis [40]. Rapid qualitative analysis is a pragmatic and efficient approach to analyzing qualitative data, designed to deliver timely and actionable results. It is often used in intervention development, implementation science, or health services research and prioritizes speed and utility over deep thematic saturation, while maintaining rigor [40-43]. Interview notes were taken from electronic recordings and organized into templated matrices, codes, and subcodes that correspond to the study's conceptual framework [42,43].

In Phase 1, notes from user development sessions were added to Excel matrices that included codes and subcodes guided by the intervention characteristics domain of the CFIR: relative advantage, adaptability, complexity, and design. This structured approach allowed the research team to efficiently synthesize user perspectives, identify patterns across participants, and implement timely revisions to the intervention content between development cycles. Three researchers independently conducted the qualitative analyses (LEH, SW, and DM).

Phase 2: Pilot Testing the Prototype

The objective of phase 2 was to pilot the prototype of iGET Living to further evaluate acceptability and feasibility.

Participants

An independent sample of participants (ie, did not participate in phase 1) was recruited from the Pediatric Pain Management Clinic at Stanford Medicine, Children's Health. To be eligible for Phase 2, youth (1) were between ages 10 and 18 years old, (2) had a diagnosis of chronic (>3 mo) pain, and (3) reported at least moderate pain-related disability (Functional Disability Inventory >13) [44]. Eligibility criteria also required English literacy and access to a computer, smartphone, or tablet with an internet connection. Exclusion criteria included significant cognitive impairment or co-occurring medical or psychiatric conditions that could interfere with participation (eg, psychosis active suicidality).

Procedures

Eligible participants were provided a link to a secure web-based screening form via REDCap, where they left contact information, completed the Functional Disability Inventory to screen for baseline pain-related disability, and the Patient Health Questionnaire-9, after which a RA followed up with a phone call to confirm eligibility. Eligible participants who selected a 1 or above (ie, several days to nearly every day) on the suicidal ideation question on the Patient Health Questionnaire-9 ("Thoughts that you would be better off dead, or of hurting yourself in some way") underwent an additional safety assessment screening call with a qualified provider. Once eligibility was confirmed, enrollment procedures were identical to Phase 1. At baseline, youth completed self-report measures assessing demographic characteristics, pain history, pain intensity, pain-related disability, pain-related fear and avoidance, emotional functioning, and quality of life. Following this, the youth were given access to the password-protected platform where the intervention was hosted. All participants were assigned a deidentified username (eg, iGL_1) that they used to sign into the intervention platform. Participants were encouraged to engage with the intervention daily. Given the number of daily modules developed (see Results below), it was estimated that iGET Living would take ≈6 weeks to complete. After the first week of the intervention, youth completed a measure assessing treatment expectancy and credibility. After completing the treatment, the youth completed measures assessing treatment acceptability and satisfaction. Participants also participated in a semistructured exit interview. The self-report assessment battery completed at baseline was repeated at discharge and 3-month follow-up. Assessment of clinical outcomes across timepoints (ie, baseline, discharge, and 3-month follow-up) will be reported separately in a subsequent outcomes-focused manuscript.

Measures

Demographic Information and Pain History

Youth reported on demographic variables such as age, gender, race, and current grade in school. Youth also reported on the onset and duration of current pain. Average pain severity was assessed using a numerical rating scale [45], ranging from 0 (no pain) to 10 (worst possible pain).

Treatment Expectancy and Credibility

To assess expectations for treatment effectiveness, participants completed the Credibility/Expectancy Questionnaire (CEQ) [46] after engaging with iGET Living for one week. The CEQ consists of 6 items rated on a 0 (not at all) to 10 (very much) Likert scale and assesses expectations related to the effects of the intervention across 2 subscales: Credibility (eg, "How confident would you be recommending iGET living to a friend with the same problems?") and expectancy (eg, "By the end of iGET Living, how much do you think your functioning will improve?"). Credibility is calculated by summing items 1 - 3, and expectancy by summing items 4 - 6. The possible range of scores for each subscale is 0 - 30, with higher scores reflecting greater perceived credibility and expectancy.

Treatment Satisfaction

Satisfaction with iGET Living was evaluated using the Pain Service Satisfaction Test (PSST) [47]. The PSST is a 20-item measure that assesses participants' satisfaction with the treatment received and is completed postintervention (eg, "I am

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satisfied with the treatment I received"). Items are rated on a 3-item scale (0 - 3). The PSST yields a total score ranging from 0 to 60, with scores greater than 40 indicating high satisfaction with the treatment. Items on the original PSST were modified slightly to fit with the current intervention.

Treatment Acceptability

The Theoretical Framework of Acceptability [48] questionnaire is an 8-item measure that assesses acceptability of an intervention across the following domains: Attitude toward the intervention ("Did you like the intervention?"), Burden ("How much effort did it take to engage with the intervention?"), Ethicality ("How fair were the demands/requirements of the intervention?"), Perceived Effectiveness ("How much do you feel like the intervention has improved your functioning?"), Intervention Coherence ("It is clear to me how the intervention will help me cope with my pain."), Self-Efficacy ("How confident did you feel about engaging in the intervention?"), Opportunity Costs ("The intervention interfered with my other priorities."), and General Acceptability ("How acceptable was the intervention to you?"). Items are rated on a 5-point Likert scale ranging from 0 (strongly disagree) to 4 (strongly agree). Scores for each domain are calculated separately. A total score can also be obtained by summing all the items. Higher scores indicated greater acceptability.

Semistructured Exit Interview

After completing the intervention, a semistructured interview guide containing Likert-rated and open-ended questions was conducted with each participant by a member of the research team to assess user experiences of engaging with the intervention and overall experience of the treatment (eg, barriers to daily engagement, likelihood of recommending iGET Living to a friend).

Data Analysis

All quantitative data were analyzed using descriptive statistics in SPSS version 26 [49]. In Phase 2, analyses were guided by the Reflecting and Evaluating construct within the Implementation Process domain of the CFIR [33], which captures end users' perception of an intervention's acceptability, feasibility, and perceived effectiveness. Qualitative data were analyzed using rapid qualitative analysis [40,41] and organized into matrices, coded deductively according to the CFIR construct.

Results

Phase 0: Prototype Development

The prototype v1.0 of iGET Living was built on the BASS4 platform (Karolinska Institutet eHealth Core Facility). BASS4 is a secure, research-hosted web platform that supports basic interactive features through HTML coding and has been widely used in digital behavioral health intervention research [50-52]. iGET Living v1.0 was organized into 4 primary content domains: Education, Values Clarification and Goal Setting, Activity Exposure, and Planning for Long-term Success. Each domain contained short daily modules (30 modules in total across the 4 domains) that included information and exercises designed for brief (5 - 15 min) engagement. This Phase 0 work established a functional prototype of iGET Living, laying the foundation for user-centered refinement in subsequent development cycles.

Phase 1: User-Centered Refinement of the Prototype

Participants

A total of 15 youth were enrolled, with 5 in each iterative cycle, resulting in 3 total cohorts across the 3 iterative cycles. Youth were 15.6 years old on average (range 10 - 18 years), with 73.3% assigned female at birth. All youth reported experiencing pain for 3+ years. The average pain rating for the sample was 5.8 (out of 10). Table 1 depicts participant demographic information across cycles. As outlined in Table 2, Phase 1 focused on iterative user-centered refinement through multiple cycles of end user feedback and real-time design iteration.

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Table . Characteristics of the sample for phase 1.

	Cycle 1 (n=5)	Cycle 2 (n=5)	Cycle 3 (n=5)
Age (years)			
Mean (SD)	15.6 (2.2)	16.2 (2.5)	15.0 (3.5)
Range	12 - 18	12 - 18	10 - 18
Gender identity, n (%)			
Cisgender female	5 (100)	4 (80)	3 (60)
Cisgender male	—[a]	1	1 (20)
Nonbinary	—	—	1 (20)
Race/ethnicity, n (%)			
Asian/Pacific Islander	1 (20)	1 (20)	—
Hispanic/Latino	1 (20)	1 (20)	—
White	2 (40)	3 (60)	2 (40)
Multiracial	—	—	2 (40)
Unknown	1 (20)	—	1 (20)
Pain diagnosis, n (%)			
MSK[b]	3 (60)	2 (40)	1 (20)
EDS[c]	—	1 (20)	2 (40)
CRPS[d]	1 (20)	1 (20)	1 (20)
Headache	1 (20)	1 (20)	—
Central sensitization	—	—	1 (20)
Average pain	4.8	6.2	6.5
Average pain duration (year)	3.6	3.8	3.8

[a]Not applicable.

[b]MSK: musculoskeletal.

[c]EDS: Ehlers-Danlos Syndrome.

[d]CRPS: Complex Regional Pain Syndrome.

Table . Replicable steps in the user-centered, implementation-informed development of iGET Living.

Phase	Key activities	Data collected	Resulting design decisions
Phase 0	Translate in-person GET[a] Living into digital prototype	Team consensus; user feedback	Microlearning modules; initial platform
Phase 1 (Cycle 1 - 3)	User interviews; think-aloud testing	CFIR-mapped[b] qualitative responses; Likert ratings	Content simplification; Development of animated videos
Phase 1	Wireframing; platform evaluation	User feedback; Design and development constraints	Migration to Squarespace
Phase 2	Pilot testing	CEQ[c], PSST[d], TFA[e], exit interviews	Final prototype readiness

[a]GET: graded exposure treatment.

[b]CFIR: Consolidated Framework for Implementation Research.

[c]CEQ: Credibility/Expectancy Questionnaire [50].

[d]PSST: Pain Service Satisfaction Test [51].

[e]TFA: Theoretical Framework of Acceptability [52].

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Cross-Cycle Iterative Refinements to Intervention Structure and Content

A summary of end user responses for the Intervention Content domain of the CFIR, along with the resulting action and iteration, is presented in Table 3. Detailed results for each iterative cycle (3 cycles in total) are described below.

Table . Summary of end user responses and iterations made across cycles mapped onto constructs in the consolidated framework for implementation research (CFIR) intervention domain.

CFIR construct	End user insight	Resulting actions and iterations
Relative advantage	• Flexibility in engagement (eg, daily vs every few d) • Asynchronous engagement with therapist	• Extended treatment length from 6 weeks to 10 weeks • Structured weekly emails from therapist
Adaptability		
Platform and Technology Infrastructure	• Like the flexibility of using computer or phone	• Explicitly acknowledge variability in pacing, encouraged alternative goal setting when necessary, emphasized process over outcome
Tone, Representation, and Inclusivity	• Appreciated attempts to include diverse perspectives and use of gender-neutral language • Emphasized the importance of acknowledging that not all youth can get back to certain activities in the same way	
Complexity	• Initial prototype described as “dense” and like a “textbook” • Some modules were described as too text heavy while others were described as clear and concise • Requested more examples to explain key concepts • Content on connection between pain and mood lacking	• Reduced text • Streamlined content in modules which resulted in creation of new modules (eg, the module ”Chronic Pain and the Pain Dilemma” became 2 modules: “What is Chronic Pain?” and “The Pain Dilemma” • Partnered with Kindea Labs to create animated videos of key concepts • Swapped text for figures and images when appropriate
Design		
Visual Layout and Engagement	• Youth consistently requested more color, dynamic visuals, and fewer static “text heavy” pages • Wanted to be able to visually see their progress through each module and the intervention	• Integration of interactive components (eg, being able to type in a text box within a theoretical figure) • Added progress bar • Integrated color and image to earlier versions when possible
Interactivity and Functionality	• Several youth were frustrated when static elements (eg, images) were not clickable • Many limitations noted regarding design flexibility, mobile responsiveness, and back-end editing. • Many wanted “drag and drop” features and to “see things move” on the web page	• Made images clickable where appropriate • Content put into “banner” style on webpage (vs list format, for example) • Integration of interactive sliders and click-to-enter response boxes • Migrated intervention to Squarespace • Updated color scheme • Inclusion of images

Relative Advantage of the Treatment

Overall, youth described the digital delivery of iGET Living as flexible, allowing them to complete sessions at convenient times and frequencies. Youth liked the microsession format, noting it would be easier to “do a quick session here and there” as opposed to going into a doctor’s office, and appreciated that the intervention was mostly self-guided. Youth also reported that daily engagement with iGET Living was feasible. Barriers to daily engagement included physical symptoms (eg, pain, fatigue, dizziness), logistical challenges (eg, other doctors’ appointments, homework), and emotional readiness and motivation to engage.

Adaptability of the Treatment

Most participants noted that they would prefer to do iGET Living on a computer, not a smartphone, because the content would be easier to view on a larger screen, and it would be easier to type in module responses on a computer. However, youth expressed the desire for an app-based intervention that would be more accessible on a smartphone (“If it were designed differently, like an app, I would definitely use my phone.”),

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noting that being able to access the intervention on a smartphone increased flexibility with when and where they would engage in the intervention. Several youth noted no preference (eg, "probably both [computer and smartphone] depending on the day."

Complexity of the Treatment

Despite rating the modules' favorability overall (Table 4), youth consistently described v1.0 of iGET Living as "textbook-like," "too boring," and "not something I would want to come back to." Figure 2 shows content from several modules that included a voice-over video made in PowerPoint and examples of images of worksheets used. Youth reported several issues with the use of static images, with one youth sharing, "I want to be able to do something with the content, not just read it."

Significant effort was made to simplify and reduce the text, which resulted in developing animated videos of core treatment concepts. Figure 3 shows the evolution of the Pain Dilemma animation from voice-over PowerPoint to VideoScribe to the final version, which was created in partnership with Kindea Labs. Overall, youth rated the videos very favorably (mean 3.6/4) and reported that the videos were "clear," "easy to follow," and "explained things pretty well." Versions 1.0 and 2.0 of the prototype contained a module titled "Chronic Pain and the Pain Dilemma," which introduced the distinction between acute and chronic pain and included an exercise based on the concept of creative hopelessness derived from acceptance and commitment therapy [53]. This element was designed to enhance youth readiness to engage with exposure-based activities by reflecting on the limits of avoidance and the potential benefits of values-driven action. In response to end user feedback, this module was divided into 2 shorter modules—What is Chronic Pain and The Pain Dilemma. The What is Chronic Pain module was also expanded to include additional psychoeducation on pain mechanisms (eg, how pain is processed in the brain, metaphors for understanding chronic pain), which had been missing from the initial prototype. The third and final cycle of user-centered interviews reflected that the content was clear and satisfactory (Table 4), as reflected in youth feedback: "The layout is easy to follow," "Things are explained in an easy-to-understand way, and nothing is too wordy."

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Table . Likert ratings of treatment content across development cycles. The following prompts were used to assess acceptability of content and design: "Were there features or content that was difficult to learn or understand?" (Difficulty); "Was it clear what you were supposed to do in this module?" (Clarity); and "How satisfied are you with the visual layout?" (Satisfaction). Items were rated on a 5-point Likert scale (0=not at all to 4=very much). Difficulty scores were reverse-scored in this table so that higher scores in each domain indicate a more favorable rating.

Key concepts	Cycle 1 (n=5)			Cycle 2 (n=5)			Cycle 3 (n=5)		
	Difficulty	Clarity	Satisfaction	Difficulty	Clarity	Satisfaction	Difficulty	Clarity	Satisfaction
Education modules									
Chronic pain and the pain dilemma	3.6	3.2	3.2	3.8	4.0	3.6	—[a]	—	—
What is chronic pain?	—	—	—	—	—	—	3.2	4.0	3.8
The pain dilemma	—	—	—	—	—	—	4.0	4.0	3.5
Pain avoidance	2.5	3.6	3.8	4.0	3.8	3.6	3.8	4.0	3.8
Pain, stress, mood	—	—	—	—	—	—	3.5	3.5	3.2
Values and goals	3.7	4.0	3.6	3.0	3.8	3.0	3.7	4.0	4.0
What is exposure?	3.2	4.0	3.8	4.0	2.6	3.4	4.0	3.7	3.7
WILD scale	3.2	3.5	3.2	3.2	2.8	3.2	3.8	3.8	3.8
Experiential exercises									
Building the exposure hierarchy	3.4	4.0	3.6	3.6	3.6	3.4	3.4	3.8	3.6
Building the coping toolkit	—	—	—	—	—	—	4.0	3.8	3.8
Values clarification exercises	3.8	3.4	4.0	3.8	3.8	3.5	3.2	3.6	3.4
Activity exposures	3.4	3.8	3.8	2.2	4.0	4.0	3.6	4.0	3.8
Problem-solving obstacles	—	—	—	—	—	—	4.0	4.0	2.8
Reflecting on accomplishments	3.8	4.0	4.0	3.8	3.2	3.8	4.0	4.0	4.0
Longtime SMART goals	4.0	3.8	3.8	3.8	4.0	4.0	3.8	4.0	4.0
Top lessons learned	4.0	4.0	4.0	3.0	3.6	4.0	3.8	3.8	3.8

[a]Not applicable.

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Figure 2. Initial prototype of iGET Living: Voice-over PowerPoint animation and static images of worksheets from the in-person intervention.

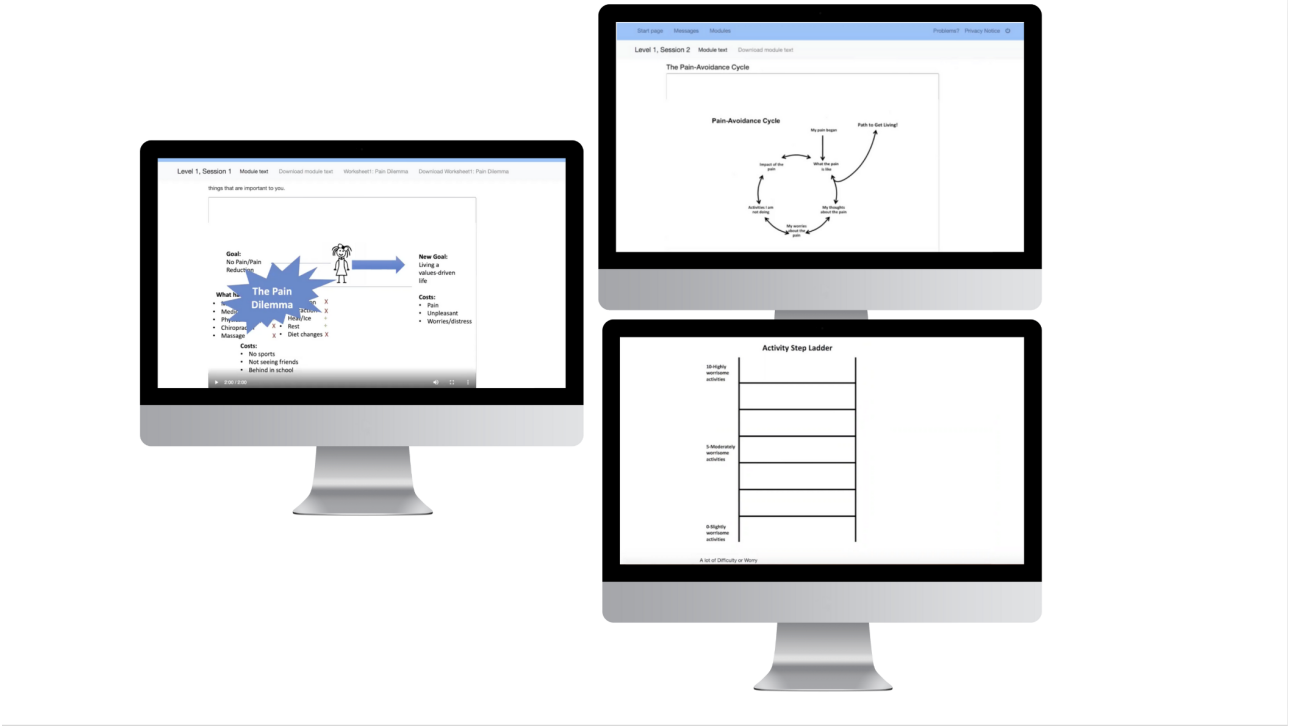
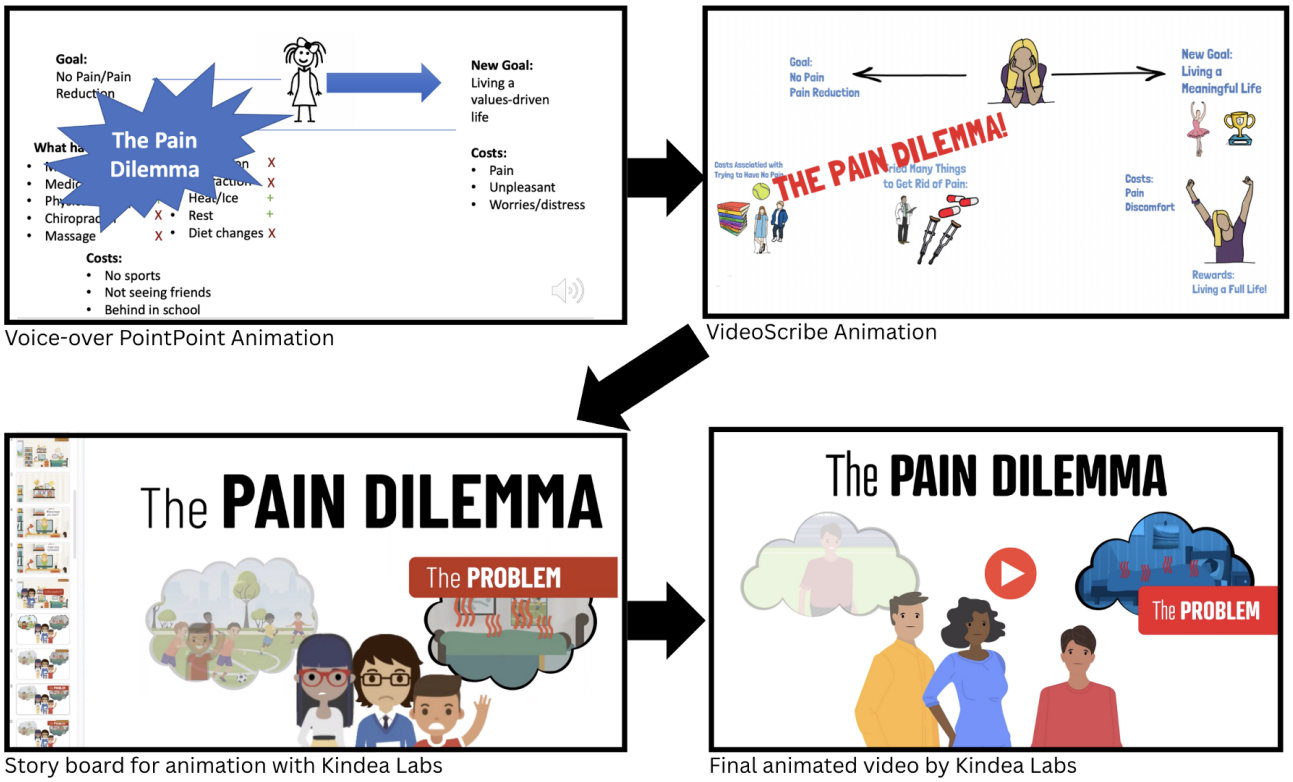


Figure 3. Example of the development process of an animation from voice-over PowerPoint to the final version created in partnership with Kindea Labs.



Design of the Treatment

Figure 4 shows the main screen and welcome page for the initial prototype (v1.0) developed in Phase 0. Treatment modules were labeled as generic "Levels." Technical barriers limited the ability to rename these initially (eg, change 'Level 1' to 'Chronic Pain and the Pain Dilemma'), and many youth noted that this was confusing and made the intervention hard to navigate. Updates to the platform allowed for descriptive headers to replace the generic "Level" label with the title of the module. A limited color palette was also integrated. With technological support from the software developers, static images of worksheets were replaced with more interactive, type-in-text box features. Figure 5 shows v2.0 of the prototype, which reflects iterations made in response to user feedback collected during cycle 1.

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Figure 4. Initial prototype of iGET Living: Homepage and introduction to the intervention.

Figure 5. Version 2 of iGET Living reflecting modifications to the home page, integration of the color palette, and the translation of static images into type-in-text features.

At the conclusion of 2 cycles of interviews (n=10) and several iterations of the intervention content, data suggested that the treatment content of the iGET Living prototype was acceptable and satisfactory to users (Table 3). However, technical and aesthetic limitations of the platform continued to be identified by the users as major barriers to future engagement in the intervention. To further the conceptualization of the intervention that incorporated users' feedback for technical modifications, wireframes (ie, a screen blueprint that can be used as a visual guide when creating the skeletal framework of a website) were drafted for each component of the intervention (Figure 6). These provided a way to sketch out the ideal layout, organization, and technical features of the intervention and facilitated concrete discussions with software developers regarding desired modifications to the existing digital platform.

Significant time and costs associated with making changes to the current platform presented barriers, and the decision was made to transfer iGET Living to Squarespace [54], a no-code, low-cost platform that contains premade, user-friendly webpage templates to facilitate the design of a website. Additionally, Squarespace has the capability to store nonprotected health information (eg, deidentified responses to exercises within intervention modules) within the platform. Canva [55], an online graphic design tool for making presentations, was used to create

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visual content (eg, images, buttons, banners), which was easily uploaded into Squarespace. Using the wireframes as a guide, our research team quickly built a new iGET Living prototype on the webpage Squarespace. Additional edits, including adjusting the spacing of content on the webpage, integration of a progress bar, and inclusion of more images, were made to v3.0 of iGET Living, resulting in a finalized prototype ready for beta testing (Figure 7). iGET Living v3.0 consisted of 4 main modules: Education, Values Clarification and Goal Setting, Activity Exposures, and Planning for Long Term Success. Each module contained self-guided microsessions (30 total across all 4 modules) designed for brief (5 - 15 min) daily engagement (Table 5).

Figure 6. Wireframes of treatment content.

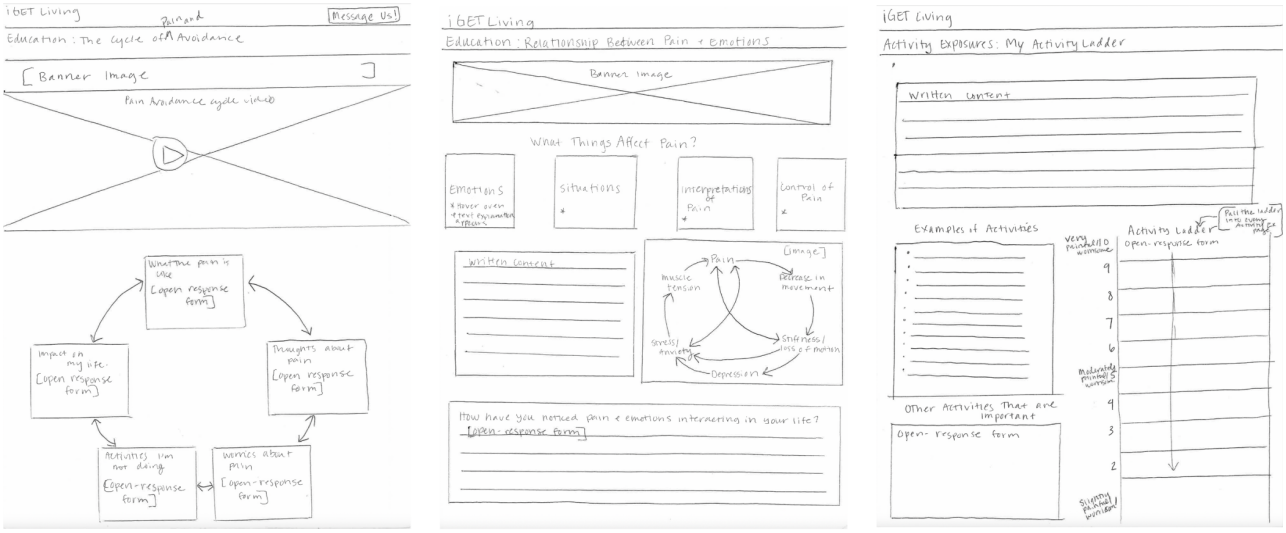

Figure 7. The final prototype of iGET Living is ready for beta testing.

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Table . Reflecting and evaluating the construct of the Consolidated Framework for Implementation Research (CFIR) (n=30) following pilot testing (Phase 2) of iGET Living. Items were rated on a 5-point Likert scale (0=not at all to 4=very much).

Question	Mean rating (range)	Participant quotes
How much did you like iGET Living?	3.6 (3-4)	• "I liked that there was a lot of time dedicated to the activity exposures—you need a lot of time and practice to work on this." [iGL_7] • "The idea of exposures can be intimidating but I liked that iGET Living focused on baby steps." [iGL_14]
Do you think iGET Living helped you get back to doing the things you need to/want to do?	3.8 (3-4)	• "It gave me some good strategies to try and taught me about pain which was cool. It did not improve my pain, but it got me back to doing things and had a positive impact." [iGL_34]
How often do you feel like you were able to engage in iGET Living daily?	2.5 (1-4)	• "Some days I just really didn't want to do it, or I would forget or get busy. If I was exhausted after doing something like school, I didn't want to come home and do this right away." [iGL_1] • "Debilitating pain, bad vertigo, schoolwork, and other doctors' appointments…this made it hard to do every day." [iGL_6] • "I would sometimes just forget or wouldn't be in the mood. It takes a lot of initiative." [iGL_12]
How likely would you be to recommend iGET Living to a friend?	3.3 (1-4)	• "I would tell them to do it—it will be beneficial one way or another." [iGL_27]
How would you describe the purpose of iGET Living?	—[a]	• "The purpose is to overcome the increasing pain that prevents kids from getting back to the things they love." [iGL_3] • "To help people with chronic pain get back to their activities." [iGL_9] • "A short 6-week program that can help you develop more strategies and help you make more goals that are more achievable." [iGL_7]
What would you like to add to iGET Living that would help you better manage your pain?	—	• "More physical exercises and stretches" [iGL_14] • "More coping strategies for pain like deep breathing and guided imagery." [iGL_18] • "Make it more accessible and easier to access. Having it be more phone friendly would be good." [iGL_30] • "I would like an app-based intervention that is more accessible on my phone." [iGL_22]

[a]Not applicable.

Phase 2: Pilot Testing the Prototype

Participants

For Phase 2, 107 youth were screened for eligibility between June 2023 and November 2024 (Figure 8). Of these, 38 youth enrolled in the study (42 were not interested in participating, 5 did not meet eligibility criteria upon further screening, and 5 were lost to follow-up). Of the 38 youth enrolled, 30 youth completed the study procedures (ie, engagement with intervention, completed nondaily and daily assessments). Youth reported an average age of 14.7 (SD 2.4), and 58.3% were assigned female at birth. Youth reported a range of pain diagnoses, including musculoskeletal pain, Ehlers-Danlos Syndrome, Complex Regional Pain Syndrome, and fibromyalgia, and over half (58.2%) of the sample reported experiencing pain for 3+ years. Youth reported an average pain intensity of 6.28 (SD 2.10), with 80.6% of youth reporting experiencing daily pain.

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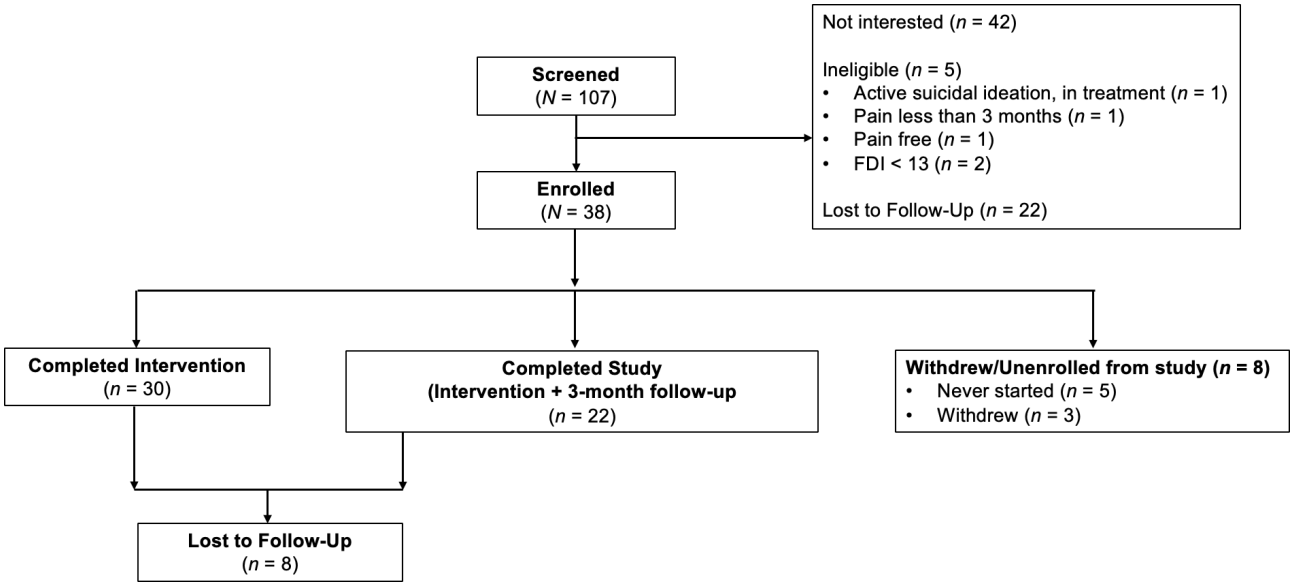
Figure 8. Screening and enrollment flow for Phase 2. FDI: Functional Disability Inventory; LTFU: lost to follow-up.



End User Perceived Success of the Intervention

On the CEQ, participants reported moderate to high perceptions of iGET Living's potential effectiveness after engaging with the intervention for one week. Summed scores for the credibility subscale were 19.71 (SD 4.34, range 9 - 30) out of a possible 30. Summed scores for the Expectancy subscale were 17.96 (SD 5.83, range 3 - 28) out of 30. Treatment satisfaction measured with the modified PSST was also high (mean 46.12, SD 11.46).

On the Theoretical Framework of Acceptability questionnaire, participants endorsed favorable ratings across most domains, including attitude toward the intervention (mean 3.32, SD 0.91), ethicality (mean 3.61, SD 0.91), perceived effectiveness (mean 3.35, SD 0.91), intervention coherence (mean 3.32, SD 0.98), and self-efficacy (mean 3.35, SD 0.84). Scores for burden (mean 3.19, SD 0.95) and opportunity costs (mean 2.90, SD 1.22) suggest some participants perceived challenges related to the effort required to engage in the intervention or competing demands. Overall, general acceptability was high (mean 3.81, SD 0.65).

Exit interview data, which contained Likert-rated items and open-ended questions, further underscored the acceptability of the intervention (Table 5). Youth described the purpose of iGET Living as helping teens with chronic pain regain function, overcome avoidance, and reconnect with valued activities. They emphasized the importance of the intervention in "getting back to what you used to do," "helping people with chronic pain get back to the things they enjoy," and "providing a step-by-step guide to get out of the chronic pain bubble." Ratings of intervention helpfulness were high, with mean scores of 3.6 - 3.8 out of 4. Participants also highlighted areas for improvement, including increasing accessibility (eg, mobile-friendly or app-based formats) and adding more physical exercises. A modified exit interview was conducted with the 3 youth who withdrew from the study. Two of the youth stated that they already knew a lot of the intervention content:

> *I've done knew a lot of research on my own about my pain so a lot of it, I felt, was just kind of repetitive for me. Like I knew a lot of the stuff already.* [Y2]

> *I feel like it's all the same information I've heard from many, many doctors and specialists.* [Y17]

The third youth also noted feeling as though it was not the right time for them to engage in this type of intervention:

> *I'm looking for a magic pill that's gonna fix everything I'm dealing with, and I'm not ready to hear all of the other stuff like, that's just where I'm at. I'm not ready for that. So, it's not the program—I thought it was great. If I was in a different space, I think I'd definitely do it.* [Y4]

An outline of the final intervention content can be found in Table 6.

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Table . Final intervention content for iGET Living v3.0 that was piloted in Phase 2.

Module	Daily microsession
Education	• What is Chronic Pain? • The Pain Dilemma • The Cycle of Pain and Avoidance • How are Pain, Mood, and Stress Related? • What are Values-Based Goals? • What is Exposure Treatment
Values and goals[a]	• Values clarification and S.M.A.R.T. Goal exercises across the following domains: Friends, Family, Education, Work, Spirituality, Hobbies, Community, Romantic Relationships, Physical Health and Wellbeing, Domain of Your Choice (x3)
Activity exposures	• Building the Activity Ladder • The W.I.L.D. Scale • Building Your Coping Toolkit • Activity Exposures (12 in total)
Planning for long-term success	• Problem-Solving Obstacles • Reflecting on Accomplishments • Long-Term Values-Based Goals • Top Lessons Learned

[a]Participants needed to complete five of the 12 values-clarification exercises to be considered "completed."

Discussion

Principal Findings

This study described the iterative, user-centered development and preliminary pilot testing of iGET Living, a digital graded exposure intervention for youth with chronic pain. Guided by the CFIR and the mHealth Agile Development and Lifecycle model, we translated an evidence-based in-person GET into a digital intervention and refined it through multiple cycles of end user feedback. Across development phases, youth participants reported favorable perceptions of credibility, satisfaction, and acceptability, and qualitative feedback highlighted the intervention's perceived role in supporting functional recovery and re-engagement in valued activities. Together, these findings suggest that integrating implementation science frameworks with user-centered digital development can support the creation of scalable behavioral health interventions for pediatric chronic pain.

The findings are consistent with recent studies showing promise of digital behavioral health interventions for chronic pain [10,11,13,14,32,52,56]. Importantly, our iterative design process aligns with best practices recommended in recent scoping reviews, which emphasize the value of integrating implementation frameworks and user-centered design features early in the development process to support future scalability and uptake [10,27,31].

The study also provides a framework for an agile, iterative development cycle that can be applied to future intervention development. Due to pragmatic constraints commonly encountered in academic digital intervention development, the initial prototype relied on static images, text-heavy content, and basic navigation features to begin translating the evidence-based GET Living protocol into a digital format. This intentionally simplified prototype allowed the research team to prioritize rapid testing of core content and usability before investing in more resource-intensive design features. This approach reflected a pragmatic starting point for development, with the understanding that early iterations would likely be suboptimal in user experience. This anticipated limitation highlights a core challenge in digital health innovation in academic settings—specifically, the difficulty of implementing sophisticated design features without dedicated development teams with substantial funding. Early user feedback played a critical role in identifying necessary improvements and underscored the importance of iterative refinement processes like those outlined in the CFIR and mHealth Agile Development and Lifecycle model. Through user interviews and visual wireframes, we were able to identify key usability challenges, collaborate with developers, and shift platforms to enable more flexible and appealing designs. The final version incorporated high-quality animated videos, interactive features, and concise language to better match youth preferences and developmental needs. As hypothesized, ratings for clarity, satisfaction, and acceptability increased across development cycles and resulted in a finalized version of the intervention suitable for further pilot testing. Feedback from youth end users led to meaningful improvements in clarity, layout, and visual design, as well as enhanced engagement and technical performance, and bolstered findings from prior digital health studies [10,14,56]. These insights underscore the importance of embedding participatory design methods throughout intervention development. The final prototype incorporated structural and aesthetic refinements, expanded content on pain education, and added new modules addressing pain-related mood and stress—all changes directly informed by youth.

This challenge is particularly salient in a digital context where youth are already exposed to health-related information through social media, which is often highly engaging but not always evidence-based. Participatory design does not aim to replicate

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social media content but rather to identify areas where evidence-based interventions feel misaligned with youths' experiences, language, or presentation. In this study, youth feedback highlighted when content felt overly dense, repetitive, or insufficiently engaging, prompting iterative refinements to structure, visual presentation, and interactivity while preserving core therapeutic principles.

Notably, our findings emphasize that iterative refinement must extend beyond content to include tone, accessibility, and representation. Youth participants raised concerns about overly clinical language, school-like visuals, and lack of diversity in character design—insights that may have been missed without a structured, participatory design process. This underscores the importance of inclusive developmental frameworks that prioritize relevance and relatability, particularly when designing interventions.

Limitations and Future Directions

While our sample size was appropriate for alpha testing, it was relatively small and recruited from a single academic medical center. Future work should examine the usability and effectiveness of iGET Living across more diverse clinical and community-based settings. Additionally, although our use of no-code platforms enabled rapid development at low cost, sustaining and scaling the intervention may require partnership with commercial developers or digital health infrastructure. Hybrid effectiveness-implementation designs [27,31] may be particularly valuable for understanding clinical outcomes and contextual determinants of adoption. In the next phase of this project (Phase 3 of the mHealth Agile Development and Lifecycle model), the preliminary efficacy of iGET Living will be evaluated using single-case experimental design methodology [57]. Single-case experimental design offers an approach for rapid evaluation of digital interventions in small cohorts, enabling close examination of individual-level patterns of change. This approach also leverages the intensive, high-frequency data collection possible within digital platforms, aligning well with the iterative nature of agile development.

Conclusions

In conclusion, this study demonstrates the feasibility of combining evidence-based graded exposure with digital health delivery to address barriers to accessing pediatric pain care. By embedding iterative, user-centered development and implementation frameworks early in the design process, iGET Living represents a promising model for developing scalable, user-informed digital behavioral health interventions. Future work will evaluate the preliminary efficacy of the intervention and examine implementation strategies to support broader dissemination in pediatric pain care settings.

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Data Availability

The datasets generated and analyzed during this study are not publicly available due to the presence of potentially identifiable participant information, but are available from the corresponding author on reasonable request and with appropriate institutional approvals.

Authors' Contributions

LEH conceptualized the study, secured funding, and led study design and supervision. LEH, LES, RKW, BDD, SNJ, SM, and ML contributed to intervention development and study procedures. SNW, EC, DM, and NJ assisted with data collection and qualitative analysis. LEH drafted the manuscript. BDD, JNS, MB, ML, RKW, and LES provided methodological input, supervision, and critical revisions to the manuscript. All authors reviewed and approved the final manuscript.

Conflicts of Interest

None declared.

Checklist 1
GUIDED checklist.
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Checklist 2
TIDieR checklist
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Abbreviations

CEQ: Credibility/Effectiveness Questionnaire
CFIR: Consolidated Framework for Implementation Research
GET: graded exposure treatment
GUIDED: Guidance for the Reporting of Intervention Development
mHealth: mobile health
PSST: Pain Service Satisfaction Test
RA: research assistant
REDCap: Research Electronic Data Capture

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Telephone-Based Mental Health Promotion for Rural Women in Brazilian Agrarian Reform Communities: Pre-Post Pilot Study

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Abstract

Background: Women living in rural agrarian reform communities face intersecting challenges related to social, economic, racial, and gender vulnerabilities, which significantly increase their likelihood of developing physical and mental health problems. Despite the potential of telephone-based interventions to promote mental health, there is a lack of studies assessing their feasibility and effectiveness among underserved populations in Brazil.

Objective: This study aimed to assess the feasibility and effectiveness of a telephone-based intervention on mental health outcomes among women living in a rural agrarian reform community in Brazil.

Methods: We conducted a descriptive, prospective pilot study with a pretest and posttest design. Data were collected at 3 time points: baseline, 1 week, and 1 month after the intervention. The outcomes assessed included quality of life, social support, self-efficacy, and common mental disorder symptoms. Nonparametric tests were used to analyze the data. The intervention consisted of 3 phone calls supported by a workbook, with content based on cognitive behavioral and psychiatric nursing principles.

Results: Of the 31 women enrolled, 23 (74.2%) completed all 3 phone-based sessions. There was a significant reduction in common mental disorder symptoms (Kendall W=0.280; P=.002), particularly in the somatic domain (P=.02). Moreover, participants reported improved perceptions of the physical domain of quality of life (Kendall W=0.131; P=.049). All women rated the intervention positively, with more than half emphasizing its practical usefulness.

Conclusions: The telephone-based intervention was feasible and showed promising results in improving mental health outcomes among women in a rural setting. These findings support integrating low-intensity, remote psychosocial strategies into primary health care, especially those led by nurses, to increase access to mental health promotion for vulnerable populations.

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KEYWORDS

women; mental health; health promotion; social vulnerability; rural population; psychosocial intervention

Introduction

Mental health care has been advocated for as a priority for developing public policies globally, and primary health care (PHC) is recognized as a key channel for expanding access to this care [1]. This is because PHC services are considered accessible to the community. They work from a comprehensive, intersectoral, interdisciplinary perspective, aiming to coordinate preventive, promotive, therapeutic, and rehabilitative actions according to users' needs [2,3].

In this context, actions aimed at mental health care have been the focus of many studies, with an emphasis on the need to think about new strategies to expand such actions [4,5]. The telephone has emerged as a valuable tool for achieving these goals because it is a useful and easily accessible means of communication. It helps fill gaps in face-to-face care resulting from an overloaded health system, a lack of interprofessional collaboration, inadequate physical space, reduced resources, and user stigma [4-7].

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Studies on the effectiveness of interventions delivered via telephone have been carried out in different countries and with diverse populations [6-8]. These interventions have proven beneficial, leading to significant reductions in depressive symptoms, worry, posttraumatic stress disorder, and anxiety; improvements in physical health; reduction in suicidal ideation; and greater satisfaction with treatment reported by participants [6-8]. However, most of these studies have focused on reducing symptoms among individuals with established diagnoses. Comparatively, less attention has been given to promoting mental health among socially vulnerable populations who may not have formal diagnoses or regular access to care.

In low- and middle-income countries, particularly in rural settings, structural barriers such as geographic isolation, limited availability of specialized services, socioeconomic disadvantage, and gender inequalities may further restrict access to mental health care. In Brazil, rural populations, including those living in rural agrarian reform communities, often face overlapping vulnerabilities related to poverty, labor instability, limited infrastructure, and restricted access to health care, education, and social services [9-12].

The Sustainable Development Goals include mental health and well-being, gender equality, and reducing inequality. Developing strategies for vulnerable populations is essential to achieving these goals. In this regard, women living in rural agrarian reform communities require special attention, as they face intersecting challenges related to social, economic, gender, racial, and other issues, which greatly increases their likelihood of developing physical and mental health problems [10-12].

Therefore, implementing accessible interventions that address both subjective and relational aspects of mental health for women living in rural agrarian reform communities is of paramount importance to expand access to mental health care, especially in the context of PHC. This study aimed to assess the feasibility and effectiveness of a telephone-based intervention on the mental health outcomes of women living in a rural agrarian reform community in Brazil.

Methods

Study Design

This is a single-group, nonrandomized preintervention and postintervention study, conducted in accordance with the Template for Intervention Description and Replication (TIDieR) recommendations. TIDieR is a tool used to describe the components of an intervention to facilitate replication and consistent implementation [13], and the TREND (Transparent Reporting of Evaluations with Nonrandomized Designs) statement provides guidance for reporting nonrandomized intervention studies. No control group was included due to the exploratory and feasibility nature of the study.

The study was conducted in a rural agrarian reform community in a municipality in the countryside of São Paulo state between August and December 2021.

Participants and Data Collection

The study population consisted of adult women registered at the basic health unit (BHU) in the aforementioned rural agrarian reform community (approximately 1000). To be eligible, participants had to be literate, aged at least 18 years, and present at the BHU during data collection. As a formative feasibility study, no formal sample size calculation was performed.

Data collection was carried out by 2 graduate-level nurses who received training to administer the instruments listed in this research. This collection took place at 3 different points: baseline (before program implementation); first follow-up (1 week after program completion); and second follow-up (1 month after program completion).

A questionnaire was administered to assess participants' socioeconomic profiles, and the following psychometric scales were applied: the World Health Organization Quality of Life abbreviated version (WHOQOL-BREF); Sarason Social Support Questionnaire (SSQ); the General Perceived Self-Efficacy Scale (GSE); and the Self-Reporting Questionnaire-20 (SRQ-20).

The WHOQOL-BREF contains 26 questions—two are general about quality of life (QoL) and the others represent each of the 24 facets divided into four domains: (1) physical, (2) psychological, (3) social relationships, and (4) environment. The questions are rated on a Likert scale from 1 to 5. The instrument contains 3 questions with inverted scores. The final score falls within a range of 4 to 20 and can be converted to a scale of 0 to 100 using the syntax developed by the authors [14]. Higher scores reflect better perceived QoL [14]. The instrument has been validated for use with the Brazilian population [14].

The SSQ consists of 27 questions addressing various situations where social support might be important for an individual. Respondents list up to 9 people per question and rate their satisfaction with the support in each situation. The mean of the scores measures both the size of the social network and satisfaction with the support [15]. This study used the SSQ's short version (SSQ6), which includes 6 items and has been translated and validated for use with the Brazilian population [15].

The GSE, validated for the Brazilian population, assesses an individual's general sense of perceived self-efficacy, aiming to predict how well they cope with daily challenges and adapt after stressful life events [16]. It consists of 10 items scored on a scale from 1 to 4, and the total score is calculated by summing the items, ranging from a minimum of 10 to a maximum of 40 points. Higher scores indicate greater perceived self-efficacy [16].

The SRQ-20 was developed by the World Health Organization to assess common mental disorders (CMDs) in low- and middle-income countries [17]. The original version contains 24 items, with the first 20 addressing nonpsychotic disorders and the last 4 addressing psychotic disorders. As the adaptation study for the Brazilian version was conducted in a PHC context, only the first 20 items are used [17]. The questionnaire includes 20 "yes" or "no" questions about emotional and physical symptoms associated with psychiatric conditions. A score of

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more than 8 positive responses suggests a possible mental disorder [17].

Intervention Protocol

A nurse with experience in mental health and a PhD student in psychiatric nursing developed the intervention protocol. Two judges, including one psychologist and one occupational therapist, were chosen to review the script based on their expertise in behavioral analysis, psychological approaches, psychosocial rehabilitation, and contextual therapy training. Additionally, the program was piloted with 2 women outside the study population to test its feasibility. The researchers selected these women based on characteristics similar to the target population; however, they resided in an urban area of the city. Following the pilot tests, the content was revised to simplify the language and enhance clarity for the intended population.

The theoretical foundation of these approaches included cognitive behavioral techniques [18,19], as well as propositions and recommendations from psychiatric nursing theories [20,21].

The intervention consists of 3 modules and a workbook. The topics covered are (1) identifying emotions, (2) relationships with others, and (3) subjectivity. The topics were defined based on a situational diagnosis conducted through field visits to the rural agrarian reform community and discussions with BHU professionals responsible for the population in the area. Contextual factors such as lack of basic sanitation, financial hardship, food insecurity, unemployment, and access issues were considered, along with epidemiological and clinical factors. The program aimed to encourage reflection on the 3 previously defined topics, promoting better integration between emotional and behavioral aspects, fostering self-awareness, strengthening or enhancing internal resources for coping with daily adversities, and identifying potential to envision future possibilities.

Both the situational diagnosis and the pandemic context were considered for structure and content. Following consultations with experts (study group members with various backgrounds, including a public administrator, mental health nurses, general nurses, and psychologists), it was decided to conduct telephone-based interventions to offer guidance, active listening, structured exercises, positive reinforcement, and tailored advice.

Three 15-minute calls were made at weekly intervals. Each call included an explanation of the topic and an invitation to reflect on it using workbook activities. During the next call, participants were invited to discuss the exercise, and researchers provided at least one piece of positive feedback and one recommendation for behavioral change. Short, individualized approaches were chosen because previous studies have shown them to be factors linked to adherence [4,22].

The workbook (*Passatempo sentiMental*) contains 6 activities related to the 3 themes, combining technical and playful elements. The workbook's development also involved collaboration with cartoonist Alexandre Beck and is currently being registered with the National Library.

Data Analysis and Processing

The primary outcome was feasibility, and secondary outcomes included changes in psychosocial measures. We analyzed the feasibility of the program considering the 31 women who participated in at least one of the proposed approaches. The main indicator used to assess the program's feasibility was the proportion of interested women who completed it. These aspects were analyzed using an adaptation of the procedures proposed by a group of British researchers [22], considering five aspects: (1) the number of women who accepted participation; (2) the number of participants who completed the sessions; (3) the number of participants who did not complete the sessions; (4) among those who did not complete the sessions, how many sessions they attended and their reasons for dropping out; and (5) an analysis of potential clinical and sociodemographic factors differentiating women who completed the program.

Descriptive statistics and nonparametric tests were used to analyze the overall picture of psychosocial measures (CMD symptoms, QoL domains, social support, and self-efficacy) and sociodemographic characteristics.

The Mann-Whitney *U* test was applied to compare the characteristics of women who completed the program with those who did not. Independent variables were the number of children; age (in years); and scores from QoL domains, social support, and self-efficacy. Pearson chi-square test and/or Fisher exact test were used to compare categorical variables, such as race (White, Asian, Black, or *pardo*); religion (Catholic, other, Protestant, or Evangelical); stable union (yes or no); paid work (yes or no); education level (elementary school, high school, or higher education); monthly income (less than one minimum wage, 2 to 5 minimum wages, or more than 5 minimum wages); most prevalent symptoms; and CMD indicative score (yes or no).

To assess the program's effect, psychosocial data from the initial assessment and subsequent follow-ups were examined. The SRQ-20 questions were grouped into four dimensions, as defined by the authors based on the study's objective: (1) somatic (questions 1, 2, 3, 7, 18, 19, and 20); (2) anxiety (questions 4, 5, and 6); (3) action and cognition (questions 8, 11, 12, 13, 14, and 16); (4) emotion and will (questions 9, 10, 15, and 17). At this stage, descriptive statistics were used to present and compare the most prevalent CMD symptoms. The Wilcoxon signed-rank test was applied to analyze differences in symptom responses between baseline and 1 month later.

The Friedman test was applied to analyze whether there were differences in psychosocial measures (CMD symptoms, QoL domains, social support, and self-efficacy) across the follow-ups (baseline, 1 week, and 1 month after the program). The tested hypothesis was that perceptions of support, QoL, and self-efficacy would increase and possible CMD symptoms would decrease after participating in the program. A significance level of 5% was adopted for all analyses. Analyses were performed using SPSS for Windows (version 25; IBM Corp).

In addition, the content of the women's feedback on the activities was analyzed and grouped descriptively by similarity criteria.

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Ethical Considerations

All participants provided their consent by signing the informed consent formethical standards established by Resolution number 466/2012 of the Brazilian National Health Council [23]. It was approved (opinion number 67, March 10, 2021) by the research ethics committee of the School of Nursing of Ribeirão Preto, University of São Paulo. Measures were taken to ensure participants' privacy and data confidentiality, and all data were anonymized prior to analysis. No financial compensation was provided to participants.

Results

Feasibility: Characteristics That Distinguished Women Who Completed All Program Activities

Participants were recruited through posters and leaflets in waiting rooms and clinics, as well as through direct approaches, with 130 women in the BHU waiting room (n=100, 76.9%) and at home (n=30, 23.1%).

Of the women who received a personal invitation to participate, 40 (30.8%) agreed to do so. They answered the pretest questionnaires and received materials to complete the activities provided in the program. However, 9 (22.5%) decided not to continue with subsequent stages of the study, resulting in a final sample size of 31 (77.5%). All participants completed the initial stage. Of the 31 women, 26 (83.9%) completed the first two stages, and 23 (74.2%) completed all three of the planned telephone-based stages (Figure 1).

Figure 1. Flowchart of sample composition and reasons for dropouts after each phase of the proposed program.

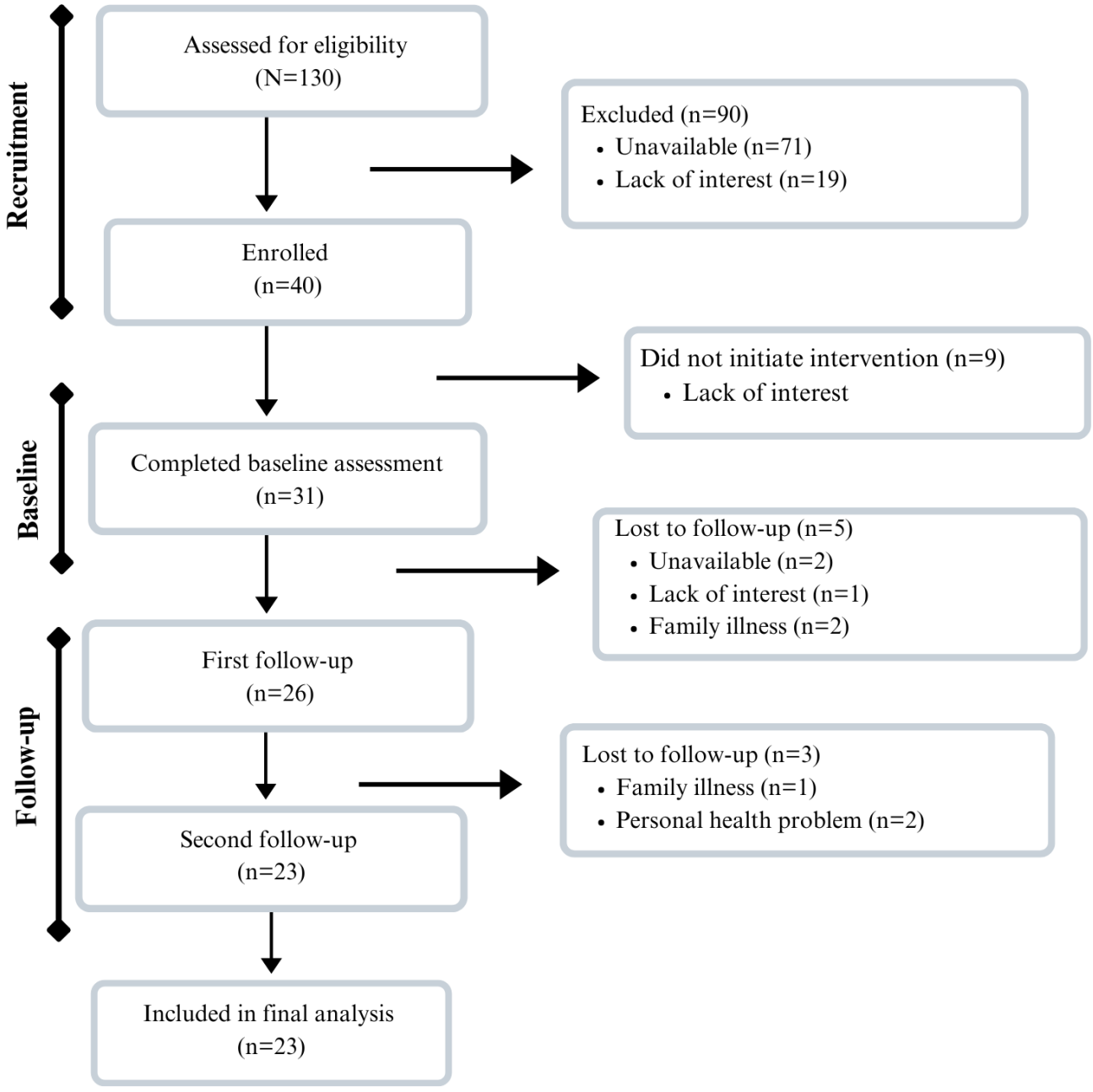

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Figure 1 shows that out of 31 participants, 23 (74.2%) completed all program activities. Most participants identified as Black or *pardo*, had children, had completed high school, and reported a household income of up to 2 minimum wages. There was no statistically significant difference in sociodemographic characteristics among those who completed the program and those who did not (Table 1).

Table . Sociodemographic characteristics of participants by group (completed and did not complete the program).

Variables	Completed (n=23)	Did not complete (n=8)	*P* value
Age (years), median (IQR)	42 (33-54)	40 (32-52.75)	.82
Race, n (%)			.99
Asian or White	7 (30.4)	2 (25.0)	
Black or *pardo*	16 (69.6)	6 (75.0)	
Religion, n (%)			.41
Catholic or other	7 (30.4)	4 (50.0)	
Protestant or Evangelical	16 (69.6)	4 (50.0)	
Stable union, n (%)			.58
Yes	15 (65.2)	4 (50.0)	
No	8 (34.8)	4 (50.0)	
Children, median (IQR)	2 (1-3)	2 (1.25-2.75)	.58
Yes, n (%)	20 (87.0)	8 (100.0)	
No, n (%)	3 (13.0)	0 (0.0)	
Education, n (%)			.69
Elementary school	11 (47.8)	4 (50.0)	
High school	10 (43.5)	4 (50.0)	
Higher education	2 (8.7)	0 (0.0)	
Household monthly income, n (%)			.93
Less than 1 MW[a]	9 (39.1)	3 (37.5)	
1 to 2 MWs	10 (43.5)	4 (50.0)	
2 to 5 MWs	4 (17.4)	1 (12.5)	
Paid work, n (%)			.69
Yes	9 (39.1)	4 (50.0)	
No	14 (60.9)	4 (50.0)	

[a]MW: minimum wage (monthly income in 2021: US $213.17).

In relation to psychosocial factors, there was a high prevalence of women with scores indicative of CMD symptoms in the entire sample (14/23, 60.9% of those who completed the program and 5/8, 62.5% of those who did not complete it). The item related to “feeling tense, nervous and worried” was the most prevalent in the pretest in both groups (Table 2 [17]). On the other hand, affirmative responses to the item “difficulty in carrying out daily life activities” were more prevalent among women who completed the program (Table 2). There was no statistically significant difference in perceived QoL, social support, and self-efficacy among the groups that completed and those that did not complete the program.

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Table . Percentage of women presenting symptoms described in the Self-Reporting Questionnaire-20 (SRQ-20; adapted from the study by Mari and Williams [17]) by group (completed and did not complete the program).

SRQ-20 factors	Completed (n=23), n (%)	Did not complete (n=8), n (%)	*P* value
Somatic			
Headaches	11 (47.8)	4 (50.0)	.99
Loss of appetite	9 (39.1)	1 (12.5)	.22
Sleep difficulties	14 (60.9)	4 (50.0)	.69
Indigestion	12 (52.2)	3 (37.5)	.69
Feeling frequently tired	12 (52.2)	5 (62.5)	.70
Easily fatigued	16 (69.6)	5 (62.5)	.99
Unpleasant stomach sensations	12 (52.2)	4 (50.0)	.99
Anxiety			
Easily startled	10 (43.5)	4 (50.0)	.99
Trembling hands	7 (30.4)	5 (62.5)	.21
Feeling tense, nervous, and worried	19 (82.6)	8 (100.0)	.55
Action and cognition			
Difficulty concentrating	13 (56.5)	3 (37.5)	.43
Difficulty performing daily activities	13 (56.5)	1 (12.5)	.045[a]
Difficulty making decisions	14 (60.9)	2 (25.0)	.11
Dissatisfaction with work	6 (26.1)	2 (25.0)	.99
Feeling incapable of playing an important role in life	2 (8.7)	1 (12.5)	.99
Feelings of worthlessness	5 (21.7)	2 (25.0)	.99
Emotion and volition			
Feelings of sadness	14 (60.9)	4 (50.0)	.69
Frequent crying	7 (30.4)	2 (25.0)	.99
Loss of interest in things	12 (52.2)	5 (62.5)	.70
Suicidal thoughts	3 (13.0)	2 (25.0)	.58

[a]indicates statistical significance.

Effect

Only data from the 23 women who completed all stages of the program were analyzed to determine its potential effect. A gradual increase in scores for the QoL physical, psychological, and environmental domains was observed at both follow-up assessments. However, statistically significant differences across time were found only for the physical domain, and the magnitude of change was small (Kendall W=0.131; P=.049). In contrast, CMD scores showed a gradual and statistically significant decrease over time, with a small-to-moderate effect size (Kendall W=0.280; P=.002; Table 3).

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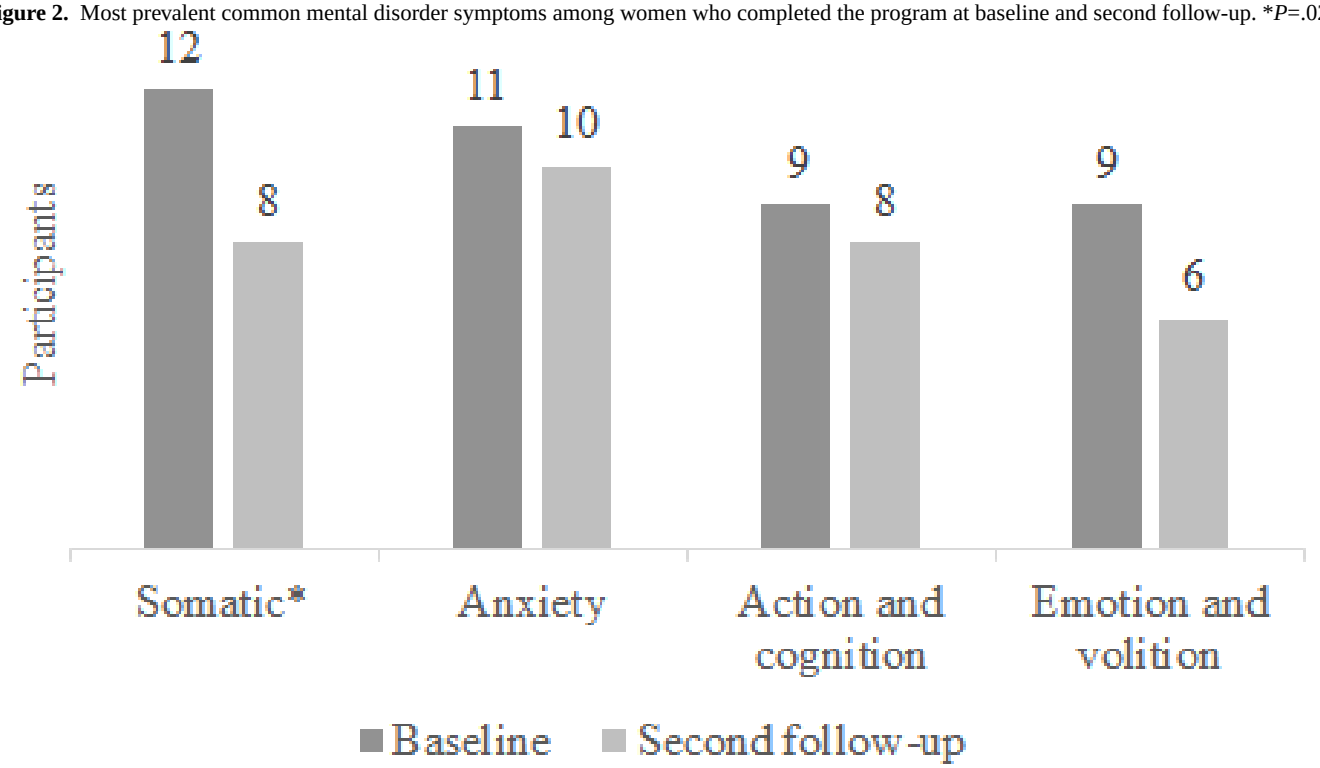
Table . Results obtained from the Friedman test at 3 assessment points (n=23).

	Baseline, median (IQR)	1 week later, median (IQR)	1 month later, median (IQR)	Chi-square (*df*)	*P* value
Quality of life domains					
Physical	57.14 (35.71-82.14)	64.29 (53.57-78.57)	71.43 (46.43-85.71)	6.0 (2)	.049[a]
Psychological	54.17 (45.83-79.17)	62.50 (50.00-79.17)	62.50 (54.17-79.17)	0.3 (2)	.85
Social relations	58.33 (41.67-75.00)	58.33 (33.33-75.00)	66.67 (41.67-83.33)	1.5 (2)	.48
Environmental	53.13 (37.50-71.88)	53.13 (40.63-71.88)	59.38 (46.88-71.88)	3.6 (2)	.16
Social support					
Satisfaction	5.33 (4.83-5.66)	5.33 (4.83-5.66)	5.17 (5.00-5.83)	0.6 (2)	.76
Number of supporters	4.00 (3.00-7.00)	4.00 (3.00-6.00)	4.00 (3.00-7.00)	5.1 (2)	.08
Self-efficacy	35.00 (27.00-37.00)	34.00 (25.00-38.00)	33.00 (24.00-38.00)	1.7 (2)	.42
Common mental disorder symptoms	9.00 (5.00-15.00)	6.00 (4.00-12.00)	5.00 (2.00-11.00)	12.9 (2)	.002[a]

[a]*P*<.05 indicates statistical significance.

The prevalence of CMD symptoms decreased across all dimensions, particularly in the somatic dimension, where this decrease was statistically significant (*P*=.02) (Figure 2).

Figure 2. Most prevalent common mental disorder symptoms among women who completed the program at baseline and second follow-up. *P=.02.



Participants' Assessment

Regarding women's assessment of the program's structure, among the 23 participants, 16 (69.6%) felt the duration of the phone calls was appropriate and 13 (56.5%) said the number of calls was sufficient. All the participants rated the program positively, and 12 (52.2%) specifically highlighted the practical value of what they learned. Some expressed this utility in a more general way:

Wonderful work that helped me a lot and can help many women, mothers, wives, daughters. Thank you. [P22]

I found the calls very interesting; I like to listen to educated people who know how to talk to us; it was very important. [P28]

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Others, on the other hand, were more specific in their comments, highlighting their favorite parts of the activities and how they applied what they learned to solve daily life issues:

> *It helped me a lot to understand that I am not obliged to carry the world on my shoulders and I cannot solve everything.* [P22]

> *I liked everything about the activity; the most interesting part was the pastime and the content; it helped me a lot because I was going through a very difficult phase and with the conversations and the notebook, I managed to organize my feelings.* [P1]

Another participant also mentioned:

> *It helped me see myself in a different light, to seek to love myself more, to pay more attention to myself. This pastime makes us think about what we are doing wrong with our body and mind.* [P2]

Some comments addressed the potential acceptance of the program by others:

> *I had never participated in an activity like this; I believe other people would enjoy these activities.* [P11]

> *I hadn't participated in an activity like this before; it was the first time and, certainly, other people would like to receive this.* [P1]

In light of perceived benefits, participants recommended that the program be offered to more people:

> *I hope it reaches more people.* [P29]

> *If possible, make sure many other women know about the work.* [P2]

Discussion

Principal Findings

This study aimed to assess the feasibility and effects of a telephone intervention on the mental health of women living in a rural agrarian reform community in Brazil. High adherence to the proposed program was identified. Previous research has identified key factors that contribute to adherence, including scheduling meetings, meeting expectations regarding the study's duration, ensuring that activities do not exceed the estimated time, and adapting session schedules to participants' needs [4,5,22]. These factors were rigorously addressed by the program proposed in this study, and most participants positively assessed its structure and content.

Five women who did not complete the program cited illness (either their own or that of a family member for whom they were a caregiver) as the reason for their nonparticipation. This suggests that the adherence-facilitating factors noted in previous research [4,5,22], along with other strategies used in this study (eg, the possibility of rescheduling sessions and non–face-to-face modalities), were insufficient to address the specific difficulties faced by some women. This highlights the need to design interventions that address the unique challenges faced by caregivers, especially women who are culturally assigned the role of caring for their loved ones and accumulate obligations and functions [10-12], which serve as barriers to adherence to programs of this nature.

At baseline, a high prevalence of women with scores indicative of CMDs was observed, with values exceeding those reported in previous studies involving women in situations of vulnerability [24-26]. These findings suggest that women living in rural areas may face unique challenges that warrant further research to identify the actual predictors of psychological distress. This research would also help better understand the relationship between psychological distress and other well-established social determinants of health, such as socioeconomic status, race, gender, food insecurity, unemployment, agricultural labor, and limited access to health care, education, sanitation, and transportation services [10-12,27].

Additionally, prioritizing actions for women in rural communities, especially in the Brazilian context of extensive social and gender inequalities, supports the Sustainable Development Goals, which envision universal respect for human rights and human dignity, equality, and nondiscrimination based on race, ethnicity, and cultural diversity [9].

Considering PHC, nurses play a pivotal role in developing strategies to address these disparities. This is because they use essential strategies for building strong patient relationships, such as welcoming, active listening, and empathy [28], in addition to providing comprehensive care that considers the community's biopsychosocial aspects and characteristics. In this context, nurses have significant potential to expand mental health care by creating safe spaces for emotional support and well-being for this population.

Regarding the program's potential effects, this study observed a statistically significant reduction in CMD scores over time, with a small-to-moderate magnitude of change. Improvements were also identified in women's perceptions of the QoL physical domain; however, the effect size was small, suggesting a modest change across assessments. These results align with propositions that emphasize the somatic dimension in manifestations of psychological distress [29,30].

Studies using interventions based on psychoeducation techniques, as well as emotional and behavioral modulation, have identified that the more patients understand their feelings and the less intrusive or aversive they consider them, the greater the reduction in somatic symptoms [31,32]. From this perspective, the program's focus on emotional issues may have contributed to changes in symptoms related to physiological dysfunctions. Although the magnitude of change in the physical domain was small, these findings highlight the possible interplay between emotional experiences and physical manifestations of distress. These findings underscore the importance of identifying and intervening on psychosocial needs, especially in the context of PHC, where such issues are frequently overshadowed by other clinical demands.

Participants' positive assessments regarding the activities and the emphasis placed on their importance highlight how these women need content that helps them deal with the adverse issues in their daily lives. The fact that many reported never having

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participated in an activity such as this raises two important issues: first, the limited access of women in general to mental health promotion, and second, the specificities related to women from agrarian reform communities.

Regarding the limited access for women in general, the findings indicated that women from the pilot test interviews (urban residents) and the study participants both reported this as their first experience with such an activity. This emphasizes the lack of mental health promotion activities for women in the general population. Concerning the specificities of women from agrarian reform communities, as they intersect various risk and vulnerability situations, it is possible that this access is even more hindered, given that local health care professionals may lack the resources or training needed to ensure access to such programs. Previous studies [10-12,33] have described issues, such as work process overload, difficulty accessing basic social rights such as health, education, and sanitation, and racial issues involving environmental, structural, and institutional racism, as significant barriers affecting the population in this study. These barriers should be further investigated to inform effective solutions.

Limitations

This study has several limitations. First, the relatively small, context-specific sample limits the generalizability of the findings. Second, the absence of a control group precludes establishing a causal relationship between the intervention and the observed changes in mental health outcomes. Improvements identified at follow-up may have been influenced by external or contextual factors unrelated to the intervention.

Furthermore, data were predominantly self-reported and based exclusively on participants' perceptions, which may be subject to reporting and social desirability biases. Contextual factors inherent to participants' living conditions may also have influenced follow-up results.

As a formative study, the primary aim was to assess feasibility and preliminary effects. Further research using randomized controlled designs with larger samples is warranted to strengthen causal inferences and further assess the effectiveness of telephone-based mental health interventions for similar vulnerable populations.

Despite these limitations, the findings provide preliminary evidence supporting the feasibility of this intervention and suggest potential benefits for mental health outcomes, warranting further investigation in controlled studies.

Conclusions

This study aimed to assess the feasibility and effects of a telephone intervention on the mental health of women from agrarian reform communities in BrazilThe study results demonstrated high adherence to the program; however, illness and caregiving responsibilities were the primary barriers to completion.

Significant improvements were identified in reducing CMD symptoms and improving physical QoL. These findings reinforce the value of integrating low-intensity psychosocial interventions into PHC for underserved populations. In this context, nurses are particularly well-positioned to lead and expand these initiatives, given their strong community engagement and essential role in health promotion, especially within the Brazilian health system.

Future research should aim to design scalable and context-sensitive approaches, such as brief structured interventions or other remote delivery strategies, that enable public policies grounded in community engagement and capable of addressing structural inequalities that limit access to mental health care for women in rural areas or other vulnerable situations.

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Data Availability

The datasets generated and/or analyzed during this study are available from the corresponding author upon reasonable request. To access the full protocol and materials, please contact the first author.

Authors' Contributions

JLdO and JdS contributed to the study and research conception or design, data analysis and/or interpretation, and final review with critical and intellectual participation in the manuscript. JCPdA, JSG, AMA, AJCdP, and DS-A contributed to data analysis and/or interpretation and final review with critical and intellectual participation in the manuscript.

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Conflicts of Interest

None declared.

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Abbreviations

BHU: basic health unit
CMD: common mental disorder
GSE: General Perceived Self-Efficacy Scale
PHC: primary health care
QoL: quality of life
SRQ-20: Self-Reporting Questionnaire-20
SSQ: Sarason Social Support Questionnaire
TIDIeR: Template for Intervention Description and Replication
TREND: Transparent Reporting of Evaluations with Nonrandomized Designs
WHOQOL-BREF: World Health Organization Quality of Life abbreviated version

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Provider-Engaged Development of a Sexual Dysfunction Screening Approach for Adolescents and Young Adult Childhood Cancer Survivors: Iterative Co-Design Study

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Abstract

Background: Sexual dysfunction (SD) is common among childhood cancer survivors, affecting approximately 20% to 50% of patients. National guidelines recommend discussions about sexuality throughout cancer care, and prior work demonstrates patient interest in SD conversations. Despite its prevalence and importance, SD is widely underrecognized and undertreated, creating gaps in comprehensive whole-person care.

Objective: Our research aims to collaborate with provider partners to co-design an SD screening intervention prototype for implementation in a clinical oncology setting. This study outlines the co-design process to serve as a case study, highlighting challenges and strategies to achieve a consensus-driven intervention and implementation plan.

Methods: We engaged pediatric cancer providers in a series of co-design sessions at a National Cancer Institute–designated cancer center within an academic children's hospital. For each co-design session, the research team created a template outlining considerations from formative work (eg, patient privacy) and key decisions to be made (eg, screening modality). Co-design session moderators facilitated discussion, guiding participants toward a consensus decision for each intervention component. A final process mapping session reviewed and outlined the entire SD prototype. We conducted a rapid qualitative analysis, compiling a templated summary synthesizing and organizing findings by discussion topic and decision point. Based on co-design discussions, the research team compiled a menu of options outlining key thematic findings, core screening intervention functions, and intervention form options to allow for future expansion and tailoring of the SD prototype.

Results: Six provider participants, including attending physicians, advanced practice providers, and registered nurses representing multiple oncology subspecialty groups, engaged in a series of 5 co-design sessions. Participants assessed specific intervention component options, reached consensus on component decisions, and determined an intervention and implementation workflow for each. Throughout, providers needed to ensure workflows aligned with patient and provider priorities from foundational work and to ensure design feasibility, acceptability, and appropriateness. Key intervention and implementation decisions included target population, screening frequency, screening modality and workflow, management of screening results, clinic reminders and cues, and provider education and training. With several decisions being interconnected, there was often a cascade effect in which one decision influenced or limited future decisions and, in some cases, required revisiting prior decisions to ensure cohesive alignment into a single prototype. Co-design session moderators used several strategies (eg, reminders, redirection, providing information on feasibility, etc) to facilitate decision-making and implementation strategy selection.

Conclusions: Engaging provider partners in co-design sessions allowed for the collaborative development of a preliminary SD screening approach for adolescents and young adults with and surviving cancer. The dynamic co-design process and moderator strategies ensured that intervention and implementation decisions reflected the patient and provider priorities identified in prior work. Future work will test, adapt, and refine the prototype SD screening approach prior to effectiveness testing and eventual dissemination.

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KEYWORDS

pediatric cancer; sexual dysfunction; health services research; adolescent and young adult cancer survivors; dissemination and implementation science; user-centered design; co-design

Introduction

Background

Childhood cancer survivors are at risk for sexual dysfunction (SD) as a result of their cancer history and treatment [1-4]. Unfortunately, while SD affects between 20% and 50% of childhood cancer survivors, it is underrecognized and undertreated, leaving a gap in whole-person health care for these patients [1,2]. This unmet need exists despite national recommendations that sexual health, including sexual function, be addressed by oncology providers throughout the cancer care continuum [5-7]. Prior studies have identified numerous patient-level and provider-level barriers to SD communication, such as patient or provider discomfort and privacy concerns, which may be heightened in adolescent and young adult childhood cancer survivors [8-11]. Our prior research suggests that some of these barriers may be addressed through the use of standardized, patient-centered SD screening [9,11,12].

Unmet SD needs among adolescent and young adult childhood cancer survivors could be identified and addressed in pediatric oncology clinics, where patients are followed throughout and after treatment. Standardized, patient-centered SD screening could serve as the first step in ensuring appropriate sexual health care for this population. However, the routine use of patient-reported outcome measures is not common practice in pediatric oncology clinics, and barriers to implementation exist [13-15]. Additionally, SD in adolescent and young adult childhood cancer survivors can be a sensitive topic for both patients and clinicians unaccustomed to discussing this topic in oncology care [8,10,11]. These challenges are among several foreseeable barriers to the implementation of SD screening in this setting related to privacy, workflow, patient and provider buy-in, and more [9].

Study Frameworks: Context, Outcomes, and Process

To develop an implementable patient-centered SD screening approach, we applied implementation science and user-centered design principles in an active, collaborative, and iterative approach to intervention design and implementation [16-18]. Through our prior and current work, this process leveraged considerations of context (guided by the CFIR [Consolidated Framework for Implementation Research] [19]) and engagement of oncology clinic partners to co-design an SD screening approach. We aimed to develop an approach that would fit within the contexts of pediatric oncology clinics, with future goals of achieving high Reach, Effectiveness, Adoption, Implementation, and Maintenance (RE-AIM) [20,21]. The RE-AIM and CFIR frameworks have been used successfully in many fields to systematically assess the robustness of interventions across settings and patient subgroups, with attention to the potential for scaling up to additional settings.

To support future dissemination and implementation of SD screening in pediatric oncology care, this study sought to develop a flexible intervention and implementation plan that can be tailored to a variety of contexts and practice settings. To do so, we adopted the implementation science–grounded concepts of "functions" and "forms" of an intervention: functions being the fundamental purpose or desired effect of an intervention or implementation strategy and forms being the intervention or strategy details, components, and activities selected to achieve specified functions. To achieve functions, forms may vary based on contextual factors influencing implementation [22,23].

Across this multiphase project, we followed the Wisconsin Interventions for Team Science Framework, beginning with a discover phase followed by an iterative design-build-test phase for the prototype SD screening approach [16]. In the discover phase, we first engaged patients and then providers through qualitative interviews, guided by the CFIR, to elicit perspectives on SD screening in the pediatric oncology setting, including potential barriers and facilitators that might impact implementation success as defined by RE-AIM outcomes [9,11,12]. These initial studies verified the need for a standardized SD screening intervention, identified the key functions of an SD screening approach, and highlighted potential forms for intervention and implementation design [9,11,12,24]. Both patient and provider participants found the National Institutes of Health Patient-Reported Outcomes Measurement Information System (PROMIS) Sexual Function and Satisfaction v2.0 Brief v2.0 (SexFS Brief) tool to be acceptable for this population and favored its use in facilitating SD conversations [9,11,12,25-27]. This tool is available in versions for male and female patients and is validated in adult cancer populations [25-27]. Subsequently, the design phase of the SD screening approach development process used collaborative, iterative co-design sessions with a group of pediatric oncology providers.

We frame this paper as a case study of the development of a consensus-driven intervention and implementation plan for an SD screening approach using the SexFS Brief in pediatric oncology clinics. The methods and results of this paper describe our process for engaging prospective users to determine the forms of the SD screening approach comprising the resulting prototype. More contentious or difficult decisions are highlighted, accompanied by descriptions of strategies for arriving at consensus in these scenarios. We also provide details about the specific design considerations and decisions for our SD screening approach, which can be used in future research investigating its effectiveness and potential for wide-scale dissemination and implementation.

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Methods

Study Design

The intervention and implementation development process used a series of co-design sessions [28-32] with a multidisciplinary group of pediatric cancer providers (physicians, advanced practice providers, and nurses) to develop an SD screening approach using the SexFS Brief in pediatric oncology clinics. Co-design session content was informed by the prior discover phase, in which providers and patients shared their preferences and recommendations for SD screening in qualitative interviews [11,12]. With the goal of developing a prototype SD screening approach through collaborative decision-making, as opposed to idea generation or brainstorming and reflecting, we engaged the same group of provider participants throughout the iterative design phase, following user-centered design principles [17]. The results of this process (ie, functions and forms of the SD screening approach as well as themes defining the decision points during the development process) will be used in the build and test phases, aiming to refine and pilot test the implementation and effectiveness of the SD screening approach.

Ethical Considerations

All study procedures were reviewed and approved by the Colorado Multiple Institutional Review Board (20‐1679). Reporting follows the StaRI (Standards for Reporting Implementation Studies) guidelines, with the co-design process considered the implementation strategy [33]. All participants provided consent for their participation in this research at the beginning of the first co-design session. Upon completion of the 5 planned sessions, each participant received a US $100 gift card.

Study Site

This study was conducted at a National Cancer Institute-designated cancer center within a quaternary academic children's hospital in the western United States. The children's hospital is a referral center with approximately 27 oncology physicians treating over 300 patients with cancer each year, drawing from an 8-state catchment region. The patient population is largely non-Hispanic White, with approximately 45% insured by Medicaid.

Sample: Multidisciplinary Design Team

Participants for the design phase were purposively recruited from provider interviews conducted in the discover phase (N=25), exploring perspectives on the use of the SexFS Brief in pediatric oncology clinics [9]. Eligible individuals were the 25 discover phase pediatric oncology medical provider participants serving in any of the following roles: faculty physician, fellow physician, advanced practice provider, registered nurse serving as a nurse care coordinator, or medical assistant (MA). There were no exclusion criteria. Co-design sessions require substantial participant engagement and rely on thoughtful in-depth discussion; additionally, our design phase participants were expected to attend several sequential co-design sessions and ultimately arrive at consensus decisions. Therefore, consistent with other studies involving medical providers in the co-design of implementation strategies [32,34-36], we sought to engage a smaller total sample size of 6 to 8 highly engaged participants. Recruitment was completed on a rolling basis with targeted outreach to achieve variation by provider role and clinical team (ie, leukemia/lymphoma, central nervous system tumors, or solid tumor). In addition to the desired variation in clinical roles, the research team considered the depth of discover phase interview responses in determining the order in which to recruit eligible participants, aiming to balance variation in roles with demonstrated capacity to share perspectives. A total of 10 participants were approached, 9 expressed interest in participation, and 6 were selected for the final sample based on the alignment of schedules and ability to commit to all or nearly all co-design sessions. The final group of participants (n=6) who committed to attending planned co-design sessions included all provider roles except for MA and represented each clinical team.

Co-Design Session Procedures

Preparation

The study team (JD, JR, CRS) developed a template for each of the 5 planned sessions. The templates, informed by prior interviews with patients and providers, identified key intervention design and implementation decisions to be reviewed and discussed [9]. For each session, the data from previous patient and provider qualitative interviews were integrated to develop (1) a list of key decisions to be made; (2) a preliminary list of options and recommendations for each of these decisions, generated by the research team based on the prior interviews; and (3) overarching key considerations to be prioritized in decision-making (such as privacy and workflow). For example, the first co-design session focused on determining the target population and the modality for screening delivery. The key decisions regarding target population and modality, options and recommendations for these intervention and implementation components, and overarching considerations to prioritize during decision-making were summarized and displayed during the co-design session. Topics of each co-design session are provided in the *Results* section and Table 1.

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Table . Outline of co-design session content for the development of a sexual dysfunction (SD) screening approach[a].

Focus	Content
Session 1	
Background	• Overview of study purpose and process mapping • Overarching design considerations
Intervention	• Target patient population • Modality for screening delivery
Session 2	
Intervention	• Session 1 review • Screening workflow/timing • Results management plan (provider responsibilities) • Location of sexual dysfunction screening • EHR[b]-specific privacy issues
Session 3	
Intervention	• Session 2 review • Follow-up on unanswered logistical questions from session 2 (EHR capabilities) • Revisiting results management plan • Frequency of screening • Screening results storage
Implementation	• Introduction of screening to patients or families • Patient-centeredness opportunities (tailoring, choice) • Workflow or capacity constraints, scheduling opportunities
Session 4	
Implementation	• Session 3 review • Accountability/sustainability (reminders, guidelines, feedback) • Role of clinical champion, leadership team • Provider buy-in • Resource needs • Provider training • Patient education
Session 5	
Implementation	• Session 4 review • Updating or revisiting reminders, feedback, and patient education • Overview of complete prototype • Process mapping

[a]Outline of 5 co-design sessions which took place from December 2021 to February 2022. The table includes the focus of each session and the content and key decision points discussed in each. Each session included a review (session 1 review focused on overarching design considerations from prior findings) to ensure alignment with previous findings to facilitate creation of a single, streamlined prototype.

[b]EHR: electronic health record.

Session Structure

Five iterative co-design sessions were conducted via the Zoom video-conferencing platform with end-to-end encryption. Sessions were 60 minutes in length and were digitally recorded with participants' permission. Each session was moderated by JD, the principal investigator and a colleague of the participants. Sessions were observed and comoderated by JR, a trained qualitative analyst who collected detailed field notes and created summaries during and immediately after each session, grouping notes by topical discussion. In the event of a participant's absence, a member of the research team independently met with the participant to review the session summary and elicit that participant's insights.

Each co-design session focused on one or more topics informing the SD screening approach design or implementation. The first co-design session included an overview of the overarching goal of the project: to develop a patient-centered, feasible approach to standardized screening for SD in pediatric oncology patients, using key user input. The goal of the co-design process itself was also outlined, reminding participants that input was welcome across all roles and that they should aim to reach consensus about various decisions for the intervention and implementation design. Subsequent sessions began with a review

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of the prior session's results, serving both as a reminder and as member checking [37]. Topics were introduced along with relevant findings from interviews with providers and patients from the discover phase [9,11,12], with examples of how specific considerations identified in that phase could impact design. Each topic was then opened for discussion and concluded with consensus decision-making for a particular aspect of the SD screening approach. If consensus could not be reached or additional information was needed, the topic was revisited at a subsequent session. If a consensus was not reached after a topic was discussed in more than 2 sessions, the majority opinion was used for decision-making.

The final co-design session involved process mapping to finalize the entirety of the prototype SD screening approach. This session was also used to anticipate potential challenges, resource needs, and promising strategies for facilitating implementation success.

Data Collection

Demographic and professional characteristics were collected from participating providers through a brief background questionnaire during the discover phase. Audio recordings and field notes for each session served as qualitative data for analysis.

Analysis

This study used rapid qualitative analysis with a deductive-inductive approach, identifying key themes emerging from co-design sessions. The research team members who were engaged in the co-design sessions and qualitative analyses (JD and JR) practiced reflexivity throughout, including reflective discussions during post-session debriefs and collaborative analysis meetings. As biases of research team members were identified and noted, their potential effects on co-design facilitation and qualitative analyses were discussed with a team member (CS) who was not present at co-design sessions, was less immersed in data collection and analysis, and did not have clinical or research relationships with participants. Through this approach, alternative interpretations of the process and data through an implementation science lens were included to minimize the effects of bias on the research process. In addition, when the research team agreed internally about the potential feasibility of co-design decisions made by participants, strategies such as gathering and objectively presenting feasibility data were used to revisit decisions and ensure consideration from multiple perspectives (moderator strategies highlighted in the *Results* section).

After each co-design session, the co-moderator (JR) synthesized the data from field notes and audio recordings to develop a triangulated summary of the session. Summaries detailed the SD screening approach decision points discussed, including barriers, facilitators, potential solutions, variations in opinions expressed, and any consensus decisions that were made. The summary also included an assessment of the quality of the discussion (eg, participant insight, participation level, rapport, problems, line of questioning). After each session summary was developed, the research team (JD, JR, CRS) met to assess the accuracy and thoroughness of the session summary, referring to field notes and the audio recording as needed. This deductive-inductive approach allowed for organization by co-design discussion topics or decision points and the identification of expected themes based on the CFIR and on interviews conducted in the earlier discovery phase (eg, clinician discomfort discussing SD, relative priority of SD in the pediatric oncology setting) as well as emergent themes. The products of these analytic meetings were revised session summaries for each co-design session, organized by design decision. Session summaries were used to identify decision points characterized by little or no consensus among multidisciplinary design team members and those characterized by high levels of consensus. The results of each session's rapid qualitative analysis were integrated into the information provided during the next co-design session as a form of member checking, in addition to any clarifications or additional information requested by providers (eg, information about electronic health record [EHR] capability, details about privacy or confidentiality regulations).

Following the completion of the co-design sessions, the research team completed a modified function and form matrix [24], mapping (1) the key themes of discover phase patient and provider interviews, (2) the core functions of the co-designed SD screening approach and strategies to support its implementation, and (3) the forms (options for intervention content and delivery to meet the defined core functions of the screening approach) recommended in the co-design process. Implementation strategies were also mapped to the Expert Recommendations for Implementing Change compilation of 73 established implementation strategies [22,38]. The product of this part of the design phase was the prototype SD screening approach.

Results

Overview

The 4 co-design sessions and the process mapping session took place between December 2021 and February 2022. The 6 co-design provider participants are described in Table 2.

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Table . Co-design provider participant characteristics.

Characteristic	Participants, n (%)
Sex	
Female	6 (100)
Race or ethnicity	
White or non-Hispanic	5 (83)
Hispanic	1 (17)
Provider type	
Advanced practice provider	2 (33)
Attending physician	1 (17)
Registered nurse	3 (50)
Oncology subspecialty group	
Leukemia or lymphoma	3 (50)
CNS[a] tumors	1 (17)
Solid tumor (excluding CNS)	2 (33)

[a]CNS: central nervous system.

Four co-design sessions were attended by five participants, and one session was attended by four participants. The moderator (JD) met individually with absent participants following missed sessions to update them on the discussion and elicit their input. The content of each session is shown in Table 1.

The findings were organized into 2 major overarching categories consistent with the goals of the co-design process: intervention design and implementation strategy selection. Within intervention design, discussions focused on 7 decision components: target population for screening, introduction of the SD topic and the need for screening of patients, screening modality, workflow, timing and frequency, patient-specific or population-specific tailoring, and clinical management of SD screening results (Table 3).

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Table . Sexual dysfunction screening intervention design topics, considerations, and decisions[a].

Components	Design considerations	Site-specific plan
Target population		
Age or development	• Patient comfort • Acceptability • Laws or regulations	• Age >15 years
Patient status	• Acceptability	• All patients
Patient choice versus “mandatory”	• Patient comfort • Reach	• Choice to “opt out” of screening • Questions can be skipped
Introduction or patient education		
Initial introduction	• Interprovider variability • Workflow • Patient comfort	• Initial primary team education • Integrate into patient education • Integrate in fertility consultation
Re-introduction	• Patient comfort • Feasibility and workflow	• Verbally explain at administration • Explanation written on tool
Screening modality		
Written versus verbal	• Patient or provider comfort • Workflow • Future access	• Written
Paper versus electronic	• Patient comfort • Confidentiality • Workflow • Future access	• Electronic
Electronic modality	• Fidelity • Confidentiality or privacy • Workflow • Future access	• EHR[b]: tablet in clinic with automatic trigger when screening is due
Workflow		
Screening timing	• Patient comfort • Fidelity or reach • Workflow integration	• During regular visit
Physical location	• Patient comfort • Privacy • Workflow constraints	• Exam room
Workflow for in-clinic	• Patient comfort • Privacy • Workflow constraints	• Room patient separately from parent
Screening timing		
Frequency	• Flexibility or window of time • Patient comfort • Feasibility	• Maximum of every 3 months (flexible if patient in clinic less often) • EHR-based automatic triggers
Initiation of screening	• Patient comfort • Relative priority	• Initiate 1 month after diagnosis
Tailoring delivery		
Language	• Patient comfort • Validity of screening • Feasibility (timing)	• Verbal screening unless translation becomes available

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Components	Design considerations	Site-specific plan
Cognitive impairment	• Patient comfort • Feasibility (time)	• Provider appropriateness discussions • If appropriate, verbal screening
Sexual function management		
Which provider	• Knowledge and comfort • Standardization • Capacity and workflow • Patient comfort or rapport	• Dedicated sexual health team with representatives across clinical teams (liquid tumor, solid tumor, neuro-oncology, survivorship)
Timing of SF[c] discussion	• Feasibility constraints • Risk loss-to-follow-up	• Same visit with telehealth as back-up • Consider adding time to appointments
Results storage (EHR)	• Confidentiality • Workflow (future access)	• Results in flowsheets • Documentation as minor consent note • No limits on provider access

[a]This table highlights key intervention topics, considerations, and decisions made throughout the co-design process for the development of a sexual dysfunction screening intervention. Organized by topic (eg, target population), we present intervention components requiring design decisions, design considerations for both providers delivering as well as patients receiving the intervention, and the site-specific plan determined by group consensus.

[b]EHR: electronic health record.

[c]SF: sexual function.

Within the implementation strategy selection, discussions addressed ways to increase clinician acceptability, buy-in, and adoption of the SD screening approach, including reminders, provider education, resources, and ongoing involvement in design, implementation, and adaptation (Table 4).

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Table . Sexual dysfunction screening approach implementation strategy topics, options, and decisions[a].

Component (implementation target)			
Subcomponent	Implementation options	Implementation plan	Rationale for initial plan
Reminders (reach, adoption, implementation/fidelity, sustainability)			
Written	• EHR[b]-based automatic triggers • Dedicated team monitors when due • EHR-based (BPAs[c], blue sticky notes) • Paper-based or existing clinic documents	• EHR-based questionnaire automatically triggers	• Feasibility • Integration into workflow • Standardization and sustainability (not reliant on team member initiation) • Minimal notification fatigue
Verbal	• Clinical champions	• Project lead • Dedicated team	• Someone leading implementation efforts • Point person for questions or concerns • Verbal reminders beneficial
Auditing and feedback	• Regular updates on screening rates • Notification of missed screening	• No auditing	• Feasibility • Notification fatigue
Provider education (effectiveness, adoption, implementation [acceptability, appropriateness])			
Modality	• Emails • Educational materials • Presentations and meetings • Online modules	• Meetings with faculty or nurses • Written resources • Online modules	• Multimodal education for increased exposure and variable learning styles
Content	• In depth versus overview	• Tailored to role • Emphasize patient desire for SF[d] screening • Explain need	• Tailoring education to the role is feasible and acceptable • Different roles have different needs and backgrounds
Who	• Only dedicated team members • All providers	• All providers receive some education • In-depth dedicated team training	• Feasibility: balance provider capacity with need for base knowledge across all providers
Provider resources (effectiveness, reach, adoption, implementation [acceptability, appropriateness])			
Written	• Evidence-based clinical decision-making tools • Referral guides or work-up flow diagram	• Evaluation or referral flow diagram	• Practical clinical resources guide decision making, address knowledge barriers, promote retention
Personnel	• Development of clinical team • Established specialist partnerships	• Development of clinical team • Establish specialist partnerships	• Reduces variability in knowledge and prioritization • Promotes referral and involvement of SF experts
Intervention design (effectiveness, reach, adoption, implementation [acceptability, feasibility])			
Planning	• Partner involvement intervention component selection and implementation planning	• Involve key partners (providers, patients, clinical leadership, RNs[e], MAs[f])	• Design intervention to fit clinical setting • Buy-in more likely if key partners involved from beginning
Iteration or scale-up or stage	• Optional stage	• Start in small setting and scale up over time (PDSA[g] cycles)	• Allow for adjustments to unforeseen challenges

[a]This table outlines key implementation topics, options, and decisions throughout the co-design process. Organized by overarching implementation components, we include options for implementation, the consensus-driven implementation plan, and the rationale for these.

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[b]EHR: electronic health record.
[c]BPA: best practice alert.
[d]SF: sexual function.
[e]RN: registered nurse.
[f]MA: medical assistant.
[g]PDSA: Plan-Do-Study-Act.

With myriad potential decisions and multiple forms available for each function of the screening approach and implementation strategies, it was important to understand how decisions would impact each other. In several instances, a cascade effect in decision-making was evident in which one decision influenced and often limited options for future decisions. Throughout the iterative process, there was a need for the co-design session moderators to remind participants of the overarching considerations guiding intervention design (eg, patient privacy and comfort) and the implications of decisions made in earlier sessions as the process progressed. Below, the decision points and process for selecting intervention components and implementation strategies are described, concluding with identified strategies used by the moderator and co-moderator in facilitating discussion and consensus-building in co-design sessions.

Intervention Design

Overview

Several intervention design decisions were reached easily during the co-design sessions, including the target population, how and when to introduce SD screening to patients, timing and frequency of screening, and how to tailor SD screening to individual patients, allowing for patient choice and flexibility in unique situations (Table 3). However, other decisions required a more iterative approach and, at times, discussions over multiple sessions. These decisions, and how the research team facilitated the co-design process, are described below.

Screening Modality and Workflow

Discussion Summary

Much of the discussion on screening modality (eg, written vs verbal, electronic vs paper) centered on key considerations of patient privacy and comfort. Participants considered the possibility of multiple delivery modalities or allowing patients to choose their preferred modality. These decisions were recognized as highly dependent on and interrelated with other decisions such as timing around visits and the location of SD screening. For example, if participants agreed that screening should take place at home prior to a clinic visit, that would limit screening modality options to a survey administered through the patient portal or sent to a patient's email. Additionally, discussions around screening modality were inherently integrated with considerations related to privacy, tracking screening responses over time, and the ability to easily share results with specialists and consultants. To support discussion and decision-making, the moderator gathered additional information about the EHR patient portal between co-design sessions, particularly related to patient privacy concerns. After learning that the EHR patient portal used in their health system was incapable of restricting questionnaires to patients (vs their guardians), participants determined that screening through the EHR patient portal was not an acceptable approach.

After further integrated discussions about modality, timing, and location of screening, participants reached a consensus decision that prioritized privacy, patient comfort, and screening results storage over workflow. Participants believed the best approach was to use an EHR feature for private in-clinic screening once a patient checked in for an appointment. To accommodate this approach, participants identified a need for a new workflow in which adolescent and young adult patients would be brought into the exam room alone by the MA to allow for privacy during screening completion, with guardians brought back afterward. Beyond SD screening, participants believed that independent rooming of adolescent and young adult patients would be beneficial to optimize their health care and promote health independence.

Strategies to Facilitate Decision-Making

To reach consensus on screening modality and workflow, the research team collected and provided additional information to support decision-making (eg, on EHR capabilities as described above), reminded participants of key considerations identified in the discover phase (ie, privacy, comfort, workflow), and redirected conversations and preliminary decisions when in conflict with prior research findings. For example, in an early co-design session, participants identified the clinic waiting room as a potential location for screening; however, this directly conflicted with numerous patients' explicit recommendations that screening should *not* occur in the waiting room. Reminding provider participants of these findings resulted in successful redirection.

Management of Screening Results

Discussion Summary

Determination of which provider or providers would be responsible for following up on SD screening results, including speaking with the patient and developing a clinical management plan, was discussed extensively over 2 sessions prior to arriving at a consensus decision. In the discover phase, provider interviews yielded variable recommendations for who should manage SD screening results [9]: the provider seeing the patient on the day of screening, the patient's primary oncology team, a separate dedicated SD person or team, an external specialist, or a dedicated person within the patient's oncology team (Table 3). Initially, there were mixed opinions across the co-design group on the best approach. Participants were reminded of prior findings including the importance of patient-provider rapport and provider expertise, as well as previously identified barriers such as variation in the relative importance or priority of SD screening between providers and limited time or capacity. Participants were also re-oriented to principles of standardization

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and sustainability when considering the best approach. After initial discussions, participants determined that each clinical oncology team (ie, liquid, solid, neuro-oncology) should have a designated individual responsible for following up on results. One participant, who had assumed a leadership role within group discussions, expressed concerns about the feasibility of a single provider being responsible for SD management. Sharing these concerns, the research team gathered additional data regarding the estimated number of screening events per team per year. This additional information served to educate and redirect the working group, who agreed that this would be too burdensome for an individual provider and that each subspecialty team should have a sexual health team of 3 to 4 individuals instead. Once consensus was reached, participants were encouraged to consider any challenges related to rapport, workflow, and scheduling. Following discussion of these challenges, participants agreed that each sexual health team should be made up of the providers who are most often available in the clinic (eg, nurses, advanced practice providers).

Strategies to Facilitate Decision-Making

To reach consensus on SD screening result management, the research team gathered additional information (eg, estimated number of screening events per clinic) to support providers in reaching an informed consensus. Research team members provided guidance on decision practicality; re-oriented participants about prior study findings (patient preference for rapport); and reminded participants to consider the goals of feasibility, scalability, and sustainability in reaching their decisions.

Implementation Strategy Selection

In addition to discussing the specifics of SD screening delivery and clinical management, the co-design participants considered implementation strategies aimed at optimizing provider buy-in, reach, adoption, scalability, and sustainability. The moderator and co-moderator introduced these co-design session topics by integrating prior qualitative interview results with information about established implementation strategies [39].

Reminders and Cues

Co-design participants discussed several implementation strategies to support standardization and, subsequently, scalability, reach, and adoption. Strategies included the use of automated EHR–based reminders and the modification of existing paper-based patient care documents (such as chemotherapy "roadmaps") (Table 4) [9]. Participants determined that the latter approach, which would rely on additional effort by individual members of the medical team, was not feasible or sustainable. Participants agreed that relying on technology-based reminders would be ideal but were uncertain about what EHR-based options were available and were concerned about reminder or pop-up fatigue. After receiving more information about EHR capabilities, participants determined that building EHR-based rules for triggering the questionnaire as "due" was ideal.

Based on both established implementation science strategies and suggestions mentioned in provider interviews, the research team also initiated a discussion about the use of "audit and feedback" or tracking benchmarks for individual provider or team success. Participants were not enthusiastic about the development of benchmarks for implementation success, nor the use of audit and feedback to monitor the use of the SD screening approach with patients.

Education and Training

Discussion Summary

As in our discover phase interviews, participants acknowledged the importance of provider buy-in for implementation success. They agreed that increasing provider knowledge about SD and its importance for the pediatric oncology population, increasing provider knowledge of the screening intervention, and increasing provider self-efficacy in managing SD would facilitate provider buy-in. One key recommendation from the co-design participants was that while all providers should receive education and training, different types and depths of education and training should be developed for different individuals to align with their roles and intervention involvement (eg, MAs, sexual health team members, and nurses and providers taking care of the patient but not directly involved in SD screening or follow-up). Participants recommended varied training formats, including in-person training with role-play, online training, and easily accessible written resources.

Strategies to Facilitate Selection of Implementation Strategies

To facilitate decision-making regarding implementation strategies, the research team integrated prior findings into co-design sessions to support and supplement participant-brainstormed approaches. Additional information was gathered between sessions (EHR capabilities) and relayed back to the working group to clarify and confirm potential implementation options.

Process Mapping Session

The primary focus of this session was a process mapping exercise outlining consensus-driven decisions from the intervention start (patient education about SD and screening approach) to completion (management of identified SD needs). In the preparation for this session, the research team compiled all decisions made in prior sessions into a process diagram (Figure 1), used to guide the discussion of every aspect of the SD screening approach.

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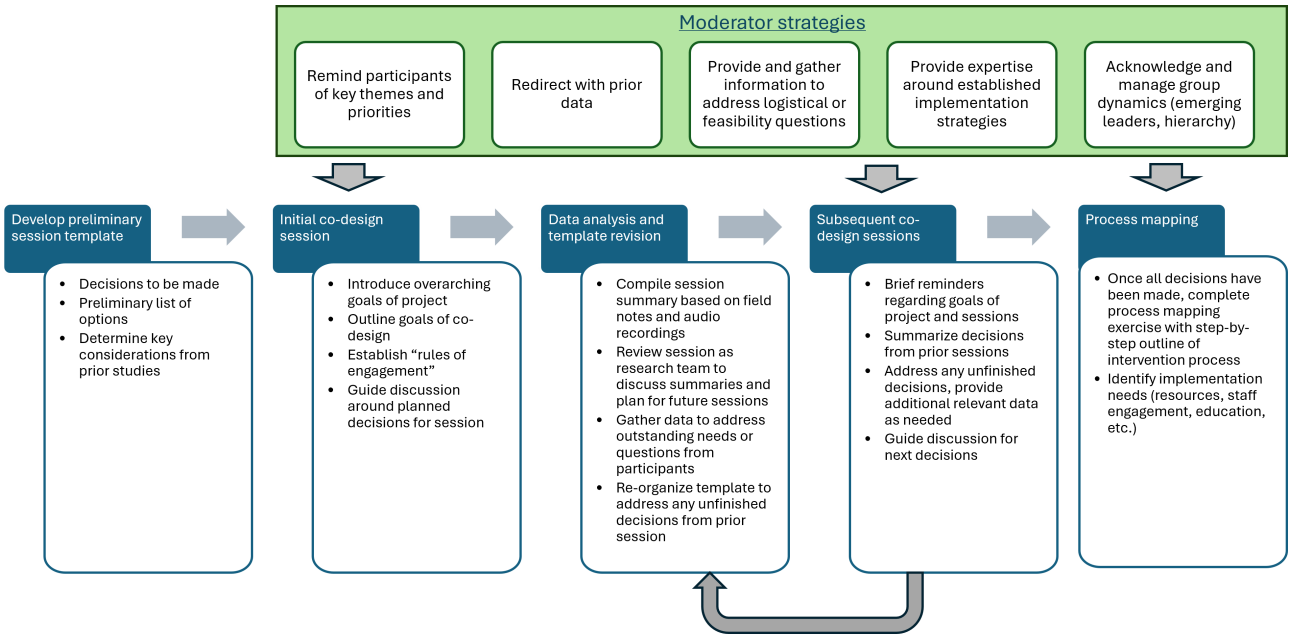
Figure 1. Co-design process for development of the sexual dysfunction screening intervention and implementation approach. To develop the sexual dysfunction screening approach, iterative co-design steps were completed over multiple sessions, culminating in a process mapping session. Moderator strategies were used to facilitate consensus-building and the development of a feasible, appropriate, and acceptable intervention prototype.



This process helped to identify additional issues, such as potential variability in patient education at the time of diagnosis and the importance of delaying the first screening so as not to screen patients on their first visit to the oncology clinic (Table 3). Additional potentially helpful implementation strategies were identified, such as the integration of a notification system, for the clinical team upon screening completion and the development of note templates for uniform documentation of sexual health team discussions.

Discussion

Through the engagement of provider partners, we developed a user-informed SD screening intervention and implementation prototype for adolescent and young adult childhood cancer survivors. This prototype specifically addresses previously identified barriers to successful SD screening (eg, patient or provider comfort) and prioritizes patients' preferences and needs (eg, patient privacy). Figure 1 demonstrates the final co-design process, which was built on user-centered design methods with the goal of developing a preliminarily acceptable, feasible, scalable, and sustainable standardized SD screening approach. This process evolved, becoming more iterative and dynamic to meet participants' needs for consensus-building. This study describes our iterative co-design method comprising the design phase of the over-arching discover-design-build-test process, which encouraged end users (providers) to integrate our prior discovery data with their own experiences, opinions, and clinical expertise and collaborate in a consensus-driven approach [16]. Consensus decisions were tailored to the context with the goal of improved alignment of needs, preferences, and workflows. This study highlights challenging decisions and co-design moderator strategies for guiding the co-design participants to consensus, providing a case study of this process. Importantly, the decisions, or "forms" of the intervention, made by participants are specific to the unique clinic setting but will remain flexible when the overall intervention design is adapted for implementation in other contexts [22,23].

Our user-centered design approach shares many characteristics with other collaborative dissemination and implementation science methods, including the use of focus groups, nominal group technique, and the Delphi method [28,29,40-44]. Each of these methods, along with user-centered design, offers a structured approach to idea generation, problem solving, and decision-making [45]. For this study, the user-centered design approach allowed us to iteratively adapt an SD screening intervention in collaboration with end users who will be responsible for or involved in intervention delivery. With the participation of providers possessing actionable insights regarding the patient population being served and the specifics of clinic workflow, co-design sessions aimed to develop an acceptable, feasible, scalable, and sustainable standardized prototype.

The importance of using an interactive iterative process was emphasized by our experiences in several of the co-design discussions wherein a decision regarding a particular intervention component or implementation strategy was later changed based on a subsequent decision. In this dynamic process, considering the full SD screening approach as a system rather than as a set of independent components was essential. While more structured methods, such as the nominal group technique and the Delphi method, may provide more assurance of equal input between participants, our process allowed for interactive and dynamic collaboration [46]. The co-design process and consensus-building aimed to achieve a middle ground among participants where decisions were collective and found to be satisfactory; this middle ground often meant that some identified needs were prioritized above others. While participants often made efforts to prioritize previously established design considerations (eg, privacy, comfort, workflow), at times the research team had to remind the group

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of their importance. Ultimately, the final prototype did affect workflow by requiring the development of a new patient rooming approach; this was discussed extensively over multiple sessions prior to arriving at this decision, with the goal of optimizing patient privacy, comfort, and sustainability while also promoting patient independence and self-advocacy.

Lazo-Porras et al [47] describe challenges associated with co-creation, including the need for the research team to obtain skills in facilitation and the risk of participants generating ideas that are not feasible, too specific, or out of scope. Through the conduct of our co-design project, we identified several strategies that may be used to facilitate discussion, consensus-building, and feasibility [47]. Specifically, the research team used strategies including (1) reminding participants of prior key research findings and key functions of the intervention; (2) redirecting when decisions were in conflict with these or with prior decisions; (3) gathering of feasibility data and answers to logistical questions; (4) providing information to support decisions, particularly related to internal or external policies or laws; and (5) and ensuring all participant voices were heard and valued across clinic roles [48]. Lazo-Porras et al [47] also identified the importance of careful selection of participants with diverse views, which we attempted to achieve by recruiting across roles and teams, and the use of an advisory board, which was beyond the scope of this work.

Additionally, group dynamics played a key role in the co-design process [48]. The research team noted that while all participants agreed on the importance of the intervention, several participants were particularly motivated to advocate for the intervention and think pragmatically to develop a feasible and sustainable approach. These participants emerged as informal group leaders and often served as “voices of reason” when considering various design forms. Importantly, these informal leaders did not follow the traditional medical professional hierarchy. Serving in a different role, another participant regularly identified subset populations for which the SD screening approach might be more difficult (eg, cognitively impaired, non-English reading), encouraging the group to consider these important scenarios. At times, the participants who emerged as informal “leaders” intervened to encourage the group to prioritize developing an SD screening approach that would work for “most” patients and situations. Notably, group formats have the risk of allowing for uneven participation and representation across roles, but this was not observed by the research team. Finally, there were times when the group did not reach consensus; in these scenarios, participants naturally defaulted to a “majority rules” approach for decision-making.

There are several limitations to our co-design approach. First, our participant demographics were not diverse; only female providers agreed to participate, and nearly all were White. It is possible that male and female participants may have different levels of comfort with discussing SD with adolescent and young adults, particularly of the opposite sex; this could impact participant recommendations for implementing SD screening. In the discover phase qualitative interviews, a few participants suggested attempting to match patient-provider sex for this reason [9,11]. During process mapping, some participants agreed that this would be ideal but challenging to implement. Second, our group lacked MAs, none of whom expressed interest in participating. Because MAs often serve a key role in administering patient questionnaires (such as those included in the developed prototype intervention), their involvement will be imperative as the prototype is implemented, tested, and revised. Third, our recruitment focused on frontline medical team members; involvement of clinical leaders may have resulted in additional insights about potential barriers and may have secured buy-in from this key group to facilitate future implementation [47,49]. Engagement of multilevel stakeholders and clinical leaders is recommended in implementation planning [22,38], and next steps in our research program will require engagement of clinical leaders who may feel ownership of clinic practices [50]. Fourth, our process engaged only 6 participants. While this sample size is small, we found it to be appropriate given that our methodology relied on robust participant engagement and consensus building over multiple co-design sessions, processes that are less feasible with larger groups [51]. Importantly, significant variability in the conduct and reporting of co-design processes [30-32,34] has hindered the identification of ideal sample sizes, with some engaging as few as 3 providers; as our program of research continues, the results of our co-designed intervention and implementation strategies will provide additional data to inform this decision. Finally, co-creation team composition was likely affected by self-selection bias, with those who declined to participate possibly being less enthusiastic or more skeptical about the use of standardized SD screening. Their input will be critical in the upcoming build and test phases.

Despite these limitations, the use of iterative co-design groups enabled the collaborative development of a preliminary SD screening approach for adolescent and young adult childhood cancer survivors. This approach not only used providers’ expertise but also integrated prior data from patients and providers to inform design decisions. Judicious use of moderation techniques ensured that patient preferences, feasibility, scalability, and sustainability remained front of mind as providers reached decisions about the screening intervention components and selected key implementation strategies to finalize the screening approach prototype. In the next phase of research, the prototype SD screening approach will undergo multistep testing and adaptation in small cycles. These real-world cycles are expected to identify unforeseen barriers and inform refinements to the prototype in preparation for effectiveness testing and the eventual dissemination of the intervention.

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Generative artificial intelligence tools were not used at any stage of the study.

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Data Availability

The datasets used and/or analyzed during this study are not publicly available but are available from the corresponding author upon reasonable request.

Authors' Contributions

JD is the principal investigator for this research and is responsible for the overall conception and study design, data collection, analysis, and writing of the manuscript. JR supported data collection, analysis, and manuscript writing and revision. EJC and PNP provided mentorship and supported study design and conception. BD supported the qualitative study design. CRS is the primary mentor, supporting study design and overseeing data collection and analysis. CRS provided dissemination and implementation science expertise and supported manuscript writing. All authors read, revised, and approved the final manuscript.

Conflicts of Interest

None declared.

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Abbreviations

CFIR: Consolidated Framework for Implementation Research
EHR: electronic health record
MA: medical assistant
RE-AIM: Reach, Effectiveness, Adoption, Implementation, and Maintenance
SD: sexual dysfunction
SexFS: Brief Sexual Function and Satisfaction v2.0 tool
StaRI: Standards for Reporting Implementation Studies

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Rangatahi Youth-Led Dissemination Campaign for Cocreated Eating and Well-Being Guidelines: Process and Pilot Implementation Evaluation

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Abstract

Background: Youth should be partners in the development and dissemination of health information created for their demographic. The Manaora Rangatahi (youth) Guidelines comprise 10 eating and 10 wellbeing messages that were cocreated with rangatahi Māori (Māori youth) in Hawke's Bay, New Zealand, and then disseminated through a digital media campaign.

Objective: This study aimed to present the process evaluation of the co-design and implementation of the pilot digital media dissemination campaign of the Manaora Rangatahi Guidelines.

Methods: The 17 rangatahi who were involved in the cocreation of the guidelines codeveloped a dissemination plan, filmed video clips for each of the 20 messages, and supported the 20-week digital media campaign. The codevelopment process over 4 wānanga (workshops) is described and critiqued, and the implementation was assessed using the data analytics from Instagram and TikTok, the main social media platforms for dissemination. The rangatahi participated in a short postcampaign review survey.

Results: The dissemination plan included a website for the messages, a campaign name and logo, apparel with messaging and QR codes, and the design of a digital media campaign featuring the participating rangatahi. Video clips of each of the guideline messages featuring the rangatahi were professionally developed with support from 3 Māori influencers and a video production company. The 10 phases of the campaign involved the release of 2 messages (one eating and one wellbeing) every fortnight over 20 weeks. Instagram and TikTok analytics showed that the campaign achieved >1.48 million impressions and >19,000 engagement actions (eg, likes, comments, and sharing). The mean engagement rate (Instagram 6.2%, TikTok 1.2%) was greater than or similar to the platforms' medians across all industries (0.36% and 1.73%, respectively). Various paid promotion strategies boosted the number of impressions, and paying one of the influencers to promote the messages in phase 8 created a more than 10-fold increase in impressions on Instagram. The estimated cost of the overall campaign was NZ $125,000 (US $72,500). The majority (about 60%) of rangatahi felt the campaign was successful and engaging.

Conclusions: Rangatahi have expert knowledge in how to disseminate messages to their peers. They successfully co-designed and pilot-tested the implementation of a low-cost digital media campaign using peer-to-peer messaging and videos, which achieved substantial reach. The dissemination reach was good, but was significantly influenced by paid promotions. The cost per thousand impressions was equivalent to or better than much larger government-funded health promotion social media campaigns targeting youth. The development and dissemination of eating and well-being messages aimed at youth should ideally involve partnering with the target audience to enhance the relevance and reach of the messages. A well-funded dissemination campaign with paid promotions through influencers and digital platforms could expect to achieve substantial awareness of the messages.

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KEYWORDS

youth co-design; rangatahi; social media campaign; dissemination; health guidelines; youth-led campaign; health advocacy

Introduction

The development and dissemination of health and well-being guidelines have typically occurred through a top-down approach by government organizations with minimal input from their target audiences. This approach can be problematic, particularly if resulting materials fail to resonate with the target population and partnership approaches during guideline development and dissemination are rare [1-3].

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Dissemination of health guidelines has typically been poorly funded. Websites, pamphlets, and web-based resources for professionals are a common, low-cost approach, but these are likely to have limited effectiveness in reaching young audiences. Major mass media-led health campaigns, which were well-funded, like the United Kingdom's Change4Life [4] and Australia's LiveLighter [5], targeting adults, can achieve widespread campaign awareness, although with small self-reported changes in behaviors [6,7]. The advent of digital media platforms has meant that dissemination campaigns using social media platforms are lower cost than paid broadcast media, can achieve wide reach, and show some promise in changing behaviors [8,9]. Youth are receptive to the use of digital health promotion [10], and campaigns targeting youth now commonly use digital platforms with promising results for increased awareness, although assessing behavior changes from such campaigns is challenging [11].

Indigenous youth face further challenges as health promotion messages and guidelines typically lack cultural relevance. Traditional knowledge and cultural connections are fundamental for the well-being of Indigenous youth [12-14], but this is not often expressed in health guidelines or dissemination pathways. In Aotearoa New Zealand, there are consistent disparities in health outcomes between Pākehā (NZ European) and Māori populations [15]. Eurocentric, biomedical approaches to health communication are doing little to reduce these disparities. Attempts to design health interventions for Māori rarely extend to partnership, let alone full design by Māori. Alternative, particularly Indigenous, interpretations of health and wellbeing are uncommon [16].

The co-design of health communications to inform healthy behaviors has led to an increased relevance and uptake by the intended end users [17]. Further, health communication campaigns are more successful if they include the cultural characteristics, belief systems, life experiences, and values of the target audience [18,19]. This approach enhances audience receptivity, message acceptance, and salience of information, leading to increased audience buy-in [20,21]. Commentators note that the active involvement of target audiences in the planning and creation of health messaging increases the inclusion of cultural characteristics and may also allow capitalization of pre-existing social networks [20,22].

In NZ, healthy eating guidelines for youth were initially developed by the NZ government in 2012 and updated in October 2021 [23]. Although web-based resources and pamphlets relating to these exist, they are not actively disseminated. Similarly, wellbeing guidelines for youth covering areas such as physical activity and sleep have been developed but are not actively disseminated [24]. Such passive approaches to dissemination mean that the impacts of these resources on the health and well-being of NZ youth are unlikely to be of any significance.

Social media platforms, such as TikTok and Instagram, have become integral to youth communication and information-seeking, with 87% of teens using these platforms to seek health information [25] and 37.8% of teens seeking information on fitness and nutrition [26]. These platforms offer unique advantages for health communication, including peer-to-peer interactions that enable knowledge exchange within established social circles. This positions the audience as active participants in the dissemination process, rather than passive recipients [20,22,27,28].

Studies are needed to address these shortcomings by working with youth to co-design messages with cultural relevance and meaning and disseminate them on the social media platforms youth already engage with and using peer-to-peer networks.

Acknowledging the need for culturally relevant and youth-created health guidelines, the Manaora Rangatahi Eating and Wellbeing Guidelines (Manaora Guidelines) project was developed with the aim of improving upon the current NZ Ministry of Health nutrition [23] and physical activity [24] guidelines for youth, especially rangatahi Māori (Māori youth). The project was in 2 parts: the cocreation of a set of eating and wellbeing guidelines, and the cocreation and implementation of a dissemination plan for these guidelines targeting youth.

The Manaora Guidelines (Figure 1) were cocreated with 17 rangatahi Māori from 4 schools in Hawke's Bay, NZ, over several wānanga (workshops) held at a marae (traditional Māori meeting place). The approach used ensured that rangatahi were positioned as active creators rather than passive recipients of the health messages, using both scientific evidence and mātauranga Māori (traditional Māori knowledge) in the guideline creation. The resulting rangatahi-created guidelines consisted of 20 messages (10 eating and 10 wellbeing) that use invitational rather than prescriptive language (eg, "Let's try to…) and acknowledge the journey that young people may face in adopting the guideline messages. A distinguishing feature of these guidelines is their integration of Te Ao Māori (Māori worldview) concepts, as shown by the incorporation of terms like mauri (life force), whānau (family), and tūrangawaewae (a place to stand) into several messages and the use of te reo Māori (Māori language) throughout. These guidelines further extend traditional health recommendations by addressing contemporary concerns such as sustainability, digital well-being, and social connections and end with an inspirational whakataukī (proverb). The guidelines were peer-reviewed by 94 rangatahi in structured feedback sessions, and the full process of the creation of the guidelines is described elsewhere [29].

The aims of this paper are to present the process evaluation of the codevelopment and implementation of a pilot digital media campaign developed to disseminate the Manaora Guidelines. In other words, how well did the partnership approach with youth work, and what level of engagement through Instagram and TikTok could the campaign achieve?

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Figure 1. The Manaora Rangatahi Guidelines for eating and well-being. Mauri is life force, whānau is family, tūrangawaewae is a place to stand.

Methods

Overview

The 17 rangatahi who cocreated the Manaora Guidelines (Figure 1) participated in this dissemination component. Principals from Hawke's Bay schools with high Māori student rolls (n=15) were invited to offer Year 12 students (16 to 17 year olds) the opportunity to participate in this rangatahi guidelines project. A total of 17 students (6 males, 11 females, 16 Māori, 1 non-Māori) from 4 schools agreed to participate in the cocreation of the guidelines [29].

This paper presents the dissemination plan and digital media campaign, which were developed in stages over 4 wānanga with the same 17 rangatahi who cocreated the guidelines. The first stage involved the co-development of the dissemination plan. Stage 2 consisted of the creation of materials, including the shooting of the videos for each message. Stage 3 involved the implementation of the digital media campaign, which was launched in March 2024 with a 2-week run-in period and 20 weeks of the campaign. Stage 4 involved a postcampaign review. All wānanga were held at the Houngarea marae in Hawke's Bay.

Planning

The first stage was a wānanga held over 3 days in November 2023. The dissemination planning process consisted of a series of presentations by senior researchers on the basic principles of social marketing and health and well-being message dissemination for personal and community benefits. Exemplars of various campaigns were presented, and aspects of each campaign that generated audience engagement and influenced consumer perception of a product or behavior were discussed. The planned nature of a communications campaign was also discussed, including the need to be very clear about the objective of the campaign, the strategies used, the style and "feel" of the delivery, the nature of the messages, and the measures of success.

While social marketing is underpinned by many theoretical models, the project colead (BS, public health physician) focused primarily on the exchange theory [30] and the stages of change transtheoretical model [31]. Commercial marketing, with which participants were very familiar, was explained in terms of its basic 4P model (product, price, placement, and promotion), and then, using existing campaigns as a guide, the parallels with social marketing were made. Exercises identifying the "exchange value" in the "products" of both commercial and social marketing helped to show how these exchanges needed to be explicit. Indeed, the structure of the wording in the guidelines made these exchanges explicit. For example, "Let's build the mauri (life force) or our whānau (family) by helping with meals, eating together, and supporting each other's health" encompasses both the costs (helping out) and the social and health benefits. An exercise reflecting on their own willingness to enact some of the guidelines showed that many rangatahi were in the early stages of change.

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The participants had considerable lived experience of social media platforms and understood the potential for viral peer-to-peer communication and influencer boosting to disseminate messages. The concepts and theories of social networking as they apply to marketing are well articulated, although the characteristics of "virality" are still being uncovered [32].

The process used allowed the rangatahi to incorporate mātauranga Māori (traditional Māori knowledge) into the guidelines and the dissemination and implementation plan. Project colead (DTL) has extensive knowledge of mātauranga Māori, and he guided the participants on these issues throughout the original development of the guidelines and this process of dissemination planning and implementation. The rangatahi were all familiar with many aspects of tikanga Māori (Māori processes), and they led many of the aspects of the work. For example, they created the name of the guidelines, conceptualized the Māori images for the logo and branding of materials, came up with many of the ideas for the videos, and starred in all the video clips.

Small group discussions were used to brainstorm potential dissemination methods from the rangatahi. A follow-on discussion covered the campaign branding and content style of a digital media campaign. By the end of this wānanga, a draft dissemination plan had been developed, including an outline of a digital media campaign, including video outlines.

Development of Materials

The draft outlines for each video developed at the wānanga were converted into scripts through discussions between the research team and the local Māori production company used to produce the videos. The scripts were also circulated to the rangatahi group for their feedback. A further 3-day wānanga was held in January 2024, focusing primarily on the creation of video content for the social media campaign. Three Māori social media influencers suggested by the rangatahi group, and popular with youth in NZ, were contracted to attend the wānanga and participate in the filming. These influencers had a combined reach of more than 385,000 accounts across TikTok and Instagram, with professional backgrounds ranging from full-time content creation on social media platforms to mainstream television hosting of Māori-centered programs.

Over the 3 days, the rangatahi, influencers, production team, and research team reviewed and revised the scripts and altered filming plans to fit the visions of the rangatahi. Collaboration between researchers, rangatahi, influencers, and filmmakers during this process ensured meaningful and relevant video materials for the campaign. The filming of the 20 messages from the Manaora Guidelines occurred at the marae and at various well-known Hawke's Bay locations. The Māori production company did the filming and postproduction of the videos for the campaign.

Implementation and Dissemination

The third stage consisted of the digital media campaign as devised by the rangatahi. This was implemented over a 22-week period running from February to July 2024. Further details on the campaign can be found below. The degree of dissemination was assessed using the data analytics provided by Instagram and TikTok. In particular, the main indicators were "impressions," which is how many times the video was viewed or partly viewed, and "engagement rate," which is the number of engagements divided by the number of impressions, expressed as a percentage. Instagram uses the term "interactions" which is akin to TikTok's "engagement," both meaning actions such as liking, commenting, sharing, downloading, and clicking on links.

Postdissemination Review

The fourth stage was held on one day in July 2024 and consisted of a review of the digital media campaign after its completion and allowed the rangatahi to reflect on their experience being part of this project. A questionnaire was developed (Multimedia Appendix 1) to allow the rangatahi to rate their engagement with the campaign and the campaign messages, as well as their peers' engagement with the campaign. Two open-ended questions were included to seek feedback on improving the reach and overall campaign. The survey was delivered via electronic tablets using Alchemer software (Alchemer LLC).

Ethical Considerations

Ethics approval was received from the University of Auckland's Auckland Health Research Ethics Committee (AH26095) and the EIT Ethics Committee Ethics Committee (EA04270123). Informed consent was obtained from each participant and their parent/caregiver before attending the wānanga. This consent included permission to use participant images and video footage as part of the campaign. The rangatahi were given a small koha (gift) at the end of the campaign as a token of their many days of contribution to the project.

Results

Planning

The dissemination plan suggested by the rangatahi centered on the use of social media to reach their target audience, specifically choosing Instagram, TikTok, and YouTube as primary channels. This was based on their understanding of peer communication and identifying their own ability to capitalize on pre-existing social circles on these platforms. The campaign strategy prioritized youth voice and experience and extended the reach by using established Māori social media influencers. All decisions were made collaboratively, with all participants having a say. There were no major points of contention and substantial issues, such as the naming of the guidelines, were decided by consensus, as is the custom on the marae.

Campaign Materials

The Manaora branding and logo evolved through collaborative discussion, with the rangatahi initially opting for "Tihei Hauora" (be alert to your health) as the campaign name. This was later replaced by a different name that the group felt better encompassed their kaupapa (mission). Thus, the group ultimately landed on the invented name "Manaora"—a blend of the words "mana" (prestige) and "ora" (health). The campaign's visual logo was inspired by their environment, featuring the kōwhaiwhai (Māori decorative design) planting pattern of a

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local community garden visited by rangatahi during the wānanga, and was one of the locations featured in the filming of campaign content.

The campaign strategy focused on creating 20 short videos explaining each of the 20 guideline messages and a 90-second trailer. The rangatahi envisioned an interactive and conversational style to the message videos, relying heavily on humor to capture and maintain audience attention. The rangatahi decided that, alongside the influencers, they should also appear in the videos due to their established knowledge on the guidelines and recognition of the importance of peer representation. These videos can be found on YouTube [33]. Supporting materials included branded merchandise (hoodies featuring QR codes linking to the Manaora webpage), comprehensive wellness summaries, and detailed guideline explanations. Table 1 displays the details of the campaign dissemination plan.

Table . Campaign dissemination plan.

Campaign components	Key details
Objective	• To disseminate the Manaora Rangatahi Guidelines messages to as large a peer audience as possible
Media	• Social media platforms: TikTok [34], Instagram [35], YouTube [33] • Manaora Rangatahi Guidelines webpage [36]
Target audience	• All New Zealand youth aged 12 to 24 years, especially Māori youth.

Content	• Social media video clips
	  • 20 videos (50 - 70 s focusing on each of the 20 Guideline messages)
	  • 90 s trailer video
	• Featuring NZ Māori influencers

Strategies	• Launch event • Release 2 guideline messages and their accompanying videos per fortnight over a 20-week period (ie, 10 campaign phases) • Branded merchandise for use as incentive to target audience for engagement with the social media campaign
Branding	• Name and logo development • Hoodies (featuring logo, tukutuku [ornamental latticework] panel design from the marae that hosted the wānanga series, and QR code linking to the Manaora Instagram account)
Materials	• Eating and Wellbeing Interactive Guidelines (comprehensive overview of eating and wellbeing messages including links and QR codes to additional resources and social media pages) [37] • Comprehensive Wellness Summary (summary of the 20 messages, for quick reference or large display poster) [38] • Eating and Wellbeing Explained (detailed explanations and references of each of the 20 messages) [39] • Posters, each spotlighting one of the 20 key messages [40] • The Roots of Our Logo (the inspiration and story behind our logo) [41]
Measures of reach	• Social media analytics (Instagram and TikTok)—Impressions and Engagement rate

Implementation

The Manaora Rangatahi Guidelines social media campaign was launched at another local marae, Waipatu, and attended by school representatives, health and community stakeholders, local Iwi (tribe) representatives, and local and national media. The rangatahi spoke about the importance of the project, highlighting their increased connection with Māoritanga (Māori cultural practices and beliefs) through the project. During the launch event, the campaign trailer and the first 2 of the 20 guideline message videos were screened to the audience.

The campaign (referred to as the Manaora campaign) ran over 22 weeks—a 2-week lead-in and 10 fortnightly phases where 2 campaign messages (one eating and one wellbeing) were released in each phase across the selected social media platforms. An additional 32 infographic resources providing background information on the guideline messages and a series of “behind the scenes” posts that showcased the filming process were also posted to Instagram. During the campaign, 4 rangatahi who had expressed interest were granted access to the social media accounts to create additional content to increase engagement.

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Various promotion strategies were tried throughout the campaign, with the small promotion funding available. During the 2-week precampaign period and the first 3 phases (ie, 6 weeks) of the Manaora campaign, the paid promotion on TikTok was directed at increasing campaign awareness. This means that the platform's algorithm targeted user views of the video content, aiming to amplify the number of individuals who saw the content. However, the engagement of video content was low during this period—the audience was seeing the messages but not necessarily watching the whole video or engaging with the content through likes, comments, saves, or shares.

Therefore, the objective of the paid promotion for TikTok was changed to target engagement for phases 4 - 8. This resulted in fewer overall views per video, but increased content interaction and user engagement. Paying for promotions to enhance either impressions or engagement clearly works. Although the overall awareness was impacted due to the change in advertising objective, meaningful interaction increased, which means that individual users spent more time watching the messages and were more likely to follow the Manaora account and engage with content throughout the campaign's entirety.

Paid promotion was used for Instagram to "boost impressions" but only for the run-in fortnight and the first fortnight (phase 1) of the campaign. At phase 8, we contracted one of the Māori influencers who was involved in the filming of the videos to make her own video clip of the campaign and her involvement with it, and to post it on her Instagram and TikTok accounts in partnership with the Manaora campaign.

Social media analytics on the impressions and engagement of the campaign content were downloaded weekly across the social media platforms (Table 2 and Figure 2). TikTok's algorithm typically generates higher impression counts due to its "For You Page."

Table . Summary of user interaction analytics for the social media platforms across the 10 phases of the campaign. Note that Instagram uses the term "interactions" for engagement. Medians for the platforms are across their 14 industry categories [42].

Platform and metric	Values
Instagram	
Impressions, n	26,916
Engagement, n	1661
Engagement rate (%)	6.2
Median platform engagement rate (%)	0.36
TikTok	
Impressions, n	1,455,643
Engagement, n	17,479
Engagement rate (%)	1.2
Median platform engagement rate (%)	1.73

A breakdown of the audience age group was available from the TikTok analytics, and it showed that 20% of the target audience was aged 13-17 years, 50% of the target audience was aged 18-24 years, and 30% of the target audience was aged 25-34 years. The campaign achieved substantial, but highly variable, reach across the platforms over the dissemination duration (Figure 2). Since impressions are the denominator for the engagement rate, there is a clear reciprocal pattern between the 2 with higher engagement rates seen during low impressions periods. Instagram impressions started at around 6000, decreasing to under 1000 per fortnight over phases 2 - 7 when there were no paid promotions. The paid influencer promotion in phase 8 resulted in a 10-fold boost in impressions on Instagram, with some hangover effects into the last 2 phases of the campaign. On TikTok, the added impressions from the influencer promotion made up for the loss of impressions through the ending of the paid promotions through the platform, but these rapidly tailed off in the last 2 phases where there was no paid promotion.

TikTok had over 50 times the number of impressions compared with Instagram, and these were especially high (about 300,000 impressions per fortnightly phase) over the first 3 phases when there was paid promotion for achieving increased awareness. With the switch to paid promotion for engagement, this indicator increased over the rest of the campaign. While the mean engagement rate for the campaign fell below the TikTok median rate, it is clear from Figure 2 that, as one marker of the success of a campaign, it is highly influenced by the level of paid promotions for engagement and the reciprocal relationship with the number of impressions.

The total costs for the digital media campaign came to around NZ$ 125,000 (US $72,500). The largest cost, accounting for 32% of the cost, was personnel costs for a research assistant who managed the implementation of the digital media campaign. The creation of the videos, which included on-site professional filming over 3 days and postproduction editing, accounted for 22% of the cost. Social media influencer engagement accounted for 15% of these costs, covering their participation in the wānanga, involvement in the filming, and subsequent content creation by one of the influencers. TikTok advertising costs and the branded apparel accounted for 4% and 3% of these costs, respectively. The remaining costs included venue hire, catering, koha (donations), and travel expenses for the wānanga series.

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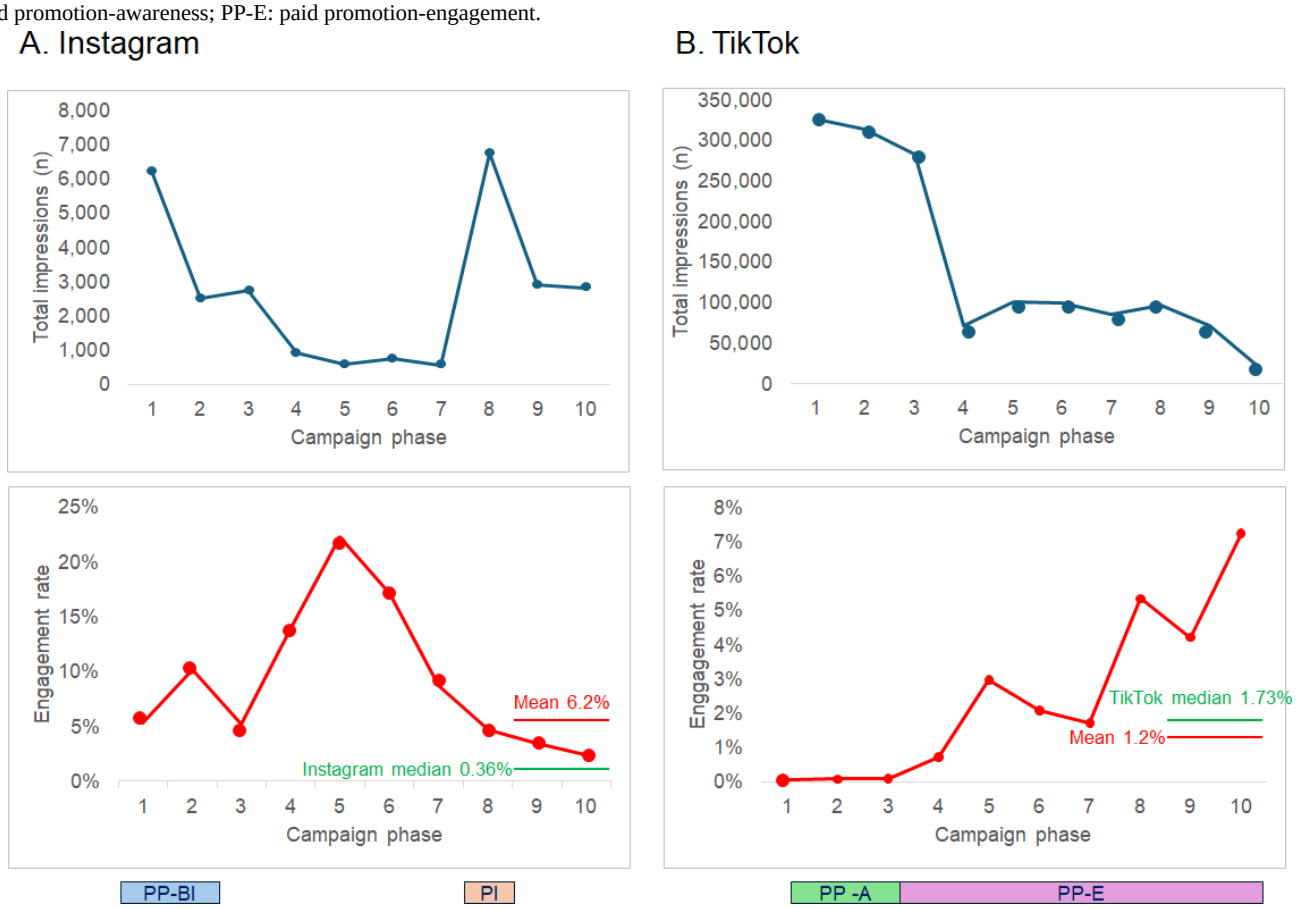
Figure 2. Instagram and TikTok analytics by the 10 fortnightly campaign phases. Total impressions (number of views) in blue and engagement rate (engagements/impressions) in red. Mean engagement rates for the campaign are in red and median rates for Instagram and TikTok across all industries are in green. The different promotion activities tried during the campaign are shown for both platforms. PP: paid promotion; PI: paid influencer; PP-A: paid promotion-awareness; PP-E: paid promotion-engagement.



Postdissemination Review

The postcampaign evaluation showed generally positive perceptions from the rangatahi on how the campaign had performed. Of the 17 rangatahi, 10 rated the campaign as successful or very successful, while 7 were neutral, and one viewed it as very unsuccessful. Engagement with the campaign was also mostly favorable, with 11 rangatahi reporting they were quite or very engaged with the campaign, while 6 felt somewhat engaged, and one was not engaged at all. Engagement of peers with the campaign was rated as successful or very successful by 10 of the rangatahi, while 7 rated it as neutral and one as very unsuccessful. The 2 open-ended questions provided a variety of qualitative feedback, but on balance, this was not considered rich enough to warrant a formal analysis.

Discussion

Principal Findings

This study evaluated the process of developing and implementing a dissemination strategy for the Manaora Guidelines with the rangatahi who cocreated the original guidelines. With guidance and professional input, the rangatahi developed an innovative digital media campaign, which included the creation of a substantial amount of campaign material. The campaign of 10 phases over 20 weeks achieved engagement rates that were much higher than industry standards for Instagram and about the industry standard for TikTok.

Achieving nearly 1.5 million impressions and more than 19,000 engagements was very positive for a low-cost campaign. The added impacts of paid promotion through the platforms and the influencer were clear in the data analytics. With a greater investment in promotions, the reach and engagements could have been considerably greater; however, as with all digital media campaigns, assessing the conversion of awareness of the messages to attitudinal and behavioral changes is a big challenge [11] requiring a more comprehensive evaluation than just the platform analytics.

While TikTok showed a much higher reach, Instagram had a 5 times higher engagement rate, and this may in part be due to the additional static content we posted, such as “behind the scenes” images from the filming process, simplified infographics, and “top tips” video content focusing on different ways to enact the guidelines. These were posted only on Instagram because these formats are not suited to the TikTok platform.

Partnering With Youth

The codevelopment process worked very well, and the rangatahi worked hard over several days and enjoyed the creative processes. However, interestingly, they did not universally rate the campaign as a success and gave informal feedback that they felt they could have worked harder on the dissemination campaign by being more actively engaged online.

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By partnering with youth, in this case Indigenous youth, in the creation and sharing of health information that was relevant and culturally appropriate, the campaign was more likely to reflect the belief systems, life experiences, and cultural values that would be relevant to that particular target audience [43] and arguably, to the wider youth audience as well, although we have no direct evidence of this. This process acknowledged that rangatahi are experts in the types of messages and delivery that are most likely to engage them and their peers [44]. Our findings extend on this by showing that, with appropriate guidance, rangatahi are well able to be full partners in all steps of health communication, from message development through to implementation and dissemination strategies. As such, they should be involved in guideline development and dissemination as genuine partners, and not just as participants; however, more formal evaluations of impact would be needed to demonstrate these assumptions. While other studies have collaborated with youth to co-design social media campaigns [45], few have involved youth in the implementation of the dissemination.

Ensuring all aspects of this project used a Te Ao Māori lens was vital throughout this project. This allowed the rangatahi to connect with the project and incorporate mātauranga Māori into the guidelines to make them relevant for themselves and their wider peer group. This was evident at all stages of the project, from the use of Māori concepts, such as mauri (life force), tūrangawaewae (a place to stand), whakatauki (proverbs), and te reo Māori (the Māori language), to the involvement of Māori influencers and locations of significance for filming. This allowed the development of a dissemination strategy that was innovative and based on cultural identity.

The co-creation of a dissemination plan was enriching on multiple levels beyond that of just the campaign outcomes. For the rangatahi, it affirmed their ideas and knowledge and positioned them as experts of their own world. The process allowed for the creative generation of innovative ideas and enhanced collaboration as they learned to work in teams with each other and alongside research and communications experts. This process not only improved the relevance and method of health message dissemination for youth in general, but also had positive effects on the partnered youth themselves, as can be seen in their reflections of their own experiences (Voices of Manaora: Unveiling our messages [46], and Manaora Reflections [47]) and what they gained from their involvement, potentially improving their health-related attitudes and beliefs.

Campaign Lessons

Twenty messages are a large number to include in any public messaging campaign. It was decided to include all the messages because they had all been co-created by the rangatahi. National dietary guidelines, including the ones used as exemplars for the cocreation of the rangatahi guidelines (Brazil, Chile, Mexico, Norway, US, NZ), typically have about 10 messages [48]. Added to that, the rangatahi included well-being guidelines for physical activity, sleep, bullying, screen time, respect, and psychological well-being. Fewer messages could potentially be used with higher impact in other circumstances, such as in nutrition curricula.

There are several lessons learned from this study. First, with guidance from public health professionals and influencers, a group of rangatahi was able to cocreate innovative and engaging material for a dissemination campaign. Both the academic concepts of social marketing and the lived experience of the rangatahi were influential in developing the plan. However, in the implementation phase, the participants themselves could have been more actively engaged online in commenting or sharing their thoughts and experiences on the messages as they were posted every fortnight. Second, it was difficult to judge the success of such a campaign just on the platform analytics. Understanding how well the messages were received and whether they resulted in a shift in the stage of behavior change would require a much more extensive evaluation. However, it would only be plausible to postulate changes in behavior if the campaign were more extensive, ongoing, and linked to other strategies, such as inclusion of messages in the curriculum and dissemination through the education and health systems. Third, the development and dissemination of the Manaora Guidelines was part of a research project, rather than a government-led exercise. This meant that there was no ongoing implementation pathway for the guidelines—a disappointing end to such an innovative project.

Implications

The implementation of the Manaora Rangatahi Guidelines dissemination plan was low-cost and did achieve meaningful engagement of almost 1.5 m impressions. While other youth-directed digital media campaigns relied on paid advertising and professional expertise, as we did, few outlined their direct campaign costs. Kearney et al [49] achieved over 3.1 million impressions using social media experts and paid advertising to combat the racial marketing of unhealthy foods, but the cost of implementing their campaign was not provided. Weir et al [50] did a cost analysis of a campaign (FinishIt) aiming to prevent youth smoking in the United States over a 3-year period. They concluded that the program was cost-effective, but the total cost of that campaign was very high at US $162 million. Similarly, Sim and Wong [51] evaluated youth engagement with a mental health campaign promoted on social media (CHAT) and found increased audience engagement with increased social media advertising, but they did not provide campaign costs. Thus, future research should include campaign costs as well as engagement rates to allow for the cost-effectiveness of health campaigns to be established. Further research is also required to explore how best to balance the organic promotion of campaign content with strategic paid influencer and platform promotions.

The role of digital media in disseminating health information is substantial. Hawke et al [28] showed that social media with infographics and videos was important in the dissemination of COVID-19 health information to youth, and Kostygina et al [52] showed that social media influencers and memes can engage youth populations by making health messages more appealing and accessible. Digital engagement also allows campaigns to target audiences, which is crucial for addressing health disparities. Our study reinforces all these findings.

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While the Manaora campaign achieved substantial reach through organic youth-led promotion and minimal advertising, our use of established influencers with pre-existing follower bases increased this reach further. Influencer costs vary based on their following size, engagement rates, and campaign requirements and need to be considered within the campaign budget. Thus, policymakers and health promotion organizations need to consider funding for digital media campaigns that incorporate both youth partnerships and strategic influencer and platform promotions.

Finding similar low-budget social media campaigns in New Zealand to compare analytics is difficult. Most health promotion campaigns that are run through social media and which have published analytics are government-funded. Their budgets, reach, and impact are all much greater than the present campaign. For example, the campaign "Love better" addressing domestic violence and targeting youth cost over NZ $10 million (US $5.8 million), ran over 3 years, achieved 4.25 million and 1.6 million "engagements" (views, reactions, comments, shares, saves) for TikTok and Meta (Instagram and Facebook) respectively. This gave engagement rates of 22% and 8% and cost per thousand views of NZ $2.75 and $3.97 (US $1.597 and 2.30) respectively [53]. The costs per thousand views in this study were NZ $0.09 (US $0.0522) for TikTok and $4.64 (US $2.69) for Instagram, showing equivalent or better cost-effectiveness.

The dissemination of the Manaora Rangatahi Guidelines through social media platforms has significant potential for wider reach and transferability. While message dissemination was successful through digital media, the model developed here has broader implementation opportunities, particularly through schools, community organizations, and health providers. Furthermore, the transferability extends beyond just that of the guidelines themselves to the youth partnership methodology that was used here, which could be scaled from local to national levels. Involving the secondary audiences, such as educators and community health workers, in the creation of the dissemination plan, alongside the rangatahi, would ensure the resources created were also fit for purpose for next-users to include in their own programs across different contexts. The findings of this study strongly suggest that governments, health, and community organizations should partner with their target audiences, particularly youth, in the development and dissemination of future guidelines regarding health and well-being messaging.

Strengths and Limitations

The strengths of this study include the high level of engagement, ownership, and innovation shown by the rangatahi. The rangatahi involved in this project remained engaged throughout the year-long process of collaboration in the development, implementation, and postevent evaluation. This highlights the strength of this method for participation retention as well as health communication messaging and dissemination. In addition, this process highlights a potentially low-cost but effective means of dissemination in a target audience that can be notoriously difficult to reach by conventional communication channels.

Limitations include the small number of rangatahi involved in the process, which may limit the generalizability of the findings or the reach of the dissemination campaign. Also, as noted, the participants could have been more actively engaged in amplifying the messages as they were released fortnightly. While the cocreation approach worked well, the pathways to scalability, sustainability, and enhancement of dissemination by participants were not evident. These are important questions for future research. While the use of influencers as message amplifiers was used in the development of materials and bolstering reach at the end of the campaign, their involvement did come with added costs. The cost-benefit of using influencers for social marketing of healthy eating and well-being messages remains an open question. We do not know whether the exposure to these youth-developed messages through the campaign resulted in behavioral or attitudinal changes in the target population, making the behavioral effectiveness of the campaign unclear. The lack of more appropriate platform benchmarks than the "all industries" medians limits the comparability of this study to other youth-focused campaigns. In addition, the sustainability of campaigns needs to be further explored to maintain campaign relevance. Rangatahi were not fulsome in their qualitative feedback on the campaign, thus limiting the richness of this aspect of the evaluation. Finally, the rangatahi were not involved in the administrative aspects of the campaign management or promotion of content, both of which are important components of any social media campaign.

Involving next-users in the dissemination would also allow for more independent feedback, assessment of structural impacts (eg, incorporation into curricula), and perhaps behavioral changes. The messages were not independently pretested before dissemination, which was a limitation, and if the guidelines were to be formally included in school curricula, they would need further evaluation for suitability for that purpose.

Conclusions

This study highlights the value and importance of youth partnership in the cocreation and subsequent dissemination of health guidelines. The success of the Manaora Rangatahi Guidelines campaign offers a model for future youth-centered health initiatives, emphasizing the importance of genuine partnership with target audiences to develop dissemination strategies that are relevant, engaging, and culturally appropriate in order to achieve greater uptake.

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above and beyond what our budget could afford for their services because they had a strong belief in the project's kaupapa (mission).

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Data Availability

The raw data generated or analyzed during this study are available from the corresponding author on reasonable request.

Authors' Contributions

LC and RR wrote the first draft of this manuscript and compiled the results. RG, BS, and DTL formulated the research and designed the study. LC, RMH, BS, and DTL ran the wānanga. All authors reviewed and approved the final version of this manuscript. Generative artificial intelligence was not used in the creation of this manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Glossary of the Māori terms and the survey questions used.
[DOCX File, 16 KB - formative_v10i1e71833_app1.docx]

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Evaluating an Incentive-Based mHealth App for Physical Activity Promotion Using the Obesity-Related Behavioral Intervention Trial Model: Small Cohort Study

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Abstract

Background: Physical inactivity remains a public health concern, with 42% (around 1 in 2) of women and 34% (around 1 in 3) of men in the United Kingdom, for example, failing to meet moderate-to-vigorous physical activity guidelines. To promote physical activity (PA) at scale, smartphone-based mHealth (mobile health) software apps offer a promising solution.

Objective: This study aims to evaluate the feasibility of implementing an mHealth app offering very small ("micro") financial incentives for PA in Leeds, United Kingdom.

Methods: A 5-week single-arm proof-of-concept study was conducted with rolling recruitment among Caterpillar Health app users between September 12 and December 12, 2022 (Obesity-Related Behavioral Intervention Trial model, phase IIa). Users earned microincentives in the form of "points," redeemable for consumer rewards (eg, movie tickets and gym passes), for meeting personalized daily step goals (US $0.13 per goal achieved; set using data from a 5-day baseline) and completing educational quizzes (US $0.33 per quiz). Descriptive statistics assessed feasibility outcomes (ie, reach, recruitment, retention, engagement, and acceptability) and preliminary effectiveness. Paired-samples *t* tests ($P<.05$) examined changes in weekly mean daily step count (from baseline) and step goal achievement over 5 weeks.

Results: Of 285 app downloads, 46 users consented to participate (recruitment rate: 16.1%). Participants (mean age: 39.9, SD 11.1 y; 71.1%, 33/46 woman) had a baseline step count of 5598 (SD 2664) steps/day. A total of 25 participants remained engaged (ie, completed at least 1 quiz) at study week 5 (retention rate: 54.3%). Acceptability was high, with 75% of respondents (12/16) indicating they would recommend the app. Weekly mean daily step count did not significantly increase from baseline (mean difference 317, SD 2273, $P=.53$). Weekly daily step goal achievement rate (%) decreased from study week 1 to 5 (−23.23, SD 22.85, $P=.02$).

Conclusions: Despite lower-than-expected recruitment and no statistically significant PA increase, relatively high engagement and acceptability suggest future pilot testing (Obesity-Related Behavioral Intervention Trial model, phase IIb) of a refined intervention (eg, wider selection of loyalty reward partners) and modified study protocol (eg, simplified consent process) is warranted.

Trial Registration: ClinicalTrials.gov NCT05294692; https://clinicaltrials.gov/study/NCT05294692

(JMIR Form Res 2026;10:e85484) doi:10.2196/85484

KEYWORDS

mHealth; digital health; financial incentives; health behavior change; physical activity; behavioral economics

Introduction

Physical inactivity remains a public health concern, with 42% (around 1 in 2) of women and 34% (around 1 in 3) of men in the United Kingdom, for example, failing to meet moderate-to-vigorous physical activity guidelines [1]. To promote physical activity (PA) at scale, smartphone-based mHealth (mobile health) software apps offer a promising solution [2]. As global smartphone ownership continues to rise (ie, 85% in 2024 vs 66% in 2018 worldwide [3], with 87% of UK adults owning a smartphone in 2023) [4], mHealth apps may be one way of promoting population-level PA [5,6]. Despite their potential, low mHealth app engagement (eg, frequency and depth of use; a common precondition for mHealth app

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effectiveness) leading to little or no effect is typical [7]. Grounding mHealth app intervention in behavior change theory (eg, behavioral economics) may boost engagement and effectiveness [7-9]. For example, a systematic review of 35 randomized controlled trials (RCTs) by Boonmanunt et al [8] found that interventions informed by theory outperformed those that were not.

Behavioral economics, a branch of economics complemented by insights from psychology, has shown promise in boosting mHealth app engagement [10]. One of the central tenets in behavioral economics is that of "decision bias." "Decision bias" refers to the systematic ways in which human decisions deviate from what would be considered rational or logical [11]. For example, "present bias" refers to the tendency for individuals to place disproportionate emphasis on the present costs and benefits of behaviors in decision-making while at the same time discounting future ones [11]. In the context of PA, for example, the immediate costs experienced with a bout of exercise (eg, discomfort) often outweigh future benefits (eg, lower cancer risk) in daily decision-making [12]. Financial incentives (FI), monetary rewards contingent on health behavior or outcome goal achievement, may encourage individuals to engage in more PA today, for instance, given the added short-term benefit of rewards [12]. There is evidence that FI-for-PA interventions can be effective [13,14]. For example, in a review of RCTs examining PA incentives, Mitchell et al [14] found that FI, worth on average about US $1.50 per day, produced short-term (ie, <6 mo), long-term (ie, ≥6 mo), and follow-up (ie, after incentive withdrawal) effects. While promising, these FI magnitudes may be cost-prohibitive when implemented at a population level, or longer-term (ie, more than 6 months, a theoretical threshold of behavior maintenance) [15]. This may be particularly true within the constraints of limited public health budgets [16]. For example, offering £1.00 (ie, US $1.33/d) per day to just 1% of the UK adult population (ie, 683,500 people) would cost £249.5 million (US $334.8 million) annually (ie, about 4.82% of the 2025 £3.85 billion [US $5.17 billion] public health budget) [17].

One way of controlling FI costs while maintaining their effects may be to limit the size of rewards, all the while maintaining integrity to behavioral economics—that is, offering FI close in time to the desired behavior or outcome to best leverage "present bias." In the 2020 Mitchell et al [14] review, several RCTs offering very small ("micro") FI increased PA (eg, US $0.09-US $0.53/d) [18-20]. For example, Rohde et al [18] offered microincentives (ie, US $0.09 - US $0.15/d) conditional on participants' weekly gym attendance (ie, FI per day). These small cash rewards, given to both regular and irregular gym visitors, led to increased attendance in both the short- (ie, <12 wk) and long-term (ie, ≥12 wk) compared to a control group receiving unconditional FI. Much of the evidence supporting microincentive impact is derived from RCTs with limited external validity, however. Few have examined their impact in real-world public health settings [21-23]. Knowing more about microincentives outside of controlled experimental settings may enhance their impact in the public sphere.

One example of microincentives for PA deployed in the real world is Carrot Rewards (2015 - 2019) [24], a Canadian mHealth app that offered microincentives for daily step goal achievement (eg, consumer loyalty points worth about US $0.03/day [ie, equivalent to 1 loyalty reward point] for movies, groceries, gas, etc). On one hand, the app saw high uptake and engagement, attracting more than 1.3 million downloads and 500,000 monthly active users and produced short- (ie, <6 mo) and long-term (ie, ≥6 mo) PA improvements [24]. On the other hand, higher than anticipated engagement resulted in large-scale daily step goal reward payouts (ie, totaling more than US $3 million over 4 years). This great cost, combined with reliance on government funds to pay for the microincentives [25], undermined the app's scalability or sustainability potential and ultimately led to its discontinuation in 2019 [24]. Given the strong uptake, high engagement, and long-term effects seen with Carrot [16,24], efforts to replicate their microincentive approach, with some modification (eg, wean users off daily step goal rewards after a year), in different contexts are warranted. Specifically, examining how digitally delivered microincentives for PA may perform in a completely different country (ie, United Kingdom) with different partners (eg, loyalty point programs, government agencies, and nongovernmental organizations) and different users (eg, who may not respond to points or incentives the same way) [26] may yield valuable insights.

The purpose of this small 5-week proof-of-concept study, therefore, is to evaluate the feasibility of offering microincentives for PA in the United Kingdom via a commercial mHealth app. The primary indicators for this study are feasibility-related outcomes (eg, uptake, engagement, and acceptability), rather than statistically significant changes in PA. This study represents an important first step in a multiphased project aiming to develop, refine, and evaluate a promising (ie, more scalable and sustainable) FI-for-PA intervention in the United Kingdom.

Methods

Study Setting and Design

This was a small 5-week single-arm proof-of-concept study with rolling recruitment between September 12 and December 12, 2022. This research was conducted in partnership with Caterpillar Health, an mHealth app designed to support PA engagement through personalized daily step goals, evidence-supported educational content, and microincentives in Leeds, United Kingdom. This preparatory study was guided by the Obesity-Related Behavioral Intervention Trial (ORBIT) model [27], a structured framework that supports the systematic development and evaluation of behavioral interventions. The ORBIT model outlines staged phases, from early feasibility (phase I-II) to large-scale effectiveness testing (phase III-IV). This study represents phase IIa (ie, proof-of-concept), which emphasizes feasibility assessment as well as identifying opportunities to refine the intervention and future study design. To ensure the intervention and study design incorporated principles of equity, diversity, inclusion, and accessibility, the World Health Organization's health equity toolkit [28] was used. This included appropriately describing categories of disadvantage (eg, gender, household income, and ethnicity), avoiding overly technical health language in both the app

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interface and recruitment materials, using inclusive imagery within the app, ensuring compatibility across different mobile operating systems (eg, Android [Google LLC] and iOS [Apple Inc]), and tailoring the approach to Leeds, United Kingdom (ie, a community with a relatively high prevalence of overweight and obese adults [63.9%]) [29] to ensure sensitivity to local health inequities. In line with the World Health Organization toolkit's emphasis on participatory design, feedback from app users within the community was sought during this study to identify potential barriers and ensure cultural relevance. In addition, subgroup analyses were conducted to examine the impact of the interventions among equity-deserving groups (eg, individuals with low income, chronic conditions, or low baseline PA) to assess whether the strategies were equitably effective across diverse populations.

To promote the app, a paid advertising campaign on social media platforms (ie, Facebook [Meta], Instagram [Instagram from Meta], and Twitter [subsequently rebranded X; X Corp]) began on August 1, 2022 (ie, outside of this study's period) to raise awareness of the app leading up to its launch on September 12, 2022. To further support app launch, Caterpillar collaborated with Leeds City Council to have emails sent to City employees, as well as to local KPMG (Klynveld Peat Marwick Goerdeler) employees and Hussle Gym members living in Leeds, United Kingdom, on August 8, 2022. Participation required several sequential steps, including app download and account registration. Informed consent to participate in this study was sought on 2 separate occasions. First, to authorize the collection of participants' sociodemographics and app engagement data (starting September 12, 2022) through an in-app consent form for study participation, and then again separately (starting September 30, 2022) to authorize the collection of device-assessed daily step count data over a 5-day baseline followed by a 5-week intervention period. This aligned with the app's "steps" feature launch on September 30, 2022, and captured participants' daily step counts in the approximately 6 weeks following the second consent. Sociodemographic and health characteristics were collected through a survey embedded in the app (Multimedia Appendix 1). This trial was registered at ClinicalTrials.gov (NCT05294692). The STROBE (Strengthening the Reporting of Observational Studies in Epidemiology) statement checklist (Checklist 1) [30] for cohort studies is provided.

Ethical Considerations

This trial was approved by Western University Health Sciences' Research Ethics Board in March 2024 (Project ID: 120615). All participants provided informed consent before participation. Participant privacy and confidentiality were maintained through the use of deidentified data, secure data storage systems, and restricted access to study records. Participants were not compensated for study participation; however, as part of the intervention, they were eligible to earn FI contingent on achieving daily step goals. Incentives were provided in British pounds (£0.10), equivalent to approximately US $0.13, based on a conversion rate of £1=US $1.34 at the time of this study.

Intervention

Caterpillar's cornerstone feature, "personalized challenges," offered microincentives for personalized daily step goal achievement (Figure 1). Users' initial daily step goals were calculated as the median step count from the 5-day (ie, no goal and no microincentive) baseline period, where users were instructed to "wear their device" as much as possible. After this baseline, users could earn microincentives in the form of points ("incentives and rewards"; equivalent to US $0.13/d) for meeting their daily goals (ie, calculated as the median step count from the previous 7-day week). These points could be redeemed for consumer goods (ie, movie tickets from Vue Cinemas and gym passes from Hussle Gym). Users could also opt into weekly "step challenges" (ie, complete 5 out of 7 daily step goals) for additional points (US $0.33). Finally, users could also complete 4 educational quizzes per week ("health education and microlearning"; US $0.33/quiz). The educational quizzes primarily covered UK healthy eating and PA guideline content (in line with the National Health Service, "live well" guidelines). The app's key features, along with their alignment to relevant behavioral economic constructs, are described in full in Multimedia Appendix 2.

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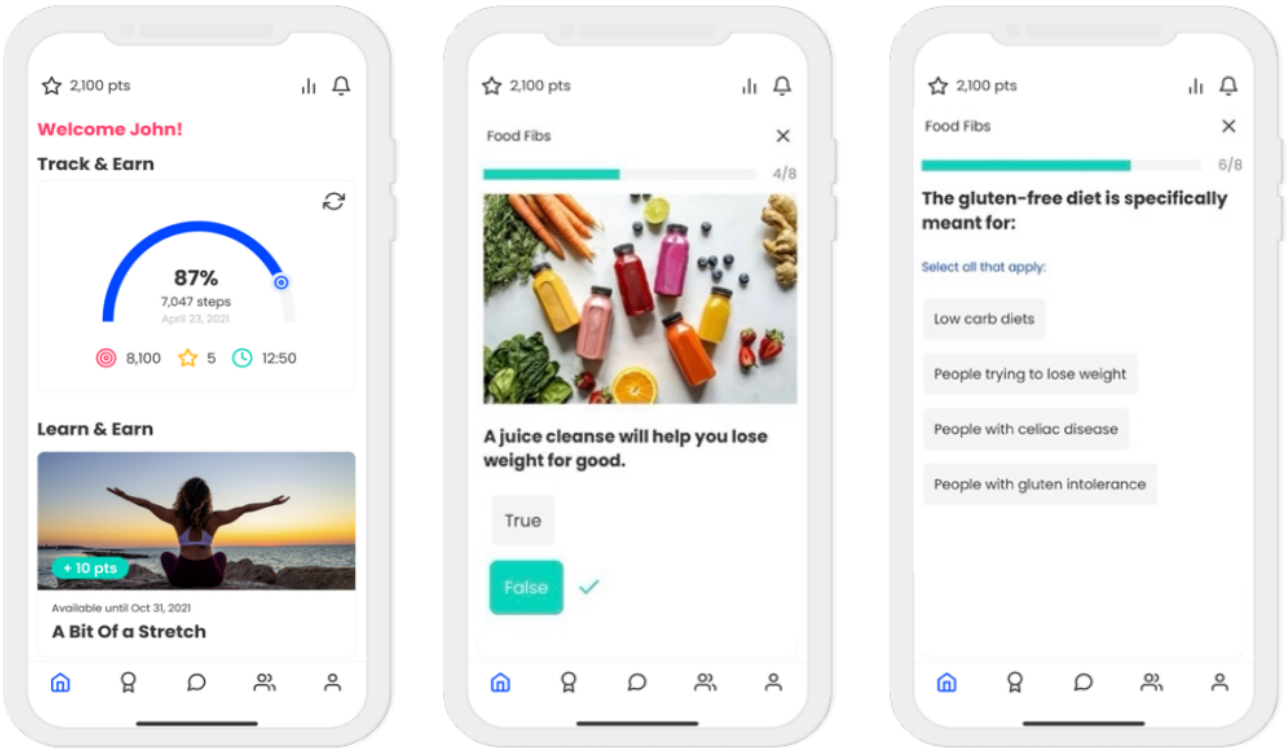
Figure 1. The Caterpillar Health mobile app allowed participants to monitor their PA, view progress toward goals, and interact with educational content designed to support engagement with the platform. PA: physical activity.



Outcomes

Several feasibility outcomes are reported, including (1) reach (ie, number of emails sent during app promotion), (2) recruitment (ie, number of app downloads and number of users providing initial informed consent) and retention (ie, proportion of participants completing an educational quiz in study week 5), (3) app engagement (ie, proportion of total possible educational quizzes completed during this study's period), and (4) intervention acceptability (ie, exit survey responses informed by the validated Mobile Application Rating Scale [31,32]; Multimedia Appendix 1) data were collected. To examine the potential impact of the app on PA, device-assessed (5) baseline and weekly mean daily step count (ie, 1000 to 40,000 steps/day considered within an acceptable range) was collected over a roughly 6-week period (ie, 5 days plus 5 weeks following "steps" feature launch), while (6) daily step goal achievement (ie, proportion of days [out of 7] a user met or exceeded their daily step goals each week) was assessed over the 5-week intervention period.

Theoretical Underpinning

The behavior change wheel (BCW) [33], an amalgamation of 19 behavior change theories, provides a structured and theory-driven framework for designing and evaluating behavioral interventions aimed at both short- and long-term behavior change. The BCW consists of 3 layers. At its core, the BCW defines behavior as an interaction between one's capability (eg, knowledge and skills), opportunity (eg, access to facilities and social support), and motivation (eg, goal setting and rewards) to engage in a particular health behavior. This is referred to as the capability, opportunity, motivation–behavior (COM-B) model. The integration of the COM-B model with microincentives may help tackle barriers to PA (eg, lack of knowledge and low engagement) and enhance the effectiveness of future interventions to sustain behavior over time. To date, several commercially available PA apps (ie, Sweatcoin, Carrot Rewards, StepBet, etc) have incorporated behavior change theories (ie, self-determination theory) within their app design, alongside FI mechanisms (ie, gamified points and lotteries) to boost PA and drive user engagement. However, further research may be needed to test the effectiveness of microincentives in real-world settings. During the design phase of the Caterpillar Health app, the research team used the COM-B model as the theoretical foundation of the app to identify and address barriers and enablers to increase daily step counts and app engagement. Specifically, the model guided the identification of key influencing factors (ie, lack of motivation and time constraints) and facilitators (ie, social support and user-friendly interfaces). These insights were then used to inform how the app's features could be designed to best elicit behavior change. The categories evaluate the intervention derived from the behavior change technique taxonomy, which systematically classifies 93 distinct techniques into 16 clusters used to design and evaluate behavior change interventions [34,35]. The app's key features are described according to the COM-B model in Multimedia Appendix 2.

Statistical Analysis

Statistical analysis was performed using SPSS (version 28.0.1.0; IBM Corp). Descriptive statistics were used to assess reach, recruitment, and retention rates, app engagement, and intervention acceptability. To assess preliminary effectiveness, paired-samples *t* tests were used to examine change in weekly mean daily step count from the 5-day baseline (vs study week 5) among the subsample of users downloading the app on or

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after September 30, 2022 (with "steps" feature included). Exploratory analyses also examined change in weekly mean daily step count by PA level (ie, physically active: ≥5000 steps/d at baseline; physically inactive: <5000 steps/d at baseline) [36], engagement (ie, high engagement: ≥50% of total quizzes completed [≥12 of 24 quizzes]; low engagement: <50% of quizzes completed [<12 of 24 quizzes]), and chronic condition status (ie, at least 1 chronic condition vs no chronic conditions). Given the small sample size in each of these subgroups Figure 2, the mean difference (MD) in weekly mean daily step counts and daily step goal achievement was reported descriptively. As this was a proof-of-concept study, a priori sample size calculation to detect statistical significance was not conducted. The results, however, will be used to inform sample size calculations for future pilot work. Nonetheless, statistical significance was measured as $P<.05$, and Cohen d for local effect sizes of weekly mean daily step counts were calculated, where $d=0.2$ indicates a small effect, $d=0.5$ a medium effect, and $d=0.8$ a large effect.

Results

Sample Characteristics

A total of 285 users downloaded the app, and 228 completed app registration. Of these, 46 users provided initial informed consent (Table 1). A subgroup of users also provided consent authorizing the collection of device-assessed daily step count data (n=22). Among the total sample, participants were primarily woman (71.1%, 32/45) with an average age of 39.9 years and a baseline daily step count of 5598 steps/day. Additionally, 65.7% (23/35) self-reported one or more chronic condition diagnoses, and 25% (9/36) reported at least one disability or impairment. Notably, a greater proportion of participants reported the use of a fitness tracker (65.9%, 27/41) and lower household income (18.9%, 7/37) compared to the general UK population (35% and 13%, respectively). These demographic characteristics may have influenced engagement and responsiveness to app-based microincentives, potentially limiting the generalizability of findings to broader populations (eg, more balanced gender distribution, lower fitness tracker use, and different health profiles).

Table . Baseline characteristics of the total sample, subgroup, and general UK population. Chronic condition defined as a diagnosis by a health professional with symptoms expected to last, or have already lasted 6 months or more, "total" sample includes participants who provided initial informed consent for data collection, "subgroup" sample includes participants who provided a separate informed consent for step count tracking. Household income of US $27,156/year is equivalent to the UK's cutoff for low household income (£21,000/year).

Characteristics	Total (N=46)	Subgroup (n=22)	UK population [36,37] (n=67,749,091)
Age (years)	39.9 (11.1)[a]	43.2 (10.5)[a]	40.7[b]
Gender (woman)[c], % (n/N)	71.1 (32/45)	86.4 (19/22)	51.0
Ethnicity (% White)[d]	80.5 (33/41)	95.5 (21/22)	81.7
BMI (kg/m^2)	27.8	29.5	27.4
Chronic condition (one or more), % (n/N)	65.7 (23/35)	65.0 (13/20)	38.4
Diagnosed disability, % (n/N)	25.0 (9/36)	19.1 (4/21)	24.0
Housing location (urban), % (n/N)	89.2 (33/37)	95.5 (21/22)	84.2
Operating system (iOS), % (n/N)	62.2 (23/37)	95.5 (21/22)	50.8
Fitness tracker (yes), % (n/N)	65.9 (27/41)	77.3 (17/22)	35.0
Household income (below US $27,156/year), % (n/N)	18.9 (7/37)	5.3 (1/19)	13.0
Steps per day (baseline mean, SD)	5598 (2664)	5547 (2619)	5444 (N/A[e])

[a]Mean (SD).

[b]As the UK population data were obtained from the Office for National Statistics (2021 Census), only the median age in years is available. The IQR is not reported in this source and therefore cannot be included.

[c]Gender was self-reported by participants based on their gender identity (e.g., man, woman).

[d]Participants selected 'Caucasian' in the original questionnaire; this has been reported as 'White' in the manuscript to reflect current terminology.

[e]N/A: not applicable.

Main Findings

In total, over 15,000 and 3000 emails were sent to Leeds City Council and KPMG employees, respectively, while more than 7000 emails targeted Hussle Gym members. The number of social media impressions was not recorded. During this study's period, Caterpillar recorded 285 app downloads, of which 46 (16%) provided informed consent and enrolled in this study. Retention at the end of the 5-week intervention was 54.3% (25/46 enrolled participants; Figure 2). Among participants providing initial consent, 95.6% (n=44) completed at least one educational quiz, and 39.1% (n=18) met the criterion for high

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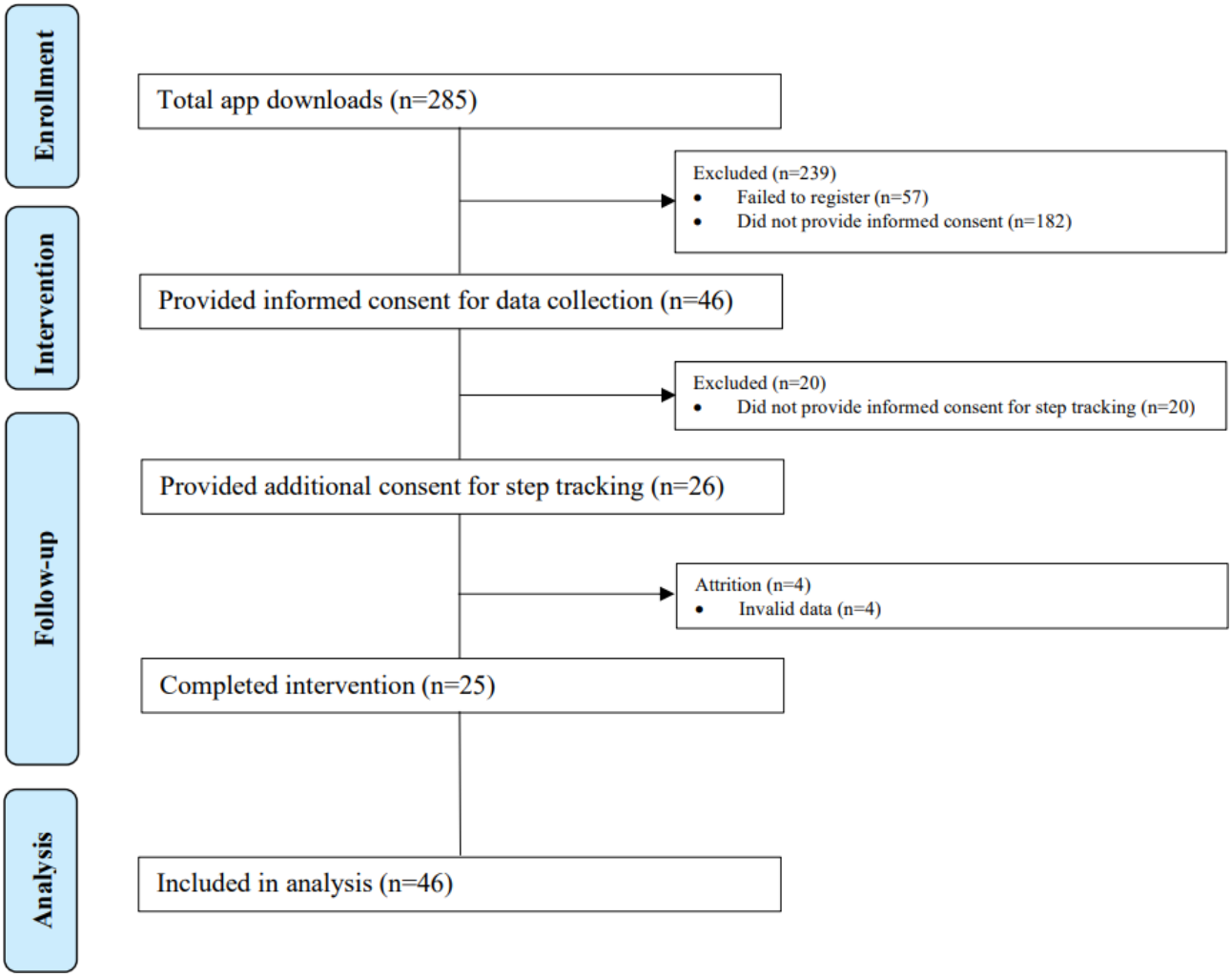
engagement, defined as completion of ≥50% of available quizzes (≥12 of 24 quizzes). On average, participants completed 8.1 quizzes over the 5-week intervention period (out of 24 quizzes offered). Intervention acceptability was high, with most participants completing the exit survey reporting "good" to "excellent" app aesthetics (15/16, 93.7%), having learned new health information (14/16, 87.5%), and, notably, they would recommend the app to others (12/16, 75%). Constructive feedback focused on the lack of customizable features (eg, user input and sharing options; 2/16, 12.5%) and dissatisfaction with daily step goal presentation (eg, not visually engaging or personalized to the user's preferences; 2/15, 13.3%).

Figure 2. Flow chart of participants in a 6-week study with rolling recruitment between September 12 and December 12, 2022, using the Caterpillar Health app. Failed to register refers to users who attempted to sign up for the app but did not complete the registration process. Did not provide informed consent includes users who accessed the platform but did not complete the consent process required for participation in this study. Invalid data includes users with less than 4 days in a week with step counts in the acceptable range (ie, 1000 to 40,000) during the 5-week physical activity assessment period (step count data were included for the 22 users who provided consent for step tracking). Completed intervention represents users who completed at least 1 quiz in study week 5.



Weekly mean daily step count did not significantly increase from baseline (MD 317, SD 2273, *P*=.53; Figure 3). Moreover, weekly daily step goal achievement rate dropped over the 5-week period (MD −23.23, SD 22.85, *P*=.02). Among inactive participants (ie, <5000 steps at baseline), the weekly mean daily step count at baseline and study week 5 was 3509 (SD 1024) and 4656 (SD 2264), respectively (Multimedia Appendix 3). In contrast, active participants accumulated 7585 (SD 2053) steps/day at baseline and 7073 (SD 1753) at study week 5. Participants with at least one chronic condition had a mean daily step count of 5104 (SD 2533) at baseline and 5734 (SD 2434) at study week 5, whereas those without chronic conditions accumulated 6279 (SD 2932) and 5853 (SD 2379), respectively. Weekly step goal achievement rates were 74.2 (SD 18.6) at week 1 and 62.8 (SD 23.9) at study week 5 among inactive participants, and 76.2 (SD 16.5) and 33.3 (SD 8.3), respectively, among active participants. Those with chronic conditions reported 74.3 (SD 18.6) at week 1 and 54.2 (SD 27.5) at study week 5; those without chronic conditions reported 76.2 (SD 16.5) and 47.6 (SD 21.8), respectively.

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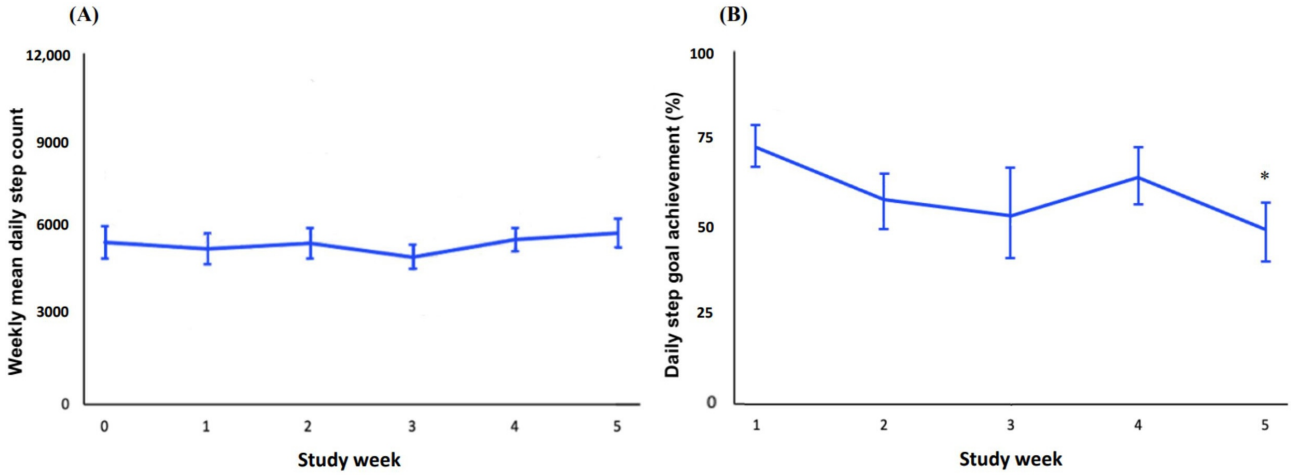
Figure 3. Weekly mean (A) daily step count and (B) daily step goal achievement with standard errors.



Discussion

Principal Results

This single-arm, proof-of-concept ORBIT model phase IIa study assessed the feasibility of implementing Caterpillar, a commercial mHealth app offering microincentives for PA in Leeds, United Kingdom. Over 25,000 emails were sent on August 8, 2022, to raise awareness of the app launch on September 12, 2022. The app was downloaded 285 times during this study's period, with approximately 15% (46/285) of users providing initial consent to participate in this study. Over the 5-week intervention, about 40% (18/46) of users were classified as very engaged (ie, completed ≥50% of quizzes [≥12 of 24 quizzes]). Intervention acceptability was high, with 75% (12/16) indicating they would recommend the app to others. Although Caterpillar did not appear to significantly increase PA, daily step goal achievement was fairly high in study week 1 (about 75%), along with exploratory subgroup trends (eg, for inactive adults), suggesting potential for impact. This finding should be interpreted in the context of a sample with relatively high baseline activity levels, which may have limited the scope for short-term, measurable increases in PA within this low-intensity, microincentive intervention. The discrepancy between high engagement and limited PA change may reflect several factors, including the short 5-week intervention duration, constraints in the incentive structure (eg, limited reward options), and potential limitations in how PA was measured (eg, reliance on daily step counts only). As this is a feasibility study, the emphasis is on effect sizes and feasibility outcomes (eg, engagement and acceptability) rather than on statistical significance; *P* values are reported for reference only. Taken together, these findings suggest the delivery of PA microincentives via Caterpillar in Leeds is feasible, with PA promotion potential given relatively high engagement and favorable subgroup trends. Pilot testing to assess the preliminary effectiveness of a refined intervention and study protocol is warranted (ie, phase IIb).

Several opportunities to improve the intervention and study protocol were identified (Table 2). For example, under "rewards and threats" in Table 2, only 2 corporations (ie, Vue Cinemas and Hussle Gym) partnered with Caterpillar to deliver consumer rewards that could be redeemed through the app, potentially limiting the app's appeal. Partnerships with a wider array of corporations to provide more rewards options may help boost uptake in the future, as suggested by studies demonstrating that perceived reward value may help drive mHealth app engagement (eg, Are rewards meaningful to the target audience?) [38,39]. Under "feedback and monitoring" in Table 2, the app targeted any-intensity daily step count to, in part, promote participant autonomy and the potential for sustained change. Future iterations could broaden the intervention to promote a wider range of PA intensities (eg, moderate-to-vigorous physical activity and high-intensity interval training) and behaviors (eg, cycling, resistance training, and sedentary behavior reduction). In addition, under "associations" in Table 2, participant feedback highlighted limited opportunities for customization (eg, setting routine-based reminders and personalized push notifications), which will directly inform future iterations of Caterpillar to enhance usability and sustained engagement. From a study protocol perspective, several enhancements could strengthen future iterations of this intervention. First, more active recruitment strategies (eg, in-person presentations and text message invitations) could be used in place of the more passive approaches used here (eg, company-wide emails and social media campaigns) [40,41]. Second, the current goal-setting approach, which relies on the user's median daily step count from a 5-day baseline and a 7-day window for each subsequent week, may be suboptimal, particularly given the observed decline in step goal achievement over time. Short baselines may not fully capture typical variability in daily step patterns, potentially resulting in goals that are too easy or too difficult and limiting motivation [33]. Future trials could improve goals by using a longer baseline period (eg, 7 days), rolling averages across multiple weeks (eg, median step count over the past 2 or 3 weeks), and goals that account for variability in step count (eg, account for both median step count and SDs), potentially offering better daily goals [42,43]. Finally, the current single-arm design limits the ability to draw causal inferences regarding the intervention's effectiveness. Later phases of research could include a pilot RCT (ie, ORBIT phase IIb) to allow for preliminary testing of intervention effectiveness and to inform the design of future fully powered trials [27].

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Table . Intervention and study protocol areas for improvement and recommendations. Valid data includes users with daily step counts in an acceptable range (ie. 1000 to 40,000). The categories evaluating the intervention derive from the behavior change technique taxonomy [34,35].

	Areas for improvement	Evidence-informed recommendations
Intervention		
Associations	• Few prompts or contextual cues to reinforce behavior	• Introduce customizable push notifications, routine-based reminders, prompts (eg, after meals), and environmental cues (eg, "take the stairs instead of the elevator") [44]
Comparison of behavior	• No social comparison or benchmarking	• Add anonymized leaderboards, user averages, or percentile rankings to show how user performance compares with peers [45]
Feedback and monitoring	• Only step count tracked; PA[a] intensity, duration, and type were not captured	• Expand intervention to include other PA types (eg, cycling, resistance training, and sedentary behavior reduction) [46] • Display personalized insights (eg, comparative analysis of PA behavior to users' previous week) [47]
Repetition and substitution	• Limited support for habit formation or alternative PA routines	• Include streak tracking and options to substitute missed step goals with alternative PA tasks (eg, cycling) [48]
Rewards and threats	• Limited consumer reward options (n=2) • Boost microincentive impact with promising incentive designs	• Offer additional reward options (eg, grocery, transit, and entertainment) [49] • Test lost-framed incentives [49]
Shaping knowledge	• Educational content delivered only through static quizzes and educational content	• Incorporate interactive learning modules, infographics, video explainers, and progressive unlocking of content based on user performance [50]
Social support	• No mechanisms to connect users or enable peer interaction	• Add features such as group challenges, friend invitations, discussion boards, or accountability buddies [51]
Study protocol		
Study setting	• Limited generalizability beyond the Leeds, United Kingdom context	• Replicate procedures in diverse geographies (eg, urban and rural North American cities) [47]
Study design	• Single-arm design limits causal inference (ie, no comparator group to isolate app effects)	• Consider (pilot) RCT[b] design, or incorporate a waitlist condition, in future phases for improved causal inference [27]
Recruitment	• Reliance on passive outreach strategies (eg, social media and company-wide email) • Lack of tailored messaging across channels • Rolling recruitment may lead to variability in exposure time and seasonal bias • Staggered consent process may have confused participants, limited recruitment rate	• Add more active recruitment, such as at community health events or workplace briefings, to reach underserved groups (eg, low-income adults) [52] • Customize messaging based on sociodemographics (eg, younger adults via Instagram and older adults via email with testimonials) [52] • Standardize recruitment windows or stratify analysis by recruitment timing to reduce confounding [53] • Combine consents or replace with an integrated consent process [54]

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	Areas for improvement	Evidence-informed recommendations
Sample	• Limited sample diversity (eg, 71% [32/45]woman, 81% [33/41] White [c]) • High prevalence of fitness tracker use (65.9% [27/41]) may limit broad applicability • Small sample size (n=46; n=22)	• Consider oversampling underrepresented groups or tailoring eligibility to target populations (eg, low-income or visible minority groups) using stratified sampling (ie, randomly sample participants from distinct strata [eg, by age group and gender]) [55] • Prioritize strategies to engage individuals who do not have access to extra digital tools at baseline (eg, fitness trackers) [55]
Outcome assessment	• Calculation of users' initial daily step goals (median step count from the 5-day baseline) may not be ideal • No data collected beyond 6 weeks of app use • Sole reliance on quiz completion for engagement measurement	• Use a full 7-day baseline period using only valid data to better represent habitual PA patterns and account for weekday or weekend differences [56] • Add postintervention follow-up to assess maintenance or motivation [57] • Track additional engagement metrics (eg, number of app opens, time spent per open, and reward redemption rates) [58]
Analysis	• Paired sample *t* test limits the ability to model time trends and handle missing data • No mediation or moderation analyses conducted	• Use linear mixed model in the future to model repeated measures [59] • Explore mediation pathways (eg, goal → engagement → PA) [60]

[a]PA: physical activity.

[b]RCT: randomized controlled trial.

[c]Participants selected 'Caucasian' in the original questionnaire; this has been reported as 'White' in the manuscript to reflect current terminology.

Despite fairly high engagement and acceptability, the lack of a significant increase in weekly mean daily step count may reflect a combination of declining adherence over time, relatively high baseline activity levels, and aspects of the intervention design that limited short-term gains in PA. The sample's mean baseline step count (5598, SD 2664 steps/day) was slightly higher than the UK population average (5444 steps/day), suggesting participants may have been more physically active at enrollment than the general population. This raises the possibility of a ceiling effect, whereby participants had less capacity for observable improvement over a short intervention period, which may partly explain the absence of a statistically significant increase in PA. Several observations warrant further consideration. First, no immediate increase in PA was observed from baseline to study week 1, contrary to findings from earlier FI interventions where behavioral effects influence PA behavior immediately and tend to decrease gradually [24,25]. This observed delay may reflect the time required for users to build awareness, navigate app features, and begin integrating new routines [24]. In a future ORBIT phase IIb study, this initial delay could be addressed by incorporating a structured onboarding process that includes guided app walkthroughs, early incentives for app exploration, and prompts to encourage immediate goal engagement. These strategies may help accelerate user activation, reduce the learning curve, and facilitate earlier behavior change. Second, the apparent increase in PA among low-active users and decrease among high-active users should be interpreted cautiously. These subgroup trends are hypothesis-generating and may primarily reflect regression to the mean (ie, a statistical tendency for extreme values to move closer to the average over time) rather than a true intervention effect, particularly in the absence of inferential statistical testing [61,62]. A future ORBIT phase IIb study may protect against this alternative explanation by including a comparison group to better distinguish intervention effects from natural variability. Third, weekly step goal achievement was initially high but declined over the 5-week intervention. Declining goal achievement may have been due to fatigue (ie, physical capability), poorer weather (ie, opportunity), or decreasing perceived value of incentives over time (ie, motivation), and importantly, the mechanics of goal recalibration, which may have unintentionally made goals more difficult over time. A future ORBIT phase IIb trial may address these factors by incorporating adaptive intervention strategies (eg, offering users the option to modify goals during periods of low capability [eg, illness and fatigue]), integrating weather-responsive prompts or indoor activity suggestions to mitigate environmental barriers, and applying variable incentive structures (eg, loss-framed) to sustain motivation over time. These refinements would help test the intervention under more dynamic, real-world conditions and better assess its potential for long-term adherence.

Comparison With Prior Work

Findings should also be considered in light of similar literature. The current study's recruitment rate (≈15% [46/285]) was lower than rates reported in similar feasibility trials of digital health interventions promoting PA with microincentives, which have ranged from 21% to 78% [23,26,63]. Several factors may have contributed to this suboptimal conversion to study participation, including passive recruitment strategies (eg, social media campaigns), limited diversity in reward offerings, and participant burden associated with a multistep consent process. Nonetheless, the observed retention rate (about half) and level of engagement (40% [18/46] of users completing ≥50% of available quizzes

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[≥12 of 24 quizzes]) were higher than rates typically reported with prior digital health interventions, where engagement, more broadly defined as state-like construct that refers to the extent (eg, amount, frequency, duration, and depth) of usage, typically ranges between 20% and 30% [58]. Notably, higher app engagement has been linked to greater intervention effects [8,38], suggesting that the fairly high engagement rate observed here (40%) is encouraging from a health behavior change perspective. Favorable exit survey responses align with previous evidence suggesting that personalized designs (eg, personalized daily step goals) and small, immediate microincentives enhance intervention acceptability [24,64]. Importantly, the sample included a relatively high proportion of low-income participants (18.9%) compared to the national average in the United Kingdom (13%). This is notable given that low-income populations often encounter more barriers to PA engagement compared to high-income groups [65]. Although significant PA changes were not observed in this feasibility study, exploratory subgroup descriptive summaries suggest potential among higher-risk groups (eg, inactive participants and those living with chronic conditions). These possible trends are consistent with prior research indicating that microincentives may be particularly effective in promoting PA among at-risk populations [13,18].

Limitations

This study has several strengths. Step data was collected using validated step tracking devices (ie, smartphones and fitness trackers in free-living conditions) [66], and the app's cost-free design may have appealed more to lower-income, higher-risk users. Nonetheless, several limitations warrant consideration. First, this study's low recruitment rate limited the sample size and statistical power to detect meaningful PA changes, as well as sample diversity. The requirement for 2 separate consents (ie, one through the app's onboarding system [n=46] and another within the app for step count data collection [n=22]) likely reduced participant recruitment. This 2-stage structure reflected a separation between consent for data collection of standard app use and consent for step count–specific data collection, a design that was partly inherent to the app's real-world deployment. However, future trials may benefit from integrating or streamlining consent procedures to minimize participant burden and improve enrollment efficiency in digital health interventions. One practical approach is the adoption of a tiered, integrated digital consent model, in which participants provide initial consent for minimal, low-risk data collection (eg, nonidentifiable engagement metrics) during onboarding, followed by feature-specific (eg, linking a wearable device), just-in-time consent prompts delivered contextually. This sandbox-style consent approach maintains ethical transparency and participant autonomy while reducing upfront friction and represents an appropriate, measurable methodological refinement suitable for evaluation in a subsequent ORBIT phase IIb study. Second, rolling participant recruitment meant the approximately 6-week evaluation window varied somewhat by participant (eg, some participant data collected in temperate September-October and some in cooler November-December), potentially introducing seasonal (eg, weather) and history bias [64]. Third, if participants did not carry their smartphones or wearable devices consistently throughout the days and weeks, there may be gaps in the data recorded at baseline and during the intervention period [66]. These gaps may lead to an underestimation of the actual number of steps taken per day (ie, measurement bias). However, incentivization may have addressed this by increasing the likelihood that participants consistently carry their devices during the intervention. Fourth, this feasibility study used a single-arm design without a control group, limiting causal inference. Without a comparator, it is difficult to determine whether observed outcomes are attributable to the intervention itself or to external factors (eg, seasonal changes and concurrent health campaigns). Fifth, although the current study's approach to assessing engagement aligns with recommended practices for reporting mHealth usage data (eg, macro-level of engagement) [67] and user-reported acceptability (eg, exit survey responses) [31], the proxy used may not fully capture the complexity of user engagement [68]. Alternative metrics (eg, frequency, duration, and other feature use) could have provided a more nuanced understanding. Such depth is important for identifying which components were most engaging, informing iterative improvements, enhancing user retention, and elucidating potential mechanisms linking engagement to PA outcomes. Without these insights, key patterns (eg, points of disengagement) may remain undetected [68]. Sixth, although the target behavior chosen for this app was to significantly increase users' daily steps, it is important to note that there are other behaviors related to movement that could be targeted. For example, in addition to encouraging users to walk or run more, the app could also support users to be less sedentary (ie, sit less) or to increase other moderate-to-vigorous intensity activities (eg, cycling to work). Seventh, although step goals were recalculated weekly based on prior step data (eg, median step count from the previous 7-day week), no explicit minimum or maximum thresholds were applied; goals were determined entirely by participant data, without the use of predefined minimum or maximum thresholds or manual adjustments. This may have contributed to potential plateau effects in participant motivation and engagement over time [69]. Eighth, participants exhibited relatively high baseline engagement with PA and self-monitoring behaviors. Mean baseline daily step counts exceeded national averages, and 65.9% of participants reported using a fitness tracker at baseline (ie, nearly double the UK population prevalence [≈35%]). This suggests that the sample may have been more motivated, health-conscious, or technologically engaged than the general population. Such preexisting engagement may have positively influenced app uptake, sustained use, and favorable acceptability ratings, and therefore, the high engagement and acceptability observed may not fully generalize to populations with lower baseline activity levels or less familiarity or interest in digital health technologies. Finally, in its current form, Caterpillar is not suitable for people who cannot adequately read and comprehend English, limiting its generalizability, particularly in diverse urban settings such as Leeds, where nearly 10% of adults report a first language other than English [70].

Conclusions

This ORBIT model phase IIa study served to assess the feasibility of the intervention and refine the delivery and

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examination of the Caterpillar app that offered microincentives to boost PA in the United Kingdom. Relatively high app engagement and acceptability, and preliminary evidence of PA increases, support advancing to a more robust (ie, 2-arm) pilot evaluation.

Acknowledgments

The authors would like to express their gratitude to the users of the Caterpillar app for their valuable feedback and participation in the development and improvement of the app. The contributions of the Active Leeds City Council and National Health Service health guidelines are also acknowledged for providing expert health information content throughout the course of this project. Appreciation is further extended to the technical team for their hard work and dedication in bringing the app to fruition. No generative AI tools (eg, ChatGPT [OpenAI], Gemini [Google LLC], or similar) were used to write or revise this paper. All content, including survey questions, data analysis, and interpretations, was developed solely by this study's team.

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Data Availability

The datasets generated and analyzed during this study are available upon reasonable request.

Authors' Contributions

BS and MSM conceptualized and designed this study, drafted the initial paper, coordinated and supervised data collection, analyzed the data, and reviewed and revised this paper. MSH, HP, LMV, and MSM critically revised this paper. BS was responsible for the overall content as guarantor. All authors (BS, MSH, HP, LMV, and MSM) approved this final paper as submitted and agree to be accountable for all aspects of this work.

Conflicts of Interest

MSH received a 50/50 grant from Caterpillar and the Mitacs Accelerate Grant to be able to conduct research and work in an industry capacity. MSM (principal investigator) provided unpaid consulting services to Caterpillar Health Inc between January 2021 and January 2023 (≈10 hours/month). The company agreed to provide funding in the form of a course buyout during a previous academic year (September 2021 to May 2022; CAD $15,000 [US $10,924.50]) to free up time for MSM to continue to provide such service. The results of this study are presented clearly, honestly, and without fabrication, falsification, or inappropriate data manipulation. This is approved by the Faculty of Health Sciences dean, Jayne Garland, PhD.

Multimedia Appendix 1
Demographic and health survey, exit survey questions, and responses.
[DOCX File, 27 KB - formative_v10i1e85484_app1.docx]

Multimedia Appendix 2
Caterpillar health BCTs (behavior change technique) and COM-B (capability, opportunity, motivation-behavior).
[DOCX File, 38 KB - formative_v10i1e85484_app2.docx]

Multimedia Appendix 3
Baseline characteristics of subgroup samples.
[DOCX File, 36 KB - formative_v10i1e85484_app3.docx]

Checklist 1
STROBE statement checklist.
[PDF File, 10287 KB - formative_v10i1e85484_app4.pdf]

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Abbreviations:

BCW: behavior change wheel

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COM-B: capability, opportunity, motivation–behavior
FI: financial incentive
KPMG: Klynveld Peat Marwick Goerdeler
MD: mean difference
mHealth: mobile health
ORBIT: Obesity-Related Behavioral Intervention Trial
PA: physical activity
RCT: randomized controlled trial
STROBE: Strengthening the Reporting of Observational Studies in Epidemiology

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A Gamified Pain Management Intervention for Adults With Chronic Pain in Mainland China: Single-Arm Pre-Post Pilot Study With Machine Learning Predictive Modeling

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Abstract

Background: The widespread prevalence of chronic pain (CP) significantly impacts daily functioning worldwide. In mainland China, maintaining engagement in biopsychosocial interventions remains challenging. Gamification, designed based on self-determination theory, can enhance motivation, while machine learning (ML) algorithms can assist clinicians in dynamically optimizing pain management.

Objective: This study aimed to (1) evaluate the preliminary effectiveness of a gamified pain management (GPM) program on CP and psychological outcomes and (2) identify key factors of significant pain improvements through the application of ML to guide intervention adjustments.

Methods: A single-arm, pre-post study was conducted with 16 participants with CP in mainland China, recruited via social media using convenience sampling. Participants engaged in a 10-week web-based GPM intervention consisting of education, physical activities, and gamified elements, including points, avatars, and feedback. Primary outcomes were pain intensity and interference measured by the Brief Pain Inventory. Secondary outcomes included anxiety, depression, and quality of life. Analysis included paired *t* tests, and ML models were trained to predict clinically meaningful pain reductions. Shapley additive explanations, least absolute shrinkage and selection operator regression, association rule mining, and Kaplan-Meier survival analysis were used to identify key predictors and optimal sessions and intervention durations across subgroups.

Results: A total of 16 participants were engaged, with a mean age of 27.63 (SD 9.584) years. Results from paired *t* tests reported significant improvements in pain intensity (decreased by 27.3%, 95% CI 1.061 to 3.064; *P*=.001), pain interference (decreased by 27.3%, 95% CI 8.159-17.216; *P*<.001), and psychological distress, including anxiety (t_{15}=3.538, 95% CI 0.969 to 3.906; *P*=.003) and depression (t_{15}=4.559, 95% CI 2.230 to 6.145; *P*<.001). The gradient boosting model demonstrated the highest predictive accuracy (area under the curve=0.89 and accuracy=0.82). Least absolute shrinkage and selection operator regression identified session 3 (β=−0.45, 95% CI −0.68 to −0.22; *P*<.001) and session 5 (β=−0.32, 95% CI −0.59 to −0.05; *P*=.02) as most predictive of clinical success, while association rule mining revealed effective session combinations for different patient subgroups. Time-to-event analyses indicated that individuals with low back pain and higher baseline severity required longer intervention durations for improvement (5 wk; *P*=.03).

Conclusions: This pilot study presents an innovative method that combines ML with dynamic engagement data from a GPM program during interventions, rather than relying on static baseline data in prior studies. The results show preliminary efficacy and identify specific optimal session combinations and personalized treatment durations for different pain subgroups. These exploratory findings contribute to the field by providing a data-driven method for adaptive, personalized digital health interventions that move beyond one-size-fits-all strategies, potentially enabling clinicians to modify content and dosage to improve engagement and outcomes if validated in larger sample trials.

Trial Registration: Chinese Clinical Trial Registry ChiCTR2400094247; https://www.chictr.org.cn/showprojEN.html?proj=245138

(JMIR Form Res 2026;10:e78823) doi:10.2196/78823

KEYWORDS

gamification; artificial intelligence; machine learning; pain management; chronic pain

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Introduction

Problem

The Global Burden of Disease Study reported a high prevalence of chronic pain (CP) globally [1]. CP, defined as pain that persists for more than 3 months, significantly disrupts various aspects of daily life, including work, physical activity, and social engagement. It is frequently comorbid with anxiety and depression, sleep disturbances, and decreased productivity [2]. In mainland China, the prevalence of CP ranges from 50% to 70% and there is a preference for self-management [3,4], highlighting the urgent need for effective pain management. Despite the growing adoption of biopsychosocial approaches in clinical guidelines [5], individuals with CP face strong barriers to adhere to regular physical activity, including fear of pain and lack of personalized plans [6,7].

Literature Review

To tackle these challenges, gamification has emerged as an innovative strategy to enhance user engagement, motivation, and adherence to health interventions [8]. Drawing on theories such as self-determination theory (SDT), gamification incorporates game design elements into nongame contexts to motivate behavior change [9,10]. While various gamified interventions have been developed to reduce pain symptoms, the treatment effects have been inconsistent. Some studies have shown immediate efficacy for both adults and older adults [11,12], with evidence suggesting that individuals across age groups find these interventions enjoyable and accessible [13]. However, other randomized controlled trials reported nonsignificant effects on pain intensity [14,15]. This heterogeneity may stem from the complex and multidimensional nature of CP, as well as insufficient theoretical grounding and inability to tailor to specific populations [16], a challenge that causes treatments to struggle to maintain adherence over time. Therefore, this study developed a gamified pain management (GPM) program for adults in mainland China, grounded in SDT, to foster intrinsic motivation through multiple game elements such as avatar, choices, feedback, and challenges.

Building on the motivational benefits of gamification, integrating artificial intelligence (AI) can further enhance personalization and long-term adherence through data-driven adaptation by addressing barriers, including accessibility and sustained engagement. Numerous studies have demonstrated that AI can assist in treatment decision-making, dynamic prediction, and behavior guidance. For instance, rule-based recommendation systems can generate personalized exercise plans based on users' pain characteristics, improving intervention adaptability [17]. AI chatbots provide psychological support and behavioral reminders through real-time interaction, enhancing user engagement and treatment adherence [18]. Machine learning (ML) models including random forests and extreme gradient boosting have been used to predict postoperative pain outcomes and determine opioid use, thereby assisting in drug management [19,20]. These advantages mark a shift from traditional, rule-based systems to dynamic, data-driven prediction models.

Unlike existing studies that primarily rely on static baseline data, our study uses dynamic real-time behavioral data recorded during the intervention engagement into ML models. Moreover, most studies focus on the binary questions of whether intervention reduces pain, but questions such as "how quickly improvement occurs" and "through which mechanisms improvement occurs" remain unexplored, thus lacking a deeper understanding of the time course and underlying processes of intervention effectiveness.

Aims and Objectives

In response to these gaps, the present pilot study aimed to (1) assess the effects of the GPM intervention on CP in adults in mainland China and (2) identify key factors that predict significant improvements in pain intensity using ML models.

Methods

Study Design

This single-arm, nonrandomized, pre-post pilot study aimed to evaluate the preliminary effects of the digital GPM intervention and to develop exploratory ML models predicting clinical pain reduction outcomes. Participants were recruited using convenience sampling through social media platforms and engaged with the intervention via a web-based platform. The study adhered to the TRIPOD-AI (Transparent Reporting of a Multivariable Prediction Model for Individual Prognosis or Diagnosis-AI) reporting guidelines (Checklist 1).

Ethical Considerations

The work described was carried out in accordance with the guidelines of the Hong Kong Metropolitan University Research Ethics Committee (reference HE-SF2024/34) and was registered on the Chinese Clinical Trial Registry (registration number ChiCTR2400094247). All participants were provided with a detailed digital informed consent form including the study purpose and procedures, potential risks and benefits (no monetary compensation), confidentiality and voluntariness, and contact information for the principal investigator. To ensure privacy and confidentiality, all data were anonymized by assigning a unique reference number, which was also used to log in to the game and surveys. All data are securely stored in an encrypted folder, and only the research team has access to the information. No images containing identifiable participant identities were obtained. No monetary compensation was provided for participation in this study.

Participants

No formal prior power calculation was performed due to the exploratory, feasibility-testing nature of this pilot study, and a sample size larger than 10 was deemed appropriate for the formative objectives [21]. Interested individuals were recruited through an online flyer via social media platforms including Redbook and WeChat. The flyer featured a QR code to access an online questionnaire for initial eligibility screening. To be eligible to participate in the study, the participants must meet all inclusion criteria: (1) aged 18 years or older; (2) able to read and understand the Mandarin Chinese language; (3) owners of smartphones with internet access; (4) have a previously

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diagnosed chronic noncancer pain condition lasting more than 3 months; (5) report a score of greater than or equal to 2 on the Visual Analog Scale [22]. Exclusion criteria were as follows: (1) patients with associated pathologies that make it impossible to perform physical exercise (myopathies, neurological diseases, cardiac disease, pregnancy, pulmonary diseases, infection, and fracture) [23]; (2) individuals undergoing surgery or invasive treatments in the last 3 months [24]; (3) concurrent participation (or participation within the preceding 3 mo) in a supervised exercise program or multidisciplinary treatment.

Intervention

The GPM was open for 10 weeks, allowing participants to complete the web-based intervention at their own pace. It integrated gamification, education, and progressive exercise within a gamified framework informed by SDT. Prior to the first session, participants received web-based instructions outlining the intervention structure. The program was structured as an escape room game, where participants, via hero avatars, progressed through themed sessions by unlocking educational content, exercise tasks, quizzes, and relaxation activities.

The educational modules covered the following information via animated videos and notes: (1) the definition and mechanisms of pain, (2) distinctions between acute and CP, (3) the biopsychosocial impact of CP, and (4) pharmacological and (5) nonpharmacological management strategies [25]. Each progressive exercise module (5 - 7 min each) included strengthening and stretching [5] routines tailored to participants' primary pain locations (eg, neck, shoulder, back, knee, or head) (Table 1). Gamification elements included a points system (awarded for quiz accuracy and exercise completion), a hero avatar, choices and challenges, and positive or corrective feedback mechanisms. To progress, a minimum of 60 points per session was required. Hidden sessions embedded within the game provided opportunities for additional exercises and engagement.

Engagement data, including treatment duration (TD) (first and last login timestamps), quiz accuracy, and session-specific satisfaction scores, were automatically recorded by the GPM platform. Biweekly WeChat reminders were manually sent to promote adherence.

Table . Descriptive statistics of engagement and feedback metrics (N=16).

Variable	Mean (SD)	Range
Engagement variables		
Treatment duration (wk)	4.38 (2.19)	1 - 10
Number of quizzes correctly answered[a]	6.94 (1.53)	3 - 8
GUESS[b]	96.25 (12.69)	68 - 115
Cumulative session feedback scores[c]		
Understandability	33.94 (5.26)	25 - 40
Comprehensibility	33.94 (5.26)	25 - 40
Applicability	32.44 (7.56)	15 - 40

[a]Higher quiz accuracy and satisfaction scores indicate greater understanding and engagement.

[b]GUESS: Game User Experience Satisfaction Scale.

[c]Scores for understandability, comprehensibility, and applicability represent the cumulative sum of a participant's ratings across all 8 intervention sessions. Each item was rated from 0 to 5 per session, resulting in a possible cumulative range of 0 to 40 for each item.

Data Collection

Participants were recruited via social media posters containing a hyperlink to an online eligibility screening questionnaire [26], where detailed study information and consent form were provided. After providing informed consent, screening questions, including pain condition, medical history, and demographic criteria were embedded within the survey. The survey system automatically submitted an incomplete survey if any exclusionary options were selected. Individuals who met the eligibility criteria were invited to voluntarily provide their WeChat ID to receive automatically generated access credentials for the intervention platform.

Baseline assessments (T0) were administered via the survey platform [26] and distributed to eligible participants through WeChat. Upon completion, participants were provided with access credentials to the GPM intervention site [27]. Postintervention assessments (T1) were collected through the same platform immediately after the intervention was completed approximately 10 weeks after baseline.

Measurements

A list of outcome measures, including instruments and score ranges, is provided in Table 2.

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Table . Summary of demographic, clinical, and intraintervention feature domains used as input variables for machine learning modeling.

Domain	Description
Demographic	• Sex (male or female), age
Clinical	
Pain	• Pain duration was assessed by demonstrating specific total months of pain experiences (divided into categories: 3 mo, 4 mo, 5 mo, 6 - 9 mo, 9-12 mo, and >12 mo) • Pain site was provided with different body sites including head, neck, shoulder, low back, and knee
Functionality	• Assessed by Brief Pain Inventory considering the total score (score range 0 - 70) and subscale scores (score range 0 - 10)
Mental health	• Assessed by the 7-item General Anxiety Disorder Scale (score range 0 - 21) and the 9-item Patient Health Questionnaire (score range 0 - 27)
Fear-avoidance and catastrophizing	• Evaluated by Fear Avoidance Beliefs Questionnaire (score range 0 - 96) and the total score and subscale scores (score range 0 - 42) • Pain Catastrophizing Scale considering (score range 0 - 52) and the total score and subscale scores (score range 0 - 24)
Medication consumption	• Considers opioid consumption (yes or no)
Quality of life	• Evaluated by the 3-level version of EQ-5D[a] considering the total score (score range 0 - 45) and subscale scores (score range 0 - 15)
Exercise adherence	• Godin Leisure Time Exercise Questionnaire was used (score range 0 - 99)
Motivation	• Game User Experience Satisfaction Scale considering the total score (score range 0 - 24) and subscale scores (score range 0 - 24)
Intraintervention variables	
Quiz accuracy	• Number of correct answers
Adverse event	• Considers adverse events (yes or no)
Intervention duration	• The time span from the first to the last day of participation
Session satisfaction score	• Summary score of understandability, comprehensibility, and applicability in each session (score range 0 - 15).

[a]EQ-5D: EuroQol 5-dimension.

Primary Outcome

Pain intensity and pain interference were assessed using the Brief Pain Inventory, rated on a scale of 0 to 10. Pain severity was calculated based on the past 24 hours and the “current pain.” The pain interference includes the interference degree of pain on general activity, mood, walking, work, social relationships, sleep, and enjoyment of life. The Chinese scale has good reliability with a Cronbach α of 0.89 [28].

Secondary Outcomes

Secondary outcomes were as follows:

- Fear Avoidance Beliefs Questionnaire and Pain Catastrophizing Scale: Used to measure pain perception including attitude toward physical activity, work, rumination, magnification, and helplessness related to pain. The Cronbach coefficients of the Chinese version of the Fear Avoidance Beliefs Questionnaire are high, ranging from 0.75 to 0.85 [29], and Pain Catastrophizing Scale is 0.91 [30].
- Godin Leisure Time Exercise Questionnaire: Used to measure exercise adherence, including times of strenuous exercise, moderate exercise, and mild exercise per week via the website. The percentage of exercises completed out of the total number of prescribed exercises is used to measure total exercise adherence. The Cronbach α is 0.64 and the κ index is 0.94 [31].
- Patient Health Questionnaire-9 items and Generalized Anxiety Disorder-7 items: Used to measure depression and anxiety. The Chinese version of the scale has excellent internal reliability; the Cronbach α of the Generalized

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Anxiety Disorder-7 items is 0.91 [32] and that of the Patient Health Questionnaire-9 items is 0.86 [33].

- The EuroQol 5-D 3-level: Used to assess an individual's perceptions of quality of life including mobility, self-care, and usual activities. The Chinese version has been treated as the standard in China [34].
- Game User Experience Satisfaction Scale: Used to evaluate overall game satisfaction, with good internal reliability (Cronbach α=0.93) [35].
- Intraintervention variables (collected during or immediately after intervention [T1]):
  - Engagement metrics were assessed through session satisfaction scores (SAT) and quiz accuracy, recorded via the GPM platform.
    - Satisfaction scores were derived from the sum of 3 items rated on a 5-point Likert scale following the completion of each session. These items evaluated the following: (1) Understandability: "Are the materials in this session easy for you to understand?" (2) Comprehensibility: "How much do you understand the materials in this session?" (3) Applicability: "To what extent do you think you would apply this session to future self-management?"
    - Quiz accuracy was calculated as the proportion of correctly answered questions in each session's embedded quiz.
  - TD was automatically calculated as the total number of weeks between a participant's first and last login on the GPM platform.

Statistical Analysis

To test aim 1, descriptive statistics for engagement metrics, including TD, quiz scores, and SAT were calculated. Paired *t* tests were conducted to compare differences between the two stages: baseline (T0) and postintervention (T1) across all outcome measures. The normality of difference scores was examined using the Shapiro-Wilk test. In case of violation of the normality assumption, the nonparametric Wilcoxon signed-rank test was applied. In addition, paired *t* tests were conducted within pain subgroups to examine the within-group intervention effects. The pain intensity level was categorized into two groups: mild-to-moderate (scores ranging from 3 to 6) and severe pain group (scores 7 or higher in Brief Pain Inventory) [36]. Given the small sample size and exploratory, hypothesis-generating nature of this study, no multiple comparisons were applied. This decision was made to minimize the risk of type II errors in this initial investigation. A significant level of $P<.05$ was applied. The analyses were performed using SPSS Statistics Version 23.0 (IBM Inc) and Python 3.11.

ML Analysis

ML modeling was exploratory and served as proof-of-concept analysis. The dataset comprised 53 features, including baseline demographic, clinical, and intraintervention engagement metrics (Table 2). The binary outcome variable, pain intensity, indicates a clinically significant improvement, defined as a ≥30% reduction in pain intensity measured by the BPI [36]. Continuous predictors were *z*-score standardized, and categorical variables were one-hot encoded.

Predictive Modeling for Pain Reduction

Five supervised classification models were trained to predict clinical pain reduction. Due to the limited sample size, model training and hyperparameter tuning used a 5-fold stratified cross-validation procedure on the training data (80% training and 20% testing per iteration) to preserve the distribution of clinical pain reduction across folds. Accuracy, recall, specificity, precision, F_1-score, and the area under the curve (AUC) were used to evaluate performance (Figure 1). To reduce overfitting, model training and evaluation relied on a 5-fold stratified cross-validation procedure, and all models were trained on standardized and encoded features only. Shapley additive explanations (SHAP) was used to identify the most influential predictors of intervention effectiveness from the best performing models (gradient boosting and random forest).

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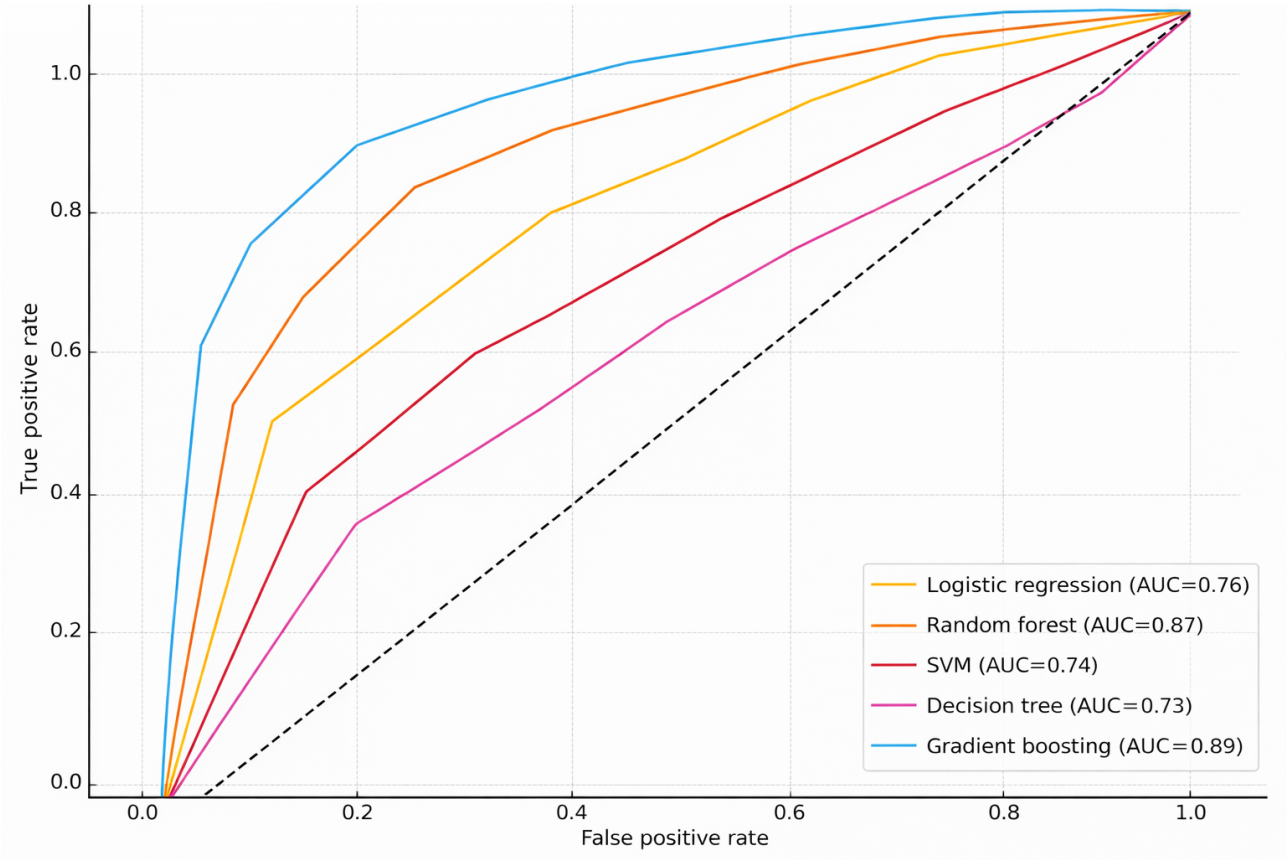
Figure 1. Receiver operating characteristic curve across models for predicting clinically significant pain reduction. AUC: area under the curve; SVM: support vector machine.



Session-Level Mechanisms of Clinical Improvement Analysis

A LASSO (least absolute shrinkage and selection operator) regression was performed to further examine each SAT's contribution to clinical pain reduction. This focused strategy sought to elucidate the role that session-specific engagement played in clinical improvement and to provide guidance for tailoring the order of interventions. A leave-one-out cross-validation approach was used to optimize training data use and guarantee reliable variable selection in the small-sample setting. In order to reduce overfitting, especially in high-dimensional, small-sample situations, this regularized regression technique enables variable selection and coefficient shrinkage. Sessions with the greatest predictive influence were identified by shrinking noninformative variables toward 0.

Association rule mining was then used to find potential interaction patterns for particular subgroups (SAT ≥12 coded as "high"), while LASSO regression identified the contribution of individual sessions. Rules linked to clinical improvement that satisfied high-confidence (≥0.75) and high-lift patterns (≥1.15) thresholds were extracted using the Apriori algorithm. Our threshold of greater than or equal to 1.15 was selected to find patterns where the session combination and clinical improvement co-occurred at least 15% more frequently than would be predicted by chance. Crucially, a lift value greater than or equal to 1 indicates a positive association. The goal of this exploratory analysis was to produce ideas for tailoring the sequencing of digital interventions.

Time-to-Improvement Analysis by Subgroup

Leave-one-out cross-validation was used with the gradient boosting model to examine the ideal intervention duration needed for clinical improvement across pain subgroups. SHAP-informed patterns in model decision boundaries were used to estimate intervention day thresholds. The robustness and CIs of these thresholds were estimated using bootstrap sampling, which supports reliability under small sample constraints.

The duration of the intervention at which the postintervention assessment satisfied the criteria for clinically significant improvement (≥30% reduction in pain intensity score) was operationalized as the time to improvement. As a result, Kaplan-Meier survival curves were used for time-to-event analysis, with the time to clinical improvement serving as the survival time variable. To investigate variations in median improvement durations by pain site and severity, subgroup comparisons were carried out. Statistical significance was evaluated using log-rank tests. All results should be viewed as preliminary and hypothesis-generating rather than confirmatory, given the small sample size.

Results

Participant Demographics

Data collection procedures were completed online between March 2025 and August 2025. A total of 23 individuals accessed the online screening survey. Of these, 5 were excluded for not meeting eligibility criteria (eg, pain duration <3 months, pain

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intensity <2). Two participants withdrew prior to the intervention due to time conflicts, so no missing data was observed. And 16 participants were enrolled in the study, with a mean age of 27.63 (SD 9.58) years. The majority of participants were employed (15/16, 93.8%), and all had a higher education background. Pain duration varied, with 25% (4/16) of participants experiencing CP for over 1 year, while others reported pain durations between 4 and 12 months. At baseline, participants reported moderate pain intensity levels (mean 5.81, SD 1.38) and pain interference (mean 38.31, SD 12.41) (Table 3).

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Table . Baseline demographics and clinical characteristics (N=16).

Variables	Values
Gender, n (%)	
Male	11 (68.8)
Female	5 (31.2)
Age, mean (SD)	27.63 (9.584)
Marriage, n (%)	
Single	12 (75)
Married	4 (25)
Occupation, n (%)	
Employed	15 (93.8)
Unemployed	1 (6.3)
Education background, n (%)	
Higher education	16 (100)
Duration of symptoms, n (%)	
3 mo	1 (6.3)
4 mo	2 (12.5)
5 mo	3 (18.8)
6 - 9 mo	5 (31.3)
9 - 12 mo	1 (6.3)
>1 yr	4 (25)
Use of pain medication, n (%)	
Yes	3 (18.8)
No	13 (81.3)
Baseline scores, mean (SD)	
BPI[a] intensity	5.81 (1.377)
BPI interference	38.31 (12.408)
FABQ[b]	58.69 (13.189)
PCS[c]	35.81 (8.796)
PHQ-9[d]	11.88 (4.674)
GAD-7[e]	9.75 (4.946)
GLTEQ[f]	97.81 (84.680)
EQ-5D-3L[g]	3.06 (2.932)

[a]BPI: Brief Pain Inventory.
[b]FABQ: Fear-Avoidance Beliefs Questionnaire.
[c]PCS: Pain Catastrophizing Scale.
[d]PHQ-9: Patient Health Questionnaire-9 items.
[e]GAD-7: Generalized Anxiety Disorder-7 items.
[f]GLTEQ: Godin Leisure Time Exercise Questionnaire.
[g]EQ-5D-3L: EuroQol 5-Dimension 3-Level.

Intervention Effectiveness and Outcome Variables

Table 4 presents the means and SDs of the key outcome measures at baseline and post intervention. Significant reductions were observed in pain intensity (t_{15}=4.392, 95% CI 1.061-3.064; P<.001) and pain interference (t_{15}=5.971, 95% CI 8.159-17.216; P<.001). Secondary outcomes, including pain catastrophizing and psychological distress, also demonstrated significant improvements post intervention. Pain-related

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catastrophizing (t_{15}=3.190, 95% CI 2.821-14.179; P=.006), depression (t_{15}=4.559, 95% CI 2.230-6.145; P<.001) and anxiety (t_{15}=3.538, 95% CI 0.969 - 3.906; P=.003) demonstrated significant improvement. Additionally, quality of life improved significantly (t_{15}=2.611, 95% CI 0.172-1.703; P=.02). Fear-avoidance beliefs and exercise adherence showed no significance (P>.05, see Table 4 and Table S1 in Multimedia Appendix 1 for details).

Participants' engagement with the GPM varied. With a range of 1 to 10 weeks, the average TD was 4.38 (SD 2.19) weeks, demonstrating high flexibility and customized completion rates. The average quiz accuracy was roughly 75%, indicating a generally high level of understanding of the course material. Table 1 displays the cumulative scores for the session feedback items, which were consistently high (mean 33.44, SD 6.03, range 0 - 40) throughout all sessions, indicating favorable opinions of the sessions' comprehensibility and applicability (Tables 1 and 5).

Table . Preintervention and postintervention comparison of key outcomes (N=16).

Outcomes	Baseline, mean (SD)	Post intervention, mean (SD)	Statistics		
			t test *(df)*	95% CI	*P* value[a]
BPI[b] intensity	5.81 (1.377)	3.75 (1.342)	4.392 (15)	1.061 - 3.064	.001
BPI interference	38.31 (12.408)	25.63 (12.387)	5.971 (15)	8.159 - 17.216	<.001
PCS[c]	35.81 (8.796)	27.31 (13.200)	3.190 (15)	2.821 - 14.179	.006
FABQ[d]	58.69 (13.189)	53.81 (16.586)	1.440 (15)	-2.342 - 12.092	.17
GLTEQ[e]	97.81 (84.680)	101.00 (93.047)	-0.237 (15)	-31.890 - 25.515	.82
PHQ-9[f]	11.88 (4.674)	7.69 (3.860)	4.559 (15)	2.230 - 6.145	<.001
GAD-7[g]	9.75 (4.946)	7.31 (4.316)	3.538 (15)	0.969 - 3.906	.003
EQ-5D-3L[h]	3.06 (2.932)	2.13 (2.579)	2.611 (15)	0.172 - 1.703	.02

[a]Paired *t* tests were used to compare preintervention and postintervention scores.

[b]BPI: Brief Pain Inventory.

[c]PCS: Pain Catastrophizing Scale.

[d]FABQ: Fear-Avoidance Beliefs Questionnaire.

[e]GLTEQ: Godin Leisure Time Exercise Questionnaire.

[f]PHQ-9: Patient Health Questionnaire-9 items.

[g]GAD-7: Generalized Anxiety Disorder-7 items.

[h]EQ-5D-3L: EuroQol 5-Dimension 3-Level.

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Table . Session-specific satisfaction scores of each session (N=16).

Session	Description		Understandability	Comprehensibility	Applicability
	Education	PA[a]	Mean (SD)	Mean (SD)	Mean (SD)
Session 1	Definition of pain	Warm and balancing	4.06 (0.772)	4.01 (0.771)	4.00 (0.966)
Session 2	Biopsychosocial aspects of CP[b]	Stretching[c]	4.19 (0.750)	4.19 (0.750)	4.06 (0.998)
Session 3	Mechanism of CP	Core strength training	4.38 (0.719)	4.37 (0.719)	4.19 (0.981)
Session 4	Mechanism of CP	Stretching[c]	4.31 (0.793)	4.32 (0.763)	4.13 (1.204)
Session 5	Pharmacological intervention	Core strength training	4.25 (0.856)	4.25 (0.856)	3.88 (1.360)
Session 6	Nonpharmacological management	Core strength training	4.38 (0.719)	4.31 (0.732)	4.06 (1.237)
Session 7	PA	Stretching[c]	4.19 (0.981)	4.19 (0.985)	4.13 (0.957)
Session 8	Goal setting strategies	Core strength training	4.19 (1.047)	4.22 (1.041)	4.00 (1.211)

[a]PA: physical activity.

[b]CP: chronic pain.

[c]Stretching for head, neck or shoulder, low back, and knee.

Predictive Modeling and Key Determinants of Treatment Response

Gradient boosting and random forest models exhibited superior performance compared to other models. Specifically, gradient boosting achieved an AUC of 0.89, F_1-score of 0.82, accuracy of 0.83, precision of 0.82, and recall of 0.81, demonstrating predictive accuracy for pain intensity changes. The random forest model also performed well (AUC=0.87, F_1-score=0.80, accuracy=0.81, precision=0.80, and recall=0.79) (Table 6).

Figures 2 and 3 illustrate SHAP value analysis, identifying the most influential predictors of treatment response. Pain interference with general activity (BPI_GenA1) emerged as the strongest predictor, suggesting that participants with greater pain interference experienced more significant reductions in pain intensity after the GPM intervention. Pain catastrophizing (rumination) and age emerged as the second most significant predictors, with variations in these measures substantially affecting intervention effectiveness. Fear-avoidance belief demonstrated a significantly negative effect on prediction. Features including depression, TD, engrossment in the game (GUESS_Eng), and pain site are also identified as highly influential factors. These patterns suggest that participants with greater pain impact and consistent engagement derive the most benefit from GPM.

Table . Performance comparison of machine learning models for predicting clinically significant pain reduction (N=16).

Model	AUC[a]	Accuracy	Recall	Specificity	Precision	F_1-score[b]	% positive[c]
Gradient boosting	0.89	0.83	0.81	0.85	0.82	0.82	50%
Random forest	0.87	0.81	0.79	0.83	0.8	0.8	
Logistic regression	0.76	0.72	0.7	0.74	0.71	0.71	
SVM[d]	0.74	0.7	0.68	0.72	0.69	0.69	
Decision tree	0.73	0.69	0.67	0.71	0.68	0.68	

[a]AUC: area under the curve.

[b]$F1$-score: the harmonic mean of precision and recall.

[c]% positive: clinical positive outcome (reduction of 30% compared to the baseline in pain intensity).

[d]SVM: support vector machine.

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Figure 2. Average absolute Shapley additive explanations values from gradient boosting and random forest models for predicting pain reduction. BPI: Brief Pain Inventory; FABQ: Fear-Avoidance Beliefs Questionnaire; GUESS: Game User Experience Satisfaction Scale; PCS: Pain Catastrophizing Scale; PHQ: Patient Health Questionnaire.

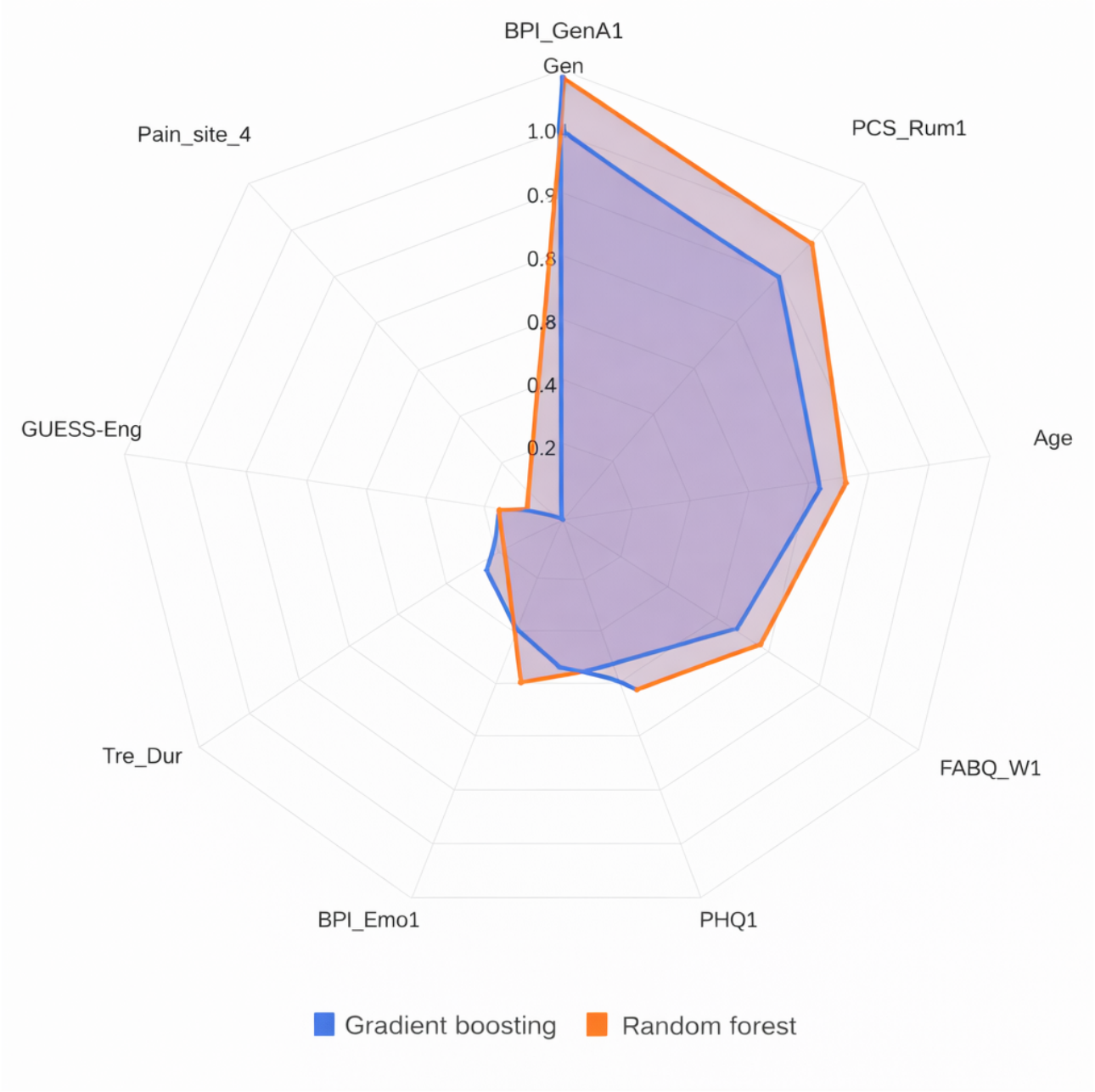

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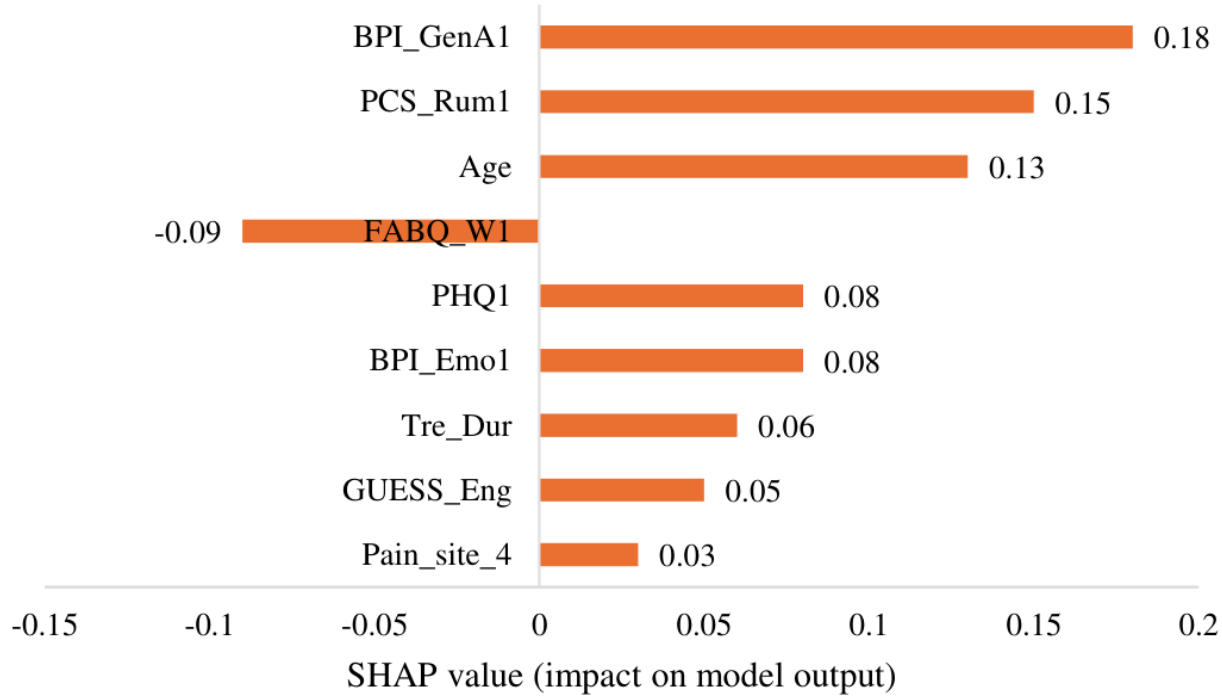
Figure 3. SHAP value for gradient boosting model predicting pain reduction. BPI: Brief Pain Inventory; FABQ: Fear-Avoidance Beliefs Questionnaire; GUESS: Game User Experience Satisfaction Scale; PCS: Pain Catastrophizing Scale; SHAP: Shapley additive explanations.



Session Level Mechanisms of Clinical Improvement

We conducted further analysis to examine session-level engagement patterns. Table 7 shows LASSO regression results linking SAT to pain improvement. Session 3 and 5 were significant predictors (P<.05), indicating that higher satisfaction in these sessions was associated with greater reductions in pain intensity. However, other sessions were assigned near-zero coefficients, suggesting minimal influence on treatment outcomes (Table 7).

Apriori association rule analysis identified effective combinations of session engagement associated with clinical improvement. The combination of high satisfaction in session 3 and session 5 exhibited the strongest association with clinical improvement (support: 0.38, confidence: 0.83, and lift: 1.65), particularly among participants with severe pain. The combination of sessions 4 and 6 was associated with improvement in the mild-to-moderate pain (MMP) subgroup (confidence: 0.78). Additionally, the combination of sessions 3, 5, and 7 had the highest confidence (0.85) and lift (1.70), suggesting a particularly potent effect for participants with severe low back pain (LBP). Other session combinations analysis is provided in Table 8 and Figure 4.

Table . Least absolute shrinkage and selection operator regression coefficients identifying key session-specific satisfaction scores associated with clinical pain improvement (N=16).

Session	Coefficient	SE	*z* score	*P* value[a]	95% CI
SAT 1[b]	−0.05	0.19	−0.26	.79	−0.42 to 0.32
SAT 2	−0.18	0.16	−1.13	.26	−0.49 to 0.13
SAT 3	−0.45	0.12	−3.75	<.001	−0.68 to −0.22
SAT 4	−0.12	0.17	−0.71	.48	−0.45 to 0.21
SAT 5	−0.32	0.14	−2.29	.02	−0.59 to −0.05
SAT 6	−0.08	0.18	−0.44	.66	−0.43 to 0.27
SAT 7	−0.28	0.15	−1.87	.06	−0.57 to 0.01
SAT 8	−0.03	0.20	−0.15	.88	−0.42 to 0.36

[a]Statistical significance was determined using the least absolute shrinkage and selection operator regression. Negative coefficients indicate higher satisfaction associated with greater pain reduction.

[b]SAT: session satisfaction scores.

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Table . Association rule patterns of session satisfaction combinations associated with clinically significant pain improvement by pain subgroup (N=16).

Session combination[a]	Support	Confidence	Lift	Subgroup
High SAT[b] 3 and 5	0.38	0.83	1.65	Severe pain
High SAT 4 and 6	0.29	0.78	1.55	MMP[c]
High SAT 1 and 8	0.25	0.75	1.50	Other pain
High SAT 2 and 4	0.27	0.77	1.53	N/SP[d]
High SAT 2 and 7	0.31	0.80	1.60	LBP[e]
High SAT 3, 5, and 7	0.19	0.85	1.70	Severe and LBP
Comprehensibility and applicability	0.22	0.81	1.68	Severe pain
High SAT 6 and applicability	0.17	0.78	1.52	MMP
High SAT 3 and comprehensibility	0.18	0.82	1.63	LBP
High SAT 5 and understandability	0.20	0.79	1.58	N/SP

[a]Data was analyzed by using Apriori association rules to identify frequent item sets of session satisfaction associated with clinical improvement. Higher lift (>1.5) indicates strong positive association between session combination and clinical improvement.

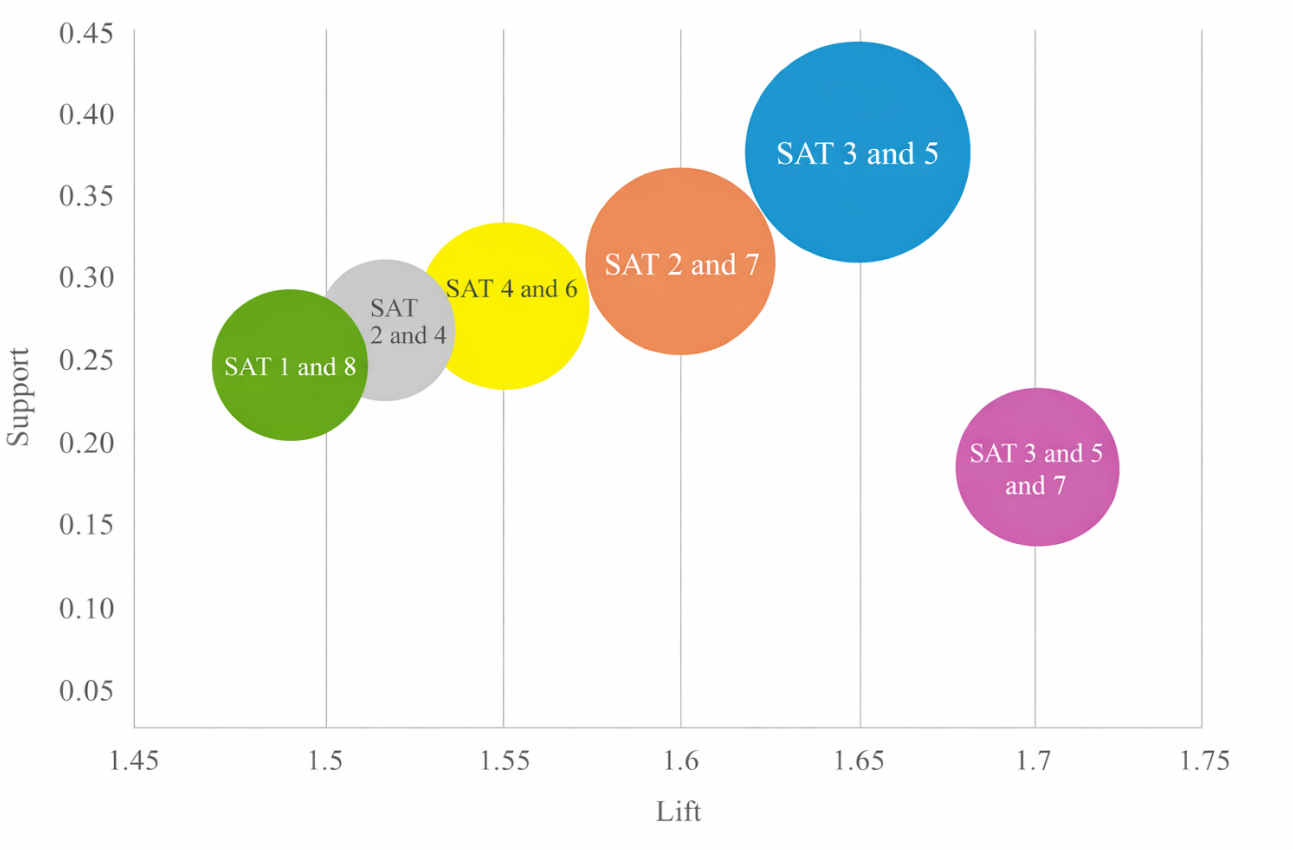
[b]SAT: session satisfaction scores.

[c]MMP: mild-to-moderate pain.

[d]N/SP: neck or shoulder pain.

[e]LBP: low back pain.

Figure 4. The bubble diagram of the grouping matrix for the 6 association rules. SAT: session satisfaction scores.



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Time-to-Improvement Analysis Across Subgroups

Table 9 presents within-group effects across different pain subgroups. Significant reductions in pain intensity were observed from baseline to post intervention in the MMP (t_{10}=3.130, 95% CI 0.367-2.179; *P*=.01), severe pain group (t_4=4.750, 95% CI 1.579, 6.021; *P*=.009), and neck or shoulder pain (N/SP) group (t_6=5.925, 95% CI 1.075-2.925; *P*=.002), indicating that the intervention had a statistically significant effect across multiple subgroups (Figures 5 and 6). These differences indicate that treatment response may depend on pain site and baseline intensity.

Table . Within-group pre-to-post changes in pain intensity across pain subgroups (N=16).

Group	Participants, n (%)	Baseline	Post intervention	Statistics		
		Mean (SD)	Mean (SD)	*t* test (*df*)	95% CI	*P* value[a]
MMP[b]	11 (68.75)	5.09 (0.94)	3.82 (1.17)	3.130 (10)	0.367 to 2.179	.01
Severe pain	5 (31.25)	7.40 (0.55)	3.60 (1.82)	4.750 (4)	1.579 to 6.021	.009
Other pain	4 (25)	5.75 (2.22)	2.75 (0.96)	2.121 (3)	−1.501 to 7.501	.12
N/SP[c]	7 (43.75)	5.86 (1.07)	3.86 (1.07)	5.925 (6)	1.075 to 2.925	.002
LBP[d]	5 (31.25)	5.80 (1.30)	4.40 (1.67)	1.510 (4)	−1.175 to 3.975	.21

[a]Paired *t* tests were used to compare preintervention and postintervention scores.

[b]MMP: mild-to-moderate pain.

[c]N/SP: neck or shoulder pain.

[d]LBP: low back pain.

Figure 5. Comparison of Brief Pain Inventory intensity scores for mild-to-moderate pain and severe pain across time.

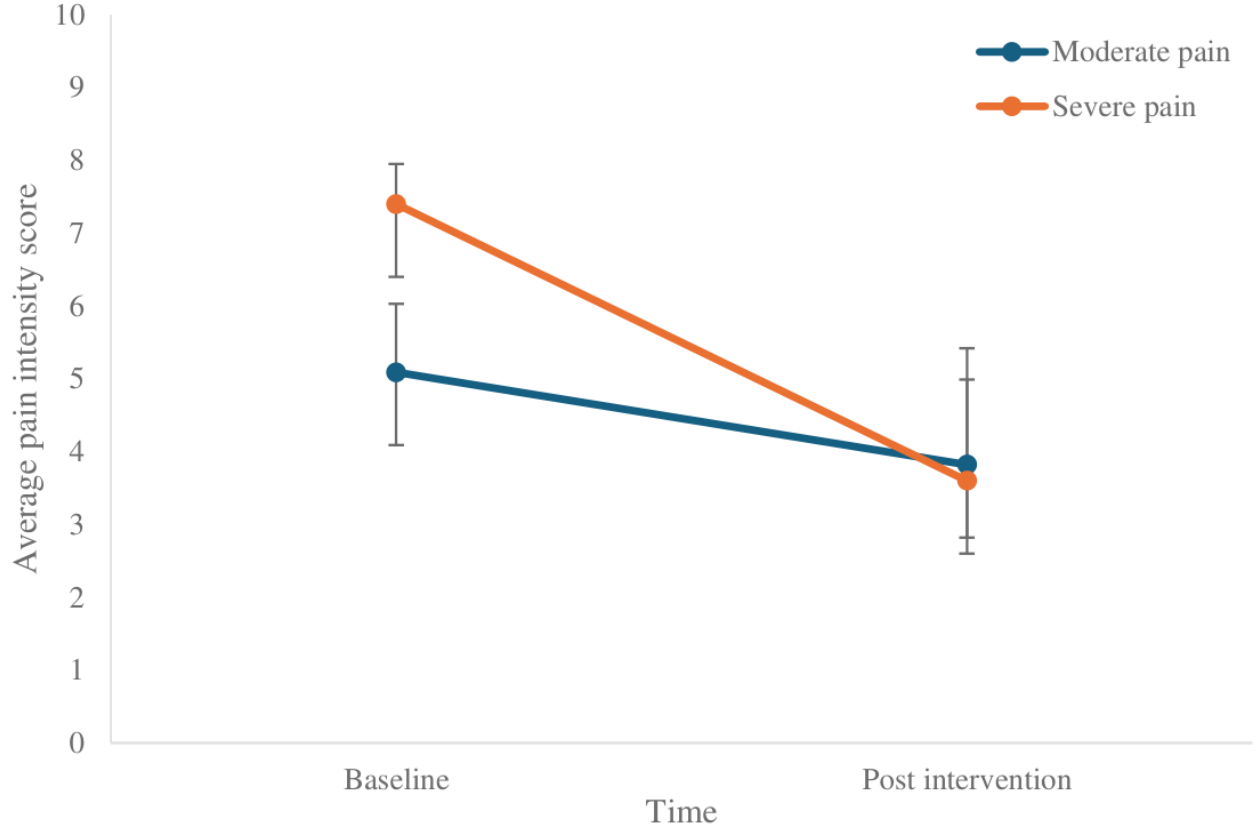

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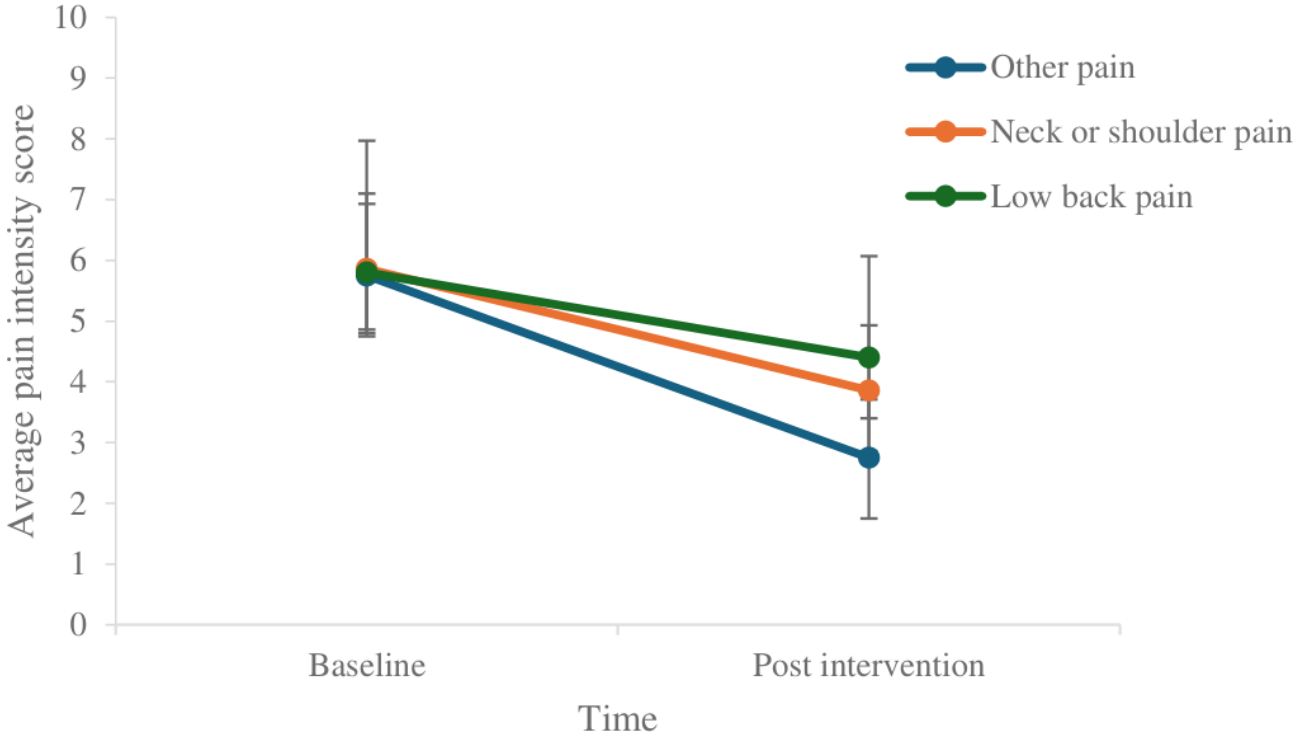
Figure 6. Comparison of Brief Pain Inventory intensity scores for different pain site groups across time.



SHAP values indicated that participants in the severe pain group required longer treatment (≥5.0 wk) for significant benefit, with session 3 identified as the top session-level predictor, while TD dominated overall predictions. An increase to 80% probability of clinically significant improvement benefit from a minimum of 5 weeks in the severe group and 3.6 weeks in the MMP group. LBP benefited after 4.6 weeks and N/SP after 4 weeks, suggesting that dose response varied by condition (Table 10).

Kaplan-Meier survival curves were generated for participants stratified by baseline pain intensity and pain site, corroborating findings with SHAP-based threshold analysis. The median time to improvement was longer for participants with severe pain (5 wk) compared to those with MMP (3.6 wk), and the difference was significant (log-rank *P*=.03) (Table 11, Figure 7). The median time to improvement was 4.6 weeks for LBP, which was longer than N/SP (3.4 wk) and other pain group (4 wk) (Table 10, Figure 8). Bootstrap validation provided support for the stability of these estimates (Table 12). However, these findings require confirmation in larger samples.

Table . SHAP[a]-informed thresholds for optimal treatment duration by subgroup (N=16).

Group	Optimal TD[b] (wk)	Probability increase (%)	Key predictors (SHAP values)
Severe pain	≥5.0	+80	SAT[c] 3 (0.45), TD (0.30)
MMP[d]	≥3.6	+70	SAT 4 (0.28), SAT 6 (0.22)
LBP[e]	≥4.6	+75	SAT 7 (0.35), TD (0.25)
N/SP[f]	≥4.0	+65	SAT 2 (0.40), SAT 4 (0.20)
Other pain	≥3.4	+60	SAT 1 (0.30), SAT 8 (0.25)

[a]SHAP: Shapley additive explanations.

[b]TD: treatment duration.

[c]SAT: session satisfaction scores.

[d]MMP: mild-to-moderate pain.

[e]LBP: low back pain.

[f]N/SP: neck or shoulder pain.

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Table . Kaplan-Meier survival estimates of time to clinically significant improvement by subgroup (N=16).

Group	TD[a] (wk), median	3-wk PCI[b] (%)	6-wk PCI (%)	Log-rank *P*
MMP[c]	3.6	50	90	0.03
Severe pain	5	20	70	0.03
LBP[d]	4.6	25	80	0.04
N/SP[e]	4	40	85	0.05
Other pain	3.4	55	75	0.15

[a]TD: treatment duration.

[b]PCI: proportion with clinical improvement.

[c]MMP: mild-to-moderate pain.

[d]LBP: low back pain.

[e]N/SP: neck or shoulder pain.

Figure 7. Kaplan-Meier survival curves for time to clinical improvement by pain intensity group.

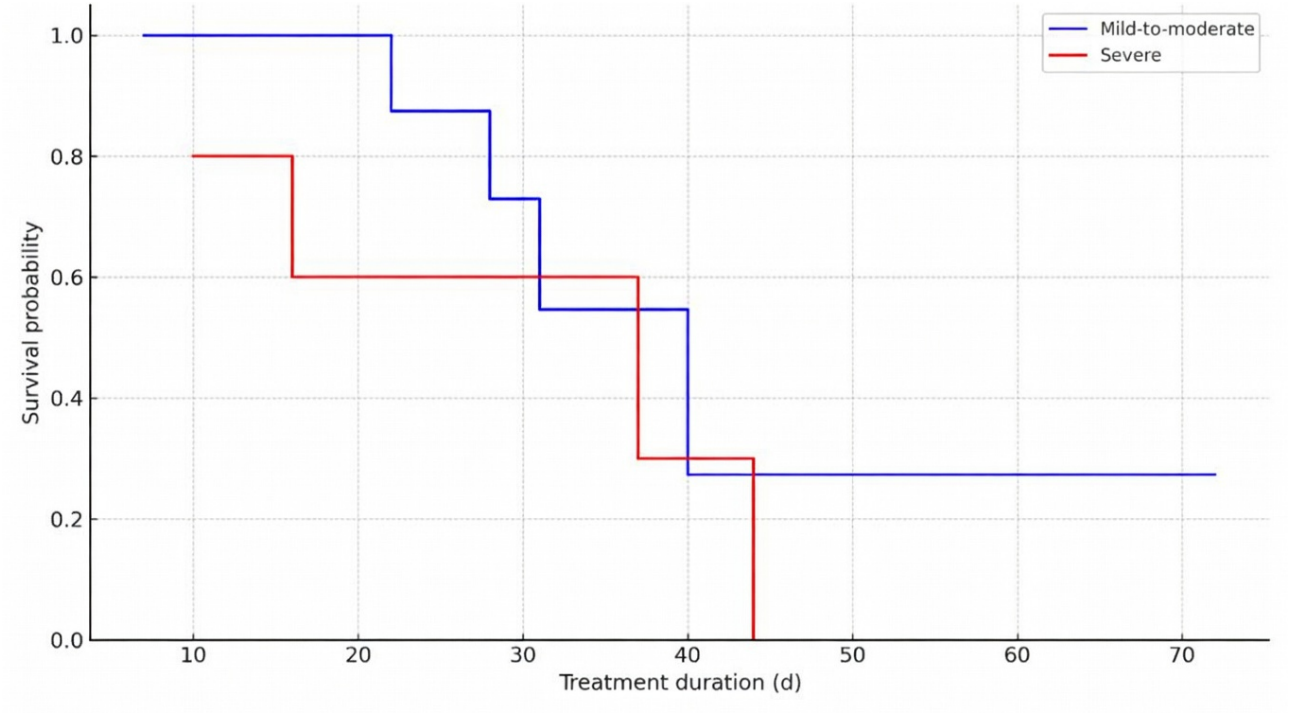

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Figure 8. Kaplan-Meier survival curves for time to clinical improvement by pain site group.

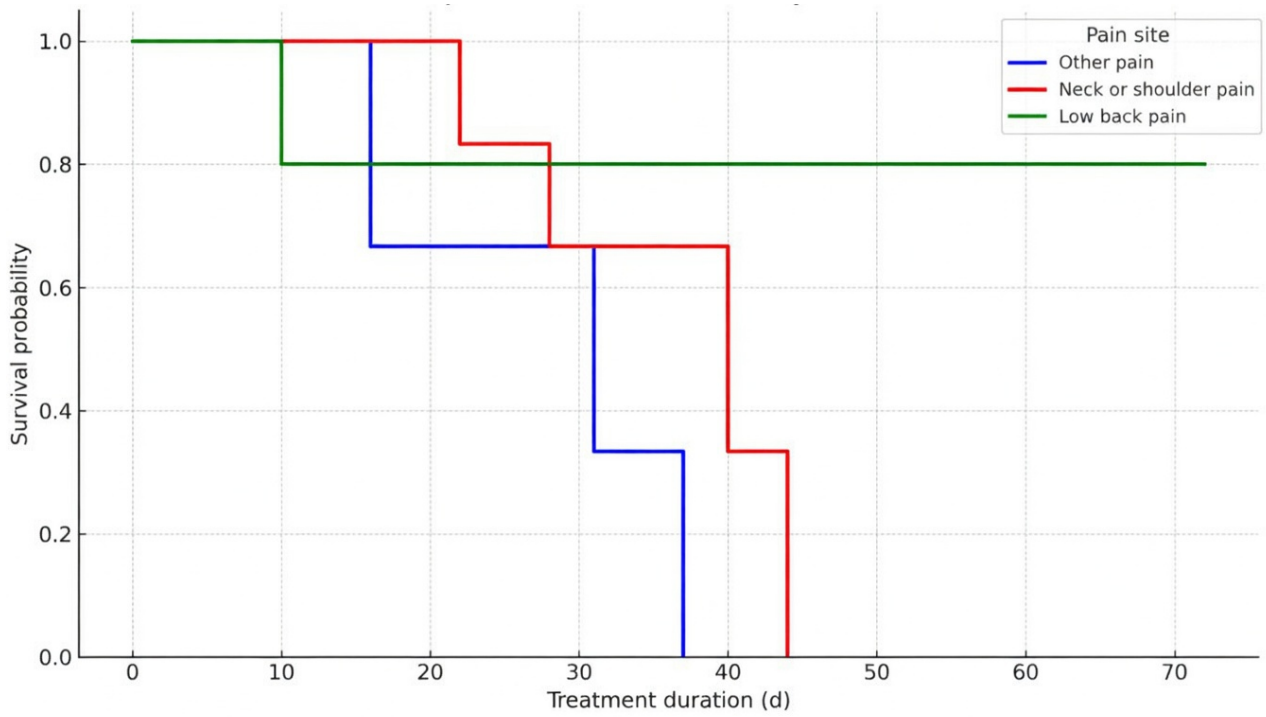

Table . Bootstrap validation of median time-to-improvement estimates by pain subgroup (N=16).

Group	KM[a] survival analysis (wk), median	Bootstrap[b] (wk), median	95% CI
Severe pain	5.0	4.9	4.4-5.4
MMP[c]	3.6	3.7	3.1-4.1
LBP[d]	4.6	4.4	4.0-5.0
N/SP[e]	4.0	3.9	3.4-4.4
Other pain	3.4	3.6	3.0-4.3

[a]KM: Kaplan-Meier.

[b]Bootstrap validation, using 1000 iterations, was conducted to assess the robustness and reliability of the median time to clinical improvement.

[c]MMP: mild-to-moderate pain.

[d]LBP: low back pain.

[e]N/SP: neck or shoulder pain.

Discussion

Principal Findings

This pilot study examined the preliminary effectiveness of GPM and explored predictive factors of clinically significant improvement using ML models, demonstrating significant effectiveness. The ML model analysis revealed that baseline pain interference, pain catastrophizing, fear-avoidance beliefs, and game engagement were identified as key predictors. The findings also highlight the optimal sessions and intervention duration by pain intensity and site subgroups, suggesting the potential for personalized pathways to achieve optimal outcomes.

Interpretation

The GPM intervention demonstrated significant improvement in pain and psychological outcomes, supporting that the integration of game elements can effectively address both physical and psychosocial dimensions of CP [9,10]. The superior performance of the gradient boosting classifier in predicting clinically significant pain reduction, consistent with previous studies, suggests that treatment outcomes are multifactorial [37-39]. The strongest predictor was baseline pain interference rather than pain intensity, supported by the Health Belief Model that individuals perceiving higher functional impairment may benefit more from self-management [40]. Furthermore, our findings demonstrated the role of cognitive and affective factors. Rumination of pain catastrophizing was a key predictor, magnifying the negative cognitive loop of pain that is related to disability [41,42]. Similarly, the impact of fear-avoidance beliefs, especially work-related fear-avoidance, suggests that maintaining daily function may be more critical than purely physical rehabilitation [43]. These findings highlight that pain management should primarily address the barriers which are strongly related to daily lives rather than pain intensity score.

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Our findings also identified session 3 and session 5 as key contributors to clinical pain recovery. Both of these sessions introduced core strength training, which was more physically demanding [44,45]. Psychoeducational content focusing on pain reconceptualization, including the alarm system and safe analgesic use, may foster self-efficacy by simultaneously providing patients with tangible tools to reduce pain-related fear and misunderstanding [46-49]. The combination of sessions 3, 5, and 7 further suggests that sequencing-targeted exercises with specific educational content may be more effective than a general exercise program. In addition, this combination was most potent for severe LBP, further suggesting that a specific sequence and combination of content are critical. The SHAP-informed modeling and Kaplan-Meier analysis further indicated that individuals with severe pain or LBP required a longer intervention period to achieve a high probability of clinical benefit compared to those with MMP or N/SP. These findings suggest an adaptive intervention strategy that patients with severe LBP could be guided toward a curriculum emphasizing core strength and pain neuroscience education (such as sessions 3 and 5) and encouraged to adhere to at least 5 weeks, while patients with neck or shoulder pain might achieve similar outcomes with a shorter intensive program.

This study established and extended previous studies on digital GPM. First, despite the existing gamified interventions [11,14,50] (Table S2 in Multimedia Appendix 1), they often reported heterogeneous effects and seldom tracked intraintervention engagement behaviors and time-to-improvement thresholds. Our study addresses this by integrating self-tracking function and satisfaction, quiz accuracy recorded functions, allowing us to analyze the high impact intervention components. Second, while recent literature on the application of ML in CP management reveals promise, most studies relied on baseline patient data rather than intraintervention dynamics, lacking behavioral, and engagement metrics [51]. Other studies focused on predictive accuracy including diagnosis or referral need [11,19,51-54], without detailing modeling or treatment engagement, session-by-session behaviors or time-to-improvement. Our study incorporated both baseline and continuously recorded variables into the ML algorithms to offer an adaptive framework for future personalized GPM intervention.

Limitations

This study has several limitations that should be acknowledged. First, the small sample size limits the statistical power and generalizability of the findings [55]. The risk of overfitting in the ML models is considerable given the high feature-to-sample ratio, although cross-validation was used to mitigate this. These results should therefore be considered preliminary and hypothesis-generating for future larger-scale studies. As the employed participants may exhibit higher motivation to reduce work-related inequities and return to work [56], larger and more diverse samples are needed to confirm the results and understand the intervention's broader applicability. Additionally, the absence of an external validation dataset limits the assessment of the ML model's generalizability. Future studies should validate model performance using independent datasets. Moreover, given the high feature-to-sample ratio, there remains a risk of overfitting despite cross-validation. Dimensionality reduction techniques or regularization methods should be considered in future models. Moreover, reliance on self-reported measures, such as pain intensity, interference, and engagement-related behaviors, may introduce subjective bias. Incorporating objective monitoring tools or physiological measures could complement self-report data and enhance data accuracy. In addition, recruitment via social media may introduce selection bias, as individuals with higher digital literacy differ from the broader CP population. Future studies should aim for more inclusive participant recruitment strategies to enhance the generalizability of the findings.

Implications

While the findings should be interpreted with caution due to the small sample size, this study highlights the potential of gamified interventions and its accompanying ML models in managing CP. The most immediate implications stem from the ML models, which demonstrated potentially predictive accuracy. With a larger sample size, clinicians could use these models as a decision-support tool to personalize pain management strategies, ensuring more effective and tailored treatment plans. To implement the proposed gradient boosting model in clinical practice, the model should be integrated into a digital platform where clinicians input patient data, incorporating data quality check by using valid scale and halt predictions for missing or invalid inputs to ensure reliability. The clinician role would be to accurately administer the required patient-reported outcome measures and interpret the probability of clinical improvement. Furthermore, the preliminary findings underscore the necessity of integrating psychological support within gamified programs. Addressing factors such as pain catastrophizing and fear-avoidance beliefs appears as crucial as targeting physical symptoms for improving outcomes. Finally, the analysis of intraintervention metrics and session-specific effects across multiple pain subgroups offers a foundation for future research, enabling the development of tailored interventions with optimized treatment lengths and content sequencing. Future research should also evaluate the feasibility of GPM through controlled trials with multiple populations.

Conclusion

In conclusion, this pilot study highlights the potential of leveraging ML models to analyze dynamic data from GPM to inform adaptive and personalized CP management. The study transcends the traditional reliance on static baseline data and overall efficacy assessments of previous studies, instead integrating continuously recorded behavioral metrics to identify key predictors, optimal session combinations, and subgroup-specific TDs. These exploratory findings present a process-oriented, data-driven paradigm that could potentially assist health care providers in customizing intervention content, sequencing, and dosage to enhance adherence in clinical practice. Future larger-scale controlled trials are necessary to validate these exploratory models and convert them into clinical decision-support systems that could improve patient involvement and outcomes.

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Data Availability

The deidentified participant data and analytical code generated during this study are available from the corresponding author upon reasonable request.

Authors' Contributions

Conceptualization: MMYT, TTOK
Data Curation: JH
Formal analysis: JH
Investigation: JH
Methodology: JH
Project administration: MMYT
Resources: JH
Software: JH
Supervision: MMYT, TTOK
Validation: JH
Visualization: JH
Writing - review & editing: MMYT, TTOK
Writing - original draft: JH

Conflicts of Interest

None declared.

Multimedia Appendix 1
Detailed preintervention and postintervention comparisons of pain and psychological outcomes.
[DOCX File, 21 KB - formative_v10i1e78823_app1.docx]

Checklist 1
TRIPOD-AI checklist.
[PDF File, 294 KB - formative_v10i1e78823_app2.pdf]

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Abbreviations

AI: artificial intelligence
AUC: area under the curve
CP: chronic pain
GPM: gamified pain management
GUESS: Game User Experience Satisfaction Scale
LASSO: least absolute shrinkage and selection operator
LBP: low back pain
ML: machine learning
MMP: mild-to-moderate pain
N/SP: neck or shoulder pain
PHQ-9: Patient Health Questionnaire-9 items
SAT: session satisfaction scores
SDT: self-determination theory
SHAP: Shapley additive explanations
TD: treatment duration
TRIPOD-AI: Transparent Reporting of a Multivariable Prediction Model for Individual Prognosis or Diagnosis-AI

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Assessment of Telemedicine Perceptions, Usability, and Implementation Barriers Among Physicians in Kazakhstan Using the Telehealth Usability Questionnaire-Model for Assessment of Telemedicine-Kazakhstan Version (TUQ-MAST-KZ) Questionnaire: Pilot Cross-Sectional Survey Study

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Abstract

Background: Health care professionals' perceptions of telemedicine, its usability, and the presence of organizational barriers are important determinants of the successful implementation of digital solutions in health care. In Kazakhstan, the use of international assessment instruments requires contextual adaptation. The Telehealth Usability Questionnaire-Model for Assessment of Telemedicine-Kazakhstan version (TUQ-MAST-KZ) questionnaire was previously developed and psychometrically validated by integrating elements of the TUQ and MAST frameworks to assess perceptions of telemedicine within the national context.

Objective: The aim of this study was to conduct the first pilot application of the TUQ-MAST-KZ questionnaire with physicians in Kazakhstan and perform an initial assessment of the organizational, technical, and educational aspects of telemedicine implementation.

Methods: This cross-sectional study involved an anonymous online survey using the TUQ-MAST-KZ questionnaire, which covers perceptions of telemedicine, formats of use, platform usability, communication-related aspects, telemonitoring, organizational conditions, and implementation barriers. Responses from 156 physicians were analyzed. Stratified nonparametric comparisons were performed by sex, age group, work experience (years), and workplace, adjusted for multiple comparisons.

Results: The most used telemedicine formats were telephone consultations (78/156, 50%), video consultations (69/156, 44.2%), chats and messaging applications (57/156, 36.5%), and mobile apps (48/156, 30.8%). The Kazakhstan National Telemedicine Network was used by 14.7% (23/156). Wearable devices were used by 5.8% (9/156). Telemedicine technologies incorporating artificial intelligence elements were used regularly by 13.5% (21/156) and occasionally by 32.1% (50/156) and not used by 50.6% (79/156). Positive ratings were as follows: 48.7% (76/156) regarding the simplicity and intuitiveness of telemedicine platforms; 56.4% (88/156) regarding the timeliness of patient condition monitoring; 51.9% (81/156) regarding the effectiveness of telemedicine for the management of patients with chronic diseases. The potential usefulness of telemonitoring for earlier detection of deterioration of a patient's condition was rated as fairly or very high by 48.7% (76/156); 41% (64/156) rated it as moderate. Only 35.9% (56/156) positively rated the connection's reliability and stability. Regarding the accuracy of wearable device data transmission, 57.1% (89/156) responded neutrally, potentially indicating ambiguity in perception, limited personal experience, or difficulty evaluating this aspect. Readiness to recommend telemonitoring at the national level was more often rated as moderate, high, or very high (78/156, 50%; 42/156, 26.9%; 14/156, 9%, respectively).

Conclusions: This pilot application of the TUQ-MAST-KZ questionnaire showed a generally moderately positive perception of telemedicine by physicians, who recognized its potential clinical and organizational value. However, we identified substantial technical and institutional barriers, including connection instability, concerns about the accuracy of data transmission, insufficient process formalization, and a need for additional training. These preliminary findings should be interpreted in light of the pilot study design; however, they may serve to inform future larger-scale research and the development of organizational measures related to physician training, protocol standardization, and infrastructure support for telemedicine implementation.

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KEYWORDS

telemedicine; digital health; implementation barriers; TUQ-MAST-KZ; physicians' perception; Kazakhstan; digital maturity

Introduction

The implementation of telemedicine and digital health services has become a priority area for health care modernization worldwide, including in the Republic of Kazakhstan [1,2]. Despite ongoing infrastructure development and the implementation of national initiatives, the adoption of telemedicine technologies is often constrained by a combination of organizational and human factors, including health care professionals' attitudes toward innovation, readiness for training, and perceptions of digital services [3-7]. Positive attitudes and physician engagement facilitate overcoming technical and regulatory barriers, whereas a lack of motivation and trust reduces the effectiveness of implementation [6,8].

The importance of these factors is also supported within specific clinical fields. For example, the review by Tully et al [9] showed that, in pediatric telemedicine, successful implementation depends on users' perceptions of the technology, organizational readiness, and the presence of factors that facilitate the acceptance of digital forms of interaction.

Traditionally, the effectiveness of telemedicine has been evaluated in terms of clinical, organizational, and economic aspects [5,10,11]. However, experience with scaling digital solutions has highlighted the central role of the human factor, particularly end users' perceptions and practical readiness [4,6,10]. To systematically examine these dimensions, validated assessment instruments and approaches are used, including the Telehealth Usability Questionnaire (TUQ) [12] and the Model for Assessment of Telemedicine (MAST) [11], as well as approaches based on patient-reported outcome measures and patient-reported experience measures [10,13], which make it possible to assess the usability of, satisfaction with, and organizational value of telemedicine services. In particular, the TUQ is focused on usability and user experience, whereas the MAST framework extends the assessment by incorporating clinical, economic, and organizational parameters [11,12]. In addition, the TUQ has been translated, cross-culturally adapted, and validated in other countries, including Danish and German versions, which supports its applicability across different linguistic and cultural contexts [14,15].

Given the national context of Kazakhstan, there was a need to adapt international methodologies to local conditions. The Telehealth Usability Questionnaire-Model for Assessment of Telemedicine-Kazakhstan version (TUQ-MAST-KZ) instrument developed and validated by our team combines the strengths of the TUQ and MAST frameworks, making it possible to simultaneously assess perceptions of telemedicine, usability, satisfaction, and barriers affecting its use in clinical practice [16]. This approach is particularly relevant for health care organizations in Kazakhstan, including institutions participating in the Kazakhstan National Telemedicine Network (KNTN), a state system of remote consultations between health care organizations at different levels as well as organizations providing remote medical services under current regulatory requirements [17].

The need for a context-adapted instrument in Kazakhstan is driven by several factors. First, telemedicine practice in the country is developing in the context of pronounced heterogeneity in digital infrastructure, differences between urban and rural health care organizations, and uneven organizational readiness of medical institutions to implement digital solutions. Second, the specific functioning of the KNTN creates a distinct institutional context for the use of telemedicine consultations. Third, international instruments developed in other health care systems do not always fully capture the barriers and conditions relevant to physicians in Kazakhstan, including issues related to local protocols, the distribution of responsibilities, technical stability, and training needs. Accordingly, the use of the adapted TUQ-MAST-KZ questionnaire appears necessary for a more accurate assessment of telemedicine perceptions, usability, and implementation barriers in the national context.

This paper presents the results of the first pilot application of the previously developed and psychometrically validated TUQ-MAST-KZ questionnaire with a pilot sample of physicians in Kazakhstan [16]. Unlike the previous publication, which focused on the development and validation of the instrument, this study focused on its practical application for assessing perceptions of telemedicine, its usability, and implementation barriers in the national context. This work should not be regarded as a final national assessment but rather as a preliminary empirical basis for subsequent larger-scale research on the readiness for the implementation of telemedicine solutions and for discussing approaches to their phased expansion in Kazakhstan.

The aim of the study was to carry out the first pilot application of the TUQ-MAST-KZ questionnaire with a pilot sample of physicians in Kazakhstan and to provide an initial assessment of the organizational, technical, and educational aspects of telemedicine implementation.

Methods

Study Design

The study used a cross-sectional design and was conducted as an anonymous online survey. Data were collected using a Google Forms electronic questionnaire between May 30, 2025, and June 9, 2025.

Ethical Considerations

The study protocol was approved by the Local Ethics Committee of South Kazakhstan Medical Academy (Protocol Number 3 dated April 25, 2025). All procedures were conducted in accordance with the principles of the Declaration of Helsinki and the requirements of national legislation [18,19]. The ethics approval document is provided in Multimedia Appendix 1.

Participation in the study was voluntary, anonymous, and uncompensated. Before completing the questionnaire,

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participants were provided with brief information about the purpose of the study, its voluntary nature, data confidentiality, and the use of the results in aggregated form only. Electronic informed consent was considered obtained once participants voluntarily proceeded to complete the questionnaire and submitted it. No personally identifiable data were collected.

Participant Recruitment

Participants were recruited using a convenience nonprobability sampling approach among physicians working in health care organizations in the Republic of Kazakhstan. A link to the anonymous electronic questionnaire hosted on Google Forms was distributed through the researcher's personal professional contacts and professional WhatsApp groups. Participants were also invited, if they wished, to forward the link to colleagues, thereby further extending the sample reach through network-based dissemination. No formal list of potential participants was compiled in advance, no centralized contact registry was used, and no individualized invitations were sent. The invitation included brief information about the purpose of the study and the conditions of participation.

Because the questionnaire was distributed through professional networks and group communication channels, the exact number of physicians who actually received the invitation to participate could not be determined. Accordingly, a valid calculation of the response rate was not possible. This is considered a methodological limitation of the study and a potential source of selection bias related to participant self-selection, as physicians with a greater interest in digital technologies, telemedicine, or innovation in health care practice may have been more likely to participate. In addition, physicians who were less engaged in digital professional communication, were not members of relevant professional groups, or were less inclined to participate in online surveys may have been underrepresented in the sample. This may have biased the results toward greater awareness of telemedicine and more favorable perceptions of digital solutions. Therefore, the findings should be interpreted with caution, and their generalizability to the overall population of physicians in Kazakhstan is limited.

Inclusion Criteria

Eligible participants were physicians working in public or private health care organizations in the Republic of Kazakhstan who represented different levels of health care delivery, were proficient in Kazakh or Russian, and were willing to participate voluntarily in the survey. Prior practical experience with telemedicine technologies was not required, as one of the aims of the study was to assess differences in awareness and perceptions of telemedicine among physicians with different levels of familiarity with this field.

Study Instrument

Data were collected using the TUQ-MAST-KZ questionnaire [16], which was developed based on the TUQ [12] and MAST [11]. The questionnaire consists of 27 items grouped into 7 domains: (1) clinical effectiveness, (2) user perceptions and satisfaction, (3) organizational aspects of implementation, (4) economic efficiency and resource implications, (5) legal safeguards and compliance with standards, (6) social impact and effects on patients, and (7) ethical and regulatory aspects of use. For the national context, additional items (Q7-Q9) were included to assess familiarity with telemedicine, formats of use, and experience with artificial intelligence (AI) technologies.

The translation and cultural adaptation of the TUQ-MAST-KZ questionnaire were carried out in accordance with international recommendations for the translation, cultural adaptation, and validation of instruments [20-22]. The procedure included forward and backward translation, expert review, and cognitive testing. Content validity was confirmed by an expert panel (n=6) using the item-level content validity index and scale-level content validity index (divided by the average) [22], and pilot testing demonstrated high internal consistency (Cronbach α=0.93). This study focused on the pilot application of the instrument among physicians in Kazakhstan. For this pilot application, the analysis focused primarily on items related to familiarity with telemedicine, formats of use, usability, communication and telemonitoring, organizational conditions, and implementation barriers; the full structure of the instrument is provided in Multimedia Appendix 2.

Statistical Analysis

Statistical analysis was performed using SPSS version 27 (IBM Corp) and Excel (Microsoft Corp). Frequencies, percentages, means, and standard deviations were calculated. Spearman correlation coefficients were used to assess the associations between the level of familiarity with telemedicine (Q7) and selected telemedicine-related indicators (Q10-Q15). Statistical significance was set at $P<.05$.

Additional comparisons of responses were conducted according to sex, age group, years of work experience, and workplace (level of urbanization). Because responses on the Likert scale were ordinal in nature, the Mann-Whitney *U* test was used to compare 2 independent groups, whereas the Kruskal-Wallis test was used for comparisons across 3 or more independent groups. To reduce the risk of false-positive findings arising from multiple statistical testing, the Benjamini-Hochberg correction was applied. When differences across multiple groups reached statistical significance, additional pairwise comparisons were performed using the Holm correction. Differences were considered statistically significant at $P<.05$.

Results

Participant Characteristics

A total of 156 physicians were included in the study. Women predominated among the participants, accounting for 97 (97/156, 62.2%) of the physicians, while men comprised 59 (59/156, 37.8%) physicians. The age group with the highest number of physicians was 23 - 30 years (50/156, 32.1%), followed by 31 - 40 years (40/156, 25.6%) and 51 - 60 years (36/156, 23.1%). In terms of work experience, the most represented categories were 3 - 5 years (63/156, 40.4%) and >20 years (52/156, 33.3%). Most respondents worked in outpatient clinics (70/156, 44.9%) and hospitals (43/156, 27.6%). According to level of urbanization, physicians from metropolitan areas predominated (87/156, 55.8%). Detailed sample characteristics are presented in Table 1.

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Table . Sociodemographic and professional characteristics of the respondents (n=156).

Question number and indicator	Results, n (%)
Q1. Sex	
Male	59 (37.8)
Female	97 (62.2)
Q2. Age (years)	
23 - 30	50 (32.1)
31 - 40	40 (25.6)
41 - 50	24 (15.4)
51 - 60	36 (23.1)
>60	6 (3.8)
Q3. Type of institution	
Outpatient clinic	70 (44.9)
Hospital	43 (27.6)
Medical center	25 (16)
Health administration	4 (2.6)
Dispensary	1 (0.6)
Medical university	8 (5.1)
Other	5 (3.2)
Q4. Work experience (years)	
3 - 5	63 (40.4)
6 - 10	16 (10.3)
11 - 15	12 (7.7)
16 - 20	13 (8.3)
>20	52 (33.3)
Q5. Place of work	
Rural area	25 (16)
Small town	15 (9.6)
Large city/urbanized area	29 (18.6)
Metropolitan city	87 (55.8)

Distribution of Respondents by Professional Profile

Within the professional structure of the sample, general practitioners predominated (37/156, 23.7%), followed by surgeons (17/156, 10.9%), otorhinolaryngologists (12/156, 7.7%), internists (11/156, 7.1%), oncologists (10/156, 6.4%), and psychiatrists (9/156, 5.8%). The remaining medical specialties were represented in smaller numbers and were grouped into the category “other medical specialties,” which made it possible to simplify the presentation of the professional composition of the sample without losing its overall structure. The detailed distribution is presented in Table 2.

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Table . Distribution of respondents by specialty groups (n=156).

Number	Specialty group	Results, n (%)
1	General practitioners	37 (23.7)
2	Surgeons	17 (10.9)
3	Otorhinolaryngologists (ENT[a] specialists)	12 (7.7)
4	Internists	11 (7.1)
5	Oncologists	10 (6.4)
6	Psychiatrists	9 (5.8)
7	Clinical pharmacologists	8 (5.1)
8	Pediatricians	6 (3.8)
9	Urologists	5 (3.2)
10	Other medical specialties	41 (26.3)

[a]ENT: ear, nose, throat.

Awareness, Telemedicine Formats, and AI (Q7-Q9)

The level of familiarity with telemedicine among physicians was heterogeneous. In routine practice, the most commonly used formats were telephone consultations (78/156, 50%), video consultations (69/156, 44.2%), chats and messaging applications (57/156, 36.5%), and mobile apps (48/156, 30.8%). Use of the KNTN was reported by 14.7% (23/156) of respondents, whereas use of wearable devices was reported by 5.8% (9/156). Telemedicine technologies incorporating AI elements were used regularly by 13.5% (21/156) of physicians and occasionally by 32.1% (50/156) of physicians, whereas 50.6% (79/156) reported not using them in their practice. Detailed data are presented in Table 3.

Table . Familiarity with telemedicine (Q7), telemedicine formats used (Q8, multiple response), and experience with the use of artificial intelligence (Q9).

Question and response categories	Results, n (%)[a]
How familiar are you with telemedicine technologies? (Q7)	
1: Not familiar at all	23 (14.7)
2: Slightly familiar	22 (14.1)
3: Moderately familiar	39 (25)
4: Familiar	48 (30.8)
5: Very familiar	24 (15.4)
Which formats of telemedicine do you use in your practice? (Q8)	
Kazakhstan National Telemedicine Network	23 (14.7)
Video consultations	69 (44.2)
Telephone	78 (50)
Mobile apps	48 (30.8)
Chats and messaging applications	57 (36.5)
Wearable devices	9 (5.8)
Have you used telemedicine technologies with artificial intelligence in your practice? (Q9)	
Yes, regularly	21 (13.5)
Yes, occasionally	50 (32.1)
No	79 (50.6)
Do not know/Not sure	6 (3.8)

[a]Percentages were calculated from valid n, and totals may not equal 100% due to rounding.

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Assessment of Usability, Effectiveness, and Technical Aspects

The distribution of responses to the scaled items showed a predominance of neutral and moderately positive ratings. The simplicity and intuitiveness of telemedicine platforms (Q10) were rated positively by 48.7% (76/156) of respondents, whereas 39.1% (61/156) selected a neutral response. The highest proportion of positive responses was observed for the item on the timeliness of patient condition monitoring (Q12), with 56.4% (88/156) of respondents providing a positive rating. The potential usefulness of telemonitoring for earlier detection of deterioration in a patient's condition (Q13) was rated as fairly high or very high by 48.7% (76/156) of physicians, while an additional 41% (64/156) indicated moderate usefulness. This finding should be interpreted with caution, as it may reflect not only respondents' practical experience but also their broader professional perceptions or expectations regarding telemonitoring. In relation to patients with chronic diseases (Q14), positive ratings accounted for 51.9% (81/256), whereas the perceived reduction in the need for face-to-face visits (Q15) was viewed more cautiously: Positive responses accounted for 41.1% (64/156), neutral responses accounted for 40.4% (63/156), and negative responses accounted for 18.6% (29/156). Technical stability remained the most vulnerable aspect, with only 35.9% (56/156) of participants giving a positive assessment of connection reliability and stability (Q17). Detailed data are provided in Table 4.

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Table . Assessment of usability, clinical effectiveness, and connection stability (Q10, Q12-Q15, Q17).

Question and response categories	Results, n (%)[a]
Telemedicine platforms are simple and intuitive to use (Q10)	
Strongly disagree	8 (5.1)
Disagree	11 (7.1)
Neutral	61 (39.1)
Agree	62 (39.7)
Strongly agree	14 (9)
Telemedicine helps to monitor patient condition in a timely and effective manner (Q12)	
Strongly disagree	11 (7.1)
Disagree	8 (5.1)
Neutral	49 (31.4)
Agree	68 (43.6)
Strongly agree	20 (12.8)
Telemonitoring (if applied) allows earlier detection of patient deterioration (Q13)	
Not effective at all	6 (3.8)
Slightly effective	10 (6.4)
Moderately effective	64 (41)
Fairly effective	54 (34.6)
Very effective	22 (14.1)
Telemedicine is effective in the treatment of patients with chronic diseases (Q14)	
Not effective at all	9 (5.8)
Slightly effective	10 (6.4)
Moderately effective	56 (35.9)
Fairly effective	59 (37.8)
Very effective	22 (14.1)
Remote formats reduced the need for in-person visits to medical facilities (Q15)	
Not effective at all	13 (8.3)
Slightly effective	16 (10.3)
Moderately effective	63 (40.4)
Fairly effective	43 (27.6)
Very effective	21 (13.5)
The connection when using telemedicine platforms is stable and reliable (Q17)	
Strongly disagree	11 (7.1)
Disagree	24 (15.4)
Neutral	65 (41.7)
Agree	46 (29.5)
Strongly agree	10 (6.4)

[a]The sum of shares for each question equals 100% (minor deviations of ±0.1% are possible due to rounding).

Readiness for Telemonitoring and Remote Care Formats

Within the section devoted to communication and telemonitoring, neutral or moderately positive attitudes predominated. The greatest uncertainty was observed for the item related to the accuracy of data transmission from wearable devices (Q18), where 57.1% (89/156) of respondents selected a neutral response option. Neutral or moderate responses were interpreted cautiously as they could potentially reflect ambiguity in perception, limited direct experience, absence of a firm opinion, or difficulty with evaluating the relevant aspect. At the

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same time, the effectiveness of establishing contact with patients through remote channels (Q19) and the preservation of communication quality (Q21) were rated more favorably, with positive responses outnumbering negative ones. Readiness to recommend telemonitoring at the national level was more often rated as moderate or high: 50% (78/156) of respondents indicated a moderate level of readiness, 26.9% (42/156) indicated a high level, and 9% (14/156) indicated a very high level. Detailed data are presented in Table 5.

Table . Communication and readiness for telemonitoring scale-up (Q18-Q21, Q23).

Question and response categories	Results, n (%)[a]
Data transmission from wearable devices (telemonitoring) works correctly and without errors (Q18)	
Strongly disagree	12 (7.7)
Disagree	13 (8.3)
Neutral	89 (57.1)
Agree	36 (23.1)
Strongly agree	6 (3.8)
I can effectively establish contact with the patient through telemedicine channels (Q19)	
Strongly disagree	8 (5.1)
Disagree	18 (11.5)
Neutral	63 (40.4)
Agree	54 (34.6)
Strongly agree	13 (8.3)
Patients feel comfortable during remote communication (Q20)	
Strongly disagree	9 (5.8)
Disagree	15 (9.6)
Neutral	74 (47.4)
Agree	48 (30.8)
Strongly agree	10 (6.4)
The remote format does not worsen the quality of my communication with the patient (Q21)	
Strongly disagree	8 (5.1)
Disagree	12 (7.7)
Neutral	67 (42.9)
Agree	58 (37.2)
Strongly agree	11 (7.1)
How ready are you to recommend the implementation of telemonitoring at the national level? (Q23)	
Very low readiness	11 (7.1)
Low readiness	11 (7.1)
Moderate readiness	78 (50)
High readiness	42 (26.9)
Very high readiness	14 (9)

[a]The sum of shares for each question equals 100% (minor deviations of ±0.1% are possible due to rounding).

Organizational Aspects

The organizational aspects of telemedicine were characterized by a pronounced need for training and heterogeneity in regulatory and organizational support. Most respondents (110/156, 70.5%) indicated a need for additional training for the effective use of telemedicine platforms, while 76.3% (119/156) recommended the use of telemedicine primarily for select categories of patients. The development potential of telemedicine was more often rated as moderate or high (111/156, 71.2%).

At the same time, only one-third (52/156, 33.3%) of participants reported having approved protocols in place at their institutions, and the most common response regarding the distribution of responsibility was the absence of a specifically designated person (57/156, 36.5%). Among the priorities for further

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telemedicine development, the most frequently mentioned were internet connection quality (56/156, 35.9%) and the need for additional training (26/56, 16.6%). Detailed data are presented in Table 6.

Table . Organizational aspects including training needs, regulatory support, coordination, and telemedicine development potential (Q11, Q16, Q22, Q24-Q27).

Questions and response categories	Results, n (%)[a]
Do you need additional training for the effective use of telemedicine platforms? (Q11)	
Yes	110 (70.5)
No	29 (18.6)
Undecided	17 (10.9)
Would you recommend the use of telemedicine for specific patient categories (eg, chronic, rural)? (Q16)	
Yes	119 (76.3)
No	11 (7.1)
Undecided	26 (16.7)
How do you assess the potential for telemedicine development in your region/country? (Q22)	
Very low	8 (5.1)
Low	25 (16)
Moderate	80 (51.3)
High	31 (19.9)
Very high	12 (7.7)
Are there approved protocols or instructions for telemedicine services in your institution? (Q24)	
Yes	52 (33.3)
No	56 (35.9)
Undecided	48 (30.8)
Who is responsible for the organization and quality of telemedicine consultations in your institution? (Q25)	
Attending physician	17 (10.9)
Department leadership	33 (21.2)
Designated coordinator	49 (31.4)
No one specifically assigned	57 (36.5)
Which topics in telemedicine would you like to study to improve your qualifications? (Q26)	
Training/professional development (including skills, basic telemedicine, information, education)	99 (63.5)
Other	10 (6.4)
Do not know/No/Undecided	47 (30.1)
In your opinion, what should be improved for the development of telemedicine and telemonitoring in Kazakhstan? (Q27)	
Internet, connectivity	56 (35.9)
Education/professional development	26 (16.6)
Governance and funding issues	4 (2.6)
Technologies	4 (2.6)
Other	30 (19.2)
Do not know/No/Undecided	36 (23)

[a]The sum of shares for each question equals 100% (minor deviations of ±0.1% are possible due to rounding).

Correlation Analysis

Spearman rank correlation analysis was conducted to assess the relationship between the level of familiarity with telemedicine (Q7) and perceptions of its usability and usefulness. Statistically significant positive correlations were identified between Q7 and Q10 (ρ=0.519; *P*<.001), Q12 (ρ=0.436; *P*<.001), Q13 (ρ=0.413; *P*<.001), Q14 (ρ=0.335; *P*<.001), and Q15 (ρ=0.389;

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P<.001). The strongest association was observed between familiarity with telemedicine and the perceived ease of use of telemedicine platforms (Q10), whereas associations with indicators of perceived clinical usefulness and organizational value were positive but less pronounced. Thus, a higher level of familiarity with telemedicine was associated with more positive evaluations of its usability and perceived effectiveness.

Additional Stratified Analysis

The additional stratified analysis showed that ratings of telemedicine platform usability (Q10) differed significantly according to sex and years of work experience. Men gave higher ratings for platform usability than women (*P*=.006; adjusted *P*=.047 after correction for multiple comparisons). Significant differences were also identified by years of work experience (*P*=.005; adjusted *P*=.047), with the highest usability ratings observed among physicians with more than 20 years of experience compared with those in the group with 3 years to 5 years of experience. In addition, readiness to recommend the implementation of telemonitoring at the national level (Q23) was higher among men than among women (*P*=.001; adjusted *P*=.04).

Differences across age groups and workplace categories showed certain trends in some cases; however, in most instances, they did not remain statistically significant after correction for multiple testing. No consistent differences were identified between the compared groups in the evaluation of telemedicine effectiveness in the management of patients with chronic diseases (Q14).

Overall, the results indicate a heterogeneous perception of telemedicine among physicians in Kazakhstan: Despite moderately positive ratings of its usefulness and a statistically significant association between familiarity with telemedicine and physicians' perceptions of it, substantial technical and organizational barriers remain, including insufficient connection stability, concerns about the accuracy of data transmission, and a high need for additional training. These findings point to a gap between the generally favorable perception of telemedicine and the persistent limitations affecting its practical implementation, which are discussed further in the Discussion section.

Discussion

Main Findings

This study showed that physicians in Kazakhstan had a generally moderately positive but heterogeneous perception of telemedicine. A substantial proportion of respondents gave positive assessments of its perceived clinical usefulness, particularly in the context of patient monitoring and the management of chronic diseases. At the same time, pronounced technical and organizational barriers remained, including connection instability, concerns about the accuracy of data transmission, the absence of local protocols, and a high need for additional training. Taken together, these findings suggest that a certain degree of readiness to adopt telemedicine solutions already exists within the professional community; however, their broader implementation continues to be constrained by infrastructural, organizational, and educational conditions.

Interpretation of the Association Between Familiarity and Perception

The correlation analysis revealed a statistically significant positive association between physicians' level of familiarity with telemedicine and their ratings of its usability, as well as its perceived clinical and practical usefulness. The strongest association was observed between familiarity with telemedicine and perceptions of the ease of use of telemedicine platforms (Q7-Q10; ρ=0.519), whereas associations with other aspects of telemedicine practice were also positive but less pronounced (Q7-Q12/15; ρ=0.335 - 0.436). This suggests that a higher level of familiarity with telemedicine was associated with a more favorable perception of digital solutions.

At the same time, the findings do not permit causal inference. Greater familiarity may facilitate technology acceptance; however, the reverse scenario is also possible, whereby a more positive initial attitude increases physicians' willingness to engage more deeply in digital practice. In addition, both variables may be influenced by external factors, including the level of technical infrastructure, organizational support, and the availability of training. The relatively stronger association between familiarity with telemedicine and perceptions of its ease of use may partly reflect the effect of prior experience or informational exposure, which should also be taken into account. Physicians who are already familiar with digital platforms may evaluate them more favorably not only because of the objective characteristics of the system but also because of greater confidence with using such solutions.

It should also be noted that, in this study, responses to items related to telemonitoring and wearable devices reflect, to some extent, physicians' professional perceptions and expectations rather than their direct practical experience exclusively. Accordingly, these findings should be regarded as a preliminary indicator of attitudes toward these technologies rather than as direct evidence of their clinical effectiveness or technical reliability in real-world practice.

Sociodemographic Differences

The additional stratified analysis showed that statistically significant differences in evaluations of telemedicine platforms were not observed across all sociodemographic characteristics. The most consistent differences were identified by sex and years of work experience with regard to platform usability and by sex with regard to readiness to recommend the implementation of telemonitoring at the national level. In particular, men gave higher ratings for the usability of telemedicine platforms and were more likely to support their broader implementation. In addition, higher usability ratings were observed among physicians with more than 20 years of work experience compared with those with 3 years to 5 years of experience. In contrast, differences across age groups and workplace categories did not remain statistically significant in most cases after correction for multiple testing. Collectively, these findings do not support the simplified assumption that attitudes toward telemedicine are determined primarily by age or length of

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professional experience; rather, they point to a more complex set of factors shaping perceptions of digital solutions.

Comparison With the International Literature

Overall, the findings of this study are consistent with international publications identifying technical limitations, insufficient digital preparedness of health care staff, a lack of standardized protocols, and limited institutional support as major barriers to telemedicine implementation [5,23-26]. The high need for additional training identified in our sample is also consistent with published evidence showing that training is regarded as one of the key prerequisites for the successful implementation of digital health services [27-29]. Thus, this study does not merely reproduce international findings; rather, it demonstrates that similar systemic barriers are also evident in the context of Kazakhstan.

Particular attention should be paid to issues of safety, confidentiality, and trust in digital health solutions. In this study, concerns about the accuracy of data transmission and the instability of digital channels may be regarded as factors that potentially limit physicians' trust in telemedicine services. These observations are consistent with international evidence showing that trust in telemedicine is closely linked to infrastructure reliability, transparency in data handling, and adherence to confidentiality principles [30]. This underscores that the technical reliability of telemedicine solutions has not only organizational but also ethical and regulatory significance.

The findings also make it possible to identify conditions under which telemedicine implementation may be more sustainable. These include organizational support, the presence of local protocols, staff training, and more active physician engagement in digital processes. These conclusions are consistent with international publications in which administrative support, procedural standardization, and systematic staff training are regarded as key conditions for the sustainable implementation of telemedicine solutions [27,29,31]. In addition, the results of this study highlight the importance of context-specific adaptation of digital solutions to the conditions of a particular health care system, the level of infrastructural readiness, and the characteristics of clinical practice, which is also consistent with international evidence [31-33].

Practical and Policy Implications

From a practical perspective, the findings make it possible to identify several priority areas for the health care system of Kazakhstan. First, systematic educational programs for physicians appear to be necessary, aimed not only at mastering digital platforms but also at building confidence in their clinical and organizational use. Second, telemedicine processes require standardization, including the development of local protocols, referral pathways, and a clearer distribution of responsibility for telemedicine consultations. Third, without strengthening the technical infrastructure—above all, the quality of internet connectivity, the stability of digital channels, and the reliability of data transmission—even a moderately positive attitude among physicians is unlikely to translate into sustained telemedicine use. Accordingly, telemedicine expansion should be accompanied by coordinated measures at both institutional and health-system levels, including workforce training, local protocol development, clearer accountability structures, and minimum technical readiness standards.

More broadly, the results are relevant not only to the practice of individual health care organizations but also to the discussion of managerial and policy-organizational approaches to the digital transformation of health care. The observed differences in levels of digital awareness and perceptions of telemedicine highlight the need for targeted measures to strengthen physicians' digital competencies, reduce disparities in physicians' digital readiness across professional and organizational contexts, and support the phased implementation of telemedicine solutions in line with the actual readiness of organizations. The findings may also serve as a reference point for improving continuing professional development programs, developing more structured organizational mechanisms for telemedicine implementation, and further advancing national approaches to health care digitalization in Kazakhstan. Thus, despite the pilot nature of the study, its results may be regarded as a preliminary empirical basis for future larger-scale research and for discussion of institutionally supported approaches to telemedicine implementation [27-29,31].

Strengths, Limitations, and Future Research Directions

The strengths of this study include the use of the previously developed and validated TUQ-MAST-KZ instrument, adapted to the national context of Kazakhstan, as well as the inclusion of physicians working in different types of health care organizations and across diverse care settings. At the same time, the study has several limitations. First, the data were based on participant self-report and may therefore be subject to reporting bias and subjective interpretation. Second, a convenience nonprobability sample was used, with questionnaire dissemination through professional networks, creating a risk of self-selection bias and preventing the calculation of an exact response rate. Therefore, the findings should be regarded as exploratory and potentially somewhat optimistic estimates of physicians' perceptions rather than as representative national estimates. In particular, physicians with a stronger prior interest in telemedicine and digital technologies may have been more likely to participate, which could potentially have resulted in more favorable assessments of telemedicine solutions compared with the overall physician population. At the same time, physicians with lower levels of digital engagement, those not connected to professional online networks, those less likely to participate in online surveys, or those less interested in telemedicine may have been underrepresented in the sample. Accordingly, the findings should be interpreted with caution and cannot be considered nationally representative of physicians in Kazakhstan.

Third, the study had a cross-sectional design, and the observed associations therefore cannot be interpreted as causal. Fourth, objective technical parameters of the digital infrastructure were not assessed. Finally, although information on participants' professional profiles was available, no separate statistical analysis of differences across medical specialties was conducted because of the high fragmentation of the sample, the small size of a number of subgroups, and the limited interpretability of

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such comparisons within the framework of a pilot study. An additional limitation is that the items related to telemonitoring and wearable devices may have reflected not only user experience but also respondents' professional perceptions, expectations, and general attitudes toward these technologies.

Promising directions for future work include studies with larger and more structured samples of physicians to examine differences across professional and regional groups, as well as interventional studies of educational programs assessing how training influences perceptions of telemedicine and readiness to use it. Further investigation is also needed for pilot telemonitoring projects, including assessments of data quality, organizational feasibility, and economic efficiency, as well as the development and testing of standard clinical and organizational protocols for integrating telemedicine solutions into the practice of health care organizations in Kazakhstan. The international literature also shows that barriers to telemedicine implementation may differ substantially by clinical specialty. For example, in pediatrics, issues of confidentiality and parental trust are of particular importance [9,34]; in psychiatry, interdisciplinary collaboration and overcoming professional resistance are especially relevant [27,32]; and in telerehabilitation, key concerns include technical limitations, organizational coordination, and doubts about the accuracy of remote patient assessment [33,35,36]. Because specialty-specific differences were not specifically analyzed in this study, this issue requires separate investigation in larger and professionally stratified samples.

Conclusion

This study made it possible to identify the key barriers and factors influencing perceptions of telemedicine among physicians in Kazakhstan. Using the TUQ-MAST-KZ instrument, the study provided an initial assessment of physicians' familiarity with digital technologies, their perceptions of usability, and the barriers limiting the implementation of telemedicine in clinical practice. The findings may serve as a reference point for the development of targeted training programs, the standardization of protocols, the improvement of infrastructure, and the strengthening of organizational support. Thus, TUQ-MAST-KZ represents a promising and context-adapted instrument for assessing perceptions of telemedicine and may be used in subsequent larger-scale studies, as well as in discussions of approaches to the phased implementation of telemedicine solutions in the Republic of Kazakhstan.

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The authors declare that this work received no financial support.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Ethical approval.
[PDF File, 2400 KB - formative_v10i1e83667_app1.pdf]

Multimedia Appendix 2
Telehealth Usability Questionnaire – Model for Assessment of Telemedicine, Kazakhstan Version.
[PDF File, 26 KB - formative_v10i1e83667_app2.pdf]

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Abbreviations

AI: artificial intelligence
KNTN: Kazakhstan National Telemedicine Network
MAST: Model for Assessment of Telemedicine
TUQ: Telehealth Usability Questionnaire
TUQ-MAST-KZ: Telehealth Usability Questionnaire-Model for Assessment of Telemedicine-Kazakhstan

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Evaluation of a Parent Multimedia and Mobile-Based Intervention to Promote Pediatric Oral Health (BeReadyToSmile): Single-Group Pre-Post Feasibility Study

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Abstract

Background: The universal adoption of mobile technologies by households has created an opportunity to provide families with young children with access to high-quality oral health information at convenient times and locations. Using community agencies (eg, Head Start and public health programs) that offer parenting education is an effective approach to reaching families in low-income households.

Objective: This study aimed to explore the extent to which a coordinated, in-person oral health prevention intervention, together with an accompanying smartphone app, BeReadyToSmile, is feasible to implement among caregivers of young children.

Methods: The BeReadyToSmile program targeted parents of children aged 0 to 6 years attending parenting education classes. This study was designed as a single-group pre-post feasibility study that included quantitative surveys and open-ended feedback. A total of 30 parents attended an in-person session on child oral health and were invited to use the BeReadyToSmile smartphone app. Preintervention and postintervention surveys were administered to assess pediatric oral health knowledge, attitudes toward child toothbrushing, brushing intention, brushing efficacy, program satisfaction, and ease of use.

Results: Significant effects were observed on parent-reported pediatric oral health knowledge, attitudes toward brushing, brushing intention, and toothbrushing efficacy. Out of the 30 parents invited to use the BeReadyToSmile app, 1 (3%) completed no sessions and 20 (67%) completed all sessions. Participants rated the app highly on measures of satisfaction and use. We found significant increases in pediatric oral health knowledge (P=.004), child brushing attitudes and intention (P=.01), and parental efficacy regarding child toothbrushing (P=.03).

Conclusions: Caregivers reported positive experiences with the implementation of BeReadyToSmile, indicating the overall feasibility of delivering oral health prevention to households with young children both in person and through a facilitated smartphone app. Further studies should include a larger and more diverse sample, randomized comparison conditions, and a longer follow-up period to assess outcomes.

Trial Registration: ClinicalTrials.gov NCT03637309; https://clinicaltrials.gov/study/NCT03637309

(JMIR Form Res 2026;10:e70346) doi:10.2196/70346

KEYWORDS

pediatric oral health; parenting intervention; digital health; mobile health; technology; disparities

Introduction

Background

Dental caries (tooth decay) is a highly prevalent chronic disease affecting a significant proportion of the US population, including young children [1]. Lower-income children are especially at risk for dental caries, and this disparity by income has been consistent for decades [1,2]. Oral disease poses a significant risk to overall health throughout one's life [3-8], although dental caries is a preventable disease that can be stopped and even potentially reversed during its early stages [9]. The American Dental Association, the American Academy of Pediatric Dentistry, and the American Academy of Pediatrics recommend fluoride toothpaste for all children, as twice-daily toothbrushing with fluoridated toothpaste is widely endorsed by dental associations as a key preventive measure against dental caries [10-12]. However, most families do not adhere to these recommendations, with nearly 80% of children starting toothbrushing later than recommended and almost one-third brushing just once daily [13]. For children aged less than 7

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years, there can be significant barriers, including parents' oral health beliefs, social norms, children's emotional reactions, and a lack of parenting skills [14].

Research indicates that parent education can be effective in improving children's toothbrushing practices and overall oral hygiene. When accompanied by social support and in-person instruction, toothbrushing promotion programs have reduced childhood caries and improved oral hygiene [14-20]. A randomized trial showed that children whose mothers received repeated rounds of oral health education experienced a significant decrease in the incidence of early childhood caries [21]. These findings emphasize the importance of providing oral health education and support to parents, particularly those from disadvantaged backgrounds, to enhance children's oral health outcomes.

One barrier to providing pediatric oral health promotion with parenting support is the inaccessibility of services for families, particularly for those who live in rural areas and for racial and ethnic minority populations. Digital or telehealth service delivery has gained significant traction in the medical field and was further accelerated during the COVID-19 pandemic [22], including teledentistry [23,24]. Pediatric dental education and behavioral interventions have been identified as promising applications of mobile health technology in the post–COVID-19 era [23,24]. In addition, there is a growing infrastructure for delivering parenting education and support via parenting classes [25], with an emphasis on reaching underserved populations. For example, in Oregon, where this study took place, the Oregon Parenting Education Collaborative (OPEC) has made significant headway in providing parenting education programs to previously underserved populations. Since 2010, OPEC has served 14,207 Oregon parents through evidence-based classes, 14,504 families through home visits, and more than 950,000 family members through parenting education activities [26]. Moreover, programs such as Head Start and Early Head Start have recognized the importance of dental health, incorporating it into child health standards [27-30].

Despite research demonstrating the positive impact of parent education on reducing childhood caries and promoting oral health behaviors, current parenting education curricula in programs such as Head Start do not adequately address children's dental health education. Most significantly, available programs are instructional in nature. They do not demonstrate evidence-based parenting skills across various age groups, particularly when faced with a child's resistance to essential dental hygiene routines. Many of the best empirically based parenting interventions start with positively oriented strategies and incorporate behavioral parent training [31,32], including Parent-Child Interaction Therapy [33], the Positive Parenting Program (Triple P [34]), and the Incredible Years programs [35]. These effective intervention approaches prioritize reinforcing appropriate and desired behaviors as the primary catalyst for improving child behavior; however, these approaches are not currently integrated into pediatric oral health education offered through Head Start and other parenting programs.

Thus, while parent-focused education and support can improve children's oral hygiene and reduce caries, families most at risk, including those in rural communities and those with lower incomes, often do not have access to in-person services. At the same time, widely used parenting and early childhood support programs do not typically provide skill-based, evidence-informed behavioral parenting strategies tailored to oral hygiene challenges. Existing content is often instructional but does not provide caregivers with the tools to respond effectively when children resist daily dental hygiene routines. Consequently, there is a need for an accessible, scalable pediatric oral health promotion program with digital delivery that integrates evidence-based behavioral parent training with established oral health guidance to help caregivers build effective routines and reduce child resistance, ultimately improving children's oral health outcomes and narrowing disparities. BeReadyToSmile was developed to be such a program, integrating empirically supported behavioral parent training with established best practices for pediatric oral health within a comprehensive, universal oral health education program.

Objectives

This feasibility study examines the practicality of implementing BeReadyToSmile in real-world settings, with a focus on caregiver knowledge, confidence, and efficacy regarding child oral health behaviors; program reach and engagement; perceived program satisfaction and usability; delivery fidelity; and logistical barriers, such as access to technology.

Methods

Ethical Considerations

This study was registered as a clinical trial at ClinicalTrials.gov (NCT03637309) on September 8, 2017. The Oregon Research Institute's Institutional Review Board approved this study (082817) on August 28, 2017. This study was deemed to pose no more than minimal risk. All participants provided informed consent before engaging in any study activities. To protect participants' confidentiality and privacy, all data were deidentified and accessible only to the research team, and all published data are presented in aggregate form. All data are securely stored and will be destroyed within 5 years of publication. Participants received US $30 per data collection session.

Participants

Participants were parents or caregivers recruited from Head Start of Lane County and OPEC. For this pilot study, the program included 2 video sessions viewed in a group setting over 2 parenting classes and a smartphone app with dental educator–facilitated goal setting and feedback. Data were collected from 30 consenting parents or caregivers participating in a group-based parent education program who also volunteered to use the BeReadyToSmile app.

Program Development

The BeReadyToSmile development process was iterative, incorporating parents' feedback and program revisions

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throughout development. In the BeReadyToSmile program, parents teaching their children oral health behaviors, such as toothbrushing, are seen as opportunities for children to learn critical health-preserving skills and for parents to strengthen their parenting skills. Research staff conducted focus groups with parents of young children in educational groups. We presented the American Dental Association video "Your Child's Teeth: Birth to Age 5" [36]. Parents completed surveys to provide feedback on the video. This information enabled us to create realistic video vignettes and strategies that were tailored to the life experiences of the target users, a key component in developing an intervention for self-learning. The final 30-minute video consists of 7 segments using a variety of approaches, including parent group discussions, animation, and direct informational content. The segments cover (1) the importance of children's teeth and dental health, (2) giving only water in bottles at bedtime, (3) the value of routine and positive reinforcement, (4) daily toothbrushing with fluoride, (5) a "Sugar Shocker" segment, (6) a conversation about fluoride, and (7) a recap and review.

The BeReadyToSmile in-person video session used videos developed for the smartphone app (Table 1). The BeReadyToSmile mobile app was designed for both iOS and Android operating systems, as well as a web browser, with three key components: (1) a self-regulated course for learning parenting skills with dynamic multimedia presentations and interactive queries, (2) an electronic messaging system for coaching support to facilitate learning and promote engagement, and (3) an online tracking system of participant knowledge acquisition and intervention engagement to facilitate progress monitoring and supervision. BeReadyToSmile was designed as a series of sequential sessions, so that before the user could proceed to the next session, the previous session must be complete. Users could return and review previously completed material in a nonlinear format. The software uses a menu-driven approach (Figure 1). Video and audio narration were used wherever possible to minimize typing skills and literacy requirements. Users could (1) view session content, (2) upload videos or images of parent-child toothbrushing, (3) view links to dental resources, (4) send a message to their coach, (5) communicate with their coach to develop an action plan and set goals, (6) view the action plan developed with their coach, (7) earn stars and badges for completing sessions or reaching goals, (8) change settings such as their password, and (9) log out of the app.

Table . Overview of the BeReadyToSmile program, delivered both in-person and via a facilitated smartphone app.

Program component and sessions	Description	Topic or activities
Videos shown during in-person parent group		
Session 1	Overview of child dental health recommendations	• Importance of children's teeth and dental health • Only water in bottles at bedtime • Value of routine and reinforcement • Daily toothbrushing with fluoride
Session 2	Reduction of sugar consumption and use of fluoride	• Sugar Shocker • Fluoride conversation • Review
Smartphone app		
Session 3	Reinforcement of videos shown in sessions 1 and 2	• Introduction • Topic 1: Sugar Shocker • Topic 2: all about fluoride • Topic 3: Bottle2Bed and toothbrushing
Session 4	Motivational interview with a coach to create a dental behavior change plan tailored to the participant and their family	• Topic 4: making a plan with your coach
Session 5	Individualized support to implement tailored plans through parent-child video, badges and stars, and coach messaging	• Topic 5: ready-set-go • Topic 6: on our way • Topic 7: let's go • Topic 8: you can do it • Topic 9: keep going • Topic 10: you did it!

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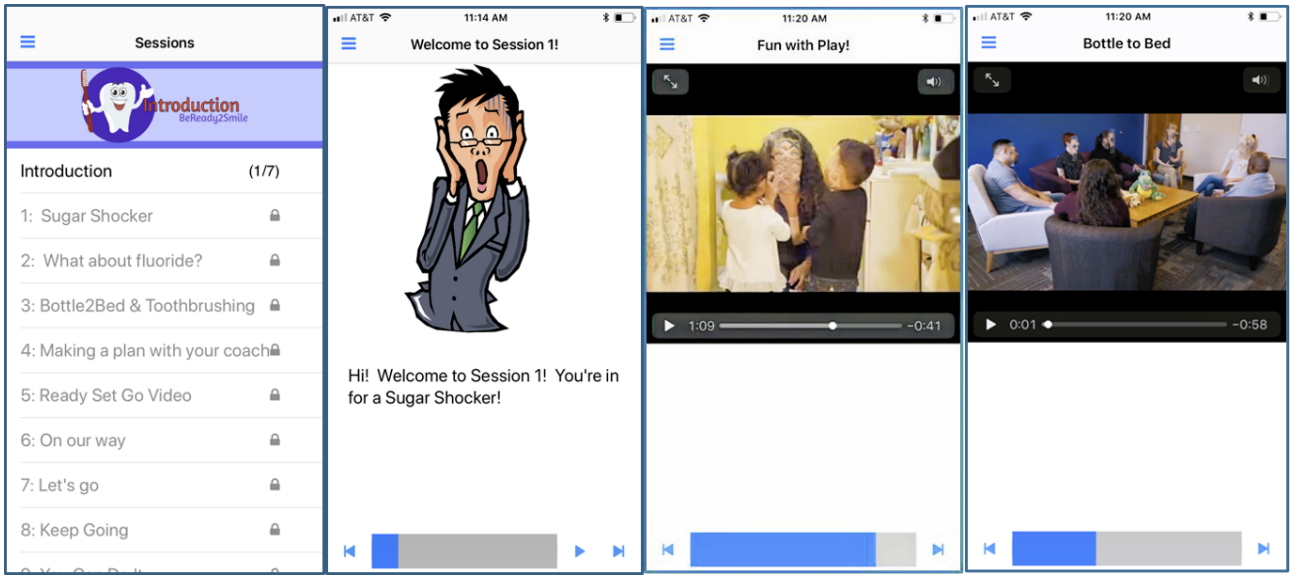
Figure 1. Screenshots from the smartphone app depicting (left to right) the topics to be covered, the beginning of Sugar Shocker, a video demonstrating how to engage young children in toothbrushing, and a video of a group discussion about using water in children's nighttime bottles.



Data Collection

This single-group preintervention and postintervention study assessed parent or caregiver knowledge, attitudes, and confidence in promoting their young child's oral health, as well as their satisfaction with, and the usability of, the BeReadyToSmile mobile app. Data collection occurred across 4 weeks. Of the 30 parents, 25 (83%) completed the preintervention survey, 17 (57%) completed both the preintervention and postintervention surveys, and an additional 4 (13%) participants completed the postintervention survey but not the preintervention survey.

The preintervention survey included demographic information and technology use, specifically internet access, mobile device use, and social media use. At preintervention and postintervention surveys, participants completed a 15-item knowledge inventory of young children's oral health [37], including recommendations for home hygiene and dental health (9 items), statements about the caries process (3 items), and dental development (3 items). For each item, participants indicated their level of knowledge on a three-point scale: (1) "didn't know," (2) "sort of know," and (3) "know for sure." The knowledge inventory was validated in a randomized controlled trial of a parent-focused intervention that significantly improved twice-daily toothbrushing among young children [37].

Participants also completed scales assessing their attitudes toward child oral health promotion: the "Importance and Intention to Brush Child's Teeth" scale (5 items) and the "Parental Efficacy in Relation to Child Toothbrushing" scale (6 items) [38]. These measures, developed by Adair et al [38], have been validated through international research on pediatric dental health. Response options were measured on a 5-point Likert scale, ranging from "strongly disagree" (1) to "strongly agree" (5) for the importance and intention items and from "strongly agree" (1) to "strongly disagree" (5) for the parental efficacy items. Participants also reported their confidence in brushing their young child's teeth, responding to the question: "If you already don't brush twice a day, how confident are you that, if you decided to, you could brush your child's teeth twice (or almost always twice) a day?" Responses were recorded using a 10-point Likert scale ranging from "not confident at all" (1) to "very confident" (10).

At the postintervention survey, participants rated their satisfaction and ease of use with either the in-person video session (T2) or the BeReadyToSmile app (T4) on a 4-point Likert scale ranging from "not at all" (negative; 1) to "very" (positive; 4). Questions included "How reasonable did you find the app?" "How much did you like the app for learning the information taught?" "How clear was the information taught?" "How useful did you find BeReadyToSmile?" and "I would recommend the BeReadyToSmile app to other parents." During app use, the software recorded participant activity in a MySQL database. The use included the following indices: (1) attrition, (2) session completion, and (3) extent of intervention participation (eg, number of app topics completed).

Results

Participant Demographics

Out of the 30 participants, 25 (83%) completed the demographic items in the preintervention survey. Parents' or caregivers' mean age was 36.64 (SD 8.18) years; 4 (16%) were male, 19 (76%) were White, and 5 (20%) were Hispanic. In total, 44% (10/23) reported working full time, but 48% (11/23) reported some or a great deal of difficulty paying monthly bills, and 57% (13/23) had a combined annual household income of US $30,000 or less. All families (N=25, 100%) reported using phones for internet access. Table 2 shows additional details.

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Table . Participant demographics.

Variable	Values
Age (years), mean (SD)	
Children (n=24)	5.34 (2.46)
Parents (n=25)	36.64 (8.18)
Number of participants living at home, mean (SD)	
Adults (n=25)	2.28 (1.02)
Children (n=24)	2.21 (1.14)
Parents living together or married (n=25), n (%)	15 (60)
Ethnic groups (n=25), n (%)	
Hispanic	5 (20)
White	19 (76)
Household socioeconomic characteristics, n (%)	
Parents with educational attainment of high school or less (n=25)	10 (40)
Parent in household working full time (n=23)	10 (44)
Parents reported “some” or “a great deal” of difficulty paying monthly bills (n=23)	11 (48)
Combined annual household income of US $30,000 or less (n=23)	13 (57)

Outcomes on Knowledge, Attitudes Toward the Importance of Brushing, and Confidence

A total of 17 participants completed both the preintervention and postintervention surveys. Using 1-tailed *t* tests, there were significant effects from the preintervention survey to the postintervention survey on knowledge (t_{16}=3.35; Cohen *d*=0.81; *P*=.004) [37], attitudes toward the importance of toothbrushing and brushing intention (t_{16}=2.75; Cohen *d*=0.66; *P*=.01) [38], and toothbrushing efficacy (t_{16}=2.41; Cohen *d*=0.59; *P*=.03) [38]. Confidence approached statistical significance (t_{16}=2.09; Cohen *d*=0.51; *P*=.05) [37]. Refer to Table 3 for pre-post outcomes. In addition, 81% (17/21) of parents reported an increase in their child’s cooperation following participation in the BeReadyToSmile program.

Table . Preintervention survey to postintervention survey outcomes (N=17)[a].

Variable	Preintervention survey, mean (SD)	Postintervention survey, mean (SD)	*t* test (*df*)	*P* value
Knowledge inventory	31.82 (8.03)	39.12 (6.19)	–3.35 (16)	.004
Importance of toothbrushing and intention to brush your child’s teeth	4.22 (0.56)	4.60 (0.45)	–2.75 (16)	.01
Parental efficacy in relation to child toothbrushing	1.82 (0.62)	1.53 (0.51)	2.42 (16)	.03
Parental confidence	7.65 (2.65)	9.06 (1.75)	–2.09 (16)	.05

[a]Response options for the 15-item knowledge inventory were 1 - 3, with 1 being “didn’t know,” 2 being “sort of know,” and 3 being “know for sure”; a higher summed score indicates a higher level of knowledge [37]. Response options for the 5 importance or intention items were measured on 5-point Likert scales ranging from 1 (“strongly disagree”) to 5 (“strongly agree”); higher mean scores indicate greater perceived importance and stronger intention to brush a child’s teeth [38]. Response options for the 6 parental efficacy items were also measured on 5-point Likert scales but ranged from 1 (“strongly agree”) to 5 (“strongly disagree”); lower mean scores indicate greater parental efficacy. Parental confidence was assessed using a 10-point Likert scale ranging from 1 (“not confident at all”) to 10 (“very confident”) in response to the following item: “If you do not already brush twice a day, how confident are you that, if you decided to, you could brush your child’s teeth twice (or almost always twice) a day?” Higher scores indicate greater confidence.

Satisfaction and Usability

Mean ratings were above 3.3 on a 4-point scale (Table 4). Caregiver comments on open-ended postintervention survey items regarding their satisfaction with, and perceived usability of, the app included the following: “I really liked using the mobile app,” “I enjoyed the break-down of the videos/sessions,” “It’s nice to hear something positive for a change,” “Making it fun by having them brush my teeth, too. I feel it will help with their ‘no,’ and I’m going to aim for 2x a day now,” and “Brushing together as a family, and making a game out of brushing teeth.”

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Table . Participant satisfaction and usability ratings (N=21)[a].

BeReadyToSmile app satisfaction and usability evaluation items	Satisfaction and usability rating, mean (SD)
How reasonable did you find the BeReadyToSmile app for learning information taught?	3.48 (0.68)
How much did you like the BeReadyToSmile app for learning the information taught?	3.48 (0.60)
How clear was your understanding of the BeReadyToSmile app information taught?	3.67 (0.58)
How useful did you find the BeReadyToSmile app in addressing questions about a child's dental care?	3.57 (0.60)
My relationship with my coach was very important to me.	3.38 (0.67)
I would recommend the BeReadyToSmile app to other parents.	3.57 (0.60)

[a]Response scales for the first 5 items were 1 - 4, with 1 being "not at all" and 4 being "very." The response scale for the final item was 1 - 4, with 1 being "not at all recommend" and 4 being "strongly recommend." Higher scores indicate higher satisfaction and usability.

BeReadyToSmile App Use

Participants actively used the app during the research period. Across the 4 weeks of testing, participating parents or caregivers spent an average of 2.63 (SD 0.76) hours using the app and completed an average of 8.33 (SD 3.99) sessions. Table 5 shows the number of sessions completed, indicating a high level of engagement, with most participants completing all 10 sessions. Between parents and the coach, 1127 text messages were exchanged. We did not find a significant relationship between the number of hours, sessions, or topics completed and outcomes, possibly due to a ceiling effect with a restricted range.

Table . Number of app topics completed by participants (N=30)[a].

Number of app topics completed	Participants, n (%)
0	1 (3)
1	2 (7)
2	2 (7)
4	1 (3)
5	4 (13)
10	20 (67)

[a]There were 10 possible topics to complete in the app.

Discussion

Principal Findings

The BeReadyToSmile pilot program demonstrated promising results in addressing a critical gap in pediatric oral health education for low-income families. As anticipated, the intervention had a significant positive impact on parental knowledge, attitudes, and self-efficacy regarding their children's oral health, echoing findings from previous studies that have emphasized the importance of education in preventing childhood dental caries [39,40]. The improvement in knowledge and attitudes among participants from the preintervention to the postintervention survey aligns with findings that education, when paired with personalized feedback and support, can effectively influence oral health behaviors [41].

A critical challenge this program addresses is the dearth of oral health resources that are both relevant and engaging for parents from diverse, low-income backgrounds. This study reinforces the need for culturally tailored interventions that address the unique barriers faced by these populations, including language differences, health literacy challenges, and culturally specific beliefs about oral health [39]. The success of the BeReadyToSmile program in integrating parents' real-life experiences into its design, as reflected in the video content and interactive app features, serves as an important model for future interventions aiming to bridge these gaps.

The high satisfaction rates reported by participants, along with the observed increases in child cooperation during toothbrushing, underscore the value of engaging, family-centered approaches to oral health promotion. Parent comments indicated that making toothbrushing a fun, collaborative activity positively impacted their children's behavior and improved consistency in daily toothbrushing routines. These findings are consistent with prior research suggesting that interventions that focus on building positive parent-child interactions around health behaviors can lead to lasting improvements in health outcomes [42].

Importantly, the high level of engagement with the BeReadyToSmile app suggests strong feasibility and acceptability. Approximately two-thirds of participants (20/30, 67%) completed all 10 app topics, and more than 1100 text messages were exchanged between parents and coaches,

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reflecting the importance participants placed on both the self-guided and interactive coaching components. As the results suggest, digital interventions can overcome barriers such as geographic distance and time constraints [42]. However, it is likely that this restricted range of high engagement did not result in a significant relationship between engagement and outcomes due to a ceiling effect.

Strengths and Limitations

One strength of the BeReadyToSmile program is its use of digital technology to increase access to oral health education. Because most families in this study already used smartphones as their primary source of internet access, the app's technology requirements were minimal, making it well suited for embedding into community-based programming without significant infrastructure changes. Thus, another strength is the program's demonstrated potential for integration into existing parent education and early childhood frameworks, such as Head Start, Early Head Start, and OPEC.

Despite the positive outcomes, several challenges were noted. First, this pilot study involved a small sample size, limiting the generalizability of the findings. A second limitation of the BeReadyToSmile program itself is its reliance on facilitated, coach-supported engagement, which requires substantial staffing resources. This limitation highlights the need for future iterations of the program to explore more scalable, self-directed formats that maintain the intervention's effectiveness while reducing staff burden. One possible approach may be integrating artificial intelligence into the coaching. Third, while the single-group design provided valuable preliminary data, future research should include a randomized controlled trial with longer-term follow-up to rigorously evaluate the program's impact and compare it with traditional oral health education methods. Objective measures of oral health outcomes, such as clinical assessments of caries incidence, would also strengthen future research. Additionally, evaluating the program's cost-effectiveness and its impact when implemented at scale could inform policy and funding decisions.

Conclusions

The BeReadyToSmile program shows promise as an innovative approach to pediatric oral health promotion, integrating accessible technology, evidence-based parenting strategies, and culturally relevant content to address disparities in early childhood caries. Findings from this pilot suggest that digital, parent-focused oral health education can effectively enhance oral health knowledge and behaviors among low-income families, particularly when paired with parenting support. Further research with larger, more diverse samples is needed to refine and confirm the model's effectiveness, but expanding access through partnerships with early childhood services could significantly improve oral health outcomes for underserved populations.

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Authors' Contributions

EW: writing—original draft, writing—review and editing, visualization.
DRS: conceptualization, methodology, software, writing—review and editing, funding acquisition
AL: conceptualization, project administration, funding acquisition
IPM: writing—review and editing
EGF: conceptualization, methodology, software, writing—original draft, funding acquisition

Conflicts of Interest

DRS and EGF are shareholders of Influents Innovations. The other authors declare no conflicts of interest.

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Abbreviations

OPEC: Oregon Parenting Education Collaborative

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Validity of Smartphone-Based Measurement for Assessing Lower Limb Power for Sarcopenia and Frailty Discrimination: Cross-Sectional Study

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Abstract

Background: Increasing life expectancy has increased focus on the health-related consequences of aging, such as sarcopenia and frailty. Given the prevalence of these conditions among older individuals and the frequent resulting long-term care needs, early detection and intervention are crucial.

Objective: This study aimed to validate a novel smartphone-based system measuring acceleration during the sit-to-stand movement to detect sarcopenia and frailty.

Methods: Participants were 587 individuals from the Otassha study cohort who underwent health assessments in 2023, of whom 569 (96.9%) completed 2 supervised sit-to-stand trials while holding a smartphone on the lower abdomen. Sarcopenia and frailty were diagnosed using the Asian Working Group for Sarcopenia 2019 criteria and the revised Japanese Cardiovascular Health Study criteria, respectively. Peak force, rising time (T1), and stabilization time (T2) were extracted from acceleration signals, and reproducibility was examined using the intraclass correlation coefficient (ICC(2,1)). Predictive models were developed using elastic net penalized logistic regression, and model performance was evaluated using 500 bootstrap resamples. Benchmark models using age and sex, walking speed, and grip strength were also constructed for comparison.

Results: Sarcopenia and frailty were identified in 16.7% (95/569) and 9% (51/569) of the participants, respectively. Peak force demonstrated excellent reliability (ICC=0.863), whereas T1 and T2 showed lower reproducibility (ICC<0.30). For sarcopenia, the smartphone model achieved a bootstrap area under the receiver operating characteristic curve (AUC) of 0.800 and an optimism-corrected AUC of 0.781 (95% CI 0.733 - 0.826), outperforming walking speed (0.663) and age and sex (0.656) and ranking second only to grip strength (0.845). For frailty, the smartphone model showed moderate discrimination, with an optimism-corrected AUC of 0.659 (95% CI 0.587 - 0.736), exceeding age and sex (0.604), whereas walking speed remained the strongest predictor (0.751).

Conclusions: Smartphone-derived sit-to-stand acceleration provides a practical and scalable approach for screening for sarcopenia and frailty in community-dwelling older adults. While traditional indicators such as grip strength and walking speed remain the most accurate predictors, smartphone-based measurements offer meaningful complementary information and may support large-scale functional screening and early detection initiatives in superaged societies.

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KEYWORDS

acceleration; aging; frailty; sarcopenia; smartphone

Introduction

As people live longer, health issues shift from being related to diseases to being related to aging [1]. In Japan, the proportion of individuals requiring nursing care increases exponentially with age. Statistics indicate that 48.1% of individuals aged 80 years and older are certified as needing nursing care [2]. Furthermore, in medical institutions, older patients must consider aging alongside their underlying illnesses [3-5]. Therefore, the interest in sarcopenia and frailty has increased [6,7]. Research papers in PubMed have identified that the use of “sarcopenia” and “frailty” as keywords has increased by 103% and 98%,

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respectively, over the past 5 years. Many studies on sarcopenia and frailty were published in the 1990s, including those on the effects of high-intensity strength training in older people [8]. A consensus was reached that sarcopenia and frailty can be reversed with the appropriate intervention at the right time even though they are phenomena associated with aging [8-10].

Taking countermeasures against sarcopenia and frailty is challenging given the gradual development of the associated symptoms [11,12], which highlights the necessity for triggers that prompt behavior change. A system that can monitor indicators of sarcopenia and frailty, similar to how weight scales and blood pressure monitors are instrumental in managing lifestyle-related diseases, is urgently needed. The diagnostic criteria for sarcopenia and frailty, as outlined by the European Working Group on Sarcopenia in Older People [13] and the Fried frailty index [14], require an initial screening that includes physical performance tests, such as walking speed, and measures of dynapenia, such as grip strength. Although we previously developed a validated system using smartphone GPS data to measure walking speed [15,16], this system does not assess dynapenia. This limitation is significant because dynapenia is a crucial factor in the comprehensive diagnosis of sarcopenia and frailty. Moreover, the definition of frailty proposed by Howlett et al [6] as an accumulation of deficits underscores the importance of a multifactorial evaluation of frailty. This further indicates the necessity of expanding our system's capabilities to include a wider range of diagnostic criteria.

The sit-to-stand test, reportedly a simple way to evaluate lower limb power [11], is considered a useful standard for determining frailty [12], risk of falling [17], and risk of disability [18] and can be undertaken on a daily basis. The only issue is that a skilled tester is required to perform the measurements [19-21]. Our research investigated the potential of using ground reaction force (GRF), captured via standard weight scales during standing, as a novel metric for assessing the strength of the lower limb muscles and detecting indications of sarcopenia [22,23]. We found that the discriminant for sarcopenia probability could be ascertained from only the peak vertical GRF during the sit-to-stand movement, with a sensitivity of 89.7% and specificity of 80.5%. Because force is the product of mass and acceleration according to Newton's second law, measuring an object's acceleration allows one to estimate force anywhere without relying on the reaction force measurement. Thus, the validity of estimating GRF using an accelerometer has been widely studied [24-26]. Because smartphones are equipped with built-in accelerometers [27], they can likely estimate the peak GRF during the sit-to-stand movement. Several previous studies have reported that smartphone accelerometers can measure human movement with accuracy comparable to that of laboratory-grade accelerometers [28,29].

We considered that, if smartphones could detect sarcopenia from acceleration measurements without measuring GRF, early diagnosis of sarcopenia and frailty would be possible even at home, facilitating early recognition of functional decline and flagging the need for behavior changes. Thus, in this study, we used acceleration measured using a smartphone during the sit-to-stand movement to determine whether sarcopenia could be discerned without requiring GRF measurement.

Methods

Study Design

This was a cross-sectional study.

Participants

We included 587 people from the cohort of the Otassha study, a longitudinal study that has been ongoing since 2011 [30], who underwent an invitation-based health checkup and completed sarcopenia, frailty, and sit-to-stand measurements from September 2023 to October 2023. All study participants lived in the community and were aged over 65 years. Participants living in care facilities, as well as individuals with contraindications for bioelectrical impedance analysis, were excluded from the study. Participants underwent comprehensive geriatric health examinations regarding their physical, cognitive, psychological, nutritional, and lifestyle habits.

Body Composition and Physical Function Measurements

Body composition was measured using a bioimpedance body composition meter (InBody 770; InBody Co, Ltd) to estimate appendicular skeletal muscle mass. Although dual-energy x-ray absorptiometry is recognized as the gold standard for measuring body composition, bioimpedance analysis has been evaluated against it and verified to provide correct measurements [31].

The participants were instructed to stand still with their arms at their sides while using the bioimpedance equipment without talking and to hold a sensor for measurement. The skeletal muscle index (SMI) was calculated as the appendicular skeletal mass, estimated from the body composition measurement, divided by the square of the individual's height. Smedley hand dynamometers were used to measure grip strength.

For grip strength measurements, participants were asked to extend their arms straight down and grip the dynamometer as strongly as possible with their preferred hand when the tester instructed them to do so.

Walking speed was measured on a 5-m course with a preceding 3-m acceleration and subsequent 3-m deceleration walkway. Participants were asked to walk the course once at a comfortable speed. The time taken to walk through the 5-m section of the course was measured using a digital stopwatch.

Acceleration Measurement Using a Smartphone During Sit-to-Stand Movement and Force Estimation

A smartphone with our app installed was secured to the lower abdomen of each participant using a commercially available sports smartphone holder (Figure 1). Participants folded their arms across their chests to minimize arm motion and trunk variability. Participants received auditory prompts from a Bluetooth speaker positioned 2 m in front of them via the smartphone app, which instructed them to stand up as quickly as possible and then hold the position for 3 seconds. After the practice attempt, the participants were evaluated twice, transitioning rapidly from a seated resting position (seat height; 42 cm) to a standing position. Acceleration during this action was captured using the smartphone app.

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Figure 1. Smartphone configuration.

The app is web based and uses JavaScript to call the operating system application programming interface and measure the smartphone's acceleration on 3 axes over a given period. To validate the accuracy of the smartphone accelerometer for use in biomechanical research, 3 healthy volunteers performed sit-to-stand trials at 3 different speeds (fast, moderately fast, and normal) to simulate a range of physical performance levels (9 trials in total). A research-grade reference accelerometer (MVP-RF8-BC; MicroStone Corp; sampling at 1000 Hz) was attached to the smartphone holder on the participants' lower abdomen to measure acceleration simultaneously with the smartphone. The resultant acceleration signals from both devices were synchronized using cross-correlation to align the waveforms temporally. We then extracted the specific "movement phase" (from the start of the rise to stabilization) and assessed the waveform similarity using the intraclass correlation coefficient (ICC(2,1); absolute agreement). The analysis demonstrated excellent agreement between the

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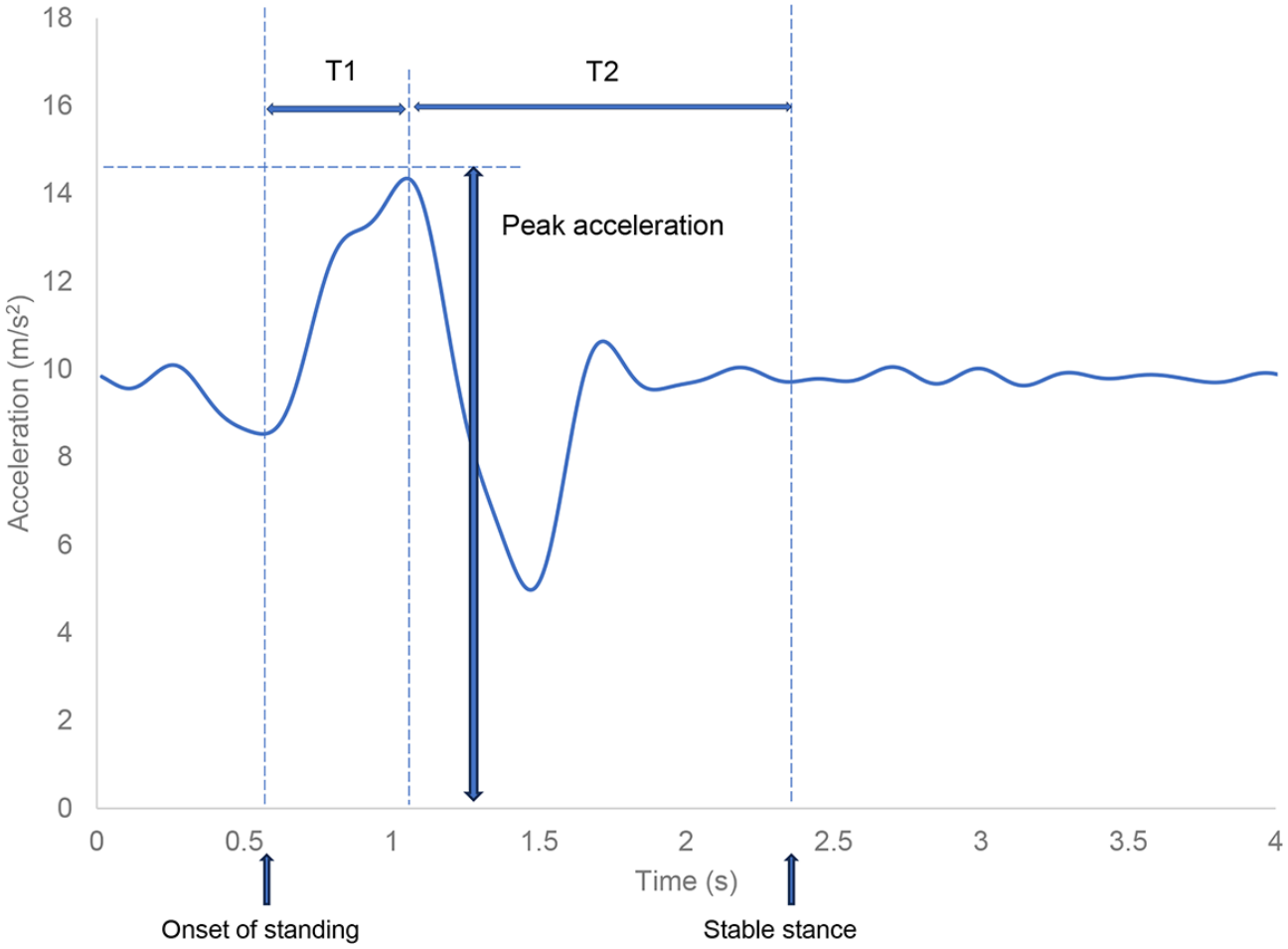
smartphone and the reference device despite the difference in sampling rates. The mean ICC(2,1) was 0.982 (SD 0.019), with a range of 0.932 to 0.995 across all trials and speeds, confirming that the smartphone's accelerometer measurements were reliably comparable to those of the dedicated biomechanical research device.

The smartphone app recorded the sit-to-stand motion at 60 Hz, and this motion was analyzed in the cloud. Data were processed using an inverse fast Fourier transform algorithm with a low-pass filter at 7.5 Hz to mitigate the impact of noise outside the physical activity domain. In traditional settings, the maximum force exerted during sit-to-stand motion is measured using a floor reaction force meter with a fixed coordinate system established upon installation. However, when using a smartphone accelerometer attached to the body, the coordinate system is affected by the user's movements. The norm of the triaxial acceleration was computed to account for these variations and ensure that the measurement was less affected by changes in the orientation of the accelerometer. The peak force exerted during the sit-to-stand motion was calculated by multiplying the resultant peak acceleration by the body weight.

Measurement of Peak Acceleration and Duration of Movement in the Sit-to-Stand Transition

The onset of standing was identified as the point at which the accelerometer registered the lowest acceleration from the start of the motion (Figure 2). Peak acceleration (measured in m/s^2) was defined as the highest acceleration recorded after starting. A stable stance was considered when the acceleration variation decreased to 1% or less of the gravitational acceleration after peak acceleration. The duration from the start to peak acceleration was termed the "rising time" (T1; seconds), whereas the duration from peak acceleration to attainment of a stable stance was termed the "stability time" (T2; seconds). The peak force (in newtons) was calculated by multiplying peak acceleration by the weight of each participant.

Figure 2. Definition of measurements.



Definition of Sarcopenia

Sarcopenia was diagnosed based on the criteria outlined in the 2019 consensus statement of the Asian Working Group for Sarcopenia [32]. Grip strength below 28 kg for men and below 18 kg for women, walking speed below 1.0 m/s, and SMI below 7.0 kg/m^2 for men and below 5.7 kg/m^2 for women were the thresholds used to diagnose sarcopenia. Participants who met the criteria for SMI and grip strength or walking speed were classified as having sarcopenia. However, sarcopenia severity was not classified, similar to our previous study [22].

Definition of Frailty

Frailty was diagnosed using the criteria outlined in the Japanese version of the Cardiovascular Health Study [14]. The criteria were an adaptation of the original Fried frailty index [33] tailored to the Japanese population. A person was classified as frail if they met 3 or more of the following criteria: an

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unintentional loss of 2 kg or more of body weight in the previous 6 months, handgrip strength of less than 28 kg for men and less than 18 kg for women, a feeling of exhaustion, a walking speed slower than 1.0 m/s, and a lack of engagement with regular physical activity.

Statistical Analysis

To confirm the reproducibility of the smartphone-derived measurements (peak force, T1, and T2), we calculated the ICC(2,1) using a 2-way mixed-effects, absolute-agreement model based on 2 consecutive sit-to-stand trials. For all subsequent analyses, the average of the 2 measurements was used.

To identify and classify sarcopenia and frailty, we developed predictive models following TRIPOD (Transparent Reporting of a Multivariable Prediction Model for Individual Prognosis or Diagnosis) recommendations. Five logistic regression models were constructed for each outcome to enable direct comparison with established clinical indicators:

- Age and sex model
- Walking speed model
- Grip strength model
- Smartphone model, incorporating age, sex, peak acceleration–derived force, rising time (T1), and stabilization time (T2)
- Smartphone reduced model, incorporating age, sex, and derived force

All models were implemented as elastic net penalized logistic regression (penalty="elasticnet"; l1_ratio=0.5; solver=saga) to mitigate overfitting and address multicollinearity among biomechanical and functional predictors. Continuous predictors were standardized using *z*-score transformation.

Internal validation was conducted using bootstrap resampling (500 iterations). For each model, we calculated the following performance metrics: apparent area under the receiver operating characteristic curve (AUC), bootstrap AUC (mean), bootstrap 95% CI, optimism-corrected AUC, corrected AUC 95% CI, calibration slope, calibration intercept, sensitivity, and specificity.

Calibration was assessed using a logistic recalibration model, from which the calibration slope and intercept were derived. We reported apparent and bootstrap optimism-corrected calibration metrics (500 resamples; percentile 95% CIs). Calibration slopes close to 1.0 and intercepts near 0 indicated good agreement between predicted and observed risk.

To contextualize the performance of the smartphone-based model, we additionally compared it against established screening measures—walking speed, grip strength, and age and sex—using identical model structures and validation procedures.

All statistical analyses and model development were conducted using Python (version 3.11; Python Software Foundation), including scikit-learn (Google Summer of Code project; logistic regression and scaling), NumPy, and pandas. The reproducibility analysis (ICC) and descriptive statistics were performed and calculated using SPSS (version 27; IBM Corp).

Ethical Considerations

This study was conducted as part of the aforementioned comprehensive cohort study. The research plan was discussed and approved by the ethics committee of the Tokyo Metropolitan Institute for Geriatrics and Gerontology (R22-034). Written informed consent was obtained from all participants. Strict confidentiality procedures were implemented. All analyses were performed using only anonymized datasets. Participants did not receive any incentives.

Results

Participant Flow

A total of 587 older adults participated in the assessment, of whom 569 (96.9%) completed the smartphone-based sit-to-stand measurement (Figure 3).

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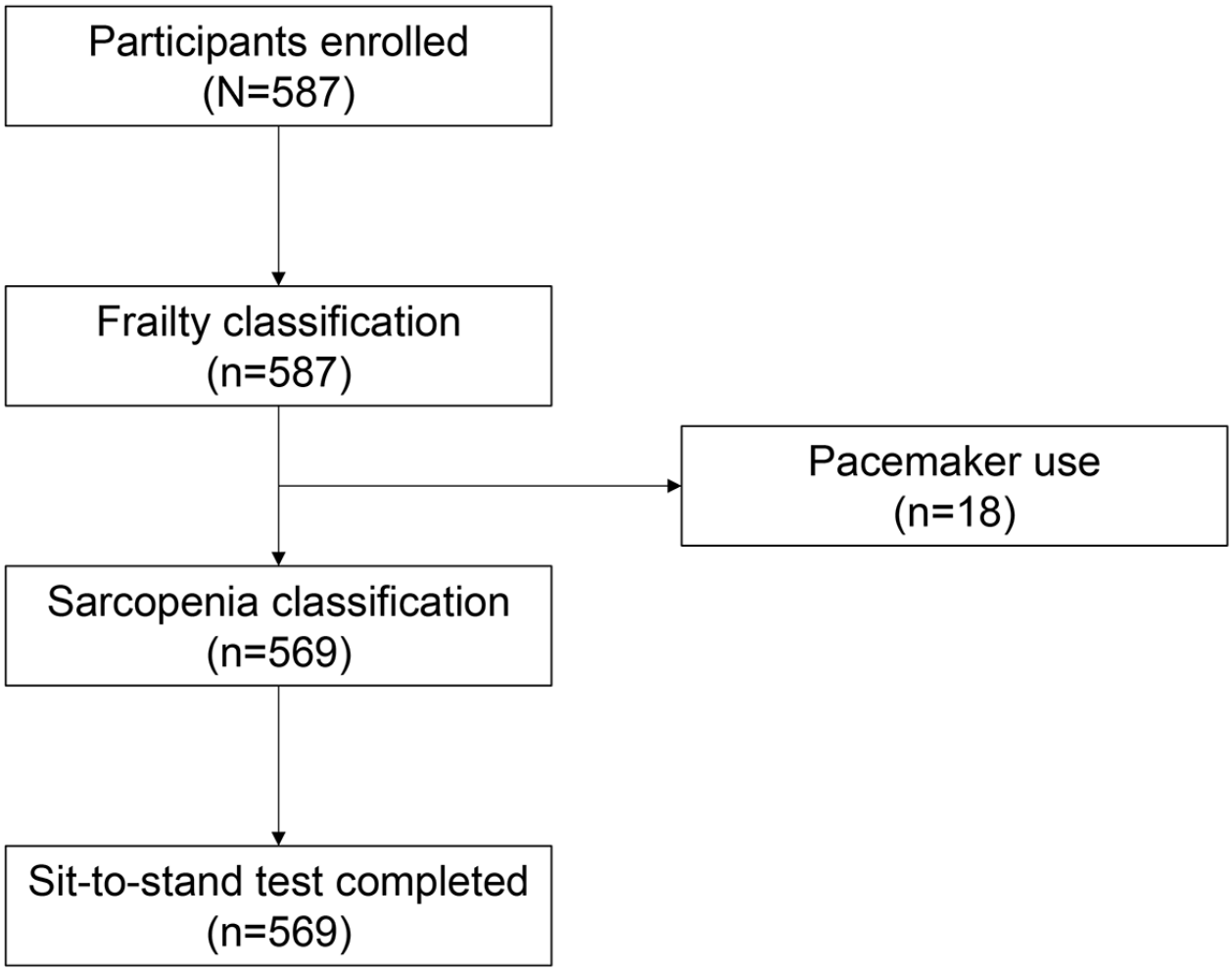
Figure 3. Participant flow diagram.



Participant Characteristics

The participants' characteristics are listed in Table 1. Among them, 95 participants (n=25, 26.3% men and n=70, 73.7% women) met the criteria for sarcopenia, and 51 participants (n=22, 43.1% men and n=29, 56.9% women) met the criteria for frailty. Compared with individuals without sarcopenia, those with sarcopenia were older (mean age 77, SD 7 years vs 73, SD 6 years; *P*<.001) and shorter and had less weight, weaker grip strength (mean 16, SD 5 kgf vs 26, SD 8 kgf; *P*<.001), slower walking speed (mean 1.25, SD 0.22 m/s vs 1.40, SD 0.23 m/s; *P*<.001), and lower peak force (mean 70.87, SD 14.98 N vs 92.56, SD 25.20 N; *P*<.001). Similarly, individuals with frailty were older (mean age 77, SD 8 years vs 73, SD 6 years; *P*=.003) and had lower grip strength (mean 19, SD 6 kgf vs 24, SD 8 kgf; *P*<.001), slower walking speed (mean 1.13, SD 0.25 m/s vs 1.40, SD 0.23 m/s; *P*<.001), and lower peak force (mean 78.56, SD 20.49 N vs 89.93, SD 25.25 N; *P*<.001) than individuals without frailty (Table 2).

Table . Participant characteristics.

	Male participants (n=223), mean (SD)	Female participants (n=364), mean (SD)
Age (years)	74 (6)	74 (7)
Height (cm)	165.9 (6.6)	152.8 (5.9)
Weight (kg)	65.1 (10.6)	51.6 (8.7)
SBP[a] (mm Hg)	131 (19)	128 (17)
DBP[b] (mm Hg)	78 (12)	74 (11)
Grip strength (kgf)	31 (6)	20 (5)

[a]SBP: systolic blood pressure.

[b]DBP: diastolic blood pressure.

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Table . Baseline characteristics and frailty phenotype components by sarcopenia and frailty status.

Variable	Without sarcopenia (n=474), mean (SD)	With sarcopenia (n=95), mean (SD)	*P* value	Nonfrail (n=536), mean (SD)	Frail (n=51), mean (SD)	*P* value
Age (years)	73 (6)	77 (7)	<.001	73 (6)	77 (8)	.003
Height (cm)	158.9 (8.7)	152.3 (7.7)	<.001	158.0 (8.8)	155.3 (9.7)	.42
Weight (kg)	58.6 (11.5)	48.2 (7.3)	<.001	56.9 (11.4)	55.2 (12.7)	.31
Grip strength (kgf)	26 (8)	16 (5)	<.001	24 (8)	19 (6)	<.001
Walking speed (m/s)	1.40 (0.23)	1.25 (0.22)	<.001	1.40 (0.23)	1.13 (0.25)	<.001
Peak force (N)	92.56 (25.20)	70.87 (14.98)	<.001	89.93 (25.25)	78.56 (20.49)	<.001
Appendicular SMI[a] (kg/m^2)	6.66 (0.99)	5.49 (0.74)	<.001	6.48 (1.03)	6.29 (1.15)	.26

[a]SMI: skeletal muscle index.

Reproducibility of Smartphone-Derived Sit-to-Stand Metrics

The reproducibility analysis based on 2 consecutive sit-to-stand trials demonstrated excellent reliability for peak force (ICC(2,1)=0.863). Rising time (T1; ICC=0.270) and stabilization time (T2; ICC=0.278) showed lower reproducibility. Therefore, the mean of the 2 measurements was used for subsequent analyses.

Frailty Phenotype Components

The distribution of the 5 frailty phenotype components is shown in Table 3.

Table . Frailty phenotype components.

Component	Nonfrail (n=536), n (%)	Frail (n=51), n (%)
Low walking speed	12 (2.2)	16 (31.4)
Weight loss	59 (11.0)	33 (64.7)
Exhaustion	127 (23.7)	46 (90.2)
Low activity	77 (14.4)	25 (49.0)
Weakness	133 (24.8)	44 (86.3)

Participants classified as frail exhibited a substantially higher prevalence of each phenotype component compared with individuals without frailty. Specifically, participants with frailty demonstrated markedly higher proportions of slow walking speed (16/51, 31.4% vs 12/536, 2.2%), weight loss (33/51, 64.7% vs 59/536, 11%), exhaustion (46/51, 90.2% vs 127/536, 23.7%), low physical activity (25/51, 49% vs 77/536, 14.4%), and weakness (44/51, 86.3% vs 133/536, 24.8%). These differences are consistent with the Japanese Cardiovascular Health Study frailty phenotype criteria and confirm that the frail group exhibited a substantially higher burden of functional and symptomatic deficits.

Predictive Performance for Sarcopenia

Model performance for sarcopenia is summarized in Table 4. Among the benchmark models, the grip strength model demonstrated the highest discrimination, with a bootstrap AUC of 0.847 (95% CI 0.797 - 0.893). The smartphone model (age, sex, peak force, T1, and T2) showed good predictive ability, achieving a bootstrap AUC of 0.800 (95% CI 0.754 - 0.848; Figure 4). After internal validation using 500 bootstrap samples, the model achieved an optimism-corrected AUC of 0.781 (95% CI 0.733 - 0.826). This performance exceeded that of the walking speed (corrected AUC=0.663) and age and sex (corrected AUC=0.656) models. Calibration of the smartphone model was modest (slope=1.04; intercept=0.06). The results for the smartphone reduced model were similar to those for the full model.

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Table . Performance of models for predicting sarcopenia.

Model	Predictors	AUC[a], bootstrap mean (95% CI)	Apparent AUC	Optimism-corrected AUC (95% CI)	Calibration slope	Calibration intercept	Sensitivity	Specificity
Age and sex	Age and sex	0.671 (0.599 - 0.737)	0.665	0.656 (0.591 - 0.725)	1.02	0.04	0.682	0.598
Walking speed	Normal walking speed	0.659 (0.599 - 0.719)	0.661	0.663 (0.603 - 0.723)	1.02	0.04	0.659	0.614
Grip strength	Grip strength	0.847 (0.797 - 0.893)	0.846	0.845 (0.800 - 0.895)	1.04	0.05	0.729	0.904
Smartphone	Age, sex, peak force, T1[b], and T2[c]	0.800 (0.754 - 0.848)	0.794	0.781 (0.733 - 0.826)	1.04	0.06	0.765	0.689
Smartphone reduced model	Age, sex, and peak force	0.796 (0.752 - 0.844)	0.795	0.788 (0.741 - 0.832)	1.04	0.05	0.800	0.680

[a]AUC: area under the receiver operating characteristic curve.

[b]T1: rising time.

[c]T2: stability time.

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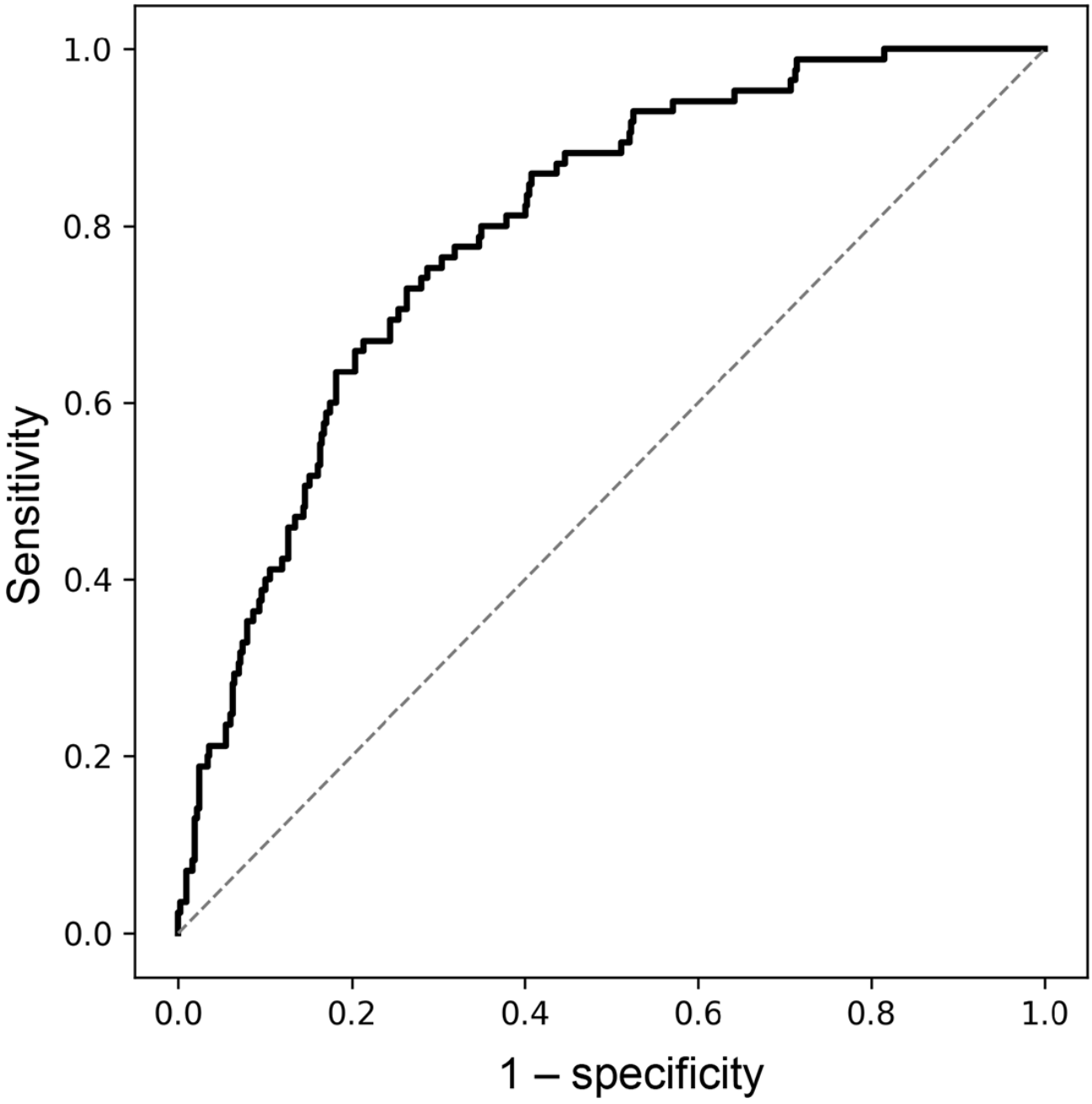
Figure 4. Receiver operating characteristic curve analysis for estimating sarcopenia.



Predictive Performance for Frailty

Model performance for frailty is shown in Table 5.

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Table . Performance of the model for predicting frailty.

Model	Predictors	AUC[a], bootstrap mean (SD; 95% CI)	Apparent AUC	Optimism-corrected AUC (95% CI)	Calibration slope	Calibration intercept	Sensitivity	Specificity
Age+sex	Age and sex	0.637 (0.543 - 0.727)	0.625	0.604 (0.517 - 0.688)	1.05	0.11	0.714	0.486
Walking speed	Normal walking speed	0.750 (0.672 - 0.826)	0.750	0.751 (0.674 - 0.828)	1.03	0.07	0.857	0.529
Grip strength	Grip strength	0.704 (0.615 - 0.781)	0.703	0.703 (0.626 - 0.792)	1.05	0.1	0.548	0.829
Smartphone	Age, sex, peak force, T1[b], and T2[c]	0.720 (0.640 - 0.796)	0.697	0.659 (0.587 - 0.736)	1.09	0.19	0.476	0.859
Smartphone reduced model	Age, sex, and peak force	0.688 (0.602 - 0.768)	0.671	0.649 (0.568 - 0.736)	1.07	0.17	0.357	0.889

[a]AUC: area under the receiver operating characteristic curve.

[b]T1: rising time.

[c]T2: stability time.

Walking speed demonstrated the highest discrimination (AUC=0.750, 95% CI 0.672 - 0.826), followed by grip strength (AUC=0.704, 95% CI 0.615 - 0.781). The smartphone model achieved a bootstrap AUC of 0.720 (95% CI 0.640 - 0.796; Figure 5). The optimism-corrected AUC was 0.659 (95% CI 0.587 - 0.736). This indicates moderate discrimination, outperforming the age and sex model (corrected AUC=0.604). Calibration of the smartphone model remained modest (slope=1.09; intercept=0.19). The smartphone reduced model had a slightly lower AUC than the full model.

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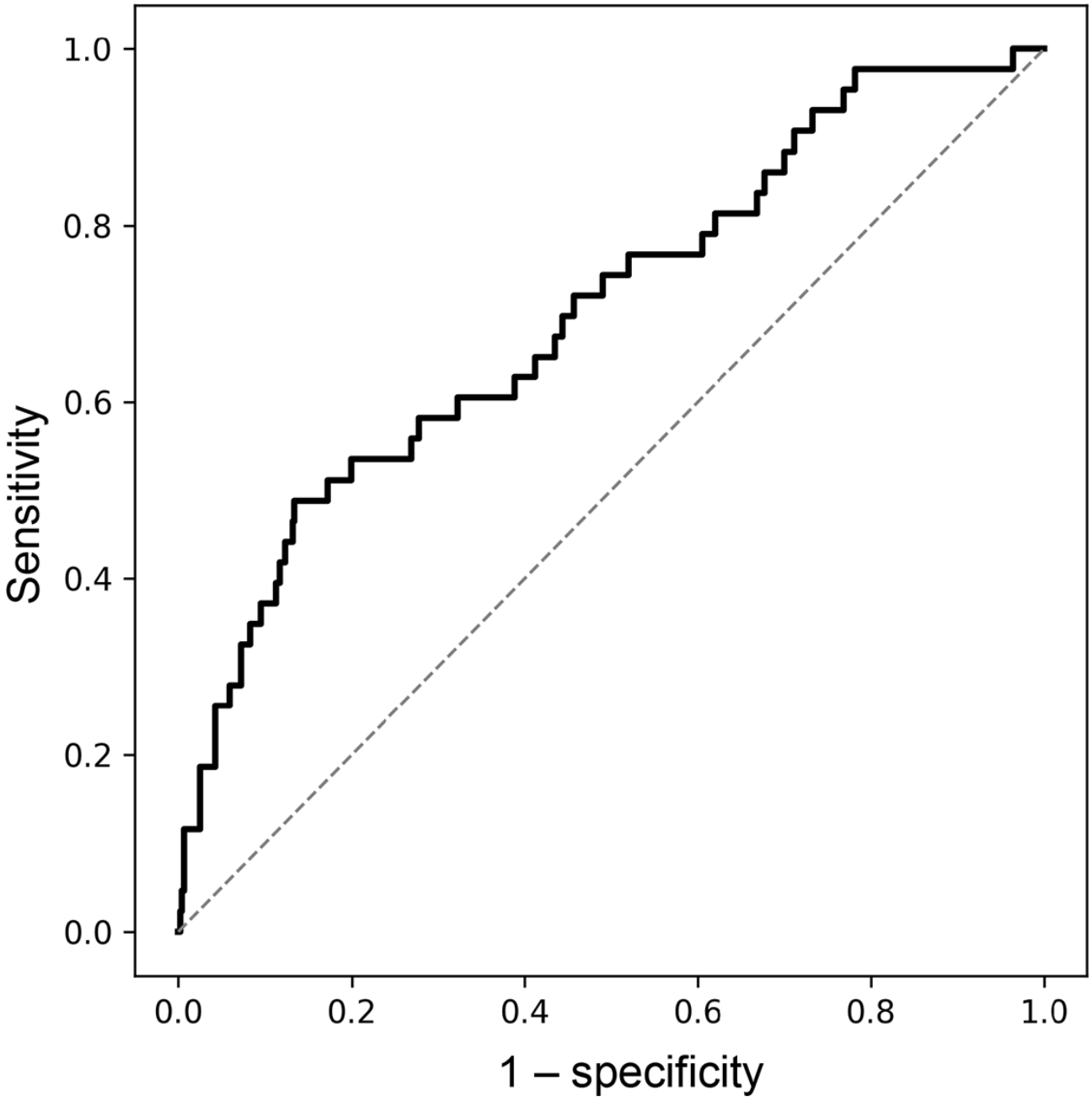
Figure 5. Receiver operating characteristic curve analysis for estimating frailty.



Overall Model Comparison

Across outcomes, the smartphone-derived sit-to-stand measurements consistently outperformed demographic models and walking speed for sarcopenia and provided moderate predictive value for frailty. Grip strength and walking speed remained the strongest predictors of sarcopenia and frailty, respectively, whereas the smartphone model functioned as a strong secondary predictor of sarcopenia and a useful complementary indicator of frailty.

Discussion

This study investigated the ability of a smartphone's built-in accelerometer to quantify sit-to-stand motion and estimate the likelihood of sarcopenia and frailty. Using elastic net logistic regression with bootstrap internal validation, we found that smartphone-derived measurements provided clinically meaningful information related to lower limb function. The optimism-corrected AUC values were 0.781 for sarcopenia and 0.659 for frailty, indicating good and moderate discrimination, respectively.

The higher predictive performance for sarcopenia than for frailty is consistent with the nature of their diagnostic constructs. Sarcopenia is defined using specific physical parameters—loss of muscle mass, weakness, and decreased physical performance—measured using indexes such as skeletal muscle mass, grip strength, and walking speed [7]. Because sit-to-stand acceleration is closely linked to lower limb power, the smartphone model aligned well with these characteristics. In contrast, frailty is a multidimensional syndrome involving physical, psychological, and behavioral components, including weight loss, exhaustion, reduced activity, slow walking speed,

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and weakness [14]. As a result, acceleration-based measurements alone cannot fully capture its complexity, which accounts for the moderate AUC observed.

Importantly, benchmark comparisons with established indicators demonstrated that the smartphone model performed substantially better than demographic factors alone or walking speed alone in predicting sarcopenia. The age and sex model and the walking speed model showed optimism-corrected AUCs of 0.656 and 0.663, respectively, whereas the smartphone model achieved a markedly higher corrected AUC of 0.781, making it the second-best performer after grip strength (corrected AUC=0.845). This indicates that smartphone-derived sit-to-stand acceleration captures key biomechanical features that are strongly aligned with sarcopenia-related muscle weakness. For frailty, walking speed remained the strongest single predictor (corrected AUC=0.751), followed by grip strength (corrected AUC=0.703). The smartphone model demonstrated moderate discrimination, with a corrected AUC of 0.659, outperforming the age and sex model (corrected AUC=0.604) by a meaningful margin. These findings support the role of smartphone-based measurements as a practical and scalable screening method that offers a performance comparable to that of established functional indicators and that complements—rather than replaces—traditional clinical assessments.

Our previous work using GRF from a weight scale reported higher AUC values (0.906 for men and 0.858 for women) [22]. Conceptually, GRF and accelerometer-derived force estimates should be equivalent if the device is perfectly aligned with the body's center of gravity (COG). However, the COG is located inside the body and cannot be directly accessed. In this study, we placed the smartphone on the lower abdomen to avoid interference with the chair backrest, which likely introduced deviation from the COG and contributed to the lower predictive performance. Differences in participant characteristics between this and our previous study may also have influenced the results.

Despite these differences, the smartphone model demonstrated good discrimination for sarcopenia. Considering that smartphones can also measure walking speed—which is strongly associated with frailty risk—and can integrate questionnaire data, their potential as multifaceted screening tools is substantial. Kawai et al [34] showed that a 1.0 m/s increase in daily walking speed measured via smartphone reduced the risk of frailty to one-fiftieth of that at slower speeds. In this study, we focused intentionally on the biomechanical aspect of dynapenia without incorporating questionnaire items, and the results suggest that predictive accuracy could be further improved by integrating behavioral and self-reported variables.

Moreover, smartphones allow for the integration of questionnaire data, which is essential for a comprehensive frailty assessment. In this study, we focused on whether smartphone measurements could capture dynapenia, a key component in the evaluation of sarcopenia and frailty, without including questionnaire items in the regression equation. Our findings revealed high and moderate AUC values, suggesting that the accuracy of sarcopenia and frailty screening can be further enhanced by adding these questionnaire items and walking speed to the regression model.

Transitioning from this supervised protocol to a scalable, unsupervised screening tool requires addressing practical challenges regarding feasibility and data reliability. In this study, although participants performed the sit-to-stand movement independently following audio instructions from the smartphone, the device was attached to the lower abdomen by a researcher. Consequently, future verification is necessary to determine whether users can correctly attach the device and obtain accurate measurements in a home setting. Furthermore, the "digital divide" presents a significant challenge for older adults, as is common with the adoption of various digital technologies. Addressing these accessibility issues and ensuring ease of use will be critical considerations for the widespread implementation of this screening tool.

Physical and social interventions are known to be effective in improving sarcopenia and frailty; however, timely behavioral adjustments remain challenging [35,36]. In 2006, Japan shifted its nursing care insurance to focus on prevention by implementing a system to screen all older individuals and offer interventions based on their symptoms through the care management process. Despite these measures, many individuals declined to participate in this initiative. One solution may be to enhance awareness of sarcopenia and frailty as health issues in old age and choose better behaviors from middle age onward when these issues become noticeable. Antonovsky [37] proposed salutogenesis; however, we believe it is important to use our internal power to adopt as many behaviors as possible that are less likely to lead to sarcopenia and frailty rather than relying on outsiders to persuade us to change our behavior. Therefore, understanding the challenges associated with aging from midadulthood is essential. A system such as the one we introduced, which enables measurements anytime and anywhere, could prove to be an effective starting point.

This study has limitations. First, the temporal variables (T1 and T2) showed low reproducibility, indicating a need for improved signal processing. Second, measurements were performed under standardized, supervised conditions with a fixed chair height, which may differ from those obtained in unsupervised real-world environments. Third, the cohort consisted of relatively healthy, community-dwelling older adults, limiting the generalizability of the findings to more frail or institutionalized populations. Finally, external validation using an independent dataset is required to fully establish the robustness of the prediction models.

In conclusion, smartphone-derived sit-to-stand acceleration provides a feasible and scalable method for estimating sarcopenia and frailty risk. Although not a replacement for clinical diagnostic assessments, the approach demonstrates sufficient accuracy for initial population screening and has strong potential for integration into community health monitoring systems in superaged societies.

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Acknowledgments

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Data Availability

The datasets analyzed during this study are not publicly available due to the ethical restrictions imposed by the ethics committee of the Tokyo Metropolitan Institute for Geriatrics and Gerontology but are available from the corresponding author on reasonable request.

Authors' Contributions

SPO contributed to the design and concept of the study. HK, TK, K Imamura, ME, HH, K Ihara, HS, YF, and SPO acquired the data. SPO, HK, and TK analyzed and interpreted the data and drafted the manuscript. K Imamura, ME, HH, K Ihara, HS, and YF revised the manuscript for important intellectual content.

Conflicts of Interest

None declared.

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Abbreviations

AUC: area under the receiver operating characteristic curve
COG: center of gravity
GRF: ground reaction force
ICC: intraclass correlation coefficient
SMI: skeletal muscle index
TRIPOD: Transparent Reporting of a Multivariable Prediction Model for Individual Prognosis or Diagnosis

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Recruiting a National Sample of First Response Agencies to Participate in an Overdose Prevention Research Project: Randomized Controlled Trial and Feasibility Study

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Abstract

Background: US overdose deaths continue to exceed 77,000 per year, the majority of which involve opioids. One evidence-based response to this crisis is overdose education and naloxone distribution (OEND). There is a large national (US) network of citizens and first response agencies connected through an app called *PulsePoint Respond*, who are engaged in facilitating rapid layperson cardiopulmonary resuscitation administration in cases of public emergencies. Our goal is to recruit these first response agencies to provide targeted messaging about OEND to this large subpopulation of motivated layperson responders. This study focuses on the first step: the feasibility of our national efforts to recruit first response agencies to participate in our project.

Objective: This study aimed to determine whether more first response agencies were successfully recruited using materials that included preemptive correction of misperceptions about overdose and naloxone than with standard recruitment materials and to investigate the recruitment parameters observed when agencies were successfully recruited.

Methods: The overall study was a randomized controlled trial in which we randomly sampled 180 first response agencies from the total set of agencies subscribing to *PulsePoint* (n=773). Agencies were randomly allocated to 3 study arms (1:1:1) with stratification for rural status. Arm 1 received standard recruitment materials, arm 2 received similar materials that directly addressed common misperceptions about overdose and naloxone, and arm 3 was recruited to serve as a control arm for later parts of the study. The primary analysis of recruitment approaches used logistic regression, contrasting arms 1 and 2. Exploratory analyses included descriptive statistics and other logistic regression models.

Results: A total of 40 agencies signed memoranda of understanding to participate in the project (n=176, 22.7% of contacted agencies; n=151, 26.5% of the agencies where a point of contact had been established). We did not find evidence that the messaging contained in arm 2 significantly affected recruitment success (odds ratio 0.754, 95% CI 0.298 - 1.904; *P*=.55). Likewise, arm assignment (3-way comparison) did not significantly affect the likelihood of an agency agreeing to participate. The recruitment process took a mean of 159.08 (SD 104.74) days per agency and involved 8.38 emails, 1.98 voicemails, 0.83 phone calls, and 1.23 video calls.

Conclusions: Recruiting first response agencies that subscribe to *PulsePoint* for participation in a national-level OEND project appears feasible, with an anticipated participation rate between 23% and 27% of agencies solicited. Successful recruitment timelines can be lengthy and involve extensive correspondence. Since the language used in our different study arms did not have a significant effect on agency recruitment, other factors (such as individual citizen responses to messaging) could reasonably be used to select the overall language used in subsequent project recruitment materials.

Trial Registration: OSF Registries osf.io/egn3z; https://osf.io/egn3z

International Registered Report Identifier (IRRID): RR2-10.2196/57280

(JMIR Form Res 2026;10:e81743) doi:10.2196/81743

KEYWORDS

recruitment; first responder; overdose; opioid; community engagement; PulsePoint; randomized controlled trial; RCT; naloxone

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Introduction

Background

Although US overdose death rates have decreased substantially in recent years, including a 26.9% reduction from 2023 to 2024 [1], the most recent 12-month-ending overdose death count (77,677 in January 2025) still exceeded every other overdose death count reported on or before April 2020 [2]. The majority of those overdose deaths involved opioids [1,2].

The national response to this overdose crisis is complex and multifaceted; one key component is the use of overdose reversal medications such as naloxone (eg, Narcan), which can safely reverse an opioid overdose [3]. Evidence suggests that overdose education and naloxone distribution (OEND) programs of various kinds are effective preventive mechanisms [4-9]. Questions remain, however, about the optimal ways to implement such programming on a national scale.

In our protocol for this project, we argue that an ideal opioid overdose reversal infrastructure is one in which "naloxone is present at or near the scene" of an overdose and "used as quickly as possible," by which we imply a saturation of (1) individuals ready, willing, and able to respond to an overdose and (2) accessible overdose reversal medication [10]. This paper outlines the first step in the systematic approach by which we are working to support such saturation.

Our Overall OEND Project

The objective of our overarching project is to partner with the "large, highly engaged system for cardiopulmonary resuscitation (CPR) that already exists nationally in the US (*PulsePoint Respond*)" to support proliferation of OEND by sending messages to *PulsePoint Respond* app users that provide information about opioid overdose, direct them to online overdose and naloxone administration training opportunities, and remind them of the importance of carrying naloxone [10]. The project involves a 2-stage process, of which the first stage is the focus of this study.

For this first phase, we randomly sampled 180 first response agencies from the total set of agencies partnered with the *PulsePoint Respond* app (n=773). We attempted to recruit those 180 agencies to participate in the second phase of our project (to send out messaging to their *PulsePoint Respond* users). The second phase, which is ongoing in conjunction with participating agencies, involves providing messaging to citizen responders subscribed to those agencies' feeds in the *PulsePoint Respond* app. We briefly describe elements of that phase to contextualize our study, but it is not the focus of this paper.

PulsePoint Respond

At the time of our proposal, the *PulsePoint Respond* app, developed by the nonprofit PulsePoint Foundation, had more than 1 million monthly active users receiving geotargeted alerts on their mobile devices in around 4800 communities in the United States represented by more than 700 agencies [10]. As of July 2025, the number of monthly active users had surpassed 1.37 million, and there are now more than 5500 connected communities [11].

PulsePoint Respond was originally launched in 2011. Now, the hundreds of agencies working with PulsePoint are located across North America [12]. "PulsePoint implementations are typically championed and led by local Fire/EMS (Emergency Medical Services) agencies" who can reach out to PulsePoint to initiate discussions about joining as a community [13]. Those agencies then use a variety of methods to encourage individual-level (eg, user) participation via community outreach.

While first response agencies can directly recruit individuals with specialized skills or professions and enroll them as "Registered CPR Responders" or "Professional Responders," our primary interest for this project is "Public CPR Responders," who compose the majority of users. These individuals "are typically community members trained in CPR and automated external defibrillator use and willing to assist if an incident occurs near them" [14]. Any individual with the *PulsePoint Respond* app is able to sign up as a Public CPR Responder. Public CPR responders receive "notification of nearby cardiac arrest events occurring in public places" any time they are in a PulsePoint-connected community. They can also sign up for community alerts in multiple communities and are "shown a filtered list of emergencies occurring in the community and offered notifications of public interest events such as traffic collisions and wildland fires" [14].

PulsePoint's Public CPR Responders

We speculate that the individuals who opt in as Public CPR Responders for the *PulsePoint Respond* app are systematically different from the general public in the sense that they have already displayed a willingness to be alerted about, and potentially respond to, emergency incidents occurring in nearby public spaces (such as an unconscious and unresponsive person). Therefore, these individuals represent promising candidates for OEND outreach. As we have noted, our overall project, of which this study is the first component, is to provide informative messaging to *PulsePoint Respond* users, alerting them to online overdose and naloxone administration training opportunities and reminding them of the importance of carrying naloxone [10]. However, the app does not have a feature by which messages can be sent to all users in the system. Instead, the highest "level" of messaging permission within the app occurs at the "agency level" (eg, subscribing to a 911 dispatch center or firehouse), which can send messages to all app users who have subscribed to that agency's alerts.

The Need to Recruit First Response Agencies to Accomplish Our Study

Therefore, in order to study whether our targeted OEND messaging approach results in higher percentages of community-level responders reporting that they carry naloxone or have been trained in opioid overdose response, we needed to recruit first response agencies as partners willing to send messages to their users. Unfortunately, such a recruitment process does not appear to have precedent in the literature.

There are many examples where individuals at first response agencies have been recruited to participate in research related to overdose and naloxone, particularly interviews and surveys. For example, studies have done so using email surveys to agency

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leaders [15,16], surveys at in-service training [17], convenience and snowball sampling for interviews [18], and email and telephone recruitment from multiple divergent sources [19]. However, we were unable to locate any systematic descriptions of studies where first response agencies were recruited to partner with researchers to conduct subsequent research tasks (as was our goal here). Given this lack of information, we developed a study of agency recruitment as part of the first phase of our overall study.

The Value of Understanding First Response Agency Recruitment

We believe it is important to fill the gap in the literature on recruiting first response agencies as research partners for several reasons. First, clear information about agency participation rates will provide useful grounding for future studies. For example, the participation rate that one might reasonably expect from such an effort (eg, the number of agencies X required to actually achieve a participating sample Y) was unknown. While such estimates can vary by context, knowing an approximate participation rate can assist with statistical and practical study planning. Second, the overall effort required to recruit such agencies had not previously been studied or documented; obtaining a precise sense of the types of procedures and the length of time required to secure a participation agreement is critical for researchers planning a study timeline and allocating staffing time and costs.

In addition, this study provided us with an opportunity to test whether different message types were more likely to result in successful agency recruitment. As we describe in our protocol [10], "misperceptions about overdose and naloxone, as well as stigmatizing beliefs about people who use drugs, may affect both layperson and first responder willingness and interest in carrying and using naloxone," a topic about which much has been written [19-28]. Research also suggests that inaccurate ideas about naloxone and overdose are relatively common among US adults [29]. Thus, we speculated that recruitment messages that proactively addressed concerns about OEND that were predicated on inaccurate information would be more effective than recruitment efforts that did not use this approach.

Objectives

Our goal was for agencies to agree to participate in a structured program to send push messages (within the *PulsePoint* app) to citizen responders to provide information about opioid overdose, naloxone, and online overdose training opportunities. This study aimed to examine the feasibility of recruiting first response agencies that already subscribe to the *PulsePoint Respond* program [13], to test the efficacy of different messaging strategies, and to estimate the parameters (eg, length of time, contact quantity, and type) involved in successfully recruiting an agency. Except for one exploratory analysis, these aims were preregistered [10].

The primary hypothesis was:

- More first response agencies will be successfully recruited by study arm 2 (which included preemptive correction of inaccurate information about overdose and naloxone) than by study arm 1 (which included standard recruitment messaging).

Exploratory analyses were also conducted to answer the following questions:

- Were there significant differences in recruitment success between any of the study arms (including arm 3, which was a control arm)? This exploratory analysis was not preregistered.
- What was the mean length of time between establishing an initial point of contact (POC) and successfully establishing a memorandum of understanding (MOU) to participate in the project?
- What were the mean numbers and types of correspondence associated with successfully establishing an MOU to participate in the project?

In our protocol, we also explicitly noted that "regardless of the results of null hypothesis significance testing, [we were also interested in obtaining] an overall sense of recruitment feasibility" [10].

Methods

Design, Setting, and Eligibility

This study was a randomized controlled trial using a parallel-group design and a 1:1:1 allocation ratio with postsampling allocation by rurality. Eligible participants were all first response agencies in the United States that subscribed to the *PulsePoint Respond* app as of January 30, 2024 (n=773). At the sampling stage, agencies were considered ineligible and replaced if they had previously worked with our study team on a similar project.

Sampling, Allocation, and Blinding

A sample of 180 agencies was drawn based on the primary hypothesis contrasting 2 of the 3 study arms. With 60 agencies per arm, 80% power, and a 2-tailed α of .05, we had the ability to detect a proportional difference of at least 0.25 (ie, a 15-agency difference between arms) [10].

A study statistician not involved with the recruitment process (LGA) produced a random computer-generated sequence of numbers and sent it to JA, who then overlaid it on the population of eligible agencies, which had been provided to our study team by the *PulsePoint* Foundation in no particular order. As prespecified, the 180 agencies with the lowest random numbers were considered to be the initial sample.

Of those agencies, 2 were excluded for active or past overdose training work with the study team on different projects, 2 were invalid entries (eg, test cases that had been left in the dataset), and one was located outside the United States. The 5 agencies with the next lowest numbers in the original sequence were then included in the sample.

Then, the rural status of each agency was determined using the procedure described in *Supplemental File: Rurality Determination Method* [30]. As planned, allocation to study arms was accomplished by allocating the lowest third of rural agencies and the lowest third of nonrural agencies to arm 1,

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then the middle thirds to arm 2, and the remainder to arm 3. Because allocation was directly determined by the initial random number sequence, one can infer that allocation was concealed until assignment.

Agencies were blinded to arm assignment; they were informed about the overall project and the total number of agencies but not that some agencies received different materials or were asked to complete slightly different tasks.

Intervention and Comparator Conditions

General Recruitment Procedures and Content Design

Outreach to all agencies as part of the recruitment process involved combinations of phone calls, emails, and voicemails. The initial points of contact were obtained through a search for the agencies' publicly available data. The initial goal was to establish a POC (eg, a person at the agency familiar with *PulsePoint* and able to discuss the project with our team) [10]. Once the POC had been identified for an agency, we requested a videoconference (~10 min) with them to discuss the project using an arm-specific slide deck. We also provided arm-specific flyer sets in PDF format (2 variants targeted at the agencies and 2 variants that the agencies could prospectively use for outreach to citizens in their coverage areas). Except for ad hoc communication about specific topics, our team used a suite of template emails and voicemails depending on the state of recruitment (see *Supplemental File: Email and Voicemail Templates* [30]).

All materials (including push message examples) provided to agencies were codeveloped with marketing professionals at IU University Communications and Marketing Creative & Web Team (CWT). Our core project team developed initial materials that were then iteratively refined by personnel at the CWT. The CWT personnel were asked to document the key gray and academic literature used to inform their decision processes around push/SMS text messaging best practices [31-33], community-based overdose and naloxone-related communication [34-37], general marketing language [38], visuals to address harm reduction [39,40], and strategies to write about harm reduction [41-45].

Study Arm 1

Arm 1 was designated the "standard" recruitment arm, which focused on general messaging to encourage engagement with our program, such as (Figure 1):

- "Your citizen responders can prevent overdose fatalities."
- "As a participating *PulsePoint* agency, you already have a network of volunteers responding to unconscious and unresponsive citizens. If those volunteers also carry naloxone and are trained to use it, they will be able to act when they encounter an opioid overdose. With an overdose, just like with cardiac arrest, every minute counts!"
- "The US Surgeon General recommends: 'Be Prepared. Get Naloxone. Save a Life."

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Figure 1. Sample agency flyer for study arm 1.

Agencies were asked to commit to sending a "push" message through the *PulsePoint Respond* app once per month for 1 year. They were also asked to send 3 sets of 2 data collection messages (baseline, 6 months, and 12 months) asking participants to indicate whether they had been trained and carry naloxone. When agencies verbally committed to the project, they were provided with an MOU outlining these procedures. Upon signing the MOU, agencies were provided with instructions and push message templates (to be shared once the citizen portion of the study is completed in 2026). All recruitment materials for arm 1 can be found in the *Supplemental File: Arm 1 Recruitment Materials* [30].

Study Arm 2

Arm 2 was designed to use most of the recruitment principles from arm 1 while preemptively providing brief statements reflecting the current state of scientific knowledge to counteract common misconceptions about opioid overdose and naloxone [29]. Examples of such statements include (Figure 2):

- "Studies show that opioid use in a community does not increase when naloxone is widely available" [46-50].
- "Studies show that most people who are revived after an overdose do not overdose again" [51-54].

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Figure 2. Sample agency flyer for study arm 2.

Except for messaging changes described above, other recruitment procedures were similar to arm 1 (see *Supplemental File: Arm 2 Recruitment Materials* [30]).

Study Arm 3

Arm 3 was designed as a control arm for subsequent studies within this project. It used the standard messaging from arm 1 except that agencies were only recruited to send the sets of data collection messages. The modified slide deck for this arm is available in *Supplemental File: Arm 3 Recruitment Slide Deck* [30].

Outcomes and Covariates

The following variables were used in our analysis:

- Agency recruitment: The "ratio of recruited agencies (MOU) to total agencies with which active communication has been established," [10] (meaning that a POC was reached). This was the primary preregistered outcome.
- Raw MOU completion: The ratio of agencies with a completed MOU to the total denominator within a study arm. This was a secondary exploratory outcome.
- Recruitment timeline: The "length of time between initial contact and agreement to participate (MOU)," [10] measured in days. This was a secondary preregistered outcome.
- Dose-response metric: The "mean number and types of correspondence associated with agreement to participate and completion of an MOU" [10]. This was a secondary preregistered outcome.

Changes to Trial Protocol After Preregistration

We made 3 specific decisions about how to analyze and report this trial following preregistration, which we detail subsequently. We also documented all other events that might plausibly have affected the results of the study but that we considered to be minor or ecological issues. That documentation was timestamped at the time it was produced and is available in the *Supplemental File: Other Considerations for Study Interpretation* [30].

First, we originally planned to include agency rurality (and vote share derived from ZIP codes) as covariates in our primary outcome analysis. As we learned throughout the data collection process, many of the agencies in the sample covered broad mixtures of rural and nonrural spaces, sometimes with agencies overlapping in the same ZIP code for different service types. As described in *Supplemental File: Rurality Determination Method* [30], we were able to calculate a rough estimate of rural status to accomplish stratified allocation. However, after learning more from agencies about their operational procedures and collaborative norms, it was not clear to us that including these

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geography-based covariates would accomplish the goal of reducing error variance [55]. Particularly since agencies had already undergone stratified allocation to study arms by rural status, we chose to exclude these covariates from further analysis.

Second, we originally proposed to treat "agreement to participate" (informal) and "signing an MOU to participate" as having the same meaning in our primary outcome variable (agency recruitment). After observing that a high number of agencies expressed interest in participating but ultimately transitioned to refusals (eg, appeared to indicate that they would participate, but ultimately did not sign an MOU), we determined that such a designation would be misleading. To more conservatively estimate recruitment feasibility, we chose to adopt the more stringent requirement (a signed MOU) as the recruitment success metric.

Third, we originally stated that we would conduct separate analyses at 6 and 12 months postcorrespondence. After conducting the project, it became clear that 6-month analyses would not yield useful information, particularly since recruitment of specific groups of agencies was temporarily paused for various ecological reasons within the 12-month period (eg, fires, hurricanes, and floods). Further, agencies were only ever informed of a final deadline (12 mo).

Statistical Analysis

Analyses of agency recruitment used unadjusted logistic regression, both on the full sample and, separately, on the subsample of agencies for which correspondence had been achieved (adjustment was not necessary due to randomization). There were no missing data to address for those analyses. Those analyses, as well as measures of central tendency and distribution for all variables, were calculated using SPSS (version 29; IBM Corp).

Ethical Considerations

The agency recruitment processes within our study were reviewed by the Indiana University Institutional Review Board and determined not to meet the federal definition of research involving human subjects (review board record number 20218). Results are reported in a manner consistent with the CONSORT (Consolidated Standards of Reporting Trials) 2025 guidelines [56] (Checklist 1).

Results

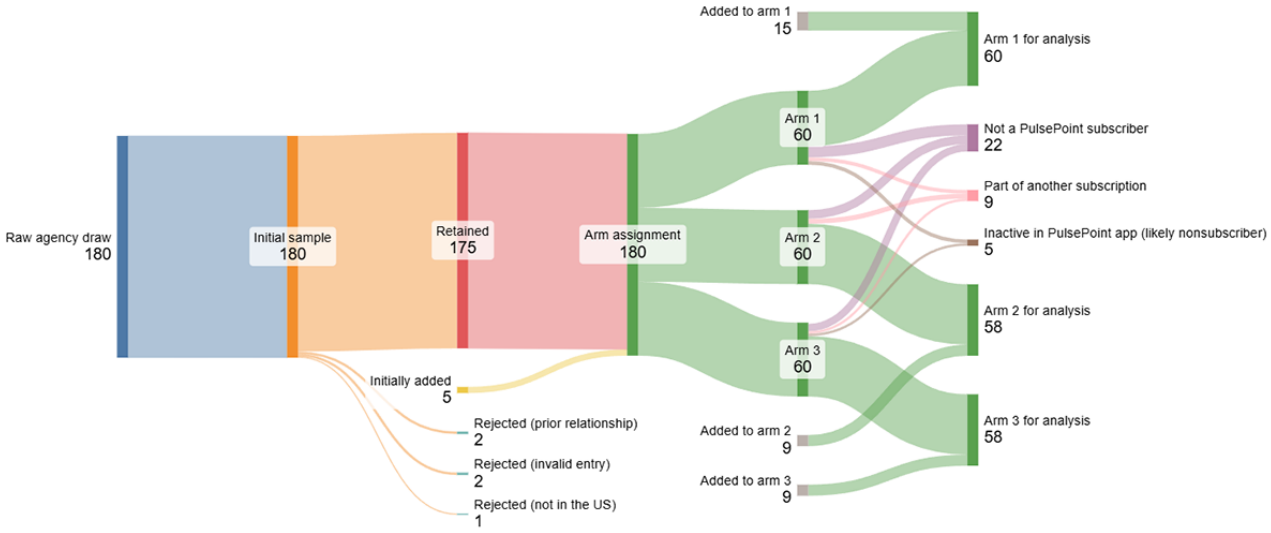
Participants

An initial sample of 180 agencies was randomly drawn from the list of 773 agency subscribers. As described in the Methods section, 5 of those agencies were removed from the sample due to ineligibility criteria and then replaced. Each agency's rural status was determined to the best degree possible, and then agencies were allocated with stratification for rural status to study arms (60:60:60). During the rolling 12-month recruitment period (May 2024 to May 2025), agencies were replaced and resampled if they:

- Confirmed that they were no longer a *PulsePoint* subscriber (n=22)
- Were completely inactive in the *PulsePoint Respond* app and did not respond to any inquiries, signifying likely nonsubscription (n=5)
- Were part of another agency that was also listed in *PulsePoint* (eg, a single agency had 2 different "listings" in the app, but they were not actually separate) (n=9)

Each of these instances was documented in real time (see *Supplemental File: Sampling Documentation [Redacted Names]* [30]). In one instance, a case of "merged" agencies was identified very near to the end of recruitment, and so those final cases were not resampled, meaning that the final denominators by arm were 60:58:58 (Figure 3).

Figure 3. CONSORT (Consolidated Standards of Reporting Trials) (Sankey) study diagram.



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Recruitment

We were able to establish POCs for the majority of agencies in study arm 1 (49/60, 81.7%), study arm 2 (56/58, 96.6%), and study arm 3 (46/58, 79.3%) (see Table 1). In most cases, failure to establish a POC reflected the inability to connect with any individual at the agency after the prescribed number of attempts; however, in some cases, the agency was also unable to determine who the correct POC would be.

Table . Recruitment statistics.

Study arm	Point of contact established, n	MOU[a] signed, n
1 (n=60)	49	12
2 (n=58)	56	11
3 (n=58)	46	17

[a]MOU: memorandum of understanding.

A total of 40 agencies signed MOUs to participate in the project (22.7% [176] of total agencies; 26.5% [151] of the agencies where a POC had been established). We did not find evidence that the nature of the messaging contained in study arms 1 or 2 significantly affected recruitment success (odds ratio 0.754, 95% CI 0.298 - 1.904; *P*=.55). We conducted exploratory analyses to examine 3-way comparisons (including the control arm) between agencies with established POCs and, separately, between all agencies, and likewise found that arm assignment did not significantly affect the likelihood of an agency signing an MOU to participate (see Table 2).

Table . Results of primary and exploratory analyses.

Comparison	OR[a]	95% CI	*P* value
Point of contact established (2-way comparison)[b]			
Arm 2 vs arm 1	0.754	0.298 - 1.904	.55
Point of contact established (3-way comparison)			
Arm 2 vs arm 1	0.754	0.298 - 1.904	.55
Arm 3 vs arm 1	1.807	0.746 - 4.377	.19
Arm 3 vs arm 2	2.398	0.984 - 5.843	.054
All agencies in sample (3-way comparison)			
Arm 2 vs arm 1	0.936	0.376 - 2.330	.89
Arm 3 vs arm 1	1.659	0.710 - 3.874	.24
Arm 3 vs arm 2	1.772	0.745 - 4.213	.20

[a]OR: odds ratio.

[b]Primary analysis for this study.

The length of the recruitment period, defined as the number of days between the initial contact attempt and our receipt of the signed MOU, was 159.08 (SD 104.74; range: 18-365) days (see Table 3).

Table . Length of recruitment period.

Study arm	Number of days, mean (SD)	Range of days
1 (n=12)	164.75 (113.47)	18 - 341
2 (n=11)	209.27 (130.82)	27 - 365
3 (n=17)	122.59 (63.42)	38 - 249
Combined (n=40)	159.08 (104.74)	18 - 365

Between the initial contact attempt (to establish a POC) and the time when a signed MOU was received for each agency, our study team sent an average of 8.38 emails, left 1.98 voicemails, and conducted 0.83 phone calls, in addition to holding 1.23 video calls during which we shared the recruitment slide deck for the project. These figures represent outgoing messages only and do not include messages received by the team.

Three agencies in the final sample were single agencies resulting from "merges" of multiple agencies that were listed separately in the *PulsePoint* app (see Figure 3). Therefore, Table 4 also provides descriptive statistics that exclude those agencies (sensitivity analysis), because some of the correspondence that reasonably might be attributed to recruiting these agencies may have been tagged as being part of other agency IDs, so we share these additional numbers for purposes of transparency.

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Table . Instances of outgoing recruitment correspondence.

	Number of emails, mean (SD)	Number of voicemails, mean (SD)	Number of phone calls, mean (SD)	Number of video calls[a], mean (SD)
Study arm				
1 (n=12)	8.17 (4.09)	2.42 (1.73)	1.17 (1.11)	1.50 (0.67)
2 (n=11)	10.09 (3.94)	2.55 (1.57)	0.91 (1.04)	1.18 (0.40)
3 (n=17)	7.41 (3.08)	1.29 (1.40)	0.53 (0.62)	1.06 (0.24)
Combined (n=40)	8.38 (3.72)	1.98 (1.62)	0.83 (0.93)	1.23 (0.48)
Study arm (sensitivity)				
1 (n=12)	8.17 (4.09)	2.42 (1.73)	1.17 (1.11)	1.50 (0.67)
2 (n=9)[b]	10.22 (4.32)	2.78 (1.48)	1.00 (1.12)	1.22 (0.44)
3 (n=16)[b]	7.69 (2.96)	1.38 (1.41)	0.56 (0.63)	1.06 (0.25)
Combined (n=37)[b]	8.46 (3.74)	2.05 (1.61)	0.86 (0.95)	1.24 (0.49)

[a]Each agency was required to have at least one video call to discuss study materials, so the lowest possible mean value was 1.

[b]Data from agencies that formed as part of "merges" were excluded

Discussion

Summary of Results

This study was designed to examine the feasibility of recruiting first response agencies that already subscribe to the *PulsePoint Respond* program to participate in a project focused on increasing OEND on a national scale in the United States. The randomized controlled trial design also allowed us to test whether proactively addressing common misperceptions about overdose and naloxone increased the number of agencies successfully recruited compared with standard recruitment messaging.

We did not find any evidence that the type of messaging included in recruitment materials (standard vs addressing misperceptions) had an effect on whether an agency was successfully recruited to participate in our project. In exploratory analyses, we likewise did not observe any pairwise differences between any of the study arms in terms of recruitment success. However, we found that recruiting agencies to participate in an OEND project was feasible, successfully recruiting 40 of the 176 agencies that we attempted to recruit from the national *PulsePoint* subscriber database.

Other Useful Findings

Even though our team understood from the outset that we would need to establish POCs for each agency, we were surprised by the average amount of time it took to recruit agencies for our project. While there were outlier agencies in each study arm that were recruited quickly (see range data in Table 3), the average recruitment process lasted a little longer than 5 months per agency. Based on our records, the factors contributing to this range of time seemed to vary. In some cases, it took a long time to identify the person at an agency who worked with *PulsePoint Respond*, but recruitment proceeded quickly thereafter. In other cases, we identified a POC quickly, but other individuals within the agency (eg, supervisors) or outside the agency (eg, legal counsel) needed to review issues around OEND, the nature of the project, and data privacy at greater length. In yet other cases, the recruitment process generally proceeded as planned, but each step took extra time due to first responders' need to prioritize ongoing emergencies such as wildfires.

Thus, depending on staffing size and capacity, we note the importance of allocating commensurate levels of time and effort at the front end of large-scale agency recruitment efforts to allow for this process to unfold. At the same time, in many cases, higher numbers of contact attempts reflected greater difficulty in determining which person in a given agency worked directly with the *PulsePoint* interface.

We also expressed concern at the outset that agencies randomized to the control arm might not participate in the project because that arm had fewer direct benefits to the community (eg, sending out push messages linking citizens to resources and training) [10]. However, agencies were just as likely to be recruited for study arm 3, with many of them expressing interest in the data that would be obtained through the control arm data collection regarding the current levels of overdose training and education, and the percentages of citizens regularly carrying naloxone.

Limitations and Alternative Interpretations

Multiple agencies were removed and replaced from the sample over the course of the project. In some cases, this resulted from agency "merges," where more than one agency was listed separately in the sampling frame, and we only learned after establishing communication that the agencies had the same controlling agreement related to *PulsePoint*. In other cases, participating agencies in different study arms were in close proximity to each other. In both types of situations, this may have resulted in some cross-exposure between study arms, but the numbers are insufficient to have affected the analytic results.

There were also multiple ecological events, particularly major natural disasters, that occurred throughout the study period. These were equally likely to have affected any given study arm

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but may have reduced the overall recruitment rate for the study as a whole. It is also possible that the overall recruitment rate was affected by other overdose prevention efforts, such as naloxone leave-behind programs [57]. Like ecological events, such effects would have been randomly distributed between study arms, but recent informal discussions between a first response coalition from a separate project and one study author (DCS; see more about his other project here [58,59]) found the potential for multiple overdose response programs to be perceived as competing priorities.

Still, this study is likely to have a high level of generalizability to first response agencies that subscribe to *PulsePoint*, but whether those agencies, in turn, are systematically different from other first response agencies in the United States or elsewhere is unclear. Caution should therefore be used in inferring these findings outside of the study frame.

The lack of a significant finding for the recruitment messaging is limited to effects on agency recruitment. In subsequent studies as part of this overall project, we will determine whether there is an effect—or not—on individual layperson responders depending on the type of messaging available through their study arm, but this component of the study does not address those differences.

Finally, this study was not designed to compare recruitment in arm 3 against the active study arms (the control arm was designed to facilitate individual-level analyses in subsequent parts of the project). Exploratory analyses suggested that none of the study arms was significantly different in terms of agency recruitment. However, the raw count for the control arm was descriptively higher than for the other arms. Based on statistics alone, we cannot infer that this difference is meaningful, but we note that our recruitment discussions often touched on the low levels of staffing and high workload in first response agencies. Thus, we think it is plausible, though not established by this study, that there may be a small recruitment advantage for the control arm (on the basis of a reduced "ask" for participation) that we were underpowered to detect.

Conclusions

This study demonstrated that it is feasible to recruit first response agencies that subscribe to *PulsePoint* to participate in an OEND project, with an anticipated recruitment success rate between 23% and 27%. The recruitment process was relatively involved, lasting slightly more than 5 months per agency on average and requiring multiple correspondence efforts across several communication platforms. Incorporating messaging designed to address inaccurate information about overdose and naloxone into messaging materials did not affect recruitment success. Supplemental qualitative analyses of recruitment materials and interviews with agency personnel about the recruitment process are underway and will provide additional clarifying information about how to optimize recruitment.

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Data Availability

Data used in the preparation of this manuscript are available through the Open Science Framework [30]. This link also provides access to the analytic code as well as the supplemental files referenced throughout the paper.

Authors' Contributions

Conceptualization: JA, CH, DCS
Data curation: JA, CH, MN, DT
Formal analysis: JA
Funding acquisition: JA, CH, DCS, MP, DT
Investigation: JA, CH, MN
Methodology: JA, CH, DCS, MP, DT, MN, LG-A, SD
Project administration: JA, CH
Resources: JA, CH, DCS, MP, DT

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Software: DT
Supervision: JA
Validation: CH, MN, LG-A, SD
Visualization: JA, CH, MN
Writing – original draft: JA, CH, MN
Writing – review & editing: JA, CH, DCS, MP, DT, MN, LG-A, SD

Conflicts of Interest

JA, CH, MP, and DCS have received funding through their employer (Indiana University) to conduct various research projects pertaining to opioids, harm reduction, and naloxone from federal, state, and local government entities and nonprofit foundations. CH was co–principal investigator of a National Institute on Drug Abuse Small Business Innovation Research grant that facilitated the development of a web-based naloxone training (Citizen Opioid Responders) being provided as an option for layperson responders in this study, but their participation was as an Indiana University employee; therefore, they do not have any mechanisms in place (eg, trademarks, patents, and access agreements) that would result in any personal profit or financial benefits accruing from the use of the training.

Checklist 1
CONSORT 2025 checklist.
[PDF File, 337 KB - formative_v10i1e81743_app1.pdf]

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Abbreviations

CONSORT: Consolidated Standards of Reporting Trials
CPR: cardiopulmonary resuscitation
MOU: memorandum of understanding
OEND: overdose education and naloxone distribution
POC: point of contact

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Social Media Promotion of Raw Date Palm Sap and Emerging Nipah Virus Transmission Risk in Bangladesh: Descriptive Analysis of Multisource Data

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Abstract

Background: Nipah virus (NiV) infection is considered one of the deadliest infectious diseases, with a case fatality rate of approximately 71%. In Bangladesh, the primary risk factor for NiV infection is the consumption of raw date palm sap (DPS) contaminated with excreta from fruit bats (ie, members of the *Pteropodidae* family). Recently, the increasing use of social media among Bangladeshi youth has enabled business groups to widely advertise and sell raw DPS. This increased access, combined with young people perceiving consumption of raw DPS as an "adventurous event," may facilitate an increase in incidences of NiV infection.

Objective: We aimed to explore and document data from social media regarding raw DPS advertisements and consumption. Furthermore, we aimed to investigate the commercial distribution of raw DPS across the country.

Methods: The data were accessed from common social media platforms used in Bangladesh, including Facebook and YouTube, between November 10, 2023, and January 31, 2024. We considered this period to capture public opinions, discussions, and reported incidents during the peak harvesting and consumption season of DPS. While DPS harvesting continues until March, early monitoring is essential for identifying the emerging concerns related to NiV transmission. Extracted variables were post dates and times, source locations, types of sources and posts, provider details (eg, sellers and *gachis*), post descriptions, user reactions, views, comments, and shares. Particular emphasis was placed on identifying the districts of both DPS suppliers and recipients. We used R version 4.3.2 and Stata version 15 for analyzing statistical data and QGIS for geographic data.

Results: Of 556 social media posts, 361 (64.9%) were advertisements promoting raw DPS. Few DPS-related posts (n= 10, 1.8%) were associated with raising awareness about DPS consumption and NiV infection. In total, 473,724 people interacted with the social media posts. The identification of supplier and recipient districts revealed 14 source districts of raw DPS. The majority of raw DPS were distributed from Rajshahi, Naogaon, Rajbari, and Faridpur, which are among the most NiV-prone districts. During the data collection period, we observed an average of 996 (SD 377) liters of raw DPS sold per day from multiple *gachhis* (sap collectors) and sellers (vendors) in Rajshahi.

Conclusions: The marketing of raw DPS through digital media platforms has increased customer interest, as evidenced by the notably high level of public engagement observed on this topic within the Bangladeshi social media context. Distributing raw DPS using digital platforms is a marketing tool that significantly increases the availability of raw DPS to previously hard-to-reach markets and potentially increases individuals' exposure to NiV infection. This study recommends a multidisciplinary approach, which incorporates context-specific public health investigations, policymaking, and digital media surveillance to address emerging public health concerns.

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KEYWORDS

Nipah virus; date palm sap; social media promotion; focused ethnography; infodemiology; zoonotic disease transmission; digital epidemiology

Introduction

Zoonotic diseases have emerged as a major public health concern in Bangladesh [1]. Among 1415 human pathogens identified globally, scientists reported that 61%, including Nipah virus (NiV), are zoonotic [2]. The World Health Organization has expressed growing concern about NiV by listing it as sixth of the next 10 possible pandemics, while Joi [3] highlighted NiV's possibility of further mutation and rapid transmission. NiV is considered one of the most fatal zoonotic infectious diseases, causing severe health consequences, including neurological symptoms [4]. Bangladesh experiences human outbreaks of bat-borne NiV infection almost every year, with a case fatality rate of 71% [5]. In 2023, a total of 14 cases were reported, including 10 fatalities [6]. Therefore, notwithstanding the smaller number of infected individuals, NiV requires significant attention from researchers with multidisciplinary approaches.

Pteropus bats are the only known reservoir for NiV in Bangladesh, and contaminated date palm sap (DPS) with bat excreta is the route of transmission. DPS, considered a natural delicacy in Bangladesh, is a food source for bats in the winter season when other food sources are scarce. Local harvesters attach pots to date trees to collect raw sap. Bats often contaminate the sap by licking or urinating in the DPS collection pots while feeding from the pot at night [7]. Thus, the virus is transmitted through saliva and urine of the bats into DPS [8]. Laboratory experiments confirm that NiV can survive several days in raw DPS, and animals exposed to contaminated raw DPS exhibit NiV infection [9]. In addition, multiple studies conducted during outbreaks in Bangladesh demonstrated a higher likelihood of NiV-infected individuals having consumed raw DPS than control groups [10-13]. Therefore, the primary cause of NiV infection in Bangladesh is the consumption of contaminated raw DPS [14]. As evident from previous studies, the consumption of raw DPS is interrelated to human NiV infection [15]. Therefore, the increased consumption rate of raw DPS may contribute to the transmission of NiV. Additionally, the distribution of raw DPS from NiV-prone regions to other areas may increase the spread of NiV.

According to the Bangladesh Telecommunication Regulatory Commission, the number of internet users increased to 126 million in March 2023, up from 1.1 million in the early 2000s [16]. In Bangladesh, accelerated digitalization has led to the widespread adoption of social media platforms as an integral part of daily life [17]. Easy accessibility, along with several features for connecting with people, sharing daily life updates, entertainment, online business, and shopping, has made the use of Facebook (Meta Platforms, Inc), Instagram (Meta Platforms, Inc), Pinterest (Pinterest, Inc), Twitter (X Corp), and YouTube (Alphabet Inc) extremely popular among people, irrespective of age and gender, in Bangladesh [17]. The contemporary pattern of online shopping has reduced the difficulty of collecting products in person, playing a tremendous role in people's lives. People can order any product from any part of the world, ranging from medicine to daily life essentials. As of 2022, a total of 50,000 small business pages run solely through Facebook for advertising and selling various products and food items within the country [18].

As the risk of contamination remains, the increased promotion and sales of raw DPS through digital media platforms can lead to a larger consumer base, facilitating the spread of NiV to new locations in Bangladesh. To evaluate this possibility, media monitoring surveillance could play a crucial role in documenting the data related to the potential social and behavioral activities and nuances contributing to NiV transmission through digital platforms. However, there is currently no evidence in the literature on how emerging digital marketplaces may facilitate or amplify exposure risks. To address this gap, our study aimed to measure the volume and nature of social media posts about raw DPS, map the networks of distribution facilitated by the digital platforms, and analyze public engagement with this content to evaluate the possibility of a new digitally driven risk of NiV transmission that may require novel surveillance and intervention strategies. In addition, we documented the volume of raw DPS and its daily distribution patterns from the original source to online sellers through on-site data collection in the Durgapur subdistrict of Rajshahi district.

Methods

Study Design and Setting

This study was a descriptive observational study that combined digital surveillance and on-site collection of data and was conducted between November 10, 2023, and January 31, 2024, in Bangladesh. The focus was on the promotion and distribution of raw DPS through social media platforms and its sales patterns in a Nipah-prone district.

Data Collection

Online Data Collection

Data regarding the sale and promotion of raw DPS were systematically collected from commonly used social media platforms in Bangladesh, including Facebook, YouTube, LinkedIn (Microsoft Corp), Instagram, Twitter, and electronic media. The majority of relevant content was identified on Facebook, whereas negligible numbers of relevant posts were found from other platforms (YouTube, LinkedIn, Instagram, Twitter, and electronic media) and were therefore not included in the analysis. The data collection team consisted of a group of researchers from the International Centre for Diarrhoeal Disease Research, Bangladesh (icddr,b), representing multiple disciplines, including anthropology, sociology, epidemiology, and statistics. A systematic search was conducted across the platforms using commonly used keywords related to raw DPS, including *Bangla* terms such as "khejurer rosh" ( ), as well as English terms such as "date palm sap," to identify relevant social media content. Duplicate and irrelevant posts were

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excluded. Only publicly available posts were included, and no direct interaction with users was undertaken. Because of privacy constraints, private inbox communications were inaccessible, and some data could not be captured (eg, recipient locations).

On-Site Data Collection

To determine the pattern of sales of raw DPS, an exploratory study was carried out in the Durgapur subdistrict of Rajshahi district, one of the Nipah-prone areas. Daily sales volume data (in liters) were collected through interviews with multiple *gachhis* (sap collectors) and sellers (vendors) and, when available, by sales records or logs. Information about districts receiving DPS shipments was also gathered during these interviews.

Sampling and Inclusion Criteria

Social media posts included in the study were selected through a keyword-based systematic search during the study period. Posts were screened for relevance to raw DPS sales or promotion. The on-site sample consisted of sellers and *gachhis* who were available and consented to participate within the specified subdistrict during the data collection period.

Variables

Extracted variables included the following: (1) date and time of post, (2) source location (if disclosed; no attempt was made to obtain undisclosed information), (3) provider details (name of seller or source, if publicly available), (4) post description and content, (5) user interaction indicators (reactions, views, comments, and shares), and (6) location of suppliers and recipients at the district level (if publicly disclosed).

Handling of Missing Data

Any information that was not publicly available or accessible (eg, the location of recipients in private messages) was recorded as missing. No imputation was performed. Analyses were conducted on available data only.

Addressing Bias and Limitations in Methods

The inclusion of publicly available posts and the use of a keyword-based search strategy could result in potential selection bias because it may not identify all the relevant content. The on-site data collection was limited to 1 subdistrict, which may not represent sales patterns in other regions. In the study design and interpretation, these limitations were considered.

Sample Size Justification

As this was an exploratory and descriptive study, no formal calculation of the sample size was performed. The study period and the search keyword were designed to capture a comprehensive dataset reflecting the DPS promotion and sales during the peak season.

Data Analysis

The data were summarized using descriptive statistics in R (version 4.3.2; R Foundation for Statistical Computing) and Stata (version 15; StataCorp). We used some graphical techniques, including epidemic curves and line-bar charts, to examine the temporal patterns. Quantum geographical information system was used to generate GPS-based maps.

Operational Definitions

The following operational definitions were applied:

- Nipah-prone districts—districts where historical NiV outbreaks have occurred
- Non–Nipah-prone districts—districts where historical NiV outbreaks have not occurred
- Advertisement posts—posts that involve direct promotion of the sale of raw DPS, including posts offering price, quantity, delivery options, or seller contact information
- Promotional posts—posts encouraging consumption or highlighting perceived advantages (eg, fresh and healthy sap is available); however, no direct sales are made
- Awareness posts—posts warning about health risks or disease transmission or recommending avoidance of raw DPS

Ethical Considerations

This study analyzed publicly accessible social media posts without interacting with the users. Following the standard digital epidemiology guidelines, all user identifiers, including names, profile images, and URLs, were removed before analysis to ensure privacy and confidentiality. No attempts were made to contact or identify social media users whose posts were included in the dataset. For on-site data collection, informed written consent was obtained from raw DPS sellers before collecting any information. Participation was voluntary, and no financial compensation was provided to participants. The research protocol (PR-22102) was reviewed and approved by the Research Review Committee and the Ethical Review Committee of icddr,b.

Results

The frequency of posts related to the sale of raw DPS through digital media exhibited a dynamic pattern over the specified period (Figure 1). In particular, the most frequent postings were made by digital marketers between December 12, 2023, and January 14, 2024. The data demonstrate fluctuations in the number of posts, with the highest numbers observed on specific dates, such as December 14, 2023; December 17, 2023; January 6, 2024; January 13, 2024; and January 14, 2024, when 16 to 23 posts were posted per day.

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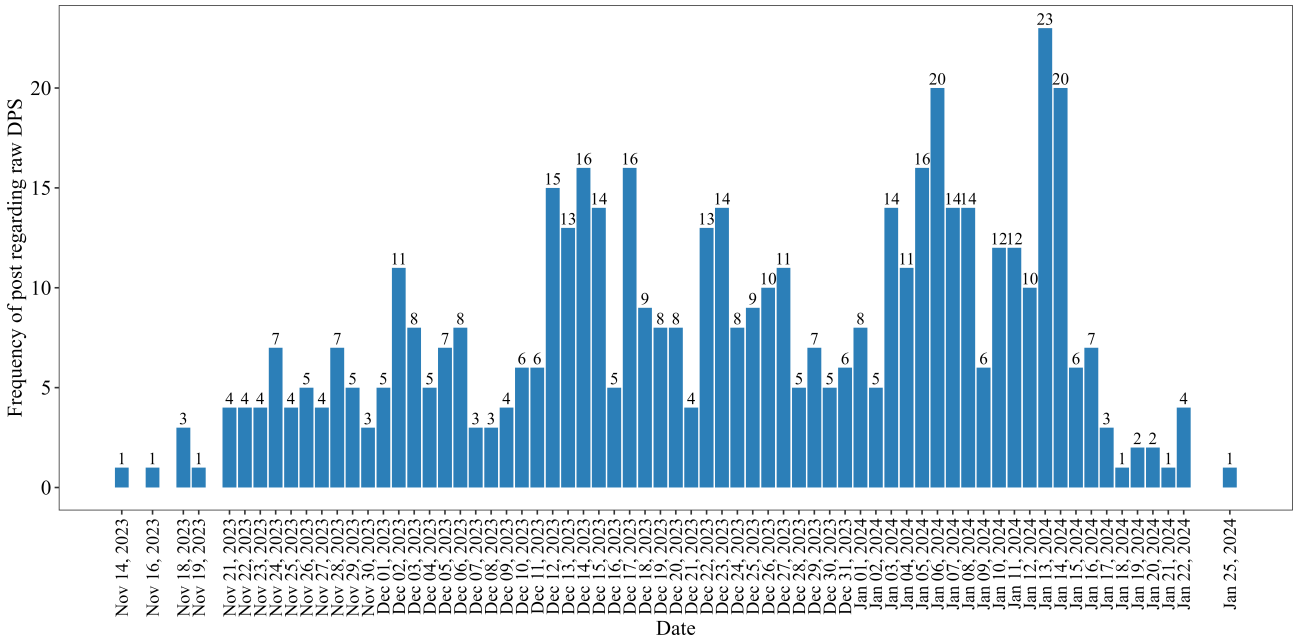
Figure 1. Epidemic curve of posts regarding raw date palm sap (DPS) on the selected social media platforms during the period from November 10, 2023, to January 31, 2024.



Findings revealed various types of posts used to promote and engage with the audience through digital platforms (Table 1) for the marketing of raw DPS. Among these social media posts, we observed a large number of advertisements of raw DPS and found it to be approximately 64.9% (361/556) of the total posts. Additionally, promotional posts (approximately 170/556, 30.6%) highlighted different aspects of raw DPS, such as taste. In addition, we found some awareness posts regarding the risk of NiV and the consumption of raw DPS. Such posts were scarce in number, accounting for 1.8% (10/556) of posts.

Table . Types of posts regarding raw date palm sap (DPS) on selected social media platforms during the period from November 10, 2023, to January 31, 2024 (N=556).

Types of posts	Values, n (%)
Advertisements	361 (64.9)
Promotional posts	170 (30.6)
Awareness posts	10 (1.8)
Personal posts	6 (1.1)
News reports on DPS collection	2 (0.4)
Posts exploring DPS sales points	7 (1.2)

We analyzed human interaction with the posts regarding raw DPS, and the results are illustrated in Figure 2. We observed a total of 473,724 people interacting with posts regarding raw DPS through social media platforms such as Facebook. Among these interactions, a total of 459,684 (97%) people expressed positive reactions such as like, love, care, haha, and wow to the posts; however, only 1285 (0.3%) people expressed negative reactions such as sad and angry. Moreover, it is worth mentioning that 5608 (1.2%) people recirculated these posts by sharing them on their own or other people's profiles.

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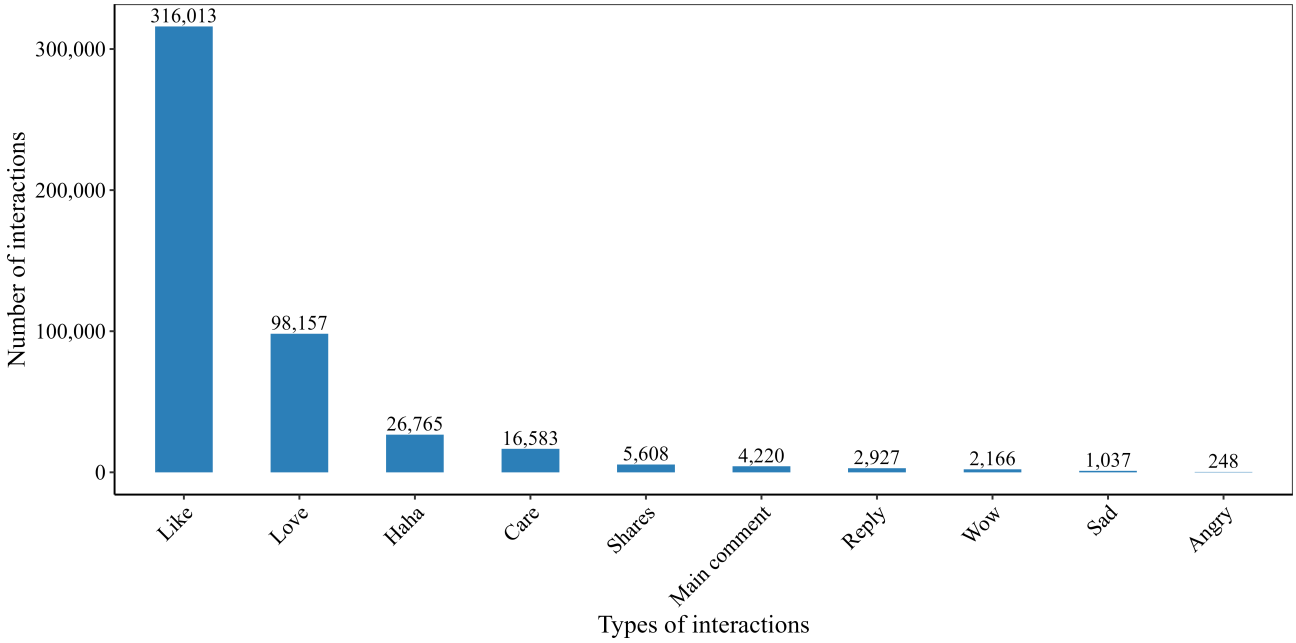
Figure 2. Interaction of people with posts regarding raw date palm sap on the selected social media platforms during the period from November 10, 2023, to January 31, 2024.



The identification of supplier and recipient districts shows the distribution network of raw DPS, as illustrated in Figure 3. Raw DPS was reportedly sourced from 14 districts and subsequently distributed to consumers across Bangladesh through digital platforms. Conversely, people in about one-third of the districts in Bangladesh collected raw DPS through digital platforms from the mentioned supplier districts. It is important to note that most of the raw DPS receiver districts were non–Nipah-prone areas of Bangladesh.

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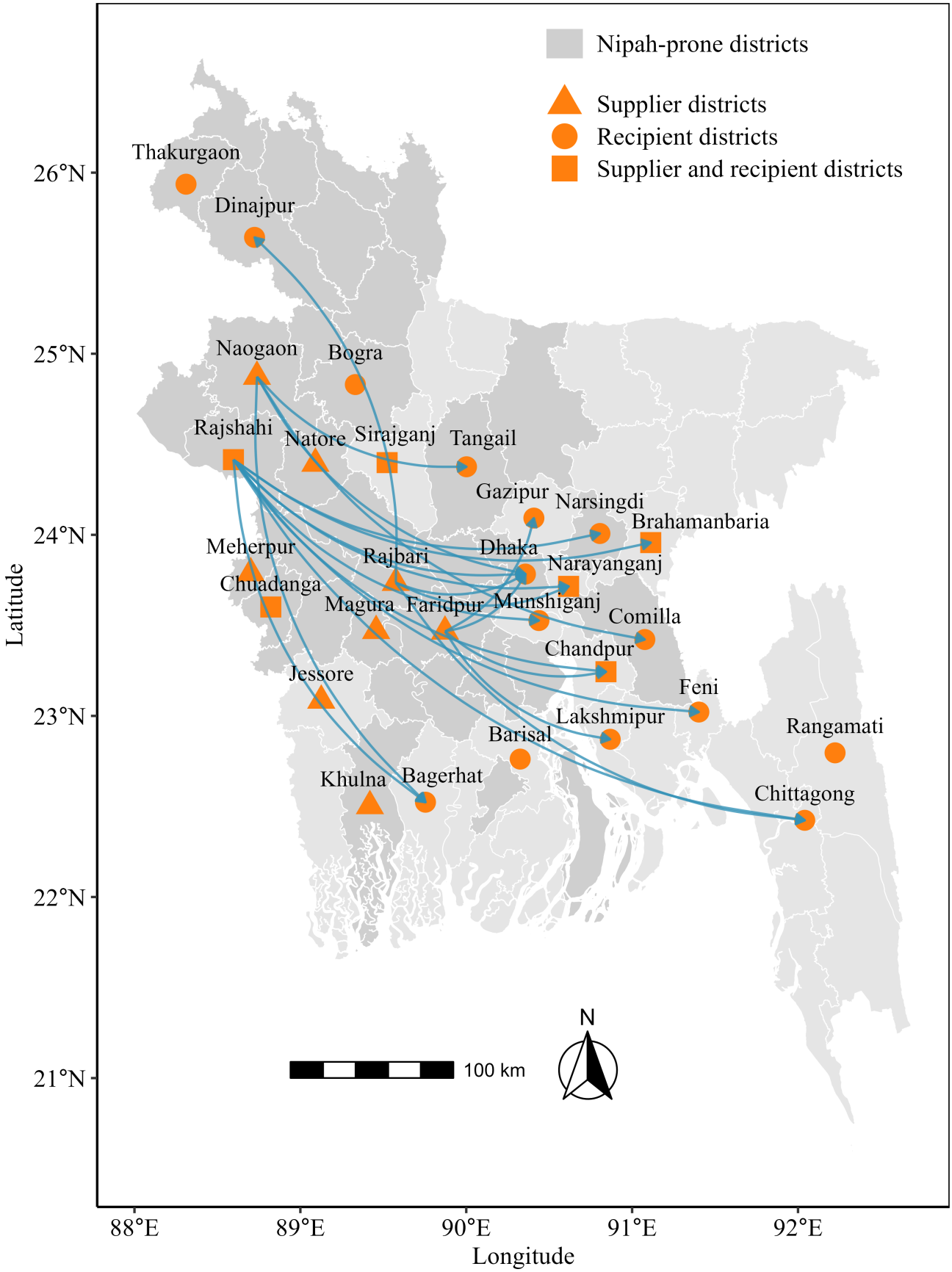
Figure 3. Geographic distribution of supplier and recipient districts and the distribution network of raw date palm sap in Bangladesh.



We examined the distribution pattern of raw DPS from 4 Nipah-prone districts (Rajshahi, Naogaon, Rajbari, and Faridpur) to other districts (Figure 3). We observed that the raw DPS from the districts of Rajshahi, Naogaon, Rajbari, and Faridpur was distributed to 9, 5, 4, and 4 districts, respectively. Raw DPS was supplied to some districts from multiple Nipah-prone districts. Notably, raw DPS from all the Nipah-prone districts

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is distributed to the Dhaka district, where the capital city of the country is located.

Figure 4 illustrates the daily sales of raw DPS (in liters) from a specific location in Rajshahi district to other districts. On average, 996 (SD 377) liters of raw DPS were sold on a daily basis. However, there was an increasing pattern in daily sales between December 5, 2023, and January 4, 2024, which started at 250 liters on December 5 and reached more than 6 times that amount by January 4, 2024. Subsequently, there was a fluctuating pattern in the daily sales of raw DPS, with an average of approximately 1120 (SD 251) liters.

Figure 4. Daily sales pattern of raw date palm sap sold (DPS; in liters) from Rajshahi to other districts during the period from December 5, 2023, to January 31, 2024.

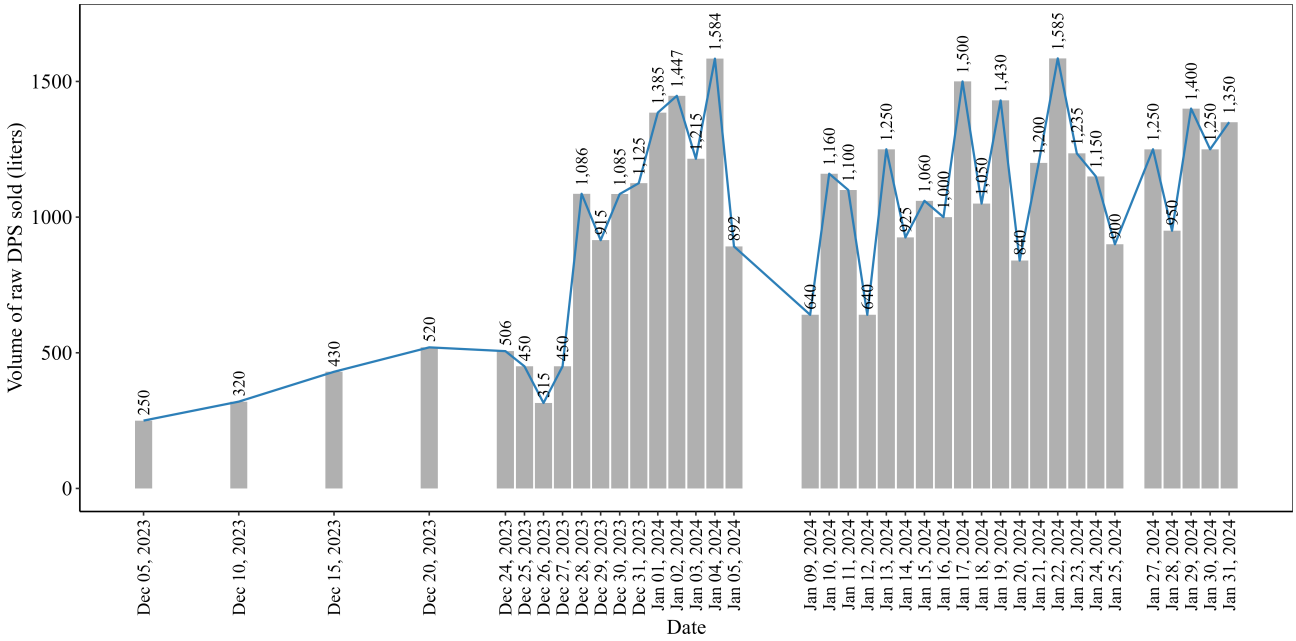
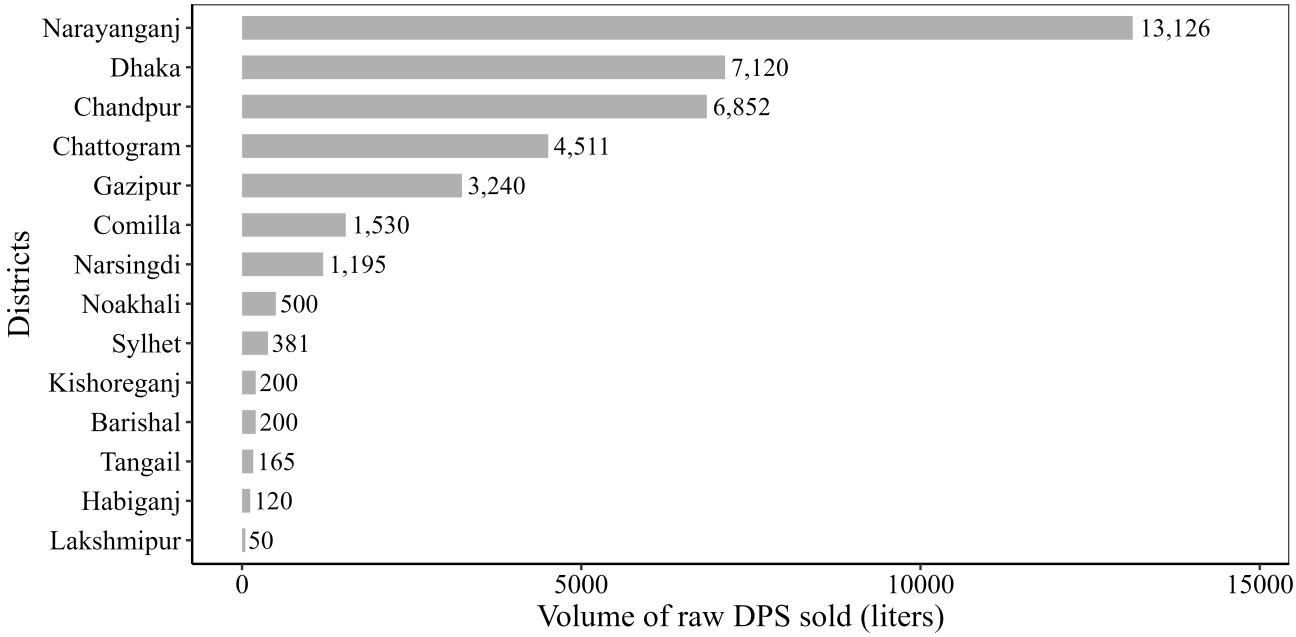


Figure 5 highlights the distribution of raw DPS, with quantities specified in liters, from a specific location in Rajshahi district to other districts during the period from December 5, 2023, to January 31, 2024. Our analysis revealed that raw DPS harvested in this particular place in Rajshahi district was sold to 14 different districts, with Narayanganj receiving the largest quantity (13,126/39,190, 33.5% liters) and Lakshmipur receiving the smallest (50/39,190, 0.1% liters). It was also revealed that the non–Nipah-prone areas (except Comilla and Tangail) received DPS from the Nipah-prone area (Rajshahi) of Bangladesh.

Figure 5. Quantity of raw date palm sap sold (in liters) from Rajshahi to other districts during the period from December 5, 2023, to January 31, 2024.



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Discussion

Principal Findings

Raw DPS contaminated by bat excreta is considered the primary cause of the transmission of NiV in Bangladesh [4,8,10-12]. While this study cannot establish a direct causal relationship, understanding the role of digital marketing in distribution patterns is important for informing public health strategies. Hence, considering the impact of digital marketing of raw DPS on the risk of NiV transmission is imperative. In our study, we have found a strong correlation between digital marketing strategies and the expanded distribution of raw DPS across districts in Bangladesh. On the basis of observed data, digital marketing appears to be associated with wider dissemination of raw DPS; however, further research is needed to establish causality [5,17].

The observed peak in raw DPS–related content from mid-December to mid-January may be influenced by seasonal and cultural factors in Bangladesh. This period coincides with the winter harvest season for DPS, when cooler night temperatures favor sap flow and preservation, increasing both availability and demand. In addition, winter months are associated with seasonal foods, vacations in educational institutions, and informal social gatherings, which may further promote consumption and online sharing of raw DPS. While our study did not directly assess cultural events or weather variables, these contextual factors may partly explain the observed temporal patterns and warrant further investigation.

The marketing of raw DPS on digital platforms generated substantial online engagement, as shown by the high volume of interactions with raw DPS–related posts. Although these data cannot help identify the change in customer interest over time or compare it with a baseline level, the cross-sectional nature of the data limits temporal analysis of customer interest patterns. This is particularly concerning given the established correlation between raw DPS consumption and NiV transmission, highlighting that the public health agencies should establish digital infoveillance systems to monitor high-risk products and launch targeted risk communication campaigns on the same platforms [5,16,17].

Facebook reactions such as “wow,” “haha,” and “love,” as well as comments on the digital content, indicate user interaction with the content. While these engagement metrics indicate the interaction, they do not directly relate to the consumption behavior. The findings suggest a substantial level of human interaction with the posts related to raw DPS on social media, particularly on Facebook. Positive reactions such as “like,” “love,” and “wow” may reflect social approval or normalization of raw DPS consumption, while “wow” and “haha” reactions could indicate that the practice is perceived as novel, entertaining, or adventurous rather than risky. The positive engagement rate indicates increased interest in raw DPS, which may affect public perceptions and consumption behaviors. This pattern raises concern regarding the potential increase in the risk of NiV transmission, specifically in the absence of appropriate safety measures. This highlights the necessity of implementing as well as promoting safety interventions to reduce the risk of transmission [11,12,15].

The widespread distribution network through digital platforms signifies a ubiquitous availability and demand for raw DPS, which potentially increased the consumption of raw DPS across numerous districts in Bangladesh. In 2013, the first outbreak of NiV occurred in Dhaka district through the consumption of raw DPS brought from Mymensingh district [19]. This outbreak emphasizes the role of interdistrict distribution in contributing to the disease spread. In addition, a noticeable upward pattern was observed in daily sales of raw DPS in the Nipah-prone districts. This extensive distribution network, combined with an upward sales pattern of raw DPS, raises concerns about the potential transmission of NiV, as raw DPS is being sourced from districts belonging to Nipah-prone areas, particularly when considering the broad scope of distribution of raw DPS through digital marketing. The transmission risk cannot be quantified in this study. However, the identified patterns demonstrate the necessity of continuous monitoring and specify the public health intervention [10-12].

Our findings suggest that social media platforms, particularly Facebook and YouTube, could be leveraged for targeted digital public health interventions to reduce the risk of NiV transmission. Possible approaches constitute countermessaging to discourage the consumption of raw DPS and encourage safer options, including boiled sap, and conducting geo-targeted campaigns in districts receiving DPS shipments during the harvesting seasons. Platform-specific tools, such as sponsored posts and short video content delivered in locally appropriate languages, may enhance reach and engagement. Partnerships between public health authorities and social media platforms could extend support for timely risk communication and misinformation control.

Limitations

This study has several limitations. First, a nonsystematic approach to collecting social media data may introduce selection bias and limit the representativeness of the relevant online content. Second, this study only summarized raw DPS promotional posts; however, it cannot establish any direct linkage between these online activities and specific NiV cases. Third, the on-site sales data came from only 1 vendor or location in 1 subdistrict; therefore, the sales volumes and patterns may not be representative of other vendors or Nipah-prone districts. Finally, laboratory testing was not conducted to establish whether the DPS under sale was contaminated with NiV or other pathogens, which limits our ability to evaluate the risk of actual infection. These limitations emphasize the importance of conducting more systematic future studies, including on-site observations in all Nipah-prone districts and laboratory testing of raw DPS that is intended to be sold.

Conclusions

This study explores and documents how a known risk factor of NiV in Bangladesh—raw DPS—gains accelerated distribution across the country through social media promotion. Thus, the study elucidates the role of digital media and human behavior in the seemingly unpredictable spread of a disease, which has

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emerged as a novel way of transmission. Moreover, future research could explore how cultural aspects can increase (or decrease) the risk of disease transmission through modern media in other regions of the world. However, these phenomena will require rigorous analysis to be understood completely. Although social media platforms expedited the wide distribution and consumption of raw DPS in Bangladesh, these platforms facilitated the implementation of public health actions such as developing social media countermessaging campaigns, partnering with platform companies to flag high-risk posts, and delivering targeted education to digital marketers of raw DPS. The study's conclusions support a multidisciplinary strategy that combines public health, policymaking, and digital media surveillance to handle the intricate problems brought on by the online marketing of goods such as raw DPS that are sensitive to health concerns.

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Data Availability

All relevant data are presented within the manuscript. However, the anonymized data supporting the findings of this study can be made available from the corresponding author upon reasonable request.

Authors' Contributions

Conceptualization: KIAC, FA, WRA, DIR, SMS
Data curation: KIAC, FA, SMZS, LA, NN, JS, AC, MMH, MTI
Formal analysis: KIAC, FA, AC
Funding acquisition: KIAC, SMS
Investigation: KIAC, FA, SMZS, SMS
Methodology: KIAC, FA, SMS
Project administration: KIAC, SMZS, LA, JS, AC, MMH, MTI
Resources: KIAC, SMZS, LA, JS, AC, MMH, MTI
Supervision: KIAC, SMS
Validation: KIAC, SMZS
Writing—original draft: KIAC, FA, NN
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Conflicts of Interest

None declared.

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Abbreviations

DPS: date palm sap
icddr,b: International Centre for Diarrhoeal Disease Research, Bangladesh
NiV: Nipah virus

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Smart Technology–Assisted Patient-Centered Management in Venous Thromboembolism: Pilot Study on Anticoagulation Adherence

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Abstract

Background: Achieving optimal adherence to anticoagulation therapy is a major challenge in the management of venous thromboembolism (VTE). Mobile health (mHealth) technologies may offer a scalable approach to supporting medication adherence and self-management.

Objective: This pilot study aimed to assess the feasibility and preliminary impact of a smart technology–assisted, patient-centered care mHealth app for managing VTE (mVTEA) on short-term anticoagulation adherence among patients with VTE or at moderate-to-high risk of VTE.

Methods: Baseline medication adherence and beliefs were assessed using the Chinese versions of the 8-item Morisky Medication Adherence Scale and the Beliefs about Medicines Questionnaire–Specific to characterize baseline status only. The primary outcome was perfect adherence at 1 month, assessed through structured telephone interviews, outpatient visits, and the mVTEA physician-patient communication module. During follow-up, researchers verified current medication regimens, recorded missed doses, assessed therapy continuation, and whenever possible, confirmed adherence through pharmacy refill records or remaining medication packaging. Secondary outcomes included the mVTEA check-in rate and clinical safety events (VTE recurrence, major bleeding per International Society on Thrombosis and Haemostasis criteria, VTE-related hospitalizations, VTE-related rehospitalizations, all-cause mortality).

Results: In total, 45 participants completed the study (mean age 60.80, SD 15.20 years; n=16, 36% female). Baseline 8-item Morisky Medication Adherence Scale scores indicated suboptimal adherence (mean 6.24, SD 1.80), with 29% (13/45) classified as good adherence and 71% (32/45) as moderate or poor adherence. The primary contributors to nonadherence were forgetting to take medication. Baseline Beliefs about Medicines Questionnaire–Specific scores showed stronger beliefs in medication necessity than concerns (17.58, SD 2.52 vs 14.56, SD 3.34; P<.001; necessity-concerns differentials: 3.02, SD 4.60). At 1-month follow-up, all 45 participants achieved perfect adherence, and 80% (n=36) used the mVTEA check-in feature. Participants who engaged in check-ins demonstrated markedly more favorable necessity-concerns differentials profiles (29/36, 81% vs 0/9, 0%; P<.001). No VTE events, major bleeding, or other adverse outcomes were reported.

Conclusions: This pilot study supports the feasibility and acceptability of the mVTEA and provides preliminary signals that it may support short-term anticoagulation adherence. Larger randomized trials with longer follow-up and objective adherence measures are warranted, along with efforts to address the digital divide to ensure equitable access to mHealth-based anticoagulation support.

Trial Registration: Chinese Clinical Trial Registry ChiCTR2200063206; www.chictr.org.cn/showproj.html?proj=175426

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KEYWORDS

anticoagulation management; venous thromboembolism; medication adherence; smart technology; patient-centered

Introduction

Venous thromboembolism (VTE), encompassing deep vein thrombosis and pulmonary embolism (PE), remains a leading cause of preventable cardiovascular morbidity and mortality globally, with an annual incidence ranging from 100 to 200 per 100,000 population [1,2]. In China, driven by an aging population and improved diagnostic capabilities, the incidence of VTE is progressively increasing, posing a significant public health challenge [3]. Beyond acute lethality, VTE is associated with debilitating long-term complications, including chronic thromboembolic pulmonary hypertension and postthrombotic syndrome, which severely impair quality of life and impose substantial economic burdens on health care systems [2]. Moreover, extended pharmacological thromboprophylaxis (ie, continued anticoagulation postdischarge) is frequently warranted for surgical patients at high VTE risk (eg, major orthopedic procedures, abdominal cancer surgeries) and specific high-risk medical populations (eg, active malignancy, prior VTE history) [4]. Consequently, optimizing comprehensive VTE management holds substantial clinical significance for improving patient outcomes and conserving health care resources.

Anticoagulation therapy is the cornerstone of VTE management [5]. However, maintaining anticoagulation adherence remains a critical challenge. Suboptimal patient adherence is multifactorial, stemming from patient-level factors (eg, inadequate disease awareness, fear of bleeding, forgetfulness), medication-related barriers (eg, cost, need for monitoring with warfarin), and follow-up management issues (eg, insufficient physician-patient communication, poor coordination among multidisciplinary care teams) [6-8]. Various strategies have been implemented to improve adherence, including systematic health education to enhance patient knowledge [9], cluster nursing interventions to optimize warfarin adherence and knowledge [10], and specialized anticoagulation clinics [11]. However, these approaches generally face limitations such as high human resource dependency, limited coverage, and challenges in implementing large-scale personalized interventions.

The digital health era offers unprecedented opportunities to address these challenges. Through mobile health (mHealth) apps, patients can conveniently record symptoms, monitor vital signs, and report medication behaviors, facilitating a shift from passive treatment acceptance to active participation in management [12,13]. While some mHealth apps exist for general anticoagulation management [14,15], there is a paucity of evidence-based platforms specifically designed for VTE patients that integrate dynamic risk assessment, personalized behavioral nudges, and patient-provider communication. To address this gap, we have developed a smart technology–assisted, patient-centered care mHealth app for managing VTE (mVTEA) [16]. This novel application can leverage real-time data to dynamically assess thrombosis/bleeding risks and deliver tailored interventions, aiming to establish a “partnership-style” interactive relationship and enhance patients’ self-efficacy and treatment engagement.

This pilot study aims to evaluate the feasibility and preliminary efficacy of the mVTEA in improving short-term anticoagulation among patients with VTE or at moderate-to-high risk of VTE. The findings will provide essential parameters for designing future definitive randomized controlled trials.

Methods

Study Design and Setting

This was a single-center, prospective, single-arm pilot study conducted at the Sixth Medical Center of the Chinese People’s Liberation Army General Hospital between August 25, 2023, and December 20, 2023. The hospital is a tertiary medical institution integrating clinical care, teaching, and research. The study was designed to evaluate the feasibility and preliminary efficacy of the mVTEA on anticoagulation adherence among patients with or at risk of VTE over a 1-month follow-up period. Both the design and reporting of this study comply with the CONSORT (Consolidated Standards of Reporting Trials) 2010 statement extension for pilot and feasibility trials [17] (Checklist 1). This study was registered with the Chinese Clinical Trial Registry (ChiCTR2200063206).

Participants and Recruitment

Potentially suitable candidates for the study were initially screened from the hospitalized patients in the Department of Pulmonary Vascular and Thrombotic Disease through the clinical decision support system for VTE risk assessment and integrated care at the Sixth Medical Center of the Chinese People’s Liberation Army General Hospital [18]. Based on the initial screening list, a final identification of whether the patient met the study recruitment needs was made on the day the patient was discharged from the hospital. Inclusion criteria were (1) age ≥18 years; (2) diagnosed with confirmed VTE (deep vein thrombosis or PE) or identified as being at moderate-to-high risk of VTE based on the Padua Prediction Score (score ≥4) or Caprini Risk Assessment Model (score ≥2); (3) currently prescribed anticoagulant medication for VTE treatment or prophylaxis for a planned duration of ≥1 month; (4) able to understand the study procedures and willing to provide informed consent; (5) proficient in the use of a smartphone and willing to download and use the mVTEA. Exclusion criteria included (1) severe cognitive impairment or mental disorders precluding the use of the mVTEA; (2) lack of access to a smartphone; and (3) participation in other interventional clinical trials.

Patients fulfilling these requirements and expressing interest in participation received a comprehensive, in-person explanation of the study objectives, procedures, potential benefits, and possible risks. Those who agreed to enroll were provided with a paper-based informed consent form for signature at the same time. The process was conducted with full respect for each participant’s preferences and autonomy. In addition, we assured

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that the rights of participants to withdraw from the study would be upheld throughout all phases of the clinical trial.

Intervention

Overview

Patients enrolled in the study were registered with mVTEA via smartphone. The registration process collected essential demographic and clinical information, including name, gender, age, height, weight, hospitalization department, use of anticoagulants, and contact details. During the inpatient period, departmental health care staff provided VTE health education as part of the institution's standard protocol for VTE prevention and management. A tailored VTE prevention and treatment plan was formulated by the patient's supervising physician. Prior to discharge, patients were asked to complete the Chinese version of the 8-item Morisky Medication Adherence Scale (MMAS-8) [19] and the Beliefs about Medication Questionnaire–Specific (BMQ-Specific). Upon discharge, the mVTEA system commenced sending reminders for anticoagulant medication administration according to the prescribed regimen. Patients were instructed to log their medication adherence using mVTEA on the day of administration or on subsequent days for additional entries. The system also provided weekly feedback on adherence data. A follow-up assessment was conducted on the 30th day postdischarge, either via telephone or in a clinical setting.

The Chinese versions of MMAS-8 and BMQ-Specific used in this study have demonstrated acceptable psychometric properties in several chronic disease populations in China [20-24]. However, neither instrument has been formally validated in VTE populations. Although some concerns have been raised regarding the MMAS-8 measurement's precision and structural stability across various clinical contexts, this scale remains widely used in medication adherence research due to its brevity, feasibility, and comparability across chronic diseases [20-22,25]. Given the exploratory and pilot nature of this study, MMAS-8 and BMQ-Specific were used as preliminary measures to characterize baseline adherence and medication beliefs. Their use enabled standardized and comparable assessments across participants and facilitated the identification of attitudinal barriers prior to the initiation of mVTEA-supported management.

The Chinese Version of MMAS-8

Medication adherence was tested using the Chinese version of the 8-item MMAS-8 (Multimedia Appendix 1). Response choices were "yes" or "no" for items 1 to 7, and Item 8 had a 5-point Likert response scale. Each "no" response was rated as 1 and each "yes" response was rated as 0 except for item 5, in which each "yes" response was rated as 1 and each "no" response was rated as 0. For Item 8, the code (0 - 4) had to be standardized by dividing the result by 4 to calculate a summated score. Total scores on the MMAS-8 ranged from 0 to 8, with scores of 8 reflecting high adherence, 7 or 6 reflecting medium adherence, and<6 reflecting low adherence [20]. The psychometric properties of the Chinese version of MMAS-8 are favorable, with high internal consistency (Cronbach α=.817) and excellent test-retest reliability (intraclass correlation=0.947) [20]. Permission to use the MMAS-8 was obtained from the copyright holder and the scale was used in accordance with the licensing agreement.

The Simplified Chinese Version of BMQ-Specific

The simplified Chinese version of BMQ-Specific was used to evaluate individuals' perceptions of taking prescribed anticoagulants (Multimedia Appendix 2). It consisted of 10 items: 5 items on medication necessity and 5 items on medication concern. A 5-point Likert scale was used for each item, ranging from 1 (strongly disagree) to 5 (strongly agree). The overall score ranged from 5 to 25, with higher values indicating stronger beliefs about necessity and concerns. Additionally, a necessity-concerns differential (NCD) was derived by subtracting the concerns score from the necessity score, producing a range of −20 to 20. This metric served as an indicator of the balance between perceived benefits and concerns, representing an individualized cost-benefit assessment of medication use [26]. The simplified Chinese version demonstrated good reliability, with Cronbach α values of 0.826 (necessity) and 0.820 (concern) and intraclass correlation coefficients of 0.784 and 0.732, respectively [23].

mVTEA-Facilitated Patient-Centered VTE Management

When designing the mVTEA, we took into account the fact that the long-term management of VTE is multifaceted, requiring individualized patient assessment and a nuanced approach to therapy. Therefore, we proposed the ABCDEF pathway for integrated management of VTE to complement mVTEA-assisted patient-centered management, thus minimizing the risk of VTE and its complications and ensuring patient safety and quality of life: (A) appropriate antithrombotic management; (B) bleeding risk management; (C) complication monitoring; (D) digital health management; (E) exercise and rehabilitation; and (F) facilitate the management of risk factors and comorbidities [16].

The mVTEA was designed as a patient-side and physician-side interface. The core functions of the patient interface were four modules: thrombosis risk assessment, bleeding risk assessment, anticoagulation management, and home rehabilitation report (Figure 1).

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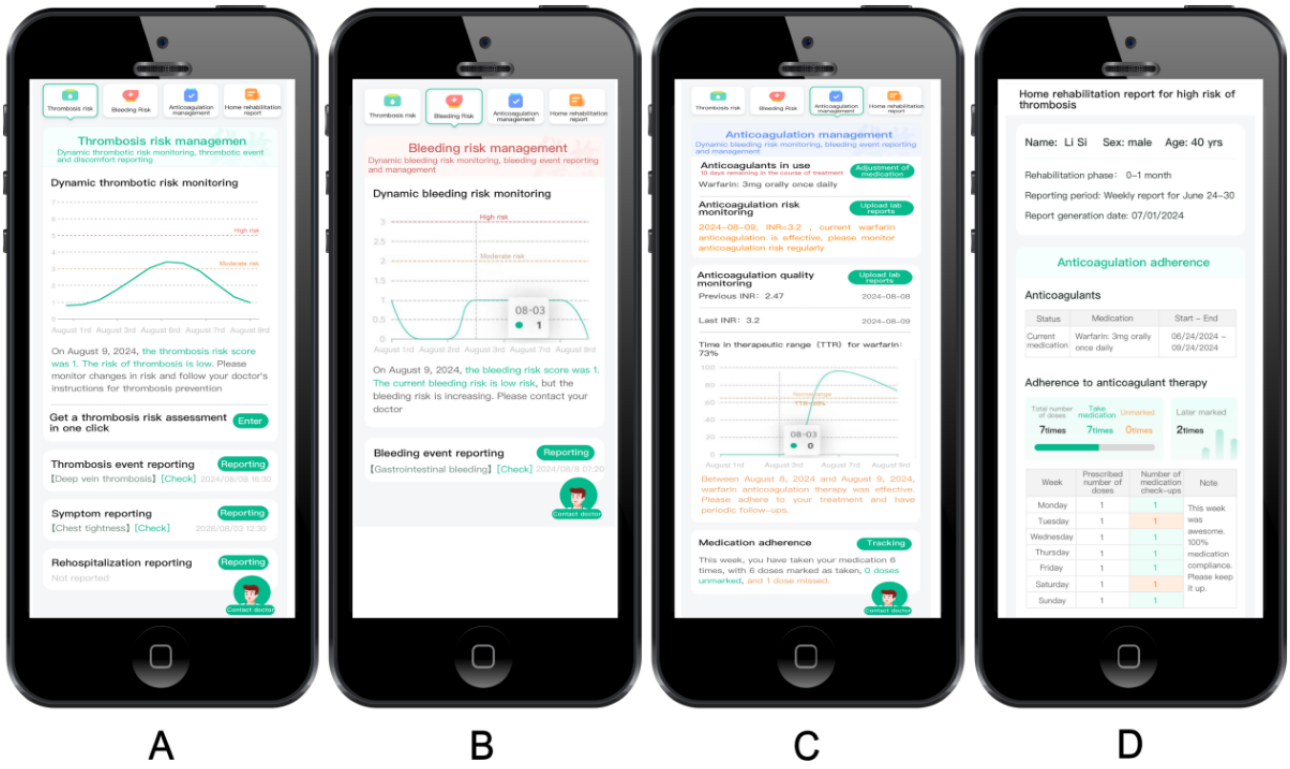
Figure 1. The core functional modules of the smart technology–assisted, patient-centered care mobile health app for venous thromboembolism management: (**A**) thrombosis risk assessment, (**B**) bleeding risk assessment, (**C**) anticoagulation management, and (**D**) home rehabilitation report.



The Thrombosis and Bleeding Risk module provides dynamic monitoring of a patient's risk for thrombosis and bleeding. Automated risk assessments were initiated when patients reported symptoms or adverse events or uploaded relevant test results. Additionally, patients might complete a thrombosis risk self-assessment form. Based on the individualized risk profile, the mVTEA patient interface generates personalized recommendations for VTE prevention and treatment. These risk assessment outcomes were also transmitted to the mVTEA physician interface for further evaluation and feedback from thrombosis specialists.

The Anticoagulation Management module was structured into four key components: anticoagulants in use, anticoagulation risk monitoring, anticoagulation quality monitoring, and medication adherence. For anticoagulation risk and quality monitoring, patients could upload test results related to coagulation or liver or kidney function. These results were synchronized with the physician interface, where thrombosis specialists performed additional evaluations and interventions as needed. The medication adherence feature allowed patients to log anticoagulant administration through a digital "punch card" system, which tracked and displayed their adherence history.

The Home Rehabilitation Report module outlined the patient's home-based rehabilitation plan, including the duration of anticoagulant therapy, historical anticoagulant usage, detailed adherence records, and VTE prevention and management recommendations. This report was automatically generated on a weekly and monthly basis for continuous monitoring and support.

Additionally, the mVTEA app offered daily medication reminders. At the end of each week, the app would provide feedback on the number of days the anticoagulant was taken as prescribed. The app also issued alerts when there were changes in thrombosis or bleeding risk assessments and monitored anticoagulation quality, such as the international normalized ratio for patients on warfarin. Patients could access their electronic health records at any time. When necessary, thrombosis specialists could deliver patient health education, including motivational interviewing, or conduct online consultations via the mVTEA doctor-patient communication module, which supported text, photo, and voice interactions. Outpatient appointments could also be arranged as needed through mVTEA.

To ensure the privacy and security of medical data during transfer from the hospital to the patient app, the mVTEA app used a novel QR code–based Security Transmission algorithm using Avro and Byte Pair Encoding (QRST-AB) [27]. The algorithm processes a deidentified dataset containing essential clinical information in a structured JSON format, including medical history, laboratory tests, and imaging results, while excluding all direct personal identifiers. This guarantees that the transmitted data alone cannot be linked to a specific individual. The QRST-AB framework integrates the ChaCha20 stream cipher for encryption and a BLAKE3 hash-based mechanism for authentication, which verifies the user's identity against a digital fingerprint of the QR code content. Data are transmitted via offline QR codes, eliminating the risk of network exposure. The security of the system is further underpinned by proprietary Avro serialization schemas and a Byte Pair Encoding tokenizer. These core components are synchronized between the encoder and decoder through secure offline channels,

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rendering the data structure and content uninterpretable to third parties, thereby collectively ensuring comprehensive data protection.

Outcome Measures

The primary end point was the proportion of patients with perfect adherence to the prescribed anticoagulant regimen at the 1-month follow-up. Perfect adherence was defined as 100% concordance between the patient's self-reported medication use (verified against pharmacy refill records and remaining medication packaging) and the prescribed regimen in terms of medication type, dosage, and frequency. Patients were classified as having "good adherence" (fully adherent) if no deviations were identified and "poor adherence" if any deviation (eg, missed doses, incorrect dosage, or premature discontinuation) was confirmed.

The secondary end points included: (1) the interactive anticoagulant therapy reminder check-in rate via mVTEA, calculated as the ratio of completed check-ins for prescribed anticoagulant doses to the total number of prescribed doses; (2) clinical safety and efficacy outcomes, including VTE events, major bleeding events defined by the International Society on Thrombosis and Haemostasis criteria, VTE-related hospitalizations, VTE-related rehospitalizations, and all-cause deaths. Hospitalization due to the new-onset VTE would be documented as VTE-related hospitalizations, while rehospitalization due to VTE recurrence, progression, or complications arising from VTE treatment would be classified as VTE-related rehospitalizations. All-cause death referred to any death occurring during the study period, regardless of the cause.

Data Collection

Patient demographic and clinical information would be extracted from the hospital information system. Baseline medication adherence and beliefs were assessed using the Chinese versions of MMAS-8 and BMQ-Specific prior to discharge. The primary measure of anticoagulation adherence at 1-month follow-up was determined through a comprehensive approach involving structured telephone follow-ups, outpatient clinic visits, and the physician-patient communication module within the mVTEA app. During these interactions, researchers recorded the current medication regimen, verified discrepancies against discharge prescriptions, documented missed doses, and confirmed therapy continuation. Whenever possible, adherence was objectively verified against pharmacy refill records or remaining medication packaging. The secondary end points were also collected during these follow-up assessments. Clinical safety events were documented based on patient reports and verified against medical records. Additionally, the interactive check-in rate via the mVTEA was automatically logged to assess patient engagement with the app.

Ethical Considerations

The study protocol was approved by the Independent Ethics Committee of the Sixth Medical Center of the Chinese People's Liberation Army General Hospital (approval HZKY-PJ-2022 - 21). All procedures adhered to the principles of the Declaration of Helsinki. All participants provided written informed consent for study participation and use of the mVTEA. They were explicitly informed of their right to withdraw from the study at any time without penalty. No financial compensation, material incentives, or other forms of remuneration were offered to participants for enrollment or study participation. Participation in the study was entirely voluntary, and refusal or withdrawal did not influence access to standard clinical care or follow-up management. To ensure data privacy and security, all patient data were deidentified and assigned a unique study code during data processing. The collected data were securely stored and managed by designated personnel, accessible only to authorized researchers for the sole purpose of this study. No data were disclosed to third parties.

Statistical Analysis

This study was a pilot study to evaluate the feasibility and preliminary efficacy of the mVTEA in improving short-term anticoagulation adherence. The calculation of sample size for this pilot study was determined using the method proposed by Viechtbauer et al [28]. Assuming the minimum detectable change in medication adherence is 0.1, under the requirement of achieving a 95% confidence interval, the minimum sample size for this study was calculated to be 29 people.

All statistical analyses were performed using SPSS (version 20.0; IBM Corp), with continuous variables presented as mean (SD) or median (IQR) and categorical variables as counts and percentages. Baseline medication adherence and beliefs were assessed using the Chinese versions of the MMAS-8 and BMQ-Specific. Based on baseline MMAS-8 scores, participants were categorized into good, moderate, and poor adherence groups, and the Kruskal-Wallis *H* test was used to analyze differences in MMAS-8 item scores among these groups. If a significant overall effect was observed ($P<.05$), post hoc pairwise comparisons were conducted using the Dunn test with Bonferroni correction to determine specific differences between groups. Based on the NCD calculated from BMQ-Specific scores, participants were divided into High-BMQ (NCD>0) and Low-BMQ (NCD ≤0) groups, and the Mann-Whitney *U* test was used to compare BMQ-Specific item scores between them. Additionally, the χ^2 test (or Fisher exact test) was used to compare the differences in mVTEA medication check-in rates across the three MMAS-8 adherence groups and the two NCD groups. Statistical significance was set at $P<.05$.

Results

Participant Characteristics

From August 25 to December 20, 2023, a total of 45 patients were enrolled, among which 87% (39/45) were diagnosed with VTE. The flowchart is shown in Figure 2. The mean patient age was 60.80 (SD 15.20) years and 36% (16/45) of the patients were females. The detailed patient characteristics are illustrated in Table 1.

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Figure 2. Study flowchart. BMQ: Beliefs about Medicines Questionnaire; MMAS-8: 8-item Morisky Medication Adherence Scale.

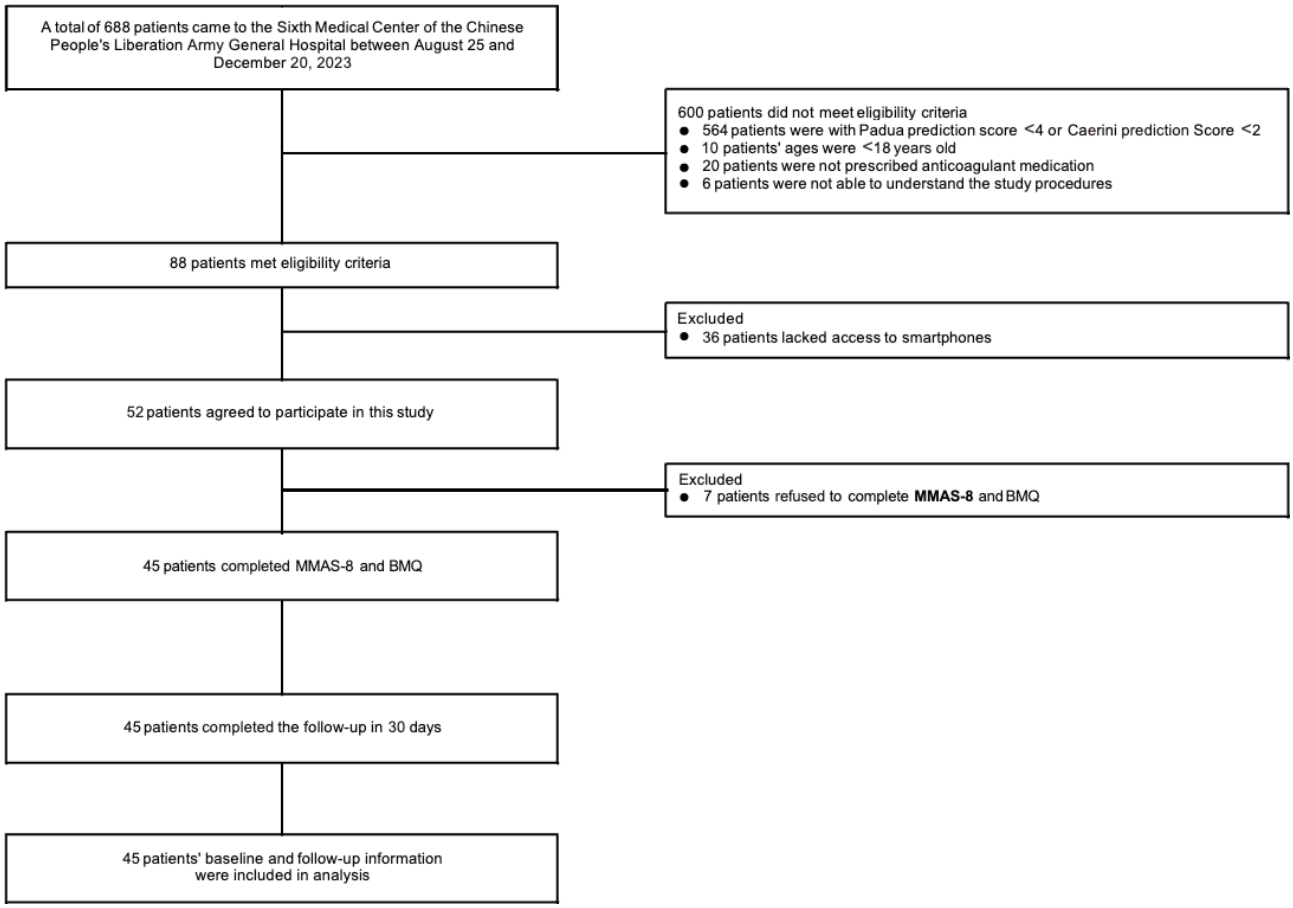

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Table . Baseline demographic and clinical characteristics of the study population.

Item	Patients (N=45）
Age (y), mean (SD)	60.80 (15.20)
Female, n (%)	16 (36)
Risk of VTE[a], n (%)	
Medium	2 (4)
High	4 (9)
VTE patients, n (%)	
DVT[b]	18 (40)
PE[c]	11 (24)
DVT and PE	10 (22)
Comorbidities, n (%)	
Hypertension	19 (42)
History of cancer	2 (4)
Diabetes	6 (13)
Previous stroke	2 (4)
Atrial fibrillation	3 (7)
Valvular heart disease	1 (2)
Others	12 (27)

[a]VTE: venous thrombosis.

[b]DVT: deep venous thrombosis.

[c]PE: pulmonary embolism.

Medication Adherence at Baseline

Tables 2 and 3 summarize the baseline MMAS-8 scores, revealing suboptimal medication adherence among participants. Specifically, only 29% (13/45) of patients exhibited good adherence, while the majority (71%, 32/45) demonstrated medium or poor adherence levels. The predominant factors contributing to this low adherence were identified as "Sometimes forget to take their medication" (Question 1) and "People sometimes forget to take their medications for reasons other than forgetting" (Question 2). Notably, these same factors were consistently reported among poorly adherent patients. Figure 3 illustrates the baseline distribution of MMAS-8 scores across the study cohort, along with the score distributions stratified by different adherence categories.

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Table . Baseline medication adherence scores measured by the 8-item Morisky Medication Adherence Scale (MMAS-8) for the study population.

MMAS-8[a] item	Scores, mean (SD)
Q1. Do you sometimes forget to take your medication?	0.62 (0.49)
Q2. People sometimes forget to take their medications for reasons other than forgetting. Thinking over the past two weeks, were there any days when you did not take your medication?	0.69 (0.47)
Q3. Have you ever cut back or stopped taking your medication without telling your doctor, because you felt worse when you took it?	0.82 (0.39)
Q4. When you travel or leave home, do you sometimes forget to bring your medication?	0.89 (0.32)
Q5. Did you take your medication the last time you were supposed to take it?	0.80 (0.41)
Q6. When you feel like your symptoms are under control, do you sometimes stop taking your medication?	0.78 (0.42)
Q7. Taking medication every day is a real inconvenience for some people. Do you ever feel hassled about sticking to your treatment plan?	0.78 (0.42)
Q8. How often do you have difficulty remembering to take all your medications?	0.84 (0.22)
Total scores	6.24 (1.80)

[a]MMAS-8: 8-item Morisky Medication Adherence Scale.

Table . Baseline medication adherence scores measured by the 8-item Morisky Medication Adherence Scale (MMAS-8) stratified by adherence levels within the study population.

Item of MMAS-8[a]	High adherence (n=13), mean (SD)	Medium adherence (n=16), mean (SD)	Low adherence (n=16), mean (SD)	*P* value
Question 1	1.00 (0.00)	0.88 (0.34)	0.19 (0.40)	<.001
Question 2	1.00 (0.00)	0.88 (0.34)	0.25 (0.45)	<.001
Question 3	1.00 (0.00)	0.94 (0.25)	0.56 (0.51)	.003
Question 4	1.00 (0.00)	1.00 (0.00)	0.69 (0.48)	.007
Question 5	1.00 (0.00)	0.63 (0.50)	0.81 (0.40)	.045
Question 6	1.00 (0.00)	0.94 (0.25)	0.44 (0.51)	<.001
Question 7	1.00 (0.00)	0.81 (0.40)	0.56 (0.51)	.02
Question 8	1.00 (0.00)	0.84 (0.27)	0.69 (0.25)	<.001

[a]MMAS-8: 8-item Morisky Medication Adherence Scale.

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Figure 3. Distribution of baseline 8-item Morisky Medication Adherence Scale scores among the study population: (A) overall distribution and (B) stratified by adherence level.

Belief About Taking Anticoagulants at Baseline

Tables 4 and 5 present the BMQ-Specific scores for individual questionnaire items. Among the 45 participants who completed the baseline BMQ-Specific assessment, the necessity score for anticoagulant therapy significantly exceeded the concern score (17.58, SD 2.52 vs 14.56, SD 3.34; P<.001). The primary factor contributing to insufficient perceived necessity was the statement "Without my anticoagulants, I would be very ill" (Question 3), while the predominant concern was reflected in the response to "I sometimes worry about the long-term effects of my anticoagulants" (Question 5). In the Low-BMQ group (NCD ≤0), inadequate belief in treatment necessity was primarily associated with responses to "Currently, my health depends on anticoagulants" (Question 1) and Question 3, whereas most of the concern-related items demonstrated elevated scores (Figure 4).

Table . Baseline anticoagulant beliefs measured by the Beliefs about Medicines Questionnaire–Specific for the study population.

Characteristics classification	Scores, mean (SD)
BMQ[a]-Specific necessity	17.58 (2.52)
Q1. Currently, my health depends on anticoagulants.	3.47 (0.70)
Q3. Without my anticoagulants, I would be very ill.	3.09 (0.73)
Q4. My life would be impossible without my anticoagulants.	3.64 (0.74)
Q7. My health in the future will depend on my anticoagulants.	3.36 (0.74)
Q10. My anticoagulants prevent my condition from worsening.	4.02 (0.50)
BMQ-Specific concern	14.56 (3.34)
Q2. Having to take my anticoagulants worries me.	2.69 (1.26)
Q5. I sometimes worry about the long-term effects of my anticoagulants.	3.29 (0.84)
Q6. My anticoagulants are a mystery to me.	2.96 (0.98)
Q8. My anticoagulants disrupt my life.	2.56 (0.89)
Q9. I sometimes worry about being too dependent on my anticoagulants.	3.07 (1.01)
BMQ-Specific NCD[b]	3.02 (4.60)

[a]BMQ: Beliefs about Medicines Questionnaire.

[b]NCD: necessity-concerns differential.

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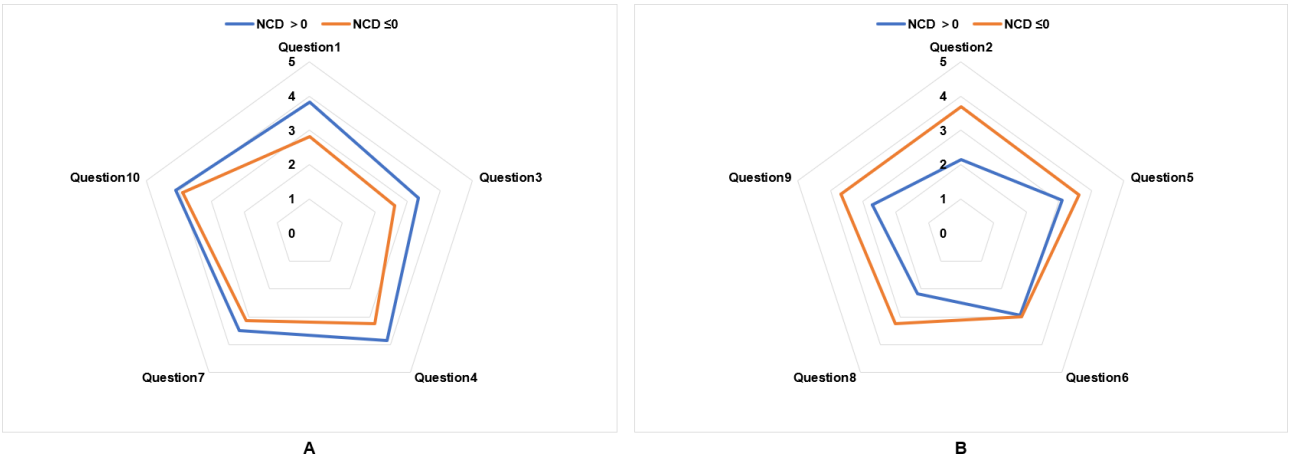
Table . Differences in baseline Beliefs about Medicines Questionnaire (BMQ)–Specific necessity and concern item scores between the High-BMQ group and the Low-BMQ group.

Item of BMQ-Specific, mean (SD)	High-BMQ[a] group (NCD >0)[b], n=29	Low-BMQ group (NCD ≤0), n=16	*P* value
BMQ-Specific necessity			
Question 1	3.83 (0.54)	2.81 (0.98)	<.001
Question 3	3.34 (0.72)	2.63 (0.50)	.001
Question 4	3.86 (0.64)	3.25 (0.77)	.005
Question 7	3.48 (0.63)	3.13 (0.89)	.19
Question 10	4.10 (0.49)	3.88 (0.50)	.14
BMQ-Specific concern			
Question 2	2.14 (0.95)	3.68 (1.14)	<.001
Question 5	3.10 (0.82)	3.62 (0.81)	.10
Question 6	2.93 (1.10)	3.00 (0.73)	.92
Question 8	2.17 (0.66)	3.25 (0.86)	<.001
Question 9	2.72 (1.03)	3.69 (0.50)	.002

[a]BMQ: Beliefs about Medicines Questionnaire.

[b]NCD: necessity-concerns differential.

Figure 4. Differences in baseline Beliefs about Medicines Questionnaire–Specific (A) necessity and (B) concern item scores between patients with positive (NCD >0) and nonpositive (NCD ≤0) NCDs among the study population. NCD: necessity-concerns differential.



The Impact of mVTEA on Anticoagulation Adherence and Adverse Events

The results showed 100% adherence to the prescribed anticoagulants for all patients at the 1-month follow-up. The check-in rate for interactive anticoagulant therapy reminders through mVTEA was 80% (36/45). Table 6 shows those participating in check-ins during the 1-month follow-up (n=36) had significantly better medication adherence and beliefs about taking anticoagulants. All patients in the no check-in group (n=9) had a negative NCD, compared to only 19% (7/36) of patients in the check-in group. No VTE events, major bleeding, or other adverse outcomes were reported at 1-month follow-up.

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Table . Comparison of baseline medication adherence and anticoagulant beliefs between patients with and without engagement in the mobile health app for patient-centered venous thromboembolism management check-ins during the 1-month follow-up among the study population.

	Check-in (n=36)	No check-in (n=9)	*P* value
MMAS-8[a], n (%)			
High	13 (36)	0 (0)	.09
Medium	11 (31)	5 (56)	
Low	12 (33)	4 (44)	
BMQ[b]-Specific, n (%)			<.001
NCD[c] ≥0	29 (81)	0 (0)	
NCD <0	7 (19)	9 (100)	

[a]MMAS-8: 8-item Morisky Medication Adherence Scale.

[b]BMQ: Beliefs about Medicines Questionnaire.

[c]NCD: necessity-concerns differential.

Discussion

Principal Findings

This pilot study assessed the feasibility of implementing the mVTEA, a patient-centered mobile health intervention designed to support anticoagulation management among patients with VTE or at moderate-to-high risk of VTE. Rather than demonstrating clinical efficacy, the findings primarily indicate operational feasibility and provide early behavioral signals relevant to planning a definitive randomized trial. A 100% adherence rate was recorded at 1 month, accompanied by an 80% engagement rate with the app's check-in function. These results should be interpreted as preliminary indicators of acceptability rather than evidence of intervention effectiveness.

Several factors likely contributed to the high adherence observed in this study. First, the baseline assessment revealed that our cohort possessed relatively strong medication beliefs, with a positive NCD indicating that patients perceived the benefits of anticoagulation as outweighing the risks. Second, the 1-month observation period captured the acute phase of treatment, a period typically characterized by high patient motivation. Third, the exclusion of patients unable to use smartphones ensured a cohort with high eHealth literacy, potentially creating a selection bias toward individuals more receptive to digital interventions.

Critically, the high adherence rate may also reflect the direct impact of the mVTEA intervention itself. Unlike passive reminders, the mVTEA uses a conversational interface and interactive modules to provide personalized feedback, actively engaging patients in self-management [16]. This real-time engagement likely reinforced disease awareness and heightened the perceived necessity of therapy, creating a positive feedback loop that encouraged strict adherence. Therefore, the 100% adherence may represent a synergistic effect of favorable baseline characteristics and the potent behavioral support provided by the technology.

The 80% check-in rate underscores the value of patient-centered design in overcoming common barriers such as forgetfulness. Moreover, the association between app engagement and favorable medication beliefs suggests that mVTEA functions as an adjunct to reinforce treatment necessity. While conducted within the Chinese health care system, these findings have broader relevance. The mVTEA model—integrating digital risk assessment with patient engagement—could be adapted for health care systems with limited outpatient resources by reducing the burden of routine follow-ups. The scalability of such tools suggests a viable pathway to support anticoagulation management in diverse settings, although the infrastructure required for digital access remains a prerequisite.

The present findings contribute to the growing evidence supporting mHealth interventions in cardiovascular disease management. Previous research has consistently demonstrated the effectiveness of smartphone apps in improving medication adherence. Specifically, Cao et al [29] and Jiang et al [30] reported that the Alfalfa app significantly improved anticoagulation control and reduced adverse events in warfarin therapy. These findings were corroborated by Talboom-Kamp et al [31], who established the safety and reliability of eHealth platforms for oral anticoagulation self-management. In contrast to prior studies, our investigation focuses on a more heterogeneous VTE population receiving various anticoagulant therapies, while incorporating a dedicated VTE protocol featuring personalized risk assessment and direct clinician-patient interaction. The mAFA trials [12,32] previously demonstrated the efficacy of an integrated mHealth approach incorporating the ABC pathway for atrial fibrillation, showing improved treatment adherence and clinical outcomes. Our study adapted this patient-centered, integrated model to the distinct clinical context of VTE management. Additionally, our results are consistent with existing literature documenting mHealth's potential to enhance patient engagement and overcome health care access barriers, as demonstrated by high participation rates in mobile-based cardiac rehabilitation programs [33, 34]. These findings underscore the need for large-scale randomized controlled trials to evaluate whether the observed improvements in adherence translate into reduced VTE recurrence and bleeding complications—critical clinical outcomes that remain insufficiently explored in contemporary mHealth research.

This study has several limitations. First, the single-arm design and lack of a control group preclude causal inference regarding

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the effectiveness of the intervention. The sample size was calculated solely for feasibility, rendering the study underpowered to detect efficacy differences. Second, the 100% adherence rate, while encouraging, must be interpreted with caution. Adherence was primarily assessed via self-report and medication logs, which are susceptible to recall and social desirability biases, compounded by the potential Hawthorne effect. Future large-scale randomized controlled trials should incorporate objective measures (eg, pharmacy refill data) and longer follow-ups to assess sustainability. Third, while the Chinese versions of MMAS-8 and BMQ-Specific are widely used [20-25], their specific validation in VTE populations is limited, and the scales' susceptibility to bias warrants caution when interpreting psychological determinants. Finally, the exclusion of patients without smartphones or with low digital literacy introduces selection bias and likely inflated adherence estimates. The excluded population is often older, has multiple comorbidities, and is precisely the group that may benefit most from adherence support. Consequently, the generalizability of these findings to the broader VTE population is limited. Future iterations of the mVTEA must address this gap, perhaps through simplified interfaces, family-assisted modules, or hybrid digital-analog models to ensure equitable access.

Conclusion

This pilot study demonstrates the feasibility and acceptability of the mVTEA to support anticoagulation management among patients with VTE or at risk of VTE and offers preliminary behavioral insights to inform the design of future trials. Larger, randomized studies with extended follow-up and objective adherence measures are required to evaluate long-term effectiveness. Addressing digital inequities will be essential to ensure that mHealth-supported anticoagulation management is accessible and beneficial to all patient groups.

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No generative artificial intelligence (AI) tools were used for manuscript generation, content creation, data analysis, interpretation of results, or figure preparation. AI-assisted tools were used solely for proofreading purposes, including checks for grammar, spelling, and typographical errors, without altering the scientific content, meaning, or conclusions of the manuscript.

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Data Availability

The datasets generated and analyzed in this study are available upon request from the corresponding author.

Authors' Contributions

ZZ, BL, and Hong Wang were involved in participant follow-up and data acquisition and were responsible for the accuracy of the data. ZZ, ZJ, YG, Hao Wang, and HZ were involved in data analysis and interpretation. YG, ZZ, and ZJ participated in the conception and design of the study. ZZ drafted the manuscript. ZZ, ZJ, and YG critically revised the manuscript for important intellectual content. ZZ performed the statistical analysis. YG and ZZ obtained funding. All authors provided input and approved the final manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1
The Chinese version of the 8-item Morisky Medication Adherence Scale (MMAS-8).
[PDF File, 209 KB - formative_v10i1e75508_app1.pdf]

Multimedia Appendix 2
The simplified Chinese version of the Beliefs about Medicines Questionnaire–Specific (BMQ-Specific).
[PDF File, 657 KB - formative_v10i1e75508_app2.pdf]

Checklist 1

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CONSORT checklist.
[DOCX File, 26 KB - formative_v10i1e75508_app3.docx]

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Abbreviations

BMQ-Specific: Beliefs about Medication Questionnaire–Specific
CONSORT: Consolidated Standards of Reporting Trials
mHealth: mobile health
MMAS-8: 8-item Morisky Medication Adherence Scale
mVTEA: mHealth app for managing VTE
NCD: necessity-concerns differential
PE: pulmonary embolism
QRST-AB: QR code–based Security Transmission algorithm using Avro and Byte Pair Encoding
VTE: venous thromboembolism

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Additive and Multiplicative Effects of Socially Stigmatized Identities Using Linear Regression to Model Effects on Self-Reported Overall Health as Reported in the All of Us Research Program: Quantitative Analysis

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Abstract

Background: Individuals with one or more socially stigmatized identities experience extensive health disparities, resulting in poorer health outcomes. However, most studies consider the effects of only individual stigmatized identities.

Objective: We aimed to quantitatively estimate the additive and multiplicative effects of stigmatized identities on self-reported overall health.

Methods: We used survey data from 387,411 participants in the All of Us Research Program, which has assembled a disease-agnostic cohort intended to reflect the US population, to statistically estimate the first- and second-order effects of 47 stigmatized identities on self-reported overall health. We used a linear model to estimate the effects of individual and pairwise stigmas on self-ratings of overall health.

Results: We began by aiming to create cohorts for all 93 stigmatized identities previously found to affect health, of which 47 (51%) could be practicably examined. We first modeled individual stigmas alone to contrast the results with those that included both individual and pairwise stigmas. After using the false discovery rate to adjust for testing multiple hypotheses in the collective model, 29 individual and 116 pairs of stigmas had statistically significant effects on self-reported overall health. All significant individual effects were negative or neutral except for skin cancer. Those with the largest negative effect on self-rated overall health were difficulty walking or climbing stairs, unemployed or unable to work, difficulty with errands, and low educational attainment. Pairs of intersecting stigmas had a mix of negative and positive incremental effects, indicating that some stigmatized identities are negative modifiers, such as depression, and other combinations are less negative than the sum of their individual negative effects, such as having difficulty with multiple types of activities of daily living. The individual stigmas with the largest number of statistically significant stigma pairs were unemployed or unable to work (14/47, 30%); depression and low income (11/47 each, 24%); and difficulty walking or climbing stairs, cognitive difficulties, obesity, and skin cancer (8/47 each, 17%).

Conclusions: Taken together, numerous pairs of stigmatized identities significantly affect self-reported overall health. While each stigmatization has both direct and indirect effects on health, the relative importance of direct and indirect effects will vary. Many of these are aligned with prior literature, and others warrant further exploration. While the large sample size of this study is a strength, we were unable to model higher-order intersectionality and encourage future research exploring this. The individual and pairwise identities with significant negative effects should be incorporated into research and clinical care by considering the multidimensionality of individuals and how that affects their overall health.

(JMIR Form Res 2026;10:e76037) doi:10.2196/76037

KEYWORDS

intersectionality; overall health; multiple marginalization; All of Us Research Program; quantitative analysis

Introduction

Individuals with socially stigmatized identities experience extensive health disparities [1,2]. This includes individuals with a race and/or ethnicity other than White; people with disabilities; lesbian, gay, bisexual, transgender, and queer populations; and people with low socioeconomic status, among many others. Individuals with multiple identities that are socially stigmatized

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report experiencing more discrimination and a lower quality of life [3,4], reflecting the connection between intersectionality and health disparities [5,6]. However, most studies of participants experiencing health disparities analyze each group in isolation. Ignoring the multifaceted nature of each individual can lead to incorrect conclusions [7]. Furthermore, the intersections of specific stigmatized identities, which we refer to subsequently as stigmatizations or stigmas, have not been quantified.

Reducing health disparities is a crucial worldwide effort, including through sustainable development goals such as the United Nations' stated goal to "leave no one behind" [8,9], which aims to reduce disparities more broadly, including reducing poverty, discrimination, and barriers that prevent accessibility. Each of these factors is inextricably intertwined, as people experiencing discrimination [10-12], poverty [13,14], and reduced access to health care [15,16] have poorer health outcomes. Furthermore, each of these effects is multipronged. Race-based discrimination often leads to lower quality health care [17,18], delayed care [19], as well as chronic stress and inflammation [20]. Taken together, racism leads to poorer mental and physical health outcomes [10,20-22]. These stigmatizations can lead to shorter life expectancies. A study using neighborhood-level data from across the United States found that social determinants of health alone accounted for 60% of premature deaths in Chicago [23]. Once disparities are well understood, interventions can be designed to address the societal and structural barriers that are responsible for them [24].

To date, concomitant quantitative estimates of additive and multiplicative effects of stigmatized identities have been lacking. A lack of the requisite sample size has precluded such an analysis, given the need for large numbers (eg, over a thousand) of simultaneous statistical estimates under a linear model. To this end, we use the large-scale and diverse participant base of the All of Us Research Program, a large disease-agnostic study funded by the National Institutes of Health that aims to reflect the US population [25,26]. Participants were recruited from the United States, through physical sites and remote enrollment, and asked to complete surveys, share biospecimens, electronic health records, and wrist-worn wearable data. The data are curated and made available to qualified researchers through the Researcher Workbench [26]. We used this resource to analyze self-reported overall health data from all 387,411 participants with available data, enabling the analysis of 47 individual and 1124 pairs of stigmatized identities that were selected from a prior study defining stigmas that affect health [27]. We statistically estimated the additive and multiplicative effects of stigmatizations on self-reported overall health in an effort to identify any synergistic pairs that should be considered in the course of health research and care. The goal of this work is to quantitatively estimate the additive and multiplicative effects of stigmatized identities on self-reported overall health.

Methods

Data Source

We used data from the All of Us Research Program in which participants completed an online consent form and several surveys. The data for this manuscript were sourced from the Basics, Overall Health, and Personal and Family History surveys, all of which are publicly available on the program's Researcher Workbench website [28].

Ethical Considerations

The original data collection for this study was approved by the All of Us Research Program's Institutional Review Board (IRB; reference number 2016-05), which governed the informed consent process. The study was reviewed by the Scripps IRB (reference number IRB-24 - 8390) and determined to be exempt from human subjects research; therefore, consent was not required for this specific work. The data were accessed between April 5, 2023, and November 15, 2024; the data were deidentified [29]. Furthermore, we followed the All of Us Research Program's Data and Statistics Dissemination Policy, which precludes disseminating information on groups of fewer than 20 participants [30]. However, poorly conducted research can cause harm beyond the direct study participants by drawing incorrect or even stigmatizing conclusions [31]. The All of Us Research Program requires all researchers accessing the Workbench to complete training on what qualifies as stigmatizing research and commit to not using program data to conduct stigmatizing research. Consequently, we have made every effort to use inclusive language that does not blame or stereotype the already stigmatized populations that are the topic of this study. Participants were offered US $25 compensation to offset the time and travel involved in participating in a blood draw, and some participants were offered additional compensation through pilots [32]; no compensation was offered for this specific study.

Analysis Methods

We explored multiple potential methods to determine which method was best suited for these data and was feasible within computational constraints. The 3 methods we explored and did not move forward with were (1) ordered logistic regression, which did not converge; (2) LASSO (least absolute shrinkage and selection operator) multinomial regression, which resulted in a high level of sparsity that was not aligned by the underlying data; and (3) ordinal regression models with an elastic net penalty, which was too computationally intense when the regularization parameters were appropriately extended. We determined that using a linear model was most suitable for this initial exploration due to computational feasibility and interpretability. We estimated the effects of individual and pairwise stigmas on overall health self-ratings. Estimates of effect sizes under the model were computed by the *lm* linear regression tool in the R (R Foundation for Statistical Computing) statistical programming language. We eliminated collinear stigmatizations so that the matrix of covariates was of full rank; the two elements that were removed were subsets of other race or ethnicity categories. Cohort creation and data analysis were completed within the Researcher Workbench using responses

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to specific surveys. Figures were created in R Studio (version 2024.09.0+375; RStudio, Inc). Our code is available in Multimedia Appendix 1 and can be copied and rerun within the All of Us Researcher Workbench.

Results

Participants

This study included 387,411 participants from the All of Us Research Program, which has assembled a disease-agnostic cohort intended to reflect the US population and, for example, includes 45% individuals with a race and/or ethnicity other than White. Participants were recruited across more than 340 physical locations and online through health care provider organizations, including several federally qualified health centers, community partners, earned media, online recruitment campaigns, and educational tours throughout the country [25,26,33]. All participants completed an online consent process that included verifying their eligibility and viewing educational videos describing aspects of the program [34]. Considerable effort was made to enable access for any interested, nonincarcerated adult in the United States, particularly those who did not have access to health systems that traditionally lead health research. Focus was placed on recruiting individuals who have been historically underrepresented in biomedical research based on their race, ethnicity, educational attainment, income, location, and other factors [26]. All participants who had completed the relevant surveys and had their responses made available through the All of Us Researcher Workbench were included in this analysis.

Stigmatized Identities

We began by aiming to create cohorts for all 93 stigmatized identities that had previously been found to affect health [27]. We created cohorts for every stigmatization within the All of Us Researcher Workbench controlled tier (version 7) [35]. Of the 93 stigmatized identities identified, 47 (51%) were included in the analyses [27] because they met the minimum sample size of 150 participants. This included 20 (43%) types of cancer; 7 (15%) disability statuses; 5 (11%) lesbian, gay, bisexual, transgender, and queer categories; 4 (9%) individuals with a race and/or ethnicity other than White; 4 (9%) socioeconomic statuses; 4 (9%) miscellaneous medical diagnoses; and 3 (6%) mental health diagnoses (see Figure 1 for the full list). Between these categories, a variety of types of stigma have been reported; for example, some people avoid others with life-threatening illnesses such as cancer due to an unwillingness to consider their own risk of cancer [36]. Ableism can be rooted in similar concerns; lack of familiarity with certain types of disabilities; and harmful, ill-informed beliefs about the value of disabled people [37]. Each category has direct and indirect effects on health [38-42], which cannot be differentiated from each other in our analysis. For example, a direct effect might be a physiological impact of a diagnosis, and an indirect effect might include the social acceptability of that diagnosis, and whether the individual experiences increased discrimination, and subsequent downstream biological consequences [10]. All participants self-described their race or ethnicity, reflecting these categories as a social construct [43] and therefore should not be equated with genetic ancestry. Some of these identities have a direct effect on health (eg, types of cancer) and an indirect effect. We intentionally selected stigmatized identities that can be both transient (eg, low income) or permanent (eg, race and ethnicity), so that their individual effects could be modeled. Individuals who reported being White and not having any of the other stigmatized identities were included in the "no stigma" group.

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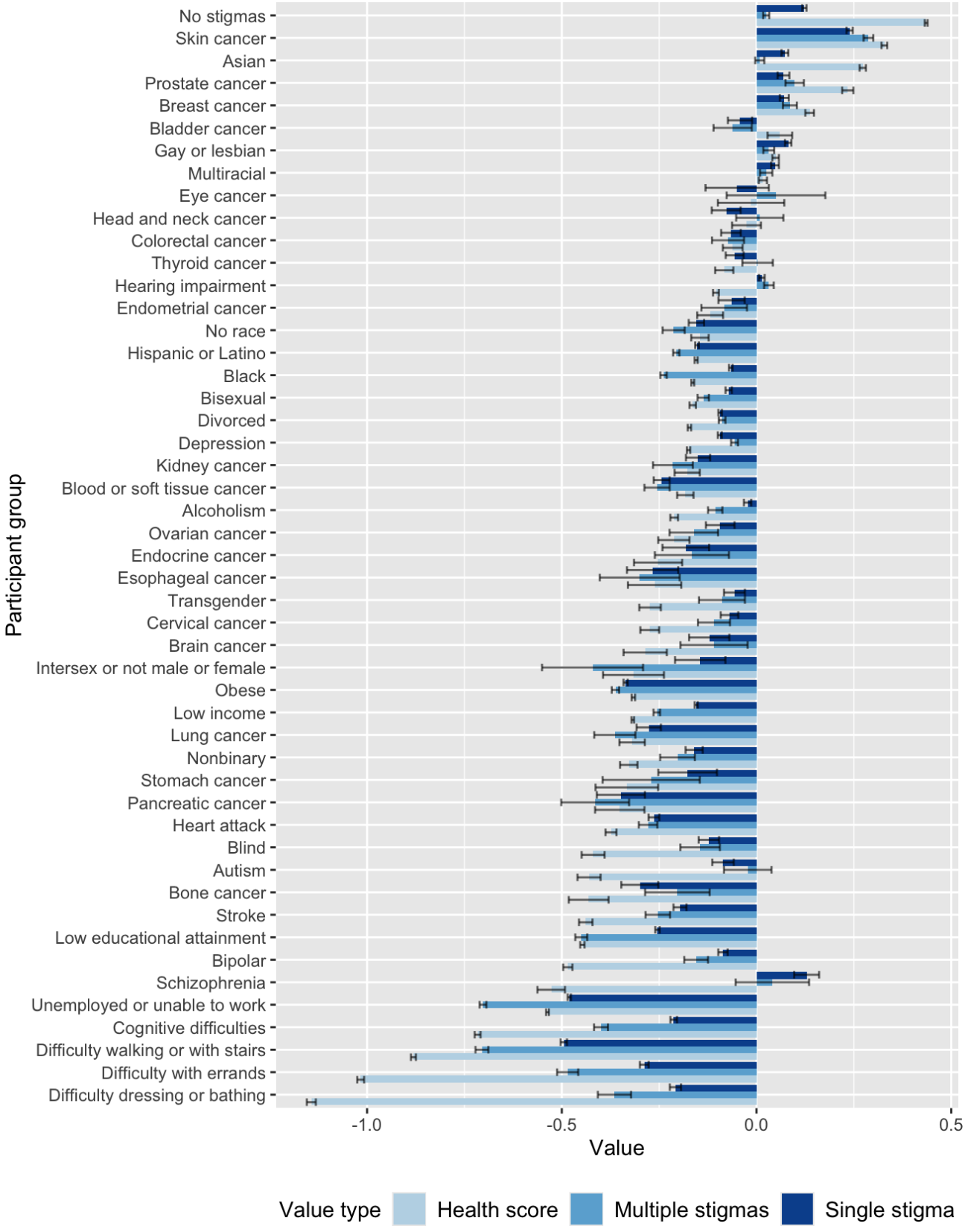
Figure 1. Values for the average overall health rating per stigma relative to the mean for the cohort as a whole (light blue), the estimated effect size of each stigma in the model with individual and pairwise effects (medium blue), and their estimated effect size in the model with only individual effects (dark blue). They are ordered from highest average overall health rating (top) to lowest (bottom). A value of "0" represents the average overall health value across the entire cohort, negative values represent a lower than average value, and positive values represent a higher than average value. A value of "1" represents 1 unit on the survey response scale (eg, a change from "good" to "fair" would be "–1"). The sample sizes for each individual stigmatized identity are included in Figure S3 in Multimedia Appendix 2.



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Data Selection

We compared the All of Us Research Program participants' self-reported overall health data [44]. We started by examining responses to questions regarding overall health, physical health, mental health, and quality of life, and found an average correlation of 0.61 between responses for a given individual (Figure S1 in Multimedia Appendix 2). For simplicity and to preserve statistical power, we constrained further analysis to overall health scores. We examined the average self-reported overall health within individual and pairs of stigmatizations. Overall health self-ratings were responses to the question "In general, would you say your overall health is: Excellent, Very Good, Good, Fair, Poor" that were converted to integers.

Single Stigma and Independent Results

Different types of difficulties with activities of daily living had the lowest average overall health self-ratings, followed by low educational attainment (Figure 1, light blue, and Figure S2 in Multimedia Appendix 2). Asian, multiracial, and gay and/or lesbian individuals as well as those with breast, bladder, or prostate cancer had higher self-ratings than the average for the cohort as a whole. Individuals without stigmatized identities had the highest self-reported overall health. Due to relatively large sample sizes (median 3756; Figure S3 in Multimedia Appendix 2), most individual stigmatizations had mutually exclusive SEs of the means.

Single Stigmatizations and Individual and Collective Results

Next, we created a model to simultaneously estimate only the effect of individual stigmatizations (Figure 1, dark blue). Then, we created a model to simultaneously estimate the effect size of all single and pairwise stigmatizations (Figure 1, medium blue). There are notable differences between the two models; for example, difficulties with activities of daily living, low educational attainment, being intersex, being Black, and being Hispanic and/or Latino have stronger negative effects in the model that estimates the independent contribution of each stigmatization.

Single and Pairwise Stigmatizations and Collective Results

When modeling both single and pairwise stigmatizations, the effect sizes of pairwise stigmatizations with individual effect sizes that were in the same direction and of relatively large magnitudes tended to have an opposite direction pairwise effect; this indicates the combined effect was less than the sum of the 2 individual effects. This is visualized with an enrichment of blue in the off-diagonal elements in the lower left of Figure 2 and an enrichment of red in the upper right, because the stigmatizations are ordered from the largest negative individual effect (left bottom) to largest positive individual effect (right top).

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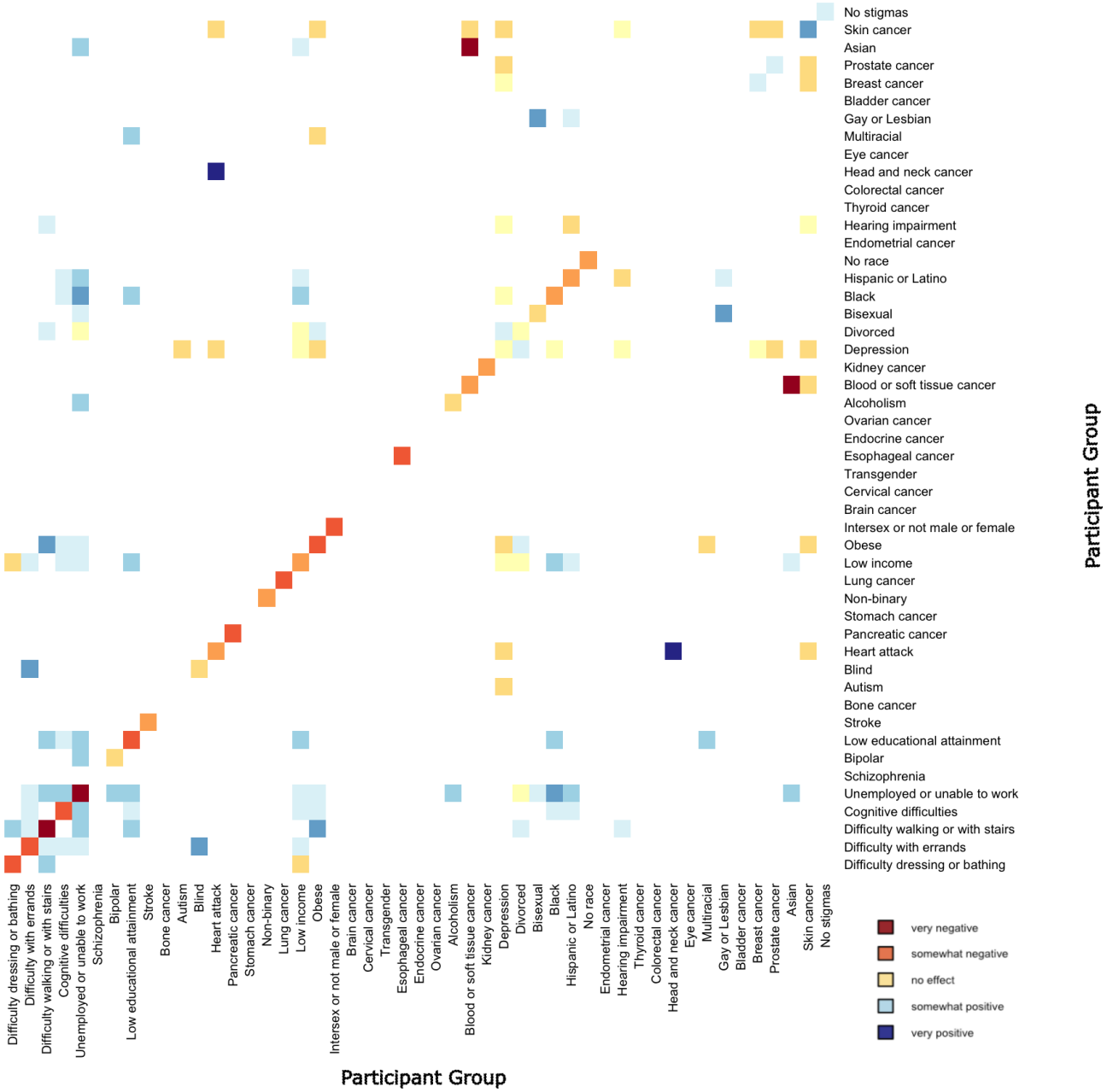
Figure 2. Results of the model of additive and multiplicative effects of socially stigmatized identities on self-reported overall health. This heat map shows the model estimates of the effect of individual (lower left to upper right diagonal) and pairwise (all other) stigmatized identities on self-reported overall health, sorted in the same order as in Figure 1. Each pair of labels meets at a small rectangle that is colored according to the effect of that pair of labels (or in the case that the two labels are the same, the single stigmatized identity). Red represents a negative effect on self-reported overall health, pale yellow represents a neutral effect, blue represents a positive effect, and white indicates that there were not enough data or the effect was not statistically significant. The number of participants in each group is mentioned in Multimedia Appendix 1.



In the model that included multiplicative effects, out of 47 individual stigmatizations, 29 (62%) had statistically significant effect sizes, as did the group that declined to report their race or ethnicity (the largest effect sizes are listed in Table 1). When examining statistical significance, we used false discovery rate to adjust for testing multiple hypotheses [45] and considered *P* values less than .05 as statistically significant; note that exact *P* values are available in Multimedia Appendix 1. The 19 stigmatized identities that did not have statistically significant effects had a small effect size and/or a small sample size. Except for skin cancer, all significant individual effects were negative. Out of 1124 possible pairwise stigmas, 758 (67%) had sufficient sample sizes to estimate an effect size (with a requirement of at least 20 based on the All of Us Research Program policies [30]), and 116 (10%) had statistically significant effects. The individual stigmas with the largest number of statistically significant stigma pairs were unemployed or unable to work (14/47, 30%); depression and low income (11/47 each, 24%); and difficulty walking or climbing stairs, cognitive difficulties, obesity, and skin cancer (8/47 each, 17%).

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Table . Individual stigmatized identities with the largest effects. This table lists the individual stigmatized identities with an effect size whose absolute value is greater than 0.15, ordered from the largest negative effect to the largest positive effect. This includes 6 cancer types; 5 disability statuses; 3 race or ethnicity categories; 2 lesbian, gay, bisexual, transgender, queer, and nonbinary identities; 2 socioeconomic statuses; 1 mental health diagnosis; and 3 miscellaneous health statuses.

Stigmatized identity	Estimate (SE)	Adjusted *P* value
Difficulty walking or with stairs	–0.705 (0.017)	<.001
Unemployed or unable to work	–0.702 (0.009)	<.001
Difficulty with errands	–0.485 (0.027)	<.001
Low educational attainment	–0.450 (0.015)	<.001
Intersex or not male or female	–0.421 (0.130)	.012
Pancreatic cancer	–0.414 (0.087)	<.001
Cognitive difficulties	–0.399 (0.018)	<.001
Difficulty dressing or bathing	–0.365 (0.043)	<.001
Lung cancer	–0.364 (0.053)	<.001
Obese	–0.362 (0.010)	<.001
Esophageal cancer	–0.300 (0.103)	.031
Heart attack	–0.279 (0.024)	<.001
Low income	–0.256 (0.008)	<.001
Blood or soft tissue cancer	–0.255 (0.032)	<.001
Stroke	–0.254 (0.031)	<.001
Black	–0.239 (0.008)	<.001
Kidney cancer	–0.215 (0.051)	<.001
No race reported	–0.213 (0.028)	<.001
Hispanic	–0.206 (0.008)	<.001
Nonbinary	–0.203 (0.045)	<.001
Bipolar	–0.155 (0.030)	<.001
Skin cancer	0.287 (0.012)	<.001

The pair with the largest negative estimated effect was Asian and blood or soft tissue cancer. Most other pairs with negative effects were cancers, combined with other types of cancer or heart attack, along with autism and depression, and prostate cancer and depression. The pairs with the largest positive estimated effect sizes were head and neck cancer and heart attack, as well as blindness and difficulty with errands. In pairs with a positive effect, most individual stigmas had negative effect sizes, indicating that the combined effect was less negative than the sum of the two individual effects.

Discussion

Findings in Context

These analyses demonstrated statistically significant effects of 29 individual and 116 pairs of stigmatized identities on an individual's rating of their overall health. The analyses revealed a wide variety of unknown causes to be further studied and pairs of intersecting variables that should be included within the analyses of specific diseases to ensure that subgroup effects are accurately characterized. This information adds to the existing literature describing multiple marginalization contributing to health disparities, that is, that having multiple stigmatized identities is often worse for one's health than having one stigmatized identity [2,46,47]. One major contributor to these outcomes is discrimination—both in general, which contributes to poorer health outcomes [3,4], and in health care specifically, where it can decrease the quality of care [11,48]. Furthermore, these data contribute to the literature that structural racism contributes to health inequities in the United States [49].

Each stigmatization has both direct and indirect effects on health. For example, a cancer diagnosis can directly affect overall health survey responses by affecting how highly an individual rates components such as their overall health and quality of life [50,51]; an indirect effect on overall health could result from reduced social support, which has been observed after cancer diagnosis [52,53]. The direct and indirect effects could not be disentangled in this study, and the relative importance of direct and indirect effects will vary; for example, a stigmatized identity that is based on a health condition will usually have a larger proportion of direct effects. The large negative estimated effect of low educational attainment is striking and indicates a need to redouble efforts to improve health literacy within this population [54]; for example, additional efforts could be made to improve access to safe, culturally competent health care (especially preventative care);

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and for health care providers to ensure their communications are accessible to their patients. In our analyses, depression alone does not substantially impact overall health in a negative or positive direction; however, it produces a synergistic negative effect with several other stigmatizations, including types of cancer; this should be considered in the clinical management of their co-occurrence. Furthermore, ableism in health care can result in discrimination during health care visits [55,56], underrepresentation of disabled individuals in health care professions [57,58], and inadequate access to health care [56,59,60].

Cultural components of self-rated overall health should be explored further to understand how they affect health care. For example, previous work has noted higher overall health self-ratings from Asian participants compared to White participants in the United States with similar characteristics [61], which correlates with the higher overall health scores observed here (Figure 1).

This study has several limitations. First, the data were collected from participants only in the United States. Second, only individual and pairwise stigmatization were considered. There are likely higher-order effects that could not be analyzed while maintaining adequate statistical power. We recommend that future studies endeavor to explore higher-order effects and consider simplifying some groups, such as collapsing cancer types into 1 variable with and without cancer. Third, we assumed a linear relationship between the stigmas and the reported overall health and used linear regression, which assumes a continuous variable, whereas we used integers within a limited range. Fourth, individuals who may be clinically evaluated to have equivalent overall health may self-report different ratings [62]. Fifth, there are cultural differences and other population-specific biases with self-reported health data [62]. Sixth, we were unable to eliminate confounders that we did not include in the model; however, we mitigated this risk by including as many relevant confounders as practicable and using the most inclusive cohort available. Seventh, we did not use an analytical technique that was specifically designed to measure intersectionality, such as multilevel analysis of individual heterogeneity and discriminatory accuracy or chi-squared automated interaction detector [63]. We encourage the exploration of these techniques in future research. Notably, although divorced was included as a stigmatized status, separated and single parent were not listed in the reference we drew stigmatized identities from, and including them may strengthen the analysis; a similar argument can be made for cisgender women. Finally, individuals may evaluate their health relative to their expectations, their lived experience, and those around them, all of which can impact health. However, in cases where an objective measure would report higher overall health than a self-reported measure, the difference remained significant, as perception of one's health can affect health outcomes [64]. We recommend that future research includes cisgender women as a stigmatized identity, given the ample documentation of the health impacts of stigma this group faces [65-68].

This work also has limitations that apply to many efforts to quantify intersectionality [46] and self-reported data. First, it was limited to studying the stigmatizations for which there were sufficient data available, and half of the stigmatized statuses could not be included [27]. Second, the participant's specific status was based on one point in time. The statuses may change over time, such as mental health diagnoses, disability statuses, and employment status. Finally, the encoding of all stigmatizations as binary variables, even those for which a larger range of options could be used (eg, educational attainment and income). These limitations can be addressed in future research, for example, by studying smaller subsets of intersectionality in greater depth and aspects of health that vary between stigmatizations (eg, physical vs mental health), and other causes of health disparities such as discrimination, access to health insurance, and access to care providers that share their race or ethnicity and have cultural competence.

Conclusions

Taken together, numerous pairs of stigmatized identities significantly affect self-reported overall health and therefore should be considered in research and clinical care. We recommend that both researchers and health care providers consider observed and potentially unobserved intersectionality when evaluating factors that affect one's overall health. Policymakers may consider strongly suggesting or even mandating training on the impacts of intersectionality and the collection of important variables in the course of research and health care. Furthermore, data on impactful socially stigmatized identities should be collected to help researchers and clinicians better understand their participants and patients.

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Data Availability

All data are available to registered researchers in the All of Us Research Program Researcher Workbench. Aggregate data are available in Multimedia Appendix 1.

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Authors' Contributions

KL and JMV conceptualized the study and had access to all data to verify results. KL, RV, and JMV performed data curation, refined the methodology, conducted formal analysis, and reviewed and edited the manuscript. JMV acquired funding, wrote the original draft, and provided supervision.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Analytical source code, aggregate data, and *P* values for all statistical tests.
[ZIP File, 95 KB - formative_v10i1e76037_app1.zip]

Multimedia Appendix 2
Other supplemental figures.
[DOCX File, 767 KB - formative_v10i1e76037_app2.docx]

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Abbreviations

IRB: Institutional Review Board
LASSO: least absolute shrinkage and selection operator

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Orchestrating the Development of a Sustainable Network IT Solution for a Research Network: Qualitative Participatory Multimethod Design

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Abstract

Background: Practice-based research networks (PBRNs) rely on sustainable and interoperable IT infrastructures to support coordination, data management, and long-term collaboration across geographically distributed primary care practices. Large federated initiatives, such as the German DESAM-ForNet (Initiative of German Practice-Based Research Networks) program, face substantial sociotechnical challenges, as diverse user groups, heterogeneous local systems, and multiple governance levels must align around shared digital solutions.

Objective: The aim of this study was to design and evaluate a participatory, consensus-driven process for developing a sustainable and interoperable IT solution that supports the coordination of multiple regional PBRNs, and to identify the sociotechnical factors that influence how such a process unfolds.

Methods: A qualitative participatory multimethod design combined an iterative consensus-based IT development process in a central working group, interdisciplinary domain-driven design workshops (N=40 stakeholders from 6 PBRNs), and qualitative content analysis of internal documents (2020 - 2025). Members of the IT working group were nominated by networks based on IT responsibility and strategic involvement; workshop participants represented general practitioners, study nurses, researchers, and coordinators. Documents (meeting minutes, workshop artifacts, and decision logs) were coded inductively by 2 authors to trace sociotechnical dynamics and decision trajectories.

Results: The analysis revealed pronounced differences in IT ambitions, resources, and established practices across the 6 PBRNs (ranging from 2 to 90 person-months), which resulted in divergent expectations and uneven readiness for joint development. This heterogeneity—spanning objectives from simple REDCap (Research Electronic Data Capture; Vanderbilt University) databases to comprehensive digitization strategies—necessitated network-specific bounded contexts within a federated architecture. Through iterative development, stakeholders reached consensus on 6 core use cases (base data management, screening or recruitment processes, study or event participation tracking, management of event participation, accreditation procedures, and standardized communication or data exchange) and 2 national proofs-of-concept: quarterly key performance indicator reporting and pseudonymized practice queries based on a shared core dataset. This collaborative process culminated in a 3-tier practice relationship management infrastructure that integrates local autonomy with central metadata management and connectors to the Medical Informatics Initiative and REDCap, and was endorsed by the steering committee as a scalable compromise balancing interoperability and data sovereignty.

Conclusions: The study shows that developing a national, interoperable IT infrastructure for PBRNs depends as much on social and organizational alignment as it does on technical solutions. Iterative participatory collaboration, transparent governance, and early stakeholder engagement were essential for building shared understanding and trust. Strengthening these relational and organizational elements will be crucial for sustaining future implementation efforts and fully realizing the potential of federated data infrastructures in primary care research.

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KEYWORDS

practice-based research networks; PBRN; health information technology; health informatics; screening; primary health care; stakeholder engagement; interoperability; data sharing; health services research

Introduction

Practice-based research networks (PBRNs) are collaborative enterprises that bring together primary care practitioners and researchers to address questions directly arising from real-world clinical practice [1]. Originating in the late 19th century, PBRNs have evolved into structured research entities that facilitate systematic data collection, conduct observational studies, and support innovation within general practice [2-6]. International experience has demonstrated the effectiveness of PBRNs in generating evidence-based knowledge, improving care quality, and engaging diverse populations [1,7].

A critical enabler of these networks is a robust IT infrastructure (ITI) [1,7], which supports data integration, communication, and coordination across practices and institutions [8]. While electronic health records (EHRs) in general practices serve primarily clinical functions, the ITI of a PBRN provides the broader technical framework required for research collaboration. This includes data management, harmonization, secure exchange, and support for network-wide activities, such as study coordination or practice engagement [9,10].

Studies in clinical settings have shown that the usability of EHR systems is strongly linked to outcomes such as professional satisfaction, workflow efficiency, and data quality [11,12]. While there is extensive literature on EHR usability in hospital and clinical care settings [13-17], much less is known about the design, implementation, and usability of ITIs that support research networks like PBRNs. Emerging evidence suggests that PBRN ITIs require complex local adaptations [18], that usability perceptions vary among different stakeholder roles [19,20], and that participatory approaches are essential to ensure broad acceptance [20]. However, engaging individuals through these participatory and equitable processes may result in variations in both the time required and the outcomes achieved in reaching organizational goals [21].

In Germany, the nationwide DESAM-ForNet initiative [22] represents a major effort to establish PBRNs across all federal states. Between 2020 and 2025, the Federal Ministry of Education and Research funded 6 independent networks—BayForNet, FoPraNet-BW, HAFO.NRW, RaPHaeL, RESPoNsE, and SaxoForN—comprising 27 university departments of general practice and primary care [23]. These networks are forging long-term partnerships with outpatient care providers and are supported by 11 additional, nonfunded associated partners, expanding the initiative's national reach (Figure 1).

Figure 1. University coordination sites of the general practitioner practices research network.

To promote coordination and integration at the national level, the DESAM-ForNet initiative established a central National Coordination Office (NCO) in 2020. This office plays a key role in enabling collaboration across networks, aligning strategic goals, and fostering knowledge exchange at administrative, operational, and scientific levels. A steering group with representatives from all networks ensures participatory governance, balancing institutional autonomy with shared

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decision-making. Within this governance framework, specialized working groups, such as the IT working group (WG IT), support targeted collaboration on essential components of the initiative.

Although each PBRN has developed independently with its own partners, standards, and pilot studies, the networks have increasingly converged around a shared objective: to create a sustainable, interoperable research infrastructure for general practice. This includes both human and technical components, training programs to prepare general practitioners for research engagement, and digital systems that enable secure data sharing and efficient coordination. A central element of this development is the creation of a practice relationship management (PRM) system, conceptually inspired by customer relationship management (CRM) models, which aims to structure and support long-term partnerships between practices and academic institutions [23].

Developing this infrastructure presents not only technical but also organizational and social challenges [24]. A federated IT system must accommodate a wide range of user needs, from IT specialists and researchers to physicians and administrative staff, each with distinct workflows, expectations, and levels of digital maturity. Prior research on the implementation of health IT systems has consistently shown that sociotechnical factors, such as role ambiguity, communication breakdowns, and insufficient user involvement, can significantly hinder progress [7,25-28]. Governance gaps, unclear strategic direction, and a lack of coordination mechanisms are further risks that may lead to fragmentation, inefficiency, and ultimately, low user acceptance.

Addressing these challenges requires participatory processes [29], early stakeholder engagement, and a shared vision [7,21,25] that aligns technical development with clinical and research priorities. Building mutual trust [30], establishing a common language, and ensuring transparent decision-making are essential steps in navigating the complexities of such a large-scale transformation.

This study, therefore, examines the sociotechnical dynamics underpinning the development of a unified ITI within DESAM-ForNet to identify the factors that facilitate or hinder progress. By doing so, it provides evidence-based insights to improve participatory development processes and enhance stakeholder coordination in large, federated primary care research networks.

Methods

Study Design

This study used a qualitative participatory multimethod design combining (1) an iterative consensus-based IT development process, (2) participatory interdisciplinary workshops grounded in domain-driven design (DDD), and (3) a structured qualitative document analysis [7,24,29]. The aim was to collaboratively design and analyze a federated ITI to support the national coordination of 6 regional PBRNs within the DESAM-ForNet initiative in Germany.

Sampling and Participants

Members of the central WG IT were nominated by each of the 6 PBRNs and the NCO to ensure representation of all relevant perspectives (IT staff, project leads, domain experts, and network coordinators). Selection criteria were (1) formal responsibility for IT or data management in the respective network, (2) involvement in strategic planning of network activities, and (3) willingness to participate in regular virtual meetings over the full project period. Workshop participants were purposively recruited via the network coordinators to cover the main professional groups involved in PBRN work (general practitioners, study nurses, clinicians, IT developers, research staff, and administrative coordinators). Each network was asked to nominate individuals with practical experience in practice-based research and familiarity with existing local IT solutions. This resulted in a sample of 40 multiprofessional stakeholders across all 6 networks.

Iterative IT Development Process (WG IT)

The WG IT was established in June 2020 to coordinate and harmonize ITI planning across 6 heterogeneous research networks. It consisted of at least 1 IT lead and 1 scientific lead per network plus representatives from the NCO. The group met in structured monthly virtual meetings (60 - 90 min) between 2020 and 2025.

The process followed agile principles and comprised repeated cycles of: (1) defining the problem domain and system boundaries, (2) formulating an abstract vision and core requirements, (3) creating and reprioritizing a backlog of tasks and goals, and (4) conducting cycles of analysis, technical design, implementation, and structured review. Each meeting used a standardized agenda (status updates, backlog review, decisions, and next steps) and concluded with explicit documentation of decisions and open issues. Consensus was sought through moderated discussion; if necessary, decisions were postponed to the next meeting after written feedback from all networks.

Task and backlog management were conducted within the Nextcloud environment using project management software with version control and change tracking. Minutes, decision logs, and design artifacts were stored in shared, access-restricted folders with date-stamped versions. Figure 2 illustrates the iterative development cycle, the associated meetings, the interdisciplinary engagement, and the core project phases that occurred among the 38 university locations between 2020 and 2025.

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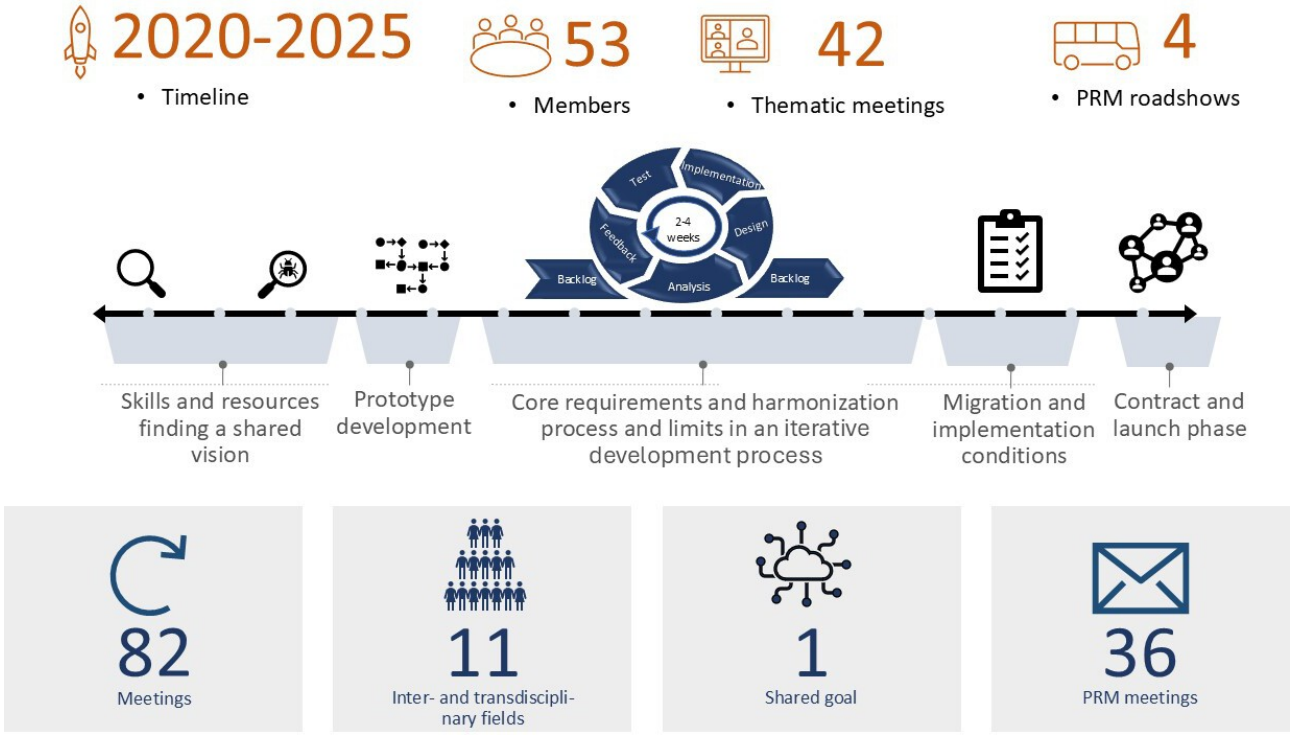
Figure 2. IT working group (WG IT) timeline, process, and sources of data material for analysis. PRM: practice relationship management.



Interdisciplinary Participatory Workshops

Workshops were organized to translate the high-level vision into domain models and concrete use cases. Over a period of 18 months, 6 major workshops (ranging from half-day to full-day) were conducted, alternating between virtual and in-person formats. Each workshop followed a predefined structure: introduction and goal setting, collaborative modeling in mixed-professional groups, plenary consolidation, and agreement on next steps. Two moderators (a project coordinator and an IT facilitator) guided the sessions using structured facilitation methods (eg, brainwriting, small-group work, and dot-voting for prioritization).

The DDD approach was applied to identify bounded contexts, ubiquitous language, and core domains. Participants co-created domain models, user journeys, and use-case descriptions on collaborative whiteboards (eg, Miro) and physical flipcharts during on-site meetings. Consensus on core requirements and use cases was achieved through iterative feedback loops: preliminary models were circulated after each workshop, commented on in writing, and revised in subsequent sessions until no substantial objections remained.

Data Generation and Documentation

Multiple data sources were generated during the iterative process as follows: (1) minutes and decision protocols from monthly WG IT meetings; (2) workshop agendas, participant lists, and field notes; (3) DDD artifacts, including domain models, user journey maps, and use case descriptions (exported from Miro as PDFs); (4) backlog entries, user stories, and issue tickets from the project management tools and GitLab; and (5) internal resolutions, steering board decisions, grant notices, and network roadshow materials.

All documents were stored in a central Nextcloud instance with role-based access control. Files were named according to a standard convention (date_network_documenttype) and versioned either through the built-in versioning mechanism or explicit version numbers in the file name. For the qualitative analysis, documents from June 2020 to December 2025 were exported, deduplicated, and organized into an analysis corpus by document type and time period.

Qualitative Document Analysis

Two authors (GA and SP) conducted a qualitative content analysis of the compiled documents. In the first open coding phase, both independently coded a shared subset of documents to identify themes related to design rationale, stakeholder priorities, coordination challenges, and emerging IT concepts. Codes were developed inductively and documented in a shared codebook (Microsoft Excel), which included code labels, definitions, and example passages.

In the second phase, the codebook was refined through discussion and applied to the full corpus by 1 coder, while the second coder reviewed coding summaries and sample documents for consistency. Discrepancies were resolved in consensus meetings, and the codebook was iteratively adapted. In a final phase, codes were grouped into higher-level categories (eg, “heterogeneity of network goals,” “trust and governance,” and “federated architecture decisions”) and mapped against the temporal sequence of meetings and workshops to reconstruct key decision points and development trajectories. No data were missing from the analysis corpus.

Tools and Technical Environment

Core collaboration and documentation were supported by a central Nextcloud installation (including shared drives, calendar, and task management modules), a project management tool for

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backlog and issue tracking, GitLab for software development and version control, and Miro for collaborative whiteboarding. For the qualitative content analysis, Microsoft Excel and document management software were used to manage the corpus and codebook. Where relevant, version numbers and configurations of the tools were documented in the project's internal technical documentation, and all major changes to the tool landscape were recorded in WG IT minutes.

Ethical Considerations

All internally accessible, anonymized documents from the working group were analyzed with the explicit approval of all WG IT members for research purposes. Networks requested to provide supplementary information were informed about the rationale and scope of the investigation. No formal ethics committee approval was required, as the study involved the analysis of deidentified internal project documents and did not include human participant research as defined by national regulations. All data protection measures adhered to the General Data Protection Regulation and relevant ethical guidelines for online and collaborative data handling, including role-based access controls, pseudonymization of any identifiable content, and secure storage within the project infrastructure.

Results

Network-Specific IT Objectives and Bounded Contexts

An initial inventory of IT objectives and available resources across the 6 research networks and the NCO showed marked heterogeneity in ambitions, existing systems, and allocated person-months. Each PBRN pursued its own IT solution and objectives, ranging from comprehensive department-wide platforms to more limited database tools, and had to navigate integration with local systems, established organizational practices, and regulatory requirements (Table 1). These differences motivated the definition of network-specific bounded contexts within an overall federated architecture.

Table . Overview of IT objectives and resources by network.

Network partner	IT objective	Available resources
NCO[a]	Creating a meta database to collect and provide general information about the regional networks	30 PM[b] IT, €200,000 (US $231,420) tender
BayFoNet	Using a REDCap[c] database (Vanderbilt University) to organize practices and studies, providing this information to a website	6 PM IT
HAFO-NRW-GRP	Aiming to develop a seamless data collection instrument (FallAkte Plus) for use in the established German care sector IT infrastructure.	2 PM IT and tender money for support
FoPraNet-BW	Building comprehensive software tools to digitize all processes in the departments and GP[d] offices (GP practice management or PRM[e] as well as study planning, monitoring, and execution (CSTM[f] or PSTM[g])	90 PM IT
Raphael	Not provided	Not specified
Response	No specific IT goal defined at project start; general support and infrastructure integration	Tender money for support
SaxoForN	Building a CRM[h]-like database to organize network processes (communication, events, and studies)	30 PM IT

[a]NCO: National Coordination Office.
[b]PM: person months.
[c]REDCap: Research Electronic Data Capture.
[d]GP: general practitioner.
[e]PRM: practice relationship management.
[f]CSTM: Clinical Study/Trial Management
[g]PSTM: Practice Study/Trial Management
[h]CRM: customer relationship management.

Harmonization Core Requirements Through the Meta-Database Initiative

The DESAM-ForNet call for tenders for a meta-database created a formal driver to harmonize requirements across networks. The grant specification required compatibility with the Medical Informatics Initiative (MII) core database and adherence to interoperability standards, prompting the WG IT to agree on a common inventory of existing structures before defining a shared core dataset.

Through structured discussions and document reviews, a set of requirements emerged as common to all networks: standardized data management for practices and professionals, support for

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screening and recruitment processes, accreditation management, and enhanced communication and data exchange. However, the requirements provided by the networks were documented in markedly different formats and levels of abstraction. Some sites submitted structured Microsoft Word or Excel catalogs with functional and nonfunctional requirements or user stories, while others contributed only single high-level needs (eg, a generic interface requirement). In 1 case, requirements were only implicitly represented in an existing PRM prototype. These differences in format, detail, and terminology, together with missing or divergent prioritization schemes, meant that seemingly similar requirements could not be assumed to reflect a shared understanding and required additional clarification. Harmonization was impeded by these heterogeneous documentation practices and varying technical expertise, which led to differing levels of detail and prioritization across networks.

Common On-Site Use Cases

Qualitative analysis revealed social challenges alongside technical heterogeneity: network leads' requirements stagnated without operational input, requiring work-level engagement for progress. Despite the heterogeneity, the participatory workshops and document analysis identified 6 core on-site use cases as relevant for all locations: base data management for practices, general practitioners, and study nurses; management of screening and recruitment processes; tracking of study participation; management of event participation; accreditation procedures; and standardized communication and data exchange. The technical implementation of these use cases was explicitly designed to strengthen relationships between sites, standardize processes, and enable cooperation; interfaces to REDCap were included to allow flexible data collection and storage.

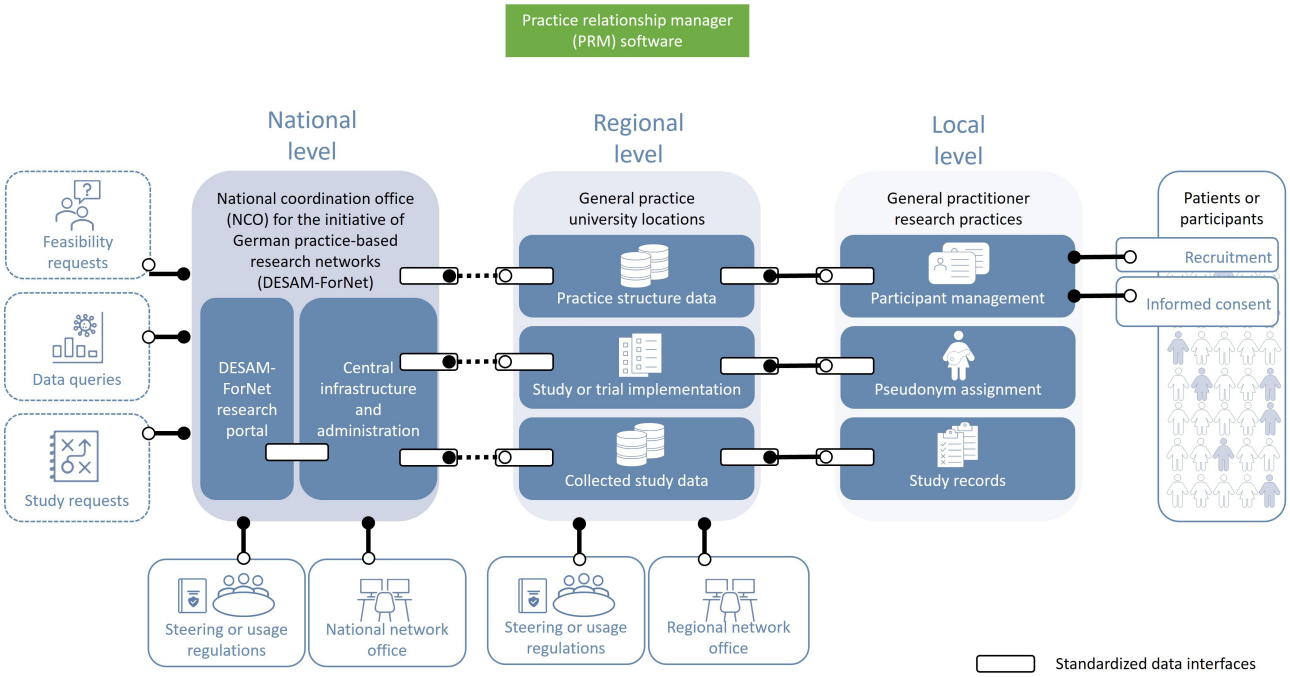
Initial requirements submitted by network leads showed limited evolution between their first compilation and the meta-database tender discussions. Substantial progress and alignment only occurred after shifting focus to small-group workshops with work-level staff (researchers, study nurses, and coordinators), where concrete processes were jointly modeled and requirements were refined.

At the national level, 2 cross-network use cases were agreed upon as initial proofs of concept. First, a quarterly key performance indicator (KPI) report summarizing, for example, the number of associated practices and ongoing studies per network. Second, a national practice query based on a consensual core dataset describing structural practice characteristics and qualifications, enabling pseudonymized partner search and characterization of the national PBRN.

Developing a Harmonized ITI

The process of aligning network-specific objectives and requirements highlighted the need for a common IT foundation, particularly for metadata management. WG IT meeting minutes from October 2020 document the proposal of a 3-tier federal infrastructure model (local network systems → central PRM metadata layer → national MII interfaces), which workshop participants endorsed as a pragmatic solution balancing local flexibility with national coordination needs (Figure 3).

Figure 3. The general 3-tier infrastructure of practice relationship management (PRM). NCO: National Coordination Office.



The initial requirements workshop in August 2020 also identified the developmental stages and specific objectives of each research network, resulting in diverse content requirements and IT concepts. Notably, disparities in resources and planned implementations were observed, with some networks compensating for limited resources through increased collaboration.

A significant advantage was the data-oriented nature of the pilot studies, which facilitated the initial harmonization of data structures. Supraregional record linkage was planned as a subsequent step, with pseudonymization and standardized

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interfaces identified as prerequisites for comprehensive data exchange. Privacy and ethics emerged as critical issues across all networks and were collectively addressed through DESAM-ForNet.

In January 2021, workshops aimed at determining the precise requirements of the general practitioner research network sites concluded that a PRM tool, based on CRM software, would be the most suitable solution. The definition of a common minimum core data set, negotiated in parallel sessions, provided a foundational basis for the meta-database.

From an interoperability perspective, the PRM software was designed with connectors to facilitate future integration of data (Figure 3). For example, the software updates general practice information using data from the German Kassenärztliche Bundesvereinigung, the governing body of the 17 statutory health insurance physician associations in Germany. It can also integrate an external study manager for various study designs and surveys with REDCap servers [10]. Discussions also explored the establishment of a trust center via DESAM-ForNet, although this was not realized within the project timeframe.

A key requirement was that the PRM be user-friendly and accessible to IT laypersons, supporting simultaneous multisite access and intuitive operation. The system was designed to accommodate a generic data-sharing concept, including standardized consent and information documents (broad consent), allowing for resource-efficient updates and adaptations. Data sovereignty remains with each respective network, while the user interface and registration processes are harmonized and integrated into the overall roadmap. The platform enables communication within and between networks, with general practitioners, and with DESAM-ForNet.

Vision Alignment With the Steering Committee

Based on the iterative consensus-building process, the WG IT submitted a vision to the steering committee that included (1) a simplified version of the FoPraNet-BW infrastructure as a model for national implementation, (2) financing through the tender for the development of a meta-database, and (3) incorporation of national use cases to ensure broad applicability and stakeholder buy-in.

The steering committee endorsed this vision, thereby formally anchoring decentralized data storage combined with centralized infrastructure management as the guiding principle for future development.

Implementation and Agreement on Core Processes

The initial implementation of the PRM focused on the administration of general practitioner research practices, including the storage of addresses, documentation of recruitment procedures, and tracking of recruitment status. The tool supports the identification of research teams at each general practice, documentation of training and certification, and the management of study invitations and participation.

In 2022, the 6 general practice networks reached an agreement on the storage and documentation of recruitment procedures, the use of 3 core questionnaires for all recruited general practitioners, event management, data exchange for reporting, and documentation of study participation. These standardized processes and questionnaires served as the starting point for the development of the IT solution, ensuring a harmonized and scalable approach across all participating networks. Finally, all implementation steps and agreements on core processes are summarized in Table 2.

Table . Summary of national use cases and practice relationship management (PRM) functions.

Use case or function	Description or outcome
Key performance indicator report	Quarterly reporting of network and study metrics
National practice query	Searchable, pseudonymized core dataset for GP[a] recruitment
PRM administration	Management of GP data, recruitment, training, and study tracking
Communication and data exchange	Standardized messaging within or between networks and GPs
Data sharing and consent	Generic, standardized consent processes and broad consent support
Interoperability	Connectors for ePA[b], MII[c] integration, and future scalability

[a]GP: general practitioner.

[b]ePA: electronic patient record.

[c]MII: Medical Informatics Initiative.

Discussion

Principal Findings

The considerable heterogeneity in IT expertise, occupation, resources, and independently funded strategic objectives among the 6 PBRNs and the NCO posed a significant challenge. This diversity underscores the sociotechnical complexity highlighted in the literature, particularly concerning the development of a nationwide interoperable ITI for primary care research. The findings of this study further confirm these complexities, illustrating the intricate interplay between various stakeholders and their differing capabilities [24-27,31]. Nevertheless, the WG IT succeeded in developing a common vision based on decentralized data storage and centralized infrastructure management. This vision was realized through an IT project that was submitted and financed in the aftermath. The project aimed to facilitate continuous moderate cooperation in the IT area as an ongoing process.

The iterative application of the DDD approach [7] facilitated the identification and harmonization of core requirements unique

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to a federated, interoperable ITI for primary care research in Germany. This process led to the development of the PRM tool and the definition of national use cases, including KPI reporting and national practice queries. These use cases not only demonstrate the technical feasibility of a federated data infrastructure but also serve as trust-building mechanisms among stakeholders.

The findings align with previous research [24,27,32], highlighting the critical role of social processes—specifically proximity, mediation, and trust—in bridging organizational and cultural differences while fostering receptiveness to new IT solutions. Although the initial lack of a comprehensive IT strategy posed challenges, these were partially addressed through continuous stakeholder engagement, iterative consensus-building, and the establishment of governance structures that effectively balanced local autonomy with national coordination.

The chosen methodology, characterized by intensive communication and regular interaction, facilitated a user-centered development process aligned with Evans' DDD [7]. The PRM solution effectively maps everyday workflows, offering a user-friendly, open, and interoperable platform tailored to the actual needs of its users. Additionally, the application of CRM-based tools to enhance efficiency in managing PBRN sites is supported by similar improvements observed in other health care domains.

One key challenge was that all grant-funded pilot studies remained network-specific and did not provide practical use cases for the federal infrastructure. Financing the establishment of infrastructure without dedicated pilots to define requirements and demonstrate benefits poses significant risks in federated structures, as the added value may not be immediately evident. Additionally, developing detailed software requirements in the research domain is inherently challenging; researchers often concentrate on high-level requirements, leaving prioritization to developers. Bridging the gap between harmonized requirements and concrete operational specifications necessitated the use of examples and mock-ups, such as the PRM from FoPraNet-BW. Furthermore, trust-building was hindered by the COVID-19 pandemic, which limited opportunities for informal exchanges and relationship development due to the absence of in-person meetings.

Integrating networks with highly variable IT solutions and differing levels of willingness to change remains a significant challenge. Some sites currently use function-oriented software (eg, Microsoft Access) and are hesitant to switch unless clear advantages are demonstrated, while others are eager to adopt new platforms due to limited existing IT support [33]. To fully realize the potential of the IT solution, it is essential to address aspects such as accessibility, intuitive usability, process mapping, and the consideration of hidden user needs.

Heterogeneity and Sociotechnical Complexity

The documented heterogeneity in IT resources (2 - 90 person-months), expertise, and strategic objectives across PBRNs exemplifies the sociotechnical challenges of federated research infrastructures, where local autonomy conflicts with national interoperability needs [24-27,31]. This mirrors experiences in other PBRN networks, where divergent organizational cultures and capacities necessitate bounded contexts to preserve network-specific practices while enabling metadata exchange. The emergence of network-specific IT goals (Table 1) underscores how such disparities can fragment progress unless addressed through structured negotiation.

Harmonization Through Core Requirements and Use Cases

Despite initial divergences, consensus on 6 core use cases and 2 national proofs-of-concept (KPI reports and practice queries) demonstrates that iterative prioritization can yield shared standards in heterogeneous settings. These agreements align with PBRN good practices emphasizing standardized data management and recruitment tracking as foundational for scalable research. Pronounced structural and organizational differences between networking resources, roles, documentation practices, and local IT solutions—initially slowed progress, as high-level requirements from network leads remained largely unchanged. This barrier was overcome by engaging work-level staff (study assistants and coordinators) in small-group workshops, which developed concrete, shared process understanding and enabled the negotiated core dataset for pseudonymized practice queries. The federated model thus balances data sovereignty with cross-network utility, facilitating targeted collaborations without centralizing sensitive patient data.

Federated Infrastructure and PRM as Scalable Solutions

The 3-tier PRM architecture—local systems, central metadata layer, MII or REDCap connectors—represents a pragmatic compromise, leveraging existing tools (eg, FoPraNet-BW) for national scalability. This design addresses interoperability gaps identified in German primary care research, where CRM-inspired tools have proven effective for practice coordination. Endorsement by the steering committee validates its feasibility, positioning PRM as a trust-building mechanism that demonstrates immediate value through KPI transparency.

Methodological Considerations

The DDD approach, applied through interdisciplinary workshops, effectively bridged clinical workflows and technical requirements by establishing a shared ubiquitous language across stakeholders. This user-centered methodology aligns with recent health care IT implementations, where DDD enhances regulatory compliance, reduces role ambiguity, and maps complex domains like recruitment and accreditation. Intensive communication via monthly WG IT meetings further mitigated cultural differences, confirming DDD's suitability for federated PBRNs despite pandemic-related constraints on in-person trust-building.

Persistent Challenges and Implications

Network-specific pilot studies highlighted federal use cases, emphasizing the risks of funding infrastructure without embedded research pilots—a pattern observed in other federated networks. Variable IT maturity (eg, Microsoft Access vs comprehensive platforms) and resistance to change remain

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obstacles that demonstrably require a participatory approach and a focus on user-friendliness. These findings imply that future PBRN IT development should prioritize governance structures, early DDD engagement, and hybrid (virtual or in-person) formats to foster trust and adoption. For DESAM-ForNet and similar initiatives, the PRM model offers a blueprint for integrating with national infrastructures like MII while preserving local flexibility. The DESAM-ForNet process demonstrates strategies applicable beyond Germany, particularly for PBRNs facing similar tensions between local autonomy and national coordination. Lessons for other federated research networks include 3-tier architectures, early engagement of work-level staff to bridge structural heterogeneity, and KPI-driven proofs-of-concept that build trust. These align with international PBRN good practices and could benefit networks coordinated by organizations like the North American Primary Care Research Group. Adaptation remains essential for varying funding models, regulatory frameworks (eg, United States Health Insurance Portability and Accountability Act [HIPAA] vs General Data Protection Regulation), and digital maturity levels, with the PRM model's modular connectors offering scalability to resource-constrained settings.

Limitations

Exploring New Communication Channels in the Context of the COVID-19 Pandemic

At the beginning of the pandemic, in-person meetings were impossible due to contact restrictions and public health measures. During the early pandemic phase, not all participating institutes initially had access to platforms such as Zoom (Zoom Communications, Inc), which made regular meetings, building trust, and effective collaboration challenging. However, as familiarity with these platforms increased, almost all communication took place online, and the project team quickly adapted to these new formats, ensuring continuity of collaborative work. Consequently, shifts in the timeline and issues of trust emerged in the absence of face-to-face interaction, and these issues manifested themselves in several project phases.

Data Processing and Documentation Practices

Although systematic data preparation was facilitated by detailed protocols, these were later streamlined. Furthermore, the heterogeneity of documents across networks posed challenges for comparison, resulting in variability in the depth of documentation between participating networks and necessitating further follow-up and clarification.

Participatory Working and Tool Adoption

The project's participatory nature embraced varying levels of digital proficiency and openness to new tools, such as Miro and Jira. Consequently, some participants continued to submit materials in familiar formats, such as Word documents, Microsoft PowerPoint presentations, and Excel spreadsheets, rather than adopting new collaborative platforms. As a result, the networks differed in how comprehensively they documented activities and outcomes, making the standardization of records challenging and necessitating supplementary inquiries in several cases. Despite these challenges, the project successfully adapted its processes, encouraged collaboration across networks, and established robust protocols to ensure the integrity and reliability of the data collected.

Conclusions

This study illustrates that the success of large-scale health IT initiatives relies not only on technical factors but also, crucially, on social and organizational processes. Key success factors identified include iterative, participatory development, transparent governance, and the early and continuous engagement of all relevant stakeholders. Additionally, the need for integration with ancillary systems has become increasingly evident and has been proactively addressed in subsequent implementations of transformative systems.

To ensure sustained effectiveness and acceptance of complex health ITIs, it is vital to foster a common vision, establish a shared language, and build mutual trust among all participants [7,28,33]. Consequently, future efforts should prioritize these relational and organizational dimensions alongside technological advancements, aiming to fully leverage the potential of both centralized and federated data management in advancing research and clinical practice.

Large-scale federated ITIs for primary care research networks face inherent sociotechnical tensions between local autonomy and national interoperability. This study demonstrates that participatory, iterative processes can overcome marked heterogeneity in resources, expertise, and objectives across 6 German PBRNs, yielding consensus on core use cases, a shared dataset, and a scalable 3-tier PRM system.

Key success factors include structured governance, continuous stakeholder engagement, and domain-driven co-design, which establish a shared language and trust. These relational mechanisms proved essential for negotiating compromises, such as decentralized data storage with central metadata coordination.

The PRM model offers a blueprint for PBRNs worldwide, balancing flexibility with MII or electronic patient record integration potential. Future initiatives should embed research pilots early, prioritize hybrid trust-building formats, and demonstrate immediate value through KPI transparency to accelerate adoption and sustain long-term collaboration in primary care research.

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Data Availability

The datasets generated or analyzed during this study are not publicly available; however, data may be made available from the corresponding author upon reasonable request and for specific research questions.

Authors' Contributions

IT working group speakers CT, SP, and AB designed the workshops, implemented the participatory approach, and managed data collection. GA and SP analyzed the data and drafted the manuscript. JS provided methodological guidance and critical feedback, which improved the clarity and rigor of the manuscript. All authors critically reviewed the manuscript, approved the final version, and accepted responsibility for the decision to submit it for publication.

Conflicts of Interest

None declared.

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Abbreviations

CRM: customer relationship management
DDD: domain-driven design
EHR: electronic health record
HIPAA: Health Insurance Portability and Accountability Act
ITI: IT infrastructure
KPI: key performance indicator

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MII: Medical Informatics Initiative
NCO: National Coordination Office
PBRN: practice-based research network
PRM: practice relationship management
REDCap: Research Electronic Data Capture
WG IT: IT working group

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Understanding Graduate Students' Perspectives on Food Apps to Inform User-Centered Design: Explanatory Sequential Mixed Methods Survey Study

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Abstract

Background: Mobile food apps have the potential to promote healthier eating behaviors and more sustainable food practices. Graduate students often struggle to maintain healthy dietary habits due to lifestyle transitions, academic stress, limited time, and constrained budgets, which can lead to poor meal planning, irregular eating patterns, and increased food waste.

Objective: This study aimed to examine graduate students' dietary behaviors, food waste practices, and preferences for mobile food app features, with the intention of informing the design of user-centered tools that promote healthy eating and reduce food waste.

Methods: This study used an explanatory sequential mixed methods design. In the first phase, 63 graduate students at the University of South Carolina completed an online survey between November and December 2024, which captured demographics, cooking habits, dietary preferences, food waste behaviors, and online recipe search behaviors. Findings from the survey shaped the design of interview questions, allowing qualitative inquiry to explain and expand upon the quantitative patterns. Ten purposively selected participants completed semistructured interviews. Quantitative data were analyzed descriptively and using the chi-square test with R software (version 4.3.1), while qualitative data were transcribed and thematically analyzed.

Results: Survey findings revealed that 54% (34/63) of the participants ate out daily or almost daily; 25.3% (16/63) consumed fast, frozen, or canned food at least 3 to 5 times per week; and only 19% (12/63) cooked daily. Most participants consumed only 1 serving of vegetables (43/63, 68.2%) and fruits (33/63, 52.4%) daily. Nearly 70% (44/63) reported food waste, primarily from leftovers and unused ingredients. A significant association was found between shopping list use and reduced food waste (χ^2_1=9.66, *P*=.008; Cramér V=0.39). The interviews contextualized these patterns: the students described time constraints, limited cooking skills, and overbuying as key barriers to healthy eating and waste reduction, while recommending app features such as nutrition tracking, batch meal planning, personalized dietary filters, ingredient-based recipe generators, and grocery list tools with reminders. Participants also emphasized the importance of simple design, multimodal content, and accurate cooking time estimates.

Conclusions: This study demonstrates that integrating quantitative and qualitative insights through the capability, opportunity, motivation-behavior (COM-B) framework provides a nuanced understanding of graduate students' dietary practices, food waste behaviors, and app feature preferences. The findings highlight the need for mobile food apps that are not only evidence based but also user centered, offering simple, time-efficient, and customizable tools that simultaneously address capability deficits, opportunity barriers, and motivation maintenance. Such apps have the potential to address barriers unique to graduate students, such as limited time, minimal cooking skills, and organizational challenges, while supporting healthier eating and reducing food waste.

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KEYWORDS

food apps; graduate students; healthy eating; food waste; mobile apps; mixed methods; COM-B model; capability, opportunity, and motivation-behavior model

Introduction

Background

Unhealthy eating patterns and poor lifestyle behaviors are major contributors to chronic conditions such as obesity, cardiovascular disease, diabetes, and certain cancers [1]. The World Health Organization estimates that up to 80% of cases involving cardiovascular illness, stroke, metabolic disorders, and type 2 diabetes can be prevented through healthier dietary choices [2]. Concurrently, technological innovation has created new opportunities for promoting health and sustainability [3,4].

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Mobile food apps now offer features such as recipe suggestions, meal planning tools, and grocery shopping assistance designed to support informed dietary decisions and environmentally sustainable food practices [5,6]. However, the adoption and effectiveness of these apps vary widely across user groups [7], making it essential to understand how specific populations engage with these tools to design inclusive, user-centered digital health solutions.

University students face particular challenges in maintaining healthy dietary habits due to academic pressures, limited time, inconsistent schedules, minimal cooking skills, and budget constraints [8,9]. These factors often lead to irregular eating patterns, reliance on convenience foods, and increased food waste [10-12]. As individuals in a transitional life stage, students are at risk of developing long-term dietary habits that impact future health outcomes [13-16]. Furthermore, studies show that busy lifestyles further hinder leftover management and contribute to food waste, making young adults and university students among the largest contributors to avoidable food waste, yet they remain an understudied group in this context [17,18].

Research indicates that graduate students are more likely to experience food insecurity than undergraduates [19]. Nearly half of graduate students experience some level of food insecurity [20-22]. Graduate students face persistent financial insecurity, chronic stress, and professional pressures that contribute to disordered eating and low dietary quality [23-26]. These challenges stem from structural constraints including low stipends, inflexible assistantship funding, high tuition, visa restrictions limiting employment, and limited opportunities for supplemental income supplemental income [27-29]. Given these unique vulnerabilities and the limited research on digital nutrition interventions tailored to this population, graduate students warrant dedicated study to develop user-centered solutions that address their specific barriers to healthy eating and food waste reduction.

To address the gap in research on mobile food apps for graduate students, this study used an explanatory sequential mixed methods design to explore their dietary behaviors, food waste practices, and preferences for app features. Survey data first identified the broad patterns and prevalence of cooking, diet, and food waste behaviors, which directly informed follow-up interview questions exploring the underlying reasons and user needs. This integration captured not only the prevalence of behaviors but also the factors driving them, ensuring that insights from both phases contributed to user-centered app design recommendations. By linking quantitative patterns with qualitative insights, this study offers guidance for developing mobile food apps that promote healthier eating and reduce food waste among graduate students.

Theoretical Framework

This study is guided by the capability, opportunity, motivation-behavior (COM-B) model, a widely used framework for understanding and designing behavior change interventions [30]. The model posits that behavior occurs when individuals have the necessary capability (physical and psychological skills), opportunity (environmental and social factors), and motivation (reflective and automatic processes). Mobile health (mHealth) apps can address barriers across all 3 components through skills training (capability), planning tools and reminders (opportunity), and goal setting features (motivation). By mapping graduate students' reported barriers and preferences to specific behavior change techniques (BCTs) [31], this study identified app features most likely to support sustained dietary behavior change and food waste reduction.

Methods

Study Design

A mixed methods study using an explanatory sequential design was conducted between November and December 2024 involving graduate students at the University of South Carolina. With this design, survey results provided a broad understanding of graduate students' cooking habits, dietary preferences, and food waste, while interviews provided deeper explanations and contextual insights that clarified and expanded upon the quantitative findings.

In the first phase, 63 participants completed a structured online survey that collected data on demographics, cooking habits, dietary preferences, food waste behaviors, and online recipe search behaviors. These results provided a broad overview of the eating and food management practices of students and revealed patterns and trends requiring further exploration.

For the second phase, survey participants indicated their willingness to participate in a follow-up interview by providing their email address at the end of the survey. From this pool, 10 participants were purposively selected to ensure diverse perspectives across key demographic and academic characteristics. Selection criteria aimed to capture variation in gender, race, and ethnicity; academic discipline; and living arrangements. The final interview sample included 5 women, 4 men, and 1 participant identifying as another gender. Participants represented diverse racial and ethnic backgrounds: 4 White, 2 Asian, 2 Middle Eastern or North African, 1 Black or African American, and 1 Hispanic or Latino/a/x. Living arrangements varied, with 3 participants living alone, 3 living with roommates, and 4 living with a partner or married. Semistructured interviews lasting approximately 30 to 35 minutes were conducted either online or in person, according to participant preference, in a private setting. All interviews were audio-recorded and transcribed verbatim for analysis.

Quantitative and qualitative data were integrated through a systematic connecting process. This study used a connecting approach to mixed methods integration [32], in which quantitative survey results directly informed the development of qualitative interview questions, and qualitative findings were then used to explain and expand upon quantitative patterns. Integration occurred at 3 distinct stages: design, data collection, and interpretation. At the design stage, the explanatory sequential structure inherently connected the 2 phases, with phase 1 (survey) results shaping phase 2 (interview) protocol development. At the data collection stage, survey data were analyzed immediately upon collection to identify patterns requiring deeper exploration. Specific quantitative findings directly informed interview question development. At the

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interpretation stage, qualitative and quantitative findings were merged through a joint display approach, systematically comparing survey patterns with interview themes to create integrated interpretations.

Participant Recruitment

Participants were recruited from the graduate student population at the University of South Carolina between November and December 2024. Graduate students registered in 4 different graduate-level courses at the University of South Carolina (total enrollment: 121 students) were invited to participate. These 4 courses enrolled graduate students from diverse disciplines across multiple graduate programs university-wide. Recruitment invitations were distributed via students' university email addresses. The email invitation described the study's purpose and time commitment and provided a link to the online survey (Multimedia Appendix 1).

Of the 121 graduate students, 63 completed the survey, yielding a response rate of 52.1%. For the interview phase, survey participants indicated their willingness to participate in a follow-up interview by providing their email address at the end of the survey. From this pool, 10 participants completed interviews, which were conducted either online or in person, according to participant preference. No incentives or compensation were offered for participation.

Interview Protocol Development

The semistructured interview protocol was developed specifically for this study on the basis of patterns and associations identified in the survey data. Following the explanatory sequential design framework [33], interview questions were crafted to explain and expand upon quantitative findings. For example, survey data showing that the majority of participants consumed only 1 serving of vegetables per day informed interview questions exploring barriers to healthy cooking and vegetable consumption. Similarly, the high prevalence of food waste and the significant association between shopping list use and reduced waste shaped interview prompts about grocery shopping habits, meal planning strategies, overbuying behaviors, and leftover management. The interview guide included open-ended questions about participants' cooking practices, dietary challenges, food waste experiences, current use of food-related technologies, and recommendations for mobile app features that would support healthier eating and waste reduction. The semistructured format allowed the interviewer to probe deeper into participants' responses while ensuring consistency across interviews in addressing key topics derived from the survey phase.

Inclusion and Exclusion Criteria

Participants were required to meet the following inclusion criteria: (1) currently enrolled as a graduate student (master's or doctoral level) at the University of South Carolina during the 2024 fall semester and (2) at least 18 years of age. No exclusion criteria were applied on the basis of degree program, nationality, dietary restrictions, or food security status. Food insecurity was not assessed as part of the screening or inclusion criteria, as the study aimed to capture a broad spectrum of graduate students' dietary behaviors and food waste practices regardless of food security status. While food insecurity may moderate the diet quality and waste behaviors, this study focused on understanding the general patterns, barriers, and app feature preferences across the graduate student population to inform inclusive app design that could benefit students with varying levels of food access and financial resources.

Ethical Considerations

This study was approved by the University of South Carolina Institutional Review Board (Pro00141073). All participants received an information sheet outlining the study's purpose, procedures, potential risks, and confidentiality protocols prior to participation. Informed consent was obtained from all participants before they completed the survey and again before they participated in interviews. Participation was entirely voluntary, and participants were informed of their right to withdraw at any time without penalty. All data were anonymized to protect participant privacy, with no personally identifiable information linked to survey responses or interview transcripts. Participants were not compensated for their participation in this study.

Data Analysis

Quantitative data were analyzed descriptively using frequencies and percentages to characterize participants' demographics, dietary behaviors, and food waste practices. Inferential analysis was performed using the chi-square test of independence to examine the association between categorical variables, specifically shopping list use and food waste occurrence. Statistical analyses were conducted using R software (version 4.3.1; R Foundation for Statistical Computing). Statistical significance was set at α=.05 (2-tailed). Effect sizes were calculated using Cramér V to assess the practical significance of observed associations. Given the exploratory nature of the quantitative phase, only 1 inferential test was conducted to avoid multiple comparison issues.

Qualitative data were analyzed using thematic analysis following the approach of Braun and Clarke [34]. Analysis was conducted manually using Microsoft Excel for data management and organization. The lead researcher conducted the initial coding by reading all transcripts multiple times; highlighting relevant text segments; and assigning preliminary codes inductively on the basis of content related to barriers, preferences, and app feature recommendations. Coded segments were systematically organized in Excel, allowing for iterative refinement and categorization of codes into broader themes. To enhance credibility and confirmability, the second author independently reviewed the coded transcripts and the emerging codebook. Discrepancies were resolved through discussion until consensus was reached on code definitions and theme structure. The lead researcher maintained analytic memos throughout the coding process, documenting coding decisions, emerging patterns, and reflexive notes about potential interpretive biases. Final themes were identified through iterative comparison across transcripts, with attention to both convergent patterns and divergent perspectives among participants.

A total of 63 graduate students participated in the study (Table 1). Most of the 63 participants were female students (n=33,

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52.4%) and aged between 22 and 32 years (n=45, 71.4%). Participants represented diverse racial and ethnic backgrounds, with the largest groups identifying as White (n=21, 33.3%), Asian (n=14, 22.2%), and Middle Eastern or North African (n=14, 22.2%). Over half (n=39, 61.9%) of the participants used iOS devices. Regarding living arrangements, the majority lived with roommates (n=32, 50.8%) or with family or partners (n=19, 30.2%), while some lived alone (n=12, 19%). This diversity across age, gender, ethnicity, and living situation provides important information for interpreting their food habits and app preferences.

Table . Demographic characteristics of the participants (N=63).

Category	Participants, n (%)
Gender	
Female	33 (52.4)
Male	25 (39.6)
Other	5 (8)
Age range, years	
22 - 32	45 (71.4)
33 - 44	16 (25.4)
45 - 55	2 (3.2)
Race and ethnicity	
White (non-Hispanic)	21 (33.3)
Black or African American (non-Hispanic)	11 (17.5)
Hispanic or Latino/a/x	2 (3.2)
Asian	14 (22.2)
Middle Eastern or North African	14 (22.2)
Multiracial/other	1 (1.6)
Smartphone operating system	
Android	24 (38.1)
iOS	39 (61.9)
Current living arrangement	
Living alone	12 (19)
Living with roommates	32 (50.8)
Living with partner or family	19 (30.2)

Results

In this section, we present the quantitative survey findings on graduate students' dietary behaviors, food choices, meal-related habits, grocery shopping practices, and self-reported food waste experiences, followed by key qualitative themes from the semistructured interviews. Table 2 shows the distribution of dietary behaviors, food choices, and meal-related habits among participants.

Table 2 shows that while nearly half of the 63 participants (n=30, 47.6%) cooked a few times a week, only 19% (n=12) cooked daily, and 14.3% (n=9) engaged in weekly meal preparation. Nutritional value influenced food choices for the majority of participants, with 85.7% (n=54) indicating that it mattered at least somewhat. Fast, frozen, or canned food was consumed a few times a month (n=24, 38.1%) or 1 to 2 times per week (n=20, 31.7%). Fast, frozen, and canned food was grouped as a single survey item to capture the overall reliance on convenience foods. While nutritionally distinct, these options share the common characteristic of requiring minimal preparation time, making them appealing choices for time-constrained graduate students.

Most participants consumed only 1 serving of vegetables (n=43, 68.2%) and fruit (n=33, 52.4%) daily, with 28.5% (n=18) reporting no daily fruit intake. Eating out was frequent, with 54% (n=34) doing so daily or almost daily. In addition, many students regularly searched for food recipes online, with 20.6% (n=13) always doing so, 44.5% (n=28) sometimes, 33.3% (n=21) rarely, and only 1.6% (n=1) never.

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Table . Dietary behaviors and food choices among participants (N=63).

Category	Participants, n (%)
Cooking frequency	
Daily	12 (19)
A few times a week	30 (47.6)
A few times a month	10 (15.9)
Meal preparation for the entire week	9 (14.3)
Rarely or never	2 (3.2)
Impact of nutritional value on food choices	
A great deal	27 (42.9)
Somewhat	27 (42.9)
Very little	9 (14.2)
Frequency of fast, frozen, or canned food consumption	
A few times a month	24 (38.1)
1 - 2 times a week	20 (31.7)
3 - 5 times a week	12 (19)
Every day	4 (6.3)
Never	3 (4.8)
Daily vegetable servings consumed	
1 serving	43 (68.2)
2 servings	9 (14.3)
≥3 servings	3 (4.8)
None	8 (12.7)
Daily fruit servings consumed	
1 serving	33 (52.4)
2 servings	10 (15.9)
≥3 servings	2 (3.2)
None	18 (28.5)
Frequency of eating out among participants	
Daily or almost daily	34 (54)
3 - 5 times a week	17 (27)
1 - 2 times a week	10 (15.9)
1 - 2 times a month	1 (1.5)
Never	1 (1.5)
Frequency of searching for food recipes online	
Always	13 (20.6)
Sometimes	28 (44.5)
Rarely	21 (33.3)
Never	1 (1.6)

Food waste was assessed by asking participants the following question: “Do you experience food waste? (Yes/No)”. Participants who responded “Yes” were then asked to identify the primary source(s) of their food waste: leftover food, unused raw ingredients, or both. The measure reflects students’ self-assessed experience with food waste rather than objective waste volumes or rates. Figure 1 shows that of the 63 participants, 44 (69.8%) reported experiencing food waste, while 19 (30.2%) indicated that they did not. Of the 44 participants who experienced food waste, 15 (34.1%) cited leftover food, 10 (22.7%) mentioned raw ingredients, and 19 (43.2%) reported both as primary sources. In the interview phase, food waste was

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explored in depth through follow-up questions that provided rich contextual detail about what the participants waste, why, and when.

Figure 1. Prevalence and primary source of food waste among participants (N=63).

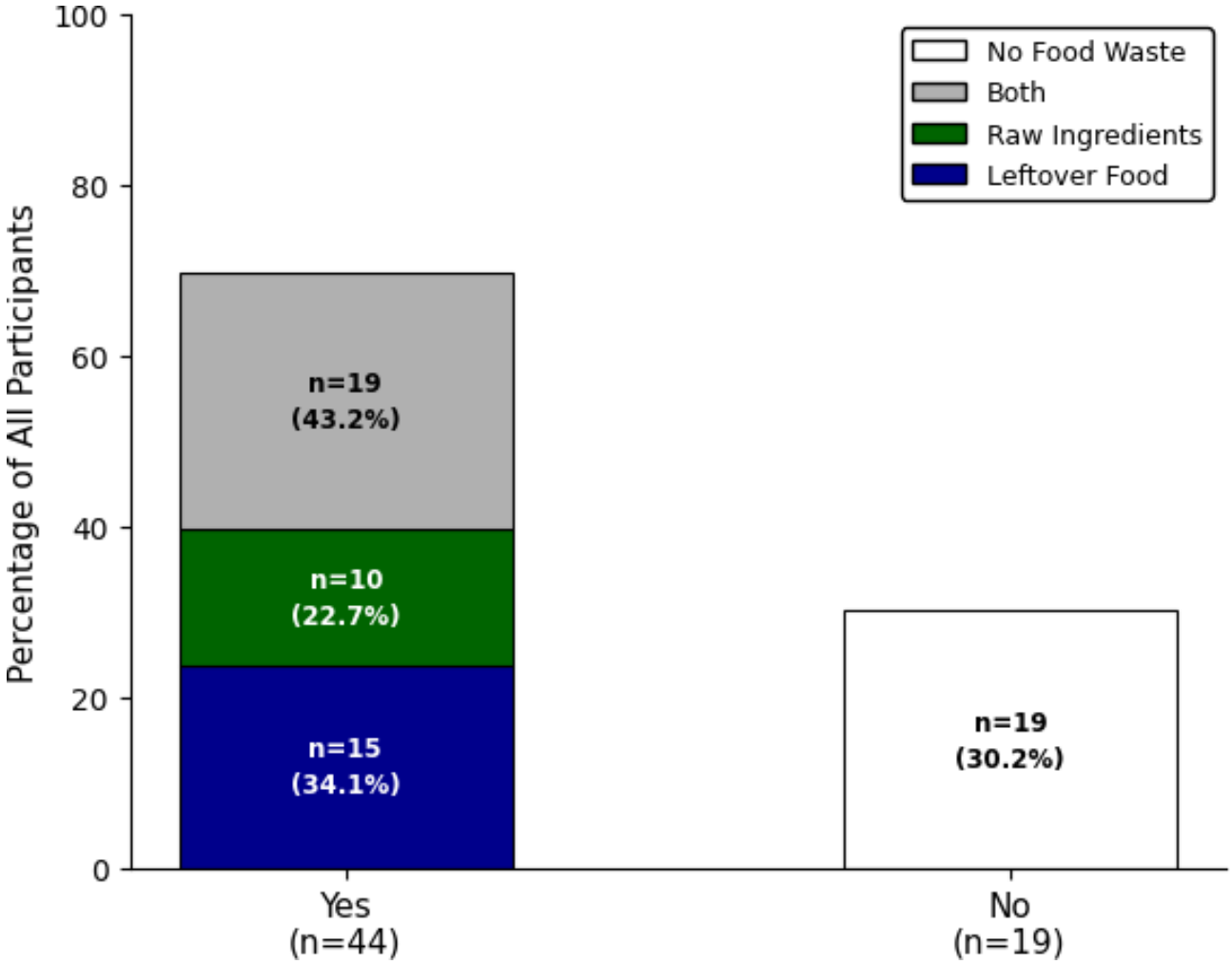

Table 3 shows that most of the 63 participants shopped weekly (n=39, 61.9%), with others shopping every 2 weeks (n=18, 28.6%), monthly (n=5, 7.9%), or daily (n=1, 1.6%). When asked about meal planning before shopping, over half (n=33, 52.4%) stated that they sometimes planned meals, while 30.1% (n=19) always planned meals. A majority (n=38, 60.3%) reported using a shopping list during grocery trips.

A chi-square test of independence revealed a statistically significant association between using a shopping list and experiencing food waste (χ^2_1=9.66, *P*=.008; Cramér V=0.39). Table 4 presents the contingency table showing this relationship. Among participants who did not use shopping lists, 92% (23/25) reported food waste compared to 55.3% (21/38) of those who used shopping lists. The medium to large effect size (V=0.39) indicates a strong association between structured planning through shopping list use and reduced food waste among graduate students.

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Table . Grocery shopping behaviors and meal planning practices among participants (N=63).

Category	Participants, n (%)
How often do you go grocery shopping?	
Daily	1 (1.6)
Weekly	39 (61.9)
Every 2 weeks	18 (28.6)
Monthly	5 (7.9)
Do you plan meals before going grocery shopping?	
Always	19 (30.1)
Sometimes	33 (52.4)
Rarely	7 (11.1)
Never	4 (6.3)
Do you use a shopping list when you go grocery shopping?	
Yes	38 (60.3)
No	25 (39.7)

Table . Association between shopping list use and food waste among participants (N=63).

	Food waste: yes	Food waste: no	Total
Uses shopping list, n (%)	21 (55.3)	17 (44.7)	38 (100)
Does not use shopping list, n (%)	23 (92)	2 (8)	25 (100)
Total, n (%)	44 (69.8)	19 (30.2)	63 (100)

Interview Findings

The semistructured interview protocol was informed by survey findings, particularly items related to cooking habits, dietary behaviors, food waste, and grocery shopping practices. For example, survey data showing that a majority of participants consumed only 1 serving of vegetables per day informed the interview questions about barriers to healthier eating. Similarly, reported challenges with food waste guided interview prompts about food waste behavior and strategies to reduce waste. Also, survey results showed a statistically significant association between using a shopping list and experiencing food waste. This quantitative finding directly shaped the interview questions about grocery shopping habits, planning strategies, and app features promoting waste minimization.

Overview

Based on the interview data, three overarching themes emerged from qualitative interviews: (1) suggestions for app features supporting healthy eating, (2) suggestions for reducing food waste, and (3) suggestions for enhancing user experience. This section presents the key themes and subthemes identified under the first category, highlighting graduate students' perspectives, needs, and expectations for mobile food apps aimed at promoting healthy eating.

Suggestions for App Features Supporting Healthy Eating

Nutrition Knowledge and Awareness

Participants expressed a strong interest in features that can enhance their understanding of nutritional values, including calorie counts, portion sizes, and macronutrient and micronutrient contents. Several noted that while they were aware of general dietary recommendations, they lacked the tools or knowledge to apply them in daily life.

> *I'd like to see how many calories and how many servings a recipe makes.* [Speaker 10]
>
> *I want to know what number of nutritional values my body and my weight need. I want calorie count and portion size count for sure in the app.* [Speaker 7]
>
> *I would like to know the food values...calories, protein amount, etc.* [Speaker 9]
>
> *I know whether I need to eat more protein or veggies...but I don't know how to count nutrition info. I like to eat healthier, but I have limited information about healthy eating.* [Speaker 4]

Participants also suggested incorporating guidance on food storage and freshness to support healthier food choices.

> *Tell me which foods are good for meal planning and what foods are good for immediate consumption.* [Speaker 7]

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Food Logging and Reminders

Given demanding academic schedules, many graduate students reported frequently skipping meals or forgetting to eat. Participants expressed a desire for gentle reminders or logging tools to help them monitor and reinforce regular eating habits.

> *Sometimes you just need that nudge...like a check-in. Have you eaten yet?* [Speaker 5]
>
> *The doctor told me, I really need to eat breakfast. I need to remind myself.* [Speaker 4]
>
> *It would be cool to have something like a logbook or reminder...like your mom asking if you've eaten.* [Speaker 5]

Personalized Dietary Filters

Participants highlighted the importance of customizing the app based on individual dietary restrictions or preferences. Suggestions included enabling filters for gluten-free, vegetarian, or vegan recipes.

> *I want vegetarian recipes..., mixed of onion, eggplants and potato, tomato, something like that...* [Speaker 7]
>
> *I don't eat red meat. I think in my belief, chicken is better than meat.* [Speaker 8]
>
> *Add gluten-free or vegan preferences to profile to filter recipes.* [Speaker 10]

Batch Meal Planning

Batch cooking was a common strategy among students to manage their time more efficiently. Many suggested that a meal planning feature, especially one tailored for weekly preparation, would be highly beneficial.

> *Most of the time, I prefer to cook at the weekend for all of the days after that. So, I need a healthy weekly plan.* [Speaker 8]
>
> *It's been close to six months that I've been scheduling weekly meals...it's working for me.* [Speaker 1]
>
> *I prefer to cook in batches on days that I don't have work.* [Speaker 7]

Simplicity and Quick Recipes

Simplicity and time efficiency were the top priorities of some participants. Students favored apps with quick, simple, and easy-to-follow recipes requiring minimum cooking skills or preparation times.

> *I want short recipes that are easy to use...not hard cooking.* [Speaker 8]
>
> *I'm not into spending...one- or two-hours cooking meals.* [Speaker 1]

Suggestions for Reducing Food Waste

Challenge of Food Waste

Graduate students acknowledged food waste as a frequent challenge, often stemming from overpurchasing, the forgetting of already purchased ingredients in the refrigerator, or a lack of time to cook.

> *I throw out a lot of food unfortunately, especially veggies, and I hate myself for that.* [Speaker 3]
>
> *Sometimes I bought [groceries] thinking I'd have time to cook...then realized I didn't.* [Speaker 2]
>
> *The main waste I deal with is fruits and vegetables that I overbuy and forget about...like getting eight apples but only eating one, so the rest go bad.* [Speaker 5]

To address these challenges, participants offered some recommendations for app features that could help minimize food waste and promote mindful consumption.

Smart Recipe Generator Based on Available Ingredients

Participants emphasized the usefulness of a smart recipe feature that generates recipes on the basis of ingredients they already have at home. This would allow them to consume existing food before it spoils.

> *You give the ingredients, and the app gives you a recipe...that would be great.* [Speaker 3]
>
> *I want to find a recipe based on what I have in the fridge.* [Speaker 7]
>
> *I want to enter what ingredients I have...and ask the app for recipes based on them.* [Speaker 9]

Grocery List Generator With Storage Reminders

Another common suggestion involved integrating a smart grocery list feature, one that is dynamic, saves previous lists, and provides reminders based on items already purchased. Participants noted that food waste occurred often due to overbuying and forgetting what they already had.

> *It should give me a grocery list according to each meal or all the meals I plan to cook for the next few days.* [Speaker 10]
>
> *I want to choose the recipes...and the app recommends what to buy and how much to buy.* [Speaker 3]
>
> *Most of the time, my food goes to waste because I overbuy, and I forget.* [Speaker 1]
>
> *Save my grocery lists and notify me— 'Oh, you still have some of this,' so you can take it off your shopping list.* [Speaker 5]
>
> *I found some tomatoes at the back of my refrigerator...and grapes...I totally forgot.* [Speaker 1]

Ingredient Substitutions

To avoid food waste due to unavailable ingredients, participants suggested including a substitution feature in the app. This would allow users to complete recipes with the available alternatives, especially when certain cultural ingredients or specialty items are hard to find.

> *Sometimes you don't really have that ingredient...alternative choices could avoid waste.* [Speaker 2]

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> *If it's Chinese food and we can't find the ingredients, what can we substitute?* [Speaker 3]

Suggestions for Enhancing User Experience

In addition to functional suggestions related to healthy eating and food waste, participants requested several preferences and expectations for the overall design and usability of the app. These proposals centered on improving clarity, personalization, efficiency, and engagement.

Video- and Text-Based Recipes

Participants emphasized the value of having both visual and textual content to accommodate different learning styles and enhance comprehension. While some preferred watching videos for better engagement and understanding of cooking techniques, others found text-based instructions essential for quick references.

> *Some easy button or colorful button with good illustration...design is important.* [Speaker 8]

> *I don't want to replay videos...text version with steps is necessary.* [Speaker 9]

> *I want to see videos of the food, how to cook them...helps me get engaged better.* [Speaker 1]

> *If you don't know what a roux is...you need to see it.* [Speaker 5]

Portion Control Feature

Participants expressed a desire for an app that supports flexible portion control options, allowing them to cook for specific durations or numbers of people. This would help them manage meal planning better, reduce waste, and avoid unnecessary leftovers.

> *I want it to give me the options to cook for one day, two days, etc....and for two people, four people...* [Speaker 1]

> *It should tell me exact amounts of ingredients, like for four persons.* [Speaker 9]

Simplified Onboarding Process

Time constraints were a recurring concern, and participants were discouraged with apps that require long registration processes. They recommended a fast, streamlined onboarding experience to improve user retention and reduce initial barriers.

> *Not a lengthy process of registration in the app...I don't have time.* [Speaker 2]

Bookmarking and Sharing Recipes

Participants believed that social and organizational features such as bookmarking favorite recipes and sharing recipes with friends were convenient and motivating.

> *I like to Favorite some recipes, share them with a friend, that would be cool.* [Speaker 5]

Accurate Time Estimates

Accurate cooking time estimates were another priority, as students needed realistic expectations to better manage their schedules.

> *I don't like when the recipe says 30 minutes cooking time...but it actually takes one hour.* [Speaker 2]

Discussion

Principal Findings

This mixed methods study examined graduate students' dietary behaviors, food waste practices, and preferences for mobile food app features to inform user-centered app design. Survey results revealed that while the majority of participants valued nutrition in food choices, most consumed only 1 serving of vegetables and fruits daily, with over half of the participants eating out daily or almost daily. Nearly 70% (44/63) reported food waste, primarily from leftovers and unused ingredients. A significant association was found between shopping list use and reduced food waste. The follow-up interviews contextualized these patterns, identifying time constraints, limited cooking skills, and overbuying as key barriers. Participants recommended app features such as nutrition tracking, batch meal planning, ingredient-based recipe generators, and smart grocery lists to support healthier eating and reduce waste.

Quantitative results indicated that while nearly half of the participants cooked a few times per week, only a small proportion of participants cooked daily or engaged in structured weekly meal preparation. This finding is aligned with existing research showing that young adults, particularly students, face numerous barriers to healthy eating due to academic pressure, stress, limited time, and low culinary skills as well as financial constraints [35,36]. Qualitative interviews expanded on these patterns, describing how busy schedules contribute to irregular eating patterns and a reliance on convenient, processed foods, a pattern echoed in this study where participants frequently consumed fast food or frozen meals. Additionally, limited intake of fruits and vegetables among participants aligns with broader dietary trends indicating inadequate nutrient consumption among college students [13]. Most participants consumed only 1 serving daily, representing less than 50% of the United States Department of Agriculture (USDA) recommendation of 2.5 cups of vegetables and 2 cups of fruit per day for adults [37]. Nearly 30% reported no daily fruit intake, suggesting substantial gaps in dietary quality that may have long-term health implications. Interviews clarified why this gap existed between students' intentions and behaviors: while nutrition "mattered," they lacked the time and skills to translate this value into practice. This pattern suggests that app features promoting vegetable and fruit consumption, such as produce-focused recipes, meal planning tools emphasizing plant-based ingredients, and nutrition tracking, are especially critical for this population.

Participants expressed strong interest in increasing their nutritional awareness, specifically requesting features such as calorie tracking, portion control, and macronutrient breakdowns. These preferences are consistent with literature showing that practical, serving-based nutritional information enhances the appeal and utility of eHealth interventions [38,39]. Students also recommended the inclusion of food logging tools and personalized dietary filters (eg, vegetarian, gluten-free, and vegan), showing their desire for tailored support in maintaining

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consistent and health-conscious routines. This reflects a broader trend in mHealth design favoring personalized digital interventions that adapt to the health goals and lifestyles of mobile app users.

The combination of survey and interview results also reveals the importance of reminders and nudges. Quantitative data showed irregular cooking habits, and the interviews explained this finding, as participants described how meals were often skipped during busy days. Therefore, participants suggested food logging and gentle reminders that could help address these disruptions. They described how simple prompts, such as reminders to eat or check in on meals, would be helpful in addressing the reality of busy graduate student life, where irregular or skipped meals are common. This is consistent with prior evidence that digital self-monitoring and behavioral nudges are effective in promoting healthy eating routines [40].

Food waste also emerged as another major theme, with nearly 70% (44/63) of participants reporting frequent waste, particularly due to leftovers and unused raw ingredients. This finding is consistent with literature identifying young adults, especially those living alone or with roommates, as major contributors to household food waste [41,42]. Quantitative results linked shopping list use to reduced waste, which was also supported by qualitative insights mentioning that lists could increase organization and prevent overpurchasing. Participants who used shopping lists were less likely to report waste, supporting previous findings that list making encourages healthier food choices and better organization [43,44]. In a previous study, automated list generation features based on meal plans were also recommended to improve app usability and long-term engagement [39].

Moreover, participants proposed additional waste reduction strategies, including smart food recipe generators based on available ingredients, ingredient substitution suggestions, and reminders for unused groceries. These features can increase interest in mobile apps that can go beyond planning to offer real-time decision support, an approach advocated in prior research [45] on behaviorally targeted interventions.

In addition, participants expressed interest in features such as batch meal planning, quick and simple recipes, and a portion control option. These preferences highlight graduate students' desire for convenience and efficiency in app design, reflecting their need for tools that can adapt to demanding schedules. Previous studies similarly noted time constraints as a barrier to healthy food provision [46,47].

Ease of use and interface design were also important features for participants. Participants expressed a strong preference for apps with intuitive design, efficient onboarding, and multimodal instructional content (eg, video and text). These preferences align with research showing that apps are more likely to be adopted and consistently used if they are visually engaging, easy to navigate, and respect users' limited time [48,49]. Video tutorials combined with text-based instructions were especially suggested for accommodating different learning styles and improving engagement. Interview participants further emphasized the need for accurate time estimates for meal preparation, as unrealistic expectations can lead to frustration and potential app abandonment.

The following sections present the systematic integration of these findings and their theoretical mapping to behavior change frameworks.

Integration of Quantitative and Qualitative Findings

The explanatory sequential mixed methods design facilitated the systematic integration of quantitative patterns with qualitative explanations. Qualitative and quantitative findings were merged through a joint display approach, systematically comparing survey patterns with interview themes to generate integrated interpretations. For each major finding, we examined (1) the prevalence and patterns from the quantitative data, (2) the underlying reasons and contextual factors from the qualitative data, and (3) how these combined insights informed app design recommendations.

The survey data identified the occurrence and prevalence of specific behaviors, whereas the interviews illuminated why these patterns emerged and what solutions participants proposed. For example, quantitative findings revealed that 69.8% (44/63) of participants experienced food waste, while interviews uncovered the key mechanisms: overbuying due to poor planning, forgetting of purchased ingredients, and inadequate leftover management. This integration showed that food waste stemmed not merely from a lack of knowledge but from interconnected barriers, including time constraints (opportunity), limited planning skills (capability), and organizational challenges.

Similarly, although 85.7% (54/63) of participants reported valuing nutritional information, interviews explained why this motivation often failed to translate into action: deficits in cooking skills (capability) combined with severe time pressures (opportunity barriers). These integrated insights enabled theoretically grounded, user-centered app recommendations that address the full range of barriers rather than isolated factors alone.

Mapping Findings to the COM-B Framework

The varied recommendations regarding nutritional support, such as time-saving features, and usability preferences can be systematically understood through the COM-B framework. Capability barriers included limited cooking skills and nutritional knowledge, which students addressed by requesting instructional features such as video tutorials and nutrition tracking. Opportunity barriers centered on time constraints and demanding schedules, leading to recommendations for action planning tools (batch meal planning), prompts and cues (eating reminders), and environmental restructuring (ingredient-based recipe generators, smart grocery lists). While motivation to eat healthily was present (85.7% valued nutrition), it was insufficient without addressing capability and opportunity deficits, highlighting the students' need for simplified interfaces and personalized dietary filters to sustain engagement. The statistically significant association between shopping list use and reduced food waste (P=.008) provides empirical support for action planning as an effective BCT in this population. This mapping demonstrates that effective app design must address

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multiple COM-B components concurrently, as apps focusing solely on motivation or capability without addressing opportunity barriers are unlikely to achieve sustained behavior change among time-constrained graduate students.

These theory-informed design recommendations provide a foundation for developing interventions that systematically target the multifaceted barriers faced by graduate students in maintaining healthy eating behaviors and reducing food waste.

Implications

This study contributes meaningfully to the growing body of mHealth research by integrating quantitative behaviors and qualitative preferences among graduate students, a population often overlooked in digital nutrition interventions. The findings demonstrate that graduate students are willing to engage with food-related apps when they are time-saving, informative, and seamlessly integrated into their routines. Key features identified as crucial for adoption included flexible onboarding, clear recipe formats, bookmarking, social sharing capabilities, and adjustable portion sizes.

For app developers and public health professionals, these findings highlight the need to balance evidence-based nutritional guidance with user-centered design principles to ensure long-term engagement and meaningful health outcomes. The systematic mapping of barriers to the COM-B framework and BCTs provides actionable guidance for developing interventions that simultaneously address capability deficits, opportunity barriers, and motivation maintenance.

Future research should build on these insights by developing and testing app prototypes, evaluating long-term usability, engagement, and health outcomes. Translating user-identified features into prioritized, testable requirements using frameworks such as the MoSCoW (Must have, Should have, Could have, Won't have) method or Kano analysis would strengthen intervention development and enable the systematic evaluation of feature effectiveness with measurable outcomes (eg, vegetable servings per day, grams of food waste per week). Considering the diverse needs of student populations, including cultural backgrounds, dietary preferences, food insecurity, and mental health concerns, future design should prioritize inclusivity and accessibility through cross-sector collaboration.

Limitations

The sample was limited to a single university in the United States and may not be representative of graduate students at other institutions or in different regions. Additionally, the study relied on convenience sampling through course-based recruitment, which may introduce selection bias. Students enrolled in the 4 targeted courses may differ systematically from the broader graduate student population in terms of academic disciplines, schedules, or other characteristics. Future research should include larger, more diverse samples encompassing students from multiple universities.

The survey measurement of food waste was intentionally broad, assessing presence or absence and primary sources without quantifying amounts, distinguishing avoidable from unavoidable waste, or specifying time horizons. Moreover, interview data relied on recall and self-report rather than objective waste measurement. Future research using food waste diaries, photography-based methods, or actual waste weighing would provide more precise quantification and enable stronger comparisons with the existing literature on food waste.

This study relies entirely on self-reported data for dietary behaviors, cooking frequency, and food waste, which are subject to well-documented biases that may affect data validity. Social desirability bias may have led participants to overreport healthy behaviors (eg, vegetable consumption, meal planning) and underreport less desirable behaviors (eg, eating out, food waste), particularly given their awareness that the study focused on healthy eating and sustainability. Recall bias is another significant concern, as participants were asked to estimate their typical behaviors (eg, daily vegetable servings, weekly cooking frequency) without reference to actual food logs or objective measurements. Research demonstrates that self-reported dietary intake is notoriously unreliable, with individuals often misestimating portion sizes, forgetting eating occasions, and inaccurately recalling consumption patterns [50,51].

Food waste estimates are particularly challenging to measure accurately, as participants may not notice or remember all discarded food, and definitions of "food waste" may vary across individuals. Similarly, cooking frequency relies on subjective interpretation of what constitutes "cooking" versus "meal preparation." The interview setting may have further influenced disclosure patterns: participants in in-person interviews may have been more susceptible to social desirability bias due to direct interaction with the researcher, while those in online interviews may have felt more comfortable disclosing less favorable behaviors but may have been more distracted or less engaged, potentially affecting response depth and accuracy.

Given these limitations, the behavioral data reported in this study should be interpreted as participants' perceptions and self-assessments of their dietary patterns rather than objective measurements of actual intake or waste. The primary value of this study lies not in precise quantification of dietary behaviors but in understanding students' experienced barriers, perceived needs, and preferences for app features—insights that remain valid even if absolute frequencies are subject to reporting bias. Future research should incorporate objective measures such as food photography, actual grocery receipts, weigh-and-measure food waste protocols, or ecological momentary assessment to validate self-reported patterns and provide more accurate behavioral data.

The sample size of 63, while adequate for descriptive analysis and the exploratory mixed methods design, provided moderate statistical power (0.78) for the single chi-square test conducted. Although this approaches conventional power thresholds and the observed association was statistically significant (P=.008), larger samples would provide greater power to detect smaller effect sizes and enable the exploration of additional potential associations. The focus on a single inferential test avoided issues with multiple comparisons and type I error inflation.

Data collection occurred during November and December 2024, which may have influenced participants' dietary and shopping behaviors. This period coincides with the end of the fall

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semester, when academic pressures and final examinations peak, potentially affecting cooking frequency, meal planning, and reliance on convenience foods. These seasonal factors should be considered when interpreting the findings, and future research conducted across multiple time points throughout the academic year would provide a more comprehensive understanding of graduate students' typical dietary patterns and food waste behaviors.

This study did not systematically assess contextual environmental factors such as participants' access to kitchen facilities, proximity to grocery stores, or availability of on-campus dining options, all of which may influence cooking frequency, shopping behaviors, and food waste patterns. Additionally, food insecurity status was not assessed although it may moderate both diet quality and waste behaviors. Future research should examine how the campus food environment and food security status shape graduate students' dietary practices and app feature preferences.

Conclusion

This study demonstrates that effective mobile food apps for graduate students must integrate evidence-based nutritional guidance with user-centered design principles that accommodate time constraints, varying cooking skills, and organizational challenges. While graduate students value healthy eating and wish to reduce food waste, practical barriers prevent them from translating intentions into behaviors.

By mapping findings to the COM-B framework and BCTs, this study identified graduate students' needs for app features that simultaneously address capability deficits (eg, nutrition knowledge and cooking skills), opportunity barriers (eg, time constraints and planning challenges), and motivation maintenance (eg, personalization and simplicity). The findings underscore 3 key design principles: first, food apps must function as comprehensive support systems offering personalized dietary guidance, proactive reminders, and waste prevention tools, not merely recipe repositories. Second, adoption and sustained engagement depend heavily on simplicity, multimodal content delivery, and realistic time expectations. Third, features simultaneously addressing both healthy eating and food waste are likely to have synergistic effects, as organized meal planning supports both nutritional goals and resource conservation.

These insights may inform mHealth tool development for other populations, apart from graduate students, facing similar time pressures and organizational challenges, including working adults, parents, and health care professionals. Future work should focus on developing and rigorously testing prototypes that incorporate these user-identified features, evaluating their real-world effectiveness in promoting sustained dietary behavior change and food waste reduction. Cross-sector collaboration involving app developers, nutritionists, behavioral scientists, and student populations will be essential for creating scalable, inclusive digital health solutions that translate user preferences into measurable health and environmental outcomes.

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Data Availability

The datasets generated or analyzed during this study are available from the corresponding author on reasonable request.

Authors' Contributions

Conceptualization: MM
Data curation: MM
Formal analysis: MM
Investigation: MM
Methodology: MM (lead), LFMC (supporting)
Project administration: MM
Resources: MM
Software: MM
Supervision: LFMC
Validation: MM
Visualization: MM
Writing – original draft: MM
Writing – review & editing: MM (lead), LFMC (supporting)

Conflicts of Interest

None declared.

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Multimedia Appendix 1
Survey questions.
[DOCX File, 19 KB - formative_v10i1e84576_app1.docx]

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Abbreviations

BCT: behavior change technique
COM-B: capability, opportunity, and motivation-behavior
mHealth: mobile health
MoSCoW: Must have, Should have, Could have, Won't have
USDA: United States Department of Agriculture

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Comparative Analysis of Japanese Clinical Note Styles Between Physicians and Large Language Models Using Identical Psychiatric Cases: Quantitative Text Analysis

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Abstract

Background: With the rapid adoption of large language models (LLMs) in clinical documentation, it is unclear whether LLMs can faithfully reproduce specialty-specific writing styles and clinically meaningful documentation patterns observed in expert notes, particularly in psychiatry.

Objective: This study aims to systematically compare the narrative styles of human physicians and LLMs when documenting identical psychiatric cases and to evaluate the extent to which LLMs replicate specialty-specific documentation patterns.

Methods: We constructed 2 standardized outpatient scenarios in Japanese (major depressive disorder and schizophrenia) and collected 134 initial notes in Japanese authored by psychiatrists and internists, alongside notes generated by 4 LLMs simulating each specialty. We conducted lexical, syntactic, semantic, and topic-level analyses using Bilingual Evaluation Understudy (BLEU), Recall-Oriented Understudy for Gisting Evaluation–Longest Common Subsequence (ROUGE-L), BERTScore, and Translation Edit Rate (TER), complemented by redundancy metrics and medical term variation analyses.

Results: LLM-generated notes were significantly longer, more repetitive, and lexically less diverse than human-authored notes. TER-based clustering revealed a uniform, template-like writing style in LLMs, diverging from the flexible, context-sensitive style of physicians. Topic modeling suggested that LLM-generated notes tended to rely on more abstract and generalized expressions, with less variation in the distribution and emphasis of documented clinical information.

Conclusions: LLMs can mimic surface-level stylistic features but fall short in reproducing nuanced, context-dependent, diagnostically relevant content typical of expert clinical documentation. Future clinical use will require careful prompt design or fine-tuning to ensure narrative depth, lexical diversity, and clinical relevance.

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KEYWORDS

large language models; clinical documentation; psychiatry; natural language processing; medical informatics

Introduction

Large language models (LLMs) are increasingly being explored in health care for automated documentation, summarization, and decision support [1-7]. Prior work suggests that LLM-generated discharge summaries and notes may achieve acceptable clarity and coverage yet may also omit clinically important details and include redundancy or hallucinations [3,8-14]. The output style varies widely across models and prompt designs [10,15], raising concerns about stability and reproducibility.

Compared with clinical notes written by human physicians, there has been little systematic investigation into the extent to which differences in style and content exist or whether specialty-specific stylistic distinctions are reflected in LLM-generated notes. Although real clinical documentation shows clear stylistic differences across specialties [16-20], it is unclear whether LLMs are capable of reproducing such variations.

In psychiatry in particular, clinical notes are primarily structured around patients' subjective reports and clinicians' interpretations, meaning that differences in style and perspective carry direct clinical implications [21]. Psychiatric notes typically integrate not only descriptions of symptoms but also clinical reasoning and risk assessment [22]. Whether an LLM can accurately reproduce such documentation styles directly affects treatment planning, information sharing within the care team, the quality of medical education, and ultimately patient safety [11]. Conversely, if an LLM fails to faithfully imitate the style

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of psychiatrists, serious clinical risks may arise, including (1) misrepresentation or omission of risk-related information such as suicidal ideation or hallucinations and delusions, which could compromise clinical judgment and patient safety; (2) misunderstandings in multidisciplinary communication, which could reduce the quality of team-based care; and (3) adoption of inappropriate documentation styles by learners, resulting in educational disadvantages [23]. Therefore, verifying LLM-generated clinical notes is not merely a technical comparison but also meaningful from the perspectives of real-world clinical practice, patient safety, and education.

To facilitate a systematic comparison, this study evaluated clinical notes along several analytic dimensions. Specifically, we examined syntactic characteristics, lexical diversity, patterns of redundancy, and topic structure using multiple quantitative natural language processing (NLP)–based metrics. These dimensions were selected to capture complementary aspects of documentation style without presupposing normative judgments about clinical quality.

Against this background, this study aimed to clarify the differences in documentation styles between physicians and LLMs when describing identical psychiatric cases. To this end, we created standardized case scenarios using LLMs and adopted a comparative analytic approach to evaluate initial outpatient notes written by both physicians and LLMs. Through this analysis, we sought to reveal specialty- and generator-specific characteristics and clinical foci, thereby contributing foundational knowledge for future AI-assisted clinical documentation, NLP applications, and educational use.

Therefore, the aim of this study was not to evaluate the maximal performance of clinically fine-tuned language models but rather to examine the extent to which currently available general-purpose LLMs can acquire and reproduce psychiatric documentation styles without additional domain-specific training. This design choice was motivated by our interest in examining how much clinical documentation style can be elicited from general-purpose LLMs through simple role-based prompting alone, without relying on domain-specific fine-tuning.

Methods

Language of Materials and Analysis

All study materials and outputs were handled exclusively in Japanese. The standardized case scenarios were prepared in Japanese and presented to clinicians in Japanese. All LLMs were prompted in Japanese and produced Japanese outputs, and the clinician-authored free-text notes were analyzed in their original Japanese form. No translation to or from English was performed at any stage of model prompting, clinician instruction, or quantitative analysis. For readability and accessibility for an international audience, English translations of representative case scenarios, prompts, and example clinical notes are provided in Multimedia Appendix 1; these are for reference purposes only and were not used in any stage of the study.

Study Design and Materials

First, we constructed two psychiatric outpatient scenarios (depression and schizophrenia) in standardized Japanese, based on items from the Japanese National Medical Licensing Examination (111th B-47 and 112th D-35). These 2 conditions were selected as diagnostically distinct yet prototypical psychiatric presentations, allowing for controlled comparison across specialties and models. The scenarios were intentionally designed to be relatively simple and to limit comorbidities, in order to minimize the confounding effects of case complexity and to focus the analysis on documentation style rather than clinical content heterogeneity. Drafts were generated with assistance from GPT-4o (OpenAI) and subsequently standardized and verified by 2 physicians. During this process, the physicians examined the content for clinical plausibility, internal consistency, and unnatural phrasing that could reflect model-specific artifacts. These scenarios were not intended to represent clinical ground truth or a gold standard but rather to serve as standardized, privacy-preserving reference cases for controlled comparisons of documentation styles. Next, psychiatrists and internists were asked to write free-text initial consultation notes in Japanese for each scenario. They were explicitly informed that the scenarios had been generated with the assistance of an LLM and were instructed to treat them as real clinical cases, freely modifying, supplementing, or correcting the content as needed, including addressing missing or unrealistic elements. In addition, 4 LLMs were given the same case scenarios and instructed to generate clinical notes, using the prompt shown in Textbox 1. The only difference from the physician instructions was the role designation at the beginning; otherwise, the text was identical.

The overall study workflow is shown in Figure 1.

Textbox 1. Clinical note generation prompt (English translation of the original Japanese prompt)

You are a psychiatrist (or an internist). Based on the scenario, please create an initial psychiatric outpatient note (summary). The format can follow the conventions of your institution. If there are missing elements (eg, differential diagnoses, questions needed to guide treatment) or unnatural aspects, please supplement or revise the content based on your clinical experience and reflect this in the note.

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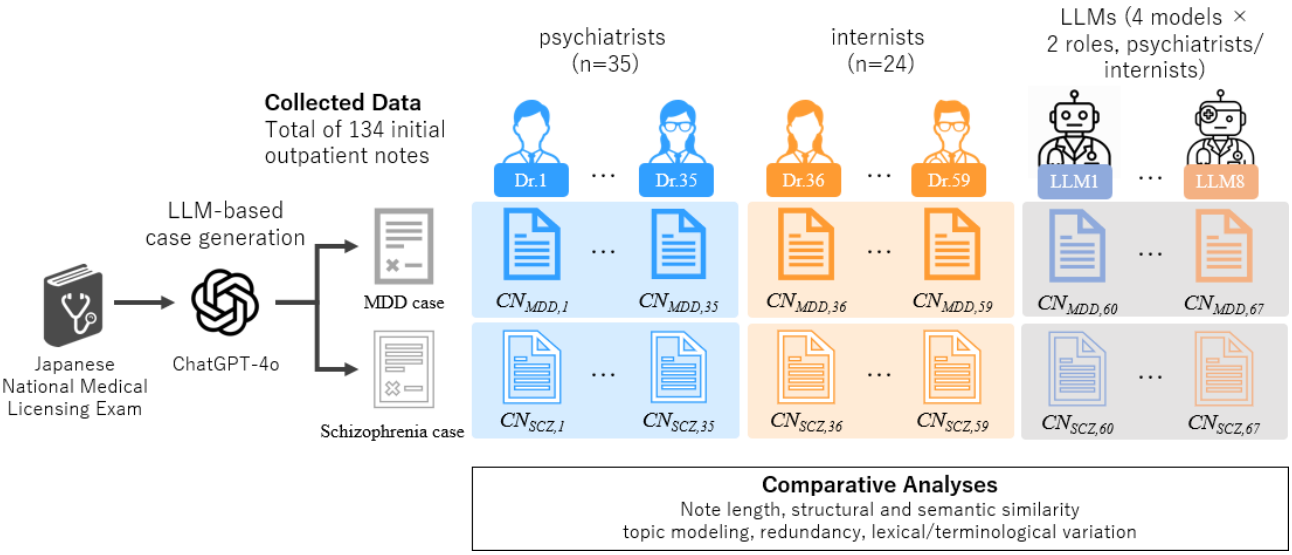
Figure 1. Overall study workflow: from case creation to note collection and analytic procedures. LLM, large language model; MDD, major depressive disorder; CN, clinical note.



Participants and Models

Physicians were recruited via the medical research platform m3.com. A total of 35 practicing psychiatrists and 24 internists participated in the study. The LLMs used in this study included widely available cloud-based models (GPT-4o and Claude Sonnet 4 [Anthropic]), as well as Japan-compatible local models suitable for medical applications (ELYZA/LLaMA3-8B [ELYZA, Inc] and DeepSeek-R1/Qwen-14B [CyberAgent, Inc]). This selection allowed comparisons from both performance and practical applicability perspectives. All models were run with their publicly available default parameters. The local models were executed via LM Studio (version 0.3.22). Generation parameters were user controllable and were fixed at temperature=0.8, top_p=.95, context length=4096, and repeat penalty=1.1 for all experiments. Text generation was performed using standard stochastic sampling, without greedy decoding or beam search. The cloud models were accessed through their graphical user interface versions, which do not permit user modification of generation parameters, and thus were used with default configurations.

Each physician and each LLM produced notes for both the depression and schizophrenia cases. In total, 70 psychiatrist notes, 48 internist notes, 4 LLM psychiatry-style notes, and 4 LLM internal medicine–style notes were collected. Excerpts from psychiatrist and internist notes for the depression and schizophrenia cases are presented in Table 1.

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Table . Representative excerpts from physician-authored initial notes.

Case	Physician attributes	Note excerpt
Depression	In their 50s; board-certified psychiatrist	• HPI[a]: after promotion to section chief, depressive mood worsened with increased work errors, dizziness, fatigue, insomnia, and appetite loss; an occupational physician recommended a psychiatry referral; mild suicidal ideation without a specific plan • Assessment and plan: suspect major depressive disorder; provide supportive psychotherapy; consider an antidepressant; discuss workload adjustment including possible sick leave
Depression	In their 50s; general internist	• S[b]: insomnia, fatigue, appetite loss, suicidal ideation • O: appears depressed • A: stress-related depressive state after promotion is suspected. • P: SSRI[c] + environmental adjustments
Schizophrenia	Man in his 20s; board-certified psychiatrist	• HPI: 1 week of insomnia and odd behaviors after a graduate-school entrance exam; found pacing and muttering for about 3 hours, poor eye contact, intermittently responding to unseen stimuli • Workup: laboratory tests, brain MRI[d], and EEG[e] unremarkable • Assessment: schizophrenia spectrum disorder versus unspecified psychotic disorder • Plan: supportive psychotherapy, consider antipsychotic, psychoeducation for family, follow-up and possible psychological testing
Schizophrenia	In their 50s; general internist	• S: hallucinations, delusions • O: communication is difficult • A: schizophrenia suspected • P: atypical antipsychotic + psychosocial support

[a]HPI: history of present illness.

[b]SOAP: subjective, objective, assessment, and plan.

[c]SSRI: selective serotonin reuptake inhibitor.

[d]MRI: magnetic resonance imaging.

[e]EEG: electroencephalogram.

Conceptualization of Documentation Characteristics in Psychiatric Notes

Clinical reasoning in psychiatry extends beyond factual reporting and encompasses hypothesis generation, differential diagnosis, structured risk formulation, and justification of clinical decisions [24-26].

However, written clinical notes do not directly represent these internal cognitive processes; rather, they constitute narrative documents through which clinicians organize, emphasize, and integrate patient information. Accordingly, this study did not attempt to measure clinical reasoning itself. Instead, we focused on observable linguistic and structural characteristics of documentation, operationalized using a set of complementary NLP metrics. Structural edit patterns, topic dispersion, lexical specificity, and redundancy were treated as descriptive indicators of how information is distributed, repeated, and integrated within clinical notes. For example, topic dispersion and lexical specificity were interpreted as reflecting the breadth and focus of documented clinical concerns, while structural edit patterns and redundancy patterns captured the extent to which information is synthesized versus descriptively repeated.

This documentation-centered operationalization enabled a systematic comparison of note-writing styles across human- and LLM-authored records, without assuming that these linguistic features constitute validated proxies for underlying reasoning quality or internal cognitive processes.

Importantly, although certain analyses (eg, topic modeling and term frequency-inverse document frequency [TF-IDF] of diagnostic terms) involved lexical and thematic content, they were interpreted in this study as indicators of how information

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was distributed, emphasized, and structured within the document rather than as evaluations of diagnostic accuracy or substantive clinical correctness. Accordingly, our focus remained on observable documentation patterns rather than on the validity or quality of clinical reasoning itself.

Analytic Overview

We conducted multidimensional analyses of length, lexicon, syntax, semantics, topics, redundancy, and term variation [14,27]. This multimetric analytic framework enabled a quantitative comparison of documentation styles while maintaining clinical interpretability, helping to distinguish surface-level textual similarity from patterns that reflect how clinically relevant information is organized and emphasized in psychiatric notes. The clinical interpretation of each NLP metric used in this study is summarized in Table 2.

Table . Clinical interpretation of natural language processing metrics in psychiatric clinical notes.

Metric	Captured textual dimension	Intended clinical interpretation
TER[a]	Structural divergence between texts	Degree of structural divergence between notes; reflects how much rewriting is required to transform one note into another
BLEU[b]/ROUGE-L[c]	Surface-level n-gram overlap	Similarity of phrasing and boilerplate expressions
BERTScore	Semantic similarity	Preservation of overall clinical meaning independent of wording
TF-IDF[d]	Lexical specificity	Use of diagnostically and clinically salient terminology
Topic modeling (LDA[e])	Thematic structure	Breadth and focus of clinical concerns addressed in the note
Redundancy metrics	Information compression versus repetition	Balance between concise synthesis and template-driven verbosity
Medical term variation	Terminological consistency and variability	Variability in diagnostic and risk-related terminology, reflecting diagnostic precision, risk framing, and alignment with psychiatric conventions

[a]TER: Translation Edit Rate.

[b]BLEU: Bilingual Evaluation Understudy.

[c]ROUGE-L: Recall-Oriented Understudy for Gisting Evaluation–Longest Common Subsequence.

[d]TF-IDF: term frequency-inverse document frequency.

[e]LDA: latent Dirichlet allocation.

With respect to LLM-generated notes, to reduce model-specific idiosyncrasies and focus on role-level tendencies, we aggregated the results of all 4 LLMs within each prompted role.

Descriptive Statistics

We computed note length statistics such as mean, median, and variance by specialty and generator, and we tested group differences using *t* tests and ANOVA for each scenario. Because the number of LLM-generated notes per model was small (n=2 per condition), we used nonparametric tests (Mann-Whitney U test) and reported effect sizes using Cliff delta. These analyses were intended as descriptive sensitivity analyses rather than definitive inferential tests.

Syntactic-Semantic Similarity

To compare the syntactic structures and semantic features of clinical notes, we computed pairwise sentence-level similarity across notes and visualized the results using hierarchical clustering. We used four metrics commonly used in NLP for sentence similarity evaluation:

- Translation Edit Rate (TER): TER evaluates structural similarity based on the number of editing operations (insertion, deletion, substitution, reordering) required to transform one sentence into another [28]. It is defined as follows (lower values indicate higher structural similarity to the reference sentence):

$$\text{TER} = \frac{\text{Number of edits}}{\text{Number of words in reference sentence}}$$

- Bilingual Evaluation Understudy (BLEU): BLEU is a machine translation evaluation metric based on n-gram overlaps and reflects the local syntactic consistency of sentences [29]. Higher values indicate a higher syntactic similarity to the reference.
- Recall-Oriented Understudy for Gisting Evaluation–Longest Common Subsequence (ROUGE-L): ROUGE-L measures syntactic overlap between 2 sentences based on the length of the longest common subsequence [30]. Higher values indicate a higher syntactic similarity.
- BERTScore: It assesses semantic similarity by comparing token embeddings generated by a pretrained bidirectional encoder representations from transformers (BERT) model [31]. Higher values indicate higher semantic similarity. BERTScore was computed using the bert-score package (version 0.3.13;[32]), with the language set to Japanese (lang="ja") and the pretrained model set to xlm-roberta-large (model_type="xlm-roberta-large"). We

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used the F_1-score for analysis, with batch_size=32 and computation performed on the specified device (central processing unit/graphics processing unit).

Using these metrics, we calculated pairwise similarity between notes. For each pair of notes denoted as CNA and CNB, when the metric produced directional scores such as TER and BLEU, we averaged the scores in both directions (CNA→CNB and CNB→CNA) to determine the similarity. Accordingly, we interpreted TER as a measure of overall structural divergence between 2 notes rather than as a unidirectional indicator of overdocumentation or underdocumentation. For each metric, a distance matrix was constructed from the similarity scores, and hierarchical clustering using Ward's [33] method was applied. This enabled the grouping of notes on the basis of their syntactic and semantic tendencies. We first normalized all texts using Unicode normalization (NFKC), standardized white space, and removed Japanese punctuation marks. We then tokenized the Japanese text using MeCab (version 0.996; developed by Taku Kudo) to obtain white space–separated tokens for the metric computations. Although BLEU and ROUGE-L were originally developed for machine translation and summarization tasks, respectively, in this study, they were used in a descriptive manner to quantify the surface-level n-gram overlap and reuse of stereotyped phrasing between texts rather than to assess translation or summarization quality. These metrics have known limitations in evaluating free-text clinical documentation, as they emphasize surface-level n-gram overlap and may not fully capture higher-order discourse structure or clinically meaningful nuance. Therefore, in this study, they were used strictly as descriptive indicators rather than as comprehensive quality measures.

Lexical Analysis

We evaluated the lexical usage patterns across the entire set of notes using TF-IDF [34]. This is a weighted measure calculated as the product of a term's frequency in a document and the inverse document frequency, which reflects how specific the term is across the full set of documents:

$$\text{TF-IDF}(t,d)=\text{TF}(t,d)\times\log\text{NDF}(t)$$

Here, t denotes a term, d denotes a document, N is the total number of documents, TF(t,d) denotes the number of times the term *t* appears in document *d*, and DF(t) is the number of documents containing the term t. On the basis of this definition, the Japanese texts were tokenized using SudachiPy (version 0.6.10; Works Applications Co, Ltd), with rule-based merging of multiword medical expressions and removal of non-informative tokens. TF-IDF features were then computed using scikit-learn (version 1.6.1) [35]. To ensure the comparability of TF-IDF values across groups, we concatenated all documents from the 4 groups and fitted a single TF-IDF vectorizer on the combined corpus so that the vocabulary and IDF weights were shared across all groups. We then computed the mean TF-IDF score for each term within each group and reported the top-ranked terms accordingly.

Topic Modeling

We applied latent Dirichlet allocation (LDA) [36] to visualize thematic tendencies, normalizing the topic scores by group size.

Medical Term Variation

Using the standardized medical dictionary JMED-DICT [37], we extracted medical terms such as disease and symptom names from the notes and analyzed the variation in their lexical forms by specialty and by author type, comparing human physicians with LLMs. For this analysis, we focused specifically on lexical variants related to "depressive state," including "depressed mood," "loss of motivation," "depression," "depressive state," and "major depressive disorder." The diversity of expressions for medical terms was quantified using lexical entropy, also known as Shannon entropy, which measures the variation in lexical forms used for the same medical concept. A larger value indicates greater diversity of expressions. Lexical entropy is defined as

$$H=-\sum i=1npilog2pi$$

where pi represents the probability of occurrence of lexical form i.

Redundancy

To quantitatively compare redundancy in clinical notes across specialties and author types, we evaluated repetition and lexical diversity biases in the text using the following 6 metrics; these measures are effective for capturing structural repetition and lexical limitation or excess:

- Number of sentences: The text was segmented by periods or line breaks into sentences, and the total number of sentences was counted.
- Lexical diversity (type-token ratio; TTR): The proportion of unique words to the total number of words was calculated. Lower values indicate more lexical repetition and thus higher redundancy.

$$\text{TTR}=\text{Number of unique words}\text{Total number of words}$$

- Inter-sentence similarity: The semantic similarity between sentence vectors within the same text was measured. Each sentence was vectorized using TF-IDF, and redundancy was evaluated with the average cosine distance between sentences.

$$\text{Redundancy}=1-\text{Average cosine distance}$$

- Compression ratio: The text was compressed using the DEFLATE algorithm, which combines LZ77 and Huffman coding, and the ratio of compressed to original size was calculated. Redundant text is compressed more efficiently, resulting in a lower compression ratio.

$$\text{Compression ratio}=\text{Compressed size}\text{Original size}$$

- Unique words per sentence: The average number of unique words per sentence was calculated to evaluate the lexical density. Lower values indicate that sentences are composed of limited vocabulary and thus exhibit higher redundancy.
- Bigram duplication rate: The proportion of repeated adjacent 2-word sequences (bigrams) in the text. Higher values indicate stronger tendencies toward lexical repetition.

$$\text{Duplication rate}=1-\text{Number of unique bigrams}\text{Total number of bigrams}$$

These metrics allow an objective evaluation of redundant vocabulary and sentence structures in clinical notes and provide

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insights into stylistic differences across specialties and author types. From a clinical documentation perspective, these redundancy patterns describe how information is distributed and repeated within notes, without directly assessing informational value or clinical adequacy.

Ethical Considerations

This study did not involve real patient data. All clinical cases used in the analysis were fully simulated scenarios created for research purposes and did not contain any identifiable personal information.

The physician-authored clinical notes were collected from licensed medical doctors who voluntarily participated in the study through an online medical research platform (m3.com). Informed consent was obtained from all participating physicians prior to data collection, and participants were informed of their right to withdraw or opt out of the study at any time without any consequences. No patient-related information was included, and all physician responses were anonymized before analysis.

Because the study involved only simulated clinical cases and anonymous textual data provided by consenting medical professionals, it did not constitute research involving human subjects under institutional regulations. According to Article 4 of the "Regulations on Life Science and Medical Research Involving Human Subjects" of Nara Institute of Science and Technology (NAIST) [38], studies that do not involve human participants, biological samples, or identifiable personal information fall outside the scope of human subject research and are not subject to institutional review board (IRB) review. As this study used fully synthetic case scenarios and did not include any patient data or identifiable personal information, formal IRB approval was not required.

Results

Descriptive Statistics

This subsection summarizes the quantitative differences in note length across specialties and generating agents, providing a baseline characterization of documentation volume before examining the structural and semantic features.

For both the depression and schizophrenia cases, we compared the length of notes between groups. Figure 2 visualizes the full distribution and dispersion of note lengths, highlighting the variability and overlap across specialties and generating agents that are not fully captured by mean values alone. We calculated the mean, median, and variance and assessed the statistical significance of group differences using ANOVA 2-tailed *t* tests. As a result, clear differences in note length were observed across groups for both depression ($F_{3,130}$=27.08, P<.001) and schizophrenia cases ($F_{3,130}$=25.73, P<.001). In contrast, no significant differences were found between LLM-psychiatry and LLM-internal medicine notes for either depression (t_6=0.38, P=0.72) or schizophrenia (t_6=–0.28, P=0.79). Further comparisons of note length across individual LLM models (Figure 3) showed that Claude Sonnet 4 produced the longest outputs, followed by GPT-4o, DeepSeek-R1/Qwen-14B, and ELYZA/LLaMA3-8B in decreasing order of mean length. Figure 3 enables a direct visual comparison of length variability across individual LLMs, complementing the aggregated analyses presented in Figure 2. Claude Sonnet 4 also exhibited a larger SD than the other models, suggesting greater variability in its outputs. These findings indicate that note style and information density varied across different LLM models.

To examine whether the observed differences in note length were driven by a specific LLM, we conducted model-wise comparisons between clinician-authored notes and notes generated by each LLM independently using the Mann-Whitney U test. Effect sizes were quantified using Cliff delta. Across all evaluated models, LLM-generated notes were consistently longer than clinician-authored notes for both depression and schizophrenia cases (all Cliff $\delta \geq 0.86$). These differences remained consistent after false discovery rate correction, and effect sizes were large across all evaluated models. These findings indicate that the aggregated length differences observed in Figures 2 and 3 were not driven solely by a single model (eg, Claude Sonnet 4) but reflected a consistent pattern across all tested LLMs.

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Figure 2. Note length distributions by specialty and generator for depression (A) and schizophrenia (B). LLM, large language model.

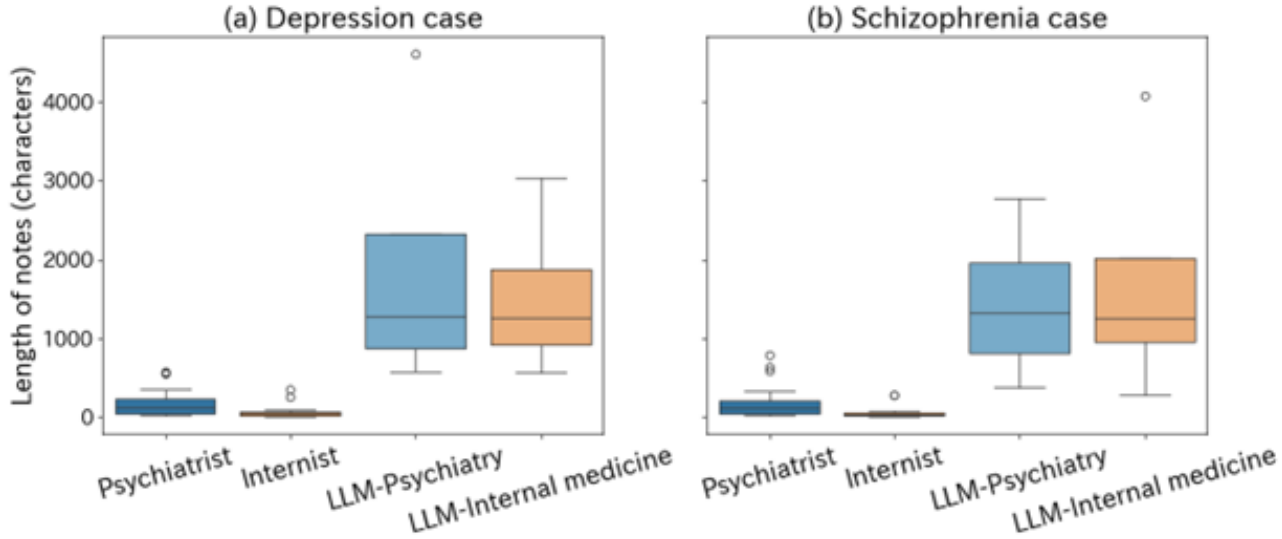
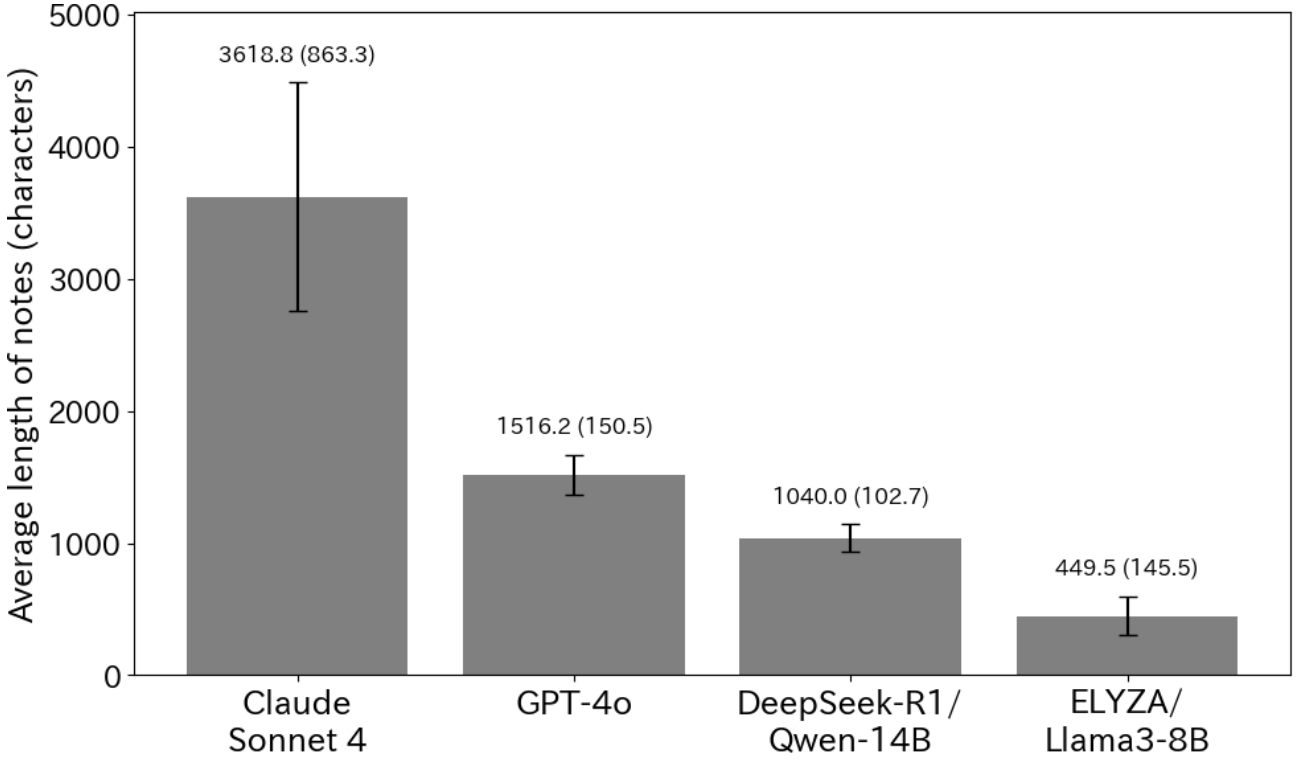


Figure 3. Mean (SD) note length by large language model.



Given the small number of LLM-generated notes per condition (n=4 per role), these statistical comparisons should be interpreted as exploratory and primarily descriptive rather than confirmatory population-level inferences. Accordingly, the reported *P* values and effect sizes are presented to characterize the distributional tendencies within the sampled texts rather than to support definitive generalizable claims.

Syntactic and Semantic Similarity

This subsection describes how clinical notes clustered according to syntactic and semantic similarity, to clarify whether differences in documentation style across specialties and generators were reflected in structural edit patterns and surface-level phrasing.

In the clustering based on TER, the differences in charting style across specialties and generating agents were clearly reflected (Figure 4). This figure provides a structural, distance-based visualization of documentation styles, revealing systematic separation patterns that are not apparent from pairwise similarity scores alone. In both the depression and schizophrenia cases, psychiatrists' notes and internists' notes written by human physicians formed distinct clusters, and this difference in syntactic features consistently appeared regardless of the case. Of particular note is that the notes generated by LLMs diverged substantially from those written by human physicians, with LLM-psychiatry and LLM-internal medicine each forming their own independent clusters. This suggests a tendency for LLM-generated notes to exhibit generation styles and sentence structures that differ from those of human physicians' records.

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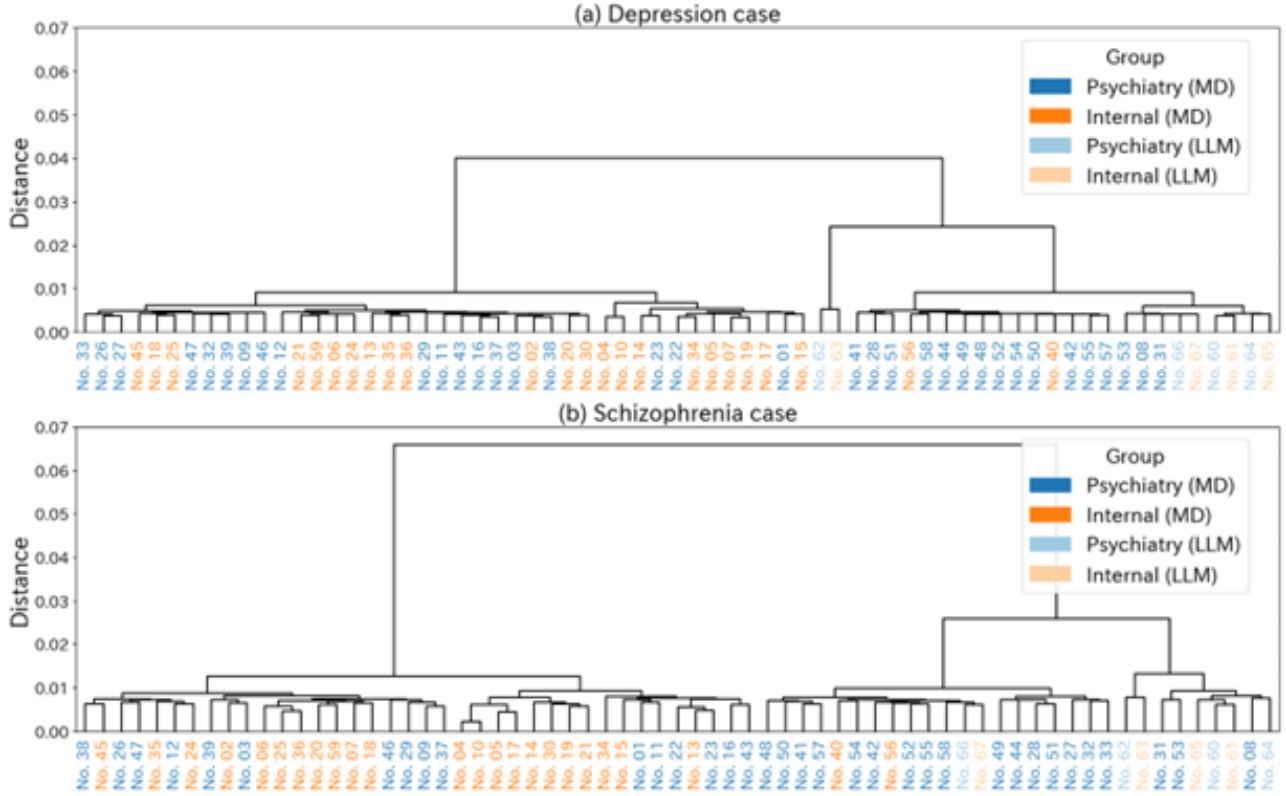
In contrast, hierarchical clustering based on surface-level n-gram similarity using BLEU or ROUGE-L did not produce a clear separation between clinician-authored and LLM-generated notes (Appendix D—Figures S1 and S2 in Multimedia Appendix 1), suggesting that these metrics were less sensitive to structural differences in charting style. Clustering based on BERTScore, which reflects proximity in contextual embedding space, resulted in substantial cross-specialty and cross-agent mixing (Appendix D—Figure S3 in Multimedia Appendix 1). This finding indicates that shared diagnostic terminology and case descriptions may dominate embedding-based similarity and should be interpreted as reflecting relative semantic relatedness rather than similarity in clinical reasoning or documentation intent.

Figure 4. Hierarchical clustering of clinical notes based on syntactic similarity (Translation Edit Rate) for the depression case (A) and schizophrenia case (B). MD, human physician; LLM, large language model.



The factors behind the clear separation achieved by TER include its high sensitivity to syntactic changes such as word order, insertion, and deletion, in addition to the influence of differences in text length. In this study, we also independently calculated the relative numbers of insertions, deletions, and substitutions, normalized by the reference sentence length, and compared them across specialties and generating agents. Shift operations were not considered due to computational cost. The comparison results are shown in Table 3.

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Table . Average relative values of each editing operation (per sentence length) across specialties and generating agents.

Comparison groups	Insertion	Deletion	Substitution
Psychiatrists-Psychiatrists	2.41	0.13	0.71
Internists-Internists	2.20	0.10	0.76
Psychiatrists-Internists	3.89	0.12	0.70
Psychiatrists-LLM[a] Psychiatry	20.81	0.00	0.63
Psychiatrists-LLM Internal Medicine	15.05	0.00	0.64
Internists-LLM Psychiatry	49.56	0.00	0.50
Internists-LLM Internal Medicine	36.20	0.00	0.49
LLM Psychiatry-LLM Psychiatry	0.42	0.46	0.42
LLM Psychiatry-LLM Internal Medicine	0.25	0.37	0.47
LLM Internal Medicine-LLM Internal Medicine	0.17	0.38	0.50

[a]LLM: large language model.

As a result, among human physicians (psychiatry-psychiatry, internal medicine-internal medicine), editing operations were relatively few, indicating stable charting styles. In contrast, between human physicians and LLMs, the average relative numbers of insertions were remarkably high, with that for internal medicine physicians and LLM-psychiatry reaching an outstanding 49.56. This suggests that LLMs tend to include more information than human physicians. The frequencies of deletions and substitutions were relatively stable, indicating that the differences in information presence (particularly the number of insertions) contributed most strongly to increasing the structural distance measured by TER. Furthermore, in comparisons among LLMs, the relative numbers of insertions were extremely low (around 0.2 - 0.4), indicating similarity in text length, whereas the frequencies of deletions and substitutions were somewhat higher, reflecting stylistic differences in syntax and word order.

Taken together, syntactic distance based on TER served as a descriptive indicator of differences in charting styles across specialties and generating agents, highlighting structural characteristics that differed between LLM-generated and human-authored notes. These results suggest that TER is a useful descriptive metric for characterizing chart structure in medical notes, particularly when interpreted alongside complementary lexical and semantic analyses.

Because the number of LLM-generated notes per condition was limited, these clustering patterns should be interpreted as descriptive structural tendencies rather than statistically validated group separations. The results therefore characterize relative distributional patterns within the present sample rather than population-level distinctions.

Lexical Analysis

Analysis of Differences in Vocabulary Usage

This subsection outlines the differences in vocabulary usage across specialties and generating agents using TF-IDF, highlighting how clinically salient terms are distributed and emphasized in each group.

Using the TF-IDF scores, we analyzed the differences in vocabulary usage across specialties and generating agents, comparing human physicians and LLMs, as shown in Table 4 and Multimedia Appendix 1 (Appendix D—Table S1).

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Table . Top TF-IDF[a]–weighted terms by group for the depression case.

Group	TF-IDF
Psychiatrists	
Decrease	0.083
Depression	0.074
None	0.064
Initiation	0.063
Symptoms	0.055
Suicidal ideation	0.055
Mood	0.053
Therapy	0.054
Depression (disease)	0.053
Mental	0.048
Internists	
Depression	0.099
Condition	0.099
Suicidal ideation	0.095
SSRI	0.075
Insomnia	0.058
Male	0.054
Mild	0.056
Depression (term)	0.064
Initiation	0.058
45	0.070
LLM[b] psychiatry	
Family	0.138
Mental	0.112
Symptoms	0.107
Patient	0.102
Evaluation	0.084
Decrease	0.085
Treatment	0.081
Disorder	0.079
Function	0.077
Tendency	0.076
LLM internal	
Family	0.168
Patient	0.146
Symptoms	0.142
Necessary	0.120
Diagnosis	0.105
None	0.112
Effect	0.105

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Group	TF-IDF
Function	0.100
Test	0.099
Mental	0.099

[a]TF-IDF: term frequency-inverse document frequency.

[b]LLM: large language model.

Depression Case

In the notes written by psychiatrists, terms such as “decrease,” “depression,” “mood,” and “suicidal ideation” appeared with high scores, reflecting emotional changes and psychiatric symptoms. In addition, words such as “initiation,” “therapy,” and “mental” were also included, focusing on treatment initiation and psychological aspects. In the notes written by internists, terms such as “condition,” “SSRI,” “insomnia,” and “mild” were more common, reflecting standardized vocabulary related to clinical findings and treatment content. In LLM-generated notes, the psychiatry-style outputs contained many abstract terms such as “family,” “mental,” “symptoms,” and “evaluation.” While structurally mimicking psychiatric-style records, they lacked clinical specificity. Similarly, in the internal medicine–style outputs, many generic terms such as “family,” “patient,” “necessary,” and “symptoms” were observed, which differed from the vocabulary actually used by human internists.

Schizophrenia Case

In the notes written by psychiatrists, the high-scoring and frequently occurring words included “schizophrenia,” “mental,” “auditory hallucination,” “risperidone,” and “behavior,” reflecting diagnostic reasoning, clinical observations, and medication names. By contrast, internists often used standardized terms such as “schizophrenia,” “suspected,” “typical,” “oral medication,” and “abnormal,” focusing primarily on diagnostic labels and treatment actions. In the LLM psychiatry–style notes, more general and abstract words such as “family,” “mental,” “symptoms,” and “university” appeared, while symptom descriptions and drug names, which were common in psychiatrist-authored notes, were scarce. A similar vocabulary pattern was observed in the LLM internal medicine–style outputs.

Overall Considerations

In human-authored notes, psychiatrists tended to use context-dependent and multidimensional vocabulary to describe patients’ subjective experiences and the treatment process, whereas internists emphasized objective findings and standardized judgments. LLMs partially mimicked these stylistic features, but their outputs tended to converge on frequently used and generic words such as “family” and “mental.” This suggests that LLM-generated notes were prone to rely on standardized and generalized vocabulary. TF-IDF–based lexical analysis was shown to be an effective method for visualizing and quantifying such stylistic differences in clinical documentation.

Topic Analysis

This subsection outlines the thematic tendencies in clinical notes using topic modeling, illustrating how different generators and specialties allocate attention across abstract descriptions, diagnostic reasoning, and observed findings.

We conducted a topic analysis using LDA on all clinical notes generated by psychiatrists, internists, and LLMs for the 2 cases of depression and schizophrenia, identifying 3 major topics. As shown in Figure 5, the distribution of average topic scores clearly reflected differences across generating agents and medical specialties. Figure 5 highlights how thematic emphasis differs across groups at an aggregate level, offering an interpretable overview that complements the term-level results reported in Table 5. The representative words and summaries of each topic are presented in Table 5.

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Figure 5. Topic distributions by specialty and generating agent (depression and schizophrenia cases) based on latent Dirichlet allocation. LLM, large language model.

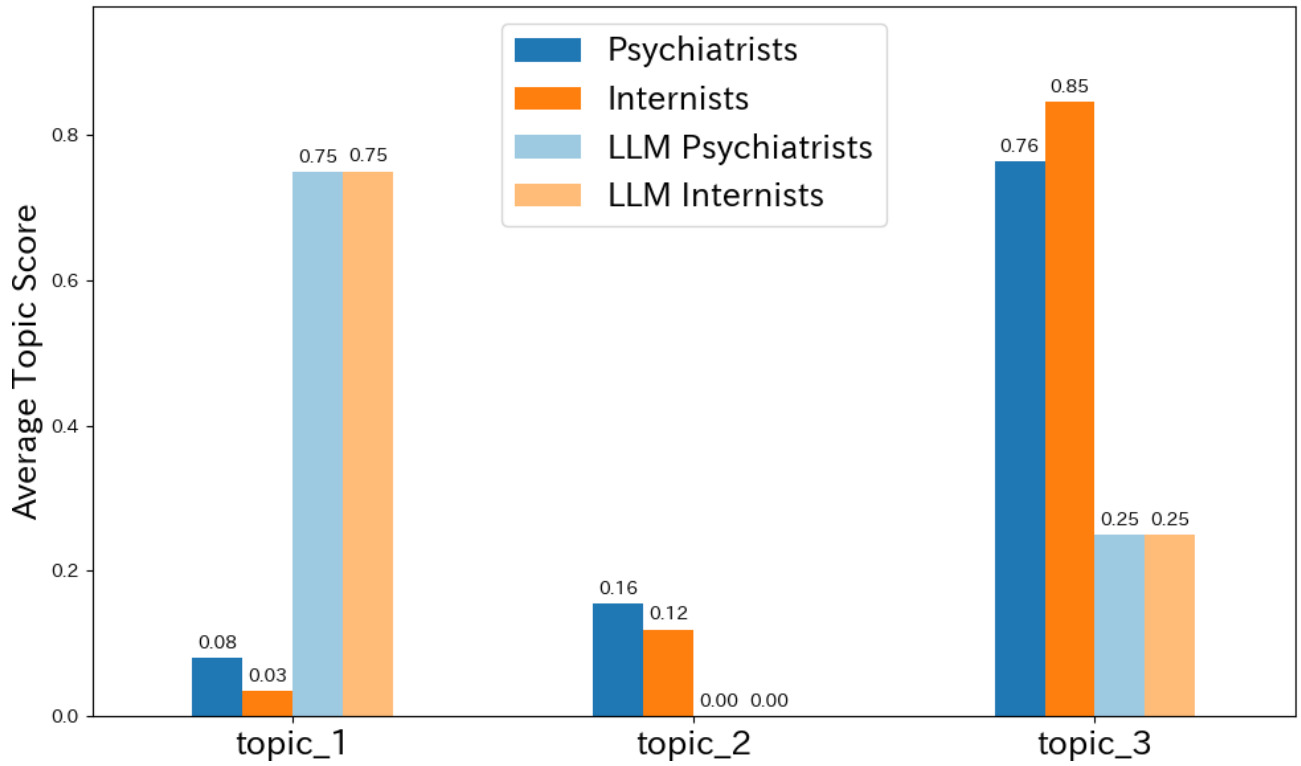

Table . Topics and associated words.

Topic	Associated words (top contributors)
Topic 1 (abstract and comprehensive description)	Mental, family, symptoms, none, disorder, treatment, evaluation, diagnosis, behavior, physical
Topic 2 (diagnostic reasoning and treatment planning)	Mental, condition, treatment, future, therapy, depression, course, suicidal ideation, medication, hallucination
Topic 3 (observed findings and stereotyped records)	None, insomnia, initiation, schizophrenia, symptoms, depression, suicidal ideation, condition, male, abnormal

Since topic scores depend on the number of words and notes, we calculated the normalized average scores for each specialty and generating agent for comparison (Figure 5). The results showed that psychiatrists had high scores in topic 2 (diagnostic reasoning and treatment planning) and topic 3 (observed findings and stereotyped records), suggesting that their documentation was based on both symptom observation and clinical reasoning. In contrast, internists exhibited an extreme bias toward topic 3, focusing primarily on stereotyped documentation of observed findings, with limited engagement in psychiatric symptoms or treatment planning.

Meanwhile, LLM-generated notes (for both psychiatry and internal medicine) were markedly biased toward topic 1 (abstract and comprehensive description), converging on template-like descriptions centered on frequent terms such as “family,” “mental,” and “none.” These results suggest a descriptive pattern in which LLM-generated notes tended to converge on abstract and generalized expressions, whereas human physicians’ notes more frequently reflected context-dependent descriptions and discipline-specific emphases.

Expression Style and Diversity of Medical Terms

This subsection focuses on the variation in lexical expressions for equivalent medical concepts, using lexical entropy to compare terminological diversity across specialties and generators.

As a preliminary examination of lexical diversity, this study focused on the variation of expressions related to “depressive state” and compared the differences in word forms across medical departments and generation sources. Using a normalized medical dictionary, we extracted word forms judged to be semantically equivalent to “depressive state” and calculated the lexical entropy based on the frequency of each word form. As a result, the medical records written by psychiatrists exhibited the greatest diversity of expressions, with a lexical entropy of **3.206**. Specifically, a variety of terms such as “depression,” “depressed mood,” “depressive mood,” “depressive state,” “depressive symptoms,” and “melancholy” were observed. In contrast, internists used only limited and formulaic expressions such as “depressive state,” “depression,” or “depressive condition,” yielding a lower entropy of **2.000**.

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In the LLM-generated records, the psychiatric style showed an entropy of **2.653**, while the internal medicine style showed an entropy of **2.322**. These values indicate an intermediate level of lexical diversity compared with human physicians. Nevertheless, the range of lexical choices remained restricted. These results suggest that in psychiatry, even for the same medical concept, physicians tend to flexibly choose expressions according to the patient's wording and context. Although the outputs of LLMs partially imitate this tendency, they still show a bias toward template-like usage.

Redundancy Analysis

This subsection focuses on redundancy and information density in clinical notes using multiple complementary metrics, clarifying whether increased length corresponds to effective information integration or repetitive structure.

To quantitatively evaluate the redundancy, information density, and lexical diversity in medical records, we analyzed each group's documentation using 6 linguistic indicators (Figure 6). This figure integrates multiple redundancy-related metrics into a single visual summary, facilitating a cross-metric comparison of repetition and information density that would be difficult to infer from individual statistics alone. The records generated by LLMs exhibited markedly different characteristics from those written by human physicians across all indicators. In particular, the number of sentences was highest in both psychiatric and internal medicine styles, suggesting a tendency for LLM-generated records to become lengthy. In contrast, the lexical diversity and number of unique words per sentence were notably low, strongly indicating structural repetition and lexical redundancy. For redundancy-related indicators such as inter-sentence similarity, bigram repetition rate, and compression ratio, the LLM groups also showed higher values (or lower compression ratios). This suggests that a reliance on specific template structures and frequent reuse of expressions may limit the effective density of information.

On the other hand, human physicians' records—especially those generated by psychiatrists—demonstrated higher lexical diversity and more unique words per sentence, providing dense, multifaceted information despite being relatively concise. Records written by internists were generally shorter and relied more on standardized phrasing; however, unlike LLM outputs, they displayed lower repetitiveness and thus higher informational efficiency. These findings suggest that while LLM-generated medical documents may superficially contain abundant information, they exhibited lower lexical diversity and higher repetition across multiple redundancy-related indicators, compared with human-authored notes. This highlights important areas for improvement in the future application of LLMs to medical documentation.

To assess whether these redundancy-related differences could be explained by sample size imbalance alone, we conducted a bootstrap-based sensitivity analysis in which physician-authored notes were repeatedly downsampled to match the LLM sample size (n=4). Several key redundancy metrics (eg, BigramRepetition and UniqueTokensPerSentence) remained systematically more extreme for LLM-generated notes, often lying outside the 95% range of the bootstrapped distributions of human physician–authored notes. This suggests that these redundancy-related patterns are unlikely to be attributable to small-sample effects alone.

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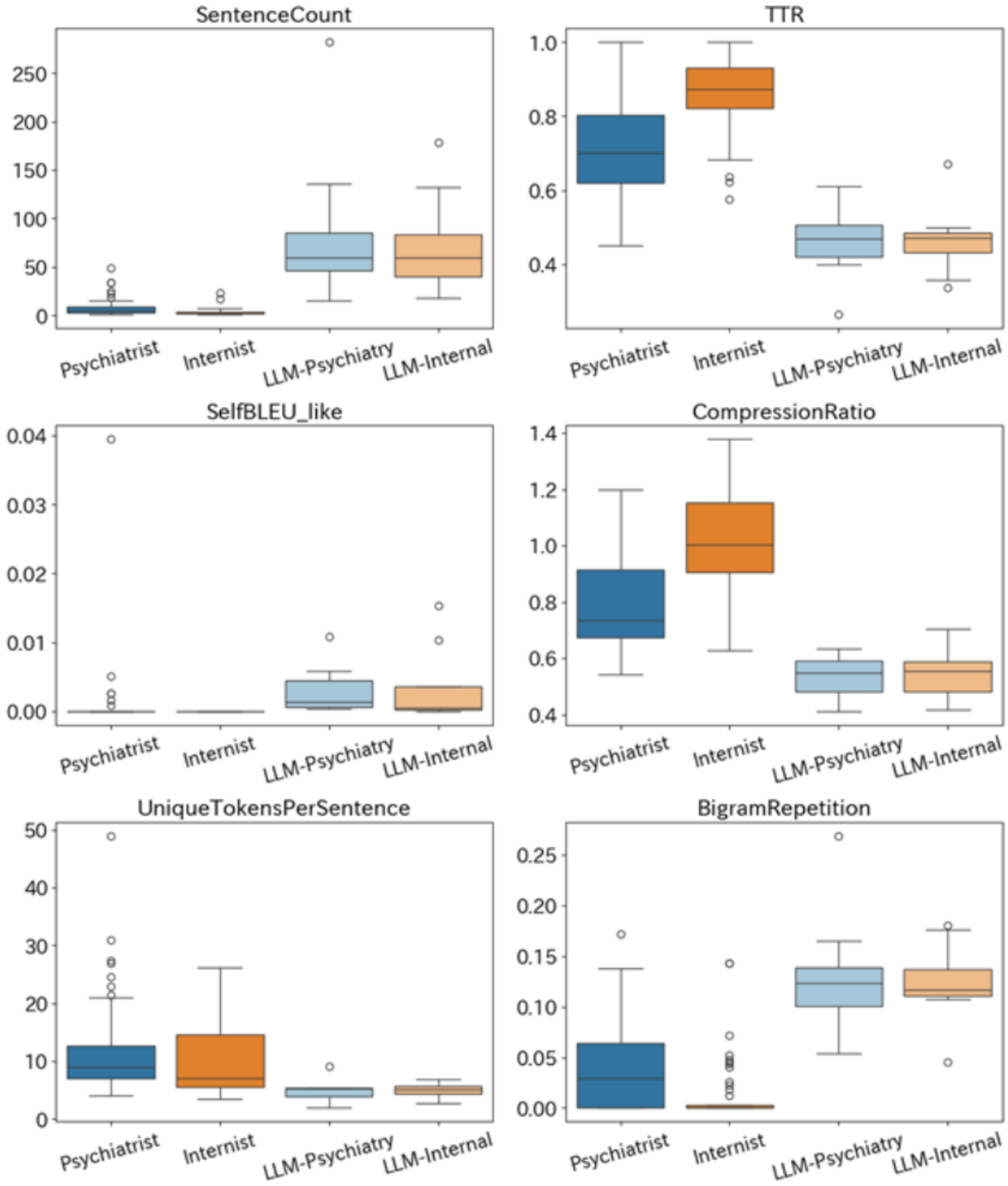
Figure 6. Redundancy and efficiency indicators across groups, showing that large language models (LLMs) exhibit greater repetition and lower lexical diversity. LLM-Internal, LLM-internal medicine.



Discussion

Significance of Clinical Documentation Style

In this study, we compared the records of psychiatrists, internists, and LLMs (psychiatric and internal medicine styles) for 2 cases of depression and schizophrenia and examined the documentation style from multiple dimensions, including syntax, semantics, vocabulary, topics, redundancy, and lexical diversity. Psychiatric documentation is not merely an administrative record but a core component of clinical communication and continuity of care, as it must capture patients' subjective experiences, contextual information, and longitudinal illness narratives. Because psychiatric practice is strongly language-centered, it has been regarded as a particularly promising domain for LLM-assisted clinical support [39]. However, recent studies indicate that while LLMs can improve surface-level fluency and efficiency, they often struggle to preserve clinically meaningful nuances, such as temporal relationships and

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context-dependent interpretation [40]. In sensitive domains such as suicidality and risk assessment, stylistic differences in documentation may influence how information is perceived or interpreted in downstream clinical or educational contexts [41], although the present analyses do not directly evaluate clinical safety or decision-making outcomes. From this perspective, stylistic alignment with human clinicians is not a cosmetic issue but a safety-relevant and epistemically meaningful property of psychiatric documentation. Accordingly, our comparative analysis was intended to examine whether current LLMs approximate deeper, domain-specific documentation practices rather than merely producing plausible-looking clinical text.

Principal Findings

A particularly striking finding was the substantial stylistic differences observed between human physicians and LLMs. Physicians' notes were characterized by richer lexical diversity and syntactic flexibility, often reflecting patients' subjective experiences and contextual backgrounds. By contrast, LLM-generated records displayed limited lexical choices, frequent repetition of similar expressions, and reliance on stereotypical syntactic patterns. Measures such as lexical entropy and redundancy further signified the uniformity of LLM-generated documentation. Lexical and topic analyses further suggested that LLM-generated notes were less likely to include certain linguistic patterns commonly associated with social context and psychological observation in psychiatrist-authored notes. Importantly, these findings should be interpreted as quantitative signals derived from textual features rather than as direct evidence of impaired or absent clinical reasoning.

We also found differences among LLMs in terms of document length and information density. Models such as Claude Sonnet 4, which produce longer outputs, appeared at first glance to provide richer information, but the content often included abstract phrasing and repetition, resulting in lower informational efficiency. On the other hand, models producing shorter records maintained conciseness but risked omitting clinically essential information. Thus, the suitability of LLMs for medical record generation should not be judged merely by their capacity for long text production but rather by their ability to adapt to discipline-specific styles, select clinically meaningful content, and provide concise yet dense documentation.

Another notable finding was that the clear stylistic differences between psychiatric and internal medicine records observed among human physicians were not reproduced in the LLM outputs. Even when explicitly prompted to take the role of a psychiatrist or internist, LLMs tended to converge toward similar, template-like styles, failing to adequately capture the discipline-specific expressions and clinical emphases evident in human-authored notes. While alternative prompting strategies, such as structured note templates or few-shot exemplars, may plausibly influence surface-level characteristics of LLM-generated records, including length, sectioning, and the inclusion of predefined content categories. They are less likely to fundamentally alter the deeper aspects of documentation observed in this study, such as lexical diversity, topic breadth, and the integration of social and psychological context. These higher-order features reflect not only prompt compliance but also the internal representations and training distributions of the models. Accordingly, although prompt engineering may partially mitigate stylistic uniformity, the persistent convergence observed across conditions suggests limitations that cannot be fully addressed through prompting alone. This suggests that merely assigning a role through prompting is insufficient for acquiring domain-specific styles of reasoning and documentation. Future approaches may require domain-adaptive training, fine-tuning, or integration with external knowledge sources to address this limitation. Taken together, these findings indicate that the automatic generation of medical documentation requires more than simply producing natural-sounding sentences. Higher-level capabilities are needed, including contextual understanding, recognition of the documentation purpose, and adaptation to the appropriate documentation style. Future developments in medical NLP should therefore incorporate approaches that engage more directly with the substantive content of records and model the underlying documentation practices.

These findings should therefore be interpreted as a stylistic and structural characterization of documentation patterns rather than an assessment of the clinical adequacy or correctness of the documented content.

Implications for Clinical Education and Patient Safety

It is important to emphasize that the metrics used in this study are descriptive indicators of textual structure and organization rather than validated measures of clinical quality, safety, or educational adequacy. Accordingly, the following implications should be interpreted as potential considerations rather than direct evaluations of risk. The observed stylistic convergence and increased redundancy in LLM-generated psychiatric notes have important implications for both clinical education and patient safety. In psychiatry, subtle distinctions in the documentation of risk-related information, particularly regarding suicidality, functional impairment, and protective factors, carry significant clinical consequences. Our findings suggest that overly verbose or templated documentation, as reflected in higher redundancy and altered topic structure, may affect the relative prominence of different types of information within narrative notes, which could be relevant when considering downstream interpretation in safety-critical contexts.

From an educational perspective, the increasing availability of LLM-assisted documentation raises hypotheses regarding how trainees and early-career clinicians might engage with clinical documentation. Specifically, there is a possibility that increased exposure to template-like or highly standardized notes could influence documentation practices, an effect that warrants direct empirical examination rather than inference from the present findings. When clinical notes emphasize surface completeness over effective information integration, there is a possibility that documentation practices become learned primarily through stylistic exposure. One open question for future research is whether extensive exposure to LLM-generated documentation might shape how clinical reasoning and context-sensitive practices are conceptualized during training, an issue that cannot be addressed by the present descriptive analysis. These findings

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underscore the need for careful governance of LLM use in psychiatric documentation, as well as explicit educational guidance to ensure that narrative notes continue to reflect clinically relevant documentation rather than automated textual patterns.

Limitations

This study has several limitations. First, it is based on only 2 standardized psychiatric scenarios (depression and schizophrenia), which restricts the generalizability of the findings to other psychiatric conditions, levels of clinical complexity, and real-world settings. Although these scenarios were intentionally designed to enable controlled comparisons, they do not capture the full diversity of clinical presentations, longitudinal disease trajectories, or comorbid conditions encountered in routine practice. As a result, the use of relatively prototypical and simplified scenarios may have contributed to stylistic convergence across clinicians and models, while potentially attenuating differences that might emerge in more complex or ambiguous clinical cases.

Second, the standardized case scenarios were initially drafted with the assistance of an LLM and subsequently reviewed and refined by the authors. Although careful efforts were made to ensure clinical plausibility and internal consistency and to remove unnatural or model-specific phrasing, it is possible that subtle linguistic or structural characteristics originating from the initial LLM drafting process remained. Such residual influences may have shaped the language or structure of the scenarios in ways that could advantage certain model outputs or influence how participating physicians documented their notes, even though physicians were explicitly instructed to freely modify, supplement, or correct the scenarios as needed. Accordingly, this potential source of bias cannot be fully excluded and should be considered when interpreting the results. In addition, because physicians were informed that the scenarios were generated with LLM assistance, this awareness may have influenced their documentation behavior, for example, by increasing vigilance toward inconsistencies or prompting more deliberate modification of the text. Such expectancy effects cannot be fully excluded.

Third, the sample size of physician-authored notes was limited, and variations in individual documentation practices or institutional conventions may not have been fully captured. Our bootstrap-based sensitivity analyses revealed that the impact of sample size imbalance was metric dependent. For lexical surface-form variation, LLM values fell largely within the range of the downsampled distributions of human-authored notes, suggesting that part of the observed differences in this measure may be attributable to small-sample effects. In contrast, several redundancy-related metrics showed robust differences that persisted even with downsampling, indicating that these patterns cannot be explained by sample size imbalance alone. Accordingly, LLM-related findings should be interpreted descriptively rather than inferentially, with attention to the specific linguistic dimension being examined. Moreover, the substantial imbalance between physician-authored notes (n=118) and LLM-generated notes (n=8 in total) may affect the stability of clustering and distribution-based analyses. Accordingly, all group comparisons in this study should be interpreted primarily as a descriptive characterization of stylistic tendencies rather than as confirmatory population-level inferences.

Fourth, this study was conducted using Japanese-language psychiatric documentation, which reflects cultural and institutional conventions specific to the Japanese health care system. In particular, Japanese psychiatric notes often rely on implicit shared clinical understanding and contextual narrative rather than explicitly articulated documentation structure or standardized sectioning. Documentation practices, levels of explicitness, and narrative styles may therefore differ across languages and regions. As such, caution is warranted when generalizing these findings to other health care systems.

Fifth, the LLMs evaluated in this study were general-purpose models and were not fine-tuned on clinical or biomedical corpora. Accordingly, the present findings should be interpreted as characterizing baseline documentation behaviors of off-the-shelf LLMs rather than the maximal capabilities of domain-adapted clinical models. In addition, results were aggregated across multiple LLMs to emphasize general documentation tendencies rather than model-specific behaviors, which may obscure meaningful inter-model variability relevant to downstream clinical or educational applications.

Sixth, although standardized prompts were used, the outputs of LLMs are inherently sensitive to prompt design and configuration. Alternative prompting strategies or model settings may yield different stylistic patterns. Moreover, we did not evaluate iterative or multi-round prompting workflows in which LLM outputs are progressively refined through repeated reprompting or human-in-the-loop revision. The present results should therefore be interpreted as reflecting baseline, single-pass generation behaviors rather than optimized or iteratively edited outputs.

Future studies should therefore include a broader range of clinical cases, documentation contexts, and prompt designs to further validate the robustness and generalizability of these findings.

Conclusions

This study conducted a multifaceted analysis of the differences in documentation styles among psychiatrists, internists, and LLMs for identical clinical cases, elucidating both the discipline-specific characteristics and the limitations of LLM-based reproduction.

Psychiatric records were characterized by rich emotional descriptions, incorporation of patient background, and a broad range of lexical expressions, demonstrating greater structural and lexical diversity compared with internal medicine records. While LLM outputs were capable of partially mimicking certain stereotypical documentation patterns, they remained prone to redundancy and rigidity of expression.

For the future application of LLMs in medical documentation support, it will be essential to go beyond superficial style imitation and to implement output control that accounts for the intentions of discipline-specific documentation and the clinical context while also ensuring pragmatic diversity. In domains

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such as psychiatric records—where a wide variety of expressions and nonstandardized information are prevalent—the auxiliary use of LLMs will require cautious design and careful human oversight.

Importantly, this study does not claim that current LLMs are ready for autonomous clinical documentation or unsupervised clinical use. Rather, the present findings are intended to delineate stylistic and structural characteristics under controlled conditions, and should not be interpreted as evidence of clinical safety, diagnostic validity, or deployment readiness.

Acknowledgments

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Data Availability

The anonymized physician-written clinical notes (in Japanese) and the large language model–generated case scenarios and question items used in this study are publicly available in [42]. Analysis code is not publicly shared but is available from the corresponding author upon reasonable request.

Authors' Contributions

Conceptualization: WA (lead), TN (equal), EA (supporting)
Data curation: WA (lead), TN (supporting)
Formal analysis: WA (lead)
Funding acquisition: EA
Investigation: WA (lead), EA (supporting)
Methodology: WA (lead), EA (supporting)
Project administration: WA (lead)
Resources: WA (lead), EA (supporting)
Supervision: EA
Validation: WA (lead), TN (supporting), SW (supporting)
Visualization: WA (lead), SW (supporting)
Writing – original draft: WA (lead)
Writing – review & editing: WA (lead), TN (supporting), SW (supporting), EA (supporting)

Conflicts of Interest

None declared.

Multimedia Appendix 1
English translations of representative case scenarios, prompts, and example clinical notes (reference purposes only); supplementary figures depicting hierarchical clustering of clinical notes; and supplementary table showing top term frequency-inverse document frequency (TF-IDF)–weighted terms by group for the schizophrenia case.
[DOCX File, 475 KB - formative_v10i1e85671_app1.docx]

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Abbreviations

BERT: bidirectional encoder representations from transformers
BLEU: Bilingual Evaluation Understudy
IRB: institutional review board
LDA: latent Dirichlet allocation
LLM: large language model
NAIST: Nara Institute of Science and Technology
NLP: natural language processing
ROUGE-L: Recall-Oriented Understudy for Gisting Evaluation–Longest Common Subsequence
TER: Translation Edit Rate
TF-IDF: term frequency-inverse document frequency
TTR: type-token ratio

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Validation of a Low-Burden, Once-Daily Obsessive-Compulsive Disorder Measure Over 70 Days: Ecological Momentary Assessment Study

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Abstract

Background: Ecological momentary assessments (EMAs) are an increasingly popular tool used to measure real-time symptom burden within mental health care, including for obsessive-compulsive disorder (OCD). However, prior studies in the literature have been limited by brief assessment periods, high participant burden, and heterogeneity in both sampling and symptom assessment methodologies.

Objective: This study aimed to validate a 12-item EMA questionnaire of OCD symptoms by evaluating its psychometric properties over an extended monitoring period.

Methods: Adults with OCD (22/41, 53.7%) and demographically matched healthy controls (19/41, 46.3%) completed up to 70 daily smartphone-delivered EMA surveys assessing the frequency and emotional impact of obsessions and compulsions. Participants with OCD also underwent clinician-administered Yale-Brown Obsessive-Compulsive Scale evaluations at weeks 0, 2, and 10.

Results: Our scale demonstrated high internal consistency (Cronbach α=0.96) and convergent validity, with significant correlation with Yale-Brown Obsessive-Compulsive Scale scores at week 2 (ρ=0.59; *P*=.004) and week 10 (ρ=0.53; *P*=.01). Participant retention (89.1%) and questionnaire completion rate (89%) were also higher than those seen in the literature (75.2% and 74.2%, respectively).

Conclusions: Overall, we provide initial psychometric support for the use of a low-burden EMA tool to capture day-to-day OCD symptom fluctuations over extended periods. Such tools may enhance longitudinal symptom monitoring, improve treatment response tracking, and address limitations inherent in traditional retrospective assessments.

(JMIR Form Res 2026;10:e86471) doi:10.2196/86471

KEYWORDS

obsessive-compulsive disorder; OCD; obsessions; compulsions; OCD symptoms; ecological momentary assessment; EMA; daily diary

Introduction

Background

Obsessive-compulsive disorder (OCD) affects approximately 2% to 3% of the general population and is characterized by persistent, intrusive thoughts (obsessions) and repetitive behaviors or mental acts (compulsions) that cause individuals significant distress and impairment in daily functioning [1]. Traditional assessments of OCD, such as the gold-standard Yale-Brown Obsessive-Compulsive Scale (Y-BOCS) [2], ask individuals to recall symptom burden across both obsession and compulsion dimensions over the previous week and require a trained clinician to administer. Self-report assessments have also been developed and validated and include the Y-BOCS-II-SR [3], the Obsessive-Compulsive Inventory [4], and the Florida Obsessive-Compulsive Inventory [5]. These symptom scales are efficient to administer, given the self-report nature, and assess symptom severity over periods ranging from 1 week to 1 month. However, the retrospective nature of these measures has the potential to miss fluctuations in OCD symptoms over shorter timescales. These caveats to standard assessment tools highlight the need for accessible, user-friendly assessments capable of tracking OCD symptoms with greater temporal precision and reduced recall bias.

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Ecological momentary assessments (EMAs), which are brief, repeated assessments delivered in real time and often sent via a smartphone in naturalistic contexts, may help fill this gap by reducing recall bias and enabling granular tracking of daily symptom burden [6]. Daily diary, a type of EMA [7], involves daily retrospective logging of experiences in lieu of in-the-moment assessments of the current state. EMAs and daily diaries both aim to minimize recall bias and maximize ecological validity, which are advantages over traditional clinical assessments [6]. In OCD research, these two approaches offer the opportunity to use technology to track day-to-day fluctuations in obsessions and compulsions in natural settings, develop person-specific modeling of symptoms [8], and consider the impact of atypical events on symptom burden [9,10].

Despite growing interest in tracking OCD symptoms using EMAs and daily diaries, prior studies have shown key limitations. One systematic review found that among 34 studies, the study periods lasted only from 1 to 7 days [7]. While allowing for OCD assessment over relatively brief intervals, this previous work did not track symptoms over more extended time spans (weeks to months). Extended monitoring is clinically meaningful, as OCD symptoms typically wax and wane across weeks to months, and improvement from treatments, including psychotherapy and pharmacotherapy, generally occurs over this timescale as well [11,12]. Still, subjective patient reports also find symptom fluctuations over shorter time frames [13], highlighting the complex nature of OCD symptoms. Additionally, current EMA protocols in the literature may be burdensome for participants, as they administer an average of 4 daily assessments and have an average dropout rate of 24.8% despite study periods lasting no longer than a week [7]. As such, these protocols may be unsustainable and impractical over longer periods, diminishing the clinical applicability of EMA. Overall, Braga et al [7] highlight the wide variation of EMA methods in all facets—from wording, scales, assessment schedules, and the like—describing the application of EMAs in tracking OCD as “fragmented” and “heterogeneous.”

Objectives

To this end, this study—conducted as part of a larger trial—aimed to validate a novel longitudinal EMA of OCD symptoms, designed to align with the gold-standard Y-BOCS. We sought to address the limitations in study duration and compliance rate found in the literature by implementing a once-daily EMA protocol lasting 70 days in adults with OCD (n=22) and demographically matched healthy controls (n=19).

During the study, participants with OCD initiated pharmacotherapy, and Y-BOCS assessments were conducted at weeks 0, 2, and 10. We used a modified version of the scale developed by Rupp et al [8], which assessed a range of OCD symptoms and changes in response to therapy using high-frequency prompts over a short duration. Our modified version, developed in consultation with an OCD expert with decades of clinical experience, aimed to minimize participant burden to allow for a longer monitoring period that reflects a realistic treatment timeline. We examined several psychometric properties of our questionnaire—including internal consistency, discriminant validity between participants with OCD and healthy controls (HCs), and convergent validity with clinician-rated Y-BOCS scores—as well as completion rates of the entire study and compliance rates to daily EMA.

Methods

To ensure comprehensive reporting, we adhered to the CREMAS (Checklist for Reporting Ecological Momentary Assessment Studies), an adaptation of the STROBE (Strengthening the Reporting of Observational Studies in Epidemiology) guideline. The CREMAS addresses key aspects of EMA research, including real-time data collection, participant burden, and the use of mobile technology for assessment [14].

Participants and Recruitment

Patients and HCs were recruited through flyers, postings on the Keck School of Medicine study recruitment website, and clinician referrals from the university’s psychiatry clinics. Eligible participants were aged 18 to 60 years. For the OCD group, inclusion required a primary OCD diagnosis, a Y-BOCS score of 16 or greater, being medication naive or off psychotropic medication for 6 months or more, being medically appropriate for pharmacotherapy, and willingness to initiate a selective serotonin reuptake inhibitor as part of standard care. HCs had no current or past OCD diagnosis. Participants’ OCD diagnosis was confirmed through the Structured Clinical Interview for *Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition* (SCID-5-CV) conducted by the study psychiatrist (ACF). The Y-BOCS, a clinician-administered, semistructured interview and widely used gold-standard measure of OCD symptom severity, was used to assess symptom presence and severity [2]. The Y-BOCS includes a symptom checklist and a 10-item severity scale that rates obsessions and compulsions separately (5 items each) across core dimensions, including time occupied (frequency), interference, distress, resistance, and perceived control over symptoms.

All participants were required to be able and willing to wear a Fitbit, complete smartphone-based EMA surveys, and undergo functional magnetic resonance imaging scanning. The exclusion criteria for both groups included active substance use disorder, active suicidality, active psychosis, current psychotropic medication use, or a primary psychiatric diagnosis other than OCD. Comorbid psychiatric diagnoses were permitted in the OCD group if OCD was the primary diagnosis.

Study Design and Procedure

The study comprised 70 consecutive days of monitoring, including weekdays and weekends. Clinical assessments were conducted at baseline (week 0), week 2, and week 10. During study onboarding, participants were trained on questionnaire completion and study technology. Surveys were administered via Qualtrics and sent once daily at a random time between 8 AM and 8 PM via SMS text messaging to participants’ personal smartphones. This random sampling approach was used to assess symptoms throughout the day (rather than at a single daily time point) and to gain additional information about participant context, as other questions—not reported herein—asked about location and activities immediately prior to survey completion. As part of a larger project, participants were instructed to wear

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a Fitbit Charge 5 smartwatch continuously throughout the study period to collect biometric data. Y-BOCS scores were assessed by the same study psychiatrist (ACF) for all participants at all time points.

Participants were given 3 hours to complete their EMA survey upon receiving it via SMS text messaging. Specifically, survey links expired after this 3-hour window, and participants were no longer able to submit survey responses for that day. To enhance ongoing participation in EMA completion over the course of 10 weeks, compensation was tied to maintaining weekly goals, and this compensation structure was modeled on other longitudinal EMA-based studies [15]. Specifically, weekly compensation (US $25 per week) was provided if participants completed 80% of daily EMAs (eg, 6 of 7 daily surveys per week) and wore their Fitbit 80% of the time each week. All data from all study participants who completed the 10-week study were included in this analysis, whether a participant met the 80% threshold for a given week. Finally, participants who met predetermined study withdrawal criteria were not included in data analysis. Specifically, lack of completion of at least 80% of the study questionnaires for 3 or more weeks and lack of wearing the Fitbit 80% of the time for 3 or more weeks met the withdrawal criteria.

Questionnaire Measures

Each daily questionnaire contained 21 items assessing biopsychosocial domains, such as OCD-related anxiety, physical activity, alcohol consumption, sleep, and social interactions. Items were assessed as state-based ("currently") or retrospective ("since the last survey"). A total of 12 items specifically assessed OCD symptoms (Textbox 1). Participants rated the frequency of obsessions and compulsions on a visual analog scale, which allowed for decimal responses. Those associated with emotions (questions 2-6 and questions 8-12) were rated on a 5-point Likert scale.

Textbox 1. Items on the ecological momentary assessment measuring obsessive-compulsive disorder symptoms.

- Question 1: Since the last survey, how frequently have you experienced obsessions? (0-100 visual analog scale [VAS]; skip logic applied, question 2-question 6 only appears if question 1>0)
- Since the last survey, in relation to obsessions, to what extent have you felt the following (1-5 Likert scale):
  - Question 2: Anxiety
  - Question 3: Guilt
  - Question 4: Helplessness
  - Question 5: Disgust
  - Question 6: Burdened
- Question 7: Since the last survey, how frequently have you experienced compulsions? (0-100 VAS; skip logic applied, question 8-question 12 only appears if question 7>0)
- Since the last survey, in relation to compulsions, to what extent have you felt the following (1-5 Likert scale):
  - Question 8: Anxiety
  - Question 9: Guilt
  - Question 10: Helplessness
  - Question 11: Disgust
  - Question 12: Burdened

The OCD-specific items were adapted from Rupp et al [8], who examined the treatment sensitivity of EMAs for OCD. Items were modified for compatibility with a once-daily schedule and to minimize participant burden. Study participants were trained on the distinction between obsessions and compulsions during the onboarding evaluation by the study psychiatrist (ACF) in the context of administration of the Y-BOCS.

Data Analysis

All statistical analyses were conducted in R (version 2024.09.0+375). Internal consistency (Cronbach α) was calculated using the "psych" package (Multimedia Appendix 1). Multilevel confirmatory factor analysis (CFA) was conducted using MPlus (version 9.0) following the CFA reliability framework provided by Geldhof et al [16] (Multimedia Appendix 1).

We adopted a composite scoring approach for our EMA scale to reduce measurement noise and place all items on a single, interpretable scale of OCD symptom severity [17,18]. This approach aligns the EMA scale to the clinical measure (Y-BOCS), which is expressed as a total severity score. We evaluated internal consistency using Cronbach α to justify aggregating items and computed α separately for obsession items, compulsion items, and the combined total item set. We estimated α at two levels: (1) prompt-level α, derived from pooling all item responses on a day-to-day level, and (2) person-level α, calculated across participants after averaging items within participants across all study days. As a complementary check on reliability, we also fit 2-level CFA with a single latent factor to estimate reliability at the within- and between-person levels for the obsession items, compulsion

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items, and the combined total item set. We considered reliability estimates of 0.70 or greater as acceptable internal consistency.

As frequency and emotion items were scored on different metrics, we rescaled the frequency scores to match the emotion scores by dividing by 20. As the visual analog scale frequency items allowed decimal responses, the rescaled score retained fractional precision, and composite scores were derived from these unrounded values.

We then tested whether the composite EMA score discriminated participants with OCD from control participants. As the EMA uses skip logic at the frequency questions (follow-up emotion items are zero when participants have not experienced any obsessions or compulsions), we anticipated a zero-predominant distribution among control participants. As such, for each participant, we calculated a person-level proportion of symptomatic days by taking the number of days where a composite EMA score was greater than 0 and dividing it by the number of total observed days. We then compared OCD versus control on this proportion using the Mann-Whitney *U* test.

Finally, we tested for convergence between clinician-rated Y-BOCS, administered at weeks 2 and 10, and the composite EMA score by correlating Y-BOCS total, obsessions subsection, and compulsions subsection scores with their EMA counterparts, calculated as a 7-day trailing average (up to and including the day of assessment) at week 2 (approximately day 15) and week 10 (approximately day 70). Specifically, we paired the Y-BOCS total with the EMA total composite, Y-BOCS obsessions with the EMA obsessions composite, and Y-BOCS compulsions with the EMA compulsions composite and estimated Spearman rank correlations for each pairing. To account for days with missing data, days within the 7-day assessment window did not have to be consecutive.

Ethical Considerations

This study was conducted in accordance with the University of Southern California Institutional Review Board approval (study ID IRB HS-21‐00835). Participants completed informed consent prior to study enrollment. Included in this consent was the ability for participants to opt out of study participation at any time. Data contained herein were anonymized and no participant identifying information is present. For their participation, participants received up to US $350 depending on their adherence to study protocols and were allowed to keep the Fitbit device.

Results

Participant Demographics

Descriptive statistics of participant demographics at baseline are presented in Table 1. The examination of baseline Y-BOCS revealed substantially higher scores for the OCD group than HCs (t_{39}=27.55, 95% CI 23.12-26.79; *P*<.001). Age did not differ significantly between groups (t_{39}=–0.06, 95% CI –2.91 to 2.73; *P*=.95). Gender distribution was also comparable (χ^2_2=1.0; *P*=.60). However, there was a significant difference in racial distribution across groups (χ^2_{12}=23.2; *P*=.03).

Table . Participant demographics and baseline assessments.

Variables[a]	Participants with OCD[b] (n=22)	Healthy controls (n=19)	*P* value
Age (y), mean (SD)	26.8 (4.9)	26.3 (4.1)	.95
Y-BOCS[c] total score, mean (SD)	24.9 (4.5)	0.0 (0.0)	<.001
Gender, n (%)			.60
Man	10 (45.5)	8 (42.1)	
Woman	11 (50)	11 (57.9)	
Nonbinary	1 (4.5)	0 (0)	
Race, n (%)			.03
White	8 (36.4)	2 (10.5)	
Black	2 (9.1)	2 (10.5)	
East Asian	2 (9.1)	4 (21.0)	
Indian	1 (4.5)	5 (26.3)	
Southeast Asian	2 (9.1)	0 (0)	
Hispanic or Latino	2 (9.1)	0 (0)	
More than one	5 (22.7)	5 (26.3)	
Prefer not to say	0 (0)	1 (5.3)	

[a]Group comparisons used independent *t* tests for continuous variables (Y-BOCS and age) and chi-square tests for categorical variables (gender and race). Significant differences were found for Y-BOCS and race; age and gender did not differ between OCD and control groups.

[b]OCD: obsessive-compulsive disorder.

[c]Y-BOCS: Yale-Brown Obsessive-Compulsive Scale.

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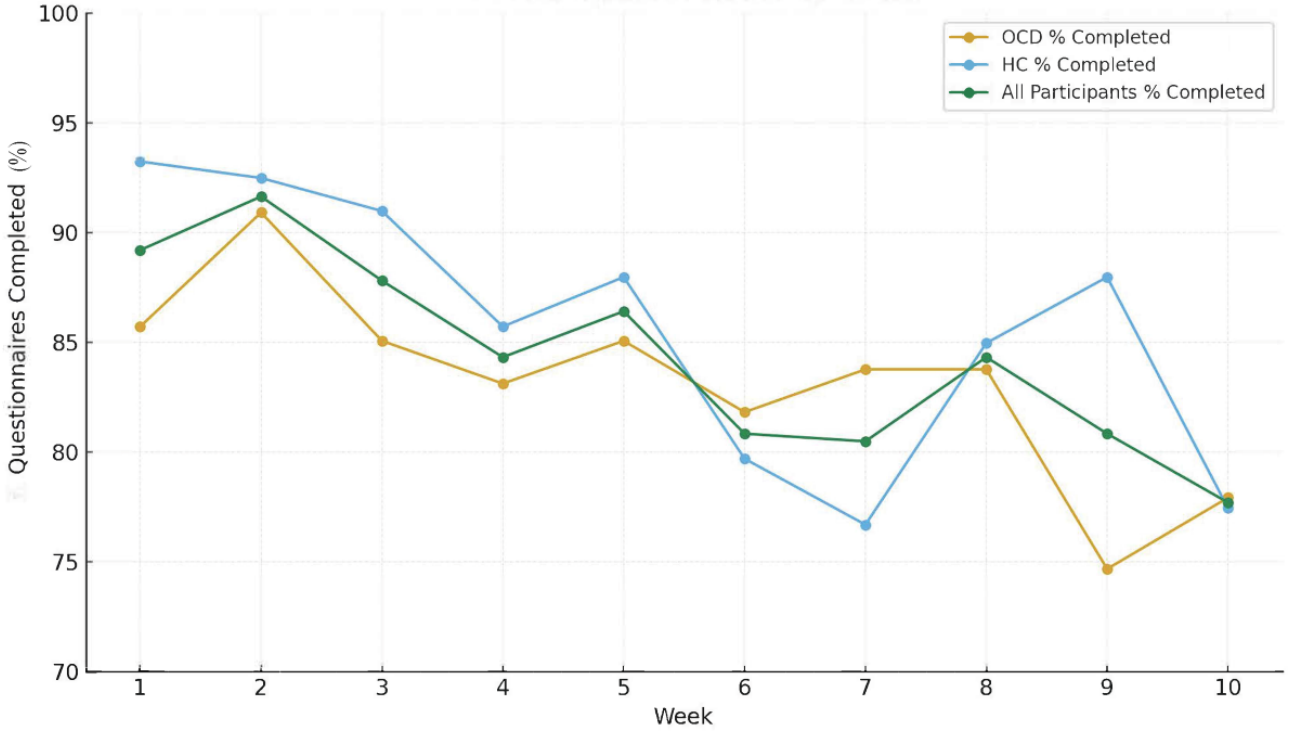
Compliance

A total of 25 participants with OCD and 22 participants serving as HCs were initially enrolled. Three (12%) participants with OCD and 2 (9.1%) HC participants were withdrawn from the study, given the lack of continued participation following predefined withdrawal criteria. Two (66.7%) of the 3 participants with OCD who were withdrawn from the study stopped answering all EMA questions and responding to study personnel inquiry after 3 weeks in the study. The remaining participant with OCD was withdrawn, given the lack of EMA completion and Fitbit weekly adherence for 6 weeks. One (50%) HC participant was withdrawn from the study after they stopped answering EMA questions and responding to study personnel inquiry after 2 weeks; the other HC participant was withdrawn following a lack of EMA completion and response to study personnel after 6 weeks, with low response rates for both participants during their time in the study. For all completed surveys, we report a median of 143 (IQR 100-230) seconds to complete the survey. In addition to the individual weeks in Figure 1, the overall questionnaire completion rates were 86.7%, 91.7%, and 89% among participants with OCD, HCs, and all participants, respectively. Within the OCD group, baseline Y-BOCS did not correlate significantly with the EMA compliance rate (ρ=−0.21; *P*=.34).

Figure 1. Ecological momentary assessment (EMA) completion rates by week. All participants' percentage completed represents the mean of the obsessive-compulsive disorder (OCD) and healthy control (HC) groups by week.



Internal Consistency

The 12-item scale demonstrated high internal consistency on a prompt level (Cronbach α=0.94, 95% CI 0.94-0.95) and person level (Cronbach α=.96; 95% CI 0.93–0.98). Subscale internal consistency was similarly high: the obsessions 6-item subscale showed α=.90 (95% CI 0.89-0.91) at the prompt level and α=.89 (95% CI 0.84-0.94) at the person level; the compulsions 6-item subscale showed α=.90 (95% CI 0.89-0.91) at the prompt level and α=.89 (95% CI 0.83-0.94) at the person level. Consistent with these high alpha estimates, 2-level CFA reliability also indicated strong within-person reliability for the total scale (ω=0.94) and obsessions (ω=0.91) and compulsions (ω=0.91) subscales. Although the CFA returned high between-person estimates, the model was unstable at this level due to the small number of clusters relative to between-person parameters. We therefore emphasize within-person CFA reliability estimates alongside the Cronbach α values. Given high internal consistency, we retained all 3 composites for analysis and proceeded in calculating 3 consolidated values: a composite obsessions, compulsions, and OCD score.

Known-Groups Validity

HCs were almost universally at floor with 1192 (99.2%) of 1202 days having a composite score of 0 (Figure 2A). In contrast, the OCD group showed a broad distribution of EMA scores with a mean of 2.03 (SD 1.07) on the 0- to 5-point scale (Figure 2B). The OCD group had significantly higher composite scores than the control group (Mann-Whitney *U*=0; Z=−5.67; *P*<.001), with a large effect size (rank-biserial correlation *r*=0.91).

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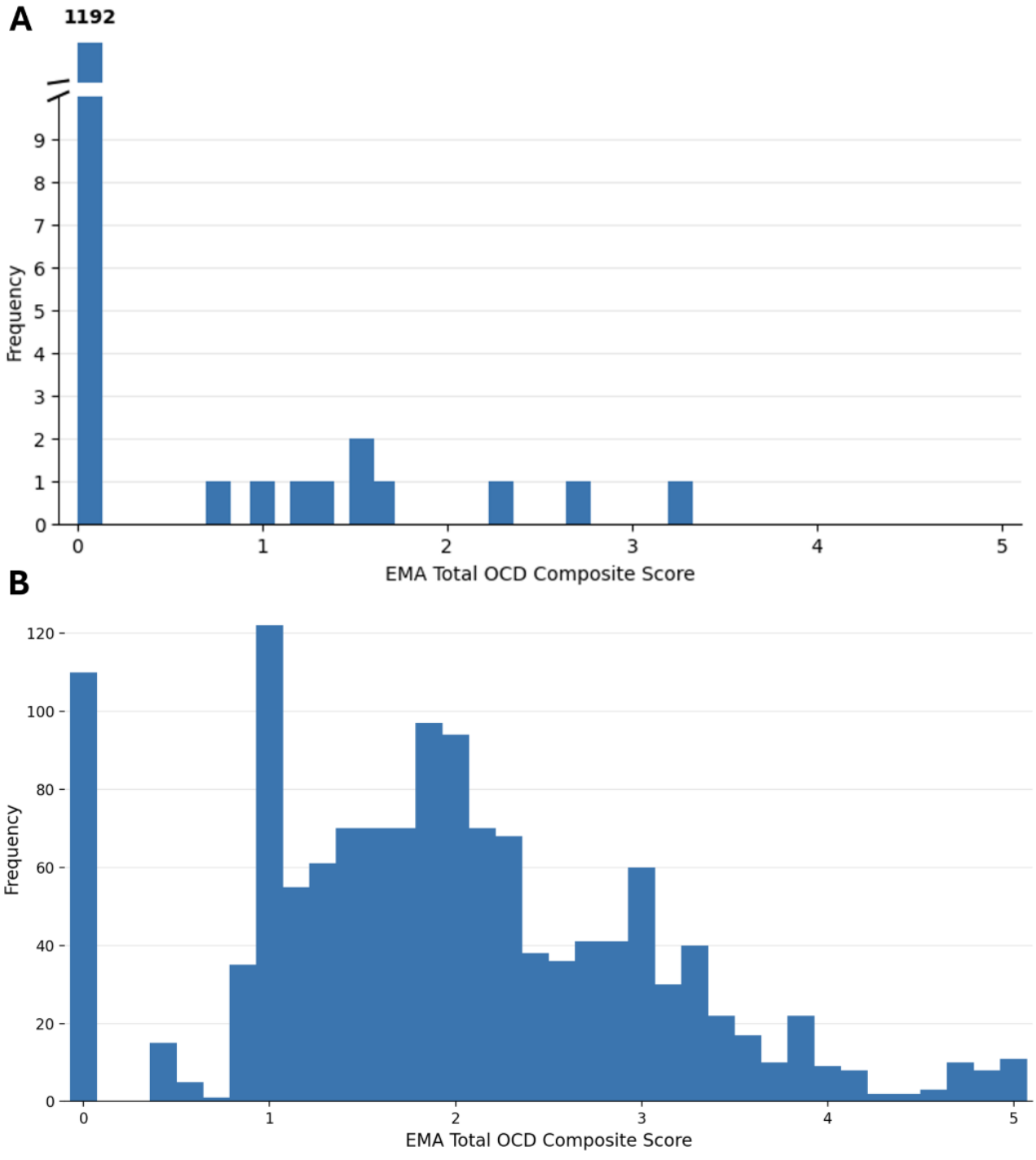
Figure 2. Distribution of the ecological momentary assessment (EMA) total obsessive-compulsive disorder (OCD) composite score by group. (A) Healthy controls (n=1202 person-days): 1192 (99.2%) days had a composite score of 0 (mean 0.014, SD 0.171). (B) Participants with OCD (n=1333 person-days; mean 2.03, SD 1.07).



Convergent Validity

Spearman ρ indicated moderate to strong correlation between the 12-item EMA total OCD composite and the Y-BOCS total at week 2 (ρ=0.59; *P*=.004; Figure 3A) and week 10 (ρ=0.53; *P*=.01; Figure 3B). The EMA obsessions subscale showed similarly robust associations with the Y-BOCS obsessions subscale (week 2: ρ=0.63; *P*=.002; Figure 3C; and week 10: ρ=0.52, *P*=.01; Figure 3D). In contrast, correlations with the Y-BOCS compulsions subscale were smaller (week 2: ρ=0.27; *P*=.23; Figure 3E; and week 10: ρ=0.44; *P*=.04; Figure 3F), and the week 2 association was not significant.

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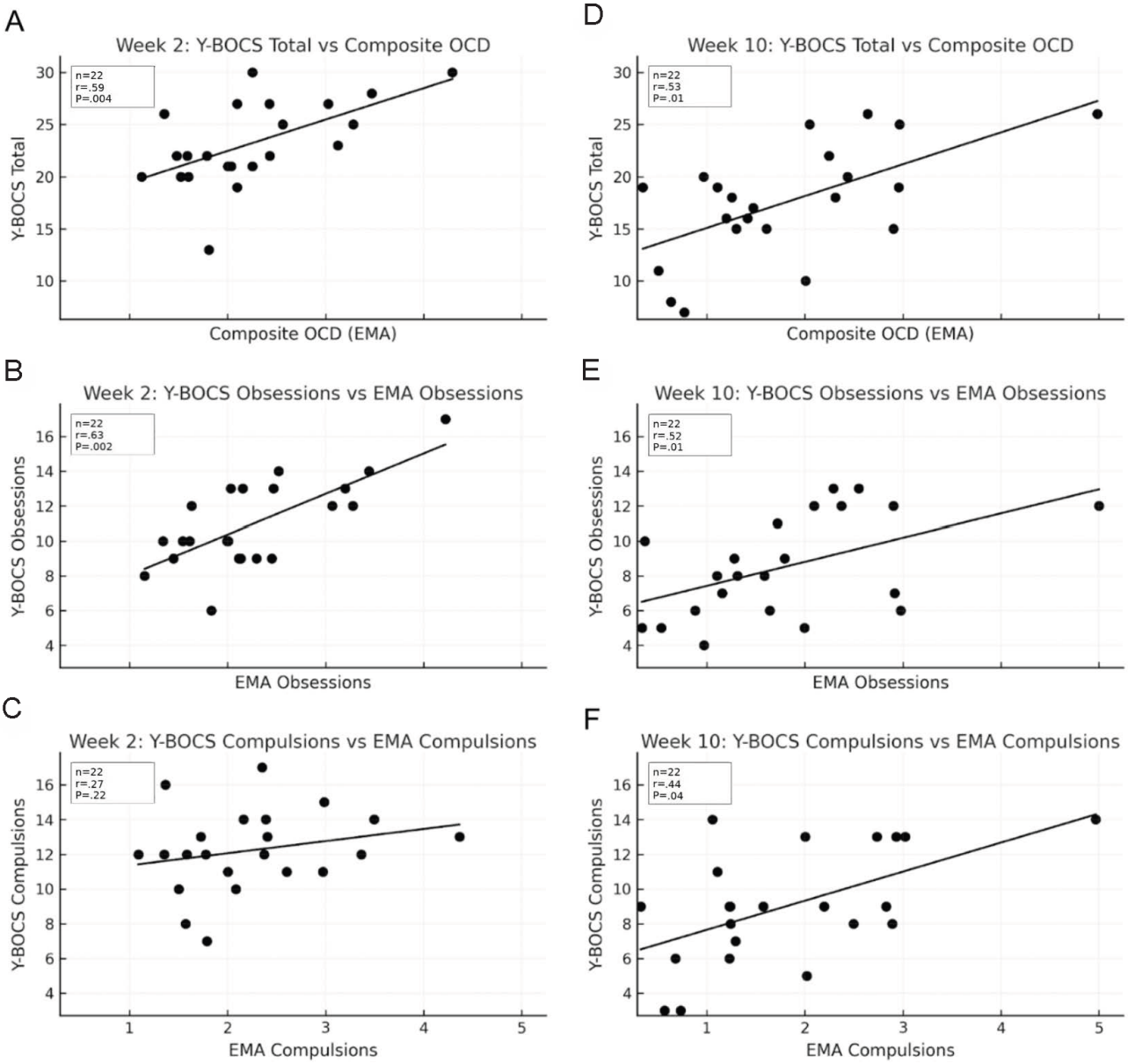
Figure 3. Spearman correlations between the Yale-Brown Obsessive-Compulsive Scale (Y-BOCS) and ecological momentary assessment (EMA)–derived trailing composite obsessive-compulsive disorder (OCD) scores. At week 2, it is separated by (A) EMA composite OCD, (C) EMA obsessions, and (E) EMA compulsions; at week 10, it is separated by (B) EMA composite OCD, (D) EMA obsessions, and (F) EMA compulsions. Correlations were moderate to strong for total OCD and obsessions composite and smaller for compulsions composite (week 2 compulsions not significant).



Discussion

Summary of Findings

In this study, we evaluated the feasibility and validity of a once-daily, longitudinal EMA protocol for monitoring OCD symptoms in naturalistic settings over extended periods (several months). Our EMA-derived OCD symptom scale demonstrated high internal consistency, known-groups validity, and convergent validity with clinician-rated Y-BOCS scores. The EMA total OCD composite score clearly distinguished participants with OCD from HCs, and EMA-derived obsession scores showed strong correlations with clinician-rated obsession severity at multiple time points. Together, these findings support the use of daily EMAs as a reliable method for capturing OCD symptom severity and fluctuations over time.

Connection to Prior Literature

OCD is a heterogeneous and dynamic disorder, characterized by day-to-day fluctuations in symptom severity [13]. Given this pronounced variability, there is a clear need for longitudinal symptom monitoring in real-world contexts. However, as emphasized by Braga et al [7], the existing EMA literature in OCD has been “scattered” in methods and EMA administration, with wide variation in survey frequency, question content, technological platforms, and study duration, limiting cross-study comparability. Moreover, most EMA-based OCD studies have been short, typically lasting only 1 to 7 days, restricting their ability to capture longer-term symptom trajectories, such as those in the context of a course of treatment.

Our implementation of a 70-day observation period provided a substantially longer timescale to detect both short-term symptom fluctuations and longer-term trends. We used a consistent,

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once-daily EMA protocol delivered via SMS text messaging to participants' smartphones, minimizing participant burden. This design contributed to a low attrition rate of 10.9%—well below the 24.8% average reported in prior EMA studies of OCD—as well as high response rates, averaging 89.0% compared with 74.2% reported in the literature [7]. This combination of extended duration, high retention, and high response rates allowed for practical and reliable symptom tracking over time.

EMA-derived obsession scores demonstrated strong and statistically significant correlations with Y-BOCS obsessions subscale scores at both week 2 and week 10. In contrast, EMA-derived compulsion scores did not correlate significantly with the Y-BOCS compulsions subscale at week 2, although correlations were stronger and more consistent by week 10. This pattern is consistent with multiple prior studies: Cox et al [19] observed stronger associations between EMA measures and Y-BOCS obsession scores than compulsion scores. Herman and Koran [20] used a modified, self-report version of the Y-BOCS administered via handheld computer in naturalistic settings and found weaker correlations to clinician-administered Y-BOCS compulsion scores, although correlations were low for both obsession and compulsion scales in that study.

Several factors may explain the initially weaker correspondence between EMA and Y-BOCS compulsion scores. During Y-BOCS administration, clinicians can educate participants on the definition of compulsions and assist in distinguishing them from obsessions and other symptoms, potentially contributing to careful partition of symptom scores within these domains. In contrast, during EMA completion, participants may not consistently separate compulsions from obsessions. The dynamic clinical course of the sample may have also influenced our findings. Many participants initiated Selective Serotonin Reuptake Inhibitor treatment during the study period, and changes in OCD symptom burden may influence the self-report of symptoms in different domains. The lack of significant compulsion correlations at week 2 may therefore reflect transient variability or unstable symptom reporting early in treatment, whereas stabilization by week 10 may have contributed to stronger and more reliable correspondence between EMAs and clinician-rated measures.

Limitations

Despite these strengths, several limitations warrant consideration. First, the OCD sample size was relatively small (n=22), which limited our ability to evaluate the latent structure of our EMA scale using exploratory factor analysis. In addition, the small number of participants precluded meaningful evaluation of between-person effects. The modest sample size should be interpreted in the context of stringent inclusion criteria and the demands of the parent study. Participants were required to have a primary OCD diagnosis, be medication naive or off psychotropic treatment for at least 6 months, and be willing to initiate pharmacotherapy, narrowing the eligible recruitment pool. In addition, this EMA validation was embedded within a larger multimodal study requiring near-continuous use of a Fitbit over 70 days alongside daily smartphone-based assessments, a combined burden that likely further constrained enrollment despite excellent retention and compliance among enrolled participants.

Second, participants were younger on average (mean age approximately 26.8, SD 4.9 years). As OCD presentation can vary by age, including differences in symptom dimensions, severity, and comorbidity patterns [21], future studies should validate these findings in larger and more age-diverse cohorts.

Third, EMA questions required participants to retrospectively summarize symptoms since the prior survey. Although this approach reduced participant burden, retrospective recall—even over short intervals—may introduce bias relative to in-the-moment assessments. The questions were designed to align with prior EMA studies and with Y-BOCS symptom domains, which necessitated some degree of retrospective reporting.

Finally, participants initiated pharmacotherapy during the study as clinically indicated, introducing additional variability in symptom trajectories. We also did not systematically account for acute life events or stressors that may have influenced symptom severity in the days preceding clinical assessments. Such state-dependent factors may have contributed to variability in correlations between EMA and clinician ratings. Additionally, clinician assessments were conducted only at weeks 0, 2, and 10, limiting validation of EMA measures to periods with temporal overlap.

Conclusions

Overall, this study demonstrates that daily EMAs of OCD symptom severity correlate well with clinician-based measures while offering substantially greater temporal resolution. EMA approaches may provide clinicians and researchers with valuable insights into day-to-day symptom fluctuations, treatment response, and individualized symptom patterns that are not captured by traditional retrospective assessments. As digital mental health tools continue to evolve, longitudinal EMA protocols may play an increasingly important role in both clinical care and research on dynamic psychiatric disorders, such as OCD.

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The authors declare the use of generative artificial intelligence (GenAI) in the research and writing process. According to the GAIDeT (Generative Artificial Intelligence Delegation Taxonomy, 2025), the following tasks were delegated to GenAI tools

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under full human supervision: literature search and systematization, proofreading and editing, and reformatting. The GenAI tool used was ChatGPT (versions 4 and 4.5) and OpenEvidence. Responsibility for the final manuscript lies entirely with the authors. The GenAI tools are not listed as authors and do not bear responsibility for the final outcomes.

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Data Availability

The datasets generated or analyzed during this study are available from the corresponding author on reasonable request.

Authors' Contributions

AJ and RL contributed to conceptualization, formal analysis, methodology, investigation, and writing the original draft. JF contributed to formal analysis and writing the original draft. ACF contributed to resources, project administration, supervision, funding, conceptualization, and review and editing.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Cronbach α analysis and confirmatory factor analysis.
[DOCX File, 1962 KB - formative_v10i1e86471_app1.docx]

Checklist 1
CREMAS checklist.
[DOCX File, 33 KB - formative_v10i1e86471_app2.docx]

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Abbreviations

CFA: confirmatory factor analysis
CREMAS: Checklist for Reporting Ecological Momentary Assessment Studies
EMA: ecological momentary assessment
HC: healthy control
OCD: obsessive-compulsive disorder
STROBE: Strengthening the Reporting of Observational Studies in Epidemiology
Y-BOCS: Yale-Brown Obsessive-Compulsive Scale

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Additional Investigations and Referrals by Primary Care Physicians in Uncertain Clinical Situations: Cross-Sectional Study Using Virtual Patient–Based Scenarios

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Abstract

Background: Uncertainty affects at least 20% of primary care consultations, possibly leading primary care physicians to order additional investigations or referrals, affecting cost-effectiveness and patient safety. Experience is a key determinant in making these orders, along with anxiety or physicians' reactions to uncertainty. Past studies addressing the links between experience and additional investigations and referrals in uncertain situations have used questionnaires, database analyses, or interviews with general practitioners, but no study has used fully standardized conditions.

Objective: This study aimed to examine the association between experience and orders for additional investigations and referrals in uncertain situations using a standardized virtual patient simulation.

Methods: A cross-sectional study was conducted with 40 physicians stratified by sex and experience (<10 vs ≥10 years). Participants engaged in a simulated clinical scenario involving a man aged 69 years with atypical dyspnea designed to evoke diagnostic uncertainty. The virtual patient was presented via first-person video to assess the physicians' decision-making process. Participants' years of clinical experience, sex, age, place of practice, type of practice, number of in-office patients, duration of consultations, State-Trait Anxiety Inventory Form Y (STAI-Y) and Physician Reaction to Uncertainty scores, and diagnostic hypotheses were collected and analyzed using multivariate regression models.

Results: The group with <10 years of experience had higher STAI-Y (mean 41.3, SD 6.8 vs mean 32.7, SD 8.2; *P*<.001) and Physician Reaction to Uncertainty (mean 20.7, SD 5.4 vs mean 14.4, SD 6.9; *P*=.002) scores. Participants with <10 years of professional experience ordered more additional investigations and referrals on average: 10.2 (SD 3.4; 95% CI 8.9-11.7) vs 8.1 (SD 3.7; 95% CI 6.5-9.9; *P*=.03). There was no effect on costs: €153.80 (US $173.45) vs €129.60 (US $146.16) (effect size 0.296, 95% CI −0.348 to 0.939; *P*=.23). Multivariate analysis showed an association between the number of additional investigations and referrals with age (relative risk 0.980, 95% CI 0.963 - 0.997; adjusted *P*=.02) and mean STAI-Y score (relative risk 0.984, 95% CI 0.968 - 0.999; adjusted *P*=.04) but not with experience (<10 vs ≥10 years; R^2=0.308).

Conclusions: Less experienced physicians do not appear to overly rely on additional investigations and referrals in uncertain situations, suggesting that clinical reasoning remains a well-preserved skill among the younger generation of physicians. Future research could explore interventions targeting physicians' anxiety and tolerance to uncertainty as potential factors influencing requests for additional investigations and referrals. In practical terms, two avenues could be explored: specific training for supervisors to help them address uncertainty tolerance in the feedback they provide to trainees and the use of virtual consultations as a complement to traditional training, with particular attention to this aspect.

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KEYWORDS

clinical decision-making; uncertainty; patient simulation; primary care anxiety; diagnostic tests; referral and consultation

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Introduction

In primary care, at least 20% of consultations are in situations of uncertainty [1,2]. In such situations, primary care physicians (PCPs) sometimes order additional investigations, such as biological testing or radiological analyses, or offer to refer patients to specialists to help decision-making [1,3-6]. Optimal management of additional investigations and referrals is an objective for cost-effectiveness and patient safety [7-10]. Numerous papers suggest that younger generations of practitioners may be losing clinical skills and using too many additional investigations and referrals [11-13].

Experience appears to be a key determinant in additional investigations and referrals ordering [14-17]. In addition to experience, several factors have been singled out in the literature for their possible influence on additional investigations and referrals ordering in situations of uncertainty. Some relate to conditions of practice, such as the time available for each patient or the availability of tests or specialists [1,5,14,18,19], or the existence and provision of forms for requesting tests [20]. Others include societal factors, such as the fear of possible prosecution or the low cost of tests in some health care systems [5]; practitioners' clinical reasoning [14,20-24]; practitioners' emotional reaction to uncertainty, fear of regrets, and anxiety [5,14,19-21,23,25,26]; influence of the patient [1,5,14,26,27]; practitioners' expectations of performance [5]; or practitioners' sex [18]. Anxiety, in particular, had been shown to be correlated with additional investigations and referrals ordering in uncertainty [5,14,23].

In studies addressing the links between experience and additional investigations and referrals in situations of uncertainty, data were obtained using questionnaires [23], database analyses [18], or interviews with general practitioners [5,14,15,26]. To our knowledge, no study has been conducted under fully standardized conditions. Standardization involves adhering to 4 key principles: all students complete the same task, all receive identical and clear instructions, no student benefits from an undue advantage, and a predetermined grading system is applied consistently across all participants [28]. This approach ensures a fair and equitable evaluation process while minimizing the influence of external factors, such as patient variability, on additional investigations and referrals performance. Thus, to gain a better understanding of the links between experience and additional investigations and referrals in decision-making in situations of uncertainty, we believe that using a standardized situation, presented by virtual patients, is a sound approach.

The objective of this study was to explore the association between experience and additional investigations and referrals in uncertain situations, using virtual primary care consultations.

Methods

Measurement Tool

We have developed a computer tool (Hello-Clinical; University of Strasbourg) that makes it possible to simulate virtual consultations to assess the decision-making process of health care professionals for training or research purposes under standardized conditions. This study represented the first use of this tool.

We divided our virtual clinical consultations into 5 stages [4] to collect the participants' diagnostic hypotheses at each stage in an open text field without suggestions for responses. The virtual patients were presented through first-person video recordings. At the beginning, the patient is seen standing in the waiting room and greeting the physician with "good morning" after being called by the PCP. The first set of diagnostic hypotheses is collected at this stage based on initial cues such as the patient's appearance and apparent health status.

Next, the patient sits down at the PCP's desk and explains the reason for the visit. A second set of diagnostic hypotheses is then collected.

The PCP can then interact with the patient by typing questions in a text field. An algorithm automatically selects and displays the appropriate video response. For example, if the PCP asks, "Have you had a fever since you started feeling tired?" a video is shown of the patient responding, "No, I haven't noticed any fever recently."

After another round of diagnostic hypothesis collection, the PCP may request parts of the clinical examination. For instance, if blood pressure is requested, the corresponding values appear on the screen. A final diagnostic hypothesis collection follows, after which the PCP can write the additional investigations and referrals deemed appropriate in an open text field.

The Population Under Study

We recruited a sample of community-based PCPs practicing ambulatory medicine in the Grand Est region of France, including urban and rural settings. Physicians worked in nonacademic practices, either solo or group based.

The sampling strategy was predefined and stratified according to sex and professional experience. We aimed to include similar numbers of men and women to reflect the gender distribution of PCPs in the region, as well as comparable numbers of physicians with less than and more than 10 years of professional experience. The 10-year threshold was chosen based on previously published work on the development of expertise [29-33].

Recruitment followed a structured snowball procedure [34]: 2 initial PCPs known by ML were contacted and agreed to participate. Each participant was then asked to systematically provide the contact details of 1 to 3 additional PCPs. Potential participants were contacted via phone or email using a standardized information procedure. Oral informed consent was obtained prior to data collection.

Although the initial inclusion criterion was being an actively practicing PCP, recruitment was subsequently guided by ongoing monitoring of the stratification variables. Additional participants were specifically sought to meet predefined sex and experience quotas. Data collection took place between June 2017 and September 2017.

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Virtual Clinical Case

We opted to use a clinical virtual vignette to simulate a scenario in which even experienced general practitioners would likely consider requesting additional investigations and referrals. Specifically, we designed the vignette around an atypical case of pulmonary embolism. The script portrayed a 69-year-old man presenting with progressive dyspnea over several days. The clinical presentation was intentionally vague, with the goal of creating diagnostic uncertainty. The goal was to contextualize the participants' decision-making by attempting to reproduce an authentic context. Details of the main characteristics of the virtual patient are provided in Textbox 1.

Participants were able to familiarize themselves with the software beforehand by tackling a tutorial script on a 60-year-old man with recent, unexplained asthenia.

Textbox 1. Main characteristics of the virtual patient used in a cross-sectional study on experience and additional investigations and referrals requests by primary care physicians in uncertain situations using standardized virtual patient simulations in France in 2017.

Medical history

- Smoking ceased in 2012: 20 pack-years
- High blood pressure since 2010
- Right ulnar head fracture in 1989
- Peritonitis in 1974

Biometrics in the virtual case

- 85 kg
- 1.86 m
- BMI 24.5 kg/m^2
- Blood pressure 132/76 mm Hg
- Pulse 110 bpm

Treatment

- Hydrochlorothiazide 25 mg/day

Variables Collected

We identified various variables known to influence additional investigations and referrals ordering in situations of uncertainty [1,5,14,15,18,20,21,23]: participants' sex, age, years of clinical experience, anxiety, place of practice, type of practice, average number of in-office patients, and average duration of consultations. Experience was defined as the number of years of practice since graduation. Place of practice (urban, rural, or semiurban), type of practice (alone or association), number of regular in-office patients, and average duration of consultation were related to practice conditions [5,14,15,18]. These data were collected through a questionnaire submitted after the simulated consultations. No confounding patient-related factors were collected, given the use of a standardized patient. Test availability was set to maximum in this virtual clinical case. We measured the participants' anxiety levels using the State-Trait Anxiety Inventory Form Y (STAI-Y) scale [35,36] in its French version, observing only the state-anxiety dimension to save time. We selected this instrument because it is a widely used and validated measure of anxiety, with a validated French version available [35,37]. It has been used in PCP trainees [38]. We gathered responses to the French version of the Physician Reaction to Uncertainty (PRU) questionnaire [39,40]. This questionnaire has been used previously in PCP populations [40,41]. We then asked participants to rate the uncertainty and authenticity of the virtual clinical case from 1 (no uncertainty) to 5 (complete uncertainty) to verify if the case was an uncertain situation for them.

ML, YC, and RK scored the severity of the final diagnostic hypotheses based on the French clinical classification of emergency patients (classification clinique des malades des urgences; CCMU):

- CCMU 1: clinically stable, no immediate risk
- CCMU 2: condition requiring prompt attention, but no immediate life-threatening risk
- CCMU 3: potentially serious condition with a risk to life or function, requiring urgent care
- CCMU 4: very serious condition with a short-term life-threatening prognosis
- CCMU 5: deceased

Additional investigations and referrals were collected after the final stage of diagnostic hypothesis generation, categorized, and assigned costs according to the French national health pricing system (Caisse Nationale de l'Assurance Maladie des Travailleurs Salariés; CNAMTS).

Statistical Analysis

In the absence of literature on the subject, we made an empirical hypothesis that PCPs with less than 10 years of experience would order a mean number of additional investigations and referrals of 10 (SD 6.0) and PCPs with 10 years or more of experience would order a mean number of additional

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investigations and referrals of 5 (SD 2.5). We then had to include 20 PCPs in each group to obtain a 90% power with a 5% type I error with an allocation ratio of 1:1. We used a 2-sample 2-tailed *t* test for the power analysis.

To conduct the descriptive analysis of quantitative variables, for each variable, we compiled position parameters and dispersion parameters. To describe qualitative variables such as sex or type of practice, we compiled the headcounts and proportions for each modality in the sample.

Comparisons of quantitative variables between groups were performed using a Poisson regression model for counting variables, a linear model for Gaussian variables, or a nonparametric Mann-Whitney-Wilcoxon test for non-Gaussian variables. For comparisons between more than 2 groups, we relied either on ANOVA (for the Gaussian data) or the Kruskal-Wallis test (non-Gaussian data). The correlation between the quantitative variables was measured using the Pearson correlation coefficient or the Spearman correlation coefficient.

A multivariate analysis was performed with all variables. We used a stepwise selection method based on the minimization of the Akaike information criterion. Analyses were performed using R software (version 3.2.2; The R Project for Statistical Computing).

Ethical Considerations

We obtained ethics committee approval from the Ethical Reflection Group of the Groupe hospitalier Sélestat-Obernai on June 20, 2017, for this study (GH/SO 20062017CY/KR). Participants contacted via email received written study information, whereas those contacted via phone were informed orally. In all cases, oral informed consent was obtained prior to data collection. This approach aligns with French regulatory requirements, specifically a 2016 law (Décret n° 2016-1537 du 16 novembre 2016 relatif aux recherches impliquant la personne humaine [42]) that distinguishes between research involving human subjects and studies that do not fall under this category.

Our study is classified as a noninterventional research not involving human subjects (as defined by Articles L. 1121 - 1 and R. 1121 - 1 of the French Public Health Code). For such studies, oral consent is considered sufficient, provided that participants are fully informed about the study's purpose, procedures, and their rights—including the right to withdraw at any time. This approach is consistent with ethical guidelines for medical education research in France, where the emphasis is on ensuring clarity, transparency, and participant autonomy without imposing unnecessary administrative burdens.

All data were anonymized. No compensation was provided to participants.

Results

Population

In total, 40 PCPs participated in the study. Half of the participants were women. The mean age of participants was 43 (SD 13) years, and the median age was 37 years (range 31-56.8). The average number of years of experience was 15.1 (minimum 1 to maximum 40; SD 13.6). Half of the participants had more than 10 years of experience. The average STAI-Y score was 37 (SD 8.6; 95% CI 34.2 - 39.8), indicating a low level of anxiety. The average PRU score was 17.6 (SD 6.9; 95% CI 15.4 - 19.8). Participants rated the scenario's uncertainty at 3.1 out of 5 (SD 0.9) and its authenticity at 4.4 out of 5 (SD 0.8).

Participants had, on average, 3 final diagnostic hypotheses (SD 0.9; minimum 2 to maximum 5), with an average CCMU score of 2.5 (SD 0.4; minimum 1.5 to maximum 3.7). They requested an average of 10.3 additional investigations and referrals (SD 3.6; minimum 1 to maximum 16), with 34 different proposals. The average cost of additional investigations and referrals per participant was €141.80 (SD 81.6; min 17.5-max 440.5; at the time of the study, the conversion rate of US$ to € was 0.8867). Details are provided in Table 1.

The group with less than 10 years of experience had, on average, fewer regular patients (158 vs 745; $P<.001$) and higher STAI-Y (mean 41.3, SD 6.8 vs mean 32.7, SD 8.2; $P<.001$) and PRU scores (mean 20.7, SD 5.4 vs mean 14.4, SD 6.9; $P=.002$).

Both groups were equivalent in terms of gender, place and type of practice, uncertainty, authenticity of the case, mean CCMU scores, main diagnostic hypothesis' CCMU score, and average duration of consultations (Table 1).

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Table . Univariate analysis of a group of primary care physicians with less than 10 years of experience vs more than 10 years in a cross-sectional study of experience and additional investigations and referral (AIR) requests in uncertain situations using standardized virtual patient simulations in France in 2017.

	Total (N=40)	<10 years of experience (n=20)	>10 years of experience (n=20)
Age (years), mean (SD)	43.1 (13.8)	31.3 (2.5)	54.9 (9.5)
Women, n (%)	20 (50)	7 (35)	13 (65)
Experience (years), mean (SD)	15.1 (13.6)	3.6 (2.3)	26.5 (9.9)
Practice setting, n (%)			
Alone	26 (65)	14 (70)	12 (60)
Association	14 (35)	6 (30)	8 (40)
Practice location, n (%)			
Urban	25 (62.5)	11 (55)	14 (70)
Semiurban	15 (37.5)	9 (45)	6 (30)
Regular in-office patients, mean (SD)	451 (413)	158 (285.9)	745 (443.9)
Locum PCPs[a], n (%)	14 (35)	12 (6)	2 (10)
Duration of consultations (minutes), n (%)			
<10	2 (5)	1 (5)	1 (5)
10 - 20	32 (80)	16 (80)	16 (80)
20 - 30	6 (15)	3 (15)	3 (15)
Uncertainty rating, mean (SD)	3.1 (0.1)	3.3 (0.8)	2.9 (1.0)
Authenticity rating, mean (SD)	4.4 (0.8)	4.5 (0.7)	4.3 (0.9)
STAI-Y[b] score, mean (SD)	37.0 (8.6)	41.3 (6.8)	32.7 (8.2)
PRU[c] score, mean (SD)	17.6 (6.9)	20.7 (5.4)	14.4 (6.8)
Number of AIRs, mean (SD)	10.3 (3.7)	11.5 (3.5)	9.2 (3.7)
Price of AIRs (€[d]), mean (SD)	141.8 (81.6)	153.8 (91.4)	129.6 (70.8)
Diagnostic hypotheses, mean (SD)	3.0 (0.9)	3.1 (1.0)	2.9 (0.9)
CCMU[e] score, mean (SD)	2.5 (0.5)	2.5 (0.5)	2.5 (0.5)

[a]PCP: primary care physicians

[b]STAI-Y: State-Trait Anxiety Inventory Form Y.

[c]PRU: Physician Reaction to Uncertainty.

[d]At the time of the study, the conversion rate of US$ to € was 0.8867.

[e]CCMU: classification clinique des malades des urgences.

Primary End Point

Participants with less than 10 years of professional experience ordered fewer additional investigations and referrals on average: 10.2 (SD 3.4; 95% CI 8.9 - 11.7) vs 8.1 (SD 3.7; 95% CI 6.5 - 9.9; *P*=.02). The difference was mostly in laboratory testing, such as C-reactive protein, liver and kidney function tests, and complete blood count. The effect size was 0.603 (95% CI −0.052 to 1.257). There was no effect on costs: €153.8 vs €129.6 (effect size 0.296, 95% CI −0.348 to 0.939; *P*=.23).

In multivariate analysis, there was an association between the number of additional investigations and referrals with age (relative risk [RR] 0.980, 95% CI 0.963 - 0.997; adjusted *P*=.02) and mean STAI-Y score (RR 0.984, 95% CI 0.968 - 0.999; adjusted *P*=.04) but not with years of experience categorized in 10-year thresholds (R^2=0.308; Table 2).

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Table . Final model of the number of additional investigations and referrals after stepwise backward selection in a cross-sectional study on experience and additional investigations and referrals requests by primary care physicians in uncertain situations using standardized virtual patient simulations in France in 2017.

	Adjusted relative risk (95% CI)	Adjusted *P* value
Experience (>10 years)	1.042 (0.673 - 1.611)	.85
Age (years)	0.980 (0.963 - 0.997)	.02
Number of regular in-office patients	1.000 (0.999 - 1.000)	.15
STAI-Y[a] score	0.984 (0.968 - 0.999)	.04
Sex (men)	0.842 (0.667 - 1.064)	.14
Number of hypotheses	1.093 (0.980 - 1.218)	.11

[a]STAI-Y: State-Trait Anxiety Inventory Form Y.

Discussion

Principal Findings

Having 10 or more years of experience was not associated with a lower number or costs of additional investigations and referrals ordered in our virtual patient scenario. The group with less than 10 years of experience had significantly higher STAI-Y and PRU scores than the group with more than 10 years of experience, and there was a statistically significant association between STAI-Y score, age, and the number of additional investigations and referrals ordered.

Comparison With Previous Studies and Interpretation

Unlike many past studies [5,8,14,15], we did not find that greater experience was associated with a decrease in the number of requests for additional investigations and referrals in primary care. There was an association between age and the number of requests in a multivariate analysis. However, neither the difference in the number of requests nor the association with age seemed clinically significant. The difference was an average of 2 additional requests, corresponding to a mean cost difference of less than €25, primarily related to common laboratory tests. Physicians with less than 10 years of experience generated only slightly more diagnostic hypotheses than those with more than 10 years of experience (3.1 vs 2.9). In light of these results, in this virtual study, younger PCPs seem to not significantly rely on additional investigations and referrals to reach a diagnosis in uncertain situations in primary care.

Several factors may explain this discrepancy. First, the study sample may reflect a selection bias, as participation in simulation studies tends to attract clinicians who are more comfortable with digital environments and reflective practice [43]. Second, the use of standardized virtual patients removes key contextual pressures, such as time constraints, patient expectations, and perceived medico-legal risks, all of which are known to influence investigation and referral behaviors in real practice [44]. These contextual pressures might weigh more heavily on less experienced physicians. Third, differences in cognitive load may help explain the findings. According to cognitive load and dual process theories, novices allocate more resources to problem-solving processes, whereas experts rely more on pattern recognition [45-47]. In a virtual environment without external pressures, cognitive load may not lead younger physicians to request more additional investigations and referrals than their senior counterparts. Finally, psychological factors such as tolerance of uncertainty and anxiety—measured using the PRU and STAI-Y—are known to influence investigation behavior (Gerrity et al [48] and Simpkin and Schwartzstein [49]). Our data suggest that while younger PCPs reported higher anxiety and lower tolerance of uncertainty, these traits did not independently predict additional investigations and referrals use once contextual biases were controlled for, indicating that experience alone may be an oversimplified predictor.

In contrast, age and anxiety seemed to be associated with additional investigations and referral requests. The small RR values (0.980 and 0.984) indicate a questionable clinical significance. There were significantly more locum PCPs in the group with less than 10 years of experience (n=12 vs n=2, respectively; *P*<.001). Locum PCPs frequently move from one practice to another. They may therefore lack this feedback loop, which is essential for enhancing diagnostic reasoning and understanding the typical clinical progression of common conditions [50]. This might be part of the explanation of why less experienced PCPs requested more additional investigations and referrals and had significantly higher PRU and STAI-Y scores. Hillen et al [51] conceptualized uncertainty tolerance (UT) as “the set of negative and positive psychological responses—cognitive, emotional, and behavioral—provoked by the conscious awareness of ignorance about particular aspects of the world”. UT could lead to decision deferral as part of a negative behavioral response to uncertainty [51]. This could help explain a higher use of additional investigations and referrals in a more anxious group. The perception of uncertainty could also lead to negative emotional responses, such as worry or fear [51]. Such responses may be part of defensive medical practice [44]. Research shows that physicians sometimes order additional investigations and referrals to reassure patients and themselves [5,20,21,26], but the effect is small on patients [52]. Although such orders may reassure physicians, it would be better to develop interventions aimed at reducing physicians’ anxiety directly rather than accept orders for additional investigations and referrals made simply for reassurance. From a medical education perspective, an effort should be made to improve the practices of primary care residents’ supervisors by offering specific feedback on experience aimed at building up positive responses of UT [14,49,51]. This may promote the

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optimal use of additional investigations and referrals in primary care by future clinicians.

Many international guidelines insist on the necessity to rationally use additional investigations and referrals after a period of watchful waiting in the absence of red flags in situations such as fatigue or unexplained symptoms [53-56]. In the present case of dyspnea that had progressed for several days in a man aged 69 years, prompt additional investigations and referrals were justified. Participants' requests were mostly adequate considering the 8 additional investigations and referrals to order in the pregraduated national learning objectives for acute dyspnea: complete blood count, blood electrolyte panel, blood glucose, brain natriuretic peptide or N-terminal prohormone of brain natriuretic peptide, D-dimers, electrocardiography, chest X-ray, and arterial blood gas analysis [57]. Our data suggest that progress could still be made on the rational use of additional investigations and referrals. Interventions such as the "five-step program for diagnostic test addiction" [58] could be used in a primary care setting: decide what diagnosis you are investigating, determine the pretest probability of the condition in question, decide whether to rule the condition in or out, decide what you will do if the test result is positive or negative, and ask whether ordering this test could hurt the patient. It would be interesting to explore the relationship between requests for additional investigations and referrals and clinical experience in scenarios where an experienced physician might choose not to rely on such requests. Such situations could provide valuable insights into how experience influences decision-making and the perceived necessity of additional tests, particularly in cases where clinical confidence may outweigh diagnostic uncertainty.

From a clinical reasoning perspective, experience is conducive to the optimization of knowledge organization in the form of clinical scripts among PCPs (clinical scripts) [4,59]. We hypothesize that with more efficient clinical scripts, PCPs could better identify situations in which to order additional investigations and referrals, when to refrain from ordering them, and when to adopt a watchful, waiting approach [56]. In contrast, Watson et al [26] showed that PCPs developed their own mental shortcuts, including blood tests. Teaching clinical reasoning could incorporate practical exercises based on clinical cases that require decisions about whether to request additional investigations and referrals in situations of uncertainty [60].

The way clinical reasoning is supervised may also positively influence students' anxiety and tolerance of uncertainty. For instance, the SNAPPS (summarize, narrow, analyze, probe, plan, select) model has been shown to encourage learners to voice more diagnostic uncertainty during supervisory encounters [61-63]. This approach explicitly targets the inherent diagnostic uncertainty of clinical care and may therefore help improve the appropriateness of requests for additional investigations and referrals among future physicians.

Limitations and Future Directions

The authenticity of the case is limited by the extent of the software's possibilities and current technical constraints. The software cannot capture certain types of information clinicians use in their reasoning, such as smells, and it is difficult for participants to fully detach from their usual practice context to engage with the simulated consultation environment [4]. The STAI-Y score only included the measurement of state-anxiety (not trait-anxiety). The impact of trait anxiety on additional investigations and referrals requests is not known. Moreover, the requests for additional investigations and referrals were self-reported and may not correctly predict real-life behavior. Experience was only defined by years of practice, although previous research has shown that the correlation between years of experience and clinical performance in medicine is often weak [32]. Qualitative insights on the participants' expertise defined by peers rather than the number of years of experience could have enriched our comprehension of the topic. The snowball sampling method allowed us to respect the stratification of participant recruitment, ensuring that the sample aligned with the intended population characteristics. However, this method may have introduced some bias into our results, as it could increase the likelihood of finding associations specific to this population that may not exist in the general population [64]. Given that the target population was not particularly difficult to reach, future studies might consider using a larger sample with random sampling method to enhance generalizability and minimize potential biases. We chose to focus on only a portion of the potential determinants of additional investigations and referrals in our data collection for feasibility reasons.

Conclusions

Less experienced PCPs do not appear to overly rely on additional investigations and referrals in situations of uncertainty, suggesting that clinical reasoning remains a well-preserved skill among the younger generation of physicians. However, these findings should be interpreted with caution, as they may not fully account for the nuances in decision-making across varying levels of experience. Future research could explore interventions targeting physicians' anxiety and tolerance of uncertainty as potential factors influencing additional investigations and referral requests. In practical terms, 2 avenues could be explored: specific training for supervisors to help them address UT in the feedback they provide to trainees and the use of virtual consultations as a complement to traditional training, with particular attention to this aspect. For instance, using methods such as SNAPPS could improve additional investigations and referral requests among future physicians by explicitly addressing clinical uncertainty. Additionally, it would be valuable to investigate scenarios where experienced physicians might consciously avoid additional investigations and referrals, providing further insights into the interplay between experience and test-ordering behavior in primary care.

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Data Availability

The datasets generated and analyzed during this study are available on Google Drive [65].

Authors' Contributions

ML designed the study, collected and analyzed the data, and drafted the manuscript. RK helped design the study, collected and analyzed the data, and helped in drafting the manuscript. YC helped design the study, collected and analyzed the data, and helped in drafting the manuscript. FL helped design the study, analyzed the data, and critically revised the manuscript. ET, NF, TP, and HM helped design the study and critically revised the manuscript.

Conflicts of Interest

None declared.

Checklist 1
STROBE checklist.
[PDF File, 169 KB - formative_v10i1e71717_app1.pdf]

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Abbreviations

PCP: primary care physician
PRU: Physician Reaction to Uncertainty
RR: relative risk
SNAPPS: summarize, narrow, analyze, probe, plan, select
STAI-Y: State-Trait Anxiety Inventory Form Y
UT: uncertainty tolerance

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Development of the Healthy Women Intervention to Increase Women's Engagement in Medication Treatment for Opioid Use Disorder: Mixed Methods, User-Centered Design Approach

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Abstract

Background: Rates of opioid use disorder (OUD) have increased among women over the past 2 decades. Medication treatment for opioid use disorder (MOUD) is effective but underused. Gender-specific treatments for women have been associated with improved substance use outcomes. However, these treatments have not specifically targeted women's engagement in MOUD, and the impact of existing gender-specific treatments is restricted by in-person delivery.

Objective: The aim of this study was to develop a digital intervention to feasibly deliver gender-specific care that addresses the individualized needs of women with OUD to increase engagement in MOUD.

Methods: A mixed methods, user-centered design approach was used to inform the development of a digital intervention. In phase 1, qualitative interviews were conducted with women with lived experience of OUD (n=20) and providers who treat women with OUD (n=8). Interviews were recorded, transcribed, and coded for themes. In addition, a larger sample of treatment providers (n=55) completed an online survey to further inform the content of the digital intervention. Phase 2 consisted of designing, beta-testing (n=5), and refining the intervention.

Results: The age of women with lived experience ranged from 21 to 59 (mean 38.5, SD 9.4) years; 63% (5/8) of providers interviewed were female participants. The qualitative interview data from women with lived experience and providers were grouped into 6 thematic categories: 3 treatment-related (1) barriers to treatment, (2) facilitators to successful recovery, and (3) important issues to address in treatment, and 3 technology-related (4) positives of using technology as part of treatment, (5) suggested technology features, and (6) barriers to using technology. Across the treatment-related categories, several themes touched on women-specific factors including family responsibilities, abusive partners, stigma, and motivation for treatment (eg, pregnancy). The technology-related categories provided information for designing the features of the intervention, as well as revealing barriers to technology use, which could be helpful in developing implementation strategies. Provider survey participants were primarily female participants (40/55, 73%), with a mean age of 42.5 (SD 12.5) years. Survey data provided additional information on barriers to treatment and suggested technology features. Based on these data and preliminary work, the *Healthy Women* intervention was created. Minor edits to content and visual design were made in the beta-testing phase. The final version includes a web-based component with 6 topic modules and a mobile component. Topics in the web-based component are presented through infographics, text, videos, and interactive questions. The mobile component includes daily motivational messages, skills practice activities (2/wk), weekly check-ins, and resources (always available).

Conclusions: Important themes and suggested features from women with lived experience and providers were incorporated into a digital intervention for women with OUD. Data on feasibility, satisfaction, and engagement with the *Healthy Women* intervention are currently being collected in phase 3, a pilot randomized controlled trial.

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KEYWORDS

internet intervention; web-based intervention; opioid use disorder; mobile apps; women; digital technology; user-centered design

Introduction

Background

In 2024, 2.48 million women had a past-year opioid use disorder (OUD) [1]. Although rates of substance use disorders (SUDs) overall are higher in men than in women, rates of OUD are equivalent, and the reverse pattern has emerged for adolescents, with higher rates of OUD in girls compared to boys [1]. Medication treatment for opioid use disorder (MOUD) is effective in reducing opioid use and the risk of overdose, but retention rates are low, particularly during the early phase of treatment [2,3]. Among adults with OUD, females are less likely to receive MOUD compared to males [1]. Therefore, it is critical to develop specific sustainable strategies to engage and retain women with OUD in MOUD treatment.

Gender-specific SUD treatments address factors that are more prevalent in women, which may affect their treatment outcomes (eg, exposure to trauma, co-occurring psychiatric disorders, relationships with children and intimate partners, and physical health issues) and are associated with increased engagement, greater satisfaction, and improved outcomes [4-7]. However, these treatments have not specifically targeted women's retention in MOUD treatment, and the impact of existing gender-specific treatment is restricted by in-person delivery. Fewer women relative to men in mixed-gender settings can be an additional barrier to implementing gender-specific treatments in substance use treatment programs [8].

Technology-based interventions are effective in encouraging treatment engagement [9-11]. Smartphone apps, in particular, are emerging as a feasible and desirable way to integrate frequent support into patient care, with recent work demonstrating high perceived usefulness, helpfulness, and enthusiasm about various apps from OUD patients and providers alike [12-16]. However, much of the current work in this area has used mixed-gender participant populations and has not specifically focused on women's experiences [9-11,13,14,16,17].

Findings from a recent review of digital interventions to support women in treatment for OUD showed that most of the existing technology in this area involves telemedicine (ie, virtual visits) rather than asynchronous digital interventions [18]. Since recent work has found that one of the biggest barriers for women in OUD treatment is time, it is crucial to fill the gap in research around self-guided recovery-focused technology [19]. The few studies that examine digital interventions created for women with OUD have targeted highly specific populations, such as women in rural areas mandated to outpatient treatment [20] and American Indian or Alaska Native women [21], highlighting the need for interventions adaptable to less specific patient populations.

Prior Work

To examine the feasibility of creating a gender-specific digital intervention for women with SUDs, we adapted material from the Women's Recovery Group (WRG) [5,6,22] to a web-based format. The WRG is an evidence-based, women-focused, single-gender group therapy for women with SUDs [5,6,22]. This 12-session group is based on a cognitive-behavioral approach and includes gender-specific content and relapse prevention skills. In a series of pilot studies [23], we adapted material from modules of the WRG that are of key relevance to women with SUDs into a web-based format within a user-friendly design. Interactive questions were included to increase engagement with the digital intervention. Next, the intervention was tested with 30 women receiving mixed-gender inpatient care in McLean Hospital's Alcohol, Drug, and Addiction Treatment Program (ADATP). Results revealed a high level of satisfaction with the intervention. Based on participant feedback, the intervention was refined, including the addition of material from two additional WRG modules. These changes directly addressed participants' interest in receiving more information on trauma and sexual abuse, as well as self-care in recovery. We then tested the intervention with 60 women receiving inpatient, partial hospitalization, or outpatient levels of care [23] and again found a high level of satisfaction with the intervention. Satisfaction scores did not differ by level of care, prior treatment experience, or age. These data support the feasibility of a gender-specific digital intervention for SUDs, show that women were highly satisfied with this type of program, and provide a prototype of the intervention for the current study.

Objective

Building on our previous work, the aim of the study was to gather data from treatment providers and women with lived experience of OUD to inform the development of a digital intervention to feasibly deliver gender-specific care that addresses the individualized needs of women with OUD, thereby increasing engagement in MOUD treatment.

Methods

Overview

A mixed methods approach was used to inform the development of the digital intervention. Figure 1 outlines the 3 phases of the study. The development process incorporated principles of user-centered design based on the Discover, Design and Build, and Test (DDBT) framework [24]. In phase 1 (discover), we conducted formative work by interviewing women with lived experience as well as providers who treat women with OUD. To further elucidate the provider perspective, we also administered a self-report survey to a larger sample of treatment providers. Phase 2 (design or build) was a modified version of the steps outlined in the DDBT framework, as we were building off an existing prototype that had already undergone 2 rounds of usability testing [23]. In this phase, we further adapted the existing prototype based on feedback from the formative phase. Next, there were two rounds of refinement: (1) following expert review and (2) after beta-testing phases 1 and 2 are reported in this paper. Phase 3 (test), a pilot randomized controlled trial of the intervention, is currently underway.

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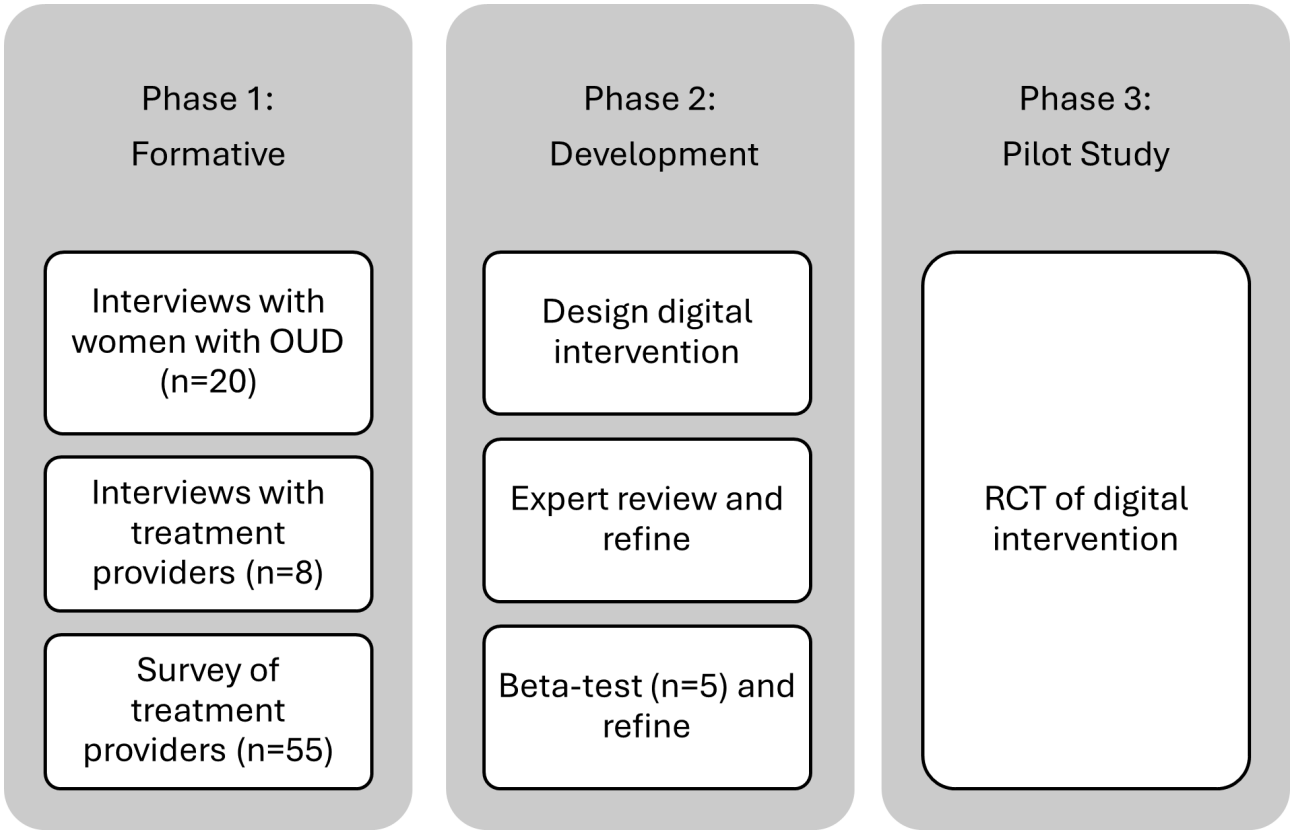
Figure 1. Overview of study phases. OUD: opioid use disorder; RCT: randomized controlled trial.



Ethical Considerations

The Mass General Brigham Institutional Review Board (IRB) reviewed and approved the protocols for this study (phase 1: protocols #2019P003747 and #2022P001902; phase 2: protocol #2023P000495) and waived the requirement for written consent for phase 1 studies. Participants were apprised of the study's objectives, content, and associated risks and benefits through online study fact sheets. Eligible participants expressed their willingness to participate by clicking on a checkbox next to the statement "I agree to participate in this research." For phase 2, participants completed electronic informed consent after reading through the IRB-approved consent form with a research staff member available to answer any questions, explain the study procedures, and review the risks and benefits of the study. REDCap (Research Electronic Data Capture) was used to obtain electronic informed consent. To protect privacy and confidentiality, participants were reminded at the beginning of the qualitative interviews to avoid disclosing identifying information. If any identifying information was inadvertently disclosed, it was removed from interview transcripts. No information concerning individual cases is referred to in public materials in such a way as to identify individuals.

In phase 1, provider participants who completed qualitative interviews received a US $25 gift card for their participation. The first 16 women with lived experience participants received a US $25 gift card. Partway through the study, there was recognition that due to the COVID-19 pandemic, individuals had increased economic needs. After discussion with clinicians in community clinics and the IRB, the women with lived experience participant payment was increased to a US $50 gift card; the final four participants received the US $50 gift card. Provider participants who completed the survey had the option to enter a raffle for a chance to win a US $50 gift card. In phase 2, participants received US $70 for the baseline visit.

Phase 1: Formative Research

Participants and Procedures

Qualitative Interviews

Women with lived experience (N=20) were recruited from inpatient (n=10), residential (n=4), and outpatient (n=6) treatment programs in the greater Boston area via referral from clinical providers or self-referral from study advertisements. Women were eligible if they were at least 18 years old and receiving care for a current OUD. Women were ineligible for the study if they were admitted to inpatient treatment involuntarily or had an acute psychiatric or medical condition or cognitive impairment that would hinder their ability to complete study procedures. Women with lived experience ranged from 21 to 59 (mean 38.5, SD 9.4) years of age and endorsed several co-occurring mental health problems in the past year, the most common being anxiety (n=20, 100%), depression (n=19, 95%), and posttraumatic stress disorder (n=16, 80%). Nearly all (n=18, 90%) had tried some form of MOUD in their lifetime, and 65% (n=13) were currently taking MOUD at the time of the interview.

Treatment provider participants (N=8) were invited to participate in the study if they provided clinical services to individuals with OUD in the McLean Hospital's ADATP continuum.

Once enrolled in the study, all participants completed semistructured interviews with the principal investigator (DES).

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Interviews were conducted either in-person at McLean Hospital or remotely over Zoom. Interviews conducted with women with lived experience explored topics most important to them regarding their treatment, treatment barriers and facilitators, and their interest in using technology and/or mobile apps in their recovery (Multimedia Appendix 1). The women with lived experience also completed a web-based survey using REDCap. The survey included questions about participant demographics, substance use, and history of SUD treatment. Interviews conducted with treatment providers explored providers' perspectives on women's reasons for initiating MOUDs, barriers to maintaining sustained MOUD treatment, and the role of technology in helping women initiate MOUDs (Multimedia Appendix 2).

Interviews were conducted between January 2021 and December 2021. All interviews were audio-recorded and then transcribed. Transcripts were coded using inductive thematic analysis in NVivo (Lumivero) [25] in accordance with the 6 phases described by Braun and Clarke [26]. For the women with lived experience interviews, 2 coders (DES and CLW) independently reviewed the transcripts and determined initial codes. The codes were reviewed, and a master code list was defined and agreed upon by the 2 coders; next, they independently coded 5 of the transcripts. Interrater reliability was established (percent agreement across the 5 coded transcripts=99%), and CLW coded the remaining transcripts. Once complete, DES reviewed the coded transcripts and met with CLW for a final time to discuss and resolve discrepancies. Next, codes were examined, and related codes were clustered together into themes based on similarity.

A similar process was followed for coding the provider interviews; however, given the small number of transcripts, two coders (CLW and FMK) independently coded all the transcripts. DES met with the two coders to discuss and resolve discrepancies.

Provider Survey

To answer an online survey, treatment providers were recruited through relevant national organizations' email listservs and snowball sampling via local treatment providers. Providers were eligible to enroll in the study if they were 18 years of age or older and had provided clinical services to women with OUD in the past year (as indicated by responses to self-reported screening questions). Providers who were eligible and agreed to participate (n=58) completed a brief self-report survey. Three of the 58 providers who agreed to participate in the study did not complete any of the survey questions. Therefore, the available sample for analysis consisted of 55 participants. Descriptive statistics were used to summarize data from the provider survey.

The self-report survey was delivered via REDCap and was conducted between September 2022 and December 2022. The survey was developed specifically for this study and included questions on provider demographic characteristics and professional background, perceptions of barriers to treating women with OUD, frequency of advising women about MOUD, and ratings of the usefulness of different features and content of a digital intervention for women with OUD.

Phase 2: Development

Beta-Testing: Participants and Procedures

The first 5 participants who enrolled in the pilot study and were assigned to the intervention condition served as the beta-testing group for the web-based component. Participants were recruited from McLean Hospital's ADATP services continuum, the Mass General Brigham online research recruitment site (Rally), and from flyers posted throughout McLean Hospital. Women were included if they (1) were 18 years of age or older, (2) had a current OUD diagnosis (moderate or severe by DSM-5 criteria), (3) initiated MOUD in the past 30 days, and (4) were able to provide informed consent. Women were excluded if they (1) had an acute psychiatric or medical condition, or cognitive impairment that would impair the ability to complete study procedures (as determined by review of medical records and confirmation from clinical staff), or (2) were admitted to their current treatment episode on an involuntary status.

All 5 participants engaged in a "think aloud" process as they navigated through the web-based portion of the intervention, which occurred at the baseline visit for the pilot study. Specifically, they were asked to describe their experiences and any challenges they encountered. The research assistant took notes during this process. Participant comments were reviewed and discussed by members of the study team (DES, NAB, SFG, and RDW).

Results

Qualitative Interviews

Overview of Thematic Analysis

Demographic characteristics of the qualitative interview participants are reported in Table 1. Themes for the qualitative interviews with women with lived experience and treatment providers were reviewed for commonalities. There was considerable overlap in the themes that emerged from the 2 sets of qualitative interviews, given that the interview questions were similar. Thus, we grouped the themes from both sets of interviews into 6 common thematic categories, which followed the main topics of the interview questions. Three categories were related to treatment, and 3 were related to technology. Table 2 shows the 6 categories and associated themes from both the provider and women with lived experience interviews. Five categories were common across both sets of participant interviews: barriers to treatment, facilitators to successful recovery, positives of using technology as part of treatment, suggested technology features, and barriers to using technology. An additional category was relevant to the women with lived experience interviews only: important issues to address in treatment. The women with lived experience participants were specifically asked a question about important topics to address in treatment, whereas treatment providers were not asked this question.

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Table . Demographic characteristics of qualitative interview participants.

Participants	Total
Women with lived experience (N=20)	
Age (y), mean (SD; range)	38.5 (9.4; 21-59)
Race[a], n (%)	
White	15 (75)
Black or African American	1 (5)
American Indian or Alaskan Native	1 (5)
Other	1 (5)
Prefer not to answer	2 (10)
Ethnicity, n (%)	
Hispanic or Latina	5 (25)
Sexual orientation, n (%)	
Heterosexual or straight	14 (70)
Bisexual	3 (15)
Lesbian	1 (5)
Pansexual	1 (5)
Prefer not to answer	1 (5)
Marital status, n (%)	
Never married	11 (55)
Married	3 (15)
Separated	4 (20)
Divorced	2 (10)
Education, n (%)	
Less than high school	3 (15)
High school graduate or GED[b]	4 (20)
Some college	7 (35)
College graduate	6 (30)
Primary residence, n (%)	
Apartment/house	15 (75)
Homeless or shelter	4 (20)
Temporary housing	1 (5)
Living situation, n (%)	
Live alone	2 (10)
Live with parents or guardians	3 (15)
Live with extended family	5 (25)
Live with friends or roommates	4 (20)
Live with partner or significant other	5 (25)
Prefer not to answer	1 (5)
Occupational status, n (%)	
Unemployed	12 (60)
Disability	3 (15)
Employed part-time	2 (10)

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Participants	Total
Student	1 (5)
Work within the home	1 (5)
Prefer not to answer	1 (5)
Have children, n (%)	14 (70)
How many? mean (SD)	2.1 (1.3)
OUD[c] treatment providers (N=8)	
Female, n (%)	5 (62.5)
Years working with OUD patients, mean (SD)	18.8 (10.4)
Discipline, n (%)	
Psychiatrist	7 (87.5)
Nurse (APRN[d])	1 (12.5)

[a]Responses are not mutually exclusive.
[b]GED: general educational development.
[c]OUD: opioid use disorder.
[d]APRN: advanced practice registered nurse.

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Table . Categories and themes from qualitative interviews.

Categories and themes	Examples codes	Discussed by	
		Women with lived experience (n=20)	Providers (n=8)
Barriers to treatment			
Co-occurring disorders	• Depression • Trauma • Chronic pain • Polysubstance use	✓	✓
Partners	• Partner who uses substances • Abusive partner	✓	✓
Negative beliefs			
Negative beliefs about SUD[a] treatment	• Belief that treatment does not work • Dislike certain treatment modalities (eg, groups, telehealth)	✓	
Negative beliefs about MOUD[b]	• Substituting one drug for another • Short-term solution • Stigma from others for being on MOUD • Concerns MOUD use will affect future care	✓	✓
Personal factors or attitude	• Lack of motivation and ambivalence • Shame and embarrassment • Guilt	✓	✓
MOUD-specific barriers	• Concerns about tapering off • Side effects or bad reaction • Issues getting on the right dose • Daily commitment (Methadone; Buprenorphine) • Waiting period to initiate (Buprenorphine) • Need to be abstinent to start (Vivitrol)	✓	✓
Family responsibilities	• Childcare and caregiving responsibilities • Pregnancy		✓
Facilitators to successful recovery			
Support from others	• Mutual help groups • Supportive friends and family • Supportive partners	✓	✓
Motivation	• Having accountability • Commitment to treatment • Factors motivating MOUD initiation (eg, withdrawal, craving, and pregnancy)	✓	✓
Structure	• Having a schedule or routine	✓	
Coping skills	• Engaging in healthy coping activities • Avoiding negative influences	✓	

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Categories and themes	Examples codes	Discussed by	
		Women with lived experience (n=20)	Providers (n=8)
Mental health treatment	• Getting treatment for co-occurring disorders	✓	✓
Education	• Education about MOUD		✓
Important issues to address in treatment			
Co-occurring disorders	• Trauma and abuse (sexual abuse, IPV[c]) • Co-occurring mental health disorders • Polysubstance use	✓	
Negative beliefs and emotions	• Stigma • Shame and guilt • Grief	✓	
Social network	• Peer support • Being around positive influences	✓	
Woman-specific issues	• Sexism • Menstrual cycle • Pregnancy and post-partum	✓	
Relationships	• Partners • Caregiving	✓	
Self-care	• Forgiveness and self-love • Honesty	✓	
Positives of using technology as part of treatment			
Availability	• Easy to access • Provides in the moment support	✓	✓
Connection with others	• Helps with connectedness • Easier to reach out to others for support through technology	✓	✓
Adjunct to treatment	• Helps address co-occurring disorders • Providers could encourage use • Help with medication adherence	✓	✓
Accountability	• Engaging with technology program regularly keeps people accountable to their recovery	✓	✓
Suggested technology features			

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Categories and themes	Examples codes	Discussed by	
		Women with lived experience (n=20)	Providers (n=8)
Reminders	• Appointment or medication reminders • Calendar	✓	✓
Tracking	• Tracking substance use and cravings • MOUD adherence • Tracking mental health symptoms • Tracking progress toward goals	✓	✓
Motivational supports	• Motivational messages • Rewards • Personalized feedback • Stories of people in recovery • Journal	✓	
Educational information	• Resources • Location services to find meetings	✓	✓
Social support tools	• Peer support • Connecting with other women • Connection with therapist • Alerts to other people when relapsing	✓	✓
Skills practices	• Meditation or mindfulness activities • DBT[d] skills	✓	
Barriers to using a technology			
Technological difficulties	• No internet connection or no data • Lack of access to phone • Too difficult to use, not tech savvy • Cost	✓	
Mental health or substance use	• Actively using substances or relapse • Mental health symptoms (eg, depression)	✓	
Lack of interest	• Lose interest or forget • Other priorities • Lack of human connection	✓	
Provider issues	• Liability concerns • Burden on provider		✓

[a]SUD: substance use disorder.

[b]MOUD: medication treatment for opioid use disorder.

[c]IPV: intimate partner violence.

[d]DBT: dialectical behavior therapy.

Thematic Category 1: Barriers to Treatment

Participants identified several types of factors that impeded their ability to seek treatment and obtain MOUD. The 7 themes in this category encompass internal factors (eg, co-occurring disorders, negative beliefs, and attitudes) and external factors (eg, partners and family responsibilities). The theme of negative beliefs was split into two subthemes: negative beliefs about

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SUD treatment in general and negative beliefs specifically about MOUD. A separate theme of MOUD-specific barriers was included, which differed from negative beliefs about MOUD. Negative beliefs were often described as reasons people did not want to initiate MOUD (eg, "some of the support groups like Narcotics Anonymous have given messages to people that, 'you're just substituting one addiction for another.'" [provider]. MOUD-specific barriers tended to be concerns or issues expressed by people who wanted to take MOUD (eg, side effects or concerns about tapering off and dosing schedule); 1 participant described:

> *I heard that it's very hard to kick, to come off of it. So that's one thing I'm kind of worried about.*

Thematic Category 2: Facilitators to Successful Recovery

In contrast to barriers, participants identified factors that were helpful to them in their recovery, including support from others, motivation, having structure, learning coping skills, getting mental health treatment for co-occurring disorders, and receiving education on MOUD.

Some themes that were identified included factors that could serve as both facilitators and barriers to treatment. For example, partners could act as a barrier to treatment if they used substances or were abusive, but partners who were supportive could serve as a facilitator. One provider described how partners can be a barrier to MOUD: "I've heard lots of different situations where their partner has sold their medication or their partner makes it difficult for them to get to their treatment appointments so they're not able to fill their script." Another provider described how partners can help with MOUD adherence: "Certainly partners that are supportive of them being on medication is a huge factor, especially if that partner is involved in monitoring the medication adherence in any meaningful way." Pregnancy could also be a barrier to treatment, particularly in deciding to initiate MOUD, or it could facilitate treatment if it motivated women to enter treatment.

Both women with lived experience and providers identified system-level barriers and facilitators. Codes related to system-level barriers and facilitators are not included in the summary table (Table 2) as they did not directly inform the development of the digital intervention. Examples of system-level barriers identified by women with lived experience and providers included housing insecurity, legal issues, problems navigating the health care system, and a lack of beds available for women in SUD treatment programs. Examples of system-level facilitators included employment, case management, insurance coverage, and having a therapist or treatment provider who was caring and supportive.

Thematic Category 3: Important Issues to Address in Treatment

Many of the themes under this category were similar to some of the identified barriers to treatment, including co-occurring disorders, negative self-beliefs, women-specific issues, and relationships. Despite the overlap, these themes were retained under separate categories, as they can inform both the implementation of the intervention and its content. Participants also indicated that peer support and self-care topics, such as forgiveness, self-love, and honesty, were important to address in treatment. One woman with lived experience described self-care as being particularly relevant for women:

> *...you're not only harming yourself, but you're also a mother and a caretaker, and you don't get a lot of forgiveness, a lot of self-forgiving. I think we try so hard to be everyone to everyone, and…this sounds so weird to say, but I feel like it's easier to forgive a man than it is to forgive a woman.*

Thematic Category 4: Positives of Using Technology as Part of Treatment

Themes in this category focused on the widespread availability of technology, the ability to easily connect with others, ways they could use digital programs with their treatment providers, and how technology-based programs could help keep them accountable to their recovery goals. Regarding accountability, 1 woman with lived experience stated:

> *It's kinda something to hold you accountable. Something to look forward to, and something that you know you've got to check in.*

Thematic Category 5: Suggested Technology Features

Participants reported several different types of features that could be helpful to include in a digital intervention for women with OUD. Suggested technology features were grouped into six themes: reminders, tracking, motivational supports, educational information, social support tools, and skills practices. With regard to tracking, there were several ways that participants thought this feature could be helpful, including monitoring substance use and cravings, MOUD adherence, mental health symptoms, and progress toward individual recovery goals. One participant described how the digital skills practice exercises could be especially helpful to individuals in recovery:

> *That would be absolutely amazing [to have a skills practice feature]. Because as addicts…we forget things. And sometimes we go on autopilot, and we act on impulse. So if we had something like that to remind us, "This is how you cope, this is how you practice." I think that would be excellent.*

Thematic Category 6: Barriers to Using Technology

Despite interest in using technology as part of treatment, women with lived experience identified some barriers to its use, including technological difficulties, lack of interest, and active substance use. Lack of access to mobile phones was one of the technological difficulties identified, particularly related to consistent access. As described by 1 woman with lived experience:

> *Sometimes it comes down to—for somebody like me—it's either food, shelter, sick, or paying my cell phone bill. My cell phone bill is going to be the last one, I'll tell you that.*

Providers expressed concerns about liability and burden on the treatment provider. For example, 1 provider wondered:

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> *...an app that they could go login and either chat with each other, post something to some kind of discussion, would be really helpful…if I [the clinician] were involved in that it would be challenging because what if somebody posted something risky or safety wise or just privacy wise?*

Provider Survey

Demographic characteristics of the survey sample are listed in Table 3. Provider survey participants predominantly identified as women and came from a range of disciplines, most commonly psychiatrists (13/55, 23.6%), other physicians (16/55, 29.1%), and psychologists (9/55, 16.4%). More than half of the samples were prescribers (30/55, 54.5%). Most providers (46/55, 83.6%) endorsed that they "usually" or "always" advise buprenorphine maintenance to women with OUD, whereas fewer providers endorsed "usually" or "always" advising naltrexone or methadone maintenance (16/55, 29.1% and 10/55, 18.2%, respectively).

Table . Demographic characteristics of the provider survey sample (n=55).

Demographic characteristics	Values
Age (y), mean (SD)	42.5 (12.5)
Gender identity, n (%)	
Woman	40 (72.7)
Man	14 (25.5)
Nonbinary or gender nonconforming or gender-queer	1 (1.8)
Race[a], n (%)	
White	45 (81.8)
Asian	8 (14.5)
American Indian or Alaska Native	1 (1.8)
Multiracial	1 (1.8)
Prefer not to answer	1 (1.8)
Ethnicity, n (%)	
Hispanic or Latino	2 (3.6)
Discipline, n (%)	
Physician (other than psychiatrist)	16 (29.1)
Psychiatrist	13 (23.6)
Psychologist	9 (15.3)
Social worker	7 (11.9)
Nurse (RN[b], APRN[c], LPN[d])	2 (3.6)
Other (recovery coach, mental health counselor, intern, student, community health worker)	8 (14.5)
Total years in practice, n (%)	
< 5 y	9 (16.4)
5-10 y	20 (36.4)
11-20 y	17 (30.9)
20+ y	9 (16.4)
Licensed prescriber, n (%)	30 (54.5)
Prescribed buprenorphine in the last 12 mo	28 (93.3)
Prescribed naltrexone in the last 12 mo	24 (80)
Referred any patients to an opioid treatment program for methadone treatment in last 12 mo, n (%)	30 (54.5)

[a]Responses are not mutually exclusive.

[b]RN: registered nurse.

[c]APRN: advanced practice registered nurse.

[d]LPN: licensed practical nurse.

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More than half of the sample categorized the following as "major barriers" to treating women with OUD: housing insecurity (37/55, 67.3%), family responsibilities or lack of childcare (34/55, 61.8%), and lack of transportation (33/55, 60%) (Table 4). Participants also had the option to write in any additional barriers that were not listed. The most common write-in responses were stigma (n=7), comorbid mental health or medical issues (n=3), employment (n=3), and lack of a mobile phone (n=2).

Table . Provider-rated barriers to treating women with opioid use disorder.

Provider-rated barriers	Major barrier, n (%)	Minor barrier, n (%)	Not a barrier, n (%)
Patient housing insecurity	37 (67.3)	16 (29.1)	2 (3.6)
Patient lack of childcare or other family responsibilities	34 (61.8)	17 (30.9)	4 (7.3)
Patient lack of transportation	33 (60)	20 (36.4)	2 (3.6)
Patient denial or resistance	23 (41.8)	22 (40)	10 (18.2)
Lack of facilities or resources for treatment of OUD[a], once identified	23 (41.8)	20 (36.4)	12 (21.8)
Patient inability to pay for treatment	20 (36.4)	15 (27.3	20 (36.4)
Patient negative beliefs about MOUD[b]	18 (32.7)	33 (60)	4 (7.3)
Partner or significant others interfering with patients' treatment	17 (30.9)	33 (60)	5 (9.1)
State reporting laws and repercussions	16 (29.1)	19 (34.5)	20 (36.4)
Lack of or inadequate financial reimbursement for opioid screening, assessment, and counseling	16 (29.1)	17 (30.9)	20 (36.4)
Patient concerns about becoming addicted to MOUD	15 (27.3)	34 (61.8)	6 (10.9)
Limited training or experience in treating patients with OUD	11 (20)	10 (18.2)	34 (61.8)
Concern about patient confidentiality issues	7 (12.7)	27 (49.1)	21 (38.2)
Patient sensitivity to this topic (eg, fear of offending patients)[c]	1 (1.8)	24 (43.6)	29 (52.7)

[a]OUD: opioid use disorder.

[b]MOUD: medication treatment for opioid use disorder.

[c]Response missing from 1 participant.

Provider survey participants were given a list of potential features and content for a digital intervention and asked to rate how useful each one would be for women with OUD on a scale of 1 (not at all useful) to 5 (extremely useful). Mean ratings are reported in Table 5. Six features received a mean score of 4 or higher: (1) peer support, (2) appointment reminders, (3) connection with treatment providers, (4) crisis resources, (5) rewards, and (6) coping skills practice.

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Table . Features or content of a digital intervention that would be most useful to women with opioid use disorder (n=55).

Features or content	Mean (SD)
Peer support	4.31 (0.88)
Appointment reminders	4.29 (0.79)
Connection with treatment provider	4.25 (0.80)
Crisis resources	4.13 (0.96)
Rewards (for medication adherence, attendance in treatment or abstinence from opioids)	4.11 (0.92)
Coping skills education and practice	4.09 (0.88)
Medication reminders	3.87 (0.92)
Motivational messages	3.85 (0.99)
Providing feedback on progress toward goals	3.87 (1.04)
Information on dealing with stigma, shame, and guilt	3.78 (0.96)
Psychoeducation on co-occurring mental health issues	3.78 (1.07)
Mutual help locator	3.78 (0.99)
Mindfulness or meditation exercises	3.73 (1.03)
Tracking (mood, substance use cravings, and medication adherence)	3.56 (1.07)
Reproductive health information	3.53 (0.98)
Education on medication treatment for opioid use disorder	3.47 (1.15)
General health and wellness tips	3.25 (0.97)

Phase 2: Development

Design Overview

Building on our prior work [23], we used the information from the women with lived experience and provider qualitative interviews, as well as the provider survey data to develop the *Healthy Women* intervention, which includes a web-based component and a mobile component. Content was reviewed by experts in treating opioid use disorder, gender-specific treatment for women, and digital therapeutics (RDW, SFG, and ANCC), and revisions were made to the digital intervention. Finally, the web-based component was beta-tested with 5 participants from the pilot trial and further refined based on their feedback.

Web-Based Component

The web-based component is directly adapted from our gender-specific digital intervention for women with SUDs [23], which used material from the WRG [5,6,22]. It was developed in REDCap and contains six topic modules: (1) opioids and treatment, (2) the effects of alcohol and other drugs on women's health, (3) navigating everyday life without using substances, (4) women and relationships, (5) violence and abuse: getting help, and (6) managing co-occurring mental health problems. The *opioids and treatment* module was developed specifically for this study based on information obtained from the qualitative interviews and survey data, as well as publicly available information from the National Institute on Drug Abuse [27] and the Substance Abuse and Mental Health Services Administration [28]. The other 5 topics were derived from the WRG and our previous work [23] and were modified based on the interview and survey data (Table 6). Topics are presented through a mix of infographics, text, videos, and interactive questions. Each topic starts with an introduction to the topic and ends with take-home messages reviewing the main points. Participants engage with the web-based component first, and it is expected to take 45 - 60 minutes to get through all 6 topics. Table 6 shows the content for each of the 6 modules and the associated themes and codes from the qualitative interviews that informed the content.

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Table . Components of web-based modules as informed by qualitative data.

Module names and content, and associated themes and codes	Interview source		Illustrative quotes
	Women with lived experience	Providers	
Opioids and treatment • **Gender differences in opioid use** • **Treatment for OUD** [a] • **Education about MOUD** [b] • **Myths and facts about MOUD** • **MOUD during pregnancy**			
Negative beliefs or stigma about MOUD	✓	✓	• "I was against [Suboxone]. I didn't believe in it. If you have to wake up every day and take something, you might as well get high." (woman with lived experience) • "They're going to get a conflicting message elsewhere that says no you shouldn't be on medication because if you are on medication then you're not in recovery." (provider)
MOUD-specific barriers	✓	✓	• "They were giving me a high dose [of methadone], and I was really sleepy, and I felt like I was dopey, like I was a drug addict again." (woman with lived experience) • "[T]hat is a more complicated discussion about staying on it versus not staying on it... Do you go off the thing that helped you become so stable?" (provider)
Family responsibilities	✓	✓	• "Because I'd like to have children, and—you know, I don't want them to be born, like, addicted to drugs." (woman with lived experience) • "I do wonder about concerns about medication and pregnancy...in general [it's] a concern of women of childbearing age, though, certainly we know that being on medication-assisted treatment is safer than using illicit substances or going through withdrawal while pregnant." (provider)
Effects of alcohol and other drugs on women's health: • **Education on polysubstance use** • **The effects of alcohol, cannabis, stimulants, and tobacco on women's health** • **Self-care strategies**			

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Module names and content, and associated themes and codes	Interview source		Illustrative quotes
	Women with lived experience	Providers	
Polysubstance use	✓		• "My drug of choice is crack. And that's what I would use first. Then I would use the opiates to come down." (woman with lived experience)
Self-care	✓		• "I've really been working on that here in this program trying to focus on me more and not so much on every different thing... So just kind of take one thing at a time, and I'm trying to learn how to love myself again. Because I've really lost that along the way." (woman with lived experience)
Navigating everyday life without using substances: • **Identifying and managing triggers** • **Avoiding high-risk situations** • **Refusing substances** • **Disclosure** • **Having fun without using substances**			
Coping skills	✓		• "I need coping mechanisms so I don't use drugs with people." (woman with lived experience) • "It's just blocking people from being able to reach me...and I'm letting people know, 'Listen, I'm clean. Stay away from me.'" (woman with lived experience)
Negative beliefs about SUD[c] treatment	✓		• "I was always against treatment. I never agreed with taking someone out of their environment, patching them up and then putting them back in their environment... I felt like, 'Why can't you teach me how to live and be in recovery in my environment, because that's where I'm going back to?'" (woman with lived experience)
Negative beliefs about SUD treatment	✓		• "When I usually relapse is during my menstrual [cycle]." (woman with lived experience)
Women and relationships: • **Positive and negative effects of partners on recovery** • **Peer support** • **LGBTQ+ [d] resources**			
Partners/relationships	✓	✓	

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Module names and content, and associated themes and codes	Interview source		Illustrative quotes
	Women with lived experience	Providers	
			• "If I go back to [my ex-girlfriend], I know I'll go back to using." (woman with lived experience) • "It's happened at least once or twice that the woman doesn't want to go onto like a replacement type therapy an agonist treatment if the partners not going to be on it." (provider)
Support from others/social network	✓	✓	• "...if the people around you are supportive. Because that's a very rare thing in recovery for females and stuff... A lot of people have already turned their backs on us. So if we do have support, we need it." (woman with lived experience) • "I think family support, family psychoeducation, as well as helping the individual rebuilding sober supports." (provider)
Violence and abuse: getting help • **Education on types of abuse** • **Examination of past or current relationship** • **Safety planning** • **Domestic violence resources**			
Trauma and abuse	✓	✓	• "The trauma that we face out there in the streets is much different for females than it is for males. We're more vulnerable and we're more easily preyed on than the men are. So it's much more dangerous for us on the street than it is men." (woman with lived experience) • "Women are more subject to intimate partner violence and everything else connected to that." (provider)
Managing co-occurring mental health problems: • **The connection between substance use and depression, anxiety, and trauma** • **Coping strategies to manage stress**			
Co-occurring disorders	✓	✓	

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Module names and content, and associated themes and codes	Interview source		Illustrative quotes
	Women with lived experience	Providers	
			• "The depression and things are important. If I can get that under wraps, then maybe my using would not take over my life like that." (woman with lived experience) • "With women with co-occurring psychiatric disorders—which that's prominent—I think that receiving treatment for more than just the opioid use disorder is an important piece of maintaining adherence with the medication." (provider)
Trauma	✓	✓	• "Past traumas probably should be worked on. Because if you're using, I feel like you're already going through enough. You're probably going to be in the streets and going through stuff." (woman with lived experience) • "The women have this ongoing trauma of different kinds. So they have multiple ACEs [adverse childhood experiences], and then multiple things going on in adulthood that continue." (provider)
Coping skills	✓		• "I want to learn more coping skills because I can't keep running away to detox when I want to stop. I have to learn how to deal with it on my own." (woman with lived experience)

[a]OUD: opioid use disorder.

[b]MOUD: medication treatment for opioid use disorder.

[c]SUD: substance use disorder.

[d]LGBTQ+: lesbian, gay, bisexual, transgender/transsexual, queer, and other minority sexual orientations and gender identities.

Mobile Component

The mobile component (Figure 2) of the intervention was developed using Catalyst (MetricWire Inc) and consists of 4 parts: (1) motivational messages, (2) skills practice activities, (3) weekly check-ins, and (4) resources. These features were selected based on the data from the qualitative interviews. Participants have access to the mobile component for 12 weeks.

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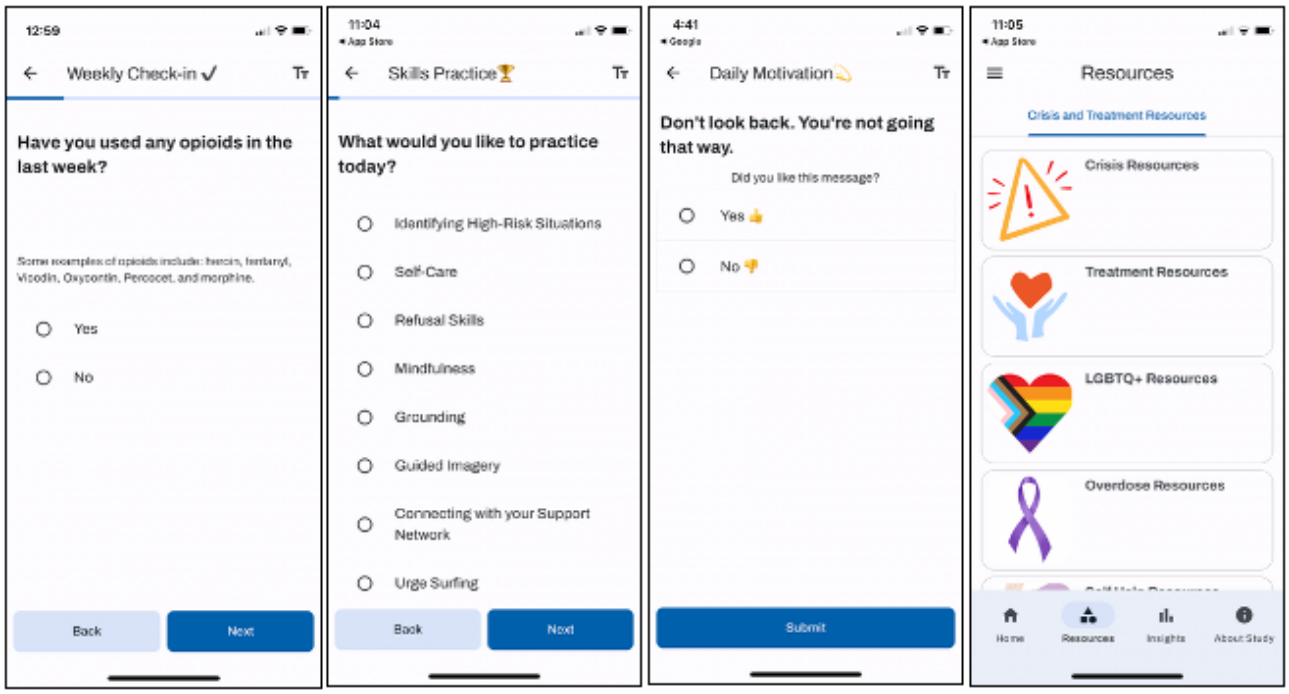
Figure 2. Mobile components of the *Healthy Women* intervention.



Motivational messages are sent daily. These messages are derived from online searches of inspirational content related to recovery and women. In addition, inspirational messages shared by qualitative interview participants are also included. Participants can "like" or "dislike" the motivational message each day, which allows us to gather data for future refinement of the mobile component.

Participants can choose from 10 different *Skills Practice* activities: (1) identifying high-risk situations, (2) self-care, (3) refusal skills, (4) mindfulness, (5) grounding, (6) guided imagery, (7) connecting with your support network, (8) urge surfing, (9) challenging negative thoughts, and (10) combating self-stigma. Skills practice activities were chosen to address key themes from the qualitative interviews, and many were derived from skills practice activities in the WRG [22]. Participants receive notifications to complete skills practices twice a week. They are encouraged to try each skill once but are not required to complete all of the skills. The guided imagery and mindfulness skills are taught through audio recordings, while the other 8 skills use branching logic to help participants learn the skills in an interactive way.

Weekly check-ins consist of questions about participants' weekly use of opioids and their adherence to MOUD. Participants who report no use of opioids and/or compliance with medication receive positive feedback. Participants who report opioid use and/or noncompliance with medication receive encouragement to focus on their recovery.

Participants can access the *Resources* tab any time they log in to the app. Resources include crisis resources, treatment finder information, overdose prevention information, mutual help group finders, and lesbian, gay, bisexual, transgender/transsexual, queer, and other minority sexual orientations and gender identities resources.

Expert Review

Content for the web-based and mobile components was reviewed independently by RDW, SFG, and ANCC, who have expertise in treating opioid use disorder, gender-specific treatment for women, and digital therapeutics. Comments were compiled, and the principal investigator (DES) discussed any discrepant comments with the reviewers to reach a resolution. Multimedia Appendix 3 provides a full list of changes that were suggested by reviewers.

The changes suggested by reviewers and implemented were categorized into four types: formatting, rephrasing, content additions, and content removal. Formatting changes included reordering content for consistency and clarity, breaking up information to reduce cognitive load, and changing the visual color scheme to improve readability. Rephrasing changes had three purposes: to improve clarity, to simplify language (eg, reduce academic language and lower reading level of words), and to increase the accuracy of the content. Two content additions were recommended and implemented: (1) to add information on the effects of xylazine and a warning that it may be mixed into other illicit drugs and (2) to add Alcoholics Anonymous to the list of mutual help groups. Content that was removed included guidelines for alcohol use, 1 of the true or false questions that reviewers felt was confusing, and an example that was deemed too general.

There were only 2 discrepant comments that needed to be resolved. One reviewer suggested giving participants the option to skip the section that provides information on pregnancy and MOUD, as it may not be applicable to some participants (eg, individuals who are beyond child-bearing age or unable to conceive). However, the 2 other reviewers felt that this information could be important for all participants, as there are many misconceptions about MOUD during pregnancy, which can contribute to stigma against women taking MOUD when

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pregnant. Therefore, it was decided not to allow participants to skip this section. The other discrepant comment was around presenting information on dietary recommendations for alcohol consumption. One reviewer recommended defining standard drinks to increase understanding of the drinking guidelines. However, another reviewer recommended removing the guidelines entirely and replacing them with information describing the importance of abstaining from alcohol while in recovery from opioids. This change was agreed upon by reviewers as it was noted that the alcohol guidelines are meant for individuals without a history of SUD.

Beta-Testing Results

The mean age of the beta-test participants was 33.4 (SD 8.5, range 24 - 42 y) years; all participants identified as White and non-Hispanic or Latina. Four of the 5 participants were unhoused or in temporary housing at the time of study enrollment (Multimedia Appendix 4 for additional demographic characteristics for the beta-testing sample). Four participants were initiated on methadone, and 1 participant was initiated on buprenorphine in the past 30 days.

A full list of participant comments is included in Multimedia Appendix 5. Two participants commented that they liked the interactive true or false questions, and 3 described appreciating the women-focused information. Three participants expressed concerns that there was too much text, which may be hard for individuals in early recovery. Therefore, we went through each module and replaced text with infographics whenever possible. We also reorganized some of the information based on participants' comments, such as adding take-home messages not only at the end of the modules but also at the beginning of each module and providing examples of triggers before asking participants to list their own triggers. One participant felt that the gender-specific information on substance use risk could give women an excuse to keep using substances; however, another participant felt that it was helpful to learn about gender-specific risks. Given that we received contradictory feedback on this issue, we decided not to make this change. Finally, 1 participant felt that the feedback given to individuals who report both positive and negative influences of a partner could be more directive on how to deal with this situation. After discussion with the study team, it was decided to keep the original wording as it was designed to help women think through the possible ways this type of partner could affect their recovery.

Discussion

Principal Findings

This study outlines the process for developing the *Healthy Women* intervention aimed at increasing women's engagement in MOUD. The multiphase, mixed methods study included qualitative interviews with women with lived experience of OUD, qualitative interviews with OUD treatment providers, a survey of OUD treatment providers, expert review of the content, and feedback from end-users.

Results from phase 1 identified important topics for engaging women in MOUD treatment, as well as features and content to include in a digital intervention. Several of the barriers to treatment and important factors to address in treatment have been identified in previous reviews of women and SUDs [5,29,30]. However, this study extends the literature by identifying factors specific to women with OUD, including family responsibilities, MOUD-specific barriers, stigma associated with MOUD, and factors motivating MOUD initiation (eg, pregnancy). Although some of these could be endorsed by men as well, women in this study often described the additional burdens on women and societal stigma toward women with OUD. This study also extends the current literature by providing information on features that would be most helpful to include in technology-based tools for women with OUD.

Data from qualitative interviews also revealed barriers to technology use in this population, which could be helpful in developing successful implementation strategies to deploy these tools to women who need them. One of the barriers to using technology as part of treatment was the lack of access to mobile phones. Although studies have shown high rates of smartphone ownership among individuals with SUD [31,32], participants in this study described inconsistent access to their phones. Individuals with SUDs are disproportionately affected by financial and housing instability, which can limit their access to smartphones and reliable data plans. Although this was identified as a significant barrier during the formative phase, the pilot trial of the *Healthy Women* intervention was not initially funded to provide phones to research participants. However, we were eventually able to secure additional funds to provide smartphones to participants, inclusive of a 4-month data plan, which was implemented after 18 participants had been enrolled. Participants are allowed to keep the phone after they complete the study. In clinical settings, digital navigators could be useful in helping patients identify options for affordable or free smartphone plans [33].

During phase 2, common themes and suggested features from the qualitative interviews and survey data were incorporated into a digital platform to create the *Healthy Women* intervention. The intervention was then reviewed by experts, who recommended additional changes to the formatting, wording, and content. Finally, additional changes were recommended by end-users to the web-based model during the beta-testing phase. Changes made in response to end-user feedback during beta testing centered on reducing the amount of text through additional infographics and reorganizing text to improve clarity and emphasize important points. A randomized controlled pilot study (phase 3) is currently underway to examine feasibility, satisfaction, and engagement with the digital intervention, as well as to collect preliminary estimates on the effect of the intervention on engagement in MOUD.

Limitations

Although we were able to incorporate many of the suggested features into the design of the *Healthy Women* intervention, some suggestions were out of scope for this initial version, such as connecting to peers and providers through the app, providing appointment reminders, and in-app rewards. There were several system-level barriers identified by women with lived experience and providers, which were also confirmed by the survey data. Examples of these system-level barriers included a lack of

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treatment beds available for women, legal issues and involvement of the Department of Children and Families, and restrictive clinic rules (eg, having to go daily to get methadone during a restricted time frame). These were out of the scope of this study but are important factors to address as part of comprehensive treatment for women with OUD. Another limitation was the lack of racial and ethnic diversity in the beta-testing sample, which may limit the generalizability of the findings. In addition, although research assistants tested the mobile component for functionality prior to launching the study, we were unable to beta-test the mobile component of the intervention with end users due to limitations on the study timeline and funding. However, data collected from the pilot trial will provide important information and feedback from end-users on the mobile component. For this study, we used separate platforms (ie, REDCap for the web-based component and MetricWire for the mobile component), as these were available to the research team and cost-effective. Ideally, the web-based components and the mobile app would be built in the same platform. If shown to be effective, future versions of the *Healthy Women* intervention could be built in an integrated platform with the potential for sustainability and broader scale-up.

Conclusions

Medication treatment is the gold standard of care for individuals with OUD, yet retention rates are low. Thus, it is important to develop sustainable strategies to engage individuals early in MOUD treatment. Gender-specific treatment for women has been associated with increased engagement, greater satisfaction with treatment, and improved treatment outcomes [4-7]. The *Healthy Women* intervention was developed to address the unique needs of women with OUD to increase their engagement in MOUD treatment. Data collected from the pilot trial, which is currently underway, will provide important information on the feasibility and preliminary effectiveness of this intervention.

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Data Availability

The datasets generated or analyzed during this study are not publicly available due to the sensitive nature and the potential risk of reidentification, but deidentified data are available from the corresponding author upon reasonable request.

Authors' Contributions

Conceptualization: DES, SFG, RDW, LAM
Data curation: DES, EAL
Formal analysis: DES, CLW, FMK
Funding acquisition: DES
Investigation: DES, CLW, EAL
Methodology: DES
Project administration: CLW, EAL
Supervision: DES, SFG, RDW, LAM, ANCC
Visualization: DES
Writing – original draft: DES, EAL, NAB
Writing – review & editing: DES, EAL, FMK, NAB, RDW, LAM, ANCC, SFG

Conflicts of Interest

RDW has consulted to Alkermes and Eli Lilly and Company. LAM reports co-ownership of Square2 Systems, Inc. and consulting fees from Click Therapeutics and Boehringer Ingelheim. These relationships are extensively managed by LAM's employer, Dartmouth College. SFG is the author of "Treating Women with Substance Use Disorders: The Women's Recovery Group" for which they receive small royalties (<US $500/y) annually. All other authors report no conflicts of interest.

Multimedia Appendix 1
Women with lived experience interview questions.
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Multimedia Appendix 2

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Provider interview questions.
[DOCX File, 22 KB - formative_v10i1e85195_app2.docx]

Multimedia Appendix 3
Feedback from expert reviewers.
[DOCX File, 21 KB - formative_v10i1e85195_app3.docx]

Multimedia Appendix 4
Demographic characteristics of beta test participants.
[DOCX File, 16 KB - formative_v10i1e85195_app4.docx]

Multimedia Appendix 5
Notes from beta testing participants' responses.
[DOCX File, 18 KB - formative_v10i1e85195_app5.docx]

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Abbreviations

ADATP: Alcohol, Drug, and Addiction Treatment Program
DDBT: Discover, Design and Build, and Test
IRB: Institutional Review Board
MOUD: medication treatment for opioid use disorder
OUD: opioid use disorder

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REDCap: Research Electronic Data Capture
SUD: substance use disorder
WRG: Women's Recovery Group

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Internet Addiction Among School Children: Cross-Sectional Analytical Study

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Abstract

Background: Internet use is rapidly increasing in Sri Lanka. Excessive use can lead to addiction with significant consequences, particularly among adolescents. While internet addiction has been documented worldwide, data from Sri Lanka remain limited. A validated local tool is required to assess the prevalence and associated factors in this population.

Objective: This study aimed to translate and validate the Young Internet Addiction Test (IAT) into Sinhala, assess the prevalence of internet addiction among school-going adolescents aged 15 to 19 years in the Western Province of Sri Lanka, and identify demographic and behavioral characteristics associated with internet addiction.

Methods: We conducted a 2-phase cross-sectional analytical study in Colombo and Gampaha districts. Phase 1 involved translation and validation of the Sinhala IAT using confirmatory factor analysis (n=200) and test-retest reliability assessment (n=40). Phase 2 involved multistage stratified cluster sampling to recruit 2835 students. Participants completed self-administered questionnaires assessing demographics, internet use patterns, and internet addiction.

Results: The Sinhala IAT demonstrated excellent internal consistency (Cronbach α=0.98) and strong test-retest reliability (r=0.95; P<.001). Among 2835 students with complete data, 1803 (63.6%) were current internet users. The overall prevalence of internet addiction among internet users was 12.6% (227/1803; 95% CI 11.2% - 14.0%), including mild addiction at 8.2% (147/1803; 95% CI 6.9% - 9.5%), moderate addiction at 3.5% (64/1803; 95% CI 2.7% - 4.5%), and severe addiction at 0.9% (16/1803; 95% CI 0.4% - 1.4%). No significant associations were found with sex (male and female; odds ratio 1.13, 95% CI 0.86-1.49; P=.14), age group (P=.23), or parental education (P=.34). The most common online activities were entertainment (1522/1803, 84.4%), gaming (1251/1803, 69.4%), and social media use (1127/1803, 62.5%). Mean daily use was 2.1 (SD 1.8) hours, with 10.0% (180/1803) reporting single sessions of ≥6 hours.

Conclusions: This study provides the first systematic evidence of internet addiction in adolescents in Sri Lanka. The predominance of mild to moderate severity suggests an opportunity for early intervention.

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KEYWORDS

internet addiction; internet gaming disorder; World Wide Web; addiction; school children

Introduction

The rapid expansion of digital technologies and internet access has transformed communication, education, and social interaction worldwide [1-3]. Over the past 2 decades, the internet has evolved from a specialized communication network into an integral part of daily life, influencing learning, entertainment, and social relationships. Adolescents constitute one of the fastest-growing groups of internet users, particularly in low- and middle-income countries, where access has expanded rapidly with the widespread availability of smartphones and mobile broadband services, and according to estimates, there are almost 3 billion users worldwide, with adolescents among the most active users [4-7]. While internet use offers substantial educational, informational, and social benefits, concerns have been raised regarding excessive and uncontrolled patterns of use. Harmful or problematic internet use has been associated with a range of adverse outcomes, including sleep disturbance; reduced academic performance; impaired social functioning; and mental health problems, such as depression, anxiety, and suicidal ideation [8-11]. These concerns have led to increasing

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attention from clinicians, educators, and public health professionals.

Internet addiction was first described by Young [9] as a behavioral condition. Internet addiction is characterized by impaired control over internet use, preoccupation, tolerance, withdrawal-like symptoms, and functional impairment [9,12-14]. Subsequent research has supported the clinical relevance of this construct, with growing consensus that certain forms of excessive internet use share features with other behavioral addictions [13,15,16]. Although internet addiction is not uniformly classified across diagnostic systems, related conditions, such as internet gaming disorder, have been recognized as conditions warranting further study [15].

The Young Internet Addiction Test (IAT) [14] is the most extensively used study tool to assess internet addiction and has been validated for use in many countries including India [17-24]. Many studies throughout the world have shown that internet addiction is becoming a bigger problem, especially for young people. Earlier studies conducted in Western populations reported wide variability in the prevalence of internet addiction. For example, Fortson et al [25] found that among 411 American undergraduate students, 50% met the criteria for internet abuse and 25% for internet dependence. Similarly, Cash et al [26] reported prevalence rates ranging from 1.5% to 8.2% among students in the United States and Europe. In Italy, Poli and Agrimi [27] reported that 0.8% and 5% of students had severe and moderate levels of internet addiction, respectively.

This pattern is not unique to Western countries, and several studies have also been conducted in Asia. Recent systematic reviews estimate the global prevalence of internet addiction among adolescents and young adults to range between 7% and 15%, with higher rates reported in Asian countries compared with Europe and North America [28]. Similar findings have been observed in Hong Kong and Taiwan, where internet addiction is often linked to gaming and social media use [29,30]. More recent studies from South Korea (2021) and Japan (2022) report rates of 14.2% and 8.7%, respectively, among adolescent populations [31,32].

Several studies on internet addiction have been conducted in the Indian subcontinent. Goel et al [31] identified a low prevalence of internet addiction, with only 0.7% of the sample of college students having features of internet addiction. This varied considerably, with a study conducted by Gedam et al [32] reporting a total prevalence of internet addiction of 19.85% in a student population in India [33]. An even higher prevalence was found in a study conducted by Subashini and Praveen [33], with 57.7% of sampled college students having features of internet addiction.

In Sri Lanka, internet penetration has increased steadily over the past decade, particularly among school-aged populations, in parallel with broader national gains in information and communication technology infrastructure [34-36]. Despite this rapid growth, local evidence on the prevalence and correlates of internet addiction among school children remains limited. Chandradasa and Rodrigo [37] reported the presence of internet gaming disorder among adolescents, highlighting the significance of internet-related behavioral problems in the local context [38]. This leaves a gap in understanding the broader patterns of internet addiction among adolescents. Moreover, no validated Sinhala language assessment tools exist, baseline prevalence data are unavailable, and risk factors specific to Sri Lankan adolescents remain unknown.

This study addresses these gaps by translating and validating the Young IAT for Sinhala-speaking populations. The study aimed to estimate the prevalence of internet addiction among school children in the Western Province of Sri Lanka and to examine factors associated with problematic internet use. A clearer understanding of these patterns is essential to inform school-based mental health promotion, preventive strategies, and policy development within the education sector.

Methods

Overview

We conducted a school-based cross-sectional analytical study in the Colombo and Gampaha districts of Sri Lanka. The cross-sectional design was chosen as the most appropriate for several reasons. This is the first systematic study of internet addiction within a large adolescent population in Sri Lanka. While this design provides essential baseline data for future longitudinal and interventional studies, it cannot establish causality. In comparison to other districts, Colombo and Gampaha were selected for several reasons: (1) the highest population density in Sri Lanka, providing efficient access to a large sample; (2) the greatest internet penetration rates in the country (>70%), ensuring adequate numbers of internet users; (3) diversity of urban and semiurban areas; (4) a range of school types (government, private, and international) and socioeconomic backgrounds; and (5) representativeness of broader trends in internet adoption and use patterns among Sri Lankan adolescents. The cross-sectional design enables understanding of multiple potential correlates concurrently.

Our primary objectives were to evaluate the prevalence of internet addiction in a Sri Lankan student population and determine personal characteristics associated with internet addiction, including age, sex (male and female), language, and year of study. We explored patterns of internet use, such as social media, gaming, and web surfing, associated with internet addiction.

Study Population

Students of both sexes were eligible for inclusion if they were aged between 15 and 19 years and studying in grades 10, 11, 12, and 13 in the Gampaha and Colombo districts of Sri Lanka. This age group was selected because adolescence is a critical developmental stage characterized by high internet use and vulnerability to behavioral addictions. As the study involved validation of the Sinhala translation of the IAT, students without adequate Sinhala proficiency were excluded. This constitutes a considerable limitation as exclusively Tamil-speaking students were not included in the study.

Sampling Methods and Sampling Strategy

A multistage stratified cluster sampling method was selected. A classroom was considered a cluster. Considering the diversity

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of the school population, the sample was stratified at 2 stages. First, the sample (clusters) was divided equally into 2 strata according to school grades. The strata were defined as grades 10 and 11 (Ordinary Level classes) and grades 12 and 13 (Advanced Level classes). Within each of these strata, the sample was divided to include students from government, private, and international schools. Students from government schools were stratified according to the functional classification of schools adopted by the Ministry of Education, namely, types 1AB, 1C, and type 2 [39].

Schools within each district were organized according to the type of school, and the number of students to be sampled from each grade was determined using probability proportional to size based on the student population in the specific grades in the different types of schools (government—1AB, 1C, and type 2; private; and international). To enhance the distribution of the sample over the district, only one class from Ordinary Level classes and one from each type of Advanced Level classes were randomly selected from a single school.

Sample Size Calculation

The required sample size was calculated using the following formula: sample size (N) = $Z^2 \times p(1–p)/d^2$, where Z is the value corresponding to the CI (1.96 for 95%), p is the anticipated population proportion (p=0.1), and d is the absolute precision (d=0.025).

On the basis of the literature, 4% to 10% of users have internet addiction [27]. Studies in the general population and adolescents report a lower prevalence of internet addiction, ranging from 0.3% to 0.07% [32]. To ensure a conservative and sufficient sample size, a prevalence of 10% of internet users was taken as the cutoff. With a 95% CI and a margin of error set at 2.5%, the minimum number of positive cases required was calculated as 554 as follows:

Sample size (n)=$Z^2 \times p(1–p)/d^2$

n=$(1.96)^2 \times 0.10(0.90)/(0.025)^2$

n=$3.84 \times 0.09/0.000625$

n=553.9, or approximately 554 internet users with addiction.

As of July 2014, approximately 19.9% of the Sri Lankan population was estimated to be internet users having access to the internet at home via any type of device (computer or mobile) [34,35]. Therefore, to obtain a sample of 139 adolescents with frequent internet use (assuming 20% of the student sample are frequent users), a total of 2800 students were targeted. Our study sample comprised 2835 students. Nonresponse was minimal; incomplete questionnaires were excluded from the final analysis.

Thereafter, the study was divided into 2 phases to allow systematic data collection: initial validation of the translated Sinhala version of the IAT (phase 1) and subsequent data collection to evaluate the prevalence of internet addiction (phase 2).

Phase 1: Validation of the Translated Sinhala Version of the IAT

It was necessary to ensure that the tool was validated before being used to measure internet addiction. Previous validations of the IAT have offered several models, ranging from 1 factor to 6 factors [32-35,37-39]. Recent studies have identified that a 1-factor or 2-factor model can be used effectively in validating the IAT and have shown no clear benefit over one another [23]. With the above evidence, we proceeded with a single-factor validation model, adopting a unidimensional approach.

On the basis of the guidelines proposed by George and Mallery [39] for interpreting Cronbach α values [40,41], internal consistency was interpreted using the criteria shown in Table 1.

Table . Interpretation of Cronbach α coefficient.

Cronbach α score	Degree of internal consistency
>0.9	Excellent
0.8 - 0.9	Good
0.7 - 0.8	Acceptable
0.6 - 0.7	Questionable
0.5 - 0.6	Poor
<0.5	Unacceptable

To measure test-retest reliability, the same test was given to the same students on 2 occasions and the scores were correlated using Pearson correlation coefficient. The score obtained the first time the test was given was T1, and the score obtained the second time was T2. The scores on the 2 occasions were then correlated. This correlation was known as the test-retest reliability coefficient, or the coefficient of stability.

The closer each respondent's scores were on T1 and T2, the more reliable the test measure. A stability coefficient of 1 would indicate that each respondent's scores were perfectly correlated; that is, each respondent scored the exact same value on T1 as they did on T2. A correlation coefficient of 0 indicates that the respondents' scores at T1 were completely unrelated to their scores at T2; therefore, the test was not reliable.

Correlation is an effect size, and the strength of the correlation between items can be described using the interpretation guide for the absolute value of the correlation coefficient (Table 2).

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Table . Interpretation of coefficients of stability for test-retest validity of a scale.

Coefficient of stability	Interpretation
≥0.9	Excellent reliability
0.8 - 0.9	Good reliability
0.7 - 0.8	Acceptable reliability
0.6 - 0.7	Questionable reliability
0.5 - 0.6	Poor reliability
<0.5	Unacceptable reliability

In our study, we used a 1-factor model assessing the Cronbach α score for the 20 items on the translated IAT. A statistical expert calculated the ideal sample size for validation before data collection. According to the widely accepted participant to item ratio approach, each item should include 2 to 20 participants, and a minimum sample size of 100 to 250 participants is required for validation [42]. A sample size of 200 individuals (10 participants per item) was considered adequate because the IAT has 20 items. To assess test-retest validity, 20% (n=40) of the sample was also enlisted.

The first 200 students who identified as internet users were included in validation analysis. This was done by calculating the Cronbach α coefficient. A score of ≥0.7 indicated that the interview schedule in Sinhala had a high level of validity and internal consistency.

For cross-cultural adaptation of psychometric instruments, the original IAT was translated into Sinhala by a nonmedical professional competent in both Sinhala and English. This was subsequently reviewed by a consultant psychiatrist and a specialist in computer technology. Discrepancies were discussed and resolved to create a single preliminary Sinhala version. They identified a few items requiring cultural modification to ensure relevance and comprehensibility: (1) modification to age-appropriate language, (2) adjustment of phrasing for natural Sinhala expression while preserving meaning, and (3) clarification to reflect Sri Lankan social context.

It was then retranslated into English by a different nonmedical professional, and the retranslated version was cross-checked by the review team. Necessary corrections and amendments were made to the translated Sinhala version so that the retranslated English version was as close as possible in meaning to the original interview schedule.

Phase 2: Data Collection and Assessment of the Prevalence of Internet Addiction

Following the abovementioned validation, the study tool was used to assess the presence and severity of internet addiction in the sample population. Internet addiction was assessed using the Sinhala translated and validated version of the IAT. A questionnaire assessing demographic data and the IAT was administered concurrently to the study population. To ensure the questionnaire was comprehensible across varying literacy levels, the language was simplified, and a research assistant was present during administration to provide clarifications when needed.

Data Management and Statistical Analysis

All gathered data were handled confidentially, with each participant assigned a unique reference number to ensure anonymity. SPSS software (version 23.0; IBM Corp) was used for data entry and analysis.

The translated IAT was validated using the first 200 entries; test-retest reliability was evaluated using the Pearson correlation coefficient, and internal consistency was evaluated using Cronbach α.

Following validation, the entire dataset was analyzed to assess the level of internet addiction and its nature. Descriptive statistics (means, SDs, frequencies, and percentages) were used to summarize sociodemographic variables and internet use patterns. Chi-square tests were used for categorical variable comparisons (sex [male and female] and academic profile), whereas independent 2-tailed *t* tests analyzed continuous variables (age differences between groups). One-way ANOVA was applied for multigroup comparisons, and the Pearson correlation coefficient was used to assess relationships between continuous measures.

Prior to statistical analysis, the dataset was screened for missing values. Missing data were analyzed for patterns using the Little MCAR (Missing Completely At Random) test to determine whether data were missing completely at random. For variables with less than 5% missing data, listwise deletion was used.

Ethical Considerations

Ethics approval and other necessary permissions were obtained prior to the study. Ethical clearance for this study was obtained from the ethical clearance committee of the Faculty of Medicine, Ragama, University of Kelaniya (P/240/12/2014). Formal permission to translate and validate the IAT into Sinhala was obtained from its author, Dr Kimberley Young. All participants received an information sheet outlining the study details and what was required of them. Parental notification was conducted through school principals, who were asked to inform parents about the study and communicate any objections to their children's participation. No parental objections or complaints were received, and students provided written assent after being informed about voluntary participation and confidentiality measures. In addition, written approval was granted by the relevant school principals to conduct the study in their respective schools, and informed written consent was obtained from students aged 18 years and above for participating in the study. No compensation was provided to participants, and participation was voluntary.

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The data collected were anonymized and stored in a password-protected electronic database accessible only to the principal investigator and authorized research staff, and all paper-based records were locked in secure storage.

Problems Anticipated and Measures Taken to Minimize Them

We anticipated that students might not provide fully accurate information regarding their internet use due to fear of reprimand or other concerns. An anonymous self-administered questionnaire was administered under the supervision of a researcher. Subsequently, students were instructed to place the completed questionnaires into a closed collection box to ensure that their responses could not be traced to them or seen by other students. Furthermore, responses on internet use duration were compared with other reported digital behaviors, such as time spent on social media, gaming, and educational browsing. Extreme or inconsistent responses were flagged and excluded during data cleaning. Nonresponse and incomplete questionnaires were excluded from the final analysis.

Results

A total of 200 students participated in the validation phase. The Sinhala IAT demonstrated excellent internal consistency with a Cronbach α of 0.98, and individual item analyses confirmed high interitem correlations (all >0.70). Test-retest reliability, assessed after a 2-week interval in a subsample of 40 students, showed a Pearson correlation coefficient of 0.95 (P<.001), indicating strong temporal stability (Table 3 and Table 4).

Table . Factors associated with internet addiction (n=1803 internet users).

Variable	Addiction present	Addiction absent	Odds ratio (95% CI)	*P* value	Effect size
Sex, n (%)			1.13 (0.86 - 1.49)	.14	0.03
Male	126 (12.9)	852 (87.1)			
Female	101 (12.3)	721 (87.7)			
Age group (y), n (%)			—[a]	.23	0.05
15 - 16	105 (15.4)	577 (86.3)			
17 - 18	106 (11.0)	855 (88.3)			
19	16 (10.0)	144 (88.2)			
Academic level, n (%)			1.10 (0.83 - 1.46)	.09	0.06
Ordinary level (grade 10 - 11)	117 (14.1)	712 (85.9)			
Advanced level (grade 12 - 13)	110 (11.3)	861 (88.7)			
Primary activities[b], n/N (%)					
Gaming			0.98 (0.74 - 1.30)	.83	0.01
Yes	156/227 (12.5)	1092/1573 (87.5)			
No	71/227 (12.9)	481/1573 (87.1)			
Social media			0.96 (0.72 - 1.27)	.69	0.01
Yes	139/227 (12.4)	985/1573 (87.6)			
No	88/227 (13.0)	588/1573 (87.0)			

[a]Not applicable.

[b]Primary activity percentages were calculated within addiction groups. Internet addiction was defined as an Internet Addiction Test score of ≥31. Of 1803 current internet users, 227 (12.6%) met the criteria for internet addiction. Data on primary activities were missing for 0.2% (3/1576) of the participants in the addiction-absent group; therefore, percentages for these variables were calculated using available data (n=1573).

[c]All effect size values represent Cramer V.

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Table . Validation results of the Sinhala Internet Addiction Test.

Psychometric property	Result	Interpretation
Internal consistency		
Cronbach α	0.98	Excellent
Item-total correlation (range)	0.72-0.90	All items contribute strongly
Test-retest reliability		
Pearson correlation (n=40[a]; 95% CI)	0.95[b] (0.91-0.97)	Excellent stability
Time interval	2 wk	—[c]

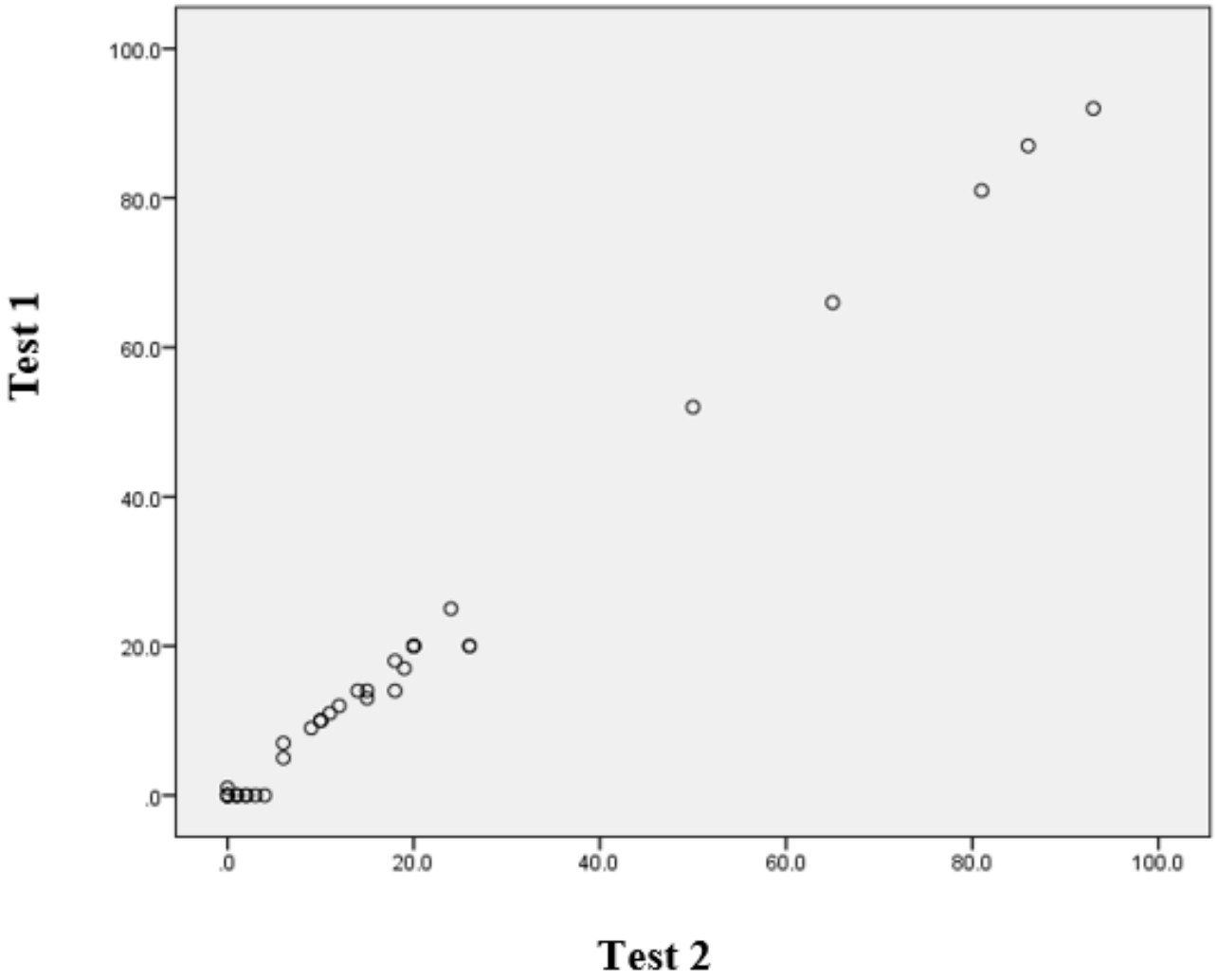
[a]The number of participants who completed the test-retest reliability assessment (ie, they took the Sinhala Internet Addiction Test twice, 2 weeks apart, to measure the temporal stability of the test).

[b]*P*<.001.

[c]Not applicable.

This high correlation coefficient indicated that the Sinhala translation maintained consistent measurement properties over time (Figure 1). These validation results confirmed that the Sinhala version of Young IAT possessed both high internal consistency and excellent test-retest reliability, making it suitable for use in the subsequent prevalence study.

Figure 1. Correlation between the test (test 1) and retest (test 2) scores.



On the basis of the scale of the internet addiction questionnaire, internet addiction score ranged from 2 to 97, with a mean score of 17.4 (SD 23.8). Among the total sample, 8.0% (227/2835) showed features of internet addiction. Among internet users specifically, the prevalence was 12.6% (227/1803). The severity of the addiction was categorized as mild, moderate, and severe. The results revealed a mild addiction (147/2835, 5.2% of the total sample; 147/1803, 8.2% of internet users) in the majority, followed by moderate addiction (64/2835, 2.3% of the total sample; 64/1803, 3.5% of internet users). However, just under

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1% (16/1803, 0.9%) of internet users showed evidence of severe addiction (Table 5 and Table 6).

Table . Sample characteristics and internet use patterns.

Characteristic	Values
Demographics	
Age (y), mean (SD)	16.7 (1.2)
Sex (n=2835), n (%)	
Female	1344 (47.4)
Male	1491 (52.6)
Academic level (n=2387), n (%)	
Ordinary level (grade 10-11)	1108 (46.4)
Advanced level (grade 12-13)	1279 (53.6)
Language (n=2387), n (%)	
Sinhala	2323 (97.3)
English	64 (2.7)
Internet use	
Current internet users (n=2387), n (%)	
Yes	1803 (75.5)
No	584 (24.5)
Among internet users (n=1803)	
Daily use duration (h), mean (SD)	2.1 (1.8)
Session of ≥6 h, n (%)	181 (10.0)
Primary devices (n=1803), n (%)	
Laptop	1408 (78.1)
Mobile phone	1273 (70.6)
Tablet	200 (11.1)
Primary location (n=1803), n (%)	
Home	1473 (81.7)
Friend’s house	449 (24.9)
Internet café	258 (14.3)
Top activities (n=1803), n (%)	
Entertainment	1522 (84.4)
Email	1307 (72.5)
Gaming	1251 (69.4)
Social media	1126 (62.5)
Schoolwork	1081 (60.0)
Pornography	371 (20.6)

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Table . Prevalence of internet addiction by severity.

Severity category	IAT[a] score	Internet users (n=1803), n (%)	95% CI	Total sample (n=2835), n (%)
No addiction	≤30	1576 (87.4)	85.9 - 88.8	1872 (66.0)
Any addiction	≥31	227 (12.6)	11.2 - 14.0	270 (9.5)
Mild	31 - 49	147 (8.2)	6.9 - 9.5	175 (6.2)
Moderate	50 - 79	64 (3.5)	2.7 - 4.5	76 (2.7)
Severe	≥80	16 (0.9)	0.4 - 1.4	19 (0.7)

[a]IAT: Internet Addiction Test.

Discussion

Principal Findings

This study demonstrates that internet addiction is prevalent among school children in the Western Province of Sri Lanka, with a substantial proportion exhibiting mild to moderate levels of problematic use. These findings add to the limited body of evidence from Sri Lanka on adolescent internet addiction and highlight that problematic use is not confined to university or clinical populations. The prevalence pattern observed in this study is broadly consistent with findings from other South Asian countries, including India and Bangladesh, where studies among adolescents have reported a wide range of prevalence estimates depending on methodology, age group, and assessment tools used [23,24,32]. Differences in reported prevalence across studies may reflect variations in internet access, cultural norms, parental supervision, and educational demands.

The predominance of mild and moderate addiction observed in this study mirrors trends reported globally. Meta-analyses and large-scale studies from China, Europe, and other regions suggest that early-stage problematic internet use is considerably more common than severe addiction among adolescents [28,43]. This pattern is important from a public health perspective, as it suggests opportunities for early identification and intervention before more severe impairment develops. The lack of significant associations between internet addiction and basic sociodemographic characteristics in this study is consistent with findings from Hong Kong, Taiwan, and South Korea [29,30,44]. Instead, behavioral factors related to patterns of use appear to be more salient. Longer duration of use and recreational or gaming-focused internet activities have been repeatedly associated with higher addiction scores across different cultural settings [15,25,38]. These findings support the view that how the internet is used may be more important than who is using it.

From a public health and educational perspective, the findings underscore the need for school-based approaches to promote healthy internet use. International evidence suggests that digital literacy education, parental engagement, and clear school policies regarding internet use can reduce harmful patterns and associated psychosocial problems [27,45]. In Sri Lanka, where internet access among school children continues to expand rapidly, integrating such interventions into existing school health and education programs may be both feasible and effective.

Limitations

While the cross-sectional study design provides a snapshot at one point in time and helps estimate prevalence and associated factors, it does not allow for the establishment of causal relationships. Therefore, future longitudinal studies are needed for more comprehensive assessment.

Colombo and Gampaha districts have the highest internet penetration, the greatest urbanization, and higher average socioeconomic status. So the prevalence, patterns, and correlates of internet addiction likely differ substantially compared with rural areas with limited connectivity, which represents a major limitation. Our findings should not be extrapolated to these contexts without appropriate research.

As the study involved validating the Sinhala translation of the Young IAT, the Tamil-speaking population was not assessed for internet addiction. Therefore, these findings may not be generalizable to the entire Western Province and limit generalizability across ethnic groups. Tamil-speaking communities may have different cultural attitudes toward technology use, different parental supervision patterns, different media consumption preferences, and potentially different prevalence of problematic use. There is potential for selection bias, as the findings may not reflect the experiences of adolescents in rural and remote areas, and the exclusion of Tamil-speaking students may introduce ethnic and linguistic bias.

The prevalence of internet addiction among internet users in the study sample was 12.6% (227/1803), and only 0.9% (16/1803) were identified as having severe internet addiction. This is less than that identified in some studies in other countries, including India [24,32,33]. This may have been due to the students not being forthcoming with information when data were collected in a school setting by research assistants, even though the questionnaire was self-administered and confidential. Students may have underreported problematic use, creating the desirability bias. Therefore, many studies in this area have been conducted using internet-based surveys, which are more anonymous and may yield more accurate information, potentially minimizing desirability bias.

We did not collect detailed socioeconomic status indicators, such as family income, parental occupation, household assets, or parental education level. This represents a significant limitation, as socioeconomic status likely operates through multiple pathways to influence internet addiction risk. We did not screen for depression, anxiety disorders,

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attention-deficit/hyperactivity disorder, conduct disorders, or other psychiatric conditions that commonly occur with internet addiction. Future research must include comprehensive mental health assessment as well.

Conclusions and Future Recommendations

Internet addiction is prevalent among school children in the Western Province of Sri Lanka, predominantly at mild to moderate levels. Patterns of internet use, rather than sociodemographic characteristics, are key correlates. Incorporating screening and preventive interventions into school health and education programs may help mitigate the long-term psychological and social consequences of excessive internet use among adolescents.

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Authors' Contributions

CW, AP, and LK conceptualized the paper and were substantially involved in the revision of the manuscript. CW, AR, and TG collected and analyzed the evidence. CW, PY, and LK drafted the manuscript. All authors checked the final manuscript before submission.

Conflicts of Interest

None declared.

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Abbreviations

IAT: Internet Addiction Test
MCAR: Missing Completely At Random

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Performance of Wearable Pulse Oximetry During Controlled Hypoxia Induction: Instrument Validation Study

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Abstract

Background: Oxygen saturation is a crucial metric used for monitoring patients with lung disease or respiratory illness who are at risk of hypoxemia (low blood oxygen saturation). Early and accurate identification of abnormal oxygen saturation is important for these patients, who may develop significant desaturation and hypoxemia symptoms during their daily activities.

Objective: This study aimed to evaluate the accuracy of Apple Watch Series 7 and a clinical-grade pulse oximeter, Masimo MightySat Rx, under hypoxemia and to assess whether measurement error is influenced by the oxygen desaturation rate (ODR).

Methods: We calculated the ODR of each measurement and conducted a comparative analysis of the displayed oxygen saturation readings from both the Masimo MightySat Rx finger pulse oximeter and Apple Watch Series 7 with arterial blood oxygen saturation (SaO_2) readings obtained from a blood gas analyzer.

Results: Both the Masimo MightySat Rx pulse oximeter and the Apple Watch Series 7 tended to overestimate oxygen saturation. The pulse oximeter readings were more likely to fall within 2% of the acceptable (as specified by Masimo) peripheral oxygen saturation (SpO_2) error range than the Apple Watch (49.03% vs 32.14%). Notably, both devices had limitations under low oxygen saturation levels (<88%), with an accuracy root mean square difference (A_{rms}) of 3.52% (95% CI 3.18% - 3.86%) and 5.82% (95% CI 5.32% - 6.31%) for the Masimo MightySat Rx and Apple Watch Series 7, respectively. Among the blood oxygen measurements taken during a high ODR (ie, ≥2% SpO_2 per minute), which is a rate clinically correlated with sleep apnea, the A_{rms} increased slightly by 0.75% for the Masimo MightySat Rx and decreased by 0.28% for the Apple Watch Series 7.

Conclusions: Both devices consistently overestimated SpO_2, with accuracy declining notably during hypoxemia. The Apple Watch Series 7 mean bias suggests a likelihood of missing instances of hypoxemia, particularly at arterial oxygen saturation values below but close to 88%. Both the Apple Watch Series 7 and Masimo MightySat Rx exhibited A_{rms} values exceeding the US Food and Drug Administration threshold under conditions of hypoxemia. While past studies have implicated high ODRs in increasing measurement error, we found no statistically significant relationship between ODR and measurement error for either device. Overall, our findings of SpO_2 overestimation and high A_{rms} values underscore the need for caution when interpreting oxygen saturation values from these devices. The small sample size and limited diversity in skin tone and age restrict the generalizability of our findings. Future studies should include larger and more diverse populations to evaluate the performance of wearable-based pulse oximetry.

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KEYWORDS

pulse oximetry; oxygen saturation; smartwatches; hypoxemia; wearable electronic devices

Introduction

Blood oxygen saturation, representing how much hemoglobin is bound with oxygen, is considered to be a useful vital sign for gaining insight into a person's health status alongside body temperature, blood pressure, heart rate, and respiratory rate [1]. Chronic lung diseases such as chronic obstructive pulmonary disease (COPD) and asthma can lead to significant desaturation and hypoxemia [2,3], and exercise-induced desaturation is common in these populations and associated with increased

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mortality [4,5]. Early and accurate identification of abnormal oxygen saturation [6] is important in patients who may develop hypoxemia symptoms and significant oxygen desaturation during exercise, rest, or sleep [7-9].

Measurement of oxygen saturation can be classified into 2 methods: invasive and noninvasive [10]. Arterial blood gas (ABG) analysis is an invasive measurement method that requires the collection of arterial blood samples and measures arterial oxygen saturation (SaO_2) by a dedicated co-oximeter machine. While ABG analysis is considered the gold standard, arterial blood sample collection is painful and impractical for continuous monitoring [11,12]. Pulse oximetry is based on the principle that the optical absorption of light across specific wavelengths differs for oxyhemoglobin and deoxyhemoglobin, and this phenomenon allows for the noninvasive estimation of blood oxygen saturation (SpO_2) [13]. SpO_2 measurement functionality was first introduced in popular consumer wearables in 2021, and roughly a decade later, in 2032, the global market value of wearable technology is projected to reach US $191.58 billion [14]. Multiple studies comparing SpO_2 measurements from the Apple Watch Series 7 and finger-placed pulse oximeters found Pearson correlation coefficients ranging from 0.76 to 0.89 [15-18]. However, these studies did not evaluate the smartwatch's capability to detect and identify hypoxia specifically, which is when accuracy is most critical because incorrect measurements can put patients at risk of delayed recognition and treatment [19-21]. Occult hypoxemia, which occurs when a person's blood oxygen level appears normal when measured by pulse oximetry (SpO_2>92%), but is actually low when measured by a more accurate test like ABG (SaO_2<88%), may be a clinically significant consequence of such unreliability [22]. In such a situation, hypoxemia is present but hidden or not detected by the pulse oximeter. Occult hypoxemia is concerning because it can delay the recognition and treatment of low oxygen levels, especially in critically ill patients or those with respiratory diseases such as COVID-19.

Additionally, while SpO_2 is often straightforward to measure when its level has reached a steady state, challenges arise in trying to accurately measure SpO_2 under dynamic change, particularly when those changes are rapid, such as during sleep apnea [23,24]. Blood oxygen levels typically decrease in people with obstructive sleep apnea (OSA) as a result of gaps in their breathing [25]. The oxygen desaturation rate (ODR), defined as the change in SpO_2 per minute, is a metric used to quantify such changes in SpO_2 over time. During rapid desaturation, pulse oximeter accuracy has been shown to decrease due to averaging-window algorithms that smooth the signal over several seconds and include values before the desaturation event [26,27], causing the reported SpO_2 value to lag behind the patient's real-time oxygenation status and resulting in incorrect values. Because pulse oximeter accuracy may be mediated by the ODR, it is important to evaluate pulse oximeter performance under conditions of rapid oxygen desaturation. While such studies have been performed in the past, they typically do not use the gold standard SaO_2 method to measure blood oxygen saturation due to the burdensome nature of sample collection [28-30]. In this study, we evaluated whether the accuracies of SpO_2 measurements from a common pulse oximeter and a smartwatch were impacted by the ODR using gold standard SaO_2 measurements.

Methods

Ethical Considerations

This study was approved by the Duke University Health System Institutional Review Board (Pro00110458) and conducted in accordance with the Declaration of Helsinki. Written informed consent was obtained from participants prior to their participation in the study. All data were deidentified before analysis, and no personally identifiable information was collected or stored. No compensation was provided to participants. The manuscript and supplementary materials contain no images or information that could identify individual participants.

Study Population

This study was conducted as an opportunistic investigation embedded within an existing controlled hypoxia study, which involved invasive arterial catheterization and prolonged exposure to reduced oxygen levels. As a result, the number of participants was constrained by the requirements of the parent study. Inclusion criteria included healthy male or female subjects between the ages of 18 and 45 years with a minimum body weight of 40 kg and a body mass index between 18 and 35 kg/m^2. Individuals were excluded if they had peripheral vascular disease, Raynaud syndrome, cryoglobulinemia, or any collagen vascular disease affecting the fingers; a history of blood clots within the past 6 months; a history of sickle cell trait or thalassemia; a positive urine cotinine test; heparin allergy; essential tremor; gel nail polish or any other non-natural, nonremovable discoloration of the forefinger; and, based on venous blood sampling, abnormal hemoglobin levels, abnormal hemoglobin electrophoresis, carboxyhemoglobin levels greater than 3 g/dL, or methemoglobin levels greater than 2 g/dL.

Equipment

Equipment was used in this study to assess skin tone, control the desaturation process, and take the SpO_2 and SaO_2 measurements. To assess skin tone, the Delfin SkinColorCatch colorimeter was used to report the individual typology angle (ITA), which classifies skin color types into 6 groups from very light to dark skin: very light (>55°), light (41° to <55°), intermediate (28° to <41°), tan (10° to <28°), brown (−30° to <10°), and dark (<–30°). In the desaturation process, we used the sequential gas delivery system RespirAct RA-MR to control the alveolar oxygen tension (PAO_2) and partial pressure of end-tidal oxygen ($PetO_2$) by changing inhaled oxygen and carbon dioxide levels [31]. The attained PAO_2 determined the partial pressure of oxygen in arterial blood (PaO_2) at the alveolar-arterial interspace in the lung. The PaO_2 in turn determined the participants' SaO_2 prior to blood gas sampling. The Radiometer ABL90 Flex blood gas analyzer was used to analyze extracted ABG samples and obtain the functional SaO_2. The Apple Watch Series 7 smartwatch (reflectance pulse

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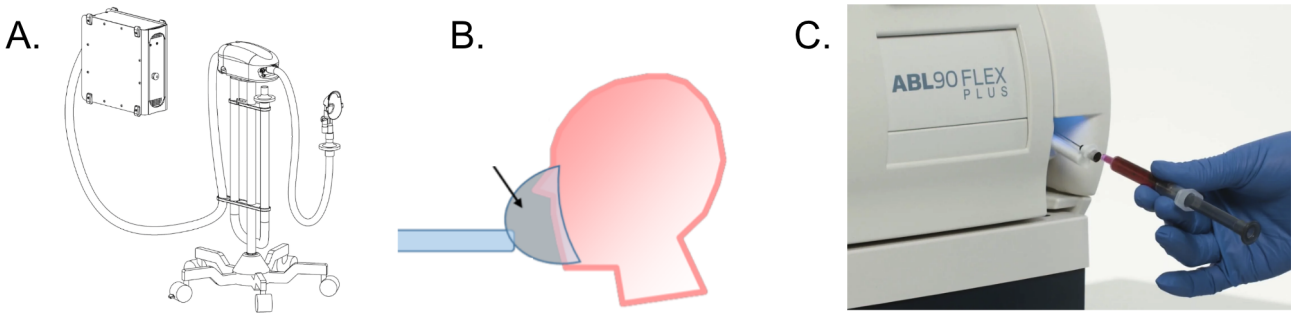
oximeter) and Masimo MightySat Rx finger pulse oximeter (transmissive pulse oximeter) were each used to measure SpO_2 separately. The Apple Watch Series 7 was chosen as it was previously identified to have the best performance among a selection of 4 commercial wearables in an analytic validation study [15,32,33], and the Masimo MightySat Rx was chosen because it is a US Food and Drug Administration (FDA) 510(k)–cleared pulse oximeter [34,35].

Desaturation Protocol

In this study, we used a controlled gas delivery system to conduct the desaturation protocol and altered SaO_2 by adjusting end-tidal oxygen ($PetO_2$) levels that participants inhaled (Figure 1). We then compared oxygen saturation (SpO_2) measurements from Apple Watch Series 7 and Masimo MightySat Rx against the gold standard ABG measurements.

Figure 1. Workflow of the equipment used to adjust $PetO_2$ and measure SaO_2. Adjusting the end-tidal $PetO_2$ setting in the RespirAct RA-MR gas delivery system (A) led the study participant to inhale gas with different oxygen, carbon dioxide, and nitrogen concentrations through a fitted mask (B). Blood samples taken once $PetO_2$ stabilized were processed by a blood gas analyzer (Radiometer ABL90 Flex) (C) to measure the resulting SaO_2 and PaO_2. PaO_2: partial pressure of oxygen in arterial blood; $PetO_2$: partial pressure of end-tidal oxygen; SaO_2: arterial oxygen saturation.



Before the desaturation procedure, participants lay in the supine position on a standard hospital stretcher with an arterial catheter placed in the forearm for blood sampling. The facemask that was connected to the sequential gas delivery system was donned by the participant. The Apple Watch Series 7 was placed comfortably but tightly on the right wrist, approximately 1 cm above the ulnar styloid process, to avoid movement during the experiment. The Masimo MightySat Rx was placed on the middle finger of the participant's right hand.

This study involved 3 phases: a sequential stepwise oxygen desaturation phase with monotonically decreasing oxygen saturation (Figure 2A, Phase 1), an oxygen saturation recovery phase (Figure 2A, Phase 2), and an interrupted oxygen desaturation phase, which included a brief increase in blood oxygen saturation during the overall desaturation sequence, enabling evaluation of pulse oximeters during directional changes in blood oxygen saturation (eg, desaturation to resaturation or resaturation to desaturation) (Figure 2A, Phase 3). Besides the oxygen saturation recovery phase, Phase 1 was designed to follow a standard step-down sequence [34], as recommended by the FDA, for assessing the performance of pulse oximeters during desaturation and hypoxemia, whereas Phase 3 was designed to evaluate device performance when the desaturation was interrupted under hypoxemia. Blood oxygen levels (SaO_2) were altered by controlling inhaled oxygen and carbon dioxide levels using the RespirAct gas delivery system, which correspondingly altered PaO_2 and $PetO_2$, which in turn altered SaO_2 [36]. In the first sequence, the oxygen saturation (SaO_2) was reduced in stepwise fashion from approximately 100% to approximately 60%, and then back to approximately 100% over the course of approximately 24 minutes. The second sequence involved holding participants' SaO_2 at approximately 100% for approximately 30 minutes. The third sequence involved decreasing participants' SaO_2 from approximately 100% to approximately 80%, then back to approximately 100% over the course of 21 minutes. The first oxygen desaturation sequence (Figure 2A, Phase 1) involved 8 steps of approximately 3 minutes each, with $PetO_2$ set to 90, 60, 50, 45, 40, 37, 34, 32, and 250 mm Hg. Using the Severinghaus formula [37], SaO_2 levels at these stages were estimated to be 97%, 90%, 85%, 81%, 75%, 70%, 65%, 60%, and 100%, respectively. Following this sequence, $PetO_2$ was held at 250 mm Hg for approximately 30 minutes to allow participants to recover their maximum oxygen saturation (Figure 2A, Phase 2). The final oxygen desaturation sequence (Figure 2A, Phase 3) consisted of 7 steps of approximately 3 minutes each, with $PetO_2$ set to 90, 60, 50, 60, 50, 45, 40, and 250 mm Hg, corresponding to an estimated SaO_2 of 97%, 90%, 85%, 90%, 85%, 80%, 75%, and 100%. During each step of the sequence, $PetO_2$ was held at a steady state using the RespirAct RA-MR until 2 ABG samples were obtained: one collected once $PetO_2$ had stabilized, and another collected 1 minute later, right before transitioning to the next target $PetO_2$ level. Consecutive plateaus were separated by approximately 2 minutes to allow the gas delivery system to reach the next target $PetO_2$ level. The only exception was the recovery period between Phase 2 and Phase 3, during which participants were given a 30-minute rest interval. A participant who completed the full desaturation protocol was expected to have 36 ABG samples corresponding to 2 samples at each of the 18 steady-state plateaus, which themselves comprised 8 plateaus during Phase 1 (initial desaturation), 2 plateaus during Phase 2 (recovery at high $PetO_2$), and 8 plateaus during Phase 3 (interrupted desaturation).

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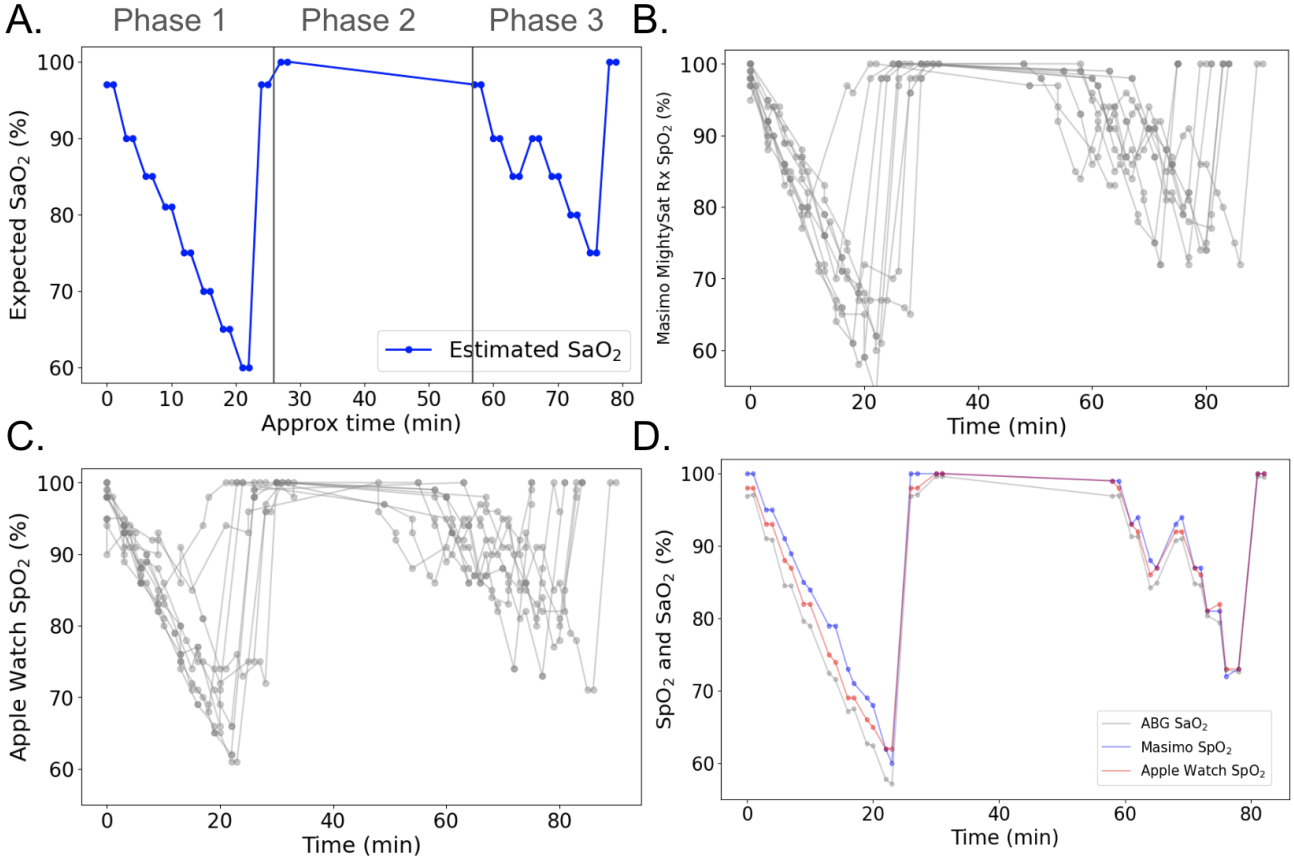
Figure 2. (A) Severinghaus-estimated SaO_2 values. The solid blue dots represent the estimated SaO_2 based on the $PetO_2$ settings at each step of the protocol, and the solid lines show the overall trajectories. The 3 phases of the study protocol (1: oxygen desaturation; 2: oxygen saturation recovery; 3: interrupted oxygen desaturation) are separated using gray vertical lines. (B and C) Actual SpO_2 measurements from the Masimo MightySat Rx (B) and the Apple Watch Series 7 (C) throughout the study protocol (N=9 study participants). (D) Actual SpO_2 and SaO_2 measurements from a representative participant resulting from the changing $PetO_2$ in the inhaled gas mixture over the duration of the study. ABG: arterial blood gas; approx: approximate; $PetO_2$: partial pressure of end-tidal oxygen; SaO_2: arterial oxygen saturation; SpO_2: peripheral oxygen saturation.



Two SpO_2 measurements, one each from the Apple Watch Series 7 and the Masimo MightySat Rx, were obtained simultaneously with each ABG sample at each steady-state plateau. Measurements on the smartwatch were manually triggered, and the participants were instructed to keep their arm still during the 15-second countdown while awaiting the SpO_2 reading. The finger pulse oximeter reading was recorded once the smartwatch produced either a successful or unsuccessful measurement. If Masimo MightySat Rx or Apple Watch Series 7 failed to produce a measurement, we recorded a missing (invalid) measurement and made another attempt after readjusting the device. If both devices successfully produced readings, the smartwatch was manually triggered again to initiate the second measurement.

Metrics and Statistical Analysis

To assess the performance of the MightySat Rx and Apple Watch Series 7, we compared each SpO_2 measurement to the SaO_2 measurements, determining whether values fell within, above, or below the acceptable error range (2%) as defined by the Masimo MightySat Rx manual. We also recorded whether the SpO_2 measurements were missing, indicating that the pulse oximetry device was unable to generate a measurement. The Bland-Altman method was used to assess the accuracy of SpO_2 measurements across all readings, with separate analysis for readings where the SaO_2 value was below 88%. The threshold of 88% was chosen in line with the British Thoracic Society guidelines [31] indicating the decision point for implementing intensive therapy to elevate oxygen saturation. The x-axes of the Bland-Altman plot are the mean of the SaO_2 and SpO_2 values and the y-axes are the difference between SaO_2 and SpO_2. Metrics used to gauge each device's performance included mean directional error (MDE) (Equation 1), missingness (Equation 2), and average root mean square (A_{rms}) difference (Equation 3), where p is the number of participants and v_i is the number of valid measurements for the ith participant. To evaluate device performance during oxygen desaturation, we excluded measurements with SpO_2 or SaO_2 more than 99% (n=57), as well as measurements collected during the resaturation process (n=79), which was defined by an increase in SaO_2 relative to the preceding measurement (ie, between Phase 1 and Phase 2 of the protocol). For the remaining measurements (n=172) with ODR at least 2% per minute or less than 2% per minute. A 2-sided paired t test was used to examine the hypothesis that MDE differs between the 2 ODR scenarios. The choice of 2% per minute stems from the 4% oxygen desaturation index (ODI-4%), which is defined as the number of events per hour with a more than 4% decrease in SpO_2 within 2 minutes (ie, the equivalent of an average of a 2% change per minute) [24]. ODI-4% is a clinically important metric to help diagnose OSA

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[38]. However, because the sampling frequency of the SaO_2 measurements is less than 1 measurement every 2 minutes, this threshold was translated into an ODR of 2% per minute. Before statistical testing, the differences between each pair of SpO_2 and SaO_2 point measurements (see Table S1 in Multimedia Appendix 1) were mean-aggregated for each person at each of the 2 ODRs, resulting in 1 MDE per person per ODR scenario. This was done separately for the Apple Watch Series 7 and Masimo MightySat Rx SpO_2 measurements. These calculations resulted in 9 participant-level MDE values for each ODR scenario and for each device (see Table S1, column 7 in Multimedia Appendix 1; Figure S1 for details of MDE values generation in Multimedia Appendix 2; Figure S2 for Boxplots of MDE values in Multimedia Appendix 3). Two paired *t* tests were performed separately, 1 for each device, on the 9 MDE values when ODR was at least 2% per minute and the 9 MDE values when ODR was less than 2% per minute to determine whether MDE values were statistically significantly different when ODR was above or below 2% per minute (see Figure S3 for normality check in Multimedia Appendix 4).

$$(1)\,MDE(Mean\ Directional\ Error)=\sum_{i=1}^{p}\sum_{j=1}^{vi}(SpO2_{i,j}-SaO2_{i,j})\sum_{i=1}^{pvi}$$

$$(2)\,Missingness\ (\%)=100-(\sum_{i=1}^{pvi}Total\ measurements)\times 100$$

$$(3)\,Arms(Root\ Mean\ Square\ Difference)=\sum_{i=1}^{p}\sum_{j=1}^{vi}(SpO2_{ij}-SaO2_{ij})2\sum_{i=1}^{pvi}$$

Results

Study Population

Nine individuals (5 males and 4 females) provided written informed consent under the Duke University Health System Institutional Review Board protocol (Pro00110458) and completed the study as described in the Methods. The median age was 25 (IQR 21 - 26) years, and the median body mass index was 24.4 (IQR 23.7-26.6) kg/m^2. The median (IQR) value of ITA of all participants was 7° (–1° to 23°) (Table 1).

Table . Participant demographics and characteristics.

Participant number	Age	ITA[a] value	Reference ITA skin classification [39,40]	Gender
1	19	23	Tan	Male
2	25	54	Light	Female
3	27	−27	Brown	Male
4	26	−8	Brown	Male
5	24	12	Tan	Female
6	19	39	Intermediate	Female
7	21	2	Brown	Female
8	28	−1	Brown	Male
9	26	7	Brown	Male

[a]ITA: individual typology angle.

Comparison Between ABG and Pulse Oximetry Measurements

Measurements were taken across 9 study participants at 18 set $PetO_2$ levels ranging from 32 to 250 mm Hg, which translates to an approximate SaO_2 values from 60% to 100% over the course of 3 phases of the study that involved monotonic oxygen desaturation, recovery, and interrupted oxygen desaturation (Figure 2A; a representative participant's trajectory is shown in Figure 2D). There were 308 measurements of the "ground truth" ABG-based blood oxygen saturation (SaO_2) which were compared with the SpO_2 measurements generated by the Masimo MightySat Rx (Figure 2B) and the Apple Watch Series 7 (Figure 2C). All participants had maximum ABG-based SaO_2 measurements of 99% and maximum Masimo- and Apple watch–based SpO_2 measurements of 100% (Table 2). The minimum SaO_2 was less than 65% for 6/9 (67%) participants, and minimum SpO_2 was less than 65% for 7/9 (78%) participants using the Masimo MightySat Rx and for 2/9 (22%) participants using the Apple Watch Series 7. In general, the Apple Watch Series 7 measurements did not reach the same nadir values as the Masimo MightySat Rx measurements (Figure 2B and C).

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Table . Maximum and minimum SpO_2 and SaO_2 values and interindividual ranges during the desaturation procedure.

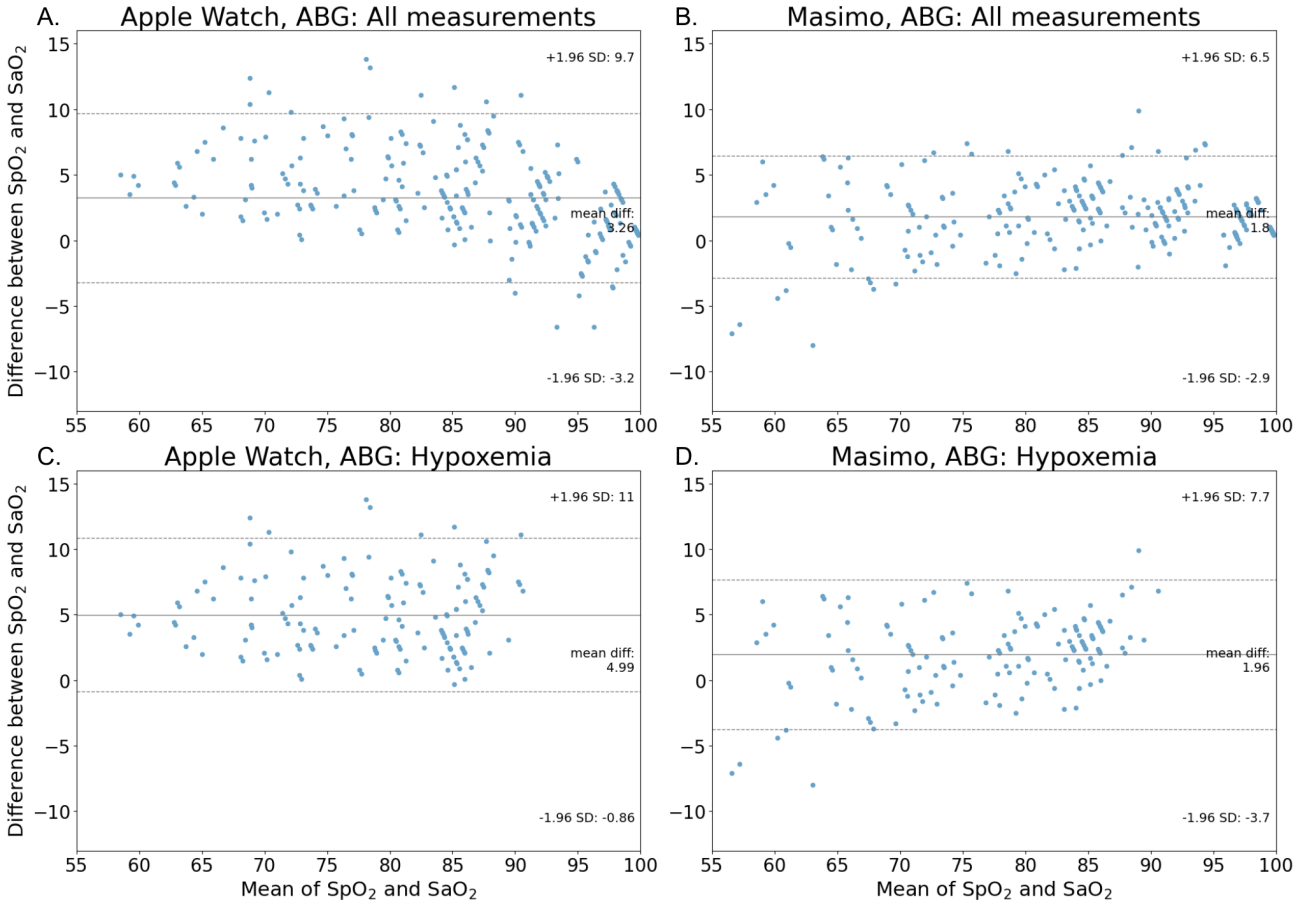
Type of measurements	Maximum, % (range)	Minimum, % (range)
SpO_2[a] measurements from Masimo MightySat Rx	100 (100-100)	53 (53-71)
SpO_2 measurements from Apple Watch Series 7	100 (100-100)	61 (61-85)
SaO_2[b] measurements	99.8 (99.2-99.8)	56 (56-70)

[a]SpO_2: peripheral oxygen saturation.

[b]SaO_2: arterial oxygen saturation.

Each measurement from the Masimo MightySat Rx and the Apple Watch Series 7 was compared with its concomitant ABG measurement to determine whether it fell within, above, or below 2% error, which was the acceptable range as defined by the Masimo MightySat Rx manual. The percentage of measurements falling into these different categories demonstrates whether there exists a trend of overestimation or underestimation of SpO_2 levels. Both the MightySat Rx and the Apple Watch Series 7 tended to overestimate SpO_2, with MDEs of 1.80% and 3.26%, respectively (Figure 3A, B, 3). The Apple Watch Series 7 had a higher proportion of overestimated measurements (n=174, 56.49% of SpO_2 measurements were overestimated) as compared with the MightySat Rx (where n=137, 44.48% of measurements were overestimated). A higher percentage of Masimo MightySat Rx SpO_2 measurements (n=151, 49.03%) fell within the 2% error range of the reference SaO_2 values compared with Apple Watch Series 7 SpO_2 measurements (n=99, 32.14%).

Figure 3. Bland-Altman plots demonstrate the differences between simultaneous ABG-based SaO_2 measurements and either all (A) or hypoxemia-only (SaO_2<88%) (C) SpO_2 measurements from the Apple Watch Series 7. The same comparisons are shown between SaO_2 and SpO_2 for the Masimo MightySat Rx (all, B; and hypoxemia-only, D). The solid line shows the mean difference of the measurements (MDE), and the dashed lines show the 95% limits of agreement. A_{rms}: average root mean square; SaO_2: arterial oxygen saturation; SpO_2: peripheral oxygen saturation.



A_{rms} across 5% SaO_2 bins demonstrated a decreasing trend (Figure 4) for both devices with increasing SaO_2. The highest A_{rms} values were observed in the lowest saturation ranges (60% - 65%), reaching 7.26% for the Apple Watch Series 7 and 4.57% for the Masimo MightySat Rx. In contrast, the lowest A_{rms} values occurred at the highest saturation range

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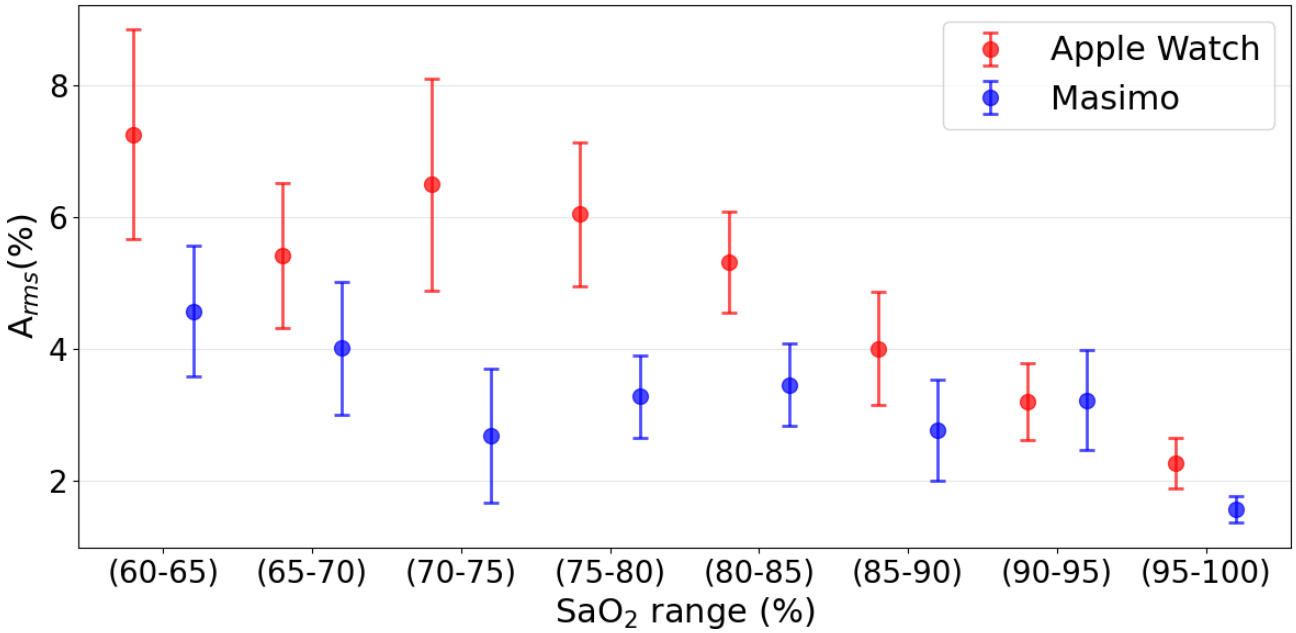
(95% - 100%), where A_{rms} decreased to 2.27% for the Apple Watch Series 7 and 1.53% for the Masimo MightySat Rx. Overall, the Masimo MightySat Rx exhibited lower A_{rms} values than the Apple Watch Series 7.

Figure 4. Average root mean square of SpO_2 measurements for Apple Watch Series 7 (red) and Masimo MightySat Rx (blue) binned by 5% oxygen saturation bins ranges from 60% to 100%. Points indicate the A_{rms} within each SaO_2 range, and dashed lines represent the 95% CIs. ABG: arterial blood gas; SaO_2 : arterial oxygen saturation; SpO_2: peripheral oxygen saturation.



A Bland-Altman analysis demonstrated that SpO_2 measurements tended to be overestimated since the points in the figure mostly lie above the zero-bias line (Figure 3). Overall, the Masimo MightySat Rx showed higher accuracy against the SaO_2 ground truth measures than the Apple Watch Series 7, with an A_{rms} difference in accuracy (95% CI) of 2.98% (2.72% - 3.25%) for the Masimo MightySat Rx and 4.63% (4.26% - 5%) for the Apple Watch Series 7.

Missingness Evaluation

Of attempted SpO_2 measurements, 305/308 (99%) and 284/308 (92%) were successfully reported by the Masimo MightySat Rx and Apple Watch Series 7, respectively. In other words, when the device was prompted to make a measurement, the Masimo MightySat Rx was unable to produce 3/308 (0.97%) attempted measurements, whereas the Apple Watch Series 7 was unable to produce 24/308 (7.79%) attempted measurements (Figure 5, blue bar). Thus, in terms of missingness, the Apple Watch Series 7 had more missingness (24/308, 7.79%) compared with the MightySat Rx (3/308, 0.97%), indicating that both have high likelihood (>90%) for successfully obtaining a measurement when a measurement was attempted.

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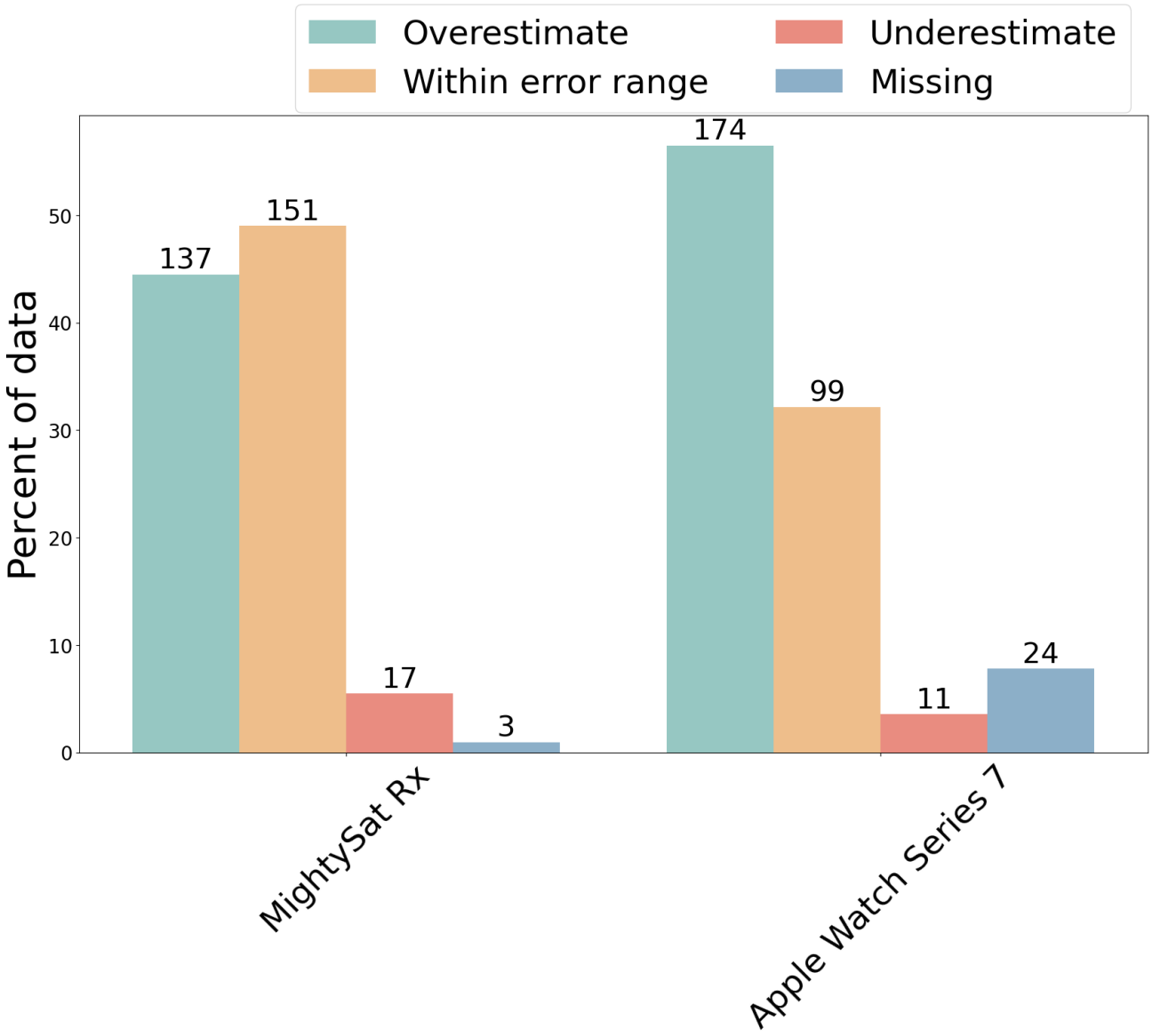
Figure 5. Relative percentages of data falling into the categories of overestimated measurements (green), measurements within acceptable error ranges (yellow), underestimated measurements (red), and missing measurements (blue) for the Masimo MightySat Rx and Apple Watch Series 7.



Accuracy of Measurements Under Hypoxemia

The clinical threshold for hypoxemia is blood oxygen saturation less than 88% [41]. As noted in the Introduction, occult hypoxemia is a situation where a patient actually has blood oxygen saturation less than 88%, but their blood oxygen saturation measurements read as higher (ie, above the threshold that would lead to a clinical intervention). Among the 308 ABG-based SaO_2 measurements, 165 (54%) were less than 88%. Among those, the Masimo MightySat Rx and Apple Watch Series 7 produced 164 (99%) and 150 (91%) simultaneous SpO_2 measurements, respectively; the remaining were attempted but the devices did not generate values and thus those values were considered missing. Among those SpO_2 measurements where SaO_2 was less than 88%, 86/164 (52.44%) of the Masimo MightySat Rx measurements and 128/150 (85.33%) of the Apple Watch Series 7 measurements were overestimated. Importantly, 3 (1.8%) of the Masimo MightySat Rx measurements and 6 (4%) of the Apple Watch Series 7 measurements were actually reported to be above 92%. These instances of occult hypoxemia occurred in participants 2 and 7 using the Masimo MightySat Rx, and in participants 2, 8, and 9 using the Apple Watch Series 7. Notably, only one measurement from a single participant (participant #2) demonstrated an instance of occult hypoxemia that was detected simultaneously on both devices.

Looking specifically under conditions of hypoxemia, the MDE of SpO_2 for the Masimo MightySat Rx and the Apple Watch Series 7 was 1.96% and 4.99%, respectively; higher than the overall MDE of 1.80% and 3.26% reported above (Figure 3C, D; Table S1 in Multimedia Appendix 1, which represents participant-level MDE of SpO_2 for Masimo MightySat Rx and the Apple Watch Series 7). The A_{rms} (95% CI) during hypoxemia was 3.52% (3.18% - 3.86%) and 5.82% (5.32% - 6.31%) SpO_2 for the Masimo MightySat Rx and the Apple Watch Series 7, respectively, which are also both higher than the overall A_{rms}.

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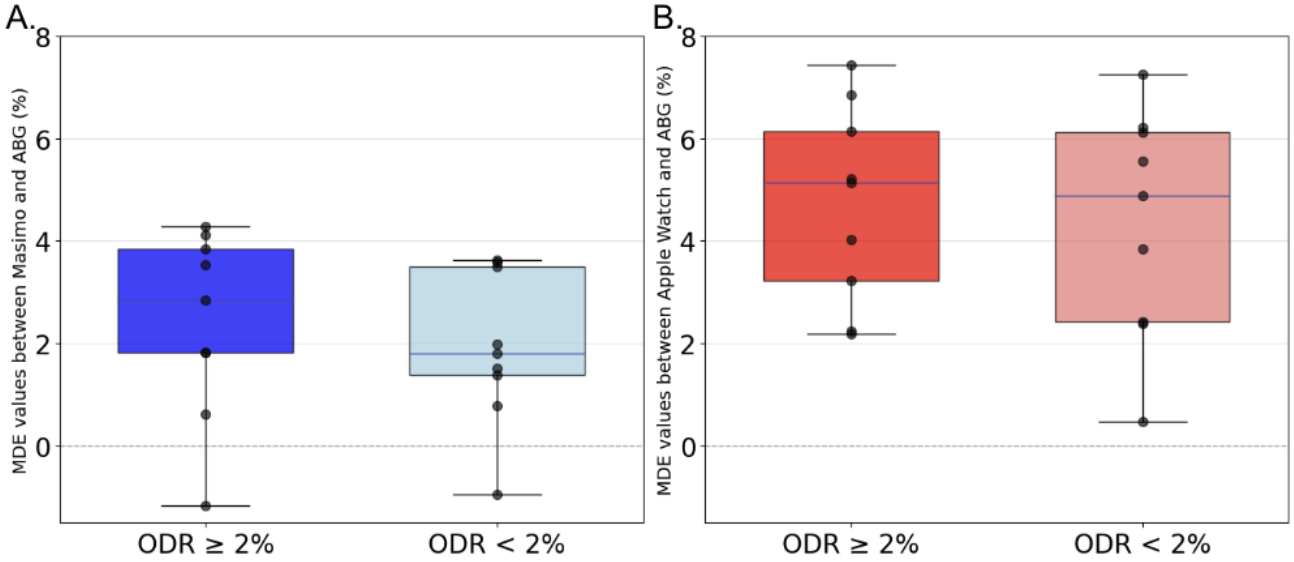
Relationship Between Device Performance and ODR

Before comparing device performance under ODR at least 2% per minute and ODR less than 2% per minute conditions, we excluded 57 fully saturated measurements (SpO_2 or SaO_2>99%) and 79 resaturation measurements. Among the remaining 172 desaturating SaO_2 measurements (Table S2 in Multimedia Appendix 5) out of the total 308 measurements, 169 and 157 SpO_2 measurements were collected from the Masimo MightySat Rx and the Apple Watch Series 7, respectively. Among those, 83/169 Masimo MightySat Rx and 78/157 Apple Watch Series 7 measurements occurred when the ODR was greater than two percent per minute.

When the ODR increased above 2% per minute, the Masimo MightySat Rx A_{rms} increased from 3.04% to 3.79%, and the MDE increased from 1.86% to 2.38%. Also at ODR greater than 2% per minute, the Apple Watch Series 7 MDE increased from 4.16% to 4.41% (Figure S2 in Multimedia Appendix 3) but A_{rms} decreased from 5.50% to 5.22%. No significant correlation was found (Figure 6) between the ODR and MDE for the Masimo MightySat Rx nor the Apple Watch (2-sided paired *t* test: *P*=.12 and .22, respectively).

Figure 6. Boxplots demonstrate the participant-level mean directional error of (A) Masimo MightySat Rx and (B) Apple Watch Series 7 between SpO_2 and arterial oxygen saturation measurements when the oxygen desaturation rate is at least 2% per minute and less than 2% per minute. ABG: arterial blood gas; MDE: mean directional error; SaO_2: arterial oxygen saturation; SpO_2: peripheral oxygen saturation.



Discussion

Principal Findings

We designed and implemented this study to evaluate the performance of optical blood oxygen saturation measurements (SpO_2) from smartwatches and finger pulse oximeters under conditions of hypoxemia that were induced by a controlled oxygen desaturation protocol. There are three main findings of our study: (1) both the Masimo MightySat Rx and the Apple Watch Series 7 often overestimate true blood oxygen saturation values, with 44% and 56% of their measurements in this study, respectively, found to be higher than the ground truth SaO_2 measures; (2) both devices have lower accuracy during hypoxemia than at normal blood oxygen saturation; and (3) both devices showed a trend toward lower accuracy when the ODR is larger than 2% per minute, but the difference is not statistically significant.

Our previous study [32], which used the Masimo MightySat Rx as the reference measurement for oxygen saturation to analytically validate four commercial wearables in 49 patients with low blood oxygen saturation, many of whom had chronic pulmonary disease, found that the Apple Watch Series 7 overestimated blood oxygen saturation measurements 17% of the time. In this current study, where we used ABG measurements of SaO_2 as the reference standard "ground truth" measure, as well as a controlled oxygen desaturation study protocol in healthy individuals to achieve low blood oxygen saturation, the Apple Watch Series 7 overestimated blood oxygen saturation 56% of the time. In this study, we also observed that the Masimo MightySat Rx, the reference standard used in the previous study, also overestimated oxygen saturation levels 44% of the time. One likely reason for the discrepancy in the Apple Watch Series 7 overestimation rate between the 2 studies is the choice of the reference standard measurement—the ABG measurements used in the current study are a more trustworthy ground truth measurement. Another likely factor is the difference in the distribution of oxygen saturation values between the 2 studies. Specifically, our previous study did not include a desaturation protocol, and the SpO_2 measurements obtained from the Masimo MightySat Rx ranged only from 82% to 100%, which may have contributed to a lower observed rate of overestimation. Blood oxygen saturation overestimation is particularly dangerous under conditions of occult hypoxemia (where the actual SaO_2 is <88% but the measured SpO_2 is >92%), when a patient's blood oxygen saturation is thought to be normal and care is delayed [42]. In our study, although the Apple Watch Series 7 had a high rate of overestimation (56% of measurements), only 6/150 (4%) of the Apple Watch Series 7 measurements and 3/164 (1.8%) of the Masimo MightySat

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Rx measurements actually fell into the category of occult hypoxemia. It is likely that, had there been more measurements concentrated only slightly below 88%, there would have been more occurrences of occult hypoxemia observed in our study. This is because the mean bias of the Apple Watch Series 7 measurements under hypoxemia conditions (4.99%) just slightly exceeds the minimum difference (4%) between SpO_2 and SaO_2 that defines occult hypoxemia (92% vs 88%).

Our study also demonstrates that the performance of both the finger pulse oximeter and the smartwatch suffers during hypoxemia as compared with conditions of normal blood oxygen saturation. The overestimation rate increased from 44.48% to 52.44% for the Masimo MightySat Rx and from 56.49% to 85.33% for the Apple Watch Series 7, while the A_{rms} increased from 2.98% to 3.52% and 4.63% to 5.82% during hypoxemia for the 2 devices, respectively. For 510(k) clearance, the FDA currently recommends an A_{rms} of less than 3% for transmission pulse oximeters (eg, Masimo MightySat Rx) and less than 3.5% for reflectance oximeters (eg, Apple Watch) [34]. According to the FDA's 2025 draft guidance, the A_{rms} specification for both sensor types will be standardized to less than 3% [43]. Both devices used in our study exhibited A_{rms} values exceeding the FDA threshold under conditions of hypoxemia. A previous study that recruited 50 healthy adults and conducted oxygen desaturation cycles from approximately 100% to 70% SaO_2 evaluated the accuracy of Apple Watch SpO_2 measurements using ABG as the gold standard; this study also reported a trend of overestimation in the Apple Watch Series 6, with an A_{rms} of 2.18% (95% CI 1.55% - 2.84%), meeting current or upcoming FDA A_{rms} requirements. The missingness in their study was 5.29% (966 of 1020 attempted measurements gave readings) as compared with 7.79% (284 of 308 attempted measurements gave readings) in our study, likely due to more measurements in our study attempted at lower oxygen saturation [44]. Another study involving 167 participants with acute exacerbation of COPD reported an MDE of 0.46% between Apple Watch Series 6 measurements and ABG-based SaO_2 measurements [30].

When the ODR exceeded 2% per minute, A_{rms} increased from 3.04% to 3.79% for the Masimo MightySat Rx and decreased from 5.50% to 5.22% for the Apple Watch Series 7. Even though the difference between SaO_2 and SpO_2 was not found to be statistically significant during desaturation, the fact that A_{rms} exceeded 3% for both devices indicates that they should be used with caution, particularly under rapid desaturation conditions. Accurate performance during oxygen desaturation is crucial not only for monitoring oxygen levels but also for clinical decision-making. This finding is especially relevant for home monitoring in patients with OSA, where the number of desaturation episodes (ie, a drop in mean oxygen saturation of ≥4% over the course of 120 s) is linked to apnea and hypopnea [24]. Inaccuracies and missingness during desaturation could result in misclassification of these episodes, leading to inappropriate assessment and treatment plans for patients.

Although current FDA guidance recommends validation of pulse oximeter accuracy within the SpO_2 range of 70% to 100%, our results highlight the importance of evaluating device performance at lower oxygen saturation levels. Device accuracy declined substantially as SaO_2 decreased from 100% to 60%, with A_{rms} increasing from 2.27% to 7.26% for the Apple Watch Series 7 and from 1.53% to 4.57% for the Masimo MightySat Rx. These results suggest that limiting validation to SpO_2 values of at least 70% may overlook performance limitations in more severe hypoxemia, where accurate measurement is critical for timely clinical interventions. Expanding regulatory validation requirements to include lower saturation ranges may therefore provide a more comprehensive assessment of pulse oximeter performance.

Limitations

The main limitation of this study is the small sample size, which resulted in insufficient representation across skin tone categories and age ranges. According to the FDA guidance for pulse oximeters, 10 or more healthy participants that vary in age and gender should be included, and a minimum of 2 subjects, or 15% of the study participant pool, need to be darkly pigmented [34]. However, in our study, only four (light, intermediate, tan, brown) out of the seven possible ITA skin types (very light, light, intermediate, tan, brown, dark, and very dark) were represented. A benefit of our study, however, was the use of objective skin tone measures using a device rather than the more common subjective human assessment using a comparison scale like Fitzpatrick or Monk (Figure S4 in Multimedia Appendix 6). Moreover, only the brown and tan skin types were represented by more than one participant, and we did not have any representation from the dark, very dark, and very light categories. This lack of diversity across skin tones limits the generalizability of our findings to individuals with lighter or darker skin tones. We recognize this as a limitation in our study as a result of the limited time and resources available to perform the study more comprehensively.

While our study captured a wide range of oxygen saturation values from 60% to 100%, covering the FDA-recommended SpO_2 accuracy validation range of 70% to 100%, we did not measure the response time of the finger pulse oximeter, and the Apple Watch Series 7 reported SpO_2 readings after a fixed 15-second countdown. Previous studies have shown that finger pulse oximeters may have a delay in displaying the blood oxygen saturation values during the onset of hypoxia [45]. Several factors can contribute to this delay, including the measurement site and poor peripheral perfusion [45]. Other research suggests that fingertip oximeters have the slowest response in desaturation changes from normoxemia to hypoxemia [46]. Future studies could consider evaluating the response time during desaturation events to ensure that pulse oximeters provide not only accurate but also timely measurements.

Although our experiment simulated the process of oxygen desaturation in healthy participants, there are additional factors to consider that may prevent these results from generalizing to patients of older age and/or who may experience oxygen desaturation as a result of a health condition. The age range of our study participants was between 19 and 28 years; COPD is most prevalent in people aged 65 to 84 [47]. Arterial stiffness of older people results in changes in the propagation of the pulse

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to the periphery, thereby influencing the peripheral pulse timing and shape characteristics which can affect the performance of pulse oximeters [48].

Finally, this protocol cannot demonstrate SpO_2 measurement performance over long periods since each participant only spent 60 minutes in the first oxygen desaturation sequence and 48 minutes in the second one. While it would be infeasible to induce oxygen desaturation for such a long period in healthy adults, clinically, it is necessary to be able to consistently monitor oxygen saturation values overnight, for example, in COPD patients who often experience nocturnal hypoxemia [2,49]. It is therefore necessary to perform clinical validation among COPD patients with nocturnal desaturation, defined as having a SpO_2 value below 90% for more than 30% of the time in bed during one or more nights [50,51]. Future clinical validation studies should thus perform real-world monitoring over longer periods, and particularly during sleep, in COPD and sleep apnea patients to capture nocturnal desaturation caused by those conditions [52].

Conclusion

In this controlled hypoxemia study, we evaluated how well the Masimo MightySat Rx and the Apple Watch Series 7 oxygen saturation measurements (SpO_2) correspond to ABG measurements (SaO_2) across a range of arterial oxygen saturation levels, ranging from approximately 60% to 100%. Both devices consistently overestimated SpO_2, with accuracy declining notably during hypoxemia. The Apple Watch Series 7 mean bias suggests a likelihood for missing instances of hypoxemia, particularly at SaO_2 values below, but close to, 88%. Both the Apple Watch Series 7 and Masimo MightySat Rx exhibited A_{rms} values exceeding the FDA threshold under conditions of hypoxemia. While past studies have implicated high ODRs in increasing measurement error, we found no statistically significant relationship between ODR and measurement error for either device. Overall, our findings of SpO_2 overestimation and high A_{rms} values underscore the need for caution when interpreting oxygen saturation values from these devices. The small sample size and limited diversity in skin tone and age restrict the generalizability of our findings. Future studies should include larger and more diverse populations to evaluate the performance of wearable-based pulse oximetry.

Funding

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Data Availability

The datasets analyzed during this study are available from the corresponding author upon reasonable request.

Conflicts of Interest

JD sits on the Google Consumer Health Advisory Board and is a consultant to Samsung Research America and Jones Day. All other authors have no conflicts to declare.

Multimedia Appendix 1
Participant-level mean directional error (MDE) and variability of SpO_2 measurement error for Apple Watch Series 7 and Masimo MightySat Rx.
[DOCX File, 13 KB - formative_v10i1e85253_app1.docx]

Multimedia Appendix 2
Workflow for generating participant-level mean directional error (MDE) values for the Masimo MightySat Rx and the Apple Watch Series 7 prior to performing paired *t* tests.
[PNG File, 180 KB - formative_v10i1e85253_app2.png]

Multimedia Appendix 3
Boxplots demonstrate the different errors of pulse oximetry between measurements with oxygen desaturation rate ≥2%/min and <2%/min (A) SpO_2 measurements of the Masimo MightySat Rx (B) SpO_2 measurements of the smartwatch (Apple Watch Series 7).
[PNG File, 46 KB - formative_v10i1e85253_app3.png]

Multimedia Appendix 4

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Quantile-quantile (QQ) plots of participant-level mean directional error (MDE) for Masimo MightySat Rx and Apple Watch Series 7.
[PNG File, 66 KB - formative_v10i1e85253_app4.png]

Multimedia Appendix 5
SpO_2 and SaO_2 measurements when oxygen desaturation rate (ODR) ≥2% or ODR <2%.
[DOCX File, 58 KB - formative_v10i1e85253_app5.docx]

Multimedia Appendix 6
SpO_2 measurement bias by sex (left panel) and skin tone (right panel) for the Masimo MightySat Rx (top row) and Apple Watch Series 7 (bottom row).
[PNG File, 132 KB - formative_v10i1e85253_app6.png]

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Abbreviations

ABG: arterial blood gas
A_{rms}: average root mean square
COPD: chronic obstructive pulmonary disease
FDA: US Food and Drug Administration
ITA: individual typology angle
MDE: mean directional error
ODR: oxygen desaturation rate
OSA: obstructive sleep apnea
PAO_2: alveolar oxygen tension
PaO_2: partial pressure of oxygen in arterial blood
$PetO_2$: partial pressure of end-tidal oxygen
SaO_2: arterial oxygen saturation
SpO_2: peripheral oxygen saturation

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User Testing an mHealth Behavioral Health App for Hopi/Tewa Youth During the COVID-19 Pandemic: Usability Study

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Abstract

Background: American Indian/Alaska Native (AI/AN) people represent a culturally diverse people group within the United States. AI/AN people experience some of the most severe health disparities in the United States, including behavioral health. A quarter of AI/AN people in the United States live on tribal lands, experiencing significant barriers to mental health resources and broadband infrastructure for telehealth. We developed Amplifying Resilience Over Restricted Internet Access (ARORA)—a mobile health (mHealth) smartphone app, promoting mindfulness practices and community building through AI/AN culture and values. Originally co-designed with both Hopi/Tewa and Navajo youth and adults, this study evaluated app resonance among Hopi/Tewa youth, supporting its iterative design. While we initially planned in-person user testing, this was moved online due to the COVID-19 pandemic.

Objective: This study assessed the potential and acceptability of an mHealth app supporting Hopi/Tewa youth practicing mindfulness inspired by their culture, values, and beliefs. This research served as preliminary work for an ongoing, iterative participatory action research study, identifying points of improvement to align with our partner community's goals.

Methods: After meeting with 6 community advisory board members and focus groups prior to this study, we developed a prototype for ARORA. This study evaluated intuitiveness and usability through testing and interviews with Hopi/Tewa youth. All meetings with stakeholders were moved online due to the COVID-19 pandemic. Using screen-sharing via Zoom (Zoom Communications, Inc) and Android emulators, we received feedback for the iterative design process.

Results: This study involved 9 participants aged 16-24 years. Of these participants, 1 was male and 8 were female; all identified as Hopi/Tewa and/or Tewa. This study included a quantitative assessment using a modified version of the User Version of the Mobile Application Rating Scale. The mean score across all questions was 3.71 (SD 0.427), suggesting generally positive reception. Qualitative results from thematically analyzing open-ended focus group data produced 5 open codes and 12 axial themes, reaching thematic saturation after engaging with 9 participants. Qualitative feedback revealed that while its use was generally enjoyable, the ARORA app could be more specific to Hopi/Tewa culture. Finally, we reflect on adaptations made to our initial protocol in response to the COVID-19 pandemic, offering guidelines for future mHealth work involving rural or hard-to-reach communities.

Conclusions: In this evaluation and usability testing of the ARORA prototype, participants expressed interest and engagement in the mindfulness activities. Participants also identified spaces in which the app could improve, both in usability and in cultural groundedness, especially with the visual dimensions of the app. Reflecting on our experience in facilitating remote user testing, we encourage future work in rural mHealth to consider practices for conducting research when in-person meetings are not feasible.

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KEYWORDS

mobile app; mHealth; mobile health; mental health; Native American; American Indian/Alaska Native; remote user testing

Introduction

American Indian/Alaska Native (AI/AN) people represent a culturally diverse group within the United States, with 574 federally recognized Indigenous tribal communities [1], each with their own distinct culture. AI/AN people experience some of the most severe behavioral health disparities in the United States, with suicide rates that are 2.1 - 4.1 times higher for youth (aged 14 - 24 years) than for White counterparts [2], and approximately 60% of AI/AN youth experiencing severe mental health distress [3]. Of the 9.7 million AI/AN people living in the United States, 25% live on tribal lands [4], which have very

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limited access to mental health resources [5] and secure broadband infrastructure, which is needed for supporting telehealth [6]. Moreover, there is often a lack of culturally centered mental health interventions for AI/AN communities [7].

Mobile health (mHealth) addresses mental and behavioral health care gaps among rural communities [8]. However, the design of mHealth technologies for hard-to-reach communities must be informed by the target populations' infrastructural affordances. Mental health and wellness practices operate most effectively when they are tailored to specific communities and populations [9], presenting challenges for tribal communities, who historically have not been included in the technology design process [10].

mHealth supports technologies designed for health care, with broad applications in the mental and behavioral health spaces [11-14]. mHealth has the potential to address barriers to care, resulting from geographical restraints, by supporting remote interventions. Prior work has highlighted mHealth's capabilities for addressing hard-to-reach populations, such as rural communities [15,16], older adult populations [17-19], and Indigenous populations [20]. Many works, particularly in the human-computer interaction research space, have noted the influence of relationality, identity, and culture in mHealth [21-23]. Universalist interventions fail to account for the identity-based contexts that inform user health and wellness, such as historical trauma or culturally specific familial dynamics [21-23]. Our work with the Hopi/Tewa community differed from prior Indigenous mHealth work in that it centers on a specific population underrepresented in the current literature. In the United States alone, there are 574 federally recognized Indigenous communities, each with their own distinct cultures, histories, and values, meaning that existing mHealth technologies for AI/AN communities may not resonate with all Indigenous communities.

Our work prioritized designing for rurality, as Hopi land is rural. An important factor in developing mHealth for rurality is understanding the target community's affordances. Wyche et al [24] deployed an mHealth app for monitoring diabetes among youth in Kenya, noting the challenges and limitations of developing a smartphone-based tool in rural areas with limited internet and electricity access. The authors' contributions support growing arguments for mHealth research to design for existing capacities at community scale, recognizing what tools are readily available for stakeholders and what cultures surround them [24,25]. Okumu et al [15] use mHealth to offer Sexual Reproductive Health information to displaced populations in Uganda, noting the importance of developing digital health content grounded in local cultures. Indeed, intersectionality plays a significant role in designing mHealth for rural communities, as they not only have distinct identity-based needs but also often overlap with culturally distinct groups. We adopted valuable guidelines from prior participatory action research (PAR), informing this work with the network issues existing on Hopi/Tewa land.

We acknowledged known challenges and needs for developing mHealth for rural communities, further tailoring our work to cater toward the remote Hopi/Tewa community. We designed Amplifying Resilience Over Restricted Internet Access (ARORA)—an mHealth smartphone app that incorporates Southwestern AI/AN culture and values into its design while promoting mindfulness practices and community building. Initially co-designed with Hopi/Tewa and Navajo community advisors and AI/AN youth in 2019 and 2020 [26], we developed a functional prototype of ARORA in 2020, while simultaneously solidifying partnerships with Hopi/Tewa Tribe Behavioral Health Services. This study reviewed the iterative and ongoing design of ARORA, requesting early feedback from stakeholders on the functional prototype, to identify needs for improvement. In particular, we reviewed the acceptability and usability of the app. In preparing for this trial, we did not publish a protocol, as guided by our National Science Foundation–funded grant proposal. Rather, we followed a PAR approach [27], maintaining adaptability both in the protocol and the design of the prototype. PAR prioritizes adaptability. We aimed to meet the needs of our target population, building trust and developing a digital artifact that resonates with the stakeholders.

Due to the COVID-19 pandemic, we had to adapt our research protocol to accommodate remote app evaluations. Initially, user testing sessions were planned to take place on Northern Arizona University's campus, with groups testing ARORA together. Rather than ceasing research due to our inability to meet in-person with participants, we pivoted to holding user testing sessions over Zoom (Zoom Communications, Inc). These evaluations offered valuable community-based feedback to be used in informing iterative versions of ARORA. Pandemic-informed adaptations to the protocol allowed us to review how users would engage with ARORA in the contexts that it ultimately would be used in: on Hopi/Tewa land and in the homes of youth.

Evaluating an early prototype in context, allowing for feedback to inform its iterative design, aligns with design concepts, such as Formative Situations. This design philosophy entails reviewing how stakeholders engage with technology within a variety of scenarios, prioritizing consistent and iterative feedback [28]. Remote user testing presented challenges that are necessary for understanding ARORA's iterative design, such as intermittent internet connectivity. Challenged network and internet access is common in rural spaces in the United States, including on Hopi/Tewa land [29]. Holding user testing sessions remotely highlighted unique needs for further adapting ARORA to operate effectively under these circumstances.

Our previous work prioritized designing ARORA, determining the activities, aesthetics, and language that were to be included in it [26]. While initial work on this project involved some user testing, ARORA was initially designed for Southwest youth in more broad contexts, rather than being Hopi/Tewa-specific. Therefore, in this work, we aimed to address the following questions:

- *Research question 1:* How can ARORA be adapted to better resonate with Hopi/Tewa culture, thus supporting Hopi/Tewa youth in practicing emotional wellness and resilience?

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- *Research question 2:* Does ARORA feasibly support youth in engaging with emotional resilience?

The contributions of this study are as follows:

- We conducted a remote user study with 9 Hopi/Tewa youth (aged 14-24 years) to evaluate the acceptability of the ARORA app using a modified version of the User Version of the Mobile Application Rating Scale [30] and a subsequent focus group. We found that while the app generally performed well at promoting mindfulness and social awareness, it could benefit from being more centered around Hopi/Tewa culture and values in further development.
- We reflect on the process of conducting remote user testing with limited connectivity and technical resources, offering guidance for future work in rural and remote mHealth.

Methods

Ethical Considerations

Our study protocol was reviewed and approved by Northern Arizona University's Institutional Review Board (number 1647272) and permitted by the Hopi/Tewa Cultural Preservation Office. Hopi/Tewa Cultural Preservation Office oversees and approves all research projects for and in collaboration with the Hopi tribe. All participants were recruited through community partnerships, and any participants younger than 18 years were required to receive explicit permission from their guardians before partaking in this study. All participants in this study underwent informed consent, with adult participants signing consent forms and minor participants signing minor assent forms with their parents or guardians. All participants of this study were compensated for their time and opinions with US $25 Amazon gift cards. Participant data in this work were anonymized and codified.

Statement of Positionality

This research was led by investigators with backgrounds in computer science, mental health, and education. Of the 4 principal investigators (MVH, AA, DHJ, and AFC) directing this project, 1 was Hopi/Tewa. Additionally, our team included a community research coordinator from the Hopi/Tewa tribe who was responsible for recruiting participants and conducting the user testing sessions. While the remaining investigators (SH and MA) were not Hopi/Tewa themselves, they collectively hold over 2 decades' worth of experience collaborating with Indigenous communities in co-designing health interventions or technologies to meet community needs and goals. Additionally, our work was overseen by a community advisory board (CAB), consisting of 6 members of the Hopi/Tewa tribe.

Development of Prototype

The ARORA prototype was developed using Java and Kotlin for Android devices and emulators. This app included 3 mindfulness-oriented activities that were ideated in collaboration with our CAB members. Each activity combined Hopi/Tewa cultural values with evidence-based mindfulness research. The mindfulness activities included a mindful walking exercise (Figure 1), a mindful breathing exercise (Figure 2), and a mindful meditation exercise. Mindful walking has been shown to reduce the effects of depression, anxiety, stress, and burnout among individuals [31,32], which inspired our design of the walking activity. The exercise incorporated peaceful audio guides for the user to listen to as they walked and observed their surroundings. The mindful breathing activity, centered on guided breathing practices shown to reduce anxiety [33], included audio guides for taking in breaths, including imagery of feathers. The meditation activity offered a mini-game, in which users would listen to the guiding audio in the background as they lined up dots on the screen, requiring them to direct their attention to the app for the entire duration of the activity [34]. The audio scripts for the breathing, walking, and meditation exercises were written by a psychologist coauthor and then modified by our CAB members, ensuring that the resulting content was grounded in Hopi/Tewa culture and reflected existing practices of resilience.

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Figure 1. Mindful walking screen.

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Figure 2. Mindfulness breathing screen.

In addition to the mindfulness activities, the app included 2 augmented reality (AR) activities that were designed to encourage collaboration and community support among users. In each of these games, users were able to view and catch animated butterflies through AR, interactively moving their mobile devices and positioning their cameras to view animated butterflies in their real-world environments. One of the AR activities called "Superfly" was collaborative, requiring players to work synchronously with one another to collect butterflies through the app and then combine their butterflies together to create a Superfly (Figure 3). The Superfly exhibited colors from each of the butterflies provided by the players, rewarding them for their collaboration. The goal of Superfly was to encourage positive and collaborative interactions between users to further build a sense of community with one another. This design choice reflects prior mHealth work with Indigenous populations, which tie community values and practices for establishing wellness and resilience, such as positive psychology [35-38]. This activity

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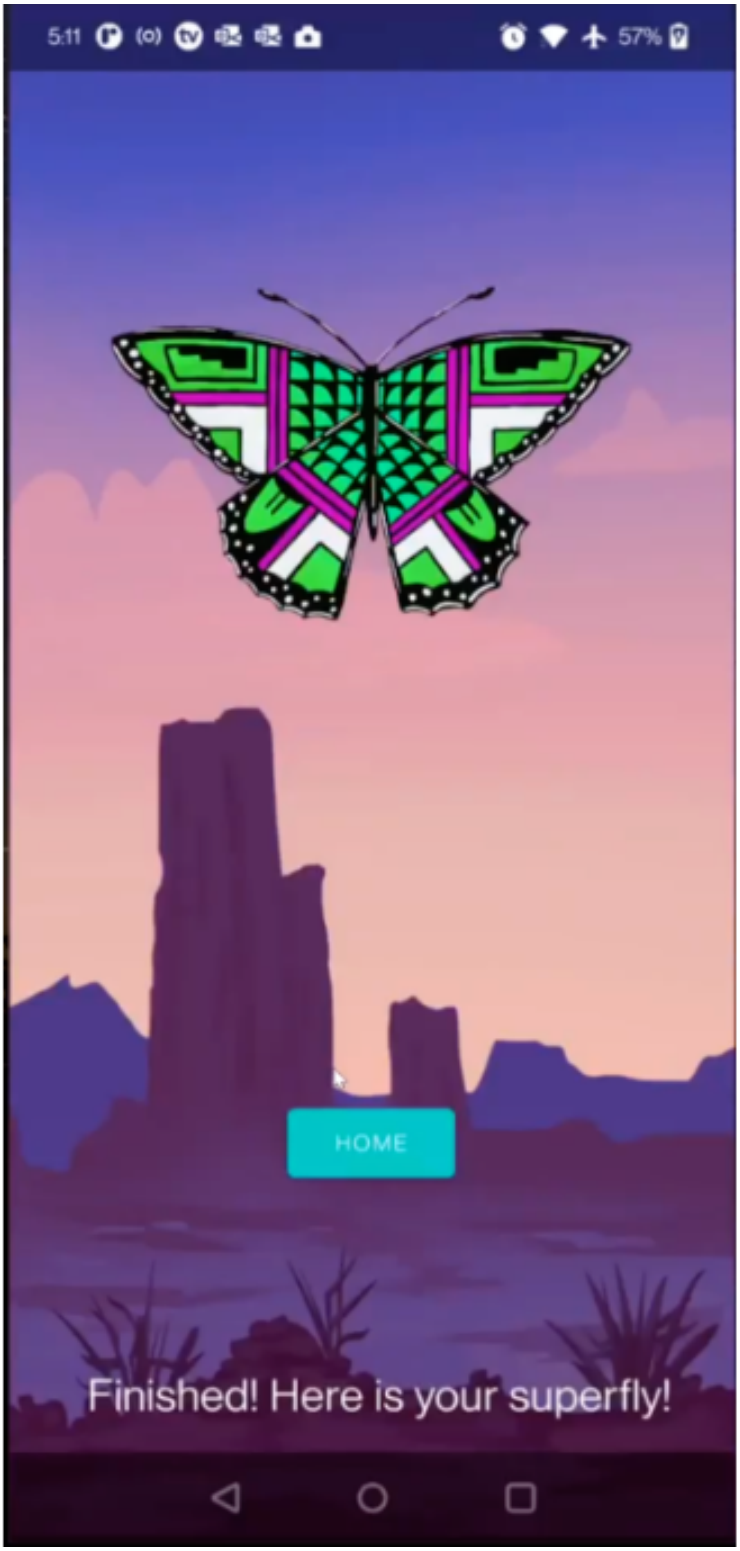
was co-designed and planned in collaboration with our community partners.

Figure 3. Users combine their butterflies to create a Superfly.



While the goal of Superfly was to promote collaboration and a sense of community, users could also capture butterflies on their own, viewing them in a virtual atrium. The virtual atrium allows users to view each of the butterflies they have caught already. Each butterfly caught had an associated, culturally centered lesson that users could view within the atrium (Figure 4).

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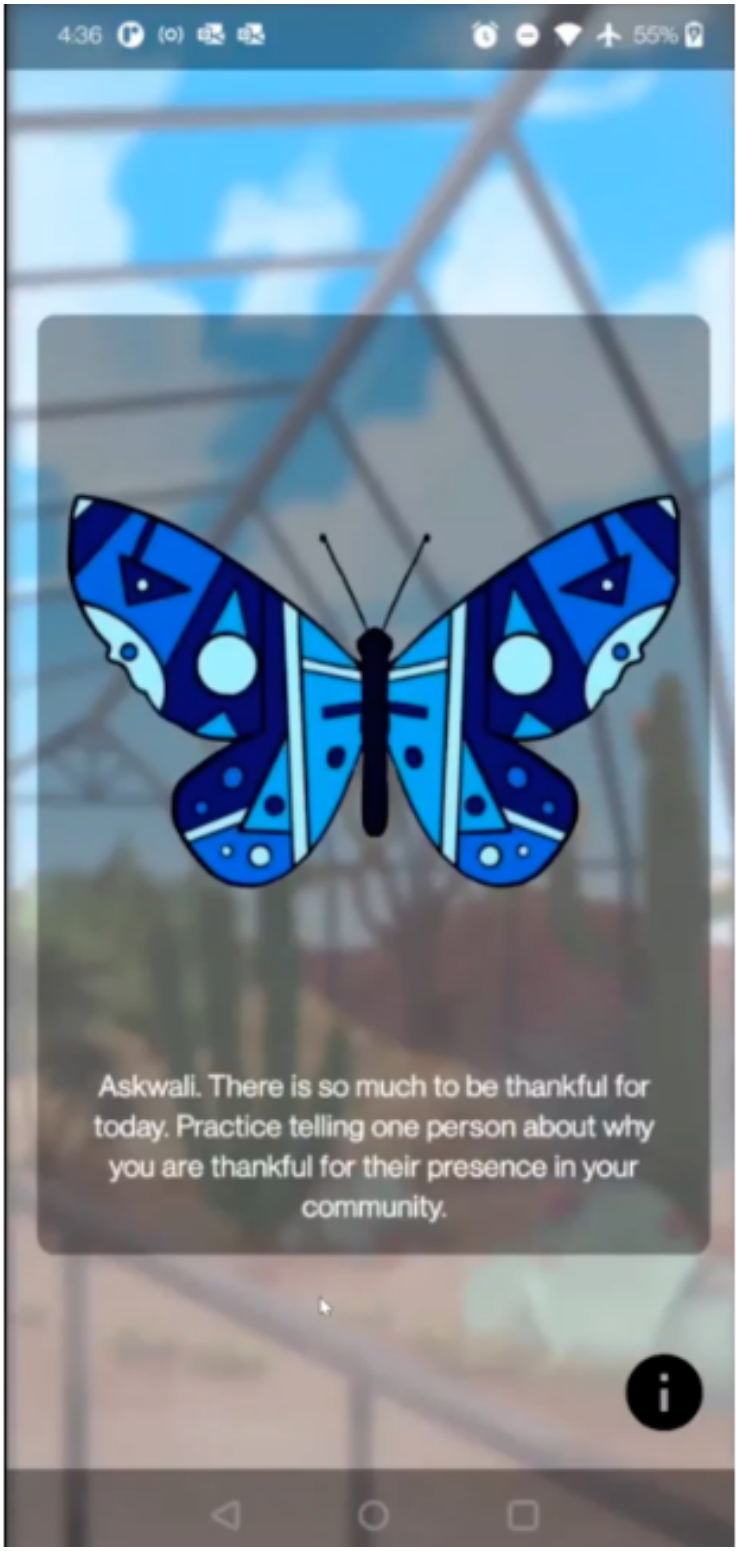
Figure 4. Lesson associated with a caught butterfly.



Adapting the Research Protocol in Alignment With PAR Practices

This work was conducted between May 2021 and August 2021, at a time when COVID-19 restrictions were omnipresent, but especially important among tribal communities. AI/AN communities were disproportionately impacted by the pandemic [39], necessitating higher precautions for holding meetings. Consequently, all user testing initially planned to be held in-person was moved online. Originally, all participants were to test ARORA on Android devices on Northern Arizona University's campus, where the research team could directly view their actions within the app. Since these studies took place over Zoom, we instead preloaded ARORA onto Android emulators running from the researcher's computers. Members of the research team screen-shared these emulators over Zoom, granting the participants remote access, such that they would be able to engage with the app using their computer mouse.

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This adaptation to the protocol required that participants engaging in this study have access not only to the internet but also to a computer.

AR-based activities, such as Superfly, were modified to no longer require cameras, instead showing the butterfly animations over a static screen. While this limited the usability testing of the AR features, offering a modified version of Superfly still allowed us to receive valuable feedback on the acceptability of the activity and areas for improvement in its design. The walking activity could not reasonably be evaluated without physical devices, so it was omitted from this study.

Maintaining a flexible protocol by following PAR practices supported our research team in establishing trust with our community partners—iteratively adapting the prototype to meet their needs and desires. By not adhering to typical research timelines or rigid requirements, this practice also supported us in establishing trust. Ultimately, the goal of this work was to develop technologies that support the needs of our community partners and responding to needs through adaptation was essential.

Participant Recruitment and Demographics

Collaborating with our community partners, we recruited 9 participants, each of whom was Hopi/Tewa. We followed a similar process for recruitment as we did for our 2019 focus groups [26]: we found participants through community messages that our CAB partners released and used snowball sampling, thereby recruiting members through word of mouth. All participants were considered "youth" if they were between the ages of 16 and 24 years. Of the 9 participants, 7 identified as having grown up in "completely rural" or "mostly rural" communities.

Focus Groups and Usability Testing

Between February and July of 2021, we held 3 focus group sessions, which were each approximately 60 minutes long, with 2-3 participants attending each session (9 participants total). These sessions focused on evaluating the usability of ARORA, also asking participants for feedback on how the app could be improved to better serve Hopi/Tewa youth. Again, while we initially planned to hold these sessions in-person, we modified our plans to hold them online due to restrictions brought on by the COVID-19 pandemic. All sessions began with the participants and researchers in 1 Zoom room. In this collective Zoom room, researchers debriefed participants in what they would be doing for the remainder of the session, obtained consent, and answered questions as needed. Participants were also asked to complete a brief background survey after joining the Zoom room, prior to testing the app.

Then, each participant was placed in a breakout room with at least 2 researchers, where they were asked to use the app. One researcher would act as a facilitator, providing the participant with instructions on what to do within the app, while the other would take notes and ask the participant questions as needed. To accommodate for focus groups being held over Zoom, 1 researcher in each breakout room ran the app from an Android emulator on their computer and shared their screens with and granted remote access to a participant through Zoom. This allowed participants to still experience the app and provide useful and important feedback on its design. We continued holding focus groups until no new themes emerged from the focus group responses [40]. Each participant was given several tasks to complete within the ARORA app. They were encouraged to complete the tasks with no guidance but could ask for help from their facilitators when needed. Our goal was to understand how easy or difficult completing each of the tasks was without assistance. The tasks participants were asked to complete are listed in Table 1.

Table . Instructions for usability testing.

Task, n	Instructions
1	Log into the app with given login credentials.
2	Complete the mood and stress survey.
3	Find the breathing learning exercise and complete it for 5 breaths.
4	Find the meditation learning exercise, select any of the available themes, and complete it for 90 seconds.
5	Find the atrium.
6	Find the blue butterfly in the atrium.
7	Read out loud the lesson associated with the blue butterfly.
8	Find the pollen points and read out loud how many points the account has.
9	Find the butterfly catching game and play it for 1 round.
10	Review how many of each color of butterflies are there in the atrium.

After testing the app, participants were asked about their experiences with and opinions toward the app. They were also asked to answer a series of open-ended questions: (1) What did you like about the app? (2) What are the things that you did not like about the app? (3) What would you change or add?

Thematic Analysis of Focus Group Transcripts

We conducted a grounded theory analysis on the transcripts from focus groups [41]. After the first focus group, the first author (SH) would apply open codes to responses to focus group

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questions and in a second pass, the first and second authors (SH and MVH) would meet to discuss and refine open codes using a consensus approach. The 2 authors then collaboratively defined axial themes that emerged to encompass each of the open codes. For the 2 subsequent focus groups, the 2 authors repeated this procedure, using a constant comparison approach to applying codes and themes to subsequent transcripts and expanding our codebook and themes for the second focus group; by the third focus group, we did not add new codes or themes. We report on the axial themes, open codes, and examples in Table 2. Emergent themes included graphics, activities and features, usability, impact, and culture.

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Table . Qualitative results from focus group sessions.

Open codes	Axial codes	Quotes
Graphics	• Hopi-specific graphics • Meaningful or visually appealing colors	• "I think it would be interesting or more valuable to highlight like the landscapes unique to the Hopi/Tewa community like the Mesa." • "[The butterfly] kind of helped establish that connection between the community and the audience, because of how it was, like, incorporated. The Native American design is there and seeing that image, it made me think of artists from within that community who use those types of designs and that style of art, so that was great." • "I really appreciated the...tie to the community as well through the background images in that they were representing the desert landscape." • "When you open an app, the visuals is the first thing that's gonna catch your eye, so the colors were really nice." • "I thought that the layout was pretty good and the colors in the app were nice."
Activities and features	• Mood and stress survey is beneficial • Want more mindfulness-focused features • Want a feature for users in crisis	• "[I liked] the little journal inputs at the beginning like the daily [survey]...I feel like that could really help you." • "I [would] put like affirmations kinds of things, like daily quotes...things that could make you think and really give you some good thoughts to start off your day because...that's always good...and just things that would help you." • "Maybe...in certain situations, like if someone is in the middle of...[a] panic attack or...something that could help with that...would be really cool." • "It was nice how you were able to put how you are feeling today and I would...like adding something to log how you feel each day so that way you or someone else can go back to how they were feeling."
Usability	• Tutorial/walkthrough for new users • Guidance for activities • Guidance on where to find specific information	• "It did take me a while to kind of familiarize myself with the kind of tabs at the bottom...But once I did familiarize myself, I believe I could find those where I'm needing to go again, easier." • "I wish that there was...more information included in some sections. I know for some areas, like the atrium portion, I wasn't sure of how to determine...what those butterflies were for and how I could use them." • "I have noticed in some previous apps they show you some features in the beginning, like kind of an intro."

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Open codes	Axial codes	Quotes
Impact	• Some youth struggle with vocalizing feelings • Having an app readily available could help youth manage stress and other negative emotions	• "I think this is really needed. I think...a lot of people my age are scared...you know...they don't want to confide or maybe talk to people about it. If they were able to do it within an app or something like that can actually help them." • "I don't like to confide in anybody, because I don't know—there's some things I can confide in people about but not all the time, so I think if an app would be a good way to help people— if its stress or if it's anxiety or anything like that it would be good because everyone is on their phone all the time. So if they have a problem and don't feel like talking about it they can just pull out their phone and go 'oh I have this app, I'm gonna use this.' It would be good help."
Culture	• Including Hopi/Tewa language • Hopi-specific, rather than a general mental health app	• "I like how you guys added 'Askwali' in there, meaning 'Thank you' in Hopi/Tewa. I thought that was really good." • "I know there's some other [mental health apps] out there and I like the idea that this app has Hopi—includes Hopi/Tewa in there. And that's what I really like about it and why it's different."

Demographics

In the background survey, participants were asked to answer basic demographic questions about themselves, specifying their gender, age, race, and tribal affiliation. Each of the 9 participants was Hopi, with 3 indicating that they had additional tribal affiliation as well. Participant ages ranged between 16 and 24 years. Additionally, we asked participants to specify the types of settings in which they grew up in: "completely rural," "mostly rural," "suburban," "mostly urban," and "completely urban." The results of the background survey indicated that the majority of participants (7 out of 9) grew up in rural areas, highlighting the importance of considering rurality in co-designing software for the Hopi/Tewa population. In addition to asking demographic questions, we also asked participants about the types of technology they had access to and the locations in which they lived. Seven of the 9 participants reported using smartphones on a daily basis, with the remaining participants using smartphones only once or twice per month. The mean average age of participants was 19.8 (SD 2.619) years; 8 of the 9 (89%) participants were female.

Results

Principal Findings

One of the most prevalent themes in our findings was a need and desire for the app to be more specific to the Hopi/Tewa community. The version of the ARORA prototype used in these focus groups was co-designed with both Hopi/Tewa and Navajo community partners and iterated on following feedback received from a focus group held in 2019. While the app was modified after the initial 2019 focus group to emphasize and reflect Hopi/Tewa culture and values, the results from this 2021 set of focus groups show that there was room for improvement in terms of its cultural responsiveness. Several participants provided specific suggestions for how to modify the app so that it would be more grounded in Hopi/Tewa culture. For example, the graphics in the app could be more Hopi-specific, with one participant stating, "I think it would be interesting or more valuable to highlight…landscapes unique to the Hopi/Tewa community like the Mesa."

Another area for improvement was usability. Several participants had difficulty finding components of the app, such as the atrium and the mindfulness exercises, at times needing help from the facilitators. Finding these components of the app also required more time from some participants, due to confusion on where they were located. One participant explained their confusion with the atrium, stating, "I wish that there was...more information included in some sections. I know for some areas, like the atrium portion, I wasn't sure of how to determine...what those butterflies were for and how I could use them." To help clarify to users how to use the app, one participant suggested that we develop an introductory tutorial, stating "I have noticed in some previous apps they show you some features in the beginning, like kind of an intro." A tutorial for new users to the app could limit the amount of time that they would need to take to familiarize themselves with its features, showing them information on what activities are available and where they can be found. While the size of this study was small, the resulting feedback was still valuable in informing the iterative design of a culturally grounded mHealth app. The goal of this study was to identify perceptions toward the prototype and areas for improvement to ensure that it effectively tied into Hopi/Tewa culture while promoting resilience.

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Quantitative Results on Perceptions of ARORA

Following testing the ARORA prototype, participants were asked a series of questions surveying their perceptions of the app, each of which they were asked to answer on a scale of 1-5, 1 meaning "highly disagree" and 5 meaning "highly agree."

The results of the survey imply neutral-to-positive reception, with all scores falling at or above the average score of 3.0, which was neutral. Additionally, we asked participants to rate the app on a scale of 1-5 (1 being "very little" and 5 being "very much") for its cultural responsiveness, social awareness motivation, mentorship motivation, competition motivation, and creation motivation. Multimedia Appendix 1 shows the average values among the responses.

Indeed, the results from these surveys suggest that the app must be adapted to have higher Hopi/Tewa cultural centeredness, reflected by the results' lowest response score. Additionally, further evaluation is necessary for determining the psychological impacts of this app.

Discussion

User Testing Results, Feedback, and Considerations for Further Development

The majority of our participants lived in a mostly rural or completely rural environment when they were growing up. This is very important to acknowledge, as rurality itself can be a critical factor in technology design—particularly as it intersects with pervasive broadband connectivity [42]. This adds a layer of complexity to the ARORA app, as it must be able to operate correctly when the internet connection is unavailable or unstable, a concern that was highlighted during these usability sessions when high network latency influenced usability. Indeed, challenges with intermittent connectivity have impacted prior mHealth work in rural spaces [24,29], presenting a barrier to telehealth. This points to a growing need in the mHealth space to develop connectivity-aware technologies that can still support individuals when internet access is limited. Reiterating reflections of Wyche et al [24] working with rural populations, mHealth technologies must be informed by community affordances.

User experiences with ARORA during intermittent connectivity and lagging reflect design theories grounded in consistent evaluations, such as Formative Situations [28]. Following this design practice, we considered the unique challenges present in using the ARORA prototype across common, lived experiences of stakeholders to understand areas for improvement. This practice is beneficial for the mHealth space, as it supports researchers and practitioners in receiving early feedback for continuous and iterative development with the goal of designing technology that meets the needs of their target audience.

Several participants emphasized a desire for the app to be more grounded in Hopi/Tewa culture. The need for ARORA to tie more closely to Hopi/Tewa lifeways is also underscored by the survey results shown in Figure 5. For instance, the average score for "This app used images that made me feel connected to my Hopi/Tewa culture" was 3.55, indicating predominantly neutral responses. This reflects ongoing calls in the human-computer interaction space to increase cultural and identity relevance in mHealth technologies [20]. At the time of writing, we have entered a formal partnership with Hopi/Tewa Tribe Behavioral Health Services to further refine the ARORA app and to address feedback from focus group sessions described in this paper. Reviewing the results from this study, we find that ARORA can be improved by increased Hopi-specific aesthetics and text-based content, being more specifically centered around a single tribal community. Future usability testing will benefit from the app being installed on physical devices (eg, testing on smartphones, rather than emulators), with in-person collaboration to fully test all activities within the app, such as the mindful walking activity.

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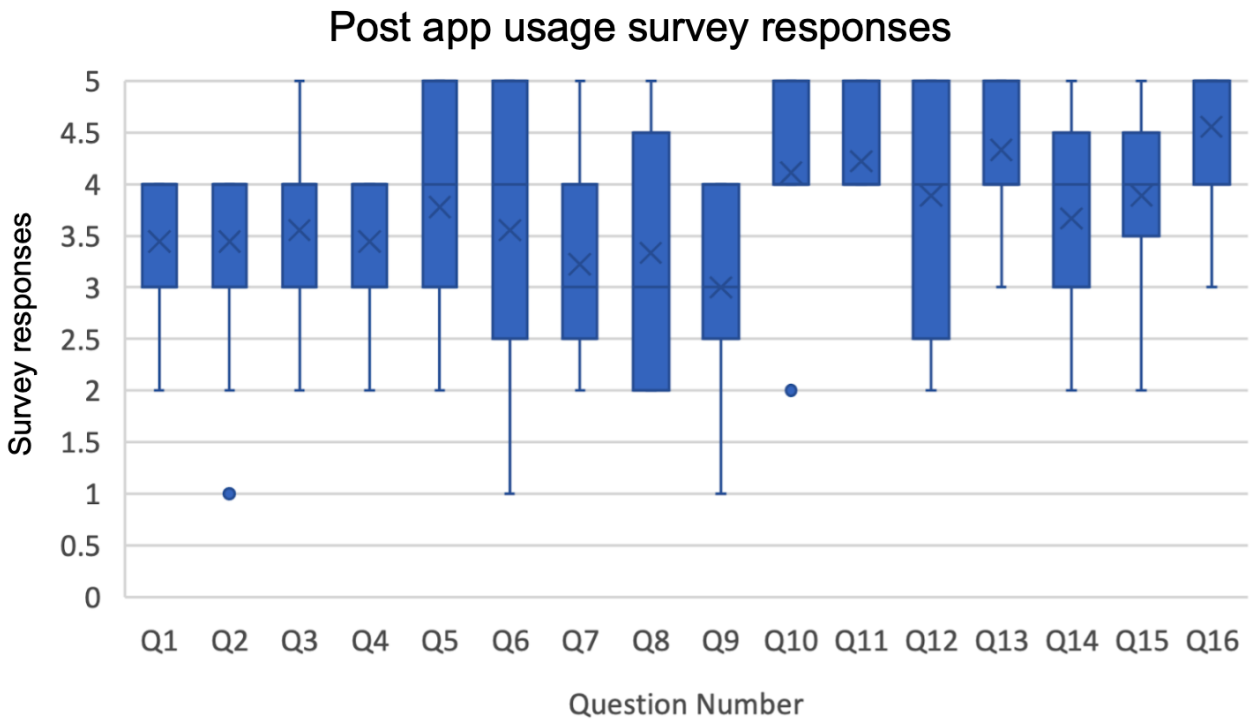
Figure 5. Survey responses.



While feedback toward ARORA's concept and purpose was valuable for its iterative design, the results of this study do not depict its impacts on mental health. The survey questions presented in Table 3 dominantly evaluated cultural alignment, with some centering on mindfulness concepts. Future work should involve more rigorous evaluation of mindfulness and mental health concepts through randomized clinical trials. Additionally, evaluating the mental health effects of this app will require a larger participant pool, as this study involved only 9 members of the Hopi/Tewa community.

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Table . Survey responses, with mean scores and standard deviation.

Survey item	Scores, mean (SD)
If given the chance, I want to use this app again.	4.55 (0.726)
Being able to participate in more individual-based competitions and activities would encourage me to use the app more often.	4.33 (0.707)
Being able to share my activities with peers would encourage me to use the app more often.	4.22 (0.972)
Learning about how my peers use this app would encourage me to use the app more often.	4.11 (0.928)
Being able to communicate and receive feedback about my activities from trusted mentors in my community would encourage me to use the app more often.	3.88 (1.270)
I am likely to recommend this app to others like me.	3.88 (0.928)
This app supports Hopi/Tewa ways of being a strong person who can deal with tough times.	3.77 (1.093)
Being able to contribute something of my own creation (eg, videos, photos, sound clips, and artwork) to the app experience would encourage me to use the app more often.	3.66 (1.0)
This app used images that made me feel connected to my Hopi/Tewa culture.	3.55 (1.424)
This app increases my knowledge of how to practice being aware of my physical surroundings.	3.55 (0.882)
Using this app is likely to increase my awareness of my surroundings.	3.44 (1.130)
Using this app is likely to increase my awareness of my feelings.	3.44 (1.130)
This app increases my knowledge of how to practice being aware of my feelings.	3.44 (0.726)
This app supported spiritual mindfulness to Hopi/Tewa ways of being.	3.33 (1.225)
This app used language/text/terms that made me feel connected to my Hopi/Tewa culture.	3.22 (0.972)
As a Hopi/Tewa community member, this app reflected me and my culture.	3.0 (1.0)

Adapting Research Protocols With Hard-to-Reach Populations to Accommodate for Remote Research

Future work in mHealth, especially work done with rural communities, must consider events that hinder in-person or synchronous evaluations, conceptualizing potential ways to digitize practices in support of limited affordances. Several factors can influence the ability to conduct research with remote communities, from infrastructural barriers to local government policies to geographic limitations. However, developing adaptable protocols can support future work in continuing progress with their partnered communities, in spite of limitations beyond their control. In this work, we were required to remove certain activities from the evaluation protocol that simply could not be adapted with the affordances available at that time. This practice of adaptation is useful for other hard-to-reach populations, such as stakeholders with lowered immune systems. Future research in mHealth can allow for this flexibility by adopting PAR frameworks and practices, emphasizing modifications to planned work as necessary.

Limitations

Due to the nature of our usability sessions occurring during the COVID-19 pandemic, we experienced limitations in how testing of the app was carried out. We needed to shift away from individual and group meetings to meet remotely so that we could prioritize the health of participants and researchers. This meant that we had participants use the app via an emulator, which was run on the researcher's computers so that participants would have remote screen access. Participants predominantly joined the Zoom meeting from Hopi, where internet connectivity tends to have a higher latency. Moreover, the emulator itself added

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delays in processing time. As a result, the app tended to lag by a few seconds whenever screens were swiped or buttons were clicked. This made completing certain tasks within the app, such as the meditation activity, difficult for participants.

This work is an example of challenges present when working with rural populations. Although evaluating digital artifacts in person is ideal for understanding user experiences and perspectives, it is not always feasible. The ability to hold in-person meetings and testing sessions hinges on geographical, infrastructural, and bureaucratic affordances. This work took place during the COVID-19 pandemic, which AI/AN communities were disproportionately affected by. Consequently, many tribal populations, including Hopi/Tewa, restricted group gatherings, especially including those external from their communities. There was still a need and interest for our work to continue, reflected by conversations with our community partners, which required that we adapt our protocol (including limiting the testing of movement-based activities).

The sample size may be considered a limitation of our study. It is important to consider that sample sizes are not unusual in qualitative research, and that of Hopi/Tewa's population is small (with approximately 7791 people living on Hopi, accounting for half of the tribe's membership). Additionally, our findings highlighted themes that emerged across focus groups. While this work could have benefitted from a larger sample size with a broader range of Hopi/Tewa participants (specifically regarding gender identity), the findings are still valuable in informing the ongoing and iterative design of an mHealth app. This process follows the PAR practice of Formative Situations, as defined by Robinson et al [28], which supports evaluating artifacts across contexts that stakeholders may experience (such as intermittent connectivity).

Conclusions

In this work, we conducted user studies on the initial prototype of a mHealth smartphone app, ARORA, designed for supporting emotional resilience among Hopi/Tewa youth. The goal of this study was to gather feedback from stakeholders as part of a larger, iterative design process, aligning with the principles of PAR. We faced challenges conducting this work due to the COVID-19 pandemic. Due to the flexibility of our protocol, we adapted our user study plans to accommodate remote evaluations. As a result, we developed a better understanding of important infrastructural limitations, such as intermittent internet connectivity, to inform our prototype's iterative design. Additionally, we received qualitative feedback on this initial prototype through focus groups, after reaching thematic saturation. The findings from this work highlight a need for increased cultural responsiveness within ARORA in further iterations of its design. Participants noted value in the existing Hopi/Tewa language incorporated in the app but concluded that Hopi-inspired aesthetics and practices could further support it in being culturally relevant.

Acknowledgments

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Data Availability

Data produced from work with Indigenous populations have historically been misused, causing harm to the communities. Therefore, we design our work such that datasets are not automatically produced or shared. The Hopi Tribe has also elected not to share data.

Authors' Contributions

SH contributed to conceptualization, project administration, software, investigation, data curation, formal analysis, original draft writing, and draft reviewing and editing. MVH, AA, MA, and AFC contributed to conceptualization, funding acquisition, methodology, project administration, supervision, draft reviewing and editing, and investigation. DHJ contributed to conceptualization, funding acquisition, methodology, project administration, and supervision.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Mindfulness survey responses.
[DOCX File, 14 KB - formative_v10i1e77898_app1.docx]

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Abbreviations

AI/AN: American Indian/Alaska Native
AR: augmented reality
ARORA: Amplifying Resilience Over Restricted Internet Access
CAB: community advisory board
mHealth: mobile health
PAR: participatory action research

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Co-Designing a Digital Platform to Support a Culturally Adapted Family Intervention (CaFI:Digital) for Psychosis Among People of Sub-Saharan African and Caribbean Descent: Agile Co-Design Approach

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Abstract

Background: People of sub-Saharan African and Caribbean descent are significantly more likely to be diagnosed with psychotic disorders than other ethnic groups in the United Kingdom. The National Institute for Health and Care Excellence in the United Kingdom recommends family therapy as a clinically effective treatment for the management of psychosis. The National Institute for Health and Care Excellence also recommends that family interventions should be culturally informed to meet the needs of an increasingly ethnically diverse population. People from minoritized backgrounds are rarely offered family therapy; however, the rise in digital mental health worldwide offers unique opportunities to support culturally informed approaches at scale and at a low cost.

Objective: The overarching aim of culturally adapted family intervention (CaFI):Digital was to help address inequalities in the provision of mental health care for people of sub-Saharan African and Caribbean descent, including those of Mixed heritage. A digital platform, CaFI:Digital, was built to support delivery of a CaFI. The purpose of developing CaFI:Digital was to provide an accessible, user-friendly, and engaging website for service users, their families, and therapists as an alternative or adjunct to in-person therapy.

Methods: We used an iterative Agile co-design approach to develop a user-friendly and inclusive website. Co-design workshops (n=2), semistructured interviews (n=2), and collaborative research team meetings (n=3) were used to capture and prioritize end-user feedback on the clinician- and service-user–facing components of the platform. The software was developed using Agile sprints, with each sprint lasting 3 weeks, allowing feedback to be integrated rapidly and revised software prototypes to be shared with end users for review, revision, and approval.

Results: Key software requirements, such as accessibility and diverse content, were identified in the co-design activities and were implemented to maximize accessibility and usability of the website. Following software development, we successfully beta-tested the software with our target end user population of service users and therapists to ensure it was defect-free and ready for use.

Conclusions: A digital platform to support delivery of CaFI for psychosis was rapidly developed through a series of co-design activities. To our knowledge, this is the first bespoke digital therapy platform that has been co-designed with and for people of sub-Saharan African and Caribbean descent who experience psychosis. This is important given the disproportionate rates of diagnosis and lack of access to psychological therapies experienced by this population.

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KEYWORDS

health inequalities; digital mental health; psychosis; mental illness; accessibility; co-design methods; family therapy; culturally adapted

Introduction

In the United Kingdom, people of sub-Saharan African and Caribbean descent, including those of Mixed heritage, have significantly elevated risk of diagnosis with schizophrenia and related psychoses compared with White British peers [1,2]. Black and Mixed heritage service users attribute this increased risk of psychosis, at least partly, to the buildup of stressors directly linked to ethnic minority status in general and racism in particular [1]. Disparities in diagnostic rates are compounded by suboptimal care and negative experiences of services, which are characterized by high rates of involuntary hospitalization and inferior access to evidence-based treatments [1,3]. There is strong evidence for the cost- and clinical-effectiveness of psychological or "talking" therapies such as family intervention for psychosis [4,5]. However, despite National Institute for Health and Care Excellence (NICE) recommendations, such treatments are rarely offered to racialized populations. Neither are they culturally informed [6,7]. Moreover, while there are studies highlighting ethnically based inequalities in access to psychological therapies, we are not aware of any robustly evaluated digital psychological interventions specifically designed for Black populations diagnosed with schizophrenia or psychosis. This population is therefore underserved both digitally and in access to evidence-based care.

A culturally adapted family intervention (CaFI) was co-designed with people of sub-Saharan African and Caribbean descent diagnosed with schizophrenia and associated psychoses and other key stakeholders [8]. The CaFI trial was designed to provide in-person culturally appropriate group psychological therapy for people who have experienced longstanding disparities in mental health care and outcomes [9,10], including rarely being offered talking treatments [9,11]. Online therapies may increase engagement and uptake among a patient population with a history of fear and mistrust of engaging with statutory mental health services [12]. In the United Kingdom, NICE recommends culturally sensitive approaches for the treatment of psychosis, as well as family intervention therapy [13]. Funding from the National Institute of Health and Social Care Research in the United Kingdom [14] supported the original development of CaFI [15] and subsequently funded a randomized controlled trial, the "CaFI trial," to investigate the effect on relapse of CaFI compared to usual care among people of sub-Saharan African and Caribbean descent diagnosed with psychosis in the United Kingdom [16].

The CaFI trial was originally planned to commence in April 2020 but was postponed due to the COVID-19 pandemic. As evidence emerged of higher rates of COVID-19 infections and mortality among Caribbean, African, and other ethnic minority populations in the United Kingdom [17], it became apparent that delivering in-person therapy was neither feasible nor ethical. In our work to develop CaFI, community members cited examples of Black people's exploitation in research, most notably the use of Henrietta Lacks' cells [18] and the Tuskegee syphilis study [19]. Thus, the development of a digital alternative was explored with former service users and community members and determined to be a potentially viable approach to improving the likelihood of engagement and participation in the study [20].

CaFI:Digital (a subcomponent of the CaFI trial: ISRCTN12622538) was created to support the delivery of online group therapy, enabling the study to continue while face-to-face consultations were not possible. The purpose of developing CaFI:Digital was to provide an accessible, user-friendly, and engaging website for service users, their families, and therapists as an alternative or adjunct to in-person therapy. CaFI:Digital is a web-based platform that provides access to a specially designed, cocreated therapy manual and resources to support therapeutic engagement. It was anticipated that the co-design of CaFI:Digital would ensure the platform was useful for service users, even after in-person therapy could resume. The CaFI trial was underpinned by the ethical imperative to improve the care of a population that has been underserved. To address trust and power issues, CaFI:Digital adopted a co-design approach that placed service users and their carers at the heart of the digital development process. The aim of this preliminary paper is to outline the specific co-design steps and work undertaken with key partners and stakeholders to develop CaFI:Digital. This includes strategies to ensure its usability and acceptability to end users. This paper will not outline methods or results of the CaFI trial, as this is still ongoing.

Methods

Ethical Considerations

Ethical approval was obtained for the CaFI trial from the Health Research Authority in the United Kingdom (19/NW/0385; IRAS ID 254857, approved July 24, 2019). Participants were provided with an information sheet and consent form ahead of the workshops to ensure informed consent was obtained. Participants were reimbursed for their time during workshops in line with National Institute for Health Research rates. Identifiable information was removed from workshop feedback to ensure the data was anonymized, in line with privacy and confidentiality guidance.

Study Setting, Participants, Recruitment, and Sample

Participants were recruited through the participating National Health Service (NHS) community mental health teams and collaborating third-sector organizations. Participants were approached by email via established networks. The sampling method was purposive-opportunistic, and all participants who responded to email approaches were invited to attend the workshops. Service user and carer respondents were included if they were individuals of sub-Saharan African and Caribbean descent and either had lived experience of psychosis or were a

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carer or family member of an individual who had experienced psychosis. Therapist respondents were included if they were trained health care professionals who had clinical experience of working with people with psychosis. The mixed stakeholder group comprised a combination of people with lived experience of psychosis and health care professionals. Demographic data of participants in each research activity were not recorded consistently; this is a noted limitation of this project. This was a patient and public involvement and engagement activity rather than a research participant activity, with feedback collected from the groups and iteratively updated in the designs. The website was co-designed using an iterative, user-centered process over a 6-month period. Three workshops were held consisting of (1) service users and carers (n=7), (2) therapists (n=4), and (3) a mixed stakeholder workshop. Two individual semistructured interviews were also conducted separately with therapists during the design process. Research team meetings (n=3) were also held to capture and prioritize end-user feedback on the clinician- and service-user–facing components of the website. To ensure the team had time to engage with all participants in the virtual workshops, the maximum number for each session was set to 8 members. Staff time for the therapist workshops was difficult to obtain; therefore, the therapist group workshop was supplemented with additional individual interviews. The mixed stakeholder group was designed to accommodate participants who were unable (because of time or other resource constraints) to attend the single stakeholder groups. The sample size was guided by the concept of "information power" [21], which emphasizes the quality and comprehensiveness of data over the quantity of participants. Rather than focusing solely on data saturation, researchers are encouraged to aim for data sufficiency, particularly when studies have narrow aims, allowing for smaller yet richer samples [22].

Workshops were conducted using Microsoft Teams and lasted between 60 and 90 minutes. The workshops followed a similar structure, starting with an overview of the project followed by a discussion of key features, requirements, and priorities for CaFI:Digital. Design prototypes were presented at each workshop to allow participants to see what the website would look like and enable the participants to provide feedback on each iteration of the designs. The prototype user interface was designed in Adobe XD [23], and interactivity was added using Marvel [24]. Usability testing was conducted using Maze [25].

Co-Design and Agile Approaches

A co-design approach was combined with Agile software methodologies [26] to support collaboration between people with lived experience, software developers, researchers, and designers. The co-design and user research approach followed the UK Government Service Design Guidelines across the 3 setup stages: Discovery, Alpha, and Beta [27]. Workshops were facilitated by the project manager, the project technical team lead, and a UX designer. In the Discovery phase workshop, service users and carers (n=7) were asked to comment on key requirements and features for the website (see Table 1).

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Table . Workshop 1 input design changes—service user and carer workshop (Discovery phase).

Feedback item	Design/software modification	Project solution
(1) Accessibility		
Ensure navigation of the site is as simple and clear as possible for service users.	Navigation of the site simplified and updated.	Therapists trained by workshop facilitators to email or text a simple web link to service users to navigate to the required webpage.
Ensure the website works well for people with visual impairments. The option to make the text larger through the browser is really helpful, as many people have visual impairments.	Website reviewed to be Web Content Accessibility Guidelines 2.1 [18] compliant. Larger-than-usual font size used. Color contrast used to ensure readability.	Training by workshop facilitators on how to increase font size through the browser provided to the research team and therapists.
Provide a "Help Page" to guide users on how to engage with the content and materials.	Development of a "Help Page"	A "Help Page" included on the website to guide users on how to engage with the content and materials.
Some service users will not have access to technology to view CaFI[a]:Digital.	No action required.	Tablets purchased and provided to service users and families where needed. The study purchased mobile data plans to ensure the website could be accessed.
Some service users will not have the skills to engage with a website.	An emphasis on simplicity of design and implementation was maintained throughout.	Volunteer digital navigators at the lead NHS[b] trust joined the project team to support service users with basic literacy skills, enabling them to access and use the website with support if they wished to do so. Volunteer digital navigators receive appropriate NHS training to support service users in developing and using digital skills.
The therapist would need to explain upfront what the website does.	No action required.	Training provided to therapists to ensure they pass on key information to service users before the website is recommended for use.
(2) Diverse content		
There should be more diversity in the images of people displayed across the website; specifically, a greater range of skin tones should be included.	No action required.	The images were updated to include a broader range of people representing diverse ethnic backgrounds (see Figure 1).
(3) Positive feedback		
Participants felt the website was very exciting and noted it was the first time such a resource has been developed for this population.	No action required.	No action required.
Participants felt the site is visually appealing.	No action required.	No action required.
Participants felt the site looked very simple to use.	No action required.	No action required.

[a]CaFI: culturally adapted family intervention.

[b]NHS: National Health Service.

The Alpha phase involved 3 stages; after each stage, the prototype was updated to incorporate feedback from the research activity:

1. A workshop with therapists (n=4) to provide feedback (see Table 2) on the website prototypes developed from the service user and carer feedback.
2. Individual discussions with 2 different therapists from those in the workshops who provided feedback during the design process.
3. A mixed stakeholder workshop consisting of service users, carers, and therapists who participated in stages 1 and 2, as well as new participants, was conducted for feedback on the finalized prototype (Table 3).

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Table . Workshop 2 design changes—therapist feedback (Alpha phase).

Feedback item	Design/software modification	Project solution
(1) Accessibility		
The navigation of the site must be very simple for service users and for therapists.	A simple link to navigate to relevant webpages was developed. This removed the need for service users to navigate large sections of the website, as the link directed them to the specific content designed for them at that stage in the therapeutic process.	Service users received the individual links by email. Therapists were provided with a "Copy Link" button to enable them to paste the link into an email.
Embed training in the website for therapists.	Training video created for therapists. Development of a "Help Page."	"Help Page" and training video included on the website.
Some service users will not have access to digital devices or data plans to access CaFI[a]:Digital.	No action required.	Tablets purchased and provided to service users where needed. The study purchased mobile data plans to ensure the website could be accessed.
Service users will also require printed materials to ensure equity of access to those who prefer to work with hard-copy materials.	No action required.	Printed materials were prepared for use with all service users.
(2) Positive feedback		
Participants felt the site looked very good.	No action required.	No action required.

[a]CaFI: culturally adapted family intervention.

Table . Workshop 3 mixed stakeholder feedback—Alpha phase (Consensus).

Feedback item	Design/software modification	Project solution
(1) Positive feedback		
Participants felt the site was visually appealing.	No action required.	No action required.
Participants felt the site looked very easy to use for everyone.	No action required.	No action required.
Participants felt the site looked very good.	No action required.	No action required.
(2) Accessibility		
Queries about whether the website worked across different kinds of devices (tablets, mobile, desktop).	Confirmed that the website worked across multiple devices.	No action required.

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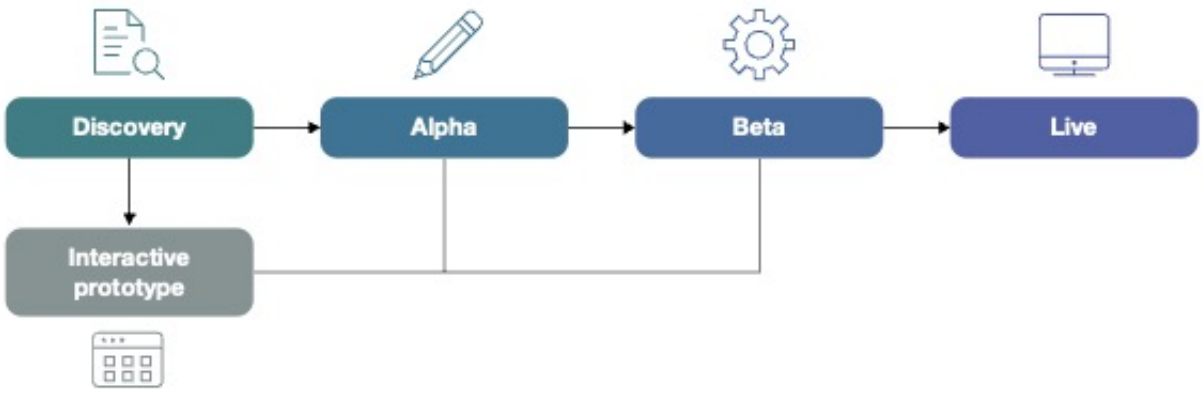
Figure 1. Four images of people from the original prototype (left), and four updated images (right). The updated images included people from North African communities, incorporating a variety of skin tones, as well as individuals wearing culturally significant clothing, such as hijabs.

The beta-test phase involved usability testing with 9 participants (including service users, carers, therapists, researchers, and software team staff) to ensure the final website, co-designed through the Discovery and Alpha phases, was defect-free and ready for use. The beta-test phase was completed by sending email requests to service users from the NHS and voluntary sectors and therapists with details of exercises to complete in their own time (for details of the tasks, see Multimedia Appendix 1). The tasks were designed to provide feedback to the team on the real-world usability and accessibility of the platform. Each task was designed to last roughly 1 hour. Figure 2 shows the development stages of the prototype.

Figure 2. Flowchart showing the development stages of the interactive prototype.



Accessibility

The website prototypes shown in the workshops had been designed and tested to be Web Content Accessibility Guidelines 2.1 compliant [28] as a baseline approach to accessibility. An accessibility discussion was included in the focus group to identify and review the specific accessibility needs participants might experience when using the website. Participants were specifically asked whether they anticipated encountering any barriers to accessing or using the website and which devices they would find most useful for accessing the website. The focus of accessibility discussions in the workshops was to identify specific additional accessibility needs that may have been particularly relevant for this target population.

MoSCoW Prioritization

Aligned with Agile approaches [26], we adopted the MoSCoW (Must have, Should have, Could have, Won't have) prioritization system [29] to triage requirements. The MoSCoW approach is widely used in software development to determine the most important features and deliverables across mixed stakeholder groups. In the MoSCoW approach, design features of the website were ranked as "must have," "should have," "could have," and "won't have." Features that were ranked as "must have" were considered essential by stakeholders; "should have" features were deemed important but would not affect the functionality of the website if they were not included; "could have" features were not necessarily related to the key aims of CaFI:Digital but were seen as additional desirable features; and features classified

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as “won’t have” were either not priorities for stakeholders or not feasible to deliver within the scope of this study. Workshop facilitators supported discussion when different priorities were identified, aiming to arrive at a consensus decision. Data from the workshops were then analyzed by the project research associate, project technical team lead, and UX designer. Notes were taken during the workshops by the project research associate. Following the workshops, the notes were discussed in detail by the project team and developed into itemized requirements lists for prioritization and implementation in the software. Similar to our approach taken in other co-design projects [30], the technical team analyzed the workshop notes, identifying common requirements and themes in the data. They grouped key themes from the notes after each workshop and identified their technical feasibility. Key requirements were then circulated to the wider research team for review. The technical team and research team then met to review and discuss the workshop insights collectively. The agreed key requirements were then prioritized for technical implementation by the software team. Where decisions were outstanding after the workshops, the research team and technical teams made the final decisions, guided by the necessity to deliver the project on time and within budget.

Tracking Usage and Engagement Metrics

Usage and engagement analytics were embedded within the platform following the AMUsED (Analyzing and Measuring Usage and Engagement Data) framework for digital health interventions [31]. The main goal was to track analytics within the platform that could help in understanding which elements of content were most visited by participants.

Results

The co-design workshops generated user needs-led software design requirements and modifications to prototypes that were demonstrated by the project UX designer. A summary of requirements and changes is included in Tables 1-3.

Workshop Feedback

Feedback in the service user and carer workshops (Table 1) focused on the need to ensure that the website was easy to use and simple to navigate. An emphasis was placed on accessibility: making the font size large to support people with visual impairments, making the text easy to read, and providing adequate support and training for people unfamiliar with digital technologies. Diversity in the images portrayed on the website was also requested, particularly in terms of diversity of skin tones depicted.

The main themes from the first workshop with service users and carers (Table 1) related to (1) the accessibility of the website in terms of navigation, disability, digital literacy, and lack of hardware; (2) the content of the website being diverse and representative of people of sub-Saharan African and Caribbean descent; and (3) positive feedback in terms of ease of use of the website and the look and feel of the content. It is important to note that discussions relating to accessibility also raised the possibility of providing audio versions of all materials; however, this was not supported in this project due to time and cost limitations. Each of the feedback items was agreed by a majority within the workshop group as a need or priority for the software.

The main themes from the second workshop with therapists (Table 2) related to (1) the accessibility of the website in terms of navigation, training therapists to use the content, lack of hardware, and a preference from some service users to work with physical materials and (2) the website being visually appealing to therapists.

The main themes from the mixed stakeholder workshop related to (1) the website being visually appealing and (2) accessibility of the website across different devices (ie, phones and laptops).

Feedback in the service user and carer workshops (Table 1) focused on the need to ensure that the website was easy to use and simple to navigate. An emphasis was placed on accessibility: making the font size large to support people with visual impairments, making the text easy to read, and providing adequate support and training for people unfamiliar with digital technologies. Diversity in the images portrayed on the website was also requested, particularly in terms of diversity of skin tones depicted.

Feedback in the therapist workshops included recommendations to prioritize simplicity of design; ensure ease of site navigation; embed training within the site; and ensure supplementary printed materials were provided to participants. The service user and carer workshop identified the positives of using digital technology to supplement therapy delivery, including reporting how digital technology “offered a way to engage with the world” even when people felt very unwell. Poor accessibility of some digital platforms was raised as a concern by service user participants in the workshops, several of whom mentioned the need to ensure the website worked well for those with visual impairments.

Analyzing and Prioritizing Workshop Feedback

Requirements from the workshops were then actioned by the software team or wider research team, as appropriate. The aim was to implement as many requirements as possible within the time and budget available. A small number of items were deemed “out of scope” because of the time and cost implications of implementation, detailed in Tables 1-3.

Digital Inequities

Participants across all workshops expressed concern about people who had limited or no access to digital technology and/or had poor digital literacy skills, stressing the need for equity in the delivery of digital solutions and therapeutic interventions more widely.

Test Results

After all the changes from the co-design workshops had been addressed, as described in Tables 1-3, 9 volunteers were asked to test the website on their own devices. The purpose of this phase was to identify any critical or major technical defects with the website that needed to be resolved. Volunteers represented (1) service users and families, (2) therapists, and (3) networks of the research team, including people with therapeutic, clinical, and/or digital backgrounds. A major

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problem was reported on a specific version of the iPhone, which blocked users from logging in. This was resolved by the software team, and the website was retested on this iPhone version. No other critical or major defects were reported by beta testers. Positive feedback on the beta testing is reported in the table below.

Accessibility-Related Changes

Accessibility was identified as a key area of focus throughout the co-design and development work packages. Additional accessibility needs were identified through the workshops. In the co-design workshops, visual impairment was identified as a common problem among the target population. To respond to this, a larger-than-usual font size was used as the default, and training was included with the trial rollout to advise how to increase the font of the website on common web browsers. Color contrast was also assessed to ensure the website worked well for people with visual impairments, a point raised by service users in Workshop 1 and by the wider research team in team meetings.

Discussion

Principal Results

To our knowledge, this is one of few studies to co-design a culturally informed digital mental health intervention to address the disparities in psychosis care experienced by people of sub-Saharan African and Caribbean descent. Another example of this is from the Care Pathways therapeutic intervention in America, which, like CaFI:Digital, was co-designed with Black American women and mental health professionals [32]. Unlike CaFI:Digital, the intervention in America was a mindfulness-based application to support anxiety and depression [32]. The CaFI:Digital co-design activities ensured the priorities of the end users of the platform are met. The target population for the CaFI trial has historically been underserved digitally through lack of provision of digital mental health tools as well as in terms of access to evidence-based psychological interventions. CaFI:Digital is an attempt to redress this imbalance. The CaFI:Digital intervention will be evaluated as part of the process evaluation of the randomized controlled trial. Metrics that include login frequency, duration, module completion, engagement with materials, accessibility, and user-friendliness will be used to evaluate usage and engagement.

The CaFI trial offered an opportunity to develop and evaluate a digital mental health intervention that was co-designed. Digitization also provides an opportunity to engage family members in therapy who may live far away from each other. This is particularly relevant for the CaFI trial target population, many of whom have family members located in different locations around the world. Moreover, unlike face-to-face interventions, the CaFI:Digital platform can be readily adapted and scaled for worldwide delivery. This aligns with national and international policy and practice to address ethnically based inequalities, aligning with both NHS priorities in the United Kingdom [33] and global approaches to enhancing delivery of health care using digital tools [34].

The findings of this study are consistent with recent policy shifts in the United Kingdom, notably the NHS Long Term Plan (2019) and NHS England's Inclusive Digital Healthcare Framework (2023), which advocate for the increased use of digital tools to enhance accessibility and equity in health care delivery [35,36]. Furthermore, CaFI:Digital aligns with NHS inclusive research practice foregrounding cultural competence, stakeholder engagement, and the reduction in health inequalities [37]. The co-design approach used in the platform's development reflects the NHS commitment to involving diverse, underrepresented communities in research and developing interventions tailored to meet the needs of Black, Mixed heritage, and other racially minoritized populations.

The combination of co-design and Agile software approaches used for CaFI:Digital enabled the software team to identify and respond to requirements and refinements identified by service users, their families and carers, and the therapists, despite the constraints on face-to-face meetings during the COVID-19 pandemic. The use of the MoSCoW prioritization system supported the rapid development cycle required to respond to the pandemic and stakeholder needs. This was particularly helpful when time-consuming or resource-intensive recommendations were identified. A key concern for participants during the development phase of the website was ensuring the website was simple to use and accessible to all, and dedicated workstreams were developed to address specific accessibility concerns raised. The beta test ensured that the software was defect-free and ready to use in the live trial. Inevitably, more suggestions were made at the co-design workshops than there was time or budget to implement. Future versions of the software could seek to address these recommendations (eg, by providing audio versions of all the website materials).

At the time of writing, the CaFI:Digital is being used in a live trial, so it is not possible to report trial outcomes or to present analyzed data on usage and engagement. We are therefore unable to comment on real-world impact and effectiveness. Another limitation is that not all suggested features, such as providing audio versions of all materials, were included because of resource constraints. Finally, although the platform has been co-designed to meet accessibility needs in terms of simplicity, conveying information within the CaFI:Digital platform can also depend on the competency of the therapist. The contribution of the CaFI trial to evidence-based practice will be evaluated as part of the ongoing trial.

The co-design and development phases have sought to make the website as usable and accessible as possible by working with service users, their families, and therapists throughout the co-design process. CaFI:Digital provides access to psychological therapies for people in underrepresented populations. Analysis from the CaFI trial using the engagement analytics embedded within the website combined with qualitative research on user experiences of the platform will enrich our understanding of how participants experienced the CaFI:Digital platform during the trial. Evaluating online group therapy interventions with underserved populations will enhance our understanding of how technology enhances care or perpetuates inequalities for already underserved and "seldom heard" populations.

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The CaFI:Digital platform presents unique opportunities to respond to NICE recommended policy guidelines in the United Kingdom [13] by enabling remotely delivered, culturally adapted family therapy. Policy recommendations stemming from this research should prioritize the integration of digital health solutions within national and international health care frameworks, particularly in relation to ethnic minority groups who experience disproportionately high rates of serious mental illnesses such as schizophrenia and related psychoses and systemic health care exclusion.

Conclusions

CaFI:Digital, an evidence-based digital therapy platform, aspires to be at the forefront of efforts to address the gap in access to mental health care for UK Black and other minoritized communities, working toward conforming to the NICE evidence standards framework for health technologies. There is potential for the platform to be rolled out internationally for people of sub-Saharan and Caribbean descent, at scale and at a competitive cost, to provide access to treatment to historically excluded and underserved groups. As with all digital mental health interventions, the potential for CaFI:Digital to widen inequalities through "digital exclusion" (by further restricting access to treatment only to people who have capabilities to use digital tools) must also be considered. It is therefore important to situate CaFI:Digital within a landscape of options for the target population rather than to promote it as a single solution that will be relevant for everyone.

However, CaFI:Digital also has the potential to address longstanding digital inequalities, aligned with 2023 NHS England guidance [35]. The NHS England guidance outlines ways to make digital health care more accessible by maximizing the relatability of the technologies, conducting mixed methods research in the digital space, and actioning user feedback, many of which have been addressed in the development of CaFI:Digital. Moreover, for a population who often have family members located internationally, the remote therapeutic delivery enables the inclusion of family members previously excluded. This is important given the disproportionate rates of diagnosis and lack of access to psychological therapies experienced by this population. Our hope is that CaFI:Digital can begin to address this historic gap in provision of CaFIs for Black populations.

Acknowledgments

The authors would like to thank all the service users, carers, health care professionals, and other co-designers for their invaluable feedback during the development of the CaFI:Digital family intervention platform.

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Conflicts of Interest

PW is a director and shareholder of a for-profit digital mental health company, CareLoop Health Ltd, and a director and shareholder of Prism Life Ltd, a small consultancy company. The other authors declare no conflicts.

Multimedia Appendix 1
Beta testing—therapist.
[DOCX File, 18 KB - formative_v10i1e73246_app1.docx]

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Abbreviations

AMUsED: Analyzing and Measuring Usage and Engagement Data
CaFI: Culturally-adapted Family Intervention
MoSCoW: Must have, Should have, Could have, Won't have
NHS: National Health Service
NICE: National Institute for Health and Care Excellence

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Increasing Physical Activity in Educational Settings Using Mixed Reality Technology: Iterative Formative Study

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Abstract

Background: As physical education classes are lost to budget cuts and recess is canceled to meet standardized testing goals, the modern school day has become dominated by sedentary digital activities. To reverse this trend, current interventions have focused on reducing screen time. However, instead of fighting this digital invasion, this study examined the use of technology, specifically mixed reality, to turn screen time from sedentary into active time, promoting physical activity in a classroom setting.

Objective: The primary aim of this study was to iteratively develop and test a mixed reality prototype that promotes physical activity (eg, jumping, squatting, and punching) during a digital classroom activity. The primary outcomes were the percentage of active time during the activity, a breakdown of the intensity of that active time, and an evaluation of the prototype's usability.

Methods: Between November 2023 and April 2025, a multidisciplinary research team developed a prototype and evaluated it during 2 rounds of pilot-testing. Participants were aged 10 to 15 years and attended local middle schools. Physical activity was assessed using a medical-grade, hip-worn accelerometer (ActiGraph wGT3X-BT). Acceptability was assessed using a validated questionnaire (the System Usability Scale) that has a maximum score of 100. To collect feedback for prototype improvements, semistructured interviews were conducted after each round of pilot-testing.

Results: In the first round of pilot-testing, students (n=22) were active for 46.0% (6.9, SD 2.7 minutes) of the headset session, which lasted 15 (SD 0) minutes. After improving the prototype using feedback from the first round, students in the second round (n=10) were active for 5.8 (SD 3.1) minutes (62.4%) of the web-based assignment, which lasted 9.3 (SD 2.41) minutes, while still reporting "good" acceptability scores (mean 73.8, SD 17.2). There were no significant differences in acceptability ratings between the 2 pilot-testing rounds (P=.16), nor were there differences between boys and girls in round 1 (P=.79) or round 2 (P=.61).

Conclusions: The results of this iterative study indicate that mixed reality can be used to elicit physical activity in a classroom setting, at least for short assignments. However, further research is needed to determine longer-term use and effectiveness.

(JMIR Form Res 2026;10:e83556) doi:10.2196/83556

KEYWORDS

digital learning tools; middle school; mixed reality; school-based physical activity; active learning technologies

Introduction

Students in the United States spend close to 7 hours each weekday in school [1], and for most of that time, they are sedentary [2]. When students transition from elementary to secondary school, academic pressures increase, and there tends to be an increase in sedentary activity [3]. In total, 89% of middle school students report being physically active for less than the recommended 60 minutes per day [4]. While recent educational policy is aimed at increasing students' academic performance [5,6], the policies have unintentionally led to decreased opportunities for physical activity [7] and increased use of sedentary digital learning tools [8].

The use of digital learning tools (ie, tablets, laptop computers, and smart boards) in school settings is not a new concept [9], but the COVID-19 pandemic catalyzed rapid adoption [10] as many schools switched to remote learning, contributing to significant increases in screen time for children [11,12]. Upon returning to in-person learning, the incorporation of technology into the curriculum became pervasive [13,14], further challenging educators and parents to find ways to decrease sedentary behaviors. Previous school-based interventions have focused on strategies such as physical activity breaks, active

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lessons, teacher training, school policy to limit screen time, and classroom modifications to encourage movement [15]. Most of these interventions focus on moderate to vigorous physical activity yet neglect light physical activity, a lower intensity of movement that is related to positive health [16,17] and academic outcomes [17,18] and may be more feasible within the space limitations of an indoor classroom. Additionally, many school-based physical activity interventions avoid technology altogether. The development and deployment of new technology, such as mixed reality, could serve as a novel approach to leverage technology as a tool to increase physical activity in the school classroom.

Mixed reality devices, most commonly headsets, are equipped with cameras that allow users to view the real world around them. This allows them to operate headsets safely without fear of collision, which was a common problem with virtual reality headsets. Furthermore, these headsets now support technology that allows for identification and interpretation of gross motor movements of the arms, hands, and head, allowing for controller-free, direct interaction between user and application [19]. A recent systematic review reported that there is preliminary evidence suggesting that mixed reality headsets could be used to increase physical activity through exergaming [20]. More specifically, 2 popular virtual reality exergames, Gorilla Tag and Beat Saber, have been shown to increase light to moderate physical activity in early adolescents [21]. Some researchers have started investigating the use of mixed reality headsets in physical education classes [22], but it is currently unknown whether mixed reality headsets could be incorporated into traditional school curriculums, replacing sedentary computer time while encouraging more active learning environments.

The purpose of this study was to design a mixed reality prototype using an iterative process to optimize physical activity and satisfaction. The population of interest was middle school students, and the prototype was designed to be integrated into typical online academic assignments (ie, reading comprehension and vocabulary). The prototype program required students to punch, jump, and squat to complete the online academic tasks. The primary aim of this study was to determine how active students were when using the mixed reality technology to complete online academic assignments. The secondary aim was to examine the students' acceptability of the mixed reality prototype.

Methods

Study Design and Setting

This iterative study consisted of four phases: (1) prototype design and personnel training, (2) round 1 pilot-testing, (3) prototype modifications, and (4) round 2 pilot-testing. A detailed timeline can be found in Figure 1. The study was led by a multidisciplinary team trained in computer science, kinesiology, and developmental psychology. Prior to data collection, the research team determined a priori the study end points (metrics of success) that would inform the number of iterative testing and modifications. Specifically, the prototype would be considered complete once the product (1) engaged users in physical activity (ranging from light to moderate to vigorous) for at least 50% of the time spent completing an online academic assignment on average and (2) achieved an average score of at least 60 on the System Usability Scale (SUS) [23,24]. While developing the prototype, the research team had several discussions regarding the movements that the prototype would use, with the limitations of the Meta Quest 3 (Reality Labs) in mind. The team aimed to encourage movement of the upper and lower body while being mindful to minimize repetitive movements as they could cause injury. The Meta Quest 3 does not support feet tracking, but it does support hand and head tracking. On the basis of these constraints, the research team determined that punching would be used to elicit upper-body movements, enabled via hand tracking, and squatting and jumping would elicit lower-body movements, enabled via head tracking.

From November 2023 to November 2024, members of the research team designed a mixed reality prototype program that, when paired with a Meta Quest 3 headset, would allow students to use their body as a "mouse" to complete an online academic assignment. Personnel training took place in November 2024. During this time, 4 middle school students used the prototype to allow the research team to refine the study protocol and prototype program. Informal conversations with the students indicated that the prototype was enjoyable and worked as expected but could benefit from the addition of audio cues. This feedback was incorporated into the prototype prior to pilot-testing. Round 1 of pilot-testing took place in February 2025 at a local middle school. On the basis of the results of round 1, minor modifications were made to the prototype in March 2025. In April 2025, round 2 of pilot-testing took place at a laboratory space on the Louisiana State University campus.

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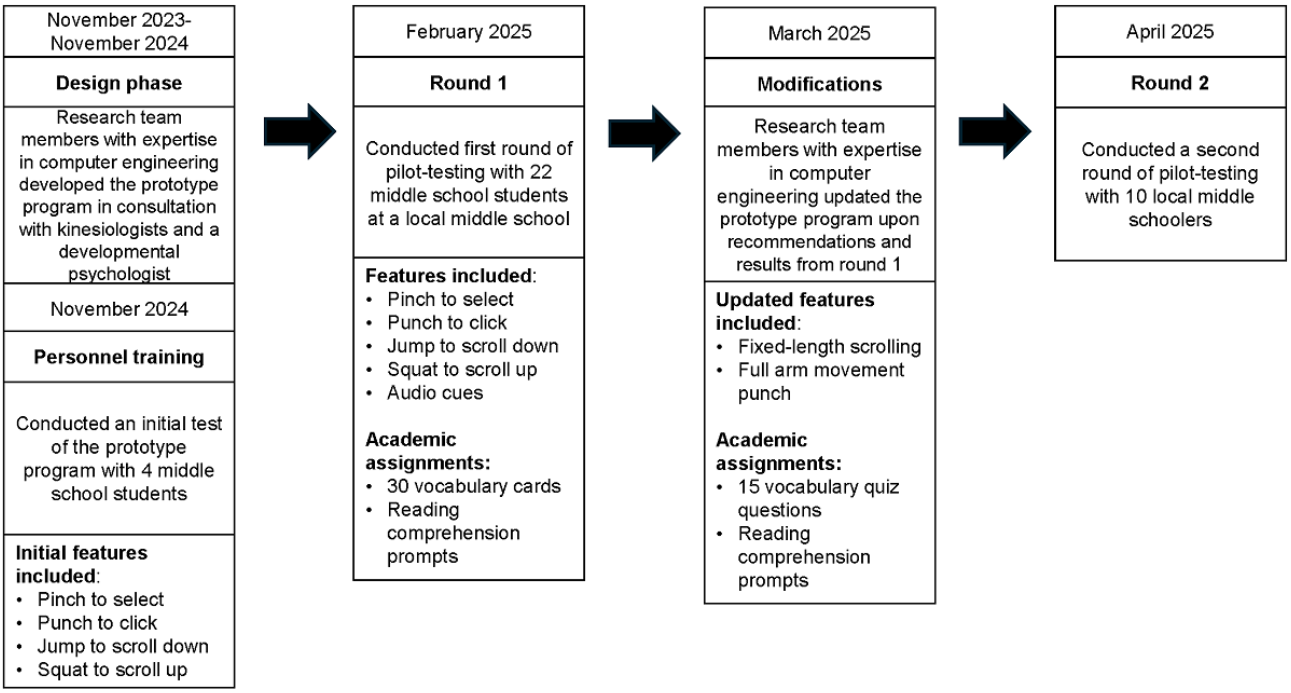
Figure 1. Iterative pilot study timeline of participant recruitment, prototype features, and modifications.



Participants and Procedures

To be eligible to participate in the pilot-testing of the prototype, students had to be aged between 10 and 15 years. Students were excluded if they did not have parental consent to participate.

The first round of testing took place at a local school that serves as a center for educational innovation and research. Prior to recruiting any participants, members of the research team met with the school administrators to provide them with details of the study and a demonstration of the prototype. After this initial meeting, the principal spoke with the sixth-grade teachers and determined that a math class would be the best option to participate in the study. Consent forms were sent home to parents. Those who agreed to allow their children to participate were asked to return a signed copy of the consent form to the school. Members of the research team collected consent forms from the school and then worked with the principal and math teacher to schedule a date and time to conduct the test. A total of 22 students returned signed consent forms and were eligible to participate in round 1 of pilot-testing.

The second round of testing took place when many of the local schools were on spring break. In an effort to not retest the same participants, local middle school students were recruited via word of mouth and flyers. In total, 10 parents returned signed consent forms, and their children were eligible to participate in round 2 of pilot-testing. After receiving signed consent forms, research team members worked with parents to schedule a testing day, which took place at a university laboratory space.

During both rounds of pilot-testing, members of the research team explained to the students, in an age-appropriate manner, what participation in the study would entail. If students were interested in participating in the study, they were asked to sign an assent form. Students were then provided with a short video tutorial created by the research team that introduced the assignments they would be working on and instructed them how to scroll and click. Members of the research team asked a few questions to ensure that the students knew how to complete the proper movements. A demonstration was provided if needed. Research team members then fitted the students with accelerometers and a Meta Quest 3 headset. Research team members recorded start and stop times. Additionally, the research team kept note of any exceptional factors that could impact testing (ie, motion sickness or ill-fitting headsets).

Prototype Program

A modified virtual reality web browser was used for the online environment during pilot-testing. Upon putting on the Meta Quest 3 headset, students were presented with a large web page (Figure 2) with a yellow button to the left of the screen and a red button to the right. To begin the assignment, students had to press the yellow button, which set their default height. The default height value was used to detect when students jumped or squatted. Once the default height was established, participants could scroll down by jumping and scroll up by squatting. Clicking was a multistep process. Students first aimed with their left hand, which would move a clicker over the screen (Figure 3A). Once the clicker was hovering over the link or button, the participant would make a pinching motion (index finger and thumb closing) to lock the clicker in place. If the student accidentally placed the clicker in the wrong spot, they could press the red button on the right side of the screen to reset it. Once the clicker was locked, a large target appeared (Figure 3B); participants were encouraged to punch the target 3 times to finalize the click. Students were instructed to make hard, fast punches. However, interactions were triggered through collision, not speed. Thus, students could trigger the click with slower punches. Despite these activity-focused interactions, the virtual reality browser otherwise functioned as a normal web browser. It could display arbitrary web content, but for the purpose of this study, the browser was restricted to only showing the standardized academic assignments and the SUS.

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Figure 2. Orientation screen that students viewed when they initially put on the Meta Quest headset, including instructions on how to click, set their default height, and reset the clicker position.

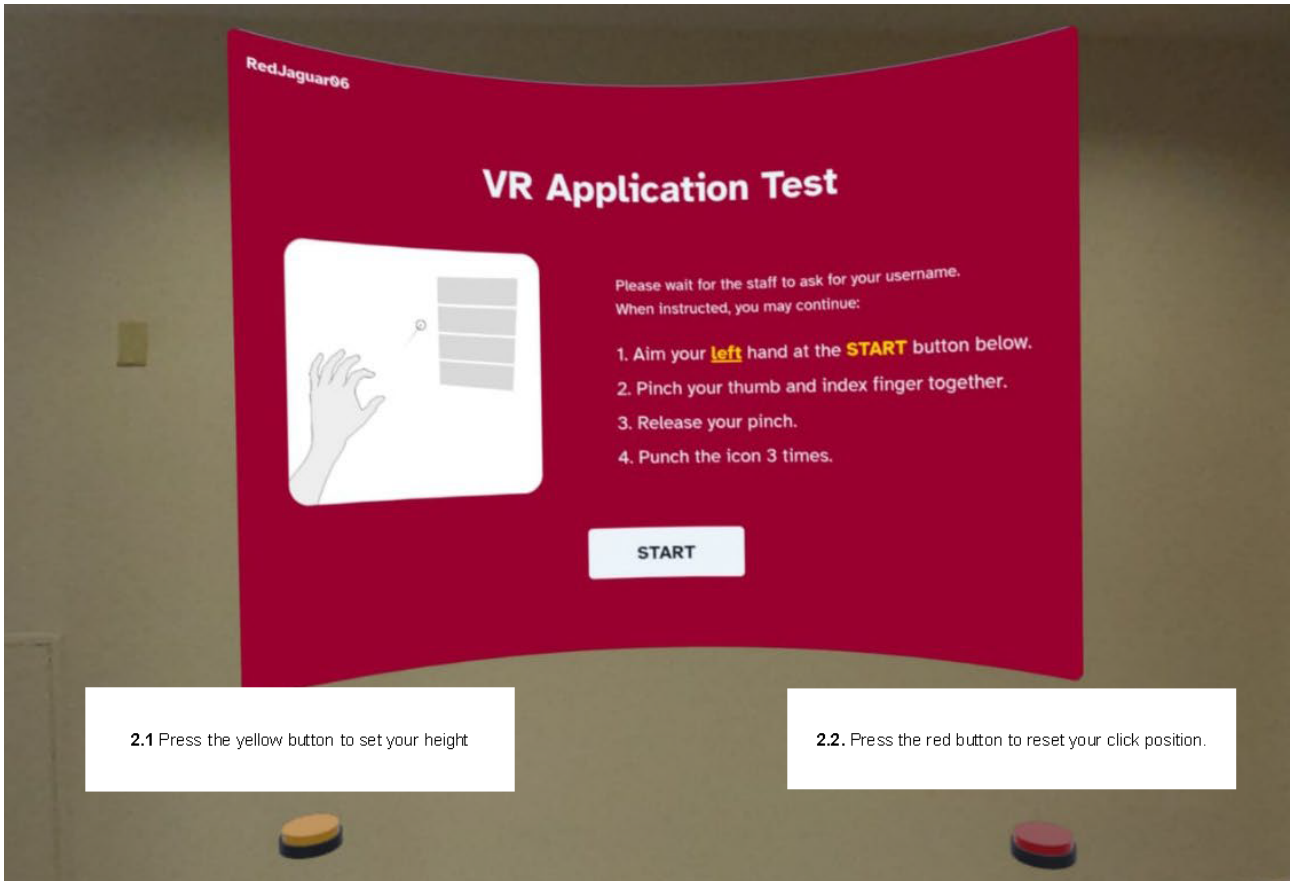

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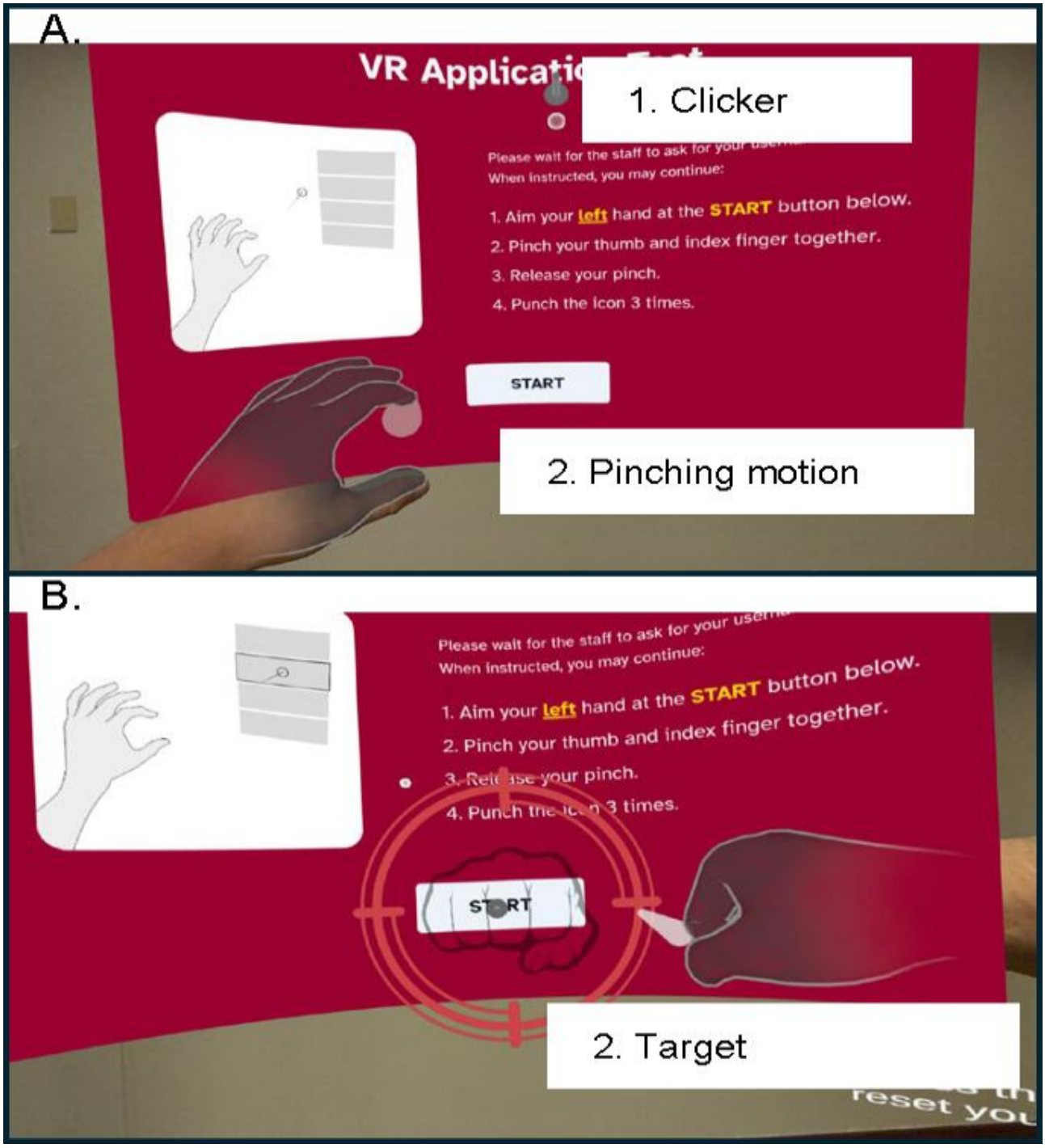
Figure 3. Visual representation of clicking procedures: (1) locating the clicker, (2) making a pinching motion with the thumb and index fingers, and (3) punching the target 3 times. (A) Process to lock in the clicker and (B) process to finalize the click.



Academic Assignments

During both rounds, students were required to complete academic assignments. For round 1, they completed a vocabulary flash card exercise matching 30 terms to their meaning. If terms were connected to the incorrect meaning, students were required to try again. In addition to the vocabulary assignment, students completed 5 reading comprehension prompts, answering questions related to each prompt. In round 2, they completed the same 2 exercises, but the vocabulary exercise was changed from a flash card format, which did not require scrolling, to a web questionnaire format, which did require scrolling. The updated vocabulary quiz only consisted of 15 questions and did not require students to correct mistakes. This change was made to encourage more physical activity and de-emphasize the notion that students needed to select a "correct" answer, which was not the purpose of this iterative pilot study. In both rounds, the order of these 2 exercises was randomized across participants.

Measures

Physical Activity

Physical activity was assessed using an ActiGraph wGT3X-BT accelerometer (Ametris) worn on a manufacturer-provided band and placed on the right hip in line with the midaxillary line.

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Research team members helped students attach the accelerometer before being fitted with the headset. Accelerometry wear time was adjusted using recorded headset start and stop times. Accelerometry data were downloaded and analyzed in ActiLife 6 (version 6.15.0; Ametris). Evenson cut points [25], which are recommended for this age group [26], in 15-second epochs were used to categorize physical activity into light, moderate, and vigorous. Percentages of time spent in total physical activity (light, moderate, and vigorous) were used as the outcome variable.

Acceptability

The SUS [23,24], which is commonly used to judge the user-friendliness of software systems, was used to measure acceptability. Students answered the 11-item survey in the modified virtual reality web browser. Questions 1 through 10 used a 5-point Likert scale ranging from 1 (“strongly disagree”) to 5 (“strongly agree”). Raw scores are converted to a score of 0 to 100. Lower scores indicated lower usability: scores from 0 to 49.9 correspond to “not acceptable,” scores from 50 to 69.9 correspond to “marginally acceptable,” and scores from 70 to 100 correspond to “acceptable.” In 2009 [24], an adjective rating scale was added to the SUS (question 11). This 11th question aimed to better understand the overall user-friendliness of the prototype using a Likert scale ranging from 1 (“worst imaginable”) to 7 (“best imaginable”). The 11th item is interpreted on its own and is not included in the total SUS score. Overall, the instrument demonstrates excellent reliability (Cronbach α=0.91) and a high level of concurrent validity (r=0.81) [27].

Prototype Program

To increase data integrity, data on device use were automatically recorded by the virtual web browser. Specifically, start times, end times, responses to the standardized assignments, SUS scores, and user identifiers were automatically recorded and stored in a remote database. Deidentified assigned nicknames were used to cross-reference physical activity data with performance data.

Semistructured Interview

Following completion of their session, students were asked multiple questions that probed their opinion on the experience with the headset program, what they liked most about the experience, and suggestions for improvement.

Statistical Analysis

The statistical software SPSS (version 29; IBM Corp) was used. Descriptive statistics were calculated for all variables. Mann-Whitney *U* tests were used to identify differences in SUS scores (ie, boys vs girls and rounds 1 vs 2). The α level was set at .05 a priori.

Ethical Considerations

This study was approved by the institutional review boards of the Pennington Biomedical Research Center (2024-052; approved on October 3, 2024) and Louisiana State University (IRBAM-24-1094; approved on December 5, 2024) and conformed to the latest Declaration of Helsinki. Written parental consent and child assent were obtained before data collection. To maintain privacy and confidentiality, students were assigned a study-specific identification number and a randomly generated code to connect physical activity data with headset use. Students were provided with small tokens of appreciation (ie, notebooks, small fidget toys, stickers, and lip balm) and snacks (ie, fruit, water, granola bars, and fruit snacks) as compensation for their participation.

Results

Overview

Results from round 1 and 2 of pilot-testing are presented separately to highlight the changes that occurred during this iterative development process. Demographic characteristics of users in each round are reported in Table 1.

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Table . Characteristics of round 1 and 2 of pilot-testing for the mixed reality prototype.

Variable	Values
Round 1 (n=22)	
Age (years), mean (SD)	12.3 (0.4)
Height (cm), mean (SD)	155.3 (7.6)
Weight (kg), mean (SD)	49.9 (14.5)
BMI (kg/m^2), mean (SD)	20.2 (4.2)
Healthy weight, n (%)	15 (68.2)
Boys, n (%)	15 (68.2)
White, n (%)	14 (63.6)
Hispanic origin, n (%)	3 (13.6)
Round 2 (n=10)	
Age (years), mean (SD)	11.8 (0.6)
Height (cm), mean (SD)	149.4 (6.5)
BMI (kg/m^2), mean (SD)	18.6 (3.3)
Healthy weight, n (%)	7 (70.0)
Weight (kg), mean (SD)	41.9 (9.8)
Boys, n (%)	6 (60.0)
White, n (%)	8 (80.0)
Hispanic origin, n (%)	0 (0.0)

Round 1

A total of 22 middle school students (mean age 12.3, SD 0.4 years; n=15, 68.2% boys) participated in round 1 of pilot-testing. Students spent 6.9 (SD 2.7) minutes (46.0%) of the session, which lasted a mean 15 (SD 0) minutes, engaging in physical activity, as shown in Table 2. The average acceptability score was 80.7 (SD 16.1), which was in the highest range for acceptability. Figure 4 [23,24], used with permission, shows how SUS scores are usually interpreted. The average acceptability score of 80.7 lies in the “excellent” range. There were no significant differences (*P*=.79) in acceptability scores between boys (mean 83.17, SD 11.47) and girls (mean 74.58, SD 24.67).

Table . Physical activity measured through accelerometry during rounds 1 and 2 of pilot-testing for the mixed reality prototype.

Variable	Mean (SD)
Round 1	
Sedentary time (min)	8.1 (2.2)
Light physical activity (min)	4.7 (1.2)
Moderate physical activity (min)	1.1 (0.6)
Vigorous physical activity (min)	1.1 (0.9)
Round 2	
Sedentary time (min)	3.5 (2.0)
Light physical activity (min)	4.2 (2.4)
Moderate physical activity (min)	1.1 (0.3)
Vigorous physical activity (min)	0.5 (0.4)

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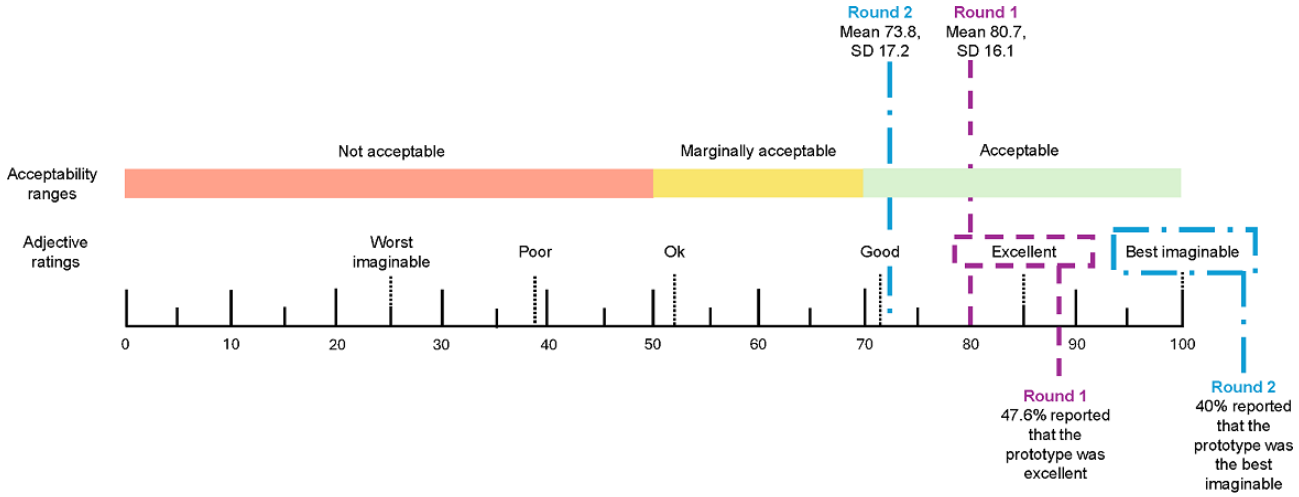
Figure 4. System Usability Scale scores from rounds 1 and 2 of pilot-testing, including acceptability ranges, adjective ratings, and mean and SD of acceptability scores (modified figure used with permission [23,24]).



Semistructured interviews and direct observation revealed several key insights. As suggested by the high SUS score, students indicated that they would be willing to use the prototype to complete school assignments both at home and at school. Students enjoyed most of the features (eg, punching, jumping, sound effects, and ease of use), but some design aspects could be improved. For example, the cursor (pinching and aiming) required precise aim to use; even a small movement could cause a student to miss a button or link. Students suggested making a larger pointer or expanding the selection area to fix this issue. Proctors noticed that some students, instead of punching the target, slapped the target 3 times by making a small movement with their hand.

Round 2

Following round 1 of pilot-testing, the research team made several adjustments to the prototype to increase physical activity and improve usability. First, the mechanism to scroll was modified to encourage more movement to meet the physical activity goal. In round 1, participants held a squat to scroll the page up. This was modified in round 2 so that, for every squat, the modified web browser would only scroll up a fixed distance, thereby requiring participants to squat repeatedly to scroll up. Second, to require full arm movement, the software was modified to require students' hands to return to their body after punching before their next punch. Finally, an internal clock was added to allow researchers to precisely analyze physical activity data. In addition to these modifications, researchers changed the vocabulary flash cards to a vocabulary quiz that would require students to scroll the page more. The reading comprehension questions did not change in round 2.

Round 2 participants comprised 10 local middle school students (mean 11.82, SD 0.63 years; n=6, 60% boys). Students were physically active for 5.8 (SD 3.1) minutes (62.4%) of the session, which lasted a mean 9.3 (SD 2.41) minutes (Table 2). The average acceptability score for round 2 was 73.8 (SD 17.2; Figure 4), which remained in the highest category for acceptability and was not statistically significantly different from that in round 1 (P=.16). There was no significant difference (P=.61) in round 2 acceptability scores between boys (mean 78.75, SD 8.48) and girls (mean 66.25, SD 25.37). Nearly half (4/10, 40%) of the participants reported the user-friendliness of the prototype program as "best imaginable," which was the highest score. Similarly to round 1 of pilot-testing, the students stated during the semistructured interview that they would use the prototype to complete school assignments. However, a few students stated that, due to the weight of the headset, they would only use the prototype to complete short (15-20 minutes) assignments. Jumping and punching remained the favorite features of both boys and girls. Additionally, the issues with aiming the cursor remained a common complaint.

Discussion

Principal Findings

This iterative study resulted in an acceptable mixed reality prototype program that engaged students in physical activity while they completed online academic assignments. To our knowledge, this is the first study to test mixed reality technology as a method for increasing physical activity while completing schoolwork. During round 2 of pilot-testing, students were physically active for most of the time it took them to complete the online assignments, and the students also provided high scores for user satisfaction. Semistructured interviews with students further emphasized that the mixed reality prototype program was a digital learning tool that they would be willing to use at school and at home. Of note, teachers and school administrators were also interested in deploying the mixed reality prototype program in their classes. By conducting 2 rounds of testing with minor modification in between, researchers were able to demonstrate that this prototype can engage students in physical activity 46% to 62.4% of the time it takes to complete online assignments. This ultimately equates to approximately 6 to 7 minutes of physical activity in a 10- to 15-minute academic task. Overall, the results of this study are congruent with those of popular virtual reality exergames such as Beat Saber or Gorilla Tag [21].

Comparison With Prior Work

Traditionally, school-based physical activity interventions have been designed to incorporate moderate to vigorous physical activity into classroom settings. These methods often result in

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modest changes in moderate to vigorous physical activity during intervention lessons [28]. Unfortunately, teachers and students might be hesitant to engage in moderate to vigorous physical activity in classroom settings. Teachers often have a limited time to incorporate physical activity into lessons [29], and the classroom size might make it difficult to engage in higher-intensity physical activity. Qualitative data indicate that students are hesitant to engage in higher-intensity physical activity because they do not want to sweat or change clothes [30], and teachers are reluctant due to limited space [31] and competing priorities [32].

Instead, replacing sedentary computer time that is already part of classroom instruction with physical activity computer time may be a less disruptive and more feasible strategy to increase minutes of physical activity. In this study, the developed prototype program elicited similar physical activity responses to those elicited by traditional interventions [28], all while working with a digital learning tool that can be easily incorporated into the learning environment.

These results contribute promising evidence to the nascent research that suggests that mixed reality technology can be used to increase physical activity [20]. Most school-based trials to date that have tested mixed reality, augmented reality, or virtual reality have focused on incorporating activity-promoting technology into physical education classes [22], whereas this prototype was designed to be integrated into a traditional academic subject matter classroom with academic assignments such as reading comprehension. One mixed reality trial integrated into physical education focused on improving children's motivation to be active and their motor skills and physical fitness but did not evaluate minutes spent engaged in physical activity [33]. A trial that did focus on increasing physical activity was conducted by Ahn et al [34] and involved a virtual fitness buddy ecosystem that would allow children aged 6 to 11 years to interact with a virtual dog to set and meet self-determined physical activity goals. Results indicated that the ecosystem was effective at significantly increasing light physical activity and decreasing sedentary behavior during an after-school program [34]. Similarly to the work by Ahn et al [34], this study found that using a mixed reality prototype primarily increased light physical activity. The integration of movement, even light physical activity, has been shown to benefit physical health and academic outcomes [16-18].

The findings of this study indicate that mixed reality technology might encourage more physical activity during a traditionally sedentary school day. The broader evidence base for exergaming and active video games is mixed. Many have found that these methods are effective at promoting physical activity and decreasing sedentary behavior [20,33-35]. Furthermore, there is evidence suggesting that exergaming and active video games might improve sleep hygiene and health-related quality of life [36]. However, one small trial of 49 children found significant increases in sedentary behavior but no significant increases in other screen time [37]. The overall quality of evidence in active video game research is low, and researchers should aim for increasing methodological rigor and more balanced reporting of findings [38].

Limitations

This study was designed to examine physical activity while wearing the headset; thus, the difference between typical student classroom activity and activity using our prototype is not known. Although typical in-class assignments are generally sedentary, future trials should examine students' physical activity levels with and without the prototype, such as comparing physical activity while using a traditional computer vs the mixed reality headset. Additionally, researchers should examine whether integration of the prototype contributes to a meaningful increase in physical activity throughout the school day and whether the effect can be sustained over weeks and months. The assignment time was set for 15 minutes. However, with the addition of an internal clock in round 2, it was evident that students completed the assignment in approximately 9 minutes, and some indicated that the weight of the headset precluded longer sessions. The difference in assignment completion time is most likely attributed to the change in the academic assignment from 30 vocabulary flash cards to a 15-item vocabulary quiz. Future studies should examine the duration of time that students will tolerate wearing the headset while balancing engagement in physical activity and acceptability. Finally, future research should examine acceptability from the classroom teachers and school administrators to ensure that the prototype is helpful and not disruptive to classroom instruction. Anecdotal information from the pilot test indicated that the school administrators were positive about the prototype and the math and science teachers were interested in integrating the mixed reality headset into the classroom, but this should be explored in a structured interview in future trials.

Conclusions

The continued use of digital learning tools in educational settings has led to increases in screen time and sedentary behavior [7,8,11]. These trends have challenged educators to identify new ways to incorporate movement into classroom settings. The results of this iterative study indicate that this mixed reality prototype program might be a pathway to increase physical activity in the classroom in a way that is acceptable and enjoyed by students. Future research is needed to determine longer-term usability and effectiveness.

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Disclaimer

Generative artificial intelligence was not used in any portion of manuscript generation.

Data Availability

The datasets generated or analyzed during this study are not publicly available due to the formative nature of the data and the small sample size but are available from the corresponding author on reasonable request.

Authors' Contributions

Conceptualization: AES, DCS
Data curation: AES, CWF, DCS, KES, MPP, PN, SC
Formal analysis: KES
Investigation: AES, CWF, DCS, KES, MPP, PN, SC
Methodology: AES, DCS, SC
Project administration: KES, PN
Software: CWF, DCS, MPP
Supervision: AES, DCS, SC
Visualization: CWF, KES
Writing—original draft: CWF, KES
Writing—review and editing: AES, CWF, DCS, KES, MPP, PN, SC

Conflicts of Interest

None declared.

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Abbreviations

SUS: System Usability Scale

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Integrated Implementation Strategies to Promote the Use of AI-Assisted Diagnostic Software for Lung Nodule Screening in China: Process Evaluation Based on the RE-AIM Framework

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Abstract

Background: While artificial intelligence (AI)–assisted diagnostic software holds promise for improving diagnostic efficiency and reducing disparities in health care delivery, its effective implementation in lower-tier health care settings remains limited in China. Most existing studies have focused on algorithm performance, while real-world implementation strategies remain underexplored, particularly in resource-constrained clinical environments.

Objective: This study aimed to design, implement, and evaluate an integrated, context-specific strategy to facilitate the effective implementation of AI-assisted diagnostic software for pulmonary nodule screening in a secondary hospital within China's hierarchical health care system.

Methods: A prospective process evaluation was conducted in a secondary hospital in Beijing, supported by a collaborating tertiary referral center. The implementation strategy integrated AI software for computed tomography–based pulmonary nodule analysis into the diagnostic workflow of the secondary hospital, enabling initial screening and identification of suspected cases. Patients meeting referral criteria were referred to the tertiary hospital through a structured mechanism facilitated by a cloud-based data transfer tool, which enabled the return of diagnostic feedback and ensured continuity through a bidirectional referral and feedback system. Short-term implementation outcomes were evaluated using the RE-AIM framework, focusing on feasibility, adoption, and areas for improvement.

Results: During the study period, 85.6% (1105/1291) of chest computed tomography scans were analyzed using the AI software, with a significant increase in the pulmonary nodule detection rate compared to the historical control group (65.2% vs 32.4%, $P<.001$). Among eligible patients, 88% (22/25) completed referral to the tertiary hospital, indicating a high level of adherence to the referral protocol. Moreover, 90.9% (20/22) of imaging data were transmitted successfully via the data transfer tool, facilitating timely diagnosis. However, several challenges remained, including the low rate of fully documented referral records (28%) and minimal use of diagnostic feedback by referring physicians. These limitations were largely attributed to disruptions in routine clinical workflows due to inadequate integration of the data transfer tool with existing hospital systems and continued reliance on manual data entry.

Conclusions: This study demonstrated the feasibility and potential value of deploying AI-assisted diagnostic software in a secondary hospital when supported by a tailored referral mechanism and interhospital data exchange systems. The findings highlighted the critical role of referral adherence, information infrastructure, and feedback mechanisms in optimizing the clinical utility of AI technologies. Further multicenter research is warranted to assess the generalizability, cost-effectiveness, long-term sustainability, and scalability of the implementation strategies across diverse health care settings.

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KEYWORDS

diagnostic support; artificial intelligence; implementation strategies; RE-AIM; hierarchical medical system

Introduction

China implemented a hierarchical medical system (HMS) in 2015 to optimize health care resource allocation and address the disproportionate distribution of patient volume across the multitiered health care infrastructure [1-3]. The system is structured to align the severity of a patient's condition with the appropriate level of care, thereby promoting both efficiency and equity. Under this framework, primary care facilities, such as community health centers in urban areas and village clinics in rural areas, serve as the first point of contact, providing basic health services, preventive care, and management of common illnesses. Secondary hospitals are responsible for managing moderately complex cases and referring critically ill or highly specialized patients to tertiary hospitals, which are equipped to handle severe and advanced medical conditions. Ideally, this structure ensures that each tier functions within its designated scope, facilitating a coordinated and balanced health care delivery system.

In practice, however, the implementation of the HMS has encountered major challenges, particularly at the primary and secondary care levels. Despite ongoing investments in infrastructure and service capacity, these lower-tier institutions continue to be underutilized [4-6]. Contributing factors include limited medical resources, lack of skilled health care personnel, and public perception that care at lower-tier facilities is of suboptimal quality [6-9]. As a result, many patients bypass community- and county-level institutions and seek care directly at tertiary hospitals, assuming that these institutions offer faster and more reliable medical services [2,10,11]. Bypassing lower-tier facilities has disrupted the intended patient flow within the HMS, placing an excessive burden on tertiary hospitals. These institutions face substantial overcrowding because they are required to manage highly specialized cases alongside a large volume of patients with conditions that could be appropriately addressed at lower levels of care. Consequently, strengthening the quality and capacity of care at primary and secondary health care institutions has become a strategic priority for optimizing China's health care delivery system [11-13].

Artificial intelligence (AI), particularly AI-assisted diagnostic software, provides a promising solution to the challenges faced by China's HMS. Functioning as a second reader, AI delivers consistent and rapid data interpretation, reducing diagnostic errors, and minimizes variability in care quality [14-16]. However, clinical implementation of AI-assisted diagnostic software in China remains predominantly concentrated in tertiary hospitals [17]. This implementation pattern is largely driven by institutional capacity, including the availability of information technology infrastructure and financial resources. As a result, adoption has been primarily limited to large, well-resourced tertiary hospitals [17]. Studies indicate that AI-assisted diagnostic software has become a valuable tool in tertiary hospitals for enhancing the diagnostic and clinical decision-making capabilities of junior physicians [18-21]. It has been widely applied across multiple clinical specialties, including pulmonary diseases [19,22,23], thyroid disorders [24,25], ophthalmology [20,21], gastrointestinal diseases [26,27], and orthopedics [28-30]. Furthermore, in high-volume tertiary care settings, AI-assisted diagnostic software has demonstrated the ability to reduce diagnostic time and improve overall workflow efficiency [22,31,32].

However, the clinical value of AI-assisted diagnostic software for senior physicians remains controversial. While some studies suggest that in complex cases, particularly those involving ambiguous or difficult-to-interpret imaging features, the use of AI can enhance diagnostic accuracy among experienced clinicians [31,33,34], others have found no significant improvement in diagnostic accuracy among senior physicians using AI-assisted diagnostic software [24,35-37]. These findings underscore the limitations of the tertiary hospital–centered implementation mode, which may not fully leverage the potential clinical value of AI technologies, especially in more diverse and complex real-world settings. More importantly, the current implementation model also hinders broader application of AI-assisted diagnostic software in primary and secondary health care institutions, where such tools may be particularly valuable in addressing resource constraints and improving diagnostic capabilities.

To advance effective implementation, a previous study used the updated Consolidated Framework for Implementation Research (CFIR) to qualitatively identify key barriers to implementing AI-assisted diagnostic software in China [38]. Building upon these findings, this study aimed to develop context-specific implementation strategies for AI-assisted diagnostic software, with pulmonary nodule screening serving as a representative clinical scenario. The strategies focused on aligning AI deployment with the clinical needs of lower-tier hospitals, establishing coordinated referral pathways to tertiary hospitals, enabling standardized and secure interhospital data sharing, and implementing diagnostic feedback mechanisms to support continuity of care. The real-world feasibility and preliminary effectiveness of these strategies were evaluated to identify areas for further implementation refinement.

Methods

Development of Implementation Strategies

Overview

The integrated implementation strategies were developed based on key barriers identified through a prior CFIR-guided qualitative interview study [38], as summarized in Table 1. These barriers were identified and prioritized using a 3-round modified Delphi process. In the first round, qualitative interviews were conducted to comprehensively elicit potential barriers, followed by 2 rounds of structured ranking to select the top 5 barriers most relevant to real-world implementation.

The Expert Recommendations for Implementing Change (ERIC) compilation was employed to develop implementation strategies tailored to the identified barriers [39,40]. As a foundational

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resource in implementation science, ERIC provides an extensive compilation of 73 implementation strategies across multiple domains. These strategies were developed through a Delphi consensus process involving the systematic engagement of stakeholders from both clinical practice and implementation research. The ERIC compilation serves as a robust theoretical basis for researchers and practitioners to select and apply context-specific strategies for implementing innovations, including AI-assisted diagnostic software.

Table . Main barriers to implementing AI-assisted diagnostic software in China.

Main barriers	Short description
Unsatisfactory clinical performance at tertiary hospitals	The AI[a]-assisted diagnostic software was predominantly implemented in tertiary hospitals, but its clinical performance was suboptimal when handling complex cases.
Misalignment between software functions and goals of tertiary hospitals	Existing AI-assisted diagnostic software functions, focused on population-level screening, did not align with tertiary hospitals' goals of providing specialized care for complex conditions.
Lack of a collaborative network between primary/secondary and tertiary hospitals	A referral mechanism for patients with positive or indeterminate results from primary or secondary hospitals to tertiary hospitals was not fully established.
Lack of information security measures and certification	The AI-assisted diagnostic software and interhospital data transfer lacked the required information protection qualifications and confidentiality measures.
Lack of performance feedback and evaluation	Insufficient evaluation of the AI-assisted diagnostic software's real-world diagnostic accuracy hindered optimization efforts and undermined user trust.

[a]AI: artificial intelligence.

In this study, implementation strategies were initially derived from the ERIC compilation and further refined using the CFIR-ERIC mapping tool to ensure both scientific validity and practical feasibility [41]. This publicly available, evidence-based tool is designed to match specific implementation barriers identified through the CFIR to relevant ERIC strategies [42]. By systematically linking barriers to targeted strategies, this tool supported the initial prioritization of evidence-informed strategies, which were subsequently refined and adapted to specific implementation contexts.

The implementation strategies evaluated in this study were developed using the following multistage process:

CFIR-ERIC Mapping and Initial Prioritization

CFIR-ERIC mapping was conducted to systematically link previously identified CFIR-based implementation barriers to candidate ERIC strategies, with endorsement levels quantified using cumulative percentages (Multimedia Appendix 1). Strategies with cumulative endorsement exceeding 50% were identified as high-priority candidates and were selected for further contextual evaluation.

Stakeholder Recruitment and Consensus Preparation

Building on these results, stakeholders who had participated in the previous CFIR-guided qualitative interview were invited to participate in a follow-up consensus discussion. Of the 40 participants invited, 27 (67.5%) participated in the consensus discussion, including 16 clinicians, 3 hospital administrators, 4 hospital informatics specialists, and 4 AI vendors, all with direct experience in AI-assisted diagnostic workflows. The consensus session began with a presentation of the key implementation barriers, their corresponding CFIR constructs, and the mapped ERIC strategies identified as high-priority candidates. To ensure a shared understanding and reduce interpretive variability, standardized definitions and practical examples of each ERIC strategy were provided prior to discussion.

Consensus Decision-Making and Strategy Selection

Participants then engaged in strategy-by-strategy discussions to appraise each candidate ERIC strategy. Evaluation was guided by predefined criteria, including (1) contextual relevance to lower-tiered hospital settings in China, (2) feasibility of implementation within existing clinical workflows and resource constraints, and (3) the logical and practical capacity of the strategy to address the corresponding CFIR-identified barriers. For each strategy, participants discussed anticipated implementation requirements, potential operational challenges, and alignment with current interinstitutional collaboration processes, data governance structures, and clinician responsibilities.

Disagreements were addressed through iterative, facilitated discussion aimed at clarifying underlying assumptions, contextual constraints, and anticipated implementation pathways. When consensus could not be achieved through discussion alone, a structured decision rule was applied. Participants were asked to indicate whether each strategy should be retained or excluded based on the predefined evaluation criteria. Strategies receiving support from more than half of participating stakeholders were retained for integration into the final implementation package.

Illustrative Example of Barrier-to-Strategy Translation

For example, the barrier "lack of information security measures and certification," categorized under the CFIR domain *External Policies and Incentives*, reflected challenges in obtaining

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recognized information security certification for AI-assisted tools, which hindered secure data exchange between secondary and tertiary hospitals. CFIR-ERIC mapping identified 7 Tier 2 strategies for this barrier, including involving executive boards (41%), altering incentive or allowance structures (41%), building a coalition (33%), capturing and sharing local knowledge (26%), identifying and preparing champions (22%), informing local opinion leaders (22%), and conducting local consensus discussions (22%).

During consensus discussions, participants emphasized that information security certification and cross-institutional data governance are primarily governed by external regulatory requirements and interorganizational coordination mechanisms rather than by internal financial incentives or locally generated experiential knowledge. Accordingly, strategies such as altering incentive or allowance structures and capturing and sharing local knowledge were deprioritized, as they were considered to have limited feasibility and weak logical alignment with the policy-level nature of the barrier.

The strategy of involving executive boards was discussed but was not retained, as participants considered hospital-level executive leadership unlikely to exert meaningful influence over externally regulated data transfer and certification processes within the current implementation context. In contrast, building a coalition with a qualified data transfer platform was prioritized, as it was perceived to support coordinated governance, regulatory compliance, and shared accountability for secure data exchange across participating hospitals.

The ERIC strategies that reached consensus and their corresponding implementation strategies are summarized in Table 2.

Table . Selected ERIC strategies and corresponding implementation strategies.

Key barrier	CFIR[a] domain	Mapping outcome	Selected ERIC[b] strategy	Specific implementation strategy
Unsatisfactory clinical performance at tertiary hospitals	Relative advantage	Tier 1 strategies: 0 Tier 2 strategies: 8	Conduct local consensus discussions	Shift the implementation focus of AI[c]-assisted diagnostic software to primary or secondary hospitals and achieve consensus among key stakeholders.
Misalignment between software functions and goals of tertiary hospitals	Goals and feedback	Tier 1 strategies: 1 Tier 2 strategies: 6	Develop a formal implementation blueprint	Develop an AI implementation plan aligned with the primary or secondary hospital's clinical needs and goals, including task assignments and timelines.
Lack of a collaborative network between primary or secondary and tertiary hospitals	Cosmopolitanism	Tier 1 strategies: 3 Tier 2 strategies: 5	Build a coalition	Establish a collaborative network to ensure smooth referral of suspected cases from primary or secondary hospitals to tertiary hospitals following AI-assisted screening.
Lack of information security measures and certification	External policy and incentives	Tier 1 strategies: 0 Tier 2 strategies: 7	Build a coalition	Collaborate with information platform providers to enable data sharing for referred patients, establishing clear protocols to ensure data completeness, timeliness, and confidentiality across hospitals.
Lack of performance feedback and evaluation	Reflecting and evaluating	Tier 1 strategies: 2 Tier 2 strategies: 6	Facilitate relay of clinical data to providers	Establish a feedback mechanism for returning final diagnoses from tertiary to primary or secondary hospitals, enabling care continuity and helping clinicians assess AI performance for sustainable use.

[a]CFIR: Consolidated Framework for Implementation Research.

[b]ERIC: Expert Recommendations for Implementing Change.

[c]AI: artificial intelligence.

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Study Design

This prospective, observational, real-world study employed the RE-AIM evaluation framework to preliminarily evaluate the effectiveness and feasibility of implementation strategies designed to integrate AI-assisted diagnostic software into China's HMS, following 3 months of implementation. The process evaluation focused on identifying practical challenges, successes, areas for optimization, and the potential to enhance patient outcomes and clinical workflows.

Ethical Considerations

Centralized ethical approval for this study was obtained from the Ethical Review Board of the China Rehabilitation Research Center (approval number: 2024-032-1). Written informed consent was obtained from all patients involved in the referral process. Patient privacy and confidentiality were strictly protected. All potentially identifying information (including names, initials, and patient identification numbers) was removed unless essential for scientific purposes. No identifiable participant information appears in the manuscript or supplementary materials. Participation was entirely voluntary, and no compensation was provided to participants in this study.

Study Settings and Tools

Study Settings

In selecting appropriate primary or secondary hospitals for AI-assisted diagnostic software deployment, the study first established that eligible sites must possess the necessary hardware infrastructure and technical support environment. Insights from the previous qualitative interviews highlighted that the availability of necessary medical equipment meeting the technical requirements was a fundamental facilitator for the successful implementation of AI-assisted diagnostic software. Given that most community health centers in China lack sufficient imaging capabilities, the study prioritized secondary hospitals with more advanced diagnostic equipment as the primary sites for deployment.

The selection process further considered several factors, including the hospital's technical capacity, the maturity of its collaborative networks with tertiary hospitals, and the willingness to participate in the study. Based on these criteria, 2 hospitals in Beijing were selected as implementation sites: a secondary rehabilitation hospital (Fengtai Rehabilitation Hospital of Beijing) and a general tertiary hospital (China Rehabilitation Research Center). Key characteristics of the participating hospitals are summarized in Table 3.

Table . Characteristics of participating hospitals.

Characteristic	Fengtai Rehabilitation Hospital of Beijing	China Rehabilitation Research Center
Location	Beijing	Beijing
Funding source	Public	Public
Tier	Secondary	Tertiary
Hospital type	Specialized	General
Specialties	Neurological, geriatric, and bone and joint rehabilitation services	Specialized respiratory, sports injury, and hearing and speech rehabilitation services
Bed capacity	211	1100
Staff number	434	1700
Annual outpatient volume	300,000	470,000

AI-Assisted Diagnostic Software

The study used a commercially available AI-assisted screening system for pulmonary nodules developed by HY Medical Technology Co., Ltd. (Beijing, China). This software received approval from the National Medical Products Administration in 2022 and obtained CE certification in 2020. It automatically identifies and segments potential lesions in chest computed tomography (CT) scans, providing a malignancy score ranging from 0% to 100% to assist physicians in assessing nodule risk. Additional details on the functionalities of the AI-assisted diagnostic software are provided in Multimedia Appendix 2.

The AI-assisted diagnostic software for pulmonary nodules was locally deployed at the secondary hospital and seamlessly integrated with the hospital's picture archiving and communication system (PACS), which supported CT image analysis and assisted clinical decision-making without disrupting routine diagnostic workflows.

Data Transfer Tool

To address fragmented information systems between the participating hospitals, the electronic source data repository (ESDR) system was employed to facilitate seamless patient data transfer. Developed by Hangzhou LionMed Medical Information Technology Co., Ltd, the ESDR system is designed to standardize real-world data collection, governance, and management, enhancing clinical research and health care interoperability. Functions and benefits of the ESDR system have been well-validated in previous studies [43-45].

The ESDR tool operated on a secure, cloud-based platform managed by the tertiary hospital, with encrypted external access links provided to both participating hospitals to ensure secure, real-time data sharing. Using the CT image ID, AI-generated results, including pulmonary nodule risk scores, clinical feature data, and chest CT images, were automatically uploaded from the PACS to the ESDR platform. This enabled physicians at the tertiary hospital to dynamically access and review CT images

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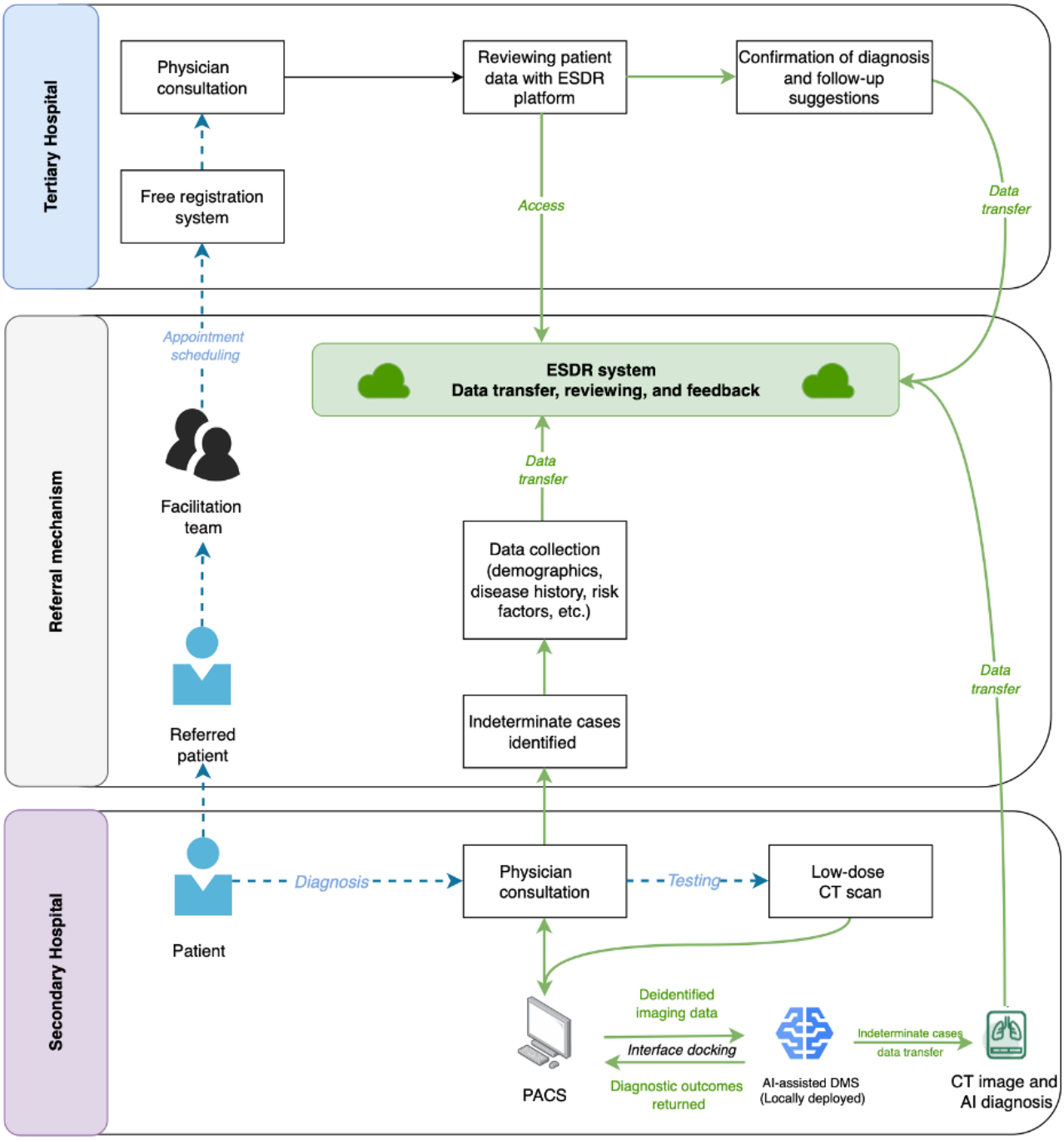
and diagnostic data directly on their terminal devices. Drawing on this information and their clinical judgment, physicians determined the final diagnosis and developed follow-up plans. The diagnostic decisions and follow-up strategies were recorded in the ESDR tool, supporting dynamic follow-up at 1, 3, 6, and 12 months.

Implementation Process

The implementation process was illustrated in Figure 1, where the dotted blue line represented patient flow and the solid green line denoted data flow.

Figure 1. Implementation process flowchart. AI: artificial intelligence; CT: computed tomography; DMS: decision-making software; ESDR: electronic source data repository; PACS: picture archiving and communication system.



The secondary hospital served as the primary site for the implementation of AI-assisted diagnostic software and functioned as the first point of care for patients with suspected pulmonary nodules. Eligible patients presenting with symptoms or undergoing routine cancer screening received an initial clinician consultation, followed by a low-dose CT scan if indicated. The AI-assisted diagnostic software, locally deployed at the secondary hospital, analyzed deidentified imaging data, and the results interfaced directly with the PACS.

When indeterminate cases were identified, physicians at the secondary hospital were responsible for uploading relevant referral information to the ESDR tool, which included:

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- Patient demographics: name, date of visit, patient ID, age, ethnicity, sex, phone number, and occupation.
- Clinical symptoms: symptom duration and presentations such as chest pain, cough, or dyspnea.
- Radiological findings: diagnostic conclusions, size, location, morphology, and risk assessment of the primary pulmonary nodule.
- AI diagnostic results and CT images: automatically extracted based on the CT image ID.
- Referral form: documentation of the referral request, reason for referral, and medical insurance information.
- Previous examinations: previous imaging records and other reports, if available.

At the tertiary hospital, a structured referral pathway was established to facilitate the comprehensive evaluation of patients with indeterminate pulmonary nodules. Supported by the ESDR tool, the referral mechanism ensured continuity of care and seamless data flow between institutions. To enhance access to tertiary care, a free registration system was introduced, allowing referred patients to bypass additional registration fees. Moreover, a facilitation team was established to streamline the referral process, assist with appointment scheduling, and provide guidance on accessing tertiary care and navigating the registration system.

Following specialist consultations, the tertiary hospital communicated diagnostic results and follow-up recommendations back to the secondary hospital through the ESDR tool, fostering a continuous feedback loop and building trust in the adoption of AI-assisted diagnostic software.

The integrated strategies were deployed over a 3-month period, from August to November 2024. Following this deployment phase, a transition period was initiated, during which on-site training sessions were held at both hospitals to familiarize physicians with the AI-assisted diagnostic software and the ESDR tool. Concurrently, both systems underwent extensive testing and fine-tuning to ensure effective deployment, with technical challenges addressed and data-sharing protocols refined. Official data collection began in December 2024.

Study Participants

The study included both physicians and patients. Eligibility criteria for physicians were as follows:

- Inclusion criteria:
  - Radiologists and respiratory physicians from the secondary hospital, regardless of professional title
  - Respiratory physicians with intermediate or senior professional titles from the tertiary hospital
  - Aged 18 years or older, with no restrictions on sex
  - Possession of a current and legally approved medical license
- Exclusion criteria:
  - Physicians who are unable to provide written informed consent

Patients seeking care or undergoing cancer screening at the secondary hospital were assessed for eligibility for AI-assisted interpretation of CT scans based on the following criteria:

- Inclusion criteria:
  - Age 18 years or older, with no restrictions on sex
  - Underwent a chest CT scan
- Exclusion criteria:
  - History of prior lung surgery

Patients with indeterminate findings were subsequently referred to the tertiary hospital for further evaluation based on specific criteria, including:

- Malignancy risk of the dominant nodule between 5% and 65%
- Dominant pulmonary nodule larger than 8 mm/200 m^3
- Rapid growth of the dominant nodule size within 6 months
- Family history of lung cancer or personal history of other cancers
- Presence of high-risk factors, including smoking history, age, and occupational or environmental exposure
- Any other conditions for which physicians recommended referral

Outcomes

As a widely recognized framework for evaluating health care interventions, RE-AIM examines 5 dimensions, including Reach, Effectiveness, Adoption, Implementation, and Maintenance, to support the translation of innovations into routine care [46-48].

1. Reach assesses the engagement, representation, and access of the target population to the intervention.
2. Effectiveness evaluates the intervention's impact on relevant clinical outcomes.
3. Adoption examines the uptake of the intervention by the intended users or settings.
4. Implementation focuses on the feasibility, usability, and integration of the intervention into existing workflows.
5. Maintenance addresses the long-term sustainability and institutionalization of the intervention.

Given that the current study was designed to assess feasibility and short-term outcomes to inform further refinement of the implementation strategies, the Maintenance dimension was not included. By addressing the remaining dimensions, the RE-AIM framework enabled a multilevel evaluation of the implementation strategies across key stakeholders, including patients, physicians, and health care institutions, providing a comprehensive perspective on their impact. This multidimensional evaluation provided a holistic understanding of the feasibility and effectiveness of the implementation strategies for AI-assisted diagnostic software in pulmonary nodule diagnosis within real-world health care settings, while also identifying opportunities for future optimization and potential scalability.

The specific evaluation indicators are shown in Table 4.

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Table . The RE-AIM outcomes adapted to the evaluation of AI-assisted diagnostic software implementation strategies.

Outcomes	Definitions	Data sources
Reach		
Patient-level		
Representativeness of participants	• Differences in patient demographic and clinical characteristics before and after implementation strategy deployment.	Secondary hospital HIS[a]/PACS[b]
AI[c]-assisted screening rate	• Proportion of eligible patients who were screened using the AI-assisted diagnostic software.	Secondary hospital PACS/AI software
Referral volume	• Total number of patients issued referral notes for tertiary care.	ESDR[d]
Representativeness of referred patients	• Demographic and clinical characteristics of patients who were recommended for referral.	Secondary hospital HIS
Provider-level		
Number of physicians who agreed to participate	• Number of participating physicians from secondary and tertiary hospitals.	Additional data collection
Effectiveness		
Provider-level		
Change in pulmonary nodules detection rate	• Differences in detection rates of pulmonary nodules before and after the deployment of the implementation strategies.	Secondary hospital PACS/AI software
Differences in CT image interpretation and reporting time	• Change in average radiologist CT[e] assessment and reporting time before and after implementation strategy deployment. • Interpretation and reporting time = Time of report completion – Time of scan completion	Secondary hospital PACS
Patient-level		
Referral participation rate	• Proportion of referred patients who visited the tertiary hospital.	Tertiary hospital HIS
Referral time	• Referral time = registration time at the tertiary hospital – referral submission time in the ESDR tool • Referral time for patients transferred from the secondary hospital to the tertiary hospital.	Tertiary hospital HIS/ESDR
Adoption		
Provider-level		
AI software adoption rate	• Proportion of eligible physicians in the secondary hospital who used AI software.	Questionnaire
ESDR adoption rate	• Proportion of eligible physicians in secondary and tertiary hospitals who used the ESDR tool.	Questionnaire
Organizational-level		
Referral acceptance rate	• Proportion of patients referred by the secondary hospital who were accepted by the tertiary hospital.	Tertiary hospital HIS

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Outcomes	Definitions	Data sources
Adoption fit	• Degree to which the deployment of the implementation strategies aligns with the strategic priorities of participating hospitals.	Questionnaire
Implementation		
Provider-level		
Ease of use	• Physicians' perceived ease of use of the AI software and ESDR tool in secondary and tertiary hospitals.	Questionnaire
Training coverage	• Proportion of physicians trained to use the AI software and ESDR tool in secondary and tertiary hospitals.	Questionnaire
Data transfer completeness	• Proportion of complete data transmitted through the ESDR tool.	ESDR
Diagnostic result feedback rate	• Proportion of eligible physicians at the tertiary hospital who provided final diagnostic results via the ESDR tool.	ESDR
Diagnostic result review rate	• Proportion of eligible physicians at the secondary hospital who reviewed the final diagnostic results of referred patients	Questionnaire
Organizational-level		
Disruptiveness to routine clinical practice	• Extent to which the deployment of implementation strategies disrupted routine clinical workflows.	Questionnaire
Referral team success rate	• Proportion of referred patients successfully managed by the referral collaboration team during the study period.	Tertiary hospital HIS

[a]HIS: hospital information system.

[b]PACS: picture archiving and communication system.

[c]AI: artificial intelligence.

[d]ESDR: electronic source data repository.

[e]CT: computed tomography.

Data Collection

During the study period, deidentified clinical data were prospectively collected for all patients who met the eligibility criteria for pulmonary nodule screening between December 1, 2024, and March 1, 2025. For patients who met the referral criteria, core referral-related data were collected upon obtaining written informed consent and securely transmitted to the ESDR cloud platform to support subsequent diagnostic evaluation and clinical decision-making.

Implementation outcome data were primarily sourced from the hospital information system (HIS), PACS, AI-assisted diagnostic software, and the ESDR tool. To enhance the comprehensiveness and multidimensionality of the data, key feedback information from participating physicians was also collected through electronic questionnaires (Multimedia Appendix 3).

Historical control data were obtained from the same hospital between December 1, 2023, and March 1, 2024. Key outcome indicators included patient representativeness, differences in pulmonary nodule detection rates, and variations in CT image interpretation and reporting times. These indicators were generally stable over time. Given the consistency within the same health care institutions in terms of diagnostic criteria, diagnostic technologies, and the demographic characteristics, disease staging, and severity of the served populations, the use of a historical control group was deemed comparable.

Data Analysis

Descriptive statistics for qualitative variables were reported as frequencies and percentages. For quantitative variables, the mean (SD) and median (IQR) were calculated. To compare baseline characteristics between the study participants and historical controls, independent *t* tests were used for continuous variables, while chi-square tests were applied for categorical variables. All statistical tests were 2-sided, and statistical significance was set at *P* less than .05.

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Results

Reach

At the provider level, physicians from relevant clinical departments at both the secondary and tertiary hospitals were invited to participate in the study. Specifically, 6 radiologists and 9 respiratory physicians from the secondary hospital, along with 13 respiratory physicians from the tertiary hospital, were approached. Of those invited, all 15 physicians from the secondary hospital and 8 respiratory physicians from the tertiary hospital agreed to participate. The demographic and professional characteristics of the participating physicians from both institutions are summarized in Table 5.

Table . Demographic and professional characteristics of participating physicians.

Characteristic	Secondary hospital (n=15)	Tertiary hospital (n=8)
Sex, n (%)		
Male	7 (46.7)	5 (62.5)
Female	8 (53.3)	3 (37.5)
Age (y), median (IQR)	44 (38.5 - 49.5)	44.5 (36.5 - 50.5)
Highest level of educational attainment, n (%)		
Bachelor's degree	12 (80)	0 (0)
Master's degree	3 (20)	4 (50)
Doctoral degree	0 (0)	4 (50)
Professional title, n (%)		
Junior	1 (6.7)	—[a]
Intermediate	6 (40)	4 (50)
Associate senior and above	8 (53.3)	4 (50)

[a]Not applicable.

At the patient level, a total of 1375 patients underwent chest CT examinations at the secondary hospital during the study period. The mean age of patients was 54 (SD 16.6) years, and 604 (43.9%) were male. The mean maximum diameter of the dominant pulmonary nodules detected was 5.4 (SD 2.3) mm, with 953 (69.3%) classified as solid nodules. Compared with the historical control group, there were no statistically significant differences in patient demographics or clinical characteristics of pulmonary nodules (Table 6).

Of the patients who underwent chest CT examinations, 84 (6.1%) were excluded based on the predefined exclusion criteria, including 76 patients under 18 years of age and 8 patients with a history of prior lung surgery. Among the 1291 patients who met the inclusion criteria, 85.6% of chest CT images were successfully analyzed using the AI-assisted pulmonary nodule diagnostic software.

During the study period, 33 patients met the predefined referral criteria. Of these, 25 (75.8%) patients provided written informed consent and were referred to the tertiary hospital. The median age of the referred patients was 63 (IQR 32 - 66) years, and 44% (11/25) were male. The median maximum diameter of the dominant pulmonary nodules was 9 (IQR 8 - 11) mm, with 28% (7/25) identified as solid nodules. Additionally, 32% (8/25) of referred patients had a history of other pulmonary diseases, 8% (2/25) had a history of cancer, and 24% (6/25) reported a history of smoking (Table 7).

Table . Comparison of demographic and clinical characteristics of pulmonary nodules.

Characteristic	Intervention group (n=1375)	Historical control group (n=1591)
Age (y), mean (SD)	54 (16.6)	53.2 (19.5)
Sex, n (%)		
Male	604 (43.9)	743 (46.7)
Female	771 (56.1)	848 (53.3)
Size (mm), mean (SD)	5.4 (2.3)	5.1 (2)
Density, n (%)		
Solid	953 (69.3)	1151 (72.3)
Subsolid[a]	422 (30.7)	440 (27.7)

[a]Including part-solid nodules and pure ground-glass nodules.

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Table . Demographic and clinical characteristics of patients who consented to referral.

Characteristic	Patients who consented to referral (n=25)
Age (y), median (IQR)	63 (32 - 66)
Sex, n (%)	
Male	11 (44)
Female	14 (56)
Other pulmonary diseases, n (%)	
Yes	8 (32)
Chronic obstructive pulmonary disease	1 (12.5)
Pneumonia	5 (62.5)
Asthma	2 (25)
No	17 (68)
Cancer history, n (%)	
Yes	2 (8)
No	23 (92)
Smoking history, n (%)	
Yes	6 (24)
No	19 (76)
Size of dominant nodule (mm), median (IQR)	9 (8-11)
Density of dominant nodule, n (%)	
Solid	7 (28)
Subsolid[a]	18 (72)

[a]Including part-solid nodules and pure ground-glass nodules.

Effectiveness

At the provider level, a total of 896 patients at the secondary hospital were identified with at least 1 pulmonary nodule, including micronodules, small nodules, intermediate-sized nodules, and mass-like lesions, resulting in an overall detection rate of 65.2%. The mean time for radiologists to assess and report chest CT images was 24.1 (SD 13.5) minutes. In comparison, during the historical control period, the overall pulmonary nodule detection rate was 32.4% (P<.001), and the mean CT image assessment and reporting time was significantly longer (30.4, SD 19.7 min; P<.001).

At the patient level, of the 25 individuals who consented to referral, 22 successfully completed the referral process by visiting the tertiary hospital, yielding a referral completion rate of 88%. The median interval from referral submission to hospital visit was 3 (IQR 2 - 4) days. The 3 patients who did not complete the referral included 2 males and 1 female, with a median age of 67 years. The median maximum diameter of their dominant pulmonary nodules was 13 mm, and 1 had a documented history of cancer.

Adoption

At the secondary hospital, an electronic questionnaire (Multimedia Appendix 3) was distributed via email and QR code to 9 respiratory physicians and 6 radiologists who participated in the study. All 15 physicians completed the questionnaire, yielding a response rate of 100%. According to the survey, 7/9 (77.8%) of respiratory physicians and all radiologists had used the AI-assisted pulmonary nodule diagnostic software, while 5/9 (55.6%) of respiratory physicians reported using the ESDR tool. In terms of perceived alignment with institutional goals, all respondents agreed that the AI-assisted diagnostic software supported the hospital's core objectives, and 6/9 (66.7%) of respiratory physicians believed that the use of the ESDR tool was consistent with those objectives.

At the tertiary hospital, all 22 referred patients who arrived were successfully received, resulting in a referral acceptance rate of 100%. Among the 8 participating respiratory physicians, the electronic questionnaire also achieved a 100% response rate. Of these respondents, 5/8 (62.5%) reported prior use of the ESDR tool, and 7/8 (87.5%) indicated that its use aligned with the hospital's strategic priorities.

Implementation

In terms of usability, 11/13 (84.6%) of radiologists and respiratory physicians at the secondary hospital who had used the AI-assisted diagnostic software reported that it was easy to use. In contrast, among respiratory physicians who had experience with the ESDR tool, only 3/5 (60%) at the secondary hospital and 4/5 (80%) at the tertiary hospital perceived the tool as user-friendly.

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Although both the AI-assisted diagnostic software and the ESDR tool achieved 100% training coverage across the two hospitals, the completeness of referral data collected via the ESDR tool remained suboptimal. Only 28% (7/25) of referred cases had complete data entries, with comprehensive datasets available for 7 patients. Missing information was primarily concentrated in key fields, including clinical symptoms, diagnostic conclusion, and referral-related variables such as insurance information. Despite a relatively high CT image transmission success rate of 90.9% (20/22), system-level failures persisted. Among the 22 patients who successfully completed the referral process, two experienced data transmission failures due to PACS system malfunctions at the secondary hospital, which prevented the upload of AI-generated results and CT images to the ESDR platform. Consequently, these patients were required to carry physical CT films to the tertiary hospital for further diagnostic evaluation.

With respect to integration into clinical workflows, 93.3% (14/15) of physicians at the secondary hospital reported that the AI-assisted diagnostic software did not interfere with routine clinical practice. However, 55.6% (5/9) of respiratory physicians indicated that the ESDR tool imposed a substantial burden on daily tasks. The primary challenge was the lack of interoperability between the ESDR system and the hospital's internal information systems, which required physicians to manually access the platform via an external web link to upload or retrieve patient data. This additional step increased workload and disrupted workflow efficiency. As a result, continuity of care was affected. Among the 9 respiratory physicians at the secondary hospital, only 44.4% (4/9) reviewed the final diagnostic results of referred patients via the ESDR tool.

At the tertiary hospital, the referral coordination team successfully facilitated the referral process for all 22 patients, achieving a referral completion rate of 100%. Nevertheless, only 50% (4/8) of respiratory physicians uploaded final diagnostic results through the ESDR system. Moreover, 62.5% (5/8) reported workflow disruptions due to challenges similar to those in the secondary hospital, particularly the reliance on external network access, which increased complexity and time demands.

Discussion

Principal Findings

This study designed, implemented, and evaluated an integrated strategy specifically tailored to support the effective implementation of AI-assisted diagnostic software within the context of China's HMS. In contrast to prior studies that primarily focused on identifying implementation barriers [49-53], this study developed a context-specific implementation framework and demonstrated tangible improvements in both diagnostic capacity and referral processes at the secondary care level. During the study period, 85.6% of chest CT images at the secondary hospital were analyzed using AI-assisted diagnostic software. As a result, the overall detection rate of pulmonary nodules significantly increased from 32.4% in the historical control group to 65.2% in the intervention group (P<.001), indicating a significant enhancement in diagnostic capacity. In addition, the introduction of a standardized referral pathway supported high levels of referral compliance. Supported by a dedicated coordination team, 88% of the 25 patients identified as referral candidates successfully completed the referral process and received timely diagnostic and therapeutic services at the tertiary hospital. The median referral time was approximately 3 days, indicating efficient coordination and strong adherence to the referral process. Moreover, 90.9% of CT images acquired at the secondary hospital were successfully transmitted to the tertiary hospital via the ESDR platform, enabling receiving physicians to access imaging data in advance and facilitating more accurate and timely diagnoses. The high transmission success rate and streamlined interhospital data exchange strengthened institutional coordination while enhancing the continuity of diagnostic and treatment services. Study outcomes collectively supported the feasibility of scaling AI-assisted diagnostic software technologies across lower-tier health care settings and demonstrated their value in strengthening referral processes and optimizing care pathways within the hierarchical health care system.

The findings aligned with a growing global consensus on the strategic importance of deploying AI in lower-tier health care settings. Internationally, the implementation of AI-assisted diagnostic software technologies varies widely, influenced by differences in software types, national health care infrastructure, policy environments, and the maturity of health information systems. Although technical and organizational challenges remain, recent research has increasingly emphasized the potential of AI to improve diagnostic accuracy for common diseases, streamline clinical workflows, and optimize health care resource use, particularly in settings such as community health centers and secondary hospitals [38,54-57]. AI technologies are especially valuable in supporting primary care providers by enabling large-scale patient management, improving early disease detection, and reducing diagnostic errors in environments where clinical experience and infrastructure are limited [58-60].

Despite the growing recognition of these benefits, most existing studies have concentrated on evaluating clinical performance metrics such as sensitivity, specificity, and referral accuracy [61-63] or have identified implementation challenges like inadequate referral adherence [63]. Relatively few studies have developed and empirically validated comprehensive implementation strategies adapted to lower-tier clinical environments. This gap highlights the need to move beyond performance-oriented evaluations toward theory-informed investigations of how AI technologies can be effectively integrated into routine care.

From an implementation science perspective, this study extended the application of ERIC strategies by demonstrating how their mechanisms of action vary across health system contexts. While ERIC strategies have largely been derived from Western health systems where hospitals and clinical units have substantial authority to determine implementation priorities, allocate resources, and adapt technologies to local workflows, recent evidence indicates that these strategies are increasingly applied in low- and middle-income country contexts, often requiring contextual adaptation. A systematic review of ERIC strategy

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use in low- and middle-income countries found that the majority of the 73 ERIC strategies have been selectively adapted to address diverse implementation barriers within resource-limited health systems, underscoring the importance of context-specific specification and tailoring to address structural and policy barriers distinct from those in high-income settings [64]. Consistent with this theoretical framing, the barriers identified in the present study were shaped primarily by system-level regulatory and structural constraints within China's HMS, leading to prioritization of system-level and inter-organizational ERIC strategies over those commonly emphasized in Western contexts. By explicitly linking CFIR-identified determinants to contextually adapted ERIC strategies, this study underscores the importance of selecting implementation strategies based on the level at which barriers operate. This theory-informed, context-sensitive approach informed the study's emphasis on feasibility and implementation processes rather than clinical performance outcomes alone.

The need for such implementation-focused research is particularly urgent in China, where structural imbalances within the HMS continue to place substantial pressure on tertiary hospitals. According to the Statistical Bulletin on the Development of China's Health Sector released by the National Health Commission, outpatient and emergency visits to tertiary hospitals rose from 2.06 billion in 2019 to 2.63 billion in 2023, a 27.7% increase over four years, indicating a sustained upward trend [65,66]. In contrast, patient volume at primary health care institutions has remained relatively stable [67], underscoring the continued underutilization of lower-tier facilities and a growing imbalance in resource allocation. To address these structural inefficiencies, the implementation strategies proposed in this study focused on enhancing diagnostic capacity at the secondary care level and reducing unnecessary reliance on tertiary hospitals.

Furthermore, inadequate referral mechanisms remain a major challenge in China's HMS [10,68,69]. A cost-effectiveness analysis of AI-assisted screening for diabetic retinopathy in community health centers in China underscored the pivotal role of referral adherence in determining the overall value of AI-based telemedicine screening [70]. The results indicated that, in the absence of improved follow-up among patients with suspected disease, the adoption of AI tools might offer no significant advantage over manual grading in telemedicine screening, as reduced long-term effectiveness and health utility would offset potential cost savings. The persistence of inadequate referrals partially reflects systemic challenges such as fragmented health information and the lack of standardized referral protocols [71-73]. These systemic gaps could compromise continuity of care, delay timely diagnosis and treatment, and reduce the overall efficiency of health care delivery [74,75]. In recent years, the application of digital tools to referral processes has shown promise in addressing these challenges by facilitating data integration and strengthening communication between institutions [76,77]. Building on this evidence, the current study integrated the ESDR platform into the referral process, which facilitated more efficient data exchange, reduced delays, and enhanced the scalability of referral pathways in lower-tier health care settings. Additionally, the patient-centered design of the referral process helped reduce administrative, logistical, and financial burdens associated with repeated patient registration and diagnostic procedures, promoting timely and high-quality care.

Taken together, the integrated implementation strategies developed in this study reinforced the role of AI in supporting stratified care within China's HMS. Within this framework, community and secondary hospitals are empowered to perform initial AI-assisted screenings to identify suspected or high-risk cases, which are subsequently referred in a timely and structured approach to collaborating tertiary hospitals for further evaluation and treatment. This allows tertiary hospitals to focus their resources on complex and critical cases, while lower-tier institutions effectively manage less severe conditions. The resulting model of decentralized screening and streamlined referral enhances patient flow across care levels, improves the responsiveness of service delivery, and ensures the timely transition of patients to appropriate levels of care. By enhancing clinical workflow efficiency and improving the use of health care resources, this approach contributes to a more functional HMS and facilitates the delivery of care that is well-coordinated, timely, and equitable across different levels of the health care system.

However, several barriers were identified that might hinder the broader effectiveness and scalability of the implementation strategies. Notably, 14.4% of cases were not analyzed by the AI software, a gap that appeared to be primarily attributable to operational and workflow-related factors rather than algorithmic limitations. These factors may include interruptions in data transmission, timing mismatches between image acquisition and AI processing, and clinician-driven decisions not to activate the AI tool in specific clinical scenarios. In addition, data incompleteness emerged as a major challenge, as only 28% of referral records contained all required information. Missing data were especially prevalent in key fields, including clinical symptoms, diagnostic conclusions, and insurance information. Poorly structured or incomplete referral documentation has been reported as a main barrier to effective communication and care coordination across different tiers of health care institutions in China [77]. These gaps would impede the clinical capacity of physicians at the tertiary hospital to perform comprehensive clinical assessments, potentially affecting diagnostic accuracy. This finding was consistent with previous studies that have emphasized the ongoing fragmentation of HISs in China, frequently functioning in isolation due to the absence of standardized data standards and limited interoperability across institutions [78,79]. Further, disruptions to routine clinical workflows were commonly reported as a main barrier to the effective adoption of digital health innovations [80-82]. Due to administrative constraints, data security concerns, and technical limitations, the ESDR platform could not be integrated with existing hospital systems (eg, HIS and PACS) and was deployed on a public cloud. As a result, clinicians were required to manually navigate multiple platforms, increasing operational complexity and workload. To address these challenges, future efforts should focus on enhancing the interoperability and operational efficiency of interhospital data exchange systems through seamless integration [78,83,84]. Such interoperability

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would reduce the operational burden associated with navigating multiple systems and manual data entry, while enhancing the accuracy, completeness, and timeliness of data transmission. Additionally, there is an urgent need for continued examination to determine the adaptability, effectiveness, and long-term sustainability of implementation strategies across diverse health care settings [85]. Such evidence is essential for supporting the widespread, equitable, and context-specific integration of AI technologies into routine clinical practice and for fully realizing their potential to improve diagnostic accuracy, streamline care coordination, and enhance overall health system performance.

Limitations

This study had several limitations that should be addressed in future research. The implementation was conducted in a single urban setting in Beijing, involving one secondary and one tertiary rehabilitation hospital, and focused exclusively on pulmonary nodule screening. Although the findings offered clinically relevant insights into the feasibility and potential refinement of implementation strategies, the complexity of other health care settings, such as community health centers or rural clinics, and the applicability to different disease domains remains insufficiently addressed.

In addition, this study did not include a formal organizational-level cost analysis. Although conducted in a real-world clinical environment, the implementation represented an early-phase deployment in a resource-constrained secondary hospital, supported through research collaboration and vendor participation. Under these transitional conditions, short-term cost estimates would be unlikely to reflect routine, institutionally financed adoption. Moreover, key cost drivers, including long-term maintenance and system integration costs, changes in personnel workload, and downstream effects on referral patterns and health care utilization, require longer follow-up periods and more stable operational contexts to be meaningfully assessed.

Further, the single-center, pre-post study design limited the ability to fully account for temporal confounding and restricted external validity. Although the preimplementation and postimplementation periods were matched by calendar months to minimize seasonal variation, unmeasured temporal factors, such as changes in patient characteristics, institutional practices, or broader system-level influences, may still have affected the observed outcomes. Moreover, as the current study primarily focused on feasibility and areas for implementation optimization, both short-term and long-term sustainability were not evaluated. To improve generalizability and strengthen internal validity, future research should adopt multicenter, prospective study designs incorporating concurrent control groups and consider Type II hybrid implementation-effectiveness approaches to enable simultaneous evaluation of implementation outcomes, clinical impact, cost-effectiveness, and long-term scalability of AI-assisted diagnostic software.

Conclusion

This study developed and evaluated an integrated strategy to support the effective implementation of AI-assisted diagnostic software for pulmonary nodule screening in a secondary hospital in China. The findings demonstrated enhanced screening capacity, referral efficiency, and interhospital coordination, highlighting the potential of AI to strengthen the hierarchical health care delivery model. As an early-phase implementation study, these results should be interpreted as preliminary and should primarily be used to inform and refine the proposed implementation strategies. To support future scalability and real-world impact, targeted actions are needed, including promoting standardized interfaces between HISs and third-party platforms to improve interoperability, strengthening governance mechanisms for secure data sharing, and optimizing referral workflows across care levels. Together, these measures offer a practical pathway toward a more precise, efficient, and sustainable health care system, while contributing to more equitable allocation of medical resources. Future research should prioritize multicenter studies and long-term evaluations to inform the broader adoption of AI technologies across diverse clinical settings.

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Data Availability

Datasets and study protocol are available upon reasonable request by contacting the corresponding author.

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Authors' Contributions

XL, CY, and DC conceptualized the study. All authors contributed to the development of implementation strategies and the deployment of the implementation pathway. Y Tang, Y Li, YF, DZ, ZZ, Y Lun, SW, LC, QW, and HZ were actively involved in the implementation process. Y Tian, YC, XS, and YZ participated in data acquisition, preparation, and collection. XL conducted statistical analysis and drafted the initial manuscript. CY and DC provided critical revisions and overall supervision. All authors reviewed and approved the final manuscript. DC is the guarantor of the study, with full access to all data and final responsibility for the decision to submit the manuscript for publication. CY is a co–corresponding author and can be reached via email at yaochen.pucri@foxmail.com.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Consolidated Framework for Implementation Research-Expert Recommendations for Implementing Change mapping process and results.
[DOCX File, 21 KB - formative_v10i1e76002_app1.docx]

Multimedia Appendix 2
Functionalities of the artificial intelligence–assisted diagnostic software.
[DOCX File, 2465 KB - formative_v10i1e76002_app2.docx]

Multimedia Appendix 3
Physician questionnaire.
[DOCX File, 18 KB - formative_v10i1e76002_app3.docx]

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Abbreviations

AI: artificial intelligence
CFIR: Consolidated Framework for Implementation Research
CT: computed tomography
ERIC: Expert Recommendations for Implementing Change
ESDR: electronic source data repository
HIS: hospital information system
HMS: hierarchical medical system
PACS: picture archiving and communication system

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Optimizing Hospital Discharge Planning: Empirical Insights and Requirements of AI-Based Technologies From an Explorative Mixed Methods Field Study

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Abstract

Background: Discharge planning (DP) is crucial for care continuity after a hospital stay but remains complex due to organizational constraints, interprofessional coordination, and administrative demands. Despite ongoing digitalization efforts, many health technologies overlook the sociotechnical nature of discharge processes, limiting acceptance and integration into clinical workflows.

Objective: This study aimed to examine real-world DP practices in 2 German university hospitals, identify user-centered needs, and derive design implications for responsibly integrating artificial intelligence (AI)–based systems into DP.

Methods: A mixed methods field study was conducted combining qualitative and quantitative approaches. In the qualitative phase, DP employees participated in workshops (n=33). Additionally, expert interviews were conducted with 2 physicians and 3 nurses (n=5). Activities explored understanding of AI, challenges in DP workflows, and best-case process scenarios; existing processes were collaboratively modeled to identify potential intervention points for technological support. Transcripts were analyzed inductively following Mayring's qualitative content analysis. Quantitative data were collected through a standardized questionnaire (n=23), focusing on workload distribution, process inefficiencies, and openness to using AI in the DP context. Descriptive statistics were used to identify high-burden segments. Findings were integrated through methodological triangulation.

Results: Persistent challenges emerged in interdisciplinary communication, documentation practices, and information continuity. Participants expressed uncertainty about the value of AI in DP, emphasizing the need for transparency, explainability, and role alignment. Questionnaire data confirmed bottlenecks in information transfer and high administrative workload. Design requirements for future systems include process transparency, support for coordination tasks, and adaptability to clinical roles.

Conclusions: DP is a sociotechnical process in which human expertise and organizational context must guide system design. Participatory, context-aware design approaches are essential for integrating AI into clinical practice. Aligning technology with everyday workflows can increase acceptance and yield more effective digital interventions.

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KEYWORDS

care transitions; artificial intelligence; human-centered design; health technology design; discharge planning; mixed methods

Introduction

Overview

Western health care systems are facing increasing pressure due to demographic change, rising number of patients with multimorbidity, workforce shortages, and growing cost burdens [1,2]. One area particularly affected by these developments is the transition from inpatient care to aftercare. In this context, discharge planning (DP) plays a central role. DP refers to the structured assessment of posthospital care needs and the coordination of appropriate medical, nursing, rehabilitative, and psychosocial services to ensure continuity and safety across care sectors [3-5]. As treatment pathways become more complex and patient needs more individualized, effective DP requires close interprofessional collaboration and timely access to accurate information [6].

When DP is insufficient or delayed, the consequences can be significant. For patients (especially older adults and those with cognitive or functional limitations), this may result in fragmented care, deterioration of health status, or avoidable rehospitalizations. At the system level, poor DP contributes to increased readmission rates, higher caregiver burden, and additional strain on outpatient and community-based services [7,8]. A structured and well-coordinated approach to DP is therefore essential for ensuring integrated and patient-centered care.

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In response to these challenges, Germany has introduced a comprehensive legal framework mandating DP as a core component of inpatient care. The foundation for this was established in § 39(1a) of the Fifth Book of the German Social Code (SGB V), which governs statutory health insurance and health care provision in Germany, and strengthened through subsequent reforms, including the Act to Strengthen Care in Statutory Health Insurance, German health care reform law enacted in 2015 to improve care continuity. A national framework agreement further operationalizes these requirements by defining procedural standards, early needs assessment, and patient involvement across the hospitalization process. Hospitals are thus obligated to ensure timely coordination of follow-up services and continuity of care, with compliance regularly reviewed through quality assurance mechanisms.

Despite these regulatory advances, DP in practice remains highly variable and shaped by organizational constraints, staffing limitations, and heterogeneous documentation and communication practices. In many cases, workflows rely heavily on professional experience, informal coordination, and manual information transfer. Against this backdrop, digital tools and artificial intelligence (AI)–based systems are increasingly discussed as potential means to support DP by improving documentation efficiency, data availability, communication, and planning accuracy [9-11]. However, although digital technologies are gaining attention in DP, research on AI-based tools in this context remains limited, particularly regarding their meaningful integration into everyday clinical practice. This gap has led to targeted funding initiatives from the Federal Ministry of Health (Federal Ministry in Germany responsible for health care policy and public health regulation) and the Federal Ministry of Research, Technology and Space (Federal Ministry in Germany responsible for supporting research, technology, and aerospace initiatives) promoting research on AI in clinical practice [12].

User-centered and participatory approaches are considered essential for the successful development and adoption of care technologies [13]. Yet, only a minority of AI projects meaningfully involve clinical end users in early design phases [14], in part because effective participation requires both technological transparency and context-sensitive design processes [15]. This study addresses these gaps by examining DP as experienced by health care professionals in 2 German university hospitals. We analyze how discharge processes unfold in practice, which organizational and communicative challenges shape them, and which forms of digital or AI-based support could meaningfully address these challenges. Based on a mixed methods approach, we derive user-centered design requirements for the responsible and context-aware integration of AI into DP.

Background and Related Work

Research on DP has used a wide range of methodological approaches to understand its clinical and organizational complexity. Quantitative studies have primarily evaluated the effectiveness of DP interventions in terms of measurable outcomes such as readmission rates, length of stay, and mortality [16]. Meta-analyses indicate that structured communication interventions at discharge can reduce 30-day readmissions [17], and systematic DP is associated with reductions in length of stay and readmission rates for certain patient groups [16].

Complementing these findings, qualitative studies have highlighted the social and organizational challenges of implementing DP in daily practice. Reported barriers include limited standardization, inconsistent communication across professional groups, and time pressure [18]. Across multidisciplinary teams, unclear roles and fragmented information flows are frequently cited as central constraints [19].

In parallel, technological approaches such as machine learning and AI are increasingly being explored to support DP. Machine learning models have been developed to predict discharge destinations [20,21], and neural network–based tools are being tested to support discharge decision-making [22,23]. Large language models are also being evaluated for automating or simplifying clinical documentation [24,25]. While these tools show potential for improving patient flow and reducing administrative burden, robust evidence for their clinical efficacy remains limited. Only a small number of systems currently achieve reliable, automated discharge prediction at scale [22].

A notable gap in the literature is that most existing work remains primarily quantitative and outcome-oriented, focusing on predictive accuracy rather than everyday implementation contexts. Studies incorporating the perspectives of clinical staff are comparatively rare, despite the fact that DP operates across social, organizational, and bureaucratic interfaces. Mixed methods research that integrates process understanding with performance outcomes therefore remains limited [26]. Furthermore, while patient experience has received increasing attention, less is known about how digital and AI-supported tools can be designed to meet the needs of the professionals who carry out DP [16].

Given that DP is a cross-sectoral, relational, and dynamically negotiated process, user-centered research is essential for developing digital systems that support, rather than disrupt, clinical workflows. This study addresses this gap by examining DP as practiced in daily work and deriving design implications for AI-supported tools directly from the perspectives of DP professionals.

Methods

Study Design

This study used a mixed methods design with participatory elements to identify user-centered requirements for AI-supported tools in DP. The mixed methods approach was chosen to capture both the sociotechnical and procedural dimensions of DP, recognizing that digitalization efforts often foreground technical implementation while the organizational and social contexts of work remain underexamined.

The study design followed the GRAMMS (Good Reporting of a Mixed Methods Study) framework for mixed methods research [27] and drew on selected MMR-RHS (Mixed Methods Reporting in Rehabilitation & Health Sciences) criteria [28]. The qualitative and quantitative strands addressed

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complementary aspects of the same research question. The qualitative strand (priority strand) focused on the organizational realities of DP, including communication structures, professional roles, and perceived challenges in daily practice. The quantitative strand extended these insights by examining (1) the distribution of administrative, coordinative, and documentation-related tasks; (2) satisfaction with procedural aspects of DP; and (3) expectations and concerns regarding the integration of AI-based systems into clinical workflows.

Data collection proceeded in a partly sequential and partly concurrent manner. Participatory workshops and interviews were conducted first to surface practice-relevant themes, followed by a standardized questionnaire administered immediately afterward to confirm and broaden the emerging patterns. This sequencing allowed the quantitative data to extend the qualitative insights while ensuring that both strands addressed shared conceptual domains. The integration of both strands occurred during the interpretation stage to develop metainferences about DP practices and potential technological support. Details of the analytic procedures and integration approach are described in the "Data Analysis" section.

In accordance with current reporting guidelines, we disclose that generative AI was used to assist in creating a flowchart illustrating the DP process. All prompts and AI outputs related to the flowchart creation are documented in Multimedia Appendix 1 for transparency.

Setting

Both sites are maximum care providers (*Maximalversorger*). This designation identifies institutions that can provide the highest level of care available in Germany. The classification is based on factors including bed capacity and scope of services offered.

- *Hospital A* (*2023*): A total of 1352 beds; >30 clinics and institutes; and 44,176 inpatient, 5489 day-case, and 318,097 outpatient cases. DP is organized under the nursing directorate with 2 units (social services and care transition).
- *Hospital B* (*2023*): A total of 1306 beds; 40 clinics and 34 institutes; and 54,757 inpatient, 2040 day-case, and 459,752 outpatient cases. DP is organized under the medical directorate with 2 professional groups (social service and case management) working in clinic-assigned teams.

Both hospitals operate heterogeneous, multivendor IT environments spanning administration, imaging, documentation, patient flow, and DP. Each site uses specialized software for case management and for identifying or arranging postacute providers, reflecting the fragmented and interoperability-constrained IT landscape typical of German hospitals (see Textboxes 1 and 2 for DP consulting areas) [29].

Textbox 1. Consulting areas of the departments in discharge planning of hospital A.

Department social service

- Medical and other rehabilitation measures.
- Social law matters.
- Inpatient care.
- Financial aid options.
- Counseling centers—therapeutic services.
- Discussion opportunities in the areas of coping with illness, future prospects, partnership and family, and social and professional environment.

Department care transition

- Advice on long-term care insurance.
- Advice on medical aids and support in their provision.
- Advice on the use of an outpatient care provider.
- Handover of necessary activities to an outpatient care provider.
- Provision of specialized outpatient palliative care and hospice registration.
- Neighborhood assistance.
- Meals and Wheels.
- Emergency call system.
- Home Care Tuesday.
- Referral to other counseling centers or care centers.

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Textbox 2. Consulting areas of the departments in discharge planning of hospital B.

Department social service

- Support in initiating rehabilitation measures.
- Support in arranging assistance in everyday life.
- Social law matters.
- Financial aid options.

Department case management

- Coordination in interdisciplinary service provision.
- Application for a care level.
- Advice and mediation of rehabilitation measures.
- Organization of nursing services to care for patients at home.

Participants and Recruitment

Participants were professionals involved in DP at 2 German university hospitals. A total of 33 nonmanagerial DP staff members took part in the workshops, and 23 of them completed a standardized questionnaire administered immediately afterward (69% response rate). Recruitment for the workshops and questionnaire was coordinated by the on-site researcher (NVG). Managers were contacted via email, introduced to the project through a brief presentation, and asked to indicate interest. Workshops were scheduled during working hours based on staff availability.

To incorporate additional clinical perspectives, semistructured interviews were conducted at hospital A with physicians and nursing staff using convenience sampling within the on-site researcher's professional network. Five physicians and 5 nurses were invited, of whom 2 physicians and 3 nurses participated (response rates: 40% and 60%). No interviews were conducted at hospital B due to the absence of an on-site researcher during the data collection period.

Demographic details (eg, age, gender, and specialty) were not collected to maintain confidentiality, given the small size of DP teams (approximately 15 - 20 staff per site), in accordance with ethics committee and works council requirements. Table 1 provides an overview of data collection methods, duration, and participant groups.

Table . Overview of data collection methods, duration, and number of participants according to university hospital.

Method	Duration	Participants, n
Workshop (hospital A)	2-hour sessions, 4 hours in total	14
Workshop (hospital B)	4 hours	19
		Total = 33
Questionnaire (hospital A)	15 minutes	8
Questionnaire (hospital B)	N/A[a]	15
		Total = 23
Interviews (hospital A)	Range 30-55 minutes; average 44 minutes	2 physicians; 3 nurses
		Total = 5

[a]N/A: not applicable.

Data Collection

A multimethods design was used, combining qualitative (workshops and semistructured interviews) and quantitative (standardized questionnaires) data collection.

Qualitative Data Collection

Qualitative data were gathered through participatory workshops with DP staff to identify challenges, needs, and expectations in everyday practice. Each workshop followed a structured, 3-phase format guided by open-ended questions to promote discussion and reflection. The sessions aimed to (1) explore participants' understanding of AI in health care, (2) assess perceived opportunities and limitations of AI in DP, and (3) collaboratively map both the current and an ideal (best-case) discharge process.

At hospital A, eight 2-hour sessions were conducted over 4 weeks (July-August 2023), with each participant attending 2 consecutive sessions. At hospital B, two 4-hour sessions were held on consecutive days in July 2024, adjusted to staff availability. Each workshop included (1) an introduction and warm-up task exploring participants' experience with AI, (2) a collaborative stakeholder and process mapping exercise, and (3) a discussion on potential technological entry points and

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influencing factors. Discussions were moderated by researchers and documented using flip charts, Post-it notes, and photographs.

Semistructured interviews with physicians and nurses complemented the workshops to capture additional clinical perspectives. Interviews lasted 30 - 55 minutes and followed a predefined guide. Sample questionnaires are provided in Multimedia Appendices 2-4. All workshops and interviews were audio-recorded using a ZOOM H5 device and transcribed verbatim for analysis.

Quantitative Data Collection

A standardized questionnaire was administered at both hospitals, covering domains related to workload distribution, satisfaction with procedural aspects of DP, and attitudes toward AI-based support. Items were rated on a 5-point Likert scale (1=strongly disagree to 5=strongly agree) and included open-ended questions. The questionnaire was identical across both sites and distributed in paper form immediately after the workshops. In line with the exploratory and iterative design of this study, the initial questionnaires (developed in 2023) were intentionally broad to capture a wide range of aspects related to DP. At that early stage, the aim was to map the field rather than to test predefined hypotheses. A sample questionnaire is provided in Multimedia Appendix 5.

Data Analysis

Qualitative data from the workshops and semistructured interviews were fully transcribed and analyzed using the software MAXQDA (VERBI). Following Mayring's [30] approach to qualitative content analysis, we applied inductive category development to derive themes grounded in the data. Coding proceeded iteratively, with categories refined through comparison across both hospital sites and professional roles. The coding system is included in Multimedia Appendix 6. A tabular overview of coded segments can be viewed in Multimedia Appendix 7. An overview of statements sorted by workshops is provided in Multimedia Appendix 8. The analysis focused on identifying recurrent patterns related to communication structures, role distribution, workload organization, and perceived opportunities and limitations for AI-supported tools. All qualitative data were collected in German. For publication, excerpts were translated into English by bilingual members of the research team, prioritizing conceptual accuracy over literal phrasing.

Questionnaire responses were analyzed descriptively (proportions and percentages) to identify salient issues. For this paper, only those items that conceptually aligned with themes emerging from the qualitative strand were retained for the integrated content analysis (workload distribution and satisfaction with procedural aspects of DP). Items that were unrelated to these integrated findings are not reported here, as they fall outside the analytical scope of this publication but remain part of the broader dataset.

The qualitative and quantitative strands were merged during the interpretation phase through methodological triangulation [31]. This integration enabled comparison of qualitative themes with quantitative indicators to assess convergence and divergence, supporting the development of context-sensitive design requirements for AI-supported systems in DP.

Ethical Considerations

This study was reviewed and approved by the Ethics Commission II (Heidelberg University, Medical Faculty of Mannheim) under reference number 2023 - 523. A subsequent review was obtained from the Ethics Commission for the second participating clinic (University Clinic Bonn) under reference number 246/23-EP. In addition, approval was granted by the local Works Council of both participating institutions. All procedures were conducted in accordance with the ethical standards of the participating universities, the Declaration of Helsinki, and relevant national legislation. Written informed consent was obtained from all participants prior to their inclusion in the study. Participants did not receive any financial or material compensation for their participation. No patient data were collected in this study. Data collection was limited to health care professionals participating in workshops, interviews, and questionnaires. No personally identifying clinical or patient-related information was recorded. All study data were handled in accordance with applicable data protection regulations. Written informed consent forms were stored separately from the research data in locked cabinets at the respective study sites. Audio recordings and transcripts were anonymized prior to analysis, and all digital data were stored in anonymized form only. Access to the data was restricted to members of the research team.

Results

Quantitative Data

Questionnaire items that conceptually corresponded to the qualitative themes were analyzed and are reported here. Data are reported descriptively without inferential testing owing to the small sample size and the exploratory character of the study. Items outside this analytical focus are not presented, as they did not contribute to the integrated interpretation. Tables 2 and 3 provide an overview of the use of working time spent on documentation and coordination as well as satisfaction with procedural aspects of DP, respectively.

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Table . Reported proportion of working time spent on documentation and coordination activities (n=22 for item 5, n=23 for item 6).

Item ID	Question (English translation)	0% - 25%	26% - 50%	51% - 75%	76% - 100%
5	What percentage of your working time do you spend on documenting information in order to determine the need for aftercare?	6	8	4	4
6	What percentage of your working time do you spend consulting with other staff members to coordinate patient treatment and aftercare?	5	13	4	1

Table . Response distribution for selected items on time, communication, and coordination in discharge planning (N=8).

Item ID	Question (English translation)	Strongly agree, %	Agree, %	Neutral, %	Disagree, %	Strongly disagree, %
1	Is the time you have for discharge planning often too short?	25	75	—[a]	—	—
2	Do you think that the discharge planning usually runs smoothly?	—	—	—	75	25
9	Does communication with other staff members (physicians and nursing staff) work well during discharge planning?	—	25	—	75%	—
10	Do you receive timely feedback from other staff members (physicians and nursing staff) when something changes in the transition planning?	—	12.5	—	75	12.5
12	Do you have enough time to plan the transition to aftercare?	—	12.5	—	87.5	—
13	Do you receive discharge notifications too late?	25	50	—	12.5	12.5

[a]Not available.

Response options indicate the estimated proportion of working time spent on the respective activities (0% - 25%, 26% - 50%, 51% - 75%, and 76% - 100%). Data are reported as counts (n) to avoid confusion with percentage-based response categories. Responses are from hospital A and hospital B. Questions are originally in German. Most respondents reported spending between 26% and 50% of their working time on documentation related to determining aftercare needs (8/22, 36%) and a similar share on coordination with other staff (13/23, 56%). Only a few indicated spending more than 75% of their time on either activity. The percentages represent the distribution of responses on a 5-point Likert scale (1=strongly disagree, 5=strongly agree). Responses are from hospital A only. Questions are originally in German. Descriptive frequencies showed agreement that the

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time available for DP was insufficient (100% agreement; item 1) and disagreement that DP runs smoothly (100% disagreement; item 2). Similar patterns of disagreement were observed for items on communication and feedback (items 9 and 10).

Integrated Content Analysis

Three thematic areas emerged from the analysis: (1) aspects describing the structure of the DP process (process description), (2) factors influencing its success (success factors), and (3) derived implications for the design of AI-supported tools in DP (core requirements). These 3 areas will be outlined in detail in the following section. Textbox 3 provides an overview of the main findings.

Textbox 3. Overview of main themes derived from the integrated content analysis.

Process description

- Initiating discharge planning (DP).
- Needs assessment and initial contact.
- Counseling and psychosocial intervention.
- Information from patients and clinical staff.
- Discharge planning.
- Implementation of DP measures.
- Final coordination and discharge preparation.

Success factors

- Staffing and personnel availability.
- Completeness and timeliness of information.
- Departmental and professional practice.
- Time constraints and deadlines.
- Documentation and consent processes.
- Changing individual care needs.
- Availability of aftercare services.

Core requirements

- Communication and notification.
- DP and aftercare planning.
- Data management and documentation.
- Needs assessment and responsibility clarification.

Process Description

Participants described the DP process as a reactive and highly individualized response to the situational demands of daily hospital operations. According to their accounts, the implementation of DP often depends heavily on the expertise, experience, and judgment of the individual staff members involved.

> *There is a process description for how discharge planning is supposed to work in theory, but in practice it deviates quite a lot. There is no single standard that everyone follows, and nothing like a 'light' version either. Much of the procedure is passed on orally. It lives in our heads and you have to learn it over time. I have a sort of process map in my mind: when a case comes in, I know at which points certain decisions need to be made and what comes next. But that depends very much on the information we receive, and often, that information is incomplete. So, we frequently have to fill in gaps or cover tasks from other departments before we can even begin our part of the process.* [Participant, Workshop 1, Hospital A]

Although a standard for DP is provided by the German Network for Quality Development in Nursing (DNQP), it primarily defines general phases and criteria rather than prescribing a concrete procedural framework. DNQP is a German network that develops expert standards to promote quality improvement in nursing practice [32]. While widely recognized and used as a reference in quality assurance, the DNQP standard remains advisory rather than legally binding, offering guidance rather than strict regulation. Moreover, neither the legal frameworks defined in the introduction nor the internal organizational guidelines provide a detailed, binding sequence of steps. Instead, certain key objectives such as timely DP, interdisciplinary coordination, and continuity of care must be achieved. These

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pillars aim to ensure legal compliance while allowing for flexible adaptation to the individual needs of patients.

In light of this flexibility, and in agreement with participants, the decision was made to present a best-case scenario for DP as there is no universally standardized process across departments. This model is grounded in shared structural elements and clearly defined steps, forming a general process framework that supports effective and patient-centered DP. Beyond its descriptive function, the model serves as a design-oriented artifact: it captures practitioners' normative expectations of how DP should function under optimal conditions. As such, it provides a valuable reference point for identifying friction points in current practices and for mapping potential entry points for AI-supported interventions. This best-case framing allows for a participatory, practice-based foundation to guide system design in line with real-world workflows and professional logics. The following sections outline the key components of this idealized model. A best-case process model can be found in Multimedia Appendix 9.

Initiating DP

The DP process typically begins with a clinical referral issued by medical staff. This involves formally requesting the services of the hospital's DP team to coordinate necessary postdischarge care. A referral is made when a medical, therapeutic, or nursing need for aftercare has been identified. According to the DNQP standard, a criteria-based initial assessment must occur within 24 hours of assuming responsibility for the patient's nursing care. This is usually performed by medical or nursing staff and serves as the formal prerequisite for initiating DP. Referrals may be issued by nursing staff, physicians, or directly by patients or their legal representatives. In practice, however, this process often deviates from the standard due to time constraints, limited systematic assessments during admission, and insufficient interdisciplinary communication.

> *At this point, we're simply relieved when we receive a notification from the nursing team at all. We no longer focus on what is written in the referral. We just hope it comes in on time. Too often we find out only the day before discharge, when we're told, "Oh, we forgot. The patient is leaving tomorrow and still needs several things arranged."* [Participant, Workshop 1, Hospital A]

Once a need for aftercare is identified and a referral is made, patients or their legal representatives are informed and receive counseling. Written consent is required to proceed, and no further steps may be taken without it. Even in cases of objective need, not all patients choose to participate. Once consent is provided, a detailed needs assessment follows.

Needs Assessment and Initial Contact

At this stage, the social services and nursing transition teams assess the patient's individual aftercare needs. This involves reviewing the medical record and conducting a personal conversation with the patient or relatives to gather contextual information on the home environment, care situation, available resources, and support systems. To plan appropriate aftercare, DP staff require comprehensive insights into the patient's broader living context. Textbox 4 outlines key categories of discharge-relevant information.

Textbox 4. Key types of discharge-relevant information as reported by participants during workshops and interviews.

- Contact details for patients and their relatives.
- Information on legal capacity and cognitive impairments.
- Existing levels of care and current care needs.
- Language or communication barriers.
- Living and care arrangements prior to hospital admission.

Among these, contact information is particularly crucial for enabling communication. Early clarification of legal competence and cognitive capacity is also important. Ideally, communication challenges such as hearing or speech impairments are identified early. If a care dependency level was previously established, it should be documented at admission to streamline planning. The DP team also consults with physicians and nursing staff to estimate the discharge date and assess the need for follow-up services. A commonly used assessment tool is the Barthel Index, which evaluates a patient's ability to perform basic activities of daily living and supports care planning. The Barthel Index is often applied in rehabilitation and geriatric care settings [33].

Counseling and Psychosocial Intervention

Once initial needs are identified, patients and, if applicable, their relatives receive comprehensive counseling about planned measures and available support services. This includes both medical or nursing and psychosocial considerations. The goal is to jointly develop a realistic and sustainable care plan. If necessary, psychosocial interventions such as crisis counseling or referrals to support services are initiated.

Information From Patients and Clinical Staff

Close coordination with the medical and nursing teams is essential, especially when assessing therapeutic needs and defining the discharge timeline. The Barthel Index continues to play a supporting role in this phase. For planned interventions, patients may be contacted prior to admission to identify support needs early.

> *Having the correct contact details is really important. Sometimes we end up playing detective, searching for phone numbers in other places. We may call someone listed as a relative and then realize it's an ex-partner or someone completely different. That can lead to very uncomfortable situations.* [Participant, Workshop 5, Hospital B]

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Discharge Planning

Based on the data gathered, an individualized discharge plan is developed. This includes the patient's care needs, living situation, and available resources. On average, plan preparation takes 6 hours per patient, although this varies with case complexity. The objective is to ensure a seamless transition and initiate necessary follow-up measures in a timely manner.

Implementation of DP Measures

In this phase, the planned measures are implemented in collaboration with other stakeholders. Textbox 5 outlines the key practical steps.

Textbox 5. Key steps in implementing discharge planning as reported by participants during workshops and interviews.

- Completing and submitting applications to cost bearers.
- Forwarding relevant documents to physicians.
- Sending requests to aftercare providers and other service organizations (eg, rehabilitation clinics and outpatient nursing services).
- Procuring medical equipment and supplies.
- Requesting and processing insurance approvals.

Timelines for these steps depend on insurance type, case complexity, and local care infrastructure. For patients residing farther from the hospital, planning often starts earlier. Ultimately, the discharge process is influenced not only by procedural tasks but also by the patient's health status and personal preferences, requiring a high degree of coordination and adaptability.

Final Coordination and Discharge Preparation

Once all measures are initiated, a final coordination is conducted among stakeholders. At this point, inquiries to care providers have been sent, necessary applications submitted, and, where possible, cost approvals obtained. Patients and families are thoroughly briefed on the discharge date, aftercare arrangements, and the next steps. This ensures a well-coordinated and needs-oriented transition and minimizes uncertainty at the point of discharge.

Factors Influencing the Success of DP

Multiple factors shape the success of DP in practice. Table 4 outlines these factors with examples.

Table . Factors influencing the success of discharge planning and implications for technology design.

Factor	Example/description	Technological implication
Staffing and personnel availability.	Staff shortages and high caseloads require workflow prioritization and can lead to placeholders (eg, "1234") in software systems, necessitating retrospective data collection and additional coordination.	Systems should support workload balancing, task automation, and asynchronous collaboration.
Completeness and timeliness of information.	Needs assessments are not always systematic. Incomplete or delayed data require follow-up, prolong processing times, and may trigger care plan revisions.	Data validation and completeness checks should be embedded early in the workflow.
Departmental and professional practice variations.	Planning practices differ across departments. While some units begin early with standardized procedures, others (eg, surgical oncology) engage in planning only postdischarge. This heterogeneity complicates coordination.	Adaptive interfaces and modular workflows can accommodate heterogeneity while promoting best practices.
Time constraints and deadlines.	Legal and contractual obligations impose strict timing. Short notice discharges or complex cases require particularly proactive coordination.	Artificial intelligence–driven scheduling and prioritization tools can support deadline compliance.
Documentation and consent processes.	While patient consent is a formal prerequisite, it is not always consistently documented. Some patients are registered for follow-up care without a thorough needs assessment, leading to potential plan adjustments later.	Intelligent workflows should include reminders, status tracking, and plausibility checks.
Changing individual care needs.	Patient needs, especially in geriatric care, can shift during hospitalization. Continuous reassessment and flexible coordination are necessary.	Systems must support flexible updates and real-time documentation to reflect patient trajectories.
Availability of aftercare services.	Regional capacity limitations, particularly in rehabilitation, pose significant planning challenges. Long wait times and lack of preregistration options often require last-minute adjustments.	Integration with real-time availability directories and decision support for service matching is needed.

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Core Requirements for Technologies

The primary goal of DP professionals is to provide personalized, needs-based aftercare. Achieving this requires a comprehensive, up-to-date, and easily accessible information base. The entire discharge process hinges on the availability, quality, and timeliness of data. In this context, digital documentation and communication systems, especially when enhanced with AI, can play a crucial role in supporting this goal. Based on our findings, the following section outlines specific requirements for the design and implementation of such technologies in DP.

Communication and Notification

In terms of communication and notifications, hospital staff expressed a strong interest in AI-based support in general. One central need is automated alerts about critical developments in a patient's treatment journey. This includes transfers, death, unplanned surgeries, or changes in surgical schedules. To tailor information flows to individual roles, staff should be able to personalize notification settings. AI could also be used to remind physicians of outstanding test results and automatically send those results, as well as other key documents such as prescriptions, to the relevant stakeholders. Our participants reported the particular importance of an automatic alert when a patient's Barthel Index changes, helping ensure that shifts in care needs are promptly addressed.

> *Once patients are discharged, they are no longer actively tracked in the system, even though we are often still working on their rehabilitation planning. For that, we frequently need medical reports. But physicians may not see these requests because they no longer reopen the digital record after discharge. An AI system could help by flagging this, for example, by notifying physicians: "Attention, reports still need to be completed."* [Participant, Workshop 5, Hospital B]

Patients could also benefit from automated reminders, both for initiating DP early and for upcoming appointments. A particularly innovative idea was the conversion of voicemail messages into text, delivered directly to staff email inboxes. This could significantly reduce time spent fielding routine inquiries via phone. AI could also sort incoming phone calls and DP requests by topic, enabling staff to respond more efficiently. Another promising feature would be the automatic routing of DP requests to the appropriate team or department, including forwarding relevant documents following contact with family members.

Staff also highlighted the need for automated alerts in cases where cost approvals for rehabilitation are still pending, a common bottleneck in the process. AI could also enhance transparency for patients and families by summarizing consultation discussions in writing, providing easy-to-understand takeaways. Similarly, sending automated introductory information could help reassure patients early in their stay. AI-generated reminders for appointments and tasks could also bring more structure to daily workflows. Additionally, AI systems could ensure that required documents are always current and help prepare consultation materials based on individual patient risk profiles.

Discharge and Aftercare Planning

Staff see significant potential for AI to improve discharge and aftercare planning by streamlining and targeting key processes. One major function would be the automated search for appropriate and available home care providers or nursing home placements. While software catering to this need exists, it is often dependent on licensing so that not all providers are listed. An automatically generated, continuously updated overview of available providers from freely available internet data would save staff time and effort both in research and in outreach.

Identifying aftercare needs early, especially for planned surgeries, was seen as vital for ensuring smooth transitions from inpatient treatment to posthospital care. AI could analyze individual needs from the data in electronic health records, suggest appropriate providers, show their availability, and even contact the relevant insurers. Ideally, this process begins automatically when the patient is first admitted, with AI refining its recommendations as clinical documentation progresses. This kind of autonomous planning could significantly reduce the administrative burden on staff. AI could also generate clinical orders automatically, either based on predefined criteria or upon staff request, provided all necessary information is available and there is a clear medical justification.

Error prevention was another important focus reported by our participants. AI systems should be able to detect and prevent duplicate discharge registrations for the same patient. Similarly, they should limit multiple or conflicting selections when specifying aftercare providers to avoid confusion and delays. The system should also flag unusual case types, for example, when patients younger than 65 years are registered for long-term care facilities. It could also ensure that document requirements for different stakeholders (such as payers or doctors) are kept up to date.

Data Management and Documentation

Staff also saw major opportunities for AI in improving data handling and documentation, ensuring that all required information is complete before initiating that DP is a key concern. AI could validate this automatically before allowing the process to proceed. To reduce repetitive work, the system should be able to transfer previously collected data when patients are readmitted. This would not only save time but also minimize errors from manual data entry. Similarly, AI could prefill or complete forms and applications using existing patient data.

> *With rehabilitation applications, I usually don't carry the forms with me because I don't know yet whether the patient actually wants or needs them and I don't want to waste paper unnecessarily. It would be very practical to have a solution that allows me to access and complete those forms directly on the ward, as needed.* [Participant, Workshop 6, Hospital B]

Another helpful feature would be automatic documentation such as logging when documents are issued. This would ensure a complete and traceable discharge process across different team members. Standardized text templates could also speed up routine documentation tasks such as report writing or formal communication. A concrete example is the automated generation

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of the Barthel Index when a DP order is initiated. To improve process quality, access to the patient record could be restricted unless the Barthel Index is present. This would help ensure that essential information is not missing. Staff also advocated for plausibility checks, particularly for the discharge report. AI could detect implausible entries and prompt users to review them. Likewise, the system should be able to verify whether cases marked as "urgent" actually meet the defined urgency criteria.

Needs Assessment and Clarification of Responsibilities

In the area of needs assessment and responsibility allocation, staff emphasized the value of AI in improving both efficiency and the quality of care. One core function would be the automatic identification of needs for medical aids. Based on patient data, AI could generate tailored suggestions and show which items are covered by insurance and available at local suppliers.

Automatically identifying the responsible payer would also reduce administrative effort and ensure a smooth flow of information. When planning rehabilitation, AI should also flag potential issues, such as homelessness or addiction, that might complicate discharge or exclude patients from certain programs. "If a physician selects both inpatient and outpatient care, the system should immediately block that. You should only be able to choose one or the other" (Participant, Workshop 6, Hospital B). Similarly, the system could enforce required isolation protocols and detect communication barriers, such as hearing loss or cognitive impairments. Automated reminders could help ensure that no essential information (eg, sensory or cognitive status) is overlooked.

Clarifying responsibilities within the hospital itself was another key area. AI could use existing data to assign cases to the right professional group or department and register patients accordingly. This would promote interdisciplinary collaboration and timely action. To further improve communication, AI could support needs assessment and automatically share relevant updates between social workers, patients, and their families via email. This would help ensure that everyone stays informed, while fostering transparency, participation, and mutual commitment.

Table 5 summarizes the key technological requirements identified in this study, directly addressing the main challenges influencing the success of DP. The requirements are organized to reflect how specific technological solutions can mitigate obstacles in communication, planning, data handling, and responsibility allocation. Requirements are derived from the integrated content analysis and categorized by the researchers.

Table . Derived categories from technological requirements addressing key discharge planning challenges.

Category	Core requirements for technology support
Communication and notification	• Automated alerts for patient events (eg, transfers, deaths, and surgery changes). • Personalized notification settings for staff. • Reminders for outstanding test results and cost approvals. • AI[a]-based sorting of phone calls and DP[b] requests. • Automated patient communications (eg, appointment reminders and consultation summaries).
Discharge planning of aftercare	• Early identification of follow-up care needs. • AI-assisted search for home care providers and nursing facilities. • Automated creation of clinical orders based on defined criteria. • Error prevention (eg, duplicate registrations and conflicting follow-up provider selections).
Data management and documentation	• Validation of data completeness before initiating DP. • Automatic transfer of existing patient data for readmissions. • Prefilling forms and applications. • Logging document issuance and using standardized text templates. • Automatic generation and validation of Barthel Index.
Needs assessment and responsibility clarification	• Automated identification of medical aid needs. • Detection of barriers (eg, homelessness, addiction, and communication impairments). • Automatic assignment of cases to appropriate departments or professional groups. • AI-supported communication between social workers, patients, and families.

[a]AI: artificial intelligence.

[b]DP: discharge planning.

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Integration of Findings

The integration of qualitative and quantitative findings provided a more comprehensive understanding of DP practices. The qualitative data offered detailed insights into contextual mechanisms such as communication barriers, unclear responsibilities, and workflow interruptions. The quantitative results quantified the extent of these issues within the participating hospitals. For example, the high administrative workload frequently mentioned in workshops was reflected in the survey, where most respondents reported spending over half of their time on documentation and coordination tasks. Similarly, the qualitative emphasis on time pressure and limited standardization corresponded with lower satisfaction scores in the questionnaire regarding the adequacy of time and clarity of procedures. Together, these converging findings strengthen the interpretation that the challenges in DP are both systemic and measurable, and that improving information flow and responsibility structures should be a central focus in the design of AI-supported solutions.

Discussion

Principal Findings

This study aimed to explore structural challenges in DP and to identify context-specific requirements for AI-supported systems from the perspectives of health care professionals, patients, and relatives. The findings show that current DP practices are characterized by limited standardization, fragmented responsibility structures, and disrupted information flows. These challenges are primarily systemic rather than individual in nature and shape both the perceived need for digital support and the conditions under which AI-based solutions may be meaningfully integrated into clinical practice.

This study examined the structure and success factors of DP as well as the potential of AI-supported systems to assist this process. The results indicate that current DP practices rely heavily on individual expertise and situational decision-making and show limited standardization in the collection and documentation of patient data. At the core of the identified challenges are deficits in responsibility structures, documentation, and information flow—findings that indicate systemic weaknesses and align with previous studies [5,34].

Systemic and Structural Challenges

Interpreting these findings, the data suggest that the observed difficulties in DP are not attributable to individual shortcomings but reflect broader structural fragmentation and insufficient interoperability within the German health care system. These findings are consistent with previous studies that describe DP as being hindered by fragmented responsibilities, insufficient information flow, and limited interoperability despite existing regulatory frameworks [5,34]. The multitude of involved stakeholders (hospital staff, external care providers, insurers, and patients or relatives) makes consistent information flow difficult. Despite existing regulatory frameworks (eg, DNQP), concrete procedural guidelines are lacking, resulting in uncertainty regarding responsibilities and coordination between the professions involved. This structural ambiguity means that the quality of DP largely depends on individual competence and experience instead of standardized, technology-supported procedures.

Role and Requirements of AI-Based Technologies

Against this background, it becomes evident that AI-supported systems are not merely technological additions but can potentially assume a structural function within DP. The application areas identified in the study (communication and notification, planning, data management, and needs assessment) show that AI is suitable for addressing key bottlenecks at the microlevel. The discussion differentiates the specific functional requirements in the following sections.

Technological Distinction (AI Versus Classical IT Systems)

Many of the proposed functions, such as automated alerts, configurable notification systems, or the forwarding of documents, do not necessarily require AI. They can also be implemented through rule-based logic in existing hospital information systems, electronic health records, or middleware solutions (“if A, then B”). However, the study shows that the practical reality in the examined health care institutions is characterized by fragmentation and limited interoperability: multiple parallel software solutions (nursing documentation, case management, billing, aftercare coordination, etc) rarely communicate seamlessly with one another [29]. Even when individual systems theoretically offer notification features, their usefulness remains limited without integration. Against this backdrop, the identified problem of insufficient digital documentation of patient data further exacerbates the issue and suggests that a solution should target the level of existing software systems.

AI becomes particularly relevant where pattern recognition, prediction, or context-dependent decisions are required, for example: (1) prioritization of alerts (“Which events are truly critical?”), (2) adaptive notification systems (“Who should receive information, depending on the case context?”), and (3) semantic data integration (“Recognition of similar cases or relevant aftercare providers across heterogeneous systems”).

In this sense, AI is not primarily the base function but a mechanism for intelligent networking, prioritization, and integration of existing systems.

Communication and Notification

A recurring problem lies in delayed or interrupted information flows. Automated alerts about relevant changes in patient status, personalized notification systems, and the integration of voice-to-text functions could directly address these deficits. In particular, the automatic forwarding of relevant documents or reminders about pending test results to the responsible person was described by respondents as practical reliefs. Intelligent integration into existing systems could increase responsiveness of the DP team and close information gaps between professional groups.

DP of Aftercare

Automating the search for aftercare providers and generating suggestions based on clinical documentation illustrate the

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potential to simplify complex coordination tasks. Adaptive systems that continuously integrate relevant data during treatment can prepare the discharge process early. This can bring efficiency gains and support error reduction through standardized plausibility checks and provide cognitive relief for staff involved in the process.

Data Management and Documentation

Redundant data entry and incomplete documentation burden staff and delay processes. This knowledge has been confirmed in other literature [21]. AI-supported mechanisms such as automatic completeness checks, prefilling of forms, or standardized report texts can save time and improve documentation quality. The ability to accelerate readmissions through data transfer highlights this potential. At the same time, the results emphasize that technological systems must be integrated into existing hospital IT infrastructures to be effective. These observations reinforce existing evidence that redundant documentation and incomplete data entry are major contributors to inefficiencies in discharge processes [21], while further illustrating how automation and AI-supported checks could mitigate these issues in practice.

Needs Assessment and Responsibilities

AI can identify risks or needs at an early stage and automatically assign cases to the appropriate professional groups. Automatic detection of rehabilitation needs, medical aids, or social risk factors could support in preventing bottlenecks and clarify responsibilities while also increasing transparency.

Social and Cultural Prerequisites

Despite the potential, the introduction of AI-based systems and their acceptance by staff remain challenging. Employees expressed both openness and skepticism toward digital support, particularly regarding learning effort, the adaptation of work routines, and possible loss of control. This ambivalence points to cultural dynamics: a strongly profession-oriented work culture, high demands for autonomy, and limited management strategies for digital transformation [29,35]. AI systems must therefore be not only technically compatible but also socially integrative, meaning that they must respect and support existing work logics. By empirically grounding these dynamics in the context of DP, the study contributes to existing discussions on why digital transformation efforts in hospitals often encounter resistance despite perceived usefulness.

Implications for the Design of Digital Systems

Participatory design processes are crucial: end users, especially nurses, social services, and physicians, must be involved early in the development process. Systems must be intuitive to use, transparent, and operable with minimal training effort. Technical prerequisites such as fully digitalized hospital infrastructure and interoperable data systems form the foundation for successful implementation.

In line with prior research on digital transformation in health care, the findings underscore that AI-based systems unfold their potential only when aligned with organizational structures, professional cultures, and interoperable infrastructures. This study demonstrates that technological innovation in DP can be effective only when embedded within organizational, infrastructural, and cultural contexts. Beyond identifying specific functional requirements, the findings underscore the importance of sociotechnical alignment as a prerequisite for sustainable digital transformation in health care. AI can standardize processes, improve information flows, and automate routine tasks, but it does not replace professional judgment or interpersonal care. Rather, it enables professionals to focus more on patient-centered tasks. Without simultaneous consideration of infrastructural, organizational, and cultural prerequisites, even technically advanced AI systems risk failing to unfold their potential in DP. These aspects are central to the successful implementation of AI-supported systems in DP.

Limitations

This study has several limitations. Participation among health care professionals was constrained by staffing pressures and clinical workload, which limited the number of interview and workshop participants. While common in applied hospital research, these conditions also reflect the environments in which AI-supported DP tools must ultimately operate. Additionally, a limited sample size and single-site interview data restrict representativeness across professional roles and institutions. The findings should therefore be interpreted as context-specific, offering in-depth, practice-based insights rather than generalizable results. The quantitative survey primarily complemented the qualitative data; 1 domain (satisfaction with procedural aspects of DP) was collected at only 1 site due to ethical constraints. The study prioritized contextual understanding over statistical breadth. While the findings are not generalizable to all hospital environments, they extend sociotechnical and technology acceptance perspectives by empirically linking organizational context, workload structures, and attitudes toward AI-enabled DP.

Future Work

Future research should differentiate between AI functionalities that are technically feasible within current hospital IT infrastructures and those requiring broader organizational or regulatory development. While features such as automated alerts, structured documentation, and notification systems can be implemented under existing conditions, more advanced applications such as predictive matching or adaptive prioritization depend on improved data interoperability, AI maturity, and clear governance frameworks. Additionally, investigations into operational outcomes such as time-to-discharge or readmission rates would provide important evidence of real-world impact. Future evaluation studies, ideally linked to pilot implementations, should include such indicators to measure the effectiveness of AI-supported systems. Although this research was conducted in the German health care context, challenges such as fragmented communication and limited digital integration are common across Western health care systems. Comparative studies could examine how these findings translate to other national and organizational settings, supporting the development of context-sensitive strategies for integrating AI into discharge management.

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Conclusions

This study highlights the complex challenges health care professionals face in coordinating seamless transitions from hospital to aftercare. Despite established standards and regulatory frameworks, DP remains dependent on individual expertise, ad hoc coordination, and the timely availability of information. The findings identify clear opportunities for AI-supported tools, particularly in improving communication, data integration, documentation, and individualized care planning. However, success depends on robust digital infrastructures and high-quality, interoperable data. AI systems that automate administrative tasks and improve access to case-relevant information can alleviate workload and enhance the efficiency and accuracy of discharge processes. Crucially, this allows health care professionals to focus more on patient-centered tasks that require empathy, judgment, and interpersonal care. Future development should emphasize participatory design and real-world evaluation to ensure that digital innovations genuinely enhance continuity of care, staff experience, and patient outcomes.

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Data Availability

The tabular evaluation, an overview of the main statements of each category, and the coding system generated during the analysis are available in JMIR Data. Workshop and interview transcripts are not publicly available due to the small sample size and sensitive nature of topics discussed. Transcripts can be accessed through the corresponding author upon reasonable request and in accordance with institutional and ethical guidelines.

Authors' Contributions

JS contributed to conceptualization, methodology, formal analysis, data curation, writing—original draft preparation, and writing—review and editing. NVG participated in the investigation, methodology, writing—extensive review and editing, and critical revisions. HB participated in project administration and funding acquisition. CK participated in project administration, funding acquisition, writing—final review and editing, and conceptual input.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Disclosure of artificial intelligence usage.
[PDF File, 146 KB - formative_v10i1e81824_app1.pdf]

Multimedia Appendix 2
Interview guide for physicians.
[PDF File, 31 KB - formative_v10i1e81824_app2.pdf]

Multimedia Appendix 3
Interview guide for nurses.
[PDF File, 31 KB - formative_v10i1e81824_app3.pdf]

Multimedia Appendix 4
Interview guide for senior physician.
[PDF File, 97 KB - formative_v10i1e81824_app4.pdf]

Multimedia Appendix 5
Questionnaire used.
[PDF File, 256 KB - formative_v10i1e81824_app5.pdf]

Multimedia Appendix 6
Coding system.
[PDF File, 145 KB - formative_v10i1e81824_app6.pdf]

Multimedia Appendix 7
Tabular overview of coded segments.

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[PDF File, 710 KB - formative_v10i1e81824_app7.pdf]

Multimedia Appendix 8
Overview of statements sorted by workshops.
[PDF File, 504 KB - formative_v10i1e81824_app8.pdf]

Multimedia Appendix 9
Flowchart of the discharge planning process.
[PDF File, 29 KB - formative_v10i1e81824_app9.pdf]

Checklist 1
Checklist for GRAMMS (Good Reporting of a Mixed Methods Study).
[PDF File, 62 KB - formative_v10i1e81824_app10.pdf]

Checklist 2
Checklist for MMR-RHS (Mixed Methods Reporting in Rehabilitation & Health Sciences).
[PDF File, 793 KB - formative_v10i1e81824_app11.pdf]

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Abbreviations

AI: artificial intelligence
DNQP: German Network for Quality Development in Nursing
DP: discharge planning
GRAMMS: Good Reporting of a Mixed Methods Study

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MMR-RHS: Mixed Methods Reporting in Rehabilitation & Health Sciences
SGB V: Fifth Book of the German Social Code

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Help on Demand, a Self-Directed Mobile App Intervention for Gambling Problems: Development and Usability Study

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Abstract

Background: Compared with other mental health problems, self-directed interventions for gambling problems lack in quantity, accessibility, and in some cases, evidence base. Moreover, engagement with these interventions remains modest. Mobile apps may be a viable format to deliver self-directed interventions that enhance user engagement.

Objective: The aims of this study were to develop a self-directed mobile app intervention for gambling problems and to conduct initial feasibility and acceptability testing with a small sample of Canadian adults with past or present gambling problems (n=30).

Methods: Participants were invited via email from a list of people who had previously volunteered in similar research in our laboratory. Theory and content of the mobile app intervention were primarily based on a self-directed workbook that has been evaluated in paperback and static web-based formats. The current app prototype included daily gambling diaries, recommended activities based on diary responses, and psychoeducation. It was available for 2 weeks, after which users provided feedback via surveys (n=30) and a virtual focus group (n=8). Quantitative and qualitative feedback, as well as app usage data, were analyzed to provide descriptive statistics and summaries.

Results: Regarding feasibility, median completion time for activities ranged from 48 (IQR 35-90) to 137 (IQR 93-328) seconds. Daily diary completion rate was 51%. One-third of activities were accessed via prompt, and two-thirds on demand. Many participants repeated at least 1 activity, and all activities were repeated by at least 1 participant. Results also indicated favorable user reviews, particularly regarding the app's credibility, ease of use, and potential impact. The feedback on some app features was highly variable, such as the perceived utility of daily diaries. Specific recommendations for improvement were provided, such as the inclusion of information on concurrent substance use and more interactive psychoeducation.

Conclusions: Overall, the app met or exceeded heuristic thresholds for feasibility and acceptability testing. These results will inform improvements and subsequent effectiveness testing. The variability in user feedback underscores the demand for further personalization.

(JMIR Form Res 2026;10:e83430) doi:10.2196/83430

KEYWORDS

gambling; addictive behavior; ecological momentary intervention; just-in-time adaptive intervention; mobile app; telemedicine; self-help; self-directed treatment

Introduction

Background

Those who seek self-directed treatment for many mental health problems are spoiled for choice. In fact, there is so much choice for some disorders that treatment selection itself can be overwhelming [1]. Paper-and-pencil workbooks, web programs, and mobile apps permeate the self-help space, particularly for mood and anxiety disorders [2-4]. Generic mental health apps, including Headspace (Headspace Inc) and Calm (Calm.com, Inc), are also highly popular [5,6]. People with gambling problems are not nearly as well-supported in their specific needs, some of which are predominant in gambling, such as financial concerns. This gap is unfortunate, given that there is a high demand for self-directed gambling treatment. Most gamblers who attempt to change do so independently [7], and many prefer to use self-directed interventions for the privacy, ease of access, and ability to control their pace and level of engagement [8-11]. The current paper describes and contextualizes the development of a self-directed, tailored mobile app for gambling problems specifically designed to enhance user engagement.

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Evidence-based self-directed treatment for gambling problems first took hold in the 1990s and 2000s, mainly in the form of cognitive behavioral bibliotherapy [12]. In the 2010s, much of the same content was delivered via the web to expand accessibility and cost-effectiveness [13]. Multiple theories and treatment approaches were implemented in these resources, many of which were offshoots of cognitive behavioral therapy (CBT) or third-wave modalities. Newer technologies, like mobile apps, virtual reality, and artificial intelligence (AI), have become a central focus of self-directed interventions for gambling problems in the 2020s [14]. These emerging modes of delivery are especially promising because, in addition to offering all the benefits of 2010s-style web-based interventions, they increasingly permit tailored, responsive, and interactive content rather than static, generalized, or read-only resources. As it stands, however, very few evidence-based options are publicly available to treatment-seeking gamblers.

In a review, Merkouris [15] identified 6 evidence-based mobile apps for gambling problems. Most were based on preexisting paperback or web-based workbooks (eg, study by Dowling et al [16]). However, only 1 French-language app was publicly available. The most thoroughly researched app, GamblingLess: Curb Your Urge (Deakin University), specifically targeted transient gambling urges with an array of cognitive, behavioral, and mindfulness-based strategies [17,18]. Preliminary results indicated good acceptability and effectiveness, albeit low uptake and compliance. The same research group has published protocol papers for the development of similar mobile apps that vary in their intended audience [19-21]. Other mobile apps for gambling problems are publicly available, but most are solely abstinence-based and do not rely on a recognizable treatment model [22]. For example, most available apps consist only of an abstinence time tracker, while some also include reminder notifications and motivational quotes. Some newer apps contain gambling website blocking software, gambling-related information, and directories of external support services, but very few were developed in conjunction with people with lived experience [23]. Taken together, there are not many viable mobile apps that target gambling problems, but preliminary research on a select few is encouraging.

Perhaps the greatest challenge in offering self-directed interventions for mental disorders, including gambling problems, has been low user engagement [24]. Engagement in this context is often measured in terms of objective and subjective indicators of treatment use, such as the number of activities completed or ratings of subjective appeal [11,25]. Engagement is not simply adherence to an intervention, although adherence is often considered one piece of engagement [26,27]. Rather, engagement likely comprises a combination of behavioral, cognitive, and affective factors, including enjoyment, motivation, and perceived relevance [27,28]. Perski and colleagues [11] proposed that subjective and objective engagement is moderated by the content and delivery of the intervention, the real-world context of its use, and the behavior it targets. Treatment outcomes are, in turn, moderated by user engagement. The recent development of tailored and adaptive interventions has been, in large part, a response to the problem of low engagement by improving intervention content and delivery.

The problem of low user engagement has been underscored in the gambling field, as intervention usage data has revealed just how modest user engagement tends to be. In our recent trial of a static self-directed web program for problem gambling [29], we found that 41% (128/313) of participants did not complete any modules, but those who completed more modules experienced greater reductions in gambling problems. Similar findings were documented in our own past work [30] and that of others [15]. This general observation is somewhat surprising given how positively users rate such interventions, and how self-directed change directly addresses barriers to traditional face-to-face treatment, such as stigma and lack of privacy [9,10].

Study Objectives

The primary aim of this study was to contribute to the growing literature on evidence-based mobile apps for gambling problems by developing a personalized self-directed mobile app intervention grounded in content from our previously developed static workbook. The intervention was designed to facilitate greater engagement relative to static self-directed interventions by making the content more appealing and the delivery more responsive to individual needs. We aimed to conduct initial feasibility and usability testing with a small sample of Canadian adults with past or present gambling problems and solicit their feedback to inform subsequent improvements and testing. Given the formative nature of this research, effectiveness and longer-term engagement were not assessed at this stage.

Methods

Ethical Considerations

This study received ethical approval from the Conjoint Faculties Research Ethics Board at the University of Calgary (REB23-0794). This approval authorized participant recruitment, informed consent, collection and storage of app usage and survey data, and participation in a focus group on Microsoft Teams. Participants were remunerated with up to CAD $40 (US $29.46) in electronic gift cards for their participation. Deidentified data from Qualtrics, *MetricWire* (MetricWire Inc), and Microsoft Teams were stored separately from personally identifying information in an encrypted file.

Participants

Canadian adults with past or present gambling problems were recruited over 3 months via email contact from researchers. These email invitations were sent to 100 participants from a previous gambling self-help trial [29] who had volunteered to be contacted for future research. We received 71 responses to an eligibility survey on Qualtrics, of which 33 were eligible, consented, and enrolled. Participants were eligible if they resided in Canada, were aged 18 years or older, and scored 5 or greater [31] on the Problem Gambling Severity Index (PGSI) [32]. Those with past problems were asked to respond to the PGSI based on their gambling at the peak of their problem instead of the typical past-year time frame. This approach was used to ensure participants without current gambling problems previously had a problem severity consistent with the app's

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likely audience, that is, people with moderate to severe gambling problems [33].

Most of those excluded from this study were excluded because they did not complete the eligibility survey in full or did not respond to the initial email contact after they were found to be eligible. Furthermore, 3 participants were subsequently dropped because they did not create an account with the mobile app and did not respond to follow-up emails.

Procedure

Enrolled participants were emailed a link and brief instructions to download and register with the third-party app, labeled *Catalyst by MetricWire*, in the Apple App Store and Google Play Store. Users interacted with our intervention via the *Catalyst* mobile app on which the intervention was mounted. We selected this platform to host our intervention because it was used successfully by our colleagues to develop a similar gambling intervention in Australia [16,18].

Participants were not given specific instructions for engaging with the app content but were informed that it was still under development, and the researchers would be interested in their feedback. Participants had access to the app for 2 weeks, after which they completed a brief feedback survey on Qualtrics and were compensated with an electronic gift card valued at CAD $20 (US $14.73). Then, 8 participants were randomly selected via a random number generator and invited to participate in a focus group facilitated remotely by author BWB and 2 research assistants on Microsoft Teams. Focus group discussions used a semistructured interview guide (Multimedia Appendix 1) to elaborate on user experiences with the app as well as their quantitative feedback. Because of ethical constraints, participants' survey responses and focus group contributions were not linked to one another. Participants who provided written or oral feedback were compensated with an additional electronic gift card valued at CAD $20 (US $14.73).

Intervention

Theoretical Framework

The intervention was grounded in the transtheoretical model of behavior change [34,35], self-determination theory [36], motivational interviewing [37], and the CBT model of gambling [38]. The transtheoretical model informs on the process of change, self-determination theory and motivational interviewing on the motivations for change, and CBT on concrete strategies for change. Taken together, the intervention worked to elicit and strengthen intrinsic motivations, which are associated with an increased readiness for change and subsequent success [39]. Specific, practical, evidence-based strategies were offered to achieve self-determined goals. These strategies generally fell into the categories of stimulus control (eg, limiting access to gambling opportunities), behavioral activation (eg, replacing gambling with other activities), and cognitive-motivational (eg, reframing cognitive distortions, especially around risk and probability). Goal selection was also based on a harm reduction approach in that users could choose to maintain their current level of gambling, cut down in various ways, or quit completely. Evidence suggests that a pretreatment abstinence goal generally does not confer an advantage over moderation in terms of gambling treatment outcomes, although abstinence may be more popular among those with severe gambling problems [40].

Content Development

App content was primarily adapted from paperback and online versions of an original self-directed workbook, *Becoming a Winner: Defeating Problem Gambling* [41]. That workbook was grounded in the same theoretical framework as the current mobile app. Both the paperback and online versions have demonstrated effectiveness for treating gambling problems [29,30,42-46]. Additional educational content was added based on historical user requests for more audiovisual material, as well as evidence for newly developed *Lower-Risk Gambling Guidelines* [47]. The content of the final intervention prototype consisted of a daily check-in survey, 10 interactive activities, and 10 noninteractive educational resources.

App Features and User Flow

Immediately upon enrollment, users completed 3 brief mandatory assessments in the app—notification time preference, gambling self-assessment, and treatment goal selection. The display of those assessments is presented in Figure 1. Time preference referred to push notifications for the daily check-ins. The self-assessment contained the 9 PGSI items and specific feedback based on the calculated level of risk (Figure 2), which was intended to inform users when selecting a treatment goal. Goal options included abstinence, moderation, and maintenance. Those who chose moderation or maintenance were given several options for setting limits, such as limiting the number of gambling types or the amount of time or money spent over a specified time frame. These assessments could not be revisited, but users could reach out via email to the research team if they wished to have their responses changed.

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Figure 1. Intervention home page on the first day.

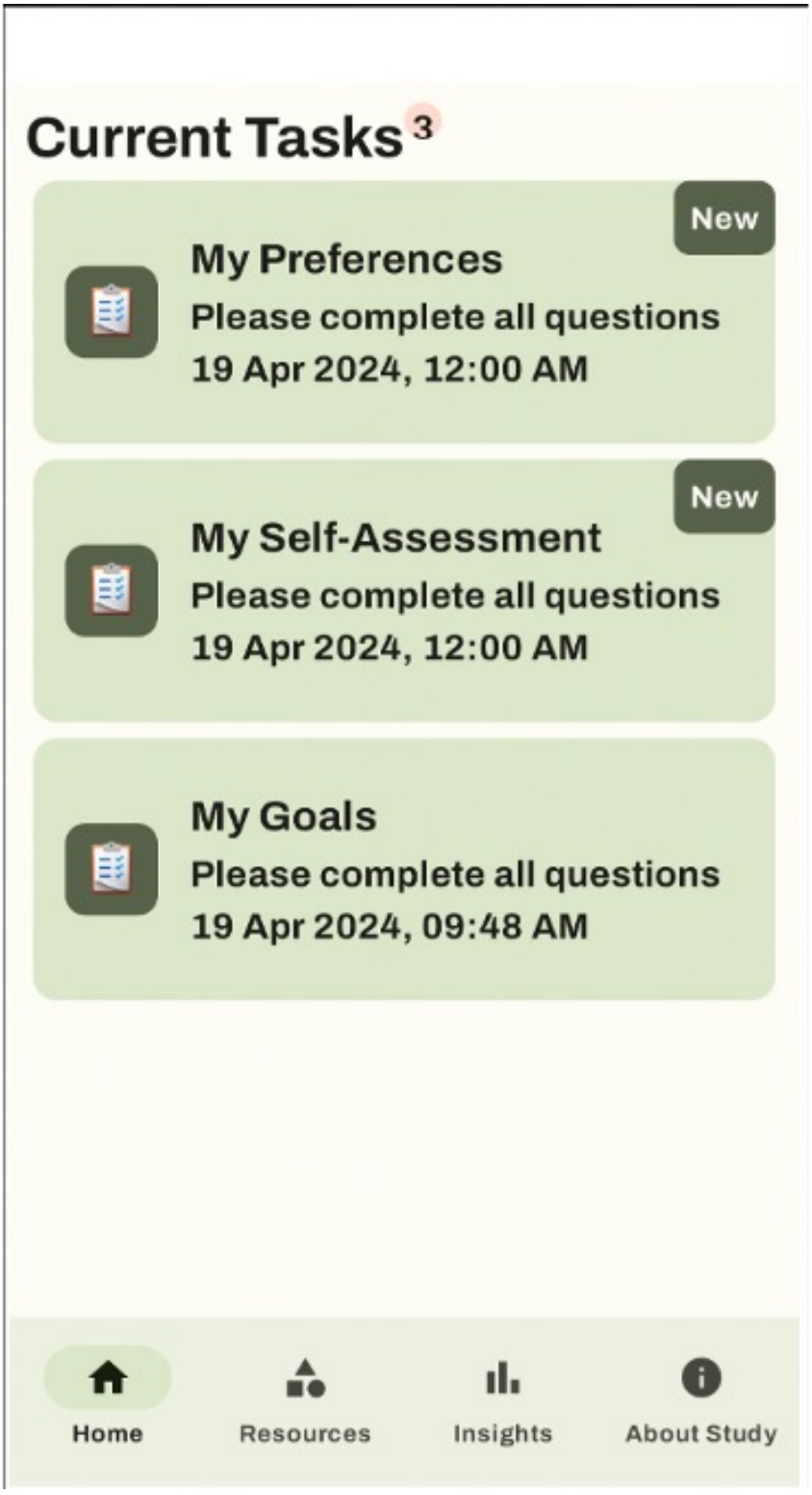

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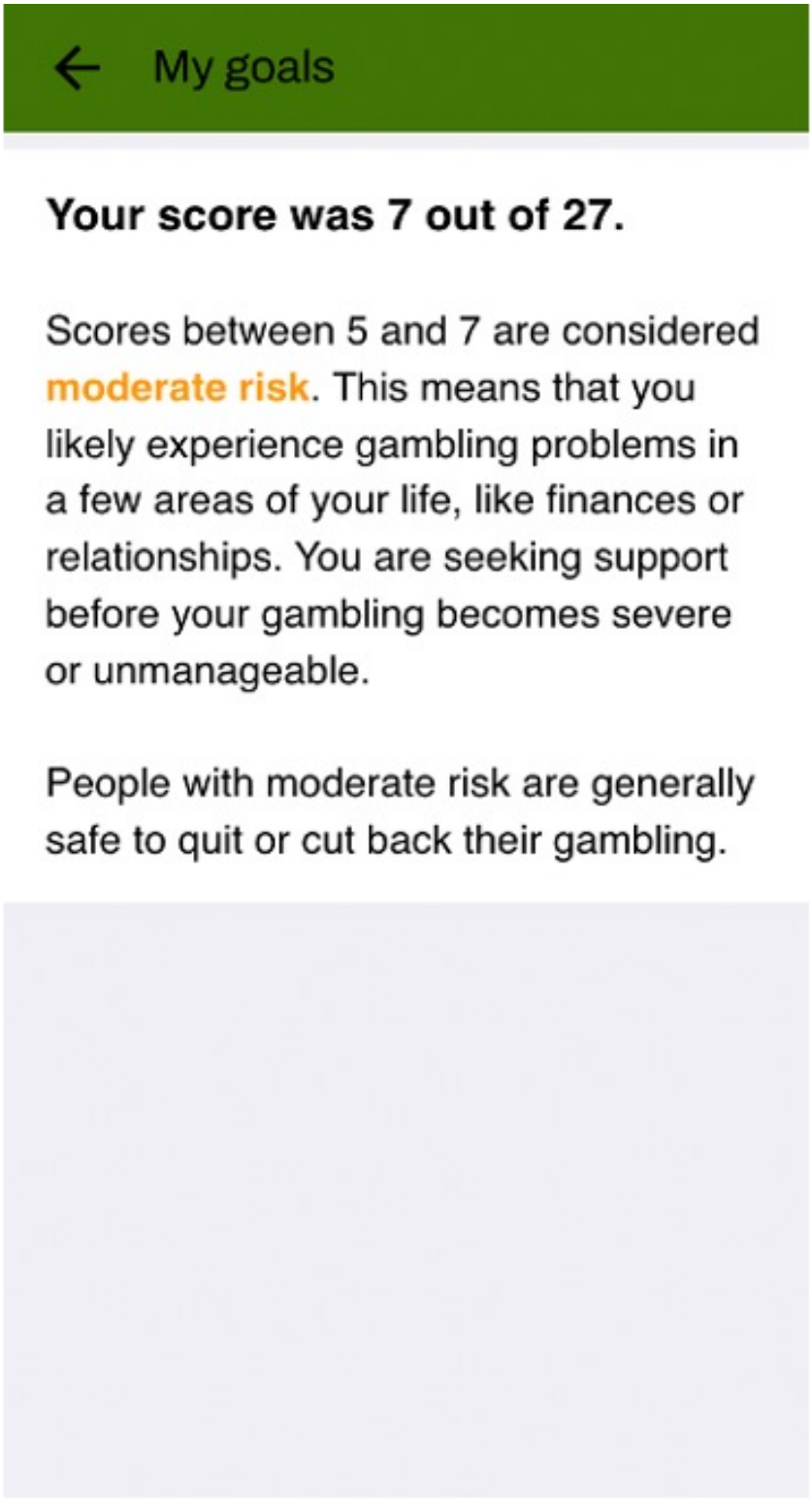
Figure 2. Sample self-assessment feedback.



Check-ins were prompted once daily via push notifications at the user-selected time. Each check-in began with a reminder of the user's treatment goal and queried whether the goal was met that day. Users then indicated how many minutes and dollars they gambled. Those who did not gamble were asked to rate their overall mood and gambling urges on 10-point scales based on the past 24 hours. Those who did gamble responded to analogous items that queried mood and urges just before gambling. Those who gambled were also asked to indicate relevant settings (eg, casino and online), types (eg, sports betting and slot machines), and motivations (eg, social and emotional) for their recent gambling. Personal data regarding gambling duration and expenditures were graphed in a separate tab within the app. In total, daily check-ins contained 4 questions for nongamblers and 10 for gamblers.

Over the first week, interactive intervention activities were triggered based on user responses to check-ins. These recommended activity prompts were delivered 5 minutes after

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the daily diary was completed. All activities, including untriggered ones, then became available in buffet style after the first week and could be completed as many times as desired and in any order. Each activity included multiple-choice and open-ended text responses. Refer to Figures 3 and 4 for sample responses in the thought record. Responses were then piped into a progress report on the final day. Furthermore, 5 noninteractive educational resources were also available immediately upon enrollment for the duration of the study. The remaining resources became available in the same manner as the interactive intervention activities (ie, based on diary responses in the first week, then available in buffet style in the second week). All app content is presented in Table 1.

Figure 3. Sample of the multiple-choice response options on the thought record.

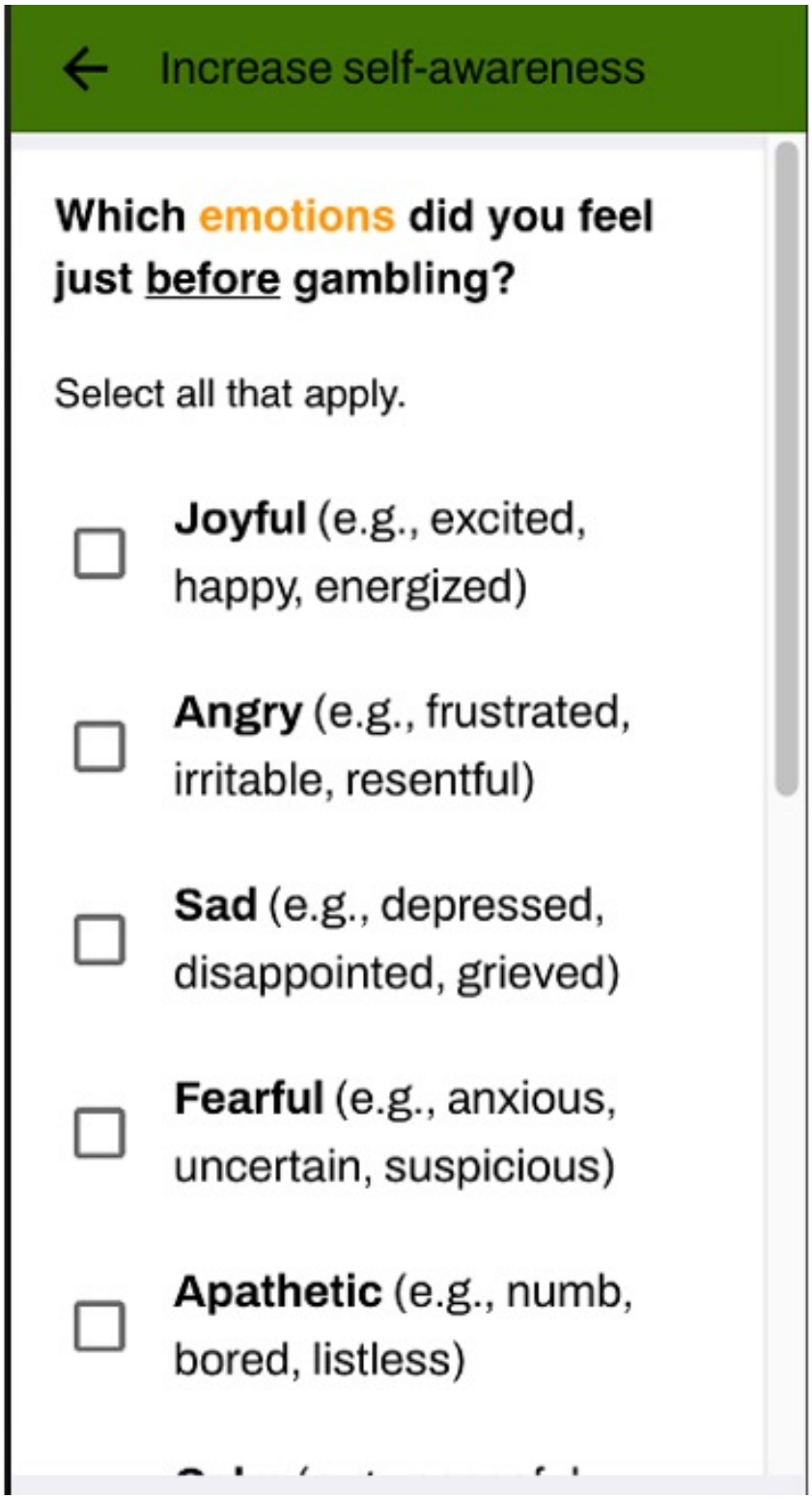

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Table . App content and delivery.

App component	Format	Delivery	Intention
Daily diary	Survey	Daily push notifications; on-demand view of expenditure graph	Permit routine self-monitoring; collect data for personalized graphs and activity recommendations
Notification preferences	Survey	Push notification upon enrollment	Assess preference for timing of daily diary push notification
Self-assessment	Survey	Push notification after completing notification preferences	Use responses to provide personalized feedback on gambling problem severity
Treatment goal selection	Survey	Push notification after completing self-assessment	Provide autonomy in goal selection
Thought record	Interactive activity	Push notification first time daily goal is not met	Identify cognitive and emotional antecedents to gambling
Gambling calendar	Interactive activity	Push notification first time daily duration exceeds 60 min	Calculate time and money spent gambling
Decisional balance exercise	Interactive activity	Push notification first day of gambling	Identify costs and benefits of gambling and not gambling
Values card sort	Interactive activity	Push notification first time goal is partially met	Clarify personal values to work towards
Motivation rulers	Interactive activity	Push notification third time goal is not met	Gage confidence, importance, and commitment to change, and identify what would make each stronger
Trigger identification and management	Interactive activity	Push notification first time a trigger is identified	Identify all triggers and reflect on how to manage them
Reflection on past behavior changes	Interactive activity	Push notification when no other activity is triggered	Identify transferable skills from past changes
Making amends with others	Interactive activity	Push notification first time gambling with others	Identify interpersonal harms from gambling and how to ameliorate them
Relapse prevention plan	Interactive activity	Push notification third time goal is met	Plan for future urges and triggers
Progress report	Personalized feedback	Push notification on last day of enrollment	View a summary of all text responses to activities
Gambling and the brain	YouTube video	Immediately available upon enrollment	Understand the neuroscience behind gambling
LRGGs[a]	Read-only web page	Immediately available upon enrollment	Familiarize with responsible gambling limits
LRGGs types of gambling	Read-only web page	Immediately available upon enrollment	Understand different types of gambling and the risk conferred
LRGGs gambling-related harm	Read-only web page	Immediately available upon enrollment	Understand types of gambling-related harm
Common cognitive distortions	Read-only article	Push notification one day after enrollment	Learn about gambling-related cognitive distortions (eg, gambler's fallacy)
Addictive features of gambling	Read-only article	Push notification three days after enrollment	Learn about addictive features of gambling games and venues (eg, losses disguised as wins)
Cognitive and behavioral coping skills	Read-only article	Push notification five days after enrollment	Refer to a list of coping skills used by past gamblers that helped them reach their goals
Urge surfing	Read-only article	Push notification first time urges rated 6/10 or higher	Learn how to manage urges mindfully
Strategies for limiting access to money and gambling	Read-only article	Push notification first day gambling in multiple settings	Identify strategies for limiting access (eg, voluntary self-exclusion)

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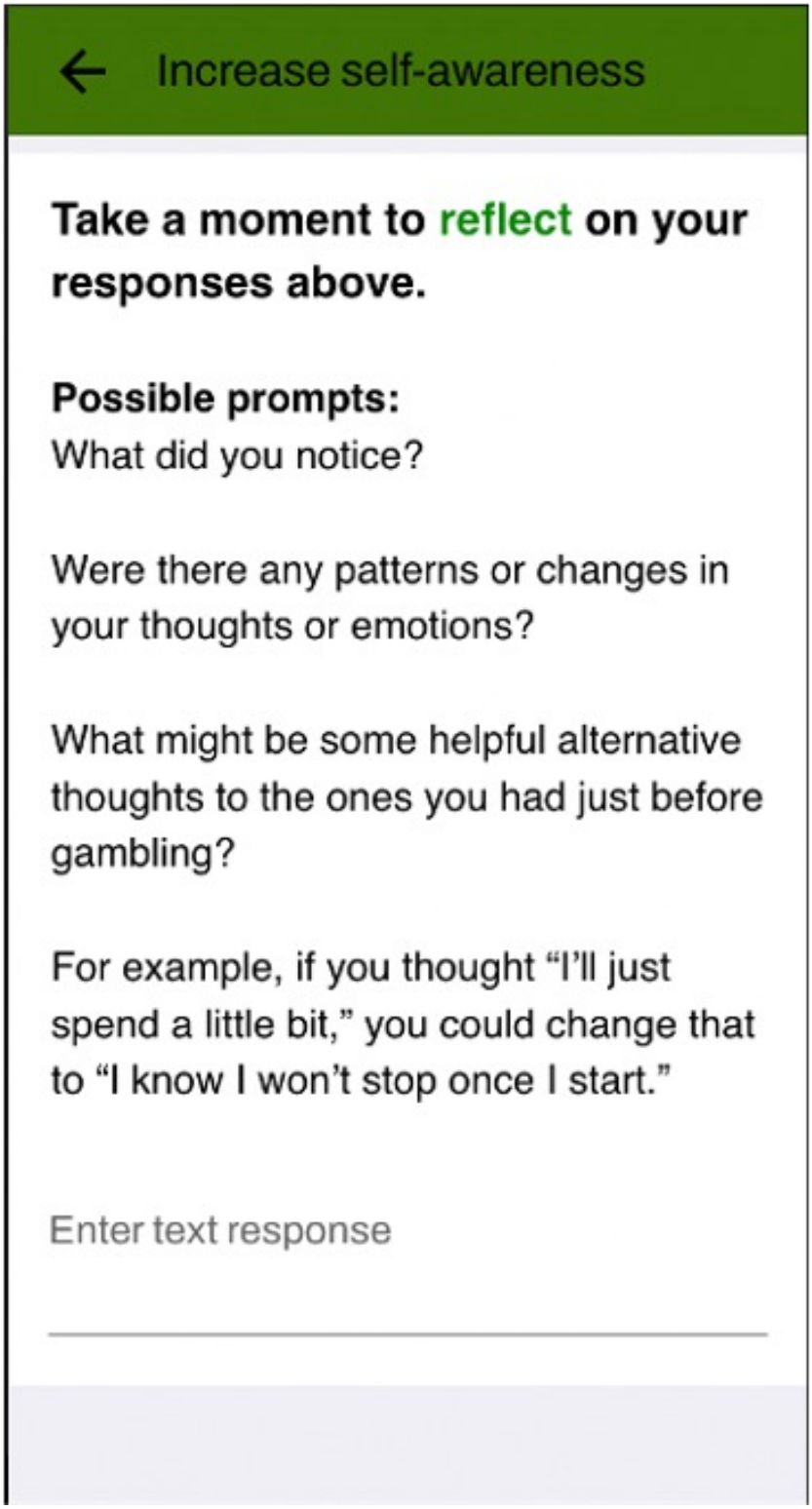
App component	Format	Delivery	Intention
List of resources and helplines in Canada	Read-only article	Immediately available upon enrollment	Connect with other resources when self-help is insufficient
App feedback	Survey	Push notification on last day of enrollment	Provide feedback on various app contents

[a]LRGG: Lower-Risk Gambling Guideline.

Figure 4. Sample of the open-ended response options on the thought record.



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On any given day except the final day, users received a maximum of 2 notifications. The first notification prompted the daily check-in, and the second one prompted 1 relevant activity or resource. If the push notification criteria for multiple activities or resources were met, only the first unseen activity or resource was prompted in order to cap the number of notifications per day. After 1 week, any remaining unseen activities or read-only resources became available. On the final day, after the progress report was viewed, users were prompted to rate each of the activities, resources, and other app features they engaged with throughout the study. They rated each activity and resource on a 4-point Likert scale from "not at all helpful" to "extremely helpful." Users were enabled to skip any rating if they did not complete the activity or view the resource.

Measures

User Feedback

On the postintervention Qualtrics feedback survey, participants completed the user version of the Mobile App Rating Scale (uMARS), which assesses user perceptions of the intervention's engagement, functionality, aesthetics, information quality, and subjective quality [48]. Mean subscale scores of 3 or greater are typically considered acceptable for recommending use with a target behavior [49]. Additional questions on the uMARS pertain to overall ratings, user likelihood of paying for the app and recommending it to others, projected use over the next year, and perceived impact on various aspects of behavior change (eg, increased knowledge of problem behavior or importance of behavior change). All 29 quantitative items on the uMARS are ranked on a 5-point Likert scale. The uMARS has demonstrated excellent interrater reliability and internal consistency (Cronbach α=0.90) [48]. We additionally asked users on the Qualtrics survey to rank order the most and least important features of the app.

App Usage Data

App usage data were automatically measured within the *MetricWire* platform. These data recorded which diaries and activities were completed and how many times, the duration to complete each activity and diary, and the delay between push notifications and app use. User device type (ie, Apple or Android) was also recorded.

Data Analyses

No generative AI tools were used in any portion of this manuscript, including the generation, analysis, or presentation of language, content, data, or references. Quantitative data were analyzed using R and RStudio [50]. Results include means and SDs for continuous data as well as counts and percentages for categorical data. There were no missing data on the PGSI or uMARS. App usage data were incomplete by design, as not all content was necessarily used by all participants, and some usage (eg, viewing read-only resources) could not be captured by the platform. Accordingly, analyses of app engagement were conducted using available-case denominators specific to each feature, and no imputation was performed.

Given the formative nature of this study, feasibility and acceptability were primarily evaluated with the uMARS. Consistent with previous use of the uMARS in early-stage app evaluations [49], mean subscale scores of 3 or greater out of 5 were treated as an acceptability heuristic rather than a hypothesis test. Engagement and adherence metrics were not prespecified as stop-go feasibility thresholds; instead, these metrics were summarized descriptively to inform targets for subsequent iterations. The primary metrics of interest were diary completion rate, activity completion rate, and median activity duration.

Qualitative survey data were subjected to a simple content analysis. Responses were reviewed line-by-line, and codes were inductively generated. Codes were then grouped into categories of feedback based on various app features, and minority views were retained. Coding was done by author BWB in consultation with the research assistants who cofacilitated the focus group. Survey data were analyzed separately from the focus group because we did not have ethical approval to link specific survey responses to focus group participants. The intention of these analyses was to contextualize or provide brief examples of quantitative data rather than to add significant new information.

Results

Participants

The sample (n=30) had a mean age of 44.0 (SD 12.4) years. Participants were mainly from Ontario (n=10, 33%) or Alberta (n=7, 23%), but all 10 Canadian provinces except Prince Edward Island were represented by at least 1 participant. The majority were White (n=22, 73%), employed (n=19, 63%), female (n=18, 60%), and in a married or common-law relationship (n=16, 53%).

In terms of gambling behavior, 26 (87%) participants regularly gambled in public settings and 12 (40%) in private settings. Additionally, 24 (80%) participants regularly gambled online. They engaged in about 4.6 (SD 2.5) types of gambling, the most popular of which were instant tickets (n=23, 77% participants), lottery tickets (n=21, 70%), video lottery terminals or slot machines (n=19, 63%), bingo (n=18, 60%), and raffles (n=16, 53%). Most participants (n=22, 73%) had ongoing (vs historical) gambling problems. The mean PGSI score of the full sample was 12.7 (SD 6.1), and there was no difference in terms of problem status (P=.55). Most participants (n=24, 80%) had previously received some form of support for gambling problems outside the context of a research study, but all had participated in the self-guided web intervention trial from which they were recruited. Only 5 (17%) participants reported they had used a mobile app similar to the current one, and 7 others heard of similar apps but never used them.

Feasibility

App Usage and Compliance

The majority of users (19/30, 63%) accessed the app from an iOS device; the rest used Android. The mean completion rate for daily diaries across users was 51% over 2 weeks (median 64%, IQR 0% - 100%). Across days, the number of diary respondents ranged from 14/30 (47%) on day 9 to 21/30 (70%) on day 5. The mean submission time was 4 PM. Participants submitted 238 of 420 possible diaries (56.7%; odds ratio [OR]

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1.3, 95% CI 51.9% - 61.3%). All diary submissions except 3 were started within 5 seconds of the respective push notification. Mean duration for the diary was 14 (SD 8) seconds for users who did not gamble on the diary day and 61 (SD 30) seconds for users who did gamble. In terms of in-app assessments, all users except 1 completed their notification preferences, PGSI self-assessment, and treatment goal selection. Furthermore, 2 users changed the time of their daily diary notification after their initial selection.

Median completion time for intervention activities ranged from 48 (IQR 35-90) to 137 (IQR 93-328) seconds. Means were higher (2-12, SD 5-25 min) because a small subset of users took over 1 hour to complete activities and typically provided thorough open-ended responses. The most frequently completed activity was the reflection on past behavioral changes, which was completed by 25/30 users (83%; OR 5.0, 95% CI 66% - 93%). The next most frequently completed activities were the decisional balance exercise, identification of triggers, making amends, and a relapse prevention plan, all completed by 23/30 users (77%; OR 3.3, 95% CI 59% - 88%). The remaining activities were the thought record (22/30 users, 73%; OR 2.7, 95% CI 56% - 86%), progress report (22/30, 73%; OR 2.7, 95% CI 56% - 86%), gambling calendar (21/30; 70%, OR 2.3, 95% CI 52% - 83%), values card sort (20/30; 67%; OR 2.0, 95% CI 49% - 81%), and importance, confidence, and commitment rulers (17/30; 57%; OR 1.3, 95% CI 39% - 73%). Many participants repeated at least 1 activity, and all activities were repeated by at least 1 participant. The most commonly repeated intervention was the thought record, which 7 of 30 users (23%; OR 0.3, 95% CI 10%-42%) completed 2 to 7 times. Of the 331 total interventions completed, 36% (n=119) were diary-prompted based on specific user data and a subsequent push notification; the rest were user-prompted (on demand). For diary-prompted interventions, the mean delay from notification to activity start time was 82 minutes 29 seconds (SD 248 min 43 s; median 2 min 31 s, IQR 29 s to 32 min 23 s).

Technical Difficulties

Some technical difficulties were encountered, but none appeared to prompt disengagement from the app, according to user feedback. The most common issue was improper variable displays (eg, push notifications stated "Hello participantFirstName" instead of actual names). There were also limitations of certain question formats and notification timing options in the *MetricWire* platform. All identified technical difficulties were resolved as soon as possible during the study.

Acceptability

Feedback was gathered from participants in 3 ways—general feedback on Qualtrics (n=30, 100% response rate), specific feature ratings within the app (n=15, 50% response rate), and a 1-hour virtual focus group. Regarding the focus group, 10 participants were randomly selected and invited to participate. Of those 10, 8 consented to the focus group, 6 ultimately attended, and 2 provided written feedback via email instead. Furthermore, 2 participants did not respond to the invitation.

General Survey Feedback

Quantitative feedback on Qualtrics was primarily collected via the uMARS (Table 2). Of the 4 objective domains, functionality was rated the highest on a 5-point scale, followed by information, aesthetics, and engagement. The highest-rated subdomains were information credibility, ease of use, and gesture functionality. The lowest-rated subdomains were customization, interactivity, and entertainment value. All subdomains except customization surpassed the acceptability heuristic threshold of 3.0.

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Table . uMARS[a] ratings out of 5 for each domain and subdomain.

Domain and subdomain	Mean (SD)
Engagement	
Entertainment	3.1 (1.2)
Interest	3.5 (1.1)
Customization	2.8 (0.8)
Interactivity	3.1 (1.0)
Target audience	4.2 (0.5)
Total	3.4 (0.7)
Functionality	
Performance	4.2 (0.8)
Ease of use	4.3 (0.7)
Navigation	4.2 (0.8)
Gestures	4.3 (0.7)
Total	4.2 (0.6)
Aesthetics	
Layout	3.8 (0.9)
Graphics	3.8 (1.1)
Appeal	3.6 (0.7)
Total	3.7 (0.8)
Information	
Quality	4.1 (0.7)
Quantity	4.0 (0.9)
Visual	4.1 (0.7)
Credibility	4.3 (0.8)
Total	4.1 (0.6)

[a]uMARS: user version of the Mobile App Rating Scale.

Overall, the mean star rating for the app was 3.6 (SD 0.8) stars out of 5. Out of 30 users, 7 (23%) indicated they would be somewhat likely to pay for the app. The remainder were either ambivalent (9/30, 30%), somewhat unlikely (5/30, 17%), or extremely unlikely (9/30, 30%); none were extremely likely. In terms of projected use over the next year, if access were available, 3% (1/30) said never, 17% (5/30) said 1 to 2 times, 40% (12/30) said 3 to 10 times, 33% (10/30) said 10 to 50 times, and 7% (2/30) said more than 50 times. The dispersion of responses was similar when users were asked if they would recommend the app to others with gambling problems; 3% (1/30) said they would not recommend it to anyone, 13% (4/30) said they would recommend it to very few people, 43% (13/30) said some people, 10% (3/30) said many people, and 30% (9/30) said they would definitely recommend it to anyone with gambling problems.

As part of the uMARS, participants were then asked to rate the perceived impact the app would have in various domains. Those who endorsed a clear or strong positive impact (vs somewhat, minimal, or no positive impact) were 63% (19/30) for knowledge about gambling problems, 43% (14/30) for further help-seeking, 40% (12/30) for attitude toward change, 40% (12/30) for motivation to change, 33% (10/30) for importance of change, and 30% (9/30) for concrete change in gambling behaviors. Across all domains, 1 person consistently reported no anticipated positive impact, but the remainder endorsed minimal or somewhat positive impacts. The user with uniformly negative ratings did not provide any qualitative responses to elaborate on their ratings.

In addition to the uMARS, participants were asked to select up to 5 of the most and least important aspects of the app for achieving the primary goal of reducing gambling problems (Table 3). The response options were derived from the uMARS. The aspects of greatest importance were ease of use, interactivity, and quality of information. The aspects of least importance were entertainment value, invitation of user feedback, and overall layout. Aspects of greater disagreement included entertainment value, visual appeal, customization, and amount of information, as these were all rated among the most and least important by at least one-third of users. Similar response variability was observed in the open-ended feedback, which was offered by 23 of 30 (77%) respondents (Table 4).

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Table . Perceived most and least important aspects of the app.

Aspect	Most important (n=30 responses), n (%)	Least important (n=27 responses), n (%)
Entertainment value	11 (37)	16 (59)
Visual appeal	11 (37)	10 (37)
Customization	9 (30)	9 (33)
Interactivity	16 (53)	5 (19)
Invitation of user feedback	8 (27)	12 (44)
Appropriate for target audience	11 (37)	5 (19)
Performance and speed	5 (17)	5 (19)
Ease of use	17 (57)	0 (0)
Overall layout	6 (20)	12 (44)
Amount of information	13 (43)	9 (33)
Quality of information	14 (47)	2 (7)
Credibility of information	13 (43)	4 (15)

Table . Summary of qualitative content analysis (n=23).

Category	Positive feedback	Critical feedback
Daily diaries or check-ins	Valued for accountability, self-reflection, and self-monitoring (n=3)	Repetitive, effortful, boring, or activating (n=5)
Personalized graphs of time and expenditures	Helpful for self-awareness and motivation (n=2)	—[a]
Triggered recommendations and notifications	—	Some disliked timing or felt interrupted (n=2)
Interactive activities	Thought-provoking (n=1)	Burdensome or insufficient (n=4)
Information and psychoeducation	Credible and useful (n=5)	Mixed views on quantity and format (n=2)
Aesthetics and layout	Clean, simple, and attractive (n=4)	Too minimal or not gamified enough (n=5)
Duration	—	Some wished for more time with the intervention (n=3)
Support structure	—	Some wished for more guidance or support (n=2)
Functionality	Ease of use and good functionality (n=3)	Technical difficulties (n=5)
Perceived impact	Helpful for increasing insight, self-reflection, and motivation (n=7)	Concern that the app added nothing unique beyond what can be found online (n=2)

[a]Not applicable.

Specific In-App Feedback

Feedback was elicited from 15 of 30 participants (50%) within the app on the final day of enrollment. Ratings are summarized below (Figure 5) in terms of the percentage of users who identified each activity as somewhat or very helpful (vs minimally or not at all helpful). All interventions and resources were completed by at least 12 of the 15 users who provided in-app feedback (80%).

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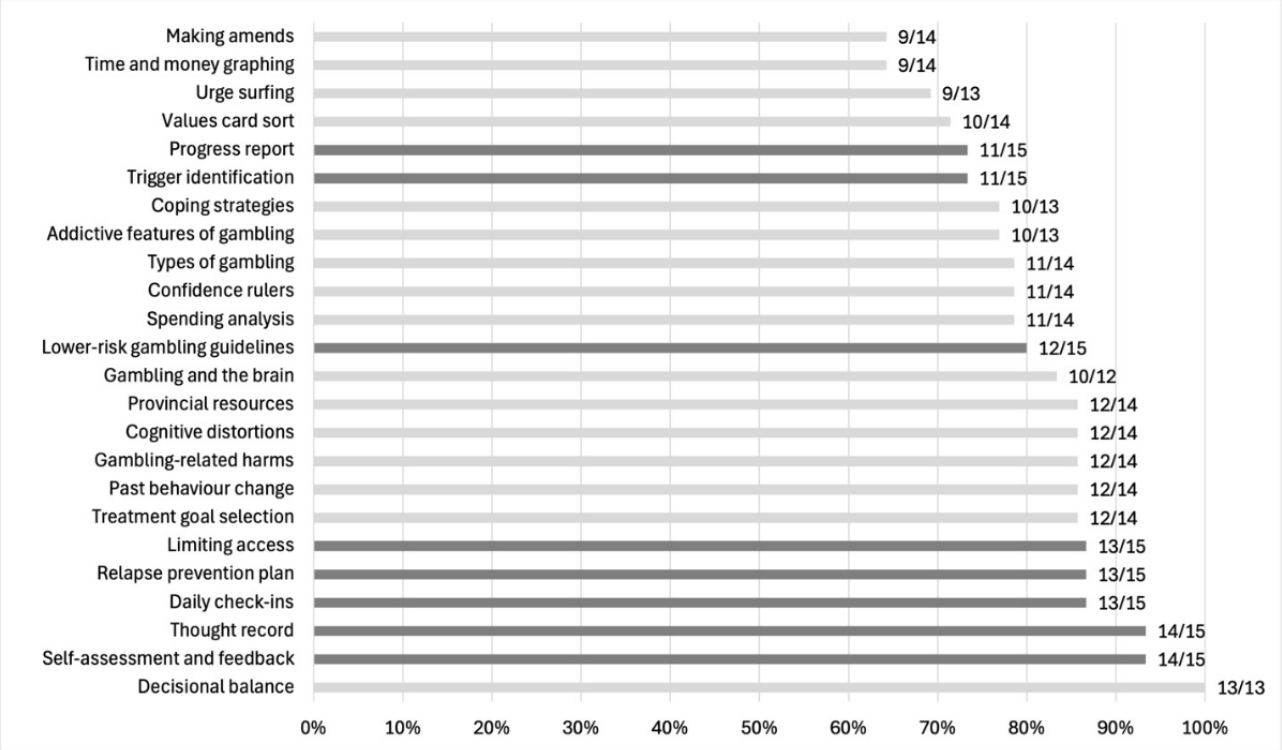
Figure 5. Proportion who rated each activity as somewhat or very helpful (numerators in the figure represent the number of people who rated each activity as somewhat or very helpful; denominators represent the total number of people who rated each activity; those who skipped the question, or those who responded they did not recall completing the activity, were excluded from denominators; and dark gray bars represent activities completed and rated by all 15 feedback respondents).



Focus Group Feedback

The sample was too small to evaluate whether focus group attendees and nonattendees differed in their app ratings, so we could not determine whether focus group responses were biased (for or against) the app. However, attendees provided both positive and constructive feedback that was largely consistent with open-ended survey responses.

By far, the most salient feedback from the focus group was the need to expand opportunities for user choice. This conclusion was largely driven by the group's high variability in individual preferences, which mirrored the variability observed in the open-ended survey responses as well as the lower customization ratings on the uMARS. For instance, some strongly preferred thought-provoking and open-ended reflections, while others gravitated toward more efficient checkboxes or multiple choice. The same pattern was observed with respect to information medium, such that some preferred audiovisual resources, whereas others preferred text. Similarly, some liked the consistency of check-in questions to reduce cognitive load, while others felt disengaged by the repetition. Many users found the check-ins to be the most helpful part of the app, particularly to track spending and remain focused on treatment goals, but 2 strongly preferred other activities and resources. Some users felt overwhelmed by the amount of information requested or provided by the app, while others desired more data tracking or informative resources. One user provided suggestions for modifications to existing resources (eg, display all the same information in both text and visual format). Moreover, 2 users would have liked more time with the app to track their gambling behaviors, and 1 suggested gamification to enhance engagement. Participants provided some feasible technical suggestions for implementing the choice (eg, constantly available rather than time-limited expenditure log).

Areas of greater agreement included the frequency of notifications, utility of tracking and graphing expenditures, and rating scales for mood and urges. Most users found the frequency of notifications (ie, once or twice daily) to be just right. A number of minor technical suggestions were also provided to further enhance ease of use (eg, including an orientation page for first-time users and editing how buttons link to various pages within the app).

Discussion

The results of this study describe early acceptability and feasibility findings that will inform subsequent modifications and testing on a larger scale. On the whole, users responded positively to the app prototype, including efforts ultimately designed to improve engagement, such as customized notification times, graphs of personal diary data, and tailored recommendations. Users believed the app was credible, easy to use, and appropriate for the target audience – factors which they indicated were among the most important for app developers to consider. The highest-rated activities were the decisional balance exercise, self-assessment feedback, and thought record; the latter was also the most repeated. Median completion time was consistently below 2.5 minutes (IQR 93-328 s) for activities and 1 minute (IQR 38-74 s) for diaries, minimizing the cognitive demand on users. When summed across all activities, activity completion time was similar to the overall 27 minutes spent on a static online intervention with nearly identical content [29].

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However, summing the mean activity completion time here still likely underestimates app use, given that it excludes time spent browsing the app or viewing read-only resources. Despite relatively lower ratings on the uMARS regarding entertainment value and aesthetics, the majority of users indicated these factors were among the least important in the effectiveness of the app to help people reduce gambling-related problems. All this feedback is consistent with our own past work [29] and others' [51]. Overall, the app prototype was rated 3.6 out of 5, and 25 out of 30 users would recommend the app to at least some others struggling with gambling problems. Importantly, however, it cannot be assumed that feasibility or acceptability at this formative stage will translate to engagement or effectiveness at a larger scale or with a different sample composition [51].

The largest gap between suggested importance and actual app delivery was for tailoring factors (eg, interactivity and customization). Indeed, the most consistent theme in the feedback was the lack of consistency, underscoring the need for a more personalized experience. This finding is concordant with other gambling intervention acceptability studies [52,53]. One major area of diverging opinion was related to the information medium and quantity. This critique applies to both the amount of information provided and the amount requested from users through check-ins and activities. Specifically, some users wanted more information and were content to input their data, while others felt overwhelmed by what was already provided and burdened by what was requested from them. Despite these critiques, users agreed on the high quality and credibility of information and overall rated the quantity of information 4.0 out of 5 on the uMARS. This finding is especially positive given that users felt the app could be most impactful in terms of increasing knowledge about gambling problems.

A more pressing area of disagreement related to the perceived utility and willingness to complete the daily check-ins. Many users believed the check-in, along with the associated graphing of personal gambling data and recommended activities and resources, were the most helpful parts of the app. Others found the daily diaries to be tedious and preferred to access activities and resources at their leisure. In fact, two-thirds of app engagement was on demand rather than based on tailored recommendations. In one sense, this finding is promising in that users will access an intervention without requiring prompting. In another sense, it presents a challenge, given that one of the primary means to personalize an intervention is by recommending various activities based on data provided in check-ins. Put another way, more data provided by users yields more tailored recommendations. This problem becomes more salient when considering that the diary completion rate was only 51% over 2 weeks. Diary completion rates have varied substantially in studies using momentary assessments of gambling behavior [17,54-57]. It is likely that with advancements in AI and machine learning (ML), it will be much more feasible to tailor interventions based on dynamically evolving individual needs in real-time, minimizing the cumbersome trial-and-error approach currently used [58]. However, AI and ML often require a very large amount of data to operate. The burden on users to provide data for tailoring may be reduced in part by passive sensor data [59]. Still, AI and ML do not provide a short-term solution, as there remain unresolved concerns about the risks of using AI and ML to inform gambling treatment [60,61] and general mental health treatment [62,63].

In addition to the mixed feedback, several relatively uncontroversial suggestions for improvement were provided by users. These suggestions included displaying more information in both text and visual formats, making the read-only resources more interactive, offering more than 2 weeks with the app for ongoing tracking of gambling data, providing additional information for special populations (eg, Indigenous gamblers) or concurrent substance use, and implementing gamification to enhance engagement. On the last point, it has been cautioned that gamification should strengthen, and not detract from, treatment content [64]. Other areas for improvement to consider include integrating the Lower-Risk Gambling Guidelines throughout the app and querying concurrent substance use and positive coping strategies in the daily check-ins. Based on observed engagement in this formative study, subsequent iterations will prespecify engagement targets (eg, diary completion and activity completion) and evaluate whether refinements improve these metrics.

This study presents some limitations. First, our sample was small and drawn from a highly selective pool of participants who had already participated in previous studies we conducted. These individuals were likely more research-experienced and more motivated relative to first-time intervention users or app store visitors. Given their participation in a similar previous intervention, their feedback was likely more forgiving than feedback from a naïve sample would have been, and thus may not generalize to other subpopulations of gamblers. Moreover, we did not solicit feedback from clinicians, other gambling researchers, or people with at-risk or low-severity gambling problems. Taken together, the feedback we received from our sample may not be representative of all stakeholders or broader population needs. However, as noted, the feedback was relatively consistent with past work. Also, the selection of focus group participants via random number generator, use of a semistructured interview guide, and inclusion of both recurring themes and outlier opinions were implemented to support balanced collection and reporting of feedback.

A second limitation is that this study did not measure the app's objective influence on engagement or gambling behavior change. While users' initial perceptions of potential impact are informative, subsequent work will need to measure these variables directly. Third, the qualitative feedback we gathered was relatively succinct and could have benefited from a more thorough mixed methods approach, such as a more thorough interview guide and additional content analyses of transcribed interviews. Fourth, there were limitations inherent to the use of a third-party software to host our intervention. Certain planned features and functionality, particularly those related to personalization, were not feasible within *MetricWire*'s platform. It was also not possible to gather data on the number of people who viewed read-only resources. Some minor technical difficulties were encountered as expected, but *MetricWire* support was responsive, and all difficulties were quickly

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resolved. While *MetricWire* provided an appropriate and cost-effective means to conduct this initial stage of testing, it would be sensible to develop independent software in the future. Finally, the results of this study do not yet inform on the primary purpose of the app – that is, to enhance engagement and reduce gambling problems.

Overall, this preliminary study provides important data to inform app modifications and testing on a larger scale. In fact, there are 2 ongoing trials using a refined version of this app, both of which will gather feedback and evaluate longer-term engagement and effectiveness in samples that are naïve to the intervention. Participants in this study responded very positively to the app prototype and agreed on its credibility, ease of use, and potential impact, although their familiarity with the content may have made their feedback particularly forgiving. Some areas of disparate opinion were encountered, the most pressing of which pertained to daily diaries, personalization, and aesthetic appeal. This app has the potential to narrow the gap in evidence-based self-guided treatments for gambling problems and provide the help they want and need on demand.

Funding

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Data Availability

Cleaned anonymized data will be made available to others by the authors upon request via email. R code for statistical analyses will similarly be made available upon request. Data and code can be requested from the corresponding author (brad.brazeau@ucalgary.ca) beginning 3 months after publication.

Authors' Contributions

BWB: Conceptualization, data curation, formal analysis, funding acquisition, investigation, methodology, software, visualization, writing – original draft, writing – review & editing.
JAC: Conceptualization, funding acquisition, writing – review & editing.
DCH: Conceptualization, funding acquisition, methodology, project administration, resources, supervision, validation, writing – review & editing.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Interview schedule.
[DOCX File, 16 KB - formative_v10i1e83430_app1.docx]

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Abbreviations

AI: artificial intelligence
CBT: cognitive behavioral therapy
ML: machine learning
OR: odds ratio
PGSI: Problem Gambling Severity Index
uMARS: user version of the Mobile App Rating Scale

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Ontology-Based Medication Named Entity Recognition Using Pretrained Transformer Models From a Thai Hospital: Model Fine-Tuning and Validation Study

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Abstract

Background: Extracting accurate medication information from Thai hospital records presents challenges due to the narrative style of medical notes, which often combine Thai and English terminology. Named entity recognition (NER) serves as the foundational step for advanced clinical information extraction (IE) tasks, including medical concept normalization and relation extraction. This study aimed to establish a robust NER framework to address these difficulties by leveraging ontology-based annotation and pretrained transformer models.

Objective: The primary objective of this study was to evaluate the performance of 5 fine-tuned pretrained transformer models—BioClinicalBERT, ClinicalBERT, PubMedBERT, MultilingualBERT, and ThaiBERT—based on Bidirectional Encoder Representations from Transformers (BERT) in extracting structured medication information from unstructured Thai hospital discharge summaries.

Methods: Ninety discharge summaries were collected from Maharaj Nakhon Chiang Mai Hospital. These documents were annotated by physicians following the annotation guidelines based on international standards, including Systematized Nomenclature of Medicine-Clinical Terms (SNOMED-CT) and Health Level Seven Fast Healthcare Interoperability Resources (HL7 FHIR). The dataset was divided into fine-tuning (70 records, 78%, 2030 annotated spans), validation (10 records, 11%, 277 annotated spans), and testing sets (10 records, 11%, 358 annotated spans). The 5 transformer models were fine-tuned and evaluated using this annotated data to recognize and classify key medication entities (substance, route of administration, unit of measure, time patterns, and unit of presentation).

Results: We found that all models had good NER performance metrics in both the validation and test datasets. Regarding test performance, ClinicalBERT achieved the highest exact F_1-score at 0.973, compared with 0.968 for BioClinicalBERT, 0.925 for PubMedBERT, 0.931 for MultilingualBERT, and 0.969 for ThaiBERT. All models showed strength in accurately identifying “Substance” and “Dosage” entities, whereas “Unit of Measure” proved to be the most challenging entity type due to implicit information in the source text for all models.

Conclusions: The findings suggest that ontology-based medication IE using transformer-based models holds promise for enhancing data standardization and interoperability within the Thai health care system. Future work will need to leverage the granular annotations preserved in the dataset to develop medical concept normalization and relation extraction models to complete the medical IE system.

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KEYWORDS

knowledge representation; ontology; named entity recognition; information extraction; deep learning; annotations; electronic medical prescriptions; natural language processing

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Introduction

Background

Over the last few decades, hospital information systems have continuously evolved from paper-based to electronic systems [1], with the promise of more efficient data collection and retrieval, as well as reducing the likelihood of errors [2,3]. Electronic health records (EHRs), hosted by hospital information systems, were initially implemented to replace paper charts but are increasingly regarded as valuable resources for health data analysis. While standards orientation and interoperability on an ontological basis [4] have been increasingly advocated, much of the EHR content is still written in a narrative style, containing crucial details about the patient, such as chief complaints, present illness, past medical history, past procedures, physical examinations, and even medication, as free text. Free text ideally supports quick human communication but poses significant challenges to content retrieval [5-7]. Only small portions of EHR content are currently structured using semantically explicit identifiers, such as *ICD-10* codes for diseases. Additionally, medication prescriptions are still mostly written in free text, despite the high relevance of medication errors to patient safety.

In Thailand, the writing style of narrative drug administration statements in discharge summaries is particularly unique due to its blend of Thai and English vocabulary, tailored for Thai physicians. They commonly mix brand names with ingredient names and tend to omit units and dosage forms such as tablets, suspensions, and eye drops whenever this does not lead to ambiguous interpretations. Style and format vary depending on the physicians' preferences and local communication norms. For example, in "fluimucil (100) 1 po bid," "fluimucil" is the trademark name with "N-acetylcysteine" as an active ingredient, "100" indicates strength (with "mg" omitted because it is known that other units are not used for this medication), "1" refers to the dose quantity for this drug, and " " is a Thai word that means "sachet." " " is an instruction in Thai meaning "mix with water" in English. "po" stands for "per os" (by mouth), and "pc" means "postprandial" (after meals) and "bid" is an abbreviation meaning "two times a day." This flexible and overly compact form poses challenges for the correct and fine-grained extraction of drug information from narrative content in EHRs.

Extracting Medication Information

Many studies have described natural language processing (NLP)-based information extraction (IE) for secondary use to improve health care research, health interoperability, hospital data analysis, and more [8]. IE from biomedical text includes 2 important steps: named entity recognition (NER) together with medical concept normalization (MCN) on the one hand, and relation extraction (RE) on the other hand. NER identifies spans of text and classifies them into broad semantic categories according to what they denote (eg, drugs, symptoms, procedures, and medication strength). MCN refers to mapping these spans to standardized terms as provided by SNOMED-CT (systematized nomenclature of medicine-clinical terms), *ICD-10*, and HL7. Some vocabulary is grounded in ontologies, that is, formal descriptions of their referents, in our context, particularly SNOMED-CT. However, effective normalization (MCN) relies heavily on the accuracy of the preceding step: identifying exactly where an entity begins and ends. If the NER model fails to correctly separate a "Substance" from its adjacent "Dosage Instruction," any subsequent attempt to map these spans to standard ontology codes will result in errors or misclassifications. Hence, robust NER is a necessary structural prerequisite for semantic interoperability.

RE involves identifying and classifying binary relations between text spans (also known as entities) as delineated by NER. Typical relations include the *location* relation between a disease and a body part, or the *value* relation between a laboratory observable and a number. In medication administration statements, typical relations connect a product name to the active ingredient(s), an ingredient to a dose quantity, and the whole medication statement to a temporal value. Some relations can also be mapped to slots in HL7-FHIR (Health Level Seven Fast Healthcare Interoperability Resources) resources.

IE in the clinical domain has evolved through several methods. Early systems, such as MetaMap [9], KnowledgeMap [10], and cTAKES [11], relied on rule-based pattern matching and terminology lookup. These were complemented by supervised machine learning approaches—particularly conditional random fields (CRFs) and support vector machines—which demonstrated strong performance in benchmark challenges such as i2b2 [12]. More recently, deep learning (DL) methods, including recurrent neural networks and transformers, have shown improved ability to capture contextual semantics in complex clinical narratives. Peterson and Liu [13] showed how DL, in particular convolutional neural network and bidirectional long short-term memory models, fared well in assigning SNOMED-CT codes to text expressions and relations. Mahendran and McInnes [14] showed that an approach based on Bidirectional Encoder Representations from Transformers (BERT)-based models outperformed other models overall and obtained state-of-the-art performance in adverse drug event extraction with an F_1-score of 94%. Hristov et al [15] proposed a multistep approach utilizing clustering, fine-tuned BioBERT classification, and mapping to predict SNOMED-CT codes for clinical texts, showing high accuracy and reliability. While "Generative artificial intelligence (AI)" (large language models) has recently gained prominence for zero-shot and few-shot tasks, we distinguish these from the encoder-based BERT models (Transformers) utilized in this study. The choice to prioritize fine-tuned BERT models over generative AI was driven by the specific requirements of clinical data extraction. In our recent study, we investigated the use of ChatGPT to perform NER tasks on the same Thai medication prescription data used in this research [16]. While that study yielded a promising average strict precision of 0.84, the model exhibited significant instability, evidenced by a poor recall of 0.66 for medication instructions. This limitation raises major concerns, as misclassification by generative AI could result in missing critical prescription details, such as dose quantity, timing, and route. Consequently, fine-tuned BERT-based models remain the superior choice for high-recall clinical extraction.

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Despite these global advancements in model architecture, we found a significant lack of application of model-based NER and gold-standard datasets suitable for hospital settings in Thailand, largely due to the unique style of drug administration expressions exemplified above. Therefore, we created an annotation guideline to standardize and enrich our drug administration dataset, making it trainable and evaluable for robust BERT architectures.

The Ontology of Medication Statements

The ontological analysis of a domain requires identifying, characterizing, and classifying the types of entities and how they are related. It helps clarify the basic assumptions on which knowledge representation artifacts are built. Main categories of being and foundational relations are provided by so-called foundational ontologies [17]. We here refer to the Basic Foundational Ontology (BFO), which has had a strong influence on domain ontologies in biology and medicine. In the domain of medication, we have the medicinal product at the center. It is a material artifact prepared for entering contact with a biological organism to produce some effect by interacting with the organism's metabolism. The medicinal product is characterized by being composed of one or more ingredients, ie, amounts of substances. Substances are collections of molecular units of a certain type. For example, sodium chloride is a substance consisting of equal amounts of sodium and chloride ions; saline is a substance containing additional water molecules as a solvent. Every medicinal product, which is, in contrast to substances, of a discrete nature (it can be portioned and counted), has one or more substances as parts. We here only consider the active substances. Each constituting substance has a defined quantity, which is characterized by a number and a unit of measurement, which is a dimension or physical quantity (milligrams, millimoles, milliliters, etc), providing a reference based on which the exact number of molecular entities can be determined. Every medicinal product has a dose form, eg, tablet, cream, or solution for injection, which optimizes the way the product's ingredients reach the target body structure. Dose forms can ontologically be described as qualities of the medicinal product. Dose form, active ingredients, and the amount of each ingredient characterize what SNOMED-CT names "clinical drug," a class that can be further divided according to the branded drugs of different manufacturers. From a clinical point of view, these subdivisions are of minor interest.

However, the context in which a medicinal product is referred to is diverse. Not all of its mentions pertain to actual medication administration processes. Alternatively, mentions can refer to past administrations, possibly with potential adverse effects, but medication mentions can also occur in the context of prescriptions or recommendations. All of these are, ontologically, processual entities or, at the level of SNOMED-CT, procedures, but their impact on the real exposure of a patient to a pharmacologically active substance is different. Processual entities, in BFO, have a specified time and location. In contrast to medication administration events, prescriptions or recommendations are plans or intentions that might not necessarily be realized in the future. In the medication section of clinical summaries, it is not always clear whether the entries refer to actual medication administration events or mere recommendations.

To translate these foundational principles into a practical schema, we developed the "Medication Annotation Guideline," primarily grounded in SNOMED-CT, which provides the semantic foundation for our entity types. Each NER label corresponds to a specific SNOMED-CT concept node using the standard format, Concept ID |Fully Specified Name|: for example, a text span annotated as Substance must conceptually descend from 105590001 |Substance|, and Route must descend from 284009009 |Route of administration value| (see Table 1 in Methods). For aspects beyond SNOMED-CT's scope as a terminology—such as dose quantity values and dosage timing structures—we relied on HL7 FHIR as a complementary framework, adopting elements from its Medication Statement resource (see Table 2 in Methods). This provides annotators with precise, unambiguous inclusion criteria, improves inter-annotator consistency, and ensures that entities extracted by our NER models are aligned with international interoperability standards.

To conclude, IE is a multistage process required to fully represent unstructured clinical data. A complete IE pipeline typically involves 3 distinct tasks: NER to identify and classify text spans, MCN to map those spans to standardized terminology codes, and RE to link these entities together.

This study focuses on the NER task as it is the foundational stage of IE. We employed an ontology-based annotation strategy using SNOMED-CT primarily as it aligns with the clinical reasoning and terminology native to annotators, who are medical professionals, and this also guarantees the dataset's extensibility: by strictly adhering to SNOMED-CT standards now, the same annotated corpus can be directly utilized for future MCN and RE tasks, bridging the gap between extracting text spans and achieving full semantic interoperability.

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Table . Entity types relevant to the medication domain, including SNOMED CT top concepts and corresponding basic foundational ontology classes.

Acro	Code	SNOMED CT[a] name	BFO[b] class	Description	Examples
Sub	105590001	Substance	object aggregate	Drug names, active ingredients, medicinal compounds	Paracetamol, Metformin, Amoxicillin, ASA (aspirin)
Uni	767524001	Unit of measure	generically dependent continuant	Units for dose quantity measurement	tab (tablet), cap (capsule), amp (ampule), vial, sachet
Tim	272103003	Time patterns	occurrent	Dosing frequency, timing, or duration	1*1 (once daily), bid, prn, pc (after meals), hs (at bedtime)
Rou	284009009	Route of administration value	object	Route of administration - how the drug enters the body	po (per oral), IV, SC (subcutaneous), IM, topical
Adm	18629005	Administration of drug or medicament	process	The procedure/event of giving medication to patient	(*zero-width annotation - implicit, not tied to text span*)
Pro	763158003	Medicinal product	object	The manufactured drug product being administered	(*zero-width annotation - implicit, not tied to text span*)
Pre	732935002	Unit of presentation	quality	Physical dosage form of the medication	tab (tablet), cap (capsule), amp (ampule), vial, sachet
Dec	1119403002	Decimal	generically dependent continuant	Numerical values for dose strength or quantity	500, 10.5, 0.25, 100/10 (compound strength)

[a]SNOMED CT: Systematized Nomenclature of Medicine-Clinical Terms.

[b]BFO: basic foundational ontology.

Table . Predicate values, their domain and range restrictions, and their interpretation as Systematized Nomenclature of Medicine-Clinical Terms (SNOMED CT) and Fast Healthcare Interoperability Resources (FHIR) expressions.

Predicate	Domain/Range	Relational expression	BFO[a] relation
doseForm	*Adm* → *Pre*	411116001 |Has manufactured dose form	bearer of
doseQuantity	*Adm* → *Dec*	FHIR:Dosage.doseAndRate.dose	bearer of
doseRoute	*Adm* → *Rou*	410675002 |Route of administration	located in
doseTiming	*Adm* → *Tim*	FHIR:Dosage.timing	has occurrent part
ingredient	*Pro* → *Sub*	127489000 |Has active ingredient	has continuant part
value	*Sub* → *Dec*	1142138002 |Has concentration strength numerator value	bearer of
		1142135004 |Has presentation strength numerator value	
unit	*Sub* → *Uni*	1142135004 |Has presentation strength numerator value	bearer of
		732945000 | Has presentation strength numerator unit	
usingSubstance	*Adm* → *Pro/Sub*	363701004 |Direct substance	has participant

[a]BPO: basic foundational ontology.

In the following sections, we describe how these concepts guided our annotation process and demonstrate how the resulting dataset was utilized to enable transformer-based models to learn and extract structured medication information from unstructured Thai clinical documents.

Methods

Ethical Considerations

This study was approved by the Research Ethics Committee, Faculty of Medicine, Chiang Mai University, Thailand (approval

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number COM-256509305, Research-ID: 9305). Consent to participate was waived in accordance with the exemption for secondary data used exclusively for research purposes. There was no recruitment of or compensation provided to participants for this study. All discharge summaries were deidentified prior to annotation: patient identifiers (names, hospital numbers, dates of birth, addresses, and other personally identifiable information) were removed before the data were made available to annotators. Annotators only accessed the deidentified text. The deidentified dataset was stored on a secure institutional server with access restricted to authorized research team members.

Study Objectives

This study aimed to first construct an ontology-based annotated corpus for Thai medication statements aligned with the international terminology standards, SNOMED-CT and FHIR. Second, we utilized this corpus to develop and validate 3 fine-tuned transformer models based on their performance in NER to extract specific medication entities—including substance, route of administration, unit of measure, time pattern, and unit of presentation—from Thai English code-switched clinical text.

Data Acquisition and Ontological Interpretation

Ninety discharge summaries with narrative content from the Maharaj Nakhon Chiang Mai Hospital, spanning the years 2018 to 2022, were randomly collected. The documents were sourced mainly from the Department of Internal Medicine, as it is the department where medical vocabularies and medication prescriptions are the most diverse. Moreover, it is the department that employs a large rotation of attending physicians, resulting in a mix of heterogeneous writing styles within the dataset. Each discharge summary document contains the complete clinical narrative for a single, unique patient admission. The following exclusion criteria were applied: (1) records with incomplete or corrupted text fields; (2) cases resulting in death, which differ significantly in documentation style; and (3) discharge summaries containing zero medication entries. Each discharge summary document contains the complete clinical narrative for a single, unique patient admission. To balance learning capability with evaluation, we reviewed comparable clinical NLP studies and found that training set allocations typically range from 60% to 75% [18-20]. Accordingly, we adopted a similar distribution:

- Training Set (n=70, 78%): Used for fine-tuning.
- Validation Set (n=10, 11%): Used for hyperparameter tuning and model checkpoint validation.
- Test Set (n=10, 11%): Used for performance evaluation on unseen patients.

The dataset was annotated by 3 general physicians according to a Medication Annotation Guideline. The summaries are divided into 3 groups (33, 33, and 34 summaries). Each of the 3 annotators was assigned to annotate 2 groups, ensuring that each summary received 2 versions of annotations by different annotators.

In Thailand, discharge summaries frequently adhere to distinct patterns among hospitals and institutes. These summaries typically include a concise summary of the patient's demographics, chief complaint, current illness, past history, physical examination, problem lists, and medication prescriptions for each hospital admission. In our dataset, we interpret medication statements as denoting real drug administration procedures, ie, we can assume as real that the patient received the mentioned products. Due to our knowledge of workflows and documentation practices, we take for granted that each medication statement denotes a real-world instance of SNOMED-CT code 18629005 |Administration of drug or medicament (procedure)|. As we can trivially assume, every instance of this concept refers to some medicinal product, as introduced above. In BFO, the products would be the participants of these administrative procedures. These procedures can be further specified in terms of the quantity of the unit over a period, the time patterns, and the route by which it enters the body. A time pattern, eg, 3 tablets a day at 7 AM, 2 PM, and 9 PM, corresponds to 3 subprocedures per day, characterized by a different time each. The route would be referred to as the anatomical location (mouth, skin, vein, etc) where each of the subprocedures takes place.

Medication Annotation Guideline

Development of Annotation Guidelines

These ontological assumptions motivated the creation of our annotation guideline, which was developed based on the standards SNOMED-CT and FHIR. It had to synthesize the perspectives of foundational ontology, the clinical ontology SNOMED-CT, and the information model HL7-FHIR, inspired by the AIDAVA annotation guideline [21,22], from which annotation training materials were derived and which were used to resolve annotation controversies. We used INCEpTION v32.1 for text annotation [23]. The medication annotation tasks are explained in the following 2 steps:

Entity Annotation

SNOMED CT is used as the main annotation terminology. The annotation process followed several rules. The first rule was "Use the most fine-grained SNOMED-CT concept." Entity annotations (ie, annotations of text spans) are performed using the most fine-grained SNOMED-CT concept possible, which represents the correct meaning of the surface term under investigation to avoid ambiguity and ensure a higher level of precision, since any necessary generalization can be applied later if required by the downstream task, rather than trying to refine a broad concept initially.

The second rule was "Zero-width annotations (not rooted in any text) are allowed only for 105590001 |Substance (substance)| and 18629005 |Administration of drug or medicament (procedure)|." These 2 concepts are crucial for expressing the meaning of a medication expression but are often only implicitly referred to [22]. Despite being annotated with fine-grained SNOMED CT codes for the provision of entity types for NER and without interest in MCN in this study, we had to map them to a small set of 8 upper-level SNOMED-CT concepts, as shown in Table 1.

The third rule was "'Clinical drug' concepts are not allowed." In narrative medication statements, many mentioned texts refer to branded or clinical drugs, which are not listed in

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SNOMED-CT, where the most detailed drug product concepts, fully defined by strengths, dose forms, and ingredients, are identified with the "Clinical drug" tag. This may cause ambiguity for annotators, for example, when choosing either 428789004 |Product containing precisely simvastatin 20 milligram/1 each conventional release orodispersible tablet (clinical drug) or 319997009 |Product containing precisely simvastatin 20 milligram/1 each conventional release oral tablet (clinical drug)|, as the difference between these 2 concepts is that one has "orodispersible tablet" and the other has "oral tablet," which may not be explicitly distinguished in the written medication statement. To avoid confusion for annotators, we excluded the clinical drug concepts from our annotation vocabulary, all the more because their coverage is currently limited. In addition, the fact that the expressions relate to medication administration is mostly implicit. This is the reason why we added 18629005 |Administration of drug or medicament (procedure)| as a zero-width annotation, ie, an annotation to which no specific text span is related. The same is often needed for 763158003 |Medicinal product (product)| in cases where only the substance is referred to in the medication statement.

Relation Annotation

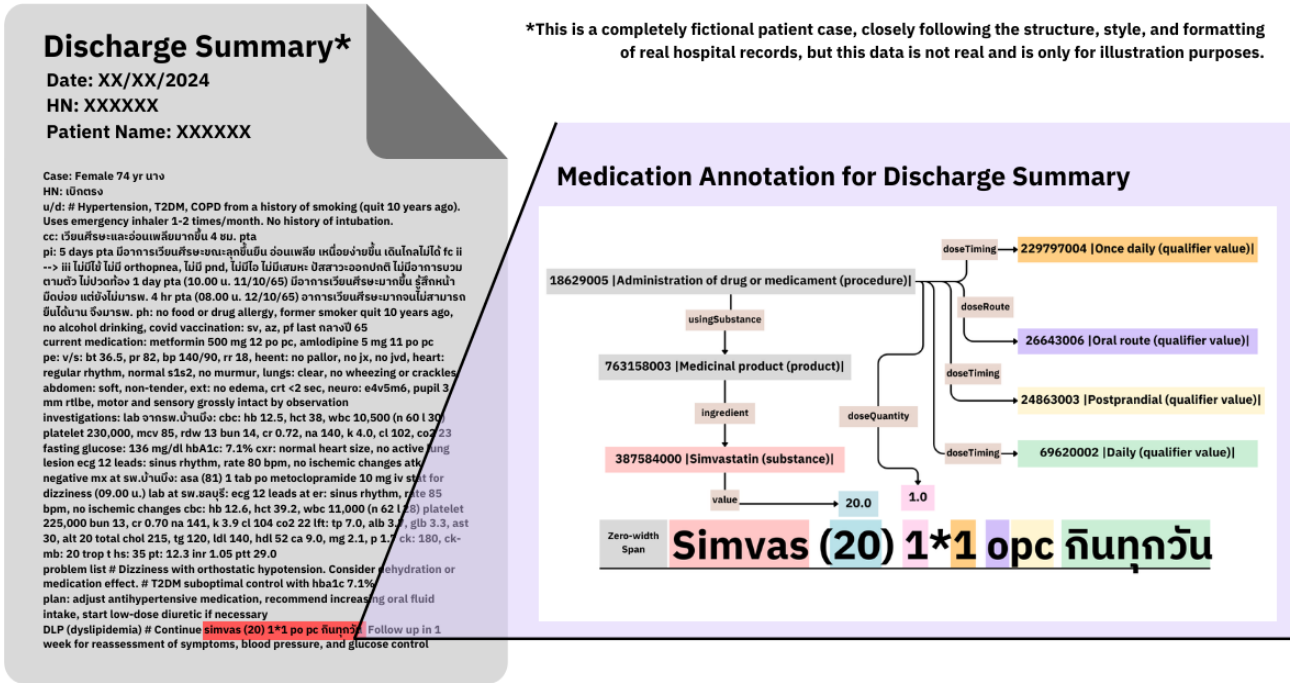
The relation annotation uses the predicates outlined in Table 2, taken from the AIDAVA annotation guide [21,22]. These predicates prioritize human understandability to facilitate the annotation process. Their semantic interpretation in terms of SNOMED CT and FHIR is listed in column 3, and their abstraction to BFO relations is provided in column 4.

Domain and range restrictions in Table 2 use the acronyms from Table 1. DoseForm relates the medicinal product to its dose form, for example, tablet, capsule, solution, etc. DoseQuantity relates drug administration to the count or amount of the drug given. If available in discrete portions, for example, tablets, it links to an integer; otherwise, it links to a number that quantifies an amount, for example, "20 mL/h." DoseRoute indicates the path through which a substance enters the body (eg, oral route, intravenous infusion, or inhalation). DoseTiming links drug administration to dosing schedule concepts, for example, "every 8 hours", or specific dates and times like "for 10 days before breakfast." An ingredient relates a medicinal product to its active ingredient(s). Value relates an ingredient to the mass or concentration present in a dosage unit of the product, together with the unit of measurement. UsingSubstance describes the relationship between drug administration and the medicinal product or the substance (if no product is specified).

Annotation Examples

From the Figure 1 example, "simvas(20) 1*1 opc" means "taking Simvastatin 20 mg 0.5 tablet once daily," The annotation starts with 18629005 |Administration of drug or medicament (procedure)| linked to 763158003 |Medicinal product (product)| by the usingSubstance predicate and links 763158003 |Medicinal product (product)| to all of its ingredients, in this case, 387584000 |Simvastatin (substance)|, using the ingredient predicate. Then we link the dosage of the substance, "20.0," to 387584000 |Simvastatin (substance)| using the value predicate.

Figure 1. Example 1 of the medication administration annotation from the discharge summary note.



The first number "1" in Thai medication prescription style indicates doseQuantity, ie, without using abbreviations or ambiguous terms. We annotated "0.5" as a decimal and linked it to 18629005 |Administration of drug or medicament (procedure)| using doseQuantity. The second occurrence of "1," as well as "pc," indicates doseTiming, so we linked 229797004 |Once daily (qualifier value)| and 24863003 |Postprandial (qualifier value)| to 18629005 |Administration of drug or medicament (procedure)| using doseTiming. "o" indicates the route of administration, so we linked 18629005 |Administration of drug or medicament (procedure)| to 26643006 |Oral route (qualifier value)| using doseRoute. Finally, " " is "to be consumed daily" in Thai, so we annotated it with 69620002

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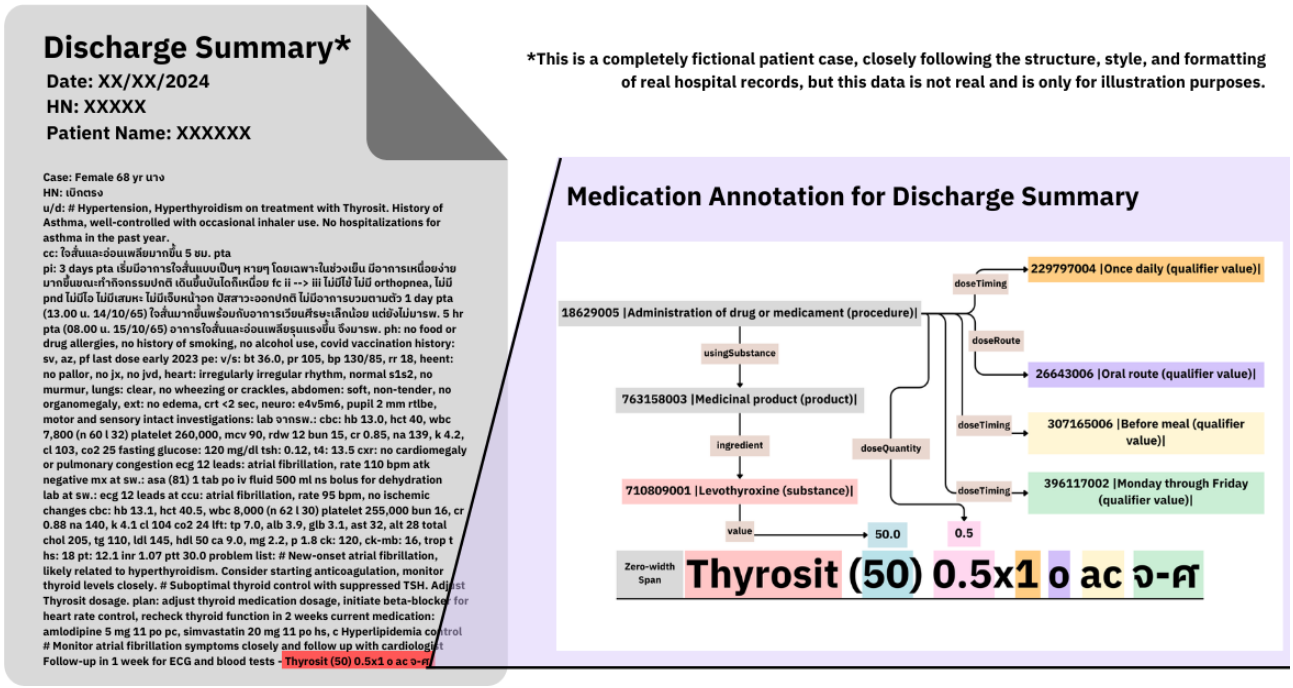
|Daily (qualifier value)| linked to 18629005 |Administration of drug or medicament (procedure)| using doseTiming.

In Figure 2, “Thyrosit (50) 0.5x1 o ac - ,” the annotation begins with 18629005 |Administration of drug or medicament (procedure)| linked via usingSubstance to 763158003 |Medicinal product (product)|, which connects to 710809001 |Levothyroxine (substance)| through the ingredient predicate. The strength “50” is linked to the substance using value. The “0.5” indicates doseQuantity (half tablet), linked to the administration procedure. The expression “x1,” combined with the Thai abbreviation “ - ” (- , meaning Monday through Friday), creates multiple doseTiming relations: 229797004 |Once daily|, 307165006 |Before meal| (from ac), and 396117002 |Monday through Friday|. Finally, “o” indicates 26643006 |Oral route| via doseRoute.

Figure 2. Example 2 of the medication administration annotation from the discharge summary note.



Gold Standard Dataset Evaluation

The agreement between 3 annotators at both the concept and relation levels was determined by Krippendorff α [24], a statistical measure that evaluates the level of agreement among raters while accounting for the possibility of agreement occurring by chance.

Model Selection and Fine-Tuning

We chose the following pretrained transformer models for model fine-tuning: (1) BioClinicalBERT [25], (2) ClinicalBERT [26,27], (3) PubMedBERT [28], (4) multilingualBERT [29], and (5) ThaiBERT [30]. ThaiBERT and multilingualBERT were included as baseline models to evaluate how general-domain language models perform on this specific NER task compared to domain-specific models. Specifically, ThaiBERT was selected to assess the performance of a model pretrained primarily on native Thai text, while multilingualBERT was chosen to investigate how a multilingual model—capable of processing both English and Thai but lacking specific biomedical background—handles the code-switched clinical narratives.

The selection of models pretrained on English corpora (BioClinicalBERT, ClinicalBERT, and PubMedBERT) is guided by the writing nature of Thai clinical documentation, which is predominantly English-centric but frequently incorporates Thai text and grammatical structure. Although Thai characters will be treated as out-of-vocabulary tokens (unknown), we believe English-pretrained models can still perform well on our dataset because they were extensively trained on vast biomedical corpora, which directly align with the medication names and clinical terms that dominate Thai clinical documentation.

After each fine-tuning epoch, the model was evaluated on the validation set. The checkpoint achieving the highest validation F_1 score was selected and subsequently evaluated for generalizability on the test set.

Data Preprocessing and Tokenization

The extracted discharge summaries were composed of unstructured narratives. To prepare the text for analysis, we performed a cleaning step to filter out special characters, common stopwords, and non-Thai or non-English vocabulary.

Then, we transformed fine-grained concepts into entity types based on SNOMED-CT, as shown in Table 1. Each fine-grained code annotated by experts (eg, 387584000 |Simvastatin (substance)|) was traced through its parent hierarchy (IS-A relationships) in SNOMED-CT until it matched one of the 8 target upper-level concepts defined in Table 1. For example:

- 387584000 |Simvastatin| → IS-A → 105590001 |Substance| → Entity type: SUB
- 26643006 |Oral route| → IS-A → 284009009 |Route of administration value| → Entity type: ROU

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- 229797004 |Once daily| → IS-A → 272103003 |Time patterns| → Entity type: TIM

18629005 |Administration of drug or medicament (procedure)| and 763158003 |Medicinal product (product)| were excluded from model development and validation because these are zero-width annotated concepts and, therefore, inferable from the ontology pattern.

Text processing was then performed using the specific subword tokenization strategies associated with each pretrained model. English pretrained models (BioClinicalBERT, ClinicalBERT, PubMedBERT), lacking a Thai vocabulary, map all Thai characters to (unknown). Consequently, they treat Thai text as delimiters and rely entirely on English medical terminology as semantic anchors. MultilingualBERT uses a multilingual vocabulary. It applies standard subword tokenization to English but often fragments Thai script into individual characters or subcharacter units due to the lack of dedicated Thai word segmentation. ThaiBERT uses a SentencePiece tokenizer trained on Thai Wikipedia. However, due to its Thai-dominant vocabulary, it lacks technical English terms and might fragment them into small, generic subwords.

Model Evaluation

Precision (P), recall (R), and the microaveraged F_1-score were used to assess model performance. The equations for these evaluation metrics are illustrated as follows:

$$\text{Precision} = \frac{\text{TruePositive}}{\text{TruePositive} + \text{FalsePositive}}$$

$$\text{Recall} = \frac{\text{TruePositive}}{\text{TruePositive} + \text{FalseNegative}}$$

$$\text{F1-Score} = \frac{2 \times (\text{Precision} \times \text{Recall})}{\text{Precision} + \text{Recall}}$$

In the assessment, we differentiated between exact match and partial match [19,31-33]. Exact Match (Strict) requires the predicted entity to match the ground truth exactly in both its boundary (start and end indices) and its entity label. Partial Match (Relaxed) counts a prediction as correct if the predicted span overlaps with the ground truth span (even partially) and the entity label is correct.

For example, consider a medication prescription, “Amlodipine (5), 1*1 po pc ,” where the ground truth for a Substance entity is marked as “Amlodipine.” If the model predicts “Amlodipine (5),” this would be classified as a failure under the exact match criterion because the character boundaries do not align perfectly, but it will be classified as correct under the partial match criterion because the core drug name (“Amlodipine”) is present, although the predicted span includes the dosage suffix “(5).”

Statistical Analysis

Statistical comparison of model performance metrics, including both exact and partial recall, precision, and F_1-score, was performed by assuming correct predictions as binomial proportions. A chi-square test for equality of proportions was initially applied to detect global differences in performance metrics among the 5 pretrained transformer models (BioClinicalBERT, ClinicalBERT, PubMedBERT, MultilingualBERT, and ThaiBERT). For the metrics that showed significant global differences, pairwise comparisons were performed using immediate 2-sample proportion tests (*prtesti* in STATA). The Bonferroni method was applied to correct for the 10 possible pairwise comparisons (5 models) per metric. Statistical significance was defined as a Bonferroni-corrected P value <.05. The statistical analysis was conducted using STATA version 17 (STATA Corp.).

Results

The evaluation of the annotated data revealed that Krippendorff α coefficients among the 3 annotators were 0.817 for entity type annotations and 0.960 for relation annotations. Table 3 presents the distribution of token types across the fine-tuning, validation, and test datasets for the NER task. Table 4 presents the development and validation results for the 5 fine-tuned models. ClinicalBERT achieved the highest overall performance, reaching an F_1-score of 0.974 for both exact and partial evaluations. Notably, ThaiBERT demonstrated strong competitive performance, securing the second-highest F_1-score of 0.970, outperforming BioClinicalBERT (0.965). In contrast, MultilingualBERT and PubMedBERT yielded lower performance metrics, with F_1-scores of 0.935 and 0.933, respectively. The high precision scores across all models (>0.990) indicate that false positives were rare, while the variations in recall suggest that ClinicalBERT and ThaiBERT performed the best in the NER task for our dataset.

Table . Number of annotated spans per category in fine-tuning, validation, and test data.

Dataset	Number of documents	Substance	Decimal	Route of administration	Time patterns	Unit of presentation	Unit of measure	Outside entity
Fine-tuning	70	441	742	307	469	55	16	35,358
Validation	10	58	103	44	62	8	2	4626
Test	10	75	128	62	83	6	4	4626

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Table . Overall performance metrics for BioClinicalBERT, ClinicalBERT, PubMedBERT, MultilingualBERT, and ThaiBERT on the fine-tuning and validation datasets.

Metrics	BioClinicalBERT	ClinicalBERT	PubMedBERT	MultilingualBERT	ThaiBERT
Exact precision	0.999	0.999	0.995	0.999	0.993
Exact recall	0.933	0.950	0.878	0.879	0.948
Overall exact F_1	0.965	0.974	0.933	0.935	0.970
Partial precision	0.999	0.999	0.995	0.999	0.994
Partial recall	0.933	0.950	0.878	0.879	0.948
Overall partial F_1	0.965	0.974	0.933	0.935	0.970

Table 5 shows that all models demonstrated good entity recognition and entity type classification in the test set. Almost all entity types had both exact and partial F_1-scores over 0.800, except for "Unit of Measure" and, in the specific case of ThaiBERT, "Unit of presentation." ClinicalBERT consistently outperformed the other models across most entity types, achieving the highest scores. Notably, it scored 0.933 (both exact and partial F_1-scores) for "Decimal," and 0.927 (both exact and partial F_1-scores) for "Time patterns." Its performance on "Substance" and "Route of administration" was also strong, with scores of 0.926/0.928 and 0.891/0.895, respectively. ThaiBERT followed closely with high overall F_1-scores (0.969 exact, 0.970 partial), yet it displayed uneven performance; while competitive in "Route of administration" (0.890), it scored significantly lower in "Unit of presentation" (0.398) compared to the ~0.88 average of other models. BioClinical BERT showed robust performance, with exact and partial F_1-scores of 0.911 and 0.914 for "Substance," respectively, and scores of 0.880 and 0.885 for "Route of administration." Similarly, MultilingualBERT proved effective, particularly in extracting "Decimal" (0.930) and "Time patterns" (0.926), comparable to the top performers. PubMedBERT, while showing comparable results, lagged slightly behind, particularly in handling "Substance" (0.782 exact, 0.791 partial) and "Time patterns" (0.846 exact, 0.847 partial). Its performance on "Decimal" and "Route of administration" was closer to that of BioClinical BERT, with scores in the mid to high 0.80s. Overall, ClinicalBERT's exact and partial F_1-scores of 0.973 across all entity types indicate its superior efficacy in accurately identifying and classifying clinical entities in the dataset. The full details of performance matrices and model comparisons on the fine-tuning and validation datasets are shown in Multimedia Appendix 1 (Table S1-S9).

Table . Comparison of F_1-scores across BioClinicalBERT, ClinicalBERT, PubMedBERT, MultilingualBERT, and ThaiBERT on the test set.

Entity type	BioClinicalBERT		ClinicalBERT		PubMedBERT		MultilingualBERT		ThaiBERT	
	Partial F_1	Exact F_1	Exact F_1	Partial F_1	Exact F_1	Partial F_1	Exact F_1	Partial F_1	Exact F_1	Partial F_1
Substance	0.911	0.914	0.926	0.928	0.782	0.791	0.909	0.912	0.757	0.768
Decimal	0.926	0.926	0.933	0.933	0.874	0.874	0.930	0.930	0.883	0.884
Route of administration	0.880	0.885	0.891	0.895	0.865	0.869	0.875	0.880	0.890	0.895
Time patterns	0.918	0.918	0.927	0.927	0.846	0.847	0.926	0.926	0.824	0.828
Unit of presentation	0.888	0.888	0.892	0.892	0.888	0.888	0.873	0.876	0.398	0.411
Unit of measure	0.692	0.692	0.692	0.692	0.607	0.607	0.667	0.667	0.623	0.623
Overall	0.968	0.968	0.973	0.973	0.925	0.925	0.931	0.932	0.969	0.970

Table 6 shows the statistical validation of the performance differences. We conducted pairwise comparisons of exact performance using a 2-proportion test with Bonferroni correction. The analysis confirms that ClinicalBERT was statistically superior to all other models in overall performance (P<.05). ClinicalBERT significantly outperformed both PubMedBERT and ThaiBERT across nearly all specific entity types. BioClinicalBERT also achieved significantly higher overall performance compared to PubMedBERT, MultilingualBERT, and ThaiBERT. BioClinicalBERT surpassed ThaiBERT in every entity type. While ThaiBERT achieved statistically higher overall performance compared to both PubMedBERT and MultilingualBERT, the pairwise breakdown reveals significant deficiencies in specific categories. For instance, ThaiBERT performed significantly worse than MultilingualBERT in "Substance," "Decimal," and "Time patterns," and significantly worse than PubMedBERT in "Unit of presentation." The comprehensive details regarding performance metrics and model comparisons on the test dataset are available in Multimedia Appendix 1 (Tables S10-S25).

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Table . League table of partial F_1-score comparison by entity types among BioClinicalBERT, ClinicalBERT, PubMedBERT, MultilingualBERT, and ThaiBERT on the test dataset.[a]

Models	BioClinicalBERT	ClinicalBERT	PubMedBERT	MultilingualBERT	ThaiBERT
BioClinicalBERT	—[b]	↓ Overall	↑ Overall ↑ Substance ↑ Decimal ↑ Time patterns	↑ Overall	↑ Overall ↑ Substance ↑ Decimal ↑ Time patterns ↑ Unit of presentation
ClinicalBERT	↑ Overall	—	↑ Overall ↑ Substance ↑ Decimal ↑ Time patterns	↑ Overall	↑ Overall ↑ Substance ↑ Decimal ↑ Time patterns ↑ Unit of presentation
PubMedBERT	↓ Overall ↓ Substance ↓ Time patterns	↓ Overall ↓ Substance ↓ Time patterns	—	↓ Overall ↓ Substance ↓ Decimal ↓ Time patterns	↓ Overall ↑ Unit of presentation
MultilingualBERT	↓ Overall	↓ Overall	↑ Overall ↑ Substance ↑ Time patterns)	—	↓ Overall ↑ Substance ↑ Decimal ↑ Time patterns
ThaiBERT	↓ Substance ↓ Decimal ↓ Time patterns ↓ Unit of presentation	↓ Overall ↓ Substance ↓ Decimal ↓ Time patterns ↓ Unit of presentation	↓ Unit of presentation ↑ Overall	↓ Substance ↓ Decimal ↓ Time patterns ↓ Unit of presentation ↑ Overall	—

[a]The 10 pairwise (5 models) comparisons were performed using a 2-proportion test with a corrected *P*-value (2-sided) calculated using the Bonferroni method. A corrected *P* value <.05 is considered statistically significant. ↑ indicates the row model performs statistically better than the column model, and ↓ indicates the row model performs statistically worse than the column model.

[b]Not applicable.

Discussion

Principal Findings

Health care has undergone significant advancements due to EHRs, shifting from paper-based records to digital systems, which improve data access and management [34]. Ideally, EHRs reduce administrative burdens, allowing health care professionals to focus more on patient care and enabling advanced data analytics to identify trends, calculate risks, and improve treatment protocols [35]. Nevertheless, many of the currently used EHR systems are not much more than substitutes for paper charts, and most information is locked within unstructured narratives. This is an unsatisfactory situation, all the more so because much effort has been invested in the development of semantic standards such as SNOMED-CT and FHIR. Increasingly based on a formal framework, these standards bear the potential to standardize clinical information, thus supporting data interoperability with the goal of improving continuity of care and ensuring data accuracy and consistency, which is essential for developing reliable clinical applications [36].

There have been many attempts to enhance health care data by bridging the gap between clinical narratives and structured, standardized data representation by leveraging clinical NLP [37]. A slow but steady evolution of the state-of-the-art in clinical IE technologies has been witnessed through competitions and shared tasks such as the i2b2 (Integrating Biology and the Bedside) challenges held in 2010, 2011, 2012, and 2018 [12,38,39]. These competitions have promoted the public sharing of valuable datasets, such as MIMIC-III and CanTeMiST [40,41]. Many techniques have evolved over the past 2 decades, utilizing predefined lists of terms to identify meaningful words and word sequences in clinical narratives and to assign terminology codes to them [11]. Rule-based approaches, relying on rules crafted by domain experts, as well as machine learning, have demonstrated their potential [42,43]. Particularly, CRFs have gained popularity for sequence labeling tasks in clinical NER [44]. More recently, deep neural networks have revolutionized machine learning and its use in (clinical) NLP scenarios, particularly with transformer-based models such as BERT. Models such as bioClinicalBERT, ClinicalBERT, and PubMedBERT, pretrained on BERT's architecture using large biomedical corpora, have shown promising performance in representing clinical domain text data, NER, and RE tasks [25,27,28,45].

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This is why we proposed an approach that uses these models on the one hand but, on the other hand, emphasizes the target structures, which required a careful analysis of the domain and existing ontological representations, such as SNOMED-CT and web ontology language, in concert with information templates such as HL7-FHIR, which provide context for the patient-level instances of ontology concepts. Accordingly, guidelines were established for representing medication information, which were used to guide our annotation process. From the annotated medication corpus, exhibiting an idiosyncratic mixture of English and Thai language elements, fine-tuning, validation, and test data were obtained to compare the performance of different pretrained DL models for medication statement annotations. All models exhibited impressive performance metrics, with ClinicalBERT consistently outperforming the other 2 models in all scenarios, indicating its robustness. Examining each of the 8 target entity types, we found "Substance," ie, the ingredients of the drugs whose administration was described.

Error Analysis

From the results, all models performed very well on the test dataset, with F_1-scores over 0.90. ClinicalBERT demonstrates the highest discrimination performance compared to the other models, achieving F_1-scores over 0.80 in all entity types except "Unit of Measure." The performance metrics for this category were the lowest across all models. We found that the errors of both ClinicalBERT and BioClinicalBERT were primarily type confusion caused by compound tokens, eg, "100u/10ml." The models classified these as "Decimals," whereas the ground truth labeled them as "Units." This misclassification can be attributed to the sub-word tokenization mechanism of BERT-based models. For a compound string like "100u/10ml," the tokenizer splits the text into a sequence of numeric heads and unit suffixes: ["100," "##u," "/," "10," "##ml"]. Because the model encounters the explicit numeric tokens (100, 10) as the initiating elements of the sequence, it prioritizes the numeric semantics—strongly associated with the "Decimal" class during training—over the unit suffixes. Consequently, the model labels the entire span as a numerical value rather than a measurement unit, whereas human annotators prioritized the "Unit of Measure" aspect. This suggests that the lower "Unit" performance score reflects a disagreement on label granularity for compound tokens rather than a failure to extract clinical information. In contrast, we found one instance where PubMedBERT misclassified "gm"(gram)—labeled as "Unit of Measure"—as a "Substance" entity type. We believe this error is due to the typical omission of units by physicians, such as in expressions like "Amlo (5) 1*1 po pc," where the unit is implicit, or the use of abbreviations like "ml" for milliliters and "mg" for milligrams. Improving the recognition of abbreviated and implicit units appears essential for better NER performance.

Models Comparison

In comparing our results to other methods, we observed the following. Tao et al [44] reported a mean F_1-score of 0.864 using CFR on the 2009 i2b2 dataset, while we achieved an F_1-score of 0.895 with ClinicalBERT. Tao et al [44] reached a higher "Route of administration" F_1-score of 0.909. Tu et al [46] used bidirectional long short-term memory-CRF on the 2009 i2b2 dataset and achieved a weighted average F_1-score of 0.985 overall, exceeding 0.70 for the medication entity type. This demonstrates similar performance to our models. Li et al [47] evaluated pretrained language models for NER in clinical trial eligibility criteria using multiple corpora (ElilE, Covance, and Chia) in the clinical domain, focusing on a broad range of entity types such as Condition, Drug, Qualifier, Measurement, Procedure, Observation, Temporal Measurement, Anatomic Location, Negation, and several others. They found that the PubMedBERT model performed best with F_1-scores of 0.715, 0.836, and 0.622 for the 3 corpora, respectively [47]. A similar study by Narayanan et al [48] also used BioClinicalBERT and PubMedBERT to extract medication information and adverse events from n2n2 2018, which included 9 different entity types for medication data. Their MT-NER-PMB model achieved strict and relaxed F_1-scores of 0.809/0.910 for n2c2 2018 and 0.809/0.910 for n2c2 2009. Looking at the performance of each class, MT-NER-PMB had a medication/drug entity type partial F_1-score of 0.935, whereas our fine-tuned ClinicalBERT showed a partial F_1-score of 0.928. However, our study uses different labels for some entity types due to our concern of referring to international standards SNOMED-CT and FHIR instead of proposing our own annotation scheme. For example, our "Decimal" entity type, which achieved a partial F_1-score of 0.933, could refer to dosage and dose quantity, with our "Time patterns" entity type referring to frequency and duration. These results are comparable to MT-NER-PMB's performance of "Dosage" (0.9438), "Duration" (0.8719), and "Form" (0.9612). Gou et al [49] demonstrated their best NER model using RoBERTa, achieving a 0.926 microaveraged F_1-score for medication event classification on the n2c2 2018 dataset. In comparison, our model showed an overall partial F_1-score of 0.973, indicating superior performance in NER regarding the identification and classification of medication-related text spans in clinical narratives. Furthermore, our study extends these comparisons by evaluating the impact of native language pretraining on code-switched clinical text. While it might be hypothesized that ThaiBERT or MultilingualBERT would outperform English-only models due to their correct tokenization of Thai script, our results indicate otherwise. ClinicalBERT consistently outperformed both ThaiBERT and MultilingualBERT. This finding can be attributed to the linguistic structure of Thai discharge summaries: while the narrative flow involves Thai grammar and instructions (eg, " "), the core medical entities—such as medication names, routes, and dosage abbreviations—are predominantly written in English or Latin (eg, "Simvastatin," "po," "bid"). Consequently, even though English-specific models treat Thai characters as out-of-vocabulary tokens, they effectively utilize the robust English medical terminology as semantic anchors. This suggests that for this specific task, biomedical domain pretraining is more critical than native vocabulary coverage.

Since 2022, the success of generative AI based on large language models, with its flagship ChatGPT, has demonstrated great performance on various tasks in NLP. It is, therefore, interesting to mention the approach regarding their NER performance,

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particularly in terms of the shift from classical annotation to prompt engineering, without the need for large training datasets. In a recent study, we investigated the use of multiple prompt commands in ChatGPT to perform NER tasks on Thai medication prescription data from the same hospital as our study [16]. This study yielded an average strict precision and recall of 0.84 and 0.75, respectively, for the best-performing NER prompt. Although this ChatGPT zero-shot approach showed promising NER performance, the model's misrecognition, evidenced by poor recall (0.66) in the entity type of instructions, raised a major concern about this approach for medication data extraction. This entity type misclassification could result in missing important parts of medication prescriptions, particularly dose quantity, timing, and route. Hu et al [50] also explored using ChatGPT to extract medical problems, treatments, and tests from synthetic discharge summaries based on the 2010 i2b2 challenge guidelines. Using different prompts and versions of ChatGPT, they reported F_1-scores of 0.436 (strict) and 0.719 (partial) for ChatGPT 3.5, and 0.526 (strict) and 0.838 (partial) for ChatGPT 4 [51].

While Generative AIs have proven useful for NER tasks, we believe that pretrained DL models still hold some advantage over Generative AIs, particularly in terms of patient data privacy and safety protocols. Utilizing commercial Generative AI application programming interfaces requires transmitting sensitive discharge summaries to external servers, which often violates strict data governance and patient confidentiality standards. In contrast, DL models are compact enough to be deployed entirely on-premises, ensuring that protected health information never leaves the hospital's secure infrastructure. Furthermore, as discriminative classifiers, BERT models are constrained to extracting existing text, inherently minimizing the risk of "hallucination"—the generation of plausible but nonexistent medical facts—which remains a critical safety liability for Generative AIs [52-54]. Therefore, while Generative AIs offer broad reasoning capabilities, fine-tuned transformers remain the most robust, privacy-compliant solution for high-stakes clinical entity extraction. Future work may explore hybrid systems that leverage the reasoning capabilities of Generative AIs—either through secure APIs or via local, on-premises model deployments—while maintaining the strict data safety constraints of the hospital environment.

Conclusion

Our study demonstrates that fine-tuned pretrained transformer models—especially those with biomedical domain pretraining—have high clinical NER performance for extracting structured medication statements from clinical narratives in a Thai hospital.

While the models achieved high F_1-scores across various entity types, certain categories, such as the "Unit of Measure," demonstrated the need for future improvement. Compared to other methods, our models exhibit competitive or superior performance, particularly in medication entity classification. The core strength of our study lies in the annotation and use of our data to fine-tune, validate, and test the model, specifically tailored for a Thai hospital setting that features Thai-English code-switched narrative clinical text. Our results also validate that English-pretrained biomedical models are a viable and robust solution for this setting, effectively utilizing English medical terminology as semantic anchors even within Thai grammatical structures.

Unlike previous studies using public datasets like n2c2 2009 or i2b2 2009, we leverage an ontology-based approach, which adds value by enhancing precision, reducing ambiguity, and enabling better integration and interoperability with standard terminology systems. This approach also provides a structured framework for handling context-specific terminology. However, there is a gap in utilizing our annotated dataset for RE tasks. Expanding the dataset to include more diverse entities, such as diseases, procedures, and temporal data, is necessary to enhance the model's capacity to extract complex medical information.

Nevertheless, we acknowledge that the current study represents only the first stage of semantic interoperability. While our models achieve high performance in the NER task, the next critical step is normalizing these entities to their specific fine-grained SNOMED-CT codes and linking their relations together. Future work will need to leverage the granular annotations preserved in our dataset to develop downstream MCN and RE models to enhance the model's capacity to extract complex medical information.

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Data Availability

The datasets generated and/or analyzed during the current study are not publicly available due to confidentiality agreements with participants, which restrict the sharing of sensitive personal data. However, the data can be made available by the corresponding author upon reasonable request, subject to institutional approval. Code scripts for the model development and performance evaluation are available on GitHub [55].

Authors' Contributions

NI, WS, SS, and MK contributed to the conceptualization and study design. NI and WS collectively investigated and curated annotated data. NI, WS, SS, and MK decided on the methodology to be used. NI, WS, and MK conducted the formal analyses. NI and WS drafted the original manuscript. NI, WS, SS, and MK reviewed, edited, and approved the final version of the paper.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Exhaustive statistical analyses and granular performance metrics of the five evaluated transformer models.
[DOCX File, 102 KB - formative_v10i1e82685_app1.docx]

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Abbreviations

AI: artificial intelligence
BERT: Bidirectional Encoder Representations From Transformers
BFO: basic foundational ontology
CRF: conditional random field
DL: deep learning
EHR: electronic health record
HL7 FHIR: Health Level Seven Fast Healthcare Interoperability Resources
IE: information extraction
MCN: medical concept normalization
NER: named entity recognition

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NLP: natural language processing
RE: relation extraction
SNOMED-CT: Systematized Nomenclature of Medicine-Clinical Terms

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Telehealth as a Strategy to Expand Access in Brazil's Unified Health System: Analysis of São Paulo State's Experience Across the Three Levels of Health Care

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Abstract

Background: The COVID-19 pandemic accelerated the adoption of telehealth as a key strategy within Brazil's Unified Health System. In São Paulo State, digital health initiatives have been developed to implement telehealth-based care models across all 3 levels of health care.

Objective: The aim of this study is to describe the implementation process of the telehealth model in public health facilities to a lesser extent.

Methods: This descriptive study reports on the implementation of telehealth services at the primary, secondary, and tertiary levels of health care in São Paulo State. Thirty primary health units, 4 specialty care outpatient clinics, and 18 hospitals were selected by the institutions participating in the project based on technical, health care, and infrastructure criteria. Teleconsultations were conducted through the institutional teleconferencing platform, ensuring data security and privacy. Data were collected through REDCap (Research Electronic Data Capture) between April and December 2024, including operational metrics and satisfaction scores (Net Promoter Score [NPS]). All participating health care facilities signed a term of adherence and data sharing agreement. Patients received care only after being informed and after signing a consent and adherence term for telehealth form.

Results: Telehealth was implemented in 52 health care facilities across 47 municipalities in São Paulo State. A total of 19,053 teleconsultations were conducted in primary health units (NPS 97) and 218 in specialty care outpatient clinics (NPS 74), and 4178 intensive care unit case discussions were held (NPS 86).

Conclusions: The findings suggest that telehealth is a feasible strategy across all levels of health care, even when implemented at a limited scale, contributing to expanded access and service coverage.

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KEYWORDS

telehealth; public health service; primary health care; secondary health care; tertiary health care

Introduction

The structure and preparedness of international health systems experienced profound changes following the World Health Organization's (WHO) declaration of a Public Health Emergency of International Concern in January 2020 due to the global COVID-19 pandemic [1]. This global emergency status demanded urgent action and the rapid reorganization of services, particularly in the health care sector. In this context, telemedicine emerged as a crucial tool, broadly defined as the use of Digital Information and Communication Technologies (DICT) to deliver medical services without in-person interaction between health care professionals and patients [2]. In Brazil,

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this scenario has intensified in recent years. In 2022, federal legislation formally regulated telehealth [3-5], highlighting its strategic role in strengthening the health care delivery network.

Beyond the immediate impacts of the pandemic, global population growth and increased life expectancy have intensified the demand for accessible, digitally integrated health care services [6]. Many of these demands have been addressed through telemedicine, particularly in the private health care sector, where its adoption has been more prevalent [7-9]. In this broader context, digital transformation and the optimization of basic health services have been recognized as viable strategies. Countries that have adopted effective public policies and strategies for digital health integration have achieved meaningful advances in health care delivery [10,11]. However, in Brazil's public health care system, telehealth implementation still faces several barriers, including technological inequalities, economic limitations, and a shortage of trained professionals. Considering that approximately 70% of the population lacks access to private health care [12], telehealth remains relatively uncommon and not widely accessible to the entire population.

São Paulo is the most populous state in Brazil, with over 44 million inhabitants, compared to countries such as Argentina or Spain. It also holds significant economic strength, with a gross domestic product exceeding US$ 500 billion, on par with the economies of France and the United Kingdom [13,14]. This demographic and economic context positions São Paulo State as a pioneer in several fields [15-19]. Nevertheless, the state continues to face major challenges in ensuring equitable and comprehensive access to public health care. Currently, over 60% of the population, around 28 million residents, depend on the Unified Health System (Sistema Único de Saúde [SUS]) for medical services [20].

Given this scenario, particularly in low- and middle-income countries, the challenges associated with successful telehealth implementation become evident [21,22]. In addition to technological barriers and the need for interoperability between systems, key enablers of effective digital transformation include shifts in organizational culture and the empowerment of both health care professionals and the population [11,23].

In this context, the development and adoption of strategies to expand access to public health care have become urgent. In Brazil, the SUS stands to benefit significantly from digital transformation initiatives, with telehealth representing a key priority. These efforts have the potential to strengthen the health care value chain, expand service networks, and improve system performance, benefiting providers, health care professionals, and most importantly, patients [24]. Furthermore, telehealth initiatives tailored to local health needs and territorial specificities may offer an innovative approach to expanding service reach and ensuring continuity of care across all levels of the health care system [25,26].

This study aims to describe the implementation process of a telehealth model in public health care facilities, conducted on a limited scale across the 3 levels of health care.

Methods

Study Design

This study describes the implementation of telehealth services across 3 health care levels in São Paulo State and presents the preliminary results of this proof-of-concept, conducted between March and December 2024.

Ethical Considerations

All participating health care facilities signed a term of adherence and data sharing form, formally confirming their participation and the sharing of individual data with the proposing health care facility. Patients seeking telehealth services at these facilities were presented with a consent and adherence term for telehealth services form and were referred to telehealth only after signing this document. The term explicitly detailed the care provisions and outlined the rights and responsibilities of both parties, including medical credentials and qualifications. This study was approved by the Research Ethics Committee for Human Subjects of Hospital das Clínicas da Faculdade de Medicina da Universidade de São Paulo (HCFMUSP; Certificate of Presentation for Ethical Review [CAAE]: 85835525.0.0000.0068, #7.366.109). The study complies with the Brazilian Data Protection Law, which sets rules and guidelines for processing and confidentiality of data [27].

Local Context and SUS

São Paulo State is one of Brazil's 27 federative units (26 states and 1 federal district), located in the southeastern region of the country, with a land area of 248,309.3 km² and a population of 44,651,714 inhabitants [28]. The state comprises 645 municipalities, approximately 78% of which are considered small (<50,000 inhabitants), while only 9% have more than 500,000 inhabitants; these larger municipalities account for 42% of the population, reflecting high population density in these areas [29]. São Paulo State is organized into regional divisions responsible for managing sectors, such as education, infrastructure, environment, and social development. For the health sector, the organization is structured into 17 regional health departments distributed across the territory [29].

Although the SUS is organized according to the Health Care Network (Rede de Atenção à Saúde [RAS]) model, which considers different levels of care and technological capacities to minimize fragmentation of health actions and services [30,31], challenges in integration remain. Consequently, efforts have been focused on advancing interoperability among SUS information systems [32]. São Paulo State identified an opportunity by establishing a digital health strategy aimed at expanding access to health care and promoting future integration across different health care levels.

The first step was the establishment of the *Centro Líder de Inovação em Saúde Digital*, affiliated with *Secretaria de Estado da Saúde de Sao Paulo* (Sao Paulo's Health State Secretariat, Brazil), *Fundacao Faculdade de Medicina* (financial support), *Nucleo de Inovação Tecnologica InovaHC*, and the *Hospital das Clinicas HCFMUSP, Faculdade de Medicina, Universidade de Sao Paulo, Sao Paulo, Brazil*. Through the *Programa de Pesquisa, Desenvolvimento e Inovação em Saúde Digital*,

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proof-of-concept proposals for telehealth-focused care solutions were developed for integration into São Paulo State's public health care system. Qualified professionals composed the operational and medical teams responsible for implementing the telehealth model. These teams operated at the *Centro Líder de Inovação em Saúde Digital* according to their assigned health care level.

Implementation of Telehealth Services

The current telehealth implementation proposal was developed within the SUS organizational framework, encompassing telehealth provision in primary health units (PHUs), specialty care outpatient clinics (Ambulatório Médico de Especialidades [AMEs]), and hospitals within São Paulo State's public health care network. Given the State's significant territorial size and population density [33], an opportunity was identified to test a proof-of-concept aimed at assessing the feasibility of expanding telehealth across the public health care network at all 3 health care levels. The telehealth model is based on a triad: health care delivery, training program, and monitoring indicators.

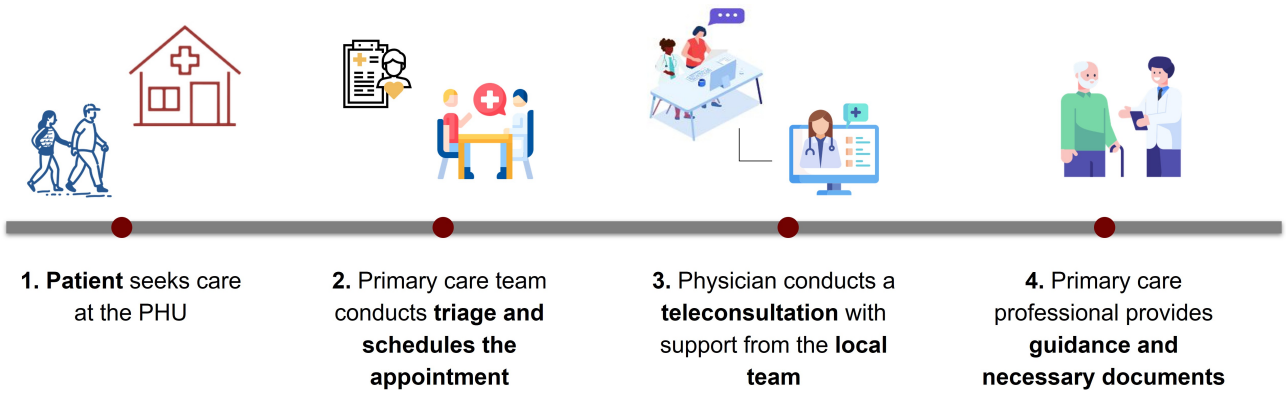
For implementation, all participating health care facilities were required to meet minimum infrastructure and technological standards. These included having a private space for telehealth services, stable internet connectivity, and appropriate desktop equipment (computer, camera, microphone, and speakers). These requirements were verified through equipment functionality tests and security checks related to remote access and telehealth service delivery. All sessions were conducted using the institutional teleconferencing platform developed by HCFMUSP, ensuring data security and patients' privacy during care delivery [34,35].

The telehealth model in primary care was designed to promote innovation and enhance health services, emphasizing health promotion through telehealth implementation at PHU. Thirty PHUs were selected based on criteria including nonparticipation in the "Mais Médicos Program", the highest number of family health teams per unit, population size distribution, and the use of the citizen's electronic health record.

Telehealth services were offered in the following modalities: teleconsultation ("remote medical consultations mediated by DICT, with the physician and patient located in different places"), teleinterconsultation ("exchange of information and opinions between physicians, supported by DICT, with or without the patient's presence, to assist in clinical or surgical diagnosis or treatment"), and teleconsultancy ("consulting activities mediated by DICT among physicians, managers, and other professionals, aimed at providing clarification on administrative procedures and health actions") [5]. These services were allocated 18 hours per week for each PHU.

The patient's journey began with attendance at the PHU to access the local physical and technological infrastructure, as well as to receive guidance and support from the unit's health care professionals. The health care teams at the participating PHU were responsible for screening and scheduling patients under this model, prioritizing cases of lower clinical severity for referral. The patient's journey is illustrated in Figure 1.

Figure 1. Patient's journey at the primary health unit (PHU) within the telehealth model.



At the secondary care level, the structured model included the provision of telehealth services in 9 medical specialties: psychiatry, orthopedics, neurology, gastroenterology, cardiology, endocrinology, infectology, nephrology, and hematology. These specialties were selected based on unmet demands in the waiting lists of São Paulo State's health care regulation system. Services were delivered through four AMEs located in different municipalities across São Paulo State. These units were selected based on having both the highest unmet demands for the selected specialties and the largest SUS-dependent population.

The telehealth strategy at this health care level involved the use of a fully remote model, designed to expand access to medical care in the 9 specialties. Teleconsultations and teleinterconsultations were offered, totaling approximately 47 hours per month per unit.

The patient's journey in secondary health care began with a medical referral from primary health care. Patients were considered eligible for telehealth services based on criteria outlined in clinical protocols developed by a team of specialist physicians from HCFMUSP. These protocols aimed to guide clinical decision-making and standardize care and include elements such as *International Classification of Diseases* codes reflecting the highest demand, eligibility criteria for telehealth services, and prioritization of patients with available diagnostic test results or those who had undergone previous procedures (Figure 2).

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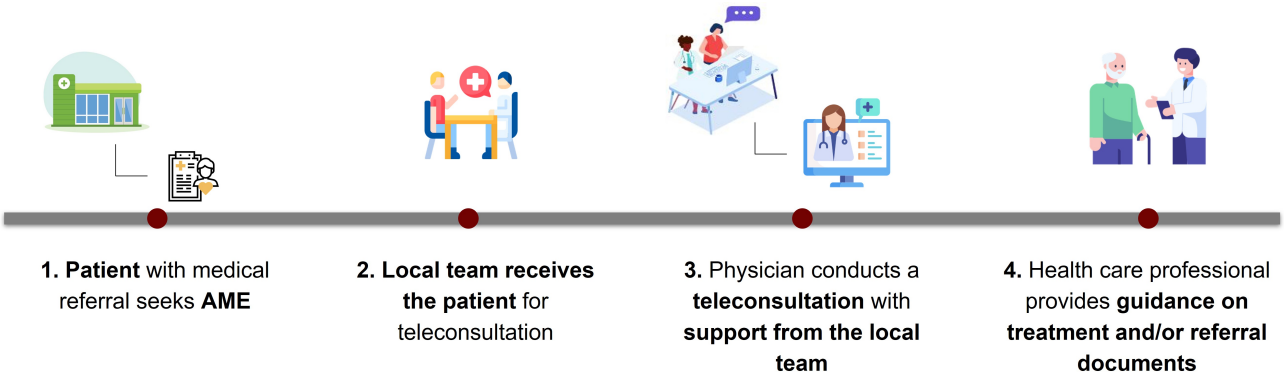
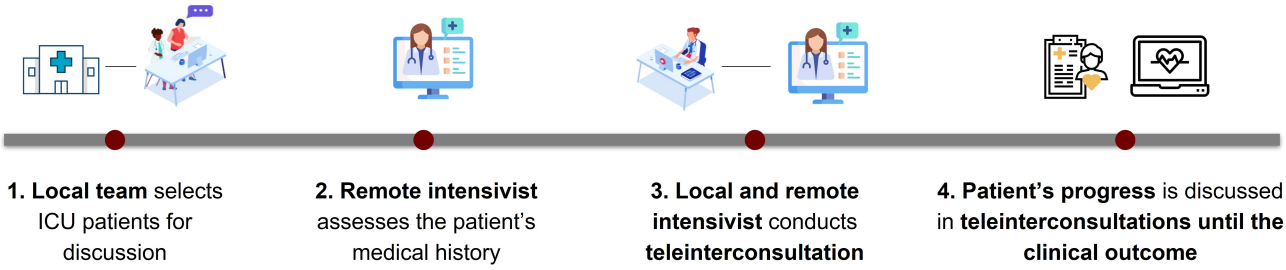
Figure 2. Patient's journey at the specialty care outpatient clinic (Ambulatório Médico de Especialidades [AME]) within the telehealth model.



At the tertiary health care level, the telehealth initiative aimed to provide qualified remote support to intensivist physicians and multidisciplinary teams working at intensive care unit (ICU) beds of public hospitals across São Paulo State. This support was delivered via teleinterconsultations (ICU case discussion between intensivists in a virtual environment). The exchange of knowledge in intensive care medicine and other specialties has the potential to significantly enhance hospital practices, as well as improve clinical decision-making among health care teams and administrators. Teleinterconsultations were offered in 18 selected hospitals based on criteria such as having 10 or more adult general ICU beds, having an electronic health record system implemented in the ICU, high ICU mortality rates, extended ICU length of stay, limited availability of on-staff specialists, and high clinical complexity of admitted patients. Teleinterconsultation was available 7 times per week to each participating hospital.

The patient's journey at the tertiary health care level began with the selection of eligible patients for case discussion. The telemedicine intensivist first reviewed the patient's medical history and then conducted the teleinterconsultation with the local intensivist. The patient's clinical progress was continuously monitored and reassessed through teleinterconsultations until the final outcome of the case (Figure 3).

Figure 3. Patient's journey in intensive care units (ICUs) within the telehealth model.



Training Program

To standardize workflows and ensure consistent knowledge across teams, training programs were offered both to internal teams (physicians responsible for providing telehealth services) and to the local teams at participating health care facilities.

For the internal teams, training took place immediately after hiring and aimed to familiarize professionals with institutional clinical protocols, telehealth medical documentation, and operational tools. For the local teams, the initial training focused on familiarizing staff with telehealth workflows and platform usage. Following the start of telehealth services, the training program continued through ongoing education tailored to the specific needs of each initiative. The training program was delivered in 3 formats: asynchronous, synchronous, and in-person.

The target audience included health care professionals (physicians, nurses, nurse assistants or technicians, physical and respiratory therapists, among others) and nonclinical staff who were part of the local health care teams at participating facilities.

Satisfaction Score

Patient and health care team satisfaction with telehealth services was evaluated using the Net Promoter Score (NPS). The NPS is derived from a single question: "On a scale from 0 to 10, how likely are you to recommend our service to a friend or colleague?" Based on the responses, the percentage of promoters (scores of 9 and 10) and detractors (scores from 0 to 6) was calculated relative to the total number of respondents. The NPS was then obtained by subtracting the percentage of detractors from that of promoters and multiplying the result by 100. A score of 76 or higher was considered to fall within the zone of excellence [36].

Data Collection

Structured questionnaires were administered using the REDCap (Research Electronic Data Capture) platform (REDCap 14.5.21, 2025; Vanderbilt University). Data related to telehealth service delivery were collected between April 2024 and December 2024. The operational indicators are presented in Table 1.

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Table . Operational metrics and indicators of the telehealth model.

Indicator	Description
Operational health care facilities	Cumulative number of units participating in the telehealth model
Number of telehealth services	Cumulative number of teleconsultations, teleinterconsultations, and teleconsultancies performed
Number of teleconsultations	Cumulative number of teleconsultations performed
Number of teleconsultancies	Cumulative number of teleconsultancies performed
Number of teleinterconsultations	Cumulative number of teleinterconsultations performed
Number of patients	Cumulative number of new patients served through telehealth
Satisfaction score (patient NPS[a])	NPS-patient satisfaction with teleconsultation
Satisfaction score (health care team NPS)[b]	NPS-health care team satisfaction with teleinterconsultation

[a]NPS: Net Promoter Score.

[b]For hospitals, the NPS was applied to health care teams.

Results

A total of 52 health care facilities participated in this study, covering all 3 health care levels. The characteristics of these participating health care facilities are summarized in Table 2. The participating PHU had an average population of 6366 (SD 5133.3) individuals and an average team size of approximately 13 (SD 5.1) health care professionals. Regarding the municipalities where these PHUs were located, 23 (77%) had populations of up to 50,000 inhabitants.

Among the 4 AMEs, the average team size was 90 (SD 42.1) health care professionals. In terms of the municipalities served by these AMEs, 2 (50%) were located in areas with 100,001 to 400,000 inhabitants, 1 (25%) in municipalities with 50,001 to 100,000 inhabitants, and 1 (25%) in municipalities with 10,001 to 50,000 inhabitants. Referral coverage for AME services ranged from 13 to 25 municipalities.

Regarding the 18 participating hospitals, the average team size was approximately 83 (SD 68.7) health care professionals. Based on the number of SUS beds, 15 (83.3%) were classified as large-sized hospitals (151 to 500 beds) and 3 (16.7%) as extra-large hospitals (>500 beds). In terms of administrative management, 17 (94.4%) were state-managed, while 1 (5.6%) was managed by Social Health Organizations. Among the 15 municipalities where the hospitals were located, 8 (53.3%) had populations between 100,001 and 400,000 inhabitants, 6 (40%) had more than 400,000 inhabitants, and 1 (6.7%) had between 10,000 and 50,000 inhabitants.

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Table . Characteristics of the participating health care facilities (N=52).

Characteristics	Values
PHU[a] (n=30)	
Population coverage of the PHU (mean, SD)[b]	6366.2 (5133.3)
Registered population at the PHU (mean, SD)[b]	5852.5 (3505.4)
Number of health care teams (mean, SD)[b]	1.8 (1.1)
Number of health care professionals (mean, SD)[b]	13.5 (5.1)
Municipality by population size, n (%)	
Up to 10,000 inhabitants	6 (20)
From 10,001 to 50,000 inhabitants	17 (56.7)
From 50,001 to 100,000 inhabitants	6 (20)
From 100,001 to 400,000 inhabitants	1 (3.3)
Over 400,000 inhabitants	0 (0)
Proportion of SUS[c]-dependent population per municipality, n (%)	
≤25%	0 (0)
25.1% - 50%	0 (0)
50.1% - 75%	8 (26.7)
75.1% - 100%	22 (73.3)
Specialty care outpatient clinics (AME) (n=4)	
Number of health care professionals (mean, SD)[b]	90.0 (42.1)
Municipality by population size, n (%)	
Up to 10,000 inhabitants	0 (0)
From 10,001 to 50,000 inhabitants	1 (25)
From 50,001 to 100,000 inhabitants	1 (25)
From 100,001 to 400,000 inhabitants	2 (50)
Over 400,000 inhabitants	0 (0)
Number of referred municipalities, n	
Botucatu	25
Dracena	17
Itapeva	15
Ourinhos	13
Hospital (n=18)	
Number of health care professionals (mean, SD)[b,d]	83.1 (68.7)
Total number of SUS beds, n (%)	
Small size (≤50 beds)	0 (0)
Medium size (51-150 beds)	0 (0)
Large size (151-500 beds)	15 (83.3)
Extra capacity (>500 beds)	3 (16.7)
Type of management, n (%)	
Municipal	0 (0)
State	17 (94.4)
Social health organization	1 (5.6)

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Characteristics	Values
Municipality by population size[e], n (%)	
Up to 10,000 inhabitants	0 (0)
From 10,001 to 50,000 inhabitants	1 (6.7)
From 50,001 to 100,000 inhabitants	0 (0)
From 100,001 to 400,000 inhabitants	8 (53.3)
Over 400,000 inhabitants	6 (40.0)

[a]PHU: primary health unit.

[b]Self-reported data by the participating facility.

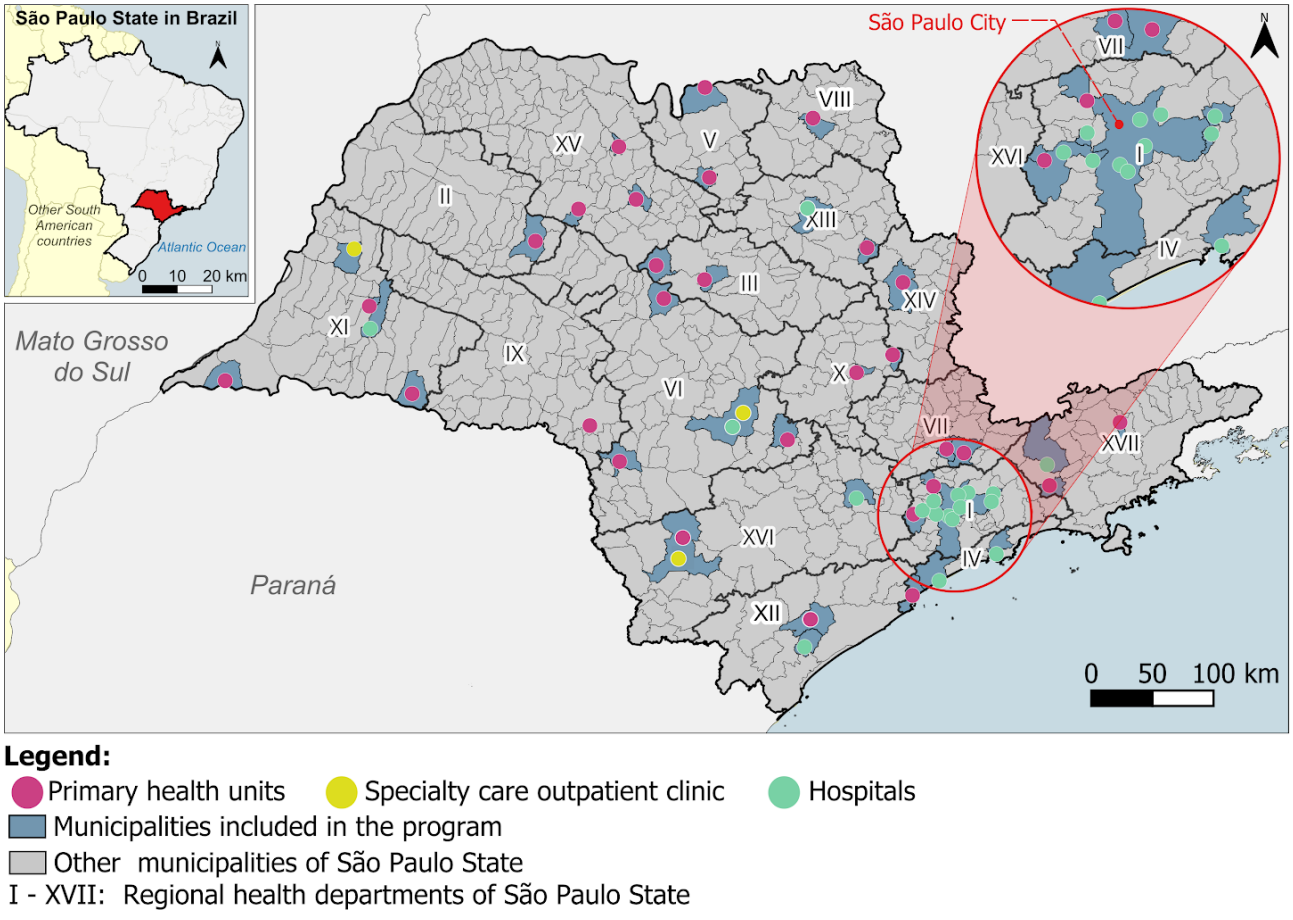
[c]SUS: Sistema Único de Saúde (Unified Health System).

[d]Data available for 13 hospitals.

[e]Includes municipalities where the participating public health care facilities were located. The city of São Paulo included 4 hospitals in the sample.

Regarding geographic distribution, 47 municipalities in São Paulo State were covered by at least 1 participating health care facility. The PHUs were located in 30 distinct municipalities, the AME in 4, and hospitals in 15 municipalities (Figure 4).

Figure 4. Geographic distribution of participating health care facilities by regional health departments in São Paulo State.



The main results of the operational indicators related to telehealth service provision are presented in Table 3. At the PHU level, a total of 19,041 telehealth services were delivered, comprising 14,686 teleconsultations, 3791 teleconsultancies, and 562 teleinterconsultations. A total of 12,584 patients were served, and the patient satisfaction score (NPS) was 97.0, classified within the “excellence zone”.

At the AME level, 218 telehealth services were provided, including 216 teleconsultations and 2 teleinterconsultations. A total of 218 patients were attended, with an NPS of 74, classified as the “quality zone.”

In hospitals, 4178 ICU case discussions were conducted, involving 725 patients. The health care team’s satisfaction score with the telehealth services was 86, classified within the “excellence zone.”

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Table . Operational metrics of the telehealth models across primary, secondary, and tertiary health care levels in São Paulo[a].

	PHU[b]	AME[c]	Hospital
Operation start	April 2024	November 2024	August 2024
Number of health care facilities	30	4	18
Number of telehealth services	18,874	219	—[d]
Number of teleconsultations	14,563	217	—
Number of teleconsultancies	3753	—	—
Number of teleinterconsultations	558	2	1206
Number of ICU[e] case discussions	—	—	4654
Number of patients	12,425	219	701
Satisfaction score (NPS)[f]	97.0[g,h]	74.0	86.0[i,j]

[a]Data refer to the period from April 1 to December 31, 2024.

[b]PHU: primary health unit.

[c]AME: Ambulatório Médico de Especialidades (specialty care outpatient clinic).

[d]Not available.

[e]ICU: intensive care unit.

[f]NPS: *Net Promoter Score.*

[g]Patient.

[h]Delight zone.

[i]Health care team.

[j]Excellence zone.

Discussion

The fragmentation of health systems and services stands out as one of the major contemporary challenges faced by public health systems worldwide [37]. In response to this issue, in 2016, the WHO proposed a significant restructuring of public health systems to its member countries [38]. This new framework emphasizes patient-centered models that integrate care across different health care levels and sectors. An opportunity was identified to encourage models aimed at the integration of health care services in order to improve service accessibility, reduce unnecessary hospitalizations and readmissions, enhance treatment adherence, increase patient satisfaction, and improve health outcomes [38].

The National Health Service in the United Kingdom is one of the most well-established public health systems globally [39]. Since its inception in 1948, the National Health Service has undergone a major legislative reform to promote a new integrated care model known as integrated care systems (ICSs) [40]. Established in 2022 across England, ICSs focus on improving health and care services through prevention, better outcomes, and the reduction of health inequalities [41]. ICSs are described as “partnerships of organizations that come together to plan and deliver joined-up health and care services and to improve the lives of people who live and work in their area.” This integration ensures holistic patient support, illness prevention, inequality reduction, and more effective management of health across primary, community, and secondary care [41].

Integration across health care levels and between health and social care sectors has also been a continuous priority in health system reforms within the Nordic countries. Each country has adopted distinct strategies to tackle challenges related to population aging, multimorbidity, and care fragmentation [42,43]. These systems are rooted in principles of universality, equity, and predominantly public financing. They are characterized by intersectoral coordination, the use of interoperable digital technologies, and multilevel governance mechanisms that foster continuity of care [42,44].

Building on these evolving health care models, telehealth has emerged as a key enabler in supporting and transforming care delivery [11]. Digital technologies are increasingly leveraged to enhance health care provision across levels of care [45]. Recent evidence has demonstrated significant benefits, including reduced hospital admissions, improved clinical outcomes, and enhanced patient experiences [46-49].

This study described the implementation process of telehealth services across all 3 health care levels in 52 public health care facilities in São Paulo State. A total of 20,464 telehealth services were delivered, covering 13,527 patients. It is important to emphasize that this initiative was designed with a limited-scale scope, aiming to implement and observe each model independently. This approach enabled a more detailed understanding of the unique characteristics and operational needs of each level of care. The insights obtained from this proof-of-concept phase are expected to inform the design of an integrated telehealth model capable of supporting patients throughout their health care journey.

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In Brazil, successful telemedicine experiences have been reported across different population groups and health conditions within the SUS at all 3 health care levels [50-53]. In 2021, the Digital Primary Health Care (APS Digital) initiative was implemented in the remote community of Paissandú district (Santarém, Pará State, Brazil). In this initiative, a family and community physician based at HCFMUSP conducted teleconsultations, supported by a local health team consisting of a nurse and 2 nursing technicians. Over a 3-month period, the initiative delivered 220 teleconsultations, achieving 95% patient satisfaction and resolving 76.6% of medical complaints, highlighting the viability of telehealth in underserved areas [50].

Also at the primary care level, a similar initiative led by HCFMUSP, in partnership with the Brazilian Agency for Support to the Management of the Unified Health System, launched the UBS+Digital project. The aim was to provide teleconsultations in PHUs lacking on-site physicians, with 18 weekly hours allocated to telehealth services. Over a 9-month period, 6312 teleconsultations were conducted, and the patient satisfaction score (NPS) reached 97, placing the initiative within the excellence zone [53].

It is worth highlighting that, in these earlier initiatives, PHUs did not have physicians as part of their health care teams. In contrast, this study specifically selected PHUs with on-site physicians, which enabled the implementation of additional telehealth modalities, such as teleinterconsultations. These sessions facilitate the exchange of clinical information and opinions between physicians to support diagnostic and therapeutic decisions [54]. In addition, the presence of a full health care team allowed the use of teleconsultancy, which supports administrative and clinical decision-making through interactions among professionals. Together, these two modalities accounted for approximately 23% of all telehealth services delivered in PHUs, suggesting that collaborative knowledge-sharing is becoming an increasingly embedded practice in primary care, one that enhances service management, team performance, and clinical outcomes [54,55].

In this study, the municipalities where participating PHUs were located had more than 50% of their populations depending on SUS. This scenario is consistent with São Paulo State's overall primary care coverage rate of 68.4%, indicating that many regions still face challenges in accessing timely and comprehensive primary health care services [56]. In this context, telehealth emerges as a crucial strategy for expanding access and reducing inequities at the primary care level.

Regarding secondary health care, AMEs were established in São Paulo State in 2007 as high-resolution health care facilities equipped with modern technologies, offering consultations, diagnostic tests, and in some cases, surgical procedures all within a single location [57]. Patients referred to AME come from primary health care services to address more complex health needs that could not be fully managed at the primary level. For the current telehealth model, 4 AMEs were selected, each offering an average of 47 hours of telehealth services per month. A total of 218 telehealth services were delivered, with a satisfaction score (NPS) of 74, which falls within the "quality zone."

Studies describing telehealth initiatives through AME remain scarce in the literature. In contrast, primary health care has increasingly been recognized as a favorable setting for integrating specialized care via telehealth projects. The "TeleAMES" project, approved by the Brazilian Ministry of Health, facilitated over 142,000 teleinterconsultations across 12 specialties at PHUs and Indigenous Health Centers in the North and Central-West regions of Brazil [58]. Similarly, other initiatives integrating specialist physicians into primary health care settings through teleinterconsultations and teleconsultancies have reported positive outcomes in terms of referral quality, patient satisfaction, and continuity of care [59-61].

Within this context of specialized health care delivery, even though implemented to a lesser extent, the telehealth model adopted in the AME of São Paulo State enabled scheduling of medical appointments across 9 specialties, reflecting the highest demand identified among the general population. The volume of telehealth services provided was dependent on scheduling availability within the Health Care Regulation System of São Paulo State, a platform designed to manage the allocation of specialized health care appointments and optimize population access to secondary health care services [62].

Initiatives in secondary health care aim to address persistent challenges in public health systems, such as inefficiencies in regulatory mechanisms, prolonged waiting lists, and the uneven distribution of medical specialists across geographic areas [58,63]. Access to secondary care services is consistently identified as one of the primary barriers to achieving comprehensive care within the SUS and is often described as the main "bottleneck" in the implementation of the RAS model [63-65]. In this context, initiatives that support the structuring and planning of strategies to alleviate pressures on the public health system and promote best practices are essential for the ongoing development of the SUS and the enhancement of user experience.

At the tertiary care level in the present study, a total of 4178 ICU case discussions were conducted through 1205 teleinterconsultations, serving 725 patients across 18 public hospitals in São Paulo State. The health care team satisfaction score was 86, placing it within the "excellence zone." Several hospital-based telehealth initiatives have gained prominence, especially during the COVID-19 pandemic. The HCFMUSP led the implementation of hospital telehealth services and the TeleICU model, which included online training for health care professionals. The Tele-ICU-SES project completed 11,823 teleinterconsultations across 34 hospitals in São Paulo, achieving a satisfaction score of 82. Its subsequent expansion to 5 additional hospitals nationwide (Tele-ICU-Brazil) resulted in 936 ICU case discussions and over 11,500 teleinterconsultations. Due to the increased risk among pregnant patients, particularly vulnerable to severe COVID-19, the project was further extended as Tele-ICU-Obstetric, providing telehealth support in 27 hospitals throughout the country [52]. At the hospital level, other methodologies were developed and adapted to broaden telehealth services across multiple specialties, totaling 140,671 telehealth services and meeting expectations for teleconsultation quality [51].

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Telehealth services in ICUs are recognized as a form of organizational innovation that enhances access to and quality of critical care [66]. Importantly, the effectiveness of these interventions is closely linked to the characteristics of the local environment and the degree of collaboration between remote providers and on-site critical care teams [66,67]. Therefore, understanding the local health care culture, available resources, and stimulating engagement among local health care professionals is crucial. In this study, the satisfaction level of participating health care teams reached the "excellence zone," reflecting high acceptance of the telehealth model implemented.

Finally, it is important to acknowledge the heterogeneity of public health care facilities in Brazil, particularly regarding resource availability across different regions and levels of care [68,69]. In this context, the successful implementation of innovative care models, such as telehealth, is often challenged by structural limitations, including insufficient infrastructure, unstable internet connectivity, and limited familiarity of health care professionals with digital tools. In this study, some participating health care facilities reported difficulties related to the availability of electronic equipment (computer, webcam, microphone, and headset), lack of private spaces suitable for remote consultations, and unstable internet connectivity. In these situations, the support provided by higher administrative levels proved essential to bridging such gaps and ensuring the successful execution of the telehealth model.

Since 2021, the WHO has been actively supporting countries in adopting digital health strategies to expand health care access [11]. These efforts align with the Sustainable Development Goals of the United Nations 2030 Agenda [70,71]. Within this framework, one of the guiding principles of digital transformation emphasizes the importance of inclusivity, aiming to reach not only socioeconomically, geographically, or culturally vulnerable populations but also those affected by digital illiteracy [72]. In this regard, DICT holds significant potential to reduce health inequalities by facilitating timely access to health information and digital tools for prevention and care [72].

Digital transformation in health care is a continuous process that requires not only the integration of new technologies but also a profound shift in organizational culture to foster a more efficient, accessible, and innovative health system. Although persistent challenges remain, including technological, cultural, and social barriers, as well as issues related to service and resource management [73], the main findings of this study are consistent with the existing literature and reinforce the understanding that telehealth represents a promising and feasible strategy to strengthen the SUS.

The findings and reflections presented in this study suggest the feasibility of implementing telehealth services across all 3 health care levels. Although applied on a limited scale, the initiative contributed to expanding access to public health care, reaching diverse regions throughout São Paulo State, and achieving favorable satisfaction scores among both patients and health care professionals.

Considering the geographic extent and regional disparities within São Paulo State, future telehealth strategies should be grounded in a comprehensive situational assessment of each territory, including evaluations of cultural context, technological infrastructure, availability of human resources, digital literacy, and the need for continuous professional training.

In this regard, the model implemented and described in this study—grounded in the triad of health care delivery, training program, and monitoring indicators—demonstrates significant potential for sustainable scale-up and reinforces the role of telehealth as a strategic and impactful approach to strengthening the public health care system.

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The manuscript was entirely written and peer-reviewed by the authors. OpenAI's ChatGPT [74] was used for English revision process to improve language clarity. The authors assume full responsibility for the content and interpretation of the manuscript.

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Data Availability

The datasets generated or analyzed during this study are available from the corresponding author on reasonable request.

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Authors' Contributions

MSSB, GBC, MLG, and CRRC contributed to the study design. MSSB and GBC contributed to data collection and analysis and wrote the first draft of the manuscript. MCCLBdA, RRdL, GGC, and CRRC reviewed the final manuscript. All authors read and approved the final version of the manuscript.

Conflicts of Interest

None declared.

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Abbreviations

AME: Ambulatório Médico de Especialidades (specialty care outpatient clinic)
DICT: Digital Information and Communication Technologies
HCFMUSP: Hospital das Clínicas da Faculdade de Medicina da Universidade de São Paulo
ICS: integrated care systems
NPS: Net Promoter Score
PHU: primary health unit
RAS: Rede de Atenção à Saúde (Health Care Network)
REDCap: Research Electronic Data Capture
SUS: Sistema Único de Saúde (Unified Health System)
WHO: World Health Organization

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Peaceful Death in Japanese YouTube Videos: Content and Network Analysis

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Abstract

Background: Death is a difficult topic to discuss for many. Notwithstanding, there is much to learn regarding the contemporary Japanese people's views on a good (peaceful) death. Particularly, shifts in public perceptions of death following the beginning of the COVID-19 pandemic should be considered by health care staff who deliver end-of-life care.

Objective: This study examined the recent representations of peaceful death in Japanese YouTube videos to understand related narratives and family structures.

Methods: We examined 457 YouTube videos about peaceful death using content and family network analyses. The videos were classified into 3 groups: ordinary people, celebrities, and fictional characters.

Results: We identified emerging medical actors who discussed end-of-life with the public. Death portrayed or discussed in the videos mostly involved adults aged 18 to 59 years (179/501, 36% ages), and the most common narrative was illness (101/839, 12% narratives). Although the most common religious stance was nonreligious (304/532, 57.14% religious stances), videos of regular people tended to mention or show a religious practice or symbol (154/272, 56.61% religious stances). There were significant differences ($F_{2, 454}$=22.81, P<.001) in terms of gender between celebrity and regular videos (P<.001, 95% CI 0.23-0.49), celebrity and fiction videos (P=.005, 95% CI 0.05-0.34), and fiction and regular videos (P=.008, 95% CI 0.03-0.29). This suggests a bias towards male representations of death among celebrities and fictional characters. Male family members were also overrepresented in videos about celebrities and fictional characters as per the visualization of family networks. The networks also suggested that common people's families were more complex than celebrity and fictional people's families. Furthermore, in common people's families, women and men were equally important when reaching out to other family members quickly and in terms of trust.

Conclusions: The current image of Japan as a nonreligious nation, and the gender bias in Japanese social media should be challenged. Furthermore, health care and research protocols related to end-of-life care for patients beyond older adults should be developed.

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KEYWORDS

end-of-life; family networks; Japan; social media; YouTube

Introduction

Background

Many find death to be a difficult topic to discuss in contemporary times, and our treatment of death impacts how we approach disability and sickness. Death may have several causes, and people adopt various attitudes according to previously agreed-upon values surrounding death. In general, Japanese people avoid talking about death. In Japan, since most people die in hospitals [1], a "good death" in medical contexts involves a grasp on diagnoses, treatment options, and whether patients and relatives decide the place to be treated or laid to rest [2]. This concept has been developed through interactions between medical staff, patients, and their kin and is linked to cultural and spiritual values [3,4]. However, not much is known about "good death" in other contemporary Japanese contexts.

In a previous study, we examined the concept of good death as a "peaceful death" on Japanese Twitter (subsequently rebranded X; Meza Xanat and Masanori, unpublished data). We found it a useful means to uncover conversations about difficult topics, as social media functions with a layer of anonymity that allows more free, open, and spontaneous discussions than conventional surveys and interviews [5]. As Japanese Twitter users talking about death tend to be young, we turned our attention to YouTube to complement previous findings. Launched in 2005, this video social media platform is the second most visited website after Google, with broader advertising revenue for male content creators (51.8% vs 48.2%) and broader advertising reach

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for male viewers (76.4% vs 66.1%, overlapped data) [6]. Additionally, it appears to appeal to a wide age range of Japanese users [7].

Therefore, our objective in this study was to examine public communication and perceptions of "good death" on Japanese YouTube. We reflected on what is considered a good death and end-of-life preparations.

Narratives of Death in Japan

Less educated people, Soka Gakkai Buddhists, and women have a greater tendency to practice religion and believe in the afterlife than others [8]. In Yamaguchi in Honshu (the largest island of Japan), 49% of the rural people interviewed had no image associated with the afterlife, recognized a continuity between life and death, and confronted it in a collective manner [9]. Meanwhile, a study found that the public does not know about the afterlife, and medical staff mostly do not believe in it; the colors associated with death were gray, white, and black; and this signaled a need for education on death [10].

Long [3,11] conducted interviews on the Japanese perception of death in hospitals and hospices, including religious themes. Patients' experience of dying, autonomy, social context, control over the dying process, and quality of end-of-life care were relevant for a good death [4]. A study on patients with cancer reported their desire to fight the disease, retain hope, unawareness of death, and prioritizing good relationships with family; whereas those who did not want to fight cancer prioritized physical and mental comfort during end-of-life care [12]. Morooka [13] found that the families of those who died at home focused on daily life and dying without causing care or financial burdens. Finally, Gould [14] noted that end-of-life products and services by Buddhism-related actors in Japan cater to lonely, stressed families through healing (*iyashi*) and a calm heart.

Regarding social media, Sueki [15] correlated clear and specific statements of wanting to commit suicide on Twitter with suicidal behavior, but not general conversations or mentions of death. Social learning theory argues that media consumption reinforces notions of what is acceptable, including suicide [16]. This theory has also been applied to celebrity studies. Katsumata [17] proposes that deaths by accident, epidemics, or environmental disasters on social media should convey the gravity of lives lost and the associated grief, with previous consent of the bereaved kin.

Death in Video-Based Social Media Platforms

Technological tools such as photography and films are not neutral. As much as they capture and recreate beauty, they can also be used to export ideas of colonialism, empire, and White supremacy, objectifying communities and societies in the context of death [18]. Varied intentions in capturing or manipulating records are not new features of video shared on social media. Furthermore, the scale and potential reach of such materials have increased due to the high rate of internet service adoptions.

Some of the earliest examinations of death on YouTube were tied to crime [19,20], which highlights the sensationalization of tragedies. Celebrity deaths were also reported [21,22]. Furthermore, 377 YouTube videos showcased framing by organ procurement organizations [23]. The music in videos featuring mourning on YouTube elicited empathy and sadness [24], even when in the background [25].

Ethnography of a multilingual YouTube video for children regarding death and grief noted that the decade-old video went viral across Spanish-speaking countries at the beginning of the COVID-19 pandemic, reaching all genders and ages, and this highlighted the gravity of sudden death in a manner that official information sources did not [26]. Content analysis of 100 videos on grief on TikTok showed that users grieved openly and emotionally [27]. Interviews with grievers during the COVID-19 pandemic, including 3 YouTube users, showed that they announced the loss, shared artistic and farewell posts, and felt that this helped them maintain a link with the deceased; however, in cases of prolonged grieving, other social media users perceived them to be insincere [28].

Regarding Japan, an analysis of 27 English YouTube videos about the Minamata disease noted that most uploaders were ordinary people using documentary clips, lacking context and explanations [29]. Uriu et al [30] published a case study of a funeral live cast on YouTube, making it more accessible to older people kin who lived far away; however, they argued that the process could be enriched further through other data formats, and there was a need to consider religious differences. A comparison of the mourning of Asian virtual YouTube uploaders with human and celebrity uploaders revealed that young viewers treated humans more like machines [31]. Finally, a study of suicidal ideation in 28 Twitter and YouTube vlogs by women revealed empathic messages, and that the belief that the ability to mitigate suicidal ideation lies in the individual has not changed in the last decade [32].

We found that studies analyze anything from 1 to over a 1000 videos, there is little research on Japanese video-based social media and death, and studies on religious narratives outside of Buddhism are lacking. Therefore, we formulated the following research questions (RQs) in the context of Japanese YouTube videos:

1. RQ1: Who are involved in creating and appearing in death-related content?
2. RQ2: What are the most common narratives regarding death?
3. RQ3: Which religions are associated with death?

Family Networks

A social network is a set of nodes representing actors (eg, persons) and their ties (relationships). Similarly, a family network is a representation of family members and their relationships. Given that the study of death in social media has not focused on end-of-life care, and that kin are crucial in making decisions in this stage in Japan, we reviewed the literature on family networks.

Social network methods broaden the definition of family by starting with individuals' definition of their family context, and key applications include national representative survey data, family networks across time, and family health networks [33].

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Recent research on family networks at the end of life has been conducted primarily in Australia. A survey among 7915 individuals over a period of 7 years indicated that care providers were of all adult ages, more than half were extended family and friends, and dying at home was common in these contexts [34]. Examining care networks across time in 9 focus groups of people dying at home revealed that these networks grow and relationships strengthen [35]. A similar study integrating surveys revealed that relationships with medical care staff were peripheral and those between staff were weak [36]. Finally, network data from an American survey conducted over a 5-year period clarified that older adults tended to substitute dead confidants more frequently than younger adults [37].

In Japan, a survey of 129 families in Tokyo identified 11 family structures and the important role of matrilineal and nonkin ties [38]. Maeda and Meguro [39] examined the strength of urban family ties, noting the influence of class. A comparison between the family networks of older men in urban and rural settings over a 7-year period revealed that mortality increased when rural men were less educated or unmarried; and this also applied to urban men who did not participate in community groups [40]. Ishiguro [41] noted that the size of kin and friendship networks slightly decreased among women, and for men, networks comprising reliable friends reduced slightly between the 1990s and 2010s. In addition, a survey among 355 older patients in Fukushima showed that those with small social networks discussed end-of-life plans less, regardless of marital status [42].

Although we identified literature on networks in Japan, family networks during the COVID-19 pandemic remained unexplored. Therefore, we added the following RQs for the portrayal of death in Japanese YouTube videos:

1. RQ4: Which kin were involved in death-related content?
2. RQ5: What structures do family networks display during the end-of-life period?

Methods

Data Collection and Organization

We tested several keywords based on narratives about "good death" in Japan [3] in Google trends and YouTube. We selected '安らかな死' (peaceful death) as a proxy for good death in medical and sociocultural contexts because of the high number of hits. A researcher extracted video data using YouTube Data Tools [43], in 2 modules that use the YouTube Application Programming Interface. The Video List module retrieves a list of videos and related information (identifier, publication date, title, description, tags, category, duration, number of views, and number of comments). The video titles were reviewed and the videos were watched to identify those related to death. This resulted in 457 out of 2074 videos, published from January 2019 to May 2023. Subsequently, a researcher used identifiers (the last part of the video hyperlink) obtained through the Video List module to extract comments using the Video Comments module.

Content Analysis

The content analysis was divided into 3 parts: human notation of video content, automatic summarization of video descriptions, and automatic summarization of video comments.

Human Notation of Video Content

The 457 videos were watched and annotated, based on previous studies [44,45] as follows:

- To answer RQ1, a researcher identified the gender of the deceased and sorted them according to age: child (0-17 y), adult (18-59 y), and older adult (≥60 y). The "About" page of the YouTube channel was consulted to identify uploaders, and speakers were considered individuals who appeared, spoke, or whose words were conveyed in the video. These were then categorized (Multimedia Appendix 1).
- To answer RQ2, a researcher used the location information on the channel's "About" page and from within the YouTube video. This information was categorized according to countries and Japanese regions. Furthermore, death and end-of-life narratives were classified based on prior studies (Multimedia Appendix 2) [7,9,10,45-47].
- To answer RQ3, we considered religion as supernatural beliefs about death and the afterlife, and activities surrounding death. Therefore, the religions mentioned, religious buildings, religious imagery, and rites displayed in the videos were annotated.
- To answer RQ4 and RQ5, kin was annotated. A sample of videos with kin information (73/164, 44.51%) was verified by a second researcher. Their agreement on family members ranged between 0.83 and 1 (Multimedia Appendix 3), and the corrected notations were incorporated into the data.

Automatic Summarization of Video Descriptions

To answer RQ1 and RQ2, we used KH Coder (Ritsumeikan University) [48] to summarize frequently appearing terms in Japanese and their relationships with other terms, generating co-occurrence–based networks. The networks were drawn as undirected and unipartite, and overlap coefficients were calculated in KH Coder. In the overlap coefficient between 2 groups of words, when group X was a subgroup of Y, the overlap coefficient was equal to 1 [49]. We used this coefficient for its capability to generate unified networks wherein word groups are still distinct. As recommended by Higuchi [50], the 60 strongest co-occurrences were drawn as network edges.

Automatic Summarization of Video Comments

To complement the response to RQ2, Kh Coder was used to summarize the most frequent words in the video comments.

Statistical Analysis

To address RQ1-RQ4, the videos were divided into 3 groups: death of a (real) regular person, death of a celebrity, and fictional death. Each parametric numerical variable that had a median over zero (speakers, religion, and deceased disclosed gender) was analyzed through a one-way ANOVA. We considered a threshold of $P<.01$ as significant. All statistical tests were run in IBM SPSS (version 29.0.10).

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Network Analysis

Network analysis involves quantitative and qualitative tools. To answer RQ 5, we focused on measurements at the node and network level based on prior studies [51-54]. While many social network studies focus on trust, Yamagishi [55] argues that Japanese people seek assurance when creating stable relationships. Thus, we considered trust as equivalent to assurance in our study. The network measurements (Multimedia Appendix 4) were calculated using Gephi version 0.10.1 [56,57]. Gephi was also used to draw unipartite undirected networks laid with the Fruchterman-Reingold algorithm of family member relationships found among the regular people, celebrities, and fictional characters.

Ethical Considerations

This study was exempt from ethical review by the Medical Board of Kyoto University because it involved big data analysis of social media records and did not use human data beyond measuring internet activity. This study follows the Ethical Guidelines for Internet Research [58] and the Ethical Guidelines for Medical and Biological Research Involving Human Subjects [59]. Based on the above, it was determined that the study did not require informed consent from participants. The findings pertaining to nonpublic persons, including those related to medical conditions, were reported in a way that masks identities.

Results

Actors in Peaceful Death

Table 1 displays the overlapping 477 uploaders found on the 457 YouTube videos, divided in videos of regular people, celebrities, and fictional characters. No significant differences were found between video groups. Among the 477 uploaders, 208 (43.60%) were citizens, 65 (13.62%) the media, and 44 (9.22%) religious actors.

Table . YouTube uploaders in 457 videos.

Actor	Regular videos (n=220), n (%)	Celebrity videos (n=122), n (%)	Fictional videos (n=115), n (%)	Total videos (N=457), n (%)
Doctor	22 (10)	0 (0)	0 (0)	22 (5)
Medical student	0 (0)	0 (0)	0 (0)	0 (0)
Nurse	1 (0)	0 (0)	0 (0)	1 (0)
Other medical staff	5 (2)	0 (0)	0 (0)	5 (1)
Donor	0 (0)	0 (0)	0 (0)	0 (0)
Recipient	0 (0)	0 (0)	0 (0)	0 (0)
Donor relative	0 (0)	0 (0)	0 (0)	0 (0)
Recipient relative	0 (0)	0 (0)	0 (0)	0 (0)
Other deceased	1 (0)	1 (1)	1 (1)	3 (1)
Other deceased relative	4 (2)	0 (0)	0 (0)	4 (1)
Association	9 (4)	1 (1)	1 (1)	11 (2)
Citizen	91 (41)	50 (41)	67 (58)	208 (46)
Government	2 (1)	0 (0)	0 (0)	2 (0)
Media	26 (12)	31 (25)	8 (7)	65 (14)
Religious actor	36 (16)	4 (3)	4 (3)	44 (10)
Educational actor	5 (2)	0 (0)	0 (0)	5 (1)
Unknown	34 (15)	36 (30)	37 (32)	107 (23)
Total overlapping actors	236 (107)	123 (101)	118 (103)	477 (104)

Regarding the 1303 overlapping speakers (Table 2), 355 (27.24%) were nonorgan donor deceased, 329 (25.24%) were citizens, and 187 (14.35%) were the kin of nonorgan donor deceased. There were significant differences ($F_{2,\ 454}$=5.72; P=.001) in terms of nondonor deceased between the videos on regular people and celebrities (P=.02, 95% CI 0.02-0.24), and those of regular people and fictional characters (P=.02, 95% CI 0.02-0.25). There was also a difference ($F_{2,\ 454}$=8.75; P<.001) between videos of regular people and fictional characters in terms of citizens (P<.001, 95% CI 0.09-0.33). This implies that nondonor deceased and citizens are less present in regular people death's videos.

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Table . Speakers in 457 YouTube videos.

Actor	Regular videos (n=220), n (%)mean, standard deviation	Celebrity videos (n=122), n (%) mean, standard deviation	Fictional videos (n=115), n (%) mean, standard deviation	Total videos (N=457), n (%) mean, standard deviation
Doctor	62 (28) 0,28, 0.45	8 (6) 0.06, 0.24	13 (11) 8.85, 0.31	83 (18) 0.18, 0.38
Medical student	0 (0) 0.00, 0.00	0 (0) 0.00, 0.00	0 (0) 0.00, 0.00	0 (0) 0.00, 0.00
Nurse	20 (9) 0.09, 0.28	3 (2) 0.02, 0.15	8 (7) 0.07, 0.25	31 (7) 0.07, 0.25
Other medical staff	15 (7) 0.07, 0.25	1 (1) 0.01, 0.09	1 (1) 0.01, 0.09	17 (4) 0.04, 0.18
Donor	0 (0) 0.00, 0.00	0 (0) 0.00, 0.00	1 (1) 0.01, 0.09	1 (0) 0.00, 0.04
Recipient	0 (0) 0.00. 0.00	0 (0) 0.00, 0.00	1 (1) 0.01, 0.09	1 (0) 0.00, 0.04
Donor relative	0 (0) 0.00. 0.00	0 (0) 0.00, 0.00	1 (1) 0.01, 0.09	1 (0) 0.00, 0.04
Recipient relative	0 (0) 0.00. 0.00	0 (0) 0.00, 0.00	1 (1) 0.01, 0.09	1 (0) 0.00, 0.04
Other deceased	156 (71) 0.71, 0.45[a]	102 (84) 0.84, 0.37	97 (84) 0.84, 0.36[a]	355 (78) 0.78, 0.41
Other deceased relative	114 (52) 0.52, 0.50	24 (20) 0.20, 0.39	49 (43) 0.43, 0.49	187 (41) 0.41, 0.49
Association	13 (6) 0.06, 0.23	1 (1), 0.01, 0.09	1 (1) 0.01, 0.09	15 (3) 0.03, 0.17
Citizen	141 (64)[a] 0.64, 0.48	90 (74) 0.74, 0.44	98 (85) 0.85, 0.35	329 (72) 0.72, 0.45
Government	47 (21) 0.21, 0.41	16 (13) 0.13, 0.33	41 (36) 0.36, 0.48	104 (23) 0.23, 0.42
Media	27 (12) 0.12, 0.32	37 (30) 0.30, 0.46	3 (3) 0.03, 0.16	67 (15) 0.15, 0.35
Religious actor	50 (23) 0.23, 0.42	9 (7) 0.07, 0.26	11 (10) 0.10, 0.29	70 (15) 0.15, 0.36
Educational actor	26 (12) 0.12, 0.26	6 (5) 0.05, 0.21	7 (6) 0.10, 0.24	39 (9) 0.10, 0.28
Unknown	0 (0) 0.00, 0.29	1 (1) 0.01, 0.24	1 (1) 0.01, 0.09	2 (0) 0.00, 0.06
Total overlapping actors	671 (305) 3.05	298 (244) 2.44	334 (290) 3.00	1303 (285) 2.85

[a]Statistically significant results.

The most common age group in 501 overlapped ages in the 457 videos was adults (n=179, 36%), followed by the unknown group (n=158, 31%), older adults (n=121, 24%), and children (n=43, 9%). For regular people, age went mostly unreported (99/256, 39%), whereas for celebrities and fictional characters, most deaths were of adults (52/122, 42% and 59/123, 48% respectively). Regarding gender, Table 3 shows that in 262 of the 550 (47.63%) overlapped genders identified, the deceased were male. There were significant differences ($F_{2, 454}$=22.81; P<.001) in terms of gender between celebrity and regular videos (P<.001, 95% CI 0.23-0.49), celebrity and fiction videos (P=.005, 95% CI 0.05-0.34), and fiction and regular videos (P=.008, 95% CI 0.03-0.29). This supports the notion that most male deaths were those of celebrities, followed by fictional characters.

Table . Overlapped perceived gender of the deceased.

Perceived gender of the deceased	Regular videos (n=220), n (%) mean, standard deviation	Celebrity videos (n=122), n (%) mean, standard deviation	Fictional videos (n=115), n (%) mean, standard deviation	Total videos (N=457), n (%) mean, standard deviation
Men	96 (44) 0.44, 0.49[a]	97 (80) 0.80, 0.40[a]	69 (60) 0.60, 0.49[a]	262 (57) 0.57, 0.49
Women	87 (40) 0.40, 0.49	30 (25) 0.25, 0.43	53 (46) 0.46, 0.50	170 (37) 0.37, 0.48
Other or unknown	90 (41) 0.41, 0.49	2 (2) 0.02, 0.12	26 (23) 0.23, 0.42	118 (26) 0.26, 0.43
Total perceived gender of the deceased	273 (124) 1.24	129 (105) 1.05	148 (128) 1.28	550 (120) 1.20

[a]Statistically significant results.

Narratives of Peaceful Death

This section presents the contexts of peaceful deaths described in the videos to address RQ2. The most common country identified in overlapping data was Japan (384/592, 64.86%), and a significant difference ($F_{2, 454}$=6.44; P=.002) was found between regular people and celebrity videos (P=.001, 95% CI 0.05-0.28). This implies that most of the celebrity deaths highlighted in the Japanese videos occurred abroad.

Figures 1-3 display the communication channels of peaceful death. The node size reflects word frequency, with thicker lines indicating stronger tie strengths between words. Nodes with the same color indicate that they belong to the same group, and

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nodes with no color are not part of a specific group. Figure 1A shows descriptions of regular people's deaths, where a purple cluster of words wherein Buddhism is connected to the Amazon store and other YouTube videos. The red cluster refers to descriptions found in videos related to spiritualism and Nnew Rreligion (the term "spirit"), linked to YouTube video channels. Figure 2A shows that celebrity deaths were communicated through YouTube, Twitter, Instagram, and the Tokyo Broadcasting System (TBS; in a red cluster). By contrast, Figure 3A shows only YouTube and Twitter.

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Figure 1. (A) Descriptions (word frequency 50 - 1356; tie strength 0.6 - 1) and (B) comments (word frequency 900 - 6649; tie strength 0.3 - 0.6) of YouTube videos about ordinary people's deaths.

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Figure 2. (**A**) Descriptions (word frequency 34 - 282; tie strength 0.8 - 1) and (**B**) comments (word frequency 600 - 3486; tie strength 0.4 - 0.8) of YouTube videos about celebrities' deaths.

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Figure 3. (**A**) Descriptions (word frequency 30 - 577, tie strength 0.6 - 1) and (**B**) comments (word frequency 300 - 2260, tie strength 0.2 - 0.8) of YouTube videos about fictional characters' deaths.

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A summary of the descriptions of regular people's videos in Figure 1A is shown in green, referring to end-of-life care in hospices and academic conferences. Although less central, there seems to be a focus on patients with cancer (orange cluster). Regarding the comments on these videos, Figure 1B shows a green cluster discussing life, family, and families. The second cluster (in yellow) expresses gratitude to medical experts for their insights, mentioning bereaved parents ("father" and "mother"). Peaceful death seems to be connected to medical death and death in hospices. The purple cluster and some loosely connected words include what is considered the opposite of peaceful death, for instance, the death penalty and euthanasia.

The descriptions of celebrities shown in Figure 2A centered around 2 men: American actor Luke Perry (purple cluster) and Japanese politician Shinzo Abe (blue cluster). There was a contrast between the formal language used for Abe and the emotional language used for Perry ("peaceful"). The video comments shown in Figure 2B were mostly about Abe's death (purple cluster), the official response of the opposition party (blue cluster), and a former political rival (Suga in the purple cluster). There were prayers for 冥福 (heavenly bliss, identified 1876 times in the red cluster) for the deaths of rakugo (traditional comedy) performers Shimura and Enraku. This is a common praying behavior in Buddhist funerals. Conversely, the word "paradise" related to Christian beliefs was found 510 times (not shown in the figure).

As for fictional deaths, the most central word group of descriptions shown in Figure 3A is based on a video about a Twitter webtoon called "*The Crocodile Who Dies After 100 Days*." This webtoon was tied to New Age beliefs (the word "chakra"). A cluster in yellow shows the term "Metal Gear Solid," an adventure stealth video game franchise connected to a "novel." A group in purple shows a character ("Walton") from *Frankenstein* by Mary Shelley and other words from videos where people read novels aloud. Regarding the video comments, although fictional deaths had various causes, most focused on suicide (yellow cluster in Figure 3B). The yellow and purple groups were comments on a webtoon that humanized a fictional former mob man. Satake and Kito (blue cluster) are also characters in a webtoon. Overall, conversations are focused on the opposite of a good death, that is, on violent deaths.

Regarding the annotated narratives that complement these figures, about a quarter (n=222, 26%) of the overlapping 839 narratives explained death, and 101 (12%) focused on illness (Multimedia Appendix 5).

Religion and Peaceful Death

In reference to RQ3, Table 4 suggests that the most identified religion stance in the overlapping data was nonreligious (304/532, 57.14%). There was a significant difference ($F_{2, 454}$=23.58; P<.001) in religion between celebrity and regular videos (P<.001, 95% CI 0.23-0.47). This suggests that religious practices were most prominent in regular people's deaths. Table 4 notes Buddhism as the most common religion, although a wide variety of religions were found. Other Asian religions included Ainu beliefs, Brahmanism, Confucianism, Feng shui, Hinduism, Onmyodo, Ryukyuan beliefs, Taoism, and beliefs of the Indigenous people in China. Other Christian groups included Evangelists, Protestants, and unspecified Christian beliefs. Finally, other Middle Eastern and Western religions included Greek paganism, Islam, Judaism, and unspecified Abrahamic beliefs.

Table . Overlapping religions in 457 videos about peaceful death.

Religion	Regular videos (n=220), n (%) mean, standard deviation	Celebrity videos (n=122), n (%) mean, standard deviation	Fictional videos (n=115), n (%) mean, standard deviation	Total videos (N=457), n (%) mean, standard deviation
Animism or spiritualism	7 (3) 0.03, 0.17	0 (0) 0.00, 0.00	3 (3) 0.03, 0.16	10 (2) 0.02, 0.14
Catholic Christianity	12 (5) 0.05, 0.22	0 (0) 0.00, 0.00	1 (1) 0.01, 0.09	13 (3) 0.03, 0.16
Other Christianity	24 (11) 0.11, 0.31	1 (1) 0.01, 0.09	4 (3) 0.03, 0.18	29 (6) 0.06, 0.24
Japanese Buddhism	14 (6) 0.06, 0.24	2 (2) 0.02, 0.12	0 (0) 0.00, 0.00	16 (4) 0.04, 0.18
Other Buddhism	48 (22) 0.22, 0.41	9 (7) 0.07, 0.26	26 (23) 0.23, 0.42	83 (18) 0.18, 0.38
New religions	14 (6) 0.06, 0.24	4 (3) 0.03, 0.17	0 (0) 0.00, sd	18 (4) 0.03, 0.19
Other Asian religions	11 (5) 0.05, 0.21	1 (1) 0.01, 0.09	5 (4) 0.04, sd	17 (4) 0.04, 0.18
Other Middle East or Western religions	9 (4) 0.04, 0.19	0 (0) 0.00, 0.00	2 (2) 0.02, sd	11 (2) 0.02, 0.15
Shinto	15 (7) 0.07, 0.25	1 (1) 0.01, sd	15 (13) 0.13, 0.33	31 (7) 0.07, 0.25
No religion	118 (54) 0.54, 0.50*[a]	108 (89) 0.89, 0.32*	78 (68) 0.68, 0.46	304 (67) 0.67, 0.46
Total of religion stances	272 (123) 1.23	126 (103) 1.03	134 (116) 1.16	532 (116) 1.16

[a]Asteriscs indicate the results are statistically significant

Family Networks of Those Deceased

To address RQ6, Table 5 displays the network measurements of 164 videos that mentioned family members. Please refer to Multimedia Appendix 4 to interpret these results. The high number of edges in the regular and fictional families implies trust (assurance). This is reinforced with the highly weighted degree and high clustering coefficient in the networks of regular

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people. Access to other family members is faster in regular families based on closeness and path length. Regular family structures are the densest and most complex, as supported by density and the number of triangles. These structures are also the most unified based on their low modularity.

Table . Network measurements of family networks calculated with Gephi.

Measure	All videos	Regular	Celebrity	Fictional
Nodes	17	13	10	14
Edges	62	30	19	32
Average weighted degree	47.529	40.6150	8.8000	12.7140
Average harmonic closeness	0.7279	0.8012	0.7111	0.6758
Average betweenness	0.0362	0.0361	0.0722	0.0540
Average clustering coefficient	0.8430	0.8830	0.7810	0.8090
Average path length	1.5441	1.3970	1.5777	1.6483
Density	0.456	0.6030	0.4220	0.3520
Diameter	2	2	2	2
Modularity	0.037	0.022	0.047	0.127
Triangles	118	96	14	32
Connected components	1	1	1	1

To answer RQ5 and RQ6, Figure 4 illustrates the role of parents as communication hubs in all the videos and in videos of regular people. The larger the label, the higher the closeness centrality, and the thicker the line, the higher the trust (assurance). Although fathers may appear to have the higher closeness centrality, and thus the fastest reach to other family members, the networks of regular people demonstrate that the mother is equally important in this role. Further, the higher trust in videos of regular people is towards sons and daughters.

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Figure 4. (A) Undirected overall family networks (closeness centrality 1 - 0.51; edge thickness 1 - 75) and (B) networks of regular people (closeness centrality 1 - 0.54; edge thickness 1 - 48). Colors indicate different member clusters in each network.

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On the other hand, Figure 5 highlights that in the separate networks of celebrities and fictional characters, male members of the family such as brothers and husbands are prominent in terms of closeness centrality and trust or assurance. Therefore, horizontal male relations are overrepresented in these networks in contrast to regular people, where vertical relationships including women were most relevant. This complements our results in terms of gender bias representation of the deceased.

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Figure 5. (A) Family networks of celebrities (closeness 1 - 0.55; edge thickness 1 - 13) and (B) networks of fictional characters (closeness 1 - 0.53; edge thickness 1 - 14). Colors indicate different member clusters in each network.

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Discussion

Social Actors in Japanese Peaceful Death

Based on word graphs, the deaths of men, mostly in the adult and older adult age groups, were broadcasted and mourned, even for foreign actors such as Luke Perry, whose last role was in Riverdale, an American streaming series targeting young adults. Based on content and network analysis, the low visibility of women in end-of-life was noted in fictional characters' death, and to some extent, in that of celebrities. This is not representative of the near gender parity in Japanese deaths [60], or of women patients' desire for social connection at the end of life [61]. These features were better reflected in videos of regular people's death, as per Table 3 and Figure 4. In particular, Figure 4B highlights how fathers and mothers have equally fast access to other family members, and how sons and daughters equally show high trust or assurance in the networks.

This bias in gender representation in the other videos may partly occur due to the broader advertising reach for male YouTube viewers [6]. In broader terms, Morioka [62] argues that hegemonic masculinity in Japan, with its goal of ensuring socially dominant roles for men, can twist lay people's perceptions regarding risks. This may extend to end-of-life scenarios with popular celebrities and fictional characters, wherein the family networks are simplified and the active roles of women as patients, caretakers, and decision makers tend to be hidden from public view.

Beyond the gender binary, a few common people videos in the other or unknown category portrayed queer individuals and their kin, particularly in mourning and honoring the dead. Significant barriers remain in access to health care and family involvement in medical decision-making and care for sexual minorities in Japan [63]. Considering that the recognition of marriage among queer people is in the process of being legalized, the visibility of queer individuals in the videos is still limited but expected to increase in the future. Consequently, it is worthwhile to conduct further studies on how their end-of-life experiences are portrayed in media and how queer health care networks are constructed. Overall, our results provide evidence that studying celebrities and fictional characters has limits in capturing contemporary end-of-life scenarios in Japan. Comparisons of these groups in other topics are also needed.

Content analysis of videos revealed that academics in conferences and open lectures, and a hospice doctor's YouTube channel provided fora and expert advice on "good death." They included the process of death, end-of-life care, and alleviating the pain of bereaved families. Although this discourse seems disconnected from other health care scenarios, it is a key connection between experts and the public. Another example of emerging discussions of good death in social media was "*The Crocodile Who Dies After 100 Days*" (Hyaku nichi go ni shinu wani). Although found in a YouTube video, the original was a toon published on Twitter and Instagram between 2019 and 2020. The protagonist is an anthropomorphized crocodile spending time with his friends, wherein the comic panel shows a descending count from 100. The author wished to open discussions about death because "being alive is to die someday" and used Twitter because it was the best way to reach a large audience quickly [64]. These examples show potential in modeling a wider acceptance of public end-of-life conversations among the Japanese public.

Narratives of Japanese Peaceful Death

Based on keyword graphs, the predominance of cancer in Japanese end-of-life scenarios was reflected in regular people's videos; however, in general, death due to illness was high. This may partly stem from COVID-19. Although the Japanese government stopped tracking this illness in 2023, the number of general excess deaths and those due to respiratory and circulatory illnesses as well as cancer has increased since the beginning of the pandemic [65]. COVID-19 can be asymptomatic and may also impact multiple organs, triggering respiratory and circulatory issues, and some forms of cancer [66,67]. Considering that young people are also more affected by long COVID-19 than older individuals [68], these trends might be reflected in the videos in our study, where most deaths were not of older adults.

Some researchers estimate that deaths in Japan might be between 1.5 and 3.9 times higher than those reported, and that there is a need to report deaths with more demographic details including age [69]. Our study provides evidence of substantiating this need in the Japanese context, wherein older adults are assumed to account for most of the deaths. We emphasize the need for end-of-life guidelines and care in both sudden death scenarios such as pandemics and long-term disability scenarios for adults of all ages.

Regarding fictional death narratives, Japanese and Western books combined with oral stories and video games appeared frequently. These stories ranged from *kaidan* (old ghost stories) to stories in modern settings, focused on male protagonists. In a previous study, book influencers were important communicators of death on Japanese Twitter (authors, under review). It seems that YouTubers have capitalized on audiovisuals to convey old and new books for monetary and social capital. This may partly explain the bias in targeting male viewers with male-centric death.

Religion in Japanese Peaceful Death

Buddhism was the most frequent religion in regular people videos, based on content analysis. Buddhist priests, temples, mentions and figures of Buddha, mentions of attaining Buddhahood status in the afterlife, and Buddhist altars for the death (called butsudan) were present in these videos. However, Buddhism was not connected to medical staff or academia. Since most videos did not mention or show a specific Buddhist sect, it is unclear how many people follow new religions masquerading as Buddhism. For example, it is estimated that approximately 3 million people or 2.5% of the Japanese population follows Soka Gakkai [70]. Some estimates of this figure combined with other new religions include 26.47% of the Japanese population [71].

Although less present in the videos, new religions were discussed in terms of the higher self, the astral body, and Wicca (modern European witchcraft). New religions were usually mixed with Buddhism and other minority religions of East Asia,

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and some videos advertised products. They seem to be diffused across several social media channels, from YouTube, which is popular among people of all ages, to Instagram, which is more popular among young adults. New religions were also inserted in viral topics such as the video about "*The Crocodile Who Dies After 100 Days*." In Figure 3A, the word "chakra," is mentioned as a form of individualistic spirituality in videos. Loove [72] mentions that these kinds of new religious practices, rather than depending on specific leadership, are tied to individualized consumer preferences. This consumerism dimension may explain the advertising efforts by practitioners.

In the celebrity videos, the death of former Prime Minister Abe was not connected to religion, according to place classification, annotated religions, and the word graphs. The 10 videos in our data related to Abe were released by Japanese national news media channels such as Ni Tele News and TBS News, and local news media such as SBS News and TV Tokyo BIZ. They focused on the words of Japanese politicians in government offices and common people interviewed in the streets. Conversely, influencers with a considerable fanbase spread the news in neighboring China using pictures and videos, relegating official news media to a less important role [73]. Moreover, a Twitter-based study suggested that the negative emotions elicited by Abe's death were short-lived [74].

To understand the role of religion in these videos, we must consider that a convergence of interests of some Shinto leaders and state officials to ally when establishing the ideological foundation for Japan. Since the Meiji era, secular politics have been understood as a more civilized form of state formation, so Shinto was redefined by the state as nonreligious immutable customs and traditions of a historically consistent and unified Japan [75]. Here, the apparent nonrepresentation of religion in the celebrity videos uploaded by Japanese news media channels seems to reinforce myths of a hegemonic Japan at the end of life through social learning.

However, we must revisit the example of religion in the Yasukuni Shrine, wherein Abe was among the proponents to enshrine World War II criminals. This act jeopardizes diplomatic relations with neighboring Asian nations that suffered under wartime aggression. Japan is the home of 3.5 million foreign nationals [76], and other ethnic denominations with various spiritual beliefs exist. Therefore, the image of Shinto emphasized by politicians such as Abe might generate discomfort among some Asian patients in Japanese hospitals.

The implication of our results regarding religion for health care providers is that it is not enough to assume that asking simple questions about spirituality at the end-of-life period will capture the beliefs and intentions of an individual and their bereaved family, as previously noted by Uriu et al [30]. Understanding the patient's concrete spiritual needs beforehand, in collaboration with kin, is recommended. The implication for Japanese media is that they should showcase more religious diversity at the end-of-life period, particularly in the case of celebrities and fictional characters.

Limitations and Future Studies

This study focused on the term "peaceful death." Social media discourse is constantly changing. Therefore, it is advisable to monitor other keywords and their combinations to understand other end-of-life scenarios in Japan and other regions.

The data on family networks was limited and did not include friendships. We recommend that more data be gathered from both social media and surveys to better understand family dynamics at the end-of-life period.

Conclusions

This study examined recent public discussions about peaceful death in Japanese YouTube videos, contributing to recent discourses about health care and end-of-life. From our analyses, we drew several conclusions:

1. Medical experts from academic and hospice contexts address regular people's deaths in Japan through social media but do not work with religious stakeholders.

2. Most deaths that were discussed were of adult men, with the cause being mostly attributed to illness.

3. Religions are more present in regular peoples' deaths than in those of celebrities and fictional characters. Buddhism was the most common religion, although various others were also observed.

4. While the deaths of celebrities and fictional characters portray male relatives as more relevant, both men and women were relevant in the deaths of regular people.

5. Networks of regular people indicated the highest assurance, fastest access to other family members, and the highest density and complexity. Fathers and mothers had the fastest access to other family members during peaceful death. Sons and daughters showed the highest assurance during peaceful death.

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Data Availability

The anonymized dataset generated and analyzed during this study is available in the Zenodo repository [77].

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Authors' Contributions

VMX and OM conceptualized the analysis, determined the methods, verified the data, and reviewed and edited the manuscript. VMX classified and interpreted the data, conducted the formal analysis, drew the data visualizations, and wrote the original draft of the manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Classification of individuality.
[DOCX File, 14 KB - formative_v10i1e81861_app1.docx]

Multimedia Appendix 2
Narratives of death.
[DOCX File, 16 KB - formative_v10i1e81861_app2.docx]

Multimedia Appendix 3
Intercoder agreement.
[DOCX File, 15 KB - formative_v10i1e81861_app3.docx]

Multimedia Appendix 4
Network measurements.
[DOCX File, 15 KB - formative_v10i1e81861_app4.docx]

Multimedia Appendix 5
Findings from the death narratives.
[DOCX File, 19 KB - formative_v10i1e81861_app5.docx]

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Abbreviations

RQ: research question
TBS: Tokyo Broadcasting System

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Features of mHealth Apps for Tobacco Cessation Important to Black Adults: Discrete Choice Experiment

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Abstract

Background: Although mobile health (mHealth) apps for tobacco cessation augment traditional cessation methods and have contributed to increases in cessation rates, Black adults are underrepresented in mHealth app studies for tobacco cessation. As a result, their mHealth app preferences are not well-known.

Objective: Our goal was to identify features of mHealth apps for cessation that are important to Black adults who use tobacco products.

Methods: We developed an online discrete choice experiment with 12 pairs of hypothetical mHealth apps for tobacco cessation. Inclusion criteria included being 21 years or older, current use of any tobacco product, and identifying as Black or African American. Participants had to be interested in tobacco cessation and have a history of mHealth app use or be willing to use one in the future. From each pair of hypothetical apps within the survey, participants had to choose the app they preferred. Each hypothetical app was made up of 7 features developed from existing mHealth literature and prior qualitative work: graphics, marketing, strategies for quitting, connection with others, personalization, benefits of quitting, and health information. Each feature had up to 4 - 5 levels (ie, variations of that attribute), and each hypothetical mHealth app was comprised of a random assortment of levels of features. Hierarchical Bayes estimation was used to determine the part-worth utility for each level within each feature for each participant, which was then used to calculate the importance score. Average importance scores across respondents were used to determine overall importance scores for each feature.

Results: We had 901 adult participants. The mean age was 41 (SD 14.02) years, and about a third of participants (377/901, 42%) were female. Two-thirds of participants (549/901, 61%) had used an mHealth app in the past, and the great majority (786/901, 87%) indicated a willingness to use an app for health purposes in the future. The features had the following importance: graphics (16%), marketing (15%), strategies for quitting (15%), connection with others (14%), personalization (13%), benefits of quitting (13%), and health information (13%). Within features, strategies for quitting had the highest and third-highest levels of "making a step-by-step quit plan" and "recommendations to manage relapse or withdrawal," respectively. Marketing had the second-highest level of "Historically Black Colleges and Universities–endorsed app." Graphics had the fourth-highest level of "short video testimonials from people who successfully quit," while connection with others had the fifth-highest level of "quit buddy program for support and accountability."

Conclusions: This study identified features of mHealth apps important to Black adult tobacco users. To enhance the appeal of mHealth apps to such adults, prioritizing inclusion of highly preferred levels in apps may lead to higher use and improved cessation.

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KEYWORDS

mobile health app; tobacco cessation; mHealth app preferred features; mobile health; cultural relevance; relatability; app preferences

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Introduction

Black adults in the United States who use tobacco products have a higher incidence of tobacco-related adverse health effects and mortality compared with adults from other racial or ethnic backgrounds [1,2]. Although Black adults who use tobacco attempt to quit and endorse intention to quit at a higher rate than White adults who use tobacco products, they are less likely to succeed [3]. One major reason for lower cessation rates for Black adults is less access to or likelihood to use evidence-based treatment, including lower rates of screening for smoking among Black patients and lower likelihood of getting cessation-related advice from health care professionals [4,5].

The use of mobile health (mHealth) interventions to support or augment mainstream treatment options has led to improved clinical outcomes for individuals with other chronic health conditions, including those from minority racial or ethnic groups [6,7]. mHealth interventions have contributed to success in tobacco cessation [8], often due to factors such as the ability to tailor content based on responses of the user, provision of real-time feedback, and low cost [9-11]. mHealth interventions for tobacco cessation can mitigate difficulties typically associated with more traditional interventions such as transportation issues, costs, and scheduling challenges [11].

Even with the known benefits of mHealth interventions for tobacco cessation, studies have shown that not all aspects of these interventions appeal to adults who use tobacco products, and participants frequently unsubscribe or disengage from an mHealth intervention program [12,13]. Black adults have more mobile phone use compared with White adults [14] but are underrepresented in mHealth studies [15]. Compounding their lack of representation, their preferences for features of tobacco-related mHealth apps have not been well documented [16,17]. One study of a single mHealth app found that Black adults who smoke cigarettes prefer unique features of mHealth apps, such as information on benefits and strategies for quitting, video testimonials, and content relevant to Black adults who use tobacco products to enhance inclusivity [18]. Findings from this study were based on a single mHealth app, which may have limited the number of features that participants were exposed to. Consequently, there remains a gap in the evidence about features of mHealth apps for tobacco cessation that may appeal to Black adults who use tobacco products. Research to remedy this gap may increase use and the overall success rate of tobacco cessation for this population.

A discrete choice experiment (DCE) is a rigorous preference elicitation method [19], developed in behavioral economics to identify which features of a product are important to consumer purchases [20]. In DCEs, respondents view hypothetical products or services with different features and choose ones they prefer, which helps to identify exact components or characteristics that make a product more appealing [21]. DCEs help to determine the relative importance of individual features of a product or intervention relative to other features and identify trade-offs between features that respondents may accept [22]. Compared with other methods to evaluate preferences such as ratings, ranking questions, or qualitative designs, DCEs have better performance with regard to internal consistency and validity [23]. DCEs have been used in some areas of tobacco research, including preferences for cigarette packaging design, pharmacotherapy, and features of electronic cigarettes [24,25]. Little research has examined the application of DCEs to mHealth interventions for the reduction or cessation of tobacco use. The objective of this study was to use a DCE experiment to identify which features of mHealth apps for tobacco cessation are important to Black adults who use tobacco products.

Methods

Study Design and Participant Recruitment

We conducted a 1-time DCE, with a survey consisting of 12 choice tasks where participants were asked to choose between 2 hypothetical mHealth apps, and each app was made up of a combination of different features. Participants were recruited from Qualtrics, a validated source for online recruitment of participants for surveys with reliable data in a short period of time [26]. Qualtrics applies a comprehensive system to recruit from third-party panels, email lists, as well as social media, and participants are targeted for recruitment based on their panel profile information. Quotas for sex and age were provided, and eligibility criteria included ages 21 years or older, who were identified as Black or African American, and who currently used cigarettes or other tobacco products. Current use of tobacco products was defined as either having smoked at least 100 cigarettes in their lifetime and currently smoking in the past 30 days and/or past 30-day use of another tobacco product. Participants had to reside in the United States, complete the survey in English, report interest in tobacco cessation, and have a history of using an mHealth intervention program in the past or willingness to use one in the future. Respondents had to complete a screening survey to confirm eligibility and pass through a CAPTCHA test after receiving the study invitation from Qualtrics to prevent automated bots. Qualtrics also applied verification methods such as IP address checks to confirm the authenticity of participants in addition to a system that detects duplicate responses and evaluates for fraud risk based on specific device and browser attributes. Consent to participate in the study was obtained through the Qualtrics opt-in system. Through this system, participants have to opt in to participate in any research study. An information sheet with a description of the experiment and the rights of participants was included at the beginning of the experiment.

The study was also guided by the CHERRIES (Checklist for Reporting Results of Internet E-Surveys; Checklist 1) [27].

Sample Size

The sample size was estimated based on power calculations using the number of features and levels [28]. In DCEs, statistical power depends on factors such as the sample size, number of choice sets, alternatives within each set, and expected effect size or β coefficients for the DCE model [28]. Based on these parameters, it was determined that a sample size of 900 was needed to achieve over 80% power to detect meaningful differences between features and levels at 95% confidence level.

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To ensure the quality of data collected, the team applied predefined criteria related to speeding or incompletion. We defined speeders as participants who completed the survey in less than half the median duration of time from start to completion for the whole sample of participants. Because Qualtrics also has an internal system to automatically remove duplicates, we are only able to report exclusions that were identified after a manual check of the dataset.

Survey Design

We developed a comprehensive list of mHealth app features for tobacco cessation from our formative work and the literature, and then conducted focus groups to improve the list. We decided not to include some features from the comprehensive list in the DCE because those features were either unanimously endorsed as favorable, for example, some form of reward or incentive, or they are basic or core features that need to be included in mHealth apps, for example, the option to anonymize an individual's identity. The experiment was focused on features with unclear or variable levels of appeal. The final list included the following potential mHealth features*:* benefits of quitting, strategies for quitting, graphics, personalization, health information, marketing, and connection with others (Table 1).

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Table . Final mobile health app features and definitions.

Feature	Definition	Levels
Graphics	Types of images that an app can have such as images about the health effects of smoking and images of people giving testimonials about their cessation journey. These images could be real human images or animation images representing one or several races.	• Short video testimonials of people who successfully quit. • Photos that feature Black people who successfully quit. • Written testimonials from people who successfully quit. • Photos of real people with health issues from tobacco use. • Photos that feature racially diverse people who have successfully quit.
Marketing	Information about endorsement of the app by individuals or groups as well as inclusion of music and pop culture references in the app.	• Features culturally relevant music and pop culture references. • Features different types of music and pop culture references. • Is endorsed by a Black celebrity who successfully quit tobacco products. • Is endorsed by a celebrity who successfully quits tobacco products. • Is endorsed by a historically Black college or university that this app can help people quit.
Strategies for quitting	Information about how to quit smoking such as other smoking cessation methods like the patch, gum, and medication. It can also include information about how to deal with stress related to quitting and how to deal with distractions.	• Makes a step-by-step quit plan. • Recommends strategies for relapse or withdrawal symptoms. • Links to online resources for tobacco cessation. • Recommends tobacco cessation medications to help with quitting. • Interactive games and videos to distract from smoking.
Connection with others	Ability to interact with other people outside of the app. This may be other users of the app, other smokers, interacting with health care personnel or a quit expert.	• Provides the ability for you to chat with other users within the app via a message board. • Provides the option to interact with a variety of support professionals (eg, quit coach). • Contains links to support groups on Facebook or motivational Instagram pages from the app. • Has a leaderboard that ranks your progress toward your cessation goals compared to other app users. • Has a quit buddy program within the app to help you support others and keep you accountable.
Personalization	Ability for a user to tailor or adjust components of the app based on their preferences. For example, a user may be able to upload personal pictures or motivation images or songs to the app.	• Has the ability for you to keep a journal in the app. • Includes the option to create a vision board to help you visualize your life without tobacco products. • Includes the option to upload your personal goals and motivations for quitting. • Includes the option to upload motivational videos or music of your choice. • Has the ability to set reminders and notifications.
Benefits of quitting	Information about what an individual who smokes can gain from quitting. These can be health benefits, financial benefits, or aesthetic benefits.	• How much money saved since quitting. • Lowers the risk of a heart attack. • Lowers the chances of getting cancer. • Improves physical appearance.

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Feature	Definition	Levels
Health information	Information about the way tobacco products have been advertised and the health consequences of using tobacco products.	• Contains information about how people who use tobacco products have a higher risk of blood pressure and heart problems. • Contains information about how Black people who use tobacco products have a higher risk of blood pressure and heart problems. • Has information about the historical targeting of the Black community by tobacco companies. • Has information about how menthol is added to tobacco products to make them highly addictive.

Following the International Society for Pharmacoeconomic Outcomes Research for Good Research Practice in Health guidelines [29], we designed a conjoint DCE with 12 choice tasks using Sawtooth Software (Sawtooth Software, Inc) [30]. We used design principles of orthogonality and level balance to ensure even distribution of levels such that levels had a similar number of appearances in the experiment and could be selected without dependence on other levels or features [31]. Each choice task was made up of a pair of hypothetical mHealth apps for tobacco cessation containing 1 randomly assigned level from each of the 7 features. We applied the balanced overlap design method in generating the DCE tasks, which allowed for simple overlap of levels within features for each task. This approach reduces excessive and unnecessary processing of information and enables respondents to focus on features that differ, which increases the likelihood of making more meaningful trade-offs as they complete each task [31]. To further reduce cognitive burden and improve consistency of choice, we applied color coding. That is, if both apps shown contained the same level of a feature, that level was grayed out so participants could focus on the differences between the 2 apps [32]. To confirm the quality of the design, Sawtooth's test design function was applied to check the integrity of the design with simulated data and verify that the relevant effects can be estimated [31]. We conducted cognitive interviews with 6 participants in an iterative manner to ensure clarity of the questions asked in the DCE. After reaching saturation, we carried out a pilot test of the survey with 53 participants recruited from Qualtrics to examine for illogical response patterns. After all concerns were addressed, we fielded the final version of the survey from April to July 2024. Each Qualtrics participant was assigned a unique identifier based on their IP addresses. Participants were compensated in accordance with the set compensation rate at Qualtrics for survey completion.

Measures

The first part of the survey began with general questions about demographics, tobacco use history, and health status. Participants were also asked questions about their age, sex, race, and ethnicity since we included those who identified as Black plus another race. We also collected information on health status, state of residence, level of education, and household income.

The second part of the survey contained an explanation of each mHealth app feature, and each feature had 4 - 5 levels (Table 1). An example of a DCE using car features was presented. After the example, participants were presented with the following scenario for each choice task: "Imagine that two new mHealth apps for tobacco cessation were recently developed and you want to quit using tobacco products. If these two apps were your only two options, which app would you choose? App A or App B?" Table 2 illustrates an example of one of the 12 DCE tasks that participants completed.

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Table . Example of a discrete choice task.

Feature	App A	App B
Benefits of quitting tobacco products	Has information about how quitting tobacco products can lower your risk of a heart attack	Includes information about how quitting tobacco products can lower your chances of getting cancer
Strategies for quitting	Has recommendations about how to manage relapse or symptoms of withdrawal	Has recommendations about how to manage relapse or symptoms of withdrawal
Graphics	Contains short video testimonials from people who successfully quit	Contains written testimonials from people who successfully quit
Personalization	Has the ability to set reminders and notifications	Has the ability to set reminders and notifications
Health information	Contains information about how people who use tobacco products have a higher risk of blood pressure and heart problems	Has information about how menthol is added to tobacco products to make them highly addictive
Marketing	Features different types of music and pop culture references	Is endorsed by a Black celebrity who successfully quit tobacco products
Connection with others	Provides the option to interact with a variety of support professionals (eg, a quit coach)	Provides the option to interact with a variety of support professionals (eg, a quit coach)
	Select	Select

Statistical Analysis

Data for demographics, tobacco use, health status, and other participant characteristics were analyzed using descriptive statistics (SPSS Statistics, version 29.0.1.0; IBM Corp). Differences among age groups were assessed using 1-way ANOVA, with statistical significance set at $P<.05$.

The response data from the DCE were analyzed with the help of Sawtooth Analytics. We first determined part-worth utilities at the individual level with hierarchical Bayes estimation within Sawtooth Software [31]. Part-worth utilities indicate the preference for levels within each feature. More preferred levels have higher utilities (above 0), and dispreferred levels have the lowest utilities (below 0). With hierarchical Bayes, we were able to apply a Bayesian method to fit a multinomial logit model at the individual level, which allows for heterogeneity while strengthening the overall sample. Our calculations were based on 12 choice tasks per participant, with each task having 2 alternatives.

Next, we determined the importance score for each feature at the individual level by calculating the range of part-worth utilities for levels within the specific feature and dividing by the sum of ranges across all features multiplied by 100. The importance score is the percentage of choice due to each feature or the measure of influence of a feature on the decision-making process to choose a product. The higher the importance score, the higher the influence of that feature on the choice of the product, in this case, the mHealth app. For each feature, the importance score at the individual level was averaged across all participants to obtain the overall importance score. We summarized aggregate preferences with multinomial logit regression with effects coding, with sample-level coefficient and goodness-of-fit statistics provided to enable us to obtain both disaggregate utilities and aggregate estimates.

In addition, we conducted exploratory analysis with paired 2-tailed *t* tests to compare importance scores across features and to compare part-worth utilities of levels within features in all possible combinations to determine statistical significance.

Ethical Considerations

The hypotheses, study design, and analytical plan were preregistered on AsPredicted [33] (#165678), and the study was reviewed by the institutional review board of the University of North Carolina at Chapel Hill and exempted (Study # 23 - 2131). At the beginning of the experiment, we included an information page with the study description and the rights of participants. All participants provided informed consent through the Qualtrics opt-in system before participating in the study. Participants were compensated according to Qualtrics set rate for compensation after completion of surveys.

Results

Overview

The analytical sample included 901 respondents. Of the initial 1304 participants, 369 were excluded due to speeding, that is, those who spent less than half median duration of time spent by all participants (239 seconds) to complete the survey, and 34 were excluded due to incomplete responses. The mean age of participants was 41 (SD 14.02) years, and 42% (377/901) were female participants. Most participants (845/901, 94%) were non-Hispanic Black and had annual household income above the federal poverty level (726/901, 81%). In total, 61% (549/901) of participants reported that they had used an mHealth app in the past, and 87% (786/901) had willingness to use an mHealth app in the future. In total, 82% (738/901) of participants reported current cigarette use, 79% (714/901) reported use of other tobacco products besides tobacco cigarettes, and 82% (738/901) reported a history of a prior quit attempt (Table 3).

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Table . Demographics, mobile health app use, and tobacco use characteristics.

	Total	21 - 24	25 - 49	50+	*P* value
Age (years)					
Mean (SD)	41.15 (14.02)	22.71 (1.12)	36.74 (6.81)	60.93 (8.33)	<.001
Race, n (%)					
Black or African American	879 (98)	100 (95)	557 (97)	222 (99)	.19
Black or African American and some other race or origin	22 (2)	5 (5)	14 (2)	3 (1)	.19
Non-Hispanic	845 (94)	97 (92)	530 (93)	218 (97)	.09
Sex, n (%)					.74
Male	524 (58)	58 (55)	337 (59)	129 (57)	
Female	377 (42)	47 (45)	234 (41)	96 (43)	
Education, n (%)					.03
High school or less	296 (33)	37 (35)	176 (31)	83 (37)	
Some college	244 (27)	23 (22)	154 (27)	67 (30)	
Associate	132 (15)	19 (18)	77 (14)	36 (16)	
Bachelor	176 (20)	18 (17)	123 (22)	35 (16)	
Graduate degree or higher	49 (5)	8 (8)	37 (6)	4 (2)	
Annual household income, n (%)					
Above federal poverty guidelines	726 (81)	82 (78)	465 (81)	179 (80)	.66
App use, n (%)					
Yes, I have used an app	549 (61)	76 (78)	377 (72)	96 (50)	<.001
Willingness to use app, n (%)					<.001
Yes	786 (87)	92 (88)	522 (91)	172 (76)	
Not sure	115 (13)	13 (12)	49 (9)	53 (24)	
Tobacco use, n (%)					
Yes	738 (82)	75 (71)	488 (85)	175 (78)	<.001
Current cigarette use in past 30 days, n (%)					.01
Less than 10 days	111 (15)	17 (23)	59 (12)	35 (20)	
10 through 20 days	137 (19)	20 (27)	101 (21)	16 (9)	
Greater than 20 days	489 (66)	38 (51)	327 (67)	124 (71)	
Current other tobacco product use, Yes, n (%)					
Cigars, for example, little cigars, cigarillos, or large cigars	536 (59)	74 (71)	400 (70)	62 (28)	<.001
Smokeless tobacco, for example, chewing tobacco, snuff, dip, or snus	34 (4)	6 (6)	25 (4)	3 (1)	.09
e-Cigarettes or other vaping devices	95 (10)	10 (9)	55 (10)	30 (13)	.29
Waterpipe tobacco or hookah	2 (0)	0 (0)	1 (0)	1 (0)	.80

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	Total	21 - 24	25 - 49	50+	*P* value
Other types of oral nicotine products, such as Velo lozenges, Rogue tablets, Lucy gum, or Pixotine	1 (0)	0 (0)	1 (0)	0 (0)	.99
Other	31 (3)	2 (2)	9 (2)	20 (9)	<.001
None	187 (21)	10 (10)	75 (13)	102 (45)	<.001
Time to first smoke after waking, n (%)					.75
Less than 5 minutes	225 (25)	28 (27)	134 (24)	63 (28)	
6 - 30 minutes	521 (58)	62 (59)	347 (61)	112 (50)	
61 or more minutes	154 (17)	15 (14)	90 (16)	49 (22)	
Ever tried to quit, n (%)					.66
Yes, and I was successful	232 (26)	31 (30)	140 (25)	61 (27)	
Yes, and I was not successful	506 (56)	55 (52)	322 (57)	129 (57)	
Quit attempts in the last 12 months, n (%)					.15
Yes	405 (45)	56 (53)	246 (43)	103 (46)	

Overall Importance of Features of mHealth App for Tobacco Cessation

Of all 7 mHealth app features, graphics was determined to have the highest average importance score at 16.5% (95% CI 16.2-16.9). Marketing and strategies for quitting were next with importance scores of 15.1% (95% CI 14.7-15.4) and 15% (95% CI 14.7-15.4), respectively. Connection with others had an importance score of 14.3% (95% CI 14.0-14.6), while personalization was fifth with an importance score of 13.4% (95% CI 13.1-13.7). The lowest-rated features were benefits of quitting and health information with importance scores of 13.1% (95% CI 12.8-13.5) and 12.6% (95% CI 12.2-12.9), respectively. Paired 2-tailed *t* test revealed that importance scores were statistically significantly different when compared with one another ($P<.001$) except for comparison between marketing and strategies for quitting ($P=.46$) and between personalization and benefits of quitting ($P=.19$). We found no statistically significant differences in the analysis by age group and sex.

Part-Worth Utility or Preferences for Levels Within Features

Within each feature, some levels were preferred more than others. The 5 most preferred levels were found within strategies for quitting, marketing, graphics, and connection with others. Within features, strategies for quitting had the highest and third-highest levels of “making a step-by-step quit plan” with a part-worth utility of 21.03 (95% CI 18.36-23.70) and “recommendations to manage relapse or withdrawal” with a part-worth utility of 16.70 (95% CI 14.68-18.73), respectively. Marketing had the second-highest level of “Historically Black Colleges and Universities–endorsed app” with a part-worth utility score of 18.33 (95% CI 15.70-20.95). Graphics had the fourth-highest level of “short video testimonials from people who successfully quit” with a part-worth utility score of 15.55 (95% CI 13.12-17.98), while connection with others had the fifth-highest level of “quit buddy program for support and accountability” with a part-worth utility score of 14.61 (95% CI 12.27-16.95; Table 4).

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Table . Part worth utility scores of levels within features.

Features and levels		Part worth utility, mean (95% CI)
Graphics		
	Contains short video testimonials from people who successfully quit.	15.55 (13.12 to 17.98)
	Has photos that feature Black people who have successfully quit.	0.93 (−2.24 to 4.11)
	Contains written testimonials from people who successfully quit.	−1.92 (−4.47 to 0.64)
	Has photos of real people with health issues from tobacco use (eg, lung or throat cancer).	−2.31 (−5.39 to 0.78)
	Has photos that feature people from a variety of races who have successfully quit.	−12.26 (−14.71 to −9.80)
Marketing		
	Is endorsed by a historically Black college or university that this app can help people quit.	18.33 (15.70 to 20.95)
	Is endorsed by a Black celebrity who successfully quit tobacco products.	5.89 (3.18 to 8.61)
	Features culturally relevant music and pop culture references.	−5.69 (−8.03 to −3.36)
	Features different types of music and pop culture references.	−5.73 (−8.34 to −3.12)
	Is endorsed by a celebrity who successfully quits tobacco products.	−12.80 (−14.97 to −10.62)
Strategies for quitting		
	Helps you make a step-by-step quit plan.	21.03 (18.36 to 23.70)
	Has recommendations about how to manage relapse or symptoms of withdrawal.	16.70 (14.68 to 18.73)
	Contains links to informational websites and free resources for tobacco cessation.	−10.62 (−12.83 to −8.41)
	Includes information about recommended tobacco cessation medications that can help with quitting.	−11.96 (−14.33 to −9.59)
	Has interactive games and videos to distract you from smoking and provide other forms of entertainment.	−15.16 (−17.74 to −12.58)
Connection with others		
	Has a quit buddy program within the app to help you support others and keep you accountable.	14.61 (12.27 to 16.95)
	Provides the option to interact with a variety of support professionals (eg, quit coach).	11.98 (9.56 to 14.40)
	Has a leaderboard that ranks your progress toward your cessation goals compared to other app users.	−0.09 (−2.39 to 2.20)
	Provides the ability for you to chat with other users within the app via a message board.	−9.40 (−11.85 to −6.94)
	Contains links to support groups on Facebook or motivational Instagram pages from the app.	−17.10 (−19.23 to −14.97)
Personalization		
	Includes the option to create a vision board to help you visualize your life without tobacco products.	5.92 (4.02 to 7.83)
	Has the ability to set reminders and notifications.	5.60 (3.11 to 8.10)

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Features and levels		Part worth utility, mean (95% CI)
	Includes the option to upload your personal goals and motivations for quitting.	2.97 (0.52 to 5.43)
	Has the ability for you to keep a journal in the app.	−2.88 (−4.95 to −0.82)
	Includes the option to upload motivational videos or music of your choice.	−11.62 (−13.96 to −9.28)
Benefits of quitting		
	Has information about how much money you can save by quitting tobacco products.	8.19 (5.78 to 10.61)
	Has information about how quitting tobacco products can lower your risk of a heart attack.	4.38 (1.98 to 6.79)
	Includes information about how quitting tobacco products can lower your chances of getting cancer.	−4.28 (−6.69 to −1.86)
	Includes information about how quitting tobacco products can improve physical appearance.	−8.30 (−10.73 to −5.87)
Health information		
	Contains information about how Black people who use tobacco products have a higher risk of blood pressure and heart problems.	9.40 (6.68 to 12.12)
	Contains information about how people who use tobacco products have a higher risk of blood pressure and heart problems.	9.40 (6.68 to 12.12)
	Has information about the historical targeting of the Black community by tobacco companies.	−6.22 (−8.21 to −4.23)
	Has information about how menthol is added to tobacco products to make them highly addictive.	−8.44 (−10.87 to −6.01)

Least preferred levels were also found. The top 5 dispreferred levels were found within connection with others, strategies for quitting, marketing, and graphics. Within features, connection with others had the least preferred level of “links to support groups on social media” with a part-worth utility of −17.10 (91% CI −19.23 to −14.97), while strategies for quitting had the second and fifth least preferred levels of “interactive games and videos to distract from smoking” with a part-worth utility score of −15.16 (95% CI −17.74 to −12.58) and “recommended tobacco cessation medications to help with quitting” with a part-worth utility of −11.96 (95% CI −14.33 to −9.59). Marketing had the third least preferred level of “endorsement by a celebrity who successfully quit” with a part-worth utility of −12.80 (95% CI −14.97 to −10.62), while graphics had the fourth dispreferred utility of “ photos of racially diverse people who successfully quit” with a part-worth utility of −12.26 (95% CI −14.71 to −9.80; Table 4).

Discussion

Principal Findings

This study identified preferred features of mHealth apps for tobacco cessation that appeal to Black adults who use tobacco products. While all features had some importance, graphics, marketing, strategies for quitting, and connection with others were the most important. We also found that within each feature, some levels were highly preferred, while others were highly dispreferred. To enhance the appeal of mHealth apps to Black adults who use tobacco products, prioritizing the inclusion of highly preferred levels and features in apps may lead to higher use and improved cessation.

Graphics was the most important mHealth feature, particularly video testimonials from others who successfully quit using tobacco. Dynamic graphics such as video testimonials are known to enhance use and interest in mHealth apps for several health conditions [18,34]. One study focused on developing a culturally relevant app for Black individuals on cardiovascular health showed that participants were interested in video narratives from prior participants of a program [34]. Video testimonials can improve the relatability and relevance of the app for the target population [34,35], which can increase engagement and use. Another study to examine features that Black adults prefer in tobacco cessation mHealth apps based on one app found that providing content through videos was appealing [18]. Using videos as a means to provide content has also been associated with increased retention of information [36].

In addition, within the levels of the graphics feature, photos of people from diverse races who successfully quit were significantly dispreferred. The evidence regarding preferences for racially diverse features in mHealth apps is mixed. While our findings support the importance of inclusivity with mHealth app features [37], a concern also exists for targeting, mentioned previously in the literature [18]. The significant dispreference

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observed may be reflective of the desire or need to protect one's self from interventions that may be considered racially targeted or that could potentially reinforce negative stereotypes, a concern highlighted in studies of medical mistrust [18,38-40]. Another factor that may have contributed to this finding is the static nature of this type of graphic. Images presented in a dynamic mode such as videos tend to be more appealing, while a lack of appeal and low likelihood of engagement with static information in mHealth apps has been described in the literature [35].

Marketing for the app was also found to be important, especially endorsement by a reliable source such as Historically Black Colleges and Universities (which was the most important level) or a Black celebrity. Relevant health information is valued by app users [37], more so if the information is from a reliable source [34]. Having a trusted group or individual endorse the app increases credibility and trust [41], which in turn can increase the likelihood of use of the app. Accuracy of information and intention toward end users are major concerns that tend to influence the decision-making process of target users [42]. As demonstrated in previous research, these concerns are especially relevant in light of the longstanding challenges associated with medical distrust [43,44]. Many Black adults who use tobacco products may be less likely to trust an mHealth app that lacks culturally relevant features and is promoted through mainstream channels, including non-Black celebrity endorsements.

Strategies for quitting were equally important, and similar to our study, previous research has shown that this feature is very important to other mHealth app users [18,45]. Provision of a practical guide for quitting has been determined to be highly desired in mHealth apps in general [45], which was the most important level of this feature in our study. One study found that Black adults who use tobacco products prefer strategies for quitting in an mHealth app, including ways to deal with cravings and healthy ways to deal with stress other than resorting to tobacco [18]. The next most important feature levels were a step-by-step plan and information on how to deal with challenges such as relapse or withdrawal symptoms. In that study, participants expressed interest in learning about alternatives to quitting abruptly (ie, the "cold turkey" method) and were particularly receptive to combining the app with pharmacotherapy [18].

The limited interest in pharmacotherapy and tobacco cessation resources observed in this study is not unexpected, as Black adults are less likely to be screened for tobacco use and, consequently, less likely to engage in discussions about cessation options [46]. Although dispreferred, the provision of this information within an mHealth app can be a key step to reducing failure rate and increasing the chances of sustained success with cessation for the target population. While interactive games in mHealth apps have been linked to increased engagement and enhanced self-efficacy [47,48], other studies, including our own, have found that such features may be less influential or valued by users [49,50].

We also found that connecting with other app users or health professionals through the app was important to participants, and such connections have been shown to keep users more engaged with apps [34,37,42]. Previous research shows that the addition of a program within the app for users to meaningfully compete among themselves is an attractive component of an app [35,37]. Participants can use competition as a way to challenge or motivate themselves as a way to reach their health goals. Similarly, connection with a health professional through the app can further strengthen the intervention [51], especially if such a connection can mitigate the need to have an in-person encounter with a provider for tobacco cessation concerns. Participants showed little interest in interacting with other users beyond accountability purposes or in connecting through social media groups. This aligns with other studies reporting the limited appeal of social networking features within mHealth apps [42,45]. Although some users may be open to sharing their health information, maintaining privacy, especially from friends on social media, may help reduce feelings of vulnerability often associated with efforts to improve one's health [42,52].

Consistent with our findings, mHealth apps that offer personalization features, such as goal setting, reminders, and notifications, are well-established as desirable and beneficial to users [34,52]. Features that keep users on track about their smoking-related behavior [18,37], provide a self-management or monitoring system [53], and enhance the ability for users to monitor their own progress have been associated with a higher likelihood of achieving the target health outcome [51,53]. Tracking positive outcomes, such as money saved by not purchasing tobacco products or the number of days between use, has also been shown to be a helpful feature for mHealth app users [18]. In addition, notifications or reminders that help individuals focus on their reasons for quitting can help to keep users motivated and more engaged with the mHealth app. Allowing users to determine the timing and frequency of these reminders can also help to further enhance the appeal and use of the app [42].

Information about the benefits of quitting was the second to the lowest importance score overall, but within that feature, participants preferred information about the financial benefits of quitting. Similar to our study, the benefit of saving money by quitting has been mentioned as appealing content for mHealth apps for tobacco cessation [35,45,54]. It is well established that many individuals who use tobacco products also experience financial hardship [55,56]. Tobacco cessation can positively impact cash flow by reducing the ongoing costs associated with tobacco use. For example, in 2025, the average cost for a pack of cigarettes in the United States is about US $10 [57]. Including information in an mHealth app about the potential monthly or annual savings from quitting tobacco may motivate users to stay engaged in the cessation process.

Within the benefits of quitting, participants also preferred information about the reduced cardiovascular risk associated with cessation but dispreferred information about reduced risk of cancer or the aesthetic benefits of quitting. Information about the association between tobacco use and an adverse health effect like cancer has been well established, and it is possible that participants were already well informed about the cancer risk; hence, they did not think that more information would be beneficial. Other studies also show that information about the

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harms of smoking in an mHealth app may not be as appealing [45].

Health information was the least important feature overall; however, participants expressed specific interest in learning about the risks of adverse cardiovascular outcomes, particularly as they relate to Black adults who use tobacco products. Studies have shown that presenting relevant health information can generate interest because the information is more relatable [18]. Information about the addition of menthol to tobacco products and its role in addiction was not appealing, as well as information about how the tobacco industry has targeted Black communities. Although information about the tobacco industry targeting can be effective by evoking negative emotions toward the industry [58], the negative response observed in this study may reflect broader concerns about racial targeting and generalized mistrust. Discomfort with targeted interventions among Black adults has been well documented in previous research [43,59,60]. While presenting health information can be beneficial, it should be delivered in a way that is inclusive and does not inadvertently isolate Black adults from broader user groups.

Limitations

We used a convenience sample, and the majority of participants reported household incomes above the federal poverty level and had attained a college degree or higher. As a result, the findings may not be generalizable to broader populations. Additionally, only a small proportion of respondents were older adults, who may be less comfortable with technology [52]. For analysis, individuals who identified as multiracial (Black and another race) were grouped with Black participants. Although multiracial participants represented only 2% of the study sample, combining them with Black participants may have affected our findings. We also excluded speeders and participants with incomplete or duplicate responses from our analysis. Although the affected participant made up less than 1% of the total sample, this may have disproportionally affected certain subgroups of participants. In addition, although we conducted several paired 2-tailed *t* tests to check for differences in importance scores and utilities across features and levels, we did not formally control for multiple comparisons; hence, some significant differences found may be due to chance. These analyses were exploratory, and our primary conclusions were based on the hierarchical Bayes estimations. Our findings are limited to the specific features and levels included in the DCE, which do not represent an exhaustive or comprehensive list. While we selected features based on existing literature and our qualitative work, it is possible that other features, equally or even more appealing to users, were not captured. Finally, we cannot determine whether incorporating all preferred features into an mHealth app will lead to sustained and meaningful use, since DCEs only capture stated preferences. Further research is needed to assess whether an app designed with these features ultimately improves tobacco cessation rates.

Conclusions

In summary, the role of mHealth apps for tobacco cessation is promising. This study highlights features of mHealth apps for tobacco cessation that highly appeal to Black adults who use tobacco products. Inclusion of these highly preferred features: graphics, marketing, strategies for quitting, and connection with others in a mHealth app, and more importantly, preferred levels within these features should be considered in the design and development process. The inclusion of preferred features may increase the appeal and use of the app by the target population. Although end-user preferences are critical in mHealth app development, some less preferred features may still offer meaningful benefits for tobacco cessation and should be carefully reconsidered before being excluded entirely. Future research to test the effectiveness of an app with these preferred features is needed.

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Data Availability

The datasets generated or analyzed during this study are available from the corresponding author on reasonable request.

Authors' Contributions

CE conceived the study idea, and funding was secured by CE, CEK, LBH-W, AOG, and RV. CE and SC were involved in launching the experiment, LG analyzed the data, and CE, LG, CEK, AOG, LBH-W, and RV interpreted the data. CE, LG, SC, AOG, LBH-W, RV, and CEK contributed to the writing of the manuscript, and all authors approved the final manuscript.

Conflicts of Interest

None declared.

Checklist 1
CHERRIES checklist.
[PDF File, 190 KB - formative_v10i1e83919_app1.pdf]

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Abbreviations

CHERRIES: Checklist for Reporting Results of Internet E-Surveys
DCE: discrete choice experiment
mHealth: mobile health

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Examination of the Acceptability and Feasibility of a Virtually Delivered Facilitator-Led and Self-Directed Cognitive Behavioral Skills Intervention in a Sample of Physicians and Medical Learners: Mixed Methods Evaluation

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Abstract

Background: The prevalence of various mental health conditions is higher among physicians and medical learners. One common barrier to receiving adequate care includes a lack of time to see a provider and follow treatment plans. As such, virtual forms of cognitive behaviour therapy with mindfulness (CBTm) were introduced to mitigate these barriers and provide care in an efficient and effective manner.

Objective: The objective of this study was to determine the acceptability and feasibility of a 5-session CBTm program, delivered in 2 virtual formats within a population of medical learners and physicians.

Methods: Participants signed up to the program using an online link and were able to choose a preferred format to participate in the CBTm program. One option was a virtual, facilitator-led class that was held once a week for 5 weeks, in a group setting (CBTm facilitator-led). Another option included a self-directed course that had identical content to the live classes but was independently completed by the participant using an online platform (CBTm self-directed). Feedback forms were collected from participants after every class and analyzed using quantitative and qualitative methods. Thematic analysis was used to qualitatively analyze open-ended questions from participant feedback forms. In addition, the mean values of questionnaire items were used to determine participant satisfaction with the program.

Results: The results indicated a good level of interest in both CBTm facilitator-led (n=15) and CBTm self-directed (n=94) groups. Of those who registered for the program, 13.8% (15/109) registered for CBTm facilitator-led and 86.2% (94/109) chose the self-directed version. The percentage of participants who participated in the majority of classes was 80% (12/15) for the CBTm facilitator-led group and 45.7% (43/94) for the CBTm self-directed group. The mean age of participants was 44.86 (SD 12.15 years), and the highest rate of uptake was among female physicians. Quantitative mean scores of participant feedback forms also showed a high level of satisfaction. For example, the Client Satisfaction Questionnaire 8 (CSQ-8) was analyzed, and the results indicated mean total scores of 28.00 (SD 3.24) and 26.46 (SD 3.55) for CBTm facilitator-led and CBTm self-directed, respectively. In addition, many themes emerged from thematic analysis and were subsequently categorized into 3 major categories. This included perceived strengths, perceived weaknesses, and suggested revisions to improve the program. Perceived strengths included improved mental health, helpful course content, and improved patient care. Perceived weaknesses included individual barriers to participation, content downfalls, and format-specific barriers. Suggested revisions included improving adherence to homework and virtual delivery of the program.

Conclusions: In conclusion, the results indicate that the self-directed and facilitator-led versions of CBTm were acceptable and feasible in this population of physicians and medical learners.

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KEYWORDS

virtual mental health intervention; physicians; medical learners; accessibility; burnout; cognitive behavior therapy

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Introduction

Background

Prevalence estimates of mental health conditions, including anxiety, depression, and burnout, have consistently been shown to be elevated among physicians and medical students when compared to the general population [1-5]. These estimates may be attributed to a number of factors, including the highly stressful nature of the occupation and an often-compromised work-life balance [4]. Despite this, many physicians do not seek help for their mental health conditions for several reasons, including fear of being stigmatized within the medical community, a tendency to self-treat, and denial of needing help [1-4]. In addition, a major barrier to seeking help is the lack of time to see a practitioner and follow treatment plans [4]. Overall, these factors place physicians and medical students at higher risk of suicide and mental disorders [2]. Poor mental health and burnout can negatively impact the health of physicians and medical students, but can also negatively impact patient care, the health care system, and society as a whole [2]. It is therefore necessary to find evidence-based strategies to promote mental wellness in this population.

Cognitive behavioral therapy (CBT), which focuses on making changes to maladaptive thoughts and behaviors to improve mental health, is the gold standard in terms of psychotherapy treatment for several mental health disorders and has been extensively researched as effectively reducing symptoms of anxiety and depression [6,7]. As a method to increase accessibility to skills from this psychotherapy, our team began offering large group CBT skills classes in 2014, called cognitive behaviour therapy with mindfulness (CBTm), with the goal of providing an introduction to evidence-based strategies to patients awaiting treatment for depression and anxiety disorders. Subsequently, a mindfulness-based component was added to our intervention on account of a growing body of evidence that mindfulness can help with a variety of mental health domains, including emotion regulation, stress management, and building resiliency [8-12]. A previous study examined the preliminary effectiveness of an earlier version of large group CBTm via a retrospective medical record review of 523 adults with a previously established mental health diagnosis [13]. Results found that participants showed significant reductions in symptoms of depression and anxiety after completing the CBTm program [13]. However, during the onset of COVID-19 in 2020, these services required shifting to online platforms [14]. This change has persisted due to the ongoing demand for virtual mental health services and the exacerbation of burnout in medical students and physicians during the pandemic [5,13].

In general, there are many computer-based programs that range from virtual one-on-one sessions to completely self-guided mental health programs [15]. The advantages of virtual platforms are extensive, but a few include lower costs and improved access to care, especially for individuals living in areas where mental health providers are scarce [16,17]. In addition to this, studies have shown that virtual interventions have the potential to be as effective as face-to-face interventions. For example, a previous meta-analysis and systematic review established that the effectiveness of guided internet-based CBT, in comparison to therapist-guided CBT, was equivalent for the treatment of a variety of psychiatric conditions [17].

As such, CBTm, a brief intervention that delivers evidence-based cognitive behavioral and mindfulness strategies in both facilitator-led and self-directed virtual formats, may serve to improve mental health outcomes by using technology to advance the accessible delivery of evidence-based therapeutic strategies. The CBTm program has typically been delivered in 2 virtual, class-based formats: one with a facilitator leading each session over Zoom (Zoom Communications, Inc; CBTm facilitator-led group) and one self-directed online course (CBTm self-directed group). The program was initially developed to address needs in the general population; however, there has since been further work to adapt the program to other populations, including a version geared toward physicians and medical learners. There are limited studies assessing the acceptability and feasibility of virtual psychoeducation programs, such as CBTm, in physicians and medical students. Acceptability and feasibility are key components to determine whether a program is suitable for implementation and real-world usage [18]. This advancement may be an important part of improving physician and medical learner well-being, as a previous study indicated that CBT-based programs can reduce psychological distress by improving coping styles and decreasing stress [19].

Objectives and Hypothesis

This study evaluated the acceptability and feasibility of CBTm delivered in 2 different formats in a sample of physicians and medical learners: a self-directed version and a Zoom-based virtual class. Acceptability is defined as whether participants appraise the program as likable [18]. Feasibility is defined as the likelihood that an intervention can be implemented for real-world use [18]. It should be noted that effectiveness, which would reflect changes in mental health symptoms using objective measures, was the focus of another study (B Garg et al, unpublished data). As such, we will examine (1) uptake and usage of the CBTm facilitator-led and CBTm self-directed programs in this sample, and (2) evaluation forms completed by participants using both quantitative and qualitative (ie, thematic) methods. We hypothesize that both versions of CBTm will be feasible and acceptable, particularly because these formats are highly accessible and could help mitigate common barriers to receiving care, including a lack of time to attend in person. We further hypothesize that there will be a preference for the self-directed online version of CBTm, as this format enables participants to integrate the sessions more flexibly into their individual schedules and can complete the program at their own pace. It should be noted that the aim of this study was not to compare the virtual and self-directed formats but rather to describe the real-world feasibility of both formats and assess future directions.

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Methods

Study Design

This study was an observational cohort study using a mixed-methods research design with integration of both quantitative and qualitative analysis.

Recruitment and Sample

Participants in this study were medical learners at the University of Manitoba and physicians practicing within Manitoba who self-referred to CBTm and who participated in the program between September 2022 and May 2023. The main method of recruitment was online advertisements that were distributed throughout the University of Manitoba Student Mental Health Services and newsletters distributed by Doctors Manitoba. Individuals would scan a QR code from the digital poster, which would take them to the CBTm website [20] on the page specifically for the program for physicians and medical learners. Once the participant clicked the registration link, registration occurred on a digital CBTm Study Portal hosted by REDCap (Research Electronic Data Capture; Vanderbilt University) through the university. Participants entered their names and email addresses in the portal and had the option to select their preferred format of the program (CBTm facilitator-led or CBTm self-directed). Participants also had the option to select a 10-session version of the CBTm course called the "wellness workshop." However, due to the different number of sessions in this option and low participant interest, evaluation data from this version were not included in this study. Direct email communication with participants was followed to engage them in this study.

Consent Process

If participants chose CBTm facilitator-led, they completed 2 forms immediately afterward that collected their consent and demographic information. Upon completing the consent and demographic forms, they were emailed a Zoom link and class materials for the first class. In contrast, if participants chose CBTm self-directed, they were asked to fill out their name, email address, phone number, and current role in the medical field. After this information was collected, they were sent access codes for the web course and were asked to complete a consent form. If consent was obtained, they were able to access the first class.

Ethical Considerations

This project received ethics approval from the Health Research Ethics Board at the University of Manitoba before implementation (HS23878 [H2020:196]). Participants were informed at the time of consent that their privacy would be protected and that their information would not be shared with anyone outside those members of the authorized research team. To enroll in the program, participants were required to consent to data collection for research purposes. In addition, participants were asked to protect the privacy of other participants, similar to privacy requirements seen within in-person group CBT classes. This included specifically instructing participants not to share the names of other participants. Participants were not financially compensated.

Intervention

The CBTm course consisted of 5 sessions, each 90 minutes in length. The content of each class is summarized below. This version was adapted to include examples and information more relevant to physicians and medical learners. For example, the CBT model, which includes thoughts, emotions, physical reactions, and behaviors, was adapted to an example of a colleague being confronted by a former patient.

- Class 1: Introduction to CBT, urgent self-help resources, mindfulness exercise, the CBT cycle, thinking traps, thought record exercise, out-of-session CBTm skills practice
- Class 2: Mindfulness exercise, review skills practice, review CBT model, basics of behavior therapy (ie, introduction to behavioral activation and exposure therapy), SMART goal setting, and out-of-session CBTm skills practice
- Class 3: Mindfulness exercise, review skills practice, nutrition and healthy living strategies, sleep hygiene, out-of-session CBTm skills practice
- Class 4: Mindfulness exercise, review skills practice, basics of anger management, assertiveness skills, self-compassion, the basics of problem-solving, and out-of-session CBTm skills practice
- Class 5: Mindfulness exercise, review skills practice, managing traumatic and stressful experiences, developing a wellness plan, and out-of-session CBTm skills practice

Participants in option 1 (CBTm facilitator-led) were emailed a Zoom link for each class before the first session. The 90-minute sessions were held live once a week for 5 weeks and led by a CBT-trained psychiatrist. The CBTm material was presented in a class-based format on PowerPoint (Microsoft Corp) slides.

Participants in option 2 (CBTm self-directed) were emailed an access code to the self-directed CBTm course available on a website. This version had identical content to the facilitator-led classes; however, it did not have a live facilitator. Instead, the information was presented on a series of slides with an accompanying prerecorded voice-over by an experienced CBTm clinician and written narration. When the participant was given access to a particular class, they were able to move through the lesson at their own pace. The participant was required to listen to the prerecorded audio as recorded by the facilitator on each slide before moving on to the next slide. Once the participant completed a class, they were emailed a link 7 days later with access to the next class. The 7-day delay was meant to mirror the timeline in the facilitator-led set of classes. This was repeated until the participant completed all 5 classes. Within the online course, participants could also click a "contact us" button to send questions to this study's oversight team. The team responded to all questions accordingly, with the consultation of a clinical psychologist, social worker, or psychiatrist if needed.

Data Collection

Participants enrolled in option 1 (CBTm facilitator-led) were asked to complete class evaluation forms after each session. A secure link to the survey was sent to the participant's email

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address, and the data were collected using the University of Manitoba's REDCap survey system. At the beginning of each class, participants were reminded by the facilitator to complete these surveys. Participants in option 2 (CBTm self-directed) were required to complete identical evaluation forms after each class, built within the course modules. Participants were given access to content for the next session 7 days after they had completed the previous class and all required questionnaires.

Measures

Sociodemographic Characteristics

A questionnaire regarding participant sociodemographic information, including age, sex, and career stage, was collected before starting the first class.

Intervention Evaluation Measures

Virtual Mental Health Questionnaire 21 (VMHQ-21)

The VMHQ-21 questionnaire is a 21-item measure that was developed based on a preexisting questionnaire, called the Telehealth Usability Questionnaire, which is a valid and reliable tool to assess participant satisfaction and usage of telehealth services [21]. This is an important measure given that the programs were virtually delivered, and the current aim of this study was to assess both the acceptability and feasibility of the formats. Quantitative items were rated on a scale of 1 to 5, where 5 denoted high satisfaction and 1 denoted low satisfaction. The total VMHQ-21 score was calculated by summing up all items, with a maximum possible score of 105 representing the highest possible satisfaction. Examples of questionnaire items included "The online CBTm course improved my access to mental health services" and "I felt that I was able to quickly navigate through the course material." VMHQ-21 subscales were generated by summation of subscale items, which included (1) usefulness (items 1-3), (2) ease of use and learnability (items 4-6), (3) interface quality (items 7-10), (4) interaction quality (items 11-14), (5) reliability (items 15-17), and (6) satisfaction and future use (items 18-21) [21]. Mean scores were reported for each subscale score and the overall total score. The CBTm research team modified this questionnaire by replacing "telehealth" with "CBTm program" to reflect the specific intervention in question. Open-ended questions, as seen in Table 1, were presented on the same web page as the VMHQ-21 to obtain feedback on the virtual format of the program. These questions were not reflected in the overall score obtained from the VMHQ-21.

Evaluation of the CBTm Session

The evaluation questionnaire was developed by the CBTm research team to evaluate the CBTm program content and format. This tool was used to gather descriptive, session-level feedback to support monitoring and improvement of the program. It was not intended to function as a psychometric measure. As such, formal validation was not pursued. These questionnaires were completed by participants before and following each session. Open-ended questions from this form can be found in Table 1. The questionnaire included quantitative items that were rated on a Likert scale from 1 to 5, where 5 denoted high satisfaction and 1 denoted low satisfaction. The quantitatively rated items from the questionnaire included "How useful was this session for you?" and "How did you like the (virtual) format?"

Table . Summary of textbox-response questions regarding acceptability and usability of CBTm[a] classes for qualitative analysis.

Questionnaire	Items
Skills practice	• What was helpful about doing the homework activities? • What made it difficult for you to complete the homework activities? • What changes could be made to improve the homework activities? • Please describe the difficulties you had.
Evaluation of the CBTm education session	• What did you like most about the session? • How could we improve the session? • Other comments.
Additional questions added to VMHQ-21[b]	• Please indicate any changes that you plan to make in your work or daily life as a result of the information you received from this activity. • What barriers might stop you from making the above changes? • Do you think these changes will affect patient outcomes? If yes, in what ways?

[a]CBTm: cognitive behaviour therapy with mindfulness.

[b]VMHQ-21: Virtual Mental Health Questionnaire 21.

Client Satisfaction Questionnaire

The CSQ-8 is an 8-item questionnaire that has high internal reliability and was designed to assess client satisfaction with a particular service [22,23]. Items on this questionnaire were rated on a Likert scale from 1 to 4, where 4 denoted high satisfaction and 1 denoted low satisfaction. Total scores were calculated by summing the items, where a total score of 32 represented the highest level of satisfaction possible. The quantitatively rated items from the questionnaire included "To what extent has our program met your needs?" and "If you were to seek help again, would you come back to our program?" This scale is one of the most common tools used to assess overall satisfaction with interventions, including mental health programs [24]. As such, we used this measure to assess overall satisfaction, and therefore acceptability, of CBTm self-directed and CBTm facilitator-led.

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Skills Practice

The Skills Practice Questionnaire was a questionnaire used to collect participant feedback on the homework activities assigned in the CBTm course. It was measured only in classes 2 through 5. The purpose of this tool was to identify which CBTm skills taught during the previous class participants practiced over the following week. The questionnaire was not designed as a psychometric measure, but rather as a practical tool to gather targeted feedback. The open-ended questions are summarized in Table 1.

Quantitative Data Analysis

The feasibility and acceptability of the program were evaluated by analyzing participant uptake into the program. This included the number of individuals who clicked a link to self-refer to the program, the number of participants registered to the course (ie, they completed consent), and the number of participants who attended the class (ie, at least 1 class attended). In addition, demographic information from evaluation forms filled out by participants in both formats was quantitatively analyzed using SPSS (version 29; IBM Corp). Questionnaires, including items on the Evaluation of the CBTm Education Session and the Skills Practice Questionnaire, total score on the CSQ-8, and subscale and total score on the VMHQ-21, were analyzed using mean and SD calculations. As this study is a pilot study to gauge overall participant uptake and satisfaction, descriptive analyses were deemed appropriate. Overall means were calculated as sample size-weighted averages across classes. Pooled SDs were calculated by combining the class-level variability and the differences between class means, with each class weighted according to its sample size. This approach produces a single summary estimate that reflects both within-class variation and between-class differences. One question from the Skills Practice Questionnaire was analyzed by calculating the frequency of participants who stated that they had completed the homework recommended by the CBTm program. The missing data included those who (1) attended the class but did not complete the questionnaire, (2) did not attend the class and did not complete the questionnaire, and (3) dropped out of the program.

Qualitative Data Analysis

To determine the feasibility and acceptability of the CBTm facilitator-led and CBTm self-directed groups, thematic analysis was used to analyze the open-ended questions included in the evaluation forms completed at every CBTm class. Braun and Clarke [25] have outlined the basic ideology underlying thematic analysis as well as 6 major steps to conducting this method rigorously. Thematic analysis is broadly described as analyzing qualitative data in a systematic way to identify meaningful patterns [25]. In the current study, data were coded by 2 coders (BG and N Muthumuni). These individuals independently coded the dataset and met weekly to check coder congruency. Four meetings occurred with a deliberator (N Mota) present, to review the data together and discuss any coding differences until a consensus was reached. Subsequently, the codes were analyzed to identify themes and subthemes emerging from the data. Reasons for dropout rates were also reported and organized into different categories based on the responses provided. The data were analyzed until saturation was achieved. One definition outlined by Urquhart [26] defines saturation as the point in analysis where no additional codes are created from the qualitative data sets [27]. Others define saturation as a point where supplemental data analysis does not yield new information [27].

Mixed Methods Integration Analysis

To achieve integration, both types of data were collected and analyzed independently, then subsequently merged [28]. Merging is a common form of convergent design to integrate qualitative and quantitative data sets [28]. For example, overall participant satisfaction with the virtual CBTm programs was examined in the current study. To perform an in-depth analysis of participant satisfaction, quantitative measures (CSQ-8) and qualitative measures (open-ended feedback) were both analyzed. These datasets were compared to one another to see if consistency between the data was present to ensure the validity of the findings.

Results

Quantitative

The demographic characteristics of participants in the CBTm facilitator-led and CBTm self-directed groups are summarized in Table 2. Most participants were female (54/76, 71.1%) and practicing physicians (64/75, 85.3%) with a mean age of 44.86 years.

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Table . Participant demographics for CBTm[a] self-directed and CBTm facilitator-led.

Characteristics	Values
Age (years, n=78)[b], mean (SD)	44.86 (12.15)
Age (years), minimum-maximum	24-71
Sex (n=76)[b], n (%)[c]	
Female	54 (71.1)
Male	22 (28.9)
Career stage (n=75)[b], n (%)[c]	
Medical student	7 (9.3)
Resident	4 (5.3)
Practicing physician	64 (85.3)

[a]CBTm: cognitive behaviour therapy with mindfulness.

[b]n varied based on participant completion of the demographic section on the questionnaire.

[c]Percentages were calculated after removing missing data, which ranged from 2.6% to 8.3%.

Figure 1 and Table 3 illustrate participant interest and uptake into CBTm facilitator-led and CBTm self-directed. A total of 233 individuals accessed a link for registration into the program; however, it should be noted that this number may include duplicate entries. Of those who registered, 86.2% (n=94) chose CBTm self-directed and 13.8% (n=15) registered for CBTm facilitator-led. The number of participants completing 3 or more classes of CBTm self-directed and CBTm facilitator-led groups was 45.7% (43 of those registered) and 80% (12 of those registered), respectively. Reasons for dropout were also collected and summarized in Table 3. Of the 111 participants who withdrew from CBTm facilitator-led and CBTm self-directed groups, 88.3% (n=98) did not respond with a reason, 6.3% (n=7) had competing priorities, and 5.4% (n=6) listed "other" as their reason. Participants attending 3 or more classes did not differ in demographic composition from those attending fewer than 3 classes or who dropped out. In both groups, females comprised the majority of participants, and career stage distributions were similar, with most participants being practicing physicians and few medical students or residents.

Figure 1. Participant interest and uptake into 5-session CBTm facilitator-led and CBTm self-directed groups. CBTm: cognitive behaviour therapy with mindfulness.

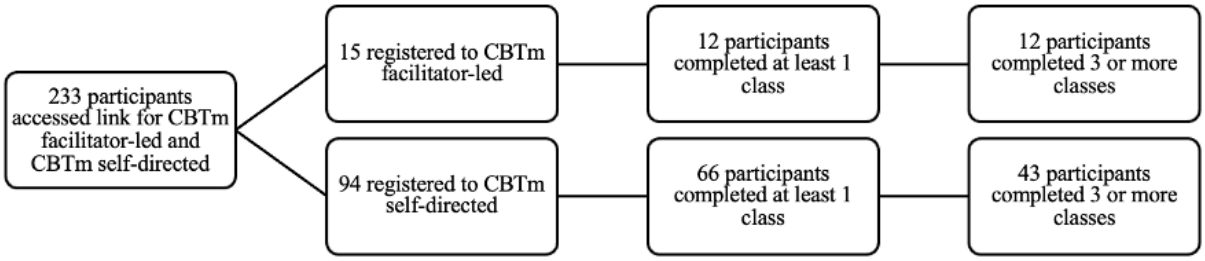

Table . Participant reasons for dropping out from CBTm[a] facilitator-led and CBTm self-directed groups (N=111).

Reasons for dropout	Values
No response to the inquiry, n (%)	98 (88.3)
Competing priorities, n (%)	7 (6.3)
Other, n (%)	6 (5.4)

[a]CBTm: cognitive behaviour therapy with mindfulness.

Session Evaluation Forms

Table 4 summarizes the mean and SD of items in the Evaluation of the CBT Education Session Questionnaire. Mean values of question items in the CSQ-8 were also analyzed for both formats and are summarized in Table 5. The total average CSQ-8 scores for CBTm facilitator-led and CBTm self-directed groups were 28.00 and 26.46, respectively. The total average VMHQ-21 scores for both formats are summarized in Table 5, indicating a mean score of 95.00 (SD 5.43) for CBTm facilitator-led and

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94.59 (SD 10.39) for CBTm self-directed. Lastly, Table 6 displays the percentage of participants who completed the recommended skills practice from the CBTm course.

Table . Summary of session evaluation ratings by delivery format.[a]

Evaluation item	CBTm[b] delivery format	
	Facilitator-led group	Self-directed group
Session usefulness, mean (SD)	4.17 (0.62)	3.95 (0.89)
Liking the (virtual) format, mean (SD)	3.72 (0.83)	4.37 (0.85)
Ability to fully participate, mean (SD)	4.26 (0.85)	4.29 (0.93)

[a]Items were measured on a Likert scale from 1 to 5, where 5 denotes higher satisfaction. Means were calculated after missing data were removed.
[b]CBTm: cognitive behaviour therapy with mindfulness.

Table . Mean values of CSQ-8[a] and VMHQ-21[b] items for CBTm[c] self-directed and CBTm facilitator-led groups.

Items	CBTm self-directed group (CSQ-8, n=28; VMHQ-21, n=27)	CBTm facilitator-led group (n=5)
CSQ-8[de], mean (SD)		
How would you rate the quality of the service received?	3.43 (0.50)	4.00 (0.00)
Did you get the kind of services you wanted?	3.39 (0.57)	3.40 (0.55)
To what extent has our program met your needs?	3.21 (0.69)	3.40 (0.55)
If a friend were in need of similar help, would you recommend our program to them?	3.54 (0.58)	3.80 (0.45)
How satisfied are you with the amount of help you have received?	3.07 (0.90)	3.60 (0.55)
Have the services you received helped you to deal more effectively with your problems?	3.21 (0.50)	3.00 (0.71)
In an overall, general sense, how satisfied are you with the service you have received?	3.39 (0.50)	3.60 (0.55)
If you were to seek help again, would you come back to our program?	3.21 (0.63)	3.20 (0.84)
CSQ-8 total score	26.46 (3.55)	28.00 (3.24)
VMHQ-21[d], mean (SD)		
Usefulness: VMHQ-21 items 1 - 3	12.86 (2.07)	12.00 (1.58)
Ease of use and learnability: VMHQ-21 items 4 - 6	13.86 (1.80)	14.60 (0.89)
Interface quality: VMHQ-21 items 7 - 10	17.61 (2.56)	18.80 (1.30)
Interaction quality: VMHQ-21 items 11 - 14	18.75 (1.78)	19.60 (0.55)
Reliability: VMHQ-21 items 15 - 17	12.56 (2.26)	10.80 (2.28)
Satisfaction and future use: VMHQ-21 items 18 - 21	18.14 (2.62)	19.20 (1.79)
VMHQ-21 total score	94.59 (10.39)	95.00 (5.43)

[a]CSQ-8: Client Satisfaction Questionnaire 8.
[b]VMHQ-21: Virtual Mental Health Questionnaire 21.
[c]CBTm: cognitive behaviour therapy with mindfulness.
[d]For the CSQ-8 and VMHQ-21 questionnaire, a higher score delineates greater satisfaction, with a maximum possible score of 32 and 105, respectively.
[e]Each CSQ-8 item is rated on a 1 - 4 scale, where 4=satisfied and 1=not satisfied.

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Table . Percentage of participants who completed skills practice, of those who filled out the questionnaire and completed the class.

Descriptors	CBTm[a] class number[b]			
	Class 2	Class 3	Class 4	Class 5
CBTm facilitator-led, n (%)	8 (72.7)	6 (66.7)	8 (80)	3 (60)
CBTm self-directed, n (%)	36 (76.6)	31 (75.6)	27 (77.1)	19 (76)

[a]CBTm: cognitive behaviour therapy with mindfulness.

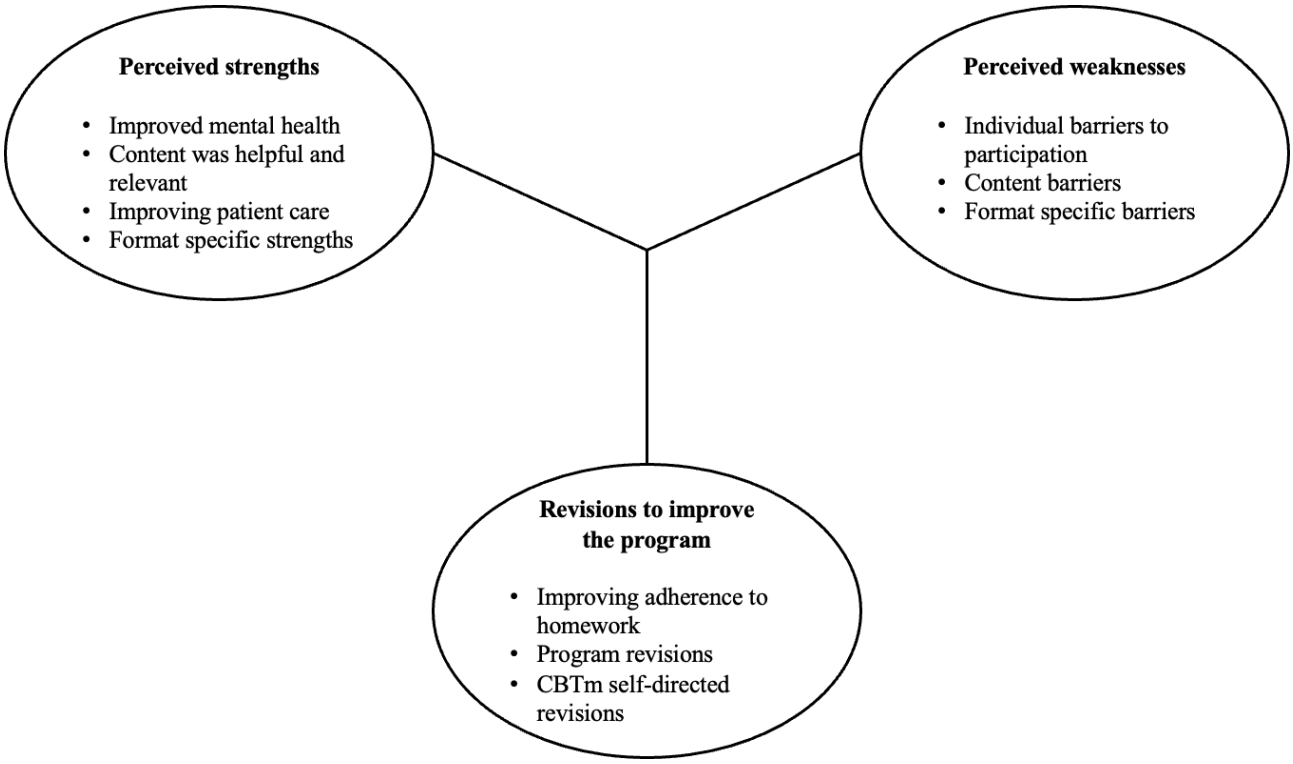
[b]Note that the skills practice is completed at the beginning of the class, following the first class.

Missing data for CBTm self-directed and CBTm facilitator-led ranged from 1.5% to 10.7% and 20% to 54.5%, respectively. The missing data reflected either noncompletion of the classes or noncompletion of the questionnaire.

Qualitative

A total of 70 participant evaluation forms from both the CBTm facilitator-led group (n=11) and CBTm self-directed group (n=59) course formats were analyzed using thematic analysis. Saturation was achieved, given that the themes emerging were consistent among participants and became redundant as data were analyzed [25]. To address our study aims, responses were evaluated with three overarching categories in mind: (1) perceived strengths, (2) perceived weaknesses, and (3) suggested revisions to improve the program. Various themes emerged under each category. While most of the themes were applicable to both CBTm self-directed and CBTm facilitator-led groups, there were also some important differences between the formats that are highlighted throughout. The major themes are summarized in a thematic map in Figure 2.

Figure 2. Thematic map of open-ended responses from participant evaluation forms. The major themes are listed under 3 overarching categories, including perceived strengths, perceived weaknesses, and revisions to improve the program. CBTm: cognitive behaviour therapy with mindfulness.



Perceived Strengths

Overview

The majority of participants commented on the strengths of the CBTm program. This category included 4 themes: improved mental health, course content was helpful and relevant, format-specific strengths, and improving patient care.

Improved Mental Health

Most participants noted that participating in CBTm or suggested skills practice in between classes improved their mental health. For some participants, for example, the classes helped them to change negative thinking patterns. One participant commented that CBTm was helpful in "reframing negative anxiety-provoking thoughts" (W033). Another participant mentioned that the program helped them to "be more conscious about what passes through [their] head" (W007). In addition, some participants reported that the program helped them to feel better and relieve stress (W055, W047, W058, and W002). For example, it helped 1 participant "clear [their] mind of worries and tension" (W034) and for another, it "actually helped calm [them] down and think about things differently" (Z001). Many others commented specifically on the mindfulness aspect of the course, helping them to relax: "Mindfulness helped me calm

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down one morning where I was stressed, and I think doing it before bed helped me fall asleep" (W014).

Course Content Was Helpful and Relevant

Content Was Applicable

Many participants spoke positively about the course content. Most participants said that the course content was applicable to their lives (W031, W046, Z010, and Z003). One participant commented that "it is immediately relevant in my life. It's the right time for me to be hearing this because I can think of examples now that apply to the exercises" (W022). Another participant said they enjoyed the fact that the sessions were "tailored to physicians" (Z002). A large group of participants found the sections on sleep particularly helpful (W037, W041, and W045), as well as sections related to thinking traps and exposure therapy. However, it should also be noted that there was a small minority of participants who commented that the material was not applicable, as described below.

Exercises Were Helpful

The vast majority of participants felt positively about the handouts and exercises provided in the course. These included the thought record, SMART goal development, and wellness plans, among others. In particular, a large portion of the participants reported that the thought record was helpful and enjoyable to complete (Z010, Z003, and W041). One participant reported that the "thought record was organized very well. I thought the progression of questions was useful in facilitating self-reflection" (Z004).

Suggested Practice: Improved Integration of CBTm Skills in Life

Participant feedback consistently showed that the skills practice was particularly helpful in integrating CBTm skills into their lives. One participant gave a specific example where they used a skill from the course: "[I] went shopping for clothes, which I have been avoiding since lockdowns. [I] realized it wasn't as bad as I was making it up in my head!" (Z007). Another participant said, "although I usually think I have a fairly balanced way of looking at situations I used the thought testing exercise to help realize that this is not always the case" (W011). Many participants reported that completing the skills practice helped them in developing new daily routines (Z008, W001, W008, W022, and W031). In addition, participants pointed out that the skills practice reinforced the course content. For example, participants said it was a "chance to practice and remember new learning for the future" (W049) and that "practice makes perfect" (W059).

Format Specific Strengths

Flexibility of CBTm Self-Directed

For CBTm self-directed specifically, most participants commented on enjoying the format due to its flexibility. Some comments included appreciating the "ability to come back, restart, review" (W040) and the "ability to review and listen to the material more than once" (W058). Other participants reported that it was easier to integrate into their lives; "I could do it on my own time" (W021). This flexibility also helped in learning the course concepts: "One could pause to think, review a link, to consolidate the learning experience and I could take the time I needed to study each part." (W002).

Facilitation of the CBTm Self-Directed Group

Many participants commented that the course content was delivered in a concise and understandable way (W048, W002, W023, and W029). For example, participants appreciated how lessons were "broken down into manageable segments" (W003) and that there were "clear explanations, instructions, [and] assignments" (W008). Others enjoyed the instructors' presentation of the course (W007 and W032). However, a minority of participants commented that facilitation could be improved by implementing a visual of the facilitator.

Interaction in the CBTm Facilitator-Led Group

A few participants in the Zoom course enjoyed interaction with other participants and with the instructor. When asked what they liked most about the session, for example, 1 participant responded with, "time to share and relate to others" (Z007), and another said, "feedback and dialogue with the instructor" (Z003). However, it should be noted that of those participants who commented on interacting with others, an equal number of participants were hesitant about interacting with others, as summarized in a section below entitled "Format Specific Barriers".

Improving Patient Care

A large majority of participants commented that the skills learned within the CBTm program could benefit patient care in 2 ways. First, they noted that improving their own well-being would translate into better patient care. For example, 1 participant indicated that, "If I am more relaxed, my interactions will be more relaxed and welcoming" (W032), while another reported that this course "will improve my wellbeing which will improve my ability to care for patients" (Z001). Another perceived way of improving patient care was through providing their patients with CBTm skills and resources. Participants said they would "discuss some of these tools with patients" (W047) and that they would support patients by "helping them access more resources and providing support and [a] safe place until seen by counselor/ psychologist" (Z003). Others noted, "I'll be able to suggest some of the things I learned to them" (Z002) and "I am using the material with patients, referencing web sites and working on my own healthy goals" (Z003).

Perceived Weaknesses

Overview

Three themes were identified regarding weaknesses of the program, including individual barriers to participation, content downfalls, and format-specific barriers.

Individual Barriers to Participation

Time Restraints

The overwhelming majority of participants mentioned that "time, being busy, other obligations" prevented participation (Z008). One participant wrote, "constantly racing from one activity to another [and] no time to think about CBT" (W044). Many mentioned that work-related duties or family obligations

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were the main competing priorities preventing participation (W043, W045, and Z001).

Burnout

A common subtheme that arose and restricted participation in the program involved feeling stressed and burnt out. This included feeling "overwhelmed at work" (W045) and "general exhaustion and apathy" (W014). Another participant said, "Unfortunately my life still feels overly full, and I have an underlying level of disquiet" (W032). A large handful of participants also mentioned being "easily distracted and tired" (W040) or "lack of motivation" (W058) as major barriers to completing the CBTm sessions or skills practice.

Forgetting Skills Practice

Other participants mentioned that forgetting was a common reason for not completing skills practice. One participant reported "I got busy and forgot about it at times" (W026) while another wrote that "remembering to do [the homework]" (Z010) was a major barrier. Participants commented on various ways to improve adherence to the program or to skills practice completion. One common suggestion was to schedule protected time during the day to improve homework adherence, to mitigate forgetting, and to address time restraints. For example, participants reported that they would try to "set aside early morning time to review homework and practice for the day" (W021) or "set a timer each evening to engage in activities" (W002). Other participants also recognized a lack of time for themselves as a barrier. As such, suggested solutions included needing "to prioritize time for myself" (W032) and "focus on my health" (W034). Another participant said, "I would like to have downloaded and/or printed the course materials ahead of time so I could fill things in and have them at my fingertips (like looking at the list of thinking traps)" (W022).

Content Barriers

Content Was Not Applicable

A few participants commented that the class content was not always applicable. One participant said, "I have previously worked on diet, exercise and do not need advice in these realms" (W049). Another participant wrote, "it would be nice to have the option to skip over sections that don't apply (for example, people who don't drink could skip the alcohol section)" (W014). An interesting insight was a participant who commented, "very focused on anxiety which wasn't applicable to me personally but could be used for my patients" (Z006).

Format Specific Barriers

CBTm Self-Directed Had Technical Errors

A variety of technical issues were raised by participants while trying to complete the CBTm self-directed course. One technical issue involved generally navigating the website (W033 and W027). As outlined by 1 CBTm self-directed participant, "sometimes the next button would take a few minutes to appear making me stuck on the same page for a while" (W027). Other participants had issues with the volume of the facilitator being too low (W032 and W043). Other technical issues included the inability to increase the speed of facilitator speech during the slide-by-slide explanations and internet connectivity issues (W021 and W037).

CBTm Facilitator-Led Participants Were Hesitant to Share

Some participants felt uncomfortable sharing in the Zoom-based CBTm environment. One concern is related to worries about privacy. One participant explained, "I was a bit reluctant to share ALL my personal details in a group setting. [And given the SMALL MD community in MB...I would have been even MORE reluctant to share]" (Z005). Other participants felt hesitant to share because not all participants were attending the program for their own mental health improvement. Some were there for personal reasons, while others were interested in tools that could help their patients. For example, 1 participant reported, "while the didactic portions of the sessions were suitable for both types of participants, I felt that the sharing portions of the sessions were a bit awkward for me since I attended primarily to learn strategies to cope with my personal depression/anxiety. It felt a bit odd to talk about personal challenges in that context" (Z010).

Suggested Revisions to Improve the Program

Improving Adherence to Homework

In order to mitigate the barrier of forgetting to complete skills practice, participants advocated for having the program "send a reminder email for an activity once a week" (W060) or an "online tracker" to monitor progress through the classes (W037).

Program Revision

Content Changes

Suggestions for content modifications varied based on individual preference. Suggestions included "increased information for mild symptoms" (W011), "more information on sleep" (W019), and "more activities/ worksheets" (W025).

Pacing

Another comment made by participants was to increase the pace of the course. Some participants reported that the pace of the course was too slow (W044, W001, W005, and W037). One participant suggested the option to "[go] through the content a little fast as we are physicians who have background knowledge" (Z006).

CBTm Self-Directed Revisions

Increase Engagement

Since the course is completely independent, some participants suggested having "more interactive questions to answer" (W044) or the ability for "human discussion" (W001). Another participant commented they desired "feedback on responses" (W037). Others suggested improving the facilitation of the course by including "a live video of the person's face who presents the class" (W035).

Improve Mobile Experience

Some participants reported having difficulties accessing the course material on their mobile devices. As such, a few

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participants suggested making it more accessible on a mobile device (W022, W055, and W012).

Discussion

Principal Findings

This study examined CBTm self-directed and CBTm facilitator-led in a population of medical learners and physicians using a mixed methods research design. Overall, the results indicate that CBTm, delivered using a self-directed or Zoom-based format, is an acceptable and feasible way to deliver mental health interventions in this population. Participants were satisfied with the program and provided meaningful recommendations to improve the program in areas where barriers were present. These results are in line with a systematic review that assessed the effectiveness of CBT for health care workers, presented in both face-to-face and non–face-to-face formats [29]. That research indicated that non–face-to-face interventions (eg, the Sleep Enhancement Training System for Shift Workers and internet-based CBT) were effective at reducing stress and insomnia [30,31]. However, the review also highlighted the need for further literature looking at the acceptability and effectiveness of non–face-to-face CBT strategies, such as the one used in the current study [29].

Principal Results

There were 3 novel findings in this study. First, there was a good level of uptake for both CBTm facilitator-led and CBTm self-directed, with a large number of participants choosing CBTm self-directed. Second, both formats had high levels of participant satisfaction, with positive feedback regarding content, skills practice, and participant mental health. Third, barriers to attendance and select program revisions suggested by participants can guide improvements to the program, which may help increase the attendance and retention of participants.

While there were high rates of interest in both CBTm self-directed and facilitator-led groups, there appeared to be a preference for the self-directed version of CBTm. The high rate of uptake for CBTm self-directed could be attributed to the fact that participants could integrate the CBTm course more easily into their individual schedules. For physicians and medical learners, this format may vastly improve accessibility, since time constraints are often cited as a barrier to participating in such interventions [4]. However, it should be noted that the ratio of participants completing 3 or more classes was 80% for the CBTm facilitator-led group. This may have been due to the increased level of accountability in a Zoom-based course with a live facilitator and other participants being present. The CBTm self-directed course was independent and therefore relied on the participants to remember and self-motivate to complete all classes. This is consistent with a previous review, which examined guided and unguided computerized CBT programs [32]. The study indicated that the number of participants who would complete the full program for guided and unguided computerized CBT programs could range from 8% - 74% to 16% - 66%, respectively, across various studies [32]. As such, the rates of completion in the current study reflect the heterogeneous participation and completion of virtually delivered CBT programs. Future research should focus on how to improve the retention of participants in virtually delivered CBT interventions. In addition, while a meta-analysis found evidence that guided internet-delivered CBT programs are as effective as face-to-face CBT, it also recognized the need for a greater number of studies to confirm these findings [16]. There is a large amount of heterogeneity between different programs of virtual-based CBT, making it difficult to make definitive conclusions about the effectiveness of these programs as a whole [16].

When examining which participants were most likely to enroll in the program, we found that practicing female physicians in the mid-forties age group had the highest level of uptake, whereas medical residents had the lowest. This finding is consistent with previous literature, which indicates lower rates of uptake for mental health interventions but high rates of mental health problems in the medical resident population [33]. This may be due to many factors, including stigma associated with accessing mental health care, concerns about confidentiality, and a lack of time [5,33]. The online formats of this CBTm intervention can help mediate some of these barriers. However, there are larger issues that must be addressed to meaningfully improve resident participation in mental health interventions. Overall, the low uptake of CBTm by residents reaffirms a need for mental health interventions that are designed to make access easier for residents. Further work should be done to examine and improve use for these individuals.

When evaluating satisfaction levels associated with the web-based CBTm programs, both quantitative and qualitative results independently indicated high levels of satisfaction. For example, the VMHQ-21 indicated a high level of satisfaction with the virtual delivery of the mental health intervention. This was consistent with the thematic analysis, where a major theme was format-specific strengths. The analytic strategy used for integration and merging ensured the results were consistent and reinforced the accuracy of the data. Many participants highlighted that the program improved their mental health and reduced feelings of burnout. These results are congruent with previous literature, where an online mindfulness program reduced feelings of emotional exhaustion within a sample of health care workers in Ontario [34].

Research regarding the connection between the quality of health care provided to patients and the mental health of physicians and medical students is limited [35]. However, research does indicate that improved well-being is an important factor in improving patient-physician relationships and is an indicator of patient satisfaction in receiving health care [35]. In addition, poor mental health can have lasting consequences on the career trajectory of medical students and physicians, in addition to the impact on overall personal well-being [36]. As such, studies should continue to examine interventions, including the one examined in the current study, to mitigate worsening mental health in this population.

Lastly, many participants provided suggestions to improve and revise the programs to improve attendance and overall satisfaction with the program. Some of the stated barriers could be mitigated by program revisions, including fixing technical issues, sending reminder emails to complete assigned homework,

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and improving the mobile experience. However, there are other concerns that may be more difficult to address, including the vast majority in both formats citing time restraints and burnout as major barriers to attendance and participation [1-4]. These barriers can be viewed as inherent to the training and stressful nature of the work being performed by physicians and medical students [1-4,37]. As such, while online formats do improve accessibility to care, they do not completely mediate individual barriers to participation. Despite this, studies do indicate that mobile apps and virtual-based programs serve as a popular way to provide mental health resources for physicians and medical students [37]. These interventions may serve as a preliminary step for this cohort to seek further treatment or therapy, if needed [37]. Further research should continue to be conducted to understand other methods that might improve the integration of mental health interventions into the work or personal lives of physicians and medical learners, given that the cohort is at a high risk of burnout.

Limitations

While the results of this study show that these CBTm programs are feasible in this sample, there were also limitations that must be mentioned. For one, there were high rates of dropout from CBTm self-directed and low rates of evaluation completion in CBTm facilitator-led, in which most participants did not provide evaluative feedback on the program. These factors are important considerations that limit the interpretation and generalizability of the findings. In addition to this, the uptake for the CBTm facilitator-led group was limited to 15 participants. This may be viewed as a finding in itself, as assessing and reporting participant uptake was an aim of this study. Despite this, a greater sample size may be required to ensure the validity and reliability of the findings in this study. Moreover, this study was conducted in 1 province within Canada; therefore, results may not be generalizable nationwide or worldwide. This study was an observational study without randomization into the 2 intervention groups, which could be associated with selection bias. Given that participants were self-referred, the generalizability of findings may be limited due to sampling bias. However, self-referral is an important aspect of this study to (1) ensure adequate access to this brief mental health intervention for all participants who needed it, and (2) remain in alignment with feasibility studies, which aim to assess real-world participant uptake and adherence. Moreover, the sample characteristics showed limited representation from diverse groups in the population. For example, all participants in this study self-declared as either male or female, which leaves out the views of gender-diverse individuals in this population. As such, it would be important to expand this program into different provinces within Canada and improve recruitment to ensure the sample size is larger and the results are more generalizable.

Conclusions

Overall, the results of this study show promising indicators that virtual methods of CBTm delivery were feasible and acceptable among physicians and medical trainees in Manitoba. There was a good level of satisfaction with both methods of delivery of the program, with a preference for the self-directed CBTm format. Additional revisions may be needed in the future to improve the uptake and retention of participants. While the qualitative data indicated positive outcomes for mental health, further research must be done to determine the effectiveness of the program, compared to similar “low intensity” interventions, and using standardized mental health measures, both pre- and postintervention. In addition, further research should determine whether CBTm has long-term benefits for the improvement of mental health in this population.

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Data Availability

The data used in this paper is available on reasonable request.

Authors' Contributions

Conceptualization: SLB (equal), N Mota (equal), BG (supporting)
Data curation: BG (equal), EP (equal)
Formal analysis: BG (lead), EP (equal), N Muthumuni (supporting)
Funding acquisition: BG
Investigation: BG (lead), EP (equal)
Methodology: N Mota (lead), SLB (equal), EP (supporting)
Project administration: BG (lead), SLB (equal), N Mota (equal)
Resources: BG (equal), SLB (equal), N Mota (equal), JS (equal)
Supervision: N Mota (equal), SLB (equal)

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Validation: N Mota (equal), SLB (equal)
Visualization: BG (lead), EP (supporting)
Writing – original draft: BG (lead), EP (supporting), SLB (supporting), N Mota (supporting)
Writing – review & editing: BG (lead), EP (supporting), SLB (supporting), N Mota (supporting), JS (supporting), TS (supporting), N Muthumuni (supporting)

Conflicts of Interest

JS received an UpToDate consulting fee for contributing to a chapter on PTSD.

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Abbreviations

CBT: cognitive behavior therapy
CBTm: cognitive behaviour therapy with mindfulness
CSQ-8: Client Satisfaction Questionnaire 8
REDCap: Research Electronic Data Capture
SMART: Specific, Measurable, Attainable, Realistic, Timely
VMHQ-21: Virtual Mental Health Questionnaire 21

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Electronic Medical Record Attitudes and Predictors of Adoption Among Ethiopian Health Professionals: Cross-Sectional Study

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Abstract

Background: Electronic medical records (EMRs) are increasingly adopted globally to improve health care delivery, yet challenges remain in their acceptance, defined here as favorable attitudes toward their use among health professionals. Understanding factors influencing acceptance is critical for successful implementation.

Objective: This study aimed to identify predictors (or factors) associated with favorable attitudes toward EMRs among health professionals in 3 Ethiopian hospitals.

Methods: A cross-sectional study was conducted from January to March 2025 in 3 Ethiopian hospitals implementing EMRs. A systematic random sampling method was used to initially select 397 health professionals, and data were collected using a structured questionnaire. Multivariate logistic regression was employed to identify predictors of favorable attitudes toward EMRs.

Results: Of the final 382 professionals, 198 (51.8%, 95% CI 0.43-0.53) showed favorable attitudes. Predictors of positive attitude included computer literacy (adjusted odds ratio [AOR] 2.66, 95% CI 1.16-6.09; *P*=.02), EMR training (AOR 2.87, 95% CI 1.80-4.56; *P*<.001), and age of 29 years or younger (AOR 3.05, 95% CI 1.58-5.9; *P*=.001)

Conclusions: Improving computer literacy, providing refresher training, and strengthening management support are key strategies for enhancing health professionals' attitudes toward EMRs. Future research should explore qualitative insights into barriers and facilitators of EMR adoption.

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KEYWORDS

health professionals; electronic medical record; EMR; EMR implementation; attitude; Ethiopia; communication; patient care; patient health information; developing countries; electronic health record; EHR; predictors

Introduction

Electronic medical records (EMRs) represent a significant advancement beyond traditional paper-based records, offering enhanced coordination and communication among health care departments and professionals, ultimately improving the quality of patient care [1]. In contemporary health care settings, EMR systems function as central platforms for interprofessional communication and care facilitation, aligning with governmental mandates for secure collection, storage, and accessibility of patient health information [2,3].

Despite global optimism surrounding EMR systems, their adoption remains limited, especially in resource-constrained regions with high disease burdens [4]. Studies consistently

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highlight health professionals' negative attitudes as a primary barrier to EMR adoption in developing countries [5-8]. Challenges such as high acquisition and maintenance costs, lack of financial incentives, limited internet and electrical infrastructure, and insufficient computer skills hinder electronic health record (EHR) adoption [9,10].

Many hospitals in Ethiopia struggle to implement EHR systems for real-time clinical data entry despite efforts to introduce computerized patient health care information systems [11]. The Ethiopian Ministry of Health (MOH) has been working on the development and cascading of health information systems and digital health-related national documents, including the Information Revolution Roadmap II (2020 - 2029), the Information Revolution Strategic Plan (2018-2025), and the ICT (Information and Communication Technology) Policy and Digital Health Strategy (2020 - 2024) [11]. Although digitalizing the health care system is a key priority of the World Health Organization and the Ethiopian MOH, there are still many challenges to the implementation of EMR [1,4,12]. Lack of funding, capacity, infrastructure issues, legal considerations, resistance to computer technology, computer system literacy, privacy, and confidentiality were the most common barriers to the implementation of EMR in Ethiopia. However, a significant challenge lies in the resistance to change exhibited by many health care professionals. This resistance, often rooted in inadequate knowledge and negative attitudes toward EMR systems, hinders widespread adoption and requires further investigation [11].

Therefore, this study aimed to investigate the attitudes of health professionals in Ethiopia toward EMR implementation in 2023, along with factors influencing those attitudes. The findings may provide valuable insights for health care professionals, health institutions, policymakers, EMR software developers, researchers, and the broader community, and may inform strategies to enhance EMR adoption in Ethiopian hospitals.

Methods

Study Design, Setting, and Duration

A multicenter cross-sectional study was conducted to evaluate attitudes and associated factors related to EMR implementation among health professionals in EMR-equipped hospitals in Ethiopia. The study was conducted in 3 selected government hospitals actively using fully integrated EMR systems: Gizawu Hospital, located in Debre Berhan town, North Shoa, Amhara Region; Yekatit 12 Hospital Medical College; and Tirunesh Beijing General Hospital. Data were collected from April 1 to April 30, 2023.

Study Population, Sample Size, and Sampling Methodology

The study population included health professionals from the 3 hospitals. The total sample size was proportionally allocated to each hospital based on the number of health professionals. A systematic random sampling approach was used to select participants who met the inclusion criterion of work experience of more than 6 months. Individuals on maternity leave, annual leave, sick leave, and those providing voluntary services were excluded. The sample size was determined using the single population proportion formula, accounting for a 5% nonresponse rate [13]. The initial sample size was 397 health professionals.

Study participants were selected using systematic random sampling within each profession. A detailed explanation of the sampling interval calculation, randomization process, and statistical justification is provided in Multimedia Appendix 1.

Data Collection Instrument and Quality Assurance

A pretested, structured, and self-administered questionnaire was used. The questionnaire was developed based on standard templates derived from a review of published articles [14-18]. Seven data collectors (5 GPs, 2 MPH graduates) and 2 trained GP supervisors monitored the data collection process. A comprehensive pilot study was conducted to ensure instrument validity and reliability. This included content validation by health informatics specialists (CVI=0.81), test-retest reliability (ICC=0.82), and cognitive interviews to refine question phrasing. Full details of the instrument validation, pilot testing, and comparative validation data are available in Table S1 in Multimedia Appendix 1.

Ethical Considerations

Ethical approval was obtained from the Ethical Clearance Review Board of the Asrat Woldeyes Health Science Campus, Debre Berhan University (protocol number IRB 01/125/2015), in accordance with the Helsinki Declaration guidelines and regulations. Permission was obtained from the participating hospitals. Written informed consent was obtained from all participants. The authors have maintained the privacy and confidentiality of research subjects' data and/or identity. The participants of this study were not compensated.

Data Processing and Analysis

The collected data were entered into EpiData (version 4.6) and exported to SPSS (version 25.0) for analysis. A chi-square test was initially performed, followed by bivariable analysis. Variables with $P<.25$ in the bivariable analysis were included in the multivariable analysis. Adjusted Odds Ratios (AORs) with 95% CI were used to assess associations. Model fitness was evaluated using the Hosmer-Lemeshow test ($P=.80$).

Dependent and Independent Variables

The dependent variable was attitude toward EMR.

The independent variables were age, computer literacy, knowledge of EMR systems, refresher training on EMR, EMR functionality interruptions, adequate computer access, management support for EMR use, and presence of an ICT center.

Operational Definition of Terms

The following terms and definitions were used in this study:

- Level of knowledge: Categorized as "Good knowledge" (at or above the mean score) or "Poor knowledge" (below the mean score) based on 12 yes/no questions.
- Attitude: Categorized as "Favorable attitude" (at or above the median score) or "Unfavorable attitude" (below the median score) based on 18 questions.

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- Computer literacy*:* Defined as capable of using basic Microsoft Office applications and Internet services.
- EMR training: Refers to refresher training provided to health professionals for at least 1 day twice per year.
- Management support: Indicated by the presence of an EMR committee that conducts regular monitoring and evaluation and takes immediate action whenever problems arise.
- Electric power interruption**:** Defined as experiencing at least one electric power interruption per day.

Results

Sociodemographic Characteristics of Study Participants

The study population consisted of health professionals from 3 hospitals, with the total sample size proportionally allocated to each hospital based on the number of health professionals (Table 1). A total of 382 health professionals participated in the study, with a response rate of 96.2%. Nonrespondent profiling was assessed by comparing the demographics of 39 nonrespondents with the sample frame using HER data. No significant differences were found in gender (*P*=.32), profession (*P*=.47), or EMR frequency (*P*=.19). To address concerns about causal inference in this cross-sectional study of EMR implementation attitudes, we implemented a multilayered methodological approach that combines design-based safeguards, advanced statistical techniques, and theoretical triangulation. These included EMR implementation timelines aligned with exposure measurement and hospital-specific rollout periods (6 - 18 mo before the survey) using health ministry deployment records. We also captured technology adoption histories through work experience items (eg, “years using digital health tools”) to verify exposure duration.

Table . Participating hospitals, study population, and sample size.

Name of hospital	Staff, n	Participants, n (%)
Yekatit 12 Hospital Medical College	1265	221 (56)
Tirunesh Beijing Hospital	611	108 (27)
Debre Berhan University, Hakim Gizaw Hospital	380	68 (17)
Total	2256	397 (100)

The majority of respondents were male (n=236, 61.8%). The mean age was 30.04 (SD 4.43) years. Nearly two-thirds of the participants (n=246, 64.4%) had less than 6 years of work experience, and 69.6% (n=266) held a Bachelor of Science degree. A high proportion of study participants (n=339, 88.7%) demonstrated computer literacy, as measured by self-reported proficiency and task completion rates, and 26.6% (n=113) reported previous experience working in private hospitals (Table 2).

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Table . Sociodemographic characteristics of the study participants in electronic medical record (EMR)–implementing hospitals, Ethiopia, 2023 (N=382).

Category	Participants, n (%)
Sex	
Male	236 (61.8)
Female	146 (38.2)
Marital status	
Single	207 (54.2)
Married	175 (45.8)
Type of professional	
Nurse/midwife	144 (37.7)
Pharmacy	36 (9.4)
Laboratory	30 (7.9)
General practitioner	67 (17.5)
Advanced practitioners	44 (11.5)
Radiology	15 (3.9)
Anesthesia	32 (8.4)
Others	14 (3.7)
Work experience	
<6 years	246 (64.4)
≥6 years	136 (35.6)
Educational status	
Diploma	9 (2.4)
BSc	266 (69.6)
MPH/MSc	63 (16.5)
Advanced practitioners	44 (11.5)
Computer literacy	
Yes	339 (88.7)
No	43 (11.3)
Part-time employment in private sector	
Yes	113 (29.6)
No	269 (70.4)

Knowledge Toward EMR

Among study participants, 251/382 (65.7%) demonstrated good knowledge of EMR (Table 3, Multimedia Appendix 2). A segmented bar chart showing health professionals' knowledge of EMR system capabilities with 95% CIs (N=382) is shown in Figure 1. Notably, most respondents were aware of the diverse functions of EMR, including handling patient data, reviewing patient problems, obtaining test results, enabling private ward access, facilitating local network operations, and updating patient information. Furthermore, approximately three-quarters of participants were knowledgeable about EMR functionalities, including laboratory order requests, prescription capabilities, and disease codes, as well as data backup systems (Table 3).

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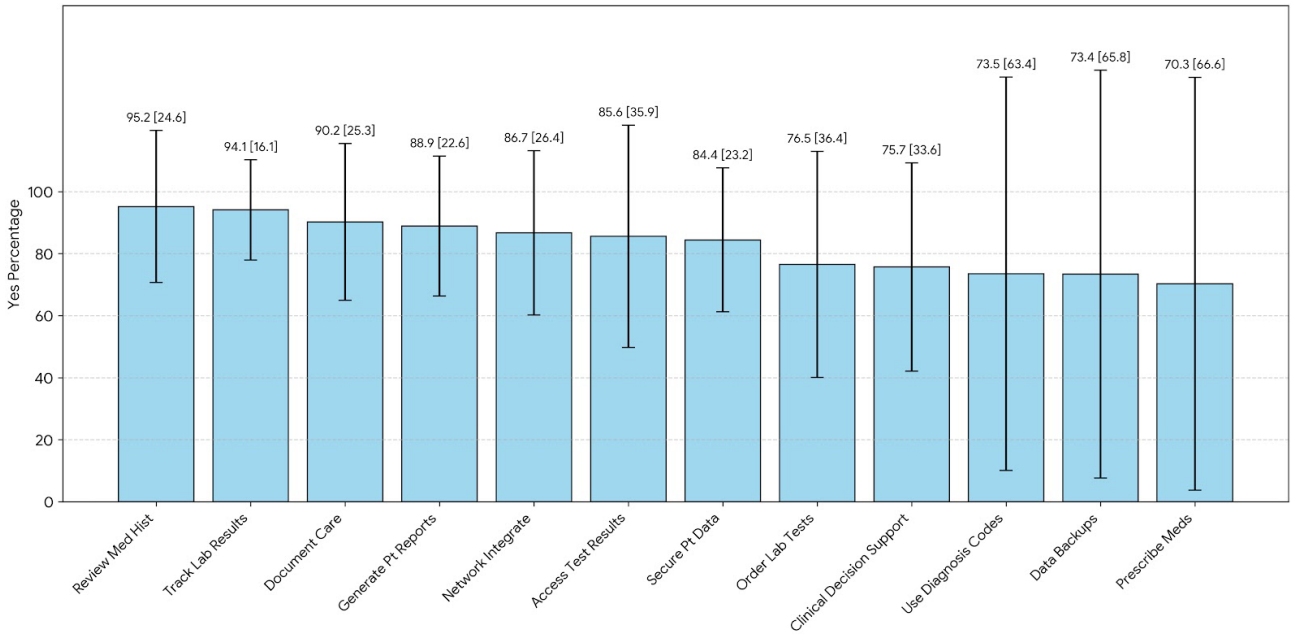
Table . Health professionals' knowledge of electronic medical records (EMRs) in EMR-implementing hospitals in Ethiopia, 2023 (N=382).

EMR system capability	Yes, n (%)	No, n (%)
Review patient medical history	364 (95.3)	18 (4.7)
Track patient laboratory results	359 (94)	23 (6)
Document patient care	343 (89.8)	39 (10.2)
Order laboratory tests	292 (76.4)	90 (23.6)
Generate patient reports	339 (88.7)	43 (11.3)
Prescribe medications	268 (70.2)	114 (29.8)
Utilize diagnosis codes	280 (73.3)	102 (26.7)
Access patient test results	327 (85.6)	55 (14.4)
Maintain data backups	280 (73.3)	102 (26.7)
Secure patient data	322 (84.3)	60 (15.7)
Integrate with local network	330 (86.4)	52 (13.6)
Support clinical decision-making	289 (75.7)	93 (24.3)

Figure 1. Knowledge of respondents about electronic medical records. The overall proportion of health professionals demonstrating good versus poor knowledge of electronic medical record (EMR) systems among participants in EMR-implementing hospitals in Ethiopia (2023; Table 3). The overall self-reported knowledge of EMR systems, showing that 66% of respondents reported "good knowledge" and 34% reported "Poor knowledge." Segmented bar chart showing percentage of respondents (in decreasing order of "yes" responses) who reported knowledge of specific EMR parameters, such as "review med hist" and "track lab res."



Attitude Toward EMR

Among the 382 study participants, only 184 (48.2%) demonstrated a favorable attitude towards the implementation of EMR (Multimedia Appendix 3). Please note that Multimedia Appendix 3 intentionally simplifies the data for visualization purposes only. Attitude responses on a 5-point Likert scale were grouped into 3 categories: positive (scores 4 - 5), neutral (score 3), and negative (scores 1 - 2). Of the 382 respondents, 210 (55%) expressed a positive attitude toward EMRs, 62 (16.2%) had a neutral attitude, and 110 (28.8%) reported a negative attitude. These distributions are detailed in Table 4 and represented in Figure 2. Percentages are accompanied by their absolute values (N=382). Study participants expressed strong agreement on several benefits of EMR, including cost-saving potential (n=117, 30.6%), ease of data entry (n=99, 25.9%), facilitation of timely decisions (n=93, 24.3%), acknowledgment of the need for training (n=166, 43.5%), reduction of medical errors (n=100, 26.2%), enhancement of productivity (n=106, 27.7%), and suitability for audit trials (n=110, 28.8%). Additionally, 156 (40.8%) strongly agreed, and 151 (39.5%) agreed that other hospitals should implement EMR (Table 4). Distribution of health professionals' overall attitudes toward EMR use across three Likert scale categories: positive (4-5), neutral (3), and negative (1-2) as represented in Figure 3. Error bars represent 95% CIs for proportions (N=382). This 3-category structure reflects respondents' sentiments and attitudes shown in Table 4.

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Table . Attitudes of health professionals toward use of electronic medical records (EMRs) in EMR-implementing hospitals, Ethiopia, 2023 (N=382).

Perceived EMR benefit	Strongly disagree, n (%)	Disagree, n (%)	Neutral, n (%)	Agree, n (%)	Strongly agree, n (%)
Easy to enter data	23 (6)	28 (7.3)	47 (12.3)	185 (48.4)	99 (25.9)
Saves cost	16 (4.2)	19 (5)	46 (12)	184 (48.2)	117 (30.6)
Saves time	21 (5.5)	46 (12)	42 (11)	161 (42.1)	112 (29.3)
Improves patient satisfaction	20 (5.2)	41 (10.7)	89 (23.3)	152 (39.8)	80 (20.9)
Improves timeliness of clinical decisions	16 (4.2)	35 (9.2)	70 (18.3)	168 (44)	93 (24.3)
Provides easy access to patient information	15 (3.9)	20 (5.2)	39 (10.2)	191 (50)	117 (30.6)
Requires training	21 (5.5)	19 (5)	33 (8.6)	143 (37.4)	166 (43.5)
Reduces the risk of medical errors	18 (4.7)	32 (8.4)	89 (23.3)	143 (37.4)	100 (26.2)
Benefits the health care facility	14 (3.7)	18 (4.7)	38 (9.9)	186 (48.7)	126 (33)
Eliminates need for physical storage	19 (5)	25 (6.5)	69 (18.1)	155 (40.6)	114 (29.8)
Increases productivity	17 (4.5)	23 (6)	66 (17.3)	170 (44.5)	106 (27.7)
Reduces workload	23 (6)	60 (15.7)	62 (16.2)	151 (39.5)	86 (22.5)
Ensures data security	20 (5.2)	22 (5.8)	47 (12.3)	190 (49.7)	103 (27)
Maintains data backup	25 (6.5)	47 (12.3)	72 (18.8)	154 (40.3)	84 (22)
Offers a consistent user interface	17 (4.5)	31 (8.1)	86 (22.5)	160 (41.9)	88 (23)
Enhances audit trail functionality	11 (2.9)	26 (6.8)	55 (14.4)	180 (47.1)	110 (28.8)
Encourages other hospitals to use EMR	14 (3.7)	20 (5.2)	41 (10.7)	151 (39.5)	156 (40.8)

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Figure 2. Attitude of respondents toward electronic medical records (EMRs). The distribution of health professionals' attitudes toward EMR system capabilities. (A) The attitudes of health professionals toward EMR systems showed that 51.8% of professionals had an "Unfavorable" attitude (orange) and 48.2% had a "Favorable" attitude (blue). (B) Stacked bar chart illustrating agreement levels (ranging from "strongly agree" to "strongly disagree") across 17 perceived benefit dimensions of EMR adoption among health professionals (Table 4). UI: user interface.

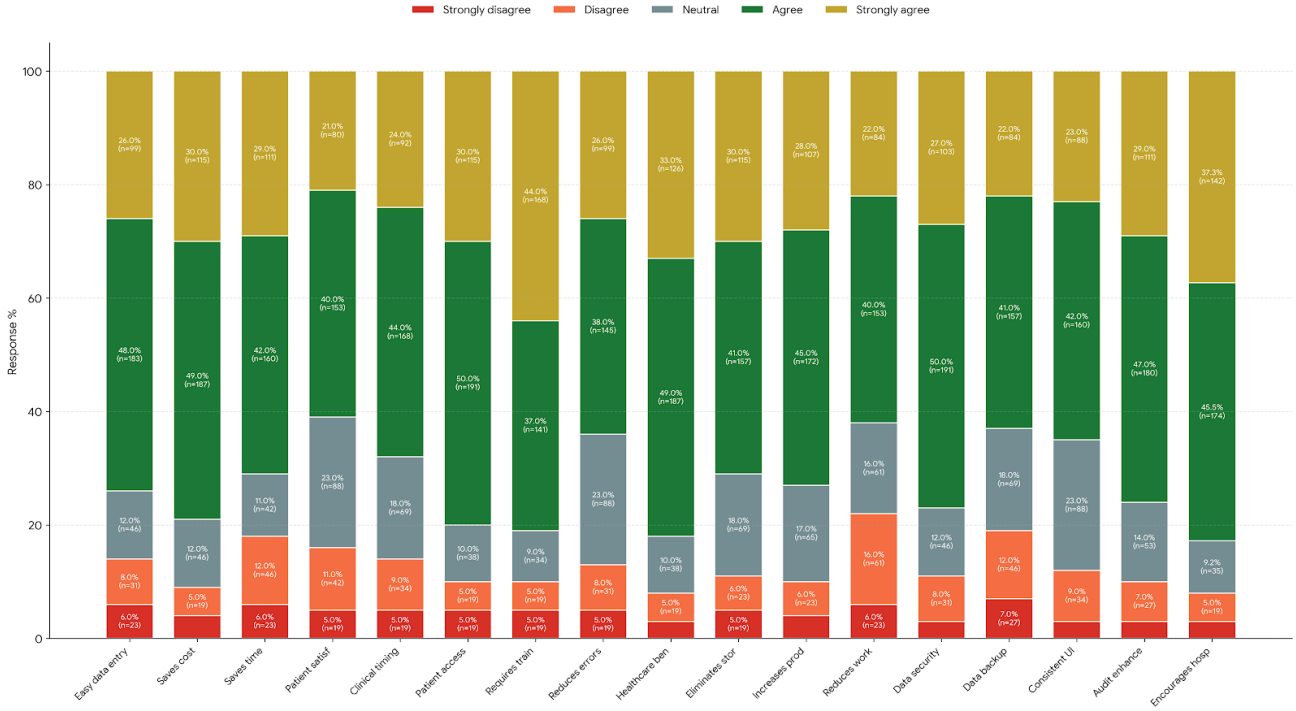

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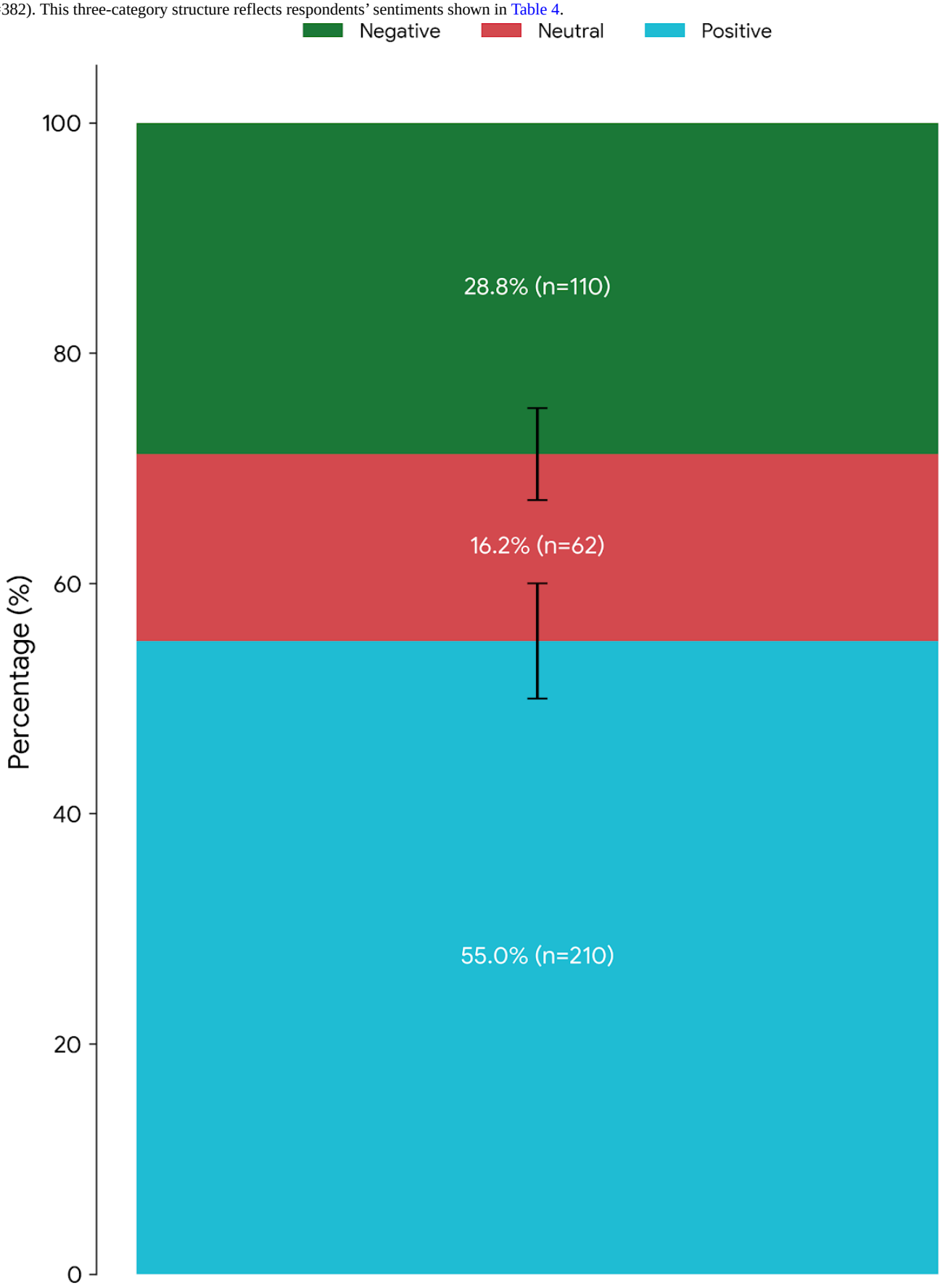
Figure 3. Overall attitudes toward electronic medical records (EMRs) implementation. Distribution of health professionals' attitudes toward EMR use and implementation across three Likert scale categories: positive (4–5), neutral (3), and negative (1–2). Error bars represent 95% CIs for proportions (n=382). This three-category structure reflects respondents' sentiments shown in Table 4.



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A subgroup analysis regarding patterns of EMR attitudes by age group, profession, and facility type is visualized for all 17 benefit dimensions in Multimedia Appendix 4. We assessed multicollinearity using variance inflation factors (VIF), with all values ranging from 1.1 to 4.7, below the threshold of 5. Moderate correlations (eg, between years of EMR experience and technology self-efficacy) were addressed by combining variables into composites or residualizing overlapping predictors. Robustness checks, including principal component regression and elastic net regularization, confirmed the stability of the results.

Technology and Organizational Readiness

Most respondents reported the fulfillment of certain organizational factors: 73% mentioned the assignment of an EMR focal person and duty person; 77.7% believed that management supports EMR implementation; and 86.4% witnessed the presence of an ICT (Information and Communication Technology) center. However, less than half of respondents received refreshment training on EMR (48.2%); only 38% perceived adequate computer access for EMR, and 39.8% responded that they had regular meetings (Table 5). A clustered bar chart (Figure 4) displays the percentage of health professionals in Ethiopian hospitals who reported technology and organizational readiness for EMR implementation across ten key factors in 2023. For each factor, the proportions of respondents answering "Yes" (indicating presence or support) and "No" (indicating absence or lack of support) are shown side by side. The chart visually highlights areas of strength, such as ICT center availability and management support, as well as gaps, including regular meetings on EMR and refresher training.

Table . Technology and organizational readiness of health professionals in electronic medical records–implementing Ethiopian hospitals, 2023 (N=382).

Variable	Yes, n (%)	No, n (%)
EMR[a] refresher training	184 (48.2)	198 (51.8)
Experienced interruption in EMR functionality	287 (75.1)	95 (24.9)
Adequate computer access	145 (38)	237 (62)
Assigned EMR focal person	279 (73)	103 (27)
Management support for EMR	297 (77.7)	85 (22.3)
Presence of EMR manual	187 (49)	195 (51)
Hospital has standby generator	269 (70.4)	113 (29.6)
Regular meeting on EMR	152 (39.8)	230 (60.2)
Hospital has ICT[b] center	330 (86.4)	52 (13.6)

[a]EMR: electronic medical record.

[b]ICT: information and communication technology.

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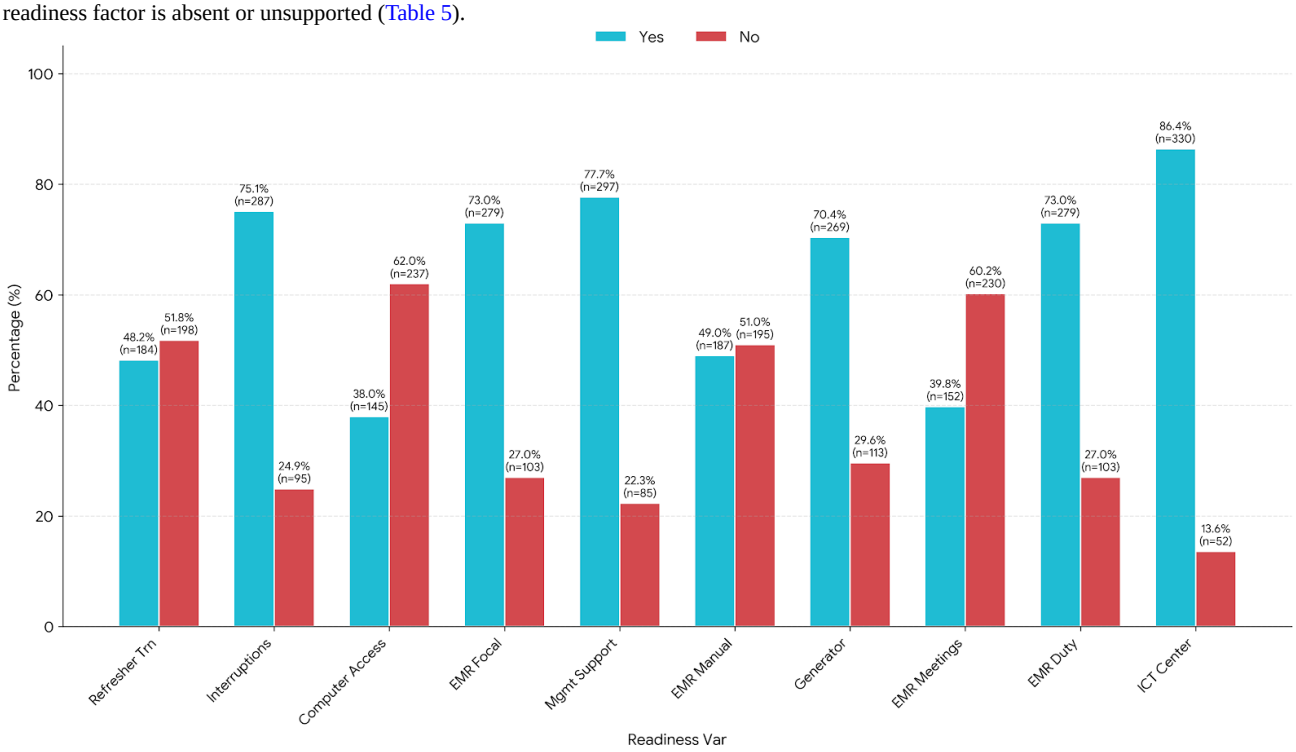
Figure 4. Technological readiness in Ethiopian hospitals. Percentage of "yes" responses (n=382) for technological and organizational readiness in Ethiopian hospitals in 2023. The figure shows the visual comparison of readiness levels across the ten key factors in the dataset. Two bars are displayed for every factor. Yes (%): Percentage of respondents indicating the readiness factor is present or supported; No (%): Percentage of respondents indicating the readiness factor is absent or unsupported (Table 5).



Advantages of EMR Systems

The study revealed a strong preference for EMR over paper-based systems among participants. A significant majority (320/382, 83.8%) reported finding EMR systems advantageous over disadvantageous for several reasons (Figure 5). Note that participants could select more than one option.

These advantages included:

- Time savings (19.2%)
- Increased data storage capacity (23.1%)
- Easier access to patient information (22.3%)
- Simplified report writing (14.2%)
- Enhanced data security (21.2%)

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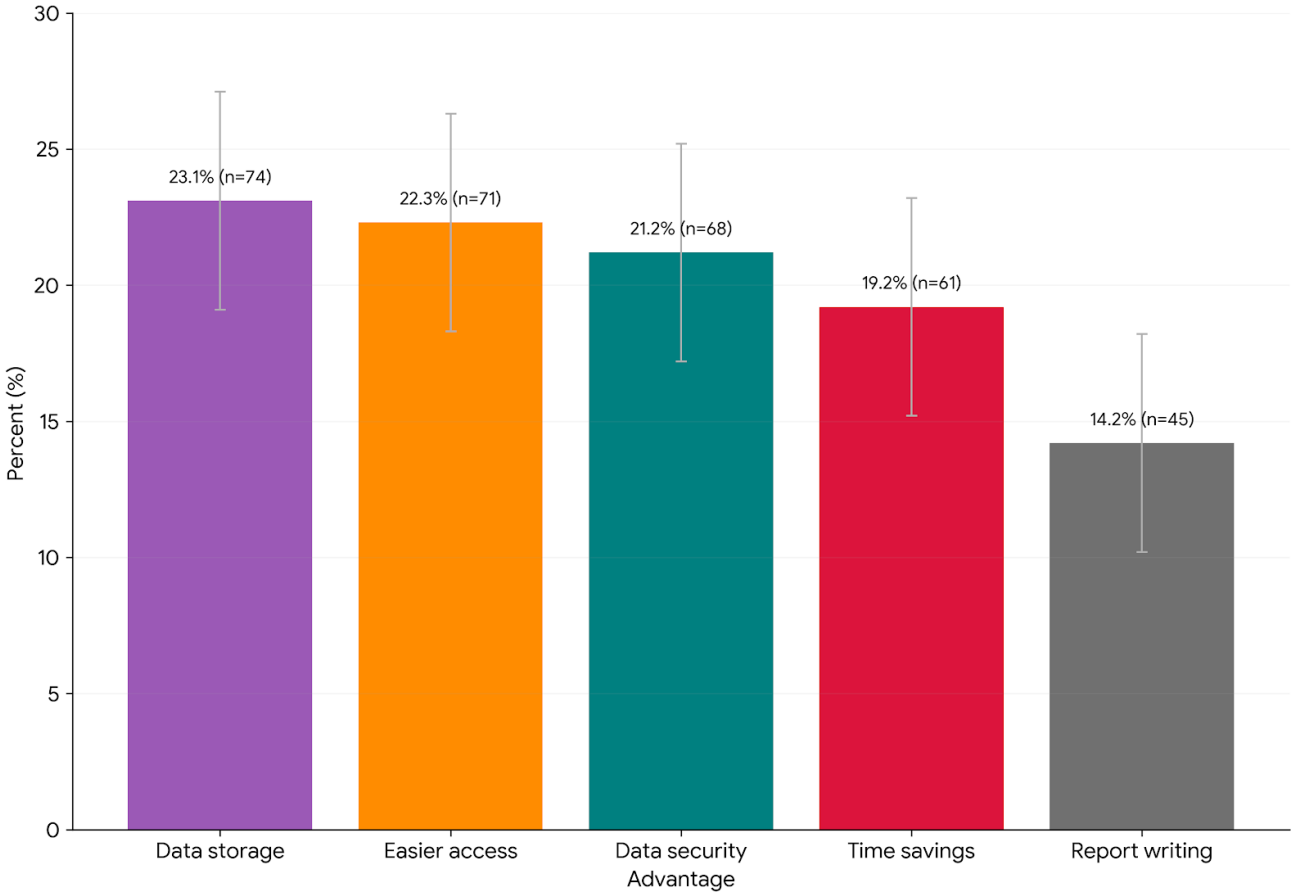
Figure 5. Advantages of electronic medical records (EMRs) systems over paper records. Bar chart of health professionals reported advantages of EMR systems versus paper-based records (n=320). Participants identified time savings, increased storage, easier access to information, simplified report writing, and stronger data security as benefits. Error bars denote 95% CIs for each proportion (Table 4).



Barriers to EMR Adoption

Although most participants favored EMR, some reported challenges. Figure 6 highlights the reasons why a minority of participants expressed reservations about EMR use. The main concerns were the time required for data entry (mentioned as a reason by some who did not prefer EMR). Again, participants can select more than one option.

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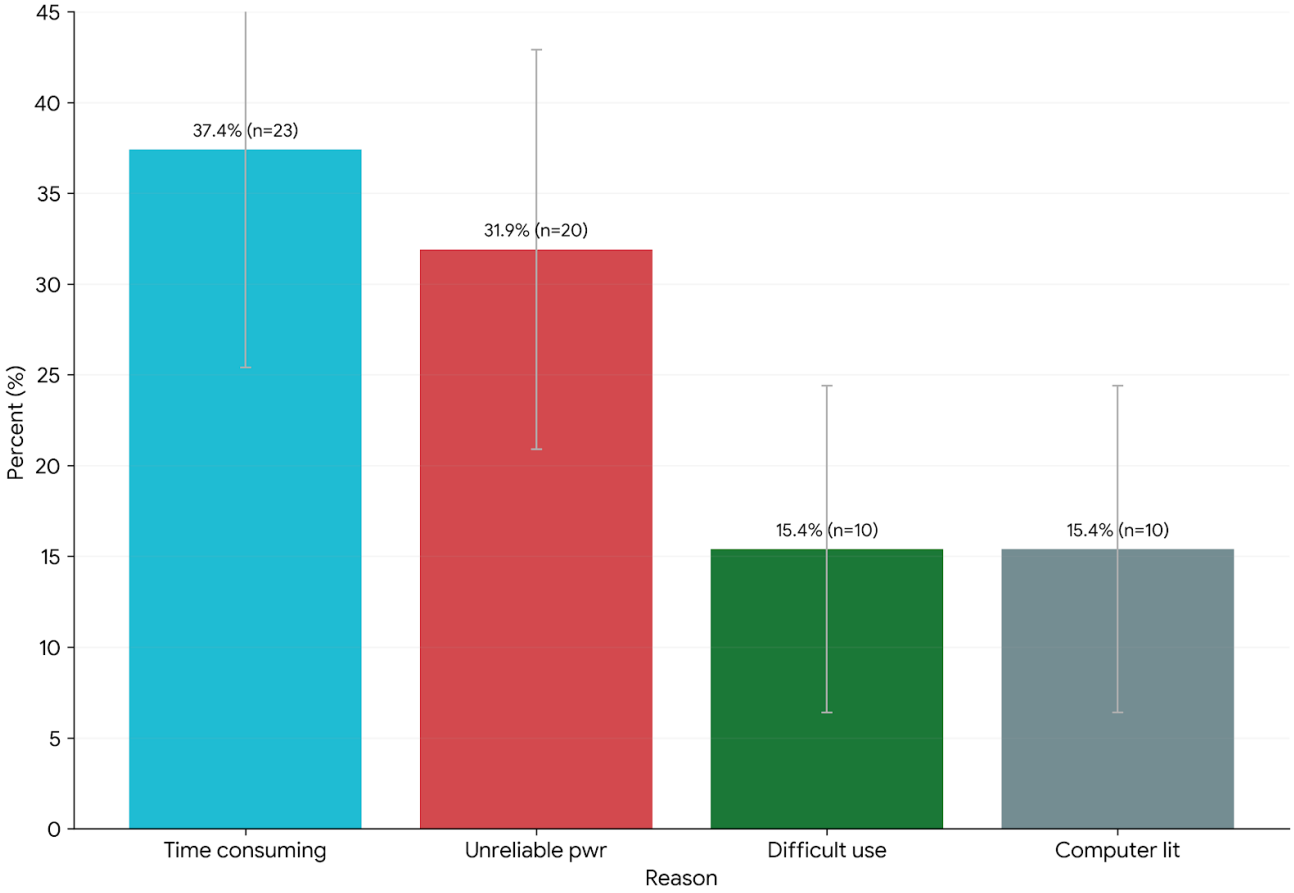
Figure 6. Barriers to adoption of electronic medical records (EMRs). Bar chart of health professionals' reasons for not preferring EMR systems (n=62) showing percent for each barrier (eg, time, power, usability, computer literacy). Respondents most frequently cited workflow burden, power outage concerns, usability challenges, and limited computer literacy. Error bars denote 95% CIs for each proportion (n=382). Computer lit: computer literacy; Pwr: power grid.



Factors Associated With Health Professionals' Attitudes Toward EMR Systems

All independent variables underwent initial computation using the chi-square test, and variables with a *P* value ≤.05 were selected for bivariate analysis. Among these, variables with a *P* value of ≤.25 were considered for multivariate analysis. Following adjustment for other variables, the multivariable logistic regression analysis revealed that respondents aged ≤29 years were three times more likely to exhibit positive attitudes towards EMR implementation compared to those aged ≥35 years (AOR –3.05; 95% CI −1.58 to 5.9; *P*=.001). Furthermore, individuals who received EMR training were 2.8 times more inclined to have a favorable attitude towards EMR implementation than those without training (AOR −2.87, 95% CI 1.80 - 4.56; *P*<.001). Negative signs before AOR values indicate inverse associations (eg, prior poor EMR experience reduces favorability).

The study administered EMR training with role-specific standardization (eg, physicians vs. nurses) but allowed site adaptations for workflow variations. While core curricula were maintained across sites using learning management systems, content delivery mixed future iterations, e-learning, and blended approaches based on staff roles and complexity levels. Health professionals with computer literacy displayed a 2.7 times higher likelihood of holding positive attitudes towards EMR implementation compared to those without computer skills (AOR 2.66; 95% CI 1.16 - 6.09), while those with good knowledge of EMR were 1.8 times more likely to have a favorable attitude towards EMR than those with poor knowledge (AOR 1.8; 95% CI 1.10 - 2.96) (Table 6).

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Table . Factors associated with health professionals' attitudes toward electronic medical record (EMR) at three EMR-implementing Ethiopian hospitals, 2023 (N=382).

Variable	Attitude toward EMR, n		COR[a] (95% CI)	AOR[b] (95% CI)	*P* value
	Positive	Negative			
Age (years)					
≤29	73	107	2.37 (1.34-4.20)	3.05 (1.58-5.9)	.001
30-34	69	65	1.52 (0.84-2.76)	1.79 (0.92-3.48)	.09
≥35	42	26	1	1	>.99
Computer literacy					
Yes	174	165	3.48 (1.66-7.29)	2.66 (1.16-6.09)	.02
No	10	33	1	1	>.99
Working in private sector					
Yes	66	47	1.80 (1.15-2.80)	1 (0.60-1.69)	.99
No	118	151	1	1	>.99
Knowledge of EMR systems					
Poor	47	84	1	1	>.99
Good	137	114	2.15 (1.39-3.32)	1.80 (1.10-2.96)	.02
Refreshment training on EMR					
Yes	116	68	3.26 (2.15-4.96)	2.87 (1.80-4.56)	<.001
No	68	130	1	1	>.99
EMR functionality interruptions					
Yes	148	139	1.75 (1.09-2.80)	1.43 (0.84-2.46)	.19
No	36	59	1	1	>.99
Adequate computer access					
Yes	82	63	1.72 (1.14-2.61)	0.91 (0.55-1.49)	.70
No	102	135	1	1	>.99
Management support for EMR use					
Yes	157	140	2.41 (1.45-4.01)	1.47 (0.81-2.64)	.20
No	27	58	1	1	>.99
Presence of ICT[c] center					
Yes	166	164	1.91 (1.04-3.52)	1.26 (0.64-2.49)	.50
No	18	34	1	1	>.99

[a]COR: crude odds ratio.

[b]AOR: adjusted odds ratio.

[c]ICT: information communication technology.

The forest plot from the regression analysis (Table 6), showing AORs and CIs for attitude predictors, is represented in Figure 7. The forest plot presents the adjusted odds ratios (AORs) and 95% confidence intervals for predictors of positive attitudes toward electronic medical record (EMR) use among health professionals in EMR-implementing Ethiopian hospitals (N=382). Significant predictors identified in the analysis include younger age (≤29 years), computer literacy, participation in refresher training, and good EMR knowledge (P<.05) (Figure 7).

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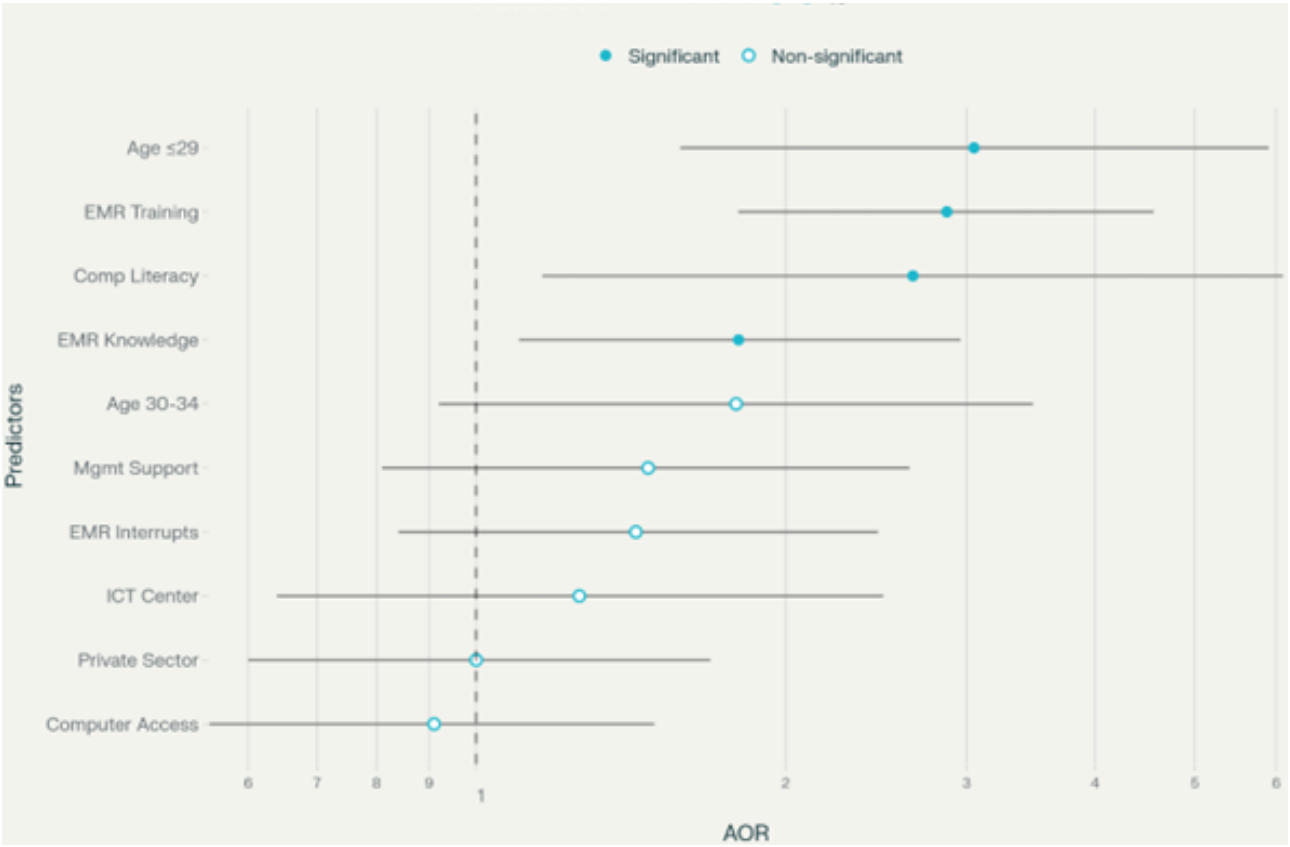
Figure 7. Predictors of positive attitudes toward electronic medical records (EMRs). Forest plot illustrating adjusted odds ratios (AORs) and 95% confidence intervals for predictors of positive attitudes toward EMR use among health professionals in EMR-implementing Ethiopian hospitals (N=382). Each horizontal line represents the 95% CI for an AOR. Variables with AOR values greater than 1 indicate a higher likelihood of a positive attitude toward EMR use. Significant predictors included younger age (≤29 y), computer literacy, refresher training, and good EMR knowledge (P<.05). ICT: information and communication technology; Mgmt: management.



Discussion

Principal Findings

EMRs represent a significant advancement beyond traditional paper-based records, offering enhanced coordination and communication among health care departments and professionals, ultimately improving the quality of patient care [1,19]. This study found that just over half (51.8%) of health professionals in the surveyed Ethiopian hospitals reported a favorable attitude toward electronic medical records (EMRs). This rate, while indicating partial acceptance, is significantly lower than that observed in high-income nations like the United States (97%) and other developing countries such as Saudi Arabia (70%) and South Africa (67.2%) [10,17,20]. This disparity likely reflects differences in resource availability, baseline technology access, and national digital health infrastructure.

Our finding is also lower than some previous studies within Ethiopia, with reported favorability rates between 50.6% and 72.8% [16,19,21,22]. This variation may stem from our study's focus on facilities with full EMR implementation, where staff experience the complete benefits and burdens, unlike settings with partial implementation or where staff are only anticipating a future system.

Interpretation of Key Predictors

The primary predictors of a positive attitude were computer literacy (AOR 2.66), EMR training (AOR 2.87), and younger age (AOR 3.05). This finding is crucial, as it underscores that EMR acceptance is not passive; it must be actively cultivated through foundational training and skills development.

The strong influence of training and literacy suggests that in the Ethiopian context, fundamental barriers such as the skills to use the system remain the primary challenge. This contrasts with research in contexts like Canada, where factors like collaborative care and financial incentives are more prominent once baseline literacy is assumed [23]. The finding that younger clinicians ("digital natives") are more receptive aligns with prior adoption models [16,22,24]. This highlights an urgent need for established, experienced professionals who may be less familiar with digital systems but whose buy-in is critical for successful implementation.

Interestingly, factors like management support, computer access, and the presence of ICT centers were not significantly associated with attitudes in our model. This finding contrasts with other studies in the Amhara region and Dire Dawa [5,21,22]. This discrepancy may suggest that while access to hardware is a prerequisite, it is not sufficient to foster positive attitudes. Rather, the skills and training to use that hardware effectively are what drive professional acceptance [16,23].

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Policy and Management Implications for Ethiopia's Digital Strategy

Our findings generate specific, actionable recommendations for Ethiopia's digital health strategy.

1. Mandate Standardized Training: The strong link between training and attitude (AOR 2.87) suggests that ad-hoc training is insufficient. We recommend a national, role-specific blended training program that combines e-learning with hands-on simulations and is reinforced by annual competency checks.
2. Invest in Foundational Skills: Computer literacy was an even stronger predictor than EMR training. This implies that EMR training will fail if staff lack basic computer skills. We recommend that hospitals form partnerships with local institutions to provide foundational computer skills workshops for all staff.
3. Develop Peer-Coach Programs: To support older or more resistant professionals, we recommend establishing peer-coach certification programs. Training "clinician informaticists" to provide on-site, department-specific mentoring can effectively address resistance and improve adoption.
4. Integrate EMR Competency: To ensure long-term proficiency and signal a systemic commitment, EMR competency requirements could be integrated into national licensure renewal processes.

Limitations and Future Research

This study has several limitations. The sample was drawn from urban hospitals, which may limit generalizability to rural settings with different infrastructure. Furthermore, the cross-sectional design is a snapshot in time and cannot establish cause-and-effect relationships; professionals with a positive attitude may be more likely to seek out EMR training, rather than the other way around.

To address these limitations, future research should employ qualitative methodologies. Longitudinal ethnography could track EMR adoption over time to identify evolving attitudes. We also recommend Participatory Action Research (PAR) to co-design training protocols with frontline staff, which can foster stakeholder buy-in. Finally, narrative inquiry—collecting stories from both "resistors" and "early adopters"—could reveal deeper, more nuanced experiential perceptions of EMR utility that our survey may have missed.

Conclusions

In this study, nearly half of the respondents had low attitudes towards the implementation of EMR. Variables related to socio-demographic (health professionals' age), personal (health professionals' knowledge of EMR), technology-related (health professionals' computer literacy), and organization-related (health professionals' EMR training) factors were significantly associated with health professionals' attitudes towards the EMR system.

Recommendations

Based on the findings of this study, it is important to focus on the gaps identified to implement EMR systems efficiently and effectively in all Ethiopian hospitals. Enhancing health professionals' attitudes and contextualizing EMR training in the health care system are highly recommended for scaling up EMR use. For future researchers interested in EMR-related research in Ethiopia**,** employing mixed methods (quantitative and qualitative) could be highly beneficial.

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Data Availability

The datasets used and/or analyzed during the current study are available from the corresponding author upon reasonable request.

Authors' Contributions

MAA contributed to the conception, design, data collection, analysis, and writing. ZAS analyzed the data, substantially edited all the figures, and rewrote the final manuscript. All other authors (AEA, TMD, BMU, MAY, GDL, AAK, ABM, DAA, ZAG, HMA, and AKF) made substantial contributions to the conception and design as well as revising of the manuscript. All authors read and approved the final manuscript and its submission for publication.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Methodological details.
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Multimedia Appendix 2
Knowledge of respondents.
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Multimedia Appendix 3
Attitudes toward electronic medical record use.
[PNG File, 690 KB - formative_v10i1e63135_app3.png]

Multimedia Appendix 4
Distribution of electronic medical record attitudes by demographic and professional subgroups.
[JPG File, 39 KB - formative_v10i1e63135_app4.jpg]

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Abbreviations

AOR: adjusted odds ratio
COR: crude odds ratio
EHR: electronic health record
EMR: electronic medical record
HIS: health information system
HMIS: health management information system
ICC: intraclass correlation coefficient
ICT: information and communication technology
MOH: Ministry of Health
SRS: systematic random sampling

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Feasibility and Engagement of a Peer-Driven Mobile Intervention for Adolescent E-Cigarette Cessation: Cluster Randomized Pilot Study

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Abstract

Background: E-cigarette use remains prevalent among US adolescents, with many reporting daily use and high nicotine dependence. Few evidence-based mobile health interventions focus specifically on adolescents.

Objective: This study aimed to evaluate the feasibility, engagement, and preliminary efficacy of vaper-to-vaper (V2V)—a multicomponent, peer-driven texting intervention supporting adolescent e-cigarette cessation.

Methods: A cluster randomized pilot study was conducted in 5 Massachusetts high schools, with schools randomized to either the V2V texting intervention (n=3) or a control group (n=2) that received a link to the National Cancer Institute's Smokefree.gov Quit Vaping website. The V2V intervention included four components: (1) peer-written messages provided motivation, tips, and strategies to support adolescents in quitting vaping, sent daily in the first 30 days; (2) peer videos featuring adolescents sharing their experiences with e-cigarettes and motivations to quit, sent regularly as links aligned with related peer message topics; (3) peer coaches—university students aged younger than 22 years who had successfully quit vaping—trained to provide support, encouragement and answers to participants' questions through the texting platform; and (4) a fictional, gamified mystery story integrated into the texting platform to promote engagement. Each gamified message included a short story segment and a question, with the next segment unlocked after a response or automatically after 3 days. The intervention was mainly delivered over 30 days, but adolescents could message the peer coach over the 3 months. Eligible participants (grades 9 - 12, current e-cigarette users) were followed for 3 months. We assessed the feasibility of recruitment and retention (target: 80 participants, ≥85% retention), engagement with intervention components, and participant satisfaction. The secondary outcomes included improvements from baseline in confidence to quit, self-efficacy to resist vaping in specific high-risk situations, and fewer days vaped. E-cigarette cessation was biochemically verified using the Abbott iScreen cotinine test.

Results: Seventy-one adolescents enrolled (intervention: 39/71, 55% ; control: 32/71, 45%), with a 96% follow-up rate at 3 months. Among intervention participants who responded to engagement items (N=37), high engagement—defined as self-reported use always, usually, or about half the time—was highest for peer messaging (n=29, 78%), followed by gamification (n=18, 49%), peer coaching (n=18, 49%), and peer video (n=13, 35%). The intervention group showed nonsignificant improvements in confidence to quit (n=17, 46%, vs n=9, 24%, moved from not at all, somewhat, or moderately confident to very or extremely confident) and in the number of days vaped in the past 30 days (−3.6 vs −2.9), while self-efficacy scores (adapted smoking self-efficacy scale range 12 - 60) were slightly lower compared to the control group (mean −0.21, SD 1.14, vs mean 0.06, SD 1.39). Cotinine-validated 7-day point prevalence abstinence was similar between groups (intervention: 21.6% vs control: 22.6%).

Conclusions: The V2V intervention demonstrated feasibility and acceptability, with strong engagement and high satisfaction. Although differences between groups were not statistically significant, findings suggest that peer-driven mobile interventions are a promising approach to support adolescent e-cigarette cessation.

Trial Registration: ClinicalTrials.gov NCT05140915 https://clinicaltrials.gov/study/NCT05140915

(JMIR Form Res 2026;10:e79667) doi:10.2196/79667

KEYWORDS

e-cigarettes; vaping; adolescents; cessation strategies; mHealth; mobile health

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Introduction

On the basis of the 2024 National Youth Tobacco Survey, an estimated 2.25 million adolescents reported using e-cigarettes (also known as vapes) [1]. While these numbers indicate a decline from 2.8 million in 2023, e-cigarettes remain the most commonly used tobacco product among adolescents [1,2]. A significant portion of adolescents who continue to use e-cigarettes report daily use and high levels of addiction [3]. Most e-cigarettes contain nicotine, a highly addictive substance that adversely affects adolescent brain development, impacting learning, memory, attention, mood, and impulse control [4]. In a national study among middle and high school adolescents, e-cigarette dependence was more prevalent among youth who reported vaping in the past compared to those who did not (17.6% vs 5.2%; $P<.001$), with many reporting cravings, urges, a strong need to use, and difficulties with concentration and mood [3]. In line with this national study, adolescents participating in formative work reported higher levels of nicotine dependence and strong urges to vape from e-cigarettes and found quitting very challenging [5,6]. Effective interventions are needed to help adolescents quit e-cigarette use.

Despite this need, there are very few evidence-based cessation interventions that exist for adolescent e-cigarette users and even fewer that leverage the digital health modalities that adolescents already use daily. To our knowledge, *This is Quitting*—a text messaging intervention developed by the Truth Foundation—is the only mobile health (mHealth) program to date that has been empirically tested with adolescents in a randomized trial [7]. A recent trial comparing *This is Quitting* to an assessment-only control found that it significantly increased point prevalence abstinence rates at 7 months, demonstrating the potential of mHealth to promote e-cigarette cessation among adolescents [7]. We also found one app, Crush the Crave, that is currently being tested among adolescents [8], with other programs such as the ACT on Vaping mobile app and the Pivot program being evaluated with young adults and adults, respectively [9,10]. Adolescents vary in their readiness to quit and may have different preferences for engaging with behavioral interventions. Therefore, a range of digital intervention options is necessary to expand support for adolescents who are addicted to e-cigarettes.

Thus, we developed the vaper-to-vaper (V2V) intervention—a multicomponent, peer-driven texting intervention. Peer influence is a key driver motivating adolescents to vape [11]. Previous research with adolescents, including our own, has shown that peer-driven interventions can counteract negative social norms associated with quitting (eg, feeling left out when close peers still use e-cigarettes) and improve outcomes [12-16]. Additionally, our previous smoking cessation work with adolescents has demonstrated that they are highly receptive to peer coaching [16]. The V2V intervention builds on insights from our work developing peer-driven mHealth programs for adults who smoke but are not yet ready to quit, recognizing that adolescent e-cigarette users present similar engagement challenges [17,18]. These strategies included proactive pushed content through text messaging, peer videos, and incorporating gamified experiences [19].

In this paper, we described the V2V intervention and presented findings from a pilot randomized study. The primary goal of this pilot study was to assess the feasibility of the study design and protocol implementation, collect key process measures (such as engagement with the intervention), and generate preliminary estimates of effect sizes for health-related outcomes [20-22]. In alignment with these guidelines, our primary hypothesis assessed the feasibility of recruiting and retaining adolescents who vape into a school-based digital cessation program (target: 80 participants, ≥85% retention). We also evaluated engagement with and satisfaction toward the V2V intervention, including interactions with text messages, peer coaching, and videos. Finally, we explored preliminary effects of V2V on vaping outcomes, hypothesizing that intervention participants would demonstrate higher confidence to quit, greater self-efficacy to resist vaping in specific high-risk situations, fewer days vaped, and higher cotinine-validated abstinence compared to controls.

Methods

Study Design

Our pilot feasibility cluster randomized study was conducted in 5 high schools in Massachusetts. Three schools were randomized to the V2V intervention, and 2 schools were randomized to the control. Adolescents assigned to the control arm were emailed a link to the National Cancer Institute's Smokefree.Gov Quit Vaping website [23]. We followed participants for 3 months and assessed feasibility and cessation outcomes. The study was conducted during the COVID-19 pandemic, which impacted school operations and led to adjustments in both the development timeline and recruitment period. Participants were recruited between November 2022 and March 2023.

Ethical Considerations

The study was approved by the UMass Chan Medical School Institutional Review Board (IRB H00021082). All participants participated in the study voluntarily. For adolescents aged younger than 18 years, parental assent was used in lieu of the informed consent (informed assent), whereas informed consent was obtained from participants older than 18 years before their enrollment in the study. Informed assent, or informed consent if the student is aged 18 years or older, was explained such that students understood they had a right to refuse to participate, that their care in the school health clinic and their grades would not be affected by whether or not they decided to participate, and that confidentiality would be maintained. Participants' identifiable information was deidentified before data analysis to ensure their privacy and confidentiality. A Data Safety Monitoring Board monitored the progress of the study and met with the study team twice a year. Participants received US $25 for completing the baseline and another US $25 for completing the 3-month follow-up.

Participants and Inclusion and Exclusion Criteria

To recruit adolescents, we mailed study information letters and a fact sheet to all parents (or legal guardians) of grade 9 to 12 students in participating schools, informing them of the study

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and asking them to contact us or the school within 2 weeks of receiving the letter if they did not want their child to participate in the study. Although the intervention was delivered in English, study materials were provided in the five most common languages across participating schools—English, Spanish, Brazilian Portuguese, Arabic, and Vietnamese—to support recruitment of adolescents from households where other languages were primarily spoken. After 2 weeks, the study was announced in health classes, school-wide announcements were made, and posters were placed throughout the school. All recruitment materials included the study's research coordinator's contact information, and students were asked to contact the study's research coordinator if they wished to participate. Nurses also encouraged students to talk with the research coordinator. We also noted in our posters and study materials that we did not share information about the participants with the schools unless the participant indicated suicidal ideation or intention to do harm. The research coordinator visited these schools once a week to enroll students in the study and to conduct the screening and baseline interviews in a private room.

Inclusion criteria included (1) enrollment in grades 9 to 12 at a participating high school, (2) currently e-cigarette user, (3) ownership of a smartphone, (4) English speaking, and (5) not having opted out. Current e-cigarette use was defined as at least 1 or more days to the question: "during the past 90 days, on how many days did you use e-cigarettes?" This eligibility criterion was adapted from the 2018 National Youth Tobacco Survey, a survey of US middle and high school students that used a 30-day time frame. Our study excluded those who were unable or unwilling to provide informed assent or consent (in the case of those aged ≥18 y).

Intervention and Comparison Arms

Intervention Arm

Our team developed the V2V intervention components with the help of a panel of adolescents (N=11) from a high school in Massachusetts, different from those participating in our pilot study. The panel participants provided informed consent if aged older than 18 years; for those aged younger than 18 years who were not opted out by their parents, assent was obtained. Our study with this panel, conducted in 2022, has been published [5,6]. Among panel participants, 27% (n=3) identified as female, 36% (n=4) identified as male, 27% identified as nonbinary (n=3), and 10% preferred not to say (n=1). The majority of the panel was (n=8, 72%) in 10th or 11th grade [5,6]. All participants vaped nicotine, and half of the participants reported not thinking of quitting. Panel participants received a US $20 gift card as compensation for their participation in the development of each of the 4 intervention components for a possible total of US $80.

In the following sections, we described the development process of each V2V intervention component and how they were delivered within the intervention.

Component 1: Peer Messaging (Prewritten, Tailored, and Push Messages via Texting)

Development Process

These peer messages were created using a procedure we have successfully used in our previous studies [24]. We asked the panel participants to respond to scenarios created based on literature reviews and the results of our qualitative study, as reported in our prior papers [5,6]. The scenarios described common challenges faced by adolescents at various phases of their e-cigarette cessation journey—whether they were not yet ready to quit, setting a quit day, amid a quit attempt, or in maintenance. Additionally, we incorporated scenarios addressing interactions with family and friends, as this was identified as a common challenge for adolescents addicted to e-cigarettes. The instructions directed the adolescents to write the messages as if they were sending a quick text, using language, abbreviations, emojis, and so on, that they would typically use when texting a friend. Each team member rated each of the messages written by the adolescents independently, followed by a group review of the top-rated messages for relevance and appropriateness. From this process, our core team selected the set of 54 messages.

V2V Intervention Delivered

Once participants from the 3 intervention high schools were enrolled in the V2V intervention, they received daily peer messages during the initial 30 days. Message frequency was reduced to sending twice or thrice weekly for the subsequent 2 months. Participants could choose the time of day they received these messages (7 AM, 11 AM, or 6 PM).

Component 2: Peer Videos (8 - 10 Videos): 6 Adolescents and 18 Videos

Development Process

Peer videos included videos of peers describing their experiences using e-cigarettes, motivations to quit, and efforts to quit using them. To create these videos, we recruited members of the panel (n=6) to describe their experiences with vaping and their efforts to quit vaping in the videos. We created a script to guide these responses based on various phases of their e-cigarette cessation journey. To be eligible, the adolescents had to express a willingness to be videotaped. We requested active parental consent as well as adolescent assent for adolescents aged younger than 18 years before videotaping the peer videos. Additionally, we required all adolescents aged younger than 18 years and their parents to sign a video release authorization form before filming the peer videos. Those aged older than 18 years had to provide written informed consent and sign the video release authorization. Adolescents were compensated for the completion of this activity with a US $30 gift card.

V2V Intervention Delivered

To share peer videos, we paired them with peer messages covering similar topics. These links were sent at regular intervals to intervention participants over the first 30 days of the intervention.

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Component 3: Peer Coaching (Asynchronous Communications With Trained Coaches via Texting)

Development Process

Peer coaches—university students aged younger than 22 years who had successfully quit vaping (with difficulty)—were hired for their lived experience and interest in behavior change counseling. Before engaging with study participants, the coaches completed a comprehensive 2-month training that included human subjects research CITI (Collaborative Institutional Training Initiative) certification, study protocol review, instruction on using the texting platform, and guidance on tailoring communication with templated messages. They also received educational resources about the hazards of youth vaping and completed online motivational interviewing modules focused on adolescent substance use. In addition, peer coaches participated in role-playing sessions with the study's MPI (multiple principal investigator) and a Certified Health Education Specialist specializing in substance use and tobacco cessation. These sessions, along with case study discussions on adolescent e-cigarette cessation, equipped coaches with the skills to handle a wide range of vaping-related questions and scenarios. Finally, the study team developed a structured peer coaching protocol that detailed procedures and expectations, including participant enrollment, communication timelines, and texting platform use. The protocol emphasized timely, empathetic, and personalized communication grounded in motivational interviewing techniques and included guidance for addressing mental health concerns.

V2V Intervention Delivered

The peer coaches provided support, encouragement, and answers to questions that study participants had about vaping and quitting. All communications and interactions occurred asynchronously over text messages through the study's texting program. The peer coach received a notification when a participant proactively texted them and was expected to review and reply to vaping-related text messages from study participants within 24 to 48 hours of receiving the texts. Coaches also received notifications when participants were sent specific motivational texts, prompting them to reach out with templated texts to build rapport. The peer coaches had access to templated text message responses that could be tailored to specific questions about vaping and quitting. The peer coaches also met weekly with the study team to review motivational interviewing techniques and to get advice on handling complex texts and challenging situations.

Component 4: Gamification (2 Game Narratives)

Development Process

To enhance intervention engagement, we incorporated a fictional, interactive mystery story based on advice from our panel. The goal was to use the game to encourage active participation. To design this game, we consulted our panel, asking them to identify their preferred top one or two games and to consider how they would develop a narrative for these games if given the opportunity. Their insights helped shape the storyline, which we then refined with a game developer.

V2V Intervention Delivered

Participants received text messages, each containing a snippet of the story, followed by a gamification question each day. The next portion of the story was only sent after the previous one was responded to or automatically resumed after 3 days.

Brief Instructions to the Participant

Once participants completed consent and baseline procedures, our staff also provided brief instructions on each component of the intervention using a script developed by the team. Participants were informed that they would receive text messages written by their peers and the approximate time frame during which these messages would be delivered. Our staff also told the participants that some messages would include links to short peer videos and encouraged them to click on the links to view them. In addition, participants were informed that a peer coach would reach out to them and that they could also initiate contact with the coach at any time. Finally, participants were told that they would receive a detective-themed interactive story that they could engage with and solve over the course of the program. Our staff asked those assigned to the intervention group to save the phone numbers from which the study messages would be delivered. They then sent a test text message to the participants to make sure it went through. Furthermore, the staff asked the participant what time they wanted to receive the peer messages (7 AM, 11 AM, or 6 PM) and informed them that the detective story messages were going to be sent around 7 PM.

Comparison Arm

At baseline, both control and intervention participants were provided a link to the National Cancer Institute SmokeFree Quit Vaping website [23]. The website included resources such as reasons to quit vaping, building a quit plan, strategies to quit vaping, and tips for dealing with cravings.

Measures and Data Collection

Baseline and 3-month follow-up data were collected from all participants in the privacy of the school nurse's office and on a study-issued tablet provided by the study staff, which included a link to the REDCap (Research Electronic Data Capture) survey. Data were collected by the research team to reduce the fear of repercussions for participating in the study. Baseline data included demographics and e-cigarette and other tobacco use. Additionally, the baseline survey assessed psychosocial factors, including perceived stress, anxiety, and depressive symptoms. Engagement was measured via self-report using a series of items beginning with the prompt, "How often did you…" followed by references to specific intervention components. Responses were recorded on a 5-point Likert scale, ranging from "always" to "never." Satisfaction was an adapted version of the Client Satisfaction Questionnaire scale [25]. Secondary outcomes assessed at both baseline and follow-up included confidence to quit vaping, self-efficacy to resist vaping in specific high-risk situations, and the number of days vaped during the past 30 days. Confidence to quit was assessed with a single-item measure of perceived ability to quit vaping. Self-efficacy to resist vaping was assessed using a 12-item scale adapted from the Smoking Self-Efficacy Questionnaire [26]. The primary outcome measure was the 7-day point prevalence

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vaping cessation, assessed using the question: "Do you currently vape (vaped even 1 puff in the last 7 days)?" Biochemical verification was conducted for those who self-reported as quitters using the Abbott iScreen Cotinine Test for qualitative detection of cotinine in oral fluids at a 30 ng/mL cutoff level. This test detects up to 1 to 4 days after nicotine use. Participants were asked to actively swab the inside of their mouth and tongue with a sponge swab and then insert the collector vertically into the cap and twist the handle to tighten the cap on the test tube. Results (positive or negative) were read and displayed on the device's screen after 10 minutes. A positive result indicated the presence of cotinine above the cutoff level, suggesting recent nicotine use. A negative result indicated cotinine levels below the cutoff, suggesting no recent nicotine use. Gift cards worth US $25 were provided to adolescents for completion of each assessment (baseline and 3-mo; US $50 total).

Randomization

We randomized at the school level to minimize within-school contamination. To reduce the chances of imbalance across conditions [27], the schools were matched based on the percentage of low income, percentage of African American students, and number of students. They were then grouped into 2 matched pairs. Within each pair, 1 school was randomly assigned to each study condition. A fifth school was added to the study arm with the smaller total number of students to maintain balance in the overall sample size.

Power and Sample Size Calculations

As pilot studies do not provide meaningful estimates of effect sizes due to the imprecision inherent in small samples [20,28], we based our proposed sample size of 40 students per condition (20 per school) on obtaining precision in estimating condition-specific retention rates, providing important information for the design and recruitment for the future R01 study. On the basis of our prior study of adolescent smoking cessation, the estimated intraschool correlation of 0.01 [29]. This corresponds to a design effect due to within-school clustering of $1+[0.01\times(20-1)]=1.19$, resulting in an effective sample size per condition of $40/1.19=34$. Assuming 85% retention, the final analytic sample size per condition is expected to be approximately 29 participants. Thus, a conservatively wide 95% exact CI for the per-condition retention rate is (68.9%-95.0%).

Data Analysis

Group comparisons for demographic characteristics and tobacco-related behaviors at baseline are presented as the N and proportion or mean (SD) in each group with a *P* value from a chi-square, Fisher exact, or *t* test, as appropriate. As the number of other tobacco products used in the past 30 days was highly skewed, a Wilcoxon rank sum test was used for the *P* value. Engagement and satisfaction items are presented as the N and proportion for categorical variables and mean or median, SD, and range for continuous variables. Change in confidence to quit was measured by dichotomizing the response options and measuring whether someone moved from not at all, somewhat, or moderately confident to very or extremely confident (+1), vice versa (−1) or stayed in the same category (0). Results are reported as N and proportion with a *P* value from a chi-square test. Self-efficacy to resist vaping was calculated as the sum of 12 items (5-point Likert scale, ranging from "not at all" to "extremely"; range 12 - 60) asking for the adolescent's perceived ability to avoid vaping in a variety of different emotional or social situations and was presented as the mean (SE). Change in past 30-day use of e-cigarettes was presented as the mean (SE) and was obtained from a linear regression model. Self-reported quitting and cotinine-validated quitting at 3-month follow-up were analyzed using a logistic regression model among adolescents with completed follow-up (completed cases). Models for vaping cessation outcomes were further adjusted for baseline confidence to quit and the number of other tobacco products used. Owing to the small number of schools and the small sample size, we used model fit statistics to compare models both with and without a random effect for school or an adjustment for school. A random effect for school was not included in the models as the amount of variance due to the random effect was 0 and models were not adjusted for school as school is confounded with randomization assignment. We used the past 90-day inclusion criterion to be maximally inclusive, recognizing that many adolescents vape intermittently rather than daily or weekly. This broader window allowed us to capture a wider range of vaping patterns, including occasional users who may still experience nicotine dependence but might not report past 30-day use. As including these users could potentially dilute intervention effects, we conducted sensitivity analyses for our primary and secondary outcomes excluding participants who reported no vaping in the past 30 days. Additionally, as use of other tobacco products at baseline could impact the vaping cessation outcome, we also conducted a sensitivity analysis excluding all those who reported using any other form of tobacco. Analyses were conducted in Stata/MP version 19.0 (Stata Corp) for Windows (Rev. October 6, 2025).

Results

Overview

Overall, we recruited 71 participants for the study (control group: n=32, 45%, and intervention group: n=39, 55%). We achieved a follow-up rate of 95.8% (Figure 1).

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Figure 1. CONSORT (Consolidated Standards of Reporting Trials) flow diagram of a cluster randomized pilot study evaluating the feasibility and preliminary outcomes of the vaper-to-vaper mobile peer-driven texting intervention for adolescent e-cigarette cessation in 5 Massachusetts high schools, 2022 to 2023.

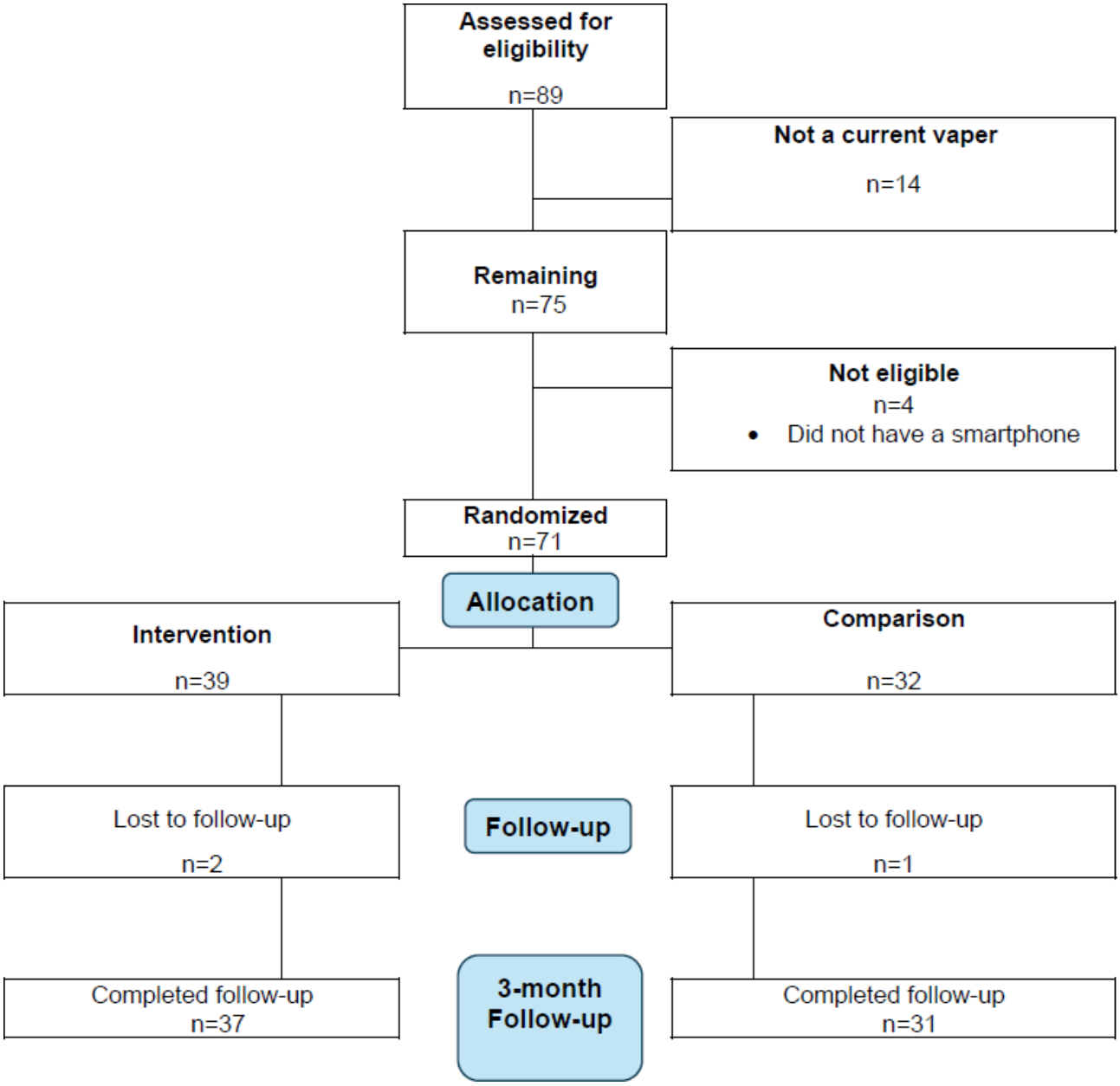

Table 1 describes the demographic characteristics. The intervention group included a higher proportion of non-Hispanic White participants versus the control (n=28, 73.7%, vs n=15, 46.9%) and a lower proportion of Hispanic participants (n=5, 13.2%, vs n=15, 46.9%; *P*=.008). Additionally, more students in the intervention group were in higher grade levels—11th and 12th grades combined (n=27, 69.3%, vs n=12, 37.5%)—compared to the control group (*P*=.004). The control group had lower self-efficacy than the intervention group at baseline (*P*=.05).

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Table . Baseline characteristics of adolescents who vape (N=71) enrolled in a cluster randomized pilot study of the vaper-to-vaper mobile text messaging intervention versus control, conducted in 5 Massachusetts high schools, 2022 to 2023.

Characteristics	Randomization assignment		*P* value
	Control (n=32)	Intervention (n=39)	
Age[a], n (%)			.24
15	2 (6.3)	3 (7.7)	
16	12 (37.5)	6 (15.4)	
17	10 (31.3)	14 (35.9)	
18	6 (18.8)	9 (23.1)	
19	2 (6.3)	7 (17.9)	
Age, mean (SD)	16.8 (1.0)	17.3 (1.2)	.08
Gender[a], n (%)			.94
Male	16 (50)	17 (43.6)	
Female	16 (50)	20 (51.3)	
Transgender	0 (0)	1 (2.6)	
Nonbinary	0 (0)	1 (2.6)	
Race or ethnicity, n (%)			.008
Non-Hispanic White	15 (46.9)	28 (73.7)	
Non-Hispanic non-White	2 (6.3)	5 (13.2)	
Hispanic	15 (46.9)	5 (13.2)	
What grade are you in[a]?, n (%)			.004
9	3 (9.4)	6 (15.4)	
10	17 (53.1)	6 (15.4)	
11	8 (25)	12 (30.8)	
12	4 (12.5)	15 (38.5)	
Retained at 3-month follow-up	32 (100)	36 (92.3)	.37
Perceived Stress Scale (range=0-16; higher score=higher perceived stress), mean (SD)	7.4 (3.1)	7. 5 (3.5)	.91
Depressive symptoms (range=16-34; higher score=more depressive symptoms), mean (SD)	27.3 (4.5)	27.7 (4.6)	.69
Confidence to quit—If you were to decide to quit vaping, how confident are you that you could stop completely, n (%)			.37
Not at all	3 (9.7)	2 (5.3)	
Somewhat	6 (19.4)	11 (29.0)	
Moderately	6 (19.4)	13 (34.2)	
Very	7 (22.6)	6 (15.8)	
Extremely	9 (29.0)	6 (15.8)	
Self-Efficacy Questionnaire (range=1-5; higher score=higher self-efficacy to restrain from vaping), mean (SD)	2.4 (.81)	2.7 (.72)	.05
Hooked on Nicotine Checklist (range=0-10; higher score=more addicted), mean (SD)	5.0 (3.6)	5.2 (3.4)	.78

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[a]*P* values were calculated using chi-square tests when all expected cell counts were >5 and Fisher's exact tests when any expected cell count was <5

Participants in both groups reported depressive symptom scores in the higher range of the scale, suggesting elevated depressive symptom burden (intervention: mean 27.7, SD 4.6; and control: mean 27.3, SD 4.5). Most participants in both groups reported cannabis use in the past 30 days (intervention: n=23, 59%; and control: n=18, 56.2%; Table 2).

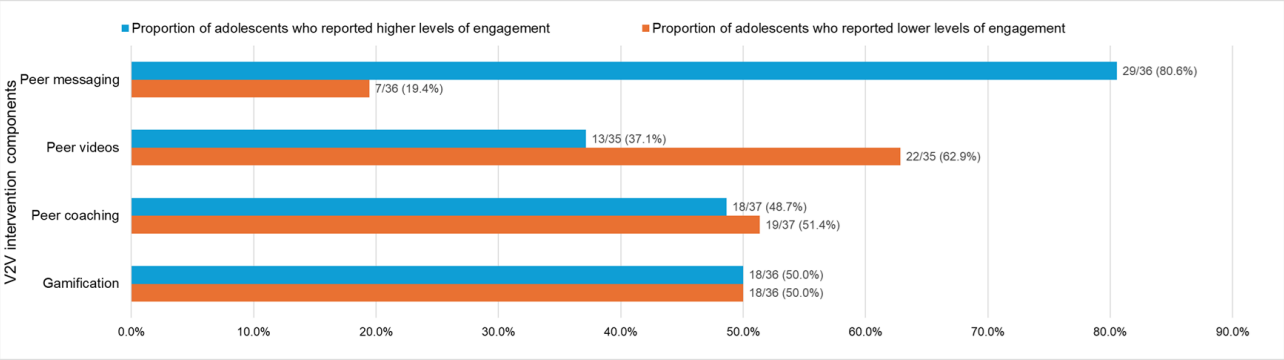
Table . Tobacco-related behaviors and "other" substance use at baseline among adolescents (N=71) who vape enrolled in a cluster randomized pilot study of the vaper-to-vaper mobile text messaging intervention versus control, conducted in 5 Massachusetts high schools, 2022 to 2023.

	Control (n=32)	Intervention (n=39)	*P* value
Number of days vaped in the last 30 days, mean (SD)	17.8 (12.2)	19.7 (11.0)	.48
Past 30 days other tobacco use, n (%)			
Chewing tobacco, snuff, or dip	0 (0)	4 (10.3)	.12
Cigarettes	1 (3.1)	6 (15.4)	.12
Blunts, cigars, and cigarillos	6 (18.8)	9 (23.1)	.77
Hookah	2 (6.2)	5 (12.8)	.45
Tobacco in a pipe (including water pipe)	0 (0)	1 (2.6)	>.99
Past 30 days marijuana use, n (%)	18 (56.2)	23 (59)	>.99
Past 30 days vaped THC (tetrahydrocannabinol), n (%)	13 (45)	20 (53)	.62

Engagement (Intervention Only)

More than 80% of participants (n=29) reported being highly engaged with peer messaging, whereas the percentages of higher engagement with gamification and peer coaching were 50% (n=18) and 49% (n=18), respectively. Engagement with peer videos was lower, with only 37% of participants (n=13) reporting high engagement (Figure 2). The Engagement Summary Score, ranging from 0 to 4, had a mean of 2.1 (SD 1.4).

Figure 2. Engagement with intervention components among adolescents randomized to the vaper-to-vaper mobile texting intervention in a cluster randomized pilot study conducted in Massachusetts high schools, with outcomes assessed over the 3-month follow-up period (n=39). Participants who selected "Prefer not to answer" were excluded from percentage calculations. Higher engaged included those who responded with "Always," "Usually," or "About half the time," and lower engaged included those who responded with "Never," or "Rarely."



Satisfaction (Intervention Only)

The Satisfaction Summary Score for the intervention group had a mean of 25.3 (SD 4.7). The summary score is the sum of 8 items, ranging from 1 to 4 (range 8 - 32), and higher scores indicate higher satisfaction.

Secondary Outcomes

Confidence to Quit Vaping

In the control group, of the 50% of participants who reported a change in confidence at 3-month follow-up, 28% (n=9) reported higher confidence, and 22% (n=7) reported lower confidence. Of the 74% of intervention participants reporting a change, 44% (n=17) reported higher confidence, and 31% reported lower confidence (n=12; Table 3). In our analysis, limited to participants who reported vaping in the past 30 days at baseline, 33% (n=8) reported higher confidence, and 21% (n=5) reported lower confidence. Among these intervention participants, 43% (n=14) reported higher confidence, and 30% (n=10) reported lower confidence.

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Table . Secondary outcome: changes in confidence to quit, self-efficacy to resist vaping, and number of vaped in the last 30 days among adolescents (N=71) participating in a cluster randomized pilot study of a peer-driven mobile texting intervention (vaper-to-vaper) versus control in Massachusetts high schools.

Category	Control (n=32)	Intervention (n=39)	*P* value
Confidence to quit, n (%)			.11
Poorer	7 (21.9)	12 (30.8)	
Same	16 (50)	10 (25.6)	
Better	9 (28.1)	17 (43.6)	
Change in, mean (SD)			
Self-efficacy to resist vape in different situations	0.06 (1.39)	−0.21 (1.4)	.39
Number of days vaped in the last 30 d	−2.9 (10.0)	−3.6 (10.8)	.79

Self-Efficacy to Resist Vaping

The mean changes in self-efficacy scores (SEQ-12) from baseline to follow-up did not differ significantly between groups (control: mean 0.06, SD 1.39; and intervention: mean –0.21, SD 1.14; *P*=.39; Table 3). The results were similar after limiting to participants who reported vaping in the past 30 days at baseline (control: mean 0.04, SD 1.01; and intervention: mean –0.36, SD 1.13; *P*=.16).

Number of Days Vaped in the Last 30 Days

Both groups reported a decrease in the number of days they vaped in the previous 30 days (control: mean −2.9, SD 10.0, vs intervention: mean −3.6, SD 10.8). None of these findings were statistically significant (Table 3). The sensitivity analysis limited to participants who reported vaping in the past 30 days at baseline did not change our results (control: mean −2.3, SD 10.1, vs intervention: mean −3.3, SD 11.2).

Vaping Abstinence

At the 3-month follow-up, cotinine-validated 7-day point prevalence was not statistically significant (intervention: n=8, 21.6%, vs control: n=7, 22.6; *P*=.90). Using an unadjusted logistic regression model, the intervention group had a nonsignificant 5% reduction in the odds of cotinine-validated quitting compared to the control group (odds ratio [OR] 0.95, 95% CI 0.30 - 2.99), which changed to a 30% increase in the odds of cotinine-validated quitting after adjustment for confidence to quit at baseline and the number of other tobacco substances used (OR 1.30, 95% CI 0.35 - 4.89; Table 4). In a sensitivity analysis limited to participants who reported vaping in the past 30 days at baseline, the intervention effect remained nonsignificant (unadjusted OR 1.06, 95% CI 0.30 - 3.80; and adjusted OR 1.18, 95% CI 0.29 - 4.90), indicating that excluding noncurrent users did not meaningfully change the results. The results did not alter meaningfully (OR 0.83, 95% CI 0.18-3.88) after excluding all those who reported using other tobacco products at baseline.

Table . Changes in vaping abstinence outcomes from baseline to 3-mo follow-up by treatment condition among adolescents with completed follow-up (n=68) participating in a cluster randomized pilot study of a peer-driven mobile texting intervention (vaper-to-vaper) versus control in Massachusetts high schools.

Variable	Control (n=32), n (%)	Intervention (n=39), n (%)	*P* value	Unadjusted OR[a] (95% CI)	Adjusted for confidence to quit at baseline and number of other substances
Self-reported vaping abstinence	9 (29.0)	12 (32.4)	.76	1.17 (0.42 - 3.31)	2.18 (0.58 - 8.11)
Cotinine-verified vaping abstinence	7 (22.6)	8 (21.6)	.92	0.95 (0.30 - 2.99)	1.30 (0.35 - 4.89)

[a]OR: odds ratio.

As a number of participants reported cannabis use and this can impact the outcome, we also conducted a stratified analysis comparing those who used cannabis at baseline and those who did not. Regardless of intervention condition, those who reported using cannabis at baseline had significantly lower odds of cotinine-validated quitting than those who did not report using cannabis at baseline (OR 0.20, SE 0.13; *P*=.01). Results for self-reported quitting were consistent with cotinine-validated quitting (OR 0.25, SE 0.14; *P*=.02). Overall, 22% of those who reported using cannabis at baseline reported not using at follow-up (n=9; *P*<.001). There were no differences by randomization assignment.

Discussion

Principal Findings

We were able to recruit 71 participants (with a target of 80), despite COVID-19–related school closures and delays. While our recruitment window was shortened (from 5 mo to 2.5),

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enrollment progressed efficiently once we were able to initiate the study. Importantly, we achieved an excellent 96% follow-up rate, demonstrating strong participant retention and study feasibility. Engagement with the intervention varied between the components. Participants in the intervention group also reported higher acceptance and satisfaction with the components compared to the control. The intervention group showed improvements in confidence to quit and the number of vapes per day in the last 30 days, although self-efficacy to resist vaping slightly reduced, with actual quitting rates not significantly differing between groups.

Our findings add to the growing evidence that mobile and text-based interventions are feasible and acceptable tools for engaging adolescents in health behavior change [30-35]. Adolescents have near-universal mobile phone ownership and frequently use text messaging [36]. Text messaging and mobile programs have been used successfully to support youth tobacco cessation by enhancing motivation and maintaining engagement [31]. As previously reported, the evaluation of *This is Quitting* demonstrated that text messaging can also be adapted to support vaping cessation [7]. Vaping cessation apps (Crush the Crave) are currently undergoing testing among adolescents [8]. To enhance accessibility and real-world applicability, we implemented our text messaging program in a school-based setting. This approach was adapted from our previous work on recruiting and engaging adults who are not yet ready to quit, with the assumption that adolescents may have similar problems with engagement and retention [17,18]. Our previous approach included text-based and peer-driven components—peer-written messages and videos, asynchronous peer coaching, and gamified storytelling—each designed to increase engagement and relevance [19]. By integrating these elements within a school-based program, we aim to both maximize participation and retention and real-world accessibility of our program for adolescent participants.

The adolescent participants noted high levels of acceptance and satisfaction with the intervention, which is important to consider for future iterations of the intervention. The peer-written messages were well-received by our participants. Consistent with prior studies, interventions that push content (such as text messages) tend to be more engaging and effective than content that a participant has to choose to view (like content on a website) [35,37,38]. Text from a peer may increase homophily—a feeling of similarity between the message writer and the message reader—which in turn can increase relevance and engagement with the provided content [24]. Prior studies have demonstrated that peer-written messages can effectively promote health behaviors among youth. Adolescents in one study wrote text messages that emphasized care, responsibility, and personal relevance to encourage friends to seek HIV or STI (sexually transmitted infection) testing, indicating the impact of text messaging among the youth [39]. Observational research also suggests that peer-to-peer communication is frequent among adolescents and strongly influences social and emotional outcomes [36]. Peer-to-peer communication, with a focus on text messaging, serves as an effective way to disseminate health information, promoting healthier behaviors, especially with the use of addictive substances such as e-cigarettes.

Peer coaching may be a promising approach to engage and help adolescents who are addicted to vaping. In a qualitative study of adolescents and young adults, peer coaching integrated into social media–based cessation groups was viewed favorably, with participants emphasizing the importance of age similarity, shared lived experience, and mentor training [40]. Such coaching can be delivered synchronously (eg, through live chat or video sessions) or asynchronously, as in our study. Evidence from prior work suggests that asynchronous peer coaching can be both practical and cost-effective, although its engagement and effectiveness vary across contexts [41-43]. This format may be particularly well-suited for school-based and youth interventions, as it can be private and allows adolescents to engage in their own time. In our study, most of the adolescent participants engaged at least once with the peer coach, although the frequency of engagement varied (range 0 - 17). One lesson may be that the peer coach needs to take a more proactive role—initiating contact rather than waiting for participants to reach out. Similar proactive outreach models by peers have been shown to promote engagement in studies that tested peer communication in a social media or discussion forum setting [44]. Alternate or adaptive content strategies—such as personalized follow-up messages—could also enhance engagement. Future studies should further test these approaches to identify the best ways to promote engagement with and the effectiveness of the intervention among adolescents.

Engagement with the gamification messages was evenly split. Rather than using strategies such as points or rewards [45], we chose to use a fictional story informed by our formative work to promote engagement. We assumed that if adolescents found the storyline engaging, it could provide a brief respite from the challenging task of quitting vaping and encourage greater participation in other intervention components. Furthermore, in our formative work, participants expressed interest in having multiple storylines, and future studies providing more choices may spur more engagement [5,6]. However, due to time and budget constraints, we only had one gamification story in our intervention—a detective story—which may not have been of interest to some participants. Including additional storylines to offer participants varied options may further enhance engagement with the gamification messages. Peer videos were the component with the lowest engagement. There may have been several factors. First, the way we distributed these peer videos (via links on text messages) may have been a barrier for adolescents. Second, the quality of the video recording was perhaps lower than what adolescents are used to when they visit social media sites such as TikTok or Instagram. Future studies should consider using these channels on social media to distribute these videos to further increase engagement with peer videos.

Of concern, at baseline, many of our participants reported elevated depressive symptom scores on the depressive symptom scale, as indicated by a mean score of 27. These levels may have been higher due to the study being conducted during the COVID-19 pandemic. Several studies, including 2 meta-analyses, showed an increase in depression symptoms during the COVID-19 pandemic [46,47]. We did not find studies that estimated the levels of depression among adolescents after

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the COVID-19 pandemic. Depression can lead to poorer outcomes among tobacco users, and future vaping cessation studies may need to assess and include methods to address depression among their participants.

Furthermore, our participants also reported high levels of cannabis use and THC vaping [48-50], reflecting broader trends of e-cigarette and cannabis co-use over the last few years. Notably, co-use of cannabis and vaping THC can also reduce the effectiveness of tobacco interventions [49,51], although the degree to which this co-use affects cessation has not been fully studied. This was evident in our study: in a secondary analysis, those who did report cannabis use at baseline had significantly lower odds of cotinine-validated quitting (OR 0.20, SE 0.13; *P*=.01), compared to those who did not report cannabis use at baseline. An interesting future research study might be to compare vaping cessation interventions that address co-use versus those that do not [52]. This might yield valuable data on how to treat adolescents who both vape and co-use cannabis.

Among the secondary outcomes, our results indicated that the intervention produced mixed changes in participants' confidence levels, with some reporting decreases and others increases in confidence. The intervention included content related to understanding addiction and the challenges of quitting, as well as practical strategies to quit. This may have helped some participants gain a better understanding of the difficulties involved in quitting, while others found the strategies useful for strengthening their confidence to quit. A similar pattern was observed in changes in self-efficacy, where control participants had a slightly greater increase in scores than intervention participants. While intervention participants may have gained new knowledge about coping and quitting strategies, greater awareness of the challenges associated with resisting vaping may have reduced their self-efficacy scores. A longer duration of exposure to the intervention may help overcome this initial reduction effect, although this needs to be tested in future studies. Intervention participants reported a greater reduction in the number of days vaped in the past 30 days compared to controls, suggesting some potential benefit of the intervention, although the absolute difference was small.

The difference in quitting rates between the control and intervention groups was not statistically significant. However, our inclusion criterion (vaping in the past 90 days) may have been broad and allowed participation of adolescents who had already quit or substantially reduced vaping. As few participants reported not vaping in the past 30 days, we conducted sensitivity analyses excluding these participants. The findings from these analyses remained consistent with the main results, suggesting that the inclusion of occasional or former users did not meaningfully alter the observed intervention effects. Overall, our results indicate some promising effects of the intervention but also highlight areas for refinement to further enhance its potential impact in future trials.

Our study had several limitations. The sample size of our pilot study was small, limiting the ability to examine differences in intervention effects between participants with higher versus lower rates of e-cigarette use. We also used e-cigarette use within the past 90 days for inclusion into the study, instead of the 30-day window. This may have resulted in the recruitment of less frequent users or those who had already quit. As noted, we added sensitivity analyses to minimize this potential bias. Engagement was assessed through self-report only. In addition, satisfaction was reported only among participants in the intervention group, which limited our ability to compare satisfaction outcomes between study groups. As several participants reported use of other tobacco products, cotinine testing may not have distinguished between those who quit vaping but continued using other products; to reduce the impact of this limitation, we report sensitivity analysis results of the cotinine-validated vaping cessation outcome excluding all these participants. Additionally, the intervention was implemented over a short period due to the challenges posed by the COVID-19 pandemic, which resulted in our development time being reduced from the planned 1 year to 4 months. This may have constrained its impact, given the challenges of quitting e-cigarettes; a longer intervention period might yield stronger effects.

Conclusion

We demonstrated the feasibility of recruiting and randomizing participants from high schools in Massachusetts, achieving high rates of follow-up. The study revealed several promising aspects of the intervention that warrant further investigation. These include the overall acceptability and satisfaction scores, as well as higher levels of engagement with certain components, such as peer messaging and peer coaching. Although vaping cessation rates did not increase compared to the control group, intervention participants demonstrated mixed but encouraging changes in confidence, greater reduction in the number of days vaped, and slightly lower self-efficacy to resist vaping compared to the control group. These findings support the feasibility and potential of the V2V intervention and provide direction for optimizing the intervention and testing it in a larger, adequately powered trial.

Acknowledgments

The authors declare the use of generative artificial intelligence (GAI) in the research and writing process. According to the GAIDeT taxonomy (2025), the following tasks were delegated to GAI tools under full human supervision: proofreading and editing and adapting and adjusting emotional tone.

The GAI tool used was Chat-GPT 5.1. Responsibility for the final manuscript lies entirely with the authors. GAI tools are not listed as authors and do not bear responsibility for the final outcomes.

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Authors' Contributions

Funding acquisition: RSS and LP
Methodology: KB, RSS, LP, CF, and BW
Software: KB and RSS
Project administration: RN and JW
Data curation: CF
Formal analysis: RSS and CF
All authors were involved in review and editing of the manuscript, while RSS wrote the original draft.

Checklist 1
CONSORT-eHEALTH checklist (V 1.6.1)
[PDF File, 1180 KB - formative_v10i1e79667_app1.pdf]

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Abbreviations

mHealth: mobile health
OR: odds ratio
V2V: vaper-to-vaper

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Usability and Acceptance Testing of an Electronic Patient-Reported Outcome Symptom Monitoring System for People Receiving Immune Checkpoint Inhibitors: Mixed Methods Study

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Abstract

Background: Immune checkpoint inhibitors are widely used in oncology but can cause immune-related adverse events (irAEs), which may be severe or life-threatening if not detected early. Electronic patient-reported outcome (ePRO) symptom monitoring systems may facilitate timely recognition and management of irAEs. Usability testing is a critical stage in ePRO system development, yet no published examples of formal usability and acceptance testing exist.

Objective: This study aims to assess the usability and acceptance of a co-designed ePRO symptom monitoring prototype for irAEs embedded within the Epic electronic medical record.

Methods: Testing was conducted at an Australian quaternary cancer center. Eligible participants were patients who had received or were receiving immune checkpoint inhibitors, their caregivers, or clinicians (oncologists and nurse specialists). Participants completed baseline digital literacy assessments (16-item Mobile Device Proficiency Questionnaire [MDPQ-16] and 12-item Computer Proficiency Questionnaire [CPQ-12]) before a structured testing session. Each session involved role-specific tasks using the patient-facing Health Hub or the clinician-facing Epic electronic medical record. Usability was assessed using the System Usability Scale (SUS). Acceptance was assessed using a customized Unified Theory of Acceptance and Use of Technology (UTAUT) questionnaire. Semistructured interviews were used to capture qualitative feedback.

Results: A total of 30 participants (7 patients, 3 caregivers, 10 oncologists, and 10 nurse specialists) completed 10 testing sessions. Median MDPQ-16 and CPQ-12 scores were higher for clinicians compared to patients and caregivers. Median SUS scores indicated high usability—patients and caregivers: 77.5% (IQR 70.0% - 86.3%), oncologists: 82.5% (IQR 80.0% - 90.0%), and nurse specialists: 80.0% (IQR 75.6% - 94.4%). Median UTAUT scores demonstrated strong user acceptance—patients or caregivers: 4.27 (IQR 4.09 - 4.58), oncologists: 4.33 (IQR 4 - 4.63), and nurse specialists: 4.23 (IQR 3.87 - 4.57). Health Hub usability themes highlighted overall ease of navigation and efficiency of reporting, but a need for clearer survey navigation, simplification of the actions page, and improved organization of trend graphs. For clinicians, themes included efficient side effect capture and intuitive system design, but a need to improve navigation to results, optimize data display, and facilitate team-based alert management. Health Hub acceptance themes highlighted patient empowerment to self-manage, enhanced patient-clinician communication, and reinforcement of existing care. However, concerns were raised about digital equity for vulnerable groups. Clinicians reported that the system streamlined side effect management between visits, aligned with existing Epic workflows, and could be tailored to personal preferences. Concerns remained regarding additional workload and medico-legal responsibilities associated with real-time alerts.

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Conclusions: The ePRO prototype demonstrated high levels of usability and acceptance across patients, caregivers, and clinicians. Limitations around navigation and data visualization, alongside equity and workload concerns, will guide refinements prior to implementation. These findings emphasize the value of rigorous formative usability and acceptance testing to optimize ePRO systems prior to deployment in routine cancer care.

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KEYWORDS

symptom monitoring; patient-reported outcomes; electronic patient-reported outcomes; digital health; usability; acceptance; immunotherapy; immune checkpoint inhibitors

Introduction

Immune checkpoint inhibitors (ICI), which block inhibitory signals of T-cell activation to promote antitumor immune responses, are now a standard of care for people with various cancer types. While ICIs have significantly improved clinical outcomes, they are also associated with immune-related adverse events (irAEs). These events can present with a variety of symptoms [1], may be severe or life-threatening [2-5], and are associated with increased acute health care use and health care costs [6-9]. Common irAEs involve organs such as the skin (eg, rash and pruritus) and the gastrointestinal tract (eg, diarrhea) [10].

Between clinic visits, people receiving ICIs and their caregivers are primarily responsible for identifying and reporting symptoms suggestive of an irAE. However, recognizing irAEs can be challenging and a source of anxiety for patients and caregivers [11-13]. Digital tools, such as electronic patient-reported outcome (ePRO) symptom monitoring, may support people to self-monitor for irAEs and facilitate early reporting of concerning symptoms to health care professionals. There is high-quality evidence demonstrating the benefits of ePRO symptom monitoring at the patient, clinician, and health care system level [14,15].

We co-designed a real-time ePRO symptom monitoring system for people receiving ICI in collaboration with end users [16]. The prototype was first developed using eSyM (Epic Systems Corporation), an ePRO symptom management program that is integrated into the Epic electronic medical record (EMR) system [17,18], as the foundation. We then adapted this prototype to address the specific needs of people receiving ICI and to align with local preferences and workflows. The final prototype consisted of a patient-facing smartphone app and website known locally as “Health Hub” (MyChart; Epic Systems Corporation) and the clinician-facing Epic EMR.

Usability testing is a critical stage in the development of digital health care tools [19]. The International Organization for Standardization defines usability as the “extent to which a product can be used by specified users to achieve specified goals with effectiveness, efficiency, and satisfaction in a specified context of use” [20]. Usability testing is the “formal assessment of the extent to which a product or system is effective, efficient, and perceived as satisfactory by users” [19]. For ePRO systems, testing would involve end users performing predetermined tasks and providing feedback. This ensures the intended purpose of the ePRO system is achieved and that users are satisfied with their user experience.

High levels of usability and acceptance are critical for ensuring user engagement and long-term sustainability of ePRO symptom monitoring. Performing usability testing iteratively during a system’s development will ensure that any issues are detected and addressed prior to implementation, ensuring the final product is fit for purpose, which may help to reduce attrition rates postimplementation [19]. However, there are no published examples of formal usability testing of ePRO systems.

The usability and acceptance of our ePRO system have not been established, and formal usability and acceptance testing of the eSyM system has not been published. Guided by the principles described by Aiyegbusi [19] for usability testing of ePRO systems, this study aimed to assess the usability and acceptance of our ePRO system with end users (patients, caregivers, and clinicians).

Methods

Study Population

Patient participants were older than 18 years and were receiving or had received ICI. Caregiver participants were older than 18 years and had direct caring responsibility for a person who was receiving or had received ICI. Clinician participants were oncologists and nurse specialists involved in caring for people receiving ICI.

Participants were identified from co-design workshops undertaken as part of preliminary work to develop the ePRO system [16] and contacted directly to discuss this study. This enabled people to participate across the entire system co-design process. Additional patient and caregiver participants were identified by screening melanoma and lung clinic lists and approached via their treating physician. These clinics were chosen as many patients and caregivers had prior ICI experience. A research assistant (IZ) then called the patient and caregiver to discuss the study and arrange consent. Additional clinician participants were identified via the research team’s professional networks and were emailed the consent form.

Sample size was determined by a number of factors [19,21]. First, for iterative testing, prior studies recommend at least 5 participants per test cycle to detect 85% of issues [22]. Second, the degree of end-user heterogeneity (eg, age and digital experience) and potential dropout should be considered [23,24]. Third, the complexity of the physical and cognitive tasks should also be considered, with 5 - 10 participants recommended for

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simple ePRO systems and up to 20 for more complex systems [25]. However, it is not clear whether this refers to each test cycle or the entire testing process [25]. Finally, the nature of the data collected should also be considered. For example, if data are predominantly qualitative rather than quantitative, sample size will be influenced by the achievement of thematic saturation [26]. To account for these factors, we aimed to recruit 10 patients or caregivers, 10 oncologists, and 10 nurse specialists to the first round of usability testing.

Our system was developed using Responsive Web Design, which enables dynamic adaptation to different screen sizes and orientations [27]. To account for the similarity between mobile and tablet interfaces [28], we aimed to test 5 patients or caregivers using a mobile phone or tablet and 5 patients or caregivers using a computer.

Data Collection

After completing the participant information and consent form, participants completed 2 online questionnaires via REDCap (Research Electronic Data Capture): the 16-item Mobile Device Proficiency Questionnaire (MDPQ-16) [29] and the 12-item Computer Proficiency Questionnaire (CPQ-12) [30] to assess their digital literacy. The MDPQ-16 assesses participants' ability to use mobile devices with each item measured on a 5-point scale ("never tried" to "very easily"). The MDPQ-16 has demonstrated excellent reliability (Cronbach α=0.96) [29]. The CPQ-12 assesses participants' computer proficiency with each item measured on a 5-point scale ("never tried" to "very easily"). The CPQ-12 has demonstrated excellent reliability (Cronbach α=0.98) [30]. For both questionnaires, higher scores indicate higher levels of proficiency. The MDPQ-16 and CPQ-12 were chosen because they were designed to assess digital literacy and are widely used. Participants were also provided with prereading materials outlining the aims of the testing session, session format, and anticipated outputs (Section 1 in Multimedia Appendix 1).

The usability and acceptance testing sessions were cofacilitated by JLK (a medical oncologist) and IZ (a research assistant). Each session lasted 1.5 hours. Seven sessions were conducted with all participants on-site, and 3 were conducted with the patient and caregiver present remotely via Zoom (Zoom Communications, Inc) to simulate ePRO completion at home. Figure 1 demonstrates the setup of the testing room. All individuals shown provided consent for their images to be included in this paper. All participants were briefed that the purpose of the session was to test the ePRO system interface, not assess the meaning or clinical relevance of questions within the ePRO survey [19].

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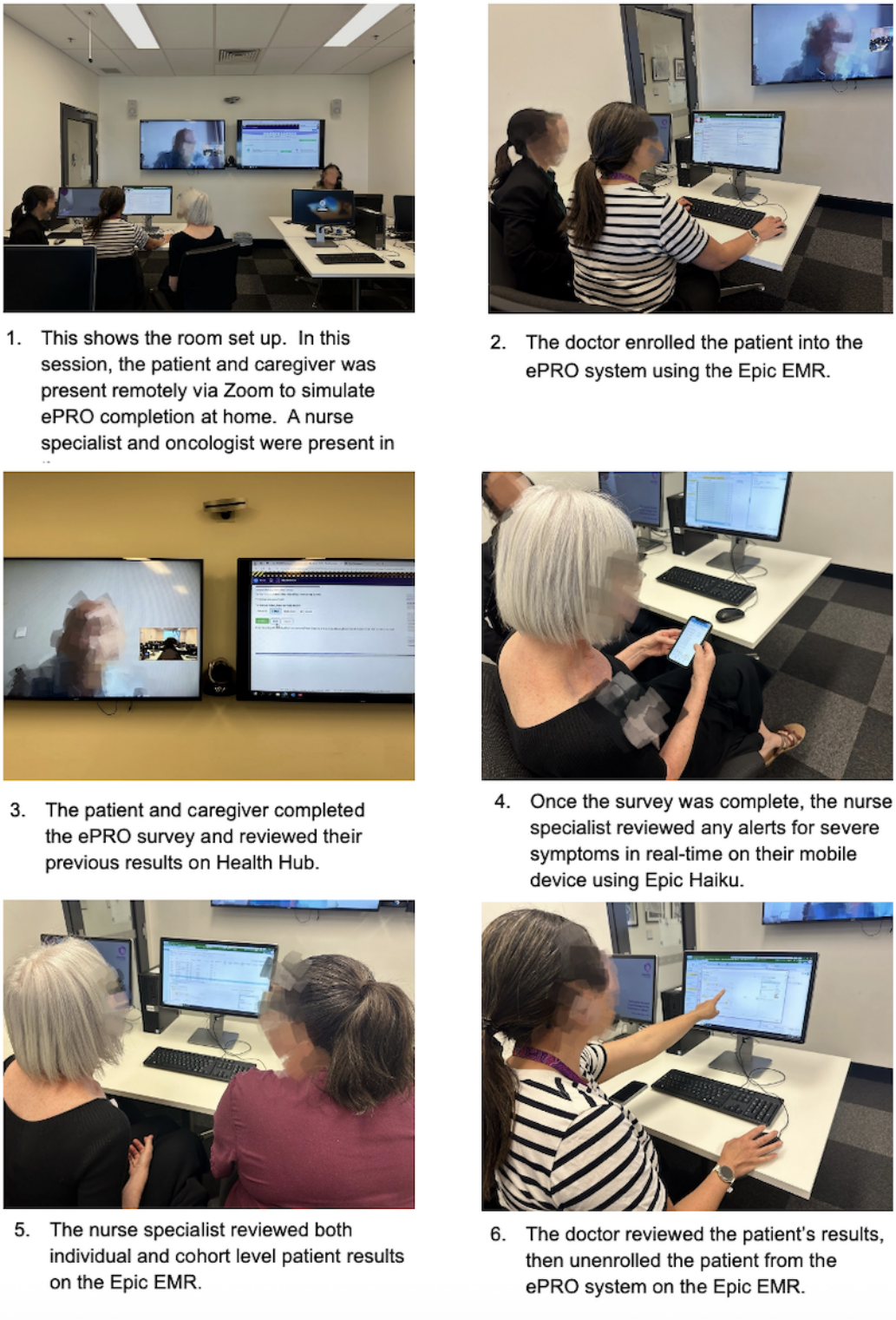
Figure 1. Room setup for usability and acceptance testing. EMR: electronic medical record; ePRO: electronic patient-reported outcome.



During each session, participants were first trained on a series of tasks that reflected their role (Section 2 in Multimedia Appendix 1), then performed those tasks independently while being observed by JLK and IZ. Patients and caregivers tested the Health Hub and clinicians tested the Epic EMR. Testing was performed as a group to reflect how the ePRO system would function in real-world practice, with the doctor enrolling the patient and caregiver into the system, the patient and caregiver completing the survey and reviewing their previous results in Health Hub, the nurse specialist reviewing alerts for severe symptoms in real-time and individual- and cohort-level patient results, and the doctor reviewing results and unenrolling the patient (Figure 2). Participant actions, verbal, and nonverbal cues were noted by JLK and IZ for probing during the qualitative interview.

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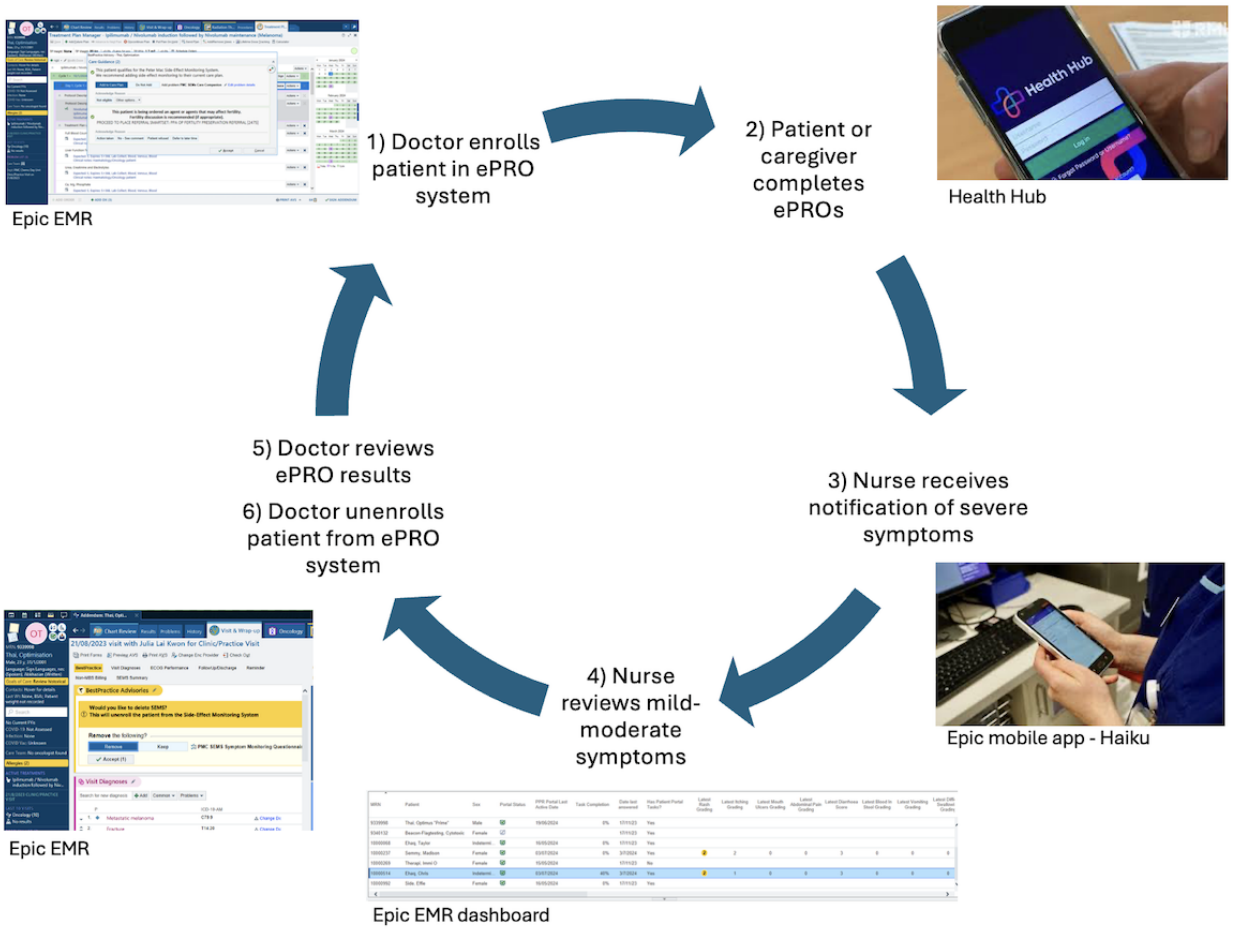
Figure 2. Usability and acceptance testing procedure. EMR: electronic medical record; ePRO: electronic patient-reported outcome.



Participants then completed a qualitative, semistructured interview regarding their experience using the system using the retrospective probing technique [19]. The interview schedule is shown in Section 2 in Multimedia Appendix 1.

Interviews were audio-recorded and transcribed using the automated transcription feature on Microsoft Teams. Transcripts were checked by IZ (a research assistant) against audio recordings to ensure their accuracy and deidentify. Participants were not invited to review their transcripts but consented to being contacted if further clarification of their comments was required. Participants were reimbursed with an AUD $50 voucher (US $33.41) for their attendance in accordance with the hospital's consumer engagement policy.

Following the testing session, participants completed 2 questionnaires on REDCap: the System Usability Scale (SUS) [31] and a customized questionnaire based on the Unified Theory of Acceptance and Use of Technology (UTAUT) [32,33] (Section 3 in Multimedia Appendix 1). The 10-item SUS evaluates the usability of software, mobile devices, websites, and apps (ie, the extent to which a system can be used effectively, efficiently, and satisfactorily) using 5 response options ("strongly agree" to "strongly disagree"). In contrast, the 15-item UTAUT assesses the degree of user acceptance of digital systems, capturing user perceptions about performance expectancy, effort expectancy, social influence, and facilitating conditions using a 5-point Likert scale ("strongly disagree" to "strongly agree"). Together, these tools provide complementary insights, with the SUS quantifying participants' direct interactions with the system to assess whether the system is easy to use, while the UTAUT assesses the likelihood of sustained engagement and integration into routine workflows. For both questionnaires, higher scores indicated higher levels of usability or acceptance. These questionnaires were chosen as they assessed the desired outcomes (usability and acceptance) and were widely used for digital health interventions.

Data Analysis

Questionnaire data regarding digital literacy, system usability, and user acceptance were analyzed in RStudio (version 4.4.1; Posit PBC). Descriptive statistics were used to summarize responses.

Content analysis [34] was used to identify responses regarding the usability and acceptance of the prototype ePRO monitoring system. Transcripts were deidentified and read line by line by JLK and IZ to familiarize themselves with the dataset. To ensure coding rigor, 20% of transcripts were coded by both JLK and IZ. Once codes were agreed upon by both JLK and IZ, the remaining transcripts were coded by IZ. Transcripts were coded in NVivo (version 12; Lumivero). Codes were grouped into themes and subthemes relating to the usability and acceptance of the system identified by the study participants. Any disagreements were resolved by discussion with coauthors. All researchers were involved in reviewing the themes and subthemes, and final interpretations were arrived at by

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consensus. Saturation was defined as no new usability or acceptance concepts being identified for each of the 3 participant groups (patients and caregivers, oncologists, and nurse specialists) and confirmed jointly by JLK and IZ.

Ethical Considerations

We conducted usability and acceptance testing sessions at a quaternary cancer center in Australia. Institutional ethics approval was granted by the Peter MacCallum Cancer Centre Low and Negligible Risk Research Ethical Review Committee (HREC/96744/Peter MacCallum Cancer Centre, August 17, 2023). Study participants were informed about the confidentiality of the data they provided, and written informed consent was acquired from all participants before being included in the study. Participants received an AUD $50 (US $33.41) voucher if they participated in a testing session. No additional incentives were offered for completing the presession and postsession questionnaires. All data collected were deidentified and stored on a secure server. The study was conducted in accordance with the National Statement on Ethical Conduct in Human Research and the Declaration of Helsinki. The authors confirm that the human research participants provided informed consent for publication of the images shown in Figure 1.

Results

Participant Characteristics

Thirty participants were recruited: 7 patients, 3 caregivers, 10 oncologists, and 10 nurse specialists (Tables 1 and 2). Patients and caregivers were mostly male (7/10, 70%), aged 61 - 70 years (5/10, 50%), spoke English at home (9/10, 90%), had an undergraduate degree (5/10, 50%), had melanoma or were caring for someone with melanoma (9/10, 90%), and had been receiving (or cared for someone receiving) ICI for 6 - 12 months (5/10, 50%). All patients and caregivers had access to the Health Hub (10/10, 100%). Patients and caregivers were “somewhat confident” (3/10, 30%) or “quite confident” (3/10, 30%) using computers, smartphones, or other electronic devices. Median MDPQ-16 and CPQ-12 scores for patients and caregivers were 32.0 (IQR 22.5 - 37) and 24.3 (IQR 22.5 - 26), respectively.

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Table . Patient and caregiver characteristics.

Characteristics	Total (n=10)
Age (years), n (%)	
41 - 50	1 (10)
51 - 60	1 (10)
61 - 70	5 (50)
>70	3 (30)
Sex, n (%)	
Male	7 (70)
Country of birth, n (%)	
Australia	9 (90)
Other	1 (10)
Language spoken at home, n (%)	
English	9 (90)
Other	1 (10)
Role, n (%)	
Patient	7 (70)
Cancer type, n (%)	
Melanoma	9 (90)
Lung	1 (10)
Duration of immunotherapy treatment (months), n (%)	
6 - 12	5 (50)
13 - 18	1 (10)
>18	4 (40)
Access to Health Hub[a], n (%)	
Yes	10 (100)
Easy to ask doctors questions regarding their health, n (%)	
Strongly agree	8 (80)
Slightly agree	2 (20)
Easy to ask nurses questions regarding their health, n (%)	
Strongly agree	7 (70)
Slightly agree	3 (30)
Confident in working with doctors to manage immunotherapy side effects, n (%)	
Very confident	5 (50)
Quite confident	4 (40)
Somewhat confident	1 (10)
Use of electronic devices[b], n	
Smartphone	8 (80)
Tablet	6 (60)
Desktop or laptop	9 (90)
Self-reported confidence in using electronic devices for online activities, n (%)	
Very confident	2 (20)
Quite confident	3 (30)

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Characteristics	Total (n=10)
Somewhat confident	3 (30)
A little confident	1 (10)
Not at all confident	1 (10)

[a]Health Hub: a secure, patient-facing mobile app and website linked with the electronic medical record, which provides information regarding appointments, medications, and some test results.

[b]Some participants provided multiple answers.

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Table . Clinician characteristics.

Clinician characteristics	Total (n=20)
Age (years), n (%)	
18 - 30	1 (5)
31 - 40	6 (30)
41 - 50	9 (45)
51 - 60	2 (10)
61 - 70	2 (10)
Sex, n (%)	
Male	5 (25)
Country of birth, n (%)	
Australia	12 (60)
Other	8 (40)
Language spoken at home, n (%)	
English	16 (80)
Other	4 (20)
Role, n (%)	
Oncologist	10 (50)
Nurse	10 (50)
Tumor stream, n[a]	
Melanoma and skin	8 (40)
Gynecological	6 (30)
Head and neck	5 (25)
Prostate	4 (20)
Bladder	4 (20)
Kidney	4 (20)
Lung	3 (15)
Breast	3 (15)
Gastrointestinal	3 (15)
Central nervous system	2 (10)
Sarcoma	2 (10)
Hematological	1 (5)
Colorectal	1 (5)
Pool (cover all streams)	1 (5)
Duration of experience in current role (years), n (%)	
<1	6 (30)
1 - 4	3 (15)
5 - 9	4 (20)
10 - 14	6 (30)
>15	1 (5)

[a]Some participants provided multiple answers.

Out of 20 clinicians, oncologists and nurse specialists were mostly female (15/20, 75%), aged 41 - 50 years (8/20, 45%), who had worked less than 1 year (6/20, 30%) or 10 - 14 years (6/20, 30%) in their current role. The majority managed patients with melanoma and skin cancers (8/20, 40%) or gynecological cancers (6/20, 30%). Median MDPQ-16 scores for oncologists

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and nurse specialists were 39.0 and 39.0 (IQR 38.5 - 40.0 and 36.6 - 40.0, respectively) and median CPQ-12 scores were 29.0 and 29.8 (IQR 28.6 - 30.0 and 28.2 - 30.0, respectively).

Usability and Acceptance Testing Sessions

Ten usability and acceptance testing sessions were conducted from July to October 2024. Each session consisted of 1 patient and caregiver, 1 oncologist, and 1 nurse specialist. All participants only completed 1 testing session. The median duration of each testing session was 70 (IQR 60.5 - 79.5) minutes.

Postsession Surveys

Median SUS scores for patients and caregivers, oncologists, and nurse specialists were 77.5%, 82.5%, and 80.0% (IQRs 70.0% - 86.3%, 80.0% - 90.0%, 75.6% - 94.4%), respectively. Median UTAUT scores for patients and caregivers, oncologists, and nurse specialists were 4.27, 4.33, and 4.23 (IQRs 4.08 - 4.58, 4.00 - 4.63, 3.87 - 4.57, respectively).

ePRO System Usability: Themes and Subthemes

Testing was continued until the point of qualitative data saturation, which was achieved after 10 interviews for each of the participant groups (patients and caregivers, oncologists, and nurse specialists).

Ten themes relating to ePRO system usability were identified (Table 3). Five themes related to the patient-facing Health Hub.

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Table . Themes regarding usability of the electronic patient-reported outcome symptom monitoring system.

Digital Health Platforms and Themes	Illustrative quotes
Patient-facing Health Hub	
The ePRO[a] system was easy to navigate	• "Once I got into it, it was pretty...quick for me to get through." (C1, male) • "Fairly easy...as I got used to it, it'd be extremely easy (to navigate)." (C3, female)
The ePRO survey promoted efficient side effect reporting	• "If you know what your side effects are...it can be quite fast. If you don't have headaches or neuropathic pain...you just scroll past." (P1, female) • "Having it described as mild, moderate and severe...it's actually really great. Diarrhea is a good example...if I have loose, watery stools...a couple of times a week, is that moderate or is that severe? Should I contact the team?...I think the app helps to classify things...which I think...that's really useful." (P6, male) • "I loved the pictures...you can just see...that one's diarrhea and that one's itch." (C3, female) • "Maybe a sweet spot would be all images, but on a single page or even just something to note that there's one of five pages." (P6, male)
Need for improved navigation within Health Hub	• "I actually thought it was very easy for the first time...it's probably because I've been using (the) patient portal so regularly, that the format reminds me of it." (P7, male) • "Those initial first couple of menus, which was a bit like, 'ok, what do I do here and where do I go'...that's a little confusing." (P6, male) • "My one concern is...the trends thing...how important that is and…whether you'd remember to go back up to that menu icon." (C1, male) • "Yes...I think...you open it up, test results, visits, things like that. Something on that (home) page." (P5, male)
Need for improved layout of the "immediate actions" page	• "You could maybe simplify and just say phone patient nurse, self-monitor, here are some links." (P6, male) • "If it says you've got mild, then it should just say, 'here's the link' and it shouldn't go to the link…like, 'here's a library of fifty things'...it should be a hyperlink immediately to the one symptom that's relevant." (O3, female)
Need for improved layout of the "Trends Dashboard"	• "It's good to have the record because it's hard to remember sometimes how bad something was and when it started...I think that's all good to have...the graphs and the records." (P3, female) • "I tend to forget what happened on what date. The nurse asks and I say I don't know, it was a couple of weeks ago. But...if I've logged in or made a complaint or looked at something...with the dates...it'd help them a lot." (P4, male) • "I think when you've highlighted...what your own issues are, you might expect that it'd come...in order, but they're in alphabetical order." (P3, female) • "If it's in alphabetical order, you have to go load more, load more. If there was a button…you type rash, you look for the rash graph. It's quicker." (P2, male)
Clinician-facing Epic EMR[b]	
The ePRO system facilitated efficient collection of side effect data to improve patient care and quality improvement initiatives	• "I really liked the concept. I think this is something that...as nurses have talked about how we can capture data about patients' immunotherapy toxicities because we don't see them that often...you rely on...their own reporting when they are...having their pre-treatment reviews." (N9, female) • "I think...from a data collection perspective and an inability to report what you do and justify why we struggle to keep up...will be helpful. (N1, female) • "Hopefully we'll see trends where we can have nurse-led interventions...this is where we thought we should be putting our efforts in but actually this is what we are missing." (N3, female)

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Digital Health Platforms and Themes	Illustrative quotes
The ePRO system was easy to learn and intuitive to use	• "It was very intuitive as to where to find things, so even though (I was) using it for the first time, I can sort of orientate myself and know which ones to click pretty easily." (O4, male) • "It was intuitive...if we didn't do the session, I think you would figure it out…relatively quickly anyway". (O8, female) • "I think there's nothing really that makes this challenging from our end at all. I don't think it adds workload." (O6, male)
Need for improved navigation to patient ePRO results within Epic	• "I couldn't remember exactly where the results were...I guess that didn't jump out at me…it blended in." (N1, female) • "If possible, have a separate tab on Epic...every time when you open it it'll pop up as a kind of tab." (N10, female) • "...we have on the top right corner several small...icons that light up whenever there's...important results. But if there potentially could be something built that would have from a nurse's point of view…specific to this as symptoms reporter...that would...highlight up there. So when you're in a desktop, you can click that it will just pull up...symptoms which are quite severe and just list out the patients...of grade 3 and above. (O4, male)
Need for optimized display of individual- and cohort-level results	• "I liked the...colour flags. I like that even when it is my first time seeing it on the phone. I could immediately go to severe." (N3, female) • "The ability to show the severity or the severe side effects very quickly with the colour coding...is really helpful." (O1, female) • "Having the ability to filter for a particular body system that you know generally gets a side effect and be able to push the rest to the bottom...if you...go, this one is notorious for GI but not for rash, you could filter it...could put GI at the top." (N8, female) • "What I didn't like particularly was just the amount of scrolling you had to do to get through all the symptoms. Would it be easier if there's something that comes up like just all the ones that are reported as an issue are the ones that come to the top." (N2, female) • "If you could have any indication of trend...that might add more information but not very much screen space." (O6, male) • "I think...have just a touch point that shows admission so that you know that you're going to have an absence of data from that point...as opposed to not being able to appreciate the change in the trend based on a very significant event." (O1, female)
Additional features to facilitate team-based alert management	• "We have 3 and some other units have 5. And they are all working at a different time, different date...you don't want to have...people thinking someone else is doing it." (N10, female) • "It will require the nurses to have the training and knowledge to...make sure that we're following up...the patients...there needs to be clear communication within our teams to make sure we are looking at the data, figuring out which teams need to see it." (N6, female) • "Have a tick box or something so they don't have to see the notes, they can just go 'it's done." (N5, female) • "You need a way of flagging it in like a basket...that it has been addressed." (O8, female)

[a]ePRO: electronic patient-reported outcome.

[b]EMR: electronic medical record.

The ePRO System Was Easy to Navigate

Patients and caregivers described the ePRO system as:

> *fairly easy... it'd be extremely easy (to navigate),* [C3, female]

even after a single training session.

The ePRO Survey Promoted Efficient Side Effect Reporting

Patients and caregivers felt that the ePRO survey facilitated efficient side effect reporting by using plain language, images to aid understanding of side effects:

> *I loved the pictures…you can just see…diarrhea and ... itch,* [C3, female]

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and the "traffic light" color system reflecting the severity of each side effect. Suggestions to improve the efficiency of side effect reporting included displaying all side effects on the first page to shorten the survey or displaying progress through the survey.

Need for Improved Navigation Within Health Hub

The ePRO survey was housed within the broader Health Hub. Many found navigating from the Health Hub home page to the ePRO survey challenging. Other confusing features of the Health Hub included navigating to the "Trends Dashboard":

> *my one concern is...the trends thing... and...whether you'd remember to go back up to that menu icon.* [C1, male]

Suggestions included having an ePRO system icon on the home page to improve navigation to the ePRO survey, naming functions such as the "Trends Dashboard" more intuitively, and removing hyperlinks used to move between pages.

Need for Improved Layout of the "Immediate Actions" Page

The "immediate actions" page indicated what side effects a patient and caregiver had reported, how severe these side effects were, and provided instructions about what to do immediately about their reported side effects. Patients and caregivers felt this page could be optimized by simplifying the language:

> *you could ...simplify and just say phone patient nurse, self-monitor, ...links.* [P6, male]

Clinicians also felt this page could incorporate links to a graph of that person's side effect over time and specific self-management advice, rather than having this a separate task to complete later.

Need for Improved Layout of the "Trends Dashboard"

Patients and caregivers found the "Trends Dashboard" helpful for reviewing past results and noting changes in side effects over time. However, the presentation of the graphs in alphabetical order made it difficult to find relevant side effects:

> *I think when you've highlighted…what your own issues are, you might expect that it'd come…in order.* [P3, female]

Suggestions for improving the usability of these graphs included allowing sorting or filtering of the graphs by newness or severity or enabling people to search for relevant graphs.

Five themes related to the clinician-facing Epic EMR interface:

The ePRO System Facilitated Efficient Collection of Side Effect Data to Improve Patient Care and Quality Improvement Initiatives

Clinicians felt that the ePRO system facilitated proactive, standardized, and systematic capture of side effect data from all patients. Nurses saw value in using aggregated data to inform the business case for additional staff:

> *I think…from a data collection perspective …will be helpful* [N1, female]

or quality improvement initiatives:

> *hopefully we'll see trends where we can have nurse-led interventions...* [N3, female]

The ePRO System Was Easy to Learn and Intuitive to Use

Clinicians found the ePRO system intuitive to use because it was integrated within existing clinician workflows in the Epic EMR. As a result, oncologists felt that the impact on their workload would be minimal:

> *I don't think it adds workload.* [O6, male]

Need for Improved Navigation to Patient Results Within Epic

While clinicians felt navigation within Epic was relatively straightforward, some found the EMR interface cluttered, making it difficult to identify where ePRO results were kept:

> *I couldn't remember exactly where the results were...it blended in.* [N1, female]

Suggestions were made to create a separate "tab" for ePRO symptom monitoring results within the EMR. If this was not possible, then banners that link to an individual patient's results should be made more prominent.

Need for Optimized Display of Individual- and Cohort-Level Results

The "traffic light" color coding of side effect severity was highly valued by both oncologists and nurse specialists for identifying severe side effects quickly. Suggestions to optimize the display of ePRO results included the ability to sort an individual's side effects by newness, severity, or body system, adding treatment-related time points to graphs, and using arrows to highlight side effect trends in the cohort-level dashboards:

> *if you could have any indication of trend...that might add more information...* [O6, male]

Additional Features to Facilitate Team-Based Alert Management

Nurse specialists highlighted that symptom monitoring was often performed by teams of nurses, and that the ePRO system should facilitate team-based alert management:

> *It will require the nurses to have the training and knowledge to…make sure that we're following up...the patients...there needs to be clear communication within our teams...* [N6, female]

Suggestions included adding an acknowledgment system for resolved alerts in the cohort-level dashboard or a system of sending severe alerts to a specific person or "in basket."

ePRO System User Acceptance: Themes and Subthemes

Eight themes relating to the user acceptance of the ePRO system were identified (Table 4). Four themes related to the patient-facing Health Hub:

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Table . Themes regarding user acceptance of the electronic patient-reported outcome symptom monitoring system.

Digital Health Platforms and Themes	Illustrative quotes
Patient-facing Health Hub	
The ePRO[a] system empowered people to self-manage their side effects	• "You report the symptom...if it's not severe...the library will tell you what to do and it's a trusted source...otherwise you have to go to the internet...and sometimes...the advice is not applicable." (P2, male) • "I've had quite a few side effects in my journey...it's really difficult to know what's...important and...difficult to know when you should contact the care team...so having that classified I think is very useful." (P6, male) • "The whole list of fact sheets...I'm wondering whether the one that is relevant to them...comes to the top." (N5, female)
The ePRO system enhanced patient-clinician communication about side effects	• "It's a good way to get across to your clinical nurse consultant...exactly where you are at." (P5, male) • "I felt like it was a bit hard to get to the nurse sometimes, and presumably if they're going to ring back if it's severe, that's really good to know." (P3, female) • "It's a good way of capturing the people who are less likely to call us." (N9, female) • "People should have an understanding of when their submissions have been received, it's been acted on...I'd find that helpful." (C2, male)
ePRO symptom monitoring was a valuable extension to current care	• "Being able to read the side effects...online, is really good...you can keep returning to that as often as you need to." (P7, male) • "When I first started on this journey...I had...been given reams and reams of paper information (which is)...just in the draw. With this system, you can just go there and have a look." (P5, male) • "Some people really like interacting with the technology...tracking their symptoms...this gives them an easy way to do it that's build into something that they would already be using." (N7, female)
Concerns regarding digital equity	• "Some older, really sick people might find this a bit hard to deal with...maybe their specialist would not put them into this program." (P3, female) • "I think carers will be assisting, particularly if the patient hasn't been feeling all that well...so the initial education session for both is important." (C1, male) • "I think there's ways around that...reporting maybe wouldn't be done at home, but it could be done before the consult...with an iPad or something that's maybe a bit bigger...I'm happy to help people do that." (N9, female)
Clinician-facing Epic EMR[b]	
The ePRO system streamlined the process for responding to side effects between clinic visits	• "...it's identifying patients that you wouldn't have necessarily followed up earlier. So definitely identifying the patients that you need to follow up is a good thing because there's patients that have symptoms that aren't contacting us." (N6, female) • "I like the concept a lot, something that will flag...this is...doing the work for us and telling us who we need to call, and for the others that are doing well, they potentially don't need anything." (N9, female) • "I like the ability to run a report once a day...as a pool person, it gives you the ability to...get a quick summary of everyone...and what you need to do for the day." (N7, female) • "If clinicians haven't got a system where they're checking it all the time...the system...tells them (the patients) to call, so it's a double up, which is good." (N6, female) • "It gives some good information that maybe we're not cold calling someone...you've got some information beforehand to go 'I've received this…we're going to have a chat about this." (N5, female)

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Digital Health Platforms and Themes	Illustrative quotes
Excellent alignment of ePRO system with existing Epic workflows	• "I liked how there were multiple ways of doing things...like the treatment plan signing...no one forces you to enroll, but to consider it. If it wasn't there, you'd forget about it." (O2, female) • "We may not be using 'reports' as a usual thing, so that...may be a new step." (N2, female) • "Having not used this system at all on my phone, it's easier to find things on the Epic screen because I use it several times a day but I don't use my phone with the Epic app at all." (N2, female)
The ePRO system was adaptable to each clinician's personal workflow	• "It was integrated pretty well into my normal workflow...it didn't require me to go into any additional section to find exactly where it was." (O4, male) • "I think the nursing side is pretty easy too. Once you get into it, you'll choose which way is easiest for you, if it's open up the application first or...go straight to your report." (N5, female) • "I liked how there were multiple ways of doing things...like the treatment plan signing...no one forces you to enroll, but to consider it. If it wasn't there, you'd forget about it." (O2, female) • "Whether they have access to those notifications or to be able to run those reports on a team...there should be a way within Epic to be able to...allocate them access to it." (N5, female) • "You may not get a reminder in a timely manner on your phone...even when I'm there on my computer, I'm not checking my phone or the Haiku app (Epic Systems Corporation) constantly...a chart alert thing would be good." (O2, female)
Concerns regarding increased workload due to ePRO symptom monitoring	• "I'm wondering if it's open to over-reporting...they just want to be engaged and that could...become more of a hindrance than a help." (P7, male) • "Whenever you give someone power to report their problems...it really is variable on how much people are going to use it...if people report symptoms very...aggressively...which they might feel is a very valid thing to do...I can imagine that overwhelming people quite easily." (O6, male) • "I can see if they are under-reporting, which is always an issue even now...they go 'it's a little bit.' But when you talk to them...oh no, it's 10 times a day I go to the toilet." (O2, female) • "You could see potentially medico-legally, someone reported a severe grade 3...you just signed off and you didn't see it and then you will be legally liable, you didn't respond to the symptoms." (O9, male) • "Would you be able to add...on health hub that...please do not do this after hours?" (N1, female)

[a]ePRO: electronic patient-reported outcome.

[b]EMR: electronic medical record.

The ePRO System Empowered People to Self-Manage Their Side Effects

The ePRO system provided reassurance about how to immediately respond to side effects and was perceived as a trusted source of self-management advice:

> *if it's not severe...the library will tell you what to do and it's a trusted source...otherwise you have to go to the internet...and sometimes...the advice is not applicable.* [P2, male]

Improvement could include prioritizing the presentation of self-management advice in the education library to ensure people can find the relevant advice quickly:

> *the one that is relevant to them...comes to the top.* [N5, female]

The ePRO System Enhanced Patient-Clinician Communication About Side Effects

The ePRO system enhanced patient-clinician communication by providing clear instructions to patients about when and how to report side effects:

> *It's a good way to get across to your clinical nurse consultant…exactly where you are at* [P5, male]

and enabling clinicians to monitor patient symptoms between visits to hospital, particularly

> *the people who are less likely to call us.* [N9, female]

Improvements could include an acknowledgment of ePRO status (ie, whether the survey had been received, reviewed, or actioned by the health care team).

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ePRO Symptom Monitoring Was a Valuable Extension to Current Care

Participants found the ePRO system complemented and reinforced existing patient education about side effects:

> *Being able to read the side effects...online, is really good...you can keep returning to that as often as you need to* [P7, male]

Health Hub was viewed as a "one-stop shop" that contained relevant information regarding all aspects of their care, including appointments and results.

Concerns Regarding Digital Equity

Vulnerable patients and caregivers (including the older adults, those with lower levels of health or digital literacy, and those without access to an appropriate device) may struggle to use the system:

> *Some older, really sick people might find this a bit hard to deal with...maybe their specialist would not put them into this program.* [P3, female]

Allowing proxy or assisted completion might help address this.

Four themes related to the clinician-facing Epic EMR interface:

The ePRO System will Streamline the Process for Responding to Side Effects Between Clinic Visits

The ePRO system streamlined nursing workflows for responding to side effects between clinic visits by flagging severe side effects in real time, thus minimizing the need for ad hoc phone reviews:

> *it gives you the ability to...get a quick summary of everyone...and what you need to do for the day.* [N7, female]

Nurses appreciated that the responsibility for alerting and responding to severe side effects was shared between patients and clinicians. It also streamlined follow-up phone calls by providing preliminary data about the type and severity of side effects.

Excellent Alignment of ePRO System With Existing Epic Workflows

The ePRO system integrated well into existing clinician processes within Epic, ensuring key steps in the symptom monitoring workflow were not missed:

> *I liked how there were multiple ways of doing things...like the treatment plan signing...no one forces you to enroll, but to consider it. If it wasn't there, you'd forget about it.* [O2, female]

Some aspects may require additional training, such as the use of Haiku (the mobile phone version of Epic; Epic Systems Corporation) for receiving severe side effect alerts, or the running of reports to update the cohort-level dashboard:

> *We may not be using 'reports' as a usual thing, so that...may be a new step* [N2, female]

The ePRO System Could Be Adapted to Each Clinician's Personal Workflow

The ePRO system provided multiple ways of performing the same tasks, ensuring it aligned with each clinicians's personal workflow:

> *It was integrated pretty well into my normal workflow...it didn't require me to go into any additional section to find exactly where it was.* [O4, male]

This could be further improved by adapting the system for different clinician preferences (eg, alerts for severe side effects to both the Haiku app and the Epic EMR, routing of alerts to different nurse specialists).

Concerns Regarding Increased Workload Due to ePRO Symptom Monitoring

Reviewing results in real time was viewed as another clinical task to perform within an already resource-constrained environment. There were also some concerns regarding medico-legal liability if severe alerts were not responded to in a timely manner, particularly outside of business hours:

> [You could see potentially medico-legally, someone reported a severe grade 3...you just signed off and you didn't see it and then you will be legally liable, you didn't respond to the symptoms. O9, male]

If a decision was made to turn the system off outside of business hours, participants suggested clearly stating this on Health Hub.

Discussion

Principal Findings

Usability and acceptance testing are critical in the development of digital health care tools, such as ePRO systems, that are fit for purpose and prioritize end-user satisfaction. Usability testing of medical devices is a regulatory requirement of the International Electrotechnical Commission (IEC 62366) [35] and the Food and Drug Administration [36]. However, there are no published examples of usability and acceptance testing of ePRO systems. To address this gap, we conducted formative, mixed methods usability and acceptance testing with end users prior to the implementation of a real-time ePRO symptom monitoring system for people receiving ICI.

We demonstrated high levels of prototype usability and acceptance on quantitative measures. Clinician usability was higher than patient and caregiver usability, whereas acceptance was similar across all participants. This may have reflected the clinicians' higher levels of baseline digital literacy and their familiarity with the Epic EMR interface. In contrast, lower levels of patient and caregiver usability may have reflected lower baseline levels of digital literacy. While all patients and caregivers had prior access to Health Hub, only 2 out of 10 participants (20%) described themselves as "very confident" in using it. As the ePRO survey is contained within Health Hub, the usability of Health Hub more broadly will therefore affect the usability of the ePRO system. This highlights the challenge of embedding ePRO systems within existing EMR infrastructure,

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as the usability of the existing EMR infrastructure may limit the usability of the ePRO system. High levels of user acceptance were identified in the quantitative assessment across all participants.

This work builds upon the existing literature by demonstrating how ePRO system content and features can impact end-user usability and acceptance. Often, usability or acceptance issues are first detected during implementation and then addressed. However, this may affect end-users' attitudes toward the ePRO system, which may be difficult to adjust following a negative user experience. This work, therefore, reinforces the importance of rigorously identifying and rectifying these issues prior to implementation, which may support sustained end-user engagement [37-39]. These findings are consistent with broader evidence from health information technology. Prior research on EMR usability has emphasized similar determinants of user acceptance, including perceived ease of use, workflow integration, and self-efficacy as key predictors of adoption [40,41]. Studies of clinical decision support systems also report that perceived usefulness, explainability, and interface design significantly affect user satisfaction and system uptake [42]. Similarly, work on patient portals demonstrates that usability and user experience depend heavily on perceived efficiency, emotional response, and ease of navigation [43,44]. By situating our ePRO results in this broader usability literature on health information technologies, we show that ePRO systems reflect many of the same human-computer interaction and acceptance challenges observed across digital health platforms. Finally, this work also highlights some of the challenges of optimizing the usability and acceptance of EMR-embedded ePRO systems as improvements may not always be possible to implement and should be considered at the point of system design.

Embedding the ePRO system within Epic had several advantages, including seamless workflow integration and real-time data capture, which was reflected in the participants' qualitative feedback. However, we acknowledge that certain usability challenges, such as navigating within Health Hub and locating results within the Epic interface, may be specific to Epic's menu structure, icon placement, and existing dashboard architecture and not generalizable to other EMRs. Other usability issues, such as the need for intuitive navigation to surveys, optimization of dashboard layout, management of real-time alerts, and digital equity and workload concerns, may reflect more general design and accessibility issues that may be relevant across ePRO platforms. While Epic's widespread adoption in oncology will ensure the findings from this study are relevant, additional testing within non-Epic environments may be necessary to confirm the broader transferability of study findings.

This study has several strengths. First, testing followed best practice guidance outlined by Aiyegbusi [19]. This included assessing the broader IT system in which the ePRO system was nested and performing a combination of "on-site" testing to allow facilitators to observe how well participants interacted with the system and "off-site" testing where patients and caregivers tested in their own environment as this more closely resembled real-life use. Second, a broad range of end users participated, including people of different ages and levels of digital experience, providing varied perspectives on the system's usability. Finally, testing was performed in real-time, enabling testing of both the ePRO system and the clinical workflow. This provided preliminary information regarding the workflow's feasibility which will inform subsequent implementation.

Limitations of the testing included the low number of participants from certain subgroups (eg, culturally and linguistically diverse groups or people with disabilities). Future usability testing will need to be enriched for these subgroups. We performed predominantly formative testing. Summative data (such as time taken to complete tasks) were not collected. While this reflects the status of our ePRO system's development (ie, co-design completed, but prototype yet to be finalized), this will need to be performed in future usability testing. Additional off-site testing for patients and caregivers could also be performed to increase the resemblance to how ePRO symptom monitoring would be conducted in real life. Finally, due to the lack of availability of IT staff, we were unable to make the suggested changes during the current testing period or perform iterative testing. Further testing will therefore be required once these changes have been implemented.

Future research will include additional postrevision usability and acceptance testing, with an emphasis on summative data not collected during the current round of testing. Participants from vulnerable groups, including older participants, those with a disability, and those from culturally and linguistically diverse backgrounds, will be specifically included in this round of testing to ensure the final ePRO system is broadly accessible. Additional strategies to improve digital equity may include structured onboarding (face-to-face demonstrations, step-by-step guides or optional training during routine appointments) to improve user confidence and engagement [45,46], allowing proxy-assisted completion by caregivers or with a clinician during clinic visits [45,47], and offering the interface in multiple languages [46]. This will be followed by implementation and assessment of the sustainability of the ePRO symptom monitoring system, including whether the efforts made upfront to assess usability result in higher levels of sustained end-user engagement.

Conclusion

The ePRO system prototype demonstrated high levels of end-user usability and acceptance. Feedback will be incorporated into future ePRO prototype updates prior to its implementation into routine care. This study highlights the value in comprehensively assessing usability and acceptance prior to implementation to ensure the ePRO system's content and functionality are fit for purpose. This will ensure the benefits of ePRO symptom monitoring are realized in routine cancer care.

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Acknowledgments

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Data Availability

The datasets generated or analyzed during this study are available from the corresponding author on reasonable request. Access may be granted to investigators who submit a proposal that is approved by an independent review committee.

Authors' Contributions

JLK contributed to the study design, data collection, data analysis, interpretation of results, manuscript preparation, and approval of the final manuscript. HF and IZ were involved in data collection, data analysis, interpretation of results, manuscript preparation, and approval of the final manuscript. CR, SB, DH, KB, and MJ contributed to study design, interpretation of results, manuscript preparation, and approval of the final manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Supplementary materials for the usability and acceptance testing study, including pretesting reading materials, the usability testing procedures and interview guide, and the customized Unified Theory of Acceptance and Use of Technology questionnaire.
[DOCX File, 291 KB - formative_v10i1e79694_app1.docx]

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Abbreviations

CPQ-12: 12-item Computer Proficiency Questionnaire
EMR: electronic medical record
ePRO: electronic patient-reported outcome
ICI: immune checkpoint inhibitor
irAE: immune-related adverse event
MDPQ-16: 16-item Mobile Device Proficiency Questionnaire
REDCap: Research Electronic Data Capture
SUS: System Usability Scale
UTAUT: Unified Theory of Acceptance and Use of Technology

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Personalized Glucose Management With AI: Pilot Study Using a Multiarmed Bandit Approach

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Abstract

Background: Personalized behavioral recommendations through mobile apps have proven effective in preventing serious chronic diseases such as diabetes. Recent studies have primarily focused on optimizing personalized recommendations using reinforcement learning. However, the main problem with these approaches is that they focus on behavioral changes and overlook clinical outcomes.

Objective: This study aimed to propose a method for online planning of dietary and exercise recommendations to optimize postprandial glucose levels through behavioral changes directly.

Methods: The proposed method is a multiarmed bandit based on a two-stage reward prediction model, where an action is a combination of the total carbohydrate intake and postprandial walking duration, and the reward is the reduction in postprandial glucose levels. We implemented the prediction of the reward for each action based on the predicted behavioral responses to an action, and subsequently, the postprandial glycemic response.

Results: In a simulation experiment, we demonstrated that the proposed online algorithm can significantly improve postprandial glucose levels with personalized recommendations, compared to the randomized policy. Furthermore, we conducted a small real-world experiment with a simplified proposed method involving a single update of the recommendation policy into a personalized one. For 6 participants, compared to the randomized policy, we observed a 23% improvement, on average, in actual glucose responses along with the behavioral adherence to the recommendations concerning carbohydrate intake and postprandial walking.

Conclusions: The preliminary effectiveness of the proposed method was demonstrated from both the simulation experiment and the small real-world experiment. However, further longitudinal real-world experiments in patients with diabetes are needed to validate and generalize the findings.

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KEYWORDS

diabetes; mobile intervention; personalization; dietary and exercise recommendation; glucose management; multiarmed bandit

Introduction

Background

The global incidence of diabetes has increased considerably in recent years, accompanied by escalating disease severity. This progression has detrimental ramifications, including compromised quality of life, multifarious complications, and expensive surgical treatment. The medical expenses for diabetes are expected to increase to approximately US $2.5 trillion worldwide by 2030 [1]. This has facilitated the urgent need to reduce the severity of diabetes. The recent national clinical practice guidelines [2] state that the basic principle of this preventive treatment is to maintain glucose levels within the normal range. The central strategy to manage glucose levels is to maintain an appropriate lifestyle of eating and exercising [3], in addition to insulin or oral medication. In recent years, technological advances in continuous glucose monitoring devices have helped patients manage their glucose levels with mobile apps at any given time and place, thus promoting self-management [4,5]. However, it is difficult for patients to learn the optimal behavioral action to maintain glucose within a normal range [6]. Therefore, a personalized system that recommends individualized optimal behavioral actions is required to ensure that glucose levels do not deviate from the normal range in the future.

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Over the past decade, it has become possible for patients with prediabetes to self-monitor their glucose levels, along with their lifestyle habits, such as diet and exercise, by visualizing them through an integrated mobile app [4,7]. While this has made it easier for patients to manage their own glucose levels daily, and maintaining high user adherence to such monitoring is achievable, as demonstrated by recent studies reporting over 90% daily adherence [8], learning the best behaviors to avoid abnormal glucose levels remains a significant hurdle [4]. For instance, the total grams of carbohydrates to be consumed or the total minutes of walking exercise to be performed vary from person to person. Therefore, the behavioral recommendations should be automatically generated for each patient by analyzing personal datasets collected daily.

Literature Review

Thus far, there has been significant research on personalized behavioral recommendations through mobile apps for the prevention of chronic diseases, including diabetes [9], and a framework called just-in-time adaptive intervention has been established. In just-in-time adaptive intervention, to improve both the short-term and long-term outcomes, decision rules regarding intervention conditions, such as content, frequency, and timing of recommendations, are personally optimized [10]. For instance, in [11], to promote physical activity in patients with hypertension, many interventions with different conditions were allocated and performed on each patient's timeline, and the best-fitting intervention conditions were identified based on the results of the interventional experiments. While this approach can robustly identify personally appropriate intervention conditions, its practical application for practitioners is constrained by the significant burden associated with prolonged experimental periods and the necessity for patients to undergo multiple interventions that may prove to be suboptimal. This underscores the need to develop more efficient and effective personalization methods.

With regard to the aforementioned factors, recent studies have focused on sequentially optimizing personal intervention conditions using reinforcement learning [12]. Yom-Tov et al [13] proposed a contextual bandit that optimized the message content of exercise interventions for patients with diabetes. In this study, an action is the message content, and a reward is the amount of activity after the recommendation. The individual optimization of message content can be adaptively performed by selecting an action based on a reward using Boltzmann sampling. Liao et al [14] proposed a framework that applies a multistep Markov decision process by introducing a user state, which represents how much intervention to increase daily walking has been received so far. This helps adjust both the intervention content and the intervention frequency to avoid user dropout caused by frequent interventions. However, while the focus of these existing methods is on patient behavior change, it is still inconclusive whether these methods can offer optimal interventions for improving clinical outcomes. For instance, in the case of diabetes, the extent to which the intervention lowers glucose levels is highly significant. In other words, further research is needed to identify the intervention conditions that can lower glucose levels most effectively to the target range.

Some studies have proposed optimizing clinical insulin interventions for people with more severe diabetes using reinforcement learning with an artificial pancreas to directly control their glucose levels [15,16]. When insulin is injected, the glucose level drops immediately. Therefore, the primary goal of such research is to determine the appropriate insulin dose and timing for each patient to ensure that the glucose level remains within the normal range. The action is the insulin dosage, the state is the user's glucose level, and the reward is the normality of the glucose levels after insulin injection. The integration of reinforcement learning helped obtain the optimal insulin dosage for each patient [17]. However, in this type of study, the variations in action were limited to clinical and direct interventions, such as insulin injection, which are not directly controlled by the patient. Incorporating behavioral interventions, such as diet and exercise recommendations, in addition to clinical interventions, is currently regarded as future work [15,16].

Objectives

Altogether, there is a lack of approaches that individually optimize behavioral recommendations such as diet and exercise to control glucose levels. In this paper, we propose a multiarmed bandit algorithm that can individually plan mobile behavioral interventions, making it easy for users to perform and reducing glucose levels after eating (ie, postprandial glucose, which is most likely to become abnormal in the daily lives of people with diabetes). The most novel aspect of the proposed method is the introduction of a two-stage reward prediction mechanism for each intervention: (1) prediction of the actual user behaviors that occur after the intervention, and (2) prediction of the postprandial glucose trajectory from these predicted behaviors.

An overview of the proposed method is provided in Figure 1. The aim is to lower postprandial glucose levels with the intervention (Figure 1A). Here, the action (or arm) is a mobile behavioral intervention that combines recommended amounts of carbohydrate intake and postprandial walking exercise, which have been proven to have specific effects on glucose levels [18,19]. Multiple alternative candidates for these recommended amounts are prepared in advance, and the optimal action for each user is selected based on the reward predicted in a two-stage manner, as provided in Figure 1B. In this reward prediction, the actual amounts of both carbohydrate intake and postprandial walking are predicted for each action candidate. For example, for carbohydrate intake, when a user receives a recommendation to take 60 g of carbohydrates, it is predicted that the participant will take 70 g because the recommended amount is small according to their dietary preference. Second, based on the predicted dietary and exercise behaviors, the temporal trajectory of postprandial glucose levels is predicted. Third, according to the predicted glucose trajectory, batched actions are selected using the ε-greedy method, based on the assumption that the greater the suppression of the increase in postprandial glucose, the higher the reward obtained by a user. Finally, after performing the selected actions using a real intervention, the behavioral adherence and glycemic response models are retrained using the buffer dataset of actual behaviors and glucose, and the parameters are updated accordingly. By repeating this experiential learning cycle, which is composed

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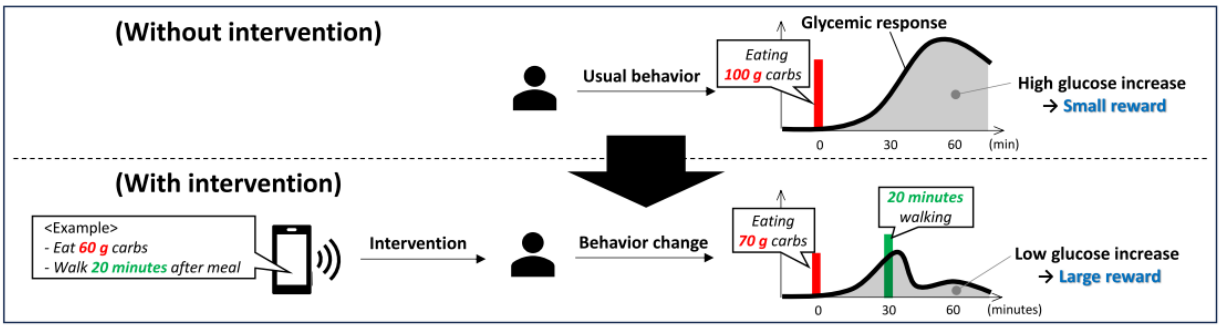
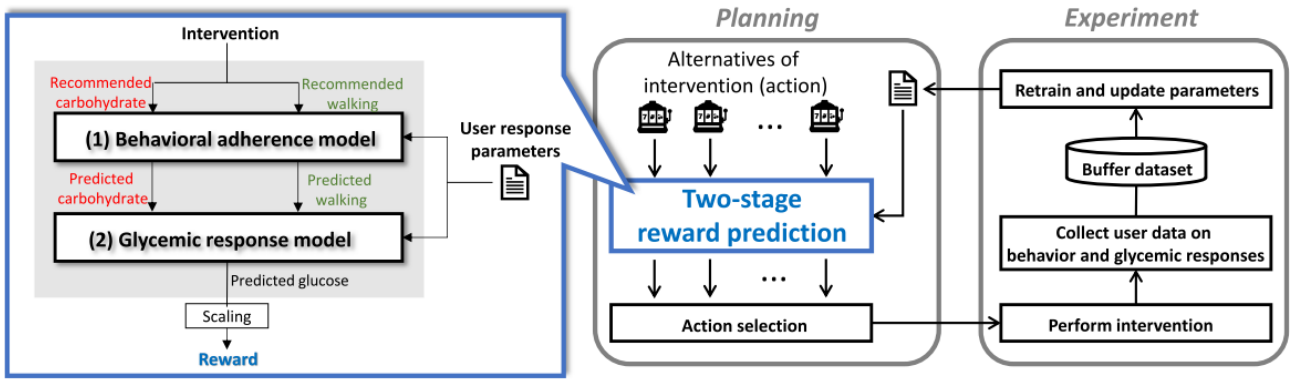
of action planning and real experiments, it is possible to fill the gap between each user's real response and the virtually predicted response, which yields a more optimal action selection for lowering postprandial glucose levels. Furthermore, to accelerate this cycle, we suggest incorporating prior knowledge into the prediction models for retraining.

We demonstrate the effectiveness of the proposed method through simulation experiments and clarify the conditions under which the proposed method works best. Then, with a simplified algorithm based on these conditions, we conducted a small-scale mobile intervention experiment with healthy participants. The results provide preliminary evidence that the proposed method improves both behavior and glucose levels. To the best of our knowledge, this is the first attempt to (1) clarify how to optimize behavioral interventions for improving glucose levels and (2) demonstrate the effectiveness of the method through simulation experiments and real-world intervention experiments.

Figure 1. Purpose of our research (A) and overview of the proposed method (B).



(A) Purpose of our research



(B) Overview of proposed method

Methods

Overview

In the following subsections, we describe the problem setting, the details of the proposed method, the simulation experiment setup, and the real-world feasibility study setup. The proposed method is formulated as a model-based multiarmed bandit framework with a two-stage reward prediction model that integrates behavioral adherence modeling and glycemic response modeling to enable data-efficient personalization of dietary and exercise recommendations. Its effectiveness is evaluated through both simulation experiments and a real-world feasibility study.

Problem Setting

The purpose of our method is to select and recommend the best action candidate for each user that is easy to perform and reduces postprandial glucose levels the most through interaction with the user. For this purpose, a multiarmed bandit algorithm is often used, as in previous literature [13,20,21]. The multiarmed bandit is one of the reinforcement learning methods. It continuously addresses the dilemma of selecting actions to gather more information (exploration) vs selecting actions to maximize immediate reward based on current knowledge (exploitation). Thus, a bandit algorithm can adjust this exploration-exploitation trade-off [22] by estimating the rewards associated with different actions.

In our method, the reward r can be defined as the function of the total increase in postprandial glucose levels after the target diet, which occurs after recommending an action A to a certain user. We mainly focus on postprandial glucose, given that glucose levels always rise after a meal and that deviations from the normal range of glucose levels occur most frequently after a meal [23,24].

An action in our method $A(\in A)$ can be represented as a combination of $A=\{ad,ae\}$, where ad means a recommendation for "how much carbohydrates in grams a user should take at maximum in target diet," and ae means a recommendation for "the minimum duration a user should walk just after target diet." For clarity, users do not directly estimate carbohydrate content; instead, it is automatically calculated by a mobile app such as MyFitnessPal (MyFitnessPal, Inc) based on inputted food items. The accuracy of MyFitnessPal's carbohydrate calculations has

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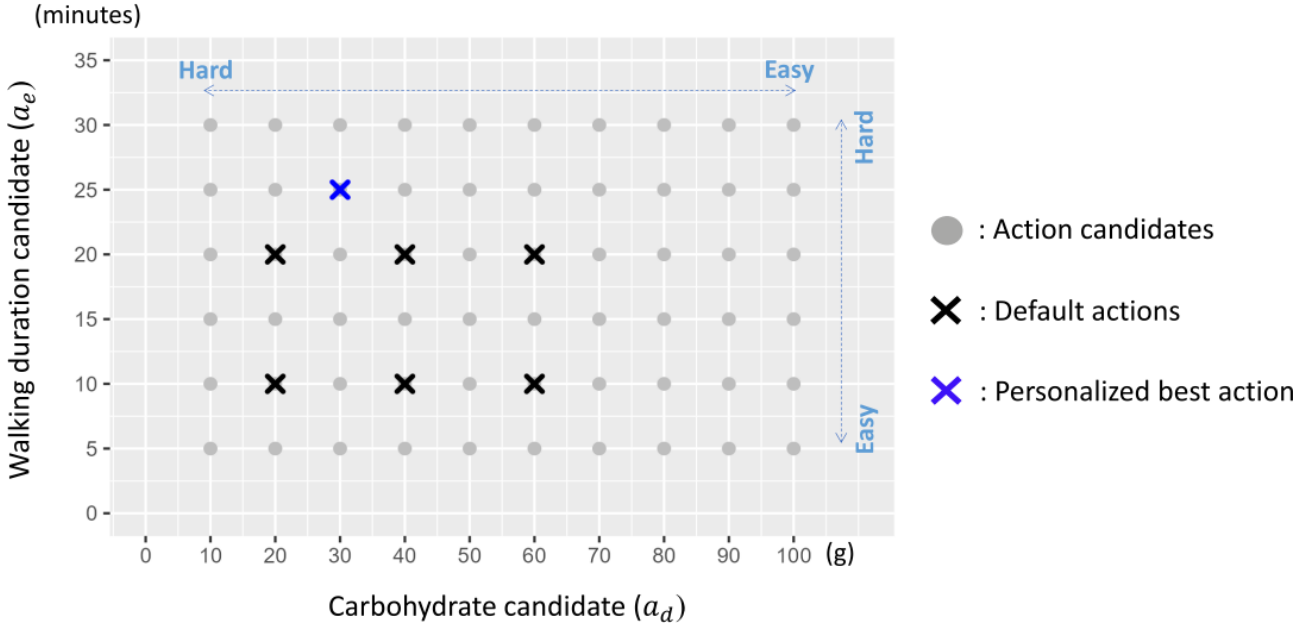
been rigorously validated, showing strong correlations (r=0.90) with established food composition databases [25]. Based on the assumption that each user has their own appropriate amounts for both actions, multiple action candidates are prepared in advance within a clinically plausible range. Regarding the amount of carbohydrate intake (ad), we prepared 10 candidates in the range of 10 - 100 g, referring to the low-carbohydrate diet recommendations [26]. In addition, regarding the amount of postprandial walking exercise (ae), we prepared 6 candidates between 5 and 30 minutes based on the experimental results of the effect of walking exercise on glucose levels [19,27-29]. Therefore, there are 60 action candidates in the action set A based on previous research [19,26-29], as shown in Figure 2.

Figure 2. Illustration of action candidates. For default actions (×), the amount of carbohydrate intake is set within the range of 20 - 60 g, and postprandial walking duration is set within the range of 10 - 20 minutes. Although it is easy to adhere to taking a large amount of carbohydrate and walking for a few minutes, this leads to higher postprandial glucose levels. The main purpose is to find the best personalized action (×) that can achieve lower postprandial glucose levels while maintaining adherence for each user.



Here, there are 2 approaches for action selection in a multiarmed bandit, that is, the experience- and the model-based approaches. The former (eg, Upper Confidence Bound) evaluates each action based on the actual observed rewards, which enables robust evaluation but requires extensive exploration for all actions. In contrast, the latter (eg, Thompson Sampling) can reduce exploratory trials because it can estimate the reward (or value) for each action by learning the parameters of the reward distribution. Returning to our setup (Figure 1A), each observation of the reward (glucose level change) requires users to wear a glucose monitoring device, imposing a recurring physical burden. Therefore, it is important to reduce the burden of exploration trials on users for real applications, and we adopted this model-based approach to predict the reward for untried actions efficiently from limited observations.

Now, the reward prediction model is represented as follows:

$$r=R(A|\Theta)$$

The input is an action A, and Θ is a model parameter set of a target user. Because Θ is unknown at the initial trial, it is sequentially updated when observing user responses to previously recommended actions. Here, the user response is composed of 3 variables, (x,y,z) as shown in Figure 3; x is the actual amount vector of each carbohydrate intake at the target diet, z is the actual walking duration vector of each walking event occurring after starting the target diet, and y is the time series of postprandial glucose levels after the start time of the target diet as $\tau*$. Because the glucose level within 1 hour after a diet is of clinical importance, we focused on user responses within 90 minutes of starting the diet. As a result, for each action, the observed data are represented as D={A,x,y,z} and are added to the buffered dataset B after observation.

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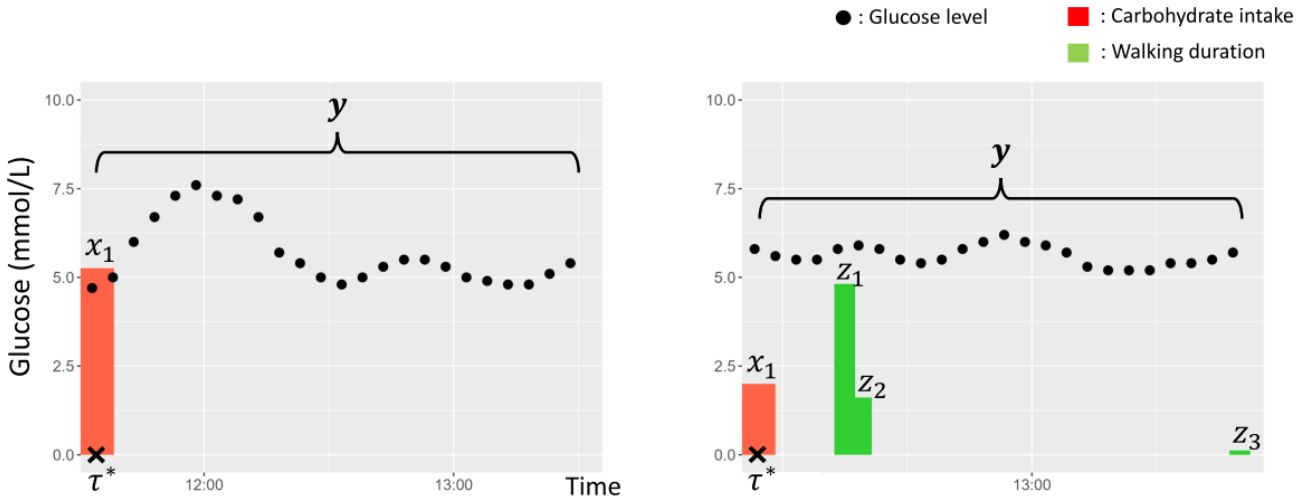
Figure 3. Two examples of observed data with a small reward (A) and a large reward (B). The greater the postprandial increase in glucose levels, the smaller the reward.



(A) Example with small reward **(B) Example with large reward**

Here, glucose levels and behaviors in 1 observation "D" would involve high uncertainty because they may be affected by many factors. Thus, a parameter set "Θ" is updated in a Bayesian fashion when obtaining batched observation data containing "M" actions and "M" user responses. That is, as shown on the right side of Figure 1B, parameter learning is executed after recommending "M" actions to the users. This can be considered as a batched multiarmed bandits setting [30]. Hereafter, the method of selecting "M" actions is referred to as the policy.

Algorithm of the Proposed Method

In this subsection, we describe the proposed multiarmed bandit algorithm based on two-stage reward prediction. The pseudocode for the proposed algorithm is shown in Textbox 1. In this algorithm, the following processes are executed in the given order: (1) actions are recommended to users according to the predetermined policy, and batch observation data are obtained; (2) the parameters of the behavioral adherence and glycemic response models are retrained using these observation data; (3) the reward for each action candidate is predicted using a two-stage reward model with retrained parameters; and (4) finally, the next batch actions are selected based on the reward prediction result using the ε-greedy method.

These processes are repeated to improve the rewards and model parameters. This predictive model–based approach allows the algorithm to estimate potential outcomes of all possible actions based on learned models, rather than requiring direct, burdensome observation for every action candidate. In the first iteration, default actions are recommended for pure parameter exploration, aiming to gather diverse data for initial model parameter estimation. Afterward, as the number of iterations increases, more robust parameter learning can be performed with more observational data, resulting in accurate reward prediction and action selection. However, if the convergence of this parameter learning requires long-term (eg, several months of) observation data owing to the uncertainty contained in the observation, the user would drop out due to the burden of such time-consuming experiments for collecting data. To prevent this, we propose introducing prior knowledge for each parameter and performing Bayesian learning.

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Textbox 1. Algorithm 1: multiarmed bandit with two-stage reward prediction.

INPUT: maximum iteration number *I*, batch size *M*, default policy π1, and action set A.

1. // ***Repeat experimental learning cycle of intervention experiment and action planning for a user***
2. **For***i***in** 1:*I*
3. // *Perform intervention*
4. **For***j***in** 1:*M*
5. Recommend the action Aj=πi (j) for the user
6. Observe the user responses yi,j,xi,j,zi,j …… (†)
7. **End**
8. Update buffered dataset Bi by adding new batch dataDi= j=1M{Ai,j,yi,j,xi,j,zi,j}
9. // *Train each user model from subset of buffered dataset*
10. Train the parameters θd(i) in dietary adherence model from the subset dataBi(d)
11. Train the parameters θe(i) in exercise adherence model from the subset data
12. Train the parameters θg(i) in glycemic response model from the subset data
13. // *Two-stage reward prediction for each action*
14. **For**Ak∈ A
15. Predict dietary behavior xk∗ with θd(i) under action Ak
16. Predict exercise behavior zk∗ with θe(i) under action Ak
17. Predict glucose increase trajectory yk∗ with θg(i) under predicted behaviors xk∗,zk∗,
18. Obtain reward rk from glucose increase trajectory yk∗
19. **End**
20. // *Action selection for next intervention*
21. **If***Rand*() < ε
22. Select actions randomly as πi+1=πrandom= m=1MRandom(A) // for exploration
23. **Else**
24. Select actions greedy as πi+1=π∗= m=1M{argmaxk rk} // for exploitation
25. **End**
26. **End**

Two-Stage Reward Prediction Model

Here, we first focus on describing a two-stage reward prediction model that integrates behavioral adherence models into a glycemic response model. The starting point for modeling is based on previous clinical findings, which state that the changes in postprandial glucose are highly dependent on the amount of carbohydrates an individual takes [31] and the amount of exercise performed after a meal [19,27-29]. Furthermore, these dietary and exercise behaviors are assumed to depend on the kind of actions recommended immediately beforehand. Based on these premises, the reward prediction model is described as follows:

$$(1) R(A|\Theta)=f(y^*(A|\Theta))$$

$$(2) y^*(A|\Theta)=g(x^*,z^*|\theta g)$$

$$(3) x^*=hd(ad|\theta d),\quad z^*=he(ae|\theta e)$$

where R(A|Θ) is the reward, y∗(A|Θ) is the glucose time series, x∗ is the amount of carbohydrate intake, and z∗ is the walking duration. Further, Θ={θg,θd,θe} and θg,θd,θe represent parameters in a glycemic response model, a carbohydrate intake model, and a postprandial exercise model, respectively. These parameters are defined for each user. In actual reward prediction, the first stage is to predict the dietary and exercise behaviors using Equation 3 with behavior adherence models hd(·) and he(·), and the second stage predicts the trajectory of the postprandial glucose increase y∗ using Equation 2 with the predicted behaviors (x∗,z∗). Finally, the glucose increase trajectory is converted into a reward scale using Equation 1.

Behavior Adherence Model

The first stage is behavior prediction. Because each user receives a specific action immediately beforehand, we can assume that they act according to this action. However, certain actions are difficult to execute in real-world scenarios. For example, most users would find it easy to keep their carbohydrate intake less than 100 g, but it is difficult to consume less than 10 g. In addition, the actual reaction to reducing carbohydrate intake to 50 g may vary for each user. This is consistent with the claim in the theory of planned behavior [32], which states that

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behavioral intentions may be influenced by "perceived behavioral control." Inspired by this, in the behavior adherence model, we hypothesize that there is a perceptual critical point specific to each user for each action candidate, as indicated in Figure 2, and that the actual behavioral tendency changes depending on this critical point. Specifically, as shown in Figure S1 (left) in Multimedia Appendix 1, we assume that if the recommended amount of carbohydrate ad is higher than the critical point Xth, the user is likely to try to behave in accordance with the action. In contrast, if ad is lower than Xth, the user is likely to ignore the action and behave normally.

Based on the aforementioned assumptions, the behavior adherence model of carbohydrate intake is represented by the following linear model:

(4)hd(ad|θd)={ad+ex1 (if ad≥Xth)ad+Xnorm(Xth−adXth)+ex2(if ad<Xth)

where θd={Xth,Xnorm} and Xth is the perceptual critical point for a target user, Xnorm is a parameter that represents the normal carbohydrate intake at the target diet. We also introduce Gaussian noises ex1~N(0,σx1) and ex2~N(0,σx2) to represent the uncertainty of carbohydrate intake from other factors. Here, different variance parameters (σx1,σx2) are set because the level of behavioral uncertainty may depend on whether the critical point is exceeded.

Subsequently, the adherence model for postprandial exercise is based on the same concept, as described for carbohydrate intake above. As shown in Figure S1 (right) in Multimedia Appendix 1, if the recommended walking duration ae included in the action is shorter than the perceptual critical point of each user, it is expected to be adhered to. Otherwise, the recommended action is not adhered to, that is, the actual walking duration tends to be zero. Specifically, the exercise adherence model is represented using the following linear model:

(5)he(ae|θe)={ae+ez1 (if ae≤Zth)ae−Zth(ae−ZthZmax−Zth)+ez2(if ae>Zth)

where θe={Zth,Zmax} and Zth is the perceptual critical point and Zmax is the parameter that represents the upper bound of walking duration in terms of the user's physical strength. In this model, it was assumed that the walking time is zero at the upper bound. Further, we introduce Gaussian noises ez1~N(0,σz1) and ez2~N(0,σz2) to represent the uncertainty of exercise behavior from other factors.

Based on these behavior adherence models, each user's dietary behavior parameters θd and exercise behavior parameters θe are inferred according to the buffered observation data Bi accumulated for each user at an iterative time point i. Then, by deploying the inferred parameters θd(i),θe(i) into each corresponding model hd(·),he(·), the behaviors x∗(i), z∗(i) in response to each action candidate can be predicted.

Glycemic Response Model

Next, the postprandial glucose trajectory y∗ is predicted based on each behavior x∗,z∗ predicted for action A. Our approach models this trajectory based on the clinical findings. First, it is well known that glucose levels increase with carbohydrate intake. For example, Ashrafi et al [33] showed that the actual postprandial glucose trajectory could be fitted by a response curve to carbohydrate intake. Second, it has been proven that exercises, such as walking, immediately lower glucose levels, as previously mentioned in this "two-stage reward prediction model" subheading [19,27-29]. The mechanism is that energy expenditure in muscle tissues due to exercise causes glucose absorption for energy supply [34]. For example, Jankovic et al [35] and Xie and Wang [36] adopted a linear additive model to predict the glucose trajectory and showed that predictive performance was improved by adding the exercise effect on glucose as a factor, in addition to the carbohydrate intake effect. Based on this glucose modeling, we hypothesized that the observed postprandial glucose trajectory y can be represented based on the summation of the response curve Rd to carbohydrate intake and the response curve Re to exercise to the baseline preprandial glucose level ybase, as follows [37]:

(6)y=ybase+Rd(x,τx)+Re(z,τz)+ey

Because the time range of the glucose trajectory that we focus on here is short-term, we assume that the baseline value ybase is constant and substitute the average of the glucose history from 15 minutes before starting the target diet. Here, ey is the vector of Gaussian noise following N(0,σy). The response curves Rd,Re are represented by the following equations:

(7)Rd(x,τx)=∑i=1Phdiexp(−0.5(Δi−3αd)2αd2),hdi=βdxi,Δi=t−τx,i

(8)Re(z,τz)=∑j=1Qhejexp(−0.5(Δj−3αe)2αe2),hej=βezj,Δj=t−τz,j

where τx,i,τz,j represents the time of event occurrence of the *i*th carbohydrate intake or the *j*th walking event, respectively. Further, P represents the number of carbohydrates consumed within the target diet, usually P=1. Also, Q represents the number of walking events that occurred within 90 minutes of starting the target diet. In these equations, we adopted a bell-shaped function as the response curve, similar to that in previous works [33,38], owing to its interpretability and the small number of parameters. Some specific examples of each response curve, Rd,Re are shown in Figure S2 in Multimedia Appendix 1. This response curve starts at the timing of event occurrence τx,i,τz,j. The response curve is then amplified based on the amount of carbohydrate intake xi or the duration of each walk zj. Here βd,βe is a parameter that represents the degree of amplification with respect to the volume of each behavior. Further, αd,αe is a parameter that represents the degree of time delay of the response. A hyperparameter of the prior is introduced for each parameter βd,αd,βe,αe, and we describe how this can be obtained in the subsequent "Parameter Learning" subheading.

Based on the above setting, specifically defined by Equations 6-8, it can be seen that the parameters of our glycemic response model θg={βd,αd,βe,αe} for each user are estimated from the observed behavior sequence (x,z) and glucose trajectory (y), at each iteration point (i). In this parameter learning, we use the observed behaviors (x,z) rather than the predicted behaviors (x∗,z∗) as training data to identify the parameters more accurately, reflecting the real relationship. In contrast, the predicted behaviors (x∗,z∗) are used as inputs for reward prediction for the action candidate A. Accordingly, the predicted postprandial trajectory is represented as follows:

(9)g(x∗,z∗|θg)=Rd(x∗,τx∗|βd,αd)+Re(z∗,τz∗|βe,αe)

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where the baseline term is removed compared to Equation 6. This is because the baseline term does not contribute to the glucose increase and, hence, the reward. Then, $y*(A|\Theta)=g(x*,z*|\theta g)$ represents the series of pure increase of postprandial glucose affected by behaviors. It should be noted that for each iteration (i), the estimated parameter values $\theta g(i)$ are used as θg in these equations.

Finally, the glucose increase trajectory, $y*$, is converted into a reward scale. The reward should be designed such that the smaller the degree of glucose increase, the higher the reward. We use the incremental area under the curve (iAUC), a traditional glucose metric [39], as the degree of glucose increase. Based on these factors, we perform reward conversion using the sigmoid function, as shown below:

$$(10) f(y*)=11+\exp\{a(iAUC-b)\}$$

$$iAUC=\sum t=\tau*\tau*+Tyt*$$

where iAUC is the total value of the trajectory of glucose increase. As described in the "Problem Setting" subheading, $\tau*$ denotes the start time of the diet, and T=90 minutes. a,b are parameters for the conversion from the iAUC to the reward scale. We set a=−3 and b=1 empirically, based on the distribution of the iAUC. Consequently, the reward value ranges between 0 and 1.

Thus, for each action candidate A, a reward calculated from postprandial glucose increase $R(A|\Theta)=f(y*(A|\Theta))$ is predicted based on our original two-stage prediction.

Action Selection

After the reward is predicted for each action candidate, the policy for selecting batched actions for the real intervention is selected. Specifically, the action that maximizes the predicted reward is selected. However, the predicted reward is not always accurate due to overfitting caused by scarce training data at the initial stage. Moreover, if the action is always selected to maximize that reward, the real action for the user becomes fixed, and the observed user response subsequently exhibits a small variation, which also leads to overfitting. Therefore, we adopt the ε-greedy method for balancing exploration and exploitation. For exploitation, assuming that the prediction model is accurate, actions that maximize the reward (π) should be selected. For exploration, assuming that the prediction model needs to be trained more, actions are selected randomly (πrandom). Such policies $\pi*$ and πrandom are taken with probabilities of 1−ε and ε, respectively. Because parameter learning is performed in a batched manner, M actions are selected simultaneously for each policy. Therefore, $\pi*$ and πrandom are represented as follows:

$$\pi*=\mathrm{m=1M}\{\mathrm{argmax_k}\, R(Ak|\Theta)\}, \pi\mathrm{random}=\mathrm{m=1M}\mathrm{Random}(A)$$

where, *Random*(A) represents an operation for extracting an element randomly from a set A. Specifically, in πrandom, this operation is repeated M times independently.

Parameter Learning

The learning of the parameter set $\Theta=\{\theta g,\theta d,\theta e\}$ in the reward model is performed at each iteration time just after M-intervention experiments are finished, and the batched observation data are accumulated in the buffered dataset. In this learning, all the buffered datasets accumulated up to the ith iteration point are used. If the ith batch of data Di are observed, the training dataset at that time becomes Bi= j=1iDj. The batched data includes a history of 4 types of data (action, postprandial glucose level, amount of carbohydrate intake, and postprandial walking duration) for M target meals. This is represented as Dj= m=1M{Aj,m,yj,m,xj,m,zj,m}. In the observation data, carbohydrate intake and postprandial walking can occur multiple times per target diet. Therefore, they are represented as vectors (recall Figure 3B). In practice, $\theta g,\theta d,\theta e$ are separately trained from the following subsets of the buffer data Bi(g),Bi(d),Bi(e) for each parameter.

$$Bi(g)= j=1i[\ m=1M\{yj,m,xj,m,zj,m\}],$$

$$Bi(d)= j=1i[\ m=1M\{Aj,m,xj,m\}],$$

$$Bi(e)= j=1i[\ m=1M\{Aj,m,zj,m\}].$$

Here, Bi(g),Bi(d),Bi(e) are the training datasets for the glycemic response, dietary adherence, and exercise adherence models, respectively.

To improve the efficiency of this learning process, we introduce prior distributions for each parameter. Specifically, for obtaining prior information for the behavioral parameter sets $\theta d,\theta e$, we ask each user to answer questions corresponding to each parameter beforehand and use the responses to define the prior distribution. For example, the question for the critical point Xth is "If you were to reduce carbohydrates in your dinner, what would you say is the minimum amount of carbohydrates?" Then, the user's answer is set to the mean μXth of the Gaussian prior distribution $N(\mu Xth,\sigma Xth)$. For the other parameters Xnorm,Zth,Zmax, each prior distribution is set similarly.

On the other hand, the glycemic parameter set θg cannot be clarified through user interviews because each parameter is related to a complex individual biological response. Therefore, we adopt a data-driven approach wherein the prior distribution is pretrained through the original upstream task. Before starting the first intervention experiment, we recruited additional participants belonging to the same disease group as the target users. Second, we collect a glucose dataset, D(g)= l=1L{yl,xl,zl} for L diet events from each participant. Third, this dataset is used to infer glycemic parameters θg for each participant. Finally, the distribution of these parameters θg among all participants is used as the Gaussian prior distribution of θg. Specifically, the mean $\mu\sim g$ and the variance $\sigma\sim g$ of these parameters θg are set as $N(\mu\sim g,\sigma\sim g)$. Here, each parameter θg is assumed to be generated independently.

Through this process, each prior distribution of the parameter set $\theta g,\theta d,\theta e$ is obtained before the first intervention experiment, and this prior is used for Bayesian parameter learning at every iteration time point. This parameter learning is performed by executing a Markov Chain Monte Carlo simulation with the No U-Turn Sampler implemented in RStan (Stan Development Team) [40].

Simulation Experiment Setup

We studied in a simulation experiment whether our online algorithm can improve postprandial glucose levels with personalized recommendations. In addition, to carry out real

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experiments with real personalized recommendations, we investigated the best setting for the proposed method to maximize performance. Specifically, we aim to clarify the following questions through simulation experiments:

- Q1: In action selection, how should the trade-off point between exploration and exploitation be set to maximize the cumulative reward?
- Q2: How fast does parameter learning converge when introducing a prior distribution into the reward prediction model?

To answer these questions, we set up several virtual users who exhibited different behavioral and glycemic responses, performed repeated action planning and pseudo-intervention experiments using the proposed method for each user, and evaluated these experimental results to address the above questions. At the same time, we also show that by introducing the proposed method, the reward performance can be improved compared to selecting default actions uniformly.

Virtual User Setting

In the real world, behavioral tendencies and glycemic responses differ from user to user. Therefore, in this simulation, a parameter set θg,θd,θe for each user was set to ensure that virtual users exhibit response patterns as diverse as possible. Table 1 shows the actual settings of parameter values for each user. The total number of virtual users was 10.

Table . User settings for each parameter.

Virtual user	Dietary adherence model		Exercise adherence model		Glycemic response model			
	Xth(g)[a]	Xnorm(g)[b]	Zth(min)[a]	Zmax(min)[c]	βd[d]	αd[e]	βe[d]	αe[e]
ID1	50	100	20	60	0.05	20	−0.15	6.0
ID2	30	60	10	40	0.05	20	−0.20	8.0
ID3	70	120	30	80	0.05	20	−0.15	6.0
ID4	90	120	5	40	0.05	20	−0.20	8.0
ID5	50	100	20	60	0.04	15	−0.15	6.0
ID6	70	120	10	60	0.04	15	−0.20	8.0
ID7	30	60	30	80	0.04	15	−0.15	6.0
ID8	90	120	5	30	0.04	15	−0.20	8.0
ID9	10	40	30	80	0.04	15	−0.20	6.0
ID10	10	40	5	30	0.05	20	−0.20	8.0

[a]X_{th} and Z_{th}: perceptual critical points for carbohydrate intake and postprandial walking duration (Equations 4 and 5).

[b]X_{norm}: normal carbohydrate intake (Equation 4).

[c]Z_{max}: upper bound of walking duration (Equation 5).

[d] β_d and β_e: the degree of glycemic amplification of carbohydrate intake and postprandial walking duration (Equations 7 and 8).

[e] α_d and α_e: the degree of time delay of the glycemic response to carbohydrate intake and postprandial walking duration (Equations 7 and 8).

As an example of user diversity, it is difficult for user ID4 to reduce carbohydrate intake because of Xth=90, whereas user ID9, with Xth=10 finds it easy to reduce carbohydrate intake. User ID4 also has βd=0.05, indicating a greater glycemic response to carbohydrate intake, while user ID5 has a lower glycemic response due to βd=0.04. Thus, each parameter value was set differently for different users. The value ranges of the behavior parameters θd,θe were within the range of the action set shown in Figure 2. These ranges were defined following established dietary and exercise guidelines. Specifically, the minimum carbohydrate intake (Xth) for virtual users was set with reference to “very low-carbohydrate” diets (20 - 50 g/d) and “low-carbohydrate” diets (<130 g/d) as defined by Oh et al [41], while the normal carbohydrate intake (Xnorm) was guided by typical daily carbohydrate intake levels (200 - 325 g/d) as described in the literature [26]. For the parameters of postprandial walking durations (Zth,Zmax), typical ranges in prior experimental studies (5 - 30 minutes) [19,27,29] and recommendations for at least 10 minutes of walking [27] informed the setting of Zth, and cases of walking up to 90 minutes [28] guided Zmax. To introduce a diverse range of realistic individual differences among virtual users, slight deviations from these foundational literature values were sometimes permitted. Nevertheless, the chosen parameter ranges for virtual users in Table 1 do not drastically diverge from the prior information collected from real participants (in Table 2), suggesting that the simulated settings are not unrealistic. In addition, the value ranges of the glycemic parameters θg were set based on the prior knowledge obtained in the upstream task.

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Table . Prior information on behavioral parameters.

Parameter	Questionnaire	ID1	ID2	ID3	ID4	ID5	ID6
Xth	"If you were to reduce carbohydrates in your target diet, what would you say is the minimum amount of carbohydrates?"	50 g	50 g	30 g	30 g	50 g	50 g
Xnorm	"How much carbohydrates in grams do you typically consume in your target diet?"	110 g	90 g	50 g	50 g	70 g	150 g
Zth	"If you were to walk after your target meal, how long do you think you could walk each day?"	30 minutes	15 minutes	15 minutes	20 minutes	25 minutes	5 minutes
Zmax	"Based on your physical fitness, how long do you think you can continue walking?"	60 minutes	60 minutes	180 minutes	60 minutes	40 minutes	120 minutes

User Response Simulator

Next, to perform the simulation experiment, it is necessary to generate a pseudo-response to any action according to each user setting. Therefore, we developed a user-response simulator that outputs 3 responses (dietary, exercise, and glycemic) to 2 inputs (an action and each parameter value), as shown in Figure S3 in Multimedia Appendix 1.

In this simulator, the simulated dietary behavior and exercise behavior for an action are the first outputs, and a simulated glucose trajectory is generated based on these behaviors. First, the simulated behaviors are pre-estimated according to the corresponding behavior adherence model in Eqs 4 and 5 by setting the input parameter values of the virtual user and input action A={ad,ae}. Subsequently, by perturbing the simulated behaviors by adding Gaussian noise, we obtain the final simulated behaviors $x\check{}$,$z\check{}$. Here, the perturbation noise for carbohydrate intake followed N(0,10), and the noise for postprandial walking duration followed N(0,5). Subsequently, these simulated behaviors, $x\check{}$,$z\check{}$ are input into the glycemic response model (Equation 9), and the obtained trajectory is then perturbed by adding Gaussian noise to generate the final simulated glucose trajectory $y\check{}$. In this perturbation, a time-independent noise following N(0,0.02) was added. Figure S4 in Multimedia Appendix 1 shows a representative example of these simulated responses.

By substituting the part (†) of the pseudocode in Algorithm 1 (Textbox 1) with the above simulator, it is possible to simulate repeated experiential learning cycles of action planning and intervention experiments, as shown in Figure 1B, for each virtual user.

Simulation Evaluation Settings

To answer the question (Q1), we tracked how the actual cumulative reward changes depending on the settings of the proposed method while changing them. One of the most significant settings is the balance of exploration and exploitation in action selection, which is determined according to the set value of ε, a hyperparameter of the proposed method. Therefore, we set multiple patterns of ε values and investigated which setting yielded the highest cumulative reward. For these value patterns, we considered ε=1.0 for random selection, ε=0.5 for high, ε=0.2 for medium, and ε=0.01 for low condition of ε.

Another significant setting is the introduction of prior distributions for each model parameter. Thus, we also investigated how the cumulative reward varied depending on whether the prior distribution was used in parameter learning. In this simulation, prior knowledge of the behavioral parameters {Xth,Xnorm,Zth,Zmax} was pseudo-generated by adding Gaussian noise to the true parameter values. This may be attributed to the fact that the results of the survey questionnaire are subject to the human cognitive errors of each user regarding their true behavior, and these cognitive errors are assumed to follow Gaussian noise. On the other hand, to set the prior distribution of the glycemic parameters {βd,αd,βe,αe}, the mean and the variance of the true values among all users were substituted. The initial batch of 6 actions was based on past clinical findings (refer to Figure 2). From the second iteration (i≥2), action selection was performed by integrating the proposed method under each setting.

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Metrics

Specifically, the cumulative reward of the virtual user (n) at iteration of the experiential learning cycle (i) can be represented as follows:

$$Gn(i)=1i\times D\sum j=1i\sum d=1Drj,d,n$$

where rj,d,n represents the actual reward transformed by Equation 10 from the glucose trajectory y˘ of the virtual user n after the dth target diet in the jth intervention experiment. Further, D is the number of target diets included in each experiment; and D=6 was used in the simulation. The average cumulative reward of N virtual users, which is used as an evaluation metric, can be represented as follows:

$$J(i)=1N\sum n=1NGn(i)$$

By increasing i to the maximum iteration time I, we can track how the metric J(i) changes depending on each condition of ε. Considering the burden on users in real experiments, I was set to 10. This means that each user must continue wearing the necessary sensors to collect user responses for a maximum of 60 meals when D=6.

In this simulation, the true value of each parameter for each user was known, as listed in Table 1. This enables the investigation of the estimation error of each parameter for any setting of our method. To answer the question (Q2), we investigated how the estimation error changes as the iteration time increases (ie, the amount of training data), with and without prior distribution. The estimation error was defined as follows:

$$p(i)=|\theta\hat{}p(i)-\theta p||\theta p|\times 100$$

This corresponds to the standard error (%). p is the parameter number, θp is the true value of the parameter in Table 1, and θ^p(i) is the estimated value of the parameter in the ith iteration time.

Real-World Feasibility Study Setup

Additionally, we conducted a preliminary set of short intervention experiments with real users using the proposed method, based on the simulation results. This experiment was positioned as a pilot study before conducting a full-scale study. The purpose of this experiment was to explore the feasibility of whether postprandial glucose levels can be improved in real users after recommending actions updated by the proposed method compared to default actions. Accordingly, in this study, we compared the performance when default actions were selected in the first experiment (referred to as the "default policy") with the performance when actions were selected by the proposed method in the second experiment (referred to as the "optimized policy") using a within-participant study design, to evaluate the feasibility of the proposed method. The optimized policy was updated from the observed participant responses in the first experiment, following the proposed method.

Experimental Protocol

First, we recruited 6 healthy participants (4 men and 2 women) as real users from April 2023 to July 2023. Because this experiment was the first feasibility study, the target group was healthy rather than diabetic. All participants were researchers at Aalto University and the University of Helsinki.

Next, each participant was assigned the goal of reducing postprandial glucose levels to prevent diabetes. To achieve this goal, the participants received daily recommendations for the target diet, including total carbohydrate intake and postprandial walking duration, via a dedicated smartphone app. The target diet was either dinner or lunch each day, and the participants chose according to their lifestyle preferences. While the recommendations in the first experiment were preset to default actions, those in the subsequent experiment were preset to actions selected by the proposed method. Participants were free to choose whether to follow the recommendations and to act accordingly. To collect a participant's behavioral and glycemic responses to the recommendation actions, they wore a continuous glucose monitoring device and an activity tracker.

This process of mobile intervention and data collection for each participant was carried out for 6 days in the first experiment and for 3 days in the second experiment. Because the first experiment corresponded primarily to the exploration phase and the second experiment corresponded to the exploitation phase, the number of days in the second experiment was set to be short.

Recommendation of Action

An action was delivered as a recommendation in a notification app on a dedicated smartphone (iPhone 12), which was provided to each participant. In the notification app, a dedicated message including the action was delivered along with a notification sound, a few hours before the target diet. The frequency and duration of this recommendation were predetermined according to participants' preferences.

An example of this message appearing on the smartphone screen is "Eat less than 60 g of carbohydrates at dinner, and walk for more than 20 minutes just after dinner." Depending on the selected action, the amount of carbohydrate and postprandial walking duration in the message changed. For default actions in the first experiment, carbohydrate intake (ad) was within the range of 20 - 80 g, and the postprandial walking duration (ae) was within the range of 5 - 20 minutes, considering the participants' preferences and previous literature [19,26-29]. For example, in the second experiment, actions were selected based on the two-stage reward prediction results of each action candidate; therefore, they were not always within this range. This reward prediction was attained by setting the parameters learned from the user response data obtained in the first experiment.

Response Data Collection

For user response data, we collected data related to the participant's continuous glucose levels, physical activity, and food records. Figure 4 illustrates how the data were collected. Continuous glucose measurements were collected every 5 minutes using a Guardian Connect medical device (Medtronic Inc), which was inserted on the participant's skin. At the same time, physical activity data were collected using the activity tracker Vivosmart 3 (Garmin Ltd), which was worn on the participant's arm. To mitigate erroneous detection of walking from various daily movements, the device identifies a walking event when characteristic arm movements indicative of

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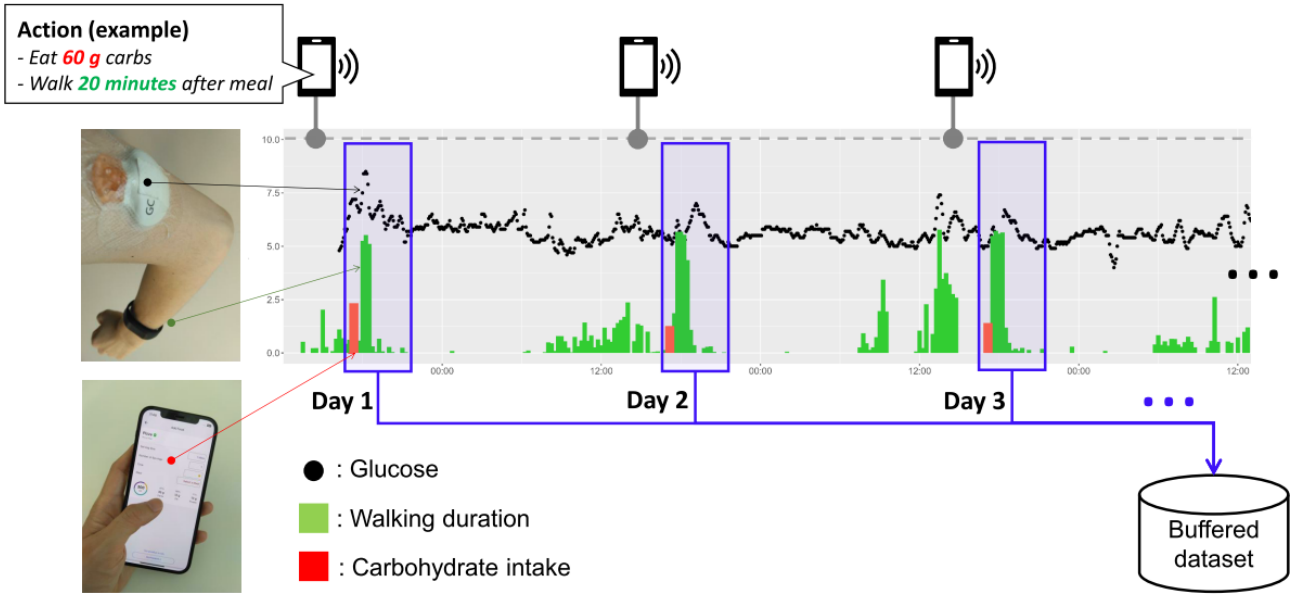
continuous walking are detected for a duration exceeding a certain minimum threshold. The physical activity data included the start time and duration of each walking event that was automatically detected by the device. A dedicated fitness tracker was chosen over participants' personal smartphones to ensure data consistency and reliability across participants, as smartphone usage and carrying patterns (eg, in a pocket or bag) can vary significantly and lead to inconsistent activity detection. This approach also minimizes issues related to battery drain on personal devices and addresses potential privacy concerns by avoiding continuous access to personal smartphone data. The glucose and activity data were continuously sent to a dedicated iPhone through a Bluetooth connection with each device. In addition, a food diary, including the amount of carbohydrates and the start time of each target diet, was recorded manually by the participant. The carbohydrate content was automatically calculated using the mobile app MyFitnessPal by inputting all food contents and amounts.

Finally, because we focus on the improvement of postprandial glucose levels, we extracted postprandial segment data from the longitudinal time series as user response data for each action. Specifically, the segment data were defined from the start of each target diet until 90 minutes later, as shown by the blue frames in Figure 4. Each data segment was added to a buffered dataset.

Figure 4. Illustration of response data collection.



Metrics

The evaluation was based on whether the reward related to postprandial glucose increased in the second experiment compared to the first. Therefore, we set the following metric as the actual reward average J′(i) for all diets of all *N* participants in the *i*th experiment, and this metric was compared between the first and second experiments.

$$J'(i)=1N\sum n=1NGn'(i),Gn'(i)=1D\sum d=1Dri,d,n$$

It should be noted that the actual reward ri,d,k is transformed by Equation 10 from the glucose increase trajectory, which is obtained by subtracting its baseline derived from preprandial glucose levels from the observed glucose trajectory y.

Acquisition of Prior Knowledge

To introduce the prior distribution of the behavioral parameters, each participant was asked to answer a questionnaire before starting the experiment. As described in the "Parameter Learning" subheading, the result was set as the mean value of the prior distribution of the corresponding parameter. Table 2 shows the actual answers for each parameter together with the corresponding question. It can be observed that the values vary according to the participant. As for glycemic parameters, we estimated the prior distribution N(μ~g,σ~g), which is common to target participants, using the glucose dataset from other participants. To obtain this, we recruited 4 additional healthy participants and collected continuous glucose levels, physical activity, and food records around lunchtime over 6 days for each participant in the same manner, as described previously. Consequently, a total of 6 segment data were obtained for each participant, as shown in Figure 4. Then, after estimating the glycemic parameters θg for each participant using his segment data, the parameters μ~g,σ~g were calculated among 4 participants, as described in the "Parameter Learning" subheading in this section. As a result of this calculation, we obtained $\mu\sim g=\{\mu\sim\beta d,\mu\sim\beta e,\mu\sim\alpha d,\mu\sim\alpha e\}=\{0.047,-0.148,19.07,6.22\}$ and $\sigma\sim g=\{\sigma\sim\beta d,\sigma\sim\beta e,\sigma\sim\alpha d,\sigma\sim\alpha e\}=\{0.028,0.035,1.91,0.39\}$.

Ethical Considerations

The study was approved by the Aalto University Research Ethics Committee (Treatment Planning Project/08.06/2023). Written informed consent was obtained from all participants before the start of the experiment. Direct identifiers were removed, and data were pseudonymized and stored securely. No personal data were shared with third parties. Additionally, to ensure participant safety, participants were informed orally and via the consent form that they could withdraw at any time if they experienced discomfort or unease.

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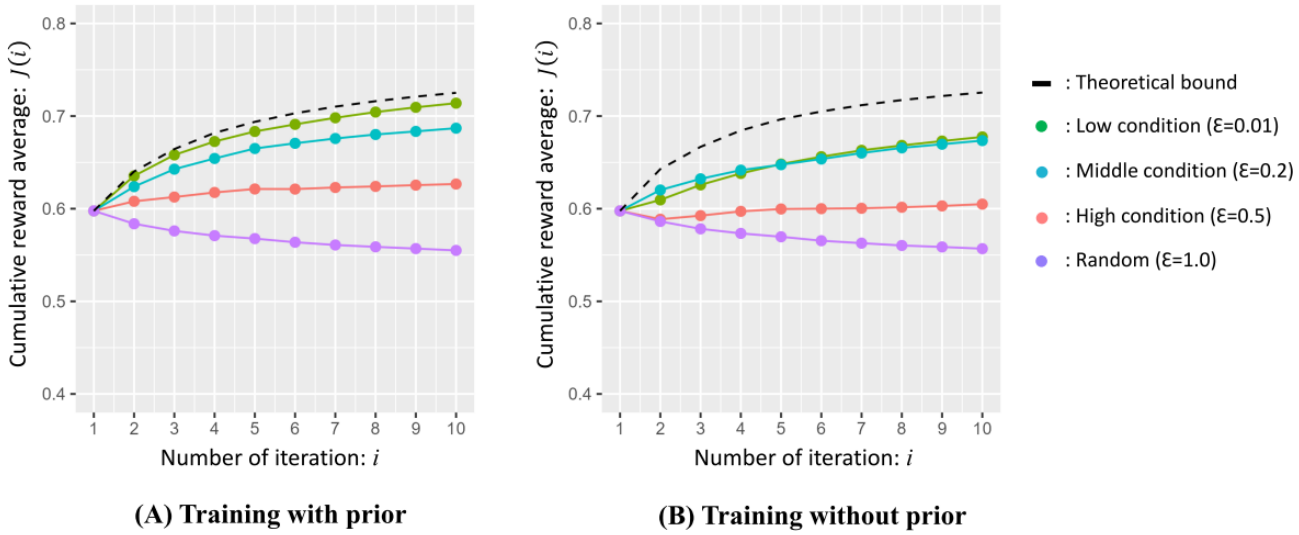
Results

Simulation Experiment Results

We present the simulated results of the average cumulative rewards (J(i)) with and without prior distribution in Figure 5. First, in any case, when an action selection by the proposed method is adopted (ie, when ε is other than 1.0), we can confirm that the cumulative reward gradually increases from the second iteration (i=2) after executing default actions at the first iteration (i=1). This demonstrates the effectiveness of action selection by the proposed method in the second and subsequent iterations (i≥2). Regarding question Q1, by focusing on the variation of ε, we can also confirm that the smaller the value of ε, the greater the accumulated reward, and the maximum cumulative reward is obtained when ε=0.01.

The theoretical boundary of the cumulative reward is shown by the black dotted line in Figure 5, and it is calculated as an ideal condition, wherein the true parameter values are known and used for action selection from the second iteration. The cumulative reward for ε=0.01 with prior knowledge shows almost the same value as that in this theoretical bound. In other words, when prior knowledge is introduced, exploration with the policy πrandom is unnecessary, and the best performance can be attained by full exploitation with the policy π that maximizes the predicted reward from the beginning. On the other hand, in the case without prior knowledge in Figure 5B, the cumulative reward decreases significantly when ε=0.01 and 0.2 are compared with the case with prior knowledge in Figure 5A. In particular, when ε=0.01, the decrease in the second iteration is remarkable.

Figure 5. Simulation results of average cumulative reward with prior distribution "(A)" and without prior distribution "(B)" of the proposed method.



(A) Training with prior **(B) Training without prior**

Next, regarding question Q2, we show the actual changes in the parameter estimation error (p(i)) of the behavioral adherence and glycemic response models in Figure 6. First, it can be seen that the case without prior knowledge (▲) has a larger estimation error than the case with prior knowledge (■) for the first iteration. This large error leads to a prediction error of the reward for each action candidate and therefore makes it easier to select worse actions with the policy π*. This may be the reason why the cumulative reward decreases immediately in case ε=0.01 and 0.2 due to the erroneous action selection at i=2 in Figure 5B. Furthermore, in the case without prior knowledge, it can be seen that the estimation errors of some parameters (such as Zmax,αe) are not improved as iteration time of experiential learning cycle increases. This indicates the potential risk in real experiments, showing that it is impossible to collect the necessary training data for stable parameter learning, even when imposing heavy burdens of repeated interventions on users. However, when introducing prior knowledge, we can confirm that the parameter errors are minimized from the first iteration for most parameters. This suggests that introducing prior knowledge can eliminate the burden on users and maximize their cumulative rewards.

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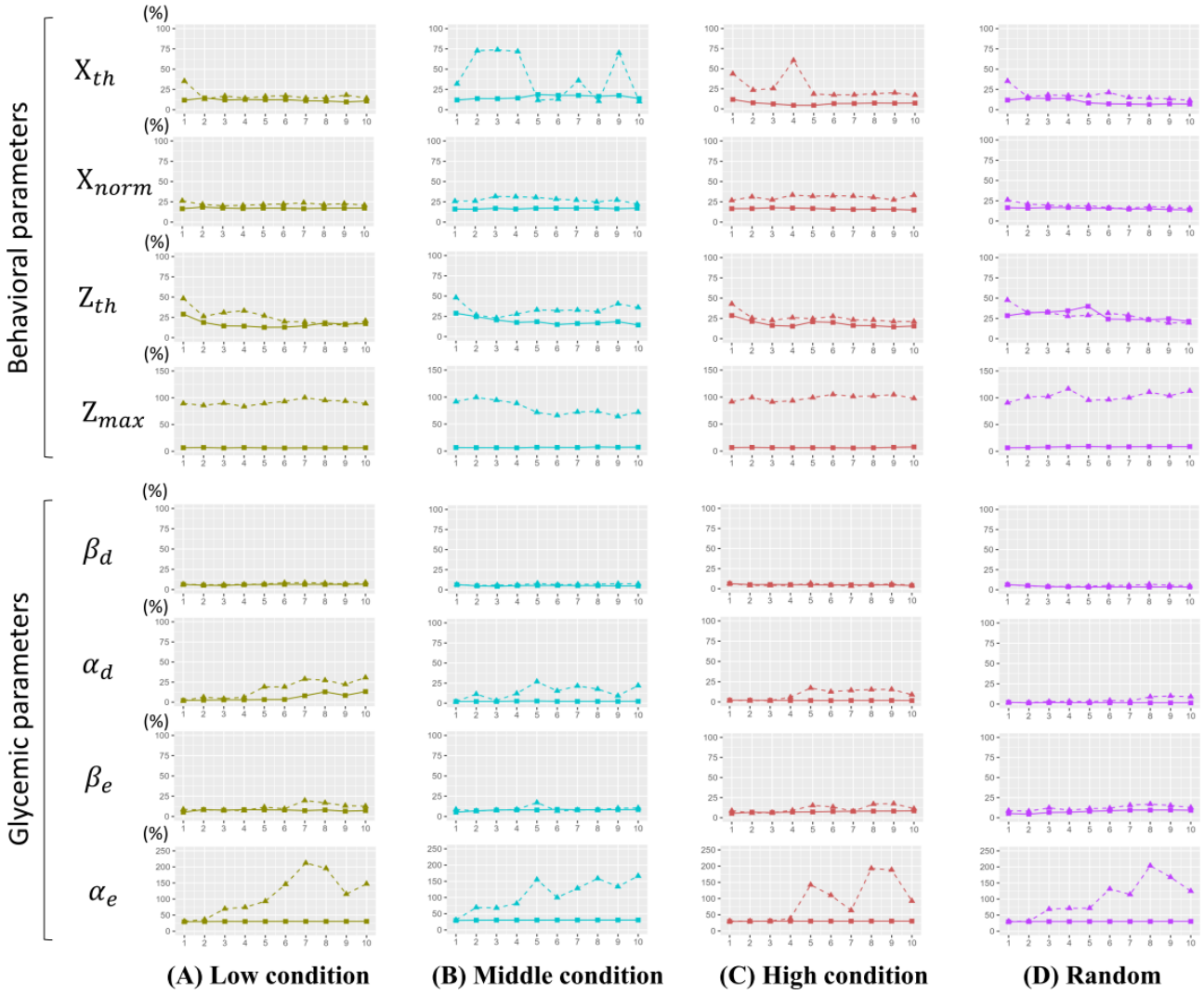
Figure 6. Average estimation error of behavioral parameters and glycemic parameters across different ε-greedy conditions: (A) low condition, (B) middle condition, (C) high condition, and (D) random. ■ represents results with prior, and ▲ represents results without prior. The vertical axis of each graph represents the average estimation error (p(i)) of the pth parameter among all 10 users, and the horizontal axis represents the iteration time (i) of the experiential learning.



Real-World Experiment Results

Based on the simulation results, we conducted a real-world experiment with a simplified algorithm involving a single update of the policy. According to the setting derived in the simulation experiment, we introduced prior knowledge for parameter learning, and we took the greedy policy with ε=0 for action selection.

The obtained metric values for each participant from the real experiments conducted on the within-participant design are shown in Figure 7A. For all participants except ID5, the simple reward average increased in the second experiment using the proposed method. On average, for all participants, this metric increased from 0.65 in the first experiment to 0.80 in the second experiment, representing a 23% increase in reward. To statistically evaluate this improvement, we performed a paired *t* test comparing the average rewards between the first (default policy, R1) and second (optimized policy, R2) experiments across the 6 participants. The analysis revealed a statistically significant increase in reward following the optimized policy (P=.04). This result indicates that action selection using the proposed method is effective for real-world applications, consistent with the simulation results.

Moreover, we show how carbohydrate intake and postprandial walking duration changed in the first and second experiments in Figures 7B and 7C. All participants showed decreased carbohydrate intake and increased postprandial walking duration. For all participants, the average carbohydrate intake decreased by 35.3% from 60.5 to 39.1 g, and postprandial walking duration increased by 34.3% from 14.0 to 18.8 minutes. To further quantify these behavioral improvements, we conducted paired *t* tests for carbohydrate intake and postprandial walking duration. For carbohydrate intake, the mean difference (R2 – R1) was −21.425 g, and the paired *t* test showed a statistically significant reduction (P=.003). Similarly, for postprandial walking duration, the mean difference (R2 – R1) was 4.780 minutes, and the paired *t* test indicated a statistically significant increase (P=.03). These statistically significant behavioral changes underscore the effectiveness of the proposed method in guiding users toward healthier actions.

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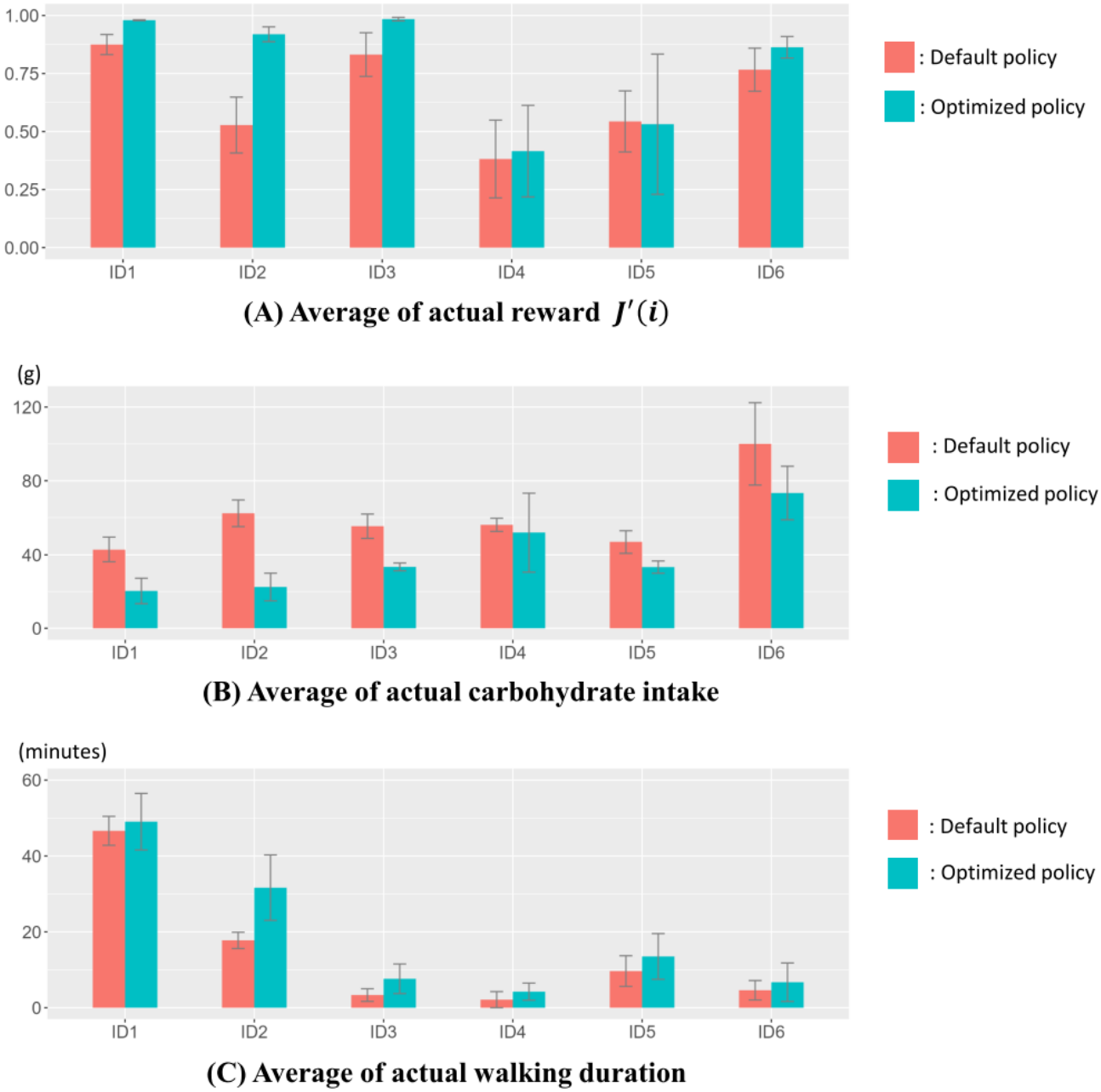
Figure 7. Changes in average reward (A), average carbohydrate intake (B), and average postprandial walking duration (C) for each participant in real experiments. Standard errors are shown as error bars. Statistically significant improvements (P<.05) were observed in each of reward, carbohydrate intake, and postprandial walking duration from the first experiment (default policy) to the second experiment (optimized policy). On average, reward increased from 0.65 (default policy) to 0.80 (optimized policy), carbohydrate intake decreased from 60.5 g (default policy) to 39.1 g (optimized policy), and postprandial walking duration increased from 14 minutes (default policy) to 18.8 minutes (optimized policy).



Furthermore, to investigate the impact on behavioral adherence, we show the actual behaviors of all participants in response to the recommended actions in Figure 8. The adherence to carbohydrate intake improved from the first experiment to the second experiment. In fact, as a result of calculating the adherence rate for each experiment, the adherence rate for carbohydrate intake increased from 45.7% to 83.3% and that for postprandial walking duration increased from 40% to 55.6%. These behavioral improvements support the hypothesis that action selection using the proposed method is appropriate for participants from the viewpoint of ease of behavior change.

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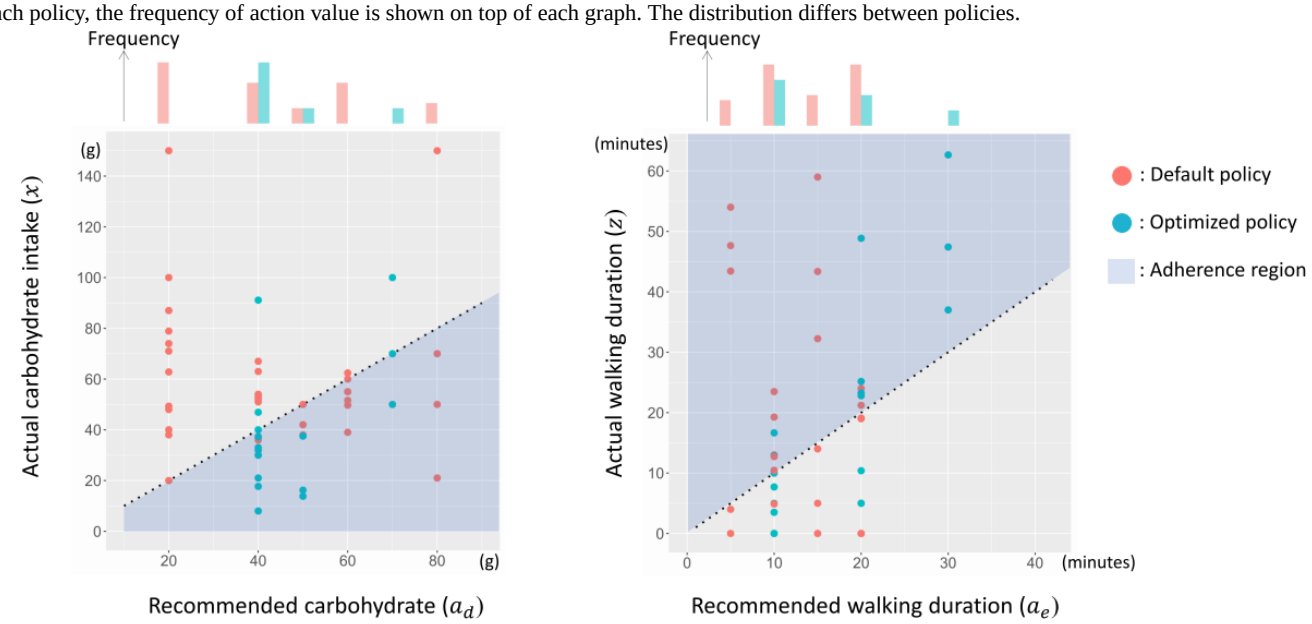
Figure 8. Recommended action vs actual behaviors in real experiments (left: carbohydrate intake and right: postprandial walking). The horizontal and vertical axes show the values of recommended action (ad,ae) and actual behavior (x,z), respectively. Each data point denotes a pair of one action and one behavior for any participant. A participant is considered to adhere to the recommended action in cases x≤ador z≥ae shown in the blue region. For each policy, the frequency of action value is shown on top of each graph. The distribution differs between policies.



Discussion

Principal Findings

In this paper, we propose a multiarmed bandit algorithm based on the two-stage reward prediction mechanism, which can individually plan mobile behavioral interventions and make it easier for users to perform actions and reduce glucose levels after eating.

From the simulation experiment results, first, we confirm that a larger cumulative reward can be obtained by adopting the proposed method than by selecting the default action. This demonstrates the effectiveness of our online algorithm for personalizing recommendations. Second, it is also demonstrated that the parameter learning converged immediately at the first iteration (i=1) by introducing prior knowledge. This indicates it is not always necessary to repeat the intervention experiment many times for obtaining accurate parameters, emphasizing the importance of the initial single update we conducted in the real-world feasibility study.

From the short-term real-world feasibility study, with a simplified proposed method involving a single update of the policy into a personalized one, it is found that actual postprandial glucose levels can be improved using the proposed method through behavioral improvements in both carbohydrate intake and postprandial walking. Specifically, we observed an average 23% improvement in actual glucose responses, which was statistically significant (P=.04), along with statistically significant improvements in behavioral adherence to the recommendations concerning carbohydrate intake (P=.003) and postprandial walking (P=.03). The adherence rates also increased notably (from 45.7% to 83.3% for carbohydrate intake and 40% to 55.6% for postprandial walking). While promising, these results are based on a small-scale pilot study with healthy participants and a simplified intervention protocol. Therefore, they should be viewed as preliminary evidence rather than definitive conclusions, primarily serving as guidance for the design of future, more comprehensive clinical trials. This demonstrates the potential effectiveness of the proposed method in a real-world setting. Crucially, this pilot demonstrated that even a single update, informed by our novel two-stage reward prediction model and based on initial user-specific data, can yield statistically significant improvements in clinical outcomes (glucose levels) and behavioral adherence in a real-world setting. This offers compelling initial evidence for the practical viability and immediate impact of our personalized approach, serving as a vital proof-of-concept for its core mechanism in a complex human context.

While simulation experiments elucidated the algorithm's behavior across diverse iteration numbers (i), the real-world feasibility study, designed as a pilot, adopted a simplified approach: a single policy update (from default to optimized after the initial experiment), prioritizing feasibility and logistical tractability. This design inherently meant that the full extent of continuous learning and adaptive capabilities, central to multiarmed bandit frameworks over extended iterations, was not fully explored. Consequently, this study primarily demonstrated the potential of personalized recommendations derived from an initial learning phase, rather than evaluating continuous adaptive optimization over a prolonged period. This outcome underscores the critical need for future investigations to deploy the full online algorithm, addressing the challenges and benefits of continuous policy updates, particularly concerning user engagement and dynamic model accuracy.

To the best of our knowledge, this is the first attempt to (1) clarify how to optimize behavioral interventions for improving glucose levels and (2) demonstrate the effectiveness of the method through simulation experiments and real interventional experiments.

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Limitation

While this preliminary study offers promising insights, it is important to acknowledge several limitations that warrant future investigation to ensure comprehensive validation and generalization. First, the real experiment was short-term and small-scale. The findings from this preliminary study, which involved only 6 healthy participants over a short duration, should therefore be interpreted with caution and are not readily generalizable to a broader population, particularly including patients with diabetes who represent the primary target group for this intervention. The exclusion of patients with diabetes in this initial feasibility study naturally limits the immediate clinical applicability of these specific real-world results. While this real-world feasibility study offers encouraging initial evidence that effective personalized policy updates could be established within a practical, short-term data collection period (eg, 6 days), future research will include a long-term and massive intervention study. This is needed to fully evaluate the sustained effects and long-term stability of parameter convergence and policy updates beyond the initial phase (ie, after the third iteration [i≥3]) in diverse real-world settings and patient populations. Also, as our target in this study was limited to healthy participants, the interventional experiments in patients with diabetes should be performed for a comprehensive evaluation, adhering to robust statistical principles, including multiple comparison adjustments.

Second, this study primarily compared the proposed online algorithm against a randomized (default) policy. While this comparison effectively demonstrated the benefit of personalization over a nonpersonalized baseline, it did not include a direct comparison with other existing reinforcement learning-based or contextual bandit algorithms from the literature. Such comparisons would provide a more comprehensive understanding of the relative performance advantages and disadvantages of our proposed method against alternative state-of-the-art approaches. Future work could aim to include these comparisons, potentially through simulation studies based on established benchmarks or by incorporating other algorithms into real-world trials. Furthermore, a limitation exists in the parameterization of our simulation experiments. While parameter ranges for virtual users (Table 1) were based on literature, specific values were partially informed by our small-scale feasibility study (Table 2). This limited sample of 6 healthy participants may not be fully representative, potentially affecting the generalizability of simulation results. Consequently, these simulations primarily served to qualitatively explore the algorithm's behavior and identify optimal operational settings (eg, epsilon values and importance of prior knowledge) for future large-scale trials, acknowledging they do not provide definitive quantitative predictions. Future research should prioritize parameter validation and derivation from larger, more diverse datasets, possibly through crowdsourcing or extensive clinical trials, to enhance simulation robustness.

Third, the predictive models, key to our two-stage reward prediction mechanism, possess inherent limitations, particularly regarding data requirements and accuracy. Furthermore, the two-stage prediction itself introduces a compounding effect of prediction errors: inaccuracies in behavioral adherence predictions can propagate and amplify errors in subsequent glycemic response prediction. This "multiplication" of noise impacts reward estimation, especially with limited data. While our preliminary study showed improvements in both glucose and behavior, the potential impact of such compounded prediction errors on long-term reward estimation and intervention effectiveness needs to be thoroughly evaluated in future large-scale studies. Finally, our behavior adherence model is simple, and user responses are also affected by external contextual factors such as weather or daily schedules [14], and adherence levels may decrease with engagement time [42,43]. Therefore, future development should focus on robustly handling limited initial data, efficient data collection strategies, precise quantification or mitigation of propagated uncertainty, and incorporating psychological and contextual factors into sophisticated behavioral models. Crucially, improving behavioral adherence through this future development is also key to minimizing the compounding effects of prediction errors within our two-stage model.

Fourth, the behavioral parameters' prior knowledge, derived from self-reported questionnaires (Table 2), may not perfectly reflect true user tendencies due to cognitive biases. Inaccuracies in these initial priors could affect the model's early parameter estimation accuracy and the speed of convergence to optimal recommendations. While our multiarmed bandit naturally adapts over time through experiential learning, more robust methods for acquiring these priors, such as integrating objective behavioral data, could further enhance initial performance and reduce the burden of exploration.

Finally, while our current action candidates are tailored around carbohydrate intake and postprandial walking, expanding the scope to include other types of exercise or dietary components would enhance personalization. Also, redesigning the reward function to align more closely with clinical guidelines for diabetes would improve its clinical relevance. Incorporating advanced behavioral change techniques [44], such as gamification, could further boost user engagement and usability.

Future Directions

Beyond the immediate limitations, our study highlights several important directions for future research and practical implementation. Foremost among these, addressing the ethical considerations and practical challenges associated with long-term behavior modification interventions is crucial for successful clinical deployment. Factors such as user fatigue from continuous data collection and potential disengagement with recommendations over extended periods need careful consideration. Moreover, the current framework does not explicitly incorporate mechanisms to prevent the recommendation of potentially clinically damaging actions. While action candidates are prepared within a clinically plausible range, individual-specific contraindications or extreme physiological states could render even a seemingly "plausible" recommendation detrimental (eg, recommending a very low carbohydrate intake to someone with specific metabolic conditions). Future work will also include empirically

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establishing practical timelines for robust parameter convergence and policy updates, considering user engagement and burden.

Another critical area concerns the data requirements and accuracy for personalized recommendations. A significant challenge, especially for initial deployment, is the need for sufficient user-specific data to effectively learn and personalize recommendations. While our method uses prior knowledge to accelerate initial learning, acquiring this initial information (eg, via questionnaires or pretraining data) can be difficult and prone to cognitive biases, as self-reported behavioral priors (Table 2) may not perfectly reflect true user tendencies. However, recent advancements in mobile health apps, such as eMOM (Helsinki University Hospital) [8], are enabling the comprehensive collection and visualization of vast amounts of user behavioral and physiological data, including glucose levels. This digital self-tracking, by visualizing relevant data, has shown a positive impact on user understanding of their own health characteristics and offers a promising avenue for acquiring more robust and objective priors. For future clinical real-world applications, directly providing recommendations without proper context carries medical risks. Therefore, a clinician-in-the-loop approach is crucial. This involves an initial phase focused on data collection and visualization (eg, through mobile apps such as eMOM [8]), followed by a collaborative process where clinicians work with users to understand individual characteristics based on the visualized data. This systematic approach ensures the quantity and quality of prior information for each user before recommendations are made. Future work will integrate such an eMOM-like mobile app within a clinician-in-the-loop framework, enabling large-scale validation of the entire process from data visualization to personalized recommendation.

To achieve full clinical deployment, it is paramount to integrate safety constraints into the action selection process, developing methods to filter out adverse clinical outcomes (eg, through real-time physiological data integration or clinician-in-the-loop systems). Future work should proactively investigate strategies to mitigate these issues, such as dynamic adjustment of intervention intensity, gamification elements to maintain sustained engagement, and robust ethical frameworks ensuring user well-being, privacy, and safety in longitudinal deployments.

Conclusions

In this study, we proposed a method for optimizing the planning of dietary and exercise recommendations to improve postprandial glucose levels through behavioral changes. The proposed method is a multiarmed bandit based on a two-stage reward prediction model, where an action is a combination of the amount of carbohydrate intake and postprandial walking duration, and the reward is the postprandial glucose level. We specifically realized the reward prediction for each action by predicting the behavioral responses to an action and then predicting the postprandial glycemic response using the predicted responses. From the simulation experiment, it was demonstrated that action selection using the proposed method significantly increased the cumulative reward compared to the default action selection. Simultaneously, we found that the most beneficial setting of the proposed method is adopting a policy to maximize the predicted rewards from the beginning, together with robust parameter learning using prior distributions for the prediction models. Finally, based on this finding, an intervention experiment was conducted on 6 healthy participants, and it was shown that the application of the proposed method provided preliminary evidence that it could improve postprandial glucose levels along with the behaviors of carbohydrate intake and postprandial walking. This initial real-world investigation, while valuable for understanding the practical considerations and informing the design of larger trials, underscores the need for extensive long-term validation in diverse patient populations, ensuring user safety and promoting sustained engagement.

Funding

No external financial support or grants were received for this work.

Data Availability

The datasets analyzed during this study are not publicly available due to ethical considerations and the privacy of personal data but are available from the corresponding author on reasonable request.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Additional material on the two-stage reward prediction model and the simulation experiment setup.
[DOCX File, 657 KB - formative_v10i1e70826_app1.docx]

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Abbreviations

iAUC: incremental area under the curve

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mHealth Intervention to Promote Nonexercise Physical Activity in Patients With Type 2 Diabetes: Secondary Analysis and Implementation Study

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Abstract

Background: Physical activity (PA) has an important role in the prevention and treatment of type 2 diabetes (T2D). Interventions with mobile-based technology (mobile health [mHealth]) seem promising in PA promotion, but their behavioral framework is often vague, and the implementation is seldom reported.

Objective: This paper examines perceived behavior change needs and implementation of an mHealth approach in increasing nonexercise PA in patients with T2D.

Methods: A 3-arm mHealth intervention was conducted in primary care. Information on perceived behavior change needs was collected with a modified capability, opportunity, motivation—behavior (COM-B) questionnaire before the intervention from a separate sample of patients with T2D (n=25) and at the intervention baseline (n=119). Implementation evaluation focused on the fidelity and acceptability of the main arm of the intervention (n=39), which included 24-hour accelerometer use, a smartphone app with personal feedback, a PA leaflet, a YouTube video on walking, and individual counseling with 3 face-to-face sessions and 4 telephone contacts. Data on fidelity were accumulated during the intervention through counseling cards and cloud computing. Data on acceptability were collected with a questionnaire at the end of the intervention (Likert scale from 1 to 5). Data analysis was mainly descriptive.

Results: The participants' responses revealed 3 items in capability and 2 in motivation, which stood out as perceived behavior change needs. Moreover, the main intervention arm showed good fidelity (eg, face-to-face sessions: 112/117, 96% and telephone contacts completed: 145/156, 93%; mean weekly accelerometer use 54%; ranging from 80% to 17% during the intervention) and acceptability (mean score ranging from 3.8 to 4.8), although some challenges were also experienced, especially in cloud-computed feedback and accelerometer-app use.

Conclusions: The findings on behavior change needs call for additional research since no comparable studies were found. In addition, the explanatory value of the COM-B model and the psychometric properties of the COM-B questionnaire deserve further attention. The main intervention arm seemed applicable to clinical practice. However, the challenges discovered underscore the importance of pretesting technology-based approaches in patients with T2D.

Trial Registration: ClinicalTrials.gov NCT04587414; https://clinicaltrials.gov/study/NCT04587414

(JMIR Form Res 2026;10:e80304) doi:10.2196/80304

KEYWORDS

accelerometer; 24/7 physical activity; smartphone app; feasibility; physical activity counseling

Introduction

Type 2 diabetes (T2D) is a global health problem, and its prevalence is steadily increasing [1,2]. In Finland, T2D has become a major public health threat, increasing in parallel with obesity [3,4]. The management of T2D, cardiovascular diseases, and their risk factors accounts for a substantial part of the burden in primary health care [2].

Physical activity (PA) is one of the cornerstones of the T2D treatment [5,6]. The current guideline for patients with T2D is to spread at least 150 minutes of moderate-to-vigorous intensity physical activity (MVPA) on most days of the week, with no

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more than 2 days between the activity bouts [7]. Unfortunately, the recommendation seems not achievable to many patients with T2D, especially among women and those who are old and have a high BMI [8].

Focusing on the nonexercise part of the PA continuum, such as replacing sedentary behavior with light-intensity physical activity (LIPA), may offer a feasible way for individuals with clinical conditions to start changing their PA behavior [9-11]. A recent systematic review with meta-analysis shows that compared with whole-day sitting without interruptions, frequent short bouts of LIPA confer favorable acute effects on postprandial glucose and insulin levels in people with metabolic impairments [9]. In many studies, the beneficial metabolic effects have been sustained until the next day [12-14]. Consequently, reducing sedentary time by interrupting prolonged sitting every 30 minutes with short bouts of LIPA has also been included in PA recommendations for patients with T2D [6,7].

The findings on the long-term benefits of breaking up sedentary time [7] or time spent in LIPA for patients with T2D are less clear [9,15]. It seems that in terms of a single-time unit, MVPA still has clear health advantages over LIPA [9,15,16], meaning that to gain the health benefits of MVPA, LIPA should last much longer. However, in a situation where there is very little or no MVPA, as it is often with many people with clinical conditions [17], the time spent in LIPA may also play a substantial health-enhancing role [11,14,18]. This is supported by a meta-analysis showing that exercise of any intensity lasting 12 weeks or more can produce favorable effects on glycemic outcomes in patients with T2D [19]. Similar findings have been discovered for walking as a specific mode of PA [20].

Mobile health (mHealth) interventions offer a promising approach to promoting PA in the general population [21,22]. Encouraging results [23,24] and protocols of new studies [25-27] in patients with T2D have been reported. However, behavioral theories are underused in designing these interventions [28], although their use has been shown to associate with improved intervention outcomes [29,30]. The use of theoretical frameworks has also been unclearly reported [31] and inappropriately linked to the expected mechanisms of behavior change and intervention constructs [32]. Making inaccurate assumptions of what needs to change may lead to failures in behavior change interventions [33].

An intervention can also fail due to incorrect or poor delivery, which emphasizes the evaluation of implementation along with effectiveness [34]. Moreover, information on implementation is critical for translating the interventions into real-world settings [35]. Despite its importance, implementation is inconsistently and insufficiently reported in interventions promoting PA in patients with T2D [36]. As part of the implementation, a notable gap exists in research concerning the perceptions of patients with T2D about mHealth technology [37-39]. Previous studies indicate large variability in the usability of mHealth apps among patients with T2D [29,40] and that satisfaction can improve the adoption of technology-assisted interventions [41].

The purpose of this study is to examine (1) the perceived behavior change needs of patients with T2D for increasing daily walking and other nonexercise PA and (2) the implementation of an mHealth approach to increase patients' daily walking and other nonexercise PA. These were the secondary aims of the clinical intervention trial. The main aim was to examine the effectiveness of the trial in increasing the daily steps of the patients, which was, however, compromised due to the outbreak of the COVID-19 pandemic in 2020. Thus, only the results concerning the secondary aims are reported here.

Methods

Intervention

The 6-month mHealth trial called "MySteps" was implemented within the primary care of the joint municipal authority for North Karelia social and health services (Siun Sote) in Eastern Finland during 2019 to 2020. By design, the trial was a randomized controlled trial and comprised 2 intervention arms and 1 comparison arm.

Providers and Participants

Two physiotherapists recruited the patients with T2D for the MySteps trial from the primary care units of the Siun Sote area and through a local newspaper. Inclusion criteria for participation were age 20-69 years, BMI of <40 kg/m^2, not meeting the current PA recommendation for health, and the ability to conduct a 6-minute walk test [42]. Exclusion criteria for participation were any problem that limited the ability to walk without an aid, any health problem that hindered participation in PA, and inability or unwillingness to use a smartphone or wear an accelerometer.

Measurements

A face-to-face session for the baseline measurements was arranged for each participant individually. The measurements included 7-day 24-hour accelerometer use, sleep diary, 6-minute walk test, and blood samples, which are not reported here. As part of the baseline measurements, the participants completed a questionnaire, which, among other things, included questions on intensity-specific PA and perceived behavior change needs for increasing daily walking and other nonexercise PA.

Delivery

After the baseline measurements, the participants were randomized into three arms: (1) self-monitoring with counseling (SMC), (2) self-monitoring only, and (3) usual care. SMC was considered the primary intervention arm of the study and is the focus of the implementation evaluation of this paper.

SMC was built around an mHealth system, which included an accelerometer (MoveSense, Suunto Ltd) and a smartphone app (ExSed 2, UKK Terveyspalvelut Oy) for 26 weeks. The accelerometer was connected to the app via Bluetooth. The app provided cloud-computed personal data and feedback on accelerometer-measured PA, sedentary behavior, and time in bed (a proxy for sleep; Figure 1). It also served as a platform for setting and monitoring personal goals.

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Figure 1. Accelerometer used in self-monitoring and examples of cloud-computed feedback views in the smartphone app (from left to right: physical activity, sedentary behavior, and sleep). The accelerometer was carried on the right hip during waking hours, replaced to the wrist for the time in bed, and instructed to be removed for any water exposure.

Previous studies on patients with T2D have shown more considerable impacts on physical behavior [11] and glycated hemoglobin [28] if self-monitoring was complemented with other intervention features. In the MySteps trial, self-monitoring with mHealth was supplemented with a PA leaflet devised for patients with T2D, 3 face-to-face counseling sessions, 4 telephone counseling contacts, and a YouTube video on how to increase daily walking. The features were designed by using information from former studies about the motivators and barriers of PA in a Finnish sample of adults at high risk of or diagnosed with T2D [43,44]. The timing, content, behavior change techniques (BCTs), and delivery modes of SMC are introduced in Multimedia Appendix 1. The BCTs were drawn from the Coventry, Aberdeen & London—Refined taxonomy refined for PA and healthy eating [45] and BCT taxonomy v1 [46].

Provider Training

The physiotherapists participated in a 4-hour training about the study protocol, measurements, and intervention contents before the first recruitment. The participant-specific counseling cards guided the physiotherapists to the protocol and contents of each intervention arm. The cards were also used in documenting the realization and duration of the sessions and contacts. At the first face-to-face session, the physiotherapists instructed the participants of the SMC and self-monitoring only group to use the accelerometer and smartphone app and to replace the accelerometer battery if necessary.

Evaluation of Perceived Behavior Change Needs

The information on participants' perceived behavior change needs for increasing daily walking and other nonexercise PA was collected with a questionnaire (Multimedia Appendix 2). The questionnaire was based on the capability, opportunity, motivation—behavior (COM-B) model, which identifies 3 critical sources of behavior: capability, opportunity, and motivation [47]. The model generally suggests that to achieve a change in the target behavior, the change must first happen in capability, opportunity, and/or motivation related to the target behavior or the behaviors supporting the target behavior [33]. Capability, opportunity, and motivation are further linked to the theoretical domains framework (TDF) with more detailed determinants of behavior [48]. Capability is mapped to knowledge, cognitive and interpersonal skills, memory, attention and decision processes, physical skills, and behavioral regulation. Opportunity is linked to social influences,

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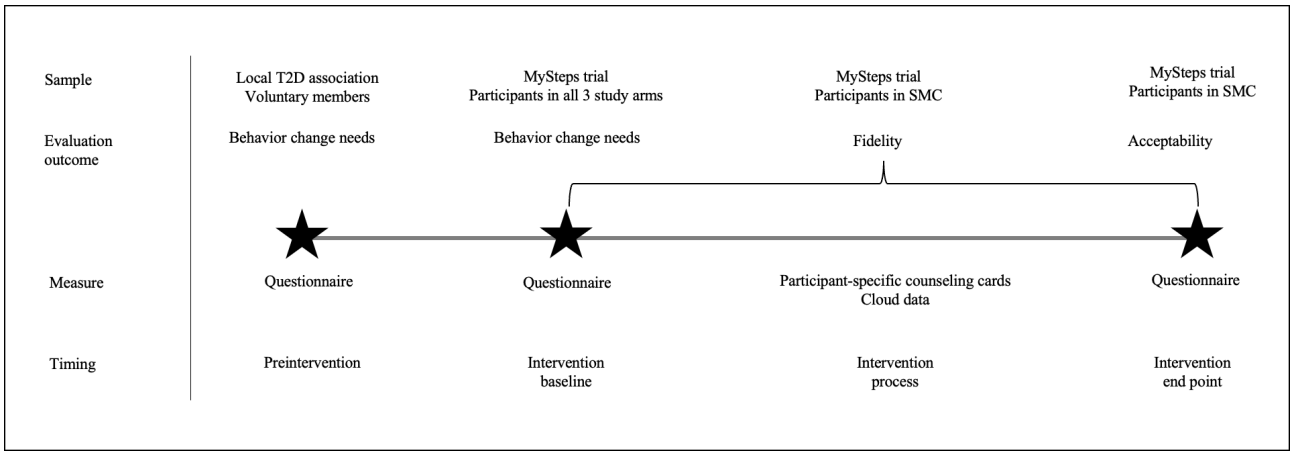
environmental context, and resources. Motivation is driven by professional or social role and identity, beliefs about capabilities, consequences, optimism, intentions, goals, reinforcement, and emotion [33].

COM-B model with the determinants is further connected to 9 intervention functions (education, persuasion, incentivization, coercion, training, restriction, environmental restructuring, modeling, and enablement) and 7 policy categories (communication or marketing, guidelines, fiscal measures, regulation, legislation, environmental or social planning, and service provision), which represent the means for changing the target behavior [33]. The means are then delivered by BCTs, which are the smallest active ingredients of the intervention [33]. All these elements together form the Behavior Change Wheel, which is a synthesis of various behavior change models and can be used for designing and evaluating behavior change interventions [47].

The questionnaire for evaluating perceived behavior change needs in capability, opportunity, and motivation was adapted for the study purposes from the COM-B Self-Evaluation Questionnaire (COM-B-Qv1) introduced by Michie et al [33]. As recommended by the questionnaire developers, the items were specifically addressed to the target behavior, which in this study was daily walking and other nonexercise PA. The first 10 items in the questionnaire represented the need for change in capability, the next 7 items in opportunity, and the last 5 items in motivation. At the end of the questionnaire, the respondents had an option to write an item in an open space. In each item, the respondents were asked to assess with a Likert scale from 1=not at all to 5=very much how much change would be needed for them to increase daily walking and other nonexercise PA.

The questionnaire also included background questions on age, gender, height, weight, perceived health, and intensity-specific PA and was first targeted to the members of the local T2D association in Pirkanmaa, Finland (Figure 2). In its newsletter, the association informed its members about the possibility of participating. The members could either complete an electronic questionnaire through a link in the newsletter or go to the association's office to complete a paper questionnaire. To increase the sample size, the same questionnaire on perceived behavior change needs was addressed to the participants of the MySteps trial as part of their baseline measurements (Figure 2).

Figure 2. Data collection for the evaluation of the perceived behavior change needs of the patients with T2D for increasing daily walking and other nonexercise physical activity and for the evaluation of SMC's implementation (fidelity and acceptability). SMC: self-monitoring with counseling; T2D: type 2 diabetes.



Implementation Evaluation

Overview

Proctor et al [34] have introduced 3 interrelated types of outcomes of implementation research: implementation outcomes, service outcomes, and client outcomes. This paper focuses on implementation outcomes, which, according to Proctor et al [34], include acceptability, adoption, appropriateness, costs, feasibility, fidelity, penetration, and sustainability. The same outcomes have been determined for evaluating the implementation of behavioral intervention technology [49]. However, the terminology and definitions related to the implementation outcomes are inconsistent, and the operationalization and measurement of the same outcome vary across the studies [34]. Especially, the constructs of acceptability, appropriateness, and feasibility have been used interchangeably [34].

The constructs selected for acceptability in the planning phase of this study (usefulness, ease of use, credibility, and satisfaction) considerably overlapped with the constructs of adoption, appropriateness, and feasibility introduced by Proctor et al [34] and Hermes et al [49]. Moreover, the rest of the introduced outcomes (costs, penetration, and sustainability) are considered more suitable for organization-level evaluation [34,49] and interventions aiming at larger-scale clinical uptake and maintenance. As a result, the fidelity and acceptability remained the most applicable implementation outcomes of the intervention.

Fidelity

Fidelity is defined as the extent to which the intervention was delivered as intended by the program developers [49,50]. The recommendations on fidelity evaluation in health behavior studies cover study design, provider training, treatment delivery, treatment receipt, and enactment of treatment skills [51]. In

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studies involving behavioral intervention technologies, fidelity is traditionally measured at the provider level [49]. Examples of typical fidelity measurements are protocol adherence, dose or amount of program delivered, and quality of program delivery [34].

Fidelity can be measured with observations, checklists, or self-reports [34]. A systematic review by Lewis et al [52] did not find any measures of fidelity in behavioral health interventions. A recent systematic review by Mettert et al [53] detected a rapid increase in measures across the implementation outcomes and identified 18 fidelity measures. However, the information on the psychometric properties of the instruments was poorly reported, which prevented us from making conclusions about their suitability.

In the MySteps trial, the fidelity of SMC was evaluated during the 6-month intervention (Figure 2) with a measure designed for the study purposes. The physiotherapists kept records of completed face-to-face sessions, telephone contacts, and their contents with participant-specific counseling cards. Compliance with using the accelerometer and smartphone app was obtained from the cloud data. A more specific description of fidelity evaluation is presented in Table 1.

Table . Fidelity evaluation by delivery feature in the main intervention arm (self-monitoring with counseling [SMC]).

Delivery feature	Data source
Accelerometer and smartphone app	Cloud computing
Number (%) of weekly use days (maximum of 273 days in the whole group)[a]	
Number (%) of high-engagement users (5-7 days per week)	
Number (%) of moderate-engagement users (3-4 days per week)	
Number (%) of low-engagement users (1-2 days per week)	
Number (%) of nonusers (0 days per week)	
Number (%) of participants failing to pair the accelerometer with the smartphone app (nonsync)	
Impact of the counseling sessions and telephone contacts on participants' weekly use of the accelerometer and smartphone app	
Face-to-face counseling	Counseling cards[b]
Proportion of realized counseling sessions (maximum of 117[c])	
Time used for all counseling sessions	
Time used for a single counseling session	
Telephone counseling	Counseling cards[b]
Proportion of realized telephone contacts (maximum of 156[c])	
Time used for all telephone contacts	
Time used for a single telephone contact	

[a]Number of participants in SMC was 39, and each participant had the possibility to use the accelerometer and app on 7 days a week.

[b]Participant-specific card, where the nurses kept record of completed counseling sessions and contacts.

[c]The number of participants in SMC was 39, and each participant had to have 3 face-to-face counseling sessions and 4 telephone counseling contacts during the 6-month intervention.

Acceptability

Low acceptability may lead to poor fidelity and weak effectiveness [50]. Acceptability has thus been recognized as a key factor for the effectiveness of interventions [54]. Consequently, acceptability has been included in some national guidelines on conducting process evaluation in complex interventions [55]. However, the definition and operationalization of acceptability have been incoherent in guidelines and interventions, which has hampered its assessment and led to a need for developing a more theoretically grounded framework [54]. Consequently, acceptability has been defined as "a multi-faceted construct, represented by seven component constructs: effective attitude, burden, perceived effectiveness, ethicality, intervention coherence, opportunity costs, and self-efficacy" [54].

Acceptability is the most evaluated implementation outcome in health care [52,56]. A systematic review [52] discovered 50 acceptability instruments, and another systematic review [53] found 32 measures used in behavioral health care settings. However, both reviews concluded that the psychometric strength of the instruments is poorly reported, and most instruments show low psychometric quality. Moreover, those with some psychometric evidence were lengthy, which raised concerns about their clinical feasibility [52].

In the MySteps trial, the acceptability of SMC was assessed retrospectively from the participants' viewpoint as part of

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6-month end-point measurements (Figure 2). The purpose was to examine the user experiences on the contents and delivery of SMC. At the time of the study design, no ready-made and valid instrument was found for the present purpose. Thus, previous literature was used adaptively in determining the constructs of acceptability [57,58]. The constructs selected were usefulness, ease of use, credibility, and satisfaction. In each construct, the participants were asked to assess the primary features of SMC, that is, accelerometer (not applicable in credibility), feedback views of the smartphone app, face-to-face counseling sessions, and telephone counseling contacts. The response alternatives were presented on a Likert scale from 1=not at all to 5=extremely. After each construct, the participants could tell in an open space what would have improved their experience.

Ethical Considerations

The study was conducted in accordance with the Declaration of Helsinki, the guidelines of the Finnish National Board on Research Integrity on the ethical principles of research with human participants and on the responsible conduct of research, and was approved by the research ethics committee of the Northern Savo Hospital District (running number 303/2017). The participants gave their written consents to participate after being fully informed about the ethical principles and data protection (EU General Data Protection Regulation and Finnish Data Protection Act) of the study, which cover also the means to secure the privacy and confidentiality of the participants' data. The participants were not compensated for participating in the study. The study has been registered in the ClinicalTrials.gov database (NCT04587414).

Statistics

Descriptive data analysis was performed, and absolute numbers, percentages, means, and SDs were provided as appropriate. Generalized linear mixed model (GLMM) with logistic regression was used to assess the effect of face-to-face counseling sessions and telephone contacts in the weeks 4 (telephone), 8 (session), 12 (telephone), and 16 (telephone) on using the app at least 3 days per week (moderate engagement). The contact in week 21 (telephone) was excluded because it was suspected that its effect may have been confounded by accelerometer battery loss. An equally long 3-week period from the preceding contact was used as a repeated measure with autoregressive-moving-average 11 covariance structure. For each participant, 4 cycles of app use were thus identified (weeks 4 - 7, 8 - 11, 12 - 15, and 16 - 19), and these cycles were applied as a random effect with a variance component covariance type. Results were reported as odds ratios and 95% CIs. Statistical analysis was done using SPSS (version 29; IBM Corp).

Results

Perceived Behavior Change Needs

Altogether, 144 patients with T2D completed the adapted COM-B-Qv1 questionnaire. In total, 25 of them were members of the local T2D association, and 119 were participants of the MySteps trial. The background and health-related characteristics of the respondents to the questionnaire are described in Table 2. The majority (86/141, 61%) of the respondents were women, aged 55 years or older (120/141, 85%), and overweight or obese (133/144, 92%). On average, their self-reported weekly engagement in MVPA was 139 minutes, which is slightly less than the minimum of 150 minutes recommendation for patients with T2D or healthy adults in general.

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Table . Background and health-related characteristics of the respondents providing information on perceived behavioral change needs for increasing daily walking and other nonexercise physical activity.

	Preintervention[a] (n=25)	Intervention baseline[b] (n=119)	Total (N=144)
Age (years), mean (SD)[c]	66.2 (7.7)	60.7 (6.9)	61.7 (7.4)
Age group (years), n (%)[c]			
40-54	1 (4)	20 (17)	21 (15)
55-65	11 (44)	65 (56)	76 (54)
>65	13 (52)	31 (27)	44 (31)
Women, n (%)[c]	18 (72)	68 (59)	86 (61)
BMI (kg/m^2), mean (SD)	30.2 (5.1)	31.8 (4.5)	31.5 (4.7)
<25	4 (16)	7 (6)	11 (8)
25-30	8 (32)	33 (28)	41 (28)
>30	13 (52)	79 (66)	92 (64)
Married or spouse, n (%)[c]	—[d]	90 (78)	—
Working status, n (%)			
Working	—	62 (53)	—
Retired	—	54 (47)	—
Perceived health, n (%)			
Fairly good or good	7 (28)	—	—
Average	15 (60)	—	—
Fairly poor or poor	3 (12)	—	—
Perceived health compared with age-mates, n (%)[c]			
Better	—	12 (10)	—
Equal	—	59 (51)	—
Worse	—	45 (39)	—
Weekly minutes of total physical activity, mean (SD)[e]	346 (211)	380 (521)	374 (480)
Light physical activity	228 (201)	237 (386)	236 (359)
Moderate-intensity physical activity	91 (85)	121 (214)	116 (198)
Vigorous-intensity physical activity	26 (46)	22 (67)	23 (63)

[a]Data obtained prior to the MySteps trial from the members of the local type 2 diabetes association.

[b]Data obtained at baseline measurements from 119/120 participants of the MySteps trial.

[c] Information missing from 3 respondents.

[d]Not available.

[e]Self-reported: questionnaire to the members of the local type 2 diabetes association and to the participants of the MySteps trial.

If the response alternatives 4 and 5 were combined, 3 items in capability and 2 items in motivation seemed to stand out in respondents' behavior change needs for increasing daily walking and other nonexercise PA (Table 3). The items in capability were "Have stronger resilience against cravings, which reduce my physical activity" (91/143, 64%; mean 3.8, SD 1.2), "More easily overcome physical barriers, which reduce my physical activity" (83/140, 59%; mean 3.6, SD 1.1), and "Having more physical stamina" (75/142, 53%; mean 3.6, SD 1.2). For motivation, the items standing out similarly were "Plan my physical activity better" (80/141, 56%; mean 3.5, SD 1.1) and "Develop a routine of being physically active without having to think about it specifically" (96/142, 68%; mean 3.9, SD 1.1). However, there was only a little variation in the percentages and means of the motivational items.

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Table . Behavior change needs perceived by patients with T2D[a] displayed with numbers of respondents, distributions (%), and means[b].

Behavior change needs	Likert scale from 1 to 5[c]					Mean score (SD)
	1, n (%)	2, n (%)	3, n (%)	4, n (%)	5, n (%)	
Capability						
Know more about the benefits of walking and other physical activity.	34 (24)	46 (32)	46 (32)	12 (8)	4 (3)	2.3 (1.0)
Know more about how to increase walking and other physical activity.	27 (19)	36 (25)	52 (37)	19 (13)	8 (6)	2.6 (1.1)
Be physically more skillful.	19 (13)	36 (25)	42 (30)	33 (23)	12 (8)	2.9 (1.2)
Learn how to reason walking and physical activity more effectively.	22 (16)	25 (18)	31 (22)	36 (26)	27 (19)	3.1 (1.3)
Be physically stronger (eg, better muscular fitness).	11 (8)	25 (18)	36 (25)	35 (25)	35 (25)	3.4 (1.2)
Have stronger resilience against cravings, which reduce my physical activity (eg, watching television, commuting by car, and preferring elevator over stairs).	7 (5)	14 (10)	31 (22)	44 (31)	47 (33)	3.8 (1.2)
More easily overcome physical barriers, which reduce my physical activity (eg, tiredness, overweight, and poor fitness).	5 (4)	19 (13)	34 (24)	47 (33)	36 (26)	3.6 (1.1)
More easily overcome mental barriers (eg, negative attitudes, images, or emotions).	15 (11)	39 (28)	41 (29)	34 (24)	12 (9)	2.9 (1.1)
Have more physical stamina (eg, better cardiovascular fitness).	8 (6)	16 (11)	43 (30)	37 (26)	38 (27)	3.6 (1.2)
Have more mental stamina (eg, better tolerance for haste and time pressure).	8 (6)	49 (35)	39 (28)	35 (25)	10 (7)	2.9 (1.1)
Opportunity						
Have more time for physical activity.	33 (23)	44 (31)	31 (22)	23 (16)	10 (7)	2.5 (1.2)
Have more money for physical activity.	63 (44)	45 (32)	24 (17)	9 (6)	1 (1)	1.9 (1.0)

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Behavior change needs	Likert scale from 1 to 5[c]					Mean score (SD)
	1, n (%)	2, n (%)	3, n (%)	4, n (%)	5, n (%)	
Have better physical activity outfits or equipment.	51 (36)	52 (36)	26 (18)	9 (6)	5 (3)	2.1 (1.1)
Have easier access to places, which enable physical activity.	51 (36)	40 (28)	31 (22)	13 (9)	7 (5)	2.2 (1.2)
Have more people around me, who are also physically active.	26 (19)	31 (22)	46 (33)	26 (19)	11 (8)	2.8 (1.2)
Have more reminders when I need to be physically active.	13 (9)	27 (19)	44 (31)	40 (29)	16 (11)	3.1 (1.1)
Have more support from family or other important people.	30 (21)	44 (31)	37 (26)	22 (15)	10 (7)	2.6 (1.2)
Motivation						
Feel more urge to be physically active.	10 (7)	21 (15)	43 (30)	33 (23)	35 (25)	3.4 (1.2)
Worry more about not being physically active.	12 (8)	27 (19)	33 (23)	39 (27)	31 (22)	3.4 (1.3)
Sense more strongly that physical activity is good for me.	12 (8)	32 (22)	29 (20)	37 (26)	33 (23)	3.3 (1.3)
Plan my daily physical activity better.	7 (5)	19 (13)	35 (25)	54 (38)	26 (18)	3.5 (1.1)
Develop a routine of being physically active without having to think about it specifically.	4 (3)	12 (8)	30 (21)	47 (33)	49 (35)	3.9 (1.1)
Other						
Do something else, what?	16 (17)	11 (12)	34 (36)	11 (12)	23 (24)	3.1 (1.4)

[a]T2D: type 2 diabetes.

[b]The responses from the local T2D association (n=25) and from the baseline measurements of the MySteps trial (n=119) are combined (n=144). The number of responses varies from 140 to 143 in the items of capability, opportunity, and motivation and was 95 in the category "other."

[c]1 indicates that not at all change would be needed and 5 indicates that very much change would be needed to increase daily walking and other nonexercise physical activity.

Implementation

Fidelity

Altogether, 39 participants of the MySteps trial were randomized into SMC after the baseline measurements. As each participant was to have 3 face-to-face counseling sessions and 4 telephone counseling contacts, the maximum number of face-to-face sessions and telephone contacts in SMC was 117 and 156, respectively.

Based on the participant-specific counseling cards, the number of realized face-to-face counseling sessions was 112 of 117 (96%). The second session was missing from 2 participants,

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and the third session was missing from 3 participants. The total time used for the 3 face-to-face sessions varied from 80 to 230 minutes, being on average 152 (SD 34) minutes. The mean time spent for 1 session was 51 (SD 11) minutes, ranging from 27 to 77 minutes.

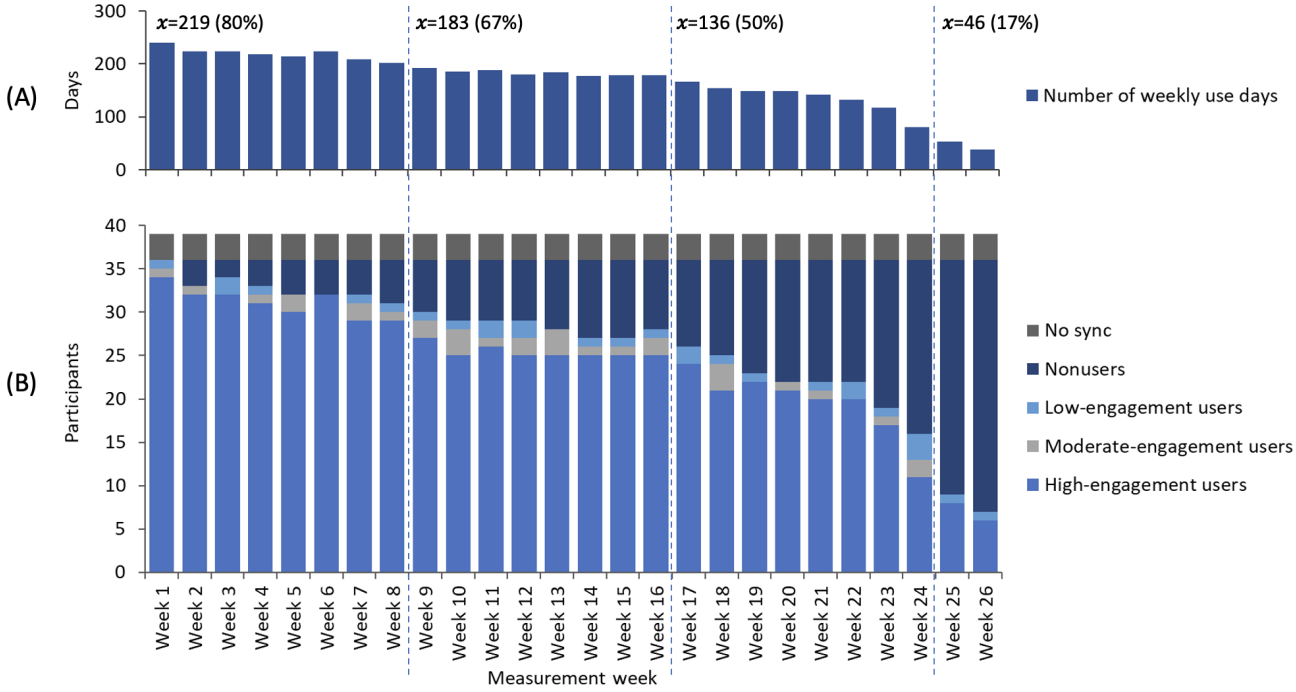
The total number of realized telephone counseling contacts was 145 of 156 (93%). In total, 2 participants missed the first contact, and 3 participants missed the second, third, and fourth contacts. The total time used for the telephone counseling sessions varied from 72 to 175 minutes, being on average 109 (SD 30) minutes. The mean time spent for 1 contact was 27 (SD 8) minutes, ranging from 18 to 44 minutes.

At the beginning of the intervention, 3 (8%) participants failed to pair their accelerometer with the smartphone app (Figure 3). In the rest of the participants, the use of the devices declined moderately and steadily until intervention week 21 and dropped notably thereafter. The number of weekly use days was on average 219 (80% from the maximum of 273) during weeks 1 - 8, 183 (67%) during weeks 9 - 16, 136 (50%) during weeks 17 - 24, and 46 (17%) during weeks 25 - 26. As a result, the mean weekly accelerometer use was 54%.

In those succeeding in pairing the devices (n=36), the mean number of users was 33 (92%) during weeks 1 - 8, 28 (78%) during weeks 9 - 16, 22 (61%) during weeks 17 - 24, and 8 (22%) during weeks 25 - 26. Correspondingly, the mean number of high-engagement users was 31 (86%), 25 (69%), 20 (56%), and 7 (19%), and the mean number of nonusers was 3 (8%), 8 (22%), 14 (39%), and 28 (78%), respectively. As shown in Figure 3, the weekly number of moderate- and low-engagement participants remained quite stable throughout the intervention.

According to the GLMM analysis, the face-to-face counseling sessions and telephone contacts in weeks 4, 8, 12, and 16 seemed to affect the participants' use of the smartphone app at least 3 days per week (moderate engagement) since the odds for lower engagement increased as the time elapsed from the contact. After the contacts, the odds ratios for using the smartphone app less than 3 days per week in the 3 following weeks increased and were 1.36 (95% CI 0.896-2.063; *P*=.15), 1.79 (95% CI 1.124-2.859; *P*=.01), and 2.49 (95% CI 1.511-4.111; *P*<.001).

Figure 3. Compliance of the patients with T2D with using the accelerometer and smartphone app during the intervention weeks broken into 4 periods with dashed lines (weeks 1 - 8, 9 - 16, 17 - 24, and 25 - 26). The upper histogram (**A**) shows the mean number and percentage of weekly use days, and the lower (**B**) presents the number of participants who failed to pair the devices (no sync), used the devices on 0 days per week (nonusers), 1 - 2 days per week (low engagement), 3 - 4 days per week (moderate engagement), and 5 - 7 days per week (high engagement).



Acceptability

A total of 34 participants in SMC (87% of the 39 participants randomized into SMC) provided information on the acceptability of SMC at the end of the MySteps trial at 6-month measurements. The background characteristics of the respondents in SMC at the end of the study did not differ from the baseline background characteristics of all participants: the majority were women (27/34, 79%), aged 55 years or older (28/34, 82%), and overweight or obese (30/34, 88%). Most participants were working (24/34, 71%) and perceived their health better or equal to their age-mates (27/34, 79%). However, at the end of the intervention, when the questionnaire on acceptability was addressed, the participants of SMC had more self-reported MVPA than all participants at baseline (mean 240 vs 139 minutes).

The construct-specific distributions (%) and means of the acceptability responses are shown in Table 4. Overall, it seems that the features of SMC were mostly acceptable to the participants. The lowest mean scores for acceptability were seen in the credibility of the feedback views and in the satisfaction related to the accelerometer.

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Table . Acceptability of the features of SMC[a] within each evaluation construct: usefulness, ease of use, credibility, and satisfaction.

Delivery modes within each evaluation construct	Distribution, n (%)					Mean score (SD)
	1=not at all	2	3	4	5=extremely	
Usefulness						
Accelerometer	2 (3)	6 (9)	6 (8)	19 (27)	37 (53)	4.2 (1.1)
Feedback views from the smartphone app	2 (3)	1 (1)	6 (9)	17 (25)	43 (62)	4.4 (0.9)
Face-to-face sessions	1 (3)	0 (0)	2 (5)	10 (28)	23 (64)	4.5 (0.8)
Telephone contacts	1 (3)	1 (3)	1 (3)	14 (39)	19 (53)	4.4 (0.9)
Ease of use						
Accelerometer	2 (3)	2 (3)	4 (6)	18 (26)	43 (62)	4.4 (0.9)
Feedback views from the smartphone app	1 (1)	2 (3)	4 (6)	11 (16)	50 (74)	4.6 (0.9)
Face-to-face sessions	0 (0)	0 (0)	2 (6)	9 (25)	25 (69)	4.6 (0.6)
Telephone contacts	0 (0)	0 (0)	0 (0)	7 (19)	29 (81)	4.8 (0.4)
Credibility						
Feedback views from the accelerometer and smartphone app	4 (6)	8 (11)	6 (9)	29 (42)	22 (32)	3.8 (1.2)
Face-to-face sessions	0 (0)	0 (0)	1 (3)	6 (17)	29 (80)	4.8 (0.5)
Telephone contacts	0 (0)	0 (0)	1 (3)	7 (19)	28 (78)	4.8 (0.5)
Satisfaction						
Accelerometer	5 (7)	4 (6)	11 (16)	23 (33)	27 (38)	3.9 (1.2)
Feedback views from the smartphone app	2 (3)	3 (4)	11 (16)	18 (26)	36 (51)	4.2 (1.0)
Face-to-face sessions	0 (0)	0 (0)	1 (3)	7 (20)	27 (77)	4.7 (0.5)
Telephone contacts	0 (0)	0 (0)	1 (3)	7 (19)	28 (78)	4.8 (0.5)

[a]SMC: self-monitoring with counseling.

Discussion

Principal Findings

First, this paper reports perceived behavior change needs for increasing daily walking and other nonexercise PA in a sample of patients with T2D. Second, the paper examines the implementation of the main intervention arm of the MySteps trial, which was designed to promote walking and other nonexercise PA among patients with T2D through an mHealth approach within a real-life health care setting. The findings may be used in developing future mHealth interventions for these patients.

The participants' responses pointed out 3 items in capability and 2 in motivation, which stood out as perceived behavior change needs. Moreover, the main intervention arm of the MySteps trial showed good fidelity and acceptability among patients with T2D, although some challenges were also experienced.

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Perceived Behavior Change Needs

Based on the responses to the COM-B-Qv1 questionnaire, it seems that to promote walking and nonexercise PA in patients with T2D, attention should be paid especially to capability and motivation as sources of behavior. The findings are in line with previous reviews, indicating that BCTs related to opportunity such as social influences and environmental issues are not among the most effective BCTs in promoting PA or improving glucose metabolism among patients with T2D [20,28,59]. Earlier studies in healthy adults similarly imply that capability and motivation are the key drivers of PA [60]. However, in a younger population [61] and special culture groups [62], opportunity and thereby social support may play a more important role.

The perceived needs for change in capability, which scored the highest, may refer to the importance of improving the patients' skills to resist cravings, overcome barriers, and develop the capacity to maintain physical effort. Correspondingly, the perceived needs distinguished in motivation seem to indicate the importance of strengthening the patients' beliefs about their capabilities to make action plans and of improving habitual engagement in PA.

The present discoveries on sources of behavior and their more specific items were much more focused and limited than in a small Chinese study involving 28 individuals with metabolic syndrome [63]. Between-study differences are likely to originate from cultural and methodological disparities, meaning that contextual factors may play an important role and should be taken into consideration when interpreting the findings on behavioral analysis and comparing them between studies.

The small sample size of this study and its selectivity limit the generalizability of the findings. Thus, the findings merely reflect the views of patients with T2D, who are mostly women, aged 55 years or older, overweight, and not physically very active. However, as women with T2D take on average fewer steps than men and the daily steps tend to decrease with age [17], there seems to be a particular need for interventions targeting this group of people. In this sense, our sample represents the population most likely to benefit from PA interventions. Still, more studies involving larger and heterogenous samples are needed to build up nationally and internationally generalizable interventions for patients with T2D.

Another obvious limitation of this study concerns the COM-B model's ability to explain PA behavior in the T2D population. Earlier studies involving healthy adults support the COM-B model's predictive validity for MVPA [60]. In young adults, the COM-B model explained 31% of the variance in PA behavior and was able to identify barriers and enablers of PA [61]. However, to our knowledge, studies on the psychometrics of applying COM-B among patients with T2D and other types of PA have not yet been published.

The third limitation is the nonvalidated COM-B measure adopted for the study. The questionnaire was not piloted but was found functional in the first set of participants, who were the members of the local T2D association. However, the information on the construct validity of the questionnaire is lacking, making it unclear whether the questionnaire correctly evaluated the intended sources of behavior. A questionnaire based on TDF has been proven reasonably reliable and valid in measuring the determinants of general PA in university students [64]. However, no previous studies were discovered that used the COM-B alone or in combination with TDF to evaluate the perceived behavioral needs of patients with T2D for increasing PA or especially walking.

Implementation

Fidelity

The counseling procedure of the main arm of the MySteps trial was implemented as intended, regardless of the COVID-19–induced challenges to patients with T2D. One reason may be that the procedure mostly included telephone contacts. Only a few sessions or contacts were missed, which suggests that the number of sessions and contacts was feasible for the participants. The mean lengths of the individual sessions and contacts also seemed reasonable in clinical practice, although there was a large variation. The large variation probably illustrates the demand for adjusting the length of the sessions and contacts according to individual needs, which may not always be executable in real-life health care settings. The findings on fidelity and length of the sessions are in line with the most comparable study to the present one, where 83% of the patients (63% with T2D and 37% with chronic obstructive pulmonary disease) received the intended intervention of 4 sessions and where most of the sessions exceeded the intended 20 minutes [65].

In the use of accelerometer and smartphone app, the number of weekly use days and number of weekly users declined during the intervention from 80% to 17% and from 92% to 22%, respectively. Similar descending trends have been found in other mHealth interventions among patients with diabetes, which show approximately 40% user rates at the end of the study [66,67]. One exception is the study by Verwey et al [65], where 88% of the patients wore the accelerometer and smartphone app until the end of the 25-week intervention period. The progressively lowering use has been recognized also in interventions involving adults without chronic diseases, although their attrition rates have been more moderate [21]. In any case, the engagement plays an important role in mHealth interventions since it has been shown that it associates with intervention effectiveness [68].

In this study, one explanation for the deep decline in use in weeks 23 - 26 may be that the accelerometer battery faded, and the participants, despite the instructions, did not replace the battery since the intervention was already coming to its end. If the weeks 23 through 26 were eliminated, the average user rate for the last weeks would be 64%. In any case, the attrition rate in mHealth studies seems generally quite high and is worth considering in future studies [68].

Interestingly, while the proportion of participants with a high engagement declined from 86% to 19%, the proportion of participants with moderate and low engagement remained practically the same, and the proportion of nonusers increased from 8% to 78%. This indicates that at least in the present

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intervention, the participants rather stopped using the devices than just reduced their use. If this discovery applies more widely, its impact on successful implementation needs to be considered in future mHealth interventions.

The relevance of individual contacts in facilitating the use of smartphone apps is seldom examined. In this study, the findings of the GLMM analysis emphasized their importance. The discovery is somewhat contradictory to a recent systematic review, which indicates that, in general, feedback on self-monitoring might not prevent attrition from self-monitoring interventions [69]. The more comparable studies, nonetheless, show that consultations are much appreciated among patients with T2D and not substitutable with an app [39].

The fidelity evaluation would have gained from more extensive cloud-based information on the use of the accelerometer and smartphone app. Unfortunately, this information could not have been extracted from the cloud data. Earlier studies have identified similar drawbacks and highlighted the importance of close collaboration with the technology team to develop tools for collecting fidelity information from raw digital data [70].

Overall, previous research shows that the delivery of PA interventions in patients with T2D is seldom evaluated at a practical level, and usually, the process data are limitedly and inconsistently reported [36]. This is regardless of the 2004 recommendation by the National Institute of Health Behavior Change Consortium to facilitate fidelity evaluation, especially in health behavior change studies [51].

With the increasing number of web-based and mHealth interventions aiming at health behavior change, the need for improving and standardizing evaluation reports has also been identified [71]. As a result, the CONSORT-EHEALTH (Consolidated Standards of Reporting Trials of Electronic and Mobile Health Applications and Online Telehealth) guideline on reporting eHealth and mHealth interventions has been published [71]. The guideline extends various checklist items of the CONSORT (Consolidated Standards of Reporting Trials) statement for randomized controlled studies and highly recommends, for example, reporting metrics of use (checklist item 17a-i) and technological problems (checklist item 19) as intervention outcomes (Checklist 1) [71]. Nevertheless, the systematic review by Blackman et al [72] shows that external validity is poorly reported in mHealth interventions promoting PA and provides specific recommendations for more comprehensive reporting including engagement.

Acceptability

The findings on the acceptability of SMC are encouraging, given that the majority of participants were women, aged 55 years or older, overweight, and physically not so active. On the other hand, the present results compare to previous studies, which show that adults with T2D appreciate self-monitoring and health professional facilitation as features of digital health intervention [39,40] and that age is not necessarily a barrier to using smartphone apps [66].

However, there were indications that some improvements would be needed to strengthen the credibility of the smartphone views and satisfaction related to the accelerometer. In the open spaces of the questionnaire, the respondents brought up similar concerns indicated in the few previous studies, including the inability of the accelerometer to account for all PA such as cycling and gymnasium activities [73] and technical problems related to a wireless connection [65,74].

The findings are not comparable with previous studies because acceptability has not been evaluated in research using mobile-based technology to promote health behavior change in people with T2D [38]. In many studies, the goal of the intervention has been to improve glycemic control through more comprehensive self-management apps [29,39]. These studies show variable satisfaction ratings and multiple usability problems such as multistep tasks, limited functionality and interaction, and difficult system navigation [29]. Usability problems, in turn, have been suggested to cause the experience of failure and additional burden to the participants, which can subsequently lead to so-called digital distress in some users [39].

A larger sample size would have brought more variance to the responses and may have shown more clearly the developmental demands related to the features of SMC. Moreover, the inclusion of the health providers' views would have deepened the understanding of acceptability, as it has been found that the technical problems, for example, are easy for the participants to manifest during counseling [73]. Providers' perspectives may have also brought out valuable information, especially about the applicability of the digital features of the intervention to everyday practice [37]. Previous studies have identified multiple influences on the use of digital tools in primary care [75]. In addition, using a measure with strong psychometric qualities would have improved the validity of acceptability findings. However, until now, only a few such measures have been identified in health care [53,56]. The unvalidated measures and specific features of the intervention may limit the generalization of the findings on acceptability.

Conclusions

In total, 3 items in capability and 2 in motivation stood out as perceived behavior change needs among patients with T2D for increasing walking and other nonexercise PA. The finding calls for additional research since no comparable studies have been done, to our knowledge. In addition, the explanatory value of the COM-B model and psychometric properties of the COM-B questionnaire concerning nonexercise PA in patients with T2D deserves further attention.

The main intervention arm of the MySteps mHealth trial based on self-monitoring and counseling showed good fidelity and acceptability in a sample of patients with T2D, which represented the people benefiting most from increasing PA. However, some challenges in acceptability were discovered regarding the smartphone feedback views and accelerometer use, but overall, acceptability proved better than expected, considering the special features of the sample. The challenges were quite similar to the ones observed in a few previous studies, underscoring the importance of pretesting technology-based approaches in interventions promoting PA in the T2D population.

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To summarize, the findings indicate that to design scalable mHealth interventions in the future to promote nonexercise PA in patients with T2D requires (1) valid measures on perceived behavior change needs, (2) studies with larger and more heterogenous samples, and (3) more comprehensive evaluation of implementation outcomes from the perspectives of both patients and professionals.

Acknowledgments

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Data Availability

The datasets generated or analyzed during this study are available from the corresponding author on reasonable request.

Authors' Contributions

Conceptualization: MA, TL, HS
Data curation: KT
Formal analysis: MA, KT, HV-Y
Funding acquisition: TL, HS
Investigation: MA, HV-Y, PH, AM, TM, TL
Methodology: MA, TL, HS
Project administration: MA, HS
Resources: MA, PH, TM, TL
Software: HV-Y, AM
Supervision: TL, HS
Validation: KT, HV-Y
Visualization: MA, HV-Y
Writing—original draft: MA, KT, HV-Y
Writing—review and editing: MA, KT, HV-Y, PH, AM, TM, TL, HS

Conflicts of Interest

None declared.

Multimedia Appendix 1
Timing, content, behavior change techniques, and delivery modes of the main intervention arm (self-monitoring with counseling).
[DOCX File, 16 KB - formative_v10i1e80304_app1.docx]

Multimedia Appendix 2
The questionnaire used in examining the perceived behavior change needs of the patients with type 2 diabetes in increasing walking and other nonexercise physical activity.
[PNG File, 604 KB - formative_v10i1e80304_app2.png]

Checklist 1
CONSORT-EHEALTH checklist (V1.6.1).
[PDF File, 355 KB - formative_v10i1e80304_app3.pdf]

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Abbreviations

BCT: behavior change technique
COM-B: capability, opportunity, motivation—behavior
COM-B-Qv1: COM-B Self-Evaluation Questionnaire
CONSORT: Consolidated Standards of Reporting Trials
CONSORT-EHEALTH: Consolidated Standards of Reporting Trials of Electronic and Mobile Health Applications and Online Telehealth
GLMM: generalized linear mixed model
LIPA: light-intensity physical activity
mHealth: mobile health
MVPA: moderate-to-vigorous intensity physical activity
PA: physical activity
SMC: self-monitoring with counseling
T2D: type 2 diabetes
TDF: theoretical domains framework

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Understanding User Perspectives to Inform Personalized Physical Activity Promotion in a Health Care App: Qualitative Focus Group Interview Study

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Abstract

Background: Health care apps are widely used to support weight loss and lifestyle modification. Many of these apps offer tailored feedback on dietary intake and nutritional behavior. However, most lack personalized features that promote physical activity (PA), which is important for weight management, metabolic health, and chronic disease prevention. To develop future personalized PA promotion functions, it is essential to understand users' perceptions of PA.

Objective: This study aimed to explore health care app users' perception of PA, including perceived motivators and barriers.

Methods: A qualitative study was conducted using focus group interviews with health care app users. Participants were recruited regardless of age, sex, or body mass index. A thematic analysis was conducted using a combination of inductive and deductive approaches. Question 1 ("How do you perceive the importance of physical activity?") was analyzed inductively, whereas questions 2 ("What are the motivating factors for engaging in physical activity?") and 3 ("What are the barriers to engaging in physical activity?") were analyzed deductively based on the social ecological model.

Results: Eleven participants were interviewed and were unfamiliar with the term "physical activity" but recognized the importance of movement and reducing sedentary behavior. The identified motivators included improvements in mood; changes in physical appearance; support from family; alignment with personal routines and conditions (eg, goal setting, feedback, reminders, and praise); and tailoring to physical condition, daily schedules, and weather. The reported barriers included time restrictions due to work, fatigue, weather, remote work, and social pressure in workplace settings.

Conclusions: This study provides user-informed insights that can inform the design of personalized approaches better aligned with daily routines, competing demands, and situational barriers. Future work should evaluate how incorporating such user perspectives into personalized support strategies affects engagement and PA.

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KEYWORDS

physical activity promotion; health care app; personalization; focus group interview; qualitative research; social ecological model; behavioral motivators; physical activity barriers; digital health

Introduction

Background

Physical inactivity (PA) is globally recognized as a critical public health issue that significantly contributes to the prevalence of obesity, cardiovascular diseases, type 2 diabetes, and other chronic conditions. The World Health Organization emphasizes that PA is essential for preventing and managing chronic diseases among diverse populations [1]. To achieve these health benefits, the World Health Organization recommends that adults aged 18 to 64 years should engage in at least 150 to 300 minutes of moderate-intensity aerobic PA or 75 to 150 minutes of vigorous intensity PA weekly [2]. Despite robust evidence supporting the benefits of PA, many individuals fail to achieve recommended levels due to perceived barriers, such as lack of time, fatigue, and environmental constraints (such as limited space and pollution) [3].

The recent development of mobile health apps has provided promising tools for behavioral modification, offering convenient and cost-effective health care interventions [4]. Advances in smartphone technology and wearable devices have enabled the integration of numerous basic personalized features, such as

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goal setting, activity reminders, self-monitoring dashboards, and adaptive feedback functions [5,6]. Recently, artificial intelligence–driven algorithms have been developed to deliver contextually tailored content that considers user real-time behavior, environmental conditions, and individual preferences [7].

Personalization generally refers to adapting intervention content, timing, or delivery to individual characteristics, preferences, and circumstances [8]. In developing personalized app functions, it is recommended to consider user factors, such as sociodemographic characteristics, adaptive goals, and timely feedback [9]. However, commercial PA apps often lack proactive and context-aware features (eg, tailored plans and context-aware prompts), and this limited ability to tailor support to individual differences and diverse circumstances may undermine effective and sustained user engagement [10].

User-centered design and qualitative inquiry are well-established approaches in digital health research for exploring users' needs and experiences. To enhance the appropriateness and effectiveness of personalization in digital health interventions, it is critical to understand user perspectives and needs rather than relying on developer assumptions only [11]. Qualitative methods are particularly well suited for the detailed exploration of subjective experiences, preferences, and perceptions, and focus group interviews (FGIs) are a widely used qualitative approach for generating data through group discussion [12,13].

Objectives

Therefore, this qualitative study aimed to explore users' experiences and preferences related to PA promotion using FGIs. The findings of this study will contribute valuable knowledge for the development of more engaging, personalized, and context-sensitive digital health interventions.

Methods

Study Design

This study used a qualitative research design utilizing FGIs and was reported in line with the COREQ (Consolidated Criteria for Reporting Qualitative Research) checklist (Checklist 1) [14].

Participants and Recruitment

Participants were broadly recruited through a health care app, CALOmama PLUS (Wellmira Inc), with no restrictions on sex, age, or BMI. CALOmama PLUS is a health care app with which users can register their daily information (diet, exercise, etc), and artificial intelligence instantly provides advice based on the registered information [15]. Interviews were conducted either face-to-face or online. In both settings, participants received a detailed explanation of the study via email in advance and were asked to provide preliminary consent to indicate their availability. The purpose and content of the study were explained again before the interview.

Data Collection and Survey

FGIs were conducted face-to-face and online via Google Meet (Google LLC). Based on participants' availability, three 1-hour interviews were held with 5, 2, and 4 participants (N=11). Focus groups are typically kept small to facilitate interaction and ensure that each participant has sufficient opportunity to contribute, with an "ideal" group size of approximately 4 to 8 participants suggested [12]. Interviews were recorded using digital voice recorders (ICD-TX650; Sony) and subsequently transcribed. All FGIs were facilitated by YN, a professor with extensive experience in conducting interviews. In addition, 4 researchers (YS, RM, SM, and TY) also participated. Two researchers (YS and RM) acted as co-facilitators, supporting the lead facilitator by asking clarification and follow-up questions to deepen participants' responses and monitoring group dynamics to ensure balanced participation. Two other authors (SM and TY) are employees of the health care app company. For participants attending face-to-face sessions, interviews were held at the company site for logistical reasons, with SM and TY present to support the on-site operation. Their involvement in the discussion was limited to a brief, clearly separated end-of-session segment addressing general app-use impressions (eg, usability). These ancillary questions were not part of the semistructured interview guide, and the data from this segment were excluded from the thematic analysis, as they were outside the study's primary aim. To minimize potential bias related to company affiliation, the core focus group discussions were led by academic researchers, and thematic coding and interpretation were conducted by researchers independent of the company's development team.

The semistructured focus group guide was created by YS and reviewed by all authors to reduce assumptions and potential bias of the first author. The review specifically focused on (1) ensuring alignment with the study aims, (2) reducing leading or value-laden wording, (3) improving clarity and neutrality of probes, and (4) confirming feasibility for a group interview. In addition, coauthors with prior qualitative interviewing experience (including JK, YS, and RM) conducted a targeted content and face-validity review, and revisions were made through iterative discussion among the research team before data collection. The semistructured FGI guide is available in Multimedia Appendix 1.

The questionnaire, sent in advance by email, collected information on 3 domains: baseline characteristics, health care app usage, and PA levels. Baseline characteristics included sex, age, height, weight, smoking status, exercise habits, walking habits, employment status, educational background, household income, cohabitation status, and marital status. For health care app usage, participants were asked about the duration of usage, reasons for use, and perceived physical changes after use. PA was assessed using the Global Physical Activity Questionnaire [16]. The interview questions were as follows: (1) How do you perceive the importance of PA? (2) What are the motivating factors for engaging in PA? (3) What are the barriers to engaging in PA?

Data Analysis

All FGI sessions were audio-recorded and transcribed. The transcripts were organized and managed using the NVivo software (MacOS Release 14.23.4; Lumivero) to facilitate thematic analysis. Thematic analysis is a qualitative method for identifying, analyzing, and reporting themes within data relevant

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to research questions [17]. Themes may be derived inductively from the data or deductively based on existing theories or frameworks [18]. Researchers are encouraged to use either or both approaches depending on the research purpose [19].

In this study, an inductive approach was applied to analyze responses to question 1, whereas a deductive approach based on the socioecological model was used for questions 2 and 3 [20]. This model considers not only individual factors but also interpersonal, organizational, and community-level environmental factors. Two researchers (YS and JK) independently reviewed the transcripts, categorizing content into "factors," "categories," and "codes." Discrepancies were discussed and resolved in consultation with a third researcher (YN) until consensus was achieved. The company-employed authors (SM and TY) did not participate in coding or in decisions regarding theme definition.

All interviews were conducted in Japanese, and the first author translated selected illustrative quotations into English. Translations were carefully checked against the original Japanese transcripts to preserve semantic meaning. Ambiguous phrasing was refined through discussion among the authors with reference to the original text.

Ethical Considerations

The study protocol was reviewed and approved by the Institute of Health and Sports Sciences at the University of Tsukuba (approval number: Tai 023‐140). Before the FGI, the researcher (YN) introduced the research staff and explained the study purpose and procedures. Written and verbal informed consent was obtained from face-to-face and online participants, respectively. To protect participants' privacy and confidentiality, all collected data were deidentified and stored on password-protected devices with access restricted to the principal investigator and research team. Any documents containing identifiable information were kept in a locked cabinet/locker in the research office, and only aggregated results are reported; quotations were presented without information that could identify individual participants. Participants received a QUO card (JPY 3000; US $19.18) as compensation for their time.

Results

Participant Characteristics

Eleven app users (3 men and 8 women) participated in the FGI; their characteristics are listed in Table 1. Participant ages ranged from 31 to 76 years. Of the participants, 2 lived alone, whereas 8 were married. Over half (6 participants) had been using the app for less than 1 year. The reasons for use included dietary (5 participants), weight (4 participants), and general health (2 participants) management. The range of values for BMI, occupational moderate-to-vigorous physical activity (MVPA), transport-related MVPA, leisure-time MVPA, and sitting time were 17.9‐28.6 kg/m^2, 0‐180 minute/week, 0-840 minute/week, 0‐560 minute/week, and 180‐840 minute/day, respectively.

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Table . Demographic characteristics of the participants (N=11).

Variables	Participants										
	A	B	C	D	E	F	G	H	I	J	K
Sex	Male	Female	Male	Female	Female	Female	Female	Female	Female	Male	Female
Age (y)	76	37	70	53	49	31	55	44	55	65	33
BMI (kg/m^2)	19.79	24.03	17.93	19.81	24.52	19.47	21.36	23.63	28.57	24.39	22.03
Exercise habits	Yes	No	Yes	No	No	Yes	Yes	No	Yes	Yes	No
Walking habits	Yes	No	Yes	No	No	Yes	Yes	No	Yes	Yes	No
Educational level	UG[a]	UG	UG	UG	JC[b] or TCG[c]	UG	JC/TCG	UG	UG	UG	JC/TCG
Duration of app use (y)	3 - 5	<1	≥5	1 - 3	<1	1 - 3	<1	<1	<1	3 - 5	<1
Reason for starting app use	Weight management	Diet management	Diet management	Health management	Diet management	Diet management	Weight management	Health management	Diet management	Weight management	Weight management
Occupational MVPA[d] (min/wk)	0	0	0	0	0	0	0	0	180	0	0
Transport-related MVPA (min/wk)	0	150	0	360	0	80	840	60	120	150	450
Leisure-time MVPA (min/wk)	180	240	560	360	120	240	0	30	0	180	150
Sitting time (min/d)	720	600	720	330	360	480	840	480	240	180	720

[a]UG: undergraduate degree.

[b]JC: junior college degree.

[c]TCG: technical college degree.

[d]MVPA: moderate-to-vigorous physical activity.

Question 1 Analysis

Overview

The responses to question 1 were analyzed using an inductive approach, and the FGI content was broadly categorized into "Awareness" and "Consciousness." To understand the current perceptions of PA, awareness was subcategorized into "Status." Furthermore, subcategories were defined as "Exercise" and "Daily activities" under "Consciousness." All participants were aware of the negative effects of prolonged sedentary behavior, whereas the term "physical activity" was not widely recognized. Some noted spending long periods sitting both at home and at work and observed a reduction in step counts due to working at home (Table 2).

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Table . Summary of awareness of the importance of physical activity (question 1).

Categories and subcategories	Codes
Awareness	
Status	• Lack of awareness
Consciousness	
Exercise	• Importance
Daily activities	• Household activities • Commuting activities • Work activities

Awareness

Recognition of the importance of PA was classified under the subcategory "Status" and coded as "Lack of awareness."

> *This is the first time I've heard the term "physical activity," and I was not clear on the difference from exercise.* [Participant B; Lack of awareness]
>
> *Aside from intentional exercise, I don't really engage in the kind of physical activity defined today. I do some gardening, but I don't think it counts for much.* [Participant C; Lack of awareness]
>
> *I just learned about physical activity today, so I haven't really paid attention to my daily movements. But now I realize that even small efforts can be effective.* [Participant B; Lack of Awareness]

Consciousness

Within "Consciousness," 2 subcategories were identified: "Exercise" and "Daily activities." Many participants expressed an awareness of the importance of exercise; therefore, the subcategory "Exercise" was coded as "Importance." For "Daily activities," based on the Global Physical Activity Questionnaire domains and participant statements, codes were created for "Household activities," "Commuting activities," and "Work activities."

> *I think exercise is important and try to do it as much as possible. I've been swimming since I was a child and still swim during my free time on weekends.* [Participant B; Importance]
>
> *I want to move as much as possible because it helps with weight management and posture and reduces stress.* [Participant F; Importance]
>
> *I make a conscious effort to walk around the house and go shopping to avoid being sedentary.* [Participant E; Household activities]
>
> *Even if I'm doing housework, I notice a big difference in calories burned and steps taken between days spent entirely at home and days when I go out, so I try to go out at least once a day.* [Participant K; Commuting activities]
>
> *During commutes, I try not to sit on the train and use the stairs instead of escalators.* [Participant K; Commuting activities]
>
> *Remote work has reduced both my physical activity and exercise, making me realize I need to move more.* [Participant B; Work activities]
>
> *I try to stand up and move my legs even when working at my desk.* [Participant A; Work activities]

Question 2 Analysis

Overview

A deductive approach was used for the second FGI question, which explored factors promoting PA. The content was classified using the social ecological model [16] into "Individual factors," "Sociocultural environmental factors," "Physical environmental factors," and "Organizational factors." In summary, individual factors, such as health checkup results and mood, were frequently cited as triggers for increasing PA. Family and friends were considered important for promoting PA, and support from health care providers was considered essential. Other factors included the work environment and mandatory workplace instructions (Table 3).

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Table . Summary of motivating factors for promoting physical activity (question 2).

Factors and categories	Codes
Individual factors	
Demographic	• Appearance
Biological	• Biological health
Psychological	• Mood • Experience
Sociocultural environmental factors	
Social networks	• Family • Peers • Social media
Smartphone application	• Goals and planning • Feedback and monitoring • Reward
Physical environmental factors	
Built environment	• Office ergonomics
Organizational factors	
Policy	• Directives

Individual Factors

Individual factors were classified as demographic, biological, and psychological. Demographic and biological categories were coded as appearance and biological health, respectively. Psychological factors were subdivided into codes, including mood and experience.

> *Seeing physical changes, such as a slimmer body line or fitting into previously tight clothes, motivates me to keep going.* [Participant E; Appearance]
>
> *Health checkup results are a major trigger for me to start exercising.* [Participant C; Biological health]
>
> *Enjoyable and fun exercise sessions, especially with others, make it easier to continue.* [Participant F; Mood]
>
> *Exercising helps clear my mind and improves my mood, which motivates me to continue.* [Participant F; Mood]
>
> *Past experiences of successfully losing weight through exercise and diet encourage me to try again.* [Participant E; Experience]

Sociocultural Environmental Factors

We classified sociocultural environmental factors into social networks and smartphone apps. In addition, the social network category was subdivided into codes, including family, peers, and social media. The smartphone app was subdivided into codes, such as goals and planning, feedback and monitoring, and reward.

> *Having family or friends to exercise with makes it easier to stay motivated.* [Participant E; Family]
>
> *Swimming classes with friends motivate me to continue exercising regularly.* [Participant B; Peers]
>
> *I often walk or attend gym sessions with friends nearby, which helps sustain physical activity.* [Participant F; Peers]
>
> *Watching YouTube videos or seeing others' experiences on social media inspires me to be more active.* [Participant E; Social media]
>
> *If an app clearly shows how to achieve weight loss through recommended routines, I would be motivated.* [Participant H; Goals and planning]
>
> *Setting clear goals and plans in the app, receiving feedback and monitoring, and getting encouragement or rewards are all motivating.* [Participant I; Feedback and monitoring]
>
> *Immediate positive reinforcement from the app for even small activities would be encouraging.* [Participant A; Reward]
>
> *Receiving compliments from characters on the application motivates me.* [Participant B; Reward]

Physical Environmental Factors

We classified physical environmental factors into built environments and coded the category as office ergonomics.

> *I wish my company had a treadmill desk so I could work while walking.* [Participant B; Office ergonomics]

Organizational Factors

We classified organizational factors into policies and coded them as directives.

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Mandatory standing breaks before meetings would be very beneficial. [Participant F; Directives]

Forced participation, like mandatory office attendance or children's school events, increases my physical activity more than voluntary measures. [Participant H; Directives]

Notifications on computers for breaks would be helpful. [Participant F; Directives]

Question 3 Analysis

Overview

A deductive approach was also used for the third FGI question, which explored barriers to PA, and the content was classified using the social ecological model into "Individual factors," "Sociocultural environmental factors," and "Physical environmental factors." In summary, the most frequently cited barriers were time constraints due to work-life balance and weather conditions. Many participants noted that remote work increased their sedentary time and made it more difficult for them to be physically active. Other barriers included a lack of knowledge about the benefits of PA and concerns about being watched by others at work (Table 4).

Table . Summary of barriers to promoting physical activity (question 3).

Factors and categories	Codes
Individual factors	
Demographic	• Age • Socioeconomic status
Biological	• Biological health • Fatigue
Psychological	• Habit • Attitude • Knowledge
Work-life balance	• Restriction
Sociocultural environmental factors	
Social networks	• Colleagues
Physical environmental factors	
Natural environment	• Weather
Work environment	• Work from home • Facility

Individual Factors

We classified individual factors into demographic, biological, and psychological factors, as well as work-life balance. Demographic and biological categories were subdivided into codes, such as age, socioeconomic status, biological health, and fatigue. Psychological factors were subdivided into codes, including habits, attitudes, and knowledge. Work-life balance was coded as restrictions.

Due to my age, I rarely go out except when necessary, and even then, I usually drive rather than walk. [Participant C; Age]

Financial constraints make it difficult to continue going to a sports club. [Participant E; Socioeconomic status]

Injuries or health issues make it hard to be active. [Participant C; Biological health]

Fatigue after work is a major barrier. [Participant E; Fatigue]

Convenient services like home delivery reduce the need for movement. [Participant H; Habit]

I tend to relax on the sofa and use my smartphone during free time. [Participant K; Habit]

I'm not sure if small activities outside of intentional exercise are really beneficial. [Participant C; Knowledge]

Time constraints due to work and household responsibilities make it difficult to be active. [Participant H; Restriction]

Sociocultural Environmental Factors

Sociocultural environmental factors were classified as social networks. In addition, the social network category was coded as colleagues.

It's hard to move when others are around at work. [Participant F; Colleagues]

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Physical Environmental Factors

We classified physical environmental factors into natural and work environments. The natural environment category was coded as weather categories. The work environment was subdivided into codes, including work from home and facilities.

> *Hot or rainy weather makes it difficult to exercise outdoors.* [Participant A; Weather]
>
> *Menstrual periods and rainy days reduce my desire to go out. Low atmospheric pressure, causing headaches, is also a barrier.* [Participant F; Weather]
>
> *Working from home leads to long sedentary periods and reduced physical activity.* [Participant B; Work from home]
>
> *During telework, sitting all day at home, I often realize I've only taken about 400 steps, which is unhealthy.* [Participant H; Work from home]
>
> *On weekdays, commuting was my primary physical activity. With partial teleworking recently, physical activity drastically decreased.* [Participant B; Work from home]
>
> *My previous job involved sitting at a desk reading and writing, with little physical activity. Even commuting was by car.* [Participant C; Facility]

Discussion

Principal Findings

In this study, FGIs were conducted to explore users' understanding of PA and their perceived motivators and barriers in promoting PA in daily life. Question 1 assessed participants' perceptions of the importance of PA, whereas questions 2 and 3 examined motivating factors and barriers.

Regarding question 1, although participants had limited awareness of the term "physical activity," they demonstrated an understanding of exercise and the need to move their bodies. Similarly, a previous study [21] reported low awareness of Japan's PA guidelines among 7000 adults aged 20 to 69 years registered with an online survey company, with 1.7% and 5.3% - 13.4% demonstrating spontaneous and assisted recalls, respectively. These findings indicate that public awareness and knowledge of PA guidelines remain limited, underscoring the need for increasing public awareness and understanding of PA guidelines.

Conversely, as indicated by participant demographic characteristics, over half (6 of the 11 participants) reported regular exercise habits. According to the 2023 National Health and Nutrition Survey [22], 36.2% of men and 28.6% of women have regular exercise habits, showing no significant changes over the past decade. However, compared with 2019 (men: 33.4%, women: 25.1%), a slight increase was observed. Even among participants without regular exercise habits, comments indicated conscious efforts to reduce sitting time and engage in incidental PA. Given participants' desire for reminder functions in apps, implementing education and promotion strategies using health care apps could be beneficial.

In question 2, motivating factors for promoting PA were analyzed using the social ecological model. At the individual level, improvements in appearance, medical examination results, and enhanced mood were identified as motivators. These findings align with previous research; for instance, a previous study [23] reported health concerns, appearance satisfaction, and emotional encouragement as motivators for individuals with obesity attempting weight loss. Moreover, positive mood after exercise has been reported as a key motivator for PA promotion, significantly correlating with achieving recommended levels of leisure-time walking [24].

At the sociocultural level, social networks and smartphone apps were identified as important factors. Participants highlighted family and peer support as crucial motivators. Similarly, one previous research [25] has emphasized that spousal support significantly influences exercise adherence in couples with diabetes. Another study [26] further demonstrated that changes in PA were positively correlated between spouses, indicating the importance of targeting couples in interventions. Participants also emphasized the motivational role of social media, consistent with prior studies showing increased exercise intention following exposure to fitness-related content [27].

The key motivating functions of smartphone apps included goal setting, feedback and monitoring, and rewards. A previous study [28] has similarly emphasized the importance of goal-setting compliance during the initial weeks of weight-loss interventions. Behavioral planning using smartphone apps has shown moderately positive associations with increased PA in individuals with cardiovascular diseases [29]. Furthermore, personalized feedback tailored to user preferences significantly enhanced PA and weight loss outcomes [30]. Digital self-monitoring techniques have also demonstrated significant effects on weight loss and moderate PA promotion in overweight adults [31]. Moreover, rewards and behavioral planning are effective strategies for promoting long-term PA [32]. Incorporating these behavioral change techniques into health care apps is expected to enhance the future promotion of PA.

Physical, environmental, and organizational factors primarily focus on workplace issues. Participants highlighted the need for improved workplace environments and policies, particularly considering modern sedentary work practices. This finding aligns with that of prior studies, suggesting that workplace interventions effectively reduce sitting time and promote PA [33]. Therefore, developing feasible intervention programs using health care apps that address these factors is essential.

In question 3, barriers to PA were analyzed using the social ecological model. Individual factors prominently emerged, with biological health issues, such as pain and injuries, identified as significant barriers, consistent with previous findings [34-37]. Fatigue and socioeconomic factors were also mentioned, aligning with existing research. Interviews with African American women identified economic constraints, physical strain, and sedentary jobs as key barriers [34]. The lack of knowledge regarding the benefits of PA was another barrier identified, consistent with previous studies reporting insufficient recognition of the benefits of leisure-time activity [35]. Time constraints due to work-life balance were the most frequently

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cited, in line with numerous previous studies [36,37]. In addition, convenient lifestyles that reduce opportunities for outdoor activities were reported as barriers, suggesting that future health care apps should propose outdoor activities to address this issue.

Within sociocultural environmental factors, social networks emerged as a barrier, with concerns about colleagues' perceptions making interruptions in sedentary behavior challenging. Participants requested discrete activity suggestions suitable for workplace environments via health care apps. Physical and environmental factors included natural and work environments. Further, weather conditions significantly influenced PA participation, with participants requesting activity suggestions suitable for indoor conditions during poor weather. Future health care apps should incorporate weather considerations into recommendations. Work environments, particularly teleworking facilities, were also significant barriers. Regarding this, the COVID-19 pandemic has altered lifestyles and increased concerns about inactivity. The 2023 National Health and Nutrition Survey [22] indicated that the average step counts have significantly decreased over the past decade, with teleworking likely contributing to reduced commuting-related activities. However, teleworking offers relative autonomy and fewer concerns regarding the perceptions of colleagues, potentially making interventions through health care apps more effective.

Implications

Building on the findings above, users' perspectives suggest that social and environmental contexts (eg, workplace norms and weather constraints) shape opportunities for PA and should be considered when designing personalized PA support in health care apps. For example, apps could provide low-burden, unobtrusive prompts to interrupt prolonged sitting in workplace settings (eg, suggesting brief, socially acceptable activities such as getting a drink, picking up a printout, or taking a short restroom break). In addition, when outdoor activity is less feasible because of weather conditions (eg, rain or extreme temperatures), apps could offer tailored indoor alternatives that align with users' preferences and available space.

Limitations

This study had some limitations. First, recruiting participants under the description "interviews regarding personalized exercise recommendation functions on health care applications" might have attracted participants already highly interested in exercise. Although 6 participants initially reported regular exercise habits, the interviews revealed that nearly all the participants were physically active, which may have biased the findings. Second, the sample (3 men and 8 women) likely skewed the results toward the perspectives of women. Considering the potential sex differences, future studies should ensure balanced sex representation. Third, the study was limited to users of a single health care app, which raises questions about its generalizability to other apps. Moreover, because CALOmama PLUS primarily focuses on diet and weight management, this context could have influenced how participants framed PA motivators and barriers. Therefore, our findings may be most applicable to digital interventions that embed PA promotion within diet or weight management apps, and themes may differ in primarily PA-focused or more general apps. Finally, this qualitative study was designed to elicit user perspectives and generate themes relevant to personalized PA support; it was not intended to elicit, rank, or prioritize specific app features.

Conclusions

This FGI study explored users' understanding of PA and identified multilevel motivators and barriers shaping their ability and willingness to be active. The findings highlight the importance of improving population-level communication of the PA concept and of considering users' day-to-day contexts when designing personalized PA support. These user-informed insights can guide the future development of personalization approaches to PA promotion in health care apps.

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Data Availability

The data presented in this study are available on request from the corresponding author. The data are not publicly available due to privacy concerns.

Authors' Contributions

Conceptualization: JK, RM, SM, TY, YN, YS
Data curation: RM, YN, YS

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Formal analysis: JK, YN, YS
Investigation: RM, SM, TY, YN, YS
Project administration: TY, YN
Resources: SM, TY
Supervision: TY, YN
Writing – original draft: YN, YS
Writing – review and editing: YN
All authors have read and agreed to the published version of the manuscript.

Conflicts of Interest

SM and TY are employees of the health care app company (Wellmira Inc). They were present only for a clearly separated end-of-session segment to ask ancillary questions about general app use impressions; these data were excluded from the thematic analysis.

Multimedia Appendix 1
Focus group interview guide.
[PDF File, 118 KB - formative_v10i1e85390_app1.pdf]

Checklist 1
COREQ checklist.
[PDF File, 255 KB - formative_v10i1e85390_app2.pdf]

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Abbreviations

COREQ: Consolidated Criteria for Reporting Qualitative Research
FGI: focus group interview
MVPA: moderate-to-vigorous physical activity
PA: physical activity

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Contextual Barriers to Health Information Systems Optimization in Underserved Communities in Kenya: Qualitative Study Informed by Frugal Innovation and Information and Communication Technologies for Development

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Abstract

Background: Health information systems (HISs) are essential for strengthening health systems in underserved areas. However, many HISs in Africa are still in the early stages of implementation, and existing systems often suffer from imbalances in data availability. Their optimization is faced with various challenges, including limited resources, which restricts their scalability.

Objective: The aim of this study is to identify contextual barriers that hinder the optimization of HIS in African underserved settings. Specifically, the study adopts the lens of frugal innovation (FI) and information and communication technologies for development (ICT4D) to explore ways to enhance the quality of health care delivery for low-income populations.

Methods: A qualitative research approach involving 32 participants was used. The study was guided by the central theme: contextual barriers and challenges hindering the optimization of HISs.

Results: Four major thematic categories emerged from the data: HIS contextualization, health system factors, service provider issues, and HIS integration. The findings offer valuable insights that can contribute to transforming HISs in underserved settings and improving health care quality.

Conclusions: The findings reflect stakeholder experiences in underserved communities in Nairobi, Kenya, and may be transferable to similar settings, subject to local governance, resources, and workflows. Despite the transformative potential of HISs in low- and middle-income countries, progress remains limited due to poor digital infrastructure and contextual barriers resulting in minimal impact from capital-intensive digital health investments and persistent data challenges. Using FI and ICT4D lenses, 4 key barriers were identified: health system, HIS contextualization, HIS integration, and HIS service provider. Rethinking HIS strategies through FI and ICT4D can enable affordable and sustainable, user-centered solutions. Future research should test scalability, sustainability, and interoperability impact in diverse settings.

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KEYWORDS

contextual barriers; frugal innovation; health care delivery; health information systems; information and communication technologies for development; underserved contexts; Kenya

Introduction

Background

Health information systems (HISs) are essential for strengthening health care systems in Africa by enabling timely data collection, processing, analysis, and reporting, supporting epidemiological surveillance and informing evidence-based health policy development, particularly in regions with limited infrastructure and resources [1,2]. Despite their importance, HIS implementation across African countries remains uneven, characterized by fragmented digital health initiatives and wide variations in data availability and system maturity [3,4]. While some of the countries have relatively advanced systems, many countries struggle with basic data collection, processing, and management functions, resulting in significant disparities. The adoption of key HIS interventions, including District Health Information Software 2, electronic health records, OpenMRS, mobile health, and telemedicine platforms, remains at an early stage in most African countries. Although uptake is increasing, driven largely by high mobile penetration, implementation continues to face substantial contextual barriers.

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Commonly reported challenges include insufficient funding, weak health infrastructure, digital divides, limited interoperability, shortage of skilled personnel, poor data quality, restrictive policy environments, sociocultural insensitivity, limited scalability, and lack of sustained commitment beyond pilot funding phases [3-10]. Funding constraints remain a major obstacle to scaling digital health initiatives, while limited capacity to effectively use available digital tools leads to the underutilization of data and missed opportunities for improving sustainable health outcomes [6,9].

Conceptual lenses, such as frugal innovation (FI) and information and communication technologies for development (ICT4D), may offer a useful way to understand how HISs can be designed, implemented, and sustained under constraints, yet these perspectives remain under-applied in HIS research in underserved African contexts. ICT4D in health aims to bridge the digital divide in low- and middle-income countries (LMICs) by facilitating health information sharing, telemedicine, disease surveillance, health record management, computer-aided diagnosis, treatment monitoring, and health education for underserved populations [11-13]. This promotes socioeconomic development by improving health and well-being [14-16] through enabling cost-effective care, improved service quality, efficient management, enhanced access to health data, and evidence-based policy-making [17]. These benefits are realized through ICT4D principles that promote efficient, effective, and person-centered care, including user-centered design, ecosystem awareness, scalability, sustainability, data-driven solutions, open standards, privacy and security, reuse, and collaboration [18-20].

FI, on the other hand, has emerged as a novel approach to producing effective and affordable products, services, and processes that use fewer resources to improve service delivery for underserved communities [21]. FI embodies the principle of “doing more with less” [22] and is guided by simplicity, accessibility, affordability, and sustainability to create cost-effective interventions [23-25]. In health care, FI focuses on developing affordable and effective solutions in resource-constrained settings [26], responding to growing demand for cost-effective, high-quality care [27]. The limited coverage of essential health services and persistent resource scarcity, especially in rural and urban poor settings, continues to restrict access to health care [22,24,28,29]. This necessitates the need for cost-effective health care innovations and increased research in frugal health care innovation [21]. By delivering low-cost, safe, and efficient solutions, FI holds significant potential to strengthen Africa’s health systems and overcome resource constraints.

This qualitative study examines contextual barriers and challenges affecting HIS optimization in underserved communities in Kenya and identifies strategies that stakeholders perceive as feasible and locally appropriate.

Related Works

Multiple relevant studies have been published; for example, a study to examine challenges related to the paucity of health data in Africa and its consequent impact on the implementation of digital health and evidence-based practice [6] found out that the availability of health data is limited and generally of poor quality in the African context. The challenges identified were inadequate infrastructure, a shortage of resources, and cultural barriers, which hindered efforts to leverage the potential benefits of information and communication technology (ICT) to build a properly functioning HIS. Notably, the authors observed that a lack of capacity and expertise in data analysis and interpretation led to the underutilization of available data. The study recommended automating the manual health data collection process for quick decision-making, engaging public-private partnerships to improve data collection, and investing in infrastructure and technology to enhance the collection and utilization of health data.

On the other hand, Shuvo et al [21] proposed a conceptual framework to lay out the underlying mechanisms of frugal health innovation to increase health care access by creating affordable solutions in resource-scarce settings. The study identified 3 components, that is, actors (health workers, hospitals, small and medium enterprises, research institutions, etc), the process (design, functionality, resource optimization, cost minimization, and cooperation), and the outcomes of frugal health innovation (profits from underserved customers, improved health care systems, and reverse innovation). The framework attempts to provide a blueprint for empirical research to guide managerial practices and initiate conversations on the development, adequacy, and adoption of frugal health innovations to increase affordability and access to health care for underserved populations. However, the framework is too generic, that is, focusing on frugal health innovation as opposed to digital health, and thus not fully contextualized to provide a deeper insight into the phenomenon under study.

According to the literature, the key contextual barriers to optimizing HISs in Africa include a lack of funding, digital infrastructure, HIS interoperability, skilled workforce, standard policy or guidelines, and sociocultural differences. To address these issues, previous studies have recommended increased funding, training health personnel on digital health, and engaging stakeholders in the design and development of HIS platforms, which requires more resources that are still unavailable, creating the gap this study seeks to address [30]. In addition, according to the literature, the lens of FI and ICT4D are underutilized in digital innovation in Africa, the health sector included [31-34], and particularly in Kenya’s digital health infrastructure, HIS platforms included. Furthermore, suggested digital health frameworks are more generic rather than context-specific, thus limiting insight into the research phenomena.

Therefore, a multifaceted approach to building resilient HIS is critical to strengthening health systems in LMIC settings, such as Africa. This means integrating and leveraging the potential of FI and ICT4D strategies to improve health care delivery for underserved African populations. This will help to address predominant environmental, social, and economic issues hindering health care delivery in LMICs, which contribute to the poor quality of health services [35,36].

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Study Aim and Research Questions

The study aims to identify key contextual barriers and challenges hindering the optimization of HISs by underserved communities in LMICs, with a focus on Kenya. This will inform appropriate strategies for designing and developing effective HIS platforms to overcome these challenges, thus contributing to transforming health systems to improve population health outcomes. The research questions to be answered by the study include the following:

1. What contextual barriers and challenges hinder HIS optimization in underserved communities in Kenya?
2. What strategies could be leveraged to deliver effective HIS platforms and strengthen health systems in this setting?

Methods

Study Setting

The study setting is urban-poor settlements, that is, Nairobi City County slums in Kenya, where residents lack basic services, which was conducted between March and July 2023.

According to Elton B Stephens Company [37], the city's total population was estimated at 5.3 million residents as of January 2025. The majority of the people live in the slums, which lack adequate social amenities, including health services, and are hence considered underserved communities. The city hosts Kibera slums, one of the largest slums in Africa, comprising 12 villages, with an estimated population of between 235,000 and 270,000 people [38]; therefore, slum dwellers were selected as the target population for the study. The study sought to identify contextual barriers hindering the optimization of HIS interventions in underserved contexts within an LMIC setting.

Ethical Considerations

Ethical approval for this study was obtained from the University of Leeds Research Ethics Committee. Ethical clearance was obtained from the Engineering and Physical Sciences joint Faculty Research Ethics Committee (Ref: MEEC 21 - 029). Ethical issues concerning research participants, the researcher, and the sponsoring organization were addressed. These requirements were observed diligently throughout the research process to avoid breaching the ethical guidelines [39,40]. Written informed consent was obtained prior to data collection. To protect privacy and confidentiality, interviews were conducted in settings that minimized third-party presence, and transcripts were deidentified (eg, removal of names and other direct identifiers) prior to analysis. Data were stored on password-protected devices/servers with access restricted to the research team. Participants received no compensation; however, they received a reimbursement of Kshs. 1000 (US $7.7) for their time and/or travel expenses.

Study Design

Overview of the Study

We conducted a qualitative study using semistructured interviews to explore contextual barriers to optimizing HIS in underserved communities in Nairobi City County, Kenya. This approach is appropriate for generating the in-depth understanding of stakeholders' experiences, perceptions, and recommendations in real-world implementation settings [41].

The theoretical theme of "contextual barriers" was adopted to guide the study design. Benefits of the qualitative research approach include its flexibility and adaptation of interview questions for clarity as the research progresses, appropriateness for a small sample or samples, and ability to collect and interpret nonverbal cues (body language) and offer opportunity clarifications for the researcher to gain a deeper understanding of the research phenomenon [42]. The approach is therefore considered appropriate for the purposes of probing participants' perceptions, attitudes, opinions, myths, and beliefs [43].

Sampling Procedure

Participants were recruited from 4 public health facilities within Nairobi slums, including Mathare North, Embakasi, Eastleigh, and Kibera South Health Centers.

Eligibility and Sampling

Various stakeholders were engaged. Community members and community health workers (CHWs) were eligible if they were aged 18 years or above, resided or served in the catchment areas of the participating facilities, and were willing to participate. Professional participants, including facility heads, health professionals (HPs), ICT experts, and policymakers, were eligible if they held roles relevant to HIS implementation or use, had at least 3 years of experience in their respective positions, possessed a minimum educational qualification of a diploma, and were working at the selected study sites during the study period [44]. Purposive sampling was used to ensure representation across stakeholder groups and facility types, complemented by snowball sampling for recruiting community members through CHWs.

Recruitment Procedures

Potential participants were contacted either in person or by phone with the assistance of the facility administrators. Interested individuals received an information sheet outlining the study aims, procedures, potential risks and benefits, privacy protections, and the voluntary nature of participation. Interviews were scheduled at participants' convenience and conducted at the study sites.

Snowball sampling technique was used to recruit initial community members with the assistance of CHWs, who were well acquainted with their communities [45]. Purposive sampling was guided by insights from facility administrators to ensure the selection of HP respondents with appropriate characteristics for addressing specific research questions and validating findings [46]. A total of 32 participants were recruited, comprising 15 professionals and 17 community members. The professional participants' category comprised 4 CHWs, four facility heads, 4 HPs, 2 ICT experts, 4 CHWs, and 1 policymaker.

Data Collection and Analysis

Interview transcripts were analyzed using thematic analysis following established procedures for systematically identifying patterns and themes in qualitative data [47]. Coding was iterative and involved developing initial codes, grouping codes into

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categories, and refining themes through the repeated comparison of data segments and analytic memos [48]. We sought to enhance analytic rigor through the clear documentation of coding decisions and theme development [49].

The data were collected using a semistructured interview guide, which lasted between 30 and 40 minutes. The thematic analysis method was performed manually, using the streamlined codes-to-theory model for qualitative inquiry [50], and participants' identities were coded for the purposes of anonymity. Data saturation was achieved with 25 after responses began to repeat; therefore, the data collection process was stopped. Table 1 is a sample summarization showing how initial codes were generated from ICT experts' responses:

Table . Example of initial coding and theme development from interview transcripts (ICT[a] stakeholder interviews; underserved communities in Nairobi City County, Kenya).

Participant ID	Main points from participant responses	Initial codes[b]	Theoretical theme[c]
ICT001	''There is lack of technical skills … and high technology and maintenance costs."	Lack of technical skills/high maintenance costs	Information management challenges
ICT001	"Donor effect creates a silo for example some partners only cater for HIV reporting and thus creating parallel reporting systems alongside the national health reporting system (DHIS[d])."	Donor effect and parallel systems	Information management challenges
ICT001	"There is a problem with policy implementation especially on devolution of health and misappropriation of funds."	Poor policy implementation	Information management challenges
ICT004	"ICT infrastructure is expensive … that is, there is high technology and maintenance costs."	Expensive ICT infrastructure	Information management challenges
ICT004	"The HR[e] element should be looked at, that is …, there is low developer capacity and technical skills that is, developers do not understand execution of systems."	Low HIS[f] developer capacity	Information management challenges
ICT004	"There is lack of clear objectives program characterised by short-term thinking … and … a lot of bureaucracy that policy people are not open with new technologies but they only favour paperwork."	No long-term strategy on sustainability of HIS projects	Information management challenges
ICT004	"There is a lot of bureaucracy that policy people are not open with new technologies but they favour paperwork."	A lot of bureaucracy	Information management challenges

[a]ICT: information and communication technology. Refers to participants with ICT expertise.

[b]Initial codes: shortened or synthesized statements capturing the key idea expressed in participant responses. Multiple ideas from a single response may be separated by a slash (/) to indicate combined coding.

[c]Theoretical theme: higher-level category used to group similar initial codes reflecting common patterns or challenges in HIS implementation.

[d]DHIS: District Health Information System, the national health reporting platform in Kenya.

[e]HR: health record.

[f]HIS: health information system.

Table 2 summarizes how the categories and data themes were generated from the initial codes derived from ICT experts' responses. Four key data themes emerged, namely service provider, HIS integration, health system, and HIS contextualization.

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Table . Generating categories and data themes from initial codes extracted from information and communication technology (ICT) experts' responses.

Theoretical themes	Initial codes[a]	Categories or subcategories[b]	Data themes[c]
Information management challenges	Lack of technical skills and high maintenance costs	Lack of expertise; high costs	Service provider
Information management challenges	Donor effect and parallel systems	Parallel systems (silos)	HIS[d] integration
Information management challenges	Poor with policy implementation	Management and leadership	Health system
Information management challenges	Expensive ICT infrastructure	Unaffordable infrastructure	HIS contextualization
Information management challenges	Low HIS developer capacity	Technical expertise	Service provider
Information management challenges	No long-term strategy on the sustainability of HIS projects	Management and leadership	Health system
Information management challenges	A lot of bureaucracy	Management and leadership	Health system

[a]Initial codes: key points extracted from participant responses.

[b]Categories or subcategories: groups of related codes reflecting common concepts.

[c]Data themes: overarching themes derived from categories, representing major patterns in the findings.

[d]HIS: health information system.

We aligned the study design with the COREQ (Consolidated Criteria for Reporting Qualitative Research) checklist, appropriate for interview-based qualitative studies [51,52]. The completed checklist is as a supplementary file (Checklist 1) upon resubmission, in accordance with JMIR recommendations and EQUATOR guidelines.

Results

This section presents the study findings on contextual barriers and challenges affecting HIS optimization in underserved communities. Four themes were identified: (1) health system factors, (2) HIS contextualization, (3) HIS integration, and (4) service provider factors.

Health System

Participant responses around this theme comprised issues related to health care policy decisions, governance, financing, resource provision, and implementation of national projects, including HIS. Sarkar defines a health system as a network of people, institutions, facilities, communities, and resources provision, including health personnel, who perform various tasks and provide health services to citizens, hence collective responsibility [53]. Key stakeholders included government (policymaking and financing), citizens (health care consumers), health care providers (hospitals and HPs), and development partners, among other stakeholders. However, it is the sole responsibility of the government to provide policy guidelines, ensuring a standard approach toward the delivery of health services, including HIS projects. The study identified various concerns during the study, most of which pointed to various weaknesses that act as barriers to successful health systems, including HIS operations. The following are quotes extracted from some of the participants' responses under this theme:

> *Regarding management of information and records, we mainly emphasise on professional training and code of conduct otherwise no organisational policy is in place to guide management health information including during referral.* [AP005]

> *There is lack of clear objectives characterised by short-term thinking … and a lot of bureaucracy that policy people are not open with new technologies but they only favour paperwork.* [ICT004]

> *Information management policies used in this place are based on WHO guidelines.* [AP002]

> *There is a problem with policy implementation especially on devolution of health and misappropriation of funds.* [ICT001]

> *There is poor retrieval of files, scarcity of storage space, and confidentiality of patient data especially Mother/Child booklet, misplacing of patient files … etc.* [HP003]

The study noted weaknesses in the health system, including a lack of standard policy guidelines regarding managing health information practices and services provided in public health facilities. Some of the facilities had no clear procedure for creation, storage, and retrieval and sharing of patient records or information during a referral. It was reported that World Health Organization information management policies were being followed, which did not consider contextual factors to meet local information users' needs. Health records were mainly managed manually due to a lack of digital infrastructure, which made retrieving records difficult; some records were disposed of prematurely, while some went missing, leading to information loss. In addition, participants reported poor policy implementation procedures in devolution regarding specific functions of both the national government and the county government, which led to poor health care funding in the country. Most of these challenges are because of resource scarcity.

HIS Contextualization

Some of the participants reported on technology-related issues that needed to be contextualized to meet local needs through an understanding of the technological environment. The digital era is becoming increasingly dynamic, while the needs of HIS users are equally increasing and changing quickly. According to observations made during the study, health care organizations

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need to adopt context-specific HIS platforms to ensure their meaningful use and increase operational efficiency. Unfortunately, most HIS in Africa lack contextualization, but they are rather based on foreign designs, and thus, they fail to respond to the needs of user systems, thereby compromising the quality of health care delivery. The following are quotes from the respondents that relate to this theme:

> *ICT infrastructure is expensive … there is high technology and maintenance costs.* [ICT004.]
>
> *The existing system for nutrition does not meet needs of the nutritionist. The system cannot generate reports so I need a tool to analyse and generate reports.* [HP006.]
>
> *You should ascertain stakeholder requirements and map user needs first.* [ICT001]
>
> *Customise software to suit users' needs for example Open MR software for doctors and nurses.* [ICT002]
>
> *Localise and customise the system to allow development of own skills.* [ICT001]
>
> *Use computers that is, laptops and desktops, servers, IoT to capture data and mobile phone for patients however … mobile phones are not meant for doctors but only patients.* [ICT001]
>
> *One should consider configurations for offline systems to enable data collection when Internet fails and ensure unique user identification.* [ICT003]
>
> *Consider affordability and quality of the technological infrastructure itself.* [ICT004]

The above extracts from participants' responses confirm the findings regarding the need for HIS contextualization in terms of the nature of the technical infrastructure, that is, considering technology acquisition and maintenance costs to make it affordable and accessible and customizing, configuring, and localizing software and hardware systems to meet different users' or stakeholders' needs to ensure the meaningful use to promote operational efficiency [54]. However, the existing digital infrastructure is unaffordable in underserved contexts due to resource limitations and high costs of technology; therefore, there is a need to combine and leverage ICT4D and FI principles to contextualize HIS. Unfortunately, the people's voices have not been heard concerning their health and well-being, but they are instead treated as passive receivers rather than active participants [55].

HIS Integration

The participants raised concerns about HIS integration across the board, which, in their opinion, was critical in enhancing national health care collaboration. A major barrier reported to have seriously hindered the optimization of HIS in an underserved context was the existence of data silos at the institutional level [56]. The silos were mainly observed to be in the interest of the donor rather than those of the government and the people (citizens). This raised serious concerns about data access by users, including personal health data by patients and HPs. This greatly hindered the care decisions, especially in situations where the patient received care in more than 1 facility, a situation that would even lead to medical mistakes due to the unavailability of pertinent information. The following are extracts from the participants to confirm this observation:

> *We have manual health information services as there is no government IT infrastructure except that of partners … for example university of Maryland transmit some data online. This creates loopholes in the health care system hence parallel health reporting which compromises efforts toward health care collaboration to improve service delivery.*
>
> *[AP003].*
>
> *HIS integration will require specific eHealth standards such as HL7 and FHIR especially in facilities with systems already installed.* [ICT002.]
>
> *The donor effect creates a silo, for example, some partners only cater for HIV reporting and thus creating parallel reporting systems alongside the national health reporting system (DHIS).* [ICT001.]
>
> *Use IT to integrate information systems, and recruit adequate personnel.* [HP009]
>
> *The impact of ICT is still low since only mobile phone is used to communicate especially during emergency.* [AP002]

The study observed that government partners and sponsors (nongovernmental organizations) established their information infrastructure in public health facilities to support reporting on their project activities or programs, without necessarily aligning it with the government's strategic plan. In most of the facilities, partners owned the entire digital information infrastructure, including computing equipment, software, ICT personnel, commodities, and so forth, to support their programs without necessarily involving government employees. Numerous challenges related to data access were observed during the study, particularly on health data security, client privacy, and confidentiality due to the nature of the information practices, thereby violating the individual's right to privacy and confidentiality. This is because information was mainly managed manually, resulting in the lack of proper mechanisms to safeguard privacy and confidentiality. Communication and sharing of information between patients and HPs were mainly done via cell phones, which were not inclusive and had numerous limitations, including small data processing and storage capacity as well as small screens, which could not be effective in an office setup.

HIS Service Providers

Service providers refer to individuals or organizations that receive support from the government to offer various health services to clients or citizens. The service provider is responsible for planning and controlling operations, capacity building, service improvement, and resource allocation in individual health care organizations. The participants' responses revolved around dissatisfaction with service provision to clients, ICT services included. The lack of ICT infrastructure, basic medical equipment, electricity, stationery, and sitting space was a serious concern, leading to clients' dissatisfaction with services rendered.

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The following are quotes extracted from participants' responses regarding ICT infrastructure that provides HISs:

> *Key factors contributing to the nature of current information services are understaffing, lack of ICT infrastructure, lack of staff training, resistance to use of computers, lack of knowledge or benefit of IT.* [AP005]
>
> *Photocopy machine and computers are available; however, computers are not used at all. Only the facility mobile phone is used by staff.* [HP011]
>
> *Staff are reluctant! And they feel its extra work to use computers since we do not have adequate personnel, lack of training and computer literacy! Health workers have a phobia with computers … and lack of equipment maintenance.* [AP001]
>
> *Information services can be improved by automation and training staff in IT literacy.* [AP002]
>
> *Improve ICT infrastructure, create awareness/training of staff in ICT and ensure global automation of departments' information services.* [AP005]
>
> *More personnel should be hired, funding for training of ICT skills be provided, and creation of more space for training and keeping records.* [AP003]
>
> *Implement ICT fully to bring transparency towards improving health care delivery.* [AP001]

Participants' accounts, therefore, suggest that the limited managerial prioritization of ICT implementation, combined with resource constraints and training gaps, contributed to low uptake of available digital tools. Most facilities had no HIS infrastructure due to a lack of the necessary equipment and skilled workforce. The situation was attributed to a lack of understanding of the value of ICT in their work activities, and thus, resistance against the quest to use computers despite having been provided by partners donating computers to some of the facilities. In addition, implementation efforts remained ineffective because essential foundational tools and services were still lacking, including reliable internet connectivity, functional electronic medical record systems, stable power supply, and ongoing technical support, thereby further limiting the practical use and sustainability of donated digital infrastructure. As a result, most of the staff were not confident in using computers due to inadequate exposure, which had become a culture, thus creating an avenue for resistance against adopting ICT. Most public health institutions in LMICs struggle to provide satisfactory services to clients due to resource limitations; therefore, adopting appropriate approaches and strategies to improve service delivery is essential.

Discussion

Principal Findings

This study aimed to identify contextual barriers and challenges affecting health information system optimization in underserved communities in Kenya and to explore feasible, locally appropriate strategies suggested by stakeholders. We found four interrelated themes, health system factors, HIS contextualization, HIS integration, and service provider factors, highlighting how governance, resourcing, workflow realities, and capacity constraints shape HIS use and perceived value. HISs are a critical tool for strengthening health systems in underserved contexts. Africa's HISs are in the early stages of implementation, while those in existence have data imbalances in data availability.

The lack of power supply, digital infrastructure, internet connectivity, interoperability standards, and skilled ICT personnel hinders the sharing, communication, and/or exchange of health data for better decision-making. The lack of integration between different HIS stakeholders leads to data silos within a country, making it difficult to share health data among health care providers and facilities [4]. According to Nyatuka and De La Harpe, most African countries do not have a national health information management strategy, resulting in the uneven adoption of HIS tools by different stakeholders, which jeopardizes the compatibility of health systems and thus leads to parallel HIS reporting on unrelated indicators [57]. Most HISs in Africa are vertical, partner-driven, and program-specific due to donor influence with limited system-wide impacts, and as a result, the majority of the projects are mainly designed to track and manage specific diseases such as HIV/AIDS, malaria, and tuberculosis, rather than providing a holistic or comprehensive historical record of a patient [4,43,53,58].

Furthermore, the absence of proper policy and regulatory guidelines and standards hinders the adoption of HISs [4,5]. Without guaranteed long-term sustainability, HIS projects will always fail, becoming merely exercises in futility with unmet expected impact, regardless of the level of investment or technological sophistication involved [3]. The situation, therefore, calls for the adoption of innovative strategies that can enhance and build the capacity for HISs in underserved contexts from LMICs to meet health data requirements. The study aims to leverage the principles of FI and ICT4D (digital development) to address contextual barriers hindering the optimization of HISs in underserved contexts. This is to be achieved through an empirical investigation to identify these barriers and recommend possible ways to overcome them using the lens of FI and ICT4D.

Despite the efforts addressing the barriers to overcome the use of FI and ICT4D, many health care systems in Africa continue to experience resource constraints and the digital divide, resulting in lower ICT penetration levels, design-reality gaps, inadequate health infrastructure, and policy issues [2,59]. Furthermore, there is a lack of attention to people's context of using technology when designing eGovernment programs, including eHealth strategies [14,60]. Noticeably, while access to ICT plays a critical role in promoting economic development, the nature and level of ICT usage do not reflect the same in most LMICs. To effectively leverage ICT4D in promoting health care, the focus should be on incorporating an FI strategy to create accessible, low-cost, and sustainable HISs, tailored to address specific local needs and contexts to reap the full benefits of ICT4D [43,61].

For example, in a study that explored the digital transformation within the health care sector in Africa, Iyawa et al [9] noted various pitfalls and challenges faced. These include a lack of

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digital health expertise and skills to develop and maintain digital interventions, a limited number of donors despite increasing demand on grant-seeking organizations, and disparate donor systems and standards, limiting interoperability and the exchange of various platforms. The authors also noted that the funding of digital health was lagging due to resource constraints, whereby early implementations lacked sustainability, given their cost-intensive maintenance nature. The study recommends digital health training in the training curriculum of health care practice for the digital transformation of global health in Africa.

Implications for Practice—Health System

These findings indicate that health system governance, financing, and infrastructure constraints limiting effective HIS implementation should be addressed through FI- and ICT4D-oriented strategies, including the development of cost-effective, scalable, and sustainable digital health infrastructure and the adoption of interoperable and affordable HIS platforms. For implementers, this implies integrating ICT4D principles, including understanding the health care ecosystem, designing for scalability, building for sustainability, and fostering collaboration into HIS design and deployment [59], alongside FI principles emphasizing affordability and sustainability to ensure feasibility in resource-constrained environments [24]. For policymakers, this implies adopting and enforcing FI- and ICT4D-aligned policies to guide investment in sustainable digital health infrastructure, enable electronic health information management, and support evidence-based decision-making by health system leaders and governing authorities. Together, these approaches can mitigate persistent resource constraints by enabling affordable HIS development and improving the availability of timely, high-quality health data to meet system needs [62,63], particularly in underserved urban LMIC settings where limited infrastructure and financing hinder HIS optimization.

Implications for Practice—HIS Contextualization

These findings suggest that HIS contextualization challenges, particularly noninteroperability and health data silos, should be addressed through FI- and ICT4D-oriented actions, including embedding these principles throughout the design, development, and implementation of HIS platforms [60-62] and adopting open-source software, interoperability standards, and open innovation approaches to support seamless workflows [63-65]. For implementers, this implies engaging end users in selecting context-appropriate technologies, prioritizing privacy, data security, affordability, and usability, and leveraging scalable and cost-efficient mobile–based and cloud-based solutions to strengthen HIS across facilities and systems [24,66]. For policymakers, this implies supporting FI- and ICT4D-aligned digital health strategies and standards that promote interoperability, sustainability, and affordability of HIS interventions, particularly in underserved urban LMIC settings where fragmented infrastructure constrains integrated health information management.

Implications for Practice—HIS Integration

These findings indicate that HIS integration challenges, especially noninteroperability and health data silos that limit information exchange, should be addressed through FI- and ICT4D-oriented actions, including applying these principles in the design, development, and implementation of HIS platforms and adopting open-source software, interoperability standards, and open innovation to enable context-appropriate workflows [15,18]. For implementers, this implies involving end users in selecting preferred technologies, ensuring HIS-supported services comply with privacy, security, and affordability requirements and prioritizing scalable mobile–based and cloud-based solutions to strengthen cross-facility and system integration [50,54].

For policymakers, this implies promoting FI- and ICT4D-aligned digital health strategies, interoperability frameworks, and investment models that support sustainable, affordable, and integrated HIS infrastructure, particularly in underserved urban LMIC settings where fragmented digital architectures constrain effective health information exchange [67].

Implications for Practice—HIS Service Provider Theme

These findings suggest that service provider-level constraints in accessing and sustaining digital health infrastructure should be addressed through the deliberate adoption of FI and ICT4D strategies, including open-source software (eg, OpenMRS), open data, open standards, and reuse of existing systems to develop cost-effective HIS platforms [20,68,69]. For implementers, this implies that health facility managers and governing authorities should improve access to digital health resources by reducing infrastructure and maintenance costs and establishing internal policies and procedures aligned with FI and ICT4D principles to support sustainable HIS implementation. For policymakers, this implies developing national and county-level digital health frameworks that incentivize affordable and sustainable HIS investments and strengthen institutional capacity for digital transformation, particularly in underserved urban settings where resource limitations hinder access to reliable health information systems.

Strengths and Limitations of the Study

We enhanced the trustworthiness of the analysis by maintaining an audit trail of coding and theme development, using iterative comparison across transcripts and documenting analytic decisions. We provide a thick description of the study setting to support the assessment of transferability. The findings should be interpreted in light of the urban informal settlement context of Nairobi City County.

The study's empirical findings offer evidence-based insights into complex HIS development challenges in an underserved setting, such as Africa, and Kenya in particular, leading to the delivery of context-specific solutions. Additionally, the identification of key contextual barriers and proposing the integration of FI and ICT4D strategies as interpretive lenses into the development process of HIS interventions provides valuable insights for digital health researchers and stakeholders to address resource limitation challenges more appropriately.

The study's findings, based on a case study of Kenya, may not be generalizable to other regions due to differing demographics, sociocultural factors, and digital health infrastructures. Limited

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research on frugal innovation strategies in African digital health contexts also constrained the study's literature base. Future research should use mixed methods to provide deeper, more valid insights into the complex issues studied.

Conclusion

The findings reflect stakeholder experiences in underserved communities in Nairobi City County, Kenya. While some barriers (eg, infrastructure constraints and parallel reporting systems) may be relevant to similar settings, transferability should be assessed in relation to local governance, resources, and workflows.

The study found out that despite the transformative potential of HISs in underserved LMIC settings, progress remains limited due to poor digital infrastructure and contextual barriers. Capital-intensive digital health investments have produced minimal impact, contributing to data quality challenges and weakened evidence-based decision-making. Using FI and ICT4D lenses, 4 key barriers were identified: health system, HIS contextualization, HIS integration, and service provider.

The findings indicate that rethinking HIS implementation strategies is necessary to improve sustainability and effectiveness. FI and ICT4D offer practical approaches for developing affordable, user-centered, and resilient HIS interventions that can strengthen health systems and promote equitable health care access in underserved communities.

Future studies should test FI and ICT4D informed HIS solutions in diverse settings to assess scalability, sustainability, and effects on data interoperability and health system decision-making.

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Data Availability

Because the dataset comprises qualitative interview transcripts from a specific setting, unrestricted public sharing may increase reidentification risk; therefore, we indicate that the deidentified data can be made available upon reasonable request subject to ethical and legal constraints.

Authors' Contributions

Conceptualization: DN, LD-M
Formal analysis: DN, LD-M
Funding acquisition: LD-M, MSRJ
Investigation: DN, LD-M
Methodology: DN, LD-M, MSRJ
Supervision: LD-M, MSRJ
Writing, review & editing: LD-M, MSRJ
Writing – original draft: DN, LD-M

Checklist 1
COREQ checklist.
[PDF File, 683 KB - formative_v10i1e78950_app1.pdf]

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Abbreviations

CHW: community health worker
COREQ: Consolidated Criteria for Reporting Qualitative Research
FI: frugal innovation
HIS: health information system
HP: health professional
ICT: information and communication technology
ICT4D: information and communication technologies for development
LMIC: low- and middle-income country

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Using Semiautomated WhatsApp Messages for Daily Stress Measurements: Integrated Usability and Feasibility Study

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Abstract

Background: Stress is a key determinant of health outcomes and may influence work performance. Questionnaire-based assessments of stress are typically broad and retrospective. Daily stress measurements via smartphones offer more granular, real-time data but have adherence issues. Using an already established communication medium (WhatsApp) and a more conversational style assessment might improve adherence and help collect more detailed insights into (work) stress, underlying stressors, and countering energy sources.

Objective: This study focuses on the usability and feasibility of semiautomated voice- and text-messages (with and without emojis) via WhatsApp as a method to collect daily data on experienced work stress, stressors, and energy sources.

Methods: A sample of 210 workers was recruited via social media and participated in a 10-workday diary study using semiautomated WhatsApp messages to rate daily stress, stressors, and energy sources. Questions (with and without emojis) were presented by a chatbot as text messages with clickable buttons (multiple-choice questions; MC) or with instructions to answer with either a voice or a text message. The study used an experimental design with 4 groups: (1) week 1 voice, week 2 text/MC with emojis; (2) week 1 voice, week 2 text/MC without emojis; (3) week 1 text/MC, week 2 voice with emojis; (4) week 1 text/MC, week 2 voice without emojis. Pre- and poststudy web-based questionnaires assessed demographics, familiarity with voice messages, and usability, including participants' preference for research studies. Open answers were coded using artificial intelligence, and the number of stressors or energy sources was compared across the 3 collection methods (MC, voice, and text messages) to determine if the amount and quality of information collected differ per method within participants.

Results: A total of 158 workers completed at least 80% of scheduled conversations. The sample was predominantly women(170/210, 81%), highly educated (173/210, 82%), and a slight majority worked part-time (109/210, 52%). Mean adherence to the daily schedule was very high (mean of 95%). The postquestionnaire revealed a strong preference for MC and text over voice messages, mostly due to ease and convenience in a variety of situations. The number of stressors per week was approximately 3 times higher in the MC-condition than in the voice condition, even though average stress levels per week did not differ significantly within participants. The number of energy sources was comparable between open answers in the voice and text conditions, but voice messages consisted of more words.

Conclusions: Collecting (work) stress data via semiautomatic WhatsApp messages is a feasible method with low effort for participants. Usability ratings indicated a strong preference among participants for MC and text messages over voice messages. Future research should explore usability in more diverse samples and in direct comparison to traditional assessment methods.

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KEYWORDS

work stress; whatsApp; chatbot; digital stress assessment; monitoring; artificial intelligence; AI; journalling; diary study; feasibility; usability

Introduction

Stress is a fundamental aspect of human life and plays an important role across various domains, including health and occupational settings. Stress is not only a key determinant of mental and physical health outcomes [1-4] but also influences work performance [5], productivity [6,7], cognitive processes [8,9], and overall well-being of employees [10].

Especially in the workplace, understanding stress and contributing factors such as long-term stressors, daily hassles,

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and sources of energy is critical for developing and applying effective strategies that support the employee's well-being. To be able to act on work-related stress in a timely manner, an important precondition is that work-related stress and contributing factors can be measured close to real-time and with enough detail to inform actions [11,12]. In the next sections, we first briefly discuss the advantages and disadvantages of different stress measurement methods in this regard. We then suggest a novel way to assess (work-related) stress and influencing factors with a conversational style assessment. We then continue by explaining how this study tests the usability and feasibility of this new approach.

Measuring stress in general, including in the workplace, is a challenge, as (work-related) stress is a highly subjective experience, depending on an individual's perception and appraisal of (potential) stressors [13]. While physiological, presumably more objective stress measures in the workplace are on the rise [14,15], the most common way to assess (work-related) stress today remains through standardized self-report questionnaires consisting of multiple items [13,16].

Commonly used questionnaires to assess (work-related) stress rely on one-time, retrospective questions covering a period of several days or weeks [13]. However, these approaches are less suitable for uncovering daily stress and hassles [13]. That is, retrospective recall is considered prone to biases, especially over longer periods of time, as individuals may misremember or reinterpret their experiences based on their current emotional state [17]. At the same time, one-time questionnaires are likely to capture a summary evaluation of stressful moments or could be impacted by a single, extreme event but fail to capture the context in which stress was experienced, making it hard to act on.

Alternatives to retrospective one-time questionnaires are diary studies and ecological momentary assessments (EMAs), which are both used to capture individuals' experiences in or near real-time with short questionnaires often consisting of single items [18]. This is tackling the problem of recall bias. With the spread of technology, these methods have become more widely applicable with specialized software and applications to facilitate web-based data collection. Traditional diary studies typically ask participants to record their thoughts, feelings, or behaviors at the end of the day or at scheduled intervals, either as open questions or short questionnaires. Similarly, EMA is a more structured and intensive version of diary studies, often involving multiple prompts for short questionnaires throughout the day to capture momentary experiences. Repeated or daily measures in these studies explicitly aim to capture the different situations in which stress might be experienced. This gives much more granular and actionable insights compared with a once-a-week or monthly measure.

Nevertheless, both traditional questionnaires and EMA face some shared challenges. Accessing context factors is taxing, as closed multiple-choice (MC) questions, while quick and convenient, might not capture a situation completely. Open questions, on the other hand, are time-intensive for both participants and analysts, especially if asked multiple times per day. Additionally, both types require time and motivation from participants to answer the questions. While traditional questionnaires require time and motivation only once or occasionally, adherence to daily questionnaires likely requires greater motivation from participants. Adherence to EMA is one of its biggest challenges, as research has shown that many participants quickly uninstall (research-related) apps, reducing long-term engagement and adherence [19,20]. On the other hand, EMA can provide more direct insights and moments of reflection for the participants [21].

To address the above-mentioned challenges (ie, collecting real-time contextual information and engaging participants in daily measurements) while keeping the advantage of real-time EMA, we suggest focusing on a more conversational style stress measurement using familiar and established conversation platforms like WhatsApp.

WhatsApp is currently the most popular messaging application globally, with 3 billion active users [22] and in the Netherlands, with 13.3 million active users [23]. Given its integration into daily life, WhatsApp makes it easier to take part in research studies and answer questions. It therefore has an advantage compared with the use of special research applications. In a conversation-like assessment via WhatsApp, questions are asked by a chatbot and can be either written chats, voice chats, clickable buttons, or a mixture of those. Providing more detailed answers or situational information to a "conversation partner" (ie, a chatbot) could feel more natural and engaging for participants, as suggested by the trend to discuss mental health topics with large language models (LLMs) like ChatGPT [24]. Being able to record voice messages instead of having to type the answer might also reduce the burden of providing open answers and increase overall adherence.

Concerning the integration of open answers from participants, the emergence of LLMs also makes it easier to process potentially large amounts of open-ended responses, whether in text or spoken form. Advanced natural language processing (NLP) techniques allow researchers to efficiently analyze and categorize responses, identifying themes [25,26] and sentiment [27,28] associated with stress.

Semiautomated chatbots using emojis or GIFs for engagement are already used in marketing for customer satisfaction surveys and interactive support [29-31], showing the potential of using this medium for measurement and intervention. In addition, the low-threshold communication might reach individuals who are less frequently included in research studies, such as young people or people with a lower education [21].

The use of communication apps for work-related stress measurements also aligns with broader trends in digital health and workplace well-being initiatives. Many organizations are exploring digital tools to monitor employee stress and well-being, with the goal of developing targeted interventions and support systems [12,32]. If harnessing commonly used communication channels for work-related stress assessments proves to be feasible, this approach could be further developed into a personalized and low-effort monitoring and support system for employees.

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This study adds valuable knowledge on the usability and feasibility of communication apps like WhatsApp as a tool for daily data collection in the pursuit of low-threshold (work-related) stress monitoring and interventions. In terms of usability, we are interested in who would be willing to participate in a study on work-related stress using this new data collection method (sample description). Another open question concerns how individuals perceive this method and their preferences regarding question types (ie, text, voice message, or MC buttons). In terms of feasibility, we need a better understanding of how this method performs in terms of uptake and adherence and the quality of information collected. In this study, we therefore investigate adherence rates as well as the effect of emojis on adherence, as emojis are a typical and easy-to-implement feature of mainstream WhatsApp communication. To evaluate the quality of the data collected, we will look at (1) potential differences in the number of reported contextual factors (ie, stressors and energy sources) per data collection method, (2) the number of words used to describe energy sources using voice or text messages, and (3) the relationship between the number of reported stressors and participants' stress ratings.

We formulated the following research questions for our exploratory study on usability (RQ1) and feasibility (RQ2 and RQ3), focusing on employees who took part in a 10-day diary study:

- RQ1: What is the user experience of participants over a 2-week period?
- RQ2: What is the level of adherence (percentage of daily measurements completed) in relation to the different collection methods and the use of emojis in WhatsApp?
- RQ3: What is the quality of the data in the different collection methods regarding the number of stressors and energy sources reported, the number of words used, and the relation of stressors to the stress rating?

Methods

Study Design

To answer the research questions, we adopted an experimental study design in a 2-week diary study on work-related stress and its contributing factors, using a semiautomated WhatsApp chatbot that asked 4 questions at the end of each workday. Each participant experienced both answer formats: voice messages or a combination of text messages and MC questions. Answer methods were switched after the first week: Half of the participants began answering questions using voice messages (voice condition) and would use MC messages (operationalized as template buttons) and text messages in the second week (text/MC-condition). The other half of the participants followed the reverse order. Additionally, both conditions were presented either with or without emojis, resulting in 4 experimental groups (Figure 1). For emojis, we chose more technical emojis, such as the battery symbol for the question on energy givers and the microphone for voice messages, to avoid adding emotional stimuli. Demographic data and user experience were collected via browser-based questionnaires before and after the daily WhatsApp interactions. Participants joined the study in 6 weekly waves between September and October 2024.

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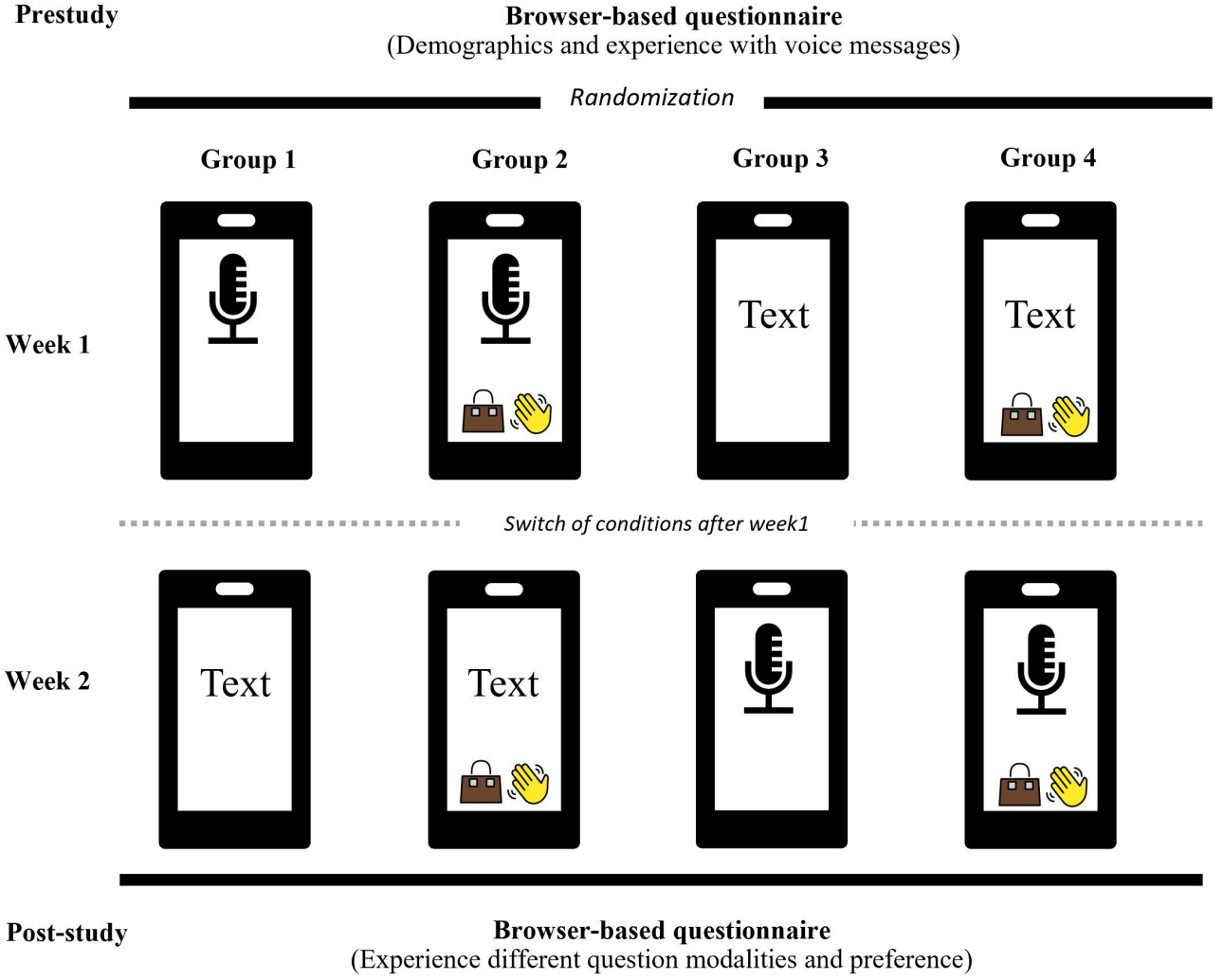
Figure 1. Study design (emojis adapted from [33], which is published under Creative Commons Attribution 4.0 International License [34]).



All daily messages were sent semiautomatically using the marketing tool [35], connected via the research organization's Meta account to a WhatsApp Business account created solely for this study. Eazy is an omnichannel marketing platform that is advertised to streamline and automate communication and support marketing campaigns; it is not routinely used in research contexts. Eazy programmed the 4 different experimental conditions as simple automatic, rule-based chatbots to interact with the participants. When participants answered a message, this triggered the next messages in the conversation script. The chatbot always instructed participants on how to respond, either by providing buttons with predefined answers or by requesting a text or voice message (Multimedia Appendix 1). Participants were informed at the beginning of the study that no human would monitor or engage in the WhatsApp conversation. All messages exchanged between the chatbot and participants were end-to-end encrypted.

Ethical Considerations

The research proposal was approved by The Netherlands Organization for Applied Scientific Research (TNO) Internal Review Board (registration number: 2024 - 071) after reviewing the research design, privacy considerations, ethical aspects, and the potential burden and risks to participants. All participants provided informed consent via a web-based survey (Survalyzer) prior to enrolling in the WhatsApp conversation. Data from the browser-based questionnaires were linked to WhatsApp conversations using phone numbers, which were subsequently removed and replaced with pseudonyms. All analyses were conducted on pseudonymized data. Participants did not receive direct compensation but could enter a lottery for 50 Amazon gift vouchers (1 × €100, 3 × €50, 46 × €20; conversion rate on payment date: 1€ = US $1.0580) if they completed at least 80% of daily measurements.

Procedure

We recruited unsystematically on social media for 6 weeks. Recruitment started on LinkedIn because of its closeness to the work setting. There, we published and shared posts from the research team members and promoted one of the posts through a paid ThoughtLeader campaign through TNO as the responsible research organization. After a limited response, we collaborated with TNO's Marketing and Communication department, which professionally organized paid advertising campaigns on Meta platforms (Instagram and Facebook) using the official TNO account. Social media campaigns were not specifically targeted

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at specific groups, as we were interested in the broad working population. All social media posts included a picture of a phone, a short description of the study (duration, topic, inclusion criteria, lottery), highlighted the use of voice data, and included a direct link to the Survalyzer sign-up platform. People clicking on the link were shown detailed participant information, including contact information to reach the study team (via email). Participants who wanted to participate could digitally sign an informed consent. Participants were then asked to fill in a short prequestionnaire on demographics, use of voice messages, and the telephone number they wanted to use. At the start, participants were informed how to disable automatic messaging by sending a stop word in the WhatsApp chat. On the final page, participants were automatically randomized and either shown a QR code to initiate the WhatsApp conversation (waves 1 - 2) or informed that the study team would add them manually using their telephone number (waves 3 - 6). During the study, the procedure was changed from QR code initiation to manual addition due to technical difficulties in renewing QR codes promptly.

The semiautomated messages were scheduled separately for each wave by the study team, starting on Thursdays. Messages were delivered Mondays through Fridays at 6 PM local time to the participants' own devices. After the first week, participants received a message informing them that they were halfway through the study and that the response method would now change. At the end of the study, participants were sent a link to an evaluation questionnaire and received a reminder one week later.

Randomization and Blinding

Randomization was done fully automated in Survalyzer. Participants were randomly assigned to one of 4 groups. Data collectors were not blinded because telephone numbers from waves 3 to 4 had to be manually transferred from Survalyzer to the marketing tool by the study team. Participants were blinded to their assigned condition.

Participants

Participants had to be 18 years or older, living in the Netherlands, and native Dutch speakers without a speech impairment. They were further required to be employed for at least 20 hours or 3 days per week, not to work night shifts, already have an existing WhatsApp account, and provide informed consent. Participants confirmed these criteria when providing informed consent.

Measurements

All data was collected through the web-based questionnaire tool Survalyzer (pre- and postquestionnaire), and through WhatsApp messages managed via Eazy.

Prequestionnaire

In the prequestionnaire, we assessed participants' gender (, woman, man, other), age (≤24, 25 - 34, 35 - 44, 45 - 54, 55+ years), number of weekly workdays (3 d, 4 d, 5 d), highest educational attainment (Dutch equivalents of low, medium, and high education), and frequency of voice message use on WhatsApp (never, occasionally, sometimes, often).

Daily Measurements

Daily measurements always started with the question of whether the participant had worked that day. If not, no further questions followed, and participants were sent a closing message wishing them a pleasant day. On a workday, the same 3 questions about experienced stress, stressors, and energy sources were asked, but the response methods differed across experimental conditions.

Experienced stress was measured consistently across all days using a single item adapted from the SMS-based stress assessment by Arapovic-Johansson et al [36]. Participants were asked: "Stress is a state in which you feel tense, restless, nervous, or anxious. Have you experienced stress today?." Participants responded using a drop-down menu ranging from 1 ("not at all") to 10 ("very much").

The questions on experienced work-related stressors and energy sources were self-developed as there were no validated single-item measurements available. The question on work-related stressors was answered either in an MC-format or with a voice message. For the MC-condition, we chose ten broad and commonly reported work-related stressors [37,38] to accommodate a broad target group (the amount of work; time pressure; emotional burden; constantly having to process information; negative atmosphere; work impediments/problems with systems or processes; uncertainty about tasks/task distribution or planning; conflicts or threats; lack of support or appreciation from supervisors; overlapping of work and private life; other [open answer]). Each stressor was presented separately with "yes" or "no" response options. In the voice condition, the question was phrased as follows, without examples: "What stressors did you experience today in your work? Share it with us in a voice message!." The question on energy sources was always an open question to be answered either by text or voice message ("Where did you draw energy from today or in which area did you have a good experience? Please describe this briefly in a [voice or text] message.").

Postquestionnaire

For the postquestionnaire, we measured participants' preferences and experiences with different communication methods using self-created items. We asked which method they found more pleasant ("Which method did you find more pleasant to use?"), easier ("Which method did you find easier to use?"), and safer ("Which method did you find safer to use?") to use, and which allowed them to express themselves best ("With which method could you best express your experiences or opinions?"). For each question, participants could choose between "voice messages," "text messages," "multiple-choice questions," and "no preference." We further asked if they experienced any technical problems ("Did you experience any technical problems?") with any of the methods. Three open-ended questions asked participants what they liked or disliked about each method ("What did you like or dislike about [text messages / voice messages /multiple-choice questions]? When or in what situation would you like to use [text messages / voice messages /multiple-choice questions]?").

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Concluding, we asked what kind of methods participants would generally prefer in research ("If you were asked to participate in a study, which method would you prefer?") with the following options: "WhatsApp questionnaires (multiple-choice questions)," "WhatsApp text messages," "WhatsApp voice messages," "A (phone) conversation," "Online questionnaires in a browser (like this one)," "A questionnaire in a special research app," "Group discussion," "Other, namely: …").

Participants who wished to enter the lottery as a token of appreciation for their effort were asked to enter their name and email address.

Statistical Analysis

To answer research questions 1 on participants' experiences, we present descriptive statistics from the pre- and postquestionnaire as well as stress ratings from the daily measurements. For research question 2, we compared adherence rates between the different conditions. Adherence was defined as the proportion of working days on which participants responded in the WhatsApp conversation, relative to the number of working days they reported in the prequestionnaire.

To test whether the use of emojis was related to the adherence, we conducted independent Wilcoxon rank tests between the emoji groups (groups 1 and 3) and the nonemoji groups (groups 2 and 4) for overall adherence and adherence per week.

To answer research question 3 concerning the differences in the number of named work-related stressors and energy sources in total, we compared groups using paired Wilcoxon signed-rank tests. The same method was used to compare the average number of words used in the text and voice answers on energy sources.

To compare the relation of number of named work-related stressors and the stress level, we report Spearman rank correlations between the number of work-related stressors reported per day/week and the corresponding stress ratings (same day and weekly average), stratified by condition. Before all analyses, we conducted a paired Wilcoxon signed-rank test to examine whether participants' average stress ratings differed significantly between Week 1 and Week 2. As no significant differences were found, all participants were included in subsequent analyses.

All statistical analyses were conducted in R (version 4.3.3; R Core Team) using nonparametric tests, as the assumption of normality was not met for most variables. A $P<.05$ was set as a criterion for significance. Missing data were analyzed as observed and not imputed.

Coding of Open Answers

Voice messages were transcribed using Whisper Model (large-v2) [39] from speech to text before content analysis as a well-tested process for transcription [40]. Transcription was performed locally to maintain data privacy. For quality assurance, we manually checked 10% of transcripts. All open answers in the daily measurements about work-related stressors and energy sources were coded into categorical variables using 2 runs with different degrees of supervision. First, a Chat-GPT-o1 model deployed in Microsoft Azure OpenAI [41] was used to generate potential labels for both work-related stressors and energy sources loosely informed by the Job Demands–Resources model [42] with instructions to also consider non-job-related factors. The prompts used to generate these labels are provided in Multimedia Appendix 2. Coding runs were done separately for work-related stressors and energy sources and based on all open texts participants sent (ie, text and voice messages, plus additional text responses for extra stressors in the MC-condition). This resulted in a total of 311 different labels for work-related stressors and 582 labels for energy sources, as many were synonyms. We cross-checked results with 2 psychologists with expertise in the work health domain (JT and MBR). Based on the review of 10% of the material, labels were combined and redefined into 29 labels for work-related stressors and 31 labels for energy sources. The translation of the redefined labels, their definition, and examples are provided in Multimedia Appendix 3. In the second run, these newly defined labels were used, limiting output to the defined categories (classification task), including examples from the material. The prompts used for the second run are provided in Multimedia Appendix 2. All answers were manually checked for coding accuracy by one of the researchers (JT). The final classification accuracy was 95%.

Open answers in the browser-based evaluation questionnaire were categorized manually by a social psychologist (MBR).

Power

To answer our research questions on feasibility, we needed to include 102 participants to detect a large effect between groups (d=0.5) with 80% power (based on a 2-sided independent *t* test). We set our recruitment goal to 250, assuming a conservative 50% dropout rate (defined as not starting or completing fewer than 80% of daily measurements) based on prior studies [19].

Data Exclusion

All messages sent by participants who did not answer a question were deleted (eg, wishing the chatbot a nice day or telling it that they would be free the next day) as were answers given after midnight, creating a 6-hour window for response. Duplicate questions and answers, as well as day entries exceeding 10 days due to technical issues, were removed; only the first valid response was retained. Conversations with 17 people from wave 1 and 2 had to be removed as their telephone numbers could not be matched to an informed consent, likely because the QR code for sign-up was shared or scanned using a different device.

Results

Participants

In total, 222 participants gave informed consent and filled in the prequestionnaire. A total of 210 (95%) participants successfully joined the WhatsApp conversation and completed at least one daily measurement. Furthermore, 158 (71%) participants completed the daily measurements for at least 80% (adjusted for working days) and 170 (81%) participants completed the poststudy evaluation questionnaire (Figure 2). The sample was predominantly women (170/210, 81%), highly educated (173/210, 82%), and working part-time (109/210, 52%) (Table 1 displays the total sample and Multimedia Appendix 4 for group characteristics). The average stress level

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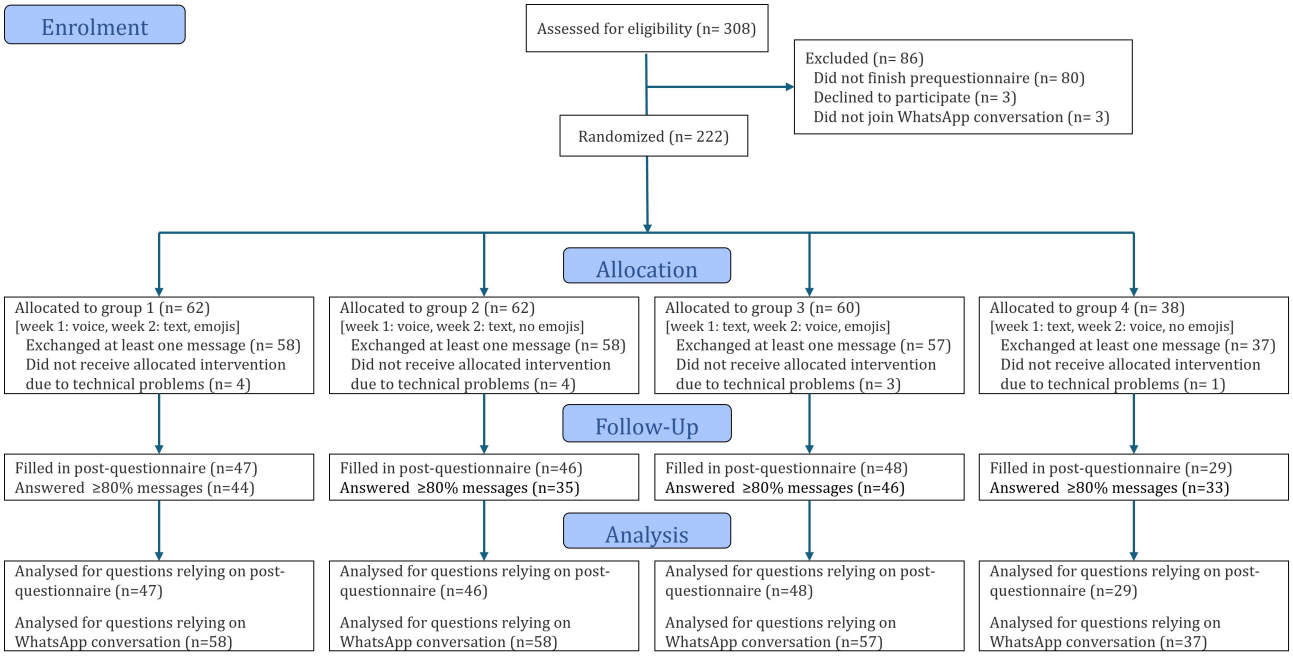
across the study period was 4.66 (SD 1.73) and did not differ between groups.

Figure 2. CONSORT (Consolidated Standards of Reporting Trials) flowchart of participants (adapted from Hopewell et al [43], which is published under Creative Commons Attribution 4.0 International License [34]).



Citation: COSORT Flowchart based on the templated provided by: Hopewell S, Chan AW, Collins GS, Hróbjartsson A, Moher D, Schulz KF, et al. CONSORT 2025 Statement: updated guideline for reporting randomised trials. BMJ. 2025; 388:e081123.

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Table . Sample description based on prequestionnaire (N=210).

Variable and category	Values, n (%)
Gender	
Woman	170 (81)
Man	38 (18.1)
Other	2 (1)
Age (years)	
18 to 24	4 (1.9)
25 to 34	44 (21)
35 to 44	47 (22.4)
45 to 54	69 (32.9)
55 or older	46 (21.9)
Education	
Low	4 (1.9)
Medium	33 (15.7)
High	173 (82.4)
Workdays per week	
3 days	17 (8.2)
4 days	92 (44.2)
5 days	99 (47.6)
Use of voice messages in everyday life	
Never	34 (16.3)
Once in a while	73 (34.9)
Sometimes	70 (33.5)
Often	32 (15.3)

RQ1: User Experience in Post Questionnaire

The postquestionnaire revealed a strong favor for the MC, as they were most frequently rated as more pleasant (75/170, 44%), easier (113/170, 67%), and safer (71/170, 42%) to use than the other methods, followed by text messages (Table 2). The open formats of text (57%) and voice messages (28%) were named more often regarding the method with which participants could better express themselves. As a general preference for research participation, WhatsApp questionnaires with MC questions (85/170, 52%) were rated highest, followed by traditional browser-based questionnaires (30/170, 18%). Technical problems were experienced by 15 participants (8.8%) with the voice messages and by 2 participants (1.2%) with both voice and MC questions.

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Table . Usability rating in postquestionnaire (n=170).

Variable and modality	Total, n (%)
Nicer method	
Voice message	14 (8.2)
Text message	67 (39.4)
MC[a] questions	75 (44.1)
No preference	14 (8.2)
Easier method	
Voice message	11 (6.5)
Text message	36 (21.2)
MC questions	113 (66.5)
No preference	10 (5.9)
Safer method	
Voice message	1 (0.6)
Text message	32 (18.8)
MC questions	71 (41.8)
No preference	66 (38.8)
Best to express oneself	
Voice message	48 (28.2)
Text message	96 (56.5)
MC questions	11 (6.5)
No preference	15 (8.8)
General preference for research method	
WhatsApp questionnaire (MC-questions)	85 (51.5)
Online questionnaire in a browser (like this one)	30 (18.2)
WhatsApp text messages	25 (15.2)
Other namely	9 (5.5)
WhatsApp voice message	8 (4.8)
(Telephone) call	4 (2.4)
Questionnaire in a special research app	3 (1.8)
Group discussion	1 (0.6)

[a]MC: multiple-choice.

The manually coded open answers to the question of what participants particularly liked or disliked about the different methods were consistent with the closed-question responses (Table 3). MC-questions yielded about 2.5 times more positive (n=138) than negative (n=55) aspects, with ease and convenience most frequently cited (n=102), although some participants noted the lack of nuance and context (n=30).

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Table . Positive and negative aspects of the 3 question modalities as named in the postquestionnaire (n=170).

Modalities	Total
Voice messages	
Positive aspects	120
Ease of completion, speed, convenience	41
Ability to think aloud and organize thoughts	41
Ability to add nuance to answers, provide elaboration, offer context, suitable for long and complex answers	17
Ability to express emotions, describe feelings, share/convey feelings	12
Ability to use own words or articulate the story well	9
Negative aspects	167
Not suitable for every situation and time, uncomfortable with by-standers	74
Unpleasant or uncomfortable to send voice messages	29
Answers cannot be adjusted, must be correct in one go, little room/time to think about the answer, no room for reflection	21
Difficulty in articulating thoughts	19
Uncomfortable sharing voice data, uncomfortable sharing personal information in this way, does not feel anonymous	17
Feels impersonal, you do not know who you are talking to	4
Technical problems when recording/sending voice messages	3
Text messages	
Positive aspects	198
Space for elaboration, nuance, providing context	54
Easy, accustomed to text messages, convenient, quick	38
Time to think about the answer and possibly adjust it, offers a moment of reflection	38
Can be completed at any time, anywhere	34
Pleasant for concise answers (or unpleasant for long answers)	14
Feels anonymous/privacy feels ensured	10
Space for elaboration, nuance, providing context	10
Negative aspects	23
It takes time, it is difficult to formulate an answer	21
Other negative comments that do not fall into any of the other categories or are not further specified	2
Multiple-choice buttons	
Positive aspects	138
Easy, quick, requires little effort from the respondent, convenient	102
Providing options gives respondents guidance, opportunity to reflect, offers frameworks	28
Other positive comments not falling into any of the other categories or not specified	8
Negative aspects	55
No possibility for nuance, providing context, lack of depth	30
Answer options were missing, options were not comprehensive, cannot share personal experiences	24
Technical problems/objections	1

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Text messages were predominantly evaluated positively, with 198 positive and 23 negative aspects reported. Participants highlighted the space for nuance and elaboration (n=54), ease of use and convenience (n=38), and time to think about the answer (n=38) as positive. A total of 21 participants mentioned that they found it difficult and time-intensive to formulate their answer in text messages.

Voice messages elicited nearly 1.5 times more negative aspects (n=167) than positive aspects (n=120). Positive aspects were similar to the ones mentioned about text messages and included ease of completion (n=41), time to reflect (n=41), and ability to provide nuance and context (n=17). Negative aspects particularly emphasized that voice messages were not suitable in all settings and that the timing of prompts was often inconvenient for recording voice messages (n=74). Twenty-nine participants reported feeling uncomfortable responding via voice messages.

RQ2: Adherence

Mean adherence to the daily schedule was high (mean 95%, SD 33%). This is partly because 78 participants responded on more days than their typical working days, resulting in adherence rates of 100% or higher, even though adherence remains high after capping adherence rates at 100% ($mean_{capped}$ 85%, SD_{capped} 23%). A screening of open responses suggests these participants may have had flexible schedules, as they mentioned working half days or completing tasks in peace. Mean adherence in week one was higher (mean 101%; $mean_{capped}$ 90%) than in week 2 (mean 89%; $mean_{capped}$ 79%). Participants tended to respond quickly to WhatsApp messages, with 50% of responses received within 13 minutes (mean 11.01 min, SD 427.79; 25th percentile: 0.35 min, Median: 13.33 min, 75th percentile: 69.38 min).

No statistically significant difference in adherence was detected between

the groups with (mean 96%, SD 36%) and without (mean 946%, SD 31%; W=5021, *P*=.43) emojis groups with the available data.

In week 1, a statistically significant difference was observed between the groups starting with the text condition (mean 107%, SD 24%) and in groups starting with the voice condition (mean 97%, SD 36%; W=6195, *P*=.046). No statistically significant difference was observed in week 2 (starting with text: mean 93%, SD 34%; starting with voice: mean 85%, SD 46%; W=5660, *P*=.48). The statistical test resulted in comparable results with the adherence rates capped to 100% (Multimedia Appendix 4).

RQ3: Differences in Work-Related Stressors and Energy Sources Reported Per Modality

A total of 29 work-related stressors and 31 energy sources were identified in the open answers and used as categories to analyze the content of open responses from voice and text messages, as well as open-text answers following selection of the MC category “Other stressors.” Not all MC options were directly represented in the categories for open responses; however, most work-related stressors from the MC options had equivalents in the open-text categories, such as “Amount of work” and “Quantitative demands.” The open-response categories also included unique items not present in the MC options, such as “Understaffing,” “Health,” and “Travel or commute burden.”

The average number of work-related stressors per day chosen in the MC-condition and coded from the open answers given as voice messages differed significantly (W=13,917, *P*<.001). In the MC-condition participants reported an average of 3.32 (SD 2.15) work-related stressors per day compared with 1.3 (SD 0.96) work-related stressors named in voice messages.

The 2 conditions also differed in terms of which stressors were reported and their frequency. Figure 3 shows that MC options were selected between 100 times (“Conflicts or threats”) and 330 times (“Constantly having to process information”). In contrast, the most frequently reported stressor in the voice condition was “Time pressure,” mentioned 111 times.

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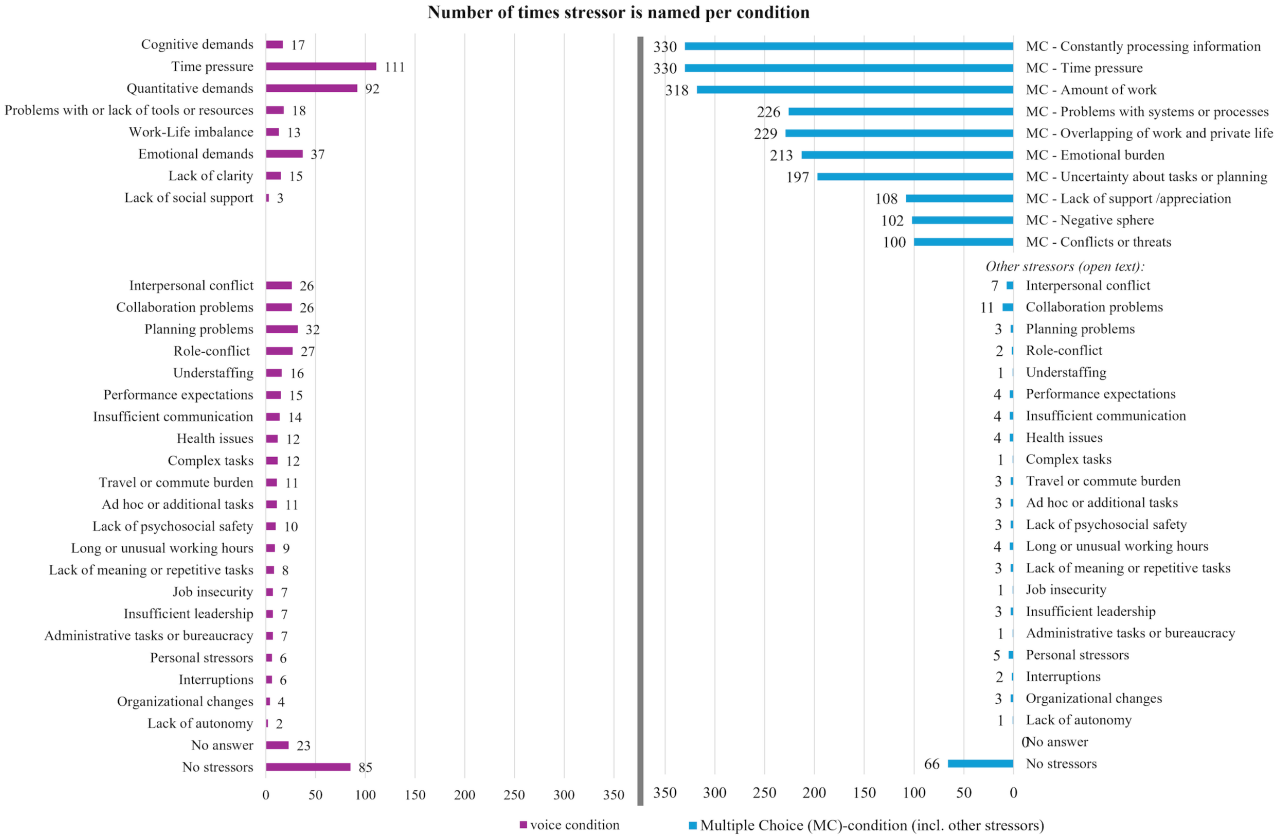
Figure 3. The number of total times work-related stressors were named in the voice or MC-condition, including open answers to the "other" category. MC-questions were not asked in the voice condition, and the closest category assigned to the open answers is presented alongside the MC-options. "Other stressors" described in open text were coded into the same categories as the voice answers. MC: multiple-choice.



The average number of energy sources per day reported in text messages and the number reported in voice messages did not differ significantly (voice: mean 1.65, SD 0.82 vs text: mean 1.55, SD 0.67; W=5231, *P*=.21). On average, participants used more words over the whole week to describe their energy sources in voice messages (mean 28.15, SD 23.48) than in text messages (mean 16.67, SD 8.92; W=10,197, *P*<.001).

The types of energy sources (Figure 4) were similar in both conditions, with the same top 3 energy sources ("Social interrelations and activities," "Accomplishment/ achievement" and "Collaboration") in both conditions.

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Figure 4. The number of total times energy sources were coded from the open answers in the voice and text conditions.

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Considering the relation between the number of named work-related stressors on a daily as well as weekly basis with the responding stress level, the correlation was higher in the MC-condition. The number of MC stressors showed a stronger correlation at the daily level (r=0.58) and weekly level (r=0.49) compared with the number of stressors reported in the voice condition (daily: r=0.43; weekly: r=0.34).

Discussion

Principal Findings

The present study set out to explore the usability and feasibility of different methods for collecting daily stress experiences in the workplace through a semiautomated WhatsApp conversation. In terms of usability, participants (predominantly highly educated women) had a clear preference for MC-questions and text messages over voice messages as answer formats. Feasibility, in terms of adherence and data quality, can be considered good. However, differences in the number of reported work-related stressors and energy sources warrant cautious reflection on the suitability of these methods.

User Experience

The results from the evaluation questionnaire indicate a strong preference of our sample for the MC-style questions with clickable buttons and text messages over voice messages. The main reasons cited were the convenience and ease of use in any situation, which is in line with general assumptions about question formats [44]. The biggest critique of voice messages was that not every situation was suitable for recording a voice message. This can be especially true in our study, as we had fixed-scheduled messages that could have occurred when participants were still in a work or commute environment, and the questions concerned that same environment. Personalizing the message schedule could therefore be advantageous. Crozier and Cassell [45] reported that participants perceived the flexibility of an audio diary as an advantage compared with a scheduled interview.

Adherence

Overall adherence to the daily message (without limiting to usual working days) was high, with 95% of messages answered. Even when limiting adherence to the number of days usually worked (ie, adherence rate capped at 100%), adherence was 85%. This is exceptionally high, given that traditional diary studies are considered prone to missing entries [21]. In a recent systematic review [19], half of the EMA studies (defined as assessing well-being at least twice daily) reviewed reported daily completion rates averaging 72% (range 43% - 95%). The review noted that associations between adherence and age or gender were rarely reported, but higher completion rates were observed in shorter studies (1 - 2 wk) [19,46]. In addition, responses to the initial message were typically quick (median 13 min), which is highly desirable for EMA studies [47]. The single daily measurement, short study duration, and restriction to working days in our study may explain the high adherence.

The use of emojis did not yield observable differences in adherence rates between groups. This is noteworthy given the vast research on emoji use in social marketing, which claims to enhance engagement [48,49] and to make chatbots more human-like [50,51]. However, this primarily relates to engagement on social media, such as “likes” and comments on specific posts or one’s own postings. In these contexts, the appeal of emojis is often attributed especially to women and younger generations [48,52].

Starting with the voice message method did, however, result in slightly lower response rates in the first week, in line with participants’ more negative evaluation of this method. Nevertheless, adherence in both groups was above 85%, even if capped at 100%. This may reflect both the selective sample and a possible novelty effect of the collection method. Our sample lacked sufficient diversity in age, gender, and adherence to examine subgroup differences, which is highly needed [19].

Differences Between Modalities

Our results indicate a great difference in the average number of reported work-related stressors per day in the different conditions (MC-conditions: mean 3.32, SD 2.15; voice: mean 1.3, SD 0.96) as well as the different number of stressors named (10 MC-options vs 29 options derived from open answers). Literature on questionnaire methodology suggests that recall and familiarity bias can play a big role in how MC-questions are answered [44]. The absence of cues or examples in the open questions may partly explain this large difference. Thus, the question of whether to use open or closed questions persists, even within new technical solutions. This notion is long-standing, as Dohrenwend [53] in 1965 already suggested that in well-conducted questionnaires, open questions do not bear higher validity or information than closed ones, and the choice of question should always depend on the research question. Similarly, in a questionnaire on resilience and coping mechanisms, the authors found no added value of open questions over closed ones in predicting mental health outcomes [54]. Our finding that the number of MC stressors correlated more strongly with stress ratings than open-answer stressors points in the same direction within the context of diary-based stress measures.

All things considered, it is noteworthy that the open answers received contained a lot of information and were barely skipped, as is often observed in traditional questionnaires. This highlights the potential of open answers to collect more detailed insights on new topics [53].

The observable difference in the number of words used to report energy sources, which was higher in the voice condition, may reflect the unedited nature of spoken responses, as participants also suggested in the postquestionnaire. This aligns with prior research from Crozier and Cassell [45], which showed that in-depth audio diaries can yield additional insights not captured in “edited” written responses or closed questions, which can be interesting for studying thought and reasoning processes. As diary and EMA studies—besides data collection—are also often reported to give insights and offer reflection moments, greater attention to the reflection process appears warranted [21]. In the evaluation questionnaire, both open-ended formats were mentioned to aid reflection, and voice messages were particularly described as helpful for “organising one’s thoughts.” Indeed, a study on teacher reflections found that written

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reflections were more summative, whereas spoken reflections provided greater detail and reasoning [55]. In the context of measuring stress, reflecting on it and potentially acting on it, these findings highlight the need for a deeper understanding of these differences in modalities.

Implications

The differences in assessed work-related stressors when using different methods support Crozier and Cassell's [45] call for pluralism in stress research. In the following section, we discuss situations and research aims for which the methods explored in this study may provide added value. Starting with participants' preferred method, the MC question, this format most closely resembles a traditional questionnaire, albeit with a different technical implementation. The evaluation survey showed a preference for WhatsApp questionnaires with buttons (MC-condition) from half the sample, followed by a traditional (browser-based) questionnaire and open-text questions in WhatsApp.

As the comparison to the open-answer question showed, participants reported on way more different stressors than we suggested with the MC options. MC questions are therefore most suitable when the symptoms or behaviors of interest are already well defined. To ensure relevant answer options, we recommend a participatory approach in which MC options are derived from the target group (eg, the most common stressor for a certain profession or type of work). Research questions then could center around incidence or accumulating effects of those stressors. To leave some more room for personalization and nuance, an alternative could be adaptive MC-questions, where next to predefined answers, participants can create their own answers, which are stored and shown to them in the following measurements as possible in specialized EMA apps [56]. However, this and other question types (eg, ranking or matrix questions) require technology beyond the consumer-ready marketing platforms currently available for social media.

The open text messages were also still conceived as convenient and quick for participants in the evaluation questionnaire. Interestingly, participants still occasionally (n=21) described them as time-intensive in the postquestionnaire, a negative aspect not raised with the voice messages. Participants acknowledged that it was easier to describe, in both open answer formats, nuanced and in context, what they experienced that day. While closed MC-questions can create a quick picture of the frequency of, for example, different work-related stressors and energy sources, open questions may play a crucial role in informing answer options, particularly for novel topics [53] and in revealing contextual information that influences measurement. If we look at the amount of different work-related stressors and energy sources, we find a large variety, including work-related energy sources such as autonomy, social support, and feedback [57] and energy sources outside of work such as hobbies, time spent with family, and recovery, indicating the open questions to be a rich information source. Insights from open responses illustrate concrete situations, offering opportunities to develop personalized advice for individuals and employers.

The general willingness to respond in written form within a conversational-style assessment suggests promise for developing stress assessments based on conversational agents rather than static chatbots, which is a rapidly emerging field. As participants increasingly recognize the conversational benefits of LLMs such as ChatGPT, the ability to systematically assess information comparable to questionnaires presents an interesting avenue for future research [58-60]. Additionally, written electronic diary entries combined with LLMs open up new therapeutic approaches that were not feasible before the advent of these models [61]. In this regard, our study demonstrates how LLMs can be used to analyze written material efficiently and semiautomatically, based on scientific models, thereby reducing barriers to incorporating open responses in stress research.

Our study does not support the idea that giving the option to answer with voice messages increased participation; it merely did not seem to hinder it in the current sample. As a standalone collection method, voice messages cannot be recommended unless explicitly designed with and for a specific target group (eg, younger individuals, people with visual impairments, or those with language difficulties [21]; . Given the comparable content, one could give participants the option to choose whether they answer per text or voice message. However, this option is already available on most smartphones via a dictation feature. Specific research questions may still require voice recordings, in which case WhatsApp or other messaging services could provide a feasible collection method. For example, research using voice recordings to diagnose and monitor health and disease [62] could facilitate audio recordings or combine them with questionnaire items or other biomarkers, thereby minimizing patient burden.

Limitations

Several limitations of this exploratory usability and feasibility study should be considered when interpreting the results. First, despite the envisioned low-threshold and inclusivity of WhatsApp as a research tool, our sample predominantly consisted of highly educated women, a demographic overrepresentation that is common in this type of research, as a systematic review revealed that more than half of EMA studies reported an overrepresentation of women and highly educated persons [19]. This imbalance was likely amplified by our recruitment strategy, which included outreach through scientific networks and opaque advertisement algorithms on social media platforms. Future studies should aim to diversify sampling strategies to ensure broader generalizability of the findings.

Second, while our study used a novel method for assessing stress, we did not compare this approach with established questionnaire-based assessments, nor did we validate the EMA items. This lack of methodological triangulation limits the evaluation of convergent validity and may affect interpretation of the measured constructs. This is a logical next step after proving the general feasibility of this collection method with this study.

Third, we used a single daily measurement, aligning our design more closely with traditional diary studies than with EMA protocols involving multiple daily prompts. End-of-day diary entries and EMA are not fully interchangeable, although they tend to yield more comparable results than weekly stress ratings [63]. This nuance may influence the granularity and ecological

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validity of the findings in our study. However, given that the overall burden was perceived as low in the evaluation questionnaire, this approach is likely also feasible with multiple prompts per day.

Fourth, logistical limitations in the technical setup may have impacted participant engagement. Participants could not begin automated data collection immediately after enrollment, as group assignment and message scheduling were handled manually. This could result in delays of up to one week, potentially reducing initial motivation. Additionally, we used 2 different data collection platforms—Survalyzer for informed consent and WhatsApp for the actual daily measures—due to ethical concerns of asking for consent via WhatsApp. Although no direct impact on participation was observed, this switch may have introduced variability in user experience and warrants refinement in future implementations. As assessments and feedback mechanisms become more complex, new technological challenges are likely to emerge.

Last, our approach to coding open-ended responses using LLMs is innovative but lacks established validation within psychological research. To mitigate this, we monitored outputs carefully, always manually double-checked 10% of responses at each stage with experienced psychologists and fully verified final categories before analysis, achieving high agreement between LLM coding and human coders. Nevertheless, the use of LLMs remains an emerging practice that requires further validation.

Conclusions

Conducting diary studies via WhatsApp as a convenient, low-threshold method was perceived positively by participants, with a preference for MC questions and text messages over voice messages, due to their convenience and suitability for responding in any situation. However, our relatively homogeneous sample of mostly highly educated women leaves open the question of whether results would differ in more diverse samples. The high adherence, richness, and completeness of information gained through the study render this method feasible and promising for future-proof (work) stress research, provided it is carefully aligned with study goals and validated through direct comparison with traditional methods.

Acknowledgments

The authors declare the use of generative artificial intelligence (GAI) in the research and writing process. In accordance with the GAIDeT taxonomy (2025), GAI tools were used under full human supervision for proofreading and editing, as well as translation. The GAI tool used was the Copilot GPT-5 model on September 12 and December 4, 2025.

Responsibility for the content and integrity of the final manuscript rests entirely with the authors. GAI tools are not listed as authors and do not bear responsibility for the final outcomes. This declaration was submitted by JT.

Copilot was used to generate a list of suggested corrections for grammar and spelling in the manuscript, and all suggested changes were critically reviewed before being incorporated. The prompts in Multimedia Appendix 2 were translated using Copilot and carefully reviewed by the first author. All Copilot conversations used in the preparation of the manuscript can be read in Multimedia Appendix 5. The use of GAI as an analysis method is described in detail in the Method section.

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Data Availability

The datasets generated or analyzed during this study are not publicly available as they contain audio recordings that potentially include identifiable voice characteristics. Other nonsensitive data may be available from the corresponding author on reasonable request and subject to appropriate legal and ethical agreements.

Authors' Contributions

EK, IN, JT, MBR, and SS contributed to the conceptualization and methodology of the study. JT and SS were responsible for data curation. Formal analysis was conducted by JT (statistics) and SS (large language models). JT and MBR carried out the investigation and validation. Project administration was managed by EK and SS. Visualization was performed by JT. JT prepared the original draft of the manuscript, and EK, IN, JT, MBR, and SS contributed to the review and editing of the manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Screenshots of conversation with the chatbot in both conditions (with emojis).

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[PDF File, 804 KB - formative_v10i1e84032_app1.pdf]

Multimedia Appendix 2
Prompts used for unsupervised coding of open answers about work-related stressors and energy sources.
[PDF File, 149 KB - formative_v10i1e84032_app2.pdf]

Multimedia Appendix 3
Final categories used to code open answers on energy sources and stressors.
[PDF File, 120 KB - formative_v10i1e84032_app3.pdf]

Multimedia Appendix 4
Sample description based split by groups and adherence rates when capped at 100%.
[PDF File, 241 KB - formative_v10i1e84032_app4.pdf]

Multimedia Appendix 5
Copilot conversations.
[PDF File, 4904 KB - formative_v10i1e84032_app5.pdf]

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Abbreviations

EMA: ecological momentary assessment
LLM: large language model
MC: multiple-choice
TNO: The Nederlands Organization for Applied Scientific Research

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Feasibility and Preliminary Efficacy of Empowered Relief in Patients With Chronic Pain Taking Methadone or Buprenorphine: Single-Arm National Pilot Study

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Abstract

Background: Approximately 45% of individuals taking methadone or buprenorphine have chronic pain. These medications are commonly prescribed for chronic pain or opioid use disorder (OUD). To optimize pain management as well as reduce opioid-related symptoms (eg, craving) and risks (misuse and overdose), there is a critical need for a brief, effective, and accessible pain skills intervention for this population.

Objective: This single-arm study aimed to examine the feasibility and preliminary efficacy of online Empowered Relief (ER), a 1-session pain relief skills class, for individuals with chronic pain taking methadone or buprenorphine for chronic pain or OUD.

Methods: A priori feasibility criteria were defined as at least 75% of enrolled participants attending the ER class and the mean satisfaction rating of at least 8 on a 0 - 10 scale. Participants were recruited nationally across the United States. Out of the 69 enrolled participants, 55 attended the ER class. Self-report measures were collected at baseline, immediately post class, and at follow-up points of 2 weeks and months 1 - 3. Additionally, qualitative interviews were conducted in a small sample (n=14) to obtain in-depth participant feedback. Among the class attendees, 51 participants (27/51, 52.9% female; mean age 48.6, SD 12.2, range 28 - 71 years) completed at least one follow-up survey, and treatment outcomes were analyzed using repeated measures ANOVA, with missing data imputed using linear regression. This analytic sample consisted of 24 participants taking methadone and 27 participants taking buprenorphine; 43.1% (22/51) endorsed at least≥2 OUD symptoms within the past 12 months, meeting the *DSM-5* (*Diagnostic and Statistical Manual of Mental Disorders* [Fifth Edition]) diagnostic criteria for current OUD.

Results: Feasibility was achieved with 79.7% (55/74) attendance and mean 8.6 (SD 2) ratings of treatment appraisal and satisfaction. Qualitative feedback demonstrated high acceptability of the class content and delivery, with suggestions for refinements. Repeated-measures ANOVAs and FDR-corrected post hoc tests revealed significant reductions at 1 month post-ER class (primary endpoint) in pain intensity (Cohen *d*=0.71), pain bothersomeness (Cohen *d*=0.54), and pain interference (Cohen *d*=0.61). At 3 months post-ER class, efficacy was maintained for pain intensity, pain bothersomeness, and pain interference (Cohen *d*=0.28, 0.44, and 0.48, respectively). No significant time effects were observed for pain catastrophizing, sleep disturbance, physical function, fatigue, depression, anxiety, social isolation, and opioid craving.

Conclusions: This study is the first to test ER in patients taking methadone or buprenorphine for pain or OUD. Findings showed feasibility, acceptability, and preliminary evidence of treatment efficacy. Participant feedback will inform future study designs. These findings support a randomized trial to fully evaluate the efficacy and scalability of ER in this population.

Trial Registration: ClinicalTrials.gov NCT05057988; https://clinicaltrials.gov/study/NCT05057988

International Registered Report Identifier (IRRID): RR2-10.2196/53784

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KEYWORDS

pain management; treatment; behavioral; online; group

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Introduction

Chronic pain affects roughly 20% of US adults [1]. Among individuals with chronic pain, nearly one-third report using prescription opioids [2]. However, long-term opioid therapy provides only modest pain relief [3-5] and is often accompanied by adverse side effects [6,7]. Consequently, those taking long-term opioids frequently report insufficient pain relief [7-9], and their overall pain management remains suboptimal. Behavioral pain interventions have emerged as a safe and potentially effective strategy to improve pain-related outcomes, which in turn may help reduce prescription opioid use [10-12]. To date, few studies have examined the effect of behavioral interventions in individuals with chronic pain taking long-term prescription opioids [10,12-14]. While meta-analytic evidence suggests that behavioral pain interventions may lead to moderate reductions in pain intensity and small reductions in opioid use, the overall quality of evidence remains limited [13,14].

Methadone (full mu agonist) [15] and buprenorphine (partial mu agonist) [16] are US Food and Drug Administration–approved and expert-recommended opioid medications for opioid use disorder (OUD) and chronic pain [17,18]. Estimates suggest that 45% of patients taking these medications have chronic pain, regardless of the primary indication for prescription [19,20]. Given that patients taking either of these medications have chronic pain, OUD, or both, targeted behavioral interventions may improve pain outcomes and/or reduce opioid use or misuse. To date, 12-session cognitive behavioral therapy (CBT; 6 - 9 h total) and 8-session Mindfulness-Oriented Recovery Enhancement (MORE; 16 h total) are among the few interventions tested in this population. The 12-session CBT for chronic pain has shown no significant effects on pain intensity and pain interference [21], although reductions in opioid misuse have been reported [22]. The 8-session MORE has shown consistent reductions in opioid use and craving across 2 in-person Phase I trials and 1 online Phase III trial [23-25]. However, findings regarding its effects on pain have varied [23-25].

Evidence is promising for behavioral pain treatment in individuals taking medications for OUD; yet, significant barriers impede broad patient access [26-28]. A 1-session pain relief skills intervention (Empowered Relief [ER]) overcomes many existing barriers to care owing to its brief format, and online delivery provides even greater access while keeping treatment burden low [29]. ER has demonstrated efficacy for reducing pain intensity, pain interference, pain bothersomeness, sleep disturbance, depression, and anxiety in heterogeneous pain conditions [29-34]. In-person ER has shown noninferior efficacy compared to traditional, 8-session CBT for chronic low back pain and has produced sustained improvements in pain catastrophizing, pain intensity, pain bothersomeness, and pain interference as well as associated symptoms (eg, fatigue, sleep, depression, and anxiety) up to 3 - 6 months [29,30]. When delivered online, ER remains effective in improving pain-related outcomes [31], and has shown preliminary efficacy among individuals with long-term use of short- or long-acting opioids [35]. To date, ER has not been tested in patients with OUD or history of OUD. The current single-arm study sought to test the feasibility and preliminary efficacy of online ER in individuals with chronic pain taking methadone or buprenorphine. We hypothesized that ER would (1) be feasible (as indexed by 75% attendance rate and an average treatment satisfaction rating of ≥8 on a 0 - 10 scale) and (2) significantly reduce primary outcomes of interest (pain catastrophizing, pain intensity, pain bothersomeness, and sleep disturbance), improve other outcomes (ie, physical function, fatigue, depression, anxiety, and anger), and reduce opioid craving at 1-month post treatment (primary endpoint). Additionally, we hypothesized that (3) these effects would be maintained at 3 months post treatment (durability endpoint). Finally, we aimed to collect qualitative interview data from a subset of participants to inform potential treatment refinements.

Methods

Overview

The Stanford Institutional Review Board approved the study procedures (IRB-60855). This study was preregistered (NCT05057988), and the study protocol is published open access [36]. Informed consent was obtained from all participants. This study was conducted in accordance with the ethical principles outlined in the Declaration of Helsinki. Data were collected using REDCap (Research Electronic Data Capture; Vanderbilt University), a secure, HIPAA (Health Insurance Portability and Accountability Act)-compliant electronic platform. Access to participant data was restricted to a limited number of study personnel, and all data were stored and analyzed on password-protected, encrypted computers.

Recruitment

Participants were recruited nationally through pain and addiction clinics via physician referrals and self-referral through research posting on a Stanford Pain Division website and the clinicaltrials.gov website. Email invitations were also sent to the Pain Division's research registry. Study advertisements invited individuals with chronic pain who were taking methadone or buprenorphine to attend a single online pain relief skills class and complete a series of surveys. The study was opened for enrollment in September 2021, and 71 participants were recruited between May 2022 and October 2023 (18 mo). Among the 69 consented participants, 55 attended an ER class (Figure 1).

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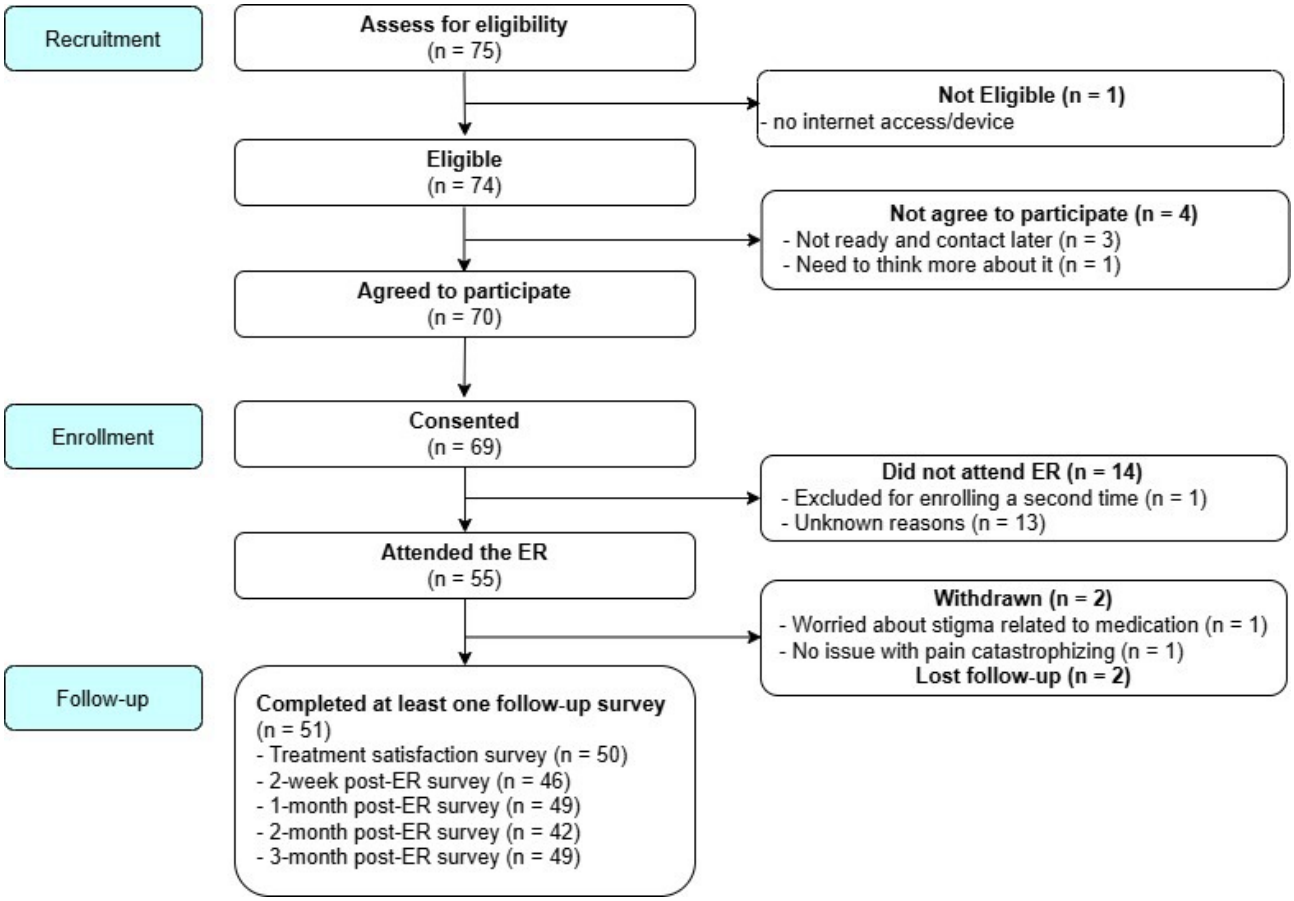
Figure 1. CONSORT diagram. CONSORT: Consolidated Standards of Reporting Trials; ER: Empowered Relief.



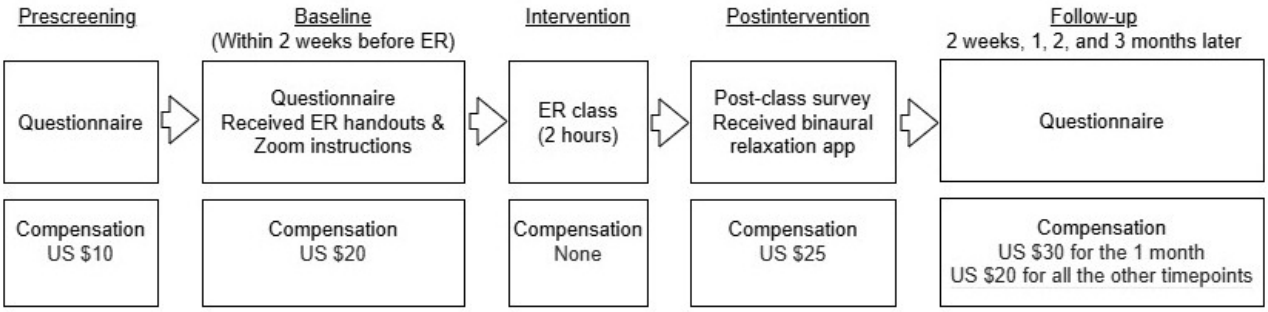
Eligibility Criteria

Inclusion criteria were participants >18 years of age, ongoing body pain for more than half of the day for >3 months, currently taking methadone or buprenorphine, and verbal English fluency. To make ER more accessible, internet or computer access was not required. Participants could use any device with video call capability, as long as the referring clinics could accommodate Zoom sessions. Written English fluency was not required as participants had an option of completing their surveys either online, via mailed paper-based format, or with research coordinator-assisted methods. None used the assisted method, and only one participant completed the survey on paper and used pre-paid postal mail to return the survey to the study team. Exclusion criteria were pregnancy or having previously received the ER intervention.

Procedures

The inclusion and exclusion criteria were posted on the study website and communicated with referring physicians. Individuals who were either self-referred or received the study flyer or study contact information from referring physicians contacted the research coordinator via a phone call, text message, or email. Following initial contact, the research coordinator scheduled a phone call to confirm eligibility (Figure 2) and explain the study goals, procedures, risks, and the compensation schedule. Those expressing interest were sent an electronic consent form and were encouraged to take as much time as needed to review the consent form and contact a research coordinator with any questions.

Figure 2. Timeline.



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Following electronic consent, participants received the baseline survey link, zoom instructions, and ER class handouts. During the ER group session, participants were asked to display only their first name and keep their cameras off for privacy. They were encouraged to ask questions either directly to the class instructor or through the online chat function. Upon completion of the ER class, participants received a document of the class slides and binaural app instructions as well as a treatment appraisal and satisfaction survey. Participants received follow-up surveys at 2 weeks, 1 month (primary endpoint), 2 months, and 3 months post treatment (durability endpoint). For the interview portion, we sent an email invitation to the first 20 participants who completed the study, and 14 provided the feedback. Compensation was provided in the form of Amazon gift cards (Figure 2) with amounts ranging from US $10 to US $30, depending on how many surveys a participant completed, and up to $145 possible. Notably, the compensation at 1 month was slightly higher to improve the data collection at the primary endpoint. Those who participated in a 30-minute qualitative interview (n=14) received an additional US $20 Amazon gift card.

ER

ER is a 2-hour didactic class consisting of pain neuroscience education, experiential and interactive exercises, and 3 core pain management skills such as cognitive reappraisal of pain catastrophizing, self-soothing, and relaxation techniques. During the class, participants self-tailor the content to create a personalized plan for ER, and they receive a binaural calming audio app for downloading onto their smartphone or other devices and with unlimited use. Participants were encouraged to use the calming app daily.

Data Collection

All study data were obtained via self-report measures and through qualitative interviews (for a subset of participants). The study was designed to be untethered from medical care and as such medical records were not accessed, nor was there any communication with participants' clinicians.

Self-Report Measures

Demographic and clinical characteristics were assessed at baseline. The demographics questionnaire included sex, age, race or ethnicity, marital status, education, employment status, household annual income, and housing situation. Clinical questionnaires included pain duration, pain location, pain diagnosis, and mental health diagnoses. Pain duration was assessed using preselected categories, such as (1) <3 months, (2) between 3 and <6 months, (3) between 6 and 12 months, and (4) >1 year. Pain diagnoses, opioid medication, and mental health diagnoses were assessed in a free text format. Additionally, prior experience with a pain self-management class was asked in a yes or no question. Finally, the *DSM-5* (*Diagnostic and Statistical Manual of Mental Disorders* [Fifth Edition]) OUD symptom checklist was administered to evaluate the participants' current OUD severity (past 12 mo) [37,38].

To assess the primary study outcome of feasibility and acceptability, 11 questions [36] were asked to evaluate (1) overall satisfaction, (2) ease of understanding the class content, (3) relevancy, (4) usefulness, (5) likelihood of using the skills, (6) likelihood of recommending the class to others, (7) ease of operating Zoom, (8) concerns about privacy while attending the Zoom class, (9) feeling comfortable engaging with the Zoom instructor and class participants, (10) feeling of connection with the instructor, and (11) preference for a single, 2-hour class or two 1-hour classes. All questions were rated on a 0 - 10 scale except for the last question with 3 response options (1: prefer single, 2-h class; 2: prefer 1-h two classes; and 3: other). When selecting "Other" as a response, a free text box was generated to elicit detailed information. To ensure consistency in directionality of scale items, (8) the concern about privacy was reverse coded. To gain deeper insight into acceptability and future refinements, structured qualitative interviews were conducted with 14 volunteers after attending the class.

Preliminary treatment efficacy was assessed with the following patient-reported outcome measures. First, the 13-item Pain Catastrophizing Scale (PCS) was administered to assess the levels of pain catastrophizing (α=.87) on a 5-point scale from 0 (not at all) to 4 (all the time) [39]. Pain catastrophizing is a maladaptive cognitive-emotional response to pain, characterized by magnification, rumination, and helplessness about pain [39]. The PCS total score ranges from 0 to 52, with higher scores indicating higher levels of pain catastrophizing. The levels of average pain intensity [40] and pain bothersomeness [41] in the past 7 days were assessed with a single-item measure. Pain intensity was rated on a 0 (no pain) to 10 (worst pain imaginable) scale and pain bothersomeness was rated on a 0 (not at all bothersome) to 10 (extremely bothersome) scale. The Patient Reported Outcomes Measurement Information System (PROMIS) sleep disturbance v1.0 (6a) short-form was administered to assess level of sleep difficulties in the past 7 days (mean 50, SD 10), with higher T-scores indicating greater difficulty [42]. Sleep disturbance was assessed because poor sleep is associated with worse pain [43] and opioid misuse [44,45], and because ER has been shown to improve sleep disturbance [29,30].

Additional Efficacy Measures

The PROMIS measure short-form questionnaires were administered to assess pain-related symptoms in the past 7 days [46]. Specifically, PROMIS-pain interference v1.1 (6a) [47], physical function v2.0 (6b) [48], fatigue v1.0 (4a) [49], depression v1.0 (6a) [50], anxiety v1.0 (6a) [50], and social isolation v2.0 (4a) were used [48]. Each measure was rated on a 1 - 5 scale. Responses on each measure were uploaded to the publicly available HealthMeasures Scoring Service to calculate T-scores (mean 50, SD 10), with higher scores indicating worse symptom or higher function. Additionally, current craving intensity was assessed on a 0 (not at all) to 10 (extremely) scale [51]. Finally, the 6-item Global Impression of Change (GIC) measure was administered at all post-ER class timepoints to assess the perceived improvement after the intervention. The 6 GIC items were about improvement on overall health, physical activity, social activity, work-related activity, mood, and pain, which were rated on a 7-point scale, ranging from 1 (very much worse) to 4 (no change) to 7 (very much improved) scale [52]. Adverse events were assessed at all follow-up time points.

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Preliminary Efficacy Endpoint at 1 Month

A prior online ER study (chronic pain and no medication inclusion criterion) showed significant reductions in PCS scores as early as 2 weeks post treatment. Significant reductions in pain intensity and pain bothersomeness consistently emerged at 1 month post treatment, which served as the primary efficacy endpoint [29,31,33,53]. These treatment effects were maintained at 3 months after ER class, which informed the durability timepoint for this study [29,31].

Analysis Plan

Feasibility Thresholds

The following criteria were evaluated to determine feasibility. First, >75% of enrolled participants would attend ER. Second, the mean scores of the primary feasibility outcome measures would meet or exceed an 80% threshold for treatment appraisal and satisfaction (8 or higher on a 0 - 10 scale) [35,54]. Content analysis was conducted by 2 authors (KE and MZ) for qualitative interview data to evaluate perceived feasibility and to identify areas for improvement.

Preliminary Efficacy

Repeated-measures ANOVAs were performed to assess whether pain and related outcomes significantly improved one month after ER (efficacy endpoint) and whether these improvements were maintained at 3 months (durability). The Greenhouse-Geisser correction was used to adjust the degrees of freedom when sphericity assumption was violated. When a significant main effect of time was found, false discovery rate (FDR) correction was applied to address multiplicity and risk of false positives. Cohen *d* was calculated to estimate the effect size of reduction at each time point compared to baseline, using the sample SD of mean difference adjusted by the correlation between measures.

Power Analysis

The G*Power 3.1.9.7. software was used to calculate sample sizes needed to detect a moderate (f=0.25) effect in a repeated measures ANOVA, with alpha level of .05 and .30 autocorrelation between time points. The analysis indicated that the sample sizes of 36, 43, and 59 would yield the power of 90%, 95%, and 99%, respectively. The final sample of 51 corresponded to an estimated power of 98%.

Missing Data

Of the 55 participants who attended ER, two participants withdrew consent after the ER class (3.6%) because one expressed concern about stigma related to the use of methadone or buprenorphine, and the other stated having no problem with pain catastrophizing. Two participants did not complete any follow-up surveys. Therefore, data from 51 participants who attended the class and completed at least one follow-up survey were analyzed. Missing rates ranged from 1.9% (pain intensity and pain bothersomeness at 1 mo post treatment) to 17.6% (PROMIS-measure at 2 mo post treatment). Missing values were estimated and replaced using linear regression (linear trend at point).

Multimedia Appendix 1 shows the results of repeated measures ANOVA with pairwise deleted data collected at baseline, 2 weeks post treatment, and 1 month post treatment (efficacy endpoint). Paired *t*-tests were conducted as a post hoc test to identify time points of significant symptom reduction and its maintenance up to 3 months post treatment. These results were consistent with analyses using missing data replacement.

Results

Participants

Table 1 summarizes the recruitment sources and demographic characteristics. Most participants were recruited from the Stanford Pain Clinic through the local research registry and study flyers (21/51, 41.2%), followed by email invitations to those who had previously participated in observational studies and agreed to be contacted for future research (14/51, 27.5%). An additional 9 of 51 participants (17.6%) self-referred after learning about the study through ClinicalTrials.gov, Stanford Pain Lab website, social media, or online searches. Notably, based on self-report, only 1 participant received opioid prescriptions from a methadone or buprenorphine clinic, whereas the majority were prescribed opioids through pain or primary clinics.

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Table . Demographic characteristics (N=51)[a].

Characteristics	Values
Age (years), mean (SD), range	48.6 (12.2), 28-71
Recruitment sources, n (%)	
Pain clinic–based referrals	21 (41.2)
Previous research connections	14 (27.5)
Online or self-referrals	9 (17.6)
Physician referrals	2 (3.9)
Missing	5 (9.8)
Gender, n (%)	
Female	27 (52.9)
Male	21 (41.2)
Nonbinary	1 (2.0)
Ethnicity, n (%)	
Non-Hispanic	42 (82.4)
Hispanic	7 (13.7)
Race, n (%)	
White or Caucasian	36 (70.6)
Black or African American	9 (15.7)
More than one race	4 (7.8)
Decline to answer	1 (2.0)
Marital status, n (%)	
Married or living together	31 (60.8)
Divorced, separated, or widowed	11 (21.6)
Never married	5 (9.8)
Partnered or not living together	2 (3.9)
Education, n (%)	
High school	3 (5.9)
Some college, no degree	12 (23.5)
Associate’s or vocational certificate	8 (15.7)
Bachelor’s or higher	26 (51)
Employment, n (%)	
Full-time	11 (21.6)
Part-time	4 (7.8)
Not employed	1 (2.0)
Retired	7 (13.7)
Not working due to medical reasons	26 (51)
Annual income (in US$), n (%)	
<10,000	6 (11.8)
10,000-24,999	7 (13.7)
25,000-44,999	10 (19.6)
45,000-64,999 (Median)	4 (7.8)
65,000-104,999	10 (19.6)
>105,000	9 (17.6)

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Characteristics	Values
Decline to answer	3 (5.9)
Housing status, n (%)	
Not homeless	46 (90.2)
Homeless sheltered	2 (3.9)
Decline to answer	1 (2)

[a]Missing n=1 for race and n=2 for all the other demographic data.

Participants reported an average age of 48.6 (SD 12.2) years and were predominantly female (27/51, 52.9%), non-Hispanic (42/51, 82.4%), White or Caucasian (36/51, 70.6%). Most participants were married or were living with a partner (31/51, 60.8%). Just over half (26/51, 51%) held a bachelor's degree or higher. While these demographic characteristics were consistent with our previous studies of participants without prescription opioids [29-31], a notable distinction was that 51% (26/51) were not working due to medical reasons, suggesting a higher burden of illness and greater disease severity than observed in prior research. The median income was between US $45,000 and US $64,999. To note, US individual annual income was $47,960 in 2022 [55]. Finally, most people were not homeless (46/51, 90.2%) and 2 of 51 (3.9) were residing in a homeless shelter.

The baseline clinical characteristics are summarized in Table 2. Most participants (42/51, 82.4%) reported experiencing pain for at least one year. While 88.2% (45/51) reported having a pain-related diagnosis, only 37 provided specific diagnoses, with an average of 2 (SD 1.6) diagnoses per participant. The five most common diagnoses were back or spine pain, arthritis, fibromyalgia, neuralgia, and migraine. Nearly half of the participants were taking methadone (24/51, 47.1%), while the remainder were on buprenorphine (27/51, 52.9%); 43.1% (22/51) met the diagnostic criteria for current OUD. The mean *DSM-5* OUD symptom severity score was 2.7 (SD 3.3), indicating overall mild OUD severity. Among the 28 participants who reported a history of mental health conditions, 26 provided specific diagnoses, with an average of 1.9 diagnoses per person (SD 0.8). Depression (18/26, 69.2%) and anxiety (13/26, 50%) were the most frequently reported diagnoses. Regarding current mental health treatment, 23.5% (12/51) were engaged in psychotherapy with a counselor, psychologist, or social worker. Additionally, 43.1% (22/51) reported prior participation in a pain management class, excluding ER.

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Table . Clinical characteristics (N=51).

Characteristics	Values
Pain duration[a], n (%)	
<6 months	2 (3.9)
6 and <12 months	5 (9.8)
1 or more years (median)	42 (82.4)
Received pain diagnosis?[a], n (%)	
Yes	45 (88.2)
No	4 (7.8)
Pain diagnosis (n=37), n (%)	
Back and spinal pain condition	9 (24.3)
Arthritis	5 (13.5)
Fibromyalgia	5 (13.5)
Neuralgia	5 (13.5)
Migraine	4 (10.8)
Connective tissue disorder	3 (8.1)
Complex regional pain syndrome	3 (8.1)
Stenosis	2 (5.4)
Pelvic pain	2 (5.4)
Orthopedic conditions	2 (5.4)
Other[b]	9 (24.3)
Opioid medication, n (%)	
Methadone	24 (47.1)
Buprenorphine	27 (52.9)
Current opioid use disorder, n (%)	
No	25 (49)
Yes	22 (43.1)
Mild (2-3)	10 (19.6)
Moderate (4-5)	3 (5.9)
Severe (6-11)	9 (17.6)
Missing	4 (7.8)
Ever received mental health diagnosis?[b], n (%)	
Yes	28 (54.9)
No	21 (41.2)
Mental health history (n=26), n (%)	
Depression	18 (69.2)
Anxiety	13 (50)
Posttraumatic stress disorder	8 (30.7)
Bipolar disorder	3 (11.5)
Other[c]	5 (19.2)
Currently seeing a therapist?, n (%)	
Yes	12 (23.5)
No	15 (29.4)

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Characteristics	Values
Decline to answer or missing	24 (47.1)
Previous pain management class?[a], n (%)	
Yes	22 (43.1)
No	27 (52.9)
Number of pain diagnosis (n=37), mean (SD), range	2 (1.6), 1-9
Number of mental health diagnoses (n=26), mean (SD), range	1.9 (0.8), 1-4

[a]Missing n=2.

[b]Other: tendonitis, pancreatitis, interstitial cystitis, restless leg syndrome, esophageal dysmotility, cerebrospinal fluid leak, viremia, stomach ulcer, frozen shoulder, sum >100% for multiple diagnoses.

[c]Other: attention-deficit/hyperactivity disorder, insomnia, obsessive-compulsive disorder, personality disorder, substance abuse, sum >100% for multiple diagnoses/person.

Primary Outcome: Feasibility

The ER attendance rate of 79.7% (n=55) exceeded the preregistered attendance threshold of 75%. A total of 50 participants completed the postclass treatment appraisal and satisfaction survey. As summarized in Table 3, all item ratings exceeded the feasibility threshold of 8.0, except for concerns about privacy during the Zoom class (mean 7.3, SD 2.2); because this single item is interpreted in the reverse direction (ie, higher scores reflect greater concerns), the mean score for the privacy concern item was notably high. The mode for feasibility and acceptability ratings was 10 across all items, indicating strong endorsement. Participants gave high ratings for ER intervention (overall satisfaction, easy to understand, relevant, useful, likelihood to use the skills learned and to recommend to others, and easy to use a zoom platform: mean 8.2 - 9.5). The lowest rating was feeling connected with the instructor (mean 8.1, SD 2.1).

Table . Primary outcome: ER treatment appraisal, satisfaction, and acceptability ratings (n=50).

Survey items	Values	Mode
Item response scale (0-10), mean (SD)		
Please rate your overall satisfaction with the class.	8.6 (2)	10
Was the content easy to understand?	9.5 (1)	10
How relevant was the class to you?	8.6 (2)	10
How useful was the information presented in the class?	8.2 (2.4)	10
How likely are you to use the skills and information you learned?	8.4 (2.1)	10
Rate your likelihood to recommend this class to another person who has chronic pain.	8.3 (2.4)	10
Please indicate how much you agree with the following statements		
It was easy for me to operate Zoom as a platform for attending the class.	8.8 (3.4)	10
While attending the Zoom class, I worried about privacy.	7.3 (2.2)	10
I felt comfortable engaging with the Zoom instructor and class participants.	8.4 (2.5)	10
I felt connected to the instructor.	8.1 (2.1)	10
Item responses (see below note for the three response options), n (%)		
Would you prefer to have a single class (2 hours) or two classes (1 hour each)?		
Prefer single, 2-hour class	43 (84.3)	
Prefer 1-hour two classes	5 (9.8)	
Other	2 (3.9)	

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Content Analysis of Qualitative Data

At the end of the study, participants provided open-ended feedback about the study processes in response to a set of questions related to four domains: class content, experience with the ER class and the study procedures, technical issues, and the recruitment strategies. A content analysis was conducted to code responses within these domains.

Class Content

All participants reported the class content easy to understand, and no participants reported discomfort with the class material. Overall, 6 participants reported that no changes were needed for future participants, while others suggested more advanced material (n=2), more time to process the class content (n=1), a more interactive component (n=1), and greater sharing of personal experiences by the moderators (n=1).

Experience With the ER Class and Study Procedures

Overall experiences were positive, with few concerns raised. Suggestions for improvement included incorporating more breaks (n=1) and providing more reminder calls prior to the class (n=1).

Technical Issues

Technical challenges were infrequently reported. Only 2 participants reported technical difficulties with Zoom and required additional support to download the relaxation audio file.

Recruitment Strategies

Most participants did not express concerns (n=13). One participant requested clearer expectations regarding the timing of a follow-up call after initial contact. Participants also suggested expanding advertising efforts through social media and video platforms (eg, Facebook and TikTok), printed materials on college campuses, flyers in clinic waiting rooms, direct referrals from physicians (including those in palliative care, pain management, and primary care), curated patient lists with targeted email invitations, and referrals from past participants.

In summary, the quantitative and qualitative findings indicate that the ER intervention was feasible and well accepted, as evidenced by high attendance, strong satisfaction ratings, and positive feedback regarding the class content and study procedures. Qualitative findings provided additional insight into specific areas for improvement, including participant engagement, technical support, and recruitment strategies.

Preliminary Efficacy

Repeated-measures ANOVAs were conducted to examine if our primary variables of interest (pain catastrophizing, average pain intensity, pain bothersomeness, and sleep disturbance) would be significantly improved after ER intervention (Table 4). The results revealed a significant main effect of time only in PCS total scores, average pain intensity, and pain bothersomeness. However, with post hoc FDR correction applied (summarized in Table 4), the PCS effect over time was lost (P>.07) while average pain intensity and pain bothersomeness retained significance (Figure 3). Compared to the baseline (mean 6.49, SD 1.70), pain intensity was significantly reduced at 2 weeks (M_{DIFF}=0.55, d=0.41; P=.01) and 1 month (M_{DIFF}=0.85, d=0.71; P<.001). Although the magnitude of the treatment effect on pain intensity was reduced to a small effect size, it remained significant at 2 months (P=.03; d=0.33) and 3 months post treatment (P=.05, d=0.28). For pain bothersomeness, compared to the baseline (mean 6.92, SD 2.05), it was significantly reduced at 2 weeks (M_{DIFF}=0.80, d=0.43; P=.004) and 1 month post treatment (M_{DIFF}=0.96, d=0.54; P=.001), and this reduction was maintained at 2 months (M_{DIFF}=1.04, d=0.48; P=.002) and 3 months post treatment (M_{DIFF}=0.94, d=0.44; P=.004).

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Table . Repeated-measures ANOVA for outcome measures (N=51).

Measures	Type III (sum of squares)	*F* test (*df*[a])	*P* value	η[b]
PCS[c]		3.01 (3.20, 160.16)	.03	0.057
Time	592.71			
Error	9837.64			
Average pain intensity		3.88 (3.03,151.28)	.01	0.072
Time	19.4			
Error	249.96			
Pain bothersomeness		4.69 (3.61, 180.62)	.002	0.086
Time	36.98			
Error	394.04			
PROMIS[d]				
Sleep disturbance		1.80 (3.22, 161.18)	.15	0.035
Time	192.45			
Error	5349.7			
Pain interference		8.61 (3.06, 153.09)	<.001	0.147
Time	485.76			
Error	2820.23			
Physical function		2.35 (3.75, 187.37)	.06	0.045
Time	63.8			
Error	1356.58			
Fatigue		1.34 (3.53, 176.60)	.26	0.026
Time	189.47			
Error	7044.62			
Depression		1.89 (3.48, 174.12)	.12	0.036
Time	211.72			
Error	5600.31			
Anxiety		0.62 (3.15, 157.45)	.61	0.012
Time	80.89			
Error	6502.87			
Social isolation		1.64 (3.11, 155.43)	.18	0.032
Time	212.23			
Error	6484.51			
Opioid craving scale (0 - 10)		2.97 (2.91, 145.28)	.04	0.056
Time	22.61			
Error	381.13			

[a]Adjusted *df* using the Greenhouse-Geisser correction.

[b]Eta-squared (η^2) of 0.01, 0.06, and 0.14 would indicate small, medium, and large, respectively.

[c]PCS: Pain Catastrophizing Scale.

[d]PROMIS: Patient Reported Outcomes Measurement Information System.

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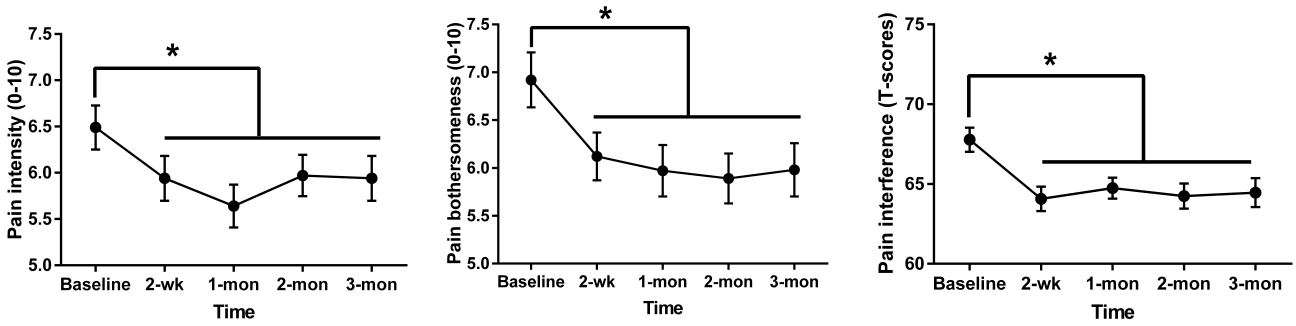
Figure 3. Results with false discovery rate–corrected post hoc tests revealed significant changes in average pain intensity (left), pain bothersomeness (middle), and PROMIS-Pain Interference T scores (right). * FDR corrected *P*<.05. Error bars denote SEM.



Taken together, our hypotheses were partially supported. Contrary to our hypotheses, pain catastrophizing and sleep disturbance were not significantly reduced after ER intervention, but pain intensity and pain bothersomeness were significantly reduced to a moderate degree at 1 month post treatment. While reductions in pain intensity attenuated over time, reductions in pain bothersomeness were sustained through the 3 months post treatment (durability time point).

Additional Measures

Repeated-measures ANOVAs were performed to examine if pain interference, physical function, fatigue, depression, anxiety, social isolation, and opioid craving symptoms would be significantly improved after ER intervention (Table 4). The results revealed a significant main effect of time in PROMIS-pain interference T-scores and opioid craving. Application of FDR correction for multiplicity revealed significant changes in PROMIS-pain interference T-scores were retained (Figure 3), but not for craving (*P*>.09, Table 5). Compared to the baseline (mean 67.78, SD 5.40), pain interference T-scores were significantly reduced at 2 weeks (mean difference [M_{DIFF}]=3.71, *d*=0.59; *P*<.001) and 1 month post treatment (M_{DIFF}=3.04, *d*=0.61; *P*<.001) and this reduction was maintained at 2 months (M_{DIFF}=3.54, *d*=.56; *P*<.001) and 3 months post treatment (M_{DIFF}=3.32, *d*=.48; *P*=.001; Figure 3). Taken together, our hypotheses were partially supported. Among our additional measures, a moderate reduction was observed only in pain interference at 1 month post treatment (efficacy endpoint), and this reduction was maintained at 3 months post treatment (durability time point).

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Table . Post hoc false discovery rate–corrected time-effect comparisons between the baseline and follow-ups (N=51).

Time points	Mean (SD)	M_{DIFF}	SE_{DIFF}	*P* value	Cohen *d*[a]
PCS[b] total scores					
Baseline	20.18 (13.53)	Ref.[c]	Ref.	Ref.	Ref.
2 weeks	17.47 (9.72)	2.71	1.41	.08	0.27
1 month	19.42 (10.65)	0.76	1.32	.57	0.08
2 months	16.27 (9.96)	3.90	1.81	.07	0.30
3 months	16.73 (11.82)	3.45	1.60	.07	0.30
Average pain intensity					
Baseline	6.49 (1.70)	Ref.	Ref.	Ref.	Ref.
2 weeks	5.94 (1.73)	0.55	0.19	.01	0.41
1 month	5.64 (1.65)	0.85	0.17	<.001	0.71
2 months	5.97 (1.60)	0.52	0.22	.03	0.33
3 months	5.94 (1.73)	0.55	0.28	.05	0.28
Pain bothersomeness					
Baseline	6.92 (2.05)	Ref.	Ref.	Ref.	Ref.
2 weeks	6.12 (1.78)	0.8	0.26	.004	0.43
1 month	5.97 (1.92)	0.96	0.25	.001	0.54
2 months	5.89 (1.87)	1.04	0.30	.002	0.48
3 months	5.98 (1.99)	0.94	0.30	.004	0.44
PROMIS[d]-pain interference					
Baseline	67.78 (5.40)	Ref.	Ref.	Ref.	Ref.
2 weeks	64.07 (5.44)	3.71	0.88	<.001	0.59
1 month	64.74 (4.68)	3.04	0.70	<.001	0.61
2 months	64.24 (5.63)	3.54	0.88	<.001	0.56
3 months	64.46 (6.46)	3.32	0.96	.001	0.48
Craving					
Baseline	2.69 (3.48)	Ref.	Ref.	Ref.	Ref.
2 weeks	2.41 (2.90)	0.27	0.28	.45	0.14
1 month	2.51 (2.81)	0.18	0.33	.60	0.07
2 months	1.83 (2.34)	0.86	0.36	.09	0.33
3 months	2.16 (2.64)	0.52	0.32	.23	0.23

[a]Cohen *d* was calculated from paired-sample *t* tests.

[b]Pain Catastrophizing Scale

[c]Ref. refers to a reference time point.

[d]Patient Reported Outcomes Measurement Information System.

Finally, ratings on the 6-item GIC measures were analyzed to examine perceived improvement at 1 month and 3 months post treatment compared to baseline (Table 6). Mean overall improvement rating on a 1 - 7 scale was modest at 1 month (mean 4.5, SD 1.1) and 3 months post treatment (mean 4.5, SD 1.2). Regarding pain improvement, 17 of 46 participants (37%) at 1 month post treatment and 21 of 49 participants (42.9%) at 3 months posttreatment rated 5 or higher on the GIC pain item.

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Table . The Global Impression of Change ratings on the 6 domains.

Improvement in	1 month post treatment (n=46)			3 months post treatment (n=49)		
	Mean (SD)	Range	>4[a] (%)	Mean (SD)	Range	>4 (%)
Overall	4.5 (1.1)	2 - 6	52.2	4.5 (1.2)	2 - 7	51.0
Physical activity	4.5 (0.9)	2 - 6	41.3	4.4 (1.1)	2 - 6	46.9
Social activity	4.3 (0.9)	2 - 7	37.0	4.5 (1.2)	1 - 7	38.8
Work-related activity	4.3 (0.9)	2 - 7	32.6	4.3 (1.2)	2 - 7	38.8
Mood	4.2 (1.1)	2 - 6	43.5	4.5 (1.2)	2 - 7	51.0
Pain	4.4 (0.8)	2 - 6	37.0	4.2 (1.1)	2 - 6	42.9

[a]Ratings of >4 would indicate perceived improvement after ER.

Adverse Events Related to ER Intervention

There were no serious adverse (SAEs) and adverse events (AEs) related to the ER intervention. Regarding SAE, 1 participant reported an emergency department visit for chest and abdominal pain at 2 months post treatment. The reported AEs included (1) injury (n=9, fall, sprained ankle, neck and back injury, second-degree burn, cat bite), (2) infection (n=7, COVID-19, flu, and infection from cat bite), (3) new medical diagnosis (n=6, rheumatoid arthritis, cancer, aneurysm, rule out brain cyst, and cannabis hyperemesis syndrome), (4) medical treatment (n=6, surgery, injection, ablation, removal of 15 teeth, and low-dose naltrexone), (5) gastrointestinal issue (n=3, bowel obstruction and stomach pain), and (6) unhealed wound (n=1).

Discussion

Overview

This single-arm pilot study investigated online ER in individuals with chronic pain taking methadone or buprenorphine. The primary goal was to evaluate the feasibility and acceptability of the ER intervention in this population. We also examined the preliminary efficacy of ER for reducing pain catastrophizing, pain intensity, pain bothersomeness, and sleep disturbance at 1 month post treatment, as well as additional outcomes (pain interference, physical function, fatigue, depression, anxiety, social isolation, and opioid craving). Further, we tested the durability of treatment effects at 3 months post treatment.

Feasibility and Acceptability (Primary Outcomes)

This study demonstrated acceptable feasibility of ER intervention, as indexed by a class attendance rate of 79.7% among consented participants, which exceeded the predefined threshold of 75%. Of the 55 class attenders, only 2 withdrew their consent and 2 were lost to follow-up. Additionally, the treatment engagement rate among all eligible participants was 74.3%, calculated as the proportion who attended the ER class. This rate fell within the range reported in other single-arm studies of single-session intervention for chronic pain (56% to 96%) [56-59]. Further evidence of feasibility might be the recruitment of 74 eligible participants over the course of 18 months, with 69 consenting to participate. However, the initial recruitment challenge should be noted. The original plan was to recruit participants exclusively through physician referrals from methadone or buprenorphine clinics in the United States, aiming to create a homogenous group with automatically verified use of these medications. However, relying entirely on external physician referrals resulted in zero participant recruitment for 8 months. Subsequently, we expanded recruitment using multiple methods, including physician referrals from pain and addiction clinics, self-referral via research posting on the Stanford Pain Lab website and ClinicalTrials.gov, and email invitations to patients with chronic pain through Stanford Pain Division's research registry and prior observational studies. This shift in recruitment strategy may have influenced the composition of the study sample by preferentially enrolling individuals who were more proactive in seeking research opportunities, potentially reflecting higher health literacy or web access compared to patients recruited exclusively through physician-based referrals from methadone or buprenorphine clinics. As a result, the final sample was clinically heterogeneous with respect to OUD severity, including no OUD (49.0%), mild (19.6%), moderate (5.9%), and severe cases (17.6%). Additionally, overall OUD symptoms were mild (mean 2.7, SD 3.3). These factors should be considered when interpreting feasibility outcomes and the generalizability of the findings to broader clinical populations receiving opioid agonist therapy.

Participants reported high overall satisfaction with the class (mean 8.6, SD 2 on a 0 - 10 scale), and high ratings of relevance, usefulness, and ease of understanding the material, in addition to high likelihood of using the skills and recommending the class to others (mean 8.3 - 9.5). Participants also reported high ratings related to feeling connected with the instructor (mean 8.1, SD 2.1). These ratings indicate strong endorsement of web-based ER intervention. Concerns about privacy during the Zoom class were notably high, with higher scores reflecting greater privacy concerns (mean 7.3, SD 2.2). To minimize privacy concerns during the class, participants were instructed to turn off their cameras and use first names only; this method was previously used to deliver a group online program for individuals with OUD [60]. Despite this approach, one participant withdrew from the study after attending the ER class due to discomfort with the study's focus on individuals taking methadone or buprenorphine and concerns about associated stigma. This highlights the potential impact of opioid-related stigma on engagement and retention in research

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and possibly group-based behavioral interventions. Accordingly, sensitive recruitment and intervention approaches should be considered. One such approach is to offer ER within the same clinics where individuals receive ongoing care for chronic pain or OUD treatment, thereby normalizing participation as part of routine care. Additionally, involvement of referring clinicians may be beneficial beyond recruitment. Initial and ongoing communication from a trusted referring physician, emphasizing ER as an evidence-based, skills-focused self-management program aimed at optimizing pain outcomes and supporting positive self-care behaviors may help reduce stigma-related concerns and reinforce the value of participation. Such clinician-supported messages may enhance engagement, retention, and acceptability of behavioral pain management interventions in this population. Although qualitative interviews were conducted to identify areas for improvement, no participants raised privacy concerns during the interviews, limiting the opportunity to explore this issue. Future study should incorporate more targeted qualitative probes, which include stratifying interviews based on reported privacy concerns in quantitative surveys, asking focused questions to better understand privacy concerns in online group interventions, and identifying strategies to address them.

Qualitative Data

This study collected qualitative feedback regarding class content, experience with the ER class and study procedures, technical issues, and the recruitment strategies. All participants found the class content easy to understand, did not report discomfort with the class material, and had an overall positive experience with the class and study procedures. Most participants did not report technical issues with the online surveys, the Zoom, and binaural relaxation app. A few participants offered suggestions to improve the content and delivery of ER. For example, 2 participants requested more advanced content, but 1 expressed a need for additional time to process the content. This opposite request is expected for group-based intervention. One solution is to provide individualized options after the ER session. For example, offering supplemental materials for those seeking more advanced content and a brief follow-up check-in for participants who need additional process time. Delivery-related suggestions included adding interactive components and time to share personal experiences. These are expected because ER is designed as a didactic format for efficient, scalable delivery. Minor suggestions for improvement will be considered in future study designs.

Preliminary Efficacy

Among our primary preliminary efficacy outcomes, pain intensity demonstrated moderate effects at 1 month post treatment (Cohen *d*=0.71). At 1 month, average pain intensity decreased from 6.49 (SD 1.70) at baseline to 5.64 (SD 1.65), corresponding to a statistically significant 0.85-point reduction on a 0 - 10 scale. Although this moderate reduction in pain intensity reflects a positive response trajectory, it falls below thresholds for clinical meaningful change (eg, ≥2-point or 30% reduction) [61,62]. These effects attenuated over time, with smaller but significant reductions observed at 2 months (mean 5.97, SD 1.60; Δ=0.52; Cohen *d*=0.33) and 3 months (mean 5.94, SD 1.73; Δ=0.55; Cohen *d*=0.28). FDR correction increases confidence that these findings represent true effects rather than spurious findings.

Pain bothersomeness showed a similar but slightly more sustained pattern of improvement. At 1 month post treatment, pain bothersomeness decreased from 6.92 (SD 2.05) at baseline to 5.97 (SD 1.92), representing a statistically significant 0.95-point reduction on a 0 - 10 scale (Cohen *d*=0.54). Reductions were maintained at 2 months (mean 5.89, SD 1.87; Δ=1.03; Cohen *d*=0.48) and 3 months (*M*mean 5.98, SD 1.99; Δ=0.94; Cohen *d*=0.44). Despite these consistent and statistically significant improvements, thresholds for clinically meaningful change in pain bothersomeness have not yet been established. As such, while ER may reduce the subjective burden of pain, its clinical impact on pain bothersomeness may be modest as currently delivered.

For the other efficacy outcome, pain interference also demonstrated moderate effects across follow-up time points. At 1 month post treatment, PROMIS pain interference T-scores decreased from 67.78 (SD 5.40) at baseline to 64.74 (SD 4.68), corresponding to a statistically significant 3.04-point reduction (Cohen *d*=0.61). These effects were maintained at 2 months (mean 64.24, SD 5.63; Δ=3.54; Cohen *d*=0.56) and 3 months (mean 64.46, SD 6.46; Δ=3.32; Cohen *d*=0.48). However, these reductions were less than 5 points, suggesting that these changes likewise fall below the thresholds for clinically meaningful improvement [63].

In summary, this pilot study suggests that ER, as a single-session intervention, may yield its statistically significant and durable effects on pain-related outcomes up to 3 months. However, modification of the intervention may be necessary to enhance its clinical impact in this population. As this was the first test of ER in this population, our hypotheses were based on prior studies conducted in other chronic pain populations. Notably, the current study did not demonstrate reductions in pain catastrophizing. While this contrasts with many ER trials conducted in chronic pain samples without opioid-related inclusion criteria, it is consistent with a growing subset of ER studies conducted in populations taking prescription opioids or with opioid misuse. In the current sample of the patient population taking methadone or buprenorphine, 43.1% (22/51) met criteria for current OUD, suggesting that ER's effect on cognitive-affective pain processes may differ in opioid-exposed population. These findings highlight the need for future research to refine ER to optimize treatment outcomes as well as improve pain-related coping in this patient population.

In multiple other studies, ER was found to significantly and clinically meaningfully reduce pain catastrophizing, with this variable often showing the largest treatment effects and multidimensional benefits. Indeed, randomized controlled trials (RCTs) of ER in general chronic pain have revealed that ER was superior to control and significantly improved multiple variables, including pain catastrophizing, pain intensity, pain bothersomeness, sleep disturbance, pain interference, physical function, fatigue, depression, anxiety, and social isolation. Specifically, one 3-arm RCT in 263 patients with chronic low back pain showed that, compared to the health education control,

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in-person ER was significantly better in improving all secondary (Glass *d*s=0.54 - 0.93[30]) and tertiary outcome measures (Glass *d*s=0.31 - 0.45[30]) at 3 months. Another RCT in a general chronic pain sample (n=104) showed that, compared to a waitlist control, online ER was significantly better in improving all secondary outcome measures (Cohen *d*s=0.60 - 0.67) at 3 months post treatment and sleep disturbance was not measured [31]. This RCT also showed that online ER was significantly better in improving some of the tertiary outcome measures at 3 months post treatment such as anxiety and anger (Cohen *d*s=0.68 and 0.59, respectively), but no significant between-group differences were found for pain interference, physical function, and social isolation at 3 months [31]. These two RCTs suggest that regardless of delivery method (in-person or online), ER significantly improved pain catastrophizing, pain intensity, and pain bothersomeness to a moderate to large degree, but pain interference was moderately improved only after in-person ER (Glass *d*=0.64) [29,30].

The surprising lack of effects for pain catastrophizing and other variables in the current trial may relate to OUD, prescription opioids, or both. To date, among 13 completed ER clinical trials [29-36,53,54,64-66], 8 show strong effects for reducing pain catastrophizing, with all of those being chronic pain studies with no enrollment criteria for prescription opioids [29-33,53,54,65]. In contrast, the 5 other studies were conducted in patients taking prescription opioids, either for chronic pain or post surgery; while we found clinical benefits resulting from ER for certain outcomes (eg, opioid reduction and pain reduction), we found null effects for pain catastrophizing reductions in these opioid-taking populations [34,36,64-66]. A single-arm study examined the feasibility and preliminary efficacy of online ER in 41 individuals prescribed daily opioids (≥10 morphine-equivalent daily dose), including both short- and long-acting medications [35]. That study demonstrated a significant small improvement in pain catastrophizing, pain intensity, and pain interference at 3 months post treatment (Cohen *d*s=0.27 - 0.39). Ziadni et al (in review; protocol [65]) conducted a RCT of ER in 213 patients taking daily prescription opioids and found no effects for PCS reduction; this study was a notable standout for showing minimal clinical benefits overall for ER. Another recently completed RCT of a digital (asynchronous) version of ER in 231 individuals with prescription opioid misuse (manuscript in development; protocol [66]) yielded significant ER impacts on pain and opioid outcomes but null effects for pain catastrophizing. Two ER RCTs in patients who underwent surgery similarly found no effect for pain catastrophizing but significant effects for reducing opioid use and pain after surgery [34,64], although a floor effect for pain catastrophizing at baseline is likely a factor. For this study, baseline pain catastrophizing was substantial and thus eliminating a floor effect hypothesis. However, the findings for these 5 studies align with a broader understanding that central nervous system calming imparts salutary effects even in the absence of cognitive and emotional distress. Moreover, population-specific differences in ER's mechanisms of action may exist. Future studies should evaluate multiple pain-coping mechanisms to elucidate ER's mechanisms of action in this population.

Finally, it is unclear whether additional treatment "dosing" might yield effects on pain catastrophizing and other variables where no effects were observed (eg, opioid craving). For instance, booster sessions, intensive or multisession interventions, or a different type of treatment may be needed to reduce pain catastrophizing and further optimize outcomes in this population. Multisession, behavioral interventions for chronic pain have shown slightly different patterns, demonstrating consistent efficacy in opioid-related outcomes, but limited effect on pain-related outcomes for this population. Specifically, multisession CBT and MORE consistently demonstrated reductions in opioid misuse, opioid craving, and other substance use [21,23-25], but their effects on pain-related outcomes were predominantly non-significant [21-25]. This contrasting pattern may be attributable to differences in sample characteristics related to OUD and pain status. The CBT and MORE studies recruited participants taking methadone for OUD [21,24], whereas the current study recruited participants taking methadone or buprenorphine for either chronic pain or OUD. As a result, 52.9% (27/51) of our participants were taking buprenorphine, and 43.1% (22/51) had a current OUD diagnosis. Craving levels in our sample were low at baseline (mean 2.69, SD 3.48 on a 0 - 10 scale) and remained low throughout the 3-month follow-up period (mean 1.83, SD 2.34 to 2.51, SD 2.81), in contrast to its levels in the MORE study sample at baseline (mean 4.5 on a 0 - 10 scale). This floor effect may have limited this study's ability to detect reductions in craving following ER. The low craving observed in our sample, drawn from pain clinics and self-referral, may reflect a relatively stable group whose opioid craving was already well managed with opioid agonist or partial-agonist treatment. Conversely, baseline pain levels were higher in our sample (mean 6.5, SD 1.7) compared to those in the CBT (mean 5.9, SD 1.5) [21] and MORE (mean 4.7, SD 3.1) [24] studies. These differences in OUD and pain characteristics should be considered when comparing treatment outcomes. Additionally, treatment hours should be taken into account: the current outcomes are based on a single-session intervention (2 h), whereas other outcomes are based on 12-session CBT (6 - 9 h) and 8-session MORE (16 h).

Limitations

Our findings should be interpreted considering study limitations. First, this single-arm pilot trial was primarily designed to examine the feasibility and acceptability of ER in individuals with chronic pain who were taking methadone or buprenorphine. Therefore, causal inferences about ER effect cannot be assumed. Observed improvements in this study could reflect regression to the mean, natural symptom variability, or nonspecific factors such as participant expectancy. Nevertheless, prior RCTs in general chronic pain populations (not specific to opioid use) have shown that ER produces clinically meaningful improvements in pain-related outcomes. Additional study, particularly an RCT of ER, is needed to establish its efficacy and exclude alternative explanations in this population. Second, although our sample size was sufficient to detect moderate changes over time, this study was likely underpowered to detect small effects, as the a priori power analysis assumed a moderate treatment effect. Several outcomes in the current study were

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small-to-moderate effect sizes, which may have limited power to detect smaller effects reliably. To address this limitation, we applied less conservative FDR correction to balance control of type I and type II errors. Our outcomes remained statistically significant after FDR correction, but null findings should be interpreted with caution given the limited power of this pilot study. Third, missing data were addressed using two approaches, regression-based imputation (linear trend at point) and pairwise deletion (see Multimedia Appendix 2). Consistent results across these two methods indicate that our results were reliable regardless of the methods used to address missing data. Fourth, the study sample consisted of predominantly white, non-Hispanic or Latino, educated individuals, with high rates of unemployment, which limits study generalizability. Future trials should examine ER efficacy in diverse and underserved patient populations who often experience greater barriers to treatment [67]. Lastly, the final sample was not representative of individuals receiving OUD treatment, but instead primarily comprised individuals with chronic pain who were prescribed methadone or buprenorphine. During the first 8 months of the study, recruitment efforts targeting specialty OUD treatment clinics were unsuccessful mainly because this was an unfunded pilot supported by a small amount of internal resources. Due to financial constraints, we were an external study team seeking to post study recruitment flyers in various clinics with no local clinic coinvestigators. Based on low engagement, we expanded our study recruitment to include pain clinics and self-referrals, where the majority of the study sample was derived. As such, the current findings do not generalize to OUD treatment environments, and future research is needed in this population specifically. Future research is also needed in other clinic environments, such as methadone clinics and pain clinics, with study designs that engage clinicians as coinvestigators to enhance local patient recruitment. Our recruitment challenges underscore the need to have pain treatment studies embedded into the clinic environment (ie, as a recruitment or study site) with local study leadership oversight and full participation from clinic staff.

Conclusions

Our findings suggest that online ER appears feasible and is a promising intervention that may improve pain-related outcomes in individuals with chronic pain taking methadone and buprenorphine. Disseminating brief, accessible, and scalable pain psychology interventions, such as ER, may enhance more equal access to effective behavioral pain treatments and reduce pain burden. A fully powered RCT in diverse patient participants is needed to determine ER efficacy in patients who are receiving methadone or buprenorphine for chronic pain or OUD.

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Conflicts of Interest

None declared.

Multimedia Appendix 1
Repeated measures ANOVA for outcome measures up to the primary study endpoint (1 month).
[DOCX File, 18 KB - formative_v10i1e86070_app1.docx]

Multimedia Appendix 2
Post hoc pairwise *t* test to compare outcomes at the baseline and follow-up points.
[DOCX File, 17 KB - formative_v10i1e86070_app2.docx]

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Abbreviations

AE: adverse event
CBT: cognitive behavioral therapy
***DSM-5*:** *Diagnostic and Statistical Manual of Mental Disorders* (Fifth Edition)
ER: Empowered Relief
FDR: false discovery rate
GIC: Global Impression of Change
HIPAA: Health Insurance Portability and Accountability Act
MORE: Mindfulness-Oriented Recovery Enhancement
OUD: opioid use disorder
PCS: Pain Catastrophizing Scale
PROMIS: Patient Reported Outcomes Measurement Information System
RCT: randomized controlled trial

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REDCap: Research Electronic Data Capture
SAE: serious adverse event

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AI-Powered Documentation for Mental Health Providers: Retrospective Observational Mixed Methods Study

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Abstract

Background: Mental health providers (MHPs) face a significant administrative burden from documentation, which can contribute to burnout and reduce time available for direct patient care. Although artificial intelligence (AI)–powered scribes have shown promise in general medical settings, their utility has not been well explored in the specific context of mental health care. This study describes the development and preliminary observational evaluation of Smart Notes, a generative AI tool designed to assist MHPs with documentation on a commercial virtual mental health platform.

Objective: This study aimed to examine MHPs' use and uptake of a generative AI documentation tool, including use patterns, perceptions of note quality, feedback and satisfaction, and changes in productivity.

Methods: Smart Notes was developed using a HIPAA (Health Insurance Portability and Accountability Act)-compliant Azure OpenAI infrastructure to securely generate session summaries from individual therapy sessions. The tool was rolled out to MHPs in a phased approach, and its use required MHP and client consent as well as a mandatory review and edit by the MHP. We conducted a 1-year retrospective observational evaluation of the feature, examining MHP use, MHP-rated note quality, MHP feedback and satisfaction, and MHP productivity (weekly working hours, session completion rate, and client caseload).

Results: Over 1 year, 162 full-time and 1366 contractual MHPs used Smart Notes to generate over 286,000 clinical notes. Use of the feature was high and stable, with nearly all (averaging 94% each week, SD 1%) full-time MHPs and most (averaging 72% each week, SD 6%) contractual MHPs using it weekly for eligible individual therapy sessions after the full launch. MHP-rated note quality was overwhelmingly positive, with 97.7% (9980/10,219) of feedback ratings among full-time MHPs and 98.4% (19,977/20,300) of feedback ratings among contractual MHPs being a "thumbs-up." Qualitative feedback from MHPs was also largely positive, praising the tool for saving time and easing administrative burden. Finally, both full-time and contractual MHPs demonstrated changes in productivity.

Conclusions: Our findings suggest that AI-powered documentation tools, such as Smart Notes, are a feasible and acceptable approach to supporting MHPs. The high adoption rate and favorable MHP feedback indicate the potential utility of these tools without compromising note quality. This study provides preliminary data regarding the application of AI documentation in the mental health care context, highlighting a promising path for future research and development in digital mental health.

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KEYWORDS

artificial intelligence; AI; generative AI; AI scribe; digital health; telehealth; natural language processing; mental health; documentation; productivity; provider burnout

Introduction

For mental health providers (MHPs), the burden of documentation presents a unique challenge that can impact both care quality and their well-being. While essential for continuity of care, the time required for meticulous charting often exceeds clinical hours and reduces direct patient engagement [1,2]. The pressure to complete timely documentation is a major driver of clinician burnout, as mental health professionals struggle to balance administrative demands with the emotional labor of therapeutic care [3-5]. Furthermore, inconsistent or poor-quality documentation increases cognitive load and threatens patient safety by obscuring critical information and hindering continuity of care [6,7].

To address documentation burden, solutions ranging from dictation and templates to medical scribes have emerged [8-10]. Human scribes, whether in person or virtual, reduce administrative time and increase direct patient interaction

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[11,12]. However, these methods can be costly, require extensive training, and face privacy and scalability issues due to high turnover [8,13]. Consequently, attention has shifted toward artificial intelligence (AI)–based digital scribe solutions. Early applications of AI in clinical documentation focused on natural language processing and machine learning for discrete tasks such as message triage. For instance, machine learning has been used to prioritize high-acuity patient portal messages, reducing clinician response delays and cognitive load [14,15]. In mental health, voice-to-text tools show promise for time savings but face hurdles regarding accuracy and workflow integration [16]. More recently, generative AI has been applied to session and discharge summarization, offering reduced clinician workload while necessitating careful oversight of note fidelity to combat issues such as AI hallucinations [17,18].

Building on these technologies, interest in virtual and AI scribes is growing to further reduce documentation burdens, and preliminary results in general health care settings are promising [8,9,18,19]. One study found that both clinicians and patients benefited from AI scribes, specifically highlighting clinicians' enhanced ability to provide personalized care [18]. Similarly, a 2021 review identified key advantages of digital scribes, including easier charting, increased patient engagement, and improved care accessibility [8]. Research further indicates that these tools improve physician-patient interactions while producing high-quality notes requiring minimal editing [18]. While generative AI research in mental health is limited, emerging studies show similar promise for AI-assisted documentation. In psychiatry specifically, AI-generated notes required only 45% of the time of manual documentation while maintaining high clinician-rated accuracy and quality [20].

In April 2024, a HIPAA (Health Insurance Portability and Accountability Act)-compliant online therapy platform Talkspace launched Smart Notes, a generative AI tool designed specifically for MHPs. Here, we describe the development and deployment of the Smart Notes feature and evaluate MHP use, quality ratings, feedback and satisfaction, and productivity over its first year of implementation.

Methods

Overview

Talkspace matches individuals (referred to here as members) with an MHP licensed in the member's state of residency. Talkspace employs both full-time and contractual (hourly) MHPs. Members, who may be able to access Talkspace via their insurance provider, employer, government program, or independently, are able to choose to connect with their MHP via asynchronous or live text, video, or audio sessions. Talkspace's offerings include specialized individual therapy, couples therapy, and psychiatry. At the time of this analysis, Smart Notes had not yet been implemented for couples therapy, psychiatry, and certain live session plans. Therefore, the analysis includes only Smart Notes generated from eligible individual therapy sessions.

Product Development and Deployment

The Smart Notes feature was developed using Azure OpenAI (Microsoft Corp) with a HIPAA-compliant infrastructure to securely process session data from live video transcripts, live audio transcripts, live messaging, and asynchronous messaging. Talkspace's AI Governance Committee, a group composed of clinical, legal and regulatory compliance, product, engineering, and industry experts, reviewed the Smart Notes feature during the design phase to ensure usability, transparency, explainability, and privacy. Various prompts were iteratively tested and refined to optimize for note quality and clinical documentation standards. The initial prototype was tested on a dummy sample conversation prior to releasing the product to the initial pilot MHPs. We used text similarity scores that use the Dice-Sørenson coefficient [21] to determine the level of agreement between the generated draft note and the submitted note. We regarded text similarity scores under 90% as low. We used these scores to inform iterations of the model prompts until the average text similarity scores were consistently above 90%. To generate a Smart Note, session content first underwent a redaction process using a combination of commercially available (Amazon Web Services Glue's entity detection; Amazon Web Services Inc) and open-source (python library "scrubadub"; Python Software Foundation) redaction software to ensure that all protected health information and personal identifying information were removed. The Talkspace app sent the deidentified contextual data, the deidentified treatment plan, and the prompt to the Azure application programming interface (API). The API then returned a draft of the clinical note, which the Talkspace app then presented to the therapist for review. The Azure API did not retain any data. Contextual data were saved on the Talkspace platform in an encrypted state.

Prior to use in a given therapy room, both the licensed therapist and individual member provided consent to the use of the Smart Notes feature to generate summarized documentation of therapy sessions. Following a session, MHPs had the option to request a Smart Note. MHPs were required to review the generated note and must make at least one edit to the generated note before submitting. To enforce this requirement, the system checked the generated note against the note the MHP was attempting to submit. If no edit was detected, the app presented a message to the MHP, prompting them to make at least one edit to ensure that MHPs were not passively accepting the AI-generated notes without any clinical input. After the edit was made, MHPs were able to submit the Smart Note as documentation of the session. Once the note was submitted, MHPs were given the option to rate and provide feedback on the note. Feedback was stored and evaluated by the team for further refinement of the feature.

Talkspace implemented a phased rollout and comprehensive training program to introduce Smart Notes to its MHP network. Following the feature's announcement, MHPs attended live online training sessions featuring step-by-step demonstrations and interactive question-and-answer segments. To ensure continuous support, training materials were distributed via email and hosted in a central MHP help center, and monthly newsletters provided regular feature updates. Additionally, dedicated support teams were established to address ongoing inquiries. Early MHP feedback primarily focused on clinical

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and administrative guardrails, specifically regarding client-informed consent and protocols for transcription storage.

In an initial pilot period, a subset of Talkspace MHPs received early access to the feature. The chosen sample included full-time and hourly MHPs who were asked to provide critical, high-quality feedback necessary for the refinement and successful full-scale launch of the system. At launch, MHPs were able to use Smart Notes for asynchronous messaging sessions only, and live session availability was released 1 month later in May 2024. Smart Notes was launched to the entire MHP network for use in individual asynchronous client sessions as well as eligible individual live session plans in June 2024.

Finally, as part of an iterative product development and quality assurance process, the Smart Notes feature underwent a proof-of-concept validation led by 5 licensed clinicians (holders of degrees in licensed clinical social work and licensed mental health counseling) from the Talkspace Quality Management and Clinical Team. Clinicians evaluated the tool's performance using a standardized clinical rubric. This rubric assessed 5 essential documentation pillars: documented diagnosis, high-risk member assessments, comprehensive mental health assessments, presenting problems, and defined treatment goals. This validation phase was intended to ensure consistency in meeting professional standards for clinical structure and content.

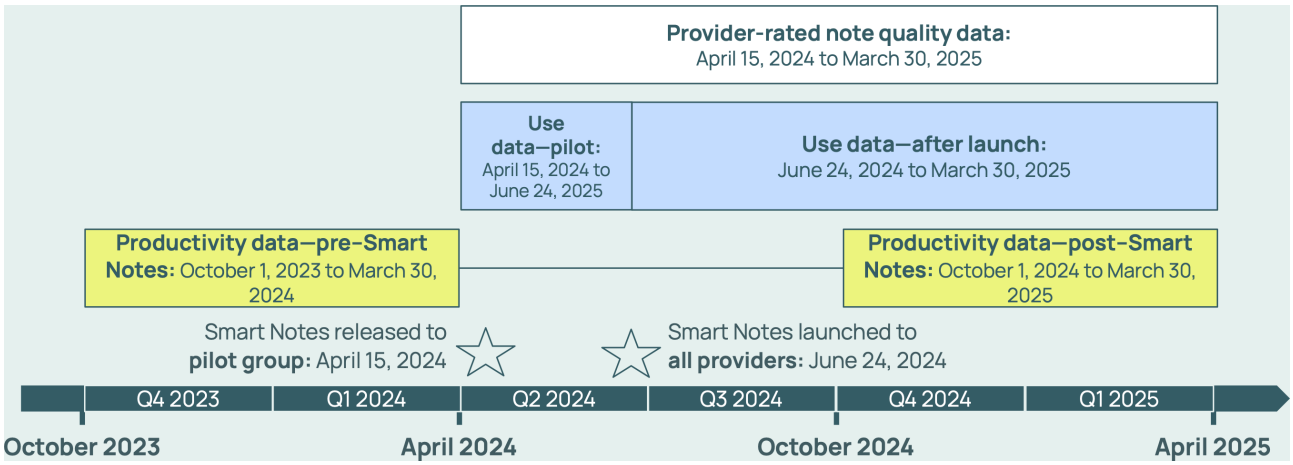
Study Design

We conducted a retrospective observational mixed methods analysis using longitudinal and cross-sectional components to examine MHPs' use of and experience with the Smart Notes tool. The study design integrated several quantitative measures collected consistently over time (Smart Notes use data, MHP ratings of note quality, generation error rates, text similarity scores, and MHPs' net promoter score [NPS]); quantitative pre-post measures of MHPs' productivity (eg, average weekly working hours); and qualitative open-ended feedback provided via quarterly MHP surveys.

Data Collection

Measures included MHPs' Smart Notes use, note quality, generation error rates, text similarity scores, feedback and satisfaction, and productivity. A timeline of data collection is given in Figure 1.

Figure 1. Data collection and analysis periods across the first, second, third, and fourth quarters of the year (Q1, Q2, Q3, and Q4, respectively).



Smart Notes Use

We examined Smart Notes use at the MHP level (ie, the number and percentage of MHPs who used Smart Notes each week, as compared with total MHPs) and at the note level (ie, the percentage of Smart Notes submitted each week, as compared with total progress notes) over time (Figure 1). We examined weekly use and uptake during the initial pilot period as well as after Smart Notes was launched to the entire MHP network. Notes were counted in the week the Smart Note was submitted, which could occur in a subsequent week after the session.

To examine the functionality over the same period, we also calculated the weekly percentage of generation errors and text similarity scores over the same period. Text similarity scores were calculated using the Dice-Sørenson coefficient [21], which gauges the similarity between two samples.

MHP-Rated Note Quality

Following each note submission, MHPs were prompted to provide optional feedback on the note with a "thumbs-up" or "thumbs down." If a thumbs down was selected, indicating a negative rating, MHPs could then identify the reason for the negative rating from 3 options: "Too many edits needed," "Summary is inaccurate," and "Summary is non-formatted." These data were collected for the year shown in Figure 1.

MHP Feedback and Satisfaction

Finally, we examined quantitative and qualitative MHP feedback from quarterly surveys that were sent to all Talkspace MHPs and could be submitted anonymously. Feedback included overall NPS (ie, not specific to Smart Notes) and open-ended, free-response feedback. For analyses of NPS and open-ended feedback data, all MHPs who submitted a survey response were included.

NPS is a metric used to gauge how likely or unlikely respondents are to recommend a given platform, product, or company based on a single question regarding respondent satisfaction. NPS was calculated using MHPs' 1 to 10 ratings on the question "How likely are you to recommend Talkspace to a colleague?" by calculating the percentage of "promoters" (scores of 9 or 10; those who are satisfied and will recommend the business) minus

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the percentage of "detractors" (scores of 0 through 6; those who are unsatisfied and might actively discourage other users). We examined whether MHPs' NPS on the Talkspace platform as a whole differed between MHPs who did and did not use Smart Notes.

MHPs' free-response feedback about Talkspace was collected quarterly alongside NPS. We examined Smart Notes–related themes in MHPs' responses submitted during the quarters after the feature had been fully launched to all MHPs, reporting the number and percent of MHPs endorsing each theme.

MHP Productivity

Finally, to assess MHP productivity, we calculated MHPs' total weekly working hours, completed sessions, and weekly caseload. Total working hours were defined as the sum of hours spent on video calls, hours spent on SMS text messaging (calculated from the number of messages at 40 words per minute), hours of voice or video messages sent, and (for full-time MHPs) hours of vacation time. Completed sessions were defined as the sum of the live video sessions and asynchronous messaging sessions. Weekly caseload was defined as the count of clients that a MHP interacted with in a given week. We then compared MHPs' productivity after the introduction of Smart Notes (post–Smart Notes) vs before Smart Notes existed (pre–Smart Notes; Figure 1). We defined a 6-month post–Smart Notes period after the feature had been fully rolled out to ensure MHP uptake had steadied. We used the same 6-month period 1 year prior as the pre–Smart Notes period for comparison to minimize potential effects of time of year. To examine this pattern over time, independent of the introduction of Smart Notes, we replicated these analyses for the previous year (October 2022-March 2023 compared with October 2023-March 2024) and for the current period with MHPs who had been active since 2022. These results are presented in Multimedia Appendix 1.

Data Analyses

For analysis of MHP use, error rates, similarity scores, note quality, and productivity, we included data from Talkspace MHPs who met the following criteria: (1) MHPs were consistently employed at Talkspace for the study period (6 quarters around deployment of Smart Notes shown in Figure 1) and (2) MHPs conducted at least 1 asynchronous or live therapy session during each of two 6-month periods before and after Smart Notes (Figure 1). For productivity comparison analyses, we also excluded MHPs who switched employment status within Talkspace (eg, from full time to contractual) at any time during the study period. Where indicated, MHP types (full time and contractual) were analyzed and reported separately because these MHPs differed in weekly workload requirements.

Smart Notes use, error rates, text similarity scores, and MHP-rated note quality are examined via descriptive statistics (counts and percents). MHP productivity was examined across total working hours, completed sessions, and client caseload using within-subjects 2-tailed *t* tests. MHP feedback and satisfaction data were presented via between-subjects 2-tailed *t* tests (NPS) and manual, data-driven thematic analysis (open-ended survey feedback) [22,23]. Open-ended survey responses were first marked for references to various product features, including Smart Notes, and positive or negative feedback about each feature mentioned. Next, all responses that mentioned Smart Notes were read and initial notes (ie, codes) were generated for each. These codes were then categorized into 6 overarching themes, with a final read to verify that the assigned themes fit each comment. Each open-ended response could receive one or more theme codes.

Ethical Considerations

All data were collected as part of ongoing business operations between October 2023 and March 2025 and were deidentified prior to analysis. The use of participant data for this research was reviewed and deemed exempt by the Advarra Institutional Review Board under 45 Code of Federal Regulations §46.104(d)(4) (case Pro00084177/TS-001, dated June 2025) [24]. Members and MHPs gave consent for the use of their deidentified data for research and product development purposes by accepting the platform's privacy policy at account creation. Model development was based on deidentified therapy transcripts, which remained in an encrypted Talkspace database and were not accessed by the researchers at any time. No compensation was provided to the participants.

Results

Smart Notes Use

Overview

Across nearly 1 year (Figure 1), 162 unique full-time MHPs submitted 88,591 Smart Notes, and 1366 unique contractual MHPs submitted 198,320 Smart Notes. The total number of Smart Notes was higher than traditional progress notes submitted over the same period—full-time MHPs submitted 51,345 traditional progress notes, and contractual MHPs submitted 186,610. Over the same period, the average generation error rate per week was 2% (SD 4%; range 0%-17%). However, during most weeks, the error generation rate was less than 0.2%. Following a similar pattern, the text similarity scores averaged 93% (SD 3%; range 83%-95%) per week, with slight dips during weeks with higher generation errors (Figure 2). These dips were due to technical service outages on the part of either Talkspace or its vendors.

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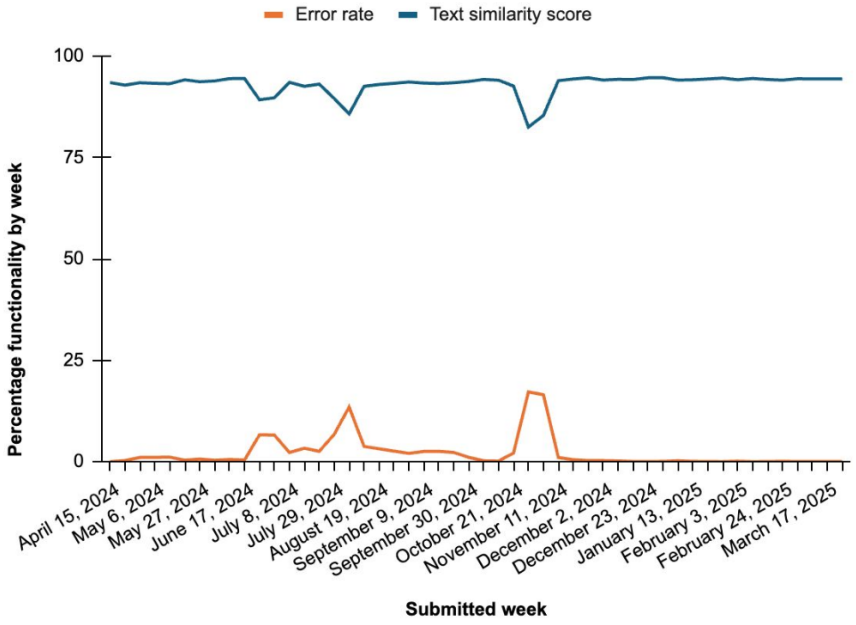
Figure 2. Smart Note functionality by week: generation error rate and text similarity scores.



Pilot

Among the subset of Talkspace MHPs who received early access to pilot the Smart Notes feature, uptake grew quickly to more than 100 full-time MHPs (Figure 3A) and 300 contractual MHPs (Figure 3B) using the feature each week during the pilot period.

Among full-time MHPs, Smart Notes use increased rapidly after the feature became available and held steady at an average of 80% of MHPs' notes for asynchronous sessions (Figure 4A, B). Full-time MHPs also used Smart Notes for live sessions as soon as the feature became available, growing quickly to 60.8% (1104/1815) of MHPs' live progress notes in the week before full launch. Among contractual MHPs, Smart Notes use grew to 56.7% (1041/1837) of MHPs' asynchronous progress notes by the fourth week, then held steady thereafter (Figure 4C, D). Contractual MHPs did not receive access to Smart Notes for live sessions during the pilot period.

Figure 3. (A) Full-time and (B) contractual mental health providers using Smart Notes during the pilot period.

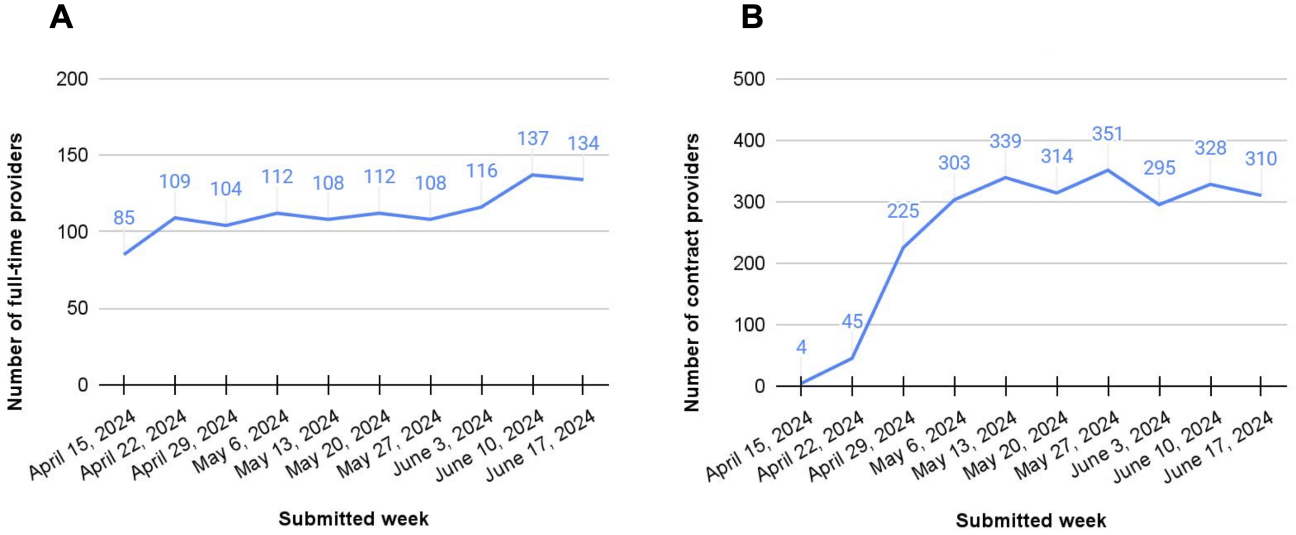


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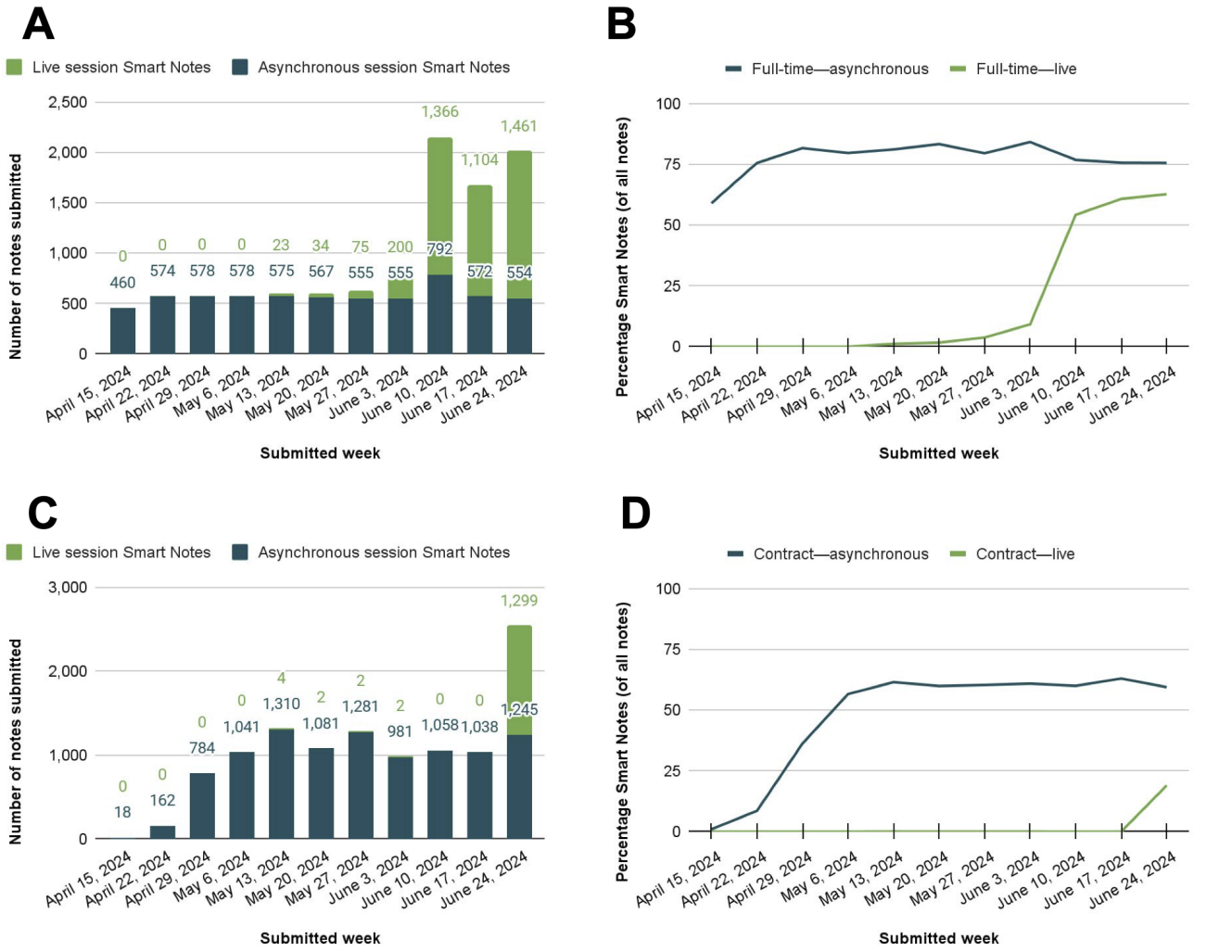
Figure 4. Smart Notes submitted by mental health providers (MHPs) during the pilot period. (A) Count of full-time MHPs' Smart Notes by week; (B) percentage of Smart Notes submitted by full-time MHPs each week; (C) count of contractual MHPs' Smart Notes by week; and (D) percentage of Smart Notes submitted by contractual MHPs each week.



After Launch

Following the pilot period, Smart Notes was made available to all MHPs on the Talkspace platform for individual asynchronous therapy sessions and eligible live therapy sessions. At launch, percent use was high among both full-time MHPs (Figure 5A) and contractual MHPs (Figure 5B). Among full-time MHPs, 96% (142/148) used the Smart Notes feature during the first week of its full launch across the platform. Use remained high over time, with nearly all MHPs using Smart Notes on a weekly basis (mean 94%, SD 1%; Figure 5A). Full-time MHPs averaged 2000 (SD 283.7) Smart Notes per week as a group or averaged 72% (SD 3%) of all progress notes they submitted (Figure 6A). Additional data broken out by asynchronous and live sessions are given in Table 1.

Among contractual MHPs, 51% (607/1181) used the Smart Notes feature during the first week of its full launch across the platform. Over time, uptake increased to an average of 72% (SD 6%) of all MHPs (Figure 5B). Contractual MHPs averaged 4739 (SD 784.7) Smart Notes per week as a group or 62% (SD 8%) of all contractual MHPs' progress notes (Figure 6B). Table 1 shows data broken out by asynchronous and live sessions.

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Figure 5. (A) Fut to ull-time and (B) contractual mental health providers using Smart Notes after launch.

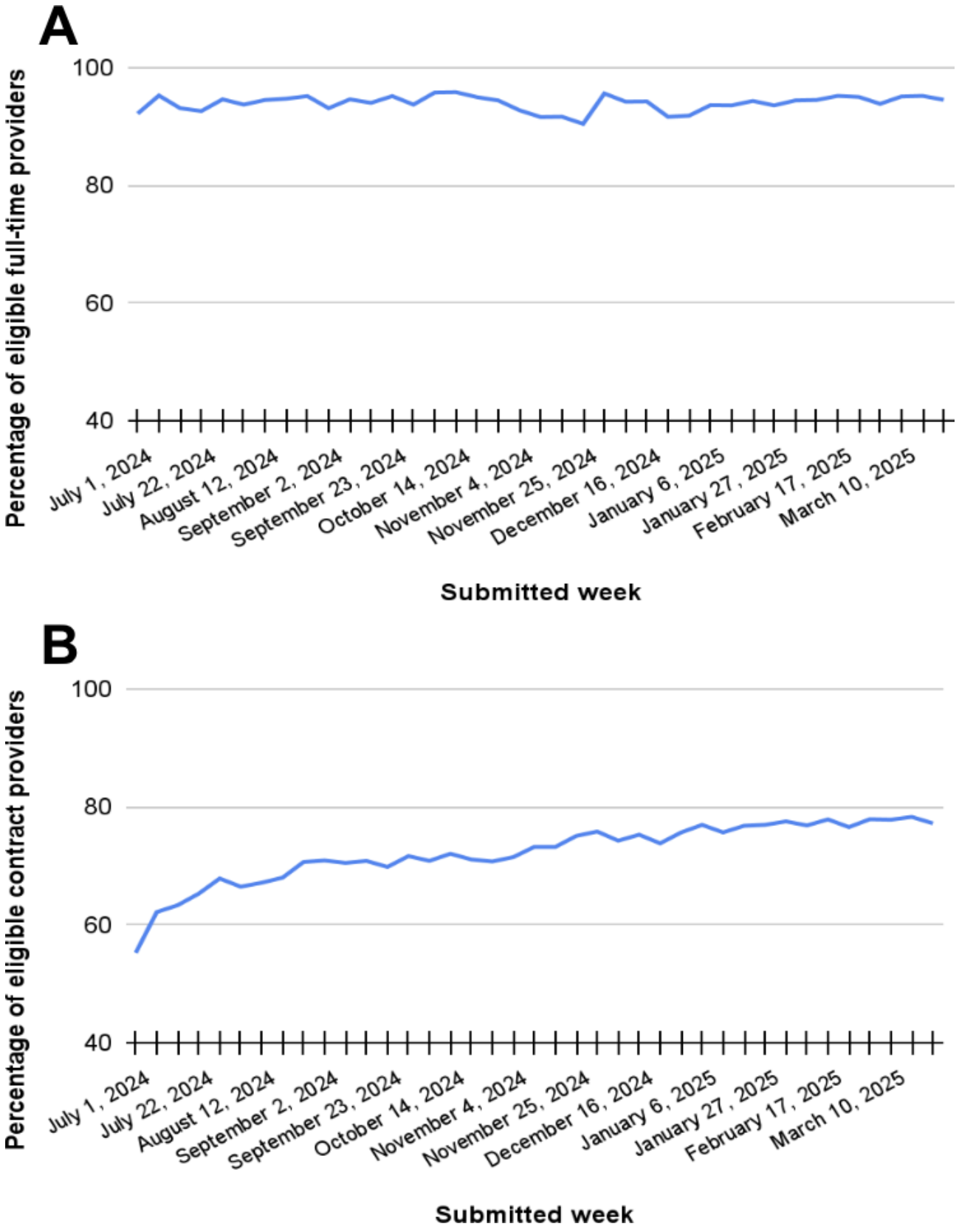

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Figure 6. Smart Notes submitted by (A) full-time and (B) contractual mental health providers during the weeks after launch.

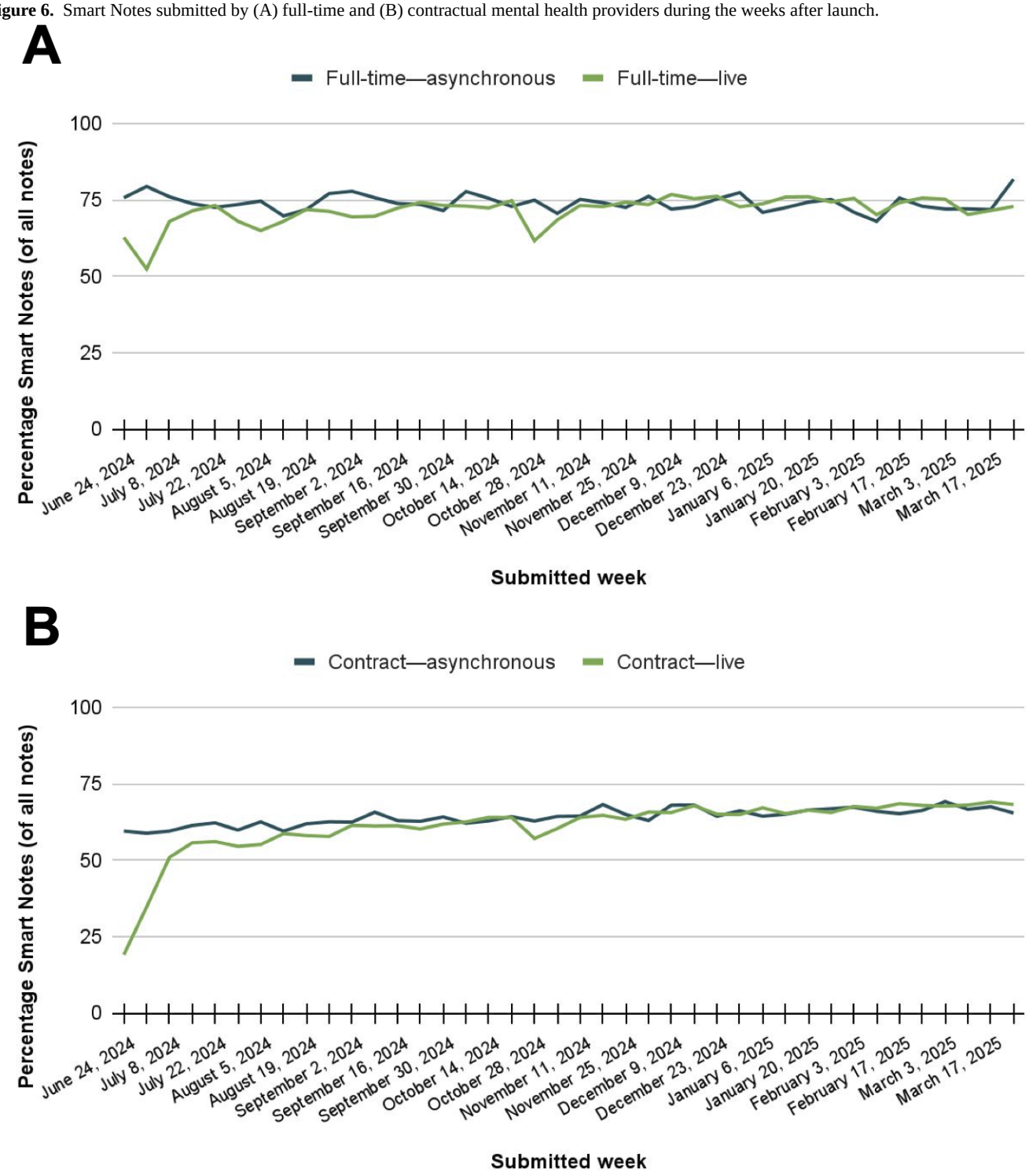

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Table . Weekly average Smart Notes submitted by mental health providers (MHPs) after launch.

	Full-time MHPs		Contractual MHPs	
	Mean (SD)	Range	Mean (SD)	Range
All sessions				
Smart Notes, n	1999.6 (283.7)	1034.0-2425.0	4738.9 (784.7)	2328.0-5755.0
Smart Notes (%)	72 (3)	59-76	62 (8)	29-69
Asynchronous sessions				
Smart Notes, n	453.7 (84.7)	268.0-666.0	919.2 (145.6)	704.0-1307.0
Smart Notes (%)	74 (3)	68-82	64 (3)	59-69
Live sessions				
Smart Notes, n	1545.9 (242.7)	766.0-1897.0	3819.7 (805.8)	1299.0-4789.0
Smart Notes (%)	72 (5)	52-77	61 (9)	19-69

MHP-Rated Note Quality

Smart Note quality was monitored on an ongoing basis. Out of 466,139 total Smart Notes, MHPs gave optional feedback ratings on 30,519 (6.5%). Of these, Smart Notes were nearly all rated "thumbs-up" (positive): 97.7% (9980/10,219) of full-time MHPs' ratings and 98.4% (19,977/20,300) of contractual MHPs' ratings were positive. Most negative ratings (n=562, 1.8%) were related to summary inaccuracy (150/323, 46.4% ratings from contractual MHPs and 125/239, 52.3% from full-time MHPs) or too many edits needed (135/323, 41.8% ratings from contractual MHPs and 97/239, 40.6% from full-time MHPs).

MHP Feedback and Satisfaction

Contractual MHPs who used Smart Notes (167/421, 39.7%; mean 7.25, SD 2.68) gave NPS ratings of Talkspace that were no different from those who did not use Smart Notes (254/421, 60.3%; mean 6.96, SD 3.11; $t_{389.92}$=1.022; P=.31). Similarly, full-time MHPs who used Smart Notes (39/73, 53.4%; mean 8.46, SD 2.21) also gave NPS ratings of Talkspace that were no different from those who did not use Smart Notes (34/73, 46.6%; mean 8.88, SD 1.39; $t_{64.854}$=0.987; P=.33).

Quarterly surveys, which included opportunities to give anonymous open-ended feedback about Talkspace, included many comments about Smart Notes. A total of 128 full-time MHPs and 685 contractual MHPs gave open-ended feedback in Q3 2024, 197 and 668 in Q4 2024, and 156 and 632 in Q1 2025. Among those respondents, the Smart Notes feature was mentioned by 3 (2.3%) full-time MHPs and 30 (4.4%) contractual MHPs in Q3 2024, 9 (4.6%) and 28 (4.2%) in Q4 2024, and 23 (14.8%) and 28 (4.4%) in Q1 2025.

Across quarters, MHPs' Smart Notes feedback was overall positive (120/126, 95.2% positive vs 6/126, 4.8% negative comments; Table 2), including general praise (eg, "I love the Smart Notes!"), specific praise (eg, saves time, makes work easier), and requests for the feature's expansion across the platform (eg, Smart Notes for couples sessions or sessions conducted in Spanish). Few comments mentioned issues with or suggested improvements to Smart Notes (eg, concerns about privacy and comparison to competitors' features).

Table . Summary of Smart Notes feedback in open-ended mental health provider (MHP) responses[a].

Theme	Full-time MHPs (n=33), n (%)	Contractual MHPs (n=82), n (%)
General praise for Smart Notes	6 (18.2)	43 (52.4)
Smart Notes saves MHPs time	4 (12.1)	4 (4.9)
Smart Notes makes MHPs' work easier	3 (9.1)	3 (3.7)
Request for Smart Notes to expand (eg, for use in couples' sessions)	26 (78.8)	31 (37.8)
Artificial intelligence privacy concerns	1 (3.0)	2 (2.4)
Issues or improvements	0 (0.0)	3 (3.7)

[a]Percentages do not add to 100 because MHPs could have mentioned more than one of these themes in their responses.

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MHP Productivity

Table 3 presents data on full-time (n=140) and contractual (n=1698) MHPs in the pre–Smart Notes and post–Smart Notes periods. For additional context, data from a second pre–Smart Notes period replicating the main results are included in Multimedia Appendix 1.

Table . Weekly average working hours, completed sessions, and clients pre–Smart Notes and post–Smart Notes.

	Pre–Smart Notes, mean (SD)	Post–Smart Notes, mean (SD)
Full-time mental health providers		
Hours	18.2 (8.15)	18.6 (8.93)
Sessions	15.5 (7.64)	16.5 (8.41)
Clients	18.0 (6.10)	19.4 (6.61)
Contractual mental health providers		
Hours	4.11 (5.80)	4.11 (6.08)
Sessions	3.91 (5.55)	4.06 (6.10)
Clients	5.48 (5.86)	5.91 (6.70)

Total working hours—neither full-time MHPs (t_{139}=1.263; P=.21) nor contractual MHPs (t_{1697}=0.175; P=.86) demonstrated a change in their total working hours between the 2 periods.

Completed sessions—both full-time MHPs (t_{139}=2.592; P=.01) and contractual MHPs (t_{1697}=2.053; P=.04) demonstrated a significant increase in weekly sessions completed from pre–Smart Notes to post–Smart Notes.

Clients—both full-time MHPs (t_{138}=3.496; P<.001) and contractual MHPs (t_{1440}=2.735; P=.006) demonstrated a significant increase in weekly caseload from pre–Smart Notes to post–Smart Notes.

Discussion

Principal Findings

This study aimed to describe the development and application of Talkspace's Smart Notes, a generative AI tool designed to assist with documentation tasks for MHPs. Our findings provide initial evidence that AI-powered documentation tools are a feasible and well-received solution for supporting mental health clinicians, in line with existing work in other medical specialties, including psychiatry [18-20]. However, to the best of our knowledge, this is the first study to specifically investigate the utility of an AI scribe service within a large-scale digital mental health care context. The results shed light on how such technology may be used in administrative workflows and its association with MHP productivity and satisfaction, highlighting a potential avenue to ultimately support access to mental health services.

Interpretation of Key Findings

Three key findings from this preliminary investigation are particularly significant. First, the rapid and sustained uptake of Smart Notes suggests that it aligns with MHP interest and demand. The consistent use, with nearly all full-time MHPs and most contractual MHPs using the feature weekly for eligible sessions, indicates that the tool was compatible with MHPs' existing workflows rather than disrupting them [16,18]. Notably, full-time MHPs adopted the feature at higher rates than hourly contractual MHPs, which may be due to their more consistent, full-time caseloads.

Second, the high-quality ratings of the Smart Notes were a critical factor in their acceptability. Nearly all note quality ratings were positive (9980/10,219, 97.7% among full-time MHPs and 19,977/20,300, 98.4% among contractual MHPs), suggesting that MHPs perceived the tool as generating accurate and useful session summaries, a prerequisite for widespread adoption in a clinical setting. The low rate of negative feedback related to accuracy and formatting indicates that the tool performed consistently with clinical standards. The required human review before submission ensured that any Smart Note not meeting clinical standards was edited or corrected by the MHP, maintaining clinical integrity and MHP accountability. High text similarity scores between the generated Smart Note and the MHP-reviewed submitted note indicate that MHPs did not need to make many edits. Ethically, the reliance on MHP review underscores the importance of the "human-in-the-loop" model. Although very few MHPs reported inaccuracies and the submitted notes were consistent with Smart Notes, the requirement for MHP sign-off aligns with recommendations for responsible AI deployment [17,18], ensuring that clinical oversight remains central to documentation.

In addition, the overall positive qualitative feedback on Smart Notes contextualizes the high use rates and further reinforces the tool's value. MHPs praised Smart Notes for saving them time and making their work easier, 2 core pain points of documentation burden that the tool was initially created to address. The strong positive reception of this specific feature suggests that targeted technological interventions can garner favorable MHP perceptions of their workload within a larger digital health care ecosystem.

Finally, our data also show that Smart Notes implementation coincided with trends in MHP productivity. Although small, the observed increase in completed sessions following the feature's introduction, without a corresponding increase in MHPs' working hours, aligns with prior research suggesting that a reduced documentation burden can improve productivity by freeing up MHPs' time for client-facing activities [8,18,19],

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ultimately increasing access to care. This finding is especially relevant for a field struggling with MHP capacity and retention.

Implications and Limitations

Although this study offers valuable insights, it is important to consider its limitations. The primary limitation is the observational design, which prevents us from establishing a causal link between the use of Smart Notes and the observed increase in MHP session completion. It is possible (and indeed, our supplemental analysis supports) that confounding factors, such as natural caseload growth, other changes to the Talkspace platform, or various external factors such as seasonality may have driven these productivity metrics independent of the Smart Notes tool. Future research might survey MHPs directly for reflections on how Smart Notes impacted their workflows and perceived documentation burden and productivity. Additional research is also needed to isolate the effects of Smart Notes use on MHPs' productivity over time.

Additionally, although we were able to assess the change in MHPs' client-facing working hours, administrative and documentation time was not measurable on the platform, limiting our ability to detect a difference in time spent on non–client-facing tasks. However, measurement of administrative time is subject to substantial variability (eg, MHPs could leave the platform open while not actively working on a task, and multiple types of tasks are included in administrative time). Focusing on shifts in the number of client-facing hours provides an early metric for tracking potential associations between Smart Notes and productivity.

Finally, the high satisfaction ratings (120/126, 95.2%) and qualitative feedback may be subject to nonresponse or extremity bias [25], particularly given the small percentage of notes (30,519/466,139, 6.5%) with submitted formal quality ratings. However, the data did not exhibit the bimodal "U-shaped" distribution typical of extremity bias [26], and negative feedback remained minimal despite multiple anonymous feedback channels. The validity of these positive ratings is further supported by high uptake and sustained longitudinal use, suggesting that MHP behavior aligns with the reported satisfaction levels. Positive feedback results also align with existing proof-of-concept research with psychiatrists [20] and psychiatrists' general views of AI documentation in mental health [27].

Our findings have important practical implications for both MHPs and mental health care organizations. This study provides preliminary evidence that AI tools can be feasible and acceptable to MHPs and garner favorable perceptions related to documentation burden, potentially supporting their capacity to deliver care. For organizations, investing in these technological solutions may be relevant for addressing MHP burnout, satisfaction, and retention. As AI tools become more integrated into mental health care, continued research is essential to understand their immediate and long-term impact on MHP well-being, patient outcomes, and the evolving nature of documentation practices.

Conclusions

This retrospective observational study suggests that AI-powered documentation tools such as Smart Notes can be successfully integrated into digital mental health workflows to support MHPs. High adoption rates, coupled with favorable MHP feedback, underscore the potential utility of these tools in assisting with administrative demands while maintaining clinical standards. Overall, this study contributes preliminary data regarding the deployment of generative AI in a behavioral health context, highlighting a promising avenue for future research into scalable solutions to address documentation burden.

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The authors declare the use of generative artificial intelligence (GenAI) in the research and writing process. According to the GAIDeT taxonomy [28], the following tasks were supported by GenAI tools under full human supervision: literature search and systematization; proofreading and editing; and adapting and adjusting tone. The GenAI tool used was Gemini (models 2.0 and 2.5). Following the use of this tool, the authors thoroughly reviewed, revised, and finalized the content and take full responsibility for the final version of the manuscript.

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Data Availability

The datasets generated or analyzed during this study are not publicly available because they were collected as part of standard business operations. However, they are available from the corresponding author on reasonable request.

Conflicts of Interest

All authors are employed by Talkspace, LLC.

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Multimedia Appendix 1
Mental health provider productivity from 2022 onward.
[DOCX File, 2799 KB - formative_v10i1e84628_app1.docx]

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Abbreviations

AI: artificial intelligence
API: application programming interface
HIPAA: Health Insurance Portability and Accountability Act
MHP: mental health provider
NPS: net promoter score

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Acceptance of Smart Contracts in Patients Receiving Primary Care: Exploratory Study

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Abstract

Background: Health care has seen several new disruptive technologies. One such innovation is the introduction of blockchain smart contracts. These smart contracts are activated automatically once preprogrammed conditions are met. Smart contracts have improved patient outcomes, the efficiency of care delivery, and reduced costs. Despite their benefits, patients have had limited interactions with smart contracts in primary care; therefore, they may not trust blockchain-based smart contracts and may perceive them as risky or have concerns about their security.

Objective: This study aimed to evaluate how patients' perceptions of smart contracts affect their adoption in primary care. Specifically, we investigated the impact of patients' perceptions of smart contract security, risk, and trust in their health care providers.

Methods: This study used an experimental survey design to evaluate acceptance of smart contracts. Patients were randomly assigned to 1 of 2 research scenarios proposing either the positive use of blockchain smart contracts or the loss of benefits if a patient opted out. We collected data from a total of 387 participants. The Likert survey used 3 items to measure 5 constructs in the conceptual model. The 5 hypotheses were that gain-loss-framed messaging, perceived security, and trust would have a positive impact on the adoption of smart contracts, whereas perceived risk and the clinical setting would have a negative impact on patients' intention to adopt smart contracts. The conceptual model was tested using structural equation modeling, and the model fit indices suggested a good fit.

Results: Most of the hypotheses were supported, except for the gain-loss-framing effect. As hypothesized, perceived security had the strongest positive influence on the intention to use smart contracts (β=.50; *P*<.001). Trust in health care providers also showed a significant positive relationship (β=.43; *P*<.001), while perceived risk had a smaller but still significant negative impact (β=–.071; *P*.048). Patients in clinic-based settings had a lower intention to use smart contracts than patients in telehealth settings, and male patients had a lower intention to use smart contracts than female patients.

Conclusions: The results of this study have implications for health care providers who intend to adopt smart contracts early, that is, early majority or late adopters. To facilitate their implementation, providers should highlight the security benefits of smart contracts and leverage patient trust. Providers should customize smart contract implementation strategies based on patient demographics such as age, health status, and gender. By understanding these factors, health care organizations can more effectively promote the adoption of smart contracts and realize the potential benefits of this disruptive technology in primary care.

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KEYWORDS

blockchain; smart contracts; trust; perceived risk; perceived security

Introduction

Background

Disruptive health care technology replaces existing technology; it benefits providers and patients because it reduces costs, promotes high-quality care, and is convenient [1,2]. Disruptive health innovation can affect processes, techniques, digital health education, diagnostics, device development, and the discovery of biological mechanisms underlying health and disease [3]. In this study, we proposed that smart contracts, a specialized blockchain mechanism, are a process-oriented disruptive health care technology that can successfully replace traditional business processes to facilitate care delivery.

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The term “smart contract” refers to a computer program that runs on multiple distributed ledger nodes when predetermined conditions are met, without third-party intervention [4]. Essentially, smart contracts contain all of the details required to execute an agreement or workflow, and they run automatically when the conditions are met, without intermediaries. In health care, smart contracts have been applied to various use cases, such as remote patient monitoring [5], clinical services such as telesurgery [6], the internet of medical things [7], care coordination [8], facilitating research [9], and optimizing supply chains [10]. The adoption of smart contracts has improved patient outcomes and increased efficiency by enhancing the management of medical sensors in telehealth, improving care delivery, providing remote access to quality health care professionals, and reducing travel and care delivery costs. However, patients have not directly interacted with smart contracts. Therefore, it is necessary to understand patients’ feelings about the implementation of smart contracts that would directly affect their health care.

In a value-based payment model, providers hold specialized contracts with insurers. They are compensated for improved patient outcomes and for reducing unnecessary medical expenses rather than based on the number of patients they diagnose and treat [11,12]. Clinical quality initiatives, such as value-based care, are designed to reduce costs, enhance patient convenience, and improve the quality of patient outcomes. Unfortunately, smart contracts are in the early adoption phase in secondary and tertiary health care settings; therefore, only a few patients and providers have been introduced to or had personal experiences with the technology. In the primary care setting, smart contracts can replace patient and clinical workflows; however, many of the benefits will be unseen or behind the scenes. Although these smart contracts work seamlessly in the background, patients must first opt to participate in their use for care delivery; this is similar to the opt-in process used for health information exchanges. The need for patient buy-in underscores the importance of understanding patient perceptions. This study focused on the implementation of smart contracts in primary care and how patients’ perceptions may impact their further adoption.

Smart contracts can improve and standardize many workflows in the primary care setting; however, an equitable consideration of associated concerns is warranted. Patients may hesitate to adopt smart contracts due to trust issues or concerns about the risk and security of smart contracts. Trust is a complex construct in health care because patients may trust their physician but not necessarily the medical technology used in care delivery [13]. Individuals may perceive potential negative consequences, such as risks to their safety or personal data. Therefore, risk-averse individuals may be less inclined to use smart contracts to manage their health care. Modern smart contract stacks commonly support upgradeability, emergency pause mechanisms, and governance-controlled parameter changes. Although these patterns improve responsiveness, they introduce new security risks and concerns. Furthermore, the decentralized nature of blockchain-based smart contracts may raise privacy concerns regarding access to sensitive patient health information, because in a trustless environment, unknown third-party companies may facilitate smart contracts. These trust and privacy concerns are valid, as Ethereum, one of the third-party intermediaries proposed for implementing smart contracts in health care [14], experienced a security breach after unknown actors exploited a vulnerability in a decentralized autonomous organization (DAO). Hackers stole US $60 million from Ethereum’s DAO [15]. This security breach underscores the importance of examining sociotechnical issues that arise during the implementation of disruptive technology. The health care community must thoroughly understand the security, governance, and policies of blockchain technology [16] before mainstream adoption of smart contracts. With data breaches and privacy concerns receiving greater public attention, primary care patients are more informed, reinforcing the need to understand patient perceptions as smart contracts remain in early implementation.

This study is timely and addresses a gap in the literature because applications of smart contracts in health care have primarily focused on business-to-business or provider-to-provider interactions, inpatient care, and long-term care settings. Specifically, research has centered on the technical and organizational perspectives regarding adoption barriers in health care [17,18]; the patient perspective remains largely unexplored. Consequently, little is known about primary care patients’ willingness to authorize the use of smart contracts for their treatment or diagnosis. Therefore, this study used an experimental survey design to evaluate acceptance of smart contracts. To understand patients’ adoption of smart contracts in primary care, we examined key factors, such as patients’ trust in their health care providers, their perceptions of the risks involved in smart contracts, and their perceived security concerns.

Patients can benefit from innovations such as blockchain smart contracts. Therefore, examining the factors that influence patients’ willingness to adopt smart contracts is crucial, and herein lies our contribution to the literature. The conceptual model developed for this study can provide health care professionals with insights to expand the adoption of smart contracts and improve health care quality across the United States.

Literature Review

The prior literature has established the unique attributes of blockchain technology, including decentralized consensus, predefined rules, accurate record-keeping, immutability, and a no-trust framework [19]. These features have proven useful in many industries, including health care. With the evolution of blockchain technology, smart contracts originated as self-executing contracts, with the terms of the agreement coded and shared between all parties, with predetermined conditions controlling further execution and enforcement [20]. In particular, blockchain technology shows great promise in health care because it offers solutions for data management, privacy, and security [20]. Moreover, blockchain technology can facilitate patient-driven interoperability in health care. Prior work has identified 5 key mechanisms: digital access rules, data aggregation, data liquidity, patient identity, and data immutability, while also addressing challenges such as

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transaction volume, privacy, and patient engagement [21]. Blockchain's role has been examined in terms of exchanging data securely among health care professionals [22], providing better data accessibility in Electronic health record (EHR) platforms and smart contracts [23], low-latency health care apps [24], internet of things health care applications [25], and federated learning for at-home health monitoring [26].

Permissionless blockchains are decentralized systems that execute transactional programs and access a fully replicated, immutable data store without requiring complete trust in any single participant or third party. These systems are open to participation; anyone can join by running a local instance of the peer-to-peer protocol. Permissioned blockchains limit participation to a designated set of users for some or all roles within the system. This type of blockchain is particularly well suited for competing enterprises seeking to collaborate without relying on third-party networks [27,28]. There is a debate about which type of blockchain to use. Researchers argue that a permissioned network loses the benefit, since chaining transactions in a closed network is no longer able to protect the data from tampering [29]. Others argue that permissionless blockchains are susceptible to Sybil attacks, in which a hacker uses multiple identities to gain access to the blockchain [30,31]. Some researchers have suggested using smart contracts to switch between permissioned and permissionless blockchains [27]. Ultimately, the choice of which to use in health care will depend on the cost of implementation and the ability of the smart contracts to uphold laws such as Health Insurance Portability and Accountability Act (HIPAA) or General Data Protection Regulation (GDPR). In health care use cases, researchers have focused on permissioned private blockchains. If permissioned systems are to be implemented mainstream, providers may face a similar dilemma to health information exchanges in terms of implementation, such as governance [32], system architecture and standards, document and data items, consent, and usability [33,34]. An in-depth discussion of the challenges is outside the scope of this study; however, additional research is required to fully understand the implications and impact of implementation on interoperability and cost.

While the choice between permissioned and permissionless systems remains under consideration, the core attributes of blockchain technology hold considerable promise for health care transformation. The decentralized nature of blockchain technology provides enhanced security, privacy, efficiency, transparency, and trust, which highlights the potential of blockchain to revolutionize health care operations [35]. Smart contracts leverage blockchain's secure and transparent nature to automate and enforce agreements without the need for intermediaries. Blockchain technology facilitates secure, private transactions and provides a transparent, immutable record, which enhances trust in smart contract applications [36]. Similarly, blockchain's ability to improve data security and interoperability is crucial for the effective implementation of smart contracts between individuals and health insurance organizations [37].

Smart contracts thus offer significant potential for automating processes, reducing overhead, and improving efficiency in various sectors, including health care. They can also enhance data transparency in clinical trials by ensuring the integrity and immutability of trial data [38]. SmartAccess uses blockchain and smart contracts to enable transparent, auditable, and distributed access control for cross-organization medical data sharing [39].

One stream of smart contracts research is focused on the development of syntactic assets, algorithmic stablecoins, and the tokenization of the investment portfolio management process [40-42]. Meanwhile, another stream of research explores the use of smart contracts to solve key challenges in health care ecosystems, such as interoperability, automatic patient acquisition across multiple sites, and patient-centric identification and authentication [25,43,44]. Smart contracts are also being used to improve efficiency by automating processes and reducing the need for intermediaries [45]. While there are research streams exploring technical and operational challenges in the field of smart contracts in health care, patient perceptions of and concerns related to the smart contracts technology within the primary care framework in the United States have been largely unexplored.

Smart contracts have many applications in the health care industry. A systematic review of the role of smart contracts in creating sustainable health care platforms recognized key themes, such as health care process enhancement and patient privacy protection [46]. The impact of smart contracts has been realized in patient data management, medication adherence, insurance claims, clinical trials, supply chain management, network security, payment transfers, reducing medicine shortages, and many more applications. For instance, Fast Healthcare Interoperability Resources (FHIR) is a standard for exchanging health care information electronically [47]. Patientory is a blockchain-based platform that allows patients to store and share their health information securely [48]. Encrypgen uses blockchain and smart contracts for DNA data transfer to empower patients to make decisions regarding the sharing of their genomic data [49]. Smart contracts enable the secure and decentralized management of patient data, thereby ensuring data integrity and privacy [46]. They can also monitor patients' adherence to their medication schedules and automate the insurance claim process to reduce administrative overhead and fraud [50]. Our focus on smart contracts in primary care has been motivated by the following properties, which are clearly distinct from EHR digitization:

1. Programmable enforceability: business rules such as referral eligibility, prior authorization criteria, and copayment logic are executable rather than merely documented; therefore, compliance is verifiable ex post via on-chain events.
2. Tamper-evident audit: an append-only log across organizations reduces disputes and supports audits.
3. Decentralized coordination: multiple parties including primary care providers (PCP), laboratories, and payers can share state without a single operator, thereby reducing reconciliation overhead.
4. Composability: smart contracts interoperate, enabling automated care pathways, for example, referral workflows that automatically trigger claims logic.
5. Governable change management: upgrades and pauses occur under explicit policy, with historical records preserved.

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Interestingly, smart contracts present challenges in health care. Trust plays a crucial role in mediating the effects of the perceived usefulness and ease of use of smart contracts, as well as privacy concerns [51]. Privacy considerations are particularly important, with different applications of smart contracts (eg, immune certificates vs EHRs) affecting privacy evaluations differently. Technical, legal, and social factors also affect the adoption of smart contracts. Human factors, such as concerns about invasiveness and potential job displacement, can hinder the acceptance of smart health care systems [52].

Although resistance to change is a significant barrier to the acceptance of smart health care technology, it can be assuaged with careful management of the patient-provider relationship [53]. Trust in the patient-provider relationship, the reliability of the communication channel, altruistic motivation to contribute to health service quality for others, and the risk of losing information agency have been identified as determinants in patients' adoption of smart health care technologies in general [54]. Yet, despite their potential benefits in addressing security, privacy, and data-sharing challenges [55], smart contracts face adoption barriers. However, demographic factors, including gender, age, and usage experience, can moderate the relationships between these factors and acceptance [51].

The scalability of blockchain networks can be another factor that limits the widespread adoption of smart contracts in health care. Ensuring that smart contracts comply with health care regulations and standards is therefore crucial. The implementation and maintenance of smart contracts require specialized knowledge and expertise. At the same time, the successful implementation of smart contracts in health care depends on patients' willingness to accept and use this technology. Ensuring that new technologies align with patients' needs and preferences is essential for providing high-quality, patient-centered care.

Overall, prior studies map a wide landscape of smart contract applications but provide limited critical synthesis across three decision-critical dimensions: (1) process locus (back-office claims vs point-of-care workflows such as referrals and prior authorization), (2) coordination model (single-operator platforms vs multiparty smart contracts that share state across organizations), and (3) assurance mechanism (narrative "security by design" vs engineering evidence such as audited libraries, governance controls, and formal methods). When organized along these dimensions, much of the literature emphasizes technical feasibility, cost, or compliance benefits. Very little empirical work examines patient intentions in multiparty smart contract settings that automate routine primary care tasks. This synthesis surfaces a specific research gap: a lack of empirical evidence on patients' intentions to use smart contract–mediated workflows in primary care, where day-to-day activities (eg, referrals, prior authorization, and copayment settlement) depend on decentralized coordination and explicit assurance mechanisms.

Our study addresses this gap by estimating how perceived security, trust in provider stewardship and governance, perceived risk, and message framing are associated with intention to use primary care smart contracts whose mechanisms include programmable enforceability, tamper-evident audit trails, and governed upgrades.

Hypotheses Development

Message Framing

Message framing, which involves presenting information in either a positive (gain-framed) or negative (loss-framed) manner, can significantly influence patient acceptance of smart contracts in health care. Research on health communication has shown that the way information is framed can affect attitudes, intentions, and behaviors related to health decisions. Gain-framed messages, which emphasize the benefits of engaging in a particular behavior, can be more persuasive than loss-framed messages, which highlight the consequences of not engaging in that behavior. Gain-framed messages are often more effective at promoting preventive health behaviors, such as using sunscreen or getting vaccinated [56].

Moreover, gain-framed messages can be more motivating because they focus on positive outcomes, which can be more appealing and less threatening to individuals. This aligns with the principles of prospect theory, which suggests that people are generally more motivated by potential gains than by potential losses [57]. The effectiveness of gain-framed messages can also depend on the characteristics of the target audience. For instance, individuals with a low preference for risk and a heuristic processing style are more likely to respond positively to gain-framed messages [58].

The framing of messages about blockchain technology and smart contracts can significantly influence patients' perceptions and acceptance of their use in health care. Gain-framed messages that highlight how blockchain enhances the security and privacy of patient data could reassure patients. For example, emphasizing that blockchain ensures data integrity and gives patients control over their health information can make them feel more secure and in control [59]. By focusing on the positive outcomes, such as improved accuracy in medical records, faster access to patient history, and better coordination between health care providers, gain-framed messages can make patients more receptive to smart contracts in health care [60]. Highlighting the transparency and trust that blockchain brings to health care processes can also positively influence patient perceptions. For instance, explaining how blockchain can prevent fraud and errors in medical billing and insurance claims can build patient trust in the system [61].

In this study, a "smart contract" refers to a program that automatically enforces referral and prior authorization rules, logs each decision to a tamper-evident, cross-organization audit trail, and settles copayments when predefined conditions are met, without a single operator controlling the workflow. The framing manipulation, therefore, targets smart contract–specific attributes such as programmable enforceability, tamper-evident audit, and decentralized governance within primary care tasks such as check-in, referrals, prior authorization, and payment. These attributes are not generic benefits of digitization. Therefore, based on prior research, we hypothesized the following.

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Hypothesis 1: In primary care smart contract workflows, a gain-framed description is associated with higher patient intention to use, relative to an otherwise identical loss-framed description.

Perceived Security

Perceived security refers to the degree to which individuals believe that their personal information is protected, safely managed, and secure when using blockchain smart contracts. In health care, perceived security is crucial due to the sensitive nature of patient information. A comprehensive review highlighted that security and privacy are paramount concerns in health care because breaches can lead to significant harm [62]. The study emphasized that addressing security concerns can enhance trust and the adoption of new technologies. Factors such as employees' training on security issues, monitoring, ethics, and technical protection contribute to this perception. When patients feel their data are secure, their trust in the health care system increases. In health care, the use of smart contracts could lead to higher adoption rates due to the perceived security they offer. Smart contracts could streamline the management of patient data, thereby ensuring that only authorized personnel have access. This would not only improve data security but also enhance patient privacy, thereby potentially increasing patients' intention to use such technology. Research on the telemonitoring of chronic conditions has shown that a sense of security is vital for patient safety and engagement [63].

The HIPAA regulates security among patients and health care providers. Smart contracts can automate administrative processes to ensure data integrity and security for the purpose of regulatory compliance. In addition to regulatory compliance, the underlying mechanisms in smart contracts use mathematical models as best practices to enhance security and trust through a rigorous verification process, whereby smart contracts encode legal or business terms using a translation process to verify that requirements are met [64]. Smart contracts can help health care organizations validate correctness, especially in settings where errors can affect patient safety. If patients are aware that smart contracts can improve precision in care delivery, their perceived security may increase, thereby enhancing their intention to use smart contracts for care delivery.

In addition, the quality of service (QoS) in health care applications encompasses aspects such as availability, reliability, performance, and security. Enhancing QoS can lead to increased patient trust and perceived security, which can lead to the increased adoption of smart contracts. A novel approach to improve the QoS of smart contracts in health care demonstrated that improved QoS can enhance patients' perceived sense of security, reduce costs, and increase intention to use [6].

In our setting, smart contracts would automate prior authorization, referral routing, and copayment settlement between the PCP, laboratories, and payers. The relevant security property is a tamper-evident, append-only audit trail for these multiparty actions, with cryptographic access control to protected health information pointers (on-chain events and off-chain records). Thus, the perceived security construct is defined as confidence in these ledgered, cross-institution workflows rather than in health IT in general. This leads to our second hypothesis.

Hypothesis 2: Higher perceived security of tamper-evident, cross-organization audit trails and cryptographic access control is associated with a higher intention to use PCP-orchestrated smart contracts.

Trust in Health Care Providers

Trust in health care providers is a fundamental aspect of the patient-provider relationship and significantly influences patients' willingness to share sensitive information and adhere to medical advice. This trust extends to the acceptance of new technologies recommended by health care providers, including smart contracts. When patients trust their health care providers, they are more likely to follow medical advice and accept new technologies recommended by them. Research has emphasized that trust in physicians is built through competence, effective communication, and professionalism [65]. This trust can extend to the technologies that physicians endorse, including smart contracts. For instance, if a physician recommends a smart contract system for managing patient data, patients who trust their physicians are more likely to adopt and use it. Increased trust by patients in their physicians leads to better treatment adherence and acceptance of smart technologies [66].

Trust in physicians can mitigate concerns about the safety and efficacy of new technologies. For example, if a physician endorses a smart contract system for managing patient data, patients who trust them are more likely to use it. This perception can reduce anxiety about potential risks, such as data breaches or misuse of personal information. Patients' acceptance of technological innovation depends on their perceived ability to both use and directly benefit from it, and this is enhanced if their health care provider conveys a positive perception of the technology [67].

An examination of the impact of trust and privacy concerns on technology acceptance in health care found that trust is a direct predictor of patients' intention to use technology in health care services [68]. A proposed smart contract–based access control framework for securing electronic medical records included mechanisms for user verification and access authorization, which are critical for building trust [69]. The research emphasized that trust in the security and privacy of the system is vital for patient acceptance. When health care providers implement such secure systems, patients' trust in their providers can translate into a higher intention to use smart contracts.

In primary care, patients rely on their PCP to vet digital tools and to act as a governance steward. These providers can pause or upgrade the contract, hold administrative keys, and know about the policy. We therefore conceptualize provider trust here as trust in the provider's stewardship of the contract's governance and upgrade policy, not merely general trust in clinicians.

Hypothesis 3: Greater trust in PCP's stewardship and vetting of smart contracts is associated with a higher intention to use.

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Perceived Risks

Perceived risk refers to patients' beliefs about the potential negative outcomes of using smart contracts, such as financial loss, data breaches, or misuse of personal information. High perceived risk can deter patients from adopting smart contracts, which makes it critical to address and mitigate these concerns. Addressing perceived risks and security concerns related to data access and sharing through robust security measures and clear communication can enhance patient acceptance. It is essential to ensure that data access and sharing are strictly controlled and that patients are informed about how their data are used and protected. Among the key barriers to blockchain-based data management systems, perceived risk was identified as a major challenge [70]. This indicates that higher perceived risk is associated with lower intention to use technologies, such as smart contracts, in health care. A similar study on the impact of trust and privacy concerns on technology acceptance in health care found that perceived privacy risk directly predicted patients' intention to accept technology in health care services [68].

Perceived risk has been negatively related to the social acceptance of smart health services [71]. Trust in city government and perceived benefits were found to be positively related to social acceptance, while perceived risks and concerns about interventions were negatively related. This suggests that a perception of risk can significantly lower the intention to use smart contracts in health care. Another study that proposed a smart contract–based access control framework for securing electronic medical records emphasized that perceived risks related to data security and privacy were critical factors that affected patient acceptance [69]. Perceived risks related to the reliability, traceability, and security of patient control over medical data also negatively affected patient acceptance [72]. A study exploring how technical, legal, and social factors affected patient privacy evaluations and their acceptance of smart contract applications in health care found that higher perceived risks were associated with lower intention to use smart contracts [51].

Smart contracts are software programs and thus are susceptible to software bugs and cybersecurity risks. Correctness of these programs is fundamentally a software engineering challenge, not just a blockchain issue. High-profile incidents such as the DAO were precipitated by subtle coding flaws; beyond testing, emerging best practices call for formal, machine-readable specifications of required behavior (pre and post conditions, invariants, and temporal properties) and mathematical verification that the code satisfies these properties before deployment [73]. These early technology vulnerabilities shape patients' security risk perceptions regarding the use of smart contracts in primary care.

Smart contracts introduce irreversibility at the transaction level and shared execution across organizations. In a primary care episode such as a referral, risks include incorrect automated denial or approval, misrouted data, or inability to quickly halt a faulty rule. Patients may specifically worry about key loss or administrator misuse. In our context, perceived risk, therefore, refers to these blockchain-specific risks. Because prior studies consistently suggested that perceived risks related to privacy, security, and data management influence patient acceptance and lower their intention to use smart contracts in health care, we hypothesized the following.

Hypothesis 4: Higher perceived risk from decentralized execution, transaction irreversibility, and governance mismanagement is associated with lower intention to use smart contracts in primary care.

Health Care Delivery Type

Patients embedded in traditional primary care practices differ from their typically younger telehealth counterparts in terms of their trust in traditional health care settings and familiarity with conventional care models, which can lead them to perceive higher risks associated with adopting new technologies such as smart contracts [68]. Patients aged 65 years and older have been found to be less likely than patients aged 18-44 years to choose telehealth [74]. Because older patients prefer traditional approaches to primary care more than their younger counterparts, the delivery mode of health care services becomes crucial to patient acceptance of new technologies in health care. Technology-related anxiety and perceived cost have been found to have a negative impact on older users' behavioral intention to use smart home health care services [75]. Patients in traditional primary care practices are more familiar with conventional care models and may perceive smart contracts as a disruptive technology. This familiarity with traditional care can result in a lower intention to use smart contracts because patients may prefer the known and trusted methods of care delivery [71].

Telehealth patients, on the other hand, are more accustomed to using digital platforms for their health care needs. Telehealth use in primary care practices is associated with lower rates of low-value care services, which suggests that telehealth patients are more open to adopting new technologies that improve care efficiency, such as various digital tools for diagnosis, treatment planning, patient monitoring, and follow-up care [76]. This adaptability and openness to digital health solutions can lead to a higher intention to use smart contracts among telehealth patients compared with traditional patients. Moreover, their prior exposure to digital health technologies can make telehealth patients more comfortable with and accepting of smart contracts, thereby leading to a higher intention to use them compared with patients in traditional primary care settings.

In conclusion, traditional primary care patients are associated with a lower intention to use smart contracts in health care due to their perception of the risks involved in new technologies, their trust in traditional health care settings, and their familiarity with conventional care workflows where face-to-face registration, referrals, and billing are currently manual. In contrast, telehealth patients show a higher intention to use smart contracts. An understanding of these dynamics led to our next hypothesis.

Hypothesis 5: Patients embedded in traditional primary care practices, compared with telehealth-accustomed patients, are associated with a lower intention to use smart contracts that automate primary care workflows.

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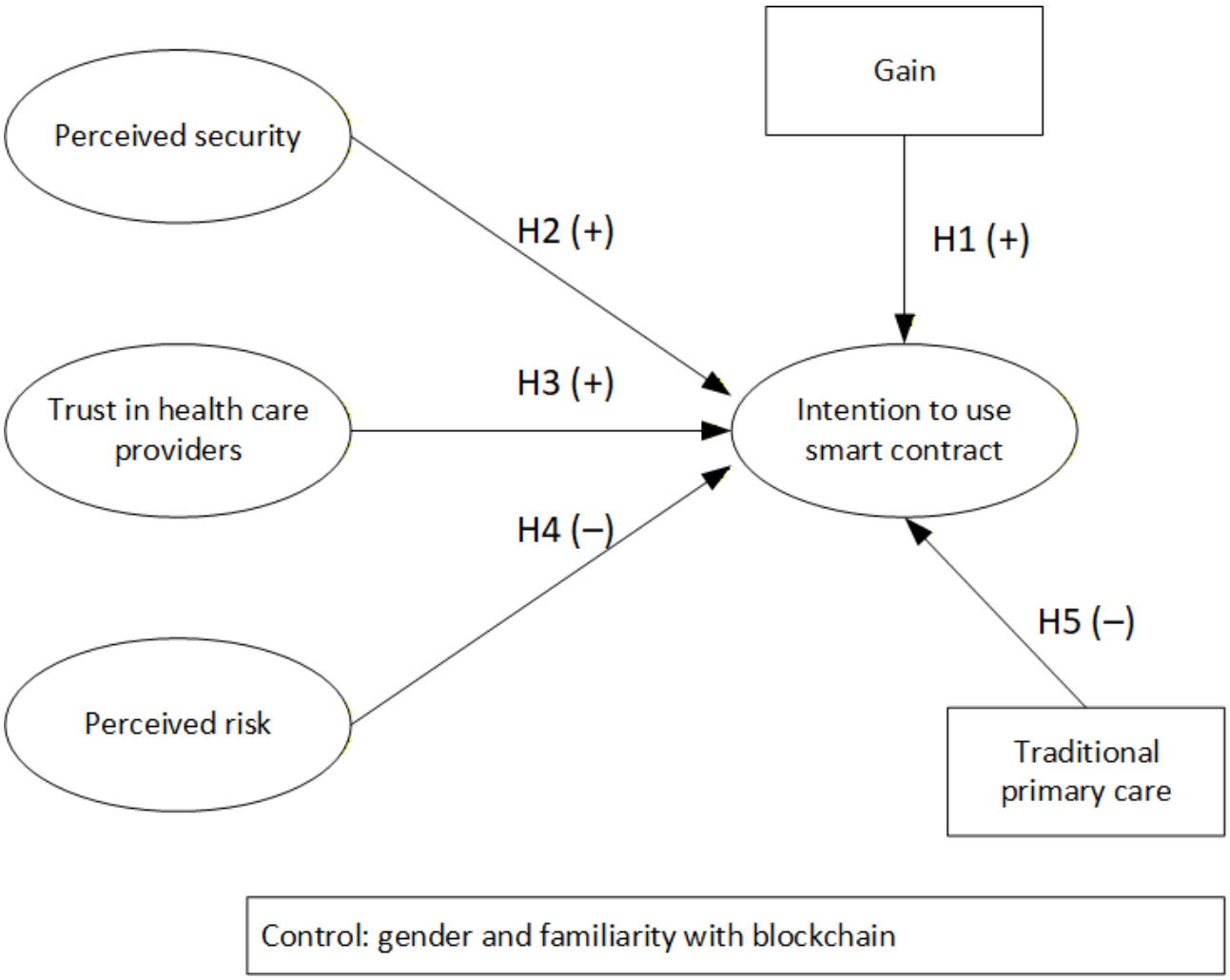
Figure 1 shows the conceptual model, which incorporates all 5 hypotheses.

Figure 1. Conceptual model.



Methods

Data Collection and Summary

The total number of respondents, including complete and incomplete responses, was 443. Figure 2 summarizes the data collection and cleaning process. Of the 443 responses, 270 were collected via Amazon MTurk and 173 were collected via the traditional clinic. The number of gain- vs loss-framed assignments was balanced at 222 and 221, respectively, due to random assignments at 50%. However, 56 respondents had incomplete responses, which resulted in the removal of these records from the final study analysis. Of the 56 invalid responses, 6 were from MTurk and 49 were from traditional clinic respondents. The traditional clinic has 30 patient visits flow per day. We ran the study for 2 weeks, which resulted in collecting data from 173 patients (124 valid responses) out of approximately 300 patients.

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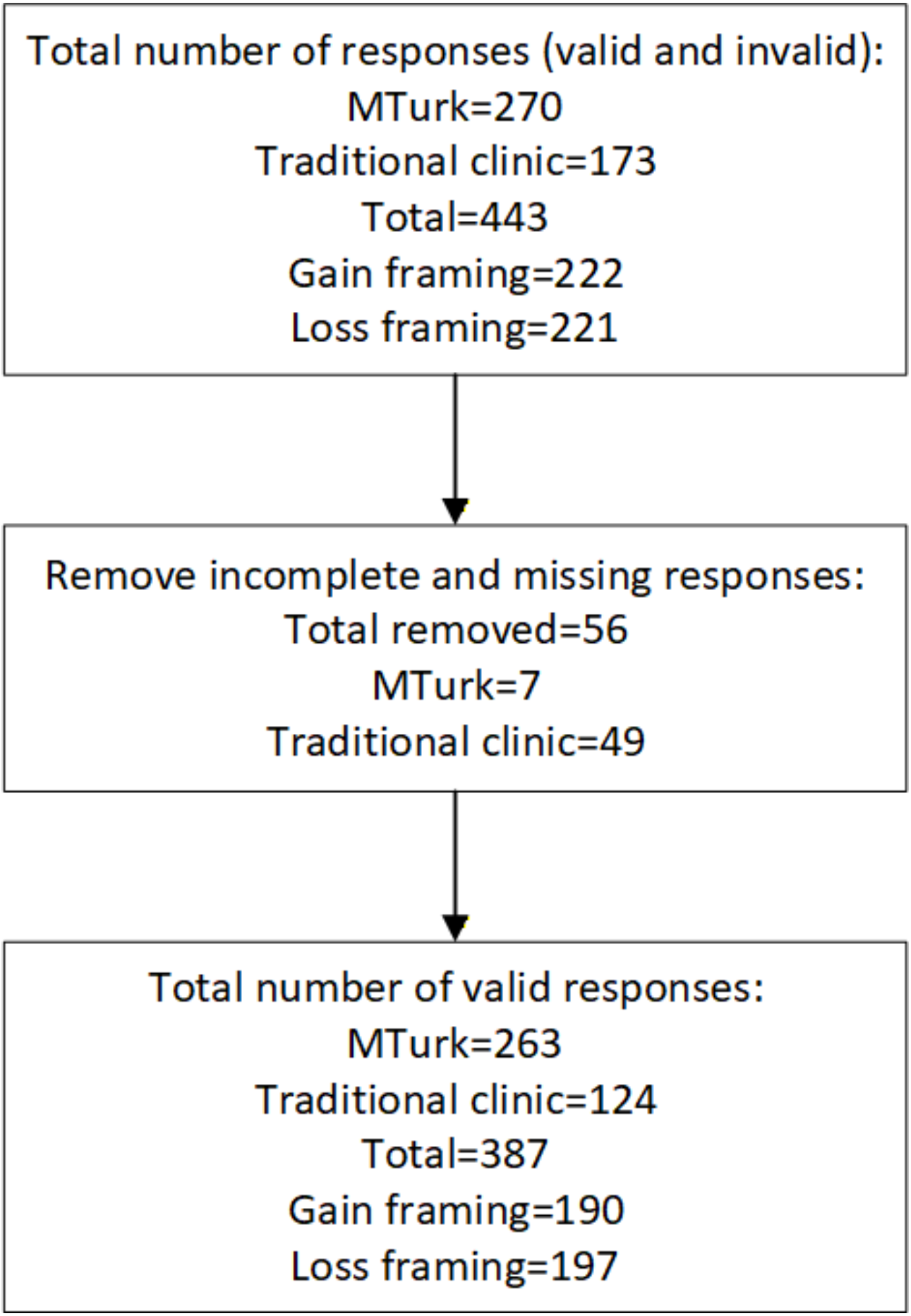
Figure 2. Data collection and cleaning process.



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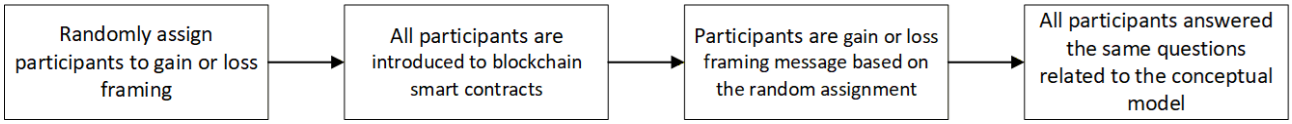
A total of 387 valid and complete responses were used in the study analysis from participants recruited through both channels, MTurk and the traditional clinic. A total of 124 responses were from the traditional patients, and 263 responses were from MTurk participants. The clinic patients represented patients embedded within traditional primary care practice as discussed in hypothesis 5. Of the 387 participants, 194 were female and 193 were male. Participants were randomly assigned to 1 of 2 scenarios (gain framed and loss framed) in which they were introduced to blockchain smart contracts and how they can be used in health care. The first paragraph of the gain-loss-framed message, which introduced a simplified explanation of blockchain and smart contracts, was identical for both groups. The second paragraph explained how smart contracts could be used in health care. Both scenarios had the same information and length of paragraphs. However, the gain-framed group read a paragraph with a positive sentiment, while the loss-framed group read a paragraph with a negative sentiment. Figure 3 shows the study design. Of the 387 completed responses, 197 participants were randomly assigned to the loss-framed condition and 190 participants were assigned to the gain-framed condition. Textbox 1 shows the paragraphs that were presented to the participants.

Figure 3. Study design.



Textbox 1. Blockchain and smart contracts farming.

Read the following text carefully before starting the survey.

What is a blockchain smart contract, and how can it be used in health care?

- A database is a tool for collecting and organizing information. Databases are used in your health care provider's office to collect, track, and store information on your personal information, insurance, diagnosis, treatment, prescription drugs, laboratory tests, and hospitalization. Blockchain technology is an advanced database that allows transparent information sharing within a business network. Smart contracts are programs stored on a blockchain that run when predetermined conditions are met. They are typically used to automate an agreement without a third party so that all participants can immediately get an outcome.

Gain

- In health care, smart contracts can be used in several ways: faster, more convenient check-in and check-out at the doctor's office, urgent care, or in the emergency room. With the smart contract, providing your medical history is much easier and less repetitive. The smart contracts allow participating doctors convenient, easy, and immediate access to your health information. Smart contracts can enable faster care decisions, thus providing greater opportunities for care coordination. For example, patients could get instant approvals for MRIs, medication, and medical procedures when necessary. Your health care provider could get paid immediately after your medical visit. That data on the smart contracts cannot be deleted or edited; corrections require adding data without deleting the old record. Smart contracts allow for efficient tracking of errors and, therefore, improve accountability.

Loss

- In health care, when smart contracts are not in use, checking in and out of the doctor's office, urgent care, or the emergency room takes a very long time. Unfortunately, you waste time repeating your medical and family history without smart contracts. Without smart contracts, your doctors have limited access to your health information, so decision-making is slower, and it limits their ability to provide improved care coordination. For example, approvals for MRIs, medication, and medical procedures could take several days or weeks. Your health care provider will wait 30-60 days to be paid for your medical visit. Without smart contracts, the data in your electronic medical record can be deleted or edited, without your knowledge, and you have no way of tracking errors or holding responsible parties accountable.

All questions in the survey were the same for all participants. After reading the introductory text (provided in Textbox 1), the participants answered questions related to their intention to use smart contracts in health care, as well as perception-based questions related to risk, security, and trust in health care providers. The table in Multimedia Appendix 1 shows the latent variable questions in the conceptual model. All latent variables used a 5-point Likert scale (strongly disagree to strongly agree). Each latent variable had 3 items. Participants were also asked to provide their gender, year of birth, race, number of health conditions, and type of insurance.

Statistical Analysis

We used IBM SPSS Statistics to manage and clean the data and IBM SPSS Amos (version 29) for the confirmatory factor analysis to assess the measurement model and structural equation modeling (SEM) to test the conceptual model. The 5 hypotheses included in the conceptual model were as follows: gain-loss-framed messaging positively impacts the intention to use smart contracts, the perceived security of smart contracts and trust in physicians are associated with a higher intention to use smart contracts, perceived risk is associated with a lower intention to use smart contracts, and patients in traditional health care settings are associated with lower behavioral intention to use smart contracts compared with their telehealth counterparts.

Ethical Considerations

We first applied to the institutional review board for approval to collect data. The inclusion criteria included participants of all genders aged 18 years and older. Individuals who were

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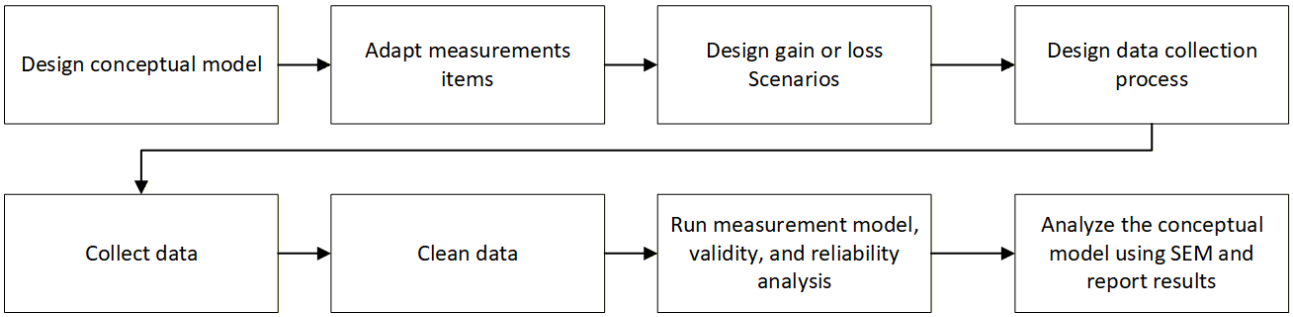
unable to read or comprehend English were excluded from the study. The application included a proposal to collect data through 2 channels: Amazon Mechanical Turk (MTurk) and a primary care clinic in upstate New York. Participants in the traditional primary care setting were recruited during the registration process when they arrived for an appointment. We received exempt approval for the study (reference no 23‐328). Participants from both channels were informed that the survey was voluntary and anonymous, and that they could stop the survey at any time. A modest compensation was given to the participants. Figure 4 shows the study procedure.

Figure 4. Study procedure. SEM: structural equation modeling.



Results

Measurement Model Assessment

Table 1 shows the confirmatory factor analysis results of the measurement model. All factor loadings for the individual items were high and significant. The factor loadings ranged from 0.814 to 0.895. The model fit indices were in line with a good model fit. For example, both the comparative fit index and the Tucker-Lewis index were well above the cutoff for a good fit criterion [77] at 0.975 and 0.965, respectively.

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Table . Measurement model.

Latent variable and item	Loadings	AVE[a]	Construct reliability	Variable inflation factor (VIF)
Intention to use (INT) smart contracts (dependent variable)		0.74	0.895	—[b]
INT_1	0.891			
INT_2	0.814			
INT_3	0.873			
Perceived security (PS)		0.765	0.907	2.728
PS_1	0.895			
PS_2	0.839			
PS_3	0.889			
Trust in health care providers (TRP)		0.728	0.889	2.561
TRP_1	0.869			
TRP_2	0.822			
TRP_3	0.868			
Perceived risk (PR)		0.713	0.882	1.316
PR_1	0.863			
PR_2	0.818			
PR_3	0.852			
Model fit				
Comparative fit index (CFI)	0.975	—	—	—
Tucker-Lewis index (TLI)	0.965	—	—	—
Root mean square error of approximation (RMSEA)	0.07	—	—	—

[a]AVE: average variance extracted.

[b]Not applicable.

Reliability and Validity

As shown in Table 1, the construct reliability showed strong reliability for all latent variables, with scores ranging from 0.882 to 0.907. The constructs also met the validity criteria, which were assessed using average variance extracted (AVE). The AVE scores for all latent variables were well above the 0.5 cutoff, with the lowest score being 0.713. In addition, the AVE scores exceeded the squared multiple correlation scores with other variables. Finally, the variance inflation factor scores for all independent latent variables were well below the cutoff of 5, indicating that the model did not suffer from multicollinearity.

SEM Results

The conceptual model was tested using SEM. The model fit indices for the conceptual model were as follows: comparative fit index=0.933, Tucker-Lewis index=0.918, and root mean square error of approximation=0.085. The root mean square error of approximation of 0.085 is slightly above ideal cutoff but still within the acceptable range of 0.08 and 0.1 [78]. In addition, the SEM results of the conceptualized model are shown in Table 2. Paths in the SEM represent associations among latent variables in cross-sectional survey data, and we refrain from making causal claims. Any directional language in figures follows conceptual ordering, not identification of causal effects. All of our hypotheses were supported except for the gain-loss effect. The results showed that message framing had no significant influence on the participants' intentions to use smart contracts, at least in this context. In other words, gain- or loss-framed messages did not seem to influence individual intentions to use smart contracts. This finding was contrary to the hypothesis developed in the theoretical background. In the "Discussion" section, we attempt to explain why this result was observed.

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Table . The conceptual model results.

Variable	Standardized estimate	*P* value
Perceived security	0.50	<.001
Trust in health care providers	0.43	<.001
Perceived risk	−0.07	.048
Gain scenario	0.01	.85
Male	−0.07	.02
Clinic	−0.14	.001
Familiarity with blockchain	−0.08	.07

Hypothesis 2 proposed that perceived security is associated with a higher intention to use smart contracts. As discussed in the background section, increased security is one of the characteristics and advantages of blockchain networks. This hypothesis was supported by the results, as shown in Table 2. The perceived security estimate was positive and significant, with an estimate of 0.504 and a *P* value of <.001. In fact, the perceived security standardized estimate of 0.504 was the highest among all of the influencing variables in the model. Therefore, perceived security seems to have the largest influence on the intention to use smart contracts. This result has implications for health care providers to emphasize the security benefits of blockchain and smart contracts to increase patients' adoption. It is important to note that the sample represents a single traditional clinic and online participants.

Hypothesis 3 stated that trust in providers is associated with a higher intention to use smart contracts. The results showed that this relationship was positive (0.433) and significant (*P*<.001), thereby providing support for this hypothesis. Thus, individuals reporting greater trust in their PCP reported higher intentions to adopt smart contracts. This is a significant finding because the COVID-19 era revealed a lack of trust between individuals and the health care industry. It is important to work on building stronger trust between providers and patients because trust has been shown to have a direct influence on individuals' decisions to adopt instructions, technologies, or medications provided by health care providers.

Hypothesis 4 emphasized that perceived risk is associated with a lower intention to use smart contracts. The hypothesis was supported with a significant negative estimate of −0.071. However, while the influence was significant, its magnitude was much smaller than perceived security and trust in health care providers. Therefore, health care providers should surface concrete assurances, such as visible audit trails for cross-party actions and clear, governed pause or upgrade controls, while building trust, thereby reducing the negative impact of perceived risk.

The final hypothesis examined whether patients in traditional primary care settings would be associated with a lower intention to use smart contracts. The results supported this hypothesis. In addition, an interesting result from one of the control variables was that male participants, compared with female participants, were associated with a lower intention to use smart contracts.

Discussion

Principal Findings

The findings of this study indicate that the disruptive technology of blockchain smart contracts can be successfully implemented in primary care. The results aligned with the hypotheses, which predicted that patients' behavioral intentions to use smart contracts in health care would be influenced by their trust in their health care providers and their perceptions of the security and risks involved in smart contracts [73,79]. The study extends previous research on technology acceptance in health care by specifically focusing on the implementation of smart contracts in primary care, thereby making it one of the first papers to address this topic.

The 2 scenarios presented in this study emphasized both the benefits of using smart contracts and the costs of not using them. Interestingly, neither framing significantly influenced participants' intentions to use smart contracts. This finding contrasts with the general effectiveness of message framing in health care when patients are uncertain about the impact of a situation [80]. Patients' increasing familiarity with disruptive technologies, such as artificial intelligence [81,82] and mobile apps [83], could have resulted in the lack of a framing effect. That is, their interaction with other disruptive technologies could have mitigated their uncertainty about smart contracts. Future research can examine this finding to understand how familiarity with disruptive technology shapes patient attitudes toward technology adoption. Our vignettes described generic efficiency gains and delays and had low stimulus specificity. This may have encouraged respondents to answer as if they were responding to digital modernization in general, thereby diluting classic gain-loss effects. Additionally, in our SEM, the standardized paths for perceived security (β=.50) and trust in providers (β=.43) dominate the framing path, plausibly swamping small framing effects. Moreover, framing effects in health decisions frequently depend on moderators such as familiarity, involvement, risk attitude, and numeracy. Blockchain familiarity and care setting, as reflected in our study design, may have been insufficient to surface framing effects. As health care providers consider implementation strategies, they should focus on educating patients about the advantages of smart contracts for care delivery rather than relying solely on message framing to increase adoption.

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Consistent with our findings, perceived security is a salient antecedent of intention, especially given recent data breaches and ransomware attacks that have resulted in the loss of millions of patients' protected health information to bad actors. Effective designs should communicate how safety is achieved (eg, auditable histories and governed responsiveness) rather than restating generic benefits. As blockchain technology gains mainstream attention in the investment markets through applications such as Bitcoin, health care providers should capitalize on this awareness to demonstrate how smart contracts can protect patient data and improve health care processes.

Smart contracts are executed on decentralized platforms hosted by unknown third parties. In many industries, this feature is seen as valuable; however, it could be seen as a barrier to adoption in health care. Patient data contains highly sensitive information, and if patients perceive that their data may be intentionally divulged or compromised by unknown third parties, their intention to use smart contracts may be impacted. As hypothesized, this study found that having a primary care physician as an intermediary in this "trust-less" [84] security apparatus can improve the likelihood of smart contract use. This finding is supported by previous research showing that patients' behavioral intentions to use mobile technology are impacted by their trust in their physicians [66]. Health care professionals should capitalize on the patient-physician relationship to promote the adoption of smart contracts in primary care by carefully highlighting the physician's role in overseeing and supporting the implementation process. Specifically, trust in the provider may serve as a bridge facilitating smart contract adoption. In the future, primary care physicians could monetize this intermediary role to supplement their practice income. For example, physicians could be compensated on a per member per month basis, similar to value-based contracts, for each patient who opts to use the smart contract.

Risk is often a significantly restraining construct for technology adoption [85]. Notably, older adults generally perceive a higher level of risk when adopting technology in health care [86]. In alignment with prior studies, participants in this study were also influenced by their perception of risk. Interestingly, although risk had a negative impact on patients' intention to use smart contracts, the magnitude was small. This result could be attributed to smart contract technology being implemented in a familiar environment and endorsed by a trusted physician. When implementing smart contracts in traditional or nontraditional primary care settings, providers should leverage the patient-physician relationship to help mitigate perceived risks. Another factor impacting the magnitude of the risk effect may be patients' perception of the security of smart contracts. While potential risks are high, security could be seen as a factor that mitigates risk. The lower magnitude of risk should not be considered negative; rather, it should be used to guide implementation strategies. For example, known risks can be discussed with patients during routine visits to help reduce their impact.

Compared with online participants, the individuals in a primary care office were generally older and had multiple chronic comorbidities; they were also less likely to intend to use smart contracts than the online participants. Additionally, an interesting finding from the control variables revealed that males were associated with a lower intention to use smart contracts compared with females. Prior research found comparable results and showed that gender, age, and complex health conditions negatively impacted technology adoption [87-89]. Health care providers and technology developers should customize implementation strategies to consider patient demographics and provide support and education for older patients, especially those with complex health conditions.

Smart contracts have improved workflows and patient outcomes in secondary and tertiary care. This study can help health care professionals and technology developers understand the factors that affect adoption in the primary care setting. The successful implementation of this disruptive technology depends on an in-depth understanding of patients' trust in physicians, their perceptions of the security and risks involved in smart contracts, and patient characteristics, so that health care providers can design adoption initiatives. This study's findings contribute to the extant literature on blockchain applications in health care and offer practical guidance for primary care providers looking to leverage smart contracts to improve patient outcomes and streamline health care processes.

Because smart contracts encode business, and at times legal logic across organizations, expressing the intended behavior as formal, machine-readable specifications enables mechanized checks that critical properties hold (eg, no payment without a valid referral and authorization; emergency pause overrides cannot be bypassed). Techniques such as model checking, theorem proving, symbolic execution, and property-based testing can then mathematically verify that implementations meet these specifications before deployment. This is especially salient in health care, where errors can carry serious consequences. Our results highlight perceived security as a key antecedent; communicating that primary care contracts are formally specified and verified provides a concrete assurance basis beyond narrative claims of "security," and aligns assurance evidence with patient expectations.

Conclusions

Our study addresses a clear gap in the healthcare blockchain literature by examining patient intentions to use smart-contract workflows in primary care, where day-to-day activities like referrals, prior authorization, and co-payment settlement require multi-party coordination and credible assurance mechanisms. Using a cross-sectional SEM, we find that perceived security and trust in provider stewardship are positively associated with intention to use, while perceived risk shows a negative but comparatively small association. In contrast, our message-framing manipulation (gain vs. loss) was not associated with patient intentions to use.

Altogether, our results suggest that adoption in primary care hinges less on promotional framing and more on visible assurances and governance. Effective designs should show how safety is achieved, through tamper-evident, cross-party audit trails and governed responsiveness, rather than re-stating generic benefits. Trust in the primary care physician appears to function as a bridge for adoption in a "trust-minimized" infrastructure. The clinician acts as a steward of governance and change

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management can strengthen patients' willingness to engage with smart-contract-mediated processes. We also observe an important heterogeneity. In-clinic participants, older patients with more comorbidities, reported lower intentions than online participants. Additionally, men reported lower intentions than women, underscoring the need to tailor outreach and support for specific demographic groups. Beyond user-facing communication, the findings highlight that perceived security can be bolstered by engineering evidence, not messaging alone. Introducing and communicating formal, machine-readable specifications of contract behavior paired with verification can provide mechanical assurance that critical properties hold before deployment. In primary care, succinct assurance disclosures may credibly raise perceived security and, in turn, intention to use.

In summary, this study advances understanding of patient acceptance of smart contracts in primary care and offers practical guidance. These include providing concrete assurances, leveraging provider stewardship, addressing risk through dialogue and design, and backing claims with verification evidence. Aligning these elements can help primary care organizations realize the benefits of programmable, auditable, and governable coordination while maintaining patient trust.

Limitations and Future Work

While this study provides valuable insights into patient perspectives on the use of smart contracts in primary health care, there are limitations that need to be acknowledged to contextualize the findings and guide future research. First, we were limited by our dataset because self-reported surveys tend to be susceptible to biases, such as social desirability or recall errors. Because the design is cross-sectional and relies on intentions, endogeneity cannot be ruled out, and findings have been interpreted as conditional associations. Although efforts were made to explain the concept clearly, varying levels of digital literacy among respondents could have influenced their responses. In addition, the collection of actual behavioral data is very challenging because the implementation of smart contracts in health care is in its infancy stages. Another limitation is that the data were collected from one primary care provider in upstate New York. Future research could benefit from soliciting responses from patients in various locations and states. In addition, the ratio between MTurk and clinic patients was skewed toward MTurk participants, with 263 out of the 387 participants. This might weaken the external validity of the study. As mentioned in the data collection section, data collection from patients in actual clinics was very challenging. Most of the invalid and incomplete responses were from participants at the clinic.

While most of the hypothesized relationships were supported, including the strong positive effects of perceived security and trust in health care providers, the gain-loss framing effect was not supported. This may suggest that patients do not yet have sufficient context or familiarity with smart contracts to meaningfully differentiate outcomes framed as gains vs losses. Future research needs to consider alternative framing strategies or deeper educational interventions before measurement.

Although the subgroup differences in the acceptance of smart contracts were significant, the cross-sectional design limited causal interpretations. Longitudinal studies could help determine whether these differences persist over time or shift with greater exposure to smart contract technologies. While diverse in terms of certain demographic and usage profiles, the current sample may not fully represent populations with limited access to digital health care, older adults, or individuals with low health literacy. Future studies need to use mixed method approaches, expand sampling across health care settings and patient types, and incorporate behavioral data from actual smart contract usage to enhance the validity and applicability of the findings.

It would be worthwhile to design studies in which the scenarios differ in the type of information they emphasize regarding the benefits of blockchain and smart contracts. For instance, one scenario could highlight accountability, another could focus on security, and another on transparency. This approach would allow us to examine which aspects of blockchain and smart contracts are most influential from the patients' perspective. Future work should also test whether assurance disclosures increase perceived security and intention compared with generic security claims and should report verification artifacts alongside clinical outcomes in field deployments.

Future studies could examine how perceptions of different security dimensions (eg, ledger robustness, smart contract code safety, and data governance) influence the adoption of smart contracts. In addition, future studies should incorporate measures of digital literacy and health literacy to better understand how varying literacy levels influence perceptions of blockchain smart contracts.

Future research could also explore several critical areas to advance the practical and systemic application of smart contracts in the health care domain. One such research direction involves evaluating the real-world implementation of smart contracts from patients' perspectives. While this study focused on perceived acceptance, future longitudinal studies could assess patient satisfaction, trust, usability, and health outcomes in settings where smart contracts are actively used for managing appointments, consent, and billing workflows.

Blockchain technologies automate and streamline administrative workflows, thereby potentially reducing burnout. Therefore, another vital research path involves understanding how provider perceptions evolve with the actual use or mandated adoption of smart contracts. Future studies could investigate changes in trust, workload, documentation efficiency, and administrative burden among clinicians and health care staff. Smart contracts can also automate repetitive tasks for physicians, such as managing referral chains, authorization checks, and follow-up reminders. Future work could prototype and evaluate smart contract–based systems that integrate with EHR platforms to automate these functions and analyze their impacts on provider time management and care coordination.

A transformative area of inquiry is how smart contracts might reshape payment models in primary care. Specifically, the shift toward value-based payment models, such as the patient-centered medical home program, could benefit from smart contracts that automatically validate and trigger payments

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upon meeting predefined quality metrics. Research could explore frameworks for encoding such contracts and pilot studies to measure financial and clinical outcomes.

Smart contracts also have the potential to transform claims processing in health insurance by enforcing logic-based rules that match submission formats, such as the 5010 standard for HIPAA-compliant transactions. Research could prototype and evaluate such systems within primary health care networks and determine their interoperability with clearinghouses and insurers. Furthermore, smart contracts can help address semantic and data consistency issues in Fast Healthcare Interoperability Resources (FHIR) and EHR integration by ensuring consensus-driven logic for health data exchange. Investigating how FHIR-compatible smart contract programs could reduce discrepancies and improve clinical data quality will be essential.

Policymakers also have a pivotal role to play. Future studies should analyze how federal and state policy frameworks can be adapted or developed to ensure cybersecurity, patient data privacy, and the ethical deployment of smart contracts in the Medicare and Medicaid programs. These studies should also explore the patient-centric payment models and reimbursement logic encoded in smart contracts that promote transparency and equity. Future research should also examine how smart contracts can support the population's health and public health initiatives, such as vaccination tracking, chronic disease management, and outbreak reporting. These programs often suffer from data silos and inefficiencies, which blockchain-based automation could alleviate. A sociotechnical analysis of deploying such solutions at scale, especially in underresourced or rural settings, would contribute significantly to both the blockchain and public health literature.

We believe future research can bridge the gap between the conceptual promise and the technical, organizational, and regulatory realities of smart contract use in primary health care. By taking a multidisciplinary approach, future work can support the development of secure, efficient, and patient-centered digital health ecosystems.

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Conflicts of Interest

None declared.

Multimedia Appendix 1
Measurement items.
[DOCX File, 20 KB - formative_v10i1e82237_app1.docx]

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Abbreviations

AVE: average variance extracted
DAO: decentralized autonomous organization
EHR: electronic health record
FHIR: Fast Healthcare Interoperability Resources
HIPAA: Health Insurance Portability and Accountability Act
MTurk: Amazon Mechanical Turk
PCP: primary care physician
QoS: quality of service
SEM: structural equation modeling

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Empowering Informal Caregivers of Persons With Early-Stage Dementia by Large Language Models: Mixed Methods Evaluation

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Abstract

Background: Acquiring relevant knowledge and support is essential for informal caregivers of persons with early-stage dementia, including awareness, access, and use of comprehensive resources for both persons with dementia and caregiver support. With appropriate strategies and early-stage support, informal caregivers can play a vital role in enhancing the well-being of persons with dementia and potentially slowing their progression. While large language models (LLMs) can provide easy access to caregiving knowledge, the risks, perceived challenges, and ways to improve LLM-generated responses in practice remain underexplored.

Objective: In this study, we aim to (1) examine the risks and perceived challenges of using a baseline ChatGPT-4o, an internet-accessible artificial intelligence model, for dementia caregiving support and (2) understand how an enhanced version of ChatGPT-4o, equipped with up-to-date dementia caregiving knowledge, can mitigate these risks and challenges.

Methods: We compiled 32 representative questions from informal caregivers seeking guidance on early-stage dementia. We developed two ChatGPT-4o conditions: C1, the publicly available baseline model, and C2, an experimental version enhanced through prompt engineering and grounded in a conceptual framework—drawn from health science and gerontology literature—to empower caregivers of individuals with early-stage dementia. Using these conditions, we generated 64 responses (32 pairs) to the questions. Twelve experts evaluated them with validated tools assessing accuracy, reasoning, clarity, usefulness, trust, satisfaction, safety, harm, and relevance. A Mann-Whitney *U* test compared the conditions. After the survey, we conducted interviews to explore experts' perceived differences, remaining challenges, and design opportunities. Interviews were transcribed and analyzed using descriptive thematic analysis.

Results: Responses in C2 showed significant improvements in 3 criteria—actionability, relevance, and perceived satisfaction—compared to C1. However, no significant differences were found in the remaining 5 criteria: response accuracy, the model's ability to understand the question, intelligibility, trustworthiness, response safety, and perceived harm. Qualitative analysis of interviews revealed two key insights: (1) differences between baseline and experimental responses and (2) possible reasons for these differences. Twelve experts evaluated wordiness, detail, empathy, satisfaction, accuracy, relevance, and bias. Both models were considered somewhat verbose, but the experimental model's responses were viewed as more detailed, relevant, and actionable. Accuracy appeared similar across models, yet participants reported greater satisfaction with the experimental model's outputs.

Conclusions: Results indicate that both conditions generated responses perceived as reasonable and intelligible. However, the experimental model offered more relevant, practical guidance on caregiving needs, providing specific information aligned with the 32 testing questions and actionable recommendations. This led to higher perceived satisfaction compared to the baseline model.

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KEYWORDS

large language model; human-computer interaction; human-AI collaboration; early-stage dementia; informal caregivers; prompt engineering

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Introduction

Informal caregivers' dementia literacy plays a critical role in mitigating the progression of dementia; however, obtaining relevant knowledge and effectively applying it in real-life situations can be difficult. These challenges are further compounded by limited access to information and resources related to caregiving. The aging population is increasing rapidly; in 2024, about 6.9 million Americans aged 65 and older are living with Alzheimer's or dementia, a number expected to double by 2060 [1]. Dementia is a leading contributor to older mortality, with one in three individuals over age 85 dying with the disease [2,3]. Informal caregivers, who support persons with dementia, typically family members, face barriers such as limited English proficiency [4], inadequate health insurance [5], low income [6], and social stigma [7], which hinder access to essential dementia knowledge and effective care strategies [8].

The lack of accessible, accurate, and personalized knowledge contributes to both ineffective care and substantial socioeconomic burdens [9,10]. In 2019, the worldwide cost of dementia care was US $1.3 trillion [11], including medical expenses, social care, and informal caregiving, with US $196 billion spent on direct medical costs in the United States alone in 2020 [12]. Beyond finances, caregivers and persons with dementia experience declines in quality of life, as persons with dementia lose autonomy and dignity [13,14] and caregivers face heightened psychological and physical stress [15], yet few tools provide tailored guidance for informal caregivers, highlighting a critical gap in support.

Addressing informal caregivers' limited access can empower them to manage their responsibilities more effectively [16] and strengthen their emotional resilience [17] by recognizing early symptoms [18], managing initial behavioral changes effectively [8], and establishing consistent routines to reduce confusion and anxiety [19]. Additionally, informed informal caregivers can create a stable and safe environment that reduces stress and enhances emotional well-being while also engaging persons with dementia in cognitive and social activities that help maintain mental function, support independence, and foster a sense of purpose [20]. To further support informal caregivers, culturally tailored support can provide personalized guidance respecting caregivers' cultural and language needs [21-23], enhancing the accessibility and relevance of dementia care information.

Although large language models (LLMs) can be an effective technological aid for providing dementia-related knowledge [24,25], there have been concerns about applying these tools to informal caregivers. For instance, using LLMs often fails at providing valid information [26], relevant answers based on personalized context, nonactionable suggestions [27,28], answers that lack genuine contextual understanding and empathy [29], and answers with bias related to age, disability, and race, thereby contributing to disparities in care delivery [30]. While studies started applying ChatGPT in various health care applications, including patient interaction [31], clinical diagnosis support [32], telehealth services [33], health education [34], personalized health advice [35], and broader health promotion efforts [36], several limitations and risks must be addressed to ensure the safe and effective integration of LLMs into dementia caregiving. Finally, it is worth noting that the use of LLMs in caregiving raises privacy and data security concerns; without robust safeguards, sensitive information may be vulnerable to unauthorized access or misuse.

While prior research has extensively documented the burden of dementia and the challenges faced by informal caregivers, fewer studies have examined the potential of artificial intelligence (AI)–driven digital health tools to support caregiving. Recent work has begun to explore the application of LLMs in this domain. For example, Kim et al [27] analyzed digital caregiving strategies for Alzheimer disease and related dementias and highlighted how AI-driven tools can align caregiving tasks with disease stage–specific needs. Pérez-Esteve et al [37] demonstrated that GPT-4o models can provide tailored guidance and reduce caregiver errors, although they do not yet replace professional instruction. Similarly, Shi et al [38] developed Carey, a GPT-4o–based chatbot to provide informational and emotional support to Alzheimer disease and related dementias caregivers, identifying key caregiver needs to inform AI design. Hasan et al [39] introduced ADQueryAid, a conversational AI system leveraging LLMs with retrieval-augmented knowledge to deliver personalized support. Additionally, Chien et al [40] showed that LLMs could accurately identify high-burden caregivers in long-term care settings, highlighting their utility in caregiver assessment. Building on these developments, our study investigates how broadly accessible everyday LLMs can both challenge and benefit informal caregivers, aiming to improve their practical utility in real-world caregiving contexts.

In this study, we used ChatGPT, a publicly available LLM model that is considered the most advanced one at the time of the study, as our baseline condition (C1). In parallel, we designed an experimental condition (C2) using a prompt-engineered ChatGPT-4o model, enhanced through a conceptual framework shown in Figure 1, which is built upon our comprehensive review of literature in geriatrics and gerontology, with a specific focus on dementia caregiving.

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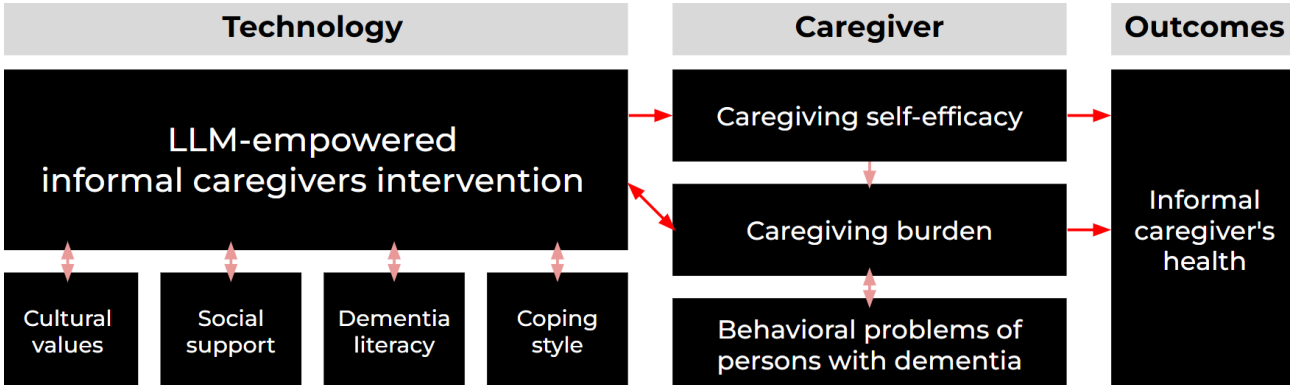
Figure 1. Conceptual framework integrating technology, caregiver factors, and outcomes in dementia caregiving. The framework integrates the sociocultural stress and coping model [41] and the self-efficacy model [42] for caregivers to illustrate the dynamic interactions among contextual, psychological, and technological factors. It comprises three main components: (1) technology, referring to LLM-empowered interventions that support informal caregivers; (2) caregiver, encompassing factors such as caregiving self-efficacy, caregiving burden, and behavioral challenges of persons with dementia; and (3) outcomes, focusing on the health and well-being of informal caregivers. LLM: large language model.



Our study uniquely explores how widely LLMs affect informal caregivers, highlighting both the challenges and opportunities they present for enhancing caregiving support in everyday, real-world contexts. Then, this study is guided by the following four research questions: (RQ1) What risks and challenges do informal caregivers encounter when using everyday LLMs (eg, ChatGPT-4o) for dementia care support? (RQ2) How can ChatGPT be enhanced through prompt engineering with dementia-related knowledge, caregiving skills, and culturally relevant supports? (RQ3) To what extent does the enhanced ChatGPT improve caregivers' experiences in terms of (1) actionability, (2) relevance, (3) perceived satisfaction, (4) response accuracy, (5) model's ability to understand the question, (6) intelligibility, (7) trustworthiness, and (8) response safety and perceived harm? (RQ4) What are the implications of these findings for the future design of AI tools tailored to caregiver–person with dementia dyads?

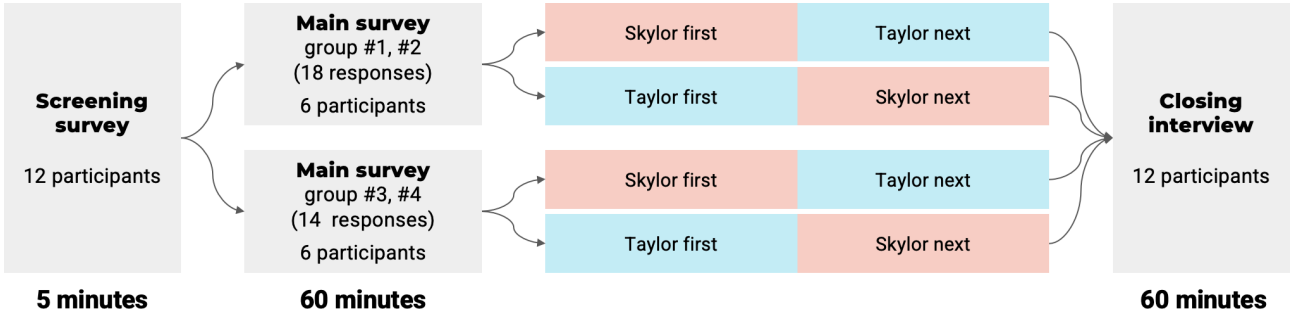
Methods

Study Design

A mixed methods study using surveys and interviews was conducted via Zoom to evaluate a prompt-engineered ChatGPT-4o compared to baseline ChatGPT-4o—an internet-accessible AI tool—based on the evaluation criteria listed above. The study aimed to assess its potential to support informal caregivers of persons with early-stage dementia.

Figure 2 shows a clear study flow diagram applied to summarize the proposed mixed methods. The overall study pipeline proceeded as follows. (1) Each participant first completed a brief 5-minute screening survey to collect professional background information. Participants who passed the screening were assigned a unique ID number used to record their results from both the quantitative (1 hour) and qualitative (1 hour) studies. (2) In the 1-hour quantitative study, participants 1 - 6 were divided into group 1 and group 2. Each group evaluated 18 testing scenarios containing 18 pairs of LLM-based responses while completing corresponding evaluation surveys. Similarly, participants 7 - 12 were divided into group 3 and group 4, and each group evaluated 14 testing scenarios with 14 pairs of LLM-based responses, also accompanied by quantitative evaluation surveys. (3) Finally, during the 1-hour qualitative study, all participants completed a semistructured interview consisting of general and specific questions. The corresponding study materials are covered in Multimedia Appendix 1.

Figure 2. Study flow diagram illustrating the mixed methods design. The study began with a 5-minute screening survey. Participants who met eligibility criteria were assigned a unique ID and participated in a 1-hour quantitative session. Participants in groups 1 and 2 (n=6) evaluated 18 pairs of test scenario–based LLM responses, while those in groups 3 and 4 (n=6) evaluated 14 pairs. Under each test scenario, two types of LLM responses were labeled "Skylor" and "Taylor." Finally, all participants completed a 1-hour semistructured qualitative interview. LLM: large language model.



Prompt Engineering Design

We used ChatGPT-4o (September 2024 till November 2024). To prepare C2, we compiled a dataset of 90 question-and-answer pairs to inform the prompt engineering of C1. These pairs were developed across 9 domains. Four of them are key domains identified in the conceptual framework: cultural values, social support, dementia literacy, and coping style. To create the question-and-answer pairs, we collaborated with community

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outreach lay health workers with over a decade of experience working with persons with dementia and their caregivers. Drawing on their expertise, these professionals generated questions commonly asked by informal caregivers of persons with early-stage dementia within each of the 4 domains. Subsequently, an experienced nurse practitioner with over a decade of clinical practice responded to the generated questions. The answers were grounded in evidence-based guidelines from credible organizations, including the Alzheimer's Association [43], the National Institutes of Health, the National Institute on Aging [44], the Retirement Research Foundation [45], and the Korean Medical Center [46]. Following the initial drafting, one of the authors (KMO) with expertise in nursing and gerontology reviewed the responses to ensure their accuracy, clarity, and relevance. This iterative process resulted in a finalized dataset of 90 question-and-answer pairs attached in Multimedia Appendix 2. Selected examples are provided in Table 1.

Table . Selected examples from the 90 question-and-answer pairs across 4 domains: cultural values, social support, coping style, and dementia literacy.

	Questions	Answers	Domains
Q1	I am Hispanic and my spouse was just diagnosed with Alzheimer's disease—how can I be sure I'm getting the care I need for my Hispanic spouse?	• The Alzheimer's Association has partnered with several agencies within different cultures to make sure care and help are provided appropriately. Your first resource would be to reach out to the National Hispanic Council on Aging and you can find them here: [47].	Cultural values
Q11	Are there places I can go to socialize? I feel so isolated since my spouse was diagnosed with Alzheimer's disease. I just need to meet some other people—I don't even have time to go meet my friends.	• Yes, there are places you can go and people you can talk to. You can start with the support groups online that you can find here: [48]. • You can find community resources close to you here: [49]. • You can also call the Alzheimer's Association's hotline and talk to an actual person that can help you 800.272.3900. Or you can click this link for resources specific to the National Capital Area (NCA) [50].	Social support
Q21	What is Alzheimer's disease? What do I tell my family?	• Alzheimer's disease is the most common form of dementia—more information here: [51]. • Regarding what to tell your family, remember Alzheimer disease is nobody's fault and there is help available. For help telling your family you can start here: [52].	Dementia literacy
Q31	My spouse is my best friend and the one I go to with everything, and now I feel like I can't because my spouse is what I'm worried about, my spouse is why I need coping help. I don't know what to do.	• It is hard when your person is the one you have concerns and worries about. There are resources available to help you. There are online support groups, local activities and support groups, and a helpline available 24/7. You can find the online support groups here: [48]. • You can find local activities and supports groups here: [49] and the helpline is 800.272.3900.	Coping style

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Prompt engineering is essential for adapting ChatGPT to specific contexts, such as supporting informal caregivers of individuals with early-stage dementia. Studies have shown that prompt design significantly influences the quality, relevance, and accuracy of AI-generated responses. For instance, Li et al [53] found that structured, role-specific prompts improved ChatGPT's performance in dementia care scenarios. Without such guidance, general-purpose models may produce vague or misleading information, particularly in sensitive health-related contexts. Parmanto et al [54] highlighted that unguided prompts often result in irrelevant or unreliable outputs. Prompt engineering helps mitigate these issues by narrowing the model's focus, reducing hallucinations, and encouraging context-specific, empathetic responses. A study by Cheng et al [55] further demonstrated that prompt-engineered AI can provide personalized, culturally sensitive support tailored to caregiver needs and the stages of dementia. Ultimately, prompt engineering enhances clarity, aligns output with user intent, and bridges the gap between general AI capabilities and the specialized demands of caregiving.

In our work, after collecting the 90 question-and-answer pairs, we proceeded to generate the corresponding 90 prompts for C2 by applying prompt engineering techniques to C1. The 90 prompts for C2 are provided in Multimedia Appendix 3. These examples show the details of how the prompts were generated with context-related information. In designing these prompts, we drew on principles of prompt engineering grounded in five fundamental factors [56]: (1) clarity and specificity—ensuring that prompts are unambiguous and clearly stated; (2) user intent—aligning the prompt with the user's needs and the desired output; (3) model understanding—considering the strengths and limitations of ChatGPT to craft prompts that maximize its capabilities while mitigating its weaknesses; (4) domain specificity—incorporating relevant terminology and context to guide the model toward more accurate and relevant responses; and (5) constraints—explicitly defining requirements such as response length or format.

Generating Responses From C1 and C2 for Evaluation

To select a natural and realistic set of questions that informal caregivers may ask frequently in practice, we collaborated with two experts: a community outreach lay health worker and an academic researcher, both with over a decade of experience working with persons with dementia and their caregivers. They were independent of the community caregiving lay health workers involved in the prompt engineering design, minimizing potential bias during the evaluation. They were asked to generate 32 test questions commonly posed by caregivers of persons with early-stage dementia across 4 domains: cultural values, social support, coping style, and dementia literacy. The dementia literacy domain includes 4 subcategories: causes and characteristics, health risks and promotion, communication and behavior, and care considerations. The 32 testing questions are provided in Multimedia Appendix 4.

Using the 32 questions, we generated 64 LLM responses: 32 from C1 and another 32 from C2. Specifically, for each question, we manually entered it into the LLM interface to initiate response generation. Once the LLM's textual output was displayed, we collected it directly as a single response. Each response was saved and assigned a unique identifier corresponding to its input question.

Participants

In January 2025, purposive sampling was used to recruit 12 participants through a screening survey assessing eligibility based on predefined inclusion and exclusion criteria. Eligible participants included informal caregivers of persons with dementia, as well as health care professionals or community outreach program leaders with at least 1 year of experience working with persons with dementia or their caregivers. Recruitment continued until qualitative data saturation was reached, that is, we intended to keep recruiting participants as long as each new case enhanced our understanding; recruitment would end once additional participants no longer offered new information. Moreover, Caine [57] conducted the analysis which revealed that 12 participants appeared most frequently among CHI papers—effectively becoming a de facto community norm for small-scale human-computer interaction (HCI) user studies. This was not presented as the optimal number, but rather as the most common practice (a cultural standard in CHI research). Furthermore, these participants are considered content experts and invited to evaluate LLM-generated responses using validated tools measuring accuracy, reasoning, clarity, usefulness, trust, satisfaction, safety, harm, and relevance.

Data Collection Procedures

From the 64 LLM responses generated by C1 and C2, content experts conducted evaluations using two methods: a quantitative survey and a qualitative follow-up semistructured interview conducted via Zoom. Each session lasted about 2 hours on average—1 hour for the survey and 1 hour for the follow-up interview. Participants received a US $50 Amazon gift card in appreciation of their time.

The 12 experts were divided into 4 groups of 3 to ensure deeper and more focused discussion, as reviewing all 32 questions together could limit individual focus and engagement. Of the 32 testing questions or scenarios, 6 are from the cultural values domain, 7 from social support, 5 from coping style, and 14 from dementia literacy. For the evaluation surveys, groups 1 and 2 assessed 18 scenarios drawn from the cultural values, social support, and coping style domains, while groups 3 and 4 evaluated the remaining 14 from the dementia literacy domain.

Selected examples are provided in Table 2.

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Table . Selected examples from the 32 test questions assigned to groups across 4 domains: cultural values, social support, coping style, and dementia literacy.

	Group ID	Test question example	Domains
Q5	G1&G2	I live in Virginia and am a caregiver for my family member with dementia. What local resources or organizations in Spanish can provide me with support, whether for caregiving or guidance on managing the situation?	Cultural values
Q10	G1&G2	As a caregiver in Virginia, I'm looking for local resources or organizations that can provide support for caregivers like me. What options are available to help me navigate this journey?	Social support
Q11	G1&G2	I'm looking to connect with other caregivers in my community for support. Are there any peer support groups or opportunities to meet others who are going through similar experiences? Can you suggest any online support groups or forums for caregivers?	Social support
Q14	G1&G2	I would like to connect with someone who is experiencing similar situations. I feel overwhelmed as I am responsible for taking care of both my children and my father at home. How can I ensure I take care of myself as well?	Coping style
Q2	G3&G4	My husband's behavior has been changing lately, and I'm not sure if it's just because he's getting older or if it could be something like dementia. He forgets things, gets confused, and sometimes doesn't act like himself. What are the early signs of dementia, and how can I tell if this is just aging or something more serious?	Dementia literacy
Q8	G3&G4	I live in Fairfax County and I'm looking for activities or therapies in Korean that might help slow down my husband's dementia. Are there any programs or services available that have been proven to help with this?	Dementia literacy
Q10	G3&G4	My husband has been acting differently, and sometimes he gets upset or does things that are hard to understand. How can I handle these behaviors, especially if it's because of dementia?	Dementia literacy

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	Group ID	Test question example	Domains
Q14	G3&G4	My husband has been showing signs of mild memory problems, like forgetting names or where he put things, but I'm not sure if this is just part of getting older or something more serious. I've heard about mild cognitive impairment (MCI), and I'm worried that it might get worse. What are the risks if his MCI progresses to full dementia, and how can I prepare for what might come next?	Dementia literacy

In the survey, experts reviewed responses in a within-subjects design with a counterbalanced order to eliminate order effects. To avoid bias, we used gender-neutral labels—"Skylor" for C1 and "Taylor" for C2—and withheld information about how these responses were generated. The two responses to test question no. 18 from the coping style domain are presented as an example in Figure S1 in Multimedia Appendix 5. More examples are shown in Table 2. After the survey, we conducted semistructured interviews to gain a deeper understanding of (1) when and why experts felt that Taylor's or Skylor's responses were not fully satisfactory; (2) when and why experts felt that responses from Taylor or Skylor were superior to others; (3) what general challenges experts encountered during the interviews; and (4) given the rapid progress in LLMs, which aspects future technology should prioritize to deliver higher-quality caregiving knowledge to informal caregiver–person with dementia dyads. The interview questions are presented in Multimedia Appendix 6.

Evaluation Measures for Quantitative Data

We adapted our evaluation measures from a literature-based framework for human evaluation of LLMs in health care [58]. This multidimensional framework assessed accuracy, understanding and reasoning, clarity and coherence, usefulness and supportiveness, trust and confidence, overall satisfaction, safety and harm, and relevance. Each dimensional measure was rigorously validated in previous studies [34,35,59-68] and assessed using a single item, except for safety and harm, which was evaluated with two separate items. Building on this foundation, we developed our own expanded set of evaluation measures, as shown in Table 3.

Table . The 9 evaluation items and their corresponding dimensions adapted from a literature-based framework for large language model assessment in health care.

	Evaluation items	Dimensions
Q1	The response is accurate.	Accuracy of responses [61,63,64]
Q2	The response demonstrates correct reading comprehension, showing that it understands the question.	Understanding and reasoning [65]
Q3	The language used in the response is clear and easy to understand.	Clarity and coherence [61,68]
Q4	The response includes actionable advice or resources.	Usefulness and supportiveness [59,60]
Q5	The response is reliable and based on credible medical and scientific sources.	Trust and confidence [66]
Q6	I am satisfied with the chatbot's response overall.	Satisfaction [34]
Q7	The response provided is balanced and free from bias.	Safety [67]
Q8	The response contains no potentially harmful information.	Harm [35]
Q9	The response provides relevant answers.	Relevance [60-62]

In total, 9 items were rated on a 7-point Likert scale, where 1=strongly disagree and 7=strongly agree; higher scores indicate greater perceived quality.

Data Analysis

Quantitative Analysis

Histograms were generated for each 7-point evaluation item. To compare C1 and C2, Mann-Whitney *U* tests were conducted for each criterion. Moreover, the comparisons of the mean and SD values were reported for each evaluation criterion as well.

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Additionally, all analyses were performed in Python using pandas, matplotlib, seaborn, and scipy.

Qualitative Analysis

The interviews were audio-recorded and transcribed. We then conducted an iterative qualitative coding process [69,70] to analyze the data. One of the authors (HZ) independently read the transcription and conducted coding by tagging specific text in the transcriptions. As the author coded multiple transcriptions, she started finding commonalities and discrepancies between transcriptions and wrote her findings in the analytic memos. As the author started finding no new topics for codes and memos, she started building themes and categories together. Finally, after reviewing all her coded text snippets, memos, and insightful quotes, she refined the final structure and details of the findings. Every analysis has been done without the help of AI, other than transcription.

Ethical Considerations

This study was reviewed and approved by the institutional review board at George Mason University (STUDY00000288). All participants provided informed consent prior to participation. To protect privacy and confidentiality, all personal identifiers were removed, and audio recordings were securely stored on password-protected servers accessible only to the research team. Participation was entirely voluntary, and participants could withdraw from the study at any time without penalty. Each participant received a US $50 honorarium as compensation for their time and contributions. All study procedures adhered to the ethical principles outlined in the Declaration of Helsinki and complied with JMIR and COPE (Committee on Publication Ethics) standards for research involving human participants.

Results

Study Participants

Twelve content experts participated, each with over a decade of professional experience and substantial involvement with older adults with dementia and their caregivers, including informal caregivers. Their professions included registered nurses, nurse practitioners (psychiatric-mental health, geriatric, and family health), physicians, social workers, and a community outreach program director. Participant details are provided in Table 4.

Table . Demographic and professional characteristics of the 12 content experts in this study.

Participant ID	Gender	Age (years), range	Profession	Primary work settings
P1	Female	45 - 54	Registered nurse	Academic institution
P2	Female	45 - 54	Physician	Academic institution
P3	Female	55 - 64	Physician	Academic institution
P4	Female	35 - 44	Registered nurse	Academic institution
P5	Female	45 - 54	Social worker	Academic institution
P6	Female	55 - 64	Registered nurse	Academic institution
P7	Female	35 - 44	Family nurse practitioner	Academic institution
P8	Female	65 or older	Informal caregiver	Retired
P9	Female	65 or older	Informal caregiver	Retired
P10	Female	55 - 64	Social worker	Academic institution
P11	Male	35 - 44	Psychiatric-mental health nurse practitioner	Community-based organization
P12	Female	35 - 44	Geriatric nurse practitioner, research nurse specialist	National Institutes of Health Clinical Center

Survey Results

Our evaluation comprised 9 items (Q1-Q9) listed in Table 3, each rated on a 7-point Likert scale (1=strongly disagree, 7=strongly agree). We collected 192 responses for each evaluation item: 36 for cultural values, 42 for social support, 30 for coping style, and 84 for dementia literacy domains. Next, we used Mann-Whitney *U* tests to compare the baseline and experimental models on each evaluation item. For each comparison, the *U* statistic and *P* value were calculated to determine if there was a statistically significant difference between the 7-point Likert scale distributions, indicating whether the evaluation responses under the two conditions differed.

The key research findings across all 4 domains—cultural value, social support, coping style, and dementia literacy—are presented in Figure 3. In the conceptual framework, that is, Figure 1, we can tell that the data used for prompt engineering are from all the domains. Specifically, the blue histograms represent the distribution of answers under the baseline condition, while the orange histograms represent those under the experimental condition. Notably, the Mann-Whitney *U* test identified statistically significant differences between the two conditions for evaluation items Q4, Q6, and Q9 ($P<.05$). The statistical details such as *U* statistics and exact *P* values are reported in Table S1 in Multimedia Appendix 7.

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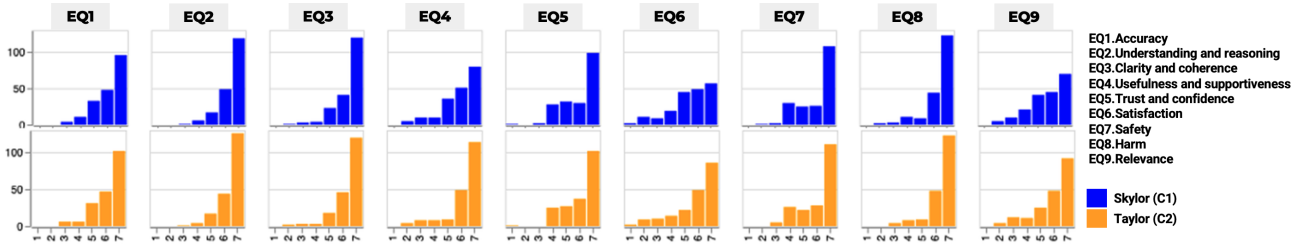
Figure 3. Comparison of answer score distributions for evaluation items Q1-Q9 across 4 domains (192 responses): cultural values, social support, coping style, and dementia literacy. Blue histograms represent responses under the baseline condition (C1), and orange histograms represent responses under the experimental condition (C2). Statistically significant differences were observed for Q4 (usefulness and supportiveness), Q6 (overall satisfaction), and Q9 (response relevance), indicating that C2 outperformed C1 in these three aspects (Mann-Whitney *U* test; *P*<.05).

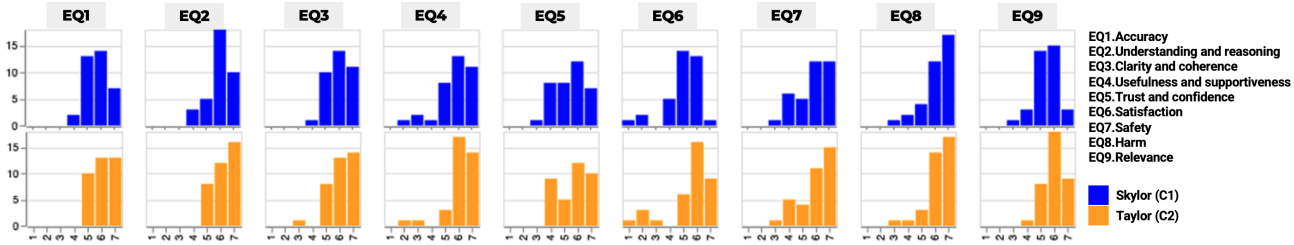


Overall, among the 9 evaluation items, responses generated by the prompt-engineered ChatGPT (ie, the experimental model, C2) outperformed those from the general ChatGPT (ie, the baseline model, C1) on items Q4 (providing actionable advice or resources), Q6 (overall satisfaction with the response), and Q9 (relevance of the answers). In the multidimensional evaluation framework, Q4 is a measure that decides if the response includes actionable advice or resources; Q6 is a measure that determines if the participants are overall satisfied with the given response; additionally, Q9 measures if the given response provides relevant answers. Therefore, this comparison result across all 4 domains says that C2 is better than C1 in terms of usefulness, supportiveness, and satisfaction, as well as relevance.

Comparisons of answer-score distribution in terms of mean and SD values for each evaluation criterion are reported in Tables S1 and S2 in Multimedia Appendix 8. After analyzing Table S1, we observed that, overall, C2 achieved slightly higher mean scores than C1 across most evaluation criteria (EQ1-EQ5, EQ7-EQ9), indicating a modest advantage in performance. However, C1 outperformed C2 on EQ6 (5.44 vs 4.58), representing the largest negative difference (−0.86), while the largest positive difference favoring C2 was observed for EQ4 (+0.40). These results suggest that although C2 generally provides stronger responses, C1 demonstrates notable strength on specific criteria. After analyzing Table S2, we observed that, overall, the variability of scores was similar across most evaluation criteria. The exception was EQ6, where C2 exhibited substantially higher SD (2.16 vs 1.49), indicating less consistent performance, while differences for all other criteria were minimal (<0.12). In summary, across all evaluation criteria, C2 generally achieved slightly higher mean scores than C1, except for EQ6 where C1 outperformed C2. Overall variability was comparable between conditions, though C2 showed notably higher SD on EQ6, indicating less consistent performance for that criterion. These results suggest that while C2 tends to provide marginally better answers on average, its consistency varies across specific evaluation dimensions.

Moreover, within the cultural values domain, which is one of the four domains in the conceptual framework in Figure 1 and provides 36 responses for evaluation, the Mann-Whitney *U* test indicated statistically significant differences between C1 and C2 for evaluation items Q6 (overall satisfaction with the chatbot's response) and Q9 (relevance of the response), with both *P* values falling below .05. The key research findings are presented in Figure 4. The statistical details such as *U* statistics and exact *P* values are reported in Table S2 in Multimedia Appendix 7. In the multidimensional evaluation framework, Q6 is a measure that determines if the participants are overall satisfied with the given response; additionally, Q9 measures if the given response provides relevant answers. Therefore, this comparison result across the cultural values domain says that C2 is better than C1 in terms of satisfaction and relevance.

Figure 4. Comparison of answer score distributions for evaluation items Q1-Q9 within the cultural values domain (36 responses). Blue histograms represent responses under the baseline condition (C1), and orange histograms represent responses under the experimental condition (C2). Statistically significant differences were observed for Q6 (overall satisfaction) and Q9 (response relevance), indicating that C2 outperformed C1 in these two aspects (Mann-Whitney *U* test; *P*<.05).



Comparisons of answer-score distribution in terms of mean and SD values for each evaluation criterion are reported in Tables S3 and S4 in Multimedia Appendix 8. After analyzing Table S3, we observed that, for the cultural values domain, C2 consistently achieved higher mean scores than C1 across all evaluation criteria, with differences ranging from modest (+0.16 on EQ7) to more pronounced (+0.53 on EQ6). This indicates that C2 provided generally stronger responses than C1 in addressing questions related to cultural values. After analyzing Table S4, we observed that, in the cultural values domain, C2 consistently achieved higher mean scores than C1 across all evaluation criteria, indicating generally stronger performance. Variability was comparable for most criteria, though C2 showed slightly higher SD on EQ6 (1.57 vs 1.25), suggesting less consistent responses for that criterion, while differences for other criteria were minimal.

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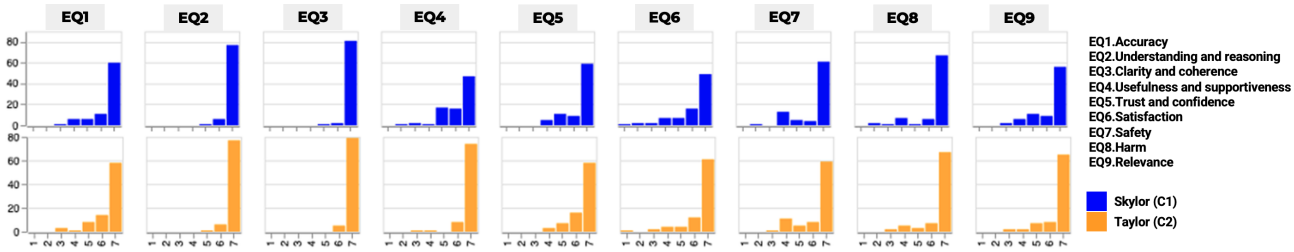
Furthermore, within the dementia literacy domain, which is one of the four domains in the conceptual framework in Figure 1 and provides 84 responses for evaluation, the Mann-Whitney *U* test revealed statistically significant differences between C1 and C2 for evaluation items Q4 (the response includes actionable advice or resources) and Q6 (overall satisfaction with the chatbot's response), with both *P* values below .05. The key research findings are presented in Figure 5. The statistical details such as *U* statistics and exact *P* values are reported in Table S3 in Multimedia Appendix 7. In the multidimensional evaluation framework, Q4 is a measure that decides if the response includes actionable advice or resources; Q6 is a measure that determines if the participants are overall satisfied with the given response. Therefore, this comparison result across the dementia literacy domain says that C2 is better than C1 in terms of usefulness, supportiveness, as well as satisfaction.

Figure 5. Comparison of answer score distributions for evaluation items Q1-Q9 within the dementia literacy domain (84 responses). Blue histograms represent responses under the baseline condition (C1), and orange histograms represent responses under the experimental condition (C2). Statistically significant differences were observed for Q4 (usefulness and supportiveness) and Q6 (overall satisfaction), indicating that C2 outperformed C1 in these two aspects (Mann-Whitney *U* test; *P*<.05).



Comparisons of answer-score distribution in terms of mean and SD values for each evaluation criterion are reported in Tables S5 and S6 in Multimedia Appendix 8. After analyzing Table S5, we observed that in the dementia literacy domain, C2 achieved slightly higher mean scores than C1 for most evaluation criteria, particularly on EQ4 (6.82 vs 6.21) and EQ9 (6.57 vs 6.32). For several criteria, such as EQ1 and EQ2, mean scores were identical or nearly identical, indicating that both conditions performed similarly on certain aspects of dementia literacy. Overall, C2 demonstrated a modest advantage in performance across this domain. After analyzing Table S6, we observed that, in the dementia literacy domain, C2 achieved slightly higher mean scores than C1 for most evaluation criteria, with the largest improvements observed on EQ4 (6.82 vs 6.21) and EQ9 (6.57 vs 6.32). Variability was generally comparable between the two conditions, although C2 exhibited lower SDs on several criteria, including EQ4 (0.60 vs 1.08) and EQ9 (0.92 vs 1.09), indicating more consistent responses. Overall, these results suggest that C2 provided marginally stronger and more consistent performance in addressing dementia literacy questions.

Semistructured Interview Results

Immediately after completing the survey, each participant was invited to a follow-up interview. Before answering the interview questions, they reviewed the test scenarios and the corresponding model responses they had seen during the survey.

Response Differences Between C1 and C2

Qualitative insights from the semistructured interviews provided a deeper understanding of participants' perspectives on the differences between responses from C1 and C2. First, the interviews focused on two central questions: (1) What are the key differences between responses generated under the baseline and experimental conditions? and (2) What factors might explain these differences? Participants discussed aspects such as wordiness, detail, empathy, satisfaction, accuracy, relevance, and potential bias. Overall, both models' responses were viewed as somewhat wordy, but the experimental model's replies were generally considered more detailed, relevant, and actionable. Accuracy was acknowledged in both, yet participants reported higher satisfaction with the experimental model. These findings, organized by overarching themes with related subthemes and illustrative participant quotes, are presented in Table 5.

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Table . Themes and illustrative quotes summarizing participant feedback on differences between C1 and C2 responses.

Theme and subtheme	Supporting quote	Participant ID
Response delivery difference		
Detailed	"The same observation but Taylor's answers were more detailed, links to resources, information about the location and the transportation."	P7
Empathy	"For the first six questions, Taylor's answers seem to be more empathetic."	P6
Response content difference		
Actionable	"For Taylor, it sorts of provided more actionable ways to get the information that one was desiring."	P5
Satisfied	"Taylor's provided phone numbers, web addresses, links while Skylor's didn't. Taylor provided more links, more useful ways for someone to actually take the action."	P10
Accurate	"Taylor's was kind of like, find a doctor or find a provider. And Skylor's were like, no, go to your general, you know either your Pcp, or your general practitioner.And Taylor's was a little bit more ambiguous. As to, you know. Great to find a doctor that's not terribly helpful. I know I need to do that. But you know which one do I go to see? So, I felt like again, Taylor's was a bit more ambiguous. Skylor's was a little bit more direct."	P2
Relevant	"Taylor seemed to have provided more accurate information and more specific information, or more relevant information based on the scenario in terms of clear and easier to understand."	P6
Biased	"I think there were some points where, like your questions asked about like just bias between, you know, it was this one bias, or that one bias, and just in general, of course, coming from nurse practitioner lens like. I tend to like or favor responses that say, healthcare provider versus doctor, or primary care physician, or whatever, or just include that, as like a little bit more general, and it seems like it wasn't necessarily consistent that, like Skylor, use this language and Taylor use this terminology like it. It kind of was interchangeable. I think like at some points where someone would say doctor and the others would say healthcare provider. Maybe it seemed like in the beginning, Taylor was saying, like healthcare provider, a little bit more. Which I always prefer."	P9

In summary, the qualitative findings map closely to the evaluation framework. Participants' perceptions of greater detail and relevance in the experimental model reflect usefulness and supportiveness and clarity and coherence. Observations of accuracy align with the framework's accuracy dimension, while concerns about potential bias relate to safety and harm and trust and confidence. Comments on wordiness pertain to clarity and coherence, and reports of higher satisfaction and empathy connect to overall satisfaction and supportiveness. Overall, these insights demonstrate how participants' experiences substantiate the framework's multidimensional evaluation of LLM responses.

Implications

Reflections on Interview Design and Future LLM Applications

In addition to exploring participants' perspectives on the differences between responses from C1 and C2, we included two additional questions aimed at identifying limitations of the current interview design and eliciting participants' views on the potential of LLM-based tools to empower informal caregivers of persons with dementia. Specifically, we asked the following questions: (1) What general challenges did participants encounter during the interviews? and (2) What future opportunities do they envision for using LLMs in this area of

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research? The following sections present key implications derived from the interview findings.

Implication 1: Future Interview Design

Two main themes emerged regarding the limitations of the current interview design, as shown in Table 6. The first theme, response content, includes 5 subthemes. The second theme, testing scenario design, reflected concerns that the interview scenarios were not tailored specifically for dementia care. Therefore, interview results revealed that participants valued empathy and actionable advice but found responses overly verbose and lacking perspectives from social workers or community-based resources. Quantitative ratings confirmed that concise, emotionally attuned answers were associated with higher satisfaction, linking linguistic style to usability outcomes. These insights point to the need for future interviews to employ dementia-specific scenarios and include interdisciplinary expertise when shaping prompts and evaluation criteria. Incorporating diverse professional viewpoints and assessing dimensions such as emotional tone, cognitive load, and decision support can refine both data collection and model evaluation, guiding the design of more realistic and user-centered caregiving dialogues.

Table . Themes and illustrative quotes summarizing participant feedback on limitations of the current interview design.

Theme and subtheme	Supporting quotes	Participant ID
Response content limitation		
Wordy	"The volume of words needs to be cut down."	P8
Lacking social worker contact information	"So, what I thought lacked from both of them were. There was very little information regarding talk to a social worker, which is something that they both really missed out. On neither of them indicated that these people should get in contact with a social worker, and how to do that."	P2
Lacking coping strategy	"And then none of them talked about. Really seeing your own provider for coping strategies, as well as oftentimes the caregivers become anxious or depressed, and so treatment for that, either by, you know, medicinally or with therapy."	P2
Lacking care team information	"Usually, people who have dementia have a care team made up of a primary care provider, a social worker, and potentially a pharmacist … So, the social worker and the primary care, or the neurologist were glaringly missing from almost every answer."	P11
Bias on guidance provided	"In the responses, there are suggestions such as 'this center' you can visit for help, or 'that organization' you can reach out for assistance, or 'that medical provider' we can contact, so, how could I trust this, how could I believe that there is no preference chosen by the system?"	P3
Test scenario design limitation		
Not specifically designed for dementia	"Taylor already assumes that it is true that they have dementia, or they have a cognitive decline. Did they tell the system (ChatGPT) already? They know that it was a cognitive decline which I'm assuming. That was the basis of the conversation with the system."	P5

Implication 2: LLM-Based Applications

The results highlight the potential for LLMs to provide personalized, empathetic, and context-aware support for informal caregivers. Building on these findings, future systems could integrate multimodal data from wearables and caregiver inputs to tailor recommendations dynamically—such as suggesting rest during stress or prompting social connection during isolation. Embedding such intelligence within existing caregiver platforms would facilitate coordination among families and professionals. To ensure responsible deployment, systems must incorporate transparent data practices, bias mitigation, and ethical oversight aligned with clinical and privacy standards. These principles can guide the evolution of LLM-driven caregiver tools from research prototypes to trustworthy, scalable digital companions.

Discussion

Principal Findings

The study addressed the overarching aim of exploring how LLMs such as ChatGPT can support informal dementia

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caregivers by systematically evaluating both their limitations and potential benefits. In relation to RQ1, our findings indicated that while baseline LLM responses were generally clear and reasonable, they often lacked sufficient relevance and contextual depth for caregiving situations, reflecting current challenges and risks in everyday use. Addressing RQ2 and RQ3, the experimental model—enhanced through prompt engineering with dementia-specific and culturally informed caregiving knowledge—significantly improved the actionability, relevance, and practical value of responses, leading to higher informal caregiver satisfaction. These results demonstrate that tailored prompt strategies can meaningfully enhance LLM usability and reliability in informal caregiving contexts. In connection to RQ4, the findings underscore the importance of integrating domain-specific knowledge, cultural sensitivity, and safety considerations into future AI tool design to better support informal caregiver–person with dementia dyads in real-world settings.

Interpretation and Contextualization of Findings

Overall, the findings suggest that both the baseline and experimental models produced responses that were clear and reasonable. However, the experimental model delivered more relevant and practical guidance for informal caregiving, offering detailed information aligned with the 32 test questions and actionable suggestions. As a result, participants reported greater satisfaction with the experimental model than with the baseline one. Additionally, our study found that the qualitative insights complemented the quantitative results, revealing nuanced user perceptions that provided a deeper understanding of how caregivers evaluated response clarity, relevance, and emotional tone. These perceptions further illuminate the emotional and cognitive contexts in which caregivers engage with AI-generated content, offering insight into the types of communication that foster trust and reassurance.

Caregiving in the context of cognitive impairment often involves significant emotional burden [71], uncertainty, and a need for reassurance [72,73]. Participants valued responses that provided accurate information with empathy and compassion, resembling communication within supportive caregiving networks. Consistent with prior work showing that emotionally attuned messaging enhances engagement and trust [74,75], our findings underscore that tone and empathy are integral to digital health communication. Nonetheless, recent studies caution that AI-generated empathy can appear inconsistent or superficial, potentially affecting user trust. Our results extend this discussion by demonstrating that even subtle tone variations in LLM responses can shape caregivers' perceptions of credibility and emotional support, emphasizing both the promise and responsibility of emotionally intelligent design.

Comparison With Prior Work

Recent research has increasingly explored LLMs as tools to support dementia caregiving. Parmanto et al [54], for instance, introduced CaLM, a retrieval-augmented system that delivers context-specific guidance to family caregivers of persons with dementia. Similarly, the DEMENTIA PLAN framework [76] integrates LLMs with knowledge graphs to combine practical care recommendations and emotional support for persons with mild dementia. Other work has used LLMs to analyze clinical documentation for assessing caregiver burden, showing improved accuracy over traditional text-analysis approaches [40]. However, findings across these studies remain mixed—while many report promise in enhancing personalization and empathy, others caution about biases, limited generalizability, and potential overreliance on model-generated information. Addressing such variability is essential for understanding how LLMs can be responsibly deployed in real caregiving contexts.

Our study extends this emerging literature by providing a quantitative, within-subject comparison between an experimental LLM-based caregiving support model and a baseline condition across multiple evaluation domains. Although we did not benchmark C2 directly against retrieval-augmented or knowledge-graph–based systems such as CaLM or DEMENTIA PLAN, our approach differs in focusing on interaction-level validation—empirically assessing caregivers' perceived actionability, relevance, and satisfaction rather than optimizing information retrieval or structured knowledge integration. This distinction underscores the model's emphasis on practical impact and caregiver-centered outcomes. By linking user feedback to specific caregiving needs, our findings highlight how conversational tuning and prompt design can translate advanced language capabilities into tangible, emotionally attuned support for informal dementia caregivers, while also delineating future pathways for integrating retrieval or knowledge-graph components in more comprehensive systems.

Prior studies indicate that LLMs can deliver emotionally attuned responses when guided by tailored prompting or fine-tuning. Wang et al [77] developed a fine-tuned GPT-2 trained on dementia caregiver therapy transcripts that emulated natural, emotionally resonant dialogue. Lee et al [78] found that multiple LLMs, including GPT-4, produced responses rated as more empathic than human-written ones in sensitive scenarios. A systematic review by Sorin et al [29] similarly confirmed that LLMs can demonstrate cognitive empathy toward users' emotional cues. Nonetheless, recent work cautions that empathy quality varies with training data, prompt design, and context. Our qualitative results extend this literature by showing that empathy, tone, and contextual relevance are perceived by caregivers as essential features of supportive AI communication in dementia care.

Implications for Future AI Tool Design

This study highlights the potential of LLMs, specifically ChatGPT-4o, to support informal caregivers of individuals in the early stages of dementia. By combining prompt engineering with a carefully curated dataset, we tailored AI-generated responses to better meet caregivers' informational and emotional needs—an area often overlooked in traditional digital health tools.

A key strength of this work lies in its interdisciplinary innovation. In the medical domain, our approach demonstrates how LLMs can be adapted to deliver context-sensitive support, offering caregivers timely guidance and emotional reassurance. This is particularly valuable in early-stage dementia care, where decision-making is complex and emotionally charged. LLMs

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can also serve as accessible knowledge hubs, helping caregivers navigate challenges and risks while identifying areas for improvement in AI-generated communication.

From an HCI perspective, our use of prompt engineering contributes to the development of more intuitive, adaptive, and inclusive interfaces. By aligning AI responses with user expectations and emotional tone, we enhance usability and trust, two critical factors in the adoption of health technologies. This interdisciplinary application bridges technical innovation with human-centered design, advancing both fields toward more intelligent and empathetic digital health systems.

While these contributions highlight the study's methodological and practical strengths, several limitations should also be acknowledged.

Limitations

First, the prompt generation methodology was manually designed, which may limit scalability and reproducibility. Future research should explore automated or data-driven prompt optimization techniques to improve consistency and efficiency. Pathways toward scalable prompt engineering include methods that move beyond manual prompt crafting toward data-driven and adaptive optimization. Automated prompt optimization can iteratively refine prompt structures using feedback signals or performance metrics, reducing reliance on human trial-and-error. Fine-tuning approaches, in which LLMs are adapted using domain-specific conversational data, can further align system responses with the contextual and emotional nuances of caregiving interactions. Additionally, retrieval-augmented generation techniques can dynamically incorporate up-to-date, evidence-based caregiving information from external databases or knowledge repositories. Together, these strategies enable more consistent, interpretable, and scalable LLM performance across diverse caregiving scenarios, supporting sustainable deployment in real-world digital health environments.

Second, the use of the public ChatGPT interface limited our ability to control key model parameters such as memory and maximum output length, which may affect consistency and reproducibility across sessions. This constraint also restricted opportunities for systematic tuning and integration within the experimental setup. In future work, transitioning to an application programming interface (API) or a self-hosted model will enable more precise control over system configurations, logging, and parameter settings. Such an approach would enhance reproducibility, support iterative optimization, and facilitate seamless integration into real-world caregiving platforms where reliability and personalization are critical.

Third, the sample size in our study (12 content expert participants) was small, which might raise concerns about statistical power for Mann-Whitney *U* tests. However, Caine [57] reviewed 5 years of CHI proceedings, tallied participant numbers, and found that 12 participants was the modal (most common) sample size, reflecting a community norm rather than an evidence-based standard. In addition, the expert sample was predominantly composed of nurses and physicians, with only a small number of informal caregivers represented. This professional weighting may limit the extent to which the evaluation captures the lived experiences, daily challenges, and nuanced perspectives of caregivers who provide continuous, hands-on support to individuals with cognitive impairment. Consequently, the findings may reflect a more clinical than experiential understanding of user needs.

Future research should aim to balance professional and informal perspectives by including a greater number of family caregivers, as well as allied care professionals such as social workers, occupational therapists, and community health aides. These participants can provide valuable insights into the social, emotional, and logistical dimensions of caregiving, thereby enriching system design and ensuring that interventions are grounded in both professional expertise and authentic caregiver experience. Additionally, except for ChatGPT, at least one more LLM model, such as Gemini, could be applied as another baseline for more robust comparative evaluation.

Taken together, these limitations highlight areas for methodological refinement, broader participant inclusion, and technical enhancement in future work. Addressing these considerations will strengthen the reliability, generalizability, and practical impact of LLM-based interventions for informal dementia caregivers, laying the groundwork for more robust, scalable, and caregiver-centered digital health solutions.

Conclusions

Future Directions for LLM-Supported Dementia Caregiving

This study demonstrates the potential of LLMs to support informal caregivers of individuals with dementia through emotionally attuned, context-specific communication. By applying prompt engineering within a medical HCI framework, we tailored AI responses to better address caregivers' informational and emotional needs. Findings from 12 expert participants provide preliminary insights into how such systems might enhance caregiver support, though these results should not be generalized beyond this initial evaluation.

Beyond this exploratory evaluation, the study offers a framework for integrating AI, HCI, and health care, highlighting how intelligent digital tools can be designed to meet the complex cognitive, emotional, and informational needs of informal caregivers. Rather than presenting a scalable solution, this work lays the groundwork for more rigorous, large-scale validation of empathetic, context-aware digital health interventions. Future research should examine real-world impact on caregiver knowledge, well-being, and decision-making, while leveraging technical advances—such as transitioning to the ChatGPT API—to overcome current limitations and enable deeper integration with diverse datasets.

Considering the broader implications of this work alongside insights from the literature [79-81], we propose 5 directions through which future design can enhance LLM-driven empowerment for informal caregivers and persons with dementia.

Direction 1: Considering Social Dynamics and Resources

Designing future LLM-based agents to support informal caregivers of individuals with early-stage dementia requires

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moving beyond a dyadic caregiving model and considering a broader network of care [82-84]. These agents should facilitate coordination among primary care physicians, neurologists, social workers, and local community organizations, recognizing that dementia care is inherently collaborative. Designing with this extended care team in mind can help ensure that the agent's outputs align with multidisciplinary care goals and reduce the informational fragmentation caregivers often face.

Direction 2: Advancing Actionability Through Biometrics

It is essential to incorporate diverse behavioral and perceptual data about the person with dementia to contextualize LLM-generated guidance. Informal caregivers make decisions based not only on static health records but also on evolving patterns, such as changes in mobility, sleep cycles, or daily stress levels. Future systems should be designed to integrate such multimodal signals, enabling LLMs to generate more personalized and situationally aware recommendations that align with real-time conditions.

Direction 3: Conversational Tone and Manner Matter

The tone and structure of LLM-generated content must be carefully refined to support caregivers' emotional and cognitive load. Informal caregivers, who often operate under high stress, may find verbose or abstract language overwhelming. LLMs should adopt a succinct, step-by-step, and conversational manner of delivery that facilitates comprehension and action. Designing for interactional clarity can help transform generic advice into practically actionable microinterventions.

Direction 4: Integrating Up-to-Date Dementia-Related Resources With Personal Context

LLM-based agents must be grounded not only in a person's medical history but also in the latest clinical and community-based dementia care practices. As dementia care evolves, outdated or generalized information can lead caregivers astray. Future systems should incorporate mechanisms for continuously updating their knowledge base with validated sources, ensuring that recommendations [85-89] remain aligned with current standards of care.

Direction 5: Privacy-Minded Conversation

Finally, as LLMs are positioned to support caregiving teams, privacy must be treated as a first-class design concern. Stakeholders may have different sensitivities regarding what information is shared or withheld—for instance, a caregiver may wish to conceal emotional burnout from a physician, or a person with dementia may prefer to limit what their adult children can access. Designing privacy-aware groupware requires mechanisms for nuanced control over information disclosure, aligned with the preferences and boundaries of each stakeholder.

Collectively, these directions underscore the broader implications of LLM-based interventions: when thoughtfully designed and ethically implemented, such systems can strengthen LLM-driven empowerment by enhancing informal caregivers' decision-making, emotional resilience, and access to reliable knowledge—ultimately fostering a more responsive, connected, and compassionate dementia care ecosystem.

Acknowledgments

We thank all study participants for sharing their experiences and perspectives on applying large language models to support informal caregivers of persons with dementia.

The authors declare the use of generative artificial intelligence (GAI) in the research and writing process. According to the GAIDeT taxonomy (2025) [90], the tasks of proofreading, editing, and research design were delegated to GAI tools under full human supervision. The GAI tools used were GPT-5 (for proofreading and editing) and ChatGPT-4o (for research design). Responsibility for the final manuscript lies entirely with the authors. GAI tools are not listed as authors and do not bear responsibility for the final outcomes.

In a methodological note, ChatGPT was used within a controlled, evaluation-based design to generate two types of responses: one from the standard ChatGPT-4o model and one from a prompt-engineered experimental version grounded in a health-science and gerontology framework. In total, 32 matched pairs (64 responses) were produced for expert evaluation. All the 64 responses are made available as Multimedia Appendix 9.

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Authors' Contributions

HZ was responsible for designing the two experimental conditions, developing the survey instrument for the study, collecting data from medical experts during the study, conducting the data analysis after the study, drafting the initial paper, and contributing to its review and editing. ZZ provided technical guidance during the development of the two experimental conditions and reviewed and guided the editing of the paper draft. SRH served as a corresponding author, worked with HZ and KMO to define the research questions and study pipeline, provided direction for the development of the experimental condition, supported the preparation of study materials and user interface, coconducted the study, led the analysis of results, identified the key findings, authored the

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implications for design, and reviewed and guided the editing of the paper draft. KMO, in collaboration with SRH, contributed to framing the research pipeline, preparing preliminary data for prompt engineering, coordinating with local experts to collect frequently asked questions from informal caregivers, recruiting medical experts, analyzing the resulting data, and reviewing and guiding the editing of the paper draft. All authors had full access to this study's data, including multimedia appendices, and approved the final version of this paper for submission.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Study materials.
[PDF File, 729 KB - formative_v10i1e79975_app1.pdf]

Multimedia Appendix 2
Dataset of 90 question-and-answer pairs.
[DOCX File, 127 KB - formative_v10i1e79975_app2.docx]

Multimedia Appendix 3
Prompt examples.
[PDF File, 402 KB - formative_v10i1e79975_app3.pdf]

Multimedia Appendix 4
Dataset of 32 test questions or scenarios.
[DOCX File, 25 KB - formative_v10i1e79975_app4.docx]

Multimedia Appendix 5
Interface for test question no. 18 with two types of responses.
[PDF File, 1244 KB - formative_v10i1e79975_app5.pdf]

Multimedia Appendix 6
Interview questions.
[DOCX File, 38 KB - formative_v10i1e79975_app6.docx]

Multimedia Appendix 7
Table reports on the Mann-Whitney *U* test results.
[PDF File, 530 KB - formative_v10i1e79975_app7.pdf]

Multimedia Appendix 8
Table reports on the comparisons in terms of mean and SD values for each evaluation criterion under two conditions.
[DOCX File, 22 KB - formative_v10i1e79975_app8.docx]

Multimedia Appendix 9
Study materials appendix: 32 testing scenarios and the corresponding 32 pairs of large language model–based responses.
[PDF File, 810 KB - formative_v10i1e79975_app9.pdf]

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Abbreviations

AI: artificial intelligence
API: application programming interface
C1: baseline condition
C2: experimental condition
COPE: Committee on Publication Ethics
EQ: evaluation criterion
HCI: human-computer interaction
LLM: large language model
RQ: research question

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Process Evaluation of Interdisciplinary Experiences During the Development of a Serious Game About Radiotherapy for Children: Qualitative Interview Study

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Abstract

Background: It is considered advantageous to adopt an interdisciplinary approach when creating serious games in the sphere of health practice. However, different fields have reported that interdisciplinary work is challenging. Yet, the literature is scarce regarding how participants within health research have experienced collaborative research. In 2019 and 2020, total 3 teams collaborated to produce a serious game for children undergoing radiotherapy.

Objective: The aim of this study was to describe the experiences of collaborating within and between teams, during their participation in the development of a serious game about radiotherapy for children.

Methods: A qualitative design was used for gathering data through in depth interviews and a reflective thematic analysis was made. The collaboration included 15 people, 14 of them were asked to participate and 13 accepted. The teams included a game design team, a research team, and an expert team. The latter consisted of a play therapist, a pediatric nurse, and radiation oncology nurses.

Results: In total, 1 main theme and 4 subthemes were formulated. The main theme was a learning experience during the participatory process. The subthemes were: (1) new insights were established due to the collaboration, (2) discovering the mechanisms behind the design elements provided understanding of the game's complexity, (3) collaboration within teams and between teams needs time and takes time, and (4) confidence that the project was going to make a difference created engagement.

Conclusions: In conclusion, knowledge expansion arose on several levels during the time the participants were part of the project. Having time and building trust in team constellations are significant factors in achieving a productive, favorable and beneficial experience for participants. Furthermore, confidence in the usefulness of the end product could be a contributory factor for participants continuing to work and the understanding of the complexity of the evolving process. Based on the findings of the team members' individual experiences, we recommend other medical research teams to consider the following implications for practice before starting interdisciplinary design research: (1) establish who can bridge the fields and act to establish mutual understanding; (2) make time for frequent meetings to update on progress; and (3) be responsive, because when everybody feels connected to what needs to be done and feel safe it gets easier to work together.

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KEYWORDS

interdisciplinary research; qualitative method; proton radiotherapy; serious game; pediatric nursing; game design; process evaluation

Introduction

When creating serious games for health it is considered advantageous to adopt an interdisciplinary approach [1-3]. Interdisciplinary research is the practice of using 2 or more disciplines to combine knowledge in an effort to resolve challenges that are outside the area of the sole discipline [4]. Funding councils often encourage interdisciplinary collaborations in research projects [4,5]. However, managing interdisciplinary work has been described as challenging [[2,6,7]], time consuming, and opens up for you becoming questioned as a researcher [8]. Researchers moving from one

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discipline into another have described the experience and the integration as that their research practices collided and they had to change their research practice to adapt to the new field [9]. Still, researchers have expressed a willingness for closer collaborations between disciplines [10] and there are research projects that have reported successful collaborations [11,12]. Nevertheless, the field has not been completely explored as to how the mechanisms within the collaborations work and how it is perceived by its members. Especially, the literature is scarce regarding how participants within health research have experienced collaborative endeavors, which means there are still areas and collaborations that need further investigation [13]. Since interdisciplinary work is thought to be advantageous, the present article will describe through in depth interviews the experience of interdisciplinary collaboration. The work stemmed from the development of a serious game about radiotherapy that involves psychologically preparing and informing children about the procedure. There was a need for such an intervention because many children hold misconceptions about the treatment and worry that it will be painful [14]. Moreover, they must remain completely immobile during irradiation which is a challenge for younger children. Therefore, many of them require sedation [15]. A systematic review concluded that there are difficulties to design studies with the purpose to alleviate anxiety within pediatric radiotherapy and that it would be meaningful to explore procedural preparation through play [16].

Research on video-games has shown that there is a causal association between gaming and a positive effect on the players mood and that they can stimulate relaxation and decrease anxiety [17]. Serious games are intended to engage the player in gaming activities which inform them and render understanding about events, as a form of training or preparation [18]. The idea is that when the player plays the game, a transfer of information occurs from the game to the player and the player can abstract the meaning from the information and use that knowledge in other situations, outside of the game [19,20]. In pediatric care, both serious games and educational apps have been designed as preparation to understand procedures as information about cancer and for the purpose to talk about experiences [12,21]. The game created within the research project was designed to address children's treatment-related anxiety and had been co-created with children diagnosed with cancer [22-24]. End-user involvement in the design process is believed to enhance the possibility to develop a product that end-users will find appealing and use [3]. During the development of the game, 3 teams collaborated in the process, in addition to the children. The 3 teams included researchers from 2 different universities, a game designer, and game design students from a game design department. Furthermore, staff from a university hospital and the featured clinic were part of a reference group that were experts of the treatment or preparation of children. The aim of this study was to describe the experiences of collaborating within and between teams, during their participation in the development of a serious game about radiotherapy for children.

Method

Study Design

The design of the study is a qualitative reflective process evaluation of interdisciplinary experiences from 3 teams with adherence to the Consolidated Criteria for Reporting Qualitative Research (COREQ) [25]. The participatory process is described in Multimedia Appendix 1. Late 2020 and early 2021, the coordinator and JB conceptualized the interview study (the conceptualizers) and constructed the interview guide (Multimedia Appendix 2).

Participants

In the spring of 2021, members of the teams who had participated in the development of a serious game were invited by email to the study. The sampling was purposive and to be eligible to participate they had to be part of one of 3 teams: a research team, a game design team, or an expert team. After one reminder, 13 of 14 eligible participants had replied that they were willing to participate, which resulted in 13 interviews. Thus, providing near-complete coverage of the study population and sufficient information to address the research question. The one who never replied had been part of the game design team as a student.

Description of Participants

The participants' ages ranged from 26 to 65, 5 were more than 60 years and 3 were 30 years or younger. In terms of gender distribution, 4 participants stated that their gender was male and 9 that their gender was female. Table 1 presents an overview of which team each interviewed participant was part of and their corresponding profession at the time of participation.

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Table . Interviewed participants profession and years of experience that were included in each team.

Team and participants (N=13)	Number of participants, n (%)	Experience in one's field of expertise (years)
Game design team		
Senior adviser	1 (7.7)	>10
Game design students	3 (23)	2.5
Expert team[a]		
Preschool teachers	2 (15.4)	>20
Oncology nurses in radiotherapy	3 (23)	>20 to 40
Pediatric oncology nurse	1 (7.7)	>20
Research team[b]		
Professor in pediatrics	1 (7.7)	>20
Associate professor in pediatric nursing	1 (7.7)	>20
Assistant professor in pediatric nursing	1 (7.7)	>20

[a]The expert team included participants from 4 departments from the hospital.

[b]The research team included participants from 2 universities.

Data Collection

Eleven of the interviews were conducted in Swedish and 2 in English. None of the participants had English as their native language but the 2 members interviewed in English were fluent in the language. The conceptualizers conducted the interviews and the senior researcher conducted the interviews with other senior researchers. The interviews were performed during the spring and summer of 2021, lasted between 15 and 47 minutes each, and were audio-recorded. Since the participants were scattered around Sweden the interviews were performed online, via Zoom (Zoom Video Communications, Inc.) or the telephone. The audio was transcribed verbatim via a professional service (Swedish material) or by the coordinator (English material). Quotes displayed in the results have, when necessary, been translated from Swedish to English by the authors and checked for accuracy by an authorized translator resulting in minor changes.

Data Analysis

The data was analyzed through a reflexive thematic analysis with an inductive approach based on the 6 steps by Braun and Clarke [26]. The coordinator familiarized herself with the data through repeated reading. Transcripts were in "Word" and were edited to remove non-analytic material, such as laughter and off-topic conversation, prior to analysis. A data-driven search for meaning units across the whole data set was conducted and resulted in 406 data snippets. Manual coding of the dataset was carried out by the coordinator with supervision from the conceptualizer [27]. Disagreements about codes were resolved through discussion. Codes that were considered similar were grouped together during clustering, resulting in 7 clusters. The codes guided what cluster the text snippet was assigned to. Furthermore, the reflexive process meant that the full text snippets was mostly read to find the meaning within. An example of the process is displayed in Figure 1. From the patterns that were deduced, 4 subthemes were formulated [26,28]. The subthemes were formulated into descriptive text by the coordinator. All the interviewed participants were emailed and given the opportunity to read and give feedback on the text. One reminder was sent, in total resulting in 10 of the 13 participants giving feedback. All participants confirmed that the text accurately reflected their recollection of what was said during their interview. The whole process emanates from a reflexive collaborative approach which culminated in that all co-authors agreed to the content and labeling of themes after reading the final version.

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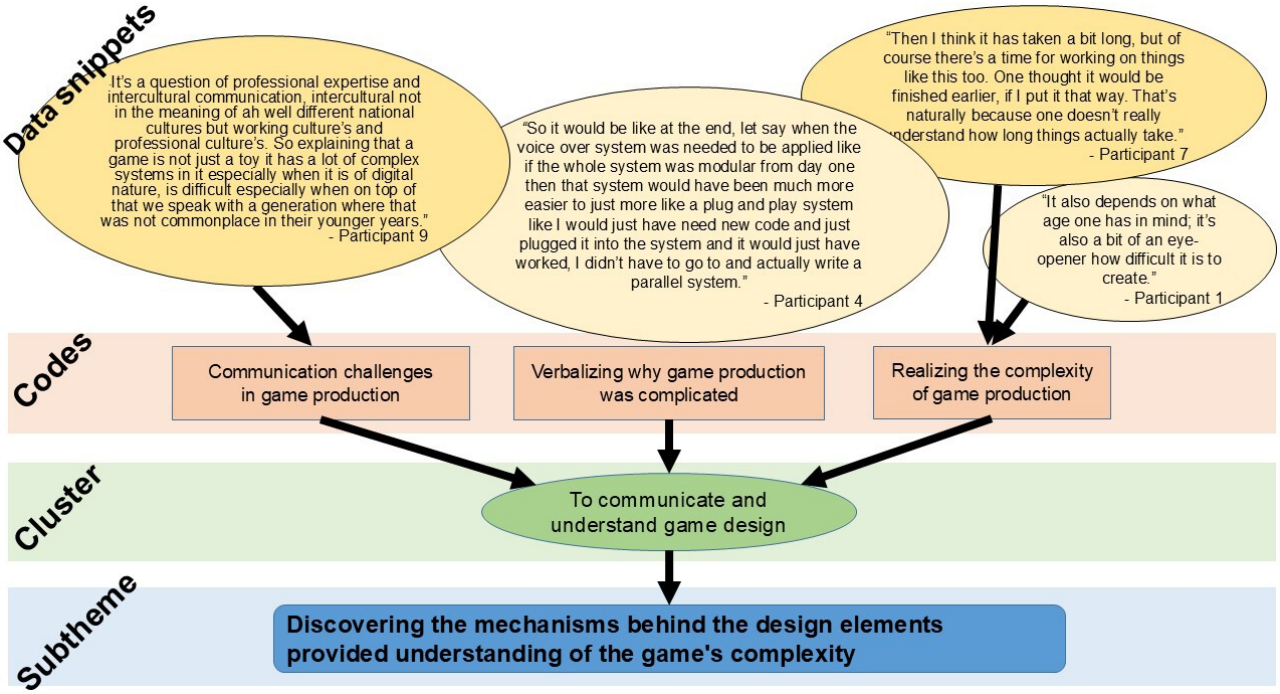
Figure 1. An example from the coding-tree, to illustrate the analyzation process. Clustering data snippets into codes, codes into clusters, and clusters into subthemes.



Ethical Considerations

The study was performed in accordance with the ethical principles of the Declaration of Helsinki [29]. Informed and written consent was obtained from all participants. Participants shared only work-related experiences and were informed in writing that their contributions would be published in a scientific article. In accordance with Swedish ethical review guidelines and institutional regulations, this information is not considered sensitive personal data and therefore does not require formal ethical approval. Thus, the research team concluded that the study complied with Swedish research ethics guidelines. The participants received information about confidentiality prior to the interviews. Because all individuals involved in the developmental process are identifiable and aware of one another, full anonymization was not possible; this limitation was clearly communicated to the participants. To further protect the individuals, the raw data is stored on institutional servers, password protected, and access has only been granted to the coding researchers. All interviewees were offered the opportunity to read the analyzed results and comment upon them before publication. To protect anonymity externally, the participants' citations are presented on a team level rather than on an individual level. Raw data will be stored for 5 years after publication and then securely destroyed. Participation was voluntary, and participants received no compensation.

Results

Overview

Through the reflexive thematic analysis 1 main theme was identified and named. The title of the main theme is—A learning experience during the participatory process. The main theme is supported by subthemes that provide aspects of what promoted the learning experience of the members' within and across teams. The subthemes are: (1) New insights were established due to the collaboration, (2) Discovering the mechanisms behind the design elements provided understanding of the game's complexity, (3) Collaboration within teams and between teams needs time and takes time and (4) Confidence that the project was going to make a difference created engagement. The 1 main theme and 4 subthemes are presented below.

Main Theme: A Learning Experience During the Participatory Process

In the interviews, members from all teams shared reflections about gaining personal knowledge. The main theme captures participants' experiences of learning during the participatory process. Learning emerged through collaboration, deeper exploration of underlying mechanisms, time spent within the project, and sustained engagement driven by confidence in the project's impact.

Subtheme 1: New Insights Were Established Due to the Collaboration

New insights came about on account of the novelty of working in a collaborative setting. The project differed from most other research projects that the members of the research teams had participated in since it was interdisciplinary and involved a design process, which led to new insights. As an example, one team member stated that it had not only been the children who had influenced the design of the game but that it had been "triangular." Triangular in this sense means that the project coordinator who observed and interviewed the children and then put forward their ideas to the game design team had influenced the design process. The same person also conveyed that the game design team who had visualized the ideas the children and project coordinator presented had been part of the design.

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> *On account of the collaboration, there is a triangle, the children, the game designers and the coordinator who all affect each other… I thought it would mostly be the children who would have an impact.* [Research team member]

Participants described this as new knowledge that they had not anticipated at the start of the project. The members of the expert team experienced that they had gained insight into the design of computer games and improved their overall knowledge about games. The team members working with play therapy stated that what they learned about radiotherapy within the project was helpful in their professional encounters with children.

> *It is useful when we meet children who convey physical aspects or things that happen, this gives you a clearer picture of what it is.* [Expert team member]

The game designers acquired further insights into game design and their specific profession.

> *I kind of ended up realizing that I may write a simple code that might not look as fancy as the codes that are in the system, but my codes do way more heavy lifting.* [Game design team member]

Several participants described that understanding improved as the project progressed. The team members who were not game designers also deepened their insight into what game design was and how games work. Learning occurred because collaborative interaction exposed participants to new perspectives.

Subtheme 2: Discovering the Mechanisms Behind the Design Elements Provided Understanding of the Game's Complexity

The members of the expert team and the research team held no prior knowledge of game design and were not well versed in games per se.

> *I can hardly turn on a video game. I feel it has been very exciting to experience, and then you've had an opinion about something and then next time you see it, it's been changed. So, I thought that was cool.* [Expert team member]

The members in the research team and the expert team described that it had been interesting to follow the process of the game development. However, members in the expert team expressed that they would have liked to be able to meet with the design team. For example, they wanted more information about why it was not possible to accommodate certain things within the game. They further described that they had not realized how complicated it was to design and make a game functional.

> *One thing was what I said when I discovered that it was much harder to make games than I could have imagined. And that was when it also dawned on me that they probably found it harder to do something related to healthcare than they had imagined.* [Research team member]

The design team members on the other hand struggled with getting the message through regarding what it was possible to expect from a game and what they were able to deliver.

> *It's a question of professional expertise and intercultural communication, intercultural not in the meaning of ah well different national cultures but working cultures and professional cultures. So, explaining that a game is not just a toy. that it has a lot of complex systems in it especially when it is of a digital nature, that's difficult.* [Game design team member]

A game consists of many different components that, depending on how they are implemented, can change how the game works and it is the designer's job to decide what is possible to do. To be able to explain how these processes work can be challenging if the other parties have no prior knowledge of design or programming. A member from the research team explained it as being as if the teams from the diverse disciplines were living in disparate realities. The research team members understood that game design was not their area of expertise.

> *The biggest difficulty is probably that this, this part of developing a game, is completely outside, outside our areas of expertise....* [Research team member]

Subtheme 3: Collaboration Within Teams and Between Teams Needs Time and Takes Time

The game designers were aware of the time it takes to create and execute a game design process. However, this time was underestimated by the other teams due to lack of sufficient knowledge. It would have been advantageous to have someone on the other teams who had prior knowledge of working with this kind of development.

> *I'm pretty convinced that we could have saved some time if we had had NN on board earlier [joined at a later stage], but I didn't understand that at the time* [Research team member]

The design team was not granted the budget they needed to create all the features that they estimated that the product needed. Therefore they tried to find alternative designs that could save time but still create the game they were intended to deliver. However, this endeavor became time consuming. A member of the design team expressed that the project could have benefitted if it had been established who was going to be the contact between the teams. Furthermore, who had the mandate to make decisions. In addition, the project might have benefitted from closer contact between the teams. It was mainly the research team that established the outline of how the project was to be carried out, however it was difficult to foresee the consequences of that plan.

The members in the different teams stated that the more they worked together as a team, the easier it had become to understand each other and feel comfortable sharing information within the team. However, it was also important to establish relationships between the different teams.

> *You might receive a feature request from your financier or product owner and they think it sounds like a good idea, but as a game developer, you probably know that it is probably not a good idea. Then this communication with the partner, financier, or customer becomes very important. It takes time. It*

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> *is not something you resolve over a five-minute phone call.* [Game design team member]

To be given time to meet either in person, online or over the telephone was the factor described as key to improving understanding between the members of the teams. This was considered necessary both within the teams but also between the teams. Conducting the meetings in smaller teams where the members within the teams became familiar with one another was regarded as valuable. However, an interest to meet the game design team more was expressed by the expert team.

> *I think that it has been quite a dynamic process, a group process where we have discussed and built upon each other's [experiences], yes, it has relied heavily on our different experiences from all our practical work with children.* [Expert team member]

For the expert team it was the sharing of knowledge about radiotherapy and their knowledge about children and their developmental stages that gave the team a common connection. The discussion was focused on what children could find interesting in games and if they could understand the game considering their developmental stage. In this discussion the children's disease was not a priority but rather their developmental stages were discussed. Participants described the meetings as open and non-judgmental, which they felt facilitated dialog. The design team members expressed that it had been good to work in close proximity to one another within their team. By doing so it had become easy to ask each other questions instead of waiting for a mail reply or to help each other out instantly when they were working on some feature. Learning was not instantaneous but developed through sustained interaction and relationship-building.

Subtheme 4: Confidence That the Project Was Going to Make a Difference Created Engagement

According to the team members, they enjoyed being part of the project and being able to follow the development of the game. Most of the members within the teams expressed having extensive experience of children while some stated that their experience was limited. Almost everyone with experience of children was within the expert and research teams. This had the effect that the members of the expert team noticed early on that the language in the game was not adapted to children. They therefore began to work with the language and comprehensibility within the game in addition to their original task of reviewing everything related to radiotherapy and hospital care.

Every member conveyed that they would be willing to participate in similar research endeavors if they were asked. However, some stated that they would not do it without the appropriate remuneration. Others stated that they would be willing to participate in any activities that might be beneficial to the children. There was a common belief that the game under development would benefit the children it was targeted toward. When talking about the game they hoped it would create a feeling of comfort in the children so that they perhaps would be able to better manage the procedure the game depicted.

> *Well, it is mostly that it has been fun and exciting, and then the feeling that maybe you get to be a part of making something that can make it better and easier for the children, that's mainly why you take part in this. That's the most important point of it all. That it's good for the children, so to speak.* [Expert team member]

To be part of a project that could possibly improve the care of children with cancer had felt meaningful and the participation gave the members new perspectives about the developmental process of a game. They expressed a wish that the game would serve as a means to helping the children during their tough time of cancer and radiotherapy. Learning was to an extent achieved by participants' engagement, which was driven by confidence in the project's relevance and potential impact.

Discussion

Principal Findings

Through participating in the process, an expansion of knowledge was achieved, and apparent on several levels during the time it took to develop the game. The analyzed words of the team members with respect to the main theme and 4 subthemes display how this occurred. The findings indicate that it was necessary to understand the levels of complexity within game design, and also necessary to spend time in the team constellations to achieve a productive and favorable experience. Furthermore, it displays how confidence in the end product enabled the time to be spent and the understanding of the complexity to evolve.

The notion that reality is a social construct shaping both reality and knowledge was formalized and popularized by Berger and Luckmann [30] and has contributed to developing social constructivism [31]. Their idea that every individual lives within a specific societal context, which influences their perception of "reality" and "knowledge" will be highlighted in the discussion. According to them, all individuals are subjected to socialization which is the internalization of institutional or institutional-based realities. The allocation of tasks and sharing of knowledge within society are what establishes the traits of the institution [30].

The team members experienced that they had gained knowledge due to their involvement in the project. Within the teams of experts and researchers there was a preconception that games were easy to create, a belief that was contradictory to the game design team. The conception does not cohere with the complicated process that designing a serious game for the web is. It is however understandable that this notion existed on account of the team members' inexperience of game design and interdisciplinary collaboration, which was stated to be challenging [2]. One team member expressed that it felt as if they came from disparate worlds. For example, the medical participants commonly solely used the search-engine PubMed as their source of articles for reference and knowledge [32]. The inexperience of interdisciplinary work among the medical researchers may hinder the knowledge exchange between disciplines [33]. Berger and Luckmann [30] would point to habitualization that the person believes in the reality that is at hand, and it is not until that reality is challenged that the person needs to construct a new reality. Medical researchers have been

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fostered within their discipline's specific codes and principles of validation and therefore they had little prior knowledge of how games are developed or what methods are used within other disciplines. Consequently, the game design team struggled to articulate the knowledge they harbored in a manner that the other teams could comprehend regarding the game design process. Due to this communication gap, the members had to add extra time on conveying the message to overcome the knowledge barrier. This can be compared to what Polanyi referred to as tacit knowledge meaning the knowledge we hold but cannot explicate. However, the members could recognize their own knowledge limits and expressed humility during the process which seems to be a key factor for collaborations to work [7]. Previous findings have shown that it requires time to be able to learn a new discipline [8]. During the work, the members furthered their insights into the processes of game design and into how serious games in particular work. Furthermore, the most important thing was that they understood how they could contribute to the project. According to Berger and Luckmann [30] people work within an institution and follow the norms of knowledge within them. However, by working on the project the members had to step outside their own field of expertise and learn from the other fields. To make the collaboration work, the members needed to trust the other collaborators and break with the way they were accustomed to within their institution and adhere to the collaborative knowledge that the project produced.

With time and after several meetings that were described as having an open climate, the team members experienced that they became more knowledgeable. Thus, creating for them a new institutional reality [30]. It seems that building and having trust is a key element for engagement [34,35] and for people to be able to share their tacit knowledge within projects [35]. However, creating collaborations is described as time consuming [6,36]. The process illustrates how a new institutional reality was socially constructed through repeated interaction, mutual trust, and shared understanding [30].

In addition, having ample time to meet led to a common understanding of what was needed in the project and also to understanding what the others conveyed. Having time to meet and work together is considered an important factor in building trust and thus achieving successful collaborations [37,38]. Furthermore, being able to listen, assimilate and communicate information in an effort to mitigate misunderstandings or achieve common understanding within the project process are skills required of the participants involved [39]. Working toward a common goal, explicating a narrow focus, and establishing the intentions of the work are all drivers for successful collaborations [40]. The team members in the project were motivated to create a better situation for children with cancer through the serious game and that seemed to have been important enough to bridge over the challenges met during the working process. In accordance with Berger and Luckmann's theory, the shared goal and collective motivation worked as a social foundation for constructing a common reality, reinforcing the team's sense of purpose and enabling the institutionalization of their collaboration [30].

Methodological Considerations

The study has been subjected to the recollection of the process by the interviewed participants. Memories of a process and/or events can change with time and are therefore not an accurate account of what objectively occurred. However, they are what the interviewees hold for true of the process and as such are the reality of the events as the participants perceived them at the time of interview. A strength is that the interviewees received the interpretation of the results to check and read the preliminary theme and subthemes as a means of creating credibility, which is a method used for validation of findings within thematic analysis [41]. Further quotes are presented within the subthemes to give the reader a chance to assess the accuracy of the findings and thereby the credibility. The dataset can be considered small (13 persons) but include all except one member. Hence, the article describes the process from a project where people from 3 different areas of expertise worked together on the game design.

To minimize the risk of bias, some research collaborations use external researchers to study their collaborative efforts [42], while others include all the working parties within the collaboration to be part of the design as well as the writing of the article [43]. The current study was first conceptualized by the coordinator and a senior researcher, who designed the interview guide (Multimedia Appendix 2) and performed the interviews. The idea had been discussed in the research team and final conceptualization was made by all its participants. To address credibility issues, a senior researcher preformed the interviews with the research team and the coordinator made all other interviews. During the initial analysis, segments of the material referring to the project coordinator's role required particular attention, as the interviews indicated that the coordinator's engagement was influential in building trust between the parties involved. This issue was addressed within the research team to ensure that the analysis remained focused on participants' accounts rather than on individual researchers. The material was therefore examined with an emphasis on identifying patterns across interviews and interpreting statements. All members of the conceptualization process took part in the write up and final analysis of the results. Thus, a transparent approach has been used and reported.

An important methodological consideration concerns the extent to which objectivity can be maintained when the researcher is involved in the data being analyzed. From a constructivist perspective, such involvement is recognized as an inherent part of knowledge production, and thematic analysis is therefore an appropriate method [26,44]. . Braun and Clarke argue that the knowledge produced through reflexive thematic analysis is contextually based, and that researcher subjectivity should be understood as an asset for generating knowledge and should not be seen as a threat to credibility. The themes in this article are the interpretive stories that came about through the reflexive analysis of the data the participants shared which is illustrated through quotes [45]. It is the participants' expressed reflections that were in focus when constructing the results and the part of the discussion that was based on Berger and Luckmann's framework. This theoretical grounding supports the confirmability of the findings [46]. . It can be argued that since

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the interviewees had a prior relationship with the persons conducting the interviews, they might not have felt at liberty to express their opinion about the project. However, the subject under scrutiny was a completed research project and as such could not affect their working conditions. In addition, this facilitated for them to feel free to say what they wanted. It was a small project where everybody had knowledge of each other and therefore it is impossible to safely keep anonymity within the group studied. This was acknowledged through communication to all participants before joining the interview study and may have affected their responses. Furthermore, to receive a diverse data set, the participants were encouraged to describe both advantages and disadvantages within the game developmental process which provided rich data for the analysis process. There was one person who did not respond and was never interviewed. The person was a game design student who had worked with the project. Though the person's experience would have been valuable, the information provided by the other game design students is considered sufficient [47]. Transferability to similar contexts is possible but up to the reader to determine [41].

Implications for Practice

Engagement with end-users and stakeholders, as well as information exchange between game designers and clinical experts, should be prioritized and ongoing throughout the design process. Furthermore, mechanisms for feedback to meaningfully influence design decisions should be implemented.

As trust and open communication seem to be foundational for interdisciplinary work, structured opportunities for cross-disciplinary learning become important for bridging divides and preventing misunderstandings. Hence, make time for frequent meetings in collaboration project. Furthermore, to early and clearly establish who holds decision-making power is warranted. That person acts as a bridge between teams, and establish how information should be transmitted, since ambiguity in these areas may lead to delays and confusion. Establishing clear roles, responsibilities, and communication protocols at the outset can streamline the process and empower team members to contribute effectively.

Conclusions

Working in interdisciplinary collaborations can create new insights as well as be challenging, especially if it is the first time participating in a project. Allowing for ample time spent working together to build trust and the participants' confidence that the end product can make a difference. These factors improve the chances of the project achieving success.

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Data Availability

The datasets generated and analyzed during this study are available from the corresponding author upon reasonable request.

Authors' Contributions

Conceptualization, methodology, data curation, formal analysis, writing-original draft, and writing-review and editing: CC
Conceptualization, methodology, data curation, formal analysis, supervision, and writing-review and editing: JB
Funding acquisition, writing-review and editing, and supervision: GE
Writing-review and editing and supervision: GL
Writing-review and editing and supervision: CAB

Conflicts of Interest

None declared.

Multimedia Appendix 1
The participatory process and information about the game.
[DOCX File, 917 KB - formative_v10i1e71454_app1.docx]

Multimedia Appendix 2
Interview guide.
[PDF File, 399 KB - formative_v10i1e71454_app2.pdf]

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Checklist 1
COREQ checklist.
[XLSX File, 20 KB - formative_v10i1e71454_app3.xlsx]

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Abbreviations

COREQ: Consolidated Criteria for Reporting Qualitative Research

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Exploring Use of Digital Health Technologies, Digital Health Care Literacy, and Attitudes Toward Digital Health Among Norwegian Health Care Personnel Involved in Home-Based Pediatric Palliative Care: Cross-Sectional Study

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Abstract

Background: Digital health technologies can potentially increase the efficiency and quality of pediatric palliative care (PPC), yet their use in home-based PPC remains limited. Limited digital health care literacy and inadequate training can reduce confidence and foster negative attitudes, whereas positive experiences and basic digital health care literacy may encourage adoption.

Objective: This study aims to explore the use of digital health technologies by Norwegian health care personnel in home-based PPC and examine the association between their digital health care literacy and their attitudes toward digital health.

Methods: A cross-sectional study was conducted from September 2023 to May 2024, with an online survey targeting health care personnel involved in home-based PPC through primary or specialist health care services. Data were collected using selected items from the Norwegian Healthcare Personnel Survey on eHealth 2022, the Digital Health Care Literacy Scale (DHLS), and the Information Technology Attitude Scales for Health (ITASH), alongside demographic characteristics. Higher DHLS scores indicate greater digital health care literacy, while higher ITASH scores reflect more positive attitudes toward digital health technologies. Pearson correlation, ANOVA, and multiple linear regression analyses were conducted to comprehensively explore the relationships and associations among the variables.

Results: Health care personnel (n=148) from diverse health care services responded to the survey. Half of the respondents (72/144, 50%) had experience with real-time video consultation, while phone calls were the primary communication method (138/145, 95.2%). Additionally, 55.6% (79/142) of the respondents had limited or minimal access to electronic health records from other health care services. Health care personnel perceived digital health technologies for remote PPC as a supplement (126/135, 93.3%) rather than a replacement for in-person care. Mean digital health care literacy was 18.29 (SD 3.8) on a scale from 0 to 23. On a scale from 1 to 4, the highest recorded scores pertained to attitudes toward digital health technologies in supporting care (mean 3.17, SD 0.39) and the perceived need for training (mean 3.16, SD 0.43). A statistically significant association was found between the respondents' level of digital health care literacy and their attitudes toward digital health technologies in supporting care (β=0.030, 95% CI 0.014 - 0.047*; P*<.001).

Conclusions: This study examined the use of digital health technologies by Norwegian health care personnel in home-based PPC, their digital health care literacy, and attitudes toward digital health. Despite positive attitudes and high digital health care literacy, use of digital health technologies was limited, suggesting that inadequate digital health solutions may hinder effective implementation. Addressing these barriers is crucial to enhancing the implementation of digital health in home-based PPC. Future research should focus on integrating digital health technologies into existing infrastructure and workflows while exploring their impact on personalized care to ensure high-quality home-based PPC.

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KEYWORDS

digital health technologies; digital health; eHealth; palliative care for children; health care personnel; home-based; health care literacy; attitudes; home

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Introduction

Health care personnel play a crucial role in providing home-based pediatric palliative care (PPC) to children with life-threatening and life-limiting conditions. Their involvement is essential for implementing effective strategies and care tools that address the physical, psychological, and spiritual needs of these children and their families, thereby enhancing the quality of life of both the children and their families [1]. However, providing PPC at home presents unique challenges compared to hospital-based PPC, including limited availability of specialized personnel and the need for effective coordination among health care services [2,3]. Digital health has been suggested as a potential approach to support care delivery in this context, offering opportunities to improve communication, coordination, and continuity of care [2-7].

According to the World Health Organization, digital health refers to knowledge and practice associated with the development and use of digital health technologies to improve health, encompassing eHealth and emerging areas such as the use of advanced computing sciences in big data, artificial intelligence, and robotics [8]. In this cross-sectional study, digital health is used to denote this broader concept, while digital health technologies refer specifically to applications of information and communication technologies, such as eHealth records, telephone, and videoconferencing, that support health care personnel in providing home-based PPC.

Digital health can help mitigate limitations in the availability and expertise of health care personnel providing home-based PPC by supporting communication, documentation, remote monitoring, collaboration, or training [4-7,9,10]. For example, real-time video consultation enables families to receive guidance from PPC specialists without traveling [4-7,10,11] while access to electronic health records supports targeted care planning [10,12-14]. Despite these benefits, challenges such as technical failures, poor connectivity, lack of interoperability, and concerns about data privacy limit effective use [4-6,14]. Moreover, health care personnel often perceive that technology cannot replace the therapeutic value of in-person care [4-7,14]. Consequently, the use of digital health technologies to support care in home-based PPC remains limited [4-7].

Health care personnel's digital health care literacy and attitudes toward digital health are critical for successful implementation [4,6,7]. Digital health care literacy refers to the ability to seek, understand, and use digital health technologies [15], while attitudes toward digital health technologies encompass perceptions and beliefs regarding their use in practice [16]. Limited digital health care literacy and inadequate training can reduce confidence and foster negative attitudes, whereas positive experiences and basic digital health care literacy may encourage adoption [16,17]. Understanding whether digital health care literacy is associated with attitudes toward technology could inform strategies to strengthen competence and increase technology use in home-based PPC.

In Norway, home-based PPC is publicly funded and provided by both primary and specialist health care services [18]. Approximately 8162 Norwegian children aged 0 - 19 years may require palliative care, based on estimates adapted from England [19], with 20% living with cancer, 40% with congenital genetic conditions, and 40% with neuromuscular diseases [20]. National PPC guidelines published in 2016 provide a framework for best practices, emphasizing shared responsibility between hospitals and municipalities, structured collaboration, respite care, and multidisciplinary teams [21]. Despite these recommendations, there is currently no national overview of how PPC is implemented or which health care personnel provide these services [19].

Parallel to these efforts, Norway's digital strategy and welfare technology program aim to integrate digital health into health care, including services for children [22]. In the Norwegian context, welfare technology typically encompasses digital tools and assistive technologies such as remote monitoring systems, communication platforms, safety alarms, and other digital health technologies that facilitate home-based care and reduce reliance on hospital services [22]. Successful integration requires time, resources, and collaboration among stakeholders, as emphasized in a Norwegian study [22]. Furthermore, improving the use of digital health technologies depends not only on the technology itself but also on the digital health care literacy of its users. According to the Digital Agenda for Norway, health care personnel with strong digital health care literacy are crucial for realizing the full benefits of digital health [23].

Norway faces a critical need to strengthen evidence on health care services for children requiring palliative care at home [19]. Although the national digital health strategy promotes technological integration, its potential remains largely unexplored in home-based PPC. Limitations persist in understanding health care personnel's use of digital health technologies, their digital health care literacy, and their attitudes toward digital health. Addressing these limitations is essential to ensure that digital health translates into meaningful improvements in home-based PPC. This cross-sectional study addresses these limitations by exploring current practices and perceptions, focusing on the use of digital health technologies in home-based PPC and the relationship between digital health care literacy and attitudes toward digital health. Results can inform Norwegian policy and contribute to the global discourse on digital health for home-based PPC and may also offer transferable strategies for improving home-based care supported by digital health technologies for other patient groups.

Methods

Study Design

An exploratory cross-sectional nationwide study was conducted using an online survey with a convenience sample to explore the use of digital health technologies, digital health care literacy, and attitudes toward digital health among health care personnel providing home-based PPC in diverse health care services in Norway. The online survey was launched on September 14, 2023, and remained open until May 3, 2024.

Reporting adheres to the STROBE (Strengthening the Reporting of Observational Studies in Epidemiology) [24,25] and the

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CHERRIES (Checklist for Reporting Results of Internet E-Surveys) guidelines [26].

Participants and Data Collection

The participants eligible for this study were medical, nursing, and allied health care personnel, including physiotherapists, occupational therapists, social workers, or psychologists, who were currently or previously involved in home-based PPC through primary (community-based) or specialist health care services (hospital-based).

The first author (JS) sourced the email addresses of health care personnel from the official websites of all, at the time, 356 Norwegian municipalities and sent the survey link with information about the study and an invitation to participate via email. The survey link was also distributed through the research network Children in Palliative Care (CHIP) [27], which the CHIP homeTec project [28] and, consequently, this study, is a part of. Additional recruitment was carried out via the official CHIP HomeTec Instagram account, the CHIP HomeTec blog, and newsletters distributed by national health care personnel associations.

The Online Survey and Measurements

The survey included selected items of the Norwegian Healthcare Personnel Survey on eHealth 2022 [29], the Digital Health Care Literacy Scale (DHLS) [15], the short version of the Information Technology Attitude Scales for Health (ITASH) [30,31], and demographic items, as shown in Table 1. Each section of the survey was displayed on a separate page in the digital survey tool.

Table . Overview of measures in the survey.

Scale and content	Items	Response scale
Norwegian Healthcare Personnel Survey on eHealth 2022		
Usage of digital health technologies when providing health care services	4	• Multiple choice questions with a single or multiple responses
Perceptions toward digital health care services	11	• Six-point Likert scale: 1=strongly disagree to 5=strongly agree, and 0=not relevant • Five-point Likert scale: 1=strongly disagree to 4=strongly agree, and 0=not relevant
Information Technology Attitude Scales for Health		
Subscale: care value of technology	4	• Four-point Likert scale: 1=strongly disagree to 4=strongly agree
Subscale: training in technology skills	6	• Four-point Likert scale: 1=strongly disagree to 4=strongly agree
Subscale: confidence in technology	6	• Four-point Likert scale: 1=strongly disagree to 4=strongly agree
Subscale: technology-related workload	5	• Four-point Likert scale: 1=strongly disagree to 4=strongly agree
Digital Health Care Literacy Scale[a]		
Items about installing apps/programs, using apps/programs, setting up video calls, and solving minor technical problems without relying on external assistance	4	• Five-point Likert scale: 1=strongly disagree to 5=strongly agree
One item about action when encountering a technical problem	1	• 1=ask someone for help and 2=try to solve the technical problem on my own – without help
Frequency of needing help with digital devices	1	• Five-point Likert scale: 1=always to 5=never
Demographic items		
Age, gender, profession, additional education, management experiences, workplace, geographical work location, and county of work	12	• Multiple-choice questions with a single response and 2 open-ended questions

[a]Sum score of six items (range 6-23). A higher score reflects a higher level of digital health care literacy.

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The Norwegian Healthcare Personnel Survey on eHealth

To explore the digital health technology use and perceptions, the Norwegian Healthcare Personnel Survey on eHealth 2022, assessing health care personnel's usage, perceptions, and satisfaction regarding digital health care services, was reviewed [29]. The survey comprised 29 items; of these, 15 were deemed relevant and included in this cross-sectional study, while 14 were excluded to avoid redundancy with the ITASH and DHLS scales (Table 1). The items examine how frequently and in what ways digital health technologies are used by the participants, as well as their perceptions of digital health care services. The included items used 6-point and 5-point Likert scales and multiple-choice responses. The Norwegian Healthcare Personnel Survey on eHealth was developed for the annual review of eHealth in the Norwegian health care services starting in 2019, but has not been validated.

ITASH

The short version of the ITASH was included to assess attitudes toward information and communication technology [30]. The instrument is translated and validated in Norwegian [32]. Permission for use was obtained from the developer [31,32]. ITASH comprises 21 items organized into 4 subscales that evaluate attitudes toward the care value of technology (4 items), training in technology skills and the desire for additional training (6 items), confidence in dealing with technology (6 items), and technology-related workload (5 items) (Table 1). All items are rated on a 4-point Likert scale, ranging from 1 = "strongly disagree" to 4 = "strongly agree." Each subscale's mean score is calculated and ranked, with higher scores on a scale from 1 to 4 indicating more positive attitudes toward digital health technologies. In this study, the Cronbach α for each subscale was 0.78 (care value), 0.77 (training), 0.87 (confidence), and 0.79 (technology-related workload), indicating acceptable internal consistency for the ITASH subscales.

Digital Health Care Literacy Scale

The Digital Health Care Literacy (DHLS) scale was developed and validated by Nelson et al [15] to assess the foundational digital health care literacy of caregivers of children receiving care at a pediatric clinic. The items were designed to be theoretically applicable to a wide range of individuals [15]. Foundational digital health care literacy encompasses the basic abilities and knowledge necessary to confidently and efficiently use digital technologies and navigate the digital platforms used in health care [15]. With permission from the developers of DHLS, the CHIP homeTec research group translated the scale from English into Norwegian using a forward-backward method [33]. To explore the relevance of the DHLS scale in a Norwegian context, all 6 items were included. Although previous research indicates a model with 3 items may be sufficient [15], we chose to retain all 6 items because this was the first time the scale was applied in Norway, and a comprehensive approach was necessary to assess its applicability in a later, separate evaluation. The 6 items (Table 1) evaluate confidence in using technological programs or services, as well as the ability to troubleshoot technical issues [15]. Following the syntax for DHLS scoring, responses to item 5 were recoded from 0 to 1 and 1 to 3, to align with other variables from this scale before calculating the total sum score [15]. The DHLS items were scored by summing all 6 items, resulting in a total DHLS sum score ranging from 0 to 23 [15]. A higher DHLS sum score indicates a higher level of digital health care literacy. In this study, the Cronbach α reliability coefficient for the DHLS scale was 0.86.

Demographic Characteristics

Demographic characteristics included age, gender, profession, additional education, management experiences, workplace, geographical work location, and county of work (Table 1). Participants were asked to report their age because it may influence health care personnel's attitudes toward digital health technologies due to differences in technological familiarity and comfort levels [34]. Workplace (categorized as either primary or specialized health care services) and geographical work location (determined by the associated driving distance) are considered organizational factors that may influence the attitudes of health care personnel [7,35,36]. Lastly, we included a variable for prior use of real-time video consultation, which participants reported as either "yes" or "no," with "yes" denoting previous experience that may influence their attitudes toward digital health technologies [37].

To simplify the presentation and analysis of the participants' characteristics, some variables were recoded. The variables nurse (36/148, 24.3%), public health nurse (6/148, 4%), and social educator (6/148, 4%) were combined under the term nurse due to their similar responsibilities within nursing, including clinical care, public health, and health education. The variable county was collapsed into the 4 regional health authorities, which are widely recognized throughout Norway, reducing the number of categories from 11 counties (the number of counties in Norway as of 2023) to 4 categories.

Furthermore, the participants' workplaces were recategorized into the dichotomous variables of primary care and specialist care. General practitioners (3/148, 2%) were included in the primary care category, while private health care services (2/148, 1.35%) and others (3/148, 2%) were excluded from the bivariate Pearson correlation (r) analysis due to the small sample sizes, which would not provide reliable statistical power for the analysis [38].

The survey underwent pilot testing by the CHIP homeTec network members, comprising professionals from diverse disciplines [28]. This pilot phase aimed to gather reflections on the relevance, comprehensiveness, and overall balance of the items used [38].

Statistical Analysis

Missing values were not imputed due to the exploratory nature of the study, and incomplete questionnaires (participants responding to less than 80% of the items) were excluded (2/150, 1.3%) [39]. All other responses were included using SPSS's pairwise deletion function, which excludes cases only when they have missing values for the specific analysis being conducted [39]. Multiple entries to the survey were not a concern in this study, and no responses were withdrawn.

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Categorical data are reported as frequencies (percentages), while continuous data are reported as mean (SD) if normally distributed and as median (IQR) if skewed. Pearson *r* was applied to examine the associations between the DHLS sum score and the variables of age, workplace, and prior use of real-time video consultation, as well as between the ITASH subscales and the same variables [39]. An analysis of variance (ANOVA) was used to determine whether there were statistically significant differences between the DHLS sum score and attitudes toward digital health technologies (ITASH subscales) among health care personnel based on the variable of work location, with associated driving distances. Bivariate statistics were used to explore the relationships between pairs of variables.

Both unadjusted and adjusted linear regression analyses were conducted to explore the association of the DHLS sum score with the 4 ITASH subscales, with the adjusted analysis accounting for demographic characteristics. The results are presented with coefficients (β), 95% CI, and *P* values. Statistical significance was set at $P \leq .05$ for 2-tailed comparisons. The data were analyzed using the Statistical Package for the Social Sciences (SPSS), version 29.

Ethical Considerations

This study was reviewed by the Norwegian Agency for Shared Services in Education and Research (reference number 657413) to ensure that well-considered information was provided to the participants and that the processing of personal data complied with data protection regulations and maintained the privacy of the participants. Consent forms and survey responses were separately stored in 2 distinct files to guarantee data deidentification and to uphold participant anonymity during the data analysis. Data collection was handled by the Nettskjema tool, a survey solution developed and hosted by the University of Oslo [40]. The data were subsequently stored in the Services for Sensitive Data system, which is specifically designed to handle and safeguard sensitive information following data protection regulations [41]. The initial page of the survey provided participants with accessible information about the research project, encompassing its objectives and highlighting their voluntary participation and the endeavors taken to secure the project data. Participants were given information about the study and required to provide digital consent via a Norwegian ID on the second page before proceeding to the survey on the third page.

Results

Sample Characteristics and the Use of Digital Health Technologies

Most respondents were female (140/148, 94.6%), with ages ranging from 25 to 67 years and a median age of 45 (37-52) years. Diverse professions were represented, with the largest group being physiotherapists (56/148, 37.8%), followed by nurses (48/148, 32.4%). The vast majority worked in primary care (117/144, 81.3%). The geographical distribution of respondents was 36.4% (51/140) from small towns with moderate driving distances, 34.3% (48/140) from rural areas with long driving distances, and 29.3% (41/140) from towns with walking distances or short drives Table 2.

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Table . Demographic variables and reported use of digital health technologies.

Variables	Values
Age in years (n=142)[a], median (IQR)	45 (37-52)
Sex (n=147)[a], n (%)	
Female	140 (94.6)
Profession (N=148), n (%)	
Physiotherapist	56 (37.8)
Nurse[b]	48 (32.4)
Occupational therapist	23 (15.5)
Physician	11 (7.4)
Other	10 (6.8)
Workplace[c] (n=144)[a], n (%)	
Primary care[d]	117 (81.3)
Work location with associated driving distance (n=140)[a], n (%)	
Small town, moderate driving distance	51 (36.4)
Rural, long driving distance	48 (34.3)
Town, walking distance or short drive	41 (29.3)
Regional Health Authorities Norway (N=148), n (%)	
South-Eastern	82 (55.4)
Western	27 (18.2)
Central	22 (14.9)
Northern	17 (11.5)
Reported use of digital health technologies (n=144)[a], n (%)	
Prior use of real-time video consultation (yes)	72 (50)
Primary communication tools with other care providers, n (%)	
Phone: very often or sometimes (n=145)[a]	138 (95.2)
Digital messaging: very often or sometimes (n=146)[a]	125 (85.6)
Real-time video consultation: very often or sometimes (n=143)[a]	61 (42.7)
Digital access to patients' electronic health records from other health care services (n=142)[a], n (%)	
Very small extent or small extent	79 (55.6)
Neither large nor small extent	31 (21.8)
Very large extent or large extent	32 (22.5)
Digital health care services with patients are in addition to in-person care (n=135)[a], n (%)	
Strongly agree or agree	126 (93.3)
Could your most recent physical patient contact have been replaced if available? (N=148), n (%)	
With real-time video consultation (yes)	29 (19.6)
With phone (yes)	13 (8.8)
With digital messaging (yes)	9 (6.1)
Require more options for digital health care services with patients (yes) (n=127)[a], n (%)	96 (75.6)

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Variables	Values
Require more options for digital communication or digital health services with other care providers (yes) (n=135)[a], n (%)	120 (88.9)

[a]Totals may not sum to 148 due to item non-response

[b]Includes public nurses (6/49) and social educators (6/49).

[c]Primary care or specialized care.

[d]Includes general practitioners (3/117).

Half of the respondents (72/144, 50%) reported prior experience with real-time video consultation. Phone calls were the most frequently used modality to communicate with other health care personnel who were engaged in the care of the child and family (138/145, 95.2%), followed by digital messaging (125/146, 85.6%). About half of the respondents reported having limited or minimal access to patients' electronic health records from other health care services (79/142, 55.6%). Most respondents (126/135, 93.3%) agreed that digital health care services should be supplementary to in-person care. Only a minority reported that their most recent physical patient contact could have been replaced with real-time video consultation (29/148, 19.6%), phone calls (13/148, 8.8%), or digital messaging (9/148, 6.1%) if available. Furthermore, a large proportion of the respondents required more options for digital communication and digital health care services, both with patients (96/127, 75.6%) and other health care personnel (120/135, 88.9%; Table 2).

Digital Health Care Literacy and Attitudes Toward Digital Health Technologies

The total sample DHLS mean score was 18.29 (SD 3.8). The ITASH subscale care value of technology displayed the highest mean score (mean 3.17, SD 0.39), followed by training in technology skills and the desire for additional training (mean 3.16, SD 0.43), confidence in dealing with technology (mean 2.55, SD 0.52), and reported technology-related workload (mean 1.95, SD 0.42) (Table 3).

The analysis showed a statistically significant negative correlation between the DHLS sum score and age (r=−0.485; P<.001). Additionally, there was a statistically significant negative correlation between ITASH confidence and workplace (r=−0.221; P=.008; Table 3). Other correlations were not statistically significant.

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Table . Bivariate statistics to explore the correlation between the Digital Health Care Literacy Scale, Information Technology Attitude Scales for Health subscales, and demographic data.

Variables	DHLS[a,b] score	ITASH[c,d] Care value	ITASH Training	ITASH Confidence	ITASH Technology-related workload
Total sample, mean (SD), n	18.29 (3.8), 142	3.17 (0.39), 146	3.16 (0.43), 147	2.55 (0.52), 146	1.95 (0.42), 144
Age					
Participants, n	137	140	141	141	138
r[e]	*–.485*[f]	–.129	–.004	.031	.149
P value	<.001	.13	.96	.72	.08
Workplace					
Participants, n	138	142	143	142	140
r[e]	–.026	–.030	.153	*–.221*[f]	.010
P value	.76	.72	.07	.008	.90
Real-time video consultation					
Participants, n	138	142	143	142	140
r[e]	–.106	–.038	.030	–.008	.156
P value	.21	.65	.72	.92	.07
Work location with driving distance, mean (SD), n					
Small town, moderate driving distance	18.29 (4.19), 48	3.25 (0.43), 51	3.18 (0.41), 51	2.58 (0.30), 51	1.90 (0.40), 51
Rural, long driving distance	18.02 (3.93), 47	3.11 (0.39), 47	3.17 (0.47), 47	2.51 (0.18), 48	1.90 (0.45), 45
Town, walking distance or short drive	18.97 (3.62), 39	3.17 (0.33), 40	3.17 (0.43), 41	2.55 (0.25), 39	2.05 (0.42), 40
P value between groups[g]	.52	.19	1	.45	.20

[a]DHLS: Digital Health Care Literacy Scale.

[b]DHLS score: sum score of 6 items (min-max: 6 - 23). Higher scores reflect a higher level of digital health care literacy.

[c]ITASH: Information Technology Attitude Scales for Health.

[d]ITASH: 4-point Likert scale 1=strongly disagree to 4=strongly agree.

[e]Pearson *r*.

[f]The correlation is significant at a significance level of ≤.05 (2-tailed).

[g]*P* values calculated by ANOVA.

The DHLS score was significantly associated with the ITASH subscale care value, in both the unadjusted (β=0.030, 95% CI 0.014-0.047) and adjusted (β=0.034, 95% CI 0.014-0.054) analyses (Table 4). This suggests that, when accounting for other factors, each one-point increase in the DHLS score is associated with an average increase of 0.034 points in the ITASH subscale care value score. The associations between the DHLS score and the ITASH subscales of training, confidence, and technology-related workload were not statistically significant.

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Table . Digital Health Care Literacy Scale sum score associated with attitudes toward digital health technologies (Information Technology Attitude Scales for Health subscales).

	DHLS score			
	ITASH[a] Care value[b]	ITASH Training[b]	ITASH Confidence[b]	ITASH Technology-related workload[b]
	Unstandardized B (95% CI)	Unstandardized B (95% CI)	Unstandardized B (95% CI)	Unstandardized B (95% CI)
Unadjusted	.030[c] (0.014 to 0.047)	.001 (–0.018 to 0.019)	–.002 (–0.013 to 0.009)	–.017 (–0.035 to 0.002)
P value	<.001	.92	.70	.07
Adjusted[b]	.034[c] (0.014 to 0.054)	.005 (–0.017 to 0.027)	–.008 (–0.020 to 0.003)	–.011 (–0.033 to 0.011)
P value	<.001	.68	.16	.33

[a]ITASH: Information Technology Attitude Scales for Health.

[b]Adjusted linear regression analysis with control for age, prior use of real-time video consultation, work location with associated driving distance, and workplace.

[c]Statistical significance at .05 (2-tailed).

Discussion

Principal Results

This study describes the use of digital health technologies, digital health care literacy, and attitudes toward digital health among health care personnel in diverse home-based PPC services. Half of the respondents had experience with real-time video consultation, while phone calls and digital messaging were the primary communication methods in and between health care services. More than half of the respondents had limited or minimal access to electronic health records from other health care services involved in the child's care. The results also indicate that health care personnel perceive digital health technologies for remote home-based PPC as a supplement rather than a replacement for in-person care. However, the health care personnel in this study warrant more options for digital health to enable and support their interaction with children, families, and other care providers. The sample showed high digital health care literacy and positive attitudes toward digital health technologies. A statistically significant but weak association was identified between digital health care literacy and positive attitudes toward digital health technologies in supporting home-based PPC.

Interpretation

Although the measured association in this study was weak and the direction of the association remains unclear due to the cross-sectional design [38], both digital health care literacy and attitudes toward digital health technologies appear to be important factors in the use of digital health technologies [10,17,37]. Even if digital health care literacy does not strongly or directly influence attitudes, its combined role in shaping health care personnel's ability and willingness to use digital health technologies should not be ignored. A high level of digital health care literacy may enable health care personnel to use digital health technologies more effectively, while positive attitudes toward digital health may drive engagement and openness to learning new digital skills [17,37,42]. This underscores the need for targeted activities to support both digital health care literacy development and positive attitudes toward digital health. Training programs, institutional support, and user-friendly technology design may ensure that health care personnel feel both confident and motivated to use digital health technologies in home-based PPC [17,37,42].

Furthermore, the reported limited use of digital health technologies, combined with health care personnel's requests for more digital health solutions, is noteworthy. These results may indicate that existing digital health technologies do not adequately meet their requirements for user-friendliness and seamless interoperability [10,14]. To address these challenges, engaging health care personnel in the needs assessment and design process of digital health can result in the creation of practical and valuable solutions that can enhance the quality of life for children with life-threatening and life-limiting conditions, as well as their families [4]. Additionally, to ensure seamless integration between different electronic health records and to avert connectivity issues for remote monitoring, it is crucial to establish the necessary infrastructure [4,12-14,17]. Ultimately, health care institutions should acknowledge the necessity of a robust infrastructure and an involving and supportive environment as their responsibility, rather than placing the burden on health care personnel in clinical practice [17,37].

The majority of health care personnel indicated that their last contact could not be replaced with technology and that digital health technologies should serve as a supplement rather than a replacement for in-person care. This hesitation to use digital health technologies instead of a physical presence is well documented in research on home-based PPC [4,6,7,12,14] and may be attributed to the unique nature of PPC, which addresses the physical, psychological, and spiritual needs of children and their families [1]. Additionally, this perception may partly reflect behavioral tendencies, as individuals often assume that established practices cannot be replaced until they experience alternative approaches [17]. Evidence suggests that attitudes toward real-time video consultation shift after direct exposure, indicating that initial resistance may not represent permanent barriers [35]. Similarly, the use of digital health technologies might affect health care personnel's identities, values, and the perceived quality of patient care, as it may conflict with their

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commitment to providing holistic, compassionate, and personalized care [4,6,7]. This tension can lead to reluctance, as health care personnel may see digital health technologies as impersonal [5-7]. However, research shows that using health technology over time, or multiple in-person visits before introducing it, can help overcome doubt and foster familiarity and acceptance [36]. The gradual integration of digital health technologies may provide health care personnel with experiences that demonstrate how its use can align with their values, thereby supporting its implementation in practice. Additionally, health care personnel's hesitation to use digital health technologies may be reduced by expanding their digital health care literacy beyond basic digital skills through targeted training programs [37,42]. Health care institutions should emphasize the importance of allowing sufficient time for health care personnel to adapt to new technologies and offer training that also focuses on developing social interaction, communication skills, self-reflection, and creativity [37,42]. Through this approach, digital health might support home-based PPC to be secure, collaborative, and effective.

Strengths and Limitations

The major limitation of this study is the use of convenience sampling, which is associated with a lack of representativeness and potential selection bias [38]. Additionally, the relatively small sample size limits the generalizability of the results [38]. These factors should be considered when interpreting the results.

The distribution of the survey through email and social media raises concerns about potential bias, favoring those with digital access and higher digital health care literacy. This could skew the data from respondents and fail to represent non-respondents [26]. Furthermore, the survey did not capture the extent to which respondents were involved in providing home-based PPC. Participants were eligible if they provided care to children with life-threatening and life-limiting conditions in home, school, or respite settings, which may include varying levels of involvement. This variability could influence responses and should be considered when interpreting the results.

A strength of this study is the inclusion of different clinical health care personnel, including nurses, physicians, physiotherapists, and occupational therapists, from both primary and specialized services, as well as participants from various geographical regions across Norway. Thus, this study offers an overview of the nationwide use of digital health technologies among health care personnel providing home-based PPC. This study stands out as one of the first to gather responses not only from nurses and physicians [17] but also from physiotherapists and occupational therapists, who play essential roles in the interdisciplinary care team [1]. Regarding participation, 338 visits to the first page with information about this study, 198 people consented to participate, and 148 questionnaires were completed. The completion rate, defined as the ratio of individuals who submitted the final questionnaire page to those who agreed to participate [26], was about 75%. This indicates engagement and a willingness to participate among those who consented.

The focus of this study was placed on reporting the applicability for health care personnel providing home-based PPC rather than generalizability [38]. However, the eligibility criteria of the target population, combined with the description of the sample, should provide the reader with a rich understanding of the respondents and context, helping to discern whether the results would be applicable in their practice. The predominance of female participants reflects the gender distribution among health care personnel in Norway [43]. While this limits the ability to explore gender-related differences, it does not necessarily indicate a sampling bias, given the professional context.

This survey included a set of validated and/or previously used items and instruments, which is a strength of our work. We avoided overlap by removing items from the Norwegian Healthcare Personnel Survey on eHealth 2022 in favor of items from ITASH. However, the scale measuring digital health care literacy was translated into Norwegian specifically for this study and has not been used in Norway or among health care personnel before. It serves as an initial attempt to explore digital health care literacy alongside attitudes toward digital health in home-based PPC. Future research is needed to fully explore these phenomena.

Conclusions

This study explored the use of digital health technologies by Norwegian health care personnel in home-based PPC and the association between their digital health care literacy and attitudes toward digital health. Despite high digital health care literacy and positive attitudes, the results indicated limited use of digital health technologies. This suggests that inadequate digital health solutions may create obstacles to their effective use in home-based PPC. Addressing these barriers is critical to enhancing the use of digital health technologies in home-based PPC.

Future research should explore how health care institutions can better integrate digital health technologies into their infrastructure and workflows. Additionally, research should examine behavioral factors that shape health care personnel's perceptions, particularly how their attitudes evolve after direct experience with digital health technologies. Research can also explore how social interaction, communication, and personalized care can be effectively applied in combination with digital health. The goal is to ensure that home-based PPC supported by digital health does not compromise the quality of care provided to children and their families.

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Data Availability

The data sets used and analyzed during this study are in Norwegian and are available from the corresponding author upon reasonable request.

Authors' Contributions

JS, KR, and HH designed this study. JS collected and analyzed the data, wrote the original draft, and participated in writing, reviewing, and editing the article. KR and HH critically reviewed and edited the article multiple times.

Conflicts of Interest

None declared.

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Abbreviations

CHERRIES: Checklist for Reporting Results of Internet E-Surveys
CHIP: Children in Palliative Care
DHLS: Digital Health Care Literacy Scale
ITASH: Information Technology Attitude Scales for Health
PPC: Pediatric palliative care
STROBE: Strengthening the Reporting of Observational Studies in Epidemiology

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Requirements for mHealth and Augmented Reality Apps for Patient Education Regarding Colorectal Cancer Surgery: Focus Group Study

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Abstract

Background: The purpose of preoperative informed consent is to provide patients with comprehensive information about their treatment, including risks and alternatives, to enable informed decision-making. However, studies have shown that patients are often unable to understand or remember important information. Mobile health (mHealth) and augmented reality (AR) apps have been identified as promising solutions to improve patient education and knowledge retention.

Objective: This study aims to identify the essential requirements for an mHealth app to support informed decision-making for patients with colorectal cancer, with a specific focus on the potential of AR for visualization. This research explores the patient and physician perspectives on these requirements, particularly regarding information delivery and visualization to guide app design.

Methods: A qualitative focus group study was conducted with groups of mostly patients with colorectal cancer and a physician's group. Topics related to patient education were discussed, guided by a semistructured interview guide covering personal experience; information content; context of use; and acceptance and presentation of content, which included presenting various visualizations in 2D, 3D, and AR. The interviews were transcribed and analyzed using qualitative content analysis.

Results: We conducted 4 focus groups with patients (n=23) and 1 focus group with physicians (n=7), for a total of 30 participants. Relevant informational content for the app and its presentation was identified. Patients consistently expressed a desire for personalized, detailed, and visual information about their condition and treatment tailored to their specific case throughout the treatment journey, so they could prepare for the informed consent discussion after diagnosis, prepare for treatment, access guidance and track progress during hospitalization, and access information and resources during recovery after treatment. Patients demonstrated a strong preference for interactive 3D visualizations, while physicians favored simpler 2D images that could be easily integrated into their existing workflow. AR visualizations were seen as a potential tool to provide a general overview of anatomy and surgical approaches but more as a novelty feature and a supplement to more traditional visualizations.

Conclusions: An ideal patient education app combines comprehensive content with interactive, customizable visualizations like 3D models and AR and should be accessible throughout a patient's treatment journey. This study highlights the need for a patient-centered design that balances detailed information with ease of understanding and considering different preferences for visualization modalities and levels of detail.

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KEYWORDS

informed consent; patient education; augmented reality; mixed reality; mHealth; smartphone; tablet; qualitative research; colorectal cancer

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Introduction

The purpose of preoperative informed consent is to provide the patient with a comprehensive explanation of the significance and scope of the proposed treatment, including treatment alternatives and the associated risks to enable them to make an informed decision [1]. Patient empowerment through education and informed decision-making has been shown to improve perioperative quality of care and increase patient satisfaction and compliance [2-4]. Physicians are often constrained by limited time, while the length of the conversation is the primary factor affecting comprehension [5]. In addition to the informed consent discussion, information sheets are provided to convey the information from the consultation. However, analyses have indicated that the text and images used in these sheets are unsuitable for supporting an informed decision [6]. Despite signing consent, most patients are not able to recall explanations about risks or alternative treatment options [7].

As colorectal cancer is the third most common form of cancer [8], it is essential to explore the challenges patients face in retaining knowledge about their condition. The experiences and perceptions of patients with colorectal cancer emphasize the need for individualized information that is tailored to their unique circumstances [9]. Mobile health (mHealth) refers to the use of mobile devices, such as smartphones and tablets, to support medical and public health practice [10], including the use of mobile apps for diagnostics and clinical decision-making, behavior change interventions, digital therapeutics, and apps that deliver disease-related education [11]. The increasing adoption of mHealth technologies offers a promising solution to improve patient education and address the need for personalized information [11,12]. mHealth platforms like apps for smartphones and tablets can provide patients with timely, relevant, and accessible information, leading to increased knowledge for patients compared with traditional educational practices [13,14].

It has been shown that the use of augmented reality (AR) apps—specifically displaying 3D models on a tablet in an AR setting by superimposing the 3D anatomical object onto the tablet's camera video image, as if it were in the real world—as a supplement to traditional patient information leads to a better understanding and greater retention of the knowledge compared with 2D representations [15]. The use of AR in patient education also resulted in increased patient satisfaction and better health outcomes, as it has the potential to make learning more engaging and reduce cognitive load [16].

One form of AR technology is AR mirror systems, which use a mirror-like interface to display virtual information on top of a user's camera image. In the context of anatomy education, AR mirrors have the potential to enhance learning by providing interactive 3D models of the human body [17-19]. So far, it has only been used in anatomy teaching for medical students.

This study used a qualitative approach using focus group interviews with patients and physicians to identify the essential requirements for an mHealth smartphone or tablet app to support informed decision-making for patients with colorectal cancer, with a specific focus on the potential of AR mirrors for visualization. This research explored the patient and physician perspectives on these requirements, particularly regarding information delivery and visualization to guide app design.

Methods

Ethical Considerations

The study was approved by the ethical review board of the Carl von Ossietzky Universität Oldenburg (registration number: 2021 - 147) and was conducted in accordance with the Declaration of Helsinki [20]. All participants provided written informed consent prior to participation, and no compensation was offered. The study data, including video transcripts and questionnaires, are deidentified. Video recordings were transcribed, with participant names replaced with abbreviations, leaving only deidentified transcripts after deletion of the video.

Methodological Approach

We used the human-centered design process, which is an iterative process focused on understanding user needs for interactive systems [21]. We used qualitative research with focus groups to achieve the initial steps of understanding and defining the context of use and defining user requirements. A focus group is a carefully planned discussion where participants share and comment on a defined topic [22] from personal experience and leads to rich insights about perceptions, thoughts, feelings, and impressions [23,24]. A moderator facilitates open, uninhibited dialog by using a nonprescriptive, semistructured approach supplementing prepared questions while also being receptive to relevant issues raised by participants [23]. The focus groups were conducted between July 2022 and September 2023.

Data Collection

The focus groups were designed as semistructured group discussions, with an interview guide provided to assist the moderators and ensure consistency across discussions. All focus groups followed the same interview guide, with items adapted to physicians and patients to allow patients to speak from experience and physicians to report information they considered most important for patients. The individual items consisted of specific questions as well as stimuli in the form of statements or illustrations, which were intended to encourage a natural discussion [25]. See Multimedia Appendix 1 for the full interview guide. The interview guide addressed the following topics: personal experience with patient education (how the patient education took place and the typical procedure), information content topics: (content that is helpful and important from participants' experience and gaps in patient education content), presentation of content (how the treatment is visualized), context of use (in which environment and with which people an app would be used), and acceptance (general opinion about the use of an app for patient education and factors that could lead to higher use).

As an incentive, the participants were presented with different types of visualization. The *Visualizations and AR Prototype* section provides a detailed description of the visualizations. The visualizations were presented sequentially, starting with the 2D images, progressing to the 3D model, and concluding with the AR mirror visualization developed for this study.

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Participants were given time to examine each visualization and discuss their impressions. The moderators asked questions about the possible advantages and disadvantages of each option.

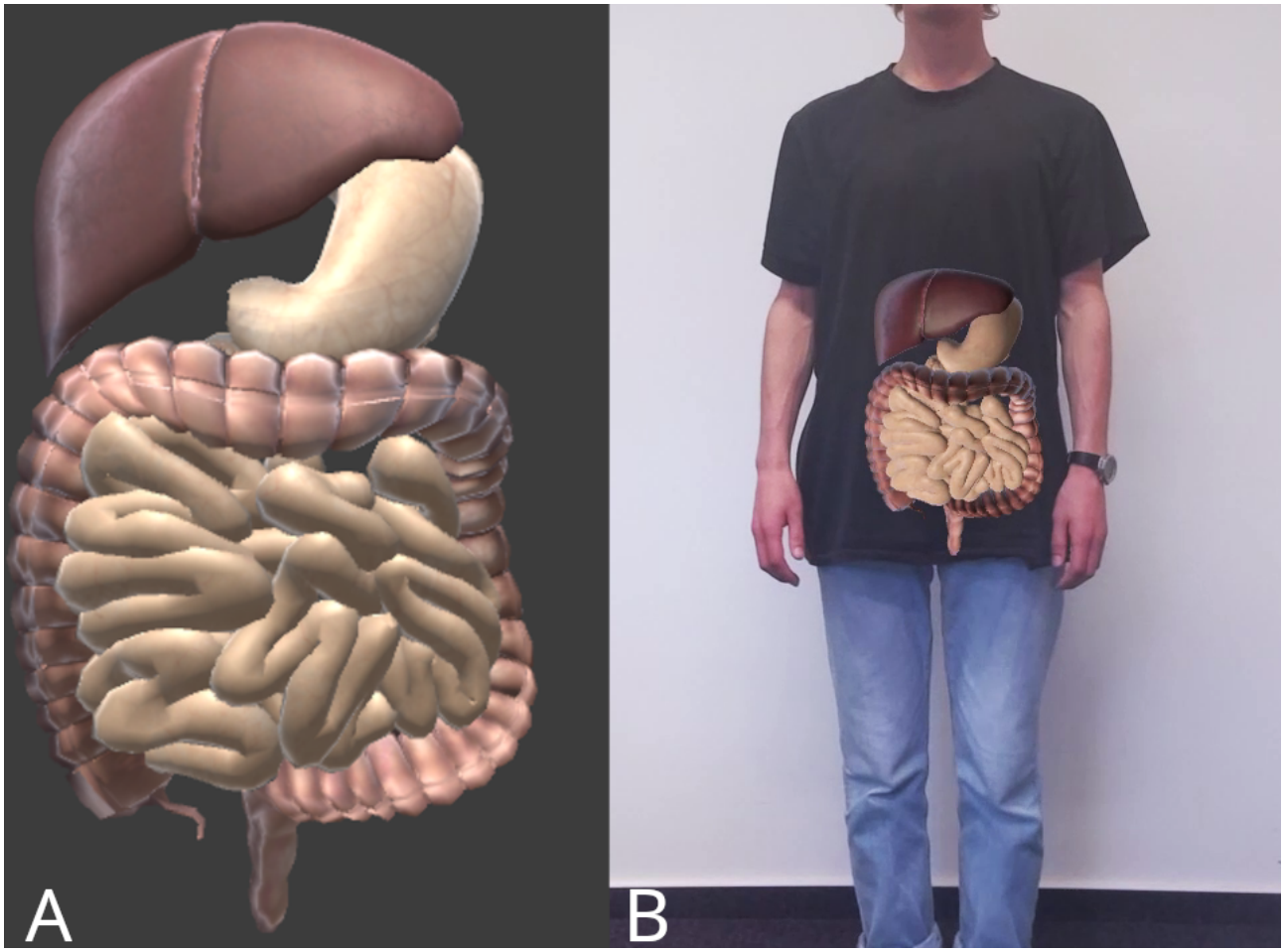
To foster an open and uninhibited atmosphere, participants were encouraged to freely express their thoughts, with the assurance that there were no incorrect responses. The questions and stimuli were presented via the use of a projector. Following the discussion, all participants were requested to complete a questionnaire regarding demographic data (age, gender) and a standardized questionnaire for technical commitment by Neyer et al [26]. This 12-item questionnaire uses a 5-point Likert scale to assess the willingness to use technology in terms of technology acceptance, competence, and control. Smartphone and tablet use were also assessed via self-reporting using a 5-point Likert scale ranging from *never* to *always* (see Multimedia Appendix 2).

The focus groups were conducted in various locations, including a meeting room at a hospital (group 1), a meeting room at the university (groups 2 - 4), and a seminar room at a rehabilitation hospital (group 5). The focus groups were conducted by the same two moderators, except for group 3, which was conducted by only one of the moderators. Audio and video recordings were made of all focus groups. The video recordings were used solely to more accurately assign the audio track to the participants.

Visualizations and AR Prototype

The visualizations used in the focus groups consisted of colored, detailed drawings of only the colon [27] and the colon with its surrounding anatomy [28], as well as less detailed, black-and-white drawings from the informed consent form [29], which also depicted only the colon and the colon with its surrounding area. Additionally, raw, unannotated sample magnetic resonance imaging (MRI) scans [30] were shown. Participants were also shown a rotatable general 3D surface model of the digestive system (see Figure 1A) and the same 3D model projected with AR onto the body (see Figure 1B).

Figure 1. (A) Rotatable 3D model of the digestive system (liver, stomach, small intestine, large intestine) and (B) augmented reality (AR) 3D model projected on a body.



The AR visualization was developed and integrated into a custom-built app on a tablet. Within the app, users positioned themselves in front of the device and viewed themselves through the front camera. The tablet's camera captures the user and projects an organ model of the digestive system onto their body. The first marker-based prototype, developed with Unity 2021.3 and the EasyAR framework 4.5.0, was used in groups 1 and 2. Participants positioned a paper marker at their abdomen. The app recognized the marker and displayed the organ model accordingly.

The second prototype did not depend on the use of a marker. It was developed with Unity 2022.3 and used the MediaPipe Unity plugin. MediaPipe offers a pose-tracking solution that outputs 3D coordinates for certain body key points from the camera

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image [31]. The 3D organ model is placed and aligned using the pelvis and shoulder key points. A Samsung Galaxy Tab S6 Lite Android tablet was used for both prototypes.

Participants and Recruitment

The study was conducted with ad hoc groups in order to minimize the risk of pre-existing relationships influencing the discussion, as pre-existing groups may have established dynamics and be affected by formal or informal hierarchy [22]. Groups were specifically formed to be homogeneous to avoid complications from mixing physicians and patients. This approach promotes stronger identification and unity within the groups while preventing the emergence of hierarchies, as status differences can contribute to inhibited participation and can stifle open discussion [32].

Participants were required to be patients who had previously undergone surgery for colorectal cancer, thereby facilitating their understanding of what information was essential and what they wished they had known about the treatment. Preoperative patients were excluded, because they are difficult to reach due to the worries and anxiety associated with their upcoming surgery.

Patients were identified from the hospital patient database, which included approximately 1300 cases. The database was screened for patients who had undergone surgery within the past 5 years and who were 65 years of age or younger. These candidates were contacted via telephone. The response rate for telephone recruitment was low; only 1 participant agreed. Therefore, patients with Crohn disease were also included in the first group, as the surgical procedures (eg, colectomy and stoma formation) [33,34] and the postoperative experiences (eg, bowel function changes, stoma care, and recovery challenges) are comparable. In addition, patients were recruited through an open participation call published in a local newspaper. Those who expressed interest in the study were provided with the relevant information via email. Additionally, a collaboration was sought with a rehabilitation clinic that houses a colorectal cancer center to create a group of patients currently undergoing rehabilitation. Flyers were placed in the patients' mailboxes to achieve this.

Inclusion criteria for physicians included regularly providing patient education about colorectal cancer. Physicians were directly engaged by presenting the study during the hospital's morning meeting and inviting interested physicians to contact the research team to schedule participation.

Data Analysis

The recordings were transcribed using the content-semantic transcription method [35]. All transcripts were revised and corrected, and the participants' identities were anonymized during this process. The transcripts were analyzed using the 7-phase framework of content-structuring qualitative content analysis by Kuckartz [36]. In this multistage process, the following main categories were first derived as a priori categories from the thematic categories of the interview guide: personal experiences, information content topics, presentation of content, context of use, and acceptance. The material was initially coded using these main categories, which led to the emergence of an additional main category "features." Next, the text segments corresponding to each main category were summarized, and subcategories were inductively formed for all main categories except "features," as no further subdivision could be determined. These categories were discussed by two persons until consensus was reached. The material was coded again using the differentiated categories in a second coding process. All text segments were reviewed again and, based on their level of generality, assigned to subcategories or, when appropriate, to the main categories. The transcription and coding processes were conducted using MAXQDA 2024 [37]. To determine the sentiment regarding the visualization modalities, a sentiment coding scheme was used. Text segments related to each visualization modality were identified and coded on a 5-point scale, ranging from "--" (strongly negative) to "++" (strongly positive), reflecting the overall sentiment expressed by the participants. The evaluation not only took into account the participants' explicit wishes but also analyzed which aspects of the disease, treatment, and patient education the participants disclosed and expressed interest in. Statements from patients and physicians were considered separately to address the research questions and to account for the distinct needs of these two groups. Technical commitment scores were calculated for each participant by summing the answers on the 1 - 5 Likert scale for the 12 items. The mean technical commitment score was then calculated for each group. For smartphone and tablet use, the mean value of the 1 - 5 Likert scale was also calculated for each group.

Results

Sample Characteristics

A total of 89 patients and 18 physicians were contacted directly to take part in the study, and 27 patients responded to the call for participation in the newspaper. We conducted 5 focus groups (see Table 1) with a total of 30 participants: 4 groups consisted of patients (n=23; 15 women, 8 men) who were previously diagnosed with colorectal cancer, with the exception of 2 participants in group 2 who had Crohn disease, and 1 group consisted of physicians (n=7; 3 women, 4 men).

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Table . Demographic characteristics and questionnaire results by focus group (5 focus groups) for participants (7 physicians and 23 patients) in a qualitative study conducted between July 2022 and September 2023 at a hospital, university, and rehabilitation clinic exploring requirements for a mobile health (mHealth) app for patient education about colorectal cancer.

Members	Focus group number	Participants, n	Age (years), mean (SD)	Gender	Technical commitment score, mean (SD)	Smartphone use (1-5), mean (SD)	Tablet use (1-5), mean (SD)
Physicians	1	7	35.6 (6.3)	3 women, 4 men	43.7 (7.2)	4.17 (0.41)	3.33 (0.82)
Patients (entire patient sample)	2 - 5	23	61.0 (11.9)	15 women, 8 men	39.5 (6.3)	4.23 (0.81)	3.56 (0.78)
Patient subset (CRC[a] and CD[b])	2	3	57.7 (7.6)	3 women, 0 men	38.3 (11.0)	4.67 (0.58)	3.00 (0)
Patient subset (CRC)	3	4	69.3 (10.8)	2 women, 2 men	41.7 (7.0)	4.33 (0.58)	3.67 (0.58)
Patient subset (CRC)	4	5	67.2 (11.1)	3 women, 2 men	38.8 (6.7)	3.80 (1.10)	3.40 (1.14)
Patient subset (CRC)	5	11	56.9 (12.3)	7 women, 4 men	39.6 (5.5)	4.27 (0.79)	3.75 (0.71)

[a]CRC: colorectal cancer.

[b]CD: Crohn disease.

A total of 28 participants completed the questionnaire. The mean technical commitment scores were 39.5 (SD 6.3) for patients and 40.4 (SD 7.2) for physicians.

Of the participants, 96% (27/28) reported using their smartphones at least occasionally (smartphone use≥3). Similarly, most of the physicians (5/6, 83%) and patients (17/22, 77%) also reported using a tablet at least occasionally (tablet use≥3). The frequency of smartphone use exceeded that of tablet use among both groups.

Category Overview

The analysis identified 23 subcategories organized according to the main categories and were mainly derived from the interview guide (see Table 2). The “features” category was added during the first coding process, reflecting participants’ feedback regarding desired app functionalities. The analysis was structured around the main categories described in the following paragraphs.

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Table . Categories derived from qualitative content analysis of focus group interviews with patients with colorectal cancer and physicians regarding requirements for a mobile health (mHealth) app for patient education.

Main category	Subcategories
Personal experiences[a]	• Course of the disease • Information-seeking • Psychological impact
Information content topics[a]	• Surgery risks and complication • Treatment alternatives • Comprehensibility and technical jargon • General information about colorectal cancer • Personalization • Life consequences and restrictions • Perioperative procedure, aftercare • Anatomy • Treatment procedure
Presentation of content[a]	• Visualization modality • Interaction • Level of detail
Context of use[a]	• Timing • People and location
Features	• N/A[b]
Acceptance[a]	• General • Data protection • Usability, technical complexity • Trustworthy, up-to-date content

[a]A priori categories derived from the interview guide.

[b]N/A: not applicable.

Within "Personal experiences," key themes included navigating the course of the disease, reflecting on life consequences, and experiencing psychological impact. "Information content topics" encompassed desired details about surgery risks and complications, treatment alternatives, and understanding colorectal cancer anatomy. "Presentation of content" focused on preferences for visualization modality (2D vs 3D vs AR), desired level of detail, and the importance of interactive features. "Context of use" explored ideal timing for information delivery, preferred locations for access, and the role of family and friends. "Features" included desires for resources like support groups, personalized information, and tools for tracking progress. "Acceptance" encompassed themes of trust in the app, concerns about data privacy, and usability considerations. These categories included all statements, regardless of participant sentiment or differing viewpoints. The results are presented in the following sections, organized by main category.

Personal Experiences

Course of Disease

Patients described their experience with colorectal cancer as a challenging and often lengthy process involving multiple surgeries, complications, long-term adjustments, and setbacks along the way. Many patients underwent multiple surgeries, including the removal of parts of the colon or rectum, creation of a stoma, and later reversal of the stoma.

> *And then, in the end, the stoma didn't help either, unfortunately. And then in May last year, my rectum was amputated. And that was a major operation.* [P3, group 2]

For some patients, the cancer was not operable or had metastasized, requiring ongoing treatment with chemotherapy, radiation, and/or targeted therapies.

Patients shared insights about the importance of regular colorectal cancer screening, even in the absence of symptoms, as many were diagnosed unexpectedly through routine check-ups or screenings. They emphasized the need for better public awareness and education about colorectal cancer screenings.

Patients felt well cared for and supported by their health care providers, especially when there was good communication, organization, and a sense of being understood. Patients appreciated feeling respected and treated as partners in their care. In contrast, poor communication, long wait times, and insensitive comments from health care staff led to negative experiences and increased anxiety.

Information-Seeking

Patients consistently emphasized the importance of being well-informed and having access to detailed information. They appreciated when physicians provided thorough explanations, visual aids like diagrams, and opportunities to ask questions. Patients felt this helped reduce their anxiety and uncertainty and allowed them to be more involved in decision-making.

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> *The people affected should be given orientation immediately. That takes away a lot of fear.* [P3, group 3]

This underscores the anxiety-reducing effect of providing patients with adequate information. However, some patients also avoided excessive information, especially if it caused them more distress or fear. They may prefer to focus on the essential details and leave the rest to the physicians. Many reported turning to additional sources like the internet, books, and support groups. However, some cautioned against relying on unverified online sources, which can lead to misinformation and increased anxiety.

> *And you don't even know what sources they used, or if they used any sources at all, or what idiots wrote what. [...] Afterwards, you're even more uncertain than you already were.* [P5, group 5]

Overall, patients emphasized the need for a balance: They wanted to be informed but also have the freedom to choose how much information they engaged with at any given time.

> *Sometimes you don't want to know anything about it.* [P4, group 3]

> *You don't have to look at it. You always have the freedom to choose not to.* [P3, group 4]

Physicians reported that patients have varying preferences regarding the level of detail they want in medical information. They try to assess each patient's individual needs and tailor the information accordingly.

> *50% of people say: "No, I don't want to know any of that."* [P5, group 1]

Psychological Impact

The diagnosis of colorectal cancer and its treatment were often associated with significant emotional distress, including fear, anxiety, and uncertainty. Participants described their initial reaction as feeling shocked and going through a breakdown as they grappled with the news.

> *I was scared, scared, and scared. […] I stood in front of the sink and shouted into the mirror: "Dear God, let me live." And that's when I had a breakdown, I was sweating and getting really hot, and I just snapped.* [P1, group 3]

Patients emphasized the importance of psychological support and coping strategies for managing the mental health challenges. They also highlighted the value of counseling or support groups.

Information Content Topics

Surgery Risks and Complications

Patients wanted to be fully informed about the procedure and any potential complications, including specific complications such as wound-related issues like infections or hernias.

> *What would be interesting and important to know are the complications that can arise.* [P3, group 3]

In contrast, physicians reported a divergence in the preferences, with some patients not wanting to know too many details about the risks and complications.

> *I would differentiate between those who simply don't want to know about the risks because they are already so nervous and afraid and those who are genuinely concerned about the risks.* [P2, group 1]

They recognized the legal requirement to inform patients about risks and complications but also try to provide this information in a less overwhelming manner. This suggests that complex trade-offs exist between legal requirements, patient preferences, and physicians' expertise.

Treatment Alternatives

Clear alternatives to treating colorectal cancer are often limited, as surgery is typically the primary and necessary course of action. Patients may seek second opinions, but physicians often find the treatment path to be straightforward with little room for alternatives.

> *With colon cancer, there is no alternative. Either you operate and cure the person, or you don't.* [P5, group 1]

Comprehensibility and Technical Jargon

Patients often struggled to comprehend medical terminology and jargon used by health care providers and felt overwhelmed by the complexity of the language.

> *I received a discharge letter at some point, and it also contained a lot of gibberish. I took a photo and sent it to my sister, who works in cardiology, and asked her what they had done.* [P1, group 5]

Patients recommended presenting medical information, such as discharge letters, test results, and additional materials, in clear and accessible language, with explanations of technical terms to improve understanding.

Physicians also recognized the importance of simplifying language and avoiding complex medical terminology for patient-friendly communication but also noted the difficulty of balancing clarity with accuracy.

> *For example, when we say "stoma," of course we try to say "artificial bowel outlet," but often we still use too many technical terms, even when we try hard.* [P2, group 1]

General Information About Colorectal Cancer

Patients were interested in learning more about general information related to colorectal cancer, particularly how it spreads and metastasizes and information about demographics. In general, however, patients wanted more specific, tailored information about their own cancer cases rather than just general cancer facts.

> *So that you really understand how it gets from the colon cancer (ie, from the tumor, to the liver, or from the left colon tumor to the right ovary).* [P2, group 5]

> *I also wanted to know the chances of survival.* [P1, group 3]

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Personalization

Patients expressed a desire for information and instructions, such as discharge instructions or dietary guidelines, to be specific to their individual surgery or treatment.

> *I would love it if it were possible for the physician to add certain items for the patient.* [P8, group 5]
>
> *[…] that this is prepared and explained for each individual case.* [P3, group 3]

This preference for personalized information reflected the desire to understand the unique implications of their diagnosis and treatment, moving beyond a one-size-fits-all approach.

However, physicians were unsure whether tumor location–specific materials are truly necessary for patients. In the case of colorectal cancer, a more standardized approach to patient education materials, rather than highly personalized content, may be sufficient. Pre-made educational materials tailored to the specific tumor location in the colon, such as the ascending, transverse, descending, or rectal parts, would allow for some level of personalization without completely individualizing the content.

> *For the colon, it may not be as relevant that it is individually adapted, but for other organs it may be more interesting.* [P5, group 1]

This highlights a potential challenge in balancing patient preferences for personalization with the practical constraints of the clinical setting.

Life Consequences and Restrictions

Patients reported experiencing a range of challenges as a result of their cancer diagnosis and treatment. Specifically, they reported struggling with daily activities, social interactions, and employment due to digestive and bowel issues, requiring the need for ongoing lifestyle adjustments.

> *The physical limitations that remain afterwards are significantly greater, leading to an inability to work or even disability.* [P1, group 3]

Additionally, patients often described experiencing nerve and muscle damage, including neuropathy, muscle weakness, and loss of sensation, resulting from chemotherapy. Many patients also reported feeling physically exhausted and debilitated, even long after treatment. Furthermore, patients had to adapt to significant dietary restrictions and challenges, which limited the types of foods they could consume.

> *For me, it was horrible what they had forbidden me to eat.* [P2, group 2]

Physicians recognized the importance of discussing the long-term consequences of procedures with patients. Patients were concerned about how their treatment would impact their overall quality of life, whether due to a stoma, dietary restrictions, or other functional limitations. They reported that patients wanted to know how these changes will affect their daily routines, relationships, and overall well-being.

> *The typical question is about a stoma. That's always where most patients experience limitations in their quality of life.* [P6, group 1]

This highlights the need to address not only the immediate medical aspects of cancer treatment but also the wider psychosocial and physical challenges that patients will face in the long term.

Perioperative Procedure, Aftercare

Patients emphasized the importance of clear information regarding the perioperative process, including rehabilitation and follow-up care after surgery, with some highlighting the value of dedicated rehabilitation facilities. This indicates that patients want to actively prepare for and manage the challenges of surgery and recovery.

Physicians emphasized the importance of a patient-centered approach throughout the perioperative phase while providing information on the organizational workflows and timelines. The app should also recommend healthy behaviors, such as smoking cessation and mobilization, and enable patient self-monitoring. This demonstrates a recognition of the need for ongoing support and patient engagement throughout the treatment journey.

> *[…] from admission to the surgical procedure, how many days patients stay in the clinic, what the goals are after the surgery (ie, freedom from pain, mobilization, post-operative recovery, etc.), and stay in intensive care.* [P3, group 1]

Anatomy

Participants expressed a desire for a basic understanding of human anatomy, such as the path food takes through the body, the functions of different organs, and the relationships between them. Several patients expressed a lack of understanding regarding the different parts of the digestive tract, such as the distinction between the small and large intestine, the function of the appendix, and the location of organs such as the liver and stomach.

> *I had no idea about size or the position of organs […] I have always thought, the stomach is horizontal here.* [P3, group 3]

This illustrates a gap in patients' preoperative anatomical knowledge, which could potentially hinder their ability to fully understand their diagnosis and treatment options.

Physicians reported providing anatomical explanations before procedures to help patients understand the surgery. These explanations were typically presented on a basic schematic level, focusing on key structures and their general locations.

This highlights the potential benefit of providing patients with accessible, anatomical resources that go beyond the specifics of their operation and support a broader understanding of their condition.

Treatment Procedure

Patients have a strong desire for detailed information about the surgery and anatomy involved. They want to know specifics, such as the location and extent of the tumor or affected area, as well as a step-by-step description of the procedure, including how the remaining parts of the colon will be reconnected. Furthermore, patients are interested in seeing "before and after"

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visualizations to better understand the changes that their body will undergo as a result of the surgery.

> *They just said, "I will cut this and that out," but I actually think it would be quite interesting to see how it's sewn together.* [P2, group 5]

This includes information about potential outcomes, such as the possibility of a temporary or permanent stoma.

> *Before that, it was about not having a stoma at all […] then he said it could heal better with a temporary stoma. And I went from not at all, to temporary, to ultimately permanent.* [P10, group 5]

Patients typically focused on the type and extent of their surgical procedures when discussing their treatment, which may include the removal of parts of the colon, the creation of a stoma, or the use of minimally invasive or open surgical techniques. Many also shared their experiences with unexpected complications or additional surgeries, such as infections or bowel obstructions, as well as their experiences with chemotherapy or radiation therapy as part of their treatment plan.

However, physicians reported that patients are more concerned about the consequences of the surgery, such as its impact on their quality of life, rather than the technical aspects of how the surgery is performed.

> *It's not so much about the details of the operation, but rather: What happens postoperatively in the short, medium, and long term? I don't think how it's done anatomically is all that relevant for the patient.* [P5, group 1]

Although patients show limited interest in the specifics of the surgical approach according to the physicians, they often ask about the extent of the resection.

> *The most frequent question is: "How many centimeters will be removed?"* [P6, group 1]

The findings suggest that patients are highly interested in the surgical procedure, whereas physicians tended to perceive patients as less concerned with technical operative details. This suggests that patient education tools should foreground the extent of the resection rather than elaborate on the technical steps of the operation.

Presentation of Content

Visualization Modality

Patients and physicians expressed different preferences for visualization modalities, as shown in Table 3. Key findings revealed positive sentiment toward 3D models (patients: ++, physicians: +) and 2D visualizations (both: +), negative sentiment toward raw MRI scans (patients: -, physicians: --), and mixed to positive sentiment toward AR (patients: +, physicians: ±).

Table . Patient and physician sentiment toward each visualization modality during focus group interviews, as coded on a 5-point scale ranging from strongly negative (--) to strongly positive (++).

Modality	Patients	Physicians
MRI[a] (raw, unannotated)	-	--
2D (black and white, colored, only colon, colon+ surrounding)	+	+
3D model	++	+
AR[b] (marker)+3D model	+	±
AR (markerless)+3D model	+	No data

[a]MRI: magnetic resonance imaging.

[b]AR: augmented reality.

Patients and physicians demonstrated different preferences for the visualization modality. Patients tended to find 2D schematic diagrams and illustrations helpful for understanding the anatomy and planned surgical procedures.

> *I could do something with that. My bowel, roughly, that's where they would cut, and that's what would come out.* [P1, group 2]

They also found 3D models and animations useful for gaining a better spatial understanding.

> *And I would say that it's much easier to see there than on a piece of paper.* [P11, group 5]

In contrast, many patients felt that abstract MRI or computed tomography images were too difficult to interpret on their own and they would prefer more user-friendly visualizations.

> *I need a lot of imagination to picture where in my body that is.* [P2, group 2]

Additionally, patients showed interest in and motivation to use AR visualizations, seeing potential for a better understanding and connection to their own body and medical condition. However, several participants expressed doubts about the practical usefulness of the AR visualization, viewing it more as a gimmick than a truly helpful tool. They generally preferred a combination approach, where the AR visualizations were supplemented by more traditional visualizations.

> *Oh, wow, awesome. […] Is the liver that big? […] It's quite nice, but what's the point of doing it like this, as opposed to the other pictures?* [P1, group 2]

Physicians tended to favor simple, 2D visualizations over more complex 3D models or medical images. They believed that 3D

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or interactive visualizations would be too confusing for patients, especially older patients. They viewed AR visualization as a novelty, rather than as a practical tool for their medical practice.

> *I mean, it's a nice gimmick, but what's the point?* [P6, group 1]

However, they were open to using short, simple videos to illustrate procedures. These divergent preferences suggest that an mHealth app should offer a range of visualization options. This would allow patients to select the modality best suited to their individual needs and learning styles. It would also provide physicians with visualizations consistent with their practice.

Interaction

Interactive features like zooming and enlarging images, cursor- or touch-activated information pop-ups, and the ability to manipulate 3D models to explore different perspectives were desired by patients.

> *If you could go there and zoom in.* [P3, group 3]

> *Also, to potentially rotate it, to get a better view of other specific parts, for example.* [P8, group 5]

Physicians wanted the ability to draw or annotate and interact with the visual aids directly on the app to further explain the surgery. They suggested using digital tools like tablets and styluses to use features like highlighting, circling, and drawing arrows.

> *Ideally, you could enter it yourself with a tablet and a pen. Basically, exactly the same as what we're doing on paper now.* [P3, group 1]

These findings suggest an app should incorporate interactive elements to cater to different needs. For patients, this would mean providing intuitive controls for exploring visualizations in detail. For physicians, this indicates a preference for digital tools that mirror their established methods of visual communication with patients.

Level of Detail

Patients wanted visualizations specific to their own individual anatomy and medical condition rather than generic organ models and wanted to see representations of their own condition. Many wanted very detailed and comprehensive visualizations that show the affected organs as well as the surrounding anatomy.

> *I definitely think the surrounding organs need to be included when it comes to the ovaries, or if the liver, stomach or something else is affected, so you can say "it's here and here."* [P4, group 5]

Some patients felt that a more stylized or simplified representation, while less detailed, can still be very helpful in understanding their condition.

However, physicians believed that too much detail and complexity in the visual aids can be overwhelming and confusing. Physicians held mixed views on the level of personalization in the visual aids. Some suggested using a generic, textbook anatomy rather than highly individualized representations. However, others proposed starting with a general overview of the human body then allowing the physician to selectively highlight or hide specific organs or areas of interest.

Context of Use

Timing

Both patients and physicians identified multiple stages of the treatment pathway where an app could be valuable: before the informed consent discussion, to prepare for the upcoming conversation, and clarify available options and resources.

> *This app should be presented during the diagnostic consultation, so you can understand what was explained to you during the informed consent discussion.* [P7, group 5]

> *It's most helpful to give it to them before the informed consent discussion, so they've already heard about it beforehand.* [P6, group 1]

During the informed consent discussion, physicians would use the app to provide information and visuals to the patient. Patients reported that many questions arose only after the discussion or even after surgery. The app could serve as a reference, allowing the patient to review the information in peace and clarify any remaining questions, as they may not have time nor the mental capacity to absorb everything during the acute phase.

> *And then, when you're more or less able to think again, that's when the questions come.* [P1, group 2]

Overall, both patients and physicians saw value in the app throughout the entire cancer care journey, from diagnosis to recovery, serving as a resource for both patients and physicians at multiple stages of treatment.

People and Location

Patients indicated they would primarily access information and use the app to review the information at home on their own or with their relatives who are often involved in the care process and need to be informed as well. In addition, they wanted to use the app to share information with other health care providers, such as their primary care physician or specialists, to ensure continuity of care.

> *To show others, or even other doctors, if, for example, you have problems with the scar afterwards, and then they ask what was done, and then you start telling them again.* [P4, group 4]

Physicians would use the app during the consultation and indication discussion to provide visual aids and explanations to the patient. This could then be saved in the app for the patient to refer to later.

Features

In addition to providing core information and educational resources, participants suggested several features that could make the app a more valuable, supportive tool. Patients requested information on resources such as certified cancer treatment centers; rehabilitation facilities; and available social services, benefits, and support resources to which they may be entitled.

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> *There's this and that, and of course it would be great if there was a list.* [P8, group 5]
>
> *Where to find reputable addresses.* [P4, group 5]

Patients often prepare notes with their questions and concerns before physician visits. To facilitate patient-physician communication, they suggested a feature allowing them to record questions and notes into the app before the visit, which the physician could then review beforehand to be better prepared.

> *Where you can enter your questions, where you can enter notes, so that when you get to your next appointment, you can see them.* [P2, group 2]

Physicians saw potential in using the app to support quality management and continuous improvement of care, such as patient outcomes tracking, and feedback mechanisms.

> *What we do verbally during rounds with the pain scale and such, they can also do themselves. This can be visualized with smileys […] in terms of quality management.* [P3, group 1]

Patients highlighted the value of centralized access to their medical records, including lab results, pathology reports, and surgical details, to ensure continuity of care across multiple health care providers. This highlights the importance of a patient-centered approach to data management that enables individuals to play an active role in their own care.

> *If all this paperwork and the visualizations were included in the app, I could really see myself using it.* [P5, group 4]

Acceptance

Overview

Most participants expressed positive attitudes toward and interest in using an app for patient education. Acceptance of the proposed technology was generally positive across all groups, though some physicians expressed concerns about increased workload for medical staff.

> *Yes, but who's going to put that in? Not me, that's for sure.* [P6, group 1]

This suggests that a successful implementation will require careful consideration of workflow integration and potential administrative burdens.

Data Protection

Participants debated the balance between data protection and the acceptance of digital health technologies. Some were concerned about data breaches and misuse, while others viewed data sharing as a way to contribute to research, which highlights the importance of transparent data privacy policies for building trust.

> *I'm not so sure about electronic health records, honestly. Look what happened where they were hacked.* [P1, group 2]
>
> *I am so transparent, I am digitized and stored everywhere, what do I want to hide? I can only contribute to a good cause.* [P1, group 3]

Usability, Technical Complexity

Although some patients were open to the use of technology in health care, others were skeptical and expressed reservations about adopting new technologies.

> *If you want to digitize everything and then no longer hand out such paper documents, then that is of course ideal.* [P1, group 4]
>
> *I won't enjoy that very much, as I'm not a techie. I'm too old for that.* [P6, group 5]

Some patients were concerned that they might feel overwhelmed by an app if they don't know how to use it. There was also concern that an app with too many features might be overloaded.

> *Of course, this should not result in users feeling abandoned with the app.* [P5, group 4]
>
> *If it's easy to use, older people will be able to handle it too.* [P1, group 2]

This variability underscores the need for a user-centered design approach that caters to a wide range of digital literacy levels. Simplicity and intuitive navigation are essential for maximizing user adoption and minimizing frustration.

Some physicians advocated for digitization for reasons of environmental friendliness and efficiency, while some expressed concerns that overly complex or digitized solutions could alienate or overwhelm some users, particularly older patients. Some stated that overly complex technology could distract from the main purpose of patient education and understanding. The focus should remain on clear and effective communication.

> *Because we live in the 21st century. And because we have everything digitally. Everything is becoming increasingly digitized […] to the "paperless hospital."* [P3, group 1]
>
> *I would also keep everything as simple as possible from a technical standpoint. We're talking about elderly people here.* [P6, group 1]

Trustworthy, Up-to-Date Content

Patients discussed the importance of having access to trustworthy health information, particularly through a reliable app, rather than relying on unverified online sources. Some patients avoided searching for information on the internet because they feared finding unreliable or even "frightening" information.

> *I googled it once, and I'll never do it again.* [P11, group 5]

There is a clear preference for content that is scientifically based and not driven by commercial interests or profit motives, unlike some websites.

> *There is always something that you are supposed to buy or do.* [P3, group 3]

This underscores the critical importance of providing scientifically sound, evidence-based content within the app, coupled with transparent content curation and ongoing maintenance to ensure continued relevance and user confidence.

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Discussion

Key Findings

This study used a qualitative approach, using focus group interviews with patients and physicians to identify the essential requirements for an mHealth app designed to support informed decision-making for patients with colorectal cancer, with a specific focus on the potential of AR for visualization. This research explored the patient and physician perspectives on these requirements, particularly regarding information delivery and visualization, to guide app design. Focus group interviews with 23 patients and 7 physicians revealed notable differences in preferences. Participants described current patient education as fragmented, insufficient, and lacking personalization and reported feeling unprepared. They expressed a desire for detailed information about surgery, complications, treatment options, and the impacts on quality of life, with a strong need for personalized content tailored to their specific treatment plan. Physicians expressed a belief that patients are often less interested in in-depth information and prefer a basic overview. Regarding visualization, patients favored interactive 3D models to understand general anatomy and procedures. Physicians preferred simpler, generic 2D images for overviews of the anatomy and procedure that could easily be integrated into their existing workflow and used during informed consent discussions. Participants were engaged by the AR visualization but generally viewed it as a novelty rather than a core component. They expressed a preference for a combination approach where the AR experience supplements more traditional visualizations. Patients envision using such an app at various stages of their treatment journey: as an educational tool to review information and prepare for the informed consent discussion after diagnosis, prepare for treatment, access guidance and track progress during hospitalization, and access information and resources during recovery after treatment. Overall, participants had positive views about a patient education app, emphasizing the importance of user-friendliness, data privacy, and trustworthy content. These findings reveal a discrepancy between patients' expressed information needs and physicians' perceptions of those needs, highlighting the importance of directly soliciting and incorporating patient perspectives into app development.

Interpretations

Patients expressed a lack of understanding of basic anatomy and medical knowledge, a deficit often underestimated by physicians [38]. This finding highlights an issue within health care communication, potentially stemming from time constraints and a reliance on technical jargon. This knowledge gap not only hinders informed decision-making but also can lead to ineffective doctor-patient communication and potentially compromise patient safety [39].

Patients demonstrated a strong desire for detailed information about their condition, such as how the tumor spreads and metastasizes, and information about demographics, consistent with the work of Jane Spalding et al [40] who emphasized that such details are essential for a thorough understanding. This desire for specific information suggests a strategy for managing uncertainty and proactively understanding their illness. Concerns for quality of life and long-term consequences highlight the profound psychological impact of colorectal cancer and the importance of addressing these concerns. O'Connor et al [41] identified a gap in patient satisfaction regarding patient education on the long-term physical and psychological impacts. In our study, patients reported that being informed about their treatment process reduced their anxiety and uncertainty, a finding consistent with the literature [40,42]. Previous studies have reported improved patient understanding with interactive digital patient education interventions [43].

It is important to recognize that patients have varying information needs. Not all patients want detailed information; some prefer a brief overview. These findings are consistent with those reported by Levinson et al [44], who observed that, although nearly all patients want to be offered choices and asked for their opinions, a significant proportion are comfortable leaving final decisions to their physicians and prefer to rely on physician knowledge. These differing preferences likely reflect variations in patients' levels of health literacy, anxiety about their condition, and preferred coping styles—factors that could be addressed through a personalized app.

Although patients demonstrated engagement with AR visualizations, recognizing their potential to make complex medical concepts more accessible, concerns were raised regarding practical implementation and usability. This suggests a disconnect between the technology's promise and its current user experience, which likely stems from the fact that the presented AR visualization was a prototype and therefore subject to technical limitations combined with the inherent unfamiliarity of the technology itself. Participants generally viewed AR as a supplementary feature to other visualizations, a perspective that contrasts with research suggesting that such an approach can lead to usability issues [16].

The patient participants exhibited levels of technology commitment similar to those reported in the literature [45]. Despite concerns that older individuals may be overwhelmed by technology, research indicates that they are interested in using mHealth, highlighting the necessity to consider the specific needs and barriers of this target group [46]. The next generation, with more experience using smartphones, may be more comfortable with the technology.

Implications

This study underscores the need for a patient-centered design approach to mHealth apps for colorectal cancer, prioritizing detailed and accessible information to support informed decision-making and patient empowerment. Specifically, app developers should prioritize features that allow for individualized content delivery, catering to varying levels of health literacy and preferences for level of information detail. An adaptable, patient-centered approach should be applied that allows for individual tailoring of the amount of information as suggested by Edwards [47]. Notably, there is a divergence between the perspectives of physicians and patients on the level of detail that should be provided. This underscores the importance of avoiding assumptions about patient preferences and tailoring information delivery to individual needs.

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An app has the potential to serve as a valuable tool throughout the entire patient journey. Specifically, providing it to patients prior to the informed consent discussion appears particularly promising for preparing them for a more informed discussion and allowing them to focus on the essential details and clarify questions without needing to cover basic information first. Poland et al [48] emphasized the importance of incorporating the perioperative phase and the entire patient pathway with timely information and promoting patient engagement. Physicians could use the app to supplement the legally formal information sheet during informed consent discussions.

These findings strongly support the importance of visual aids in patient education. This finding is consistent with research demonstrating that visualizing medical information enhances comprehension of written materials [49]. However, our study revealed differing preferences, suggesting that an app should offer a range of visualization options to satisfy patient preferences while also providing physicians with accessible visuals compatible with their current practice. Future research should investigate the feasibility and usability of AR features in clinical settings. Specifically, studies should investigate the potential of an AR mirror feature to enhance patient understanding and engagement throughout the patient journey, particularly during informed consent discussions. Given patients reported a stronger connection to their bodies when using AR, further studies should explore whether AR visualizations improve their ability to accurately map anatomical structures onto their own bodies, potentially enhancing overall comprehension.

Successful implementation requires careful attention to usability, interface design, data privacy, and security [50]. These factors are essential for ensuring the app is accessible, is trustworthy, and effectively meets the needs of a diverse patient population, ultimately contributing to more informed and empowered patients navigating the life-altering challenges of colorectal cancer.

Limitations

One of the primary limitations of this study is the participant cohort. The focus groups, comprised of patients who expressed an interest in patient education, may not be representative of the average patient population. This potential bias is due to the self-selection of participants, who may have a higher level of engagement and interest, thereby limiting the generalizability of the findings to the broader patient population. Additionally, the retrospective nature of the study may have introduced recall bias, with treatments occurring from a few weeks to several years ago. This study was limited by the relatively small sample size (n=30) and the focus on patients with colorectal cancer. Therefore, caution should be exercised when extrapolating these results to other cancer types or patient populations. Finally, the participants in the study were younger than the typical cohort presenting with colorectal cancer, whose median age is generally older than 70 years [51]. To improve generalizability and validity, future studies should consider interviewing patients currently undergoing treatment. Furthermore, the study's reliance on physicians from a single hospital may also limit its generalizability.

Conclusions

This study found that patients with colorectal cancer require detailed, personalized, and visual information about their condition, treatment, and potential complications. Although physicians sometimes underestimate patients' need for information, they recognize the challenges that patients face in comprehending the information provided. The ideal approach for a patient education app would combine comprehensible detailed content with interactive customizable visualizations. Patients appreciated interactive 3D models and AR visualizations, which can introduce complex medical concepts in an accessible and engaging way. However, concerns remain regarding practical implementation and usability. Patients preferred to access the app at various points in their treatment journey. This study highlights the crucial role of a patient-centered approach when designing mHealth apps and emphasizes the potential benefits of including AR visualizations as a supplementary feature to enhance patient engagement and understanding.

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Data Availability

The datasets generated or analyzed during this study are available from the corresponding author on reasonable request.

Authors' Contributions

Conceptualization: SB, VU, SF, VÖ, SH, AUB, AH, DW
Data curation: SB
Formal analysis: SB, VU

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Funding acquisition: DW, VU, AH, AUB, VÖ, SF
Investigation: SB, VU
Methodology: SB, VU, SF, VÖ, SH, AUB, AH, DW
Project administration: SB, VU, SF, VÖ
Resources: SB, VU, DW, AH
Software: SB
Supervision: VU, SF, VÖ, SH, AUB, AH, DW
Visualization: SB
Writing – original draft: SB
Writing – review & editing: SB, VU, SF, VÖ, SH, AUB, AH, DW

Conflicts of Interest

None declared.

Multimedia Appendix 1
Interview guide used in focus groups with patients and physicians.
[PDF File, 213 KB - formative_v10i1e75972_app1.pdf]

Multimedia Appendix 2
Questionnaire used in the focus groups assessing smartphone and tablet use and general demographic information.
[PDF File, 144 KB - formative_v10i1e75972_app2.pdf]

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Abbreviations

AR: augmented reality
CT: computed tomography
mHealth: mobile health
MRI: magnetic resonance imaging

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A Social Media Single Session Intervention Designed to Promote Healthier Social Media Use: Youth Focus Group Feedback

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Abstract

Background: The effects of social media use on an individual's well- or ill-being are highly contextualized to the individual's characteristics and their specific type of social media use. Youth have variable levels of insight about how social media affects them, knowledge about different ways they can change their use, and self-efficacy to make changes. Interventions designed to promote youth modifications of their social media use are needed to minimize harm in an individualized manner.

Objective: The objective of this study was to first develop a Social Media Single Session Intervention (SM SSI) intended to improve insight about effects of social media use on well/ill-being, knowledge of potential changes to make and self-efficacy to make changes and to gather youth feedback related to the SSI's acceptability, feasibility, perceived helpfulness and how it could best be implemented.

Methods: A total of 3 (one in-person and two virtual) focus groups were held between June and October 2024. Feedback from 7 youth aged 16 - 20 (average age 17.43, SD 1.62) years was collected and summarized.

Results: Summarized feedback from the focus groups indicated that the SM SSI is acceptable, feasible, and has the potential to help young people. Youth gave recommendations to include information about additional social media applications, to include an additional peer story exploring other specific challenges, and to include crisis resources. They generally enjoyed going through it together as a group and thought people would use it if assigned by school or a health provider or if they could earn credit for it.

Conclusions: Requested changes will be incorporated into a final iteration of the SM SSI to be piloted in a future study. This initial feedback shows promise that youth would find value in, learn from, and change behavior as a result of this SSI.

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KEYWORDS

social media; youth; mental health; single session intervention; online; web

Introduction

Research demonstrating both increases in ill-being and well-being associated with social media use led to conceptualizing social media influence on two separate spectra [1]. Because social media experiences and users are unique, efforts have shifted towards education and intervention [2]. Some youth are aware of how social media affects them and have made changes to their use due to this awareness [3]; however, some youth may lack this insight, lack knowledge of potential changes to make, or lack the self-efficacy to make those changes. Because digital single session interventions (SSIs) are both highly accessible and effective for youth mental health concerns [4-6], we designed a SSI to improve youth insight about how social media affects them, knowledge about potential changes to make, and self-efficacy to make those changes. Key components of digital SSI's include relevant science summary, establishing user authority in the topic, user summarization of knowledge gained, and stories from peers [7]. Digital SSIs are uniquely feasible as they remove barriers such as privacy concerns, transportation, and time. Motivational interviewing (MI) is a therapeutic gold standard approach to encourage behavior change [8,9] and has strengths in adaptability to digital platforms and autonomy promotion [10]. Therefore, we took an MI-informed approach to create a SSI which invites ambivalence by exploring user likes and dislikes about social media use. This self-guided intervention complements school- [11] and clinician-based [12] educational

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interventions. The primary objective of this study was to gather youth feedback related to the SSI's acceptability. We were also interested in youth feedback about the SSI's feasibility, perceived helpfulness, and how it could best be implemented.

Methods

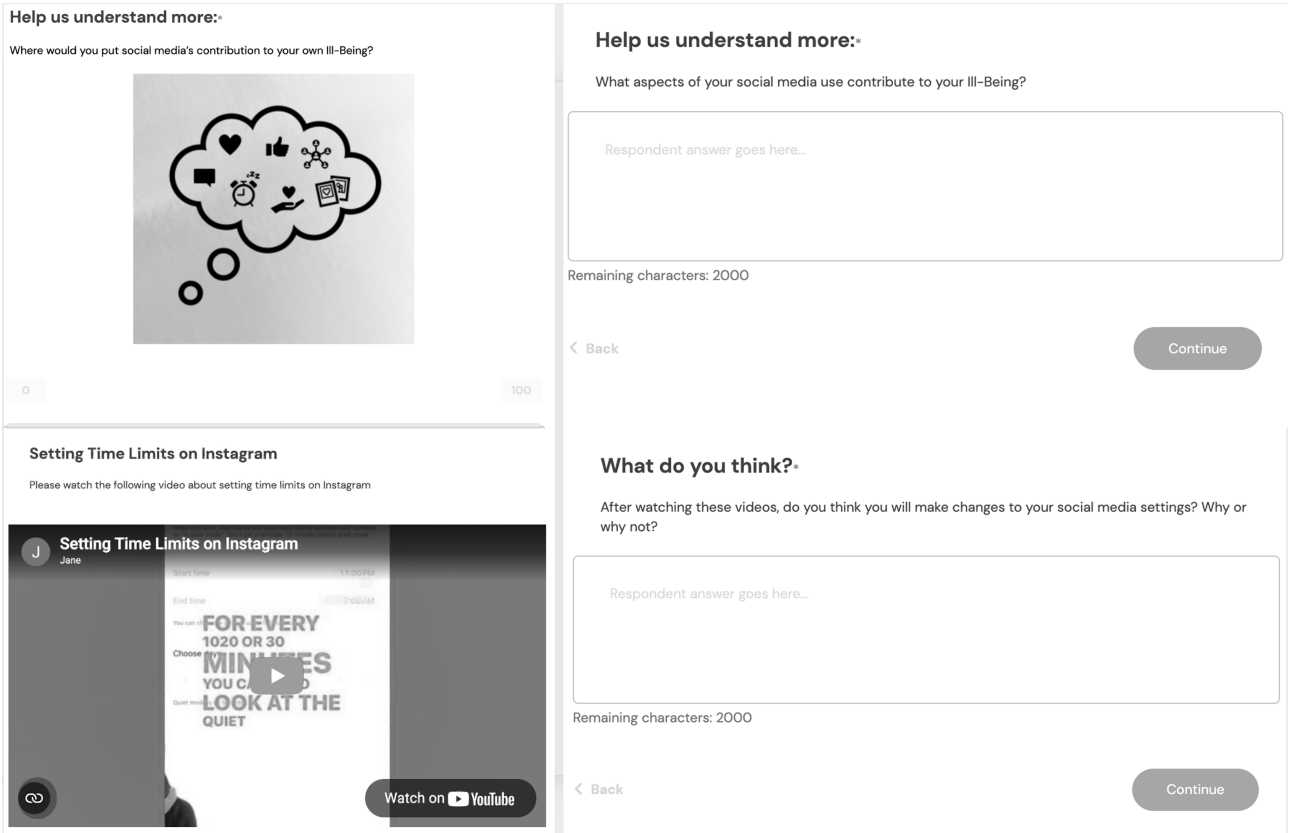
Procedure

Focus group participants (n=7) from a youth advisory board were hosted in person and virtually between June and Oct 2024. Focus groups lasted for 1 - 2 hours and were recorded. The in-person focus group was hosted at the youth advisory board's usual meeting place and the virtual focus groups were hosted on a secure institutional Zoom meeting. One adult leader of the youth advisory board was present for all of the focus groups in addition to the PI and consultants. Inclusion criteria were age 14 - 24 years and membership of a youth advisory board. After consent was obtained, youth were asked a few questions and then the digital social media single session intervention (SM SSI) was projected as feedback was requested page by page. Youth were asked questions at the end of the intervention to gather additional feedback. Please refer to Multimedia Appendix 1 for the full list of pre- and post-SSI questions.

Intervention

The SM SSI was created on Computerized Intervention Authoring System (CIAS)[16]. Figure 1 demonstrates screenshots of the SM SSI. The intervention is a self-guided 30-minute virtual experience. The intervention introduces thinking about social media's influence on both well-being and ill-being on separate spectrums with examples. Next, users are invited to read two vignettes about a teen's specific social media experience, quantify and qualify the social media experience's contribution to the teen's well/ill-being and devise advice for the teen in the story. Next, users are invited to think about social media's contribution to their own well/ill-being, positive and negative aspects and what they like and dislike about social media. They are asked what (if anything) they have done anything to change their social media use in the past and why. They are invited to watch 3 short (30 - 61 s) videos about how to turn off like and view counts, how to set time limits, and how to change the content they are presented with on Instagram. They are asked if they think they will make changes to their social media settings and why or why not. Development of the SSI was guided by examples from Dr. Schleider's lab as she was a consultant for this project.

Figure 1. Example Images of the SM SSI. SM SSI: Social Media Single Session Intervention.



Participants

Participants were recruited from a youth advisory board. The advisory board leaders distributed study information and consent and assent forms to group members via email. Members were encouraged to read all the information and ask any questions via email to the study and advisory board leaders. Interested individuals let the advisory board leader know that they would like to participate and arrangements were made for either in person (one total on 6/26/2024) or virtual (two total on 10/22/2024 and 10/27/2024) focus groups.

Ethical Considerations

The University of Michigan Institutional Review Board approved this study (HUM00242288). Parental consent was not necessary due to the minimal risk of the study. Guardians were

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allowed access to the SSI if they wished, but there were no requests. We reviewed the IRB approved consent form and electronic consent was obtained from all minor participants at the beginning of each focus group. Participants were compensated $100. Measures taken to promote privacy and confidentiality included separate collection of identifying information necessary for compensation purposes and removing identifying information from the transcripts.

Data Analysis

Because of our small sample size, we did not use formal qualitative analysis of the transcripts. Transcripts from each focus group were combined and organized in chronological order by question and page of the SSI by the PI (JH). Feedback was further collapsed into key themes using an inductive approach. Topics were discussed among the other authors who attended the focus groups virtually (SED and HR).

Results

Demographic Information

A total of 7 youth provided feedback about the SM SSI. The average age of focus group participant was 17.43 (SD 1.62; range 16 - 20) years. Our sample was 42.8% Asian (3/7), 28.6% Multiracial (Asian/White) (2/7), 14.2% Black (1/7), and 14.2% White (1/7); 100% female and 100% not Hispanic or Latinx. Feedback was organized into the three following categories.

Acceptability of the SM SSI

Youth participants reported that they viewed the SM SSI and its content as helpful and enjoyable. They felt that the stories were realistic, although names should be changed. Participants shared that they would recommend it to all their friends or specific friends. They found the videos to be useful and even learned new information, with participants sharing that the how-to videos encourage change. Focus group participants appreciated that the tone of the SSI was partnership around shared goals rather than it being overly commanding.

Recommended Changes to the SM SSI

Participants wanted one more story exploring comparison with peers on social media and concerns about their “digital footprint.” They wanted additional videos related to TikTok, Snapchat and artificial intelligence. One participant recommended including 988 and crisis information along with a link tree of other resources such as “OK2SAY” and additional videos. They also recommended adding information about the science related to social media and youth mental health. Feedback on smaller details included a less computer-like narrator, smoother transitions between the sections, deleting the captions in the videos (as they could be turned on if needed) and removing the video narrator from the screen.

Implementation Recommendations

Some participants said that they might leave the free response questions blank. This led to discussions about how they preferred to go through it in a small group like we did during the focus group, with one participant sharing it was comforting to know they were not alone in thinking about this topic. Participants did not think that people would click on a social media advertisement for the SSI due to the prevalence of false advertising on social media, but would engage if it was assigned by their school. One person thought that it would be a good precollege class registration requirement. A QR code for the SSI on a poster at school or work would be feasible. They suggested that people could earn a certificate to be displayed on their LinkedIn page if it was offered there. One participant suggested SM SSI administration in a clinical setting by a doctor or therapist.

Discussion

The focus group feedback gathered during this study shows promise that youth would find value in, learn from, and change behavior as a result of this SSI. They appreciated the collaborative style over a commanding or didactic style. The main recommendations were to make further additions. The stylistic recommendations will be incorporated into the next iteration of this SSI to be put forward for further piloting. Youth provided valuable insight that they would be unlikely to click on a social media ad taking them to the intervention’s external website due to concern about false advertising. A systematic scoping review of interventions for adolescents with chronic health conditions [13], emphasized the importance of leveraging social media in future interventions rather than requiring an app download [14]. Interventions involving social media content are possible: adaptation of the #chatsafe guidelines for social media involved co-design with youth to create a resonant social media campaign about communicating safely about suicide on social media [15]. Youth involved in the co-design process also indicated a need for linked resources [15].

A limitation of this work is that we received feedback from only females and youth who reside in a small geographic area. Social desirability bias is likely due to the nature of the group setting. Minimizing social media harms has the potential to significantly influence a person’s life. An online self-guided SSI on this topic could promote equity by supplementing the heterogeneous information youth receive.

Acknowledgments

We used Computerized Intervention Authoring System (CIAS) for creation of the SSI. The website can be found here [16]. Generative AI was not used in any portion of the manuscript generation.

Funding

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Conflicts of Interest

SED receives honoraria to present research on problematic media use at non-profit organizations, schools, and hospital/health systems. She has consulted with health systems and private practice clinics on problematic media use and mental health. In 2023, SED consulted with Pixel Digital Health, LLC, on their school-based prevention curriculum. She was on the board of the Smart Gen Society until May 2024. JH receives research funding through the American Foundation for Suicide Prevention (AFSP), the Ouida Scholar Award (University of Michigan) and the Research Scouts (University of Michigan). All other authors report no conflicts of interest.

Multimedia Appendix 1
Focus group questions.
[DOCX File, 17 KB - formative_v10i1e73780_app1.docx]

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Abbreviations

CIAS: computerized intervention authoring system
MI: motivational interviewing
SM SSI: social media single session intervention
SSI: single session interventions

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Digitally Assisted Clinical Decision-Making in Traditional Chinese Medicine: Comparative Study of 5 Large Language Models

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Abstract

Background: Traditional Chinese medicine (TCM) clinical decision-making involves complex integration of syndrome differentiation, constitutional assessment, and individualized treatment selection, creating challenges for standardization and quality assurance. While large language models (LLMs) demonstrate capabilities in medical knowledge integration and clinical reasoning, their application to TCM remains largely unexplored, particularly regarding syndrome differentiation principles and prescription formulation.

Objective: This study evaluated 5 contemporary LLMs in TCM clinical decision-making and assessed human–artificial intelligence (AI) collaboration compared with independent approaches. Specific objectives were to benchmark LLM performance in TCM knowledge assessment, evaluate clinical case analysis capabilities, identify the optimal model, and assess the quality, efficiency, and acceptability of human-AI collaboration.

Methods: In total, 5 mainstream LLMs were evaluated—Claude 3.7 Sonnet-Extended (Anthropic), ChatGPT 4.5 (OpenAI), Grok3-DeepSearch (xAI), Gemini 2.0 Flash Thinking Experimental (Google), and DeepSeek-R1 (DeepSeek). The evaluation consisted of four phases, (1) TCM knowledge assessment using 160 standardized questions, (2) clinical case analysis of 30 cases representing different disease systems and complexity levels, (3) optimal model selection using weighted scoring (40% knowledge and 60% clinical analysis), and (4) clinical application assessment involving 10 TCM practitioners and 2 experts comparing physician-only, AI-only, and human-AI collaboration across 5 clinical cases. Statistical analysis included descriptive statistics, reliability analysis, comparative testing, and regression analysis.

Results: DeepSeek-R1 demonstrated superior performance across both evaluation domains, achieving 96.7% accuracy in knowledge assessment and 17.31/20 (SD 2.65) in clinical case analysis, significantly outperforming other models (P<.001). Human-AI collaboration achieved significant improvements compared with physician-only decision-making, with 16.1% quality enhancement (33.62 vs 28.97; P<.001) and 66.1% time reduction (162.6 s vs 479.2 s; P<.001). System usability was rated favorably (System Usability Scale score=76.8; P=.002), with high acceptance rates (74.25% adoption, 24% modification, and 1.75% rejection). AI assistance provided the greatest benefits in prescription formulation and medication selection (P<.001).

Conclusions: LLMs, particularly DeepSeek-R1, demonstrate substantial capabilities in TCM knowledge assessment and clinical case analysis. Human-AI collaboration significantly enhanced clinical decision-making quality and efficiency while maintaining high physician acceptance. These findings provide compelling evidence for the clinical value of AI-assisted decision-making in TCM, suggesting potential solutions to current challenges in knowledge standardization, clinical training, and health care delivery efficiency. Strategic implementation of AI assistance could significantly enhance the quality, efficiency, and accessibility of TCM care while preserving fundamental principles of individualized treatment.

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KEYWORDS

traditional Chinese medicine; large language models; clinical decision support; human-AI collaboration; digital health; artificial intelligence; medical informatics; clinical decision making

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Introduction

Background and Rationale

Traditional Chinese medicine (TCM) clinical decision-making involves complex integration of syndrome differentiation, constitutional assessment, and individualized treatment selection. Unlike Western medicine's disease-centered approach, TCM uses syndrome-pattern recognition ("bian zheng lun zhi" meaning treatment based on pattern differentiation) that synthesizes information from multiple diagnostic modalities to characterize the patient's overall pathophysiological state [1]. Two patients with identical biomedical diagnoses may receive entirely different TCM treatments based on variations in syndrome patterns—for instance, chronic gastritis may present as liver-qi stagnation, spleen deficiency, or stomach-yin deficiency, each requiring distinct therapeutic approaches. This individualization, while therapeutically advantageous, creates challenges for standardization and quality assurance. Furthermore, TCM expertise relies heavily on tacit knowledge accumulated through clinical experience, creating bottlenecks in practitioner training and contributing to geographic disparities in care quality.

Large language models (LLMs) demonstrate remarkable capabilities in medical knowledge integration and clinical reasoning tasks, with recent models achieving performance approaching human physician levels on medical licensing examinations [2,3]. These capabilities suggest potential applications in addressing knowledge management challenges, supporting clinical decision-making, and augmenting practitioner capabilities. However, applying these technologies to TCM presents unique challenges. TCM syndrome differentiation requires pattern recognition according to theoretical frameworks, including yin-yang balance and 5-element correspondences—reasoning patterns that differ substantially from biomarker-driven diagnostic logic. Prescription formulation exemplifies this complexity—classical formulas use sovereign-minister-assistant-courier hierarchies with individualized modifications based on subtle clinical distinctions. Additionally, TCM terminology presents semantic challenges, as concepts like "liver-qi stagnation" represent theoretical constructs without direct biomedical equivalents.

Previous Work and Research Gap

Existing artificial intelligence (AI) research in TCM has primarily focused on specific diagnostic tasks, such as tongue diagnosis and pulse analysis, addressing narrow functions rather than comprehensive clinical decision-making [4,5]. These systems implement computer vision or signal processing for isolated diagnostic components; yet, comprehensive evaluation of AI capabilities across the full spectrum of TCM clinical competencies—including syndrome differentiation and prescription formulation—remains absent.

AI applications in Western medicine have demonstrated broader clinical value, with studies showing improved diagnostic accuracy and efficiency through human-AI collaboration [6-8]. Recent randomized controlled trials provide compelling evidence that LLM assistance enhances physician clinical reasoning, with the greatest benefits in complex scenarios requiring the synthesis of multiple information sources [9]. The nature of human-AI interaction in clinical decision-making requires careful consideration of role allocation. AI systems excel at rapid information processing, comprehensive database access, and consistent rule application, while human clinicians contribute contextual judgment, patient-specific considerations, and ethical reasoning [10,11]. Effective collaboration positions AI as a decision support tool providing recommendations for physician review, rather than autonomous decision-makers—preserving clinical authority while leveraging AI capabilities. This framework proves particularly relevant for TCM, where clinical decisions must integrate standardized knowledge with individualized treatment principles.

Current gaps include the absence of comprehensive LLM benchmarking studies in TCM contexts and the lack of evidence regarding human-AI collaboration effectiveness in traditional medicine. Understanding which clinical domains benefit most from AI assistance and optimal collaboration strategies remains essential for clinical implementation.

Study Objectives and Hypotheses

This study aimed to evaluate 5 contemporary LLMs in TCM clinical decision-making and assess human-AI collaboration effectiveness. Specific objectives were to (1) benchmark LLM performance in TCM knowledge assessment; (2) evaluate clinical case analysis capabilities; (3) identify the optimal performing model; and (4) assess the quality, efficiency, and acceptability of human-AI collaborative decision-making.

We hypothesized that significant performance variations would exist among LLMs, with models having enhanced access to Chinese medical literature demonstrating superior performance. We further hypothesized that human-AI collaboration would demonstrate superior clinical decision quality and efficiency compared with independent approaches, particularly in complex areas such as prescription formulation.

Methods

Selection and Configuration of LLM

Model selection was based on three criteria: (1) release timing within January-February 2025 to ensure contemporaneous comparison and avoid confounding temporal effects, (2) accessibility through official application programming interfaces or web interfaces for reproducible testing, and (3) Chinese language proficiency, essential for TCM terminology comprehension and syndrome differentiation reasoning.

This study selected 5 mainstream LLMs for evaluation, including Claude 3.7 Sonnet-Extended (Anthropic), ChatGPT 4.5 (OpenAI), Grok3-DeepSearch (xAI), Gemini 2.0 Flash Thinking Experimental (Google), and DeepSeek-R1 (DeepSeek), all of which were released between January and February 2025. Claude 3.7 Sonnet-Extended is built on an improved transformer architecture with enhanced reasoning capabilities; ChatGPT 4.5 optimized knowledge synthesis functions based on the GPT transformer framework; Grok3-DeepSearch integrates transformer models with real-time retrieval and reasoning mechanisms; Gemini 2.0 Flash Thinking Experimental embeds experimental reasoning modules within the Gemini transformer

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architecture, and DeepSeek-R1 uses a reinforcement learning–enhanced transformer architecture without supervised fine-tuning. All models were accessed through their official application programming interfaces or web interfaces under standard configuration environments, with all testing completed in March 2025. The testing process used uniform input formats to ensure fair comparison across all evaluation systems. Table 1 provides detailed characteristics and configuration information for all evaluated models.

Table . Large language model characteristics and configuration details[a].

Model	Developer	Release date	Architecture	Key features for TCM[b] applications	Clinical advantages
DeepSeek-R1	DeepSeek	January 20, 2025	Mixture-of-Experts Transformer (671B total, 37B activated; large-scale RL[c] without SFT[d])	Large-scale RL training, enhanced reasoning, open-source	Cost-efficient, performance comparable to leading models, no supervised fine-tuning
Claude 3.7 Sonnet-Extended	Anthropic	February 23, 2025	Transformer with extended thinking (hybrid reasoning; customizable thinking budget)	"Extended thinking" capability, hybrid reasoning model	Switches between rapid response and deep reflection, enhanced instruction following
Gemini 2.0 Flash Thinking Experimental	Google	February 4, 2025	Transformer with reasoning modules (transparent chain-of-thought; 1M token context)	Transparent reasoning process, mathematical reasoning	Fast response, reasoning transparency, complex problem-solving
ChatGPT 4.5	OpenAI	February 27, 2025	GPT Transformer framework (enhanced post training; reduced hallucination)	Improved accuracy, contextual understanding	Reduced hallucination, broad knowledge base, suitable for medical tasks
Grok3-DeepSearch	xAI	February 18, 2025	Transformer with integrated search (DeepSearch agent; trained on Colossus supercluster)	"DeepSearch" functionality, real-time information retrieval	Advanced reasoning, real-time search integration, extensive computational training

[a]All models were accessed through official application programming interfaces or web interfaces under standard configurations during March 2025 testing period.

[b]TCM: traditional Chinese medicine.

[c]RL: reinforcement learning.

[d]SFT: supervised fine-tuning.

These models represent diverse architectural paradigms and training methodologies. DeepSeek-R1 uses a mixture-of-experts architecture with 671 billion total parameters and 37 billion activated per forward pass, using large-scale reinforcement learning without supervised fine-tuning [12]. Claude 3.7 Sonnet-Extended is the first hybrid reasoning model that can produce quick responses or extended step-by-step thinking with customizable thinking budgets for complex reasoning tasks [13]. Gemini 2.0 Flash Thinking implements transparent chain-of-thought reasoning with extended context processing (1 million token context window) [14]. GPT-4.5 uses enhanced posttraining methodology to reduce hallucination and broaden knowledge base coverage [15]. Grok3-DeepSearch integrates real-time web search capabilities through its DeepSearch agent, trained on the Colossus supercluster [16]. These architectural differences enable comparative evaluation of distinct technical approaches to medical reasoning tasks.

Evaluation Framework

The evaluation methodology of this study consists of 4 parts. The first part is TCM fundamental knowledge assessment, using 160 single-choice questions from the TCM Practitioner Qualification Examination (Multimedia Appendix 1), with sample size determined through effect size analysis (Cohen d=0.5, power=0.80, α=.05). Questions were selected through stratified sampling to ensure balanced representation across 8 TCM disease systems—pulmonary disorders (24/160, 15%), cardiac disorders (8/160, 5%), cerebral disorders (16/160, 10%), spleen-stomach disorders (24/160, 15%), hepatobiliary disorders (24/160, 15%), renal disorders (24/160, 15%), qi-blood-fluid disorders (24/160, 15%), and limb-meridian disorders (16/160, 10%). Difficulty stratification included basic-level questions (n=60, 37.5%), intermediate-level questions (n=60, 37.5%), and advanced-level questions (n=40, 25%), with difficulty classification jointly determined by 6 experienced TCM practitioners through consensus evaluation. Each model was independently tested using standardized input formats and triple repetition testing. The second part included 30 clinical cases from the TCM Practitioner Qualification Examination, selected through stratified sampling (Multimedia Appendix 2). Cases were distributed across 7 TCM disease systems—pulmonary (8/30, 26.7%), cardiac (6/30, 20%), spleen-stomach (5/30,

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16.7%), hepatobiliary (5/30, 16.7%), qi-blood-fluid (3/30, 10%), renal (2/30, 6.7%), and limb-meridian (1/30, 3.3%) disorders. Demographic characteristics included sex distribution (20/30, 66.7% male and 10/30, 33.3% female) and age stratification (≤19 y: 1/30, 3.3%, 20-39 y: 7/30, 23.3%, 40-59 y: 13/30, 43.3%, and ≥60 y: 9/30, 30%). Complexity (15/30, 50% simple and 15/30, 50% complex) was determined by 6 TCM physicians, with simple cases defined as single-system pathology and complex cases as multisystem involvement. Clinical case analysis established 7 scoring dimensions based on TCM Practitioner Examination standards. Quality control measures included blinded evaluation processes, evaluator training and calibration meetings, and dual independent assessments.

The third part implemented weighted calculation (40/100, 40% fundamental knowledge, and 60/100, 60% clinical cases) to determine optimal model selection. This allocation reflects TCM competency frameworks emphasizing clinical skills as the most important practitioner competency [17,18]. Clinical case analysis requires complex syndrome differentiation and prescription formulation—core competencies aligned with AI-assisted decision-making. Sensitivity analyses testing alternative weighting schemes (30:70, 50:50, 60:40, and 70:30) assessed selection robustness. The fourth part used 5 previously reported real clinical cases to evaluate clinical application effectiveness and human-AI collaboration models (Multimedia Appendix 3). The study enrolled 10 TCM practitioners with more than 5 years of clinical experience and 2 chief physician-level experts, comparing the clinical performance of the physician group, AI group, and human-AI collaboration group, respectively. The specific method of human-AI collaboration involved LLMs first providing complete syndrome differentiation and treatment plans, which were reviewed and modified by physicians to form the final treatment plans. Throughout the process, decision-making time and situations of plan adoption, modification, or rejection were recorded.

Outcome Measures

Primary outcome measures included fundamental theoretical knowledge test accuracy rates, comprehensive clinical case analysis scores, and quality differences between the human-AI collaboration mode and the independent decision-making mode. Secondary outcome measures covered decision-making time efficiency, clinical application value assessment, physician experience, and usability scores (Multimedia Appendix 4), and detailed situations of adoption, modification, or rejection of plans during the collaboration process (Multimedia Appendix 5).

Statistical Analysis

Statistical analysis implemented the following methods, (1) descriptive statistics were used to calculate overall accuracy rates and their 95% CIs for each model, with stratified accuracy analysis for different characteristics; (2) reliability analysis included using intraclass correlation coefficient (ICC) to assess interrater consistency, Fleiss κ coefficient to assess intramodel consistency, and Cohen κ coefficient to assess intermodel consistency, comparative analysis used nonparametric testing methods such as Friedman test and Nemenyi post hoc test, paired comparisons used McNemar test, and interaction analysis used 2-factor ANOVA; regression analysis was conducted to determine factors predicting answer accuracy rates and calculate odds ratios (ORs) with their 95% CIs; effect size calculation used Cohen *d* values for intergroup comparisons to quantify the degree of differences between different treatment conditions (Multimedia Appendix 6).

Ethical Considerations

This study did not require ethical review as it used publicly available examination questions and published clinical cases. Participating physicians provided informed consent, and no patient privacy issues were involved.

Results

Overview

This study evaluated 5 LLMs in TCM clinical reasoning and assessed their integration into clinical practice. DeepSeek-R1 demonstrated the strongest performance in both knowledge assessment and clinical case analysis. Physician-AI collaboration significantly improved clinical decision quality and efficiency compared with physicians or AI working independently. The AI-assisted approach was well-accepted by practitioners, who retained final decision authority while benefiting from AI-generated recommendations.

Phase 1: TCM Knowledge Assessment Performance

Overall Model Performance

Across 160 TCM knowledge single-choice questions with 3 repetitions per question, totaling 480 responses per model, the 5 LLMs demonstrated significant performance differences. DeepSeek-R1 achieved the highest overall accuracy rate of 96.7%, significantly outperforming all other models. Claude 3.7 Sonnet-Extended ranked second with an accuracy rate of 66.3%, followed by Gemini 2.0 Flash Thinking Experimental with 65.6% accuracy. GPT-4.5 and Grok3-DeepSearch performed poorly, with accuracy rates of 52.5% and 50.6%, respectively. illustrates the comparative performance across all models, with Table 2 providing comprehensive accuracy metrics and reliability measures.

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Table . Traditional Chinese medicine knowledge assessment performance across models[a] (*P*<.001 for all based on the Friedman test for overall comparison across models).

Model	Overall accuracy, % (95% CI)	Basic level, % (95% CI)	Intermediate level, % (95% CI)	Advanced level, % (95% CI)	Internal consistency (Fleiss κ)
DeepSeek-R1	96.7 (94.7 - 97.9)	100.0 (97.9 - 100.0)	98.3 (95.2 - 99.5)	89.2 (82.3 - 93.6)	0.969
Claude 3.7	66.3 (61.9 - 70.3)	85.6 (79.6 - 90.0)	66.1 (58.9 - 72.7)	37.5 (29.2 - 46.6)	0.764
Gemini 2.0	65.6 (61.3 - 69.7)	86.1 (80.2 - 90.5)	62.2 (54.9 - 69.1)	40.0 (31.5 - 49.1)	0.953
GPT-4.5	52.5 (48.0 - 56.9)	67.2 (60.0 - 73.7)	47.2 (40.0 - 54.6)	38.3 (30.0 - 47.4)	0.803
Grok3	50.6 (46.2 - 55.1)	67.2 (60.0 - 73.7)	52.8 (45.4 - 60.0)	22.5 (15.8 - 30.9)	0.614

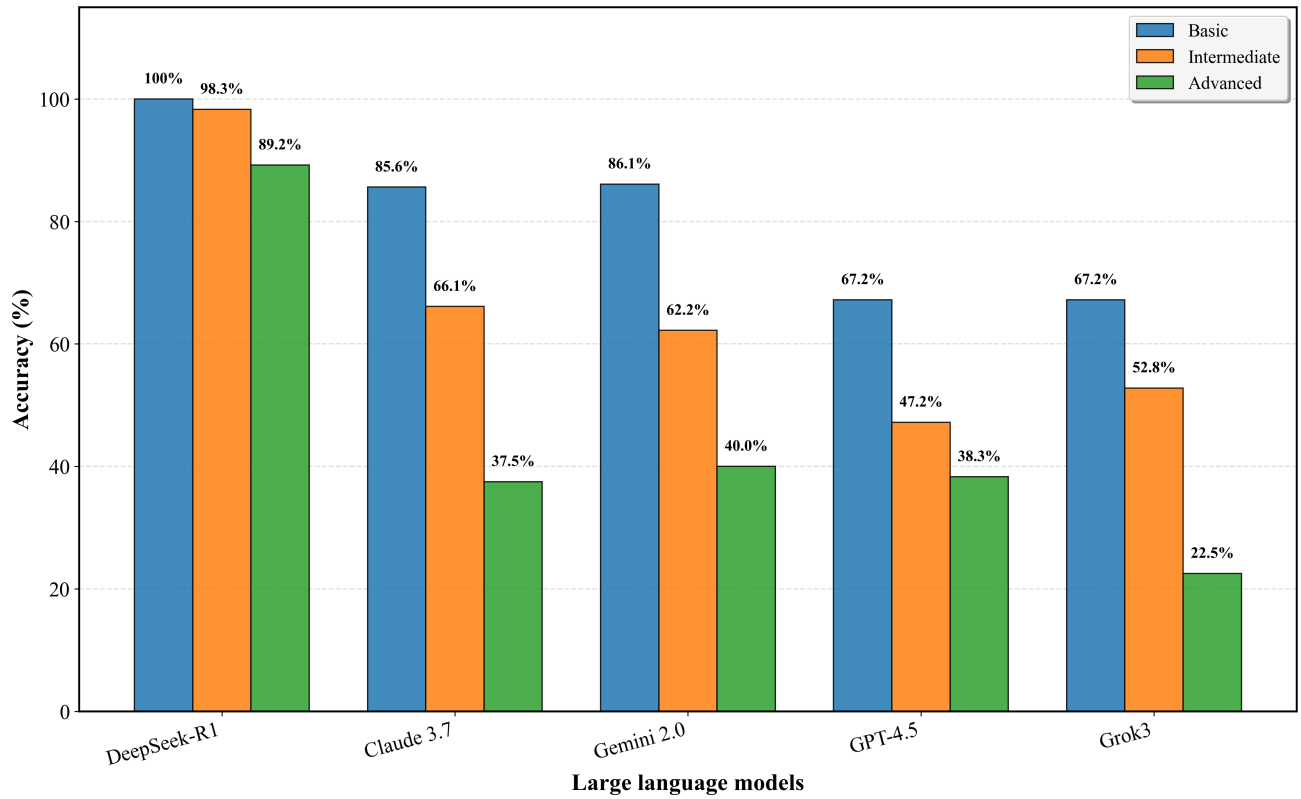
[a]Based on 160 single-choice questions from Traditional Chinese Medicine Practitioner Qualification Examination, with 3 repetitions per question (total 480 responses per model).

[b]Friedman test for overall comparison across models.

Disease System and Difficulty Level Analysis

In the evaluation across 8 major TCM disease systems, DeepSeek-R1 consistently performed optimally, with accuracy rates ranging from 91.7% (blood and fluid disorders) to 100% (pulmonary disorders). Claude 3.7 showed moderate but variable performance, achieving the highest accuracy of 87.5% in limb and meridian disorders and the lowest of 52.8% in blood and fluid disorders. Stratified analysis by question difficulty revealed a clear gradient effect across all models—basic-level questions generally achieved higher accuracy than advanced-level questions. DeepSeek-R1 maintained excellent performance across all difficulty levels with accuracy rates of 100% for basic questions, 98.3% for intermediate questions, and 89.2% for advanced questions, while other models showed a significant decline in advanced questions, such as Claude 3.7 decreasing from 85.6% to 37.5% and Gemini 2.0 from 86.1% to 40%. Figure 1 demonstrates the performance gradient across difficulty levels for all evaluated models.

Figure 1. Model accuracy across 3 difficulty levels in traditional Chinese medicine knowledge evaluation.



Error Patterns and Model Consistency

Error pattern analysis indicated that “formula misuse” was the most common error type across all models, followed by “theory knowledge deficits” and “syndrome differentiation inaccuracy.” DeepSeek-R1 maintained the lowest error rates across all error categories (total error rate=3.3%), while other models had error rates ranging from 33.8% (Claude 3.7) to 49.4% (Grok3). Internal consistency analysis using Fleiss κ demonstrated excellent reliability for DeepSeek-R1 (κ=0.969) and Gemini 2.0 (κ=0.953), with moderate to good reliability for other models—Claude 3.7 (κ=0.764), GPT-4.5 (κ=0.803), and Grok3 (κ=0.614). Intermodal consistency analysis revealed moderate agreement between Claude 3.7 and Gemini 2.0 (Cohen

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κ=0.631), with generally lower consistency between other model pairs.

Statistical Comparisons and Predictive Factors

The Friedman test confirmed significant differences among models (χ^2_4 =159.2, P<.001). Nemenyi post hoc testing revealed significant differences between DeepSeek-R1 and all other models (all P<.001), as well as between Claude 3.7 and Grok3 (P=.04), and between Grok3 and Gemini 2.0 (P=.02). McNemar paired comparison tests indicated significant performance differences between most model pairs, with the largest effect observed between DeepSeek-R1 and other models. A 2-factor ANOVA showed significant main effects for both question difficulty ($F_{2,2385}$=132.03; P<.001) and model type ($F_{4,2385}$=93.43; P<.001), with a significant difficulty×model interaction ($F_{3,2385}$=6.06; P<.001), indicating that performance gaps between models varied with question difficulty.

Logistic regression analysis performed well in predicting factors influencing correct responses (area under the curve=0.817, accuracy=74%). The analysis revealed that selecting the DeepSeek-R1 model was the strongest predictor of correct responses (OR 13.75, 95% CI 2.67 - 2.80), followed by basic difficulty questions (OR 2.73, 95% CI 0.37 - 0.39), and specific knowledge types including diagnostic key points (OR 2.68, 95% CI 2.60 - 2.72) and treatment principles (OR 2.66, 95% CI 1.77 - 1.85). Disease system analysis showed that compared with hepatobiliary disorders, limb and meridian disorders had higher odds of correct responses (OR 1.86, 95% CI 1.11 - 1.16).

Phase 2: Clinical Case Analysis Performance

Overall Case Analysis Scores

Analysis of 30 clinical cases (15 simple and 15 complex) using a 20-point scoring system revealed significant performance differences among models. DeepSeek-R1 achieved the highest overall mean score of 17.31 (SD 2.65; median 18.00, IQR 17.33-18.67), followed by Gemini 2.0 with a mean score of 16.16 (SD 3.06; median 17.00, IQR 15.00-18.58). Claude 3.7 demonstrated moderate performance with a mean score of 14.57 (SD 4.21; median 15.00, IQR 12.67-17.83), while Grok3 and GPT-4.5 showed lower performance with mean scores of 12.40 (SD 4.10; median 13.00, IQR 8.38-15.38) and 10.02 (SD 3.80; median 10.00, IQR 7.46-11.92), respectively. A 1-way ANOVA confirmed significant differences among models ($F_{4,145}$=118.03; P<.001). Complete performance metrics across all evaluation dimensions are presented in Table 3.

Table . Clinical case analysis performance by model and evaluation dimensions[a] (P<.001 based on one-way ANOVA for overall comparison across models).

Model	Overall score[b], mean (SD)	Simple cases, mean (SD)	Complex cases, mean (SD)	Disease diagnosis[c], mean (SD)	Syndrome diagnosis[c], mean (SD)	Differentiation basis[d], mean (SD)	Disease differentiation[c], mean (SD)	Treatment method[e], mean (SD)	Formula name[e], mean (SD)	Medicinal composition[c], mean (SD)
DeepSeek-R1	17.31 (2.65)	17.61 (2.26)	17.00 (2.96)	2.72 (0.85)	2.89 (0.41)	3.86 (0.44)	2.73 (0.58)	1.93 (0.25)	1.40 (0.68)	1.78 (0.71)
Gemini 2.0	16.16 (3.06)	16.53 (3.49)	15.78 (2.53)	2.49 (1.05)	2.80 (0.54)	3.79 (0.48)	2.59 (0.86)	1.83 (0.37)	1.24 (0.86)	1.41 (0.92)
Claude 3.7	14.57 (4.21)	15.19 (5.09)	13.96 (2.99)	2.33 (1.19)	2.68 (0.77)	3.51 (0.91)	2.42 (0.90)	1.81 (0.39)	0.84 (0.93)	0.99 (1.04)
Grok3	12.40 (4.10)	13.46 (3.73)	11.34 (4.20)	1.81 (1.20)	2.56 (0.85)	3.34 (1.16)	1.98 (1.14)	1.66 (0.53)	0.41 (0.67)	0.63 (0.91)
GPT-4.5	10.02 (3.80)	11.04 (3.80)	8.99 (3.53)	1.00 (1.22)	1.87 (1.26)	2.37 (1.26)	2.14 (0.98)	1.57 (0.67)	0.43 (0.72)	0.63 (0.87)

[a]Based on 30 clinical cases (15 simple and 15 complex) evaluated using Traditional Chinese Medicine Practitioner Examination standards. Values are mean (SD).

[b]Total score out of 20 points.

[c]Maximum score: 3 points.

[d]Maximum score: 4 points.

[e]Maximum score: 2 points.

Performance by Case Complexity

Complexity analysis revealed differential impacts across models. For complex cases, DeepSeek-R1 maintained the highest performance (mean 17.00, SD 2.96; median 18.00, IQR 17.00-18.67), followed by Gemini 2.0 (mean 15.78, SD 2.53; median 16.00, IQR 14.67-17.33), Claude 3.7 (mean 13.96, SD 2.99; median 15.00, IQR 12.83-15.00), Grok3 (mean 11.34, SD 4.20; median 13.00, IQR 8.08-14.75), and GPT-4.5 (mean 8.99, SD 3.53; median 10.00, IQR 7.08-11.17). For simple cases, the ranking remained similar with DeepSeek-R1 (mean 17.61, SD 2.26; median 18.00, IQR 17.67-18.83), Gemini 2.0 (mean 16.53, SD 3.49; median 18.00, IQR 15.33-18.83), Claude 3.7 (mean 15.19, SD 5.09; median 18.00, IQR 13.00-18.58), Grok3 (mean 13.46, SD 3.73; median 14.00, IQR 10.83-15.75), and GPT-4.5 (mean 11.04, SD 3.80; median 12.00, IQR 9.92-12.42). A 2-factor ANOVA revealed significant main effects for both model type ($F_{4,290}$=122.62; P<.001) and case complexity ($F_{1,290}$=32.75; P<.001), with no significant model×complexity interaction ($F_{4,290}$=1.78; P=.13), indicating consistent

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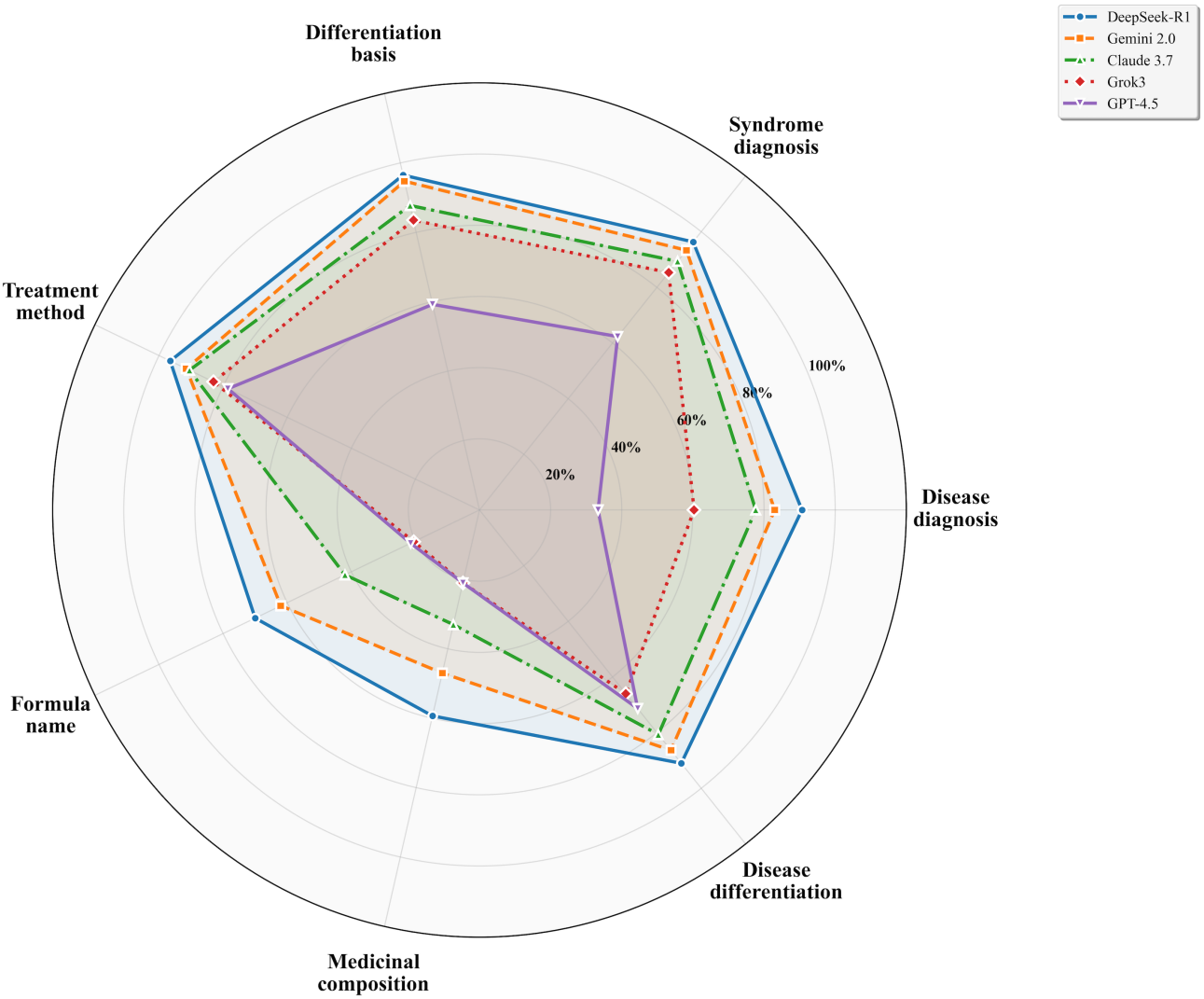
performance patterns across complexity levels. The performance gap between simple and complex cases varied among models, with GPT-4.5 and Grok3 showing the largest decrements (2.06 and 2.11 points, respectively), while DeepSeek-R1 demonstrated the smallest impact (0.61 points).

Performance by Evaluation Dimensions

Dimensional analysis across seven evaluation criteria showed significant differences among models in all dimensions (all $P<.001$). DeepSeek-R1 consistently achieved the highest scores across dimensions—disease diagnosis (mean 2.72, SD 0.85), syndrome diagnosis (mean 2.89, SD 0.41), differentiation basis (mean 3.86, SD 0.44), treatment method (mean 1.93, SD 0.25), formula name (mean 1.40, SD 0.68), medicinal composition (mean 1.78, SD 0.71), and identification (mean 2.73, SD 0.58). Gemini 2.0 demonstrated competitive performance in most dimensions, particularly in differentiation basis (mean 3.79, SD 0.48) and syndrome diagnosis (mean 2.80, SD 0.54). Claude 3.7 showed moderate performance across all dimensions, with notable strengths in differentiation basis (mean 3.51, SD 0.91) and syndrome diagnosis (mean 2.68, SD 0.77). GPT-4.5 and Grok3 exhibited substantial deficits in formula name (GPT-4.5: mean 0.43, SD 0.72, and Grok3: mean 0.41, SD 0.67) and medicinal composition (GPT-4.5: mean 0.63, SD 0.87, and Grok3: mean 0.63, SD 0.91) dimensions, indicating particular challenges in prescription-related assessments. Figure 2 provides a visual comparison of model performance across all 7 evaluation dimensions using a radar chart representation.

Figure 2. Clinical case analysis performance by evaluation dimensions for five large language models.



Interrater Reliability and Model Stability

Interrater consistency analysis between evaluators demonstrated excellent agreement across all models. Gemini 2.0 showed perfect interrater agreement (mean absolute difference 0.00), followed by DeepSeek-R1 (0.033), Claude 3.7 (0.078), Grok3 (0.133), and GPT-4.5 (0.144). Model output stability analysis across multiple attempts revealed varying degrees of consistency, with Gemini 2.0 demonstrating the highest stability (mean 16.16, SD 0.55), followed by DeepSeek-R1 (mean 17.31, SD 0.69), Claude 3.7 (mean 14.57, SD 1.13), GPT-4.5 (mean 10.02, SD 1.99), and Grok3 (mean 12.40, SD 2.04). The stability analysis indicated that superior-performing models generally exhibited greater consistency in their outputs, with the exception of Gemini 2.0, which showed the highest stability despite moderate overall performance.

Phase 3: Optimal Model Selection Results

Comprehensive scores were calculated using a weighted methodology with fundamental knowledge performance (40%)

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and clinical case analysis capability (60%). DeepSeek-R1 achieved the highest comprehensive score of 90.61 points, followed by Gemini 2.0 (74.72 points), Claude 3.7 (70.23 points), Grok3 (57.44 points), and GPT-4.5 (51.06 points). Based on superior performance across both evaluation domains and a significant advantage of 15.89 points over the second-ranked model, DeepSeek-R1 was selected as the optimal model for phase 4 clinical application and human-AI collaboration assessment.

To assess the robustness of the 40:60 weighting scheme, alternative knowledge:clinical ratios were tested (30:70, 50:50, 60:40, and 70:30). DeepSeek-R1 maintained first rank across all tested scenarios, with composite scores ranging from 89.59 to 93.63. The model demonstrated consistent superiority with margins of 14.87 to 23.45 points over the second-ranked model across all weighting variations. This finding confirms that the final model selection was robust to weighting parameter variations and would remain unchanged even with substantially different weighting schemes.

Phase 4: Clinical Application and Human-AI Collaboration

Quality Comparison Analysis

Analysis of 5 clinical cases across 3 evaluation groups revealed significant performance differences. The AI-only group achieved the highest mean score of 33.80 (SD 1.12), followed closely by the human-AI collaboration group with 33.62 (SD 2.50), while the physician-only group scored 28.97 (SD 4.94). Kruskal-Wallis test confirmed significant differences among groups (H=35.003; $P<.001$). Pairwise comparisons revealed that human-AI collaboration significantly outperformed physician-only decision-making (paired $t_{49}=6.603$, Cohen $d=0.943$; $P<.001$), representing a 116.1% quality improvement. No significant difference was observed between AI-only and human-AI collaboration groups ($t_{49}=-0.271$, Cohen $d=-0.074$; $P=.79$), while AI-only significantly outperformed physician-only approaches ($t_{49}=-5.358$, Cohen $d=-1.015$; $P<.001$). Comprehensive comparison results across all outcome measures are detailed in Table 4.

Table . Comparison of decision-making approaches in clinical case analysis[a].

Outcome measure	Physician-only (n=50), mean (SD)	AI[b]-only (n=5), mean (SD)	Human-AI collaboration (n=50), mean (SD)	Statistical test	*P* value	Effect sizes[c]
Quality measures						
Total score	28.97 (4.94)	33.80 (1.12)	33.62 (2.50)	35.003[d]	<.001	0.943[e]
Disease diagnosis	4.41 (0.76)	4.40 (0.82)	4.51 (0.69)	0.474[d]	.79	No significant differences
Syndrome and treatment	3.65 (1.26)	4.55 (0.51)	4.31 (0.84)	7.510[d]	.02	Moderate to large effects
Prescription and medication	2.75 (0.78)	3.45 (0.37)	3.51 (0.57)	23.967[d]	<.001	Large effects favoring AI approaches
Precautions	2.39 (1.33)	4.00 (0.00)	4.00 (0.00)	76.680[d]	<.001	Very large effects favoring AI approaches
Efficiency measures						
Completion time (s)	479.2 (169.5)	86.0 (15.2)	162.6 (35.2)	14.541 (49)[f]	<.001	Large time reduction effects
Quality-time efficiency[g]	6.92 (3.19)	40.29 (7.00)	21.60 (4.74)	—[h]	—	Substantial efficiency improvements

[a]Based on evaluation of 5 clinical cases representing diverse disease systems and complexity levels.

[b]AI: artificial intelligence.

[c]Cohen *d* interpretation: small (0.2), medium (0.5), and large (0.8). Effect sizes reported for the primary comparison (human–artificial intelligence collaboration vs physician-only).

[d]Kruskal-Wallis test.

[e]Large positive effect: human–artificial intelligence collaboration significantly outperformed physician-only decision-making. Additional pairwise comparisons (physician-only vs artificial intelligence–only: Cohen $d=-1.015$; human–artificial intelligence collaboration vs artificial intelligence–only: Cohen $d=-0.074$) available upon request.

[f]Paired *t*-test for completion time comparison (human-artificial intelligence collaboration vs physician-only).

[g]Calculated as expert score/completion time×100.

[h]Not applicable.

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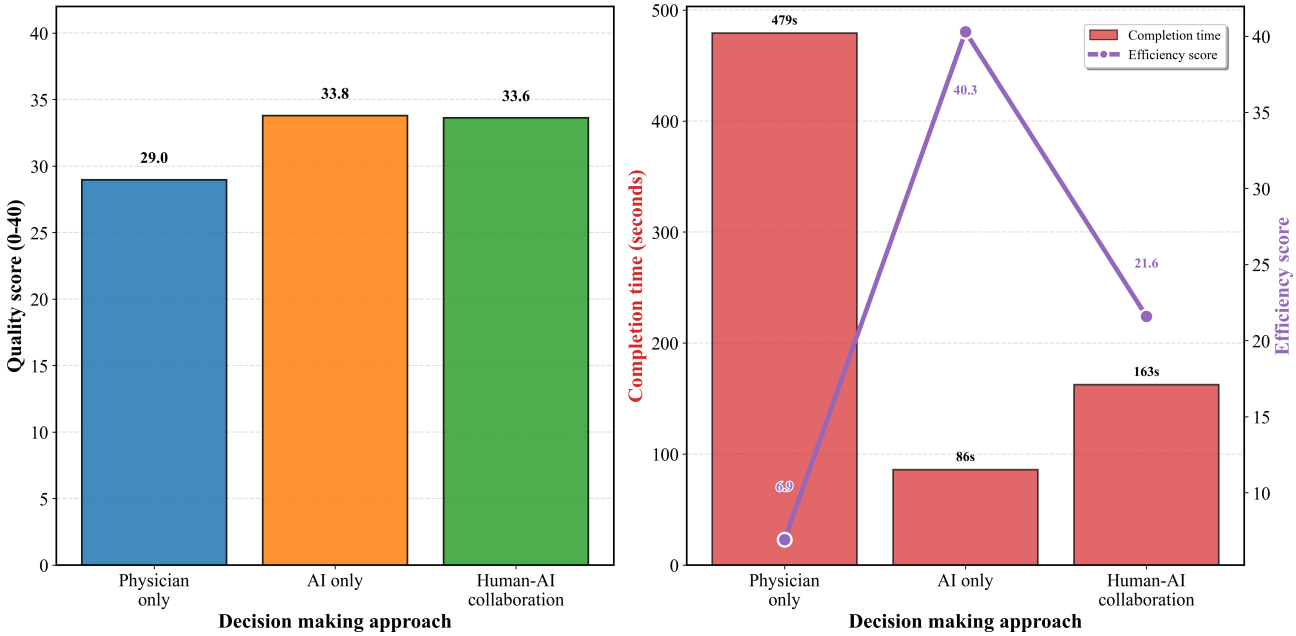
Efficiency Analysis

Completion time analysis demonstrated substantial efficiency gains through human-AI collaboration. Physician-only decision-making required the longest time (mean 479.2, SD 169.5 s, range 160 - 900 s), while AI-only analysis was fastest (mean 86.0, SD 15.2 s, range 70 - 110 s). Human-AI collaboration achieved intermediate completion times (mean 162.6, SD 35.2 s, range 110 - 270 s), representing a 66.1% time reduction compared with physician-only approaches. Paired *t* test confirmed significant time savings (t_{49}=14.541; *P*<.001). Quality-time composite efficiency analysis (expert score/completion time×100) showed dramatic improvements—physician-only (mean 6.92, SD 3.19), human-AI collaboration (mean 21.60, SD 4.74), and AI-only (mean 40.29, SD 7.00), with human-AI collaboration demonstrating 212.2% efficiency improvement over physician-only decision-making. Figure 3 illustrates both quality improvements and efficiency gains achieved through human-AI collaboration.

Figure 3. Quality and efficiency comparison across three decision-making approaches. AI: artificial intelligence.



Dimensional Performance Analysis

Evaluation across 5 core dimensions revealed varying collaboration benefits. Safety considerations showed consistently high performance across all groups with no significant differences (H=0.510; *P*=.78). Disease diagnosis demonstrated equivalent performance among groups (H=0.474; *P*=.79). However, significant improvements were observed in syndrome differentiation and treatment planning (H=7.510; *P*=.02), where human-AI collaboration (mean 4.31, SD 0.84) and AI-only (mean 4.55, SD 0.51) outperformed physician-only approaches (mean 3.65, SD 1.26). The most substantial benefits occurred in prescription and medication domains (H=23.967; *P*<.001), with human-AI collaboration (mean 3.51, SD 0.57) and AI-only (mean 3.45, SD 0.37) significantly exceeding physician-only performance (mean 2.75, SD 0.78). Precautions showed the largest effect size (H=76.680; *P*<.001), with both AI-only and human-AI collaboration groups achieving maximum scores (4.00) compared with physician-only approaches (mean 2.39, SD 1.33).

Expert Interrater Reliability

Interrater expert consistency analysis demonstrated excellent reliability across all evaluation dimensions. ICC revealed perfect agreement for Western diagnosis (ICC=1.000) and safety considerations (ICC=1.000), with near-perfect agreement for precautions (ICC=0.997, 95% CI 1.000 - 1.000) and total scores (ICC=0.987, 95% CI 0.980 - 0.990). Other dimensions showed strong to excellent reliability; TCM diagnosis (ICC=0.990, 95% CI 0.990 - 0.990), treatment methods (ICC=0.986, 95% CI 0.980 - 0.990), TCM syndrome differentiation (ICC=0.956, 95% CI 0.930 - 0.970), medication composition (ICC=0.945, 95% CI 0.920 - 0.960), and prescription formulation (ICC=0.861, 95% CI 0.800 - 0.900). These findings confirmed the robustness and consistency of expert evaluations.

Clinical Application Value and Physician Experience

Clinical application value assessment revealed positive ratings across 3 domains. Clinical practicality achieved good ratings with operational feasibility (mean 3.60, SD 0.80), resource accessibility (mean 4.00, SD 0.77), and complex case analysis capability (mean 3.90, SD 0.83). Integration of TCM with Western medicine showed moderate ratings for laboratory interpretation (mean 3.30, SD 0.78), diagnostic accuracy (mean 3.10, SD 0.30), and evidence-based support (mean 3.30, SD 0.46). Clinical efficiency improvements were rated positively for diagnostic time impact (mean 4.10, SD 0.83), quality-time balance (mean 3.10, SD 0.83), and workload changes (mean 3.40, SD 1.11).

Physician experience evaluation demonstrated favorable collaboration outcomes. System usability received high ratings (mean 4.50, SD 0.67), while workflow integration showed moderate acceptance (mean 3.30, SD 0.64), and information presentation clarity was rated positively (mean 4.00, SD 0.77). Capability enhancement perception indicated moderate benefits

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for learning value (mean 3.20, SD 0.40), rare syndrome assistance (mean 3.20, SD 0.40), and clinical thinking expansion (mean 3.60, SD 0.80). Human-AI collaboration quality showed strong ratings for complementarity (mean 4.00, SD 0.77), workflow smoothness (mean 3.50, SD 0.67), and decision confidence enhancement (mean 3.90, SD 0.83).

System Usability and Collaboration Pattern Analysis

System Usability Scale evaluation yielded positive results with a mean score of 76.8 (SD 5.9, range 65.0 - 87.5). A 1-sample *t* test confirmed that usability significantly exceeded the acceptable threshold of 68 points (t_9=4.433; *P*=.002). Distribution analysis showed 10% (n=1) of physicians rated the system as excellent (≥80.3), 80% (n=8) as good (68 - 80.3), and 10% (n=1) as needing improvement (<68).

Collaboration pattern analysis across 400 total decisions revealed high acceptance rates—74.25% (297/400) adoption, 24% (96/400) modification, and 1.75% (7/400) rejection. Field-specific analysis showed variable adoption patterns; Western diagnosis achieved the highest adoption (98%), followed by TCM treatment methods (88%) and syndrome differentiation (80%), while medication recommendations showed lower adoption (32%) but high modification rates (62%). Common modification types included quality optimization (17 instances), medication adjustments (14 instances), and evidence supplementation (8 instances). Rejections were primarily due to philosophical differences (7 instances), predominantly in treatment philosophy and prescription selection domains. Figure 4 illustrates the detailed collaboration patterns across different clinical domains, while Table 5 presents comprehensive usability assessment and physician experience evaluation results.

Figure 4. Human-AI collaboration patterns by clinical decision domains. AI: artificial intelligence; TCM: traditional Chinese medicine.

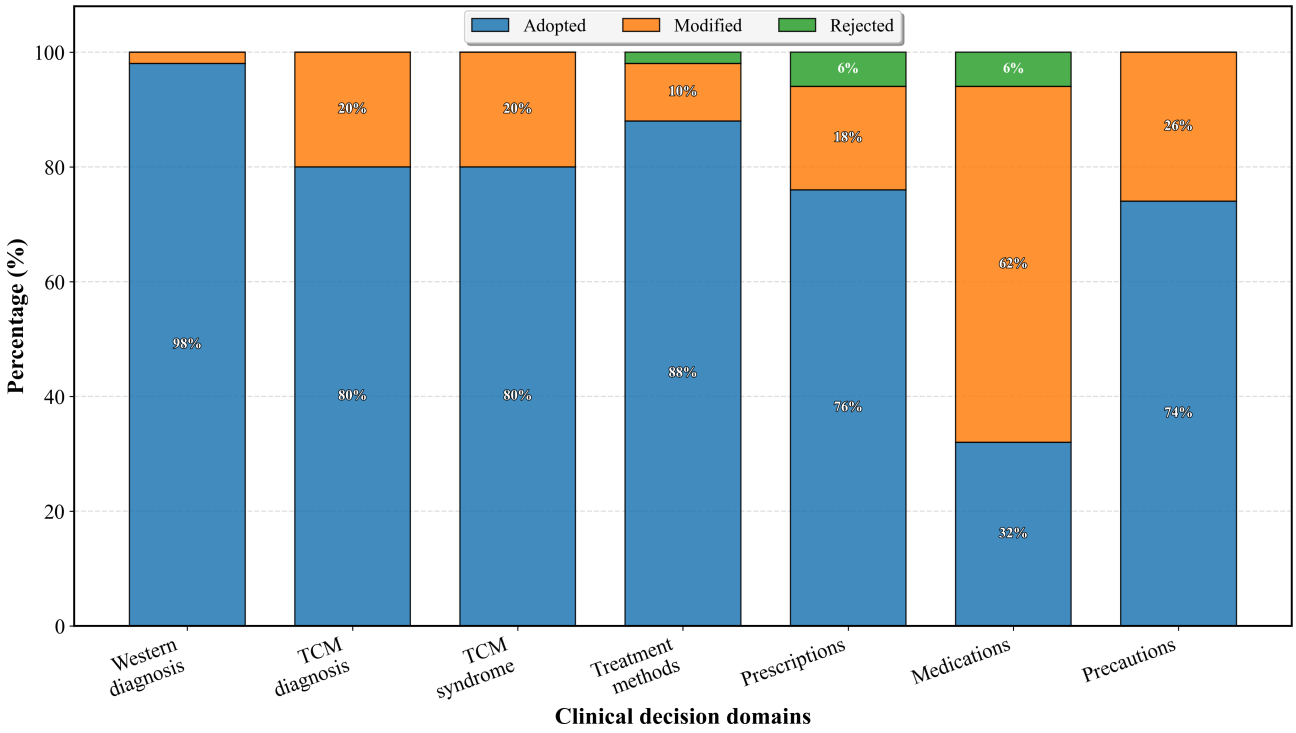

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Table . System usability assessment and physician experience evaluation[a].

Assessment domain	Mean (SD)	Range	Rating level[b]
System Usability Scale			
Overall score[c]	76.8 (5.9)	65.0 - 87.5	Good
Excellent (≥80.3), n (%)	—[d]	—	1 (10.0)
Good (68 - 80.3), n (%)	—	—	8 (80.0)
Needs improvement (<68), n (%)	—	—	1 (10.0)
Clinical application value			
Clinical practicality			
Operational feasibility	3.60 (0.80)	2.0 - 5.0	Good
Resource accessibility	4.00 (0.77)	3.0 - 5.0	Good
Complex case analysis capability	3.90 (0.83)	2.0 - 5.0	Good
TCM[e]-Western Medicine Integration			
Laboratory interpretation rationality	3.30 (0.78)	2.0 - 5.0	Moderate
Diagnostic transformation accuracy	3.10 (0.30)	2.5 - 3.5	Moderate
Evidence-based medicine support	3.30 (0.46)	2.5 - 4.0	Moderate
Clinical efficiency enhancement			
Diagnostic time impact	4.10 (0.83)	2.0 - 5.0	Good
Quality-time balance	3.10 (0.83)	2.0 - 4.0	Moderate
Workload changes	3.40 (1.11)	1.0 - 5.0	Moderate
Physician experience assessment			
Collaboration experience			
System usability	4.50 (0.67)	3.0 - 5.0	Excellent
Workflow integration	3.30 (0.64)	2.0 - 4.0	Moderate
Information presentation clarity	4.00 (0.77)	3.0 - 5.0	Good
Capability enhancement perception			
Learning value	3.20 (0.40)	2.5 - 4.0	Moderate
Rare syndrome assistance value	3.20 (0.40)	2.5 - 4.0	Moderate
Clinical thinking expansion	3.60 (0.80)	2.0 - 5.0	Good
Human-AI collaboration quality			
Human-AI[f] complementarity	4.00 (0.77)	3.0 - 5.0	Good
Collaboration smoothness	3.50 (0.67)	2.0 - 4.0	Good
Decision confidence enhancement	3.90 (0.83)	2.0 - 5.0	Good

[a]Based on responses from 10 traditional Chinese medicine practitioners with ≥5 years of clinical experience.

[b]Rating levels: 1.0 - 2.4 (poor), 2.5 - 3.4 (moderate), 3.5 - 4.4 (good), and 4.5 - 5.0 (excellent).

[c]One-sample *t*-test versus baseline score of 68: t=4.433, P=.002.

[d]Not applicable.

[e]TCM: traditional Chinese medicine.

[f]AI: artificial intelligence.

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Discussion

Principal Results

This evaluation of 5 LLMs in TCM yielded significant findings. DeepSeek-R1 demonstrated superior performance in both knowledge assessment (96.7% accuracy) and clinical case analysis (mean score 17.31/20, SD 2.65). Human-AI collaboration enhanced decision-making quality by 16.1% while reducing time by 66.1%, with high system usability (System Usability Scale score=76.8) and acceptance rates (74.25% adoption). AI assistance provided the greatest benefits in prescription formulation and medication selection.

Performance Analysis of LLMs

Substantial performance variations among models highlight the importance of systematic assessment in medical AI applications. DeepSeek-R1's exceptional performance (96.7% accuracy) may stem from advantages in accessing Chinese medical literature and the domestic development context. The model's consistent superiority across disease systems and difficulty levels indicates robust knowledge representation.

Error pattern analysis revealed formula misuse as the most common failure mode, reflecting the complexity of TCM prescription formulation. This underscores the challenge of integrating syndrome differentiation, constitutional assessment, and individualized treatment principles. DeepSeek-R1's low error rates (3.3% total) suggest that leveraging extensive Chinese medical literature repositories through advanced natural language processing may be more effective than relying solely on general medical training datasets.

Human-AI Collaboration Effectiveness

The demonstrated effectiveness of human-AI collaboration validates the complementary strengths of artificial and human intelligence in TCM decision-making. The 16.1% quality improvement achieved through collaboration represents a clinically meaningful enhancement, particularly given the already high baseline performance of experienced practitioners. The finding that AI-only and human-AI collaboration achieved comparable quality scores (mean 33.80, SD 2.50 vs mean 33.62, SD 1.12) while human-AI collaboration maintained superior consistency suggests that human oversight provides valuable quality assurance without compromising AI capabilities.

The efficiency gains observed (66.1% time reduction and 212.2% composite efficiency improvement) have profound implications for clinical practice scalability. The collaboration model appears to capture the rapid analytical capabilities of AI while preserving the contextual judgment and patient-specific considerations that characterize expert clinical practice. The dimensional analysis revealing selective benefits in prescription and medication domains suggests that AI assistance may be most valuable in knowledge-intensive tasks where comprehensive database access and pattern recognition provide clear advantages over individual practitioner knowledge.

Clinical Implications

The findings have substantial implications for TCM practice transformation. The demonstration that AI assistance can significantly enhance both quality and efficiency suggests potential solutions to current health care challenges, including practitioner shortage, training standardization, and knowledge dissemination. The high adoption rates observed (74.25%) indicate that integration of AI assistance into existing clinical workflows may be feasible with appropriate system design and training protocols.

The educational implications are particularly noteworthy, as the AI system demonstrated consistent performance across complex cases that typically require years of clinical experience to master. This suggests potential applications in medical education, continuing professional development, and clinical decision support for junior practitioners. The detailed feedback and reasoning provided by AI systems may serve as valuable teaching tools, particularly in syndrome differentiation and prescription formulation, where tacit knowledge transfer has traditionally been challenging.

The findings also support the evolution toward precision medicine in TCM practice. The AI system's ability to process comprehensive patient information and provide evidence-based recommendations may facilitate more individualized treatment approaches while maintaining consistency with TCM principles. This represents a significant advancement toward integrating traditional medical wisdom with contemporary health care delivery models.

Comparison With Previous Work

This study provides the first comprehensive evaluation of LLMs in TCM applications. While previous studies demonstrated AI effectiveness in Western medicine diagnostic tasks [6-8], and recent randomized trials show that LLM assistance enhances physician clinical reasoning [9], TCM-specific challenges—including syndrome differentiation and individualized treatment formulation—remained largely unexplored. Our findings extend the demonstrated benefits of human-AI collaboration to traditional medicine contexts [10,11].

The high modification rates in medication domains (62%) contrast with high adoption rates in other medical AI applications [19], reflecting TCM practitioners' preferences for individualized prescription modifications. This underscores the importance of AI systems that support rather than replace clinical judgment.

Framework of Human-AI Collaboration

It is essential to clarify that the AI systems evaluated in this study function as clinical-decision support tools rather than autonomous decision-makers. The human-AI collaboration framework positioned LLMs as assistive technologies that augment rather than replace physician clinical judgment. In this framework, AI systems provided initial syndrome differentiation and treatment recommendations, which were then critically reviewed, modified, and approved by licensed TCM practitioners. Physicians retained full clinical authority and responsibility for final decisions.

This physician-supervised approach is necessary for several reasons. First, TCM clinical practice requires consideration of patient-specific factors and contextual elements that current AI

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systems cannot fully capture. Second, clinical responsibility and ethical accountability must remain with licensed health care providers who can integrate AI recommendations within the broader context of patient care. Third, the study results demonstrate that optimal outcomes were achieved through collaborative approaches where physicians leveraged AI capabilities while exercising critical oversight.

These findings should not be interpreted as suggesting readiness for autonomous AI deployment in TCM practice. Rather, they support the clinical value of AI as a decision support tool within physician-supervised frameworks, where human expertise guides and validates AI-generated recommendations.

Limitations

This study has several important limitations that should be considered when interpreting the findings. First, the evaluation used examination cases from the TCM Practitioner Qualification Examination rather than real-time clinical encounters. While this methodological choice was necessary to ensure standardized evaluation and fair comparison across models, examination cases present with complete, well-organized information and predetermined diagnostic conclusions, whereas real clinical practice involves incomplete information, evolving presentations, and genuine diagnostic uncertainty. The structured format may favor certain AI reasoning patterns and lacks the dynamic elements of actual patient care, such as real-time communication, physical examination, and decision-making under time pressure. These factors suggest that the observed performance levels may not directly translate to real-world clinical settings, although this represents an essential first step before clinical validation studies.

Second, the clinical case evaluation sample size (n=30) was determined through stratified sampling to ensure representation across 7 major disease systems and balanced complexity distribution. Post hoc power analysis based on the observed large effect size (Cohen *f*=0.72, corresponding to mean score differences ranging from 10.02 to 17.31 on a 20-point scale) indicated that this sample size provided adequate statistical power (0.89) for detecting the substantial performance differences observed among the 5 models. The sample size was constrained by the substantial resources required for comprehensive expert evaluation (2 chief physician-level experts [Y. Wang and H. Shang] conducting detailed assessments across 7 dimensions per case). Future studies with larger, multi-institutional case sets would enhance confidence in the generalizability of these findings across the full spectrum of TCM pathologies, particularly for rare conditions and atypical presentations.

Third, despite implementing multiple quality control measures—including evaluator training, blinded evaluation, dual independent assessments, and structured scoring rubrics—the expert scoring methodology inherently involves subjective judgment. TCM clinical reasoning incorporates both explicit knowledge and tacit expertise that can be difficult to standardize completely across evaluators. The study demonstrated excellent interrater agreement between the 2 chief physician-level evaluators, suggesting these measures successfully limited variability. However, some degree of subjective judgment remains inherent to evaluating complex clinical reasoning, particularly in areas where multiple valid approaches may exist.

Additionally, the evaluation framework was based on contemporary TCM education standards and the TCM Practitioner Qualification Examination criteria, which prioritize evidence-based approaches and standardized diagnostic principles. While this framework ensures consistency and reproducibility in evaluation, it may not fully capture the theoretical diversity of different TCM schools (such as Shanghan school, Wenbing school, and various regional traditions) or individual practitioner variations in diagnostic and treatment preferences. The scoring rubrics emphasized core competencies that transcend school-specific approaches—including fundamental syndrome differentiation logic, treatment principle adherence, and medication safety—but may underrepresent the value of school-specific theoretical frameworks that experienced practitioners might preferentially use in clinical practice. Finally, this study was conducted in the context of China's health care system, and findings may not directly generalize to TCM practice in other cultural contexts. The evaluation was also conducted at a specific point in time (March 2025) with models released in early 2025, representing a temporal snapshot of AI capabilities.

Future Research Directions

Two critical research priorities emerge from these findings. First, large-scale prospective clinical trials in real-world TCM practice are essential to validate the human-AI collaboration benefits observed in this controlled evaluation, particularly regarding patient outcomes, diverse populations, and long-term effectiveness. Such trials should use rigorous randomized designs with clinically meaningful end points beyond decision quality metrics.

Second, multicenter collaborative research across different health care systems and cultural contexts is needed to assess generalizability and identify implementation considerations for broader clinical adoption, including practitioner training requirements, workflow integration, and patient acceptance across diverse traditional medicine settings.

Conclusions

This study provides compelling evidence that LLMs, particularly DeepSeek-R1, demonstrate substantial capabilities in TCM knowledge assessment and clinical case analysis. The findings support the clinical value of human-AI collaboration, which achieved significant improvements in both decision-making quality (16.1% improvement) and efficiency (66.1% time reduction) compared with traditional approaches. The high system usability and favorable collaboration patterns indicate strong potential for successful integration into clinical practice.

These findings suggest that AI-assisted decision-making may address key challenges in TCM practice, including knowledge standardization, clinical training, and health care delivery efficiency. However, the study also highlights the continued importance of human clinical judgment, particularly in medication selection and individualized treatment formulation, where practitioner expertise remains essential.

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For clinical practice, we recommend piloting human-AI collaboration systems in controlled clinical environments with appropriate training and support protocols. For policy development, these findings support investment in AI research and development specifically targeting traditional medicine applications, along with regulatory frameworks that ensure patient safety while facilitating innovation. The demonstrated benefits of this technology suggest that strategic implementation of AI assistance could significantly enhance the quality, efficiency, and accessibility of TCM care while preserving the fundamental principles and personalized approach that characterize this medical tradition.

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Authors' Contributions

Weiwei Liu: Conceptualization, study design, methodology, formal analysis, investigation, writing – original draft, writing – review & editing, funding acquisition. These authors contributed equally to this work and share first authorship. Shuchang Miao: Conceptualization, study design, methodology, formal analysis, investigation, writing – original draft, writing – review & editing. These authors contributed equally to this work and share first authorship. Qun Ma: Investigation, writing – review & editing. Yuxin Li: Investigation, writing – review & editing. Yinxiang Deng: Investigation, writing – review & editing. Xiaoqiu Wang: Investigation, writing – review & editing. Xinwei Zhang: Investigation, writing – review & editing. Nuosha Ma: Investigation, writing – review & editing. Hanchi Miao: Investigation, writing – review & editing. Yang Si: Investigation, writing – review & editing. Qingxia Shi: Investigation, writing – review & editing. Lin Zhu: Investigation, writing – review & editing. Hongtao Shang: Validation, writing – review & editing. Yue Wang: Supervision, writing – review & editing, funding acquisition.

Conflicts of Interest

None declared.

Multimedia Appendix 1
160 basic knowledge test questions.
[DOC File, 40 KB - formative_v10i1e80167_app1.doc]

Multimedia Appendix 2
Detailed content of 30 case analyses.
[DOC File, 45 KB - formative_v10i1e80167_app2.doc]

Multimedia Appendix 3
Complete materials of 5 clinical cases.
[DOC File, 15 KB - formative_v10i1e80167_app3.doc]

Multimedia Appendix 4
Assessment scales and questionnaires.
[XLS File, 13 KB - formative_v10i1e80167_app4.xls]

Multimedia Appendix 5
Collaboration process records.
[XLS File, 12 KB - formative_v10i1e80167_app5.xls]

Multimedia Appendix 6
Detailed scoring results.
[XLS File, 99 KB - formative_v10i1e80167_app6.xls]

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Abbreviations

AI: artificial intelligence
ICC: intraclass correlation coefficient
LLM: large language model
OR: odds ratio
TCM: traditional Chinese medicine

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Individual Variability in Physiological Responses and Psychological Conditions Associated With Methamphetamine Use: Pilot Ecological Momentary Assessment Study Using a Wearable Device and Self-Monitoring Mobile App

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Abstract

Background: Digital mental health approaches offer a novel means to monitor and reduce harms associated with substance use in daily life. However, limited evidence exists on their application for methamphetamine (MAMP) use, particularly regarding individual variability in physiological responses and psychological conditions.

Objective: This pilot study aimed to explore inter- and intraindividual differences in craving, emotion, and heart rate associated with MAMP use, using data collected from a wearable device (Fitbit) and a mobile-based self-monitoring app.

Methods: Participants were individuals with MAMP use disorder receiving outpatient treatment in Japan. The analysis included 7 participants who used MAMP during an 8-week observation period. Physiological data, including heart rate and sleep patterns, were collected using Fitbit devices, while daily self-reported MAMP use, craving intensity, and emotional status were recorded via a mobile app. After syncing the data, we visualized and summarized individual MAMP use patterns in detail. Correlations between physiological and psychological indicators and the frequency of MAMP use per day were analyzed. In addition, heart rate trends before and after MAMP use events were evaluated using a linear mixed effects model, and both interindividual variability and intraindividual variability were assessed.

Results: Patterns of MAMP use varied widely across participants, with it most commonly occurring in the morning or at night, regardless of the day of the week. Craving and negative emotions were frequently reported on MAMP use days and were positively correlated with the number of MAMP use episodes per day. Participants who used MAMP more frequently exhibited relatively higher resting heart rates. Following MAMP use, heart rate increased significantly and remained elevated for up to 9 hours. Sleep duration and frequency were reduced or absent on MAMP use days. Approximately 64% of the variance in heart rate was attributable to interindividual differences, while 12% reflected variability across events within the same individual.

Conclusions: This pilot study demonstrates the feasibility and value of using digital tools to examine physiological responses and psychological conditions associated with MAMP use in real-world settings. Persistent cardiovascular activation and disrupted sleep highlight the potential risks of long-term MAMP use. Individual differences in heart rate responses, craving, and emotional states underscore the importance of personalized intervention strategies. Integrating real-time self-monitoring, notifications for elevated heart rate, and online cognitive behavioral therapy into digital therapeutic interventions may improve health outcomes for individuals with MAMP use disorder.

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KEYWORDS

methamphetamine; wearable device; physiological data; mobile app; ecological momentary assessment; self-monitoring; digital therapeutic intervention

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Introduction

Digital mental health is a promising approach to assessing and predicting mental health conditions [1-3], including issues related to alcohol and other drug use [4-8]. It enables the real-time and continuous collection of data in daily life through wearable devices and mobile apps. By leveraging these data, researchers can obtain deeper insights into both objective physiological indicators (eg, heart rate, sleep patterns, physical activity) and subjective, self-reported mental health conditions (eg, mood, sleep quality, substance use, craving). Additionally, researchers can develop predictive models of mental health conditions and intervention strategies. In fact, wearable devices and mobile apps have been used in numerous studies to address issues of mental health and substance use [9-11]. However, digital mental health studies related to substance use are less common than those focused on other mental health issues, and there is a lack of sufficient evidence to validate the effectiveness of remote monitoring of substance use disorders (SUDs) using wearable devices [12,13]. Implementing evidence-based digital health interventions for individuals with SUDs remains challenging [14,15].

When analyzing data from wearable devices and mobile apps, complex analytical methods, such as machine learning, are required depending on the study purpose and characteristics of the data obtained [16,17]. These datasets often contain large volumes of continuous and repeated measurements (ie, minute-by-minute, hourly, or daily data), as well as missing data. Physiological and psychological health indicators change over time and are influenced by an individual's characteristics. Therefore, addressing both interindividual and intraindividual variability is crucial when analyzing data or developing interventions based on the analysis results. However, standardized methodologies for data analysis and intervention development have not yet been well established [16,18]. More findings from studies in the field of digital mental health are needed to effectively apply complex data to real-world interventions, particularly in the area of substance use.

Moreover, few studies have focused on individuals who use methamphetamine (MAMP), as most research has concentrated on those who use alcohol, tobacco, or cannabis [6,8,19]. MAMP use is becoming more prevalent worldwide [20], with significant effects on the cardiovascular system, sleep, psychotic symptoms, and behavior [20,21]. Analyzing real-world data from individuals who use MAMP is crucial for assessing their physiological and mental health conditions during MAMP use and identifying key features that predict harms associated with MAMP use. Several laboratory-based studies have demonstrated that MAMP administration produces acute increases in heart rate and blood pressure, as well as significant disruptions in sleep architecture, including prolonged sleep latency and reduced REM sleep [21-25]. Self-reported studies among people with MAMP use disorder have similarly shown persistent insomnia and poor sleep quality during abstinence. However, these findings have been largely derived from controlled laboratory or inpatient settings, where ecological validity is limited. In contrast, very few studies have examined real-world physiological changes associated with MAMP use. Existing ecological momentary assessment (EMA) studies have primarily focused on psychological and behavioral dimensions, such as craving, mood, and contextual triggers (eg, Reback et al [26]), but momentary physiological indices, such as heart rate, activity, and sleep patterns, have rarely been captured in daily life. Integrating EMA with wearable sensing technologies therefore represents a promising novel method to elucidate the dynamic interplay between MAMP use, heart rate, and sleep conditions in naturalistic settings. Accordingly, this aimed to combine EMA and wearable physiological monitoring to explore how MAMP use affects real-time fluctuations in heart rate and sleep among individuals in their everyday environments. These insights could be valuable for developing new ecological momentary interventions, such as relapse prevention [27].

This pilot study aimed to preliminarily evaluate detailed patterns of MAMP use and physiological and psychological status when using MAMP and to explore both the interindividual and intraindividual variability in heart rate using physiological data from a wearable device (Fitbit) and self-reported data from a mobile-based substance use self-monitoring app. The findings may contribute to a better understanding of the health effects of MAMP use and will be useful for informing the protocol design of a subsequent larger-scale study.

Methods

Participants

Participants were patients with MAMP use disorder receiving outpatient treatment at a psychiatric hospital in Japan. Because MAMP use is illegal in Japan and many people who use it are concerned about the confidentiality of their information, recruiting participants from the general population was considered difficult. Therefore, we targeted individuals receiving outpatient treatment, for whom face-to-face recruitment was feasible. The inclusion criteria were (1) severity of MAMP use within the past year assessed as a score between 1 and 8 on the Drug Abuse Screening Test 10-item version (DAST-10) [28,29], (2) ownership of a smartphone (iOS 14 or later or Android 7.0 or later), (3) ability to wear a Fitbit continuously and to record daily entries using a self-monitoring app for 8 weeks, and (4) age 20 years or older. The exclusion criteria were (1) inability to speak or write in Japanese, (2) lack of internet access or inability to complete web-based surveys, (3) inability to participate for the entire 8-week study period, and (4) determination by the primary physician that study participation was inappropriate.

Psychiatrists specializing in SUDs screened potential participants based on the predefined inclusion and exclusion criteria. All participants were informed of the study aim and procedures and submitted written informed consent. A total of 13 participants were enrolled from September 2021 to April 2022. For this study, we used data from the 7 participants who used MAMP during the study period and with Fitbit data when they used MAMP. We excluded participants (n=6) who did not use MAMP at all during the study period or did not wear a Fitbit device when they used MAMP.

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Devices and Measurements

We previously reported the study protocol [30], providing an overview of the obtained data and preliminary analysis methods. In this study, we conducted a more detailed analysis, focusing specifically on individual differences in physiological responses before and after MAMP use events.

Fitbit Data

Fitbit is a wearable activity tracker, designed for use with both Android and iOS smartphones. In this study, Fitbit Inspire 2 [31] was used. To reduce measurement variability, all participants in this study used the same Fitbit Inspire 2 model and were provided with standardized wearing instructions throughout the study period. The device collects data such as heart rate per minute, sleep duration and quality, daily step count, and overall physical activity. Participants were instructed to wear the Fitbit device for 8 weeks and to regularly sync it with their smartphones via the Fitbit app. If a participant had missing data for 3 or more consecutive days, research staff sent reminder emails encouraging them to wear the device and sync it regularly. The synchronized data were retrieved daily from the Fitbit server through an application programming interface (API) and securely stored in a research database developed for this study, with all data anonymized to protect participant privacy.

We assessed two types of heart rate data in this study. The first was daily resting heart rate, as estimated by the Fitbit algorithm. The second was interval-based mean heart rate, which captures the average heart rate across 3-hour intervals before and after reported MAMP use. Specifically, we analyzed 6 time intervals: 6 hours to 9 hours before, 3 hours to 6 hours before, 0 hours to 3 hours before, 0 hours to 3 hours after, 3 hours to 6 hours after, and 6 hours to 9 hours after MAMP use. These intervals were chosen based on the approximate half-life of MAMP, which is approximately 10 hours [32]. By covering up to 9 hours on either side of MAMP use, we aimed to encompass the period during which the stimulant's physiological effects were likely to persist. Segmenting the data in this way allowed us to observe heart rate fluctuations potentially associated with the acute effects of MAMP.

Sleep condition was also assessed using two metrics: (1) sleep count (the number of sleeps detected by Fitbit in a single day) and (2) total main sleep time (the primary overnight sleep duration, excluding short naps). This latter metric reflects the continuous period from initial bedtime to final awakening.

Additionally, we calculated Fitbit device wearing rates by dividing the total number of minutes during which heart rate data was recorded by the total number of minutes in a day (ie, 1440 min). This measure was used to assess data completeness and to help identify behavioral patterns that may occur when participants remove the device in specific situations, such as during MAMP use.

Fitbit devices have been extensively evaluated in validation studies and systematic reviews, demonstrating acceptable validity for heart rate measurement, particularly under resting and low-to-moderate activity conditions, although slight underestimation compared with criterion measures has been reported [33,34]. Measurement accuracy is known to vary according to activity intensity, device model, and wearing conditions. For sleep assessment, Fitbit devices show high sensitivity for detecting sleep versus wake states but relatively lower specificity for detecting wakefulness [33,35]. As a result, total sleep time and sleep efficiency may be overestimated, while wake after sleep onset may be underestimated when compared with polysomnography [35]. Newer Fitbit models, including the Inspire 2, incorporate combined sensing approaches using accelerometry and heart rate–based algorithms, which have demonstrated improved performance over earlier generations.

In this study, physiological data were collected under an EMA framework in free-living conditions. Unlike biometric measurements obtained under standard circumstances, such as laboratory-based or clinically supervised settings with controlled posture, activity, and timing, the data in this study were captured continuously during participants' daily lives and in temporal proximity to self-reported events. As a result, collected data reflect real-world physiological states and may include greater variability due to uncontrolled environmental and behavioral factors.

Self-Monitoring App Data

Self-monitoring is widely used in the field of substance use and has been shown to effectively reduce drug use [36]. In ecological momentary studies, various types of self-reported data have been assessed, including substance use (use of MAMP and other drugs), craving, and emotions [10,11]. We developed a self-monitoring app for this study. Participants recorded the following data once a day for 8 weeks: (1) type of drug used; (2) start and end times of the drug use; (3) emotion status for the day, selected from 4 common emotional icons (good, not good, sad, angry); and (4) craving intensity, rated on a slider scale ranging from 0 to 10. These data were also stored securely and anonymously in the research database.

We summarized MAMP use patterns to confirm the frequency and timing of MAMP use both across participants and for each individual. Specifically, we examined the total number of days of MAMP use during the 56-day study period, average number of days of use per week, consecutive days of use, weekend use (ie, use on Saturdays and Sundays), the number of uses per day on days when MAMP was used, and the time of day MAMP was used (morning: 6 - 12 AM, afternoon: 12 - 6 PM, night: 6 - 12 PM, midnight: 12 - 6 AM). Additionally, we summarized craving intensity and emotional status on days when MAMP was used.

Analysis

Imputation of Missing Data and Noise Correction

Fitbit data were missing when the device was not worn. Heart rate, sleep, and activity data during these periods were treated as missing values. However, for graphical visualization purposes, these missing values were displayed as zero.

Heart rate data often contained noise, potentially affecting its accuracy and interpretation. We identified and corrected two types of noise: transient noise occurring whether the device was

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worn or not and continuous noise occurring while the device was worn. To address transient noise, we applied a moving average to smooth brief fluctuations in heart rate. Specifically, a 3-minute window was used to average out short-term spikes or drops, preserving the overall trend without overly distorting the data. For continuous noise, we applied a moving maximum with a 5-minute window, which more effectively captured upper boundary values in segments where heart rate readings were consistently unstable.

On days with no app entries, all questions were treated as missing. Even on days with entries, any unanswered questions were also considered missing. If the question regarding MAMP use was missing for a given day, that day was excluded from calculations related to MAMP use.

Descriptive Statistics

First, demographic characteristics of the participants, emotional status, craving, heart rate, and Fitbit wearing rate were summarized during the study period. Second, for each participant, patterns of MAMP use, Fitbit wearing rate, emotional status, craving, and heart rate on MAMP use days were calculated and visualized. In addition, physiological data collected by Fitbit during the study period were visualized to examine individual trends. Python (3.10.10), with the pandas (2.2.3), matplotlib (3.7.3), and seaborn (0.12.2) libraries, was used for these analyses and visualizations.

Analysis of Interindividual and Intraindividual Differences

To examine the relationship between psychological and behavioral states and MAMP use, both within individual participants and across all participants, we assessed the correlations between the amount of MAMP use on MAMP-use days and emotion, craving, and heart rate using Pearson correlation coefficients. When calculating the correlation coeffficients, the 4 emotional categories were operationally converted into numerical values as follows: good=1, not good=0, sad=−1, angry=−2. These calculations were performed in Python (3.10.10) using the scipy.stats.pearsonr function from scipy (1.15.2).

To examine interindividual differences in heart rate trends before and after MAMP use, we categorized the mean heart rate when using MAMP for each participant into 6 time intervals: 6 hours to 9 hours before, 3 hours to 6 hours before, 0 hours to 3 hours before, 0 hours to 3 hours after, 3 hours to 6 hours after, and 6 hours to 9 hours after. We included only the data collected when heart rate could be monitored for 9 hours before and after MAMP use. Moreover, to examine intraindividual differences in heart rate before and after MAMP use, we calculated the mean heart rate trend for each MAMP use event. A linear mixed effects model was used to evaluate changes in heart rate before and after drug use and to assess interindividual and interevent differences. This model is most appropriate for handling repeated daily measurements nested within individual participants [37]. The interval-based mean heart rate was set as the dependent variable. The time periods (6 - 9 h before, 3 - 6 h before, 0 - 3 h before, 0 - 3 h after, 3 - 6 h after, and 6 - 9 h after) were included as fixed effects. The period 6 hours to 9 hours before drug use was set as the reference category for comparison with other time periods. The participant ID was treated as the primary random effect, and MAMP use events nested within each participant were treated as an additional random effect. Additionally, to account for the autocorrelation among consecutive measurements within each event, a first-order autoregressive model was used. The model was estimated using restricted maximum likelihood and analyzed using the nlme package in R (version 3.1.167). We excluded a participant who did not wear a Fitbit on days of MAMP use from the linear mixed effects model analysis. The statistical significance of differences between time periods was evaluated using *t* tests, with the significance level set at $P<.05$.

To quantify the magnitude of interindividual differences, we examined the variance components of the model and calculated the intraclass correlation coefficient. The proportion of total variance attributable to differences between participants was calculated to determine the extent of interindividual variability in heart rate responses. Similarly, the significance of interevent differences was evaluated by examining the proportion of total variance attributable to event-specific variability within the same individual.

Ethical Considerations

This study was approved by the Ethics Committee of the Faculty of Medicine and Graduate School of Medicine at Tokyo Medical and Dental University (M2020-189) and the participating hospital. Data collected from the self-monitoring app and the Fitbit server were automatically stored in a secure database without any personally identifiable information. These datasets were then matched using participant IDs. All participants provided written informed consent prior to participating in the study. The participants received a prepaid card worth JP¥ 3,000 (US $19.36) as a reward for participating in the study, and received a Fitbit used in the study as compensation after the study.

Results

Participant Characteristics and MAMP Use Patterns

Table 1 presents the demographic characteristics and conditions related to MAMP use during the study period. The mean age of participants was 47.0 (SD 9.7) years, and the majority were male (6/7, 86%). The average Fitbit wearing rate throughout the study period was 70.1%. The severity of drug dependence assessed using DAST-10 was substantial, with a mean score of 6.0 (SD 1.3). The mean resting heart rate over the study period was 69.8 (SD 8.2) bpm. Emotional status was most frequently reported as “good” (121/308, 39.3%) or “not good” (129/308, 41.9%).

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Table . Participant characteristics, device wearing rate, craving, emotional status, and heart rate during the study period (n=7).

Characterics	Results
Age (years), mean (SD)	47.0 (9.7)
Gender (male), n (%)	6 (86)
Fitbit device wearing rate (%), mean (SD)	70.1 (36.1)
DAST-10[a], mean (SD)	6.0 (1.3)
Craving[b], mean (SD)	3.9 (3.7)
Resting heart rate (bpm), mean (SD)	69.8 (8.2)
Emotion, n (%)[c]	
Good	121 (39.3)
Not good	129 (41.9)
Sad	46 (14.9)
Angry	12 (3.9)

[a]DAST-10: Drug Abuse Screening Test 10 (range: 0 to 10).

[b]Assessed using a numerical rating scale (range: 0 to 10).

[c]n=308.

Detailed patterns of MAMP use are presented in Table 2 and Multimedia Appendix 1. The mean number of days of MAMP use during the study period was 13.4 (SD 13.9) days over the 56-day study period, ranging from 1 day to 41 days across participants. The number of consecutive days of MAMP use and days of weekend use varied among participants, with mean values of 2.3 (range 1.0-5.9) days and 4.3 (range 0-13) days, respectively. On MAMP use days, the average number of uses was <2 (mean 1.4, SD 0.8). The most frequently reported time of MAMP use depended on the participant; however, it was most commonly in the morning (6-12 AM) or at night (6 - 12 PM), accounting for 48.8% (63/129) and 21.7% (28/129) of use events, respectively. Participants who used MAMP frequently (IDs B and C) showed relatively higher resting heart rates than those with less frequent MAMP use.

The completion rate of self-monitoring during the study period and psychological and physiological conditions on MAMP use days are shown in Table 3 and . Throughout the study period, the mean completion rates for self-monitoring of craving and emotional status were 64% (SD 28.4%) and 78.6% (SD 27.3%), respectively. On days when participants used MAMP, emotional status was most frequently reported as “not good” (mean 51%, SD 54.3%) or “sad” (mean 20%, SD 21.3%). The mean craving score was 5.8 (range 2.2-9.8), and resting heart rate averaged 71.3 (range 60.0 to 78.2) bpm; both were higher than the overall averages for the study period. The mean Fitbit wearing rate was 82.1% (range 0%-94.3%), indicating that participants wore the device relatively consistently even on days they used MAMP. However, econsiderable variation in emotional status and craving existed between participants. Sleep duration and frequency tended to be reduced or absent on MAMP-use days or the day afterand Figure S1 in Multimedia Appendix 2).

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Table . Patterns of methamphetamine (MAMP) use among participants (n=7).

Participant ID	MAMP-use days in 56 days (days), n	MAMP use per week (days), mean (SD)	Consecutive MAMP use (days), mean (SD)	Weekend use (days), n (%)	Number of MAMP uses on MAMP use days, mean (SD)	Time period of MAMP use, n (%)				Total MAMP uses, n
						Morning[a]	Afternoon[b]	Night[c]	Midnight[d]	
A	7	0.9 (1.0)	1.0 (0.0)	2 (28.6)	1.1 (0.4)	0 (0)	2 (25)	6 (75)	0 (0)	8
B	22	2.8 (1.7)	2.2 (1.5)	8 (36.4)	1.7 (0.7)	4 (10.5)	11 (28.9)	13 (34.2)	10 (26.3)	38
C	41	5.1 (2.4)	5.9 (4.5)	13 (31.7)	1.2 (0.8)	49 (96.1)	1 (2)	0 (0)	1 (2)	51
D	5	0.6 (0.9)	1.3 (0.4)	0 (0)	1.0 (0.0)	2 (40)	0 (0)	3 (60)	0 (0)	5
E	6	0.8 (0.9)	1.5 (0.5)	4 (66.7)	1.8 (1.2)	3 (27.3)	3 (27.3)	3 (27.3)	2 (18.2)	11
F	12	1.5 (1.2)	1.7 (0.7)	3 (25)	1.3 (0.6)	5 (33.3)	1 (6.7)	2 (13.3)	7 (46.7)	15
G	1	0.1 (0.4)	1.0 (N/A[e])	0 (0)	1.0 (N/A)	0 (0)	0 (0)	1 (100)	0 (0)	1
All participants	13.4 (13.9)[f]	1.7 (1.7)	2.3 (2.7)	4.3 (26.9)[f]	1.4 (0.8)	63 (48.8)[f]	18 (14)[f]	28 (21.7)[f]	20 (15.5)[f]	129

[a]6 - 12 AM.

[b]12 - 6 PM.

[c]6 - 12 PM.

[d]0 - 6 AM.

[e]N/A: not applicable.

[f]Mean (SD).

Table . Completion rate of self-monitoring during the study period and device wearing rate, emotional status, craving, and heart rate on days with methamphetamine (MAMP) use (n=7).

Participant ID	Completion of self-monitoring during the study period, n (%)		Fitbit device wearing rate on the day of MAMP use (%), mean (SD)	Emotion, n (%)					Craving[a], mean (SD)	Resting heart rate (bpm), mean (SD)
	Craving days	Emotional status days		Good	Not good	Sad	Angry	No record		
A	50 (89.3)	49 (87.5)	71.2 (29.3)	3 (42.9)	2 (28.6)	1 (14.3)	1 (14.3)	0 (0)	4.1 (0.6)	69.8 (2.3)
B	32 (57.1)	35 (62.5)	94.3 (11.4)	2 (9.1)	17 (77.3)	2 (9.1)	0 (0)	1 (4.5)	9.0 (1.3)	71.2 (4.2)
C	23 (41.1)	54 (96.4)	88.7 (18.3)	11 (26.8)	3 (7.3)	0 (0)	0 (0)	0 (0)	4.6 (1.3)	78.2 (2.0)
D	28 (50)	55 (98.2)	84.6 (21.1)	0 (0)	2 (40)	3 (60)	0 (0)	0 (0)	4.0 (1.7)	67.3 (3.5)
E	52 (92.9)	48 (85.7)	25.8 (34.3)	0 (0)	2 (33.3)	1 (16.7)	0 (0)	3 (50)	9.8 (0.4)	60.0 (2.6)
F	53 (94.6)	54 (96.4)	77.4 (32.3)	1 (6.7)	4 (26.7)	10 (66.7)	0 (0)	0 (0)	2.2 (2.6)	64.6 (4.7)
G	13 (23.2)	13 (23.2)	0 (N/A[b])	1 (100)	0 (0)	0 (0)	0 (0)	0 (0)	8.0 (N/A)	N/A
All participants	64 (28.4)[c]	78.6 (27.3)[c]	82.1 (27.9)	18 (19.1)[c]	51 (54.3)[c]	20 (21.3)[c]	1 (1.1)[c]	4 (4.3)[c]	5.8 (3.4)	73.1 (6.4)

[a]Craving: assessed using a numerical rating scale (range 0 to 10).

[b]N/A: not applicable.

[c]Mean (SD).

Craving and Emotions

Table 4 shows the correlations between psychological and behavioral states and MAMP use. Negative emotions (such as feeling sad or angry) were associated with a higher number of MAMP uses per day. Craving (r=0.32, P<.001) and resting heart rate (r=0.16, P<.01) were positively correlated with the number of daily MAMP uses. However, these correlations varied

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across participants and were not observed in some cases. The Fitbit wearing rate was positively correlated with the number of MAMP uses per day (r=0.17, P<.001), suggesting that participants tended to wear the device even on days when they used MAMP.

Table . Correlations between the number of methamphetamine (MAMP) uses per day and emotion, craving, and heart rate on MAMP use days (n=7).

Participant	Correlation with number of MAMP uses per day			
	Emotion[a], *r*	Craving, *r*	Resting heart rate (bpm), *r*	Device wearing proportion on days of MAMP use, *r*
Participant ID A	0.02	0.37[b]	−0.02	−0.08
Participant ID B	0.00	0.02	−0.11	0.20
Participant ID C	0.20	0.01	−0.05	−0.03
Participant ID D	−0.40[b]	−0.36	−0.20	0.22
Participant ID E	−0.07	0.50[c]	−0.07	−0.43[b]
Participant ID F	−0.63[c]	0.25	0.18	0.03
Participant ID G	0.08	0.03	N/A	−0.06
All participants	−0.12[d]	0.32[c]	0.16[b]	0.17[c]

[a]Assessed using 4 emotional status categories (good=1, not good=0, sad=−1, angry=−2).

[b]P<.01.

[c]P<.001.

[d]P<.05.

Heart Rate Response and Interindividual and Intraindividual Differences

Heart rate tended to increase following MAMP use (Figures 1 and 2, Figure S1 in Multimedia Appendix 2). Table 5 presents the results of a linear mixed effects model evaluating changes in heart rate before and after drug use. A total of 122 observations were included in the analysis, with 5 to 50 observations per participant. The model demonstrated a good fit (log-likelihood=−2626.359). The mean heart rate during the reference period (6 - 9 h before drug use) was 89.89 (95% CI 76.88 to 102.89) bpm. At 0 hours to 3 hours postdrug use, mean heart rate increased significantly compared with the reference period (+5.44, 95% CI 3.26 to 7.62 bpm; P<.001), and this elevated level was maintained at 3 hours to 6 hours postuse (+5.51, 95% CI 3.04 to 7.98 bpm; P<.001). A significant increase was also observed at 6 hours to 9 hours postuse (+3.84, 95% CI 1.27 to 6.41 bpm; P=.003). Heart rate during the 0 hours to 3 hours before drug use did not differ significantly from the reference period. However, at 3 hours to 6 hours before drug use, heart rate was significantly lower than during the reference period (−2.71, 95% CI −5.25 to −0.17 bpm; P=.04).

Analysis of variance revealed substantial interindividual and intraindividual variability in heart rate responses. Variance was observed at multiple levels: between participants (SD 15.88 bpm), between events within participants (SD 6.76 bpm), and in the residual error (SD 9.80 bpm). The between-participant variance was 250.66, with an intraclass correlation coefficient of 0.64, indicating that approximately 64% of the total variability in heart rate measurements was attributable to differences between individuals. The variance between events within participants was 45.9, accounting for roughly 12% of the total variance. The residual variance was 96.0, suggesting that the same individual may exhibit different heart rate responses to MAMP use on different occasions.

Figure 1. Interindividual differences in methamphetamine use event and heart rate. Box plot of mean heart rate per methamphetamine use event across 6 time intervals for each participant, highlighting interindividual variability and temporal changes in physiological responses. Participant ID G was omitted because only one methamphetamine use record was available, preventing further calculation.

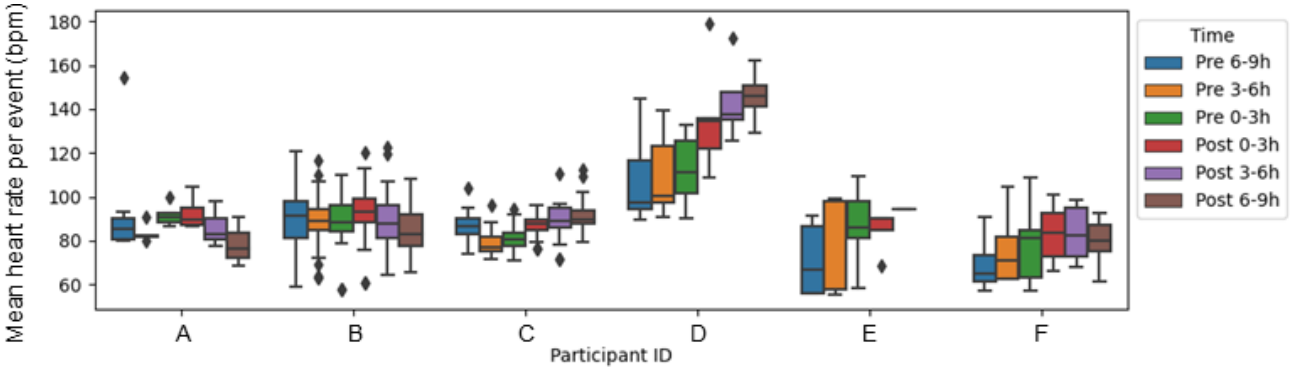

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Figure 2. Intraindividual variability in heart rate responses across methamphetamine-use events, shown as changes in mean heart rate across 6 defined intervals surrounding each methamphetamine-use event, represented as a line, for individual participants: (A) participant ID A, (B) participant ID B, (C) participant ID C, (D) participant ID D, (E) participant ID E, and (F) participant ID F. Lines ending prematurely indicate missing heart rate data due to device removal. The red dotted line indicates the average resting heart rate. Participant ID G was omitted because only one methamphetamine use record was available, preventing further calculation.

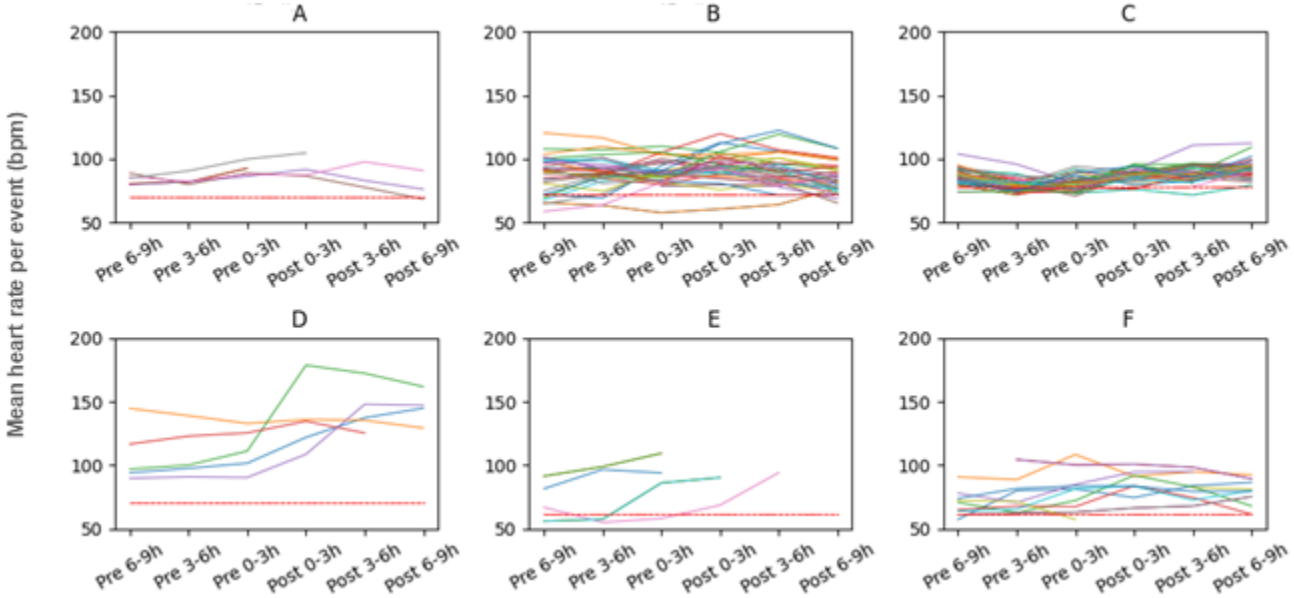

Table . Results of a linear mixed effects model on heart rate changes before and after methamphetamine (MAMP) use (n=6; 122 data points included in the analysis): random effect std: participants=15.88 bpm (intraclass correlation coefficient=0.64), events within participants=6.76 bpm (intraclass correlation coefficient=0.12), residual=9.80 bpm.

Time period of MAMP use	Change in heart rate (bpm), coefficient (95% CI)	SE	*t* test	*P* value
Before (pre-; hours)				
6 - 9 (Reference)	89.89 (76.88 to 102.89)	6.62	13.58	<.001
3 - 6	−2.71 (−5.25 to −0.17)	1.28	−2.10	.04
0 - 3	0.13 (−2.37 to 2.65)	1.29	0.11	.92
After (post-; hours)				
0 - 3	5.44 (3.26 to 7.62)	1.11	4.9	<.001
3 - 6	5.51 (3.04 to 7.98)	1.26	4.38	<.001
6 - 9	3.84 (1.27 to 6.41)	1.31	2.94	.003

Discussion

Principal Findings

This pilot study presented detailed patterns of MAMP use, along with interindividual and intraindividual variability in physiological and psychological data, using Fitbits and a mobile-based self-monitoring app with individuals with MAMP use disorder. Patterns of MAMP use varied across participants. Craving for MAMP and negative emotions tended to be associated with the number of MAMP uses per day. A persistent increase in heart rate was observed following MAMP use. However, these trends differed between individuals and across MAMP use events. Because the sample size was small and there was considerable variability in the number of MAMP use days across participants, a larger-scale study will be necessary to further examine these associations. In particular, additional analyses are needed to clarify the relationships among craving, emotional states, and MAMP use.

Variability of MAMP Use Patterns

Among the participants, the frequency of MAMP use varied widely, with the total number of use days ranging from 1 day to 41 days, and consecutive days of use ranging from 1.0 day to 5.9 days. In contrast, the number of MAMP uses per day was relatively consistent among the participants, typically fewer than 2 times per MAMP use day. The participants tended to use MAMP in the mornings and at night on both weekdays and weekends. MAMP is often used to improve performance for daily activities or work, staying awake, helping manage stress, or increasing sexual performance and impulses [38,39]. The participants might also use MAMP when they need to motivate their behavior for specific purposes, whether on weekdays or weekends. This finding is consistent with previous

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wastewater-based epidemiology studies, which revealed no significant differences in MAMP use between weekdays and weekends [40-42].

Additionally, abstinence following prolonged MAMP use can lead to withdrawal symptoms such as sleep disturbances, difficulty concentrating, fatigue, irritability, agitation, anxiety, sadness, depression, and an inability to engage in normal daily activities [43]. Some participants may struggle to manage these withdrawal symptoms and return to MAMP use. As a result, cycles of binge use and abstinence may occur among individuals with MAMP use disorder. To date, no medications have shown consistent effectiveness for treating MAMP withdrawal [44], and psychosocial treatments remain the primary approach. Cognitive-behavioral therapy (CBT) can be useful for managing withdrawal and craving, supporting sustained abstinence, and facilitating recovery following lapses or relapses [45,46]. Recently, online and computerized forms of CBT have become more widespread and have been shown to be safe, effective, and durable when compared with standard clinician-delivered therapy [47,48]. Incorporating online CBT modules into ecological momentary interventions may be a promising approach for supporting individuals with MAMP use disorder.

Relationship of Craving and Emotions

On MAMP use days, cravings and negative emotions (eg, feeling sad or unwell) were more frequently reported than in the overall study period. Significant correlations were observed between craving and the number of MAMP use episodes per day, consistent with findings from previous studies. MAMP craving has been shown to persist for at least 5 weeks into abstinence, with individuals being vulnerable to relapse during the first 7 days to 14 days [49] Craving is considered a significant predictor of subsequent MAMP use [50,51]. Negative emotions often intensify cravings, and individuals may be more likely to use MAMP if they do not effectively address these emotions [8,52]. Although the causal relationship between negative emotions and MAMP use was unclear in this study, some participants without adaptive coping strategies may use MAMP as a way to cope with negative emotions. When developing ecological momentary interventions for individuals with MAMP use disorder, incorporating modules for self-monitoring may be helpful to increase awareness of the relationships between emotions, craving, and MAMP use, even during abstinence periods. Additionally, modules for coping with negative emotions may be promising approaches to support MAMP use management.

Overall, tendencies for correlations between MAMP use and craving or negative emotions were observed; however, these relationships and trends varied across the participants. There were some participants without significant correlations between MAMP use and craving or negative emotions. MAMP is often used to reduce withdrawal symptoms from other substances or to cope with pain and discomfort [39]. Additionally, increased tolerance or experiencing a critical life event may lead to increased MAMP use [29]. A previous study suggested that individuals who initiate MAMP use at a later age may do so to "self-medicate" in response to stressful life events [19]. Long-term MAMP users may become less sensitive to cravings due to tolerance. Moreover, some individuals with chronic pain or persistent psychiatric symptoms (eg, depression, anxiety) may use MAMP regardless of craving and emotions. Promoting appropriate and fundamental treatments to address the underlying causes of MAMP use, such as chronic pain and mental health issues, is also essential.

Heart Rate and Sleep After MAMP Use

After using MAMP, reduction or loss of sleep and a tendency for increased heart rate were observed. Participants with frequent MAMP use exhibited high resting heart rates. MAMP has a strong and relatively long-lasting stimulant effect on the central nervous and cardiovascular systems [20]. Findings from the linear mixed effects model suggest that the cardiovascular effects of MAMP persist for up to 9 hours after use, with an increase of 3 bpm to 5 bpm compared with baseline levels. In line with previous experimental studies [22], heart rate increased following MAMP use. Laboratory-based studies often evaluate short-term cardiovascular responses using standardized doses and predefined routes of administration. In contrast, this study suggests that, in real-world settings, heart rate elevation following MAMP use may persist for up to 9 hours. This study examined naturally occurring MAMP use events under free-living conditions, and despite variability in dosage, routes of administration, and contextual factors, sustained elevations in heart rate were observed. The average heart rates among the participants (approximately 60 bpm to 78 bpm) were within the normal range; however, chronically elevated heart rate can still lead to cardiovascular dysfunction [53-55]. Unexpected harms related to MAMP use, such as stroke, coronary artery disease, and sudden cardiac death, may occur in individuals who use MAMP frequently, even among young adults [19,55,56]. The implementation of an alert system within an ecological momentary intervention app designed to detect and notify individuals of sudden heart rate increases or arrhythmias may contribute to the prevention of cardiovascular events.

Interindividual and Intraindividual Differences in Heart Rate Response

Findings from the analysis of varianceA indicated that increases in heart rate were attributable to both individual differences and MAMP use events. Approximately 64% of the variance in heart rate was due to differences between participants, suggesting significant heterogeneity in individual responses to MAMP use. Previous studies have suggested that gender differences and genetic variations may help explain individual differences in responses to MAMP use [57,58]. Identifying individuals who exhibit substantial increases in heart rate following MAMP use and providing real-time notifications of elevated heart rate may be a useful strategy for risk management. In contrast, variance between events within individuals accounted for approximately 12% of the total variance, indicating that even the same individual may experience different cardiovascular responses to MAMP on different occasions. These findings have important clinical implications, emphasizing that drug effects are not consistent, even within individuals. These differences may be influenced by the duration of MAMP effects and bioavailability, which are affected by various factors such as the route of administration (eg, injection, smoking) and the amount of

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MAMP used [20,43]. Even among individuals with relatively mild cardiovascular responses, any changes in the administration or dosage of use should be approached with caution. To comprehensively understand variability in heart rate response to MAMP use, it is essential to consider both interindividual and intraindividual variability.

Implications for Future Research

As a pilot study, these findings provide important insights for the design of future EMA-based research on MAMP use. Specifically, the results can inform the optimization of EMA protocols, including the timing and frequency of pre- and post-MAMP use. In this study, we were unable to determine causal relationships between psychological states and MAMP use, as craving and emotional status were assessed only once per day. More frequent self-monitoring may enable more precise assessment of craving and emotional states and help elucidate their temporal associations with MAMP use. Such refinements may enhance the ability to capture within-person dynamics and identify high-risk periods that could be targeted in future intervention studies. Furthermore, the study findings may inform the development of personalized interventions that account for both between-person and within-person variability in associations with MAMP use and physiological responses or psychological states.

Limitations

This pilot study has several limitations. First, self-monitoring was conducted only once per day, which limited our ability to evaluate causal relationships between craving, emotions, and MAMP use. In our ongoing study, self-monitoring is conducted 3 times per day using an EMA approach to address this limitation. Second, we did not assess nor adjust for potential confounding factors such as smoking habits, night shift work, or the use of alcohol and other substances, which may influence heart rate and sleep patterns. Although other drug use, such as opioids, was rare among participants in this study, these variables are assessed in our ongoing research. Third, the sample size was small, and the participants were only individuals who received outpatient treatment. This may have biased the results. Further research with a larger sample and individuals with more active MAMP use is needed, along with strategies to improve adherence to wearable devices and response rates to self-monitoring prompts. Last, we did not collect data on the route of administration or the quantity of MAMP. To more precisely evaluate heart rate responses, information on how MAMP is used and in what amounts may be important.

Conclusions

This pilot study captured psychological status and physiological responses related to MAMP use, using an EMA framework. Patterns of MAMP use varied among individuals with MAMP use disorder. Overall, craving and negative emotions were correlated with the frequency of MAMP use per day; however, this relationship differed across participants. Similar physiological responses were commonly observed following MAMP use, including persistent increases in heart rate and sleep disturbances, which can lead to cardiovascular dysfunction. Heart rate increased significantly by approximately 3 bpm to 5 bpm compared with the period before MAMP use and remained elevated for up to 9 hours. However, increases in heart rate were explained not only by MAMP use events but also by individual differences. To better understand the individualized predictors for use and physiological responses to use, it is essential to assess both interindividual and intraindividual variability. The findings should be interpreted as exploratory and reflective of within-person patterns rather than representative of group-level trends. Further studies with larger and more diverse samples are needed to assess generalizability.

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Data Availability

The datasets in this study are not available because we did not obtain permission from the participants to disclose raw data or approval from the ethics committee in each institution for data sharing.

Authors' Contributions

AT, JS, and TM were involved in the study design and protocol. AT, K Ono, and TM were involved in participant recruitment, data collection, and study management. AT and K Okuda were involved in preliminary data consideration and analysis and drafted the manuscript. All authors critically revised the manuscript and approved the final version.

Conflicts of Interest

K Okuda and JS are employed by Humanome Lab Inc. All authors declare no other competing interests.

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Multimedia Appendix 1
Heatmaps visualizing daily physiological responses and psychological conditions, with METH Use Event reflecting the number of drug use events, Weekend indicating whether a day is a weekend (weekdays are shown in lighter shades), and emotions color-coded as follows: angry, dark red; sad, light red; not good, light blue; good, dark blue. Darker colors for METH Use Event, Device Wearing Rate, Sleep Count, Total Main Sleep Time, and Resting Heart Rate indicate higher frequency of drug use, longer durations of device use, a greater number of sleep episodes, longer sleep duration, and a higher resting heart rate, respectively. METH: methamphetamine.
[PDF File, 989 KB - formative_v10i1e73790_app1.pdf]

Multimedia Appendix 2
Physiological data collected during the measurement period, with each row representing 1 week, starting from Monday.
[PPTX File, 6299 KB - formative_v10i1e73790_app2.pptx]

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Abbreviations

API: application programming interface
CBT: cognitive-behavioral therapy
DAST: Drug Abuse Screening Test
EMA: ecological momentary assessment
MAMP: methamphetamine
SUD: substance use disorder

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Evaluation of the Accuracy of Probabilistic Record Linkage Across Sociodemographic Categories in 4 Databases: Exploratory Study

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Abstract

Background: Accurate patient record linkage is essential for clinical care, health information exchange, research, and public health surveillance. However, linkage accuracy may vary across demographic groups due to differences in data completeness, quality, and the structural factors underlying how demographic information is captured.

Objective: This study aimed to explore whether probabilistic patient matching accuracy varies by age, sex, race, and ethnicity and to identify potential sources of bias that may influence matching performance.

Methods: We used 4 Indiana data sources—the Indiana Network for Patient Care, Newborn Screening, Social Security Administration Death Master File, and Marion County Public Health Department—and applied a modified Fellegi-Sunter probabilistic linkage algorithm accommodating missing data under a missing at random assumption. Gold standard match status was established through dual manual review with adjudication. For each dataset, matching sensitivity, positive predictive value, and F_1-scores were estimated and stratified by age, sex, race, and ethnicity. Data completeness, distinct value ratio, and Shannon entropy were assessed to characterize data quality. Ninety-five percent bootstrap CIs were used to assess significance.

Results: The algorithm-matching F_1-score was greater than 0.82 for all age strata, ranging from 0.88 to 0.97 for sex, 0.85 to 0.99 for race, and 0.88 to 0.99 for ethnicity. Sensitivity ranged from 0.70 to 0.97 across age strata, 0.76 to 0.97 across sex, 0.85 to 0.99 across race, and 0.85 to 0.989 across ethnicity. Lower sensitivity and F_1-scores were consistently observed in strata with greater missingness or discordance, particularly in Newborn Screening and Social Security Administration Death Master File. Race and ethnicity exhibited the highest missingness and lowest informational diversity, coinciding with the largest declines in accuracy. Shannon entropy and distinct value ratio varied across demographic groups and were strongly associated with performance, indicating that both low and excessively high informational diversity can impair matching.

Conclusions: Probabilistic patient matching accuracy is not uniform across demographics and is strongly influenced by data quality and completeness. Although overall matching performance, as assessed by the F_1-score, remained above 0.8, it varied across datasets when stratified by sociodemographic characteristics. Sociodemographic data missingness is associated with lower matching accuracy, raising equity and ethical concerns for clinical, research, and public health applications. Routine demographic-stratified evaluations of matching accuracy, improved standardization of sociodemographic data, and fairness-aware linkage methods are essential to prevent the amplification of structural inequities in linked health datasets.

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KEYWORDS

record linkage; data quality; sociodemographic characteristics; matching algorithms; matching accuracy

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Introduction

Clinical Significance

Patients receive care in many settings along their health care journey; however, their information is often stored in separate, organization-specific electronic health records. Each encounter—whether in a hospital, outpatient setting, laboratory, or public health department—generates new patient data that may not be accurately linked across health systems. Errors in patient identification can lead to duplicate or incomplete health records, jeopardizing patient safety and wasting health care time and resources.

Duplicate records occur in approximately 5% to 10% of hospital electronic health records, with up to 92% resulting from human error during registration [1]. These errors increase health care costs—averaging US $1950 per inpatient stay and more than US $800 per emergency department visit [2]. Overwriting one patient's record with another's data introduces additional safety risk and can compromise clinical care. Identification inaccuracies also contribute to financial inefficiencies—approximately 33% of all denied insurance claims are linked to patient identification errors, costing the US health care system over US $6 billion annually [3]. Collectively, record linkage errors affect patients, providers, and payers and have both clinical and economic consequences.

Background

Accurate linkage of individual patient records is essential for integrating information across encounters and creating reliable, longitudinal data resources. Record linkage supports basic intrasystem tasks—such as matching laboratory results to the correct patient—as well as more complex information exchange across health care organizations. Several methodologies exist for matching health care records, including (1) deterministic rule–based approaches, (2) probabilistic methods that assign match weights or scores, (3) machine learning–based models, and (4) hybrid approaches combining multiple techniques [4,5]. Thus far, no single approach has emerged as universally superior [6].

Matching algorithms rely on identifiers such as name, date of birth, social security number, address, and their performance depends on how complete, accurate, and consistently formatted these fields are [6]. Consequently, effective patient linkage depends on both data quality [7,8] and the robustness of the matching method [9]. In this context, data quality reflects completeness—a populated field rather than missing—and correctness, the concordance of field values across datasets. Data quality is well established as foundational to reliable analytics and decision-making [10-12]. Structural and organizational factors can introduce systematic biases, and linkage errors arise when information is missing, incorrect, or inconsistent, leading to (1) missed matches (records belonging to the same individual are not linked) or (2) false matches (records from different individuals are erroneously linked) [13]. Linkage errors do not occur at equal rates across populations. Patients from ethnic minorities, particularly those with naming conventions not aligned with Western standards, experience higher rates of missed or incorrect matches [14].

Additionally, missing demographic data are more prevalent among specific populations due to social, linguistic, or contextual factors [15]. Sociodemographic characteristics, such as age, ethnicity, race, social vulnerabilities, geographical setting, and health status, have been associated with lower data completeness and higher error rates [15,16]. However, the degree to which matching performance itself varies across these factors has not been systematically examined. Given the documented disparities, identifying and understanding sociodemographic patterns associated with linkage errors is essential for recognizing and mitigating bias in patient record linkage.

Study Objective

Unlike deterministic record-matching approaches that require exact agreement across fields, probabilistic methods assign probabilities based on weighted combinations of multiple attributes. This design makes them more sensitive to variations in data quality and demographic characteristics and therefore relevant for studying potential algorithmic bias. The Fellegi-Sunter (FS) framework is one of the most widely used and well-characterized probabilistic methods in operational US health care environments. In this study, we selected the FS framework to evaluate a core linkage approach representative of real-world practice. Although many operational systems incorporate additional deterministic or hybrid rules, such configurations are highly customized and not easily generalizable. Focusing on the probabilistic foundation most commonly deployed allows us to assess how demographic factors may influence match accuracy. Accordingly, the objective of this study was to explore whether probabilistic patient matching accuracy varies by age, sex, race, or ethnicity and to identify potential data-related sources of bias that may influence matching performance.

Methods

Patient Demographic Data

This study used 4 Indiana-based patient demographic data sources. First, the Indiana Network for Patient Care (INPC), a statewide health information exchange containing over 47 million registration records across more than 100 clinical data sources, including emergency department visits, hospital admissions, and large outpatient health care clinics from across the state [17]. Second, Newborn screening (NBS) data, consisting of demographic data derived from health information exchange-wide Health Level 7 messaging for children aged under 12 months. This dataset includes limited newborn screening information collected within 5 days of birth, mandated by Indiana law. Third, Social Security Administration Death Master File (SSA), containing records of individuals issued a Social Security number whose deaths were reported to the SSA. Fourth, Marion County Public Health Department (MCPHD), the county's infectious disease reporting database. Marion County is Indiana's largest county, with a population of just over 966,000.

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Generation of Patient Record Pairs

This study leveraged analytic datasets from previous studies on patient matching and record linkage [2,18]. The FS model was chosen for this project due to its widespread use and flexible maximum-likelihood framework. To accommodate missing data in real-world settings, we applied an established modification of the FS model under the missing at random (MAR) assumption [19,20]. Under the MAR assumption, missing fields are handled using the full-information likelihood approach, which incorporates all available data while excluding only the specific missing fields, assuming conditional independence across variables. Using the modified FS probabilistic algorithm [21], we identified matches and nonmatches across four dataset pairs: (1) INPC to INPC (labeled as INPC), (2) NBS to NBS (labeled as NBS), (3) INPC to SSA (labeled as SSA), and (4) INPC to MCPHD (labeled as MCPHD). Matching variables included medical record number, first and last name, middle initial, sex, telephone number, address, ZIP code, social security number, and components of the date of birth.

Manual Review of Record Pairs

To construct a gold standard reference, we randomly sampled record pairs from each dataset for manual review. For each sampled pair, complete reference data from both records were provided to the reviewers to support accurate adjudication [2,22]. Using a balanced, incomplete block design, 2 independent reviewers assessed each pair's match status [20], while a third reviewer resolved any discrepancies. A total of 62,000 pairs were manually reviewed: 15,000 INPC, 15,000 NBS, 16,500 SSA, and 15,500 MCPHD. As the reviewers' identities were inconsistent during the assessment of pairs' match status, Cohen κ no longer applied; therefore, the overall agreement rate was calculated. The detailed methodology and outcomes of this manual review process were described previously [22]. For the current analysis, all gold standard referential pairs were stratified by race, ethnicity, sex, and age.

Analysis

We conducted an exploratory analysis of sociodemographic variables—age, sex, race, and ethnicity—evaluating each variable independently for each record pair. Record pairs were assigned to a given stratum (eg, *Asian*) only when both records contained nonmissing, concordant values for that variable. *Missing* data (one or both fields absent) were distinguished from *discordant* data (both fields present but disagreeing). Pairs with discordant values for a specific variable were excluded from the performance calculations for that variable's stratum. However, they could contribute to analyses of other sociodemographic strata where their values were concordant. As a single record could appear in multiple pairings, individuals may be represented more than once. Missing data were addressed using the MAR-modified FS model, which uses all available information without defaulting to disagreement for missing values. Previous research shows that this modification improves linkage accuracy and F_1-scores compared with traditional missing data handling [18]. The linkage algorithm was applied separately within each sociodemographic stratum, supporting the MAR assumption within these more homogeneous groups. While MAR is reasonable in many operational contexts, data can be missing not at random (MNAR). Evaluating MNAR scenarios would require alternative missingness models and sensitivity analyses, which we identified as an area of future work.

Accuracy of Probabilistic Record Linkage

For each stratum, we compared the algorithm's declared match status with the gold standard referential reviewer classification. We estimated sensitivity, positive predictive value (PPV), and F_1-score, along with 95% CI derived from 1000 bootstrap samples, using the percentile method. CIs were reported to indicate the precision of estimated performance measures rather than to support formal hypothesis testing or draw inferential conclusions. Given the exploratory nature of this analysis, no corrections for multiple comparisons were applied.

Data Quality Assessment

To evaluate data quality across sociodemographic strata, we calculated (1) missing data ratio (MDR), measures *data completeness* as percent of records in which a field was missing; (2) distinct value ratio (DVR), measures *data uniqueness* as number of unique values for a field divided by the number of nonmissing records; and (3) Shannon entropy (SE), a measure of *information content*, increasing when values are numerous and evenly distributed [8,23].

Ethical Considerations

This research was approved by the Indiana University Institutional Review Board (IRB 170375536) under category 5 (research involving materials collected for nonresearch purposes), which granted a waiver for informed consent. The study used retrospective data collected during routine care, with no contact with individuals and minimal risk to privacy or welfare. Although datasets contained identifiable information, data were stored on Health Insurance Portability and Accountability Act–compliant remote servers and accessed only by authorized personnel via encrypted connections. All project-related data were managed according to the university security protocols and institutional storage infrastructure. As confidentiality protections were deemed adequate, no ongoing institutional review board monitoring beyond the approval determination was required. All accessed data were governed through data sharing agreements with each contributing entity.

Results

Reviewers' Agreement on Match Status

During the creation of the referential gold standard–linked datasets, reviewers agreed on the match status for 96.1% of record pairs; the remaining 3.9% required adjudication by a third reviewer due to disagreement.

Data Quality Assessment

Table 1 summarizes the sociodemographic characteristics of the record pairs included in the referential gold standard datasets. For each variable, the table reports the number of record pairs (N) with nonmissing values in the INPC, NBS, SSA, and MCHD datasets; variables not collected in a dataset are marked "n/a."

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Notably, race and ethnicity are absent in the SSA and MCPHD datasets; therefore, they were excluded from the analysis. In the NBS dataset, age was not assessed because all newborns were within 12 months of age.

Table . Sociodemographic characteristics of the record pairs included in the referential gold standard datasets.

Sociodemographic variables	INPC[a] record pairs (n=15000)	NBS[b] record pairs (n=15,000)	SSA[c] record pairs (n=16,500)	MCHD[d] record pairs (n=15,500)
Age (years)				
<18	1746	N/A[e]	22	4002
18 - 65	10,178	N/A	2894	10,683
>65	3035	N/A	9610	735
Sex				
Male	4867	6280	N/A	4759
Female	7368	5503	N/A	6256
Race				
White	8551	8712	N/A	N/A
Black	1323	2397	N/A	N/A
Asian	413	492	N/A	N/A
Pacific Islander	332	334	N/A	N/A
Native American	30	47	N/A	N/A
Ethnicity				
Hispanic	275	1214	N/A	N/A
Not Hispanic	7483	9309	N/A	N/A

[a]INPC: Indiana Network for Patient Care.

[b]NBS: newborn screening.

[c]SSA: Social Security Administration.

[d]MCHD: Marion County Health Department.

[e]N/A: not available.

Table 2 presents the degree of missingness and disagreement across demographic variables in the referential gold standard datasets. In the INPC dataset, ethnicity shows the highest level of missingness, followed by race. In the SSA dataset, missing values in the ethnicity, race, and sex fields are noteworthy. Within the NBS dataset, more record pairs have missing ethnicity and race values than discordant values, whereas the sex field shows more discordance than missingness.

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Table . Missingness and disagreement in demographic characteristics in the referential standard–linked datasets.[a]

Sociodemographic variable and record missingness or disagreement	INPC[b] dataset (n=15,000 pairs; 30,000 records)	NBS[c] dataset (n=15,000 pairs; 30,000 records)	SSA[d] dataset (n=16,500 pairs; 33,000 records)	MCPHD[e] dataset (n=15,500 pairs; 31,000 records)
Ethnicity				
Missing	14,266	8102	33,000	31,000
Discordant	422	1398	N/A[f]	N/A
Sex				
Missing	196	320	33,000	540
Discordant	5334	6112	N/A	8430
Age				
Missing	16	N/A	52	2
Discordant	66	N/A	7896	248
Race				
Missing	8504	5062	33,000	31,000
Discordant	2060	2674	N/A	N/A

[a]The data reflect the raw number of individual records within a pair with missing or discordant demographic values.

[b]INPC: Indiana Network for Patient Care.

[c]NBS: newborn screening.

[d]SSA: Social Security Administration.

[e]MCHD: Marion County Health Department.

[f]N/A: not available.

The relative proportion of missing sex, race, and ethnicity values varies considerably across datasets, as presented in Table 3. Across datasets, the MDR ranges from 0.20 to 0.65 for race, 0.40 to 0.84 for ethnicity, and 0.003 to 0.5 for sex. As sex, race, and ethnicity each contain only a few valid categories, the DVR provides limited additional insight into data quality. SE, which generally measures the information diversity in the data, can be falsely elevated by artifacts, errors, or inconsistent encoding. SE values for sex were similar across datasets, ranging from 1.01 to 1.4, whereas the broader range observed for race and ethnicity probably reflected data quality issues rather than true variability (Table 3).

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Table . Measures of data quality: missing data ratio (MDR), distinct values ratio (DVR), and Shannon entropy (SE) measured in bits.

Dataset and sociodemographic variable	MDR	DVR	SE (bits)
INPC[a]			
Sex	0.0037	0.0001	1.0117
Race	0.6171	0.0002	1.2863
Ethnicity	0.8416	0.0001	0.6863
SSA[b]			
Sex	0.5012	0.00009	1.4946
MCHD[c]			
Sex	0.0089	0.0001	1.0623
NBS[d]			
Sex	0.0058	0.0001	1.0455
Race	0.2067	0.0002	1.6530
Ethnicity	0.4002	0.0001	1.3313

[a]INPC: Indiana Network for Patient Care.

[b]SSA: Social Security Administration.

[c]MCHD: Marion County Health Department.

[d]NBS: newborn screening.

Algorithm Matching Accuracy

Figure 1 and Table S1 in Multimedia Appendix 1 summarize the matching accuracy and corresponding CIs across all sociodemographic strata. Across age groups, matching sensitivity ranged from 0.7 to 0.97, the PPV exceeded 0.88, and the F_1-scores were greater than 0.82. When stratified by sex, sensitivity ranged from 0.76 to 0.98, PPV ranged from 0.80 to 0.98, and F_1-score ranged from 0.84 to 0.97. Across race groups, the algorithm's matching sensitivity ranged from 0.58 to 0.99, PPV ranged from 0.85 to 0.98, and F_1-score ranged from 0.85 to 0.99. For ethnicity, the matching sensitivity ranged from 0.85 to 0.989, the PPV ranged between 0.88 and 0.99, and the F_1-score ranged from 0.88 to 0.99. Compared with INPC and MCPHD, the SSA dataset showed significantly lower sensitivity and F_1-scores across all age strata (<18 y, 18-65 y, and >65 y), as indicated by nonoverlapping 95% CIs. Similarly, for both males and females, matching sensitivity and F_1-scores in SSA and NBS were significantly lower than those observed in INPC and MCPHD. In the NBS dataset, the matching sensitivity, F_1-score, and PPV for Asians, Blacks, and White racial groups were lower than those in the INPC dataset, with statistically significant differences indicated by nonoverlapping 95% CIs. The same pattern was observed across Hispanic and non-Hispanic ethnicities, with all 3 performance metrics in NBS markedly lower than in INPC.

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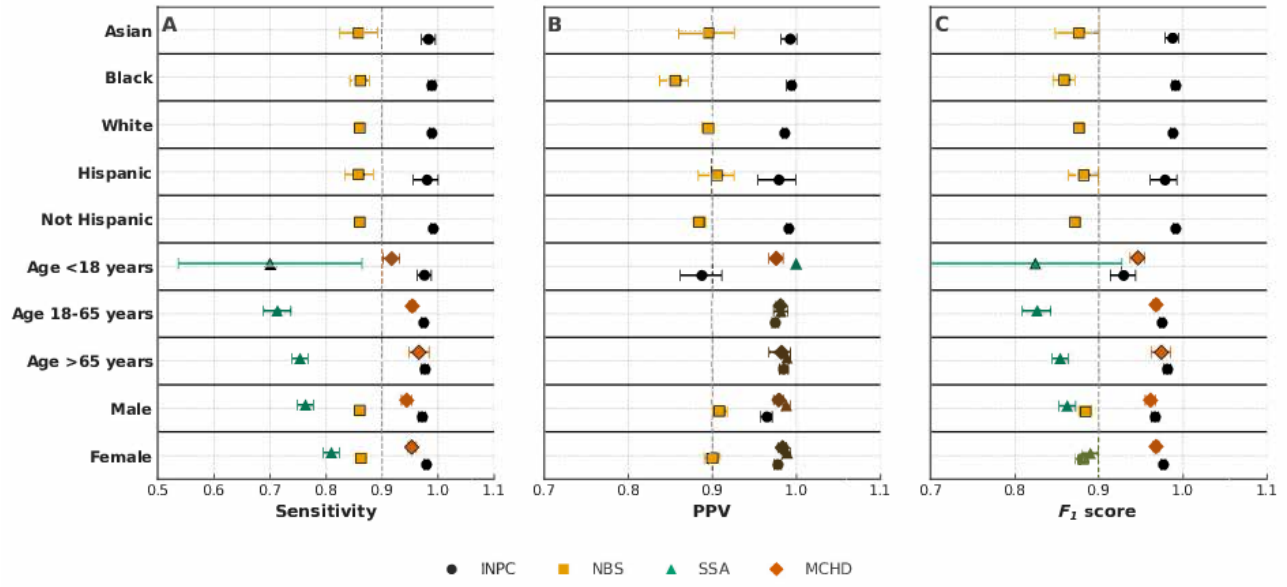
Figure 1. (A) Sensitivity, (B) positive predictive value (PPV), and (C) F_1-score for probabilistic patient matching performance across demographic groups. Points indicate the estimated metric, and horizontal bars represent 95% CIs. Results are shown for 4 data sources. INPC: Indiana Network for Patient Care; MCHD: Marion County Public Health Department; NBS: newborn screening; SSA; Social Security Administration.



Across all datasets, the largest variability in matching performance was observed among pairs with missing or discordant field values. Data quality–performance plots (F_1-score vs DVR; F_1-score vs SE) show that the relationship between data quality and linkage accuracy varies across datasets, particularly for race and ethnicity in NBS and INPC (Figures 2 and 3). For age, performance differences among datasets appear to stem more from differences in date of birth documentation formats than from true demographic variability. In INPC, the algorithm maintained consistently high performance despite variation in data quality. In contrast, the NBS dataset showed relatively similar performance across race, ethnicity, and sex groups, despite substantial differences in data quality.

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Figure 2. DVR quality versus F_1-score plots. Mean refers to the DVR quality indicator (unitless ratio between 0 and 1), while MAR refers to the F_1-score using the missing at random approach (dimensionless value between 0 and 1). DVR quality indicator=q11-ms1+q2(1-ms2)+…+qP(1-msp)P; in which missing percentage=ms_i. DVR: distinct value ratio; INPC: Indiana Network for Patient Care; MAR: missing at random; MCHD: Marion County Public Health Department; NBS: newborn screening; SSA: Social Security Administration.

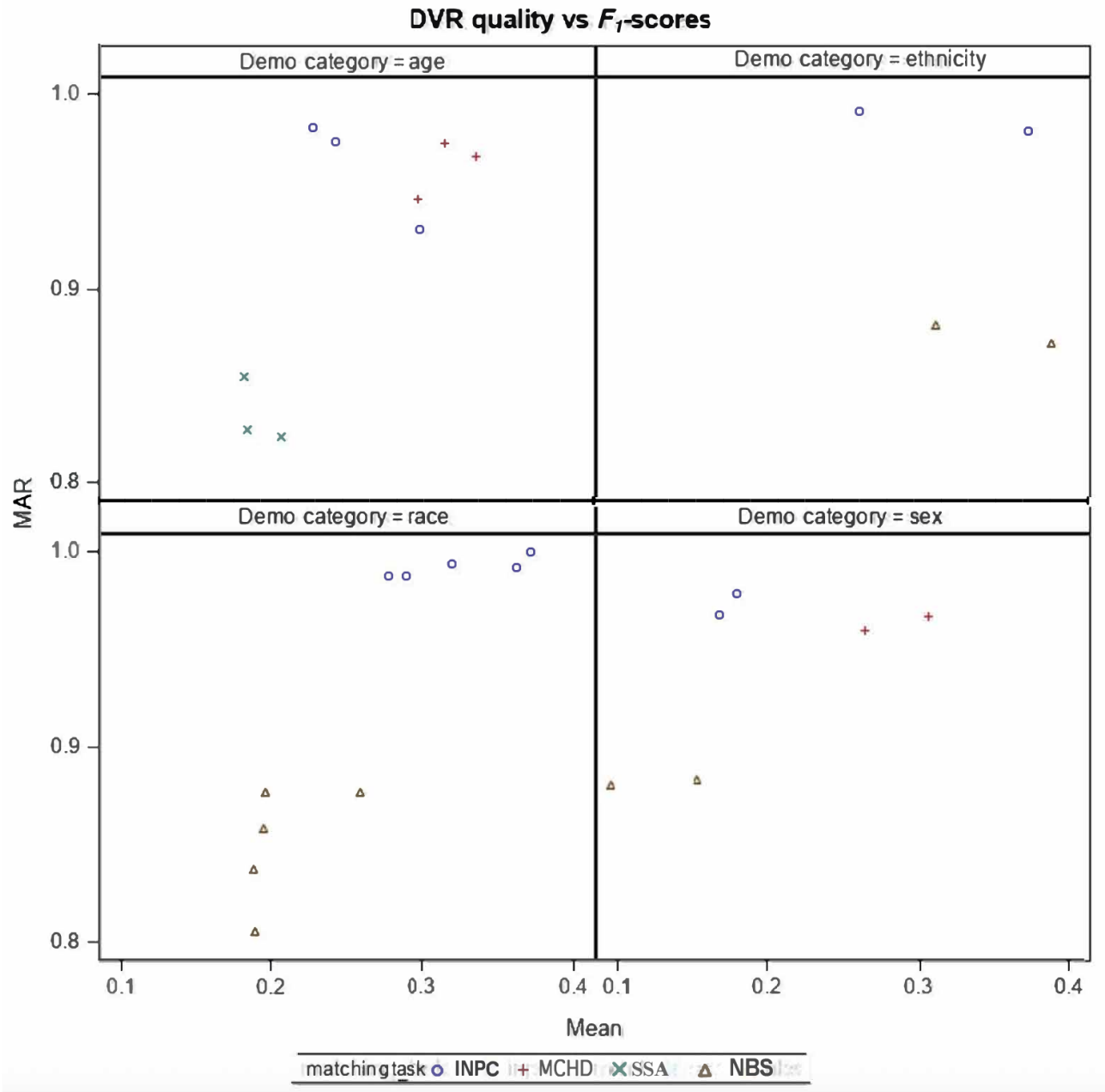

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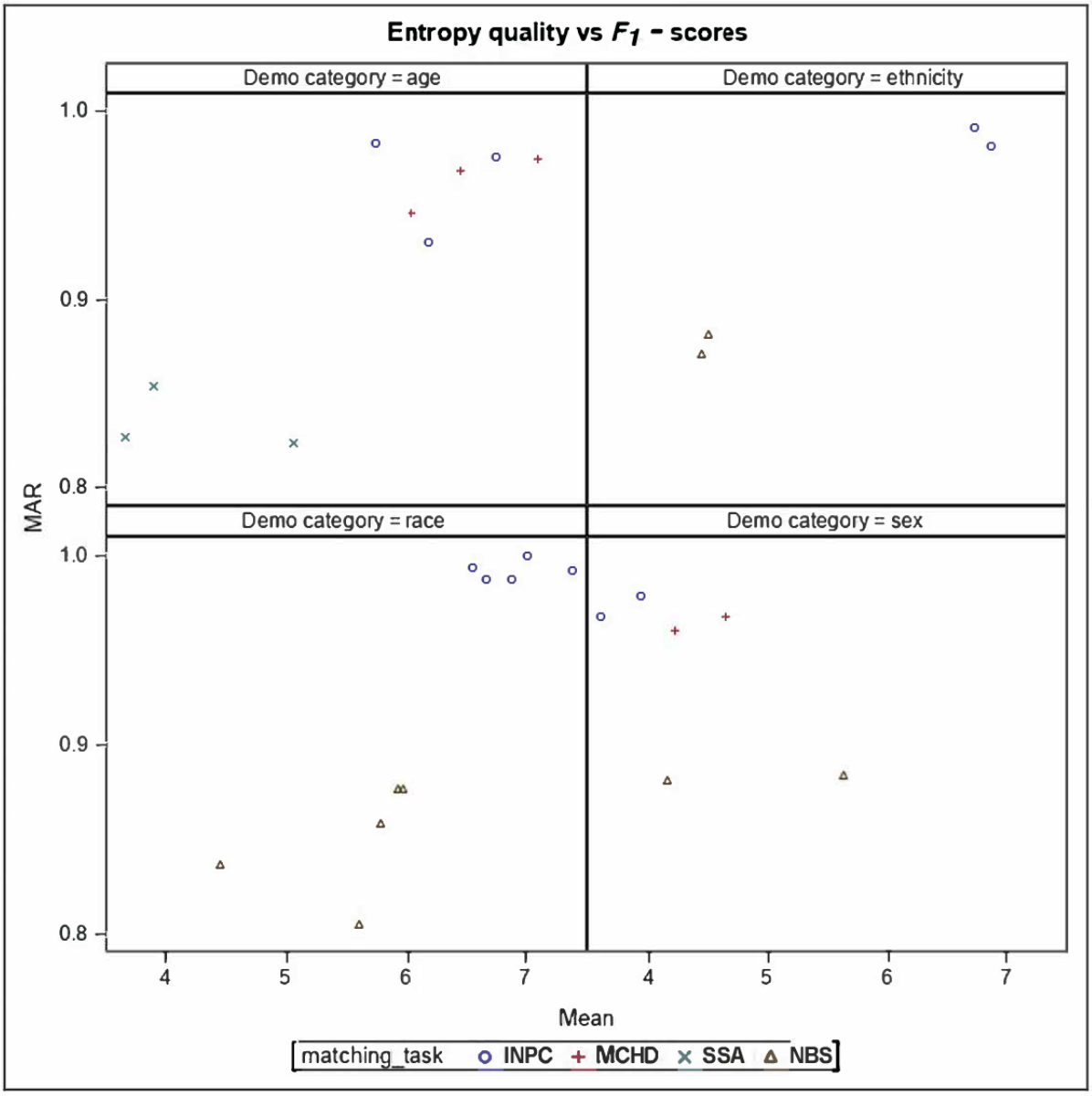
Figure 3. Shannon entropy quality versus F_1-score plots. Mean refers to the Shannon entropy quality indicator (measured in bits), while MAR refers to the F_1-score using the missing at random approach (dimensionless value between 0 and 1). Entropy quality indicator=e11-ms1+e2(1-ms2)+…+mP(1-msp)P; in which Shannon entropy=e_i; missing percentage=ms_i. INPC: Indiana Network for Patient Care; MAR: missing at random; MCHD: Marion County Public Health Department; NBS: newborn screening; SSA: Social Security Administration.



Discussion

Summary of Key Findings

This study examined whether probabilistic patient matching accuracy varies by age, sex, race, and ethnicity and sought to identify data-related sources of bias that may influence matching performance. Across 4 large, operationally relevant datasets, matching sensitivity, PPV, and F_1-score varied by demographic strata, with several statistically significant differences indicated by nonoverlapping CIs. These findings show that probabilistic linkage accuracy is not demographically uniform and is influenced not only by algorithmic design but also by underlying data quality and completeness—both of which can bias matching performance.

Variation in Data Completeness (MDR) and Its Impact on Performance

Data completeness varied across datasets. Race and ethnicity exhibited the highest levels of missingness, consistent with prior work documenting gaps in demographic data capture [24,25]. Age was generally complete except in the SSA dataset, which contained substantial discordance across linked records. These completeness patterns were directly reflected in performance: the most significant declines in sensitivity and F_1-score occurred in strata with missing or inconsistent fields, and the lowest overall performance was observed in the NBS and SSA datasets, where missingness was most pronounced.

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Variation in Data Quality (DVR and SE) and Its Impact on Performance

Data quality varied across demographic fields. While the DVR showed only modest variability, SE differed substantially, particularly for sex, race, and ethnicity, indicating increased variation in the information content of these fields. Fields with lower SE or DVR values, such as those with more missing data, standardized naming conventions, or limited variability, provide less discriminative information for probabilistic algorithms, increasing the risk of false matches or missed linkages. These patterns may disproportionately affect populations with less consistent data capture, such as individuals with non-English names, hyphenated surnames, or variable address formats. Fields with more distinct values or more evenly distributed unique values have higher DVR and SE. Such fields provide more discriminative information for the linkage algorithms, improving the algorithm accuracy. The theoretical maximum entropy reflects the upper limit of information a variable could contain if all its possible values were equally likely. Comparing a variable's observed entropy to this maximum indicates how fully the variable uses its potential informational range [8]. The plots of data quality indicators—SE and DVR—versus F_1-score (Figures 2 and 3) demonstrate a correlation between the 2 variables and warrant further exploration in future studies. Previous studies have identified similar relationships between data quality and record linkage performance [26,27].

Systematic assessment of data completeness and data quality using metrics such as the MDR, DVR, and SE extends and strengthens traditional probabilistic record linkage approaches by explicitly quantifying the informational value of matching fields and linking these properties to performance disparities. MDR captures the degree of missingness that directly reduces the discriminative power of identifiers, while DVR and SE characterize the uniqueness and information content of variables that are central to assigning match weights in probabilistic models. SE, in particular, has been used extensively to assess how effectively a variable differentiates individuals within a population, while distinct value–based metrics have been shown to correlate with linkage performance by reflecting the degree of identifier uniqueness [28,29]. Previous studies have demonstrated that linkage accuracy is highly sensitive to both missingness and variability in identifying fields, and entropy-based measures have been widely used in record linkage and data integration to evaluate information content, guide field selection, and optimize matching rules [6,28]. Similarly, distinct value–based metrics have been shown to correlate with linkage performance by reflecting the degree to which identifiers distinguish true matches from coincidental agreements [6]. Compared with deterministic linkage methods, which rely on exact or rule-based agreement and have been shown to perform poorly in settings with heterogeneous data quality or incomplete identifiers [30,31], probabilistic approaches derived from the FS framework remain the most widely used in health care and administrative data linkage due to their flexibility, interpretability, and ability to accommodate partial agreement and missing data [21,32]. However, previous evaluations of probabilistic linkage have largely focused on aggregate accuracy metrics, often obscuring subgroup-specific errors and masking the role of data quality in generating disparate performance [29].

By integrating these metrics into a probabilistic framework derived from the FS model, one of the most widely used and interpretable approaches for health care and administrative data linkage due to its ability to accommodate partial agreement and missing data [18,33], this study advances beyond deterministic and hybrid methods, which often perform poorly in settings with heterogeneous data quality or high missingness [34-36].

The framework deployed in this study improves upon these approaches by integrating a modified FS model under an MAR assumption with explicit, field-level data quality diagnostics and demographic-stratified performance assessment. This combination enables detection of prealgorithmic bias, directly links observed performance disparities to measurable data characteristics, and supports targeted mitigation strategies such as adaptive weighting, selective data cleaning, or alternative blocking schemes [13,31,36]. Compared with hybrid or black-box machine learning–based linkage methods, which may offer gains in accuracy but often lack transparency and equity assessment capabilities [37,38], this framework balances operational feasibility, interpretability, and fairness, aligning with best practices in modern record linkage and algorithmic fairness research and supporting its applicability in large-scale health information exchange environments. This integration improves transparency, interpretability, and equity assessment relative to black box or rule-based approaches, while remaining compatible with large-scale operational health information exchange systems [19,31,35,39,40].

Potential Data-Related Sources of Bias

Multiple structural and administrative factors contribute to missing or inconsistent demographic fields, creating sources of prealgorithmic bias—bias embedded in the data before any matching occurs. Examples include self-reported or manually entered race and ethnicity, inconsistent naming conventions, and institutional practices such as assigning newborn race based on the birthing parent or the SSA's merging of race and ethnicity into a single field [41]. These practices disproportionately affect racial and ethnic minorities and produce several forms of data-related bias. Inconsistent capture of race and ethnicity introduces measurement bias, while failure to record key demographic fields results in omitted-variable bias [42]. Biased or incomplete data can cause algorithms to reproduce and amplify inequities. When models are trained on historical datasets that reflect past discrimination, they learn these patterns and unfairly penalize underrepresented groups. Missing or sparse data for marginalized populations leads to poorer performance for those groups.

Underrepresentation bias can arise when certain groups are sparsely represented in datasets used to tune or validate linkage models [19,43-45].

Reviewer bias may further influence the construction of referential standards, particularly when adjudicators encounter unfamiliar names or naming conventions [43,46]. Finally, population-specific characteristics, such as the newborn population in the NBS dataset, whose records are newly created

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and collected under mandated screening workflows, can introduce additional variability in data completeness and quality.

Clinical, Ethical, and Research Implications of Disparities in Patient Matching Accuracy

Differences in linkage accuracy across demographic groups have implications for clinical, ethical, and research practice. Disparities in patient matching accuracy can have cascading effects on health care analytics, policy, and clinical practice. When linkage accuracy is lower for underrepresented populations, their health data may be fragmented or misclassified, leading to biased reporting of outcomes and inequitable policy or clinical decisions. Record linkage errors have direct consequences for patient safety and care quality. Missed matches fragment longitudinal histories, obscuring essential information such as allergies, prior diagnoses, or medications, while false matches may merge records from different individuals, leading to inappropriate treatment, misdiagnosis, or exposure of sensitive information. These errors disproportionately affect populations whose demographic data are inconsistently captured—including racial and ethnic minorities, immigrants, individuals with unstable housing, and very young or older patients—who often experience higher missingness and discordance in key identifiers [7,47]. As a result, linkage inaccuracies can impair clinical decision-making, compromise continuity of care, and exacerbate existing health care disparities.

The ethical implications of linkage errors extend beyond clinical harm to include threats to privacy, autonomy, and fairness. Erroneous merges can reveal sensitive information and increase risks of reidentification, identity theft, or unauthorized disclosure. At the same time, missed matches can lead individuals to lose control over how their information is used across systems. These concerns are amplified for groups already affected by structural inequities, who face greater risks of linkage failure due to inconsistent or incomplete demographic data [24,25]. Such patterns mirror findings in the algorithmic fairness literature [48], which emphasizes that data completeness, representativeness, and informational balance in preprocessing must be monitored to prevent the reinforcement of structural inequities [7,44,47,49,50]. Biased model outputs can also create reinforcing feedback loops, where discriminatory decisions generate new biased data that further entrench inequity [51]. Ultimately, these mechanisms produce systematic performance disparities—algorithms perform least well for underrepresented or inaccurately recorded populations, even when no discriminatory intent exists [51]. Persistent errors can erode trust in health care organizations and public institutions, discouraging individuals from sharing information or seeking care, particularly among historically marginalized communities.

Record linkage errors also compromise the validity of research and public health surveillance. False matches introduce noise and bias estimates toward the null, whereas missed matches reduce sample size, weaken statistical power, and may undercount exposures or outcomes. These errors distort estimates of disease prevalence, treatment effectiveness, and health disparities, particularly when linkage success varies systematically across demographic groups. Unequal linkage accuracy can produce unrepresentative analytic datasets, misinform policy decisions, and result in inequitable resource allocation. As linkage errors are not randomly distributed—disproportionately affecting racial/ethnic minorities, immigrants, and individuals with unstable housing—these disparities can amplify existing inequities in population-level research and public health practice [7,47]. Accurate and consistent capture of sociodemographic information is therefore essential for evaluating algorithmic equity and ensuring fair and reliable downstream analyses [24,25]. Accurate capture of race and ethnicity is therefore essential for evaluating and ensuring equitable algorithmic performance.

Implications for Future Work

This study's strengths include the use of 4 large operational datasets, manually adjudicated gold standard pairs, and the integration of data quality metrics such as DVR and SE to contextualize performance variation. The findings underscore the importance of assessing linkage accuracy within demographic subgroups rather than relying on aggregate performance, which can obscure disparities.

Future work should evaluate deterministic and hybrid linkage approaches to determine whether demographic disparities persist across algorithm types. Fairness-aware linkage methods and improved demographic data capture—especially standardized race and ethnicity fields—represent promising mitigation strategies. Simulation-based analyses of MNAR mechanisms may provide insight into bias introduced by unobserved missingness. Further research should quantify the relationship between measures of data quality and the performance of the matching algorithm. Finally, research should explore the downstream consequences of linkage disparities for surveillance metrics, risk prediction models, and health equity analyses.

Limitations

This study has several limitations. First, missing demographic data for race and ethnicity prevented comparisons of linkage performance across all race categories. Although current reporting guidance includes categories such as Native American and Pacific Islander, the small number of records in these groups precluded subgroup analyses. Sex-stratified analyses were similarly constrained by limited availability in some datasets.

Second, all data were drawn from a single US state, which may limit generalizability. Nonetheless, the inclusion of heterogeneous sources—particularly a statewide health information exchange aggregating data from more than 100 clinical organizations—supports broader applicability across diverse health system environments. Although these datasets originate in Indiana, the observed disparities in probabilistic linkage accuracy likely reflect fundamental issues of data completeness, standardization, and attribute weighting that are common across health systems. Replicating this work in multistate or international settings will be important to confirm broader relevance and to guide equity-focused improvements in patient matching methods.

Third, missing data were addressed using a modified FS model under a MAR assumption. We did not evaluate MNAR

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mechanisms, which may introduce additional forms of linkage bias. Future work will examine MNAR processes to characterize better and mitigate these effects.

Finally, jurisdiction-specific workflows (eg, newborn screening processes in the NBS dataset) may influence data availability and structure, potentially limiting comparability with datasets from other health systems.

Conclusions

This study found statistically significant differences in probabilistic patient matching accuracy across age, sex, race, and ethnicity. These disparities were closely aligned with variation in data completeness, uniqueness, and informational richness across datasets, demonstrating that matching performance is shaped as much by data quality as by algorithm design. Datasets with greater missingness, discordance, or low information diversity, particularly in race and ethnicity fields, consistently showed lower sensitivity and F_1-scores. This underscores the critical role of data quality in linkage performance. Such deficits in data quality and completeness introduce prealgorithmic bias, including underrepresentation bias, which can directly affect the accuracy of probabilistic matching.

As linkage errors disproportionately affect groups with poorer or less standardized demographic data, these disparities raise important clinical, public health, and ethical concerns. Fragmented records, misclassified cases, and biased population estimates can perpetuate inequities in care delivery, surveillance, and policy. Routine demographic-stratified evaluations of matching accuracy are therefore essential to detect and mitigate algorithmic bias. Future work will focus on improving the capture and standardization of sociodemographic data, developing fairness-aware linkage methods, and assessing bias from records with missing or discordant fields.

When implementing patient matching systems, performance should be monitored across subpopulations to identify prealgorithmic bias, characterize which groups are at risk, and assess the potential severity of downstream harms. Policymakers should advocate for consistent frameworks to assess matching algorithms, establish accountability mechanisms, and standardize the collection of race, ethnicity, and other important demographic factors. Improving the quality of demographic data and monitoring equity in linkage performance are critical to ensure that linked health data support fair, reliable, and inclusive clinical, research, and public health decision-making.

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Generative artificial intelligence was not used in any part of the manuscript creation.

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Data Availability

The data used for this study are subject to the Health Insurance Portability and Accountability Act and cannot be made publicly available. Access to these data for reproducibility should be negotiated through Indiana University and the Regenstrief Institute.

Authors' Contributions

SJG and CB designed the study in consultation with LL, AM, XL, and HX. LL, FO, XL, and HX provided data analysis. CB, XL, and HX provided interpretation of the study results. CB and KSA wrote the manuscript with input from SJG, XL, and HX. All authors read, reviewed, and contributed critical revisions to the manuscript. AG contributed supervision and oversight.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Matching performance parameters, stratified by sociodemographic groups across all datasets.
[DOCX File, 39 KB - formative_v10i1e78622_app1.docx]

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Abbreviations

DVR: distinct value ratio
FS: Fellegi-Sunter
INPC: Indiana Network for Patient Care
MAR: missing at random
MCPHD: Marion County Public Health Department
MDR: missing data ratio
MNAR: missing not at random
PPV: positive predictive value
SE: Shannon entropy

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Formative Research to Identify Contributors to Risky Drinking and Adapt an Alcohol Reduction Intervention Among Young Adults Vulnerable to HIV: Qualitative Focus Group Study

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Abstract

Background: Across populations, risky drinking has been demonstrated to increase HIV risk behaviors. This is of special concern for sexually minoritized cisgender men and gender-diverse young adults (aged 18 - 34 years), who report greater incidence of hazardous drinking (as defined by the Alcohol Use Disorders Identification Test - Consumption criteria) and HIV compared to their heterosexual and/or cisgender peers.

Objective: This study aimed to examine alcohol perceptions, patterns of use, and the role that anti-LGBTQ+ (lesbian, gay, bisexual, transgender, queer) policies and discrimination played in alcohol risk behaviors for sexually minoritized cisgender men and gender-diverse individuals. Results were used to inform the development of an alcohol reduction intervention for this population.

Method: A qualitative study was conducted with data collected via 4 focus groups among young adult sexually minoritized cisgender men and gender-diverse individuals in the United States from April to June 2023 (N=21). Participants were grouped according to identity as cisgender men, transgender men, transgender women, and nonbinary individuals. Transcripts were analyzed using codebook thematic analysis.

Results: Alcohol use was described as a way to navigate belonging, social connection, and identity expression within LGBTQ+ contexts. Alcohol was viewed as a mainstay of LGBTQ+ spaces, with many using it as a social lubricant and coping mechanism for LGBTQ+-related stress, as well as for relaxation and having fun. Drinking intensity was often tied to an individual's comfort with their evolving sexually minoritized cisgender men and gender-diverse identity, with drinking being higher in earlier stages of exploration. The consequences of drinking discussed by participants included impaired decision-making and negative effects on mental and physical health. Anti-LGBTQ+ laws and policies were seen as contributing to the further stigmatization of sexually minoritized cisgender men and gender-diverse individuals, and hazardous use of alcohol was used as a means of escape and coping.

Conclusions: Alcohol use among sexually minoritized cisgender men and gender-diverse individuals is an important aspect of negotiating identity within different social settings and coping with stigma. Findings have valuable implications for tailoring alcohol reduction interventions for sexually minoritized cisgender men and gender-diverse young adults as they encounter stressors in real time.

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KEYWORDS

alcohol use; formative research; alcohol intervention; sexual minority; transgender; young adults; focus group

Introduction

The relationship between alcohol use and HIV risk is well defined, especially among sexually minoritized cisgender men and gender-diverse individuals, including transgender and nonbinary people [1-3]. Risky alcohol use, including binge drinking, is associated with condomless anal sex and sex while under the influence of other substances, which increases HIV and sexually transmitted infection risk [4-8]. Sexually minoritized cisgender men and gender-diverse individuals tend to have higher alcohol use than their heterosexual and/or cisgender peers [9-12]. Gender-diverse individuals, including transgender women, transgender men, and nonbinary individuals, are more likely to report hazardous drinking patterns, including both binge and heavy drinking, and they have a higher risk of alcohol use disorders compared to their cisgender peers [13-16]. Binge drinking is defined as consuming 5 or more drinks for males or 4 or more drinks for females in about 2 hours, while heavy drinking refers to having more than 15 drinks per week for males and more than 8 drinks per week for females [17,18]. Currently, there is limited guidance for defining binge or heavy drinking among gender-diverse individuals. Data from a nationally representative study by Kerridge et al [19] found that sexual minority adults have approximately 1.6-1.9 times greater odds of meeting criteria for past-year alcohol use disorder (AUD) and 1.7-2.4 times higher odds of lifetime AUD, relative to their heterosexual peers. Similarly, gender minority populations face increased risk. Azagba et al [13] found that gender nonconforming individuals had more than twice the odds of heavy drinking compared to cisgender women, while transgender men in particular reported 1.48 times higher odds of heavy drinking relative to cisgender women. Another large-scale study of health insurance claims found that transgender adults had a 2.75-fold higher prevalence of diagnosed AUD compared to cisgender adults [15]. Additionally, young adult sexually minoritized cisgender men and gender-diverse individuals are more likely to engage in risky alcohol use than older individuals [7].

Some of the strongest predictors of alcohol use in young adults are social norms and peer pressure, such as the expectation to drink heavily in social settings like parties, the belief that alcohol helps reduce social anxiety, or the pressure to conform to group behaviors in drinking games. These patterns appear to be consistent for sexually minoritized cisgender men and gender-diverse individuals [20-23], though one study found that sexually minoritized cisgender men and gender-diverse individuals were less influenced by their sexually minoritized peers to drink alcohol [24]. For some sexually minoritized cisgender men and gender-diverse young adults, alcohol plays a central role in personal identity, such as drinking to gain confidence to enter the queer social scene, drinking to meet gender norms, and drinking because queer events are often centered around alcohol [25-27]. One study found that sexually minoritized cisgender men and gender-diverse individuals tend to consume more alcohol around their sexually minoritized cisgender men and gender-diverse peers vs their cisgender heterosexual peers [28]. Elevated rates of anxiety and depression among sexually minoritized cisgender men and gender-diverse individuals have also been linked to increased alcohol use, with some research suggesting that these mental health challenges contribute to drinking as a form of self-regulation or coping [29]. Another study found that cisgender young adults had more positive motivations for drinking, such as celebrating and having a good time, while sexually minoritized cisgender men and gender-diverse young adults endorsed more negative reasons for drinking, such as drinking to decrease stress and interpersonal concerns [16].

In addition to the social aspects of alcohol use, location also plays a role in sexually minoritized cisgender men and gender-diverse individuals' drinking behavior. Some sexually minoritized cisgender men and gender-diverse individuals seek out queer drinking spaces to reject gender norms related to drinking and feel more comfortable in the space [30]. Cisgender gay and bisexual men who report drinking across multiple types of settings (eg, their homes, friends' homes, restaurants, and bars) are more likely to engage in heavy alcohol use and unprotected anal intercourse. Drinking across varied settings may provide more opportunities for alcohol consumption, increase exposure to different social and sexual environments, and reduce inhibitions or risk perception, thereby elevating the likelihood of risky sexual behavior [31]. This demonstrates the importance of considering locations in assessing risk behavior. There is limited research on the impact of drinking locations for transgender and nonbinary individuals.

In addition to the social aspects of alcohol consumption, stigma plays a significant role in influencing drinking behavior. The minority stress model [32] suggests that sexually minoritized cisgender men and gender-diverse individuals experience stigma, discrimination, and prejudice, which can create a stressful and unwelcoming social environment. This, in turn, contributes to negative mental health outcomes [32,33] and increased alcohol and substance use [21,34].

Beyond interpersonal stressors, the broader social and policy environments also shape drinking patterns among sexually minoritized cisgender men and gender-diverse individuals. Hatzenbuler and Link [35] define structural stigma as "societal-level conditions, cultural norms, and institutional policies that constrain the opportunities, resources, and well-being of the stigmatized." Structural stigma, such as current state and federal legislation that restricts the rights of and access to health care in queer communities, leads to increased health inequities and negatively impacts mental health, as well as increased substance and alcohol use for sexually minoritized cisgender men and gender-diverse individuals [26,36-39]. Pachankis et al [40] found that experiencing past structural stigma was related to increased alcohol use. Restar and colleagues [41] also found that antitransgender policies were linked to increased harmful alcohol use and problematic substance use in transgender adults.

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Understanding the motivations behind alcohol use, along with the social and physical contexts in which drinking occurs, is essential for developing effective interventions aimed at reducing alcohol use and associated sexual risk behaviors. Whether the goal is prevention or harm reduction, having an understanding of mechanisms, lay beliefs, and perceptions driving alcohol and sexual risk behaviors is essential for improving the effectiveness of interventions, especially those targeting marginalized and understudied populations. The goal of this formative study was therefore to examine alcohol perceptions, including anticipated benefits and perceived harms, patterns of use, and the role that anti-LGBTQ+ (lesbian, gay, bisexual, transgender, queer) policies and discrimination play in alcohol risk behaviors for sexually minoritized cisgender men and gender-diverse individuals in order to inform an alcohol reduction intervention adapted for this population. In this context, alcohol risk behaviors refer to patterns of use that increase the likelihood of negative outcomes, including binge drinking, heavy drinking, drinking to cope with stress or trauma, unprotected sex, and alcohol use in high-risk situations or environments with limited protective norms. Although national surveys have documented elevated alcohol use among sexually minoritized cisgender men and gender-diverse populations [2,11,13], there is limited research on the social and structural factors that shape alcohol use among sexually minoritized cisgender men and gender-diverse young adults. Much of the existing work relies on quantitative data, which often overlooks the lived experiences, interpersonal dynamics, and contextual influences that contribute to drinking behaviors. This study addresses that gap by using qualitative methods to explore contextually rich themes about how sexually minoritized cisgender men and gender-diverse young adults perceive and engage with alcohol.

Methods

Study Design

This study used a qualitative approach, with focus group discussions to gain a deeper understanding of alcohol perceptions, patterns of use, and the impact of anti-LGBTQ+policies and discrimination on alcohol risk behaviors among young adult sexually minoritized cisgender men and gender-diverse individuals. Focus groups are particularly useful in the quest to elicit and observe dialogue between participants, as well as gauge thematic consensus on issues [42,43].

Participants and Setting

A total of 21 participants were recruited between April and June 2023 from the sexually minoritized cisgender men and gender-diverse community to participate in 4 focus groups. Participants were recruited using a combination of strategies, including flyer outreach in locations frequented by sexually minoritized cisgender men and gender-diverse individuals, such as LGBTQ+community centers, bars, and health clinics, referrals from other previous studies, social media recruitment, a dedicated study website, and institutional collaborations with academic and community partners. All participants were recruited in the United States. Inclusion criteria required participants to self-identify as a gender minority individual (eg, transgender man, transgender woman, or nonbinary person) or sexual minority man (ie, identifies as a man and with a sexual orientation other than heterosexual), be aged 18 - 35 years, own a smartphone, self-report as HIV-negative, and screen positively for at-risk alcohol use. Individuals were considered to engage in at-risk alcohol use if they scored a 4 or higher on the Alcohol Use Disorders Identification Test - Consumption, a validated and widely used instrument for assessing harmful alcohol use [44].

This study focused specifically on sexually minoritized cisgender men and gender-diverse young adults because it was designed to inform the larger TRAC-ER (Tracking and Reducing Alcohol Consumption and Environmental Risk) alcohol intervention currently being tested through a randomized controlled trial with young adult sexually minoritized cisgender men and gender-diverse individuals [45]. While alcohol disparities among sexual minority women are well-documented, their exclusion reflects the intervention's targeted scope on those most at risk for HIV rather than an assumption of lesser relevance. These criteria ensured alignment between the formative data and the intervention's eligibility framework.

All focus group sessions were conducted virtually using the Zoom (Zoom Communications) platform. Focus groups were stratified according to sexual and gender identity groups (cisgender men, transgender men, transgender women, and nonbinary individuals) in order to increase participant comfort and obtain feedback about drinking culture specific to individuals' communities. For focus group composition, if a participant selected multiple gender identities and one was a binary transgender identity (transgender man or transgender woman), the participant was scheduled into the corresponding transgender man or transgender woman group. If no binary transgender identity was selected (eg, nonbinary and genderqueer), the participant was scheduled into the nonbinary group. For descriptive statistics purposes only, participants who selected more than one gender identity are reported in a separate "multiple identities" category to avoid double-counting. Focus groups had an average of 5.3 (SD 2.2) participants per group. The target sample size was determined a priori based on feasibility, prior qualitative studies with similar populations, and the goal of reaching thematic saturation across diverse sexually minoritized cisgender men and gender-diverse identities. Saturation was assessed through ongoing analytic review of transcripts and was considered reached when no new themes or perspectives were observed in the final group discussions.

Procedures

All consenting procedures were conducted remotely and electronically using the REDCap (Research Electronic Data Capture; Vanderbilt University) electronic consent framework. Eligibility was determined after completion of a screening survey and an additional video-based screening interview, which involved verbal confirmation of identity, consistency checks based on screener responses, and verification of contact information. If participants were determined to be eligible during the screening interview, the study coordinator reviewed the

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consent form with them and sent them the link to sign it electronically. The coordinator then scheduled focus group sessions based on participant availability and sent participants a brief demographics questionnaire to complete prior to the focus groups. Focus groups were conducted by 3 study team members who facilitated discussions, took notes, and managed the logistics of the Zoom session. Focus group sessions lasted 60 - 90 minutes. Zoom audio recordings of sessions were saved, and all recordings were initially transcribed using Descript, a transcription software. Transcripts were then manually reviewed and corrected for accuracy by a research staff member (FS), with a secondary check conducted by another staff member (SK) to ensure reliability. Participants were deidentified using pseudonyms, which were used in all reporting of qualitative data.

Focus Group Guide

Focus groups were conducted using a semistructured question guide (refer to Table 1 for a list of example questions). Questions were designed to address the general role of alcohol within the sexually minoritized cisgender men and gender-diverse community, alcohol use patterns, perceived benefits, negative consequences, and the impact of anti-LGBTQ+ policies, legislation, and discrimination on drinking behaviors. Question development was informed by a review of existing literature and refined through an iterative process with input from the study team over the course of 3 meetings held across a 4-week period.

Table . Summary of focus group guide.

Section	Example questions

General role of alcohol, perceptions of alcohol use, and alcohol use patterns	• What role, if any, would you say that alcohol plays within the queer community?
	• How does alcohol play a part in socializing within the queer community? How about your friend group?
	• What types of situations do you typically associate with drinking? Probes:
	  • What places? Are these places more or less affirming?
	  • Are there certain situations or places that are uniquely associated with partying for the queer community?

Pros and cons of drinking	• What do you see as the main benefits of drinking alcohol? Why do you or others like to do it? Probes:
	  • Any social effects?
	  • Any mental health effects?
	• And what do you see as the cons or drawbacks of drinking? Probes:
	  • Social effects?
	  • Physical health effects?
	  • Effects on the use of other substances?

Influence of anti-LGBTQ+[a] laws and policies on drinking behavior	• With the rise in anti-LGBTQ+ laws and policies being debated and enacted, we are curious to hear how these could be affecting you. How have these laws and the rhetoric surrounding them impacted your life? Probes:
	  • How have they affected your mental health?
	• How have these laws impacted your drinking behaviors? Probes:
	  • What about the drinking behaviors of your friends? The cisgender gay, transgender, nonbinary community at large?
	  • Are there certain members of the cisgender gay, transgender, nonbinary community who may be more likely to drink in response to these laws?

Conclusion	• What do you think is the most important thing for us to include in our health promotion program to help reduce drinking within the queer community?

[a]LGBTQ+: lesbian, gay, bisexual, transgender, queer.

Data Analysis

The analytic approach used in this study was codebook thematic analysis, where both deductive and inductive approaches are combined [46,47], aimed at ensuring the accuracy, reliability, and depth of thematic analysis. To begin, a codebook was developed, which served as the foundation for the coding process. This codebook was informed by both existing literature around drinking among sexually minoritized cisgender men and gender-diverse individuals [25,26,48,49] and an initial reading

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of the transcripts, allowing for a blend of deductive and inductive coding approaches. The inclusion of previous literature ensured that the coding was grounded in established knowledge, while the initial transcript reading allowed for the emergence of novel themes specific to the current data.

To enhance the credibility and trustworthiness of the analysis, we used several strategies recommended for qualitative research. Once the initial codebook was drafted, it underwent a review process by the entire study team, including the principal investigators (CL and TK), and was revised. Subsequently, 2 study team members (FS and SK) performed an initial independent coding of 2 transcripts and discussed coding decisions to establish consistency. Discrepancies were noted and resolved through consensus-based discussion first between the 2 coders and then among the wider research team to arrive at final code definitions. All 5 transcripts were then entered into Dedoose (SocioCultural Research Consultants LLC), a qualitative data analysis software, and coded by FS and SK using the revised codebook. Codes were first grouped into conceptually related clusters that captured shared ideas across participants. Through iterative discussion, the research team reviewed these clusters to identify broader patterns and overarching narratives. Themes were developed to reflect not only the content of participant responses but also the underlying meanings and social processes conveyed through their accounts. Finally, key themes and participant quotes from these data were then summarized and discussed by the study team during regular peer debriefing sessions to critically examine interpretations and ensure consistency with the data. Member checking was conducted with a subset of participants who later served as members of a Community Advisory Board (CAB). These individuals provided feedback on the thematic structure and interpretations. These procedures supported analytic rigor, transparency, and the dependability of the findings.

The research team included individuals with backgrounds in behavioral science, public health, psychology, and LGBTQ+ health research, some of whom identify as members of the LGBTQ+ community. The team acknowledged its shared investment in addressing health disparities and approached data collection and analysis with reflexivity regarding their own social positions, disciplinary training, and experiences. Regular team discussions were held to reflect on potential biases and to promote interpretive rigor throughout the coding and theme development process.

Ethical Considerations

The study was approved by the Institutional Review Boards of the University of Kentucky and Yale University. All participants were aged 18 years or older and completed electronic informed consent prior to any study procedures. Participants received a US $40 electronic gift card upon completion of the focus group session. To protect confidentiality, all transcripts were deidentified by removing personal names and any potentially identifying details.

Results

Overview

Findings from the focus group discussions were organized into six broad themes: (1) navigating belonging and identity through reflections on alcohol in LGBTQ+ social contexts, (2) place-based drinking patterns in queer life, (3) anticipated benefits and reasons for drinking alcohol, (4) acknowledging the downsides of alcohol use, (5) individual and community impact of anti-LGBTQ+ discrimination on drinking behavior, and (6) alternative coping strategies for limiting alcohol consumption. Each of these broad themes is discussed in further detail below with its respective representative quotes.

Sample Characteristics

As can be seen in Table 2, out of the 21 focus group discussion participants with an average age of 25.6 (SD 4.7) years, the largest group according to sexual orientation consisted of those who selected multiple sexual orientations (8/21, 38%), followed by gay (5/21, 24%). For gender identity, 8 out of 21 (38%) participants identified as nonbinary, gender nonconforming, or agender; 4 out of 21 (19%) as cisgender men; 4 out of 21 (19%) participants as transgender men; 1 out of 21 (19%) participants as transgender women; and 4 out of 21 (19%) participants selected multiple gender identities. Among those selecting multiple identities, 2 out of 4 (50%) participants included “trans woman,” and another 2 out of 4 (50%) included “trans man.” For focus group scheduling, participants with multiple identities that included a binary transgender identity were placed in the corresponding trans woman or trans man group, although they remain counted under “multiple identities” in Table 2 for descriptive clarity. Furthermore, the majority of participants had some college or higher education (19/21, 90%) and identified as non-Hispanic White (14/21, 67%). Finally, employment status and personal income varied, with 11 out of 21 (52%) participants being students or students who also worked and also earning less than US $15,000 annually.

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Table . Demographic information for study participants (N=21).

Demographics characteristic	Values
Age (years), mean (SD)	25.6 (4.7)
Sexual orientation, n (%)	
Gay	5 (24)
Bisexual	2 (10)
Fluid	1 (5)
Pansexual	1 (5)
Queer	2 (10)
Lesbian	2 (10)
Multiple orientations	8 (38)
Gender identity, n (%)	
Cisgender man	4 (19)
Transgender man	4 (19)
Transgender woman	1 (5)
Nonbinary, gender nonconforming, or agender individual	8 (38)
Multiple identities	4 (19)
Hispanic or Latino origin, n (%)	
No	18 (86)
Yes, another Hispanic, Latino or Latina, or Spanish origin	1 (5)
Yes, Mexican, Mexican American, or Chicano or Chicana	2 (10)
Race, n (%)	
Black or African American	1 (5)
Multiracial	3 (14)
Non-Hispanic White	14 (67)
Asian	3 (14)
Education, n (%)	
Completed high school (graduate or GED[a]) - 12 years	1 (5)
Post–high school training other than college	1 (5)
Some college	8 (38)
College graduate	8 (38)
Postgraduate degree	3 (14)
Personal income (in US $), n (%)	
Less than 14,999	11 (52)
15,000-24,999	4 (19)
25,000-34,999	1 (5)
35,000-49,999	3 (14)
75,000-99,999	2 (10)
Employment status, n (%)	
Employed full-time (40+ h/wk)	5 (24)
Employed part-time (less than 40 h/wk)	3 (14)
Unemployed, not currently looking for work	1 (5)
Self-employed	1 (5)
Student	3 (14)

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Demographics characteristic	Values
Student and working full- or part-time	8 (38)

[a]GED: General Educational Development certificate.

Theme 1: Belongingness, Identity, and Alcohol in LGBTQ+ Social Contexts

Overview

Participants reflected on the roles that alcohol played in their communities and described alcohol as a meaningful part of their social and personal journeys, particularly within LGBTQ+ spaces. For many, alcohol consumption was an important part of sexually minoritized cisgender men and gender-diverse social settings; others reflected on its widespread visibility and consistent presence. Several participants also explored how alcohol use related to their evolving sense of identity, including using it as a temporary tool for self-acceptance or social ease and later distancing from it as they grew more confident in themselves. These narratives reveal how, for some sexually minoritized cisgender men and gender-diverse individuals, alcohol intersected with experiences of belonging, visibility, and identity formation.

Subtheme 1.1: Role of Alcohol in Social Settings

Among participants, alcohol's role served a social function within the sexually minoritized cisgender men and gender-diverse community, acting as an icebreaker and facilitator for social interactions, and was often perceived as a necessity for engaging in community events. This sometimes led to the notion that drinking, drug use, and sexual activity were integral to the queer social fabric, as evidenced by the following quotations:

> *If I'm looking for a place to, you know, feel safe and welcoming and, you know, have a good time with others in the community, it would be a gay bar, right? Or some sort of gay event where alcohol is, is present and prominent in the experience of the event.* [Cisgender man]

> *I'll say for me, my primary interaction with queer people is at the bar. Like I go to a bar every Friday night. So, it's centered around drinking.* [Transgender an]

> *If I'm with friends, I guess I found myself like drinking a little bit more 'cause like it's just easy to be like, oh, do you wanna go get like a cheap beer and go play board games? So, I feel like in some ways drinking can be like a little inexpensive way of hanging out.* [Cisgender man]

Subtheme 1.2: Observing the Popularity of Drinking in Queer Spaces

Several participants commented on the visible popularity and near-ubiquity of alcohol in queer social settings. They described drinking as a commonly encountered and widely accepted part of LGBTQ+ gatherings, events, and nightlife. These reflections highlighted how frequently alcohol was present, often as a default offering or unspoken feature of communal space, leading participants to reflect on the centrality of drinking to social rituals, leisure, and entertainment within their communities.

> *I mean, it seems pretty popular. Again, I have a hard time speaking for just like the queer community in general. But I mean, it definitely seems to be pretty popular as far as everyone I talk to. Various substances, but yeah, alcohol is definitely one of them.* [Transgender woman]

> *As someone who is relatively new in my queerness, and you know, like what I see of the queer community is often revolved around alcohol, sex, or drugs. So, like my perception as someone who is trying to figure out my sexuality said, oh, these are the things that go along with it.* [Cisgender man]

The second quote above illustrates not a judgment of the community, but a personal account of how their early impression of queer community life was tied to alcohol, as well as reflecting how cultural visibility of alcohol may shape emerging self-concepts.

Subtheme 1.3: Relationship Between Alcohol and Identity

The relationship between participants' identities and their alcohol use was particularly salient. For some, alcohol initially served as a tool for fitting in or easing the discomfort of social scrutiny. One participant noted:

> *I personally just like drink a lot just to like make myself feel like I fit in, just to feel like the other people's eyes aren't like prying at me.* [Transgender man]

For others, alcohol facilitated the journey to self-acceptance, with its role diminishing as comfort with their identity grew.

> *So, I, I think it helped me come out of the closet. And I think it's, it's just been a little evolution of my drinking habits. It's been more of switching the mindset from like, I'm gonna get blasted drunk and stuff to more like, I'm just gonna use alcohol to relax, destress and that could be by myself and it doesn't have to be binge drinking.* [Cisgender man]

> *I think as I've grown more used to and more comfortable with my sexuality, I don't need alcohol to talk about these topics and to talk about my sexuality and to, to just express myself a little bit better. Alcohol definitely still helps. But it's not like a necessary ingredient in the formula anymore, as much as, or as much as it was before.* [Cisgender man]

Theme 2: Place-Based Drinking Patterns in Queer Life

Participants noted the context of their physical and geographic environment as an important influence on drinking behaviors. In particular, participants felt queer bars played a significant

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role in alcohol consumption for sexually minoritized cisgender men and gender-diverse community individuals. One participant explained:

> *I think in a lot of cities where there are queer spaces outside of like maybe an LGBTQ club center, most of the queer spaces are queer bars or queer clubs. So, there's very few queer sober spaces I know.* [Nonbinary individual]

However, this experience was not universal. For people who did not regularly patronize queer bars, they understated the role of alcohol in the community, as this participant highlighted:

> *I think, funny enough, I find alcohol not really common in my experiences. I don't really go to bars that much and I really don't go to big gay bars that much.* [Cisgender man]

This illustrates the diversity within the community, where the significance of alcohol varies widely depending on personal spatial habits and preferences.

In addition, participants also believed that locations played a critical role in shaping how individuals use alcohol, particularly as a tool for managing social anxiety in novel and/or unfamiliar spaces. As one participant put it:

> *When I go to new spaces that I haven't been to before, that's when the anxiety is the absolute worst. I definitely will drink alcohol. Because it just really makes that anxiety go away and makes me not care.* [Nonbinary individual]

Furthermore, some participants also described regularly drinking at home. This was often discussed within the context of being seen as a more affordable way to drink, or at least "pregame" before going drinking at bars. For others, drinking at home, either alone or while hanging out on online or virtual platforms like social networking websites with other queer people, was viewed as safer than drinking in public places.

> *And those [drinking] spaces would always be either somebody's house, somebody's suite and then it would move on to maybe a frat house or like another person's party.* [Cisgender man]

> *I don't know if online [online or virtual platforms] is necessarily like a place to drink. But I mean, for me personally it is. If I want drinking socialization, I'm not gonna go to the bar. Not to mention the fact that like, I'm poor. So, it's a waste of money. I can just spend $ 6 and get a bottle of Barefoot Moscato at Walmart and then just chug that through the night with my friends.* [Transgender woman]

Theme 3: Anticipated Benefits and Reasons for Drinking Alcohol

Overview

Participants expressed a multilayered relationship with alcohol, revealing its perceived benefits and the various motivations behind consumption. It was seen as a conduit for confidence, pleasure, coping, social connectivity, and a response to normative pressures. This complexity reflects both the enjoyment derived from drinking and its functional use as a tool for navigating the various dynamics of social life within the LGBTQ+ community.

Subtheme 3.1: Increases Confidence and Social Connectedness

For many, alcohol served as a confidence booster and social catalyst, lowering inhibitions and granting a level of boldness that can be difficult to muster in sober moments. The capacity of alcohol to diminish self-doubt, enhance personal openness, and provide liquid courage in social settings was encapsulated by the following participant comment:

> *It's a lot more comfortable to say some of those things that you're coming to terms with and you're not fully sure when you have one layer of your guard down, which alcohol can help you do.* [Cisgender man]

Among participants, drinking was often perceived as an enabler of connections, lowering barriers to forming relationships. Bars were viewed as a common starting point for many relationships within the community, partly due to alcohol's role in reducing social anxiety. Some participants admitted that certain levels of conversations and intimacy could also be facilitated by alcohol, which can lead to spontaneous and sometimes intense connections:

> *Ask me if I will talk to somebody in a bar face-to-face that I find attractive or that I would love to go have a hook up with. No, hell no. I struggle with that now. Add a drink in my hand. Oh, we can have a conversation all night long. I will make out with you. We can go home together, we can cuddle, we can have sex.* [Cisgender man]

Continuing on this theme, the feelings of not fitting neatly within conventional labels can make socializing daunting. Alcohol is then used as a social tool for inclusion:

> *I don't necessarily feel I fit in with many groups. Like as my label, I label myself as queer. I sometimes feel like I'm not gay enough to fit into the gay community. I'm not straight enough to fit into the straight community. I'm not bi enough. So, like for me, if I'm in a group of people, socially, there's probably a drink in my hand just because I'm trying to fit in.* [Cisgender man]

Subtheme 3.2: Enjoying the Act of Drinking

Participants also described a more intrinsic enjoyment of drinking, detached from its social functions. The simple pleasure of intoxication, especially in the company of friends, is highlighted as a desirable state. Moreover, the act of drinking can be a solitary form of indulgence and self-care, where a glass of wine accompanies a movie in a moment of personal relaxation:

> *It's like I enjoy beverages, like literally just the taste of them. And so I think for me it's enjoyable to just actually drink alcohol, but then too, it, it is like something to do while you're hanging out with people.* [Nonbinary individual]

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> *I'm gonna put on a movie, have a couple of glasses of wine, and I'm just gonna vibe with myself.* [Cisgender man]

For others, the ambiance of drinking settings contributed to its allure, turning a simple activity into an aesthetic statement:

> *There's kind of like a really fun aesthetic to drinking. My partner works at a bar. I like to go dress up when they're working and just go and read at a bar. It's not so much drinking, it's just happens to be like, that's the place I'm gonna be, but I wanna look cool doing it.* [Cisgender man]

Subtheme 3.3: Social Norms and Social Influence

The normalization of drinking within certain social circles can create an environment where alcohol consumption is not just accepted but expected. The decision to drink can be influenced by the observation that "everyone else is doing it," which can make the act seem both inconsequential and socially desirable. In discussions, social influence often emerged as a subtle yet powerful force that encouraged drinking behaviors. Participants in the focus groups recognized this social influence, with one individual stating:

> *Sometimes you kind of think, well, everyone else is doing it too, at like parties and everything, so what's the big deal?* [Transgender man]

Another participant reflected on this normalization in relation to their identity, noting that it facilitated the initiation and continuation of their drinking habits:

> *And I definitely do not personally associate it with my sexuality, but I know it's normalized. So, it's definitely has been easier for me to start drinking and keep drinking 'cause it's normalized.* [Cisgender man]

The role of social influence was also evident in the dynamics of flirtation and socializing, where the offer of a drink can serve the triumvirate role of invitation, validation, and obligation:

> *But men want to buy me alcohol and so I really struggle to say no. Where like you'll just be sitting and talking to somebody and they'll be like, hey, do you want another one?… and it's so easy to be like, yeah, sure, 'cause you want to flirt or you want to appear, I don't know, fun and friendly. But then like my friend group, they'll be like, oh, let's do shots. Like, let's do all this. And I've never been super rowdy, but there's like a big pressure to, you know, sort of fit in or to like, get male attention, which is something I really want. Especially being a trans guy. Like, oh, I want those men to like me.* [Transgender man]

Subtheme 3.4: Drinking to Cope With Anti-LGBTQ+–Related Stress

A common observation among participants was how the intersection of LGBTQ+ identity and societal pressures can lead to heightened levels of stress, for which alcohol becomes a coping mechanism. The desire to seek some reprieve and relief from the weight of this particular life stress through alcohol is shared among participants:

> *Geez. I don't know. It's just life's hard. Especially being queer. And for me and my friends, it's at least a way to feel a little more free, a little more relaxed, a little more jovial when everything else is so terrible.* [Transgender woman]

For those grappling with gender dysphoria or anxiety in romantic encounters, alcohol may also be used as a means to alleviate personal discomfort and affirm their identity:

> *I have a lot of dysphoria still, and I haven't had top surgery or anything like that. When I do meet someone, like if I meet someone on Grindr or on some kind of dating app. Prior to meeting up, I'm more likely to drink as well, just to kind of lower my own anxiety and try and get in that head space to where like, I'm, you know, I'm valid as a trans man and not just like trying to pretend.* [Transgender man]

Theme 4: Acknowledging the Downsides of Alcohol Use

Overview

While participants highlighted various perceived benefits of alcohol consumption, they also identified its potential drawbacks. The negative consequences of alcohol use spanned from immediate physical effects to more profound impacts on mental health, decision-making, and social dynamics. These reflections were often framed not in terms of addiction or dependence, but rather as moments of dissonance, recognizing when alcohol's impact extended beyond its intended benefits.

Subtheme 4.1: Impaired Decision-Making

One of the more concerning aspects of alcohol use discussed by participants was its association with increased sexual risk-taking. Alcohol can impair judgment and lead to unprotected sex or forgetting to take medications like pre-exposure prophylaxis:

> *Whether it be you forget to take your PrEP or you forget to use a condom or things like that, it can put you at a very high risk for contracting like STDs. It also puts you at a higher risk for like sexual assault, because it's harder to emphasize no when, when you're drinking.* [Transgender man]

For some, the influence of alcohol on sexual decisions was a conscious trade-off, where the immediate gratification outweighed the potential risks:

> *That is me. Hello! Alcohol leads me to make poor decisions for my sexual health. It's important to point out, it's not always that I forget. I just don't want to or don't care. It's very like, nope, I can't be bothered with this. Oh, I, there's a park in my backyard. Let's go walk around the park and see who's around. Like, not always the best choices.* [Transgender man]

Apart from sexual behaviors, alcohol was reported to impair decision-making in other significant ways. The influence of alcohol can extend to decisions that participants later regret,

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such as driving under the influence and making poor financial decisions:

> *My family could not know the things I was doing at bars, so I was traveling across state lines to do a lot of that. That meant I was driving back either drunk or under the influence or however I got home.* [Cisgender man]

> *I feel like it's so easy to like, you know, get drunk and keep buying more drinks. And then in the morning you're kind of like, oh shit! Like half my credit card limit has been reached. Like, oh, I bought drinks for a ton of people last night. People I don't even know.* [Cisgender man]

> *A con could be you might do something stupid that you might regret.* [Transgender woman]

Subtheme 4.2: Negative Effects on Physical and Mental Health

In the discussions, the physical consequences of excessive drinking, such as hangovers and potential long-term health issues, were not overlooked. Participants were acutely aware of the immediate and long-term effects on their physical health, especially as they also got older:

> *I know it has health risks and all that, but I mean, everything does.* [Transgender woman]

> *I'm at that point where I drink too much and then I feel like shit the next day. So that's hard.* [Transgender man]

Participants also expressed concerns about the exacerbation of negative emotions and mental health issues following alcohol consumption. Those with preexisting conditions like bipolar disorder also emphasized the particular risks of combining alcohol with their medications:

> *I get very, very depressed and I'll stay in my bed for a long time.* [Nonbinary individual]

> *It really affects me mentally as well because I have bipolar disorder and I'm on medication for that. So, mixing alcohol with those medications that you prescribe for your mental health can also affect you negatively.* [Transgender man]

Subtheme 4.3: Negative Effects on Social Relationships

Excessive drinking was also identified as a factor that can strain social relationships, leading to situations where one might say or do things that harm their interpersonal, professional, and social connections:

> *I've also had the next morning where I sober up and I'm like, what did I say last night? Should I really have said that?* [Cisgender man]

> *That comes with the hangover later on being like, why was I so aggressive out there? Why can't I just be shy and cute? And then I would still have friends.* [Nonbinary individual]

Subtheme 4.4: Effect of Alcohol Use on Other Substance Use

Participants acknowledged the risky connections between alcohol and other substance use. Participants spoke to the gateway nature of alcohol, where lowered inhibitions can lead to experimentation with and increased use of other substances:

> *Like drinking opens a doorway to try other substances. If I'm drinking and someone says, hey, wanna try an edible? Sure! No, I shouldn't probably. But the drinking, I've lowered it [inhibition], then the next day you're dealing with trying to figure out what happened the night before.* [Cisgender man]

> *There's a very fine slippery slope from, you know, having too much to drink and having it be much more easier to say yes to the drugs that have like, really, ruined my life in the past five years.* [Cisgender man]

Subtheme 4.5: Creates False Confidence

Finally, the temporary confidence granted by alcohol was seen by some as artificial, with the recognition that reliance on substances like alcohol for self-assurance was unsustainable:

> *I feel like it wasn't good that sometimes I was using substances as a crutch to like give myself confidence. And I feel like I've gotten much better at being like, no, I don't need to drink, I don't need to smoke. Like, I should be able to dress myself and like be happy with what I'm wearing and like that should be it.* [Cisgender man]

Theme 5: Impact of Anti-LGBTQ+ Discrimination on Individuals' Drinking Behavior

The experience of anti-LGBTQ+ discrimination cast a significant shadow over the lives of participants, with repercussions for alcohol use. Laws and the increasingly negative societal attitudes toward the LGBTQ+ community not only impacted participants' mental health but also their drinking behavior, often leading to alcohol use as a form of escapism and maladaptive coping:

> *I mean, it's, it's all terrible and I, I hate it and it just drives me to wanna drink even more to just not focus on it. Yeah. I hate that it's even a political issue. It is just people existing.* [Transgender woman]

> *I definitely think that it has a huge effect on the queer population abusing substances more, not just using, but also abusing substances more because it's an escape.* [Transgender woman]

> *I think definitely, at least for the people that I know and for me who are like, mostly nonbinary or, queer or like trans fem, alcohol has definitely been like a coping mechanism, unhealthy coping mechanism for just like the general climate of like, oh, like they wanna kill us kinda energy that's going on in America and also just around the world.* [Nonbinary individual]

From the discussions, social media appeared to influence perceptions of anti-LGBTQ+ discrimination and its ultimate

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impact on alcohol consumption. Social media amplified the effects of discrimination, where negative portrayals and hostile legislation frequently populated newsfeeds, contributing to stress and influencing drinking habits. This relationship was captured in the below participant quote:

> *We actually played a game and everybody had to open up their social media apps on their phone and we had a bottle of tequila on the table. And we had to scroll through our social media and every time that we saw something, whether it be attacking transgender people, a shitty meme about transgender people or something about the bills passing, we had to take a shot. Let's just say a party of seven trans men was trashed in less than 30 minutes ! It was just a lot to realize that like, it wasn't just my timeline that was just flooded with all of these things.* [Transgender man]

Theme 6: Alternative Coping Strategies for Limiting Alcohol Consumption

In response to the normalization of alcohol within their social environments and its attendant risks, participants discussed strategies they used to moderate their drinking. These control mechanisms, ranging from self-imposed limits and self-monitoring of social media consumption to seeking social support, served as vital tools for managing their alcohol consumption.

Some individuals set explicit financial limits before engaging in social drinking, a practical strategy that naturally helped to cap their alcohol intake due to budget constraints. One participant explained their approach:

> *Now, I'm like, all right, I'm going out to the bar. I might take 50 bucks. I might take a hundred bucks. That ain't gonna get me drunk. Like the tolerance is high. So, I'm like, once that's gone, if I've bought everybody a shot in the first round and I ain't got no more money, probably going home, so I'm safe.* [Cisgender man]

Awareness and education about the risks of excessive drinking also play a significant role in shaping participants' drinking behaviors. Participants believed that by understanding the adverse effects of alcohol and the fact that extreme intoxication was not the norm, individuals were more inclined to drink responsibly:

> *So, I think a lot of people when they're in a community that drinks a lot, they think it's very normal to get like blackout drunk and having that kind of information that like, hey, actually most people don't do that.* [Nonbinary individual]

Another less conventional but illustrative example of a strategy came from a participant who discussed the need to self-monitor their social media exposure. The participant framed this behavior as a way to manage emotional overwhelm and prevent spiraling into distress and stated they linked it to past drinking episodes. By minimizing exposure to triggering content, particularly related to anti-LGBTQ+ discrimination, the participant sought to maintain emotional stability without relying on alcohol:

> *But I think the biggest issue, you know, is just having to constantly monitor my own consumption of social media so that I'm not sad all the time.* [Transgender man]

The above findings across 6 thematic areas captured a range of experiences and insights that reflect the intricate relationship between alcohol consumption and the lived experiences of sexually minoritized cisgender men and gender-diverse individuals.

Discussion

Principal Findings

The conversations we had with our participants provided insight into the role alcohol plays in this sample of sexually minoritized cisgender men and gender-diverse individuals. We identified 6 themes that described how alcohol functions in sexually minoritized cisgender men and gender-diverse young adults' lives, spanning community belonging, place-based patterns, anticipated benefits, negative effects, discrimination-related influences, and alternative coping strategies. Our participants discussed how drinking existed in various facets of their own lives as well as the larger LGBTQ+ community. Alcohol worked as both a way for individuals to build, explore, and express aspects of their identity and as a coping mechanism, while also having clear impacts on mental health, sexual behaviors, polysubstance use, and navigating social relationships. Finally, sexually minoritized cisgender men and gender-diverse individuals also contextualized how the increased prevalence of anti-LGBTQ+ policies and legislations has impacted how they move through the world, focusing particularly on what it means for their alcohol use behaviors.

Our findings have been consistent with other research related to alcohol use among sexually minoritized cisgender men and gender-diverse people. While overall there is limited research in this area, there are a few studies that have explored the ways in which alcohol operates as a boundary object for LGBTQ+ identity construction and placemaking [27,50,51]. For instance, Peralta [27] suggests that commercial gay scenes, such as bars and clubs, provide safe and affirming spaces that enable detachment from heteronormative hegemonies [27]. These social settings, similar to ones our participants discussed, play central roles in enabling communality and inclusivity within queer spaces [30]. As Hunt and colleagues [30] further discerned from their sample of LGBTQ+ youth, alcohol lowered inhibitions that allowed participants to feel free and less restricted from occupying their spaces, similar to the level of intimacy and depth our participants disclosed from drinking [30]. These findings provide insight into the existing gaps surrounding how alcohol use works toward sexual and gender identity formations of sexually minoritized cisgender men and gender-diverse people.

The pervasiveness of alcohol use and its place-based meaning were also highlighted by the sexually minoritized cisgender men and gender-diverse people in our study. According to critical geography and queer theory, queer spaces remain unfixed and spatially heterogeneous landscapes that are constructed within authoritative configurations of meaning [52-54].

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Particularly, sexually minoritized cisgender men and gender-diverse young adults described how the nature of their alcohol use is dependent on the spaces they occupy. For instance, participants felt that gay or queer bars were places that felt "safe" and "welcoming" to socialize and drink. For individuals who do not frequent gay or queer bars, alcohol may be less meaningful. Additionally, sexually minoritized cisgender men and gender-diverse individuals who enter unfamiliar spaces rely on alcohol to ease social anxieties and increase their confidence to maneuver through them, which has been linked to forming relationships, having easier experiences with connecting with people, and finding joy through indulgence [25,55,56]. Thus, sexually minoritized cisgender men and gender-diverse spaces can be understood as a network of interconnected experiences, bringing together diverse ways of interacting with physical spaces, personal identity development, and social behaviors or practices [57]. For instance, a gay bar may serve as more than just a place to drink, as it acts as a space where sexually minoritized cisgender men and gender-diverse individuals can express their identities, connect with others, and challenge societal norms. An increased understanding of the place-based meaning of alcohol use has important implications for innovative alcohol reduction interventions that attend to the real-time and nuanced characteristics of sexually minoritized cisgender men and gender-diverse spaces. Particularly for alcohol reduction interventions, understanding the contextual meanings of locations that potentially influence sexually minoritized cisgender men and gender-diverse alcohol use will help enable future researchers to mobilize more tailored prevention and harm reduction interventions.

Despite the reported benefits and the meaning that alcohol use has within LGBTQ+ spaces, many of the sexually minoritized cisgender men and gender-diverse participants discussed drinking in relation to coping against larger structural forces, such as anti-LGBTQ+ discrimination, stigma, and heterosexism and cissexism. This was unsurprising given that sexually minoritized cisgender men and gender-diverse individuals, who experience greater hostility and stress, tend to cope by engaging in greater alcohol use [26,27,58,59]. To our knowledge, this is one of the few qualitative studies that discusses specific alcohol-related implications at the intersection of sexually minoritized cisgender men and gender-diverse identities, place, and anti-LGBTQ+ systems and structures of oppression. Participants' narratives described in this study related to the escalation of anti-LGBTQ+ rhetoric have been previously hypothesized to shape a greater inclination toward alcohol use and binge-drinking behaviors, as well as exacerbate other negative consequences related to mental health and well-being and sexual health [40,49,60]. However, future research, both qualitative and quantitative, should explore how anti-LGBTQ+ policies reconfigure queer spaces and sexually minoritized cisgender men and gender-diverse individuals' negotiation of alcohol use. In particular, future research may benefit from identifying intervention components or content that can disrupt the linkage between adverse mental health stressors and alcohol and substance use, as well as how these outcomes may be buffered via training on healthy coping strategies and harm reduction approaches.

Limitations

While our study possesses various strengths, it is not without limitations. The responses discussed here were provided as one part of a larger focus group to obtain feedback on an alcohol reduction program and its app-messaging materials. Thus, this may have limited the extent to which we were able to engage all participants for each aspect of the discussion. Social desirability and potential recall bias may have informed how participants responded, given that these conversations involved sensitive topics involving alcohol use, as well as other experiences related to substance use and sexual health. Participants were largely conveniently sampled through universities and proximal community organizations. As such, the transferability of findings to other sexually minoritized cisgender men and gender-diverse people located in different areas in the United States may be limited.

Study Implications

This study poses important implications for research and interventions for alcohol use. Our findings suggest that alcohol reduction interventions can benefit from discussions around queer-affirming and place-based technologies. They also underscore the importance of acknowledging the perceived benefits of drinking and the role alcohol plays in fostering community among sexually minoritized cisgender men and gender-diverse young adults. These insights highlight the value of harm reduction approaches, because harm reduction offers a safe, flexible, and effective framework for supporting individuals in cultivating healthier relationships with alcohol.

Furthermore, insights from this study lead to broader lessons for tailoring alcohol interventions to sexually minoritized cisgender men and gender-diverse populations. First, intervention strategies should be adapted to reflect the diversity of motivations for drinking, as well as to address the negative effects of harmful alcohol use among target populations. Second, identity-specific stressors, such as anti-LGBTQ+ discrimination and place-based stressors, should be explicitly addressed when identifying drinking triggers and developing coping strategies. Third, the incorporation of harm reduction principles is essential, in acknowledgment of the central role that alcohol plays in the social lives of many sexually minoritized cisgender men and gender-diverse individuals, making complete abstinence unlikely or undesirable. Fourth, interventions can be strengthened by using customizable, real-time technologies, such as smartphone apps, to deliver personalized prevention messages that are both context-sensitive and user-generated. We leveraged these broader lessons to inform the adaptation of the manualized TRAC-ER alcohol intervention, originally developed for people with HIV and now being tested through a randomized controlled trial with young adult sexually minoritized cisgender men and gender-diverse individuals [45]. While the intervention is still undergoing testing, the formative insights presented here supported its alignment with participants' lived experiences and offer scalable implications for future alcohol reduction interventions targeting sexually minoritized cisgender men and gender-diverse populations.

Building on the broader lessons above, several themes informed specific TRAC-ER adaptations. Themes 1, 3, and 4 (belonging

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and identity in LGBTQ+ contexts; anticipated benefits and reasons for drinking; downsides of alcohol use) led us to revise the counseling sessions that focus on developing change plans and identifying triggers so that content now reflects the diversity of motivations for drinking (social connection, coping, and relaxation) and explicitly addresses negative effects discussed by participants. Themes 2 and 5 (place-based patterns and impact of anti-LGBTQ+ discrimination) informed updates to the triggers session to include identity-specific stressors (eg, anti-LGBTQ+ discrimination) and place-based stressors, along with planning prompts and messaging to support safer choices in bars, clubs, and home settings. Themes 4 and 6 (downsides of alcohol use; alternative coping strategies) motivated the addition of a harm-reduction session that supports nonabstinence goals (eg, pacing and spending caps) and strengthens self-monitoring and peer support. Finally, across themes, we added a smartphone feature that allows participants to author their own prevention and harm-reduction messages tailored to personal triggers and current location, delivered in real time (user-generated, context-sensitive support).

From a policy perspective, reducing alcohol-related harm among sexually minoritized cisgender men and gender-diverse young adults requires addressing structural stigma that drives stress-related drinking. At the population level, protections that safeguard gender-affirming care, antidiscrimination enforcement in employment and housing, and safe public accommodations may reduce stress-induced alcohol use. In practice, harm-reduction–oriented interventions should include goal-setting beyond abstinence (eg, drink counting, pacing, and low-risk drinking plans), trigger mapping for identity-specific and place-based stressors, and linkage to culturally competent mental health and social support. Embedding these elements in LGBTQ+-affirming community spaces and digital tools may improve uptake and equity.

Conclusion

Alcohol use among sexually minoritized cisgender men and gender-diverse young adults is intertwined with identity, social context, and exposure to structural stigma. Interventions should be adapted to the diversity of motivations for drinking, including social connection, coping, and mood regulation, while directly addressing the negative effects of harmful use. Pairing harm-reduction strategies with attention to identity-specific and place-based triggers, as well as policies prioritizing protections that lessen stigma-related stress, can better align support with lived experience. Finally, interventions can be strengthened through customizable, new areas of implementation that use mobile technology to support sexually minoritized cisgender men and gender-diverse individuals by delivering personalized, context-sensitive, user-generated prevention and/or harm-reduction messages in the settings where decisions are made. Future work should evaluate these design principles at scale and alongside policies that reduce stigma-related stressors.

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Data Availability

All data generated or analyzed during this study are included in this published article and its supplementary information files.

Conflicts of Interest

None declared.

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Abbreviations

AUD: alcohol use disorder
CAB: Community Advisory Board
LGBTQ+: lesbian, gay, bisexual, transgender, queer
REDCap: Research Electronic Data Capture
TRAC-ER: Tracking and Reducing Alcohol Consumption and Environmental Risk

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Patient-Centered Education Through A Massive Open Online Course (MOOC) for Patients With Multiple Myeloma and Caregivers: Descriptive Study of Knowledge Gains by French Association of Patients With Multiple Myeloma (AF3M) and French-Speaking Myeloma Intergroup (IFM)

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Abstract

Background: Multiple myeloma (MM) is a chronic hematologic malignancy characterized by complex therapeutic strategies, repeated relapses, and substantial information and psychosocial needs. Advances in oral therapies and outpatient management have shifted greater responsibility to patients and caregivers, emphasizing the need for accessible, high-quality educational resources. Therapeutic patient education (TPE) aims to empower patients to understand and manage their condition more effectively. Digital education tools such as massive open online courses (MOOCs) represent an innovative approach to deliver structured, interactive, and scalable learning experiences to large patient populations. However, few MOOCs have been specifically designed for patients with oncological or hematological disorders, and even fewer have been rigorously evaluated for their educational impact.

Objective: This study aimed to develop and evaluate a MOOC co-designed with patients, caregivers, and health care professionals to improve knowledge, skills, and empowerment among patients living with MM and their relatives. Secondary objectives included assessing participant satisfaction, engagement, and the feasibility of this digital education model at a national scale.

Methods: The MOOC "Understanding and Living with Myeloma" was jointly developed by the French Association of Patients with Multiple Myeloma (AF3M) and the French-Speaking Myeloma Intergroup (IFM). The program consisted of 5 thematic modules delivered over 8 weeks, covering disease mechanisms, diagnosis, treatment options, side-effect management, and daily-life adaptation. Content combined educational videos, self-assessment quizzes, peer-tutoring forums, and live web conferences with experts. Participants self-assessed their knowledge using a 52-item questionnaire rated from 1 (poor) to 5 (excellent) before

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and after completing the program. Descriptive and inferential analyses were performed using the Wilcoxon signed-rank test (2-sided α=.05).

Results: During the first session, 254 participants registered for the course. Among them, 76 (30%) completed all modules and both evaluations. The mean global knowledge score increased from 3.06/5 before to 4.21/5 after the MOOC (mean gain + 1.15, + 38%; *P*<.001). Improvements were consistent across all knowledge domains, including understanding of treatments (+40%), recognition of warning signs (+35%), and self-management skills (+39%). Overall, 98% (74/76) of respondents reported being satisfied or very satisfied with the course, and 99% (75/76) would recommend it to other patients. Since 2018, the MOOC has been conducted 6 times at different periods, enrolling a cumulative total of 2400 participants, confirming its sustainability and scalability.

Conclusions: Participation in this co-designed, patient-centered MOOC was associated with a statistically and educationally significant improvement in knowledge among patients with MM and their caregivers. The program was highly valued by users and demonstrates the feasibility of large-scale digital patient education in oncology. As a freely accessible, repeatable, and peer-supported resource, this MOOC complements medical consultations and traditional TPE programs. Its design and outcomes may serve as a model for future digital health education initiatives targeting other chronic diseases.

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KEYWORDS

MOOC; multiple myeloma; patient; medical education; therapeutic patient education; massive open online course

Introduction

Cancer is now often regarded as a chronic condition. Today, more than 3 million people in France are living with or after a cancer diagnosis. Within the objective of preserving quality of life, education and information for patients play a central role. Health professionals are now expected to engage in educational activities that empower patients while acknowledging the various barriers they face at different stages of illness. Prevention and therapeutic education strategies are crucial to limit the negative impact of disease and treatment on patients' daily lives and to support their social and professional reintegration. A major challenge in modern oncology is thus the implementation of educational programs that help patients cope better with treatment and its associated difficulties [1]. Multiple myeloma (MM) accounts for approximately 10% - 15% of blood cancers. Despite therapeutic progress leading to improved survival, MM remains incurable and is marked by successive relapses. Recent advances have shifted care toward outpatient and home-based treatment, often involving oral therapies. This evolution highlights the need for new, patient-centered communication strategies. Unfortunately, the growing number of patients and limited consultation time often prevent health care professionals from fully engaging in their educational mission within hospital settings.

Therapeutic patient education (TPE) draws on medical science, education, and the social sciences [2]. It encourages patients to become active participants in their care. According to the World Health Organization, TPE aims to help patients acquire or maintain skills necessary to better manage life with a chronic illness. It is a personalized, multidisciplinary approach involving both health care providers and patient associations. In this context, digital tools such as massive open online courses (MOOCs) offer an innovative solution. A MOOC is a free, open-access online course that combines video content, quizzes, self-assessments, and discussion forums to encourage both learning and interaction. MOOCs are primarily used for training students and health care professionals; few have been designed for patient education [3-5]. Learners can proceed at their own pace, interact with peers and instructors, and revisit content as needed, features that are particularly well-suited for patients living with complex diseases, but few are designed to improve understanding of diagnostic processes [6] or to prepare patients for surgery [7]. Originally developed by North American academic institutions, MOOCs are now recognized for their potential in medical education, especially among patients with chronic conditions, by improving health literacy, self-management, and engagement in their care. Recent studies have demonstrated the feasibility and positive impact of digital self-management and educational interventions on chronic conditions; for example, the MyRelief program showed that an online educational platform could effectively support self-management and improve outcomes in patients with persistent low back pain [8]. The importance of user-centered and co-designed digital education tools has also been highlighted in other chronic disease contexts; for instance, integrating lived experience and expert input in the development of a digital stroke prevention platform enhanced its usability, engagement, and potential for behavior change [9]. In the field of education for patients with oncological disorders, Álvarez-Pérez et al [10] demonstrated that co-creating a MOOC with patients and professionals can effectively enhance digital health literacy and promote person-centered care among women living with breast cancer, underscoring the value of participatory design in digital health interventions. The potential of MOOCs as accessible educational interventions for chronic musculoskeletal conditions has been further explored in the MOOC-osteoarthritis randomized controlled trial, which aims to evaluate whether a MOOC can improve disease-specific knowledge and pain self-efficacy among patients with hip and/or knee osteoarthritis [11]. In oncology, MOOCs have also been successfully used as professional training tools, like a nationwide French MOOC on geriatric oncology that effectively disseminated specialized knowledge and fostered interdisciplinary collaboration among health care professionals involved in the care of older patients with cancer [12].

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Despite the availability of information, many patients report insufficient understanding of the disease, its mechanisms, treatment side effects, and patient rights. Traditional TPE programs require small-group settings and significant time investment and have not been consistently implemented across all regions. The French Association of Patients with Multiple Myeloma (AF3M) has shown a strong commitment to developing innovative educational solutions. To our knowledge, no MOOC had previously been developed for patients with MM. The main objective of our work was therefore to create and implement a MOOC specifically for such patients and their relatives. The goal was to help participants acquire knowledge, skills, and abilities to improve disease self-management and quality of life. The impact of this educational tool was assessed using a pre- and postcourse self-evaluation of knowledge.

Methods

Overview

The MOOC "Understanding and Living with Myeloma" was developed by the AF3M, a nonprofit organization founded in 2007 by 27 patients and relatives. As of today, this association includes more than 2000 members and over 100 volunteers and has held ministerial recognition since 2012. Its missions include providing information and support to patients and caregivers, advocating for patient rights, promoting public awareness of MM, supporting research, and facilitating therapeutic education initiatives across France. To promote access to reliable information and empower patients to better manage their illness, the AF3M made the decision to innovate through digital education. In response to the growing relevance of online learning, it initiated the development of this MOOC dedicated specifically to patients. The French-Speaking Myeloma Intergroup (IFM), a cooperative clinical and research network created in 1994, partnered with the AF3M on this project. The IFM includes hematologists, clinicians, and biologists in France and has been instrumental in conducting large-scale clinical trials and advancing both basic and translational myeloma research.

Expertise in pedagogical engineering, audiovisual production, and digital learning design was provided by HB Motion, an educational media company. The project received institutional support from the Janssen laboratory (Johnson & Johnson Group). A steering committee was established, initially composed of patients and caregivers, and subsequently expanded to include members of the AF3M's scientific board, comprising approximately 30 health care professionals affiliated with the IFM. The final project team consisted of a dozen AF3M volunteers, patients, relatives, and multimedia learning engineers, who worked in close collaboration to create content tailored to patient needs (Textbox 1). Participants were recruited between September 2018 and October 2018 through the AF3M networks. Announcements were systematically disseminated via AF3M's website, newsletters, hospital hematology departments, and social media. No exclusion criteria were applied other than language proficiency in French and internet access. Enrollment was open to all interested participants via online registration. Recruitment was therefore open and national in scope, ensuring representation from various French regions. Participation in the MOOC was also open to caregivers and health professionals wishing to deepen their understanding of the disease, therapeutic approaches, and patient-centered challenges. The MOOC was officially launched during the National Myeloma Information Day in 2018. A self-assessment questionnaire at the start of the MOOC had to be completed online. The questions were about initial knowledge and skills. The same questionnaire was administered again at the end of the MOOC to participants who completed the entire program. The pre-MOOC and post-MOOC self-assessments of the 2018 edition were analyzed and compared.

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Textbox 1. Goals of the massive open online course (MOOC) concerning knowledge, skills, and capacities.

Improve knowledge

- Understand what multiple myeloma is
- Know the treatments for multiple myeloma
- Know the side effects of the treatments

Increase know-how

- Knowing how to interpret results
- Know how to prepare your consultation with the hematologist
- Use tips and tricks to improve your daily life
- Learn to better manage your pain and fatigue during and after treatments
- Help patients to control their illness and its consequences
- Seek help for the sick as well as for the "helpers"

Reinforce skills

- Be more comfortable with your illness and the consequences on daily life
- Be more comfortable in a consultation
- Communicate better with loved ones
- Be an attentive caregiver

After attending a therapeutic education program, the person may be able to

- Better understand their illness and thus be able to accept it
- Know the preventive measures to be adopted: environmental planning, taking preventive treatment
- Recognize an aggravation and know how to react adequately
- Identify the factors or circumstances triggering peaks of resurgence of the disease to better avoid them
- Overcome daily difficulties linked to the disease (improve everyday life)

All statistical analyses were conducted using Bioconductor packages in the R programming language (R Core Team). The unpaired Wilcoxon test was used to compare pre- and posttest continuous variables, and Fisher exact test was used for categorical variables. All statistical tests were 2-sided, and *P* values less than or equal to .05 were considered statistically significant.

Ethical Considerations

This study did not involve any biomedical experimentation or collection of identifiable personal data. Under French law, only research involving the human person (RIPH) requires prior review by an Institutional Review Board. RIPH is legally defined as research that is organized and conducted on persons with the aim of developing biological or medical knowledge (French Public Health Code Article R1121-1) [13]. This study consisted of the evaluation of an educational program developed for patients with MM and their caregivers by the AF3M in collaboration with the IFM using anonymized self-assessment questionnaires and did not entail any biomedical intervention, randomization, or modification of usual care. It therefore falls outside the scope of RIPH and did not require the Ethics Committee for the protection of persons review under the applicable framework. National guidance issued by the French National Agency for Medicines and Health Products Safety (ANSM) confirms that such noninterventional educational evaluations are exempt from ethics committees for the protection of persons' authorization. Data were anonymized before analysis, and data processing complied with the European General Data Protection Regulation and the French Data Protection Act. Participation was voluntary, and all users provided electronic informed consent when registering on the MOOC platform.

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Results

Participant Engagement and Expectations

Following the survey sent by email to all AF3M members, 398 responses were obtained from 344 patients with MM (86%), 47 relatives (12%), and 7 (2%) health professionals. The average age of patients with MM was 64.8 years (range 32 - 86), with 54% being male. Only 10 patients (3%) had participated previously in TPE programs. Responses were geographically distributed across the country. The median follow-up of patients with MM was 5 years. Respondents expressed their expectations regarding knowledge, skills, and attitudes to be developed to improve the management of the disease. In total, 68% (n=270) of respondents said they were interested in the MOOC project. The classification of attitudes that patients wished to develop was optimism (71.9%), resilience (62.7%), fighting spirit (57%), self-confidence (56%), autonomy (55%), courage (46%), attention to relatives (46%), perseverance (39%), attention to medical prescriptions (36%), listening skills (35%), communication (34%), self-control (33%), adaptability (27%), and organization (17%).

MOOC Development and Structure

The educational path includes 5 modules that are divided into 15 stages over a period of 8 weeks for each session of the MOOC (Textbox 2). All modules contain short videos, patient testimonials, interviews with health professionals, and analyses conducted from real situations. The modules end with a challenge, a summary, a quiz, feedback on the proposed activities, an assessment of the skills acquired, and a validation badge. At the end of each module, participants can attend a thematic web conference, led by a health care professional and an AF3M representative, where they can ask questions by webchat. These exchanges are able to be replayed. The interactive MOOC is tutored by peers and AF3M volunteers. From the second session, the tutors are accompanied and supported by an onco-psychologist to help enable them to handle any emergency situations. When registering for the MOOC, participants complete a questionnaire on demographic characteristics (Table 1).

Textbox 2. Schedule of the massive open online course (MOOC)

Module 1: Introduction: Presentation of the MOOC and instructions for use
Module 2: What is multiple myeloma?
Module 3: Treatments for multiple myeloma
Module 4: Living better with multiple myeloma
Module 5: How to manage relationships with those around you?
Conclusion

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Table . Characteristics of massive open online course (MOOC) participants (N=288).

Characteristics	Values, n (%)
Sex	
Female	118 (41)
Male	170 (59)
Time from diagnosis (year)	
<1	37 (13)
≥1-5	121 (42)
≥5-10	58 (20)
≥10	14 (5)
Missing	58 (20)
Type of participant	
Patient	181 (63)
Caregivers	75 (26)
Health care professional	23 (8)
Other	9 (3)
Age (years)	
<40	17 (6)
41–50	40 (14)
51–60	78 (27)
61–70	95 (33)
71–80	49 (17)
>80	9 (3)
Status	
Active worker	78 (27)
Medical leave	35 (12)
Invalidity	30 (7)
Retired	138 (48)
Other	17 (6)

Participation and Satisfaction Rate

At the first edition of the MOOC, 30% of participants (76/254) completed all modules (Figure 1), and 98% of participants rated this training as satisfactory or very satisfactory, and 99% would recommend this MOOC to other people. The results regarding the satisfaction rates are summarized in Table 2. The different sessions gave rise to many exchanges between the participants and the volunteer tutors responsible for responding to and encouraging them. In total, more than 7500 contributions (questions and messages) have been published. This MOOC has been conducted 6 times at different periods, with a cumulative enrollment of 2400 participants. This knowledge assessment was conducted only during the first session.

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Figure 1. Flowchart of massive open online course (MOOC) participation.

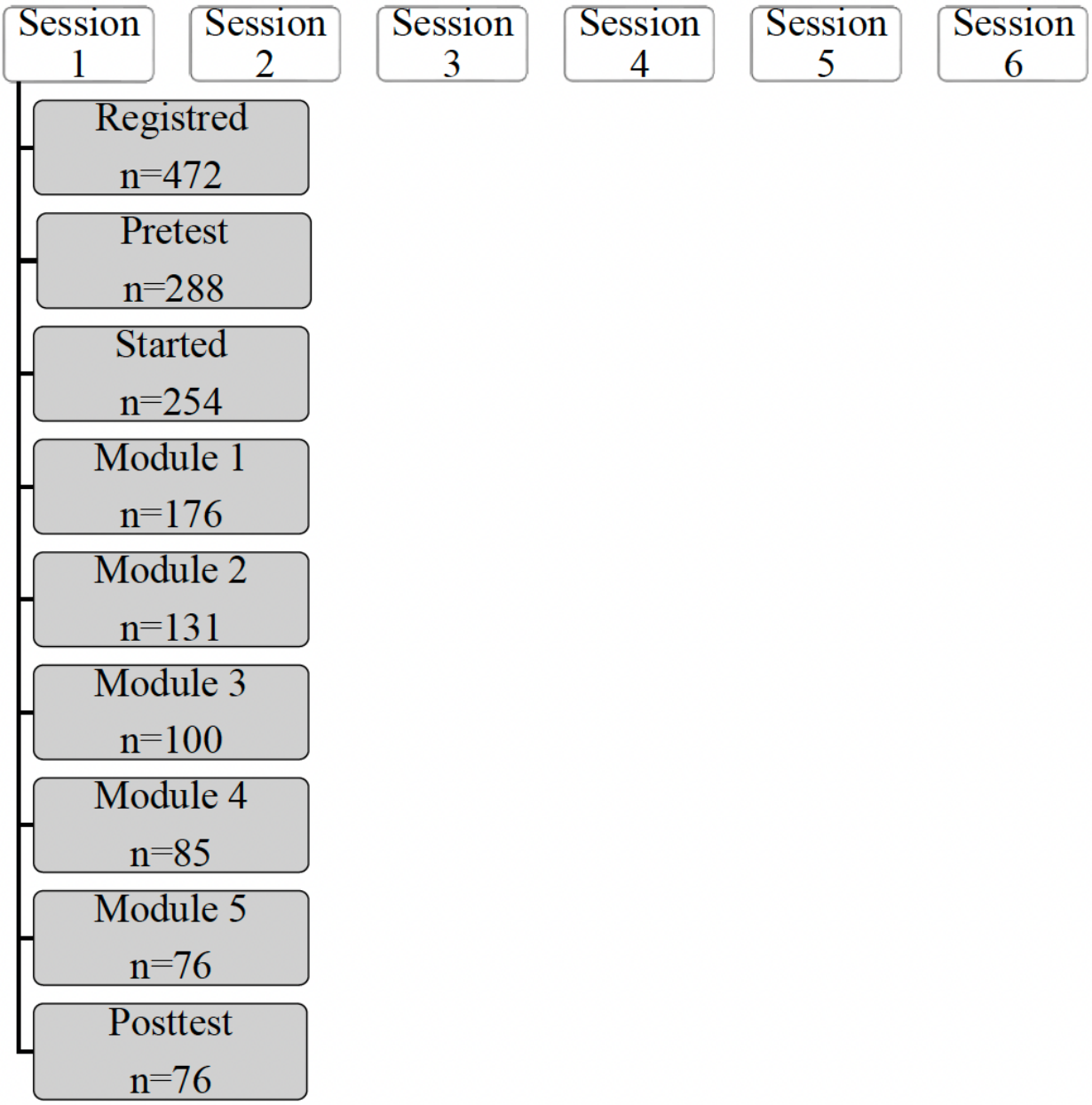

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Table . Results regarding the rates of satisfaction.

Questions	Responses, n (%)
Overall assessment of the MOOC[a]	
Very satisfied	50 (70)
Satisfied	17 (24)
Moderately satisfied	3 (4)
Not very satisfied	2 (2)
Would you recommend this MOOC to a loved one or a patient?	
Yes	71 (99)
No	1 (1)
How useful was this session?	
Very useful	54 (75)
Useful	17 (24)
Not very useful	1 (1)

[a]MOOC: massive open online course.

Knowledge: Pretest and Posttest Evaluations

General knowledge of MM, warning signs, treatments, know-how, and skills (52 items in total) was assessed by the patients themselves before starting the MOOC (n=288) and at the end of the training (n=76) by scoring items from 1 to 5 (5 representing excellent knowledge) (Figure 2). Mean knowledge scores improved from 3.06/5 pretest to 4.21/5 posttest (gain of +1.15, 38%; P<.001) (Table 3).

Figure 2. Patients' response to pre- and posttest surveys (number of responses, level of knowledge: 1=poor; 2=fair; 3=good; 4=very good; 5=excellent). A. What is a multiple myeloma disease? B. What is a monoclonal gammopathy of undetermined significance? C. What are the symptoms of multiple myeloma disease? D. What are the risks of relapse?

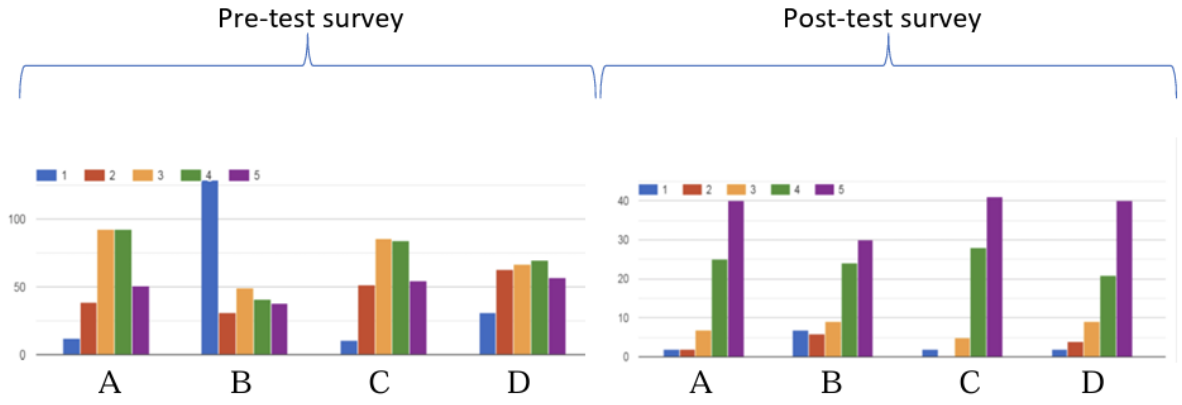

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Table . Results of the pre- and posttest surveys and change.

Item to be scored using scale of 1 to 5 (5 represents excellent) of the knowledge	Before MOOC[a] (n=288), mean (SD)	After MOOC (n=76), mean (SD)	Wilcoxon test, mean difference (%)	*P* value
General knowledge of multiple myeloma				
What is multiple myeloma	3.46 (1.06)	4.30 (0.94)	+0.84 (+24%)	.045
What is a monoclonal gammopathy of undetermined significance	2.40 (1.49)	3.84 (1.29)	+1.44 (+60%)	.03
Symptoms of the disease	3.42 (1.1)	4.39 (0.83)	+0.97 (+28%)	.01
Risks of relapse	3.20 (1.28)	4.22 (1.03)	+1.02 (+32%)	.03
The role of white blood cells	3.25 (1.2)	4.22 (0.97)	+0.97 (+30%)	.01
The mechanisms of multiple myeloma	2.85 (1.18)	4.03 (1.1)	+1.18 (+41%)	.008
The monoclonal peak	3.08 (1.28)	4.13 (1.06)	+1.05 (+34%)	.04
Clinical and biological monitoring of the disease	3.01 (1.21)	4.03 (1.08)	+1.02 (+34%)	.01
Knowledge of the warning signs linked to multiple myeloma and its treatments				
Pain	3.32 (1.26)	4.34 (0.89)	+1.02 (+31%)	.01
The risk of thrombosis	2.73 (1.33)	3.96 (0.96)	+1.23 (+45%)	.02
Beginning of infection	3.00 (1.33)	4.12 (0.97)	+1.12 (+37%)	.01
Neuropathy	2.99 (1.43)	4.28 (0.96)	+1.29 (+43%)	.04
Side effects of drugs	3.06 (1.29)	4.22 (0.89)	+1.16 (+38%)	.046
Name of medication	3.40 (1.46)	4.14 (1.19)	+0.74 (+22%)	.02
Know the therapeutic objective of each drug	2.80 (1.35)	3.78 (1.15)	+0.98 (+35%)	.04
Identify myeloma-specific drugs from other drugs	3.04 (1.46)	4.07 (1.11)	+1.03 (+34%)	.005
Know the dosage of treatments and when to take them	3.24 (1.52)	4.25 (1.18)	+1.01 (+31%)	.007
Understand the discontinuous rhythm of treatment	2.85 (1.41)	4.12 (1.12)	+1.27 (+45%)	.03
Describe the potential side effects of treatment	3.09 (1.32)	4.20 (1.08)	+1.11 (+36%)	.04
Know the possible impact of treatment on sex life	2.69 (1.4)	4.05 (1.11)	+1.36 (+51%)	.03
Know the effects of treatment on fertility and the teratogenicity	2.81 (1.46)	4.04 (1.2)	+1.23 (+44%)	.04
Understand treatment with autograft	3.14 (1.44)	4.32 (1.11)	+1.18 (+38%)	.01
Differentiate between autograft and allograft	3.49 (1.53)	4.43 (1.02)	+0.94 (+27%)	.01
Other knowledge				
Social rights	2.33 (1.19)	3.83 (1.09)	+1.50 (+64%)	.006
The value of physical activity	3.40 (1.28)	4.66 (0.78)	+1.26 (+37%)	.03

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Item to be scored using scale of 1 to 5 (5 represents excellent) of the knowledge	Before MOOC[a] (n=288), mean (SD)	After MOOC (n=76), mean (SD)	Wilcoxon test, mean difference (%)	*P* value
The benefits of a balanced diet	3.49 (1.18)	4.58 (0.88)	+1.09 (+31%)	.02
The advantage of practicing an adapted physical activity	3.36 (1.24)	4.61 (0.87)	+1.25 (+37%)	.01
External aid	2.61 (1.25)	4.08 (1.02)	+1.47 (+56%)	.01
Know how to				
Detect onset of fever	3.10 (1.34)	4.28 (0.93)	+1.18 (+38%)	.01
Persistent pain	3.08 (1.3)	4.28 (0.92)	+1.20 (+39%)	.01
Fatigue	3.14 (1.27)	4.42 (0.9)	+1.28 (+41%)	.04
Signs of thrombosis	2.58 (1.38)	3.89 (1.05)	+1.31 (+51%)	.007
Persistent infectious signs	2.96 (1.37)	4.21 (1.05)	+1.25 (+42%)	.02
Signs of neuropathy	2.82 (1.39)	4.36 (0.93)	+1.54 (+55%)	.045
Appearance of side effects of treatments	2.86 (1.44)	4.11 (0.88)	+1.25 (+44%)	.03
Manage medication administration calendar	3.72 (1.46)	4.63 (0.91)	+0.91 (+25%)	.048
Manage the stock of medicines	3.73 (1.48)	4.61 (0.91)	+0.88 (+24%)	.001
Plan how to take treatment	3.58 (1.53)	4.58 (1.12)	+1.00 (+28%)	.02
Know what to do if you forget to take treatment	3.04 (1.45)	4.26 (0.9)	+1.22 (+40%)	.048
Identify how to take treatment regularly	3.56 (1.41)	4.51 (1.07)	+0.95 (+27%)	.02
Know what to do in case of side effects of treatment	2.86 (1.58)	4.05 (1.58)	+1.19 (+42%)	.01
Self-inject drugs subcutaneously	2.32 (1.41)	3.28 (1.31)	+0.96 (+41%)	.02
Know how to self-medicate	2.43 (1.26)	3.51 (0.94)	+1.08 (+44%)	.03
Skills				
Communicate with caregivers about the disease	3.24 (1.2)	4.29 (1.02)	+1.05 (+32%)	.04
Explain the illness and the treatments to family and friends	3.16 (1.31)	4.33 (0.86)	+1.17 (+37%)	.01
Alert in case of adverse effects of the treatment	3.21 (1.35)	4.34 (0.94)	+1.13 (+35%)	.03
Know how to call in case of warning signs or worsening	3.18 (1.33)	4.41 (0.93)	+1.23 (+39%)	.02
Know how to ask for help	2.98 (1.32)	4.33 (0.93)	+1.35 (+45%)	.03
Discuss difficulties with the medical team	3.11 (1.3)	4.34 (0.95)	+1.23 (+40%)	.045
Express difficulties with family or a caregiver	2.99 (1.39)	4.22 (0.93)	+1.23 (+41%)	.02

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Item to be scored using scale of 1 to 5 (5 represents excellent) of the knowledge	Before MOOC[a] (n=288), mean (SD)	After MOOC (n=76), mean (SD)	Wilcoxon test, mean difference (%)	*P* value
Know who and how to call in case of alert or aggravation	3.13 (1.39)	4.34 (1.14)	+1.21 (+39%)	.02
Share experience of the disease with someone	2.91 (1.33)	4.17 (1.07)	+1.26 (+43%)	.03
All items	3.06 (0.33)	4.21 (0.27)	+1.15 (38%)	<.001

[a]MOOC: massive open online course.

Web Conference Impact

The interactive online conferences brought together an average of 100 participants and are widely consulted in replay. An expert is interviewed by a mediator for one hour. During the COVID-19 pandemic, which further exacerbated existing anxiety and concerns among patients with MM, the AF3M provided help and support to them and their families during this exceptional health crisis. In response, the AF3M hosted web conferences on COVID-19. In total, 600 people registered for the first web conference, which was substantially more than the expected amount (Table 4). This outcome confirmed the importance of opening a virtual space for patients with hemopathies to ask questions and obtain answers from experts and from cooperative groups. The level of satisfaction rose to 98% by the third web conference. These web conferences delivered clear information, enhanced knowledge, enabled interaction with experts, and addressed COVID-19 from medical, psychological, legal, and social perspectives.

Table . Web conference data during the COVID-19 crisis.

Conference	1	2	3	4
Number of registrants	590	603	636	330
Number of participants	473	466	485	262
Questions raised before the web conference	49	36	24	15
Number of questions asked through the chat	—[a]	230	182	51
Satisfaction rate (%)	68	84	98	88
Speaker 1	Infectious disease specialist	Hematologist	Hematologist	Hematologist
Speaker 2	Hematologist	Hematologist	Hematologist	None
Speaker 3	None	Onco-psychologist	Onco-psychologist	Onco-psychologist
Speaker 4	None	Health lawyer	Health lawyer	None

[a]Not applicable.

Discussion

Principal Findings

This MOOC represents one of the first educational platforms specifically designed to support patients with MM and their relatives. Completion of the MOOC led to a substantial improvement in participants' understanding of MM, including disease mechanisms, warning signs, available treatments, and self-management skills. The mean knowledge score rose from 3.06 to 4.21 out of 5, a+38% increase (P<.001), confirming the educational effectiveness of the program.

Interpretation and Comparison With Existing Literature

Developed in collaboration with patients and health care professionals, it addresses key needs, including access to scientifically validated information, support in coping with treatment-related challenges, and the opportunity to share experiences within a safe, anonymous, and interactive environment. This initiative offers important advantages. It provides free and accessible information to patients across all geographic areas, including those who may be isolated or far from specialist centers. The platform fosters open peer-to-peer and patient-expert discussions. The inclusion of web conferences and replays further enhances the value of the program, allowing patients to engage in real time or at their convenience. Additional strengths are the availability of web conferences, interactive exchanges, and tutoring. The overwhelmingly positive feedback and high satisfaction rates observed across four conference editions demonstrate both the relevance and the acceptability of this digital educational tool. Our findings align with and expand upon previous work demonstrating the value of digital and co-designed educational interventions for patients with chronic diseases [7]. Similar knowledge gains were observed in oncology-focused MOOCs, such as the program described for women with breast cancer, where a

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participatory design approach improved digital health literacy and engagement [10]. Comparable improvements in knowledge (25% - 40%) have been reported in other chronic conditions, including the MOOC-osteoarthritis trial for osteoarthritis and the MyRelief self-management platform for persistent low back pain [8]. These results collectively suggest that structured, user-centered digital education can promote understanding, self-efficacy, and behavioral adaptation across diverse patient populations.

In contrast to most previously published MOOCs, which primarily targeted health care professionals or single disease educational objectives, our study uniquely focused on patients with a specific hematologic malignancy and actively involved caregivers and advocacy groups from the outset. This co-construction process with AF3M and IFM ensured content relevance, scientific accuracy, and a strong sense of community ownership. The 38% relative improvement in knowledge and very high satisfaction rate (98%) are therefore consistent with the literature while confirming the added value of participatory design and peer tutoring in enhancing engagement.

Furthermore, our results support evidence that interactive components, such as web conferences, discussion forums, and tutor guidance, substantially increase learning outcomes and emotional support compared with passive e-learning formats. These findings reinforce earlier observations from geriatric oncology and bariatric surgery MOOCs, in which interactivity and peer exchange were key determinants of user satisfaction. Together, these comparisons highlight that the present MOOC not only replicates but also extends existing evidence by demonstrating that co-designed digital education can be successfully implemented and sustained in a complex oncologic setting.

Limitations

Nevertheless, several limitations must be acknowledged. First, the digital nature of the program poses challenges for some patients. Barriers include limited access to computers or mobile devices, unfamiliarity with digital tools, or language limitations, as the MOOC is only available in French. This is particularly relevant in MM, a disease that predominantly affects older patients, some of whom may also experience physical or cognitive impairments (neuropathy, fatigue, or pain) that can interfere with concentration and learning. While basic computer literacy is required, the presence of peer tutors and access to technical tutorials aim to mitigate these barriers. Second, the potential for selection bias must be considered. Participants were largely recruited through the AF3M's network, likely including patients already motivated to learn more about their condition. In addition, self-assessment questionnaires, while informative, are subjective in nature and were developed by the team involved in designing the MOOC, raising concerns about possible measurement bias [14]. Although more objective outcome measures (quality of life and adherence) would strengthen the evaluation, such endpoints typically require a clinical trial framework [14]. As commonly observed in MOOC-based learning, we noted a progressive decrease in participant engagement over time. Only 30% of learners completed the full program.

Interestingly, the 10 hours of structured patient education provided by the MOOC may, indirectly, allow clinicians to focus on more personalized and specific aspects of care during consultations. In this way, the MOOC complements rather than replaces the essential in-person interactions with medical and paramedical teams. Beyond knowledge acquisition, this program may also support emotional well-being, enhance patient autonomy, and foster a sense of community among participants. The platform also proved highly adaptable, offering timely content during the COVID-19 pandemic, when patients' anxiety was heightened and access to care was disrupted. This success of the web conferences underlined the critical importance of offering a virtual space for reliable, empathetic, and timely medical communication.

Broader Implications and Conclusions

MOOCs represent a flexible and scalable solution for therapeutic education, allowing for regular updates as scientific knowledge evolves and offering a customizable approach that supports patients throughout their care journey, from diagnosis to long-term follow-up. The key advantages include access to scientifically validated information, flexibility to learn at one's own pace, and the opportunity to revisit content as needed. Remaining questions concern the long-term impact of such programs on clinical outcomes, adherence, and quality of life. Beyond improving knowledge and engagement, this MOOC fosters patient self-management and strengthens the partnership between patients and health care professionals. Its success underscores the importance of co-designing educational resources with patients and highlights the potential of digital platforms to advance chronic disease care in a sustainable, equitable, and patient-centered manner. The program was highly valued by users and demonstrates the feasibility of large-scale digital patient education in oncology. Its design and outcomes may serve as a model for future digital health education initiatives targeting other chronic diseases.

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Data Availability

All data generated or analyzed during this study are included in this published article and its supplementary materials.

Authors' Contributions

Conceptualization: AT, BD, LG
Data curation: AT, BD, LG
Formal analysis: AT, BD, LG
Funding acquisition: BD, LG
Investigation: BD, LG
Methodology: AT, BD, LG
Project administration: AT, BD, LG
Resources: AT, BD, LG
Software: AT
Supervision: OD
Validation: All authors
Visualization: AT, BD
Writing – original draft: AT, BD, LG
Writing – review & editing: All authors

Conflicts of Interest

AT reported advisory board participation and/or honoraria from Amgen, GSK, Janssen, Pfizer, Sanofi, and Stemline Menarini. LK reported advisory board participation and/or honoraria from BMS, Janssen, Pfizer, Takeda, Sanofi, and Amgen. M Macro reported advisory board participation and/or honoraria from Amgen, BMS/Celgene, GSK, Janssen, Sanofi, and Takeda. CS reported advisory board participation and/or honoraria from Janssen, Amgen, BMS, Sanofi, Pfizer, and Stemline. All other authors (BD, LG, BA, HAL, CB, LF, KK, M Mohty, AP, CH, CT, PM, and OD) declared no competing interests.

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Abbreviations

AF3M: Association Française des Malades du Myélome Multiple (French Association of Patients with Multiple Myeloma)
ANSM: French National Agency for Medicines and Health Products Safety
IFM: Intergroupe Francophone du Myélome (French-Speaking Myeloma Intergroup)
MM: multiple myeloma
MOOC: massive open online course
RIPH: Research Involving the Human Person
TPE: therapeutic patient education

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The Role of Digital Tools in Meeting the Needs of Adults With Tourette Syndrome: A Human-Centered Design Approach

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Abstract

Background: Individuals with tic disorders (TDs) have access to a small but growing number of digital tools (such as apps and websites) for tic management and support. While prior work has shown promise for these tools, they have traditionally been designed by researchers first and evaluated by members of the TD community after tool development is complete. A human-centered design process targeting this domain has the potential to reveal new insights relevant to the development of future tools. We seek to establish a preliminary understanding of how the TD community uses and perceives current resources for tic management and support as well as their overall concerns and needs in this area.

Objective: This study aimed to explore the design potential of future digital tools for helping adults manage their tics by gathering an initial set of needs and requirements from adult members of the TD community in the United States.

Methods: An online survey was distributed via TD community groups and also via TD clinicians and researchers in the United States. The survey contained a combination of dichotomous, multiple-choice, and open-ended questions, with opportunities for participants to specify how they currently receive support, rank their preferred features and requirements, and express their needs and concerns relevant to future work. Qualitative responses were analyzed with inductive thematic analysis.

Results: Most respondents typically sought answers from digital platforms first (124/158, 78.5%) when confronting a question about their tics. Even so, only 18.4% (29/158) reported having previously used a digital tool to help with their tics or any other aspect of their health. Simultaneously, 88.9% (136/153) indicated that they would be very (81/153, 52.9%) or somewhat (55/153, 35.9%) likely to use a digital tool designed for adults with tics. Of those listing concerns (42/158, 26.6%), common reported concerns included the tool being too time-consuming, difficult to use, or generally not meeting accessibility standards. When asked to rank the one feature of a digital tool that they believed to be most important, tic monitoring (66/154, 42.9%) and trigger monitoring (54/154, 35.1%) were among the most popular requested features as opposed to other options, such as information gathering, reminders to practice a therapeutic skill or take medicine, social support, or opportunities to share their story. While screen navigation was most preferred, results indicated that a multimodal design overall would support the most users.

Conclusions: Our study participants reported a lack of useful technology for tic management and indicated a need for accessible tools to assist in tic and trigger monitoring in particular. Other concerns included that new tools would be difficult to use or learn due to tics. Findings suggest a cautious excitement for future digital tools in this area.

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KEYWORDS

Tourette syndrome; tics; tic disorders; user experience; user research; accessibility; qualitative analysis; online; internet; apps; mobile phone

Introduction

Tourette syndrome (TS) and persistent tic disorder (collectively referred to as tic disorders or TDs) are neurodevelopmental disorders characterized by sudden, rapid, repetitive motor movements or vocalizations (ie, tics) that develop in childhood, persist for more than a year (although waxing and waning are common), and are not attributable to a substance or other medical condition [1]. Common tics include eye blinking, head jerking, sniffing, throat clearing, and simple vocalizations [2,3]. Most individuals with tics also report uncomfortable physical sensations (eg, an itch, pressure, or ache) that precede some or all of their tics and are temporarily relieved by the tics [4,5]. These premonitory sensations are thought to play a critical role in the development and maintenance of TDs [6] and are sometimes described as more distressing than the tics themselves [7]. TDs affect between 0.3% and 0.9% of the general population [8,9]. Recent reviews suggest that contrary to popular belief, tics persist into adulthood for the majority of individuals, with

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complete remission occurring in only 10% - 20% of individuals [10].

Although clinical guidelines for the treatment of TD and TS have been developed [11], a study by Cuenca et al [12] indicated that individuals with TDs and their allies within the TD community (including their parents) perceived health professionals as having limited knowledge about them. The authors also found that access to behavioral treatment, the recommended first-line intervention, was limited despite the fact that 76% of parents wanted the treatment to be available for their child. This is consistent with other reports documenting difficulty accessing specialty care [13], negative experiences when receiving care [14], and a global paucity of specialized TD clinics [15]. Another challenge, particularly for adults with TDs, is that because tics emerge in childhood, most of the treatments and resources are designed for younger audiences. This is unfortunate given that tics do commonly persist into adulthood [10] and adults with TDs continue to experience impairment and lower quality of life [16].

Many researchers have hoped that technology could help close this treatment gap and ensure that individuals within the TD community receive more support. As a result, a variety of ways in which technology can be used to increase access have been proposed. These approaches range from therapist-delivered online interventions (eg, telehealth services [17,18]) to stand-alone websites, apps, and wearables with no human interaction at all [19-21].

It is crucial that any such technology be designed with these users and their allied stakeholders in mind. Still, little work has been done to gather feedback from these communities prior to building tools and services. One exception might be [22], which examined user experience relevant to online support communities for TDs. There may be additional tools or support systems that could meaningfully benefit individuals with tics, but we currently lack a clear understanding of how users perceive existing technologies in this area (eg, TicVision [23]) and what they identify as their most pressing needs.

The aim of this study was to provide initial data to support a human-centered design approach for the next generation in technology for individuals with tics. To this end, we evaluated how adults with tics in the United States use and perceive available resources for tic management and support. We also included questions to better understand their reported concerns about using technology in this way, as well as what they would like this kind of technology to do for them.

Methods

Survey

We designed an exploratory online survey created and administered via Qualtrics to obtain rapid input from a geographically dispersed sample. The survey consisted of 17 questions pertaining to demographic information (age, gender, race, ethnicity, and state of residence), clinical characteristics (diagnostic status, age of onset, and treatment history), sources of tic-related information and support, and experiences with, preferences for, and concerns about a digital tool for managing one's tics. We define *support* for adults with tics as "anything that helps adults with tics manage or feel better about their tics," which could include but is not limited to treatment, accommodations at school or work, encouragement, or understanding from others. A combination of dichotomous, multiple-choice, and open-ended questions were used, including 3 conditionally displayed items to allow participants to provide more detail to a positively answered dichotomous question.

To develop the questionnaire items, we first identified domains from our research aims and specified the constructs to be measured. All authors jointly drafted and reviewed items in working sessions, resolving discrepancies by consensus. We compared our draft wording with items used in prior studies and relevant guidance, adapting where appropriate to maintain conceptual alignment and plain language. While we did not conduct a separate pilot, we performed internal usability checks (skip logic, option ordering, and readability) on desktop computers, laptop computers, tablets, and smartphones (iOS) before launch. To reduce participant burden and accommodate potential completion difficulties, most survey items were left optional. Because our approach was reach rather than depth, findings should be interpreted with this limitation in mind. We expect pilot testing and further validation of the instrument in future work.

Recruitment

The survey was distributed to adults with motor or vocal tics who were living in the United States via an advertisement on the Tourette Association of America (TAA) website (tourette.org) and emails to state and local TAA chapters and support groups, as well as TD clinicians and researchers.

Data and Participants

Data were collected between December of 2022 and April of 2023. The survey received 170 entries, with 2 noted duplicates. Of the 168 unique individuals who accessed the survey, 152 completed it fully (completion rate=90.5%). Responses were excluded from analysis if they indicated they did not wish to participate (n=1), a duplicate response was recorded (n=2), or they completed only the consent and eligibility section and nothing else (n=9). Data from partial completers (n=6) are included where available.

Among completers, the mean completion time was 26 minutes (SD 44 minutes; median 21 minutes, range 4 - 532 minutes). The IQR was 13 minutes (IQR/median=0.65, indicating high variability). Excluded responses (n=12) and partial responses (n=6) were not included in the completion time analysis.

Data Analysis

Quantitative Analysis

For categorical variables, we calculated frequencies and proportions (counts divided by the total number of responses) reported as counts and percentages. Analyses were performed in Google Sheets (Alphabet Inc).

Qualitative Analysis of Open-Ended Responses

We conducted an inductive thematic analysis of open-ended survey responses following Braun and Clarke's 6-phase

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approach [24]. Coding and theme development were driven by the data rather than preexisting frameworks. In phase 1 (familiarization), all responses to the open-ended survey questions were read to establish initial impressions. In phase 2 (generating initial codes), each response was coded by assigning concise labels that captured the meaning of each segment of text (eg, "confidentiality," "price," and "time-consuming"). Coding was conducted in Google Sheets (Alphabet Inc) to organize data systematically. In phase 3 (searching for themes), related codes were grouped into broader candidate themes. For example, codes such as "boring" and "doesn't attract attention" were combined into the candidate theme "Lack of engagement."

In phase 4 (reviewing themes), candidate themes were reviewed against the coded data and the entire dataset to ensure coherence within themes and clear distinctions between themes. Discrepancies were resolved through discussion. In phase 5 (defining themes), we refined the scope and focus of each theme and developed clear definitions and names that captured their essence. In phase 6 (writing the report), we selected representative participant quotes for each theme to illustrate key points when reporting results. Quotes are presented with participant IDs (labeled as P1-P168), which were assigned based on what time the survey was submitted. After coding all responses, we calculated the number and proportion of participants whose comments were assigned to each theme. This allowed us to report both qualitative descriptions and quantitative distributions of concerns.

Ethical Considerations

The study was reviewed and deemed exempt by the institutional review board at the authors' institution (Bowdoin College) per Exemption 45 CFR 46.104(d)(2) for Educational Tests, Surveys, Interviews, or Observation of Public Behavior. A limited review was conducted to ensure that there were adequate provisions to protect the privacy of participants and to maintain the confidentiality of data. All participants completed an informed consent checkbox, and data were stored on a secure, password-protected server with no identifying information. Participants received a US $10 Amazon gift card for their participation.

Results

Demographic Information

Among completers and partial completers (N=158), participants were predominantly male (n=105, 66.5% male; n=49, 31.0% female; and n=4, 2.5% nonbinary) and ranged in age from 18 to 87 years (mean 29.3, SD 12.8 years). Altogether, 65.2% (n=103) of participants identified as White, 23.4% (n=37) as Black or African American, 5.1% (n=8) as more than 1 race, 3.8% (n=6) as Asian, 1.9% (n=3) as another race, and 0.6% (n=1) did not report their racial identity. In all, 6.3% (n=10) were of Hispanic origin.

Participants were asked where they currently lived as a nonrequired question. One participant came from the District of Columbia, and the remaining participants lived in 42 different states across the United States. Of those who responded (N=157), the largest overrepresentation was California (n=13, 8.3%), New Jersey (n=12, 7.6%), and Washington (n=12, 7.6%). The largest underrepresentation (n=0, 0%) was Alaska, Maine, Mississippi, Montana, North Dakota, Rhode Island, South Dakota, and Wisconsin. Given the limited literature on comparable demographic distributions, comprehensive benchmarking is not feasible. Nevertheless, our sample appears consistent with prior reports regarding high male preponderance [25,26].

Clinical Characteristics

Among respondents (N=158), the vast majority (n=143, 90.5%) of the participants reported having been formally diagnosed with TS by a health care provider. An additional 3.8% (n=6) reported having been diagnosed with persistent or chronic motor or vocal tic disorder, while 1.9% (n=3) were diagnosed with provisional or transient tic disorder and 1.3% (n=2) with another TD (eg, tic disorder not otherwise specified). The remaining 2.5% (n=4) did not disclose that they were formally diagnosed, leaving their answer blank. We chose to include these respondents as part of our analysis because formal diagnosis is often limited by access and affordability of care [27].

Participants were asked, "What age did your tics begin?" and provided their answers in a text field. Two respondents gave a generic answer ("teens" and "toddler"), and 1 partial completer did not answer the question. Among respondents who gave an age in years (N=155), the reported median age of onset was 7 (IQR 6 - 8) years. The range was between 1 and 55 years (mean 7.8, SD 4.6 years).

Participants were asked, "Have you ever received any of the following treatments for your tics?" and were asked to select any options that best fit their experience. Six partial completers did not respond. Among respondents (N=152), the majority reported receiving at least 1 type of treatment for their tics, with comprehensive behavioral intervention or habit reversal therapy being the most common (n=131, 86.2%), followed by exposure and response prevention (n=96, 63.2%), medication (n=92, 60.5%), other therapy (n=12, 7.9%), other interventions (n=4, 2.6%, self-described as meditation, anxiety management, and radio frequency), and deep brain stimulation (n=2, 1.3%).

Sources of Information and Support

Information

Participants were asked to report where they had previously sought information about tics. They were provided with 21 possible sources and also permitted to enter additional sources. Online sources were the most commonly endorsed and were the only sources that greater than 50% of the respondents selected. These included tourette.org (n=143, 90.5%), Google (n=134, 84.8%) and YouTube (n=125, 79.1%), hospital websites (eg, Mayo Clinic, n=83, 52.5%), and Instagram (n=83, 52.5%). When asked where they would first look for the answer to a current question, we saw similar patterns: the majority of respondents typically sought answers from digital platforms first (124/158, 78.5%), with tourette.org (45/158, 28.5%), YouTube (30/158, 19.0%), and Google (27/158, 17.1%) as the most commonly selected. Social media generally (45/158, 28.5%) was almost as popular as more credible sources, such as PubMed, WebMD, MEDLINE, hospital websites, or the

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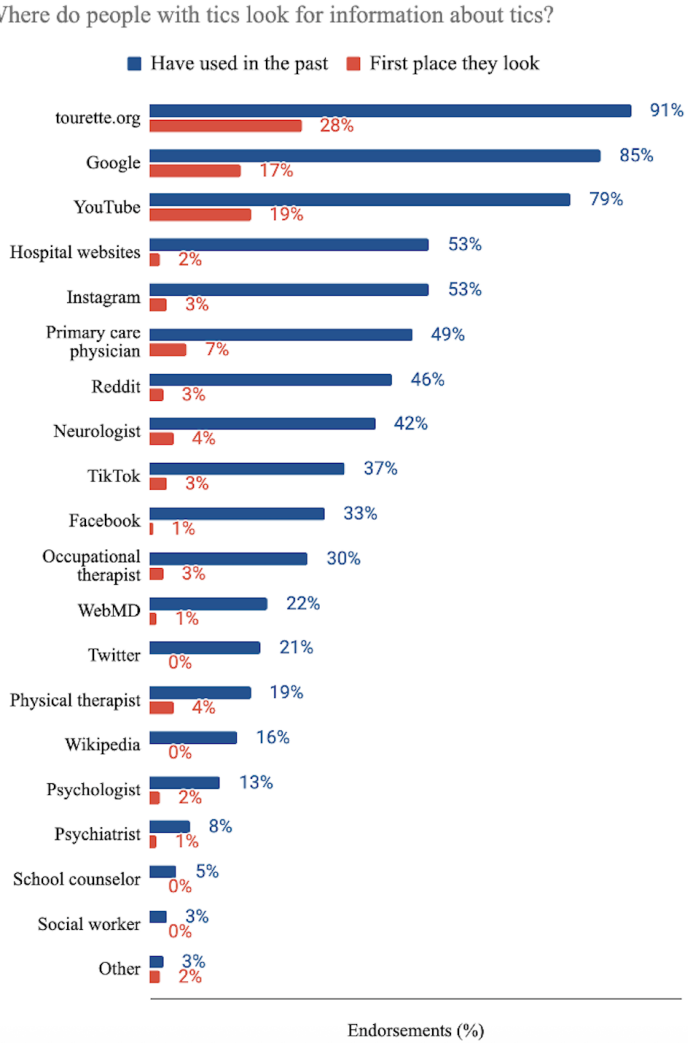
TAA's website (53/158, 33.5%). See Figure 1 for a complete accounting of responses.

Figure 1. Percentage of endorsements for information sources on tics are reported as percentages (N=158) for each category: tourette.org (have used: n=143, 91%; first place they look: n=45, 28%), Google (have used: n=134, 85%; first place they look: n=27, 17%), YouTube (have used: n=125, 79%; first place they look: n=30, 19%), hospital websites (have used: n=83, 53%; first place they look: n=3, 2%), Instagram (have used: n=83, 53%; first place they look: n=5, 3%), primary care physician (have used: n=78, 49%; first place they look: n=11, 7%), Reddit (have used: n=72, 46%; first place they look: n=4, 3%), neurologist (have used: n=67, 42%; first place they look: n=7, 4%), TikTok (have used: n=58, 37%; first place they look: n=5, 3%), Facebook (have used: n=52, 33%; first place they look: n=1, 1%), occupational therapist (have used: n=47, 30%; first place they look: n=4, 3%), WebMD (have used: n=35, 22%; first place they look: n=2, 1%), Twitter (have used: n=33, 21%; first place they look: n=0, 0%), physical therapist (have used: n=30, 19%; first place they look: n=7, 4%), Wikipedia (have used: n=26, 16%; first place they look: n=0, 0%), psychologist (have used: n=21, 13%; first place they look: n=3, 2%), psychiatrist (have used: n=12, 8%; first place they look: n=2, 1%), school counselor (have used: n=8, 5%; first place they look: n=0, 0%), social worker (have used: n=5, 3%; first place they look: n=0, 0%), other (have used: n=4, 3%; first place they look: n=3, 2%). For the question posed to participants, refer to Multimedia Appendix 1 (Survey Instrument, Q1).



Support

Participants were asked a nonrequired question: "Where do you receive support for your tics? Support might include treatment, accommodations at school or work, encouragement, understanding, and more. It's basically anything that helps you manage or feel better about your tics." They were provided with 13 possible sources and also permitted to enter additional sources. Among respondents (N=156), intimate relationships were the primary sources of support, including family members (n=137, 87.8%), friends (n=74, 47.4%), and spouse or partner (n=55, 35.3%). Of note for this particular survey, online communities and message boards were the least endorsed sources of support (n=2, 1.3%). Figure 2 displays all responses received for this question.

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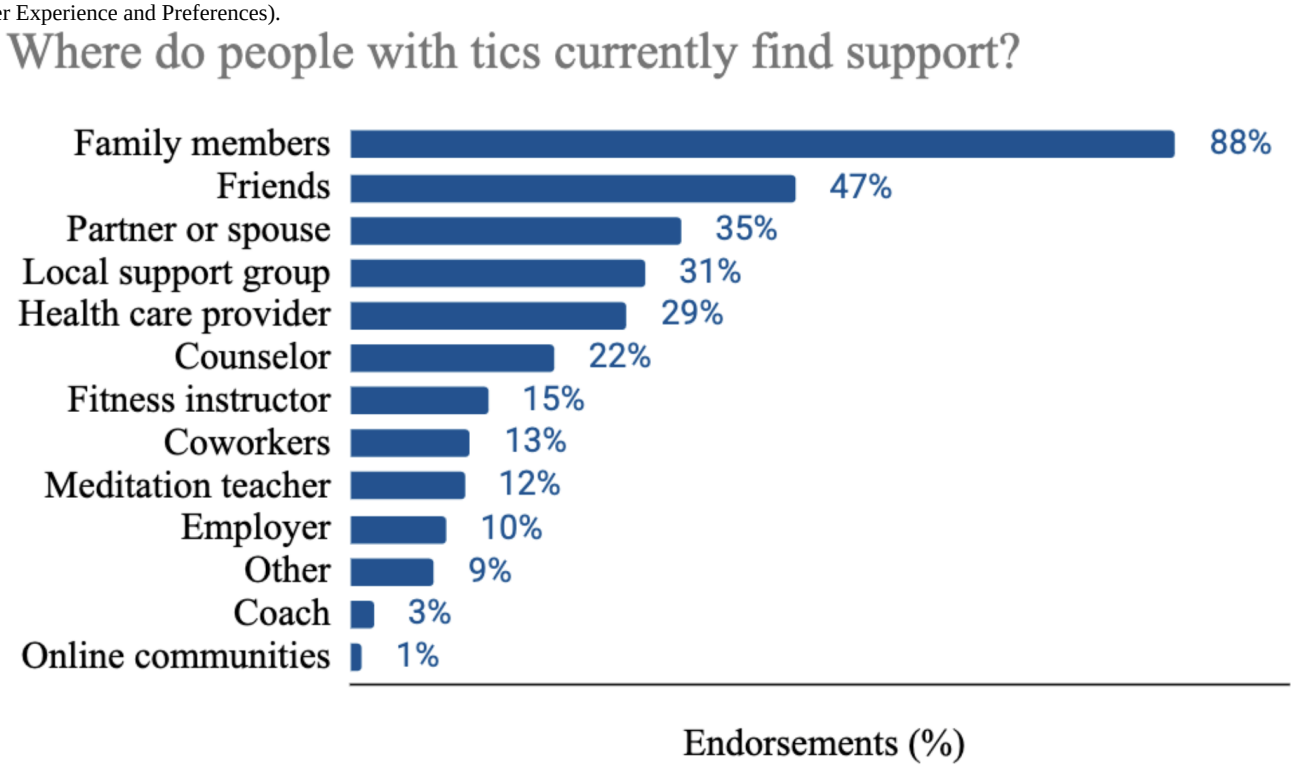
Figure 2. Current sources of support for individuals with tics are reported as percentages (N=156) for each category: family members (n=137, 88%), friends (n=74, 47%), partner or spouse (n=55, 35%), local support group (n=49, 31%), health care provider (n=46, 29%), counselor (n=34, 22%), fitness instructor (n=23, 15%), coworkers (n=20, 13%), meditation teacher (n=19, 12%), employer (n=16, 10%), other (n=14, 9%), coach (n=4, 3%), online communities (n=2, 1%). For the full question posed to participants, refer to Multimedia Appendix 1 (Survey Instrument, Q4. Existing Digital Tools: User Experience and Preferences).



Participants were also asked whether there are any forms of support that they wish they had, but do not. This question was not required to be filled in. Among completers and partial completers (N=158), 82.3% (n=130) of the participants left their answer blank and 1.9% (n=3) stated “No” or “N/A.” In total, 5.1% (n=8) of the participants named other forms of support they already had in their lives, including pets (n=4, 2.5%), gardening (n=2, 1.3%), neighbors (n=1, 0.63%), and participating in a prayer group (n=1, 0.63%). The remaining participants (n=17, 10.8%) reported a range of responses. The most commonly reported themes were better access to treatment (n=6, 3.8%) and social support specifically for adults with tics (n=5, 3.2%). On better treatment access, participants talked about access to a professional therapist, deep brain stimulation, medication without significant side effects, a version of the TicHelper online intervention designed for adults, and better treatment options generally. On social support for adults with tics, participants reported that it was difficult to get to know others with TDs as an adult, especially women. Three other themes that emerged also had to do with support group access. The remaining themes had to do with more research on treatment and support for communicating to others about their tics. A summary table of responses is shown in Table 1.

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Table . Example participant responses for each theme identified in response to the question "Are there any forms of support that you wish you had, but don't?"

Theme	Definition	Example quote
Better access to treatment	Participants wished better treatment options existed.	"I wish there was more/better options to treat them [I'm] 28 now and experiencing my tics worse than I ever had" [Participant 40].
Better support as a child	Participants wished they had access to better support as a child.	"Not much was known about this disorder when I first showed symptoms…Once there was a name to put with this, things were different" [Participant 23].
More research on treatment	Participants wished more studies were being conducted to support individuals with TDs[a].	"I would like to see more studies on treatment options other than pharmacological" [Participant 152].
Professional support group	Participants wished for a support group led by professionals with relatable content.	"Sometimes I want an adult support group made up of professionals. But not an adult group about parenting" [Participant 14].
Social support for adults with tics	Participants wished for at least 1 other person who can relate to them as an adult with tics.	"I'd love an in-person support group for ADULTS with Tourettes where we can hang out and talk and share stories" [Participant 61].
Support for communicating to others about their tics	Participants wished for support that would help them feel more comfortable sharing with others that they had tics.	"I wish there was like, some kind of something that would've supported me to tell my parents about my tic development without as much stress that they would go crazy over it" [Participant 25].
Support group relevant to academics	Participants wished for a support group that could provide them with strategies and resources relevant to attending school.	"Support centered around college-related activities, including socialization, academics, and how to deal with TS's impact on those areas of life" [Participant 72].

[a]TDs: tic disorders.

Existing Digital Tools: User Experience and Preferences

Prior Experiences

Among respondents (N=158), 18.4% (n=29) reported having previously used a digital tool to help with their tics or any other aspect of their health. Only 1 app was described as being consistently used that was specifically designed for the TD community (BT-Coach English [28]), although 1 individual did mention telehealth and another mentioned that they had tried to make their own app for the TD community due to the lack of apps in this domain. The majority (22/29, 75.9%) of reported tools were used for mental health support and wellness. Others (4/29, 13.8%) reported using built-in productivity tools (Notes app for tic tracking, Calendar app for tic tracking or appointment management, alarms for medication reminders, speech-to-text for motor tic support, or online search for information) and fitness tracking (Fitbit or Weight Watchers). The most popular tool reported overall was the Calm app for mental health (8/29, 27.6%), followed by Sanvello (4/29, 13.8%). A number of users reported that while mental health tools were "not specifically developed to treat tics," they did indirectly help them in other ways. A summary table of example responses is shown in Table 2.

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Table . Example participant responses when asked to describe the digital tools they have used and identified themes.

Theme	Definition	Example quote
Apps specifically designed for the TD[a] community	Participants used apps that are specifically for individuals with tics (eg, tic monitoring).	"I have used an app called The BT-Coach English, I like it because it tracks the number of tics and the strength of the need to tic" [Participant 27].
Built-in productivity tools	Participants used built-in productivity tools that are not necessarily designed for individuals with tics.	"I use alarms to remind me to take medications. My pharmacy auto fills my prescriptions. I use my cell phone calendar to manage doctor's appointments" [Participant 3].
General health	Participants used apps designed for general health.	"Fitbit App—good, just didn't always keep my Fitbit charged and I didn't like that it didn't track other kinds of exercise (other than walking) as accurately" [Participant 14].
Mental health support and wellness	Participants used apps designed for mental health and wellness.	"I have used some apps to control my negative thoughts, stress and anxiety, because there are no apps for people with tics or tourette syndrome" [Participant 54].
Unmemorable due to negative experience	Participants could not remember what app(s) they used because they had a negative experience.	"I don't remember the name of the app, I didn't like it, I spent a lot of time answering questions and I didn't get anywhere. It didn't help to improve my tics either, so I uninstalled it" [Participant 86].

[a]TD: tic disorder.

Most individuals reported positive results with the digital tools they had tried, with only a few (4/29, 13.8%) explicitly stating that they had a negative experience. However, many (13/29, 44.8%) mentioned that the tools they used (whether for mental health support or otherwise) were unrelated to tics. Overall, this was the most common criticism of the digital tools these individuals had tried. Other critiques included the app experiences being tedious, boring, difficult, and generally not what they expected. One user stated, "I believe I tried tracking tics long ago but it was just too frequent to keep up with it and there were no consistent triggers to record" [Participant 14].

Navigation

Participants were asked, "Do your tics make it difficult or frustrating for you to use a computer, smartphone, tablet, or other digital device?" Among respondents (N=158), 48.1% (n=76) responded "yes," 48.7% (n=77) responded "no," and 3.2% (n=5) left the question blank. Those who answered "yes" were asked a follow-up as to the nature of the difficulty or frustration. Most often, these individuals mentioned frustration with tics because they physically interrupted what they were doing such as typing or looking at a screen (26/76, 34.2%). Some further noted that using digital devices might be a trigger due to prolonged usage (5/76, 6.6%) or other, mostly unspecified reasons (7/76, 9.2%). Other difficulties included the unpredictability of tics, damage to devices (from dropping or throwing), slowness (due to having to restart or wait), needing assistance to use the device, losing concentration on tasks, submitting the wrong input (such as typos, accidentally changing the screen orientation, or moving the mouse to the wrong place), and experiencing embarrassment or discomfort. A summary table of example responses is shown in Table 3.

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Table . Example participant responses when asked how their tics make it difficult or frustrating to use digital devices.

Theme	Definition	Example quote
Can't concentrate	Participants report frustration with tics causing them to lose focus.	"Yes, tics hinder some activities such as using devices because they require...concentration." [Participant 168]
Can't see screen	Participants report frustration with not being able to see or read from the device.	"It makes it difficult for me to read and see the screen, because I blink and twist my neck, although it is occasionally." [Participant 42]
Can't sit still	Participants report frustration with being unable to sit still to use the device.	"Needing to sit still." [Participant 153]
Device acts as a trigger	Participants report frustration that tics are exacerbated when using their digital devices.	"The brightness or light from the screens bothers my eyesight and I start to blink so I can't concentrate on what I'm doing, so I have to stop, go somewhere else, calm down, and wait to sit down in front of the device again." [Participant 27]
Loss of control	Participants report frustration with losing control of their body.	"I still can't get used to the tics, it frustrates me not being able to control my body." [Participant 163]
Manageable but still frustrating	Participants explain that their frustration has lessened over time due to tics decreasing in frequency, intensity, or both.	"My tics have decreased in intensity, from time to time they appear, but they don't affect me as before." [Participant 123]
Prolonged device usage	Participants report frustration that using devices for a long time will trigger tics.	"It makes me uncomfortable and stressful to use touch screens for a long time, my hands shake as part of a tic." [Participant 33]
Prevents action	Participants report frustration with not being able to take a desired action.	"I can't use digital tools until my tics subside." [Participant 86]
Require assistance	Participants report frustration with tics causing them to depend on someone else to use their digital device.	"My tics make it difficult for me to use computers so much so that sometimes someone uses the computer for me and explains what they are doing." [Participant 97]
Slip due to tics	Participants report frustration that tics cause an unintentional action.	"Sometimes when I use the mouse or the screen and I want to choose an option, my arm loses control for seconds and I select another option." [Participant 74]
Social comparison	Participants report frustration when comparing themselves with others.	"Even when I'm calm my tics kick in and my arms shake uncontrollably, it frustrates me because I can't use devices calmly like other people." [Participant 70]
Social judgment	Participants report frustration that their tics cause others to treat them differently.	"The looks of the people around me make a simple daily activity like calling by phone in something very difficult." [Participant 136]
Time-consuming	Participants report frustration with how much time it takes them to use their digital devices.	"Using a computer takes me time, and it frustrates me." [Participant 168]
Unexpected tics	Participants report frustration with tics that appear unexpectedly with an unknown cause.	"My tics make appearances at the least expected moments, even when I'm relaxed they trigger." [Participant 41]

Next, participants were asked, "How do you prefer to navigate on your digital devices?" Participants were presented with 5 means of navigation and instructed to rank order the choices. Means given higher rankings were assigned fewer points (eg, the first priority was given 1 point whereas the last priority was given 5 points). The overall preference of a means of navigating was computed as the mean of all ranking scores with lower scores indicating greater preference. The screen was most preferred (mean 1.97, SD 1.02), followed by mouse (mean 2.57, SD 1.26), voice commands (mean 3.01, SD 1.42), trackpad (mean 3.62, SD 1.33), and keyboard (mean 3.83, SD 1.12).

Future Digital Tools: Perceptions and Expectations

Desired Functionality

Participants were asked, "A digital tool can do lots of different things. Please consider the list below and rank order the various features from most to least important." A total of 14 possible desired functionalities for a digital tool were presented to participants. Functions given higher rankings were assigned fewer points (eg, the first priority was given 1 point whereas the last priority was given 14 points). The overall importance of a function was computed as the mean of all ranking scores

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with lower scores indicating greater importance. Table 4 shows the functions from most to least important. Overall, tic monitoring (66/154, 42.9%) and trigger monitoring (54/154, 35.1%) were ranked as most important to respondents.

Table . Possible functionalities of a digital tool for the tic disorder community, ranked from most (lower score) to least (higher score) important by participants in the study (N=154).

Functionality	Mean (SD)
Tic monitoring (eg, a way to monitor how often your tics occur and see how they change over time)	2.32 (2.17)
Trigger monitoring (eg, a way to track factors that make your tics better or worse)	2.52 (2.26)
Mood/anxiety/stress monitoring (eg, a way to monitor your emotional states and see how they change over time)	5.35 (2.91)
Information about tics (eg, how common they are and what causes them)	6.56 (3.09)
Stress reduction/relaxation strategies (eg, progressive muscle relaxation and physical exercise)	7.15 (3.18)
Tools for managing negative thoughts you may have about your tics	7.95 (3.09)
Anger management strategies	8.02 (3.38)
Ways to connect with others who have tics (eg, a message board)	8.12 (3.72)
Encouragement	8.22 (3.13)
Tips for talking about tics with others	9.33 (3.68)
Mindfulness-based tools (eg, meditation, breathing exercises, and yoga)	9.47 (3.48)

We examined associations between responses to Q11 (“Have you ever used a digital tool to help with your tics or any other aspect of your health?”) and how participants ranked each of the 14 features (Q6) using Pearson correlations. For Q11, we coded “Yes” responses to 1 and “No” responses to 0. For Q6, we reversed the ranking values so that a positive *r* value would denote the “Yes” group preferring a feature more than the “No” group (and a negative *r* value would denote the “Yes” group preferring a feature less than the “No” group).

Across all features, correlations were small ($|r|<0.17$). The strongest positive correlation was observed for the “managing negative thoughts” feature, but this effect was small and not statistically significant ($r=0.116$, $P=.152$; N=153). The strongest negative correlation was observed for the “encouragement” feature: respondents who answered “Yes” to Q11 (indicating that they had used a digital tool to help with their tics or health) tended to give “encouragement” lower priority than those who answered “No” ($r=-0.169$, $P=.037$; n=153). However, this association did not survive a Bonferroni correction for 14 tests (adjusted $\alpha=.0036$). These results overall should be interpreted as exploratory.

Following this question (Q6), participants were asked, “Are there any other things that you would like a digital tool to do for you?” A number of responses elaborated on the functionalities shown in Table 4, including how to reduce tics, using tic management techniques such as Exposure Response Prevention, helping individuals “take their mind off tics” to lessen their severity, managing negative thoughts (in particular, intrusive thoughts from comorbid conditions such as obsessive-compulsive disorder), linking anxiety states with tic severity, and supporting sleep. One individual noted that tic monitoring would make their tics worse, emphasizing the need for mental health support instead. Beyond these, responses included (1) resources for the general public to help destigmatize TDs and promote acceptance, as well as tips for what others should or should not say to someone who tics; (2) reminders for individuals with TDs that it is okay to tic in public; (3) support for physical pain associated with tics; and (4) features relevant to legal rights, advocacy, and workplace accommodations, as well as the experience of discrimination in public places when tics could be disruptive.

Promise and Appeal

Participants were asked, “Do you think a digital tool designed for adults with tics, specifically, could be helpful?” Among respondents (N=153), the majority of participants (n=115, 75.2%) responded “Yes” (n=57, 37.3%) or “Possibly” (n=58, 37.9%). The remaining participants responded “Unsure” (n=37, 24.2%), or “Unlikely” (n=1, 0.65%). No participants responded “No.” There was a significant small positive relationship between agreement on this question (Q13) and Q11, which asked, “Have you ever used a digital tool to help with your tics or any other aspect of your health?” (Spearman $\rho=0.291$, $P<.001$; n=153). Results were similar using Pearson *r* ($r=0.286$, $P<.001$; N=153).

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Participants were also asked, "How likely would you be to use a digital tool for adults with tics?" Among respondents (N=153), the majority of participants (n=136, 88.9%) responded "Very likely" (n=81, 52.9%) or "Somewhat likely" (n=55, 35.9%). In total, 7.8% (12/153) of the participants responded "Neither likely nor unlikely," 3.3% (5/153) responded "Somewhat unlikely," and no participants responded "Very unlikely."

Finally, participants were asked, "Which type of tool would be most appealing to you?" Among respondents (N=153), the majority of participants indicated that a website and an app would both be appealing to them (n=73, 47.7%), followed by an app (n=50, 32.7%), a website (n=28, 18.3%), and neither (n=2, 1.3%). A chi-square test of independence revealed that there was no significant association between type of tool chosen as most appealing (app, website, both, or neither) and whether participants indicated that their tics made it difficult or frustrating to use a digital device (Q9), χ^2_3=2.99 (n=153); *P*=.394.

Concerns

Participants were asked, "Do you have any concerns about using a digital tool for managing your tics?" Among respondents (N=158), 70.3% (n=111) answered "No," 26.6% (n=42) answered "Yes," and 3.2% (n=5) left the answer blank. Of those who answered "Yes" (N=42), many were concerned about whether the digital tool would be time-consuming (n=13, 31.0%), too complicated or difficult to use (n=11, 26.2%), not accessible given their tics, such as not including the possibility for voice commands (n=9, 21.4%), and expensive (n=9, 21.4%). Other concerns included that the tool would be ineffective or not meet their expectations (6/42, 14.3%), not allow another person to help them use it (3/42, 7.1%), be boring (3/42, 7.1%), trigger tics (2/42, 4.8%), not protect confidentiality (2/42, 4.8%), be difficult to learn how to use it (2/42, 4.8%), contain inaccurate information or otherwise fail to educate (2/42, 4.8%), or that they would forget to use it (1/42, 2.4%). In total, 4.8% (2/42) did not provide more detail about their concerns. A summary table of example responses is shown in Table 5.

Table . Example participant responses when asked to explain their concerns (if they had concerns) about using a digital tool for managing their tics.

Theme	Definition	Example quote
Abandonment	Participants expressed concerns that they would forget to use the digital tool.	"Remembering to use the app" [Participant 147].
Inaccessibility	Participants expressed concerns that a digital tool would be inaccessible to someone with tics.	"For me it is important that it include voice command, so I don't use my hands all the time and I don't trigger my tics" [Participant 33].
No bridge to human assistant	Participants recognized that a digital tool would need to allow another person to help them with the app.	"The web page must offer an assistance service so that another person can help in carrying out the tasks defined on the web page" [Participant 97].
Lack of confidentiality	Participants believed that a digital tool would not be confidential enough.	"Confidentiality" [Participant 79].
Cumbersome interface	Participants expressed concerns that a digital tool is difficult to use because it would have too many tasks or options.	"If manipulating the app is difficult...I'm not going to use it" [Participant 77].
Poor educational capacity	Participants expressed concerns that a digital tool would contain inaccurate information or otherwise fail to educate.	"I worry that the app...doesn't teach me anything" [Participant 69].
Inefficacy	Participants believed that a digital tool may not meet their expectations or be ineffective overall.	"I am concerned that it does not help me improve my tics, that it creates false expectations about whether it can help people with tics" [Participant 87].
Lack of engagement	Participants expressed concerns that a digital tool would be dull or uninteresting.	"It can be slow, boring, and it doesn't attract attention" [Participant 74].
Poor learnability	Participants expressed concern that they would need to spend a lot of time to understand the digital tool.	"I am concerned that it takes a long time to learn how to use the app" [Participant 87].
Price	Participants believed that a digital tool would be costly.	"I'm somewhat pessimistic about the tech industry...over-charging users for a simple collection of tools" [Participant 10].
Time demands	Participants perceived a digital tool as too time-consuming.	"I think they should develop activities for the app or website that can be done in a short time, so I don't worry about my tics" [Participant 35].
Trigger tics	Participants believed that a digital tool would trigger their tics.	"I am concerned about its design, that it includes strong colors or that it does not consider other characteristics that could somehow trigger a tic attack" [Participant 104].

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Discussion

Summary of Findings and Connections to Prior Work

This study aimed to gather information toward (1) how adults with tics use and perceive available resources for tic management and support, (2) better understanding of the concerns adults with tics have about using technology for tic management and support, and (3) what adults with tics would like technology to do for them. Our findings indicate that adults with tics predominantly look for resources from the internet and find solace in family members; have concerns about future digital tools being complicated, time-consuming to use, and inaccessible; and are looking for tic and trigger monitoring in digital tools.

It is concerning that a social media site such as YouTube was a common and even first source of information for participants as opposed to consulting with professionals in the field. While this finding appears to align with prior work noting difficulties in accessing specialty care [12,13], studies have indicated that TS portrayals on YouTube and other social media may "inadvertently reinforce negative stereotypes and spread misinformation" [29]. It is unfortunately possible that participants are reaching out to these kinds of sources first not only out of convenience but also due to negative experiences with professionals [14].

At first glance, family being a more commonly noted source of support than friends appeared to differ slightly from prior work, which has suggested that individuals aged 16 years or older and who are current users of at least 1 online support community for TDs place considerable importance on being supported by their peers versus family and other forms of support [30]. However, it is to be expected that any study exclusively recruiting from online support communities would yield participants who place greater reliance on online peers.

In this study, tic, trigger, and mood, anxiety, or stress monitoring were ranked as the 3 most desired features in a digital tool. In contrast, prior work has reported that young people with TS commonly consider the following as desired features of a digital tool: "ways to learn more about TS" (including interaction with others), "activities that help to keep the [young person] calm" (such as games or music), and "functions that help them organize their activities" (such as a scheduling tool) [31]. The results from this study appear to suggest that adults with tics believe more in the value of monitoring themselves and their individual situation as opposed to learning by interacting with others. Self-monitoring tics and triggers are known by the medical and research communities to be part of effective therapeutic activities for TDs [32,33], so it is a hopeful result that participants saw the value in these features. By gathering systematic data on the frequency and correlates of their tics, individuals might be better able to design personalized strategies for mitigating their influence similar to the function-based interventions central to behavior therapy for tics. Stress, too, has traditionally been associated with increased tic severity [34] and so tools to identify and manage stress could result in overall reductions in tic severity. Relaxation therapy has also been found to be significantly effective in decreasing the severity or the frequency of tic symptoms, although not as much as self-monitoring and habit reversal [35]. Empirical testing would be necessary to determine whether self-directed use of a digital tool would be sufficient to produce clinical gains or whether it would be better conceived as an adjunct to clinical care.

Intriguingly, our study participants for the most part did not engage with tools specifically for tic management, citing that such tools were not available. Given that tic and trigger monitoring were popular choices as the top requested feature, this finding suggests that the currently existing tools were either not well known or did not support users enough to be useful. Instead of tools directly related to tics, participants relied heavily on tools for mental health support. One user also noted difficulty with self-monitoring tics or triggers: "I believe I tried tracking tics long ago but it was just too frequent to keep up with it and there were no consistent triggers to record" [Participant 14].

The findings here suggest that even when our study participants are familiar with certain tic-related tools, they have come away lacking, often due to user experience issues related to engagement or accessibility. However, they have found benefits from other apps that provide mental health and community support. The majority (115/153, 75.2%) are enthusiastic about new tools being developed to more specifically help them manage their tics and day-to-day life, but simultaneously some (42/158, 26.6%) express concern that such tools would not ultimately be able to help them.

Limitations

Our study has several limitations that should be considered. First, technology changes quickly. It is possible that participants would now have new thoughts, desired features, or concerns relevant to digital tools for TDs with the proliferation of generative artificial intelligence models and other advances.

To limit participant burden and prevent fatigue effects, we did not include any formal assessment of current tic symptomology, such as the Adult Tic Questionnaire [36], which would have substantially increased item count. We acknowledge that this may limit comparability with studies that use that instrument.

We used a 14-item ranking section for item 6 of our questionnaire, which asked participants to rank possible features of a digital tool from most to least important. While this question was designed to better understand the features that adults with tics were most interested in, it is possible that the number of items contributed to survey fatigue. In addition, 1 participant reported that they found the survey difficult to complete. A future version of this instrument might instead have respondents rate each of the 14 items on a Likert scale (eg, from "Very Unimportant" to "Very Important"). Future work might also look into face validation of the survey instrument through pilot testing or personal interviews.

Our participants consisted of volunteers and may also show an increased tendency to rely on online resources and tourette.org, specifically, as we recruited participants in part via this website. Furthermore, it is possible that those who answer an online survey are more likely to endorse a digital means of capturing or receiving information.

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We note, too, that our participant pool consisted only of adults with tics, and people younger than 18 years may have differing perspectives. In addition, we do not claim that the results presented here are entirely exhaustive of understanding the TDs community as a whole, and tics and related needs may vary greatly by individual. However, these data represent a key step toward better understanding the current user experience for individuals with tics and the next steps toward supporting them.

Broader Considerations

We were able to reach our study participants through state and local chapters as well as through an advertisement on the TAA website and expect that a future tool, if effective, could be disseminated through community groups in a similar way. Ideally, such an app would also be designed in collaboration with an organization of repute (such as the TAA) to ensure that any information or support it provides is accurate and trustworthy, in line with the concerns expressed by our study participants. Collaboration with a user experience professional would also be crucial, given that participants overwhelmingly feared that such an app would not adhere to recognized usability standards. In addition, we recommend that experts in data security as well as legal and regulatory compliance be involved, given the concern for data confidentiality. Risk assessments, as well as reviews to maintain compliance with common standards (eg, HITRUST Common Security Framework), should be conducted regularly.

Overall, people with tics, and particularly adults with tics, appear to be underserved when it comes to digital tools. We hope this formative work serves as a first step toward future human-centered technologies for adults with tics.

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Data Availability

The datasets generated or analyzed during this study are not publicly available due to participant confidentiality. Permission to share data with individuals outside the research team and/or deposit data in a publicly available depository was not obtained at the time of consent. Illustrative quotes are included in the paper (including Tables 1-3 and 5); aggregated results are provided in Table 4 and Figures 1 and 2, with key values reported in-text where noted. The survey instrument is available in Multimedia Appendix 1. A preexisting reporting checklist for internet e-surveys (CHERRIES [Checklist for Reporting Results of Internet E-Surveys] [37]) is included to assist in reporting our survey results.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Full questionnaire items and response formats used in the study.
[PDF File, 197 KB - formative_v10i1e78328_app1.pdf]

Checklist
CHERRIES checklist.
[PDF File, 126 KB - formative_v10i1e78328_app2.pdf]

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Abbreviations

CHERRIES: Checklist for Reporting Results of Internet E-Surveys
TAA: Tourette Association of America
TD: tic disorder
TS: Tourette syndrome

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Acceptability and Effectiveness of Text Message Reminders to Improve Patient Attendance During the Sociopolitical Crisis in Haiti: Telephone-Based Survey

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Abstract

Background: The sociopolitical crisis in Haiti affects health care center attendance, creating significant challenges in ensuring patient compliance with medical appointments.

Objective: This study aimed to assess the effectiveness of text message reminders on patient attendance in the context of the sociopolitical crisis of Haiti, examining the influence of patient perceptions, behaviors, and socioeconomic factors.

Methods: We conducted a cross-sectional study using a telephone survey of 386 randomly selected patients who had an appointment during the third quarter of 2024 at 2 health care centers in the Port-au-Prince metropolitan area. We collected appointment and socioeconomic data, as well as perceptions and behaviors toward text message reminders. We described patients' perceptions and behaviors toward text message reminders, as well as appointment attendance and patient characteristics. We performed bivariate and multivariate logistic regression models to assess whether receiving text message reminders and socioeconomic factors influenced overall appointment attendance.

Results: Among 386 patients, 259 attended their appointments on either the appointment day or at a later date for an overall attendance rate of 67.1 % (95% CI 62.4%-71.8%). Attendance rates were higher among the 147 patients who confirmed receiving a reminder (77.6%) compared to the 239 who did not (60.7%). SMS text messaging reading behavior varied among patients. Overall, 219/386 (56.7%) patients always, 66/386 (17%) often, 75/386 (19%) sometimes, 21/386 (5%) rarely, and 5/386 (1%) never read their SMS text messaging. All patients liked the initiative of sending reminders and found them helpful. In the multivariate analysis, patients who confirmed receiving a reminder were more likely to attend their appointment compared to those who did not (adjusted odds ratio [AOR] 2.0, 95% CI 1.18-3.39). A patient satisfaction rate of 8 or higher with their physicians was significantly associated with higher attendance rates, compared to 6 or lower, with AORs increasing with satisfaction. Travel time less than 30 minutes (AOR 2.31, 95% CI 1.03 - 5.19) and 30-60 minutes (AOR 2.78, 95% CI 1.24 - 6.21), and being with a chronic disease (AOR 0.42, 95% CI 0.23-0.79) were also associated with appointment attendance.

Conclusions: Our study highlights the potential of text message reminders to improve appointment attendance in Haiti, despite the sociopolitical crisis. The overall acceptability and positive perceptions of SMS text messaging reminders suggest that they can be a valuable tool in health care settings, especially when adapted to the local context. We recommend that health care centers in Haiti consider integrating SMS text messaging reminder systems into routine patient management to enhance adherence and optimize care delivery.

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KEYWORDS

patient appointment; reminder systems; text messaging; sociopolitical crisis; haiti

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Introduction

Haiti is facing a profound sociopolitical crisis characterized by escalating gang violence, political instability, and widespread displacement. As of early 2025, it was reported that 85% of the Port-au-Prince metropolitan area was controlled by armed gangs, resulting in the displacement of approximately one in ten of the population [1]. The crisis has a significant impact on the health system. By early 2024, 60% of the health care centers across Haiti were unable to function, and up to 20% of health professionals had left the country [2,3]. Increasing insecurity and the high risk of kidnapping affect health care center attendance, creating significant challenges in ensuring patient adherence and compliance with scheduled medical appointments.

While structural barriers like transportation and roadblocks may cause missed appointments, these factors do not fully explain the high rates of nonattendance observed. In many cases, patients simply fail to prioritize their health appointments due to competing daily demands, forgetfulness, or a lack of perceived urgency [4,5]. Improving attendance therefore requires interventions that address not only logistical obstacles but also behavioral and motivational factors by targeting the proportion of missed visits not caused by uncontrollable external barriers.

Text message reminders have proven to be a useful tool for addressing the challenges of medical appointment compliance in a variety of settings and contexts. Studies in low- and middle-income countries have shown that text message reminders significantly improve antenatal and postnatal care attendance rates, as well as childhood vaccination coverage [6,7]. Text message reminders were found to be effective in reducing nonattendance among patients requiring long-term follow-up for chronic illnesses [8]. Mobile phones are very popular in low- and middle-income countries; studies have shown that the majority of patients often read their text messages and are willing to receive health-related information [9-11].

Haiti has relatively wide mobile network coverage, with approximately 90% of the population residing in areas served by a mobile signal [12,13]. Given that adults constitute less than 60% of the total population, the country recorded a telephone subscription rate of 65 subscriptions per 100 inhabitants in 2022, according to the most recent data available from the World Bank [14,15]. Considering the popularity and accessibility of mobile phones among the population, text messaging may represent an effective tool to address low health care center attendance during periods of sociopolitical crisis.

In Haiti, a first study assessed the effectiveness of text message reminders to improve patient attendance [16]. Using administrative data, the authors accounted for patients showing up on the appointment day only but did not control for socioeconomic factors. Through this study, we aimed to go further, examining the influence of patient perceptions, behaviors, and socioeconomic factors to assess the effectiveness of text message reminders on patient attendance in the context of the sociopolitical crisis of Haiti in 2024.

Methods

Study Setting

Two health care centers implementing a patient reminder system decided to follow up on a primary study published in 2024 that assessed the effectiveness of the patient reminder system. They followed the recommendation of this study and decided to go further by conducting a telephone survey among patients who had an appointment during the third quarter of 2024 in order to assess the effectiveness of text message reminders on patient attendance, examining the influence of patient perceptions, behaviors, and socioeconomic factors. These 2 health care centers are located in lower Delmas, near the stronghold of one of the most feared gangs in the Port-au-Prince metropolitan area. One is a 37-bed facility that serves approximately 2000 patients per month and provides a package of services, including internal medicine, surgery, orthopedics, pediatrics, gynecology, emergency care, medical laboratory, pharmacy, and imaging. The other is an outpatient clinic that serves approximately 350 patients per month and provides a package of services, including internal medicine, surgery, orthopedics, pediatrics, gynecology, urology, ophthalmology, medical laboratory, and pharmacy. Patients initially arrive at health care centers as drop-in visitors, and physicians schedule follow-up appointments using the reminder system.

Study Design and Sample Size Calculation

Between December 2024 and January 2025, we conducted a cross-sectional study using a telephone survey of a random sample of patients who had an appointment during the third quarter of 2024 at 2 health care centers in the Port-au-Prince metropolitan area to assess the effectiveness of text message reminders on patient attendance in the context of the sociopolitical crisis of Haiti, examining the influence of patient perceptions, behaviors, and socioeconomic factors. Text message reminders were sent via email or SMS text messaging to patients before their appointment day, using an automated reminder system. Email reminders incurred no cost to either the health care centers or the patients; however, not all patients had access to an email address. SMS text messaging reminders were free for patients but involved a cost to the health care centers. To facilitate the delivery of SMS text messaging reminders, system administrators were required to recharge the SMS text messaging account. All patients had a phone number, but not all received SMS text messaging reminders, as system administrators did not consistently recharge the SMS text messaging account in a timely manner [16]. The primary outcome was overall attendance, defined as attendance at either the scheduled appointment or a later date. We examined patient perceptions and behaviors regarding text message reminders and compared overall attendance rates between those who confirmed receipt of text message reminders prior to their appointment day and those who did not, controlling for socioeconomic factors.

Sample size was calculated using confidence interval methodology with a confidence level of 95% and a margin of error of 5%, as recommended for cross-sectional studies and surveys and commonly applied in epidemiological research

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[17,18]. Given the sociopolitical crisis and resulting population instability due to displacement, which made the nonresponse rate difficult to predict, we aimed for the largest feasible sample size and adopted the maximum-variability assumption (50%), representing the most conservative approach given the uncertainty in population parameters (Eq. 1) [19]. The required sample size was estimated to be 386, ensuring adequate precision to detect meaningful associations between attendance, receipt confirmation of reminder, and socioeconomic factors.

(1)n=(z2 X p(1−p) 2)

Where n is the sample size, *z* is the *z* score (1.96) associated with a 95% CI, is the margin of error (5%), and *p* is the overall population attendance rate (the conservative estimate of 50%).

Data Collection

The survey was conducted via structured telephone interviews. Nurses from the respective health care centers were trained and served as interviewers to enhance the acceptability of the survey among patients. The survey was administered by the trained interviewers using a standardized questionnaire to minimize interviewer bias and ensure consistency in data collection. The questionnaire and survey tools were bilingual, with all components in both French and Haitian Creole. The eligibility criteria were having a medical appointment during the third quarter of 2024 (July-September) at the two selected health care centers in the Port-au-Prince metropolitan area. A randomly sorted list of 1682 eligible patients was used as the sampling frame. Patients were contacted by telephone and enrolled progressively, following the order of the randomly sorted list, until the target sample size was reached. This strategy follows the principle of simple random sampling, in which each eligible patient has an equal and independent chance of being selected. In addition, this approach offers the advantage of ensuring that the targeted sample size can be reached despite an unexpected nonresponse rate, as the list can simply be followed until the required number of participants is enrolled. This method provided flexibility in addressing the unpredictable nonresponse rate due to the sociopolitical crisis context. Informed consent was obtained from the participants or their parents. Kobo (Harvard Humanitarian Initiative) was used to facilitate data entry, allowing real-time data quality monitoring.

Data collected in the survey included attendance at the scheduled appointment, late attendance (voluntarily return at a later date after missing the original appointment), time to voluntarily return at a later date after missing the original appointment (in days), reasons for late or nonattendance, receipt confirmation of reminder (did the patient receive a reminder before their appointment day), means of reminder (SMS text messaging or email), SMS text messaging reading frequency, Patient's perception toward reminders (liking text message reminder initiative, whether reminders were helpful or not, and means of reminder preference), travel time (number of minutes spent by the patient from their home to reach the health care center), modes of transportation used by the patient, financing medical expenses (whether the patient took in charge their medical expenses or did they receive financial support from someone else), perceptions of service costs (did the patient find service costs affordable, reasonable, or expensive), satisfaction with the physician (rated on a scale of 1-10, where 1 is very dissatisfied and 10 is very satisfied), occupation of respondents (occupation of adults and children's parents), education level of respondents (education level of adults and children's parents), and being with a chronic disease (defined as an illness that requires ongoing medical care, based on the patient's self-report of whether they endure from a chronic condition).

We used appointment data from the reminder system as well. These data included means of reminder and sending status (whether a reminder was sent or not and via which means), day and time at which SMS text messaging reminders were sent, time to appointment (number of days between the scheduled date and the appointment date), patient age, patient gender, and having children (for adults and children's parents).

Statistical Analysis

We described patient perception and behavior toward SMS text messaging reminders, as well as appointment attendance and patient characteristics. We performed bivariate and multivariate regression analyses using logistic regression models to assess whether receiving text message reminders and socioeconomic factors impacted overall appointment attendance. A 2-way stepwise analysis based on the Akaike Information Criterion was performed to select the best model for the multivariate analysis.

We conducted a sensitivity analysis to explore nonresponse bias using appointment data from the reminder system. Nonresponse rates were compared across reminder groups, clinical specialties, gender, and age groups using the Pearson chi-square test (Multimedia Appendix 1).

All statistical analyses were performed using Python (version 3.12.8; Python Software Foundation) with the following packages: statsmodels (for logistic regressions), SciPy (for Pearson chi-square test), matplotlib (for plots and graphs), seaborn (for plotting the heatmaps), pandas (for data manipulation and descriptive analysis), and numpy (for numerical operations and array handling). The Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) checklist (Checklist 1) was used to report the findings [20].

Ethical Considerations

Ethics approval for the study was granted by the Haiti Ministry of Health National Bioethics Committee (#2425 - 8). Informed consent was obtained verbally from all participants or their parents. Participation was entirely voluntary, and participants were informed of their right to withdraw from the study at any time without any impact on their access to medical care or other services. Patient information was anonymized and deidentified before being handed over for analysis. No compensation was provided to participants. All methods were carried out in accordance with relevant guidelines and regulations.

Results

Overview

Between December 2024 and January 2025, 386 patients participated in the survey, resulting in a response rate of 63.0%.

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Of these patients, 259 attended their appointments on either the appointment day or at a later date for an overall attendance rate of 67.1% (95% CI 62.4%-71.8%).

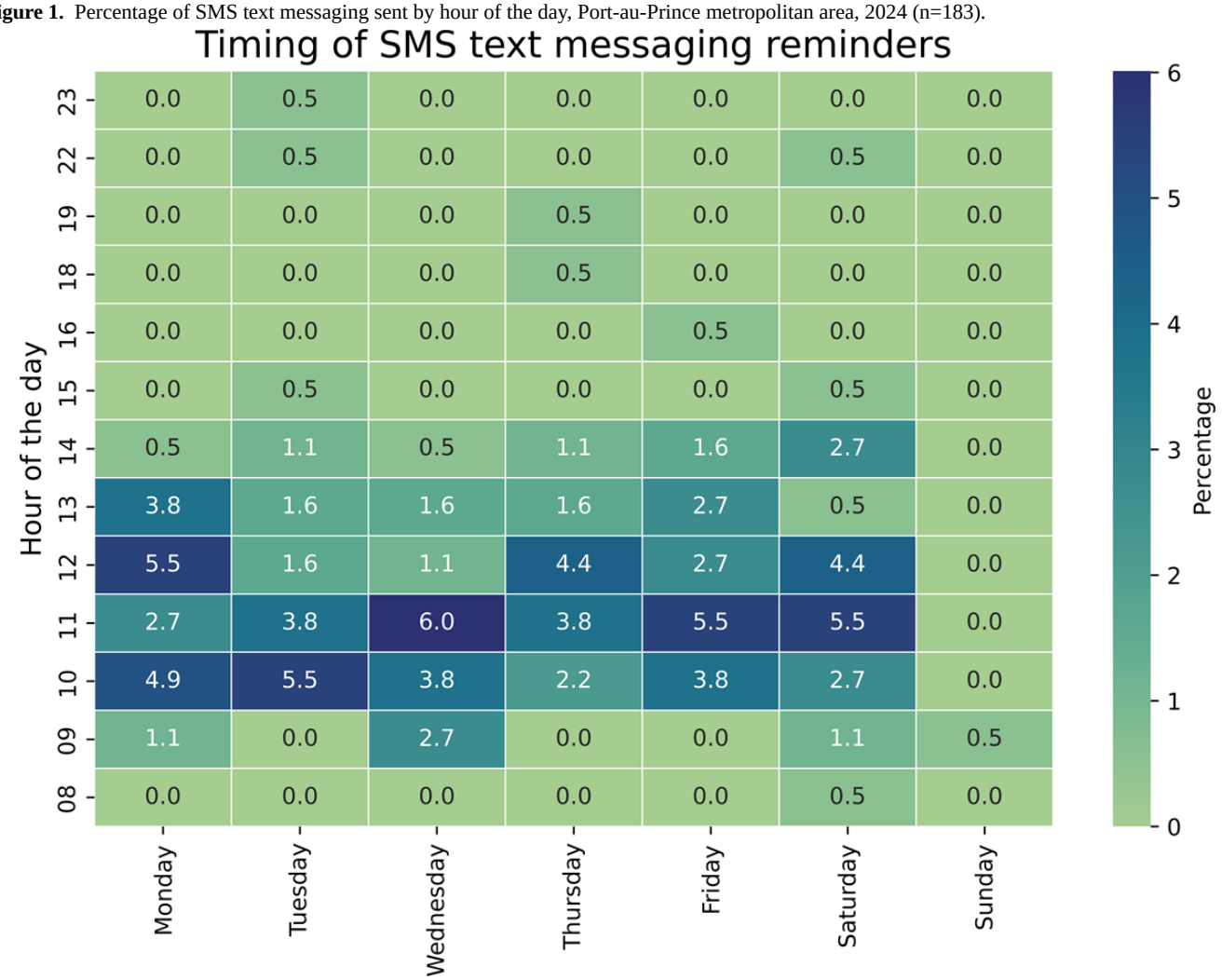
SMS Text Messaging Reading Behavior and Reminder Receipt Confirmation

A total of 183 patients (47.4% of the total sample) were sent an SMS text messaging reminder before their appointment day. Among these SMS text messaging reminder recipients, 143/183 (78.1%) confirmed receipt of the reminders (Table 1). The majority of SMS text messaging reminders (174/183, 95.0%) were sent between 9:00 and 14:00 Monday through Friday (Figure 1).

Table . Reminder receipt confirmation, Port-au-Prince metropolitan area, 2024.

Means of reminder	Sent	Receipt confirmation, n (%)
SMS text messaging	183	143 (78.1)
Email	19	10 (53)

Figure 1. Percentage of SMS text messaging sent by hour of the day, Port-au-Prince metropolitan area, 2024 (n=183).



SMS text messaging reading behavior varied among patients. Overall, 219/386 (56.7%) patients always, 66/386 (17%) often, 75/386 (19%) sometimes, 21/386 (5%) rarely, and 5/386 (1%) never read their SMS text messaging. The proportions of patients who always or often read their SMS text messaging were higher among those who confirmed receipt of reminders compared to those who did not: 92/143 (64%) and 27/143 (19%) versus 127/243 (52.3%) and 39/243 (16%). The trend was reversed for patients who sometimes, rarely, or never read their SMS text messaging. Among patients who confirmed receipt of reminders, 22/143 (15%) sometimes, 2/143 (1%) rarely, and 0/143 (0%) never read their SMS text messaging. And among those who did not confirm receipt of reminders, 53/243 (22%) sometimes, 19/243 (8%) rarely, and 5/243 (2%) never read their SMS text messaging (Figure 2).

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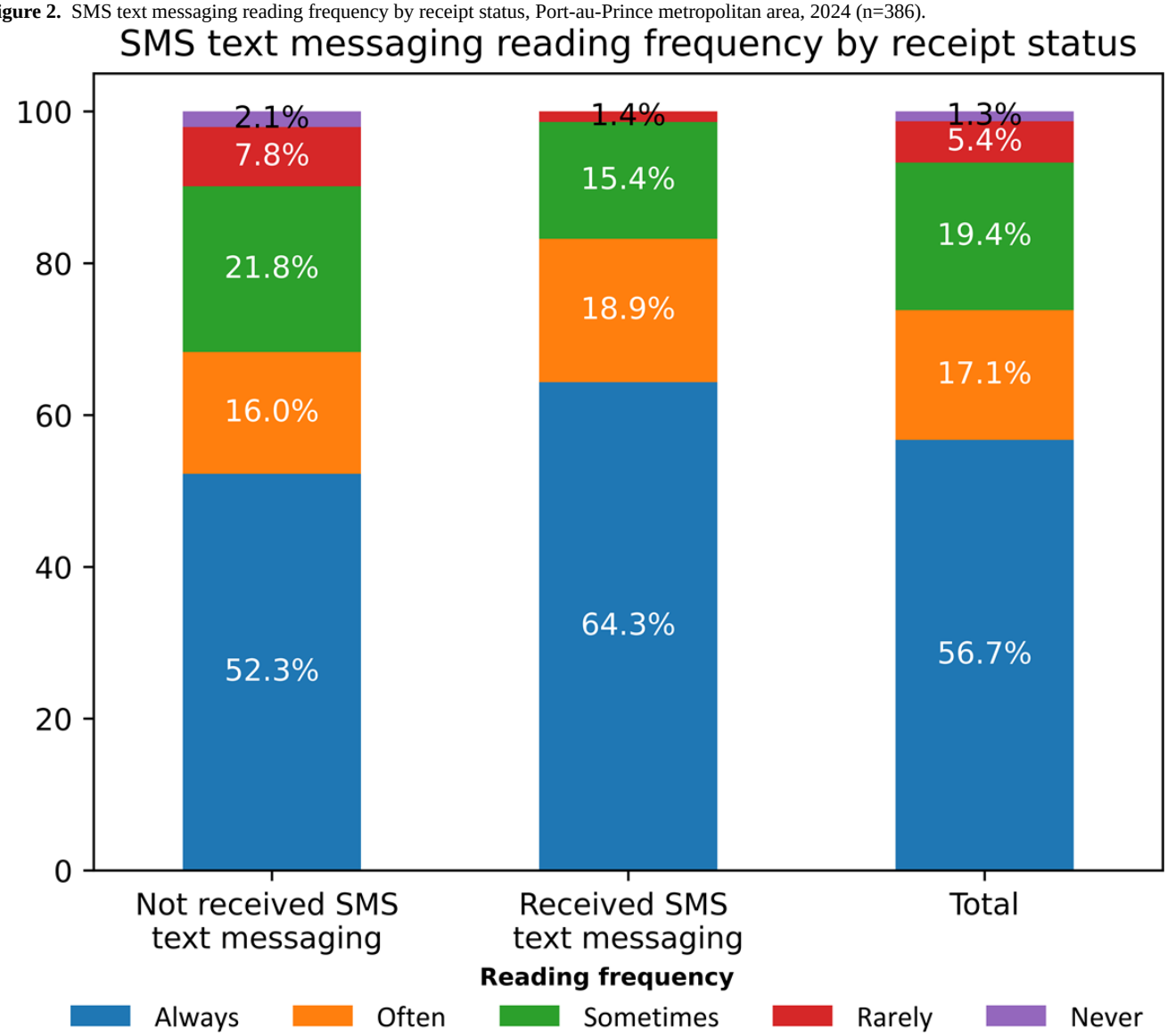
Figure 2. SMS text messaging reading frequency by receipt status, Port-au-Prince metropolitan area, 2024 (n=386).



Patient's Perception Toward Reminders

All patients (N=386, 100%) liked the initiative of sending reminders before the appointment day and found the reminders helpful. The near-totality of patients (385/386, 99.7%) would like to receive reminders in the future. Of all patients, 271/386 (70%) either had no preference or preferred receiving reminders via SMS text messaging and often or always read their SMS text messaging. In contrast, 19/386 (5%) of patients expressed a preference for reminder methods other than SMS text messaging and rarely or never read their SMS text messaging (Figure 3).

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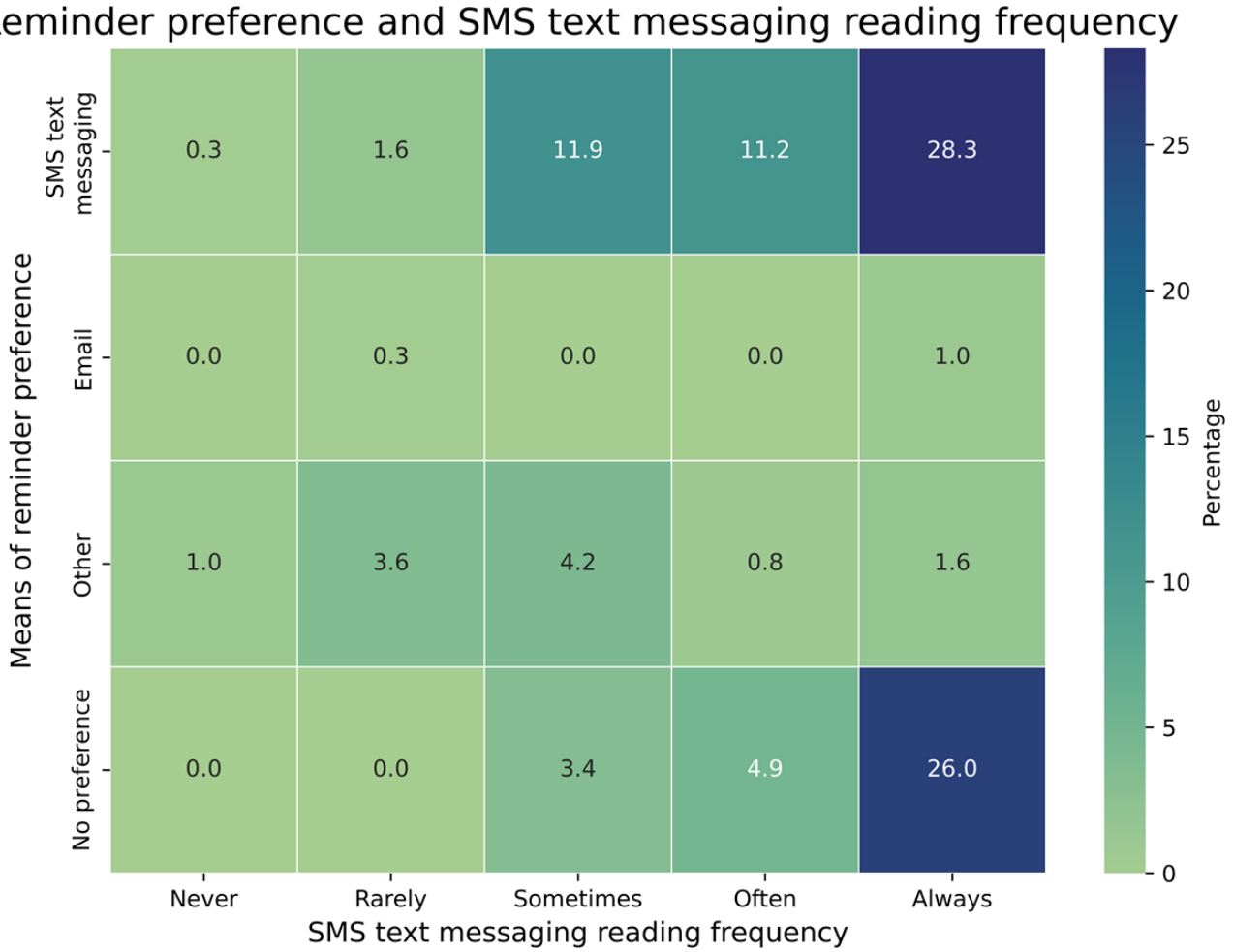
Figure 3. Means of reminder preference and SMS text messaging reading frequency, Port-au-Prince metropolitan area, 2024 (n=386).



Late and Nonattendance

Among 158 patients who missed their original appointments, 31/158 (20%) of them voluntarily returned at a later date to see their physician. Most commonly reported reasons for late or nonattendance were the sociopolitical situation of the country (63/158, 40%), being occupied or experiencing emergency situations (26/158, 17%), feeling cured (13/158, 8%), transportation or economic issues (11/158, 7%), fear or bad experiences with the health care center (8/158, 5%), and relocation outside the Port-au-Prince metropolitan area (6/158, 4%) (Figure 4). The majority of patients (26/31, 84%) who voluntarily returned to their appointment did so within 15 days after the original appointment. The remaining 5/31 (16%) returned between 15 and 31 days after the original appointment.

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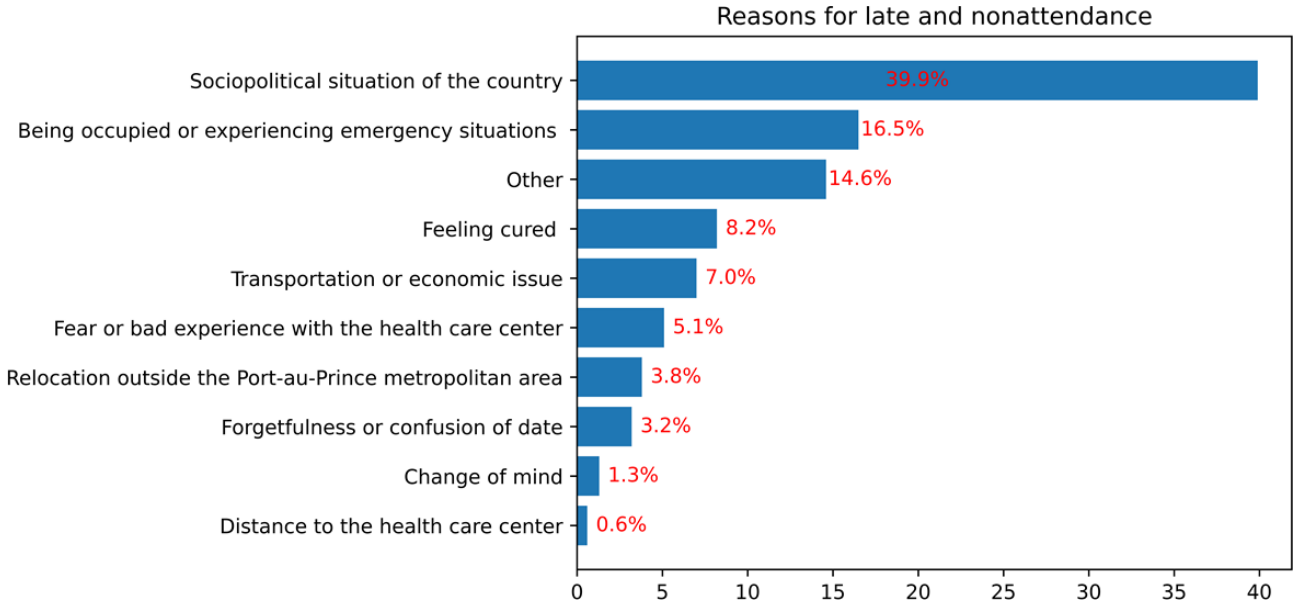
Figure 4. Reasons for late and nonattendance to medical appointment, Port-au-Prince metropolitan area, 2024 (n=158).



Overall Attendance Rates and Patient Characteristics

Attendance rates were higher among patients who confirmed receiving a reminder compared to those who did not (114/147 [77.6%] vs 145/239 [60.7%]), with a crude odds ratio (COR) of 2.24 (95% CI 1.40-3.57). Patients with a chronic disease had a lower attendance rate than those without (26/58 [45%] vs 230/324 [71%]), with a COR of 0.33 (95% CI 0.19-0.59). Attendance rates were higher among patients who traveled less than 60 minutes to the health care center 92/129 (71%), 114/152 (75%), and 20/37 (54%) for less than 30 minutes, between 30 and 60 minutes, and 60 minutes or more, respectively. The CORs among these groups were 2.11 (95% CI 1.00-4.48) for less than 30 minutes and 2.55 (95% CI 1.21-5.36) for between 30 and 60 minutes. Attendance rates increased as patient satisfaction with their physicians increased. Attendance rates did not differ significantly among other socioeconomic factors, such as mode of transportation, self-covering of medical expenses, perceived cost of services, occupation, education level, patient age groups, and patients' sex (Table 2).

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Table . Bivariate analysis of appointment attendance and patient characteristics, Port-au-Prince metropolitan area, 2024.

Patient characteristics	N	n (%)	COR[a] (95% CI)
Sample	386	259 (67.1)	—[b]
Receipt confirmation of reminder			
Yes	147	114 (77.6)	2.24 (1.40-3.57)
No	239	145 (60.7)	1 (Ref.)
Time to appointment (in days)			
<8	134	93 (69)	1.24 (0.71-2.17)
8-15	49	32 (65)	1.03 (0.50-2.12)
15-22	95	61 (64)	0.98 (0.54-1.78)
22-30	12	11 (92)	6.03 (0.75-48.74)
≥30	96	62 (65)	1 (Ref.)
Being with chronic disease			
Yes	58	26 (45)	0.33 (0.19-0.59)
No	324	230 (71)	1 (Ref.)
Travel time (in minutes)			
<30	129	92 (71)	2.11 (1.00-4.48)
30-60	152	114 (75)	2.55 (1.21-5.36)
≥60	37	20 (54)	1 (Ref.)
Unable to estimate	68	33 (49)	0.8 (0.36-1.79)
Modes of transportation			
Walking	28	18 (64)	0.87 (0.39-1.95)
Tap-tap	124	82 (66)	0.94 (0.60-1.47)
Motorcycle taxis	94	59 (62)	0.78 (0.48-1.26)
Car taxis	19	12 (63)	0.83 (0.32-2.17)
Private motorcycle	29	20 (69)	1.1 (0.48-2.48)
Private car	215	149 (69.3)	1.25 (0.82-1.92)
Self-covering medical expenses			
No	50	32 (64)	1 (Ref.)
Yes, partially	152	106 (69.7)	1.3 (0.66-2.54)
Yes, entirely	181	120 (66.3)	1.11 (0.58-2.13)
Perception of service costs			
Affordable	56	40 (71)	1.36 (0.71-2.61)
Reasonable	125	87 (70)	1.25 (0.77-2.02)
Expensive	193	125 (64.8)	1 (Ref.)
Don’t know	12	7 (58)	0.76 (0.23-2.49)
Satisfaction with the physician			
≤6	40	19 (48)	1 (Ref.)
7	66	32 (49)	1.04 (0.47-2.28)
8	132	96 (73)	2.95 (1.42-6.11)
9	90	66 (73)	3.04 (1.40-6.61)
10	58	46 (79)	4.24 (1.74-10.30)

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Patient characteristics	N	n (%)	COR[a] (95% CI)
Occupation of respondents			
Merchant	42	23 (55)	1 (Ref.)
Self-employed	33	23 (70)	1.9 (0.73-4.96)
Entrepreneur or Investor	25	17 (68)	1.76 (0.62-4.95)
Employee	148	109 (73.6)	2.31 (1.14-4.69)
Managerial staff (employee)	18	12 (67)	1.65 (0.52-5.23)
Student	44	28 (64)	1.45 (0.61-3.43)
Other	12	6 (50)	0.83 (0.23-2.98)
Unemployed	54	33 (62)	1.3 (0.57-2.94)
Prefer not to answer	10	8 (80)	3.3 (0.63-17.45)
Education Level of Respondents			
Secondary or less	204	132 (64.7)	1 (Ref.)
Post secondary	153	108 (70.6)	1.31 (0.83-2.06)
Prefer not to answer	29	19 (66)	1.04 (0.46-2.35)
Having children			
Yes	251	175 (69.7)	1.4 (0.90-2.17)
No	135	84 (62)	1 (Ref.)
Patient age (years)			
≤16	128	39 (70)	1.16 (0.64-2.10)
16-30	83	55 (66)	1 (Ref.)
30-45	121	87 (72)	1.3 (0.71-2.38)
>45	54	28 (52)	0.55 (0.27-1.11)
Patient sex			
Female	275	87 (68)	1.22 (0.77-1.94)
Male	111	71 (64)	1 (Ref.)

[a]COR: crude odds ratio.

[b]Not applicable.

Socioeconomic Factors Associated With Overall Attendance Rates

In the multivariate regression analysis, patients who confirmed receiving a reminder were more likely to attend their appointment compared to those who did not (AOR 2.0, 95% CI 1.18-3.39). A patient satisfaction rate of 8 or higher with their physicians was significantly associated with higher attendance rates, compared to 6 or lower, with adjusted odds ratios increasing with satisfaction. Patients traveling less than 60 minutes were more likely to attend their appointment compared to those traveling 60 minutes or more, with AORs of 2.31 (95% CI 1.03 - 5.19) for less than 30 minutes and 2.78 (95% CI 1.24 - 6.21) for 30-60 minutes. Patients with a chronic disease were less likely to attend their appointment compared to those without (AOR 0.42, 95% CI 0.23-0.79). Fully or partially covering medical expenses, gender, and having children were not associated with attendance rates (Figure 5). The regression result table was provided as well in the appendix (Multimedia Appendix 2).

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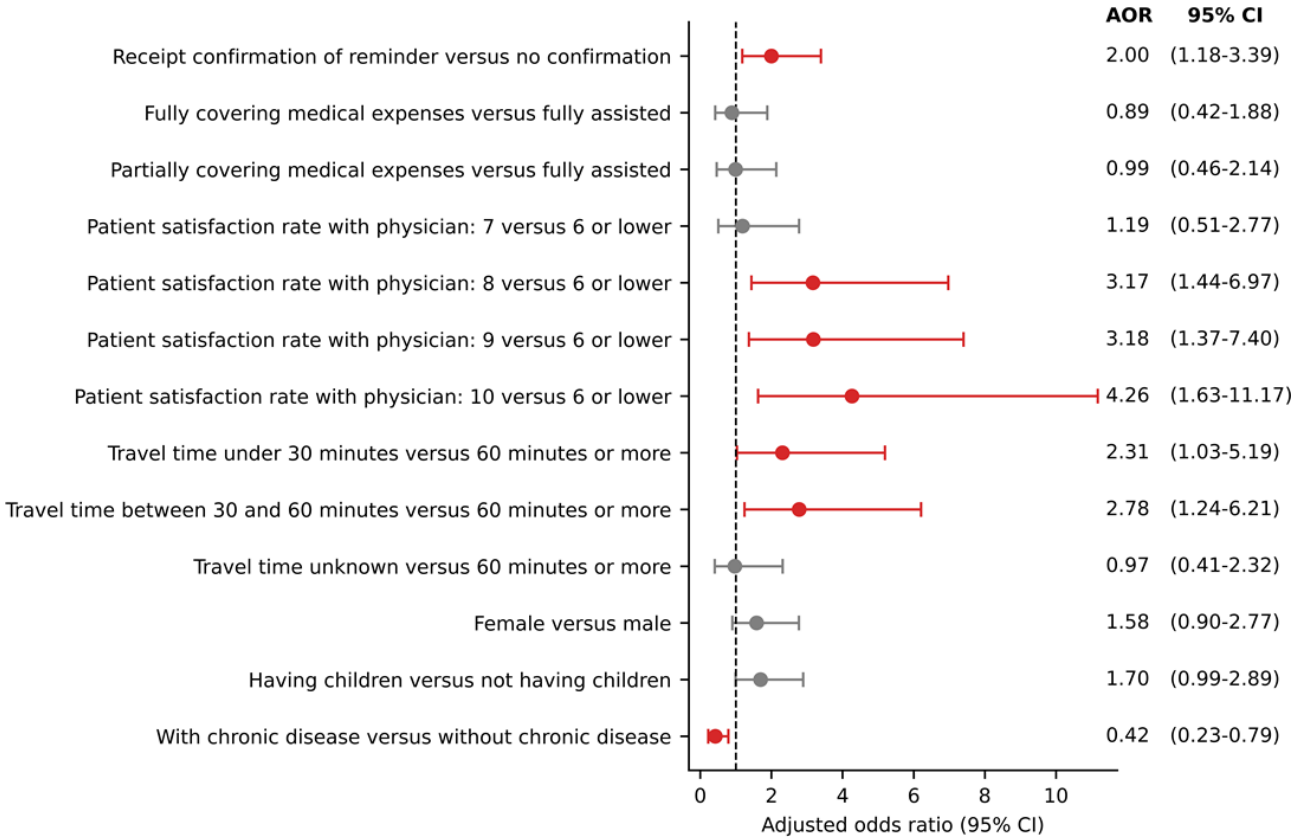
Figure 5. Socioeconomic factors associated with overall attendance rates in Port-au-Prince metropolitan area, 2024. AOR: adjusted odds ratio;



Discussion

Principal Findings

Through this study, we aimed to assess the effectiveness of text message reminders on patient attendance in the context of the sociopolitical crisis of Haiti. After controlling for socioeconomic factors, we found significantly higher attendance rates among patients who confirmed receiving a reminder compared to those who did not, with an AOR equal to 2.0, suggesting that text message reminders have the potential to improve appointment attendance in Haiti despite the sociopolitical crisis. This finding confirms the results of the previous study, conducted between January 2021 and November 2023, on the effectiveness of reminder systems to improve appointment attendance in the sociopolitical context of Haiti, where the odds of attending appointments were 2.95 for patients who received an SMS text messaging reminder compared to those who did not receive a reminder [16].

Other Factors Influencing the Effectiveness of Text Message Reminders

The effectiveness of text message reminders has been influenced by a variety of factors, including patient perceptions, behaviors, and socioeconomic conditions. Travel time was independently associated with appointment attendance. Patients traveling less than 60 minutes to their health care centers were more likely to attend their appointments. The burden of travel, both in terms of time and financial cost, can discourage patients from attending appointments, leading to missed opportunities for care and treatment. In addition to being a classic determinant of health care accessibility, travel time as a factor associated with appointment attendance in our study may also be explained by the sociopolitical crisis. In a sociopolitical crisis where armed gangs control the majority of the Port-au-Prince metropolitan area, every minute spent outside increases the risk of being the victim of a kidnapping or terrorist attack [1]. A study following up on nonattendance at a teaching hospital in a semiurban city in southwestern Nigeria in 2023 reported that distance to the hospital was an independent predictor of nonattendance [21].

Perception of physician service quality was a key determinant of patient appointment attendance. Patient satisfaction with their physician was significantly associated with higher attendance rates, with AOR increasing with satisfaction. In addition, 5% of patients who missed their original appointment reported that they did not return because of fear or a bad experience with the health care center. Patient satisfaction has previously been reported to be a significant determinant of attendance at medical appointments. A study on the relationship between patient experience and quality and use of primary care services, including 8355 primary care patients from 22 sites in the United States between January 2012 and July 2014, found a significant association between patients' reported experiences with their providers and their likelihood of attending scheduled appointments. Positive interactions with providers were associated with lower no-show rates, highlighting the impact of patient satisfaction on attendance [22]. A meta-analysis on physician communication and patient adherence to treatment, including 127 studies in 2009, reported a 19% higher risk of nonadherence among patients whose physician communicates poorly than among patients whose physician communicates well [23].

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Patients with a chronic disease were less likely to attend their appointments. Patients with chronic conditions often face challenges that can impact their attendance at medical appointments [24,25]. However, a study on failure to keep appointments at a community health center in Israel reported a lower nonattendance rate among patients with a chronic disease requiring follow-up compared to patients with an acute disease (8% vs 43% for children, 21% vs 38% for adults, and 28% versus 83% for older adults, respectively) [26]. In contrast, in situations of sociopolitical crisis, where going outside is highly life-threatening, the trend is reversed, suggesting that those who attended their appointments in these circumstances had a more acute illness and required emergency care.

Attendance Trends and Voluntary Return

The overall attendance rate improved significantly over time, increasing to 67.1%, which is 4 times higher than the 17.6% rate observed in a previous study on the effectiveness of a patient reminder system in the Port-au-Prince metropolitan area, conducted between January 2021 and November 2023 [16]. This improvement can be partially explained by a higher implementation of the reminder system. The proportion of SMS text messaging reminders sent to patients increased from 8.1% to 47.4% [16]. The other reason that may explain this finding is the fact that the earlier study was based only on attendance at the appointment day, while the later study took into account patients who voluntarily returned to their appointment at a later date after missing the original one.

We found that 20% of patients who missed their original appointments voluntarily returned at a later date. This finding is substantially lower than that reported in a study on the reasons for missed appointments among patients with stable chronic conditions who needed medication refills, conducted in South Africa between 2014 and 2015 [25]. The authors reported that 67% of patients who missed their original appointments voluntarily returned at a later date to obtain medicines. This difference may be due to the sociopolitical crisis in Haiti. Because of terrorist attacks and the high risk of kidnapping, people are afraid to venture into the streets for their activities. In our study, the sociopolitical crisis in the country was reported by 40% of patients who missed their original appointment as a reason for late or nonattendance. Displacement as a result of the sociopolitical crisis may also explain this difference. It was reported that approximately one in ten of the population was displaced due to gang violence [1]. Additionally, 4% of patients who missed their original appointment attributed their absence to relocation outside the Port-au-Prince metropolitan area.

Acceptability of Text Message Reminders

The patient population in the Port-au-Prince metropolitan area is very receptive to appointment reminders, despite the sociopolitical crisis of Haiti. All patients liked the initiative of sending reminders before the appointment day and found the reminders helpful. The near-totality of patients would like to receive reminders in the future. A pilot study assessing the feasibility and acceptability of text message reminders among patients with chronic noncommunicable diseases in a rural health care facility in Haiti found that all reminder recipients liked the idea of receiving reminders, and 92.7% expressed a desire to receive further messages [27]. SMS text messaging appears to be a promising tool for increasing the reach of text message reminders in Haiti. We found that more than two-thirds of patients enrolled in the study often or always read their text messages, and only 1% of patients never read their SMS text messaging. This finding is substantially higher than that reported by other studies in low- and middle-income countries. A study to understand the sociodemographic factors associated with intention to receive SMS text messages for health information in Bangladesh reported that less than half of the patients who owned a mobile phone could read SMS text messaging [28]. In Kenya, a national survey on the ownership and use of mobile phones among health workers and patients reported that 71.4% of patients who owned a phone used SMS text messaging [10].

Despite the fact that most SMS text messaging reminders were sent on weekdays during busy hours, 78.1% of SMS text messaging reminder recipients confirmed receipt of the reminders. SMS text messaging reminders appear to be more widely accepted in Haiti than in some other settings. A randomized controlled trial designed to assess the effectiveness, feasibility, and acceptability of SMS text messaging and consultation to manage the blood pressure of Chinese patients with hypertension reported that only 68% of the patients reported reading the messages sent by the researchers. And 60% of those who did not read the messages reported having not read them, as they did not have the habit of reading messages [29]. However, unlike our study, the patient population in the previously cited study consisted only of patients with hypertension.

Limitations and Recommendations

Our study had few limitations. The retrospective nature of the study may introduce a potential recall bias. However, patients were interviewed within a 6-month window around their appointments. This balanced timeframe allowed time for them to return at a later date if they had missed the original appointment and was recent enough to minimize the risk of forgetting information related to the appointment. Our study was conducted in 2 private health care centers. Given the sociopolitical crisis, which is a key aspect of the study context, affects individuals regardless of socioeconomic status, we believe our sample is representative of the population in the Port-au-Prince metropolitan area [1,30]. The SMS text messaging system was not consistently deployed throughout the study, as the health care centers occasionally failed to recharge their SMS text messaging accounts on time. However, the system did not discriminate in who reminders would be sent to: all patients were sent a reminder when the system was recharged, and no SMS text messaging reminders were sent when the system was out of credit. This provided a reliable comparison group and strengthened the robustness of our findings. While the reasons for patient appointments were unknown, which could have influenced whether or not a patient attended their appointment, the nondiscriminatory nature of the reminder system meant that this potential bias was probably nondifferential between those who received reminders and those who did not. Of the respondents, 37% did not agree to participate in our study. It is possible that these are mainly those who did not attend their appointment. However, our sensitivity analysis

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showed that this potential nonresponse bias is likely to be nondifferential between those who confirmed receipt of reminders and those who did not, and therefore does not alter the measure of association.

To enhance appointment adherence in Haiti or crisis-affected settings, health care centers should consider integrating text message reminder systems into their patient management workflows, ensuring that messages are personalized and delivered in a timely manner. Additionally, efforts should be made to address barriers such as travel time and patient experience with the health care system, as these factors significantly influence attendance and treatment adherence.

Conclusion

Appointment attendance was influenced by receipt status of text message reminder, travel time, patient satisfaction with their physician, and chronic conditions in the Port-au-Prince metropolitan area. The overall acceptability and effectiveness of SMS text messaging suggest that they can be a valuable tool in health care settings to improve appointment attendance despite sociopolitical crises, especially when adapted to the local context and individual needs. We recommend that health care centers in Haiti consider integrating SMS text messaging reminder systems into routine patient management to enhance adherence and optimize care delivery.

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No generative artificial intelligence (AI) technology was used to generate the text, figures, or any other content included in this manuscript.

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Data Availability

The datasets generated or analyzed during this study are not publicly available due to privacy policy but are available from the corresponding author on reasonable request. However, prior authorization from related health care centers to access those data is mandatory.

Authors' Contributions

MP conceptualized the study, developed the methodology, performed the formal analysis, and wrote the original draft of the manuscript. CPA, JRQ, and MA contributed to the review and editing of the manuscript. All authors read and approved the final version.

Conflicts of Interest

MP was involved in the development of the reminder system used to automate the sending of text messages to patients. JRQ is responsible for Jerusalem Medical Clinic, one of the sites where the research was conducted. All other authors declare no conflicts of interest.

Multimedia Appendix 1
Nonresponse analysis, using appointment data from the reminder system.
[PDF File, 118 KB - formative_v10i1e77010_app1.pdf]

Multimedia Appendix 2
Table regression from the multivariate logistic model. It is a supplement to the forest plot provided in the main manuscript.
[PDF File, 145 KB - formative_v10i1e77010_app2.pdf]

Checklist 1
Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) checklist
[PDF File, 18 KB - formative_v10i1e77010_app3.pdf]

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Abbreviations

AOR: adjusted odds ratio
COR: crude odds ratio
STROBE: Strengthening the Reporting of Observational Studies in Epidemiology

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Parental Acceptance of Telemedicine in Pediatric Surgery and Its Implications for Future Care Models: Survey Study

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Abstract

Background: Digitalization has profoundly transformed health care delivery, including the increasing use of telemedical applications in pediatric care. While the economic benefits and improved access associated with telemedicine in rural regions are well documented, data on caregiver acceptance and demand in metropolitan areas remain limited.

Objective: This study aimed to assess caregivers' willingness to use telemedical tools in the context of pediatric surgery in a metropolitan area.

Methods: A 15-item survey was distributed to caregivers of pediatric surgical patients between May and November 2023 at the Department of Pediatric Surgery of the University Medical Center Hamburg-Eppendorf. The survey included questions on sociodemographic factors, previous experience with telemedicine, and preferences regarding telemedical support. Data were analyzed using descriptive statistics. Group comparisons were performed using the χ^2 test or Fisher exact test, where appropriate.

Results: A total of 100 families participated in the study. The median age of the pediatric patients was 5 years (IQR 11.75), and the median age of caregivers was 37 years (IQR 14). Congenital conditions accounted for 65% (n=65) of the underlying diagnoses. Overall, 90% (n=88/98) of the interviewed families expressed interest in telemedicine as an integrative health care solution for their children, whereas only 15% (n=15) reported on previous experiences. A primary telemedical consultation was considered acceptable by 53% (n=50/95) of the participants. Caregivers' preferences were not significantly associated with distance to the nearest hospital (*P*=.77), employment status (*P*=.89), and family size (*P*=.59).

Conclusions: Caregivers in an urban pediatric surgical setting show substantial interest in telemedical care options. Acceptance appears to be independent of geographic proximity to health care facilities, suggesting that telemedicine may represent a relevant addition to pediatric surgical care even in metropolitan regions. Further studies are needed to evaluate practical implementation, including technical, legal, and compliance-related aspects.

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KEYWORDS

telemedicine; pediatric; pediatric surgery; digitalization; telehealth

Introduction

Digital technologies in medicine are being used in various forms of telemedical applications, including the documentation of vital parameters via mobile applications, electronic communication between out- and inpatient sectors, and video consultations [1-4]. In addition, digitalization allows the needs of increasingly empowered and health-conscious patients to be considered [5-8].

However, telemedicine is still underrepresented in pediatric and adolescent medical care, due to the limited experience of practitioners in this field and the associated organizational and logistic challenges [9]. Contact restrictions changed everyday hospital life during the SARS-CoV-2 pandemic, leading to a significant increase in the use of telemedical measures worldwide. A high level of satisfaction was also registered among health care professionals, willing to pursue further innovation [10,11]. Even in mandatory telemedical exchange during the pandemic, patients showed support and acceptance [12]. In the specialty of pediatrics, parents have also expressed a high level of approval and satisfaction with telemedicine measures. The integration of telemedical solutions, particularly within the domain of pediatrics, which is characterized by a

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youthful demographic, appears to hold considerable potential for enhancing diagnostic and therapeutic processes [13-15]. This is especially important since pediatric and adolescent medicine occupies a unique position. The patients are minors, and thus their interests are inherently represented by their legal guardians; in the context of medical appointments, this can result in double absences from educational institutions and work, which may be accompanied by a loss of earnings and travel expenses [8].

Several studies have demonstrated that telemedical care can yield economic and ecological benefits. Goedeke et al showed that telemedical follow-up in pediatric surgery has been shown to significantly reduce days of absence from school and work, loss of earnings, as well as travel costs and time. A cost analysis by Adroher Mas et al further demonstrated that telemedical follow-up with remote telemonitoring at home for pediatric conditions achieved a 9% reduction in costs compared to inpatient treatment. Moreover, telemedicine can lead to a reduction in the number of visits to the pediatric emergency room and has proven to significantly ameliorate depression and anxiety during hospital admission of both the patients and their parents [16,17]. In addition, telemedicine has been proven to enhance the provision of adequate, specialized medical care in rural areas, where it is known to be notably deficient, even in European countries [2,4,8,15,18-21].

Yet, studies exploring the impact and reception of telemedicine, especially in densely populated regions, are missing. Therefore, the primary objective of this study was to explore the willingness and demand of caregivers for telemedical care in the field of pediatric surgery in a metropolitan area in Germany.

Methods

Data Collection and Inclusion Criteria

A 15-item survey was designed by the Department of Pediatric Surgery of the University Medical Center Hamburg-Eppendorf (UKE). The questionnaire (Multimedia Appendix 1) was developed independently in two ways. First, it was developed with regard to clinical practice in our hospital. Second, it was modified on the basis of the extant literature describing the effects of telemedicine on health care and patients [8,13,22-24].

It featured both single-choice and multiple-choice questions, gathering information about the patient's place of residency, familial, as well as parents' professional status. The survey inquired about an absence from work, school, and kindergarten to attend the scheduled appointment, as well as participants' previous experiences with telemedicine and their willingness to engage in telemedical treatment.

Upon informed consent, the questionnaire was distributed during the scheduled presentation in the pediatric surgical clinic, between May and November 2023, and was completed by one of the caregivers.

All patients scheduled for an elective outpatient appointment, whether for initial or follow-up examinations, at the Department of Pediatric Surgery of the UKE were included in the study. Exclusion criteria comprised patients' or custodians' language barrier and patients' age above 18 years. Patients with pediatric trauma conditions were also excluded from the study.

Ethical Considerations

The study adhered to the principles outlined in the Helsinki Declaration and received approval from the Hamburg Ethics Committee (2023 - 101015-BO-ff). The inclusion of patients was carried out after the caregivers had been provided with information about the study and had given voluntary consent. Participants did not receive any financial compensation. Data were deidentified to safeguard participant information. Following the conclusion of the study, the data were anonymized.

Statistical Analysis

Statistical analysis was carried out using Microsoft Excel for macOS (version 16.59) and Prism 9 for macOS (version 9.5.0). The significance level was set at $P<.05$ for all statistical analyses. Descriptive statistics are presented in total numbers. Continuous variables were checked for deviation from normal distribution (Shapiro–Wilk test) for each comparison. Differences between groups were calculated using the χ^2 test or Fisher exact test. Missing data were excluded from the statistical calculation. A post hoc power analysis was performed to evaluate whether the available sample size (N=100) provided sufficient statistical precision for the primary outcome, defined as the proportion of caregivers expressing interest in telemedicine. Using the observed agreement rate of 90% and a conservative hypothetical reference proportion of 70%, the achieved power to detect such a difference was 99.7% at a two-sided α of .05. This indicates that the study was adequately powered to detect a clinically meaningful deviation from the reference proportion.

The manuscript was written based on the STROBE (Strengthening the Reporting of Observational studies in Epidemiology) cross-sectional checklist [25].

Results

A total of 100 families participated in the study. The related patients consisted of 69 boys and 31 girls. The median age of the patients was 5 years (IQR 11.75); that of their accompanying custodians was 37 years (IQR: 14). A total of 65% (n=65) of the patients presented with a congenital disorder, ranging from minor pediatric surgical diseases like inguinal hernia to chest wall deformities or major surgical diseases like esophageal or anal atresia, gastroschisis, and Morbus Hirschsprung. In 63% (n=63) of cases, the patients were accompanied by their mother, while in 34% (n=34) of cases, they were accompanied by their father.

Key demographics and sociodemographic characteristics are detailed in Tables 1 and 2.

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Table . Key demographics of patients and caregivers in our clinic's outpatient pediatric surgery consultation between May and November 2023.

Characteristics	Participants (N=100)
Sex, n	
Female	31
Male	69
Patients age in years (median, IQR)	5 (11.75)
Congenital disorder, n	65
Accompanying person, n	
Mother	64
Father	34
Other	2
Custodians' age in years (median, IQR)	37 (14)

Table . Sociodemographic criteria of pediatric surgery patients' caregivers in our clinic's outpatient consultation between May and November 2023.

Sociodemographic criteria	Participants (N=100), n
Number of children	
1	36
2-3	50
>3	14
Distance between home and hospital (km)	
<5	15
5-10	21
>10	63
n/a[a]	1
Occupation	
Employed	71
Self-employed	6
Unemployed	14
No information	8
n/a	1
If applicable, absence from[b]	
Work	26
Kindergarten/School	34
Utilization of annual leave	25

[a]No answer was given.

[b]Multiple answers allowed; patients and caregivers.

In 90% (n=88/98), the participants expressed an interest in the use of telemedical applications in the treatment of their children, whereas only 15% (n=15) had previous experience with telemedicine. It was found that 53% (n=50/95) of participants would opt for a primary telemedical appointment, under the assumption that the quality of treatment would remain consistent. The existing general treatment process was considered to be sufficiently digitalized (eg, online appointment scheduling or integration of previous examinations and documents) by 57% (n=51/89) of the respondents.

Patients and caregivers were further categorized into two groups based on their median age: children under and over five years old, as well as caregivers under and over 37 years old. No significant differences were observed between these groups regarding the preference for a primary telemedicine appointment.

The results indicated a marginal preference for downloading free applications for telemedical information exchange (n=52/98, 53%). Thirty-eight percent of caregivers opted for a download

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of fee-based programs. However, 7% (n=7) of participants would not download additional programs for the telemedical treatment of their children.

A substantial proportion of the participants (88%, n=86/98) expressed their willingness to transmit photographic documentation as part of the telemedical information exchange. Concerns regarding adherence to data protection guidelines were documented by approximately one-third of the participants (36%, n=35/98).

Regarding the expressed interest in a primary telemedicine appointment, no statistically significant differences were found regarding selected sociodemographic criteria. A significant increase in the preference for a primary telemedicine appointment was observed only among guardians who consented to downloading paid applications (*P*=.01). The results are displayed in Table 3.

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Table . Results of the sociodemographic and medical criteria of the participating families in relation to a preferred primary telemedical appointment[a].

Variables	Primarily telemedical counseling, n (%)	No primarily telemedical counseling n (%)	*P* value
Congenital disorder			.96
Yes	32 (33.7)	29 (19)	
No	18 (30.5)	16 (16.9)	
Pre-existing illness			.49
Yes	6 (6.3)	3 (46.3)	
No	44 (3.2)	42 (44.2)	
Questionnaire completed by			.12
Mother	29 (30.5)	31 (32.3)	
Father	21 (22.1)	12 (12.6)	
Other	0 (0)	2 (2.1)	
Number of children			.59
1	15 (15.8)	18 (18.9)	
2-3	27 (28.4)	21 (22.1)	
>3	8 (8.4)	6 (6.3)	
Distance home-hospital (km)			.77
<5	7 (7.4)	8 (8.5)	
5-10	10 (10.6)	10 (10.6)	
>10	33 (35.1)	26 (27.7)	
Occupation of the caregiver			.89
Employed	37 (39.4)	32 (34)	
Self-/Unemployed	13 (13.8)	12 (12.8)	
Day of absence			
Work			.39
Yes	15 (15.8)	10 (10.5)	
No	35 (36.8)	35 (36.8)	
Vacation day			.65
Yes	14 (14.9)	11 (11.7)	
No	35 (37.2)	34 (36.2)	
Kindergarten/School			.81
Yes	17 (18.1)	16 (17)	
No	33 (35.1)	28 (29.8)	
Download of applications			
Free of charge			.33
Yes	24 (25.8)	26 (28)	
No	25 (26.9)	18 (19.4)	
Fee-based			.01[b]
Yes	25 (26.9)	11 (11.8)	
No	24 (25.8)	33 (35.5)	
Concerns about data protection			.24
Yes	14 (14.9)	18 (19.2)	
No	35 (37.2)	27 (28.7)	

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[a]Missing data were excluded from the statistical calculation.

[b]Statistical significance (*P* value<.05).

Discussion

Principal Findings

This survey showed a high level of interest among the patients' caregivers in the implementation of telemedicine in pediatric surgery in Hamburg, a metropolis with a population of nearly two million people and a high density of medical professionals [26].

This finding is particularly significant in the context of current literature on telemedicine in pediatrics, which often focuses on providing medical expertise in rural areas [2,4,15,18-21]. Moreover, the present findings corroborate the favorable patient feedback concerning telemedicine documented in the existing literature [10,11]. However, a mere 15% of the participants stated previous experience with telemedicine, underscoring the necessity for additional research in order to establish and advance digitalization in these specialist areas.

Despite the overmentioned high level of interest, the results indicated that only slightly more than 50% of caregivers would select a primary telemedical consultation, even under the assumption that the standard of treatment would remain equivalent. It is thus reasonable to conclude that personal contact with the treating physician still plays a relevant role in pediatric medicine nowadays [14].

The influence of sociodemographic factors on families' preference for a primary telemedical appointment (given equivalent quality to an in-person one) was analyzed. It is interesting to note that no significant differences were identified among subgroups defined by the distance between the subjects' place of residence and the hospital. This suggests that the proximity to the nearest hospital does not influence the preference for primary telemedical treatment within the studied population. In previous studies, it has been displayed that telemedical treatment has the capacity to mitigate patients' loss of work and wages, as well as less travel time [8,27]. A longer journey is generally more time-consuming, which could lead to the assumption that a telemedical appointment should be favored by those participants who live further away from the hospital [28].

Also, the number of children in a family did not impact caregivers' desire to receive a primary telemedical consultation. 64% of the participants had more than one child; as it has been shown that mothers of two children have higher parenting stress than those with one child, we initially assumed that telehealth consultation would be preferred by those with more children [29]. Luchtenberg et al showed that the child-doctor relationship is characterized by intimacy and trust, which may not be fully achieved through virtual interaction [30]. When implementing telemedicine in pediatric medicine, it is therefore essential to establish a trusting and secure interaction between patient, their caregivers, and health care providers [31].

Furthermore, our results did not show a significant preference for telehealth consultation based on the caregiver's employment status. Again, one could argue that, for example, self-employed caregivers are more dependent on their free time, therefore more likely to prefer a quicker, non-personal encounter. On the contrary, employed custodians showed a similar willingness compared to self-employed and non-employed ones.

Nearly 70% of the patients were accompanied to their appointments by female caregivers. This confirms a recent study which found that mothers are significantly more likely to be in charge in the cases of children's medical appointments, both scheduled and not [32]. However, it should be noted that the questionnaire was only completed by one caregiver, despite the possible presence of both parents at the appointment. Consequently, it cannot be definitively established whether most patients were accompanied only by their mothers.

Regarding the question of whether patients' caregivers would be willing to pay for a medical application, the findings of our study indicated a slight majority of 53% opting for free applications instead of paid ones. Existing instant messaging applications with a video-call function represent a viable option in this regard, on the condition that they follow data protection laws. Since approximately 90% of all participants would be willing to transmit photographs, this is of even greater significance.

Limitations

It is imperative to acknowledge certain limitations in our study. The analysis did not consider the rejection rate, which could have provided a more comprehensive overview of general participation in the study, which is therefore susceptible to selection bias [33]. The documentation of possible reasons why legal guardians refused to participate could also have provided greater insight.

Due to the limited number of 100 participants, our results may not be representative, but rather provide a preliminary overview of the subject. In addition, as a university hospital and tertiary referral center, our patients' spectrum is not fully comparable with that of other primary and secondary referral centers in Hamburg, located in other areas of the city. Moreover, the collective comprises a highly heterogeneous selection of patients who presented with a variety of diseases both pre- and postoperatively.

Caregivers of patients with other underlying conditions may have responded differently to our questionnaire. Further, the present study did not investigate whether different socio-economic or cultural aspects might influence the general willingness to use telemedicine in pediatric surgery [34]. A further potential limitation is the distribution period, which may be subject to a temporal or seasonal bias.

Methodically, our questionnaire contained only 15 items; it served as a cursory opinion survey, on whose basis more detailed follow-up studies can be tailored.

As previously stated, a mere fraction of the study's participants had prior experience with telemedical applications. This limited experience may hinder one's ability to envision how a

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telemedicine consultation would occur and whether it could match the quality of an in-person encounter. Anyway, the study population accurately reflects the current patient pool at our clinic, thereby ensuring the validity of the findings. The external validity of the study results applies only to a limited extent here, as country-specific regulations and infrastructure can have a decisive influence on the use of telemedicine.

Conclusion

In conclusion, the potential use of telemedicine in the treatment of pediatric surgical patients in urban areas and cities is perceived and viewed positively and is regarded as a welcome addition. We were able to show that a significant majority of caregivers had considerable interest in utilizing such measures, even in a big city with a high density of health care providers. This could be established through various means, including video consultations, preoperative consultations, post-operative follow-up checks with photographic documentation, and the further integration of artificial intelligence. The implementation of these measures has, for example, the potential to result in a reduction of visits to pediatric emergency departments or to support the transition of pediatric surgical patients to adult medicine [16,35,36]. In this context, it is essential to ensure that reimbursement by health insurance companies is guaranteed in order to offer telemedicine measures on a generalized and sustainable basis [37].

However, the study also evidenced that telemedicine does not play a significant role in the current day-to-day pediatric surgical treatment in Hamburg, the second largest city in Germany.

The necessity for the routine establishment of telemedical infrastructures is thus apparent. Further studies may elucidate how to correctly implement telemedicine in pediatric surgery, for example, by documenting parents' and practitioners' compliance as well as listing technical and legal obstacles.

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Data Availability

The datasets generated or analyzed during this study are available from the corresponding author on reasonable request.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Questionnaire.
[DOCX File, 57 KB - formative_v10i1e81091_app1.docx]

Checklist 1
Completed STROBE checklist (where applicable).
[PDF File, 183 KB - formative_v10i1e81091_app2.pdf]

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Abbreviations

STROBE: Strengthening the Reporting of Observational Studies in Epidemiology
UKE: University Medical Center Hamburg-Eppendorf

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TikTok as a Platform for Patient Education and Health Information in Rare Genetic Diseases: Cross-Sectional Study

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Abstract

Background: Rare genetic diseases pose significant diagnostic and therapeutic challenges, often leading to delayed diagnoses, misinformation, and patient isolation. Social media platforms have emerged as prominent spaces for health information dissemination and community building among patients with rare diseases.

Objective: This study aimed to evaluate the role of TikTok videos in patient education, community engagement, and information quality related to 5 rare genetic conditions: Ehlers-Danlos syndrome, Marfan syndrome, cystic fibrosis, Wilson disease, and Gaucher disease.

Methods: A cross-sectional analysis was conducted on 184 TikTok videos identified via disease-specific hashtags. Included videos were 15 seconds to 4 minutes long and directly discussed the target diseases. Advertisements, promotional content, and product marketing were excluded. Videos were categorized by creator type: physicians, medical professionals, patients, influencers, nonprofit organizations, and others. Content quality was assessed using the Global Quality Scale (GQS) and a modified DISCERN tool (mDISCERN). Engagement metrics (views, likes, and shares) were recorded. Kruskal-Wallis and chi-square tests evaluated differences across creator categories.

Results: Of the 184 TikTok videos, 88 (47.8%) were created by patients or family members; 31 (16.8%) by influencers, 24 (13.0%) by physicians, 17 (9.2%) by nonprofit organizations, 15 (8.2%) by general users, and 9 (4.9%) by others. Collectively, the videos amassed more than 123 million views. Influencer-generated content accounted for the highest cumulative view count, totaling approximately 60.9 million views. Content produced by medical professionals and physicians demonstrated higher information quality, with mean GQS scores of 3.89 (SD 0.66) and 3.62 (SD 0.71) and mDISCERN scores of 3.11 (SD 0.58) and 3.21 (SD 0.65), respectively. In contrast, videos by influencers and patients exhibited lower quality scores (influencers: GQS mean 1.48, SD 0.60; mDISCERN mean 1.42, SD 0.55; patients: GQS mean 1.57, SD 0.58; mDISCERN mean 1.38, SD 0.52). For Ehlers-Danlos syndrome (n=40 videos, 21.7%), Wilson disease (n=40 videos, 21.7%), and cystic fibrosis (n=34 videos, 18.5%), significant differences in quality scores among creator types were observed ($P<.001$, $P<.001$, and $P\leq.04$, respectively). For Marfan syndrome (n=40 videos, 21.7%) and Gaucher disease (n=30 videos, 16.3%), no significant differences were observed ($P=.43$ and $P=.07$, respectively). Chi-square analysis indicated no association between creator type and inclusion of peer-reviewed references ($\chi^2_5=10.6$; $P=.07$). Overall, only 7 (3.8%) videos cited scientific literature.

Conclusions: TikTok serves as a key platform for rare disease awareness and community engagement, although the quality and accuracy of health information vary widely. Although medical professionals produced higher-quality content, it tended to receive less visibility. Increasing the presence of health care professionals and improving visibility of evidence-based content could enhance patient education and safer health information sharing.

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KEYWORDS

rare diseases; social media; patient education; health misinformation; TikTok; Ehlers-Danlos syndrome; Marfan syndrome; cystic fibrosis; Gaucher disease

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Introduction

Rare genetic conditions such as Ehlers-Danlos syndrome (EDS), Marfan syndrome, and Wilson disease often present with nonspecific or variable symptoms. These characteristics contribute to diagnostic delays, fragmented care, and social isolation for affected individuals [1,2]. This aligns with broader evidence that individuals with rare disorders often face significant gaps in health literacy, limited access to information, and barriers to effective self-management, which underscores the importance of peer support and alternative educational tools [3]. In the absence of robust institutional resources or consistent health care professional familiarity, many patients and caregivers turn to social media for support, disease education, and practical guidance [4,5]. These 5 rare genetic conditions (EDS, Marfan syndrome, cystic fibrosis, Wilson disease, and Gaucher disease) were selected to capture diversity in etiology (connective tissue, metabolic, and pulmonary) and representation on TikTok. Each condition has a distinct clinical profile and active online patient community, which facilitates consistent comparison of creator engagement and educational content across diseases [6-8].

Among social media platforms, TikTok has emerged as a dominant venue for health discourse. With over 1 billion monthly users globally and strong penetration among adolescents and young adults, TikTok is uniquely positioned to influence health knowledge, particularly in underrepresented or rare conditions [6]. The platform's algorithmic design enables rapid exposure to highly personalized video content, often delivered without intentional searching. This makes TikTok a powerful yet potentially unreliable source of health information [7].

Despite TikTok's popularity, little research has specifically examined the accuracy and educational impact of rare disease–related content, a gap this study aims to address. In rare disease communities, TikTok fosters connection and visibility. Patients and families use hashtags such as #RareDisease and #ChronicIllness to share lived experiences, raise awareness, and advocate for research and support services [8]. Video content frequently documents diagnostic journeys, daily management, and emotional coping. These narratives contribute to psychosocial support and patient empowerment [8,9]. However, the ease of content creation also raises concerns about the quality and accuracy of medical information that reaches potentially vulnerable audiences [10,11].

Recent studies across several health domains reveal that TikTok videos commonly lack references to scientific literature and often include misinformation, especially those created by influencers or nonmedical users [12,13]. For example, a review of prostate cancer–related videos on TikTok found that nearly half of informational videos contained false or misleading statements [14]. Similar trends have been observed in videos addressing attention-deficit/hyperactivity disorder (ADHD), fibromyalgia, sinusitis, and eating disorders, where professional content consistently surpasses user-generated videos in quality [15,16].

Validated tools such as the Global Quality Scale (GQS) and DISCERN have been used to assess the reliability and usefulness of online medical content, including short-form videos [11,17]. Although originally developed for written or long-form materials, these tools are now applied to TikTok videos to enable comparisons across different content creators [18,19]. To address their known limitations in short-form contexts, the modified DISCERN (mDISCERN) version, adapted for audiovisual and short-form media in prior research, was used in this study alongside GQS to maintain cross-study comparability while improving contextual relevance [18].

This study evaluated the information quality and audience reach of TikTok videos related to 5 rare genetic conditions: EDS, Marfan syndrome, cystic fibrosis, Wilson disease, and Gaucher disease. Using established quality measures, we examined whether content produced by medical professionals differs from that produced by patients, influencers, and general users. We also analyzed how these differences correspond to viewer engagement. Through this approach, we aimed to highlight both the educational potential and the limitations of TikTok as a platform for rare disease communication.

Methods

Overview

This study used a cross-sectional observational design to evaluate TikTok videos discussing 5 rare genetic conditions: EDS, Marfan syndrome, cystic fibrosis, Wilson disease, and Gaucher disease. Videos were identified using TikTok's native search function within the mobile app. Raters created new TikTok accounts to avoid the influence of personalized algorithms. For each condition, standardized English-language hashtags were entered into the search bar and manually screened in descending order of view count as displayed by the platform. The following search terms were used:

- For EDS, #EhlersDanlos, #EDS, #EhlersDanlosSyndrome
- For Marfan syndrome, #Marfan, #MarfanSyndrome
- For cystic fibrosis, #CysticFibrosis, #CFWarrior, #CFCommunity
- For Wilson disease, #WilsonsDisease, #WilsonDisease, #CopperToxicity
- For Gaucher disease, #GaucherDisease, #Gaucher

The first 40 videos with the highest visible view counts were included for eligibility screening, yielding 200 total videos. Videos were eligible if they were posted between January 2022 and October 2024, directly discussed the target condition, and were between 15 seconds and 4 minutes in duration, consistent with the length range of short-form health content on TikTok reported in prior studies [17]. Exclusion criteria included advertisements, promotional content, duplicate uploads, and non-English videos. After exclusions, 184 unique videos remained for analysis. All searches were conducted in December 2024 to ensure that the dataset reflected the most current content available at the time of analysis. The inclusion period (January 2022 to October 2024) was selected because TikTok expanded its maximum video length from 50 seconds to 10 minutes in early 2022, allowing for more substantive educational content. The cutoff of October 2024 was chosen to include approximately

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3 years of postexpansion content while maintaining a manageable and temporally consistent dataset.

Videos were categorized by creator type based on account biographies, stated credentials, and linked websites. Categories included physicians, medical professionals, patients, influencers, nonprofit organizations, and others. Creators were classified as physicians if their profile or linked page listed an MD, DO, or an international equivalent medical degree (eg, MBBS). Medical professionals included other licensed health care workers such as registered nurses, genetic counselors, pharmacists, or physical therapists who reported professional credentials but did not hold physician degrees. This distinction was made to explore whether engagement and information quality differed between physician-led and allied health–led educational content, reflecting the unique training and communication roles of each group in digital health spaces. Influencers were defined as creators with a substantial follower base (typically exceeding 10,000 followers) or self-identified content creators who regularly produced health-related or lifestyle videos for a broad public audience but did not hold formal medical credentials or represent nonprofit organizations. Any ambiguity in classification was resolved by consensus among 5 reviewers to minimize misclassification bias.

All videos were coded using a standardized data extraction form developed for this study. The form included fields for creator type, disease, category, engagement metrics, and the quality assessment instruments (GQS and mDISCERN), allowing reviewers to score each video within the same structured framework. Five reviewers independently coded all videos, with each reviewer assessing approximately 20% of the total sample and at least 2 reviewers overlapping on every video to ensure consistency. Coding discrepancies were reviewed collectively after initial scoring and resolved by consensus at the end of data collection to ensure consistency across raters. For videos that claimed to cite peer-reviewed literature or clinical guidelines, reviewers verified the presence of such sources through in-video text, captions, or linked resources. If verification was not possible, the citation claim was coded as absent.

Video quality was assessed using 2 established tools: the GQS and the mDISCERN instrument. The GQS, originally developed for patient-facing websites and adapted for short-form videos, rates content on a 5-point Likert scale (1=poor, 5=excellent) based on flow, educational value, and comprehensiveness (Table 1) [20]. The mDISCERN, adapted from the original DISCERN framework for written materials, evaluates reliability, balance, and overall quality (Table 2) [21]. The full mDISCERN tool can be found in Multimedia Appendix 1.

Table . Global Quality Scale scoring framework.

Likert scale score	Quality assessment of the content	Information coverage	Patient utility
1	Poor quality	None	Very unlikely to be of any use to patients
2	Poor quality	Some information present	Of very limited use to patients
3	Suboptimal flow	Some information covered but important topics are missing	Somewhat useful to patients
4	Good quality and flow	Most important topics covered	Useful to patients
5	Excellent quality and flow	Most important topics covered	Highly useful to patients

Table . Modified DISCERN tool description.

Category	Example question	Explanation
Reliability of content	Are the aims of the video clear?	Does the creator state the purpose (eg, educate, raise awareness, and share experience)?
Quality of treatment information	Does the video discuss multiple perspectives?	If treatments are mentioned, are pros, cons, and alternatives presented?
Overall rating	Rate the overall quality of the video	Consider all criteria above to provide a holistic score

Both instruments have been successfully applied in prior analyses of TikTok health content [12,17]. These instruments were selected because they provide standardized, validated frameworks for assessing health information quality, which allow cross-study comparisons despite their limitations in capturing certain stylistic features of short-form videos, such as pacing and audiovisual emphasis. To address these limitations, we applied the mDISCERN instrument, which has been adapted for short-form and audiovisual health content in prior TikTok-based research [18] and used alongside GQS in several video-based quality evaluations [17,19], and conducted reviewer calibration to ensure consistent scoring. Prior to data collection, all reviewers completed calibration exercises using sample videos to ensure consistent scoring. Any discrepancies in scoring were resolved through consensus discussion among the 5 reviewers. Table 2 was developed for this study using criteria derived from the original DISCERN instrument.

Descriptive statistics summarized the distribution of videos across creator types and diseases. GQS and mDISCERN scores were compared across creator types using Kruskal-Wallis tests due to nonparametric score distributions, followed by Dunn post hoc tests for pairwise comparisons. Chi-square tests examined associations between creator type and the citation of

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peer-reviewed literature or clinical guidelines. All analyses were conducted using SPSS (version 28.0; IBM Corp), with significance set at $P<.05$.

Engagement metrics, including views, likes, shares, and comments, were recorded. To adjust for variability in posting time, a normalized engagement ratio (NER; interactions per 1000 views) was calculated using the formula:

$$NER=likes+comments+sharesviews/1000$$

This allowed for standardized comparisons of audience interaction, as supported by prior TikTok engagement studies [15,19]. A higher NER reflects proportionally greater viewer interaction relative to exposure; however, it does not necessarily indicate the quality or meaningfulness of that engagement.

Ethical Considerations

This study analyzed publicly available TikTok videos related to rare genetic conditions. All data were deidentified and obtained from open-access sources that do not require an account or login for access. In accordance with the determination provided by the Sam Houston State University Institutional Review Board (IRB), the project was classified as not human subjects research under 45 CFR 46.102. Therefore, formal IRB review was not required. The IRB confirmed that this classification applied because no identifiable private information or interaction with human participants occurred.

Results

The distribution of videos by disease and creator type is summarized in Figure 1. Patient-created content consistently represented the largest proportion across most diseases. Collectively, 184 videos amassed more than 123 million views and 9.6 million likes. Influencer-generated content accounted for the highest total views (60,992,870/132,058,986, 46.2%), followed by patient-generated videos (45,469,801/132,058,986, 34.4%) and physician-generated videos (19,000,622/132,058,986, 14.4%). Medical professional– and nonprofit organization–generated content contributed smaller proportions of total views (2,413,400/132,058,986, 1.8% and 2,964,198/132,058,986, 2.3%, respectively), with other creator types accounting for the remaining 0.9% (1,218,095/132,058,986) of views (Table 3).

Figure 1. Distribution of TikTok videos by creator type and disease category.

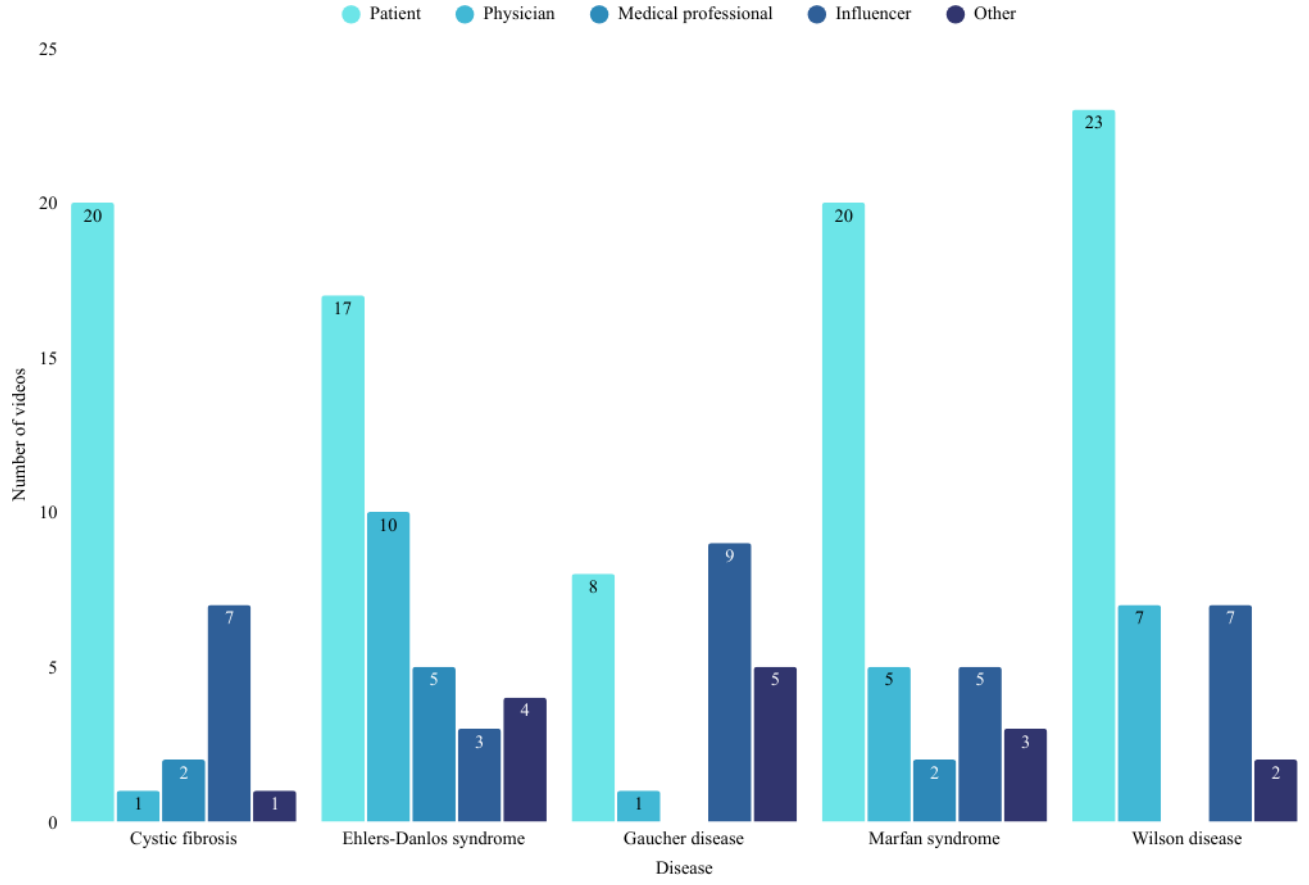

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Table . Summary of TikTok engagement metrics and normalized engagement ratios (NER) by creator type (N=188).

Creator type	Average views (SD)	Average likes (SD)	Total views (N=132,058,986), n (%)	Total likes and shares (N=9,836,670), n (%)	NER (per 1000 views)
Physician	791,693 (1,310,843)	25,851 (41,535)	19,000,622 (14.4)	704,288 (7.2)	2433.50
Patient	516,702 (1,489,930)	37,997 (127,974)	45,469,801 (34.4)	3,428,069 (34.9)	48.8
Influencer	1,967,512 (8,715,477)	174,542 (896,043)	60,992,870 (46.2)	5,455,019 (55.4)	30.2
Medical professional	268,156 (390,437)	12,975 (27,601)	2,413,400 (1.8)	128,585 (1.3)	32.9
Nonprofit organization	71,653 (157,967)	2587 (7034)	2,964,198 (2.3)	72,740 (0.7)	29.2
Other	197,613 (483,735)	4624 (7713)	1,218,095 (0.9)	47,969 (0.5)	28.3

While influencers and patients generated the highest overall engagement, with 60.9 million (46.2%) and 45.5 million (34.4%) views, respectively, physician-created videos had the highest NER, averaging 2433 interactions per 1000 views. This was substantially higher than the ratios for medical professionals (48.8), influencers (30.2), patients (32.9), nonprofit organizations (29.2), and other creators (28.3). The NER adjusts for differences in video reach, providing a clearer measure of content's interactive quality rather than just popularity. Full results are shown in Table 3.

Content produced by physicians and medical professionals demonstrated significantly higher quality and reliability, as measured by the GQS and the mDISCERN. Physician-created videos had a mean GQS score of 3.62 (SD 0.71) and mDISCERN score of 3.21 (SD 0.65), while videos from medical professionals scored slightly higher (GQS mean 3.89, SD 0.66; mDISCERN mean 3.11, SD 0.58). In contrast, videos from influencers and patients exhibited notably lower-quality scores (influencers: GQS mean 1.48, SD 0.6; mDISCERN mean 1.4, SD 0.55; patients: GQS mean 1.57, SD 0.58; mDISCERN mean 1.38, SD 0.52; Table 4). A full breakdown of consensus data is available in Multimedia Appendix 2.

Table . Average Global Quality Scale (GQS) and modified DISCERN (mDISCERN) scores by creator type.

Creator type	GQS score, mean (SD)	mDISCERN score, mean (SD)
Physician	3.62 (0.71)	3.21 (0.65)
Medical professional	3.89 (0.66)	3.11 (0.58)
Influencer	1.48 (0.60)	1.42 (0.55)
Patient	1.57 (0.58)	1.38 (0.52)
Nonprofit organization	2.92 (0.70)	2.60 (0.66)
Other	2.73 (0.68)	2.48 (0.61)

For EDS (40/184, 21.7%), Kruskal-Wallis tests revealed significant variation in GQS scores (H=24.28; P<.001; ε^2=0.57, 95% CI 0.41 - 0.72) and in mDISCERN scores (H=24.09; P<.001; ε^2=0.56, 95% CI 0.39 - 0.71). For Wilson disease (40/184, 21.7%), significant differences were found in GQS (H=30.50; P<.001; ε^2=0.75, 95% CI 0.60 - 0.84) and mDISCERN (H=29.89; P<.001; ε^2=0.73, 95% CI 0.58 - 0.82). For cystic fibrosis (34/184, 18.5%), significant variation was observed in GQS (H=12.36; P=.03; ε^2=0.26, 95% CI 0.04 - 0.47) and mDISCERN (H=11.96; P=.04; ε^2=0.25, 95% CI 0.03 - 0.45). No significant differences in quality scores were found for Marfan syndrome (GQS: H=4.87, P=.43; mDISCERN: H=7.04, P=.22) or Gaucher disease (GQS: H=8.59, P=.07; mDISCERN: H=5.46, P=.24; Table 5). No statistically significant differences in quality scores were found among creator types for Marfan syndrome (GQS: H=4.87, P=.43; mDISCERN: H=7.04, P=.22) or Gaucher disease (GQS: H=8.59, P=.07; mDISCERN: H=5.46, P=.24). The lack of significance may be attributed to smaller sample sizes and limited variation in creator type representation.

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Table . Statistical analysis of information quality scores by content creator type for each rare genetic disease.

Disease	Highest-scoring creator types	Global Quality Scale score			Modified DISCERN score		
		H	*P* value	ε² (95% CI)	H	*P* value	ε² (95% CI)
Ehlers-Danlos syndrome	Medical professionals and physicians	24.28	<.001	0.57 (0.41-0.72)	24.09	<.001	0.56 (0.39-0.71)
Wilson disease	Medical professionals and physicians	30.50	<.001	0.75 (0.60-0.84)	29.89	<.001	0.73 (0.58-0.82)
Cystic fibrosis	Medical professionals and physicians	12.36	.03	0.26 (0.04-0.47)	11.96	.04	0.25 (0.03-0.45)
Marfan syndrome	Nonprofit organizations and others	4.87	.43	0 (0-0.08)	7.04	.22	0.06 (0-0.13)
Gaucher disease	Physicians and patients	8.59	.07	0.15 (0.02-0.29)	5.46	.24	0.09 (0-0.22)

Dunn test with Bonferroni correction revealed that physician-generated videos scored significantly higher on the GQS than both influencer videos (adjusted *P*=.004) and patient-created videos (adjusted *P*=.007). Likewise, content from other medical professionals outperformed influencer videos on GQS (adjusted *P*=.01). On mDISCERN, physician videos again exceeded influencer (*P*=.003) and patient videos (*P*=.005), and other content exceeded influencer videos (*P*=.02). No other pairwise contrasts reached significance. Full pairwise comparison results are available in Multimedia Appendix 3.

Chi-square analysis of the proportion of videos citing peer-reviewed literature or official guidelines showed no statistically significant differences among creator types (χ^2_5=10.6; *P*=.07). Overall, only 7 (3.8%) videos included scientific references. Videos created by medical professionals had the highest citation rate (3/28, 11%), followed by those categorized as by others (1/15, 7%) and by physicians (3/88, 4%). Despite these relative differences, the consistently low citation rates across all creator groups highlight a general lack of evidence-based referencing in TikTok content related to rare diseases (Figure 2).

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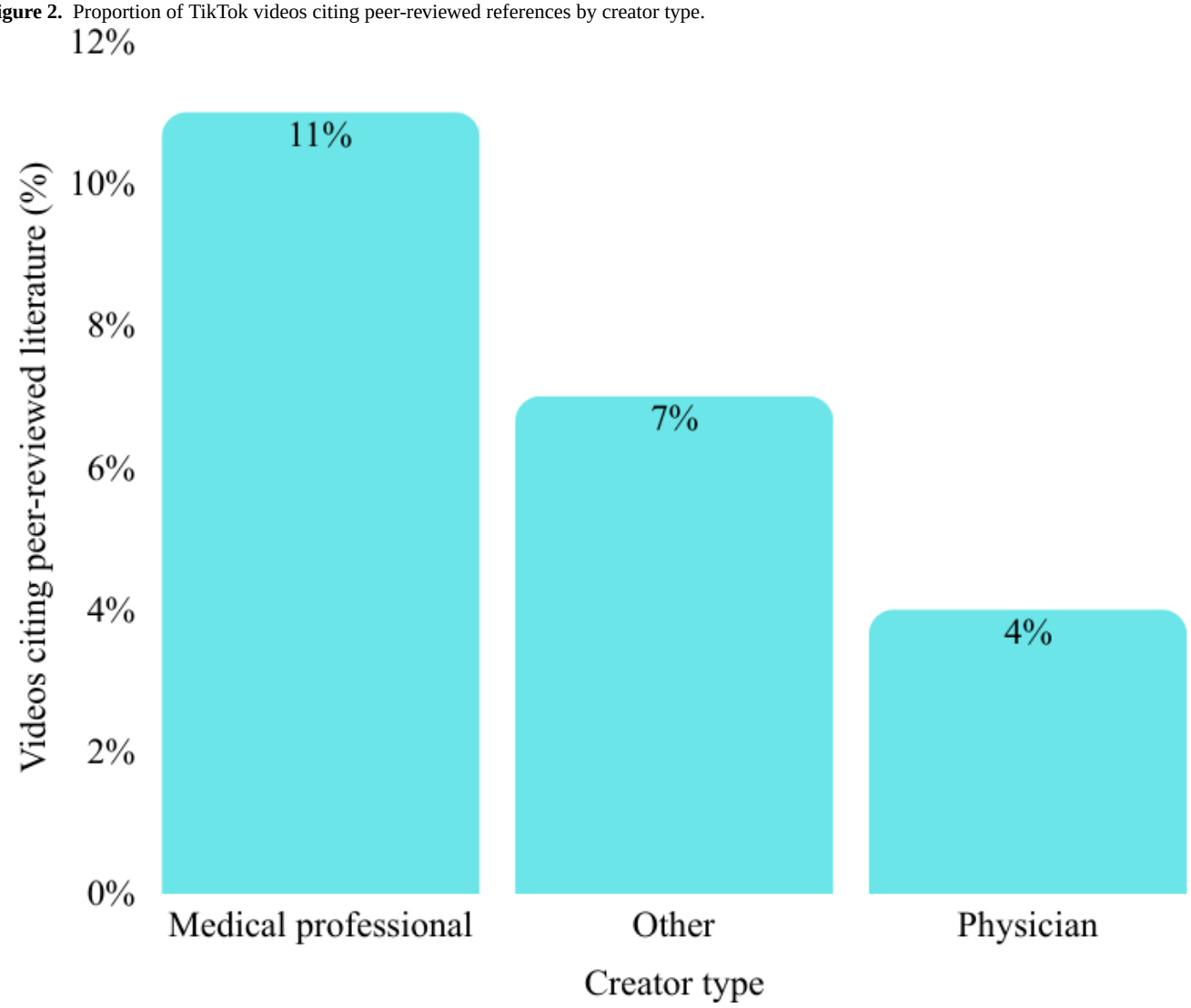
Figure 2. Proportion of TikTok videos citing peer-reviewed references by creator type.



Discussion

Principal Findings

This study highlights the growing importance of TikTok as a platform for rare disease awareness and education, while also emphasizing critical disparities in the quality of medical information shared. Most videos analyzed were created by patients and influencers, who collectively attracted the highest levels of viewer engagement. Despite this popularity, these videos generally contained lower-quality medical information compared with content produced by medical professionals and physicians. This pattern aligns with previous research across other health conditions, where content created by medical professionals typically receives less audience engagement despite higher-quality scores [14,16]. Although physician-generated videos represented fewer total uploads and reached smaller audiences overall, they demonstrated higher NER compared with those produced by nonphysicians, suggesting that audience interaction may be influenced by perceived credibility or informational clarity rather than entertainment value, reflecting prior TikTok research showing a mismatch between content popularity and quality [11,13].

This study found substantial differences in quality scores across creator types. Physician- and medical professional–generated videos consistently demonstrated higher quality based on the GQS and the mDISCERN. Conversely, influencer-created and patient-generated videos scored notably lower on these scales. These findings mirror results from previous TikTok evaluations of various health topics, including diabetes, fibromyalgia, and coronary artery disease, where professionally created content consistently demonstrated greater accuracy but attracted less viewer attention [11-13].

An important observation of this analysis was the pronounced mismatch between content quality and viewer engagement. Physician- and medical professional–generated videos, despite higher quality, received fewer views and interactions compared with influencer- or patient-generated content. Influencer-created videos, in particular, garnered substantial viewership despite notably lower-quality ratings. This discrepancy, previously documented in studies on sinusitis and eating disorders on TikTok, raises significant concerns regarding public health literacy and underscores the risks associated with widespread misinformation on short-form video platforms [13,16]. The NER further emphasizes this mismatch, demonstrating that high-quality physician-created videos, despite fewer total views,

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generated significantly higher engagement per view. This suggests that viewers might interact more meaningfully with accurate, high-quality content even when encountered less frequently.

In the context of rare diseases, this disconnect between popularity and accuracy is particularly problematic. Patients frequently experience prolonged diagnostic delays, inconsistent expertise of health care professionals, and fragmented health care management [1,5]. Therefore, many individuals rely on platforms like TikTok for disease-specific information, emotional support, and practical management strategies [4,8]. This trend aligns with broader findings within rare disease communities, where patients and caregivers commonly use digital tools to access reliable information, reduce isolation, and navigate fragmented health care systems [22]. Foster and Ellis [23] suggest that self-diagnosis behaviors driven by platforms like TikTok may reflect complex motivations, including identity exploration, community seeking, and barriers to formal health care access. However, while patient-generated videos offer considerable emotional and community building value, they often include medically inaccurate, incomplete, or misleading information, reinforcing concerns highlighted by prior research [12,15].

Another critical finding was the notably low rate of citing peer-reviewed literature or clinical guidelines across all types of creators. Although medical professionals and physicians cited evidence slightly more frequently than influencers or patients, overall citation rates remained exceptionally low. This aligns with previous analyses of TikTok content in osteoporosis, cancer, and gastrointestinal health, where minimal referencing of credible sources was also noted [17,19]. The absence of evidence-based citations severely limits the educational effectiveness of these videos, hindering viewers' ability to evaluate content credibility and posing tangible risks to patient safety, particularly within vulnerable rare disease populations [6].

Despite these challenges, TikTok presents significant opportunities for community support, increased visibility, and patient empowerment within rare disease communities. Patient-generated content can effectively raise awareness, provide emotional support, and amplify visibility for conditions often overlooked in mainstream health care and research [2,9]. Prior research demonstrates that hashtags like #RareDisease and #ChronicIllness serve as valuable online gathering spaces, facilitating supportive communities and collective advocacy [8,24]. For individuals living with rare conditions, often marked by isolation and limited support, sharing personal experiences can foster identity formation, validation, and belonging. Patient-created videos may help reduce stigma, increase awareness among peers, and promote self-advocacy, even when medical accuracy is imperfect. These peer-to-peer interactions complement rather than replace professional education and highlight the platform's potential as a space for empowerment and community building.

To effectively leverage TikTok's potential while addressing content accuracy and reliability, a multifaceted approach is required. Institutional support, such as training health care professionals in digital health communication, actively involving patient advocates in content creation, and implementing platform-level enhancements, including verified creator badges and algorithms prioritizing credible, evidence-based content, could significantly improve the quality and reliability of shared information [25-27]. Additionally, enhancing digital health literacy through targeted educational initiatives can empower viewers to critically evaluate online health information, fostering safer online communication practices [3,28].

In addition to institutional and platform-level interventions, collaboration between health care professionals and patient influencers may represent a promising strategy for improving the quality and reach of health information. Training programs that equip patients and influencers with foundational health communication and media literacy skills could strengthen the accuracy and clarity of their content while preserving authenticity. Likewise, structured partnerships between physicians, allied health professionals, and experienced content creators could expand credible outreach and help translate complex medical concepts into accessible, patient-centered narratives. Within rare disease communities, such training initiatives could be developed in collaboration with established advocacy organizations such as the National Organization for Rare Disorders, which already supports educational outreach and patient empowerment programs. Such approaches may ultimately enhance trust, reduce misinformation, and promote more equitable participation in digital health education.

While these strategies may offer promising directions for improving content quality and engagement on social media platforms, several limitations of this study should be acknowledged. While EDS, Wilson's disease, and cystic fibrosis showed significant variation in information quality across creator types, results for Marfan and Gaucher diseases were not statistically significant. This likely reflects smaller sample sizes and limited creator diversity within these subgroups, which reduced statistical power to detect true differences.

The cross-sectional design captures only a single snapshot in TikTok's rapidly evolving content environment, potentially limiting generalizability. The reliance on hashtags and English-language videos may have excluded relevant content, highlighting the need for broader multilingual research approaches. Additionally, the inclusion of only the most viewed videos introduces potential selection bias, as this approach may overrepresent popular content while underrepresenting less visible yet potentially higher-quality educational videos. The GQS and mDISCERN tools, though validated, were originally developed for longer-form content, underscoring the need for specialized assessment tools tailored specifically to short-form videos [29]. It is possible that certain diseases were more likely to include peer-reviewed citations than others, reflecting differences in research visibility, professional engagement, or the maturity of patient advocacy communities; however, this relationship was not specifically examined in this analysis. Future research using longitudinal designs could provide deeper insights into the direct impact of social media content on health behaviors and outcomes, further elucidating the platform's long-term educational efficacy.

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Conclusions

TikTok has become a significant platform for health communication, especially for rare disease communities, facilitating patient empowerment, advocacy, and education. However, our findings highlight substantial gaps in the quality and reliability of TikTok content on rare genetic conditions. Videos from patients and influencers are highly popular yet frequently lack medical accuracy and proper citations. In contrast, physicians and medical professionals produce consistently higher-quality content that remains comparatively underviewed.

Although physician-generated content had significantly higher-quality scores, influencer- and patient-generated videos dominated views. This discrepancy raises concerns about misinformation and its implications for patient safety, consistent with prior findings. Institutional support, such as targeted training in digital health communication, could empower health care professionals to produce engaging, evidence-based content. Addressing this imbalance requires increased collaboration between clinicians and patient creators, institutional training in digital health communication, and targeted platform-level interventions such as verified badges and enhanced algorithmic visibility for credible content. Additionally, improving digital health literacy is essential to equip users to critically evaluate health information online. Such coordinated efforts can transform TikTok into a more reliable and effective tool for rare disease education and community support.

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The authors declare the use of generative artificial intelligence (GenAI) in the research and writing process. According to the GAIDeT taxonomy (2025), the following tasks were delegated to GenAI tools under full human supervision: proofreading and editing; formulation of conclusions; and reformatting. The GenAI tool used was ChatGPT.

Responsibility for the final manuscript lies entirely with the authors. GenAI tools are not listed as authors and do not bear responsibility for the final outcomes.

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Data Availability

The datasets generated or analyzed during this study are available from the corresponding author on reasonable request.

Authors' Contributions

JMW and RMH conceptualized the study and designed the analysis framework; conducted data extraction and statistical analysis; and led the writing and interpretation of results. HGA, as the corresponding author, took primary responsibility for coordinating manuscript revisions by initiating additional analyses, recommending relevant references, refining figure scales, and enhancing the clarity and quality of the final manuscript. All authors reviewed, edited, and approved the final manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Pairwise Dunn post hoc comparisons of TikTok video quality by creator type: *z* statistics with 2-tailed asymptotic *P* values and Bonferroni-adjusted *P* values for Global Quality Scale and modified DISCERN scores.
[DOC File, 34 KB - formative_v10i1e79978_app1.doc]

Multimedia Appendix 2
Modified DISCERN scoring system for TikTok.
[DOCX File, 15 KB - formative_v10i1e79978_app2.docx]

Multimedia Appendix 3

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Descriptive overview of TikTok videos by creator type and disease category. Video counts, mean Global Quality Scale and modified DISCERN scores, total views, likes, shares, and number of videos citing peer-reviewed references.
[DOC File, 75 KB - formative_v10i1e79978_app3.doc]

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Abbreviations

ADHD: attention-deficit/hyperactivity disorder
EDS: Ehlers-Danlos syndrome
GQS: Global Quality Scale
IRB: institutional review board
mDISCERN: modified DISCERN
NER: normalized engagement ratio

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Smart Kiosk for Nutritional Management of People With Diabetes in Underserved Communities: Development and Technical Evaluation

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Abstract

Background: Diabetes is a chronic disease with a high global prevalence, increasing from 200 million people in 1990 to 830 million in 2022, with a higher burden in low- and middle-income regions and high mortality in Mexico and Veracruz. These inequalities limit access to treatment and nutritional education, requiring technological solutions such as interactive kiosks based on artificial intelligence (AI) that contribute to the nutritional management of people with diabetes in marginalized communities.

Objective: This study aimed to design and evaluate an interactive kiosk based on AI that generates culturally relevant and personalized meal plans for people with diabetes in marginalized communities.

Methods: A low-cost prototype was developed, with a database of local foods and a multilayer perceptron trained with synthetic data based on national clinical guidelines. Performance was tested through an experimental evaluation that measured (1) the accuracy of nutritional recommendations compared with ideal meal plans (accuracy, precision, sensitivity, and F_1-score); (2) performance, measured by recording response time with 1 to 50 simultaneous requests; and (3) usability, assessed using heuristic evaluation and the System Usability Scale (SUS).

Results: The smart kiosk was experimentally evaluated in three dimensions: nutritional recommendations, system efficiency, and usability. The model achieved AI metrics of 87.3% overall accuracy, 90.5% precision, 92.1% sensitivity, and 91.3% F_1-score. The average response time was 2.36 (SD 0.24) seconds in all load tests. A maximum time of 4 seconds was obtained in the simulation of 50 concurrent users. In the usability evaluation, an average score of 89 (SD 2.89) out of 100 was obtained on the SUS, which is considered excellent, along with a success rate of 98.3%.

Conclusions: The AI-based kiosk demonstrated technical feasibility, adequate performance, and satisfactory usability. Its ability to operate without the need for internet and its low cost make it an equitable option for diabetes self-management and a replicable model in public health.

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KEYWORDS

smart health kiosk; diabetes management; nutritional recommendation system; artificial intelligence; underserved communities

Introduction

Diabetes mellitus is a global public health problem. In 1990, it affected approximately 200 million people; by 2022, this number had surpassed 830 million. This increase has occurred primarily in low- and middle-income countries, where more than half of those with the disease are not receiving treatment [1]. The outlook is grim: by 2050, diabetes mortality is projected to increase by 59.7%, reaching 1.31 billion cases [2]. In Mexico, cases are also on the rise; prevalence increased from 16.8% in 2018 [3] to 18.3% in 2022 [4].

Diabetes is not a biological disease; it is a social one. There is a well-established gradient in which the poorest people become ill more frequently and die earlier [5]. Veracruz, for example, was the second poorest state in the country in 2022, with 4.2 million people living in poverty and almost half of its population lacking access to health care [6]. In the municipality of Pánuco, where the interactive kiosk evaluated in this study is planned,

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48.9% of the population lived in poverty in 2020 [7], and there was only one physician for every 1000 inhabitants [8].

Diabetes management requires comprehensive self-care strategies and nutritional education, as proper nutrition and the adoption of healthy lifestyles are fundamental to preventing complications [9].

In this context, artificial intelligence (AI) has become relevant in health care, as it can process large amounts of clinical data and aid in decision-making, and the market for AI-powered health technologies is growing rapidly [10,11]. In response to this scenario, this project aims to develop a low-cost, culturally adapted, offline-operating smart kiosk with a local database and a user-friendly interface for people with limited digital literacy. These technologies, developed primarily in community and low-resource settings, promote digital inclusion and equitable access to health care in nonhospital settings [12,13]. Evidence exists for the use of health kiosks for chronic disease monitoring [14,15] and their effectiveness in nutritional education and glycemic control [16-18].

In this context, this study aimed to develop and test an AI-powered interactive kiosk that can provide personalized nutritional recommendations to people with diabetes in vulnerable communities. The device was designed to be autonomous, requiring no on-site health care personnel, and to provide understandable information on nutrition and individualized meal plans. Its effectiveness was evaluated quantitatively and experimentally in terms of accuracy, efficiency, and ease of use.

Methods

Overall Research Design

This study adopted a quantitative approach with an experimental design to verify the technical performance of the AI-based interactive kiosk before its public launch. The accuracy of the nutritional recommendations produced by the system was evaluated, as well as its performance and ease of use. To this end, an experimental evaluation was carried out with predefined test data that simulated real-life usage scenarios. The working hypothesis was that the intelligent system could (1) generate personalized nutritional recommendations with an accuracy level greater than or equal to 85%, based on ideal expert recommendations; (2) maintain adequate performance (response times of less than 3 seconds per query); and (3) meet basic usability criteria (high task success rate and low user error rate). On the basis of this hypothesis, quantitative metrics and acceptance thresholds were established in accordance with software engineering standards. The entire process was structured into three main phases: (1) development of the AI-based interactive kiosk, (2) training and validation of the AI model, and (3) experimental evaluation of the system.

Phase 1: Development of the AI-Based Interactive Kiosk

Overview

In this phase, the kiosk infrastructure was built, both in terms of software and the user interface (UI), and the AI engine responsible for generating recommendations was integrated. An agile incremental methodology was adopted, which allowed for iterative progress and continuous validation of each component. In addition, contributions were incorporated from 3 nutrition specialists from the Autonomous University of Tamaulipas, Tampico, Tamaulipas, and 3 physicians in computer systems specializing in human-computer interaction from the Higher Technological Institute of Pánuco, Veracruz. The design is based on three principles: low cost, offline operation, and cultural relevance in a regional context. The system can be synchronized with a remote server to store or update data when connectivity is available, thereby ensuring data integrity.

The following sections describe (1) the architecture and components of the kiosk, (2) the UI, (3) the AI module, (4) the nutritional database, (5) the synchronization or server component (optional), (6) data initiation and recording, (7) processing and generation of recommendations, (8) presentation of results to the user, (9) the interactive education section, and (10) system shutdown and additional options.

Kiosk Architecture and Components

The interactive kiosk was designed as a comprehensive solution consisting of various software modules integrated into a low-cost hardware platform, designed to operate autonomously in marginalized communities. The elements that make up the kiosk's hardware are a Raspberry Pi 4B (4 GB RAM), a 10.1" HDMI touchscreen, a USB audio module, a 5V/3A power supply, an acrylic structure, and a mini thermal printer. Its architecture allows users to interact via a touchscreen, enter personal data, and receive nutritional recommendations generated by a neural network that consults a specialized database. Optionally, the AI model can be synchronized with a remote server to store data or receive updates. In terms of security, Transport Layer Security and HTTP Secure data encryption and token authentication are used (Figure 1).

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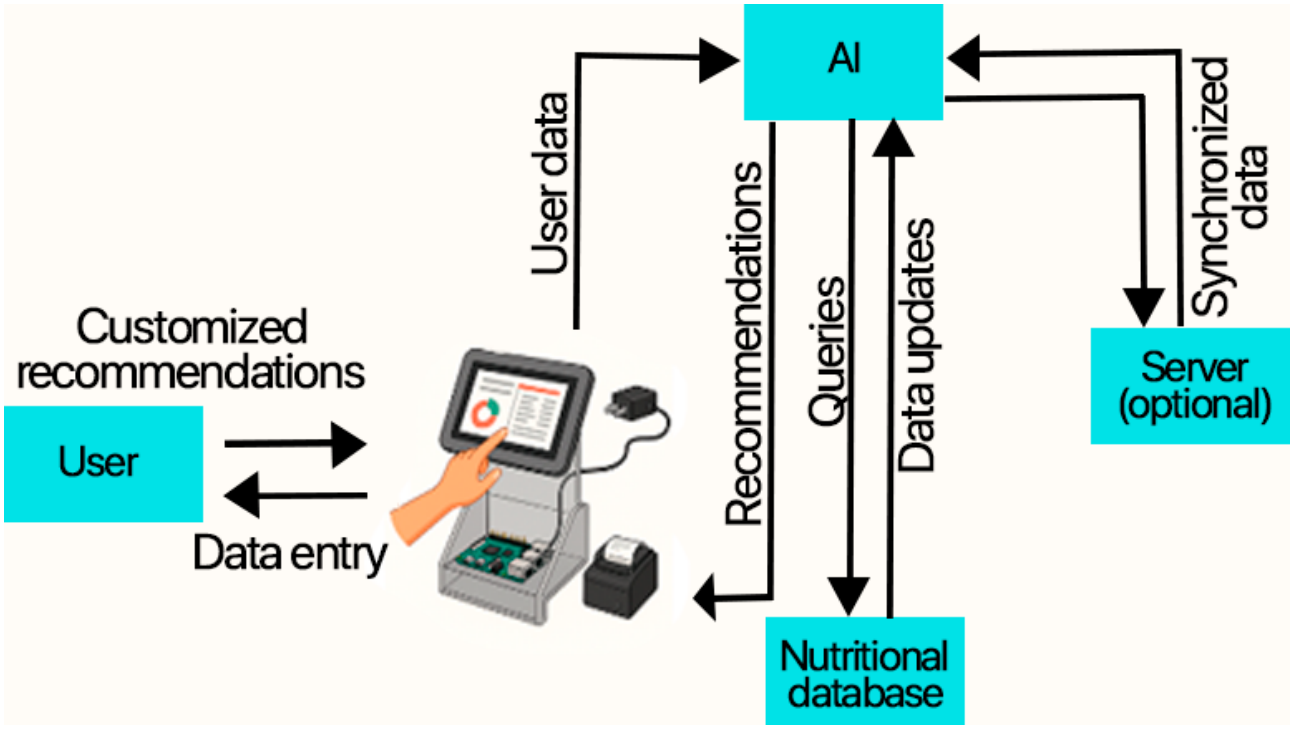
Figure 1. Architecture of the artificial intelligence (AI)–based interactive kiosk: diagram showing the process for the user to receive nutritional recommendations.



User Interface

The interface was developed as a local web application, specifically designed for use by users with low literacy levels. It uses touch controls, large buttons, intuitive pictograms, and a minimalist design. It runs in full-screen mode using an integrated browser. In addition to Spanish text, it includes an audio system that reads instructions and recommendations, with the aim of facilitating use by people with reading difficulties. All these features help the user minimize typing errors when entering data. The process begins with the user entering data, calculating energy requirements using conventional equations (modified Harris-Benedict), and running the AI model, which generates the optimal menu based on dietary and metabolic restrictions. Finally, the meal plan is displayed on the screen and can be downloaded via a QR code or as a PDF file, or printed.

AI Module (Recommendation Engine)

The AI engine represents the core of the system and is programmed in Python using TensorFlow version 2.12 (Google). On the basis of the information provided by the user, the system calculates the BMI and estimates daily calorie requirements. It then generates a personalized nutrition plan that includes a distribution of calories by macronutrients, portions by food group, and examples of specific dishes.

Nutritional Database

This local database, developed with SQLite, stores detailed nutritional information on foods and recipes typical of the region, including dishes of cultural significance. It also incorporates dietary rules that allow the AI engine to adjust recommendations according to the patient's profile. When generating suggestions, the system selects food combinations that meet caloric and macronutrient requirements, prioritizing those suitable for people with diabetes. Its offline functionality is achieved through real-time SQL queries. The main sources of information were NOM-015-SSA2-2023, NOM-043-SSA2-2012, NOM-051-SCFI/SSA1-2010, NOM-008-SSA3-2017, the Mexican Food Composition Tables (INCMNSZ, 2020), local community recipe books, and national clinical nutrition guidelines for diabetes (Centro Nacional de Excelencia Tecnológica en Salud), ensuring the technical validity and cultural adaptation of the system.

Synchronization Component and Server (Optional)

Although the kiosk is designed to operate offline, a synchronization module was included that allows, when connected, to send usage statistics to a central server and receive system updates. This functionality was developed in Python and allows the system to be kept up to date with new prescriptions or changes in medical guidelines. Communication with the server is carried out using Transport Layer Security (TLS) and HTTPS, with token-based authentication to ensure information security during the synchronization process.

Processing and Generation of the Recommendation

When logging in, users must fill out a questionnaire with information such as age, weight, type of diabetes, level of physical activity, and dietary preferences. The system verifies the information entered using type and range checks, predefined fields, internal consistency rules, and semantic validation to avoid errors, ensuring that the data provided are consistent and suitable for processing (Figure 2).

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Figure 2. Interactive kiosk home screen displaying the icon to start a questionnaire where the user's personal and clinical data are entered, which is automatically validated before processing. It also has an audio system to repeat the instructions.

Once the data have been entered and verified, the system begins processing the recommendation. The AI engine calculates key indicators such as the BMI and establishes individual caloric requirements. With this information, it generates a personalized meal plan tailored to the user's profile. The nutritional plan is presented on the screen in a visual and organized manner: it includes a calorie summary and menus for each meal time. The user can explore each section, review the nutritional information for each dish, and even substitute foods for equivalent alternatives. At the end, the user has the option to print a summary of their plan or store their information using an alias or a QR code for future sessions. The average duration of each session is 5 minutes. The system is designed to automatically reset for the next user. Figure 3 shows an example of a nutritional plan generated by the kiosk.

Figure 3. Presentation of the nutritional plan with content that combines simple texts, images, and explanatory audio, allowing users to better understand the recommendations proposed.

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Phase 2: Training and Validation of the AI Model

The AI engine was developed in the Python programming language using the TensorFlow version 2.12 library.

A multilayer perceptron was designed for multiclass classification, trained with 10,000 synthetic data points. Data were based on Mexican clinical nutrition and diabetes standards and guidelines and the nutritional ranges recommended by Encuesta Nacional de Salud y Nutrición Continua (ENSANUT) 2022. The dataset was enriched with recipes and local dishes from northern Veracruz.

Energy ranges between 1200 and 2800 kcal/d and macronutrient distributions within acceptable ranges (carbohydrates, 45% - 65%; proteins, 10% - 35%; and fats, 20% - 35%) were defined.

The data were obtained by stratified random sampling, with controlled variation in anthropometric profiles and dietary patterns. Each entry coded 15 informative variables that capture demographic, clinical, and nutritional aspects, such as diagnosis, level of physical activity, caloric needs, macronutrient distribution, predominant food group, and dietary adherence.

To maintain population realism, the proportions of each stratum were scaled to the distribution in the Mexican population with type 2 diabetes according to ENSANUT 2022. Values outside defined physiological ranges (eg, BMI <15 kg/m² or >40 kg/m²) were automatically removed, and nutritional consistency filters were applied. The final dataset was exported in CSV format to train and validate the multilayer neural network model in an 80% and 20% partition scheme (training and testing).

The model consists of 3 hidden layers of 64 neurons with rectified linear unit activation. Batch normalization was also implemented, along with a dropout technique with a rate of 0.3 to prevent overfitting.

The output layer consists of three neurons with softmax activation, corresponding to the different classes: “suitable,” “minor adjustment,” and “consultation required.” The model was trained using the Adam optimizer (learning rate=0.001) and the categorical cross-entropy loss function, incorporating an early stopping criterion when the validation loss stopped improving or after reaching 100 epochs. The data were divided as follows: training (80%) and validation (20%), and to improve the generalization of the model, L2 regularization was applied. The model used variables such as age, sex, height, weight, physical activity, type of diabetes, glycemic control, and food preferences to calculate BMI and calorie requirements. A deterministic submodule based on nutritional heuristic rules generates a personalized meal plan, prioritizing low-glycemic and high-fiber foods. The result is provided in an interactive graphical UI that displays a summary of calories, macronutrients, and menus by meal times, in which equivalent foods can be substituted to allow flexibility and improve adherence to the diet.

Phase 3: Experimental Evaluation of the System

Overview

Once the prototype was built, quantitative tests were performed. These tests were classified into three categories: (1) performance of the AI model in generating nutritional recommendations, (2) system performance and efficiency (response times and resource usage), and (3) interface usability.

Performance Testing of the AI Model in Nutritional Recommendations

A test dataset was defined that covered the essential functionalities of user data recording, nutritional recommendation generation, and educational information display. To evaluate performance, the recommendations issued by the system for each profile were compared with their reference equivalents, previously validated by nutritionists at the Autonomous University of Tamaulipas, Tampico, Tamaulipas. On the basis of this comparison, several indicators were calculated: overall agreement rate (accuracy), precision, sensitivity, defined as the ability to choose the right foods for each patient, and the F_1-score. In addition, each suggestion was verified to comply with basic nutritional guidelines, such as not exceeding a specific carbohydrate threshold per meal for people with diabetes and including essential food groups. The test data were user registration, nutritional recommendations, and educational content.

System Performance and Efficiency Testing

The system response time was measured with variable loads. The time from when the user enters data to when the recommendation appears was recorded.

To ensure validity, each case was run several times, and response times were recorded to calculate mean values with their corresponding SD.

The scalability of the system was evaluated with loads of 5, 10, 20, and 50 users. For each test, the average response time, standard deviation (SD), and average CPU and RAM usage were recorded. The software was run offline to simulate the behavior of the system in a low-cost, resource-limited environment, such as the community spaces where it will operate. Performance tests were conducted on the kiosk's own hardware, simulating multiple concurrent users using threads.

Interface Usability Testing (Simulated Heuristic Evaluation)

As no real patients were involved, this evaluation focused on identifying interface design issues and determining whether the application was understandable and easy to use for the target population (adults with basic education). All data collected during testing were stored for subsequent statistical analysis. For each metric, mean values were calculated, and, where applicable, 95% CIs were estimated. As the study did not have a human control group, the analysis was enriched by a technical comparison between the AI-based recommendation engine and an alternative module based on fixed rules (without advanced personalization), using the same test profiles to quantify the improvement provided by AI. In addition, by using synthetic

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data and operating locally, the system guarantees user privacy, which eliminated the need for ethical approval. This methodology allowed for a comprehensive evaluation of the system in a controlled environment.

According to Nielsen and Molich [19], between 3 and 5 expert evaluators can detect most usability problems. Similarly, Sauro and Lewis [20] pointed out that 30 to 100 task executions are sufficient to obtain reliable metrics of success, error, and interaction time. Therefore, the 60 tasks evaluated by 3 experts were sufficient for this stage, as they fell within the suggested range.

Ethical Considerations

In accordance with the Regulations of the General Health Law on Research and NOM-012-SSA3-2012, this study is not classified as research involving human participants: the tests were exclusively technical, and no personal data were collected, nor were any interventions performed on participants. This study did not involve experiments on humans or animals, nor did it involve the collection of sensitive personal data. It focused exclusively on the development and technical evaluation of the smart nutrition management kiosk. A controlled experiment was conducted with synthetic data (fictitious patients), and no private or identifiable information was accessed or stored; therefore, approval from an institutional review board was not required.

Reporting Guidelines

This manuscript was prepared following the STARE-HI (Statement on Reporting of Evaluation Studies in Health Informatics) guidelines to ensure a clear and transparent description of the development and technical evaluation of the AI-based nutritional kiosk. A STARE-HI checklist is included as Checklist 1, indicating the section of the manuscript where each of the required criteria is addressed.

Results

Experimental Evaluation of the System

The results of the experimental evaluation of the system (phase 3) are presented. The tests and experiments carried out have enabled objective data to be collected on the operation of the smart kiosk. The findings are classified into three categories: (1) performance of the AI model in generating nutritional recommendations, (2) system performance and efficiency (response times and resource usage), and (3) usability of the interface.

Performance of the AI Model in Nutritional Recommendations

Table 1 shows that the model achieved an overall accuracy of 87.3%, along with a precision of 90.5%, a sensitivity of 92.1%, and an F1-score of 91.3%. The results indicate that the model can distinguish between adequate meal plans and those that require review by a nutritionist, with a good balance between sensitivity and precision. The “Minor_Adjustment” class achieved 85.1% accuracy, 82.2% sensitivity, and an F_1-score of 83.6%, which is slightly lower but still very consistent. On the other hand, the “Requires_Consultation” class obtained values above 80.0% in the 3 main metrics, which is an acceptable result considering the smaller number of samples in this class. On average, the macro average gave 85.2% accuracy, 84.8% sensitivity, and 85.0% F_1-score, and the weighted average gave 87.3% in the 3 metrics, indicating good overall calibration of the model. These results indicate that the system strikes a good balance between coverage and precision, generalizing well across classes without significant bias. The performance and learning curves indicate that the synthetic set of approximately 10,000 records saturated the multilayer perceptron, with no improvements observed when increasing the training size, suggesting that it was sufficient for training.

Table . Performance metrics of the artificial intelligence–based nutritional recommendation model during the technical evaluation conducted in Veracruz, Mexico (2025).[a]

Class	TP[b]	FP[c]	FN[d]	Support	Precision (%)	Recall (%)	F_1-score (%)
Adequate	152	16	13	165	90.5	92.1	91.3
Minor adjustment	74	13	16	90	85.1	82.2	83.6
Requires consultation	36	9	9	45	80.0	80.0	80.0
Macro average	—[e]	—	—	—	85.2	84.8	85.0
Weighted average	—	—	—	—	87.3	87.3	87.3
Micro average (overall accuracy)	—	—	—	—	87.3	87.3	87.3

[a]Metrics include class-level precision, recall, F_1-score, and overall accuracy across 300 simulated patient profiles.

[b]TP: true positive.

[c]FP: false positive.

[d]FN: false negative.

[e]Not applicable.

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System Performance and Efficiency

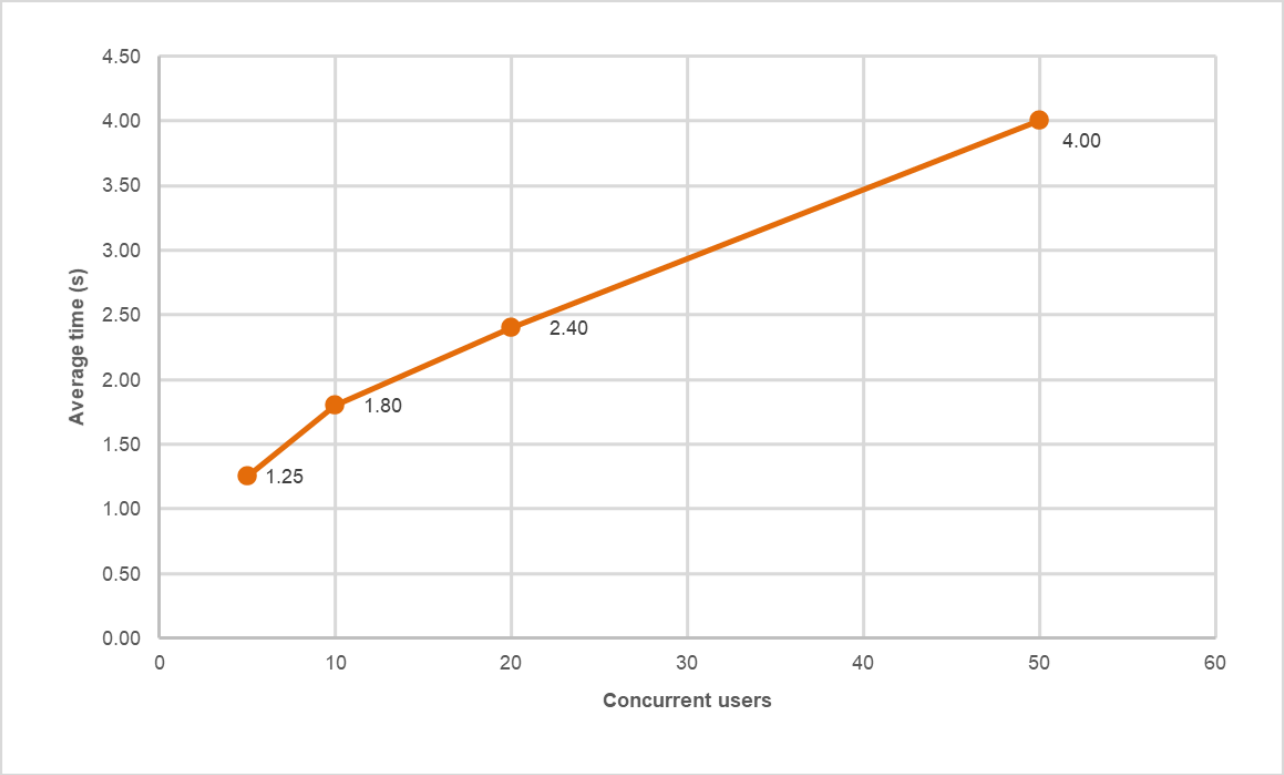
Table 2 and Figure 4 summarize the main performance indicators of the smart kiosk software. The average response time was 2.36 (SD 0.24) seconds, with a maximum of 4 seconds under peak load (50 concurrent users). The SD of 0.24 seconds shows that the system consistently responds in a similar manner; there is little variation between requests.

Table . System performance and resource utilization of the artificial intelligence–based nutritional kiosk under simulated concurrent user loads (5 - 50 users) during experimental testing in Veracruz, Mexico (2025).[a]

Concurrent users	Average time (s)	SD (s)	Average CPU (%)	Average RAM (%)
5	1.25	0.12	35.0	42.0
10	1.80	0.18	47.0	46.0
20	2.40	0.25	59.0	51.0
50	4.00	0.40	77.0	63.0
Total average	2.36	0.24	54.5	50.5

[a]Measures include average response time, CPU usage, and RAM consumption.

Figure 4. Scalability analysis of the interactive kiosk software during stress-testing simulations (2025). Average response time increased from 1.25 s (5 users) to 4.0 s (50 users), demonstrating a linear growth pattern under increasing computational demand.



Resource usage remained at acceptable levels, with an average CPU usage of 54.5% and RAM usage of 50.5%, allowing the system to operate on embedded hardware or mid-range computers without compromising stability. The results demonstrate that the software core is stable, efficient, and scalable, making it suitable for environments with limited connectivity (Figure 5).

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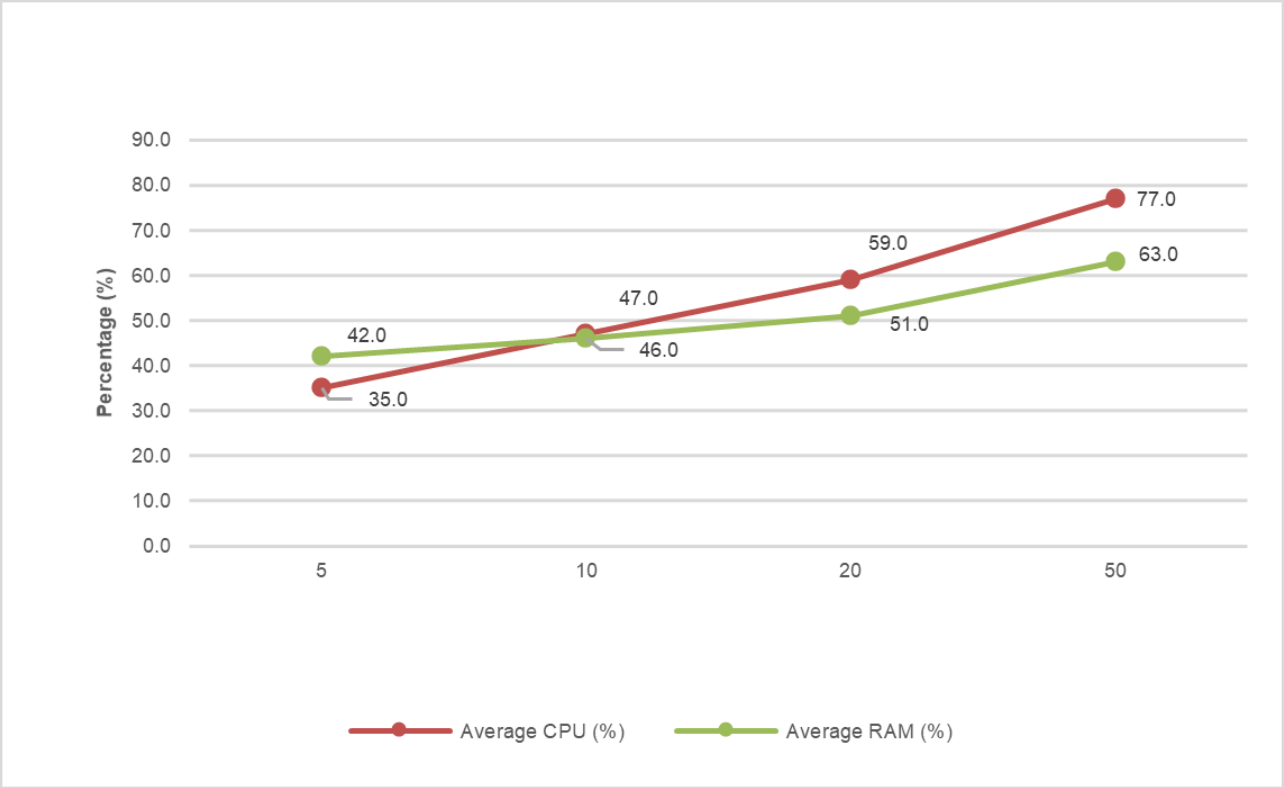
Figure 5. CPU and RAM utilization of the kiosk system during simulated load increments (5 - 50 concurrent users) in the experimental evaluation (2025). Resource usage increased linearly without reaching saturation.



Interface Usability

The combination of expert inspection and simulated testing provided valuable information on the kiosk's ease of use. Overall, the 3 evaluators (PhDs in Computer Systems from the Higher Technological Institute of Pánuco, Veracruz) agreed that the interface is intuitive and accessible.

The evaluators highlighted the clear iconography, the legible font size for older adults, and the audio narration to guide the user. Among the improvements, they proposed adding a "back" button on all screens to correct input errors and highlighting foods "to avoid" in the summary, thus reinforcing critical information. No bugs or navigation problems were reported. The interface meets essential accessibility criteria: high color contrast, touch areas of at least 48 pixels to facilitate tapping, and audio playback for all important text, especially benefiting users with low vision or limited literacy.

Satisfaction was measured using the System Usability Scale (SUS) adapted to Spanish, with a Likert scale ranging from 1 (strongly disagree) to 5 (strongly agree). On average, the evaluators gave very high scores: ease of use, 5 out of 5; feature integration, 4 out of 5; confidence in independent use, 5 out of 5; and a low perceived need for prior learning, 2 out of 5. When these ratings were converted to the standardized SUS metric (0 - 100), the interface achieved approximately 90 out of 100, placing it in the "excellent" usability range.

Table 3 presents that the average score for each evaluator (87.5%, 92.5%, and 87.5%), as well as the overall average score for the SUS, which was 89.17 (SD 2.89) out of 100, is classified as "excellent" (A). This score indicates that the system is usable, with an intuitive interface and easy navigation. The success rate was 98.3%, with a 95% CI, indicating that most actions were completed. The error rate, which was below 0.05, indicates the robustness of the interface and the clarity of the instructions. These indicators reveal that the smart kiosk software is highly usable.

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Table . Usability evaluation results of the artificial intelligence–based nutritional kiosk obtained through heuristic expert testing (3 evaluators and 60 simulated tasks) performed in Veracruz, Mexico (2025).[a]

Indicator	Value
Participant 1 (%)	87.5
Participant 2 (%)	92.5
Participant 3 (%)	87.5
Average SUS[b] score (0 - 100; %)	89.17
Standard deviation (SUS score)	2.89
SUS classification	Excellent (grade A)
Task success rate, Wilson score (95% CI)	98.3% (Wilson) (91.1 % - 99.7 %)
Estimated error rate	<0.05

[a]Metrics include SUS score, task success rate, and estimated error rate.
[b]SUS: System Usability Scale.

Discussion

Comparison With Previous Work

Multiple studies have verified that educational interventions supported by digital technologies significantly improve glycemic control and self-care in people with diabetes [21-25]. Furthermore, AI has been able to predict events, manage chronic diseases, and provide personalized nutritional recommendations, with demonstrated improvements in treatment adherence and health outcomes when incorporated into structured interventions [26-39].

For type 2 diabetes, for example, various AI-powered apps have been developed for patient education, diagnostic support, clinical decision-making, and nutritional guidance, resulting in improved quality of life and more efficient care processes [40-61]. However, most of these solutions have not been implemented in low-resource clinical settings.

Given this reality, interactive health kiosks represent an innovative alternative for bringing health services to communities. Evidence supports their application in diagnostic support, telehealth, and health education, with growing international acceptance [62-70]. Furthermore, these devices have been useful for monitoring clinical variables and educating patients with diabetes, especially those with limited education or access to health care services [71-73].

Unlike previous research, this study proposes an AI-powered autonomous kiosk for underserved communities that does not require medical personnel or personal devices to reduce technological, economic, and educational barriers, thereby expanding nutrition and self-care education in vulnerable environments.

Principal Findings

The results demonstrate that the AI-based interactive kiosk is not only technically feasible but also has the potential to improve nutritional management significantly. Controlled tests validated the accuracy of the recommendation engine, operational efficiency, and interface usability, laying the groundwork for its pilot implementation in real-world settings. The 87.3% agreement rate with plans designed by nutritionists shows that the neural network successfully learned the complex rules that experts apply when personalizing diets. This result is comparable to that achieved by initiatives such as PROTEIN in Europe, which also achieved expert-level automated recommendations [17]. Furthermore, the 92.1% sensitivity underscores that the kiosk incorporates almost all critical dietary components, thus minimizing the risk of nutritional deficiencies.

In addition, by incorporating local ingredients such as tortillas, nopales (prickly pear cactus), and beans, it aligns with the principles of precision nutrition and improves adherence, something rarely observed in studies focused on European or North American diets.

The average response time of 2.36 (SD 0.24) seconds ensures a smooth interactive experience, which is a critical factor in preventing early abandonment. This finding aligns with observations in health kiosks targeting African American communities, where interface speed was key to user acceptance among those with low literacy and limited patience [12]. Furthermore, the ability to operate for extended periods using low-cost hardware opens the door to its use in rural clinics, community centers, and mobile units.

Experts valued the clarity of the iconography, text size, and audio support elements recommended in the literature for rural and low-literacy settings [16]. A user-friendly interface not only facilitates initial adoption but also promotes repeated use, maximizing the health impact. While the kiosk can operate autonomously, its true potential emerges when integrated with the work of physicians and nutritionists. A hybrid model would allow usage data to provide feedback to local clinics and for the generated plans to be reviewed periodically by professionals. In communities with sporadic medical visits, monthly access to the kiosk could promote self-management and, in the long term, be reflected in better clinical indicators.

Limitations

The findings confirm that the kiosk is a viable tool for improving nutrition education. Its low cost and offline capability make it ideal for rural areas; however, it still has some limitations. The

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AI model was trained with synthetic data, so it requires a second training phase with real data to verify its generalizability.

Furthermore, the high levels of digital literacy among the evaluators could influence the high values of the usability metrics. However, as proposed by Nielsen and Molich [19], the participation of specialists with a technical background is appropriate in a heuristic phase, which should not be considered a bias, but rather a valid methodological criterion for this phase of the research.

Another limitation is that the system focuses on the nutritional component of diabetes treatment, while neglecting other important components such as medication and exercise. These elements will be considered in future versions.

The architecture is adaptable, but the nutritional framework was designed for communities in the northern part of the state of Veracruz, Mexico; therefore, its application to other communities would require adaptations. Despite these limitations, the study represents a promising first step toward creating feasible, culturally appropriate, and sustainable community digital health solutions.

Recommendations and Future Work

In the short term, a kiosk is expected to be installed in the community of Vega de Otates, Veracruz, Mexico, and a second phase of model training will be carried out using real data from patients with diabetes. This new phase will include incremental and federated learning to improve its performance without compromising user privacy.

The data generated will be used to calibrate the model, so that recommendations can be progressively adapted to demographic, nutritional, and socioeconomic profiles for applicability in other communities. Furthermore, the plan is to integrate continuous glucose monitoring with wearables and AI algorithms and expand the system with personalized physical activity tips and medication reminders. This will allow progress toward a personalized medicine approach, with real-time data collection and dynamic adaptation of nutritional recommendations through automatic pattern recognition.

Finally, a longitudinal field study is planned to evaluate usage indicators, user perceptions, changes in weight, and glycated hemoglobin levels to assess the system's real impact on health.

Conclusions

An AI-based interactive kiosk was designed, developed, and technically validated to provide personalized nutritional recommendations. The model achieved satisfactory performance, with an accuracy of 87.3%, precision of 90.5%, sensitivity of 92.1%, and an average F_1-score of 91.3%. The results show a correlation between coverage and precision. In the usability evaluation, the software achieved a mean score of 89.17 (SD 2.89) points on the SUS scale (grade A) and a success rate of 98.3%. Its free, offline, and adaptable nature makes it an innovative tool for promoting nutrition education and reducing health inequalities. The software features an AI recommendation engine, a user-friendly interface, and a local nutritional database with response times of 1.25 to 4 seconds, ensuring its accessibility. The results show that AI technologies can support nutritional self-management. Implementation of the kiosk and its validation in a community pilot study are planned. This project represents a step toward the equitable digitization of nutritional care, establishing and offering the scientific community a replicable, scalable, and sustainable model for public health for communities in Latin America (Multimedia Appendix 1).

Acknowledgments

The authors declare that no generative artificial intelligence tools were used to generate, edit, or draft any portion of this manuscript. All writing, analysis, and revisions were conducted manually by the research team.

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Data Availability

The data generated and analyzed during this study are not publicly available due to institutional data governance restrictions but are available from the corresponding author upon reasonable request.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Statistical analyses.
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Checklist 1
STARE-HI checklist.

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Abbreviations

AI: artificial intelligence
ENSANUT: Encuesta Nacional de Salud y Nutrición Continua
STARE-HI: Statement on Reporting of Evaluation Studies in Health Informatics
SUS: System Usability Scale
UI: user interface

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Using Large Language Models to Summarize Evidence in Biomedical Articles: Exploratory Comparison Between AI- and Human-Annotated Bibliographies

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Abstract

Background: Annotated bibliographies summarize literature, but training, experience, and time are needed to create concise yet accurate annotations. Summaries generated by artificial intelligence (AI) can save human resources, but AI-generated content can also contain serious errors.

Objective: To determine the feasibility of using AI as an alternative to human annotators, we explored whether ChatGPT can generate annotations with characteristics that are comparable to those written by humans.

Methods: We had 2 humans and 3 versions of ChatGPT (3.5, 4, and 5) independently write annotations on the same set of 15 publications. We collected data on word count and Flesch Reading Ease (FRE). In this study, 2 assessors who were masked to the source of the annotations independently evaluated (1) capture of main points, (2) presence of errors, and (3) whether the annotation included a discussion of both the quality and context of the article within the broader literature. We evaluated agreement and disagreement between the assessors and used descriptive statistics and assessor-stratified binary and cumulative mixed-effects logit models to compare annotations written by ChatGPT and humans.

Results: On average, humans wrote shorter annotations (mean 90.20, SD 36.8 words) than ChatGPT (mean 113, SD 16 words) which were easier to interpret (human FRE score, mean 15.3, SD 12.4; ChatGPT FRE score, mean 5.76, SD 7.32). Our assessments of agreement and disagreement revealed that one assessor was consistently stricter than the other. However, assessor-stratified models of main points, errors, and quality/context showed similar qualitative conclusions. There was no statistically significant difference in the odds of presenting a better summary of main points between ChatGPT- and human-generated annotations for either assessor (Assessor 1: OR 0.96, 95% CI 0.12 - 7.71; Assessor 2: OR 1.64, 95% CI 0.67 - 4.06). However, both assessors observed that human annotations had lower odds of having one or more types of errors compared to ChatGPT (Assessor 1: OR 0.31, 95% CI 0.09 - 1.02; Assessor 2: OR 0.10, 95% CI 0.03 - 0.33). On the other hand, human annotations also had lower odds of summarizing the paper's quality and context when compared to ChatGPT (Assessor 1: OR 0.11, 95% CI 0.03 - 0.33; Assessor 2: OR 0.03, 95% CI 0.01 - 0.10). That said, ChatGPT's summaries of quality and context were sometimes inaccurate.

Conclusions: Rapidly learning a body of scientific literature is a vital yet daunting task that may be made more efficient by AI tools. In our study, ChatGPT quickly generated concise summaries of academic literature and also provided quality and context more consistently than humans. However, ChatGPT's discussion of the quality and context was not always accurate, and ChatGPT annotations included more errors. Annotated bibliographies that are AI-generated and carefully verified by humans may thus be an efficient way to provide a rapid overview of literature. More research is needed to determine the extent that prompt engineering can reduce errors and improve chatbot performance.

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KEYWORDS

annotated bibliography; artificial intelligence; ChatGPT; evidence synthesis; information management; large language model

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Introduction

The fields of medicine and public health are dynamic and constantly evolving, with a continuous influx of new research articles and evidence. Staying up to date with the latest literature poses a significant challenge for researchers and practitioners alike [1], and it is difficult to familiarize oneself with the literature when diving into a new subject area [2]. Evidence summaries such as meticulously curated reviews and guidelines are lengthy and often complex, and their number has exponentially increased over the past decade [3,4]. In the past, individuals (oftentimes students) may have resorted to sources such as blogs or Wikipedia to understand the basics of a topic, ideally before diving into more reputable peer-reviewed publications. However, this approach has been superseded by use of artificial intelligence (AI) large language models (LLMs) such as ChatGPT, which provide summaries based on accessible scientific literature but often have questionable accuracy and frank errors [5,6].

As a research tool, annotated bibliographies may be a valuable remedy for efficient and insightful literature exploration. These condensed summaries highlight the main points, findings, and scientific validity of the respective articles, while also providing context by relating them to existing knowledge within the field [7].

Recent studies on the use of LLMs show mixed evidence for these as evidence synthesis methodologies. While newer models may provide good summaries, it is unclear whether they have improved in their ability to effectively summarize and analyze scientific materials [5,6,8,9]. AI chatbots and LLMs may have limitations in capturing nuances and answering specific requests accurately, in addition to their known challenges of hallucinating information and citations [5,6,9]. These limitations may stem from an inability to discern the main points of articles (for example, distinguishing factual statements in findings from background material) and may result in output that diverges from the intended context [10]. On the other hand, developing the skill to write succinct and insightful annotations requires time and practice, as well as a solid background knowledge of the subject matter [11]. LLMs with specialized training datasets or access to current bibliographic databases have the ability to provide output based on a breadth and depth of knowledge that other LLMs likely do not, making them an even more promising technology [12]. Keeping abreast of recent advancements and understanding them in the context of existing knowledge can be a daunting task, even for experienced professionals in the field.

Given the varying opinions about the utility of LLMs in generating summaries and citing them in context, our objective was to explore the quality and comparability of annotated bibliographies produced by authors of varying professions and levels of training with outputs generated by a widely available LLM-powered chatbot, ChatGPT [13]. By describing the strengths and weaknesses of both human-authored and ChatGPT-generated annotated bibliographies, we aim to explore the potential utility of ChatGPT in the context of literature exploration and synthesis in medicine and public health.

Methods

Overview

We conducted an exploratory study to describe the similarities and differences in characteristics (word count and readability) and subjective assessments from 2 assessors (errors, inclusion of main points, and presence or absence of quality assessment and contextualization) of annotated bibliographies that were created by 2 researchers (JT and MD) and 3 versions of ChatGPT (ChatGPT, models GPT-3.5, 4, and 5, OpenAI) [13]. Our data, statistical code, and research materials are available on the Open Science Framework (OSF) [14] and we provide links and descriptions to each OSF file (Table S1 in the Multimedia Appendix 1).

Ethical Considerations

Ethics approval was not required because this study involved secondary analysis of published data and did not include human participants.

Annotation Creation

Article Selection

We searched Web of Science for publications in life and biomedical sciences published from May 1, 2013 to May 1, 2023. From this search, we sampled 15 publications [15-29] that were the most highly cited, open access, and had 15 or fewer pages of main text. Our full article selection procedure, including search strategy and sampling methods, is described on OSF (Table S1 in the Multimedia Appendix 1).

Human Annotators and Chatbot Prompters

Two human annotators (JT, a professor in public health, and MD, a dentist and recent public health master's degree graduate) and 3 chatbot prompters (MD, the same master's degree graduate; FA, a graduate student; and RQ, an epidemiologist specializing in evidence synthesis) from our research team created annotated bibliographies using the same set of 15 publications. Each chatbot prompter was restricted to using one version of ChatGPT. MD was a human annotator and a chatbot prompter. To avoid MD being influenced by annotations written by ChatGPT, MD read and annotated all 15 annotations before beginning his role as a chatbot prompter.

The human annotators and chatbot prompters completed their annotations in August 2023. To update our assessment during the peer review process in September 2025, RQ used ChatGPT-5 to create another set of annotations using the latest version of ChatGPT.

Directions Given to Human Annotators and Chatbot Prompters

The 2 human annotators (JT and MD) and 3 chatbot prompters (MD, FA, and RQ) received instructions from members of our research team on how to write an annotated bibliography. RQ instructed the human annotators to review 1 video and 2 webpages that described how to write an annotated bibliography (Box S1 in the Multimedia Appendix 1).

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MCC emailed instructions to the chatbot prompters (Box S2 in the Multimedia Appendix 1) on how to create ChatGPT-generated annotations, including uploading the text of each article into ChatGPT using the web-based ChatGPT Splitter [30] and using a naturalistic approach with few limits to prompt generation of summaries. As chatbot annotations were completed in August 2023 prior to ChatGPT being able to process PDF files directly, a text file was generated from each PDF. An initial pilot test demonstrated that ChatGPT produced long summaries, so instructions were updated to restrict responses to 90-150 words to be more consistent with human annotations, providing better masking. ChatGPT-5 was restricted to 3-4 sentences. We altered the prompt for ChatGPT-5 to sentences rather than word count to see what kind of effect this would have on the resulting word counts.

Project Management and Workflow

For the human annotations, the 15 publications were uploaded to PICO Portal [31], where the human annotators read each publication, wrote their annotations, and documented how long it took to complete each annotation in minutes.

Chatbot prompters who reported that the prompt did not generate a summary were instructed to approach the situation however they wanted to (eg, using additional prompts or the "Regenerate response" button) until a summary was created. Researchers who generated responses through AI designated a final annotation that was then scrubbed (see example below) and used in analysis. All annotations were created in single ChatGPT sessions without clearing ChatGPT's memory between citations. All ChatGPT conversations are available on OSF (links can be found in Table S1 in the Multimedia Appendix 1).

The chatbot annotations were scrubbed to remove formatting anomalies and recurrent patterns which may have unmasked ChatGPT-generated annotations. For example, ChatGPT often added titles or citation information to responses. An example of scrubbing an original annotation is shown below:

> *Selected Text From Original Response (ChatGPT-3.5)*
>
> *Title: Theta Band Activities and Cognitive Control: A Mechanistic Perspective. This article provides an insightful overview of recent advancements in cognitive neuroscience.*
>
> *Scrubbed Version Used in Analysis*
>
> *This article provides an insightful overview of recent advancements in cognitive neuroscience.*

Additional examples of scrubbing original annotations are presented in Table S2 in the Multimedia Appendix 1.

We did not scrub body text of the annotations themselves, even if they contained clear errors. For example, the article by Cavanagh and Frank [17] is a narrative review that discusses the role of frontal theta band activities in the medial prefrontal cortex as they relate to cognitive control mechanisms. Yet, ChatGPT-3.5 incorrectly stated the publication focused on the "mid-frontal cortex" while ChatGPT-4 said the research "employ[ed] a variety of experimental methods." Additional examples of errors can be found in Table S3 in the Multimedia Appendix 1.

After scrubbing annotations created by ChatGPT, we combined all annotations for each article (n=75 annotations in total) into a Microsoft Excel file and numbered them individually. We randomly ordered all annotations using random.org and masked the source of the annotations by removing the column which identified the versions of ChatGPT or the human annotator that produced each annotation. We used this file to collect data on the following outcome measures.

Outcome Measures and Definitions

For each annotation, we assessed (1) word count, (2) Flesch Reading Ease (FRE), (3) capture of main points, (4) presence and severity of errors, (5) presence of a quality assessment and contextualization of the publication's results, and (6) we guessed whether the annotation was generated by AI or a human. We entered each annotation into a web-based calculator to measure word count and FRE. FRE is a reliable test with no grade-level ceiling that measures how difficult it is for a person to read and understand written material [32]. Scores range from 0 to 100, where higher scores indicate easier to understand material (ie, grade or middle-school students), and lower scores indicate harder to understand material (ie, college graduates or professionals) [33].

Two epidemiologists (RQ and KN) specializing in evidence synthesis methods independently evaluated the 3 remaining outcome measures (eg, main points, errors, and presence or absence of quality assessment and contextualization). First, they rated main points on an ordinal scale from 1 to 7, where a score of 1 indicated the annotation included little relevant information, a score of 4 indicated the annotation focused on minor rather than major points of the publication, and a score of 7 indicated the annotation included all relevant information about the publication's main purpose. Second, they measured the extent of errors in each annotation using four ordinal categories: no errors, one minor error, one major error, or multiple errors. Errors were measured by ensuring each claim in the annotation appeared in the main text of the publication. Third, they assessed whether each annotation discussed the quality of the study (ie, risk of bias, methodology) and contextualized the study's results in comparison to the body of literature. They assigned a value of "yes" if *both* quality and context were present, regardless of whether quality and context were technically incorrect or irrelevant to the publication, and a value of "no" if *either* quality or context were missing from the annotation. If quality and context were *both* present but incorrect, this was still counted as "yes" but also counted towards the assessment of errors in the annotation.

Analysis

We analyzed data using R software (version 4.5.1; R Foundation for Statistical Computing) [34], and the *tidyverse* [35], *psych* [36], *ordinal* [37], and *lme4* [38] packages.

Word Count and Flesch Reading Ease

We calculated measures of central tendency and spread for word count and FRE for all 5 annotators. We first aggregated analysis of central tendency and spread by the 2 human annotators vs the 3 versions of ChatGPT, then split into individual annotators (2 humans and 3 ChatGPT versions). Due to the exploratory

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nature of our study, we did not conduct inferential tests on differences in these measures.

Assessing Interrater Agreement and Disagreement

To better address aspects of subjectivity in our expert ratings of annotations, we evaluated interrater agreement between the 2 assessors using Cohen kappa for the quality and context binary rating and weighted Cohen kappa for the ordinal variables (main points and errors). Following the recommendations by Agresti [39], we also investigated patterns for systematic disagreement by applying the McNemar test for the quality and context rating (without continuity correction) and ordinal quasi-symmetry models for main points and errors. See Text S1 in the Multimedia Appendix 1 for additional details.

Main Points, Errors, Quality and Context, and Guesses

We first calculated frequencies and percentages of each response option for both assessors' evaluations of main points, errors, quality and context, and if they correctly guessed whether annotations were written by a human or ChatGPT. Because RQ was the chatbot prompter for ChatGPT-5, he did not guess the source of the 15 annotations generated by ChatGPT-5. We then fit assessor-stratified binary and cumulative mixed-effects logit models with a binary predictor for source of annotation (human vs ChatGPT). We always set ChatGPT as the reference group. Additional details on our modeling strategies, including our assessment of the proportional odds assumption and whether we needed a random intercept for publication or annotators are reported in Text S1 in the Multimedia Appendix 1.

Statistical significance was defined as $P<.05$; however, because the goal of our analysis was exploratory, we reported results with a focus on describing our observed data rather than intending to draw inferences to a population of studies beyond the scope of this paper.

Results

Overview

Each annotator and chatbot prompter produced one annotation for each of the 15 publications, which resulted in 75 annotations. On average, it took the professor 13.7 (SD 3.4) minutes and the master's degree graduate 21.1 (SD 15.7) minutes to write 1 annotation. Chatbot prompters observed that ChatGPT generated summaries within seconds per publication, but without timestamps being available, we did not measure the exact time.

Word Count and Flesch Reading Ease

When aggregated by chatbot vs human, ChatGPT annotations were longer and had less variation in word count (mean 113, SD 16) than human annotators (mean 90.2, SD 36.8). ChatGPT annotations had lower average FRE scores (mean 5.76, SD 7.32) than the human annotators (mean 15.3, SD 12.4), although both chatbots and human annotations fell in the "very difficult" range [40].

Individually, the annotations generated by ChatGPT-3.5 and 4 always stayed within the lower and upper bounds of their restricted word counts of 90-150 words. ChatGPT-5's word count distribution was almost identical to ChatGPT-3.5's word count, even though ChatGPT-5 had a 3 - 4 sentence limit rather than a word count limit (Table 1).

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Table . Word count and Flesch Reading Ease score for 15 annotations.

	Mean (SD)	Median (minimum-maximum)
Word count		
Overall ChatGPT[a]	113 (16)	114 (86-148)
GPT-3.5	125 (113)	124 (105-148)
GPT-4	97.8 (10.2)	96 (86-119)
GPT-5	117 (12.2)	120 (102-148)
Overall human[a]	90.2 (36.8)	79.5 (41-170)
MD (MPH graduate)	68.8 (25.1)	63 (41-143)
JT (professor)	111.6 (34.6)	120 (61-170)
Flesch Reading Ease score[b]		
Overall ChatGPT[a]	5.76 (7.32)	2.6 (0-22.4)
GPT-3.5	6.95 (7.43)	4.9 (0-20.7)
GPT-4	9.11 (8.56)	10 (0-22.4)
GPT-5	1.22 (2.07)	0 (0-6.4)
Overall human[a]	15.3 (12.4)	14.6 (0-37)
MD (MPH graduate)	15.9 (13.5)	15 (0-37)
JT (professor)	14.6 (11.7)	14.2 (0-34)

[a]Aggregated results by annotator (ChatGPT or human)

[b]Flesch Reading Ease score potential range is from 0 to 100, with 0 indicating low readability (scientific level, eg journal articles) and 100 indicating high readability (very easy, eg, comic books) [40].

Assessing Interrater Agreement and Disagreement

Detailed results for assessing agreement and disagreement are reported in Text S1, Tables S4-S8, and Figures S1-S3 of the Multimedia Appendix 1. Briefly, Cohen κ showed that assessors had fair to moderate levels of agreement for their assessment of main points (κ=0.32, 95% CI 0.11 - 0.52), errors (κ=0.43, 95% CI 0.23 - 0.63), and quality and context (κ=0.46, 95% CI 0.26 - 0.67). As for disagreement, ordinal quasi-symmetry models revealed systematic disagreement where one assessor was stricter than the other. The stricter assessor had lower odds of assigning higher categories of main points (OR 0.49, 95% CI 0.30 - 0.71) and higher odds of assigning higher (ie, worse) categories of errors (OR 3.05, 95% CI 1.69 - 7.56). For quality and context, there was no evidence of systematic disagreement (McNemar χ^2=0.2, *P*=.655). Despite our assessments of the raters' levels of agreement or disagreement, the assessor-stratified models in Table 2 showed that both assessors' ratings resulted in similar qualitative conclusions about main points, errors, and quality and context.

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Table . Assessors' ratings of 45 ChatGPT- and 30 human-annotated bibliographies[a].

Indicator	Assessor 1			Assessor 2		
	GPT, *f* (%)[b]	Human, *f* (%)	Statistical tests, OR (95% CI)[c]	GPT, *f* (%)	Human, *f* (%)	Statistical tests, OR (95% CI)[c]
Main points			0.96 (0.12 - 7.71)			1.64 (0.67 - 4.06)
1	1 (2)	0 (0)		5 (11)	1 (3)	
2	0 (0)	0 (0)		4 (9)	0 (0)	
3	4 (9)	1 (3)		1 (2)	1 (3)	
4	5 (11)	4 (13)		6 (13)	6 (20)	
5	5 (11)	7 (23)		10 (22)	8 (27)	
6	16 (36)	9 (30)		16(36)	13 (43)	
7	14 (31)	9 (30)		3 (7)	1 (3)	
Errors			0.31 (0.09 - 1.02)			0.10 (0.03 - 0.33)
None	29 (64)	25 (83)		16 (36)	22 (73)	
1 Minor	7 (16)	3 (10)		4 (9)	5 (17)	
1 Major	1 (2)	1 (3)		5 (11)	1 (3)	
Multiple	8 (18)	1 (3)		20 (44)	2 (7)	
Quality and context			0.11 (0.03 - 0.33)			0.03 (0.01 - 0.10)
Absent	12 (27)	22 (73)		9 (20)	27 (90)	
Present	33 (73)	8 (27)		36 (80)	3 (10)	
Correct guess[d]						
Correct	18 (60)	18 (60)		43 (96)	28 (93)	
Incorrect	12 (40)	12 (40)		2 (4)	2 (7)	

[a]n=45 ChatGPT annotations written by 3 versions of ChatGPT: 3.5, 4, and 5 (ChatGPT, OpenAI) [13]; n=30 human annotations from 2 annotators.

[b]*f* (%): frequency of response (percent).

[c]OR: odds ratios estimated from cumulative (for main points and errors) or binary (for quality and context) mixed-effects logit models. Assessor 2's main points were collapsed into 3 categories (1 - 3, 4 - 5, and 6 - 7) to satisfy the proportional odds assumption. A random intercept for publication was used in all models except for Assessor 2's evaluation of quality and context, where a single-level fixed-effect model was used. A random intercept for annotators was used in Assessor 1's evaluations of main points, and Assessor 2's evaluation of errors. The estimated variances of the random intercepts are reported in Table S8 in the Multimedia Appendix 1.

[d]Assessor 1 used ChatGPT-5 to produce annotations, so his percentage of correct guesses were out of 30 annotations created by Chat GPT-3.5 and 4 only.

Main Points, Errors, Quality and Context, and Guesses

We did not find a statistically significant difference in humans' or ChatGPTs' odds of presenting a better summary of main points (see Table 2). Although not statistically significant for assessor 1, error ratings were more similar, where both assessors found that humans had lower odds of including errors compared to ChatGPT (Assessor 1: OR 0.31, 95% CI 0.09 - 1.02; Assessor 2: OR 0.10, 95% CI 0.03 - 0.33). Findings for presence of quality and context were also similar, with both assessors finding strong evidence that humans had lower odds of describing a paper's quality and context (Assessor 1: OR 0.11, 95% CI 0.03 - 0.33; Assessor 2: OR 0.03, 95% CI 0.01 - 0.10).

Finding that ChatGPT had higher odds of reporting quality and context is noteworthy given that ChatGPT was not explicitly prompted to do so. However, ChatGPT's discussion of quality and context was not always appropriate. For instance, in 40% (6/15) of ChatGPT-5's annotations, it said that these studies may be at risk of "selection bias" because the studies used non-systematic (eg, narrative) review methods to search for eligible studies [17,21-23,25,26]. ChatGPT-5 was correct to point out the limitations of narrative review methods, but did not understand that the correct term in this context was publication bias rather than selection bias.

Furthermore, both assessors found ChatGPT capable of serious errors beyond the use of inaccurate terminology. For example, ChatGPT-5 hallucinated and gave an annotation for a publication on human papillomavirus instead of the assigned publication on diagnostic criteria for temporomandibular disorders [26]. We describe this further and provide additional examples in Table S3 in the Multimedia Appendix 1.

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Discussion

Principal Findings

Our goal for this exploratory study was to compare the strengths and weaknesses of ChatGPT- and human-generated annotated bibliographies. We did not find a difference in capture of main points across ChatGPT and human annotation. However, we found that ChatGPT-generated summaries had increased odds of being in a worse error category than human summaries. And even though ChatGPT had increased odds of describing a publication's quality and context, the discussion of the quality and context was sometimes inaccurate.

Comparison to Prior Work

There are many apps and platforms that build upon existing LLM frameworks (eg, ChatGPT, Claude 3, Gemini, Bard, Co-Pilot, etc) that use more specific training sets to help with specialized tasks [41]. While we do not include a formal evaluation of these more customized GPTs in this study, we expect these approaches would perform better than the base ChatGPT interface on OpenAI's website because those models were trained on the more specialized scientific literature. Other studies have found that custom GPTs can perform some tasks better than base GPT and this is likely generalizable to other base LLMs and customized models [13,42]. Some have been trained on scientific articles and have access to PubMed and other bibliographic databases—a feature that base ChatGPT does not have—which gives them a greater ability to provide useful contextualization and even suggest potentially related references [12,43,44].

This potential advantages of AI summaries was supported by our finding that chatbot annotations more often provided quality assessment and contextualization than did the human annotations. While the first chatbot prompts did not include a request to contextualize the findings within the broader literature, it may be that the mechanism of an LLM allows it to infer what is "expected" given the request to make a summary for an annotated bibliography. This difference in effective contextualization likely arose because LLMs are predictive models—their very mechanism involves calculation of words in context—thus they may be able to produce an overall summary and extrapolation/contextualization about the literature on a topic based on whatever is available in its training set. Given their access to and training on the scope of their "reading," this task is relatively simple. However, such a task is very difficult for humans unless they are familiar with the literature already. That said, we found that contextualization was not always appropriate or accurate, with AI summaries sometimes including statements that were not relevant or were incorrect.

Strengths and Limitations

Our pragmatic approach to this study carries with it the standard strengths and limitations of a naturalistic and exploratory study, including strengths and limitations related to how humans interact with AI. First, one limitation of using chatbots that was reflected in our findings is the varying nature of output and how this was related to the naturalistic prompts that were used. We purposely did not use a standard set of prompts for each version of ChatGPT. Our human annotators were given the same training materials, but they had different levels of experience (by design) and also applied the training differently in generating their summaries. Similarly, in having a different human write their prompt for each chatbot, we had greater variation in the prompt styles that is more generalizable to the real world, in which people are more apt to use their own prompts before finding "standardized" prompts that may have been developed on a different set of literature. This variation is worth noting—while the capacity may be present for AI to produce accurate summaries that are comparable to those produced by humans, people with less experience writing prompts or with barriers such as language fluency might also produce AI-generated summaries that are less effective [45,46].

Further, prompt engineering continues to advance as a technique for producing higher-quality outputs. For example, there are now more advanced ways to prompt which can produce better responses (eg, encoding a prompt a certain way in a JSON file format or directly interfacing with the backend through application programming interfaces. We did not explore these other options or make inferences about prompt engineering techniques, however, because such interaction is likely beyond what the average user is capable of or would undergo for normal use [47].

Second, the interactive and chat-based interface of most LLMs means that the settings within a standard GPT are easily customizable, which may lead to responses being different for each user [48]. Although LLMs are functionally large predictive models with trillions of parameters, given the same prompt, a model will return different results each time a prompt is run [48]. This is a limitation of using these models to summarize literature because different annotations will be produced for the same article. While this variability is also true of multiple human annotators, and both humans and AI can make mistakes, humans may be better able to adapt prompts or instructions to different settings and situations in a way that LLMs cannot. The potential risk is that a carefully written prompt that produces an accurate summary of a paper in one LLM may not produce a reliable or valid summary (1) of a paper that has a different structure (eg, social science vs medical literature) or (2) in an LLM built upon a different framework. Multiple evaluations of LLMs have found the ability to summarize literature accurately varies depending on the context and can be prone to errors such as overgeneralizing statements beyond a given setting [10,49].

We asked both our AI and human annotators for a very specific kind of summary (ie, an annotated bibliography) which is different from other types of summarizations (eg, extractive summaries, descriptive summaries, evaluative summaries, synoptic summaries, etc). This specificity may limit the generalizability of our results to other types of summaries. Another limitation is the potentially low readability of the annotations produced here by both humans and chatbots; however, in our study this may have come from the fact that we were summarizing scientific articles and did not prompt the AI (or instruct the human annotators) to write for a better readability score. Finally, for our original sets of annotations in ChatGPT-3.5 and ChatGPT-4 we fed only article text directly

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into the LLM: this is a limitation as papers contain multimodal information such as tables and figures which humans may use to make their summaries but may be inaccessible or incomprehensible to LLMs. While this was a potential limitation of the early LLMs that could not handle such information, current versions of LLMs are able to process entire papers including information contained in tables and figures, so we believe the utility should not be affected by this going forward [50].

As our intention was to explore the comparability of AI and human annotations, our sample was small, and we did not power our assessment for any quantitative hypothesis testing. For our generation of annotations, assessments, and comparisons, we followed a predefined protocol as closely as possible.

Future Directions

Contrary to other studies that look only at AI summaries or answers to questions [5,6,9,51], our findings suggest that LLMs produce summaries of academic articles that are comparable to human annotators in errors and more often include quality assessment and contextualization. While the annotations were not perfect and sometimes needed further prompting to produce better summaries, summaries did not take 10 minutes to create (as they did for human annotations once papers were read) and did not require the experience and training of human researchers. The utility of being able to create summaries without the requisite content expertise at a much lower cost (time * expertise) cannot be understated. Future evaluations should use larger sample sizes that are powered for statistical hypothesis testing instead of exploration and description. It would also be useful for future research to explore AI generation of different kinds of summaries, including single sentence approaches, to deepen our understanding of the use and limitations in different contexts [52]. Future studies should also evaluate the ability of AI to group the studies thematically as this kind of presynthesis would also be helpful for managing libraries of studies in grouping similar concepts together.

Conclusions

While our findings show promising speed and accuracy of LLMs for producing summaries of papers, when compared with human annotators there is still a risk of errors which necessitates human verification. When approached with these things in mind, we believe the utility is clear, and that human-assisted AI annotation—even through casual and naturalistic interactions with chatbots where output accuracy is verified by a human—will be the most efficient way to create annotated bibliographies that can be used to provide a rapid overview of a breadth of literature for a wide range of users.

Acknowledgments

Disclosure of Delegation to Generative AI

The authors declare the use of generative AI in the research and writing process. According to the GAIDeT taxonomy (2025), the following tasks were delegated to GAI tools under full human supervision:

- Literature search and systematization

- Writing the literature review

- Data collection

The GAI tools used were ChatGPT 3.5, ChatGPT 4.0, ChatGPT 5.

Responsibility for the final manuscript lies entirely with the authors.

GAI tools are not listed as authors and do not bear responsibility for the final outcomes.

Declaration submitted by: Collective responsibility

The authors used a brief discussion with ChatGPT 3.5 to create a first draft of the Introduction, which was extensively revised by all authors. Chat GPT3.5, 4 and 5 generated annotations were the subject of the study. These were generated as described in the paper.

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Data Availability

The datasets, statistical code, and research materials are available on OSF [14].

Authors' Contributions

Conceptualization: MCC, RQ, DA, JT
Data curation: MCC, RQ, KN
Formal analysis: MCC, RQ, KN, JT
Funding acquisition: MCC, JT

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Investigation: MCC, RQ, KN, FA, MD, DA, JT
Methodology: MCC, RQ, KN, FA, MD, JT
Project administration: MCC, DA, JT
Supervision: MCC
Validation: MCC, RQ, KN, JT
Writing – original draft: MCC, RQ, FA, MD, DA, JT
Writing – review & editing: MCC, RQ, KN, FA, MD, DA, JT

Conflicts of Interest

RQ declares consulting with PICO Portal from 2020 to 2025. The other authors declare no competing interests.

Multimedia Appendix 1
Additional information for Methods and Results.
[DOCX File, 355 KB - formative_v10i1e69707_app1.docx]

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Abbreviations

AI: artificial intelligence
FRE: Flesch Reading Ease
LLM: large language model
OSF: Open Science Framework
PICO: population, intervention, comparator, outcome

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Physician Perspectives on Web-Based Real-World Statistics for Better-Informed Drug Selection in Epilepsy: Mixed Methods Study

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Abstract

Background: Lately, big data studies have shown promise in using patient characteristics to rank the likelihood of retention of antiseizure medications (ASMs), a measure indicating tolerability as well as effect. How such results can be integrated into clinical practice has yet to be studied. We developed EPstat, a noncommercial tool that provides physicians with real-world treatment retention data from 33,998 patients with epilepsy.

Objective: This study investigated the user experience of EPstat after its pilot launch.

Methods: EPstat was developed in an iterative process with first a prototype and then a final version accessible on the health care region intranet. EPstat was launched in 2022 through emails and information meetings at neurology departments. After 1 year, an online questionnaire was distributed to physicians in our health service region's neurology clinics (5 hospitals). Descriptive statistics and thematic analysis were used to summarize responses. To supplement the survey, 3 semistructured workshops or group interviews with neurologists and residents were used to gather further feedback.

Results: Of the 27 survey respondents, 19 (70%) were aware of EPstat and 10 (37%) had used it. Users rated EPstat highly for ease of use (median 5, IQR 4 - 5) and applicability in clinical practice (median 4, IQR 4 - 4). Two of the 10 respondents who had used it indicated that the platform had influenced their choice of ASM. Workshop participants advocated for expanding the platform to include retention data on newer ASMs and general information relevant to epilepsy management.

Conclusions: The notion of using big data to improve ASM selection was well received. However, there were barriers to the initial use, and users requested a more comprehensive resource that also incorporated other information related to epilepsy. EPstat is now being updated with more recent ASM statistics, including information on newer ASMs. Mobile access, more information for physicians, and mentioning the tool in regional guidelines are some possible measures to increase use. Linking multinational statistics could also increase the precision of the presented data and, thus, increase usefulness. Study of EPstat will continue and should include thematic analysis of representative and rigorously sampled workshop participants. Such studies are also likely to provide information on how physicians and health services receive web-based tools, which are likely to soon be driven by artificial intelligence. In similar projects, we recommend greater participatory involvement of both health care providers and patients already at the design stage.

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KEYWORDS

seizure; quality improvement; health care innovation; antiepileptic drug; retention rate; antiseizure medication discontinuation; ASM discontinuation

Introduction

Antiseizure medication (ASM) selection is a fundamental aspect of epilepsy care. A key challenge is the availability of over 25 ASMs, each with a different mechanism of action and side effect profile, and the related difficulty of selecting the most appropriate drug for each individual patient. Current decision-making mainly relies on clinical trials and guidelines that may not fully capture the diversity of real-world clinical scenarios. For instance, the most commonly prescribed first ASM in Sweden is levetiracetam [1,2], although there is randomized controlled trial evidence suggesting that lamotrigine is equally efficacious with lower risk of side effects [3]. This discrepancy highlights a gap between available evidence and everyday clinical practice.

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Ideally, when deciding which ASM to prescribe, the type of epilepsy indicates a range of suitable options, with the final choice being based on patient-specific factors such as presumed side effect sensitivities, comorbidities, drug interactions, and patient preference. ASMs are typically approved after clinical trials have demonstrated an effect on seizures and assessed short-term safety, but these trials often lack the necessary details to guide personalized treatment. Indeed, observational data suggest that the tolerability of certain ASMs may vary across different age groups and epilepsy etiologies [4,5].

Recently, big data sources such as administrative registers or claims data have been used to track ASM use in thousands of patients [5,6], which allows for stratification by patient characteristics. Retention rate, an often-used measure in epilepsy trials integrating effect and tolerability, can be captured in administrative data [7]. For instance, we have used prescription data to track ASM use in Swedish patients and shown that lamotrigine and levetiracetam have superior retention rates to that of carbamazepine in patients developing epilepsy after stroke [8], which agrees with small randomized trials in the same patient group [9,10]. In subsequent studies, we have demonstrated that age, sex, and comorbidities affect which ASM has the highest likelihood of retention, indicating a need for more personalized ASM selection [5]. Lamotrigine has the highest retention rate in focal epilepsy, providing real-world support for the results from large randomized trials [11]. Interestingly, retention rates in Swedish prescription data also agree closely with expert advice on which ASM suits which patient [12].

Big data on epilepsy hold clear potential for personalized medicine and tailored management; by tracking ASM use and assessing drug retention in specific patient groups, it becomes possible to determine which ASM has the highest probability of success for individuals across different age groups and those with various comorbidities and concurrent medications. In the future, artificial intelligence (AI)–based suggestions of ASM selection are not unlikely [13], making it important to study how big data tools are received in everyday health care.

In a regional innovation project aimed at improving ASM selection by looping data from routine health care into the decision-making process, we developed a web-based resource called EPstat designed to assist in selecting first and second ASMs (Figure 1). To evaluate the perceived value of the tool, we conducted a cross-sectional survey and held semistructured workshops with neurologists and neurology residents in our region.

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Figure 1. Schematic of EPstat concept. Data from routine health care registers are processed to generate statistics on retention rates. This is accessible through a website, thereby providing real-world treatment retention rates, supporting clinicians in the selection of antiseizure medications.

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Methods

We used a mixed methods approach comprising a quantitative cross-sectional survey evaluating EPstat's user experience and clinical applicability and a series of qualitative workshops to gather suggestions for potential improvements to the platform. The manuscript follows the Standards for Quality Improvement Reporting Excellence reporting guidelines [14].

Ethical Considerations

The EPstat project was approved by the Ethical Review Authority (approval 2022-214). No personal data were processed; thus, according to Swedish law, this study did not require consent. There was no compensation given to participants.

About EPstat

The EPstat platform is web-based and noncommercial and was conceptualized by clinicians in close collaboration with the IT department of Region Västra Götaland (health care provider for 1.7 million inhabitants). The design of the website presenting the underlying research results was iterated through interviews with clinicians outside the research group (prototype), and once a suitable concept was obtained, the website was built by the IT department in collaboration with DL and JZ (both neurologists). It was launched in 2022 through information meetings at 5 neurology clinics (1 tertiary center and 4 regional hospitals). After introductory meetings with clinicians, they were encouraged to try out the tool themselves during their routine clinical duties and were informed that they could contact the responsible parties if they had any questions. EPstat is currently only accessible on computers within the health care provider's network because the project is still in its concept development stage.

The information on the platform is based on nationwide health care administrative data from encounters with specialized care, including all neurology clinics and all dispensations of prescription drugs at pharmacies. It includes ASM retention rates based on data from 33,998 patients with epilepsy onset after the age of 25 years (presumed focal epilepsy) from 2007 to 2019. The cohort characteristics, the data sources, and the method for tracking ASM treatment using prescription data have been described previously [5].

EPstat's interface is minimalistic, presenting information on ASM retention rates (including 95% CIs), which refers to the proportion of patients continuing to use the drug at a specific point in time. High treatment retention is preferable and suggests that the regimen is efficacious and tolerable for many patients receiving it. The user has the choice to use the entire cohort or stratify the information according to adjustable age groups; sex; common causes of epilepsy; or, if relevant, one previous treatment regimen. Only ASMs with an indication for focal epilepsy according to recommendations from the Swedish Medical Products Agency [15] are included; in certain situations in which a specific ASM is clearly contraindicated, such as valproic acid for women of childbearing potential, that ASM is excluded.

Survey

In 2023, approximately 1 year after EPstat's pilot launch, an online survey was emailed to physicians at the 5 neurology clinics to evaluate their awareness of and experiences with the platform. Approximately 100 neurologists and residents are employed at the sites, but some are unavailable at any given time due to various types of leave, such as parental, sick, or research leave. The head of each clinic forwarded the survey invitation to the employees. The survey was designed to be brief and anonymous, with main outcome measures comprising rating scales from 1 to 5 for ease of use, clinical applicability, the likelihood of recommending the platform to a colleague, and the desire for EPstat to continue to be available and maintained. We asked additional questions about whether EPstat had influenced the respondents' choice of ASM (yes or no) or whether they felt that any functions were missing (open-ended). Key questions had mandatory fields to ensure completeness. We summarized the responses using descriptive statistics and conducted thematic analyses of the open-ended responses to identify common themes and suggestions for improvement.

Workshops

Three workshops were conducted with author DL as the moderator. The main goal was to gather ideas for improvement of the platform. Participants comprised physicians (intended users) at the participating neurology clinics, up to 6 in each workshop. To ensure diverse perspectives, we recruited both experienced neurologists and residents early in their training. The feedback was documented and then qualitatively analyzed by DL and JZ to identify common themes. The analytic approach was qualitative based on content coding; each comment (individual or group derived, as described in the next paragraph) was labeled using descriptive codes, which were then grouped by themes.

The interviews were semistructured, starting with a brief project description, including a presentation of the survey findings, followed by a brainwriting session (brainstorming with affinity mapping) in which participants first reflected separately and then took turns sharing individual comments on paper notes, which were subsequently grouped to identify common themes, which were then developed further in the group. The participants also had the opportunity to share their opinions and thoughts about EPstat openly.

Results

Survey

Of the 27 physicians who responded to the survey, 23 (85%) were neurologists, and 7 (26%) described themselves as subspecialized in epilepsy. The number of physicians who received the survey invitation is estimated to be less than 100 based on the number of physicians in the participating departments, resulting in a response rate of ≥27%. A total of 70% (19/27) were aware of the EPstat resource, but nearly half (9/19, 47%) had not used it. Among the 10 who had used the platform, it was rated highly on a scale from 1 to 5 for ease of use (median 5, IQR 4 - 5) and applicability in clinical practice (median 4, IQR 4 - 4). The likelihood of recommending the

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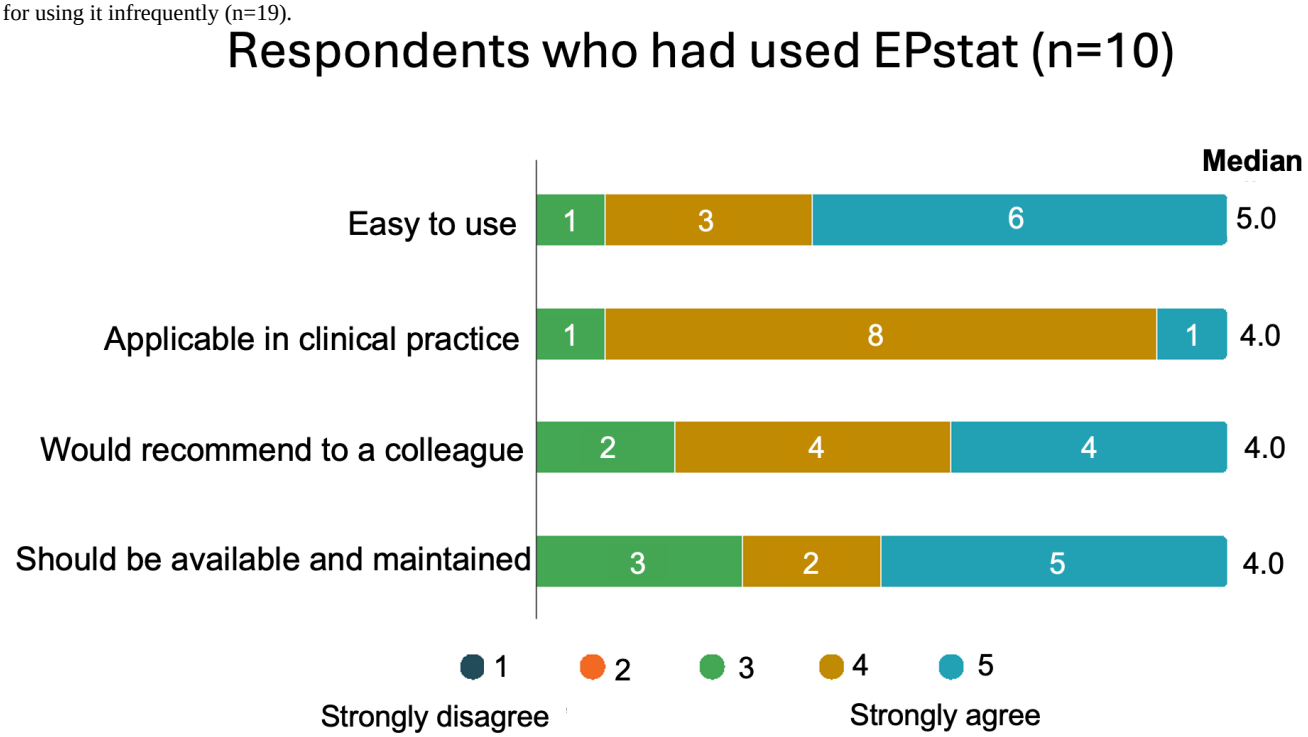
platform to a colleague (median 4, IQR 4 - 5) and support for its continued availability (median 4.5, IQR 3 - 5) was also positively rated on the same scale (Figure 2). In total, 20% (2/10) of the respondents who had used it indicated that the platform had influenced their choice of ASM. Among those who had heard of the resource but had not used it, forgetfulness was cited as the primary reason by 58% (11/19), that the results did not differ from routine clinical practice by 21% (4/19), that Epstat was used as much as needed by 10.5% (2/10).

Figure 2. (A) Survey responses from 10 physicians who used EPstat, rating their agreement with statements about the platform's ease of use and usefulness on a scale from 1 to 5. (B) Distribution of the survey responses from the physicians who indicated their primary reason for not using EPstat or for using it infrequently (n=19).



The questionnaire also included 1 free-text question about anything they felt was missing in EPstat and another for additional comments or feedback. However, there were only 2 responses to these questions, both specifying why the respondent had not used the platform. The first respondent mentioned forgetfulness and time constraints, whereas the second noted that EPstat was probably a helpful tool but that they had not encountered the right situations to use it.

Workshops

We conducted 3 workshops with a total of 10 participants representing 4 different neurology clinics (the tertiary center and 3 regional hospitals). Table 1 provides a summary of the feedback and identified themes. Participants generally found the platform easy to use and appreciated its appearance. However, several reported that they felt that the information provided was too basic, especially for experienced specialists. Challenges typically only arise after selecting the third or subsequent ASMs or when typical first-line drugs are unsuitable. They also observed that lamotrigine was usually the drug with the highest retention regardless of age group and other characteristics, which limited the need to visit the platform regularly. It was suggested that the platform might be more beneficial for junior physicians.

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Table . Summary of feedback and identified themes from the workshops. The themes are listed in order of perceived prominence in the discussions.

Theme	Included codes	Summary
Expand data scope	Combination therapy, comorbidities, compliance, detailed patient stratification, discontinuation reasons, efficacy statistics, generalized epilepsy, less common ASMs[a], longer retention rates, more recent data, and third ASM data	Include retention data on third ASMs and combination therapies; update the tool with recent information; provide data on long-term retention; and incorporate data on epilepsy type, various comorbidities, and characteristics that may influence drug suitability to allow for detailed patient stratification. Participants also requested information on reasons for drug discontinuation, including inefficacy, side effects, and reduced compliance.
Expand drug information	Drug information, drug interactions, pregnancy risk, seizure recurrence risk, serum concentration, side effects, steady state, and treatment guide	Include information regarding the most clinically relevant side effects and drug-drug interactions, as well as target ranges (trough levels) and timing for blood concentration tests. Participants were also interested in pregnancy-related drug information and the risk of recurrent seizures and whether it varied between different ASMs. Others advocated for a more comprehensive treatment guide with all relevant drug information compiled.
Accessibility and usability	Accessibility, data presentation, direct link in EHR[b], exclude drugs, mobile app, retention graphs, and visual design	Ensure that the tool can be found via search engines or integrated directly into the electronic medical record system. Several participants suggested developing a mobile app version. Data could be presented in graphs, and the visual design could be improved with a more interesting color scheme, possibly allowing users to pick their preferred scheme. Additionally, the ability to exclude selected drugs would be a valuable feature.
General epilepsy educational resources	Basic epilepsy information, diagnostic guide, epilepsy surgery, guidelines, and link compilation	Include basic epilepsy information tailored to junior physicians; a diagnostic guide for identifying and classifying seizure types; and a collection of educational links to reputable sources, including current guidelines.
Practical tools for clinical use	Patient information, patient logging, prediction tool, and titration plans	Include printable patient information and standardized titration plans that can be copied and pasted. There were also suggestions for an additional feature in which patients could log seizures and side effects.
Limitations	Junior physicians, lack of resolution, misinterpretation risk, and too basic	Several participants considered the information provided too basic for their needs; there were suggestions that it might be more useful for junior physicians. Some thought that the recommendations lacked resolution, causing them to rely on other individual factors when making decisions. Additionally, overly stratifying the information could generate strange results that might be misinterpreted.
Promotion and stakeholder involvement	Involve epilepsy process team, local guidelines, promotion, and promotion to junior physicians	Suggestions included involving the regional epilepsy process team, adding information about EPstat to local guidelines for new-onset epilepsy consultations, promoting the tool during continuing education, and targeting advertisements to junior physicians.

[a]ASM: antiseizure medication.

[b]EHR: electronic health record.

Notably, requests for information on combination therapy retention and third ASM data (under the “Expand data scope” theme), information on drug interactions and side effects (under the “Expand drug information” theme), and a link compilation (under the “General epilepsy educational resources” theme) were consistently suggested during all 3 workshops. Other

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common suggestions discussed during at least 2 workshops included incorporating general and drug-specific patient information for printing and copying, compiling general epilepsy information, increasing accessibility by making the platform searchable through Google or other search engines, or developing an app.

Discussion

We used a multicenter mixed methods approach to investigate how physicians experienced EPstat. Few had used it, but those who had generally perceived the platform as clinically relevant and backed its continued availability, indicating that the concept of a web-based resource to support ASM selection was well received. Notably, 2 of 10 users stated that the platform had impacted their ASM choice. However, despite the high ratings in the survey, several workshop participants thought that the information provided was too basic for a specialist's needs and requested additional information on subsequent ASMs and combination therapy and the possibility of a more detailed stratification. They also asked for further drug information; general educational resources; and other practical resources, including patient information and standardized treatment titration schedules. Participants considered accessibility to the platform to be low and suggested that the site should be searchable online or accessible via a mobile app.

The suggestions of a gap between the platform's current content and the needs of experienced clinicians are interesting. While several participants felt that the information provided did not differ from clinical routine, there is recent observational evidence suggesting that lamotrigine, the drug with the highest real-world retention in most subgroups, is only prescribed as the first choice in approximately one-third of all cases in our region. Therefore, it is possible that information perceived as basic could still improve management. Moreover, while there were requests for more advanced data, some participants also suggested adding information on fundamental concepts, illustrating the diverse needs among users. It is interesting that only 7% (2/27) of the respondents indicated that EPstat had an influence on their clinical decisions. This could represent early-stage barriers but also that EPstat provides information supporting routine practice. Most early users are probably epilepsy-interested physicians who know treatment guidelines, and for them, EPstat offers limited new information. As we only introduced data until 2019, there are also intrinsic limitations—we could only include older ASMs that have been on the market for a long time. As register data grow, EPstat will be able to provide information on newer ASMs. For instance, we have recently published a new retention rate study on data until 2023 [16], and these data will be incorporated into new EPstat versions. In this new version, there are enough data points to offer statistics on retention of new ASMs such as lacosamide and brivaracetam, so we hope that EPstat will be perceived as more informative for clinical decisions in the future. We also hope that EPstat will be increasingly used by junior physicians and physicians not experienced in epilepsy (the tool is now introduced in local guidelines as a resource). The survey responses indicated that forgetting about the existence of EPstat was a major reason for nonuse, so better marketing and prompting is also important. The restricted access (only within the health care provider network) could be another factor, but the effect should be minor as all outpatient rooms have permanent in-network computers that are used during patient visits for electronic health records and prescriptions.

In hindsight, it would probably have been advantageous to conduct even more participatory research in the design of EPstat. Although we did reach out to clinicians and conducted interviews during the development, we could have added other features that could have served as attractants (patient information leaflets on risk mitigation for printing, national guidelines, or similar resources). With regard to actual participatory research—involving citizens and patients—the EPstat development could also have been designed in a better manner. Culture may well be an important factor in this case; we did identify patients as stakeholders at the start of the project and had meetings with the local patient organization during development, and the reception of the tool was generally positive, the framing being that it is good if all patients in our large health region receive their selected epilepsy medication on a similar basis. EPstat was perceived as an effort to enhance the quality of care outside tertiary centers. However, Swedish health care is very strict on equality between different diseases and patient groups, and there is no strong tradition of involving stakeholders in a manner similar to other countries, where patient organizations or charities can be more directly involved. In later stages of the project, we encouraged physicians to use EPstat in patient discussions—when the patient and physician decide on which drug to choose (generally a shared decision). Thus, later in the project, patients became target users, and it would have been better to involve them as participants earlier in the project. In participatory framework terminology [17], their level of involvement in this study was low (informing). For future versions or similar endeavors, a higher level of participation (partnership) could be achieved through earlier involvement of patients and their representatives and by allocating more resources to that involvement. A higher degree of participation could probably help in disseminating EPstat use; patient questions could, for instance, spur physician engagement with the tool.

EPstat is the first clinical tool to use real-world data as feedback to support physicians in selecting ASMs. A similar tool, EpiPick, uses an algorithm that uses input from expert consensus to provide tailored ASM recommendations. The recommendations of both tools often align [12], and both contribute valuable information for clinicians. However, as the data provided by EPstat reflect actual patient outcomes, we believe that they provide complementary insights compared to expert opinions, which may be more theoretical. EPstat also offers the potential advantage of feedback from continuous health care updates from the country where the physicians practice.

When interpreting the feedback from the workshops, it becomes clear that participants want EPstat to evolve into an epilepsy go-to hub that incorporates both real-world treatment retention data and a wide range of other information. They suggested several fitting additions, such as general drug information on potential side effects, drug-drug interactions, target ranges and timing of blood concentration tests, and pregnancy-related

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considerations, as well as general epilepsy educational resources and patient information. However, several suggested improvements under the "Expand data scope" theme, which was prominent in the discussions, cannot be addressed as easily. Prescription data have inherent limitations, making distinguishing between monotherapy and polytherapy in the context of multiple dispensed ASMs challenging. While it may be possible to include retention data on the third and subsequent ASMs, validation against medical records would likely be necessary to confirm accuracy. More detailed patient stratification may also be possible, but administrative data typically lack disease-specific details, for example, on epilepsy severity, and some comorbidities, such as some psychiatric disorders and vascular risk factors, have low sensitivity in the national registers due to primarily being managed in primary care.

This study's strengths lie in the active involvement of clinicians, ensuring that platform development was user-centered, and the multicenter mixed methods approach, gathering both quantitative and qualitative insights into EPstat's usefulness and potential for improvement. The main limitation is the small sample of survey respondents. There was probably nonresponse bias in that nonresponders may be different from responders. While this is acceptable for a qualitative analysis, it clearly affects generalizability. The small sample also limits analysis of variations within the data. To partly counter this, and because the investigators mainly have a tertiary center perspective, we conducted the workshops and made sure to recruit participants representing multiple clinics in our region. As the project progresses, larger evaluations are needed with methodological improvement. Additionally, the survey instrument was not formally validated; however, we believe that the questions were intuitive and easy for our colleagues to understand. We would also like to conduct larger and even more representative qualitative workshops with improved sampling of participants and content coded and thematically analyzed in a systematic manner. Such workshops are under preparation together with an external partner evaluating health care digitalization.

EPstat is a digital and data-driven decision support tool and, thus, is similar to future possible AI tools (trained on patient data but then generating their own suggested clinical decisions). Although it is technically distinct from such solutions, EPstat can clearly provide insights on user adaptation and how such tools will be received by health services. Therefore, experiences from the introduction of EPstat, we hope, are likely to provide information that is valuable for the introduction of AI tools. Specifically in epilepsy, it may also be useful as a platform for distribution of such tools.

In conclusion, this study highlights EPstat's potential to improve epilepsy care in general and ASM selection in particular. This is also the first example of big data being looped back to the clinic to improve decision-making, making it conceptually interesting. Survey respondents generally perceived the platform as user-friendly and relevant, but only a few had tried it—which is an important lesson for the future development of tools, including AI, that provide decision support. To make the platform more appealing and attract more users, the current offering could be expanded; easily accomplished additions would be to provide summaries of important drug information and checklists for epilepsy management. Long-term sustainability would require an automatic (or semiautomatic) feedback process with continuous updates to maintain the platform's relevance. Other potential long-term developments include broadening the scope of the data to encompass the third ASM and incorporating data from neighboring countries with comparable data sources. Important next steps will be a sustainable ownership and integration into the electronic health record system in the region. Mobile access is another important step as sometimes ASMs are recommended by neurologists being called for advice by physicians in other specialties (not neurology outpatient clinics). Cross-national data linkage would be a significant advantage if it could be achieved—vastly increasing the precision of the calculated retention rates and providing more rapid information on early use of new ASMs; if a drug is very well retained, that would become evident faster if many countries contributed with data. In 2025, we started a regional awareness campaign and investigation of how the ASM prescription pattern changed since EPstat's initial launch. If this provides proof of impact, development will continue.

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Data Availability

The datasets generated or analyzed during this study are available from the corresponding author on reasonable request.

Authors' Contributions

Conceptualization: JZ

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Formal analysis: DL, JZ
Investigation: AI, DL
Methodology: AI, DL, JZ
Software: SH
Supervision: JZ
Visualization: DL
Writing—original draft: DL
Writing—review and editing: AI, DL, SH, JZ
JZ serves as the guarantor for this study.

Conflicts of Interest

JZ has received speaker and advisory board honoraria from UCB, Eisai, Angelini Pharma, and Orion Pharma and, as an employee of Sahlgrenska University Hospital (without compensation), has been an investigator in clinical trials sponsored by Bial, UCB, SK Life Science, Angelini Pharma, and GW Pharmaceuticals. All other authors declare no other conflicts of interest.

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Abbreviations

ASM: antiseizure medication

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Community Participatory Co-Design and Development of a Digital Diabetes Prevention Education Program for Hispanic Families With Obesity: Mixed Methods Study

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Abstract

Background: Digital health interventions (DHIs) can extend the reach of disease prevention interventions; however, few are evidence-based, theoretically grounded, or developed for high-risk youth and families. Co-design approaches engage end users in the design and development of the DHI, which can lead to increased accessibility and engagement.

Objective: This study aimed to describe the adaptation of an evidence-based diabetes prevention program for remote, digital delivery.

Methods: The adaptation of the in-person intervention was guided by a modified Inclusive Digital Health Intervention Design to Promote Health Equity framework and conducted in collaboration with Hispanic adolescents (n=23) with obesity (BMI ≥95th percentile) and their parents (n=15). Focus groups identified digital, health education, and support needs. An expert and community panel assisted in developing solutions based on these findings. A sample content session with a food tasting experience was created and reviewed by participants. The research team subsequently built a digital platform to host the content. Participants assessed the usability of the platform, including the ease of use, design components, and technical issues. A second meeting of the expert panel provided recommendations for further refinement and feedback.

Results: Findings from focus groups indicated that most participants (31/36, 86.1%) reported stable internet access and multiple digital devices. With regard to format, a few parents (2/9, 22.2%) preferred synchronous content sessions, while most youth and parents favored asynchronous sessions (7/9, 77.8%) lasting 40 to 60 minutes. Health education needs included interactive content, healthy recipes, and the ability to ask questions. Experts suggested offering asynchronous sessions with monthly synchronous meetings to meet both parent and youth needs. After viewing a sample session, families found the content easy to understand and mostly engaging, with (17/21) 81% participating in the food tasting activity and all participants reporting that the activity was feasible. Experts recommended using a more conversational, interactive teaching style to improve the content and using a food box with nonperishable items to increase the ease of food tasting activities. While the digital platform was functional and easy to use, families highlighted the need for larger font and icon sizes, easier navigation, and better color contrasts. On the basis of this feedback, experts advised creating tutorial videos and an orientation session for platform training. The content and platform will continue to be refined before further evaluation in a 12-week feasibility pilot study.

Conclusions: The use of a co-design approach provided opportunities to make content more interactive and engaging and to increase the ease of use of the digital platform. Describing the adaptation process using a guiding framework in collaboration with the focus population will inform future studies aiming to adapt evidence-based interventions to a digital platform.

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KEYWORDS

digital health; Hispanic health; diabetes prevention; family-based intervention; digital education; obesity; digital health intervention; disease prevention; diabetes; DM; diabetes mellitus; type 2 diabetes; type 1 diabetes; endocrinology; adolescents; digital devices; digital platform; feasibility pilot study; evidence-based interventions

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Introduction

The rapid advancement of digital technology in the health sector has led to developments promising enhanced interventions, increased patient engagement, and improved outcomes [1]. Digital health interventions (DHIs) that are thoughtfully designed, equitably implemented, and effectively used have the potential to address health disparities and build equitable disease prevention solutions. For example, Hispanic youth are disproportionately affected by obesity and consequently are the most insulin-resistant pediatric subgroup in the United States [2,3]. DHIs are especially promising for today's youth, who are digital forerunners with more exposure to and use of digital technology compared to previous generations [4]. Smartphone ownership among Hispanic youth is comparable to that of non-Hispanic White youth (95% vs 94%); adolescents are the highest users of SMS text messaging, averaging 60 messages a day; and nearly two-thirds of adolescents report using a smartphone app to support changes in diet or physical activity [5]. These digital tools are familiar, relevant, and potentially cost-effective, given the high rate at which they are currently owned and used by youth across sociodemographic levels. However, there are many digital tools and services in the marketplace that are not developed with the guidance of health behavior change experts, nor are they evidence-based, limiting their ability to lead to clinically meaningful changes in disease outcomes [6-8].

In addition to the need for more evidence-based DHIs, there is also a need for DHIs with equitable design and access, especially among high-risk populations [7]. Apart from access to digital tools and services, engagement in DHIs also requires a high level of digital literacy and self-efficacy [9,10]. For DHIs to be effective, individual- and environment-level digital determinants must be considered, such as design needs, user preferences, and community infrastructure available among the focus population [11,12]. One strategy for establishing equitable access and identifying the individual and environmental determinants that impact engagement and participation in DHIs is to collaborate with the end user in the design and development process. Using community-engaged strategies to foster collaboration with the end user can assist in the development of DHIs that integrate the end user's background and contextual determinants into the design and implementation of the program [13]. Without equitable design and access, digital health strategies can potentially contribute to and exacerbate health and digital disparities [9,10]. Unfortunately, few studies have engaged youth in the design and development process, and few DHIs have been developed and tested among Hispanic youth [9,10].

To address current limitations in DHIs and digital equity, there is a need for more evidence-based solutions that are co-designed with the focus population. To date, only one culturally grounded, family-based type 2 diabetes (T2D) prevention program has been developed and rigorously tested among Hispanic adolescents and families [14-16]. This study was developed using core constructs of the national diabetes prevention program and has demonstrated feasibility, acceptability, and efficacy for improving insulin sensitivity, adiposity, and delaying the onset of T2D when implemented in a community setting [15,17]. The purpose of this study was to adapt an evidence-based diabetes prevention program for remote, digital delivery among Hispanic adolescents with obesity and their families. The objective of this manuscript was to describe the use of community-engaged strategies to guide the adaptation process to ensure that the adapted DHI is co-designed with Hispanic youth and meets the health and digital needs of high-risk Hispanic youth and families. By detailing the adaptation process, this manuscript will inform future studies aimed at adapting evidence-based disease prevention programs in collaboration with the focus population for delivery via digital tools and services.

Methods

Participants

Participants were recruited from the greater Houston metropolitan area through collaborations with local pediatric clinics (5/36, 13.8%), the United States Department of Agriculture Children's Nutrition Research Center volunteer research database (3/36, 8.3%), community organizations (21/36, 58.3%), and word of mouth (7/36, 19.4%). Interested participants were screened for inclusion and exclusion criteria via telephone. Participants met the inclusion criteria if they self-identified as Hispanic or Latino, had obesity (BMI ≥95th percentile and <120% of the 95th), were between the ages of 14 and 16 years, and owned a mobile smartphone. Participants were excluded if they had a diagnosis of T2D, were taking medication, or had received a previous diagnosis of a condition that influences activity, sleep, or cognition. Families were informed that this study included a series of 3 community-engaged activities. All participants were invited to all 3 community-engaged activities; however, families were also informed that participation was voluntary and that they could participate in as many or as few activities as they desired.

Ethical Considerations

The study protocol and all study-related materials were approved by the Institutional Review Board at Baylor College of Medicine (H-50331). Before any study procedures, trained research team members obtained written parental consent and child assent. All study-related documents were available in English and Spanish, with bilingual or bicultural research staff administering consent, conducting data collection, and answering questions. Participants were informed that their participation was voluntary, and they were free to withdraw from the study at any time. Participants were also informed that nonparticipation would not affect any health or medical services they currently receive and that confidentiality would be maintained using unique identification numbers and a password-protected database. This study is registered at ClinicalTrials.gov (identifier: NCT06943001). Participants were compensated US $25 for participation in virtual focus groups and surveys and US $30 for the in-person think-aloud assessment.

Evidence-Based Intervention

The evidence-based intervention to be adapted in this study draws from the national Diabetes Prevention Program (DPP). Using a rigorous process, core constructs from the DPP were

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culturally grounded and tailored for Hispanic youth and families in collaboration with community stakeholders [18]. The resulting nutrition and well-being curriculum includes 12 family-based, group sessions (Table 1). Sessions are adapted to meet the developmental needs of adolescents and to integrate Hispanic cultural values such as *respeto* (respect) and *familismo* (familism). For example, the value and importance of family are emphasized throughout the curriculum, and family-focused "homework" assignments are included, such as preparing a healthy meal together or going on a walk as a family [16]. Traditionally, the intervention is delivered in person by bilingual or bicultural implementers in 1-hour sessions, once a week. The intervention promotes changes in diet and physical activity by fostering social support and enhancing self-efficacy within families, between participating families, and among families and the implementers. Every session begins with a tasting experience in which youth and families are exposed to a healthy snack and are encouraged to engage in mindful eating practices. Every session has 30 to 40 minutes of nutrition education content with clear learning objectives, and the content builds continuously from week to week. At the end of each session, families are encouraged to set a behavior change goal that is specific, measurable, achievable, relevant, and time-bound (SMART). Time is also allotted for families to discuss and share information on successes and challenges with their behavior change goals [10,16,17].

Table . Curriculum topics.

Topic number	Topic
1	Getting started
2	Health awareness
3	Roles and responsibilities
4	Keep it moving
5	How sweet are you?
6	Champions with breakfast
7	Slim the fat
8	Fast food
9	Snack attack
10	Stay strong
11	Self-esteem
12	Balancing act

Adaptation Framework

Co-Design Framework

To adapt the in-person intervention for delivery via a remote, digital platform, we used a modified version of the Inclusive Digital Health Intervention Design to Promote Health Equity or iDesign framework (Figure 1). This framework was selected as it centers on the needs, values, and preferences of the end user. iDesign provides a structured framework for guiding the design of DHIs by applying community-engaged principles, including the end user, and addressing challenges in engaging diverse populations [19]. To fulfill the objective of this study, we used the 7 steps within the iDesign framework to guide the adaptation process. The study activities performed in each step are described in the following sections.

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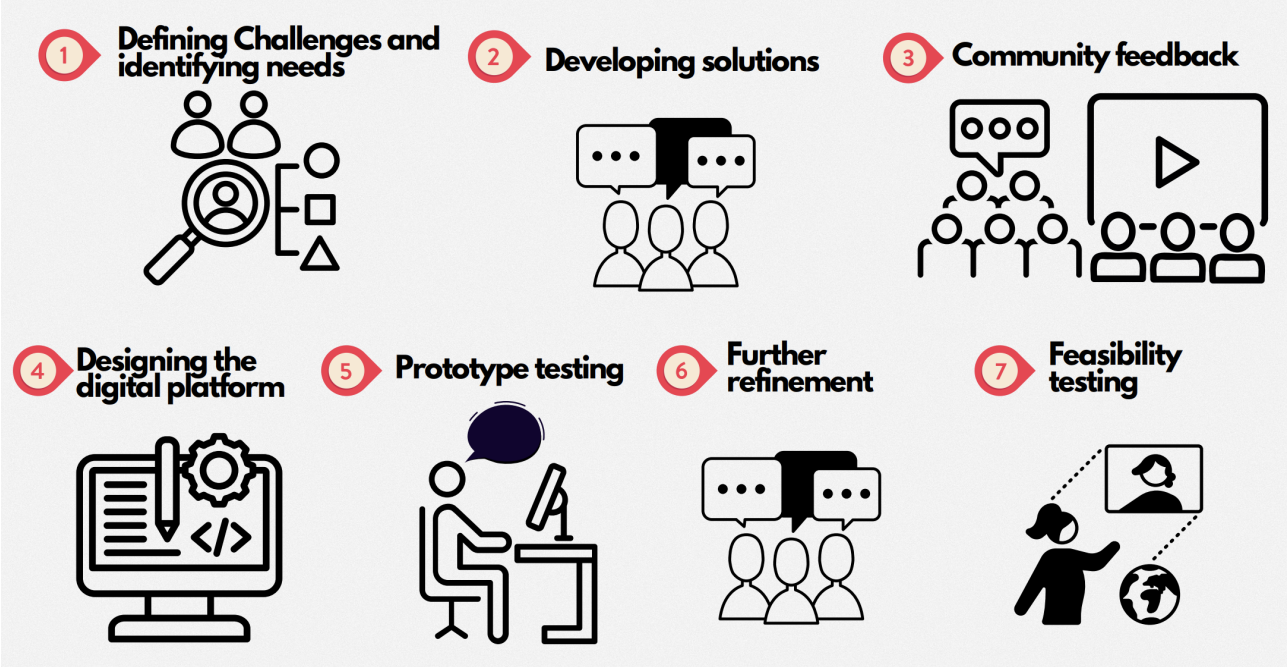
Figure 1. Modified inclusive digital health intervention design to promote health equity framework.



Step 1: Defining Challenges and Identifying Needs

In step 1, youth (n=12) and parents (n=9) were invited to participate in separate focus groups (n=5 per group), which took place via a private, secure Zoom link (Zoom Communications, Inc) or at a convenient community location from November 2022 to January 2023. Focus groups were audio recorded to capture community input. Following the focus groups, youth (n=15) were invited to participate in an interactive survey. This survey included multiple-choice and short-answer questions. Using an audio recording function, participants could respond to short-answer questions to provide narrative responses. This was done to obtain in-depth information while removing the burden of writing out their answers. The goal of the focus groups and the interactive survey was to elicit information on the (1) preferred format and timing of intervention sessions, (2) diet and physical activity education needs, (3) technology within the home environment, (4) guidance on adapting in-person activities to a digital platform, and (5) strategies for making the intervention engaging and fun for youth. Data collected from step 1 were analyzed and used to develop a report.

Step 2: Developing Solutions

In step 2, a 1.5-hour workshop-style meeting was conducted with a panel of experts (n=5) in May 2023. Experts consisted of medical and research professionals with experience and expertise in pediatrics, endocrinology, community-engaged research, diabetes prevention, and digital health. The data report from step 1 was presented to the expert panel. The goal of this meeting was to obtain feedback on data from step 1 and to brainstorm solutions for key needs and barriers expressed by participants, including (1) the format of the digital intervention, (2) family engagement and interaction, and (3) strategies for meeting the health education needs of families. Feedback on these key areas was added to the data report and used to develop a preliminary plan for adapting the evidence-based intervention. The preliminary adaptation plan was sent to 2 community health experts who led the development of and currently implement the original curriculum in community and clinic settings. The community health experts were asked to ensure that key components within the intervention were retained while integrating new adaptations to meet family preferences and needs expressed in the focus group.

Step 3: Community Feedback

In step 3, feedback from research and community experts was used to develop and record a sample nutrition education and wellness session. Most of the families (n=16) were invited to watch the sample session from their home environment and were asked to complete an evaluation survey following their viewing (Multimedia Appendix 1). Two families (n=5) were asked to attend a live viewing of the sample session via Zoom, with the research team in attendance. Following the live viewing, a focus group was conducted among participants to elicit more in-depth feedback on the session content, the level of engagement of the content, the evaluation of the teaching style, and perceptions of the length of the session and to elicit suggestions for improvement. This focus group was audio recorded to fully capture feedback on the sample session. Families that attended the live viewing were also asked to complete an evaluation survey following their viewing.

Step 4: Designing the Digital Platform

In step 4, the research team focused on developing an online learning platform that could meet the needs that were discussed in step 1. The initial features considered in the design of the digital online platform included hosting video content, the ability to upload additional resources such as PDFs, a messaging system to ask questions regarding educational content and report technical issues, and a platform that could be password protected to maintain participant confidentiality. On the basis of counsel from the expert panels, we focused on a platform that could measure metrics associated with participant engagement (eg, interactions with content, logins, and activities completed).

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Step 5: Prototype Testing

In step 5, youth and families from step 1 were invited to participate in a "think-aloud" assessment using a prototype of the platform. Four adults and 4 teens participated in this assessment. Parents were asked to complete the assessment on a laptop computer, while youth were asked to complete the assessment on their own mobile smartphone to test the usability on both types of devices. Participants were given 15 minutes to complete six tasks: (1) navigate to the website, (2) create an account with a username and password, (3) watch a sample from lesson one (2 min), (4) complete a brief activity for lesson 1, (5) post their activity answers on the discussion board, and (6) use the "Ask the Instructor" feature to ask a nutrition-related question from the video. Using the "think-aloud" approach, participants were asked to voice their thoughts while performing the 6 tasks. Research team members observed participants while they completed the assessment and rated the degree to which participants completed every task and noted comments made by participants. Immediately following the assessment, parents and teens were engaged in a follow-up focus group to elicit feedback on how to improve the design, ease of use, and functionality of the platform. Research team members also asked questions about tasks that seemed difficult to complete, comments that were made during the assessment that needed clarification, and other observations made during the assessment.

Step 6: Further Refinement

In step 6, another 1.5-hour workshop-style meeting was conducted via Zoom with our panel of research experts in May 2024. The purpose of this meeting was to review findings from the "think-aloud" assessment and allow the expert panel to make additional recommendations for improving the design and usability of the digital platform.

Step 7: Feasibility Testing (Future)

In preparation for this step, we will prepare for the implementation of a 12-week feasibility pilot study by incorporating all the feedback gained throughout the previous steps into the development of the digital diabetes program. This includes modifying the learning platform and filming and recording all nutrition education and wellness sessions in English and Spanish. Feasibility testing will be conducted in a larger group of patients (n=48).

Results

Step 1 Results

Audio from focus groups was transcribed using a medical professional transcription company, and data gathered from focus groups and interactive surveys were coded by 2 trained, independent coders and were qualitatively analyzed using NVivo version 9 (QSR International). Thematic content analysis was used to identify emergent patterns and insights from focus groups and interactive surveys. Findings from the focus groups and interactive surveys revealed the desired format of the digital intervention, health education, and technology needs of Hispanic youth and families. With regard to the format of intervention sessions, most participants (27/36, 75%) preferred virtual, asynchronous sessions compared to hybrid (asynchronous or synchronous; 5/36, 13.9%) or synchronous (4/36, 11.1%) sessions. Those desiring hybrid or synchronous sessions were mostly parents. They expressed that they perceived these format styles as providing more accountability for program attendance and engagement. In contrast, youth primarily preferred asynchronous sessions, stating that it can feel uncomfortable to discuss health-related topics in front of other participants. The recommended length of intervention sessions was 40 to 60 minutes. When asked about factors that make it challenging to attend intervention sessions, most families felt that schedule conflicts and other household responsibilities (eg, cleaning and cooking) could be potential barriers. Suggestions for making intervention sessions engaging included having activities (eg, worksheets, meal planning, and games) and making the content interactive with quizzes and fun facts. The original intervention included a tasting experience where families were provided with a small, healthy snack to taste, with the purpose of exposing them to potentially new fruits or vegetables or new recipe ideas. When asked about the feasibility of conducting the tasting experience on their own at home, almost all participants (34/36, 94.4%) expressed that they preferred to conduct the tasting experience at home. Perceived barriers included not having all the ingredients or cooking equipment needed, the need for simple instructions, and having a busy schedule with little time for complicated recipes or additional grocery shopping. Facilitators of conducting the tasting experience on their own included having a planned schedule of recipes at the beginning of the intervention, so that they could be prepared, having the entire family participate and help prepare the food items, providing a gift card for the food items needed, and having instructional videos to demonstrate the recipes. With regard to their health education needs, families shared that it would be important to be able to ask questions about the content. They also expressed the desire to receive suggestions for healthy meals and snacks. When asked about the best digital format for asking questions, 52.7% (19/36) of participants preferred a discussion board, and 33.3% (12/36) recommended using SMS text messaging to send questions to the research team, with few respondents selecting email or social media. To further evaluate accessibility, we asked families if they would need access to the internet or digital devices to participate. While 83.1% (31/36) of participants reported that they have reliable internet connectivity and access to multiple internet-connected digital devices, 16.6% (6/36) were not sure. Further discussion revealed that families who were not sure felt that there might not be enough devices in the household for all family members to participate in the program.

Step 2 Results

Given mixed findings regarding the session format, research and community experts recommended asynchronous intervention sessions as well as monthly, live synchronous sessions. The purpose of having asynchronous sessions would be to add flexibility, given that schedule conflicts are a common barrier to participation. It was recommended that synchronous sessions should focus solely on providing a platform for asking questions about the nutrition education content as well as fostering discussion around successes and challenges with progress toward behavioral goals to meet needs for engagement and

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accountability. This may also foster social support and relatedness between families. On the basis of the experience of the expert panel, it was suggested that live, synchronous sessions be conducted separately for parents and youth. This would make it more comfortable for youth and parents to ask questions and discuss sensitive topics. When discussing feedback on making the intervention engaging, community experts shared the importance of setting the tone for engagement by hosting an orientation session where families are informed of expectations, given clear instructions on how to complete intervention activities, and provided a call to action, encouraging the whole family to commit to supporting and working together on this journey. Other strategies that have been successful in increasing engagement include small incentives for completing intervention activities such as raffle prizes, movie tickets, and small exercise resources (eg, jump ropes, yoga mat, and resistance bands). With regard to adapting the food tasting experience, community experts had previous experience using gift cards for the food experience and found that few participants followed through with making the recipe on their own. Other members of the expert panel shared past experiences using a food box given to families at the beginning of the intervention. Panel members recommended that we test an adapted version of the food experience to gather more information on the feasibility of families completing this activity on their own. It was also suggested that we develop a space on the digital platform to provide additional recipes to meet the need for healthy meal and snack ideas. Both panels advised that we should be responsive to the need for a discussion board to provide an additional platform for asking questions. In light of participant concerns that they may not have enough internet-connected devices, panel members also advised that our platform should be adaptable so that it can be easily viewed on multiple types of devices.

Step 3 Results

The sample intervention session included an adapted version of the food tasting experience to be conducted at home, education content, and time for setting a SMART goal. The sample session lasted 28 minutes. To participate in the food tasting experience in their home, all families were given instructions on preparing ingredients for a healthy snack of apples and peanut butter. The recorded session started with a demonstration of the food preparation, followed by a series of questions that encouraged mindful eating (1.5 min). The nutrition education content consisted of PowerPoint slides with one instructor delivering content (26.5 min). Slides were designed at a fourth- to sixth-grade reading level and included images and brief explanations, and participants were provided with an accompanying sample workbook that provided additional explanation of the education content and a SMART goal worksheet. Findings from the evaluation survey following the viewing of the sample session are presented in Table 2.

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Table . Community feedback on sample educational session (n=21).

Theme	Values, n (%)
Food experience	
Perceptions of food experience	
Liked the food experience	18 (81)
Neither liked nor disliked the food experience	1 (5)
Did not like the food experience	0 (0)
Did not participate	3 (14)
Willingness to participate in food experience	
Would be willing to make the food recipe every week	21 (100)
Would NOT be willing to make the food recipe every week	0 (0)
Barriers to food experience	
Difficulty getting ingredients	8 (38)
Time or schedule constraints	6 (29)
Nothing	7 (33)
Facilitators of food experience	
Deliver a weekly food box	8 (38)
Grocery store gift card	8 (38)
Pickup order at grocery store	5 (24)
Educational content	
Most liked session components	
Everything	4 (19)
Concepts or learning objectives	11 (52)
Visual aids or slides	4 (19)
Suggestions for improvement	
More engaging speakers	2 (10)
Shorter session	3 (14)
Perceptions of session length	
Too long	2 (10)
Just right	17 (81)
Too short	0 (0)
Perceptions of engagement	
The *overall session* was engaging	18 (86)
The *teachers* were engaging	17 (81)
The *activities* were engaging	17 (81)
Self-reported comprehension	
The session was easy to understand	18 (86)
The learning objectives were clear	21 (100)
The illustrations and examples were easy to comprehend	19 (90)
Perceptions of feasibility	
Very likely to participate in the full 12-wk program	16 (76)
Not sure if I would participate in the program	5 (24)
Not likely I would participate in the full 12-wk program	0 (0)

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Most participating families, except for 3, made the snack on their own (n=18/21; 85.7%); however, all participants reported that they were willing to participate in the tasting experience on their own. Once again, audio from focus groups was transcribed and coded using a thematic content analysis approach to identify emergent themes regarding feedback on the live session. The focus group discussion revisited potential challenges, which continued to include obtaining the ingredients and time constraints. However, some participants expressed that completing the tasting experience on their own would not be challenging. When presented with a list of cooking equipment, most families reported having access to the most common appliances and utensils, including measuring cups, a stove, a blender, a microwave, and cooking utensils, suggesting that access to cooking equipment was less likely to be a barrier. Recommended resources for making the tasting experience more feasible included a weekly box of food items, a gift card, and curbside pickup orders at the grocery store. Participating families reported that the content was easy to comprehend, the learning objectives were clear, and there was high agreement that the examples used to illustrate concepts were easy to understand. While some felt the session was too long, most felt the length was just right. Additionally, most participants felt that the content was engaging and that the health educator delivering the content was also mostly engaging. This feedback was used to adapt the sessions in the following ways: (1) session format was maintained as asynchronous, virtual; (2) families were provided with a food box containing nonperishable items (eg, peanut butter, tuna, and oatmeal), and the food tasting experience was limited to 4 sessions designed to be quick and made with affordable ingredients; (3) instructional delivery of the content was changed from 1 to 2 instructors who used conversational speech; (4) session length was kept at 30 minutes or shorter; and (5) activities were kept as central parts of sessions with clear instructions and cues from instructors on when and how to complete activities.

Step 4 Results

In collaboration with an online course platform, Learnworlds, we were able to design a website and accompanying mobile smartphone app to deliver the intervention. This platform is a password-protected website, and the app mirrors the website, allowing participants to seamlessly access content across multiple devices (eg, computer, tablet, and smartphone) and web browsers (eg, Google and Safari). This platform allows for content to be presented on demand but also allows for live sessions to be hosted by connecting a personal or institutional Zoom account to the eLearning platform. To address suggestions for engagement, Learnworlds facilitates the development of interactive session videos with features including pop-ups, animations, quiz questions, and subtitles to enhance comprehension. This platform is dual language, and participants can view the website as well as subtitles and content in English and Spanish. In response to feedback from participants, we designed additional pages within the website to host a discussion board, a digital e-workbook, healthy meal and snack recipes, and a closed-loop messaging system so that participants can ask the research team questions about the content or technical issues experienced. The discussion board has multiple channels and allows participants to post digital media. This will allow us to host a channel for discussing challenges and successes in achieving behavioral goals as well as other channels for posting activities, such as displaying recipes made or posting pictures of participants engaging in healthy behaviors, to foster engagement among participants. The digital workbook will mirror the physical workbook and provide an additional opportunity for participants to access program resources. In response to the need for healthy meal ideas, the research team developed a brief series of 4 food demonstration videos and used the recipes page to recommend meal and snack ideas that are healthy and culturally appropriate. To assess engagement, the Learnworlds dashboard provided the research team with metrics for each individual participant, including the number of logins, the amount of time spent on the platform per login, and the completion rate of each task (eg, minutes of a video session that were played).

Step 5 Results

Observations from trained research team members during the “think-aloud” assessment demonstrated that participants perceived the online learning platform to have moderate to high usability. Two parents failed to complete all 6 tasks within the time limit; however, they completed 4 of the 6 tasks (15 min). In contrast, youth participants completed all 6 assessment tasks within the time limit. Thematic content analysis in NVivo was used to identify common themes expressed by parents during the follow-up focus group and included difficulty in finding the login button (2/4, 50%, parents), finding course content (3/4, 75%, parents), and confusion about whether to fill out SMART goals in the digital workbook or in their paper workbook (2/4, 50% parents). Feedback obtained regarding the design of the platform mostly came from parents and included recommendations for increased font size, larger icons for sessions, more contrasting colors, larger tabs for additional pages, such as the discussion board, and creating multiple pathways for accessing the additional pages. Regarding functionality, participants felt that the digital workbook, which was uploaded in PDF form, should be more interactive and “fillable.” All other aspects of the platform functioned as designed.

Step 6 Results

After careful review of the results from the think-aloud assessment, expert panel members recommended that we develop tutorial videos that should be located on the landing page so that participants have a reference tool for logging in, navigating to session content, and asking questions. It was also suggested that a brief training be given at orientation before the intervention. In this meeting, we discussed any remaining items that had yet to be finalized, such as the tasting experience. The experts recommended that food tastings should be implemented monthly and that a food box with nonperishable food items should be given to families at the beginning of the intervention (eg, canned garbanzo beans for hummus, peanut butter, and tuna) to reduce financial and time burdens. The expert panel proposed that families should be awarded extra “points” for making additional recipes. Given that the discussion board allows for photos and the use of hashtags, it was suggested that

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we create a discussion board channel dedicated to sharing experiences in making and trying healthy recipes so that families can encourage each other toward healthy eating.

Step 7 Results

The feasibility pilot study to test the feasibility and acceptability of the digital diabetes prevention program began in October 2024. Feasibility criteria that were evaluated within the pilot include the following: (1) recruit 40 Hispanic adolescents aged 14 to 16 years; (2) retain 80% of participants for postassessments; (3) integrity of the study protocol defined as ≥70% completion of content sessions, Fitbit wear on ≥5 d/wk (Fitbit LLC) with response to 80% of text messages when prompted; (4) ≤10% technical issues; and (5) obtain ≥80% satisfaction from participants. After completion, we will continue to incorporate feedback from participants to iteratively refine this prevention program.

Discussion

Principal Findings

The COVID-19 pandemic accelerated the growth and implementation of telemedicine and the remote, digital delivery of behavioral health services. The Centers for Medicare & Medicaid Services temporarily changed federal and state health policies to expand access to telemedicine for all Medicare beneficiaries. These policy changes were extended through 2024, and it is believed that they may be extended in the future [20]. These types of policy changes could pave the way for disease prevention programs to be remotely delivered via digital platforms, making them more accessible and underscoring the need for evidence-based DHIs. However, there is a significant gap in the literature regarding frameworks and guidelines for adapting interventions to a digital format [21]. This study describes the process by which an existing, evidence-based diabetes prevention program for Hispanic youth and families was adapted for remote, digital delivery, using a co-design approach. Few studies have used similar qualitative and engagement strategies to co-design DHIs among adolescents, specifically Hispanic adolescents [22,23]. Use of the co-design approach provided novel insights and an in-depth description of the perceived needs, preferences, and contextual factors that impact participation in a digital diabetes prevention program among Hispanic youth and families.

The use of a co-design approach led to increased accessibility across several dimensions, including access to technology, usability of the platform, access to the information, which speaks to the user's ability to understand and comprehend health-related information in their language of preference, and the format and implementation of the program. This is consistent with a recent scoping review on DHIs for youth that reported high levels of acceptability and accessibility among studies that use collaborative development methods [22]. This program is accessible across multiple devices, many of which are already owned and operated by Hispanic families, to address concerns regarding limited devices. Selecting a dual-language platform and engaging end users in the evaluation of the platform and content worked to ensure that the platform is easy to use and that nutrition information is easy to comprehend [11]. A review of barriers and facilitators to accessibility in DHIs found that having digital tools available in the participant's first language is critical to increasing participation and engagement with intervention content [24]. The asynchronous format was selected to meet requests for flexibility to overcome time and schedule conflicts. Schedule conflicts and lack of program flexibility are consistently named among the most common reasons parents withdraw their children from traditional disease prevention interventions, making it important to provide a delivery format that meets the needs of our focus population [25]. It was of high importance, particularly among parents, to have the ability to ask questions, and several mechanisms were developed to provide this support, including live, synchronous sessions with instructors, a discussion board, and a closed-loop messaging system. Human support is a core component across most behavior change interventions, and previous studies have found that it is critical to retain modifications that still allow for guidance, support, and feedback after adaptations for digital delivery have been made [26].

In addition to accessibility, significant consideration was given to making sure that sessions were engaging [24]. This is consistent with other studies that have highlighted the importance of having engaging content, as digital strategies with low visual appeal or a lack of interactivity are seen as frustrating and boring [24]. Several interactive features were integrated into session videos (eg, quizzes), and the use of other components, such as the discussion board, will also encourage engagement between participants. These design elements, particularly games, challenges, and social elements, have been shown to enhance engagement [24]. It was also critical to the team to be able to assess engagement. With a user dashboard through the Learnworlds platform, all participant activity can be monitored in great detail, including the length of time participants engaged in a session video and the completion percentage of all activities. These types of engagement metrics will greatly contribute to understanding the feasibility and acceptability of using a digital learning platform for disease prevention. Additionally, engagement is tied to effectiveness, and therefore, more rigorous measures of participant engagement with digital tools can be used to understand efficacy within DHIs [27].

It is important to recognize that youth and parents reported different needs, preferences, and digital literacy skills. For example, some parents were more open to synchronous sessions, whereas all youth preferred asynchronous sessions. While all youth were able to easily complete tasks associated with the think-aloud assessment, parents found the tasks to be more challenging. Differences across age in needs and preferences for DHIs have been previously reported and are attributed to the fact that today's youth have an increased level of comfort with technology due to high exposure to technology from an early age, and they also exhibit an increased willingness to receive health benefits from digital health tools [28]. Low digital health literacy among adults, including the skills and knowledge needed to navigate digital tools, is a significant driver of poor engagement in DHIs, further warranting the use of co-design approaches to develop a feasible platform [29]. At times, it was challenging to balance the needs and preferences of youth and

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parents in the context of a family-based intervention, which is in line with best practices for disease prevention [30]. This led to decisions such as hosting live sessions separately for youth and parents, which may provide the opportunity to address separate needs.

Our study also demonstrates that some components within in-person interventions are more challenging than others to adapt for digital delivery, such as the food tasting experience. In the original intervention, this component was used to teach basic principles of hunger and fullness cues and mindful eating and to expose participants to new fruits and vegetables to encourage greater intake of healthy foods. This was a very acceptable and engaging component within the original intervention; however, adapting this component proved to be challenging. The new delivery context, such as a digital platform, can pose new challenges during the adaptation process, leading to the need to make adjustments based on the user's needs and preferences. Previous studies have reported that challenging adaptations within DHIs must be iteratively developed and tested to ensure that the "active ingredients" of the original intervention are retained and remain effective within the new digital context [31]. In this study, the use of the co-design process allowed us to work iteratively through a cycle of feedback between experts and community members until the most appropriate solution was identified.

Limitations

This study is not without limitations. Given the focus on high-risk Hispanic adolescents and families, our findings may have limited generalizability to other age groups or ethnic and racial subgroups. However, this framework can be used to adapt and co-design DHIs to meet the needs and preferences of other populations. Additionally, more research is needed to confirm that adapting DHIs using a co-design framework can improve the feasibility, acceptability, and efficacy of digital strategies. As this study progresses toward a feasibility pilot trial, the adaptations and decisions made through this co-design process will receive further testing and feedback from Hispanic youth and families, which will lead to additional refinements and provide evidence on the importance of engaging youth through co-design processes.

Conclusions

This study provides a framework for adapting an evidence-based diabetes prevention program for remote delivery via a digital platform. The use of a co-design approach served to increase the accessibility and engagement of the adapted digital intervention by informing the format, the design of the platform, and the design features. In addition to identifying the preferences and needs of the focus population for a digital disease prevention program, this study also highlighted challenges in adapting in-person interventions to a digital format. Certain components that were integral to the in-person intervention, such as the tasting experience, required greater input from end users and experts to adapt for remote delivery. This adaptation process was followed by a 12-week feasibility pilot to further assess the feasibility and acceptability of the digital diabetes prevention intervention. Describing the adaptation process in collaboration with end users will inform future studies aiming to adapt evidence-based interventions to a digital platform.

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Data Availability

The datasets generated or analyzed during this study are available from the corresponding author on reasonable request.

Authors' Contributions

SM and EGS conceptualized this manuscript and worked to adapt the framework. SM led the writing of this manuscript with supervision and collaboration from EGS. SM, MP, and LV contributed to data collection and the analysis of data. All other authors provided critical feedback and contributed to the final manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1
English sample session survey.
[DOCX File, 23 KB - formative_v10i1e67800_app1.docx]

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Abbreviations

DHI: digital health intervention
DPP: Diabetes Prevention Program
SMART: specific, measurable, achievable, relevant, and time-bound
T2D: type 2 diabetes

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Acceptance of Men Living With HIV Toward Treatment-Supportive Mobile Apps Using the Unified Theory of Acceptance and Use of Technology: Cross-Sectional Study

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Abstract

Background: Despite a 40-year prevalence of HIV, the AIDS epidemic prevails. Effective AIDS treatment requires specialist care and high adherence often hindered by structural issues in care access. Innovative eHealth solutions like treatment-supportive mobile apps can help address these issues. Successful implementation depends on user acceptance. Acceptance can be operationalized as behavioral intention and measured through the Unified Theory of Acceptance and Use of Technology (UTAUT).

Objective: This study examines the acceptance and its influencing factors of treatment-supportive mobile apps among men living with HIV.

Methods: A cross-sectional study was conducted among 172 men living with HIV between September 2021 and April 2024. In addition to the collection of sociodemographic, medical, and eHealth-related data, acceptance and its influencing factors were assessed by applying the UTAUT model. A multiple hierarchical regression analysis was conducted.

Results: High acceptance of treatment-supportive mobile apps in men living with HIV was reported by 45.3% (n=78) of the participants. Significant predictors of acceptance were age (β=−0.27; *P*<.001); health literacy regarding disease (β=0.11; *P*<.001); eHealth literacy (β=0.10; *P*=.001); internet anxiety (β=−0.18; *P*=.04); and the UTAUT predictors: effort expectancy (β=0.38; *P*<.001), performance expectancy (β=0.24; *P*<.001), and social influence (β=0.40; *P*<.001). The UTAUT model explained 72% of the variance in acceptance.

Conclusions: Since the acceptance of eHealth services is a reliable indicator of the actual usage behavior, the results of this study are a promising basis for the successful implementation of eHealth offerings in the group of men living with HIV.

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KEYWORDS

HIV; eHealth; mobile health; mHealth; mobile app; people living with HIV; telemedicine; Unified Theory of Acceptance and Use of Technology; UTAUT

Introduction

Background

Worldwide, 37.7 million people are infected with HIV [1]. Current statistical records show that HIV infection continues to be a globally significant disease. In Germany, the number of people living with HIV was approximately 97,000 in 2020 [2]. Complete elimination of the virus from the human body is not possible due to latent infection of cells, which have a long survival time in the body [3].

The supply of care for people living with HIV is fraught with several problems. Access to medical care is gradually deteriorating. Comprehensive medical coverage is difficult to provide for an aging population, as obstacles arise due to high costs and distances between patient and health care provider to be bridged [4]. In general, a trend toward urban oversupply in treatment options and rural undersupply becomes apparent [5,6].

Highly active antiretroviral therapy, a combination of several antiviral drugs that inhibit the replication of HIV, raises the life expectancy of people living with HIV to almost the same level as the general population if the therapy is effective [7,8]. The prescribed substances can have a variety of side effects, such

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as lipoatrophy, fat distribution disorders, liver dysfunction [9], or weight gain [10]. Nonadherence or inconsistent intake leads to disease progression in the vast majority of patients [11-13]. Previous work has shown that nonadherence can be caused by multiple factors such as forgetting to take medication or changes in daily routine [14]. Moreover, mental disorders are positively related to low adherence [15,16]. The prevalence of mental disorders [17,18] and incidences of suicides [19] in people living with HIV are higher compared to the general population.

eHealth describes applications that use the possibilities offered by modern information and communication technologies to support the treatment and care of patients. eHealth and mobile health (mHealth) are related concepts, with eHealth encompassing the broader use of digital technologies in health care, while mHealth refers specifically to the use of mobile devices to support medical and public health practice [20]. In terms of health-related outcomes in many mental and somatic disorders, eHealth interventions are effective options to support treatment [21-23]. Moreover, eHealth services are often less expensive and more flexible regarding time and location [24]. Medical care problems of people living with HIV are largely structural, stemming from systemic issues like stigma, limited health care access, and lack of integrated services [25]. Regarding the needs of people living with HIV, therefore, the implementation of eHealth technologies offers several advantages: they ensure care beyond direct contact with professionals [26], are less time-consuming and transport-intensive, and offer more flexibility [27]. Furthermore, they offer more privacy by avoiding social stigma and providing the possibility to discuss sensitive issues in a familiar, secure environment [28,29]. In addition, a study about a mobile app that allows virtual visitation of patients demonstrated that medical apps can greatly simplify patient contact [30].

The COVID-19 pandemic has opened the door to a groundbreaking revolution in eHealth services and has highlighted the importance of these innovative tools. The pandemic offered a unique opportunity to further develop and establish eHealth applications for people living with HIV [31].

Despite the aforementioned benefits, the implementation of eHealth applications in routine care has proven to be difficult [32]. Essential for the implementation of eHealth technologies is the target groups' intention to use them in the first place [33]. The acceptance of these offers can also be operationalized as intention to use such technologies [34], which makes acceptance a significant prerequisite for the successful implementation of eHealth technologies. Studies that were previously conducted to assess the acceptance of eHealth technologies among people living with HIV yielded mixed results: in an online multicenter study from France, 30.8% of respondents were eHealth skeptics and 69.2% were supporters [35]. Another study in two HIV clinics that provided telemedicine consultation during the pandemic found that about 58% of participants did not find the offer useful [27]. The spectrum of eHealth offerings is vast, so more complex assessments on influencing factors of acceptance are needed.

As men represent a significant proportion of the HIV-positive population, it is particularly important to assess their acceptance to eHealth applications. In many regions, men who have sex with men are infected with HIV at a higher rate than average rate compared to the rest of the population [36]. This group not only has a higher risk of HIV, but also tends to be underserved in traditional health care systems, as studies have shown that men are less likely to seek regular medical care [37].

These structural barriers result in structural deficits and undersupply among men living with HIV, which could be addressed effectively with eHealth technologies by offering flexible, low-threshold, and stigma-reduced options for care. Examining how well these technologies are accepted by men living with HIV is therefore essential for their effective implementation and for assessing their potential impact.

Previous studies have applied theoretical models to measure the acceptance of health technologies. The technology acceptance model [38] assumes that perceived usefulness and perceived ease of use determine the intention to use a technology. The Unified Theory of Acceptance and Use of Technology (UTAUT) [34] extends the technology acceptance model by integrating constructs from 8 acceptance models, including social influence and facilitating conditions. It states that acceptance is mainly influenced by the 3 core predictors: performance expectancy (PE), effort expectancy (EE), and social influence (SI) [34]. PE stands for the extent to which an individual believes he or she will benefit from using a technology. EE refers to the amount of effort an individual believes he or she has to expend to use a technology. SI describes the extent to which an individual believes that important people, such as friends or family, would approve of the use of a technology. Acceptance itself is operationalized as behavioral intention (BI) as the fourth parameter in the model. The UTAUT model has proven superior in predicting the BIs. The model has also been validated in the context of eHealth technologies [39] and has been applied multiple times in different samples [40-48] including studies focusing on men who have sex with men [49]. However, there is currently no validated assessment of the acceptance of eHealth technologies and its influencing factors among men living with HIV.

Objectives

The well-established and validated UTAUT model is applied and extended to assess possible influencing factors of acceptance beyond its 3 core predictors. While the original UTAUT model includes the 3 core predictors: PE, EE, and SI, the expanded UTAUT model additionally considers sociodemographic, medical, and eHealth-related factors. These include age, educational level, employment status, HIV-specific clinical markers, and previous experience with eHealth. It has been shown that the acceptance of digital health services is also influenced by structural, health-related, and technological factors [50,51]; therefore, the extended UTAUT model was applied in this study. By including additional parameters, we expect to capture a broader range of barriers and facilitators to the acceptance of telemedicine services, thereby reflecting the complexity of health care use among people with chronic conditions such as HIV.

This study aims to investigate the acceptance of treatment-supporting mobile apps among men with HIV using

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an extended version of UTAUT. In particular, the study has three objectives as follows:

1. To assess the general acceptance level of treatment-supporting mHealth apps in this population group.
2. To assess the extent to which the three core indicators of UTAUT (PE, EE, and SI) can predict acceptance.
3. To determine the additional contribution of sample-related factors, including sociodemographic characteristics, medical variables, health literacy, eHealth literacy, and internet anxiety, by explaining variations in acceptance beyond the core constructs of UTAUT.

By integrating these expanded predictors into the UTAUT framework, the study aims to provide a more comprehensive understanding of the determinants that influence adoption and support the targeted development of the user-centered digital health interventions for men living with HIV.

Methods

Ethical Considerations

The study was conducted in accordance with the Declaration of Helsinki and was approved by the ethics committee of the Medical Faculty of the University of Duisburg-Essen (19-89-47-BO). Electronic informed consent was mandatory to participate. Participation in the study was voluntary, data were anonymous, and no compensation was provided.

Study Design, Participants, and Procedure

A cross-sectional online-based survey study was conducted to examine the acceptance of treatment-supportive mobile apps in a convenience sample of men living with HIV. Recruitment was carried out via flyers and posters in centers specialized in HIV treatment and bars within the queer community in Germany, as well as posts made on HIV-specific social media channels and online support groups on Facebook. Data collection was conducted between September 2021 and April 2024. Participants with a diagnosed HIV infection, adult age (≤18 y), sufficient German language skills, and internet access were eligible for the study. The survey was conducted using the online platform Unipark [50]. Participation was voluntary and anonymous with no financial compensation being offered. Electronic informed consent was mandatory before starting the survey.

The average execution time of the survey was approximately 18 (SD 13) minutes. Out of 336 participants who initially started the survey, 191 completed the survey, which equals a completion rate of 56.8%. Furthermore, 19 participants were excluded because they did not meet the inclusion criteria (sex: male). Ultimately, 172 participants were included in the final data analysis.

Assessment Instruments

To address the research questions, the online survey contained items on sociodemographic characteristics, medical, and eHealth-related data. The study questionnaire was designed by experts from the fields of medicine, psychology, and eHealth and is provided in Multimedia Appendix 1. The primary outcome was acceptance, operationalized as BI, which was assessed via an adapted version of the UTAUT model [34].

Sociodemographic and Medical Data

Sociodemographic data were assessed using self-generated items and included age, sex, marital status, educational as well as occupational status, and place of residence (population size).

Medical history was queried via self-generated items toward duration of disease, hospitalizations, and comorbidities. Duration of disease was assessed by the item “How long have you known you are infected with HIV?” Responses were given in years as whole numbers. Hospitalization was assessed by the item “Have you been hospitalized due to your illness?” Respondents could either agree or disagree with this question. Comorbidities were assessed via the item “Do you have any other diseases besides HIV?” Respondents could choose between the options “no” and other exemplary chronic diseases (eg, hepatitis C or diabetes mellitus). In addition, self-generated items about health literacy regarding disease, therapy satisfaction, and adherence to therapy were added. Health literacy regarding disease was assessed by 6 items (eg,“Do you feel well informed about HIV infection and AIDS?”). Responses were given on a 7-point Likert scale (1=“strongly disagree” to 7=“strongly agree”). Internal consistency was good with Cronbach α=0.88. Therapy satisfaction was assessed by 4 items (eg,“When you think of your current HIV therapy, how satisfied are you with the following aspects: type of therapy?”). Responses were given on a 7-point Likert scale (1=“not at all satisfied” to 7=“completely satisfied”). Internal consistency was good with Cronbach α=0.82. Adherence to therapy was assessed by one item (“Do you take the medication for your HIV therapy as prescribed by your doctor?”). Responses were given on a 5-point Likert scale (1=“no,” 2=“rather no,” 3=“undecided,” 4=“rather yes,” and 5=“yes”). Physical health, mental health, and quality of life were rated on a scale from 0 to 100, with higher scores indicating higher levels of subjective health and quality of life.

eHealth Data

Furthermore, eHealth literacy was assessed using the revised German version of the eHealth Literacy Scale [51]. Responses were given on a 5-point Likert scale (1=“strongly disagree” to 5=“strongly agree”). Internal consistency was excellent (Cronbach α=0.92). Furthermore, digital overload was assessed with 3 items (eg,“I feel burdened by the constant availability”) [45,48,51,52]. Answers were given on a 5-point Likert-type scale (1=“strongly disagree” to 5=“strongly agree”). Internal consistency was good (Cronbach α=0.75). Internet anxiety was also assessed via 3 items (eg,“I am afraid I might make an irreversible mistake when using the Internet”) [47,48,53]. Answers were given on a 5-point Likert-type scale (1=“strongly disagree” to 5=“strongly agree”). Internal consistency was good (Cronbach α=0.7).

UTAUT Predictors and Acceptance

To assess acceptance, operationalized as BI, and its influencing factors, an adapted version of the original UTAUT model was applied [34]. The modified UTAUT model contained 3 items in total, with 4 items assessing BI (eg,“I would like to try an app to support my HIV treatment”), and 3 items each assessing

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SI (eg,“People close to me would approve of me using an app to support my HIV treatment”), PE (eg,“An app to support HIV therapy could help me improve my personal health”), and EE (eg,“Using an app to support HIV treatment would not be an additional burden for me”). Answers were given on a 5-point Likert scale (1=“strongly disagree” to 5=“strongly agree”). Internal consistency for acceptance and its predictors was excellent (BI: Cronbach α=0.91; PE: Cronbach α=0.9; SI: Cronbach α=0.84; and EE: Cronbach α=0.77).

Statistical Analyses

Statistical analyses were performed using R (version 4.4.0; R Foundation for Statistical Computing) [54]. Sum scores were calculated for the revised German version of the eHealth Literacy Scale. Mean scores were calculated for digital overload, Internet anxiety, health literacy regarding disease, therapy satisfaction, and for the UTAUT scales (BI, EE, PE, and SI). Acceptance was operationalized as BI and was further categorized in accordance with prior research [43,45,47]: scores from 1 to 2.34 indicate low acceptance, scores from 2.35 to 3.67 indicate moderate acceptance, and scores from 3.68 to 5 indicate high acceptance. Descriptive statistics were applied for sociodemographic, medical, and eHealth data. Multiple hierarchical regression analysis was conducted to examine drivers and barriers of acceptance of treatment-supportive mobile apps for men living with HIV. Predictors were included blockwise: (1) sociodemographic data, (2) medical data, (3) eHealth data, and (4) UTAUT predictors. The variance inflation factor was used to verify the absence of multicollinearity (all variance inflation factor values <2.0). Visual inspection of QQ plots of the residuals showed no signs of violations against normality. Therefore, a normal distribution of the residuals was assumed. Scatter plots of the standardized residuals and the adjusted predicted values verified homoscedasticity. The level of significance was set to α<0.05 for all tests. Effect sizes were reported according to the *Statistical Power Analysis for the Behavioral Sciences* [55], with values around 0.2, 0.5, and 0.8 indicating small, medium, and large effects, respectively.

Results

Study Population

Of the 172 participants, the average age was 43.14 (SD 12.76) years. The youngest participant was aged 19 years, whereas the oldest participant was aged 80 years. On average, participants were diagnosed with HIV for 11.60 (SD 8.97) years. Health literacy regarding disease was high (mean 6.36, SD 0.95; range 1 - 7). Participants also reported high therapy satisfaction (mean 6.07, SD 0.99; range 1 - 7).

The vast majority (n=169, 98.8%) indicated being adherent to treatment. See Table 1 for a complete description of the study population.

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Table . Sample characteristics (N=172).

Characteristics	Value, n (%)
Marital status	
Single	67 (39)
In a relationship	38 (22.1)
Married	53 (30.8)
Divorced or separated	9 (5.2)
Other	5 (2.9)
Educational status	
No or lower secondary education or other	60 (34.9)
Higher secondary education	25 (14.5)
Higher education entrance qualification	30 (17.4)
University education	57 (33.1)
Occupational status	
Student	5 (2.9)
Nonworking	7 (4.1)
Sick leave	7 (4.1)
Employed	119 (69.2)
Self-employed	10 (5.8)
Retired	20 (11.6)
Other	4 (2.3)
Place of residence (population size)	
Large city (>100,000 residents)	122 (70.9)
Medium-sized city (>20,000 residents)	36 (20.9)
Small town (>5000 residents)	10 (5.8)
Rural area (<5000 residents)	4 (2.3)
Comorbidities	
Hepatitis C	8 (4.7)
Diabetes mellitus	9 (5.2)
Oncological comorbidities	3 (1.7)
Chronic kidney disease	2 (1.2)
Kaposi sarcoma	5 (2.9)
Infectious diseases (eg, esophagitis, pneumonia, or fungal)	6 (3.5)
Hypercholesterolemia	14 (8.1)
Hospitalization	62 (36)

Participants reported mean moderate levels of physical health (70.69, SD 19.96; range 0 - 100), mental health (70.85, SD 24.46; range 0 - 100), and quality of life (74.17, SD 23.89; range 0 - 100).

In terms of eHealth, participants reported mean moderate levels of eHealth literacy (22.52, SD 5.80; range 8 - 40). Internet anxiety (2.37, SD=1.71; range 1 - 10) was low and digital overload was moderate (4.41, SD=2.23; range 1 - 10).

Predictors of Acceptance of Treatment-Supportive Mobile Apps

Acceptance of treatment-supportive mobile apps was moderate (mean 3.44, SD 1.17; range 1 - 5). Overall, 45.3% (n=78) of the participants reported high acceptance, 30.2% (n=52) reported moderate acceptance, while 24.4% (n=42) reported low acceptance.

Multiple hierarchical regression analysis was computed to determine predictors of acceptance of treatment-supportive mobile apps in men living with HIV.

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In the first step, sociodemographic data were included (R^2=0.131; R^2_{adj}=0.09; $F_{7,164}$=3.52; P=.002). Age (β=−0.27; P<.001) was a significant predictor of acceptance. The explained variance of the first step was 13.1%.

In the second step, medical data were included (R^2=0.149; R^2_{adj}=0.096; $F_{10,161}$=2.82; P=.002). This step significantly increased the explained variance to 14.9% (ΔR^2=0.18, $F_{3,161}$=3.39; P<.02). However, no specific medical variable was a significant predictor of acceptance.

In the third step, eHealth data (R^2=0.175; R^2_{adj}=0.108, $F_{13,158}$=2.59; P=.003) significantly increased the explained variance to 17.5% (ΔR^2=0.026; $F_{3,158}$=4.89; P=.003). Internet anxiety (β=−0.18; P=.04) was a significant predictor of acceptance.

In the final step, the 3 UTAUT predictors EE, PE, and SI were included (R^2=0.720; R^2_{adj}=0.691; $F_{16,155}$=24.93; P<.001). Explained variance of the final model was significantly increased to 72% (ΔR^2=0.545; $F_{3,155}$=126.67; P<.001). EE (β=0.32; P<.001), PE (β=0.21; P<.001), and SI (β=0.40; P<.001) were significant predictors. Additionally, health literacy regarding disease (β=0.11; P<.001) and eHealth literacy (β=0.10; P=.04) were significant predictors in this step. Table 2 contains the final UTAUT model of acceptance and its significant predictors. The full hierarchical regression model is provided in Multimedia Appendix 2.

Table . Hierarchical regression model of acceptance of treatment-supportive mobile apps for men living with HIV (N=172). Only significant predictors of the final model are detailed.

Predictors	B[a]	β[b]	*t* test (*df*)	R^2[c]	ΔR^2[d]	*P* value
Step 1: sociodemographic data				0.131	0.131	
Step 2: medical data				0.149	0.018	
Health literacy regarding disease	0.13	0.11	−2.08 (155)			.04
Therapy satisfaction	0.12	0.10	1.87 (155)			.06
Step 3: eHealth data				0.175	0.026	
eHealth literacy	0.16	0.10	−2.05 (155)			.04
Step 4: UTAUT[e] predictors				0.720	0.545	
EE[f]	0.38	0.32	5.28 (155)			<.001
PE[g]	0.23	0.21	3.39 (155)			.001
SI[h]	0.48	0.40	6.60 (155)			<.001

[a]*B*: unstandardized beta.

[b]β: standardized beta coefficient.

[c]R^2: determination coefficient.

[d]ΔR^2: changes in R^2.

[e]UTAUT: Unified Theory of Acceptance and Use of Technology.

[f]EE: effort expectancy.

[g]PE: performance expectancy.

[h]SI: social influence.

Discussion

Principal Findings

The aim of this study was to assess acceptance of treatment-supportive mobile apps among men living with HIV and to determine factors influencing acceptance. The average acceptance of treatment-supportive mobile apps in the study population was moderate. Nonetheless, almost half of the participants reported high acceptance, which is consistent with previous studies in people living with HIV [28,30,36]. The moderate acceptance level could be primarily attributed to the benefits of eHealth services being offset by privacy and security concerns [56]. . Some studies using the UTAUT model showed partly similar results [57,58], while the overall acceptance in other studies was higher [40,42,45,47]. However, studies explicitly examining the acceptance of telemedicine services among patients with HIV showed comparatively low acceptance rates [27,35]. .

Considering that men with HIV often face structural barriers and participate less in routine health care [36], these findings

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are particularly relevant. Men, especially men who have sex with men, demonstrate lower health awareness and face stigma-related barriers, which overall leads to deficits in treatment [36,37]. The predictors of acceptance identified in this study therefore not only reveal individual factors influencing the use of eHealth, but also provide insight into how digital health tools could help address these structural deficits.

Among the sociodemographic parameters, younger age emerged as a particularly significant predictor of higher acceptance. Previous studies also found age to be an important influencing factor, though it does not necessarily determine acceptance rates. Both younger [40,43,47] and older patients [4,59] have been found to accept eHealth in previous studies. The low acceptance among older people may be explained by the fact that older people need more support when using eHealth services [60]. The age-related differences in digital usage could also be explained by lower internet access or less affinity for technology, as well as lower media literacy [61,62]. It is important to take these findings into account when developing suitable future technologies that should also be used by older people, as these eHealth technologies offer the possibility to bridge arising problems in modern health care such as the challenge of providing medical care for an aging population [4]. Other sociodemographic parameters such as level of education and place of residence were not significant predictors in this study, which aligns with the results of previous studies [39,40,45,47,48,57,58]

Including the eHealth parameters, internet anxiety in particular proved to be significant, as has been shown in previous studies [46,47,63]. This suggests that perceived limitations in technological competence and user-friendliness may negatively affect acceptance of eHealth services [64].

Previous studies have shown that patients who are well informed about their disease have better self-management and are more interested in using telemedicine services [65]. In addition, patients with higher eHealth competence, which includes eHealth literacy, also show a higher acceptance of eHealth [66]. This may explain why, in the present study, both health literacy and eHealth literacy emerged as significant predictors of acceptance.

The UTAUT core predictors EE, PE, and SI were important and significant influencing factors. This is consistent with the results of previous studies [39,40,45,47,48,57,58]. In this study, SI was found to be the strongest predictor. These results show that men living with HIV, whose social environment approves of the use of an app to support the treatment, show a higher acceptance of this app. Considering that people living with HIV are still socially excluded and discriminated against nowadays [67], it is essential to involve the environment of these individuals as well as their treating specialists for a more successful implementation of eHealth offerings like a mobile app. Other studies have found PE to be the strongest predictor of acceptance, which aligns with the results of this study [40,43,58,68]. In addition, the strong influence of EE shows that it is important to design apps that require as little effort as possible for the user.

The results of this study indicate that, among men living with HIV, promoting eHealth literacy, implementing interventions to reduce internet anxiety, and providing comprehensive information about the infection may enhance the acceptance of eHealth applications. As the recruitment strategy may have selectively favored individuals who are more interested in health-related topics and more digitally experienced, the predictors identified in this study may manifest differently in populations that are less health-conscious or less digitally proficient. Future studies should therefore specifically target these groups to generate robust and generalizable evidence on the acceptance of treatment-supportive mobile apps. Moreover, our findings indicate that designing applications tailored to both younger and older patient groups is essential to bridge the age-related barriers and to enable eHealth tools to serve as a beneficial addition to treatment.

Limitations

Some limitations must be considered when evaluating this study. The study did not focus on a single, standardized eHealth tool, but rather referred to “treatment-supporting mobile apps” in a broader sense. While this allowed participants to draw on personal experiences and preferences, it also led to heterogeneity in the interpretation of the concept. Some respondents may have considered highly specialized adherence apps, while others may have thought of more general health monitoring tools. This variability limits the specificity of our results and should be taken into account in future studies by examining the acceptance of defined interventions.

Recruitment relied on participants’ internet access and their connection to queer community bars, HIV clinics, and social media channels. This approach was selected for a more digitally literate, socially connected, and health-engaged sample. Selection bias, therefore, needs to be considered when interpreting the results. More vulnerable groups of men living with HIV should be given special consideration in future research, as eHealth could offer particularly stigma-free and barrier-free access to health care.

Moreover, a long recruitment time for a small number of participants can cause a selection bias. Therefore, the generalizability of these findings to the broader population is limited. Only men living with HIV were included in this study, which also limits the generalizability of the results. However, the prevalence of HIV is higher among men and especially homosexual men than among women [69], so the presented results remain of high relevance for the treatment of HIV. To assess the general validity of the results, the differences between the recruited men and the male HIV-positive population in Germany must be discussed. Furthermore, participants may have been reluctant or untruthful in their responses due to the stigma associated with HIV. The risk of biased answers was reduced as much as possible by the anonymous approach of the study. The health-related variables in this study refer to self-assessed physical and mental health, rather than objective clinical indicators such as CD4 cell count, viral load, or treatment regimen. Although subjective assessments are important predictors of health behavior, the inclusion of clinical data could strengthen the validity of future analyses. The lack

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of such data in our study was due to its anonymous and online-based design, but future studies in clinical settings could combine both subjective and objective measures to enable a more comprehensive understanding of the determinants of acceptance. Finally, this study assesses acceptance and influencing factors but does not determine actual use. Further longitudinal studies are needed to address these limitations, particularly in populations with no experience with digital media, and to assess the true impact of the influences identified for specific applications. It is essential that women are targeted in future studies, as acceptance might differ in this cohort.

Conclusions

This study examined the acceptance of treatment-supporting mobile apps among men with HIV using an extended UTAUT model. Overall, participants showed moderate acceptance, with nearly half expressing a high intention to use such tools. Acceptance was strongly influenced by the core predictors of UTAUT (PE, EE, and SI). Beyond the core predictors, age, internet anxiety, eHealth literacy, and health literacy related to HIV emerged as additional influencing factors.

Since acceptance is an important prerequisite for actual use and sustainable adoption of digital health solutions, the identified predictors provide valuable insights for the development and implementation of user-tailored eHealth interventions in HIV care. As SI emerged as the strongest predictor of acceptance, future implementation strategies should explicitly leverage social endorsement mechanisms. This may include the involvement of treating physicians and HIV specialists as active advocates, as well as the use of peer educators or testimonials from other men living with HIV, to enhance perceived social approval and normalize app usage within this population. By translating SI into a targeted implementation strategy, acceptance of treatment-supportive mobile apps may be further increased, thereby facilitating their successful integration into routine HIV care.

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Data Availability

The data supporting the results presented in this manuscript is available upon reasonable request to the corresponding author.

Authors' Contributions

Conceptualization: AB, FK, MT
Data curation: RC, LMJ
Formal analysis: RC, LMJ
Methodology: AB, RC, LMJ
Project administration: AB, FK
Supervision: AB, MT
Writing – original draft: FK, AB, RC, LMJ
Writing – review and editing: FK, AB, MT, RC, LMJ, SE
All authors have read and agreed to the published version of the manuscript.

Conflicts of Interest

The authors declared no conflicts of interest with respect to the research, authorship, and/or publication of this article.

Multimedia Appendix 1
Study questionnaire.
[DOCX File, 4094 KB - formative_v10i1e83065_app1.docx]

Multimedia Appendix 2
Full hierarchical regression model of acceptance of treatment-supportive mobile apps for men living with HIV.
[DOCX File, 19 KB - formative_v10i1e83065_app2.docx]

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Abbreviations

BI: behavioral intention
EE: effort expectancy
mHealth: mobile health
MSM: men who have sex with men
PE: performance expectancy
SI: social influence
UTAUT: Unified Theory of Acceptance and Use of Technology

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Personalized Diabetes Treatment Support Using Large Language Models Fine-Tuned on Electronic Health Records: Development and Evaluation Study

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Abstract

Background: Effective diabetes management requires individualized treatment strategies tailored to patients' clinical characteristics. With recent advances in artificial intelligence, large language models (LLMs) offer new opportunities to enhance clinical decision support, particularly in generating personalized recommendations.

Objective: This study aimed to develop and evaluate an LLM-based outpatient treatment support system for diabetes and examine its potential value in routine clinical decision-making.

Methods: Three compact LLMs (Llama 3.1-8B, Qwen3-8B, and GLM4-9B) were fine-tuned on deidentified outpatient electronic health records using a parameter-efficient low-rank adaptation approach. The optimized models were embedded into a prototype hospital information system via a retrieval-augmented generation framework to generate individualized treatment recommendations, laboratory test suggestions, and medication prompts based on demographic and clinical data.

Results: Among the models evaluated, the fine-tuned GLM4-9B demonstrated the strongest performance, producing clinically reasonable treatment plans and appropriate laboratory test recommendations and medication suggestions. It achieved a mean Bilingual Evaluation Understudy for 4-grams score of 67.93 (SD 2.74) and mean scores of 44.30 (SD 3.91) for Recall-Oriented Understudy for Gisting Evaluation for overlap of unigrams, 27.34 (SD 1.85) for Recall-Oriented Understudy for Gisting Evaluation for overlap of bigrams, and 37.67 (SD 2.88) for Recall-Oriented Understudy for Gisting Evaluation for Longest Common Subsequence.

Conclusions: The fine-tuned GLM4-9B shows strong potential as a clinical decision support tool for personalized diabetes care. It can provide reference recommendations that may improve clinician efficiency and support decision quality. Future work should focus on enhancing medication guidance, expanding data sources, and improving adaptability in cases involving complex comorbidities.

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KEYWORDS

GLM4-9B; artificial intelligence; AI; large language model; diabetes; electronic health record; EHR

Introduction

Diabetes is a chronic metabolic disorder characterized by elevated blood glucose levels, which over time can cause serious damage to the heart, blood vessels, eyes, kidneys, and nervous system. The most common is type 2 diabetes, which accounts for approximately 90% to 95% of diabetes cases [1] and affects mainly adults. According to the World Health Organization, approximately 422 million people worldwide have diabetes, most in low- and middle-income countries, and 1.5 million people die each year as a direct result of diabetes [2]. The incidence and prevalence of diabetes have been steadily increasing over the last few decades [1]. As patients with diabetes require long-term medication to control blood glucose levels and prevent complications [3], they can face several challenges during the treatment process, such as medication

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selection, dosage adjustment, and management of adverse effects. Failure to address these issues in a timely manner can compromise the efficacy of medication and even pose a threat to patients' lives [4]. Therefore, people with diabetes need timely medication advice, health education, and nutrition support to help them use their medicines correctly, safely, and effectively, thereby improving adherence and quality of life. To better serve patients and increase the efficiency of health care professionals, we aim to optimize the management of patients with diabetes through the application of artificial intelligence.

With the significant success of ChatGPT in tasks related to understanding and generating humanlike responses [5], large language models (LLMs) have attracted considerable attention. They have shown strong performance in various natural language processing tasks and the ability to generalize to unfamiliar tasks, demonstrating their potential as a unified solution for natural language understanding, text generation, and dialogue. Although ChatGPT has shown promising results in medical document summarization and decision support [6,7], as well as in passing the US Medical Licensing Examination Steps 1 and 2 [8], the exploration of these broad-domain LLMs in the medical field is still relatively limited [9]. Currently, there is a lack of specifically trained LLMs in the field of health care. To address this gap, we plan to fine-tune an LLM using deidentified data from patients with diabetes with the aim of exploring its application in diabetes management. In addition, harnessing the potential of LLMs will open up new opportunities for medical research and practice and drive advances and innovation in health care technology.

Methods

Ethical Considerations

This retrospective study used encrypted and deidentified data from West China Hospital involving no patient privacy–sensitive information or clinical interventions. Data extraction and study procedures were approved by the ethics committee of West China Hospital, Sichuan University (approval 2024-126), in accordance with informed consent requirements.

Data Collection

This study used the big data integration platform of West China Hospital as the primary source of data [10]. We collected electronic health record data from patients diagnosed with diabetes who visited the outpatient department from January 2022 to February 2022. The collected data included information such as the patients' department of visit, age, gender, chief concern, present illness history, and diagnosis, which served as input for the model. In addition, we obtained data on patients' outpatient medications, laboratory test items, examinations, and physician opinions, which were used as model outputs. Patient data with missing chief concerns and present illness history were excluded to ensure data quality and usability. Furthermore, we collected an additional set of data from 300 patients (visiting in March 2022) as a test set to evaluate the performance of the optimized model.

Data Preprocessing

Before model training, we performed systematic preprocessing on the collected patient data, including data cleaning, standardization, and anonymization. Data cleaning involved removing missing values, outliers, and duplicate records to ensure the integrity and reliability of the model inputs. Standardization ensured consistency in format, units, and value ranges across different data types. For text data, including chief concerns, present illness history, examinations, and laboratory test results, we applied cleaning, terminology unification, and segmenting of key information while removing sensitive information to protect patient privacy. The processed data were then organized into a question-answer format (instruction-input-output) suitable for LLM fine-tuning: patient basic information and clinical text (eg, department, gender, age, diagnosis, chief concern, and present illness history) were used as the input, and corresponding medical orders, examinations, recommended laboratory tests, and treatment recommendations were integrated as the output (shown in Textbox 1). This approach ensured that both structured and unstructured information was effectively used for model training. The dataset was then split into training and test sets in an 8:2 ratio.

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Textbox 1. Data example for large language model fine-tuning in clinical diabetes recommendations.

Instruction

- "You are a diabetes clinical recommendation model. You will receive the patient's basic information and laboratory results, and you are expected to provide tailored clinical recommendations for the patient."

Input

- Department: endocrinology ward
- Sex: male
- Age: 55 years
- Diagnosis: type 2 diabetes mellitus with hypertension
- Chief concern: polydipsia; polyuria for 6 months
- Present illness history: "The patient reports excessive thirst and frequent urination over the past six months, with a weight loss of approximately 3 kg. History of hypertension for 5 years, blood pressure poorly controlled. Recent fasting blood glucose ranges from 8–10 mmol/L, postprandial blood glucose up to 12 mmol/L. The patient is not on regular insulin or oral hypoglycemic therapy."

Output

- Provision of a blood glucose monitoring device and test strips
- Laboratory tests: fasting plasma glucose, 2-hour postprandial glucose, glycated hemoglobin, liver and renal function, and lipid panel
- Examinations: fundoscopy, foot examination, and electrocardiogram
- Treatment recommendations: adjust insulin or oral hypoglycemic agents according to blood glucose levels, monitor blood pressure, and implement dietary and exercise interventions

Model Selection

In this study, we compared 3 LLMs for clinical text prediction tasks: Llama 3.1-8B (Meta AI) [11], Qwen3-8B (Alibaba Cloud) [12], and GLM4-9B (THUDM/Z.ai) [13]. Llama 3.1-8B is an open-source model optimized for efficient generalization and complex text understanding. Qwen3-8B is a multilingual LLM with strong capabilities in both structured and unstructured medical text processing. GLM4-9B, developed based on the general language model architecture, is designed for bilingual question-answering tasks and supports local deployment through model quantization. All models were fine-tuned and evaluated using a single H100 graphics processing unit (NVIDIA). Smaller model sizes were chosen to facilitate clinical deployment and wider adoption in practical settings while still maintaining competitive performance for downstream tasks.

Model Fine-Tuning

To adapt the selected LLMs for clinical treatment recommendation tasks, we used a parameter-efficient fine-tuning strategy that combines instruction-based prompting with low-rank adaptation (LoRA) [14]. Instruction templates were designed to explicitly guide the model in interpreting patient information and generating clinically appropriate treatment suggestions. Building on this, LoRA was applied to the attention layers to enable efficient task-specific adaptation while updating only a small number of parameters. During fine-tuning, we explored multiple hyperparameter configurations, including learning rate, batch size, and LoRA-specific parameters such as rank and scaling factor. Model performance was assessed on a held-out validation set using both automatic text generation metrics (eg, Bilingual Evaluation Understudy [15] and Recall-Oriented Understudy for Gisting Evaluation [16]) and clinically oriented evaluation criteria, including the correctness and appropriateness of the recommended treatments. This combined approach provided a balanced trade-off between computational efficiency and clinical relevance, offering practical guidance for deploying LLM-based treatment recommendation systems in real-world clinical settings.

Physician Assessment of Recommendations

To ensure a rigorous and clinically meaningful evaluation of our LLM-generated diabetes treatment recommendations, we implemented a structured, multidimensional physician assessment protocol. Six dimensions were assessed: treatment appropriateness, medication accuracy, relevance of suggested examinations, safety, logical reasoning, and overall clinical usefulness. Each dimension was rated using a standardized 5-point Likert scale [17] ranging from 1 ("completely unreasonable or not useful") to 5 ("fully reasonable and clinically valuable"). Five board-certified endocrinologists (each with more than 5 years of independent clinical practice) served as expert raters. All assessments were performed independently and in a fully blinded manner: raters were unaware of which LLM produced each recommendation and were prohibited from discussing cases. Each physician reviewed the same 300 treatment recommendations generated by the 3 LLMs, including both base and fine-tuned versions. Recommendations included medication plans, dosage adjustments, and suggested laboratory tests. This protocol ensured a systematic, reproducible, and clinician-centered evaluation of model outputs, enabling identification of potential risks and areas requiring refinement.

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Retrieval-Augmented Generation and Agent-Assisted Clinical Data Processing

We implemented a retrieval-augmented generation (RAG) [18] framework to integrate hospital knowledge resources, including the medical order database, diabetes treatment guidelines, and clinical protocols, enabling the model to dynamically retrieve relevant knowledge during treatment recommendations and provide context-specific, up-to-date clinical information. An agent system was developed to interface with the hospital information system. It handles data cleaning, integration, and monitoring by extracting and standardizing patient data, consolidating heterogeneous sources into a structured format suitable for RAG, and ensuring data integrity and consistency. By combining RAG with agent-driven data management, the system efficiently leverages internal knowledge bases to support clinically grounded, accurate, and interpretable treatment recommendations. The overall workflow of this clinical application system is illustrated in Figure 1.

Figure 1. Schematic workflow of the clinical application system integrating retrieval-augmented generation (RAG)– and agent-driven data management. AI: artificial intelligence; LLM: large language model.

Results

Overview

As shown in Figure 2, the final dataset comprised 20,619 patients, with 80% allocated for model training and 20% held out as a test set for performance evaluation. Figure 2 illustrates the data collection process.

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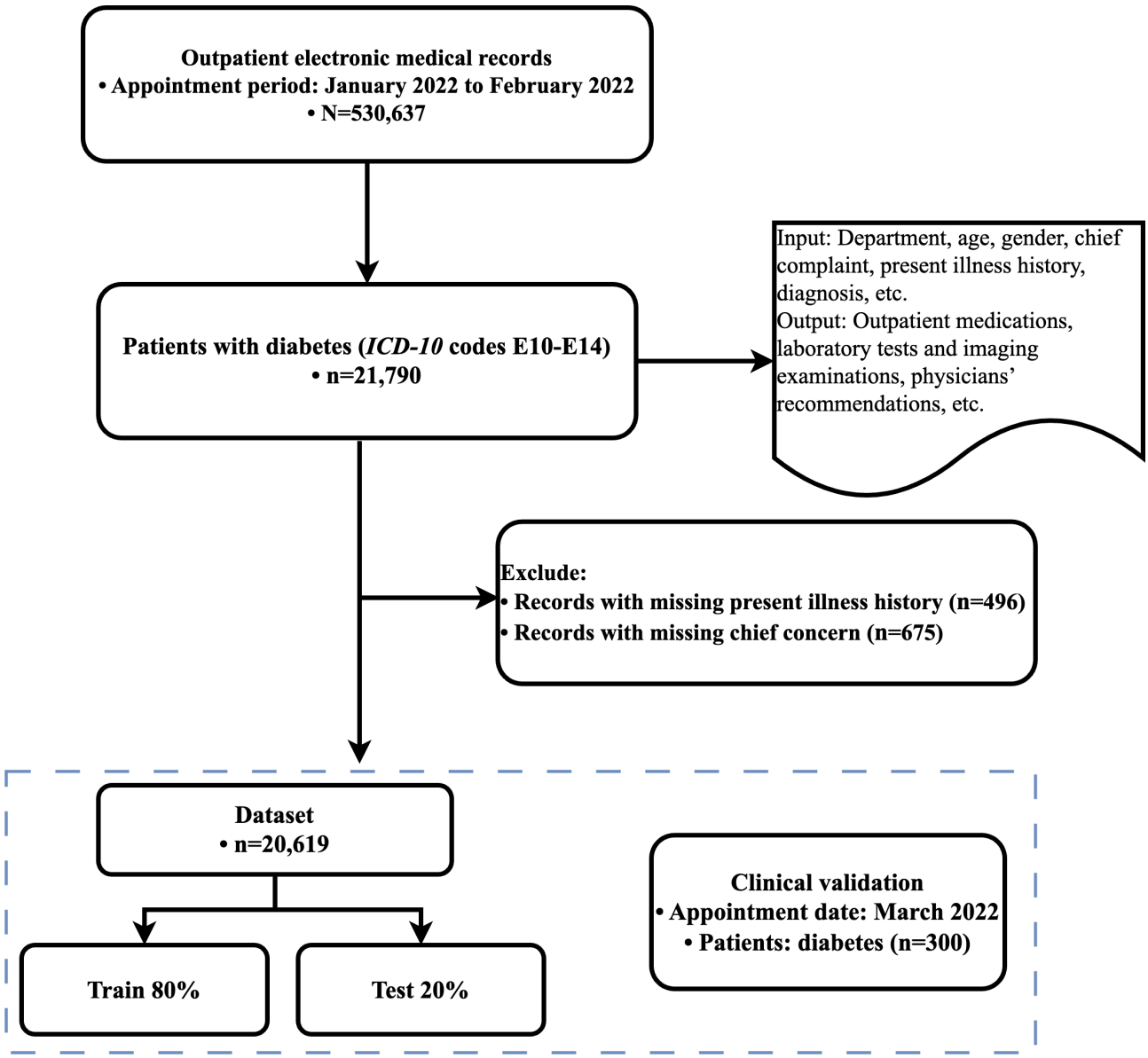
Figure 2. Flowchart of patient inclusion and exclusion criteria



All 3 LLMs—Llama 3.1-8B, Qwen3-8B, and GLM4-9B—were evaluated before and after LoRA fine-tuning. Their training and test loss curves are shown in Figure 3, and model performance was assessed using both automatic text generation metrics and clinical physician evaluations.

Figure 3. Training and test loss curves for Llama 3.1-8B, Qwen3-8B, and GLM4-9B.

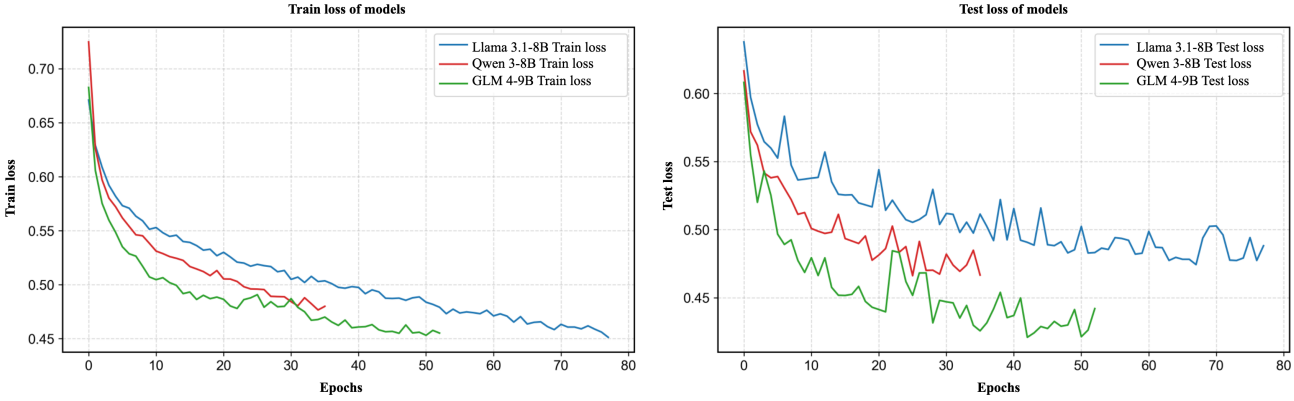


Table 1 summarizes the comparative performance of the baseline and fine-tuned models measured using Bilingual Evaluation Understudy for 4-grams (BLEU-4), Recall-Oriented Understudy for Gisting Evaluation for overlap of unigrams (ROUGE-1), Recall-Oriented Understudy for Gisting Evaluation for overlap of bigrams (ROUGE-2), and Recall-Oriented Understudy for

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Gisting Evaluation–Longest Common Subsequence (ROUGE-L). Before fine-tuning, the 3 base models demonstrated moderate capability in generating clinically relevant recommendations, with mean BLEU-4 scores ranging from 45.13 (SD 1.98) to 50.84 (SD 1.87) and ROUGE-L scores ranging from 9.83 (SD 0.54) to 13.90 (SD 0.74). Among the base models, GLM4-9B achieved the highest performance across all metrics. After fine-tuning, all models showed significant gains in both lexical similarity and content relevance. The BLEU-4 mean score increased by 14.48 points for Llama 3.1-8B, 15.95 points for Qwen3-8B, and 17.09 points for GLM4-9B. ROUGE-1 and ROUGE-L exhibited similar patterns, with improvements exceeding 20 points for all 3 models. The fine-tuned GLM4-9B outperformed all models, achieving the highest BLEU-4 (mean 67.93, SD 2.74), ROUGE-1 (mean 44.30, SD 3.91), ROUGE-2 (mean 27.34, SD 1.85), and ROUGE-L (mean 37.67, SD 2.88) scores.

Table . Performance analysis based on Bilingual Evaluation Understudy for 4-grams (BLEU-4) and Recall-Oriented Understudy for Gisting Evaluation scores.

Model	BLEU-4, mean (SD)	ROUGE-1[a], mean (SD)	ROUGE-2[b], mean (SD)	ROUGE-L[c], mean (SD)
Base Llama 3.1-8B	45.13 (1.98)	12.55 (0.68)	3.12 (0.21)	9.83 (0.54)
Base Qwen3-8B	47.92 (2.11)	15.33 (0.75)	4.46 (0.26)	11.77 (0.63)
Base GLM4-9B	50.84 (1.87)	17.92 (0.82)	5.71 (0.31)	13.90 (0.74)
Fine-tuned Llama 3.1-8B	59.61 (3.21)	36.12 (3.44)	22.48 (1.78)	31.44 (2.93)
Fine-tuned Qwen3-8B	63.87 (3.18)	40.58 (3.72)	25.01 (1.92)	34.80 (3.12)
Fine-tuned GLM4-9B	67.93 (2.74)	44.30 (3.91)	27.34 (1.85)	37.67 (2.88)

[a]ROUGE-1: Recall-Oriented Understudy for Gisting Evaluation for overlap of unigrams.

[b]ROUGE-2: Recall-Oriented Understudy for Gisting Evaluation for overlap of bigrams.

[c]ROUGE-L: Recall-Oriented Understudy for Gisting Evaluation–Longest Common Subsequence.

Regarding the clinical evaluation, the performance of the original models and their LoRA fine-tuned versions is summarized in Textbox 2.

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Textbox 2. Performance of the original models and their low-rank adaptation fine-tuned versions.

Input

- Department: endocrinology and metabolism medical unit
- Gender: male
- Age: 68 years
- Diagnosis: type 2 diabetes; hyperlipidemia
- Chief concern: diabetes follow-up visit
- Medical history: diabetes for 2 or more years

Real clinical data output

- Laboratory tests: liver and kidney function, glucose and fat-a, and glycated hemoglobin (HbA_{1c}; biochemistry 2)
- Medication: 11 units once a day of Ganjing insulin injection (3 mL: 300 prefilled units), 5 mg of OuTangning once a day (5 mg × 7 tablets), and 10 mg of atorvastatin calcium tablets once every night (10 mg × 28 tablets)

Base GLM4-9B output

- "A patient with diabetes attending a follow-up visit requires a comprehensive medical history review and physical examination to better assess their condition and guide treatment planning. According to your description, the patient has type 2 diabetes and hyperlipidemia. Type 2 diabetes is a chronic condition that necessitates long-term management, while hyperlipidemia is a common metabolic disorder that can negatively impact cardiovascular health and increase the risk of cardiovascular disease. During follow-up, the patient should monitor blood glucose levels and adjust management strategies—including medication, diet, and exercise—accordingly. Regular monitoring of blood lipid levels is also necessary, with treatment plans tailored based on the results. Common treatment strategies for diabetes include oral medications, insulin therapy, blood glucose monitoring, and dietary control. Successful management requires active patient engagement, adherence to lifestyle recommendations, and consistent follow-up to maintain stable and healthy blood glucose levels."

Fine-tuned GLM4-9B output

- Laboratory tests: HbA_{1c} and liver and kidney function tests, lipase A, fasting insulin, 2-hour postprandial insulin, fasting plasma glucose, 2-hour postprandial C-peptide, and 2-hour postprandial plasma glucose (biochemistry 1)
- Medication: 11 units once daily of Ganjing insulin injection (3 mL: 300 units/prefilled) and 5 mg of OuTangning once daily (5 mg × 7 tablets)
- Physician's recommendation: regular follow-up visits are advised to monitor treatment response and adjust therapy as needed

Clinical Evaluation

Table 2 shows the results of 5 endocrinologists' evaluation of the 300 treatment recommendations generated by the 3 fine-tuned LLMs. Overall, the mean scores indicated that most recommendations were clinically relevant to diabetes management (mean usefulness scores above 4 for all fine-tuned models), whereas the base models received substantially lower ratings. Approximately 10% of the recommendations (32/300, 10.7%) were judged by at least one rater as potentially risky (eg, inappropriate escalation or overtreatment), underscoring the need for human oversight.

Table . Physician assessment of recommendations.

Model	Treatment appropriateness (1-5), mean (SD)	Medication accuracy (1-5), mean (SD)	Relevance (1-5), mean (SD)	Safety (1-5), mean (SD)	Logical reasoning (1-5), mean (SD)	Usefulness (1-5), mean (SD)
Base GLM4-9B	3.28 (0.38)	2.96 (0.37)	3.52 (0.34)	3.60 (0.53)	3.60 (0.50)	3.44 (0.30)
Fine-tuned GLM4-9B	4.72 (0.31)	4.48 (0.43)	4.76 (0.36)	4.66 (0.47)	4.78 (0.20)	4.78 (0.16)
Base Llama 3.1-8B	2.50 (0.53)	2.80 (0.70)	2.94 (0.18)	2.86 (0.29)	2.54 (0.36)	2.60 (0.54)
Fine-tuned Llama 3.1-8B	4.58 (0.47)	4.68 (0.43)	4.70 (0.42)	4.40 (0.49)	4.36 (0.57)	4.60 (0.39)
Base Qwen3-8B	3.42 (0.42)	2.98 (0.41)	3.00 (0.85)	3.14 (0.62)	3.32 (0.48)	3.24 (0.51)
Fine-tuned Qwen3-8B	4.50 (0.71)	4.26 (0.50)	4.16 (0.78)	3.80 (0.37)	4.44 (0.55)	4.44 (0.38)

As shown in Figure 4, the radar chart highlights the multidimensional improvements achieved through LoRA fine-tuning across all 6 evaluation metrics. For all 3 models, the fine-tuned versions consistently exhibited higher scores than their base counterparts. Among the models, GLM4-9B (fine-tuned) achieved the highest performance across nearly all

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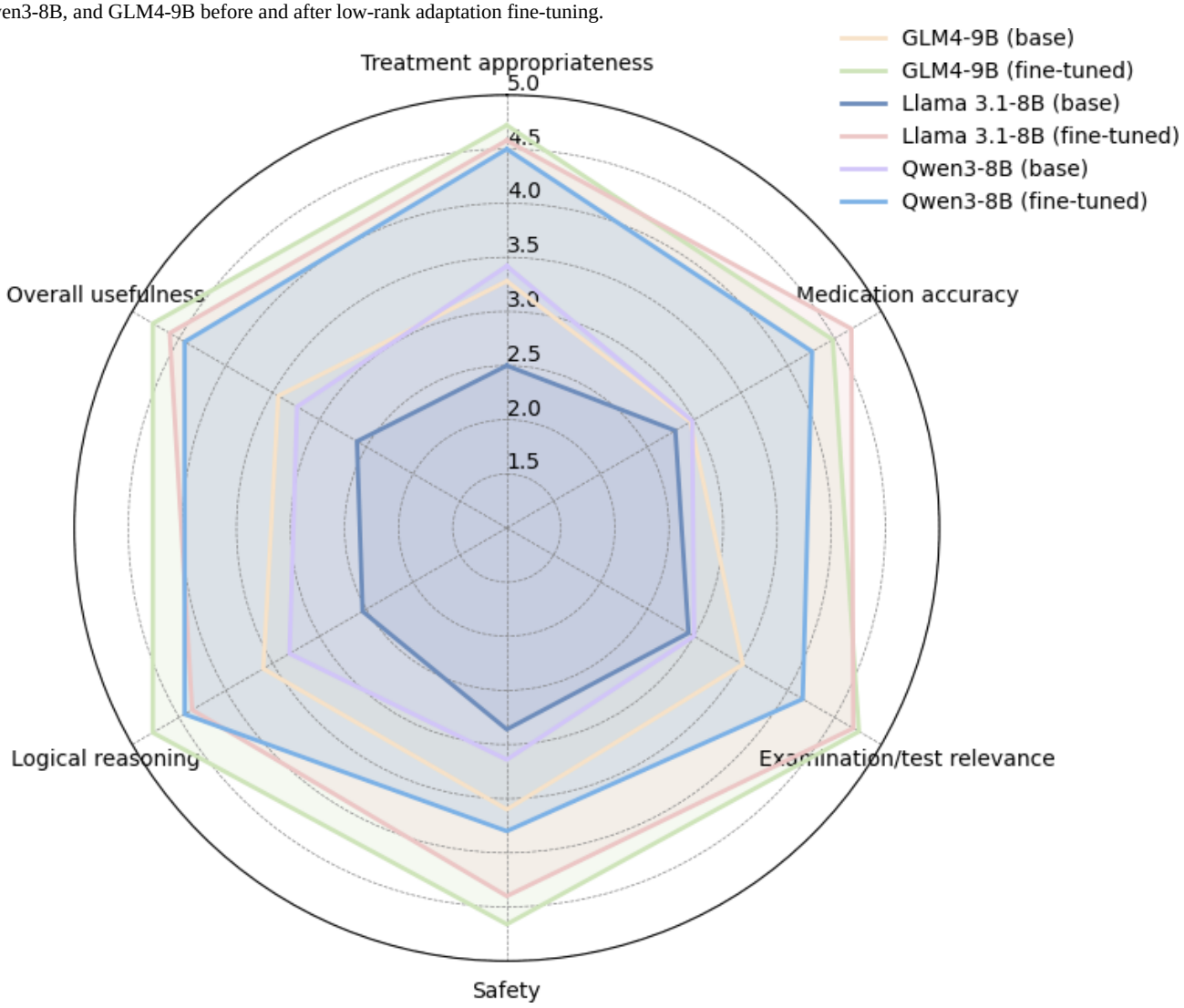
dimensions, particularly in treatment appropriateness, relevance, and overall usefulness.

Figure 4. Radar chart illustrating the multidimensional physician assessment scores of treatment recommendations generated by Llama 3.1-8B, Qwen3-8B, and GLM4-9B before and after low-rank adaptation fine-tuning.



Discussion

Principal Findings

This study systematically evaluated the performance of 3 LLMs (Llama 3.1-8B, Qwen3-8B, and GLM4-9B) on a clinical treatment recommendation task for diabetes and explored a parameter-efficient optimization strategy combining instruction-based prompting and LoRA fine-tuning. It should be noted that all 3 models are general-purpose open-source LLMs and were not specifically fine-tuned on medical data, serving as preliminary baselines for clinical recommendation tasks. The untuned base models achieved moderate performance in generating clinically relevant recommendations, with mean BLEU-4 scores ranging from 45.13 to 50.84 and mean ROUGE-L scores ranging from 9.83 to 13.90, among which the base GLM4-9B model performed best across metrics. These findings indicate that even relatively small models possess nontrivial text generation capabilities but exhibit limitations in content relevance and accuracy for specialized clinical tasks. After LoRA fine-tuning, all models showed substantial improvements on both automatic evaluation metrics and clinician assessments. BLEU-4 scores increased by approximately 14 to 17 absolute points on average, whereas ROUGE-1 and ROUGE-L scores improved by more than 20 points, suggesting that fine-tuning effectively enhanced lexical similarity and information completeness in the generated texts. In clinician evaluations, scores increased markedly across the 6 dimensions—therapeutic appropriateness, medication accuracy, examination relevance, safety, logical reasoning, and overall usefulness. Among them, fine-tuned GLM4-9B achieved the best performance on key dimensions such as therapeutic appropriateness, relevance, and overall usefulness, whereas fine-tuned Llama 3.1-8B and Qwen3-8B also demonstrated varying degrees of improvement (Figure 4). The radar chart clearly illustrates these multidimensional gains, underscoring the effectiveness of combining LoRA with instruction-based prompting to enhance clinical applicability. Furthermore, by leveraging an RAG framework and an agent-based data processing and knowledge retrieval pipeline (Figure 1), the models can dynamically access up-to-date institutional clinical guidelines, medication order databases, and diabetes treatment standards, thereby enabling individualized, context-aware

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clinical recommendations. This approach not only improves the accuracy and safety of the generated suggestions but also strengthens their interpretability and practical usability in clinical settings. After repeated debugging and testing of the model, we found that, for a subset of patients with complex medical records, the model output can be potentially harmful and fail to assist health care professionals in their treatment. This situation can occur for the following reasons:

- Data imbalance or sample bias [19]: the model may have been trained on an overrepresentation of certain types of patient records, leading to an inadequate understanding of other types of patients. This bias can lead to inaccurate or harmful treatment recommendations for certain patients.
- Unknown or rare scenarios [20]: if the model encounters unfamiliar or infrequent situations during training, it may struggle to make accurate predictions or appropriate recommendations. Complex patient records often contain such unknown scenarios, rendering the model's output ineffective.
- Limitations of the model [21]: the model may have inherent design or training limitations that prevent it from adequately accounting for factors specific to complex medical records. As a result, the model's outputs may lack accuracy or reliability in these cases. Additionally, the fact that the models are not medically fine-tuned may contribute to these limitations, highlighting the importance of exploring medically fine-tuned LLMs and larger, multi-institutional datasets in future research.
- The size of the training data has a direct impact on the performance of large models. Therefore, it is crucial for us to explore methods to increase the scale of our dataset (Multimedia Appendix 1).

Limitations

This study has several limitations. First, the proposed framework has been evaluated only in a controlled experimental setting and has not yet been prospectively validated in real-world clinical workflows. As such, its clinical effectiveness and operational impact remain to be systematically assessed. Second, we only used relatively small-scale models, which have substantially fewer parameters than larger frontier models such as DeepSeek R1 [22], Qwen3-32B, or Llama 3-65B. While the smaller models reduce computational requirements and facilitate low-cost intranet deployment, they may limit performance and generalization compared with larger models. Third, the training data for this study were collected from a single medical institution and are relatively limited in size, which may affect the robustness and external validity of the results. It is important to understand that, while LLMs often perform well in many scenarios, they may have limitations when dealing with complex medical records. Therefore, model outputs should not be the sole basis for decision-making. Health care professionals should rely on their expertise and clinical judgment and integrate model outputs with comprehensive assessments to make informed decisions [23]. Additionally, we plan to fine-tune domain-specific medical LLMs (such as MedGemma 27B [24]) and explore the integration of medical knowledge graphs to incorporate structured clinical knowledge, enhance model reasoning [25], and further improve the consistency and reliability of the generated recommendations. Future research will also focus on leveraging larger models and multi-institutional datasets to strengthen model performance, generalizability, and robustness.

Conclusions

Overall, this study validates the feasibility and effectiveness of combining small-scale LLMs with LoRA fine-tuning and an RAG- and agent-assisted data processing and knowledge retrieval strategy for clinical treatment recommendations in diabetes. The fine-tuned models not only achieved superior performance on automated text generation metrics but also generated treatment recommendations deemed safe, clinically appropriate, and of substantial reference value in structured clinician evaluations. These findings provide a viable pathway for the responsible deployment of LLMs in real-world medical applications. Future research should scale up training datasets; extend validation to a broader range of disease entities; and incorporate longitudinal real-world evidence to further assess long-term clinical effectiveness, safety, and generalizability.

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Data Availability

Considering data security, the data will not be publicly available on the website for now. However, the data and code used in this study are available from the corresponding author on reasonable request.

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Authors' Contributions

JL and SH conceptualized and designed the study, performed the experiments, conducted model analyses, analyzed the data, and drafted the manuscript. JL provided clinical guidance, oversaw data processing, and contributed to manuscript revisions. All authors contributed to manuscript revisions, approved the final version, and accept accountability for all aspects of the work.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Supplementary material demonstrating the outputs of the large language models before and after fine-tuning. Screenshots illustrate how different fine-tuning strategies (P-tuning and low-rank adaptation) improve clinical response accuracy; provide structured treatment suggestions; and reduce harmful or inaccurate recommendations in typical, complex, and rare patient scenarios.
[DOCX File, 691 KB - formative_v10i1e71541_app1.docx]

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Abbreviations

BLEU-4: Bilingual Evaluation Understudy for 4-grams
LLM: large language model
LoRA: low-rank adaptation
RAG: retrieval-augmented generation
ROUGE-1: Recall-Oriented Understudy for Gisting Evaluation for overlap of unigrams
ROUGE-2: Recall-Oriented Understudy for Gisting Evaluation for overlap of bigrams
ROUGE-L: Recall-Oriented Understudy for Gisting Evaluation–Longest Common Subsequence

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Evaluating a Wearable-Based Pain Monitoring System in Palliative Cancer Care: Usability and Feasibility Study

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Abstract

Background: Effective pain management is a cornerstone of cancer palliative care, yet it remains challenging in low- and middle-income countries due to limited resources, regulatory constraints, and a lack of objective tools. While wearable technologies offer promise for augmenting pain-related patient-reported outcomes with physiological data, their usability in palliative settings in low- and middle-income countries is underexplored.

Objective: This study aimed to evaluate the technology usability and implementation feasibility of the NEST (Non-intrusive Devices for Telemedicine) system, a low-cost, smartwatch-based pain monitoring solution for palliative cancer care co-designed with health care staff from a cancer hospital in Ecuador.

Methods: An observational usability study was conducted with 7 patients with cancer receiving palliative care treatment, combining hospital- and home-based monitoring phases. We used a qualitative and quantitative approach to assess the usability of the NEST system and to identify sociotechnical factors affecting feasibility using the NASSS (Nonadoption, Abandonment, Scale-up, Spread, and Sustainability) framework.

Results: Quantitative results showed a strong preference for the smartwatch over the mobile phone for submitting patient-reported outcomes (246/296, 83%), with wear-time adherence of the smartwatch ranging from 36% to 92% of the time. Qualitative feedback from patients and health care staff indicated good usability and perceived clinical value, though technical and organizational challenges, such as charging habits, training needs, and dashboard integration into the daily workflow of health care staff, were noted. As for feasibility, most of the complexity was found in the dynamics of the health condition, while the technology shows clear promising signs of having value to patients and health care staff.

Conclusions: Our findings suggest that the commonly reported usability hurdles of a smartwatch-based sociotechnical health solution are surmountable given fluid communication between stakeholders during all stages of design and deployment. The primary threats to feasibility in our context seem to lie in the highly complex and dynamic environment of palliative cancer care, regulatory ambiguity regarding the use of medical devices, and the workload burden on health care staff.

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KEYWORDS

palliative care; smart health care; telemedicine; user centered design; wearable devices

Introduction

Pain management is a key component of oncology palliative care, as pain remains one of the most common and life-limiting symptoms reported by patients with cancer receiving ambulatory palliative services [1,2]. In low- and middle-income countries (LMICs), precarious health services infrastructure, limited availability of specialized health care personnel, and highly restrictive policies on opioid prescription [3] create additional pressures to implement efficient and effective pain management strategies in outpatient palliative care. Moreover, with global populations aging and the prevalence of oncologic conditions rising, the demand for palliative care is expected to increase significantly in the coming years [4]. In this context, sociotechnical interventions that extend existing telemedicine services have the potential to provide some relief by providing health care staff effective means to monitor a patient's well-being and optimize their pain management treatment [5-8].

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Palliative care is a specialized medical approach focused on improving the quality of life of patients and their families facing life-threatening illnesses through the prevention and relief of distress [9]. In outpatient settings, where care is delivered at home or during scheduled visits, patient-reported outcomes (PROs) typically refer to a patient's self-assessment of pain and related symptoms, conveyed verbally during scheduled clinical visits [6,10] or recorded manually using paper-based questionnaires by the patient or their caregiver. PROs are considered the gold standard for pain assessment and management in this context [11-13]. However, they are inherently subjective, influenced by cultural, contextual, and psychosocial factors [12-14], and susceptible to issues, such as recall bias and patient noncompliance [15].

Sensor-enabled technologies, including wearable devices and smartphones, have increasingly been adopted to collect real-time digital biomarkers and PROs in outpatient settings across various clinical conditions [6,10,14]. Recent studies suggest that digitizing PROs could improve patient adherence and that integrating them with physiological data from wearable sensors, such as heart rate, could provide complementary objective biomarkers, thereby enhancing the reliability of pain monitoring [12,13,15-17]. However, there is currently no universally accepted biomarker for pain [12,13,18], and evidence supporting the clinical effectiveness of wearable sensors in palliative cancer care remains scarce. For instance, Sandic et al [16] identified only 6 studies involving wearable technologies in palliative care for patients aged 65 years and older, none of which were conducted in LMICs. Similarly, Cloß et al [19] emphasize the need for further research on the short- and long-term impacts of wearable technologies across different phases of cancer care, while studies from Olmedo-Aguirre et al [6] and Leroux et al [15] point to usability issues and low acceptance of these technologies and stress the importance of additional usability studies.

The NEST (Non-intrusive Devices for Telemedicine) system was developed to address these gaps by designing and piloting a wearable-based telemedicine solution tailored to the needs and constraints of outpatient palliative care in an LMIC setting. This project was established through a collaborative partnership between ESPOL (Escuela Superior Politécnica del Litoral) University and the Society for the Fight Against Cancer (Sociedad de Lucha Contra el Cáncer [SOLCA]) in Ecuador, in cooperation with the Vrije Universiteit Brussel (VUB) in Belgium.

Through a participatory design process with the palliative care team at SOLCA's hospital, we developed a low-cost, noninvasive smartwatch-based solution paired with a mobile app capable of collecting and transmitting photoplethysmography-derived physiological data and pain-related PROs. This study presents the NEST system and the results of an observational study with the objective of evaluating its implementation feasibility in an LMIC setting and usability among patients with cancer receiving outpatient palliative care within SOLCA's hospital network. To interpret the findings and assess implementation and scalability potential, we apply the NASSS (Nonadoption, Abandonment, Scale-up, Spread, and Sustainability) framework; a tool developed at the University of Oxford to identify and analyze the sociotechnical factors influencing the long-term adoption of health technologies [20].

This study contributes to the emerging literature by presenting one of the first feasibility and usability studies of wearable technology for pain monitoring in palliative cancer care conducted in an LMIC, addressing a critical gap in evidence from underrepresented settings.

Methods

Our methodology to design the NEST system and evaluate its usability and feasibility in an LMIC setting comprises a participatory design stage, guided by the principles of Design Thinking, and an observational study for evaluation. We used a thematic analysis for usability and a NASSS framework–guided analysis for feasibility (Figure 1).

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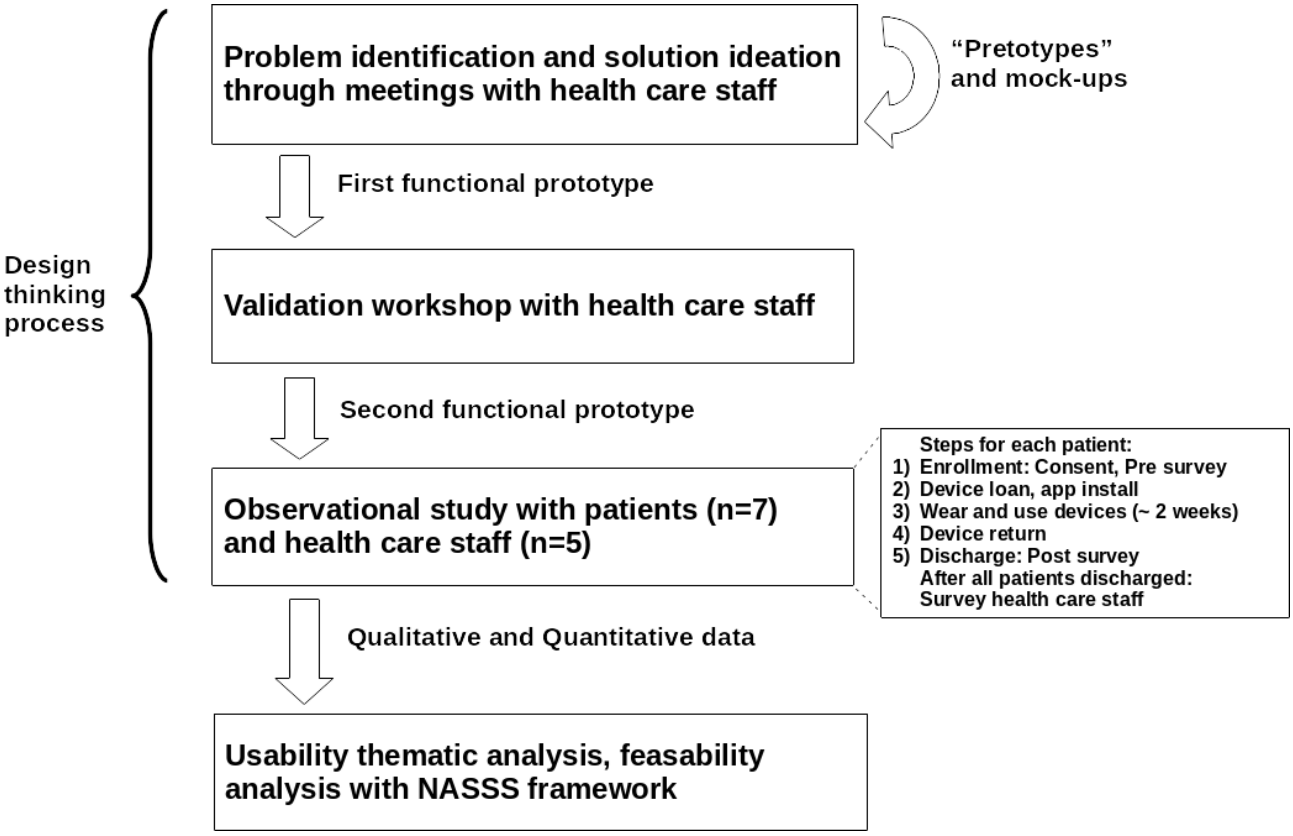
Figure 1. Design and evaluation stages of the NEST (Non-intrusive Devices for Telemedicine) system. NASSS: Nonadoption, Abandonment, Scale-up, Spread, and Sustainability.



NEST System Design

The NEST system started with the aim to design a sociotechnical solution to support SOLCA's telemedicine programs. Early on in the start of the project, the telemedicine program of SOLCA's palliative care unit was identified as the ideal starting point. In total, 17 health care workers (9 doctors, 6 nurses, 1 therapist, and 1 administrative staff) from this unit and 2 specialists from ESPOL (a computer science engineer and a mechatronics engineer) embarked on a participatory design effort using tools from Design Thinking, a human-centered, problem-solving methodology found to be effective at promoting innovation in the health sector [21]. Design Thinking is an iterative process structured around 5 stages—Empathize, Define, Ideate, Prototype, and Test—that emphasizes rapid prototyping and stakeholder participatory design [22]. During the empathy and problem definition phase of the Design Thinking process, we identified pain management as one of the most pressing challenges faced by staff and patients who are ambulatory in SOLCA's palliative care unit. Specific issues included ensuring appropriate use and dosage of analgesics, as well as consistent completion of the "pain diary," a customized PRO questionnaire that patients or caregivers were expected to log regularly.

During the ideation and prototyping phases of the design process, a wearable device for logging PROs and measuring digital biomarkers emerged as a promising solution. Early in the design process, insights gathered from meetings with health care staff helped define the essential features of the proposed solution. The wearable device should adopt a smartwatch form factor to remain small and lightweight, minimizing interference with users' daily activities. At the same time, it should incorporate the largest feasible touchscreen to enhance accessibility, complemented by both virtual and physical buttons. The inclusion of physical buttons was strongly emphasized by clinicians from SOLCA, as their manipulation served as a therapeutic distraction during pain episodes. The device should also offer reasonable water resistance and the capability to continuously measure at least heart rate (other digital biomarkers were a plus but not essential). To ensure usability and redundancy, PRO entry should also be possible via a companion mobile app, which offers a larger display. Additionally, health care staff should have access to a web-based dashboard to visualize patients' health data in real time.

NEST System Architecture

For the last 2 phases of the design process, prototype and test, we developed a functional prototype resembling as much as possible the features collected in the previous phases. This functional prototype is the first version of the NEST system and consists of 3 components including a smartwatch, a mobile app, and a web dashboard. Figure 2 depicts the NEST system architecture and how its components interact with each other and with their respective users.

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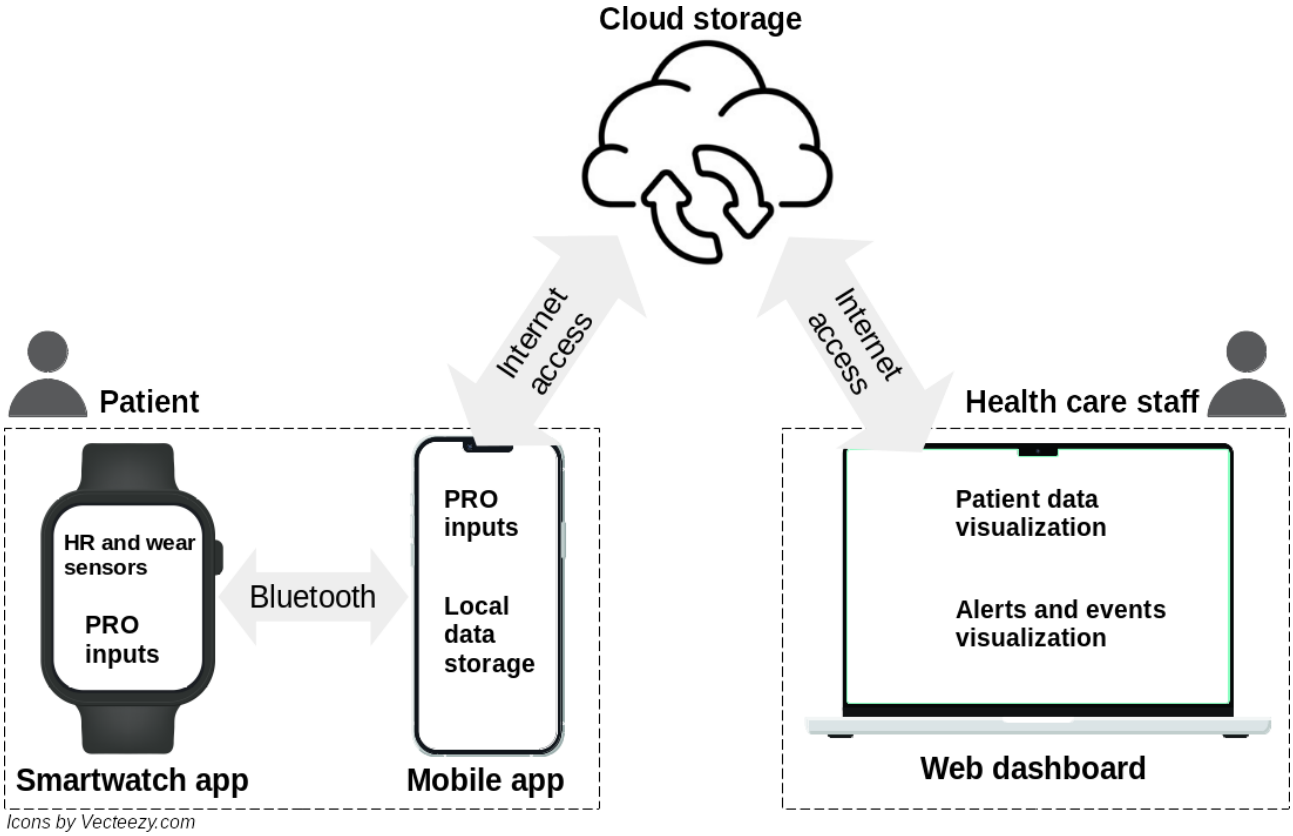
Figure 2. The NEST system consists of 3 components, including a smartwatch, a mobile app, and a web dashboard. HR: heart rate; PRO: patient-reported outcome.



One of the primary features of the NEST smartwatch is the pain diary, which enables patients to complete a structured pain assessment PRO. This feature, derived and adapted during the initial design process from the original paper–based pain diary used by SOLCA's staff, consists of 4 questions that prompt users to describe the type of pain they experience, assess whether it limits their daily activities, rate its intensity on a predefined scale, and select the precise pain location using an interactive body map interface. Additionally, users can register an emergency use of their prescribed analgesic, called a rescue, using a designated button function on the watch. The smartwatch also provides real-time heart rate monitoring, displaying the patient's current heart rate directly on the screen. All registered data, pain diary answers, rescue events, heart rate, and battery level are transmitted to the NEST mobile app via Bluetooth for further processing. Screenshots of the NEST smartwatch, the NEST mobile app, and the NEST web dashboard can be found in Multimedia Appendix 1.

All the features described above were iteratively refined and tested through 2 participatory design workshops with staff from SOLCA's palliative care unit. To validate the final prototype in a real-world context with patients who are ambulatory, an observational study was conducted. The methodology of this study is detailed in the following section.

Participants and Protocol

Our study was designed as an observational study for product usability, as our main objective was to evaluate the usability and feasibility of the NEST system within the real day-to-day workflow of SOLCA's staff.

Participants were recruited by SOLCA's palliative care team through the home-based care program, which provides medical visits to patients who are unable to travel regularly to the hospital for consultations. Upon initial contact with the patient, at home or at the hospital, a member of the team performed a direct clinical evaluation to assess the patient's Karnofsky Performance Status (KPS), a widely validated objective measure (ranging from 0 to 100) to assess patient survival in oncology clinical trials [23]. This evaluation, following KPS criteria, was based on observation of the patient's functional status and a structured clinical interview to determine the patient's ability to perform daily activities, their level of dependence, and their need for medical assistance. Following the evaluation, if the inclusion and exclusion criteria were met, the clinician informed the patient of the NEST project, its objectives, benefits, and expected commitments. If the patient agreed to participate, recruitment began by obtaining written informed consent directly from the patient, with a family member present to support the process. Inclusion criteria were (1) adult patients with cancer capable of providing informed consent, (2) a KPS above 50, (3) current pain requiring monitoring, and (4) ownership of an Android smartphone (although one could be provided on loan if needed). Exclusion criteria included cognitive impairment, physical limitations preventing smartwatch use (eg, edema or cachexia), lack of family support, residence outside the city, and being younger than 18 years.

The protocol was divided into two phases: (1) hospital-based monitoring for one week and (2) home-based monitoring for one week. During both phases, participants wore the NEST smartwatch continuously and logged their PROs and rescue

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medication use through the smartwatch or the NEST mobile app. At recruitment, the patient and a family member received basic training on the use of the NEST system by SOLCA staff. Additionally, a small, structured interview was conducted to collect demographic data on the patient. The palliative care team conducted daily check-ins during the hospital phase and remote follow-ups every 2 days during the home phase.

After the conclusion of the hospital and home phase, a final in-person evaluation and structured interview were conducted to collect qualitative feedback on patient user experience. This interview took place at the hospital when the patient returned the wearable device and was administered by a member of the SOLCA staff. All questions were read aloud to the participants. Given the patients' delicate emotional and physical condition at the conclusion of the study, their responses were not audio-recorded; instead, the interviewer took written notes.

In parallel, qualitative feedback was also obtained from health care staff who had direct contact with participants and the NEST system. This feedback was gathered via a structured survey sent and collected by email at the end of the study.

We designed both questionnaires to accommodate the specific constraints of our palliative care context, where health care staff face high workloads and patients are likely to be in fragile health toward the end of the study. As a result, both interviews and surveys were intentionally kept brief and focused. Several questions were adapted from the mHealth App Usability Questionnaire (MAUQ) developed by Zhou et al [24], which evaluates app usability in health care settings for both patient- and provider-facing stand-alone mobile apps. Modifications were made to account for the real-time data synchronization capabilities of the NEST app and the inclusion of a wearable device, which made the system deviate from a typical stand-alone configuration as defined in the MAUQ.

The full interview and survey scripts are available in Multimedia Appendix 2.

Devices and Data

The smartwatch models used in the study were the Samsung Galaxy Watch 5 (SM-R910, 44 mm screen) and Galaxy Watch 6 (SM-R940, 44 mm screen), as previous studies have validated the suitability of these smartwatch models for patient home monitoring [25]. These devices were delivered to participants with the NEST WearOS app preinstalled. At recruitment time, the NEST mobile app was installed on each participant's phone and synchronized with the smartwatch by SOLCA's staff; a technician from ESPOL was on hand for support during this stage.

The photoplethysmography sensor on the smartwatch was used to obtain heart rate measurements and to assist with wrist detection. The inertial measurement unit on the wearable was used solely to complement wrist detection by identifying motion patterns indicative of active wear. Both heart rate and wrist detection were derived from processed data generated by the device's proprietary internal algorithms. No raw sensor data were collected during the study. In summary, collected data included the following:

1. Time-stamped pain diary entries and rescue usage reports
2. Time-stamped heart rate measurements
3. Device usage metadata (watch battery level, report source, and device status)
4. Qualitative feedback from participants on usability, comfort, and perceived usefulness
5. Qualitative feedback from health care personnel on usability, impact, integration, and perceived usefulness.

All quantitative data were automatically synced to a secure server accessible to SOLCA's clinical team through the NEST web-based dashboard.

Ethical Considerations

The study received ethical approval from the Human Research Ethics Committee of the Universidad Técnica de Manabí on August 12, 2024 (approval code CEISH-UTM-EXT_24-06-21_FXDB). Patient screening and recruitment commenced shortly thereafter and ended on September 15, 2024. Only palliative care unit staff interacted with participants. All participants signed an informed consent form prior to participation and received no compensation for participating. All personally identifiable information was kept as confidential by SOLCA, and the participants' identities were anonymized using sequential numerical identifiers (User1, User2, etc) in data transmissions and in reports shared with the rest of the project.

Results

Overview

Overall, 7 patients from SOLCA's palliative care unit volunteered and met the inclusion criteria for participation in the study. Around 4 were recruited during outpatient consultations at the hospital and 3 during home-based care visits. Of these, 5 patients used the NEST system for more than 1 week, and 4 patients completed the study by using the system for 2 weeks or more. The study was conducted over a 7-week period in Q3 2024.

Table 1 details the demographic characteristics of the 7 patient participants. In addition to these patients, 5 members of the palliative care unit participated in the study, including 3 medical professionals and 2 nurses, who provided clinical support. Notably, 3 of these health care providers are coauthors of this study. One of the participating physicians also offered technical assistance to the patients, having received prior training on the use of the wearable devices. Detailed disaggregated demographic data of all participants are provided in Multimedia Appendix 3.

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Table . Demographic characteristics of patient participants (N=7).

Characteristics	Value
Age (years), range (median)	35 - 77 (47)
Gender, n (%)	
Man	1 (15)
Woman	6 (85)
Marital status, n (%)	
Single	2 (29)
Married	3 (43)
Divorced	1 (14)
Widowed	1 (14)
Self-reported socioeconomic status, n (%)	
Low-income household and high school diploma	2 (29)
Middle-income household and higher education	5 (71)

User 1 was unable to cooperate with the medical team at the end of the study, and as a result, the closing interview was not conducted, and the smartwatch was not returned. User 5 experienced an extended hospital stay, and the medical team judged that it was best to remove the smartwatch during the closing interview at the end of his hospitalization. User 6 chose to withdraw from the study after 1 day due to her rapidly deteriorating health condition. User 7 encountered an unrecoverable technical failure with her mobile phone after 2 days, which prevented further participation.

Quantitative Analysis

The NEST watch transmits a telemetry ping to the cloud database every 5 minutes while worn on the participant's wrist. Each ping includes the current heart rate reading and battery level of the device. When combined with participants' self-reported events (pain and rescue), these pings offer valuable insight into usage patterns of the NEST system by allowing the reconstruction of individual timelines throughout the study. Figure 3 presents a visual timeline of each participant's interaction with the NEST system (identified as User 1, User 2, etc). Colored bands indicate periods during which participants wore the NEST watch, either at home or in the hospital. Distinct point shapes mark PROs, either self-reported pain or rescue medication events, recorded via the NEST watch or mobile app. Usage data (eg, watch wear time and event reports) were retrieved from the NEST system database, while location information (home or hospital) was derived from anonymized reports provided by SOLCA's palliative care unit.

Figure 3. Telemetry pings were used to infer when the NEST (Non-intrusive Devices for Telemedicine) watch was actively worn.

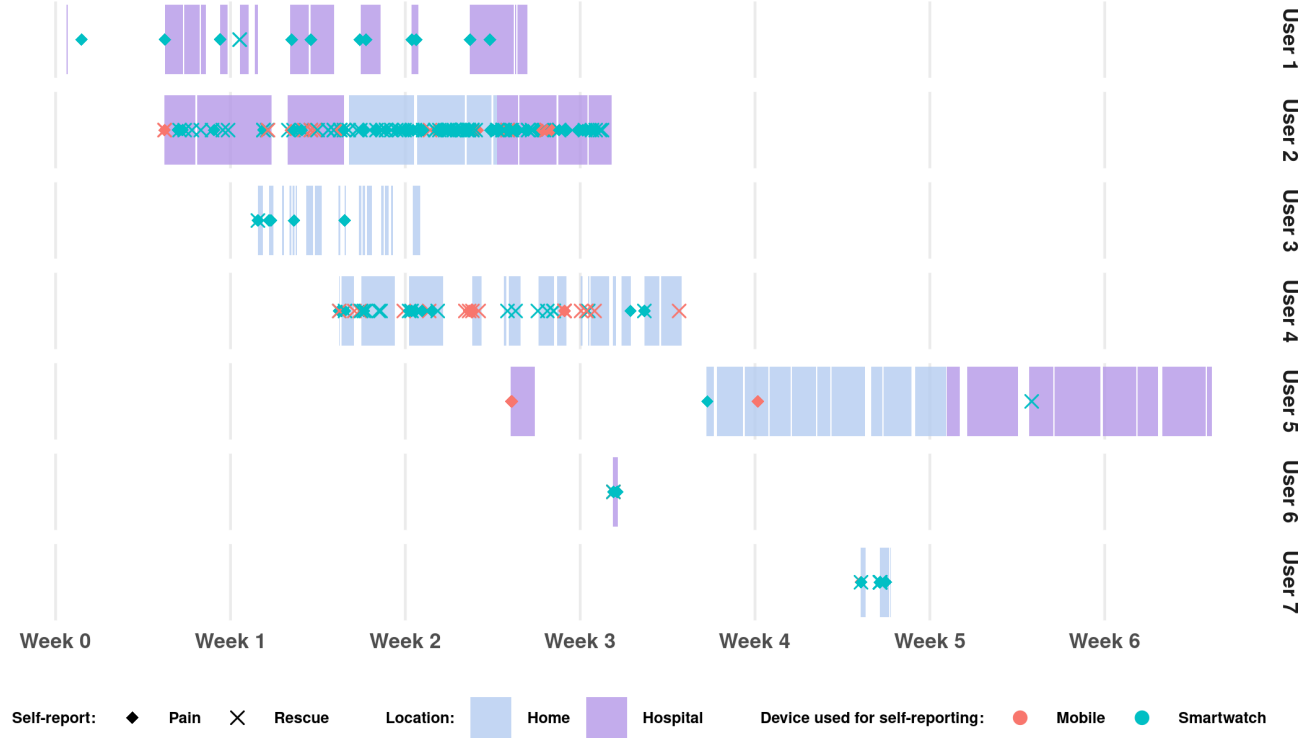

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Table 2 summarizes the NEST watch usage for each participant. "PROs" is the total amount of self-reports (pain diary and rescue) per participant, and "Possession" refers to the total number of days participants had the device assigned to them. "Wear time" indicates the total number of hours the watch was actively worn during that period. "Wear rate" represents the percentage of time the device was worn relative to the total possession period. Table 3 breaks down the distribution of self-reports by input method, either the NEST watch or the NEST mobile. Figure 4 presents a breakdown of the number of telemetry pings received per participant across different times of day. This figure reveals that, except for User 3, users mostly used the smartwatch at night during sleeping hours. Users 6 and 7 were omitted from these statistics because they only used the NEST watch for a day or less, precluding the possibility of discerning daily patterns in their data.

Table . NEST[a] watch usage per participant.

User	PROs[b] (n)	Possession (days)	Wear time (hours)	Wear rate (%)
User 1	15	18.4	176	39.8
User 2	193	17.9	396	92.1
User 3	6	6.5	55.9	35.8
User 4	56	13.7	189.8	57.6
User 5	5	28.1	460	68.3

[a]NEST: Non-intrusive Devices for Telemedicine.

[b]PRO: patient-reported outcome.

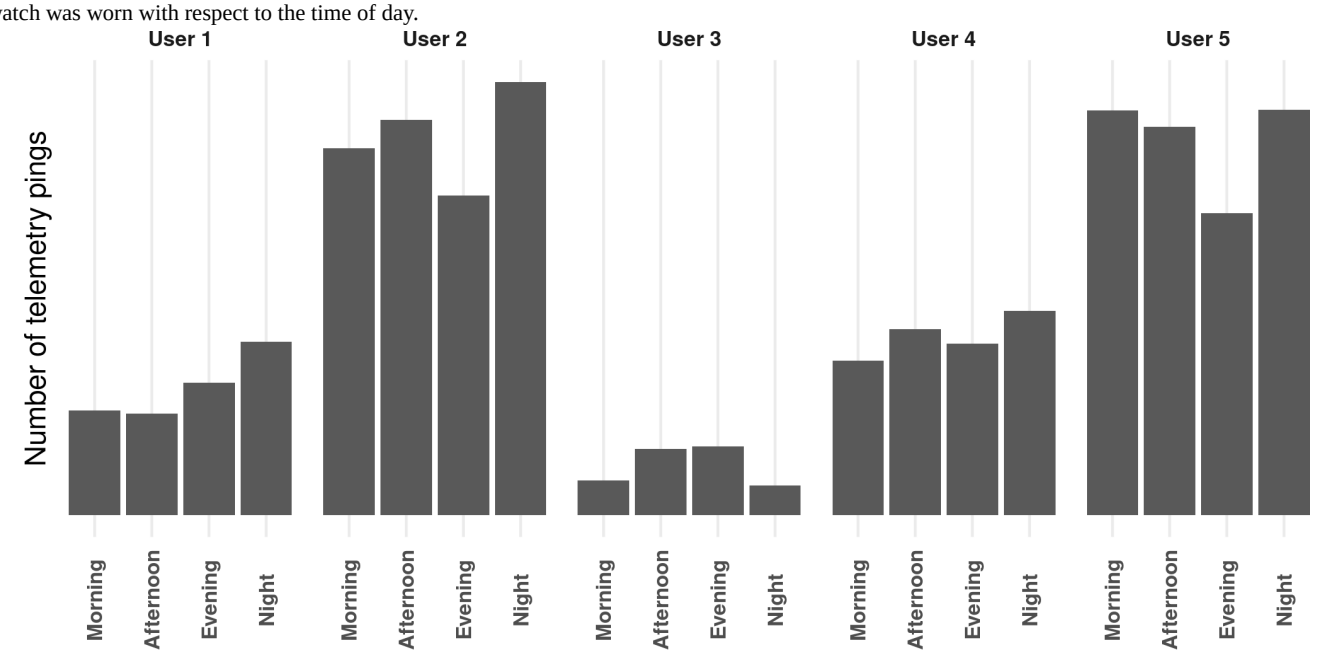
Table . Distribution of patient-reported outcomes for pain and rescue reports by input method.

Input method	PROs[a]		Total PROs, n (%)
	Pain reports (n)	Rescue reports (n)	
NEST[b] mobile	19	31	50 (17)
NEST watch	124	122	246 (83)

[a]PRO: patient-reported outcome.

[b]NEST: Non-intrusive Devices for Telemedicine.

Figure 4. The number of telemetry pings sent to the cloud database is used here to estimate when the NEST (Non-intrusive Devices for Telemedicine) watch was worn with respect to the time of day.



Among users 1 through 5, adherence to wearable use (defined as wearing the smartwatch on the wrist) varied, with User 2 showing the highest usage, 92% over 18 days, and User 3 the lowest, 36% over 7 days. In contrast, PRO inputs showed greater variability, ranging from 193 reports by User 2 to only 5 by User 5 across a 28-day period (Table 2). All participants overwhelmingly preferred the NEST watch over NEST mobile for PRO inputs (Table 3), and no statistically significant

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dependency was found between input method, location, and self-report type.

Previous studies have identified limited battery life and the need for frequent charging as significant barriers to the adoption of wearable devices in health care settings [11,25]. Accordingly, this study included an evaluation of how these factors impacted the usability of the NEST system.

Table 4 presents the battery discharge statistics per participant and the number of charges (for the NEST watch) per participant.

Discharge rates observed during the study were consistent with those reported by the device manufacturer (up to 40 hours or ~2.5% per hour), suggesting that the NEST WearOS app and typical usage do not significantly impact battery performance. When considered alongside Figure 4, which indicates lower device usage in the evening and increased usage during the night, this pattern suggests that users commonly charged the watch prior to wearing it to sleep. More detailed battery usage statistics can be found in Multimedia Appendix 4.

Table . Battery discharge statistics and charging frequency by participant.

User	Charges (n)	Discharge duration (hours), mean (SD)	Discharge rate per hour (%), mean (SD)
User 1	6	43.1 (15.2)	1.8 (0.2)
User 2	10	39.6 (17.8)	1.7 (0.3)
User 3	5	22.2 (10.6)	2.7 (0.6)
User 4	7	34.9 (10.5)	2.7 (0.5)
User 5	14	33.2 (14)	2.6 (1.0)

Qualitative Results

At the conclusion of the study, semistructured interviews were conducted with the 7 participating patients to evaluate their overall experience with the NEST system. These interviews, consisting of 8 open-ended questions on usability, were administered by health care staff from SOLCA and took place upon the formal return of the smartwatch. Additionally, qualitative feedback was collected from the 5 members of SOLCA's palliative care team who participated in this study in clinical and technical roles.

Patients

Of the 7 participants, 6 completed the full feedback interview. One participant (User 1) did not return the device, and thus no responses were obtained despite follow-up attempts.

Usability and Ease of Use

Around 6 of the 7 participants reported that both the wearable device and mobile app were easy to use, indicating that the interface was intuitive and required minimal adaptation time. Two participants adapted within days, while another reported immediate ease of use. Only one participant mentioned a specific difficulty related to uncertainty about how to charge the smartwatch.

> *It took me 3 days to adapt to the smartwatch and the app…* [User 3]
>
> *It took me a week to adapt to the smartwatch…* [User 4]

Technical Functionality

User 6 reported that the watch disconnected from the mobile app after a few days and therefore stopped using the device. User 2 noted minor, unspecified technical problems, whereas the rest reported smooth functionality throughout the study.

Pain Management Support

In total, 5 of the 7 participants perceived the device as beneficial for managing their pain. One participant emphasized the usefulness of being able to track medication frequency through the app:

> *Thanks to the device, I could easily see how many rescues I used throughout the day. This made it easier to track my pain and the number of interventions needed.* [User 2]

Suggestions for Improvement

Users recommended several improvements. One participant suggested making the rescue logging function more prominent within the app interface and providing sound alerts if necessary.

Another user expressed interest in a voice-enabled option for enhanced accessibility.

> [It would be nice if the smartwatch could talk…] [User 3]

There was also a suggestion for a more compact device, as one user declined to use the smartwatch outside the study context due to its size. Also, User 6 suggested adding an alert button to the device:

> *I found the system mildly useful…it would have been beneficial if the smartwatch was linked to the nurses' station… [for alerts]* [User 6]

Daily Life Integration and Future Use

In 4 of the 7 participants expressed a willingness to continue using the wearable system beyond the research setting. Reasons included its practicality, its usefulness for tracking pain and activity levels, and the added sense of monitoring and safety. One participant specifically noted the value of step and heart rate tracking for daily well-being. In contrast, User 2 was reluctant to use the device regularly due to its size.

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Health Care Staff

A questionnaire with 14 questions on user experience, impact on pain management, integration into the hospital environment, suggestions, and ethical considerations was distributed to the 5 members of SOLCA's palliative care team who had direct contact with participating patients. Table 5 outlines the roles within the project of the health care personnel involved.

Table . Demographic characteristics of palliative care unit staff involved in patient-facing activities during the study.

Participant ID	Gender	Role	Experience in palliative care (years)
D1	Woman	Project supervisor	3
D2	Man	Medical support	1
D3	Man	Medical and technical support	3
N1	Woman	Nursing support	3
N2	Woman	Nursing support	2

User Experience

Overall, staff reported that patients found the NEST watch and mobile app moderately easy to use. While most participants adapted to the system quickly, initial challenges were observed with setup and charging. Three staff members emphasized that the training provided to patients was insufficient in some cases, especially regarding device configuration and battery management. Suggestions included improving initial training or incorporating hands-on practice sessions prior to deployment. The project supervisor noted:

> *It was a good experience, [the system] provided monitoring to selected patients and they were attentive to its use as a good tool that gave them security.* [D1]

However, one of the attending nurses remarked:

> *I heard a lot of comments about how the main problem was charging the watch.* [NI]

From the staff perspective, the web-based monitoring dashboard was consistently described as clear and easy to use. The user interface enabled timely access to pain reports and physiological data, although occasional connectivity or synchronization issues were noted.

Impact on Pain Management and Clinical Workflow

All clinicians observed positive changes in patient behavior related to pain reporting. Compared to paper-based diaries, the digital system allowed more consistent and immediate self-reporting, which was perceived to empower patients and support open discussions about pain management. The attending nurses remarked:

> *It was gratifying to see how some patients felt empowered by being able to monitor their own pain …* [NI]
>
> *[the system] … facilitated more accurate and timely decisions, especially in the administration of painkillers.* [N2]

However, the project supervisor was more cautious, suggesting the influence of the Hawthorne effect, where individuals modify their behavior because they are aware of being observed [19], on the more consistent use of the digital system. Moreover, 2 respondents cautioned that not all participants used the device continuously, which limited its influence on clinical decision-making.

Regarding physiological monitoring, views were mixed. Some professionals saw the device's continuous tracking as a promising complement to traditional methods, while others felt that its clinical value was limited without further optimization or integration with other systems. About the clinical usefulness of the data, the doctors remarked:

> *I don't think [the information collected by the device] is clinically useful, but it has allowed tracking without the need for direct contact, which sometimes takes a little longer.* [D1]
>
> *It is a useful tool, but I don't think it replaces traditional methods.* [D2]
>
> *It is no more useful than performing a direct interview with the patient.* [D3]

Integration Into Hospital Environment

Staff were optimistic about the compatibility of the NEST system with existing palliative care workflows. While full integration with electronic health records was not implemented during the study, all respondents agreed that the system could be linked effectively with telemedicine platforms or other digital tools to enhance multidisciplinary coordination.

The long-term viability of the device was considered plausible but dependent on certain conditions such as improved patient onboarding, dedicated technical support, and clear allocation of staff resources for monitoring.

Suggestions for Improvement

Common suggestions for improvement included adding medication reminders, improving battery life notifications, and incorporating features for broader tracking of symptoms (eg, anxiety or physical activity). All respondents emphasized the need for ongoing technical support, including troubleshooting, software updates, and user training, particularly given the variable levels of digital literacy among patients.

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Discussion

Principal Findings

This study addresses a critical gap in the current literature by exploring the feasibility and usability of wearable technology for pain monitoring in palliative cancer care within an LMIC setting. To our knowledge, it is among the first studies to explore this technology in such a context. For usability, limited battery life emerged as the primary usability challenge, as reported in qualitative feedback from both patients and health care staff and as reported in previous similar studies [11,25]. Nevertheless, usage logs indicated that 5 of 7 patients learned to routinely charge the smartwatch overnight and wore it during sleep. Although the small screen was noted as a barrier, all users still preferred the smartwatch over the smartphone for reporting PROs. Together with generally positive qualitative feedback, these findings suggest that typical usability barriers associated with wearable technologies can be successfully mitigated in this context.

As for the feasibility of implementation, we used the NASSS framework as a lens to identify two key issues: (1) the complexities and unknowns to manage toward scaling up and (2) long-term adoption of our sociotechnical solution. Our main insight is that, in our LMIC context, most of the complexity was found in the dynamics of the health condition while the technology shows clear promising signs of having value to patients and health care staff. However, a larger study is necessary to address the complexities inherent in palliative cancer care and to explore three key uncertainties: (1) how to enhance the system's value proposition by integrating it into the workflow of a palliative care unit, (2) what the actual cost–benefit balance of the technology is for health care organizations, and (3) how to manage third-party technological dependencies within an evolving and often ambiguous regulatory landscape for biomedical devices. These findings add to the emerging body of literature on digital health interventions in palliative care by uncovering the potential and pitfalls of wearable solutions in resource-constrained environments.

NASSS Framework Analysis

The NASSS framework, developed by Greenhalgh et al [20] in 2017 at the University of Oxford, provides a comprehensive approach for evaluating the implementation of health technologies across sociotechnical contexts. The framework consists of seven domains: (1) the health condition, (2) the technology, (3) the value proposition, (4) the adopter system, (5) the organization, (6) the wider context, and (7) the interaction and adaptation over time (refer to Figure 5 for more details). Each domain can be categorized as simple (predictable, few components), complicated (multiple interacting elements), or complex (dynamic, uncertain, and difficult to disaggregate). When multiple domains are classified as complex, implementation and long-term adoption tend to be significantly hindered [20].

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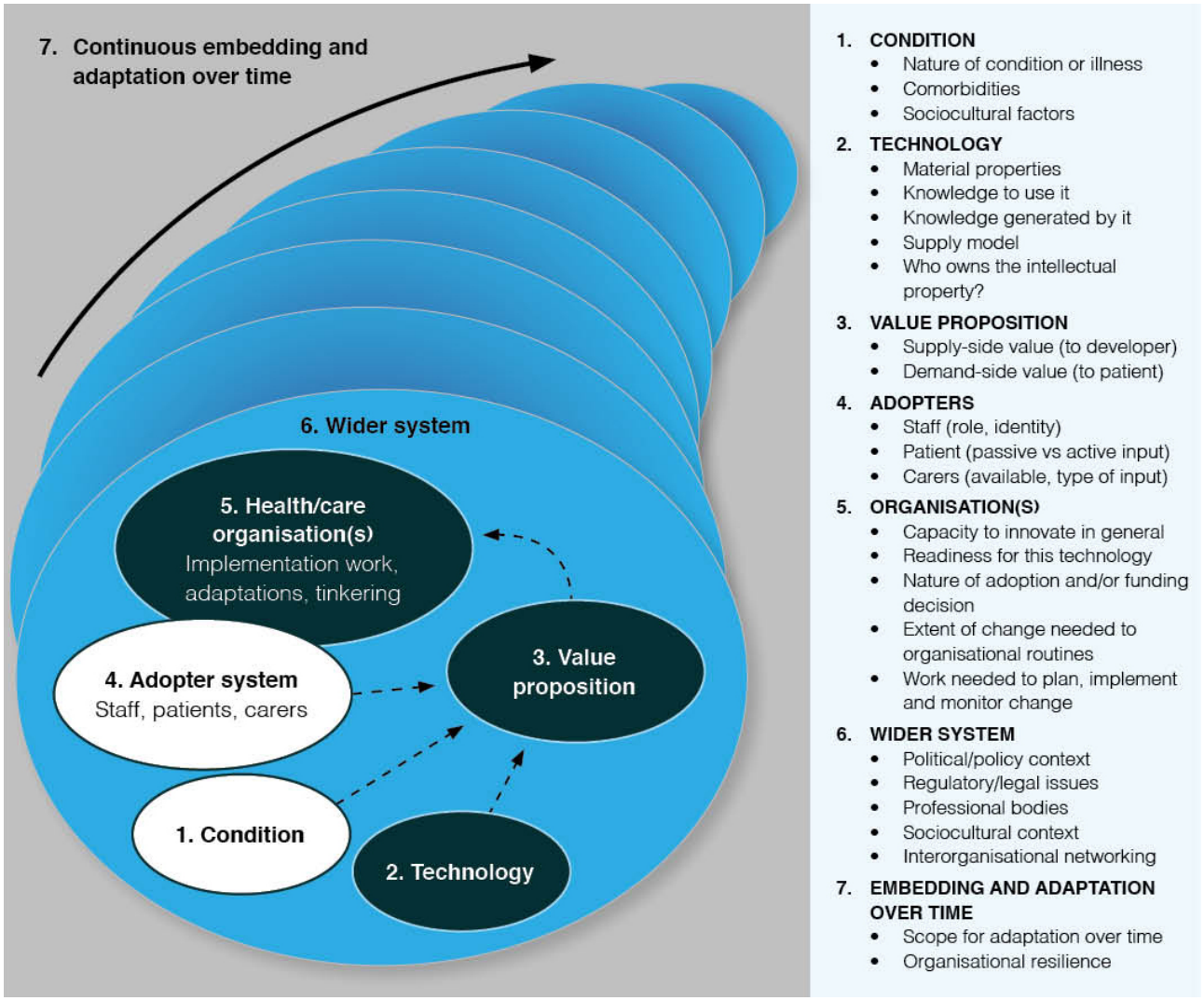
Figure 5. The NASSS (nonadoption, abandonment, scale-up, spread, and sustainability) framework helps to inform the design of new eHealth technologies (reproduced from Greenhalgh et al [26], which is published under Creative Commons Attribution 4.0 International License [CCBY reference citation #27).



In the case of the NEST system, the results of the observational study can be examined ex-post through the NASSS framework to identify current strengths, challenges, and areas requiring further development [20,26,28]. To reflect the exploratory nature of this study, we introduce a fourth category, to be determined, to denote domains where insufficient evidence prevents definitive classification. A detailed discussion and classification of each domain is provided below.

Condition

The condition addressed in this study is cancer, at any stage, requiring palliative care. Palliative care delivery is inherently individualized, shaped not only by the patient's clinical needs but also by the needs of companions and caregivers [4]. The complexity of this condition is heightened by the frequent presence of comorbidities and the dynamic nature of symptoms, particularly in the outpatient context. In our context, sociocultural factors further complicate care. Palliative care is often stigmatized or misunderstood, and its objectives may be dismissed or resisted by patients' families and social networks. These challenges were reflected in this study through recruitment difficulties leading to limited sample size, as well as issues with participant retention and study protocol adherence. This domain is therefore classified as complex.

Technology

The NEST system comprises 3 interconnected components, including the NEST watch, the NEST mobile app (for Android smartphones), and the NEST web dashboard. These components must communicate with each other in soft real-time to ensure the timely and accurate exchange of health data between patients and health care providers. In general, qualitative feedback from all stakeholders was largely positive. Notably, patients had a clear preference for using the smartwatch interface to submit self-reports, despite initial concerns about the small screen size. This preference remained consistent in both hospital and home settings.

However, several challenges were identified during the study (refer to Textbox 1), and these technical limitations suggest that this domain is best classified as complicated.

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Textbox 1. Technology domain challenges.

- NEST (Non-intrusive Devices for Telemedicine) watch: Although the customized software did not significantly reduce battery life, remaining close to the manufacturer's specified discharge duration, users typically needed to recharge the device every 2 days or less.
- NEST mobile: The diversity of devices within the Android ecosystem posed challenges for app setup and contributed to variability in performance and reliability across users.

Value Proposition

The value proposition of the NEST system can be considered across the 3 primary stakeholder groups, namely health care staff, patients, and institution (refer to Textbox 2).

Textbox 2. Value proposition for all stakeholders.

- Health care staff: Perceived value among health care professionals ranged from moderate to high. Poststudy feedback was generally positive, though some reservations were made, particularly regarding the limited use of the dashboard. The dashboard represented an additional interface to manage during their already demanding workflows. This underusage may reflect workflow integration challenges or limited perceived utility, indicating a potential barrier to realizing full value in clinical practice.
- Patients: Both qualitative feedback and quantitative usage data suggest that patients derived clear value from using the NEST (Non-intrusive Devices for Telemedicine) system. Participants engaged consistently with the wearable and mobile app, indicating acceptability and perceived usefulness. However, the extent and sustainability of this value require further investigation through long-term studies and larger samples.
- Institution (SOLCA [Sociedad de Lucha Contra el Cáncer]): From an institutional perspective, the financial burden of implementing and scaling the system, including the cost of smartwatches, backend infrastructure, and support, would likely fall on the health care provider rather than the patient. Thus, the long-term institutional value of NEST hinges on a more comprehensive evaluation of its impact on clinical outcomes, workflow efficiency, and cost-effectiveness.

Given these uncertainties, particularly around integration into clinical workflows and institutional cost-benefit, this domain is best classified as to be determined.

Adopters

The primary adopters of the NEST system are health care staff within the palliative care unit and their patients. The early involvement of health care staff in the design process translated later into a critical but positive attitude toward the system and its perceived usefulness. This is key to ensuring future adoption, and it is consistent with empirical findings on similar palliative care sociotechnical solutions [7,29].

For health care staff, the NEST system supplements rather than replaces existing telemedicine tools, offering additional value without significant disruption to established workflows. However, some reservations were noted regarding the consistent use of the dashboard and the need for additional training, suggesting that further refinement or integration with existing clinical systems may be needed to support regular use.

As for patients, study data indicate that patients were generally willing to engage with technology, particularly when encouraged or instructed by staff. Given the variation in patient readiness and the need to address integration issues for staff, this domain is best classified as complicated.

Organization

SOLCA, the hosting institution for the study, demonstrates openness to innovation and a willingness to explore new technologies for improving patient care. However, as a semiprivate organization reliant on government funding and operating under budgetary constraints, large-scale adoption of the NEST system would require careful financial consideration. Future adoption will depend on lowering investment costs (cheaper wearables, less reliance on technical support, etc) and convincing key stakeholders of the technology's value, and for this, a more extensive study is needed. This domain is best classified as to be determined.

Wider System

External risks beyond SOLCA's control, such as potential government funding cuts, pose a threat to sustained adoption. Although no issues were noted regarding user or data safety, the regulatory landscape for medical devices in Ecuador remains unclear and potentially contradictory. Given that these uncertainties will have to be managed, this domain is best classified as complicated.

Embedding and Adaptation Over Time

The growing need for palliative care suggests an expanding potential user base, strengthening the long-term value proposition of the NEST system. However, the system's current reliance on third-party commercial platforms (eg, Samsung wearables and Google's WearOS) introduces significant limitations. These platforms are typically high-end consumer products, subject to proprietary constraints, limited researcher access to raw sensor data, and opaque data processing algorithms [13,30,31]. Furthermore, future updates to these platforms may inadvertently disrupt existing deployments, undermining system stability and continuity of research.

This reliance is particularly problematic in the context of optimizing digital biomarkers for LMICs. For instance, photoplethysmography sensors embedded in commercial wearables are often calibrated primarily for lighter skin tones [32,33], reducing accuracy for diverse populations. Additionally,

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the development of novel digital biomarkers better suited for pain management remains constrained by restricted data access.

This complexity could be managed by pursuing a custom-made low-cost hardware solution, but this in turn requires navigating the regulatory environment, which remains insufficiently defined and may pose challenges to sustained adoption. These factors highlight the need for further research. Given these uncertainties, this domain is best classified as to be determined.

Limitations

The main limitation of this study is the sample size. It is therefore underpowered for a more thorough quantitative analysis and unbalanced in several demographic variables (eg, gender, socioeconomic status, and education). Also, positive qualitative responses may be influenced by novelty and Hawthorne effects [19], wherein participants alter their behavior or report more favorable experiences simply due to heightened attention during the study period. Palliative care in patients with cancer is a dynamic and complex environment, especially in an LMIC setting, where patients are extremely vulnerable and health care staff are normally underpaid, overwhelmed, and work with limited resources. Any study in this context will face challenges regarding retention, engagement, and data quality. Despite these constraints, prior research suggests that usability testing with as few as 5 participants can reveal most usability issues [34,35]. Moreover, Greenhalgh et al [20,26] have advocated for applying the NASSS framework early in the development of sociotechnical health solutions to ensure alignment with the clinical context and inform the design of future, larger-scale evaluations.

Conclusion

Our findings suggest that the commonly reported usability hurdles of a smartwatch-based sociotechnical health solution may be surmountable given fluid communication between stakeholders during all stages of design and deployment. While our results should not be broadly generalized to all LMICs due to regional variability, the commonly held concerns regarding feasibility in LMICs, such as unreliable internet access and the high cost of internet-capable devices [36-38] were not observed in our study. Instead, the primary threats to feasibility in our context seem to lie rather in the highly complex and dynamic environment of palliative cancer care, regulatory ambiguity regarding the use of medical devices, and the workload burden on health care staff. To navigate this complexity, future scale-up efforts could benefit from applying complexity assessment tools developed by Greenhalgh et al [26] as part of the NASSS framework extension, which supports the implementation of sociotechnical health care systems, such as NEST. These next steps will be critical to ensuring the system's robustness, scalability, and sustainability in the context of palliative care in low-resource settings.

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Authors' Contributions

Conceptualization: FD, MV, EP, WF, AV, FP, BDS, JS
Data curation: FD, JH
Formal analysis: FD
Funding acquisition: FD, BDS, JS
Investigation: FD, JH, JB, MV, EP, WF, AV, FP
Methodology: FD, MV, AV, FP
Project administration: FD, MV, EP, BDS, JS
Software: JB
Writing–original draft: FD, JH, JB
Writing–review & editing: FD, MV, EP, WF, AV, FP, BDS

Conflicts of Interest

None declared.

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Multimedia Appendix 1
Screenshots of NEST (Non-intrusive Devices for Telemedicine) devices.
[DOCX File, 1100 KB - formative_v10i1e78098_app1.docx]

Multimedia Appendix 2
Qualitative data collection scripts.
[DOCX File, 21 KB - formative_v10i1e78098_app2.docx]

Multimedia Appendix 3
Demographic characteristics of patients receiving palliative care who participated in our study.
[DOCX File, 15 KB - formative_v10i1e78098_app3.docx]

Multimedia Appendix 4
Detailed battery usage.
[DOCX File, 197 KB - formative_v10i1e78098_app4.docx]

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Abbreviations

ESPOL: Escuela Superior Politécnica del Litoral
KPS: Karnofsky Performance Status
LMIC: low- and middle-income country

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MAUQ: mHealth App Usability Questionnaire
NASSS: Nonadoption, Abandonment, Scale-up, Spread, and Sustainability
NEST: Non-intrusive Devices for Telemedicine
PRO: patient-reported outcome
SOLCA: Sociedad de Lucha contra el Cáncer
VUB: Vrije Universiteit Brussel

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Family-Based Digital Lifestyle Intervention for Hispanic Adolescents and Their Parents: Iterative Co-Design and Development Study

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Abstract

Background: Hispanic youth in the United States have the highest rates of pediatric obesity and do not often meet national guidelines for physical activity and dietary intake. Family-based interventions can improve health outcomes in both youth and their parents and are highly relevant to Hispanics due to the cultural value of familismo (familism). However, few existing family-based obesity prevention interventions for Hispanics target adolescents and their parents, and those that do are not designed to facilitate widespread reach.

Objective: This study describes the development of Healthy Juntos (Healthy Together), a family-based intervention for Hispanic adolescents and their parents that leverages the web and smartphone technology to prevent the onset of adolescent obesity by promoting healthy lifestyle behaviors (physical activity and diet).

Methods: We used an iterative co-design process guided by the Integrate, Design, Assess, and Share (IDEAS) framework, which outlines 10 phases for developing digital interventions. Hispanic adolescents at risk for obesity and their parents (n=90; 45 dyads) participated across different phases of the intervention development process. We conducted qualitative interviews to understand their needs and preferences and to gather feedback on a series of intervention prototypes (conceptual, paper and minimally functional, and fully functional).

Results: Participants reported using technology for their health in limited ways (eg, to search for medical symptoms and recipes). They described the importance of having interactive and social features as part of a family-based digital health intervention. Their suggestions related to content, functionality, and aesthetics resulted in a fully functional prototype of a digital lifestyle intervention for Hispanic adolescents and their parents.

Conclusions: The iterative co-design process was crucial for refining the Healthy Juntos intervention. Our next steps are to evaluate its feasibility, acceptability, and preliminary effects through a pilot randomized controlled trial.

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KEYWORDS

digital health; family-based; obesity prevention; Hispanic; adolescent; user-centered design

Introduction

Obesity disproportionately affects Hispanics in the United States, with Hispanic youth experiencing the highest prevalence (26%) relative to non-Hispanic Black (24%), White (16%), and Asian (9%) youth [1]. This disparity continues into adulthood, where the prevalence of overweight or obesity is higher for Hispanic men (88%) and women (79%) compared to

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non-Hispanic White men (75%) and women (66%) [2,3]. Furthermore, Hispanic adolescents exhibit a greater increase in BMI from ages 12 to 19 years compared to their non-Hispanic White peers [4,5]. Likely contributing to these rates, most Hispanic youth and adults do not meet national guidelines for physical activity or diet [6-9]. Hispanic youth engage in only 35 of the recommended 60 minutes per day of moderate-to-vigorous physical activity (MVPA) and are sedentary for ~10 hours daily [6]. They also show poor adherence to US dietary guidelines, as indicated by a low mean Healthy Eating Index (HEI) score of 53.8 out of 100, including low scores for whole fruit (2.1 out of 5) and total vegetable intake (2.0 out of 5) [7]. With Hispanics comprising 62.5 million Americans and projected to represent nearly a quarter of the US population by 2040 [10,11], the delivery of culturally relevant, evidence-based, and scalable obesity prevention interventions in this population is a major public health priority.

Adolescence represents a critical window for obesity prevention efforts. Although youth with obesity are 5 times more likely to have obesity in adulthood, this pattern is driven largely by adolescents, an estimated 70% of whom continue to have obesity after age 30 years [12]. We conducted a comprehensive systematic review and meta-analysis of pediatric obesity prevention and treatment interventions among Hispanic youth aged 0‐18 years [13]. Our quantitative synthesis of 105 interventions published between 2000 and 2020 showed small but significant overall effects on youth weight status (Hedges g=−0.15), waist circumference (Hedges g=–0.15), physical activity (Hedges g=0.12), fruit and vegetable intake (Hedges g=0.08), and sugar-sweetened beverage intake (Hedges g=–0.07). Importantly, interventions targeting early-to-middle adolescents (aged 12‐15 years) showed significantly larger effects on weight status (Hedges g=−0.27) compared to those conducted during early childhood (Hedges g=−0.13), childhood (Hedges g=−0.03), and late adolescence (Hedges g=−0.09), underscoring the importance of this developmental stage.

During early to middle adolescence, although adolescents begin to seek independence, parents still exert significant influence on eating habits (eg, overseeing grocery shopping, determining the frequency of family meals, and establishing normative expectations), as well as on household physical activity patterns [14,15]. Because Hispanic parents prioritize familismo (familism), or family interdependence and loyalty, and generally have later age expectations for youth to engage in independent behaviors than other ethnic groups [16,17], family-based approaches (ie, those that actively involve family members in the behavior change process) remain highly culturally relevant throughout adolescence. Interventions in our meta-analysis involving the family had significant effects on Hispanic youth's weight status (Hedges g=−0.19). Despite this, only 6 of the 25 interventions for early-to-middle adolescents were primarily family-based, reinforcing the need for more family-based obesity prevention efforts among Hispanic adolescents [18].

Digital technology offers a promising avenue for delivering family-based lifestyle interventions to Hispanic adolescents and their parents. While digital interventions have been shown to improve adolescent weight [19] and lifestyle behaviors [20,21], especially when involving parents [19,22,23], their application among ethnic minority youth and their families remains limited [24]. In our aforementioned meta-analysis, for example, only 4% of studies leveraged some form of technology (eg, the internet, SMS text messaging) [13]. Thus, there is a clear opportunity to increase digital lifestyle intervention research among Hispanics, who are just as likely as non-Hispanic Whites to own smartphones (93% vs 91%) and more likely (20% vs 12%) to be smartphone-only internet users [25]. Hispanic adolescents aged 13‐17 years also report high access to smartphones (96%) and are more likely than their non-Hispanic White peers to report using the internet "almost constantly" (55% vs 38%) [26]. By capitalizing on the widespread adoption of digital technologies, researchers should prioritize the development and evaluation of digital interventions that can empower Hispanic youth and their families to adopt healthier lifestyles. As such, the purpose of this study is to describe the development of a family-based digital intervention, Healthy Juntos (Healthy Together), for promoting healthy lifestyle behaviors (physical activity and diet) in Hispanic adolescents. We systematically report how user-centered qualitative and quantitative feedback from Hispanic parents and adolescents was integrated to refine the intervention's content, functionality, and aesthetic design, resulting in a fully functional prototype ready for evaluation in a pilot randomized controlled trial (RCT).

Methods

Overview

We used the Integrate, Design, Assess, and Share (IDEAS) framework to guide our intervention development and iterative co-design process [27]. The IDEAS framework outlines a systematic set of 10 phases for developing and evaluating digital health interventions, which include (1) empathizing with target users, (2) specifying target behavior(s), (3) grounding intervention development in behavioral theory, (4) brainstorming implementation strategies, (5) prototyping potential products, (6) gathering user feedback, (7) building a minimum viable product, (8) pilot testing, (9) evaluating efficacy, and (10) sharing findings. While these phases are outlined sequentially, this framework encourages a flexible and iterative approach, allowing developers to revisit and refine different phases as needed. This initial report outlines our application of the first 7 phases of the IDEAS framework (Table 1).

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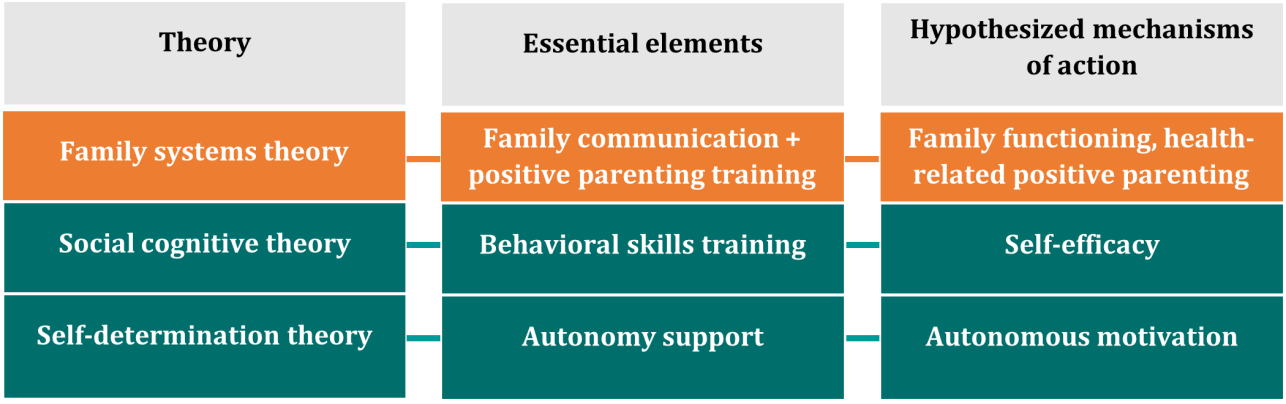
Table . Application of the IDEAS framework to the development of Healthy Juntos.

IDEAS framework	Healthy Juntos
Empathize with users	Interviews and focus groups using conceptual prototypes (n=20 dyads)
Specify target behaviors	Moderate-to-vigorous physical activity (MVPA), diet quality, sedentary behavior, BMI
Ground in theory	Family systems with social cognitive and self-determination theories
Brainstorm	Development of paper and minimally functional prototypes
Prototype potential products	Development of paper and minimally functional prototypes
Gather user feedback	Evaluation of paper and minimally functional prototypes (n=15 dyads)
Build a minimum viable product	Development and evaluation of fully functional prototype (field trial; n=10 dyads)
Pilot test	Next steps
Evaluate efficacy	Next steps
Share findings	Next steps

During phase 1 of the IDEAS framework, we collected qualitative data from Hispanic parents and their 12 - 15-year-old adolescents to better understand their lifestyle behaviors and use of technology for health and to gather their feedback on initial intervention concepts and prototypes ("conceptual prototypes"). During phases 2-3, we specified our target behaviors (ie, increasing MVPA, improving dietary intake, reducing sedentary behavior) and grounded our intervention development in behavioral and motivational theories. Given recommendations to integrate family systems theory [28] with social cognitive [29] and self-determination theories [30] to develop interventions for addressing obesity in high-risk youth [31], our conceptual framework integrated family communication and positive parenting with behavioral strategies (eg, goal setting) and elements involved in fostering autonomous motivation (eg, autonomy support; Figure 1). We additionally considered Hispanic cultural values and constructs, including familismo (familism), confianza (trust), personalismo (personal connection), and acculturation (ie, the process by which individuals from one culture adapt to the behaviors, attitudes, and values of another culture) [32] in our conceptualization of the intervention. During phases 4-5, we designed initial intervention prototypes ("paper and minimally functional prototypes"). In phase 6, we gathered qualitative feedback on these prototypes from Hispanic parent-adolescent dyads, which informed the development of a "fully functional" prototype. The fully functional prototype was then assessed in phase 7 through a small-scale field trial.

Figure 1. Conceptual framework.



Participants

A total of 45 different sets of Hispanic-parent adolescent dyads participated across the 7 phases of the intervention development process.

Eligibility Criteria

Families were eligible to participate if (1) the adolescent's primary caregiver self-identified as Hispanic; (2) the adolescent was between the age of 12 and 15 years; (3) the adolescent lived with an adult primary caregiver (ie, biological parent or legal guardian; herein referred to as "parent") willing to participate; (4) both parent and adolescent owned a smartphone with internet

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access; (5) the adolescent did not meet recommendations for fruit and vegetable intake as determined by the fruit and vegetable brief measure [33]; (6) the adolescent did not meet physical activity guidelines as determined by the 60-minute MVPA screening measure [34]; and (7) the adolescent self-reported engaging in more than 2 hours of daily screen time, based on three items from the Youth Risk Behavior Surveillance Survey [35].

Families were excluded if (1) the adolescent's BMI-for-age-and-gender was <5% (underweight) or ≥ 95% (obesity); (2) the adolescent had a chronic medical condition (eg, type 2 diabetes) that required intensive lifestyle modification; (3) the adolescent had a diagnosed developmental delay that would interfere with understanding program materials; (4) the parent or adolescent had a diagnosed medical or psychiatric condition and was taking medications that would interfere with changes to physical activity or diet (eg, adolescent was diagnosed with Attention Deficit Hyperactivity Disorder and was on stimulant medication); and (5) the family was planning to move out of South Florida during the study period.

Recruitment

We used several recruitment strategies, including partnering with local pediatric primary care clinics in South Florida, drawing from consent to contact lists, offering monetary incentives for referrals from enrolled study participants, advertising the study on social media, and distributing flyers at community events.

Our research team contacted a total of 540 potential families. Of those, 45% were ineligible, 31% did not respond to our calls, 12% refused to participate, and 2% were enrolled in a competing study (see Multimedia Appendix 1 for participant flow diagram). Of the 55 eligible families, 82% (n=45 families) provided written informed consent and assent and agreed to participate in the study.

Procedures

Overview

We prescreened potential participants in person at pediatric primary care clinics or by phone. To confirm the adolescent's eligibility, study staff measured their height and weight and calculated their BMI percentile. Due to the COVID-19 pandemic and the university policy to conduct research remotely at the time, we conducted recruitment for our field trial (IDEAS phase 7) exclusively by phone and determined adolescent eligibility using parent-reported height and weight to estimate adolescents' BMI percentile.

We audio- or video-recorded all qualitative data collection sessions, and they were transcribed verbatim by a professional transcription agency (National Captioning Institute). Transcription was performed singly, and a member of our research team conducted quality checks of the transcripts against the original audio recordings to ensure completeness and accuracy. If participants did not consent to being recorded, extensive notes were taken instead.

Different sets of Hispanic parent-adolescent dyads participated across 3 phases of data collection (conceptual prototypes, n=20 dyads; paper and minimally functional prototypes, n=15 dyads; and fully functional prototype, n=10 dyads). Procedures for each of these phases are detailed below.

Conceptual Prototypes

Parents and their adolescents (n=20 dyads) participated in separate focus groups or individual interviews. We initially set out to conduct focus groups; however, due to scheduling challenges, we used a combination of group-based and individual interview approaches. The purpose of these initial focus groups or interviews was to understand the needs and behaviors of our target users. Prior to qualitative data collection, each participant completed a brief demographic survey. Parents self-reported their age, sex, country of birth, years living in the United States, marital status, education, employment, household income, and potential history of diabetes. Adolescents self-reported their age, sex, country of birth, and years of living in the United States. Parents and adolescents also completed the Mobile Device Proficiency Questionnaire (MDPQ-16) [36], a 16-item validated instrument that assesses proficiency related to mobile device use. Sample items include "I can find health information online," "I can listen to music," and "I can send emails" (all using a mobile device). Participants rated their level of proficiency on a 5-point response scale ranging from never tried at all to very easily. The measure yields 8 subscales (eg, communication, entertainment) and one total score, with higher scores reflecting greater mobile device proficiency.

We used a semistructured guide (Multimedia Appendix 2) with open-ended questions designed to understand participants' current lifestyle behaviors (eg, "How [if at all] are you healthy together with your parent/adolescent?") and use of technology for health (eg, "How [if at all] have you used technology for your health/health care?"). We additionally gathered participants' feedback on initial intervention concepts and prototypes ("conceptual prototypes"). Bilingual study staff conducted focus groups and interviews in participants' homes or at the University of Miami in either English (one adolescent focus group [n=3], n=8 individual adolescent interviews) or Spanish (one adolescent focus group [n=2], n=7 individual adolescent interviews; all parent focus groups and individual interviews). Focus group sessions were ~55 minutes, and individual interviews were ~36 minutes. Participating parents and their adolescents received US $50 and 2 movie tickets, respectively.

Paper and Minimally Functional Prototypes

Based on feedback from our initial focus groups and interviews, our team developed a series of paper and minimally functional prototypes, or those that meet some, but not all, specifications for a product. Our paper prototypes consisted of physical printouts of illustrations depicting intervention features. Our minimally functional prototypes consisted of a webpage accessed via smartphone with learning activities that aligned with didactic content.

A different set of parents and adolescents (n=15 dyads) completed the aforementioned demographic survey and participated in separate individual interviews. We used a semistructured guide (Multimedia Appendix 3) with open-ended

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questions designed to solicit participants' feedback on potential logos (eg, "What images come to mind when you hear 'Healthy Juntos' [Healthy Together]") and to encourage participants to "think aloud" while interacting with the paper and minimally functioning prototypes to understand their navigation of the intervention, identify potential problems, and assess their interpretation of the prototype's design elements. We also collected feedback on participants' favorite and least favorite components, suggested improvements for the functionality of game prototypes, and impressions of the overall design of the program. Bilingual study staff conducted interviews in participants' homes or a public setting (eg, library) in either English (n=13 adolescents, n=3 parents) or Spanish (n=2 adolescents; n=12 parents). The parent and adolescent interviews lasted ~42 minutes and ~30 minutes, respectively.

After the interviews, participants completed the Usefulness, Satisfaction, and Ease of use (USE) questionnaire [37]. This 30-item measure assesses four dimensions of usability: usefulness (8 items), ease of use (11 items), ease of learning (4 items), and satisfaction (7 items). Response options ranged from 1 (strongly disagree) to 7 (strongly agree). The 4 mean scores were averaged to calculate a total usability score, with higher scores indicating greater usability and satisfaction. Participating parents and their adolescents received US $60 and 3 movie tickets, respectively.

Fully Functional Prototype

Based on feedback from the paper and minimally functional prototypes, our team developed a fully functional prototype of a web-based application, available in English and Spanish, for an 8-week family-based intervention. Although ≥26 contact hours over 2 - 12 months are recommended for pediatric obesity treatment [38], no equivalent recommendation exists for preventive interventions, with prior meta-analyses (including our own) finding no clear relationship between intended dose and weight outcomes [13,39]. The initial intervention duration was informed by the principal investigator's (PI) prior work developing and evaluating an 8-week family-based (face-to-face) intervention that demonstrated postintervention improvements in the lifestyle behaviors of non-Hispanic Black adolescents and parents [40,41].

We evaluated our fully functional prototype in a field trial (n=10 dyads). Field trials involve the collection of data in users' natural environments and evaluate technology for flaws that will only emerge through use over time [42]. We gave parents and adolescents a physical activity monitor (Fitbit) to track their steps and held a one-hour videoconference call to set up their usernames, sync their Fitbit devices to the app, and introduce them to our intervention. At the end of each week, participants rated the week's content and provided feedback on what they liked, disliked, and would change about each session, as well as any technical issues they encountered. Participating families also received a follow-up phone call after Week 4 to check on their progress. At the end of the eight weeks, study staff invited families to participate in exit interviews via videoconference using a semistructured guide with open-ended questions (Multimedia Appendix 4). The interview guide was designed to capture participants' experience using the program (eg, "How [if at all] did the program help you meet your goals?" and "How [if at all] did the program impact your relationship with your adolescent/parent?"). Bilingual study staff conducted interviews in either English (n=7 adolescents, n=1 parent) or Spanish (n=1 adolescent; n=7 parents). Interviews lasted an hour on average. Parents received a US $5 digital gift card for every weekly survey and a US $40 digital gift card for participating in the exit interview. Adolescents received a US $30 digital gift card for participating in the exit interview. Parents and adolescents were allowed to keep their Fitbit devices once the study was completed.

Data Analysis

Quantitative Data

We summarized quantitative data using descriptive statistics and did not perform any inferential statistical tests. Analyses were conducted in SAS (version 9.4; SAS Institute Inc).

Qualitative Data

We used a rapid qualitative analysis to analyze qualitative data [43-45]. Rapid qualitative analysis leverages a team-based approach to summarize key points from qualitative data into a matrix, allowing for efficient and systematic exploration of relevant themes. This method can facilitate the development of technology-based interventions [46]. At each phase of qualitative data collection, we first reviewed transcripts for accuracy against the original audio or video recordings. We then developed a summary template to condense data from each transcript across a series of domains generated from the questions in the interview guides. Study staff created matrices that displayed all participant responses corresponding to each domain. In the matrices, each focus group or interview was represented by a unique row, and each domain was represented by a unique column. We distributed our completed matrices to study staff for revision and used a team-based discussion approach to draw key conclusions that informed our intervention development.

Ethical Considerations

This study was approved by the institutional review board of the University of Miami (protocol ID number 20160415). Our team obtained written informed consent and assent from all participants in person or via video conference prior to data collection. We securely stored participant data on a protected, access-controlled University server.

Results

Participant Characteristics

A total of 45 Hispanic adolescents, identified as at-risk for obesity due to not meeting national recommendations for fruit and vegetable intake, physical activity, and sedentary behavior, and their parents participated in the development and co-design of Healthy Juntos (Table 2). Adolescents had an average age of 13.8 (1.2) years and a BMI percentile of 67.9 (23.7). They were predominantly female (27/45, 60%), US-born (23/45, 51%), and preferred English as their primary language (30/45, 67%). Parents had an average age of 44.3 (5.7) years and a BMI of 29.3 (8.6). They were predominantly female (42/45, 93%), married or living with someone (34/45, 73%), born outside the

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United States (43/45, 96%), had lived in the United States for more than 10 years (23/45, 51%), preferred Spanish as their primary language (40/45, 89%), and reported an annual household income below US $50,000 (41/45, 91%).

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Table . Participant characteristics.

Characteristic	Total (n=45 adolescents and parents)	Conceptual prototype (n=20 adolescents and parents)	Paper and minimally functional prototype (n=15 adolescents and parents)	Fully functional prototype (n=10 adolescents and parents)
Adolescents				
Age (years), mean (SD)	13.8 (1.2)	13.5 (1)	14.2 (1.3)	13.9 (1.3)
BMI (%), mean (SD)	67.9 (23.7)	59.1 (26.1)	81.3 (10.5)	65.3 (25.5)
Sex (female), n (%)	27 (60)	13 (65)	9 (60)	5 (50)
Country of birth, n (%)				
United States	23 (51.1)	7 (35)	10 (66.7)	6 (60)
Venezuela	9 (20)	5 (25)	2 (13.3)	2 (20)
Cuba	5 (11.1)	3 (15)	1 (6.7)	1 (10)
Other	8 (17.8)	5 (25)	2 (13.3)	1 (10)
Years living in the United States, n (%)				
Less than 1 year	5 (11.1)	5 (25)	—	—
1 - 9 years	18 (40)	8 (40)	4 (26.7)	6 (60)
More than 9 years	22 (48.9)	7 (35)	11 (73.3)	4 (40)
Spanish as preferred language, n (%)	15 (33.3)	8 (40)	4 (26.7)	3 (30)
Parents				
Age (years), mean (SD)	44.3 (5.7)	43.2 (6.2)	46.27 (4.7)	43.70 (5.6)
BMI, mean (SD)	29.3 (8.6)	30.1 (12.2)	30.36 (3.8)	25.83 (2.5)
Sex (female), n (%)	42 (93.3)	18 (90)	14 (93.3)	10 (100)
Relationship with adolescent				
Biological parent	44 (97.8)	19 (95)	15 (100)	10 (100)
Legal guardian	1 (2.2)	1 (5)	—	—
Country of birth, n (%)				
Venezuela	13 (28.9)	6 (30)	4 (26.7)	3 (30)
Cuba	8 (17.8)	4 (20)	3 (20)	1 (10)
United States	2 (4.4)	—	1 (6.6)	1 (10)
Other	22 (48.9)	10 (50)	7 (46.7)	5 (50)
Years living in the United States, n (%)				
Less than 3 years	10 (22.2)	9 (45)	—	1 (10)
3 - 10 years	12 (26.7)	4 (20)	3 (20)	5 (50)
More than 10 years	23 (51.1)	7 (35)	12 (80)	4 (40)
Spanish as preferred language, n (%)	40 (88.9)	19 (95)	12 (80)	9 (90)
Marital status, n (%)				
Married or living with someone	34 (75.6)	15 (75)	12 (80)	7 (70)
Divorced or separated or widowed	9 (20)	3 (15)	3 (20)	3 (30)
Single	2 (4.4)	2 (10)	—	—
Education, n (%)				
Up to high school	12 (26.7)	5 (25)	3 (20)	4 (40)

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Characteristic	Total (n=45 adolescents and parents)	Conceptual prototype (n=20 adolescents and parents)	Paper and minimally functional prototype (n=15 adolescents and parents)	Fully functional prototype (n=10 adolescents and parents)
Some college or college degree	26 (57.8)	13 (65)	11 (73.3)	2 (20)
Graduate or professional	7 (15.6)	2 (10)	1 (6.7)	4 (40)
Work status, n (%)				
Working full-time or part-time	29 (64.5)	10 (50)	11 (73.3)	8 (80)
Homemaker	5 (11.1)	4 (20)	1 (6.7)	—
Working in temporary jobs	5 (11.1)	3 (15)	1 (6.7)	1 (10)
Unemployed	6 (13.3)	3 (15)	2 (13.3)	1 (10)
Total household income, n (%)				
Less than US $25,000	22 (48.9)	13 (65)	4 (26.7)	5 (50)
US $25,000 - $49,999	19 (42.2)	7 (35)	8 (53.3)	4 (40)
US $50,000 or more	2 (4.4)	—	1 (6.7)	1 (10)
Refused to answer	2 (4.4)	—	2 (13.3)	—

Iterative Development Process

Conceptual Prototypes

Twenty adolescents (mean 13.5, SD 1 year old, 13/20, 65% female, BMI percentile: mean 59.1, SD 26.1) and their parents (mean 43.2, SD 6.2 years old, 18/20, 90% female, BMI: mean 30.1, SD 12.2) participated in this phase. Participants' responses on the MDPQ-16 showed high mobile device proficiency for both parents and adolescents across all eight dimensions (Multimedia Appendix 5).

In focus groups and individual interviews, parents and adolescents defined a healthy lifestyle as one that includes exercise, healthy eating (eg, fruits and vegetables, limited junk food and sugar), adequate hydration, and sufficient sleep. They rated their health as "average" or "in between," acknowledging both positive habits and their need for improvement. They described limited use of technology for health purposes, primarily for internet searches related to medical symptoms, recipes, and workouts. Most reported not having any health-related apps installed on their smartphones. When asked about features they liked about either health apps or their favorite apps in general, parents and adolescents emphasized the importance of interactive, social features, such as the ability to communicate with others, and regularly updated content or information. Participants, particularly adolescents, expressed a desire for minimal reading requirements.

Participants viewed conceptual prototypes in their preferred language (English or Spanish) developed by the PI using PowerPoint (Microsoft Corp) to illustrate 3 possible components or features of a family-based digital lifestyle intervention based on the conceptual framework: (1) didactic information on healthy lifestyle behaviors, (2) a family behavior change tool, and (3) a positive parenting tool (Figure 2).

In response to these prototypes, participants suggested that the intervention provide culturally relevant healthy meal recipes, information about nutrition labels, and appropriate portion sizes. They also recommended that we describe the benefits of exercise for adolescents and adults and offer workout routine ideas. Regarding behavior change, participants suggested that we include individualized goal setting with visuals to track their progress, a way for family members to share goals and progress, and reminders and motivational messages. Finally, regarding parenting, parents suggested that we provide strategies to improve family communication, tips on how to deal with difficult situations, and ways to motivate and reward adolescents. They also recommended that we include affordable options for family activities.

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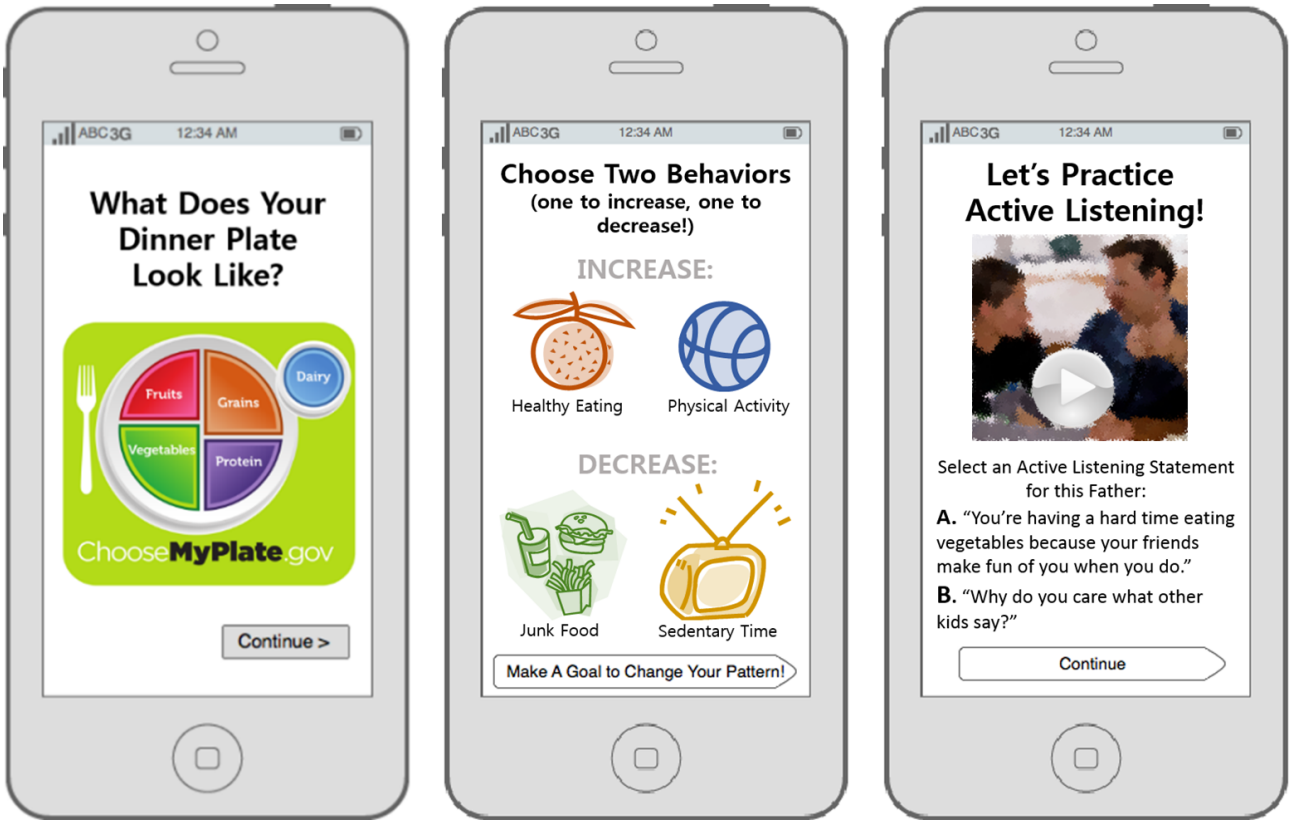
Figure 2. Conceptual prototypes.



Paper and Minimally Functional Prototypes

We developed a series of 10 paper prototypes using PowerPoint, and our technology partners (led by author RS) developed minimally functional prototypes to preliminarily assess product usability (Figure 3).

The paper prototypes included representations of different icons and features of the intervention (ie, a sample log-in page, a home page with key icons, and separate pages that corresponded to each icon). Illustrations showed educational tools (ie, didactic health videos, serious games, culturally tailored recipes, and exercise tutorials), behavior skills training tools (ie, step counting, monitoring diet, and physical activity), and parenting and family motivational tools (ie, a parenting podcast, family goal comparison, and family activities). We envisioned that participants would receive weekly didactic content, set and monitor physical activity and healthy eating goals, and engage in weekly family discussions and health challenges. Parents would also have access to a parenting "podcast" to learn skills for positive communication and parenting (eg, active listening). Both parents and adolescents could compare progress, exchange preselected encouraging messages, maintain a food photo journal, participate in weekly games (eg, create your own healthy plate), and learn about the cultures and traditions of different Latin American countries each week. The minimally functional prototypes were of learning activities that aligned with didactic content. These activities included tasks like dragging and dropping healthier food options onto a plate, reading and answering questions about a nutrition label, and timing themselves while doing various physical activities.

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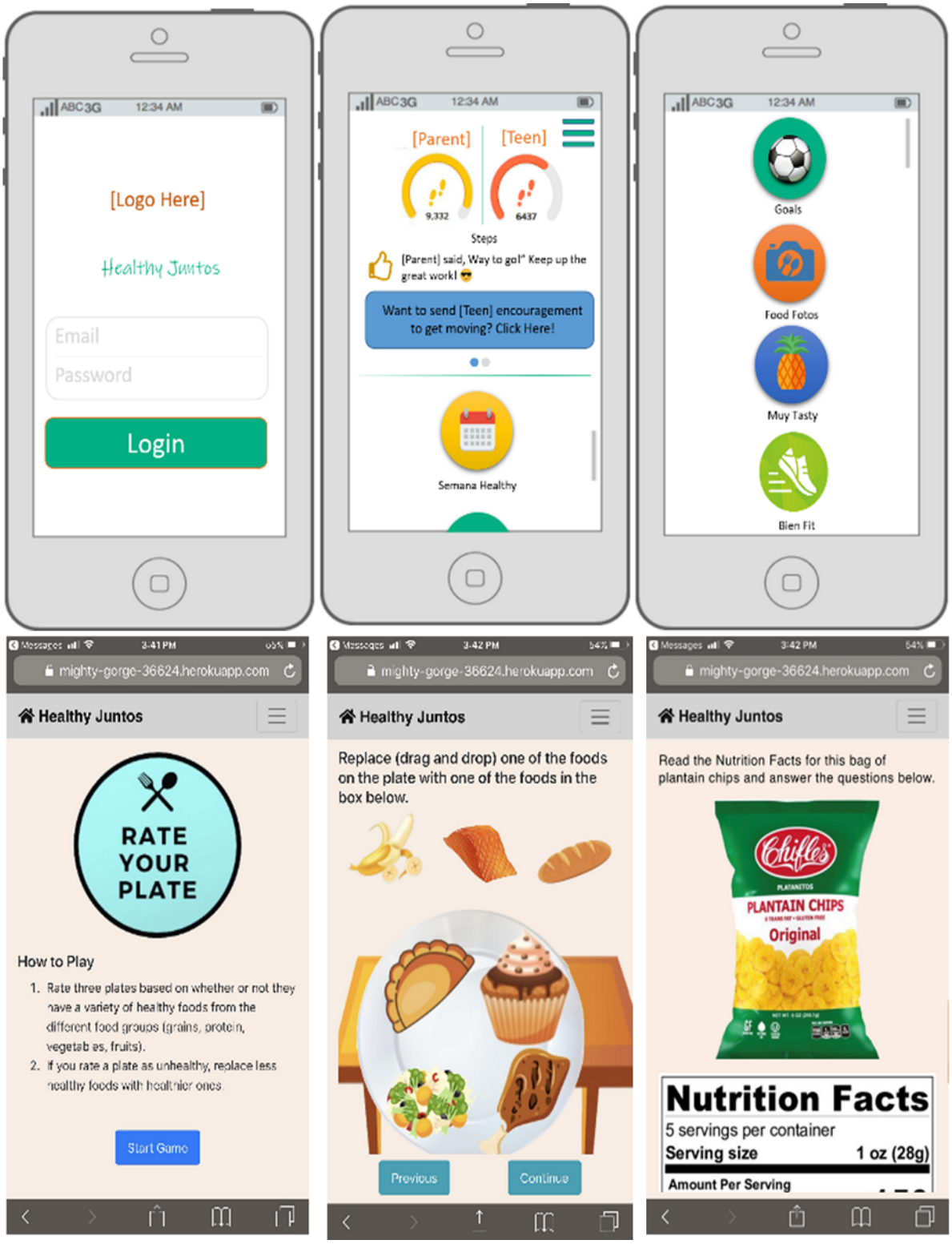
Figure 3. Paper and minimally functional prototypes.



Fifteen adolescents (9/15, 60% female; mean 14.2, SD 1.3 years) and their parents (14/15, 93% female; mean 46.3, SD 4.7 years) participated in this phase. Participants suggested improvements related to aesthetics (eg, icon design, image quality) comprehension (eg, simple directions, better feature descriptions), content (eg, removal of certain features), and functionality (eg, different buttons; Table 3). Overall, participants provided mostly positive feedback on the prototypes, highlighting ease of use, functionality, the ability to compare parent and adolescent progress, and enthusiasm for recipes and exercise components. Adolescents were content with the organization of the pages and the color scheme. The intervention prototypes received positive ratings from both parents and adolescents, with USE questionnaire average scores higher than 5 (out of 7) across all four usability dimensions (Multimedia Appendix 5).

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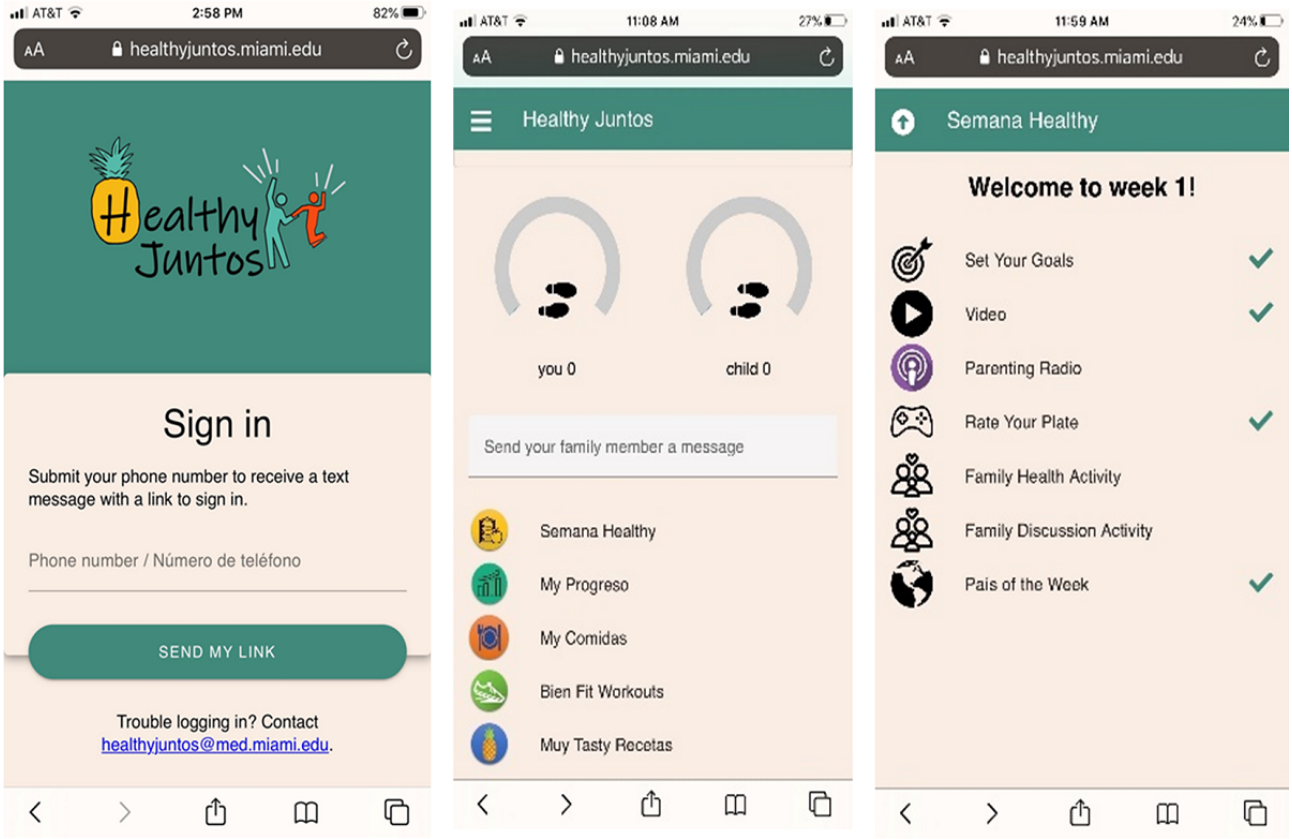
Table . Participants' feedback on paper/minimally functional prototypes and corresponding modifications.

Feedback	Illustrative quotes	Modifications
Aesthetics • Intervention logo should include representation of family, healthy eating, and/or physical activity • Replace icon images • Change background color	"Well, because it involves family and it involves parents and the kids, that's why I'm thinking of like the logo of like, you know, you see the silhouette, like the stick figures type deal, with like a bigger one, a smaller one, where you could tell it's a family." (Parent 009)	• Logo developed with all these features • For example, replaced soccer ball icon with progress graph to represent "set your goals" feature • Replaced white background with light peach color
Comprehension • Lack of clarity about functioning and tasks related to certain features • Parents did not understand meaning of "podcast"	"The 'Podcast,' is that like people who are in the same boat. Like a community something?" (Parent 006)	• Clearly labeled icons, included simple instructions when needed, and developed instructional welcome video to describe all features of intervention • Replaced "podcast" with "radio"
Content • Lack of clarity about functioning and tasks related to certain features • Lukewarm response to photo food diary	"It could also be like. I don't know, [.] instead of putting photos and types of foods, put the calories, like putting. Today, I ate this many calories." (Adolescent 005)	• Clearly labeled icons, included simple instructions when needed, and developed instructional welcome video to describe all features of intervention • Replaced photo food diary feature with simple food log for self-monitoring
Functionality • Faulty "drag and drop" feature in minimally functional game prototype • Parents did not understand the gallery-style dots indicating the need to swipe to move to next page	"Maybe add 'linear,' because they like that, because it kind of tells them: You're going up and down." (Parent 006)	• Replaced with "click to select" • Replaced with a toggle switch that required clicking rather than swiping

Fully Functional Prototype

We made significant changes to our prototypes and worked with our software development partners to build out a fully functional prototype (Figure 4) that included eight modules of content and corresponding activities.

Figure 4. Fully functional prototype version 1.0 (before field trial).



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We made changes to aesthetics (eg, updated icons and logo), comprehension (eg, enhanced clarity through clearly labeled icons and an instructional welcome video), and content (eg, workout videos to emphasize proper form and incorporated healthy alternatives to typical Hispanic foods). To address issues with the functionality of games, we added clear instructions to each page, replaced the "drag and drop" feature with a simpler "click to select," and incorporated congratulatory messages upon game completion. We simplified food tracking by requiring participants to simply enter consumed foods, reducing the burden on users. In addition, our team created animated video clips to deliver didactic content, identified publicly available video clips of culturally relevant recipes, produced short exercise suggestion and safety videos, recorded audio clips to deliver positive parenting content, and worked on programming behavior change features (eg, goal setting, self-monitoring, and family support).

As illustrated in Figure 4, the home page gave participants access to content and features through five icons: (1) Semana Healthy (healthy week), (2) My Progresso (my progress), (3) My Comidas (my foods), (4) Bien Fit Workouts (very fit workouts), and (5) Muy Tasty Recetas (very tasty recipes). Although all content was available in English and Spanish (based on participants' preferred language), the icons on the home page were labeled in Spanglish (ie, combination of English and Spanish) to appeal to adolescents' biculturalism [47]. The Semana Healthy icon contained all weekly modules (for a total of 8 modules; see Table 4). Within Semana Healthy, participants could complete self-guided weekly tasks that included setting weekly goals for daily steps and healthy meals, watching two to three 2-to-5-minute animated didactic videos, playing a game that reinforced weekly didactic content, and learning about physical activities (eg, salsa dancing) and foods from a featured Spanish-speaking country. Parents additionally had access to one weekly 10 - 15 minute "Parenting Radio" episode hosted by the PI that discussed family communication and positive parenting skills. Except for the "Parenting Radio" feature, all content was the same for parents and adolescents. Finally, within Semana Healthy, parent-adolescent dyads were prompted to increase healthy interactions and communication through health and discussion activities. For family health activities, participants were prompted to select at least one of three healthy activities (eg, go for a walk together). For family discussion activities, participants discuss 2 - 5 open-ended questions. Participants could document their completion of these activities through typing a summary in a text box. The app also included self-monitoring features ("My Progreso," "My Comidas") that allowed participants to view their own and their dyad member's average daily steps (read in from Fitbit) and type in the foods they ate. They could also access a library of 40 workout videos with cues for form and safety created by our team ("Bien Fit Workouts") as well as links to 46 culturally relevant video recipes from Kiwilimón.com ("Muy Tasty Recetas").

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Table . Healthy Juntos module content.

Module	Didactic videos	Family health activity	Parenting radio	Family discussion activity
1	• What is Healthy Eating? • Making the Switch to a Healthy Lifestyle • How Much Should I Eat?	• Option 1: Cook a healthy meal together. • Option 2: Go grocery shopping together and pick two new healthy foods you will try. • Option 3: You choose!	Family Communication: Active Listening	• How are we doing with our healthy eating as a family? • What are we each doing well with our eating habits? What can we improve? • How well do we listen to one another when we are communicating?
2	• All About Exercise • Let's Move! The Benefits of Exercise • Are You Sitting Too Much?	• Option 1: Go for a walk together after a meal. • Option 2: Do a workout from "Bien Fit" together • Option 3: You choose!	Family Communication: Responding	• How are we doing with our physical activity as a family? • What are we each doing well with our physical activity? What can we improve? • How well do we respond to one another when we are communicating?
3	• Reading Food Labels • Decode the Food Label • Crazy Food Cravings	• Option 1: Read and discuss the nutrition labels of 2 - 3 items in your pantry. • Option 2: Make a cooking swap. For example, try using whole wheat pasta instead of white pasta. • Option 3: You choose!	Supporting Autonomy and Giving Praise	• What are some ways we can support one another with healthy eating? What can we say to encourage each other? What can we do to help each other on hard days? • What are some ways we can support one another with physical activity? What can we say to encourage each other? What can we do to help each other on hard days?
4	• Cardio 101 • Step It Up!	• Option 1: Do jumping jacks during breaks while watching your favorite show together. • Option 2: Work together to calculate your maximum heart. Do 30 seconds of jumping jacks and take your pulse (see Video 1 this week). • Option 3: You choose!	Family Problem Solving	• What rules could we come up with as a family to help us improve our healthy lifestyle behaviors? (Come up with 1 - 2 rules for your family related to either physical activity, sedentary behavior, or healthy eating) • How can we help each other stick to these rules? • What happens when we follow the rules? What happens when we don't?

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Module	Didactic videos	Family health activity	Parenting radio	Family discussion activity
5	• Food is Medicine • What Can Food Do For Me? • The ABCs of Vitamins	• Option 1: Cook a healthy meal together. • Option 2: Make a healthy smoothie together. • Option 3: You choose!	Monitoring and Managing Peers	• Our friends can influence us in many different ways, both positive and negative. • How do our friends influence our eating habits? • How do our friends influence our physical activity? How can we involve our friends in making healthy choices with us?
6	• Resistance Training 101 • Strength and Endurance	• Option 1: Complete the Fitbit Weekend Warrior challenge. • Option 2: Do an active household chore together. • Option 3: You choose!	Managing Other Influences on Our Health	• How does our extended family influence our eating habits? • How does our extended family influence our physical activity? • Who in our extended family should we tell about our health goals? • What kind of support do we want from them? • What (and when) will we tell them?
7	• I Can Do That In My Sleep • How to Become a Super Sleeper • Eating Mindfully • Mindful Eating: Practice	• Option 1: Try the Healthy Juntos mindful eating activity together. • Option 2: Turn your TVs and cell phones off one night! Have a family game night instead. • Option 3: You choose!	Managing Parenting and Other Stress	• Stress can get in the way of our physical activity and healthy eating habits. • What makes you feel stressed? • How do you know when you feel stressed? • How does stress impact your physical activity and eating habits? • What are some things we can do to better handle stress?
8	• Flexibility 101 • Stretch and Reach for the Stars	• Option 1: Start the morning with a healthy breakfast together and 3 yoga poses. • Option 2: Do a flexibility workout from “Bien Fit” together. • Option 3: You choose!	Staying Healthy and Juntos	• What has our family learned from doing Healthy Juntos? • What positive changes have we made? • How will we maintain or continue to make progress toward our health goals? • How will we continue to support one another?

Ten adolescents (mean 13.9, SD 1.3 years old; 5/10, 50% female, BMI percentile: mean 65.3, SD 25.5) and their parents (mean 43.7, SD 5.6 years old; 10/10, 100% female, BMI: mean 25.8, SD 2.5) agreed to participate in this phase. Eight of ten families enrolled in our field trial completed all weekly sessions and postintervention interviews. Results from the USE questionnaire showed scores above 6 (out of 7) for both parents and adolescents across all 4 usability dimensions, indicating high satisfaction with Healthy Juntos and perceiving the intervention as useful and easy to learn and use (Multimedia Appendix 5).

In exit interviews, participants reported a positive experience, with many indicating improved communication and a sense of “feeling closer.” In addition, they reported increased physical activity levels and healthier dietary choices, such as consuming more vegetables and reducing unhealthy food intake. In terms

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of intervention usage, most parents reported completing the required weekly activities in a single session, while adolescents often fell behind their parents' pace. The most positively received intervention components were the didactic videos, parenting radio episodes, and the healthy games feature. However, the messaging feature was underused, with participants preferring verbal motivation. In addition, many participants found the progress tracking feature confusing and commented that logging their meals was tedious, as was keying in summaries of their family health and discussion activities. Most did not use the recipes and suggested including easier, more diverse, and "fun" recipes.

Notably, all but one parent expressed interest in having weekly or biweekly human contact to help them overcome barriers and provide feedback. Our experience managing the field trial also indicated the need for more systematic human support. To encourage families to complete sessions, we supplemented automated text reminders with phone calls to parents. Parents used these calls to solicit technical and problem-solving support.

Based on participants' feedback, we made a final round of modifications to enhance aesthetics, comprehension, content, and functionality in preparation for a pilot randomized controlled trial (Table 5 and Figure 5). We also developed a health coaching protocol for brief weekly video conference consultations with parents.

Table . Participants' feedback on fully functional prototype and corresponding modifications.

Feedback	Illustrative quote	Modifications
Aesthetics, Comprehension, Functionality • Having to log in to the app prior to each use was a barrier • Underused messaging feature; some said they "did not notice it" on the home page • Participants did not know to swipe to see the progress bars for healthy meal tracking on the home page • Did not like keying in foods on our food log—reported it was tedious • Typing summaries of family health and discussion activities was cumbersome	"At first, it [log-in process] made me uncomfortable, but then I got used to it." (Parent 1001)	• Developed simplified log-in procedures • Made messaging feature more prominent on the home page—outlined in a box • Included a single set of progress bars (that had outer layer for viewing steps and inner layer for viewing meals ratings) • Leveraged Fitbit to track meals (to facilitate simpler search for foods); added a self-rating of their logged meals (read in from Fitbit) as healthy, a little healthy, or not healthy to our app • Added the option to record a brief audio clip to report on family health and discussion activities
Content • Positive feedback on didactic videos, parenting radio episodes, and healthy games feature • Did not use the recipes; suggested easier, more diverse, and "fun" recipes	"Since there's people that like me that are picky, there are times that the breakfast one. I wouldn't like the options they had, so maybe, yeah, more simple ones will be nice." (Adolescent 1005)	• Audited suggested recipes; replaced "difficult" ones with those that required less ingredients; attempted to include more diverse cuisines based on country of origin

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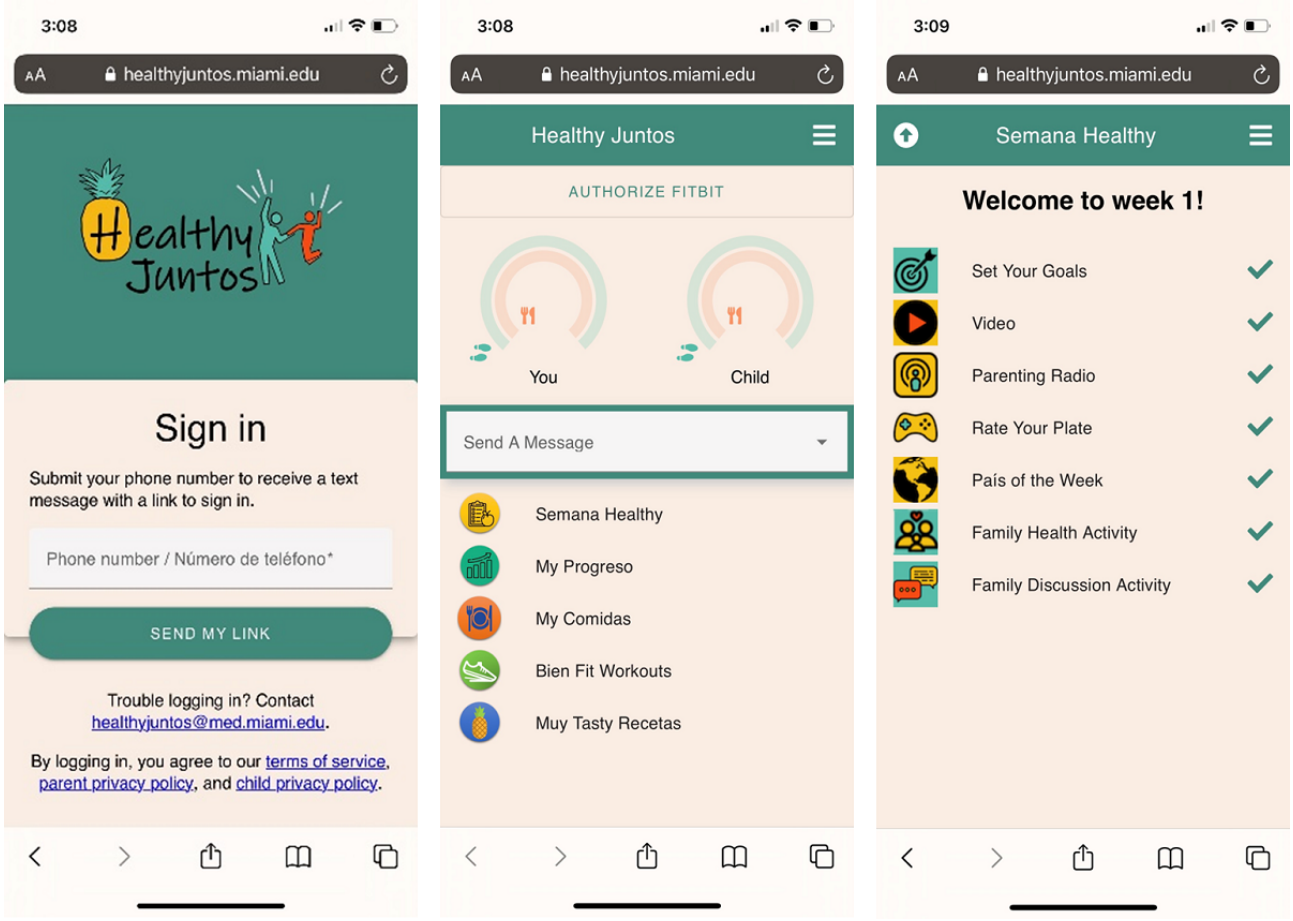
Figure 5. Fully functional prototype version 2.0 (after field trial).



Discussion

Principal Findings

Digital interventions hold great promise for delivering family-based lifestyle interventions to Hispanic youth by providing accessible, scalable, and personalized support for sustaining behavior change. The current study informs the development of a digital family-based lifestyle intervention for Hispanic adolescents and parents. We followed the first seven phases of the IDEAS framework to align end user needs and preferences with theoretical constructs and intervention concepts and prototypes. Active involvement of participants in the development process was crucial for refining the intervention and ensuring cultural relevance.

Previous studies have used co-design processes to develop digital lifestyle interventions for Hispanic youth [48,49]. These collaborative approaches provided crucial insights for generating content that is both engaging and relevant. By involving Hispanic adolescents and their parents in the iterative development process of Healthy Juntos, we collected valuable data that directly informed the content, design, and functionality of our intervention. We were responsive to participants' feedback and Hispanic cultural values through including culturally relevant recipes, encouraging exercise using everyday household items, and producing content (eg, parenting radio) that covers topics Hispanic parents are likely to encounter raising adolescents in the United States.

Based on the participants' usage of the fully functional prototype and their qualitative feedback, we identified several actionable changes that have already been implemented. These changes include simplifying the log-in process, increasing the frequency of text reminders with standard motivational messaging, and reducing the reporting burden for family health and discussion activities (through the addition of an audio recording option). Because participants found the manual logging of diet to be tedious, we also enhanced integration with the Fitbit app to simplify meal tracking. In light of documented challenges with self-monitoring lifestyle behaviors among adolescents [50,51], this change was intended to improve adherence to self-monitoring, a key determinant of successful health behavior change [52,53].

Another significant finding with direct implications for our future pilot RCT was the high demand for human support. In response, we developed a protocol for weekly health coaching sessions to foster supportive accountability through personalismo (personal connection) and confianza (trust), which have been shown to enhance the engagement and retention of Hispanic study participants [54]. This need for human support in digital health mirrors findings from other co-design studies in this population. For instance, Spierling Bagsic et al [55] evaluated Dulce Digital-Me, an adaptive mobile health (mHealth) intervention for Hispanics with diabetes, comparing personalized feedback via automated text messages to health coach phone calls. Participants in the health coach arm were more engaged in the intervention [55] and showed greater

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improvements in diabetes self-management behaviors (eg, healthy diet) than those in the automated text message arm [56]. We hypothesize that incorporating health coaching sessions as part of Healthy Juntos will enhance engagement and retention of Hispanic participants.

A pilot RCT (n=50) will evaluate the feasibility, acceptability, and preliminary effects of the refined Healthy Juntos intervention on improving physical activity and diet quality among Hispanic adolescents and their parents (IDEAS phase 8). We anticipate that our intervention will be both feasible and acceptable among our target population. Furthermore, we hypothesize that participants in the Healthy Juntos arm will show promising effects compared to the control group in increasing MVPA, reducing sedentary behavior, and improving diet quality among adolescents at postintervention.

Limitations and Strengths

The small sample size may limit the generalizability of the findings to a broader population. That said, we followed a systematic framework to guide our intervention development process, providing a model that other researchers can replicate in different contexts and populations. In addition, we acknowledge that our findings might be affected by social desirability bias, in which participants could overstate positive feedback or understate negative aspects of the prototypes to please the researchers. However, by actively involving end users (ie, Hispanic adolescents and their parents) throughout the development stages, we ensured that the intervention addresses their specific needs and preferences. A user-centered design approach may increase the relevance and acceptability of the intervention, facilitate iterative improvements, and enable the timely identification and resolution of potential issues.

Regarding reliance on technology, although Hispanic adolescents tend to use their phones more than other groups, this does not guarantee ongoing engagement with a health app. Initial interest might fade, leading to app abandonment. Future steps include testing the refined intervention in a pilot RCT and soliciting additional qualitative feedback from participants to make further improvements.

Conclusions

The iterative process of developing Healthy Juntos through qualitative feedback and a field trial was crucial for its refinement. Hispanic families actively contributed to the development of the intervention and found it easy to learn and useful. Hispanic parents were especially enthusiastic about the parenting radio content and opportunities to engage with their adolescents. Adolescents reported enthusiasm for videos and games. Moving forward, we will rigorously evaluate its feasibility, acceptability, and efficacy through a pilot study and a fully powered randomized controlled trial.

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We are grateful to our study participants for their insights and to all study staff and students who contributed to the development of the intervention.

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Conflicts of Interest

None declared.

Multimedia Appendix 1
Participant flow diagram.
[DOCX File, 183 KB - formative_v10i1e73848_app1.docx]

Multimedia Appendix 2
Conceptual prototypes question guide.
[DOCX File, 18 KB - formative_v10i1e73848_app2.docx]

Multimedia Appendix 3
Paper and minimally functional prototypes question guide.
[DOCX File, 18 KB - formative_v10i1e73848_app3.docx]

Multimedia Appendix 4
Fully functional prototype question guide.
[DOCX File, 16 KB - formative_v10i1e73848_app4.docx]

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Multimedia Appendix 5
Participants' mobile device proficiency and usability.
[DOCX File, 19 KB - formative_v10i1e73848_app5.docx]

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Abbreviations

HEI: Healthy Eating Index
IDEAS: Integrate, Design, Assess, and Share
MDPQ-16: Mobile Device Proficiency Questionnaire
MVPA: moderate-to-vigorous physical activity
PI: principal investigator
RCT: randomized controlled trial
USE: Usefulness, Satisfaction, and Ease of use

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Designing a Case Management Mobile Health App for Violence Intervention Programs: Mixed Methods Human-Centered Design Study

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Abstract

Background: Hospital-based violence intervention programs have shown promise in mitigating the effects of violence, but their impact is limited by time constraints and inefficient practices faced by the violence prevention professionals (VPPs) who function as case managers. Mobile health (mHealth) apps offer the potential to enhance communication and service delivery between VPPs and clients, but few have been specifically designed for vulnerable populations.

Objective: This study aims to design an mHealth app to improve communication and access to resources between survivors of violence and their VPPs using human-centered design (HCD) and iterative prototyping methods.

Methods: HCD methodology was used, including rounds of Participatory Design, Low-fidelity Prototype Testing, and High-fidelity Prototype Testing. The Participatory Design phase included in-depth interviews and co-design, followed by inductive qualitative analysis to inform the mHealth app's initial low-fidelity design. The Low-fidelity Prototype Testing phase included in-depth interviews with probing questions about the low-fidelity design, followed by inductive qualitative analysis to inform the mHealth app's initial high-fidelity design. The High-fidelity Prototype Testing phase used the Rapid Iterative Testing and Evaluation (RITE) method and inductive qualitative analysis to rapidly collect and integrate VPP feedback into the mHealth app's final design approved for implementation.

Results: Nine VPPs participated in 3 rounds of testing and feedback. Participatory Design identified four key themes: (1) trust, (2) personal connection, (3) tailored resource curation**,** and (4) management of administrative burdens. Low-fidelity Prototype Testing identified three additional key themes: (5) intuitive and comprehensive design, (6) dynamic journey and sense of progress, and (7) standardization of verbiage and design choices. High-fidelity Prototype Testing through RITE identified 181 actionable issues, with 133 addressed, achieving a 73% impact ratio (used to measure the effectiveness of usability improvements). High-fidelity Prototype Testing identified 9 key themes, reaffirming 5 themes from prior testing sessions (themes 2, 3, 5, 6, and 7) and uncovering four novel themes: (8) control over boundaries, (9) celebration of client successes, (10) client empowerment, and (11) warm handoff. The final mHealth app version adapted from 3 low-fidelity digital representations (wireframes) to 25 high-fidelity wireframes of a mHealth app to support case management.

Conclusions: The combination of HCD and RITE methodologies resulted in an mHealth app tailored to the needs of VPPs working with survivors of violence. This approach may be transferable to the development of other mHealth apps for specialized populations, although further research with larger samples would be needed to establish generalizability.

(JMIR Form Res 2026;10:e79533) doi:10.2196/79533

KEYWORDS

mHealth; mobile app; violence prevention; human-centered design; RITE method; case management; mobile phone; mobile health

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Introduction

Violence is a public health crisis that disproportionately affects vulnerable populations [1,2]. Hospital-based violence intervention programs (HVIPs) are evidence-informed initiatives designed to address the social determinants that increase the risk of violence and to prevent repeat injury [3]. While HVIPs have demonstrated promise, their overall impact is often constrained by inefficient communication and labor-intensive case management workflows [4]. Building strong, trust-based relationships between HVIP case managers, known as violence prevention professionals (VPPs), and patients impacted by community violence who enroll in HVIPs (clients) is central to the success of these programs. However, this process is time-consuming and difficult to sustain, given limited resources and high caseloads [4].

Despite more than 350,000 violence-related emergency department visits each year in the United States [5], no mobile app, to our knowledge, currently exists to support the unique case management needs of HVIPs. Addressing community violence is critical, not only because of its immense human cost but also due to the opportunity for substantial impact on health care systems. Survivors frequently endure lasting psychological and physical trauma, including a high prevalence of posttraumatic stress disorder [6]. These burdens on individuals and families are also magnified into system-level effects. In the year of 2016, violence-related injuries cost the United States an estimated US $2.7 billion in health care expenses [7].

Previous research [8] conducted within a San Francisco HVIP identified several barriers faced by both clients and VPPs that could be mitigated through mobile health (mHealth) solutions. These challenges include the need to balance consistent emotional support with professional boundaries, offer communication that feels personal yet efficient, and recognize healing as a long-term journey requiring skill development and lifestyle changes. From this work, key design opportunities emerged: (1) maximize personal connection while regulating access, (2) enable personalized yet automated interactions, and (3) promote accountability while celebrating client progress. This research, along with other studies, suggested that a tailored mHealth app could reduce the risk of reinjury and reperpetration of violence by improving communication between clients and staff in HVIPs [5,8]. However, developing such tools requires design approaches that directly address VPP workflow challenges, including time constraints, fragmented systems, and the need to balance relationship building with professional boundaries. Translating these complex requirements into functional digital solutions demanded a systematic, user-centered methodology capable of capturing both explicit needs and latent design opportunities.

Existing digital health research has shown that mHealth apps can effectively influence health behaviors [9,10]. This potential is especially relevant for HVIPs, which serve young and vulnerable populations [11]. Given the high rates of smartphone use among emergency room patients, including those with violent injuries, mHealth apps may be a valuable tool in this context [12,13]. The recent increase of mHealth apps used to support health care delivery [9,10] highlights the importance of designing effective tools, yet many of these mHealth apps lack evidence of effectiveness and fail to involve end users in the design process [14]. Without adequate consideration of user needs, these mHealth apps risk the aforementioned ineffectiveness or potentially causing harm. This would exacerbate existing issues in the health care system [15,16]. Few digital interventions have been designed for and with vulnerable populations, and existing digital interventions for vulnerable populations often have low usage rates [17-19], indicating that they do not adequately meet user needs in the context of their daily life. This underlines an avenue for better addressing those user needs: involving users in designing mHealth apps. A human-centered design (HCD) approach offers a framework for iteratively designing and testing mHealth app concepts to enhance their acceptability and usability, which is applicable to the HVIP context.

HCD is a methodology used to design novel interventions that meet real human needs through empathetic, rigorous qualitative investigation and iterative design of prototypes [20]. HCD has been used to develop and enhance the effectiveness of mHealth tools [21] as well as other health care innovations. HCD emphasizes iteration and collaboration by incorporating user feedback into each of its 3 key stages, including the “Inspiration Phase,” “Ideation Phase,” and “Implementation Phase” [22]. The “Inspiration Phase” involves understanding the problem by thematically analyzing qualitative data gathered from key users and stakeholders through in-depth interviews in order to uncover underlying design opportunities [23]. The “Ideation Phase” entails brainstorming solutions, co-designing prototypes with users and stakeholders, and testing the desirability, feasibility, and viability of prototypes and iteratively refining them as needed [23]. The “Implementation Phase” pilot-tests refined prototypes in context, allowing for further iteration and evaluation [22]. HCD methodology therefore involves end-stage users in every step of the design process.

In health care, HCD has been used effectively to design and improve innovations that improve service and patient experience. For example, HCD was leveraged for developing a game-like simulation for lower back pain [24] and for creating virtual reality experiences to alleviate symptoms of posttraumatic stress disorder [25,26]. While many mHealth studies using HCD have focused on developing patient self-management or caregiver support tools [27-29], none have addressed mHealth apps for care teams and case management. Few mHealth design studies have documented the use of the Rapid Iterative Testing and Evaluation (RITE) method for usability testing, whereby design changes are made immediately after issues are identified (often after just 1 user). Historically, the RITE method has most commonly been used to iteratively enhance video games [30,31]. The RITE method allows for rapid iteration and continuous improvement throughout the testing process. It also adds structure to rapid testing by classifying usability issues into categories based on clarity of cause and feasibility of solution, enabling actionable issues to drive rapid changes [31]. In a mixed methods approach, HCD ensures cultural consonance, while RITE adds analytic rigor by quantifying and prioritizing usability defects in real time, a

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combination rarely reported in mHealth app development [32-34].

Our study aimed to apply HCD, with a focus on the "Ideation Phase," to develop an mHealth app tailored to the needs of vulnerable populations and their care teams, with the goal of enhancing service delivery and effectiveness within HVIPs. It builds on prior research conducted during the "Inspiration Phase" [8], which laid the groundwork for this initiative. Our approach was to (1) co-design and iteratively refine the mHealth app with HVIP VPPs using an HCD and RITE mixed methods approach, and (2) report the resulting usability metrics and emerging qualitative themes for the development of future HVIP digital tools.

Methods

Study Design and Setting

We conducted a prospective observational mixed methods study using HCD methodology paired with the RITE method [31] to develop an mHealth app to improve communication and access to resources between clients and their VPPs.

Our study was a collaboration between the San Francisco Wraparound Project (WAP) and The Better Lab. WAP, an HVIP at Zuckerberg San Francisco General Hospital and Trauma Center, supports survivors of intentional violence by connecting them with culturally congruent VPPs at the point of care. VPPs help clients access resources, such as employment, education, legal aid, and mental health services, to reduce reinjury risk [4,23]. The Better Lab is a design research laboratory based in the University of California San Francisco (UCSF) Department of Surgery dedicated to innovating health care service solutions through HCD that enhance care and health outcomes of vulnerable populations. Research occurred from 2020 to 2024. Due to COVID-19 shelter-in-place orders, data collection took place remotely via videoconferencing in 2020 - 2021. From 2022 to 2024, activities took place on-site at Zuckerberg San Francisco General Hospital.

Ethical Considerations

This study was approved by the UCSF Institutional Review Board (protocol number 17 - 23752). Verbal informed consent was received from each participant prior to their engagement in any research activities. To protect participant privacy, remote interviews (2020 - 2021) were conducted via videoconferencing with participants in private locations, while in-person sessions (2022 - 2024) occurred in private offices at San Francisco General Hospital. All recordings were stored on password-protected servers accessible only to the research team, and participant identifiers were removed from transcripts and replaced with codes. All data were managed in compliance with UCSF data security policies. Upon study completion, each participant received modest compensation in the form of a Visa gift card for US $50.

Participants

Inclusion criteria for VPP participants included (1) current employment at WAP as a VPP or supervisor, and (2) active involvement in direct case management with clients enrolled in the HVIP. No minimum experience threshold was required, allowing us to capture perspectives from both new and veteran staff. Demographic data (age, gender, and race or ethnicity) were not systematically collected to preserve participant privacy in this small, identifiable sample; however, the WAP team reflects the demographic diversity of the communities they serve, with multilingual and multicultural representation among staff. Due to significant staff turnover between 2020 and 2024, a total of 9 VPPs participated in user testing, although only 4-5 were employed by WAP at any one time. Only 1 VPP, the supervisor, remained consistent throughout the entire study, participating in all 3 rounds of user testing. Participants ranged in experience from less than 1 year to more than 20 years in violence intervention work.

Ideation Phase Methods

This research focused on 3 specific subphases of the HCD methodology within the "Ideation Phase": Participatory Design, Low-fidelity Prototype Testing, and High-fidelity Prototype Testing (Figure 1). High-fidelity Prototype Testing was enhanced by the addition of the RITE method to increase the rigor of HCD with a mixed methods approach.

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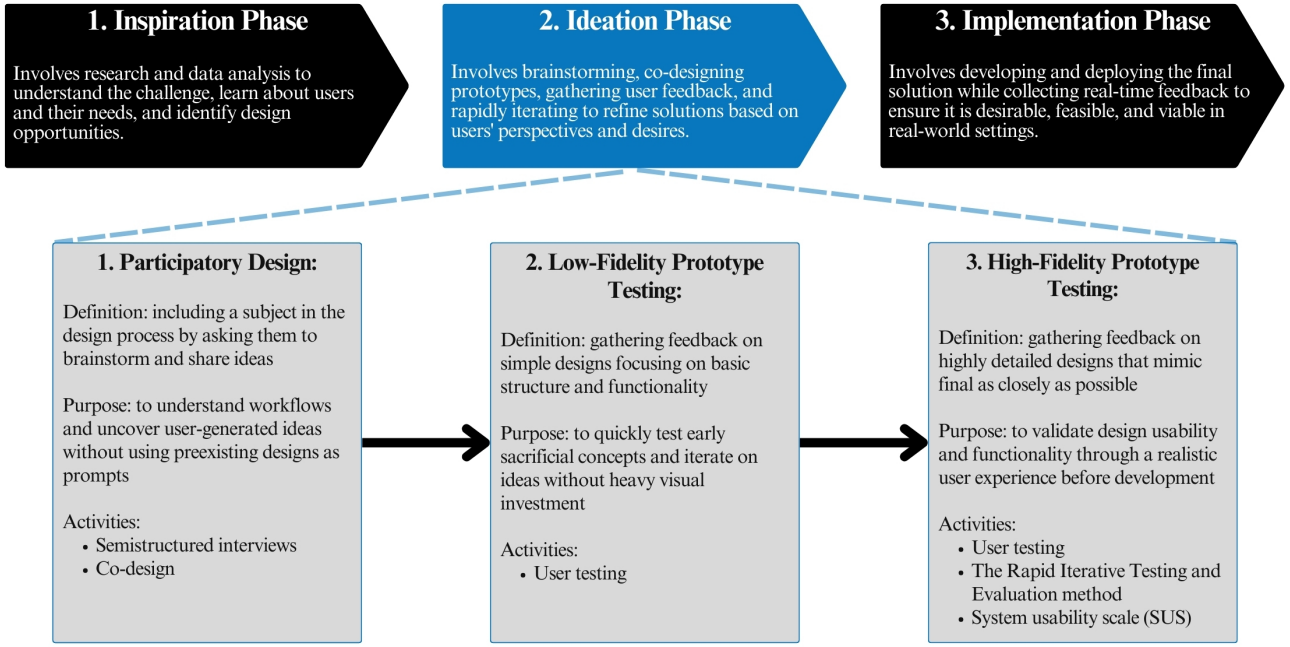
Figure 1. A 3-phase model of human-centered design methodology highlighting the methodologies within the Ideation Phase.



Participatory Design and Thematic Analysis

Participatory Design involves the active inclusion of nondesigner stakeholders in the design process by asking them to brainstorm their own ideas. This approach aims to promote ethical engagement and mitigate traditional research power dynamics. It also aims to generate innovative concepts sourced directly from users, rather than validating pre-existing ideas [35]. Qualitative analysis of feedback from the Participatory Design phase informed the development of initial low-fidelity prototypes.

In this phase, semistructured interviews were conducted with VPPs to understand their roles, daily workflows, key client interactions, and challenges. VPPs also participated in co-design activities [36] by sketching visual concepts for the mHealth app on paper templates or guiding the interviewer in illustrating their ideas.

A remote interview lasting 60 - 90 minutes was conducted in 2020 with each of the WAP's 5 VPPs on staff at the time. A pair of researchers facilitated each session: 1 design researcher (DP) led the interview while an observer took detailed notes. Due to privacy concerns raised by the VPPs, sessions were not audio-recorded or transcribed. Instead, notes from the observing researcher were analyzed inductively using general thematic analysis [37]. Two researchers (DP and AB) independently reviewed observation notes and generated initial codes. The research team then collaboratively conducted affinity mapping [38] using the MURAL digital collaboration platform, grouping related codes into candidate themes. Key themes were identified and validated through confirmation from the VPP supervisor, who confirmed that the themes accurately reflected VPP experiences and priorities. These themes were then used to inform the design of initial low-fidelity digital representations, known as "wireframes," of a mobile app interface.

Low-Fidelity Prototype Testing and Thematic Analysis

The Low-fidelity Prototype Testing phase involved gathering user feedback on simple design representations focusing only on basic structure and functionality [39]. At the completion of this phase, qualitative analysis of feedback informed the development of a final low-fidelity prototype. This final low-fidelity prototype was then iterated to an initial high-fidelity prototype. This was a VPP prototype, with plans for subsequent development of the client interface.

Initial low-fidelity prototypes were created using a digital low-fidelity prototype development tool called "Balsamiq." These prototypes included wireframes of a client dashboard, client profile, and resources section. Each wireframe included specific features identified as essential by prior research [8] and initial interview data collected during the Participatory Design phase. VPPs were presented with these prototypes and guided through a semistructured interview with prompts related to each wireframe. Feedback was used to evaluate the relevance of the low-fidelity wireframe features.

A semistructured interview was conducted and audio recorded with each of WAP's 5 VPPs in 2020. Each session lasted 60 - 90 minutes and was led by a design researcher (DP) with an observing researcher present. Two researchers (DP and AB) independently coded transcripts and then met to compare codes and resolve discrepancies through discussion. The coding team used affinity mapping in MURAL to cluster related codes and identify emergent themes. Preliminary themes were reviewed with the VPP supervisor to ensure alignment with VPP workflows and needs. Thematic analysis guided refinement of wireframes and informed the creation of a final low-fidelity prototype in Balsamiq.

At the end of the Low-fidelity Prototype Testing phase, the final low-fidelity Balsamiq wireframes were transitioned into initial high-fidelity prototypes using Figma (Figma Inc). Figma is a digital prototyping software that creates partially interactive

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wireframes that allow users to click through core functions, simulating realistic user experiences. Visual design choices, including layout and color, were refined using both participant feedback and established user interface design principles [40].

High-Fidelity Prototype Testing, Thematic Analysis, and the RITE Method

High-fidelity Prototype Testing involved presenting refined wireframes of the mHealth app in Figma to simulate real user experiences [41]. These prototypes were used to test functionality, usability, and visual design before implementation. Thematic analysis and the RITE method [31] were used to guide iterative improvements and to create a final high-fidelity prototype.

The RITE method was adapted for this study as an alternative to traditional usability testing. We extended the standard 4-category RITE framework with 2 additional categories: "category 5" captured positive feedback to ensure that valued features were preserved in subsequent iterations, and "category 6" documented conflicting feedback between VPPs to guide decisions about user configurability versus standardization. This modified 6-category framework (Table 1) allowed us to not only track usability problems but also design successes and areas requiring flexible solutions.

Table . Rapid Iterative Testing and Evaluation method categories.

Category	Definition of category	Example
Classic RITE[a] method categories		
1	Issues with an obvious cause and obvious solution that can be implemented quickly.	Text changes, relabeling buttons, and rewording dialog boxes.
2	Issues with an obvious cause and obvious solution that are difficult to implement quickly or within an appropriate time frame.	Difficult new features, current features that require substantial design and code changes.
3	Issues with no obvious cause and therefore no obvious solution.	Not enough information to assign a cause.
4	Issues due to other factors.	Test script, interaction with participant.
Added RITE method categories		
5	Positive feedback	Satisfaction, excitement, and agreement.
6	Feedback conflicts with another user's feedback	Conflicting feedback from 2 or more users.

[a]RITE: Rapid Iterative Testing and Evaluation.

"Category 1" issues were fixed immediately in Figma before the next session. "Category 2" issues were either implemented between testing rounds or verbally validated with subsequent participants before committing resources. "Category 3" issues were explored through follow-up questions in future sessions or discussed with the VPP supervisor. "Category 4" issues were addressed by modifying research protocols.

"Category 5" feedback (positive responses) was documented to ensure that valued features were preserved in subsequent iterations. "Category 6" conflicts were resolved by (1) asking clarifying questions in subsequent sessions to understand underlying needs, (2) exploring design solutions offering user configurability when possible (eg, privacy toggles), or (3) making final decisions collaboratively with the VPP supervisor when configurability was not feasible.

Eight semistructured interviews were conducted: 5 with the WAP VPPs in 2020 and 4 with the WAP VPPs in 2024, with the consistent VPP supervisor participating in both rounds of interviews. Each 60‐ to 90-minute interview was led by a design researcher (AB in 2020 and MGS in 2024) with an observing researcher (DP in 2020 and DG in 2024). Participants were guided through the Figma prototypes, focusing on navigating the wireframes. They were asked to complete tasks (Table 2) and verbalize their thought process. Researchers observed difficulties and confusion, and follow-up questions probed usability, relevance of information, and emotional responses to the mHealth app.

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Table . Key tasks identified for testing the mobile health app wireframes using the Rapid Iterative Testing and Evaluation method.

Wireframe titles	Key task
Sign-up	Create account with the mHealth[a] app
Login	Log in to the mHealth app
Patients impacted by community violence who enroll in HVIPs (client) dashboard	
	Acknowledge client check-in reminder
	Filter clients by priority
	Clear client filter
	Add a client
Client profile	
	Access client profile
	Send badge to client
	Access client “Care Plan”
Care plan	
	Access client “Care Plan”
	Access client milestones
	Add a milestone
	Access client tasks and subtasks
Resources	
	Acknowledge resource updating reminder
	View employment resources
	Search for specific job
	Add job posting
	View new posting detail
	See options for interacting with job posting
	Send job posting to client
	Add job posting to correct milestone in “Care Plan”
	Search youth resources
Messaging	
	View all messages
	Navigate to new message
	Send message in an existing chat
	Add message from client as task to “Care Plan”
VPP[b] profile	
	Access VPP profile
	Edit VPP profile
	Grant client access to other VPPs
	Access achievements

[a]mHealth: mobile health.

[b]VPP: violence prevention professional.

Each interview was transcribed, and feedback was categorized by wireframe and RITE classification. Actionable feedback (“categories 1 and 2”) was prioritized for immediate revision before the next testing session unless technical limitations prevented doing so. If a “category 1” or “category 2” change could not be implemented immediately, it was verbally tested with future participants. For example, interviewers asked questions such as: “How would you feel about including a VPP

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profile?" or "How would you feel if we added a photo of you?" "Category 3" and "category 4" feedback was reviewed with the VPP supervisor and subsequently addressed. To address "category 6" feedback (user disagreement), clarifying questions regarding the topic(s) were asked in future testing sessions. When disagreements persisted, solutions allowing user choice were explored. If the user choice was not feasible, final design decisions were made in collaboration with the VPP supervisor.

In addition to categorizing feedback using the RITE method, thematic analysis of data from the High-fidelity Prototype Testing phase was conducted using affinity mapping in MURAL. Two researchers (MGS and DG) independently coded interview transcripts and observation notes and then collaboratively synthesized codes into themes through iterative affinity mapping sessions. The VPP supervisor reviewed and validated final themes to ensure that they accurately represented VPP perspectives and operational realities. The emerging themes informed further improvements and inspired the creation of new wireframes. All feedback was organized by wireframe and used to guide iterative design refinements. Testing continued until saturation was reached when no novel themes emerged in the final 2 interviews. By the ninth session, feedback focused on refinements rather than new problems, indicating adequate sampling for prototype development. Together, the results from the RITE method and thematic analysis shaped the final high-fidelity prototype.

Results

Overview

Nineteen user-testing sessions were performed in total (5 in Participatory Design, 5 in Low-fidelity Prototype Testing, and 9 in High-fidelity Prototype Testing). A total of 11 key themes emerged from qualitative analysis of the testing sessions, with some themes emerging across several of the 3 phases (Table 3). Feedback captured during High-fidelity Prototype Testing was coded into 1 of 6 RITE categories. The mHealth wireframes were iterated toward an implementable solution, expanding from 3 initial low-fidelity wireframes to a final number of 25 distinct and interactive high-fidelity wireframes. These wireframes were approved for implementation by the VPPs and the program director of the WAP.

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Table . Overview of themes by testing phase.

Theme	Description	Representative quote from VPP[a]	Phase of testing		
			Participatory design	Low-fidelity prototype testing	High-fidelity prototype testing
1. Trust	VPPs emphasized the importance of gaining trust from their clients to create space for vulnerability within the app.	"[redacted] seen me in the community but didn't really know me. We had to build a rapport..."	✓	N/A[b]	N/A
2. Personal connection	VPPs emphasized the importance of using the app to build personal relationships with their clients.	"...because now, my client also gets a little bit of information about me."	✓	N/A	✓
3. Tailored resource curation	VPPs expressed a need for curated, easily accessible resources within the app that are tailored to specific demographics.	"What about for the women? It's a slight different need…finding child care, making sure the kids are in the appropriate schools...there's been more of a lack of resources for the young women."	✓	N/A	✓
4. Management of administrative burdens	VPPs desired to remain organized and efficient by using the app to reduce administrative burdens.	"[if I had the app] I probably wouldn't even text. I could just send him that information to go check out that place."	✓	N/A	N/A
5. Intuitive and comprehensive design	VPPs highlighted that the app should be intuitively designed and include only relevant features.	"If I'm just going to click on here and...apply for a job...where? What? When?"	N/A	✓	✓
6. Dynamic journey and sense of progress	VPPs wanted a way to track and manage client progress over time.	"Now, it should be like...progressing, not progressing, or completed."	N/A	✓	✓
7. Standardization of verbiage and design choices	VPPs emphasized the need for consistent language and design throughout the app to avoid confusion.	"I think it should be standard...one of the things that I'm learning with this job, we got to speak the same language."	N/A	✓	✓
8. Control over boundaries	VPPs expressed the need for both them and their clients to control how much or little personal information they share in the app.	"...think it should be private because...people are picky...who's going to see this? I think the outside world should not see this."	N/A	N/A	✓
9. Celebration of client successes	VPPs highlighted the importance of recognizing and celebrating small achievements along a client's journey in the app.	"...he or she sees that they're getting affirmation...it gets them a boost of confidence...everyone needs a little pat on the back."	N/A	N/A	✓

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Theme	Description	Representative quote from VPP[a]	Phase of testing		
			Participatory design	Low-fidelity prototype testing	High-fidelity prototype testing
10. Client empowerment	VPPs wanted their clients to feel empowered by having access to as much information as possible in the app to support their healing and recovery independently.	"...this is the empowerment side of the app to help the client start to follow their own care plan and do their due diligence of completing the tasks."	N/A	N/A	✓
11. Warm handoff	VPPs emphasized the importance of directly and personally referring their clients to resources in a personal manner within the app.	"...like to warm hand off to clients, so I will contact the resource and let them know that I have a client that I'm sending over."	N/A	N/A	✓

[a]VPP: violence prevention professional.

[b]N/A: not applicable.

Ideation Phase Results

Participatory Design and Thematic Analysis Results

Participatory Design involved interviewing VPPs about their case management workflows as well as asking them to sketch concepts that could be incorporated in the mHealth app. Through general thematic analysis of these testing sessions, 4 key themes emerged: trust, personal connection, tailored resource creation, and management of administrative burdens. Trust (theme 1) was a central theme, with VPPs emphasizing the need to "build trust by following through on their word" and noting that "if clients don't trust, they don't share." For instance, VPPs described scenarios where clients initially withheld concerns or personal struggles until multiple successful follow-throughs on small promises demonstrated reliability. Establishing rapport was seen as essential to successful case management. Personal connection (theme 2) was the second theme, with participants highlighting the importance of maintaining a "human factor in the app" to promote strong relationships. VPPs described wanting to share personal details such as their own music preferences or hobbies to help clients see them as real people, not just institutional representatives, which facilitated more authentic conversations about difficult topics. Tailored resource curation (theme 3) was a third theme, as VPPs described difficulty in finding and disseminating relevant information. VPPs described scenarios such as parents needing employment that accommodated childcare schedules, or a client with limited English proficiency requiring services with specific language support, situations where generic job boards or resource lists failed to meet actual needs. They noted that referring clients to a specific person, rather than a general service, was more effective, and that sorting through extensive lists could be overwhelming. Management of administrative burdens (theme 4) was the fourth theme, as participants saw potential for the mHealth app to replace administrative functions, allowing them to automate routine tasks and create more face-to-face time with clients. VPPs described spending hours each week manually updating spreadsheets, copying client information across multiple systems, and sending the same resource links repeatedly via text message. These administrative tasks reduced time available for in-person meetings and relationship building with clients.

The Participatory Design feedback and thematic qualitative analysis informed the development of an initial low-fidelity prototype in Balsamiq. This iteration included 3 wireframes (Table S1 in Multimedia Appendix 1). The wireframes incorporated specific features sketched by the VPPs, as well as themes uncovered through thematic analysis and synthesis of more nuanced feedback.

Low-Fidelity Prototype Testing and Thematic Analysis Results

The Low-fidelity Prototype Testing phase involved collecting feedback on the noninteractive wireframes described in Table S1 in Multimedia Appendix 1. Through general thematic analysis of these user feedback sessions, 3 themes emerged and are described below.

Intuitive and comprehensive design (theme 5) was the first theme uncovered in this phase, with participants describing how the mHealth app should be kept simple and straightforward with only necessary data and features included and clear direction for navigation. VPPs emphasized the need to balance completeness with simplicity, including essential information while avoiding cognitive overload that might discourage app use. Another theme was dynamic journey and sense of progress (theme 6), as participants described that the mHealth app should shed light on the clients' background and experiences as well as future goals to promote effective case management that is flexible, holistic, and solution-oriented. They also highlighted the importance of tracking progress as a means for motivating the clients to continue their healing journeys. The final theme was standardization of verbiage and design choices (theme 7), meaning the mHealth app should be standardized to avoid confusion and promote inclusion. VPPs noted that inconsistent terminology created confusion when training new staff or explaining the system to clients.

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The thematic qualitative analysis of feedback obtained during this phase informed the development of a final low-fidelity prototype in Balsamiq. This iteration included enhancements of the 3 initial wireframes (Table S2 in Multimedia Appendix 1). The enhancements incorporated specific feature requests from VPPs, as well as themes uncovered through thematic analysis and synthesis of more nuanced feedback.

Before transitioning to the High-fidelity Prototype Testing phase, the fidelity of the final low-fidelity wireframes (Table S2 in Multimedia Appendix 1) was enhanced from basic sketches in Balsamiq to an interactive mHealth app interface, using Figma. Qualitative interview feedback from VPPs was used to adjust and transform the final wireframes from the Low-fidelity Prototype Testing phase from 3 unique wireframes into 16 unique wireframes, adding embedded wireframes clickable within "Client Dashboard," "Client Profile," and "Resources" wireframes, as well as novel "Login" and "Messaging" wireframes (Table S3 in Multimedia Appendix 1).

High-Fidelity Prototype Testing, Thematic Analysis, and the RITE Method Results

Using the RITE method, 342 pieces of feedback were noted during High-fidelity Prototype Testing of a functional mHealth app in Figma, and each was coded into 1 of 6 categories. Between each feedback session, the 16 initial Figma wireframes were updated with adjusted features, workflows, and user interface based on user feedback. Through general thematic analysis of these testing sessions, 9 key themes emerged, which are described later in this section. The final testing results included 25 unique wireframes (Table S4 in Multimedia Appendix 1).

Examples of feedback (summaries and direct supporting quotes), RITE categories, and steps taken associated with feedback for each principal wireframe are detailed in Table 4. A total of 181 feedback items were identified as actionable and coded as either "category 1" or "category 2." Sixty-two feedback items were designated as nonactionable and coded as either "category 3" or "category 4." Ninety-three feedback items were positive comments and coded as "category 5." Six feedback items were identified as disagreements between VPPs and coded as "category 6."

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Table . Feedback and coding examples from Rapid Iterative Testing and Evaluation method interviews.

Wireframe	Noted feedback or observation	RITE[a] category assigned	Steps taken/notes
Sign-up	• VPPs[b] want the option to mark specific personal information as private during the sign-up process. • Supporting quote: "I would like to have that option to make certain things private and certain things to the public."	"Category 1": Obvious cause, obvious solution, and easy to implement	Privacy toggle added for individual fields on the sign-up screen.
Login	• The purpose and context of the app were unclear on the login screen. VPPs suggested adding a brief welcome or explanation. • Supporting quote: "I think it'll be important...to put 'Welcome to Wraparound,' let's say, at this hospital, because people might...look at it like, well, what's that mean?"	"Category 1": Obvious cause, obvious solution, and easy to implement	Introductory message added to clarify that the app is part of The Wraparound Project at UCSF[c].
Client dashboard	• The filtering feature lacked visual cues, making it unclear which clients were high priority. • Supporting quote: "When I clicked it, I saw that it moved around and adjusted, but as I'm perusing through [the client list] I don't see anything that indicates to me that one is more priority than the other."	"Category 1": Obvious cause, obvious solution, and easy to implement	Added subtle color-coded rings to client avatars to indicate priority.
Client profile	• VPPs had differing opinions on showing postdischarge timing. One wanted a clear indicator for the critical early weeks; the other felt it wasn't needed. • Supporting VPP 1 quote: "Those three weeks are critical, how can I help you in that critical time?" • Supporting VPP 2 quote: "I wouldn't need to know the 12 days post discharge, I don't think that's information on the app that I would need."	"Category 6": Disagreement between VPPs	Replaced "days postdischarge" with "date of injury"; discharge date included as a milestone.
Care plan	• VPPs felt that tasks under milestones lacked actionable guidance, such as where or how to apply for jobs. • Supporting quote: "So yeah, if I'm just going to click on here and say, apply for a job, where? What? When? How informative is this link or this check box if it doesn't have a comment box to say what, when, how, and where? Does that make sense?"	"Category 2": Obvious cause, obvious solution, and hard to implement	Enabled VPPs to link specific resources to individual "Care Plan" tasks (eg, job listings).

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Wireframe	Noted feedback or observation	RITE[a] category assigned	Steps taken/notes
Resources	• An alert prompting action appeared in the VPP interface, although the action was not possible in the prototype. • Supporting quote: "So alert, administrative assistant job hasn't been updated in over six months. Please update. So it's giving me an alert to have to sub—fill in something?"	"Category 4": Issue due to other factors	No action taken—issue due to Figma prototype limitations, not actual design.
Messaging	• Desire for communication to feel more personal and human, rather than robotic. • Supporting quote: "I want to interact more with the client, that would be great. I want to have that feeling of talking to a human versus talking to an app."	"Category 3": No obvious cause, no obvious solution	Flagged for thematic analysis—exploring ways to humanize communication.
VPP profile	• VPPs appreciated that clients could view their profiles, seeing this as a way to build trust and connection. • Supporting quote: "I like it a lot because now, my client also gets a little bit of information about me…and that's empowering. That is so empowering."	"Category 5": Positive feedback	Positive feedback noted—reinforces current design approach and themes uncovered from thematic analysis.

[a]RITE: Rapid Iterative Testing and Evaluation.

[b]VPPs: violence prevention professionals.

[c]UCSF: University of California San Francisco.

Among the 181 usability issues coded as actionable (with identifiable solutions), 133 were resolved through wireframe revisions, resulting in a 73% (133/181) impact ratio. This ratio, which measures the proportion of identified issues successfully addressed during iterative testing, indicates strong effectiveness of the RITE method and is comparable with impact ratios reported in other user-centered design studies [31]. Of the 48 actionable problems that remained unresolved, many related to customizable accessibility, for example, making the mHealth app accessible in multiple languages. These did not affect core functionality for usability testing and were deemed too difficult to prototype rapidly but were noted as essential to be addressed as the mHealth app moves into the "Implementation Phase." The "category 6" example in Table 4 illustrates our conflict resolution process: rather than choosing 1 VPP's preference, we identified the underlying needs (tracking critical recovery period vs avoiding unnecessary detail) and designed a compromise that accommodated both through strategic placement of information.

Thematic analysis of High-Fidelity Prototype Testing identified 9 key themes, 5 of which were consistent with earlier testing phases. Participants noted the importance of personal connection (theme 2), highlighting the need for humanized interactions between VPPs and clients that foster trust and rapport. Tailored resource curation (theme 3) pointed to the need for a streamlined, individualized process to enhance clients' access to relevant support services. Intuitive and comprehensive design (theme 5) reaffirmed participants' desire for the mHealth app to remain straightforward and user-friendly, with only essential features and clear navigation. In addition, dynamic journey and sense of progress (theme 6) underscored the value of enabling visibility into a client's background, present status, and future goals to support holistic, flexible case management. Standardization of verbiage and design choices (theme 7) was also emphasized to prevent confusion and promote clarity, consistency, and inclusivity.

Four additional themes emerged uniquely during this phase. Control over boundaries (theme 8) reflected the need to give both clients and VPPs greater control over who can access sensitive information, helping to protect psychological safety and respect privacy. VPPs described situations where clients might be comfortable sharing their recovery progress with their assigned caseworker but not want other staff members viewing person details. Similarly, VPPs expressed varying comfort levels sharing personal information such as their own photographs or biographical details. Celebration of client successes (theme 9) highlighted the motivational power of recognizing and affirming clients' progress. VPPs wanted to acknowledge milestones such as a client's first week of consistent employment, completion of academic course, or attending their first therapy session. Client empowerment (theme 10) spoke to the importance of supporting clients as active participants in their healing journey,

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with tools that encourage autonomy and ownership. Rather than VPPs controlling all aspects of the care plan, clients could view their own milestones, mark tasks as complete, and access resources independently, shifting from a model where clients passively received services to one where they actively drove their recovery. These 3 themes had also surfaced during the earlier Inspiration Phase of this work [8]. Finally, warm hand-off (theme 11) highlighted the importance of humanizing referrals by ensuring that clients are personally connected to external resources, rather than being left to navigate systems on their own. For example, rather than simply texting a client a link to a job-training program, VPPs described calling the program first, speaking with a specific contact person, confirming eligibility and availability, and then introducing the client by name, creating accountability on both sides and significantly increasing the likelihood of successful connection.

These findings led to several feature enhancements. Specifically, a customizable "Care Plan" was added that uploads as a standard template of general milestones, tasks, and subtasks for HVIP clients designed from experienced VPP input but can be tailored to individual needs. The "Care Plan" wireframe shown in Figure 2 empowers clients to personalize their healing journey and manage their goals and timelines. To minimize overwhelm and enhance relevance, the ability to link specific resources from the "Resource" wireframe shown in Figure 3 directly to relevant tasks within the "Care Plan" was integrated. The "VPP Profile" wireframe shown in Figure 4 was also added to enhance the human touch element of the mHealth app, as participants noted that it was important to share personal information about themselves to build trust with clients. However, recognizing the varying comfort levels around information sharing, personalized privacy settings were added to allow VPPs to customize the sensitive information displayed on their profiles. An out-of-office automation feature was also implemented to prevent VPPs from being contacted outside working hours while providing emergency contact options for clients. Finally, to facilitate the "warm handoff" approach, features enabling VPPs to connect clients with resources through direct contacts were incorporated, ensuring a more guided and meaningful support system. More examples of the 25 final high-fidelity wireframes and associated features are shown in Table S4 in Multimedia Appendix 1.

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Figure 2. High-fidelity WrapApp client care plan wireframe. VPP: violence prevention professional.

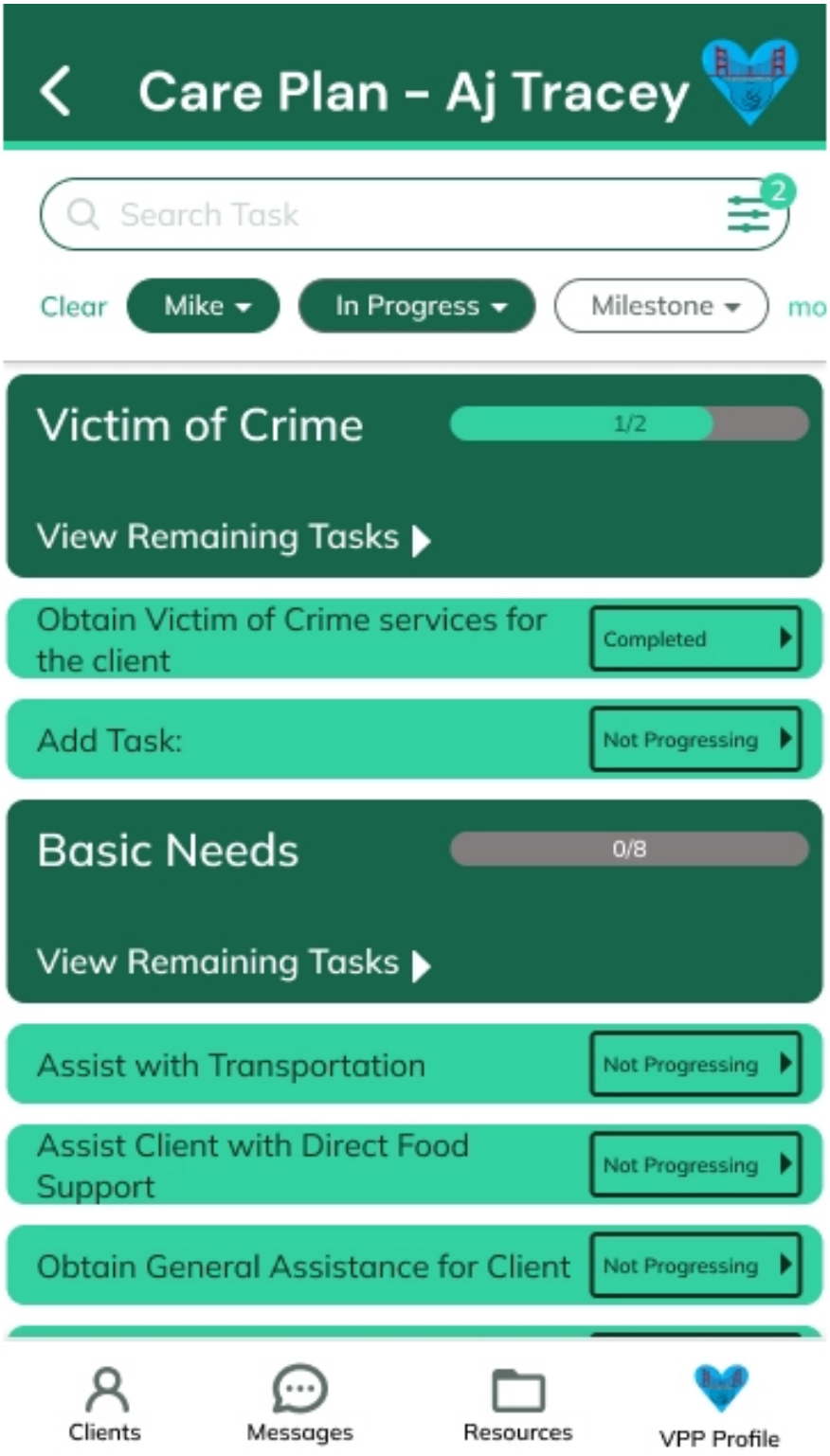

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Figure 3. High-fidelity WrapApp resources library wireframe. GED: general educational diploma; SF: San Francisco; UX: user experience; VPP: violence prevention professional.

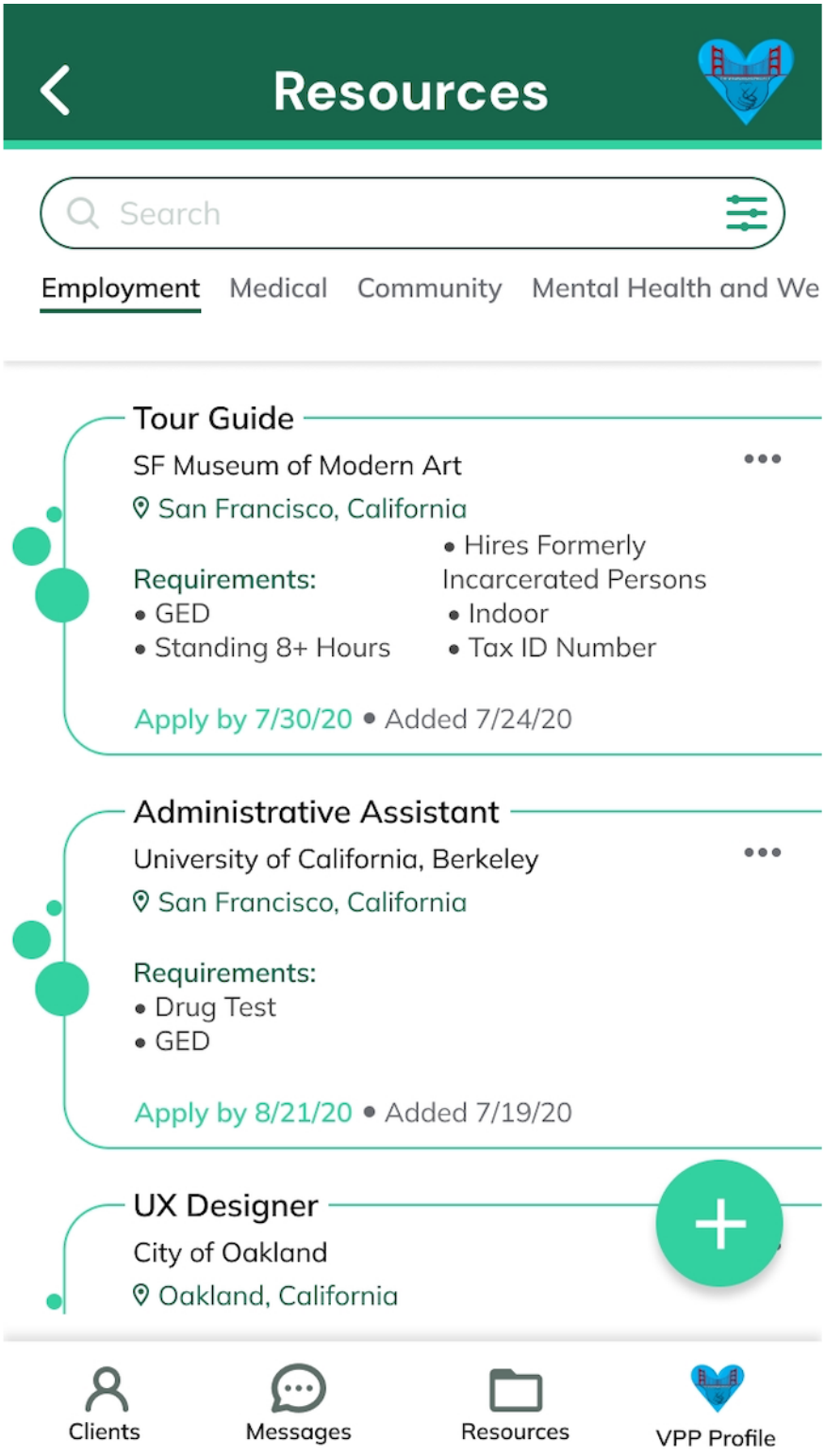

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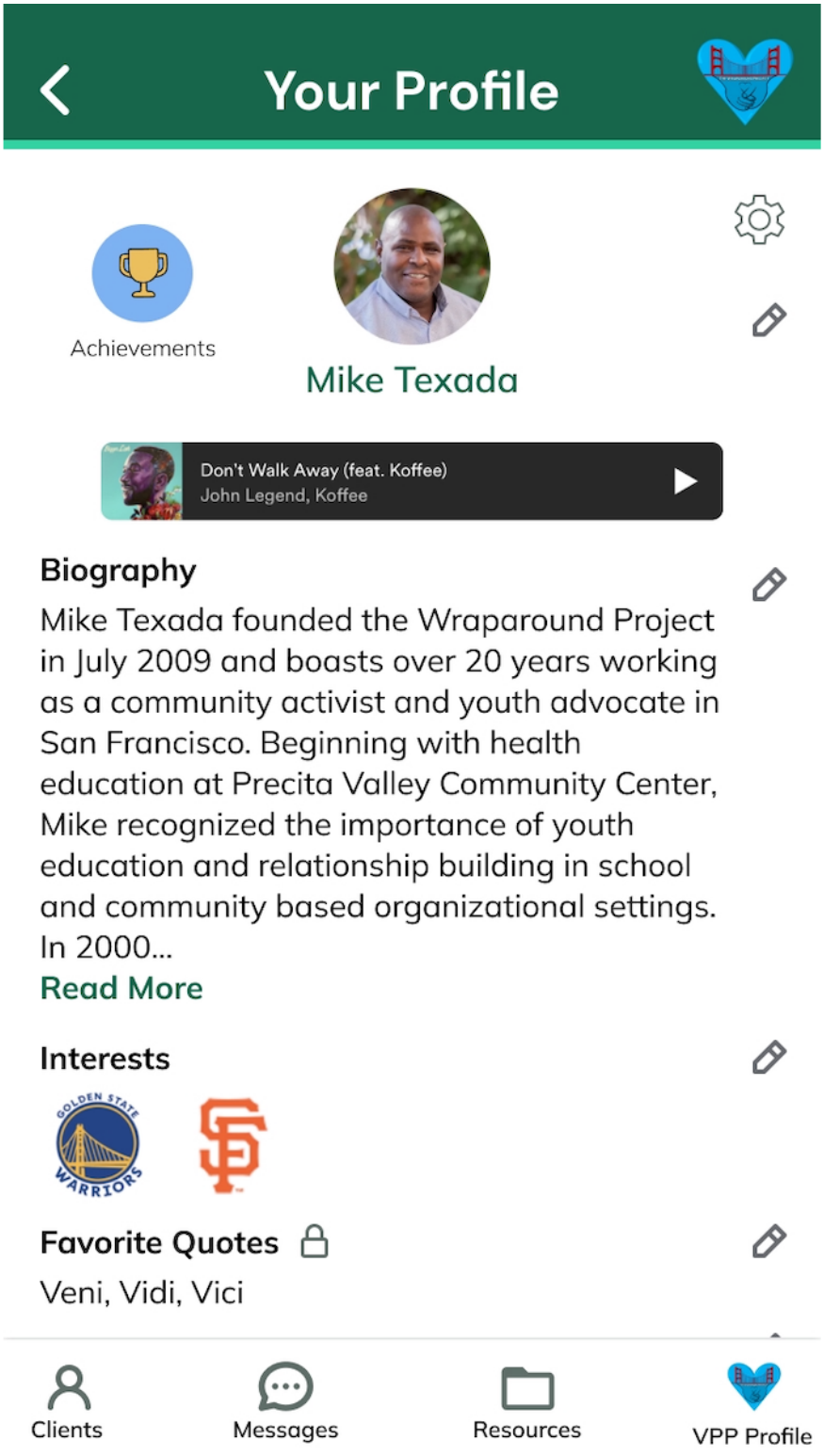
Figure 4. High-fidelity WrapApp violence prevention professional caseworker profile wireframe. VPP: violence prevention professional.



Discussion

Study Overview and Key Findings

We integrated HCD with rapid iterative testing to develop a prototype mHealth app tailored to the workflow needs of an HVIP. Across 9 rapid-cycle testing sessions, 133 of 181 identified actionable usability issues were addressed, yielding an impact ratio of 73%. The prototype expanded from 3 initial wireframes to 25 high-fidelity screens. This process clarified 3 design priorities for VPPs.

First, features needed to strengthen trust while preserving professional boundaries, which informed inclusion of profile photographs, recognition badges, and out-of-office automation. Second, a client-owned care plan with editable milestones and visible progress indicators supported motivation and accountability. Third, personalized resource sharing mattered more than static lists, leading to workflows that allow a VPP to

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send a resource directly into a client's care plan or message thread and include a named point of contact when available. Together, these results illustrate how combining HCD with RITE can translate complex case management relationship-based requirements into concrete interface designs for a highly individualized, functional, and desirable mHealth tool that is useful for partner organizations and attuned to the complex needs of their users.

Comparison With Existing Research

This subsection explains how our approach aligns with and extends prior guidance on sustainable digital health development, with particular attention to end user engagement and equity. As mHealth technologies play a central role in making continuous health care possible [42], growing evidence shows that mHealth projects succeed when end users shape every design phase. Consistent with An et al [43], we engaged end users throughout design to support relevance, usability, and longer-term adoption readiness. In parallel with World Health Organization guidance on digital interventions, we prioritized deep user engagement and attention to equity considerations during design, given the vulnerabilities and barriers faced by violence survivors and the caseworkers who support them [44]. Our contribution extends this literature in 3 ways. First, the primary end users were a specialized workforce delivering relationship-based, trauma-informed services, rather than patients engaging in self-management. Second, we paired participatory design and qualitative thematic analysis with rapid-cycle usability testing that generated quantifiable, actionable defect tracking during prototyping. Third, the design targets a dual-user ecosystem, where staff workflows shape what is feasible and safe for eventual client-facing functions.

Many existing mHealth apps are built for large, relatively uniform user populations and emphasize generic self-management activities such as tracking diet or medication adherence [45-47]. By contrast, our prototype was developed for a highly specialized care context in which relationships, trust, emotional safety, and boundary setting are foundational to effective use. This study demonstrates a replicable approach to designing digital tools that accommodate diverse workflows and emotionally sensitive communication within HVIPs, addressing a gap in documented iterative development processes for dual-user health care systems.

Design and Clinical Implications

Our mHealth app has the potential to enhance the delivery of HVIP services. Operationally, the prototype consolidates tools such as spreadsheets, paper notes, and ad hoc texting into a single dashboard, with the goal of reducing administrative burden and preserving time for client engagement. Features such as the VPP Profile and Client Profile**,** in-app messaging, and achievement celebrations were designed to foster trust, enhance communication, and strengthen the therapeutic alliance between clients and VPPs. In addition, the app's ability to provide clients with a tangible view of their healing progress through the "Care Plan" feature can boost motivation, increase self-efficacy, and promote engagement. Client empowerment was operationalized as making the plan visible, editable, and progress-oriented, so clients can see what they are working toward, what steps are next, and what has already been completed. In case management practice, this can support motivation between visits and reduce repeated explanation during time-limited contacts. VPPs can also use the app to provide real-time resource referrals with warm handoffs, ensuring better continuity of care and improved client outcomes. In practice, a warm handoff involves more than sending a link. Caseworkers often contact an organization first, identify a named person, confirm eligibility requirements, and then introduce the client to that contact. The prototype supports this workflow by allowing caseworkers to attach a resource to a specific care plan task, include application instructions, and share a named contact when available, reducing the likelihood that clients are left to navigate complex systems alone. Finally, the app promotes clearer boundary setting by offering structured communication channels and time-sensitive prompts that help both parties maintain role clarity.

Methodological Contributions

This subsection highlights how pairing HCD with rapid iterative testing can increase speed and rigor during prototype refinement for complex interventions. Our approach of combining this modified RITE method with HCD provides a scalable and agile framework for mHealth app development, particularly in complex, high-stakes environments where deep user engagement and system integration are essential. Traditional usability testing in HCD involves limited rounds of user feedback and freezes a prototype until an entire round of feedback is complete [48]. In contrast, RITE facilitates immediate design modifications, making the development process more agile and responsive [31]. By integrating HCD with rapid iterative testing, we continuously incorporated caseworker feedback during prototyping, supporting a responsive development cycle aligned with the needs of HVIPs. Although rapid-cycle iteration can be resource intensive, the approach is adaptable, and teams can calibrate how frequently changes are implemented between sessions based on available design and development capacity. For example, RITE changes do not necessarily need to be comprehensively implemented between participants. This option would allow RITE to be approachable for organizations that may be low on time or resources. We ourselves have demonstrated in this paper an approach to modifying RITE to fit our own organizational needs.

We also expanded the classic 4 RITE codes by adding categories for positive feedback and for conflicting feedback. Capturing what users were most positive about ensured that later revisions did not inadvertently remove valued elements and allowed us to continue incorporating features that were favorable. Documenting conflicts between VPPs helped the team decide when a configurable option, rather than a single global solution, was warranted. This allowed us to maintain consistency while accommodating variability in case management approaches. The enhancements to the RITE method can be adapted to suit various community-based interventions and programs that require rapid iteration and responsiveness to user needs, particularly in multidisciplinary settings where individualized interventions are critical, such as community mental health work and oncology patient navigation.

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Limitations and Future Research

Several limitations should be considered. The sample was small (9 caseworkers) and drawn from a single HVIP, which limits generalizability. In addition, this phase focused on the caseworker-facing prototype; client input is still needed before finalizing a client-facing experience. Staff turnover also limited longitudinal participation across phases. Future studies should explore the applicability of this methodology to larger, more diverse user groups and settings.

Next, we will design and test the client-side interface using the same iterative methods and then pilot the combined system with WAP caseworkers and clients. Looking ahead, integration with an electronic health record such as Epic could enhance coordination between violence intervention teams and clinical providers. Since 2023, caseworkers in the WAP have documented client progress in Epic, which increases visibility of nonmedical needs for clinical teams. However, clients typically do not have a clear, usable view of the recovery plan described in clinical documentation. From a technical standpoint, integration could be approached by mapping selected care plan fields to structured data elements and exchanging data through Epic-supported interfaces (eg, standards-based application programming interfaces where available). Implementation would require clear governance decisions about what information is appropriate for bidirectional exchange, role-based access controls for sensitive social and safety data, and auditability of changes made by staff versus clients. Additional challenges include aligning terminologies across systems, minimizing duplicate documentation burden for caseworkers, managing consent and privacy preferences for trauma-related information, and ensuring usability within existing workflows. These considerations will inform our implementation-phase pilot planning. This pilot will include surveys, usage metrics, and qualitative feedback and will also assess workflow fit alongside existing documentation practices in Epic.

Conclusions

A mixed methods approach to mHealth app development that combines RITE testing and HCD methodology strengthens the iterative design process, particularly for vulnerable populations. The detailed user feedback and agile design allowed us to rapidly adapt the app to the needs of VPPs, ensuring its usability and acceptability for VPPs. This approach is a promising way to develop customized, culturally congruent digital tools for social care programs and, if validated in larger trials, could serve as a blueprint for other violence prevention and community health interventions.

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Authors' Contributions

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Data curation: MGS (lead), DP (equal), AB (supporting)
Formal analysis: MGS (lead), DP (equal), AB (equal)
Funding acquisition: AS (lead), DP (equal)
Investigation: DP (lead), MGS (equal), AB (supporting), JW (supporting), DG (supporting)
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Supervision: MGS (lead), DP (equal), AS (equal), MT (supporting)
Validation: MGS (lead), CVH (supporting), AS (supporting), MT (supporting)
Visualization: MGS
Writing – original draft: AB (lead), DP (supporting)
Writing – review & editing: MGS (lead), CVH (supporting), DP (supporting), AS (supporting)

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Conflicts of Interest

AS is the owner and founder of the Empathy Studio LLC, a human-centered design consultancy. During the study period, DP was a part-time design consultant for the Empathy Studio, LLC. All other authors declare that they have no competing interests.

Multimedia Appendix 1
Tables of WrapApp wireframes in development from low to high fidelity.
[PDF File, 2908 KB - formative_v10i1e79533_app1.pdf]

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Abbreviations

HCD: human-centered design
HVIP: hospital-based violence intervention program
RITE: Rapid Iterative Testing and Evaluation
UCSF: University of California San Francisco
VPP: violence prevention professional
WAP: Wraparound Project

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A Telehealth-Based Behavioral Intervention for Cancer-Related Cognitive Decline in Older Adults Undergoing Systemic Therapy for Breast Cancer: Development and Usability Testing

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Abstract

Background: Cancer-related cognitive decline (CRCD) is a significant problem; interventions are needed to mitigate CRCD for older adults (aged ≥65 years).

Objective: Our objective was to develop and evaluate the usability of Memory and Attention Adaptation Training–Geriatrics (MAAT-G), a CRCD intervention for older adults with breast cancer undergoing systemic treatment.

Methods: We conducted an intervention adaptation study to develop MAAT-G. MAAT-G is a cognitive behavioral therapy–based intervention delivered by a health professional over the course of 10 weekly individual workshops via videoconferencing. To develop MAAT-G, the contextual, cohort-based, maturity, and specific challenge framework was used for preliminary adaptations. Patient advocate collaborators guided further refinement, reviewing MAAT-G workshop content, the participant workbook, and intervention delivery via videoconferencing to optimize relevance and usability for older adults. The usability of MAAT-G and its videoconferencing delivery were subsequently evaluated in 4 older adults with breast cancer using the System Usability Scale (score range 0 - 100; >67 being above average) and through semistructured qualitative interviews.

Results: Numerous adaptations were made to address the unique needs of older patients using the contextual, cohort-based, maturity, and specific challenge framework and patient advocate feedback. Usability testing included 4 female patients with breast cancer (mean age 73.3, SD 3.77; range 67-77 years). Patients were receiving systemic therapy (2 receiving adjuvant therapy and 2 receiving advanced-stage disease therapy). One patient had an educational level lower than high school; 3 had some college education or higher. All 4 patients completed study procedures, including 10 MAAT-G workshop sessions (100% intervention adherence). The mean System Usability Scale score was 90.6 (SD 13.51), indicating good usability.

Conclusions: MAAT-G is a behavioral intervention developed to mitigate CRCD. It is designed specifically for older adults and showed above-average usability in this population.

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KEYWORDS

geriatric oncology; older adults; telehealth or videoconferencing; cognition; cancer-related cognitive decline

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Introduction

Cancer-related cognitive decline (CRCD) is a significant problem. Up to 75% of patients receiving active cancer treatment experience CRCD, which may manifest as difficulties in attention, processing speed, executive function, and memory [1-3]. In addition to CRCD, older adults with cancer (aged ≥65 years) also experience age-related cognitive decline, further compromising their cognitive health [4-8]. For instance, half of older adult women receiving adjuvant chemotherapy for breast cancer report worsening of cognition, and 25% have measurable declines on neuropsychological testing 6 months after chemotherapy [9,10]. CRCD can also compromise the functional independence of older adults, such as the ability to remain independent with managing medications or finances (eg, activities of daily living) [11]. Thus, addressing the cognitive needs of older adults with cancer is essential to promote independence, enhance their well-being, and promote healthy aging. However, CRCD interventions tailored to them do not exist [12].

Memory and Attention Adaptation Training (MAAT) is a cognitive behavioral therapy (CBT)–based intervention for CRCD that focuses on an individual's psychological response to injury as compared to the biological events triggering CRCD [13]. MAAT has 8 manualized workshops supplemented by a participant workbook and is individually delivered by a psychologist via videoconferencing. Together, the workshops and workbook provide instruction and practice with adaptive behavioral coping skills, stress management techniques, and compensation strategies to manage CRCD symptoms [14]. Although MAAT has been associated with greater scores on perceived cognition functioning, verbal memory, and processing speed in 3 separate studies, these populations were primarily middle-aged survivors of breast cancer who completed treatment months before enrolling in the intervention [13-15]. Thus, additional research is necessary to examine the effectiveness of MAAT in other populations, such as older adults with cancer. However, adapting the intervention to their specific needs and resources is essential to increase their usability and potential benefits.

Older adults are more likely to be diagnosed at later cancer stages [16] that may require extended treatments. Furthermore, due to the increased risk of age-related cognitive decline and CRCD, adapting MAAT to intervene earlier (eg, concurrent with cancer therapy) has the potential to improve outcomes in this vulnerable population. Thus, the goals of this study were to (1) adapt MAAT to the unique needs of older adults with breast cancer (eg, develop Memory and Attention Adaptation Training–Geriatrics [MAAT-G]) and (2) evaluate the acceptance and usability of MAAT-G in a sample of older adults with breast cancer receiving systemic therapy.

Methods

Overview

We conducted an intervention adaptation study to develop MAAT-G. Specifically, MAAT-G was developed in two phases: (1) preliminary adaptations based on the contextual, cohort-based, maturity, and specific challenge (CCMSC) framework [17]; and (2) refinement with collaboration of patient advocates. We then conducted an evaluation of the usability of MAAT-G and its telehealth delivery model in a single-arm study of older adults receiving systemic therapy for breast cancer.

MAAT-G Adaptation

Preliminary Adaptation

The CCMSC model [17] is informed by research on aging and older adult social contexts and has been previously used to adapt CBT-based interventions [18,19]. To optimize the relevance and usability of MAAT for older adults, study authors (AM, RJF, LD-R, and DM) made initial adaptations based on CCMSC model principles as follows:

- Contextual: identification of the unique social and environmental factors that influence the targeted population, such as considering the patient's living situation (eg, retirement communities, aging services, and long-term care facilities), community infrastructure, social support network and role changes
- Cohort-based: analysis of specific factors of the population of interest, such as their cognitive abilities, educational level, word use, normative life paths, and social-historical life experiences, as well as considering the fact that older adults may identify with an aging cohort with specific beliefs and attitudes and unique needs (eg, additional technological support)
- Maturity: consideration of factors associated with aging, such as potential preexisting conditions (eg, comorbidities) and cognitive and emotional complexity, as well as analyzing how family and life experiences may influence perspectives, expertise, areas of competence, and accumulated interpersonal skills
- Specific challenge: examining conditions or situations that may create barriers to engagement, such as chronic illnesses, disabilities, and age-related conditions (eg, hearing loss and visual impairment), as well as additional exploration of social challenges associated with aging, such as grieving for loved ones and requiring caregivers

Additional Refinement

Following the initial adaptations, study authors (AM and GD) presented the protocol to a local older patient advisory board (Stakeholders for Care in Oncology and Research for Our Elders Board [SCOREboard]) with experience in the design of clinical trials for older adults with cancer [20-23]. Authors collected high-level feedback from the full patient advisory board and made initial modifications as necessary. Next, study authors met with 2 SCOREboard members (LM and VT) to conduct an in-depth review of MAAT-G and its delivery method. Four meetings were conducted, each focusing on a separate aspect of MAAT-G; workshop content (across 2 meetings); participant workbook content, presentation, and formatting; and aspects of the intervention (eg, technology interface and development of instructions and support materials). The meetings lasted between 1 and 2 hours, and SCOREboard members reviewed materials before and in between meetings.

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Assessment of Usability and Delivery Mode

Eligibility

Following the adaptations, we tested the usability of MAAT-G in an open single-arm study. To be included in the usability phase, participants had to (1) be aged ≥65 years, (2) be diagnosed with breast cancer (any stage), (3) be receiving systemic therapy with at least 2 cycles remaining, (4) be able to speak and read English, and (5) have decision-making capacity. We focused on patients aged ≥65 years as they experience the highest rates of breast cancer incidence and are more likely to experience CRCD, and there are no existing interventions focusing on their unique needs [24].

Recruitment

Patients were recruited from the Comprehensive Breast Cancer Center at the Wilmot Cancer Institute in Rochester, New York. The study team obtained approval to screen clinic schedules using electronic medical records for prospective patients. Following the identification of a prospective patient, the study team contacted the patient's primary oncologist to inquire about the patient's decision-making capacity for informed consent and obtain approval for approaching the patient about study participation. The study staff next approached patients at the clinic to present the study, answer study questions, and obtain informed consent.

Usability Assessment

We assessed the usability of MAAT-G quantitatively using the System Usability Scale (SUS) [25,26]. Possible scores range from 0 to 100, with a score greater than 67 indicating average or good usability [27,28]. This threshold was used as the benchmark for determining usability in this study. We also examined the usability qualitatively through semistructured interviews. The semistructured interviews consisted of 4 questions on patients' experience over the course of the study regarding the workshop content, the use of the tablet, the participant workbook, and the potential impact of MAAT-G. All interviews were conducted by 1 staff member not involved with intervention administration. All interviews were also audio recorded to generate a transcript.

Procedures

Following informed consent, we provided patients with a bound copy of the patient workbook, a tablet with a HIPAA (Health Insurance Portability and Accountability Act)-compliant videoconferencing application, and a set of instructions on the use of the tablet. The intervention took place over the course of 10 to 12 weeks and consisted of 10 MAAT-G workshops delivered one-on-one. One member of our study staff (psychology postdoctoral fellow) delivered all workshop sessions after receiving appropriate training. Each workshop session was delivered over videoconferencing approximately once per week. All intervention sessions were video recorded; videos were then reviewed by the principal investigator to ensure fidelity to the intervention delivery protocol.

Data Analysis

To assess the usability of MAAT-G, we summed the responses on the SUS for each participant and then computed a mean value across patients [25,26]. All quantitative analyses were conducted using SPSS (version 28; IBM Corp). Qualitative interview transcripts were imported into the MAXQDA software (VERBI GmbH) for sorting, coding, and analysis. The principal investigator and a senior staff member (both with prior experience in qualitative data analysis) independently read the transcripts to familiarize themselves with the data. They then met to jointly code the transcripts using an inductive approach; any coding discrepancies were discussed until consensus was reached. We opted for a joint coding process considering the low number of transcripts. Emerging codes were then grouped into categories based on similarity, and categories were grouped into themes, consistent with the content analysis approach [29].

Finally, quantitative and qualitative data were compared against each other to examine how the SUS scores aligned with the perceived intervention experience. These results were used to determine whether additional intervention refinements were necessary and, if so, guide such modifications.

Ethical Considerations

The Institutional Review Board of the University of Rochester oversaw and approved the study (STUDY00003900). All participants provided informed consent before study enrollment and data collection. The information provided by the participants was deidentified and kept on a secure, password-protected platform. Participants received US $30 per workshop session they completed. The authors confirm that participants were made aware of and provided informed consent for the publication of the study findings and example quotes.

Results

MAAT-G Adaptation

As shown in Table 1, the preliminary adaptations comprised a reduction in the quantity of material covered in each session. This helped reduce the quantity of information provided in one sitting, concordant with CCMSC principles. However, this adaptation subsequently necessitated an extension in the number of workshops from 8 to 10.

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Table . Examples of Memory and Attention Adaptation Training–Geriatrics (MAAT-G) adaptations implemented through the contextual, cohort-based, maturity, and specific challenge (CCMSC) model and stakeholder feedback.

CCMSC[a] component	Preliminary adaptation conducted by expert investigators	Intervention refinements based on patient advocates' (SCOREboard[b]) input
Contextual factors	• Content experts added a section to the MAAT-G interventionist manual on social context factors and how they may influence compensatory strategies for older adults • Added a screening question to the MAAT-G interventionist manual to assess social support to encourage leveraging social support resources for compensatory strategies	• Case scenarios were updated to be more age relevant (eg, modification in occupations: removing "work" and replacing it with "volunteering" or "household chores")
Cohort-based factors	• Added a section to the interventionist manual on cohort-based factors and their potential influence on coping mechanisms and stress responses • Modified the patient workbook by minimizing complex terminology to accommodate potentially lower educational levels	• Reviewed workbook changes and suggested logistical modifications (eg, using thick paper to print the workbook in case the patient was experiencing neuropathy) • Developed technology support materials to enhance inclusiveness of those with limited fluency with technology
Maturity factors	• Added a section to the interventionist manual on maturity factors and their effect on pace of information receipt, coping mechanisms, and stress response • Extended the workshop number from 8 to 10 to decrease the amount of material in each workshop • Reduced complexity of examples in patient manual	• Updated the intervention materials to be sensitive to patients living alone (eg, widowed); highlighted the relevance of acknowledging these factors to the intervention • Suggested providing materials (eg, stylist and stand) to facilitate engagement during the intervention sessions
Specific challenge factors	• Added a step to the interventionist manual to screen for hearing loss, allowing the interventionist to proactively adapt volume and rate of speech while delivering the intervention • Adjusted font type and size (eg, Aptos body, 15 points, double spaced) in the patient workbook to accommodate potential visual impairments	• Checking the technological devices provided to facilitate their use (eg, step-by-step guide to access the Zoom application) • Flexibility in delivery and scheduling to account for potential health challenges (eg, having sessions in the evening instead of early in the morning and a flexible window between sessions to adapt to the patients' calendars)

[a]We followed the CCMSC model as determined by Knight [17] and with involvement of patient advocate collaborators.

[b]SCOREboard: Stakeholders for Care in Oncology and Research for Our Elders Board.

The patient advocates reviewed each adaptation based on CCMSC components and confirmed the appropriateness of the modifications. Most of the additional feedback provided by the patient advocates centered on logistical adaptations to improve the intervention delivery (eg, the type of paper needed to print the workbook and development of a technology user's manual) and refinement of case examples to ensure their relevance (eg, removing wording associated with work and employment and replacing it with other occupations, such as household chores or volunteering). Furthermore, patient advocates (SCOREboard members) played a key role in the development of robust technology support materials to which patients could refer if questions arose during the study. The materials described basic operations such as how to log into the tablet, how to charge it, and how to log into the Zoom application—including photographs of steps in addition to text instructions. Different versions were developed to accommodate the participants' technological needs (eg, patients who received a data-enabled vs Wi-Fi–only tablet). The content of the adapted intervention, MAAT-G, is shown in Table 2.

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Table . Content overview of the adapted intervention: Memory and Attention Adaptation Training–Geriatrics (MAAT-G).

Session number	Title	Overview
1	Introduction	• Presentation of MAAT-G • Education on the impact of cancer and its therapy on memory and attention • Importance of self-monitoring memory and attention and strategies
2	Relaxation skills	• Review of session 1 materials and skills • Education on the impact of stress on the body • Strategies to manage stress (progressive muscle relaxation and brief relaxation)
3	Self-instructional teaching	• Review of session 2 materials and skills • Memory and attention adaptation skills (self-instructional training, verbal and "silent" rehearsal skills, and rhythmic skills)
4	Cognitive flexibility	• Review of session 3 materials and skills • Education on cognitive flexibility • Skills to increase cognitive flexibility (probability re-estimation and decatastrophizing)
5	Keeping a schedule and memory routines	• Review of session 4 materials and skills • External skills to assist with memory and attention problems (scheduling and memory routines)
6	External cueing and distraction reduction	• Review of session 5 materials and skills • Education on external cues to assist with memory and attention • Strategies to help with distraction reduction
7	Activity scheduling and pacing	• Review of session 6 materials and skills • Education on the importance of scheduling and pacing • Strategies to assist with scheduling and pacing (active listening, summarization, and clarification)
8	Fatigue management and sleep quality	• Review of session 7 materials and skills • Education on fatigue and sleep improvement • Skills for managing fatigue (activity pacing, relaxation skills, and exercise and diet) • Skills for sleep quality improvement (sleep hygiene and exercise and diet)
9	Visualization skills	• Review of session 8 materials and skills • Education on visualization skills • Visualization skills
10	Tying it all together	• Review of materials and skills covered in the workshops • Tying together all MAAT-G skills learned • Development of strategies to maintain the use of the skills learned

Assessment of Usability

Overview

A total of 4 patients were approached to participate in the usability assessment of MAAT-G. All consented to participate, suggesting preliminary acceptance of recruiting older adults with breast cancer receiving systemic therapy. All participants also completed all study procedures, including 10 MAAT-G workshop sessions, without delay (100% intervention adherence).

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Sample

The clinical and demographic characteristics of the participants included in the usability phase are shown in Table 3. Briefly, all participants were women with breast cancer. The mean age was 73.3 (range 67-77) years, and all identified as White individuals. Two of the patients were married and currently lived with their spouses, whereas 2 were widowed and lived alone. Annual household income ranged from less than US $20,000 to over US $100,000. All patients were enrolled in Medicare. Two patients were presently employed (1 part time and 1 full time). All but 1 participant (who had an educational level lower than high school) had at least some college education. All patients were also receiving active systemic therapy at the time of study participation (2 were receiving adjuvant chemotherapy–based regimens, and 2 were receiving advanced-stage disease regimens with cyclin-dependent kinase 4 or 6 inhibitor therapy).

Table . Clinical and demographic characteristics of phase 2 participants.

	ID01	ID02	ID03	ID04
Age (y)	77	67	74	75
Race and ethnicity	White; ethnicity not reported	Non-Hispanic White	Non-Hispanic White	Non-Hispanic White
Marital status	Widowed	Married	Married	Widowed
Living situation	Living alone	Living with spouse	Living with spouse	Living alone
Income (US $)	>20,000	<100,000	Not reported	Between 50,000 and 100,000
Health insurance	Medicare	Medicare	Medicare	Medicare
Employment status	Retired	Employed full time	Homemaker	Employed part time
Highest educational level	9th-11th grade	Junior college degree	Some college	Advanced degree
Cancer stage	Local	Local	Advanced	Advanced
Cancer treatment	ACT[a]	ACT	CDK[b] 4 or 6 with aromatase inhibitor	CDK 4 or 6 with aromatase inhibitor
System Usability Scale score	100	67.5	100	95

[a]ACT: adriamycin, cyclophosphamide, and taxol.

[b]CDK: cyclin-dependent kinase.

The session delivery audit conducted by the principal investigator did not suggest significant deviations from the administration protocol. Thus, fidelity to the protocol was considered high.

Usability

Quantitatively, we found that the mean total score on the SUS was 90.6 (SD 13.51; range 67.5 - 100), suggesting above-average usability [25,26] and exceeding our a priori usability threshold (>67). Although the lowest score was also higher than the a priori usability threshold, we paid special attention to the qualitative data from this participant to examine specific recommendations. However, the qualitative data were consistent between participants regardless of usability score. The content analysis yielded 4 themes (technology support, comfort with technology, experience with the intervention, and utility of its content) and suggested areas of further modification (Table 4).

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Table . Qualitative themes and example quotes from interviews on usability.

Qualitative theme	Example quotes from participants
Technology support	• "It worked out really well. The only time I didn't know where to push the volume; I didn't know where that was. I found it to be a great tool. I found the information you gave me on how to set it up, how to get started with Zoom, it was simple to operate it by reading the pamphlet you gave me. I found that—it made the class easy without guessing." • "I thought having your phone number, the one time we couldn't get in to him [interventionist] for some reason—I'm not sure why—but we had your phone number and we were able to make contact right away. That was really good."
Comfort with technology	• "The iPad was very easy to use, much easier than the computer."
MAAT-G[a] experience	• "Yes, it was useful. I was pretty diligent; I did my homework every week. As a matter of fact, I read a little ahead of time because I liked to be a little familiar. We took notes." • "I felt very little anxiety looking for something. Usually my anxiety kicks in. I just relaxed myself for a little bit and then I remembered where I put my glasses after a few minutes of doing that." • "Basically, the whole experience was great." • "I think it was the right number of sessions."
Areas for further MAAT-G modification	• "The only thing I did not like about it is the paper, you can't get it to write on it with pencil, it doesn't show." • "...putting page numbers on the book."

[a]MAAT-G: Memory and Attention Adaptation Training–Geriatrics.

Overall, the patients found the technological support manual and staff guidance to be useful for learning how to operate the tablet. Furthermore, it was helpful to reach the study staff via phone for technological support in joining the videoconference session or operating the tablet. Over the course of the study, patients reported increased comfort with the tablet. The participants also described that the material covered during the workshops was useful. There were no additional suggestions on intervention content or delivery methods. Instead, participants' suggestions centered on the workbook materials. Specifically, they suggested printing the workbook on nonglossy paper so that they could take notes in the margins, as well as adding page numbers to the workbook to easily locate different sections. These 2 logistical suggestions were incorporated into our current randomized controlled trial. Other intervention aspects did not change.

Discussion

We adapted a CBT-based intervention to address CRCD symptoms among older adults with cancer undergoing systemic therapy and examined its usability and acceptability. MAAT-G engages participants in a 1:1 telehealth setting to explore and learn coping skills, stress management techniques, and methods to target episodes of CRCD [1]. We strove to promote universal usability and acceptance using telehealth and early and meaningful involvement of patient advocates throughout the intervention adaptation process.

Although several studies have evaluated behavioral interventions to address CRCD symptoms, their scope is limited [30]. Similar to MAAT-G's parent intervention (MAAT) [13-15], most existing interventions focus on younger survivors of cancer and individuals who have completed treatment months to years before enrollment. For instance, Cherrier et al [31] studied the effect of a 7-week workshop among middle-aged (mean age 58.9 years) people with breast, bladder, prostate, colon, and uterine cancer with an average of 4.84 years after treatment completion. Similarly, ReCog, a group cognitive rehabilitation intervention, improved perceived cognitive functioning in survivors of cancer with an average of 3 years since treatment completion [32]. Our findings expand the current literature by providing a CRCD intervention for older adults undergoing treatment and showing preliminary evidence of its usability.

MAAT-G was designed as a telehealth delivery model given that older patients in active cancer treatment often have frequent in-person appointments. Thus, having additional in-person study visits may create accessibility barriers for those no longer driving independently. This design was based on other studies demonstrating that telehealth provides participants with the flexibility and comfort of completing all study-related tasks from home [14]. Additionally, a one-on-one intervention delivery model such as that of MAAT-G was preferred due to its scheduling flexibility, which allows sessions to be coordinated around existing clinic and therapy appointments.

Previous studies have demonstrated that the inclusion of patient advocates as research collaborators has significant benefit in clinical trials [33,34]. For this study, we collaborated with the Cancer and Aging Research Group (CARing) SCOREboard, a patient advocate advisory board supported by the Cancer and Aging Research Group. CARing SCOREboard members provided critical insights about study design, aspects related to intervention adaptation, and guidance on technology support.

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The inclusion of the patient perspective throughout the study design and intervention adaptation led to more patient-focused study procedures and design, which contributed to the favorable usability of the resulting intervention and, ultimately, advocated for and prioritized the study participants' needs.

The foundation of the MAAT-G intervention was developed using the CCMSC model [17], which has been previously used in other CBT adaptation studies for older adult populations. For example, Trevino et al [35] used the CCMSC framework to develop the Managing Anxiety From Cancer (MAC) intervention, which addresses anxiety symptoms among older adults with cancer. Both the MAC and MAAT-G adaptations emphasize the cohort component of the CCMSC model, which highlights ideas such as membership and beliefs about and attitudes toward the problems. As such, MAC minimized the psychological language and developed examples with situations that older participants with cancer may experience. Similarly, MAAT-G revised the language of the intervention materials and created examples based on real-life experiences of older adults receiving cancer therapy. Despite this, the 2 interventions differed in some CCMSC components, particularly the specific challenge and maturity components. For example, MAAT-G accounted for the technological challenges of telehealth intervention delivery by adjusting the font size of the materials, developing a tablet manual, and screening for hearing loss, among others. Regarding the maturity components, MAC decreased the total number of sessions to minimize the participants' time commitment. In contrast, MAAT-G increased the number of sessions to reduce the quantity of information delivered during each session.

This study had multiple strengths, such as the comprehensive, evidence-based adaptation approach; the intensive patient advocate involvement; and the patient usability and engagement rates. Allowing patients to provide direct input on their experience helped the research team prioritize intervention components and delivery factors and overall tailor the intervention based on input from the targeted population. Furthermore, the technological support manual allowed older adults to feel more comfortable with the technological components of the intervention over time. Thus, our findings highlight activities that can promote technological engagement among older adults, which have the potential to improve the representation of this population group in future technology-based clinical trials.

A limitation of this study is the small sample size of the usability phase. However, our sample size is congruent with those of other usability studies in the field [36]. Furthermore, there was low variability in the clinical and demographic characteristics of the participants (all were recruited from a single cancer center, identified as non-Hispanic White individuals, and were older women undergoing systemic treatment for breast cancer but healthy enough to complete the intervention, and most of them also reported high educational levels), so generalizability to other populations of older adults, particularly those most often affected by CRCD and digital barriers, is limited, and further adaptations of the intervention might be required for those populations. Finally, capacity for study participation was confirmed by the patients' treating oncologists; future studies could consider a more standardized method for capacity assessment for participation.

In summary, we developed MAAT-G, a CBT-based intervention to address CRCD symptoms among older adults receiving active treatment for breast cancer and showed its preliminary usability and acceptability in a small cohort. A comprehensive, evidence-based, and patient-informed approach was followed, which improved accessibility, usability, and engagement. The feasibility and preliminary efficacy of MAAT-G are currently being evaluated in a pilot randomized clinical trial testing its effects on CRCD symptoms among older adults undergoing systemic breast cancer treatment.

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Data Availability

Data are available from the corresponding author on reasonable request.

Authors' Contributions

All authors contributed to the study conception and design.

Conflicts of Interest

None declared.

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Abbreviations

CARing: Cancer and Aging Research Group
CBT: cognitive behavioral therapy
CCMSC: contextual, cohort-based, maturity, and specific challenge
CRCD: cancer-related cognitive decline
HIPAA: Health Insurance Portability and Accountability Act
MAAT: Memory and Attention Adaptation Training
MAAT-G: Memory and Attention Adaptation Training–Geriatrics
MAC: Managing Anxiety From Cancer
SCOREboard: Stakeholders for Care in Oncology and Research for Our Elders Board
SUS: System Usability Scale

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Capturing Optimal Mobile 2D Facial Images in Remote Aesthetics Medicine Clinical Trials: Technical Considerations for Facial Severity Analysis

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Abstract

Background: In aesthetic clinical trials, image self-capture using mobile devices may help reduce burden on clinic resources, increase data quality, and lower barriers to study participation.

Objective: This study aimed to develop a mobile device app to help participants self-capture clinically usable images.

Methods: The Allergan Aesthetic (an AbbVie Company) mobile image app was designed to auto-capture images while directing study participants on distance, head position, and expression to capture a high-quality clinical image. To assess resolution and optimal lighting conditions, images captured using the app in office, at home, and in outdoor settings were compared with those from a Canfield VISIA-CR system (Canfield Scientific). Objective image quality assessment of facial images captured using the app with an iPhone XR (Apple Inc) and iPhone 12 (Apple Inc), compared with images captured using the Canfield VISIA-CR with a digital single-lens reflex camera and the Canfield mobile image capture app with a variety of Android (Google) and iOS (Apple Inc) devices, was conducted using the Blind/Referenceless Image Spatial Quality Evaluator (BRISQUE). Clinical utility was assessed by calculating inter- and intrarater variability for severity ratings of participants' lateral canthal lines (LCL) or forehead lines (FHL) obtained from app-captured images compared with ratings based on in-person evaluations performed by a physician. Usability was assessed according to the ISO (International Organization for Standardization)/IEC (International Electrotechnical Commission) 250101 standard.

Results: The Allergan Aesthetic mobile image app was found to perform best under natural light and had image resolution insufficient for assessing minor facial structures, but appropriate for larger structures (eg, FHL). A total of 3968 images were assessed using BRISQUE. Images captured with the Allergan Aesthetic mobile image app had better image quality than those captured using other modalities, as indicated by lower mean BRISQUE scores of 14.05 - 19.81 compared with Canfield VISIA-CR with a DSLR (34.47) and the Canfield mobile image capture app (23.43). LCL and FHL were rated both in person and digitally in 68 and 71 participants, respectively (median age 52 - 56 y; 48% to 52% female; 75% to 78% White). Interrater reliability between clinician live evaluations and independent photo review of self-captured photos based on intraclass correlation coefficients (ICCs) was substantial (0.61 - 0.80) to almost perfect (0.81 - 1.00) for all raters (LCL: ICC 0.75 - 0.91 at rest and 0.79 - 0.89 at maximum contraction; FHL: ICC 0.77 - 0.93 at rest and 0.70 - 0.89 at maximum contraction). After 2 iterations of improvements, mean usability ratings of the app experience (out of 5) were as follows: easy to complete=3.2, enjoyable=3.1, satisfied with the level of guidance provided=3.2, and likely to complete a full session without exiting=4.1.

Conclusions: The Allergan Aesthetic mobile image app delivers consistent, high-quality images that allow for assessment of LCL and FHL in good agreement with in-person evaluation. Image self-capture using mobile devices may help reduce clinic costs and remove barriers to participation in aesthetic clinical trials.

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KEYWORDS

forehead lines; lateral canthal lines; 2D facial image capture; consultation, remote; augmented reality guidance

Introduction

The first documented use of photography in reconstructive surgery was in the late 1840s, and in recent decades, it has become a mainstay of aesthetic medicine [1,2]. Photography has been used for procedure planning, postprocedure assessment, and follow-up, as well as education [3,4]. In some settings, 3D imaging may be preferred over traditional 2D photography, but it remains expensive and often requires a large amount of office space [5].

The consistency of images can be affected by lighting conditions, such as use of ambient light, flash photography, or

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more complex setups, regardless of the exact mode of image capture [6,7]. For example, when using natural light, differences in lighting direction and intensity can make images taken at different times difficult to compare [8,9]. Furthermore, facial wrinkles can be washed out by light that is too strong [8]. These issues can have a significant impact on image assessment. Before the advent of digital photography, shutter speed, aperture, and film speed, as well as darkroom procedures, all had the potential to impact image consistency [2,3]. Although shutter speed and aperture remain important parameters in digital photography, further complexity and inconsistencies may be introduced through variations in sensor resolution and sensitivity, white balance, and processing of the image after capture [2,5].

There has been much effort in recent decades to maximize the consistency of image capture [2,3,8]. This includes adoption of specialized equipment, such as digital single-lens reflex (DSLR) cameras, 3D photography systems, and standardization of camera settings, lenses, lighting, and background [2-5,9,10]. Some clinical practices go as far as to set aside space for dedicated in-office studios, and even hire professional photographers [7,8,11]. All of these approaches require significant resource use in terms of equipment costs, space, and staff time, as well as the need for repeated office visits by patients.

The trend toward telemedicine and the desire to minimize office visits, driven by the COVID-19 pandemic, further increases the potential utility of mobile phone image capture in aesthetic medicine [12-14]. Almost everyone today has a good-quality camera integrated into their mobile phones. The utility of mobile phone cameras in medicine has already been shown to be effective in the teledermatology setting for assessment of clinically important skin conditions, such as skin cancer and psoriasis [15-17]. Despite this, some authors have cautioned against the use of mobile phone cameras due to their limitations [5]. One potential limitation of mobile phones is that, in most cases, the camera, if used as a camera app only, will automatically adjust settings to optimize the image [5]. However, recent advances in mobile phone operating systems provide increased controls over automatic adjustments, enabling the app to control image quality and consistency.

The objective of this study was to develop a mobile phone app with optimized and standardized camera settings that produce reproducible and consistent images that have clinical utility for medical professionals. Mobile imaging will allow patients to take photographs themselves in mobile-based aesthetic clinical trials, as well as drive efficiencies of cost and scale by reducing office time for both patients and clinic staff.

Methods

Mobile Image Capture App Development

A base set of criteria, including lighting, position (rotation, tilt, and distance), and expression, was established as the first steps in the development of the Allergan Aesthetic mobile image app (version 1.0; an AbbVie Company). Images were captured under a range of lighting conditions, including overhead lighting similar to an office setting (color range of 6000 Kelvin), incandescent lighting similar to an at-home setting (5000 Kelvin), and natural outdoor light on sunny days. These images were compared with those captured using a Canfield VISIA-CR system (Canfield Scientific). The optimal distance from the face was assessed over a range from 1 to 10 inches. Values for the position parameters were set with only a small degree of freedom, such that a greater than 5° difference prompted the user to reposition their head rotation or tilt. To achieve this, AR Foundations face tracking and recognition technology (Unity Technologies) was implemented; this approach allowed for images to be reproducibly captured from different aspects. Facial recognition technology was also used to help control for expression. In order to control for intersubject variability, as well as for the effects of treatments such as onabotulinumtoxinA and hyaluronic acid fillers, facial recognition was used to establish a baseline at the start of each session. This calibration tool also provides a facial outline in the app that acts as a guide to establish where the face should be (rotation and tilt) for each image. Expression staging was separated from other staging functions to limit screen prompts, thus preventing cognitive overload. Expression was assessed at the end of staging immediately before image capture. If the participants made the correct facial expression (eg, smile), the app asked the user to remain still and counted down to the final capture.

Images for all studies described here were auto-captured on an iPhone XR (Apple Inc) and an iPhone 12 (Apple Inc) using the mobile devices' built-in software. Auto-capture was critical to ensure images were only collected (or captured) when staged within the tight parameters discussed above. Auto-capture also obviates the need for the participants to press a button, which can be difficult, especially when the desired image is not straight on. A built-in audio guide instructs the participants to adjust their position so they do not need to look at the screen. Key specifications for cameras used in these studies are listed in Table 1.

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Table . Specifications of cameras used for image capture in this study.

Specification	Canfield VISIA-CR and Canon EOS 6D	iPhone XR	iPhone 12
Resolution, megapixels	20.2	7	12
Sensor size	35.8×23.9 mm	1/2.55 inch	1/3.6 inch
Pixel dimensions	3648×5472	1908 ×3392	2268×4032
Pixel size, µm	6.54	1.4	NR[a]
Aperture	f/16	f/2.2	f/2.2
Aspect ratio	3:2	16:9	16:9
Focal length, mm	24 - 105	30	23

[a]NR: not reported.

Image Quality Assessment

Objective image quality assessments were conducted using the Blind/Referenceless Image Spatial Quality Evaluator (BRISQUE; University of Texas) [18] within Matlab (Mathworks, Inc). In total, 4 sets of images were collected in a clinical setting and subjected to the BRISQUE algorithm to calculate a mean score, as well as maximum and minimum scores. The team collected images using 4 different sets of devices and software. The BRISQUE algorithm was then applied to images of faces under the different lighting conditions tested to calculate mean (minimum, maximum) scores. Lower scores indicated better image quality. Image set 1 was collected using the Allergan Aesthetic mobile image app (version 1.0) with an iPhone XR running iOS (iOS 14.2); image set 2 was collected using the Allergan Aesthetic mobile image app with an iPhone 12 running iOS (iOS 14.2.1); image set 3 was collected using the Canfield VISIA-CR Blue (version 7.5.4) with a DSLR camera (Canon EOS Rebel T3i; Canon); and image set 4 was collected using the Canfield mobile image capture application with a variety of Android and iOS devices.

Clinical Analysis

Outputs from the Allergan Aesthetic mobile image app were assessed by a plastic surgeon and a clinical dermatologist (clinical photo raters) at a single site in the United States. This was a 3-part, noninterventional study. In order to ensure a wide range of facial types, there were no restrictions on entry criteria. Participants were recruited by a third party (Clinical Trial Media) from existing databases, online, and through traditional advertisements, such as flyers. In the first part of the study, physicians conducted a live in-person assessment of the severity of participants' lateral canthal lines (LCL) and forehead lines (FHL). In the second part of the study, participants were randomized to have photographs taken using standard DSLR image capture or to self-capture images via the Allergan Aesthetic mobile image app. In the third phase of the study, the captured images were subjected to independent photo review by 2 clinical photo raters, a plastic surgeon and a clinical dermatologist, not involved in any other aspect of the study. Traditional photonumeric scales were used for the live rating and the standard photography for LCL and FHL; these included the Allergan Aesthetic scales at rest and maximum expression for FHL (forehead lines severity scale [FHLSS]) and LCL (lateral canthal lines severity scale [LCLSS]). The clinical photo raters were trained on the 4 photonumeric scales used in the study and asked to rate the severity of LCL and FHL at rest and at maximum contraction (ie, natural smile for the LCL and maximum brow elevation for the FHL). For measurement of intrarater reliability, rating of images was performed in 2 reviews (independent photo reviews 1 and 2) conducted at least 2 hours apart. Each clinician photo rater logged onto a secure web-based photo evaluation and data collection system to complete ratings of the photos in a prespecified random order. The results of independent photo review were then compared to in-person assessment in order to evaluate whether images from standard photography and self-capture using the mobile app are comparable to in-person assessment. Overall interrater reliability and intrarater reliability for the LCLSS and FHLSS among the clinician image raters were evaluated using the same statistical methods as those for clinician live raters. The one-to-one interrater reliability for the LCLSS and FHLSS between each clinician live rater and clinician image rater was evaluated using intraclass correlation coefficients (ICC) (2,1) at image validation 1 and separately at image validation 2. SAS macro "INTRACC" was used to calculate ICC (2,1). CIs were obtained based on the formula described by Shrout and Fleiss [19]. The estimated degree of agreement between raters was classified based on ICCs as follows: <0=poor, 0 - 0.20=slight, 0.21 - 0.40=fair, 0.41 - 0.60=moderate, 0.61 - 0.80=substantial, and 0.81 - 1.00=almost perfect [20].

Usability

Usability of the Allergan Aesthetic mobile image app (version 1.1) was assessed according to the ISO (International Organization for Standardization)/IEC (International Electrotechnical Commission) 250101 standard, which ensures "the degree to which a product or system can be used by specified users to meet their needs to achieve specific goals with effectiveness, efficiency, freedom from risk, and satisfaction in a specified context of use" [21]. Usability research was conducted by McDougald Research (Columbus, Ohio). After an initial round of research, feedback was addressed and iterative changes were made to the app; usability was then reassessed in a second round of research.

The study was divided into 2 main sections. The first was a priming activity, in which participants watched a video summarizing the research background and then were asked to

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download the app and attempt 2 capture sessions over the course of 3 - 4 days. After completing both capture sessions, which were recorded using the Lookback.io platform (Lookback), participants rated the app in response to a series of questions (Multimedia Appendix 1). Participants rated the app on a 6-point scale from 0 (not easy at all) to 5 (very easy). The second part of the study was the remote interview, in which participants were asked to recount their experience using the mobile image capture app and share insights and pain points. While this feedback was qualitative in nature, the full body of data (responses) was quantitatively analyzed to uncover patterns in user feedback.

Ethical Considerations

The study was approved by the Advarra Institutional Review Board (Pro00074163) and conducted according to the principles of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use Guidelines for Good Clinical Practice [22] and the Declaration of Helsinki [23]. All participants provided written informed consent and were compensated with giftcards in the amount of $100 for study participation. The study data contains identifying information which was encrypted. Images were captured and delivered to a secured GXP-compliant system under consistent review of compliance. Event logging on this system ensures the data is tracked and all interactions monitored to ensure safety of study subject data.

Results

Mobile App Development

Figure 1 shows typical results obtained with the Allergan Aesthetic mobile image app under the different lighting conditions tested, compared with an image from a Canfield system using cross-polarized light. Natural light provided the closest match to that obtained using the in-office Canfield system. However, there was some variability with images taken outdoors depending on the orientation of the participants relative to the sun and the degree of cloudiness.

The resolution of the mobile device used had an impact on the quality of images produced under different lighting conditions. As illustrated in Figure 2, a pimple with a white cap is clearly shown with the Canfield system. However, the coloring under incandescent light conditions consistently masked such features that were otherwise clearly identifiable in other modes. Although the redness of the pimple is evident with full light and natural light, the white cap is not visible due to the limited resolution.

The optimal distance from the face to capture images was determined to be 6 inches, as this allowed for optimal resolution and cropping while permitting the participants some latitude to sway from side to side in the image frame. The app was further designed to limit the amount of head rotation and tilt. As illustrated in Figure 3, this results in consistent image capture between participants.

Figure 1. Examples of images captured by a participant (25-year-old Hispanic female, Fitzpatrick skin type IV) using the Allergan Aesthetic mobile image app with an iPhone XR under different lighting conditions (full overhead light, incandescent light, and natural light) compared with a Canfield VISIA-CR system.

Color temperature	5608.92431640625	4732.73828125	5961.48828125	Not known
Lumens	2660.98266601562	3750.22900390625	2258.8505859375	

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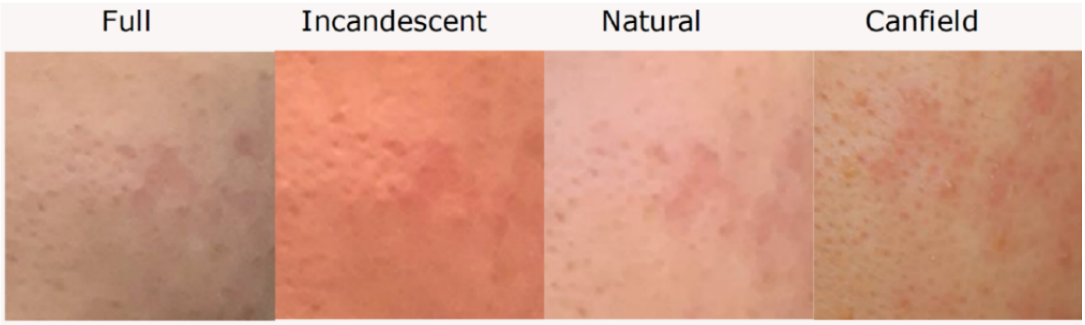
Figure 2. Close-up images of a pimple captured by a mobile device used with the Allergan Aesthetic mobile image app under different lighting conditions (full overhead light, incandescent light, and natural light), showing lower resolution compared with an image captured using a DSLR camera with the Canfield VISIA-CR.



Color temperature	5608.92431640625	4732.73828125	5961.48828125	Not known
Lumens	2660.98266601562	3750.22900390625	2258.8505859375	

Figure 3. Example image series captured by 2 participants (top row: 48-year-old Caucasian female, Fitzpatrick skin type II; bottom row: 62-year-old Asian female, Fitzpatrick skin type III) with the Allergan Aesthetic mobile image app using an iPhone 12 (top row) and an iPhone XR (bottom row), demonstrating the reproducibility of face position with different angles and expressions. Participants were instructed to follow the positioning and facial-expression prompts provided by the app during auto-capture. The on-site clinician provided additional instruction on how to hold and position the device (ie, hold the phone with 2 hands and place elbows on the table or against the body to stabilize the captures).

Image Quality Assessment

A total of 3968 images were assessed using BRISQUE. Overall, BRISQUE scores ranged from −0.24 to 61.83. As illustrated in Table 2, image sets 1 and 2 (captured with the Allergan Aesthetic mobile image app) had lower mean BRISQUE scores of 14.05 and 19.81, respectively, compared with image sets 3 and 4 (captured with Canfield VISIA-CR with a DSLR and the Canfield mobile image capture app, respectively), which had mean scores of 34.47 and 23.43, respectively.

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Table . Comparison of image quality as assessed by BRISQUE[a] for the Allergan Aesthetic mobile image app and other image capture modalities.

	Image set 1: Allergan Aesthetic mobile image app v1 with iPhone XR	Image set 2: Allergan Aesthetic mobile image app v1 with iPhone 12	Image set 3: Canfield VISIA-CR blue v7.5.4 with DSLR[b] Canon EOS Rebel T3i	Image set 4: Canfield mobile image capture app with a variety of Android and iOS devices
Image count	560	494	134	2444
Mean	14.05	19.81	34.47	23.43
Minimum	7.00	11.89	18.55	−0.24
Maximum	32.08	30.94	61.83	62.51
Minimum and maximum range	25.08	19.05	43.28	62.75

[a]BRISQUE: Blind/Referenceless Image Spatial Quality Evaluator.

[b]DSLR: digital single-lens reflex camera.

Medical Professional Clinical Analysis

A total of 208 participants were screened for LCL live scale validation; 71 were randomized, out of which 68 (96%) completed the study. Similarly, 208 participants were screened for FHL live scale validation; 73 were randomized, out of which 71 (97%) completed the study. Participants' characteristics are summarized in Table 3.

The reliability of image assessments of the severity of LCL and FHL using standard digital photography and the participants' self-capture app is summarized in Table 4. Evaluation of the severity of LCL using independent photo review of standard digital photograph assessments showed that intrarater reliability was almost perfect (overall weighted κ=0.87 - 0.88 at rest and 0.89 - 0.94 at maximum contraction), and interrater reliability was substantial to almost perfect (ICC=0.73 - 0.88 at rest, ICC=0.83 - 0.86 at maximum contraction). Interrater reliability between clinician live assessments and independent photo review of standard digital photograph assessments was moderate to almost perfect for both raters (ICC=0.42 - 0.89 at rest, ICC=0.49 - 0.89 at maximum contraction). For independent photo review of participants' self-capture photograph assessments, intrarater reliability (overall weighted κ=0.93 - 0.94 at rest and 0.96 at maximum contraction) and interrater reliability (ICC=0.89 - 0.91 at rest, ICC=0.91 - 0.95 at maximum contraction) were almost perfect. Interrater reliability between clinician live assessments and independent photo review of participants' self-capture photograph assessments was substantial to almost perfect for both raters (ICC=0.75 - 0.91 at rest, ICC=0.79 - 0.89 at maximum contraction).

Similar results were observed for the assessment of FHL severity. For independent photo review of standard digital photograph assessments, intrarater reliability (overall weighted κ=0.92 at rest and 0.91 at maximum contraction) and interrater reliability (ICC=0.90 - 0.91 at rest, ICC=0.86 - 0.94 at maximum contraction) were almost perfect. Interrater reliability between clinician live assessments and independent photo review of standard digital photograph assessments was substantial to almost perfect for both raters (ICC=0.77 - 0.92 at rest, ICC=0.61 - 0.87 at maximum contraction). For independent photo review of participants' self-capture photograph assessments, intrarater reliability (overall weighted κ=0.94 at rest and 0.92 at maximum contraction) and interrater reliability (ICC=0.91 - 0.95 at rest, ICC=0.90 - 0.92 at maximum contraction) were almost perfect. Interrater reliability between clinician live assessments and independent photo review of participants' self-capture photograph assessments was substantial to almost perfect for both raters (ICC=0.77 - 0.93 at rest, ICC=0.70 - 0.89 at maximum contraction).

Table . Characteristics of participants undergoing LCL and FHL severity rating (via captured images and in person) in the clinical analysis study.

Characteristic	LCL[b] (n=68)	FHL[a] (n=71)
Age (y), median (IQR)	56 (21-89)	52 (20-78)
Female sex, n (%)	52 (77)	48 (68)
White race, n (%)	53 (78)	53 (75)
Fitzpatrick skin type, n (%)		
I/II	36 (53)	29 (41)
III/IV	20 (30)	27 (38)
V/VI	12 (18)	15 (21)

[a]FHL: forehead lines.

[b]LCL: lateral canthal lines.

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Table . Evaluation of standard digital photographs and self-capture photographs obtained using the Allergan Aesthetic mobile image app.

Areas of interest	LCL[a] (n=68)	FHL[b] (n=71)
Independent photo review of standard digital photographs		
Intrarater reliability (overall weighted kappa)		
At rest	0.87 - 0.88	0.92
At maximum contraction	0.89 - 0.94	0.91
Interrater reliability (ICC[c])		
At rest	0.73 - 0.88	0.90 - 0.91
At maximum contraction	0.83 - 0.86	0.86 - 0.94
Interrater reliability between clinician live assessments and independent photo review (ICC)		
At rest	0.42 - 0.89	0.77 - 0.92
At maximum contraction	0.49 - 0.89	0.61 - 0.87
Independent photo review of participant self-captured photographs		
Intrarater reliability (overall weighted kappa)		
At rest	0.93 - 0.94	0.94
At maximum contraction	0.96	0.92
Interrater reliability (ICC)		
At rest	0.89 - 0.91	0.91 - 0.95
At maximum contraction	0.91 - 0.95	0.90 - 0.92
Interrater reliability between clinician live assessments and independent photo review (ICC)		
At rest	0.75 - 0.91	0.77 - 0.93
At maximum contraction	0.79 - 0.89	0.70 - 0.89

[a]LCL: lateral canthal lines.

[b]FHL: forehead lines.

[c]ICC: intraclass correlation.

Usability

In total, 2 rounds of usability research were conducted with a total of 12 participants in the first round and 10 participants in the second round. Although users had some difficulties using the app during the first round of testing, iterative improvements in response to these issues resulted in a much more usable app. In the second round of testing, users rated the app above average in terms of how easy the app experience was to complete (mean rating 3.2 out of 5), how enjoyable the app experience was (3.1), satisfaction with the level of guidance provided (3.2), and likelihood of completing a full session without exiting (4.1). The second round of testing will be used as future inputs for continued refinements to the overall user experience.

Discussion

Principal Findings

The use of photography for planning, documentation, and follow-up evaluation of procedures has been a mainstay of aesthetic medicine for decades [2-4]. Clinical practices commonly use specialized equipment and complex setups to maximize image quality and consistency [3,7,8,10,11]; however, in the setting of a clinical trial, the resources and repeated office visits required for this approach can be limiting. The Allergan Aesthetic mobile image app was developed to facilitate clinical trial data collection by making it possible for patients to perform remote self-capture of clinical-grade facial images. In this analysis, the app was found to provide high-quality, reproducible images. Furthermore, participants were satisfied with the app's ease of use as well as the overall user experience.

The image resolution of a mobile phone is somewhat less than that available with a DSLR, with 7 - 12 megapixels for the iPhones used in this study versus 20.2 megapixels for the Canon EOS 6D DSLR, and a pixel size of 1.4 µm versus 6.54 µm, respectively. While this may limit the utility of the app for assessing smaller structures such as pores, pimples, and fine lines, it is adequate for the assessment of larger structures, such as glabellar lines and FHL. When the app was used in an at-home setting, natural light was found to be superior to incandescent light due to the reddish pall conferred by the indoor

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lighting. However, different lighting conditions may be of benefit depending on the indication for the photograph.

The image quality achieved with a mobile phone using the Allergan Aesthetic mobile image app was on par with professional image capture systems widely used in aesthetic medicine trials, even surpassing that achieved using Canfield VISIA-CR with a DSLR, as assessed by BRISQUE analysis. Furthermore, image quality was very consistent, with a narrow range of image quality scores compared with that seen with Canfield used in combination with both a DSLR and a mobile device. This finding may prove to be more important than overall quality because consistency is key when collecting images in a study for clinical analysis by medical professionals. However, while the use of BRISQUE for quality assessment is directional in nature, we would refrain from using it as an analysis tool in the future, given the weight and superiority of clinical analysis.

The primary evaluation of the Allergan Aesthetic mobile image app is its utility in a clinical setting. Assessment of LCL and FHL by trained raters in images captured using the app was highly consistent both by the same rater and between raters. Importantly, results were also consistent with in-person assessments of LCL and FHL. Although not directly compared, the clinical utility of images captured using the app was similar to that achieved with images captured using standard digital photography. Taken together, these findings indicate that the app is capable of providing clinically relevant results, offering flexibility in the execution of future clinical trials. In addition to providing high-quality, reproducible images, the mobile technology described in this report may help improve diversity in aesthetic clinical studies by allowing enhanced remote prescreening and removing barriers to participation, for example, by minimizing required clinical site visits, which can encumber participation in underserved communities [24]. To our knowledge, the Allergan Aesthetic mobile image app is one of the first apps shown to enable the capture of patient images suitable for use in clinical dermatology research. A recent report from Jin et al [25] describes the development of SkinTracker (RedBlink Inc), a mobile app for integrated collection of patient skin photos, patient-reported outcomes, and biometric data. Results from a pilot study suggest that SkinTracker has the potential to facilitate the collection of patient data in clinical trials of atopic dermatitis and other skin conditions; however, the consistency of ratings obtained via assessment of images captured using SkinTracker versus standard photography or in-person assessment has not yet been examined [25].

The Allergan Aesthetic mobile image app was developed to provide a high level of reproducibility and broad applicability, which requires an information framework designed to support the user's mental model and deliver actionable information. Mental models are an individual's representation of reality and aim to foresee how users will interact with a product [26]. Although selfie images appear to be the norm today, mobile image capture (a selfie in its simplest sense) is still a new behavior for users, requiring users to accomplish a certain level of learning while simultaneously performing a series of tasks to ensure standardization. Developing a complex application of this sort is an iterative process. In just 2 iterations of development and testing of the user experience, success was achieved with the second round of testing showing that users had an overall positive experience with the app, returning above-average ratings for all metrics tested. While the latest version of the app appears to be acceptable, there remains an opportunity to further improve the app by providing more guidance to ensure a smoother and more enjoyable experience for all users.

A limitation of this research is that the population enrolled lacked diversity; for example, gender assignment in this study was binary. Future studies should include gender-diverse participants. In addition, the study population was predominantly female (68% to 77%) and White (75% to 78%), with 18% to 21% of patients having Fitzpatrick skin types V/VI. Skin color and anatomical variations according to gender, race, ethnicity, and age can contribute to inaccuracies in image analysis [27-29]. Consequently, it will be critical to further validate the Allergan Aesthetic mobile image app in various populations, including by race, sex, age, and severity of LCL and FHL. However, it is noteworthy that despite this potential limitation, this study was still more diverse than historical aesthetic studies; by comparison, typical reported clinical trial populations are approximately 80% to 94% female, approximately 87% to 98% White, and <5% Fitzpatrick skin types V/VI [30-35]. Another limitation is that we could not control all lighting scenarios, so there was a fair degree of variability in lighting. However, the favorable intra- and interrater agreement indicates that the app is largely able to overcome this problem, which can be considered a positive given the natural variability that will exist in real-world apps.

Conclusion

The Allergan Aesthetic mobile image app delivers consistent, clinical-grade facial images that can be effectively used for remote assessment of LCL and FHL and yield rater assessments comparable with that of in-person visits. Users had little difficulty using the app, and future iterations will aim to make the experience even smoother and more enjoyable. The Allergan Aesthetic mobile image app has the potential to transform the conduct of clinical trials in aesthetic medicine by reducing the burden on clinic resources, increasing data collection opportunities and quality, and lowering barriers for future study participants.

Acknowledgments

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relevant data and participated in the drafting, review, and approval of this publication. No honoraria or payments were made for authorship.

Data Availability

AbbVie is committed to responsible data sharing regarding the clinical trials we sponsor. This includes access to anonymized, individual, and trial-level data (analysis datasets), as well as other information (eg, protocols, clinical study reports, or analysis plans), as long as the trials are not part of an ongoing or planned regulatory submission. This includes requests for clinical trial data for unlicensed products and indications. These clinical trial data can be requested by any qualified researchers who engage in rigorous, independent, scientific research and will be provided following review and approval of a research proposal, Statistical Analysis Plan (SAP), and execution of a Data Sharing Agreement (DSA). Data requests can be submitted at any time after approval in the United States and Europe and after acceptance of this manuscript for publication. The data will be accessible for 12 months, with possible extensions considered. For more information on the process or to submit a request, visit AbbVie.

Conflicts of Interest

DC and SK are employees of AbbVie and may own stock in the company.

Multimedia Appendix 1
User rating questions in usability survey**.**
[DOCX File, 26 KB - formative_v10i1e64764_app1.docx]

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Abbreviations

BRISQUE: Blind/Referenceless Image Spatial Quality Evaluator
DSLR: digital single-lens reflex
FHL: forehead lines
FHLSS: forehead lines severity scale
ICC: intraclass correlation coefficient
IEC: International Electrotechnical Commission
ISO: International Organization for Standardization
LCL: lateral canthal lines
LCLSS: lateral canthal lines severity scale

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Central Neuromuscular Reactivation Using Digital Mindfulness and Motor Imagery Intervention for Chronic Knee Pain in Patients With Obesity: Prospective, Single-Center Study

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Abstract

Background: Chronic musculoskeletal pain, particularly in patients with obesity, poses significant challenges due to increased pain sensitivity, reduced mobility, and systemic inflammation. Obesity aggravates mechanical constraints on the joints and increases systemic inflammation, exacerbating certain medical conditions and making conventional therapeutic approaches less likely to succeed. Conventional therapies often show limited efficacy, necessitating innovative approaches.

Objective: This pilot study evaluated the short-term effectiveness of a mindfulness and motor imagery-based intervention delivered via an app (SAS YUZIT), on the pain, functionality, and quality of life of patients with obesity and chronic knee pain.

Methods: A prospective, single-center study was conducted over 1 month by including 30 patients (BMI >30 kg/m^2) experiencing chronic knee pain (≥3 months) who did not need surgery. Patients underwent two video-guided motor imagery sessions, focusing on neuromuscular reactivation. Functional scores, including the Single Assessment Numeric Evaluation (SANE) score, Knee Injury and Osteoarthritis Outcome Score (KOOS), and 36-Item Short Form Health Survey (SF-36) score, were assessed before and after intervention. Paired *t* tests were used to analyze score improvements, with *P*<.05 deemed significant.

Results: Significant improvements were observed across all parameters. The mean overall SANE score improved by 51% (*P*<.001). The minimal clinically important difference was therefore approximately 6.7 points. The observed mean improvement (25 points) exceeded this threshold by more than threefold, indicating a clinically meaningful improvement in functional status. The mean (SD) KOOS score increased by 56% (*P*<.001) from 40.89 (16.7) to 63.79 (14.6). The mean (SD) SF-36 scores showed substantial enhancements in both physical (from 39.7 [20.8] to 65.9 [18.8]; +66%; *P*<.001) and mental components (from 47.2 [23.1] to 64 [21]; +36%; *P*<.001). Patient satisfaction with this method was rated 4.5/5, and no adverse effects were reported.

Conclusions: Video-guided motor imagery demonstrated significant efficacy in reducing pain and improving the functionality and quality of life of patients with obesity and chronic knee pain. By targeting central neuromuscular circuits through guided visualization exercises, this non-invasive intervention addresses central activation dysfunction, a proposed novel concept in neuromuscular disorders that originates from hypotheses derived from clinical observations. This interesting concept requires further exploration to ensure its neurophysiological validation through future studies with larger sample sizes, control groups, and long-term follow-ups, all of which could explore CAD as a therapeutic target.

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KEYWORDS

obesity; knee pain; motor imagery; central neuromuscular reactivation; digital mindfulness

Introduction

Chronic musculoskeletal pain poses a major limiting factor to functional capacity and can negatively impact quality of life, particularly in patients with obesity (BMI >30 kg/m^2) [1,2]. A higher BMI is associated with increased pain sensitivity, reduced mobility, and multiple comorbidities that complicate management paradigms. Obesity aggravates mechanical constraints on the joints and increases systemic inflammation, exacerbating certain medical conditions and making conventional therapeutic approaches less likely to succeed [3-5]. The impact on the knee joint is particularly significant, and it is well demonstrated that being overweight is a risk factor for chronic knee pain and even degenerative progression [6-8]. Chronic musculoskeletal pain carries a significant physical burden on patients but also represents a significant overall cost to society [3].

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Traditional methods, such as drug treatments, weight loss, and regular physical practices, show limitations in this population [9,10] due to the increased risk of complications, subtherapeutic responses, and significant financial costs [8,9]. Chronic pain impacts all areas of the patient's life and often leads to global societal, personal, and professional complications [11,12]. Resolving this problem is therefore a public health issue.

Therapeutic approaches do not always take into account the central impact that pain has on the patient's overall motor control [11,13], particularly in patients with obesity who have more difficulties with postural or neuromotor performance [14]. Modern therapies target central rehabilitation aimed at using brain neuroplasticity to improve patient conditions [15-17]. Emerging digital rehabilitation tools are now available to patients, such as augmented reality, various biofeedback devices, mental imagery with low frequency sounds, or smartphone apps [18].

This pilot study describes and evaluates a new method for treating knee pain in patients with obesity to complement existing therapies. This innovative, non-invasive therapy combines mindfulness and motor imagery [19]. This specific form of guided motor imagery known as neuromuscular reactivation (NMR) can be undertaken via an app. It consists of NMR sessions, designed to activate central neuromuscular circuits without requiring physical movement [20].

The gradual development of NMR occurred in response to neuromuscular activation deficits after an ACL tear [21]. Scientific research has proven that these deficits are of central origin and that it is potentially interesting to target this area to improve patient outcomes [22]. Despite these advances, there remains limited evidence regarding the clinical efficacy of app-based neuromotor interventions in cohorts of patients with obesity.

This pilot study aimed to evaluate the short-term effectiveness (1 month) of NMR on perceived pain, functionality, and quality of life of patients with obesity and chronic knee pain. The primary objective was to evaluate the method's impact on pain (Single Assessment Numeric Evaluation; SANE) and quality of life (36-Item Short Form Survey; SF-36) scores at a minimum 1-month follow-up. Secondary objectives were to explore improvements in objective functional scores (patient-reported outcome measures) and to assess patient satisfaction after the intervention. We hypothesized that a standardized motor imagery-based intervention would significantly improve the different clinical parameters in a patient group at high risk of chronicity.

Methods

Study Design

This was a prospective, observational, monocentric, continuous study conducted over a 1-month period at a medical center with consecutive patient inclusions. The inclusion criteria were as follows: patients had to have a BMI greater than 30 kg/m^2, be of legal age, and present with chronic knee pain (>3 months) with a magnetic resonance imaging scan showing no need for surgery. Patients were recruited in clinics from January 2025 to March 2025.

Data were collected by the practitioner during the consultations through the use of single-blinded questionnaires. The standardized forms used were intended to reduce collection bias. During the initial assessment, complete demographic data were collected, as well as the following functional scores: the SANE score (global and for the painful limb), the SF-36 score, the KOOS score, and patient satisfaction.

The intervention consisted of two video-guided motor imagery sessions, delivered via an app (Yuzit), 3 weeks apart. Patients were guided to visualize specific movements by associating them with optimal muscle sensations, without performing any physical movement per se.

Session Description

The sessions were conducted in a quiet room, where each patient was seated alone with a digital tablet. They would then launch the first video, lasting 53 minutes, designed to guide a structured session of motor imagery.

This video followed a precise sequence: It starts with an explanation of the session's progression (1 min), followed by a mindfulness phase (3 min 20 s). Then, for each exercise, a visual demonstration of the movement is given, followed by guided visualization, with eyes closed, focusing on internal muscle sensations, without any physical execution.

The first session included 12 exercises, performed with bilateral visualization, following the same educational structure. The movements demonstrated in the video were as follows: (1) hip extension, leg straight, in a supine position; (2) hip flexion, in a prone position; (3) locking against resistance (pressure applied to the plantar aspect of the foot) in triple flexion, lying on the back; (4) dorsal and plantar flexion of the foot, lying on the back; (5) fist squeezing (clenched fist under the knee), lying on the back; (6) abduction/adduction of a straight leg, lying on the back; (7) knee extension, in a seated position; (8) unipedal stance (balance on one leg); (9) rising onto tiptoes with locking in a unipedal stance; (10) unipedal squat; (11)"schuss", that is, shifting body weight to one leg in semi-flexion; (12) sitting down on a chair.

The second shorter session (approximately 30 min), focused on the painful side (or bilateral in cases of bilateral pain), following the same structure (visual understanding followed by visualization). It included 6 unilateral exercises: (1) leg raise with the leg straight, lying on the back; (2) triple flexion, lying on the back; (3) knee flexion, lying on the stomach; (4) standing position on both feet, then on one foot (unipedal stance); (5) going up and down stairs; (6) sitting position.

The same functional scores were collected 1 month after the last session during a follow-up visit, in addition to the quality scores. All patients completed the exercises with practitioner oversight intermittently throughout the duration of the two video sessions.

The Standards for Reporting Qualitative Research was followed to write this paper.

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Ethical Considerations

This study was conducted in accordance with the ethical principles of the Declaration of Helsinki. Ethical approval was obtained from the French ethics committee of Saint-Étienne (approval number 2025-A01476-43). Where applicable, informed consent was obtained from all participants prior to their inclusion in the study. Data were anonymized and de-identified to ensure confidentiality of all participants. No compensation was provided to any participant.

Statistical Analysis

Continuous variables were described using means, SDs, and ranges. The normality of changes before and after the intervention was assessed using the Shapiro–Wilk test. Data were analyzed using paired one-tailed *t* tests to compare pre- and post-intervention scores. A significance threshold of $P<.05$ was used. The minimal clinically important difference was estimated using a distribution-based method, calculated as 0.5 × SD of the change scores. The SD of change was computed from baseline and follow-up SDs, assuming a pre–post correlation coefficient (r) of 0.7, in accordance with common practice for functional outcome measures.

Results

Patient Characteristics

A total of 30 patients were included in the study. Their clinical and demographic characteristics are described in Table 1.

Table . Clinical and demographic characteristics (N=30).

Characteristic	Value
Age, years	
Mean (SD)	48.4 (12.7)
Range	22 - 75
Weight, kg	
Mean (SD)	92.9 (16.8)
Range	68 - 110
Height, cm	
Mean (SD)	168 (11.3)
Range	150 - 190
BMI, kgm^2	
Mean (SD)	33.1 (3)
Range	30.1 - 42.2
Sex, n (%)	
Male	12 (40)
Female	18 (60)

Changes in Functional and Qualitative Scores

The mean (SD) overall SANE score was 49 (18.4) before the intervention versus 74 (14.3) after 1 month. The mean improvement was 51% ($P<.001$). The mean (SD) SANE score for painful limbs before surgery was 41.9 (19.6) versus 71.16 (15.2) after 1 month. The mean improvement was +69% ($P<.001$). Based on a distribution-based approach, the SD of change scores was estimated using an assumed pre–post correlation of 0.7, yielding an SD of 13.3. The minimal clinically important difference was therefore approximately 6.7 points.The observed mean improvement (25 points) exceeded this threshold by more than threefold, indicating a clinically meaningful improvement in functional status.

The mean (SD) KOOS score before surgery was 40.89 (16.7) versus 63.79 (14.6) after 1 month, with a mean improvement of +56% ($P<.001$). The SF-36 quality of life score showed a significant mean (SD) improvement of +66% in the physical component ($P<.001$), increasing from 39.7 (20.8) to 65.9 (18.8). The mental component of the score also significantly improved, increasing from 47.2 (23.1) to 64 (21), representing an improvement of +36% ($P<.001$), as shown in Table 2.

The mean satisfaction score assigned by patients to the method was 4.5/5. It should be noted that no side effects were found in this study.

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Table . Changes in functional and qualitative scores.

	Score before intervention (out of 100)	Score after intervention (out of 100)	Improvement (%)
SANE[a] (global)	49	74	+51
SANE (affected knee)	41.9	71.1	+69
KOOS[b]/HAGOS[c]	40.9	63.8	+56
SF-36 PCS[d]	39.7	65.9	+66
SF-36 MCS	47.2	64	+36

[a]SANE: Single Assessment Numeric Evaluation.

[b]KOOS: Knee Injury and Osteoarthritis Outcome Score.

[c]HAGOS: Copenhagen Hip and Groin Outcome Score.

[d]SF-36 PCS: 36-Item Short Form Health Survey Physical Health Component.

[e]SF-36 MCS: 36-Item Short Form Health Survey Mental Health Component.

Discussion

Principal Findings and Comparison With Previous Works

The hypothesis of this study was confirmed. The results show significant improvements in pain, functionality, and quality of life scores after an intervention based on mindfulness and motor imagery via an app. This method, by targeting central neuromuscular circuits, represents an innovative, non-invasive approach suited to complex population, such as patients with obesity and chronic knee pain.

To our knowledge, there is no literature addressing the problem of chronic knee pain in patients with obesity using alternative treatments targeting the central origin of these symptoms and relying on cerebral neuroplasticity [23]. This central pathophysiology has been partly explained by the analysis of anterior cruciate ligament trauma.

Knee trauma causes a neuromodulatory reflex loop that reduces quadriceps activation capacities and increases that of the hamstrings [24]. The resulting corticomotor deficits have been explored by several authors [25-27] who investigated corticomotor excitability, corticospinal reflex excitability, motor unit sizes, and voluntary action in a series of patients undergoing ACL surgery. Zunzarren et al [21] found out that this inactivation induced by knee trauma also affected the contralateral quadriceps, thus leading to the hypothesis that changes in the neuromuscular response involve phenomena that go beyond a simple corticomotor reflex [28] and finds its origin in the cortex. Piskin et al [29] confirmed this phenomenon and demonstrated that it can affect both legs. These neuromotor consequences have significant repercussions as patients experience a double trauma (the injury and the reflex). A growing number of studies [22,30] highlight the need for rehabilitation targeting central stimulation, using patients' cerebral neuroplasticity [31]. The objective is to restore the patient's overall capacity to recruit all the muscle fibers via a central action (through global neuromuscular activation), before stimulating short corticomotor circuits, and thus, obtain maximum efficiency [32]. This complex phenomenon can affect any joints [22]. These findings are essential because they pave the way for very significant changes in the management of knee injuries and pain by integrating the notion of central neuromuscular damage [30]. This has led doctors and physiotherapists to formulate novel rehabilitation techniques, notably to mitigate persistent muscular deficits.

To achieve optimal efficacy, it appears that a "central disinhibition" is necessary. Other NMR therapies (stimulating the corticospinal stage) have recently emerged, notably a technique using mental representation and proprioception associated with low-frequency sounds, with promising results [16,29]

In this study, the significant increase in the SANE score (from 41.9 to 71.2) and the KOOS score (from 40.9 to 63.8) illustrates a significant reduction in perceived pain and functional improvement. These results are particularly encouraging given the limitations associated with obesity, including greater pain intensity and a poorer response to conventional interventions.

Improvements in the physical component of the SF-36 (+23.5 points) reflect a better perception of physical capacity, while the increase in the mental component (+19.4 points) reflects a reduction in the psychological impact. These results highlight the importance of considering neuro-cerebral dimensions in the management of musculoskeletal pain.

The Potential Role of Central Activation Dysfunction

Overview

One of the major lessons learned from this study is the validation that muscle activation disorders are not exclusively related to peripheral mechanisms but also to central disorders. This is the reason why the term "arthogrenic muscle inhibition" [31], which is widely accepted as an explanation for muscle deficits in post-traumatic or inflammatory conditions, is insufficient to describe the whole phenomenon.

We introduce the concept of central activation dysfunction (CAD) to describe a central disruption of neuromuscular circuits. Unlike arthogrenic muscle inhibition, which relies on joint inhibitory reflexes, CAD involves an alteration of central sensorimotor mechanisms. This phenomenon could be explained by a disruption in the cortical representation of the injured

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muscle, a functional disconnection between the motor centers of the central nervous system and peripheral motor neurons and a chronic negative conditioning, where persistent pain permanently alters muscle perception.

These muscle activation disorders, which we group together under the term CAD, are based on empirical observations from clinical practice. Although this concept has not yet been validated by in-depth neurophysiological studies, it offers a coherent hypothesis to explain muscle activation deficits that don't come with an obvious articular or peripheral origin. We identified several possible mechanisms contributing to these disorders, grouped into three categories: physical trauma, consequences of surgical interventions, and chronic pain and psychosocial factors.

Physical Trauma

Physical trauma like muscle injuries, whether intrinsic (eg, tears) or extrinsic (eg, direct trauma such as heavy crutches), or even some joint trauma, can lead to persistent muscle activation deficits. In these cases, pain likely acts as a central factor disrupting the connections between the brain and the affected muscles.

Consequences of Surgical Interventions

Postoperative outcomes, although they address structural pathologies, often leave unexplained functional sequelae. These deficits, traditionally considered purely mechanical or inflammatory, could also be due to a central activation defect. This appears to be particularly common when pain persists in the absence of identifiable mechanical complications.

Chronic Pain and Psychosocial Factors

In young patients with chronic pain, we have observed that muscle activation deficits are rarely associated with identifiable structural abnormalities. These disorders could be linked to several factors, including physical trauma (acute or long-standing), with the associated pain potentially disrupting central control mechanisms; rapid growth requiring a centralized reappropriation of the body, which is often disrupted; and emotional issues such as depression, family conflicts (eg, parental divorce), or psychological trauma. These contexts directly influence the central nervous system, contributing to functional deficits.

Our hypothesis is based on the idea that, in these situations, pain is not only a symptom but also a major disruptor of central sensorimotor circuits. While this hypothesis remains to be validated by further research, it appears rather logical. By proposing the concept of CAD, we offer a new perspective to explain why some conventional approaches fail to restore optimal muscle activation. This conceptual framework also paves the way for specific interventions, such as motor imagery.

Study Limitations

Although the results are promising, this preliminary study has several limitations. First, the low number of patients included in this paper (30 patients) can be seen as decreasing the statistical power of the study; however, the differences found in this study reached statistical significance. Given this is a pilot study, we deemed this to be sufficient to allow preliminary findings to be made. Then, the short follow-up failed to provide long-term data. The long-lasting effect of the method has to be evaluated. Finally, a control group was missing to improve the level of proof of this paper.

Conclusions

The results of this preliminary study suggest a mindfulness-based method that could be effective in reducing chronic pain and improving quality of life of patients with obesity. By introducing the concept of CAD, this study opens new perspectives for understanding and treating muscle activation disorders. Given the preliminary nature of this study, the broader implications of this research could identify other patient groups who could benefit from this type of treatment. These results warrant further research to refine protocols and better integrate this approach into clinical practice. If adopted, this could prove to be a cost-effective and non-invasive method for rehabilitation. A randomized or sham-controlled trial would be needed to draw conclusions about efficacy and safety.

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Data Availability

The data that support the findings of this study are available from the corresponding author upon reasonable request.

Authors' Contributions

GZ and BG formulated the initial project. JM developed the theory and performed computations. GZ and JM verified the analytical methods. GZ reviewed the findings of this study. SM reviewed the article. All authors discussed the results and contributed to the final manuscript.

Conflicts of Interest

BG and GZ participated in the development of the app. None of the other authors have any conflicts of interest.

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Abbreviations

CAD: central activation dysfunction
KOOS: Knee Injury and Osteoarthritis Outcome Score
NMR: neuromuscular reactivation
SANE: Single Assessment Numeric Evaluation
SF-36: 36-Item Short Form Health Survey

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Requirements and Use Cases for eHealth Solutions in Flexible Assertive Community Treatment Teams: Design Science Study

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Abstract

Background: Health care delivery is often fragmented, with different services being delivered by different organizations. Various forms of teamwork are often used in health care, aiming to mitigate the challenges related to this fragmentation. One example of teamwork in mental health is Flexible Assertive Community Treatment (FACT). FACT is a model for comprehensive and integrated care for patients with long-term, serious mental illness. FACT teams deliver services using assertive outreach to treat patients who can be hard to reach by health care services. However, Norwegian FACT teams have issues with the current eHealth solutions related to the fragmentation of health care.

Objective: This study aimed to identify requirements and develop use cases and use case diagrams for eHealth solutions that support effective teamwork within FACT teams, using them in a case study for collaborative health care delivery.

Methods: A design science framework was used to explicate the problems of eHealth solutions in FACT teams. This included performing the subactivities of defining the problem precisely, positioning and justifying the problem, and finding root causes. Based on this explication, we derived a set of requirements, use cases, and use case diagrams for FACT teams.

Results: We present the explication of the problems of eHealth in Norwegian FACT teams. Building on the results, we present functional and nonfunctional requirements for electronic health records, electronic whiteboards, video conference solutions, and digital questionnaires. Improved integration across these systems was identified as a recurring need. We also provide use cases and diagrams illustrating system use in practice.

Conclusions: FACT teams in Norway require more integrated and tailored eHealth solutions. The requirements and use cases presented in this study offer a foundation for developing tools that better support the collaborative and mobile nature of FACT team operations.

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KEYWORDS

mental health; FACT team; eHealth; requirements specification; use cases; electronic health records; electronic whiteboards; design science

Introduction

Recent trends in health care emphasize integrated care [1] and patient-centered care [2]. Integrated care delivers health care services coordinated across various providers, while patient-centered care focuses on patient involvement and establishing strong relationships between the patient and health care workers [1,2]. Both approaches depend on effective teamwork, which is increasingly regarded as essential for delivering high-quality health services [1-3]. However, studies have revealed variation in how teamwork is interpreted and practiced in health care, encompassing aspects such as interaction, roles, and team fluidity [4].

The Flexible Assertive Community Treatment (FACT) model is a comprehensive and integrated approach to care provision for patients with long-term, serious mental illness, which relies on teamwork [5]. Most FACT teams target adults, although FACT youth teams target youth aged 12 to 25 years, demonstrating the model's adaptability and effectiveness [6]. FACT teams deliver a wide range of services, including mental health care, using assertive outreach and targeting patients who are often hard to reach for traditional health care services. The care provided to patients of FACT teams varies according to their needs. In stable phases, patients receive individual case management from 1 team member. In phases when they need intensive follow-up, a collaborative approach is adopted, involving multiple team members in a shared caseload [5]. In Norway, FACT teams are managed within the public health care system and serve as a cooperation between primary care, managed by the municipalities, and specialist care, under the responsibility of the Regional Health Authorities. Norwegian

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FACT teams therefore consist of employees from both sectors, working together in an integrated team. In this paper, we focus on Norwegian FACT teams, hereafter referred to as FACT teams, as a case study of teamwork, owing to the well-defined structure and roles of these teams [7]. In addition to team organization, the delivery of care in Norway is shaped by standardized patient pathways for specific diagnoses. These pathways structure treatment through requirements for patient communication, clearly defined responsibilities, and set timeframes for service delivery. They aim to reduce treatment variation, strengthen user involvement, and improve coordination among services. Although no pathway is tailored specifically for FACT, patients in FACT teams follow general mental health pathways, which influence how their care is organized [8].

In a previous study [9], we described how FACT teams use a range of eHealth solutions, including electronic health record (EHR) systems [10], calendars [11], video conferencing solutions [12], digital questionnaires [13], and electronic whiteboards [14]. However, the effectiveness of these tools is limited by the fragmentation of health care, where services are delivered by different organizations at varying levels of care [15]. This fragmentation contributes to medical errors and poses particular risks for mental health patients, who often depend on multiple health and social care providers [16]. One consequence is that health care workers often have limited access to relevant patient data across systems [17]. Because many eHealth solutions are developed as stand-alone products from single vendors, they cannot always exchange data, thereby restricting the flow of information [17-20]. FACT teams are particularly vulnerable to these challenges, since they operate across both municipal and specialist care and rely heavily on mobile and outreach-based work. This increases the need for digital solutions that can support coordination and information sharing across organizational boundaries [9]. Addressing these issues highlights the challenge of integration, which we define as the connection of data, applications, and application programming interfaces (APIs) to improve system interoperability [15]. Thus, the goal of integration is to enable seamless data exchange between health care applications. Two examples of projects that address integration challenges in health care include a comprehensive set of requirements for data integration based on a systematic literature review [21] and the Valkyrie project, which aims to develop a technical prototype of an information and communications technology (ICT) architecture to improve health care delivery [22].

The development of eHealth solutions typically involves the specification of requirements [23] and use cases [24]. In this study, we define requirements as statements describing the functions or qualities that an eHealth system must fulfill to support FACT team operations. We distinguish between functional requirements, which specify what the system should do, and nonfunctional requirements, which describe how the system should perform. We define a use case as a description of how users interact with a system to achieve a specific goal, often illustrated through use case diagrams [24]. These concepts form the basis for this study.

This study aimed to define the requirements and use cases for eHealth solutions that support teamwork in health care settings, with the goal of improving data access for health care professionals and reducing fragmentation through integration. To achieve this, we applied the initial 3 steps of the design science framework, using teamwork as a case study, focusing on FACT teams. The design science framework is a stepwise approach to developing practical solutions to real-world problems, and it is particularly suited for eHealth research because of its systematic and rigorous structure. In this paper, we present the results of our investigation as a set of requirements and use cases that specify the proposed eHealth solutions. Our results aim to inform policymakers, with the intention of demonstrating the needs of FACT teams and thereby laying the foundation for the technical development of tailored eHealth solutions.

Methods

Design Science Framework

For this study, we used the design science framework [23] to guide the development of requirements and use cases for eHealth solutions for FACT teams. This framework was chosen as it aligns with our goal of creating user-centered eHealth solutions that are well adjusted to teamwork. It supports a structured approach and emphasizes an iterative process in artifact development. Design science consists of a set of iterative steps: (1) explicate the problem, (2) define requirements, (3) design and develop an artifact, (4) demonstrate the artifact, (5) evaluate the artifact, and (6) communicate artifact knowledge [23]. We focused on the initial 3 steps of this framework to inform the development of eHealth solutions that support teamwork in health care settings.

Problem Explication

In the first step of the design science framework, we defined the problem that the eHealth solutions aim to address. We defined the problem precisely to make it clearer and easier to communicate; positioned the problem in a context; and justified the identified problem to demonstrate its significance, relevance, solvability, and level of challenge. The explication also included an analysis of its root causes, which provides additional context, ensuring focus on the causes of the problem rather than its symptoms. Unless otherwise specified, analytical steps were conducted collaboratively, with the first author leading the analysis and the coauthors contributing through iterative discussion and review.

To define the problem precisely, we built on the results of a previous thematic analysis of observations and interviews in both urban and rural FACT teams [9]. In that study, initial themes were defined and coded. During review, subthemes were added to differentiate distinct aspects of the data. In this study, these themes and subthemes formed the foundation for problem definition. The narratives underlying each theme and subtheme were analyzed in light of the existing eHealth infrastructure and regulations governing eHealth in Norway [19].

The initial identification of problem situations was conducted by the first author, who reviewed each theme and its associated

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coded extracts to identify instances where current digital tools hindered teamwork, coordination, or patient care. These preliminary interpretations were then presented to the coauthors, who provided methodological and domain-related feedback. Through iterative discussion in project meetings, the problem descriptions were refined as necessary. This process ensured analytic rigor by combining the detailed perspective of the primary analyst with validation from experienced researchers.

The resulting set of problem descriptions was subsequently grouped into broader categories representing the general shortcomings of current eHealth solutions. Table 1 provides an overview of the themes and subthemes applied in this study, and full details of their derivation have been reported previously [9].

Table . Themes and subthemes used for problem definition [9].

Main theme	Subthemes
Communication	Suitability of video consultations
Documentation	Documentation while traveling
Organization	Systems not adapted to FACT[a] teams
COVID-19	Maintaining team capacity; maintaining contact with patients
Technologies	Electronic health records; electronic whiteboards; calendars; lack of integration

[a]FACT: Flexible Assertive Community Treatment.

Although no patient data were used in this study, ethical considerations regarding patient privacy and data security were considered when analyzing FACT team needs and designing requirements. Ensuring that eHealth solutions enable data sharing while protecting sensitive health information informed the extraction of problem descriptions and requirements.

To position the problem, we performed a document analysis [25] of 2 central sources: the FACT model description [5] and a national evaluation report of FACT teams [26]. The analysis followed a structured process of identifying, selecting, appraising, and synthesizing information from these documents. The documents were first read superficially to gain an overview and then examined in depth to extract descriptions of the purpose of FACT teams, their core activities, their organizational structure, stakeholder involvement, and the environments in which they operate. This contextualization ensured that the problem definition was not limited to the technical shortcomings of eHealth solutions but was situated in the organizational and operational realities of FACT teams, thereby informing the relevance and scope of the requirements.

Similar to the precise problem definition, the justification of the problem was based on an analysis of the results of the thematic analysis reported previously [9]. In this step, we re-examined the themes in relation to their degree of solvability (ie, whether they could realistically be addressed by digital interventions) and level of challenge (ie, the practical and organizational difficulties involved). This evaluation was informed by our knowledge of the Norwegian eHealth infrastructure and regulatory environment [19]. The purpose of this step was to assess whether the problems were significant for FACT teams and whether they represented broader structural issues in Norwegian health care.

To analyze the root causes of the problem, we used the "five whys technique" defined by Serrat [27], by starting with the basic problem and then repeatedly asking the question *why* until we reached explanations that pointed to the root causes of the problem. At each stage, the answers were informed by contextual knowledge of the Norwegian eHealth infrastructure and regulatory environment [19], ensuring that the reasoning remained realistic and grounded. This systematic approach helped distinguish surface-level symptoms from structural issues, guiding us toward a technical framing of the root problem that directly informed the design of potential solutions.

Together, the positioning, justification, and root-cause analyses established a structured understanding of the problem. These steps provided the conceptual and contextual foundations for the subsequent design work. By systematically connecting prior findings, contextual documents, and infrastructure knowledge, this phase ensured that the later definition of requirements and design of artifacts were grounded in the realities of Norwegian health care.

Requirement Definition

Following the second step of the design science framework, we outlined an artifact that solves the explicated problem and defined requirements for the artifact. To outline the artifact, we chose the type of artifact that should be designed to solve the problem and briefly described the main functionality. To define requirements for the eHealth solutions, the first author created a table in Microsoft Excel in which each element of the problem description was entered as a separate row. For each row, the corresponding narratives from the thematic analysis were reviewed to identify the underlying user needs, workflow challenges, and contextual constraints. This table served as the analytical structure for translating empirical insights into requirements and was iteratively discussed and refined in project meetings with the coauthors.

Some requirements were derived directly from clearly stated needs within the themes, while others required further interpretation and design reasoning, where the themes pointed to broader challenges that implied more complex system functionality. For the electronic whiteboard, we additionally examined existing solutions to understand what information is typically displayed and how it supports coordination. Each

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requirement is linked to the corresponding element of the problem explication, ensuring transparency and traceability in how empirical insights informed the requirements. The requirements are presented at different levels of abstraction, with the electronic whiteboard receiving the most detailed specification due to its critical role in improving coordination in FACT teams. We defined functional requirements, describing what each eHealth solution can accomplish, as well as nonfunctional requirements, which apply across all the eHealth solutions.

Finally, 2 field experts with extensive experience supporting FACT teams reviewed the requirements for the electronic whiteboard. The review process involved providing written feedback on the draft requirements, followed by a meeting to clarify and discuss the comments. The experts evaluated the clarity, feasibility, and relevance of the proposed requirements. Their input was instrumental in refining the requirements, particularly by ensuring that the functionality aligned with real-world team workflows and that the terminology accurately reflected clinical practice.

Designing Artifacts

The third step of the design science framework involves designing an artifact according to the requirements and the explicated problems [23]. In this paper, we present use cases and use case diagrams for an eHealth solution and justify the design proposals.

To generate ideas for the design of the eHealth solution, all 3 authors participated in a structured, guided brainstorming session. The session was conducted in person and facilitated by the first author, who prompted idea generation using the explicated problem, the defined requirements, and our shared knowledge of Norwegian eHealth infrastructure and regulations [19] as framing inputs.

During the session, ideas were presented, discussed, and clustered into emerging solution concepts. These concepts were then reviewed and refined based on their anticipated feasibility and usefulness in the Norwegian context (eg, alignment with existing infrastructure, compliance with regulations, and integration potential). The first author took notes throughout, capturing both the proposed ideas and the reasoning behind them.

After the session, the first author drafted the design rationale for the major design decisions, which was subsequently reviewed by the coauthors to ensure accuracy and shared agreement. Building on the selected ideas and the requirements, we developed use cases that describe the actors, goals, and interaction flows of each proposed eHealth solution. The first author also used a Unified Modeling Language (UML) 2.0 diagram [24] to visualize system functionality and relationships.

Ethical Considerations

The project received approval from the Data Protection Official at Innlandet Hospital Trust (reference: 137877) and was reviewed by the Regional Ethical Committee, which deemed the project outside of their mandate (reference: REK Sør-Øst 104537). All participants provided signed informed consent. No patient data were gathered. The data were stored securely and deidentified. No compensation was given to the participants.

Results

Overview

In this section, we present the results obtained from the initial 3 steps of the design science framework. These reflect the explication of the problem to be addressed by the proposed eHealth solutions, the definition of requirements, and the creation of use cases that can guide the development of solutions.

Explicated Problems

Problem descriptions are presented in Table 2, along with the source of each part of the description. Themes and subthemes in the table refer to the data analysis presented previously [9].

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Table . Problem descriptions extracted by previously identified themes and subthemes [9].

Description part #	Source of problem description, themes, and subthemes	Problem description
1	Lack of integration	There is a lack of integration among the eHealth solutions in use by FACT[a] teams, resulting in incomplete EHR[b] information becoming available to the teams and impeding workflows.
2	Electronic whiteboards	Current electronic whiteboards in FACT teams are hard to use and, in some cases, lose information when transferring patients between intensive care and case management. FACT teams are not able to extract statistics from electronic whiteboards for administrative purposes.
3	EHRs	Depending on local configurations, FACT teams are not able to access EHR data from both primary and secondary care. In some cases, they use various cumbersome workarounds to access EHR data.
4	Calendars	FACT teams lack a good overview of the planned activities of their team members for administrative and safety purposes. Some calendar solutions in use are not able to track consultations that provide reimbursement.
5	Suitability of video consultations	Video consultations are not available as a tool in all FACT teams, even in situations where they are suitable for treating patients.
6	Technologies	Questionnaires used by FACT teams are paper-based, which is a hindrance to optimal workflows for storing data.
7	Documentation while traveling	FACT team members travel extensively and need to be able to access relevant eHealth solutions while outside the office.

[a]FACT: Flexible Assertive Community Treatment.

[b]EHR: electronic health record.

The precisely defined problem should also be positioned in a larger context. This context is provided in Textbox 1, which presents the purpose, stakeholders, activities, and operational environments of the teams.

Textbox 1. Context overview of Flexible Assertive Community Treatment (FACT) teams, including stakeholders, activities, and operational environments.

Purpose: Provide care and treatment to patients

Stakeholders: Patients, FACT team members, other health care workers, social services, and next of kin

Activities: Providing, planning, coordinating, and documenting care

Operational environments: Patients' homes and social arenas, FACT team offices, primary care offices, and specialist care environments

In the context of this paper, we define the various stakeholders as follows:

- Patients: Persons who receive care and treatment from the FACT teams
- FACT team members: Persons who are employed in the FACT teams, and give care and treatment to patients
- Other health care workers: Persons employed in the health care service, who can provide care and treatment to patients, including general practitioners, employees in specialist health care, and employees in municipal services
- Social services: Persons employed in Norwegian social services
- Next of kin: Relatives or friends of the patient, whom the patient has authorized to assist in receiving care

The activities of the FACT teams can be divided as follows:

- Providing care: Give care to FACT team patients
- Planning care: Plan future care of patients
- Coordinating care: Coordinate the care of patients with other FACT team members and other health professionals
- Documenting care: Document care that has been given and plans in relevant systems

The operational environments are as follows:

- Patients' homes and social arenas: Areas where patients live and live their social lives

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- FACT team offices: Offices where FACT team members work
- Primary care offices: Offices for general practitioners, municipal services, and other primary care
- Specialist care environments: Hospitals and district psychiatric centers

To justify the problem, we built on our thematic analysis reported previously [9]. The analysis showed that team members of Norwegian FACT teams have highlighted the significance of the challenges associated with current eHealth solutions, by stressing the practical difficulties experienced in health care delivery, and identified the need for integrated eHealth solutions that can effectively support the complex, multidisciplinary nature of their work [9]. Although the identified challenges are technically manageable, they are complicated by the eHealth infrastructure and regulations in Norway [19]. This complexity affects not only FACT teams but also other multidisciplinary teams in Norway, indicating a general interest in improving the coordination of Norwegian health care. Together, these findings show that the problem is significant and of general interest in health care.

The results of the five whys technique are presented in Table 3. We started with the following basic problem: "FACT team members have difficulty using their eHealth solutions optimally for providing efficient care." The technique showed that the root cause is a lack of integration between the systems in different health care sectors.

Table . Findings of the five whys technique.

Question	Answer
Why do FACT[a] team members have difficulty using their eHealth solutions optimally for providing efficient care?	FACT team members have problems accessing some relevant data from eHealth solutions needed for providing efficient care.
Why do FACT team members have problems accessing data from relevant eHealth solutions?	FACT teams are divided into primary and specialist care, and thus have different eHealth solutions available within the team.
Why is this division a problem?	FACT team members have difficulty accessing relevant data from other health care sectors than those in which they are employed.
Why do FACT team members have difficulty accessing relevant data from other health care sectors?	Because there is a lack of communication between systems in different health care sectors.
Why is there a lack of communication between systems in different health care sectors?	Because there is a lack of integration between systems in different health care sectors.

[a]FACT: Flexible Assertive Community Treatment.

Defined Requirements

In this section, we outline the artifacts that meet the explicated problem and define the functional and nonfunctional requirements for eHealth solutions for FACT teams.

To outline the artifacts we aim to design, we classify them as instantiations (systems that can be used within a practice) [23]. These include the following eHealth solutions: EHRs, electronic whiteboards, calendars, video conferencing solutions, and digital questionnaires. EHRs represent the central storage of patient data. Electronic whiteboards are used in daily meetings to coordinate treatment and care. Calendars are used for scheduling appointments and treatments, and they provide team members with an overview of both their own calendars and the team's calendar. Video conferencing solutions allow for meetings and video consultations, and digital questionnaires can be used to gather various patient information. To ensure that the systems are integrated, we assume that an integration and access engine is in place, which routes messages between the systems and ensures that the information is in the correct format. The basic outline and structure of these eHealth solutions are illustrated in Figure 1.

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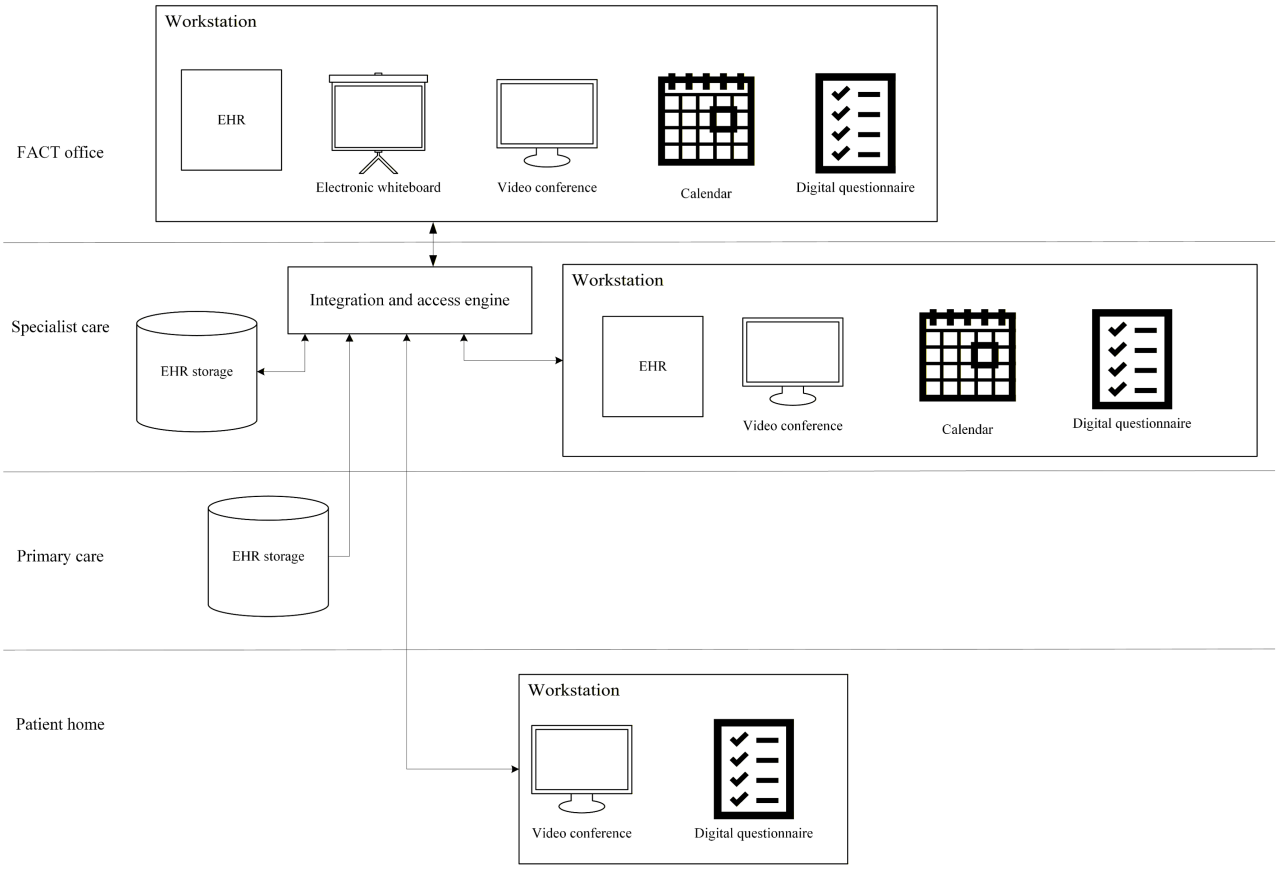
Figure 1. Basic outline of eHealth solutions. EHR: electronic health record; FACT: Flexible Assertive Community Treatment.



The proposed requirements and use cases are based on several underlying assumptions. Technically, the design assumes that key systems, such as EHRs and scheduling tools, can communicate through standard APIs and that local IT infrastructure allows integration of new modules. Furthermore, we assume that the necessary hardware and infrastructure are in place. Legally, it is assumed that solutions will be implemented in compliance with data protection regulations, including the General Data Protection Regulation (GDPR), and that access to patient data will follow existing legal frameworks and institutional policies. These assumptions define the boundaries of the design and should be considered when evaluating its feasibility and applicability in practice.

Shared Functional Requirements

Certain functional requirements apply across multiple eHealth solutions, including integration with EHR systems and between calendar and video consultation solutions. These shared requirements are described here, while solution-specific requirements are detailed in the following subsections.

Integration With the EHR System

Electronic whiteboards, calendars, video conferencing solutions, and digital questionnaires must all be integrated with the EHR system. This ensures seamless information flow between eHealth solutions and maintains the completeness and accuracy of the patient record [28].

The source of the requirement is as follows: problem description #1 (lack of integration), #2 (electronic whiteboards), #3 (EHRs), #4 (calendars), #5 (suitability of video consultations), and #6 (technologies) (Table 2).

Integration Between the Video Consultation Solution and Calendar

FACT team members should be able to launch planned video consultations directly from the calendar. This enables the calendar to function as an effective tool for planning team activities.

The source of the requirement is as follows: problem description #1 (lack of integration) and #5 (suitability of video consultations) (Table 2).

Functional Requirements: Electronic Whiteboards

Data Fields of the Electronic Whiteboard System

Table 4 specifies the data fields identified as required for inclusion in electronic whiteboards. These data fields include various aspects of patient information, treatment plans, and team coordination. These data fields were identified based on interviews, observations, and descriptions of existing electronic whiteboards.

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Table . Data fields of an electronic whiteboard system.

Name of the data field	Description
Name	Name of the patient
Date of birth	Patient's date of birth
Start date	Date of patient's inclusion into the FACT[a] team
Living situation	Description of the patient's living situation
Phone number	Patient's phone number
Network/family	Description of the patient's network and family
Goals and wishes	Description of the patient's own goals and wishes
Resources	Description of the patient's social and practical resources
Diagnoses	Patient's diagnoses
Legal status	Legal status related to forced treatment
Case manager	Name of the team member who is the case manager
Week plan	A plan for what contact the FACT team will have with the user for the current week
Standardized patient pathway	List of relevant standardized patient pathways allowing team members to assign the appropriate pathway to a specific patient; Overview of the pathways the patient is following, allowing tracking of progress and associated deadlines
Evaluations	Name of evaluations and when they were done
Treatment plan	Status of the treatment plan, if the patient has one, and when it was last updated
Crisis plan	Information on whether a crisis plan exists and is up to date
Why on the whiteboard?	Reason for being on the whiteboard
Questionnaires	Short description of questionnaires being used
Responsible individual	Team member responsible for the patient
Medication	Up-to-date information on the patient's medication

[a]FACT: Flexible Assertive Community Treatment.

The source of the requirement is as follows: problem description #2 (electronic whiteboards) (Table 2).

Patient List Management

Electronic whiteboards must maintain 2 separate lists for patients receiving intensive follow-up and case management. Furthermore, team members must be able to transfer patients between these categories without any loss of information. Electronic whiteboards must allow for adding new patients and removing patients when they are no longer receiving treatment from a FACT team. This will facilitate effective care coordination, ensure comprehensive patient care, reduce the workload for team members, and minimize errors. This was identified in our observations and interviews.

The source of the requirement is as follows: problem description #2 (electronic whiteboards) (Table 2).

Patient Information Transfer and Elimination

Electronic whiteboards must be able to receive referral messages for the FACT teams. If a patient is accepted, relevant patient information must be directly transferred to the whiteboard from the EHR. While a patient is listed on the electronic whiteboard, team members can also add relevant patient information manually. When a patient is no longer treated by the FACT teams, their data are removed from the electronic whiteboard, and any remaining information must be transferred to the EHR. This will ensure consistency of information between EHRs and electronic whiteboards and reduce errors.

The source of the requirement is as follows: problem description #2 (electronic whiteboards) (Table 2).

Functional Requirements: EHRs

Central Repository for Patient Information

A fundamental component of eHealth solutions for FACT teams is the EHR system, which must serve as the central repository for patient information, storing data from various sources. By serving as the central repository, the EHR system is able to consolidate and manage patient information from the diverse eHealth solutions used by FACT teams. This ensures a comprehensive and up-to-date view of the patient's health data.

The source of the requirement is as follows: problem description #3 (EHRs) (Table 2).

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Integration With eHealth Solutions and Comprehensive Data Management

The EHR system must be able to integrate with electronic whiteboards, enabling the display of relevant patient information directly within the electronic whiteboard interface. In addition to electronic whiteboards, the EHR system must be able to integrate with other eHealth solutions used by the FACT teams, such as video conferencing solutions, digital measures, and calendars [9]. This integration is a critical requirement to streamline clinical workflows.

The source of the requirements is as follows: problem description #1 (lack of integration) (Table 2).

Statistical Reporting

The teams should be able to extract statistical information on their work, such as the number of patients who receive intensive follow-up or case management, the number of patients with different diagnoses, and the number of patients with forced treatment. To preserve patient privacy, statistical information must be anonymized. This will allow the EHR system to be used as an administrative tool. This was identified through interviews with FACT team members.

The source of the requirement is as follows: problem description #2 (electronic whiteboards) (Table 2).

Functional Requirements: Calendars

Appointment Tracking for Reimbursement

The calendar must be able to be used to track all patient consultations. This will enable calendars to be used for the tracking of treatment reimbursement.

The source of the requirement is as follows: problem description #4 (calendars) (Table 2).

Team Member Schedules

Team leaders should have an overview of the location of their team members. This is for both practical coordination purposes and the added safety of team members while traveling.

The source of the requirement is as follows: problem description #4 (calendars) (Table 2).

Functional Requirements: Video Conference Solutions

Patient Identification

The calendar must provide identification information of the current patient to the video conference solution, to ensure that the correct patient is involved in the video consultation.

The source of the requirement is as follows: problem description #5 (suitability of video consultations) (Table 2).

Consultation Documentation

Calendars should create templates for documentation of consultations, which can be filled out by team members. This is because team members use calendars to keep track of their appointments with patients.

The source of the requirement is as follows: problem description #5 (suitability of video consultations) (Table 2).

Unplanned Video Consultation

Video conference solutions should support the ability to launch an unplanned video consultation, in addition to starting video consultations from calendars. This ensures flexibility to respond to unplanned patient needs.

The source of the requirement is as follows: problem description #5 (suitability of video consultations) (Table 2).

Functional Requirements: Digital Questionnaires

Remote Patient Engagement

FACT team members should be able to send a digital questionnaire link to patients who are able to complete it independently. Alternatively, they can cooperate with patients to complete the measurement together. This allows for the distribution of digital questionnaires to patients.

The source of the requirement is as follows: problem description #6 (technologies) (Table 2).

Nonfunctional Requirements

In addition to the functional requirements, this study identified nonfunctional requirements that define the qualities that determine how well these systems operate in practice. Unless otherwise specified, these nonfunctional requirements apply to all eHealth solutions.

Security and Legal Compliance

All systems must adhere to the GDPR and relevant Norwegian regulations, including the Code of Conduct for Information Security and Data Protection in Healthcare [29]. This includes secure authentication and access control. Norwegian law also grants patients the right to access their own EHRs [30]. This right also includes the data stored within electronic whiteboards, emphasizing the importance of electronic whiteboards to adhere to relevant data protection and privacy laws and regulations.

Multidevice Support

FACT teams are highly mobile and therefore require access to their eHealth solutions across different devices, such as PCs, tablets, and smartphones. For patient-facing tools, such as digital questionnaires and video consultations, multidevice compatibility is important to ensure participation regardless of available equipment.

Usability and Accessibility

Interfaces should be designed for ease of use in clinical workflows, minimizing cognitive load. Digital questionnaires and video conference solutions must accommodate patients with varying levels of digital literacy and accessibility needs.

Performance and Reliability

Systems must provide high levels of availability and responsive performance, particularly for video consultations. Offline functionality or synchronization mechanisms are important in settings with unstable connectivity.

Scalability and Interoperability

Solutions should be designed for long-term scalability and compatibility with international interoperability standards (eg,

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HL7 FHIR [Health Level 7 Fast Healthcare Interoperability Resources] and SNOMED CT [Systemized Nomenclature of Medicine – Clinical Terms]). This ensures future adaptability and potential use beyond Norwegian FACT teams.

Design Rationales and Use Cases

In this section, we present the rationales behind our design choices and use cases for the proposed design.

Design Rationales

In Table 5, we present the design rationales of the various components of the eHealth solutions, by showing the decisions, reasons for decisions, and alternatives that were considered.

Table . Design rationales.

Part of the design	Decision	Reasons for the decision	Alternatives that were considered
Overall design	Integration between the included eHealth solutions	Data quality, accuracy, and integrity; support of modular design	—[a]
Electronic whiteboards	Patient list management	Support workflows of FACT[b] teams	Electronic whiteboard as a built-in module of the EHR[c]
EHRs	Central repository for patient information	EHR is best suited as the central repository for patient information	—
Calendars	Team features	Supporting teamwork	Calendar as a built-in module of the EHR
Video conference solutions	Consultation documentation, unplanned video consultation, multidevice support	Support for ad-hoc consultations; support for various patient equipment	—
Digital questionnaires	Multidevice support	Support for various patient equipment	—

[a]Not applicable.

[b]FACT: Flexible Assertive Community Treatment.

[c]EHR: electronic health record.

Use Cases

Use case diagrams for the eHealth solutions are presented in Figures 2-6. These figures provide a high-level overview of the main interactions between the different systems and user groups, highlighting the functional scope of each solution. Although some use cases may involve multiple eHealth solutions, each is depicted only within the solution where it is initiated, to enhance clarity and maintain readability. Together, these figures illustrate how the individual solutions contribute to the overall integrated eHealth ecosystem.

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Figure 2. Use case for an electronic whiteboard. FACT: Flexible Assertive Community Treatment.

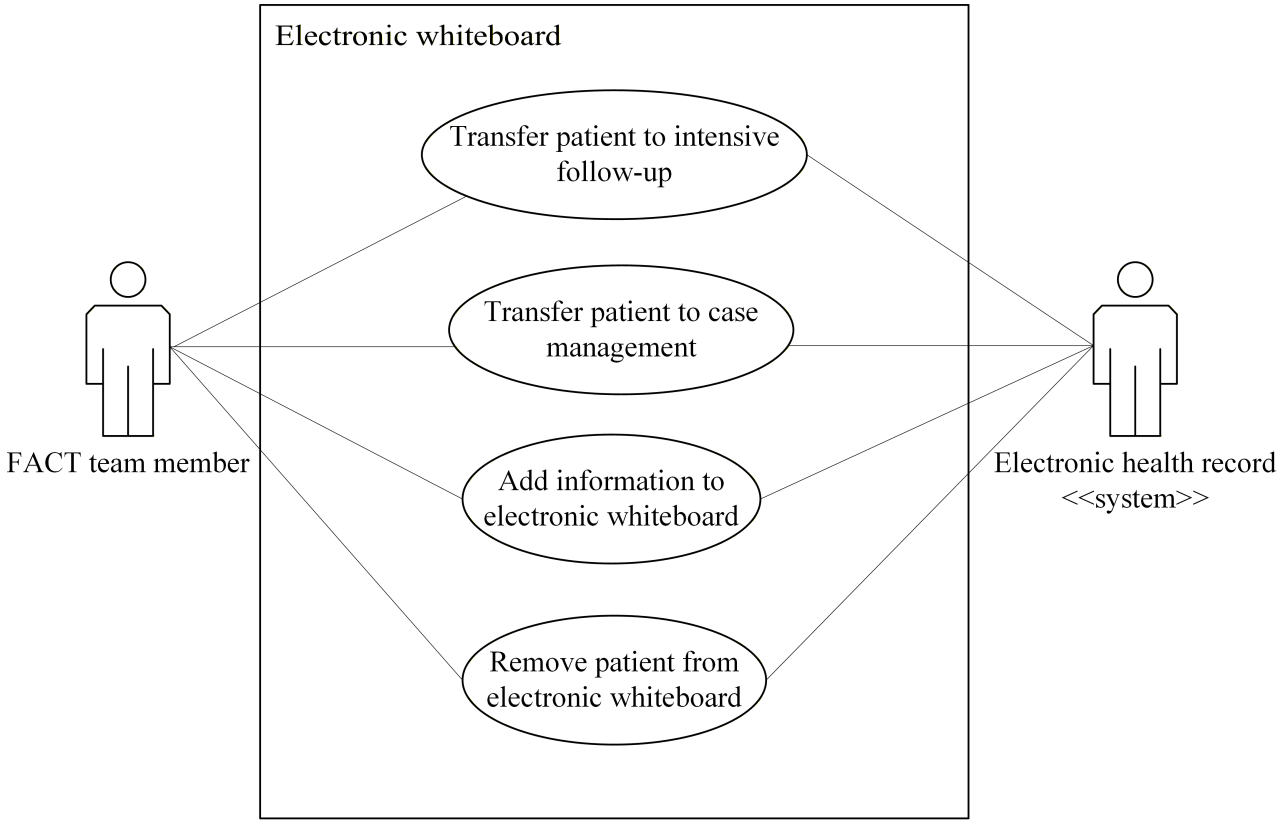

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Figure 3. Use case for an electronic health record (EHR) system. FACT: Flexible Assertive Community Treatment.

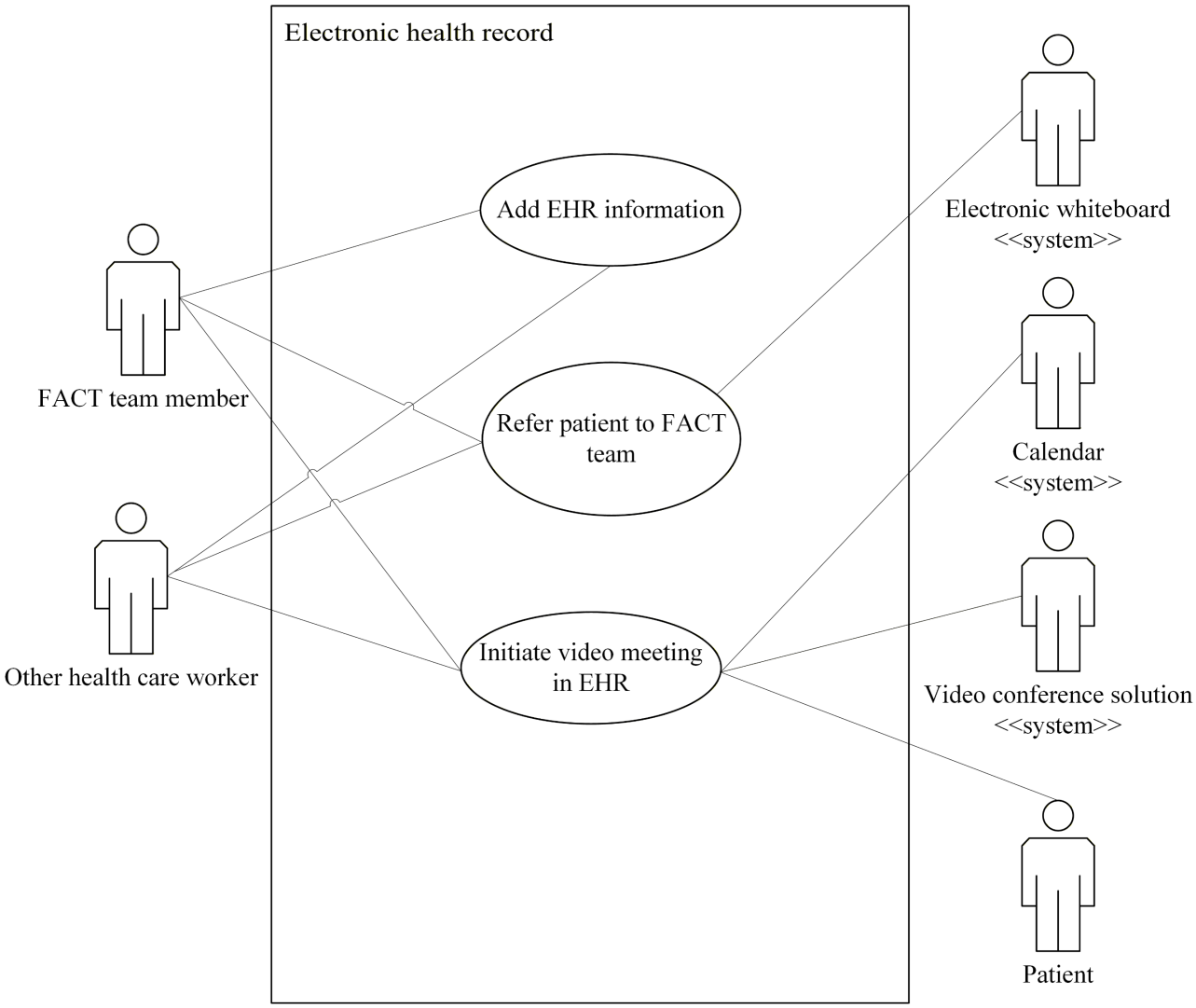

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Figure 4. Use case for a calendar solution. FACT: Flexible Assertive Community Treatment.

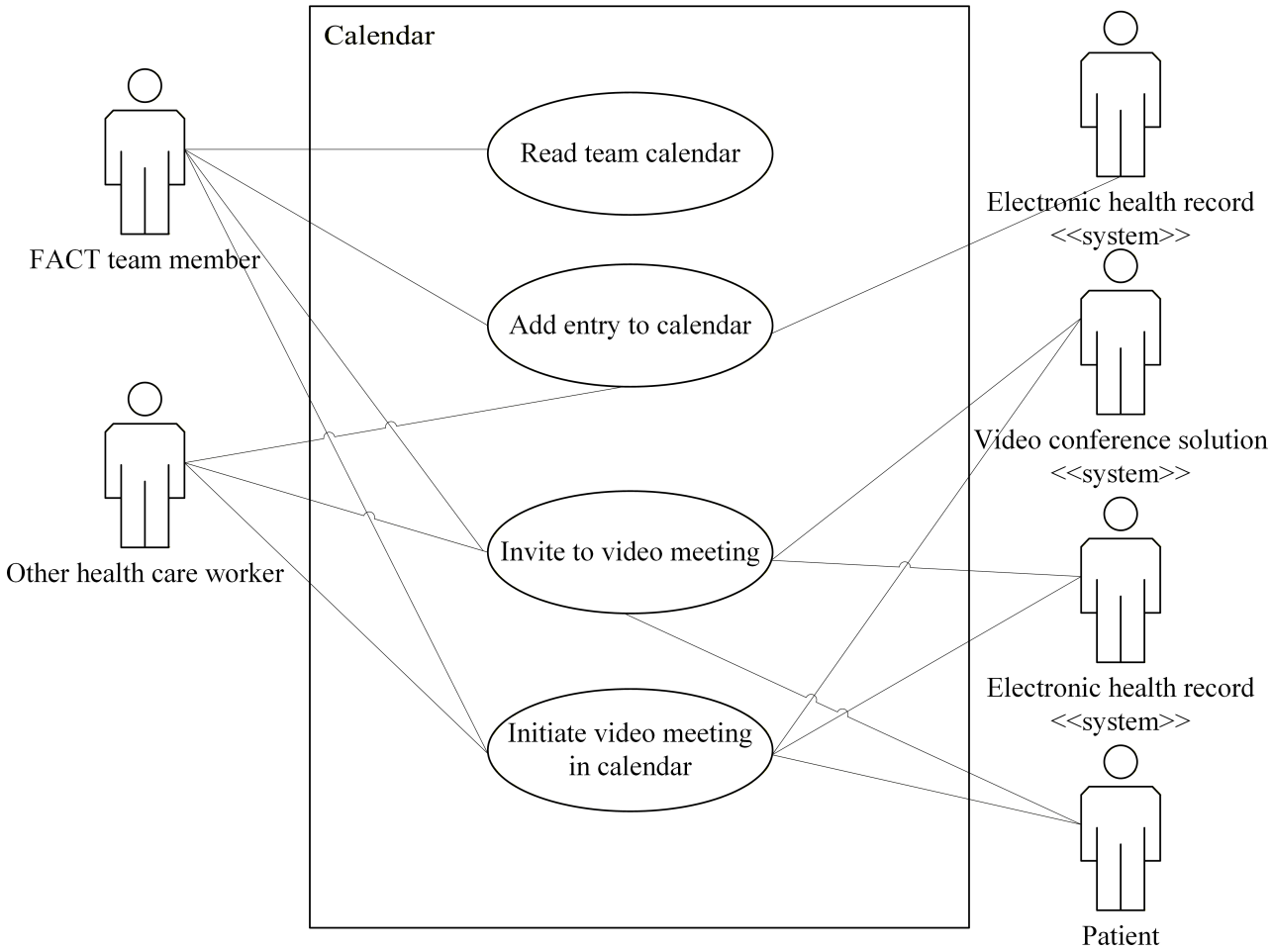

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Figure 5. Use case for a digital questionnaire. FACT: Flexible Assertive Community Treatment.

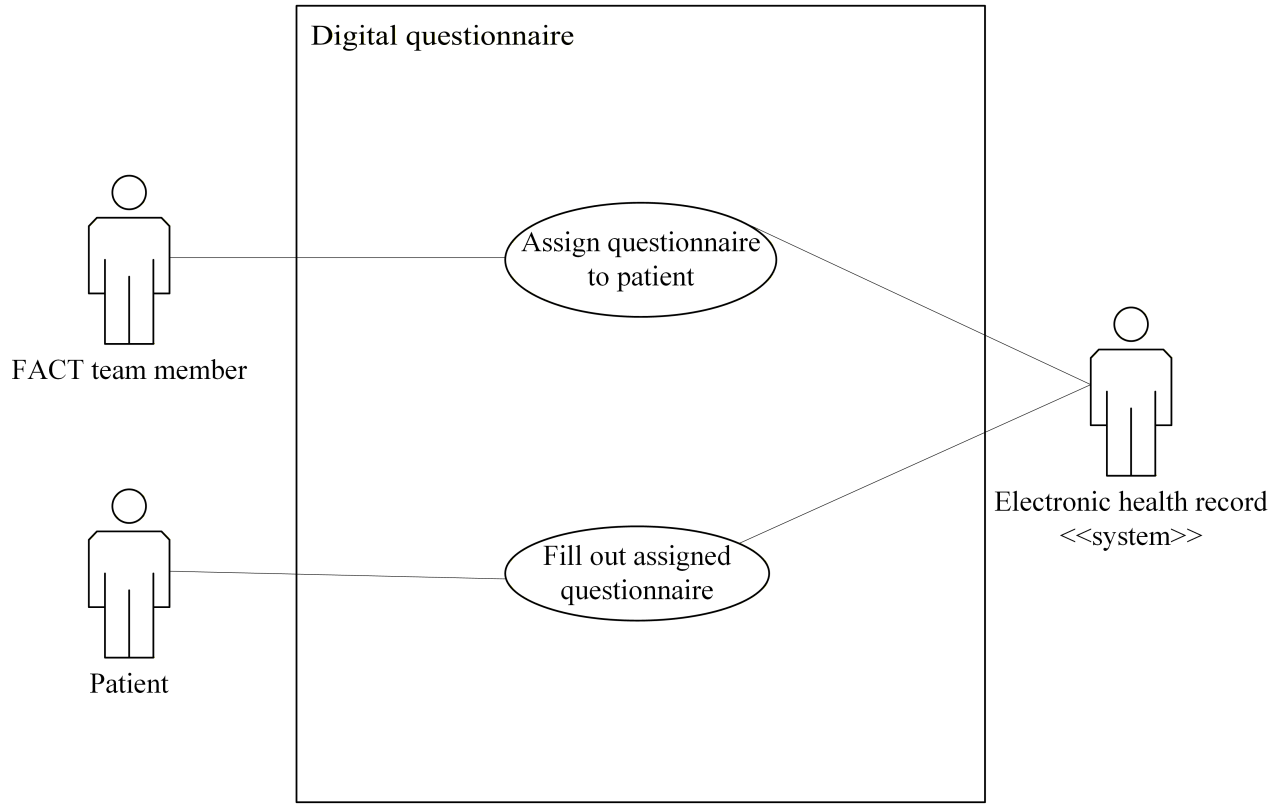
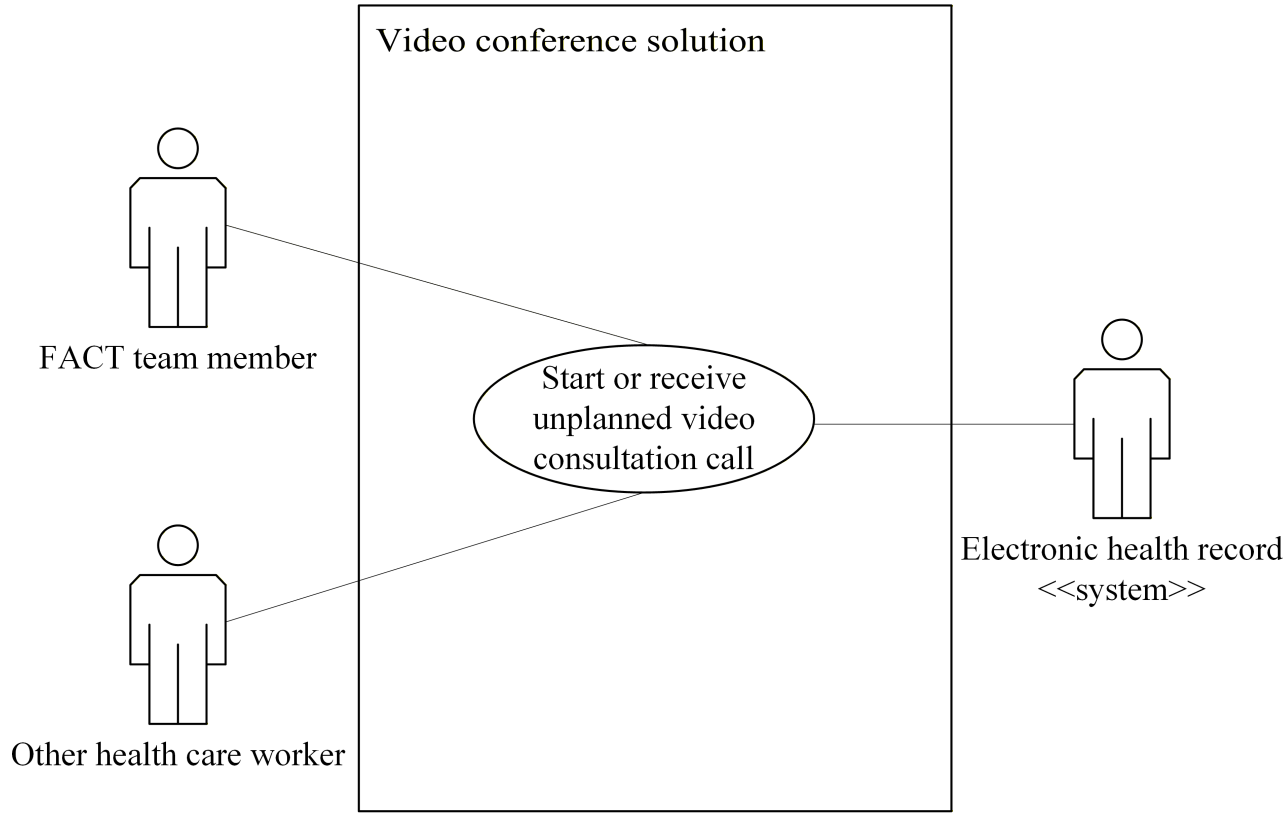


Figure 6. Use case for a video conference solution. FACT: Flexible Assertive Community Treatment.



The use case descriptions are presented below.

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Transfer a Patient to Intensive Follow-Up

For this use case, the actor is a team member. The goal is to transfer a patient who is currently listed under individual case management on the electronic whiteboard to intensive follow-up on the whiteboard. The actions for this use case are as follows:

1. A team member selects a patient on the electronic whiteboard.
2. The team member selects an option for transferring the patient to intensive follow-up.
3. The electronic whiteboard transfers the patient from the list of patients who receive individual case management to the list of patients who receive intensive follow-up. The team member responsible for the decision is recorded. All information about the patient is retained in the system.
4. The team member commits the updated information on the electronic whiteboard to the EHR.

Transfer a Patient to Individual Case Management

For this use case, the actor is a team member. The goal is to transfer a patient who is currently listed under intensive follow-up on the electronic whiteboard to individual case management on the whiteboard. The actions for this use case are as follows:

1. A team member selects a patient on the electronic whiteboard.
2. The team member selects an option for transferring the patient to individual case management.
3. The electronic whiteboard transfers the patient from the list of patients who receive intensive follow-up to the list of patients who receive individual case management. The team member responsible for the decision is recorded. All information about the patient is retained in the system.
4. The team member commits the updated information on the electronic whiteboard to the EHR.

Add Information to the Electronic Whiteboard

For this use case, the actor is a team member. The goal is to add information about a patient to the electronic whiteboard. The actions for this use case are as follows:

1. A team member selects the electronic whiteboard entry for an identified patient.
2. The team member selects the relevant fields of the electronic whiteboard and enters new information in the fields. After completing this, they commit the information to the EHR system.
3. The information is stored on the electronic whiteboard.
4. The updated information in the electronic whiteboard is committed to the EHR.

Remove a Patient From the Electronic Whiteboard

For this use case, the actor is a team member. The goal is to remove a patient from the electronic whiteboard since they are no longer receiving care from the FACT team. The actions for this use case are as follows:

1. A team member selects a patient on the electronic whiteboard.
2. The team member selects an option for removing the patient from the electronic whiteboard.
3. The electronic whiteboard commits information about this decision and the identity of the team member to the EHR.

Add EHR Information

For this use case, the actor is a team member or other health care worker. The goal is to document the treatment of a patient in the EHR. The actions for this use case are as follows:

1. A team member selects a patient in the EHR.
2. The team member creates a new journal entry for the patient.
3. The team member adds information regarding the treatment and patient status.
4. The updated information in the EHR instance is committed to the EHR storage.

Refer a Patient to the FACT Team

For this use case, the actor is a health care worker. The goal is for a health care worker to refer a patient to a FACT team for possible inclusion in the team. The actions for this use case are as follows:

1. The actor writes a referral message to a FACT team, identifying themselves, the patient, and the team. Clinical information relevant to the referral is also added to the message.
2. The actor sends the referral from the EHR system to the electronic whiteboard of the FACT team.
3. FACT team members open the referral in the inbox of the electronic whiteboard.
4. The responsible FACT team members decide if the referral is accepted or rejected.
5. A FACT team member uses the electronic whiteboard to send a message back to the EHR, stating that it has been accepted.
6. The EHR sends information that is relevant for the electronic whiteboard to the electronic whiteboard. A message is sent to the referrer informing them about the decision.
7. The electronic whiteboard creates a new entry for the accepted patient. Relevant information from the EHR is added to the corresponding fields in the patient's electronic whiteboard entry. This includes patient identification.
8. The patient is added to the list of patients who receive intensive follow-up.

An alternative flow is for rejection of the referral. If the referral is rejected, the following steps occur after step 4:

- The electronic whiteboard sends a message to the EHR about the rejection.
- The EHR sends an acknowledgment message to the electronic whiteboard, saying that the rejection has been received. The EHR then documents that the referral has been rejected and sends a message to the referrer, informing them about the decision.
- The electronic whiteboard deletes the referral after receiving the acknowledgment message.

Initiate a Video Meeting in the EHR

For this use case, the actor is a FACT team member or other health care worker. The goal is to start a clinical video meeting

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from an actor's calendar, carry out the meeting, and document the results. Participation of a patient is optional. The actions for this use case are as follows:

1. The actor selects a patient in the EHR and selects a planned meeting consultation for the patient.
2. The actor selects an option in the EHR to start the video meeting.
3. The EHR sends a message to the video conference solution, identifying the actor and stating that they want to start or connect to the video meeting.
4. The video conferencing system starts the video meeting with the actor as a participant.
5. Other FACT team members or health care workers can also connect using a link in the calendar or in the patient's EHR system.
6. The video conference solution creates a template for the documentation, which includes the identification of any patient and the health care workers in the conference.
7. All health care workers involved in the video meeting are granted access to this template and can fill out information during the conference.
8. After the video meeting is finished, all involved health care workers can update the video consultation documentation.
9. When all involved health care workers have approved the documentation, it is committed to the EHR by the responsible health care worker.

An alternative flow involves patient connection. If a patient is to participate in the video conference, the following steps occur after step 5:

- The video conferencing system sends a notification to the patient, saying that the video consultation has started.
- The patient clicks on the provided link to connect to the video consultation.
- The video conferencing system connects the patient to the video call.

After these steps, the flow resumes at step 6.

Add an Entry to the Calendar

For this use case, the actor is a team member. The goal is for the team member to add a new appointment to their calendar to keep track of appointments and activities. The actions for this use case are as follows:

1. A team member creates an entry in their calendar, detailing an appointment.
2. The entry is stored in the team member's own calendar.
3. The entry is stored in the team calendar, including an identification of the team member.
4. Information about the appointment is transferred to the EHR and added to the patient's record.

Read the Team Calendar

For this use case, the actor is a team member. The goal is for a team member to get an overview of the calendar appointments of other team members. The actions for this use case are as follows:

1. A team member accesses the team calendar section of the calendar.
2. The team member reads the calendars of the employees in the same team

Invite to a Video Meeting

For this use case, the actor is a FACT team member or other health care worker. The goal is to invite one or more other actors (FACT team member, patient, or other health care worker) to a planned video meeting. The actions for this use case are as follows:

1. The actor creates a calendar entry for a meeting.
2. The actor adds a time and location for the meeting to the calendar entry.
3. The calendar solution sends a message to the video conference solution, requesting a link to the video meeting.
4. The video conference solution generates a link to the video meeting and sends it to the calendar solution.
5. The calendar solution adds the link to the calendar entry for the meeting.
6. The actor sends the invitation to the other actors through the calendar solution.
7. A copy of the invitation is also sent to the EHR to store information about the upcoming video meeting there. This includes the link used to connect to the video meeting.
8. The meeting is stored in the sender's calendar, with a link that can be used to connect to the video meeting
9. The receiver gets an invitation on their device, containing the link to the future video consultation, as an SMS text message or email. The receiver can accept or decline this invitation, in which case a message with the reply is sent back to the sender.
10. If the receiver is a FACT team member or other health care worker and accepts the invitation, the appointment is added to their calendar with the specified time for the meeting.

Initiate a Video Meeting in the Calendar

For this use case, the actor is a FACT team member or other health care worker. The goal is to start a clinical video meeting from the actor's calendar, carry out the meeting, and document the results. Participation of a patient is optional. The actions for this use case are as follows:

1. The actor selects the calendar entry that contains a link to an upcoming video meeting.
2. The actor selects an option in the calendar entry to start the video consultation.
3. The calendar sends a message to the video conference solution, identifying the actor and stating that they want to start or connect to the video meeting.
4. The video conference solution starts the video meeting with the actor as a participant.
5. Other FACT team members or health care workers can also connect using a link in the calendar and the patient's EHR system.
6. The video conference solution creates a template for the documentation, which includes the identification of any patient and the health care workers in the conference.
7. All health care workers involved in the video conference are granted access to this template and can fill out information during the conference.

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8. After the video conference is finished, all involved health care workers can update the video consultation documentation.
9. When all involved health care workers have approved the documentation, it is committed to the EHR by the responsible health care worker.

An alternative flow involves patient connection. If a patient is to participate in the video conference, the following steps occur after step 5:

- The video conferencing system sends a notification to the patient, saying that the video consultation has started.
- The patient clicks on the provided link to connect to the video consultation.
- The video conferencing system connects the patient to the video call.

After these steps, the flow resumes at step 6.

Start or Receive an Unplanned Video Consultation Call

For this use case, the actor is a team member or other health care worker. The goal is to start an unscheduled video conference with another health care worker. The actions for this use case are as follows:

1. The actor selects a receiver for the video conference, using a unique identifier for the receiver.
2. The actor places a video call to the receiver.
3. The video conferencing solution notifies the receiver about an incoming video call and displays information about the caller.
4. The receiver gets an option to accept the video call.
5. If the receiver accepts the video call, a video conference is set up between the caller and receiver.
6. The video conference solution creates a template for the documentation, which includes the identification of any patient and the health care workers in the conference.
7. All health care workers involved in the video conference are granted access to this template and can fill out information during the conference.
8. After the video conference is finished, all involved health care workers can update the video consultation documentation.
9. When all involved health care workers have approved the documentation, it is committed to the EHR by the responsible health care worker.

Assign a Questionnaire to a Patient

For this use case, the actor is a team member. The goal is to assign a questionnaire for a patient to fill out. The actions for this use case are as follows:

1. A team member identifies a patient.
2. In the digital questionnaire solution, the actor selects a digital questionnaire for the patient to fill out. Information about filling out the questionnaire repeatedly is included if relevant.
3. This information is stored in the digital questionnaire solution and transferred to the EHR, which also stores the information.
4. The questionnaire solution presents the questionnaire to the patient at a relevant time.

Fill Out an Assigned Questionnaire

For this use case, the actor is a patient. The goal is to fill out an assigned questionnaire. The actions for this use case are as follows:

1. A patient is notified about a questionnaire that has been assigned.
2. The patient opens and completes the questionnaire. This could be with the help of team members or next of kin.
3. When the patient indicates that they are done filling out the questionnaire, the results are transferred to the EHR.
4. The EHR stores the results of the questionnaire.

Discussion

Summary of the Main Findings

This study aimed to identify the requirements and use cases for eHealth solutions that support teamwork in fragmented health care settings, with a focus on FACT teams. The problem analysis showed that limited access to patient data and poor integration across existing systems hinder coordinated care. From these challenges, we derived a set of requirements emphasizing interoperability and modular design. The resulting use cases illustrate how electronic whiteboards, EHRs, calendars, video conferencing solutions, and digital questionnaires can support core FACT workflows.

Although developed in a Norwegian context, the challenges of fragmented infrastructure, lack of shared information spaces, and mobile work are widely recognized across health care settings [16-18,20], indicating that the proposed requirements may be generalizable to other interdisciplinary and integrated care models.

Discussion of the Main Results

With emerging trends like integrated care and patient-centered care, it is vital to support teamwork in health care [1,2]. In this study, the analysis showed that current digital infrastructure does not adequately support the forms of collaboration that integrated and patient-centered care rely on. The identified requirements highlight that teamwork requires systems that enable continuous coordination across distributed actors and settings. These findings situate the need for technical integration within a broader, workflow-oriented perspective, in which the goal is to connect systems and to support the collaborative practices that define integrated and patient-centered care.

Efforts to address integration challenges in health care more broadly provide useful context for our work. Kinast et al [21] have defined a comprehensive set of requirements for data integration, encompassing data acquisition, processing, analysis, storage, and security. Their work focuses on the technical and data management layers of integration, thereby ensuring that information can be exchanged reliably and securely across systems. In contrast, this study addresses a higher level of abstraction, defining requirements and use cases that support team-level coordination and shared clinical workflows. The Valkyrie project offers another perspective by proposing a

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prototype ICT architecture centered on a virtual health record that provides cross-level access to patient data [22]. Such an infrastructure could enable the implementation of many of the requirements identified in this study, particularly those related to shared information spaces and cross-organizational coordination.

Our findings suggest that effective support for teamwork in FACT settings depends on an eHealth architecture that enables reliable interoperability across the diverse systems used in daily workflows. The proposed integration and access engine addresses this need by supporting both syntactic and semantic interoperability through established standards such as HL7 FHIR, SNOMED CT, and ICD (International Classification of Diseases). Because primary and specialist care in Norway rely on heterogeneous IT platforms, the requirements were formulated at a system-independent level to support interoperability across sector-specific infrastructure.

Key design decisions and their rationales are summarized in Table 4. Rather than embedding all functionality within the EHR, we chose a modular approach in which tools, such as electronic whiteboards and calendars, operate as separate systems but integrate through shared standards. This reflects the need for flexible, task-specific views that support daily coordination in FACT teams while still ensuring that essential information remains available within the core clinical record. Some functional overlap remains, for example, planned consultations appear in both the calendar and the EHR. However, this redundancy helps maintain continuity of documentation. While consistency between systems is critical, detailed mechanisms for synchronization, conflict resolution, and data ownership were beyond the scope of this study and would need to be addressed during subsequent technical design and implementation. Similarly, enabling video consultations to be initiated from either system supports the varied work practices of teams and preserves the EHR as a central workspace. Calendars retain integration with video conferencing systems to facilitate scheduling without constraining the modular architecture.

Beyond integration and system design, several of the identified requirements focus on the workflows of FACT teams, such as managing patient lists, conducting video consultations, and assigning digital questionnaires. These ensure that essential functionalities are in place before addressing nonfunctional requirements, such as accessibility across devices and patient inclusion.

A nonfunctional requirement is the availability of eHealth solutions on a range of devices. This is required since FACT team members often travel to meet their patients and therefore need access to eHealth solutions on mobile devices. For eHealth solutions that involve patients, it is important that the patients can access the solutions on their devices. While this study focused on the perspectives of health care professionals, the requirements for digital questionnaires and video consultations involve patient interaction. In practice, not all patients are able or willing to complete questionnaires independently, which highlights the need for flexible solutions that allow for assisted reporting when necessary. Similarly, the suitability of video consultations in psychiatric care varies across patients and situations, as discussed in previous research [9]. Their use in psychiatric care therefore requires clinical judgment, as limitations in assessing nonverbal cues and managing acute situations may pose safety risks.

Building on these requirements, we defined use cases for the eHealth solutions and illustrated the use cases in UML use case diagrams. These use cases were helpful in detailing the functionality of each solution and can serve as a foundation for communication with stakeholders and for guiding future development efforts.

Strengths and Limitations

A key strength of this study is its grounding in real-world clinical practice. The design science approach enabled us to build on empirical insights from prior observations and interviews of FACT teams, complemented by document analysis and contextual knowledge of the Norwegian eHealth infrastructure. By structuring the work through the iterative steps of problem explication, requirement definition, and design of use cases, the study adhered to core design science principles that emphasize problem-driven development closely linked to practice. This ensured that the proposed eHealth solutions were informed by the actual workflows, constraints, and coordination challenges experienced by FACT teams.

While the study provides a structured foundation for designing eHealth solutions for FACT teams, several limitations must be acknowledged. First, the requirements and use cases were derived through document analysis, thematic analysis of prior empirical material, and expert review, but were not validated through direct empirical testing with end users. This limits certainty about how well the proposed solutions align with real-world practices. Although grounding the work in existing evidence and expert input helped mitigate this limitation, future studies should include workshops, usability testing, and pilot implementations. Second, the design recommendations were developed within the context of the Norwegian eHealth infrastructure. As a result, adaptations may be necessary in countries with different infrastructure. However, challenges, such as fragmented systems and limited data access, are widely reported, suggesting that the underlying design principles may still be transferable. Third, the study focused primarily on the perspectives and needs of health care professionals. While patient-facing functionalities, like digital questionnaires and video consultations, were considered, direct patient involvement fell outside the present scope. This may have constrained the identification of needs related to usability, digital literacy, and patient experiences. Future work should therefore incorporate input from patients and caregivers. Fourth, the study did not consider financial or policy-level feasibility. Evaluating costs, sustainability, and prioritization will be important in future work to inform decisions about implementation at scale.

Conclusion

This study shows how current eHealth solutions influence teamwork and care coordination in FACT teams and how digital support can reduce fragmentation and improve information flow. The requirements and use cases developed here provide

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a foundation for designing solutions that align with real-world workflows and the needs of multidisciplinary teams.

Although grounded in the Norwegian context, the core design principles of interoperability, timely access to information, and support for distributed decision-making are relevant across health care settings. The findings therefore have implications for not only technical development but also policy, highlighting the importance of digital infrastructure that actively enables collaborative work.

More broadly, the study illustrates how workflow-oriented design can strengthen integrated and patient-centered care models that rely on effective teamwork. By focusing on how technology can support collaboration, the work offers insights applicable to multidisciplinary health care teams beyond FACT.

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Data Availability

The datasets generated during the observations and interviews on which this study builds are not publicly available due to ethical and legal restrictions, as the consent provided by participants does not permit public data sharing. Other materials supporting the findings of this study are available from the corresponding author upon reasonable request.

Authors' Contributions

Conceptualization: EB, CG, TS
Funding acquisition: CG, TS
Investigation: EB, CG, TS
Methodology: EB, CG, TS
Supervision: CG, TS
Visualization: EB
Writing – original draft: EB, CG, TS
Writing – review and editing: EB, CG, TS

Conflicts of Interest

None declared.

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Abbreviations

API: application programming interface
EHR: electronic health record
FACT: Flexible Assertive Community Treatment
GDPR: General Data Protection Regulation
HL7 FHIR: Health Level 7 Fast Healthcare Interoperability Resources
ICD: International Classification of Diseases
ICT: information and communications technology
SNOMED CT: Systemized Nomenclature of Medicine – Clinical Terms
UML: Unified Modeling Language

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Exploring the Role of App Features in Providing Continuity of Care to Users on a Digital Mental Health Platform (Wysa): Retrospective Mixed Methods Observational Study

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Abstract

Background: Despite digital mental health services growing at a rapid pace to address global mental health needs, there exist challenges of low engagement and attrition. Ensuring continuity of care in the digital context can positively impact mental health care delivery and adherence to treatment, helping to establish digital mental health interventions (DMHIs) as a viable option for mental health support.

Objective: This study aimed to examine the impact of adjunct app features of the mental health app Wysa and their ability to promote engagement and adherence to the text-based coaching sessions.

Methods: This retrospective mixed methods observational study was based on real-world app data from users (n=1213) who subscribed to text-based sessions with mental health coaches (MHCs) between February 1 and July 31, 2022. Their engagement with the adjunct app features, such as brief interventions with the conversational agent, self-management tools, and journaling, was analyzed quantitatively using descriptive statistics. Acceptability of the app features was also assessed using qualitative feedback data. Adherence to sessions with MHCs was compared between app feature users (n=1042, 85.9%) and nonfeature users (n=171, 14.1%) using inferential statistics. Subgroup analysis was not feasible in the absence of demographic and clinical user data, potentially limiting the generalizability of the findings.

Results: Findings demonstrated high use of the adjunct app features, which allowed communication with the MHCs in between sessions. The thematic analysis captures user experiences of helpfulness within the app and with the MHCs. The Mann-Whitney U test indicated that users who accessed one or more features completed significantly more sessions compared with users who did not use any feature (Mann-Whitney U=154,085.0; $P<.001$; $r_B=0.73$) with a large effect size. The odds ratio analysis indicated that users were almost thrice as likely to complete sessions after using the adjunct app features (odds ratio 2.91, 95% CI 2.24-3.38; $P<.001$).

Conclusions: Inclusion of adjunct app features enhances continuity in care delivery between sessions with MHCs and is associated with improved engagement with DMHIs. Further efforts are needed to assess the impact of this approach in DMHIs on clinical mental health outcomes.

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KEYWORDS

Wysa; continuity of care; relational continuity; digital mental health interventions; DMHI; conversational agent; mental health coaches; artificial intelligence; AI

Introduction

The global burden of mental health disorders has increased significantly over the past decade. The World Health Organization (WHO) estimates that about 970 million people were living with a mental disorder in 2019 [1]. Availability of mental health services remains widely inaccessible, unaffordable, and inadequate. Social stigma around mental health disorders further widens the gap between access and care, leaving a significant number of people without timely and adequate mental health support [2]. Studies estimate that only a third of people with depressive disorders receive formal mental health care globally, signifying the urgent need for innovation to offer timely support and equitably deliver appropriate care [3].

Health care access and delivery systems create a complex environment for patients to navigate, and this complexity adversely affects continual access to necessary care and overall health outcomes [4]. A cohesive, interconnected, and efficient system is especially necessary to address the care needs of patients with complex physical and mental health challenges [5,6]. Continuity of care, as a concept, focuses on a

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patient-centered approach to enhance the quality of care delivered by coordinated services [7-9]. It is the support that an individual receives throughout the process of care delivery, within and outside a consultation session with a health professional [7]. This can be bridged by allied health professionals, social support systems, and digital technologies. Health care providers and patients emphasize the role of continuity in decreased symptom severity and enhanced health outcomes [5,10].

In mental health, continuity of care is often linked to the therapeutic alliance between the health care provider and the patient. A meta-analytic review in mental health found a moderate effect size in the relationship between clinical outcomes and the therapeutic alliance [11], which relies on the ability to access necessary information, maintain an ongoing patient-therapist collaboration, and have access to self-management options [12,13].

Digital mental health interventions (DMHIs) have emerged as a compelling solution to bridge the continuity gap due to their ability to increase access across geography and time of day [14]. They offer users low-cost support at their convenience, without requiring appointments or transportation [15-17]. DMHIs have been studied separately to examine their ability to improve mental health outcomes, but their impact on parallel engagement with mental health coaching has not been examined.

This mixed methods retrospective observational study examines this ecosystem of care using real-world data from the mental health app Wysa (Wysa Inc) to explore the following objectives: (1) to assess the use and acceptability of the adjunct app features between sessions among users who had subscribed to mental health coaching on a text-based platform and (2) to determine whether higher use of adjunct app features leads to improved engagement and adherence to sessions with mental health coaches (MHCs).

Methods

App Background

Wysa is a digital mental health app that has been publicly available since 2016. The app's direct-to-consumer version is anonymous for users and consists of an artificial intelligence (AI)–enabled conversational agent (CA), weekly sessions with MHCs, asynchronous messaging with MHCs, and cognitive behavioral therapy (CBT)–based brief interventions. All Wysa CA resources have been clinically validated by licensed mental health professionals.

The features within this app are not a replacement for face-to-face psychotherapy and are not used for diagnosis, prognosis, treatment, or to provide any type of state-regulated mental health services in the client's country of residence. Users who expressed suicidality or self-harm were signposted to appropriate helpline services. The Wysa CA is free for all users, while access to certain tools and sessions with the MHCs is offered as paid features.

Wysa App Features

Mental Health Coaching

This service connects users to qualified mental health and well-being professionals, who have undergone standardized in-house training to provide legal, ethical, and clinically safe psychological support and mental health care. The MHCs are psychologists with master's- or doctoral-level qualifications. Each session with an assigned MHC is scheduled for 30 to 45 minutes and is conducted through a live text-based messaging system on the platform.

Adjunct App Features

Asynchronous Communication With MHC (Journaling)

Users who subscribe to sessions with MHCs also have the option to send messages to their assigned MHC in between scheduled sessions to receive continued support. The MHC typically responds within 24 hours.

Conversational Agent

Wysa, an AI-enabled CA, provides a digital therapeutic space for users to receive brief evidence-based CBT interventions and access guided listening. User conversations occur with a free-text CA supported by models developed using natural language processing and natural language understanding. The CA also provides users with self-management tools that leverage evidence-based therapy techniques including CBT, acceptance and commitment therapy, and mindfulness-based approaches. The tools cover a range of interventions that support users through difficulties such as anxiety, depression, anger management, and sleep-related concerns, among others.

Ethical Considerations

Wysa's privacy policy and terms of service strictly ensure the anonymity and privacy of its users. Users could directly access the app without registration, with no personally identifying information collected during app use. Furthermore, any inadvertently shared personally identifying information (such as name, nationality, location, gender, etc) was redacted from the backend. Thus, only anonymized data were used in the research. An independent researcher reproduced all primary reported results and validated the reported findings to minimize any impact of the conflict of interest.

The study protocol was reviewed by Pearl Institutional Review Board (Indianapolis, Indiana, United States) and determined to be exempt from institutional review board oversight as it involved retrospective analysis of deidentified user data (exemption determination: 2025 - 0025, 01/17/2025).

Study Design and Sampling

This study followed a mixed methods retrospective observational design to examine the real-world usage, engagement, and feedback data of anonymized global users of Wysa from February 1 to July 31, 2022. The inclusion criteria for this study were users who subscribed to text-based sessions with MHCs during the study period. As the dataset consisted of anonymized user records, no additional inclusion or exclusion criteria were applied, and the sample was considered representative of Wysa's global user base. This resulted in a sample of 1213 users. A

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total of 1042 (85.9%) users used at least 1 adjunct app feature, whereas 171 (14.1%) users did not use any app features between sessions with their MHCs during the study period.

Data Analysis

Objective 1: Use and Acceptability of Sessions With MHCs and Adjunct App Features

The use metrics of the features (sessions and tools used with the CA, journaling frequency, and sessions with MHCs) were analyzed using descriptive statistics. The acceptability of these features and sessions with the MHCs was quantified using a helpfulness rating and also assessed qualitatively by conducting a thematic analysis [18] of feedback provided by the users. Thematic coding was performed independently by 2 researchers, with discrepancies resolved through discussion to enhance reliability. This was initiated by the generation of preliminary codes, which were then grouped into potential subthemes and themes. The data were then verified for relevance to the themes at each level, and the initial set of themes was verified in relation to the coded extracts. The themes were finalized on the basis of their relevance to the objective.

Objective 2: Impact of the Adjunct App Features on Engagement and Adherence With MHC Sessions

Inferential statistics were used to examine whether the adjunct app features improved engagement and adherence to MHC sessions. The analysis compared users who used at least 1 adjunct app feature with users who accessed sessions with MHCs without using any other app feature. Normal distribution of the data was assessed using the Shapiro-Wilk test for normality, and as the data were not normally distributed, the Mann-Whitney U test was used to measure groupwise differences in completion of sessions with MHCs between feature users (1042/1213, 85.9%) and the comparative group of users who did not use features (171/1213, 14.1%). Furthermore, an odds ratio (OR) analysis was conducted to explore whether using the adjunct app features (exposure) resulted in completion or noncompletion of the subsequent session with the MHC (outcome).

Results

Objective 1: Use at and Acceptability of Adjunct App Features and Sessions With the MHCs

Sessions With MHCs

For app feature users (n=1042), a total of 10,116 sessions were scheduled with MHCs on the app between February 1 and July 31, 2022. Of these, 6854 (68.4%) sessions were completed, and 3162 (31.6%) were either missed or canceled. Users who did not use any other app features (n=171) scheduled 243 sessions, completed 94 (38.4%) sessions, and missed or canceled 149 (61.3%) sessions during the study period. App feature users, on average, scheduled 9.61 (SD 10.99) and completed 6.57 (SD 8.20) sessions compared with non–app feature users, who scheduled and completed an average of 1.42 (SD 1.41) and 0.55 (SD 0.96) sessions, respectively. The overall data of scheduled sessions across both groups indicated a right-skewed distribution with a positive skewness of 2.13.

The user-rated helpfulness of MHC sessions across both groups was assessed using quantitative user feedback from 7823 sessions obtained on a scale of 1 to 3, out of which 6869 (87.8%) sessions were found to be very helpful. Among adjunct app feature users, 0.9% (69/7620) found the MHC sessions to be not helpful compared with 3.95% (8/203) of nonfeature users.

Use of Adjunct App Features

Asynchronous Communication With MHC (Journaling)

Out of 1042 app feature users, the journaling feature that enabled asynchronous communication with MHCs was used at least once by 813 (78%) users, who sent an average of 136.38 (SD 296.06) messages per user over the study period and 14.86 (SD 20.81) messages per user per journaling session. Some users provided feedback that this feature gave them opportunities to express their thoughts and emotions beyond the sessions. One stated how their "sessions are very helpful whenever (they) use the journal."

AI-Led Tools Through the CA

Out of 1042 app feature users, 946 (90.8%) used the CA feature in this period. The average rating given to the CA was 3.86 out of 5, largely indicating positive feedback. Additionally, 29 users (2.4%) provided qualitative feedback, commenting on the helpfulness of the CA. For instance, one user said, "Wysa helps me see the brighter side of things." Many users also highlighted the therapeutic relationship, commenting that the CA was "comforting" and "helpful" in rethinking and "breaking negative thought cycles." However, few users also felt that the CA was "too robotic," "limited," and "not helpful." The most used tools delivered by the CA were the mindfulness-based interventions, sleep, and stress management tools. One of the users shared, "I liked the idea of having tools and steps to help me move forward with my goals as well as helping me cope with unwanted isolation."

Qualitative Feedback on MHC Sessions

User feedback on the helpfulness of MHC sessions was overwhelmingly positive, with 87.8% (6869/7823) of sessions rated as very helpful across both groups. The thematic analysis of qualitative feedback (n=959) on Wysa's MHC sessions provided by 322 (30.9%) out of 1042 users yielded 2 major themes: quality of services and personal growth and development.

Access to Support and Safe Spaces

Users positively described the quality of services and continued *support received* from Wysa's MHCs and the *establishment of an emotionally safe space through the app*.

Users often felt truly understood and attributed their progress to their MHCs, whom they described as caring, trustworthy, and compassionate. A user emphasized, "My therapist has helped me make huge progress in my capacity to handle life and difficult situations, and I am constantly learning from her. Her support has made a big difference in my life."

A user also stated that it is "great to have a safe space where I can share my thoughts and feelings," while another user expressed their gratitude for a trusting space for expression and

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emotional regulation: “Thank you. It’s actually difficult to open up about these things and thank you for this very safe space to do so.”

However, some users also expressed discomfort with the text-based form of MHC sessions and noted difficulty in communicating at times with their assigned MHCs. A user wrote, “Lag with texting and the responses were slow.”

Personal Growth and Development

The users also attributed personal growth and development to the MHC sessions, stating that these sessions helped improve self-esteem, confidence, and skill building. One user reported, “This session really helped me refocus on strengths and rebuild my self-esteem.” Another user emphasized how MHC sessions were “helping me recognize my wins and that I am able to calm myself down and make rational decisions really helped boost my confidence in myself.”

A positive response to MHC support was also noted, as users reported enhanced self-awareness and learning skills, such as goal setting, reframing dysfunctional thoughts, and adopting diverse perspectives for actions and behaviors. One user described learning to “see the kind of harshness I project towards myself.” Users also emphasized the benefits of using tools and techniques recommended by their MHCs. One user mentioned, “I liked the idea of having tools and steps to help me move forward with my goals as well as helping me cope with unwanted isolation.” In some cases, users also specifically asked for *goal-oriented approaches*. One user stated, “I feel like we should focus on coping skills.”

Furthermore, users also highlighted specific requests and advice they sought from their MHCs, such as “some tips for building boundaries before my next shift,” “discuss ways to improve my time management,” or “more concrete plans that I can act on.” This indicated the specific types of personalized and continual care and support the users sought from their trusted MHCs.

Objective 2: Impact of the Adjunct Features on Engagement and Adherence

The number of sessions completed with MHCs among app feature user and nonfeature user groups was right skewed, with a positive skewness of 1.95 and 3.91, respectively. The Mann-Whitney U test indicated that the adjunct app feature users (1042/1213, 85.9%; mean 6.57, SD 8.2) completed significantly more sessions (mean difference 6.02; Mann-Whitney U=154,085.0; P<.001; r_B=0.73) with a large effect size, compared with users who did not use any features (171/1213, 14.1%; mean 0.55, SD 0.95).

Results from the OR analysis indicate that the odds of completing the subsequent session increased significantly when users used any of the adjunct features (OR 2.91, 95% CI 2.24-3.38; P<.001). Thus, users were almost 3 times as likely to complete their next session with their MHC after using at least one of the app features than when they did not use any feature in between sessions.

Discussion

Principal Findings

This retrospective observational study explores the use of a DMHI, Wysa, using real-world data to understand its association with improving user adherence and engagement with MHC sessions. The study results indicate that users who engaged with the chatbot and its integrated brief interventions are significantly more likely to engage with subsequent MHC sessions compared with those who do not use any adjunct app features. These findings support recent studies where patients have demonstrated a higher level of acceptability and readiness to access help after the use of a brief digital intervention [19,20].

DMHIs are a scalable solution that supports the effective expansion of access to mental health resources to wider populations [21] and can enhance relational continuity within care provision [22]. Previous studies have found that human support, text-based communication [23,24], integration of conversational agents [25], and self-management tools [26] can facilitate the development of a therapeutic alliance, improve continuity of care, and increase engagement with the DMHIs [22].

Asynchronous journaling with the MHCs, a text-based messaging feature, was used the most, providing insight into the need to be able to communicate outside of the session. It has been suggested that the features supporting text-based communications are an effective means of maintaining continued contact between patients and primary care providers, which enables timely exchange of vital information and needs and develops a strong working alliance [27,28].

The high use of self-management tools has been seen to provide a holistic care environment and promote a sense of agency and responsibility among patients [29]. Self-management tools in mental health care have been established as a cost-effective resource [30] that improves overall patient outcomes [31] when offered as an adjunct to standard-of-care therapies. Our study corroborates these findings, showing that users notably engage with self-management tools and that integrating them in DMHIs is a vital component in establishing a sustained therapeutic relationship.

More recently, AI-based CAs have emerged as a compelling solution that can provide a sense of constant presence and comfort, as they help in integrating disparate aspects of a digital platform [32,33]. A CA-monitored user interface can be a personalized tool that provides relevant information, self-management resources, reminders for adherence, and a platform to effectively monitor symptoms to support continuous care delivery to patients [34,35]. Similarly, high patient uptake and the use of Wysa’s AI-based CA were also noted in our study and were associated with improved overall engagement with the MHC sessions, suggesting its ability to support development of a therapeutic alliance. A meta-analysis noted that additional factors correlated with high engagement in DMHIs include gender, higher socioeconomic status, lower symptom severity, and education [36].

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Improving user engagement and ensuring continuity of care is an essential factor to maximize the potential of DMHIs [37,38]. Research conducted in traditional mental health services also finds that providing resources that enhance continuity of care between treatment sessions improves engagement and adherence to overall treatment cycles and reduces the need for frequent hospital visits [39-43]. Improved relational continuity in traditional care delivery settings has also been associated with better overall mental health outcomes and a reduction in symptom severity in patients with severe mental health and psychiatric disorders, further highlighting the necessity of also integrating the construct in scalable digital mental health care delivery mechanisms [44,45].

Therefore, this study has important implications for the design and development of DMHIs as well as the broader mental health services. It highlights the need to consider a holistic approach and an overall quality of support while designing digital interventions to deliver mental health care. As demonstrated in this study, adjunct features such as evidence-based self-management tools, AI-based conversational agents, and journaling features can be some effective tools to provide continuous support that can be leveraged to improve patient adherence and engagement with the app-based DMHIs, along with other correlated factors. These features can be associated with sustained therapeutic relationships between patients and their MHCs in a digital environment and support client empowerment [43]. Thus, DMHIs could be designed to incorporate features based on similar principles to increase their effectiveness, improve user satisfaction, and maximize their application as an effective task sharing tool. Future research should further investigate the effectiveness of tools and factors in enhancing continued care delivery systems in the context of digital mental health and the impact of improving continuity of care on clinical mental health outcomes.

Strengths and Limitations

To our knowledge, this study is unique in its approach of using real-world evidence to examine whether provision of certain adjunct app features in DMHIs is associated with building therapeutic relationships and improving overall patient engagement with mental health apps. Moreover, the approach draws its strength from the objectivity of its methodology. The retrospective observational approach enables examination of real-world user behaviors. The qualitative feedback reported further adds to the richness of information by providing nuanced user perspectives. In addition, potential user selection bias was minimized by applying a broad inclusion criteria and no exclusion criteria to the anonymized user data. However, the study also has several limitations. First, we were unable to measure the impact of improved continuity of care on differences in clinical efficacy and changes in symptom severity due to limitations of the dataset. Additionally, we could not measure any meaningful differences between demographic or clinical characteristics between app feature users and nonfeature users due to the retrospective design of the study, which limits the generalizability of the findings. Finally, another methodological constraint arising from the retrospective design was the uneven distribution and missingness of the data between app feature users and nonfeature users that limited the ability to triangulate the findings in this study.

However, this research lays the groundwork for more comprehensive exploration of continuity of care within the context of DMHIs. Therefore, future research could examine how providing adjunct features on a mental health app can impact overall engagement and further improve the clinical mental health outcomes for individuals, along with comparative investigations into the effectiveness of different adjunct features in increasing engagement and adherence. Subsequent studies can also delve into the experiences and perspectives of health care providers and users, along with prospective trials to explore feature use that enables continuity in the care delivered. Furthermore, DMHI services can also benefit from research using standardized methods for assessing continuity of care in the digital context, which in turn requires further investigation and guidelines.

To successfully scale mental health services to meet growing public mental health demands, it is necessary to build comprehensive digital mental health platforms that encompass various services such as coaching services, provide personalized knowledge and information, and support self-management [14,46]. The positive associations between developing relational continuity and improved clinical outcomes for individuals with mental health concerns underscore the importance of ongoing efforts to enhance care continuity in the digital context [6].

This study has used the STROBE (Strengthening the Reporting of Observational studies in Epidemiology) checklist for observational studies to enhance clarity and reproducibility of the findings (Checklist 1) [47].

Conclusions

The use of DMHIs as a powerful tool to expand access to MHCs and services has increased substantially. Despite methodological constraints, this study provides foundational evidence that integrating additional features, such as AI-enabled CAs, self-management tools, and free communication platforms, among other factors, can support improvements in engagement and adherence to DMHIs and the delivery of continued support to patients outside of sessions with MHCs. Further exploration and evidence are needed to assess factors that improve the effectiveness of DMHIs through increased engagement, support a strong therapeutic relationship, enable a holistic digital care environment, and subsequently improve clinical mental health outcomes.

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Authors' Contributions

CS designed the study. CS, SM, DD, and RT worked on the quantitative and qualitative data analysis aspects of the study, contributed to the review, and final presentation of the manuscript. CS and SM wrote the first versions of the manuscript. CS and RT completed the final version and prepared the final review of the manuscript. RT ensured the accuracy of the analysis and the manuscript across revisions. All authors contributed to the article and approved the submitted version.

Conflicts of Interest

CS, DD, SM, and RT are employees of Wysa. The authors only had access to anonymized user data for the purpose of this study and had no role in the delivery of services or user interactions. The data collection and retrieval were segregated and occurred independently from the team that worked on the analysis. All analyses were conducted using predetermined methods, interpretations were made independently, and the results are reported transparently irrespective of the direction and magnitude of the findings. Additionally, an independent researcher reproduced all primary reported results to validate the work.

Checklist 1
STROBE checklist.
[DOC File, 86 KB - formative_v10i1e73033_app1.doc]

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Abbreviations

AI: artificial intelligence
CA: conversational agent
CBT: cognitive behavioral therapy
DMHI: digital mental health intervention
MHC: mental health coach
OR: odds ratio
STROBE: Strengthening the Reporting of Observational studies in Epidemiology
WHO: World Health Organization

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An Innovative Population Health Tool for Overall Health Status Assessment: Prospective Observational Study

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Abstract

Background: The World Health Organization reported that noncommunicable diseases (NCDs) contribute to around 74% of deaths worldwide. A similar phenomenon can also be observed in Brunei Darussalam. One of the most cost-effective approaches to control the growing burden of NCDs is to reduce related modifiable risk factors.

Objective: This study aims to propose a composite health score called Health Index, inspired by the 6 pillars of lifestyle medicine, which acts as a measure of health and can show how health changes over time at an individual and national level.

Methods: Health Index is a series of questionnaires that captures users' health status on several domains of health and, upon completion, the users are categorized as either healthy, at risk, or in poor health. Users will also be able to view health advice based on their answers to the questionnaires.

Results: The field testing results show Health Index as a promising population health management tool. 13.8% (166/1200) of the targeted users completed Health Index within 1 month, with 85% (1019/1200) of them in the "At Risk" category. We also identified diet as the most prominent health issue.

Conclusions: In conclusion, the Health Index potentially enables early detection and management of NCD risk factors to mitigate the high cost of advanced disease and complications. In the future, we aim to retrospectively and prospectively validate the Health Index through several statistical analyses.

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KEYWORDS

population health tool; overall health assessment; digital health application; chronic diseases; health score

Introduction

Background

Noncommunicable diseases (NCDs) are a diverse group of chronic conditions that are nontransmissible. They typically develop over a long duration and are often the result of a combination of genetic, physiological, environmental, and behavioral factors. There are 4 main diseases that are dominant in NCDs' mortality and morbidity, which are cardiovascular diseases (CVDs), cancer, chronic respiratory diseases, and diabetes. NCDs are now the leading cause of death globally, posing a major challenge to public health and sustainable development.

According to the World Health Organization (WHO), 74% of deaths are due to NCDs worldwide [1]. Each year, around 17 million individuals aged 70 years and below die prematurely due to NCDs [2]. CVDs account for most NCD deaths by contributing around 17.9 million deaths annually. Subsequently, cancers contribute to 9.3 million deaths, chronic respiratory diseases to 4.1 million, and diabetes to 2 million. Similarly, NCDs, including CVDs, diabetes mellitus, and cancer, are major causes of death in Brunei Darussalam [2]. In 2021, the top 5 NCDs that led to death and disability (disability-adjusted life years) in Brunei Darussalam were ischemic heart disease, stroke, diabetes, chronic kidney disease, and lung cancer [3]. In 2019, the World Health Assembly called for the development of an Implementation Roadmap 2023 to 2030, which aims at reducing one-third of premature deaths from NCDs by 2030 [4]. While these statistics provide an important overview of NCD burden, they must be interpreted with caution. Global estimates from WHO are often based on modeled data and may be influenced by limitations in data collection, particularly in low- and middle-income countries where health surveillance systems

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may be less robust. Similarly, national data from Brunei Darussalam may face challenges related to the completeness of health records and time lags in reporting.

Most NCDs are the result of several factors, including genetic, environmental risk factors, metabolic risk factors, and modifiable behavioral risk factors [2]. The latter includes smoking, low physical activity, unhealthy diet, and excessive consumption of alcohol, all of which increase the risk of NCDs. The top metabolic and behavioral risk factors that contribute to disability-adjusted life years in Brunei Darussalam include high fasting plasma glucose, high BMI, an unhealthy diet, smoking, and high blood pressure [5]. Hence, the majority of NCDs are preventable, as their onset typically stems from lifestyle factors early in life. Therefore, reducing the major modifiable risk factors is the most cost-effective way to control the growing burden of NCDs. Despite being preventable, efforts to reduce these modifiable risk factors have seen limited global success. One of the main barriers is the general lack of awareness and understanding of NCDs and their risk factors among both the public and policymakers. This underscores the pressing need to enhance education and public health communication. Technology, including digital health platforms, can support these efforts by enabling scalable, personalized, and timely dissemination of health information and empowering individuals to take proactive steps toward healthier lifestyles [6].

Given the growing burden of NCDs and the importance of early risk identification, there is a need for accessible, evidence-based tools that can support population-level NCD prevention efforts. One concept that has been becoming increasingly popular is the use of a Health Score [7-11]. It quantifies an individual's overall health condition comprehensively as a number. It factors in multiple aspects of health, such as physical health, physical activity, diet, and others. The health score is the result of integrating various data points into a single, actionable metric. Key limitations of current health scores are limited health domain coverage and limited downstream applications.

Lifestyle medicine is a field of medicine that applies therapeutic lifestyle interventions as the primary approach for managing chronic conditions, such as CVDs, type 2 diabetes, obesity, and others. There are 6 pillars of lifestyle medicine, which are mental well-being, healthy relationships, physical activity, healthy eating, sleep, and minimizing harmful substances.

Given the limitations of the existing health scores and based on the lifestyle medicine concept, we propose a composite health score called Health Index, which acts as a measure of health and can show how health changes over time at the individual and national level. Health Index addresses some of the major limitations of existing health scores. Health Index covers 5 important health domains, which are inspired by the pillars of lifestyle medicine. Furthermore, Health Index supports a broader range of downstream applications and also health care system connectivity. This initiative comes from a partnership between the Brunei Darussalam Ministry of Health and EVYD Technology Sdn Bhd. The Health Index score is calculated based on users' health status in several domains of health. It is developed as a dynamic digital solution that updates the user's health status based on data from health records and self-reported information that will be available on BruHealth (EVYD Technology Sdn Bhd).

BruHealth is Brunei Darussalam's national mobile health app (mHealth app) launched in May 2020 as a response to the COVID-19 pandemic to assist with contact tracing. The app was later expanded during the rollout of the National COVID-19 vaccination as it was used as a platform for booking vaccination appointments. It has been reported that about 4,37,711 users have registered with BruHealth [12]. Over time, as the pandemic responses were scaled down, BruHealth has evolved into a platform for health promotion programs and health management plans.

Problem Statement

So far, there is no scientifically proven single set of measures that can fully describe the health of a large and diverse population. Most measures only scrutinize one aspect of health, for example, cardiovascular risk [13], kidney health [14], and cancer [15,16]. These measures are not ideal when assessing the overall health status of individuals or a population.

The Centers for Disease Control and Prevention (CDC) and other global health agencies often consider life expectancy and mortality data to assess overall population health. However, it is worth noting that these metrics do not consider different aspects of health. Therefore, actionable insights cannot be obtained from such metrics. Pano et al [7] proposed a health score derived from a combination of sociodemographic, anthropometric, and lifestyle data, called "Lifestyle and Well-Being Index (LWB-I)," which takes into consideration 12 lifestyle-related features. However, several limitations exist in the proposed index. First, all the features are self-reported and do not take into account physical health-related variables, such as biomarker levels and early metabolic changes. Second, the index was evaluated only on the young adult population who were followed up for 4 years. The evaluation process excluded other age groups, such as the older population, who are more at risk of developing chronic diseases and poor health. There are also several commercially developed health scores available, such as Sprout [8], ConnectedLife [9], Aktivo Score [10], Dacadoo [11], and others. Table 1 summarizes the differences between these products and our proposed Health Index.

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Table . Summary of commercially available health scores and comparison with Health Index.

Aspects	Sprout [8]	ConnectedLife [9]	Aktivo score [10]	Dacadoo [11]	Health Index
Country	Canada	Singapore	Singapore	Switzerland	Brunei Darussalam
Target customers	Employers	Individuals and employers	Individuals, insurers, and employers	Health providers, insurers, and employers	Health providers, public health policymakers, and individuals
Domains of health	BMI, waist circumference, sleep, drinking, and smoking habits	Smartwatch data (physical activity, sleep, nutrition, and stress) and self-logged metrics, such as BP[a], lipid, HbA_{1c}[b], HRV[c], HR[d], SpO2[e], temperature, sleep, and exercise	Physical activity, sleep, sedentary behavior, nutrition, and sleep	Physical activity, mindfulness, sleep, mental well-being, physical health, nutrition, and self-control	Physical health, mental health, diet, physical activity, and frailty
Data sources	Self-reported data	Wearable devices and self-reported data	Wearable devices and self-reported data	Wearable devices and self-reported data	EMRs[f], validated questionnaires (DASS-21[g], SFFFQ[h], IPAQ-SF[i], and FRAIL[j])
Downstream actions	Coaching, rewards, and incentives	Habit-forming programs, digital health coach, and rewards	Challenges	Personalized lifestyle recommendations	Risk screening, personalized lifestyle recommendations, incentives, policymaking, and links to health care services

[a]BP: blood pressure.

[b]HbA_{1c}: hemoglobin A_{1c}.

[c]HRV: heart rate variability.

[d]HR: heart rate.

[e]SpO2: blood oxygen saturation.

[f]EMR: electronic medical record.

[g]DASS-21: Depression Anxiety and Stress Scale-21.

[h]SFFFQ: Short Form Food Frequency Questionnaire.

[i]IPAQ-SF: International Physical Activity Questionnaire-Short Form.

[j]FRAIL: Fatigue, Resistance, Ambulation, Illnesses, and Loss of weight.

These existing commercially available health scores mostly target either individual users, employers, or insurers. Most of the products only cover limited domains of health, including a combination of biometric and self-reported data to assess domains, such as physical activity, sleep, nutrition, and mental well-being. Common downstream applications include personalized digital coaching and incentive-based health promotion. Most of the products do not integrate with the national health data infrastructure and do not provide links to health care services.

In addition, most of these health scores are either commercially driven or focused on behavior modification within corporate wellness or insurance settings. In contrast, the Health Index was designed within a public health framework in Brunei Darussalam. It incorporates a wide range of health factors into the computation, and supports a broader range of downstream applications, including risk screening, policymaking, personalized lifestyle recommendations, and health care system connectivity. This positions Health Index as a more holistic and contextually adaptable tool for population-level health monitoring and policy planning.

Furthermore, although these methods were scientifically developed, to the best of our knowledge, there are no relevant scientific publications to show their effectiveness. To assess their scientific validity, we conducted a structured search across gray literature sources, including company websites, product white papers, and regulatory filings where available. Our search found limited evidence of formal validation studies published in the scientific literature. In most cases, the details of the algorithm were proprietary, and there were no rigorous evaluation or clear documentation of the predictive accuracy.

Objective

Overall, our Health Index research will span over several phases as follows:

1. To design and develop the Health Index — a composite score that measures overall health status across multiple domains.
2. To validate the Health Index at both domain and overall levels, assess responses, individual item scores, domain weights, and cut-off points using appropriate statistical analyses.

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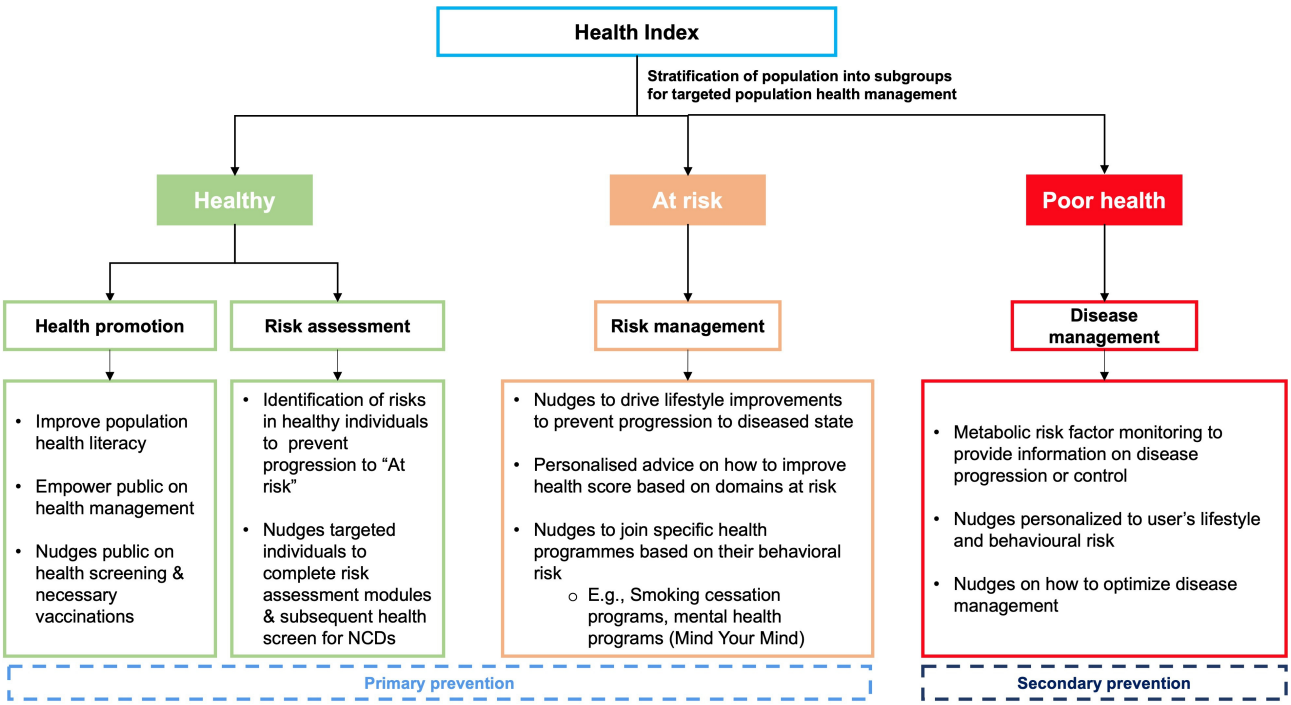
3. To create a shorter version of the Health Index that retains strong psychometric properties.
4. To incorporate a machine learning (ML)-based predictive analysis tool into the validated and stable Health Index tool to estimate disease risk and enable timely preventive action.

In this study, as the first phase, we propose a Health Index to tackle the limitations of existing health scores, which is developed based on the concept of lifestyle medicine. The module would be embedded into the BruHealth app, and users can update their profile and their overall health status using the Health Index. The users will be stratified into either one of healthy, at-risk, or poor health groups for targeted population health management (Figure 1). The objective of this study is to describe the concept of Health Index and its pilot deployment. This pilot implementation focuses on the integration of Health Index into the national mHealth app and the initial rollout to the general population. While statistical evaluation is outside the scope of this study, future phases will scientifically assess the effectiveness of Health Index, describing individuals' overall health status using health care use data.

Figure 1. Health Index targeted population health management for healthy, at-risk, and poor health groups. NCD: noncommunicable disease.



Methods

Study Design and Participant Flow

This is a prospective observational study conducted through the national BruHealth mobile app launched in 2023. The objective of this study is to describe the concept of Health Index and its pilot deployment. This pilot implementation focuses on the integration of Health Index into the national mHealth app and the initial rollout to the general population.

Apart from describing the concept and pilot implementation, this study also presents the preliminary results derived from 166 early participants to find out the relationship between Health Index results and health care use. In the field study, users were invited to participate through the BruHealth mobile app. After giving consent, participants then proceeded to complete the Health Index questionnaires. The outcome measure, which was used for the preliminary analysis, is the count of NCD-related outpatient visits within 1 year before the completion of the Health Index. This variable was extracted from the national electronic medical record (EMR) system, Brunei Health Information and Management System (Bru-HIMS).

Users Information

Given that the Health Index is a population health tool and will be available for all accounts with the latest version of BruHealth mobile app, users are invited to participate in the Health Index. Participation is completely voluntary and is open to all BruHealth users who are 18 years and older (which is also the qualifying age for BruHealth). Individuals who are pregnant or aged 17 years and younger are excluded.

Data Management

Users of BruHealth will be invited to participate in this validation study. Users will be prompted to take the Health Index either through push notifications, banners, or cards on the BruHealth mobile app, after which they will be directed to a Participant Information Sheet (PIS) and Consent Form (Figure 2). As part of our localization effort, the PIS and Consent Form are also translated into the Malay language. They will be sent 2 types of notifications: (1) for recruitment to participate in the Health Index, and (2) reminders to nudge for completion of questionnaires to get a final Health Index result. Only the first completed data for each participant will be collected for data analysis.

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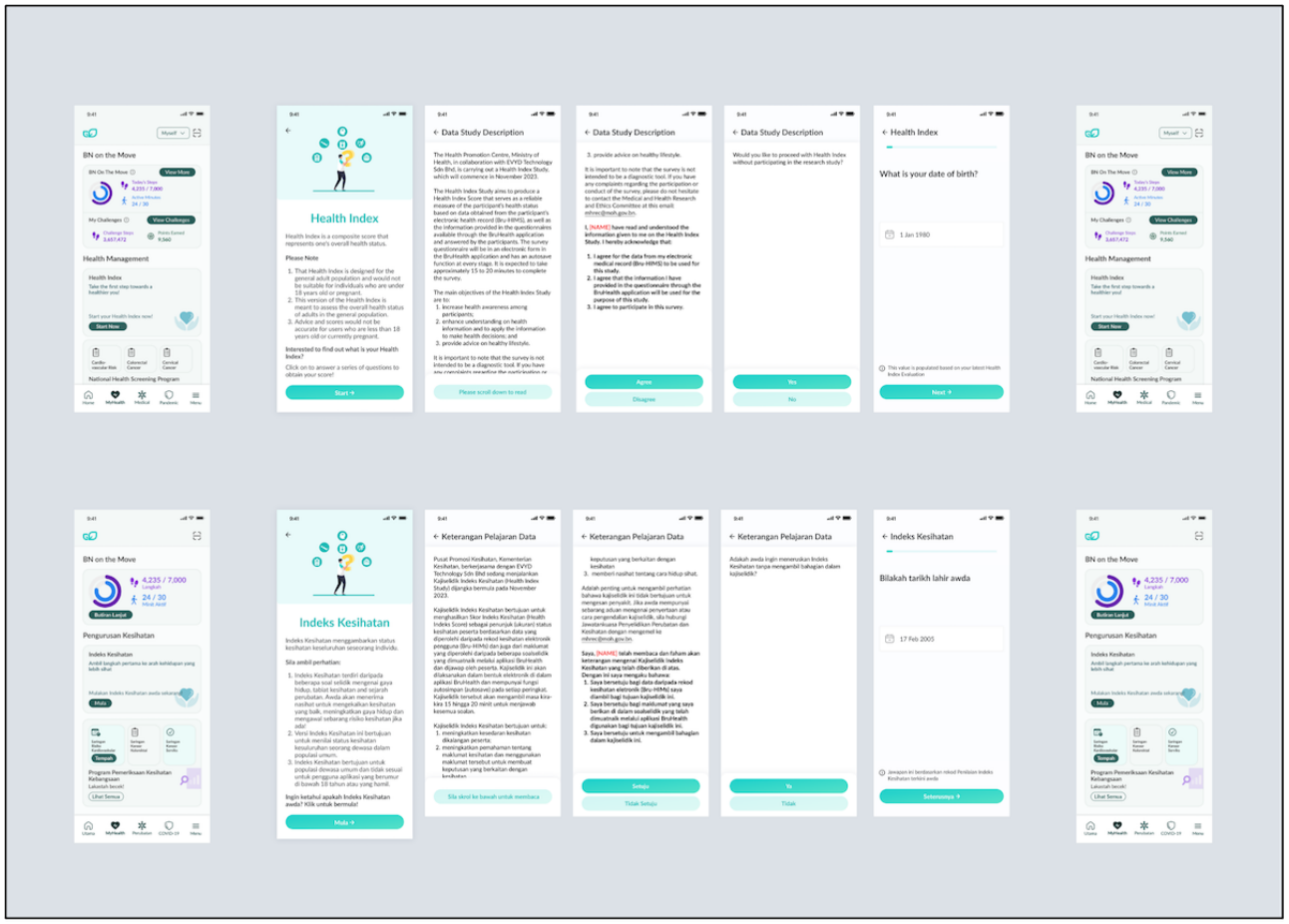
Figure 2. English and Malay user interface of Health Index.



Data for the study will be collected from (1) the national EMR system, Bru-HIMS, and (2) BruHealth (mobile app). Prior to analysis, all records will be desensitized and anonymized by removing personal identifiers (eg, names, identity card numbers, dates of birth). The Ministry of Health, Brunei Darussalam, retains full data ownership and authorizes access only to approved researchers, who are subject to security audits.

The anonymized dataset will be aggregated into data tables and stored in secure servers that meet national data governance and security standards. Data will be stored for 5 years after the completion of the research study and will be destroyed thereafter in compliance with the Ministry of Health's regulations.

Structure of Health Index

This study describes the pilot deployment of Health Index, which is integrated into the national BruHealth mobile app. The Health Index comprises 5 domains as follows:

1. Physical health: the physical health domain captures users' basic profiles, important biomarkers, and lifestyles that are correlated to the development of NCDs.
2. Mental health: as one pillar of lifestyle medicine, mental health problems can lead to several health issues, such as obesity and immune dysfunction.
3. Diet: food intake has a large impact on health. An unhealthy diet, especially low fiber, high sugar, and saturated fat intake, can contribute to the development of NCDs.
    a. Physical activity: Physical activity is an area where related literature is abundant and continuously shows its health-promoting benefits. Regular physical activity can result in better psycho-physical health.
4. Frailty: we measure frailty for users older than 60 years as a way to predict the risk of adverse outcomes associated with frailty. Based on the results, specific interventions or treatment plans can be developed.

The selection of health domains included in the Health Index was informed by a combination of literature review and expert consensus. The physical health domain is useful to capture biomarker information that is commonly used by health professionals to identify and manage chronic diseases. Some of the biomarkers asked in Health Index are blood pressure, low-density lipoprotein level, and hemoglobin A_{1c} level, all of which are important biomarkers of metabolic syndrome and other common NCDs. Mental health, diet, and physical activity are 3 of the main pillars of lifestyle medicine, which is a branch of evidence-based health care prioritizing disease prevention rather than treatment [17]. Mental health and stress are known risk factors affecting chronic diseases and mortality [17]. Moreover, multiple studies have confirmed the benefits of a healthy diet on chronic disease prevention and even reversal [17]. Physical activity is another pillar of lifestyle medicine that has a profound impact on longevity and health span [17]. Finally, frailty assessment is useful to identify older adults who are at higher risk of adverse health outcomes.

Once entering the Health Index page, users' health profiles will be created, and the overall health status will be calculated based

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on 3 main sources of data, including (1) EMR, (2) self-reported data, and (3) validated questionnaires on mental health, diet quality, physical activity, and frailty. First, users will be asked a series of basic demographic questions followed by physical health and lifestyle questions. These include biochemical lab tests that have been conducted, as well as family history and past medical history (Figure 3). Basic demographic data and the latest available biochemical data (defined as relevant tests conducted within the past 1 year prior to filling in the Health Index), if available, will be extracted from Bru-HIMS and auto-populated in the respective questions. Table 2 lists all the questions that capture this kind of information.

Figure 3. Health Index user workflow. DASS-21: Depression Anxiety and Stress Scale 21; FRAIL: Fatigue, Resistance, Ambulation, Illnesses, and Loss of weight; HbA_{1c}: hemoglobin A_{1c}; IPAQ-SF: International Physical Activity Questionnaire-Short Form; LDL: low-density lipoprotein; SFFFQ: Short Form Food Frequency Questionnaire.

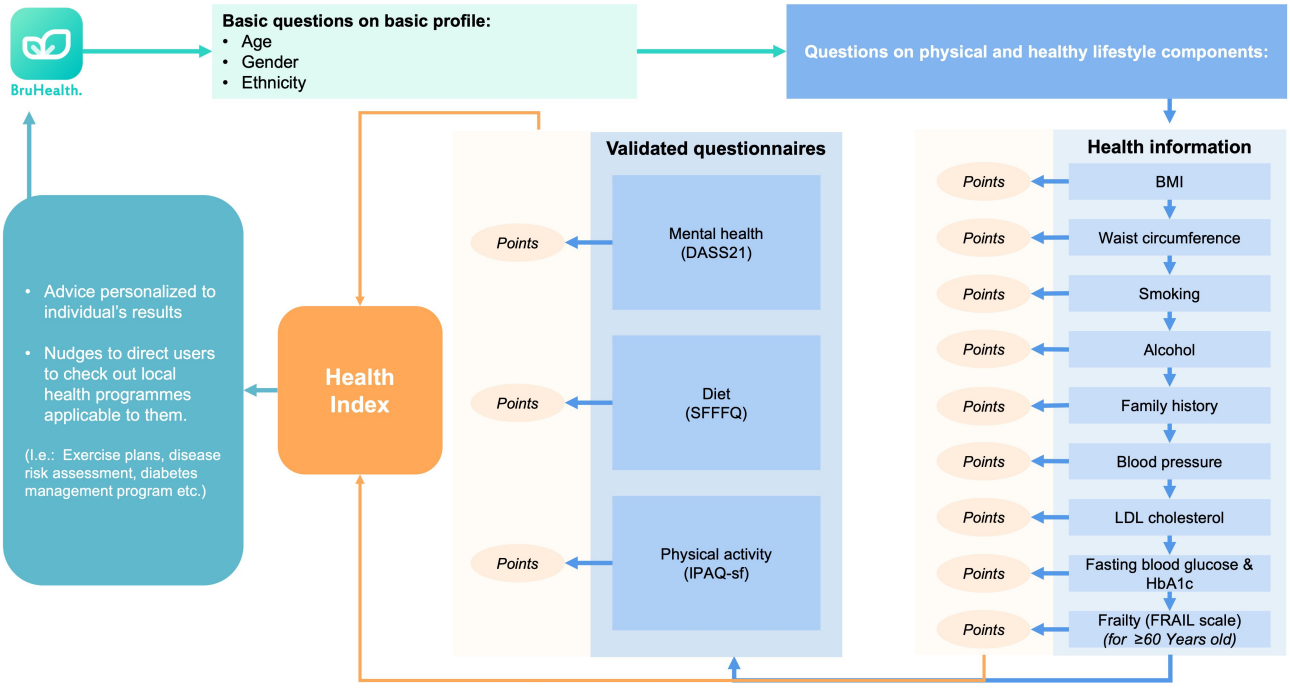

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Table . List of questions to capture users' physical health and lifestyles.

Domains	Questions
Basic profile	• What is your date of birth? • What is your birth gender? • What is your ethnicity?
Physical health	• What is your height? • What is your current weight? • What is your most recent waist circumference?
Lifestyle	• What is your smoking status? • Do you drink alcohol? • On average, how many standard drinks do you drink a week? (Regular beer: 1 can, 330 ml; hard liquor: 1 shot, 30 ml; wine: 1 small glass, 100 ml)
Basic profile	Do you have any family members who are diagnosed with any of the following? • Diabetes mellitus • First-degree family member with premature CVD[a] (male <55 y, and female <65 y) • Familial hyperlipidemia (genetic condition that leads to high cholesterol levels) Do you have any medical history of the following conditions: • CVDs • Cerebrovascular diseases • Cancer • Hypertension • Diabetes • Unsure
Physical health	• What is your most recent systolic blood pressure (the upper reading on monitor)? • What is your most recent diastolic blood pressure (the lower reading on monitor)? • Have you ever been diagnosed with hypertension (high blood pressure) before? • What is your most recent LDL[b] cholesterol level (bad cholesterol)? • Have you ever been diagnosed with dyslipidemia (high cholesterol) before? • Have you ever been diagnosed with type 2 diabetes mellitus before? • What is your most recent fasting blood glucose level? • What is your most recent HbA_{1c}[c] level?

[a]CVD: cardiovascular disease.

[b]LDL: low-density lipoprotein.

[c]HBA_{1c}: hemoglobin A_{1c}

Bru-HIMS is a national e-health initiative that was launched by the Ministry of Health in September 2012 [18]. The initiative adopts the concept of "One Patient, One Health Record," where each individual's health care data from all government hospitals, outpatient services, treatment centers, and clinics is together under one EMR. This will allow health care professionals access to patient records in real time at the point of care throughout government hospitals and health centers nationwide.

Next, users will be asked to complete a series of questionnaires for objective assessment. These questionnaires are used to assess users' mental health status, diet quality, and physical activity level. These questionnaires include the Depression Anxiety and Stress Scale 21 (DASS-21) for emotional states of depression [19], anxiety, and stress; the Short Form Food Frequency Questionnaire (SFFFQ) for diet quality [20]; and the International Physical Activity Questionnaire-Short Form (IPAQ-SF) to measure physical activity level [21]. For users aged 60 years and above, an additional questionnaire will be included to screen for frailty. The validated Fatigue, Resistance, Ambulation, Illnesses, and Loss of Weight (FRAIL) scale questionnaire is used for this purpose [22]. We have obtained approvals from relevant bodies to use these validated questionnaires in the Health Index.

The Health Index scores will then be calculated using all 13 factors of health criteria mentioned above. It is computed using a multidomain, rule-based scoring framework that integrates all the 13 health factors. While the exact algorithm and weightages are proprietary and cannot be publicly disclosed,

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the scoring system, including weightages, was designed with input from a multidisciplinary panel of local medical domain experts based in primary health care, community nutrition, sports and exercise medicine, psychiatry and psychology, geriatrics, as well as health promotion. The scoring methodology is as follows:

$$HI = S_i [physical_health \times w_1 + mental_health \times w_2 + diet \times w_3 + physical_activity \times w_4 + frailty \times w_5]$$

where *HI* is Health Index; S_i is normalized score (0 to 100 scale with min-max normalization); w_i are weights for each domain (for users under 60 y, the weight for frailty is 0 and the weights are redistributed proportionally among the other 4 domains). In the current Health Index, we apply equal weightages (w_i) for all 5 health domains. However, as we gather more data, we aim to recompute the weightages by applying various statistical techniques, such as the graded response model (of item response theory), and ML techniques in the future.

A scoreboard system is used to map the severity of risk factors to derive the final numerical score, which is a number between 0 and 100. No normalization is performed, and the raw value is used for mapping. The panel considered the relative impact of each factor on overall health, based on both clinical experience and literature review. The scores for each health domain are derived through appropriate guidelines from different validated sources (Table 3). Future research will focus on validating the algorithm's predictive performance and real-world use. Future versions of Health Index will explore the application of ML techniques to replace the fixed, arbitrary, and rule-based scoring systems.

Table . Scores for health domains based on different guidelines.

Health domains	Guidelines and their references
BMI	• WHO[a] [23,24]
Waist circumference	• WHO [24]
Blood biomarkers	• Brunei Darussalam National Hypertension Guideline [25] • Brunei Darussalam National Hyperlipidaemia Guidelines [26] • Ministry of Health Singapore Clinical Practice Guidelines: Lipids [27] • Brunei Darussalam National Health Screening Guideline on NCDs[b] 2020 [28]
Smoking	• WHO [29]
Alcohol	• The American College of Cardiology/American Heart Association Guideline [30]

[a]WHO: World Health Organization.

[b]NCD: noncommunicable disease.

However, while Health Index gives a more comprehensive view of an individual's overall health status, it is important to acknowledge the limitations of the data sources. Self-reported data are often subject to recall bias, social desirability bias, and misreporting, which can affect the reliability of inputs such as lifestyle behaviors or perceived health conditions. Similarly, EMRs may vary in completeness and accuracy due to inconsistent documentation practices, missing data, or differences in coding standards. All these limitations may present uncertainty in the calculation of the Health Index and should be considered when interpreting results.

Finally, a Health Index result will be generated to assess users' health status, categorizing them as either healthy, at risk, or in poor health (Textbox 1). The preliminary risk classification thresholds based on expert consensus are as follows:

Textbox 1. A sample of description of the "At Risk" category.

> Your result places you in the "At Risk" category. You may have certain risk factors that may contribute to poor health outcomes in the future. To find out more about how you can improve your overall health and reduce your risk of developing chronic diseases, tap on the cards under health advice.
>
> Disclaimer: To improve the accuracy of your score, do ensure that you completed all questions with the most accurate information.

1. Healthy: score ≥82 indicates minimal risk. The cutoff equals the total of each health domain's low-risk minimum score multiplied by its weightage.
2. At risk: scores between 31 and 81 indicate moderate risk requiring intervention. The cutoff is calculated by multiplying the minimum and maximum scores of the moderate-risk categories in each health domain by their respective weightages and then summing the results.
3. Poor health: score ≤30 indicates significant risk. The cutoff is determined by summing the weighted maximum scores of the high-risk categories across all health domains.

Users will also be able to view health advice based on their answers to the questionnaires (Textbox 2). Figure 4 depicts the general flow of the Health Index model.

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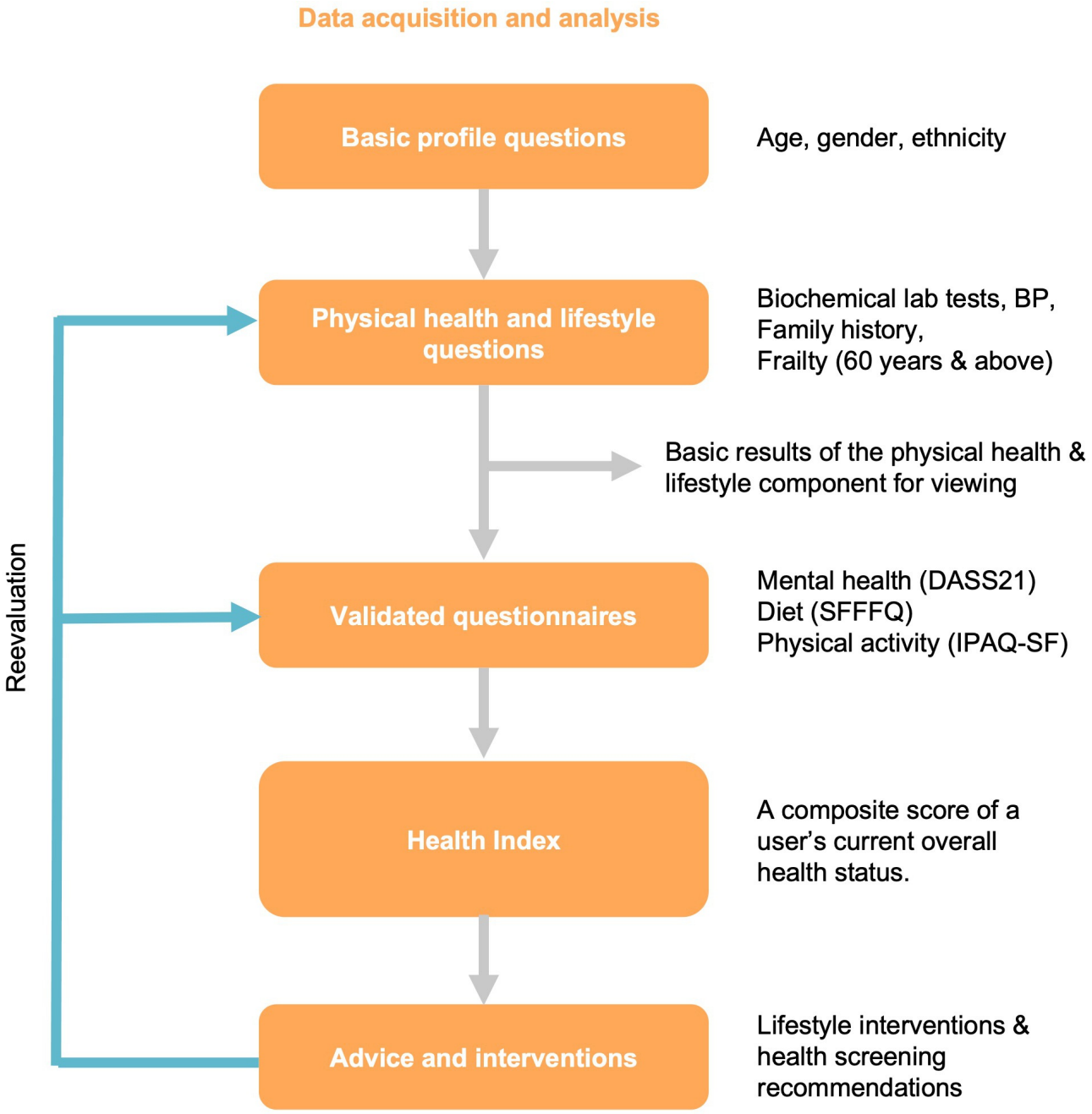
Textbox 2. A sample of health advice that will be received by users.

Health domain (BMI) and Score (at risk), overweight (≤29.9 kg/m^2)
Health advice: your BMI is in the overweight category. Being overweight puts you at risk of developing chronic diseases such as diabetes, hypertension, and coronary heart disease. Start adopting a healthy and active lifestyle before it's too late! Lowering your BMI starts with increasing your physical activity and sticking to a healthy eating plan.

Figure 4. General flow of Health Index. BP: blood pressure; DASS-21: Depression Anxiety and Stress Scale 21; IPAQ-SF: International Physical Activity Questionnaire-Short Form; SFFFQ: Short Form Food Frequency Questionnaire.



Data Analysis and Validation Strategy

The Health Index is intended to undergo future validation using appropriate statistical methods to assess its reliability. These validation efforts will include assessing the potential associations with clinical outcomes using real-world health data.

The objective of the data analysis is to retrospectively investigate if the Health Index score is correlated with participants' actual health outcomes using the existing data in Bru-HIMS. The health outcomes of interest are NCDs, including but not limited to diabetes, ischemic heart disease, stroke, chronic kidney disease, breast cancer, colorectal cancer, chronic obstructive pulmonary disease, lung cancer, and other morbidities. We consider NCD-related health care use, which includes length of hospital stays, number of visits to primary care centers, as well as hospitals, and the medication prescription status. To note, health

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care use has been used as a target variable when validating risk prediction tools [31-33].

To validate the Health Index framework, several statistical tests will be conducted to examine whether there are statistically significant differences in the NCD-related health care use among participants with different Health Index scores and categories. As we would only use the data for participants who have completed the whole Health Index questionnaire, missing data are not expected in the study. First, differences in health care use across different Health Index categories ("healthy," "at risk," and "poor health") will be assessed using one-way ANOVA or Kruskal-Wallis tests. Next, we could investigate if participants in 3 different health categories have a significantly different ratio of individuals with morbidities using a chi-square test. Moreover, the correlation between the Health Index raw score and health care use can be assessed using the Pearson correlation coefficient. Stratification may be done to control for potential confounding factors, including age, sex, and comorbidities. The receiver operating characteristic analysis will be used to evaluate Health Index's discriminative ability for predicting NCD diagnoses. Sensitivity and specificity metrics will be used to assess whether Health Index performs as indicated by cross-validation with existing NCD diagnoses in predicting NCD outcomes and health care use. Exploratory factor analysis (EFA) and subsequent confirmatory factor analysis (CFA) will be used to assess convergent and divergent (discriminant) validity. EFA will be used to explore the underlying items of Health Index's 5 domains to ensure that items load primarily on their intended domains with minimal cross-loadings. Whereas, CFA will confirm the factor structure, using fit indices, of the domains in the survey as a whole.

In addition to the above analysis, an assessment of the Health Index test–retest reliability is also planned. A subset of consenting participants may be invited to repeat the Health Index assessment after a defined time interval (eg, 2 weeks), enabling evaluation of temporal consistency using intraclass correlation coefficients or Cohen kappa.

Furthermore, to assess the initial scoring and weights mentioned above and move from expert consensus to data-driven weightages, we will use the graded response model (of item response theory), EFA, and CFA, structural equation modeling for multivariable outcomes, using clinical outcome variables as a criterion reference. In addition to receiver operating characteristic analysis, regression-based cutpoint estimation, and change-point or segmented regression models will be used to establish the cut-off points for risk levels.

Using G*Power software (Heinrich Heine University) [34], we calculated the sample size needed using the following parameters: (1) effect size=0.3, (2) α=.05, and (3) power=0.80. Based on these inputs, it estimated a total sample size of at least 36 participants per Health Index category needed.

Ethical Considerations

This study was reviewed and approved by the Medical and Health Research and Ethics Committee of the Brunei Darussalam Ministry of Health, under approval reference number MHREC/MOH/2023/22(1). All participants provided informed consent electronically within the BruHealth mobile app. A consent form has been obtained for all participants, and no financial compensation was given for taking part in this study. All data collected were stored in safe, password-protected computers, which were only accessible to the researchers. All data were de-sensitised and anonymised prior to analyses by removing all personal identifiable information such as names, identity card numbers and dates of birth.

Results

Previously, a preliminary national field test for Health Index was conducted to obtain health-seeking behavioral insights on the Health Index use. A total of 1200 active users on BruHealth were randomly selected according to age and gender. A total of 13.8% (166/1200) of the targeted users completed the questionnaires within 1 month. One of the main findings was 85% (1019/1200) of the participants were in the "At Risk" category, 13.9% (167/1200) of them were in the "Healthy" category, and 1.2% (14/1200) of them were in the "Poor Health" category. Another interesting finding is that diet was the most prominent outcome of potential concern (Figure 5).

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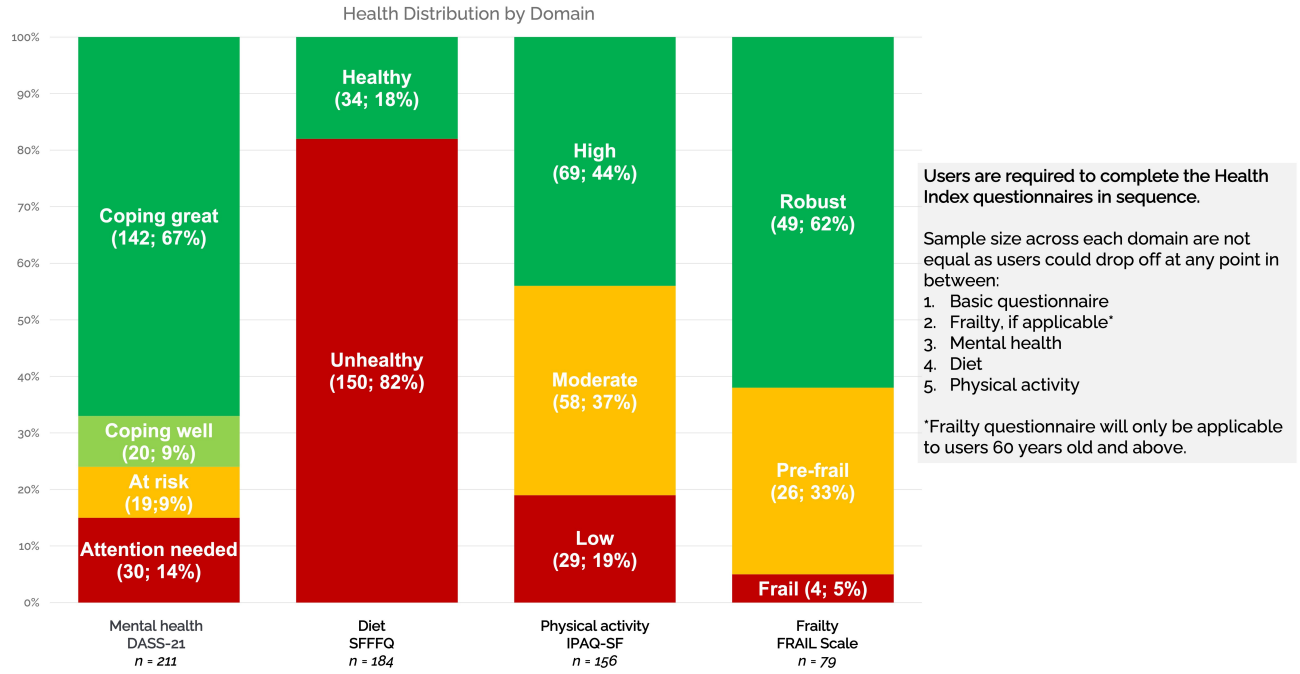
Figure 5. Unhealthy diet as the most prominent outcome of potential concern. DASS-21: Depression Anxiety and Stress Scale 21; FRAIL: Fatigue, Resistance, Ambulation, Illnesses, and Loss of Weight; IPAQ-SF: International Physical Activity Questionnaire-Short Form; SFFFQ: Short Form Food Frequency Questionnaire.



The median age of the participants was 45 (interquartile range (IQR) 36 - 58) years. The female-to-male ratio was 53% (636/1200): 47% (564/1200). In terms of ethnicity, 83.1% (997/1200) were Malays, 11.5% (138/1200) Chinese, and 5.4% (65/1200) from other ethnic groups. The distribution of participants across districts was as follows: 75.9% (911/1200) from Brunei Muara, 15.7% (188/1200) from Belait, 7.2% (86/1200) from Tutong, and 1.2% (14/1200) from Temburong. These figures are similar to the population figures provided by the Department of Economic Planning and Statistics, Ministry of Finance and Economy, Brunei Darussalam [35].

Furthermore, we tried to briefly analyze the correlation between Health Index and NCD-related health care use as the health care outcome, which is the number of outpatient visits related to NCDs in the past 1 year (Figure 6). In this preliminary analysis, we identify differences between different health categories in terms of the counts of outpatient visits. Those people in at-risk and poor health groups tend to have higher NCD-related health care use compared to those in the healthy group. However, we acknowledge that the results are preliminary, and we have a small sample size as well as group imbalance. Therefore, we are committed to continuing to validate our Health Index with a larger sample size in the future.

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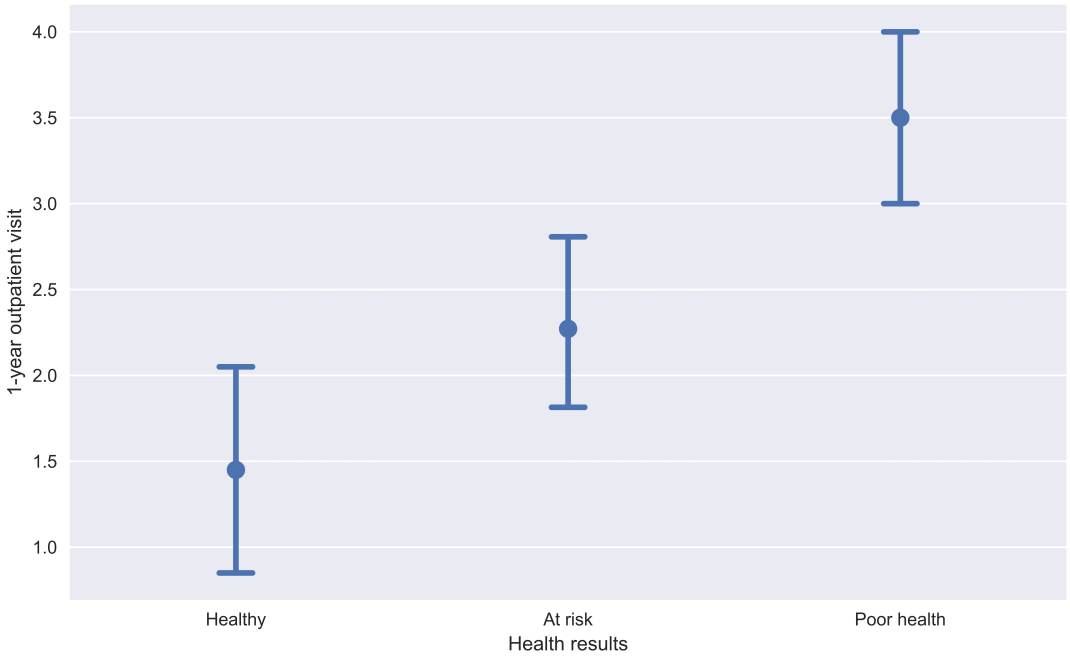
Figure 6. Noncommunicable disease–related health care use among different Health Index categories.



With effective nudging strategies, which can potentially increase public interest in participation, the Health Index is able to capture a holistic health status of participants while considering existing diagnoses, showing great promise as a population health management tool.

Discussion

Principal Findings

In this study, we present the initial user engagement to assess its feasibility for large-scale deployment, laying the groundwork for future validation studies. Health Index can improve early identification of individuals at risk of developing NCDs and support health promotion through personalized feedback, thus contributing to more targeted and effective prevention strategies. Long-term goals include improving health literacy, promoting the adoption of healthier behaviors, and enabling earlier identification of individuals at risk for NCDs. These outcomes will be measured using follow-up user surveys, behavioral tracking, and linkage to health care use data. As discussed above, we acknowledge several limitations of the Health Index in its current form, including its reliance on self-reported data, which are often subject to bias. To address this, we plan to enable users to give permission for the app to extract data from their EMR stored in the Bru-HIMS to complete several physical health-related questions or use wearable devices to answer lifestyle-related questions. Apart from that, we plan to perform a reliability analysis to measure the consistency of the Health Index when repeated several times within a short period. Another limitation is the arbitrary thresholds and small pilot sample size. To tackle these issues, we plan to perform a graded response model, EFA, and CFA, and apply ML models to assess the initial scoring and weights. As the sample size would continuously increase, we would repeat our validation approaches to revalidate the Health Index on a larger sample size. Furthermore, we recognize the potential of ML to improve accuracy and personalization in future iterations. At this stage, the integration of ML has not been implemented or evaluated in the current version of Health Index. In the future, we plan to incorporate ML into the Health Index. The Health Index framework will be improved by identifying any clinical factors (eg, lab tests, demographics, family history, etc) based on Brunei population data that are associated with good prediction of the health outcomes of interest, which have not been identified in the current framework.

One possibility is to use ML to calculate the importance of each domain in the Health Index. One popular method to apply is the Shapley additive explanations (SHAP) method [36], which is a game theory-based method for explaining the results generated by any ML model. Based on the weights derived from SHAP, the weights of the domains in Health Index can be adjusted to better capture the effects of specific factors on users' health care outcomes. Not only can the domain weights be computed, but also the weight for each of the questions in the questionnaires if sufficient data can be collected. Different populations may have different magnitudes of importance of factors that affect the health care outcomes. Through weight adjustment, the Health Index can be continuously improved to meet the needs of different populations with different characteristics.

Another possibility where ML can play an important role in the Health Index is dimensionality reduction or feature selection. In the future, we aim to reduce the number of questions to improve the user experience. To implement this, several ML models can be used. First, SHAP could still be applied to find

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out the importance of each question in the questionnaires. Then, top *k* questions can be chosen based on the importance, while the rest can be removed. Other ML techniques that can be used for this purpose are information gain, Fisher score, and wrapper methods.

Conclusions

NCDs typically develop over many years and cause symptoms. Therefore, identifying the risk factors and addressing them early is the most cost-effective solution for public health. In this study, we have proposed a simple yet practical composite health score called "Health Index." From a health perspective, an increasingly robust Health Index over time is intended for a timelier prompt of NCDs risk assessment for users, which in turn will allow early detection of the key risk factors of NCDs for early actions and health risk management. Resource-wise, findings from the Health Index can support policymakers in planning and allocating appropriate and adequate efforts and resources more effectively in the country. Identified risk factors can also direct national health plans and strategies in Brunei Darussalam. Finally, it can also support policymakers in setting outcome-based measures to drive overall quality and value improvements. In the future, we aim to retrospectively and prospectively validate the Health Index, as well as address some of its limitations as discussed previously.

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Conflicts of Interest

RWO, JT, and JJFL are full-time employees of EVYD Technology, while RO, SYC, and PW are affiliated with EVYD Technology. EVYD Technology is the technology partner and research collaborator of this study. EVYD Technology is the developer of the BruHealth mobile app used in this study. The authors declare that there is no other conflict of interest.

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Abbreviations

Bru-HIMS: Brunei Health Information and Management System
CDC: Center for Disease Control and Prevention
CFA: confirmatory factor analysis
CVD: cardiovascular disease
DASS-21: Depression Anxiety and Stress Scale 21
EFA: exploratory factor analysis
EMR: electronic medical record
FRAIL: Fatigue, Resistance, Ambulation, Illnesses, and Loss of Weight
IPAQ-SF: International Physical Activity Questionnaire-Short Form
LWB-I: lifestyle and well-being index
mHealth: mobile health
ML: machine learning
NCD: noncommunicable disease
PIS: participant information sheet
SFFFQ: Short Form Food Frequency Questionnaire
SHAP: Shapley additive explanations
WHO: World Health Organization

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Use Patterns and Challenges of the Social Media Platform X Among Physiotherapists in Saudi Arabia: Cross-Sectional Study

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Abstract

Background: Social media platforms have become salient channels for health care professionals' continuous education and professional development. Among them, X (formerly known as Twitter) is used by physiotherapists for engaging in evidence-based discussions and accessing emerging research. In Saudi Arabia, a country with a high social media penetration rate, the platform offers unique opportunities and challenges for physiotherapy-related knowledge acquisition and networking.

Objective: This study aimed to determine how physiotherapists in Saudi Arabia engage in physiotherapy-related debates on X, explore their use patterns, and identify associated challenges and perceived professional benefits.

Methods: We conducted a cross-sectional online survey among licensed physiotherapists registered with the Saudi Commission for Health Specialties. The questionnaire covered demographic data, social media use, interaction patterns, perceived challenges, and motivations for use. Descriptive statistics and chi-square tests were used to examine demographic data, use patterns, challenges and concerns, perceived professional benefits, and the association between demographic characteristics and use patterns. Statistical significance was set at $P<.05$.

Results: Of 193 responses, 188 (97.4%) were valid and included in the data analysis. Among the respondents, 76.1% (143/188) reported having an active account on X. Most respondents were female (109/188, 58.0%) and aged 31 to 40 years (79/188, 42.0%). The time spent on the platform varied, with 32.9% (47/143) spending 4 to 6 hours a week and 27.3% (39/143) spending less than an hour per week. Respondents' interaction extent was moderate, with 35.7% (51/143) reporting occasional interaction. The respondents mainly interacted with knowledge-sharing posts (102/143, 71.3%), followed by training- or workshop-related posts (94/143, 65.7%). The respondents reported difficulty in finding reliable information (75/143, 52.4%), time constraints (58/143, 40.6%), communication barriers (69/143, 48.3%), and conflicts of interest (74/143, 51.7%) as challenges concerning engaging in physiotherapy-related debates on X. Despite these concerns, many respondents acknowledged the platform's value as 60.1% (86/143) agreed that it helped them stay updated with emerging research, 68.5% (98/143) believed that it fostered knowledge sharing, and 67.8% (97/143) believed that it enhanced critical thinking among the community.

Conclusions: Physiotherapists in Saudi Arabia demonstrated active engagement with physiotherapy-related content on X for professional development. While the platform offers valuable opportunities for learning and collaboration, notable barriers such as information credibility and time limitations must be addressed. Enhancing digital literacy and establishing clear guidelines for professional social media use may help maximize the platform's potential as a tool for continuous development in physiotherapy practice.

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KEYWORDS

social media; professional development; physical therapists; knowledge management; health education; cross-sectional studies; evidence-based practice; Saudi Arabia; internet communication tools; social networking

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Introduction

Social media has transformed the way in which health care professionals engage in continuous learning, networking, and professional development [1]. Among the numerous social media platforms, X (formerly known as Twitter) serves as a prominent platform for discussions concerning evidence-based practice, clinical decision-making, and new research findings among physiotherapists. As health care disciplines become more digitally integrated, X and analogous platforms facilitate real-time knowledge exchange and professional dialogue [2,3]. Within the scope of digital professionalism, health care professionals are encouraged to engage in ethical, effective, and respectful online communication. When such professionalism is present, digital platforms such as X can promote professional participation, collaboration, and knowledge sharing. Online learning frameworks, particularly those presented by Anderson [4] and Garrison et al [5], underscore the significance of social presence, cognitive presence, and teaching presence in establishing a successful online learning environment. Therefore, platforms such as X can function as venues for professional learning via interaction and discussion. Furthermore, health communication theories such as the social cognitive theory [6] emphasize how individuals' behaviors are influenced by observing others, particularly within online communities. Accordingly, health care professionals may adopt best practices and engage in evidence-based discussions through X.

While X provides opportunities for information dissemination and online learning, challenges such as content reliability, engagement barriers, and ethical concerns remain understudied, particularly in the context of physiotherapy practice in Saudi Arabia [1,7,8]. Saudi Arabia has one of the highest social media penetration rates worldwide [9-11], making it a fertile ground for exploring how digital platforms influence professional development among physiotherapists. Previous studies have examined the application of social media in health care [1,7,8]. However, research on the engagement patterns, challenges, and perceived benefits of X within the physiotherapy community remains limited [1,12,13]. Addressing this gap can provide insights into how physiotherapists use X for knowledge acquisition, professional networking, and overcoming practice-related challenges. Therefore, this study aimed to (1) assess the professional use of X among physiotherapists in Saudi Arabia (prevalence of active accounts, time spent on use, interaction level, and primary purpose of engagement) and (2) identify the challenges and motivations concerning physiotherapy-focused debates on X.

Methods

Design and Setting

This cross-sectional study was conducted in accordance with the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE), Checklist for Reporting of Survey Studies (CROSS), and Checklist for Reporting Results of Internet E-Surveys (CHERRIES) guidelines to enhance methodological rigor, survey transparency, and reporting completeness. Data were collected via an online survey conducted among licensed physiotherapists practicing across various health care settings. Furthermore, we adhered to established research guidelines to ensure validity and reliability.

Participants and Recruitment

This study targeted licensed physiotherapists who were registered with the Saudi Commission for Health Specialties (SCFHS) and were actively working in Saudi Arabia. Physiotherapy students, interns, and professionals without an active SCFHS registration were excluded. Using convenience sampling, we distributed participation invitations within physiotherapy-focused professional groups on social media platforms such as WhatsApp, Telegram, and X. The invitation stated the following: "Licensed physiotherapists in Saudi Arabia are invited to participate in a voluntary and anonymous survey examining physiotherapists' use of X for professional development." This wording was consistent across all channels used for dissemination. Additionally, the invitation described the study's purpose and eligibility criteria.

Survey Instrument

A structured questionnaire was developed based on a comprehensive review of relevant literature and prior studies investigating social media engagement in health care [8,12-18]. This review provided the initial pool of survey items covering use patterns, interaction behaviors, and challenges and motivations related to engagement on X. Consequently, the questionnaire comprised 4 main sections.

Through 6 items, the first section collected demographic information (age, sex, years of experience, highest level of education, and workplace setting [government hospital, private clinic, private hospital, or academic institution]) and whether the respondent had an active account on X. The second section comprised 3 items and collected data on social media use and interaction: frequency of use, time spent on X, preferred content type (eg, debates, knowledge sharing, mentorship, and training), and pattern of engagement. The third section consisted of 5 items and collected data on challenges and concerns regarding engaging in physiotherapy-related debates on X, such as time constraints, information credibility, communication barriers, and conflicts of interest. The final section comprised 5 items and explored the motivations for and perceived benefits of following physiotherapy-related debates on X.

The questionnaire included a combination of multiple-choice questions and Likert-scale items. We conducted a pilot test among 10 to 15 licensed physiotherapists to assess clarity, comprehension, flow, and item relevance. On the basis of their feedback on phrasing, ease of completion, and the appropriateness of the response options, we refined several items for clarity, removed ambiguous statements, and reordered questions for readability and coherence. The final version demonstrated satisfactory internal consistency (Cronbach α=0.87), ensuring reliability and content validity before full deployment.

Data Collection

The survey was conducted on SurveyMonkey (SurveyMonkey Inc) from January 5, 2024, to February 10, 2024. The

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participants were required to provide informed consent before starting the survey. The survey spanned 5 pages, which included the consent page, demographic items, use questions, and challenge- and motivation-related items. The estimated completion time was 10 to 15 minutes. To ensure data quality and prevent duplicate responses, we activated SurveyMonkey's built-in "Prevent multiple submissions" feature (cookie based) and enabled IP address tracking and time stamp checks. The IP addresses were automatically collected by the platform for quality control but were not analyzed, linked to individual responses, or included in the exported dataset.

Data Analysis

Descriptive statistics (frequencies and percentages) were used to summarize participant characteristics and patterns of professional use of X. Next, we examined the association between demographic characteristics and use patterns using chi-square tests. Because the variables in this study were primarily categorical, no *t* tests or ANOVA were conducted. Missing data were assessed to determine the underlying mechanism, and patterns suggested that data were missing completely at random as there was no systematic association between missingness and participant characteristics. Therefore, pairwise (available-case) deletion was used to handle missing values rather than imputation. Subsequently, inferential analyses were performed to explore associations between physiotherapists' demographic characteristics and their professional use of X. Statistical significance was set at $P<.05$, and all analyses were conducted using SPSS Statistics (version 28; IBM Corp).

Ethical Considerations

This study complied with the principles outlined in the Declaration of Helsinki. Ethics approval was obtained from the King Saud Medical City Institutional Review Board (H-01-R-053). Participation was entirely voluntary, and informed consent was obtained electronically before the start of the survey. To ensure privacy and confidentiality, responses were anonymized before analysis. SurveyMonkey automatically collected IP addresses for quality control; however, these addresses were not analyzed, linked to responses, or included in the exported dataset. Participants did not receive any financial or nonfinancial compensation for taking part.

Results

Characteristics of the Participants

A total of 193 individuals accessed the survey. However, of these 193 individuals, 1 (0.5%) refused to participate, and 4 (2.1%) were not SCFHS-registered physiotherapists practicing in Saudi Arabia. After excluding these individuals, 97.4% (188/193) of the responses were used for data analysis (response rate consistent with the CROSS guidelines). Most participants were female (109/188, 58.0%) and in the 31- to 40-year age group (79/188, 42.0%). Regarding work experience, 38.8% (73/188) of the participants reported 11 or more years of experience, 36.7% (69/188) reported 0 to 5 years, and 24.5% (46/188) reported 6 to 10 years. Most participants held a bachelor's degree (132/188, 70.2%), followed by a master's degree (43/188, 22.9%) and a PhD (13/188, 6.9%). Most of the participants (113/188, 60.1%) worked in governmental hospitals, whereas 16.5% (31/188) worked in private clinics, 13.3% (25/188) worked in private hospitals, and 10.1% (19/188) worked in academic institutions. Furthermore, most participants (143/188, 76.1%) reported having an active account on X (Table 1).

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Table . Demographic and professional characteristics of licensed physiotherapists participating in a cross-sectional survey conducted in Saudi Arabia between January 2024 and February 2024 (n=188).

Characteristic and categories	Participants, n (%)
Age (years)	
20 - 30	66 (35.1)
31 - 40	79 (42.0)
41 - 50	31 (16.5)
51 - 60	12 (6.4)
Sex	
Female	109 (58.0)
Male	79 (42.0)
Experience (years)	
0 - 5	69 (36.7)
6 - 10	46 (24.5)
≥11	73 (38.8)
Highest level of education	
Bachelor's degree	132 (70.2)
Master's degree	43 (22.9)
PhD	13 (6.9)
Workplace setting	
Academic institution	19 (10.1)
Governmental hospital	113 (60.1)
Private clinic	31 (16.5)
Private hospital	25 (13.3)
Active account on X	
No	45 (23.9)
Yes	143 (76.1)

Patterns of Professional Use of X Among Physiotherapists in Saudi Arabia

Regarding the time spent per week following or viewing professional physiotherapy-related posts, 32.9% (47/143) of the participants spent 4 to 6 hours, 27.3% (39/143) spent less than an hour, and 25.9% (37/143) spent 1 to 3 hours. Regarding the extent of interaction with physiotherapy-related debates, 35.7% (51/143), 27.3% (39/143), and 18.2% (26/143) of the participants interacted occasionally, rarely, and frequently, respectively. Furthermore, the participants predominantly interacted with knowledge sharing–related (102/143, 72.3%), training- or workshop-related (94/143, 66.7%), or debate-related (37/143, 26.2%) posts (Table 2).

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Table . Patterns of professional use of X among licensed physiotherapists in Saudi Arabia based on a cross-sectional survey conducted between January 2024 and February 2024 (n=143).

Item and categories	Participants, n (%)
"How much time per week do you spend following or viewing professional physiotherapy-related posts on X?"	
Less than an hour	39 (27.3)
1 - 3 hours	37 (25.9)
4 - 6 hours	47 (32.9)
7 - 10 hours	11 (7.7)
More than 10 hours	9 (6.3)
"Please indicate the extent to which you interact with physiotherapy-related debates on X. (Interaction refers to commenting, reposting, liking, quoting, bookmarking, or sharing)"	
Very frequently	3 (2.1)
Frequently	26 (18.2)
Occasionally	51 (35.7)
Rarely	39 (27.3)
Not at all	24 (16.8)
"What types of professional posts do you interact with? (Please select all that apply). (Interaction refers to commenting, reposting, liking, quoting, bookmarking, or sharing)"	
Debates	37 (25.9)
Knowledge sharing	102 (71.3)
Collaborative projects	33 (23.1)
Teamwork or collaboration	25 (17.5)
Training or workshops	94 (65.7)
Mentorship or mentoring	11 (7.7)
I do not interact (only follow or view posts)	29 (20.3)

Association Between Demographic Characteristics and Use Patterns

Demographic Characteristics and Time Spent on the Platform

The chi-square tests revealed that the time spent following or viewing professional physiotherapy-related posts was significantly associated with sex (χ^2_4=18.8; *P*=.001) and workplace setting (χ^2_{12}=24.2; *P*=.02). In contrast, the time spent was not significantly associated with the highest level of education (*P*=.13), as shown in Table 3.

Table . Associations between demographic characteristics and patterns of engagement with physiotherapy-related debates on X among licensed physiotherapists in Saudi Arabia (cross-sectional study, 2024).

Demographic characteristic and outcome variable	Chi-square (*df*)	*P* value
Sex		
Time spent	18.8 (4)	.001
Interaction extent	7.7 (4)	.10
Highest level of education		
Time spent	12.4 (8)	.13
Interaction extent	7.1 (8)	.52
Workplace setting		
Time spent	24.2 (12)	.02
Interaction extent	27.7 (12)	.006

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Demographic Characteristics and Extent of Interaction

The extent of interaction (eg, liking, sharing, and commenting) was significantly associated with workplace setting (χ^2_{12}=27.7; *P*=.006). However, it was not significantly associated with sex (χ^2_4=7.7; *P*=.10) or highest level of education (χ^2_8=7.1; *P*=.52; Table 3).

Challenges and Concerns Regarding Engaging in Physiotherapy-Related Debates on X

Among the respondents, 49.0% (70/143) agreed or strongly agreed that they had encountered challenges or negative experiences, with 31.5% (45/143) remaining neutral on this issue. Lack of time was also a significant concern, with 40.6% (58/143) agreeing or strongly agreeing that it affected their interaction with physiotherapy-related debates, although a third of the respondents (48/143, 33.6%) disagreed or strongly disagreed. Finding relevant and reliable information was another challenge, with 52.4% (75/143) of the respondents agreeing or strongly agreeing that they experienced this issue, whereas 36.4% (52/143) remained neutral. Communicating ideas effectively was problematic for 48.3% (69/143) of the respondents, whereas 51.7% (74/143) reported experiencing conflicts of interest related to their personal or professional involvement (Table 4).

Table . Perceived challenges and concerns regarding engaging in physiotherapy-related debates on X among licensed physiotherapists in Saudi Arabia based on a cross-sectional survey conducted in 2024 (n=143).

Item and categories	Participants, n (%)
"I have encountered challenges or negative experiences while interacting with or following physiotherapy-related debates on X."	
Strongly disagree	7 (4.9)
Disagree	21 (14.7)
Neutral	45 (31.5)
Agree	59 (41.3)
Strongly agree	11 (7.7)
"Lack of time is a challenge that affects my interaction with physiotherapy-related debates on X."	
Strongly disagree	18 (12.6)
Disagree	30 (21.0)
Neutral	37 (25.9)
Agree	44 (30.8)
Strongly agree	14 (9.8)
"I have experienced challenges or difficulties in finding relevant and reliable information while following physiotherapy-related debates on X."	
Strongly disagree	2 (1.4)
Disagree	14 (9.8)
Neutral	52 (36.4)
Agree	55 (38.5)
Strongly agree	20 (14.0)
"I have experienced challenges or difficulties in communicating ideas effectively while participating in physiotherapy-related debates on X."	
Strongly disagree	3 (2.1)
Disagree	26 (18.2)
Neutral	45 (31.5)
Agree	51 (35.7)
Strongly agree	18 (12.6)
"I have experienced personal or professional conflicts of interest while interacting with or following physiotherapy-related debates on X."	
Strongly disagree	2 (1.4)
Disagree	19 (13.3)
Neutral	48 (33.6)
Agree	52 (36.4)
Strongly agree	22 (15.4)

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Motivations for and Perceived Benefits of Following Physiotherapy-Related Debates on X

As shown in Table 5, a significant proportion of physiotherapists (60% - 70%) saw value in engaging with debates on X as it allowed them to stay informed about new research; catered to their personal interests; and provided potential benefits for the wider physiotherapy community in terms of knowledge sharing, collaboration, and critical thinking. Among the respondents, 39.2% (56/143) agreed and 21.0% (30/143) strongly agreed that they engaged in physiotherapy-related debates because it offered them the opportunity to keep up with new and emerging research. Meanwhile, 39.2% (56/143) agreed and 23.8% (34/143) strongly agreed that they were motivated by their personal interest in the topics being discussed. Similarly, 42.0% (60/143) agreed and 26.6% (38/143) strongly agreed that the debates could facilitate knowledge sharing, collaboration, and networking among the physiotherapist community. Furthermore, 42.7% (61/143) agreed and 25.2% (36/143) strongly agreed that the debates could promote critical thinking and reflection on current practices. A total of 29.4% (42/143) to 33.6% (48/143) of the respondents remained neutral on these issues.

Table . Motivations for and perceived benefits of following physiotherapy-related debates on X among licensed physiotherapists in Saudi Arabia based on a cross-sectional survey conducted in 2024 (n=143).

Item and categories	Participants, n (%)
"I follow or interact with physiotherapy-related debates on X because it allows me to keep up with new and emerging research."	
Strongly disagree	3 (2.1)
Disagree	12 (8.4)
Neutral	42 (29.4)
Agree	56 (39.2)
Strongly agree	30 (21.0)
"I follow or interact with physiotherapy-related debates on X because I have an interest in the topics being discussed."	
Strongly disagree	2 (1.4)
Disagree	12 (8.4)
Neutral	39 (27.3)
Agree	56 (39.2)
Strongly agree	34 (23.8)
"Following or interacting with physiotherapy-related debates on X can facilitate knowledge- and experience-sharing among the physiotherapist community, thereby fostering collaboration and networking."	
Strongly disagree	2 (1.4)
Disagree	5 (3.5)
Neutral	38 (26.6)
Agree	60 (42.0)
Strongly agree	38 (26.6)
"Following or interacting with physiotherapy-related debates on X can promote critical thinking and reflection on current practices among the physiotherapist community."	
Strongly disagree	1 (0.7)
Disagree	8 (5.6)
Neutral	37 (25.9)
Agree	61 (42.7)
Strongly agree	36 (25.2)
"To what extent would you recommend physiotherapy students or colleagues to follow or interact with physiotherapy-related debates on X?"	
Strongly disagree	2 (1.4)
Disagree	9 (6.3)
Neutral	48 (33.6)
Agree	48 (33.6)
Strongly agree	36 (25.2)

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Discussion

Principal Findings

The findings of this study align with those of previous research indicating that social media platforms, particularly X, serve as valuable tools for professional development and knowledge sharing among health care professionals [12,13]. Similar to prior studies, this study found that physiotherapists in Saudi Arabia actively use X for knowledge acquisition and training opportunities [17,18]. However, as this cross-sectional survey–based study collected self-reported data, the associations should be interpreted with caution, and causal inferences cannot be drawn about practice changes. The high engagement rate suggests that X is widely accepted as an informal learning tool and it may complement traditional educational methods in physiotherapy [16].

However, this study also highlighted significant challenges associated with the use of social media for professional development. Concerns about information credibility and time constraints were commonly reported, mirroring the findings of studies involving other health care professionals [14,15]. Moreover, previous studies have reported that the difficulty in distinguishing between evidence-based content and misinformation hinders effective engagement on health care–related social media channels [19]. Addressing these concerns through improved content curation and institutional guidelines may enhance the usability of X as a source of professional development. Furthermore, recent studies, particularly those in the health care field, have reported concerns about unprofessional behavior on social media. Vukušić Rukavina et al [20] emphasized the importance of defining and addressing unprofessional behaviors online to ensure that health care professionals maintain ethical standards in digital spaces.

Similar to our findings, Alasfour et al [1] reported that, while X positively affects physiotherapists' professional development, a substantial portion of users remain passive consumers rather than active participants in discussions. In this study, demographic variables such as sex and workplace setting strongly influenced the time spent on the platform. This finding aligns with those of other research suggesting that personal motivation or digital literacy may play a larger role in determining platform use patterns, which reflects global trends in health care professionals' social media engagement [7,21]. Future efforts should increase active participation through strategies such as structured online discussions, mentorship programs, and incentives for contribution. Social media presents not only benefits but also potential risks for health care professionals. Vukušić Rukavina et al [22] reviewed the dangers and benefits of social media use, stressing the potential for professional growth and networking while cautioning against the risk of diminished professionalism if used improperly. These findings underscore the necessity of establishing professional guidelines and enhancing digital literacy to maximize the advantages of online engagement while safeguarding against its potential pitfalls.

The recommendations in this study align with those of previous research advocating for clearer professional guidelines on social media use for physiotherapy professional growth [12,13]. Establishing best practices and offering professional training on effective digital communication can further enhance the platform's role in facilitating continuous learning and professional networking. Overall, the findings reinforce the importance of social media as an emerging tool for physiotherapy education while emphasizing the need for addressing engagement barriers to maximize its potential.

Limitations

This study has several limitations. First, the use of convenience sampling may have introduced selection bias and limited generalizability. Because recruitment was conducted through physiotherapy-focused social media groups, the sample likely overrepresented physiotherapists already active on social media platforms. Consequently, the findings may not fully reflect the behaviors and perspectives of all SCFHS-registered physiotherapists, particularly those who are less digitally engaged or not present in such online communities. Second, the reliance on self-reported data may have led to recall or social desirability bias. Third, while inferential tests were conducted, the study's design was descriptive. Therefore, these analyses should be interpreted with caution. Future studies should use probability sampling or mixed methods approaches.

Conclusions

There is a high prevalence of active X accounts among SCFHS-registered licensed physiotherapists. With 1 to 6 hours a week spent on the platform, they exhibited high levels of engagement with physiotherapy-related debates on X. While the platform offers substantial benefits, it also presents challenges that must be addressed to maximize its potential as a professional tool. By understanding and addressing these challenges, X can become an effective resource for physiotherapists, contributing to their ongoing development and improving patient care outcomes.

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Data Availability

The datasets generated or analyzed during this study are not publicly available due to ethical restrictions as the data contain potentially identifying information but are available from the corresponding author on reasonable request.

Authors' Contributions

M Alasfour conceptualized the study, designed the methodology, and led the data analysis and manuscript drafting. RA contributed to study design, data collection, and interpretation of the results. M Amri assisted with data analysis and manuscript editing. SA contributed to the literature review and manuscript revision. SH assisted in data curation and validation. KA contributed to reviewing and refining the final draft. M Alsinan supervised the overall project, provided critical feedback on the Methods and Discussion sections, and approved the final version of the manuscript. All authors reviewed and approved the final manuscript.

Conflicts of Interest

None declared.

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Abbreviations

CHERRIES: Checklist for Reporting Results of Internet E-Surveys
CROSS: Checklist for Reporting of Survey Studies
SCFHS: Saudi Commission for Health Specialties
STROBE: Strengthening the Reporting of Observational Studies in Epidemiology

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Awareness and Use of Home-Based Respiratory Pathogen Testing Services in the Internet Era: Postpandemic Questionnaire Study

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Abstract

Background: Home-based respiratory pathogen testing services (HRPTS), an emerging internet-based health care model, enable rapid pathogen identification within hours through digital platforms and eCommerce logistics. This decentralized approach overcomes conventional testing delays to accelerate diagnosis. However, public awareness, adoption, and influencing factors remain largely unknown.

Objective: In this study, we aimed to investigate digitally connected metropolitan residents' awareness and intention to adopt HRPTS and analyze factors influencing adoption intention.

Methods: This study used a structured questionnaire grounded in the technology acceptance model, which measured perceived usefulness, ease of use, risk, and behavioral intention. Questionnaire development involved focus group discussions to ensure content validity. Statistical analysis included descriptive statistics and multivariate linear regression, with scale reliability and validity confirmed by exploratory factor analysis. Using a convenience sampling strategy, 1850 volunteers completed questionnaires via Wenjuanxing. After data validation, 1756 surveys met the inclusion criteria (effective response rate: 94.92%) and were analyzed.

Results: Among 1756 respondents, 54.7% (n=961) knew about HRPTS for respiratory diseases, and 15.3% (n=269) had previously used them. Perceived usefulness was high among respondents: fast pathogen identification (n=1092, 62.2%), early treatment (n=1136, 64.7%), time or cost savings (n=1119, 63.7%), and anxiety alleviation (n=1110, 63.2%). Regarding perceived ease of use, 55.9% (n=982) of the respondents cited robust logistics, 53.8% (n=945) cited online appointment convenience, and 54.2% (n=952) cited simple self-sampling. However, respondents expressed concerns regarding privacy (n=925, 52.7%), test accuracy questions (n=871, 49.6%), and insufficient regulations (n=948, 54.0%). Nevertheless, >70% of the respondents were willing to adopt HRPTS, if available. Multivariate regression showed that higher education (β=.598; P<.001), living with family (β=.271; P=.04), and absence of underlying chronic diseases (β=.321; P=.03) were significant predictors of adoption intention. Additionally, not having used HRPTS before (β=−1.203; P<.001) and less frequent health care–seeking behaviors were negatively associated with adoption intention.

Conclusions: HRPTS as an internet-based health care service holds value for early diagnosis, treatment, and health care optimization in urban China. However, significant concerns regarding test accuracy, data privacy, and regulatory accountability within this evolving digital health sector should be addressed to strengthen respiratory disease prevention in the postpandemic era.

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KEYWORDS

home-based testing; internet-based health care; respiratory pathogens; technology acceptance; testing

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Introduction

Respiratory infectious diseases are contagious and rapidly spreading illnesses caused by pathogens (eg, viruses and bacteria) transmitted through the respiratory tract. These conditions, characterized by high transmissibility and rapid spread, adversely impair global public health and provoke wider socioeconomic consequences [1-3]. For instance, seasonal influenza imposes substantial global burdens annually, causing 4 - 23 million hospitalization cases of lower respiratory tract infections and 290,000 - 650,000 seasonal influenza-associated respiratory deaths [4]. During the COVID-19 pandemic, 760 million cases were reported worldwide, with 6.81 million deaths [5]. Given the high pathogenicity and transmissibility of respiratory infectious diseases, accurate pathogen testing is essential to interrupt transmission chains and reduce the disease burden.

Advances in medical technology have facilitated the widespread adoption of respiratory pathogen testing, which enhances efficient identification for accurate early diagnosis and treatment [6] and optimizes clinical decision-making and therapy planning [7,8]. Current detection approaches for respiratory pathogens include at-home antigen detection and polymerase chain reaction (PCR) tests in hospital settings and clinical laboratories. Although antigen detection tests offer rapid results, they exhibit lower sensitivity [9,10] and carry a high risk of false-negative results, thereby necessitating frequent confirmatory testing [10,11]. The PCR test is a gold standard of respiratory pathogen testing owing to its high accuracy, broad detection spectrum, and standard operating procedures [12-15]. However, it depends heavily on clinical laboratories and requires patients to navigate a multistep and lengthy process from appointment scheduling and sampling to results waiting [16]. Moreover, during seasonal influenza or pandemic outbreaks, crowded hospitals face dual challenges: higher cross-infection risks in crowded waiting areas [17,18] and potential hospital congestion [16]. These critical limitations hinder rapid diagnosis and effective containment of respiratory diseases.

Therefore, in the postpandemic era, eCommerce platforms have pioneered the home-based respiratory pathogen testing service (HRPTS), leveraging “proactive screening” awareness developed by frequent COVID-19 nucleic acid tests and the extensive internet network and efficient logistics systems in China. The model operates via internet-based health care platforms with three core components: (1) an online booking system for users to select among 12 testing items (eg, influenza virus, SARS-CoV-2, *Mycoplasma pneumoniae*), schedule flexible home-collection hours, and follow standardized sampling instructions; (2) a digital logistics system, based on intelligent scheduling algorithms, integrated with logistics personnel or local couriers to deliver samples, thereby ensuring biosafety in transportation; and (3) a telereporting platform delivering reports to users within 3 hours of laboratories’ conducting nucleic acid extraction, amplification, and data analysis using PCR and other testing technologies. It is important to note that, as an emerging service, HRPTS availability is primarily concentrated in major metropolitan areas of China, leveraging existing dense logistics networks. Compared with conventional testing, HRPTS transcends barriers of time and space owing to its three advantages: (1) patients can finish self-sampling to reduce cross-infection risks, instead of registering at hospitals for sampling; (2) a quick response mechanism with a 3-hour turnaround time dramatically improves diagnostic efficiency, particularly for mass screening during influenza seasons or pandemic emergencies; and (3) HRPTS supports public health authorities in optimizing methods of prevention and control by offering pathogen prevalence analysis in regions.

Although the HRPTS demonstrates considerable potential for rapid respiratory disease diagnosis, it is available only in certain first-tier cities in China. Public awareness regarding the HRPTS consequently needs to be increased; however, its adoption intention may be hindered by factors such as accuracy concerns, privacy issues, and limited accessibility [19,20]. Therefore, we aimed to investigate HRPTS value, convenience, and ease of use from the consumers’ perspective in first-tier cities to determine their genuine adoption intentions and concerns. Additionally, we aimed to explore how individual characteristics (eg, age, education, and health literacy) influence its adoption. This study addresses research gaps in this specific urban context by improving the framework of public adoption of the HRPTS and provides empirical evidence for policymakers and service providers in metropolitan areas to optimize HRPTS implementation and regulation.

Methods

Questionnaire Design

The questionnaire items were drawn from validated scales used in prior studies based on the technology acceptance model (TAM) framework [21] and were adapted to fit the context of HRPTS adoption. The TAM framework focuses on perceived usefulness (PU) and perceived ease of use (PEOU) to explain and predict users’ acceptance of a new technology. To ensure the constructs were clearly defined and relevant to the HRPTS context, we operationalized them as follows: PU was measured through items capturing its clinical and practical benefits (eg, accelerating pathogen testing and enabling early intervention). PEOU assessed the accessibility and simplicity of the service process. Perceived risk (PR) was explicitly tied to salient concerns in home-based testing, including test accuracy, data privacy, and regulatory safeguards. We extended the TAM by incorporating variables, such as PR (eg, privacy concerns and test reliability), to comprehensively evaluate service acceptance. To ensure the content validity and contextual appropriateness of the questionnaire, we convened a panel of 12 authoritative experts—including public health researchers, clinicians, and patient advocates—and employed a focus group discussion to screen and refine the questionnaire items. After discussing service adoption scenarios, potential barriers, and privacy concerns, the final questionnaire comprised 31 items, assessing demographic information (13 items), and the 18 items of the TAM scale, which covered PU (6 items), PR (5 items), PEOU (4 items), and behavioral intention (BI; 3 items). While our measures are derived from the TAM framework, our analytical objective differs from traditional model testing. We do not

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examine the structural relationships among TAM constructs (eg, the effect of PU on BI). Instead, we treat PU, PEOU, PR, and BI as separate outcome variables in regression models to directly assess how demographic factors influence each dimension. This approach aligns with our goal of identifying population-specific determinants for targeted interventions.

Questionnaire Validation

We collected 300 pretest responses to assess the reliability and construct validity. Exploratory factor analysis using principal component analysis with varimax rotation was performed. The Kaiser-Meyer-Olkin measure was 0.91, and the Bartlett test of sphericity was significant (χ^2_{153}=4389.2; P<.001), confirming that the data were suitable for factor analysis. Exploratory factor analysis extracted 4 factors with eigenvalues greater than 1, which together explained 73.69% of the total variance (see Table S1 in Multimedia Appendix 1 for detailed variance explained). All items exhibited factor loadings greater than 0.64 on their theoretically expected factors, with no substantial cross-loadings (>0.40) on other factors (see Table S2 in Multimedia Appendix 1 for the complete factor loading matrix). Reliability was assessed using Cronbach α for each construct: PU (α=0.915), PR (α=0.927), PEOU (α=0.884), and BI (α=0.888), indicating excellent internal consistency. The overall scale reliability was 0.850. These results support the strong psychometric properties of the adapted TAM scale in the HRPTS context.

Questionnaire Survey and Implementation

This web-based survey assessed data collected using WenJuanxing, a mainstream online survey platform. The survey primarily targeted digitally connected residents of major Chinese metropolises (ie, Beijing, Shanghai, Guangzhou, and Shenzhen), supplemented by a smaller cohort from other provinces. This sampling strategy aimed to capture the perceptions of populations with access to and familiarity with internet-based services. Data collection occurred over a 12-day period (January 17 - 28, 2024). This period was deliberately chosen to coincide with a peak influenza season, as HRPTS is most relevant and its perceived value is most salient when respiratory infection prevalence is high. While this may limit generalizability to nonseasonal periods, it allows us to capture adoption intentions under conditions of high practical relevance. After excluding invalid responses (ie, responses with completion times of less than 60 seconds, which were considered inattentive or insincere) and respondents <18 years old (n=94), we retained 1756 valid samples, with a valid response rate of 94.92%. This procedure yielded 1329 responses from first-tier cities and 427 from provincial areas.

Ethical Considerations

This study strictly adhered to the World Medical Association Declaration of Helsinki and was approved by the Ethics Committee of China–Japan Friendship Hospital (approval no. 2024-KY-254). The research was conducted anonymously, and no personally identifiable information was collected. All respondents provided informed consent; for this online survey, consent was obtained electronically where participants indicated their agreement to participate after reading a detailed information page that outlined the study purpose, risks, benefits, and data confidentiality measures. Participants were informed that their data would be used solely for academic research purposes, and all questionnaire submissions were fully anonymized. As a token of appreciation, each participant received an electronic red packet reward of 2 RMB (US $0.3) upon completion of the survey.

Statistical Analysis

Preliminary data management was conducted using Microsoft Excel 2021. Descriptive statistics were analyzed with SPSS Statistics 22 to summarize demographic characteristics and core TAM variables (PU, PR, PEOU, BI).

We used multivariate linear regression to examine factors influencing HRPTS adoption. The dependent variables were continuous composite scores for PU, PR, PEOU, and BI, calculated by summing responses to all items within each multi-item construct. Summing Likert-scale items to create composite scores is a common practice that approximates continuous data suitable for linear regression. Categorical predictors were converted into dummy variables for analysis. The coding scheme and reference categories were as follows: Sex: 0=Male (reference), 1=Female; Age: 0=<60 years (reference), 1=≥60 years; Education: 0=Less than bachelor's degree (reference), 1=Bachelor's degree or higher; Living arrangement: 0=Lives alone (reference), 1=Cohabiting with others; Previous respiratory infection: 0=Yes (reference), 1=No; Previous HRPTS use: 0=Yes (reference), 1=No; Health care–seeking behavior: A 3-category variable entered as 2 dummy variables, with "Always seek care" as the reference; Underlying chronic diseases: 0=Yes (reference), 1=No. Due to the mandatory-response setting on the online survey platform (Wenjuanxing), there were no missing data for the key variables included in the regression analyses.

Prior to interpretation, key regression assumptions were validated. Visual inspection of histograms, Q-Q plots, and residual scatterplots indicated no severe violations of normality or homoscedasticity. All variance inflation factor values were below 1.5 for individual predictors, confirming the absence of substantial multicollinearity, and Durbin-Watson statistics (range: 1.88 - 1.93) suggested independent residuals. Detailed model fit indices (R^2, adjusted R^2, F-statistic, Durbin-Watson, variance inflation factor) are reported in Table S3 in Multimedia Appendix 1. The results are presented comprehensively in the supplementary materials: Table S2 in Multimedia Appendix 1 reports the unstandardized coefficients (β) with 95% CIs and P values, while Table S3 in Multimedia Appendix 1 additionally provides the standardized coefficients (β) to facilitate the comparison of the relative strength of predictors within and across models.

Results

Respondent Information

As shown in Table 1, among 1756 individuals, most (n=1064, 60.6%) respondents were female, and 31.1% (n=546) were aged 30 - 39 years. Bachelor's degree holders formed the largest group at 40.3% (n=708), followed by individuals with a high school education or less at 26.8% (n=470), and individuals with

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an associate degree at 21.8% (n=383). Additionally, 70.0% (n=1229) of the respondents cohabited with family members, of whom 56.8% (n=698) lived with older family members and 62.3% (n=766) lived with their children. In addition, 173 individuals, representing 14.1% of the cohabiting respondents, resided with family members with underlying diseases. Moreover, 448 (25.5%) respondents reported hypertension, diabetes, or other underlying diseases. When experiencing cold or influenza-like symptoms (eg, fever, cough, sore throat, and nasal congestion), 448 (25.5%) respondents consistently sought medical care, whereas 326 (18.6%) opted not to visit health care facilities. The remaining 982 (55.9%) indicated that their decisions depended on their condition.

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Table . Respondent information.

Variable	Response, n (%)
Sex	
Male	692 (39.4)
Female	1064 (60.6)
Age (y)	
18 - 29	345 (19.7)
30 - 39	546 (31.1)
40 - 49	332 (19.0)
50 - 59	142 (8.1)
60 - 69	393 (22.4)
70 - 79	108 (6.2)
80 - 90	10 (0.6)
Education	
High school or less	470 (26.8)
Associate degree	383 (21.8)
Bachelor's degree	708 (40.3)
Master's degree	156 (8.9)
Doctoral degree	39 (2.2)
Habitation pattern	
Lives alone	408 (23.2)
Cohabiting with family	1229 (70.0)
Cohabiting with roommates	91 (5.2)
Cohabiting with strangers	28 (1.6)
Cohabitant type (multiple responses)	
Elderly	698 (56.8)
Children	766 (62.3)
Pregnant women	36 (2.9)
Family members with underlying chronic medical conditions	173 (14.1)
Other	143 (11.6)
Have underlying chronic diseases	
Yes	448 (25.5)
No	1308 (74.5)
Type of underlying chronic diseases (multiple responses)	
Hypertension	238 (53.1)
Diabetes	185 (41.3)
COPD	84 (18.8)
Coronary heart disease	112 (25.0)
Cancer	71 (15.9)
Other	37 (8.3)
Respiratory pathogen infection (eg, influenza, SARS-CoV-2) in the previous year	
Yes	816 (46.5)
No	940 (53.5)
Health care–seeking frequency for cold or influenza-like symptoms	

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Variable	Response, n (%)
Always	448 (25.5)
Depending on the condition	982 (55.9)
Never	326 (18.6)
Familiarity with HRPTS[a]	
Very familiar (detailed knowledge)	259 (14.8)
Familiar (core tests/process)	285 (16.2)
Moderately familiar (service awareness)	417 (23.8)
Slightly aware (vague recognition)	307 (17.5)
Unaware (no exposure)	488 (27.8)
Previous use of HRPTS	
Yes	269 (15.3)
No	1487 (84.7)
HRPTS recipient (multiple responses)	
Self	170 (63.2)
Elderly family member	115 (42.8)
Children	119 (44.2)
Other family member	23 (8.6)
Symptoms triggering HRPTS consideration (multiple responses)	
Dyspnea/chest tightness	956 (54.4)
Fever	530 (30.2)
Cough	1145 (65.2)
Myalgia	351 (20.0)
Headache	250 (14.2)
Sore throat	364 (20.7)
Nasal congestion	430 (24.5)

[a]HRPTS: home-based respiratory pathogen testing service.

A total of 961 (54.7%) respondents were aware of HRPTS. However, among all respondents, only 259 (14.8%) were very familiar with the detailed information and procedures, whereas 488 (27.8%) had never heard of HRPTS. Among 269 (15.3%) previous users, 170 (63.2%) purchased the service for personal use, while 115 (42.8%) and 119 (44.2%) used the service for their elderly family members and children, respectively. Additionally, more than half of the respondents considered using the HRPTS when experiencing chest tightness or dyspnea (n=1145, 65.2%) or fever symptoms (n=956, 54.4%), followed by cough (n=530, 30.2%) and myalgia (n=430, 24.5%).

HRPTS Public Adoption Intention

We assessed HRPTS perceptions across 4 dimensions using a structured questionnaire: PU, PR, PEOU, and BI. The detailed results are presented in Figure 1.

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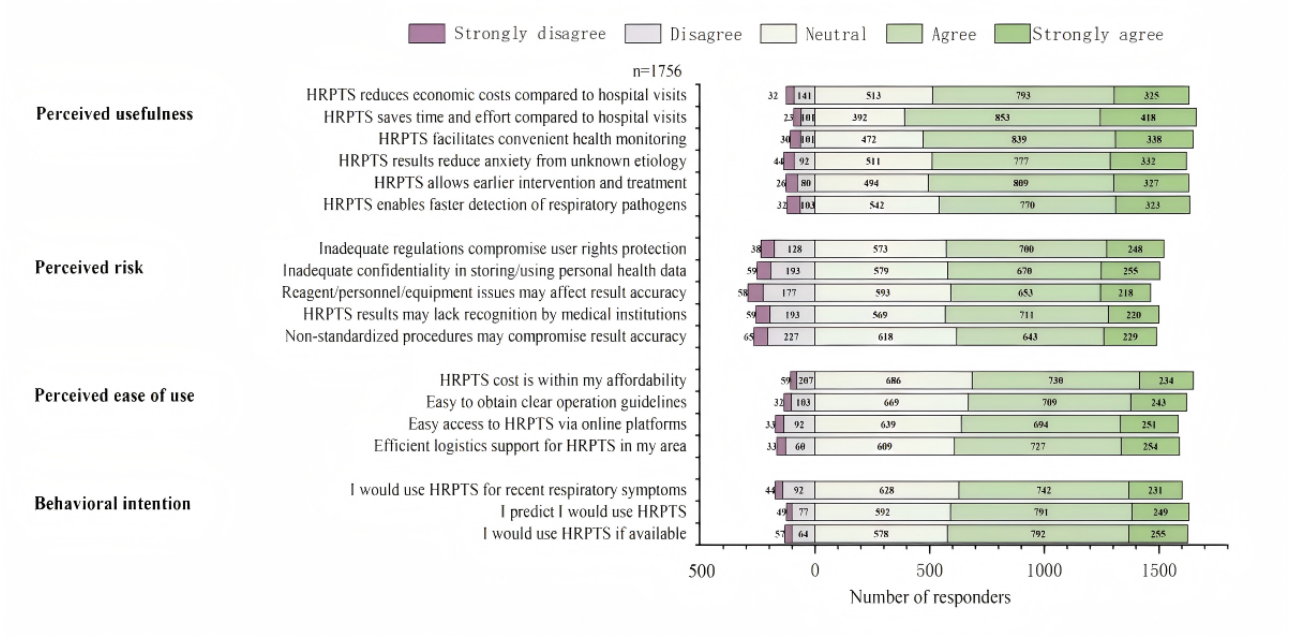
Figure 1. Home-based respiratory pathogen testing services (HRPTS) adoption intention survey.



Most participants agreed that the HRPTS promoted rapid pathogen identification (770 [43.8%] agreed; 323 [18.4%] strongly agreed) and early intervention (809 [46.1%] agreed; 327 [18.6%] strongly agreed). The HRPTS also reduced anxiety caused by undiagnosed symptoms (777 [44.2%] agreed; 332 [18.9%] strongly agreed) and facilitated family health monitoring (839 [47.8%] agreed; 338 [19.2%] strongly agreed). However, 93 (5.3%) individuals disagreed that the HRPTS saved time and energy, and 1118 (63.7%) individuals agreed or strongly agreed that it reduced costs.

Additionally, more than half of the respondents thought that robust local logistics could support the HRPTS (727 [41.4%] agreed; 254 [14.5%] strongly agreed), and accessing the HRPTS on online platforms was easy (694 [39.5%] agreed; 251 [14.3%] strongly agreed). Moreover, most participants suggested that they could effortlessly obtain clear and easy-to-follow instructions (709 [40.4%] agreed; 243 [13.8%] strongly agreed). Among the participants, 964 (54.9%) considered the HRPTS affordable, 686 (39.1%) remained neutral, and 106 (6.0%) found it expensive.

Substantial concerns have emerged about the HRPTS's potential risks, despite its high ratings for PU and PEOU. When evaluating the challenges associated with HRPTS adoption, respondents expressed strong agreement on 2 primary issues: 40.5% (n=711) agreed and 12.5% (n=220) strongly agreed that test results may not be recognized by medical institutions, whereas 39.9% (n=700) agreed and 14.1% (n=248) strongly agreed that existing inadequate regulations on HRPTS could not guarantee their rights. Moreover, 37.2% (n=653) agreed and 12.4% (n=218) strongly agreed on reliability concerns regarding detection reagents, personnel, and equipment; 36.6% (n=643) agreed and 13.0% (n=229) strongly agreed that improper operations could compromise test accuracy; and 38.2% (n=670) agreed and 14.5% (n=255) strongly agreed on safeguards for data privacy.

Therefore, we further assessed BI to use the HRPTS after understanding the respondents' awareness. Most expressed a willingness to adopt an HRPTS if it were available in the market (792 [45.1%] agreed; 255 [14.5%] strongly agreed), a few refused to adopt it (23 [1.3%] strongly disagreed; 101 [5.8%] disagreed), and 585 (33.3%) remained neutral. Additionally, 742 (42.3%) individuals agreed and 231 (13.2%) strongly agreed that they would use the HRPTS for pathogen testing if experiencing recent respiratory infection symptoms.

Analysis of Individual Characteristics Influencing HRPTS Adoption

Multivariate linear regression analysis was used to examine the associations between 8 demographic characteristics (eg, sex, age, and education) and health behaviors and the HRPTS adoption intention (Table 2). The results showed the differential effects of these factors on PU, PR, PEOU, and BI. The respondents were subsequently grouped, based on age, using a threshold of 60 years and education (ie, nontertiary education [associate degree, high school or less] vs tertiary education [bachelor's, master's, or doctoral degree]).

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Table . Linear regression analysis on multiple factors influencing home-based respiratory pathogen testing services (HRPTS) adoption intention.

Variable	PU[a]			PR[b]			PEOU[c]			BI[d]		
	β	95% CI	*P* value	β	95% CI	*P* value	β	95% CI	*P* value	β	95% CI	*P* value
Sex												
Male	Reference			Reference			Reference			Reference		
Female	.755	0.361 to 1.194	.001	−.058	−0.472 to 0.355	.78	.142	−0.139 to 0.423	.32	.066	−0.157 to 0.289	.56
Age (y)												
<60	Reference			Reference			Reference			Reference		
≥60	−.594	−1.204 to −0.016	.06	−.59	−1.164 to −0.016	.04	−.412	−0.802 to −0.023	.04	−.242	−0.552 to 0.068	.13
Education												
Less than a bachelor's degree	Reference			Reference			Reference			Reference		
Bachelor's degree or higher	.887	0.404 to 1.370	<.001	.774	0.320 to 1.229	.001	.519	0.210 to 0.827	.001	.598	0.353 to 0.844	<.001
Living arrangement												
Lives alone	Reference			Reference			Reference			Reference		
Cohabiting with others	.611	0.107 to 1.116	.02	−.089	−0.565 to 0.386	.71	.371	0.049 to 0.694	.02	.271	0.014 to 0.527	.04
Previous respiratory pathogen infection (within 1 y)												
Yes	Reference			Reference			Reference			Reference		
No	−.211	−0.659 to 0.237	.36	−.233	−0.655 to 0.189	.28	.038	−0.249 to 0.325	.80	.052	−0.176 to 0.280	.65
HRPTS utilization												
Yes	Reference			Reference			Reference			Reference		
No	−.831	−1.482 to −0.180	.01	−1.266	−1.879 to −0.653	<.001	−1.596	−2.012 to −1.179	<.001	−1.203	−1.534 to −0.872	<.001
Health care–seeking for Influenza-like symptoms												
Always seek care	Reference			Reference			Reference			Reference		
Seek care depending on context	−1.002	−1.547 to −0.457	<.001	.102	−0.411 to 0.615	.70	−.384	−0.732 to −0.036	.03	−.411	−0.688 to −0.134	.004
Never seek care	−1.221	−1.919 to −0.522	.001	.072	−0.586 to 0.730	.83	−.553	−1.000 to −0.107	.02	−.609	−0.965 to −0.254	.001
Have underlying chronic diseases												
Yes	Reference			Reference			Reference			Reference		

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Variable	PU[a]			PR[b]			PEOU[c]			BI[d]		
	β	95% CI	*P* value	β	95% CI	*P* value	β	95% CI	*P* value	β	95% CI	*P* value
No	.506	−0.64 to 1.076	.08	−.09	−0.627 to 0.446	0.74	.376	0.011 to 0.740	0.04	.321	0.031 to 0.611	.03

[a]PU: perceived usefulness.

[b]PR: perceived risk.

[c]PEOU: perceived ease of use.

[d]BI: behavioral intention.

Multivariate regression analysis revealed significant associations between sex, education, habitation patterns, previous usage, and health care–seeking behaviors with HRPTS-PU. Compared with men, women had higher ratings for PU (β=.755, *P*=.001). Respondents with a bachelor's or higher degree perceived greater usefulness than less educated respondents (β=.887, *P*<.001). Cohabiting individuals perceived higher usefulness than individuals living alone (β=.611, *P*=.09). Nonusers reported lower PU than previous users (β=–.831, *P*=.01). Additionally, stratified statistics on health care–seeking behavior revealed a stepwise decline in PU: relative to the "always seeking care" subgroup, the "occasionally seeking care" (β=–1.002, *P*<.001) and "never seeking care" (β=–1.221, *P*=.001) subgroups showed progressively lower PU.

The main factors associated with PR were age, education, and previous usage. Age had a negative association with respondents aged ≥60 years showing lower PR (β=–.59, *P*=.04). By contrast, individuals with tertiary education were correlated with a higher PR against individuals with lower education (β=.774, *P*=.001). HRPTS previous users reported lower PR than nonusers (β=–1.266, *P*<.001).

PEOU was associated with age, education level, and underlying disease status, among other factors. Older adults (aged ≥60 y) had a negative association (β=–.412, *P*=.04); cohabiting individuals perceived a greater PEOU than individuals living alone (β=.371, *P*=.024). Individuals with tertiary education were associated with better ease-of-use evaluations than less-educated individuals (β=.519, *P*=.001). Service experiences showed significant effects, with nonusers reporting a precipitous decline in PEOU (β=–1.596, *P*<.001). Individuals without underlying diseases reported more positive ease-of-use perceptions than individuals with diseases (β=.376, *P*=.043).

Thus, education level, previous usage, and health care–seeking behaviors were markedly associated with BI to use the HRPTS. Individuals with tertiary education predicted stronger adoption intention (β=.598, *P*<.001). Stratification of health care–seeking behaviors revealed that, compared with the "always seeking care" subgroup, the "occasionally seeking care" (β=–.411, *P*=.004) and "never seeking care" (β=–.609, *P*=.001) subgroups had progressively lower BI. Additionally, nonusers exhibited lower BI (β=–1.203, *P*<.001). Cohabitation (β=.271, *P*=.039) and absence of underlying diseases (β=.321, *P*=.03) also positively influenced adoption intention.

Discussion

This study uses the constructs of the TAM as a conceptual foundation but adopts a distinct analytical focus. Rather than testing the structural pathways within TAM (eg, the effects of PU and PEOU on BI) in the current analysis, we treat its core dimensions—PU, PEOU, PR, and BI—as separate outcomes. Future research will explicitly examine these interconstruct relationships to elucidate the pathways to adoption. This present approach allows us to directly examine how demographic and health-behavioral factors influence each dimension, facilitating the identification of key subgroups for tailored strategies.

The aim of this study was to investigate the awareness and intention to adopt HRPTS among residents in major Chinese metropolitan areas and analyze factors influencing adoption intention. Our findings, reflecting the attitudes of a predominantly young, educated, and digitally literate urban sample, indicate that more than half of the respondents were aware of the HRPTS for respiratory diseases and 15.3% (n=269) had previously used it; factors significantly associated with a stronger adoption intention included higher education level, living with family, and absence of underlying chronic diseases. Previous non-use of HRPTS and less frequent health care–seeking behaviors were associated with lower adoption intention. The HRPTS provides multiple benefits for disease prevention, treatment, and public health. First, the HRPTS accelerated pathogen identification, as acknowledged by 62.2% (n=1092) of the respondents. Additionally, when users manifest respiratory symptoms, such as fever or cough, they can bypass hospital visits by scheduling an HRPTS through a mobile app. Test reports covering 12 common pathogens (eg, influenza virus, SARS-CoV-2, and *M pneumoniae*) are therefore produced within 3 hour, allowing prompt identification. This process effectively prevents a condition from worsening due to delaying treatment and facilitates early identification while supporting public health interventions. Moreover, 64.7% (n=1136) of the participants recognized its role in early interventions because targeted antiviral drugs (eg, optimal oseltamivir administration within 48 hours against influenza A [17,22,23]) are administered after pathogen identification, thereby reducing antibiotic misuse and improving efficacy. Furthermore, this approach provides particular clinical value for high-risk groups, such as children and older adults, thereby preventing progression to severe complications (eg, pneumonia and respiratory failure).

Second, the HRPTS provides significant economic benefits. In conventional health care, patients incur direct costs (eg, transportation and registration fees), in addition to the time and

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effort required for queuing. Based on our findings, 63.67% (n=1118) of the respondents recognized the cost reduction effects of the HRPTS and 72.4%（n=1271） acknowledged its time-saving advantages. Additionally, during respiratory disease outbreaks (eg, influenza seasons and pandemics) [24,25], tertiary hospitals frequently experience limited medical resources, leading to lower care efficiency and higher cross-infection risks. The HRPTS was designed to leverage internet-based technologies to address this crisis through decentralized community- or home-based testing. By enabling remote sample collection coordination and digital result delivery, it efficiently redistributes patient flows, alleviates institutional strain, and optimizes medical resource allocation.

Third, the HRPTS helps alleviate anxiety among patients and their families. When susceptible populations (eg, children, the elderly) develop respiratory symptoms, their family members often experience anxiety due to the difficulty of assessing illness severity [26,27]. For instance, 1 study [28] on respiratory tract infection in children reported a 39% reduction in the level of anxiety in their parents after a definitive diagnosis. Therefore, our results showed that 63.2% (n=170) of the respondents recognized the anxiety-relieving effects of the HRPTS through rapid pathogen identification, thereby reducing diagnostic uncertainty and providing a safer health care alternative that avoids hospital-acquired infection risks.

Fourth, while the convenience and ease of use of the HRPTS are critical determinants of public adoption, efficient logistics underpin the HRPTS end-to-end service chain (ie, collection–transportation–testing), ensuring timely sample delivery and reliable testing. Statistical analysis revealed that 55.9% (n=982) of the respondents reported accessible and efficient logistics support via mature networks (JD Logistics; Meituan Delivery), which enable a 3-hour average turnaround time in urban cores. Smart algorithms can further optimize routing (eg, avoiding midday congestion) [29,30] and “emergency supply chain for testing,” which is added during influenza seasons, ensures timely specimen delivery [31].

Fifth, handy digital platforms proved equally essential, with 53.8% (n=945) of the respondents confirming easy access to the HRPTS via these platforms. These platforms, serving as the primary interface for the HRPTS, automatically recommend appropriate testing panels to users and functions, such as appointment scheduling, logistics tracking, and results checking to enhance service accessibility and transparency. Evidence indicates that electronic appointment platforms substantially reduce efforts into offline coordination [32]. Furthermore, the HRPTS utilizes geolocation to identify the nearest testing facilities, allowing users to monitor real-time logistics and laboratory progress via mobile apps or online mini programs. These digital platforms consequently streamline test scheduling and result queries for patients, improve service accessibility and transparency, and deliver timely and efficient health care services to community members.

Finally, standardized sampling for the HRPTS reduces the processing time. Another previous study [33] reported that user error rates are positively correlated with procedural complexity. In this study, 54.2% (n=952) of the respondents reported receiving clear, easy-to-follow instructions, which enabled successful self-sampling with nasopharyngeal or oropharyngeal swabs and subsequent specimen transportation. Thus, well-designed procedures are pivotal for HRPTS adoption, featuring simple and easy-to-follow instructions that enable nonprofessionals to perform accurate self-sampling. Furthermore, the process incorporates biosafety reminders and standardized biosafety-compliant packaging.

Despite its convenience and benefits, the HRPTS has multiple risks. A primary concern regarding the HRPTS is data privacy breaches in its adoption, with 52.7% (n=925) of the respondents expressing concerns about the confidentiality of their personal information. These concerns stem from multistage data exposure risks from user registration (eg, names, addresses, and symptom complaints) to test results transmission (eg, pathogen types and linkages with electronic health records) because each stage involves the collection and sharing of sensitive health data. Data from a previous study [34] indicated that 32.5% of the health care data breaches between 2010 and 2020 resulted from cyberattacks or information technology incidents, primarily targeting decentralized services, such as home health monitoring platforms and telehealth diagnosis systems. Additionally, an empirical study by Smith [35] revealed that 19% of the medical data breaches originated from supply chain loopholes (eg, unencrypted logistics interfaces, contractor privilege misuse), with each incident affecting an average of 87,000 individuals. These findings underscore security issues in cross-institutional health data exchanges. Therefore, delivery terminals should not display users’ detailed addresses, and the security of the recorded video storage must be strictly controlled during front-end data collection. Moreover, all data transmissions should utilize encrypted channels, and expired data should be purged using established protocols. Clear boundaries should also be established for third-party data sharing to ensure complete anonymization of all shared data.

Testing accuracy is another major concern in HRPTS implementation, with nearly half of the respondents expressing apprehension about potential inaccuracies owing to user errors or technical limitations. This aligns with our operationalization of PR to explicitly include accuracy concerns. These concerns are primarily derived from potential issues in 2 key links: improper self-sampling practices and technical limitations of detection systems. For instance, common problems associated with self-swabbing from the nasopharynx include insufficient sampling depth and inadequate swabbing duration. Additionally, temperature fluctuations during specimen transportation may reduce viral viability to >50% of that observed under stable low-temperature conditions, whereas nucleic acid integrity can decrease by up to 40% [36]. Although these changes directly affect a test’s sensitivity, these concerns may be addressed because evidence indicates that self-collected throat and nasal specimens can achieve pathogen (or other analyte) detection accuracy comparable to that of samples obtained by health care workers [37]. In this regard, regulatory approval of the HRPTS indicates that its detection system has been certified by relevant authorities and complies with established standards. Nevertheless, government agencies should rigorously monitor laboratory certifications, ensuring that qualification reviews,

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operational procedures, and data management comply with regulations to further alleviate user concerns. This oversight is crucial to prevent enterprises from prioritizing efficiency over quality.

Finally, the lack of supportive policy frameworks is another major public concern, with over half of the respondents expressing apprehension regarding the insufficient HRPTS regulations and insufficient protection of users' rights. Additionally, inconsistent recognition of third-party rapid testing results by medical institutions may lead to discrepancies in clinical decision-making [38]. For instance, patients may wonder whether inconsistent recognition of test results will trigger redundant tests, delays in treatment, and worsening resource depletion if hospitals dismiss test reports from other testing facilities. Furthermore, when issues such as sample contamination, misdiagnosis, or privacy breaches occur, identifying the liable party is difficult for any of the detection agencies, service personnel, or technology platform providers that could become the subject of disputes. Ambiguity also arises from the lack of detailed provisions for these emerging services, leaving consumers without a clear recourse. Therefore, defining the scope of the HRPTS validity, entry criteria for institutions, and dispute resolution mechanisms through administrative action is crucial.

A notable finding is the apparent gap between positive adoption intention (>70% willingness) and low actual usage (15.3%), coupled with a substantial proportion of neutral attitudes. This pattern suggests a "BI-action gap" commonly observed in the adoption of novel health technologies. Several contextual factors may explain this discrepancy. First, as an emerging service, HRPTS naturally faces initial public caution; awareness does not immediately translate into use. Second, the service's limited geographic coverage (primarily first-tier cities) physically restricts access for many. Third, when experiencing actual symptoms, individuals may revert to habitual health care–seeking pathways (eg, hospitals) despite prior expressed interest in alternatives. Finally, the significant concerns regarding accuracy, privacy, and regulation, as identified in our study, likely act as critical psychological barriers that inhibit the conversion of positive intention into actual trial. Future longitudinal research is needed to track how adoption evolves with increased service maturity, publicity, and policy support.

This study revealed group differences in HRPTS adoption intention linked to interactions between individual characteristics and health behaviors. In particular, older participants aged ≥60 years demonstrated negative associations between PR and ease of use, which may reflect higher risk perception and lower adoption intention potentially related to limited digital literacy and health knowledge [39,40]. Community-based interventions and assistance from family doctors are consequently required to improve service accessibility for this population. Additionally, individuals living alone exhibited negative correlations between PU and BI, associated with insufficient social support [41]. Therefore, establishing robust social support networks may be important for encouraging proactive health management is imperative. Moreover, the "occasionally seeking care" and "never seeking care" subgroups exhibited negative attitudes toward service usefulness and BI, indicating lower acceptance rates. This finding suggests that low health motivation can dampen new service adoption, which is consistent with the health motivation component of the health belief model [6,42], and that primary care screening and health education interventions should be implemented to enhance engagement. Furthermore, individuals without underlying diseases showed notably stronger positive correlations between PU and BI, indicating that healthier individuals prefer convenient and efficient services and demonstrated a higher acceptance of new health care services. Thus, we propose a tiered implementation strategy comprising the following components: publicizing the service among populations with different education levels, optimizing procedures with a focus on user experience, offering directed support for susceptible groups such as elderly individuals and individuals living alone, and reinforcing public motivation by monitoring their health behaviors. This strategy aims to improve the social acceptance and efficacy of the HRPTS as a health service.

This study has several limitations. First, the generalizability of the findings is constrained by the sampling method and scope. Our online convenience sample predominantly represents younger, more highly educated, and digitally literate residents of major Chinese cities and may not reflect the attitudes of the general population, including older adults or those in rural areas. Second, the cross-sectional design captures perceptions at a single point in time and cannot establish causality or track evolution. Third, the context of data collection—a 12-day period during peak influenza season—while relevant for capturing high-demand scenarios, may limit extrapolation to other times of the year. Fourth, as an emerging service, HRPTS is currently self-paid and geographically limited, and its technical and policy frameworks are still evolving; thus, acceptance may shift with future developments. These factors should be considered when interpreting the results.

In conclusion, this study systematically elucidated the value, adoption determinants, and risks of the HRPTS among metropolitan residents in China. More than 60% (n=1054) of the respondents acknowledged its core value in accelerating pathogen identification, initiating early treatment, reducing economic burden and health care delays, and alleviating distress. Efficiency emerged as a critical adoption driver, with 55.9% (n=982) appreciating internet-facilitated logistics (eg, a 3-h turnaround time in urban cores), 53.8% (n=945) endorsing digital platform accessibility, and 54.2% (n=952) completing self-sampling using clear protocols. However, 3 key barriers were identified: 52.7% (n=925) of the respondents were concerned about privacy breaches, which require data encryption and supply chain security; approximately half of respondents questioned the accuracy of the results, highlighting the need to strengthen laboratory qualifications and sampling training; and half of respondents were concerned about the lack of policies, indicating the urgent need to clarify the service validity, access criteria, and dispute resolution mechanisms for the HRPTS. We predominantly evaluated the use of the HRPTS by residents in first-tier cities, highlighting its contributions to ensuring early diagnosis and treatment, improving clinical workflows, and redistributing strained medical resources through internet-mediated care pathways. However, our results also

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indicated that efforts must address challenges related to privacy concerns, testing accuracy, and regulation through technological optimization, policy improvement, and public education to help build a more resilient prevention and control system for respiratory diseases. Nevertheless, the HRPTS has broad prospects for application and promotion in first-tier cities and urban clusters across the world that are equipped with internet and logistics infrastructure and face limited medical resources or higher demand for convenient health care (eg, high-density Asian cities, Western metropolitan areas, and health care hubs across Africa and Latin America).

Funding

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Data Availability

The datasets generated or analyzed during this study are available from the corresponding author on reasonable request.

Authors' Contributions

Conceptualization: CJ, ZY
Data curation: RZ
Formal analysis: NH
Funding acquisition: ZY
Investigation: RZ
Methodology: CJ
Supervision: WC, ZY
Validation: NH
Writing – original draft: CX
Writing – review & editing: CX, WC
ZY had full access to all data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Supplementary material Tables S1-S3.
[DOCX File, 25 KB - formative_v10i1e83767_app1.docx]

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Abbreviations

BI: behavioral intention
HRPTS: home-based respiratory pathogen testing service
PCR: polymerase chain reaction
PEOU: perceived ease of use
PR: perceived risk
PU: perceived usefulness
TAM: technology acceptance model

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Online Racism, Digital Mental Health Tools, and Online Mental Health Communication Among Black Young Adults With and Without Depression or Anxiety: Cross-Sectional Quantitative Study

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Abstract

Background: Use of technological resources that provide support for mental health (ie, digital mental health tools) and opportunities to use the internet to communicate with others or receive information about mental health (ie, online mental health communication) are growing in popularity among young adults (aged 18 - 29 y). However, whether exposure to the negative experience of racism online is associated with the use of digital mental health tools and online mental health communication remains an important empirical question for Black young adults, given their frequent online use and engagement.

Objective: This study sought to examine (1) how the frequency of exposure to online racism is associated with the use of digital mental health tools and engagement in online mental health communication and (2) how these associations differ for Black young adults with either anxiety and depression versus those without.

Methods: Conducted from July to September 2024, data came from a larger cross-sectional study of 1005 monoracial Black young adults (mean age 24.07, SD3.04 y; 50.6% women) who completed an online survey and self-reported measures of exposure to online racism, use of digital mental health tools, frequency of engaging in online mental health communication, and anxiety and depressive symptoms. Two separate path analysis regression models were conducted for the outcomes of depression and anxiety.

Results: Our results showed that more frequent exposure to online racism was associated with a greater likelihood of using digital mental health tools (odds ratio [OR] range 1.72 - 1.84; *P*<.001) and a greater engagement in online mental health communication (β range=.31-.36; *P*<.001). Those with depression and anxiety also had a greater likelihood of using digital mental health tools (depression OR 2.02; *P*=.001; and anxiety OR 1.71, *P*=.005) and a greater engagement in online mental health communication (depression β=.21; *P*<.001; and anxiety β=.16; *P*<.001). Neither anxiety nor depression was a significant moderator.

Conclusions: Exposure to online racism, digital mental health tools use, and online mental health communication are linked for Black young adults. Black young adults may use digital mental health tools and engage in mental health communication online when they experience online racism or may experience online racism when they use these tools and engage online, necessitating further longitudinal analyses of these relationships. Complementary digital intervention implementation strategies that support mental health while mitigating online racism are needed. Ensuring that digital tools and mental health communications opportunities are safe, culturally relevant, and free from online racism is a set of mutually reinforcing priorities for digital interventions.

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KEYWORDS

digital health; digital mental health; mental health; young adults; racism; depression; anxiety

Introduction

Given their convenience and accessibility, digital mental health tools and communication about mental health online are popular among young adults (aged 18 - 29 y) [1], who are *almost constantly* online [2] to connect with others and seek advice [3]. Broadly, digital mental health tools are technologies (eg, apps, online services, and teletherapy) that provide support for

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mental health symptoms [4-6] and are used by those with [7] and without [8] formal mental health diagnoses. Young adults may also engage in online mental health communication (online engagement with mental health–related content and conversations), such as joining a mental health–related online group and sharing personal mental health experiences [8,9]. Given the early onset and prevalence of anxiety and depression in young adulthood [10], understanding how young adults use digital mental health tools and engage in online mental health communication can inform digital mental health interventions for this population.

Black young adults who experience mental health challenges may particularly benefit from the convenient and accessible use of digital mental health tools and online mental health communication due to the barriers they face to receiving traditional mental health care (eg, financial factors, stigma, and discrimination) [11]. At the same time, Black young adults may face negative race-related experiences while they use digital mental health tools and engage in online mental health communication. One such experience is exposure to anti-Black racism (hereafter racism), defined as a sociopolitical system that manifests in differential and negative treatment of and cultural messages about Black individuals [12]. Racism is easily disseminated in digital and online spaces due to a *digital freedom of speech* afforded to users, where engagement in racist acts may be more overt than in nonanonymous, offline settings [13]. For Black young adults, exposure to online racism can entail not only being the direct target of interpersonal racist attacks (eg, receiving negative comments or threats online because one is Black) but also vicariously witnessing racist interactions online or being exposed to derogatory content about Black individuals (eg, user comments calling a dark-skinned Black woman in a video ugly or hypersexual) [13-15]. Some of these vicarious and second-hand exposures involve traumatic content, such as images and videos of people being assaulted or even killed [16,17]. Aligned with a racial trauma framework [18], exposure to online racism is stressful, threatening one's sense of self and emotional and social well-being [19-21]. Therefore, such exposure may be associated with the degree to which Black young adults use digital mental health tools and engage in online mental health communication.

Although much of the research has focused on social media specifically, the theory of online and digital spaces as both a stressor and a coping tool [22] suggests that digital mental health tools and online mental health communication could be engaged as ways of coping with the stressor of online racism. Many Black young adults go online to seek support [23] and find racially affirming social connections [24,25]. Therefore, the use of digital mental health tools and online mental health communication may help Black young adults proactively create and sustain networks of social support—emotional, instrumental, and informational—that can be engaged in reaction to race-related challenges they may face [21,26,27]. For instance, exposure to online racism for Black young adults may promote increased engagement in antiracist online spaces [28,29], such as online support groups, thereby potentially increasing communication with others about emotionally impactful and stressful racist content and interactions. To the extent that digital mental health tools and engagement in mental health communication online are believed to be effective mental health supports during times of stress, more frequent exposure to online racism may be associated with greater use.

Conversely, perhaps using some digital mental health tools or engaging in online mental health communication is itself associated with more exposure to online racism. In this case, Black young adults may not be using these digital resources to cope, but rather, more frequent exposure to online racism may be an unfortunate but unavoidable part of their digital experience. Research and theory on the health impacts of digital platforms and online contexts suggest that online racism is a structural part of many technologies, including educational tools and resources, which may perpetuate denigrating or stereotypical ideas about Black people in their design choices and content [15]. In this way, Black young adults who use digital mental health tools and engage in more frequent online mental health communication may face greater exposure to online racism. The theory of online and digital spaces as both a stressor and a coping tool [22] also suggests that online racism could be an additional potential source of stress in an already stressful, racist digital environment. Negative experiences in digital spaces may reduce digital engagement more broadly due to concerns about increased exposure to negative content or social interactions. Exposure to online racism is one type of negative interaction online that can cause stress [22]. Such stress may lead some Black young adults to disengage as a means of coping to preserve mental health [30]. To the extent that digital mental health tools and online mental health communication are seen as a part of a unified digital landscape, Black young adults' more frequent exposure to online racism could be associated with less use of these tools or engagement.

Associations between exposure to online racism, digital mental health tool use, and online mental health communication engagement may also differ for those with versus without depression or anxiety. In general, those with depression or anxiety use digital mental health tools, including mental health forums, websites, apps, and crisis lines, at higher rates than those without [31]. However, these tools and general engagement in communication about mental health online are also used by the general public to support their mental health and manage stress and negative emotions as well [32]. Black young adults with depression or anxiety may show higher use or engagement compared to Black young adults without these symptoms due to having more frequent or severe symptoms of depression or anxiety than Black young adults without these conditions. The severity or frequency of symptoms may mean that they experience relatively more psychological distress from exposure to racism [11]. Whether exposure to online racism is associated with use of digital mental health tools and engagement in online mental health communication differently for Black young adults with versus without depression or anxiety remains an empirical question. In this study, we examine moderation by depression or anxiety to inform the degree to which implementation and intervention efforts focused on digital mental health tools and resources should be tailored by mental health status.

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This study aimed to describe whether Black young adults' use of digital mental health tools and frequency of engagement in online mental health communication are associated with exposure to online racism. We also examined whether associations between online racism and digital mental health tool use and engagement in online mental health communication differed for those with depression or anxiety. To investigate these aims, we conducted an initial exploratory investigation, as several distinct hypotheses could be drawn from the extant literature, and we acknowledge the potential bidirectional nature of the findings. As digital mental health resources are growing in popularity, such initial descriptive research can elucidate considerations for seeking digital mental health tools among Black young adults using digital and online technologies.

Methods

Procedures

Data came from a larger investigation of mental health and help-seeking conducted via the completion of an online cross-sectional survey from July to September 2024. As the purpose of the larger study was to understand the mental health of Black and Asian American, Native Hawaiian, or Pacific Islander young adults, we included anyone aged 18 to 29 years who self-identified as Black American or Asian American and resided in the United States. Potential participants were asked, "Please describe your race or ethnicity (select all that apply): American Indian or Alaska Native; Asian or Native Hawaiian/Pacific Islander; Black or African American; Hispanic or Latino; Middle Eastern or North African; White." Individuals who selected Black or African American or Asian or Native Hawaiian or Pacific Islander were included in the study.

Participants were recruited online through Qualtrics Panels, a service through which prequalified individuals complete surveys for research purposes, generating a nonprobability online convenience sample. Quotas were implemented for gender, education, and geographic region to ensure sufficient representation of these factors among survey participants. The validity of Qualtrics panel data is comparable to a traditionally recruited community sample [33]. Each participant panel has its own confirmation procedures to ensure participant verification and data quality. All panel partners verify respondent address, demographic information, and email address using third-party validation platforms (eg, TrueSample, RelevantID, and USPS). Qualtrics Panels removed those who completed the survey too fast, straight-line responders, and multiple responders from the same IP addresses. The online survey also included a reCAPTCHA to detect potential nonhuman responses and 2 attention check questions. Participants who failed these were excluded. With these rigorous data quality standards, only 40% of initiated responses were able to qualify.

Measures

Use of Digital Mental Health Tools

Participants indicated whether they had tried to get help from digital tools for problems with their mental health or emotions in the past year, using items developed for the survey. They were provided with a list of digital tools and asked to select all that they used, including (1) wellness apps or websites; (2) apps or websites for treating depression, anxiety, or other mental health conditions; (3) online or telephone-based therapy services; and (4) online support groups. They were also given additional space to write a description of other tools (eg, watching YouTube videos for mental health information). Participants' selected responses were coded into a dichotomous variable, with 0 representing no reported use of any tools and 1 representing reported use of one or more tools, including those that participants wrote into the textbox.

Online Mental Health Communication

Participants indicated how often they had communicated about mental health online in the past year using 4 items developed for the survey. The items included (1) joining forums or closed social media groups on specific mental health topics, (2) doing hashtag searches for mental health topics on social media, (3) following people online who share about mental health conditions, and (4) sharing about their own poor mental well-being online. Participants indicated the frequency of each item using a Likert-type response scale from 0 (*never*) to 4 (*once a week or multiple times a week*). The mean score was computed from the items to represent the overall frequency of online mental health communication, such that a higher score indicates more frequent online mental health communication. The internal consistency of the scale was acceptable (sample α=.87).

Exposure to Online Racism

The Perceived Online Racism Scale-Very Brief [34] was used to measure exposure to online racism. Participants indicated how often they had experienced 6 items online in the past 6 months, using a Likert-type scale, ranging from 1 (*never*) to 5 (*always*). Example items include "seen online videos that portray my racial/ethnic group negatively" and "received posts with racist comments." A mean score was calculated such that higher scores indicated more frequent exposure to online racism. The internal consistency of the scale was acceptable (sample α=.90).

Depression or Anxiety

Depression was measured using the Patient Health Questionnaire-9 (PHQ-9) [35]. Participants indicated how often they had been bothered by 9 common depressive symptoms over the past 2 weeks on a Likert-type scale from 1 (*not at all*) to 4 (*nearly every day*). Example items include "little interest or pleasure in doing things" and "feeling down, depressed, or hopeless." Participants' responses were scored by computing the sum of items. The internal consistency of the scale was acceptable (sample α=.90). Continuous scores were dichotomized to correspond to clinical cutoffs for major depressive disorder. Depression not indicated (PHQ-9 score <10) was coded as 0. Depression indicated (PHQ-9 score ≥10) was coded as 1. Anxiety was measured using the General Anxiety Disorder 7-item scale (GAD-7) [36]. Participants indicated how often they had been bothered by 7 common anxiety symptoms over the past 2 weeks on a Likert-type scale from 1 (*not at all*) to 4 (*nearly every day*). Example items included "feeling nervous, anxious, or on edge" and "not being able to stop or control worrying." Participants' responses were

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scored by computing the sum of items. The internal consistency of the scale was acceptable (sample α=.92). Continuous scores were dichotomized to correspond to clinical cutoffs for generalized anxiety disorder. Anxiety not indicated (GAD-7 score <10) was coded as 0. Anxiety indicated (GAD-7 score ≥10) was coded as 1. Having depression (yes or no) and having anxiety (yes or no) were 2 separate variables in our analyses.

Analytic Covariates

Age, gender, and internet use were included as covariates. Age was reported in the number of years. On the basis of participant responses, there were three categories of gender identity present in the sample: woman; man; and transgender, fluid, or nonbinary. Participants were asked to report their internet use by indicating how often they used the internet on a typical day, with response options from 0 (*not at all*) to 4 (*almost constantly*).

Analysis Plan

We first examined the presence of missing data. Participants in the analytic sample had missing data on the following variables: use of digital mental health tools (n=50, 4.98%) and gender (n=8, 0.80%). Taken together, 57 (5.67%) participants had any missing data. Those with missing data had lower daily internet use ($t_{59.19}$=2.34; *P*=.02), did not have consistent internet access (χ^2_1=10.3; *P*=.001), and reported less exposure to online racism (t_{1003}=2.68; *P*=.007). There were no differences between those with or without missing data on outcome variables by geographic region (χ^2_3=0.5), age ($t_{1003=}$1.58; *P*=.12), frequency of engagement in online mental health communication (t_{1003}=1.15; *P*=.25), depression (χ^2_1=0.3), or anxiety (χ^2_1=0.3). In sensitivity analyses, we also ran our analytic models excluding those with missing data. Results did not differ.

We first conducted descriptive statistics to describe exposure to online racism, the use of digital mental health tools, engagement in online mental health communication, and rates of depression or anxiety in our sample. Next, we conducted 2 separate path analysis regression models using maximum likelihood estimation, which were each run in Mplus. Path analysis models can handle multiple outcome variables in each model, including outcome variables of different types (eg, binary, continuous). Our model 1 included predictors of online racism and *depression*, and the interaction between the two, on outcomes of use of digital mental health tools (modeled with logistic regression) and engagement in online racism (modeled with linear regression). Our model 2 included predictors of online racism and *anxiety*, and the interaction between the two, on outcomes of use of digital mental health tools (modeled with logistic regression) and engagement in online racism (modeled with linear regression). As depression and anxiety were relatively strongly correlated (r_{1003}=0.61; *P*<.001), we included these variables in separate models and used a Bonferroni α adjustment (α=.05 divided by 2 models for a corrected α=.025) to account for artificial type 1 error inflation due to multiple comparisons [37]. In this way, a *P* value less than .03 for any given model parameter was considered significant. If the interaction term (ie, multiplication of online racism and depression or anxiety) was significant, this was evidence of moderation. Exposure to online racism was grand mean centered, and the interaction term was computed using this mean-centered variable. These path analysis models were fully saturated (ie, all possible parameters were estimated), such that model fit indices were not a consideration.

A conservative post hoc power analysis [38] for the most complex model effect (ie, interaction term) using the smallest observed correlations between model variables, observed variable alpha reliabilities, and a Bonferroni-adjusted critical α level of .025 indicated that our power was .99 with a sample size of 1005.

Ethical Considerations

The study was approved by the University of Southern California Institutional Review Board (APP-24 - 05114; principal investigator: HO). All participants provided informed consent before completing the study, and all data were deidentified before data analysis. Participants who completed the survey received compensation based on their preference, such as cash, airline miles, and vouchers.

Results

Participant Demographics

Our research questions are focused on Black young adults. Therefore, the analytic sample for the current investigation included 1005 monoracial Black young adults aged 18 to 29 (mean age 24.07, SD 3.04) years from the larger study (Table 1). Although multiracial Black young adults were included in the larger study from which the data are drawn, we only included monoracial Black young adults in the current investigation because their experiences of online racism are likely to differ compared to those of their multiracial Black peers. There were approximately equal numbers of women (504/1005, 50.6%) and men (490/1005, 49.1%) in the sample. Most participants resided in the southern United States (481/1005, 47.9%) and had health insurance (89%). A majority indicated that they were almost constantly on the internet (610/1005, 60.7%) and had internet access at home or work (988/1005, 98.3%).

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Table . Characteristics of the analytic sample of Black monoracial young adults (N=1005).

Characteristic	Values
Age, mean (SD), years	24.07 (3.04)
Gender, n (%)	
Woman	504 (50.6)
Man	490 (49.1)
Transgender, nonbinary, or fluid	3 (0.3)
Internet use, n (%)	
Not at all	9 (0.9)
Less than a few times a day	25 (2.5)
A few times a day	107 (10.6)
Many times a day	254 (25.3)
Almost constantly	610 (60.7)
US region, n (%)	
Midwest	203 (20.2)
Northeast	235 (23.4)
South	481 (47.9)
West	86 (8.6)
Health insurance, n (%)	
No	111 (11)
Yes	894 (89)
Internet access at home or work, n (%)	
No	17 (1.7)
Yes	988 (98.3)
Exposure to online racism, mean (SD)	2.58 (1.10)
Use of digital mental health tools, n (%)	
None	437 (45.8)
One or more	518 (51.5)
Online mental health communication, mean (SD)	1.21 (1.15)
Depression, n (%)	
No	508 (50.5)
Yes	497 (49.5)
Anxiety, n (%)	
No	579 (57.6)
Yes	426 (42.4)

Descriptive Statistics

Most of the sample (891/1005, 88.66%) reported any exposure to online racism in the past 6 months. On average, exposure occurred between ‘sometimes’ and ‘half the time’ in the past 6 months (mean 2.58, SD 1.10). This mean frequency was comparable to that in other studies using the same measure [39]. Approximately half (518/1005, 51.5%) of the sample reported using 1 or more digital mental health tools in the past year, while the remainder reported no use of digital mental health tools. On average, participants engaged in online mental health communication less than once a month (mean 1.21, SD 1.15). On the basis of their PHQ-9 and GAD-7 scores, approximately half (497/1005, 49.5%) of the participants in the sample were classified as having depression, and approximately 40% (426/1005) were classified as having anxiety. Thirty-six percent (362/1005) of participants had both depression and anxiety. Bivariate correlations among study variables are presented in Table 2.

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Table . Bivariate correlations among study variables.

Variable	Internet use	Age	Gender	Online racism	Depression	Anxiety	DMHT[a]	OMHC[b]
Internet use	—[c]	—	—	—	—	—	—	—
Age	.04	—	—	—	—	—	—	—
Gender	.05	−.08[d]	—	—	—	—	—	—
Online racism	.01	−.03	.03	—	—	—	—	—
Depression	−.10[e]	−.04	.04	.35[f]	—	—	—	—
Anxiety	−.04	−.04	.05	.33[f]	.61[f]	—	—	—
DMHT[a]	.07*	−.02	−.09[e]	.29[f]	.25[f]	.20[f]	—	—
OMHC[b]	−.08[e]	.02	−.03	.42[f]	.32[f]	.28[f]	.57[f]	—

[a]DMHT is the use of digital mental health tools.

[b]OMHC is engagement in online mental health communication.

[c]Not applicable.

[d]*P*<.05.

[e]*P*<.01.

[f]*P*<.001.

Path Analysis

Exposure to online racism was associated with the greater use of digital mental health tools and more frequent online mental health communication, controlling for depression and anxiety (Multimedia Appendix 1). In both models 1 and 2, more frequent exposure to online racism was associated with a significantly increased likelihood of using digital mental health tools (model 1, odds ratio [OR] 1.72, 95% CI 1.42-2.08; *P*<.001; and model 2, OR 1.84, 95% CI 1.53-2.21; *P*<.001). More frequent exposure to online racism was also associated with more frequent online mental health communication (model 1, β=.31, 95% CI 0.23-0.39; *P*<.001; model 2, β=.36, 95% CI 0.29-0.44; *P*<.001).

Controlling for online racism, having depression or anxiety was also positively associated with the use of digital mental health tools and online mental health communication. Black young adults who exhibited clinically significant depressive symptoms were more likely to report using digital mental health tools (OR 2.02, 95% CI 1.52-2.69; *P*=.001) and reported more frequent engagement in online mental health communication (β=.21, 95% CI 0.15-0.27; *P*<.001). Similarly, Black young adults who exhibited clinically significant symptoms of anxiety were 71% more likely to use digital mental health tools (OR 1.71, 95% CI 1.28-2.28; *P*=.005) and were more frequently engaged in online mental health communication (β=.16, 95% CI 0.10-0.22; *P*<.001). The association between exposure to online racism and use of digital mental health tools and frequency of online mental health communication did not significantly differ for those who had depression or anxiety compared to those who did not (see for nonsignificant interaction statistics).

Discussion

Principal Findings

As members of a generation that grew up with digital technologies, Black young adults are especially likely to use digital mental health tools and engage in online mental health communication. Despite this, a majority of the existing literature on digital mental health tools and online mental health communication among young adults has tested associations in predominantly White samples [6,8,9]. This body of literature has also neglected the role of negative race-related online experiences in shaping the use of digital mental health resources, leaving gaps in our understanding of the unique digital mental health–related experiences of Black young adults. As digital and online mental health solutions continue to be developed as promising and accessible new treatments for youth [6], this study directly informs the yet unexplored role of online racism in how Black young adult populations seek digital mental health resources and provides design and research implications for such solutions for this population.

More frequent exposure to online racism was associated with greater digital mental health tool use and more frequent online mental health communication. Although we cannot know the degree to which Black young adults used tools or engaged online in response to online racism specifically, our findings align with research suggesting that Black young adults may engage with digital tools in an attempt to cope with racism-related stress or protect their well-being. For instance, when engaging on social media apps, Black young adults curate their online environment by filtering content, participate selectively in culturally affirming communities, and use engagement tools such as hashtags to foster safety and connection [40-42]. Black young adults may use digital mental health tools when experiencing more frequent online racism because they perceive these tools to be helpful. This assertion is aligned with evidence that attitudes toward digital mental health solutions are positive, that behavioral control is high, and that there is already a subjective norm of using these tools among young adults [32,43]. Black young adults are also likely to share personal experiences about their mental health from stressful, negative experiences in online spaces such as support groups [29]. Although engagement in

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online mental health communication was relatively low in the sample, it may be that more frequent exposure to online racism is a stressor that catalyzes this engagement as a coping response [28,30]. Conversely, it could be that those who use digital mental health tools or engage more frequently in online mental health communication are exposed to more online racism in these digital contexts. Although it has been theorized that exposure to online racism can be embedded in any technological creation [15], most research examines social media rather than specific mental health tools and resources. The degree to which exposure to online racism in digital mental health content and resources particularly impacts their use remains an important future direction for research. Another related potential explanation for our findings is that Black young adults may perceive a distinction in the contexts in which online racism occurs and the contexts in which they use mental health resources and engage in online mental health communication. If their online racism exposure is occurring primarily on social media, using a wellness app (eg, Headspace) would not necessarily increase their exposure to online racism. In this way, Black young adults may flexibly draw on digital mental health tools and resources that they feel are safer during times of stress.

Exposure to online racism was associated with more digital mental health engagement regardless of clinical levels of anxiety or depression. Higher psychological distress has been associated with greater use of online mental health programs among young adults [44]. Yet some studies find no evidence that baseline symptom severity affects digital mental health app use [45]. In this way, perhaps Black young adults turn to digital mental health tools and engagement in online mental health communication when they feel stress and sadness, including from online racism [16], intending to remedy the negative emotions from these experiences. This finding suggests that online racism may be associated with the use of digital mental health tools and engagement in online mental health communication for a wide swath of Black young adults, even if they do not meet the diagnostic criteria for depression or anxiety, signaling the potential reach and utility of these digital mental health resources for this population. Although the association between exposure to online racism and digital mental health resources did not vary by depression or anxiety, Black young adults with these conditions used digital mental health tools at higher rates and engaged in more online mental health communication compared to those without depression or anxiety. This finding is supported by literature that suggests young adults experiencing mental health challenges are more likely to use online mental health–related resources [8]. This study extends this body of research by examining digital mental health tools and online mental health communication among Black young adults with anxiety or depression.

Limitations and Future Directions

Our study is not without limitations. Although the role of online racism as a stressor impacting behavioral outcomes, rather than the reverse, has been theorized [46] and documented [47], we are unable to infer causality or test the directionality of variables in this cross-sectional correlational study. It may be that those more likely to use digital mental health tools and engage in online mental health communication may experience online racism, or vice versa. Future research should examine these variables using longitudinal designs to measure use and engagement specifically in response to both general stress and specific stressors such as online racism. For instance, a daily diary study assessing the frequency of online racism experienced and the use of digital mental health tools and engagement in online mental health communication in response to such experiences on a given day could provide promising insights regarding Black young adults' reliance on online support resources when experiencing online racism. Such findings could further establish a temporal relationship showing that when experiencing online racism, Black young adults may turn to online social support resources (ie, digital mental health tools and online mental health communication) as coping strategies. This could have implications for the expansion and development of culturally tailored digital mental health tools and online mental health communication mechanisms (eg, a private online support group for experiencing online racism) specific to the needs of Black young adults. Second, although the time frame of measures of online racism (ie, past 6 mo) and outcomes (ie, past year) is appropriate for these constructs, they are assessed via self-report measures that may be affected by recall bias. Additionally, our measure of digital mental health tools was broad, with usage measured as a binary indicator. Although this approach allowed us to generate initial evidence for associations as a starting point for future research, it did not capture nuanced patterns of usage, preferences, or satisfaction. Previous literature has suggested that young adults have preferences in features or types (ie, web-based or mobile self-help) of their digital mental health tools [8] that could be impacted by their level of care needs for mental health conditions, such as depression or anxiety. As Black young adults have tailored their online experiences, such as by using culturally affirming hashtags and engaging in online communities specific to members of their racial group [41,42], future research investigating distinct aspects of digital mental health resource use (eg, intensity of use, digital platform–specific effects, and types of digital mental health resources used) is integral and has implications for developing culturally relevant digital mental health interventions for Black young adults.

Another future direction is to investigate the types of online spaces (eg, social media platforms and online forums) where Black young adults use digital mental health tools and engage in online mental health communication. Research suggests that Black young adults may feel more comfortable discussing these experiences in anonymous communities than on social networked or public platforms such as Facebook feed [29]. Future work could explore how platform type, privacy, and identity shape help-seeking. Our sample was drawn using quota sampling; while this method enhances demographic balance, it remains a form of convenience sampling and is not probabilistic. Participants who enroll in online survey panels may differ systematically from those without the same internet access or who lack interest in online research participation, which limits generalizability. In this study, we focused on monoracial Black young adults, but the online racism experiences of multiracial Black young adults could differ, and we do not necessarily expect our results to generalize to this population. Future research that considers intersectionality and samples large

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enough numbers of Black multiracial populations to appropriately center on their unique experiences remains an important future direction. Finally, most participants were from the southern United States; however, as the availability of certain digital mental health tools varies by state [48], our results may not generalize to other regions. Our findings are focused on online racism and therefore do not capture intersectional experiences of discrimination (eg, gendered racism and racist ableism) that Black young adults may experience online. Further development or adaptation of measures is needed to contextualize such experiences and their impact on digital mental health resources and engagement.

Conclusions

This study highlights the use of digital resources aimed at promoting mental health, such as digital mental health tools and online mental health communication, for Black young adults. Exposure to online racism was linked to greater use of digital mental health tools and more frequent online mental health communication. Mental health practitioners should be aware of the role that digital contexts play in shaping the experiences of Black young adults, both positive and negative, and consider asking about current use or suggesting tools and online mental health communication as resources for clients, when appropriate. At the same time, ensuring that these tools and opportunities for communication are safe, free of online racism, and culturally relevant remains an ongoing parallel priority for researchers, policymakers, and developers.

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Data Availability

The datasets generated or analyzed during this study are available from the corresponding author on reasonable request.

Authors' Contributions

Conceptualization: MCH (equal), VVV (equal), HO (equal), BTHK (supporting) Data curation: HO Formal analysis: VVV Funding acquisition: HO Investigation: HO Methodology: HO Project administration: HO Resources: HO Software: HO Supervision: VVV (equal), HO (equal) Validation: HO Visualization: VVV (lead), MCH (supporting) Writing – original draft: MCH (lead), KAW (supporting), OOB (supporting), VVV (supporting), BTHK (supporting), JH (supporting), HO (supporting) Writing – review and editing: MCH (lead), KAW (supporting), OOB (supporting), VVV (supporting), HO (supporting)

Conflicts of Interest

None declared.

Multimedia Appendix 1
Results of regression analyses assessing associations with the use of digital mental health tools and online mental health communication (N=1005).
[MHT File, 154 KB - formative_v10i1e80657_app1.mht]

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Abbreviations

GAD-7: Generalized Anxiety Disorder-7
OR: odds ratio
PHQ-9: Patient Health Questionnaire-9

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Preliminary Case Series of the Worth Warrior Mobile App for Young People With Low Self-Esteem and Mild Eating Disorders: Pre– and Post–Follow-Up Study

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Abstract

Background: Eating difficulties are increasingly prevalent among young people, yet service capacity remains limited. Digital interventions may provide accessible, scalable support, particularly for those with mild, subthreshold, or early-stage symptoms who do not meet criteria for specialist care. Low self-esteem is widely recognized as a key psychological risk factor in the onset and persistence of eating disorders, and negative self-evaluation, particularly around body image and social acceptance, can heighten vulnerability to the maladaptive thoughts and behaviors seen in conditions such as anorexia nervosa, bulimia nervosa, and binge-eating disorder. Clarifying this relationship is essential for developing effective prevention and early intervention strategies.

Objective: This pilot case series reports on 5 individuals aged 19-25 (mean 22, SD 2.19) years with mild eating disorders who used the Worth Warrior app, a mobile intervention incorporating principles of enhanced cognitive behavioral therapy strategies targeting low self-esteem, body image concerns, and disordered eating behaviors.

Methods: An uncontrolled 3-phase design (baseline, post–app familiarization, and follow-up) was used. Participants completed standardized self-report tools, including the Eating Disorder Examination Questionnaire and Rosenberg Self-Esteem Scale. Feedback on usability, acceptability, and safety was also collected via online questionnaires.

Results: Outcome measures at follow-up showed improvements in eating disorder symptomatology in 3/5 cases, and in self-esteem in 4/5 cases; those with milder symptomatology indicated the most benefit. Reductions in eating concerns, weight concerns, and related behaviors were observed in most, though not all, cases. Participants valued interactive enhanced cognitive behavioral therapy features and journaling functions, while noting areas for improvement such as reminders and incentives for use and preventions for maladaptive use of the free-text facilities.

Conclusions: Findings suggest the Worth Warrior app may be suited as an acceptable and effective standalone tool for individuals with mild eating disorder symptoms, and used as an adjunct to traditional treatment alongside clinician supervision for those with more severe presentations to promote the greatest patient safety. These exploratory case study findings suggest that the app has the potential to support improvements in self-esteem and mild eating disorder symptomatology; however, as a preliminary case series, these results are not generalizable but provide a foundation for larger, controlled studies of digital early intervention.

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KEYWORDS

mental health; eating disorders; body image; self-esteem; mobile phone app; cognitive behavioral therapy; CBT-E; digital tool; young people; mobile phone

Introduction

Background

Eating disorders are common and distressing mental health conditions with significant psychological, physical, social, and economic impacts. An individual with an eating disorder controls their food intake in some way to manage difficulties such as strong emotions, and these disorders involve negative thoughts and behaviors about oneself, eating, and physical appearance, often resulting in food restriction and/or binging, as well as associated behaviors such as excessive exercising [1-3]. The most common forms of eating disorder are anorexia nervosa, bulimia, and binge eating disorder [1].

The Prevalence of Possible Eating Problems and Clinical Eating Disorders in Young People

An estimated 1.25 million people in the United Kingdom (UK) are currently living with an eating disorder, a considerable proportion of whom are younger than the age of 25 years [4,5].

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The number of referrals for eating disorders to National Health Service (NHS) child and adolescent mental health services in England has almost doubled from prepandemic levels, and these rates have remained elevated since, with those younger than 25 years making up 48% of total hospital admissions for eating disorders [5-8]. In 2023, a total of 3% of those aged 11 - 16 years, 13% of those aged 17 - 19 years, and 6% of those aged 20 - 25 years were identified as having an eating disorder [7]. This all points to a persistent and rising tide of eating disorder problems among young people in the United Kingdom.

Furthermore, the prevalence of "possible eating problems" among young people is even higher [7,9]. A possible eating problem typically refers to behaviors, attitudes, or symptoms associated with disordered eating that may not meet the full clinical criteria for an eating disorder, but are nonetheless concerning and can impair health and well-being. In 2023, almost 60% of those aged 17 - 25 years and 12% of those aged 11 - 16 years had a possible eating problem [8]. This is of concern because subthreshold cases represent a vulnerable group at heightened risk of progressing to full-syndrome eating disorders.

Self-Esteem, Body Dissatisfaction, and the Development of Eating Disorders in Young People

The etiology of an eating disorder is complex, with overlapping biopsychosocial and cultural factors implicated in its onset and development [10]. Research indicates that the mean age of onset for eating disorders such as anorexia nervosa and bulimia nervosa is between about 15 and 19 years, while binge-eating disorder tends to emerge slightly later, at around 23 and 24 years [1,3,11]. These disorders are often triggered and/or maintained by biopsychosocial factors that can include sociocultural pressures, puberty and changing bodies, low self-esteem, and body dissatisfaction [12-14].

Indeed, low self-esteem and body dissatisfaction are consistently identified as significant, transdiagnostic vulnerability factors for and predictors of the onset and maintenance of eating disorders [15-20]. "Self-esteem" is defined here as a person's subjective evaluation of themselves and their worth [21,22], and individuals with chronically low self-esteem may attempt to regulate feelings of inadequacy and negative self-evaluation through control of overeating, weight, and shape [23]—all factors involved in eating disorders. Furthermore, longitudinal studies show that low self-esteem in adolescence predicts later onset of disordered eating behaviors [24,25].

Moreover, low self-esteem is closely linked with body dissatisfaction, which is a form of body image involving a negative attitude toward the appearance of one's body [26] and one of the strongest predictors of eating pathology [27,28]. "Body image" refers to a dynamic and multidimensional construct, incorporating a person's cognitive, affective, and evaluative perceptions of their own body and how it appears [29-31]. When a person places excessive value on their weight and shape and is dissatisfied with their body, they too may develop disordered eating behaviors and pathologies to try and regulate or "improve" this body image [19,29].

Importantly, these factors have also been shown to be reciprocally related, such that low self-esteem can enhance body dissatisfaction and vice versa [15,32,33]. For example, of particular interest in eating pathology is appearance-contingent self-esteem, wherein a person's self-esteem is dependent upon their evaluation of their physical appearance [34,35]. When individuals base their self-esteem predominantly on appearance, they are more likely to experience body dissatisfaction, which in turn contributes to lower self-esteem and poor mental health outcomes, including anxiety, depression, and disordered eating (eg, Adams et al [36], 2017; McLean and Paxton [17], 2019; Mora et al [18], 2017). This process creates a cycle where body dissatisfaction undermines broader self-value, increasing the risk of restrictive or compensatory behaviors. Clinical models, such as Fairburn's transdiagnostic theory, therefore identify low self-esteem as a maintaining mechanism that interacts with perfectionism and self-criticism, thereby perpetuating the cycle of dietary restraint, binge eating, and compensatory behaviors [23].

Consequently, addressing body dissatisfaction and self-esteem may be an important preventive and early intervention target, particularly with regard to building self-esteem that is not dependent on weight or body image. Evidence indeed suggests that therapeutic approaches that target self-esteem and body dissatisfaction, such as enhanced cognitive behavioral therapy (CBT-E), are effective in reducing eating disorder symptoms [37,38]. Interventions that foster body acceptance, promote diverse standards of beauty, and encourage self-esteem rooted in internal qualities rather than appearance have been shown to mitigate the aforementioned risks of appearance-contingent self-esteem and support healthier psychological development and can therefore be a valuable inclusion in the prevention and treatment of eating disorders [39-41]. As part of this, therefore, identifying and supporting subthreshold cases is crucial.

The Importance and Difficulty of Early Intervention and Long-Term Treatment

With varied and serious health risks associated with eating disorders, including mortality, growth delay, hypovolemia, and relapse, adequate and timely treatment is essential, and prevention and early intervention are ideal [12,42]. Intervening during the early stages of an eating disorder has multiple benefits, including preventing functional deterioration, neuroadaptation, and habitual behavior patterns, as well as the challenges associated with prolonged illness [43]. Early intervention can reduce progression to severe disorders, decrease health care use, and improve quality of life, while also generating economic savings by offsetting the high health, social, and economic costs associated with the illness [44-47].

Despite this, delays in treatment are common, with many young people in the United Kingdom being left on long waiting lists or unable to access care, and NHS targets for timely treatment are not currently being met [5,48]. With stretched services having to prioritize higher-severity cases, the duration of untreated eating disorders has been estimated at around 3 and a half years [49]. These treatment delays are largely due to demand rapidly outpacing treatment capacity, service funding being cut, and early-stage disorders often going undetected or

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untreated for long periods due to stigma, lack of access to care, and insufficient service provision [4,46,50]. Unfortunately, treatment delays are associated with poorer outcomes, with the best prognosis found in young people with a short duration of illness [51-54], and this is particularly concerning given that anorexia nervosa has the highest mortality rate of any psychiatric disorder, with mortality risk in those aged 15‐24 years exceeding that of other major adolescent illnesses such as asthma or type-1 diabetes [48,55,56].

Lastly, these issues are further compounded by the fact that eating disorders are complex, chronic conditions that frequently require extensive and long-term treatment. Recovery often takes several years, and relapse rates are high, and guidelines emphasize the need for sustained, multidisciplinary approaches [1,48,57]. While early intervention clearly improves outcomes, the reality of long-term care further compounds capacity pressures, underlining an urgent need for scalable and accessible solutions to this growing problem.

Mobile Health Apps for Eating Disorders and Self-Help Treatment

This increased demand, coupled with delays in accessing care, therefore highlights the need for expanded capacity for effective, accessible support and early intervention for eating disorders in young people. Digital interventions can thus play a potential role in delivering timely care at scale by enabling young people to manage symptoms before they become severe, serving as an adjunct while awaiting or receiving treatment, or helping patients to stay well and avoid relapse following treatment [58-60]. In particular, given that approximately 96% of adolescents aged 12‐17 years own or have access to a mobile phone [61], mobile health apps could increase access to psychological therapies by providing treatment-informed techniques to a wide audience in a digital format. These applications also offer additional advantages to traditional in-person support, such as face-to-face cognitive behavioral therapy, including scalability at low marginal cost, capacity to reach underserved populations (eg, rural or low-income groups), and the potential to reduce stigma and facilitate early triage for specialist care [59,62,63].

There are some existing mobile health apps for the management of eating disorders, which typically aim to provide either information, self-monitoring, assessment, or support to users, or a combination [60]. However, evidence for the safety, efficacy, and effectiveness of the majority of such tools remains limited at best [64]. Many existing apps lack grounding in evidence-based frameworks, incorporate minimal user involvement in their design, and omit robust safety protocols [64-66]. The scope of these apps also varies widely; in a systematic clinical appraisal by Fairburn and Rothwell (2015) [64] assessing 39 such apps, only one-third provided psychoeducational information to users, 60% purported to provide support or advice, and just 10% facilitated self-monitoring of eating habits. Given the complexity of eating disorders and the need for a multidisciplinary approach to treatment, a comprehensive intervention would ideally incorporate all of these elements. More concerningly, 85% of those who provided psychoeducational information to users and 70% of those who provided support or advice were found to provide either unreliable, misleading, or harmful content. Furthermore, the unique potential of smartphone technologies—such as ecological momentary interventions and automated self-monitoring—remains largely underexploited in existing tools, restricting the advantages these digital interventions could offer over traditional treatment approaches [65].

Results from a systematic review by Wasil et al [67], 2021, do at least suggest that most active app use focuses on a select few apps for eating disorder management that are evidence-based. However, none of these most prominent apps appear to focus specifically on addressing the aforementioned relationship between body image, self-esteem, and eating disorders that can be critical to both the development and maintenance of these illnesses, nor are they designed and intended for children and young people specifically. Many also have some or all features behind a paywall and/or require clinician involvement, all of which can restrict the accessibility and scalability advantages that can be afforded by apps.

The Worth Warrior Mobile App Intervention

In response to this, the Worth Warrior mobile app is a clinician-developed intervention intended to address this gap in the existing digital mental health landscape by providing young people at risk of developing eating disorders with access to evidence-based support that addresses the transdiagnostic risk and maintenance factors of low self-esteem and body dissatisfaction. Its applicability spans mild forms of eating disorders including anorexia nervosa, bulimia nervosa, binge-eating disorder, and avoidant/restrictive food intake disorder, reflecting the transdiagnostic nature of eating disorders.

It is therefore designed to support young people who have low self-esteem, body dissatisfaction, and mild eating difficulties, drawing on principles of CBT-E. In particular, the app focuses on breaking the aforementioned cycle of poor body image and low self-esteem that leads to eating-related thoughts and behaviors, delivers psychoeducation, and helps to monitor and change negative or critical thoughts, eating-related behaviors, the daily impact of negative self-image, and emotional regulation—all factors that can contribute to a young person's eating behavior and negative self-esteem.

The app seeks to address limitations in the existing digital health landscape in its evidence-based focus and comprehensive CBT-E components, its leveraging of smartphone technology (such as automatically populated self-monitoring and both personalizable and interactive activities), and its prompts to seek further help when times of high risk are identified [65,66,68]. Its development also involved collaboration with young people and clinical experts, with iterative safety reviews, mitigating the aforementioned risk of providing potentially harmful information.

However, evidence is required to demonstrate the app's effectiveness and safety.

This Study

This paper presents a preliminary evaluation of the Worth Warrior app in the form of a case series of 5 young people with

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mild eating disorders who used the app for 7 weeks, with a focus on any clinical change in their eating disorder–related thoughts and behaviors and self-esteem throughout the intervention period, as well as their reception of the app itself (specifically its usability, acceptability, and safety). “Mild” eating disorders were identified as self-reported eating difficulties that were subthreshold, or above but without a formal diagnosis, professional treatment, or indicators of greater severity such as previous hospital admission.

Due to the small number of participants completing all phases of this study (expanded upon later), this study has been written up qualitatively as a case series. Case reports and series can be a crucial first step in developing evidence of the impact of a new treatment intervention, prompting further research and highlighting questions to address, as well as centering on the patients’ perspectives and experiences [69].

Method

Study Aims

This preliminary evaluation of the Worth Warrior app aims to present a case series of 5 individuals’ experiences of using the app over 7 weeks, with a focus on any clinical changes in eating disorder and/or self-esteem levels over the intervention period, along with their perceived usability, acceptability, and safety of the app. The objective of this research was to ascertain whether these individuals found the app useful in managing and/or reducing their mild eating disorders and low self-esteem, to contribute toward preliminary evidence of the effectiveness of the Worth Warrior app as a tool for young people with such difficulties.

Intervention Design and Components

About the Intervention

The Worth Warrior smartphone app is a clinician-developed, standalone tool for individuals aged 12 years and older who are experiencing self-esteem issues or body image concerns, and who may be at risk of developing, or be at the early stage of, disordered eating behaviors. The app provides structured interactive modules that address cognitive, behavioral, and emotional processes associated with eating-related difficulties, based on the principles of CBT-E.

It is intended for multiple groups, including (1) young people who do not meet threshold criteria for specialist treatment, (2) those awaiting specialist services, (3) individuals receiving treatment where the app may serve as an adjunct, and (4) those posttreatment seeking to maintain progress and prevent relapse. It can also provide key support to those young people aged 16 - 25 years who meet First Episode Rapid Early Intervention for Eating Disorders criteria. It is important to note, however, that the intervention is not intended as a substitute for assessment and intervention by a mental health professional.

CBT-E Components

The CBT-E components of the app include (1) cognitive restructuring of negative self-thoughts (“change the story”), (2) behavioral modification and response prevention (“change the action”), (3) development of alternative emotional regulation strategies (“change the emotion”), and (4) body image–focused exercises aimed at challenging distorted assumptions (“change the way I view my body”).

See Figure 1 for example screens of some of these sections of the app.

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Figure 1. Example screens in the "change the…" sections of the Worth Warrior app, the digital intervention used in this preliminary case series for young people with low self-esteem and mild eating disorders.

The app does not, however, incorporate the tracking component of traditional CBT-E in which the person monitors their nutrition and weight, as it was determined that this would not be suitable in a tool that can be used independently, and was also a preference expressed by young people during co-design. Instead, the app offers psychoeducation on food and eating, along with perfectionism, body dissatisfaction, and conditions such as body dysmorphic disorder, avoidant/restrictive food intake disorder, and eating difficulties associated with autism spectrum conditions.

Risk management is supported through a "keeping safe" section (see Figure 2 for example screens), which allows users to identify supportive strategies, contacts, and personalized positive statements. Self-monitoring features enable users to track progress, journal thoughts and feelings, and access motivational prompts.

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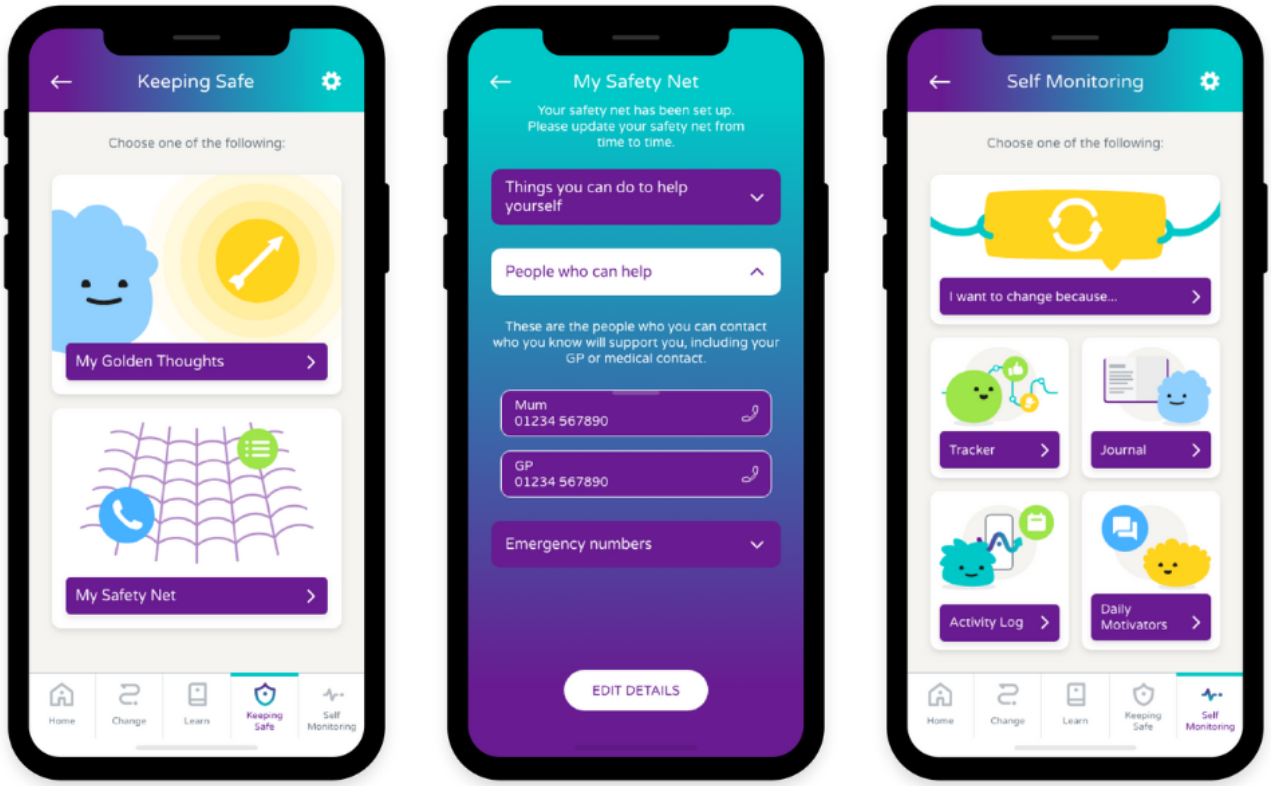
Figure 2. Example screens of the keeping safe, safety net, and self-monitoring sections of the Worth Warrior app, the digital intervention used in this preliminary case series for young people with low self-esteem and mild eating disorders. GP: general practitioner.



Co-Design

Worth Warrior was designed to include age-appropriate design elements for adolescents and young adults, and co-design occurred at multiple stages in development. Initial ideas on the content of the app, design, and tone of voice were obtained by involving 5 young people with lived experience and 1 parent as well as a group of 10 young people aged 15 - 17 years from the community. All individuals involved were diverse in terms of gender and ethnicity.

The groups were approached again once a minimal viable product was designed for further feedback on user journeys and to provide feedback on challenges and strengths. A total of 8 young people in the community then tested the app and provided feedback. Additionally, 4 young people had early stage body image issues. Moreover, 12 young people with lived experience of a variety of mental health difficulties were involved in the research design. Clinicians comprising 4 clinical psychologists specializing in eating disorders, 2 child and adolescent psychiatrists, a psychotherapist, and an eating disorder researcher all contributed to feedback on the app and attended 2 clinical hazard workshops for input and feedback.

Safety and Regulatory Considerations

The app is a noninvasive, noncontact digital health intervention with flexible usage patterns. While no physical risks are associated with its use, clinical oversight is recommended in moderate presentations. It is not intended as a substitute for professional assessment or treatment; users are directed to medical consultation where necessary. The app complies with clinical safety standards (eg, NHS DCB0129) and prioritizes data protection through minimal data collection and privacy safeguards. This is particularly pertinent considering that the 2 most common perceived barriers to eHealth interventions for eating disorders found by Linardon et al [63], 2021, are concerns regarding data privacy and information accuracy.

Evaluation Design and Participants

Overview

This study applied a 3-stage, pre– and post–follow-up, case series design.

Sample, Recruitment, and Consent

Participants were recruited using a combination of sampling methods with the intention of involving a diverse and representative sample. This included reaching out to several national eating disorder organizations (Beat, National Centre for Eating Disorders, SWEDA, and First Steps ED), specialist eating disorder services (Birmingham Women's and Children's NHS Foundation Trust), leaflets and posters in national community centers, and universities, who shared about this study's recruitment with their community groups and/or on their website. The recruitment advertisement sent to these organizations can be found in the Multimedia Appendices (Multimedia Appendix 1). Additionally, this was shared via stem4's (the app developer's) website and existing social media networks.

Messaging in these advertisements included, "Do you have low self-esteem and think you have a sub-clinical or early stage eating disorder?" A 13-item screening tool, developed for the purposes of this study, was used to assess the young person's

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eligibility (Multimedia Appendix 2). Participants also needed to sign a statement confirming their fitness to participate.

Participant inclusion criteria included (1) young people aged between 17 - 25 years, (2) those who presented with body image issues or eating-related difficulties (assessed via the screening tool; Multimedia Appendix 2), and (3) were not currently receiving treatment from secondary mental health services.

"Mild" eating disorders in this study were identified as those scoring below the Eating Disorder Examination Questionnaire (EDE-Q) clinical threshold, or above but without a formal diagnosis, professional treatment, or indicators of greater severity such as previous hospital admission. This was determined via responses to the screening tool and EDE-Q scores obtained from the baseline questionnaire.

See Multimedia Appendix 3 for the full inclusion criteria and each corresponding screening question.

Exclusion criteria included anyone at high risk (eg, with active suicidal ideation or considering or planning suicide) or currently experiencing a crisis or episode of illness. This also excluded those diagnosed with a severe and enduring mental health problem, such as psychosis, or a significant learning disability, or individuals who may be misusing alcohol or substances which may have hampered their use of the app.

Eligible participants were given an information sheet informing them of this study's details, risks, and benefits before being asked to complete an informed consent form. Only those who provided their informed consent went on to enter this study.

Evaluation Procedure

Overview

Textbox 1 shows this study's procedure. We also consulted with 8 people (aged between 14 and 17 years) to provide feedback on this study's proposal and procedure regarding their preferences concerning web-based data collection.

Textbox 1. Procedure for this preliminary case series pilot study of the Worth Warrior app for young people with low self-esteem and mild eating disorders.

Recruitment and consent

- Advertise the Worth Warrior app evaluation and invite young people to participate
- Check the eligibility of young people interested by using the screen questionnaire
- Obtain informed consent from young people

Baseline and app familiarization (stage 1)

- First questionnaire with the consenting young person, if preferred
- Completion of all quantitative measures via an online link
- Downloading the app with instructions for use
- Familiarization with the app over 1 week

Postfamiliarization review (1 week following baseline; stage 2)

- Completion of the measures and questionnaires via online link
- Shorter questionnaire to review the app to assess safety and any problems with use, if preferred
- Decision of young people to proceed with using the app and taking part in the evaluation

Use of the Worth Warrior app for 6 weeks

- Participant to use the app when needed over the next 6 weeks

Follow-up (stage 3)

- Participants complete outcome measures online for the last time
- Final questionnaire to assess the app's safety, usability, and acceptability, and whether they contacted someone for help

The evaluation procedure comprised three data collection stages: (1) baseline and app introduction (stage 1), (2) post–app familiarization of one week (stage 2), and (3) follow-up after six weeks (stage 3).

Baseline (Stage 1)

Participants were provided with online instructions on using the Worth Warrior app and the evaluation procedure. Once their eligibility was determined and informed consent was given, they were asked to complete 3 baseline clinical assessments online to measure symptoms of self-esteem and eating disorder symptomatology (details of these questionnaires are provided below). Participants also completed a brief, standard questionnaire to collect data on their demographic characteristics.

Participants were asked to download the Worth Warrior app and familiarize themselves with it over the next week. Alongside obtaining baseline measures, this familiarization period was to manage risk and ensure participants' safety until they became

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fully versed in using the app, were aware of signs and symptoms to look out for, and had input information in their "safety net" section.

Post–App Familiarization (Stage 2)

One week after baseline, an online questionnaire was sent to participants to gauge their assessment of the app and any problems they may have had. The person could then decide whether they wished to continue with this study. If they chose to continue, they completed the standardized measures online. Participants could then use the app as often as they wanted over the following 6 weeks.

Follow-Up (Stage 3)

After 6 weeks, participants were asked to complete the clinical measures and user questionnaire for the final time.

Following Up on Nonresponders

At the postfamiliarization and follow-up stages, participants were contacted by email and asked to complete the follow-up questionnaires. If no response was received, the researchers made 2‐3 attempts to contact the participant. If no contact was made, the researchers assumed the participant no longer wished to take part in the evaluation.

Data Collection

Clinical Outcome Measures

Two standardized clinical measures were used to assess the main study outcomes: mild symptoms of eating disorders and levels of self-esteem. These were the EDE-Q (version 6.0; [70]) and the Rosenberg Self-Esteem Scale [71].

About the EDE-Q

The EDE-Q is a 28-item self-reported questionnaire that assesses the range and severity of features associated with an eating disorder diagnosis, using 4 subscales (restraint, eating concern, shape concern, and weight concern), measures of behavior frequency, and a global score. It uses a 7-point Likert scale to assess the number of days and frequency of symptoms (ranging from "no days=0" to "everyday=6," and "not at all=0," to "markedly=6"). The scale can be used both to identify whether an individual can be considered to have a clinical eating disorder and the severity of any eating disorder–related psychopathology [72]. Its reliability and validity have been supported for both adults and adolescents, and in both clinical and nonclinical samples [72-75].

Global EDE-Q scores of 4 or more are generally accepted to indicate the presence of a clinical eating disorder [72].

Rosenberg Self-Esteem Scale

The Rosenberg Self-Esteem Scale is a 10-item self-report scale that measures global self-esteem. Each item is a statement relating to overall feelings of self-worth or self-acceptance, and items are rated using a 4-point scale ranging from "strongly agree" to "strongly disagree." Individuals' global scores from this scale can range from zero (the lowest possible score) to 30 (the highest possible), wherein scores within 15‐25 are generally considered to indicate "normal" levels of self-esteem, and those below 15 to indicate low self-esteem [76]. As such, the higher the score, the higher the level of self-esteem.

Again, the reliability and validity of this scale have been supported for both adults and adolescents [77-80].

Worth Warrior App User Questionnaire

A further questionnaire, developed for this study from a template from a previously published app evaluation [81], and administered online, involved 21 items to measure participants' satisfaction with the Worth Warrior app (Multimedia Appendix 4). It used a combination of Likert rating scales, multiple choice questions, and open-ended questions with free-text fields to address the following domains: (1) usability—ease and frequency of use (seven items assessed this domain, such as "how easy was the app to use?" [1‐5 Likert scale]); (2) acceptability—participants' opinions regarding the app and its usefulness, and how and why they chose to use it (ten items assessed this domain, such as "what features did you not like and why?" [free-text field]); and (3) safety—extent to which the app promoted positive outcomes (provided reassurance, reduced negative self-evaluation, and helped to contact someone when needed) and did not increase negative outcomes (four items assessed this domain, such as "did the app increase negative self-evaluation when you used it?" [free-text field]).

Participants were asked to complete this questionnaire at the postfamiliarization and follow-up time points.

All measures and questionnaires were entered onto an online platform, Survey Monkey, a link to which was sent to participants at baseline, post–app familiarization, and follow-up.

Ethical Considerations

Ethical Approval and Informed Consent

Ethics approval for this study was obtained from the London—City and East Research Ethics Committee (United Kingdom; 22/HRA/1778), and all practices and procedures throughout the research process were in line with the stipulations of the Declaration of Helsinki. This included that participants needed to provide informed consent before commencing this study.

Participants were given a £30 (US $41.25) Amazon voucher as an honorarium upon completion of the final stage.

Participant Safeguarding

Participant exclusion criteria included anyone at high risk (eg, with active suicidal ideation or considering or planning suicide) or currently experiencing a crisis or episode of illness. Anyone who, at the initial screening, presented with increased risk was supported by the researchers to contact emergency numbers provided, including signposts to Beat (an eating disorder charity), NHS 111, and/or health services.

Additionally, as part of their informed consent, participants were told that the researchers could not offer counseling or any other form of support except for the Worth Warrior app for early stage eating disorders, which does not replace traditional treatment. They were also signposted to sources of help from

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the outset, and any take-up of these resources was noted where possible.

The inclusion of the app familiarization phase, as mentioned in the evaluation procedure, was also to facilitate participant safeguarding.

Data Protection and Privacy

To maintain confidentiality and anonymity, eligible and consenting participants were allocated an anonymous study ID number by a project administrator separate from the researchers. All participants' data were anonymized, collected, and stored securely, and managed solely by the researchers.

Ongoing Monitoring and Risk Assessment

Throughout this study, participants self-reported their eating disorder symptoms and self-esteem levels at regular intervals, as well as indicators of relevant symptoms signaling worsening health. If they reported high scores or emerging new symptoms, they were encouraged to consult a general practitioner or, depending on the severity, seek more urgent help. After this study, participants were given resources on maintaining well-being.

stem4, the owners of the app, had a clinical safety protocol and hazard mitigation list that was managed and reviewed regularly, with clear timelines of response. Their clinical safety officer was available to respond to inquiries daily.

Data Analysis

Overview

The demographic profile of participants and other quantitative data were described using frequencies, percentages, and means. Scores derived from the outcome measures were compared between baseline, postfamiliarization, and follow-up using Google Sheets and Looker Studio (Google LLC).

App User Questionnaire

Each subscale of the app user questionnaire was scored by averaging total ratings of the corresponding scales, resulting in a maximum score per subscale of 5.

Thematic analysis was conducted of the qualitative data from open-ended text responses, following the principles of Braun and Clarke [82], 2006, and, in particular, structured tabular thematic analysis as advocated by Robinson [83], 2021. Since this was a preliminary and exploratory evaluation of a new technology, an inductive approach was used for coding, in which codes and themes were generated naturally, from the bottom up, rather than guided by pre-existing theory. This decision was to foster an open-minded interpretation of participants' experiences [84].

Along with this quantitative and thematic analysis, individual case reports were written for each participant, and all analysis is synthesized into the following Results section.

Results

Overview

The recruitment for this study took place between September 2022 and July 2024. Due to the stringent eligibility criteria, 99 people registered their interest in taking part in this study, but 53 (54%) of these did not meet the eligibility criteria, and a further 13 people did not complete the eligibility form. Of the 33 who were eligible, 17 (52%) did not provide informed consent to take part, 2 (6%) did not pass the ID check (this was necessary to ensure all participants were unique), and a further 6 (18%) dropped out before commencing stage 1. Ultimately, 8 people entered this study; see Figure 3 for details of the recruitment flow.

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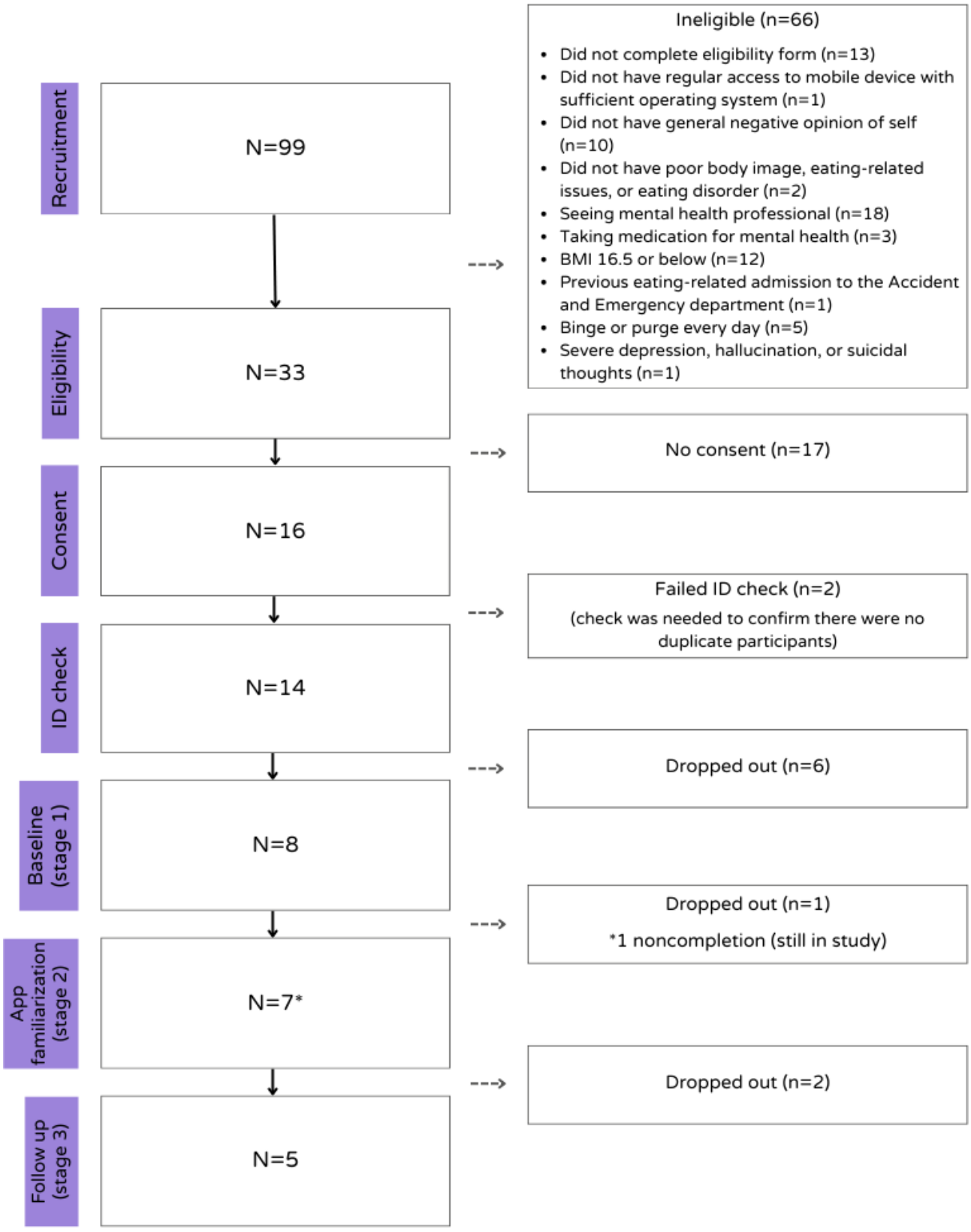
Figure 3. PRISMA participant flow diagram of the recruitment process for this preliminary case series pilot study of the Worth Warrior app for young people with low self-esteem and mild eating disorders. PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-Analyses.



Participant Demographics

Of the 8 individuals who began the study, 5 (63%) completed stage 3 approximately 7 weeks later (a 38% attrition rate). One of these individuals did not complete the questionnaires at stage 2, but did complete stages 1 and 3, and so has been included in this preliminary evaluation.

These 5 participants (female=4, nonbinary=1) ranged in age from 19 to 25 (mean 22, SD 2.19) years. All 5 were

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White-British, with 3 in full-time employment, 1 in college, and 1 stay-at-home mother. See Table 1 for full details.

Table . Characteristics of the participants at baseline (stage 1) of this preliminary case series pilot study of the Worth Warrior app for young people with low self-esteem and mild eating disorders (N=5).

Characteristic	Values
Gender, n (%)	
Women	4 (80)
Nonbinary	1 (20)
Country, n (%)	
England	5 (100)
Ethnic background, n (%)	
White-British	5 (100)
Employment or study status, n (%)	
Employed (full time)	3 (60)
Student (full time or part time)	1 (20)
Unemployed: stay-at-home mother	1 (20)
Marital status, n (%)	
Single	2 (40)
Married or cohabiting	2 (40)
Other: engaged	1 (20)
Age (years), n (%)	
19	1 (20)
20	1 (20)
23	2 (40)
25	1 (20)

Overview

Table 2 details EDE-Q and Rosenberg Self-Esteem Scale scores, per study stage, for each participant; see Table 3 for cohort mean scores and SDs, per stage.

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Table . Mean EDE-Q[a], Rosenberg Self-Esteem Scale, and Worth Warrior app[b] scores per participant, at each stage of this preliminary case series pilot study of the Worth Warrior app for young people with low self-esteem and mild eating disorders.

Scale and subscale	P9			P10			P12			P15			P17		
	Stage 1	Stage 2	Stage 3	Stage 1	Stage 2	Stage 3	Stage 1	Stage 2	Stage 3	Stage 1	Stage 2	Stage 3	Stage 1	Stage 2	Stage 3
EDE-Q, mean															
Global score	2.8	N/A[c]	0.5	4.3	0.5	0.8	4.0	4.0	2.0	5.1	4.7	5.3	4.8	4.8	5.2
Restraint	2.0	N/A	0.4	0.6	0.0	0.0	1.2	2.8	0.2	4.0	4.4	4.6	5.0	5.2	5.2
Eating concern	1.6	N/A	0.2	5.2	0.4	0.0	4.0	3.4	1.2	5.8	5.0	5.6	2.8	2.8	4.0
Shape concern	3.4	N/A	0.5	5.9	0.9	1.6	5.5	4.8	3.3	5.5	4.9	5.9	5.9	5.8	5.9
Weight concern	4.4	N/A	1.0	5.6	0.8	1.4	5.4	5.2	3.2	5.2	4.6	5.0	5.4	5.4	5.8
Behavior frequency	1.2	N/A	0.0	1.7	0.0	0.0	2.0	0.5	0.8	1.2	1.5	1.8	0.5	0.5	1.0
Rosenberg, mean (subscale N/A)	13	N/A	20	3	12	17	1	3	9	7	12	10	9	10	6
App (rating scales only)[b], mean															
Usability	N/A	N/A	5.0	N/A	5.0	5.0	N/A	4.5	3.5	N/A	2.5	4.0	N/A	5.0	3.5
Acceptability	N/A	N/A	5.0	N/A	5.0	5.0	N/A	3.5	3.5	N/A	3.5	3.5	N/A	5.0	2.5
Safety	N/A	N/A	5.0	N/A	5.0	5.0	N/A	3.7	3.0	N/A	3.3	2.7	N/A	3.0	3.3

[a]EDE-Q: Eating Disorder Examination Questionnaire.

[b]This user questionnaire was developed for this study; each subscale is scored by averaging total ratings of the corresponding rating scales, resulting in a maximum score per subscale of 5. However, this does not take into account users' qualitative responses, which are addressed in the main body.

[c]N/A: not applicable.

Table . Mean scores and SDs, per study stage, for the scales and subscales used in this preliminary case series pilot study of the Worth Warrior app for young people with low self-esteem and mild eating disorders.

Scale and subscale	Stage 1		Stage 2		Stage 3	
	Mean (SD)	n	Mean (SD)	n	Mean (SD)	n
EDE-Q[a]						
Restraint	2.56 (1.68)	5	3.10 (1.99)	4	2.08 (2.31)	5
Eating concern	3.88 (1.54)	5	2.90 (1.65)	4	2.20 (2.22)	5
Shape concern	5.23 (0.94)	5	4.06 (1.88)	4	3.43 (2.18)	5
Weight concern	5.20 (0.42)	5	4.00 (1.87)	4	3.28 (1.90)	5
Global score	4.22 (0.78)	5	3.52 (1.75)	4	2.75 (2.10)	5
Rosenberg	—[b]	5	9.25 (3.70)	4	12.40 (5.24)	5
App ratings						
Usability	—	—	4.25 (1.03)	4	4.20 (0.68)	5
Acceptability	—	—	4.25 (0.75)	4	3.90 (0.97)	5
Safety	—	—	3.75 (0.76)	4	3.80 (1.00)	5

[a]EDE-Q: Eating Disorder Examination Questionnaire.

[b]Not available.

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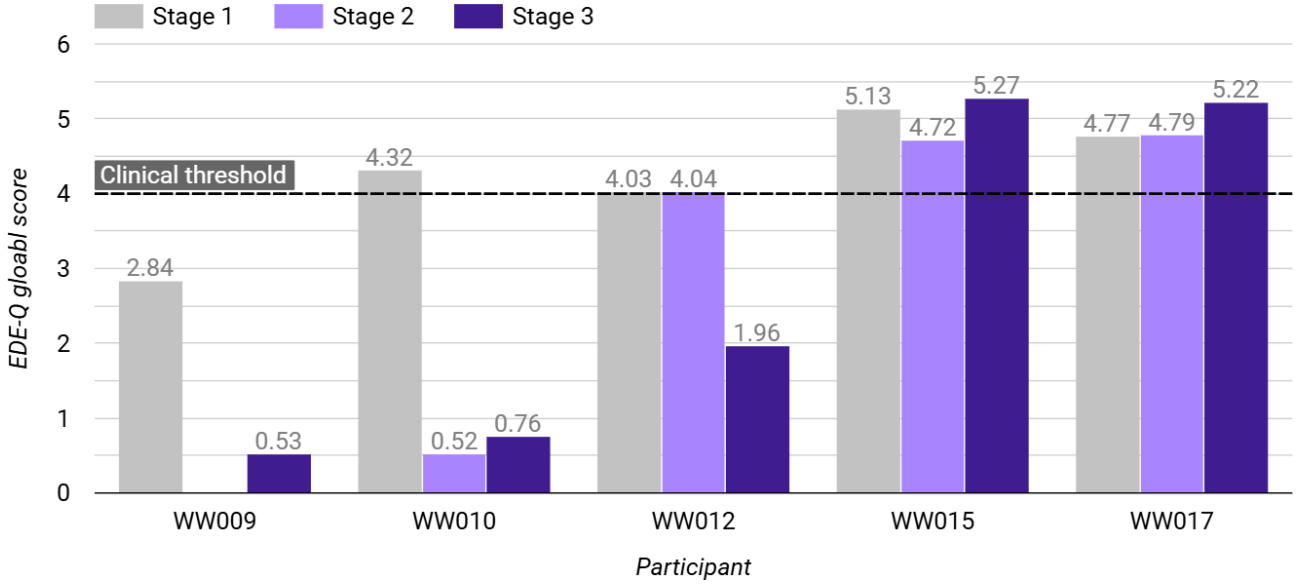
Baseline (Stage 1)

At the point of commencing this study, all 5 participants were classed as either a "healthy" weight (n=3, 60%) or "overweight" according to their BMI, and all expressed current methods of coping with low self-worth that were either nonexistent or maladaptive (such as overreliance on family and friends or starving oneself in response to low self-worth). All indicated problematic attitudes and behaviors toward their eating, 4 of whom scored above the clinical threshold on the EDE-Q, with the remaining participant (P9) still scoring well above their (nonclinical) population mean (average EDE-Q global score=4.2, SD 0.8, range=2.8 to 5.1; clinical threshold≥4; [72]); see Figure 4.

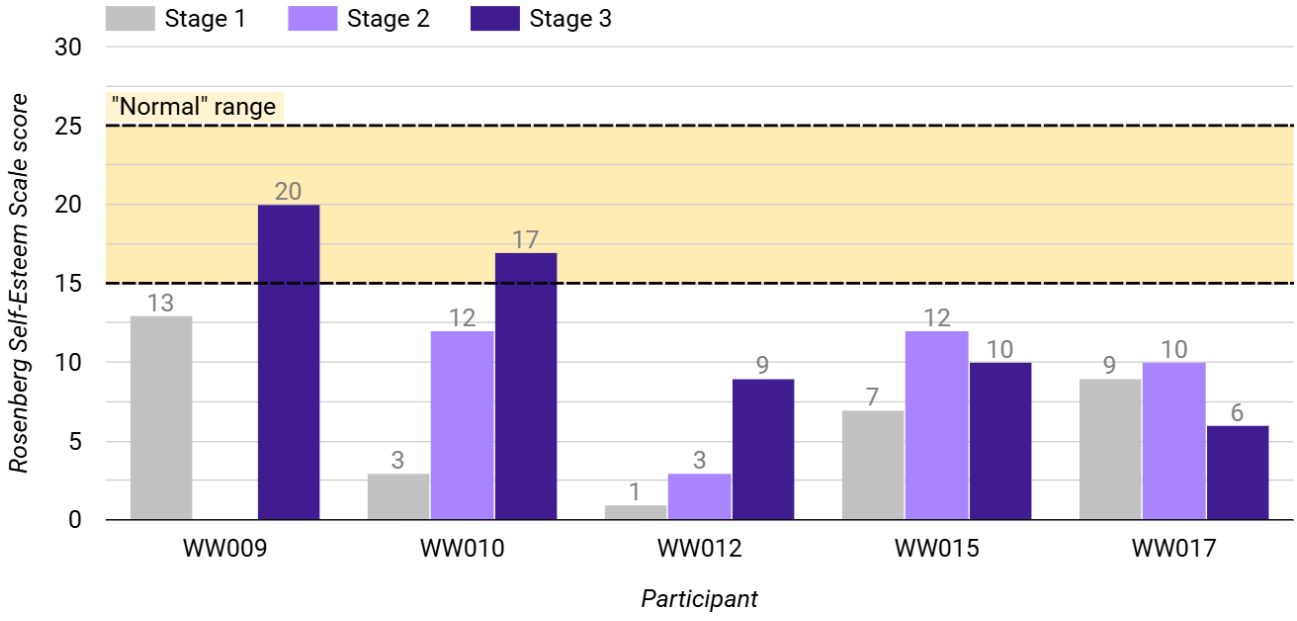
Figure 4. Participants' global EDE-Q scores at each stage of this preliminary case series pilot study of the Worth Warrior app for young people with low self-esteem and mild eating disorders. The clinical threshold of EDE-Q scores ≥4 is indicated by the dashed line. EDE-Q: Eating Disorder Examination Questionnaire; WW: Worth Warrior.



All participants also indicated at least some elements of restraint, shape concern, eating concern, and weight concern, with 3/5 (60%) indicating their biggest problem as shape concern. Behaviorally, all participants reported instances of exercising compulsively within the past month, and all but one (P17) reported instances of feeling like they had lost control over their eating.

Additionally, all indicated moderately low to extremely low levels of self-esteem (average Rosenberg Self-Esteem Scale score=6.6, SD 4.27, range=1 to 13; "low" self-esteem≥15); see Figure 5.

Figure 5. Participants' Rosenberg Self-Esteem Scale scores at each stage of this preliminary case series pilot study of the Worth Warrior app for young people with low self-esteem and mild eating disorders. The range of scores considered to indicate "normal" levels of self-esteem is indicated between the dashed lines. WW: Worth Warrior.



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Postfamiliarization Phase (Stage 2)

Having been introduced to the Worth Warrior app, participants spent an average of 12 (SD 7.66) days in the post–app familiarization phase (stage 2). Most (4/5, 80%) used it on an iPhone, with the remaining participant using an Android phone. Excluding P9, for whom there is no postfamiliarization data, during this phase, all participants reported using the Worth Warrior app fairly infrequently (either several times a week: 1/4, 25%; weekly: 2/4, 50%; or less than once a week: 1/4, 25%); and most (3/4, 75%) used it in the evenings or late at night, with the remaining participant using it at any time.

At the check-in at the end of this study stage, outcomes were mixed. A total of 2 participants had maintained their above–clinical threshold global EDE-Q scores from stage 1, while 2 had improved their attitudes and behaviors (ie, demonstrated decreased EDE-Q global scores, one of −0.4 points and the other of 3.8 points). One of these participants (P10) illustrated a change from above to below the clinical threshold.

Regarding EDE-Q subscales, all participants indicated at least a little improvement in their shape concern by this stage (average subscale decrease=1.6 points, SD 1.96, range of decrease=0.13 to 5.00), while restraint appeared to have slightly increased for 3/4 (75%) participants (average increase=0.73 points, SD 0.62, range=0.20 to 1.60). Eating concern and weight concern decreased for all but 1 participant (P17), for whom it stayed the same as at stage 1 (average decrease=1.97 points, SD 2.01, range=0.20 to 4.80).

Behaviorally, 2/4 (50%) participants indicated reductions in their behavior frequency (average decrease=1.6, SD 0.1, range=1.50 to 1.67), one remained the same (P17), and one showed a minor increase (+0.3; P15). Additionally, 2 participants reported no instances or only 1 instance of some of the eating disorder–related behaviors that they had engaged in regularly before starting this study. One participant (P10) also said that the app helped them to contact their mother about their difficulties with eating and body image.

In terms of self-esteem, all participants (4) also indicated increases in their self-esteem at this stage compared to the first (average increase in Rosenberg Self-Esteem Scale score=4.25 points, SD 3.1, range=1 to 9).

Follow-Up (Stage 3)

Participants then spent an average of 40 (SD 1.6) days, or approximately 5 and a half weeks, using the Worth Warrior app in the intervention phase. During this time, the reported usage pattern was largely similar to that observed for stage 2, with no one using it every day and the majority (3/5, 60%) using it less than once per week, and most (4/5, 80%) using it either in the evening or late at night.

From stage 1 to 3 (baseline compared to postintervention), 3/5 (60%) participants indicated improvements in their eating disorder symptoms (average EDE-Q global score decrease=2.6 points, SD 0.65, range of decrease=2.06 to 3.56), with 2 moving from above to below the clinical threshold and 1 further reducing their subthreshold score from the beginning of this study; Figure 4. The formula by Jacobson and Truax [85], 1991, for the Reliable Change Index (RCI) was used to determine whether these improvements could be considered instances of reliable change, as opposed to expected fluctuations due to measurement unreliability. In all 3 cases, participants' standardized RCI values for their EDE-Q global score reductions (range=−5.73 to −10.03) well exceeded the significance threshold of ±1.96, suggesting that these were statistically reliable changes at a 95% CI.

The remaining 2/5 (40%) participants showed very mild increases in their EDE-Q global scores (average increase=0.3, SD 0.2, range of increase=0.14 to 0.45), both of whom were already above threshold. Furthermore, neither of these EDE-Q increases was found to be reliable according to their standardized RCI values (range=0.57 to 1.15).

Additionally, 60% (3/5) of participants demonstrated reductions in all 5 of the EDE-Q subscales, with the largest reduction (−5.2 points) occurring for P10's eating concern, which scored 0.0 by stage 3. Eating concern and weight concern reduced in all but 1 (P17) of the participants (4/5, 80%; average subscale reduction=2.5, SD 1.7, range of reductions=0.2 to 5.2), and restraint, shape concern, and behavior frequency reduced in 3/5 (60%; average subscale reduction=1.84 points, SD 1.1, range of reductions=0.6 to 4.25).

Behaviorally, 3/5 (60%) participants reported no instances of at least one of the eating disorder–related behaviors that they reported engaging in before starting this study, and 2 participants reported that the app helped them to contact someone for support, with one of these (P17) specifying contacting a mental health lead at their work.

Furthermore, 80% (4/5) of participants demonstrated increased levels of self-esteem from stage 1 to 3 (average increase=8 points, SD 3.94, range of increase=3 to 14), with 2 demonstrating a move from "low" self-esteem at baseline to the "normal" range by stage 3; Figure 5. The remaining participant (P17) illustrated a small decrease (−3 points) compared to their baseline.

Usability, Acceptability, and Safety

Overview

The user questionnaire, delivered at the end of stages 2 and 3, facilitated insight into participants' experiences with the Worth Warrior app over the total 7 weeks of this study, with a particular focus on perceived usability, acceptability, and safety.

User Ratings Following App Familiarization

Overall, the app was rated fairly favorably by participants at stage 2, receiving an average rating of 4.3/5 for both usability (SD 1.03, range=2.5 to 5.0) and acceptability (SD 0.75, range=3.5 to 5.0). In comparison, its safety was rated lower overall, at an average of 3.8/5 (SD 0.76, range=3.0 to 5.0). This predominantly came from 3/4 (75%) participants scoring 3/5 on some of the questions regarding whether the app helped reassure them when their self-worth was low or reduced negative self-evaluation.

Furthermore, the average usability scores varied the most at this stage, in which P15 rated a 3/5 for the app's ease of use and 2/5 for how smoothly it ran (though reported no technical issues),

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while the remaining 3 participants rated usability at either 4.5 or 5 out of 5.

User Ratings Following the Intervention Phase

Following 6 weeks of use, the Worth Warrior app was again rated fairly favorably overall at stage 3, with the cohort rating its usability at an average of 4.2/5 (SD 0.68, range=3.5 to 5.0) and its acceptability at 3.9/5 (SD 0.97, range=2.5 to 5.00). Moreover, 2/5 (40%) participants rated both these constructs at 5/5, with 1 saying there was nothing that they did not like.

Two participants specified the "change" sections of the app as being the most useful for them, another 2 said the journal, and the remaining participant specified the psychoeducation information. This is reflected in participants' qualitative answers regarding their preferences, in which 2 key subthemes were the active and interactive elements of the change activities and the facility for self-insight provided by the journal and self-monitoring section; this is discussed in further detail below. P12 reported finding the app a little harder to use than before, while P15 found it a little easier. Overall, however, participants' usability ratings hovered at around 4/5, with relatively little variability.

Conversely, the average acceptability score had decreased slightly from 4.25 at stage 2 (−0.35/5). This came from a reduction in P17's scores for this subscale, in which they rated lower satisfaction with the app and found it less useful than before. This aligns with this participant's qualitative responses, in which they expressed dissatisfaction with some aspects of the app's design (namely, requiring users to initiate their own use and activities), which is further discussed below. There was also greater variability in participants' acceptability scores this time compared to the stage 2 check-in, ranging from 2.5/5 for P17 to 5.0 for P9 and P10.

In terms of safety, like at stage 2, the app was rated lower overall for its safety at stage 3 in comparison to the other constructs, at an average of 3.8/5 (SD 1.00, range=2.7 to 5.0). Additionally, as with usability scores, the cohort's average rating for the app's safety remained largely unchanged from stage 2. There was also a moderate amount of variability in participants' scores for the app's safety, ranging from 2.7/5 for P15 to 5/5 for P9 and P10.

P12 and P15 reported minor decreases in their average safety subscale scores compared to stage 2 (both −0.67/5). For P12, they were ambivalent about the app's effectiveness in reassuring them when their self-esteem was low or in reducing negative self-evaluation. Both P15 and P17 were also ambivalent about the app helping to reassure them and were unconvinced (scoring 2/5) about it reducing negative self-evaluation.

See Multimedia Appendix 5 for a breakdown of responses to the safety subscale of the user questionnaire at stages 2 and 3.

Finally, at the end of this study, 2/5 (40%) participants gave the app the maximum score for all 3 categories (usability, acceptability, and safety).

Qualitative Findings

Six key themes were identified from the qualitative data derived from responses to the user questionnaire, along with associated subthemes; Figure 6. These were (1) alternatives to using the app, (2) hopes and expectations for the app, (3) user preferences, (4) barriers to use, (5) transference from the app into real life, and (6) safety.

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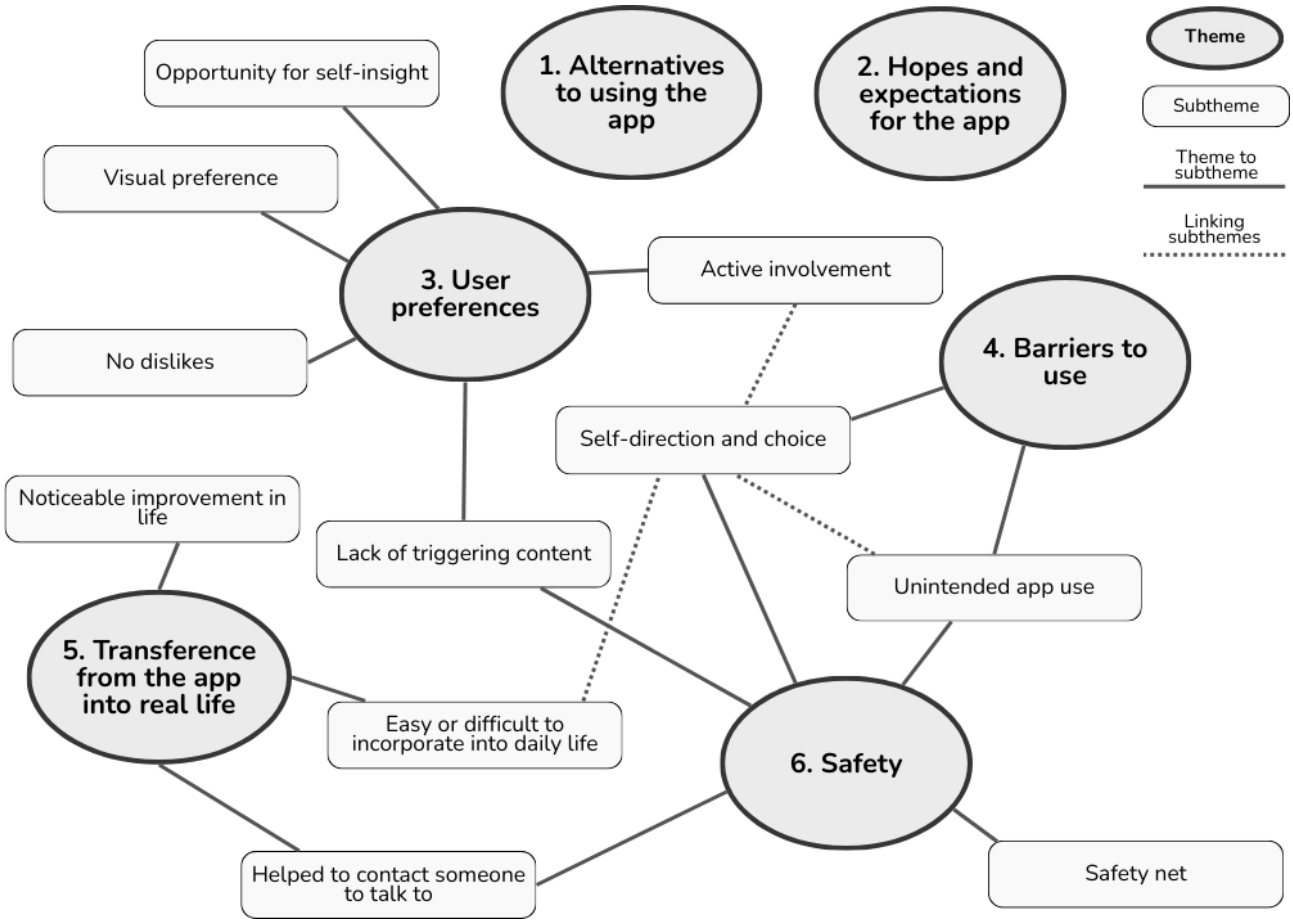
Figure 6. Thematic map of the themes and subthemes identified from qualitative responses collected in this preliminary case series pilot study of the Worth Warrior app for young people with low self-esteem and mild eating disorders.



These are discussed below. The direct quotes from participants used throughout have been selected to provide a balance between clearly exemplifying the subthemes and themes and representing a balance of all participants.

Hopes and Expectations for the App

Before starting the study, participants' expectations for the Worth Warrior app had been varied. A total of 2/5 (40%) participants had anticipated that the app would facilitate self-insight and reflection, while another 2 participants had expected a step further, thinking using it would help boost their confidence and reduce negative thinking.

> *[I was expecting a] chance to consider my opinions around my self worth.* [P17]
>
> *To help me help myself deal with my feelings and thoughts, so hopefully I wouldn't need to rely on other people as much.* [P9]

Some (2/5, 40%) had comparatively low expectations ("not much, just a journal" [P15]).

Additionally, some participants (2/5, 40%) had also been somewhat unsure or unclear about what to expect, such as P9: "although I had expectations of what it could do for me, I didn't have expectations about what the app would do to achieve it." Interestingly, one of these participants (P12) stated that they did not know what they had expected of the app, though in later responses revealed a preconception that it would have involved inputting BMI or monitoring weight, which they were then glad to find it did not include as they would have found it triggering.

By the end of stage 3, most participants (3/5, 60%) stated that the app had met their expectations, with the remaining 2 participants saying it had either "helped in some ways" (although they had not expressed any specific expectations) or had "not massively" met their expectation of facilitating self-insight.

> *[The app helped] more than I expected- with confidence, self respect and thought, changing perspective.* [P10]

Alternatives to Using the App

A total of 3/5 (60%) participants mentioned having no other support available to them before entering this study. For example, P17 said that a "lack of available help from local GP [General Practitioner]" had led them to try using the Worth Warrior app, and P12 said that normally to manage low self-worth, they would just "deal with it on [their] own." Additionally, 3 participants mentioned usually engaging in maladaptive behaviors, such as restriction and negative thinking (2/5, 40%) or a self-professed overreliance on other people (1/5, 20%).

> *[Normally, to manage low self-worth I would engage in] bad habits, think about food and failure. Just overthinking and doing nothing.* [P10]

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Of the 2 participants who did not directly mention typically engaging in maladaptive behaviors to manage low self-worth, 1 participant said that they had "no other support in place" and expressed a desire for change (P17), and the other participant said they would talk with friends (P15).

> *[I feel] that something has to change with my current eating situation.* [P17]

User Preferences

Active Involvement

Most participants (4/5, 80%) mentioned that they valued the active involvement required in the app, in which activities are interactive and involve user input. This was especially so for the activities involving cognitive restructuring, and particularly the "change the way I feel about my body" activities, which were mentioned as favorite activities by 3/5 (60%) participants.

Additionally, P17, when asked about the features they liked using most, expressed liking the immediate support afforded by the interactive process of this section of the app:

> *Changing the way I view my body gave me immediate help with strong self-perceptions.* [P17]

Furthermore, 2/5 (40%) participants had said that they were hoping the app would provide an opportunity for self-reflection and to assess their own habitual thought processes, which may relate to this general preference of most participants for the cognitive restructuring activities.

> *I liked the change your perspective part as it made you think in a more positive way instead of the first thought… thinking is it factual or a thought.* [P10]

Another participant also said that they most liked the "change" features in general:

> *I like [the Change features] because it's more personalised and it helps me to keep that frame of mind outside the app.* [P9]

Interestingly, however, some participants (2/5, 40%) expressed dislikes that relate to the level of active involvement asked of users, in contradiction to the above, instead desiring something more prescriptive. This is discussed later as its own subtheme within "barriers to use."

Opportunity for Self-Insight

> *[I wanted a] chance to consider my opinions around my self-worth.* [P17]

As mentioned, 2/5 (40%) participants referenced a desire for facilitating self-reflection and insight with the app, which is also reflected in the fact that 2 other participants mentioned that they liked using either the journal or self-monitoring features.

> *I liked monitoring myself through the journal.* [P12]

Prompts

One participant (P17) mentioned liking the prompts in the app that help the user determine what they might want to say throughout the process of cognitive restructuring activities.

Lack of Triggering Content

One participant (P12), as mentioned, said that they were glad that the app did not include BMI or weight monitoring, as they had expected it might, as they would have found this triggering.

Visual Preferences

Lastly, P9 expressed that they did not like how the app was organized visually, in which each section is presented as a tab along the bottom of the screen. This was the only visual preference expressed by any of the participants.

Finally, 1/5 (20%) of participants said that there was nothing about the app that they did not like.

Barriers to Use

Self-Direction and Choice

A concept that was continually identified in the data was the sense of a difficult and sometimes variable balance between user autonomy and guidance. As mentioned, several participants said that they valued the active involvement of app activities and personal configurability of the app, and P9 had also stated that they hoped the app would increase their own agency in managing their well-being: "[I was expecting the app to] help me help myself deal with my feelings and thoughts, so hopefully I wouldn't need to rely on other people as much."

However, 2/5 (40%) participants suggested that the app afforded perhaps too much independence and agency from them at times. In particular, P17 stated that they wished the app would send reminders to prompt use, and also to specify what to do in the app each day, rather than selecting it themselves.

> *Generally I found it difficult to find the motivation to use the app without something specific to complete every day. … [I didn't like] having to prompt myself to open it- reminders would be good.* [P17]

They also said that the abundance of choice for what to work on in the app was "overwhelming" and "not what I want when I'm looking for help."

For P12, they stated that they found difficulty with progressing to a more positive or neutral thought about themselves when the app prompted this: "I struggled with the complimenting myself after saying what's wrong. I'm not in the head space to say what I like about myself when I've just said I dont." Relatedly, this participant also said that they had set themselves maladaptive goals in the free-text fields in the app when they were prompted to set a positive goal, demonstrating a potential issue in giving users the freedom to specify their own targets.

Unintended App Use

This participant (P12), therefore, exemplifies another barrier, which was the unintended use of the app. Using the free-text fields in app features to enter unhelpful comments was, of course, unintended, and this participant also appears to have misunderstood the process in the cognitive restructuring activities in which the user is guided to replace a negative, automatic thought about themselves with one that is more neutral or objective. The prompts in the app state, "Can you think of a more accurate and factual thought?" along with examples;

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however, P12 appears to have misinterpreted this as a direction to input positive or complimentary thoughts about themselves, which they have then found difficult to do, and potentially distressing.

Transference From the App Into Real Life

A total of 3/5 (60%) participants mentioned that the app had helped to produce noticeable improvement in their lives, such as helping them to contact someone to talk to about their mental health where needed (2/5, 40%), increasing their confidence or reducing negative thinking (3/5, 60%), or achieving their hope of relying on others less (1/5, 20%).

> *I like [the Change features] because it's more personalized and it helps me to keep that frame of mind outside the app. … With the app there I could casually use it without needing much thought.* [P9]

While P9 mentioned that the app facilitated use in their daily life without much effort, the opposite was found for P17. As mentioned, this participant found that they struggled to either remember to or find motivation to use the app and wanted reminders and prescribed tasks to help with this, suggesting that they struggled to integrate the app into their daily life.

Safety

Additionally, most participants (4/5, 80%) mentioned elements relating to app safety in their qualitative responses to the user questionnaire. In terms of positives, 1 participant mentioned (as referenced earlier) that they were glad that the app did not include content they would find triggering, and (as also referenced earlier) 2/5 (40%) participants said the app helped them to contact someone, such as their mental health lead at work (P17).

For negatives relating to app safety, some have also already been covered elsewhere: P17 said that the abundance of choice in the app was "overwhelming" for them and "not what I want when I'm looking for help" and P12 said that they were not prevented from writing maladaptive goals or content in their journal, given the free-text fields provided there. In this sense, the earlier subtheme of unintended app use can also apply here.

Finally, 1 participant (P15) said that they did not like the safety net in the app, which is an area where the user inputs things to do to help themselves and people to contact when they need extra support. Interestingly, this was the only time the safety net was mentioned by participants, and unfortunately, this participant did not expand on why they did not like it.

Discussion

Principal Findings

This case series is the first to offer insight into 5 young people's experiences of using the Worth Warrior app to manage low self-esteem and mild eating difficulties. After 7 weeks of app use, outcome measures at follow-up showed reliable improvements in eating disorder symptomatology in 3/5 cases, and increases in self-esteem in 4/5 cases. Participants gave detailed feedback suggesting the app was acceptable, usable, and safe for some, though less so for others, and possible reasons for this, along with the outcome measures, are discussed below. Overall, the app shows considerable promise in providing an accessible standalone tool for managing mild eating disorder symptoms and low self-esteem in young people; however, this may be dependent upon particular factors such as symptom severity, and study limitations should be noted when interpreting these findings.

While this preliminary case series of a small sample means that no causal conclusions or attempts to generalize findings can be made, it provides a valuable first step in the form of in-depth insight into the app's potential to be an effective and acceptable early intervention tool for young people, how it may most successfully be used, and cases in which it may not be best placed. It also identifies ample areas for further research.

Furthermore, case series offer the advantage of greater external validity than, say, randomized controlled trials [86], potentially therefore offering valuable insight for use in real-life settings. However, future research with larger and more diverse samples would be necessary to help determine generalizability.

Potential Effectiveness

A total of 3 participants showed statistically reliable improvements in eating disorder symptomatology at follow-up, in which 2 participants had moved from above to below the clinical threshold of the EDE-Q, and 1 participant further reduced their subthreshold baseline score. Pre- and postintervention data for these 3 participants suggest that the app has potential to be effective across all 4 subscales of the EDE-Q (eating concern, weight concern, shape concern, and restraint) as well as behaviorally, and aligns with existing literature indicating that traditional eating disorder treatments, such as CBT-E, can be effectively delivered digitally [66]. It is also promising to note that, at follow-up, these 3 participants reported no instances of at least one of the eating disorder–related behaviors that they reported engaging in before starting the current study. Research with a larger sample and control group would be an important next step to clarify whether these observed changes are generalizable and can be confidently attributed to the use of the Worth Warrior app.

Conversely, the remaining 2 participants exhibited comparatively mild increases in EDE-Q global scores from stages 1 to 3, which, owing to the corresponding RCI values not exceeding the significance threshold, is likely from the scale's inherent variability rather than any meaningful change in symptomatology. It may therefore be more appropriate to say that these remaining 2 participants did not exhibit any meaningful change in their pre- vs postintervention eating disorder symptomatology. Additionally, one of these participants also did not show improvements in self-esteem.

Further research would therefore also be beneficial to clarify reasons for these mixed results, as well as whether any potential increase in symptomatology is a result of app use rather than measurement variability, and who would be most likely to benefit from the app. For example, a longer period of use may be necessary for individuals with greater eating disorder symptomatology before positive change can be observed; longitudinal research would therefore be helpful to ascertain

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whether individuals with higher EDE-Q starting scores can see further benefit from the app over a longer time frame than that used in this study, and would also provide insight into whether any improvements can be maintained over time.

An alternative explanation is that the app may not be suitable or as effective as a standalone intervention for individuals with moderate to severe eating disorder symptomatology, as the 2 participants who did not show improvements at follow-up were those with the highest baseline scores (global scores of 4.8 and 5.1), and similarly the 2 participants who showed the greatest benefit were among those with the lowest starting symptomatology (global scores of 2.8 and 4.3). This study did not clarify whether participants had early-stage or more established disorders, as it did not obtain information regarding participants' illness duration or time of onset, or whether they had previously been treated for an eating disorder. This information could have been helpful to provide insight into whether the app was more suited for individuals with early-stage, mild disorders vs those that are more established. The Worth Warrior app does indeed position itself as a tool for subclinical or early-stage disorders, and it may be argued that the present results therefore have limited applicability to populations classified as "early stage." This identifies another avenue for further study, which would be useful to clarify this point.

Additionally, 4/5 participants showed increased self-esteem by stage 3, with 2 participants moving from "low" to "normal" levels. Interestingly, this includes those with the lowest baseline self-esteem levels of the cohort, suggesting that a user's level of self-esteem may not impact the effectiveness of the app in the same way that their severity of eating disorder symptomatology may do, as proposed above.

Usability, Acceptability, and Safety

The Worth Warrior app was well received by the cohort in general (though more so for its usability and acceptability than safety, as further discussed below), and the interactive features offering immediate support, cognitive restructuring exercises, and journal facilities were particularly favored. Additionally, 3/5 participants also said that it met or exceeded their expectations.

That said, some participants did express dislikes, and, as mentioned, participants had more mixed experiences regarding the app's safety than for its usability or acceptability. These all align with the variations in outcome measures at follow-up as discussed earlier, such that those with the highest starting eating disorder symptoms were those who expressed the greatest barriers to use or dislikes with the app, and were also those who gave the lower ratings for the app's safety and reported the least (or no) improvement in outcome measures. This does make theoretical sense; people with eating disorders are a group often known to resist change or treatment and display low motivation to engage in interventions [60,87]. While an app intervention may be desirable in this respect for some, allowing the person to feel in control of their engagement and treatment, for others—and likely those with greater symptomatology [87]—the burden to initiate one's own engagement with the app may prove to be a barrier, and this has been particularly exemplified in P17's reported experience. Consequently, it is not surprising that any difficulties in engaging, and engaging safely, with the app could transfer into its effectiveness as well as negatively impact the experiences of these users.

Similarly, eating disorder symptomatology can be associated with persistent negative self-talk or emotional dysregulation, which, such as in the case of P12, may be a reason why some users could struggle to engage with the directions of the app to input neutral self-statements or productive journal entries, in contrast to the directions of the app, thus compromising the app's safety [88,89]. This is a further reason why the Worth Warrior app may therefore be best suited as a standalone tool only for mild presentations and should be used with clinician guidance and supervision in moderate to severe cases.

Additionally, these findings highlight areas for improvement in the app, such as greater guidance where necessary to ensure appropriate activity use (perhaps clearer prompts and instructions to input only neutral or positive statements), or even limitations on user-inputted text. Offering a more prescriptive approach to the activities, instead of requiring the user themselves to decide, could also be helpful for those individuals who can find the abundance of choice overwhelming, as in P17's case, or incorporating regular reminders to use the app via device notifications—something that may also alleviate some of the dropout issues often found in digitally delivered eating disorder interventions [66].

It is promising to note that using the app encouraged 2 of the participants to contact people in their lives for additional support. This includes P17, who otherwise indicated no benefit in their eating disorder symptomatology or self-esteem, though they did express that "'Change the way I view my body' gave me immediate help with strong self-perceptions." This is a promising finding regarding app safety, particularly for those with higher starting symptoms.

It is also interesting to note that 3/4 of applicable participants' restraint, as measured by the EDE-Q, increased following app familiarization. It may be the case that, at first, engaging with the app can produce a greater awareness of one's restraint behaviors and preoccupation with these, which further app use may then help to alleviate. This is a further reason why the app should be used with clinician guidance for stronger presentations to monitor this potential adjustment phase.

The findings, therefore, indicate that the app does show potential, particularly for mild presentations, though further clarification of appropriate target populations and expected timeframes for seeing meaningful change would be beneficial, and care should be taken to ensure the app is used appropriately and safely, particularly for individuals with greater symptom severity. This may require clinical supervision, particularly for anything greater than mild presentations, and/or clearer guidance in problem areas of the app to ensure users are suitably understanding what is being asked of them, and that they are engaging appropriately and safely. The app may therefore be best placed as an early motivation-enhancing tool when self-guided, with possible potential for early intervention alongside guided support.

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Study Limitations and Areas for Further Research

The limited diversity of the present sample should, however, be noted, as should the possibility of recruitment bias in which opportunity sampling, self-selection, and attrition may have resulted in a biased sample. This study sought to ensure ethnic diversity by recruiting participants from Birmingham (United Kingdom) and surrounding areas known for their high ethnic mix, as well as both the user and research advisory groups, including individuals from a range of cultural backgrounds, who contributed to shaping this study's design, protocol, and questionnaires to ensure cultural sensitivity and relevance. Despite this, relatively few candidates from minority backgrounds commenced this study (n=2, one of Black-African and one of Asian/Asian-British ethnicity), and none completed all stages (additionally, the ethnicity of ineligible study applicants is unknown). It may be the case, therefore, that few candidates from minority backgrounds applied, or that many of those who did did not meet inclusion criteria, such as those who were already engaged with services or presented with significant symptoms beyond the study's remit; however, this is purely speculative.

Accordingly, future research should further explore barriers to participation among ethnically diverse communities. Potential strategies include (1) collaborating closely with community and faith leaders to identify and address trust or stigma-related barriers; (2) enhancing transparency about research aims and participant safeguards to build confidence in the process; and (3) using purposive sampling, directly engaging with underrepresented groups, and inviting them to participate.

These steps would help ensure future studies are more inclusive and representative of the population affected by eating disorders.

For example, with all participants being White-British, and all but 1 participant identifying as female, it is as yet unclear whether experiences of using the app and its effectiveness may differ depending on factors such as ethnicity, gender, location, or age. This is particularly so considering how eating disorders can vary in prevalence, symptomatology, treatment seeking, and treatment response, as well as in biological and psychosocial factors and vulnerabilities, across factors including gender, age, sexual orientation, culture, and race [90,91]. Indeed, the one nonbinary participant in this study did indicate lower app effectiveness than some other participants, suggesting that there may be differences in the app's effectiveness depending on demographic factors; however, this would require future research to determine. This also includes whether results can generalize to younger and older age groups than those involved in this study, as well as whether the type of eating disorder or the presence of any comorbidities makes any difference in the intervention's effectiveness.

Furthermore, the recruitment difficulties and high attrition rate of this study may also suggest that the app had low appeal or acceptability to a lot of the target population and may have resulted in a biased final sample consisting of individuals who already found the app particularly acceptable. Including reminders to use the app, as suggested by P17, may also help to reduce user dropout in this way. It is also possible that the materials used to recruit participants may have introduced bias; for example, the background image used in the recruitment flyer most prominently displays White individuals, which, given the all-White resulting sample of the study, may possibly have discouraged non-White individuals from applying.

Finally, follow-up research over a longer period of time would also be valuable to explore whether any effects of using the Worth Warrior app can be sustained over time and/or continue to improve with prolonged use. This is especially as there was variability in the times at which participants indicated change, such as P10, who was the only participant to show their greatest change at stage 2 rather than 3, or P15, who showed a dip in EDE-Q scores at stage 2 but a reversal of this by stage 3. Comparisons with alternative treatments (such as other digital interventions or face-to-face treatments) would also be valuable to more clearly ascertain the app's value in relation to alternative treatment options. Lastly, research examining the app's cost-effectiveness in both the treatment and prevention of eating disorders in young people would also be a valuable addition.

Conclusion

Summary of Findings

This preliminary investigation provides early support for the feasibility and acceptability of delivering cognitive behavioral therapy for eating disorders (CBT-E) via a mobile app, Worth Warrior, to individuals presenting with mild eating disorder symptoms. Although the sample size was limited, findings indicate that multiple participants experienced improvements in self-esteem and eating disorder symptomatology and reported positive engagement with the intervention, and the app was largely well-received, particularly regarding its usability and acceptability. Notably, the "change" modules in the app, targeting the identification and modification of negative cognitions related to body image, were perceived as particularly beneficial in fostering cognitive and emotional shifts.

However, some participants found difficulty with the level of self-direction and independence required of using the app as a standalone tool and did not see improvement in outcomes at follow-up. Relatedly, user safety would likely be maximized by ensuring that individuals with more severe eating disorder presentations use it alongside clinician guidance, and it is recommended that the app be used as a standalone intervention tool only for those with mild symptomatology. Several areas of improvement were also identified for the app to encourage appropriate use and promote user safety and engagement.

As this was an exploratory pilot study, these findings should be interpreted as indicative rather than conclusive.

Limitations and Future Research

Given that only 5 participants completed this study, these findings should be interpreted with caution and regarded as exploratory, as the small sample size restricts both the generalizability and statistical power of the results. Additionally, the absence of a control group prevents conclusions regarding causality or comparison with standard CBT-E delivery methods. Future research should therefore aim to replicate and extend these results using larger, more diverse samples and rigorous study designs, including randomized controlled trials and

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longitudinal follow-up. Such investigations would help to clarify the efficacy, mechanisms of change, and sustainability of outcomes associated with app-based CBT-E interventions.

Nonetheless, the current findings underscore the potential of digital CBT-E tools such as the Worth Warrior app to enhance self-esteem and address core cognitive features of eating disorders at a mild stage, thereby contributing to accessible and preventative approaches within the continuum of eating disorder care.

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Data Availability

The datasets generated and analyzed during this study are not publicly available due to conditions outlined as part of the participants' informed consent, as well as the data compliance regulations of stem4; however, they may be available from the corresponding author on reasonable request.

Conflicts of Interest

Both authors work for stem4, the charity that owns and has produced the Worth Warrior app and were involved in its development. Study design was developed with guidance from an independent third party (Informed Thinking), who also conducted all data collection.

Multimedia Appendix 1
Example advertisement used for recruitment in this study.
[PNG File, 673 KB - formative_v10i1e79770_app1.png]

Multimedia Appendix 2
The full screening tool used in this study.
[DOCX File, 200 KB - formative_v10i1e79770_app2.docx]

Multimedia Appendix 3
Screening questions and inclusion criteria for this preliminary case series pilot study of the Worth Warrior app for young people with low self-esteem and mild eating disorders.
[DOCX File, 16 KB - formative_v10i1e79770_app3.docx]

Multimedia Appendix 4
Worth Warrior app user questionnaire.
[DOCX File, 2047 KB - formative_v10i1e79770_app4.docx]

Multimedia Appendix 5
A breakdown of responses to the safety subscale of the Worth Warrior app user questionnaire at stages 2 and 3 of this preliminary case series pilot study of the Worth Warrior app for young people with low self-esteem and mild eating disorders.
[DOCX File, 16 KB - formative_v10i1e79770_app5.docx]

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Abbreviations

CBT-E: enhanced cognitive behavioral therapy
EDE-Q: Eating Disorder Examination Questionnaire
NHS: National Health Service
RCI: Reliable Change Index

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Evaluation of a Novel Web-Based Active Learning Tool for Primary Care Physicians' Continuing Professional Development (The Community Fracture Capture Learning Hub): Quantitative Analysis

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Abstract

Background: The lack of osteoporosis treatment initiation following fragility fractures is a recognized gap, particularly in primary care. Primary care physicians' (PCPs) barriers to treatment, such as uncertainties in investigation, initiation, and concerns about drug side effects, remain challenging. It is also unclear whether knowledge gaps and barriers vary by region or if active learning platforms are more effective than passive methods in improving treatment rates, and how PCP demographics influence learning outcomes. With time constraints, PCPs are increasingly using online platforms for continuing professional development, and the interactive online Community Fracture Capture (CFC) tool has emerged as a promising alternative to traditional methods. Our CFC pilot study tested this program's design and content, revealing its potential effectiveness.

Objective: The study aimed to assess the operational characteristics, educational effectiveness, and acceptability of the interactive online CFC model in enhancing Australian PCPs' knowledge and skills in community-based fracture treatment. Additionally, it sought to examine how PCPs' knowledge and treatment gaps relate to their demographic characteristics and clinical practice backgrounds.

Methods: The CFC Learning Hub is a secure, adaptable online platform that promotes community learning. It includes an interactive forum where participants share case studies and engage in discussions with bone specialists and senior PCP facilitators. The hub also offers a knowledge repository and allows participants to post inquiries. Online surveys and back-end analytics track baseline knowledge, activity levels, and improvements in knowledge and confidence over time, offering insights into participants' learning and program development.

Results: Four 6-week small-group cycles involved 55 PCPs, with over 80% working in metropolitan-based practices and a median (IQR) of 22 (16-34) years in practice. Topic modules covered osteoporosis diagnostics, treatment, monitoring, and challenging conditions, using a multidisciplinary approach with participant case studies. A total of 35 (64%) PCPs provided evaluation data, with 86% (n=30) joining to learn from experts or improve patient management and 83% (n=29) being satisfied with the content. Preferred learning methods included small group learning (n=13, 37%), live webinars (n=9, 26%), interactive learning (n=7, 20%), and on-demand videos (n=6, 17%), and 57% (n=20) found the platform easy to use. The most popular access times were evening (n= 23, 66%) and weekends (n=10, 29%). At completion, 89% (n=31) would recommend the training, and 78% (n=22 out of 28 respondents to the postprogram expectations meeting survey) were fully satisfied that their training needs were met, with 22% (n=6) partly satisfied. In addition, following the course completion, almost everyone reported being confident or very confident in managing osteoporosis.

Conclusions: The CFC program was created by bone specialists, PCPs, software engineers, and information technology specialists. This collaboration produced a user-friendly, case-based, interactive, time-flexible, and highly acceptable program

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bridging investigation and management gaps in osteoporosis. It is customized to address challenges faced by PCPs and is potentially relevant for implementation in a wide range of fields, both health-related and others.

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KEYWORDS

case-based education; CFC; community-based fracture capture learning hub; continuing professional development; CPD; online learning platform; osteoporosis; PCPs; primary care physicians; VCoP; virtual communities of practice

Introduction

Addressing the Global Challenge of Osteoporosis: Investigation and Treatment Gaps

Osteoporosis poses a significant global health concern, affecting approximately 500 million individuals worldwide, and is associated with 37 million fragility fractures annually in people aged over 55 years [1,2]. This burden is expected to escalate with the aging global population, with projections indicating a 310% increase in hip fractures for men and a 240% increase for women by 2050 [3,4]. Despite this increasing prevalence of osteoporosis and the presence of effective diagnostic tools, fracture risk assessment tools (eg, Fracture Risk Assessment Tools and dual-energy X-ray absorptiometry scanning), and appropriate medications, there persists a treatment gap, with only 20% to 30% of patients with fragility fracture receiving guidelines-based care [4,5]. For instance, a study of 145,185 Medicare-enrolled patients with fragility fractures in the United States found that only 30.4% of the cohort received an osteoporosis treatment in the 12-month postfracture period [6].

In Australia, a societal cost of Aus $2.6 billion (approximately US $1.7 billion) was attributable to osteoporosis in 2022 alone [4]. Australian and international hospital–based fracture liaison services (FLS) have shown cost-effectiveness in secondary fracture prevention [7,8], successfully addressing this treatment gap among patients presenting with low-trauma fractures. Yet, a relative scarcity of Australian FLS centers was noted in the International Osteoporosis Foundation Capture the Fracture's recent survey [4]. Furthermore, patients experiencing low-trauma fractures, such as those involving the vertebra or radius, which may not necessitate tertiary care, are typically assessed and treated exclusively or mainly within primary care settings, potentially bypassing hospital-based services [9]. Similar to that observed in tertiary care, primary care also faces a challenging investigation gap in primary fracture prevention, as evidenced by the plateau in bone density requests among Australian older adults despite an aging population [7,9-11].

Enhancing Fracture Prevention: Challenges at the Primary Care Level

Adapting the hospital-based model of care to the community level presents a rational approach to enhancing fracture prevention outcomes. However, different from the hospital-based FLSs, which rely on coordinators to manage and oversee their functions, community-based fracture capture places the responsibility solely on primary care physicians (PCPs) to diagnose, examine, and treat osteoporosis [12]. Despite the availability of effective treatments and guidelines, the translation of evidence into clinical practice, particularly by PCPs, remains low in Australia, resulting in suboptimal care for many Australians eligible for osteoporosis-related investigations and therapies [5,13]. While hospital FLSs prioritize secondary fracture prevention, PCPs should additionally emphasize primary fracture prevention to prevent the first fracture [14].

Navigating Challenges: Harnessing Virtual Communities for Professional Development in Health Care

PCPs encounter substantial challenges in managing various chronic health conditions and their associated complications within limited consultation times. Despite these constraints, PCPs must continually expand their knowledge of evidence-based practices [15,16]. Seeking online resources for continuing professional development (CPD) has become increasingly common among PCPs [17-19], offering a flexible alternative to traditional learning methods [20]. Therefore, using social media tools for CPD has emerged as a popular approach, facilitating collaborative learning in online group settings [18,21]. Virtual communities of practices (VCoPs) are among the web-based tools gaining traction in health care [22,23], particularly as their relevance became more prominent during the COVID-19 pandemic [24]. VCoPs offer health care professionals unrestricted opportunities for learning, collaboration, and information sharing, overcoming barriers like geography, cost, and time constraints [21,25,26]. Participation of health professionals in VCoPs has been associated with the alleviation of professional isolation, potentially improving program retention, fostering interprofessional collaboration, and providing a risk-free environment for active participation [27,28].

Bridging Gaps: Exploring the Role of Virtual Communities in Addressing Osteoporosis Care Challenges

Despite the potential benefits of VCoPs to optimize health professionals' knowledge, confidence, and practice, only a handful of recent studies, including our Community Fracture Capture (CFC) Learning Hub pilot study, have explored the effectiveness of internet-based learning activities in addressing the osteoporosis care crisis, facilitating education, maximizing health care resources, and enabling practitioners to deliver more accessible osteoporosis care at reduced costs [29,30]. Our exploration of the hurdles encountered by PCPs in using VCoPs for continuing medical education underscores the significance of fostering trust, effective time management, and collaborative learning among health care professionals to establish successful VCoPs [31]. The CFC Learning Hub program integrates flexible,

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asynchronous participation with a structured, interactive case-based introductory format for each topic, encouraging information to be directly linked with participants' clinical experience. Unlike conventional lectures or scheduled webinars [32], it allows participants to engage at their own pace, accommodating clinical and personal commitments. Through continuous access to peer-to-peer and PCP-to-specialist interaction, the platform adopts collaborative knowledge exchange and critical reflection rather than unidirectional instruction and supports deeper cognitive engagement and a more nuanced understanding of clinical concepts [33]. The program's distinctive combination of flexibility, interactivity, and collaboration differentiates it from traditional educational models and underpins the rationale for its formal evaluation in terms of operational performance, educational effectiveness, and professional impact.

Consequently, our goal is to tackle the community osteoporosis treatment gap by introducing a novel, interactive CFC learning hub, designed to create a health professionals' VCoP that aims to facilitate knowledge transfer and overcome obstacles in osteoporosis recognition and management. We hypothesize that a CFC Learning Hub can offer a unique peer-to-peer learning platform, delivering current information on primary and secondary fracture prevention to PCPs across various regions, demographics, and experience levels. Additionally, we propose that the enhanced confidence and motivation in osteoporosis investigation and treatment through interactive web-based discussions among PCPs and expert facilitators can be quantified using analytics tools.

The primary objective of this study was to evaluate the operational characteristics and educational effectiveness of the interactive online CFC Learning Hub model in offering PCPs professional training and skills related to community fracture−related care. Secondary objectives were to (1) examine associations between PCPs' demographic and practice backgrounds and their learning outcomes; (2) assess engagement in CPD through VCoPs and the impact of engagement levels variations on learning and knowledge acquisition; (3) describe the performance features of a tailored, interactive, case-based learning hub designed to enhance PCPs' osteoporosis management; and (4) obtain feedback from PCP participants on the acceptability of the program.

Methods

Study Design and Participant Recruitment

The CFC Learning Hub is a secure and versatile online platform designed to cultivate a learning community. It includes an interactive Discussion Forum where participants share case studies and engage in guided discussions led by bone specialists and senior PCP facilitators to achieve learning goals. Moreover, the hub incorporates a robust knowledge repository and allows participants to post queries and comments. Using online surveys and back-end analytics, the platform measures baseline preactivity knowledge, monitors activity levels, and assesses progress, offering valuable insights into participants' learning experiences and enhancements in knowledge following course completion.

Based on the literature, a relatively small group of 12 to 20 participants in a VCoP fosters greater motivation for active engagement and knowledge seeking [34,35]. Therefore, we aimed to enroll 12 to 16 PCPs per CFC Learning Hub cycle.

Participants were recruited via Praxhub, a web-based medical education platform, with electronic consent for data use after deidentification [36]. Invitations were sent through professional bodies and the platform's internal registry. Interested PCPs were contacted by the project manager, who screened for eligibility and enrolled those who met the criteria, consented to participate in the 6-week program, and approved data use for auditing and research. Recruitment ran from May 2022 to August 2023. To foster engagement and apply clinical practicality, participating PCPs were asked to submit their own anonymized case studies, which were discussed throughout the program. We used Praxhub, an Australian-based web and mobile platform that provides free access to CPD resources and facilitates medical education for health care professionals worldwide [36]. Within customized private groups, participating PCPs accessed presentations, case studies, and discussion forums, engaged with peers and facilitators, and shared multimedia content to enhance collaboration and professional development. Comprehensive information on the study protocol has been published recently in Fathalla et al [33].

The Learning Hub explored various critical aspects of osteoporosis management through detailed topic modules. These topic modules were designed to cover osteoporosis etiology, diagnosis, its treatment and monitoring strategies, and the management of challenging conditions associated with the disorder.

Ethical Considerations

The Melbourne Health Human Research Ethics Committee approved this project (site reference 2016.24), adhering to institutional ethical review processes for research involving human participants. Electronic informed consent from PCP participants who joined the CFC Learning Hub was obtained to use their deidentified data for research and auditing purposes. The electronic consent process included a waiver of consent for case study patients, whose anonymized information was also used in the project. The data collection and management of electronic consent were carried out using Praxhub tools [36], ensuring appropriate safeguards for privacy and confidentiality. The data used in this study were fully anonymized to protect participant identities. No financial compensation was provided to participants in this program.

Results

Participant Demographics and Engagement in Practice Experience Evaluation

Four 6-week small-group cycles involved 55 PCPs (total number of enrolled PCPs, N_{total}=55), with 80% (44/55) of the participants practicing in metropolitan areas, and the median (IQR) years of practice being 22 (16-34) years. Of the 55 participants (N_{total}), 35 PCPs (N_{eval}; 64%) actively participated in the end-of-cycle evaluation process. There were no demographic or clinical practice differences between those who

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participated in the evaluation study and those who did not (data not shown).

The results show that those in cycles 3 and 4 had fewer years in practice (*P*=.005), were less active with a lower number of activities or clicks (*P*=.001), and accessed fewer resources (*P*=.002) compared with those in the first two cycles. Those in cycle 3 participated in less education activities (*P*=.03) and spent less time on the platform (*P*=.03) compared to those in cycles 1, 2, and 4. The weekly attendance ranged from 50% to 76%, and 61% attended 5 weeks or more.

Overall, participants were active on the platform: median (IQR) number of activities recorded via platform analytics was 42 (14-87), and all participants accessed at least 1 resource (median 6, IQR 3-10; range 1 - 15; Table 1).

Table . Demographic characteristics and participation data of the study cohort[a].

Characteristic	Cycle 1 (n=11)	Cycle 2 (n=14)	Cycle 3 (n=11)	Cycle 4 (n=19)
Years in practice, median (IQR)	25 (22 - 44)	26 (19 - 33)	16 (10 - 22)	15 (11 - 27)
Total number of different education activities[b], median (IQR)	8 (4-14)	9 (4-13)	4.5 (2-9)	7 (5-11)
Number of resources[c] accessed, median (IQR)	9 (6-11)	12 (4 - 13)	2 (2-4)	5 (2-8)
Total number of various activities[d], median (IQR)	85 (40-166)	91.5 (30-133)	15 (5 - 28)	43 (11 - 55)
Time spent on each activity (min), median (IQR)	22.5 (3.6 - 76.9)	26 (6.8 - 200.2)	9.5 (2.1 - 55.4)	31.4 (4.7 - 97.4)

[a]A full demonstration of resources, education activities, and various activities can be found in the program protocol [33].

[b]Education activities are learning activities undertaken by participants including the activities of access to case studies, knowledge hub, and educational webinar.

[c]Resources refer to learning resources of the program such as Osteoporosis Australia Clinical Guidelines (OACG), dietary approach for bone health, and case studies.

[d]Various activities refer to the group of activities conducted by participants such as provision of comments, view resources, and view education summary.

Access Patterns and Motivations in Osteoporosis Management Program

The survey results indicate that the evening was the most popular access time for participants, with 23 of the 35 (66%) respondents opting for this time, followed by 10 of the 35 (29%) participants choosing weekends as their preferred access time, and a smaller proportion, 2 of the 35 individuals, preferred accessing it before and during working hours (Table 2). This distribution is supported by the back-end user log showing that 61% of activities were conducted during the evening or early morning hours (4 PM to 2 AM) and that 28% of activities took place on weekends (Saturday to Sunday).

Regarding reasons indicated for joining the program, 24 of the 35 (69%) individuals indicated a desire to improve patient management as their primary motivation. Additionally, 8 of the 35 (23%) participants wanted to learn from experts, while 3 of the 35 (9%) participants had other reasons for joining the program.

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Table . Posteducation feedback.

Feedback	Overall, n (%)	Cycle 1, n (%)	Cycle 2, n (%)	Cycle 3, n (%)	Cycle 4, n (%)
Platform use					
Very easy or easy	20 (57)	3 (30)	6 (60)	2 (67)	9 (75)
Neutral	4 (11)	3 (30)	1 (10)	0 (0)	0 (0)
Some difficulties or very difficult	11 (31)	4 (40)	3 (30)	1 (33)	3 (25)
Profile setup					
Very easy	11 (31)	2 (20)	5 (50)	0 (0)	4 (33)
Easy	14 (40)	5 (50)	3 (30)	2 (67)	4 (33)
Neutral	7 (20)	3 (30)	2 (20)	1 (33)	1 (8)
Some difficulties	3 (9)	0 (0)	0 (0)	0 (0)	3 (25)
Motivation for participation					
Earn CPD[a] points	2 (5.7)	2 (20)	0 (0)	0 (0)	0 (0)
Improve the management or treatment of patients	24 (69)	6 (60)	8 (80)	2 (67)	8 (67)
Learn directly from specialists	6 (17.1)	2 (20)	1 (10)	1 (33)	2 (17)
Learn from other PCPs[b] or peers	2 (5.7)	0 (0)	0 (0)	0 (0)	2 (17)
Other	1 (2.9)	0 (0)	1 (10)	0 (0)	0 (0)
Best time					
After work	23 (66)	7 (70)	5 (50)	2 (67)	9 (75)
Before work	1 (3)	0 (0)	1 (10)	0 (0)	0 (0)
During work hours	1 (3)	0 (0)	1 (10)	0 (0)	0 (0)
Weekends	10 (28.6)	3 (30)	3 (30)	1 (33)	3 (25)
Device					
Desktop or laptop	23 (66)	6 (60)	8 (80)	1 (33)	8 (67)
Smartphone	7 (20)	2 (20)	1 (10)	1 (33)	3 (25)
Tablet	5 (14)	2 (20)	1 (10)	1 (33)	1 (8)
Group size					
The right size	29 (83)	9 (90)	7 (70)	3 (100)	10 (83)
Too few	5 (14)	1 (10)	3 (30)	0 (0)	1 (8)
Too many	1 (3)	0 (0)	0 (0)	0 (0)	1 (8)
Total facilitators					
1 PCP and 1 specialist	29 (83)	8 (80)	9 (90)	2 (67)	10 (83)
1 PCP	4 (11)	1 (10)	1 (10)	1 (33)	1 (8)
1 Specialist	2 (6)	1 (10)	0 (0)	0 (0)	1 (8)
Satisfied with content					
Very satisfied	19 (54)	3 (30)	9 (90)	1 (33)	6 (50)
Satisfied	10 (29)	5 (50)	0 (0)	1 (33)	4 (33)
Neutral	5 (14)	2 (20)	1 (10)	1 (33)	1 (8)
Unsatisfied	1 (3)	0 (0)	0 (0)	0 (0)	1 (8)
Satisfied overall					

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Feedback	Overall, n (%)	Cycle 1, n (%)	Cycle 2, n (%)	Cycle 3, n (%)	Cycle 4, n (%)
Very satisfied	15 (43)	3 (30)	7 (70)	1 (33)	4 (33)
Satisfied	17 (49)	6 (60)	3 (30)	2 (67)	6 (50)
Neutral	2 (6)	1 (10)	0 (0)	0 (0)	1 (8)
Unsatisfied	1 (2.9)	0 (0)	0 (0)	0 (0)	1 (8)
Preferred learning style					
Interactive learning	7 (20)	1 (10)	2 (20)	0 (0)	4 (33)
Live webinar	9 (26)	0 (0)	3 (30)	1 (33)	5 (42)
On-demand video	6 (17)	4 (40)	1 (10)	0 (0)	1 (8)
Small group learning	13 (37)	5 (50)	4 (40)	2 (67)	2 (17)
How likely are you to recommend the training					
Very likely	17 (49)	3 (30)	7 (70)	1 (33)	6 (50)
Likely	14 (40)	6 (60)	2 (20)	2 (67)	4 (33)
Neutral	2 (6)	1 (10)	1 (10)	0 (0)	0 (0)
Unlikely	1 (3)	0 (0)	0 (0)	0 (0)	1 (8)
Very unlikely	1 (3)	0 (0)	0 (0)	0 (0)	1 (8)

[a]CPD: continuing professional development.

[b]PCP: primary care physician.

Participant Preferred Model of Learning

The study's findings revealed diverse preferences among participants regarding their preferred model of learning, with 37% (n=13) favoring small group learning, followed by live webinars (n=9, 26%), interactive learning (n=7, 20%), and on-demand videos (n=6, 17%; Table 2). According to our results, 83% (n=29) of the participants found this method of learning, including the small group size and the method of facilitation (combining both PCPs and specialists), as the most appropriate.

Program Satisfaction and Improved Confidence

Overall, a high level of satisfaction with the provided materials was reported among respondents (29/35, 83%). Moreover, 89% (31/35) indicated that they would likely recommend the program to others, although only 57% (20/35) found the platform easy to use. A higher percentage (9/11, 75%) of the participants in cycle 4 reported easy navigation of the activity compared to participants in cycle 1 (3/10, 30%; Table 2).

At week 1, 34% (n=10) of the PCPs were confident or very confident in applying the current guidelines of managing patients, and less than 40% (n=11) were confident or very confident in applying the current guidelines for osteoporosis investigation. Following the course completion, almost everyone reported being confident or very confident in these topics (Figure 1).

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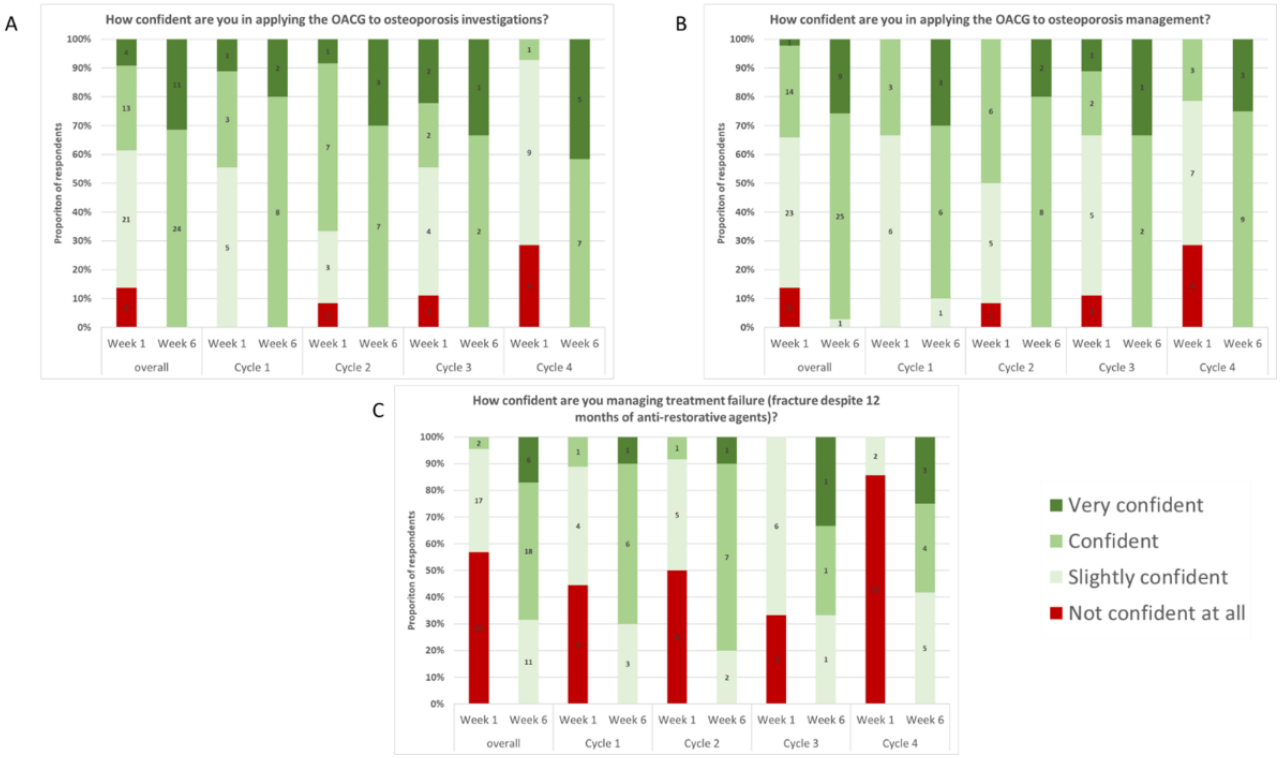
Figure 1. Change in primary care physicians' (PCPs) confidence in osteoporosis at the end of the learning cycle. OACG: Osteoporosis Australia Clinical Guidelines.



Quiz Results or Level of Knowledge or Self-Assurance Gain

The average marks for the individual module-related quiz questions were 70%, ranging from 22% to 100% (Figure S1 and Table S2 in Multimedia Appendix 1).

The results show that 98%-100% (n=34-35) of the participants provided correct answers to osteoporosis risk factors and pharmacological treatment (questions 10-17), while 22%-33% (n=8-12) of the participants provided correct responses to osteoporosis therapy−related questions (questions 37-39; Figure S1 in Multimedia Appendix 1).

Levels of participants' postprogram confidence are demonstrated in Figures 1 and 2 and Table S1 in Multimedia Appendix 1. The results show that 86% (n=24) of the respondents rated the activity as entirely relevant to their practice. Additionally, 68% (n=19) of the respondents reported that they were able to design a structured procedure for monitoring osteoporosis.

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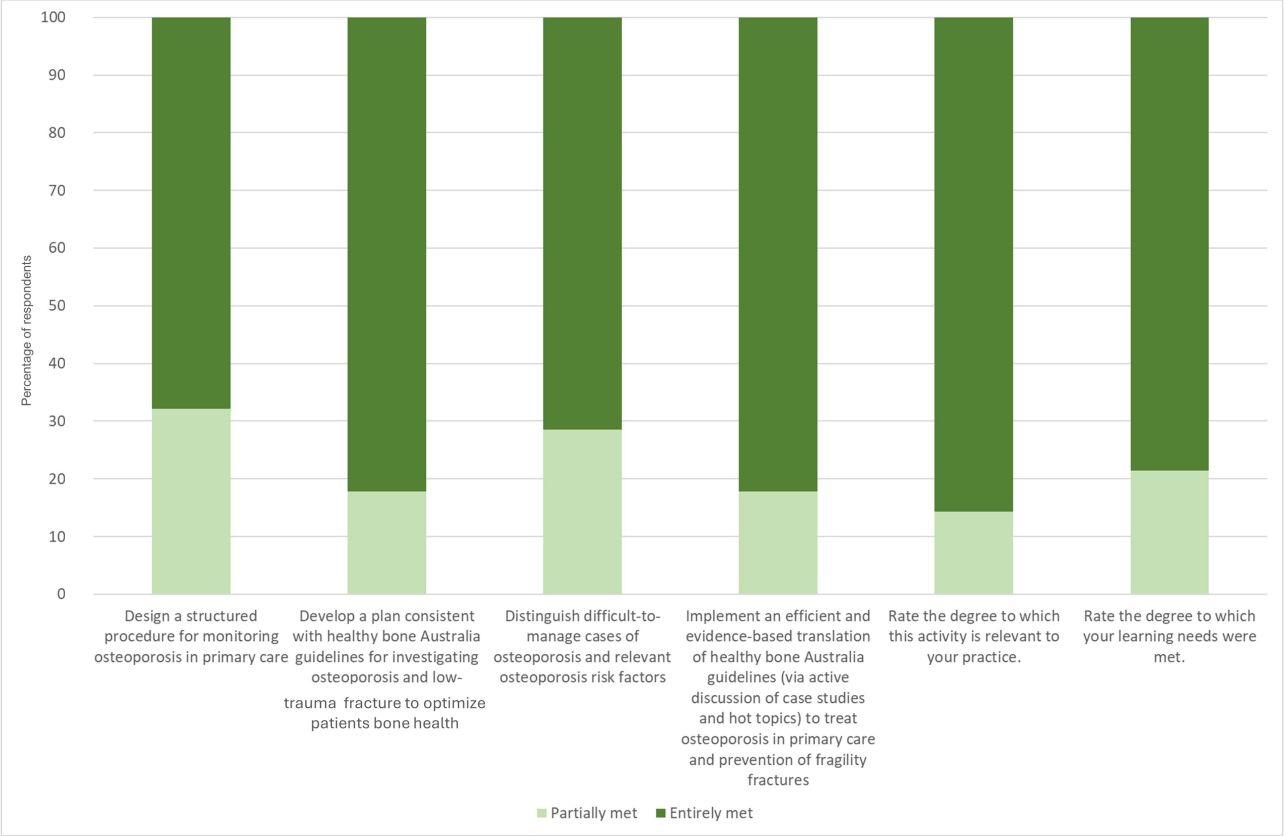
Figure 2. Postprogram self-assurance level of participants.



Discussion

Principal Findings

Our findings demonstrate that the participating PCPs reported a considerable boost in their knowledge and confidence in osteoporosis management in primary care. While hospital-centered FLSs are cost-effective for secondary fracture prevention [7,37], their expansion in Australia is projected to have a limited impact on reducing minimal trauma fractures in older adults, with high associated costs [38], necessitating alternative strategies. Many patients rely on PCPs for postfracture care [39], underscoring the need for updated guideline adherence. However, global and Australian underuse of osteoporosis guidelines in primary care persists, leading to underdiagnosis and undertreatment [7,37,40-43]. Furthermore, a considerable proportion of Australians lack timely access to osteoporosis care in primary health care settings, with studies demonstrating low treatment rates for those meeting intervention criteria [16,39,44]. For instance, 2 Australian studies revealed that only 30% of the postmenopausal women with fractures received osteoporosis therapy [9], and 76% of the fractured men remained untreated for 1 year postfracture [16]. The CFC Learning Hub, a tailored VCoP, was developed to address these disparities through evidence-based education and peer collaboration.

PCPs face daily challenges in delivering optimal care for patients with chronic health issues, requiring evidence-based treatment for the best outcomes [29,31]. VCoPs for CPD can help overcome barriers such as time limitations and preferences for in-person learning [23]. Despite their potential to enhance PCPs' knowledge and skills, challenges remain in their effective use for CPD. Our team identified 7 key areas vital for crafting and maintaining efficient VCoPs, including distrust of online information, accommodating individual learning preferences, and bridging communication gaps between PCPs and specialists [31]. Based on these insights, our pilot program developed the CFC Learning Hub to enhance PCPs' understanding of osteoporosis management, supporting the implementation of evidence-based guidelines [29].

The CFC pilot program identified osteoporosis treatment and prevention strategies, as well as risk assessment, as the topics initiating the most discussion, indicating an interest in these areas. Thus, the CFC Learning Hub program's topic modules focused on osteoporosis, treatment, monitoring, and challenging conditions. The program received high satisfaction rates in that about 83% (n=29) of the program evaluation respondents were satisfied with the content, most respondents were either entirely (n=22, 73%) or partly (n=6, 23%) satisfied that their training needs had been met, and 89% (n=31) expressed that they were likely to recommend the training, reflecting the program's ability to instill confidence in the PCP participants. It is pinpointed that efficient VCoPs depend on knowledge exchange among members, which can be implemented in clinical settings [45]. Health professionals showed greater engagement when VCoPs focused on patient-centered approaches, emphasizing patient needs, concerns, and preferences [46]. Overall, in terms of structure, it appears that our project successfully crafted a program that fulfills PCPs' requirements for an interactive curriculum with practical, relevant content. Moreover, for VCoPs seeking to foster peer-to-peer interaction and enhance

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program satisfaction, it is advisable to design their content and modules incorporating clinically relevant practice-based cases.

Particularly since the COVID-19 pandemic, the workload of PCPs has significantly increased, stretching their time commitments and exacerbating their isolation from peers [47,48]. VCoPs leveraging technology offer opportunities for learning, collaboration, and information exchange, overcoming barriers like geography, cost, and time zone differences [21,25-27]. However, time remains a major barrier to participation in VCoPs [49,50], with flexibility in scheduling being critical for engagement. Compared to timed webinars and their fixed question times, the trend of high popularity of participation during evenings (n=23, 66%) and weekends (n=10, 29%) in our learning activity underscores its ability to deliver the needed flexibility, catering to participants' preferences for accessing content outside traditional work hours, with fewer opting for weekdays (n=2, 5.7%). Further, analyzing the preferred access times of PCPs for the program enabled us to pinpoint optimal communication windows, ensuring maximum engagement during peak activity periods and tailoring our outreach efforts accordingly. This aligns with evidence that adaptable VCoPs mitigate time barriers [27]. Overall, a VCoP tailored for PCPs' professional education must cater to their demanding schedules, offering flexibility for participation during off-hours such as evenings and weekends. In addition to scheduling flexibility, ease of use is vital for VCoP effectiveness. For a virtual community to thrive, participants must possess a basic level of technical proficiency in using information and communication technologies [51]. However, mastering e-communication tools can impose a steep learning curve, demanding time from already busy health professionals [52]. Some studies highlight a deficiency in health professionals' competence with the technology necessary for effective VCoP engagement [50]. For instance, a study exploring an online platform for professional development found that nurses and other health professionals, despite considering themselves "computer literate," required substantial mentoring and support in the virtual environment [53]. In our activity, just over half (n=20, 57%) of the participants reported finding the platform user-friendly, with the majority of access problems reported in the first two cycles of the 4 cycles conducted. To address PCPs' unpreparedness with platform use, we implemented an induction session with a video recording available throughout the 6-week activity, which led to a significant decrease in access issues in later cycles. Proactive communication during registration and before the activity further familiarized participants with the platform, nearly eliminating complaints about usability. This supports the idea that technical skills for VCoPs should be developed during prequalifying education to ensure a solid foundation for virtual collaboration in clinical practice [54]. Indeed, it is argued that to ensure interprofessional teams can collaborate effectively, practicing professionals are required to communicate in both face-to-face and virtual environments [54]. Hence, the availability of preactivity induction tools on platform navigation and functionality could enhance participation rates and mitigate potential nonparticipation among PCPs due to technical limitations.

A primary motivation behind online communities is to establish networks of individuals sharing common interests, despite being geographically distant [21]. Virtual communities thrive when there is a collective eagerness to exchange knowledge and experiences; however, without community-driven engagement, participation tends to be sporadic and restricted [55]. To foster trust and cohesion, our program specifically recruited PCPs, excluding other health care practitioners. Also, recruitment advertisements emphasized the activity's focus on bone health advancements, attracting participants with shared interests, particularly the desire to improve patient bone health management (a motivation nominated by 24, 69% of the respondents). It is indicated that VCoPs with a specialized focus tend to attract more engaged members [45]. Additionally, our program was free, aligning with the understanding that health care practitioners engage more when resources are accessible and low-cost [46]. Besides targeting homogenous groups of members and ensuring the program's affordability, group size also influences engagement; smaller groups (12 - 20 members) enhance participation and learning [34,56,57]. Our four 6-week cycles involved 55 PCPs (average of 13 - 14 per cycle), fostering a sense of community. Studies show that small VCoPs reduce isolation and increase knowledge sharing [34]. Similarly, most participants in our CFC Learning Hub indicated that the size of their groups was suitable for their educational experience. Finally, VCoP's facilitators play a key role in maintaining engagement by setting clear rules, focusing discussions, and promoting respect [21]. Learning from experts (n=8, 23%) ranked as the second-highest motivation for joining the activity. In the CFC Learning Hub, experienced PCP peers led discussions, supported by specialists to guide case analyses and foster engagement. Facilitators' detailed profiles and access to support ensured high satisfaction and participation. All in all, the management of participation issues related to VCoPs, such as sense of community, affordability, and proper facilitation, may contribute to increased active participation and engagement.

Health care VCoPs use various digital formats, including teleconferences, webinars, videoconferences, online meeting spaces, websites, emails, intranets, and social media [58]. Some also feature blogs, online discussion forums, or file repositories [59]. One example is Project Extension for Community Healthcare Outcomes, using real-time videoconferencing to connect rural primary care providers with specialists [32], resulting in significant improvements in provider confidence and addressing treatment gaps through education and knowledge-sharing. Social media platforms like Facebook, X (formerly known as Twitter), and LinkedIn can also host VCoPs [27]. The diversity in digital formats among VCoPs reflects the diverse preferences and interests of health professionals, highlighting the absence of a one-size-fits-all format. Similarly, such variation in interests was demonstrated in our program. The study's results indicated varying preferences among participants regarding their favored learning models, with a significant proportion (n=13, 37%) endorsing small group learning, followed by live webinars (n=9, 26%), interactive learning methods (n=7, 20%), and on-demand videos (n=6, 17%). Clearly, a small group online VCoP such as our program must leverage various digital formats to effectively disseminate information and knowledge, catering to the diverse learning

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preferences of participants. For instance, based on feedback received in earlier cycles, we proceeded to incorporate additional knowledge-sharing formats, such as the introduction of short videos to the modules. Overall, a successful health VCoP must adapt to the diverse preferences in learning models among health professionals. Therefore, it may be advantageous to use multiple learning formats to ensure broad participation among participants.

PCPs play a crucial role in managing fragility fractures, highlighting the importance of equipping them with adequate resources and knowledge. However, PCPs globally, including in Australia, demonstrate low-level adoption of evidence-based osteoporosis management guidelines, leading to underdiagnosis and undertreatment. Our program aimed to address these gaps by developing an interactive online educational platform, the CFC Learning Hub, targeting PCPs to enhance their understanding of osteoporosis management models. The program's success was evidenced by high participant satisfaction rates and high engagement levels. This success was supported by our program implementing strategies to avoid time barriers (including allowing flexible times of engagement), reduce access-related issues, and enhance participant engagement. Overall, our educational initiative transforms the learning experience by offering flexible time arrangements, interactive peer collaboration, and detailed insights into osteoporosis management; tailoring to various patient demographics; and facilitating practice-oriented learning for PCPs.

Limitations

The time data were based on the time between clicks and may not accurately represent the time spent by PCPs on learning or accessing educational materials. Specifically, it was not possible to differentiate between the use of a single or dual screen or switching between different documents once opened or downloaded. While this is not a live-video interaction, it is possible that the participants opened the website without actually learning. Therefore, the true duration of the learning cannot be confirmed. Additionally, participants were recruited via the Praxhub platform, and the vast majority of them were practicing in metropolitan areas and had over 10 years of practice experience. Therefore, our results might not be transferable to all practitioners, particularly targeting regional PCP practices and younger practitioners. Third, participants were not asked to complete a knowledge quiz prior to the training, which could lead to an overestimation of the effect of the intervention on improved knowledge.

Conclusions

Addressing the treatment gap in osteoporosis care, especially within primary care, where PCPs are pivotal, is urgently needed. Challenges like low trust of online information sources, communication gaps, and inadequate patient information sharing highlight the necessity for tailored educational interventions like the CFC Learning Hub. The program, characterized by its user-friendly, case-based, interactive, and time-flexible nature, effectively bridged investigation and management gaps in osteoporosis. Specifically designed to tackle challenges encountered by PCPs, this platform holds promise for professional development across various health-related fields.

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Data Availability

All data analyzed up to the time of submission of this manuscript are included in this published article and Multimedia Appendix 1.

Authors' Contributions

Conceptualization: AMF, CC, RA, SC, JDW
Data curation: AG (lead), AMF, CC, RA, TD, SC, JDW
Formal analysis: AG
Investigation: AMF, CC, RA, AG, SC, SS, CJY, RDB, SP, LC, JDW
Methodology: AMF, CC, RA, AG, SC, SS, CJY, RDB, SP, LC, JDW
Project administration: AMF (lead), CC (equal), RA (equal), SC (equal), JDW (equal)

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Visualization: AG
Resources: SS (liaison with Praxhub)
Supervision: JDW, CC, SC
Writing – original draft: AMF (lead), CC (equal), RA (equal), SC (equal), JDW (Lead)
Writing – review & editing: AMF, CC, RA, AG, SC, SS, CJY, RDB, SP, LC, TD, JDW
All contributors listed under CRediT roles have reviewed, provided feedback on, and approved the final version of the manuscript for publication.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Quiz performance, postprogram participant feedback, and quiz item details.
[DOCX File, 155 KB - formative_v10i1e76216_app1.docx]

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Abbreviations

CFC: Community Fracture Capture
CPD: continuing professional development
FLS: fracture liaison service
PCP: primary care physician
VCoP: virtual community of practice

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Involving End Users in Co-Designing Mobile Health Interventions for Hypertension Self-Management: Formative Study

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Abstract

Background: Mobile health (mHealth) interventions are prevalent, yet people from marginalized communities are less likely to use digital health technologies to support self-management behaviors. Community engagement can inform health care design to enhance a hypertension self-management mHealth intervention.

Objective: We applied human-centered design (HCD) to determine appropriate iterations of an existing hypertension intervention.

Methods: Through an equity-focused, community-centered approach, we strove to optimize an mHealth app. We used validated theories and frameworks as well as an HCD methodology organized into three fundamental design skills: (1) methods to directly observe user experiences, (2) methods to analyze barriers to ideal intervention use, and (3) methods to design future iterations.

Results: In October 2023, we conducted a series of HCD activities with a community advisory board (n=8) to refine an mHealth intervention for hypertension. Participants tested app prototypes with blood pressure monitors and suggested content modifications to enhance intervention fidelity. Among 6 participants, usability testing scored 67.5 (benchmark 68, “above average”), with all users finding the tool easy to use. Feedback identified critical needs, barriers, and work-arounds for future mHealth iterations.

Conclusions: This study was a novel use case example of HCD as a patient-centered methodology to improve a hypertension management tool.

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KEYWORDS

community-engaged research; hypertension; intervention design; human-centered design; mobile health; mHealth

Introduction

Hypertension is a public health crisis and is a leading modifiable cause of cardiovascular disease (CVD) worldwide [1,2]. Control of hypertension in the United States plateaued over a decade ago, and current recommendations of blood pressure (BP) of less than 130/80 mm Hg are achieved by only 19% of patients [3-5]. Furthermore, populations experiencing social and structural inequities (eg, due to race) face significant disparities in clinical outcomes [6]. Race-based differences in hypertension self-management may exacerbate preventable health disparities in stroke, kidney disease, atherosclerosis, and mortality [7]. Professional society guidelines prioritize nonpharmacological and behavioral interventions for adults with elevated BP and hypertension and advocate for implementation strategies to overcome race-based disparities [8,9]. Behavioral strategies for monitoring and managing BP can moderate the progression of hypertension and potentially address disparities.

Newer research has shown that mobile health (mHealth) technologies can yield meaningful health behavior change. Technology-based behavior change interventions can demonstrate measurable and clinically meaningful effects. When

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used for chronic disease management practices, they can be engaging and easily adopted in some patient populations [10]. Successful self-management technologies can include individualized, patient-facing content [11,12], such as mHealth virtual coaches that provide lifelike, digital education, monitoring, and problem-solving [13-17]. mHealth has emerged as a scalable technological advance to support behavior change for hypertension self-management [18,19]. The popularity of mHealth for hypertension and CVD management is rising in part because smartphone use has become nearly ubiquitous [20]. However, a divide in health care and technology access across race, ethnicity, economic status, geography, and education levels remains [21], potentially perpetuating health care inequity [22,23]. Despite the prevalence of mHealth interventions, people from marginalized communities, including Black people, are less likely to use digital health technology to support self-management behaviors [24,25]. Community engagement [26] and community-based approaches can be important when tailoring technological interventions to meet the needs of unique patient populations [27,28].

Self-management behaviors for hypertension are central to the prevention of comorbid disease [29]. The targeted behaviors should include home BP monitoring, medication adherence, and lifestyle modifications such as healthy nutrition and physical activity [30]. Our group's preliminary mHealth work demonstrated the usefulness of a bespoke virtual mHealth coach among participants with CVD. In a pilot study (n=120), our group showed that our mHealth tool was feasible, acceptable, and engaging for participants, the majority of whom were White with moderate incomes [19]. Although this intervention was designed to be patient centered, preliminary testing had not been conducted among a diverse patient population. What is unknown is whether and how such tools can be useful and optimized in sociodemographically diverse populations [10,31]. Optimizing our existing mHealth tool for hypertension will allow further development using validated, patient-centered, theory-informed behavioral methodology among racially minoritized populations, including Black patients. This study was part of a larger research project designed to inform hypertension management for an underserved patient population. The overall research goal was to empower individuals from marginalized backgrounds to develop an acceptable technological tool for hypertension self-management. The project was informed by a community advisory board (CAB) as a validated approach to intervention design. We used human-centered design (HCD) to engage the CAB in testing the existing mHealth tool and guide iterative changes [32]. To supplement our HCD activities, we used the validated Framework for Reporting Adaptations and Modification to Evidence-Based Interventions (FRAME) model to document details of proposed modifications to track when, how, and why modifications were being suggested [33]. Through our community-informed HCD approach, we sought to ensure that our intervention captured the needs, preferences, and capabilities of our population of focus. Thus, in this study, we hypothesized that through an iterative, community-informed approach, we could enhance a hypertension mHealth self-management intervention to facilitate use among racially minoritized patients at risk for hypertension disparities.

Methods

Group Members

Community partners and people living with hypertension were integral to guiding this user-centered process. Community-based methods have been described by others as critical to designing interventions that are informed by feedback from community partners, including people with the condition of interest, advocates, and community leaders [34]. AJ, EM, and JB had previously worked together to establish a CAB that would guide research goals, including the HCD activities, dissemination of research findings, and participation in community events. The CAB included racially diverse individuals from Black, White, and Asian backgrounds. Several CAB members had self-described hypertension or CVD. They resided in urban communities with high economic adversity and included community leaders involved in neighborhood-level transformation. Eight CAB members participated in the HCD activities described herein. The participants were included through convenience sampling based on their availability to attend the HCD session. Table 1 provides details about the HCD session participants.

Table . Session attendees.

Participant	Expertise
21-y-old Black man	Community activist and has participated in HCD[a] previously
21-y-old Black woman	Master's student in public health
60-y-old Black man	Living with chronic illness and has hypertension
38-y-old Black woman	Works in health professions and has parents with hypertension
57-y-old White man	Retired primary school teacher in disenfranchised school system and has hypertension
35-y-old Black man	Living in a racially segregated neighborhood and has hypertension
19-y-old Asian woman	Health professions student and has parents with chronic illness
52-y-old Black man	Community activist and has hypertension

[a]HCD: human-centered design.

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The Existing mHealth Tool

Our mHealth virtual tool facilitates human-device interaction and is delivered via a smartphone app. The program incorporates one-on-one coaching and education modules to support behavior change, self-management, medication adherence, and improved quality of life. The patient engages with the smartphone app by selecting options on the touch screen as shown in Figure 1. By choosing responses, patients "converse" with a virtual health coach and develop a therapeutic alliance. The program can record responses to simulate a 2-way conversation. As patient self-monitoring works best when paired with counseling and education [35], our mHealth tool was created to integrate home BP monitor use with educational components to teach patients how to track their BP data. The intervention tested in the present study included (1) patient-centered strategies to address barriers to treatment adherence, (2) disease-specific education, and (3) self-management strategies, including guided physical exercise, heart-healthy diet, and stress mitigation.

Figure 1. Example screenshots of the intervention. The app is a virtual coaching platform that allows users to perform blood pressure measurements via Bluetooth. Users can view readings and historical data. Educational modules feature several topics relevant to hypertension management and lifestyle modification. (A) "Conversation" with the coach in which she introduces herself to the patient. (B) Menu of educational topics. (C) Example patient data with 2-wk trends of recent blood pressure readings.

HCD Activities

We applied HCD to determine appropriate iterations of the existing intervention that would encourage lifestyle modifications and self-management behaviors among Black patients with hypertension. Through an equity-focused, community-centered approach, we strove to optimize an existing intervention to achieve participant consensus [36]. Table 2 includes the HCD elements incorporated into our theory-driven approach. The LUMA Institute is a design firm specializing in a "practical, flexible and versatile approach" to HCD methodology [37]. Their HCD process includes a proprietary set of 36 methods organized into three fundamental design skills: (1) looking methods to directly observe user experiences in real time; (2) understanding methods to analyze barriers to ideal intervention use; and (3) making methods to design future iterations [37]. We sequentially used activities from each of the 3 groups of fundamental skills to encourage a thorough, multifaceted discussion. The sessions were moderated by AJ, a LUMA-certified HCD practitioner.

Our goal was to take the existing mHealth tool and progressively apply HCD methods, beginning with looking methods. The "that's on your radar" activity encouraged session participants to categorize and rank the essential requirements for hypertension management. Next, "think-aloud testing" allowed participants to envision ways BP monitoring can be improved while audibly describing the process of using the intervention. This step was an opportunity to reveal flaws or inefficiencies in the mHealth tool design. The third looking method, "critiquing the system," was built upon think-aloud testing by providing a forum for constructive feedback. Participants

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critically appraised the current ways in which hypertension is managed with our existing tool, with particular attention to barriers to and facilitators of self-management. We followed the critiquing step with the validated System Usability Scale [38] to score key aspects, including ease of use, technical difficulty, and one's confidence in using the tool. The System Usability Scale includes 10 questions answered on a Likert scale, ranging from 1 (strongly disagree) to 5 (strongly agree) [38]. Survey responses were deidentified. Our next activity was an understanding method to frame participants' experiences with hypertension management, called the "importance and difficulty matrix." Another understanding method, "rose, thorn, bud," encouraged participants to describe aspects as positive, negative, or having potential (a rose, thorn, or bud, respectively). Finally, we used the "cover story" activity as our making method for envisioning future possibilities of hypertension management.

Attendees had access to working BP monitors and a beta version of the intervention app on study smartphones. Session activities are described in Table 2, in which relevant FRAME process elements are also explained. The HCD process allowed the group to progressively work through each specially designed activity with naturally occurring moments of ideation, wherein thoughts were discussed and elaborated upon. Additionally, the process allowed the group to concentrate on concepts that required deeper exploration or more intense focus while testing out the tool in real time. Figure 2 visually represents the HCD process for ideation, testing, and optimizing an effective hypertension management tool.

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Table . Session activities.

Activity	HCD[a] method	Possible adaptations and modifications	Emergent themes relating to self-care
What's on your radar	• Looking method • Encourages participants to creatively describe the scope of a situation (in this case, BP[b] management)	• Facilitated discussions of the contexts in which one manages BP • Aspects of BP management most related to fidelity were plotted in the center of the diagram • Proposed modifications to the intervention included categorization into 1 of 5 topics: patient-related factors, clinician-related factors, access to health care or mHealth[c], behavior, and technology use • Significant components of BP management included self-care, education, and behavior change	• Positive and negative attitudes about physical activity • Negative attitudes about the health care industry and patient-physician relationships • Beliefs about one's ability to control health behaviors including sleep, diet, physical activity, and mental health
Think-aloud testing	• Looking method • Encourages participants to evaluate a process and provide constructive feedback • Session was audio recorded	• Use of intervention prototype facilitated discussions of possible content modifications • Participants overall found the process of BP monitoring satisfactory • Proposed modifications included cultural adaptations (what the virtual coach looks like) • Suggested modifications regarding cost and access (making the tool affordable and accessible) were discussed	• Positive attitudes about self-care • Norms about self-care • Beliefs and perceived power • Related being able to control one's BP • Perceived power about education through the mHealth tool versus other modalities
Critiquing the system	• Looking method • Encourages participants to critique the system or process • Participants completed a survey to assess usability	• Survey results revealed that improvements could be made to module integration • All but 1 participant found the intervention cumbersome to use	• Participants were asked if other people would be able to learn to use this system very quickly: responses were neutral • Thinking of others who would use this mHealth tool could normalize BP self-care behaviors
Importance and difficulty matrix	• Understanding method • Allows for thoughtful framing and understanding of patterns and priorities about BP management	• Facilitated discussion of how important or difficult modifications to the mHealth intervention might be. • Modifications that were both important and difficult were considered strategic priorities for future mHealth interventions: Building trust in technology, actualizing what one's BP numbers mean, and understanding how behaviors affect BP • Accessing the mHealth tool and improving knowledge were considered high-value modifications	• Subjective norms were emphasized, including the need for behavior change and stress mitigation • Perceived power was reflected in the participants' view that BP management should become habitual

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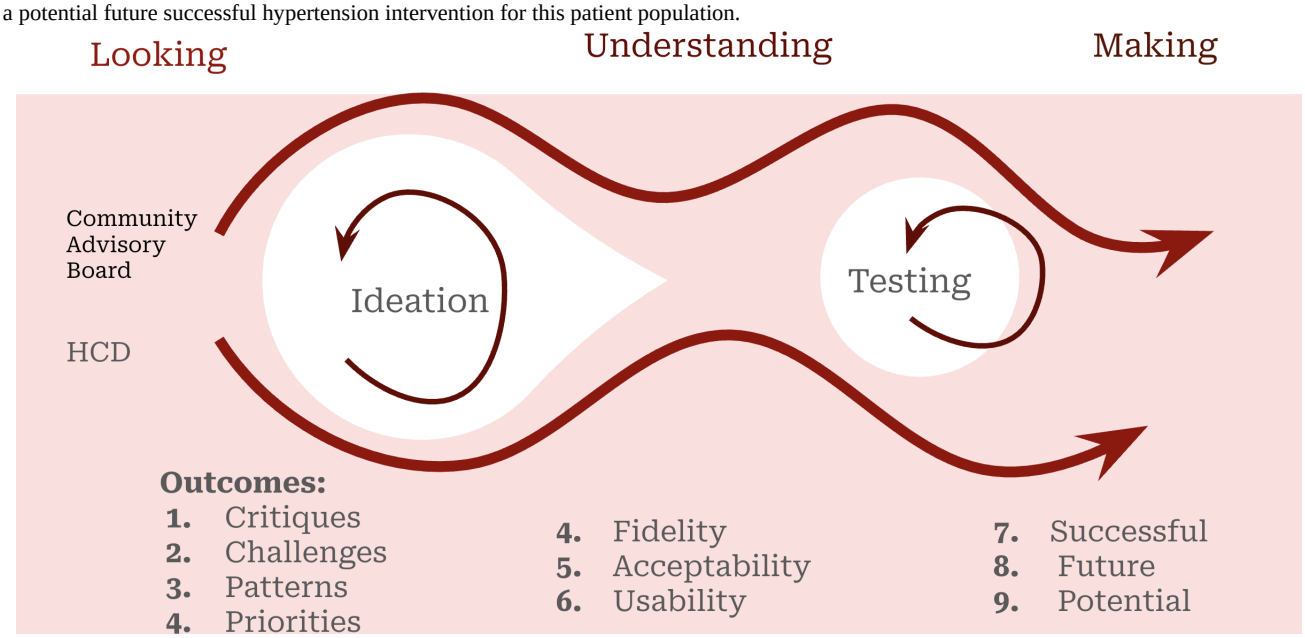
Activity	HCD[a] method	Possible adaptations and modifications	Emergent themes relating to self-care
Rose, thorn, bud	• Understanding method • Allows participants to understand and characterize • BP management • Technique identified factors of the intervention as positive, negative, or having potential	• Process of BP monitoring could be modified so that self-management is less of a hassle • The intervention could be modified to provide direct feedback on whether the BP readings are normal and how to respond to abnormal results • Potential modifications (eg, increased educational modules) to mHealth would help overcome health disparities	• Positive attitudes included improving BP for a healthier, longer life • Having hypertension is common and could be addressed at the community level • Control beliefs regarding abnormal BP readings often lead to uncertainty or fear • Perceived power was described regarding being able to take action on one's hypertension
Cover story	• Making Method • Encourages the design of a future tool with discussion of the required actions for the intervention to thrive	• Modifications (eg, facilitation of blood pressure management with clinicians) for successful future of BP management could lead to thriving communities and health equity	• Leading heart-healthy lifestyles has implications for neighborhoods as well as individuals • mHealth tools could facilitate health equity, which would in turn lead to longer, happier lives • Positive findings would benefit society

[a]HCD: human-centered design.

[b]BP: blood pressure.

[c]mHealth: mobile health.

Figure 2. Human-centered design (HCD) process. This figure depicts the human design workflow using LUMA's looking, understanding, and making methods in which the intervention underwent critiques from the community advisory board members. Outcomes of the ideation and testing process included narrative descriptions of patterns, qualitative assessment of priorities, and appreciation of intervention usability. The end result was a description of a potential future successful hypertension intervention for this patient population.



Theory-Informed Intervention Assessment

In addition to the HCD activities, we used validated frameworks to complement the assessment of the end user experience. The FRAME method includes documenting details of proposed modifications to track when, how, and why modifications are being suggested [33]. We were particularly interested in modifications relevant to digital equity in mHealth interventions, including increased accessibility and usability [25]. Additionally, we used the Theory of Planned Behavior to conceptualize evidence-based, clinically meaningful behavior change techniques to enhance the intervention. Compared to other theories used to guide mHealth interventions for chronic disease self-management, the Theory of Planned Behavior features validated constructs for designing, implementing, and evaluating interventions and has been shown to be effective in hypertension management [39,40]. Our work was also informed by the recommended health behaviors identified in the American Heart

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Association's Life's Essential Eight schema, including physical activity and a heart-healthy diet [41]. These frameworks facilitated our understanding of possible ways to optimize our intervention.

Anticipated Observations

As this was a formative process, we hoped to gain important insight for future iterations of the mHealth intervention. Direct observation allowed the session leaders to document the interplay of people, objects, and tools while completing the session activities. Therefore, target outcomes included observations of processes and themes that would be used to enhance future design efforts. Parts of the sessions were photographed or audio recorded and transcribed. The goals of our observations were to understand needs, barriers, and work-arounds to be optimized in future intervention design.

Data Analysis

We used qualitative methodology to interpret the study observations. Audio data were recorded using a digital recording device, transcribed verbatim, and coded by AJ. Confidentiality, transparency, and verbal consent to record were established before activities. Deductive coding summarized qualitative themes based on the overarching research goals as reflected in the HCD methodology. During coding, unique observations were added to the predefined categories, such that the analysis also allowed for an inductive analytical process where appropriate. Summarized data across all activities were entered into a single matrix organized by possible future intervention iterations and self-care goals. Co-authors met to review the matrix, identify themes and unique insights across activities, and contextualize themes for clinical relevance and design implications. Disagreements were adjudicated until consensus was reached. Additionally, co-authors reviewed figures to ensure transparency and accuracy based on the HCD activities that occurred. Descriptive data are listed, and we provide the calculated usability survey results, including mean scores, SDs, and total scores for each respondent.

Ethical Considerations

This study underwent ethical review by the University of Pittsburgh Institutional Review Board and was determined not to be human subjects research, and therefore, informed consent was not required. CAB members were compensated US $500 after their 12-month involvement with the advisory board's overarching research program. For CAB member privacy and confidentiality, data were deidentified prior to analysis as a protective measure to safeguard personal information.

Results

Group Members

In October 2023, we met to conduct HCD activities for optimization of the hypertension management mHealth intervention. The meeting's 8 attendees were CAB members aged 19 to 60 years and included 3 (38%) women and 5 (63%) men. Six (75%) of the attendees self-identified racially as Black, and all self-identified as advocates for health concerns related to the Black community (Table 1).

HCD Activities

Looking: Methods to Observe User Experiences

The first activity, "what's on your radar?" encouraged participants to contextualize important aspects of BP monitoring and hypertension self-management as shown in Figure 3. Participants categorized components of hypertension management according to their relevant contexts, such as patient-related behavioral aspects, including eating a healthy diet. Components of hypertension management were also prioritized as being of high, medium, or low importance.

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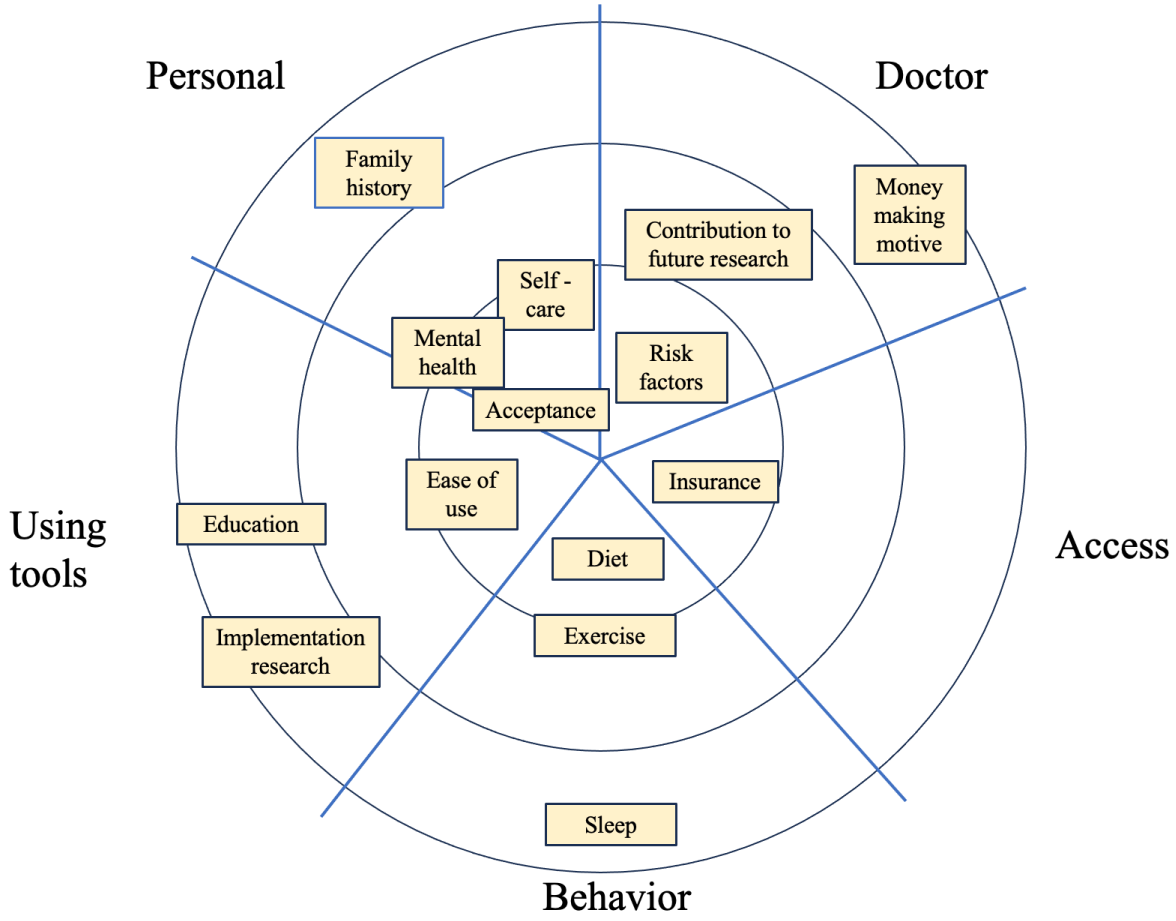
Figure 3. Looking activity—What's on your radar? Participants categorized components of hypertension management and prioritized them as being of high, medium, or low importance.



In the next activity, "think-aloud testing," participants used prototypes of the intervention and were able to narrate potential modifications to the intervention's content, interface, and operation. This session was audio recorded and transcribed to assess themes of observed user experiences. All proposed modifications were proactive, meaning that they would be optimizations to the existing mHealth tool, thereby encouraging intervention fidelity [33]. Using the Theory of Planned Behavior, participants' attitudes, subjective norms, control beliefs, and perceived power were elicited through guided questions from the session moderator (AJ) [39]. Table 3 includes quotes from the recorded session with connections to possible mHealth design elements.

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Table . Results from think-aloud testing.

Quote	Interpretation	Design implications [25,36]
Man 1: I was expecting [the virtual health coach in the app] to say something and she didn't... then for her to say, "We're excited about the progress that we're making." First... what progress?... we moved right away to come into the self care section and the scripting here seems to assume that someone is going to go through the topics in order... It seems out of context. Man 2: It should simply tell you. It should start at the beginning... She's just making assumptions that we know... there needs to be a clear order of how to progress through the thing.	• The participant expresses some confusion about the sequence of dialog as he goes through the educational segments. • Later, other participants also describe a lack of clear progression from one subject to the next.	Older adults may have significant difficulty with mHealth[a], especially when conversational agents do not communicate in natural conversation styles.
Man 2: Stress?... is that like environmental stress? Like outside? Working out? Traffic?	• The virtual health coach describes the effect of stress on BP[b], but the participant reports that the type of stress is not clear.	Stress mitigation is an important feature of smartphone apps to manage hypertension.
Woman 1: I think like the topics are helpful. They're very related... And all of the stuff they talk about and each of the topics were also very relevant [to BP].	• The participant appreciates that the included topics are useful and related to hypertension self-management.	—[c]
Woman 2: then this doctor was saying that like wait... is she a doctor? Man 3: And every time I hear that she learned something from somebody... I thought she was somebody that had credentials. I don't know. Woman 2: I thought that she was a doctor. But then she's not really dressed like a doctor.	• Two participants discuss confusion about the virtual health coach's credentials. They describe wanting to trust the coach but are unsure if she is trustworthy.	Transparency and trust are important, especially among racially minoritized or marginalized groups. Knowing the credentials of the person delivering information is key. Occupation-specific attire can improve credibility.
Man 3: I mean I guess you know this app is made for people to learn about the subject. So you know I feel like I could just like just get to the point. I could just Google the stuff too... you would have to be very motivated to stick with it.	• The participant describes that if the goal is to gain knowledge, there are easier, less cumbersome ways to achieve that goal.	—
Man 2: She's mentioning someone named Paul. We have no idea who Paul is so... Man 1: "Sometimes I am reminded that if Paul is not having symptoms, his blood pressure is still high." And I should care because???	• The participants describe confusion about parts of the virtual health coach's dialogue. They express frustration that some parts of the conversation do not feel relevant.	Researchers and designers may have a perspective of what constitutes a valuable insight that differs from the perspective of the end user.
Man 3: I feel like the personal appearance of somebody to make them more relatable is pretty relative to the person using it though.	• The participant describes the importance of cultural representation in the virtual health coach but recognizes that diverse end users would each require something different.	Physical attributes and conversation style could be optimized to reflect the end user. However, design experts suggest that trust and credibility are more likely gained from the system's professionalism and knowledge.
Man 4: 138 over 88. I mean I know it's high. It's definitely elevated. But what does this mean and what does that mean? That's what I always wanted to know... If like she says your blood pressure is elevated what should you do about it? Woman 2: Sometimes I wonder what the numbers mean. I think it's cool to know, to have that information.	• The participants react to their BP readings and express not understanding what the numbers mean.	The mHealth system should provide suitable education, personal feedback, and interaction reflective of disease severity. If critical findings occur, there should be a mechanism to communicate with relevant medical professionals.
Man 5: But it's about access. It's a 100 dollar thing [BP monitor]. Man 1: Fixed income. You gonna beat yourself and pay for pills or buy a new monitor?	• The participants describe potential difficulty with high costs and a lack of access to mHealth tools in addition to the requirements such as medication.	Barriers to accessing technology can lead to a "digital divide" in which people from marginalized backgrounds are not able to benefit from mHealth. Technological advances should be designed for easy implementation into various communities.

[a]mHealth: mobile health.

[b]BP: blood pressure.

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[C]Not applicable.

Furthermore, participants completed the "critiquing the system" activity. Figure 4 shows a summary of usability results from the 6 (75%) participants who completed the usability survey. Table 4 presents individual responses to the usability survey.

Overall, the group found the mHealth tool to be of average usability. Per the survey's scoring system, total scores above 68 are considered "above average." Our participants' total scores ranged from 52.5 to 80, with a group average of 67.5 (SD 11.4). All participants rated the intervention as "easy to use." Participants reported low technical difficulty and a moderate level of self-confidence in using the intervention.

Figure 4. Summary of usability results. Participants found the tool to be about average in overall usability. Specifically, the tool was rated as easy to use, with low technical difficulty. Participants ranged in their confidence of using the intervention, with scores of 2 to 5, average 3.3. To calculate the total score for each respondent: for odd-numbered questions, subtract 1 from the response; for even-numbered questions, subtract the response from 5. Then, add the scores for all ten questions to calculate the total score out of 100 [38].

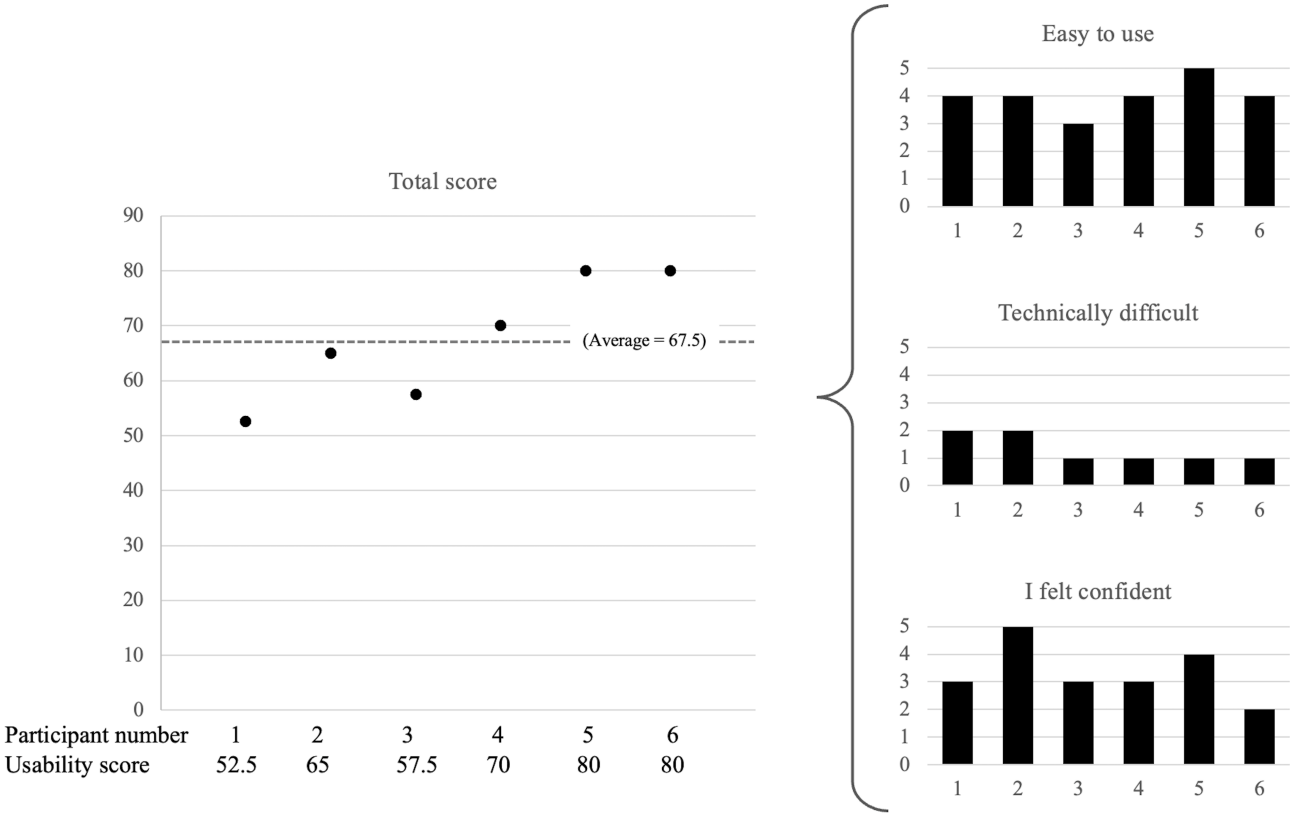

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Table . Individual participant results from system usability survey.

Question	Participant 1	Participant 2	Participant 3	Participant 4	Participant 5	Participant 6	Response[a], mean (SD)
I think that I would like to use this system frequently.	2	4	3	3	4	4	3.3 (0.82)
I found the system unnecessarily complex.	3	2	3	1	2	1	2 (0.89)
I thought the system was easy to use.	4	4	3	4	5	4	4 (0.63)
I think that I would need the support of a technical person to be able to use this system.	2	2	1	1	1	1	1.3 (0.52)
I found the various functions in this system were well integrated.	3	3	4	3	4	4	3.5 (0.55)
I thought there was too much inconsistency in this system.	3	3	3	2	1	1	2.2 (0.98)
I would imagine that most people would learn to use this system very quickly.	2	4	3	3	4	4	3.3 (0.82)
I found the system very cumbersome to use.	3	4	3	3	4	1	3 (1.1)
I felt very confident using the system.	3	5	3	3	4	2	3.3 (1.03)
I needed to learn a lot of things before I could get going with the system.	2	3	3	1	1	2	2 (0.89)
Calculated total score	52.5	65	57.5	70	80	80	67.5 (11.4)

[a]To calculate the total score for each respondent: for odd-numbered questions, subtract 1 from the response; for even-numbered questions, subtract the response from 5. Then, add the scores for all 10 questions to calculate the total score out of 100 [38].

Understanding: Methods to Analyze Barriers to Ideal Intervention Use

The "importance and difficulty matrix" activity encouraged participants to thoughtfully describe perceived patterns and priorities about hypertension management. During this activity, the moderator and participants used a whiteboard to create a poster with a 2×2 table. Four quadrants were drawn with axes representing the importance (high vs low) of each aspect of hypertension management, as well as difficulty (high vs low). Figure 5 is a reproduction of the original table created from the whiteboard and handwritten sticky notes. Participants identified *partnership* as one aspect of hypertension management that is both low difficulty and low importance. Participants discussed that partnership between patient and physician should be easily accomplished but did not feel that it was as important as other concepts that were identified by the group. This low importance, low difficulty quadrant is labeled as "targeted" because these are the simple tasks that are achieved with little thought or effort. The upper left quadrant contains "luxurious" aspects that are costly with little return. The group felt that *exercising* belonged in this high difficulty, low importance quadrant. The upper right

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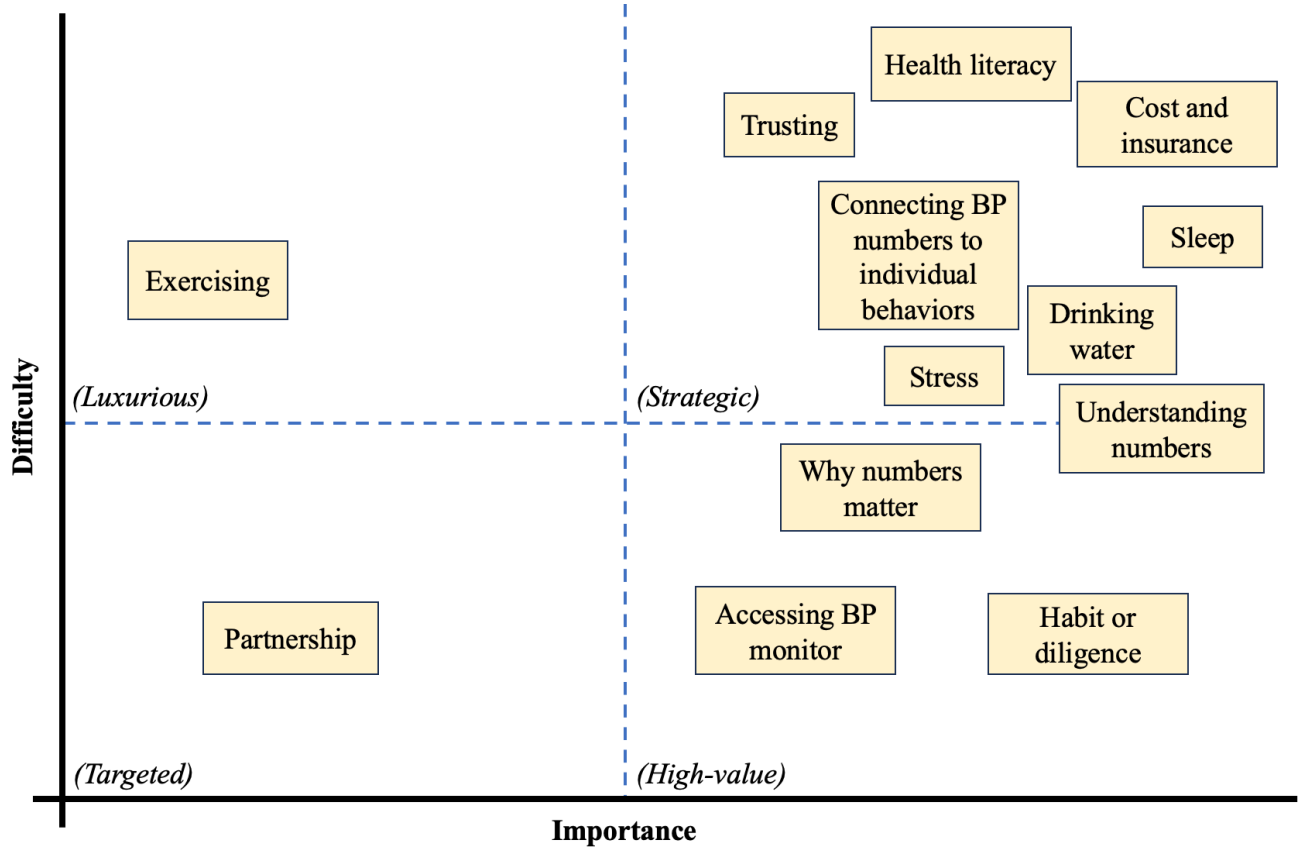
features "strategic" aspects that produce big results via large effort. Finally, the "high value" quadrant features relatively lower effort items with high impact. Some complementary concepts were felt by the group to be of high value, including *trusting* the health care system, *health literacy*, and *understanding* the BP numbers. *Cost* of and *access* to hypertension management tools were also classified as highly important.

Figure 5. The importance and difficulty matrix. The axes represent the importance (high versus low) and difficulty (high versus low) of aspects of hypertension management. Four quadrants are labeled as follows: low importance, low difficulty quadrant is labeled as "targeted" because these are the simple tasks that are achieved with little thought or effort. The upper left quadrant contains "luxurious" aspects that are costly with little return. For example, the group felt that *exercising* belonged in this high difficulty, low importance quadrant. The upper right features "strategic" aspects that produce big results via large effort. Finally, the "high value" quadrant features relatively lower effort items with high impact.



The "rose, thorn, bud" activity further fostered prioritization of future design iterations. This activity encouraged participants to codify aspects of our hypertension intervention as being positive, negative, or as having promise, as shown in Figure 6. Participants felt that hypertension management would lead to positive outcomes such as better BP control, good health, and longevity. The group also identified that patients who use the intervention would be empowered to improve their health. Negative aspects of hypertension management related to the task of physically taking one's BP and problems with not understanding the results. Important insights about the potential of our mHealth intervention were related to mitigating CVD risk and overcoming disparities at the community level.

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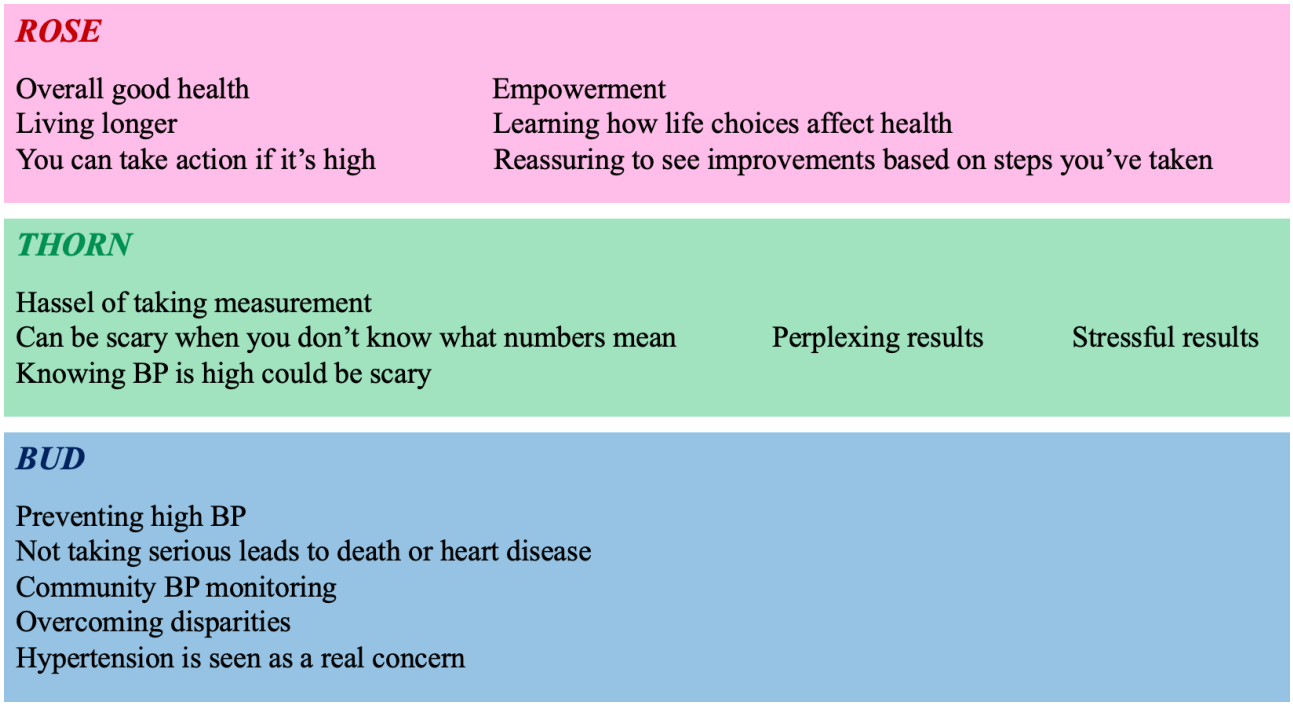
Figure 6. Rose, thorn, bud. The "rose, thorn, bud" activity encouraged participants to codify aspects of the hypertension intervention as being positive, negative, or as having promise (rose, thorn, or bud, respectively). BP: blood pressure.



Making: Methods to Design Future Iterations

As shown in rose, thorn, bud, participants agreed upon the benefit of the hypertension management intervention, and this final activity encouraged the group to further envision the possibilities of hypertension management with a future iteration of our mHealth intervention. The "cover story," informed by the prior activities, resulted in the group envisioning mHealth as a conduit for marginalized communities to obtain a healthy lifestyle in the future. The activity asked participants to imagine a headline news story and create quotes, pictures, and text to convey a successful future of hypertension mHealth for Black patients in their community. Participants supported a shared vision in which Black residents of their city would be thriving and healthy. Their cover story was entitled, "Pittsburgh, Now a Livable City for Blacks."

Discussion

Principal Findings

In this HCD study, community representatives found an existing mHealth hypertension app to be useful and revealed important elements to enhance the intervention's future health equity outcomes. Facilitators to our intervention's success included educational topics that were perceived as relevant to hypertension self-management. We also determined key findings for equitable mHealth design and implementation. Through HCD, we received feedback for future modification, specifically for stress management, community health, and improved design fidelity. This sequence of methods facilitated ideation, led to discussion of insightful feedback, refined design priorities, and helped with envisioning future solutions.

Comparison With Prior Work

To date, educational features have been among the most studied mHealth hypertension self-management functionalities [42]. Our intervention included educational modules about understanding BP results, which participants noted to be useful and relevant. Future mHealth work should focus on educational opportunities to better facilitate an understanding of one's BP results, as had repeatedly emerged in our study. However, as was also indicated in our study, educational features alone will not ensure user satisfaction. Experts recommend that technological interventions are not only educational but that they are also usable and accessible for the target population as has been shown for conditions such as hypertension, mental health, diabetes, and chronic pain [22,31]. According to our survey results, our current intervention was easy to use. Our participants reported low technical difficulty and a moderate level of self-confidence when using the intervention. A systematic review of mHealth hypertension management programs found that interventions can lead to BP control if they use multifaceted functions and messaging that are individually tailored to the needs of each patient [43]. Those authors recognized that further research about the cultural adaptation of interventions is needed [43]. Our findings help to fill the knowledge gap regarding patient-centered, community-engaged ways to test mHealth tools for usability and accessibility.

Although we did not measure device adherence in this study, others have shown that the value derived from using technology must be sufficiently high for patients to adhere to the intervention as part of their routine [44]. Defining patient-perceived value as it relates to hypertension deserves further study. As our results indicate, strategic next steps should prioritize features that are of high importance to end users. Design aspects that can build trust in the health care system, facilitate health literacy, and improve patients' understanding

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of their BP will be important. Systematic reviews have shown that chronic disease management requires multimodal interventions that feature educational, tailored messages, interactive communication, and multifaceted functions [7,43]. The mHealth literature underscores the importance of digital health literacy, especially among vulnerable populations [45]. Data suggest that disproportionately affected and disadvantaged populations often lack the technological resources to keep pace with the rapid technological developments in health care [46]. Many mHealth programs require high literacy and are inaccessible for individuals with limited educational attainment or limited health and digital literacy [47]. Our participants felt that presenting information at an appropriate level for patients' level of health literacy and providing education to improve hypertension knowledge were of central importance in an mHealth tool. Furthermore, our study revealed participant frustration over system redundancies and a perceived lack of flow between modules. A lack of app functionality integration could lead to intervention nonadherence, whereas platforms with seamless data integration may have high adherence [48]. Nevertheless, our group of users found the technology to be usable in its current state. Participants reported a moderate level of self-confidence in using our mHealth tool.

These findings suggest future technological tools may hold promise for marginalized patient populations. By involving participants from backgrounds that are often excluded from clinical trials, researchers can ensure that technological advances are applicable to broader audiences, thus potentially overcoming barriers to equitable hypertension management. mHealth self-management tools are best designed when their functionalities and modules are based on one or more theoretical models for behavior change [42]. Our theory-informed approach assisted our critique and understanding during the HCD session and bolstered our analyses with validated conceptual models of chronic disease management [49]. The Theory of Planned Behavior has been used to conceptualize hypertension management previously, especially among vulnerable patients such as older adults and women [40]. Other researchers have presented another dynamic behavior model that includes trust and lived experiences as determinants of BP management efforts [50].

Hypertension self-management interventions should provide clarity of what one's BP results mean and how to respond to them in real time. Such features would likely lead to higher confidence in using mHealth, thus supporting patient autonomy as well as patient-clinician partnerships [51]. Key functionalities of hypertension self-management tools should incorporate communication with clinicians, possibly by exporting users' data via a personal platform or patient portal that ensures privacy and security [42]. Others have reported the desire for patients to use mHealth to bridge the communication between patients and their clinicians in co-managing hypertension [24]. Interestingly, our group rated patient-clinician partnerships as a simple, basic component of hypertension management. While the literature supports mHealth as a tool for comanagement between clinicians and patients, all too often, minoritized, vulnerable groups do not achieve therapeutic partnerships with their clinicians to the same degree as White patients [52]. Standardized methods for handling accumulated BP readings and communicating the readings to clinicians are needed. Health care organizations and clinical institutions should invest in the development of mHealth platforms that can securely communicate with patients.

Our findings suggest that future hypertension mHealth tools should facilitate equitable BP management and hypertension care beyond the individual patient. Community-level interventions could include improved neighborhood access to digital, internet-based technology. Our group provided insights regarding future mHealth interventions to address hypertension disparities and mitigate heart disease risk at the community level. Community involvement with app design can positively impact the trust of minoritized participants and should be further explored to build meaningful mHealth interventions for hypertension and other conditions [25]. Furthermore, cultural knowledge and conversational idioms could enhance acceptance among marginalized groups [25]. Virtual agents, such as the one used in our study, use life-like features and attributes to enhance users' perceptions of friendliness and empathy. Our findings suggest that details such as professional attire, title, and credentials had more influence on trust and credibility than did physical attributes. Future iterations could make the virtual health coach appear more racially inclusive and relatable, but professional characteristics should be emphasized as well. Design experts note that a clear designation of character roles is important. For example, physician-specific attire could increase participants' perceptions of clinical credibility [25].

Limitations

Limitations of this work include the small sample size. In this convenience sample, CAB member participation was limited by availability to attend the scheduled HCD session. However, HCD is primarily a qualitative, rather than quantitative, process. Thus, while a low number of participants limits statistical analysis, it was an ideal group size for HCD activities [37]. Another limitation is that not all participants had hypertension, and 3 of 8 had self-described prior health care knowledge, thus potentially limiting the generalizability of these findings to patients with hypertension. Experts have recommended that advisory boards reflect the community of interest, which can be demonstrated by shared identities, illnesses, experiences, histories, or cultures [53]. By these standards, our board was inclusive and representative. Finally, although our work was helpful in generating a discussion about digital equity, we were unable to fully assess implementation barriers to equitable digital technology use. For example, others have described the lack of affordable internet access and limited smartphone availability as barriers that disproportionately affect people from minority backgrounds [22]. Future work is required to better understand the cost and policy implications of equitable mHealth use for hypertension care.

Conclusions

Our comprehensive, integrated approach to intervention development combined theory and evidence to ground our intervention in an in-depth understanding of the avenues for behavior change and facilitators specific to our participant demographics [12]. Future research should include pragmatic

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and implementation science methodologies to iteratively test new mHealth developments. The results showing "average" usability are important because they allow the development of future iterations that will later be compared to this baseline. Our findings emphasize that both high monetary cost and limited access to hypertension technologies create barriers to BP management. Therefore, policy implications include disseminating evidence-based mHealth that uses affordable technology and devices.

This study was a novel use case example of HCD as a patient-centered methodology to improve a hypertension management tool. Interest in HCD is growing in medical education and in global health innovation as a response to the needs of end users [54]. However, clinical researchers have not used HCD methods as readily. Our study is among a growing body of research to evaluate the impact of HCD for clinically relevant interventions. Despite our study's limitations, we showed clear and actionable ways to improve future mHealth tools for hypertension. By regarding mHealth through an equity lens, clinicians, designers, and researchers can begin to move the field of chronic health management forward and implement successful strategies in the future.

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Data Availability

The datasets generated or analyzed during this study are available from the corresponding author on reasonable request.

Authors' Contributions

Conceptualization: AJ (lead), PN (supporting), AA-H (supporting), JB (supporting), EM (supporting), JM (supporting)
Data curation: AJ (lead), DB (supporting), JB (supporting)
Formal analysis: AJ (lead), PN (supporting), AA-H (supporting), MP (supporting), SK (supporting)
Funding acquisition: AJ (lead), JM (supporting)
Investigation: AJ (lead), JB (supporting)
Methodology: EM (equal), JM (equal), CNH (supporting)
Project administration: AJ (lead), JB (supporting), JM (supporting)
Resources: AJ (lead), JB (supporting)
Supervision: JWM (lead), EM (supporting)
Validation: CNH (equal), SK (equal)
Visualization: PN (lead), DB (supporting)
Writing – original draft: AJ (lead), AA-H (supporting), JM (supporting)
Writing – review & editing: AJ (lead), EM (supporting), MP (supporting), SK (supporting), JM (supporting)

Conflicts of Interest

None declared.

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Abbreviations

BP: blood pressure
CAB: community advisory board
CVD: cardiovascular disease
FRAME: Framework for Reporting Adaptations and Modification to Evidence-Based Interventions
HCD: human-centered design
mHealth: mobile health

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Exploring the Preferences and Behavioral Trends of e-Patients in Psychosomatics Towards Telemedicine During and Post COVID-19 Pandemic: Cross-Sectional Analysis

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Abstract

Background: COVID-19 accelerated the adoption of health services, with a growing number of psychosomatic patients turning to the internet for health-related decisions. This study explored changes in communication behavior, information-seeking habits, and post-pandemic consultation preferences among psychosomatic patients during and after COVID-19.

Objective: This study explored changes in communication behavior, information-seeking habits, and post-pandemic consultation preferences among psychosomatic patients during and after COVID-19.

Methods: In a cross-sectional study, 150 adult patients (>18 y) from the psychosomatic outpatient department in Tübingen, Germany, were invited to complete an ad hoc questionnaire to identify e-patients' preferences related to communication, information-seeking behavior, subjective explanations, and postpandemic preferences. Group comparisons and multiple linear regression analyses were conducted.

Results: The study revealed a slight increase in online-based communication between patients and caregivers (eg, caregivers' system use +10.8%; live video consultations +30.8%), as well as in patient–patient interactions (eg, online correspondence +16.9%). Significant group differences were observed for social media correspondence by patient age (χ^2¬=17.44, P<.001) and for live video consultations by gender (χ^2¬=70.17, P<.001). For both age and gender, significant group differences were found in the use of medical videos (age χ^2¬=6.36, P=.04; gender χ^2¬=76.70, P<.001). Age, gender, and preferences for live video consultations were identified as significant predictors ($F_{1,11}$=14.195, P<.001, R^2=0.299) of patients' future preferences for on-site versus online consultations.

Conclusions: Although a slight increase in online-based communication was observed, resilience in patient–caregiver and patient–patient communication indicated relative stability under challenging circumstances. Older adults and female patients expressed a preference for on-site consultations, emphasizing the significance of in-person care. Male patients demonstrated greater openness towards online consultations, indicating potential for expansion of eHealth services. Identifying preferences is a core essential for providing future eHealth implementations that account for diverse patient needs and for designing care offerings. Incorporating these findings may enhance patient engagement and satisfaction in the evolving landscape of eHealth services for better health care outcomes.

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KEYWORDS

COVID-19; pandemic; eHealth; e-patient; preferences; gender differences

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Introduction

eHealth refers to the delivery of health services and information via the internet or other electronic technologies [1]. During the COVID-19 pandemic, the role of eHealth in medicine achieved its highest level of importance while combating the deadly virus [2]. The accompanying social distancing norms further expedited digital developments in this field [3]. eHealth has presented promising evidence for its effectiveness [4,5], improving care quality, while reducing health care costs [6]. During the pandemic, eHealth services facilitated communication between caregivers and patients while maintaining distancing policies, thereby reducing hospital visits and direct contact [3,7,8]. During the COVID-19 pandemic, patient–caregiver communication was conducted via webcam-enabled computers, smartphones, and telephone conferencing [9,10]. This assisted caregivers in making patient-centered clinical decisions [11].

Reflecting the growing emphasis on patient involvement in decision-making, eHealth has enabled patients to use the internet as a source of empowerment. Consequently, patients are able to play a more active role in their own medical care, for example, by presenting information during consultations [12] and making informed decisions [13]. Patients who use the internet to inform themselves about health are termed “e-patients” [14,15]. In this study, e-patients refer to patients who actively use digital technologies to seek health information, which distinguishes them from broader digital health users who may passively use online health services without engaging in informed decision-making.

As nonmedical experts, e-patients often seek practical advice on social media [16,17]. The use of these platforms is influenced by patients’ awareness of health problems and their attempts to reduce the risk of illness [3]. Apart from social media, e-patients use general search engines (eg, Google), medical sites (eg, UpToDate, WebMD), and medical journals (eg, BMJ, Lancet) for information [18-20]. Moreover, health apps and wearables provide relevant health-related information (eg, tracking COVID-19 infection) that has been incorporated into medical treatments [21]. This shift has resulted in a more informed e-patient population than in previous decades, as is evident in patient–physician interactions [22].

The growing literature on patients’ experiences with eHealth during COVID-19 indicates high satisfaction rates, including such factors as dealing with concerns, communication, usefulness, reliability, time savings, access, and cost-efficiency [23]. In managed care, eHealth is pivotal in promoting patient-focused care. However, challenges remain [24], particularly the technical demands of using eHealth [25]. To ensure that patient involvement remains a core element in the future implementation of eHealth after the COVID-19 pandemic [26], further investigation into patients’ preferences and behaviors is required.

Thus, this study aims to examine patient adoption of eHealth, changes in patients’ behavior, and patients’ explanations for those changes during and after the COVID-19 pandemic. Specifically, it focuses on the dimensions of preferences and experiences in communication, information acquisition and the use of health apps and wearables in a German psychosomatic outpatient clinic.

Methods

Study Design

This cross-sectional study was conducted from October 1, 2020, to March 31, 2021, at the Outpatient Department of Psychosomatic Medicine and Psychotherapy in Tübingen, Germany. A total of 175 patients aged 18 years and older were invited to voluntary participate and were asked to complete a specially-designed questionnaire. It took approximately 15 to 20 minutes for patients to complete the written questionnaire.

Patients were seen by a medical doctor or psychologist in the outpatient department for diagnostic consultations, including clinical interviews and psychometric assessments. Admission to the outpatient service was voluntary, and most patients had been referred by general practitioners, psychiatrists, or psychologists because of mental health complaints. Participation in the study was entirely voluntary. Patients with insufficient German language proficiency or severe psychiatric disorders were excluded, and no responses were excluded during data analysis.

Ethical Considerations

This study was conducted in accordance with the ethical standards of the Declaration of Helsinki [27], and was approved by the Ethics Committee of Tübingen Medical Faculty (no. 243/2022BO2). Patients provided written, informed consent prior to participation, after being informed about the study’s aim, the voluntary nature of participation, their right to withdraw without consequences, and the measures taken to ensure data security. For analysis, data were anonymized to ensure that patients could not be identified. The authors did not have access to information that could identify individual participants during or after data collection. No incentives were provided. No images of individual participants or users are included in the manuscript or supplementary material.

Assessment Instruments

Drawing from the literature on current e-patient activities and changes in physician–patient interactions during the COVID-19 pandemic [28,29], an ad hoc questionnaire was created to examine e-patients’ activities and the impact that COVID-19 had on them. The think-aloud technique was used in the development of the ad hoc questionnaire items, as no validated questionnaire on e-patients’ activities existed [30]. The questionnaire assessed four main domains: (1) changes in communication compared to 2019, (2) changes in patients’ use of eHealth compared to 2019, (3) patients’ interpretations of changes attributable to COVID-19, and (4) patients’ preferences post-COVID-19 pandemic. Items regarding communication and changes in patients’ use of eHealth explored whether patients’ health-related electronic activity had changed (eg, decreased, increased, no change) since December 2019 in terms of communication with caregivers or other patients, specifying the medium used (eg, video calls, emails, medical websites, wearable devices, apps) or the method of information acquisition (eg, medical books, videos, medical journals, networking).

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Changes were quantified on a 3-point Likert scale (1='not at all', 2='somewhat', 3='very') to evaluate subjective explanations linked to COVID-19. Patients' preferences for future interactions (face-to-face vs eHealth) were assessed using their reaction to the following statement: "After things return to normal, I would like to interact with my doctors in the following way: only face-to-face; mostly face-to-face; face-to-face and online equally; mostly online; or only online."

Statistical Analysis

Statistical analyses were run using SPSS software (version 28; IBM Corp) [31]. Sociodemographic data and responses to the ad hoc questionnaire were evaluated descriptively. Respondents were categorized into two age groups based on the mean age (<37 y and ≥37 y). Group differences were determined using χ^2 tests. The statistically significance was set at $P<.05$. A multiple linear regression analysis was performed with the consultation format preference (on-site vs online) as the dependent variable, assessed on a 5-point ordinal scale (only face-to-face, mostly face-to-face, face-to-face and online equally, mostly online, and only online). For analysis, this variable was treated as continuous to approximate the linear trend across levels, enabling the use of multiple linear regression. This approach was chosen because the preference scale reflects a spectrum of consultation preferences rather than discrete categories. The potential predictors incorporated in the model included age, gender, communication preferences, and modes of medication and information acquisition. These predictors were selected based on their theoretical relevance from prior studies [25,32]. Multicollinearity was assessed using variance inflation factors (VIF), and no issues were identified (all VIF <2). Model fit was evaluated using R^2 and the Durbin–Watson statistic to prove autocorrelation in residuals.

Results

Sociodemographic Data

A total of 150 patients participated in the study, yielding a response rate of 85.7%. The mean age of the participants was 37.06 (SD 12.4) years, with the majority being female (n=88, 58.7%; unspecified n=41, 27.3%). Most patients (92/125, 73.6%) reported undergoing an in-person examination in the department, while 33/150 patients (22.0%) reported an online consultation. In-person examinations were cited as the preferred consultation type by 70.9% of patients (61/86), with no significant differences observed regarding age or gender.

Changes in Patients' Communication in Relation to the Timeframe of 2019

The results indicate an increase in online-based communication methods since 2019, including both written communication (eg, email, social media) and direct consultations (eg, via electronic systems, video calls). However, there was a noted decrease in live video consultations among 51/133 patients (38.3%). Patient-to-patient communication did not show significant changes. Significant group differences were observed for social media correspondence by age ($\chi^2=17.44$, $P<.001$). Regarding gender, significant group differences were found for live video consultations ($\chi^2=70.17$, $P<.001$) (see Table 1).

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Table . Changes in communication behaviors among patients with mental health complaints attending the outpatient department of psychosomatic medicine and psychotherapy at Tübingen University Hospital, Germany (cross-sectional study, October 2020 to March 2021), compared with the prepandemic year 2019.

Communication partner, eHealth type, and changes in use	Total responses, n (%)
Correspondence with physicians	
Changes in email correspondence (n=90)	
Indifferent	51 (56.7)
Increase	37 (41.1)
Decrease	2 (2.2)
Social media correspondence (n=83)	
Indifferent	71 (85.5)
Increase	5 (6.0)
Decrease	7 (8.4)
Patient–physician communication	
Caregivers' system (n=102)	
Indifferent	67 (65.7)
Increase	11 (10.8)
Decrease	24 (23.5)
Live video consultation (n=133)	
Indifferent	41 (30.8)
Increase	41 (30.8)
Decrease	51 (38.3)
Patient–patient correspondence	
Internet use (n=83)	
Indifferent	60 (72.3)
Increase	14 (16.9)
Decrease	9 (10.8)

Changes in Patients' E-Health Use in Relation to the Timeframe of 2019

Aligned with the results on communication, an increase was observed for wearables and eHealth apps. However, no significant changes were observed regarding the purchase of medication and obtaining medical information via the internet. However, when closely examining the increase in obtaining online medical information, the greatest growth is observed for online medical books and videos compared to the others.

Significant group differences were detected concerning online purchase of medication (χ^2=6.94, P=.03), medical books (χ^2=9.43, P=.009), medical videos (χ^2=6.36, P=.04), medical journals (χ^2=9.53, P<.05), and wearables (χ^2=8.92, P<.05), in regard to the patient's age. Regarding gender, significant group differences were found for medical videos (χ^2=76.70, P<.001), medical websites (χ^2=43.67, P<.001) (see Table 2).

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Table . Changes in behavior regarding e-health activities by patients with mental health complaints attending the outpatient Department of Psychosomatic Medicine and Psychotherapy at Tübingen University Hospital, Germany (October 2020 to March 2021), compared to the pre-pandemic year 2019).

Category, specification, and changes in use	Total , n (%)
Medication	
Online purchase (n=87)	
Indifferent	54 (62.1)
Increase	30 (20)
Decrease	3 (3.4)
Obtaining medical information	
Medical books (n=87)	
Indifferent	62 (71.3)
Increase	20 (23.0)
Decrease	5 (5.7)
Medical videos (n=132)	
Indifferent	58 (43.9)
Increase	27 (18.0)
Decrease	47 (35.6)
Medical websites (n=107)	
Indifferent	61 (57.0)
Increase	22 (20.6)
Decrease	24 (22.4)
Medical journals (n=87)	
Indifferent	71 (81.6)
Increase	7 (8.0)
Decrease	9 (6.0)
Networking sites (n=88)	
Indifferent	65 (73.9)
Increase	13 (14.8)
Decrease	10 (11.4)
eHealth technology	
Wearables (n=133)	
Indifferent	100 (75.2)
Increase	21 (15.8)
Decrease	12 (9.0)
Health applications (n=104)	
Indifferent	53 (51.0)
Increase	46 (44.2)
Decrease	5 (3.3)

Changes Due to COVID-19

Patients' communication was moderately affected by the COVID-19 pandemic, with a mean score of 1.69 (SD 0.53). A similar impact was observed in their search for online information (mean 1.24, SD 0.47). However, a more significant change due to the pandemic was observed in two aspects: the online acquisition of medication (mean 1.70, SD 0.68) and the use of eHealth technology (mean 2.23, SD 0.45). For a detailed analysis of the changes caused by COVID-19, see Figure 1.

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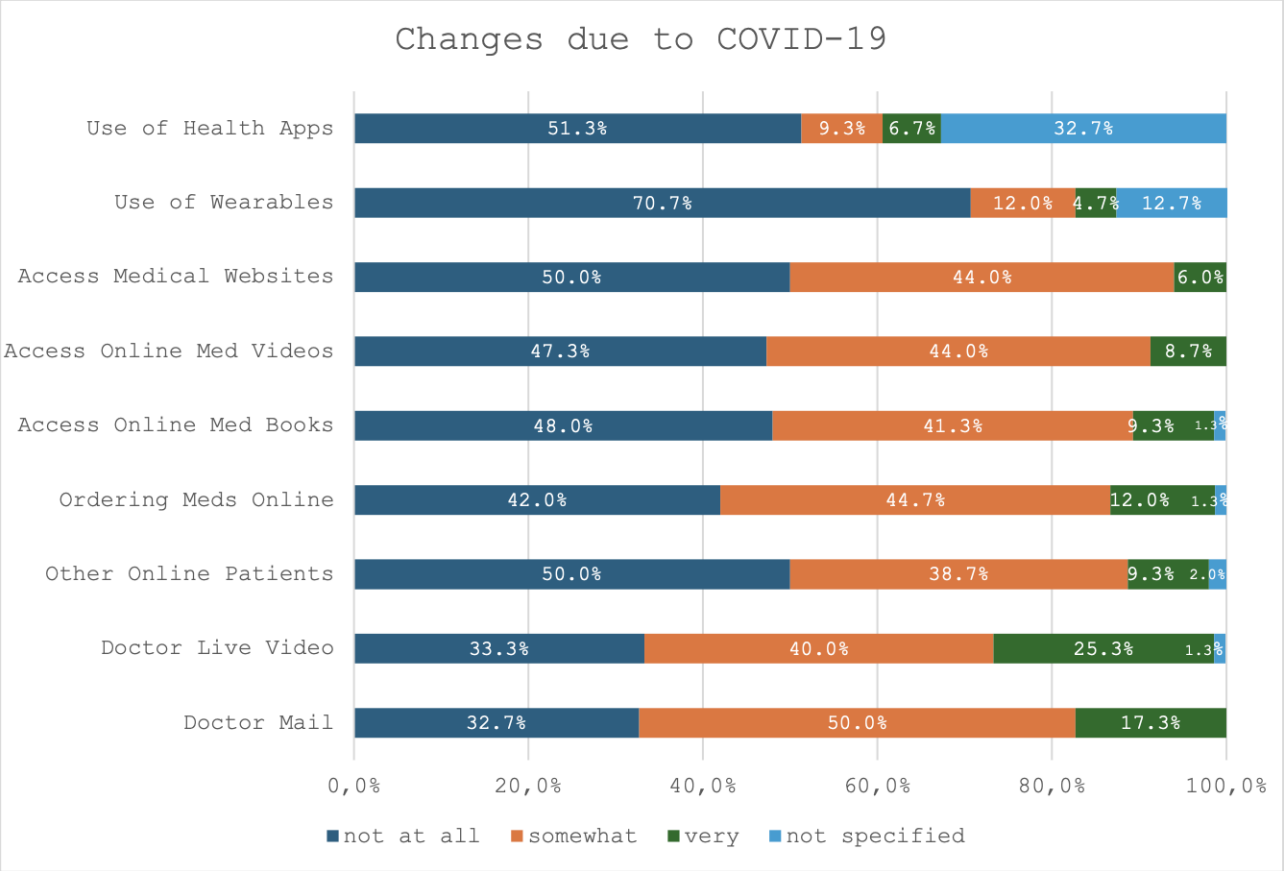
Figure 1. Changes in patient communication, information acquisition, online purchase of medication, and wearables and eHealth apps among patients attending the outpatient department of psychosomatic medicine and psychotherapy at Tübingen University Hospital, Germany (cross-sectional study, October 2020 to March 2021) caused by the COVID-19 pandemic.



Explanation of Changes Due to COVID-19

In terms of patient communication, changes in email correspondence were attributed to COVID-19 by 16/90 patients. Social media correspondence was reported to have changed due to COVID-19 by 3/83 patients. A total of 8/102 indicated that the caregivers' system had changed, while 27/102 patients reported alterations in live video consultations.

With respect to eHealth use, the online purchase of medication was identified as having changed due to COVID-19 by 7/87 patients. A total of 5/87 patients reported informing themselves more via medical books. Changes in the use of medical videos were reported by 4/132 patients , while 3/107 patients reported changes in the use of medical websites. A total of 3/87 patients indicated changes in the use of medical journals. Lastly, the use of wearable technology was reported to have subjectively increased due to COVID-19 by 5/130 patients.

Patients' Post-COVID-19 Pandemic Preferences

After most restrictions due to COVID-19 were lifted, most patients (n=120/147, 81.7%) stated a preference for seeing a medical caregiver on-site. Correspondingly, patients preferred patient–patient interactions to be on-site (n=88/145, 60.7%). Approximately, one-third of patients (n=48/145, 32.0%) were open to ordering medication both on-site and online, although most patients (n=81/145, 55.1%) chose the on-site option. Finally, when obtaining medical information, patients regarded on-site and online channels as equal (n=66/146, 45.2%).

Predictors of Preference for on-Site vs Online Consultations

The results of the multiple linear regression analysis revealed a statistically significant model ($F_{1,11}$=14.195, P<.001) that explained patients' future preferences regarding on-site versus online consultations. Significant predictors included age (B=−0.011, SE=0.005, t=−2.29; P=.02), gender (B=0.491, SE=0.113, t=4.35; P<.001), and changes in live video consultation use during COVID-19 (B=0.270, SE=0.084, t=3.20; P=.002). This finding suggests that patients of older age are more inclined towards on-site consultations. Furthermore, the data indicates that males prefer online consultations, while female patients show a tendency towards on-site consultations. An increase in the preference for live video consultations due to COVID-19 was positively correlated with a willingness to engage in online consultations. However, online communication via email (P=.95), online searches for medical information (books (P=.70) or videos (P=.12)) and online medication purchases (P=.11) were not found to be statistically significant predictors (see Table 3).

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Table . Multiple linear regression analysis identifying predictors of patients' preferences for on-site versus online consultations in a cross-sectional study of patients with mental health complaints at the outpatient department of psychosomatic medicine and psychotherapy, Tübingen University Hospital, Germany (October 2020–March 2021).

Variables	R^2 [a]	SE[b]	B[c]	t test[d]	95% CI	*P* value
Constant	1781	0.344	—	5181	1101 to 2461	<,001[e]
Age	−.011	0.005	−0.169	−2289	−0.020 to −0.001	.02
Gender	0.491	0.113	0.389	4347	0.268 to 0.715	<.001[e]
Online purchase of medication	−0.159	0.099	−0.136	−1599	–0.356 to –0.038	.11
Correspondence via mail	−0.006	0.094	−,006	−0.069	–0.192 to 0.179	.95
Live-video consultations	0.270	0.084	0.262	3204	0.104 to 0.437	.002[f]
Information via medical books	0.059	0.151	0.048	0.391	−0.240 to 0.358	.67
Information via medical videos	−0.245	0.156	−0.196	−1573	–0.553 to 0.063	.12

[a]R^2: coefficient of determination.

[b]SE: standard error.

[c]B: unstandardized regression coefficient.

[d]T: t statistic.

[e]*P*<.001.

[f]*P*<.05.

The model demonstrates a sufficient fit with an R^2 of 0.299, indicating that 29.9% of the variation can be explained by the independent variables. The Durbin–Watson test statistic 1.354, suggests no evidence of autocorrelation in the residuals. Additionally, the collinearity diagnostics did not indicate any multicollinearity.

Discussion

This study explored alterations in eHealth patients' behavior and their inclinations towards eHealth throughout and following the COVID-19 pandemic. This investigation demonstrated slight variations in how patients and caregivers communicated, as well as the interactions between patients themselves. Two notable shifts due to the pandemic were evident: an increase in online obtaining of medication and an increasing deployment of eHealth technology. This study determined that age and gender were key factors influencing patients' future decisions for in-person or virtual consultations. Older adults and female patients leaned towards on-site consultations, while male patients preferred online consultations. Furthermore, a preference for live video consultations predicted patients' openness towards online consultations.

eHealth reduces disease transmission and is especially suitable for self-isolating or high-risk patients [33]. Its growth, accelerated not only by the COVID-19 pandemic, presents several advantages, such as protection, time-saving, and cost reduction, yet it also carries disadvantages, such as difficulties in building a stable relationship between caregivers and patients, assessment challenges, technological issues, and data protection concerns [34,35].

This study's findings underlined, on the one hand, a significant increase in using online-based communication but also showed no remarkable changes in its overall utilization. This resilience of communication indicated that patients made only minimal changes to their communication behavior even though social distancing was strongly regulated by the German government. This is in line with international discrete choice experiments indicating a top preference for in-person consultations for most clinical scenarios [36,37]. To sustain the eHealth revolution in health care delivery [38], an in-depth understanding of communication, currently lacking, is necessary.

The research identified crucial points for a successful implementation of eHealth. First, a clear differentiation in e-health applications is needed, as some authors suggest (eg, specific diseases, specialties, technologies, clinical problems [39]). Second, comprehensive investigations must be conducted to provide evidence (eg, chronic pain [40], oncology [41], palliative care [42]). Third, eHealth communication necessitates best practices (eg, use of plain language, reducing information overload, application of teach-back [43]), ideally provided by national or international organizations such as the World Health Organization [44].

While adhering to best communication practices, patients' information level must be respected. Reasons for information-seeking vary widely, from discussing specific diseases to social and emotional support through peer-to-peer interactions [45]. The increasing health-related internet use by patients results in both positive and negative effects on the caregiver–patient relationship [46]. Positive effects were observed when patients openly discussed their findings with caregivers, thereby enabling active participation in

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decision-making, which alters traditional consultation models [47].

A primary objective of eHealth may also be a central aspect in guiding patients within the framework of managed care programs [48]. Conversely, misleading health information may have a serious impact on an individual's health or mental state [49], such as the phenomenon of cyberchondria [50], which involves excessive fear of symptoms resulting from reviewing of search results and references on the Web, higher medical costs [51], and overall lower quality of life due to poor health care management [52]. This study's analysis showed only a slight increase in online-based information-seeking; however, during the pandemic, most studies found an increased desire to understand the virus's risk situation and to cope with uncertainty [53].

Wearables and eHealth apps played a vital role in detecting the spread of the coronavirus [54], and their usage for monitoring physical activity has risen [55]. This aligns with an increase in the use of wearables and e-health apps in this sample. Wearables and health-related apps are promising tools for managing long COVID [56] and, in general, for empowering patients to take responsibility for their health and care [57,58]. In research, wearables have become essential for data collection in population-based research, experimental outcome assessment, prognostic forecasting, and explorative analysis of big data sets [59].

In addition to the rise of wearables, online medication procurement also increased, in line with recent research [60]. However, a large number of online pharmacies have failed to comply with regulations [61], leading to deaths [62] and emphasizing the need for greater awareness and stricter government laws [63].

Despite substantial literature demonstrating high satisfaction with eHealth across all ages and genders [23,64], this investigation revealed a clear preference for on-site consultations, in line with recent findings [32]. This may be specific to the psychosomatic sector, where comprehensive examinations of both psyche and body are part of daily practice. To elaborate on these findings, regression analysis provided more insights: older adults and female patients expressed a preference for on-site consultations, highlighting the importance of personalized, in-person care. This aligns with findings from large and international surveys that especially older people prefer in-person consultations [65] and also supports the argument that e-health may not completely replace face-to-face consultations [38]. Conversely, male patients demonstrated greater openness towards online consultations. Recent studies have found a correlation between male sex and satisfaction with treatment plan or follow-up via eHealth [66], controversially also female sex was associated with higher satisfaction of eHealth services [67]. Further influencing factors, such as positive promotion of e-health by caregivers [68], as well as personality structure or cultural background, need to be further explored.

Limitations of this study include its cross-sectional design, which captures a retrospective snapshot of patient behavior without enabling the tracking of changes over time. Moreover, while the ad hoc questionnaire addressed context-specific topics, it was not formally validated, which restricts the reliability and generalizability of its measures. Although the think-aloud method was used during development to improve clarity and content relevance, no psychometric evaluation was conducted prior to its use. This limitation may limit the generalizability and interpretability of the findings. However, evidence suggests that data from ad hoc clinician-generated patient questionnaires can be aggregated into valid factors [69] which indicates ad hoc questionnaires may still provide meaningful insights into patient behaviors and preferences.

Potential selection bias due to the voluntary participation of patients may also be a limitation. An additional limitation is missing data regarding the participants' gender, which may have introduced bias or reduced the validity of gender-related analyses. While the regression model still identified significant associations with gender, the missing data may have affected the robustness of these results. Patients in psychosomatic medicine suffer from psychological disorders, which may have influenced their preferences and behavior. Nevertheless, recent studies have shown that eHealth services are an effective and appropriate therapeutic tool [70] to reduce mental complaints [71] and stress symptoms [72].

In conclusion, the study indicates that recognition and accommodation of diverse preferences is critical in designing and implementing future eHealth services, which might be central in managed care programs. Although this investigation focused on the pandemic context, eHealth services can be expected to remain an integral component of health care delivery [73]. By integrating these findings, especially accommodating the age and gender of patients, a potential rise in patient engagement can be anticipated within the transforming eHealth environment. These results highlight the need for a tailored approach to diverse patient requirements to improve health care outcomes as eHealth services continue to progress and evolve.

Data Availability

The datasets generated or analyzed during this study are available from the corresponding author on reasonable request.

Conflicts of Interest

None declared.

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Abbreviations

VIF: variance inflation factors

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Support Community Formation on a Mobile App for People Living With HIV and Substance Use Disorder: A Computer-Mediated Discourse Analysis

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Abstract

Background: People living with HIV and substance use disorders (SUDs) have complex health care needs requiring adaptive and effective support systems. While mobile health apps can foster virtual communities grounded in shared lived experiences, little is known about the dynamics within these digital spaces.

Objective: We examined the formation of a virtual community on the Addiction Comprehensive Health Enhancement Support System (A-CHESS; The Center for Health Enhancement Systems Studies, University of Wisconsin-Madison College of Engineering) message board, a mobile app designed to support HIV care engagement among individuals living with HIV and SUD.

Methods: We conducted a computer-mediated discourse analysis of A-CHESS message board posts to examine communication patterns, interaction structures, and engagement dynamics. Quantitative comparisons were used to assess differences between posters and nonposters using *t* tests and chi-square tests. We then applied qualitative coding to categorize messages by type, speaker, and function to understand how staff and participants coconstructed a supportive virtual environment.

Results: Among 208 participants, 87 (42%) posted at least once on the A-CHESS message board, contributing 1834 messages between April 2019 and May 2021. Posters and nonposters did not differ significantly in age (t_{206}=–0.64; *P*=.52), gender (χ^2_1=0.14; *P*=.71), or race (χ^2_1=0.52; *P*=.47). We identified 3 message types: premeditated, adlib, and participant-driven. Staff initially led with premeditated messages (eg, recovery stories, HIV risk information, and "Thought of the Day" inspiration), which participants often interpreted and adapted to their own SUD recovery. Over time, staff incorporated adlib messaging styles using personalized narratives and polls to sustain engagement. Participants then developed their own posts using similar formats, incorporating Alcoholics Anonymous literature, sharing legal and personal challenges, and suggesting new app features (eg, medication check-ins to support adherence).

Conclusions: A-CHESS staff adapted communication styles to increase engagement, while participants appropriated the app's message board to reflect personal goals and lived experiences. Mobile health interventions may benefit from design elements that support participant-led discourse and customization, fostering ownership, support, and relevance within virtual care communities.

Trial Registration: ClinicalTrials.gov NCT03873129; https://clinicaltrials.gov/study/NCT03873129

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KEYWORDS

HIV; mobile app; social support; computer-mediated; discourse analysis; virtual community; people living with HIV; substance use disorders; SUD; online support; online communities; mHealth; mobile health; HIV care; opioid use disorder; qualitative analysis; OUD

Introduction

The HIV infection is highly prevalent among people who use drugs and alcohol. Among an estimated 8.9 to 22.4 million people who inject drugs globally, approximately 0.9 to 4.8 million are HIV positive [1]. Additionally, alcohol dependence is found in 40% to 50% of individuals living with HIV, and rates of cannabis and stimulant use are also higher among people

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living with HIV compared to the general population [2,3]. Individuals with comorbid HIV and substance use disorder (SUD) also experience a lower quality of life, with higher rates of comorbidities, psychological distress, and social stigma than those living with HIV alone [4-6]. With the widespread availability of mobile phones, individuals living with SUD and HIV can access social support through mobile health apps [7]. Message boards within these mobile health interventions are recognized as critical sources of social support for people living with HIV, facilitating communication and support among community members [8].

Despite recognizing message boards' importance and widespread usage, only a few studies have explored the dynamics within these boards to optimize participant engagement and enhance social support. Previous studies have mainly focused on the feasibility [9], frequency [10], and types of messages posted on the message boards [11,12] and the characteristics of individuals posting [13,14]. Further examination is needed to explore how a supportive community is formed within these apps, especially for the key population of individuals with comorbid HIV and SUD.

To address the research gap, our study used discourse analysis to examine the formation of virtual communities that offer social support for people living with HIV and SUD. Discourse analysis explores natural talk and texts, revealing how language patterns and practices shape society and individuals [15]. Previous studies have used discourse analysis in HIV research to explore communication on HIV informative posters regarding treatment adherence and the prevention of stigmatization [16]. Discourse analysis has also been used to understand the behaviors of men who use drugs concerning viral load and reliance on antiretroviral therapy during sexual encounters [17]. However, discourse analysis has not yet been applied to explore virtual support communities of individuals living with HIV and SUD in the context of social communities.

Our study used computer-mediated discourse analysis [18] to explore the community message board feature of the Addiction Comprehensive Health Enhancement Support System (A-CHESS; The Center for Health Enhancement Systems Studies, University of Wisconsin-Madison College of Engineering), a mobile health app designed to provide social support and improve engagement in HIV care for individuals living with HIV and SUD [19].

Methods

A-CHESS App Overview

A-CHESS is a modified version of the evidence-based CHESS, which has proven efficacy in preventing relapse among individuals with alcohol use disorder [20]. A-CHESS was adapted for use among people living with SUD and HIV by expanding additional features aimed at promoting medication adherence, facilitating regular treatment evaluations, providing access to a community message board, offering case management services, and conducting weekly surveys to monitor recovery progress and evaluating protective and risk factors in the social environment [19]. The A-CHESS app was based on Self-Determination Theory, emphasizing competence, autonomy, and social relatedness to motivate participants to engage in healthy behaviors [21].

Setting and Participant Recruitment

Participants were recruited through the distribution of recruitment flyers at HIV clinics and collaboration with case managers and physicians for referrals. Inclusion criteria required participants to be 18 or older, have a documented HIV infection, be able to speak and write in English, and have a history of SUD. SUD was determined based on positive screening results, current engagement in substance use treatment, a lifetime history of problematic drug or alcohol use, or recent substance use–related incarceration. Enrollment occurred on a rolling basis from January 2019 to April 2019.

Eligible participants were instructed to download the A-CHESS app onto their smartphones. Case managers provided tutorials to guide participants through the process of using the app, including creating a deidentified username to protect their offline identities and ensure anonymity. Participants were then familiarized with the app's various features, receiving step-by-step instructions on navigating and using its functionalities.

Data Source

The primary data source for our study was the A-CHESS message board, a public forum within the A-CHESS app where participants could engage with case managers, research staff, and peers. Our analysis included all messages posted by the participants and messages from the research staff and case managers, recognizing their membership in the virtual community and their contributions to community formation [22]. Participants were provided with guidelines on appropriate message board use and respectful dialogue. Participants were instructed not to share personally identifying information on the message board, and informed that their posts were immediately visible to other users. The study team monitored the message board content, and personal contact through phone or text was available. In addition to the message board data, we collected baseline survey information to describe participants' demographics, history of HIV, history of SUD, and substance use patterns.

Data Sampling

To conduct a longitudinal examination of virtual community formation, we analyzed all the messages posted on the message board throughout the 26-month study period. Research staff extracted the information from the message board, including the posted messages, usernames, and time of posting for the analysis. Each message board posting or comment was placed into separate cells within an Excel (Microsoft) workbook. The unit of analysis was an individual message posted. When examining data in a virtual community, various approaches can be used, such as random selection of messages, analyzing messages by theme (eg, all messages in a particular thread), focusing on specific time frames (eg, messages from a particular week), studying specific phenomena (eg, messages related to jokes or conflict negotiation), or analyzing messages by group (eg, messages posted by women or individuals who identified

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a particular substance as their drug of choice) [18,23]. Our sampling strategy combined sampling based on time and theme. Initially, we organized all the messages posted on the message board based on their respective time stamps, arranging them chronologically from the first to the last post on the message board. We refined our data management approach by reorganizing the messages based on the threads they belonged to, considering the corresponding time. For example, if a thread had an initiation message posted in May 2019 and a response message posted in December 2019, we analyzed the May and December messages together as they formed part of the same thread.

Data Analysis

For the demographic data, we conducted independent samples *t* tests and chi-square tests to examine differences between posters (participants who posted at least once on the A-CHESS message board) and nonposters. Age was summarized using means and SDs; categorical variables were summarized using counts and percentages. A significance level of $P<.05$ was used.

The authors used a computer-mediated discourse analysis (CMDA) approach to understand how a virtual community is being formed on the A-CHESS message board [23]. CMDA analyzes language use in online communication, including social media, chat rooms, and email by examining the linguistic features, communication strategies, and interaction patterns of the communication. CMDA additionally examines social dynamics in online communication and how their structure reveals social behaviors. According to Herring [18,23,24], virtual communities are formed when individuals use computer-mediated platforms, such as A-CHESS, by establishing structure, deriving meaning in their communication, interacting, and engaging in social behaviors within these virtual communities.

Quantitative Analysis: Structure and Interaction of A-CHESS Virtual Community Formation

To explore the structure and interaction patterns of the virtual community, we conducted a quantitative analysis of user interactions on the A-CHESS message board. This involved quantifying message types, examining discourse structure, and describing the participants' demographics in virtual community formation. Through this analysis, we identified patterns in language use, key participants, reciprocity of engagement, and the occurrence of extended conversations. Descriptive statistics were performed using SPSS (v28; IBM Corp) to describe the study participants' characteristics.

Qualitative Analysis: Meaning, Social Behaviors, and Engagement Patterns of the Discourses in the Message Board

The qualitative analysis explored how participants constructed meaning in their interactions and the language used to indicate their social behavior. This included examining participants' responses to messages, the types of messaging they initiated, and the level of participation exhibited by community members. By focusing on these aspects, we gained valuable insights into the evolving nature of the app discourse. We explored the range of topics discussed and how participants engaged with, responded to, and shaped the overall patterns of interaction.

Coding Process and Framework

The coding framework used in this study was developed by the researchers (AT and KP) to capture the various aspects of the messages, including their structure, meaning, interaction, and social behaviors. AT, who has received training in qualitative research methods, thoroughly reviewed the messages over 2 months. Following an inductive approach, the researchers examined the patterns of interaction on the message board. Initially, a quarter of the data were coded sequentially, with extensive discussions held for each message to reach a consensus on the assigned codes. These codes were then applied to the remaining data. Each message was assigned one or more codes to capture specific actions and behaviors. The researchers categorized these behaviors based on the structure of the messages, identifying common themes and patterns. Additionally, the messages were grouped according to the key participants involved, focusing on understanding the actors within the interactions.

To ensure rigor and trustworthiness, we drew on Lincoln and Guba criteria of credibility, transferability, dependability, and confirmability [25]. Credibility was enhanced through prolonged engagement with the data, iterative coding discussions between 2 trained researchers, and the lead analyst's (AT) sustained involvement in the HIV community. AT and KP developed codes inductively, refining them through joint review and consensus. Transferability was supported by providing rich contextual detail on the A-CHESS platform, participant characteristics, and the broader setting of HIV and substance use recovery, along with representative excerpts in the results. Dependability was addressed through consistent documentation of coding decisions, a staged and collaborative coding process, and an audit trail of coded data. Confirmability was strengthened through analytic transparency, discussion of researcher positionality, and linking interpretations to both direct participant excerpts and the guiding discourse analytic framework. To further promote transparency, the manuscript follows the Standards for Reporting Qualitative Research (SRQR) [26]; the completed checklist is provided in Checklist 1.

Reflexivity Statement

Qualitative researchers AT and KP bring complementary clinical and methodological expertise to this analysis. AT is a pharmacist with PhD training in health services research, and KP is a nurse and PhD-trained Associate Professor of Nursing who teaches advanced qualitative research methods. Both researchers have cared for people living with HIV in their clinical roles. AT has also developed relationships with members of the HIV community outside research through volunteer participation in community-based social events. Additionally, AT is trained under the team that developed A-CHESS and has been involved in the app's redesign, which informs a deep familiarity with the platform's context and use.

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Ethical Considerations

This study received ethical approval from the University of Wisconsin–Madison Institutional Review Board (2016-1190). All participants provided informed consent at enrollment, including agreement for the use of their deidentified app data for research purposes. To protect privacy and confidentiality, participants used pseudonymous usernames on the A-CHESS message board, and all data were deidentified prior to analysis. No identifiable personal health information was included in the dataset. Participants were compensated for completing weekly surveys and milestone activities within the app, while they were not compensated for posting on the message board.

Results

Overview

Between March 13, 2019, and April 30, 2021, a total of 2071 messages were shared on the A-CHESS message board by research staff (including case managers) and study participants. Blank and duplicate posts were excluded from the analysis, resulting in 1834 posts being included in the discourse analysis. All 208 study participants were provided access to the A-CHESS message board and information on how to post to the message board. Approximately 42% (87 individuals) of all study participants posted on the message board at least once. The distribution of age, race, sex, employment, and education was similar for A-CHESS study participants who actively engaged with the message board (n=88), and those who did not post at all on the message board (n=120) are shown in Table 1.

Table . Demographic characteristics of participants who posted on the message board vs. nonusers.[a]

Variable	Message board users (n=88)	Message board nonusers (n=120)
Mean (SD), age (years)	45.88 (11.5)	46.69 (11.0)
Sex, n (%)		
Male	65 (74.7)	91 (75.8)
Female	22 (25.3)	26 (21.7)
Other	1 (1.1)	—[b]
Race, n (%)		
Black	57 (64.8)	80 (66.7)
Education, n (%)		
Four-year college	31 (35.2)	45 (37.5)
Employment, n (%)		
Yes	54 (62.1)	85 (70.8)
No	34 (39.0)	35 (29.2)

[a]Values are presented as mean (SD) for continuous variables and number (percentage) for categorical variables. Percentages may not total 100% due to rounding. Only selected categories are shown.

[b]Not available.

Posters and nonposters did not differ significantly in age, t_{206}=–0.64, P=.52; gender, χ^2_1=0.14, P=.71 (n=210); or race, χ^2_1=0.52, P=.47 (n=197).

Out of the 1834 messages posted on the message board, the majority (n=1,283, 70%) were contributed by study participants, while the remaining 30% (n=550) were posted by research staff members, including 2 case managers. A small subset of participants played a significant role in contributing to the engagement on the message board. Specifically, 5 participants were responsible for 40% (n=733) of all the posts, with one alone accounting for 12% (n=220) of the messages. A significant portion (n=62, 70%) of the participants posted between 1 to 10 messages. Less than 22% (n=403)of the posts were single posts without further engagement.

Meaning, Social Behaviors, and Engagement Patterns of the Discourses in the Message Board

The discourse analysis on the app usage identified 3 coexisting message structures: premeditated and adlib messaging (both driven by case managers and research staff) and participant-driven messaging. Initially, research staff and case managers implemented a planned and structured approach to communication by posting premeditated messaging, using predetermined topics, scheduled posts, and automated motivational messages within the app. Adlib messaging emerged approximately 1 month into the study, with research staff leading the communication. Compared to the premeditated messaging, the staff began incentivizing participant engagement and shared personalized stories to encourage active participation. In the participant-driven phase of messaging, participants actively shaped the app's interaction patterns, taking ownership and initiating discussions, fostering autonomy and creativity within the community by sharing unique messages alongside and

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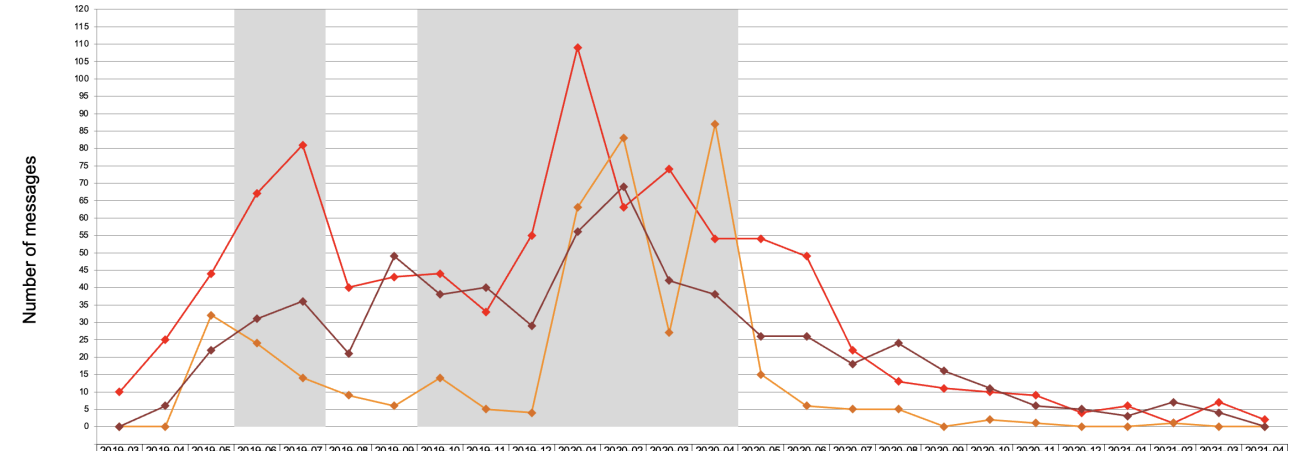
inspired by the premeditated messages of the research staff. Although the premeditated phase occurred at the start of the app use and dominated through the 14 months of app usage, the messaging had transitions between phases, with elements of each phase coexisting or overlapping with others (Figure 1). Figure 1 shows the monthly message types on the A-CHESS app message board among people living with HIV and SUDs from 2019 to 2021.

Figure 1. Distribution of messaging type on the Addiction Comprehensive Health Enhancement Support System message board. A-CHESS: Addiction Comprehensive Health Enhancement Support System.



	2019-03	2019-04	2019-05	2019-06	2019-07	2019-08	2019-09	2019-10	2019-11	2019-12	2020-01	2020-02	2020-03	2020-04	2020-05	2020-06	2020-07	2020-08	2020-09	2020-10	2020-11	2020-12	2021-01	2021-02	2021-03	2021-04
Premeditated	10	25	44	67	81	40	43	44	33	55	109	63	74	54	54	49	22	13	11	10	9	4	6	1	7	2
Participant-driven	0	0	32	24	14	9	6	14	5	4	63	83	27	87	15	6	5	5	0	2	1	0	0	1	0	0
Adlib	0	6	22	31	36	21	49	38	40	29	56	69	42	38	26	26	18	24	16	11	6	5	3	7	4	0

Premeditated Messaging

The research staff followed a structured approach by planning and scheduling their posts in advance. They created a weekly schedule to outline the topics they intended to cover on the app, encompassing various subjects such as raising awareness about current issues, providing news resources, and sharing health-related information.

Premeditated Messaging: Thought of the Day

The A-CHESS app includes automated "Thought of the Day" (TOTD) posts shared with participants daily at 4:00 PM, featuring short motivational quotes attributed to their authors. One participant started responding to these TOTD messages in the first month of the study by stating their agreement with the TOTD message. A month later, other participants started to engage in the same behavior and provided interpretations of the TOTD.

Aligning With TOTD

When participants responded to the TOTD posts, some showed alignment with the posts by expressing an agreement or endorsement using words such as "yes" or "I agree." In the example below, JAXSTORM responded to the TOTD post by simply agreeing that the TOTD is true. The response from JAXSTORM demonstrates a brief affirmation of the TOTD without further elaboration or explanation (Textbox 1).

Textbox 1. Example of participant alignment with a "Thought of the Day" post through brief affirmation.

A-CHESS App| April 17, 2020, 04:00 PM

Thought of the Day–"The sleeper gets nothing but the dream."

JAXSTORM | April 17, 2020, 06:19 PM

Yes that is true.

The TOTD uses the metaphor of sleep and dreams to represent a state of inaction or passivity in pursuing one's goals. JAXSTORM uses the word "true" to not only agree but signal that the message holds truth. Similar alignments to TOTD show participants agreeing with the messages, usually using "yes" and rarely questioning, disagreeing, or offering further detail to align with the TOTD posts.

Interpreting TOTD

Participants interpret the TOTD messages by sharing a personalized interpretation of what they mean and what the message tries to communicate to them or others (Textbox 2).

Textbox 2. Example of a participant's personalized interpretation of a "Thought of the Day" message.

A-CHESS App| May 05, 2020, 04:00 PM

Thought of the Day–Today I have the courage to look without fear at what needs to be changed in my life.

AsherTwilight18 | May 05, 2020, 07:51 PM

Don't be afraid to change whatever is holding you back.

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AsherTwilight18 shares an interpretation encouraging others to embrace change and not fear what might hold them back, interpreting the TOTD message as a call for courage to make changes people fear. While the TOTD included a personal message using an "I" statement, the participant's interpretation uses "u," which frames the interpretation as a message to others rather than oneself. AsherTwilight18 changes the message from an "I" statement (with" have the courage") to a more directive statement ("don't be afraid"). AsherTwilight18 also interprets what needs to be changed as "whatever holds a person back," going further than the initial quote by suggesting that a change is needed because something is holding people back.

Applying TOTD to Self

When participants apply TOTD posts to themselves, they often connect the message and personal experiences to their addiction and sobriety. This personal application of TOTD posts allows participants to find meaning and relevance in the TOTD messages based on their experiences. The TOTD example below shows a participant responding to a message about a behavior change (Textbox 3).

Textbox 3. Example of a participant applying a "Thought of the Day" message to personal behavior change.

A-CHESS App| March 05, 2020, 04:00 PM

Thought of the Day–The change of one simple behavior can affect other behaviors and thus change many things. Jean Baer

Allen18 | March 03, 2020, 08:05 PM

I don't drug today. Instead I get good sleep and can achieve more positive outcomes.

Allen18 identified their "change of one simple behavior" as not doing drugs. They used "I" statements to apply the message of the TOTD to themselves in their present day. While the TOTD is about change, the participant uses "instead" to show their behavior change—getting good sleep instead of doing drugs. Marking that sleep is "good" also shows the effect of not doing drugs on another behavior (sleep), as the change of one behavior affecting another is suggested in the original quote.

Responses Combining Aligning, Applying, and Interpreting TOTD

In posts with several responses, 1 participant may apply the message within the post by connecting it to their personal experiences, behaviors, or challenges. At the same time, other participants may interpret the TOTD by offering their insights, perspectives, or alternative ways of understanding the message. These multiple functions within a single response demonstrate the richness and complexity of participant engagement with the TOTD. Participants bring their own experiences, interpretations, and reflections to the message, resulting in multifaceted interactions. Here is an example of these occurring responses to the same TOTD post (Textbox 4).

Textbox 4. Example of participant responses combining alignment, interpretation, and application of a "Thought of the Day" message.

A-CHESS App| April 29, 2020, 04:00 PM

Thought of the Day–God Listens to Knee Mail.

PsycheLark | April 30, 2020, 12:00 PM

Simply to pray everyday.

Luna12 | April 30, 2020, 12:39 PM

He Sure Does.

AsherTwilight18 | May 1, 2020, 12:26 AM

Bend your knees.

JAXSTORM | May 1, 2020, 2:55 PM

God listens to all his children.

In this thread, 4 participants responded uniquely to the TOTD post about God listening to "knee mail," a metaphor for prayer, an example of using recovery language. PsycheLark interpreted the TOTD by explaining that it encourages praying every day. Their response focused on understanding the message conveyed by the TOTD. Luna12, on the other hand, aligned with the TOTD by agreeing that God, "He," does indeed listen. Their response showed support for the sentiment expressed in the TOTD. The response from AsherTwilight18 was brief but still connected to the TOTD by suggesting to "bend your knees," reinforcing the concept of prayer. Finally, JAXSTORM also interpreted the TOTD by stating that God listens to "all his children." Their response aligned with the idea of God's attentiveness to prayers. These participants, without directly interacting with one another, demonstrated different ways of engaging with the TOTD, including interpretation, alignment, and brief expressions related to the message of the TOTD.

Premeditated Messaging: News

The research staff shared the news to disseminate information about what was happening in the study setting or noteworthy happenings relevant to the study group participants. Usually,

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the news posts were approximately a paragraph (longer than TOTD) and had external links providing the news source and more information about the news (Table S1 in Multimedia Appendix 1). The news posts focused on recovery, health care topics, or recovery news. In contrast to the active engagement observed with TOTD posts, the news shared in the message thread did not elicit any responses from the participants. In addition to news reports, case managers and research staff raised awareness on issues similar to news but corresponded to months dedicated to these efforts, such as stress awareness month.

Premeditated Messaging: Raising Awareness

The research staff intentionally posted messages to raise awareness on relevant topics for the study participants. These posts focused on stress awareness, sexual assault awareness, important historical days related to HIV, and other health-related subjects. In addition, awareness included appreciation for health care professionals, Drug Enforcement Administration (DEA) drug-take-back days, mental health awareness days, overdose awareness days, and significant events such as World AIDS Day on December 1. These topics were selected to share pertinent news and actively engage participants in discussing their SUD or HIV status.

Participants responded more frequently to the awareness topics compared to the news posts. The research staff's efforts to tailor the information to the participants' experiences and interests likely contributed to their engagement and willingness to participate in discussions on these topics. Table S1 in Multimedia Appendix 1 shows an example of an awareness message shared by a case manager about the HIV "U=U campaign" sharing an external link to an American Medical Association message about HIV transmissibility and viral load suppression.

Most of the premeditated messages did not attract engagement from participants. To address the low engagement in the message board, the research staff and case managers posted more adlib messages that followed a similar framework as the premeditated messages but included overt incentives and direct questions to engage participants actively. By incorporating incentives and asking specific questions, the staff encouraged participants to actively participate in discussions about the awareness topics and increase engagement with the posts.

Adlib Messaging

The research staff and case managers introduced adlib messages to increase participant engagement. Some incorporated incentives and encouraged active participation. They started incentivizing engagement by offering rewards or benefits to participants who actively participated in discussions. In addition, the staff used various techniques to encourage participation, such as sharing polls on different topics of interest.

Table S2 in Multimedia Appendix 1 describes messages in the spontaneous phase of the study, characterized by research staff and case managers sharing entertaining messages, destigmatizing struggles, and incentivizing participant engagement.

Adlib Messaging: Sharing Entertainment

Research staff and case managers began sharing entertainment posts to engage participants. These entertainment posts ranged from jokes to memes and riddles. While some of the adlib entertainment received engagement, the research staff further simplified the means of engagement with these messages by creating polls where participants could select an answer option. These polls were introduced 6 months into the study, coinciding with when engagement on the app saw a decline, as seen in August in Figure 1. The polls were well received, and the research staff incentivized responses to these polls to drive engagement. An example of the incentivized polls is in Table S2 in Multimedia Appendix 1.

Other entertainment posts followed similar message patterns as the premeditated message where case managers raised awareness about fun topics such as "National Chocolate Covered Anything Day!" They provided external links to resources about chocolate, similar to when they raised awareness about HIV and SUD topics when posting premeditated messages.

In addition to entertaining messages, case managers approached adlib messaging by including more personalized stories about their everyday struggles to normalize difficult life experiences.

Adlib Messaging: Normalizing Struggles

Case managers openly shared various topics, including their weaknesses and challenges. This shift in messaging type showed case managers revealing more about themselves, sharing personal stories about pet loss, lack of motivation, living with pain, and other relatable experiences. These personal messages were also followed by external resources or directed questions to engage participants about their experiences that may be similar to those of the case managers. An example in Table S2 in Multimedia Appendix 1 shows a case manager sharing their pain experiences and providing resources for pain relief.

These adlib entertainment and personalized posts allowed others to engage with the staff's posts. However, only participants who typically respond to posts engaged with those posts. However, posts that incentivized participant engagement received responses from participants who had never responded to a message on the board.

Adlib Messaging: Incentivizing Participant Engagement

The research staff members occasionally introduced incentives such as challenges or contests to encourage further participation. These incentives could include gift cards, recognition, or tangible or symbolic appreciation. Incorporating these incentives motivated participants to engage with the app actively. In the example below, a user disagrees with the crowned winner of a weekly challenge.

Example interaction (Table S3 in Multimedia Appendix 1) shows the case manager named a winner and invited feedback as commonplace with the adlib messaging. NovaBliss challenges the announcement of the winner in several ways. First, by asking who the participant is (displaying their perceived lack of participation in the app); second, by asking about eligibility; third, by more overtly disputing that the winner had engaged in discussion with sensory evidence ("I didn't even see"); fourth,

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by asking about how the winner is selected; and fifth, by sharing their feelings about who should have won. This shows the participant's comfort in confronting the staff and standing up for other group members. Case manager also uses exclamation marks in their explanation, which suggests a friendlier tone that may be used to resolve the conflict [27]. Although NovaBliss was not satisfied with the response to their question, Luna12 stepped in and shared their appreciation, starting with "aww" as a description of how they felt about NovaBliss's gesture.

Although this post first declared the winner of a contest incentivizing participant engagement, the responses work through conflict negotiation, which often demonstrates togetherness and allyship in communities. This interaction also signals participants' knowledge of their peers' contributions, especially the key contributors. Key contributors such as Luna12 often responded to the adlib and premeditated messages. However, they also adapted those messaging styles to create posts relatable to their experiences and other participants. These messaging types are described as participant-driven messaging.

Participant-Driven Messaging

During this phase, participants mirrored messaging styles the research staff and case managers created while tailoring them to their sobriety and HIV needs. As described in Table S2 in Multimedia Appendix 1, participants adopted the TOTD posts as a model and provided similar messaging that pertained to their journey toward sobriety. Participants also applied the adlib messaging approach by crafting their own polls and sharing their entertainment content. Finally, participants used the message board beyond modeling the type of messages posted by the research staff, including case managers to seek advice, share their substance use experiences, and address psychosocial needs, including dating and local activities. These messaging types signify the emergence of an autonomous and engaged community where participants take ownership of the app, fostering a supportive network and sharing valuable resources.

Participant-Driven Messaging: Model Following

Participants followed the model created by research staff similar to the premeditated and adlib messages that involved sharing TOTD, sharing entertainment, and creating polls to drive engagement. However, when participants created their initial contributions, they tailored them to things specific to their experiences and recovery. For example, one participant started sharing messages similar to the TOTD. However, their messages were daily using Alcoholics Anonymous literature.

Participant-Driven Messaging: Seeking Tailored Support

Participants who had limited engagement on the app began seeking personalized support. They reached out through messages to ask specific questions, seeking guidance on various topics such as dating, substance use, COVID-19 protocols, or legal assistance. In these instances, both case managers and peers played a role in responding to these inquiries.

Table S2 in Multimedia Appendix 1 shows a contrast between how research staff interacted with participants when they sought advice, which differs from when participants interacted with one another.

London57 discusses their potential need for legal assistance soon but expresses uncertainty about the exact circumstances. Research Staff shares a link to a legal aid service without further inquiring about the situation of London57. In contrast, when participants engaged with one another, they tended to ask more questions before offering support. This approach may serve multiple purposes, such as a better understanding of how they can provide assistance or getting to know the individual better to establish camaraderie. Additionally, participants started sharing a desire to include additional features in the app, which differs from advice where they are asking for support.

Participant-Driven Messaging: Adapting the App Use

Adapting the use of the app involved a few participants who took the initiative to create message types specific to their recovery and medication use. Some participants shared their profiles for dating, using the app as a platform to meet someone, similar to a dating app. In the example below, Luna12 starts medication check-in, adding that checking on one another is what the group is for (Textbox 5).

Textbox 5. Example of participant-driven adaptation of app use through a medication adherence check-in initiative.

Luna12|April 05, 2020 05:54 PM

2020-04-05 17:54:33 UTC

Check in: Hi everyone. Let's start doing a I took my meds today check-in. Starting tomorrow. How about it?

Case Manager|April 06, 2020 07:19 AM

This is an awesome idea!! Thank you for organizing this.

Luna12|April 06, 2020 11:49 AM

That's what this group is about. We need to check on each other.

In this example, Luna12 introduces an idea centered on a daily behavior check-in. They also seek direct feedback from other participants. The case manager uses exclamation marks to signal their enthusiasm and support for the idea proposed by Luna12. However, after several attempts to start medication check-ins, there was a lack of engagement and follow-up; thus, Luna12 discontinued the medication check-in.

Including new features shows participants focus on doing something daily on the app and how they perceive the group's use. As such, participants also perceived the group as a place

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they could plan to meet and interact with others with whom they shared similar lived experiences.

Participant-Driven Messaging: Community-Building Beyond the App

Participants wanted to connect outside the app, indicating a need for an in-person community. They took the initiative to plan meetups and events, sharing their phone numbers and discussing potential activities in their local areas. This demonstrated their eagerness to foster real-life connections and engage in social interactions beyond the digital realm of the app. In the example below, SpiritSeeker shares their number to ask participants to connect with them (Textbox 6).

Textbox 6. Example of participant-driven community-building through sharing contact information to connect beyond the app.

SpiritSeeker|January 20, 2020 01:36 PM

Need a ear,That's Me. You you need a ear,some one to listen,I here,M/ number is [phone number] call any time,I care.

Luna12|January 20, 2020 03:45 PM

Thank you.

SpiritSeeker identifies themselves as a caring person. Although they do not contribute frequently with other participants, they asked to be reached anytime outside the app. Gratitude expressed by Luna12 and the case manager shows an appreciation for the gesture of SpiritSeeker. Other participants also offered to contact them and connect outside the app, showing community building moving from the mobile app to in-person meetings.

Discussion

Principal Findings

Our study used computer-mediated discourse analysis to investigate the formation of a virtual community among individuals living with HIV and SUD on the A-CHESS mobile health app. Using CMDA, we identified three different types of messaging: premeditated, adlib, and participant-driven, operating within the A-CHESS message board to shape the evolving norms, tone, and purpose of the community. Of particular interest is how the discourse evolved over time: staff initiated communication with structured posts and motivational content while participants progressively mirrored, repurposed, and transformed those formats to address their own needs, including support around recovery, medication use, and social connection. This study is one of the few to examine how virtual community formation unfolds within a mobile health platform, and to our knowledge, the first to do so among individuals living with both HIV and SUD. Rather than focusing solely on usage metrics or predefined support categories, our approach surfaces the evolving discursive norms, message structures, and participant adaptations that shaped the A-CHESS message board. We offer a novel perspective on how meaning, alignment, and ownership emerged through digital peer interaction in a multiply marginalized population for virtual community formation.

While there is no universally agreed-upon definition of an online community, it is often characterized as individuals engaging in virtual interactions, guided by established norms and policies, and supported by technology [28,29]. Notably, the formation of the A-CHESS virtual community was characterized by the active involvement of case managers and staff in driving participant engagement through adapted messaging styles, aligning with previous research emphasizing the role of community moderators in facilitating interaction [30]These findings suggest opportunities for future research to examine how different roles, such as peer navigators or moderators or patient navigation services, may support engagement and clinical outcomes when integrated into mobile app based support interventions. Of note, participants tended to mirror the behaviors of staff and their peers. The messaging types showed, particularly in adlib messaging, a shared understanding of the established norms of message response, consistent with the influence of social dynamics within online communities [31]. Participants mirrored sharing approaches that were similar to engaging with motivation TOTD and also used polls for engagement. Participants also demonstrated agency by shaping the app to meet their individual support needs, showcasing a sense of empowerment and ownership within the community.

Active engagement and interaction among members are vital to fostering online community relationships [32]. Our 26-month study revealed interesting trends in participant engagement and interaction. While only a subset of participants interacted with messaging, this aligns with research on app engagement that has shown engagement frequency to be limited to a few individuals [31,33]. It is important to acknowledge that other participants may have engaged passively, commonly referred to as "lurking" by reading and benefiting from message board content without posting. As noted in the literature, the 90-9-1 rule describes this dynamic, where approximately 90% of users are "lurkers," 9% contribute occasionally, and just 1% are highly active [34]. This form of invisible engagement is not captured through message analysis but may still reflect meaningful interaction with the app and community [35]. Within A-CHESS, active app participation peaked between months 10 and 14 but experienced a decline from month 18, which was 9 months before the study's conclusion. It is worth noting that the COVID-19 lockdown started during month 14, which could explain the increase in participant-driven messages during March 2020. Nonetheless, our study's pattern of engagement differed from findings in a study on an HIV message board, where post numbers peaked in the first 6 months, decreased between months 6 and 12, and then increased again between months 18 and 24 [10]. Additionally, our study identified a gradual increase in participant-driven interaction during the first year, indicating a shift toward seeking tailored support and taking ownership of the conversations within the app.

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The premeditated motivational messages in our study received the highest level of interaction from all study participants compared to all other messaging types, underscoring the significance of motivational messages within the virtual community. This finding is consistent with a study focused on improving engagement in HIV care, where participants expressed enthusiasm for receiving motivational messages [36]. Our study participants also demonstrated a unique way of responding by applying, aligning, or interpreting the messages. The alignment observed in virtual community formation is often seen in agreement or shared perspectives among group members [37], but in this case, participants aligned themselves with automated messages. Mobile health apps can continue integrating motivational messages to enhance user engagement and encourage users to interact with and respond to such messages actively.

It is worth noting that premeditated news and awareness messages in the A-CHESS virtual community did not generate significant interaction from participants. This lack of engagement can be attributed to the primary focus of participants in recovery groups on addressing feelings of loneliness and uncertainty, as observed in previous studies on support-seeking behaviors in individuals with SUDs [38]. This finding aligns with results from an HIV online support group where messages providing jokes and pleasantries were posted as often as messages providing emotional support [39]. The discrepancy in engagement underscores the significance of incorporating varied message types that cater to community members' diverse needs and preferences. Despite different feelings and emotions, our study shows that attending to these emotions is beneficial compared to sharing news or raising awareness.

The adlib messages from case managers played a significant role in fostering virtual community formation within the A-CHESS app. Research studies have highlighted that members of online communities are more likely to form relationships when they have opportunities for self-disclosure and learning about each other [31]. By personalizing their messages, case managers allowed participants to gain insights into the staff and case managers. While incentives encouraged participation, they also introduced tension, as some participants perceived the reward structure as unfair or misunderstood. These moments suggest a need for further research on how extrinsic motivators shape digital peer dynamics, especially within marginalized populations.

In the participant-driven message types observed in our study, key participants played an important role in initiating and maintaining interactions among participants, including responding to questions. These findings align with previous research on message board usage among people living with HIV, which also identified the influential role of a few individuals in driving engagement [14]. Our study highlighted the unique use of the message board by participants seeking support and guidance regarding dating, reflecting the ongoing relevance of discussions about intimacy and relationships within online communities for individuals living with HIV [40]. Additionally, our findings revealed that initial online connections often developed into offline meetups, reflecting the establishment of deeper relationships within the community.

We also observed differences in how staff and case managers interacted with participants compared to how participants interacted with each other within the virtual community. Participants were more likely to ask follow-up questions, while research staff primarily provided informational support. The act of asking questions is valued in online communication as it promotes efficiency, purposefulness, and clear understanding [41], fostering interaction within these communities. Additionally, studies have indicated that responses to questions and requests for advice from participants are often met with emotional support in online environments [42].

While our study focused on the A-CHESS virtual community, it is worth noting that messaging app usage has often been associated with younger, white individuals of higher socioeconomic status [43]. However, participants contributing to the A-CHESS message board were predominantly older, Black, and unemployed. This demographic disparity highlights the importance of exploring the specific types of social support individuals from different racial backgrounds seek within mobile health apps. Future research could examine the preferences and needs of diverse populations, informing the development of tailored apps that enhance engagement and user experience for individuals from various racial backgrounds.

Online communities thrive when members actively interact, maintain the community infrastructure, share new and updated information, and provide social and emotional support to fellow members [31,44]. In the context of the A-CHESS app, the collaborative efforts of case managers, research staff, and engaged participants collectively contribute to forming and sustaining the virtual community for the study duration. We recommend that future mobile health interventions for people living with HIV and SUD support virtual community formation by integrating diverse message types and fostering participant agency. Facilitating participant-driven discourse can help individuals tailor the app to their needs, strengthening feelings of ownership and peer connection. Future app design and implementation strategies should therefore consider not only incentivizing engagement but also supporting the organic development of peer-to-peer communication, including opportunities for participants to shape content and norms. Further research could explore how different messaging types influence recovery outcomes across alcohol, opioid, stimulat use, as well as HIV treatment engagement , and how nonvisible engagement (such as passive participation) contributes to community cohesion and support.

Limitations

Our study has several limitations that should be acknowledged. First, while discourse analysis provides insights into participants' expressed intentions and behaviors, it does not provide direct access to their thoughts and motivations, limiting our ability to determine the intended behaviors behind each message posted. Additionally, the message board as the source of discourse limits the ability to explore how participants navigated certain emergent dynamics, such as minor conflict or unacknowledged support requests, beyond what was expressed in writing within the board. Second, the generalizability of our findings may be limited due to the

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specific population under study. The A-CHESS app was distributed to individuals living with HIV and SUD in a midwestern state, and the unique characteristics and context of this population may influence their engagement and interactions within the virtual community.

Conclusion

In conclusion, we identified three message types shaping interaction on the A-CHESS mobile app: premeditated, ad lib, and participant-driven messages. Staff-initiated messaging contributed to patterns of engagement observed on the message board, while participant-driven posts reflected peer connection and shared recovery experiences relevant to SUD in people living with HIV. Our research staff and case managers drove participant engagement through premeditated and adlib messaging. Participants contributed tailored messages, demonstrating their interest in engaging and connecting with peers. When developing mobile apps for social support, it is important to identify the role of those leading the platform in driving engagement and to adapt engagement strategies to meet participants' needs.

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Data Availability

The datasets generated or analyzed during this study are available from the corresponding author on reasonable request.

Authors' Contributions

RW contributed to conceptualization, funding acquisition, methodology, project administration, resources, software, supervision, validation, and writing – review and editing. AT was responsible for data curation, formal analysis, investigation, methodology, visualization, writing – original draft, and writing – review and editing. KP contributed to formal analysis, methodology, validation, writing – original draft, and writing—review and editing. CL was involved in the investigation, resources, and software. SD contributed to the investigation, resources, and software. YS was responsible for conceptualization, supervision, and writing – review and editing.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Addiction Comprehensive Health Enhancement Support System message board threads.
[DOCX File, 37 KB - formative_v10i1e66564_app1.docx]

Checklist 1
Standards for Reporting Qualitative Research (SRQR) checklist.
[DOCX File, 26 KB - formative_v10i1e66564_app2.docx]

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Abbreviations

A-CHESS: Addiction Comprehensive Health Enhancement Support System
CMDA: computer-mediated discourse analysis
DEA: Drug Enforcement Administration
PWUD: people who use drugs
SRQR: Standards for Reporting Qualitative Research
SUD: substance use disorder
TOTD: Thought of the Day

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Contribution of an Online Intervention to Developing Communities of Practice: Mixed Methods Evaluation of an Online Safety Hub to Address Harmful Online Content in Relation to Self-Harm and Suicide

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Abstract

Background: Online harm affects many people and has been associated with self-harm and suicidal ideation. Although there is an emerging body of evidence that addressing adverse online experiences should be part of the support offered to people who are at risk of self-harm and suicide, there has been little guidance to date on how this support might be provided and how safe conversations can be had on the subject. A UK charity dedicated to offering emotional support to anyone experiencing mental discomfort, having difficulty coping, or being at risk of suicide developed a digital intervention, the Online Safety Hub (the Hub), to address this shortfall.

Objective: The study aimed to evaluate the impact of the Hub on practitioners (people who provide support) and people with lived experiences of suicide and self-harm and to determine what learning environment is best suited to increase and maintain learning in the context of the Hub.

Methods: A sequential explanatory mixed methods evaluation comprised a rapid literature review, data collected from people with lived experience (n=6) and practitioners through an analysis of the Hub's activity data, 2 surveys (survey 1: n=45; survey 2: n=368), interviews (n=9), and focus groups (n=7). Surveys were analyzed for descriptive purposes only, and the interview and focus group analyses comprised coding of data and thematic analysis. The study design was informed by a panel of people with lived experience of online harm resulting in either self-harm and/or suicidal ideation.

Results: Initially, the evaluation found limited uptake of the Hub. Engagement with the Hub was impeded by a lack of clarity on the part of practitioners as to whether they were the intended audience. The evaluation process prompted the charity to design and deliver webinars to facilitate uptake of the Hub. Practitioners who engaged with the Hub via webinars found the content useful and were able to consider incorporating their learning into practice. The webinars offered a more social learning experience than individual engagement with the Hub, providing a community of practice for people with common interests across diverse organizational settings. Opportunities for shared learning and the supportive nature of the community of practice were valued when learning about the sensitive and difficult topic of online harm in relation to self-harm and suicide. The Hub contributed to awareness-raising and shared learning.

Conclusions: Online resources alone may not be sufficient for an intervention to effectively raise awareness and change practice. Social learning facilitated through communities of practice can enhance engagement, uptake, and learning.

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KEYWORDS

communities of practice; digital intervention; online intervention; mental health professionals; self-harm; suicide; suicide prevention

Introduction

Background

When people are experiencing psychological, psychiatric, or emotional difficulties, the internet can have a pivotal function in managing their stress and emotions. For people with suicidal ideation or who self-harm, however, accessing the internet during periods of suicidal crisis or when experiencing the urge to self-harm does not always have positive and supportive effects [1,2]. The potential for harm to come to vulnerable individuals, particularly those who struggle with suicidal thoughts or self-harm, through their engagement with the internet is a growing concern. Not only does the internet expose individuals

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to suicide and self-harm–related content passively, for example, when they come across such content accidentally, but it can also provide them with tools they might actively seek out for self-harm and suicide-related purposes, which can lead to a downward spiral of increased suicidality and despair [3]. Therefore, the internet is an essential area of concern in terms of mental health, suicide, and self-harm, with the question of how to address engagement with online content increasingly central to the consideration of mental health support.

Online interventions such as training websites, e-learning modules, and webinars are standard means of contemporary professional development in many fields, including health and medicine [4,5]. Offered to staff starting new roles and as refresher training, online interventions allow organizations to provide mandatory and voluntary training efficiently and flexibly. Online interventions are available 24 hours a day, 7 days a week, allowing users to undertake training at their chosen time and pace, on site or off site, within a given timeframe [6]. Beyond mandatory staff training, online interventions are also used by professionals who seek to develop in particular areas needed for their roles and enhance their practice [7,8]. However, the availability of online resources does not necessarily result in uptake; the design, content, and format of the online resources play a role in adoption [9], and other less easily adjustable factors, such as workload pressures, can prevent uptake.

The Samaritans, a UK charity dedicated to offering emotional support to anyone experiencing mental discomfort, having difficulty coping, or being at risk of suicide, developed an online intervention in 2022 to raise awareness and increase knowledge about online harm: the Online Safety Hub (hereafter referred to as the Hub) [10]. The Hub was coproduced by the charity's online excellence team and people with lived experience of online harm resulting in either self-harm and/or suicidal ideation. It comprised a range of resources aimed at supporting anyone involved in counseling people about suicide or self-harm who may have been exposed to online harm. The Hub is one response in the United Kingdom to concerns about harmful online content increasing risks of suicide and self-harm; other responses include legislation (the Online Safety Act 2023) and engagement with online providers. The latter was taken on by the Office of Communications, the designated online safety regulator in the United Kingdom, that set out detailed plans requiring providers of online services to protect their users from illegal content and to protect children from harmful content, including pornography. However, to the authors' knowledge, there is currently no standard of care for practitioners in the United Kingdom when it comes to advice directed toward online harm. In addition, there is no published research about the implementation and use of online interventions such as the Hub by practitioners to address suicide and self-harm. The evaluation of the Hub provides an opportunity to address this knowledge gap. We analyzed the data gathered through the evaluation to answer the research question: how can diverse practitioners be supported by an online intervention to enhance their practice?

The concept of communities of practice (CoPs) can be used to account for how the online intervention connected diverse practitioners working in a wide range of organizational settings but with a common interest in supporting people at risk of suicide and self-harm. The term was coined by Lave and Wenger [11] in 1991 to describe groups of people who share an interest in something they do and learn how to do it better as they interact regularly [12]. These groups are found in various settings, such as educational institutions, professional networks, and business organizations. CoPs are characterized by a flat hierarchy and a confidential atmosphere, which promotes knowledge sharing and emotional support [13]. Although traditionally described as communities that regularly meet face to face, CoPs also exist online. Online CoPs have been found to manifest the characteristics of conventional CoPs, with members actively engaging in shared practice and identity development while pursuing a joint enterprise [14]. Online CoPs are further considered to offer greater accessibility and flexibility when compared to traditional CoPs; however, it is noted that they may face challenges in fostering trust among their members due to the more anonymous online format [15]. While traditional CoPs excel in building personal connections, they are at the same time constrained by physical and temporal limitations [16]. Furthermore, online CoPs can be a valuable interface for connecting experiences and uncovering challenges and opportunities in various fields, such as public health [17].

An Overview of Online Harm

Online harm has been an increasing social and policy concern in the United Kingdom, leading to the Online Safety Act 2023. The act provides a regulatory framework that aims at "making the use of internet services… safer for individuals in the United Kingdom" [18]. By doing so, it regulates how social media and other internet services moderate and manage harmful and abusive online content to protect users from being exposed to certain harm. The legislation covers the restriction of dangerous content and the removal of illegal material. However, broader harms relating to online activity are still prevalent and are of particular concern in relation to suicide and self-harm.

There is no single definition available for online harm. Online harm is associated with harmful relationships mediated by online connections (eg, cyberbullying), interrelated with concerns about internet "addiction" or pathological use of the internet. Online harm can, therefore, mean any detriment arising from or through the use of the internet. It is also associated with specific content that presents and promotes self-harm and suicidal behavior. Such content can provide harmful information and has been understood by some researchers as acting as a form of "contagion" [19,20]. A contagion is perceived as a multiplicator mechanism resulting from the presence of suicidal content in media, including social media, that leads to people copying behavior they would otherwise not have been confronted with [20,21]. People might actively seek out content related to self-harm and suicide or inadvertently come across content that might be experienced as harmful. Such online interactions have the potential to adversely affect people in a range of ways, including causing some people to feel the urge to self-harm or ideate suicide [22]. "Online" in this context encompasses the full range of modes of connecting via the internet (including mobile devices, apps, and websites) and the modality of "being" online and participating in online "spaces."

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Online harm is predominantly associated with young people. However, anyone using the internet may be harmed by online activities, such as cyberbullying or cyberstalking, or targeted, for example, by online scams or, for women, online misogyny [23,24]. Previous research indicates that online harm can lead to adverse emotional and psychosocial consequences, particularly for those with personality traits such as sensation-seeking, low self-esteem, and psychological difficulties, as well as social factors like lack of parental support and peer norms [23,25]. Exposure to harm-advocating online content, such as proeating disorder, pro–self-harm, and prosuicide material, has been associated with lower subjective well-being among young people [26,27], with similar risks for vulnerable adults. Additionally, real-world online activity data have shown that multiple online risk factors, including cyberbullying, violence, hate speech, and sexual content, are associated with youth suicide-related behavior [28]. However, not all online risks result in self-reported harm, and the prevalence of these risks does not appear to rise substantially with increasing access to mobile and online technologies [24].

Harmful content alone will not necessarily lead to adverse outcomes such as increases in self-harm or suicide. The subjective nature of online harm is emphasized in several studies [29,30]. Content and interactions that might be experienced as harmful for one person at a point in time (eg, by normalizing or reinforcing self-harm) could be helpful for another person or, indeed, that same person at a different point in time if they encounter it as part of seeking help—and it is essential to note that some people prefer to seek help online rather than in person. People with mental health conditions, for example, often use the internet to learn about their condition, and research has further indicated that young adults with mental health conditions frequently use social networking sites, for example, as a means to find support and build a community around the issue [31]. Furthermore, adolescents often share self-injury content online, which can have both positive and negative effects [32]. Positive effects can include getting positive reactions from peers, such as being offered help, connecting, or receiving empathy, whereas negative effects can include eliciting negative online comments containing harassment and being misunderstood.

Efforts to avoid and address online harm include legislation, moderation of content and interactions (for example, by social media platforms such as Facebook, Instagram, and YouTube, as well as by individual moderators of sites and groups), media guidelines and frameworks aimed at producers of content and platforms, guidance for practitioners supporting people experiencing online harm (such as that offered by the Samaritans), and support for those directly experiencing online harm. People with mental health problems sometimes disclose their online experiences with their therapists [33]; however, scrutinizing the online activity of clients proactively has so far been a mostly neglected area in mental health practices. Nonetheless, empirical research indicates that mental health practitioners could helpfully address the online activity of young people during mental health consultations [34], although statistical evidence about the total rate of mental health practitioners who inquire about their patients' online activities is not yet available. Accordingly, previous research identified a lack of guidance for practitioners on how to have those conversations [35].

In sum, the online environment is dual in nature; it can be both harmful and helpful. Certain content can be distressing and triggering, and online connections can be abusive and exploitative. However, people can find solace and help online through positive connections and useful information. Efforts to shut down online harm risk removing opportunities for online help. Resources to support people exposed to online harm and who are at risk of self-harm and suicide are therefore needed. This paper draws on an evaluation of an online intervention that aims to assess the impact of the Hub on practitioners (people who provide support) and people with lived experiences of suicide and self-harm and to determine what learning environment is best suited to increase and maintain learning in the context of the Hub.

Methods

Research Setting

The Hub consists of a public-facing website containing guidelines for practitioners, downloadable content, including handouts, and a social media tool kit. The website is supplemented by an e-learning module hosted on a National Health Service (NHS) platform, which requires a user account to access. The Hub and resources were co-designed with people with lived experience. The Hub was launched in November 2022 and advertised to a range of professional networks, including mental health practitioner networks, the Samaritans' networks of practitioners and supporters, and on social media including LinkedIn, throughout the United Kingdom in early 2023, resulting in a considerable initial uptake among practitioners in subsequent months, with activity data indicating up to 350 module launches per month. The resources were primarily aimed at encouraging practitioners to raise the topic of online harm and to highlight the potential benefits of having supportive, safe conversations about online harm in the context of supporting people with self-harm and suicide.

The study aimed to evaluate the impact of the Hub on practitioners (people who provide support) and people with lived experiences of suicide and self-harm and to determine what learning environment is best suited to increase and maintain learning in the context of the Hub.

An evaluation of the Hub was conducted between 2023 and 2024 to assess practitioners' engagement and experience with the Hub, its impact on their practice, and barriers and enablers to its implementation. In addition, the evaluation aimed to assess service users' perspectives on the potential impact of the Hub on their interactions with their practitioners. The design of the evaluation was guided by a lived experience group and informed by a rapid evidence review. Data were collected from people with lived experience and practitioners through surveys, interviews, and focus groups, and an analysis of activity data was generated through the use of the Hub. The rapid evidence review on online harm; online interventions for suicide and self-harm; and usability, user engagement, and implementation of online mental health interventions informed the development

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of survey instruments and topic guides for interviews and focus groups. Common themes found in the evidence review were the pervasive and dual nature of online communications and content, the fluid sources of informal and formal mental health support, and the individual, technical, and social factors shaping the use of online interventions. The importance of engaging in discussions about online harm and involving people with lived experience in designing interventions was also apparent from the evidence review and taken forward into the instruments to gather data for the evaluation.

Ethical Considerations

Focusing on the experiences of practitioners and people with lived experience regarding online harm, the study needed ethical approval from the researcher's institution. This was granted after following the standard procedures of reporting the planned research and its methods to the school's ethical board (School of Business, University of Leicester; approval 42217).

All participants of this study were provided with information about the evaluation and their voluntary participation, and were asked to consent to participate. This was obtained from all participants either by ticking respective boxes in the online survey or by filling in written informed consent forms. Participants who had not provided their consent before a focus group session or interview did so before the start of the focus group or interview. Their verbal responses were audio recorded, saved, and encrypted on the institution's online storage service. An informed consent form was, in this case, filled in and signed by the researcher on behalf of the study participant. One online survey participant denied consent despite completing the survey. Their replies were deleted and excluded from analysis. As participation in the study and its components was voluntary, no compensation was paid to any of the study participants. Participants of focus groups and interviews were informed that all collected data would be anonymized and identifiable information deidentified before analysis and publication.

Recruitment

Two surveys scrutinizing experiences and expectations of the Hub were circulated through Samaritans' existing networks of practitioners and agencies supporting individuals at risk of harm or suicidal behavior, as well as through their lived experience networks that consisted of individuals with relevant knowledge through experience around the subject of online harm. The surveys also aimed at facilitating the recruitment of interviewees and focus group participants (all instruments used for this evaluation such as surveys and interviews or focus group topic guides are available in Multimedia Appendix 1). However, initially, very few practitioner participants (n=4) were recruited who could offer experience of engaging with the Hub. In response, the Samaritans, in collaboration with the evaluation team, offered three webinars in March 2024 as an alternative modality to promote engagement with the Hub and deliver the online training content while recruiting evaluation participants. The webinars had a high uptake; each webinar offered 500 slots, which were all prebooked and had a waiting list; at minimum, every session was attended by more than 50% of those who had signed up. A total of 920 people attended the three webinars at peak times. All participants were invited to complete a survey at the session's end by displaying a QR code in the webinar's presentation and sharing a survey link in the webinar's chat. The survey also inquired if participants would consider attending a follow-up focus group, interview, or both.

Data

Activity data from the Hub showing usage between November 2022 and December 2023 were collated through analysis of Google Analytics data charts to which access was granted by the charity. The lived experience survey was circulated through the Samaritan's lived experience networks and received 45 responses, and 6 people with lived experience attended two focus groups (however, one focus group was unfortunately terminated prematurely due to technical issues and is thus not considered as data for this paper). The Samaritans and the evaluation team circulated an evaluation request for interviews through their practitioner networks, which resulted in 4 practitioner participants. The practitioner survey administered through Microsoft Forms at the end of each webinar session received 368 responses, and as a result, a further 5 practitioners were interviewed, and 7 practitioners attended three focus groups. Interview and focus group participant recruitment came to an end after this (Table 1). All surveys applied in this evaluation were analyzed for descriptive statistics analysis only using Microsoft Excel producing charts with frequency analysis of the respective answers to questions about usage of and expectations toward the Hub. However, as this paper aims to discuss the best-suited delivery modality for training on online harm, we mainly focus on presenting qualitative data here. The importance of the delivery modality was a result of the analysis and only emerged after noticing a significant uptake of the webinars, which were themselves a mitigation strategy for the low uptake of the Hub. The webinar survey was prepared before this became apparent and hence did not survey any relevant data in this regard that could be presented here. Both lived experience focus groups and practitioner focus groups were informed by results from the preliminary analysis of the respective survey data, for example, through scrutinizing some of the results further. The practitioners' interviews, however, followed a topic guide that was already drafted before the webinar survey was applied and was instead informed by the results of the evidence review.

The interviews and focus group sessions for this evaluation followed semistructured interview topic guides (see supplementary appendices) and were conducted online using Microsoft Teams between December 2023 and April 2024. They were recorded, and verbatim transcripts of each were produced and thematically analyzed [36]. All qualitative data were analyzed by the first author, results were presented to and, if needed, challenged by the coauthors. As this process did not include analyzing the data originally by more than one researcher, no measurement for intercoder reliability was obtained. Transcripts were thematically analyzed using the qualitative data analysis software MAXQDA (version 11.2.5; Verbi GmbH); initial coding was undertaken to identify common experiences of using the Hub; this was then compared with the concept and components of CoPs, with the results presented in the Results section.

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Table . Data sources and participants' details.

Data source	Participant perspectives/roles	Number of participants/respondents	Data
Focus groups	People with lived experience of online harm resulting in either self-harm and/or suicidal ideation	5 (4 male, 1 female)	1 transcript of 55 min of audio
Focus groups	Practitioners from voluntary sector, NHS[a], public health, local authorities, etc	7 (2 male, 5 female)	3 transcripts of combined 146 min of audio
Survey	Practitioners from voluntary sector, NHS, public health, local authorities, etc	368 (sex/gender was not collected)	Free text/Likert scale responses
Survey	People with lived experience of online harm resulting in either self-harm and/or suicidal ideation	45 (27 female, 11 male, 4 nonbinary, 3 preferred not to say)	Free text/Likert scale responses
Qualitative interviews	Practitioners from voluntary sector, NHS, public health, local authorities, etc	9 (3 male, 6 female)	9 transcripts of combined 385 min of audio
Hub activity data	All users	—[b]	Quantitative internet usage data

[a]NHS: National Health Service.

[b]Not applicable.

Results

Overview

Although the analysis of the quantitative and qualitative data collected through surveys, interviews, and focus groups revealed that the Hub resources were deemed very useful by those who had used them, analysis of the activity data indicated there had been relatively limited uptake of the Hub. The launch of the Hub in late 2022 resulted in some uptake of online training (with a total of 539 module launches between November 2022 and April 2023) and up to 3900 visits to the Hub web pages each month between March and May 2023 (visits to the guidelines landing page). However, after this peak in user visits, the number of users declined and remained on a low monthly average (between 20 and 90 visits from June to December 2023; Figure 1).

Practitioners represented a wide range of organizational settings and roles, including frontline mental health workers, people with organizational safeguarding roles, student counseling services, and freelance online consultants (Table 2).

Figure 1. Number of online visitors to the Hub's landing page and e-learning module between November 2022 and December 2023. Samaritans Online Safety Hub data from Google Analytics.

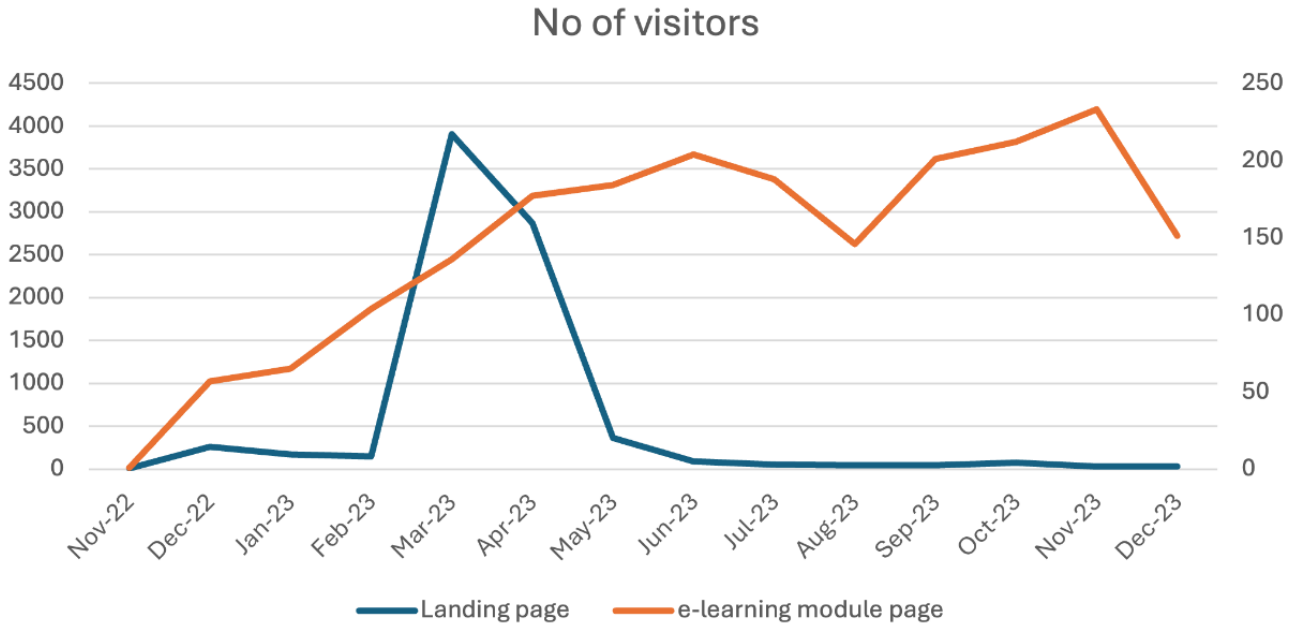

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Table . Organizations of the online safety webinar participants (N=368).

Category	Value, n (%)
Charity, community, or voluntary sector	98 (26.6)
Education provider (including school, college, or university)	80 (21.7)
Local authority	52 (14.1)
NHS[a] Trust (acute, community, or mental health)	98 (26.6)
Other	22 (6.0)
Primary care	17 (4.6)
Missing answer	1 (0.3)

[a]NHS: National Health Service.

The comparatively high demand for the webinars offered by the Samaritans, which used the same resources as were provided on the Hub, indicated that the modality by which practitioners might engage with those resources was of great importance. We found that synchronous or "live" webinars were experienced as a more sociable form of learning than individual self-directed learning, which was what the Hub had previously provided. We applied the concept of CoPs to the qualitative evaluation data to consider the importance of different modalities of learning for practitioners' experiences and use of the Hub. We present our findings in the sections about the sociable nature of learning, community membership, learning about the sensitive topic of online harm, and incorporating learning into practice.

Sociable Learning

The comparative popularity of the webinars compared with the use of the website and e-learning resources indicated a preference for the more sociable experience offered by participating in a webinar to that available from independent learning. Learning from and engaging with peers was found to be important to participants in the webinars:

> *I also enjoyed the Q&A, the interaction, and the interactive aspect...Because that opens up kind of again that less presentation style, kind of dialogue about something, it makes you back up a bit when you're in an online webinar because you want to see what's coming in from other people sitting behind their desks. […] I also think it gives a perspective of what other people think of in the room, aside from the facilitators.* [Practitioner 7, public health officer for community engagement within local authority]

Listening to the experiences of other members of this new community was felt to be a valuable component of the webinars:

> *'I just feel like I do normally enjoy that part of benefiting from hearing other people's pressing questions or examples because it then makes you think even more widely outside the box as to what it means.* [Practitioner 7, public health officer for community engagement within local authority]

When asked how the Hub might develop and improve, practitioners suggested more opportunities to facilitate the sharing of issues and challenges on the subject, for example, through discussion forums. Practitioners identified social learning as important in allowing them to incorporate new knowledge into their practice; when asked what they might do differently as a result of attending the webinars, some suggested sharing the resources with colleagues, for example, in team meetings. The social experience of participating in focus groups and interviews was also noted as useful in learning and reflecting more on the issue of online harm.

Some participants noted the importance of creating a comfortable learning environment, aware that the course content could trigger negative emotions. This sense of creating a caring and protected community was noticed explicitly by one practitioner who summed up her webinar experience:

> *I always really enjoy the way the courses [sic] are delivered. It's obviously such a really sensitive way. They have a real focus on not only learning what our patients are experiencing but actually, I really like how there's always a focus on actually looking after ourselves as well. Which is just a really nice touch, I think. And obviously, there's such a wealth of experience and knowledge there that it just always feels like a really warm environment where you can ask any sort of question, and it's not going to be like a silly question or anything. So I thought the information was really interesting. I definitely learned a lot [...] And again, there was that sense of kind of no question was off limits.* [Practitioner 8, health and well-being coach in NHS GP partnership]

The ways in which participants indicated they valued the webinars align closely with the benefits associated with CoPs. This social aspect of learning during webinars was also experienced in focus groups, where participants reflected on the benefits of having time to discuss online harm with other practitioners.

Community Membership: Who is a "Practitioner"?

A wide range of people are potentially involved in counseling people about online harm in relation to self-harm and suicide. The pervasiveness of internet access, and therefore the potential for online harm, was a feature of people's personal as well as their professional lives. The term "practitioners" was used to encompass the diverse people who offer support around the issues of self-harm and suicide, and the online resources were titled "Guidelines for Practitioners." This generic term avoided specific job roles to deliberately encompass people working in

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a range of organizational settings, including NHS services, local authorities, and the voluntary sector. Despite the use of this general term, some people were uncertain if the Hub (and in particular the e-learning module) was intended for them, as they did not recognize themselves as practitioners because they did not work in mental health services or NHS organizations. Although the content was designed for and valued by a broader range of audiences than mental health practitioners in the NHS, the process of accessing the e-learning module involved creating an account on the NHS online platform, which appeared to require an organizational background in health-related professions. Similarly, while many people signed up for the webinar, some were initially doubtful if it was aimed at them, as one interviewee said:

> *There's something about the comms about who is a practitioner and who this learning is for. So, I'd say that needs to be a bit clearer. I wasn't sure when I joined the webinar. Am I OK to be here? Basically, because I'm a consultant supporting people who are helping people at risk of self-harm and suicide. So, hopefully, it was OK for me to be there, but it did feel a little bit like I was surrounded by a bunch of people who had very different jobs to me, and I just didn't know whether I was in the right place. So, there's something about the comms around that.* [Practitioner 5, freelance online community management consultant]

Recommendations from practitioners aimed at improving the Hub included greater clarity about the target audience. One way to achieve this, as suggested by participants, was to create more tailored and adapted versions of the resources. For example, different settings (cultural backgrounds and age-related stages) in which people may encounter harmful online experiences could be specified in the Hub, which could both reflect the specific needs of service users and the community of practitioners. A more personalized approach would align well with other practices:

> *I think personalisation is a huge place of where we're at. Our well-being network operates on the same basis. People are given choices of topics, age groups of people they work with, and the areas they work in. And so the only information they receive is related to it directly to those. So there's a lot of information they miss out on that other people get based on their individual choices. So questions like why are you here? You know what do you do? Do you support people? OK, are you aware? Click on these areas that you're already aware of, and then it narrows everything down and deletes what's not, you know, necessary.* [Practitioner 4, health improvement specialist in mental health team of local authority]

Participants contemplating how to raise the issue of online harm in their professional practice made connections with how they might talk about it with other people in their lives, particularly younger people in their roles as parents, aunts, or uncles. As one participant noted, their learning from the Hub was of broader social benefit:

> *As a person with regular contact with young people in other roles and capacities as a parent, as an auntie, as a [youth group] leader, as you know, other things that I do in my role, in my life, I would say it probably has, like I might not have previously thought, to ask somebody about what they're accessing online and how that's making them feel and I feel confident to start that conversation with someone. So I would say yes, it has made me feel a little bit more confident and highlighted that that's a conversation I might need to have.* [Practitioner 2, public health practitioner and suicide prevention lead]

Through their engagement with the Hub, practitioners recognized the importance of raising online harm with people, whether those seeking support from them as practitioners or other people in their lives. In this respect, the Hub had achieved one of its key aims. However, the low uptake of the Hub appeared to be related to people not being sure if they were the intended audience. This has implications for how a CoP is created and how resources need to be targeted to those who might be able to use them.

The Sensitive Topic of Online Harm

The reason for people engaging with the Hub—online harm—was commonly reported to be a sensitive and challenging topic for people to talk about. Similarly, the topics of self-harm and suicide are generally considered to be difficult and sensitive. Expertise in dealing with sensitive issues generally, familiarity with online social life, and a shared understanding of the rationale for raising online harm all contributed toward helping practitioners feel more confident in having discussions about online harm.

We found that some practitioners were not used to raising the subject of online harm, which they connected to their own lack of familiarity with the different platforms used and less personal use of, for example, social media. Some of these practitioners associated their lack of familiarity with online life with being from an older age group. However, when they were already skilled and experienced at talking about the sensitive topics of self-harm and suicide, they were able to reflect on their existing competence in discussing difficult issues when considering how to raise the additional topic of online harm. This gave them some confidence when planning to incorporate the topic of online harm into their practice, as one practitioner described:

> *I ask all the generic, you know, do you have any thoughts to harm yourself and the scale and what's the intent and how often and frequent, but I don't actually ask a question about accessing material online and have they done so...I'm sort of thinking...what sort of question would be relevant to maybe add to that? To capture more people that maybe are using the internet or being exposed to content that is maybe not helpful. I am very familiar with the Samaritans because I've done their training previously as a Samaritan. I feel really confident to ask people about suicide....* [FG1 participant 3, private counselor and supervisor]

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One practitioner (who reported they were very familiar with a wide range of social media platforms) explained that they would routinely include discussion of online activities or triggers when talking to their clients:

> *...it's something that we do so routinely that they start to feel comfortable with us doing it, that they just sort of like, it's kind of like asking if, hey, are you OK? Is there anything you want to talk about that we asked him? Hey, the content that you've consumed on the internet, do you want to talk about it and how does it make you feel? And they do just answer it like any other question that we ask of them.* [FG1 participant 2, mental health worker in high-dependency rehab unit]

A central message of the Hub was that talking about online harm can be helpful and does not have to be avoided. This echoes much of the guidance about talking to people about suicide and self-harm; talking openly about these topics can help people explore their feelings and avoid secrecy and judgment [35,37,38]. The inclusion of videos of people talking about their lived experience of self-harm and online harm in the Hub was helpful in this respect, as one participant reported:

> *[T]here was that balance of some online access being supportive to somebody...who might self-harm and they might want to talk to somebody else, you know, to kind of let that out. To talk, you know, as an outlet, if that makes sense. But also there was that other extreme of, you know, I have seen stuff in media where by somebody's encouraging somebody to, you know, cause extreme harm to themselves or indeed end, you know, end their life so and so yeah it was I found it informative and educational.* [FG3 participant1, operations director for statutory advocacy services, organizational safeguarding lead]

Some participants suggested that resources, such as information and coping mechanisms, should be developed and provided directly to people at risk of online harm in relation to suicide and self-harm, in addition to the resources developed for practitioners. Practitioners who suggested this were aware of their limitations in reaching all the people who might be affected by online harm and felt that the ubiquitous nature of online life and potential harm needed further action to address. One participant framed this in terms of a "warning" that should be included when people buy a mobile phone, for example, alerting them to the potential negative aspects of accessing social media. The pervasive nature of online harm and the breadth of the population who might be affected were acknowledged by many participants. Sharing experiences during focus groups was also valued by participants, particularly by those who learned that others were routinely raising the topic of online harm in their work.

Incorporating New Knowledge Into (Shared) Practice

A raised awareness about the seriousness of online harm was frequently described as a result or outcome of taking the training and engaging with the Hub, for example, when asked about the main benefit of the Hub, one participant responded:

> *...bringing it up to people's attention because I am realising more and more that the internet has a big impact on our lives, and that can be positive; it can be negative. But I think just mainly putting it out there so that people are aware to consider it and not skim over it or think about the impacts because really people are using it in different ways. Some people might not even use it at all, but it's really hard to avoid the internet now.* [Practitioner 3, public health practitioner & previous frontline mental health practitioner]

Raised awareness was reported as a first step to eliciting change in the practitioner's practice. In both interviews and focus group sessions, participants shared how they had changed their practice or planned to change their practice as a result of engaging with the Hub. It was evident that some practitioners not only reflected on the impact the gained knowledge would have on their practice but also on how they could share and recommend what they learned to fellow practitioners in their organization and beyond. For example, when asked if the training had already improved the experience of interacting or engaging with service users, one practitioner answered that their service would now regularly inquire about adverse online experiences with all their service users in the future:

> *...now we are thinking of making it a part of our initial assessment. So there is an initial assessment that we do for us to measure what kind of crisis and what level, and taking this component and putting it there already, I think it'll be quite helpful for us because it would also give us a broader overview of where that person is and what kind of content they're engaging.* [Practitioner 9, manager of crisis hub]

Both the survey and focus group session with people with lived experience indicated the important role of being asked about online behavior by their practitioners. During focus groups, practitioner participants started to formulate specific conversation starters and questions as they reflected on how their engagement with the Hub could impact their practice, for example:

> *…the question which I think would be hugely beneficial even to friends, family or clients is to ask about is there anything you know that distresses you about the use of the internet and that can come up, that can be brought in at any time, more as part of the intake.* [FG1 participant 3, private counselor and supervisor]

Shared learning was expressed during the focus groups, as other participants agreed they would use similar questions and discussed how they found the evaluation itself useful in articulating their learning and changes to their approach.

The evaluation of the Hub showed that the key messages of encouraging and supporting practitioners to raise the topic of online harm with people they were supporting with the issues of self-harm and suicide were well received and likely to lead to changes in practice. Practitioners articulated a number of ways in which they planned to incorporate their learning from the Hub into their work. Despite working in diverse

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organizational settings, participants identified a common purpose and a shared interest in learning together about how to address online harm for people at risk of self-harm and suicide. The emergent CoP that engaged with the Hub was made up of people with shared concerns and experiences about addressing sensitive and difficult topics. Whereas the provision of online resources alone was insufficient in generating wide uptake, a more social approach to learning, which we conceptualize as a CoP, engaged practitioners more effectively.

Discussion

Principal Findings

This evaluation of the Samaritans' Hub, derived from activity data, survey data, qualitative interviews, and focus group sessions with practitioners, shows that the resources of the Hub were found to be helpful in informing and creating awareness about online harm by relevant practitioners. However, uptake of individual e-learning and downloadable resources was low in comparison with the opportunity to learn about the resources in the more sociable modality of synchronous or "live" webinars. We interpret these findings as an indication of the value and benefits of participating in a CoP. Our work adds to the previous literature on CoPs [11-17], to the evidence on interventions aimed at addressing online harm in relation to self-harm and suicide [19,22,31,35], and to the broader knowledge about how to implement online interventions [5,6,9,39].

Previous research identified the importance of being explicit about whom a CoP may benefit and fostering a sense of belonging among its members in order to prevent early dropout [40]. This was particularly important for the online CoP that emerged as people in diverse roles engaged with the Hub via the webinars. Uncertainty about membership of the community was linked to being unclear about the target audience of the intervention. It is important to "get the pitch right," as one interviewee noted (participant 2, public health practitioner and suicide prevention lead). Uncertainty about membership was resolved by participating in online webinars where people could share experiences and engage in a process of collective learning. While the CoP evolved from a shared interest (in this case for online harm, suicide, and self-harm), ways of identifying members, including the language used (eg, "practitioners"), and processes of sign-up (such as to e-learning from an institutional account) could impede community forming. Previous research has analyzed multiple ways in which online CoPs form [39], sometimes as a planned and organized endeavor, and at times, they are set up to stay in touch with other professionals, for example, after meeting at a conference [39]. An important feature of this CoP was the need to deal with a sensitive topic, supporting people with online harm, self-harm, and suicide, and the safe space that was provided for practitioners to discuss unfamiliar or unknown areas of the online world. In this context, the care taken by the webinar facilitators to acknowledge the potentially distressing nature of the subject matters of online harm, self-harm, and suicide, and the need for everyone involved to protect their own well-being was noted as an important strength by participants. This aligns with previous research indicating that delivering sensitive topics through sociable learning environments offers several benefits, which may explain the preferential uptake but may also have some drawbacks [41]. It fosters social interaction among participants, leading to social presence and the emergence of a sound social space, which in turn explains the quality of the learning experience. However, while it is essential for students in health and social sciences to receive education on sensitive topics such as sexual violence [42] or, in our case, to educate practitioners about online harm, increasing awareness of these topics can elicit emotional or distressed responses among learners [43]. Learning together through a CoP allows for peer and facilitator support.

Positive feedback from people who had engaged with the Hub about the contents and key messages indicated that this was an intervention that could help address online harm related to self-harm and suicide. The integration of knowledge about online harm with preexisting expertise in supporting people with self-harm and suicidal ideation was facilitated by the sociable learning of webinars and the sharing of knowledge about online life, such as social media, endorsed the Hub resources.

The online intervention shaped and informed the development of a CoP. However, the CoP also shaped the intervention. Changing the delivery modality of the intervention during the evaluation process to recruit more evaluation participants caused an increased uptake. What started as a mitigation strategy for low uptake of an evaluation resulted in a permanent addition to the online resource, with more webinars on the subject now being held regularly by the charity, resulting in a total number of about 1800 participants educated on the subject through the webinar by the charity in 2024. Furthermore, the question and answer sections of these webinars were especially emphasized as suitable ways to discuss and receive suggestions for individual experiences on the subject and to raise awareness about the issue. When a CoP simultaneously interacts with facilitators responsible for the webinar content, this can create a short feedback loop for the participants. The area of online harm is a quickly evolving field, necessitating such rapid feedback loops to keep the intervention, in this case, the Hub, responsive and up to date, which could facilitate knowledge uptake into practice.

Limitations and Strengths

Initially, we received very few responses to the survey, limiting our ability to evaluate the Hub. A strength of the evaluation was the flexibility of the charity in developing a new method of engaging people in the Hub and the evaluation through the delivery of webinars. This resulted in more responses. However, those responses were from webinar participants rather than practitioners who took the online training immediately after it became available. As such, it was not possible to evaluate how effective the Hub had been in changing practice, and further follow-up would be required to achieve this. An additional strength of the evaluation was the ongoing support and engagement of people with lived experience in the evaluation process who provided insights into what was helpful and important for those experiencing online harm, self-harm, and suicidal ideation.

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Conclusion

Online interventions that seek to facilitate training and implementation of evidence-based prevention strategies need to be supported by and are activated through collective learning processes such as CoPs. CoPs provide an infrastructure to support social learning and knowledge sharing, particularly in complex or uncertain contexts. Supportive, collective learning is particularly important when dealing with sensitive topics and concerns that are pervasive, such as online harm, and that are novel, for example, to people with less experience with internet safety and harmful online activity.

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Data Availability

Data available upon request.

Authors' Contributions

Conceptualization: GH, GM
Data curation: AM
Formal analysis: AM, GH, GM
Funding acquisition: GH, GM
Investigation: AM, GH, GM
Methodology: GH, GM
Supervision: GH, GM
Writing – original draft: AM
Writing – review & editing: GH, GM
All authors agreed on the final version of the manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1
The lived experience survey, postwebinar practitioners survey, interview topic guide, and topic guide for focus group.
[DOCX File, 1787 KB - formative_v10i1e72130_app1.docx]

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Abbreviations

CoP: community of practice
NHS: National Health Service

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Expanding the Digital, Donor-Assisted Conception Tool to Empower Parental Telling and Talking (TELL Tool) Intervention to the Pregnant and Early Parenthood Periods: Findings From a Qualitative Study

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Abstract

Background: Many parents who use donor-assisted conception to form their families struggle with telling their children about how they came to be. To address this problem, we created the Tool to Empower Parental Telling and Talking (TELL Tool), a digital, psychoeducational, and decision-support intervention for parents with children aged 1 to 16 years. Recently, we completed a pilot randomized controlled trial of the TELL Tool that showed feasibility, acceptability, and promise. However, in its current version, the TELL Tool does not include content for pregnant, expecting, or new parents with children less than 1 year of age.

Objective: The aim of this formative study was to understand the views of pregnant, expecting, and new parents who used donor-assisted conception to form their families, along with the views of practicing clinicians about disclosure to expand the TELL Tool for use during the pregnant and early parenthood periods in the United States.

Methods: Using a qualitative descriptive approach, a purposive sample of 20 parents and 10 practicing clinicians was recruited using a multifaceted recruitment plan. Each participant completed an in-depth, semistructured interview over Zoom that was recorded, auto-transcribed, checked for accuracy, and subsequently analyzed for themes. The rigorous and accelerated data reduction technique was incorporated into the analytic plan.

Results: Parents comprised pregnant (n=6) or new parents (n=15), as one parent was both pregnant and had a child less than 24 months of age. The 10 clinicians, consisting of an array of multidisciplinary health care professionals, were practicing in fertility/infertility (n=4), obstetrics and women's health (n=3), and reproductive or family health (n=3) settings. Four themes were identified from the analysis. In "Reasons for What Matters Most," all parents spoke in favor of disclosing to their children and shared their reasons, while clinicians reported the time limitations in clinical settings. In "Managing Emotions, Conflicts, and Needs," a myriad of emotions, including conflict, were entwined in the parents' experiences, and clinicians recognized parents' feelings and needs as well as their own. Within "Desired Content of a Digital Tool," participants provided invaluable feedback on what material and content would be helpful to both parents and clinicians. Participants voiced the design features that would resonate or be useful to them or their patients/clients in "Recommended Design and Usability Features."

Conclusions: Findings illustrate the distinct needs and desires of parents-to-be, new parents, and clinicians about providing expanded content for the TELL Tool that is informed by current evidence and end users, ultimately advancing best practices in this area. Future plans include testing the TELL Tool tailored to this additional developmental period of pregnancy/early parenthood.

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KEYWORDS

decision aid; digital health; disclosure; donor conception; embryo donation; family building; family support; gamete donation; parent-child relationship; pregnancy

Introduction

Donor-assisted conception, referred to as third-party reproduction, consists of the donation of gametes (sperm, oocytes) and embryos with the specific intent to assist others in establishing a family. As a family-building option, heterosexual couples who cannot conceive with their own gametes, same-sex couples, and single women or single men who want to establish a family often turn to donor-assisted conception. Individuals or couples who are at high genetic risk for passing on an inherited disease to their future children may also opt to use donor-assisted conception to avoid this risk [1,2]. Although prevalence data about donor-assisted conception are challenging to obtain [3-5], recent reports indicate an overall upward trend in the use of donor-assisted conception both globally and in the United States [6-9].

The landscape surrounding parental openness and information sharing (ie, disclosure) to donor-conceived children and individuals has undergone significant changes in the past several decades. Historically, donor-assisted conception was sought and performed in secrecy in efforts to protect parents and their children from psychosocial and legal implications, as the family-building option was viewed as a form of adultery [10,11]. However, in the 1990s, clinicians and researchers began to question the practice of secrecy [12], and a growing number were advocating for openness [13,14]. With the advent of direct-to-consumer genetic tests and the proliferation of social media, clinicians and researchers began to foretell the end of secrecy [15]. Despite this movement, disclosure is not universally accepted worldwide, and some countries mandate anonymity or even ban the use of donated gametes [16,17].

As the number of donor-conceived people (DCP) who are aware of their genetic origins has grown, knowledge about the effects of parents' openness has been examined. A review of 50 studies with 4666 DCP identified a positive relationship between early parental disclosure of donor conception origins and psychological well-being [18]. Moreover, most DCPs who learned of their conceptual origins in adolescence or adulthood were significantly more likely to be dissatisfied with the timing of the information shared and were more likely to react with negative emotions (eg, shock, confusion, anger) compared with those who were informed earlier [19]. Studies of family functioning in third-party reproduction have substantiated these findings [20-23]. Additionally, the ability of health care professionals to provide health care for children or adolescents is based on the accuracy of their health history [24]. Yet, parents who find it difficult to share information with their children also find it challenging to communicate the donor conception origins to their children's health care providers [25].

Nationally, US guidelines recommend that individuals and couples undergoing donor-assisted conception receive psychoeducational counseling from a qualified licensed mental health professional who has training and education in third-party reproduction. This counseling is "strongly recommended," and the guidelines list "disclosure" as a topic for the counseling session. More specifically, the American Society for Reproductive Medicine (ASRM) strongly encourages parents to inform donor-conceived children about the use of donated gametes or embryos in their conception, ultimately leaving the choice to the parents [26]. Individuals and couples undergoing donor-assisted conception can opt to select either a known or "directed" (eg, open-identity/open ID) gamete donors or a "nondirected" (eg, nonidentified, or anonymous) donor, although the ASRM purports that "anonymous" donors have become a rare occurrence due to the increasing access to direct-to-consumer genetic tests [2].

Notably, the European Society of Human Reproduction and Embryology Working Group on Reproductive Donation [27] heightened the need for disclosure and, in 2022, developed "Good Practice Recommendations for Information Provision." These recommendations state that parents need to be supported and informed on how they can talk age-appropriately with their children about their donor conception origins [27].

To begin to address the issue of disclosure, we created the Tool to Empower Parental Telling and Talking (TELL Tool), a digital, psychoeducational, and decision-support intervention. We designed the TELL Tool to aid parents in making informed and sequential decisions about sharing information (ie, telling and talking) about the donor-assisted conception with their resulting children [28]. The TELL Tool is comprised of 4 modules and includes interactive and multimedia (eg, audio and video clips, visuals, parent workbook) components. To provide age-appropriate information, the tool is tailored to 3 children's age-based categories (1 - 7 years, 8 - 12 years, and 13 - 16 years) guided by Jean Piaget's theory of cognitive development about children's thinking and reasoning [29-31].

As part of the TELL Tool's development process, we completed a mixed methods alpha test with 9 donor-gamete-recipient parents and 8 clinicians with expertise in counseling parents and families. We then revised and refined the tool [32]. Next, we carried out a randomized parallel, 2-group, attention-controlled clinical pilot trial of the TELL Tool among 75 donor-gamete-recipient parents [33]. Within and across these studies, we found the TELL Tool to be feasible and acceptable to parents, families, and clinicians. Importantly, the TELL Tool also demonstrated promising results in helping parents inform their children about their donor conception origins compared with attention controls [33]. Parents and pediatric nurse practitioners (PNPs) also provided in-depth responses about how to integrate the TELL Tool into pediatric settings [25]. While at present, the TELL Tool is designed for parents who have 1- to 16-year-old children, pregnancy and early parenting periods are critical for the formation of early bonding and

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attachment relationships between parents and infants and can be a powerful time for intervention [34,35]. To address this gap, the aim of this formative study was to understand the views of pregnant, expecting, and new parents who used donor-assisted conception and the views of practicing clinicians about disclosure to expand the TELL Tool intervention for use during the pregnant and early parenthood periods in the United States.

Methods

Study Design

This descriptive, qualitative study was conducted between September 2023 and February 2024 with donor oocyte, sperm, or embryo recipient individuals or couples who were pregnant, expecting, or new parents, as well as health care professionals who were actively practicing in fertility/infertility, obstetrics, women's health, family health, or reproductive health care settings. The rigorous and accelerated data reduction (RADaR) technique [36] that we [25] and others [37] have used in prior intervention development research informed the qualitative descriptive approach [38,39].

Ethical Considerations

Institutional Review Board examination and approval of the protocol (#HUM00232409) as exempt were obtained from the University of Michigan prior to the recruitment of participants to ensure the ethical conduct of the study. All participants provided verbal informed consent prior to data collection. The data collected for the study were deidentified to promote participant confidentiality. Each parent and clinician received a $25 gift card for participating in the study.

Sample and Setting

Overview

Parents and clinicians were purposefully selected based on their desired characteristics and the needs of the study [40]. "Parents" were defined as individuals or couples who were pregnant or expecting (eg, partner of pregnant individual), or a new parent with children 24 months or younger. The inclusion of new parents with children equal to or less than 24 months expands the sample to include those who were pregnant or expectant in the recent past. "Clinicians" were defined as health care professionals (eg, physicians, registered nurses, advanced practice nurses, psychologists, social workers) actively practicing and providing health care for individuals and couples who were undergoing or had undergone successful donor-assisted conception.

The inclusion criteria for both parents and clinicians were English-speaking and living in the United States, and the exclusion criteria were non-English speaking and not living in the United States. English-speaking participants were approached because the research team conducting the qualitative interviews was English-speaking. We required that participants live in the United States because governmental policies and cultural norms for donor-assisted conception vary among countries, and the target population for the TELL Tool is parents in the United States. Parent-specific criteria were that the individual or couple were pregnant, expecting, or a new parent through donor-assisted conception, and willing to talk about their views, insights, needs, and experiences about sharing conceptual information with their (future) children during the pregnancy and early parenthood periods. Clinician-specific inclusion criteria were that they provided health care for individuals and couples who were undergoing or had undergone successful gamete donation and were willing and able to express their views about expanding the TELL Tool into the pregnant and early parenthood periods. To ensure the clinician participants were knowledgeable about the TELL Tool, a form that contained key information about the tool, such as its purpose, content, and modules, was provided to each clinician prior to the interview.

The sample size was set at 12 - 20 for parent participants and 7 - 10 for clinician participants. The sample size and number of interviews were appropriate for achieving the purpose of the study based on our prior research as to when saturation occurred [25,32], International Patient Decision Aid Standards [41-43], expert recommendations for decision aid development [44,45], and experts in qualitative research [46]. The setting for the interviews was web-based, and the participants and the interviewers used a quiet, private location of their choice (eg, a room in their home or a discrete office room).

Sample Recruitment

We used a multifaceted recruitment plan that included web-based advertisements posted on websites and other digital media sites that were tailored to pregnant individuals and new parents; flyers were sent to professional email lists that were specific to fertility, obstetrics, or women's health clinicians; and our research newsletter. The principal investigator or other research team members would also relay information about the study when speaking professionally. All parents meeting eligibility requirements participated in the study; no eligible parent declined participation.

Data Collection Procedures

The qualitative interviews were conducted by one of two expert qualitative researchers who were also fertility/family (PEH) or obstetrics/women's health (KA) clinicians, and one junior member of the research team (Ruchi Bhagat). The interviewers completed field notes during and following each interview. Due to the wide geographical distance of the sample, online video/audio conferencing (Zoom Communications, Inc) was used to conduct each interview, which was digitally recorded and transcribed. Of the 20 parents, all used the camera feature, although one turned it off near the end of the interview, and 2 others had it on intermittently; all but 3 of the 10 clinicians used cameras. The research specialists (Ruchi Bhagat and MBR) verified all transcripts for accuracy, corrected errors, and deidentified them to maintain confidentiality.

Two-parent families were encouraged to complete the interviews jointly, to promote understanding of the dynamics of couple interaction. In instances where only one partner in 2-parent families was available to participate, the interview was conducted with only one parent because the TELL Tool intervention was designed to be used by couples, solo parents, or one partner in 2-parent families to allow for a wide range of

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family types and real-life situations among donor-conceived families. Pilot testing of the semistructured Interview Guide, which contained elements of the think-aloud method for interviewing, occurred during our prior qualitative research with donor-recipient parents and clinicians about disclosure [25,32,47]. The think-aloud method is useful when data are needed to understand how participants think and problem-solve tasks and is recommended for formative intervention research [48-50]. Examples of questions used in the interview guide are provided in Table 1.

Table . Semistructured interview guide: sample questions.

Question type	Parents	Clinicians
Broad opening question	• Think aloud about any thoughts that go through your mind about telling your (future) children about their donor conception origins and say what you are thinking and feeling. Be as detailed or take as much time as you need to express your thoughts and feelings.	• Think aloud about any thoughts that go through your mind as you educate and counsel [or how you might educate and counsel] your pregnant or postpartum patients/clients about how they can best prepare for telling their (future) children about their donor conception origins. Be as detailed or take as much time as you need to express your thoughts and experiences.
Follow-up questions	• As you think about telling your future children about their donor conception, what matters to you most? • Is there anything about your telling your (future) child that you would like to know during the pregnancy or as a new parent? If so, what would that be and why? • What materials or features of a digital tool or app would be most beneficial to you during your time as a parent-to-be or new parent? • What are some of the challenges (eg, concerns, worries) you have or foresee about telling your (future) child about how they came to be? • Are there any other types of information, thoughts, or feelings that are or will be important to you about telling your (future) children that we have not discussed that you would like to share? If so, please tell me what they are.	• What features of a digital tool or app do you see as being essential to help pregnant individuals, couples, or new parents achieve disclosure to their (future) children? • Prior to having pregnant or new parents use the TELL Tool[a], what qualifications or features would you like to know about before you recommend it to your patients/clients? • What concerns do you think your patients/clients would have about using a digital tool or app such as the TELL Tool? • Would you encourage your pregnant or new parents to use a digital tool *like* the TELL Tool? Why or why not? • Was there anything else about your patients' or clients' experience and the incorporation of a digital tool or app into clinical practice that is important but was not discussed or mentioned? If so, tell me what it was and why it is important.

[a]TELL Tool: Tool to Empower Parental Telling and Talking.

Data Analysis

A qualitative descriptive approach guided the data analysis to provide in-depth information required directly from those experiencing the phenomenon under investigation [38]. To complete the analysis, promote trustworthiness, and establish intercoder reliability, 2 participant transcripts were double-coded by 2 researchers, achieving over 80% of coding agreement across each transcript. Disagreements in coding were identified, discussed, and a consensus was established. Transcripts were then coded independently by the 2 researchers who met weekly over 3 months to discuss the coding process and debrief as the themes were developed and identified to capture the views and perceptions of the participants. In instances where dyadic parents participated jointly, each parent's data was analyzed separately, and couple interaction was examined for shared themes and differences. Consistent with the RADaR technique [36], comprehensive data tables for parents and clinicians were created in Microsoft Word as coding ensued. Then, data reduction and revision iteratively took place to produce more concise data tables that contained the identified themes. As the data tables were merged, reduced, and revised, areas of commonalities and differences across or between participants or the 2 participant groups (ie, parents, clinicians) were identified and grouped, which allowed for data triangulation. Field notes and initial analyses were also reviewed and compared for additional insights and nuances throughout the iterative analytic process, and these data were integrated when appropriate, further supporting intercoder reliability and coding consistency. Last, to further promote trustworthiness through researcher triangulation, an additional member of the research team participated in the analytic meetings, and the larger transdisciplinary research team members provided feedback about the emergent themes. Including multiple team members is a critical component of the RADaR technique [36].

Results

Sample Characteristics

The sample consisted of 20 parents and 10 clinicians. Parents were comprised of pregnant (n=6) or new parents (n=15), with one pregnant parent having a child less than 24 months of age.

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The parents ranged in age from 27 to 52 years, and most identified as female (n=18), White (n=15), and straight (n=18). Among the new parents, their children's ages ranged from 3 to 24 months. Fifteen parents were either married or living with a partner, and 5 were single (either single by choice or single never married). The donor-assisted conception type used by the parents was oocyte (n=11), sperm (n=5), embryo (n=3), and oocyte and sperm (ie, double donation, n=1). The sample of parents included one straight parent-couple family and one individual who used reciprocal in vitro fertilization (ie, a lesbian couple that uses donated sperm to fertilize one partner's oocyte to create an embryo, which the other partner carries) and was the gestational parent.

Clinicians (n=10) actively practiced in fertility/infertility (n=4), obstetrics and women's health (n=3), and family and reproductive health (n=3) settings and consisted of an array of multidisciplinary health care professionals that included Advanced Practice Nurses (n=4), Registered Nurses (n=2), and a Psychologist and Clinical Counselor (n=2). The clinicians reported an average of 16.65 years (SD 15.31) in practice (range 3 - 47 y) and nearly all were female (n=8) and White (n=9). Half of the clinicians identified as straight, and the other half represented sexual and gender minorities (ie, lesbian, bisexual, or queer). One clinician also participated as a parent.

Interviews

The in-depth interviews for the parents ranged from 24 to 75 minutes, with an average of 45 minutes (SD 16 min), while the clinicians' interviews ranged from 25 to 75 minutes, with an average of 36 minutes (SD 15 min). The one-parent-couple dyad in the sample participated jointly in the interview with their camera on; the one parent-clinician participant simultaneously completed the parent and clinician interviews.

Themes

Overview

Four interrelated themes were identified from the descriptive analysis across the parent and clinician interviews: Reasons for What Matters Most; Managing Emotions, Conflicts, and Needs; Desired Content of a Digital Tool; and Recommended Design and Usability Features. The interrelated themes are not mutually exclusive; rather, they developed as central areas of the participants' views about disclosure during the pregnant and new parenthood periods. Parent and clinician numeric codes are used in the text below to enhance understanding and provide further insight, yet maintain participant confidentiality. Tables 2 and 3 link the numeric codes to components of the parents' and clinicians' (respectively) demographic and contextual information.

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Table . Parent codes linked to demographic components. In certain instances, demographic data components have been disguised to enhance the confidentiality of the participants while maintaining contextual understanding.

Code	Donor anonymity type[a]	Race and ethnicity	Marital status	Donation type	Pregnant, expecting, or new parent[b]
21	Nondirected	White and Non-Hispanic	Married	Egg	Pregnant
23	Nondirected	Asian and Non-Hispanic	Married	Egg	Pregnant
25	Directed	White and Non-Hispanic	Single, never married	Egg, sperm (double donation)	Pregnant
58	Nondirected	Other and Hispanic	Married	Egg	New parent
27	Directed	White and Non-Hispanic	Married	Sperm	Pregnant
42	Nondirected	White and Non-Hispanic	Married	Embryo	New parent
53	Directed	White and Non-Hispanic	Single by choice	Embryo	New parent
29	Nondirected	White and Non-Hispanic	Married	Egg	Pregnant
44	Nondirected	White and Non-Hispanic	Married	Egg	New parent
51	Nondirected	White and Non-Hispanic	Married	Egg	New parent
46	Nondirected	White and Non-Hispanic	Married	Egg	New parent
32	Directed	White and Non-Hispanic	Single, never married	Sperm	New parent
36	Directed	Black African and Non-Hispanic	Single by choice	Sperm	New parent
38	Nondirected	White and Non-Hispanic	Married	Sperm	New parent
34	Nondirected	White and Non-Hispanic	Single by choice	Sperm	New parent
57	Nondirected	White and Non-Hispanic	Married	Egg	New parent
49	Nondirected	White and Non-Hispanic	Married	Egg	New parent
55	Nondirected	Other and Hispanic	Living with a partner	Egg	New parent
40	Nondirected	White and Non-Hispanic	Living with a partner	Egg	New parent
26	Nondirected	Black and Non-Hispanic	Living with a partner	Embryo	Pregnant

[a]Donor anonymity type at the time of the donation. Nomenclature is based on the recommendations from the Practice Committee of the American Society for Reproductive Medicine & Practice Committee for the Society for Assisted Reproductive Technology [2].

[b]One participant was pregnant and also a new parent; however, this linkage is not denoted to maintain confidentiality.

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Table . Clinician codes linked to demographic components. In certain instances, demographic data components have been disguised to enhance the confidentiality of the participants while maintaining contextual understanding.

Code	Employment status	Race and ethnicity	Health care discipline	Health care practice setting	Practice experience (years)
504	Full-time	White and Non-Hispanic	Registered Nurse	Fertility/Infertility	4
510	Full-time	White and Non-Hispanic	Registered Nurse	Fertility/Infertility	10
512	Full-time	White and Non-Hispanic	Psychologist	Reproductive/Family Health	12
513	Full-time	White and Non-Hispanic	Advanced Practice Nurse	Fertility/Infertility	13
515	Full-time	White and Non-Hispanic	Social Worker	Fertility/Infertility	22
518	Full-time	White and Non-Hispanic	Advanced Practice Nurse	Obstetrical and Women's Health	18
533	Full-time	Black and Non-Hispanic	Clinical Counselor[a]	Reproductive/Family Health	3
541	Part-time	White and Non-Hispanic	Advanced Practice Nurse, Midwife	Obstetrical and Women's Health	41
547	Full-time	White and Non-Hispanic	Physician	Obstetrical and Women's Health	40
554	Full-time	White and Non-Hispanic	Advanced Practice Nurse, Midwife	Reproductive/Family Health	4

[a]Bachelor's degree prepared.

Theme 1: Reasons for What Matters Most

Throughout the interviews, parents reflected on the importance of open communication with their (future) children. All parents spoke in favor of disclosing to their children and shared their reasons for it. Fifteen of the participants explicitly mentioned "honest," "open communication," and "no secrecy," and several shared insights into the value placed on openness, such as, "It felt better knowing that we weren't keeping the secret." (Parent 55). Parent 44 stated, "I want it to be clear. I want it to be transparent. I don't want there to be any shame attached to it." Another reason was fueled by the desire for the child to know they were wanted. Parent 38 said, "I want them to know how wanted they were," and Parent 32 added, "I think, like I want her to know that I was like really intentional creating her, and that like she's really valued and loved and appreciated."

Parents expressed other reasons for needing education and information about how to share their children's conceptional origins with them. One reason was parents' perceptions about inadequate education or an alternative focus on the counseling sessions that took place as part of their clinical experience. Parents made statements such as: "We had to talk to someone to get cleared." (Parent 38), or that they underwent "An evaluation of my husband and me" (Parent 23).

Parents recalled that clinicians provided beneficial education and counseling about the details needed to talk with and share information with their child.

> *Part of our fertility clinics requirements in order to do donor egg IVF, was a meeting with a psychiatrist in order to do an evaluation of my husband and me, and I found that evaluation to be really helpful.* [Parent 58]

However, some parents perceived that no clinician had discussed disclosing the conceptual origins to their children with them. One pregnant parent (21) replied when asked about any clinician addressing disclosure as part of the health care she received, said: "No, not a soul. Nobody except for the therapist, and that was because [it was required]." Another parent (32) shared, "…and no one, no healthcare professional, has talked with me about that at all."

The clinicians expressed reasons why a tool like the TELL Tool was not only to aid parents in their openness to their children, but they also recognized the often time-limited situations that occur in the clinical setting and the priorities surrounding clinical health care during the patient-clinician encounter.

> *In my current practice I am [time] limited. We only have 15-minute appointments. And I have to make sure I touch on all the important things about whether they're getting their third trimester labs on. Or, you know, do they want the new RSV vaccine; and giving them information about that. And they have to check with their insurance company, etc., etc. So, I hadn't even thought of talking to [patients] about that [disclosure to their children].* [Clinician 541]

Clinicians also reported their support for the TELL Tool because of the time spent addressing patients' emotional needs and the resulting stigma. For example, Clinician 504 said: "So usually what takes the most amount of time is just them telling me about

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the family situation and how they're afraid their children [will] get disowned [emphasis added]."

Theme 2: Managing Emotions, Conflicts, and Needs

Parents reported a myriad of emotions, including conflict entwined in the processing of using donor-assisted conception and contemplating their future disclosure with their children; and for many, the anticipation of unknown outcomes following telling. Clinicians also recognized parents' emotional and other needs, as well as their own needs as clinicians.

Most parents expressed the need for emotional support during their clinical care or when transitioning to parenthood. As Parent 55 stated, "I think there was maybe the lack of kind of explaining… the emotional aspect of it…. I think it was just left on our shoulders to try to figure that out." This notion was also recognized from a clinical standpoint by Clinician 513, as they expressed the need for the tool to "Talk about dealing with the emotional piece."

Parents went on to report specific emotions, such as experiencing grief, loss, and even trauma that surrounds the use of donor-assisted conception. "It is like death. It is like processing a death." (Parent 21). Another parent (51) stated, "I did want to process the grief. I wanted to make sure that when I went through this process that I like I had acknowledged [it]." Drawing from clinical experience, clinician 515 supported these sentiments by adding, "So I think it's a lot of the grief." Parent 21, who was pregnant at the time of the interview, reflected further about the impact of grief on her ability to tell her future child:

> *It's really emotional going through the process of looking at people's pictures [to select a gamete donor]. It's like you're shopping for somebody that's like you. But nobody is gonna be like you. And you have this weird mixture of excitement but sadness…. And you need to get through all that in order to make it to the end stage of being the parent, and then from there on out, being able to tell them… So that you tell them in a healthy way. And in order to get to the point of being able to tell them in a positive way, you have to process your own grief and trauma.*

Fear of their child rejecting them as a parent when they are told about their donor-assisted conception was acknowledged by many parents. Parents alluded to the emotional pain and the fears that disclosure evokes: "I worry about that hurting my heart" (Parent 53) and "I'm scared to have those conversations" (Parent 38). Parents specifically referred to fearing rejection and hoping for acceptance, as relayed by Parent 36, "…and the biggest question that comes to my head, and my greatest fear is still acceptance. Her, you know, accepting what I did. And not finding faults in it at the end of the day is like my greatest fear." Parents also voiced concerns about their (future) child navigating feelings and emotions such as shame or resentment, or feelings that would arise from being a "second choice" child. As Parent 49 explained, "I don't want them to ever feel like they are second choice, because obviously it's like 'Oh! She tried, she tried, she tried it, didn't work, and she couldn't have one the other way. So her last resort was us.'"

Notably, the emotions parents discussed were not always negative emotions. Rather, parents provided examples of pleasurable emotions such as feeling happy, celebratory, or optimistic. For example, Parent 38 framed her concern about her child not being a "first choice" as a positive emotion. She explained:

> *We're so happy that this is what this is who our family is, and I would want them to understand that piece. I don't want them to ever feel like that is like something shameful about them, or something that they need to hide or not talk about. I think it's like it is something that's slightly different about them than other kids. But like that's everyone has things that are different about them. And so like, that's the most important thing for me of just like feeling really proud [of] who they are. …and it wasn't our first choice. That's the reality, but it it's the best choice for us. [emphasis added]*

Managing the emotions that arose from partner conflicts about whether to disclose was viewed as a challenge by parents who were either married or living with a partner. Clinicians also recognized this challenge. While most dyadic partners agreed about sharing information early on: "We've typically landed on the same page." "So, we're both on the same page" and, "We really didn't run into any big discrepancies." (Parents 51, 23 and 27, respectively), several had stark differences as relayed by Parent 55:

> *I think the most challenging was the different perspectives we had in the beginning. I mean, we were kind of completely at opposite ends of the spectrum. So that was that probably initially, was probably the most difficult in coming to an agreement.*

In awareness of the interpartner dynamics and conflict that many parents face, Clinician 515 added that parents need to: "Recognize that, you know, if they have a partner, their journey is different than their partners journey."

As parents delved into their experiences with their partners, how and when to share information was also viewed as a source of conflict. Parent 38 stated: "He's like, 'Our kids are so little. Why is this a conversation that we're having right now?'" And further illustrated by Parent 29, "…I think it was just in the beginning, deciding like how often or how to bring it up to her." Last, one pregnant parent (26) reported having minimal discussion with their partner, in terms of disclosure, "We've not had much discussions about that because we're a little bit confused [about how to tell]. But I think it's something that we saved for the future."

Parents expressed the value placed on and the significance of receiving guidance from a health care provider who was knowledgeable and could field questions about navigating disclosure. And while clinicians, especially those practicing outside of a fertility setting, recognized their own need for education about how to counsel parents on best practices for disclosure, this well-informed counsel was expressed as a need by parents. Clinician 518 said: "Oh, I feel completely unqualified to do that [educate parents about disclosure]. I feel like that's an incredibly personal, like, parent decision. And I

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don't think it's something that I have any training or knowledge and feel confident, giving any advice about at all whatsoever." Concurrently, Parent 36 shared, "…make sure that whoever is talking to [you], ... passes the information in a way that is not hurtful that way. You know, you get to derive meaning…" This is further illustrated from the parent vantage point in Parent 44's observation, "…but I feel like every time I've hit a healthcare professional with like, 'she's donor conceived,' like they are like deer in headlights, like they don't know what to do. They don't know what to say."

Theme 3: Desired Content of a Digital Tool

Parents and clinicians gave invaluable feedback as they reflected on what content or materials of a digital tool would be helpful to them and their patients or clients. Parents emphasized the need for information about understanding how selecting a donor impacts the disclosure process. Parent 27 remarked, "But I do think it's important to, for parents to know what that [donor selection] process is and isn't, and sort of the difference between open ID and anonymous [donors]." Parent 44 alluded to regret and how, if better informed, she would not have chosen an "anonymous" donor: "I would not have gone -- I would not have gone with an anonymous donor by any means. I would have entered into a different contract than the one that I am currently in."

Parents sought guidance and information on how to discuss the donor conception with others, such as family and friends. While Parent 42 asked for guidance specifically on how to talk about disclosure with close family members, Parent 58 expanded on this sentiment: "And then also like what would be our game plan for telling people…close family members, friends, strangers." Parent 51 acknowledged, "I understand that she [her daughter] lives in a world that's beyond our little family bubble" and then recounted:

> *And then I find when I'm you know, talking to family, they don't have the language around it… like I said, my mother. my own mother said something about like, "Oh, do you know anything about the mother?" And like, I understand, for some people that would have really hurt.*

From a clinical standpoint, clinicians appreciated the challenge faced by parents and recognized the need for resources to aid in their support of parents. Clinician 515 stated, "To tell the people in their circle, then, is to tell the child. So, maybe telling their parent, or telling their in-laws, or telling their sister or their siblings, or whoever it is, touches that child every day. … I find that that's a little bit challenging for them as well." Across interviews with parents and clinicians, requests for and support of insights about the disclosure process from other parents who have experienced it were frequent. Parent 21 described the potential efficacious insights that could be gathered from others who are "ahead of my timeline," she said:

> *But those are the people whose insights I could use more from, I guess, because they've already been raising children in this circumstance. And so they're ahead of my timeline. And I wanna like, just sit down and like talk to them forever like about everything they've done -- and what they wish they had done differently. What's worked, what's not worked, and what is their plan for the next [step].*

Conversely, one parent (25) explained that hearing from others would not be helpful: "…I've noticed that I don't want to use other people's methods for my own method, because I tend to, then, second, guess myself. And so I'm planning on just instinctively, you know, going by it rather than creating a narrative, creating a strategy." This parent acknowledged that if she was underestimating the challenges within the disclosure process, it would be nice to know that the TELL Tool was available.

Parents also recommended that the tool contain insights and stories from DCP. Parent 29 said: "Oh, you know, stories from other, other donor conceived families. But stories from donor conceived adults -- and I think that, that would be more helpful." Concurring, Parent 32 shared, "… I would have really enjoyed and appreciated hearing other people's [DCP] stories and reflections on what was important to them growing up that would've been super helpful." Clinician 512 added that having a few DCPs talk about their experiences, such as "Here's what I wish my parents had said, or here's what I'm glad my parents have said to me" would be beneficial.

Details about the disclosure process, "I wanted to know the best way to do it." (Parent 51), including when to disclose and the frequency of follow-up conversations, were mentioned by every parent participant. While some parents touched on being told or knowing they should tell their child when they are "young" or "early" in life and "often" as stated by Parent 44, "…We obviously need to tell her early and often, is what I'm gathering." Yet parents, for the most part, were perplexed by what exactly this meant. Sharing in this sentiment, Parent 42 stated, "Then how do you know if you're talking too much?" Similarly, Parent 25 thought aloud: "And you're not gonna have these conversations with the kid until they're at least 3, I guess right?" further illustrating parents' uncertainty about the disclosure process.

Parents also requested guidance about terminology in relation to donor conception. Parents wanted to know what terms to use for gamete donors as well as others within the donor kinships. As examples, Parent 51 mentioned, "I'm still not sure how to talk about the donor herself. Right now, we're just talking about the fact that it's a donor." As parents thought aloud about the disclosure process, they requested age-appropriate, inclusive language and guidance about uncertainties and important aspects of the conversations. Parent 42 stated, "Even talking points that are age appropriate would be helpful." Parent 40 said, "What are the most critical things to share with her from a developmental standpoint?"

Parents referred to the potentiality of their children being in contact with or knowing the donor and donor siblings. Thoughts about these potential future relationships sparked parents to request guidance about conversing with their children and navigating these relationships. Parent 49 simply said, "How do I do that? That's something to think about in the future. Do I connect them? Do I not connect them?" Parent 23 echoed this thought, "… another concern I definitely have is just the concept

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of other siblings out there -- definitely like [to know] how to handle those conversations." Further illustrating confusion surrounding this facet, Parent 26 remarked:

> *… the kind of relationship I'll establish between my child's and the donor's [child(ren)]. So I feel I'm really so confused…Will I treat them as members of extended family, or I treat them as strangers, and all that? So I'm really confused about that.*

Theme 4: Recommended Design and Usability Features

Parents and clinicians reflected and thought aloud about the design, including the tool's usability features and the optimal time for accessing the tool during the pregnancy and new parenthood periods. Regarding the optimal time, almost all parents indicated that early in the donor-assisted process would be most beneficial. Parent 26 said, "I think the appropriate time should be even before the whole process of maybe going for embryo donation or egg donation." At the same time, many parents recommended multiple time points as illustrated by Parent 58: "It's important to do it multiple times. I would recommend it at the initial stage." Clinicians' opinions varied on the optimal time for administering the tool. Some clinicians felt it was best used in the fertility setting, while others viewed it as best once pregnancy was established. Other clinicians envisioned multiple times for its use, such as Clinician 510, who said:

> *I think we would definitely like send it off with them when they graduate after the pregnancy has been established, and they're going off to their OB, but I really also think there's a decent population of women who would find this incredibly helpful in their decision-making process [during initial clinical care].*

In terms of other specific features, slightly over half of the parents spoke of wanting the tool to provide a mechanism for connecting with other parents who were navigating the disclosure process. Parent 42 said, "It's nice to know you're not alone." Parents also recommended a chat feature or the inclusion of forums.

Parents and clinicians spoke of the variability of donor-assisted family types (eg, single mom by choice, heterosexual, same-sex), and shared they would find it helpful if the tool had the ability to provide customization based on family type and also donation type (eg, oocyte, sperm, embryo), as well as customization by the donor anonymity type (ie, directed or nondirected). These suggestions centered on ways to tailor the tool, as Parent 51 illustrated, "The ability to customize some of that information or instructions on how to personalize things" and Clinician 547, who said: "I'd say have it divided into sections like sperm donor conceptions."

Usability was a key design feature that parents and clinicians recognized as important, and remarked that the difficulty of use could be a challenge to parents. Suggestions included "ease of navigability" (Parent 58) and that the tool be "pretty smooth" and not "clunky" or "wonky" (Parent 21), and in general well-organized. Clinician 533 stated: "It should be easy to use." Parent 32 summarized these sentiments and said:

> *Sometimes the apps can be not very easy to navigate, and my frustration tolerance is really low right now. So, if it isn't easy or intuitive, if I can't skim it and kind of see that I'm gonna get something useful out of it, if it's hard to like get back to where I was. Like, say, the app closes or I get pulled away from my phone… I can imagine that it would be harder for me to use or for me to get much out of it.*

Additionally, parents described how they would ideally engage with a digital tool and their preferences for how the content is delivered. Parents and clinicians pointed out that the tool should be appealing to different types of learners and, as such, would have audio, video, and written text components. Clinician 533 said, "You know some people are auditory learners, you could, you know, have some little clips of clinicians or something, and explaining the process." In another example, Parent 36 preferred to watch videos and listen to podcasts or audio clips because the tone and emotion helped to make the information clear and provided comfort.

A potential challenge that some parents and clinicians identified with the design was regarding accessibility, particularly the financial cost of accessing the tool. Cost was perceived as a barrier to use, especially if there was a fee associated with its use. Clinician 554 stated: "My patients… are already spending a million dollars trying to do this [donor-assisted conception]."

Both parents and clinicians recognized privacy as a potential challenge of using a digital tool. Clinician 518 said, "I think confidentiality could be an issue with them [parents]." Confirming these clinician observations, one parent (26) explained, "I'm much concerned about the data privacy… such that every person's, every user, every user's information is protected, and no one else gets to access it." However, another parent (42) stated that although they were not specifically worried about privacy, their partner would see that as a challenge.

Evidence-based information and access to research and articles were revealed as important design features by parents and seen as a requirement of clinicians for a digital tool. Parent 23 stated: "Resources to like studies, maybe, and resources to books that we could -- we could leverage just for us to mentally understand it [talking with their children]" and Parent 32 simply added, "Yeah. Researched information." While Parent 44 shared, "I think it would be huge to have people that are pursuing this path like, to let them know it is actually best for the child, according to most research." From a clinical standpoint, safety and validity were of utmost importance, as concisely put by Clinician 533: "Has been tested" and illustrated by Clinician 547, "That it's evidence based."

Discussion

Principal Findings

To our knowledge, this study is the first to detail thick, rich data that reports pregnant, expecting, and new parents' and the clinicians' perspectives on disclosure to provide a foundation for expanding a digital tool, the TELL Tool, for use during the pregnant and early parenthood periods in the United States.

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Although we completed an earlier alpha test [32] and a pilot randomized controlled trial [33] using the existing TELL Tool, pregnant women and parents with infants were not eligible for these studies. Thus, from these parents' and clinicians' views, 4 themes: "Reasons for What Matters Most;" "Managing Emotions, Conflicts, and Needs;" "Desired Content of a Digital Tool;" and "Recommended Design and Usability Features" were identified that provide detailed and nuanced insight for expanding the TELL Tool into the pregnant and early parenthood periods. For example, the analysis for Theme 1, "Reasons for What Matters Most," revealed that all 20 parents wanted and intended to inform their children about their donor-conception origins. Their reasons for disclosing varied from wanting to prevent shame and avoiding the harm of secrecy within the family to ensuring their children felt loved and wanted. A 2024 comprehensive review reported similar parental reasons for disclosure [51]. However, we are less certain if all 20 parents will disclose as they intend, as research in the United States has demonstrated that many parents are unable to disclose or have not disclosed even when they have intentions to do so during pregnancy or in early parenthood [52,53]. Nevertheless, knowledge about deeply held reasons for disclosure during pregnancy/early parenthood is important to accomplishing our aim regarding expanding the TELL Tool.

An important finding was the varied experiences reported by parents regarding the Practice Committee of the ASRM's [2] recommended counseling session for individuals and couples undergoing donor-assisted conception. We found that some parents reported the session as beneficial, while others viewed it as a required step in the process or stated they did not recall any discussion about disclosure with a health care professional. This finding is noteworthy as our sample comprised those who recently underwent treatment (ie, pregnant/new parents) and were closer to recalling a counseling session versus those in our alpha test and pilot randomized controlled trial studies. Although it was beyond the aim of the study to verify if counseling sessions occurred and the quality of the sessions, this finding demonstrates the need for tools to supplement clinical counseling even during pregnancy. The topic of disclosure is one that parents will probably need to hear about multiple times from multiple people over a period of time—in ways that are developmentally appropriate for their children and for them as parents. The TELL Tool provides a detailed way to hear about this information, without the time pressure that office visits entail, and without any knowledge limitations of a particular provider.

This finding also links to the clinicians' self-identified needs for clinical education and counseling regarding disclosure in Theme 2: "Managing Emotions, Conflicts, and Needs," especially among those practicing outside of fertility settings. In our prior research, PNPs also expressed this need [25]. We acknowledge the multitude of ethical issues and clinical challenges this quandary presents. Steps such as ASRM's formation of the "Needs and Interests of Donor Conceived People and Their Families" Taskforce to examine provider education regarding the needs of families formed from gamete donation [54] and European Society of Human Reproduction and Embryology's practice recommendations [27] and research agenda to include developing innovative care models [55] provide blueprints for needed change. In our own work and given these findings, the next step in our program of research is developing interventions that provide high-quality education for clinicians about disclosure.

Regarding Theme 2, parents expressed the challenges of navigating negative (eg, fear, worry) emotions while at the same time appreciating positive (eg, happiness, pride) emotions. These findings imply that counseling via the TELL Tool, or when administered by clinicians, should address emotional support and include aspects of both positive and negative emotional states. Parents also interjected their concerns about their resulting child's emotional reactions and "acceptance" of their reproductive decision to use donor-assisted conception. Current literature supports early parental disclosure to promote acceptance [19-23] and, more globally, parenting interventions delivered in the first 3 years of a child's life have been found to support children's socioemotional development and infant-caregiver attachment in early childhood [56].

Conflict between partners in 2-parent families about disclosure was a concern expressed by both parents and clinicians. The findings highlighted the underlying reasons for dyadic-partner conflict, such as parents' lack of knowledge and, hence, the disagreement about knowing when to begin telling conversations with their children. This is a key finding that will be an important component for expanding the TELL Tool to this earlier developmental stage of pregnancy/parenting so that parents in 2-parent families can have more time to work out their understandings and reach, ideally, a shared approach.

Participants provided rich contextual information that captured nuances and subtleties for content surrounding disclosure in Theme 3, "Desired Content of a Digital Tool." Content about how the donor anonymity type (ie, directed, nondirected) can impact disclosure was suggested as helpful information within a digital tool. How to talk with others and learn from others' disclosure experiences—from both the parent and the DCP perspective—was also touted as essential content. Participants also suggested content on the "best way" or best practices to disclose, such as what age to inform their children and how often to return to disclosure conversations as their child grows. These findings point to parent and clinician recommendations for fostering a "healthy disclosure" that promotes parent, child, and family well-being, which is the fundamental aim of the TELL Tool intervention.

Despite the growing support for openness, understanding the specific components of a healthy disclosure is understudied in the field and provides a critical direction for future research. Notably, evidence supporting early disclosure has burgeoned [19,23] yet gaps remain about other disclosure components that lead to positive or healthy outcomes for parents and children over the life course [55]. For example, Best et al [57] in their reporting of in-depth research with 10 DCPs found that although early disclosure was preferred, other efforts to reduce DCPs' experiences of stigma and discomfort were the need for ongoing conversations with their parents about their donor-assisted conception. Future research that identifies disclosure components for best practices, such as those identified by Best

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et al [57] and in this study (eg, consider donor anonymity type when selecting a donor), would be helpful to families and desired content for the expanded TELL Tool.

Another critical need recognized by participants was the recommendation for content about navigating issues regarding the larger donor kinship. Parents and clinicians relayed concerns about talking about kinships and potentially establishing and navigating the presumed complex relationships with the donors, the donor's family, and donor half-siblings or donor whole-siblings (in the case of embryo donation). Other investigators including ourselves have examined these relationship nuances [19,58-63], and it has been documented that there is an ongoing need for supporting parents in navigating these relationships [64]. Our findings add to the growing call from clinicians, scientists, and parents alike that guidance and clear recommendations are needed to aid families in navigating relationships within the wider donor kinship.

Findings from Theme 4, "Recommended Design and Usability Features," represent participants' recommendations for how the tool's design can best help parents. The findings suggest that information about disclosure is needed early in the donor-assisted conception process. While several parents and clinicians suggested the best timing would be once pregnancy is established, others reported a clear need for information earlier in their clinical care, as gamete donors were being selected. This finding is important as we move forward with implementing design features into the expanded TELL Tool.

The finding that parents requested a tool that would allow them to connect with other parents was also conveyed in our earlier alpha testing research with donor-recipient parents [32]. These parallel findings may be because many parents who use donor-assisted conception constitute a hidden and often stigmatized population, and they are seeking a safe community where they can share similar life experiences. In a related population, and adding support for our interpretation of this finding, Rhee and Kim [65] found that mothers who experienced postpartum depression joined online support groups to fulfill a desire for connectedness and reassurance and to obtain information. Yet, it is possible the need to connect was more prevalent in this select group of parents who volunteered to participate in the study than in the broader population.

Other important findings were the requirement that parents' privacy be maintained if they use the tool and that it be accessible in terms of cost (ie, minimal cost or free). Given the historical context of donor-assisted conception and the secrecy, stigma, and lack of consistent parentage rights associated with third-party reproduction, we were not surprised that parents viewed privacy as a key feature for the tool. Other investigators have also identified privacy as a key feature of high-quality digital tools designed for parents [66] and that no- or low-cost digital tools increase parents' accessibility and use [67]. Clinicians voiced an added usability requirement that the tool be validated and found to be effective. In our study with PNPs about implementing the existing TELL Tool into pediatric settings, PNPs emphasized the need for a valid and reliable tool [25], and clinician views in this study were consistent, in further support of those findings. Our next step to further refine the tool is to include testing the TELL Tool tailored to this additional developmental period of pregnancy/early parenthood, as we did with the prior version of the TELL Tool, further strengthening the intervention. Future global research is needed with parents from other countries and from other cultural and political backgrounds to significantly expand knowledge about the disclosure needs of all parents.

Strengths and Limitations

The primary strength of the study is the engagement of pregnant and new parents who will be the end users of the expanded TELL Tool and the inclusion of clinician perspectives. Involving end users in formative research for developing decision support tools can lead to higher quality and potentially increase usability of the tool [43,45]. Another strength is the thick, nuanced, and insightful data provided by participants about the content and design features for expanding the TELL Tool. Additionally, parent participants were comprised of a range of family types and donor anonymity types, which provides a diverse set of perspectives. In the same vein, clinician experiences in providing health care ranged from 3 - 47 years, providing fresh outlooks as well as more seasoned expert perspectives. The clinician's areas of practice and discipline were varied, providing a breadth of experiences from which to draw insight.

Despite these strengths, the study has several limitations. First, the sample of parents was likely biased toward openness and disclosure by their willingness to participate in the study. We have found in our qualitative [52] and quantitative [33] research that US parents who are less open to disclosure or are more fearful of the consequences of it opt not to participate in our studies examining disclosure. Furthermore, in one of the few longitudinal studies examining disclosure, we found that even though 86% of pregnant women in the sample intended to tell their children or were undecided about whether to tell, only 14% were able to do so at the 12-year follow-up [52]. It is likely that some parents in this study may find disclosure difficult or challenging in the future. The findings need to be viewed through the lens of this sampling bias, such that parents who find disclosure difficult or are considering secrecy during the pregnant and early parenting periods may have other views that were not captured. We acknowledge that parents were English-speaking, US-based, and mostly White and female, which limits transferability, especially to parents of other racial or ethnic backgrounds and those living outside of the United States, where disclosure laws differ, or those who speak other languages. Because the purpose of the study was to expand the TELL Tool for use in the United States, we caution application of the findings to a wider, global audience of parents and clinicians.

Conclusions

The 4 interrelated themes that were identified from the parents' and clinicians' perspectives illustrate the distinct needs and desires of end users and clinicians to provide a formative road map for expanding the TELL Tool for use during the pregnant and early parenthood periods. These insights include knowledge about what drives parents' decisions for disclosure, which is critical to formulating the expanded content within the TELL Tool. Participants clearly described the impact and subtleties

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regarding emotions and the need to manage them when planning for and sharing information with children. Understanding nuances, such as between-partner conflicts about disclosure and the need for clinical education, was also an important finding. Thorough and comprehensive information about design and usability features, such as the need for the tool to ensure privacy and be low- or cost-free, was conveyed. Several important areas for future research were also identified. Notably, research that illuminates best practices that can aid parents in navigating the larger donor kinship relationships that disclosure brings forth is needed, as is research that identifies specific disclosure components that can lead to healthy parent and child outcomes over the life course. Future global research among parents from different racial, cultural, and political backgrounds would enhance understanding and likely improve parent and child health as well.

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Data Availability

Participants in the study were assured that all data would be kept strictly confidential and not shared, given the sensitive nature of the interview topic regarding children's genetic origins through gamete or embryo donation and the qualitative approach of the study. Specific inquiries about the data should be directed to PEH at phersh@med.umich.edu

Authors' Contributions

PEH contributed to the conceptualization of the study and was responsible for supervision, project administration, and funding acquisition. PEH also conducted the investigation and formal analysis and led the writing of the original draft as well as the review and editing of the manuscript. KA contributed to the investigation and formal analysis and participated in the review and editing of the manuscript. MBR was responsible for data curation and formal analysis and contributed to the review and editing of the manuscript. ALM contributed to the review and editing of the manuscript. CF, MD, HDG, SCK, and LAP each contributed to the conceptualization and formal analysis and participated in the review and editing of the manuscript. AMG contributed to the conceptualization and methodology, conducted formal analysis, and participated in the review and editing of the manuscript.

Conflicts of Interest

PEH discloses honoraria for speaking at The Donor Egg Meeting 2024 and the European Society of Human Reproduction and Embryology 2025 Annual Meeting. The Tool to Empower Parental Telling and Talking (TELL Tool) intervention is copyrighted by the Regents of the University of Michigan Innovation Partnerships (Invention Number 2023- - 596) and the University of Illinois Board of Trustees, University of Illinois Chicago (Invention Identification Number UIC-2020- - 151). The authors receive no monetary compensation for use of the TELL Tool and aim to keep the TELL Tool cost-free for parents.

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Abbreviations

ASRM: American Society for Reproductive Medicine
DCP: donor-conceived people
IVF: in vitro fertilization
OB: obstetrician
PNP: pediatric nurse practitioner
RADaR: rigorous and accelerated data reduction technique
RSV: respiratory syncytial virus
TELL Tool: Tool to Empower Parental Telling and Talking

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Survey Evaluation of the Role of Social Media and Social Support for Transgender, Nonbinary, and Intersex People: Observational Study

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Abstract

Background: Transgender and gender-diverse (TGD) people experience greater health disparities than their cisgender counterparts. Social determinants of health are linked to these health disparities in minority communities, including the TGD community. Lack of social support contributes significantly to these disparities for the TGD community.

Objective: The aim of this study was to evaluate the role of social media and social support groups among TGD patients who attend a transgender clinic.

Methods: A questionnaire was developed through an iterative process and emailed to TGD people attending a tertiary care TGD-focused clinic. The survey assessed social media use (platforms, duration, and adverse effects), social support groups (past participation and interest in current participation), and demographic characteristics (age, gender, race and ethnicity, educational level, religious affiliation, and income).

Results: Our survey garnered 48 responses. Of these participants, 50% (n=24) identified as transfeminine or transgender women, 29.2% (n=14) identified as transmasculine or transgender men, 8.3% (n=4) identified as nonbinary, 2.1% (n=1) identified as genderfluid, and 10.4% (n=5) identified as another identity. Our respondents' average age was 35 (SD 15.6) years. Nearly 70% (n=31, 64.6%) reported at least monthly transphobia, and 35.4% (n=17) reported at least weekly transphobia. Primary social support was reported as coming from an in-person significant other or friend 49% (n=24) of the time and from social media or online friends 12.5% (n=6) of the time. Social media was used for the primary purpose of interacting with queer or TGD people by 65% (n=33) of respondents, and the most common sites used were Discord, Reddit, and Instagram. Among respondents who either were attending or had attended a gender identity–focused support group, 61% (14/23) reported them being beneficial. In total, 52% (25/48) had never attended a support group related to their gender identity, and 60% (15/23) were open to attending.

Conclusions: This study found that social media is already being used by TGD people for the purpose of interacting with other queer and transgender people but also that there are risks associated with its use. Given this reality, counseling patients on social media use should focus on safety in use and honest discussions of both the risks and benefits associated with its use. Regarding social support groups focused on gender identity, many current or previous attendants reported that support groups were helpful for finding social support, especially early on in one's transition and when other avenues of support are not present. Additionally, many respondents who had never attended a support group were interested in attending for the perceived benefits of increased social support and interest in meeting other community members. Engaging TGD patients in the use of social media and social support groups for gender identity may help improve support, although exposure to hate and transphobia is a risk that comes with social media use.

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KEYWORDS

transgender; gender diverse; social support; social media; support group

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Introduction

Transgender and gender-diverse (TGD) people face hostile social and political landscapes in the United States. This includes rejection from social groups and family as well as discrimination both socially and politically [1]. Importantly, in relation to recent increases in antitransgender legislation, TGD people who have reported worry about rights being taken away have been shown to have higher rates of depressive and anxious symptoms [2,3]. Transgender people also face discrimination and harassment to a greater degree than cisgender people, including harassment specifically due to gender identity [4,5].

Largely as a result of discrimination and social stigma, TGD people experience greater health disparities than their cisgender counterparts. TGD people have higher rates of depression, attempted suicide, HIV, and experienced trauma. Nearly 60% of surveyed TGD people who reported a suicide attempt said that their family chose not to speak to or spend time with them or reported discrimination, harassment, or bullying at school and/or work [6].

The environments in which we live, work, and age can influence our health. Research has demonstrated correlations between social determinants of health and many health outcomes [7]. Social support is an important determinant of health [8]. An important component of social support, especially among younger populations, is social media. Social media has been shown to have both positive and negative effects on the mental health of queer people [9-11] but is understudied among TGD people of all ages. Moreover, tools used to measure social support are often underdeveloped when studying this population [12].

The objective of this study was to assess social media use among TGD people, including preferred platforms, reasons for social media use, and noted adverse effects associated with social media. Additionally, we aimed to gain a deeper understanding of the desires of TGD patients in relation to organized support groups.

Methods

Ethical Considerations

This study was reviewed and determined to be exempt from institutional review board approval (application 24-001890) by the Mayo Clinic institutional review board. This included a review of the finalized survey, recruitment email, and recruitment process as outlined in the application. Although this research focused on a minority population, this study was found to be exempt due to the lack of identifying information collected. Informed consent was collected in the form of a recruitment email that emphasized the optional nature of the survey, the benefits of completing the survey, and the fact that no known risks were identified in association with completing the survey. No identifiable information was recorded during the survey, and responses were recorded using HIPAA (Health Insurance Portability and Accountability Act)-compliant software. The participants were not compensated.

Setting, Population, and Data Collection

The questionnaire was developed by the survey team through an iterative process as no validated questionnaire existed (see the adherence to the Checklist for Reporting Results of Internet E-Surveys protocol [13] in Checklist 1). Survey questions collected information about social media use, social support groups, and demographic characteristics. Social media use information ranged from sites used, hours used, and adverse effects noted. Social support questions gathered information on support groups centered on past participation and desire for present participation. Demographic information collected included age, gender, race and ethnicity, educational level, religious affiliation, and income. No other identifiable information was collected. Volunteers were recruited via email through the listserv of the lesbian, gay, bisexual, transgender, and queer employee resource group to review the questionnaire and provide feedback to the survey team. We had 3 volunteers who provided feedback on the questions and answer choices. The full survey is available in Multimedia Appendix 1.

TGD people receiving care from the Transgender and Intersex Specialty Care Clinic (TISCC) at the Mayo Clinic in Arizona were recruited for this study. There were no exclusion criteria among this population. A list of emails was compiled from patients who were seen at the TISCC at the Mayo Clinic in Arizona between August 16, 2021, and August 14, 2024. The list of emails was screened, and duplicates were removed. Emails were sent out with individualized links, which only allowed for 1 response for each individual.

Using this list, surveys with informed consent documentation were sent out via email with reminders sent at 10 and 20 days after initial survey distribution. Recruitment and survey completion took place over the months of September 2024 to October 2024.

Statistical Analysis

Continuous variables were described using means, SDs, medians, IQRs, and ranges. Categorical variables were described using frequencies and proportions. Group comparisons were conducted using the Kruskal-Wallis test and chi-square test for continuous and categorical variables, respectively. All analyses were carried out using SAS (version 9.4; SAS Institute).

Results

Overview

A total of 48 responses, out of 236, were received, yielding a response rate of 20%. Additional demographics can be found in Table 1.

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Table . Demographics of the survey respondents (N=48).

Characteristic	Values
Age (year), mean (SD)	35.5 (15.6)
Age (years), median (IQR; range)	28.5 (23.5-45.5; 18-74)
Gender identity, n (%)	
Transfeminine or transgender woman	24 (50)
Transmasculine or transgender man	14 (29.2)
Nonbinary	4 (8.3)
Genderfluid	1 (2.1)
Other	5 (10.4)
Educational level, n (%)	
Some high school	1 (2.1)
High school graduate or GED[a]	4 (8.3)
Some college or 2-year college degree	24 (50)
4-year college graduate	8 (16.7)
Higher than 4-year college degree	11 (22.9)
Race, n (%)	
White	41 (85.4)
Other or preferred not to answer	7 (14.6)
Employment status, n (%)	
Working full time	22 (45.8)
Working part time	9 (18.8)
Student	8 (16.7)
Not currently working	7 (14.6)
Retired	2 (4.2)
Household income (US $), n (%)	
<25,000	6 (12.5)
25,000 to 39,999	5 (10.4)
40,000 to 54,999	4 (8.3)
55,000 to 69,999	2 (4.2)
70,000 to 84,999	2 (4.2)
85,000 to 99,999	3 (6.3)
100,000 to 149,999	5 (10.4)
≥150,000	12 (25)
Preferred not to answer	9 (18.8)
Religious affiliation, n (%)	
Agnostic	15 (31.3)
Atheist	11 (22.9)
Mormon	1 (2.1)
Catholic	2 (4.2)
Other Christian	5 (10.4)
Judaism	1 (2.1)
Other	7 (14.6)
Preferred not to answer	6 (12.5)

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[a]GED: General Educational Development.

Social Support and Social Media Use of Our Population

A total of 50% (24/48) of the respondents indicated that their support came from a significant other, spouse, partner, or in-person friends as evidenced in Table 2. In total, 12.5% (6/48) of the respondents reported that their primary source of support regarding their gender identity was online friends or social media.

Table . Social support (primary resources and discrimination) and social media use (sites used and adverse effects; N=48).

Question	Participants, n (%)
"What is your primary resource for emotional support regarding your gender identity?"	
Spouse, partner, or significant other	14 (29.2)
Friends, in person	10 (20.8)
Therapy	8 (16.7)
Family	6 (12.5)
Friends, online	4 (8.3)
Social media	2 (4.2)
Support group	1 (2.1)
Other	3 (6.3)
"How often do you deal with transphobia in your daily life?"	
Never	16 (33.3)
Monthly	14 (29.2)
Daily	9 (18.8)
Weekly	8 (16.7)
Social media as social support—respondents who reported that their primary purpose for using the following sites was "Interaction with other queer, transgender, or gender diverse people":	
Discord	18 (37.5)
Reddit	9 (18.8)
Instagram	6 (12.5)
Tumblr	5 (10.4)
TikTok	4 (8.3)
Snapchat	3 (6.3)
X (formerly known as Twitter)	3 (6.3)
Facebook	2 (4.2)
YouTube	1 (2.1)
LinkedIn	0 (0)
Pinterest	0 (0)
"Do you struggle with any of the following in relation to social media?"	
Exposure to hate	27 (56.3)
Exposure to transphobia	26 (54.2)
Self-consciousness	22 (45.8)
Overuse	16 (33.3)
Bullying	3 (6.3)
Addiction	1 (2.1)
Other	7 (14.6)
Did not use social media	2 (4.2)

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Regarding social media use as support for gender identity, 64.6% (31/48) of the respondents reported that they used at least one social media platform with the primary purpose of interacting with other queer or TGD people. The most common social media sites used with this as the primary purpose were Discord, Reddit, and Instagram, in that order.

Nearly 70% of respondents (31/48, 64.6%) reported experiencing transphobia at least monthly, with 35.4% (17/48) reporting experiencing transphobia at least weekly. Nearly 60% of the respondents reported that they were exposed to hate and/or transphobia on social media (27/48, 56.3% and 26/48, 54.2%, respectively), with these being the most common adverse experiences reported in relation to social media. Other common reported adverse experiences included self-consciousness and overuse.

Social Support Group Desires and Attitudes

In free-text responses, participants mentioned that social support groups helped allow attendees to "meet others like me" and that they helped in "extending my support network." Other responses mentioned the importance of social support groups, especially after recently coming out.

Among the 14 participants who reported that they had participated in a social support group but were no longer attending, responses were mixed about the effectiveness of support groups (Table 3). Some respondents reported that they were helpful, stating that "community is important when I first came out" and "social support groups are helpful by providing people with a safe space to exist." However, other respondents reported that they were less helpful, citing "differences" between themselves and other participants. Of these 14 respondents, approximately half (7/14, 50%) reported that they either were or were maybe interested in attending a social support group once again. Responses referenced the importance of making friends and social connections, whereas others stated the difficulties of making time for such commitments.

Table . Social support groups: use, perceived benefits, and desire for attendance.

	Participants, n/N (%)
"Are you currently, or have you ever attended a support group?"	
"Yes, and I'm currently attending"	9/48 (18.8)
"Yes, but no longer attending"	14/48 (29.2)
"No"	25/48 (52.1)
"Was this beneficial to you?" (Among responses of "Yes, and I'm currently attending")	
Yes	8/9 (88.9)
No	1/9 (11.1)
"Was this beneficial to you?" (Among responses of "Yes, but no longer attending")	
Yes	6/14 (42.9)
Mixed	2/14 (14.3)
No	6/14 (42.9)
"Would you like to attend a support group?" (Among responses of "Yes, but no longer attending")	
Yes	5/14 (35.7)
Maybe	2/14 (14.3)
No	7/14 (50)
"Would you like to attend a support group?" (Among responses of "No")	
Yes	9/25 (36)
Maybe	6/25 (24)
No	10/25 (40)

In total, from the population of respondents who were not currently attending a support group, 56.4% (22/39) reported that they either were interested or were maybe interested in attending a social support group. Respondents who were interested in attending a group cited wanting more "social interaction," "community," and "support." Some respondents who were not interested in attending a social support group reported that their support systems were "enough" and "adequate."

Discussion

Principal Findings

In a group of TGD people presenting to a tertiary care clinic, most (33/48, 65%) used social media to connect with people in their community. However, a smaller percentage (2/48, 4.2%) turned to social media as their primary source of social support. Among those who used social media, Reddit, Discord, and Instagram were the most popular social media sites used by

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respondents specifically for the purpose of interacting with other queer and transgender people. Our survey also demonstrated concerning risks, including exposure to hate, transphobia, and self-consciousness in association with social media use, but also benefits in finding community and support.

Beyond the use of social media, our results demonstrated that individuals such as spouses, friends, and family are important for social support. In our study, many of those who were attending a social support group reported that they found participation to be beneficial, especially for social support and for finding others in the community like themselves. Among those who had attended a social support group but did not find it beneficial, a common theme was differences between other participants and themselves. Among respondents who had never attended a support group, many reported some level of interest in attending a support group and cited interest in finding community, support, and others like themselves. Among those who did not report interest in attending support groups, many reported already having enough support among family and friends or that they were concerned about differences (including demographic differences such as age and years since transition began) between potential support group participants and themselves. This points to social support groups as a potential valuable resource, especially for those without other avenues of support.

Comparison With Past Literature

Prior studies have demonstrated the importance of social media as a tool for social support among TGD populations, although more research on social media use as support for TGD individuals has been focused on youth populations [14]. Social media has been shown to facilitate transgender adolescents' connections with peers and identification with role models. Among lesbian, gay, bisexual, transgender, and queer adults, social media has been identified as a place to seek social support from other individuals who share facets of one's identity (such as sexual orientation and race) [15,16]. The use of social media among younger populations has been thoroughly studied and shown to have effects such as exposure to cyberbullying and impacts on mental health [17]. Past studies have shown that, among TGD adults, exposure to transphobia, cyberbullying, and victimization has been noted as a potential adverse effect of social media use [18,19]. Beyond social media and known friends and family, in-person support groups have been found to be beneficial for marginalized communities [20] and specifically TGD people [21]. This is consistent with other studies [22] that have shown that TGD people who have never attended a support group view them as ways to find peer support and community. Social workers can engage patients and their families in the forming of these support groups and look to well-established clinics for resources [23].

Limitations

The limitations of this study include the small sample size as well as the lack of an existing validated questionnaire. As no validated questionnaire exists specifically for the purpose of assessing social support among TGD people in relation to gender identity, we had to create our own. Additionally, our survey response rate was 20% (48/236). A systematic review found that the average response rate in counseling journals is approximately 34.2% [24], which puts our response rate slightly below but within 1 SD of the average from the latter study. Still, this relatively low response rate could introduce nonresponse bias, and to better understand our population, we will need a future study with a strategy for a higher response rate. Finally, our sample for this study comprised patients at the TISCC at the Mayo Clinic in Arizona, which is not demographically representative of the TGD community across the country. Thus, our survey suffers from nonresponse bias and, additionally, may not be generalizable to transgender adults across the United States.

Conclusions

Our data help further the understanding of social media use and social support groups for TGD people to better inform physical and mental health professionals as to how to best meet the needs of TGD people. This study found that social media is already being used by TGD people for the purpose of interacting with other queer and transgender people, but also that there are risks associated with its use. With both positive and negative effects of social media use among TGD adults, counseling with patients seeking social support can be focused on safety in use. Although more research on this is necessary, forums where interactions occur among known groups with moderators (such as Discord and Reddit, identified by survey respondents as being used for connecting with other queer individuals) may provide safer ways to find social support.

In addition to social media, support groups were reported by many attendees to be helpful for finding social support, especially early on in one's transition and when other avenues of support are not present. Offering support groups as part of TGD care may be something to consider given the disproportionate social stigma and resultant health disparities faced by this population.

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Data Availability

The datasets generated or analyzed during this study are available from the corresponding author on reasonable request.

Authors' Contributions

Conceptualization: KN, RH, JMK, BT
Data curation: CD
Formal analysis: CD
Funding acquisition: JMK, BT
Investigation: KN, VCI, RH, JMK
Methodology: KN, VCI, RH, JMK, BT
Project administration: RH, JMK
Resources: KN, VCI, RH, JMK, BT
Supervision: RH, JMK, BT
Validation: CD
Visualization: KN, VCI, RH
Writing – original draft: KN, VCI
Writing – review & editing: KN, VCI, RH, JMK

Conflicts of Interest

None declared.

Multimedia Appendix 1
Survey as presented to participants.
[DOCX File, 19 KB - formative_v10i1e79614_app1.docx]

Checklist 1
CHERRIES checklist.
[DOCX File, 19 KB - formative_v10i1e79614_app2.docx]

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Abbreviations

HIPAA: Health Insurance Portability and Accountability Act
TGD: transgender and gender-diverse
TISCC: Transgender and Intersex Specialty Care Clinic

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Using a Transdisciplinary Approach in Learning Communities for Designing Wearable Stress Management for Vulnerable Populations: Development and Usability Study

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Abstract

Background: Software solutions for wearable-based stress monitoring offer significant potential in health care, particularly for vulnerable populations such as individuals with dementia or persistent physical symptoms. Despite technological advances, designing user-centered, ethically grounded, and contextually relevant software remains challenging. Vulnerable populations often have specific cognitive, physical, and emotional needs that require customization, yet these are rarely prioritized in mainstream development. Our so-called Sensors2Care project addressed these challenges by co-developing stress-monitoring prototypes in collaboration with stakeholders from health care, law, and technology within a transdisciplinary setting.

Objective: This article has two aims: first, to describe how the Sensors2Care project operationalized the transdisciplinary approach (TDA) within a learning community (LC) to guide the development of stress-monitoring software; second, to share stakeholder needs and design requirements for wearable technologies in complex health care contexts, derived from this process.

Methods: The Sensors2Care project applied a TDA embedded in an LC. This approach combined participatory design research with mixed methods across 3 iterative components: requirements gathering, prototype development, and early-stage evaluation. Research activities included scoping reviews, semistructured interviews, focus groups, legal analyses, and field testing. In the LC, students and researchers from health professions, computer science, and law collaborated with patients, (in)formal caregivers, and industry partners in a transdisciplinary consortium. User stories served as both a methodological tool and design outcome, helping to capture stakeholder needs and align input from technical, health, and legal domains. Feedback was collected continuously and used to refine requirements and prototypes throughout the development process.

Results: User stories revealed 7 key themes relevant to developing and using wearable-based stress monitoring, including strategic use, notifications, user input, data insight, data access and sharing, hardware design, and support. Stakeholders emphasized the need for customization, durability, and comfort, aligned with the cognitive and physical needs of the target populations. Prototype evaluations indicated the practical relevance of these features and revealed a need for training and insight into long-term usability. Beyond their role in capturing content-driven input, user stories also supported transdisciplinary collaboration by aligning legal, health, technical, and experiential perspectives. This was facilitated by the LC structure, which enabled sustained engagement between students, researchers, and societal stakeholders and illustrated the feasibility of implementing TDA in a university context.

Conclusions: This project illustrates how TDA, when embedded in an LC, supports the co-development of ethically grounded, contextually relevant, and practically applicable stress-monitoring software for vulnerable populations. The iterative design process enabled early integration of legal, health, and technical considerations, while user stories supported structured collaboration across domains. Although the project resulted in concrete prototypes and clustered design requirements, further research is needed to assess long-term use and real-world implementation across health care contexts. Embedding TDA in LCs may strengthen future professionals' ability to address complex health care challenges collaboratively.

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KEYWORDS

transdisciplinary research; learning communities; wearable technology; stress monitoring; participatory design; digital health

Introduction

Overview

Technological advancements in wearable devices, data acquisition, and algorithmic processing (eg, machine learning) are transforming health care by enabling continuous and minimally invasive health monitoring [1]. Wearable devices are increasingly studied in health care, for instance, in smart health monitoring systems [2]. By being worn directly on the skin at various locations (eg, wrist, finger, chest, ankle), these devices facilitate continuous data collection, providing valuable insights into both physical and mental health parameters. Notably, they allow the tracking of stress, an essential factor in health management, through physiological markers such as heart activity and skin conductance [1]. The ability to monitor stress in daily practice in a minimally invasive way holds a particular promise for improving care and outcomes for individuals with complex health needs.

Despite this promise of wearable devices, their design and implementation often focus on younger, healthier populations, leaving vulnerable groups underserved [1,3]. Wearables for health care are typically developed for general lifestyle improvements [4], rather than addressing the specific needs of vulnerable populations, in health and care contexts. The complexity of designing systems that are both effective and feasible for these populations highlights the need for inclusive approaches. Designing and implementing wearables in diverse, real-life, care settings remains preliminary, complex, and requires cross-sectoral collaborations between academia, health care, industry, and users [5,6].

Recent reviews and studies provide further evidence of these challenges. Most work has concentrated on technical feasibility and algorithmic accuracy, with relatively little attention to usability, acceptability, and long-term adoption in health care contexts [2]. Although an increasing number of wearable devices are available, research on their validity, reliability, and usability, including user-friendliness and user acceptance, remains limited [7]. Evidence involving vulnerable populations shows both potential and barriers: Wearable biofeedback, for example, has shown promise for people with mild intellectual disabilities, but required substantial caregiver support and was difficult to integrate into daily routines [8]. Moreover, stress-tracking technologies often produce non-transparent scores that are difficult to interpret, increasing the risk of misinterpretation or misguided actions based on misleading feedback [9]. These challenges highlight the responsibility of designers to ensure that wearable feedback is meaningful and supportive.

To facilitate inclusive designs in health care, this study introduces the Sensors2Care project, which demonstrates how a transdisciplinary approach (TDA) can be applied within learning communities (LC) through 2 use cases of vulnerable populations.

Sensors2Care Project

Designing wearables for stress monitoring involves making choices that need to balance technical possibilities with contextual requirements. Studying multiple use cases helps to distinguish context-specific from general requirements, strengthening the relevance of resulting design insights. Early identification and monitoring of stress are particularly beneficial for persons with various health conditions [2,10], highlighting the relevance of examining multiple contexts. The Sensors2care project, therefore, focused on 2 health care use cases: dementia and persistent physical symptoms (PPS).

Dementia is often associated with challenging behaviors [11] like anxiety and agitation, influenced by underlying stress [12,13]. These behaviors can negatively impact the quality of life of individuals and place a heavy burden on caregivers [14-16]. The other use case, PPS, includes distressing somatic complaints, such as pain and fatigue, that last several months or more, regardless of their cause. These symptoms occur in the context of somatic diseases, functional somatic disorders, mental disorders, and undiagnosed conditions and are a core problem in a wide range of medical disciplines [17]. PPS is characterized by a close interplay between symptoms and stress regulation: difficulties in perceiving bodily signals [18], regulating emotions [19,20], and maintaining autonomic balance [21] may exacerbate stress responses, which in turn can worsen symptoms [22]. These symptoms often limit daily functioning and create a substantial burden for patients and health care providers. In both use cases, PPS and dementia, stress management is already part of usual care [23,24], as timely stress identification can support tailored interventions, improve well-being, and reduce care burden.

Stress can be assessed using multiple methods, such as wearable devices that provide objective physiological data [2], caregiver observations, or self-reports like the Perceived Stress Scale [25]. The use of stress data depends on the context: individuals may use it for self-management and personal insights (quantified me), while (in)formal caregivers may monitor and support others (quantified you). Wearable devices enable real-time, remote stress monitoring, offering potential for timely interventions and quality of life improvements. However, prior research on wearables has mainly demonstrated technical feasibility, while challenges of usability, integration into daily routines, and long-term adoption remain insufficiently addressed [2,7]. Designing a wearable-based system that meets the practical and contextual needs of vulnerable populations and can be implemented successfully remains a complex challenge.

The Sensors2Care project explores how wearable-based stress-related measurements could be integrated into health care by developing prototypes that address social, technical, legal, and clinical requirements throughout the design process. The project combined TDA principles with LCs to address the complex challenges of designing stress-measurement wearables for vulnerable populations. Dementia care often relies on caregivers (quantified you) to interpret stress data, whereas PPS

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emphasizes the role of self-monitoring (quantified me) to empower individuals in managing their symptoms. Together, these contrasting yet complementary use cases provide a diverse testing ground for research and design activities informed by TDA. Considering both use cases in parallel allowed for a systematic analysis of requirements across different care contexts. This strengthened the robustness and practical relevance of the design insights.

Transdisciplinary Approach

Designing and implementing wearable-based systems in real-life care settings involves challenges that extend beyond technology. The Non-adoption, Abandonment, Scale-up, Spread, Sustainability (NASSS) framework [26] highlights how implementation of innovative health care technologies frequently fails when challenges in key domains remain unaddressed, including the technology domain (eg, feasibility, interoperability), the value proposition and adopter system (eg, legal compliance, data governance), and the condition and context (eg, clinical relevance and fit with care practices). These domains represent common barriers to sustainable adoption in complex care settings and are therefore essential to consider in early stages of design and development.

Addressing these domains requires cross-sectoral collaboration, demanding approaches that integrate diverse types of knowledge and experience. TDA is particularly suitable for this task [27]. TDA extends beyond interdisciplinary research by integrating academic knowledge from diverse disciplines and incorporating non-academic perspectives, such as those of caregivers, health care providers, and technology companies [28]. By combining scientific, experiential, and local knowledge, TDA supports the co-creation of solutions that are relevant, robust, and practicable, thereby facilitating adoption and implementation in practice.

Despite the increasing number of studies on TDA, debate remains regarding its definition and methodological application. For an overview of diverse TDA definitions and shared characteristics, see [28]. A core characteristic of TDA is the integration of multidisciplinary and non-academic knowledge to address complex real-world problems, enabling context-sensitive and actionable insights grounded in scientific, professional, and lived experience. Another key characteristic of TDA is reflexivity. The continuous consideration of the broader research context and the alignment of project components and activities throughout the process. Such reflexive practice supports coherence within complex collaborations and the joint development of robust and societally relevant knowledge [27,28]. Through cross-sector collaboration, TDA offers a framework to design solutions tailored to the needs of vulnerable populations, such as individuals with dementia and PPS. Designs that are informed by such integrative processes are more likely to be accepted, adopted, and sustained in real-world care settings [26,28].

In the Sensors2Care project, TDA functioned as an overarching framework that was operationalized through participatory design approaches. Participatory methods, including human-centered design [29], generative design research, and the use of probes and prototypes [30], emphasize collaboration by actively involving end users to shape interventions that address their specific needs and circumstances [31]. Within TDA, participatory approaches provide concrete practices for co-creation, while TDA itself complements them by integrating knowledge across disciplinary and sectoral boundaries and fostering collaboration at multiple levels [27,28,32].

Learning Communities

LCs play a key role in facilitating TDA by providing a collaborative framework for knowledge exchange and co-production. In this article, an LC is considered a structured, participatory environment where diverse stakeholders, including students, professionals, researchers, and experts by experience, engage as co-learners to share knowledge, address disciplinary barriers, and collaboratively develop innovative solutions. Cundill et al [33] describe how communities of practice facilitate TDA by enabling external partners to engage with core group activities, thereby addressing disciplinary power imbalances. Rather than being artificially created, such communities are nurtured through mutual engagement and collaboration. Within TDA, co-producing knowledge is viewed as a process where experts from different fields come together as co-learners to develop a “shared vocabulary“ that fosters shared understanding and vision [34]. Learning is thus framed as a social process, embedded in practices that are central to successful knowledge exchange [35]. As such, LCs form a foundation for developing innovative and inclusive solutions to complex health care challenges.

While LCs have been recognized as valuable tools for transdisciplinary collaboration, their practical organization remains challenging, particularly when involving students from different disciplines. Challenges include ensuring equitable participation, sustaining meaningful collaboration, and managing the complexities of co-creation across academic and non-academic boundaries [33,35]. In transdisciplinary research, enabling students from diverse disciplines, such as health care, computer sciences, and law, to collaborate with professionals and researchers, provides a structured way to integrate perspectives and develop shared solutions to complex challenges.

As highlighted by Lawrence et al [28], more empirical examples are needed to demonstrate how transdisciplinary collaboration can be organized and implemented in practice. The purpose of this article is twofold: first, to show how the Sensors2Care project used LCs as a setting for applying transdisciplinary research, to develop a stress-monitoring system using wearables for individuals with dementia and PPS; and second, to share insights into stakeholder needs and design considerations that emerged from this approach. By detailing the project’s co-exploration and conceptual design stages [29,30], we illustrate how LCs can bring together students, researchers, and professionals to foster knowledge exchange and collaboration in transdisciplinary research projects.

Methods

Organization of the Learning Community

In the 2-year Sensors2Care project, TDA was adopted within our LC. The project was explicitly designed to integrate

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academic and non-academic knowledge across scientific, professional, and experiential domains [27,28]. Disciplines relevant for both prototype development and implementation [26], including health, computer science, and law, were represented by researchers and students as future professionals. These domains were included based on known implementation challenges described in the NASSS framework [26], ensuring that technical, organizational, and contextual barriers were methodically addressed in the design process. This design was guided by the TDA principle that "rigor in applied science meets societal relevance" [28]. Additionally, the LC involved non-academic stakeholders, including (in)formal caregivers and patients from 4 health care institutions (2 specializing in PPS treatment and 2 nursing homes for individuals with dementia) and 6 small to medium enterprises (SMEs) in the IT sector. The LC functioned as a collaborative and reflexive environment in which participants considered the broader project context, aligned activities, and integrated diverse insights to co-produce knowledge. Together, these academic, professional, and experiential contributors represented diverse knowledge domains, operationalizing TDA's principle of co-production across these domains.

The research activities followed a structured, iterative process designed to facilitate co-learning and knowledge integration among health care, computer sciences, and law [34]. All phases, from requirements gathering to application development and evaluation, were informed by diverse expertise and stakeholder input. The overall research framework is illustrated in Figure 1 and elaborated in "research activities." Researchers provided continuity and methodological guidance, while students participated as active contributors through graduation projects and internships. Their participation was supported by the university's programmatic assessment framework [36,37], an educational approach that emphasizes continuous feedback and reflection rather than single-point evaluation. Within this system, students collected feedback from multiple stakeholders in the LC, including professionals, researchers, and end users, thereby fostering reflexivity and knowledge exchange in line with TDA's principles [27,28,33]. The LC structure (Figure 2) combined recurring student participation with stable involvement of researchers and non-academic partners, ensuring effective knowledge transfer and continuity over time. This rhythm supported iterative cycles of learning and reflection. Each semester, 3 LC-wide meetings facilitated cross-sectoral collaboration and iterative feedback: at the outset (orientation and expectation management), midway (joint evaluation and refinement), and at the conclusion (integration and dissemination of outcomes). Additionally, smaller groups within the LC met in various configurations as needed over time to address specific research activities. Together, these structured and flexible interactions maintained coherence and fostered ongoing joint reflection throughout the process, consistent with reflexivity as a continuous, collaborative practice within transdisciplinary research [35].

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Figure 1. Research framework of the Sensors2Care project, including research and design activities. The project followed an iterative, transdisciplinary process structured around three key components: (1) requirements gathering, (2) application development, and (3) evaluation. Each component integrated expertise from health care, information technology, and law to address technical, clinical, and regulatory aspects. Activities included stakeholder consultations, exploratory wearable studies, legal analyses, and software development. Project outcomes (user stories, prototypes, and evaluation reports) were continuously refined and validated. This framework provided a structured approach to developing stress-monitoring wearables for vulnerable populations.

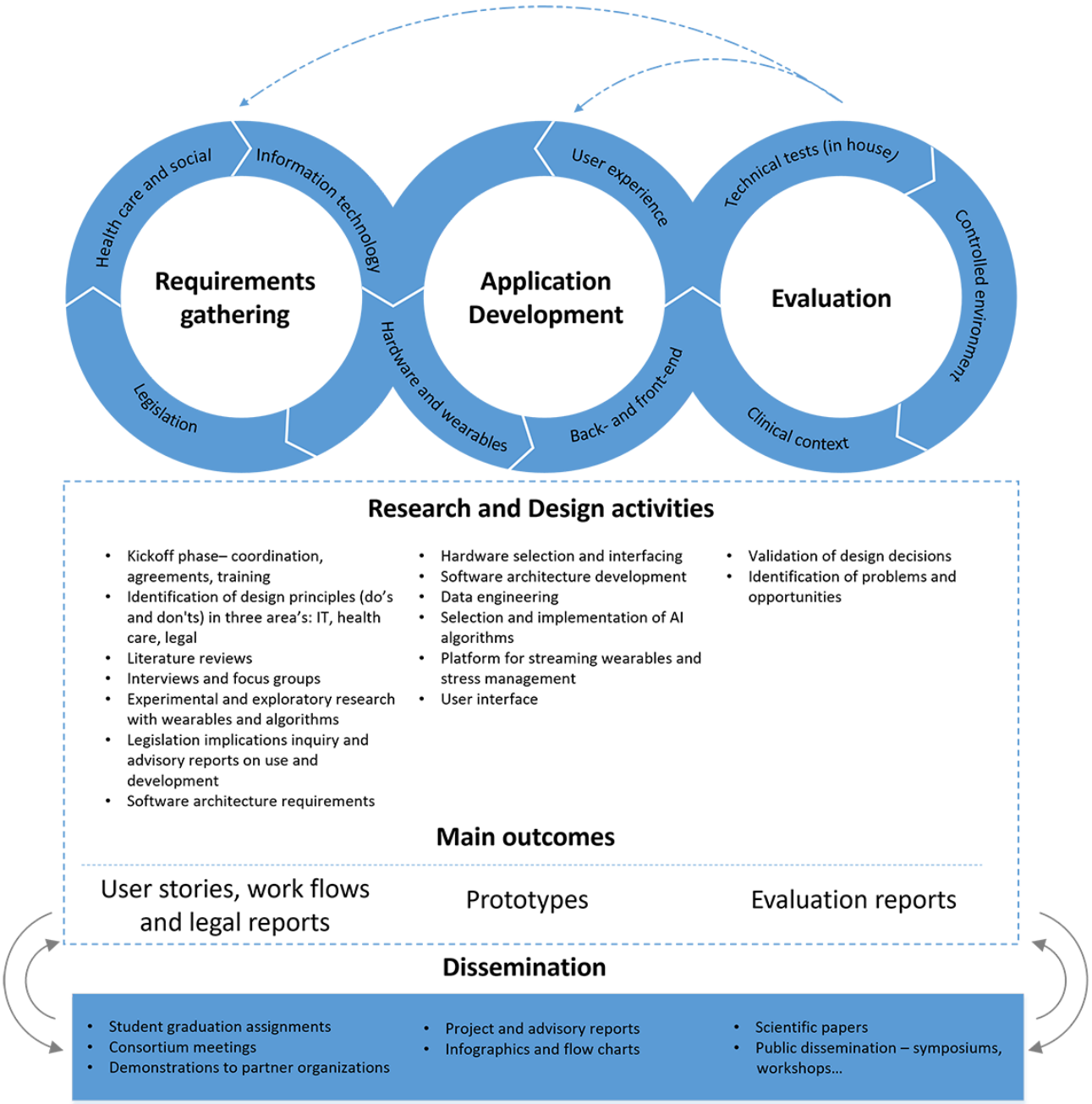

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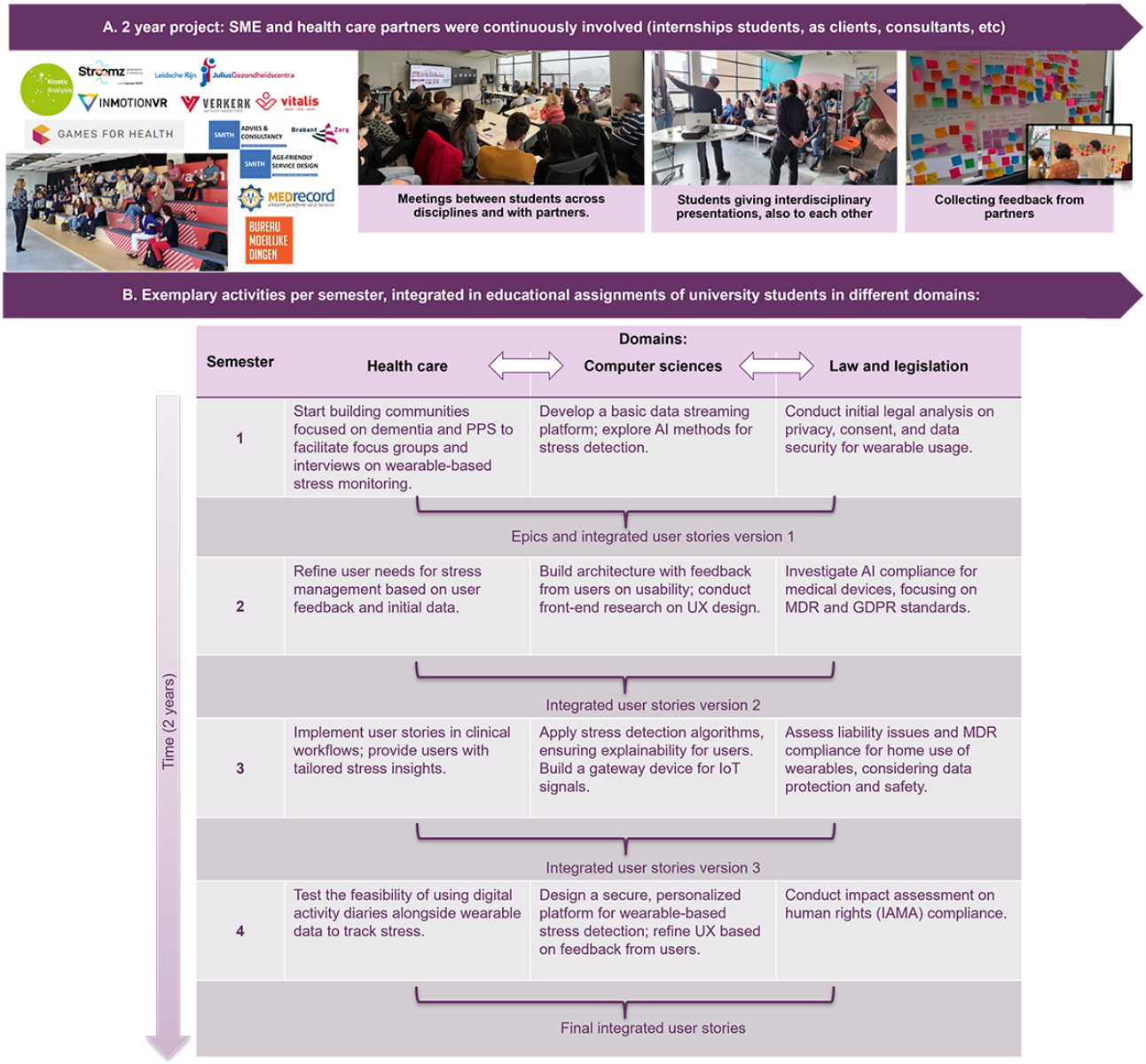
Figure 2. Operationalization of TDA within a learning community involving students, university researchers, health care professionals, and industry partners. (**A**) Stakeholders (small and medium enterprises and health care partners) were continuously engaged, together with students and university researchers. (**B**) The 2-year project was aligned with academic semesters to maximize student participation. In semester 2, epics and initial integrated user stories were defined collaboratively. At the end of each subsequent semester, interdisciplinary results and deliverables were synthesized into updated user stories, informing the subsequent semester. Through 4 iterative cycles, this process ensured continuous interdisciplinary refinement, leading to validated user stories and prototypes. AI: artificial intelligence; GDPR: General Data Protection Regulation; IoT: Internet of Things; MDR: Medical Device Regulation; PPS: persistent physical symptoms; SME: small to medium enterprise.



User Stories as a Methodological Instrument

As this project aimed to develop prototypes that are informed by clinical, technical, and legal perspectives, a structured approach was required to support transdisciplinary collaboration and integrate diverse expertise. Therefore, we adopted a method inspired by agile software design practices [38], enabling the translation of broad project goals into actionable design and research activities.

"Epics" were introduced as overarching themes capturing the main development goals. Two epics were established: one for individuals with dementia and their caregivers, and another for patients with PPS and their physical therapists. These epics were defined during a dedicated stakeholder meeting involving academics, health care professionals, and representatives from the involved SME. Broad themes were collaboratively formulated based on stakeholder expertise and clinical experience. Subsequently, each epic was broken down into user stories.

A user story, traditionally used in software development to document system functionalities, describes a concrete need or requirement from the perspective of a particular user, following a standardized format [38]: as <user role>, I want <functionality> so that I <goal>. For example, "As an individual with PPS, I want to access a weekly overview of stress moments, so that I understand and can discuss my stress levels with my physiotherapist."

In this project, user stories were adapted as a transdisciplinary tool for reflection, integration, and iteration within the LC. Their

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structured format enabled diverse stakeholders, including health care professionals, patients, students, IT developers, and legal experts, to refine requirements, align technical and ethical considerations, and ensure the practical relevance of the prototypes.

By synthesizing insights from various research activities (Figure 1), including literature reviews, focus groups, interviews, legal analyses, and prototype evaluations, user stories provided a structured yet flexible method for integrating stakeholder needs throughout the project (Figure 2). The thematic clustering and final synthesis of user stories, including their role in guiding prototype development, is discussed in "Analysis: Synthesizing user stories."

Research Activities

Within the TDA context of this project, mixed methods were applied [39], and findings were triangulated to integrate insights from different disciplines into the development and refinement of user stories regarding wearable-based stress-monitoring for individuals with dementia and PPS. General principles of participatory design research [30,40,41] were applied in an iterative process, primarily covering co-explorative and conceptual design stages. Research and design activities took place in three defined main components: (1) requirements gathering, (2) application development, and (3) evaluation (Figure 1). These components ran in parallel and informed one another, although the primary focus shifted over time. In the initial phase, the focus was on initial requirements gathering (from a health care, social, legal, and technical perspective), with limited prototyping and evaluation. As time progressed, the focus shifted toward prototyping and evaluation, while requirements activities were mainly aimed at refinement.

Expertise feedback and requirements from 6 SME's (ie, IT companies developing software) and 4 health care institutes were frequently (3 times per semester) collected during the LC meetings. During those meetings, students of different domains (health, computer science, and law), supervised by university researchers, presented their research and outcomes. Extracted user stories, developed prototypes, and evaluations were discussed in this transdisciplinary setting. Feedback collected during those meetings was applied to subsequent research activities. Next to sharing expertise and reflecting with all stakeholders together, these meetings were also intended to contribute to the feeling of cohesion.

As detailed in the following sections, research activities in this phase included literature reviews, focus groups, and interviews with people with dementia, PPS, health care providers, and caregivers, producing legal advisory reports, and starting with initial prototyping of the system's infrastructure.

Requirements Gathering

Overview

This first component focused on identifying user needs, legal considerations, and technical constraints related to stress monitoring using wearables. To this end, several scoping reviews, stakeholder interviews, focus groups, and legal research were conducted.

Interviews and Focus Groups

Throughout the project, focus groups and individual interviews were conducted with stakeholders. For the dementia case, 14 sessions were conducted with health care professionals, 5 with informal caregivers, and 10 with people with dementia. For the PPS case, 11 sessions were held with physiotherapists and 11 with patients. During the first interviews and focus groups, prototypes were not available yet. Instead, existing visualizations from off-the-shelf technology (Figure 3) were used as probes during the interviews and focus groups, such as the Empatica E4 (Empatica Inc., Milan, Italy) and the Moodmetric ring (Vigofere Ltd., Helsinki, Finland). These probes were not presented as candidate solutions, but as a tool for participants to reflect on feasible possibilities in stress monitoring and articulate preferences in a more concrete way than abstract questioning would allow. Requirements emerging from those interviews and focus groups informed subsequent prototype development. Once prototypes were available, these visualizations were used as probes instead of off-the-shelf technology.

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Figure 3. Off-the-shelf technology, which measures stress, was used as a probe to gather the first requirements of end users. (**A**) The Moodmetric ring with an exemplary visualization and (B) the Empatica E4 with an exemplary visualization.

The complete methodology and outcomes of these interviews and focus groups are extensively detailed in a forthcoming research paper (van Westrienen et al, unpublished data, 2026). In the dementia use case, 2 focus groups were organized, including 5 health care professionals and 2 informal caregivers. Additionally, individual interviews were conducted with 3 informal caregivers, 6 health care professionals, and one person with dementia. For the PPS use case, individual interviews were held with 11 health care professionals and 13 PPS patients.

All interviews and focus groups followed a semistructured protocol [42], enabling both structured comparability and open-ended exploration. Discussions focused on perceived challenges and opportunities of wearable stress monitoring, ethical concerns regarding privacy and autonomy, and the feasibility of integrating such technology into existing health care workflows. To enhance reliability, member checks were performed, allowing participants to verify the accuracy of interpretations [43].

In addition to health care stakeholders, SME representatives from IT companies were actively involved in focus groups and interviews. Their participation ensured that technological feasibility, industry standards, and potential implementation challenges were taken into account from the early stages of the project. Discussions addressed data processing, sensor integration, and stress detection models; aligning technical capabilities with end user needs.

Legislation

Legal researchers were involved from the beginning of the project to provide early-stage advice, ensuring that legal considerations were integrated throughout the development process, rather than at the end when the prototype was (almost) finished. Key regulatory frameworks, including the General Data Protection Regulation, the Medical Device Regulation (MDR), the EU Artificial Intelligence (AI) Act, the Dutch Care and Compulsion Act, and Dutch intellectual property laws, were reviewed to ensure compliance from the outset. Legal advisory reports were generated, outlining potential constraints and ethical considerations, which were then integrated into user stories and early system requirements. Additionally, a Fundamental Rights and Algorithm Impact Assessment was performed to evaluate broader societal implications. This assessment ensured that the solutions developed were not only legally compliant but also ethically sound and respectful of fundamental human rights.

Scoping Reviews

To complement empirical insights, 2 scoping reviews of the literature were conducted. The first review focused on AI-powered wearables for mental health, examining studies retrieved from PubMed, CINAHL, PsycNet, ACM Library, and ScienceDirect. The second review explored biofeedback interventions for stress monitoring in PPS patients, using PubMed, CINAHL, and PsycInfo. These scoping reviews were conducted by students under the researcher's supervision. Their purpose was preparatory: to inform user-story development in

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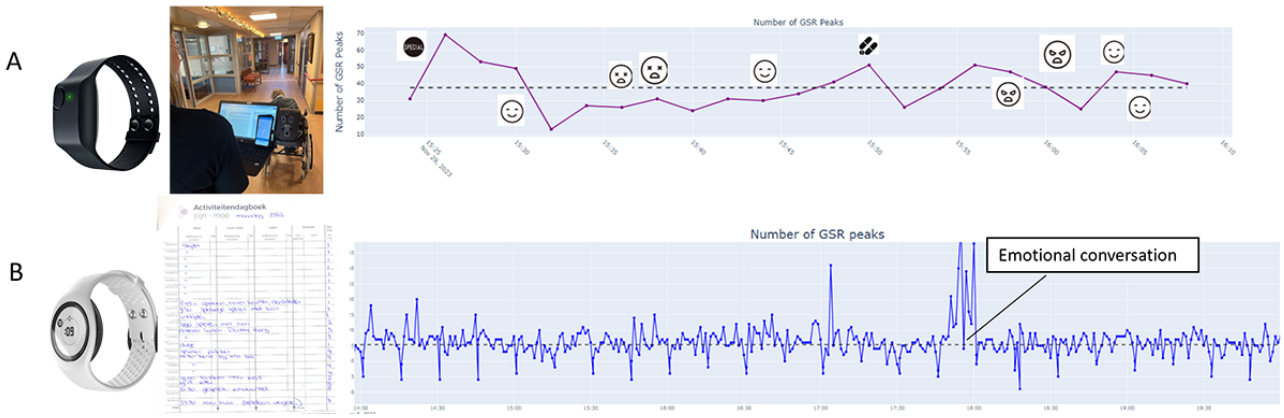
this project rather than to serve as stand-alone systematic review outputs. Accordingly, the Preferred Reporting Items for Systematic reviews and Meta-Analyses extension for Scoping Reviews methodology [44,45] was applied as a guiding framework, but not all checklist items could be addressed in full (Checklist 1). Specifically, the reviews helped identify intersections between health care, social, technical, and legal requirements. User requirements that impacted the user stories of this project were extracted from the reviews.

Application Development

This second component focused on translating user stories, informed by requirements gathering, into functional prototypes that were used for evaluation and subsequent refinement of user stories. Software prototypes of the back-end and front-end components were iteratively developed. The back-end architecture facilitates real-time data streaming, processing, and stress detection, integrating algorithms and cloud services. Details can be found in a dedicated paper [46]. Stress detection algorithms were developed using the open-source and validated WESAD dataset [47], applying established feature extraction of physiological parameters, including skin conductance components [48]. Regarding the front-end, physiological data were visualized in line diagrams using the Plotly library (Figure 4 [49]).

Figure 4. During field testing, different prototypes were tested. (**A**) A short (30 min) measurement on a person with dementia, combined with behavioral observations. By clicking on a pictogram, the user was linked to the observation notes of that time point. (**B**) A fragment (6 h) of a long-term 7-day measurement on a client with persistent physical symptoms, where a diary was kept as part of the usual care. In both prototypes, a semiautomated pipeline was used, in which data from the wearable was processed through a validated Trough-to-Peak (TTP) algorithm [50] and manually combined with behavioral observations or the diary.



As hardware development was beyond the project's scope, we integrated existing commercial wearables, the Empatica E4 and EmbracePlus devices, into the prototyped platform. Both devices, which are medical-grade wearables with CE marking and designed for wrist wear, offer comprehensive access to raw signal data. They measure peripheral skin temperature, electrodermal activity at 4 Hz, movement via a 3-axis accelerometer (ranging from 32 Hz in the E4 to 64 Hz in the EmbracePlus), and heart rate and blood pulse volume through photoplethysmography with 1-channel (E4) or 4-channel (EmbracePlus) at 64 Hz.

During prototype development, the Technology Impact Cycle Tool (TICT; [51]) was used as part of the computer science curriculum. TICT supports designers to estimate and understand the impact of new technologies, and critically think about privacy, data, human values, and sustainability.

Evaluation of Prototypes

Developed prototypes (Figure 3) were evaluated using interviews after real-life experiences with those prototypes. For dementia, the Empatica E4 wristband was used (Figure 4A). Ten people with dementia living in a nursing home were selected by the nursing staff as residents with challenging behaviors, eligible for wearing the sensor. Depending on the subject, the sensor was worn for 30 to 60 minutes. After processing the data, caregivers were presented with stress measurements (using the developed prototype) combined with behavioral data observed by the researchers and interviewed to gather their insights and opinions about their experience with the stress measurements.

In the case of PPS, the EmbracePlus (Empatica Inc) wristband was used (Figure 4B). Twelve individuals with PPS who were treated by a physiotherapist wore the wristband continuously for a week. While they had the option to wear it 24/7, participants were free to remove it for charging or in situations where they felt uncomfortable being measured. Additionally, participants kept a paper diary as part of the usual care. After processing the data, individuals with PPS and their physiotherapists were presented with stress measurements per day (using the developed prototype; Figure 4B) and interviewed to gather their insights and opinions about their experience with the stress measurements.

Analysis: Synthesizing User Stories

After it was established that extracting new user stories (eg, during focus groups and interviews after field testing, see Figure 2) did not yield new information (ie, saturation occurred), a dedicated working session was organized to categorize the user stories (197 in total) into themes. As the project was situated in the co-exploration and conceptual design stages of an iterative, participatory process, the analysis approach, in line with TDA principles, emphasized joint reflection and integration of perspectives [28] rather than the resolution of differences [34].

To organize the large number of user stories collected from various sources, we grouped them thematically according to

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user context. This clustering helped to identify shared needs, preferences, and challenges, supporting user-centric design, prioritization, and decision-making throughout the development process. To this end, at the start of the working session, separate lists were compiled for the PPS (136 user stories) and dementia (61 user stories) contexts. For each user context, 2 dedicated analysis groups were formed (making 4 groups in total). Each group consisted of at least 3 LC members, including both health care and computer science experts involved in the project. These groups independently categorized the user stories within their respective context, creating thematic clusters. Subsequently, the themes were compared within and across groups (peer review), leading to a shared understanding and final consensus on the central themes derived from the user stories. This stepwise process emphasized joint reflection and integration of perspectives rather than the resolution of all differences, ensuring that multiple stakeholder viewpoints remained represented in the final thematic structure. To enhance shared understanding and final consensus, these central themes were subsequently discussed in LC-wide meetings.

Reflection in the Learning Community

Important elements of (our) transdisciplinary work were sharing information, iteration, and reflection. As such, we reflected with the students involved in the project, team members, and partners from various domains (ie, health care, law, and computer sciences). We obtained feedback on the following three questions: (1) Reflecting on the last 2 years, what do you see as the main successes or benefits of working in a transdisciplinary learning community? (2) What did you experience as the main challenges or difficulty? (3) Would you recommend working in such a transdisciplinary learning community in the future? If so, what would you improve or do differently? The written reflections were analyzed qualitatively by 2 researchers (IM and MPS). Responses were reviewed and thematically grouped according to the structure of the 3 reflection questions. Recurrent ideas and notable formulations were identified and summarized to capture shared experiences.

Ethical Considerations

The local board of research and ethics (Fontys Commissie Ethiek van Onderzoek) reviewed the use of wearables in PPS "86peeters30082022," and the Medical Ethical Board of Brabant reviewed the use of wearables in dementia "NW2021-45." All procedures were conducted in accordance with institutional and national ethical standards and with the Declaration of Helsinki. Participants were adults; no financial compensation was provided. All identifying data were anonymized by the researchers and processed confidentially. All participants or their representatives were informed that participation was voluntary and that they could withdraw at any time without providing a reason. All participants in this study gave their informed consent after receiving verbal and written information.

In nursing homes, formal caregivers and legal representatives of residents with dementia provided proxy consent in accordance with institutional guidelines. Procedures included ongoing assessment of assent and comfort. A professional caregiver who knew each participant well assisted with putting on and taking off the wearable device and observed for any signs of distress, discomfort, or resistance. Any such behavior would have been interpreted as a withdrawal of consent. No indications of non-consent were observed during the study.

Results

Overview

We report the main findings of each research activity that impacted the user stories. Finally, we show an integration of the results in the formation of the user stories, and a reflection by the LC members regarding the TDA.

Epics

The following epic was formulated for the dementia use case:

> *The goal is to support the clinical reasoning of healthcare professionals to optimize the quality of life for a client (person with dementia and challenging behaviors). For this purpose, personalized insights are gained during stress moments by biometrics. The healthcare professional or caregiver uses a wearable as a supportive tool during a period in which the client is observed. The combination of the data can be analyzed by a behavioral expert (healthcare professional) afterwards to take a substantiated decision.*

The following epic was formulated for the PPS use case:

> *The goal is to support the clinical reasoning of the healthcare professional in order to optimize the quality of life for the client (person with PPS). To this end, an adult with PPS (client) wears a wearable for up to one week during the activity registration in the treatment period with the physiotherapist (healthcare professional). This way, insight into the client's stress moments is obtained through biometry, along with the activity registration. The physiotherapist can then discuss this stress measurement with the client afterwards, along with the activity registration, so that both gain insight into the relationship between exercises and activities with stress and relaxation and its impact on the experience of the symptoms. This insight can be used to make informed decisions during the treatment period for the therapist and support sustainable behavior change for the client.*

Requirements Gathering

First Interviews and Focus Groups

During the first requirements gathered from end users, using off-the-shelf technology as a probe, the following needs were indicated. No differences were found between dementia and PPS. In both use cases, patients and informal caregivers indicated they want to obtain insight into stress levels, specifically in relation to an individually predetermined measurement goal. They also wanted the ability to share data with specified formal and informal caregivers. Furthermore, they emphasized the importance of being able to wear the device long-term during daily life and to integrate the technology into care as usual. Esthetic, non-stigmatizing wearables were

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preferred. In addition, users wanted the option to modify notifications and to add contextual information, such as perceived stress or relevant events.

Legislation

The legal advisory reports produced during the project provided detailed insights crucial for the development of user stories and prototypes. Specifically, the following points were addressed:

- MDR (EU): The advisory report identified that the wearables used most likely fall under risk class IIa, necessitating compliance with specific safety and performance requirements. This included conducting risk assessments, implementing a quality management system, and ensuring post-market surveillance. Additionally, informed consent procedures had to be meticulously followed, with clear communication to participants about the wearable's purpose and data handling.
- General Data Protection Regulation (EU): The reports emphasized the need for robust data protection measures. This involved obtaining explicit consent for data processing, pseudonymizing personal data at the earliest opportunity, and maintaining a data processing register. Data portability and the right to withdraw consent were also highlighted as essential compliance elements.
- AI Act (EU): The advisory report identified that the AI algorithms used most likely fall under the category "high risk" (because of the use of AI algorithms within a medical device), necessitating compliance with specific safety and performance requirements. Compliance with the AI Act required ensuring that the AI algorithms used in stress detection were transparent, explainable, and non-discriminatory. The legal advisory highlighted the importance of conducting regular audits and impact assessments to monitor the ethical deployment of AI.
- Care and Compulsion Act (Dutch): The project had to navigate the legal requirements for using wearables in the context of dementia, especially regarding compulsory care. The advisory recommended implementing the use of a decision-making framework to ensure that any compulsory use of wearables was justified and legally compliant, and to involve legal representatives in the consent process where necessary.
- Dutch Intellectual Property Laws: The reports provided guidance on protecting the intellectual property generated during the project and on preventing infringement of third-party IP rights. This included ensuring that all contributions from various stakeholders were appropriately credited and protected, also when open source software is used for developing the application.

These specific legal insights were integral to the user stories, ensuring that each phase of prototype development was compliant with relevant regulations. For example, the user stories for health care professionals included requirements for transparent data handling and the ability to easily obtain and manage patient consent, while those for developers focused on embedding regulatory compliance into the design and functionality of the wearables.

Literature Reviews

Overall, the 2 reviews identified the prevalent use of wearable devices, particularly those worn on the wrist. However, significant gaps were found in the literature regarding acceptability, user experience, and usability, all of which are crucial components for the development of user stories. Many studies focused on the development and accuracy of machine learning algorithms, while aspects related to user acceptability, such as real-life experience, comfort, and ease of use, were addressed far less frequently. Regarding usability, participants expressed preferences for comfort and discretion in wearability, with some suggesting that integration into clothing or shoes would be beneficial. Personalization was also valued, with preferences for distinctive features such as colored or differently textured bands to identify one's own device. Additionally, participants appreciated being able to track information such as their step count on the wearable device. Practical difficulties were reported, such as having to remove the device for charging or bathing, as well as annoyance caused by audible beeps emitted by the device. Moreover, the limited inclusion of long-term follow-up data in the studies restricts insight into sustained use and user experience over time.

Evaluation of Developed Prototypes

The final prototypes used for evaluation in this project are shown in Figure 4. These prototypes were exploratory artifacts developed to translate user insights into tangible design directions rather than finalized products.

In the dementia case, formal caregivers considered the measurements useful. They indicated that the short-term graph with annotations (prototype Figure 4A) provided a clear overview. Caregivers appreciated the use of neutral blue colors and the inclusion of pictograms that served as hyperlinks to the observational log corresponding to the same time points. To be able to work effectively with the data, they explicitly expressed the need for additional information or training on how to interpret the measurements.

Patients with PPS (prototype Figure 4B) and their caregivers experienced the measurements as useful. They appreciated the neutral blue color of the graph, the daily overview of measurements, and the interactive nature of the Plotly graph (ie, the ability to zoom in and out on specific time periods during the day). As an improvement, patients and caregivers expressed a wish for an additional weekly overview in a single graph, as well as the ability to add contextual information digitally. Importantly, some patients indicated that they found it difficult to interpret and apply the measurements and explicitly expressed a need for more information or training. Most participants disliked the aesthetic appearance of the EmbracePlus device. Notably, after viewing the prototype, patients and caregivers expressed differing views regarding notifications: patients stated they would like to receive notifications about stress moments, either in real time or as a daily summary, whereas caregivers were more hesitant, noting that this could lead to an unhealthy focus on stress. Caregivers emphasized that they want to control the notification settings for their patients to ensure that measurements do not interfere with treatment.

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Final User Stories

Overview

Analysis of the final set of user stories, which were developed through multiple iterations (Figure 2) within the framework of the 2 epics, revealed the same 7 themes for both the dementia and PPS contexts. These themes portray the needs and requirements of the users. The order of appearance does not reflect the relative importance of the themes. For each theme, it is described how it was reflected in the conceptual prototypes that were evaluated as part of the co-exploration and conceptual design stages.

Data Insight and Analysis

This theme revolves around displaying the data collected by the wearable. Users seek a clear and straightforward overview of the data, enabling them to quickly grasp both short-term and long-term trends and draw conclusions efficiently.

> *As a nurse, I want to see the data of multiple days, so that I can easily recognize patterns* [Health care professional dementia]
>
> *As a person with PPS, I want to use a wearable 24/7 so that every situation in my daily life can be taken into account.*

Both in the dementia and the PPS context, the importance of being aware that stress can also be something positive was acknowledged:

> *As a person with PPS, I want the color to show my stress level not to be red because stress is not always negative.*

This theme was reflected in the conceptual prototypes by displaying daily and weekly overviews of stress levels, in a neutral color scheme (Figure 4), allowing users and their therapists to explore both short- and long-term trends.

User Input (Context)

In this theme, the focus is on adding context and feedback to the physiological data. Users want to express their experiences and feelings related to stress and relaxation, using notes, smileys, or scores.

> *As a nurse, I want to be able to report what caused the peak and at what time it occurred when dealing with relaxation and stress.* [Health care professional dementia]
>
> *As a physiotherapist for a person with PPS, I want patients to be able to pick between five different smileys to measure their stress level so that I have more context about the stress level.*

In the conceptual prototypes, contextual input was collected using paper-based methods that reflected existing care practices of the participants (ie, care as usual). In the dementia case, caregivers used observation forms with time-stamped notes to record behavioral events, which were later linked to the physiological stress data in the prototype using clickable pictograms (Figure 4A). In the PPS case, participants kept a paper diary during field testing to annotate situations that caused or relieved stress (Figure 4B), which was later discussed alongside the physiological data.

Notifications

This theme addresses receiving notifications or alerts from the wearable or app when stress levels become too high or when action is needed. Users also desire the ability to customize notifications based on their preferences and needs (including sensitivity and specificity, to influence the likability of false positives and negatives).

Both health care providers for people with dementia, as persons with PPS, want a notification function to signal increased stress levels:

> *As a nurse, I want the wearable to be able to prevent stress. It should provide a notification before stress reaches its peak, so that healthcare professionals can take action before the stress becomes too intense.* [Health care professional dementia]
>
> *As a person with PPS, I want to receive a signal from the device when the stress peak happens because then I can be ready or take some actions with it to prevent the complaints caused by the stress.*

However, health care professionals do not all agree with a notification feature for their patients:

> *As a physiotherapist for a person with PPS, I want to have a turn-off notification from my patients so that I do not have to get every stress peak from my patients, and I can avoid an unhealthy focus on their stress.*

This theme was discussed but deliberately not implemented in the conceptual prototypes due to ethical and practical considerations. While some PPS clients expressed interest in receiving real-time stress alerts or daily summaries, others, especially therapists, preferred to avoid notifications to prevent fixation or anxiety. As a result, data were reviewed retrospectively together with an expert, enabling participants to reflect on stress episodes without triggering immediate reactions during daily life.

Data Access and Sharing

How does the data from the wearable/app travel to its final destination (eg, cloud storage), and who can access it? Users want control over who can view and use their data. In the PPS context, it was furthermore explicitly found that users also want to transfer data quickly, securely, and reliably from the wearable to the client's or health care professional's records or system. Additionally, people with PPS want to discuss the data with their physical therapist to improve and support their treatment.

> *As a nurse, I want to share the results of the stress measurement with legal representatives of the person with dementia, so I can keep the family up to date.* [Health care professional dementia]
>
> *As a person with PPS, I want the healthcare professionals to have an authority to look into the data because then I can see if a treatment is helpful for me or not.*

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Also, users were conscious about their privacy:

> *As a person with PPS, I want to be asked for the permission for my treatment so that I can keep my privacy.*

This theme was reflected through the development of a decision-making matrix to clarify data access rights, especially in dementia care, where legal representatives are involved. Additionally, in dementia care, a tool was developed to ensure compliance with the Dutch Care and Compulsion Act when wearables were used.

Wearable (Hardware)

Users expect a device that is comfortable, durable, and easy to use.

> *As a nurse I want a wearable which is made of soft material, so that (skin) irritations in people with dementia are prevented.* [Health care professional dementia]

> *As a person with PPS, I want the wearable to be durable and compact, so that I can use it in various treatments such as exercise therapy.*

This theme was reflected in the selection of the Empatica E4 and later the EmbracePlus devices, as these are comfortable, durable, and wrist-worn wearables that allowed practical evaluation of usability and long-term wear in both contexts.

Support

This theme focuses on providing information and support to users of the wearable and app. Health care professionals require clear instructions to ensure correct use of the wearable. Users want a manual or an FAQ page where they can find answers to their questions or issues. They also want the option to contact technical support if they need assistance.

> *As a nurse, I want clear instructions, otherwise the wearable is perceived as too complex. The interest of healthcare professionals needs to be piqued first, after which a workshop can potentially be provided. This way, we know how to properly use the wearable.* [Health care professional dementia]

> *As a physiotherapist for a person with PPS, I want there be a short schooling for me and my colleagues about the use of the wearable so that I know how to use the wearable.*

This theme was reflected by providing short instruction sessions before data collection and on-demand support from a researcher during measurements, ensuring correct use and confidence among participants. This clear onboarding was essential; without it, caregivers hesitated to adopt the wearable due to perceived complexity.

Strategic Use of Wearable

This theme emphasizes purposeful use of the wearable. Users want the wearable to measure stress levels and assist in anticipating or managing stressful moments. This is crucial for preventive care as well as the adoption of the technology.

> *As an informal caregiver I want to measure until we reached the goal of the measurement. It should be continuously evaluated if the measurement's goal is reached and the person with dementia still needs the wearable.* [Informal caregiver for someone with dementia]

> *As a person with PPS I want an overview of my stress level during the day so it can help me recognize my stressful moments.*

This theme was reflected in the decision to use the wearables only in cases where stress monitoring could address a concrete care question, ensuring goal-oriented and meaningful application. In the PPS context, wearables were deployed episodically to help clients and therapists assess progress and behavioral triggers. In the dementia setting, the wearable was reserved for residents with challenging behaviors, allowing care teams to identify stress patterns and evaluate the timing or necessity of interventions.

Reflection on the Learning Community and Transdisciplinary Approach

Several aspects were highly emphasized by many of the LC members. Dominantly, the possibility to learn from each other and learn how to better communicate with other disciplines was highly emphasized. LC members appreciated the willingness of others to be "open-minded," "step outside their own knowledge bubble," and to receive feedback and opinions from very different points of view. Several members further elaborated that the TDA created an atmosphere in which all parties are more engaged, motivated by the mutual work, which also pushes the project forward. Growth, in particular, of the students was also mentioned as a benefit of the mutual learning experience. Particularly, specific disciplines (eg, the legal perspective) can exchange and provide valuable input throughout all phases of the research and design process, rather than being involved only in later or specific phases. This created a sense of progression, and more importantly, as emphasized by many participants, allows a combination of knowledge and expertise to tackle larger societal challenges.

Nevertheless, TDA can also create challenges. The main challenge presented is related to the management of a large group, with many partners and phases. This also requires good coordination, time management, planning, as well as more meso-organizational flexibility and understanding from the University of Applied Sciences for these efforts. More so, specifically in our TDA project, new students were introduced each semester. While several students stayed involved in the project even after their graduation (as well as co-authors of this paper), the constant change of students required them to start over, re-educate themselves on how to communicate transdisciplinary, and created a challenge to transfer the accumulated knowledge in an organized way.

Notably, most LC members indicated that they are content with the conducted TDA. Many emphasized that, in their opinion, this should be the way to conduct research, especially when dealing with complex societal and applied issues. Participants expressed a high willingness to join new TDA projects in the future.

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Discussion

Principal Findings

This Sensors2care project demonstrates the practical application of the TDA within LCs, responding to earlier calls to move beyond conceptual discussions of transdisciplinary research [32]. It specifically addresses the co-exploration and conceptual stages of participatory design, where reflection and alignment, rather than finalized technical solutions, are central outcomes. From the outset, sustained, iterative collaboration between academic and non-academic stakeholders, including health care, IT, and legal experts, enabled practical knowledge integration, collaborative reflection, and transparent synthesis throughout the project. Shared communication across stakeholders was operationalized through user stories, which supported alignment throughout the process. Generative probes and early prototypes further helped elicit feedback, guiding the development of proof-of-concept prototypes with practical implementation in mind.

By integrating perspectives from students, researchers, health care professionals, informal caregivers, and industry partners, the LC facilitated knowledge exchange and mutual understanding across disciplinary and sectoral boundaries. This setting enabled the co-development of a wearable-based stress-monitoring system tailored to the needs of vulnerable populations. The iterative, mixed methods approach helped refine specific requirements throughout the project phases, which included literature reviews, focus groups, field testing in which prototypes served as tangible prompts for stakeholder reflection and feedback [30], and thematic analysis of user stories. By structuring needs in an accessible, user-centered format, user stories enabled reflection and alignment across technical, clinical, legal, and experiential perspectives. Reflexivity, a core TDA principle described as awareness of the broader context and ensuring the coherence and compatibility between project components [28], was embedded throughout the process to align stakeholder input, ethical considerations, and evolving technical design.

This inclusive approach grounded technological design choices in the clinical, social, legal, and ethical realities of individuals with dementia and PPS, populations often underrepresented in wearable technology research. Although user stories of both populations showed shared requirements in wearability, data confidentiality, and ease of use, unique cognitive and physical challenges of each group necessitate customization within the design for the specific population. Themes like strategic use, notifications, user input, data insight, access, and sharing highlighted the importance of personalization aligned with the intended goals of stress monitoring. This finding aligns with previous research on the balance between user burden and customization [52]. The wearable (hardware) theme further confirmed the need for comfort and durability, consistent with prior research [53,54]. Importantly, these shared themes emerged during the early, exploratory stages of co-exploration and conceptual design. It is expected that these broad, high-level requirements will evolve further into context-specific differentiations during later development and implementation stages.

Together, these insights demonstrate how the transdisciplinary process can translate diverse perspectives into concrete design requirements. While results are specific to the dementia and PPS, the described TDA process suggests methodological transferability that could inform similar practice-oriented innovation projects, particularly in chronic health care domains where technological, clinical, and legal perspectives intersect. As such, this exploration and conceptualization phase illustrates how TDA can be adapted and applied in diverse health care innovation settings.

Methodological Limitations

Several methodological limitations should be considered when interpreting the findings. Because the project focused on the exploration and conceptualization phases of the design process, evaluation activities were short and small in scale. This reflects the agile, iterative design process, which relies on rapid prototyping and brief evaluation cycles to generate timely feedback and inform subsequent iterations. Consequently, findings from this stage should be interpreted as exploratory rather than generalizable.

While participatory design principles were applied throughout the project, user engagement with prototypes was limited to relatively short periods (ranging from a single session to several weeks). This limits the assessment of long-term usability and acceptability. Users often find it difficult to anticipate how emerging technologies will affect their daily lives, and short-term use may not reliably predict future use [55]. Additionally, the frequency and impact of discrepancies between subjective experience and physiological stress measurements require further investigation. Overall, sustained longitudinal user engagement, especially when designing for vulnerable populations, should be a key focus of future research.

In addition, the use of off-the-shelf wearables in the early exploration phase may have influenced participants' perceptions of technological possibilities. These devices were intentionally presented as generative probes to stimulate discussion and reflection, not as candidate solutions, and were later replaced by project-specific visualizations once available. To mitigate potential bias, multiple commercial devices were used and explicitly framed as illustrative examples rather than evaluation objects. Nevertheless, early exposure may have shaped participants' expectations regarding functionality or design.

Challenges and Reflections on Stakeholder Involvement

TDA's principles [28], including knowledge unity, real-world problem orientation, and reflexivity, were central to our LC. Active participation of non-academic stakeholders, such as care providers, industry representatives, and legal experts, helped ensure that prototypes are adaptable to clinical practice and integrate ethical and legal considerations. For example, legal assessments informed data security and patient consent processes, which are pivotal when designing for vulnerable populations. The TICT [51] was used to assess the societal implications of wearable deployment, showing the value of

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tools that promote ethical and practical considerations during the design process. It is important to recognize that the MDR and the AI Act are relatively recent European Union frameworks. As such, they do not always provide concrete or prescriptive standards. Some legal interpretations in this project were necessarily anticipatory, based on current guidance rather than judicial precedent. In the coming years, further clarification is expected as case law and additional regulatory commentary emerge. This highlights the importance of continuous legal reflection within long-term innovation trajectories.

Despite the successful use of TDA principles within the LC, some limitations emerged. Key societal actors such as policymakers and insurance companies were not involved, constraining the exploration of systemic factors that influence adoption and scalability in real-life settings. Moreover, although early prototypes were tested in practice, the project did not extend to the evaluation of market-ready solutions or their long-term integration into health care systems. These limitations align with recognized challenges in the NASSS framework, particularly within the adopter system, value proposition, and wider institutional and societal context [26,28]. This highlights the importance of extending the LC model in future work to include a broader range of societal stakeholders to support sustainable implementation.

Implications for Transdisciplinary Education

By involving students from health, legal, and computer sciences, a meaningful contribution to transdisciplinary research was provided. While student participation requires careful guidance to maintain research quality, our experience aligns with previous work showing that well-structured, real-life research projects can provide valuable learning experiences and produce outcomes of academic relevance when appropriate supervision is in place [56]. This project shows that TDA principles, such as the integration of diverse forms of knowledge, reflexivity, and addressing real-world problems [27,35], can be taught early in professional development. This observation aligns with recent work of Amelink et al [57], which conceptualizes how transdisciplinary learning environments foster complex thinking by engaging students from different disciplinary backgrounds in real-world, problem-based collaboration. Their findings reinforce our conclusion that the TDA helps students connect disciplinary perspectives, enhance creativity, and approach health care challenges more holistically. Embedding TDA thinking within curricula across disciplines prepares future professionals to tackle complex societal challenges collaboratively, beyond the scope of their own fields.

These observations highlight the need for further research into how educational institutions can structurally support the long-term integration of TDA principles beyond individual projects and sustainably embed them within curricula and institutional frameworks. Moreover, given the evidence that integrating technology into the education of health students facilitates technology adoption in clinical practice [58-60], future studies should explore how to optimize this effect across all relevant domains. Such efforts can help prepare students as versatile, technology-savvy professionals capable of contributing to transdisciplinary projects and creating sustainable solutions in health care.

Conclusions

This project demonstrates that applying a TDA within an LC enables the integration of legal, technical, and health perspectives from the earliest stages of innovation. The collaborative LC structure, organized through recurring meetings and stakeholder engagement, fostered mutual learning and reflexivity. Early involvement of legal expertise helped ensure that design choices were not hindered by regulatory constraints but instead guided by legal possibilities. Technically, the iterative development of prototypes, grounded in user stories, allowed for early validation and continuous refinement of requirements. Methodologically, user stories proved to be a valuable instrument, not only as a design outcome, but also as a structuring tool to align interdisciplinary contributions. Together, these insights show that LCs can serve as valuable environments for transdisciplinary research, where students, researchers, professionals, experiential experts, and industry partners co-create solutions to complex health care challenges. While the findings are context-specific and stem from an exploration and conceptualization phase, the applied TDA approach illustrates potential methodological relevance for other health care innovation contexts where transdisciplinary collaboration is essential.

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Data Availability

The datasets generated during this study are part of the larger Sensors2Care project and are not publicly available because they will be reported in forthcoming discipline-specific publications. Data may be made available upon reasonable request to the corresponding author after publication of these related studies.

Authors' Contributions

Conceptualization: MP (lead), PH (support), NL (support)
Data curation: MP (lead), PW (equal), LD (equal), PH (equal), NL (equal)
Formal analysis: MP (lead), PW (equal), LD (support), EG (equal), NL (equal)
Funding acquisition: MP (lead), GS (equal), EW (equal)
Investigation: MP (lead), IM (equal), AE (equal), KV (equal), PW (equal), LD (equal), EG (equal), PH (equal), NL (equal)
Methodology: MP (lead), IM (equal), PW (equal), PH (equal), EG (equal), NL (equal)
Project administration: MP
Software: PH (lead), EG (equal)
Supervision: MP
Visualization: MP
Writing – original draft: MP (lead), IM (support)
Writing – review & editing: MP (lead), all authors (support)

Conflicts of Interest

None declared.

Checklist 1
Preferred Reporting Items for Systematic reviews and Meta-Analyses extension for Scoping Reviews checklist.
[DOCX File, 96 KB - formative_v10i1e75836_app1.docx]

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Abbreviations

AI: artificial intelligence
FCEO: Fontys Commissie Ethiek van Onderzoek
FRAIA: Fundamental Rights and Algorithm Impact Assessment
GAI: generative artificial intelligence
LC: learning community
MDR: Medical Device Regulation
NASSS: Non-adoption, Abandonment, Scale-up, Spread, Sustainability
PPS: persistent physical symptoms
SME: small to medium enterprise
TDA: transdisciplinary approach
TICT: Technology Impact Cycle Tool

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Using AI Chatbot to Assist Students' Behavior Management for Obesity Prevention in Middle Schools: Feasibility Study

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Abstract

Background: Adolescent obesity remains a pressing public health challenge, particularly among socioeconomically disadvantaged populations. Artificial intelligence (AI) holds the promise for supporting students in managing daily health behaviors, but few existing studies used AI-based interventions in naturalistic settings such as schools.

Objective: This study evaluated the feasibility and preliminary impact of ProudMe Tech (Louisiana State University), an AI-assisted web app designed to help students manage 4 obesity-related behaviors: physical activity, screen time, diet, and sleep.

Methods: The 8-week, 1-arm pilot intervention study recruited 172 participants from 5 middle schools in Louisiana and used the ProudMe Tech to set behavior goals, track behaviors, record reflections, and receive AI-generated feedback. Both engagement (primary focus) and behavior impacts (secondary focus) were examined.

Results: Engagement metrics indicated varying levels of usage, averaging 8.9 (SD 7.6) behavior entries and 30.0 (SD 28.3) reflections per student, and receiving 33.5 (SD 29.7) AI feedback messages. Overall, participants recorded 6164 valid daily goals, of which 3934 (63.8%) were achieved. Natural language processing of the reflections and AI feedback messages revealed an overall neutral to positive sentiment. Pre- to postcomparisons showed (1) a significant reduction in screen time from 4.3 (SD 2.6) to 3.4 (SD 2.5) hours per day (21.6% decrease; t_{164}=6.18, P<.001), (2) a small but significant decrease in fruit and vegetable intake from 5.7 (SD 3.8) to 5.2 (SD 3.5) servings per day (8.9% decrease; t_{169}=2.27, P=.46), and (3) no significant changes in physical activity and sleep.

Conclusions: These findings suggest that ProudMe Tech is a feasible AI chatbot that can engage adolescents in health behavior management, but more adaptation is needed to effectively elicit improvements in health behaviors and lower the obesity risk in middle school students.

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KEYWORDS

adolescence health; behavior intervention; large language models; school-based; mobile health

Introduction

The prevalence of adolescent obesity is high and demands innovative interventions. 2024 national surveillance data show that more than 20% of American youth aged 10 to 14 years have obesity, and the prevalence is even higher among racial and ethnic minorities and those from socioeconomically disadvantaged households [1]. Early adolescence marks a key developmental stage for the formation of healthy behavioral patterns, as youth have increased autonomy for physical activities, screen time, diet, and sleep—4 influential health behaviors related to obesity [2,3]. If not addressed, unhealthy behavior habits and obesity may track into adulthood [4]. Furthermore, existing behavior interventions for adolescent obesity prevention have shown limited effectiveness due to reasons such as low participation, poor personalization, and inadequate scalability [5]. Researchers have increasingly turned to novel technologies to promote behavior changes to prevent obesity. Digital tools such as mobile apps, wearable trackers, virtual or augmented reality, and gamifications have shown promising feasibility and effect in promoting physical activity, healthy diet, and sleep hygiene [6]. These technological innovations have permeated schools and homes and are naturally drawn to adolescents. Some have become important educational technologies in schools [7], but most have limited capacity to

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support continuous self-adjustment or personalized learning at a low cost.

Large language model-powered artificial intelligence (AI) chatbots represent an emerging and scalable technological intervention for delivering cost-effective and personalized behavioral counseling for adolescents. AI chatbots can simulate natural conversations, respond to user input in real time, and customize messages according to the user's preferences, goals, and progress [8,9]. Early research results of adult health apps showed that compared with traditional manual guidance, AI chatbots enhanced participation and enthusiasm and improved health at a low cost [10,11]. However, little research used AI-based technology for health intervention in the younger populations (eg, for adolescent obesity prevention), especially in naturalistic settings such as schools. Rarely has prior research investigated the feasibility and impact of an AI chatbot in supporting adolescents' management of health behaviors.

To fill the gap, this study aimed to evaluate ProudMe Tech, an AI chatbot that helps users (1) set specific, measurable, attainable, realistic, and timely (SMART) goals for physical activity, screen time, diet, and sleep. ProudMe Tech is part of a multicomponent intervention called ProudMe (Preventing Obesity Using Digital-assisted Movement and Eating), which was adapted from the evidence-based SWITCH-MS intervention [12,13]. The ProudMe intervention has 4 components, including (1) a 12-lesson health and physical education curriculum, (2) the simplified Smarter Lunchrooms Movement strategies, (3) professional development for teachers and staff, and (4) the ProudMe Tech. The design of ProudMe Tech is grounded in the Self-Determination Theory [14] and the Self-Regulation Theory [15] with the goal to foster users' perceived competence, self-efficacy, and intrinsic motivation. When engaging with the ProudMe Tech, users receive informational and emotional social support from the AI as a virtual coach to improve their goal-setting, self-monitoring, and self-reflection skills to manage their health-related behaviors [16]. ProudMe Tech implementation was unsuccessful in the first round of ProudMe intervention in 2024 for unexpected reasons in reality (eg, web link blocked by the district IT, challenges with user registration, and lack of teacher buy-in) [13], but it had undergone significant refinement and beta testing. The purpose of this study was to field-test the integration of the refined ProudMe Tech into schools by evaluating its user engagement and impact on users' health behaviors. The research team hypothesized that adolescents would actively engage with the ProudMe Tech platform and demonstrate favorable short-term changes in targeted health behaviors.

Methods

Setting and Participants

ProudMe Tech, as a component of the larger ProudMe intervention, was implemented in 5 public middle schools recruited within one school district from the Baton Rouge metropolitan area, Louisiana. These 5 schools primarily consisted of socioeconomically disadvantaged student populations, with a mean free and reduced-priced meal percentage of 50.4%. The ProudMe Tech intervention involved students in 6th grade, with the exception of a few 7th-grade classes. Because the ProudMe intervention was approved as an educational program, the participating teachers, at their discretion, were given authority to decide whether they would involve all students or just a selection of students. Of the 670 students taught by the participating teachers, 487 (72.7%) created a ProudMe Tech account. However, only 172 (35.3%) of those who created accounts returned parent and guardian consent forms and participated in the study. In addition, 3 students transferred to other schools during the study period, thus their partial data were removed from analysis.

ProudMe Tech was implemented in the spring semester of 2025. During the 8-week intervention period, participants accessed the ProudMe website via school-assigned laptop computers during their health and physical education classes and were expected to use the technology for at least 3 days per week. Their health and physical education teachers received standardized training at the beginning of the semester on how to use ProudMe Tech, and these teachers subsequently provided instruction for their students to create user accounts and engage with the AI chatbot. The process required limited teacher facilitation upon the initial instruction. In addition, the users were encouraged to use the technology by logging into the website beyond class time both in and out of school.

ProudMe Tech Website Overview

ProudMe Tech is a web-delivered platform designed to help middle school students manage 4 health behaviors, including physical activity, screen time, diet, and sleep. Each user is expected to create a user account, set up daily goals, report their behaviors, type in a written reflection on progress toward each goal, and receive personalized feedback from the AI-powered chatbot (GPT-4). These user data subsequently generate behavior charts (line chart and progress bar chart) which offer intuitive, color - coded visualizations of user progress relative to their goals. Users can also access daily reports which provide a calendar - based summary of each day's logged activities and reflections. Below provides an outline of the app interface and computer science implementation.

App Interface

As shown in Figure 1, on ProudMe Tech, users were instructed to create their own specific, measurable, attainable, realistic, and timely (SMART) goals and consider these principles when reflecting on goal attainment. In the first week of ProudMe Tech engagement, trained teachers taught the users of SMART goal setting and provided a demo on how to use the website app. For physical activity, users can select their activity type (eg, walking, running, basketball, and football) from a dropdown list, activity intensity (ie, strenuous, moderate, and mild), and activity volume (in hours and minutes). Screen time is categorized as academic (eg, online class and homework) and nonacademic (eg, gaming and social media) screen time. Users are prompted to select the type and amount for both goals and their actual behaviors. For diet, users tap "Add Fruit/Vegetable," choose specific items (eg, apple and spinach) from the menu, and enter the number of servings consumed. For items not listed by default, users can manually add them. For sleep, users report their bedtime and wakeup time for both goals and actual behaviors (eg,

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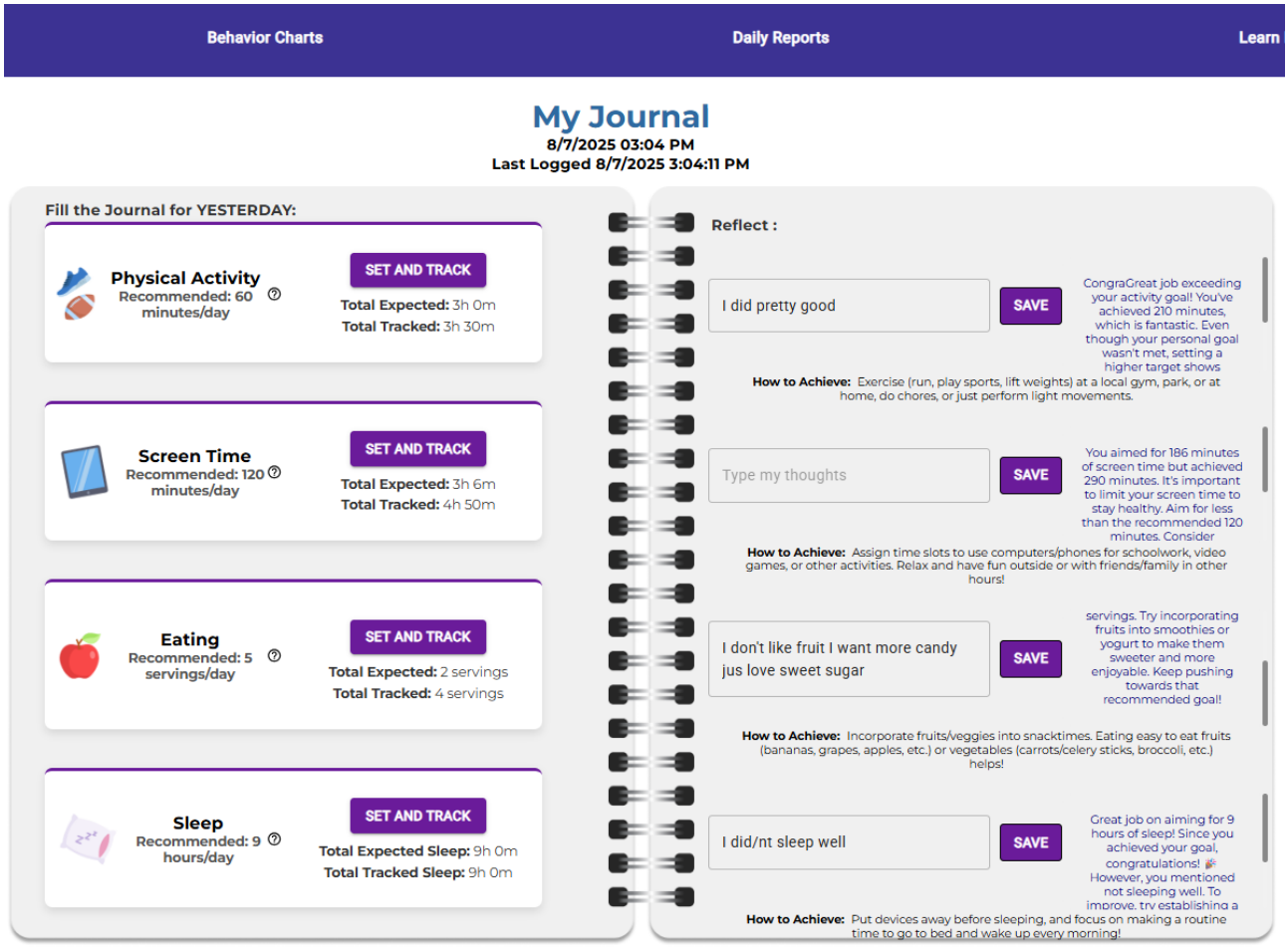
"10:30 PM-6:45 AM"), and the system instantly computes sleep duration for users to view results prior to reflection. AI feedback was generated using a rule-based engine that matches logged behaviors to goals and delivers one of several tone-specific messages (eg, praise and suggestion).

Figure 1. ProudMe journal.



Computer Science Implementation

The ProudMe Tech web app was developed using a full-stack architecture: React.js (front-end), Node.js and Express.js (back-end), and MongoDB for secure data storage. It was hosted via Render Cloud Platform and deployed using an agile development approach. The app has built-in timestamps and dropdown menus for selecting activity types, entering durations, and categorizing screen time. Back-end logs automatically track every goal, actual behavior, reflection, and AI-generated feedback message. The app has incorporated automated routines that calculate counts and timestamps directly from those logs. In addition, the platform consists of a rule-based AI chatbot module that generates and delivers feedback prompts. The research team built a simple feedback service in Node.js and Express that receives each goal or reflection a user submits. The service pulls that user's latest data from MongoDB and then uses our OpenAI API (Application Programming Interface) key (kept in an environment variable) with the OpenAI package to call GPT4 for context-aware feedback. Key model parameters were specified to ensure reproducibility: temperature=0.9, max_tokens=75, and response_format = "json/text." The system runs each response through OpenAI's Moderation API to filter out any inappropriate content, then saves the full conversation plus a 0 - 2 keyword score in our database. Finally, the system pushes real-time feedback to users via *Socket.io* while implementing request throttling through the bottleneck library to ensure optimal performance, security, and compliant API usage.

Instrumentation

Behavior Goal, Actual Behavior, Behavior and Goal Ratio, and Behavioral Impact

Behavior goals are defined as the specific behavioral targets each student sets for themselves. Participants were prompted to enter a numeric value into the ProudMe Tech app's "Goal" field (eg, "30min Tennis" to indicate 30 minutes of playing tennis) for each of the 4 targeted behaviors: physical activity, screen time, diet, and sleep. No default goals were provided, and students set their goals independently without preset guidance from the system. These user-set goals served as the criteria against which actual behavior was compared. Actual behavior captures what the users self-reported for each of the 4 behaviors. Similar to behavior goals, participants were prompted to self-report the type and amount of the health

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behaviors on the same day (eg, "45min Tennis" for 45 minutes of playing tennis). To quantify goal attainment, the research team calculated the behavior and goal ratio variable for each behavior entry recorded in the database (ratio=1 means that the goal is met; ratio >1 means that the goal is exceeded; ratio <1 means that the goal is not achieved). Finally and importantly, the research team extracted a subset of complete baseline and end point behavior entries to determine the pre-to-post behavioral impact of the ProudMe Tech.

User Reflection

On the app, for each behavior entry, participants were prompted to write a brief reflection on their goal attainment and how they felt about their progress. Although the raw reflections are qualitative text, the research team derived 3 quantitative measures from them: total number of reflection entries from baseline to end point, length of each entry in characters, and the timestamp of submission. These reflection data were extracted from the ProudMe Tech database without transformation. In addition, sentiment of user reflection was obtained through a sentiment analysis [17] of the users' reflections upon their daily goals and behaviors (after viewing the feedback received from the AI chatbot). Sentiment analysis enabled us to characterize the user reflections.

Feedback

Feedback denotes the AI-generated feedback messages pushed to users in response to their behavior entries. The system prompts that the research team designed explicitly instructed the AI chatbot to generate tone-specific feedback according to users' goal achievement percentages for each behavior (eg, praise for meeting goals, educational tips for partial completion, and constructive suggestions for low completion). This design ensures consistent and reproducible feedback generation across users, while also eliciting meaningful and useful feedback for the users' behavior management. Users' engagement data were recorded automatically in the system, which was processed in real time and then later classified by mood through sentiment analysis. Feedback was quantified using the total number and length of messages delivered to each user.

Data Collection

Prior to data collection, the researchers informed the participants of the research purposes, procedures, benefits, and harms of the project, as well as their rights to participate in, decline, or withdraw from the study. Trained researchers handed out the consent and assent forms to the students, who were instructed to bring home the forms and seek parental consent. The same consent and assent forms were also shared virtually to parents and students by the teachers through the Google Classroom platform and email. During the 8-week school intervention, all data were automatically saved on the ProudMe Tech database instantaneously upon user entries. The participants were initially instructed to create accounts and then engage with the technology. They recorded their behavior goals, actual behaviors, reflections, and called for AI chatbot feedback. Data were extracted from the back-end database for processing and analysis.

Data Reduction

Based on descriptive scatterplots and pre-post summaries, the authors removed extreme observations as outliers that could distort visual scales. For each domain, the 1st and 99th quantiles of the behavior and goal ratio were computed on the pooled baseline-plus-end point data. Physical activity and screen time limited to 0 - 12 hours, fruits and vegetables limited to 0 - 20 servings, and sleep limited to 3 - 12 hours. Observations outside this range were tagged as outliers and excluded. By design, the trimming retained ≈98% of the records. Screen time goals were evaluated using reverse logic, where goals were considered achieved when actual screen use was less than or equal to the preset limit. Missing or zero goals were automatically excluded from the denominator to ensure that only meaningful goal-behavior pairs contributed to the analysis.

Data Analyses

The authors first conducted descriptive analyses of behavior entries (mean, median, SD, maximum, minimum, frequencies, *n*, percentage, etc), including behavior goals, actual behaviors, behavior and goal ratio, users' reflections, and feedback. The authors next analyzed the number and percentages of behavior goals met based on the goal and behavior ratio data and then visualized the goal and behavior ratio results by behavior using scatterplots on *ggplot2*. To determine the preliminary behavioral impact of the ProudMe Tech, the authors calculated the changes in behaviors from baseline to end point using absolute (Δ) and relative (Δ%) change scores:

$$\Delta = \text{Mend point} - \text{Mbaseline}$$

$$\Delta\% = 100 \times \Delta / \text{Mbaseline}$$

To evaluate user engagement with the ProudMe Tech platform, 2 distinct sets of user-generated text data were analyzed using natural language processing: user reflection and feedback. Each dataset underwent tailored analytic procedures to reflect its unique linguistic and functional characteristics. All the reflection and feedback data in the ProudMe Tech were analyzed using the *sentimentr* package (v2.9.0) [17] in R (R Core Team). This lexicon-based tool performs sentence-level sentiment scoring by identifying affective vocabulary, negations (eg, "not"), and intensifiers (eg, "very") within the context of grammatical structure. Each sentence received a sentimental score ranging from −1 to +1, where higher values indicated a more positive sentimental tone. Scores were aggregated to compute a mean sentiment score per user, reflecting their overall sentimental valence [18]. This approach provides an interpretable index of the sentimental tone in users' reflections and AI's feedback. The lexicon-based sentiment analysis methods (such as those implemented in the *sentimentr* package) have been increasingly used and reported in health communication and psychological text analysis contexts, supporting their interpretability and reliability in short, user-generated reflections [19].

To categorize the types of feedback received from AI, the authors used a manual, rule-based keyword procedure implemented in R (*mutate(), str_detect() from stringr*) to map each message to one of 4 categories: positive reinforcement (eg, "great/awesome/congratulations/nice/excellent/cool"), constructive suggestion (eg, "try/consider/you could/might want

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to"), educational prompt (eg, "helps to/improves/ is important for/ is linked to/ reduces/ promotes/is key for/research shows that"), or other (no match).

To determine the preliminary impact of the ProudMe engagement on health behaviors, the authors conducted paired-samples *t* tests to compare baseline and end point outcomes across each of the 4 health behaviors.

Ethical Considerations

This study was conducted in accordance with the Declaration of Helsinki and was approved by the Louisiana State University Institutional Review Board (IRB; protocol code IRBAM-21 - 0702). Written informed consent was obtained from parents or legal guardians, and assent was obtained from all participating students. All collected data were deidentified prior to analysis and securely stored on encrypted, password-protected servers accessible only to the research team. Participants received a gift card as compensation for their participation.

Results

Across the intervention, the authors captured 6164 goal-behavior pairings (1541 per domain), 5192 reflections, and 5804 AI chatbot feedback messages. A total of 172 participants recorded an average of 8.9 entries (mean 8.9, SD 7.6), with a median of 6 entries. About 53% (92 users) met or exceeded the median. Of the 6164 valid daily goals, 3934 (63.8%) were achieved based on their self-report. Table 1 presents the demographic characteristics of the participants, most of whom were 12 years old (129/172, 75%) in 6th grade (162/172, 94.7%) with slightly more girls (96/172, 55.8%) than boys (76/172, 44.2%).

Table . Sample distribution of age, sex, and grade level.

Characteristics	Participants (N=172)
Age (years), n (%)	
11	22 (12.8)
12	129 (75.0)
13	18 (10.5)
14	2 (1.2)
15	1 (0.6)
Sex, n (%)	
Female	96 (55.8)
Male	76 (44.2)
Grade level, n (%)	
6th	162 (94.2)
7th	10 (5.8)

Table 2 summarizes the behavior and goal ratios across domains, showing that users on average slightly exceeded their targets. Variability was highest for screen time and physical activity and lowest for diet. Figure 2 presents the trimmed scatterplot distributions of the behavior and goal ratios for each behavior domain. Each dot represents a record of a user. The horizontal axis represents participant identifiers and the vertical axis represents the ratio of the user's actual completion of the behavior to the set goal. The purple reference line indicates the behavior and goal ratio being 1 (goal is met but not exceeded). For physical activity, most of the observations were distributed around 1 (indicating most goals were met), some of them more than 2, indicating that some users reported abnormally high physical activity relative to their goal. For screen time (reverse), most observations were below 1, indicating that the actual screen time of users was generally lower than or close to the target value, and the goal completion was high. For diet, the observations were concentrated between 1 and 3, indicating that many users exceeded their set goals in diet (eg, eating more fruits and vegetables than their self-selected goals). For sleep, the dataset was concentrated and close to 1, indicating that the sleep behavior of most users was consistent with their goals. A correlation analysis indicated no statistically significant association between engagement frequency and self-reported goal completion rate (r=0.12, 95% CI –0.03, 0.26; P=.12).

Table . Descriptive results of the behavior and goal ratio.

Behaviors	n	Ratio, mean (SD)	Min-Max
Physical activity	1489	1.3 (1.2)	0-40
Screen time	1447	1.3 (2.0)	0-60
Diet	1471	1.1 (0.7)	0-10
Sleep	1258	1.0 (0.2)	0-2.36

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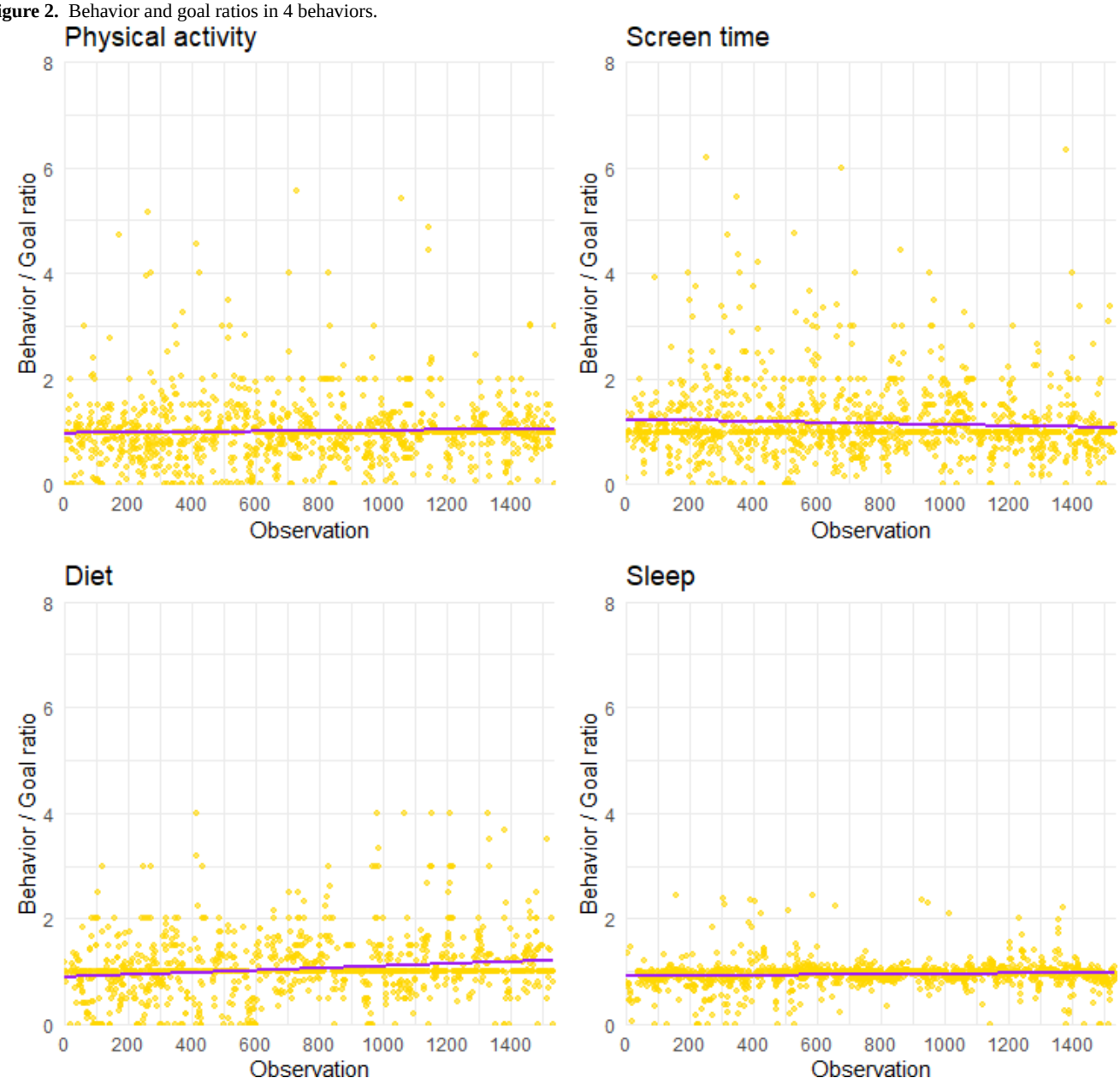
Figure 2. Behavior and goal ratios in 4 behaviors.



Participants posted an average of 30 reflective notes (SD 28.3, range 1 - 127; overall total of 5192), averaging roughly 10 words per entry (mean 9.9, SD 9.2). A density plot, Figure 3, was used to examine the distribution of average reflection word counts per user, here as a proxy for engagement. As shown in Figure 3, length ranged from completely blank submissions to a detailed reflection of 195 words, indicating that while most reflections were very brief, a small number of participants were considerably more elaborate and drove the wide variation in word counts (range 0 - 195).

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Figure 3. Reflection word count density.

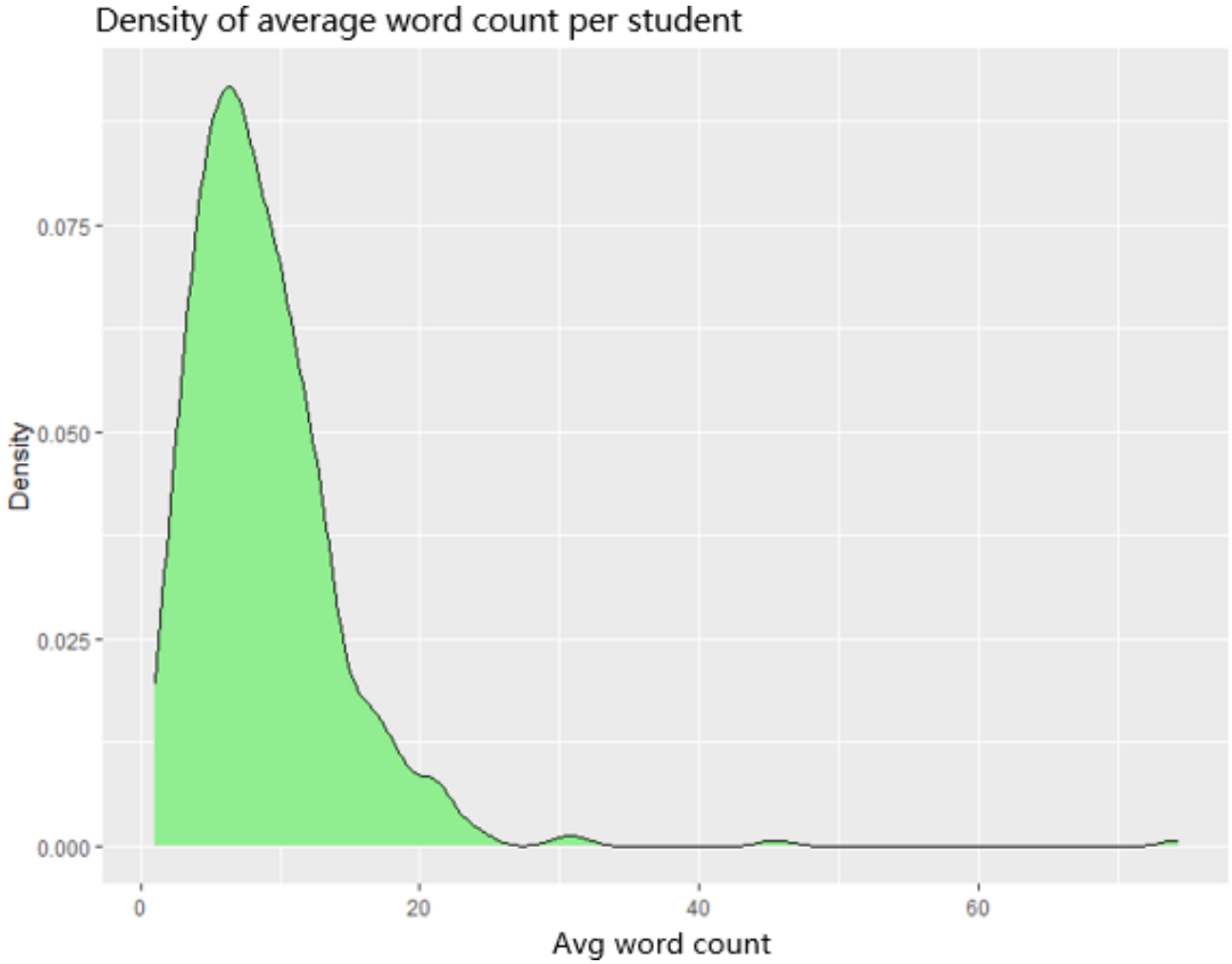

Figure 4 plots each user's average reflection sentiment score (*x* axis) against their total number of reflection entries (*y* axis). Each red dot represents a user's combined data: most sentiment scores cluster around zero (neutral tone), ranging from approximately –0.25 (more negative reflections) to +0.50 (more positive reflections), while total reflections span from 0 up to over 120 entries. The purple regression line, with its wide gray 95% confidence band, lies nearly flat, indicating a statistically nonsignificant association between how positively or negatively users wrote and how often they reflected.

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Figure 4. Average reflection sentiment versus total reflection.

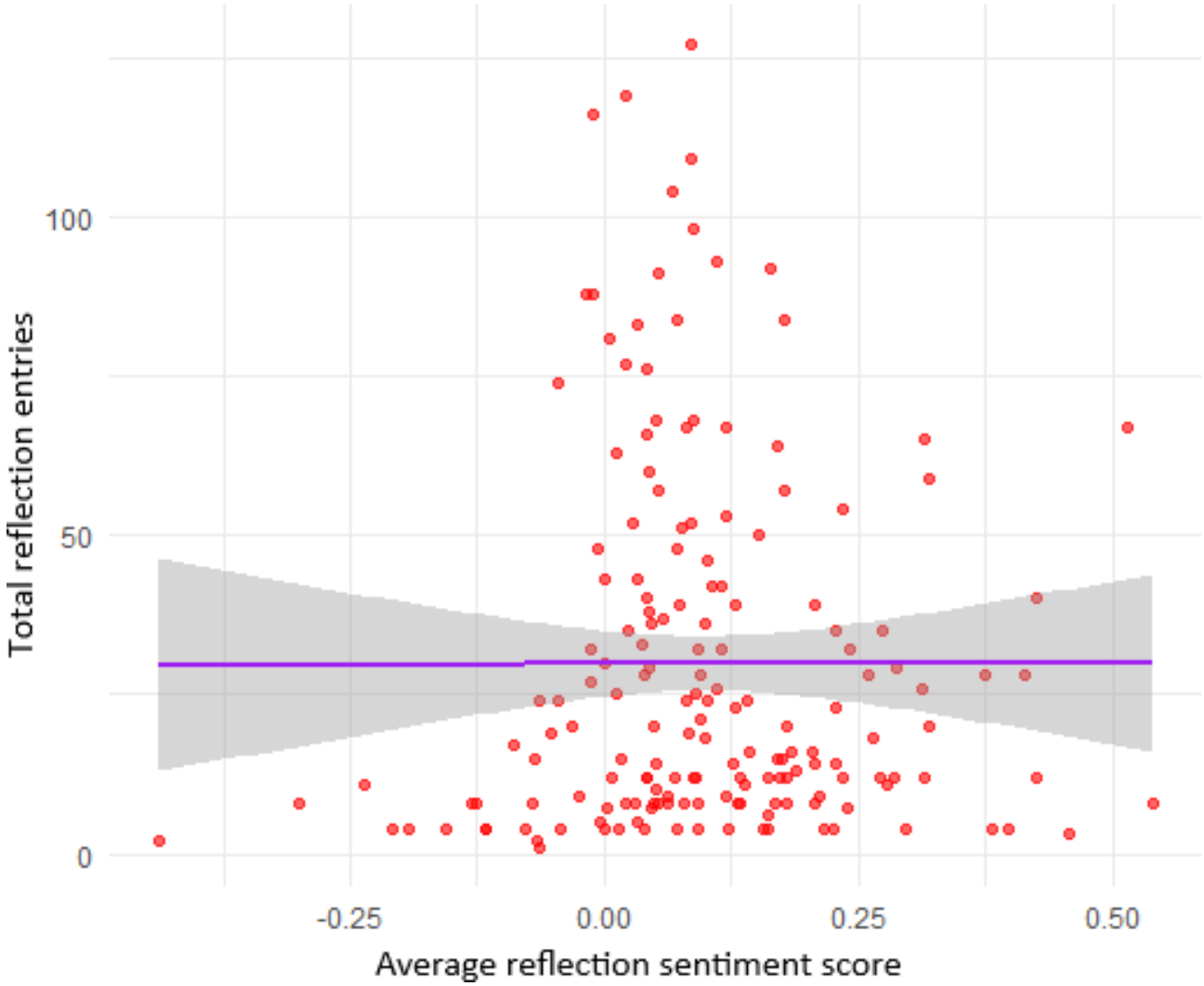

Table 3 presents a total of 5804 AI-generated feedback messages categorized into 4 tone types. "Positive reinforcement" dominated the chatbot output, accounting for 3493 messages (60.2%). This was followed by "Educational prompts" totaling 1595 (27.5%). Only 675 "constructive suggestions" (11.6%) and 41 "other" remarks (0.7%) were observed.

Table . Total frequency of feedback tone categories.

Feedback category	Frequency (n)	Percentage (%)
Positive reinforcement	3493	60.2
Educational prompt	1595	27.5
Constructive suggestion	675	11.6
Other	41	0.7
Total	5804	100.0

Figure 5 depicts the distribution of feedback per user. "Positive reinforcement" was the most frequent category averaging 20.2 messages (SD 19.5) per user. "Educational prompts" was the second most frequent feedback type (mean 9.2, SD 8.8) followed by "constructive suggestions" (mean 3.9, SD 4.5,) and "Other" (mean 0.2, SD 0.5). Overall, the AI chatbot feedback skewed toward affirmation rather than instruction or corrective messaging.

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Figure 5. Distribution of feedback types per student.

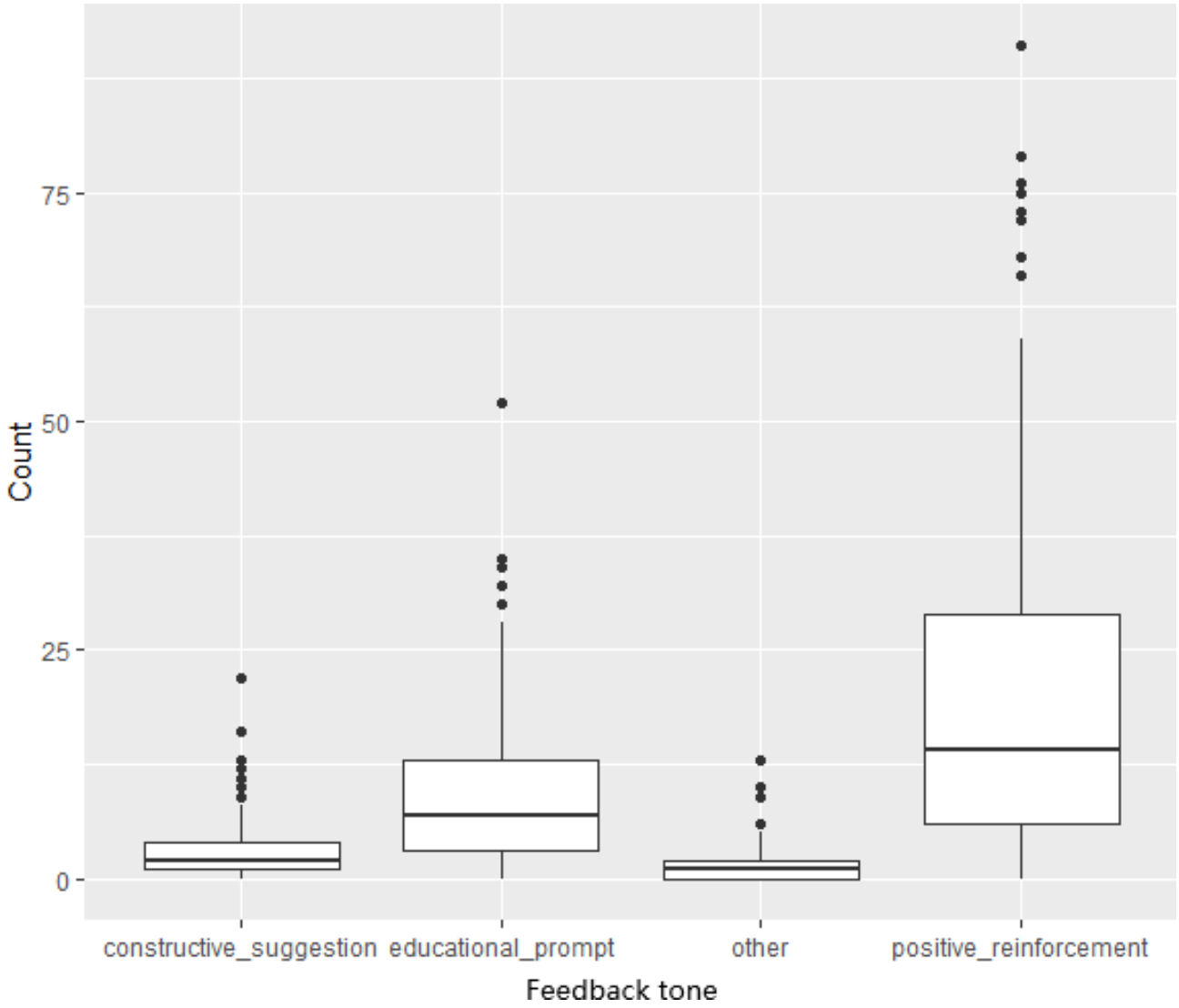

Figure 6 illustrates the relationship between the average sentiment scores of AI feedback and the total number of feedback received per user. Overall, most sentiment scores were above zero, indicating a generally neutral to mildly positive tone across the feedback messages. The association between the quantity of AI-generated feedback received and the average sentiment score of that feedback was statistically nonsignificant.

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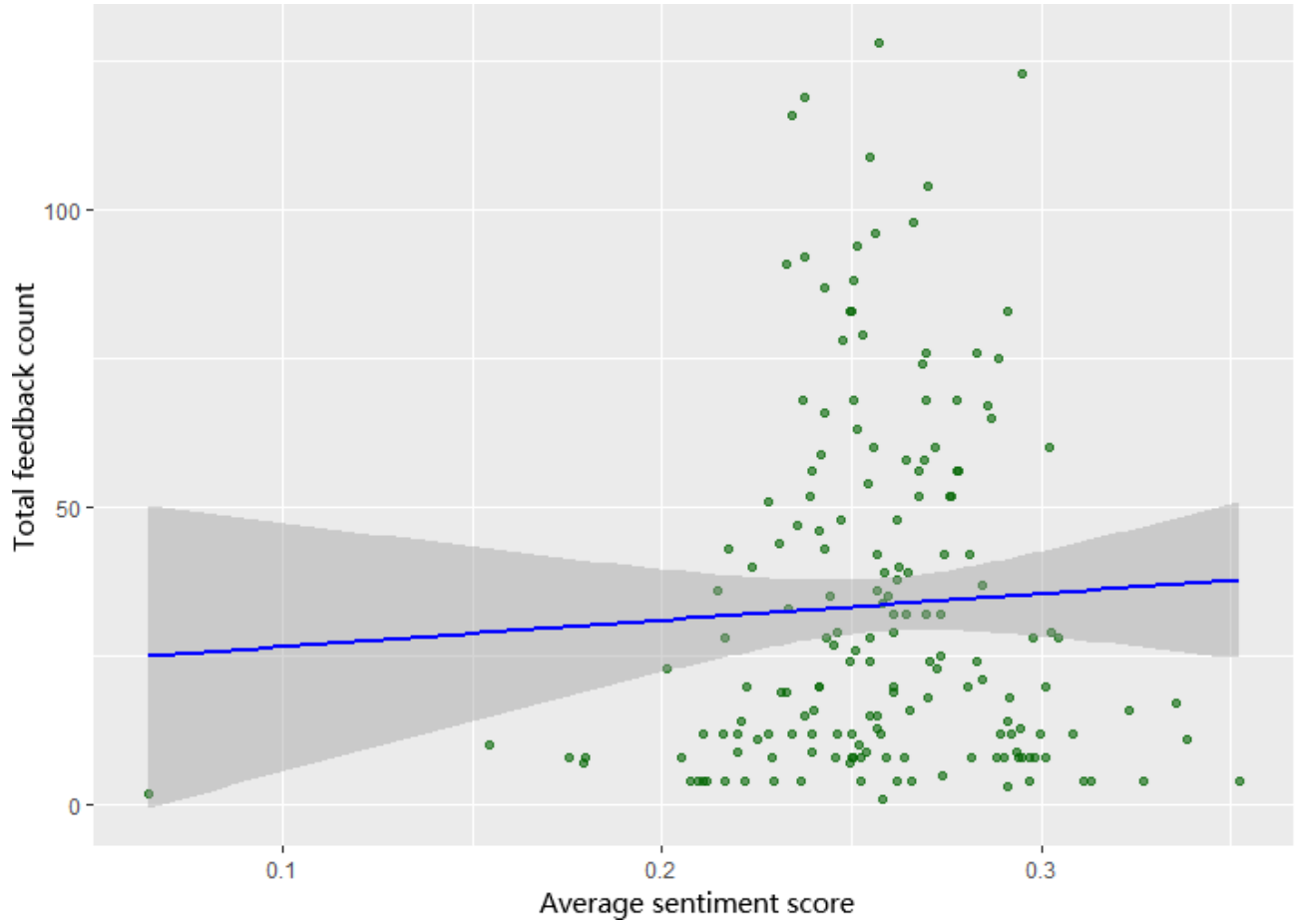
Figure 6. Scatterplot of average feedback sentiment versus total feedback.



In Table 4, results indicated that screen time decreased significantly from 4.3 (SD 2.6) hours at baseline to 3.4 (SD 2.5) hours at end point (t_{164}=6.18, P<.001), reflecting a 21.6% reduction. Fruit and vegetable intake also declined significantly, from 5.7 (SD 3.8) to 5.2 (SD 3.5) servings (t_{169}=2.27, P=.02), an 8.9% decrease. In contrast, physical activity and sleep did not significantly change (P=.20).

Table . Paired *t* test results of the health behaviors by time (baseline and end point).

Behavior	N	Baseline, mean (SD)	End point, mean (SD)	Δ (absolute)	Δ %	*t* test (df)	*P* value
Physical activity (hours)	169	2.5 (2.3)	2.4 (2.3)	–0.12	–4.7	1.29 (168)	.20
Screen time (hours)	165	4.3 (2.6)	3.4 (2.5)	–0.93	–21.6	6.18 (164)	<.001
Fruit and vegetables (servings)	169	5.7 (3.8)	5.2 (3.5)	–0.50	–8.9	2.27 (168)	.02
Sleep (hours)	157	7.6 (1.5)	7.7 (1.5)	+0.06	+0.8	–0.74 (156)	.46

Discussion

Principal Findings

The participants demonstrated sustained engagement with ProudMe Tech over the 8-week deployment, though the engagement metrics varied considerably between individuals. Results showed acceptable feasibility of the ProudMe Tech, showing an average of 8.9 behavioral entries, 30 reflections, 33.5 AI-generated chatbot feedback messages per participant, and 63.8% of the daily goals achieved. Compared to existing adolescent AI chatbots or digital health interventions (around 50% usage) [9,10], the usage and engagement metrics reported in this study were deemed acceptable. The users demonstrated a wide spectrum of engagement, with some users engaging with the platform daily, producing frequent and detailed reflections that prompted substantive feedback, while others participated sporadically, resulting in fewer and briefer interactions. Such variations in both quantity and quality of the users' behavior entries, reflections, and AI-generated feedback appeared to be characteristic of adolescent engagement patterns as shown in similar prior digital health interventions, where individual motivation, access, and contextual factors play decisive roles [20]. It is noteworthy that engagement frequency was not

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associated with self-reported goal completion rate in this feasibility study. This suggests that higher engagement alone may not necessarily lead to greater goal attainment, possibly due to the brief intervention duration and variability in user motivation. Future studies with larger samples and longer follow-up periods should further explore this relationship and the underlying reasons. Notably, our data records indicated that 72.7% (487) of the students from the participating schools created accounts and engaged with the ProudMe Tech platform, but only 35.3% (172) of them were participants (with signed parental consent and assent). This limited our data analysis to a subsample, which might have constrained the feasibility and impact of the ProudMe Tech interaction. The relatively low enrollment suggests the difficulty of obtaining parental consent for studies that occur at underresourced schools. Future research should address this barrier to attain a higher participation rate to improve feasibility and success.

Beyond the user engagement metrics, the nature and quality of engagement with ProudMe Tech are meaningful to mention. The participants achieved 63.8% of their goals, eliciting positive reinforcement and educational prompts from the AI chatbot (87.7%). Meeting personal goals and receiving meaningful feedback might have fostered the users' perceived competence, self-efficacy, and functional social support through this AI chatbot platform [14,15,21,22]. The combination of regular goal achievement and supportive feedback may have created a reinforcing loop where users have felt competent upon meeting goals and receiving affirmation, encouragement, and constructive suggestions from the chatbot. Previous studies have shown that such feedback structure, in conjunction with encouragement with actionable suggestions, can significantly increase behavior adoption and adherence in youth populations [8,9,23]. It is important to note that these feedback patterns reflect the programmed structure of the ProudMe chatbot rather than dynamic learning throughout the trial; the observed reinforcement and prompts were generated from a predefined rule-based system responding to user inputs.

Furthermore, our pre-post comparisons revealed measurable changes in 2 of the 4 health behaviors, underscoring the preliminary impact of the ProudMe Tech engagement on these behaviors. Of the 4 behaviors, screen time decreased by 0.9 hours per day (from 4.3 to 3.4 hours) and fruit and vegetable intake showed a significant decrease (8.9%), but the endpoint average score still exceeded the recommended 5 or more servings per day (ie, 5.18 servings). These changes align with prior evidence that digitally mediated self-monitoring, coupled with timely feedback, can quickly influence screen-related behaviors [24]. The unexpected decrease in fruit and vegetable intake suggests possible ceiling effect, as these participants in the present study on average reported over 5 servings per day. Intervention to promote consumption of fruits and vegetables is important, as only 18% of children between 5 and 15 years of age meet this recommendation [25]. It is also important to note that our baseline data were collected in early February and end point data in mid-May. Seasonal changes in daylight, weather, and the proximity to end-of-semester exams may have influenced students' daily routines related to screen time and dietary intake (even sleep) behaviors independent of the intervention. These significant behavior changes in screen time suggest that these children might have been responsive to immediate environmental cues (eg, device reminders and goal prompts) and were able to make adjustments (eg, reduced recreational device use) [26].

In contrast, physical activity and sleep did not show changes in light of the ProudMe Tech engagement. These results highlight the greater difficulty of modifying these 2 behaviors as the more ingrained, effort-dependent, chronic health behaviors within a short timeframe. One possible explanation is the lack of family engagement in this feasibility study. While adolescents may express interest in being more physically active, many of the daily choices around physical activity opportunities are heavily impacted by the home environment and parental influence. Without consistent parental support, for example, providing transportation to sports and recreational activities or reminding children to stick with sleep routines, children's capacity to make and sustain meaningful changes in these behaviors would be constrained [27]. Shifting physical activity and sleep patterns often demand overcoming environmental (eg, access to facilities and food environments) and individual barriers (eg, time constraints and motivation) [28,29] and not all of these barriers were addressed in the ProudMe Tech app.

Despite the feasibility and impact of the ProudMe Tech intervention, this study has several limitations. First, the relatively small sample size per school and low parental consent rate might have limited the generalizability of the results. However, recruiting a large sample in an intervention study like this, from underresourced schools in particular, is difficult. Our research team used various strategies to recruit and enroll a large sample. Obtaining signed parental consent without coercion from low socioeconomic families (despite incentives) is a significant reality challenge. These said, it is typical for early-stage digital health feasibility trials conducted in real-world school settings to have smaller sample sizes than fully powered randomized controlled trials. Second, our behavioral assessment as well as students' goal setting was self-reported in nature, which is susceptible to recall inaccuracies and social desirability bias [30,31]. The young participants (~12 years old) in this study might have experienced difficulty in setting SMART goals, tracking their health behaviors, and engaging in in-depth self-reflections. Future studies should integrate objective measures (eg, accelerometers and Fitbit trackers) to more accurately capture health behaviors in this age group [30,32]. Nevertheless, the ultimate purpose of engaging these adolescent users on the ProudMe Tech platform was to educate them about behavior management and provide them with a technology-assisted tool to practice these behavior management skills. Third, the study lacked a control group and was limited to an 8-week implementation period, restricting our ability to draw strong causal inferences about the long-term effectiveness of the intervention [23]. Although having a control group with a longer intervention period to compare the behavior impact of the ProudMe Tech would be more preferable, this feasibility study was designed to primarily evaluate engagement, usability, and short-term behavioral change trends rather than efficacy. Future research with emphasis on efficacy or effectiveness of the intervention should adopt the randomized

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controlled trial designs [23]. Fourth, our AI chatbots primarily delivered affirmation and educational prompts and offered relatively few constructive suggestions. Although affirmation and informational prompts can increase motivation and raise awareness, the limited presence of constructive suggestions may have reduced opportunities for adolescents to receive behavior-corrective feedback or actionable strategies [18]. Therefore, refining the chatbot algorithm to balance educational information with more frequent constructive suggestions in the future could provide adolescents with not only motivational support but also practical guidance to strengthen self-regulation and long-term health outcomes [23]. Finally, the ProudMe Tech should use strategies to educate and engage parents, because parental support plays a critical role in shaping adolescents' dietary and physical activity behaviors and reinforcing behavior changes outside of school.

In summary, our findings suggest that our AI-assisted ProudMe Tech website app can be feasibly integrated into the middle school curriculum to engage adolescents in daily behavior management and elicit meaningful behavior shifts for screen time behaviors, but further adaptations are needed to improve physical activity and sleep behaviors. ProudMe Tech provides an example for low-cost, school-based, AI-assisted health behavior interventions.

Conclusions

These findings suggest that ProudMe Tech is a feasible AI chatbot that can engage adolescents in health behavior management, but more adaptation is needed to effectively elicit improvements in health behaviors and lower the obesity risk in middle school students.

Acknowledgments

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Data Availability

The datasets generated and analyzed during this study are not publicly available due to confidentiality concerns and ethical restrictions. However, data may be made available from the corresponding author on reasonable request and after approval by the Institutional Review Board.

Authors' Contributions

Conceptualization: SC
Resources: RRR, AES, SC
Investigation: YN (equal), PS (equal), QT (equal), SC (equal)
Data curation: QT (lead), YQ (supporting), YN (supporting), PS (supporting), SC (supporting)
Formal analysis: QT (lead), SC (supporting)
Writing – original draft: QT (equal), SC (equal)
Writing – review & editing: QT (equal), SC (equal), YN (supporting), PS (supporting), YQ (supporting), AES (supporting), FW (supporting)
Supervision: SC
Project administration: SC

Conflicts of Interest

None declared.

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Abbreviations

AI: artificial intelligence
API: Application Programming Interface
SMART: specific, measurable, attainable, realistic, and timely

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Multimodal Transformer–Based Electrocardiogram Analysis for Cardiovascular Comorbidity Detection: Model Development and Validation Study

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Abstract

Background: Cardiovascular diseases remain the leading global cause of mortality, yet traditional electrocardiogram (ECG) interpretation shows subjective variability and limited sensitivity to complex pathologies.

Objective: This study aims to address these challenges by proposing the Cardiovascular Multimodal Prediction Network (CaMPNet), a transformer-based multimodal architecture that integrates raw 12-lead ECG waveforms, 9-structured machine-measured ECG features, and demographic data (age and sex) through cross-attention fusion.

Methods: The model was trained on 384,877 records from the Medical Information Mart for Intensive Care IV - Electrocardiogram Matched Subset database and evaluated across 12 cardiovascular disease labels. To further assess temporal robustness, a temporal external validation was performed using the most recent 10% of the data, withheld chronologically from model development.

Results: On the internal test set, the model achieved a mean area under the curve (AUC) of 0.845 (SD 0.04) and area under the precision-recall curve of 0.489, outperforming the residual networks-ECG baseline (AUC=0.848 but F_1-score=0.152) and all single-modality variants. Subgroup analyses demonstrated consistent performance across demographics (male AUC= 0.846 vs female=0.843; youngest quartile 0.884 vs oldest 0.811). CaMPNet retained moderate discriminative ability in temporal external validation with a mean AUC of 0.715 (SD 0.03) and area under the precision-recall curve of 0.298, although performance declined due to temporal distribution shifts. Despite this, major disease categories, such as atrial fibrillation, heart failure, and normal rhythm, maintained high AUCs (>0.84). Attention-based visualization revealed clinically interpretable patterns (eg, ST-segment elevations in ST-segment elevation myocardial infarction), and ablation experiments verified the model's tolerance to missing structured inputs.

Conclusions: CaMPNet demonstrates robust and interpretable multimodal ECG-based diagnosis, offering a scalable framework for comorbidity screening and continual learning under real-world temporal dynamics.

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KEYWORDS

cardiovascular diseases; Electrocardiogram; multimodal deep learning; comorbidity detection; model interpretability; ECG

Introduction

Cardiovascular diseases (CVDs) [1] remain the leading cause of death worldwide, accounting for approximately 17.9 million deaths annually (32% of all global deaths) [2-4]. As a noninvasive, cost-effective, and widely available diagnostic tool, the electrocardiogram (ECG) [5-7] plays a vital role in screening and monitoring cardiac conditions, such as arrhythmias and myocardial ischemia [8]. However, traditional ECG interpretation often relies on expert-driven heuristics or rule-based algorithms, which can struggle with noisy signals or atypical patterns, limiting their use in early or complex disease detection [6,9-12].

Recent advances in deep learning (DL) [13] have enabled more effective ECG analysis by learning complex temporal and morphological features directly from raw signals [14-18]. Architectures such as convolutional neural networks [19], long short-term memory [2,3,9], and transformers [20] have demonstrated impressive performance in arrhythmia classification [2], heart failure (HF) prediction [11,21], and atrial fibrillation detection [4]. The availability of large public datasets (eg, Massachusetts Institute of Technology - Beth Israel

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Hospital, Medical Information Mart for Intensive Care - Electrocardiogram [22], and Physikalisch-Technische Bundesanstalt - XL) has further supported model development and validation [10,23]. Building on this progress, DL-based approaches have begun to address the limitations of conventional analysis [24-27], identifying precursors to atrial fibrillation [2,3] and predicting conditions such as ventricular dysfunction with high sensitivity [2,11]. Methodological advances have also explored fusing electronic health record data with ECG signals to emulate multimodal diagnostic workflows [6,28].

Despite this progress, 3 critical gaps persist in current ECG-based artificial intelligence systems. First, most prior studies focus on single-disease classification, failing to address the reality that cardiovascular comorbidities are highly prevalent, particularly among elderly and critically ill patients [11]. Second, the majority of models rely solely on raw ECG waveforms, overlooking the structured, machine-measured ECG features (eg, interval timings and electrical axes) that are routinely generated by hospital acquisition systems. These parameters contain clinically meaningful morphological descriptors but are often discarded in end-to-end DL pipelines. Third, model evaluation is frequently restricted to small or single-center datasets, raising concerns regarding robustness and generalizability across diverse populations.

To bridge these gaps, this study aims to answer a central question: Can a unified multimodal learning framework that intelligently fuses raw ECG waveforms with structured clinical features improve the detection of multiple cardiovascular comorbidities compared to single-modality approaches? Specifically, we sought to develop a model capable of leveraging the complementary information in machine-measured parameters while remaining robust to the missing or noisy data inherent in real-world clinical settings.

Recent advances in ECG-based DL have demonstrated the capability of convolutional architectures, particularly residual networks (ResNet), to extract robust diagnostic features directly from raw waveform data. For example, the ResNet-based model proposed by Kalmady et al [29] leveraged a large population-level cohort to predict multiple cardiovascular conditions and established deep residual learning as an effective backbone for ECG waveform analysis. This model serves as an important benchmark, as it represents a strong waveform-only approach that captures temporal morphology but does not incorporate structured ECG measurements or demographic information. Moreover, most existing models, including the ResNet baseline, adopt late or simple feature fusion strategies and therefore cannot explicitly model cross-modal interactions between waveform and structured inputs. In contrast, our proposed framework introduces an early cross-attention mechanism that allows structured ECG features to guide the selection of clinically relevant waveform segments prior to encoding. This design enables richer multimodal representation learning and provides a principled advantage over waveform-only models and traditional fusion strategies. To allow for a fair comparison, we include the ResNet-ECG model [29] as a key baseline and contextualize its differences from our method in both architecture and modality integration.

In this study, we developed Cardiovascular Multimodal Prediction Network (CaMPNet), a transformer-based multimodal framework developed using the large-scale Medical Information Mart for Intensive Care IV - Electrocardiogram Matched Subset (MIMIC-IV-ECG) database [22]. Unlike conventional fusion methods, CaMPNet introduces a query-conditioned early fusion mechanism to efficiently retrieve relevant waveform information using structured features. We rigorously validate the model's performance across multilabel classification tasks, assess its robustness to missing inputs, and demonstrate its interpretability through attention maps that align with physiological patterns. This work represents a significant step toward scalable, clinically deployable artificial intelligence for comprehensive cardiovascular risk assessment.

Methods

Datasets and Cohort Selection

We used a total of 384,877 standard 12-lead ECG recordings from the publicly available MIMIC-IV-ECG database [22,30,31] hosted on PhysioNet, jointly curated by Massachusetts Institute of Technology-Beth Israel Deaconess Medical Center. To ensure consistency in model development and diagnostic label interpretation, we focused on the 13 most prevalent diagnostic categories. The 13 diagnostic categories considered in this study comprised one "Normal" rhythm class and 12 CVD classes, atrial fibrillation, supraventricular or ventricular tachycardia, cardiac arrest, atrioventricular block, unstable angina, ST-elevation or non–ST-elevation, myocardial infarction, pulmonary embolism, hypertrophic cardiomyopathy, aortic stenosis or insufficiency, mitral valve prolapse or stenosis, pulmonary hypertension, and heart failure. These disease labels were derived from the corresponding *International Statistical Classification of Diseases and Related Health Problems 10th Revision* codes associated with each ECG recording.

Table 1 summarizes the baseline demographic and clinical characteristics of the study population, including the distribution of age, gender, and the prevalence of each diagnostic category. It also presents the sample counts and proportions of the 13 diagnostic categories, across the entire dataset and its designated training, validation, and test splits, providing insights into (1) the representational balance across disease categories, (2) the presence of rare or underrepresented conditions, and (3) the need for targeted strategies, such as weighted loss functions or resampling techniques to address class imbalance during model training.

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Table . Baseline characteristics.

Characteristics	Values (N=384,877)
Sex, n (%)	
Female	183,073 (47.6)
Male	201,804 (52.4)
Age (years), mean (SD)	64.8 (17)
Clinical labels, n (%)	
Normal	151,476 (39.4)
Atrial fibrillation	123,898 (32.2)
Heart failure	122,681 (31.9)
ST-Elevation or non-ST-elevation myocardial infarction	45,116 (11.7)
Pulmonary hypertension	29,018 (7.5)
Supraventricular or ventricular tachycardia	24,980 (6.5)
Hypertrophic cardiomyopathy	21,398 (5.6)
Aortic stenosis or insufficiency	19,682 (5.1)
Mitral valve prolapse or stenosis	18,716 (4.9)
Atrioventricular block	18,057 (4.7)
Unstable angina	13,067 (3.4)
Pulmonary embolism	8524 (2.2)
Cardiac arrest	7593 (2)

CaMPNet Overview

We propose CaMPNet, a novel multimodal transformer architecture designed for automatic classification of cardiac abnormalities. The model is specifically designed to embed and fuse heterogeneous data sources, including raw ECG waveforms, structured clinical features, and patient metadata, within a unified diagnostic framework. As shown in Figure 1, the model begins by processing the raw 12-lead ECG signals. They are divided into a series of nonoverlapping patches, which are then mapped into ECG patch tokens using a 1D convolutional network. This preserves essential temporal and morphological information from the waveforms. Meanwhile, structured clinical features and patient demographic information (age and sex) are each embedded into independent feature tokens via separate feed-forward networks, allowing the model to retain distinct semantics from each modality.

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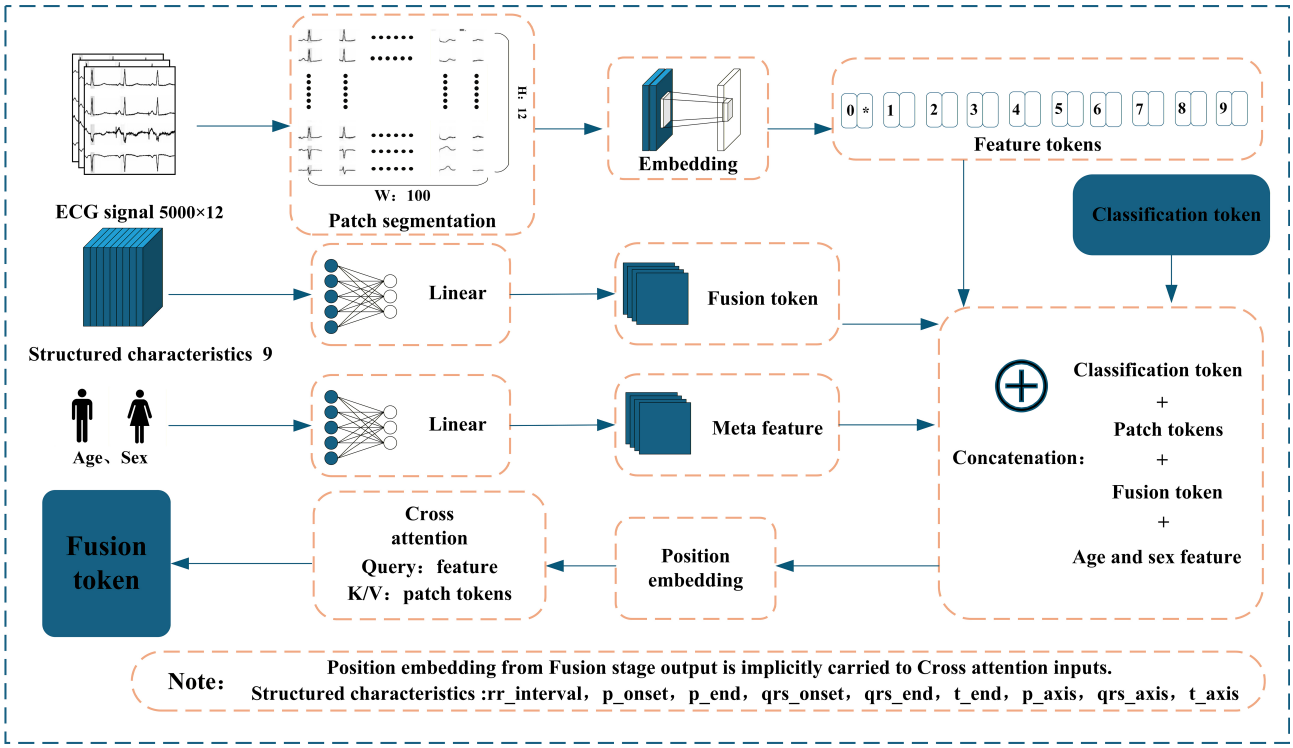
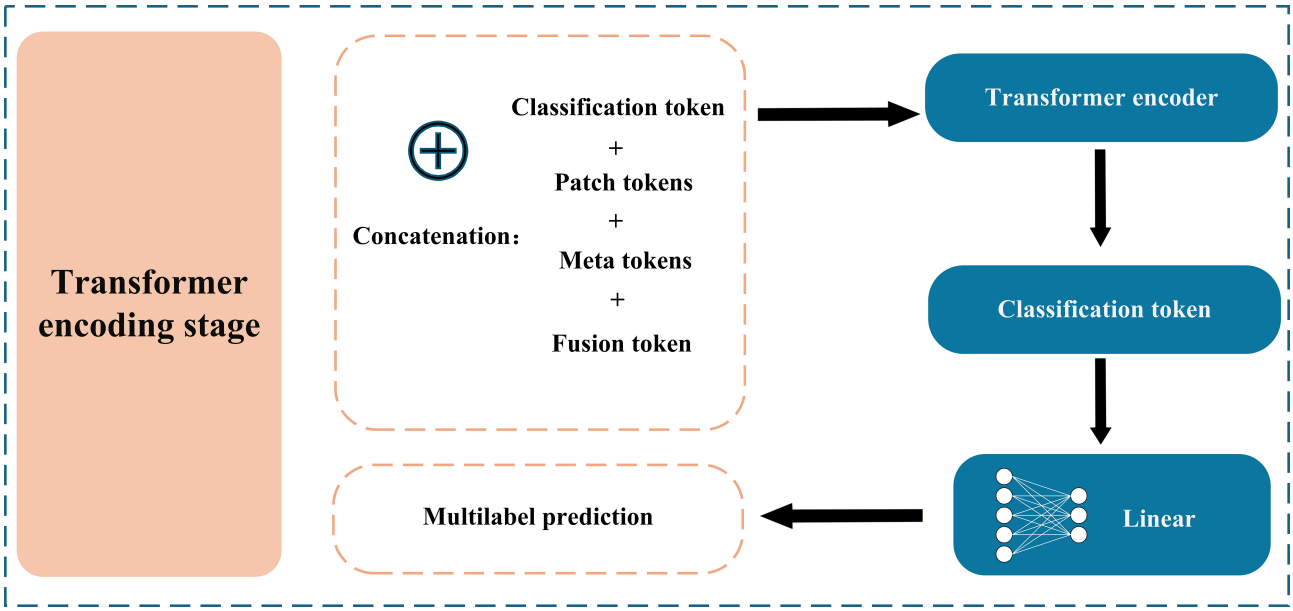
Figure 1. Overall architecture of the cardiovascular multimodal prediction network. The multimodal input embedding and fusion module jointly processes raw electrocardiogram waveforms, structured clinical features, and demographic metadata. A cross-attention mechanism generates a context-enhanced fusion token to integrate waveform and feature information. ECG: electrocardiogram; K/V: key value.



The core innovation of the CaMPNet lies in its early fusion strategy prior to the transformer encoder. Before entering the main transformer encoder, the model uses a cross-attention module, where the structured feature token acts as the query, actively retrieving and integrating the most relevant waveform information from the ECG patch token sequence (context), thereby generating an enhanced feature token enriched with low-level signal context.

Subsequently, the fusion token is concatenated with the original ECG patch tokens, metadata tokens, and a CLS token. Positional encodings are then added to form the final input sequence. As illustrated in Figure 2, the resulting sequence is fed into a standard multilayer transformer encoder, which deeply models all information through global self-attention mechanisms. Finally, the output state of the CLS token is used by a linear classification head to predict cardiac abnormality categories. This fusion-before-encoding strategy based on hybrid attention allows the model to more precisely exploit multimodal information, thereby improving diagnostic applications.

Figure 2. Transformer encoding and classification. The fused token sequence, including the electrocardiogram path tokens, fusion token, metadata token, and CLS token, is passed through a multilayer transformer encoder. The output from the CLS token is used for final multilabel cardiac classification.



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The novelty of CaMPNet lies in its hierarchical cross-modal attention fusion, which closely mirrors a clinician's diagnostic reasoning process by jointly analyzing waveform dynamics, structured clinical metrics, and patient context, while maintaining computational efficiency.

Mathematical Formulation of Cross-Attention Fusion

Let Xp∈ RB×Np×Ddenote the ECG patch embeddings (context) and Xs∈ RB×1×Dthe structured ECG feature token (query). The cross-attention mechanism is defined as:

(1)Q=XsWQ, K=XpWK,V=XpWv

(2)A=Softmax(QKTD),Z=AV

(3)X~=ln(Xs+FFN(Z))

where W_Q, W_K, and W_V are learnable projection matrices, and LN denotes layer normalization. In this design, the structured ECG feature token serves as the query, while ECG patch tokens provide key-value context. This allows the model to selectively retrieve waveform regions that are physiologically relevant to each structured feature (eg, QRS widening, focusing on QRS complexes), thereby achieving clinically interpretable multimodal fusion.

Experiment and Design

This study aimed to develop and evaluate CaMPNet, a transformer-based multimodal DL framework capable of automatically distinguishing normal ECGs and 12 distinct cardiac abnormalities through the integration of raw 12-lead ECG waveforms, derived structured ECG features, and demographic metadata.

A comprehensive evaluation was performed in five methodological stages: (1) standardized data preparation and preprocessing; (2) model training with systematic hyperparameter optimization; (3) validation through cross-validation techniques; (4) final performance assessment on an independent test set to ensure unbiased diagnostic evaluation; and (5) temporal external validation, designed to assess the model's robustness over time and simulate real-world deployment scenarios. Because acquiring an independent external validation cohort was highly challenging, existing ECG repositories either lacked confirmed diagnostic annotations or missed key structured clinical variables (9 tabular features in our framework). We followed a temporal split strategy similar to that used in the study by Gustafsson et al [26] on myocardial infarction prediction in emergency departments.

Specifically, the dataset was divided chronologically, and the earliest 90% of samples were used for model development (further split into training, validation, and internal testing), while the most recent 10% were reserved as a temporally separated test cohort. This design enabled evaluation of the model's temporal generalization under potential distributional shifts, providing a practical alternative to external validation when access to fully labeled multimodal data was limited.

Data Preprocessing

The dataset was first chronologically divided into 2 partitions to enable temporal generalization analysis: the earliest 90% of records were used for model development, while the most recent 10% were reserved as a temporally separated external validation cohort. Within the development portion, data were further randomly split in a 7:1:1 ratio into training, validation, and internal test subsets to ensure robust model tuning and unbiased evaluation, following recommended practices [12]. This temporal split strategy was adopted to simulate real-world deployment scenarios and mitigate potential time-related data leakage.

Table 2 summarizes the distribution of the 13 diagnostic categories, comprising one "Normal" rhythm class and 12 CVD classes, across all dataset partitions (total, training, validation, test, and temporal test). Each cell reports both the sample count and its percentage within each subset. The table highlights a notable class imbalance, with normal, atrial fibrillation, and HF being the most prevalent, whereas rare but clinically significant conditions, such as pulmonary embolism and cardiac arrest, remain underrepresented, underscoring the necessity of adaptive loss weighting and resampling strategies during model training.

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Table . Distribution of diagnostic labels across all dataset splits.

Description	Total, n (%)	Training, n (%)	Validation, n (%)	Test, n (%)	Temporal test, n (%)
Atrial fibrillation	123,898 (32.2)	86,100 (32)	12,404 (32.2)	12,315 (32)	13,079 (34)
Aortic stenosis or insufficiency	19,682 (5.1)	139,42 (5.2)	2021 (5.3)	2026 (5.3)	1693 (4.4)
Atrioventricular block	18,057 (4.7)	12,856 (4.8)	1830 (4.8)	1755 (4.6)	1616 (4.2)
Cardiac arrest	7593 (2)	5385 (2)	763 (2)	745 (1.9)	700 (1.8)
Hypertrophic cardiomyopathy	21,398 (5.6)	15,011 (5.6)	2152 (5.6)	2098 (5.5)	2137 (5.6)
Heart failure	12,2681 (31.9)	84,812 (31.5)	11,995 (31.2)	12,146 (31.6)	13,728 (35.7)
Mitral valve prolapse or stenosis	18,716 (4.9)	12,990 (4.8)	1966 (5.1)	1851 (4.8)	1909 (5)
Normal	151,476 (39.4)	106,371 (39.5)	15,105 (39.2)	15,219 (39.5)	14,781 (38.4)
Pulmonary embolism	8524 (2.2)	6076 (2.3)	847 (2.2)	845 (2.2)	756 (2)
Pulmonary hypertension	29,018 (7.5)	20,046 (7.4)	2908 (7.6)	2886 (7.5)	3178 (8.3)
ST-elevation or non-ST-elevation myocardial infarction	45,116 (11.7)	32,017 (11.9)	4567 (11.9)	4579 (11.9)	3953 (10.3)
Supraventricular or ventricular tachycardia	24,980 (6.5)	17,594 (6.5)	2515 (6.5)	2466 (6.4)	2405 (6.2)
Unstable angina	13,067 (3.4)	9196 (3.4)	1346 (3.5)	1333 (3.5)	1192 (3.1)

ECG Signal Processing

Raw 12-lead ECG signals were preprocessed by replacing missing values with zeros, resampling each record to 5000 samples (10 s at 500 Hz) through truncation or zero-padding, and applying per-lead z-score normalization ($\mu=0$, $\sigma=1$).

Structured Feature Processing

Nine clinically derived ECG features were standardized using statistics computed from the training set only to avoid data leakage. Missing feature entries were imputed with zeros and accompanied by binary validity masks to explicitly indicate feature availability. Age values were further normalized to mitigate scale imbalance across modalities.

Label Processing

Diagnostic codes were converted into multihot vectors to support multilabel classification. The fixed sequence length of 5000 samples (10s at 500 Hz) was chosen to conform with the MIMIC-IV-ECG standard, in which most 12-lead ECGs are recorded at 500 Hz over 10-second intervals. This uniform input length ensured consistent model representation while preventing information loss from shorter signals through zero-padding when necessary.

Experiment Setup

All experiments were implemented using PyTorch (v2.6; Meta AI) as the primary DL platform with standard scientific-computing toolkits. Input ECG sequences consisted of 5000 samples per lead and were divided into 50-sample nonoverlapping patches (100 patches per record). Together with structured features, these patches were projected into a 768-dimensional embedding space, consistent with the dimensionality used in Vision Transformer and Bidirectional Encoder Representations from Transformers architectures, to capture comprehensive temporal and morphological information. The model architecture comprised a 6-layer Transformer encoder with 8 attention heads per layer, jointly processing waveform and structured inputs. Training batches were constructed with random shuffling to promote generalization, while validation and test phases used fixed ordering for reproducibility. This configuration achieved an appropriate balance between computational efficiency and temporal integrity of ECG sequences.

Training Protocol

Optimization and Training Strategy

Model optimization was conducted using an adaptive gradient–based algorithm with a carefully tuned learning rate and regularization to ensure stable convergence. Training proceeded for up to 200 epochs, with gradient clipping applied to prevent numerical overflow. Throughout training, model performance was continuously monitored on the validation set.

To more comprehensively reflect generalization ability, a combined performance indicator integrating both discriminative power and classification accuracy was used to guide the learning-rate scheduler and early stopping mechanism. When the improvement of this integrated metric plateaued, the learning rate was automatically reduced with a decay schedule that incorporated relative thresholds and cooldown periods to enhance stability.

Early stopping was triggered when no meaningful improvement was observed for several consecutive epochs, and the checkpoint corresponding to the best validation performance was retained

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as the final model. All experiments were performed on high-performance computing hardware equipped with NVIDIA RTX 4080 graphics processing units.

Class-Imbalanced Loss Function

To address label imbalance across disease categories, we used an adaptive weighted binary cross-entropy loss that dynamically adjusts class-specific positive weights according to the prevalence of each cardiac condition.

$$(4)L=-1C\sum c=1c[wcyclog\sigma(y\hat{}c)+(1-yc)log(1-\sigma(y\hat{}c))]$$

Where σ(·) is the sigmoid function, yc the ground-truth label, y^c the predicted logit, and wlc=(N−lnc)/(nlc+lε) the adaptive positive weight computed from the training-set statistics. This formulation effectively enhances sensitivity to minority cardiovascular conditions while maintaining balanced optimization.

Evaluation Protocol

The best-performing model identified from the validation phase was subsequently evaluated on the independent test set under inference mode with gradient computation disabled. Model predictions were generated for all samples in the validation, internal test, and temporally external test cohorts. Evaluation was performed consistently across all cohorts to ensure reproducibility and comparability.

To assess generalization, the first 90% of ECG records were used for model development and the most recent 10% for temporal external validation. Within the development cohort, data were split into training, validation, and internal test sets in a 7:1:1 ratio. This temporal division simulated real-world deployment and mitigated potential time-related data leakage.

Statistical Analysis

The statistical analyses were performed to quantitatively evaluate model performance and interpretability. All metrics, including area under the precision-recall curve (AUPRC), F_1-score, recall, precision, accuracy, and specificity, were computed per disease label and averaged across all 13 categories using the macro-average strategy. A combined metric (0.5×AUC+0.5×accuracy) was used to guide learning rate scheduling and early stopping during training. To assess calibration reliability, predicted probabilities were further evaluated using Platt scaling, and calibration curves were generated to visualize agreement between predicted and observed outcomes. Subgroup analyses were conducted by gender and age quartiles to examine demographic robustness and potential bias. All analyses were implemented in Python 3.11 (Python Software Foundation).

Ethical Considerations

The MIMIC-IV-ECG database used in this study was developed by the Massachusetts Institute of Technology and Beth Israel Deaconess Medical Center. The data collection and archiving procedures were approved by the Institutional Review Boards of Massachusetts Institute of Technology and Beth Israel Deaconess Medical Center (institutional review board protocol number 2001P001699). Because the database consists of retrospective data that were fully deidentified in accordance with the Health Insurance Portability and Accountability Act Safe Harbor provisions, the requirement for individual informed consent was waived by the institutional review boards. No identifiable private information was accessed, and all analyses adhered strictly to the data privacy and confidentiality policies outlined by PhysioNet.

The authors completed the Collaborative Institutional Training Initiative Program for human subjects research (certification number: 67231809) and signed the PhysioNet Credentialed Data Use Agreement prior to accessing the database. The study used only publicly available, anonymized data, and therefore, no additional institutional ethical approval or participant compensation was required.

Results

Overall and Condition-Specific Performance

Our CaMPNet demonstrated robust diagnostic capability across all evaluation metrics on the independent test set, as summarized in Table 3. Specifically, CaMPNet achieved a mean area under the receiver operating characteristic (ROC) curve (mean AUC=0.845, SD 0.04), comparable to the clinically validated ResNet-ECG baseline (AUC=0.848), while substantially outperforming it in average precision (AUPRC=0.489 vs 0.398,+22.8%) [29], reflecting enhanced reliability in handling imbalanced class distributions. In terms of F_1-score, CaMPNet yielded 0.501 compared to 0.152 for ResNet-ECG, corresponding to a relative gain of +229%, indicating significantly better balance between precision and recall. CaMPNet maintained a favorable trade-off between sensitivity and specificity, with recall=0.493 and precision=0.515, alongside strong overall accuracy=0.923 and specificity=0.949. These results demonstrate CaMPNet's ability to provide both accurate and clinically meaningful findings.

ECG-based predictions suggest its potential use as a decision-support tool in multilabel cardiovascular diagnostics.

At the condition-specific level, the model exhibited consistently high discrimination for prevalent diagnoses. As shown in Table 4, CaMPNet achieved near-perfect classification for normal ECGs (AUC=0.963, AUPRC=0.931, and F_1-score=0.877) and excellent performance for atrial fibrillation and HF (AUCs=0.907 and 0.887, respectively). However, performance degraded for rarer conditions, such as pulmonary embolism (AUPRC=0.217 and F_1-score=0.295) and aortic stenosis or insufficiency (AUPRC=0.390 and F_1-score=0.427), which is likely attributed to their subtle ECG manifestations and low sample prevalence in the dataset. These findings highlight the model's robust generalization in common cardiovascular conditions while indicating challenges in capturing rare but critical pathologies.

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Table . Classification performance of the Cardiovascular Multimodal Prediction Network on the independent test set, with per-condition metrics reported across 13 diagnostic categories, including area under the curve, area under the precision-recall curve, F_1-score, recall, precision, accuracy, and specificity.

Labels	AUC[a]	AUPRC[b]	F_1-score	Recall	Precision	Accuracy	Specificity
Atrial fibrillation	0.907	0.836	0.761	0.776	0.746	0.844	0.876
Aortic stenosis or insufficiency	0.832	0.390	0.427	0.435	0.419	0.939	0.966
Atrioventricular block	0.888	0.456	0.485	0.477	0.494	0.954	0.977
Cardiac arrest	0.797	0.276	0.336	0.285	0.410	0.978	0.992
Hypertrophic cardiomyopathy	0.849	0.473	0.501	0.475	0.530	0.948	0.976
Heart failure	0.887	0.781	0.727	0.747	0.707	0.823	0.857
Mitral valve prolapse or stenosis	0.771	0.300	0.347	0.316	0.385	0.943	0.975
Normal	0.963	0.931	0.877	0.913	0.844	0.899	0.890
Pulmonary embolism	0.794	0.217	0.295	0.251	0.358	0.974	0.990
Pulmonary hypertension	0.796	0.389	0.410	0.371	0.458	0.920	0.964
ST-elevation or non-ST-elevation myocardial infarction	0.880	0.620	0.595	0.605	0.586	0.902	0.942
Supraventricular or ventricular tachycardia	0.805	0.6376	0.400	0.381	0.422	0.927	0.964
Unstable angina	0.820	0.306	0.352	0.375	0.331	0.952	0.973
Mean (SD)	0.845 (0.04)	0.489 (0.03)	0.501 (0.04)	0.493 (0.02)	0.515 (0.03)	0.923 (0.07)	0.949 (0.06)

[a]AUC: area under the curve.

[b]AUPRC: area under the precision-recall curve.

ROC Curve Analysis

To further illustrate the classification performance, we visualized the ROC curves of CaMPNet across the top 13 diagnostic categories, as shown in Figure 3. The ROC curve characterizes the relationship between the true positive rate (sensitivity) and the false positive rate (1–specificity) across varying decision thresholds, with the AUC serving as a comprehensive indicator of discriminative ability. The closer the AUC value is to 1.0, the better the model's discriminative ability.

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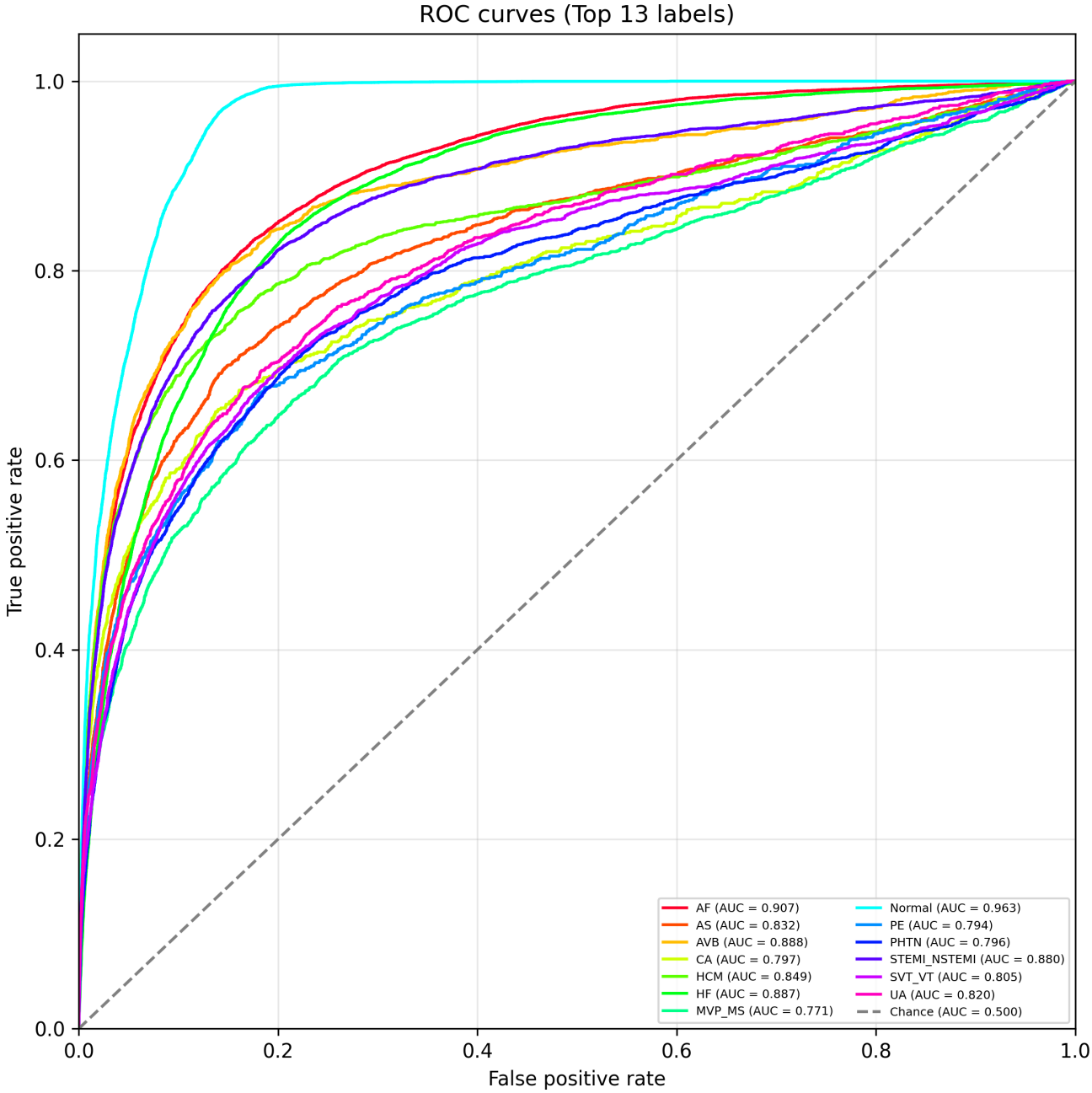
Figure 3. Receiver operating characteristic curves for the top 13 heart condition labels. Each curve shows the true positive rate (sensitivity) versus the false positive rate (1–specificity) across thresholds. The diagonal line denotes random chance (AUC=0.500). AF: atrial fibrillation; AS: aortic stenosis; AVB: atrioventricular block; CA: cardiac arrest; HCM: hypertrophic cardiomyopathy; HF: heart failure; MS: mitral stenosis; MVP: mitral valve prolapse; PE: pulmonary embolism; PHTN: pulmonary hypertension; STEMI-NSTEMI: ST-elevation myocardial infarction and non–ST-elevation myocardial infarction; SVT-VT: supraventricular tachycardia and ventricular tachycardia; UA: unstable angina.



As illustrated in Figure 3, all plotted ROC curves substantially exceeded the diagonal line representing random chance (AUC=0.500), indicating that CaMPNet learned meaningful representations across all categories. Notably, the model achieved the highest AUC for the "Normal" class (AUC=0.963), reflecting its strong ability to distinguish normal cardiac activity. Other conditions with excellent AUCs included atrial fibrillation (AUC=0.907), atrioventricular block (AUC=0.888), and HF (AUC=0.887). These results confirm that the model is particularly effective in detecting common, well-represented cardiovascular conditions with distinct ECG signatures.

Meanwhile, for categories such as pulmonary embolism (AUC=0.794) and mitral valve prolapse or stenosis (AUC=0.771), the AUCs were slightly lower yet still demonstrated predictive value beyond random guessing. The shape and placement of the curves further reflect how performance varies at different operating points, offering clinically interpretable insights into the trade-offs between sensitivity and specificity per condition. Overall, the ROC analysis underscores CaMPNet's strong and consistent ability to discriminate a broad range of cardiac conditions.

Calibration Curve Analysis

While AUC quantifies discrimination, calibration curves provide insight into the reliability of predicted probabilities. As shown in Figure 4, we plotted calibration curves for the same 13 diagnostic categories to evaluate the agreement between

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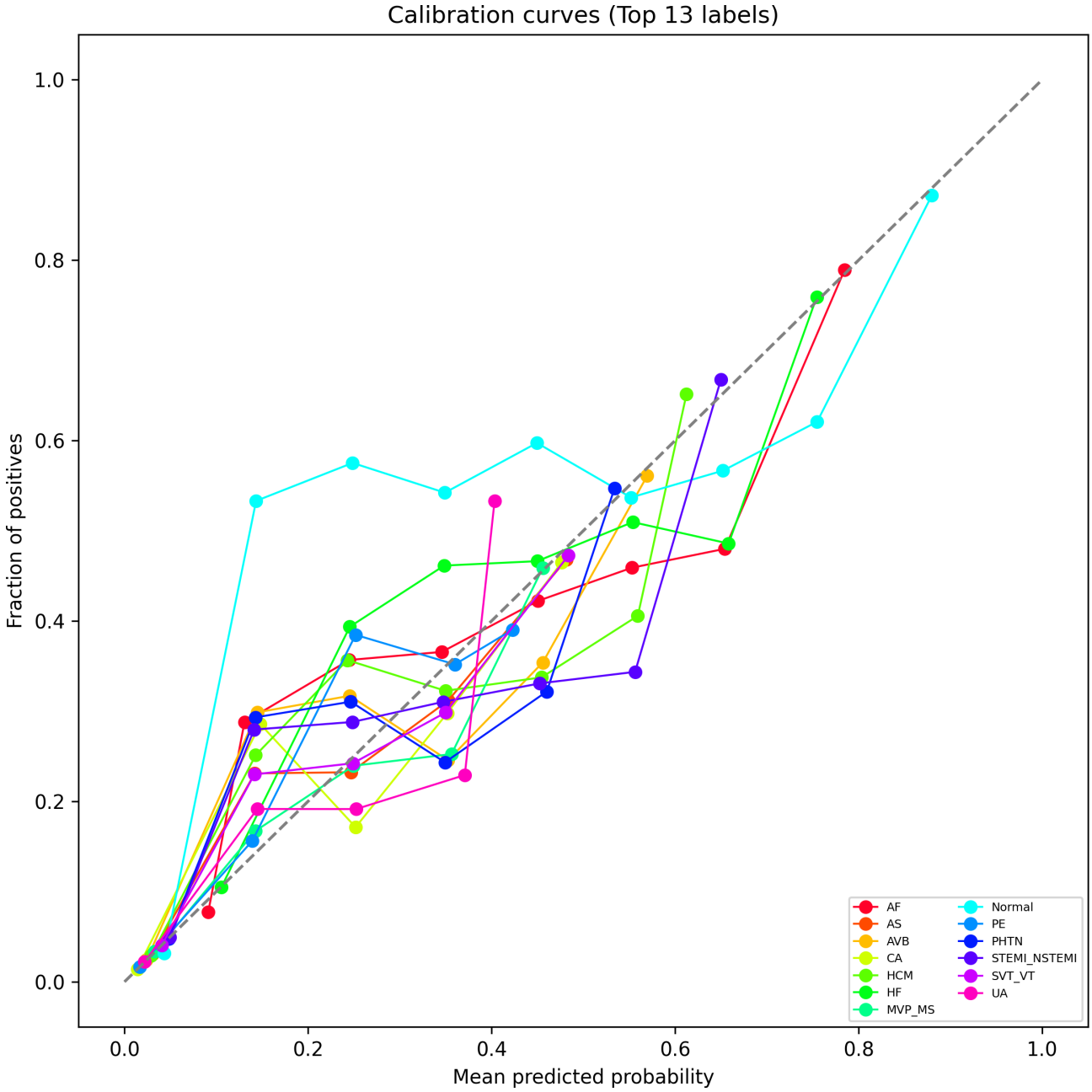
predicted risk and actual observed frequency. Ideally, well-calibrated predictions should lie close to the diagonal line, where predicted probability equals empirical outcome frequency.

Figure 4. Calibration curves for the top 13 diagnostic categories. Each curve compares predicted probability versus the actual observed frequency. The diagonal line indicates perfect calibration. AF: atrial fibrillation; AS: aortic stenosis; AVB: atrioventricular block; CA: cardiac arrest; HCM: hypertrophic cardiomyopathy; HF: heart failure; MS: mitral stenosis; MVP: mitral valve prolapse; PE: pulmonary embolism; PHTN: pulmonary hypertension; STEMI-NSTEMI: ST-elevation myocardial infarction and non-ST-elevation myocardial infarction; SVT-VT: supraventricular tachycardia and ventricular tachycardia; UA: unstable angina.



Despite some deviations, particularly in higher probability ranges, the overall upward trends of the curves confirm that the model's output probabilities are not arbitrary but reflect meaningful likelihood estimates. This implies that CaMPNet can be trusted not only for classification decisions but also for risk stratification tasks where probability calibration matters.

Subgroup Evaluation

To further assess the generalizability and fairness of CaMPNet across diverse patient populations, we conducted subgroup evaluations based on gender and age quartiles. Performance was measured using a comprehensive set of metrics, including AUC, AUPRC, F_1-score, recall, precision, accuracy, and specificity.

Gender Analysis

As illustrated in Figure 5, the model exhibited highly consistent performance across male and female subgroups. Specifically, AUC values were similar for females (0.838) and males (0.848); AUPRC was 0.465 for females and 0.502 for males, F_1-score was 0.480 for females and 0.513 for males, recall values were 0.466 for females and 0.509 for males, precision scores were

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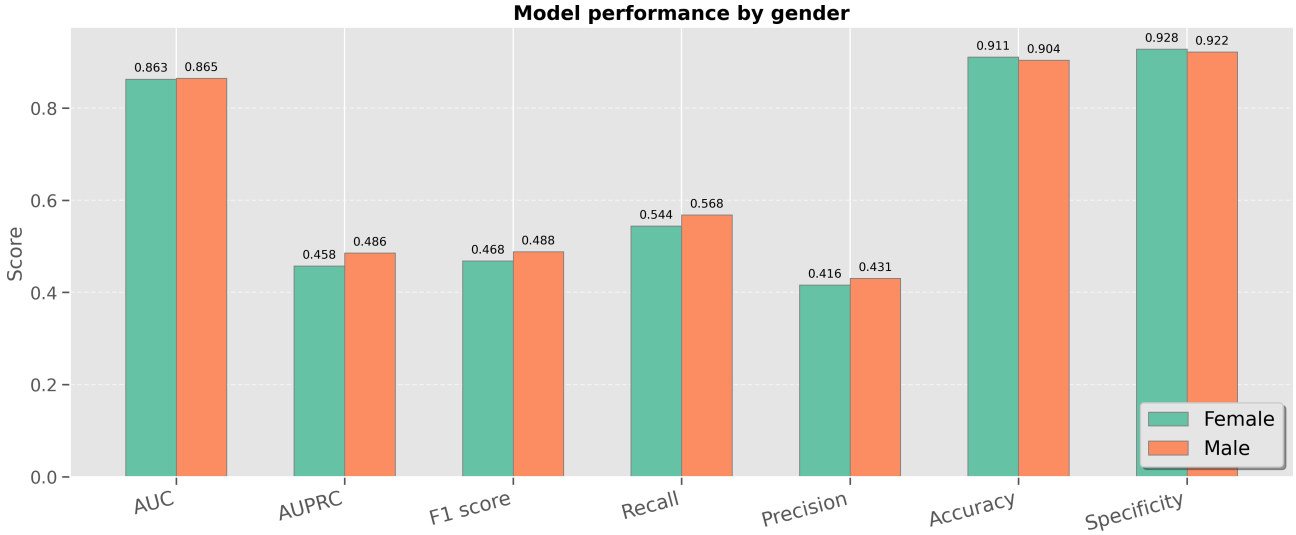
0.500 (female) and 0.521 (male), accuracy remained high in both groups—0.927 for females and 0.920 for males, and specificity was similarly high at 0.952 (female) versus 0.946 (male). These results demonstrate that CaMPNet performs robustly and fairly across genders, showing minimal variability and no significant performance degradation, which suggests low susceptibility to sex-related bias in multilabel ECG-based prediction tasks.

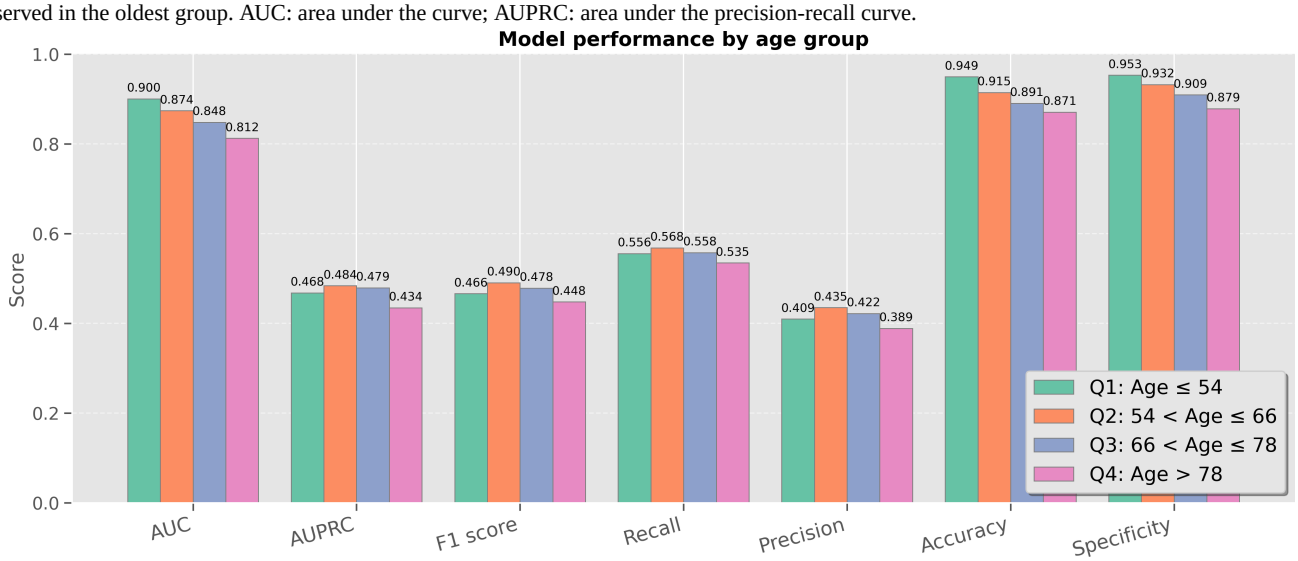
Figure 5. Model performance stratified by gender (male vs female), showing consistent diagnostic results and minimal sex-related variation. AUC: area under the curve; AUPRC: area under the precision-recall curve.



Age Stratification

We also stratified model performance by patient age using quartile splits, as shown in Figure 6.

Figure 6. Model performance stratified by age quartiles (Q1: Age ≤54, Q2: 54 - 66, Q3: 66 - 78, Q4: Age >78). A slight performance decline was observed in the oldest group. AUC: area under the curve; AUPRC: area under the precision-recall curve.



The results suggest a subtle but notable trend: The Q1 group (age ≤54 y) achieved the highest performance across several metrics (AUC=0.872, AUPRC=0.496, F_1-score=0.515, recall=0.524, precision=0.511, accuracy=0.956, specificity=0.964). The Q2 group (54<Age≤66 y) also performed well (AUC=0.847, AUPRC=0.486, F_1-score=0.500, recall=0.496, precision=0.513, accuracy=0.928, specificity=0.952). The Q3 group (66 y<Age≤78 y) showed moderate performance (AUC=0.834, AUPRC=0.490, F_1-score=0.502, recall=0.494, precision=0.515, accuracy=0.909, specificity=0.938). The Q4 group (Age>78 y) displayed a slight performance drop (AUC=0.811, AUPRC=0.448, F_1-score=0.457, recall=0.451, precision=0.468, accuracy=0.894, specificity=0.920). The gradual decline in performance with increasing age, especially in Q4, could be attributed to the greater clinical complexity in older patients, including increased comorbidities and more variable ECG morphologies. Despite this, the model maintained acceptable performance even in the oldest group, indicating robust generalization across age cohorts.

The subgroup analysis indicates that CaMPNet maintains equitable performance across genders and demonstrates strong generalization across age groups. While younger subgroups

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benefit from slightly better performance, the model's predictive capacity in older patients remains clinically viable.

These findings suggest that targeted model calibration or feature refinement for specific age ranges may offer opportunities for further performance enhancement.

Attention Mechanism Interpretation

Building upon the quantitative evaluation of model performance, we further explore how CaMPNet makes multilabel diagnostic decisions by interpreting its internal attention patterns. Specifically, we visualize the cross-attention distribution between structured clinical features and ECG signal patches, aiming to understand which temporal segments of the ECG the model focuses on when predicting specific cardiac conditions.

These visualizations highlight the model's cross-attention mechanism, where structured feature tokens serve as queries attending to ECG patch tokens. The highlighted vertical bands in each ECG plot indicate areas with relatively high attention weights—darker shades may correspond to stronger attention. Through case-based analysis, we reveal how attention is distributed across ECG cycles, providing insight into the model's interpretability and potential clinical reasoning.

Figure S1 in Multimedia Appendix 1 presents a representative 12-lead ECG recording. The true and predicted labels are identical, "heart failure, ST-Elevation or Non-ST-Elevation myocardial infarction, supraventricular or ventricular tachycardia", indicating a fully correct classification. Dark vertical bands denote ECG segments receiving stronger attention from the structured-feature token. The highlighted regions correspond primarily to the QRS complexes and adjacent ST segments across multiple precordial and limb leads (notably leads I, II, III, and V3-V5). These regions coincide with morphological features characteristic of acute ischemic injury and ventricular conduction abnormalities, manifested as widened QRS complexes, ST-segment elevations, and secondary repolarization changes. The network's focus on these segments suggests that it captures both ischemic (ST-Elevation/Non-ST-Elevation Myocardial Infarction) and ventricular rhythm (supraventricular or ventricular tachycardia) signatures while also integrating the broader waveform flattening and amplitude modulation associated with HF-related remodeling.

Figure S2 in Multimedia Appendix 1 depicts another ECG recording with true labels "atrial fibrillation, hypertrophic cardiomyopathy" and model predictions "atrial fibrillation, hypertrophic cardiomyopathy." Compared with Figure S1 in Multimedia Appendix 1, the attention map is more compact and periodic, concentrating around recurrent QRS complexes with moderate intensity in leads II, V1, and V3-V5. The focused attention reflects stable fusion between waveform and structured tokens when comorbid noise is minimal. The model achieves fully correct predictions, confirming that consistent rhythm morphology enables more decisive cross-attention alignment between structural ECG features and waveform segments.

Figure S3 in Multimedia Appendix 1 demonstrates an example where the true labels are "atrial fibrillation, cardiac arrest, hypertrophic cardiomyopathy, HF, ST-elevation or non-ST-elevation myocardial infarction" and the model predicts "Atrial fibrillation, aortic stenosis or insufficiency, cardiac arrest, hypertrophic cardiomyopathy, HF, ST-elevation or non-ST-elevation myocardial infarction." Attention peaks align with the QRS and ST-segment elevations in precordial leads V1–V4, consistent with acute anterior ischemia. The model accurately detects ST-elevation or non-ST-elevation myocardial infarction and major comorbidities but adds mild over-prediction (aortic stenosis or insufficiency), reflecting partial confusion between ischemic and valvular patterns. The broader distribution of attention compared with Figures S1 and S2 Multimedia Appendix 1 indicates the model's attempt to capture multiple concurrent abnormalities, revealing both its interpretability and current limitations in disentangling overlapping disease signatures.

In summary, these case studies demonstrate that attention visualization can effectively elucidate how CaMPNet integrates multimodal information to reach its diagnostic decisions. The highlighted regions reveal that the model consistently attends to physiologically meaningful waveform segments, particularly QRS complexes and ST-segment deviations, providing interpretable cues that align well with established clinical features. At the same time, the visualizations expose residual limitations: attention occasionally spreads across overlapping pathologies, leading to partial or excessive predictions in complex comorbidity cases. Together, these observations underscore both the interpretability and the current boundaries of CaMPNet's reasoning process, motivating the discussion on its strengths and limitations in real-world multilabel ECG classification.

Ablation Studies and Comparative Analysis

To systematically evaluate the contributions of each component within the proposed multimodal fusion model (CaMPNet) and benchmark its performance against related methods, we conducted a series of ablation experiments and comparative analyses. All models were trained and tested under identical data splits and evaluation metrics, with detailed configurations described previously. The results, summarized in Table 3, demonstrate the overall superiority of CaMPNet across multiple key metrics, compared to both unimodal and baseline models. A visual summary of the same results is provided in Figure 7, where a grouped bar chart clearly highlights CaMPNet's superior performance across 7 evaluation metrics.

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Figure 7. Model performance comparison across key metrics for cardiovascular multimodal prediction network, baseline models, and ablated variants. The cardiovascular multimodal prediction network achieves the highest area under the precision-recall curve, F_1-score, precision, accuracy, and specificity, demonstrating its superior multimodal fusion capability. AUC: area under the curve; AUPRC: area under the precision-recall curve; CAMP-Net: consistency-aware multi-prior network; ECG: electrocardiogram; ResNet: residual neural network; XGBoost: extreme gradient boosting.

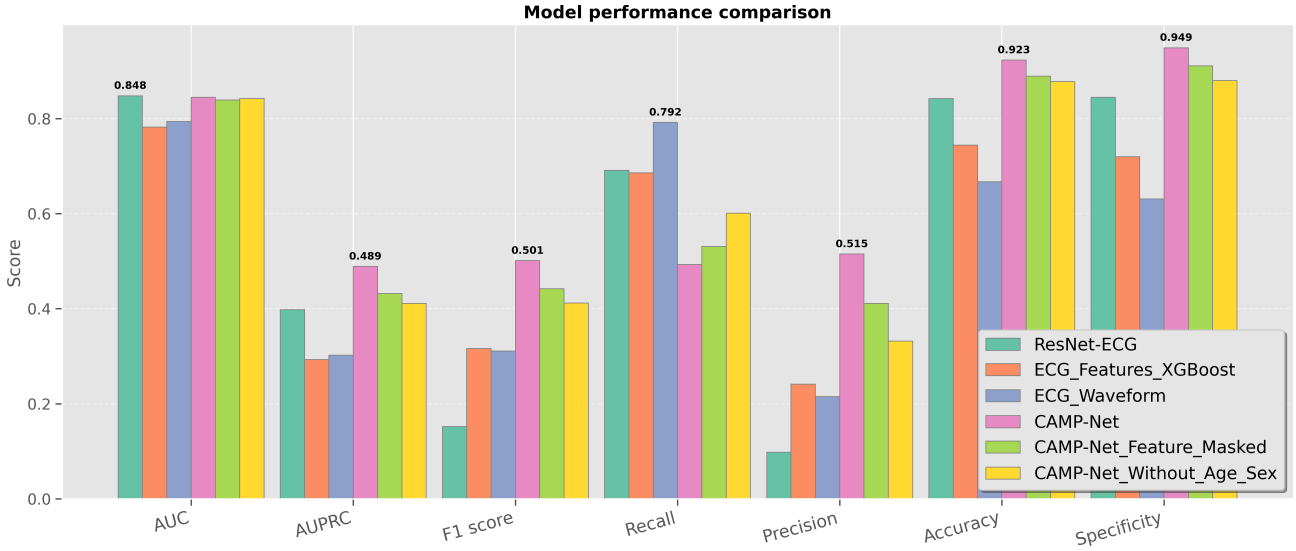

Table . Performance comparison of the Cardiovascular Multimodal Prediction Network and baseline models across multiple evaluation metrics.

Models	AUC[a]	AUPRC[b]	F_1-score	Recall	Precision	Accuracy	Specificity
ResNet-ECG[c, d]	0.848	0.398	0.152	0.691	0.098	0.842	0.845
ECG_Features_XGBoost[e]	0.782	0.293	0.316	0.686	0.241	0.744	0.72
ECG_Waveform	0.794	0.302	0.311	0.792	0.215	0.667	0.631
CaMPNet[f, g]	0.845	0.489	0.501	0.493	0.515	0.923	0.949
CaMPNet_Feature_Masked	0.839	0.432	0.442	0.531	0.411	0.889	0.911
CaMPNet_Without_Age_Sex	0.842	0.411	0.412	0.601	0.332	0.878	0.88

[a]AUC: area under the receiver operating characteristic curve

[b]AUPRC: area under the precision-recall curve.

[c]ResNet: residual network.

[d]ECG: electrocardiogram.

[e]XGBoost: extreme gradient boosting.

[f]CaMPNet: Cardiovascular Multimodal Prediction Network.

[g]Proposed model used in this study.

In the following, we first present a detailed performance comparison across different model variants, highlighting the advantages of CaMPNet in terms of classification effectiveness.

Overall Performance Comparison

CaMPNet achieved the highest overall performance across all evaluation metrics on the independent test set. Specifically, it attained an AUC of 0.845, comparable to the baseline ResNet-ECG (AUC=0.848), while substantially outperforming it in other metrics, such as AUPRC and F_1-score. Compared with the waveform-only model ECG_Waveform (AUC=0.794) and the structured feature-based model ECG_Features_extreme gradient boosting (AUC=0.782), CaMPNet maintained superior balance across all evaluation criteria. In terms of average precision, CaMPNet achieved the best AUPRC of 0.489, indicating enhanced capability to handle class imbalance and improve confidence in positive sample recognition. It also reached the top F_1-score of 0.501, reflecting a well-balanced trade-off between sensitivity (recall=0.493) and precision (precision=0.515). While the ECG_Waveform model exhibited the highest recall (0.792), CaMPNet demonstrated notably better precision, resulting in fewer false positives and more reliable positive predictions. Moreover, CaMPNet achieved the best accuracy (0.923) and specificity (0.949) among all models, confirming its robustness and superior diagnostic reliability across diverse evaluation criteria. These performance trends are clearly visible in Figure 7, where CaMPNet consistently appears as the leading bar in most metrics.

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Taken together, these results highlight that CaMPNet achieves large relative improvements over the strong baseline ResNet-ECG. As shown in Table 3, while the AUC of CaMPNet (0.845) remained comparable to ResNet-ECG (0.848), it achieved a +229% increase in F_1-score (0.501 vs 0.152), a +23% gain in AUPRC (0.489 vs 0.398), and a remarkable +425% boost in precision (0.515 vs 0.098). Overall accuracy and specificity also improved by +9.6% and +12.3%, respectively, reflecting enhanced reliability in distinguishing disease from normal conditions. Although recall decreased moderately (−29%), this trade-off was compensated by substantially higher precision, resulting in much stronger overall discriminative performance under class-imbalanced conditions. These relative improvements underscore the robustness and efficiency of the proposed multimodal cross-attention fusion mechanism compared to conventional convolutional neural network–based ECG classifiers.

Robustness and Contribution of Structured Clinical Features

Considering the common issue of missing structured clinical features in real-world data, we further evaluated CaMPNet's robustness by keeping the ECG waveform unchanged and zero-masking all 9 structured features at inference (denoted as CaMPNet_Feature_Masked in Table 3). The masked model exhibited only minor performance degradation, with an AUC decrease of 0.006 (from 0.845 to 0.839), AUPRC reduction of 0.057 (from 0.489 to 0.432), and F_1-score drop of 0.059 (from 0.501 to 0.442), confirming the model's tolerance to incomplete structured information. As shown in Figure 7, CaMPNet_Feature_Masked (green bars) remains close to the full CaMPNet variant across nearly all metrics, reinforcing the quantitative findings. Notably, even with masked features, CaMPNet_Feature_Masked still outperformed all unimodal models across most evaluation metrics, underscoring the crucial contribution of structured features during multimodal training. The cross-attention mechanism within the transformer encoder enables ECG feature extraction to leverage high-level semantic cues from structured variables, enhancing noise resilience and focusing on clinically salient pathological patterns. This multimodal interaction strengthens ECG representations, maintaining accurate and stable predictions even under feature absence at inference.

Contribution of Demographic Attributes (Age and Sex)

To further investigate the role of demographic information, specifically age and sex, within the multimodal fusion framework, we conducted an ablation experiment in which both features were removed during training and inference (denoted as CaMPNet_Without_Age_Sex in Table 3).

The results show that the removal of demographic attributes led to slight performance degradation across all metrics, with AUC decreasing to 0.842, AUPRC to 0.411, and F_1-score to 0.412. This marginal decline can also be observed in Figure 7, where the yellow bars representing CaMPNet_Without_Age_Sex remain close to those of the full CaMPNet, indicating only a subtle reduction across metrics. These findings suggest that age and sex provide useful prior knowledge for ECG-based diagnosis, yielding a modest yet consistent performance gain when included in the model. Notably, even without demographic inputs, CaMPNet_Without_Age_Sex still outperformed all baseline and unimodal models across most metrics, confirming that the model's core advantage lies in the deep fusion between ECG waveform and structured clinical features, with demographic information serving as a valuable but auxiliary complement to this foundation.

In summary, these ablation and comparative analyses collectively demonstrate the strong complementarity between deep ECG representations and structured clinical variables. By systematically isolating each modality, we show that the cross-attention–based multimodal fusion module is the principal driver of CaMPNet's performance gains and its robustness to incomplete data. Moreover, incorporating demographic attributes (age and sex) yields selective yet meaningful improvements across disease categories. The largest gains were observed in age- and sex-associated conditions, such as HF, hypertrophic cardiomyopathy, aortic stenosis or insufficiency, and pulmonary hypertension, while rhythm and ischemic disorders (eg, atrial fibrillation, supraventricular or ventricular tachycardia, ST-elevation or non–ST-elevation myocardial infarction) showed minimal changes. This indicates that demographic priors enrich the contextual understanding of chronic structural diseases rather than uniformly boosting all predictions.

Overall, the proposed architecture integrates richer and more nuanced discriminative cues, enabling superior and well-balanced results on the challenging multilabel cardiac abnormality task. These findings affirm the effectiveness of CaMPNet's multimodal design and its key components in enhancing diagnostic accuracy, resilience, and overall clinical applicability.

Temporal External Validation

To further assess the temporal robustness and real-world generalization of the proposed model, a temporal external validation was conducted using the most recent 10% of the available ECG data.

This subset was chronologically separated from the model development data to simulate prospective deployment conditions, ensuring that no temporal information leakage occurred between training and evaluation phases.

Compared with the internal test results, the overall performance of CaMPNet decreased, as shown in Table 5, when applied to the temporally separated cohort, indicating a noticeable temporal distribution shift between historical and recent ECG data. The mean AUC dropped from 0.845 (SD 0.04) to 0.715 (SD 0.03), and the mean AUPRC from 0.489 (SD 0.03) to 0.298 (SD 0.02), accompanied by reductions in F_1-score (from 0.501 to 0.322) and accuracy (from 0.923 to 0.906). Despite this decline, diagnostic categories with abundant and stable ECG patterns, such as normal, atrial fibrillation, and HF, maintained relatively strong discriminative ability (AUCs=0.969, 0.862, and 0.845, respectively).

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Table . Performance comparison of cardiovascular multimodal prediction network on temporal external validation cohort across multiple evaluation metrics.

Label	AUC[a]	AUPRC[b]	F_1-score	Recall	Precision	Accuracy	Specificity
Atrial fibrillation	0.862	0.771	0.703	0.707	0.699	0.797	0.843
Aortic stenosis or insufficiency	0.670	0.104	0.150	0.162	0.141	0.920	0.954
Atrioventricular block	0.772	0.231	0.314	0.313	0.316	0.943	0.970
Cardiac arrest	0.569	0.032	0.048	0.039	0.063	0.972	0.989
Hypertrophic cardiomyopathy	0.682	0.178	0.231	0.199	0.276	0.927	0.969
Heart failure	0.845	0.729	0.683	0.667	0.700	0.779	0.842
Mitral valve prolapse or stenosis	0.578	0.084	0.115	0.096	0.143	0.926	0.970
Normal	0.969	0.936	0.898	0.958	0.845	0.916	0.891
Pulmonary Embolism	0.654	0.065	0.119	0.099	0.149	0.971	0.989
Pulmonary hypertension	0.641	0.176	0.212	0.174	0.270	0.893	0.958
ST-elevation or non–ST-elevation myocardial infarction	0.779	0.373	0.417	0.437	0.399	0.874	0.925
Supraventricular or ventricular tachycardia	0.625	0.122	0.160	0.140	0.186	0.908	0.959
Unstable angina	0.658	0.075	0.131	0.132	0.131	0.946	0.972
Mean (SD)	0.715 (0.03)	0.298 (0.02)	0.322 (0.03)	0.317 (0.03)	0.332 (0.04)	0.906 (0.05)	0.941 (0.06)

[a]AUC: area under the curve.

[b]AUPRC: area under the precision-recall curve.

Conversely, low-prevalence or morphologically heterogeneous conditions, such as cardiac arrest, mitral valve prolapse, mitral valve prolapse or stenosis, and pulmonary embolism, exhibited pronounced degradation (AUC <0.65), reflecting the sensitivity of rare-class predictions to evolving clinical data distributions.

These findings suggest that while CaMPNet retains substantial diagnostic capacity over time, its performance can be affected by long-term temporal drift in ECG acquisition, instrumentation, and labeling practices. The results underscore the importance of periodic model recalibration and continuous monitoring when deploying multimodal ECG classifiers in clinical practice to ensure sustained reliability in dynamically changing hospital environments.

Interactive Clinical Prototype for ECG-Based Diagnosis

To facilitate the practical application and convenient evaluation of the proposed multimodal cardiac abnormality prediction model, we developed a user-friendly online prediction interface. This interface aims to provide a straightforward platform for users to obtain diagnostic predictions based on individual ECG signals and clinical information.

Input Module

Users are prompted to upload a standard 12-lead ECG signal in a CSV format, where each lead contains 5000 sampling points. Additionally, users are required to manually enter 2 basic demographic attributes (age and sex). The interface also offers optional input fields for submitting a predefined set of 9 structured ECG-derived features.

Prediction Mechanism and Model Robustness

Upon submission, the system invokes the pretrained CaMPNet model to perform multimodal inference. A key feature of this system is its adaptability; even when the 9 structured features are not provided, the model can still generate valid predictions based solely on the ECG waveform and demographic information. While full input coverage (including all structured features) leads to the highest prediction accuracy, experimental results have shown that the model maintains stable performance even in the presence of missing structured data, demonstrating strong robustness to incomplete inputs.

Result Presentation and Interpretability

Once the “Predict” button is clicked, the right-hand panel displays the model’s multilabel prediction outcomes. To enhance interpretability, the uploaded 12-lead ECG waveform is

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rendered, overlaid with an attention heatmap. This visualization highlights specific ECG segments that were most influenced by the structured features during the cross-attention phase, revealing which regions of the ECG the model deemed most relevant for decision-making.

Clinician Feedback Collection via Experience-Based Rating System

To gather real-world clinical feedback and continuously improve model performance, a rating mechanism has been embedded into the interface. After reviewing the predictions and attention visualizations, users are invited to rate the model's prediction quality on a 1‐ to 5-star scale. Simultaneously, the interface records the user's self-reported clinical experience level. All feedback entries, including scores and experience levels, are stored in the backend database in JSON format. This allows the research team to analyze how users of different expertise levels perceive the model's reliability, offering valuable insights for iterative model refinement and clinical readiness assessment.

The development of the interactive prediction interface not only validates the feasibility of deploying the proposed model in real-world settings but also provides clinicians and researchers with an intuitive tool to explore model behavior and interpret its decision-making logic. Through integrated attention-based visualizations, users can gain deeper insights into how the model reaches its predictions, an essential step toward building trust, promoting clinical adoption, and guiding future iterations of model refinement. These features bridge the gap between algorithmic predictions and human interpretability, fostering a more transparent and collaborative human-AI interaction paradigm in cardiology.

Discussion

Principal Findings

In this study, we developed CaMPNet, a transformer-based multimodal ECG diagnostic framework that integrates raw 12-lead waveforms, structured machine-measured ECG features, and demographic attributes through an early cross-attention fusion mechanism. Our main findings demonstrate that CaMPNet substantially improves multilabel cardiovascular comorbidity detection compared with strong unimodal baselines, achieving a higher AUPRC (+23%), markedly improved F_1-score (+229%), and better overall diagnostic balance than the ResNet-ECG benchmark. The model also showed robust performance across demographic subgroups and retained moderate discriminative ability under temporal distribution shift. The novelty of our approach lies in its query-conditioned early fusion design, which allows structured features to selectively retrieve physiologically relevant waveform segments, yielding richer representations and clinically interpretable attention patterns. These findings highlight CaMPNet's potential impact as a scalable, interpretable tool for comprehensive ECG-based screening in real-world clinical workflows, especially in settings where multimodal inputs vary in completeness.

Limitations

Despite the promising performance of the proposed CaMPNet in multimodal ECG-based multilabel classification tasks, several limitations remain. Unlike prior multimodal ECG systems that fuse by concatenation or shared self-attention, CaMPNet's query-conditioned early cross-attention enforces directional information flow (structure → waveform) and natively tolerates missing inputs via validity-aware embeddings, which we found to be key to both robustness and interpretable retrieval. Although CaMPNet is designed for comorbidity detection, case analyses (Figure 7) show occasional omission or misclassification of concurrent conditions. This limitation arises from label co-occurrence sparsity and overlapping ECG manifestations. Future work will incorporate comorbidity-aware loss functions (eg, correlation-weighted binary cross-entropy) and graph-based label modeling to explicitly learn interdisease dependencies, enhancing the model's clinical use in complex multimorbidity scenarios.

The model was trained and evaluated solely on 12-lead ECG samples from the MIMIC-IV-ECG database, which is predominantly sourced from intensive care unit settings in a North American tertiary medical center. To further assess robustness under temporal distribution shift, a temporal external validation was performed using the most recent 10% of data chronologically withheld from model development. Compared with the internal test set (mean AUC=0.845, SD 0.04; AUPRC=0.489), performance decreased in the temporal cohort (mean AUC=0.715, SD 0.03; mean AUPRC=0.298, SD 0.02; mean F_1-score=0.322, SD 0.03). While CaMPNet maintained strong discriminative ability for common conditions, such as atrial fibrillation, HF, and normal rhythm, its accuracy declined for rare or morphologically variable disorders, suggesting sensitivity to evolving clinical practices and instrumentation. These findings highlight the importance of continuous model recalibration and multicenter external validation to ensure sustained clinical reliability.

The dataset also shows substantial class imbalance conditions, such as pulmonary embolism, cardiac arrest, and mitral valve disease, which were underrepresented, leading to relatively poor performance on these rare classes. Although class-weighted loss functions were applied, they cannot fully mitigate data scarcity in minority categories.

CaMPNet leverages 9 structured ECG features through a cross-attention mechanism to enhance predictive accuracy, yet these features may be missing or inconsistently measured in real-world clinical settings. Masking and zero-filling strategies provide partial robustness, but extensive or systematic missingness may still affect reliability. Moreover, the extraction of these features depends on specific analytic pipelines and acquisition devices, which may vary across hospitals and limit model portability.

While attention heatmaps improve interpretability by highlighting waveform segments attended by structured features, the internal reasoning of deep transformer models remains largely opaque. The current explanations do not always align with clinical diagnostic reasoning. Future work should incorporate expert domain knowledge and physiological priors

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into the interpretability module to improve transparency and clinical trust.

Finally, the dataset primarily represents adult patients in the intensive care unit with relatively homogeneous acquisition hardware and sampling rates. The model's performance on pediatric populations, diverse geographic regions, and ECGs recorded at different sampling frequencies (eg, 250 Hz or 1000 Hz) remains untested. Future evaluations across multi-institutional, demographically diverse, and device-heterogeneous datasets will be essential to establish population-level generalizability.

Future Directions

To support broader clinical adoption of CaMPNet, several directions merit future exploration. First, large-scale external validation across multiple centers and heterogeneous populations is needed to rigorously assess generalizability in real-world clinical environments. A major direction for future work is to further enhance model performance on rare but clinically critical cardiac conditions, such as pulmonary embolism, cardiac arrest, and mitral-valve prolapse, mitral valve prolapse or stenosis, which currently show limited recall and precision. Beyond the adaptive class-weighted loss used in this study, future efforts will explore more advanced imbalance-mitigation strategies, including focal or class-balanced focal loss to emphasize hard positive samples, synthetic data augmentation based on physiologically plausible waveform perturbations, and meta-learning or curriculum-based reweighting to dynamically adjust training focus. These approaches may help improve sensitivity to low-prevalence but high-impact pathologies and thus strengthen the model's clinical applicability. Third, improving interpretability by aligning attention mechanisms with clinically recognized ECG features could enhance transparency and clinician trust. Finally, prospective clinical pilot studies incorporating user feedback will be essential to evaluate usability, guide interface design, and refine the model for deployment in routine health care workflows.

Conclusions

This study demonstrates that CaMPNet provides a strong and clinically meaningful improvement in multimodal ECG-based diagnosis by effectively combining raw waveforms with structured ECG features through a novel cross-attention mechanism. The model achieved consistently higher precision, superior calibration behavior, and more balanced multilabel performance than conventional waveform-only architectures. Its robustness to missing structured features and stable performance across sex and age subgroups further support its use in real-world environments, where data completeness and patient heterogeneity are common challenges. The attention-based visualizations also offer an interpretable window into the model's decision-making process, aligning learned representations with physiologic ECG patterns.

While several limitations remain, including rare-label performance, single-center data, and temporal distribution shifts, our findings underscore the strengths of the proposed multimodal framework and its potential as a foundation for clinically deployable ECG decision-support systems. Future efforts focusing on multicenter external validation, comorbidity-aware learning, and enhanced interpretability may further extend CaMPNet's reliability and applicability in diverse health care settings.

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Data Availability

The datasets are available from the corresponding author upon reasonable request.

Authors' Contributions

Conceptualization: MB (lead) and ZY (equal)
Data curation: ZY (lead) and XW (supporting)
Formal analysis: MB (lead) and ZY (supporting)
Funding acquisition, project administration, resources, and supervision: MB
Investigation: JW and QG
Methodology and visualization: ZY
Software: ZY (lead) and XD (supporting)

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Writing – original draft: ZY (lead), XW (supporting), HL (supporting), and YX (supporting)
Writing – review and editing: MB, ZY, and JZ

Conflicts of Interest

None declared.

Multimedia Appendix 1
Visualization of attention regions on three representative electrocardiograms alongside multi-label predictions and ground truth diagnoses.
[DOCX File, 1211 KB - formative_v10i1e80815_app1.docx]

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Abbreviations

AUC: area under the curve
AUPRC: area under the precision-recall curve
CaMPNet: cardiovascular multimodal prediction network
CVD: cardiovascular disease
DL: deep learning
ECG: electrocardiogram
HF: heart failure
HIPAA: Health Insurance Portability and Accountability Act
MIMIC-IV-ECG: Medical Information Mart for Intensive Care IV - Electrocardiogram Matched Subset
ResNet: residual network
ROC: receiver operating characteristic

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Technology Access, Digital Literacy, and Enrollment Support Preferences in a Federally Qualified Health Center: Cross-Sectional Study

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Abstract

Background: Biomedical research studies are increasingly using digital tools to enroll, recruit, and collect data from participants. However, variability in digital literacy and technological acceptance can be challenging for recruitment from groups traditionally underrepresented in research, including those served by Federally Qualified Health Centers.

Objective: This study aimed to (1) measure participant accessibility and comfort with digital platforms and (2) examine the interrelation of technology access, digital literacy, and support preferences during enrollment and data submission.

Methods: A cross-sectional analysis was conducted using enrollment data from Federally Qualified Health Centers participating in the All of Us Research Program. Participants had the option of High-Touch (staff-assisted) or Low-Touch (self-directed) support for enrollment and survey completion. Survey items assessed internet access and technology comfort, while support type was recorded by the research staff based on participants' actual selection. Logistic regression models evaluated relationships between technology access, comfort, and enacted support type, while controlling for age, consent language, and education, as well as race and ethnicity.

Results: The analytic sample included 605 participants. The majority reported access to the internet (539/605, 89.1%) and felt comfortable with technology (448/605, 74.1%). In the group requesting High-Touch support (n=346), 14.5% (n=50) reported no internet access, and 31.5% (n=109) felt uncomfortable with technology. In the group requesting Low-Touch support (n=259), 6.2% (n=16) had no access to the internet, and 3.9% (n=10) reported feeling uncomfortable (P<.001). In the adjusted models, much greater comfort with technology was significantly correlated with reduced odds of requesting High-Touch support (comfortable: adjusted odds ratio 0.118, 95% CI 0.055 - 0.255 and neutral: adjusted odds ratio 0.212, 95% CI 0.077 - 0.587), but internet access was not significantly correlated.

Conclusions: The strongest predictor for support preference for digital enrollment among the participants was their comfort with technology rather than access alone. These findings illustrate the significance of participant-centric design methods coupling adaptive support paths, mixed enrollment strategies, and individualized onboarding methods aligned with digital confidence to promote equitable engagement in precision health research.

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KEYWORDS

digital literacy; technology access; participant engagement; high-touch support; federally qualified health center

Introduction

Biomedical studies should engage diverse populations to ensure findings are generalizable and advances in medicine are inclusive and accessible [1,2]. Historically, research participation has been disproportionately high among certain demographics, thereby creating inequities in prediction, prevention, and treatment [3,4]. Genome-wide association studies, for example, have focused predominantly on European-derived populations, representing around 78% of worldwide datasets, thus limiting their generalizability to other populations [4]. These disparities highlight the need for inclusion on multiple levels, recognizing that both biological determinants as well as social determinants of health impact equal participation in research [3-9].

Disparities also arise from the digital tools and methodologies used for participant engagement and recruitment in research. An increasing number of large-scale research studies are transitioning toward the use of digital technologies, including electronic health records (EHRs), apps, wearables, and web platforms, to facilitate recruitment, remote engagement, and remote collection of data [10,11]. Although these tools can

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reduce geographic barriers, optimize study logistics, and enable decentralized clinical trials, their effectiveness is contingent upon participants' access to devices, internet connectivity, and comfort with technology [10,12-14]. However, numerous studies indicate variability in both the willingness and ability of individuals to use digital platforms, especially for activities such as digital consent, which raises concerns that technological advancements alone could exacerbate existing disparities [10-12].

The digital divide, defined by gaps in device ownership, internet access, and digital literacy, is one of the biggest barriers for equitable engagement in this digital arena [11]. The digital divide disproportionately impacts disadvantaged older adults, those from lower socioeconomic backgrounds, and those with limited digital literacy [11,15]. For initiatives such as the National Institutes of Health's (NIH) All of Us Research Program (AoURP), which relies heavily on web-based consent, surveys, and remote biospecimen collection, these disparities risk reinforcing exclusion rather than fostering equity [11,15]. Studies across diverse communities, including Latino [16], Asian American [16], and other underserved communities [17,18], as well as among older adults [19], demonstrate persistent gaps in digital readiness. While such studies report barriers, few measure the extent to which digital access, literacy, and comfort correlate with participants' support preferences during enrollment. For example, a High-Touch support approach is one where a staff member facilitates the consent and survey process, as well as provides the digital tools needed to complete the enrollment process. A Low-Touch approach is when the participant has access to the digital tools and is able to complete the enrollment process completely independently. Likewise, variation among Federally Qualified Health Centers' (FQHCs') patient portal enrollment processes accentuates the lack of unified methods to allow for digital readiness [20]. This represents an important gap. Without data on the relationship between readiness and support needs, programs risk misaligning strategies from the desired expectations among their participants, with the potential result that participation is inequitable.

To frame these relationships, this study is guided by the Digital Divide Framework, which details digital participation inequalities under 3 interconnected dimensions: structural (device and internet access), cognitive (ability and literacies to make use of digital tools), and motivational (attitudes, trust, and readiness to make use of technology) [21,22]. Under this framework, comfort with technology is conceptualized as an indication of digital self-efficacy, reflecting both skill and confidence in using digital tools. This aligns with constructs from the technology acceptance model (TAM) and the unified theory of acceptance and use of technology (UTAUT), both of which link perceived ease of use and confidence to adoption of digital systems [23,24]. By locating technological comfort within the theoretical constructs, this study examines how digital literacy and psychosocial factors interactively impact the study participants' tendencies toward High-Touch from Low-Touch enrollment modes.

It is necessary to design participant-focused digital systems that are able to support varying digital readiness. Flexible support models, from the self-managed (Low-Touch) level to staff-assisted models (High-Touch), have the potential to ensure equal participation across varied populations [15,21,22]. This study used data collected during enrollment in the NIH's AoURP, a national initiative designed to advance precision medicine by building one of the largest databases of participant-provided information, biospecimen samples, and DNA sequencing data. For this analysis, we focused on participants enrolled at Community Health Center Inc (CHCI), the largest FQHC in Connecticut.

Grounded in the Digital Divide Framework, we analyze the influence of structural, cognitive, and motivational factors on the support need, so as to develop strategies for fostering inclusive digital participation among FQHCs and other underrepresented groups, and supporting the equity objective of national-scale precision medicine initiatives such as AoURP. We hypothesized that participants who reported lower comfort with technology, which reflects lower digital literacy and self-efficacy, would be significantly more likely to prefer a High-Touch, or staff-assisted, enrollment support, even after accounting for internet access and sociodemographic characteristics.

Methods

Study Design

This cross-sectional study analyzed secondary data collected during enrollment into the NIH's AoURP. The study followed the STROBE (Strengthening the Reporting of Observational Studies in Epidemiology) guidelines for reporting observational research [25].

Study Setting

The NIH's AoURP is dedicated to optimizing precision medicine by instituting the most complete database, comprised of information provided by the patient, biospecimen banks, and DNA sequencing data. Nationally, enrollment activities and retention were conducted over the full spectrum of sites, including the community-based activities, the primary care clinics, the academic medical centers, and FQHCs. The study targeted the enrollments from CHCI, the largest FQHC in the state of Connecticut. CHCI's patient base is predominantly made up of low-income individuals (with 89% of the patient base living below the 200% federal poverty level) and is racially and ethnically mixed (61% Hispanic or Latino, 13.5% Black and African American, and 2.8% Asian).

Participants

Eligible participants were more than 18 years old, able to provide independent consent, and resided in the United States. Enrollment into CHCI's AoURP occurred between 2017 and 2023. CHCI offers services to the predominantly urban Connecticut area, where the participants are likely to have closer access to the broadband network compared to rural areas, which is relevant given known associations between rurality, internet access, and digital literacy. The participants whose data were incomplete were not considered, giving rise to potential selection bias if the participants whose data were incomplete systematically varied on digital access or digital comfort. The

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participants were not sampled by health condition nor by any previous exposure to technologies.

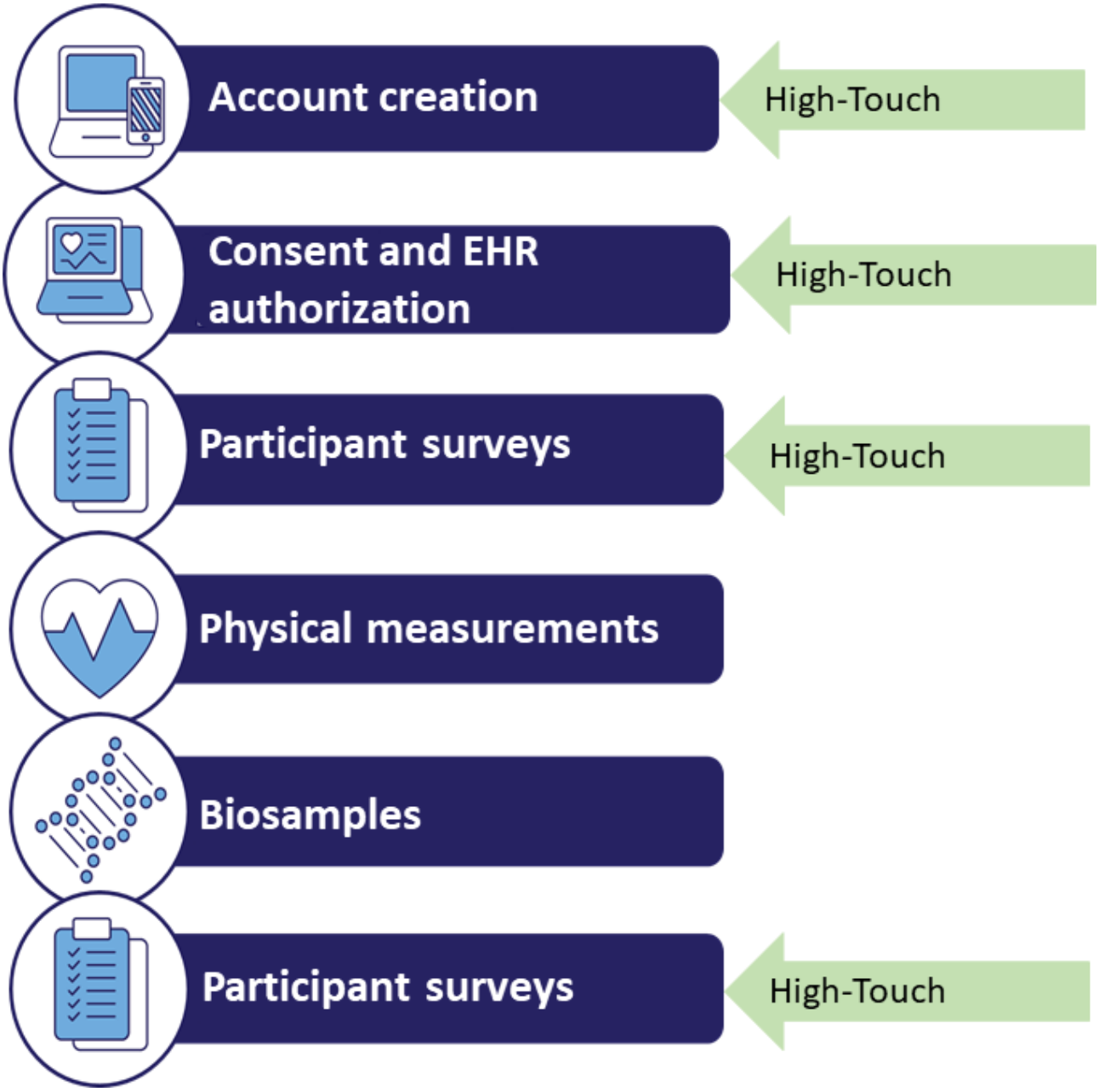
Recruitment and Enrollment

Outreach was done by telephone calls as well as face-to-face contact, such as in the waiting rooms of the clinics. The enrollment process had participants enroll on the AoURP online platform, where they viewed and signed online informed consent documents, including general, EHR, as well as optional genomic consent. Participants completed 6 questionnaires on environmental factors, lifestyle, medical history, health care use, and digital readiness. Physical measures as well as biospecimens were also collected. The survey data and biospecimen data were linked by a single ID.

Enrollment Support Models

Participants were able to choose different levels of support during the enrollment process. Under the High-Touch model (Figure 1), AoURP staff helped participants enter their answers into the corresponding systems. The staff also helped participants gain access to necessary technologies, including tablets and internet connectivity, while also providing remote support by computer-assisted telephonic interviews, videoconferencing, and screen sharing. On the other hand, under the Low-Touch method, the participants filled out the forms and questionnaires by themselves, either on-site through the use of a tablet or off-site on their own device after receiving the call from the staff. The AoURP staff recorded the particular level of support used by the participants.

Figure 1. Patient journey. Enrollment process for the All of Us Research Program and places where the High-Touch strategy is implemented. EHR: electronic health record.



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Variables

The main outcome was the preference for High-Touch over Low-Touch support by the participant. Independent variables were internet access (yes and no) and level of tech comfort (comfortable, neutral, and uncomfortable). Covariates included age, gender, race and ethnicity, level of education, and consent language.

Measures

Comfort with internet access and technology was assessed by survey questions completed during enrollment by the AoURP. They were prompted by the question "Do you have access to the internet at home?" (multiple response answers: yes, no, sometimes [<50% of the time], sometimes [>50% of the time], unknown or not reported, prefer not to answer). This question was very specific for defining internet access on any device at home and did not account for access at work, school, or other public locations. Internet access was dichotomized during analysis as "yes" versus "no" only, excluding "sometimes," "unknown," and "prefer not to answer" answers.

Comfort with technology was also measured with the question: "How comfortable are you using technology?" (very comfortable, somewhat comfortable, neutral, somewhat uncomfortable, not at all comfortable, prefer not to answer). Comfort with technology was combined into 3 groups: "comfortable" (very or somewhat comfortable), "neutral," and "uncomfortable" (somewhat or not at all comfortable). The individual item on technology comfort, although self-reported, is used as a pragmatic proxy measure for digital literacy and self-efficacy. There is potential for future studies to consider proven multi-item scales from TAM and UTAUT to assess perceived ease of use and behavioral intention to use digital systems.

These scales were constructed for practice purposes between varied enrollment sites and are not standardized psychometric scales. While objective measures of technical proficiency (ie, timed exercises and direct observation of device usage) were not available, the self-report items provide pragmatic, standardized measures of participants' reported digital literacy and self-efficacy. The adoption of self-report entails potential recall bias and social desirability bias, identified as a study limitation. Future research can incorporate objective digital proficiency measures or device metrics as an augment to reported comfort.

Sample Size and Power Considerations

There was no a priori sample size calculation conducted as the data were observational. Post hoc calculation found >80% power to detect odds ratios (ORs) ≥2 among dichotomous predictors at α=.05. Smaller effects, particularly among small case subgroups (eg, no internet access), may not have been detectable.

Analysis

Descriptive statistics (frequencies and percentages) were made for participant characteristics, access to technological tools, and technological comfort. Bivariate associations between internet access, technologic comfort, and type of support preferred (High-Touch vs Low-Touch) were examined by chi-square test. The key predictors were internet access, technological comfort, age, race and ethnicity, education, and language given for consent. The interactions were included to test the influence of technological comfort changing by age, race and ethnicity, education, or consent language.

Due to the scarce data present in particular categories, a penalized maximum likelihood estimate including Firth correction for bias was conducted by logistic regression (LR) using PROC LOGISTIC. The model included the key effects of internet access, technology comfort, age, race and ethnicity, education level, and the consent language, alongside 2-way interactions between technology comfort × age, technology comfort × race and/ethnicity, internet access × age, and internet access × race and ethnicity. All the categorical variables were presented using reference coding. ORs with Wald 95% CI values were reported for the key and interaction effects. The fit of the model was determined by −2 log likelihood, Akaike information criterion, and Schwarz criterion, while predictive discrimination was assessed by using the concordance statistic (c-statistic). Missing data were managed by complete-case analysis, where 8 participants were excluded due to missing values.

Sensitivity analyses were conducted to test the stability of the major conclusions. The procedures for the sensitivity analyses included the inclusion of age as a continuous measure, testing alternative categorizations of race and ethnicity, the use of standard LR models without Firth's correction, and multiple imputation methods to handle covariate data. Additional interaction terms, including technology comfort with age, race and ethnicity, education, and consent language, were also tested. The conclusions were the same under all these different models, hence the confirmation of the identified associations' stability and robustness.

Ethical Considerations

This study was approved by the All of Us institutional review board of the NIH (AoU IRB protocol number 2016 - 05). All participants provided informed consent online for data linkage and voluntary genomic testing. To protect participant privacy and confidentiality, all data collected were deidentified prior to analysis. Unique identifiers were assigned to securely link survey responses, EHR data, and biospecimen samples while preventing the disclosure of personal information. Participants who completed the primary consent, EHR consent, return of genomic results consent, all 3 enrollment surveys, and physical measurements and provided biospecimen samples received a US $25 gift card as compensation for their time and contribution to the program.

Results

Participant Characteristics

There were 605 participants, 64.5% (390/605) of whom were women. Most participants were contained within the group aged 50 - 59 years (172/605, 28.4%) and 40 - 49 years (111/605, 18.4%). The majority specified their ethnicity as Hispanic (343/605, 56.7%). For race, participants reported White (182/650, 30.1%) and Black (66/605, 10.9%) as the 2 highest

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categories. Most specified the highest level of education as high school (191/605, 31.6%).

The majority reported access to the internet (539/605, 89.1%), whereas 10.9% (66/605) had no access. Nearly 3 quarters of participants (448/605, 74.1%) reported feeling comfortable with computers, 6.3% (38/605) felt neutral, and 19.7% (119/605) felt uncomfortable (Table 1).

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Table . Study participant demographics. A cross-sectional analysis using participant-reported data to examine technology access and comfort and enrollment support preferences among Federally Qualified Health Centers participants. Missing data were minimal (<1% per variable) and handled via complete-case analysis.

Demographics	Values (N[a]=605)
Age (years), n (%)	
18 - 29	97 (16.03)
30 - 39	80 (13.22)
40 - 49	111 (18.35)
50 - 59	172 (28.43)
60 - 69	111 (18.35)
70 - 79	31 (5.12)
≥80	3 (0.50)
Ethnicity[b], n (%)	
Hispanic	343 (56.69)
Non-Hispanic	262 (43.31)
Race[b], n (%)	
Asian	8 (1.32)
Black	66 (10.91)
Middle Eastern	1 (0.17)
Mixed race	76 (12.56)
Other	2 (0.33)
White	182 (30.08)
Native American	7 (1.16)
Gender identity, n (%)	
Men	207 (34.21)
Nonbinary	1 (0.17)
More than 1 gender identity	4 (0.66)
Transgender	3 (0.50)
Women	390 (64.46)
Language, n (%)	
English	422 (69.75)
Spanish	183 (30.25)
Education, n (%)	
Never attended school or only attended kindergarten	1 (0.17)
Grades 1-4 (primary)	25 (4.13)
Grades 5-8 (secondary)	40 (6.61)
Grades 9-11 (some high school)	82 (13.55)
Grade 12 or GED (high school graduate)	191 (31.57)
College 1-3 years (some college or technical school)	169 (27.93)
College 4 years or more (college graduate)	66 (10.91)
Advanced degree (Master's, doctorate, etc)	31 (5.12)

[a]Participants enrolled in the Community Health Center Inc All of Us Research Program (2017 - 2023)

[b]Self-reported and are presented as underrepresented versus nonunderrepresented for analysis purposes.

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Descriptive Results

Table 2 depicts the correlation among internet accessibility, technological proficiency, and the participants' inclination toward either a High-Touch or Low-Touch approach to the completion of consent. These factors are examined within the context of the Digital Divide Framework, highlighting both accessibility (internet connectivity) and competencies or comfort (digital literacy) as essential determinants of the enrollment method.

Table . Distribution of internet access and comfort with technology by consent interaction level (High-Touch, Low-Touch, and NA). Bivariate analysis between access and comfort with technology and enrollment support preference was conducted. Missing data were excluded from analyses (complete-case).

Bivariate analysis[a]	High-Touch[b] (n=346)	Low-Touch[c] (n=259)	Test statistic	*P* values
Access to internet, n (%)				
Yes	296 (85.6)	243 (93.8)	10.4	<.005
No	50 (14.5)	16 (6.2)		
Comfort with technology, n (%)				
Comfortable	211 (61)	237 (91.5)	78.1	<.001
Neutral	26 (7.5)	12 (4.6)		
Uncomfortable	109 (31.5)	10 (3.9)		

[a]Chi-square tests were used to examine bivariate associations between internet access and technology comfort and consent preference.

[b]High-Touch indicates preference for in-person or staff-assisted consent.

[c]Low-Touch indicates preference for self-guided consent.

Of those needing High-Touch support (n=346), 14.5% (n=50) had no internet access and 31.5% (n=109) felt uncomfortable with technology. In comparison, from the Low-Touch group (n=259), only 6.2% (n=16) had no internet access and 3.9% (n=10) felt uncomfortable with technology (*P*<.001). These trends are also aligned with the constructs from UTAUT, namely the performance expectancy and effort expectancy on the take-up of technologies, where usability comfort from digital platforms and subjective ability to access them are antecedents to the uptake of Low-Touch channels. The chi-square test also determined that the type of support was significantly correlated with access to the internet (*P*<.005) and feeling uncomfortable with technology (*P*<.001).

Unadjusted and Adjusted Association Between Internet Access, Technology Comfort, and Completion of Consent Method Preference

Since a few cells existed for some categories, penalized maximum likelihood estimates, including Firth's correction for bias, were conducted by LRs. The adjusted model contained covariates age, race and ethnicity, education level, and preferred consent language so that the potential confounding variables may be adjusted. Two-way interactions, namely, technology comfort × age, technology comfort × race/ethnicity, internet access × age, and internet access × race and ethnicity, were tested but found not to be statistically significant (all *P*>.24), thus suggesting the absence of moderation effects. All the categorical variables were coded by reference coding. ORs, together with their Wald 95% CI values, were presented for the main effects as well as the interaction effects.

As evidenced by the data included in Table 3, the unadjusted outcome indicated that participants with internet access had significantly lower chances of using the High-Touch method compared to their counterparts without internet access (OR 0.390, 95% CI 0.217-0.702; *P*<.005). Furthermore, participants who were neutral or comfortable with computers had reduced chances favoring the High-Touch method compared to participants uncomfortable with computers (comfortable: OR 0.082; *P*<.001 and neutral: OR 0.199; *P*<.005).

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Table . Logistic regression model: unadjusted and adjusted odds ratios for access to the internet and comfort with technology in relation to use of the High-Touch method for consent completion. Models adjusted for age, race and ethnicity, education, and consent language. Analysis used Firth bias correction for small-cell adjustment.

Variables[a]	Values (N=605)	*P* value
Access to internet, unadjusted OR[b] (95% CI)		
Yes	0.390 (0.217-0.702)	<.005
No	Reference	
Comfort with technology, unadjusted OR (95% CI)		
Comfortable	0.082 (0.042-0.160)	<.001
Neutral	0.199 (0.077-0.510)	<.005
Uncomfortable	Reference	
Access to internet, adjusted OR (95% CI)[c]		
Yes	1.029 (0.498-2.125)	Not significant
No	Reference	
Comfort with technology, adjusted OR (95% CI)[c]		
Comfortable	0.118 (0.055-0.255)	<.001
Neutral	0.212 (0.077-0.587)	<.005
Uncomfortable	Reference	

[a]Findings reflect the relationship between structural (internet access) and cognitive (technology comfort) dimensions of the Digital Divide Framework. The adjusted model included age, race and ethnicity, education, and consent language as covariates to account for potential confounding. Penalized logistic regression using Firth bias correction was applied due to sparse cells in some categories. Interaction terms between technology comfort × age, technology comfort × race and ethnicity, internet access × age, and internet access × race and ethnicity were tested but were not statistically significant (all *P*>.24). Missing covariate data were handled via complete-case analysis (8 participants excluded). Sensitivity analyses were conducted and confirmed the robustness of the primary findings.

[b]OR: odds ratio.

[c]Covariates included in adjusted models: Age (18 - 29, 30 - 39, 40 - 49, 50 - 59, 60 - 69, 70 - 79, ≥80 y), race and ethnicity (underrepresented vs non–underrepresented), education (1-8), and consent language (English vs Spanish).

After adjustment for covariates (Table 3), the correlation for internet access with preference for High-Touch was no longer significant (AOR 1.029, 95% CI 0.498-2.125; *P*=.94). Comfort with tech was still significant (AOR comfortable 0.118 and AOR neutral 0.212). This outcome highlights the point that digital proficiency and self-confidence (both key elements within the Digital Divide Framework) are superior predictors over access alone, as suggested by TAM and UTAUT, where behavioral intent and adoption are driven by perceived usability ease and confidence with one's ability to use tech.

Model fit was estimated by Akaike information criterion, Schwarz criterion, and −2 Log Likelihood, respectively. The predictive discrimination was examined by the c-statistic (concordance index). The model diagnostics revealed a good fit. The interaction terms were not significantly different from 0 (all *P*>.24), so the relations did not differ across subgroups.

Sensitivity Analyses

As an additional test of the robustness of our results, we carried out a number of sensitivity analyses. Results were concordant with the main models, with technology comfort still significantly associated with preference for High-Touch consent and internet access still not significant after adjustment. The replication of technology comfort as a predictor strengthens the theoretical correspondence to TAM and UTAUT constructs, emphasizing the importance of end user's perceived ability (effort expectancy) for the preference for digital over human-mediated channels. Furthermore, we contrasted complete-case analysis with multiple imputation for missing covariate data and saw equivalent effect estimates by approach. Finally, we estimated standard LR without Firth's correction and tested interaction terms one-by-one. These alternative specifications did not substantially alter the identified associations. Altogether, the combined set of analyses suggests that our results are stable and robust to different analytic assumptions as well as variable codings.

Discussion

Summary of Main Findings

In alignment with the study objectives, this study examined support preference with digital access and comfort with technology levels for large-scale enrollment in research. Although most participants had internet access (539/605, 89.1%), technological comfort, represented by ease of use in TAM and effort expectancy in UTAUT, was the primary driver of High-Touch compared to Low-Touch preference. Those reporting discomfort with technology were significantly more likely to choose a High-Touch (staff-mediated) enrollment support preference. Although unadjusted analyses implied lack of internet access was related to High-Touch support preference,

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this relationship was no longer significant when adjusted for covariates age and race/ethnicity. These results extend the Digital Divide framework from connectivity, including user skill, confidence, and behavioral intention as key determinants of behavior [26-28].

Interpretation and Comparison to Existing Literature

Findings from this study suggest substantial implications for digital health research infrastructure. Continued access to device and broadband service is needed, but the TAM and the UTAUT models indicate enrollment behavior is stronger when the participant's perceived ease of use (comfort level) and the influence of others (endorsements from staff members or colleagues) are present compared with access only. This is consistent with emerging evidence demonstrating digital self-efficacy, rather than access alone, is the greatest predictor of participation in the digital healthcare and research space [29,30].

The decreased significance for internet access in the adjusted models may also be an indication of the effect of the sociodemographic covariates. For instance, participants without internet access were frequently older or from underrepresented populations, which were already accounted for within the adjusted models. Again, the relatively small group of participants without internet access may have also limited statistical power. This highlights the point that the noted absence of significance does not necessarily mean no effect but instead suggests an achievable contextual or sample-specific restriction. This supports the need to consider both access characteristics as well as user characteristics within strategies to foster digital inclusion.

The findings from this study are consistent with other studies that show overlap of digital literacy with ease of convenience, trust, and privacy, especially among underrepresented groups in biomedical studies. By implicitly correlating the above results with TAM and UTAUT and Digital Divide frameworks, this study clarifies the mechanisms through which digital comfort impacts research enrollment. Hannemann et al [27] discussed participants' typology from "digital skeptics" to "digital illiterates," with the standard of nonparticipation generally founded upon ease of convenience rather than accessibility. Similarly, Batterham et al [28] showed that significant proportions of participants placed importance upon trust and support ahead of convenience, especially for taking on difficult health-related processes through the internet. With projects like the Biobank of the UK or the AoURP, there has also been increased application of self-directed digital tools of consent with improved scalability; however, there is a risk of excluding nondigitally literate consumers [31-33]. Our study adds to this notion by suggesting that mere access to the internet does not fully explain support preference. Instead, functional comfort with technology is a stronger predictor, highlighting a potential gap in prior work that emphasizes connectivity alone. Hybrid consent models, where remote tools are supplemented with human facilitation, appear aligned with digital equity models that advocate for context-aware and culturally sensitive systems [31,32,34,35].

Digital enrollment processes for precision medicine studies like AoURP should include TAM and UTAUT principles of perceived ease of use, an index of technological comfort, together with performance expectancy, the belief in one's ability to perform things by oneself. One example is the use of short digital literacy tests within consent procedures, allowing for the allocation of potential participants into either the Low-Touch or the High-Touch track. Subjects with low digital comfort level are offered automated human assistance or alternative means of consent, like videoconferencing or face-to-face assistance [11,33,36,37]. These participant-oriented design principles support the main principles of digital equity in terms of meeting participants where they are, both experientially and technologically [35]. They are also backed by research findings indicating that there is the possibility of technical discomfort causing withdrawal, mistrust, or outright refusal of research access, even when barriers to access have been overcome [13,14,36,37].

Implications for Research Design and Practice

The significant correlation between the level of technological comfort and the High-Touch enrollment preference is an indication that factors such as confidence among staff, past experiences, and cultural orientations have the potential to serve as mediators on effort expectancy and intentions to behavior, as the UTAUT model suggests. Specifically, factors such as confidence among research staff members, research staff's past experience with digital technologies, or cultural orientations toward digital technologies are likely to have potential as mediators on the relationship between the level of technological comfort and enrollment preference for High-Touch support. High-Touch designs, characterized by guided support via telephone, videoconferencing, or face-to-face interactions, are essential for facilitating engagement from participants who are hesitant to use technology. To translate these insights into practice, FQHCs and other health centers could develop flexible enrollment pathways that include (1) a concise digital literacy assessment during the intake process, (2) automatic direction to either Low-Touch or High-Touch support based on the assessment outcomes, (3) training and use of digital navigators to offer immediate assistance, and (4) monitoring of enrollment results to continuously refine the triage process. Success for implementing this framework in practical settings depends on the development of triaged workflows, evaluations of digital literacy, the use of digital navigators, and a combination of support options, all of which collectively seek to bridge the digital divide.

Strengths and Limitations

The study capitalizes on real-world data regarding internet access and technology comfort from patients covered by an FQHC. However, this study does have its limitations. First, the analysis only contained participants with complete question answers from the survey, raising the possibility of selection bias if the participants with missing data had different levels of internet access or technology comfort. Second, the study was conducted by means of a single-site study, so generalizability to other sites, for example, rural clinics or academic medical centers, is limited. This study dichotomized support preference

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as High-Touch versus Low-Touch paths, but enrollment engagement is well-known to exist on a continuum and not as dichotomies, with some participants using a hybrid of different strategies. It was not possible with the current dataset to empirically test the evaluation of the hybrids of enrollment engagement models, an important limitation. Quantification of gradient support strategies with subsequent measurement of their performance among participant subgroups will become an important area of future studies, allowing for better nuance and adaptability of digital enrollment systems.

Another study weakness is the absence of an a priori power calculation, as the survey was based on existing program enrollment data rather than the prospectively determined sample. Although the overall sample was sizable, subgroup samples, such as those without internet access, were small. Thus, the nonsignificant outcome for the adjusted relationship between internet access and High-Touch preference may indicate an index of poor statistical power rather than an index of the true null effect. Furthermore, the statistically nonsignificant adjusted relationship between internet accessibility and High-Touch preference could indicate poor statistical power or adjustment for covariates instead of a genuine null effect. Potential confounding factors such as previous digital training, proficiency with language, health literacy, or cultural orientations toward technology are able to influence both comfort and support preference. Their omission may impede causal inference.

Finally, the reliance on self-reported measures for technology comfort presents the potential for biases toward social desirability and recall, whereas the cross-sectional design precludes the possibility of making causal inferences. Despite these limitations, the study contributes valuable insight into the relative importance of comfort with technology relative to limited access to the internet, informing the dichotomy between High-Touch versus Low-Touch approaches to researching enrollment. In addition, despite the limitations, the conceptual synthesis provides improved insight into the influence associated with digital literacy with user-friendliness on enrollment preference over access.

Conclusions and Broader Implications

This study demonstrates that participants' level of tech-savviness, more than internet access, has a significant influence on their preference toward High-Touch instead of Low-Touch enrollment practices in large-scale digital health research. These outcomes contribute toward existing work on the digital divide by underscoring that participation barriers are determined by an intersection between digital expertise and psychosocial constructs, including trust and previous experiences with online technologies.

From a research perspective, these results point out the need to consider the measure of technological comfort, digital expertise, and psychosocial mediators during the design of enrollment procedures. From a policy perspective, funding and guidance for digital health projects should prioritize flexible, participant-centric enrollment models that are able to accommodate varied levels of technological comfort and digital expertise.

In practice, FQHCs and other similar settings can implement the following achievable strategies: (1) triaged enrollment procedures, (2) concise digital screenings during the intake process, (3) use of digital navigators, and (4) hybrid support methods combining digital portal access with human assistance. Programs must also track outcomes from an enrollment perspective by level of comfort among the participants and provide multiple opportunities for the development of skills so that the process is equitable.

Based on these findings, future research is necessary to build and test frameworks permitting participant interaction with research initiatives like the AoURP. Additional research is also necessary to test potential mediators, including research staff trust, histories of online exposure, and cultural orientations to technologies, to assess their effect on the interdependence between technological comfort and support preferences. Sensitivity analyses, as well as alternative specifications for the model, must be done to test the robustness of the conclusions, particularly among the subgroup that has limited access.

Hybrid enrollment procedures combining digital portal and human-assisted methods need testing, especially for FQHCs or low-resource sites. Some concrete strategies may include the addition of short digital literacy screenings during intake procedures, the adoption of trained staff as digital navigators, and the provision of on-demand support by one-on-one, phone, or video. Hybrid or mixed enrollment strategies also need to be tested empirically so the flow of participants between the Low-Touch and the High-Touch paths is better understood, as well as whether different combinations offer improved retention and data quality.

Additional research is also needed to assess interventions for enhancing digital confidence and digital literacy among the research participants, their families, and the underrepresented group members. Modular digital skills training, digital mentoring by the community, as well as staff-piloted mobile technology toolkits by the FQHC staff, are some of the interventions to be included. Completion rates of enrollment, retention of the participants, data quality, as well as the level of comfort the technology provides to the participants should all be included as measurable outcomes.

Subsequent studies must incorporate digital literacy as a routine survey question so that inclusion trends are measurable over time. Mixed-method studies should test mediators (previous experience, cultural attitudes, and trust) and test adaptive, participant-centered enrollment strategies. Long-term end points of the interventions will inform a scalable, equity-focused digital health research infrastructure.

Future research should also address these specific, measurable questions:

1. Does digital literacy initiative participation contribute to the increase in Low-Touch enrollment pathway selections?
2. Does trust in staff, prior online experience, or cultural perceptions mediate the association between technology comfort and support preference?

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3. How do sociodemographic variables influence the effectiveness of mixed enrollment strategies and by what mechanisms?
4. What is the impact of digital navigators combined with adaptive support on enrollment completion, retention, and data quality?

The combined implementation of these approaches can make digital health research infrastructure scalable, fairer, and more inclusive. This assists in getting all stakeholders meaningfully involved, particularly members from disadvantaged groups, in precision medicine activities.

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Data Availability

The datasets generated or analyzed during this study are not publicly available due to considerations of privacy and ethics, but deidentified data are available from the corresponding author on reasonable request.

Conflicts of Interest

None declared.

Checklist 1
STROBE checklist.
[PDF File, 180 KB - formative_v10i1e78850_app1.pdf]

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Abbreviations

AoURP: All of Us Research Program
EHR: electronic health record
FQHC: Federally Qualified Health Center
LR: logistic regression
NIH: National Institutes of Health
OR: odds ratio
STROBE: Strengthening the Reporting of Observational Studies in Epidemiology
TAM: technology acceptance model
UTAUT: unified theory of acceptance and use of technology

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Original Paper

Adoption of an Electronic Decision Support Tool for Capacity Building of Community Health Workers: Mixed Methods Study

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Abstract

Background: Complimentary subscriptions to UpToDate, a decision support tool, were provided to community health workers (CHWs) in rural and remote primary care sites as part of a government-funded health system research program. A feasibility evaluation conducted after the first year of implementation showed that UpToDate was acceptable among CHWs despite infrastructural barriers.

Objective: This follow-up study evaluated the longitudinal adoption of UpToDate among CHWs and examined how sociocultural, political, and environmental factors influenced its use. Drawing on the nonadoption, abandonment, scale-up, spread, and sustainability framework, this study aimed to understand not only use patterns but also broader challenges to scale-up, spread, and sustainability in a complex health system.

Methods: An explanatory mixed methods design was used combining analysis of use and program activity logs; program reports; and focus groups with CHWs, health care professionals, and program implementers. Quantitative analysis of use logs (March 2021 to September 2023) compared adoption over time by using descriptive statistics, CIs, and chi-square tests. Qualitative data came from the reanalysis of previous focus group transcripts and program reports and from a new focus group with program implementers. Reflexive thematic analysis was used to interpret how CHWs and implementers perceived and used the tool, and findings were integrated to explain quantitative trends.

Results: Use of UpToDate was modest and declined over time. Monthly active use among CHWs and midwives fell substantially from 3.57% (97/2720 person-months) in 2021 to 1.07% (37/3456) in 2022 and remained low at 1.50% (39/2592) up to 2023, with markedly higher engagement in the rural site than in the remote site. Peaks in use coincided with program activities, whereas prolonged troughs followed typhoons, power outages, and other disruptions. Log data showed that users primarily consulted patient education articles rather than clinician-oriented decision tools. Qualitative analyses revealed that CHWs appropriated UpToDate as a learning aid and source of professional credibility. Structural shocks, heavy workloads, language barriers, and limited device access constrained individual use, and communal practices (shared devices and learning activities) meant that meaningful engagement often went unrecorded in vendor metrics.

Conclusions: Our findings show that acceptability does not guarantee sustained use and that adoption cannot be captured fully by log-in counts. UpToDate's value for CHWs lay in how it was domesticated as a tool for building capacity and professional credibility, not in its intended function as a decision aid used at the point of care. Therefore, evaluations of digital health tools should incorporate indicators of learning and social capital alongside use metrics. Policymakers should recognize that infrastructural

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fragility and communal adaptation shape digital health uptake. Embedding tools into ongoing training and peer learning structures, providing offline and multilingual support, and investing in resilience planning will be crucial for meaningful scale-up and sustainability.

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KEYWORDS

community health workers; clinical decision support; health systems research; digital health; UpToDate; quantitative analysis

Introduction

Community health workers (CHWs) are locally selected health aides who live in the communities they serve, are accountable to those communities, receive support from the health system without being fully integrated into it, and generally undergo less training than professional health workers [1]. Their responsibilities include delivering health education, providing basic care, and referring patients to formal services. However, their ability to perform these roles is constrained by limited access to reliable health information and ongoing training [2,3]. Digital health interventions (DHIs) offer potential solutions to these capacity gaps. Tools such as mobile apps, clinical guideline repositories, and point-of-care decision support systems have been deployed to support CHWs, but most are limited to pilot projects or narrowly scoped disease programs [4-7].

UpToDate is a commercial point-of-care tool [8] and web-based information resource [9] that covers a broad range of health topics and decision tools. Systematic evaluations among point-of-care summaries have shown that no single tool consistently outperforms across all domains; for example, DynaMed and eMedicine scored highest for volume of coverage, whereas Clinical Evidence and UpToDate tied for editorial quality [10]. A later independent review similarly found that, while several tools met high quality standards, DynaMed and UpToDate were among those consistently scoring high in terms of breadth and editorial rigor, whereas others such as Medscape were less consistent in transparency and referencing [11].

In this study, UpToDate was chosen for implementation not only for its broad content and usability but also for its inclusion of a structured patient education corpus (“The Basics” and “Beyond the Basics”) written in lay language. Taken together, these factors justified its selection as one of the interventions in the Philippine Primary Care Studies (PPCS). The PPCS is a government-funded health system research program supporting universal health care reforms. From 2019 to 2023, the PPCS program provided free UpToDate subscriptions to CHWs and other frontline workers in rural and remote primary care sites accompanied by onboarding sessions and journal club sessions (ie, small group meetings where participants discuss clinical cases and related evidence).

In 2021, a feasibility evaluation drawing on the technology acceptance model (TAM) framework was conducted after the first year of implementation of the free UpToDate subscriptions [12]. This evaluation identified barriers to the uptake of UpToDate, which included digital literacy, limited language options, and poor information and communications technology infrastructure [13]. Despite these barriers, the technology was highly acceptable among CHWs, a notable finding given that the features were not specifically designed for this cadre.

TAM was appropriate for that feasibility phase as it is widely validated to predict technology adoption, including in resource-limited settings [14]. However, while TAM can capture acceptability and intention to use, its focus on individual and organizational acceptance means that it is less able to interrogate the infrastructural and political factors that shape sustained use [15]. Moreover, previous evaluations using TAM have not reviewed vendor longer-term use data, leaving a gap on whether expressed acceptability translated into continued adoption. To address this, this study also used the nonadoption, abandonment, scale-up, spread, and sustainability (NASSS) framework [16,17], which was developed to explain why digital health technologies are variably adopted or abandoned and how complexity across multiple domains shapes long-term outcomes. The NASSS framework comprises 7 interacting domains: the condition, the technology, the value proposition, the adopter system, the organization, the wider system, and adaptation over time. It has been applied to complex health technologies, including video-based outpatient consultations, remote monitoring systems for chronic illness, and assistive technologies for older adults [17].

This study addressed the research gap by providing the first formal analysis of adoption patterns and examining broader dimensions of value beyond vendor-defined metrics, situated within broader infrastructural, political, and system-level challenges across NASSS domains. Specifically, this study was guided by two primary research questions: (1) How does UpToDate fit into the CHWs’ roles in primary care? (2) How do the wider sociocultural, political, and environmental systems influence the adoption of UpToDate among CHWs?

Methods

This manuscript followed the Checklist for Mixed Methods Research Manuscript Preparation and Review [18] (Multimedia Appendix 1) and the Standards for Reporting Qualitative Research for the qualitative components [19] (Multimedia Appendix 2).

Setting

Within the PPCS program sites, only those with CHWs were selected. These included 2 sites: Bulusan, a geographically isolated municipality bordered by the Pacific Ocean (hereafter referred to as the “remote site”) and the municipality of Samal, situated west of Manila Bay (the “rural site”). Both sites exhibited a health care professional density of 0.01 per 10,000

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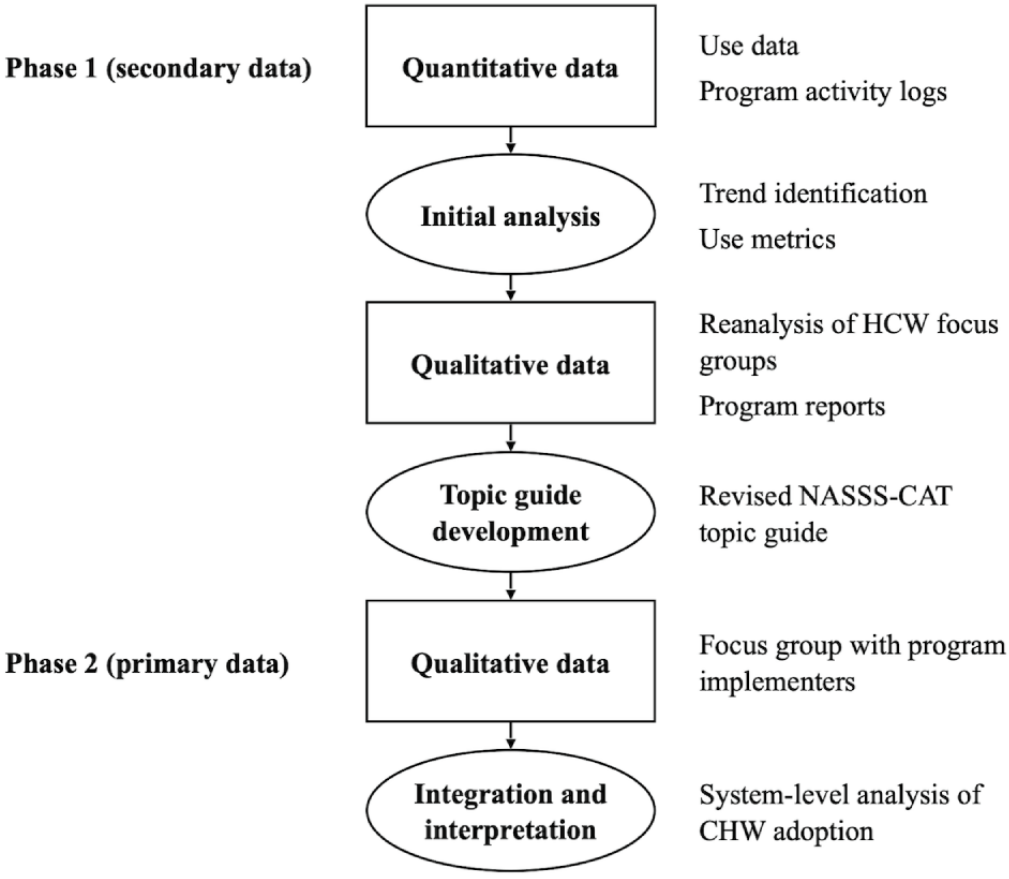
people [20], starkly below the estimated requirement of 25 per 10,000 for adequate primary care service coverage [21].

Study Design

This study used a multiphase explanatory mixed methods approach (Figure 1). Quantitative analysis of vendor use data first provided a population-level description of adoption patterns among CHWs and midwives. These findings then informed a rereading of existing program reports and transcripts of focus group with health workers. Because use data had not been available in previous evaluations, this rereading allowed previous findings on acceptability to be revisited through a new lens, highlighting inconsistencies between reported intention to use and actual adoption. Together, the quantitative findings and this secondary qualitative analysis pointed to missing perspectives, particularly regarding organizational processes and wider system influences. To address these gaps, we developed a targeted interview guide (Multimedia Appendix 3) for program implementers, who were best positioned to comment on these broader domains. Integration took place after analysis of quantitative and qualitative data, where use patterns, frontline accounts, and implementer perspectives were brought together to produce a more comprehensive interpretation of adoption and nonadoption.

This sequencing allowed the researchers to zoom out to identify population-level trends, zoom in to explore individual and organizational experiences, and zoom out again to situate these micro-level insights within broader system dynamics. This layered approach provided a more comprehensive analysis and minimized bias from relying solely on decontextualized metrics or from overly narrow qualitative sampling.

Figure 1. Multiphase explanatory mixed methods study flowchart. CHW: community health worker; HCW: health care worker; NASSS-CAT: nonadoption, abandonment, scale-up, spread, and sustainability framework complexity assessment tool.



Reflexivity and Positionality

This study was conducted within an interpretivist paradigm, which recognizes multiple participant meanings regarding the adoption and nonadoption of UpToDate. Purposive sampling was used to capture a range of perspectives from users and program implementers, and reflexive thematic analysis was used to interpret the data [22]. The research team comprised clinicians and digital health researchers, some with previous involvement in the PPCS program and related health system research. Collectively, the team drew on experiences with underserved communities, which informed a sensitivity to power and equity issues. This positionality facilitated access and contextual understanding but also carried risks of interpretive bias, which were mitigated through team-based discussion and iterative cross-checking against the raw data.

Phase 1: Secondary Data Collection and Analysis

Quantitative Data

Use data from 2021 to 2023 stratified by health care provider type were requested from UpToDate's service provider, Wolters Kluwer. These data were available only in monthly intervals and in aggregated form, precluding matching specific users with their use frequency. Physicians and nurses were reported as

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separate categories, whereas CHWs and midwives were combined by the vendor into an "Others (CHW/midwife)" category, reflecting the novelty of the technology for these user types. As a result, our quantitative analysis focused on this aggregated subgroup of CHWs and midwives. All CHWs and midwives enrolled in the PPCS program and who were provided with access to UpToDate between 2021 and 2023 were included in the vendor use data. Subscriber counts were based on annual employee data of health care workers assigned to each barangay (the smallest administrative unit in the Philippines). For analysis, we treated each subscribed CHW or midwife as contributing one subscriber person-month for each calendar month in which their account was active.

As a measure of adoption, monthly active users (MAUs) were defined as the proportion of registered CHW and midwife subscribers who logged at least one session in that month; the denominator was the number of subscribed CHWs and midwives at the site that month. From March 2021 to September 2023, CHWs and midwives comprised 89.04% (7807/8768 person-months) and 10.96% (961/8768) of the subscribers, respectively (remote site: 4481/4760, 94.14% CHWs; rural site: 3326/4008, 82.98% CHWs). Estimated MAUs are presented with Wilson 95% CIs. Sessions per user were defined as total sessions divided by the number of unique active users in that month and were summarized monthly.

For inferential statistics, observations were aggregated to nonoverlapping calendar years within the window (2021 to 2023). We first conducted chi-square tests of homogeneity on aggregated counts: a 3 × 2 test comparing years pooled across sites and a 2 × 2 test comparing sites across the window. To quantify effects, we reported absolute percentage point differences with 95% CIs computed using the Newcombe score method for independent proportions (year to year within each site, year to year with both sites pooled, and the overall contrast between the rural and remote sites).

Content type measures the number of user interactions for each topic category defined by Wolters Kluwer. This content is segmented vertically by specialties (eg, dermatology, gastroenterology, and psychiatry), horizontally by levels of care (eg, primary care and patient education), and by app features (eg, calculators and clinical pathways). This metric was assessed as a percentage of total content views per month to allow for inferences about different uses of UpToDate.

Program activity logs were obtained from the program secretariat, who supplied records of CHW-led journal club sessions supervised by the PPCS. These dates were superimposed on plots of MAUs and sessions per user to infer associations between use and the engagement of program implementers with users.

Qualitative Data

Data from 2 sets of focus groups were reanalyzed in this phase. The first was conducted by Calderon et al [13] in April 2021 to assess the feasibility and acceptability of UpToDate. The second was conducted by De Mesa et al [23] in July 2023 to explore barriers to role performance among CHWs. Eligible participants in the study by Calderon et al [13] were all UpToDate subscribers (CHWs, physicians, midwives, and nurses), whereas the study by De Mesa et al [23] included only CHWs. Both studies used a pilot-tested semistructured topic guide adapted from a similar study [24], which elicited discussions regarding the feasibility and acceptability of using UpToDate in relation to health care worker roles. The study by Calderon et al [13] included 4 online focus groups of 4 to 8 participants each, whereas the study by De Mesa et al [23] included 6 in-person focus groups of 5 to 7 participants each. Sessions were moderated in Bikol, English, and Filipino languages by trained multilingual research assistants. Audio recordings were manually transcribed, anonymized, and translated into English.

A reanalysis of focus group transcripts from the studies by Calderon et al [13] and De Mesa et al [23] was undertaken to address questions not covered in the original studies. Although the focus groups were designed to explore different research questions, the breadth of the discussions provided sufficient material relevant to adoption, particularly within the adopter and technology domains of the NASSS framework. Program reports comprising published and unpublished PPCS manuscripts were assessed for relevance to the research questions. Relevant reports provided social context and organizational descriptions of the remote and rural settings.

Following the reflexive thematic analysis approach by Braun and Clarke [22,25], coding of transcripts and program reports was undertaken (by AE) as an interpretive process to identify meaningful patterns in the data. Initial codes were developed by reading through the interviews. Further reading and coding were informed by concepts and domains from the NASSS framework. Codes were organized and managed using NVivo (version 14; Lumivero). To support theme development, a "one sheet of paper" method was used to visually map how codes clustered and related to one another. Candidate themes were then developed through iterative reflection and sensemaking, and team discussion explored coherence and distinction in these themes. Themes were reviewed and further refined by returning to the full dataset to ensure that they meaningfully represented the complexities of participant accounts. Preliminary themes were integrated with quantitative findings to explain use patterns and identify knowledge gaps, particularly about the wider system, where health care worker perspectives were sparse. While this phase primarily focused on the technology, adopter, and condition domains of the NASSS framework (consistent with the a priori TAM lens), it offered limited coverage of the remaining NASSS constructs. These gaps informed the development of a topic guide (Multimedia Appendix 3) used for the phase 2 focus group based on the NASSS complexity assessment tool [26].

Phase 2: Primary Data Collection and Analysis

This phase involved collecting qualitative data from an online focus group conducted in April 2024 with 6 PPCS program implementers involved in the UpToDate deployment. Participants were selected based on their involvement with PPCS in any capacity, including protocol development, data collection, data analysis, and manuscript writing. This phase addressed the second research question by providing social, organizational, and policy contexts not covered in detail in phase

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1. The focus group with program implementers was moderated, audio recorded, manually transcribed, and anonymized by the lead author.

Transcripts were coded (by AE) using a theory-driven approach informed by the NASSS framework [17], enabling structured yet flexible analysis of how the intervention interacted with its evolving implementation context [16,27]. Coding procedures mirrored those used in phase 1. The NASSS domains guided analysis by mapping responses to relevant constructs. For example, organizational enablers were categorized under the organization domain, whereas system-level constraints were captured under the wider system domain. These codes were integrated with phase 1 data to refine internally coherent and analytically distinct themes [25] following the same reflexive and iterative approach described previously. To enrich the analysis, a coauthor not involved with the PPCS team (CP) also independently examined the qualitative data and contributed to discussions on coding and initial theme development (with AE).

Integration and Interpretation

Candidate themes were reviewed (by AE and CP) and iteratively revised in relation to the entire dataset, encompassing findings from phases 1 and 2.

During this process, use metrics were re-examined alongside qualitative findings to explore associations between patterns of use and contextual factors such as user roles, implementation activities, and site-specific infrastructure. The content accessed on the UpToDate platform was interpreted in relation to how CHWs described using the tool and how this aligned with its intended functions as described by implementers and the service provider. Cross-site comparisons were also informed by available contextual data, such as internet connectivity and local implementation timelines. Triangulation was operationalized through this comparative process, integrating 3 sources of evidence: use analytics, CHW perspectives, and program implementer insights. Member checking of the final themes was conducted with program implementers to confirm the relevance and accuracy of interpretations.

Ethical Considerations

Ethics approval was granted by the University of Oxford Medical Sciences Interdivisional Research Ethics Committee (R92309/RE001). This study served as an extension of the PPCS program and remained aligned with its original objectives. Ethical clearance for the broader program, including the previously collected qualitative data, was granted by the University of the Philippines Manila Research Ethics Board (2015-489-01) and the Department of Health Single Joint Research Ethics Board (2019-55). All participants provided informed consent, including consent for the future use of anonymized transcripts. Participants did not receive compensation for taking part in this study. All research data, including audio recordings and anonymized transcripts, were securely stored on encrypted Nexus365 university servers, with access restricted to the lead author. In accordance with ethics approvals, data will be retained for 3 years following publication and permanently deleted thereafter.

Results

Use Data and Program Activity Logs

Use data spanning 31 months (March 2021 to September 2023) for the vendor-designated “other” user type (CHWs and midwives) were reviewed. Program activity logs from the implementing agency during the same period were also reviewed. The proportion of MAUs who were CHWs and midwives declined since the initial program evaluation in 2021 (Figure 2).

Adoption differed between the rural and remote sites between March 2021 and September 2023 (P=.006). CHW and midwife adoption in the rural site exceeded that in the remote site by 0.82 percentage points (95% CI 0.24-1.44). Pooled across sites, adoption differed across years (P<.001), and CHW and midwife monthly activity fell from 3.57% (97/2720 person-months) in 2021 to 1.07% (37/3456) in 2022 (−2.50 percentage points, 95% CI −3.32 to −1.75) and then did not clearly change in 2023 versus 2022 (+0.43 percentage points, 95% CI −0.13 to 1.06).

Engagement periods with program implementers coincided with higher MAU rates at both sites. The number of sessions per user varied and showed no clear association with the MAU rates or journal club sessions.

The service provider’s logs could not disaggregate CHW users from other health care professionals, highlighting the pragmatic challenges of tracking specific user types. Nevertheless, these data indicated that UpToDate was primarily used to search for patient education content (2424/6784 content views, 35.73% of total content views), a practice reinforced during CHWs’ onboarding and journal club sessions. This was followed by searching for infectious diseases (636/6784, 9.38%). Decision tools, including calculators (115/6784, 1.70%) and clinical pathways (5/6784, 0.07%) designed for medical professionals, represented only a minority of content views throughout the observation period.

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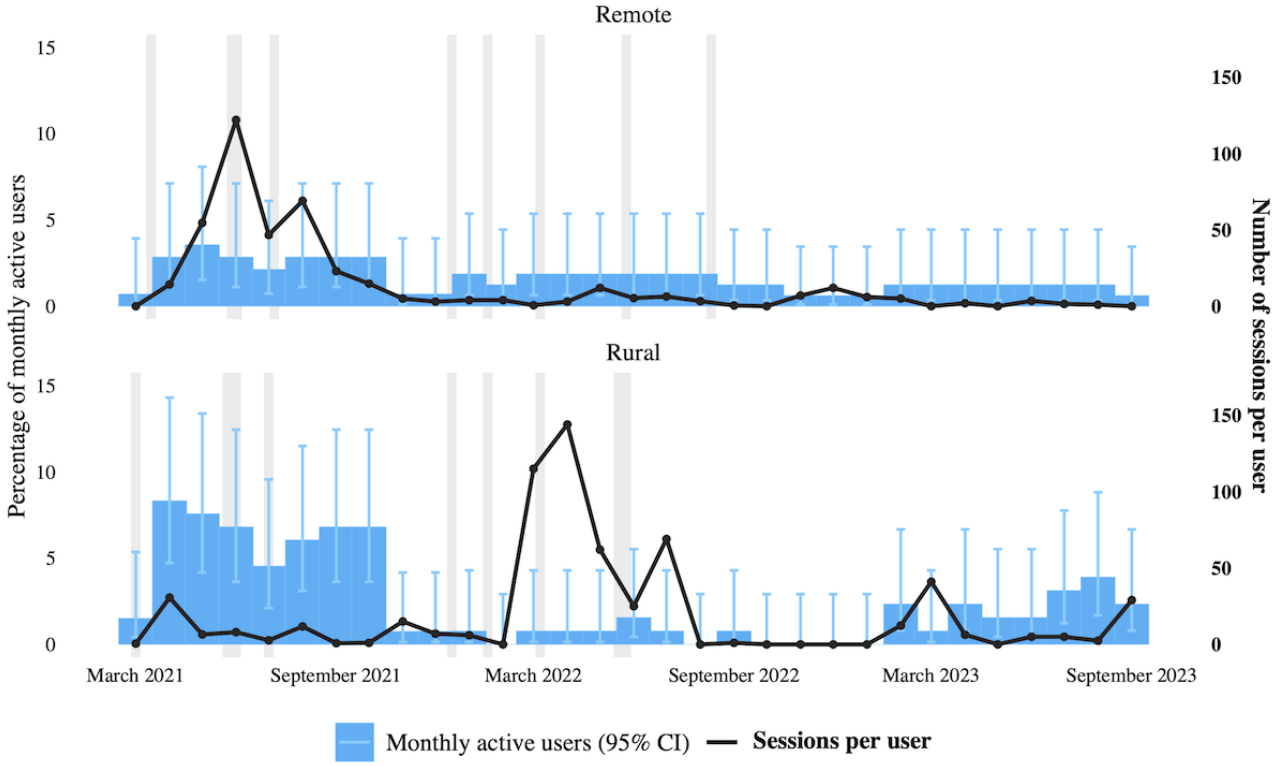
Figure 2. Use patterns of UpToDate among community health workers and midwives in the remote (Bulusan) and rural (Samal) sites across a 3-year period, with periods of engagement with the implementing agency highlighted in gray.



Integration and Interpretation

Focus Groups and Program Reports

Thematic analysis was undertaken using secondary data from 4 focus groups conducted by Calderon et al [13] and 6 focus groups conducted by De Mesa et al [23] and primary data from the additional focus group with program implementers. Most focus group participants (42/60, 70%) were CHWs, with all but one (41/42, 98%) being female (Table 1). Physician and nurse participants were generally younger than their CHW and midwife counterparts.

Five program reports that were relevant to the study's research questions were included: 4 (80%) focused on the health workforce [13,23,28,29] and 1 (20%) focused on leadership and governance [30]. Through iterative rounds of coding and thematic analysis, two key themes were identified: (1) the multiplicity of intended uses and value propositions of the DHI and (2) acute shocks and everyday constraints to adoption.

Table 1. Characteristics of the focus group participants.

Participant type	Participants in the remote site, n	Participants in the rural site, n	Characteristics	
			Age (y), median (IQR)	Sex (female), n (%)
CHW[a] (n=42)	23	19	46 (42-53)	41 (98)
Physician (n=4)	2	2	30 (26-46)	2 (50)
Midwife (n=4)	2	2	41 (33-53)	4 (100)
Nurse (n=4)	2	2	32 (30-42)	4 (100)
Program implementer[b] (n=9)	4	5	46 (36-60)	3 (50)

[a]CHW: community health worker.

[b]Three program implementers were coordinators for both sites.

Theme 1: Multiplicity of Intended Uses and Value Propositions

One of the strongest patterns derived from the qualitative data was the plurality of intended uses of the intervention, which varied not only by design but also by stakeholder positioning. These uses included clinical decision support, educational programs (capacity building), and social capital.

Individual Clinical Decision Support (Technology)

For the vendor, UpToDate was marketed and envisioned primarily as a clinical decision support tool to be used by

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physicians at the point of care. Physicians echoed this, describing how the tool provided "summarized management guidelines at the tip of your finger" (D01), enabling them to manage patients locally rather than automatically referring them to higher-level facilities. This notion of decentralized care also filtered down to CHWs, who were increasingly positioned to support primary care through access to the same evidence base.

Part of an Educational Program (Organization)

However, for the implementers and program coordinators, the intervention's perceived value proposition shifted toward capacity building. Implementers stressed how the tool was deployed less as a strict decision aid and more as a professional development and educational resource. One program coordinator noted the following:

> *Because CHWs are very well integrated in the community and trusted, they get asked about all sorts of conditions....UpToDate allows them to look for answers, even for rare diseases, if they are not familiar.* [P06]

This illustrates how implementers framed adoption in terms of capacity building, professional identity, and continuous training, positioning the technology within broader health system capacity agendas.

Symbolic and Social Capital (Adopters)

Among CHWs, UpToDate was reinterpreted less as a formal clinical tool and more as a form of symbolic and social capital. CHWs emphasized how access to the tool elevated their perceived authority ("UpToDate boosts my morale and confidence..." [C22]) and made them "trusted by clients for their knowledge" (P03). In contexts in which their legitimacy was fragile and their authority was frequently contested, having access to a globally recognized resource allowed them to anchor their advice in evidence, thereby enhancing credibility. In this way, UpToDate's function exceeded its technical design; it became an instrument for reinforcing social standing and negotiating professional boundaries.

Quantitative Integration (Adoption Over Time)

This multiplicity of intended uses complicates how adoption trends are interpreted. Vendor-reported log-in data implicitly privilege the clinical decision support framing. As a result, alternative uses such as informal community teaching or preparation for health talks remained invisible. This explains why use patterns appear inconsistent with the qualitative accounts of continued relevance. Therefore, declining log-in counts may not signal abandonment but rather a misalignment between what the metrics capture and what frontline workers actually value on the ground.

Theme 2: Acute Shocks and Everyday Constraints to Adoption

There were several barriers to the adoption of UpToDate, including acute shocks from calamities and fragile infrastructure and everyday constraints such as limited time, heavy workload, and literacy barriers.

Fragility Amid Calamities and Infrastructure Gaps (Wider System)

Even though UpToDate was designed with flexible features (offline access, mobile compatibility, and cross-cadre accounts), its adoption remained deeply vulnerable to wider systemic shocks. Participants from the remote site of Bulusan repeatedly emphasized how typhoons and fragile infrastructure disrupted sustained use. One physician explained the following:

> *We frequently face typhoons, impacting electricity and internet [access]. UpToDate is useful when accessible, but connectivity is challenging.* [D01]

Even when offline features were available, their utility was constrained by device limitations and repeated outages. A CHW explained that they had "two desktops, but they were damaged due to intermittent power outages" (C19).

In contrast, rural Samal, though also hit by outages, showed faster recovery. A program coordinator explained the difference:

> *The success in the connected area of Samal was so high.... UpToDate [usage] was greater, telemedicine was also greater in Samal, mainly because they had connectivity. Bulusan was very difficult to connect.* [P01]

This divergence reflects not only baseline differences (the rural site had cable infrastructure, whereas the remote site relied on patchy mobile signal) but also relative resilience capacities across sites.

Everyday Constraints (Adopter and Organization)

Beyond the acute disruptions caused by typhoons and outages, participants described a set of everyday constraints that limited how UpToDate could be integrated into practice.

Time and workload pressures were the most immediate barrier. One physician observed that "when the work demand is high, [CHWs] tend to many patients and can only use UpToDate during free hours" (D01).

Language and literacy barriers compounded these pressures. UpToDate content was in English, and while some workers relied on Google Translate, this slowed down their ability to use information directly with patients. One CHW noted the following:

> *It would be better if it were in Tagalog. You could explain it [to patients] much more clearly.* [C04]

Local workarounds also emerged. Legal and ethical constraints were less salient at the local level. In practice, sharing log-ins was tolerated, even normalized, as a pragmatic response to limited access. One CHW remarked the following:

> *I just use other people's devices to access [UpToDate].* [C11]

Another CHW explained how UpToDate supported not only patient education but also the sharing of credible information among CHWs themselves:

> *I appreciate UpToDate even if I don't know how to use a phone. I can ask other colleagues about the*

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> *topics they've read. UpToDate helps us pass on credible information to colleagues and patients.* [C40]

These communal practices demonstrate that adoption was not strictly individual but collective as workers adapted access to fit resource and skill constraints. In this sense, the tool was not simply used "as designed" but reshaped to fit local realities.

Quantitative Integration (Adoption Over Time)

The site-level comparison illustrates how systemic constraints left distinct signatures in use data. In the rural setting, interruptions appeared as short-lived dips in activity, often recovering within weeks. In the remote setting, interruptions cascaded into prolonged troughs, with some months registering near-zero activity. These patterns suggest that remoteness not only lowered baseline adoption but also eroded resilience against shocks. At the same time, account sharing also helps explain why log-in counts understate actual use as activities carried out collectively often left no trace in the data.

Discussion

Principal Findings

This mixed methods evaluation shows that UpToDate's usefulness in primary care for CHWs goes beyond its marketed role as a clinician-facing decision support tool. Across sites, CHWs and program implementers reinterpreted the tool, using it as a capacity-building resource and source of credibility. However, use trajectories were strongly shaped by acute environmental shocks (eg, typhoons and outages), and communal practices were conditioned by resource constraints.

Theoretical Implications

Our findings highlight how adoption and nonadoption were shaped by the interactions between the adopter and technology domains of the NASSS framework. Misalignment between CHWs' formal roles and the intended use of the tool opened space for domestication. Domestication refers to how users appropriate technologies into everyday practice that reshape routines and the meaning of the tool over time [31]. In our case, while adoption indicators suggested low or declining use, domestication was evident as CHWs redefined UpToDate in 2 ways.

First, UpToDate functioned as a form of symbolic capital, an unintended consequence of CHWs' precarious professional positioning. Symbolic capital, in this sense, arose when the use of digital tools themselves operated as a form of capital that signaled competence and supported status attainment [32]. The association with an internationally branded resource further amplified that symbolic capital as part of its value derived from its Western provenance and the global authority it carried [33].

Second, the tool was reworked into a communal rather than individual resource. Shared log-ins and shared devices (practices that might be framed as misuse in other contexts) emerged as pragmatic, equitable adaptations to scarcity. In other low- and middle-income countries, studies similarly note reliance on borrowed or shared phones to access mobile health services, particularly for sexual and reproductive health, even when privacy risks are significant [34]. In our context, where the tool carried no patient data, communal access reduced exclusion without raising clinical confidentiality concerns. In other clinical settings, in contrast, privacy and security considerations may take precedence.

These dynamics underscore a broader contrast in implementation strategies. In many high-income settings, digital health implementation often emphasizes co-design with end users before deployment [35]. In our lower-resource setting, co-design was constrained by structural and resource barriers: the cost and expertise to maintain a continuously updated evidence base and the weak value proposition where CHWs were not the primary intended users. Importantly, adaptation after implementation is not a failure mode as even co-designed interventions are routinely modified during real-world implementation to maintain fit and effectiveness [36]. In such contexts, domestication can substitute idealized co-design, making adaptation after deployment a significant pathway to alignment.

Finally, within the wider system and organization domains, our findings highlight environmental and institutional drivers of domestication. The built environment (ie, mountainous terrain, island geography, and increasingly frequent severe typhoons) directly constrained digital access, making infrastructural fragility a central barrier to adoption. Organizationally, embedding the DHI in group routines (eg, journal clubs and peer discussions) aligned with evidence that structured training and peer practices help CHWs appropriate and circulate health education content [37]. At the same time, these organizational activities also legitimized communal use of UpToDate. While high-income setting debates on the wider system often foreground legal and regulatory hurdles regarding advanced technologies [27,38], in our setting, infrastructure and climate exposure were the more immediate constraints.

Practice and Policy Implications

MAU metrics are more informative than crude log-in counts as frequent log-ins may be important for clinical decision support but CHWs often use the tool for education or peer learning, where even monthly access can be meaningful. However, consistent with extant use studies, MAU remains an insufficient proxy for value [39]. Milne-Ives et al [39] have recommended multidimensional evaluation strategies for DHIs. For UpToDate, this would mean assessing not only how often CHWs log in but also whether they draw on the tool to prepare health talks or improve the quality of counseling. Such dimensions of value could be captured through periodic group discussions or short surveys with CHWs to complement routine use data.

Positioning the tool to support extending primary care to underserved areas highlights its relevance for universal health care reforms in the Philippines. For scale-up, spread, and sustainability, policymakers and funders applying health technology assessment under universal health care reforms will need to reframe how they assess "value for money." Narrow cost-effectiveness analyses risk undervaluing benefits that accrue through patient trust and professional development. For UpToDate, relevant outcomes may include improved patient education and workforce development and retention. Frameworks for complex interventions (eg, that by Skivington

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et al [40]) recommend capturing these multilevel outcomes and revisiting them iteratively as interventions adapt [40].

Digital health strategies in low- and middle-income countries should also require resilience planning as a funded component of procurement and implementation. Contracts and budgets should include technical safeguards tailored to climate vulnerabilities, such as backup power for typhoon-related outages and offline caching. At the same time, procurement should reflect how tools such as UpToDate are used in practice: not only across cadres but also in collective formats such as peer learning sessions. For the Department of Health, this means negotiating subscription arrangements that accommodate multicadre access and embedding peer learning structures such as journal clubs into program design.

Limitations

Vendor logs lacked complete role metadata for CHWs and midwives, which limited finer-grained quantitative analyses of adoption by cadre. While this restricts cadre-specific analysis, CHWs represented the large majority of this group (7807/8768 person-months, 89.03% overall; 4481/4760, 94.13% in the remote site; 3326/4008, 82.98% in the rural site), suggesting that observed patterns are more likely to reflect CHW activity. Notably, the most striking finding was the apparent nonadoption among these groups. Consistent with the "science of attrition" by Eysenbach [41], nonuse itself warrants explanation. By linking longitudinal use data with qualitative insights, we were able to interpret these patterns as reflections of measurement misalignment and systemic constraints rather than simple user disinterest.

The qualitative component drew partly on secondary focus group data collected for previous evaluations, and this may have constrained the generation of new themes. However, the collection of additional primary qualitative data and analysis alongside quantitative data enabled a more comprehensive understanding and allowed for the inclusion of broader participant types. That said, male CHWs were largely absent from the qualitative data, reflecting their scarcity in the workforce. As a result, the findings primarily represent the perspectives of female CHWs, which is consistent with the gendered composition of the CHW workforce but may limit the transferability of these findings to their male counterparts. Transcripts were translated from Bikol and Filipino into English, and while multilingual teams ensured accuracy, some culturally embedded meanings may not have been fully conveyed. Researcher involvement with PPCS implementation also posed a risk of insider bias. To address this, we used reflexive practices and cross-perspective triangulation to check interpretations against the data.

Finally, this study was limited to 2 sites, which constrains generalizability. These sites represent common resource-limited contexts in the Philippines, making the findings potentially transferable to similar primary care settings where CHWs face comparable infrastructural and organizational constraints.

Conclusions

UpToDate's value lay in how CHWs adapted it to their everyday practice as a resource for professional development and as a marker of credibility. These adaptations show that apparent nonuse in use logs may still conceal meaningful engagement, underscoring the need for multidimensional evaluation frameworks that capture such complexities. At the same time, uptake was constrained by infrastructural fragility and recurrent climate shocks, highlighting that resilience planning, both technical and social, must be incorporated into digital health strategies from the start. For global digital health, these findings point to the importance of complementing engagement metrics with indicators of learning and system resilience when assessing the success of digital tools in primary care.

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Conflicts of Interest

UpToDate subscriptions were provided at no cost by Wolters Kluwer as part of the program. The researchers received no financial or other compensation from Wolters Kluwer.

Multimedia Appendix 1
Checklist for Mixed Methods Research Manuscript Preparation and Review.
[DOCX File , 23 KB - formative_v10i1e69874_app1.docx]

Multimedia Appendix 2
Standards for Reporting Qualitative Research checklist.
[DOCX File , 26 KB - formative_v10i1e69874_app2.docx]

Multimedia Appendix 3
Topic guide for the focus group with program implementers.

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[DOCX File , 11 KB - formative_v10i1e69874_app3.docx]

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Abbreviations

CHW: community health worker
DHI: digital health intervention
MAU: monthly active user
NASSS: nonadoption, abandonment, scale-up, spread, and sustainability
PPCS: Philippine Primary Care Studies
TAM: technology acceptance model

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Original Paper

Linking Patient-Reported and Clinician-Assessed Wound Status via Chatbot-Based Digital Surveillance for Wound Infection: Retrospective Observational Study

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Abstract

Background: Digital wound monitoring has become increasingly feasible with the widespread use of smartphones and mobile messaging platforms. Although most previous studies have focused on chronic wounds and demonstrated the clinical benefits of remote monitoring, little is known about how patients with acute wounds perceive and report wound-related changes after discharge; these factors may affect the accuracy and reliability of patient-facing digital health systems.

Objective: This study aimed to evaluate the diagnostic performance of patient-reported infection symptoms in predicting clinician-initiated callbacks within a chatbot-based wound monitoring platform. A secondary objective was to identify wound features most strongly associated with patient-reported infection and examine differences between acute and chronic wound populations.

Methods: This retrospective observational study was conducted at a tertiary medical center in Taipei, Taiwan, between June 30, 2022, and March 1, 2023, as part of an institutional digital health initiative. Within this program, adults with acute or chronic wounds voluntarily joined a chatbot-based monitoring system deployed through the Line messaging app using a bring-your-own-device model. Participants submitted daily symptom reports and wound photographs through the chatbot interface. For each submission, patient self-report of infection served as the primary predictor variable, while an independent review by a senior plastic surgeon determined the reference standard (callback vs no callback). Logistic regression and generalized estimating equation models were applied to account for within-subject correlation, with covariates including age, sex, and wound type. Analyses were performed separately for acute and chronic wounds.

Results: This study included 159 patients; 88 (55.3%) had acute wounds and 71 (44.7%) had chronic wounds. Across the study period, 4764 wound photographs were submitted, with a median of 5 (IQR 2-18) photographs per patient. Diagnostic performance differed by wound type. For acute wounds, the area under the receiver operating characteristic curve was 0.702, with 52.6% sensitivity (95% CI 31.7-72.7) and 87.8% specificity (95% CI 84.7-90.3). For chronic wounds, the area under the receiver operating characteristic curve was 0.907, with 94.9% sensitivity (95% CI 93.3-96.2) and 86.4% specificity (95% CI 85.2-87.5). In symptom correlation analyses, redness was significantly associated with patient-reported infection in the acute wound subgroup (odds ratio [OR] 3.94, 95% CI 1.97-7.90; P<.001), whereas in the chronic wound subgroup, both redness (OR 86.35, 95% CI 57.11-130.56; P<.001) and skin darkening (OR 358.55, 95% CI 244.79-525.16; P<.001) showed significant associations (all P<.001).

Conclusions: This study highlights the differences in how patients perceive and report infection-related symptoms between populations with acute and chronic wounds. Lower diagnostic accuracy for acute wounds underscores the influence of limited experience and contextual constraints on patient self-assessment. These findings suggest that patient-facing digital wound

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monitoring systems should be tailored according to wound chronicity and patient experience, incorporating adaptive feedback and artificial intelligence–assisted screening to enhance patient-reported symptom interpretation.

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KEYWORDS

wound infection; patient-reported symptoms; telemedicine; chatbot; diagnostic accuracy; digital health; artificial intelligence; AI

Introduction

Digital health interventions have become increasingly feasible with the widespread availability of smartphones and mobile internet connectivity [1-3]. Among these, remote wound monitoring has emerged as a promising approach for postdischarge care, enabling patients to share wound information with clinicians as a personalized, value-added service that enhances continuity of care [4-8] and may help reduce health care costs [9]. Previous studies have shown that home-based telemedicine—encompassing remote telemonitoring and teleconsultation—can improve clinical outcomes, including reductions in rehospitalization [10] and mortality rates [9,11,12]. Contemporary telemedicine tools, such as email, telephone, video calls, and mobile apps, now facilitate the secure transmission of wound photographs, allowing clinicians to perform remote assessments with confidence and demonstrating diagnostic and therapeutic efficacy comparable to conventional face-to-face wound care in terms of healing rate and safety [13].

Beyond photographic information, patient-reported symptoms (PRSs) provide complementary insights into patients' subjective perceptions of wound changes [14,15]. PRSs and outcome measures are increasingly recognized in wound care as valuable tools that capture patients' subjective experiences and perceived health status and can support earlier recognition of complications [13,16,17]. Previous studies have demonstrated that PRSs combined with remote wound monitoring can enhance patient-clinician communication and enable more timely intervention, thereby potentially reducing delays in complication detection [5,6,18]. However, most of this work has focused on using PRSs and wound photographs to assist clinician evaluation in remote care. In practice, accurate patient recognition of clinically significant wound changes can reduce unnecessary clinic visits and enable timely intervention [5,7,19], whereas poor accuracy may delay care or generate unnecessary anxiety [20-22].

Building on these previous findings, we developed and implemented a chatbot-based digital wound-monitoring platform that integrates PRS collection with wound photography through the widely used Line messaging app in Taiwan [23]. The system was designed to support continuous postdischarge follow-up and examine how patients perceive wound changes and how these perceptions align with or differ from physicians' assessments. Understanding this perceptual gap represents a critical step toward advancing patient-centered digital wound care.

Accordingly, this study aimed to (1) evaluate the diagnostic performance of patient-reported infection in predicting physician-initiated callbacks and (2) identify which observable wound characteristics (eg, redness and skin darkening) are most strongly associated with patients' self-assessments. By characterizing both concordance and discordance between patient and clinician perspectives, this research seeks to inform the design and development of more effective, patient-centered models for digital wound care.

Methods

Study Design and Participants

This retrospective observational study was conducted at a tertiary medical center in Taipei, Taiwan, between June 30, 2022, and March 1, 2023. It was nested within a broader institutional digital health initiative launched in 2020 during the COVID-19 pandemic to maintain continuity of care through remote monitoring programs implemented across multiple medical subspecialties. Within the institutional wound care program, adults with acute or chronic wounds were enrolled and followed longitudinally through a chatbot-based digital wound-monitoring platform. Participants voluntarily joined the mobile health program using a bring-your-own-device model and provided complete follow-up data during the study period. Each day, participants submitted symptom reports and wound photographs via the chatbot interface. For each image submission, the patient's self-reported presence or absence of infection served as the primary predictor variable, while the reference standard was established through an independent review by a senior plastic surgeon with more than 20 years of experience, who classified each case as requiring a callback (follow-up contact) or no callback.

The overall study workflow is illustrated in Figure 1. The primary analysis evaluated diagnostic accuracy metrics—area under the receiver operating characteristic curve (AUC), sensitivity, and specificity—comparing patient-reported infection with physician-determined callback status. In the secondary analysis, we explored how patients formed subjective judgments of infection by examining coreported symptom descriptors (eg, redness and skin darkening). Because acute and chronic wounds differ inherently in clinical course, symptom dynamics, and expected follow-up duration, they were analyzed as 2 distinct cohorts to account for potential differences in how patients perceive and report infection-related changes. Logistic regression models estimated odds ratios (ORs) for these symptom features associated with the self-reported infection label.

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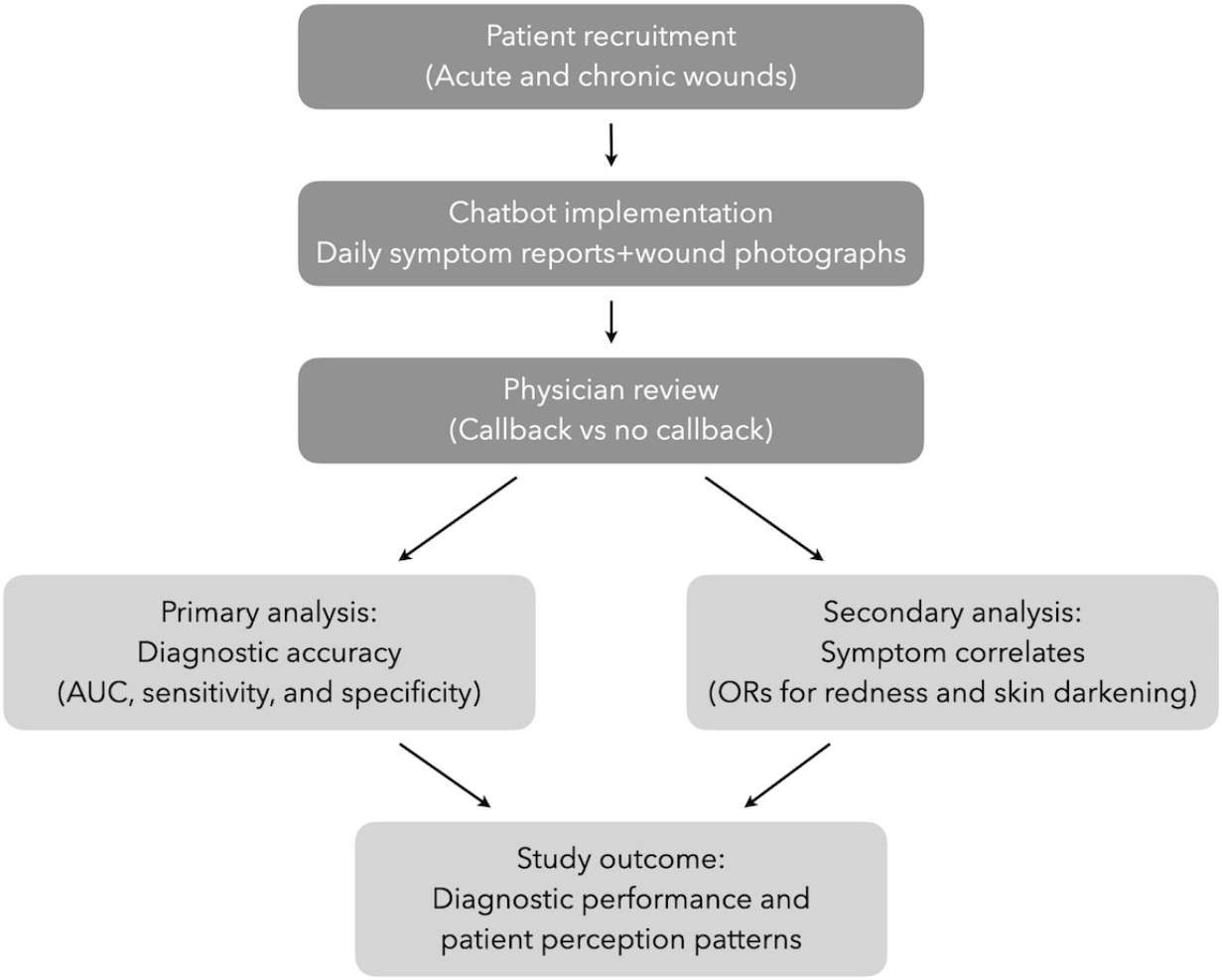
Figure 1. Schematic representation of the study workflow. Patients with acute or chronic wounds were recruited and submitted daily symptom reports and photographs through the chatbot. Physicians subsequently reviewed the data and determined the need for a callback. Primary analyses focused on diagnostic accuracy and secondary analyses examined symptom correlates. AUC: area under the receiver operating characteristic curve; OR: odds ratio.



Patient-Facing Chatbot Design and Implementation

The patient-facing chatbot evaluated in this study was developed as part of the institutional digital health program to support remote wound monitoring and patient self-management. It was designed to enhance postdischarge engagement and facilitate early identification of wound complications through structured symptom reporting and image submission. The development of the chatbot followed a structured, multiphase process grounded in previous literature and expert consensus. First, the chatbot's architecture and user interactions were developed through an evidence-informed design approach, referencing previous studies on wound care telemonitoring and digital adherence interventions [1,6,24,25]. These studies guided the refinement of message tone, literacy level, and interaction flow to improve comprehension and adherence in remote wound self-monitoring.

Second, an initial prototype was constructed based on the hospital's existing wound care discharge instructions and supplemented by patient-education materials and discharge guidance documents from other tertiary medical centers in Taiwan. Third, expert consultations were held with a senior plastic surgeon, 2 wound care nurse practitioners, and a digital health usability specialist. These experts reviewed the chatbot's structure, clinical terminology, and message sequencing through several iterative sessions. Refinements emphasized clarity, consistency with institutional wound care guidance, and user-friendliness for patients with limited digital literacy.

The chatbot interface was implemented through the Line messaging app. Patients accessed the chatbot by scanning a QR code provided at hospital discharge, which led to in-app registration. Once enrolled, participants received 1 automated message per day prompting them to report wound status and upload photographs. Multimedia Appendix 1 provides a representative chatbot-patient conversation flow, illustrating how patients reported wound status and submitted photographs through the Line messaging app interface.

Before full implementation, a 10-patient pilot test was conducted to assess readability, usability, and response compliance [26]. On the basis of feedback, message content was simplified, and the daily symptom reporting options were refined into 3 categories: *normal*, *redness*, and *infection*. This design aimed to balance clinical informativeness with ease of patient interpretation.

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Submitted reports and images were automatically stored within a secure cloud database (Amazon Web Services) and reviewed by the wound care team as part of routine remote monitoring. Feedback was provided only when image quality allowed adequate clinical evaluation or when reported symptoms suggested possible deterioration. If wound progression or complications were suspected, the clinical team initiated contact for further evaluation or follow-up scheduling. All chatbot interactions were logged within the broader institutional digital health evaluation program to ensure compliance with data protection and usability standards.

Data Collection

Patients were recruited from the plastic surgery outpatient clinics and the emergency department at a tertiary care center in Taipei, Taiwan. Eligible patients were introduced to the digital wound monitoring program during their initial clinical visits. Physicians explained the purpose and procedures of the chatbot-based system and invited patients to participate. Enrollment was voluntary and based on convenience sampling. Inclusion criteria were as follows: (1) being aged 18 years or older, (2) having a diagnosis of an acute or chronic wound, and (3) being able to use a smartphone and the Line messaging app. Exclusion criteria were as follows: (1) having an immediate need for surgical revision, (2) declining participation in the digital wound-monitoring program, and (3) having insufficient digital literacy or limited access to a compatible smartphone or stable internet connection.

Once enrolled, participants were followed through a secure mobile chatbot platform that supported asynchronous wound symptom reporting. Patients were instructed to submit daily symptom checklists and wound photographs. Each data entry was time-stamped and linked to a unique patient identifier. The wound care team accessed these inputs via a clinician dashboard, where photo quality was assessed, and clinical decisions regarding follow-up were recorded. All data used in this study were extracted retrospectively from the system database after the study period.

Statistical Analysis

All data were deidentified before statistical analysis. Age and follow-up duration were treated as continuous variables, while all other covariates were treated as categorical.

For the primary analysis, we evaluated the diagnostic accuracy of patient-reported infection in predicting the need for callback, as determined by the wound care physician. ORs, sensitivity, specificity, and AUC were calculated using physician-determined callback as the reference standard.

For the secondary analysis, we examined the internal consistency of patient-reported infection by evaluating whether these self-reports were systematically associated with coreported symptom descriptors (eg, redness and skin darkening) across repeated submissions. Each photo level PRS entry was dichotomized as *infection* or *no infection*, and regression models were used to estimate the strength of these associations. Consistent relations across time would indicate that patients applied a stable internal criterion when identifying infection, whereas the absence of such patterns would suggest inconsistency in self-assessment. We used generalized estimating equations (GEEs) to account for the clustering of multiple photograph submissions per patient, which would otherwise violate the independence assumption of standard regression models. This approach accounted for the within-subject correlation in repeated submissions and yielded variance-adjusted SE estimates and approximately valid CIs under the assumed correlation structure. Given the convenience sampling design, available demographic and clinical covariates—age, sex, and wound type (acute vs chronic)—were included in all models to mitigate potential confounding. GEE models were used in both primary and secondary analyses. However, other potentially influential factors, such as comorbidity burden, wound etiology, and patients' digital literacy, were not systematically collected in the retrospective dataset and could therefore not be adjusted for.

All analyses were conducted using SAS (version 9.4; SAS Institute Inc) for Windows. A 2-tailed P value of <.05 was considered statistically significant.

Ethical Considerations

This study was approved by the institutional review board of the Shin Kong WHS Memorial Hospital, Taipei, Taiwan (approval 20211001R). The requirement for written informed consent was waived because of the retrospective study design involving previously collected clinical photographs. All data were anonymized before analysis, and confidentiality was maintained throughout the study. All images and multimedia materials included in the manuscript have been carefully reviewed and deidentified before publication. No financial or material compensation was provided to participants.

Results

Overview

A total of 159 patients were included in the final analysis, of whom 88 (55.3%) were classified as acute wound cases. On average, the patients were aged 45.6 (SD 1.25) years. Throughout the study period, 4764 wound photographs were submitted through the mobile digital health platform, with a median of 5 (IQR 2-18) photographs per patient. Among these, patients reported suspected infection in 1352 (28.4%) instances, redness in 1542 (32.4%) instances, and skin darkening in 1040 (21.8%) instances. The detailed demographics are summarized in Table 1.

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Table 1. Baseline characteristics of patients and wound photographs.[a]

Patient characteristics	Overall (N=159)	Acute wound (n=88)	Chronic wound (n=71)
Age (y), mean (SD)	45.6 (1.25)	35.5 (1.14)	58.0 (2.21)
Sex: male, n (%)	94 (59.1)	56 (63.6)	38 (53.5)
Total photos uploaded, n	4764	559	4205
Uploaded photos per patient, mean (SD)	30.0 (7.16)	6.4 (0.89)	59.2 (15.48)
Patient reported suspected infection, n (%)	1352 (28.4)[b]	76 (13.6)[c]	1276 (30.3)[d]
Redness, n (%)	1542 (32.4)[b]	252 (45.1)[c]	1290 (30.7)[d]
Skin darkening, n (%)	1040 (21.8)[b]	129 (23.1)[c]	911 (21.7)[d]
Callbacks, n (%)	886 (18.6)[b]	19 (3.4)[c]	867 (20.6)[d]

[a]Values are presented as mean (standard deviation, SD) for continuous variables and n (%) for categorical or photograph-level variables.

[b]n=4764.

[c]n=559.

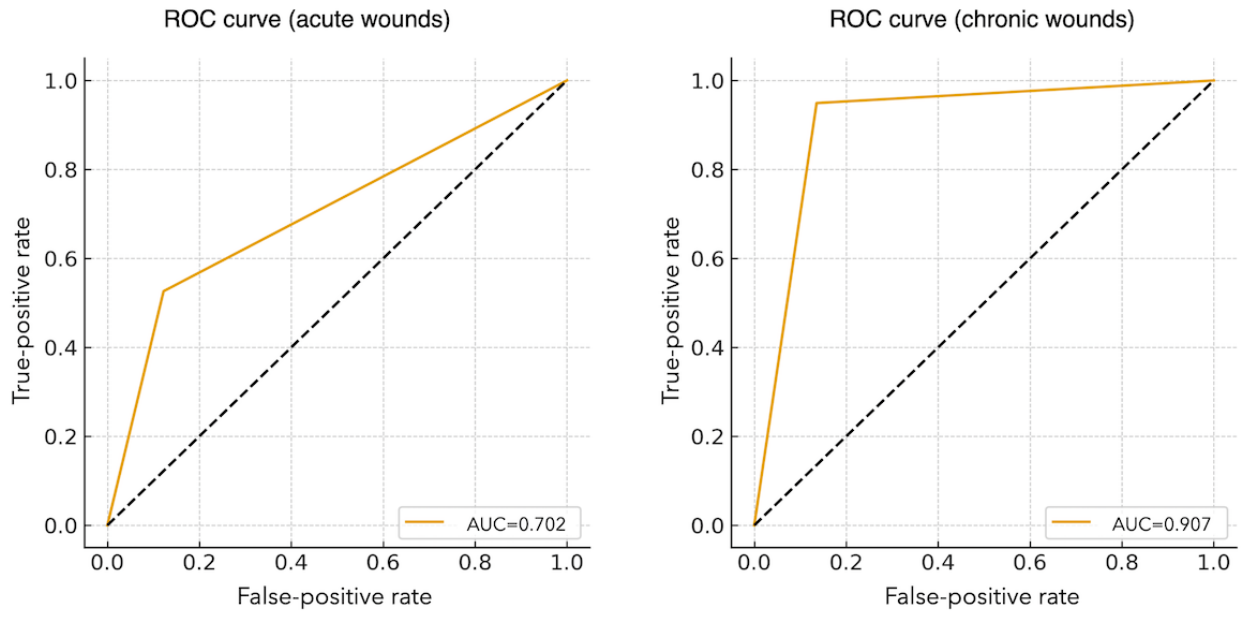
[d]n=4205.

Primary Analysis: Diagnostic Performance of PRS-Reported Infection for Predicting Callbacks

A total of 1352 wound images were marked by patients as showing infection in the symptom checklist. Among these, 886 (65.5%) images were also classified as requiring callback by the reference physician reviewer and were used to evaluate diagnostic performance. Overall, patient-reported infection demonstrated strong diagnostic accuracy for predicting physician-initiated callbacks, with an overall sensitivity of 94% (95% CI 92.3-95.4) across all cases.

When stratified by wound type, diagnostic performance differed markedly between the 2 cohorts (Figure 2). For acute wounds, the AUC was 0.702, corresponding to a sensitivity of 52.6% (95% CI 31.7-72.7) and a specificity of 87.8% (95% CI 84.7-90.3). This indicated only modest accuracy of patient self-assessment in acute wound contexts. The positive predictive value (precision) for the acute wound group was comparatively low, indicating a higher proportion of false-positive results. The wide CIs observed for this subgroup further reflected its small sample size and low callback rate; therefore, the results should be interpreted with caution. In contrast, chronic wounds demonstrated substantially higher diagnostic performance, with an AUC of 0.907, sensitivity of 94.9% (95% CI 93.3-96.2), and specificity of 86.4% (95% CI 85.2-87.5). The receiver operating characteristic curve for chronic wounds exhibited a steeper initial rise, reflecting a higher true-positive rate at lower false-positive thresholds and greater alignment between patient-assessed and physician-assessed infections.

Figure 2. Diagnostic accuracy of patient-reported infection for predicting physician-initiated callbacks among acute and chronic wound patients. Receiver operating characteristic (ROC) analysis shows reduced discriminative performance, with an area under the curve (AUC) of 0.702 for acute wounds and 0.907 for chronic wounds.



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To account for repeated photo submissions per patient, we fitted a multivariable GEE model as an exploratory analysis (Table 2). After adjusting for age, sex, and wound type (acute vs. chronic), PRS-reported infection remained a statistically significant predictor of callback (adjusted OR 113.65, 95% CI 24.44-528.48; *P*<.001). However, the wide CIs reflected the limited sample size and potential instability of the estimates. For comparison, a conventional logistic regression model without GEE adjustment yielded narrower CIs but may underestimate variance by ignoring intrapatient correlation. The non-GEE results are provided in Table S1 in Multimedia Appendix 2.

Table 2. Multivariable generalized estimating equation estimates for predicting physician-initiated callback.

Variable	Adjusted odds ratio (95% CI)	*P* value
Patient-reported symptom–reported infection	113.65 (24.44-528.48)	<.001
Age (y)	1.06 (1.03-1.09)	<.001
Sex: male	0.99 (0.20-5.04)	.99
Wound type: acute	0.26 (0.07-0.98)	.047

Secondary Analysis: Symptom Correlates of Patient-Reported Infection

To examine the internal consistency of patient-reported infection assessments, we analyzed whether the selection of infection was associated with other simultaneously reported symptom features in each wound subgroup (Table 3). In the acute wound cohort, redness was significantly associated with patient-reported infection (OR 3.94, 95% CI 1.97-7.90; *P*<.001), indicating that patients who noted redness were nearly 4 times more likely to label their wounds as infected. Other features, including skin darkening (OR 0.42, 95% CI 0.10-1.79), age (OR 1.01, 95% CI 0.99-1.04), and sex (OR 0.73, 95% CI 0.33-1.59), were not significantly associated with infection reporting.

In contrast, in the chronic wound cohort, both redness (OR 86.35, 95% CI 57.11-130.56; *P*<.001) and skin darkening (OR 358.55, 95% CI 244.79-525.16; *P*<.001) were strongly associated with infection reports (all *P*<.001), whereas age (OR 1.03, 95% CI 1.02-1.03; *P*=.01) and male sex (OR 1.53, 95% CI 1.10-2.13; *P*=.01) also showed modest but significant associations (all *P*=.01). These findings suggested that patients with chronic wounds demonstrated more consistent symptom-infection linkages, particularly between wound color changes and perceived infection.

Table 3. Odds ratios (ORs) for symptom correlates of patient-reported infection.

Effect	Acute wound, OR (95% CI)	Chronic wound, OR (95% CI)
Redness	3.94 (1.97-7.90)	86.346 (57.11-130.56)
Skin darkening	0.42 (0.10-1.79)	358.548 (244.79-525.16)
Age	1.01 (0.99-1.04)	1.025 (1.02-1.03)
Sex: male	0.73 (0.33-1.59)	1.534 (1.10-2.13)

Discussion

Overview

This study evaluated a chatbot-facilitated PRS system for remote wound monitoring and identified distinct diagnostic performance patterns between populations with acute and chronic wounds. The subsequent sections discuss these subgroup differences, underlying mechanisms of diagnostic discordance, and their implications for digital integration in real-world wound care.

Early Identification Through Patient Self-Assessment

Patient-reported infection demonstrated meaningful clinical utility for supporting remote triage; however, its diagnostic performance varied notably between wound types. In the chronic wound cohort, sensitivity was high, and patient assessments were largely concordant with clinician callback decisions, whereas in the acute wound cohort, sensitivity was lower (52.6%) and agreement with clinician judgment was less consistent. These differences underscore that the reliability of patient-reported assessments is strongly influenced by wound chronicity and patient familiarity with symptom trajectories.

In the acute wound subgroup, infection reporting was primarily driven by overt visual cues, such as redness. This suggests that patients with acute wounds can recognize obvious inflammatory changes but may overlook or misinterpret subtler alterations, leading to variability in self-assessment. Their limited experience and lack of reference points—typical of postsurgical or trauma contexts—may constrain their ability to differentiate normal healing responses from early infection [21,27]. The lower precision and wider CIs observed in this subgroup are also likely attributable to the smaller sample size and lower callback event rate, which limit the statistical stability of performance estimates. Therefore, findings from the acute wound subgroup should be interpreted with caution, and future studies with larger cohorts are needed to validate these preliminary observations.

By contrast, the chronic wound cohort demonstrated stronger alignment between patient-reported infection and clinician callback decisions. Patients with chronic wounds appeared to recognize a broader spectrum of wound color changes as potential infection indicators, suggesting the development of experiential knowledge through long-term wound observation

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[14,20,27]. Taken together, these subgroup differences underscore that PRS-based surveillance tools should be context aware and dynamically adapted to different user populations and clinical environments.

Discrepancies and Possible Explanations for Diagnostic Discordance

Diagnostic discrepancies between patient-assessed and clinician-assessed infection were evident across wound types and provided insight into the behavioral mechanisms underlying differences in diagnostic precision. In the acute wound cohort, patient self-assessment showed only modest sensitivity and low precision (positive predictive value), reflecting a tendency toward false-positive reporting. Patients in this group often interpreted normal postoperative inflammation—such as transient redness or mild swelling—as signs of infection, likely due to limited experience and heightened vigilance immediately after injury or surgery [21,27,28]. These perceptual and emotional factors may help explain why patients with acute wounds frequently overreported infection despite the absence of clinician-confirmed pathology [18,20].

By contrast, the chronic wound cohort demonstrated high sensitivity and more balanced specificity, indicating strong alignment between patient and clinician assessments. Patients with chronic wounds appeared to interpret visual cues, such as redness and discoloration, in a more calibrated manner, likely reflecting experiential learning from long-term self-observation and repeated feedback [20,27]. This familiarity may enable them to better distinguish stable wound conditions from early signs of deterioration.

Beyond these behavioral differences, several factors may further contribute to the observed diagnostic discordance. First, limited symptom literacy could represent a key underlying contributor; patients without medical knowledge may misinterpret normal inflammatory changes or fail to recognize early indicators of infection, a challenge commonly noted in previous self-monitoring research [4,21,27]. Second, patients often assess wounds predominantly through visual inspection, without access to tactile or contextual cues that typically inform clinical reasoning [25,28]. Third, home-based assessments are likely influenced by practical constraints such as poor lighting, rushed circumstances, or inconsistent photographic quality—which may introduce additional variability [18,22,25]. Finally, previous illness experience and emotional state appear to influence how patients interpret wound changes; individuals without a history of complications tend to underreport symptoms, whereas those who are anxious about infection may overreport, potentially contributing to both false-negative and false-positive results [3,20,27].

Collectively, these findings extend previous research on digital wound monitoring, which has largely focused on chronic wound populations [13,29] and has paid limited attention to how perceptual or interpretive processes may differ across care contexts [22,28]. Our results suggest that such differences become particularly salient in acute wound settings, where patients encounter distinct cognitive and contextual challenges when interpreting wound changes. These findings underscore the importance of contextualizing PRS systems according to wound chronicity and patients' experience.

Clinical Implications and Future Directions

This study supports the integration of chatbot-facilitated PRS systems into routine wound care as a scalable strategy for extending surveillance beyond traditional clinical settings. The high sensitivity observed suggests strong potential clinical utility as a triage tool, particularly for patients with chronic wounds requiring ongoing monitoring. However, the lower accuracy observed in acute wounds highlights the need for tailored approaches—such as real-time image quality checks [25] or artificial intelligence (AI)–assisted design [18]—to improve performance in contexts where subjective interpretation may be less reliable.

Although some may have questioned the necessity of PRSs when image-based AI tools are available, the 2 modalities serve complementary rather than redundant roles. PRSs capture subjective and longitudinal information—such as pain, odor, drainage, and daily symptom changes—that images alone cannot provide. When combined with automated image analysis, PRSs can enhance contextual understanding, flag discrepancies between visual and symptomatic cues, and facilitate earlier patient engagement. Because chatbot-based PRS collection incurs minimal marginal cost once deployed [1,9], the potential to prevent infection-related revisits may offset additional resource requirements [8,19]. Future studies should formally evaluate the economic impact and optimal integration of PRSs with image-based AI systems.

Limitations

Several limitations must be acknowledged. First, the use of convenience sampling may limit generalizability, as participants with greater digital literacy were more likely to enroll. Second, the statistical approach also warrants caution. Given the small sample size and correlated structure of repeated submissions, the GEE model should be interpreted cautiously [30]. Although a non-GEE logistic regression yielded more stable CIs, it could not account for within-patient clustering. Therefore, we retained the GEE model as the primary analysis but emphasized its exploratory nature when interpreting the results.

Third, all callback decisions were made by a single senior plastic surgeon reviewing the chatbot dashboard. Although this ensured consistency, it may also introduce interpretive bias and limit the generalizability of our comparator standard. Additionally, reliance on patient-captured photographs introduces variability in image quality that could affect both patient and clinician assessments [25,28]. Fourth, participants received standard printed wound care education materials outlining routine care procedures and warning signs but did not receive any instruction that defined or exemplified redness or skin darkening. No photographic exemplars or audiovisual materials were provided, which may have influenced secondary analyses that depend on patient interpretation of wound color changes. This lack of targeted symptom education may have affected how patients interpreted visual changes and contributed to variability in self-reported infection assessments [20]. Future work should evaluate whether integrating structured visual

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education—through images, short videos, or in-app microlearning modules—can improve the consistency and accuracy of patient-reported data.

Fifth, we were unable to adjust for additional potential confounders, such as health literacy, app use patterns, comorbidities, wound severity, or physician workload, as these were not systematically collected. We also did not systematically measure participants' digital literacy, internet access, or previous experience with social messaging apps, which may have influenced engagement. Observations during recruitment suggest these factors could play a role, but this hypothesis requires formal evaluation in future studies. Finally, subgroup analyses, such as the acute wound cohort, were based on fewer photographs per patient, which may explain the lower AUC observed in this subgroup relative to the overall sample. Moreover, although this study evaluated the diagnostic alignment between patient reports and clinician decisions, it did not assess patient-centered outcomes, such as healing time, complication rates, or patient satisfaction. These outcomes should be addressed in future longitudinal studies. Incorporating qualitative feedback and equity-focused evaluations will also be essential for optimizing system design and ensuring broader applicability.

Conclusions

This study demonstrates the feasibility and clinical value of a chatbot-facilitated PRS system for remote wound monitoring. PRS-based assessments, when contextualized by wound type, can meaningfully reflect clinical conditions and support early identification of cases requiring follow-up. Although patients with chronic wounds showed high diagnostic concordance with clinician evaluations, patients with acute wounds displayed greater variability, underscoring the importance of tailoring digital surveillance tools to different care contexts. These findings highlight the complementary role of PRSs alongside image-based analysis in enhancing diagnostic consistency and patient engagement. Future work should focus on integrating adaptive educational modules and hybrid PRS-AI models to improve accuracy, efficiency, and scalability in real-world wound care.

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The authors confirm that generative artificial intelligence tools (eg, ChatGPT [version 5; OpenAI]) were used solely for language polishing after full manuscript drafting by the authors. All intellectual content, analyses, and interpretations are author generated.

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Data Availability

The datasets generated and/or analyzed during this study are not publicly available due to patient privacy and institutional restrictions but are available from the corresponding author on reasonable request. The full image dataset cannot be made publicly available to protect participant privacy. Deidentified data underlying the study findings may be made available from the corresponding author on reasonable request and with appropriate institutional and ethical approval.

Authors' Contributions

YCS contributed to the study methodology, data analysis, statistical modeling, and drafting of the Results and Discussion sections. YHL was responsible for clinical implementation design and execution, ensuring research and procedural quality, and providing clinical feedback to guide practical application. MYH, as the corresponding author, oversaw the overall study design and supervision, software and digital system development, postimplementation monitoring, data interpretation, and manuscript writing and revision. All authors reviewed and approved the final version of the manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Video walkthrough of patient-reported symptom entry via chatbot.
[MP4 File (MP4 Video), 16720 KB - formative_v10i1e77685_app1.mp4]

Multimedia Appendix 2
Comparison of logistic regression results without generalized estimating equation adjustment for repeated observations.
[DOCX File , 7 KB - formative_v10i1e77685_app2.docx]

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Abbreviations

AI: artificial intelligence
AUC: area under the receiver operating characteristic curve
GEE: generalized estimating equation
OR: odds ratio
PRS: patient-reported symptom

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Original Paper

Early Prediction of Cardiac Arrest Based on Time-Series Vital Signs Using Deep Learning: Retrospective Study

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Abstract

Background: Cardiac arrest (CA), characterized by an extremely high mortality rate, remains one of the most pressing global public health challenges. It not only causes a substantial strain on health care systems but also severely impacts individual health outcomes. Clinical evidence demonstrates that early identification of CA significantly reduced the mortality rate. However, the developed CA prediction models exhibit limitations such as low sensitivity and high false alarm rates. Moreover, issues with model generalization remain insufficiently addressed.

Objective: The aim of this study was to develop a real-time prediction method based on clinical vital signs, using patient vital sign data from the past 2 hours to predict whether CA would occur within the next 1 hour at 5-minute intervals, thereby enabling timely and accurate prediction of CA events. Additionally, the eICU-CRD dataset was used for external validation to assess the model's generalization capability.

Methods: We reviewed and analyzed 4063 patients from the MIMIC-III waveform database, extracting 6 features to develop a deep learning–based CA prediction model named TrGRU. To further enhance performance, statistical features based on a sliding window were also constructed. The TrGRU model was developed using a combination of transformer and gated recurrent unit architectures. The primary evaluation metrics for the model included accuracy, sensitivity, area under the receiver operating characteristic curve (AUROC), and area under the precision-recall curve (AUPRC), with generalization capability validated using the eICU-CRD dataset.

Results: The proposed model yielded an accuracy of 0.904, sensitivity of 0.859, AUROC of 0.957, and AUPRC of 0.949. The results showed that the predictive performance of TrGRU was superior to that of the models reported in previous studies. External validation using the eICU-CRD achieved a sensitivity of 0.813, an AUROC of 0.920, and an AUPRC of 0.848, indicating excellent generalization capability.

Conclusions: The proposed model demonstrates high sensitivity and a low false-alarm rate, enabling clinical health care providers to predict CA events in a more timely and accurate manner. The adopted meta-learning approach effectively enhances the model's generalization capability, showcasing its promising clinical application.

(JMIR Form Res 2026;10:e78484) doi:10.2196/78484

KEYWORDS

cardiac arrest; prediction; electric medical record; vital signs; deep learning

Introduction

Cardiac arrest (CA) is characterized by the abrupt cessation of the heart's blood-pumping function, marked by the absence of major arterial pulsations and heart sounds. This leads to severe ischemia and hypoxia in vital organs (eg, the brain), ultimately culminating in death. The most common cause of CA is ventricular fibrillation [1]. In the United States, there are

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approximately 209,000 cases of in-hospital CA each year, and the global survival rate is less than 25%. Previous studies have demonstrated that early recognition of CA can improve the survival rate within the first hour by approximately 29% and before hospital discharge by 19% [2]. Therefore, it is essential to develop a model that can reliably predict the occurrence of CA events.

In clinical practice, traditional assessment methods based on scoring, such as the Simplified Acute Physiology Score II, Sequential Organ Failure Assessment, and Modified Early Warning Score, have long served as crucial reference tools for clinicians to identify the risk of clinical deterioration and initiate timely interventions [3-5]. However, such scoring systems generally suffer from the dual limitations of low sensitivity and high false alarm rates. In recent years, machine learning has been applied extensively in health care data analysis, showing significantly better predictive performance than traditional scoring systems. Nevertheless, machine learning still faces challenges in analyzing high-dimensional and complex time-series data, which makes these approaches inadequate to meet the demands of current clinical practice.

Kim et al [6] developed a CA prediction model using the TabNet classifier to predict CA events. Their model achieved an area under the receiver operating characteristic curve (AUROC) of 0.79 on the MIMIC-IV dataset. Wu et al [7] developed a CA prediction model using extreme gradient boosting (XGBoost) based on 20 variables, including vital signs, laboratory results, and electrocardiogram reports. The model accuracy was 0.889, and the AUROC was 0.958. Similarly, Yijing et al [8] extracted vital sign data from the MIMIC-III database and used XGBoost to develop a model that achieved an accuracy of 0.96 and an AUROC of 0.94. An early warning model based on a recurrent neural network was proposed by Kwon et al [9], which yielded an area under the precision-recall curve (AUPRC) of 0.04 and an AUROC of 0.85.

Current methods based on deep learning and machine learning have demonstrated good performance in predicting CA events. However, they still suffer from low sensitivity and high false alarm rates as well as the inability to make real-time predictions. In particular, the method proposed by Lee et al [10] exhibited significant performance fluctuations when predicting CA events within 24 hours, a limitation that has also been demonstrated in previous studies. These shortcomings will lead to a substantial waste of medical resources and an increase in operational costs. As a result, current CA prediction methods face significant challenges in practical applications.

In this study, we propose TrGRU, a deep learning–based model that accurately predicts CA events within an hour using only 6 limited clinical vital signs without relying on patient laboratory test results. Meanwhile, we adopt a meta-learning framework, which significantly improves the adaptability of the model across different datasets and clinical settings [11,12].

Methods

Dataset

In this study, we used 2 databases: the MIMIC-III database [13] and eICU-CRD [14]. The MIMIC-III database, developed by the Massachusetts Institute of Technology Laboratory for Computational Physiology, contains data from 53,432 adult patients and 8100 neonatal patients admitted between 2001 and 2012. The database includes demographic data, vital signs, medications, laboratory measurements, physician orders, procedure codes, diagnosis codes, imaging reports, hospitalization duration, and survival data, among others.

The eICU-CRD is a multicenter intensive care unit (ICU) database that covers data from more than 200,000 ICU admissions across 208 hospitals in the United States between 2014 and 2015. The data were collected through Philips eICU program, which includes vital sign measurements, nursing documentation, severity of illness scores, diagnostic information, treatment details, and more.

We randomly allocated 70% (2844/4063) of the dataset for the training set to develop the model, with10% (406/4063) as the validation set to adjust and determine the hyperparameters of the model, and the remaining 20% (813/4063) as the test set to evaluate the model performance; this portion was not used in the model training.

Ethical Considerations

This study used publicly available critical care databases, including the MIMIC-III and the eICU-CRD. Both databases received institutional review board approval from the hospitals that originally contributed the data, and informed consent was obtained at the time of data collection. All patient records were deidentified in accordance with the Health Insurance Portability and Accountability Act (HIPAA). Access to the databases was granted through the PhysioNet credentialing process. Therefore, according to institutional policies regarding secondary research using publicly deidentified data, additional ethics approval from our institution was not required.

Problem Definition

As shown in Figure 1, let the given set of patients be $P = \{p_1, p_2, ..., p_n\}$ feature vector V_t = [*hr, rr, sbp, dbp, map, spo2*]. V_t represents the vital sign monitoring data of patient p at time point t, including “heart rate” and “systolic blood pressure,” among others. These data were continuously collected during the hospitalization period T, $T = \{t_1, t_2, \ldots, t_j\}$ and $t_i - t_{i-j} = 5$ minutes. Then, represents the multivariate time-series feature vectors of the patient at all time points during hospitalization. Therefore, the CA prediction task can be formally described as follows: given the multivariate time-series feature vector V for patient p in the hospitalization interval T, the goal of the prediction task is, for any time point $t_i \in T$, to use the 24 multivariate time-series feature vectors from the time window (t–24 and t) to predict the probability of a CA event occurring within the time window (t and t+12) using the TrGRU model.

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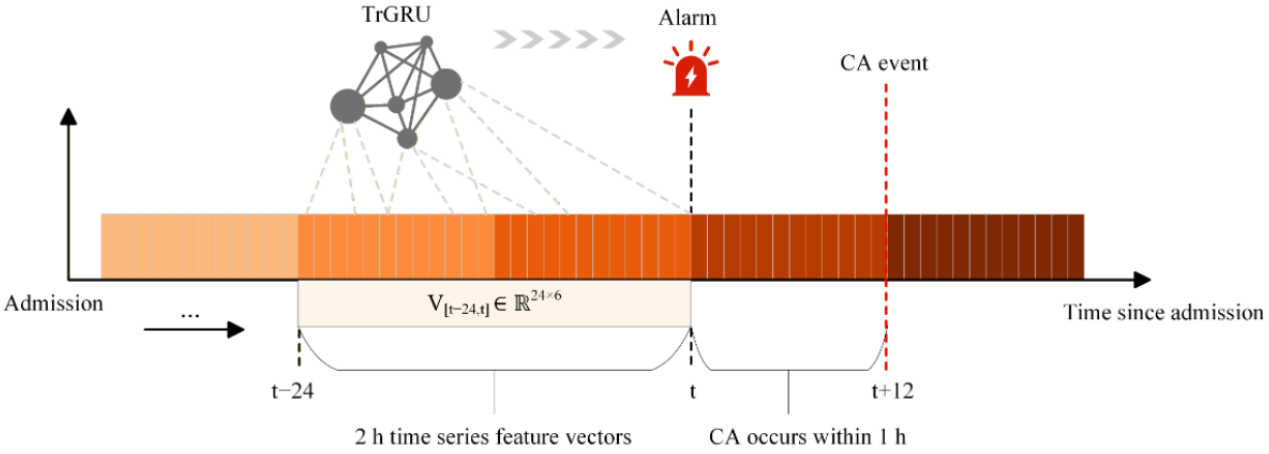
Figure 1. Cardiac arrest (CA) event monitoring process for the proposed TrGRU model.

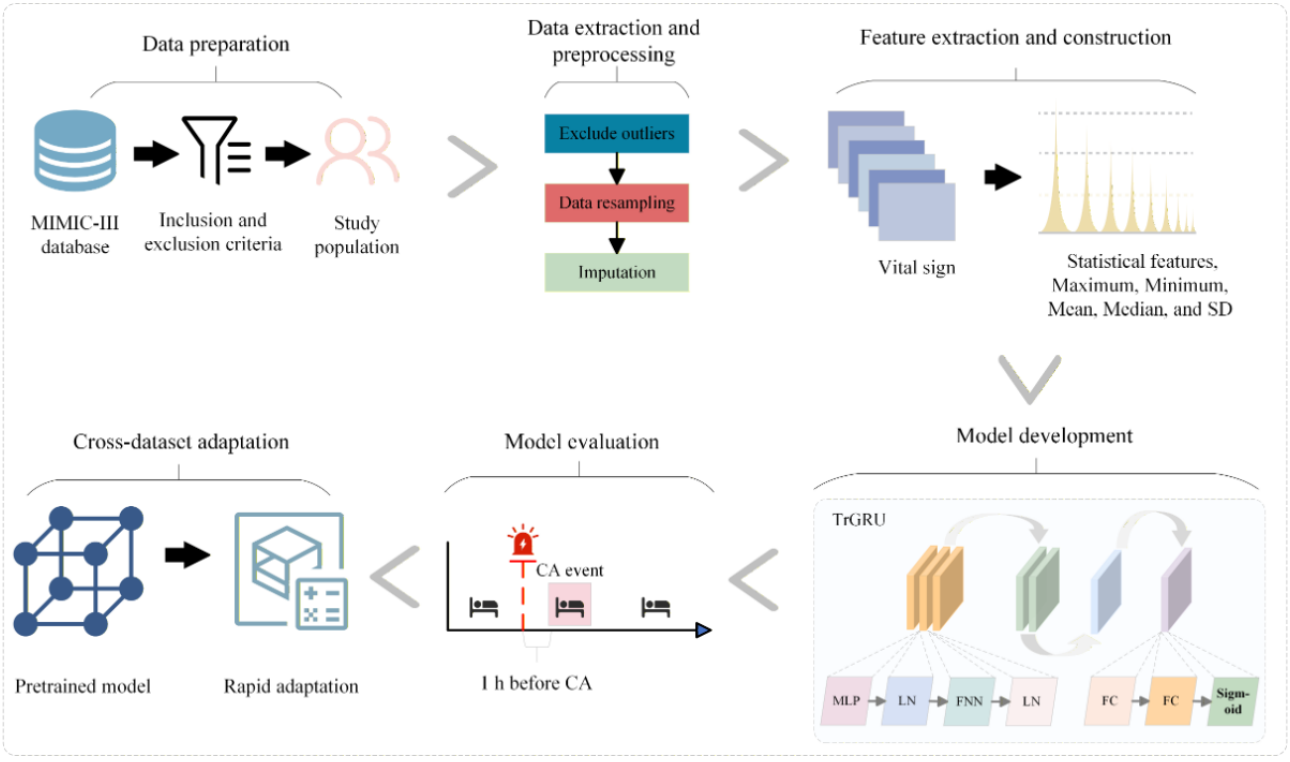


Development Process

Review

As shown in Figure 2, the development process of the TrGRU model consisted of 6 steps: data preparation, data extraction and preprocessing, feature extraction and construction, model development, model evaluation, and cross-dataset adaptation.

Figure 2. Development process of the TrGRU model. The development process of the TrGRU model consists of 6 steps. FC: fully connected layer; FNN: feedforward neural network; LN: layer normalization; MLP: multilayer perceptron.



Data Preparation

We extracted data from the MIMIC-III databases and eICU-CRD to construct a study cohort that met the inclusion and exclusion criteria. The patients in these 2 databases differ. The MIMIC-III database includes patients admitted to the ICU as well as some hospitalized patients not admitted to the ICU, while the eICU-CRD database contains only patients admitted to the ICU. The number of CA events for each patient also varies between the 2 databases. While each patient in the eICU-CRD frequently records several CA events, each patient in the MIMIC-III database typically only records one CA event. To increase the sample size of CA events, we treated multiple CA events experienced by a single patient as independent samples for model development.

A series of criteria were applied during the inclusion and exclusion process of the MIMIC-III database to select the study cohort. As shown in Figure 3, 20,193 patients were included in this study, with 38 (0.19%) patients younger than 16 years and those who experienced CA within 2 hours of admission being excluded. In addition, 11 (0.05%) patients with outliers were

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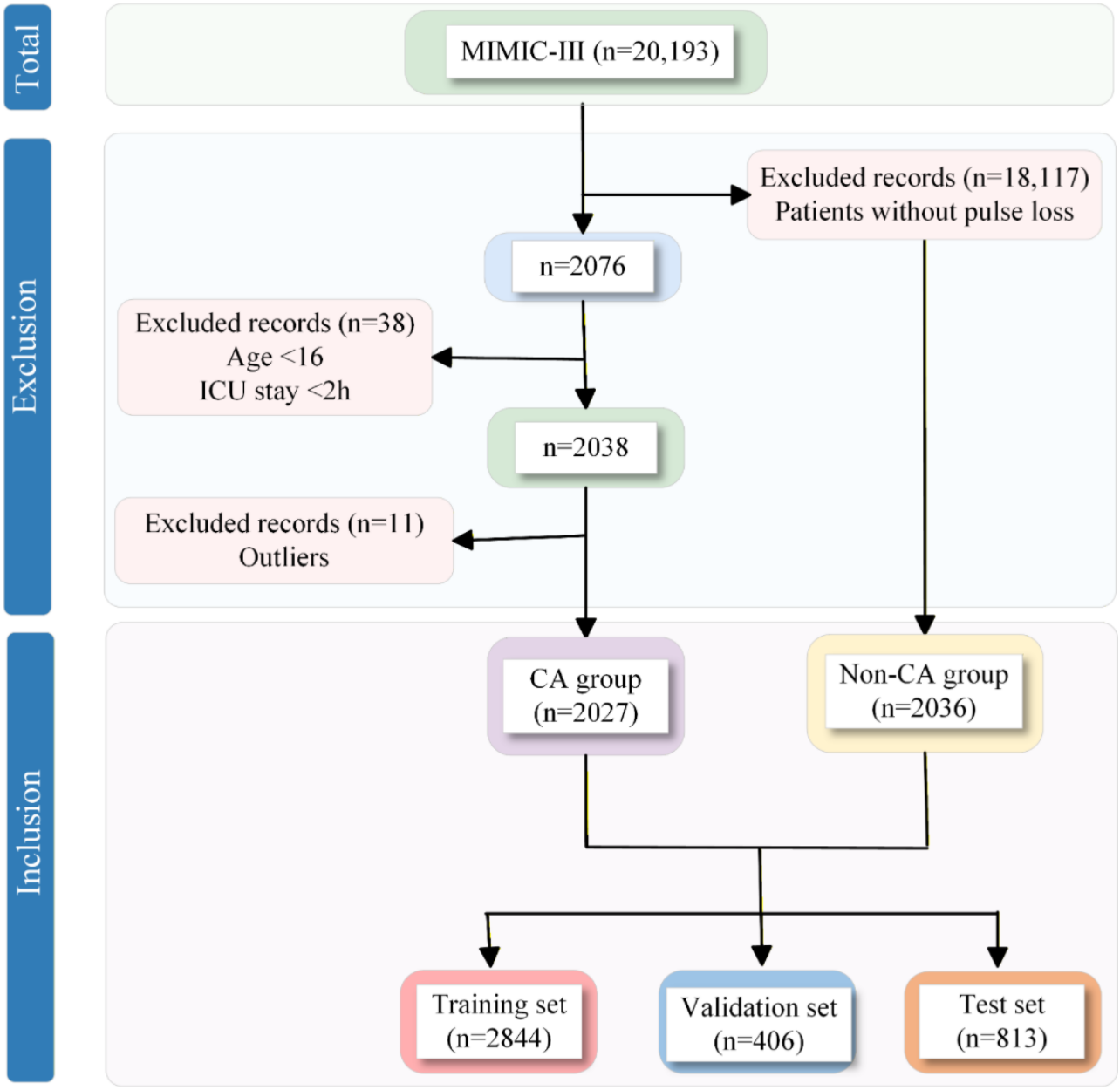
excluded. CA is defined as the loss of a detectable pulse during attempts at resuscitation, and patients in this category were included in the CA group. Patients in the non-CA group were randomly selected from the remaining patients who did not experience a loss of pulse. Ultimately, the study population consisted of 4063 (20.12%) patients, with 2027 (49.89%) in the CA group and 2036 (50.11%) in the non-CA group of whom were not.

The inclusion and exclusion criteria applied to the eICU-CRD were the same as those used for the MIMIC-III database.

Figure 3. Patient inclusion and exclusion flow diagram for the MIMIC-III. CA: cardiac arrest; ICU: intensive care unit.



Data Extraction and Preprocessing

In this study, patient vital sign data were extracted from the MIMIC-III database, including heart rate (HR), respiratory rate, systolic blood pressure, diastolic blood pressure, mean arterial pressure, and oxygen saturation (SpO_2). Due to the potential for data errors caused by equipment malfunction, the acceptable range for each vital sign value was determined based on the advice of medical experts. Data falling outside these ranges were considered outliers and excluded. Subsequently, the vital signs time-series data with a 1-minute sampling frequency were resampled to a 5-minute frequency. For time points without sampled values, these were marked as missing. We used median imputation to handle these missing values [15]. This method fills in missing values by identifying the median of the data, which is less affected by extreme values and thus provides a relatively stable substitute.

Additionally, because each feature is measured on a different scale, we applied minimum-maximum normalization to standardize them. Minimum-maximum normalization is a linear transformation method that maps data values to a fixed range. In this study, the values were scaled to the range (0,1). This process is achieved by scaling the minimum and maximum values of the data, ensuring that the transformed values are independent of the scale and range of the original data.

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Although the number of patients included in the CA and non-CA groups was nearly equal, the samples input into the model were generated using a 2-hour sliding time window, and CA events occurred far less frequently than nonevents; that is, the number of positive samples was substantially lower than that of negative samples, resulting in class imbalance at the window level. Therefore, we mitigated the impact of class imbalance on model training by increasing the number of positive samples through oversampling and reducing the number of negative samples through undersampling.

Feature Extraction and Construction

We used 6 preprocessed vital signs as model features: HR, respiratory rate, systolic blood pressure, diastolic blood pressure, mean arterial pressure, and SpO_2. These vital signs are widely used in clinical practice, and abnormal fluctuations in these measures are associated with the occurrence of CA. Previous studies also demonstrated that models developed based on these vital signs performed well in predicting CA events, making them suitable as model features [16,17].

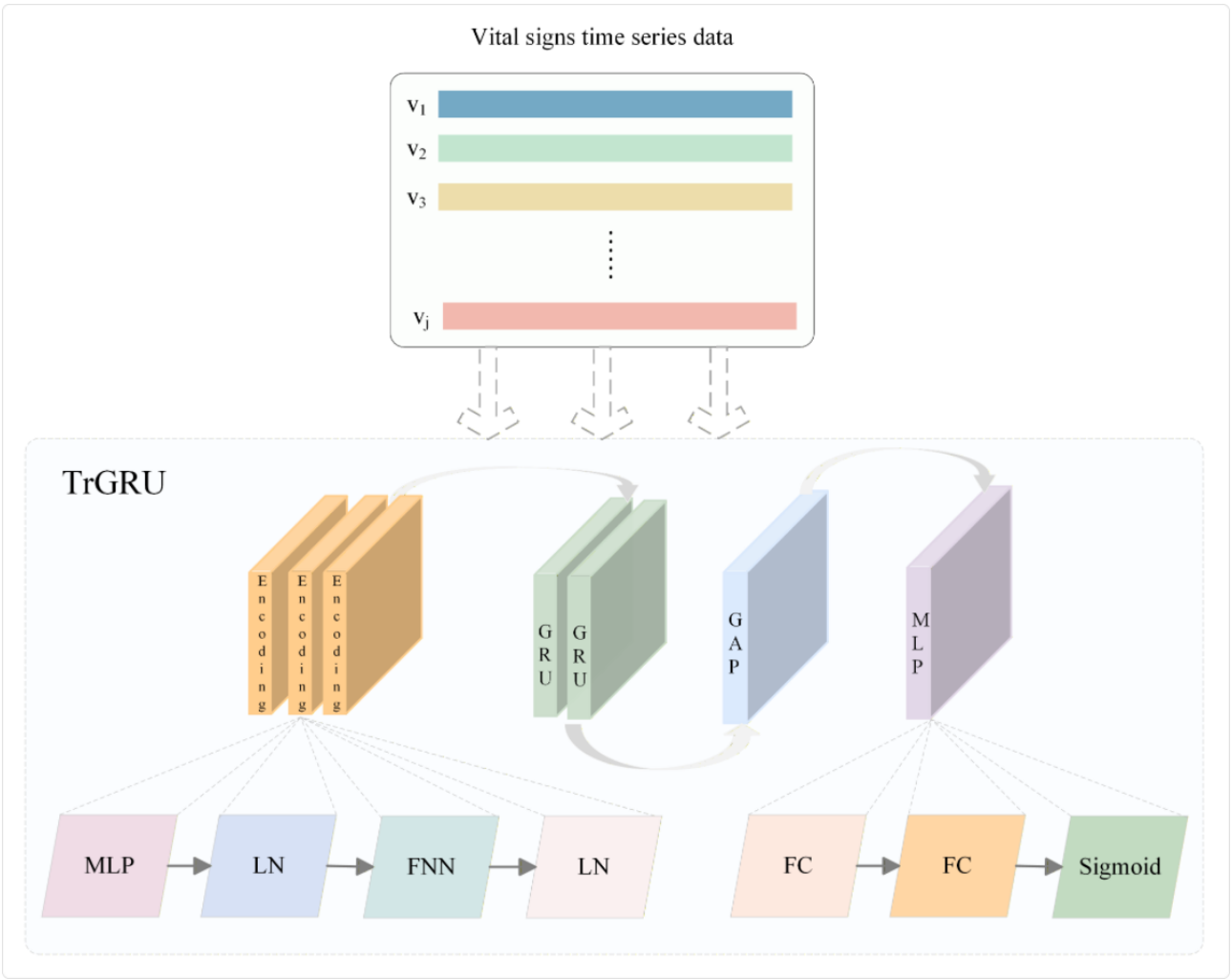
In addition, we also created statistical features based on a sliding window. A fixed-length sliding window of 2 hours was applied, with a 5-minute time step, to segment each vital sign. The mean, median, minimum, maximum, and SD of each feature were then calculated for the time-series segments of the vital sign data within each window.

Model Development

We developed the TrGRU model based on deep learning methods, transformer [18] and gated recurrent unit (GRU) [19], using 2-hour time window vital sign data to predict CA events within the next 1 hour. By inputting the 2-hour data into the model, the risk score for a patient experiencing CA within the next 1 hour was evaluated. When the predicted score exceeded the risk threshold, it indicated a higher likelihood of the patient experiencing CA within 1 hour, and the patient was labeled as an event.

As shown in Figure 4, the TrGRU is a hybrid model that combines a transformer and a GRU, designed to handle time-series data. Typically, the transformer is composed of an encoder and a decoder. In the TrGRU architecture, 3 encoder layers were stacked first, followed by 2 GRU layers. After the GRU layers, global average pooling is applied to compress the dimensionality of the time-series data, which pools the output feature vector of each sequence into a fixed-length vector. The pooled output was further processed by a multilayer perceptron head, in which the decoder was replaced with fully connected layers, as decoding was no longer necessary.

Figure 4. Architecture diagram of the TrGRU model. V1, V2, V3, and Vj are multivariate time-series feature vectors. GAP: global average pooling; GRU: gated recurrent unit; FC: fully connected layer; FNN: feedforward neural network; LN: layer normalization; MLP: multilayer perceptron.



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Model Evaluation

Baseline Models

To evaluate the performance of the proposed model, it was compared with 4 baseline models: random forest, logistic regression, XGBoost, and light gradient boosting method (LGBM).

Evaluation Metrics

We used accuracy, sensitivity, specificity, AUROC, AUPRC, and the false alarm rate to evaluate the performance of the model. AUROC is a metric that measures the performance of a binary classification model across different thresholds. The closer the AUROC value is to 1, the better the classification ability of the model. Sensitivity is also an important performance metric, representing the ability of the model to correctly identify actual positive samples (CA events). Developing a highly sensitive model is essential for the CA prediction task because a model with low sensitivity may miss CA events, which could lead to severe consequences for patients. Therefore, the goal of this study was to develop a prediction model with high sensitivity and a low false alarm rate. The false alarm rate is defined as the proportion of incorrectly detected CA events among all alarms. The calculation of the false alarm rate is as follows:

$$FAR = 1 - (N_{True}/N_{All})$$

where FAR is the false alarm rate, N_{True} is the number of correct alarms, and N_{All} is the total number of alarms.

Cross-Dataset Adaptation

We used meta-learning combined with fast adaptation to solve the problem of model adaptation across different datasets, aiming to equip the model with the ability to learn new tasks quickly and adapt to unseen tasks with a small number of samples [20,21]. Specifically, the model was first pretrained on the MIMIC-III dataset to acquire a general learning strategy, thus achieving a good initial state that allows for rapid adjustment when faced with new tasks. Once the model was pretrained, it underwent fast adaptation on the eICU-CRD dataset, where parameters were quickly adjusted using a small amount of data to improve performance on the new dataset. With this approach, the issue of poor generalization capability of existing models was solved, allowing for better adaptation to various clinical settings.

Experimental Setup

Overview

In addition to model evaluation, comparison with baseline models, and cross-dataset adaptation experiments, 3 other sets of experiments were conducted: evaluation of time-phased prediction performance, the impact of feature sets on prediction performance, and the trends of feature changes over time. The subsequent sections will introduce these 3 sets of experiments.

Performance Evaluation of Time-Phased Prediction

This experiment evaluated the ability of the model to predict CA 30, 20, and 10 minutes in advance. The primary evaluation metric was sensitivity, which assessed the ability of the model to identify CA events.

Impact of Feature Set on Prediction Performance

We constructed 3 types of feature sets: raw features based on vital signs, statistical features, and a combination of raw and statistical features. Various feature set experiments were conducted to determine the impact of each feature set on the performance of the model.

Trends of Feature Changes Over Time

We analyzed the average trends of different vital sign values in the CA and non-CA groups over the 30 minutes before the occurrence of CA and visualized these trends.

Results

Model Performance Evaluation

This section presents the evaluation results of the model prediction performance, which were evaluated using accuracy, sensitivity, specificity, AUROC, AUPRC, and false alarm rate. Additionally, the performance of the proposed model was compared with that of the baseline models.

In the MIMIC-III dataset, several models used in existing studies were compared with the proposed model to evaluate its performance in predicting CA events. As shown in Figure 5, the proposed model achieved an AUROC of 0.957 and an AUPRC of 0.949, significantly outperforming the baseline models. In addition, other performance metrics were also compared to fully assess the validity of the model in relevant clinical contexts. As shown in Table 1, the proposed model achieved an accuracy of 0.904, a sensitivity of 0.859, a specificity of 0.933, and a false alarm rate of 0.067, all of which outperform the baseline models, yielding the best performance among these.

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Figure 5. (A) The receiver operating characteristic (ROC) curve and (B) the precision-recall curve on the test set. AUROC: area under the receiver operating characteristic curve; AUPRC: area under the precision-recall curve; LGBM: light gradient boosting method; XGBoost: extreme gradient boosting.

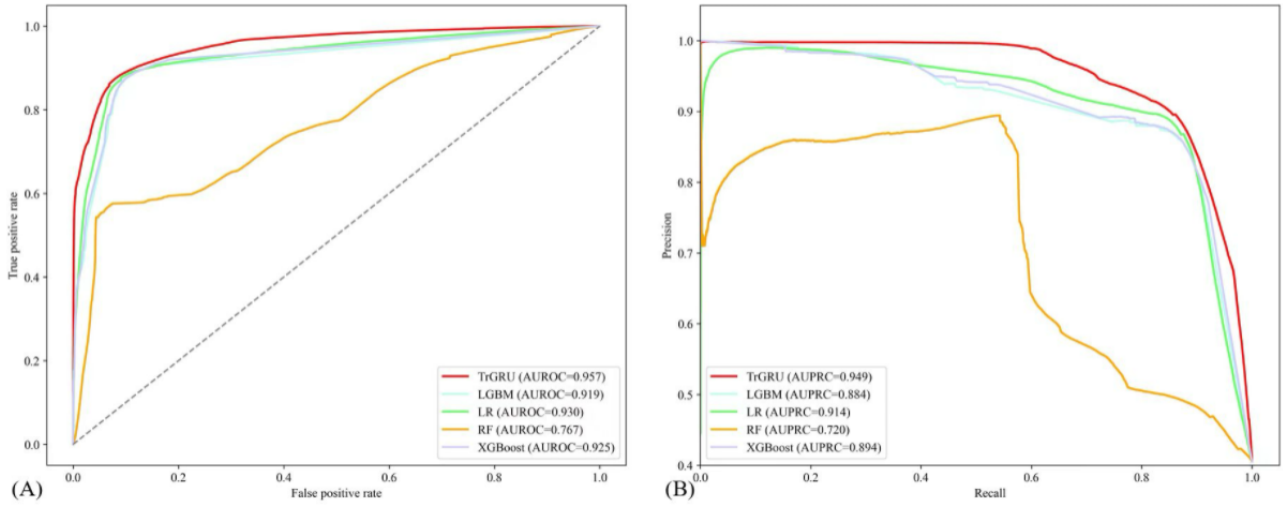

Table 1. Performance comparison of the proposed TrGRU model with baseline models.

Model	Accuracy (95% CI)	Sensitivity (95% CI)	Specificity (95% CI)	False alarm rate (95% CI)	Area under the receiver operating characteristic curve (95% CI)	Area under the precision-recall curve (95% CI)
Logistic regression	0.895 (0.895-0.897)	0.841 (0.851-0.854)	0.931 (0.925-0.927)	0.069 (0.073-0.075)	0.930 (0.930-0.931)	0.914 (0.913-0.915)
Extreme Gradient Boosting	0.890 (0.889-0.891)	0.852 (0.851-0.854)	0.916 (0.915-0.916)	0.084 (0.084-0.085)	0.925 (0.924-0.925)	0.894 (0.893-0.895)
Light gradient boosting method	0.869 (0.868-0.869)	0.775 (0.773-0.776)	0.933 (0.932-0.934)	0.067 (0.066-0.068)	0.919 (0.918-0.919)	0.884 (0.883-0.885)
Random forest	0.663 (0.662-0.664)	0.708 (0.706-0.709)	0.633 (0.631-0.634)	0.367 (0.366-0.369)	0.767 (0.766-0.768)	0.720 (0.717-0.722)
TrGRU	0.904 (0.903-0.904)	0.859 (0.858-0.861)	0.933 (0.933-0.935)	0.067 (0.065-0.067)	0.957 (0.956-0.957)	0.949 (0.949-0.950)

External Validation

We used a meta-learning and rapid adaptation–based approach to perform the cross-dataset CA prediction task. On the MIMIC-III dataset, a model was pretrained through multitask meta-learning. After pretraining, the lower-layer parameters of the model were frozen on the eICU-CRD, and only the last 2 fully connected layers were fine-tuned. Domain adaptation was achieved through adaptive training. The experimental results showed that the model achieved a sensitivity of 0.813, an AUROC of 0.920, and an AUPRC of 0.848 on the independent eICU-CRD, demonstrating significantly better cross-dataset adaptation ability compared to current models. These results indicated that the framework effectively used knowledge from the source domain to enhance the few-shot learning performance in the target domain.

Performance Evaluation of Time-Phased Prediction

We also evaluated the ability of the model to predict CA 30, 20, and 10 minutes in advance, using sensitivity, specificity, AUROC, AUPRC, and the false alarm rate as evaluation metrics, as shown in Table 2.

Table 2. Predictive performance of the TrGRU model across different time windows before cardiac arrest (CA).

Before CA	Sensitivity	Specificity	Area under the receiver operating characteristic curve	Area under the precision-recall curve	False alarm rate
30 min	0.906	0.926	0.967	0.955	0.073
20 min	0.926	0.923	0.971	0.958	0.077
10 min	0.948	0.919	0.977	0.963	0.081

The proposed model could identify 90.6% (737/813) of the patients experiencing CA 30 minutes in advance, 92.6% (753/813) of the patients 20 minutes in advance, and 94.8% (771/813) of the patients 10 minutes in advance, with a false

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alarm rate of 8% or lower within 30 minutes. Compared to other studies, the model proposed in this study exhibited higher sensitivity and a lower false alarm rate.

Impact of Feature Set on Prediction Performance

We constructed 3 types of feature sets: raw features based on vital signs, statistical features, and a combination of raw features and statistical features. The 3 types of feature sets were input into the model for training to determine the impact of different feature sets on the model prediction performance. The results are shown in Table 3.

Table 3. Impact of different feature sets on model prediction performance.

Feature sets	Accuracy	Sensitivity	Specificity	Precision	F_1-score	Area under the receiver operating characteristic curve	Area under the precision-recall curve
Raw features	0.904	0.859	0.933	0.898	0.878	0.957	0.949
Statistical features	0.918	0.894	0.934	0.903	0.898	0.980	0.972
Combination features	0.918	0.892	0.935	0.904	0.898	0.981	0.973

Regarding accuracy, sensitivity, AUROC, AUPRC, and F_1-score, the model performed better when statistical features were used than when raw features were used. When a combination of statistical and raw features was fed into the model, its predictive performance was also superior to that obtained using only raw features. However, its performance showed almost no difference compared to using only statistical features. Consequently, it can be inferred that statistical features enhanced the prediction performance of the model.

Trends of Feature Changes Over Time

Vital sign patterns over time for patients in the CA group and the non-CA group are shown in Figure 6. Compared to the non-CA group, the CA group exhibited lower HR, SpO_2, and blood pressure values before the event, while respiratory rate was slightly higher. Vital signs began to decline 25 minutes before CA. The decline became more noticeable within the 10 minutes preceding the event. Among all the vital signs, blood pressure and SpO_2 showed an earlier decline. Compared to the CA group, the vital signs of the non-CA group remained relatively stable.

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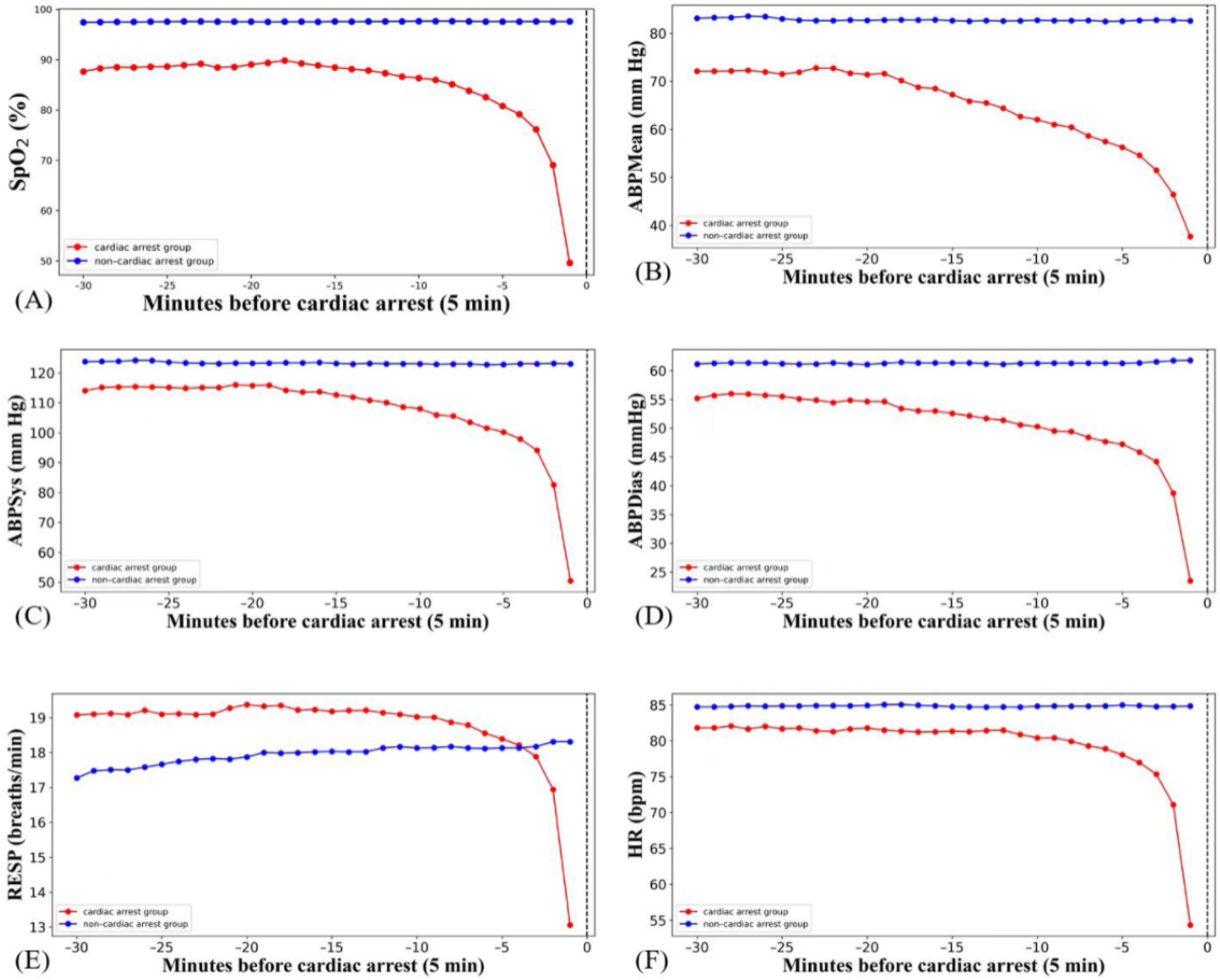
Figure 6. Average trends of vital signs over time in the cardiac arrest and non–cardiac arrest groups. ABPDias: diastolic blood pressure; ABPMean: mean arterial pressure; ABPSys: systolic blood pressure; RESP: respiratory rate; SPO2: oxygen saturation.



Discussion

Principal Findings

A deep learning model with real-time capability, high sensitivity, and a low false alarm rate was developed using only 6 vital signs based on the MIMIC-III database. The model relied on clinically accessible indicators to determine whether a patient would experience CA within the next hour at 5-minute intervals. It enabled real-time and continuous monitoring by overcoming the limitations of traditional prediction models that rely on a large number of features or features not commonly used in hospitals. The outcomes demonstrated that the model achieved excellent prediction performance. The TrGRU model developed in this study outperformed logistic regression, LGBM, and random forest across all metrics. Notably, compared to other models, TrGRU achieved both high sensitivity and a low false alarm rate. Table 4 presents a comparison between this study and other studies. Layeghian et al [22] developed a prediction model using ensemble learning methods based on multivariate features, vital signs, and clinical latent features, achieving an AUROC of 0.82 on the MIMIC-III dataset. However, their model was not designed for real-time monitoring.

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Table 4. Comparison with previous studies.

Study	Database	Features	Model	Real time	Cross-validation	Area under the receiver operating characteristic curve
Kim et al [6]	MIMIC-IV	Vital signs, statistical Features, and Gini index	TabNet classifier	Yes	Yes	0.86
Kwon et al [9]	Clinical database	Vital signs	Recurrent neural network	Yes	Yes	0.85
Yijing et al [8]	MIMIC-III	Vital signs	Extreme Gradient Boosting	Yes	No	0.94
Layeghian et al [22]	MIMIC-III	Multivariate, vital signs, and clinical latent	Ensemble learning	No	No	0.82
Our work	MIMIC-III	Vital signs	TrGRU	Yes	Yes	0.96

The experiments investigating the impact of different feature sets on model prediction performance demonstrated that statistical features outperformed raw features in accuracy, sensitivity, AUROC, and AUPRC. When a combination of raw and statistical features was used, performance was also superior to that obtained using raw features alone but comparable to that obtained using only statistical features. Therefore, statistical features played a crucial role in predicting CA events.

Class imbalance is a critical issue that affects model training performance. When the data are severely imbalanced, models often perform poorly in predicting minority classes (ie, they tend to favor predicting negative samples). This situation is particularly common in medical datasets, as in the context of this study, the occurrence of CA events was much rarer than in normal conditions. To address this problem, we used upsampling to replicate positive samples and downsampling to reduce negative samples, thereby balancing the ratio of positive and negative class samples. This solution effectively improved the sensitivity of the model (sensitivity increased from 80.6% before sampling to 85.9% after sampling).

The TrGRU can identify 85.9% (689/813) of the patients 1 hour before a CA event, 90.6% (737/813) of the patients 30 minutes before, and 92.6% (753/813) and 94.8% (771/813) of the patients 20 and 10 minutes before, respectively. These results imply that even when it is too late to prevent CA, medical staff still have a certain amount of time to intervene, thereby improving patient survival rates. This is because the faster cardiopulmonary resuscitation is performed after CA, the greater the patient's chance of survival, with the survival rate decreasing by 10% per minute before cardiopulmonary resuscitation is initiated. The model proposed by Yijing et al [8] identified 80% of the patients 25 minutes before CA and 93% of the patients 10 minutes before the event. The model proposed by Kwon et al [9] could also only identify 78% of the patients 30 minutes before CA. Therefore, the model proposed in this study demonstrated excellent performance in predicting CA events in advance, outperforming some existing studies.

Due to the "black box" nature of deep learning, it is challenging to establish relationships between real-time prediction results and features. In contrast, TrGRU provided a certain level of interpretability. We analyzed patterns of feature values over time by comparing the changes in vital signs between the CA group and the non-CA group before the occurrence of CA. This provided health care professionals with an objective basis for assessing physiological conditions. Clinical studies have shown that synergistic abnormal changes in vital signs (such as a sharp increase in respiratory rate combined with abnormal fluctuations in body temperature) often exhibit significant characteristic patterns before the occurrence of CA [23-25]. These patterns provide crucial evidence for clinical prediction and the determination of intervention windows.

To improve model generalizability, we used a meta-learning approach to address the issue of the model's inability to adapt to different datasets. Using the MIMIC-III dataset as the pretraining dataset and the eICU-CRD dataset as the target for rapid adaptation, the pretrained model requires only a small number of samples to quickly adjust and adapt to the new dataset. The results demonstrated that the method proposed in this study significantly improved the generalization of the model's capability and achieved excellent performance. Kim et al [6] trained their model on the MIMIC-IV dataset and subsequently conducted cross-dataset testing on the eICU-CRD dataset, achieving an AUROC of 0.80. Kwon et al [9] also performed cross-dataset validation on their proposed model, ultimately achieving an AUROC of 0.837 and an AUPRC of 0.239.

Contributions

This study primarily made 4 contributions. First, compared with existing studies, we developed a highly sensitive CA prediction model. Sensitivity exceeded 90% in predicting CA events within 30 minutes, which could allow health care professionals to intervene earlier and improve patient survival rates. Second, we used a meta-learning approach to enhance the generalizability of the model, enabling it to adapt to different datasets rapidly. To the best of our knowledge, this was the first study to use meta-learning to address the adaptability of medical prediction models across different datasets. Third, the model in this study significantly reduced the false alarm rate, which could effectively help avoid unnecessary interventions or treatments, thereby improving the efficient use of medical resources and reducing health care costs. Additionally, reducing false alarms helps prevent "alarm fatigue" [26], ensuring that health care

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professionals remain highly alert and responsive to each alarm. Fourth, we developed a prediction model using fewer variables, overcoming limitations of existing models that rely on variables not commonly used in hospitals. This approach offers the advantage of being applicable to various hospital settings.

Limitations

Our work mainly involves 3 limitations. First, due to the "black box" nature of deep learning, it is unable to establish relationships between prediction results and input data, and the interpretability of results is a critical factor for clinicians in making medical decisions; therefore, deep learning–based medical decision support still faces practical challenges. In recent years, the interpretability of deep learning has been explored in research [27-31], which is a key focus for our next steps. Second, CA may be caused by a variety of diseases, and in this study, we did not consider the heterogeneity between patients with different diseases [32]. Therefore, the generalizability of TrGRU cannot be guaranteed. Accordingly, it is necessary to expand the dataset to cover various types of diseases to further enhance the generalizability and robustness of the model. Third, we did not conduct feature selection. However, based on the research results, it appears that this omission did not significantly affect the performance of the model. In the future, feature selection could be used to further optimize the model presented in this study.

Conclusions

CA is a sudden and critical event with extremely low survival rates and a poor prognosis, posing a severe threat to patients. Existing CA prediction systems often suffer from low sensitivity and high false alarm rates. Consequently, there is an urgent clinical need for a reliable prediction system to assist health care professionals in real-time monitoring of CA events. The model proposed in this study can accurately predict CA events in real time, with high sensitivity and a low false alarm rate. Additionally, the use of meta-learning significantly enhances the adaptability of the model across different datasets. The TrGRU model shifts the golden resuscitation time window forward for patients who experience CA, which will play a significant role in improving patient survival rates. Moreover, its applicability to different clinical settings facilitates broader adoption.

Funding

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Data Availability

The datasets generated or analyzed during this study are available from the corresponding author on reasonable request.

Authors' Contributions

YL and LL are co–first authors who jointly designed the research; LL performed experiments and wrote the manuscript. YL supervised the project and revised the manuscript. XW contributed clinical expertise and guidance.

Conflicts of Interest

None declared.

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Abbreviations

AUPRC: area under the precision-recall curve
AUROC: area under the receiver operating characteristic curve
CA: cardiac arrest
GRU: gated recurrent unit
HIPAA: Health Insurance Portability and Accountability Act
HR: heart rate
ICU: intensive care unit
LGBM: light gradient boosting method
SpO2: oxygen saturation
XGBoost: extreme gradient boosting

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Original Paper

Acceptability of and Implementation Supports for Video Directly Observed Treatment to Enhance Methadone Dosing Flexibility in a Multisite Opioid Treatment Program: Qualitative Rapid Needs Assessment Study

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Abstract

Background: Methadone is a first-line treatment for opioid use disorder, which is delivered in federally regulated opioid treatment programs (OTPs). Federal policies require directly observed dosing of methadone followed by graduated provision of nonobserved doses to take at home (ie, “take-home” dosing) after demonstrated stability is achieved. Policy changes since the COVID-19 pandemic have greatly expanded take-home dosing. Video directly observed treatment (video DOT) is an approach in which patients submit videos of themselves taking medications, which are asynchronously reviewed to verify adherence.

Objective: In preparation for an implementation trial evaluating the adoption of video DOT in OTP settings, we conducted a rapid needs assessment with multidisciplinary stakeholders to assess acceptability, perceived benefits, and needed support for video DOT to monitor take-home methadone dosing.

Methods: In our rapid needs assessment, we explored perspectives of multidisciplinary stakeholders (N=20) at 3 clinical sites within a single OTP in western Washington state. Trained qualitative researchers took ethnographic field notes during meetings with organizational leadership and in-person site visits with clinical and administrative staff. Field notes were analyzed via a team-based rapid assessment process using coding templates informed by the Consolidated Framework for Implementation Research. Summaries of qualitative data were iteratively reviewed by the study team and further confirmed with site stakeholders.

Results: Stakeholders included leadership (n=6, 30%), medical providers (n=4, 20%), substance use disorder counselors (n=7, 35%), and clinic managers and support staff (n=3, 15%). Stakeholders perceived that video DOT could lessen the barriers patients face, including travel burden (eg, time and cost) and stigma. They also identified that video DOT could have important impacts on early care retention, given expansions of take-home dosing. However, stakeholders anticipated an added burden for clinical

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staff and emphasized the need for implementation supports that would limit burden, such as additional staff support for video submission review and clear communication pathways when video submissions require additional clinical input.

Conclusions: A rapid needs assessment of OTP sites for a future implementation study suggested that stakeholders saw potential benefits for patients receiving video DOT, but there were concerns that this would add to their work burden. Learnings informed the subsequent tailoring of clinical use cases and implementation supports.

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KEYWORDS

opioid use disorder; methadone; addiction treatment; mobile health; mHealth

Introduction

Opioid use disorder (OUD) remains a major cause of morbidity and mortality in the United States. As of 2024, an estimated 4.5 million American adults had OUD [1]. Since 2008, opioid overdose has exceeded motor vehicle accidents as a cause of death of adults [2], and mortality rates have markedly increased with the emergence of fentanyl as the prevailing opioid used, with the highest rates of increase seen among Black American, Native American, and Hispanic or Latinx American individuals [3]. Although there has been a recent downward trend in fatal overdose events nationally, not all parts of the country have witnessed declines, and the absolute number of overdose deaths—87,000 from 2023 to 2024—remains unacceptably high [4]. Opioid use is linked to recent outbreaks of HIV and increased incidence of hepatitis C virus among young adults in both rural and urban areas of the United States [5-8]. In addition, untreated OUD is a major burden on society, leading to excess health care use, loss of work productivity, crime, and incarceration [9].

Methadone was the first medication approved for OUD, has been a cornerstone of treatment for decades, and is associated with reductions in opioid use [10] and related mortality [11]. The arrival of fentanyl has posed challenges with initiating buprenorphine due to the risk of precipitated withdrawal, which has led to renewed interest in methadone as a treatment modality for OUD among patients and health care providers. In the United States, daily or frequent supervised treatment with visual confirmation of ingestion (directly observed therapy; DOT) is the standard of care for methadone treatment in federally licensed opioid treatment programs (OTPs). DOT mitigates the risk of medication poisonings and diversion; however, these same policies present major challenges for many clients due to potentially long travel times; interference with other obligations (eg, work, school, and family responsibilities); perceived stigma; and lost autonomy stemming from the requirement of frequent in-person visits, which are not required for almost all other medications.

In response to the COVID-19 pandemic, the Substance Abuse and Mental Health Services Administration released adjusted rules governing OTPs, allowing states to request blanket exceptions for all “stable” clients to receive 28-day take-home dosing and for “less stable” clients to receive 14-day take-home dosing if OTP medical providers believe that this level of take-home dosing could be safely handled [12]. The evidence to date suggests that relaxing regulations during the COVID-19 pandemic resulted in OTPs granting more take-home methadone doses without a substantive increase in methadone-involved overdose [13], and this change was recently codified as part of 42 Code of Federal Regulations Part 8 [14]. However, clients and health care providers also articulate drawbacks from the loss of structure and accountability from DOT [15]. In addition, with the loss of strictly codified algorithms for take-home doses, a greater weight of decision-making is transferred to the subjective assessments of OTP medical providers. Given shifting drug supplies and increases in fentanyl and methamphetamine use (which are associated with fatal overdose trends), health care providers are increasingly burdened with finding the right balance between flexibility and convenience and safety in a setting where there are high stakes and low tolerance for errors in medication taking.

Video directly observed therapy (video DOT) is an approach in which patients submit videos of themselves taking medications, which are asynchronously reviewed to verify adherence. Such an approach may be a middle ground in obviating the need for in-person visits while retaining the benefits of confirmed ingestion. We conducted a clinical pilot during the COVID-19 pandemic that demonstrated the feasibility of implementing video DOT via smartphone app for methadone dosing [16-18]. The pilot study also found that the video DOT app was associated with higher rates of confirmed doses; compared to matched control clients in the same setting, clients who used video DOT demonstrated higher rates of observed dosing (eg, mean 53.2 days vs 16.6 days with an observed dose over the first 60 days [17]) and higher rates of “graduating” to an increased number of take-home doses within the first 60 days (61% vs 0%). While multiple previous usability studies, including our own, have found app-based technologies acceptable for take-home methadone dosing [19-21], few studies have explored which implementation supports are needed to scale these technologies across the clinic. Implementation supports that enable and promote adoption of new technologies in clinical practice often need to be tailored to the local context, highlighting the benefit of formative evaluation in the early stages of implementation research [22,23].

Evidence that video DOT can be implemented in multiple OTPs can inform policies and reimbursement mechanisms that support video DOT as a means to achieve more flexible, client-centered models of methadone treatment. In preparation for an implementation trial evaluating the adoption of video DOT in OTP settings, we explored stakeholder perspectives on acceptability, perceived benefits, and needed supports for video DOT implementation to monitor take-home methadone dosing

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as part of the needs assessment conducted during the preimplementation phase.

Methods

Study Design Overview

As a component of formative evaluation activities for our hybrid type 2 effectiveness-implementation study that tested implementation and clinical outcomes for video DOT for methadone across a multisite OTP, we conducted a rapid needs assessment with multidisciplinary stakeholders at 3 implementation sites to prepare for implementation.

Intervention Description

The video DOT technology involves (1) a patient-facing app, used on smartphones to submit routine videos of their methadone dosing, and (2) a web-based portal for clinical staff that allows staff to manage patient enrollment, monitor adherence, and message patients directly about video submissions and other issues. To initiate a patient's use of video DOT, clinical staff need to create an account for them and provide information about their methadone dosing (eg, dose amount and timing), assist the patient in downloading the app to their phone, and provide any additional training on navigating the app. Once enrolled, patients receive daily reminders to take their dose and instructions within the app on how to submit their videos (including showing their dosing bottle and verifying dose ingestion). Videos can be recorded offline and submitted for review once patients have access to Wi-Fi or cellular data. Patients are also able to use messaging functions and monitor their adherence via a tracking calendar. Video submissions are reviewed by members of the team to assess whether they meet criteria for acceptance and provide patient education as needed. Clinical teams are alerted to any clinical issues or missed video doses via email and web portal notifications. Clinical teams can also log into the web portal to review patient, caseload, and clinic-level metrics on enrollment and adherence in real time. When a patient has completed their use of video dosing, clinical staff can deactivate their account in the web portal.

Study Population and Setting

The study setting is a large OTP serving more than 2500 clients at 3 sites in cities in western Washington state (ie, Seattle, Renton, and Olympia). The OTP serves a broad swath of patients from those cities as well as surrounding suburban and rural areas (>300 zip codes). The organization played a leading role in developing procedures to respond to the COVID-19 pandemic, culminating in a revision to federal policy to relax requirements for supervised DOT ingestion [12]. The organization serves a high percentage of clients who are unhoused or unstably housed and vulnerable to disruptions in care as well as individuals from diverse racial or ethnic backgrounds [17,24].

For the rapid needs assessment, we engaged clinical stakeholders across the 3 clinical implementation sites. Stakeholders included organizational leaders, clinic managers, medical providers (all physician assistants and advanced registered nurse practitioners), behavioral health providers (ie, counselors), and other staff.

Data Collection

In the preimplementation phase of the study, we conducted 3 site visits (1 per site) and held a series of meetings with organizational leadership to discuss program needs and goals for video DOT. During all site visits and meetings, we engaged in participant observation and data collection in the form of ethnographic field notes. Site visit discussions followed a semistructured discussion guide that asked staff to reflect on how video DOT might support methadone care delivery and what implementation approaches would be most supportive. Site visits also involved informal discussions with staff while on site, in accordance with ethnographic data collection methods [25-28]. Trained qualitative researchers (EJA, ECW, and JAD) took ethnographic field notes consisting of near-verbatim typed notes documenting the contents (eg, conversations and actions) of all implementation meetings and site visit discussions. This is an ethnographic method of data collection that is recommended in formative evaluation [23,26,29], which our team has used in several previous studies to understand barriers and facilitators in real time and address barriers with adaptive implementation strategies that capitalize on facilitators [30-32]. The rapid needs assessment meetings with health care providers and clinical staff members were facilitated by research team members (JIT, KAH, EJA, ECW, and JAD) to develop a shared and more precise understanding of (1) program-level challenges with integrating video DOT into clinical workflows (including time requirements for staff to review videos and respond to messages from the application about missed videos), (2) attitudes and concerns related to video DOT, (3) how to identify clients for whom video DOT is appropriate, (4) expectations for how video DOT can lead to fewer in-person visits and more take-home doses with the ultimate goal of accelerating the timeline to unobserved take-home doses, (5) whether to use add-on features that might enhance monitoring or case management (including, but not limited to, appointment reminders; 2-way chat; and links to community resources, such as food banks, syringe service programs, housing resources, and COVID-19 testing), and (6) when to discontinue video DOT (both criteria for discontinuation and completion of video DOT) and any changes to clinical care that may be needed if video DOT is discontinued (eg, changes in take-home frequencies). The results of the rapid needs assessment informed training and practice support materials, workflow diagrams, case examples, and decision-support guidance in the implementation period.

Analysis

Ethnographic field notes were analyzed by formative evaluation team members with qualitative analysis expertise (EJA and JAD) using a rapid assessment process (RAP), an intensive, team-based qualitative inquiry process that uses triangulation, iterative data analysis, and additional data collection to develop an understanding of a situation from the insider's perspective [29,33-35]. Consistent with our previous research using the RAP [30-32], data from all notes from participant observations were reviewed iteratively and coded in structured templates guided by the domains of the Consolidated Framework for Implementation Research: characteristics of the intervention and individuals using it, the outer and inner settings in which implementation occurs, and the implementation process [36].

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In each of these 5 broad domains of the Consolidated Framework for Implementation Research, there are multiple subdomains; together domains can be used to guide implementation efforts and identify strategies for implementation in post hoc analysis. Analyses involved a combination of deductive and inductive approaches that allowed for emergent themes that characterized potential influencing factors and needed supports for the implementation. Analyses were conducted iteratively and shared with the entire investigative team for further interpretation.

Ethical Considerations

The University of Washington Institutional Review Board provided oversight and approval for this research (STUDY00011142). For collection of the ethnographic field notes described above, the institutional review board determined the informed consent process could be waived and that compensation for participation was not required. To maintain privacy and confidentiality of staff members, neither demographic nor identifiable information were collected as a part of the ethnographic field notes.

Results

Overview

Across the 3 sites, 20 individuals participated in preimplementation discussions, of which 8 (40%) were frontline clinical care providers, 9 (45%) had a supervisory administrative role, and 3 (15%) had a leadership role in the organization. Among clinical care providers, 8 (40%) were counselors, 8 (40%) were medical providers (who were advanced practice providers, either nurse practitioners or physician assistants), and 4 (20%) had nursing or other roles. Among the 3 sites, the average patient census was estimated to be approximately 900 (range 500-1250).

A total of 4 themes that emerged from analyses of the data are detailed subsequently and summarized in Table 1. These themes characterized perspectives on using video DOT in routine practice and contributed to the design and tailoring of implementation supports. Through discussions, several case use scenarios for video DOT emerged; these are summarized in Table 2 along with potential outcomes to measure the success of use.

Table 1. Summary of themes and implementation team response.

Needs assessment theme	Implementation team response
Perceived benefit for patients facing access burdens	• Expanding video DOT[a] eligibility criteria to prioritize patients with high access burdens • Revising use cases to accommodate additional clinical scenarios that patients with high access burdens commonly face
Potential tool to help clinical teams respond to changing guidelines and drug supply	• Developing potential secondary use cases that may be piloted (eg, use of video DOT to help reach therapeutic dose, buprenorphine tapering, and callbacks to verify medication supply)
Need to center implementation on ease of use and team-based communication	• Identifying and preparing multidisciplinary champions at each site • Co-designing implementation support materials (training and workflows) • Incorporation of local team-based communication modalities
Challenge of balancing harm reduction and safety in video DOT use	• Co-design of protocols for video DOT monitoring and notification of clinic staff for unexpected issues (escalation) • Use of team-based communication strategies for escalation scenarios • Ongoing audit and feedback

[a]Video DOT: video directly observed treatment.

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Table 2. Summary of potential video directly observed treatment (video DOT) use cases and goals.

Stage of care	Potential video DOT use case	Outcomes of interest
Treatment initiation	• Monitor initial methadone dose titration	• Shortened time to reach therapeutic dose • Improved adherence or reduction in missed doses
Treatment monitoring	• Provide additional support for patients increasing take-home doses • Enable virtual callbacks for patients on take-home doses • Provide encouragement or positive reinforcement to patients for consistent engagement or adherence (eg, through asynchronous video or SMS text messages from the care team) • Provide additional structure for patients needing short-term exceptions (eg, an unexpected need for take-home doses) • Provide monitoring for patients with split dosing	• Increased take-home doses per patient • Improved MOUD[a] adherence and days of coverage (ie, fewer missed doses) • Improved engagement and retention in care • Reduced diversion or misuse of methadone • Reduced illicit opioid and polysubstance use • Reduced time and cost associated with transportation and access burden for patients • Improve recognition and responsiveness to patient health needs (eg, communication about side effects and dosing issues) • Increased patient and health care provider satisfaction with care delivery
Treatment completion and transition to the next phase of care	• Monitor transition to buprenorphine or other MOUD	• Shortened time to reach therapeutic dose

[a]MOUD: medications for opioid use disorder.

Theme 1: Video DOT May Be Most Beneficial for Patients Facing Structural Barriers to Accessing the Clinic

As clinical teams considered adding video DOT to their practice, they identified many potential clinical and patient-centered benefits of video DOT across the OUD care continuum (Table 2). They acknowledged that some patients experienced heightened structural barriers to accessing the clinic and may therefore benefit more greatly from video DOT. For example, participants shared that many patients travelled long distances to get to the clinic. One participant shared that their clinic covered patients across the 5 neighboring counties, a large geographic region. Another participant described that their clinic was only accessible by 1 bus route, making public transportation to the clinic arduous. One participant shared the following:

> *Transportation is a lot of our big issues, because we cover a lot and we're it, it's a real struggle for some of them to get here.* [Participant A15]

Another echoed this, saying the following:

> *I see this as something really positive, it's so much [less] stress for them to not have to travel or take time off work.* [Participant A20]

Participants also articulated that video DOT "might be helpful for folks with mobility issues" (participant A18). Participants described that patients with mobility issues or physical disabilities often struggled to get to the clinic. One participant said the following:

> *Just the disability…this would really serve that population.* [Participant A16]

Overall, participants believed that video DOT might be suitable for some but not all patients, which would still make it a helpful tool. One participant expressed the following:

> *If you help one person, it's worth it.* [Participant A16]

Theme 2: Video DOT May Help Clinical Teams Be More Responsive to How Methadone Treatment Delivery Is Rapidly Evolving

Participants described how shifting drug supply and the revision of federal policies governing methadone treatment during the COVID-19 pandemic have changed the landscape of day-to-day care for OUD treatment with methadone. For example, the practice of take-home dosing has expanded rapidly, such that daily in-person clinic dosing is *the exception not the rule now* (participant A8). While participants viewed the shift to increased take-home doses positively, they also felt challenged by maintaining patient engagement in care in the context of fewer in-person clinic interactions. Participants considered video DOT a useful bridge for facilitating patient engagement when fewer in-person dosing visits were happening:

> *Can we show that we have better engagement and retention?...if we get better engagement then it pays for itself.* [Participant A9]

Similarly, another participant shared that video dosing may help clinical staff trying to manage increased caseloads, saying the following:

> *As caseloads grow, [clinical staff] are getting very frustrated...this might be an option that encourages better attendance.* [Participant A16]

Participants also described that increasing fentanyl use among patients has been a challenge for initiating methadone. Fentanyl is a highly potent synthetic opioid that quickly leads to high physical dependence. It may also be retained in adipose tissues, leading to physiological persistence. As a result, severe and prolonged withdrawal may occur, necessitating higher doses of methadone to control cravings and withdrawal symptoms. One participant shared the following:

> *Just with fentanyl use, it's made everybody's dose much higher.* [Participant A4]

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Rapidly achieving higher doses of methadone to adequately treat fentanyl withdrawal is accompanied by risks for oversedation (and related complications, such as accidents and falls). Participants viewed video DOT as a potential tool to help them find that balance between rapid dose escalations and the need to monitor in-person for safety. One participant shared the following:

> *Especially if you didn't have to connect with the provider, that would be an amazing tool because we're constantly talking about how we can get people to higher doses quicker.* [Participant A9]

Theme 3: Implementation of Video DOT Needs to Center on Ease of Use and Team-Based Communication Strategies

When reflecting on using video DOT in routine practice, participants worried that it might add burden to their day-to-day workload. Participants expressed that video DOT needed to be easy to use to ensure uptake among busy team members:

> *We do like simple.... The counselors get loaded down with a lot.* [Participant A16]

As part of this, participants emphasized the importance of having clear and inclusive communication pathways about video DOT use by their patients. Specifically, participants reflected that communication about any patient issues with video DOT needed to involve the entire clinical team (ie, medical, counseling, and nursing) to support team-based decision-making. Yet, communication also needed to be clear on which team member is accountable for subsequent actions:

> *My concern over shared accountability is that there is no accountability. So having a designated person and maybe depending on the case allowing someone to delegate.... I want to say "[team member] that was your job."* [Participant A9]

Although there was a desire for clear workflows and accountability related to video DOT use, participants were reluctant to develop rigid policies regarding video DOT eligibility and adherence thresholds, given that each patient and clinic may have unique scenarios to consider. One participant further expressed that it "might be nice to see how [video dosing] functions differently in different settings because we have vastly different populations" in each clinical site (participant A9).

Finally, there was a shared consensus that the primary goal of leveraging video DOT should be to increase take-home dosing for patients who might not otherwise qualify. As one participant described, video dosing should prioritize patients who are "really on the fence or folks that are on the bubble [that] we could get to take-homes faster" (participant A9); another participant shared that video dosing would be ideal for "that patient [who] is stuck at [daily dosing] for a while and I know they really should be on monthlies" (participant A4).

Theme 4: Balancing Harm Reduction and Safety May Be a Challenge in Video DOT Use

Participants noted that their perspectives on harm reduction have changed in response to changing policies regarding take-home dosing. One participant shared the following:

> *We are less restrictive than we use to be.... If you walk in the door, we will do what we need to do to get treatment.* [Participant A12]

Another participant described the following:

> *The take-home policy is so vastly different than it was the first time around and the real focus is safety. It's really a safety lens for daily dosing.* [Participant A10]

Participants identified that using video DOT in routine practice may introduce new, unforeseen scenarios related to patient safety and diversion. One participant shared an example related to diversion, reflecting on the need to identify patients who had the best chance of being successful with video DOT:

> *We talked originally about diversion...there's not a ton we can do. There's ways to have the tamperproof bottles...so we can have confidence [that the patient has taken the correct dose]. It's really about selecting a population that's going to benefit from this and that it will be meaningful for.* [Participant A9]

Other participants discussed the need to have ongoing discussions and implementation adaptations to address evolving needs to support patient safety, which is a priority within the culture of the organization. One participant summarized, their organization "has always erred on the side of caution" (participant A15).

Discussion

This rapid needs assessment of 3 clinic sites within a large OTP in western Washington was conducted during the preimplementation phase of a planned hybrid effectiveness-implementation study and offered valuable insights from stakeholders on anticipated acceptability, benefits, and needed supports for implementing video DOT to monitor take-home methadone dosing. A key theme was the belief that video DOT can address several access barriers patients face, including travel burden (both in terms of time and cost) and mobility or physical disability issues. Participants also perceived value in how video DOT may help clinical teams adapt to new expectations for methadone care delivery, namely the expansion of take-home dosing and more rapid up-titration of dosages, as well as its potential in helping clinical teams strike the right balance between a risk reduction approach and ensuring patient safety. Stakeholders emphasized the need for implementation support that would limit burden for clinical staff, such as additional staff support for video submission review and clear communication pathways for when video submissions require additional clinical input. Findings from this work subsequently guided the tailoring of implementation supports—including training and practice support materials, workflow diagrams, case examples, and decision support guidance for video DOT for methadone—that were co-designed with OTP stakeholders in preparation for the study's launch of video dosing.

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This study builds on previous research demonstrating the feasibility of video DOT for methadone, including an observational study that showed video DOT increases rates of observed dosing and "graduation" to increased take-home doses within the first 60 days of use [17], as well as usability studies showing that patients and counselors are able to use the video DOT app correctly [16]. The research is timely, as many of the federal policy changes for OTPs implemented during the COVID-19 pandemic have been made permanent or extended to increase access to treatment for OUD [14]. Patients on methadone may benefit from expansion of this intervention, considering the myriad challenges these patients face with expectations for in-person dosing with regard to costs, travel time, exposures to drug activities, and stigma. Evidence that video DOT can be implemented in OTPs may help actualize the end goal of such policies that strive to ensure more flexible, client-centered methadone delivery. While federal policy made it easier for patients to receive take-home doses, heterogeneity in practice exists in part due to variability in approaches among clinics and health care providers [37]. Thus, there is still an urgent need to create systems of care delivery that will facilitate more take-home doses and reduce the need for travel to clinic visits [38]. It is notable that our discussions with stakeholders revealed other potential use case scenarios beyond advancing take-home doses, such as monitoring patients on split dosing or rapid dose escalation. We anticipate that future research will provide additional valuable information on how this technology can be feasibly adapted to best serve patients and health care providers.

There are limitations to the generalizability of findings from this RAP. While we attempted to draw in as many provider stakeholders as possible at the sites, the findings do not represent all perspectives or opinions. Similarly, our focus on a single OTP may limit generalizability. The rapid needs assessment process relied on qualitative ethnographic methods intended to capture an in-depth understanding of a local context. As the goal of the research was to quickly obtain an understanding from an insider's perspective to guide implementation efforts, we felt this was the most expeditious approach. However, further methods—particularly those that capture quantitative and additional qualitative methods with expanded samples—would support a better understanding of the implementation context and outcomes for video dosing use in OTP settings. We will examine these issues as part of the ongoing implementation trial at the single OTP in which we are working.

In summary, a rapid needs assessment of OTP sites for a future implementation study suggested that stakeholders saw potential benefits for patients with video DOT for methadone, but there were concerns that this would add to staff work burden. In the context of in-person dosing becoming the exception instead of the norm, stakeholders perceived video DOT as being a potentially useful tool for a subset of patients and mainly to facilitate advancement of take-home doses, and additional unique case scenarios for video DOT use were identified. The findings inform our next steps in implementing video DOT for methadone in the OTP clinic sites and measuring the success of implementation and its impact on clinical outcomes.

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Data Availability

The datasets generated or analyzed during this study are available from the corresponding author on reasonable request.

Conflicts of Interest

None declared.

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Abbreviations

DOT: directly observed treatment
OTP: opioid treatment program
OUD: opioid use disorder
RAP: rapid assessment process
Video DOT: video directly observed treatment

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Original Paper

Exploring the Acceptability, Appropriateness, and Utility of a Digital Single-Session Intervention (Project SOLVE-NZ) for Adolescent Mental Health in New Zealand: Interview Study Among Students and Teachers

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Abstract

Background: Globally, we face a significant treatment gap in mental health care, with extensive wait times, exorbitant prices, and concerns about appropriateness for non-Western clients. Digital single-session interventions (SSIs) may offer a promising alternative. SSIs target particular mechanisms that underlie broad-ranging psychopathology, including deficits in problem-solving skills.

Objective: Developed in the United States, Project SOLVE is a digital SSI that teaches problem-solving skills to adolescents. This study evaluated the acceptability, appropriateness, and utility of an adapted version, Project SOLVE-NZ, among *rangatahi* (young people) in Aotearoa New Zealand. Additionally, we evaluated a comparable online activity, Project Success-NZ, as a potential active control condition in a future randomized controlled trial of Project SOLVE-NZ.

Methods: A sample of school students and teachers completed Project SOLVE-NZ and Project Success-NZ. Feedback on the interventions was collected through focus groups and semistructured interviews. Interviews were recorded, transcribed, and analyzed using reflexive thematic analysis.

Results: In total, 12 students (aged between 13 and 14 years; female students: n=6, 50%) participated in a focus group, and 8 teachers (teaching experience: mean 8.75, SD 7.96 years; female teachers: n=5, 62.5%) participated in individual interviews. Participants endorsed the sociocultural relevance of Project SOLVE-NZ and Project Success-NZ to *rangatahi* in Aotearoa New Zealand and viewed all existing adaptations favorably. Participants felt that the interventions would be valuable to a wide range of *rangatahi*, helping to fill gaps in students' learning and providing benefits to mental health. Participants also believed that the interventions may be particularly relevant for youths experiencing economic hardship. Interestingly, most participants had no preference for either Project SOLVE-NZ or Project Success-NZ, and they believed that both interventions could provide ongoing support to *rangatahi* throughout the school year. Teachers provided some suggestions on increasing student engagement with the interventions, namely, through increased cultural and gender representation, visual and literacy aids, *whakawhanaungatanga* (relationship building), and teacher guidance. Overall, interviews revealed that both interventions were perceived as acceptable, appropriate, and useful for *rangatahi* in New Zealand and highlighted further adaptations that could be made prior to a randomized controlled trial of Project SOLVE-NZ across schools nationwide.

Conclusions: Digital SSIs show promise in addressing the mental health treatment gap for adolescents. Both Project SOLVE-NZ and Project Success-NZ were well-received by students and teachers in Aotearoa New Zealand and may provide benefits to youth mental health. We make the following recommendations for others interested in designing digital SSIs or similar tools for young people: involve *rangatahi* and relevant stakeholders in the design process, consider how the intervention will be implemented,

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ensure that the intervention accommodates a range of cognitive abilities, and ensure that the intervention reflects the diversity of *rangatahi* today.

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KEYWORDS

digital single-session intervention; mental health; adolescent; co-design; qualitative methods; problem-solving skills

Introduction

Background

Globally, we face a significant treatment gap in mental health care. Despite the existence of numerous evidence-based interventions, most individuals experiencing mental distress receive little or no formal support [1-3] for reasons including extensive wait times, exorbitant prices, and concerns about their cultural appropriateness for non-Western clients [4-8]. One alternative approach to existing treatment options may be single-session interventions (SSIs). Digital SSIs require less time and fewer resources than traditional psychotherapies and are increasingly—and effectively—being used in the treatment and prevention of various mental health conditions [9-15].

SSIs aim to address underlying, often transdiagnostic mechanisms or skill deficits implicated in broad-ranging psychopathology rather than provide comprehensive treatment for specific diagnoses. At present, SSIs have targeted numerous transdiagnostic mechanisms associated with psychopathology, including negative problem orientation [16], avoidance [12,17], cognitive distortions [9,10,13], and negative self-perceptions [18,19]. Problem-solving skills are another transdiagnostic mechanism linked to psychopathology [20-24] and targeted with digital SSIs [16,25]. In clinical psychology, problem-solving or "social problem-solving" is defined as the "self-directed cognitive-behavioral process by which an individual, couple, or group attempts to identify or discover effective solutions for specific problems encountered in their everyday living" [26].

In their seminal paper, D'Zurilla and Goldfried [27] theorized that individual differences in problem-solving ability are due to variance in two processes: (1) problem orientation and (2) problem-solving style. Problem orientation is the motivational force behind problem-solving, including the individual's metacognitive beliefs about their problems and ability to solve them. Positive problem orientation views problems as solvable challenges, while negative problem orientation views problems as unsolvable and distressing threats. Problem-solving style refers to the idiosyncratic way an individual attempts to conceptualize their problems and generate effective solutions. Although some heterogeneity exists in stylistic approach, most individuals tend to be rational, impulsive or careless, or avoidant problem solvers. Rational problem-solving is the most adaptive problem-solving style and involves the deliberate and systematic application of problem-solving skills, including (1) defining the problem, (2) formulating multiple solutions, (3) deciding the "best" solution, (4) implementing that solution, and (5) monitoring the effectiveness of that solution.

It has been argued that some presentations of psychopathology are due to underlying problem-solving deficits, and improvements in these presentations require a shift to more positive problem orientations and rational problem-solving styles [26]. Indeed, this literature shows that deficient social problem-solving has been associated with a range of mental illnesses, including depression [20,24], anxiety [21,28], schizophrenia [22,29], and borderline personality disorder [23,30,31].

Problem-Solving and Adolescents

Adolescents are a group who may particularly benefit from problem-solving interventions. Older adolescents (aged 13 to 14 years) show increased tendencies toward negative problem orientation, avoidant problem-solving style, and impulsive or careless problem-solving style compared to younger adolescents (aged 11 to 12 years) [32,33]. Additionally, marked sex differences have been observed, with rationality being more characteristic of girls in both age groups and impulsivity and avoidance being more characteristic of boys in the younger age group. Adolescence is also a developmental period marked by increases in stressors, which may benefit from problem-solving interventions, including interpersonal challenges, identity concerns, and worries about the future [34-36].

Project SOLVE

Project SOLVE is a digital SSI developed by researchers at Harvard University [16]. Through a 30-minute self-guided intervention, Project SOLVE provides young people with adaptive strategies to face their everyday problems. Specifically, Project SOLVE aims to foster positive problem orientations and rational problem-solving styles among users: adolescents learn that some of their problems are solvable challenges using the "SOLVE" framework (ie, say what the problem is, one goal to aim for, list some solutions, vote for the best solution, and explore what works) rather than threats to be impulsively dealt with or avoided. A recent school-based randomized controlled trial (RCT) in the United States found that adolescent students who completed Project SOLVE showed significant reductions in internalizing symptoms at a 3-month follow-up assessment, relative to Project Success, an active comparison program focusing on study skills [16]. In addition, participating students reported significantly reduced hopelessness and increased goal-planning confidence from pre- to postintervention, and they rated Project SOLVE as acceptable and helpful.

Project SOLVE and Aotearoa New Zealand

Like other developed nations, Aotearoa New Zealand is facing a growing mental health crisis, with adverse yearly trends in a variety of youth mental health indicators [37]. Converging systemic inequities contribute to poorer mental health outcomes for *rangatahi* (young people; a list of translated terms is

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provided in Multimedia Appendix 1) with 1 or more historically marginalized identities, including *Māori* youths (the indigenous people of New Zealand), Pasifika youths, and LGBTQIA+ (lesbian, gay, bisexual, transgender, queer, intersex, asexual, and other diverse sexual orientations, gender identities, and sex characteristics) youths [38,39]. One in five *rangatahi* report difficulty in accessing help for their mental and emotional concerns [38], and the New Zealand mental health care system has been "characterized by long delays, overworked staff, inadequate environments, and a lack of clear information" [7]. Additionally, there have been calls for the current system to be more responsive to the needs of *Māori* and Pasifika youths, who often have difficulty receiving effective and culturally appropriate care [8,40].

As a low-cost and low-resource digital SSI, Project SOLVE may be an effective means of expanding evidence-based treatment to *rangatahi* in Aotearoa. To this end, a school-based pilot study explored the perceived acceptability, helpfulness, and appropriateness of an adapted version of Project SOLVE for *rangatahi* in Aotearoa [25]. Adaptations included changes to the intervention vignettes, avatar, spelling, vocabulary, and overall aesthetic design and elicited overwhelmingly positive feedback from students using a brief qualitative survey (ie, the Program Feedback Scale [41]). However, it is important to note that these adaptations were guided by relevant literature and academic expertise rather than consultation with young people themselves. Indeed, consultation is an important aspect of cultural adaptation, as it provides individuals with the opportunity to "impact, lead, and shape the things that influence their lives" [42]. This process of consultation or "co-design" is particularly important in the context of Aotearoa, as current mental health services do not satisfactorily accommodate the diverse cultural needs, preferences, and world views of our people [7,8], and particular cultural groups (eg, *Māori* and Pasifika communities) have been historically excluded from and oppressed by Western research practices [43-46]. Ultimately, research methodologies that incorporate co-design allow mental health tools to be developed in collaboration with their intended recipients, which may improve their cultural appropriateness and overall efficacy.

This Study

Building on the previous pilot study, we conducted a series of interviews with *rangatahi* and their teachers to gain a more in-depth understanding of their experience with the adapted Project SOLVE. Additionally, we asked participants about a comparable online activity, Project Success, that could be used as an active control condition in a future RCT of Project SOLVE. The interviews aimed (1) to determine the perceived acceptability, appropriateness, and utility of the SSIs for Aotearoa New Zealand and (2) to identify any further adaptations needed to the interventions prior to a nationwide RCT of Project SOLVE.

Methods

Ethical Considerations

All procedures across both the student focus group and the individual teacher interviews were approved by the University of Waikato Human Ethics Committee (HREC[Health]2024#15). Participants were provided with an information sheet about the study, and consent was attained prior to participation in an interview. They were informed that participation was voluntary, that they could decline to answer any question, and that they could leave the interview at any stage. Students and teachers received US $11.56 and US $23.12 vouchers, respectively, as *koha* (a gift) for their participation.

Study Context

This study was conducted between October 2024 and March 2025. The student focus group was conducted in collaboration with a public high school in Aotearoa New Zealand with approval from the senior leadership team.

Methods were also guided by Sonja MacFarlane's Cultural Enhancement Framework [47] (CEF)—a tool that has been used extensively by the New Zealand Ministry of Education to adapt programs originally designed for use overseas and aims to enhance the cultural appropriateness of *mahi* (work) done in New Zealand (Macfarlane, personal communication, June 2024). The CEF was particularly relevant for this study, as it provided a scaffolding to appropriately and ethically engage with participants, therefore increasing the likelihood of positive participant experiences and effective final products. For example, MTB met with leadership at the participating school to explain the purpose of this *mahi* and facilitate a *kōrero* (discussion) around any concerns or questions. We also worked with our school partners to ensure that parents were appropriately informed of the research, the (classroom) setting was conducive to *rangatahi* engagement, and *rangatahi* felt safe to express their *whakaaro* (thoughts and views) without fear or objection.

Study Design

We conducted a qualitative study using focus groups and semistructured interviews. Focus groups involve a moderated discussion with a predetermined group of people to assess the opinions, beliefs, and experiences of a particular phenomenon [48]. Increasingly, focus groups, or similar style interviews, are being used by researchers to co-design mental health interventions with their intended recipients [49-51]. In this study, student feedback was elicited using focus group discussions, and teacher feedback was elicited using individual semistructured interviews following completion of Project SOLVE and Project Success.

School Partnership

The majority of student participants were recruited from a large, public high school in New Zealand. This school is coeducational and categorized as "decile 1," meaning that it is among the 10% of New Zealand schools with the highest proportion of students living in low socioeconomic communities. Additionally, the student population is disproportionately comprised of historically marginalized ethnic groups, with almost 60% and 30% of students identifying as *Māori* and Pasifika, respectively. (The most recent census reports 17.8% [887,493/4,993,923] of the New Zealand population as *Māori* and 8.9% [442,632/4,993,923] as Pasifika [52].)

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In an effort to align with culturally sensitive practices, we consulted the CEF as well as the participating schools' deputy principal and head of physical education and health on how to best work with this specific community (eg, methods of gaining parental consent, determining participant compensation, and building positive rapport with students).

Student Participants

From the school partnership, 2 classes of year 9 students (ages 13-14 years) were invited to participate in this study. All students in these classes completed the interventions during a regularly scheduled health lesson. All students were also invited to participate in a focus group interview outside of class hours, which required parental consent.

Teacher Participants

First, health and physical education teachers from the partner school were invited to participate in this study. Based on these 2 interviews, we then used snowball sampling to recruit additional teachers from schools of other socioeconomic and cultural contexts to gain alternative perspectives on the interventions. Teachers gave informed consent before participating.

Interventions

Project SOLVE-NZ

Project SOLVE is a 30-minute self-guided activity delivered via Qualtrics, an online survey platform. First, students are shown a welcome screen that introduces the activity and the avatar, *Māia*. *Māia* then guides the students through a series of modules, including an introduction to problem-solving and which types of problems might be most appropriate for this skill, a description of how the brain facilitates problem-solving, vignettes demonstrating how older adolescents have solved their problems, scientific evidence that problem-solving can work, practice exercises, and activities to encourage the use of problem-solving in daily life. The intervention teaches students how to solve problems via the "SOLVE" framework: say what the problem is, one goal to aim for, list some solutions, vote for the best solution, and explore what works. In this study, participants completed Project SOLVE-NZ, the adapted version of Project SOLVE used in the previous pilot study in New Zealand [25]. This version included voiceover recordings of the paragraph text to accommodate diverse learning needs.

Project Success-NZ

Project Success is comparable to Project SOLVE in format and length and was used as an active controlled condition in a previous RCT of Project SOLVE [16]. Instead of problem-solving skills, Project Success teaches young people 3 strategies to reach their academic goals: how to take effective notes, how to break big assignments down into smaller tasks, and how to ask trusted others for help. Like Project SOLVE, Project Success was originally intended for use among American youths. Therefore, adaptations were made by MTB prior to this study to create Project Success-NZ (ie, using voiceover recordings, the same aesthetic design, avatar, New Zealand English, *te reo Māori* [the *Māori* language], and vocabulary more common to *rangatahi* in New Zealand). These adaptations matched Project Success-NZ to Project SOLVE-NZ to ensure that any future RCT comparisons between the interventions were based on content rather than superficial differences.

Procedure

Students

On the study day, students attended their usual health class, where MTB welcomed them and engaged in *whakawhanaungatanga* (relationship building), sharing brief information about herself and the study. Using laptops, students were emailed a Qualtrics link to read the study information and assent form. MTB also explained the process orally to support diverse learning needs. Students then completed demographic questions (age, gender, and ethnicity) before working through Project SOLVE-NZ (problem-solving skills) and Project Success-NZ (academic strategies) at their own pace.

Two 30-minute focus groups were held later that day during morning interval and lunch, led by MTB using a semistructured guide. MTB, a first-year postgraduate student in clinical psychology at the University of Waikato, had no prior relationship with the students. *Karakia* (prayer) opened and closed each session and *kai* (food) was provided.

Teachers

Teachers received a Qualtrics link to the interventions via email and could complete them at their convenience before their interview. MTB conducted individual ~20-minute semistructured interviews with each teacher via Zoom (Zoom Video Communications) or phone, based on their preference. *Karakia* was also offered.

Analysis

Focus group discussions and individual interviews were audio-recorded and transcribed with assistance from Otter.ai (version 3.8.0; Otter.ai, Inc). MTB then anonymized the transcripts to preserve participant confidentiality. After familiarizing herself with the transcripts, MTB coded the data using the "comments" function in Microsoft Word (version Microsoft 365; Microsoft Corporation). These codes were then distilled and organized visually into themes using Miro, a digital workspace for collaborative brainstorming. Themes were reviewed by coauthors and supervisors and consolidated through discussions with MTB. The transcripts were revisited throughout the analysis to ensure that the findings remained grounded in the original data. To illustrate the themes, participant quotations are presented in the subsequent sections, annotated with participant number, self-identified gender, and age (if a student) or years of experience (if a teacher).

Results

Participant Characteristics

Students

A total of 12 students aged between 13 and 14 years participated in a focus group (mean 13.67, SD 0.49 years), with an even number of male (6/12, 50%) and female (6/12, 50%) students. Half of the participants identified with only 1 ethnicity, while half identified with multiple ethnicities. Pasifika ethnicities

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were most represented (Samoan: n=6; Tongan: n=3; Cook Islands *Māori*: n=2; Fijian Indian: n=1), followed by *Māori* (n=4), New Zealand European (n=4), American (n=1), and Indian (n=1).

Teachers

A total of 8 teachers participated in individual interviews, with 5 identifying as female teachers. The teachers ranged in teaching experience from 1 to 23 (mean 8.75, SD 7.96) years. In total, 6 teachers identified as New Zealand European, with the remaining 2 identifying as "other." The teachers represented 7 schools of varying socioeconomic and cultural backgrounds, including single sex, coeducational, low decile, middle decile, and high decile ranking.

Thematic Findings

Major Themes

Participant feedback was categorized into 4 themes, with each theme containing multiple subthemes. These subthemes were labeled as either positive (+), negative (–), or mixed (+ or –), as shown visually in Table 1.

Table 1. Qualitative feedback of rangatahi and teachers about Project SOLVE-NZ and Project Success-NZ organized into themes and subthemes.

Theme	Subtheme
Sociocultural relevance	• Avatar of Māia (+) • Vignettes (+) • Te reo Māori (+) • Relevance to youths experiencing socioeconomic inequities (+)
Value of interventions	• Learning new skills (+) • Benefits to mental health (+) • Past, present, and future value (+) • Pedagogy of interventions (+) • Difficulty remembering content (–)
Delivery of interventions	• Digital delivery feasible (+) • Class setting appropriate (+) • Self-guided may present challenges (+ or –) • Voiceovers (+)
Suggestions	• Increased diversity • Visual and literacy aids • Whakawhanaungatanga • Teacher support

Theme 1: Sociocultural Relevance for Aotearoa New Zealand

Overview

Students and teachers unanimously agreed that Project SOLVE-NZ and Project Success-NZ were appropriate for use in Aotearoa New Zealand. Specifically, the majority of students described *Māia* (the avatar) as "cool" and "relatable" (11/12), with 1 male student disagreeing. These feelings were reflected in the comments of teachers, who liked the design of *Māia* but thought a female character may limit the engagement of young boys:

> *I don't know whether you would want to make it a bit more ambiguous about their gender, or whether you just make it male ... If you had a boy's version of that image, that might be more relatable for them.* [Teacher 6, female, 2 years of experience]

> *I think with some boys, especially that age, it's really hard to get them to be honest with themselves, and a female figure could just be another barrier to them opening up.* [Teacher 7, female, 16 years of experience]

Participants also provided positive feedback on the adapted vignettes. All students reported liking the vignettes, saying that the selection included figures that students could "idolise" (Student 3, female) and "really connect to" (Student 1, female) and provided "good examples [of problem solving] because they were all from New Zealand" (Student 2, female). Overall, teachers also had positive experiences with the vignettes, commenting that they were "fabulous choices" (Teacher 4, female) and "relatable to a New Zealand audience" (Teacher 8, male). One teacher was unsure whether young people would recognize Valerie Adams (a New Zealand Olympian who retired in 2022), but all students reported knowing who she was.

Finally, participants spoke to the inclusion of *te reo Māori*, which was appreciated by the students and believed to facilitate their learning: "We grew up learning te reo and [including] it will help us understand more" (Student 2, female).

Furthermore, the students did not believe that including *te reo Māori* would be a barrier to nonspeakers, citing the English translation and commenting that young people "should learn te reo if [they] are growing up in New Zealand" (Student 2, female). Incorporating *te reo Māori* means that nonspeakers "can get to know our [Māori] culture better" (Student 3, female).

Overwhelmingly, this perspective was shared by the teachers; however, one commented that including additional cultures could better represent the diversity of classrooms across Aotearoa:

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> *It was great that it had te reo in it ... I just think, for New Zealand, it could be in different languages every now and then. Like Māori and then maybe Chinese. Just to better reflect our makeup now.* [Teacher 5, female, 10 years of experience]

Relevance to Youths Experiencing Socioeconomic Inequities—"Those kids end up missing out ..."

Discussions on the general sociocultural relevance of Project SOLVE-NZ and Project Success-NZ also brought to light the specific relevance to youths experiencing socioeconomic inequities. One teacher noted how the economic disadvantage of many families in Aotearoa seems to affect the development of problem-solving and study skills in their children:

> *These skills are generally transferred to children through their parents, but a lot of our kids don't necessarily live with their parents, or they live with other caregivers, or there's a lot of other kids in the house. The parents are just so busy trying to earn a living that they don't have the time to go through those skills or the patience to teach those skills, so those kids end up missing out ...* [Teacher 7, female, 16 years of experience]

While this perspective implies that both interventions could be particularly valuable to youths facing socioeconomic hardship, another teacher commented that Project Success-NZ may be less relevant to students from low-decile schools, as they tend not to prioritize academic achievement:

> *I would say very few of our students study. Some might, but the general culture within the school would be no. I mean, they don't even do homework ...* [Teacher 1, male, 23 years of experience]

However, he continued by acknowledging the intrinsic value of study skills and expressed a desire for these students to still have that learning opportunity:

> *But that doesn't mean these students shouldn't understand this is actually how you do it. If you want to study, this is what you can do—this is what you have to be able to do to achieve academically.* [Teacher 1, male, 23 years of experience]

Another teacher agreed on the general importance of learning study skills but ultimately believed that Project SOLVE-NZ may have more relevance in low socioeconomic contexts:

> *I thought the content was really beneficial ... But I think the problem solving one is probably a good one to focus on at this [low socioeconomic] school. Not saying that the academic stuff isn't important, but it would probably be helpful to figure out what the target audience is [of the interventions] and how relevant study skills actually are.* [Teacher 2, female, 1 year of experience]

However, this sentiment was not shared by the students at this school, the majority of whom had no preference for either intervention (9/12).

Theme 2: Value of Interventions to Students

Overview

In addition to sociocultural relevance, students and teachers commented on the value of Project SOLVE-NZ and Project Success-NZ to *rangatahi* in New Zealand. Specifically, participants described the interventions as tools to learn new skills and improve mental health through ongoing engagement and appropriate pedagogy.

Learning New Skills

Many teachers believed that the interventions would provide an opportunity for students to learn skills they may not be familiar with. In terms of Project SOLVE-NZ, teachers described the intervention as an effective way for students to learn a more adaptive approach to overcoming their daily challenges:

> *[Students] actually don't have the skills to say: "Okay, this has happened. Let me figure it out. Am I going to try and make new friends in the netball team? Am I going to go to the chess club because I love chess? Am I going to ask mum if I can have some new classmates come over for a sleepover?" They need to be stepped through those suggestions or problem-solving strategies because it's not embedded in them yet.* [Teacher 7, female, 16 years of experience]

These perspectives were also reflected in the student comments, with participants sharing that Project SOLVE-NZ taught them how to "take on overwhelming situations" (Student 1, female), "manage [their] problems" (Student 12, male), "break down [their] problems" (Student 5, female), and "find the best way to solve a problem" (Student 6, female). One student also noted the link between learning problem-solving skills and emotion regulation:

> *[We] didn't learn how to problem solve ... It hasn't been explained to us in a good way, so then when it comes to problem solving, we just get angry.* [Student 2, female]

According to participants, Project Success-NZ also provided *rangatahi* with an opportunity to learn valuable skills. Indeed, teachers unanimously agreed that study skills are important for students to know, and some questioned whether presuming competency in skills like those taught in Project Success-NZ is justified:

> *One of the things that dawned on me is, like, I don't actually know if students have ever been taught to take notes before—how to do that effectively. So I think, as a crash course, [Project Success–NZ] is pretty cool. It made me reflect on my own practice and whether I need to spend more time teaching those skills. Because I'll put up slides or do a talk, and part of me just expects that students are going to take note of a few things I say, but they really just sort of look at me ...* [Teacher 8, male, 4 years of experience]

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Additionally, teachers believed that Project Success-NZ would provide a beneficial learning opportunity for students across academic abilities:

> *I think whether they're high achieving students that are being extended and have tons of pressure on them, or they're lower achieving and struggling just to get an "Achieved" [grade], [Project Success–NZ] is going to help them figure out what study skills are going to work for them.* [Teacher 6, female, 3 years of experience]

Benefits to Mental Health—"I feel like SOLVE would really help a lot of kids"

Students perceived that Project SOLVE-NZ could have a positive impact on *rangatahi* mental health. For example, one student commented that Project SOLVE-NZ could help students "get to know their body, thoughts, and feelings better" (Student 5, female), while another commented explicitly on the mental health crisis facing *rangatahi* in Aotearoa today:

> *I feel like SOLVE would really help a lot of kids ... Because New Zealand has a very high, like, mental health rate, I feel like if [Project SOLVE–NZ] were given out to kids across New Zealand, it would really help them.* [Student 1, female]

Teachers agreed that Project SOLVE-NZ could provide benefits to youth mental health and identified some potential benefits of Project Success-NZ. For instance, one teacher thought that Project SOLVE-NZ may help students "move toward their purpose and develop forward thinking" (Teacher 1, male, 23 years of experience). He then expanded by linking Project SOLVE-NZ to self-autonomy:

> *I think if students can learn that some things are in their control, that's everything. You're more getting taught now that the tough things happening to you are not really because of you and you don't have control of this or that ... But I think that you can still achieve, you can still do this. And I think going back to that message is good.* [Teacher 1, male, 23 years of experience]

This teacher also noted how problem-solving skills may help students cope with the adversity in their lives:

> *A lot of our students are in survival mode, which means they're only really thinking an hour ahead ... So I find the forward thinking is not quite there. It's almost like "When life becomes easy, then we can start thinking about the future." But it's not like that. Life is hard, so they have to learn these skills.* [Teacher 1, male, 23 years of experience]

A similar sentiment was shared by this teacher, who believed that Project SOLVE-NZ may provide benefits to mental health by bridging the gap between students' aspirations and reality:

> *They need things to help them cope with [their problems] because even though we've got TikTok and Snapchat and all the different apps that kids use, there's nothing in those apps that give them the tools. They just see what they have to be like, or what they need to be like. They don't have that middle block of, "How do I get there?" Or, "How can I be my own self and get to express myself in that way?" They don't have those tools currently ...* [Teacher 7, female, 16 years of experience]

Past, Present, and Future Value—"I wish I knew this last year before I got suspended"

Both students and teachers commented on the value of the interventions at earlier and later stages of development. All students agreed that ongoing access to Project SOLVE-NZ would be helpful, and one student noted how younger age groups could benefit from problem-solving skills too: "This would have been really helpful in intermediate because everyone has emotions and problems—even when we are younger" (Student 1, female).

A similar sentiment was shared by this student, as she reflected on her younger self: "I wish I knew this last year before I got suspended" (Student 2, female).

Teachers agreed that students are beginning high school with underdeveloped problem-solving skills, with one thinking that this trend is getting worse over time:

> *With the kids we see coming into high school now, a lot of them lack problem solving skills and the ability to actually figure out how to study and write notes correctly. And I think it's deteriorating.* [Teacher 3, male, 1 year of experience]

He also believed that earlier exposure to Project SOLVE-NZ could be helpful:

> *I think it's even good for kids in a younger setting to have a look at it early on, so that when they go to high school, they already have some familiarity with the skills.* [Teacher 3, male, 1 year of experience]

Teachers, in general, endorsed ongoing use of the interventions throughout the school year. For example:

> *I would say it needs to be an ongoing program. [Project] SOLVE is fabulous, but what's next? Are they reminded to use it again? What's the prompt for them to use it each time they have a problem? It needs to be in your face. Like it needs to be something that's not just going to disappear. Something that's a bit regular and talked about.* [Teacher 4, female, 12 years of experience]

Appropriateness of Pedagogy—"I thought it was a neat approach"

For the most part, students and teachers had positive experiences with how the interventions taught problem-solving and study skills. Specific strengths included the overall layout, which teachers considered would be effective and engaging for their students:

> *I thought it was really well done, honestly. I thought it was a neat approach to something that's not necessarily that easy to talk about without either being boring or repetitive and saying the same thing. I really like that. It gives them options to choose from, and*

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> *they have to think about what they're doing.* [Teacher 6, female, 3 years of experience]

Participants also liked the use of multiple-choice and short-answer questions to break down the content in a digestible way:

> *I liked how there was a mix of like multi choice and short written response questions. Because I think that the shorter the response, the better it is for the younger kids. And even though they had to think for the answers, they didn't have to write a paragraph explaining it—they could just fire down whatever was in the top of their mind ... Otherwise they're like "Oh my God, how much do I have to write?"* [Teacher 5, female, 10 years of experience]

Students enjoyed practicing the skills by helping fictitious young people with their problems: "I liked how they put us in the shoes of the characters, and we could answer the questions from their perspective" (Student 1, female).

Teachers liked the selection of exemplar problems, commenting on how students could cater the intervention to their specific interests or needs:

> *It was kind of like that Bear Grylls show where you can choose the ending. It gives them some agency, which I thought was cool, because they can see how the decisions that they make are going to impact the way that they solve a problem. And it gets them thinking, which is always good.* [Teacher 6, female, 3 years of experience]

Finally, one student liked the privacy of a tool that is online and self-guided: "There's more privacy. You're able to open up and share what you're going through" (Student 6, female).

The only negative feedback regarded difficulty remembering content from the interventions. For example, students retained the general underpinnings of Project SOLVE but struggled to recall what each part of the acronym stood for. This difficulty was foreseen by teachers:

> *The content is really good, and I definitely agree that it's super important to get out to them. It's just, how do you get them to retain it and not just have it fly out of their mind.* [Teacher 2, female, 1 year of experience]

> *They're probably not going to remember 80% of what goes on in the middle of the activity, but if they can take away the acronym—a step-by-step breakdown about how they could solve their problems—then they could reflect on it and use it when those issues and conflicts present themselves in their day to day life.* [Teacher 8, male, 4 years of experience]

Theme 3: Delivery of Interventions in Schools

Feasibility of Digital Delivery—"Most of our lessons are supposed to be designed around technology now"

The majority of students preferred doing activities online (11/12), and teachers said that most schoolwork is now delivered digitally. One teacher highlighted how young people's familiarity with and preference for digital content needs to be acknowledged when encouraging help-seeking behavior:

> *Yes, [students] need tools and things to deal with people and have social relationships in person, but a lot of who they are is online ... I think something like [these interventions] are a really good "can opener" for those kids. They need to find something to open themself up to what they're really feeling. How could they cope with it? What could they do?* [Teacher 7, female, 16 years of experience]

More practically, most teachers had few concerns about students' access to digital devices to complete the interventions:

> *There would be no issues with [access to devices] at our school. There's so much funding for devices now, and so much of the teaching we do needs a device. So I would say nearly all schools would have access to them.* [Teacher 3, male, 1 year of experience]

However, one teacher recounted her difficulty with online activities and cautioned that some schools may have limited internet access:

> *At [my current school], we're now fully BYOD, so every kid has a device ... But not all schools have internet access. At [my previous school], I was in a classroom and wanted to watch a video, but the students said, "No, you can't do that in this classroom. The internet is too bad."* [Teacher 5, female, 10 years of experience]

Appropriateness of Classroom Setting—"They say they'll do it at home, but they won't"

The majority of students (10/12) preferred to complete the activities at school, rather than at home. These students felt a class setting would be more conducive to their engagement and understanding:

> *I feel like you're also more likely to do it properly and then remember it later on in the day if you get too overwhelmed. If you're just like, "Oh yeah, that thing I learned a couple hours ago, I can use it here."* [Student 1, female]

Students also noted how help is more easily accessible in a class setting, and there tend to be less distractions in class than at home:

> *There're no distractions at school, and it was helpful to have other people around me.* [Student 6, female]

> *If I needed help, I could just look over at my friends' work, and, at school, you don't have dramas with anybody ... you don't have people coming in and out of your house all of the time distracting you.* [Student 2, female]

In contrast, 2 students felt as though their engagement with the interventions would be better at home: "There is more discipline at home, so I would be able to concentrate on it better" (Student 4, female).

All teachers believed that it would be better to complete the interventions in class, noting that some students would not

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appropriately engage with the interventions outside of school hours, if at all:

> *They won't [do it at home]. They say they'll do it at home, but they won't. Maybe one might. One or two, and it'll be as a very specific type of kid.* [Teacher 1, male, 23 years of experience]

The majority of students (10/12) agreed that they were unlikely to do it at home without teacher instruction ("I'm just not gonna do it at home" [Student 11, male]) or because their home lives are busy with other priorities ("I've got chores to do [instead]" [Student 5, female]).

The Challenges of Self-Guided Interventions

The self-guided nature of the intervention received mixed reviews. Students noted how they felt their class was more settled and engaged than usual when completing the interventions: "It was really quiet, and there was nothing flying around" (Student 2, female).

Additionally, most teachers thought that self-guided activities would be appropriate for their students. For example:

> *I don't think it would be an issue for our boys to be led by themselves. I think they're used to doing that, so I don't see that as being a problem ... There might be some students that struggle to get started, but you would just go and work with them one-on-one.* [Teacher 6, female, 3 years of experience]

> *I'm a big fan of group work ... but I think when you're trying to get strong outcomes, it's quite difficult to get that in a group setting, and so I think getting kids independently to work through it with headphones would be a really good way of doing that.* [Teacher 8, male, 4 years of experience]

However, teachers were also conscious that the success of self-guided interventions may vary between schools and within classroom settings:

> *Sometimes you'll have a super academic class who would absolutely thrive in those surveys, and sometimes you'll have people who can't sit still for 10 minutes in the class.* [Teacher 2, female, 1 year of experience]

The Role of Voiceovers—"It helped us understand more"

All students reported that the voiceovers were helpful. For example:

> *[The voiceovers] were actually really helpful because sometimes I just can't be bothered reading, so I multitask, and I listen to it and do the work at the same time.* [Student 2, female]

Another student explained that the voiceovers helped her understand the content better:

> *I feel like if we were to read it, we would just skim through it ... We would not really take it in. The voiceover was slow, and it helped us understand it more.* [Student 1, female]

Teachers also endorsed the inclusion of voiceovers, noting the low literacy of many *rangatahi* in New Zealand and how this can impact learning:

> *Literacy is terrible ... so I think listening to it is definitely a lot better. Some kids will read it and be able to read it fast as, but a lot of kids, especially if it's aimed at Year 9s and Year 10s, would definitely want to listen to it.* [Teacher 3, male, 1 year of experience]

> *I think you definitely would have engaged them more by having someone talk to them, rather than them just sitting there trying to read the same thing 100 times because it doesn't make sense.* [Teacher 2, female, 1 year of experience]

Experiencing an increase in neurodivergence among her students, one teacher also felt that the voiceovers would be crucial to accommodate learning differences:

> *There's a massive amount of dyslexia coming out now as well. [The voiceover] just helps take away that struggle that can hinder them from actually trying, because "Oh, I've gotta read all this stuff," or "I don't know how to read it, so I don't know how to respond."* [Teacher 7, female, 16 years of experience]

Theme 4: Suggestions for Improvement

Overview

Participants were asked how the interventions could be improved. While students did not suggest any improvements, teachers believed that getting students to "take [the interventions] seriously" would be the biggest challenge:

> *I think the only challenge will be how can we make sure that everyone's going to take it seriously? Because obviously some people will really like it—that's the same with everything—but how do we make sure everyone gets the most out of it they can?* [Teacher 3, male, 1 year of experience]

These concerns in mind, teachers suggested improving student engagement through (1) increasing the cultural and gender representation throughout the interventions, (2) adding more visual and literacy aids to supplement paragraph text, (3) engaging in *whakawhanaungatanga* with students, and (4) providing adequate support to teachers so they can confidently implement the interventions.

Increasing Diversity—"To better reflect our makeup"

Teachers felt that the interventions could better represent the diversity of classrooms in Aotearoa. As mentioned previously, teachers believed that having a boy character to accompany *Māia* may increase the engagement of male students. One teacher also noted room for increased cultural representation in the interventions.

Adding More Visual and Literacy Aids—"A range of learners"

As mentioned previously, teachers liked the content of the interventions but felt that students may struggle to remember the skills. Teachers suggested that more visuals or animation

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throughout the interventions might help students better grasp the concepts:

> *I find that having more visuals for them to latch on to probably would help them remember a bit better, particularly with the range of learners that might be neurodiverse and can't sort of engage so much with the text version, they might be able to engage more with the visual aspect of it.* [Teacher 8, male, 4 years of experience]

Additionally, one teacher also noted that a shorter video in Project Success-NZ could be more effective: "The only thing was that I did find the video a bit boring, but that might just be my ADHD brain ..." (Teacher 4, female, 12 years of experience).

Students also discussed ways to remember the skills, with most students liking the idea of a follow-up email reminder or a poster displayed in their classroom. One student took a photo of the SOLVE skill so she could remember it; others said it would have been helpful if their teacher prompted them to do so. No student thought that a handout would be helpful, with most believing "a paper [reminder] is just going to get lost" (Student 1, female).

In terms of literacy concerns, teachers praised the inclusion of voiceovers, but one suggested further addressing literacy challenges by adding definitions:

> *Literacy and reading are terrible, so even if you think there's a word that might be a little bit complicated for them to understand, you could always have a little definition at the bottom as well.* [Teacher 3, male, 23 years of experience]

Another teacher believed that it would be helpful for the word to be highlighted as the voiceover is playing:

> *Some students have got such low literacy, so the voiceovers were fantastic. And as the voiceover is voicing, it could even be good to highlight each word. That would be very helpful for students too, especially ESOL students.* [Teacher 4, female, 12 years of experience]

Engaging in Whakawhanaungatanga—"Relationships are the most important thing"

Many teachers felt that student engagement would rely on the strength of the relationship between the class and the teacher delivering the intervention: "I think if the teacher has some good rapport or a good relationship with the learners they will buy into it more" (Teacher 8, male, 4 years of experience).

Another teacher commented how relationship building or *whakawhanaungatanga* is especially important at schools with high Māori and Pasifika populations "because relationships are the most important thing at a school like this to ensure [the students] actually care" (Teacher 2, female, 1 year of experience).

Providing Teacher Support—"The teacher knows the students best"

As future champions of these interventions, teachers felt that a support resource could be helpful in increasing student engagement. One teacher noted:

> *I think engagement comes down to the attitudes of the students a little bit, which you have to push as a team—as teachers. But if the teachers are educated—if there's some teaching before it and the boys understand, or the students understand what the point of it is—then it might work better.* [Teacher 3, male, 1 year of experience]

Another teacher commented how it might be helpful for teachers to know more about the interventions and what they are (and are not) designed to target:

> *Maybe you could develop [that support piece] and be like, "Well, you know, this is the realm of sort of 'normal problems.' But some people might be experiencing things outside of this, and if that's the case for you, that's okay. Here's some other things that you can do."* [Teacher 6, female, 3 years of experience]

Teachers also felt that there would need to be flexibility in delivery, providing teachers with delivery options so they can cater to the specific needs of their class or individual learners:

> *I don't think you could just give them something and say, "This is how you're going to teach it." I think there would need to be options and for teachers to be able to put their little twist on it because, at the end of the day, that is the teacher that has built the relationship and knows those students the best.* [Teacher 2, female, 1 year of experience]

For example, one teacher felt as though small groups, rather than self-guided, would work best for his class:

> *I find that one of the secrets to engagement is getting them talking about it. If you can get them talking, you're kind of winning ... I feel that could be done with your activity. I think the ideal thing would be the students in small groups, and they'd be discussing it.* [Teacher 1, male, 23 years of experience]

Although beneficial in general, it was also noted that the helpfulness of a support resource may be dependent on the experience of the teacher:

> *Maybe for the first-year teachers, [a support resource] would be really beneficial ... but with more teaching, you'd know what you're wanting out of the kids, and I would feel confident just doing [the activities] off the cuff.* [Teacher 5, female, 10 years of experience]

Discussion

Principal Findings

This study explored the experience of students and teachers with 2 digital SSIs: Project SOLVE-NZ and Project Success-NZ.

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Participants reported that the adapted interventions felt relevant for *rangatahi* in Aotearoa New Zealand, liking the character of *Māia*, the selection of vignettes, and the inclusion of *te reo Māori*. Participants also felt that both interventions would be valuable for a broad range of students by building their skills and supporting their mental health and may be especially helpful for youths experiencing socioeconomic hardship. Students and teachers agreed that the interventions would be best delivered in class, with fewer distractions and greater access to technology than most homes or other settings. Teachers provided some suggestions on increasing student engagement with the interventions, namely, through increased cultural and gender representation, visual and literacy aids, *whakawhanaungatanga*, and teacher guidance. Overall, participants viewed both interventions as acceptable, appropriate, and useful for *rangatahi* in Aotearoa New Zealand while identifying further adaptations to consider before an RCT of Project SOLVE-NZ nationwide.

Comparison With Prior Work

At present, the body of literature on digital SSIs is emerging and primarily focuses on their potential utility as mental health support for young people. While the results of these studies have been favorable, the bulk of research has been conducted with American youths, making it unclear whether digital SSIs have utility in other parts of the world. This study sought to adapt existing digital SSIs for use among *rangatahi* in Aotearoa, using feedback from students and teachers. A similar study was conducted by Wasil et al [51] with students and teachers in India; however, these digital SSIs focused on gratitude, growth mindsets, and behavioral activation. Interestingly, the Indian students and teachers commented on different aspects of their digital SSIs to the New Zealand participants in this study. For instance, Indian teachers largely focused on how the content of the SSIs could be improved (eg, including neuroscience concepts), while our New Zealand teachers were more concerned about optimizing the interventions' delivery (eg, ensuring that teachers had enough flexibility to accommodate their learners). Furthermore, the Indian students were seemingly forthcoming with ways to improve their digital SSIs (eg, how to make the vignettes more relatable), whereas the New Zealand students made no suggestions for improvement and claimed to be accepting of the interventions as is. On the one hand, this finding may suggest that Project SOLVE-NZ and Project Success-NZ are particularly well suited to the New Zealand context. On the other hand, it is possible that the *rangatahi* in this study did not feel comfortable voicing their suggestions for or criticisms of the interventions. Indeed, the majority of students in this study identified as Māori or Pasifika, and these communities have been historically harmed by Western psychological research practices and individuals of European descent (of which MTB is) [43-46]. Therefore, it is possible that the *rangatahi* in this study felt subject to a relational power dynamic in which criticism would be unacceptable.

Recommendations

Based on our participants' experiences, below are recommendations for researchers and developers of digital interventions for adolescent mental health.

Involve Rangatahi and Relevant Stakeholders in the Design Process

Researchers should work directly with *rangatahi* to ensure that the intervention meets their needs, as the youths in our study identified several areas for further adaptation that had not been considered by academics or teachers. In addition, engaging relevant stakeholders—such as teachers, parents, and coaches—can provide useful collateral information about the needs of *rangatahi* and potential challenges related to implementation.

Consider How the Intervention Will Be Implemented

Implementation success is likely to vary depending on factors such as the suitability of the environment in which the intervention is delivered (eg, school vs home), the relationship between the implementer and the *rangatahi* (such as researcher-*rangatahi* vs teacher-*rangatahi*), and the design of the intervention itself (for instance, a single session vs repeated engagement).

Ensure the Intervention Accommodates a Range of Cognitive Abilities

This may include providing a voiceover option, defining complex words, supplementing text with photos or videos, keeping the intervention to approximately 20-30 minutes where possible, and following up with brief content reminders, such as sending *rangatahi* a graphic summarizing what they learned.

Ensure the Intervention Reflects the Diversity of Rangatahi Today

If characters are used, offering options that represent a range of gender identities and cultural backgrounds is beneficial. In addition, developers should aim to balance representations of Indigenous cultures with those of other historically marginalized communities or cultural minorities.

Strengths and Limitations

This study provided in-depth qualitative data on the experiences of *rangatahi* and teachers with Project SOLVE and Project Success. In analyzing participant responses, we were able (1) to deduce the acceptability, appropriateness, and utility of Project SOLVE-NZ as a digital SSI for adolescent mental health in Aotearoa New Zealand and (2) to establish whether Project Success-NZ would be a comparable active control condition in a future RCT of Project SOLVE-NZ nationwide.

Nonetheless, this study has some notable limitations. The sample of participants was gender balanced; however, all students were sampled from one low-socioeconomic school in New Zealand. Consequently, the sample of students consisted mostly of Māori and Pasifika young people, who are presumed to come from low socioeconomic backgrounds. This school partnership was purposeful; we wished to co-design Project SOLVE-NZ and Project Success-NZ with the *rangatahi* who likely have the most therapeutic need and potential benefits from a low-cost and low-resource intervention. Indeed, some of the students believed that the interventions would be particularly helpful for Māori and Pasifika youths; however, they also endorsed the use of the interventions across schools in New Zealand. The teachers

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in this study shared a similar sentiment, with some highlighting the applicability of the interventions to Māori and Pasifika youths, specifically, and others citing the potential benefits of the interventions to youths regardless of their cultural identity or socioeconomic status. That said, future research is needed to confirm how other young New Zealand people—of wide-ranging ethnic and socioeconomic identities—experience these interventions.

It is also possible that participants demonstrated social desirability bias in the interviews, concealing their criticisms about the interventions to please the interviewer. Attempts to mitigate this bias were made, with MTB having no prior connection to the students and encouraging honesty throughout the focus groups. However, as mentioned previously, no student made a suggestion on how the interventions could be improved and may have felt voicing criticism was unacceptable. Students may have also had limited insights into improving the interventions, as problem-solving and study skills appeared to be relatively new concepts. MTB knew 2 of the teachers whom she interviewed, but it was noted that these teachers provided constructive feedback and suggestions on improving the interventions going forward. Future research could use anonymous self-report questionnaires to gather additional data on students' experiences.

MTB checked that all students completed the interventions before their focus group interview; however, there was no assessment of whether the interventions were completed appropriately (eg, checking the quality of a student's response to the intervention questions). Therefore, it is possible that some students participated in the focus group without engaging with the interventions as the researchers intended. Looking ahead, it will be crucial to examine the quality of engagement with Project SOLVE-NZ and Project Success-NZ in order to obtain a valid indication of their effects on *rangatahi* mental health.

Finally, there is an opportunity for greater involvement of *rangatahi* in the development of these interventions and others similar. While this research integrated elements of co-design (ie, attaining user feedback to guide future adaptations), "true" co-design would develop a problem-solving intervention with *rangatahi* from the ground up. Indeed, earlier involvement of *rangatahi* may better guide the framing and pedagogy of an intervention, which could lead to greater skill development and mental health outcomes. True co-design with diverse *rangatahi* may also highlight needs and considerations that are specific to certain groups (eg, accessibility concerns for students with learning challenges).

Conclusions

Digital SSIs are a promising means of closing the treatment gap in mental health care. Our findings suggest that Project SOLVE-NZ, an adapted 30-minute digital SSI that teaches problem-solving skills, is acceptable and appropriate for youths in Aotearoa New Zealand and was perceived to have potential benefits to youth mental health. Additionally, we found evidence that Project Success-NZ, a comparable digital SSI that teaches study skills, was also well received. Overwhelmingly, *rangatahi* and their teachers endorsed the use of Project SOLVE-NZ and Project Success-NZ in high schools across New Zealand, citing perceived benefits to adolescents from diverse cultural and socioeconomic identities. Teachers also provided suggestions on how to enhance student engagement with the interventions in the future.

Beyond Project SOLVE-NZ and Project Success-NZ, our findings suggest that digital tools for youth mental health may benefit from involving *rangatahi* and relevant stakeholders in the design process. This involvement could support researchers to build interventions that appeal to *rangatahi*, accommodate a range of cognitive abilities, represent diverse identities, and overcome the challenges of implementation [42,53-55]. Informed by this study, we look forward to examining the effects of Project SOLVE-NZ and Project Success-NZ on *rangatahi* mental health outcomes in the future.

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Authors' Contributions

MTB performed the study procedures under the supervision of NS and AB. HM served as supervisor and cultural advisor.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Translation of te reo Māori words.
[DOCX File , 17 KB - formative_v10i1e81259_app1.docx]

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Abbreviations

BOYD: Bring your own device
CEF: Cultural Enhancement Framework
LGBTQIA+: lesbian, gay, bisexual, transgender, queer, intersex, asexual, and other diverse sexual orientations, gender identities, and sex characteristics
RCT: randomized controlled trial
SSI: single-session intervention

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Original Paper

Developing a Customizable Texting Intervention for Diabetes Self-Management: Participatory Design Approach

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Abstract

Background: Uncontrolled diabetes contributes to serious comorbidities and mortality. Effective self-management can improve outcomes, though barriers such as limited education and support often prevent patients from engaging in such behaviors. Automated texting systems show promise to deliver diabetes self-management education as they are accessible and scalable. Furthermore, customizing these systems may further enhance patient engagement compared to standard, one-size-fits-all approaches. However, such customization is more resource-intensive, and it remains unclear whether the added effort meaningfully enhances diabetes self-management and outcomes.

Objective: This study aimed to describe the development of 2 versions of an automated texting system intervention for diabetes self-management: (1) a standard, education-only intervention (Diabetes Self-Management Support; DSMS) and (2) an interactive, customizable intervention (Diabetes Self-Management Support + Interactive and Customizable Messages; DSMS+).

Methods: Two versions of an automated texting system intervention were developed using a participatory design approach that incorporated input from veterans and expert clinicians. Message content was refined through feedback from a multidisciplinary team, veteran coinvestigators, national surveys, interviews, clinical expert panel reviews, and beta testing. Surveys were mailed to 1000 potential participants, oversampling rural, low-income, minority, and female participants. Respondents rated message relevance and provided preferences for content, timing, and frequency. Interviews provided customization preferences. A clinical expert panel reviewed all messages for safety and appropriateness. Beta testing informed final refinements.

Results: Ninety-two surveys were completed (9.2% response rate). Respondents rated 62% of the messages as personally relevant and 61% confidence-enhancing. Interviews with 23 respondents revealed a preference for 1-2 texts per day, emphasizing topics such as healthy eating and weight management. The clinical expert panel reviewed 536 messages, flagging 81 for revision.

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Beta testing confirmed feasibility and informed refinements to clarity and timing. The 2 resulting interventions were built in the US Department of Veterans Affairs' automated texting system, Annie.

Conclusions: Two text messaging interventions, DSMS and DSMS+, were developed to support diabetes self-management among US veterans. DSMS delivers standard educational content, while DSMS+ incorporates interactive features and personalization. The subsequent clinical trial will assess whether customization enhances engagement and improves diabetes outcomes, providing insights into the potential of tailored mobile health interventions for chronic disease management.

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KEYWORDS

text messaging; type 2 diabetes; veterans; mobile phone; self-management

Introduction

Background

Diabetes is a serious chronic health condition that can exacerbate multiple comorbidities and increase the risk of death [1]. This disease affects nearly 15% of US adults and almost 25% of US veterans [2,3]. Furthermore, diabetes is disproportionately prevalent in minority groups and in those from low socioeconomic status, particularly males from minority groups and females from low socioeconomic status [4]. Effective diabetes self-management behaviors, such as healthy eating, exercise, medication adherence, and glucose control, can significantly improve health outcomes and quality of life [5,6]. There is evidence that programs such as self-management interventions and diabetes education may improve outcomes. However, there is a need to increase the reach and sustainability of these programs [7].

Automated texting systems (ATSs) have become more popular as a delivery method for diabetes self-management education for several reasons [7]. For one, they have demonstrated effectiveness in promoting a wide range of healthy behaviors [8-10] across a range of diseases, such as HIV, chronic obstructive pulmonary disorder, cardiovascular disease, and asthma [11]. ATS can reinforce healthy behaviors by providing reminders and offering disease education, resulting in improved outcomes [12-14]. One meta-analysis reported significantly better glycemic control post-ATS intervention [15]. Additionally, given the ubiquity and relatively low cost of cell phones compared to more complicated digital health interventions, ATS likely do not require as much digital literacy and they are relatively accessible and scalable [7].

The US Department of Veterans Affairs (VA) has a proprietary ATS, called "Annie," named after Veteran Annie Fox who was the first nurse to be awarded a Purple Heart. VA's Annie is a disease-agnostic SMS texting system that can send 1-way messages and receive and respond to patient messages if the messages follow specific syntax. Responses to 2-way messages use rule-based branching logic [16,17]. Previous research has shown that Annie improved patient self-management for the hepatitis C virus [16]. Annie has also been used to deliver educational content related to COVID-19 (precautions and monitoring symptoms). Veterans reported that receipt of Annie's messages prevented them from contacting VA by phone, secure message, or visiting, thus saving VA resources [18]. Messages from an Annie intervention for caregiver stress management resulted in caregivers reporting that they felt more cared for and more confident [19]. Annie has also been leveraged to be customized to the needs of specific subgroups, such as hypertension management in African American veterans [20]. While there are currently thousands of veterans actively using Annie, this is just a small percentage of US veterans and work is needed to understand how to make these systems as engaging as possible so that users will want to adopt and continue using them.

Customizing the text messaging intervention can increase its impact by addressing individual needs and preferences. Tailoring content and timing to each patient's unique circumstances, such as their current knowledge level, specific challenges and schedules, and personal goals, makes interventions more relevant and engaging. Personalization fosters greater autonomy and empowerment, increasing the likelihood of active engagement and adherence to self-management strategies, ultimately improving health outcomes [21]. Past implementation evaluations of Annie found that the ability to tailor ATS content and timing encouraged patient use and enhanced patient autonomy [17]. While a customized intervention can be resource-intensive to develop, the effort may be worthwhile for patients needing more individualized support. In contrast, a standard intervention may be less resource-intensive and easier to implement at scale, but it may not fully address the unique needs of each patient, potentially limiting its effectiveness for those with diverse or complex challenges. Indeed, a recent review suggests that ATS programs with daily messages and additional features to support customization were more effective in diabetes outcomes than interventions that had infrequent, fully automated messages [7]. A recent systematic review and meta-analysis of tailored text messaging interventions for type 2 diabetes highlighted significant limitations in prior studies [12]. Specifically, most previous work has tested these personalized interventions in high-income settings and among patients with relatively well-controlled diabetes. These populations are less likely to represent those who could benefit most from additional support.

Current Study

This study details the development of 2 versions of a text messaging intervention for diabetes self-management that are uniquely focused on developing content designed to be tailored to US veterans who face greater challenges in achieving glycemic control, particularly in more diverse and underserved settings. The first version is a standard, education-only intervention. The second is an interactive, customizable texting

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self-management intervention developed through a participatory design process that incorporates veteran preferences, clinician input, and evidence on effective texting self-management modules. This study details the development of these interventions as part of a larger study aiming to compare the effectiveness of these 2 interventions on diabetes control.

Methods

Platform

The Annie texting system is a mobile messaging service designed to support veterans by sending automated, health-related text messages [22]. These messages provide reminders, education, and encouragement for managing various health conditions, including diabetes, to promote better self-care and adherence to treatment plans. Annie can send 1-way messages, which do not solicit a response, and 2-way messages, which ask the user to respond (Figure 1). The timing and content of messages are flexible. Each message is capped at 160 characters and must include "Annie" as an identifier. Short URLs can also be incorporated. For 2-way messaging, responses must be closed-ended and preprogrammed into the system using keywords.

Figure 1. Sample messages from the 2 diabetes self-management automated texting system interventions, developed for the Annie platform within the Veterans Health Administration. Panel A shows sample 1-way educational messages. Panel B shows sample 2-way messages between the automated texting system and the patient.

Below we describe our participatory design approach to developing 2 versions of a text messaging intervention in Annie within the US Veterans Health Administration: a standard Diabetes Self-Management Support-Only Intervention (DSMS) and a customizable, patient-centered intervention (DSMS+); refer to Figure 2. Intervention development drew on the Behavior Change Technique Taxonomy (version 1.0), which integrates overlapping behavioral theories, including Social Cognitive Theory and Self-Determination Theory. These theories discuss the association between patient autonomy, intrinsic motivation, and self-efficacy to support patient engagement and health outcomes [13,23,24]. Text messages were initially drafted by a multidisciplinary research team and then iteratively refined through feedback from veterans and a clinical expert panel review. The final DSMS and DSMS+ interventions were programmed into the Annie texting system by the study team, reviewed for programming errors by the VA Office of Connected Care staff, and finalized. Veterans' feedback was gathered throughout the development process from veteran coinvestigators, surveys, qualitative interviews, and beta testing.

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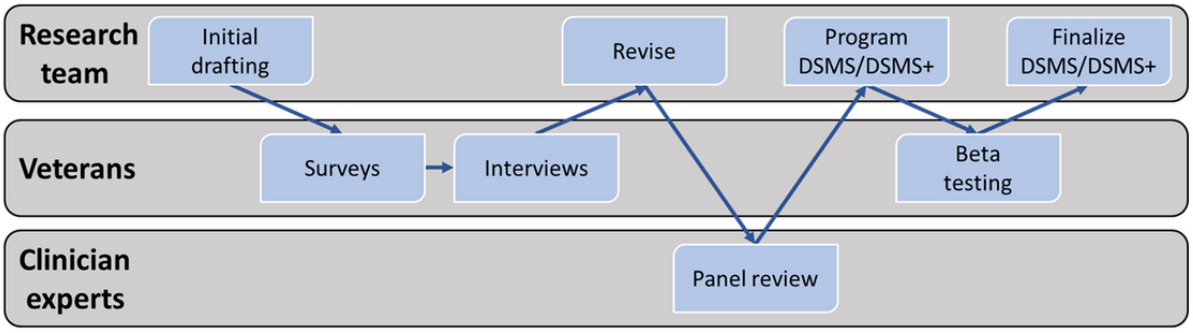
Figure 2. Diabetes self-management automated texting system intervention development stages and stakeholder involvement. The research team included health services researchers, veteran coinvestigators, and clinicians. Veterans included Veterans Affairs patients living with diabetes. Clinician experts included Veterans Affairs and non-Veterans Affairs clinician experts, of which 4 were on the research team. DSMS: Diabetes Self-Management Support-Only texting intervention; DSMS+: customizable, patient-centered version of DSMS.



Initial Drafting

A multidisciplinary team worked together to draft text messages for use in the 2 versions of our interventions. This team included health services researchers, clinicians, and veterans living with diabetes ("veteran coinvestigators"). Our team met weekly to develop and review the text messages, identify the most relevant and appropriate ones, and iteratively edit them for character count and content.

Text message development for both DSMS and DSMS+ began with modules outlined in standard diabetes educational materials. Initial message and content creation used established diabetes guidelines from updated VA and Department of Defense Self-care Skills for Patients with Diabetes [25], the Association of Diabetes Care and Education [26], and existing Annie protocols (Weight Management Protocols, Blood Glucose Monitoring, and the Blood Pressure 2-way messaging protocols [20]). Most of this content centered on disease education and encouragement to be an active member of the health care team. Our team collated and linked resources to educational materials from the National Institutes of Health, Centers for Disease Control and Prevention, Mayo Clinic, Veterans Health Administration, Food and Drug Administration, American Diabetes Association, US Department of Agriculture, Association of Diabetes Care and Education Specialists, and Department of Health and Human Services. These links were added to relevant text messages. In the end, we developed 160 messages designed to be delivered over the 6 months of the study period. All messages were written aiming for a 5th-grade reading level as recommended by the Joint Commission [27,28].

As part of the research team, veteran coinvestigators were invited to help design the Annie interventions. Three veteran coinvestigators were recruited through VA clinics from 2 VA facilities, though one later dropped out due to timing difficulties. To be eligible, veterans needed a diagnosis of type 2 diabetes and current care through the VA health system. As working members of the research team, veteran coinvestigators were offered hourly compensation for their time. They provided initial feedback on whether the texts were motivating, useful, or needed removal or rewording. Their insights on veteran culture, living with diabetes, and the phrasing and delivery of the messages were invaluable. They also wrote some messages for the "Vet Tips" module to be delivered to other veterans living with diabetes.

Survey

National feedback from veterans was obtained via surveys. Veterans living with diabetes who owned cell phones were identified using the VA Corporate Data Warehouse, which provides centralized electronic health record data across all VA facilities nationwide. To ensure adequate representation from populations that are often underrepresented in veterans research and disproportionately affected by diabetes, we purposefully oversampled women, rural, minority and low-income veterans. This oversampling captures perspectives from those facing unique barriers to care and self-management, thus improving generalizability. We initially selected 400 participants, oversampling women, Black, rural, low-income veterans, and patients with a mental health diagnosis within the last 2 years. Low income was identified as the bottom quartile of the median household income, identified by ZIP code areas, as reported in the American Community Survey conducted in 2019 [22]. Due to lower responses from Black, low-income, and those with mental health diagnoses, we oversampled these groups by adding 600 more potential participants. Our final list of 1000 was 25% female, 40% Black, 25% rural, 40% low income, and 41% had a mental health diagnosis within the last 2 years.

Eight versions of the survey were developed, each containing different randomly selected text messages. Surveys were randomly sent to the final list of 1000 potential participants and administered between June and November 2021. They reported their demographics and previous engagement in text messaging. They also rated their comfort across 13 technology-related behaviors (eg, checking email and using the internet) on a scale from 0 (not at all comfortable or confident) to 5 (very comfortable or confident), with an option to indicate "not applicable." Scores on comfort levels (scored from 0 to 5) were averaged across behaviors.

Participants were asked about their preferences for message timing, frequency, and topics (eg, reminders for checking blood sugar and blood pressure, physical activity tips, diabetes coping, healthy eating, etc). They also rated their confidence across 10 diabetes self-management behaviors on a scale from 1 (totally confident) to 5 (not at all confident), with an option to indicate

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"not applicable," which was not factored into the mean composite score.

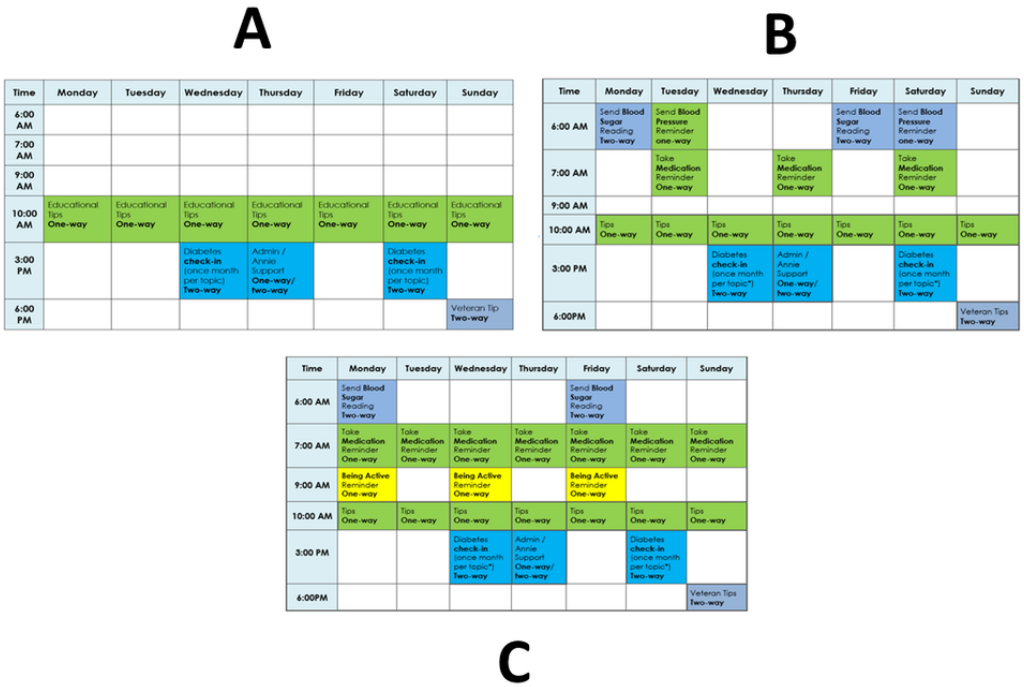
Survey participants were invited to create their own diabetes-related text messages and to react to a set of 25 different messages, indicating "yes" or "no" if they felt the message was personally relevant or made them feel more confident in managing their diabetes. They could also provide edits to messages they did not like. Survey responses were used to refine our messages, design sample calendars, identify questions for follow-up interviews, and select a diverse group of participants for interviews. Participants also had the option to write their own messages for other veterans, offering encouragement, tips that worked for them, helpful information for managing diabetes, or recommended online resources. These messages were combined with ones written by veteran coinvestigators for the Vet Tips module.

Interviews

In-depth interviews (n=23) were conducted to elicit qualitative feedback on text message content, frequency, and timing. Survey respondents who indicated they were willing to participate in an interview were contacted by phone up to 2 times to schedule the interview. The interviews were recorded using Microsoft Teams. There was one main interviewer and one notetaker who filled out a data collection form based on the participants' responses.

The interviews followed the introduction of the proposed text messaging program. Types of text messages (eg, 1-way or 2-way) and sample calendars were shown to participants on the types of text messaging schedules that were available (Figure 3). Participants were asked to rank their interest in example text messages on a scale from 1 (not interested at all) to 5 (very interested) and whether the messages addressed specific struggles in managing their diabetes. They also provided feedback on text messages written by survey participants and on hypothetical messaging schedules.

Figure 3. Sample weekly schedules for Diabetes Self-Management Support + Interactive and Customizable Messages, a diabetes self-management automated texting system intervention, developed for the Annie platform within the Veterans Health Administration. Participants asked which panel they preferred, with each showing a range of frequencies and timing of 1-way and 2-way messages.



Clinical Expert Panel Review

In June 2022, a group of 4 VA and 4 non-VA clinician experts, including 4 members of the research team (SC, VV, HG, and CU), gathered virtually for a clinical expert panel. The panel included physicians and nurse practitioners with expertise in endocrinology, primary care, nursing, and obstetrics and gynecology. This panel was tasked with reviewing, rating, and discussing the safety and appropriateness of the text messages to be used in the 6-month randomized control trial. One VA and one non-VA clinician were paired together to review, rate, and discuss 2-3 diabetes-related message topics each. These clinical experts were also asked to independently flag any texts they thought would be problematic from a clinical standpoint. They were all provided with a structured template for feedback and asked to meet with their paired reviewer virtually at another time to discuss any conflicting messages. The experts delivered their final recommendations about which messages to use, drop, or discuss further to the larger team.

Beta Testing

To identify potential beta testers, we randomly selected 50 patients who met the same eligibility criteria as the planned comparative effectiveness trial. Eligibility criteria included being a veteran and active Veterans Health Administration patient with type 2 diabetes (at least 4 outpatient encounters in

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the previous year and a future appointment scheduled), access to a smartphone or cellphone, not hospitalized or institutionalized, did not participate in the text message development survey or interview, had at least 2 hemoglobin A_{1c} (HbA_{1c}) lab values in the 12 months prior to recruitment, and had inadequate glycemic control for at least half of the 6 months prior to recruitment. These eligible participants were invited by mail and then contacted by the study coordinators up to 3 times by phone to further screen for eligibility and interest and schedule a baseline visit. This screening excluded anyone without access to a cellphone or smartphone, those not willing to text, those with visual impairment that would prevent them from reading or replying to text messages, and those with cognitive impairment as identified by the Short Blessed Test [29]. Phone screening took 6-15 minutes to complete.

Of the 50 potential participants, 33 declined, 8 were never reached (7 were left a voicemail and 1 was an invalid phone number), and 9 were screened (all eligible). All 9 eligible were scheduled for a baseline in November-December 2022. Seven participants ultimately enrolled. These participants were assigned to beta test the DSMS+ Annie message subscription, testing the experience of selecting which support messages they wished to receive for a customized experience. Beta testers also completed all trial procedures, such as baseline and follow-up survey completion, to ensure readiness for the larger trial. Veterans were invited to participate in a follow-up interview and 6 chose to do so. Messages were further refined based on their feedback.

Ethical Considerations

This study was approved by the VA Central Institutional Review Board (IRB; Project Number 19-30). The study received an IRB waiver of documentation of informed consent. Survey participants were provided with an information sheet with the mailed surveys. Interview and beta testing participants provided verbal informed consent before interviews and beta testing enrollment. All participants were adults and understood participation was voluntary, meaning they could withdraw at any time and skip any question without penalty. Mailed paper survey data were entered into a VA-approved secure web platform for managing survey data; beta testers were also able to complete surveys electronically so that data were directly captured. Interviews were conducted in Microsoft Teams. Recordings and transcriptions were immediately exported and stored on a server that only IRB-approved research team members could access. All electronic data were stored behind the VA firewall and accessible only to IRB-approved research team members. A unique study ID was assigned to each veteran participant with an identification key kept in a separate file accessible only to team members with a need to access. Participants were compensated with gift cards of US $25 for the survey, US $30 for the interview, and US $50 for beta testing.

Results

Survey

Out of the 1000 surveys mailed, 92 were returned fully completed (9.2% completion rate). We received surveys from 8 to 17 participants per version, totaling 92. Mean age was 64.5 (SD 7.2) years, ranging from 45 to 76 years. Of the 92 respondents, 63.0% (n=58) were male, 42.4% (n=39) African American or Black, and 28.3% (n=26) White. Additionally, 82.6% (n=76) did not consider themselves to be Hispanic or Latino, 67.4% (n=62) lived in an urban area, and 40.2% (n=37) had a bachelor's or associate's degree. More demographic details are listed in Table 1. Regarding familiarity with technology and texting, the majority (84.8%, n=78) reported they had sent or received text messages. Participants' mean comfort in technology was 3.8 (SD 1.6), where a number closer to 0 indicates less comfort and a number closer to 5 indicates greater comfort. Participants' mean confidence in diabetes self-management was 2.08 (SD 0.81), where a number closer to 1 indicates less confidence and a number closer to 5 indicates greater confidence.

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Table 1. Demographic characteristics (N=92) of survey participants for the formative development of 2 diabetes self-management automated texting system interventions designed for the Annie platform within the Veterans Health Administration.

Demographic characteristics	Values
Age (years), mean (SD)	64.53 (7.23)
Sex,[a]n (%)	
Female	34 (37.0)
Male	58 (63.0)
Race,[a] n (%)	
African American or Black	39 (42.4)
American Indian or Alaska Native	11 (12.0)
Asian	3 (3.3)
Native Hawaiian or Other Pacific Islander	12 (13.0)
White	26 (28.3)
Unknown	1 (1.1)
Ethnicity, n (%)	
Hispanic or Latino	7 (7.6)
Not Hispanic or Latino	76 (82.6)
Missing	9 (9.8)
Living area[a], n (%)	
Rural	30 (32.4)
Urban	62 (67.4)
Education, n (%)	
High school graduate or GED[b] or less	18 (19.6)
Some college or vocational school (1-4 years)	24 (26.1)
Bachelor's or associate's degree	37 (40.2)
Master's or Professional school degree	9 (9.8)
Missing	4 (4.3)
Employment, n (%)	
Employed full-time	14 (15.2)
Employed part-time	8 (8.7)
Not employed, looking for work	1 (1.1)
Not employed, not looking for work	0 (0.0)
Retired	38 (41.3)
Disabled, not able to work	36 (39.1)
Missing	3 (3.3)
Relationship status, n (%)	
Married, civil union, engaged, or in a relationship	49 (53.3)
Divorced, separated, or widowed	22 (23.9)
Single, never married or in a civil union	18 (19.6)
Missing	3 (3.3)
Low income[a] (bottom quartile of median household income, identified by ZIP code), n (%)	
No	52 (56.5)
Yes	40 (43.5)

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Demographic characteristics	Values
Perceived difficulty paying for basics like food and heating or cooling, n (%)	
Very hard	7 (7.6)
Hard	6 (6.5)
Somewhat hard	31 (33.7)
Not very hard	38 (41.3)
Don’t know	4 (4.3)
Prefer not to answer	5 (5.4)
Missing	1 (1.1)
Diabetes care location, n (%)	
I get all my diabetes care in the VA[c]	66 (71.7)
I get most of my diabetes care in the VA, with some outside care	14 (15.2)
I get most of my diabetes care outside the VA, with some care in the VA	6 (6.5)
I get all my diabetes care outside the VA	3 (3.3)
Missing	3 (3.3)
Mental health diagnosis within last 2 years,[a] n (%)	
No	47 (51.1)
Yes	45 (48.9)

[a]Data extracted from the VA Corporate Data warehouse, all other data self-reported via survey.

[b]GED: General Educational Development.

[c]VA: Veterans Affairs.

Across all 8 versions of the survey, containing a unique combination of 25 messages, participants rated 62% of the messages as personally relevant. Additionally, 61% of the messages made them feel more confident that they could manage their diabetes (range across surveys: 46.7%-78.8%). The most popular reminder topics were reminders to measure blood sugar, measure blood pressure, and exercise (Table 2). The most popular tips related to managing blood sugar, coping with diabetes, being active, and eating healthy.

Table 2. Frequency of survey participants (N=92) who endorsed specific topics for inclusion during the formative development of 2 diabetes self-management automated texting system interventions developed for the Annie platform within the Veterans Health Administration.

Topic	Participants, %
Reminders	
Reminder to check blood sugar	52.2
Reminder to check blood pressure	40.2
Reminders to take medications	30.4
Physical activity reminder	38.0
Tips	
Tips for managing blood sugar	55.4
Tips for coping	52.2
Tips for healthy eating	51.1
Tips for being active	51.1
Tips for setting health goals	47.8
Tips for managing weight	46.7
Other educational topics	46.7
Tips for managing blood pressure	40.2
Tips for managing medications	38.0

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For each topic, participants were asked to choose how many days per week and at what times they would prefer to receive each message. Respondents could choose a default time (eg, 9 AM or 3 PM), a custom time, or indicate no preference. The majority preferring blood sugar and medication reminders requested customization (56% for blood sugar reminders, 60% for diabetes medication reminders, and 64% for tips on being active). For blood pressure measurement and physical activity reminders, a slim majority accepted the default time (51% for each). Among those preferring tips for being active, 46% chose the default time (3 PM), with other preferred custom times between 10 AM and 12 PM. For tips for managing blood sugar, 73% chose the default option or indicated no preference. Generally, activities that occur at times that vary across individuals (medications and blood sugar checks) were most consistently seen as important for customization, whereas blood pressure measurement and physical activity reminders were less consistently seen as requiring customization. Tips elicited more varied responses; among those wanting a custom time, most preferred between 10 AM and 12 PM. Across all topics, respondents preferred to receive messages "some days" versus "every day," except for the diabetes medication reminder—60% wanted to receive that reminder every day.

Interviews

Rapid analysis captured overall preferences and feedback from participants. Of the 92 returned surveys, 57 (61%) indicated interest in an interview and 23 (25%) completed interviews from December 2021 to March 2022. Among the 23 interview participants, 43% were female (n=10), 40% were African American (n=9), 17% were married (n=4), 35% lived in rural areas (n=8), 26% were retired (n=6), and 52% struggled to pay basic needs (n=12).

Interviewed participants were most interested in receiving text messages on these topics: tips for healthy eating and weight management, tips from other veterans, blood sugar testing, physical activity, and preventive care reminders. They were least interested in messages related to diabetes medication and blood pressure reminders. Participants were presented with 3 hypothetical calendars showing possible timing and frequency and were asked to provide feedback on their preferred option (Figure 3). Most participants preferred Calendar A (n=12), which had the lowest frequency of messages per week. The majority indicated a preference for 1-2 text messages sent per day. Preferences for the timing of 1-way text message reminders (eg, taking medication) were found to be very specific to the individual.

The findings of these interviews directly informed the design of the protocol for the DSMS+ intervention version, allowing participants to customize their automated texting system protocol based on their interests (eg, healthy eating, weight management, physical activity, and preventative care) and to determine the timing and frequency of the messages.

Expert Panel Review

A total of 536 messages were reviewed by 4 pairs of clinical experts. They reviewed 113 messages from existing Annie protocols, 299 messages (1-way), and 124 messages (2-way; prompts and responses from Annie based on participant responses). Overall, experts changed or rewrote 68 messages, flagged 4 messages for removal, and flagged 9 messages to be removed if the participant became pregnant while interacting with Annie. The messages flagged for removal related to type 1 diabetes or urine ketones (eg, "ANNIE-DM: Check urine or blood ketones if you have repeated blood sugars over 250 mg/dL. Call your provider if your ketones are high - they can make you sick."). Messages flagged for pregnancy concerns were related to weight management or exercise recommendations (eg, "Annie-DM: Make it a goal to be active every day! Don't go more than 2 days without activity. https://go.usa.gov/xHwaG"). Further details on how many messages were changed, flagged, and removed are in Table 3.

Table 3. Results from expert panel review of text messages during the formative development of 2 diabetes self-management automated texting system interventions designed for the Annie platform within the Veterans Health Administration.

Action taken	Existing Annie protocols	1-way messages	2-way messages	Total messages
Rewritten	15	49	4	68
Flagged to be removed for all	1	3	0	4
Flagged to be removed for pregnancy concerns	1	4	4	9

Beta Testing

Beta testing highlighted several important considerations for ensuring a successful interactive texting experience. We recognized the need for users of the final protocol to practice responding to Annie with the correct format during enrollment. Opportunities to improve message clarity were identified. In particular, some participants answered messages that included rhetorical questions, triggering an automated error message in return. Thus, messages were reworded to avoid such questions. For example, "Take off your shoes and socks! Do you notice any changes to your feet? Cuts, sores, swelling or red spots are harder to heal with diabetes." was reworded to "Take off your shoes and socks! Notice any changes to your feet. Cuts, sores, swelling or red spots are harder to heal with diabetes."

New outreach messages were created to address free-text responses. The messages reminded participants they could call their coordinator to change text message frequency and that their text replies were not monitored. Beta testing prompted us to add more flexibility to the timing of messages. Because some participants requested reminders at different times on different days of the week (eg, weekends vs weekdays), we made it possible for Annie to accommodate this.

Overall, beta testing results supported the acceptability of DSMS+. Participants appreciated the opportunity to change frequency, timing, or topics of texts, though they never took

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advantage of this opportunity during beta testing. Beta testing informed the final development of DSMS and DSMS+.

Final Texting Protocol Description

Final components of the 2 versions of the Annie automated texting system interventions, DSMS and DSMS+, can be seen in Table 4. Receipt of the intervention requires a smartphone or cell phone and will occur over 6 months. DSMS+, by nature, will be customized to the participant's preferences and needs through a baseline visit questionnaire. A member of the research team will then implement the customizations.

Table 4. Intervention elements included in the 2 diabetes self-management automated texting system interventions developed for the Annie platform within the Veterans Health Administration.

Intervention element	DSMS[a]	DSMS+[b]
Start (practice) message	Yes	Yes
Educational messages	Yes	Yes
Hyperlinks to relevant resources	Yes	Yes
Tips Written by other veterans living with diabetes ("Vet Tips")	No	Yes
Assessment messages	No	Yes
Annie use reminders	No	Yes
Optional modules	No	Yes
Ability to customize timing and frequency	No	Yes

[a]DSMS: Diabetes Self-Management Support.

[b]DSMS+: Diabetes Self-Management Support + Interactive and Customizable Messages.

Diabetes Self-Management Support

For DSMS, 163 educational messages were created, 85 of which linked to a video or a website. The majority of the messages provided disease education and encouraged users to be active members of their health care team. The final average Flesch-Kincaid Grade Level for all generated messages was 6.79, excluding any hyperlinks.

Diabetes Self-Management Support + Interaction and Customizable Messages

DSMS+ contained all the messages in DSMS and 4 additional sets of messages: "Vet Tips," assessments, Annie use reminders, and optional modules. "Vet Tips" were messages originally written by veterans living with diabetes, refined with the research team and veteran coinvestigators. If the participants sent "VETTIP YES" at any time, they received one of these tips. The tips came from surveys and interviews with veterans living with diabetes and veteran coinvestigators. Assessment messages asked participants to reflect on their management of different diabetes self-management behaviors. Annie use reminders periodically reminded users that the messages were automated or that they could call a research coordinator to make changes to their message topics and frequency. The final optional module topics were reminders for medication, blood sugar, and blood pressure, modules about foot care, physical activity, weight management, and finally, goal setting (Table 5). Many optional modules were based on existing Annie texting protocols. All messages, those in both DSMS and DSMS+, and those exclusive to DSMS+, went through the same development and expert review process.

Table 5. Optional modules and descriptions for the customizable diabetes self-management automated texting system intervention, Diabetes Self-Management Support + Interactive and Customizable Messages (DSMS+).

Optional module	Direction	Description
Medication reminder	1-way	Reminder to take medication at a specific times
Blood glucose reminder	2-way	Reminder to measure and send in blood glucose level
Blood glucose reminder	1-way	Reminder to measure blood glucose level
Blood pressure reminder	2-way	Reminder to measure and send in blood pressure
Foot care	1-way	Weekly tips for diabetes foot care
Physical activity	2-way	Send in minutes of physical activity for specified days
Exercise prompt	1-way	Encourages movement at specified times
Steps	2-way	Reminder to be active and later to send in step count
Weight goal setting	2-way	Asks readiness to set a weekly weight management goal
Weight management	1-way	Provides weight management tips
Diabetes self-management goal	2-way	Asks readiness to set a monthly diabetes self-management goal

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Discussion

Principal Findings

We aimed to leverage the experience of veterans living with diabetes and clinical experts to design 2 versions of a text messaging program to support diabetes self-management. One program uses 1-way messaging to deliver diabetes self-management support without the option to customize timing or frequency (DSMS), and another delivers customizable, interactive diabetes self-management support (DSMS+). Our goal was to ensure the veteran and patient perspective was meaningfully integrated into our programs by including veterans as members of our research team, seeking feedback via surveys and interviews, and beta testing DSMS+. We also incorporated the clinician perspective by involving expert clinicians as team members and seeking feedback via a panel review.

Following this iterative, rigorous development of DSMS and DSMS+, we conducted a comparative effectiveness trial (ClinicalTrials.gov: NCT04227379). Participants were randomly assigned to either DSMS or DSMS+ to evaluate whether DSMS+ results in better outcomes for diabetes management among US veterans with uncontrolled type 2 diabetes. The primary outcome was participants' time spent in glycemic control [30]. Secondary outcomes will include self-reported adherence to diabetes self-care recommendations, low-density lipoprotein cholesterol levels, blood pressure control, self-reported diabetes self-efficacy, and diabetes-related distress. These measures aim to capture both the clinical and psychosocial impacts of the interventions. Enrollment for this trial extended from February 2023 to April 2024, and the analysis of results is underway. By comparing the effectiveness of a customizable approach to a standard texting intervention, we seek to generate important evidence on how customization of mobile health strategies can address disparities in diabetes care within a veteran population.

Comparison to Prior Work

A recent meta-analysis suggests that tailored or interactive ATS may be more effective than those delivering standardized content, though questions remain in regards to their development and effectiveness [15]. For example, Dobson et al [31] reported that, compared to usual care, significant improvements in HbA_{1c} were observed among those who received text messages that were tailored to their needs, goals, and demographics. In contrast, Peimani et al [32] found that, compared to those receiving standard messages, patients receiving messages customized to their disease management barriers reported greater improvements in diabetes self-care and self-efficacy, though notably not HbA_{1c}. Similar preferences for customization have been documented in other Annie texting protocols outside of diabetes. For example, evaluations of 2 Annie COVID-19 protocols found that veterans desired messages that were more tailored to their demographic group, needs, and circumstances [18]. Together, this previous work has highlighted both the promise of tailoring and uncertainty about what type and extent of tailoring result in clinically meaningful health improvements.

Most prior ATS studies have focused on evaluating patient perspectives and outcomes; there has been limited description about how such interventions were developed (eg, initial drafting and integrating stakeholder feedback). This limitation may hinder others' ability to compare across studies or reproduce similar interventions. This study aims to address this gap and adds to prior literature by describing our structured participatory process which incorporated veteran feedback and clinical expertise.

This participatory process reflects best practices in patient-centered technology-based intervention design [33,34]. Additionally, our process was guided by implementation science. For example, the Practical, Robust Implementation and Sustainability Model ([35]) considers the characteristics of the users, intervention, and broader context to support implementation success. Tailoring message content to veteran preferences and experiences may, therefore, enhance both implementation and sustained adoption. By documenting the development process of DSMS and DSMS+, we provide a transparent account of how we developed our ATS interventions.

Limitations

A key strength of our study is the integration of veteran perspectives and clinical expertise to ensure that the text messaging programs are clinically relevant and meaningful to veterans living with type 2 diabetes. Additionally, our study successfully engaged a diverse sample of patients in underserved settings, enhancing the relevance of the findings for those who may benefit most from diabetes self-management support. Despite these strengths, there remain limitations to consider. The low response rate for the survey may limit the generalizability of our findings, as respondents might differ significantly from nonrespondents. Additionally, our small beta testing sample may not fully capture the diverse experiences and preferences of the broader veteran population. Finally, while our veteran-informed text messaging interventions are customized to veterans, some messages (eg, Vet Tips) may not be as meaningful to nonveterans. However, the participatory design process used in our study should generalize well to other target populations.

Conclusions

We developed 2 text messaging interventions to support diabetes self-management: a standard 1-way messaging intervention that delivers diabetes education (DSMS) and an interactive, customizable intervention designed to deliver personalized diabetes self-management support (DSMS+). By incorporating the perspectives of veterans living with diabetes and clinical experts, we aimed to create text messaging interventions that were both clinically relevant and meaningful to veterans. A subsequent trial will evaluate whether customization supports engagement and improves diabetes outcomes, offering valuable insights into the potential of tailored mobile health interventions for managing chronic diseases.

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Acknowledgments

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Data Availability

The datasets generated or analyzed during this study are not publicly available as they belong to the US Government but may be available from the corresponding author on reasonable request..

Conflicts of Interest

None declared.

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Abbreviations

ATS: automated texting system
DSMS: Diabetes Self-Management Support
DSMS+: Diabetes Self-Management Support + Interactive and Customizable Messages
HbA1c: hemoglobin A1c
IRB: Institutional Review Board
VA: Veterans Affairs

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Original Paper

Evaluating the Efficacy of AI-Based Interactive Assessments Using Large Language Models for Depression Screening: Development and Usability Study

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Abstract

Background: The evolution of language models, particularly large language models, has introduced transformative potential for psychological assessment, challenging traditional rating scale methods that have dominated clinical practice for over a century.

Objective: This study aimed to develop and validate an automated assessment paradigm that integrates natural language processing with conventional measurement tools to assess depressive symptoms, exploring its feasibility as a novel approach in psychological evaluation.

Methods: A cohort of 115 participants, including 28 (24.3%) individuals diagnosed with depression, completed the Beck Depression Inventory Fast Screen via a custom ChatGPT interface (BDI-FS-GPT) and the Chinese version of the Patient Health Questionnaire–9 (PHQ-9). Statistical analyses included the Spearman correlation (PHQ-9 vs BDI-FS-GPT scores), Cohen κ (diagnostic agreement), and area under the curve (AUC) evaluation.

Results: Spearman analysis revealed a moderate correlation between PHQ-9 and BDI-FS-GPT scores. The Cohen κ indicated moderate diagnostic agreement between the PHQ-9 and the BDI-FS-GPT (κ=0.43; 76.5% agreement), substantial agreement between the BDI-FS-GPT and the clinical diagnosis (κ=0.72; 88.7% agreement), and moderate agreement between the PHQ-9 and the clinical diagnosis (κ=0.55; 71.4% agreement). The BDI-FS-GPT demonstrated excellent diagnostic accuracy (AUC=0.953) at a cutoff of 3, detecting 89.3% of participants with depression with an 11.5% false-positive rate compared to the PHQ-9 (AUC=0.859) at a cutoff of 5 (sensitivity=71.4%; false-positive rate=13.8%). Participants also reported significantly higher satisfaction with the automated assessment compared to the traditional scale (*P*=.02).

Conclusions: The automated assessment paradigm framework combines the interactivity and personalization of natural language processing–powered tools with the psychometric rigor of traditional scales, suggesting a preliminary feasibility paradigm for future psychological assessment. Its ability to enhance engagement while maintaining reliability and validity provides encouraging evidence, warranting validation in larger and more diverse studies as large language model technology advances.

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KEYWORDS

large language models; automated assessment paradigm; AAP; natural language processing; NLP; ChatGPT; Beck Depression Inventory Fast Screen; BDI-FS; mental health assessment; artificial intelligence; AI; psychology

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Introduction

Numerous studies have used numerical rating scales to capture participants' feelings using predefined scoring responses to represent complex psychological states. When asked certain questions (eg, "Are you satisfied with your partner?"), people often provide descriptive, open-ended responses in words (eg, "Most of my expectations are met, but...") rather than closed numerical or categorical answers (eg, 7="strongly agree" or 1="strongly disagree"). For over a century, rating scales have dominated psychological assessment, providing valuable insights but also limiting how people express more nuanced or atypical mental states [1-3]. As a result, important contextual information, such as how individuals interpret questions or which situational factors shape their responses, often remains unmeasured.

Natural language is our inherent way of conveying inner experiences and psychological states, characterized by high ecological validity and rich, multidimensional information [4]. Natural language models have advanced from early statistical methods (eg, n-grams) to neural architectures (eg, transformer), culminating in large language models (LLMs) trained with instruction tuning and reinforcement learning from human feedback. This advance enables the structured analysis of open-ended narratives, helping address the limitations of conventional rating scales [5,6]. Previous studies have validated the potential of natural language processing–based approaches in psychological measurement. Kjell et al [7,8], for example, demonstrated that latent semantic analysis and context-based embedding models such as bidirectional encoder representations from transformers can reliably quantify open-text responses, yielding results highly consistent with those of traditional psychometric scales. Similarly, Son et al [9] applied language analysis to early interview transcripts of 911 responders and successfully predicted the development of posttraumatic stress disorder symptoms, identifying specific linguistic markers such as word frequency patterns and topic distributions generated via latent Dirichlet allocation. These findings laid the groundwork for integrating natural language processing into psychological assessment but were largely limited to post hoc analyses of isolated text samples or sentiment classification.

Recent reviews have mapped the growing landscape of LLM applications in mental health, including depression detection, suicide risk prediction, and clinical decision support [10-13]. Representative studies illustrate current directions. Guo et al [14] built a GPT-3.5–based Patient Health Questionnaire–9 (PHQ-9) chatbot that guides users through fixed response options, returns a summed score, and provides resource information; the system was tested using simulated personas and a small convenience sample recruited online. Mixed methods work comparing chatbot responses with those of licensed therapists has described strengths such as validation and psychoeducation alongside safety gaps in crisis handling and inquiry depth [15]. Method proposals such as MAQuA and PsyLLM explore adaptive question selection and therapy navigation using LLMs [16,17].

Taken together, most prior systems rely on static, prelabeled text or fixed-option questionnaires (eg, Reddit, X [formerly known as Twitter], the DAIC-WOZ database, and Weibo); yield categorical labels or simple sum scores; and seldom map open-text responses to standardized, scale-anchored psychometric scores in real time. To our knowledge, few studies have evaluated such scores against a concurrent clinical diagnosis in a routine care setting. This study introduced the automated assessment paradigm (AAP), which embeds a validated rating scale (the Beck Depression Inventory Fast Screen [BDI-FS]) into an LLM-powered dialogue. This approach enables the automatic generation of standardized scores directly from participants' natural language responses, bridging the flexibility of conversational artificial intelligence (AI) with the rigor and comparability of traditional psychometric tools.

Beyond methodological concerns, the application of AI to mental health raises critical ethical challenges. Mental health data are highly sensitive, and issues of privacy, data security, algorithmic bias, and potential misuse mean that technical validity alone is not sufficient. Equally important is whether individuals feel respected, comfortable, and willing to engage with AI-based systems when discussing their psychological states. Without participant trust and acceptance, even technically sound tools may fail in practice. Therefore, this study sought not only to test the diagnostic performance of an AAP that embeds a validated rating scale within an LLM-driven dialogue but also to examine whether such an approach is acceptable and engaging to users. By considering both measurement validity and participant experience, we aimed to provide a more balanced evaluation of the feasibility of AI-assisted psychological assessment. Given that text-based LLM assessment requires basic digital literacy and stable internet access, this study was conducted in a university-affiliated center that routinely serves urban adults, including both university students and local residents.

Methods

Participants

Participants were recruited from the Psychological Crisis Early Warning and Monitoring Technology Research Center at Zhengzhou Normal University in Zhengzhou, China, which provides routine psychological consultation and diagnosis for local residents and university students. Between July 2024 and January 2025, a total of 164 attendees (aged ≥18 years) were screened sequentially in the order they presented, comprising adults who provided consent, returned for the study session, and were classified as either diagnosed with depression or not diagnosed with depression, without any other primary mental disorder. Of these 164 attendees, 49 (29.9%) were diagnosed with depression, and 115 (70.1%) were not. All 115 individuals without depression were invited. Of the 49 individuals diagnosed with depression, 12 (24.5%) with severe depression were not invited to participate. The AAP in its current form is an exploratory tool and not yet validated for high-risk situations, so administering it to individuals who are severely ill without established safety evidence was considered ethically

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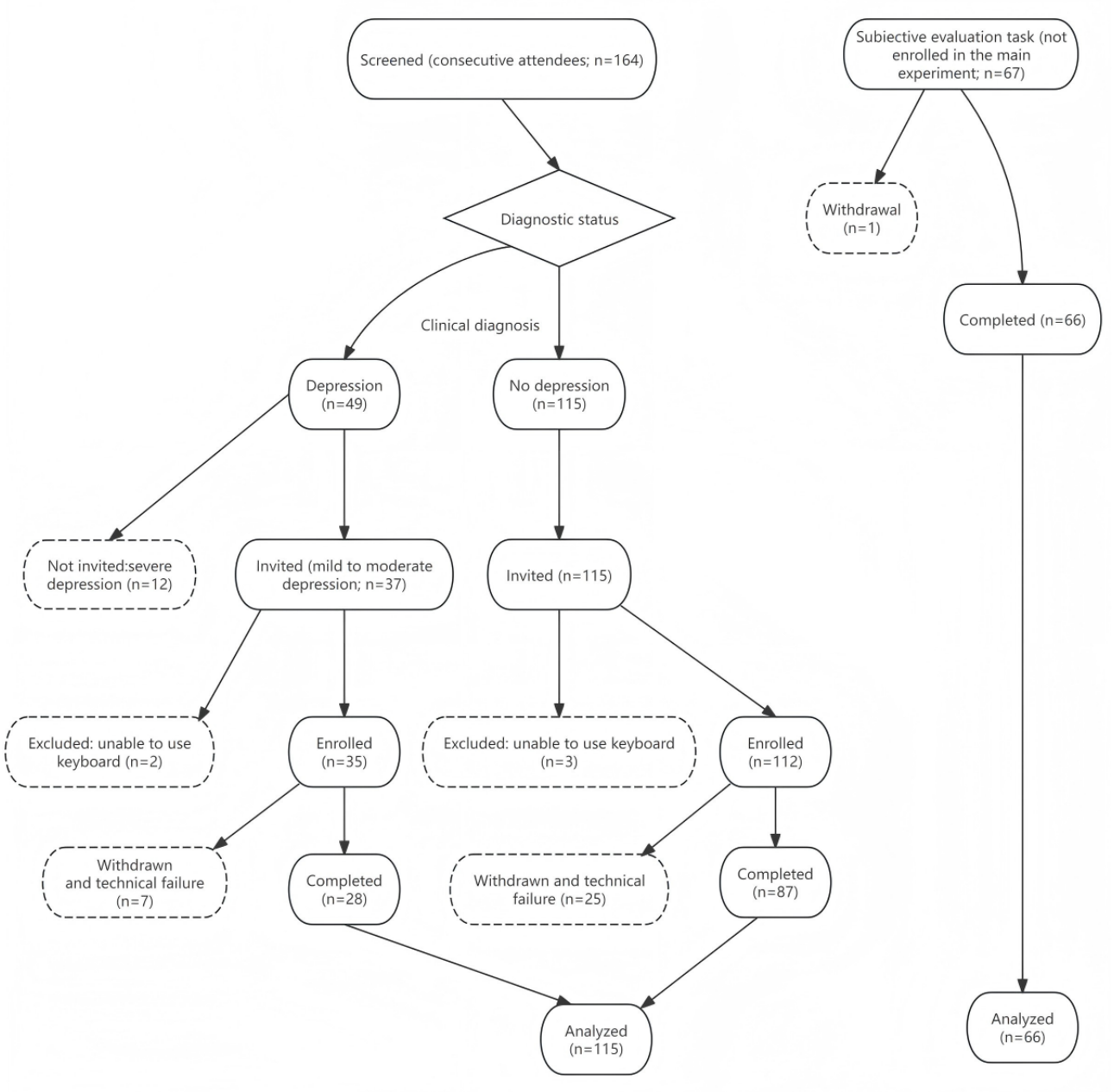
inappropriate. Of the 37 attendees in the depression group who were invited, 2 (5.4%) were excluded due to impairments that prevented completion of the assessment (ie, inability to interact with the keyboard), and 7 (18.9%) withdrew or could not complete the session because of technical interruptions (eg, sudden software errors or network failures), leaving 28 participants. In the group without depression, of the 115 attendees, 3 (2.6%) were excluded for testing-impairing conditions, and 25 (21.7%) withdrew, leaving 87 participants (Figure 1). Each diagnosis was conducted by a licensed psychiatrist on duty at the center according to the Diagnosis and Treatment of Mental Disorders Guidelines (2020 Edition) of the National Health Commission of the People's Republic of China. A total of 67 additional university students participated in the satisfaction measurement regarding the assessment methods.

Figure 1. Participant flow from screening to analysis.



In the study by Elben et al [18], the BDI-FS demonstrated a significantly higher agreement with the clinician's diagnosis of depression at the index visit than would be expected by chance, with a Cohen κ of 0.39 (81% agreement; P<.002). In contrast, Golden et al [19] reported that the BDI-FS showed a Cohen κ of 0.42 in agreement with the *Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition* (*DSM-IV*) diagnosis, which they considered to be less than ideal. When setting the minimum acceptable κ (κ_0) value to 0.39 and the expected κ (κ_1) value to 0.8, with an estimated depression prevalence of approximately 30% among individuals seeking psychological consultation [20], a sample size of 85 participants was required to achieve a statistical power of 80% (1 – β) at a significance level of .05 [21]. The final analytic sample exceeded the minimum required sample size.

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Materials

The BDI-FS is an abbreviated version of the 21-item Beck Depression Inventory–II consisting of only 7 items [22]. It has been validated for use with the general population, college students, and inpatients [18,23], as well as in the Chinese population [24]. The diagnostic cutoff value for the BDI-FS is ≥4. On the basis of the BDI-FS, custom versions of ChatGPT-4o (OpenAI; BDI-FS-GPT) were created on June 7, 2024. Specifically, we implemented a fixed, prespecified sequence of 10 prompts based on the BDI-FS. For instance, when addressing self-criticalness in the BDI-FS, the prompt asks the respondent three questions: (1) "Compared to before, do you find yourself more self-critical?" (2) "Do you blame yourself for your shortcomings?" (3) "When something bad happens, do you worry it's your fault?" The agent asks each question in order and waits for the participant's response before proceeding. The agent provides only courteous responses without commenting on the answers. Scoring follows the original BDI-FS criteria. After collecting free-text responses, the agent assigns item scores of 0, 1, 2, or 3 by matching the aggregated meaning to the BDI-FS anchors (eg, self-blame: 0="I do not blame myself," 1="I blame myself more than before," 2="I blame myself for my faults," and 3="I blame myself for anything bad that happens"). The aggregation and mapping steps are deterministic and rule based. Full prompts and deidentified response examples are available in our Open Science Framework repository [25]. A board-certified psychiatrist reviewed the exact Chinese prompts and the domain mapping before data collection to ensure semantic consistency with the BDI-FS and confirm the absence of potentially offensive wording.

The Patient Health Questionnaire, developed by Kroenke et al [26] based on the *DSM-IV*, is a self-assessment tool for evaluating mental disorders in primary health care settings. The PHQ-9 is a subset of the Patient Health Questionnaire used specifically to assess depression, consisting of 9 items based on the 9 symptom criteria for major depressive disorder as outlined in the *DSM-IV*. Regarding severity, the PHQ-9 comprises 5 categories, where a cutoff point of 0 to 4 indicates no depressive symptoms, 5 to 9 indicates mild depressive symptoms, 10 to 14 indicates moderate depressive symptoms, 15 to 19 indicates moderately severe depressive symptoms, and 20 to 27 indicates severe depressive symptoms.

The subjective evaluation was adapted from the Usefulness, Satisfaction, and Ease of Use Questionnaire [27] and included 5 items assessing perceived usefulness, considerateness, respect, satisfaction with the time required, and overall satisfaction. These measure satisfaction with the information obtained, the degree to which the process felt considerate, and the extent to which the measurement method made the respondent feel respected. The scale includes 3 reverse-scored items, with higher scores indicating greater comfort. The internal consistency of the acceptance measurement for the BDI-FS and BDI-FS-GPT was 0.67 and 0.72, respectively.

Procedure

The center's social-psychological services regularly accommodate inhabitants from the local communities and universities, who typically receive psychological consultation and diagnostic services. After obtaining participants' consent, the research procedures were integrated into the regular intake process, with participants invited for a follow-up visit within 48 hours after the standard service. Participants completed the BDI-FS-GPT and the Chinese version of the PHQ-9 in a private space guided by 2 trained research assistants familiar with the operational procedures who were unaware of the diagnostic results. The order of the 2 assessments was counterbalanced, with a 2-minute interval between them. The assessment concluded when ChatGPT displayed the following concluding statements and final question: "Our conversation ends here. Thank you for your participation. Would you like to see your scores?" Participants then exited the program. The research assistant reviewed and recorded the scores. Risk management procedures were in place throughout. Individuals with severe depression or acute suicide risk as determined in the initial clinical assessment were not invited into the study and, instead, received appropriate clinical management and referral. If a participant's responses indicated marked emotional distress (eg, suicidal ideation) during the AAP session, the research assistant immediately informed the on-duty psychiatrist, who conducted an in-person risk assessment and arranged appropriate follow-up in accordance with institutional protocols. The 67 participants in the satisfaction evaluation group did not participate in the aforementioned experiment. They only completed the traditional BDI-FS and BDI-FS-GPT measurement in a counterbalanced order and subsequently filled out the subjective evaluation scale, and 1.5% (1/67) withdrew from the study.

Ethical Considerations

The experimental procedure was approved by the Academic Ethics Committee of Zhengzhou Normal University (approval ZZNU2023LL019). All participants provided written informed consent prior to participation. This included consent for the use of deidentified data in secondary analyses and for the publication of results. To protect participants' privacy and confidentiality, only a limited set of demographic variables (sex, residence, and age) was retained in the final dataset. Participants were offered a ¥50 (US $7.10) incentive, although 13.9% (16/115) of the participants completed the procedure but declined the compensation. All participants were free to withdraw at any time without providing a reason.

Results

Participant characteristics by depression status are summarized in Table 1. The Cronbach α was 0.80 (95% CI 0.725-0.847) for the PHQ-9 and 0.71 (95% CI 0.60-0.78) for the BDI-FS-GPT. Spearman correlation analysis showed significant correlation between the total scores on the PHQ-9 and the BDI-FS-GPT, with a correlation coefficient of 0.45 (P<.001). The agreement of diagnoses between the 2 measures as assessed using the Cohen κ was significant, with a value of 0.43 (76.5% agreement; P<.001). The BDI-FS-GPT diagnosis showed significantly higher agreement with the current diagnosis of depression, with a Cohen κ of 0.72 (88.7% agreement; P<.001). The PHQ-9 diagnosis also agreed significantly more often than chance with a present diagnosis of depression, as indicated by a significant Cohen κ of 0.55 (71.42% agreement; P<.001). Median PHQ-9

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scores were 6 (IQR 4-8.75) in the depression group and 2 (IQR 0-4) in the nondepression group, and median BDI-FS-GPT scores were 6 (IQR 4-6.75) in the depression group and 0 (IQR 0-2) in the nondepression group.

Table 1. Participant characteristics by depression status (N=115).

	No depression	Depression
Sex, n (%)		
Female	57/87 (65.5)	21/28 (75.0)
Male	30/87 (34.5)	7/28 (25.0)
Residence, n (%)		
Urban	66/87 (75.9)	23/28 (82.1)
Rural	21/87 (24.1)	5/28 (17.9)
Age (years), mean (SD)	28.76 (8.84)	26.86 (7.25)
BDI-FS-GPT[a] score (0-21), mean (SD)	0.75 (1.15)	5.36 (2.31)
PHQ-9[b] score (0-27), mean (SD)	2.30 (2.13)	6.46 (3.55)

[a]BDI-FS-GPT: Beck Depression Inventory Fast Screen based on a custom ChatGPT interface.

[b]PHQ-9: Patient Health Questionnaire–9.

The area under the receiver operating characteristic (ROC) curve for the BDI-FS-GPT was 95.3% (95% CI 90.0%–100.0%). The ROC analysis indicated that a cutoff score of 3 provided the optimal balance between sensitivity (89.3%) and specificity (88.5%; Youden index=0.778), supporting its use as the primary threshold for the BDI-FS-GPT in this sample. For the PHQ-9, ROC analysis indicated that a cutoff of 5 provided the optimal balance between sensitivity (71.4%) and specificity (86.2%), with the highest Youden index (0.576). The BDI-FS-GPT demonstrated strong discrimination performance, with an area under the precision-recall curve of 0.921. For the sample in this study, the logistic regression model for the BDI-FS-GPT (cutoff=3; logit[p(depression)]=1.376BDI-FS-GPT – 4.741; $P<.001$) and the logistic regression model for the PHQ-9 (cutoff=5; logit[p(depression)]=0.574PHQ-9 – 3.438; $P<.001$) revealed better performance of the BDI-FS-GPT than the PHQ-9. Sensitivity, specificity, positive predictive value, and negative predictive value across alternative cutoff values for both instruments are presented in Table 2.

The confusion matrix for the BDI-FS-GPT classification (cutoff=3) against the clinical diagnosis is shown in Table 3.

Table 2. Sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) at different cutoffs for the Beck Depression Inventory Fast Screen based on a custom ChatGPT interface (BDI-FS-GPT) and Patient Health Questionnaire–9 (PHQ-9).

Cutoff value	Sensitivity	Specificity	PPV	NPV
BDI-FS-GPT				
1	0.964	0.655	0.474	0.983
2	0.964	0.736	0.54	0.985
3	0.893	0.885	0.714	0.963
4	0.786	0.977	0.917	0.934
5	0.643	1	1	0.897
PHQ-9				
1	0.964	0.299	0.307	0.963
2	0.964	0.402	0.342	0.972
3	0.929	0.575	0.413	0.962
4	0.821	0.713	0.479	0.925
5	0.714	0.862	0.625	0.904
6	0.536	0.931	0.714	0.862
7	0.393	0.954	0.733	0.83
8	0.286	0.977	0.8	0.81
9	0.25	0.989	0.875	0.804

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Table 3. Confusion matrix for the Beck Depression Inventory Fast Screen based on a custom ChatGPT interface (BDI-FS-GPT) versus clinical diagnosis.

	Clinical depression	
	Positive (n=28)	Negative (n=87)
BDI-FS-GPT		
Positive (n=35)	25 TPs[a]	10 FPs[b]
Negative (n=80)	3 FNs[c]	77 TNs[d]

[a]TP: true positive.

[b]FP: false positive.

[c]FN: false negative.

[d]TN: true negative.

Participants reported slightly higher satisfaction with the AAP powered by generative pretrained transformer–based language models (mean 20.26, SD 2.46; range 13-25) compared to the traditional BDI-FS (mean 19.50, SD 2.60; range 11-24). The Wilcoxon signed rank test confirmed that this difference was statistically significant ($z=-2.35$; $P=.02$), indicating a preference for the more interactive, AI-driven assessment process.

Discussion

The BDI-FS-GPT demonstrated acceptable internal consistency. The high correlation between the PHQ-9 and BDI-FS-GPT suggests that they are consistent in assessing depressive symptoms. This result strengthens our confidence in the congruence and validity of the BDI-FS-GPT compared to traditional scales measuring the same construct. The diagnostic agreement between both tools and actual diagnoses was significantly higher than random consistency. The BDI-FS-GPT showed particularly high agreement with the actual depression diagnosis. Specifically, a BDI-FS-GPT score of ≥3 is better interpreted as a flag for further clinical assessment rather than a definitive diagnosis, balancing a low miss rate with an acceptable number of false positives. Although discrimination performance was strong (area under the precision-recall curve=0.921), calibration analysis indicated that the model tended to underestimate depression risk on average (calibration intercept=−4.741) and produced a calibration slope greater than 1 (1.376), suggesting that symptom differences may be amplified at higher severity levels. These calibration characteristics are expected in early-phase models developed on modest sample sizes.

Typically, the development of rating scales follows a rigorous process of validity and reliability testing to establish scientific scoring rules and norms. The logic of the AAP is relatively simple: it adapts traditional scale questions into a structured interview format, which is then administered via an AI interactive question-and-answer system. The AI system collects the responses, and semantic analysis based on traditional scoring rules is used to automatically assign scores. While existing research has explored various integrations of AI, structured interviews, and rating scales [28-31], there are no direct examples to our knowledge that integrate these elements into a system and predict actual symptoms in practice. In some studies, AI has been used to assist with rating scales, such as sentiment analysis or emotion recognition based on text analysis, or assess participants' emotional tendencies or mental states. For instance, AI has been used to classify emotions in responses to open-ended questions, but these studies have generally used predefined sentiment analysis models and not incorporated semantic automatic scoring of rating scales, often focusing on specific areas such as sentiment analysis or emotion recognition rather than comprehensive psychological measurement. Other studies have attempted to apply AI or machine learning to automate the scoring systems of traditional rating scales, primarily focusing on automating analysis and pattern recognition of survey data.

In contrast to traditional structured interviews, the virtual avatar-based assessment method significantly reduces human interference, addresses the privacy limitations of structured interviews, and saves time costs. With further advancements in AI technology, questions from classic rating scales could be presented in multimodal formats. The use of the AAP provides a more participant-centered, open-ended, and interactive experience for participants while retaining psychometric reliability, marking a new direction for digital mental health measurement. Because the BDI-FS-GPT is fully automated, a natural next step is to embed it as a previsit or waiting room screener in multiple clinics coupled with predefined referral or follow-up rules when scores exceed agreed thresholds. Future trials can use this workflow to evaluate longitudinal stability, responsiveness to change, and the impact on clinicians' workload and triage decisions. While the AAP demonstrated satisfaction, the integration of conversational AI into mental health requires careful consideration of the user-agent relationship. Previous research by Brandtzæg et al [32] has highlighted that young users can form emotional attachments to chatbots used for social support, which poses risks if the AI fails to respond appropriately to distress. However, it is crucial to distinguish the AAP from companion-oriented chatbots. The AAP is designed as a brief, structured clinical screening tool rather than a platform for longitudinal emotional support. The interaction is goal oriented and confined to specific diagnostic inquiries, which inherently limits the potential for users to develop deep emotional dependencies or misunderstand the AI as a sentient friend.

However, it is important to note that not all classic scales or measurement methods are suitable for technological innovation, just as not all scales are appropriate for adaptation into structured interviews. Moreover, although this study used an AI-based

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automated assessment method, this approach is still in its early stages and has not fully integrated all possible AI technological applications. As of the drafting of this report, products such as DeepSeek R1, ChatGPT-5, Claude, Grok, and others are rapidly evolving, and there are differences in how systems understand prompts and analyze various languages. While comparing the performance of different models or products was beyond the scope of this study, several other limitations warrant careful consideration. First, the sample was relatively homogeneous, with most participants being young adults living in urban areas and a mixture of university students and local residents. This limits the generalizability of the results to more diverse demographic groups, including older adults or individuals from different socioeconomic and cultural backgrounds. Second, participants with severe depression were excluded from the study. While this decision was made to ensure participant safety and avoid confounding factors such as impaired interaction with the automated system, it also means that the findings may not fully capture the system's utility in more severe clinical contexts. Completion of the AAP in this study required stable internet and virtual private network access, and several withdrawals were attributable to technical access issues, which are unlikely to be systematically associated with depressive status and, thus, may approximate missingness completely at random. Nonetheless, some selection effects cannot be fully excluded. Third, the interactive assessment relied on 1-language responses and was validated within a single cultural context. Given that LLMs can exhibit variability in comprehension and semantic interpretation across languages and cultural nuances, future studies should examine cross-linguistic and cross-cultural adaptations of this paradigm to ensure robustness and fairness. In addition to these methodological considerations, ethical and practical concerns warrant deeper reflection. Overreliance on AI in mental health assessments carries notable risks, and we emphasize that these tools should complement the clinical judgment of trained professionals rather than attempt to replace it. LLMs can reflect biases from their training data, which may affect how responses are interpreted across different demographic or cultural groups. To ensure that the AAP is used safely and fairly, ethical safeguards, including human oversight, bias monitoring, and ongoing validation, need to be integrated alongside technical improvements.

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Conflicts of Interest

None declared.

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Abbreviations

AAP: automated assessment paradigm
AI: artificial intelligence
AUC: area under the curve
BDI-FS: Beck Depression Inventory Fast Screen
BDI-FS-GPT: Beck Depression Inventory Fast Screen via a custom ChatGPT interface
DSM-IV: Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition
LLM: large language model
PHQ-9: Patient Health Questionnaire–9
ROC: receiver operating characteristic

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Original Paper

Personalized Transdiagnostic Cognitive Behavior Therapy With Midtreatment Stepped Care to Improve Mental Health Among University Students in Sweden: Feasibility Study for a Randomized Controlled Trial

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Abstract

Background: University students show a high prevalence of diverse mental health problems, requiring adaptable interventions to assist them in improving their mental health.

Objective: This study aimed to evaluate the feasibility of transdiagnostic internet-delivered cognitive behavioral therapy (ICBT) for anxiety and depression in preparation for a randomized controlled trial. ICBT incorporated 2 innovative approaches to increase precision: user-steered content personalization and within-treatment adaptive modification based on early symptom trajectory.

Methods: This single-group, open-label study was conducted online in Sweden in the autumn of 2021, recruiting from students who had completed the World Health Organization (WHO) World Mental Health International College Student (WMH-ICS) mental health survey. Participants were eligible if they scored 5-19 on the Patient Health Questionnaire-9 (PHQ-9), or ≥5 on the Generalized Anxiety Disorder-7 (GAD-7), or both. Participants completed an 8-week ICBT program with therapist support. They initially personalized their program by selecting a primary problem orientation, anxiety or depression, and choosing additional elective modules, and could consult their therapist regarding these choices. At midtreatment, stepped care was piloted, in which participants without symptom improvement were randomized to adaptive enhancement of therapist support or to continue treatment as before. The main feasibility outcomes included data on reach and uptake, intervention acceptability, stepped care procedures, and assessment retention up to 6 months. The GAD-7 and PHQ-9 were the primary outcome measures, with changes in scores calculated using mixed effects models.

Results: Of 749 invited students, 55 (7%) completed the study screening, and 28 (4%) were included. The GAD-7 baseline score was 9.5 (SD 4.4), and the PHQ-9 baseline score was 11.2 (SD 5.2). Participants opened 6.2 (SD 2.2) out of the 8 treatment modules. The user-directed personalization yielded 27 unique treatment configurations across 28 participants. At week 4, 16/27 (59%) participants remaining in treatment were randomized in the stepped care procedure. Ratings on self-report measures showed

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acceptable to good therapeutic alliance and treatment satisfaction. Eleven participants reported increased stress associated with the treatment. Reductions in depression and anxiety symptoms were observed at postmeasurement and 6 months follow-up, with 43% attrition at those times.

Conclusions: This pioneering study of personalized ICBT with adaptive change among university students demonstrated the overall feasibility of the treatment. To enhance the design of a future definitive trial, modifications are necessary to mitigate assessment attrition and reduce treatment-related stress.

Trial Registration: ClinicalTrials.gov NCT05509660; https://clinicaltrials.gov/study/NCT05509660

(JMIR Form Res 2026;10:e68698) doi:10.2196/68698

KEYWORDS

depression; anxiety; internet-based cognitive behavior therapy; university students; transdiagnostic; precision; eHealth; prevention; screening; WMH-ICS; World Mental Health International College Student

Introduction

Background

Approximately one-third of university students report experiencing one or more probable mental disorders within the past 12 months, with mood and anxiety disorders being the most prevalent [1]. In Sweden, approximately 50% of young adults aged 18-29 years attend higher education [2], reporting higher rates of mental health problems compared to their nonacademic peers [3]. Despite a preference for psychological interventions over pharmacotherapy [4,5], the availability of such treatments often fails to meet demand [6]. This gap is further compounded by attitudinal barriers, including self-reliance and stigma, discouraging students from seeking mental health care [7,8]. Consequently, only approximately 25% of students with mental health disorders report receiving treatment in the past year [9]. Students request prompt and flexible access to mental health services, including after-hours support, reduced wait times, walk-in clinics, and online modalities [8]. Digital mental health interventions (DMHIs) have emerged as a promising strategy, garnering justifiable interest and acceptance among students [5,8,10]. In Sweden, the near-universal daily internet use among young adults [11] supports the application of DMHIs. Notably, internet-delivered cognitive behavioral therapy (ICBT), a low-threshold DMHI for mild to moderate mental health problems, has been integrated into Swedish health care [12] based on evidence demonstrating its efficacy in alleviating mental health symptoms when including brief therapist support [13-15]. Nonetheless, ICBT has not been specifically developed or deployed for the student population, nor has it been integrated into student health services, which in Sweden serve as auxiliary primary care facilities for students [16]. The evidence for ICBT among students also highlights the need for improved efficacy. A meta-analysis demonstrated that DMHIs using CBT yield larger effect sizes in anxiety and depression compared to alternative therapeutic modalities [17]; nonetheless, the overall effect sizes remain small. Another meta-analysis highlighted high attrition rates and low engagement among students using DMHIs, suggesting a potential misalignment between intervention design and user preferences [18]. A possible significant contributing factor is the substantial heterogeneity in mental health presentations, contrasted with the limited scope of DMHIs, including ICBT programs. Consequently, this research is increasingly focused on enhancing ICBT efficacy by integrating precision-targeted strategies into treatment.

Treatment Personalization

Treatment personalization aims to optimize treatment precision through clinician-guided efforts of tailoring interventions to individual patient needs [19]. This approach is supported by substantial evidence that integrating patient preferences enhances mental health outcomes [20-22], including better outcomes and reduced dropout when patients receive their preferred choice of therapy [22]. In the realm of ICBT, evolving from static, disorder-specific protocols to transdiagnostic, personalized frameworks to better address prevalent comorbidities such as depression and anxiety represents a form of treatment personalization [23]. A meta-analysis reports moderate to large uncontrolled effect sizes for transdiagnostic ICBT in anxiety and depression outcomes compared to controls, also indicating that a transdiagnostic approach may outperform disorder-specific ICBT for depression [24]. Recent studies have taken personalization a step further, exploring patient-driven tailoring of ICBT that aligns with patient co-decision principles [25]. A Swedish primary care trial demonstrated that ICBT for anxiety, where participants selected modules and the desired modality of therapist support, yielded greater symptom reduction and perceived control compared to standardized ICBT [26]. A factorial trial evaluated a user-driven personalization approach to ICBT for depression, where participants selected 6-13 modules from a pool of 15. Compared to a therapist-prescribed approach (8 modules), the user-driven approach resulted in small but statistically significant reductions in depressive symptoms [27]. The evidence for transdiagnostic and personalized ICBT among university students is limited, with inconsistency in findings across 3 prior studies: one study demonstrated moderate to large effects relative to a waitlist control [28], another found no significant benefit over treatment as usual [29], and a third reported higher remission rates for ICBT with therapist support compared to unsupported ICBT and treatment as usual [30]. These discrepancies highlight the need for research to clarify the efficacy.

Precision Medicine

Precision medicine aims to enhance treatment precision through data-driven, algorithmic, and quantitative decision-making [19]. Notably, clinical data acquired during treatment can be more predictive of outcomes than baseline measures [31,32], and

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using real-time monitoring of outcomes can improve clinical results [33]. In this context, precision medicine is particularly pertinent to stepped care models, in which initial low-intensity interventions are escalated based on clinical indicators of response. However, conventional stepped care approaches require completing an entire course of low-threshold, entry-level treatment before assessing the need for escalation. This methodology may delay necessary adjustments, potentially leading to patient frustration, demoralization, and associated risk of dropout. To address this limitation, earlier decision points within the initial treatment process have been proposed [34]. ICBT presents a suitable entry treatment in stepped care frameworks, and its typically embedded monitoring systems facilitate within-treatment adaptive modifications. A Swedish primary care trial demonstrated that monitoring early symptom trajectories during ICBT for insomnia and implementing adaptive changes in the treatment for patients who were indicated as nonresponders early in treatment significantly improved treatment outcomes as compared to no change [34]. The adaptive change involved enhanced, more personalized therapist guidance for the remainder of treatment, in line with evidence on the role of human support in DMHI efficacy [35]. Another trial compared coach-supported ICBT incorporating an adaptive step-up component to full-protocol telephone-administered CBT for depression. The study demonstrated the noninferiority of the adaptive ICBT approach, which involved participants who were nonresponders at early, mid, or late treatment stages, based on symptom severity, being escalated to telephone-administered CBT [36]. A study on youth anxiety further supports this approach, reporting self-guided ICBT augmented with therapist support for initial nonresponders to be noninferior to ICBT including therapist support from the outset [37]. Collectively, these findings suggest that adaptive allocation of therapist resources based on clinical indicators may enhance precision and outcomes in ICBT.

Objectives of the Study

No research has examined within-treatment adaptive modifications in ICBT among university students. Similarly, investigations into user-driven personalization within this demographic remain limited. Notably, no studies have concurrently explored the integration of adaptive modifications and personalization in ICBT, despite their shared potential to enhance treatment efficacy through increased precision. From a theoretical standpoint, combining these approaches could yield synergistic effects, thereby advancing the clinical utility of ICBT.

We propose to evaluate a personalized, midtreatment stepped-care ICBT framework targeting anxiety and depression among university students. Treatment will be offered following mental health screening within university settings to ensure relevance and applicability for future systematic university initiatives. The trial will compare self-guided and therapist-supported ICBT with adaptive and personalized features against a waitlist control [38]. Before conducting a definitive randomized controlled trial, preliminary feasibility assessments are essential to identify potential challenges, refine methodologies, and optimize trial design [39-41]. This feasibility study was undertaken to evaluate the proposed intervention and the trial procedural framework. Given existing evidence supporting the feasibility of similar ICBT trial designs using the planned digital platform [27,42], a single-group design was chosen. This design focused on the most resource-intensive component, therapist-supported ICBT, and enabled the testing of all novel and core trial procedures and operational elements. Feasibility was assessed across multiple domains, including reach, uptake, engagement, treatment configuration, therapist support processes, participant acceptability (credibility, satisfaction, therapeutic alliance, and adverse events), and retention rates. Exploratory analyses of changes in primary depression and anxiety outcomes from baseline to follow-up were also conducted. No predefined feasibility benchmarks were established; instead, results were contextualized against current evidence from comparable procedures, DMHI frameworks, and student populations.

Methods

Study Design

This study used a 6-month single-arm feasibility trial in which all participants underwent ICBT treatment in an online setting at Uppsala University, Sweden. The study recruited students at 2 universities who had completed the Swedish branch of the World Mental Health Initiative Survey (WMH-ICS) epidemiological mental health screening [43] in the previous year. Recruitment occurred in October 2021, treatments were implemented from November to December 2021, and follow-up was conducted in April 2022. The study is reported in accordance with the CONSORT (Consolidated Standards of Reporting Trials) criteria applicable for nonrandomized feasibility studies [39] (Multimedia Appendix 1). The treatment is reported according to the TIDieR (Template for Intervention Description and Replication) [44] (Multimedia Appendix 2).

Eligibility inclusion criteria were ≥18 years, and meeting at least one of the following: score of 5-19 on the Patient Health Questionnaire-9 (PHQ-9; [45]), or score of ≥5 on the Generalized Anxiety Disorder-7 (GAD-7; [46]). Exclusion criteria were one or more of the following: ongoing other psychological treatment, antidepressant medication with a stable dose for less than 3 weeks, severe mental ill-health, or a score above 1 on the PHQ-9 suicidal ideation item in the screening.

Procedures

Students received an email outlining the study objectives and intervention, along with a link to the consent and screening procedures. Eligible participants were subsequently invited to confirm their participation by completing a second pretreatment survey that included the secondary outcomes. Participants who completed this step proceeded to treatment initiation. At week 4 of 8 in treatment, participants who did not show symptomatic improvement were randomized to either adaptive treatment changes or to continue treatment as originally prescribed. Measures were collected at baseline, pretreatment, during treatment, posttreatment, and follow-up at 6, 12, and 24 months via email surveys, with 2 automated reminders. All but weekly measures were collected via Qualtrics (Qualtrics International Inc); weekly measures were collected in the study treatment platform [42]. Safety protocols included providing emergency

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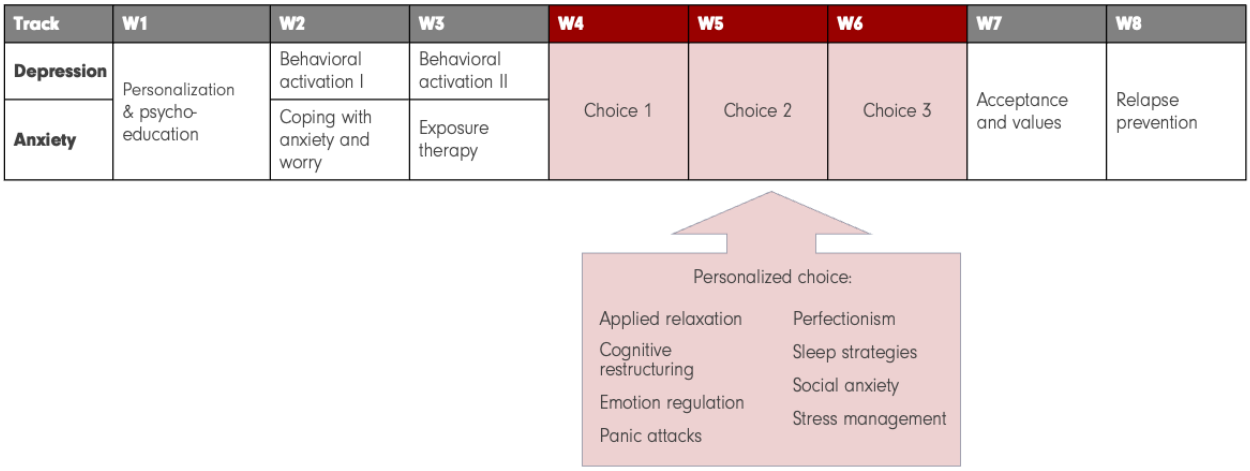
contact information at treatment initiation, and monitoring and following up on symptom deterioration during treatments, with guidance to regular care resources as needed.

Personalized Transdiagnostic CBT With Midtreatment Stepped Care

The treatment comprised a structured 8-module program delivered via a secure, web-based platform with a validated track record for administering DMHIs [42]. The treatment is rooted in CBT, emphasizing the interplay of cognitions and behaviors in symptom manifestation, with the objective of facilitating skill acquisition and application to improve these domains. Treatment modules were derived from ICBT protocols validated for depression and anxiety [47-49]. The investigators adapted the core anxiety and depression modules for a student population, informed by feedback from an MSc psychology student.

Figure 1 shows the treatment outline. The treatment included brief written therapist support, user-steered personalization, as well as adaptive changes in therapist support based on early clinical indicators. Treatments were delivered individually and commenced with an introductory phone call with the assigned therapist, during which the treatment and administrative details were outlined and any questions resolved. All participants initiated treatment with a psychoeducational module focusing on the theoretical underpinnings of CBT for depression and anxiety. As part of this module, based on written explanations, participants selected a primary treatment focus, either anxiety or depression, that determined the content of modules 2 and 3. They also chose 3 additional elective modules from a pool of 8, which dictated modules 4 through 6. The final 2 modules were standardized across all participants and included values-based and acceptance strategies, and skills maintenance. Participants had the opportunity to consult with therapists about their selections and could request changes to the contents before access. Individual module plans were programmed to be pushed weekly. Starting in week 5 of treatment, adaptive change was implemented for participants who had not demonstrated symptom improvement. The adaptive change entailed modifying the therapist's support in terms of intensity, guidance, and the modality of contact. Modifications could include adding telephone check-ins, setting reminders, or providing weekly suggestions, with the participant and therapist collaboratively determining adjustments. The adaptive framework followed principles for a previously validated ICBT framework for insomnia [34].

Figure 1. Treatment tracks and elective modules in personalized transdiagnostic 8-week internet-delivered cognitive behavioral therapy (ICBT).



Therapists, Treatment Guidelines, and Treatment Fidelity

Therapist support was implemented within the framework of the pilot version of a national advanced course in digital psychology for clinicians, taught by investigators (NT and AHB). This entailed the intended implementation model for the definitive trial. The therapists included 2 licensed CBT psychologists and 14 therapists in training: final-year MSc students enrolled in a 5-year clinical psychology program specializing in CBT. Therapists underwent general and treatment-specific preparatory theoretical and technical training in DMHI implementation. In the treatment phase, therapists in training underwent mandatory weekly supervision with CBT psychologists experienced in ICBT (MK and CS) and adhered to a detailed study-specific manual that included illustrative examples, weekly checklists for treatment fidelity, and guidelines for permissible adaptive modifications in therapist support. The therapists' fidelity to treatment was monitored during clinical supervision, supplemented by compliance monitoring by a clinical practicum coordinator. Clinical supervisors participated in treatment planning meetings and had access to the treatment manual.

Feasibility and Acceptability Outcomes

Feasibility outcomes included reach and uptake, defined as the proportion (%) who initiated the study screen, were eligible for, and initiated treatment. Treatment engagement was measured using platform metrics, including module openings, skill practice completions, and treatment configurations. The therapist's time spent in treatments was estimated via self-reports. Participants evaluated the following acceptability measures: (1) credibility via the Credibility-Expectancy Scale (CEQ; range 3-30; higher scores indicate greater credibility [50]), (2) therapeutic alliance with the Working Alliance Inventory-Short Revised (range 12-84; higher scores denote stronger alliance [51]), (3) treatment

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satisfaction with the Client Satisfaction Questionnaire (range 0-32; higher scores reflect greater satisfaction [52]), and (4) negative effects with the Negative Effects Questionnaire-20 (NEQ-20; [53]). The NEQ-20 identifies 20 potential negative effects; for those endorsed, the user indicates whether attributed to treatment and rates the impact severity from 0 (not at all) to 4 (extremely). An open-ended item is included. The CEQ was administered at pretreatment; other measures at midtreatment (week 4) and posttreatment. Reasons for participant dropout were documented.

Eligibility for Adaptive Change in Treatment

Participants' eligibility rates for adaptive change in treatment were determined based on their scores on the PHQ-9 and GAD-7 in the first 3 weeks of treatment. Specifically, eligibility was assessed by comparing week-one scores to the average of scores obtained at weeks 2 and 3. Participants who exhibited no improvement or showed deterioration on either or both measures across this period were eligible for adaptive change, as were participants with missing data. Participants were randomized (1:1) to receive adaptive change or to continue treatment without change.

Adherence to the Assessment Schedule

Participants' adherence was assessed by the proportion of completed assessments weekly in treatment, posttreatment, and 6-month follow-up. In addition to acceptability measures and the primary outcomes, the assessment protocol included a comprehensive battery of secondary measures planned for the definitive trial. These measures and their corresponding assessment points are detailed in the protocol for the definitive trial [38]. Implementation between this study and the trial is aligned, except that the trial includes an additional midtreatment assessment point for the CEQ.

Symptom Severity Outcomes (Planned Primary Outcomes)

Anxiety was assessed using the GAD-7 (scores ranging from 0 to 21; higher scores indicate greater severity). Published cutoff scores for anxiety levels are: mild (scores 5-9), moderate (10-14), and severe anxiety (15-21). Depression severity was assessed using the PHQ-9 (scores ranging from 0 to 27; higher scores denote more severe depression). Published cutoff scores for depression levels are mild (5-9), moderate (10-14), moderate to severe (15-19), and severe depression (20-27).

Analyses

The achievable sample size was determined by the available pool of students who had completed the WMH-ICS screening [43]; assessing the uptake rate in this setting was a study objective. No formal sample size calculation was performed. Descriptive statistics were computed using frequencies, means, and percentages. Means for self-reported acceptability measures were calculated for valid cases. Estimates of therapist time omitted cases of 0 minutes recorded for participants who had dropped out. For the GAD-7 and the PHQ-9, mixed-effects models with random intercepts using the nlme package in R Studio (José C Pinheiro and Douglas M Bates) [54] estimated changes in measures from baseline to posttreatment and to 6-month follow-up. Participants were randomized to adaptive treatment using the randomization function in IBM SPSS Statistics (version 28). For the NEQ-20 measure, only adverse effects attributed to the treatment were reported, with the average number based on all available assessments. When a participant reported the same type of effect at 2 assessment points, it was recorded as a single effect. Alignment of baseline symptom severity and selected treatment focus of depression or anxiety was exploratively examined (aligned, or not aligned) based on categorizing participants into predominant symptom domains based on severity thresholds for the PHQ-9 and GAD-7 (eg, score of 5-9 on the PHQ-9 indicating mild severity). In cases when severity levels were equivalent across both measures, participants were also categorized in alignment. An error in the distribution of the NEQ-20 resulted in missing information for the cause and severity of sleep problems in 3 responses. An error in the randomization to adaptive treatment led to the exclusion of 5 eligible participants who had unchanged symptom severity scores or a < 2.5-point deterioration.

Ethical Considerations

Participants provided written informed consent before screening. They received no monetary or other incentives for study participation. Ethical approval was provided by the Swedish Ethical Review Authority (ref ID 2021-03599). The study was retrospectively registered on August 22, 2022 (ClinicalTrials.gov NCT05509660).

Results

Treatment Reach and Uptake

Participant recruitment was conducted over a few weeks in alignment with therapist availability. Recruitment was discontinued once this predefined window closed. Figure 2 provides the study flowchart. Of 749 potential participants invited, 55 (7.3%) completed screening, with 47 (6.3%) meeting eligibility criteria. During the enrollment confirmation step, 19 (40.4%) withdrew or declined to continue, resulting in a final sample of 28 participants (59.6% of the eligible cohort). Two participants who did not fully meet the eligibility criteria were subsequently enrolled following a phone consultation with the principal investigator. Enrollment was permitted based on the study's capacity to conduct treatment procedures and was deemed ethically justified considering the participants' interest and potential benefits. These procedural exceptions do not apply to a definitive trial. The sample was predominantly female, 85.7% (24/28), and full-time students, 78.6% (22/28), with a mean age of 27.1 (SD 4.6) years. A minority identified as international students, 10.7% (3/28). The majority, 75% (21/28), exhibited both depressive and anxiety symptoms (ie, scores of ≥5). All participants initiated treatment.

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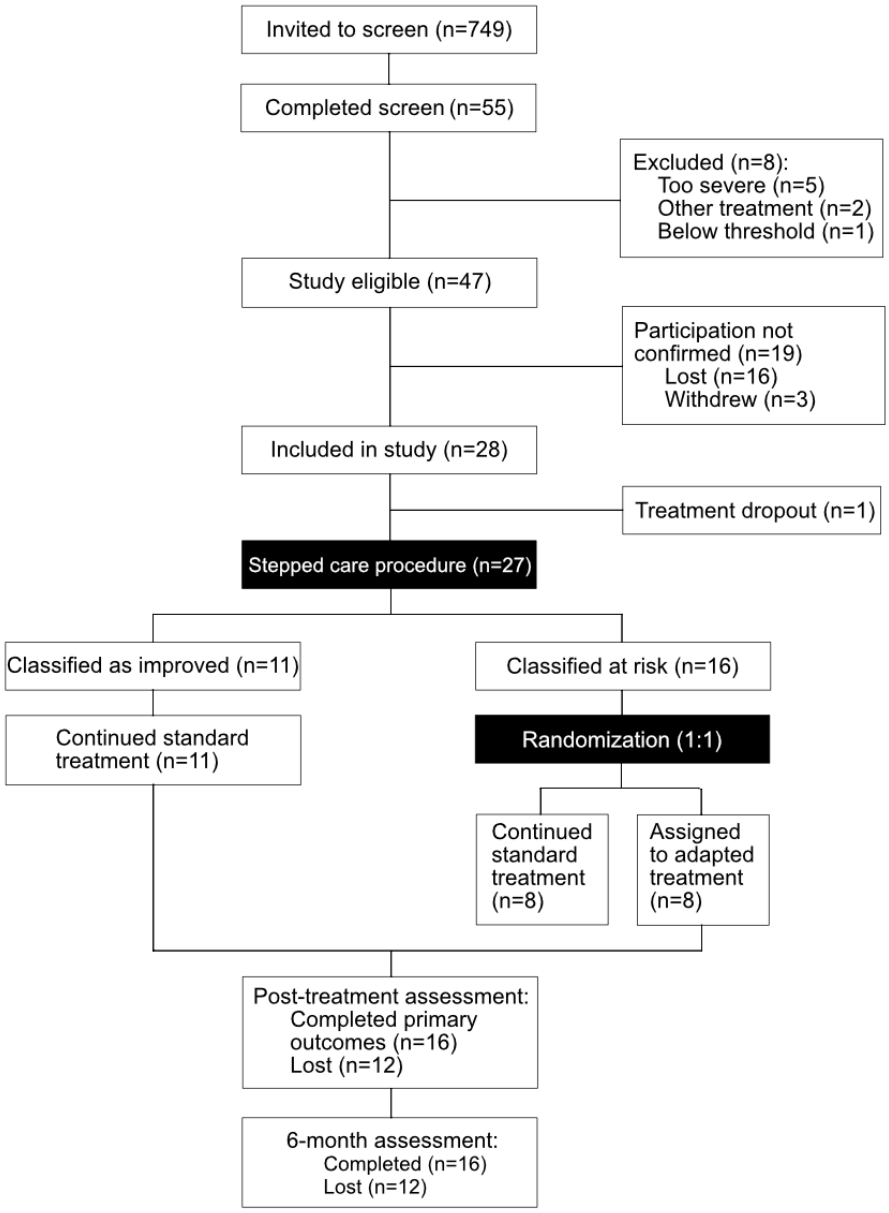
Figure 2. Flowchart of participants throughout the study.



Treatment Engagement

Participants logged into the treatment platform a mean of 22.4 (SD 23.2; median 18, IQR 12-26.75) times, with one outlier exhibiting higher login frequency. Most participants (n=19, 67.9%) switched between modes in accessing treatment (computer, phone, and tablet), but the predominant mode of access was via computers, with a mean of 16.9 (SD 24.6) logins. Regarding treatment preference, 64.3% (n=18) selected ICBT for Depression (ICBT-DEP), and 35.7% (n=10) selected ICBT with an anxiety focus. On average, participants opened 6.2 (SD 2.2; range 2-8) modules out of 8. They completed 5 (SD 2.3; range 1-8) modules, defined as engaging in at least 1 homework exercise per module. ICBT-DEP participants opened 6.7 (SD 2; n=18) modules, whereas ICBT for anxiety participants opened 5.3 (SD 2.5; n=10) modules. Among participants eligible for adaptive change at midtreatment, those assigned to remain in the standard treatment mode opened 5 modules (n=8; SD 2.8; range 2-8), and those assigned to adaptive change opened 6.1 modules (n=8; SD 2.1; range 3-8). Participants not eligible for adaptive treatment change at midtreatment opened 7.4 (SD 1.2; n=11) modules. Tests for significant differences are not included due to small sample sizes.

Table 1 shows the distribution of elective module selections. Modules covering perfectionism (15/28, 54%), stress management (14/28, 50%), and cognitive restructuring (13/28, 46%) were most frequently chosen. Participants in ICBT-DEP predominantly selected the stress module, 56% (10/18). Regarding module prioritization, cognitive restructuring was most often selected for delivery first (8/28, 29%). Overall, the combination of treatment orientation, elective modules, and module order yielded 27 unique treatment configurations among 28 participants. Exploratory analysis showed that 76.9% (20/26) of participants selected a treatment track consistent with their relative baseline anxiety and depression levels. Participants who did not meet eligibility criteria were excluded from this categorization.

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Table 1. Participants' choice of elective content in transdiagnostic internet-delivered cognitive behavioral therapy (ICBT) treatment.

Module	Total[a], n (%)	First priority[b], n (%)
Perfectionism	15 (53.6)	4 (14.3)
Stress management	14 (50)	1 (3.6)
Cognitive restructuring	13 (46.4)	8 (28.6)
Emotion regulation	12 (42.9)	4 (14.3)
Social anxiety	10 (35.7)	4 (14.3)
Sleep strategies	9 (32.1)	4 (14.3)
Applied relaxation	7 (25)	2 (7.1)
Panic attacks	4 (14.3)	1 (3.6)

[a]Participants selecting the module as 1 of 3 elective options.

[b]Participants choosing the module to be delivered first among elective options.

Credibility, Alliance, Satisfaction, and Negative Effects in Treatment

Participants rated a mean credibility score of 17.9 (SD 5.4; range 8-30; n=28) on the CEQ. Therapeutic alliance yielded WAI-S scores of 68.1 (SD 12.4; range 40-82; n=22) at midtreatment and 67.5 (SD 12.9; range 41-83; n=16) at posttreatment. Participants reported mean Client Satisfaction Questionnaire satisfaction scores of 22.6 (SD 5; range 11-29; n=22) at midtreatment and 23.5 (SD 6.1; range 9-31; n=15) at posttreatment. Among participants who completed assessments, 73% (16/22) reported negative effects attributed to the treatment. The mean number of effects was 2.9 (SD 2.9; range 0-9) out of 20, with "more stress" most frequently reported (n=11). Participants' ratings of the severity of negative effects averaged 1.46 (SD 0.73; range 0-3) on a scale from 0 (not at all) to 4 (extremely), with most (12/16) rating impact below 2 (moderate). Free-text comments (n=7) included increased stress due to a demanding work-study schedule, feelings of gratitude or uncertainty toward the therapist, previous familiarity with the treatment content, and that the treatment did not adequately address how to handle real-life risk situations in daily life. Four participants ended treatment early, citing increased stress (n=3) or the treatment not suiting their problems (n=1). No adverse events were recorded in the study.

Adaptive Change in Treatment and Therapist Time

At the time of the eligibility assessment for adaptive change in treatment, 16/27 (59.3%) of participants who remained in treatment became eligible; 7 out of 16 (43.8%) due to partially incomplete assessments. Correcting for participants mistakenly omitted (refer to "Analyses" section), 20/27 (74.1%) were eligible. In the second part of treatment, weeks 5-8, therapists spent on average 18.7 (SD 13.3; range 0-80) minutes per participant per week in the standard treatment and 22.4 (SD 13.3; range 5-60) minutes per participant per week in the adaptive treatment; a nonsignificant difference (t_{93}=1.257; P=.21; 95% CI –9.58 to 2.15, mean difference -3.71).

Adherence to the Assessment Schedule

During the treatment, self-reported assessments were available for between 89% (25/28) and 64% (18/28) of participants, depending on the week, with 177 out of 224 (79%) weekly measurements collected. At posttreatment, data for the PHQ-9 and GAD-7 were available for 16 out of 28 (57%) participants, and data for secondary outcomes were available for 15 out of 28 (54%) participants. At 6-month follow-up, data were available for 16 out of 28 (57%) participants.

Primary Outcomes

In the total sample, there were reductions in overall symptom burden of depression and anxiety at posttreatment compared to baseline pretreatment levels, with similar reductions observed at 6-month follow-up. Multimedia Appendix 3 shows means, SDs, and exploratory Cohen *d* effects for the primary outcomes PHQ-9 and GAD-7 at pre- and posttreatment and at the 6-month follow-up.

Discussion

Principal Findings

This study represents the first investigation of personalized ICBT with midtreatment adaptive stepped care for university students experiencing depression and anxiety. The primary objective was to determine the feasibility of a definitive trial. Feasibility was demonstrated through key procedures: recruitment in an online university setting, delivery of the novel treatment features, and the implementation of therapist support within a therapist-in-training supervision model. Treatment acceptability was indicated by substantial engagement, personalization, and adequate ratings of therapeutic alliance and satisfaction. Exploratory examinations showed reductions in depression and anxiety following treatment, indicating that further investigation of efficacy is warranted. Identified challenges included assessment attrition and elevated stress levels associated with the treatment, necessitating modifications to improve these outcomes in a definitive trial.

The recruitment model of targeting students who had previously been screened for mental health issues resulted in a 7% screening completion rate, consistent with a meta-analysis of DMHIs recruiting college students in similar contexts [55]. The modest uptake likely reflects the broad invitation strategy, which did not tailor invitations based on previous symptomatology. In addition, students were approached approximately 1 year after they participated in the WMH-ICS screen. To improve the

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timeliness and potentially increase screening rates in the definitive trial, this interval will be shortened. Among students who completed the study screening, the eligibility rate was high, indicating successful engagement of students presenting within the targeted range of mild-to-moderate symptoms. A logistical challenge was the multistep enrollment process, which necessitated that eligible participants complete an additional survey to confirm participation and to be transferred onto the digital platform used for treatment; this step led to attrition. Previous research has identified key barriers to enrollment and initial engagement in DMHIs, including uncertainty about their usability and a perceived lack of value [56]. Given this, it is worthwhile to explore whether enhanced study communication about the CBT paradigm and potential benefits may increase initial interest and motivation to complete the enrollment procedure. Attrition ceased after enrollment, with all confirmed participants initiating treatment, indicating the acceptability of the treatment and the digital platform. By the time of a definitive trial, the eligible participant pool, comprising students with completed WMH-ICS surveys [43], is expected to have significantly increased, with over 10 universities anticipated to participate in the Swedish WMH-ICS. Accordingly, the projected uptake rates are acceptable as they stand.

Participants rated the therapeutic alliance and satisfaction as acceptable to good and engaged with an average of 78% (6.2/8) modules of treatment in a trial setting without monetary or other incentives for participation. Notably, self-prescribing treatment content led to 27 unique treatment configurations among 28 participants. The majority also selected treatment focus aligned with their relative baseline symptom severity of anxiety and depression. Adherence metrics confirm that, in general, participants engaged with all of their personalized content (modules 1-6). These findings indicate the treatment's acceptability, and although important to note that assessing efficacy was not an objective in this study, the engagement levels are promising regarding the suggested dose-response relationship in behavioral interventions. Compared to previous reports for transdiagnostic ICBT with college students [28,29,57], the engagement levels appear favorable. A meta-analysis of DMHIs in student populations found that about 50% of studies achieved average completion rates of 70% or higher [58]. The integration of patient preferences and adaptive support mechanisms in the current treatment may positively affect treatment relevance and, thereby, engagement and adherence. This aligns with evidence that patient-centered treatment approaches can reduce dropout rates and improve clinical outcomes [20-22]. Participants' content preferences related to baseline symptoms and outcomes will be investigated as part of a definitive trial.

The enrollment and eligibility rates derived from this study provide valuable estimates to inform therapist resources in a definitive trial. The eligibility criteria for the within-treatment stepped care procedure were highly inclusive, resulting in a high estimated maximum proportion of participants eligible for adaptive treatment modifications. However, a notable proportion of eligibility decisions were based on missing data, which may reflect participants' perceived lack of benefit and could coincide with treatment dropout. While the procedures were designed to identify such cases, the accumulation of missing data before this step suggests that initiating the stepped care process even earlier in treatment may be advantageous to enhance treatment individualization and mitigate data attrition. This approach is supported by existing evidence indicating that early treatment response is predictive of clinical outcomes [31,32]. The findings for therapist support in this treatment support the feasibility of the implemented clinician-in-training model. The preparatory training and clinical supervision model used aligns with best-practice implementation of human support in DMHIs [59]. Although the workforce guiding within DMHIs is diverse, including personnel without clinical qualifications and peer support workers [59], this clinician-in-training model ensures the delivery of qualified, feedback-driven support. Past evaluations show that individuals participating in similar best-practice training report developing skills beneficial for their professional practice [60]. Therapists tended to allocate slightly more time to support in adaptive treatment than standard treatment, but variability was observed across cases. To preserve training standards, it is advisable to limit caseloads in the definitive trial, although increasing the caseload is feasible. During the feasibility assessment, therapist fidelity was monitored primarily through clinical supervision. For the upcoming definitive trial, monitoring will be expanded to include assessment of therapist adherence to the treatment manual checklists, such as whether feedback is sent on time and whether the content is accurate. Adaptive changes in treatments will be documented.

Challenges to treatment feasibility primarily stem from elevated stress levels among participants related to treatment, as identified through the systematic evaluation of treatment-related adverse effects. Although psychological treatments are generally effective, adverse effects, including increased stress, are not uncommon; approximately 1-2 out of 3 individuals undergoing psychological treatment report adverse outcomes, often involving symptom worsening [61]. In this study, participants rated the impact of stress and related effects primarily as "none" to "moderate," suggesting limited overall influence; however, 3 participants discontinued treatment prematurely due to stress. Notably, at least half of the participants may have experienced pre-existing high stress levels, as evidenced by their selection of stress management content within their personalized treatment plans. Given that the treatment is largely self-managed and based on cognitive-behavioral principles involving self-directed skill practice, it inherently imposes internal pressures. Among university students, academic workload peaks and employment obligations are well-documented stressors [62]. Engagement in highly self-directed treatments, such as ICBT, amid these pressures likely increases the risk of exacerbated stress, particularly if participants perceive themselves as falling behind or struggling to find adequate time for engagement. Previous research reports that a "busy schedule" is a primary reason for dropout from transdiagnostic ICBT among college students [63], and a qualitative study reveals that some students experience frustration stemming from the perceived time-consuming and cognitively demanding nature of ICBT, and that perceived time constraints impede engagement [64]. These accumulating data underscore the need to explicitly address stress management in ICBT for university populations.

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To this end, a forthcoming trial will incorporate supplementary standardized and individualized procedures to mitigate and manage stress levels. These will include an expanded initial briefing for all participants, consisting of a standardized introductory message from the study team that will precede personalized messages regarding introductory phone calls and that concerns therapist support. This introductory communication will clarify the self-directed nature of the intervention, emphasize flexibility in engagement timing and methods, and specify a typical weekly time commitment of several hours. It will also communicate that the typical schedule involves completing 1 module per week, aligned with automated weekly delivery of treatment modules; however, it will explicitly advise participants to adapt the pace to their individual capacity if this is challenging, especially given the variability in module complexity. Furthermore, the briefing will explicitly note that there is a 2-week catch-up period after the final module, with all materials also available for download for continued or future use. Therapists' training will also be revised to include additional guidance on the occurrence of stress among university students in ICBT, and therapists will be informed that participants' selection of a stress management module may indicate increased stress risk. The protocol for therapists' initial telephone consultation will be expanded to reiterate that, while modules are delivered weekly, circumstances (such as academic demands, illness, or additional work commitments) may necessitate acceptable pace adjustments. During treatment, the emphasis will be on tailoring the pace to individual needs rather than rigid adherence to module pacing. This aligns with the principles of personalized treatment. These measures aim to mitigate feelings of overwhelm or inappropriate pacing by improving participants' preparedness and awareness of potential stressors, preventing potential misconceptions about participation requirements, and normalizing fluctuations in capacity and available time due to academic or personal circumstances. These measures will augment existing protocols for communicating with participants who express a desire to discontinue treatment, including emphasizing the option to continue treatment aligned with their capacity. Existing protocols also address risk management by continuously monitoring participants' symptom severity and safety, through symptom tracking and communication with therapists and study staff, and by managing participants identified as at risk in accordance with established risk management protocols.

The study faced significant attrition rates in primary outcomes at both posttreatment and follow-up assessments, which threatens the validity of the findings by introducing bias and impairing interpretability. In a definitive trial, high attrition rates reduce statistical power and can lead to underestimation or overestimation of treatment effects, thereby compromising the efficacy evaluation [65]. Retention strategies in this study included 2 automated email reminders for assessments. Although less comprehensive than strategies involving telephone follow-ups or financial incentives, approaches often used in clinical trials, applying these strategies was not feasible in this study and will also not be feasible in a definitive trial due to funding constraints. Systematic reviews of trial retention strategies [66,67] recommend additional approaches, such as timely prompts, flexible data collection modalities, clear communication about the importance of follow-up, and guidelines for discussions about withdrawal. Despite the caveat that concerns about coercion may apply to some strategies, and despite the lack of high-quality evidence supporting the efficacy of recommended retention strategies [67], it remains essential to intensify retention efforts moving forward. Specifically, in a definitive trial, the retention strategy framework will be strengthened by increasing the frequency of reminders. Ethical approval will be sought to increase the number of reminders from 2 to 5 and to add SMS text messaging reminders, thereby enhancing participant engagement. In addition, the strategy will be expanded to include, as a last resort, an abbreviated assessment including only primary outcome measures for participants who remain unresponsive despite multiple reminders. This alternative assessment approach aims to reduce dropout rates and preserve essential data by reducing the assessment burden and focusing exclusively on primary outcomes. To account for the high attrition observed in this feasibility study, the sample size and statistical power calculations for the definitive trial will also be adjusted accordingly. This is especially pertinent given that the definitive trial will include long-term outcomes beyond 6 months, a period for which feasibility data on attrition are currently lacking. Increasing the sample size could partially offset attrition but may also introduce biases related to sample representativeness. Dropout analyses will be incorporated into the trial to identify potential biases and to strengthen the robustness of the findings.

The study experienced methodological shortcomings related to funding and resource constraints. The randomization errors highlight the need for more robust, multistep review processes to prevent similar issues in future trials. The protocol for the definitive trial will therefore be strengthened and safeguarded by involving additional team members in critical procedures. The study also raised concerns regarding retrospective registration and deviations from predefined eligibility criteria. The focus of feasibility studies is on testing procedures and interventions, and, relatedly, they are more flexible and less rigorous than trials [40]. However, retrospective registration and eligibility deviations are unacceptable in definitive trials and will not be applicable. Prospective registration for a definitive trial has been completed in accordance with established standards.

Limitations

Study findings should be interpreted cautiously due to methodological limitations. While providing rich information on feasibility metrics to inform a definitive trial, the small sample size may have been insufficient for some feasibility parameters [68], and the missing data further limit conclusions. Allowing 2 participants who did not fully meet eligibility criteria constitutes a deviation that may bias results. Although the feasibility assessment was comprehensive and transparently reported, the absence of prospective registration is a limitation that undermines methodological rigor. The study did not predefine progression criteria for advancing to a definitive trial; instead, decisions relied on investigator judgment and existing literature on ICBT and university populations. While predefined feasibility criteria are recommended by guidelines, caution and flexibility are also advised to account for variability and avoid

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reliance on arbitrary thresholds that may distort feasibility assessments [39]. The feasibility evaluation followed the general principles of feasibility assessment, including necessary modifications before scaling. Ethical considerations concerned balancing potential benefits and risks. Another limitation is the lack of qualitative data on participants' perspectives to clarify acceptability, especially regarding novel treatment features. Nevertheless, inclusion of validated feasibility measures, systematic retention monitoring, open-ended responses, and dropout reasons provided valuable contextual insights. While generalizability to real-world settings is not a primary aim of feasibility research, trial methods mirror those planned for a definitive trial and are also similar to those in Swedish primary health care for ICBT, where digital self-application and screening are increasingly adopted [12].

Conclusion

This study represents the first evaluation of personalized, adaptive ICBT for the treatment of anxiety and depression in a university student population. Findings indicate the feasibility of this approach, supported by metrics of treatment engagement, personalization, and adequate acceptability ratings. However, challenges—notably poor assessment retention and treatment-related stress—were observed, necessitating the development of optimized frameworks to improve these outcomes in a definitive trial.

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Data Availability

The CBT treatment materials (in Swedish) are available upon request. The datasets analyzed during this study are available upon reasonable request.

Authors' Contributions

The study was conceptualized by NT, P Lindner, CA, P Lindfors, MB, and AHB. Data curation was conducted by NT, and formal analysis was performed by NT and OM. Funding was acquired by P Lindner, CA, P Lindfors, and AHB. NT and AHB carried out the investigation, and the methodology was developed by NT, P Lindner, CA, P Lindfors, MB, and AHB. Project administration was managed by NT and AHB, with resources provided by NT, GA, and AHB. Software development was conducted by NT, GV, and AHB. Supervision was provided by NT, MK, CS, and AHB, and validation was performed by AHB. NT drafted the original manuscript.

Conflicts of Interest

MB owns a private company (Alexit AB) that maintains and distributes evidence-based digital lifestyle interventions. AHB owns a private practice psychotherapy company (Otimus AB). Neither company played any role in developing this report.

Multimedia Appendix 1
CONSORT 2010 checklist of items to include when reporting a pilot or feasibility trial.
[PDF File (Adobe PDF File), 76 KB - formative_v10i1e68698_app1.pdf]

Multimedia Appendix 2
The TIDieR (Template for Intervention Description and Replication) checklist.
[PDF File (Adobe PDF File), 114 KB - formative_v10i1e68698_app2.pdf]

Multimedia Appendix 3
Anxiety and depression outcomes.
[DOCX File , 15 KB - formative_v10i1e68698_app3.docx]

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Abbreviations

CEQ: Credibility-Expectancy Scale
CONSORT: Consolidated Standards of Reporting Trials
DMHI: digital mental health intervention
GAD-7: General Anxiety Disorder-7
ICBT: internet-delivered cognitive behavior therapy
ICBT-DEP: ICBT for Depression
NEQ-20: Negative effects questionnaire-20
PHQ-9: Patient Health Questionnaire-9
TIDieR: Template for Intervention Description and Replication
WHO: World Health Organization
WMH-ICS: World Mental Health Initiative Survey

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Original Paper

The Effect of Telehomecare on Patients' Health-Related Quality of Life, Satisfaction, Disease Self-Management Skills, Provider Satisfaction, and Informal Caregiver Strain: Longitudinal Cohort and Cross-Sectional Study

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Abstract

Background: Heart failure (HF) and chronic obstructive pulmonary disease (COPD) are responsible for a significant amount of the economic and chronic disease burden that impacts the Ontario health system. Telehomecare, a home self-management program launched by the Ontario Telemedicine Network (OTN), was created to improve access to quality care and limit health care use. However, few data are available on patient-, caregiver-, and provider-reported outcomes of telehomecare.

Objective: This study aims to evaluate the impact of the OTN telehomecare program on the health-related quality of life (HRQoL), disease-management skills, and satisfaction of patients with HF and those with COPD; informal caregiver strain index; and nurse satisfaction with telehomecare.

Methods: We used a prospective longitudinal cohort design, including patients with HF and those with COPD enrolled in Ontario's telehomecare program, informal caregivers of patients in the program, and nurses providing services in telehomecare. Patients and informal caregivers were administered telephone surveys at baseline, month 3, month 6, and month 12 follow-up from July 2016 to December 2019. The outcomes for the longitudinal surveys were patient-perceived HRQoL, disease self-management skills, perception of telehomecare (ease of use and usefulness), satisfaction with telehomecare, and informal caregiver-perceived strain. Cross-sectional surveys were conducted with nurses to assess nurse perception and satisfaction with telehomecare. Participant data were analyzed using general linear mixed models in SAS Statistical Software (version 9.4; SAS Institute Inc).

Results: Overall, a total of 194 patients (HF, n=117; COPD, n=77), 62 caregivers, and 24 nurses participated, with an overall response rate of 51% (280/551). The average age of patients with HF and those with COPD was 71 (SD 11.3) years and 70 (SD 11.1) years, respectively, and 52% (100/194) were men. A significant improvement in overall HRQoL was observed among patients with HF at month 12 (−18.37, P<.001). Minimal clinically important differences were observed across all HRQoL domains for people with HF, indicating clinically meaningful improvement over the study period. No statistically significant improvement in HRQoL was observed among patients with COPD; however, minimal clinically important differences were observed in the physical functioning dimension. Patients reported being confident in self-managing their diseases throughout the study, but as patients aged, their perception of and satisfaction with telehomecare was shown to decrease (P=.002 and P=.002,

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respectively). Caregivers reported relatively low strain scores (mean 10.3, SD 5.9) throughout the program, and nurses reported moderate levels of satisfaction (mean 6.7, SD 1.5) with telehomecare at follow-up.

Conclusions: In this population, telehomecare demonstrated an ability to improve the HRQoL of patients with HF and those with COPD. However, the long-term sustainability of HRQoL improvements in patients following telehomecare requires further investigation. Furthermore, telehomecare was shown to decrease informal caregiver-perceived strain, and nurses described moderate levels of satisfaction and perceived quality of care with telehomecare.

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KEYWORDS

chronic obstructive pulmonary disease; heart failure; longitudinal data analysis; patient-reported outcomes; remote patient monitoring; telehomecare

Introduction

Chronic diseases are the leading cause of death and disability in Ontario and require continued comprehensive care and monitoring. Heart failure (HF) and chronic obstructive pulmonary disease (COPD) are responsible for a significant amount of the economic and chronic disease burden that impacts the Canadian health system [1-3]. An estimated 1 million Canadians are currently living with HF [4], which is projected to have a direct cost of CAD $2.8 billion (US $2.03 billion) per annum, with hospital readmissions due to HF costing nearly CAD $500 million (US $365 million) a year [5]. COPD is estimated to be the sixth leading cause of mortality in Canada, with the national burden estimated to be CAD $1.5 billion (US $1.09 billion), and exacerbations projected to cost between CAD $650 million (US $474.5 million) and CAD $740 million (US $540.2 million) annually for moderate and severe events, respectively [6]. Patients with HF and those with COPD have been known to have poor health-related quality of life (HRQoL), diminished life expectancy, suffer from frequent acute exacerbations, and experience various other comorbidities, such as other cardiovascular diseases, diabetes, cancer, depression, osteoporosis, and malnutrition [7,8]. Informal caregivers play a central role in the health outcomes of patients with HF and those with COPD, but caregiving has also been shown to have a substantial impact on caregiver outcomes. Informal caregivers of patients with HF and those with COPD face complex situations; besides providing practical help, caregivers face physical, psychological, and social burdens in providing care and support [9,10]. Additionally, caregiving has been associated with an increased risk of depression, mortality, and poor quality of life [10,11].

Telemedicine and virtual care are innovative solutions to chronic disease management [12,13]. The use of remote patient monitoring allows for targeted follow-up and improved continuity of care [14]. Telemedicine programs can improve patient self-management and increase self-efficacy [15], quality of life, and satisfaction [16]. Telemedicine programs have been successfully implemented in various countries around the world [17]; however, before the COVID-19 pandemic, Canada's adoption of telemedicine lagged behind most other nations [18]. The pandemic has accelerated the global adoption of telemedicine, changing how people in Canada access health care by speeding up digital transformation. Many patient consultations, both primary and specialist, are now conducted virtually [19].

The Ontario telehomecare program was launched in 2007 through collaboration with the Ontario Telemedicine Network (OTN), Ontario Ministry of Health and Long-Term Care, and the Canada Health Infoway to improve access to quality care for patients with HF and those with COPD and limit potential health care use [20]. Telehomecare, a 6-month home self-management program delivered by nurses using health coaching and remote patient monitoring, allows patients with chronic conditions the opportunity to be actively involved in their care [20,21]. The results of the program's clinical outcomes, implementation, and adoption have been reported elsewhere [3,22-24]. However, the long-term perceptions of the patients' quality of life and self-management, as well as those of caregivers and providers involved within telehomecare, have not yet been reported, highlighting the need for further longitudinal research. The importance of highlighting patient-centered care in designing and implementing a comprehensive telehomecare program allows for greater attention to detecting sudden changes in overall health, which patients find most important. Patient-reported outcomes, such as HRQoL, are reports coming directly from patients about how they feel concerning a health condition and its therapy, without interpretation of their responses by a clinician or caregiver [25]. Patient reported-outcomes are important because they provide patients' perspectives on treatment benefits and provide another opportunity to measure treatment benefits beyond survival, disease, and physiological markers [26].

This study aimed to (1) evaluate the impact of the OTN telehomecare program on HRQoL, disease self-management skills, and satisfaction with the program among patients with HF and those with COPD and (2) determine informal caregiver strain and nurse satisfaction with telehomecare.

This study highlights the importance of not only focusing on patient outcomes but also on informal caregivers and telehomecare nurses when evaluating an intervention. Understanding the OTN telehomecare's impact requires a comprehensive view of all stakeholders involved. Informal caregivers assist with transmitting the clinical data daily to the telehomecare nurses, who monitor the data and ensure patient safety. Examining these stakeholders helps to understand how the technology influences health outcomes and support systems, leading to more effective, patient-centered care.

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Methods

Ethical Considerations

Before engaging potential study participants, the intervention evaluation protocol was approved by the Research Ethics Board of the University Health Network (Reference No: 16-5136). Ethics approval was secured from 77 sites, including hospitals, Community Care Access Centers, community health centers, and family health teams participating in the telehomecare program across 8 local health integration networks (LHINs). The evaluation study team contacted potential patient participants by telephone, and if they agreed to participate, verbal consent was obtained using a telephone consent script approved by the Research Ethics Board. All other stakeholders who agreed to take part in the study provided consent either in person or by telephone. Participants who provided consent received a copy of the study information and consent form and were informed that the research findings would be published in reports, articles, and presentations. All study data were anonymized and deidentified.

Study Design and Population

This study followed the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) guidelines [27]. This study used a prospective longitudinal cohort and cross-sectional design, and the population included patients with HF or COPD enrolled in the telehomecare program, telehomecare nurses, and informal caregivers participating in telehomecare across 8 LHINs in Ontario from July 2016 to December 2019. The LHINs were created to plan, coordinate, integrate, and fund health services at the local level and are separated into different geographical catchment areas. Patients and caregivers were referred to the program through the LHINs or self-referrals and were screened for program eligibility criteria by telehomecare staff. Patients and caregivers were approached and purposively selected to ensure variation in sampling from each LHIN (urban vs rural) and disease type. Those patients and caregivers who agreed to participate were administered longitudinal surveys. The OTN, in collaboration with the LHIN engagement leads, referred telehomecare nurses to the evaluation study team. Nurses who were delivering telehomecare at the time of the evaluation were considered and approached to participate in the cross-sectional surveys.

Eligibility for Telehomecare

Patients and caregivers qualified with a documented HF or COPD diagnosis, with or without comorbidities. “Heavy users” had recent respiratory or cardiac hospitalizations or multiple emergency visits. They also may have been receiving nursing services or had frequent primary care visits. Eligibility included being aged 18 years and older, capable of consent, fluent in English, able to operate telehomecare equipment, and residing in a private or retirement home with a landline. Additional criteria for the intervention study required consent to telehomecare, sharing contact and health information, and participating in evaluations. Patients were contacted and enrolled in surveys within 2-3 weeks of their telehomecare start date. Health care providers were included if they had referred a patient who had previously been enrolled in the telehomecare and/or had participated in delivering telehomecare as a provider or care administrator. For surveys, nurses needed at least 2 months of experience in providing care using telehomecare.

Patients aged 18 years or younger, those without an established diagnosis of COPD or HF, those unable or unwilling to provide verbal informed consent, and those demonstrating nonadherence to the telehomecare program were not eligible. The telehomecare nurse worked with each patient on a case-by-case basis to assess their willingness to participate in their own care and to determine if missed consultations and their reasons reflected overall nonadherence. Additionally, individuals who could not or would not use telehomecare equipment, or who did not have a regular caregiver to assist with the equipment if needed, were also excluded. Health care providers who did not practice in any of the 8 LHINs were excluded.

Telehomecare Program Intervention

The telehomecare program intervention has been described extensively elsewhere [22]. Telehomecare aims to improve self-management skills for patients with HF and those with COPD by providing remote monitoring and nurse-delivered individualized health coaching sessions using the 5A’s (assess, advise, agree, assist, and arrange) Behavior Change Model [23,28,29]. Patients are provided with a touch-screen tablet, weight scale, blood pressure monitor, and pulse oximeter for weekday submission (Monday-Friday) of clinical information and self-report [23,30]. Telehomecare nurses monitor incoming patient information and respond to any deteriorating conditions or alerts triggered due to data received outside “normal” thresholds [31]. Following an alert, a nurse follows up and determines a course of action. If an alert impacts a patient’s well-being, telehomecare nurses immediately communicate with the patient’s care team.

Outcome Measures and Data Collection

The outcomes for the longitudinal surveys were patient-perceived HRQoL, disease-management skills, perception of telehomecare, satisfaction with telehomecare, and caregiver-perceived strain. Cross-sectional surveys were conducted to assess nurse perception and satisfaction with telehomecare. Patients and caregivers were administered telephone surveys at baseline, 3, 6, and 12 months after starting the program from July 2016 to December 2019. Participants were contacted for a follow-up at least 4 (maximum 10) times and within 1 week before and 1-2 weeks after the scheduled date. Validated questionnaires were used to evaluate patients’ general and disease-specific HRQoL, satisfaction with telehomecare, self-management skills, and telehomecare perception. A complete list of survey instruments and details can be found in Multimedia Appendix 1.

Questionnaires

Minnesota Living With Heart Failure Questionnaire

The Minnesota Living with Heart Failure (MLHF) is a 21-item questionnaire that evaluates the impact of frequent physical and emotional symptoms in patients with HF, with a higher score representing a worse impact on HRQoL [32]. The minimal clinically important difference (MCID) has been estimated to

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be 2.56 points in the physical domain, 0.98 points in the emotional domain, and 4.84 points in the overall domain [33].

Seattle Obstructive Lung Disease Questionnaire

The Seattle Obstructive Lung Disease Questionnaire (SOLD) is designed to monitor HRQoL in patients with COPD using 29 items and 4 scales. Larger scores in each dimension reflect a greater perception of HRQoL [34]. A change of approximately 5 points was observed for the MCID [34].

EQ-5D

The EQ-5D is a generic HRQoL measure which consist of an index score (0-1) and a visual analog scale (VAS; 0-100), with scores ranging from worst (0) to best health (1 or 100, respectively) [35].

Short-Form-12

The Short-Form-12 (SF-12) version 1 measures general HRQoL using 2 composite domains, with scores ranging from 0, the lowest, to 100, which represents the highest level of health in the physical component score (PCS) and mental component score (MCS) summary dimensions [36]. Within patients with HF, an MCID of 1.26 points in the PCS and 2.28 points in the MCS was reported [33]. There is limited information on the MCID for patients with COPD using the SF-12 version 1.

Chronic Disease Self Efficacy Scales Questionnaire

The Chronic Disease Self Efficacy Scales (SES) Questionnaire measures disease management skills with 6 items on a scale of 1-10, with higher scores indicating an improved level of self-confidence [37].

Telemedicine Perception Questionnaire

The Telemedicine Perception Questionnaire (TMPQ) measures patient perception of telehomecare and includes 17 items, with higher scores indicating a more positive perception of telehomecare [38].

Client Satisfaction Questionnaire

The Client Satisfaction Questionnaire–4 (CSQ-4) measures client satisfaction with program services, with higher scores indicating greater satisfaction [39].

Modified Caregiver Strain Index

Caregivers' perceived strain was captured using the Modified Caregiver Strain Index (MCSI) with higher scores ranging from 0 (no strain) to 26 (highest level of strain) [40].

Nurse Satisfaction Questionnaire

Cross-sectional surveys using the Nurse Satisfaction Questionnaire (NSQ) were conducted with the nurses involved in the program to capture their satisfaction levels with telehomecare and perceived quality of care. The NSQ was administrated from August 2016 to March 2018 and scored on a 1-10 (best) scale.

Data Missingness

Missing values at the survey level were imputed for the MLHF using its predetermined methods to neutralize the effects of missing values when calculating and comparing changes in scores [41]. Item number 10 within the MLHF was found to have a large proportion of item-level missingness, likely due to the item reflecting sexual activities. The TMPQ can only be scored when all items have been completed. Responses missing completely at random for the TMPQ were imputed using the last recorded observation for that question carried forward [42]. Missing values within the SOLD, SES, CSQ-4, MCSI, and NSQ were not imputed within the dataset, as this did not impact the ability to score the surveys. Missing values in the SF-12 were not imputed, and incomplete responses were not analyzed.

Statistical Analysis

All analyses were performed using SAS Statistical Software (version 9.4, SAS Institute Inc). Descriptive statistics were used to summarize patient, provider, and caregiver survey data. Continuous variables were described using means and SDs. Categorical variables were described using counts and percentages. The entire cohort of patients was used to analyze the survey data for the SF-12, EQ-5D, SES, TMPQ, and CSQ-4. To look at telehomecare's impact on the varying disease types (HF vs COPD), analyses using the MLHF and SOLD were performed using the respective patient cohorts. Repeated measures of the patient and caregiver surveys for continuous values were analyzed using generalized linear mixed models to determine if outcome measures of HRQoL, client satisfaction, telemedicine perception, and self-management scores were changing over time. A separate analysis was conducted for each outcome measure. The models were selected using the Akaike Information Criterion and used Restricted Maximum Likelihood estimation methods. Covariates included LHIN, disease type, age, gender, time, and the interactions between these variables of interest (time × diagnosis and time × gender). The Kenward-Roger approximation was used for the degrees of freedom, and the α level was set at 0.05 for all parameter tests [43]. EQ-5D-3L utility index scores were calculated using the Canadian value set [44]. Additionally, to address potential response bias, patient demographics of participants who consented and those who declined participation were analyzed using chi-square and 2-tailed Welch *t* tests.

Results

Study Enrollment

Between July 2016 and December 2019, a total of 318 participants consented to take part in the study. Of those, 38 participants were excluded because they subsequently declined the surveys, withdrew, and were nonresponsive when contacted. In total, 194 patients (HF, n=117; COPD, n=77), 62 caregivers, and 24 nurses were enrolled in the program. An overall participant response rate of 51% (280/551) was observed. Figure 1 outlines the flow of participants through the study. The average age of patients with HF and those with COPD who participated in the surveys was 71 (SD 11.3) years and 70 (SD 11.1) years, respectively, and 52% (100/194) were men.

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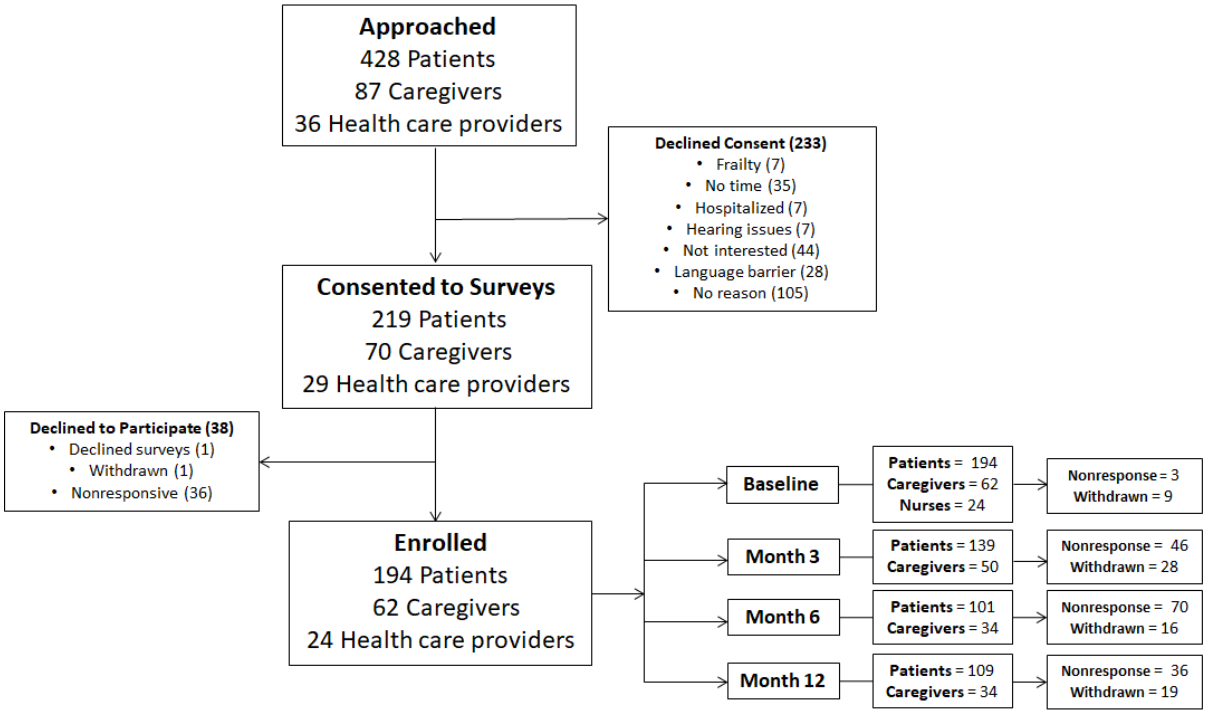
Figure 1. Patient flowchart.



To assess potential response bias, we examined the characteristics of patients who consented to surveys and those who declined. The declined group consisted of patients who refused participation, whether they were approached directly or identified through the Patient Management and Monitoring System. There were no differences seen in relation to gender and condition; however, patients who declined to participate in surveys were older adults (Table 1). There is a possibility that older patients may have been in worse health and may not have benefited from being enrolled in telehomecare.

Table 1. Demographic characteristics of patients who consented and declined telehomecare participation.

Category and demographic	Consented (n=218)	Declined (n=402)	*P* value
Condition, n (%)			.85
HF[a]	129 (59.2)	241 (60)	
COPD[b]	89 (40.8)	161 (40)	
Gender, n (%)			.76
Male	108 (49.5)	194 (48.3)	
Female	110 (50.5)	208 (51.7)	
Age (years)			<.001
Missing, n	4	3	
Mean (SD)	69.6 (11.4)	74.6 (11.2)	
Range	29.0-98.0	30.0-102.0	

[a]HF: heart failure.

[b]COPD: chronic obstructive pulmonary disease.

Survey Administration

We administered longitudinal survey instruments at baseline, month 3, month 6, and month 12 for patients and caregivers; however, not all participants completed the surveys at all timepoints. Cross-sectional surveys were administered to nurses with at least 2 months of experience in providing care using telehomecare. As noted in Table 2, the administration of surveys declined over the study duration due to participants being nonresponsive or withdrawing at various timepoints; a patient could complete the baseline surveys but fail to complete subsequent follow-ups. Across each instrument 40% (47/117; MLHF) to 42% (47/112; SES, TMPQ, and CSQ) of patients with HF completed surveys at all timepoints, 34% (26/77; SOLD) to 36% (27/76; SES, TMPQ, and CSQ) of patients with COPD completed surveys at all timepoints, and 37% (23/62; MCSI) of informal caregivers completed surveys at all timepoints.

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Table 2. Complete survey administrations by population.

Population and instrument	Baseline, n	Month 3, n	Month 6, n	Month 12, n	Completed all timepoints, %
Patients with heart failure					
MLHF[a]	117	87	60	68	40
EQ-5D	117	87	60	68	40
SF-12[b]	116	86	60	63	41
SES[c]	112	85	60	68	42
TMPQ[d]	113	86	59	66	42
CSQ[e]	113	85	59	64	42
Patients with chronic obstructive pulmonary disease					
SOLD[f]	77	51	40	41	34
EQ-5D	77	52	41	41	34
SF-12	77	51	40	39	35
SES	76	50	40	41	36
TMPQ	76	52	40	41	36
CSQ	76	52	40	41	36
Informal caregivers					
MCSI[g]	62	50	34	34	37
Nurses					
NSQ[h]	24	N/A[i]	N/A	N/A	N/A

[a]MLHF: Minnesota Living with Heart Failure.

[b]SF-12: Short-Form-12.

[c]SES: Self Efficacy Scales.

[d]TMPQ: Telemedicine Perception Questionnaire.

[e]CSQ: Client Satisfaction Questionnaire.

[f]SOLD: Seattle Obstructive Lung Disease Questionnaire.

[g]MCSI: Modified Caregiver Strain Index.

[h]NSQ: Nurse Satisfaction Questionnaire.

[i]N/A: not applicable.

Findings

MLHF

A total of 117 patients with HF completed the MLHF, contributing 332 observations across all timepoints. From baseline to month 12 the overall domain scores ranged from 44.6 (SD 23.8) to 21.5 (SD 15.7), physical domain scores from 20.3 (SD 10.8) to 12.2 (SD 8.2), and emotional domain scores from 10.4 (SD 7.4) to 3 (SD 3.3), indicating an improved (lower) score over time in each domain (Table 3). When adjusting for age and gender within the overall, physical, and emotional domains patients, with HF were shown to significantly improve over the 12-month follow-up (−18.37, $P<.001$; −5.77, $P<.001$; and −6.63, $P<.001$), respectively. Within the overall and physical domains, women were shown to have higher scores (worse health) than men (10.8, $P=.01$; 4.4, $P=.02$, respectively). However, within the overall and physical domains, women were shown to have significantly lower scores than men at month 12 (−9.53, $P=.03$; −5.42, $P=.01$, respectively), indicating a greater improvement in health over the study period. Across each timepoint and domain, the MCID was observed, indicating a clinical improvement in HRQoL for patients with HF receiving telehomecare (Table 4).

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Table 3. Mean scores of survey instruments.

Instrument, domain, and diagnosis	Baseline, mean (SD)	Month 3, mean (SD)	Month 6, mean (SD)	Month 12, mean (SD)
MLHF[a]				
Overall				
HF[b]	44.6 (23.8)	31.3 (24.7)	29.1 (21.4)	21.5 (15.7)
Physical				
HF	20.3 (10.8)	15.5 (11.2)	14.8 (10.1)	12.2 (8.2)
Emotional				
HF	10.4 (7.4)	5.4 (5.7)	4.9 (4.7)	3 (3.3)
SOLD[c]				
Physical function				
COPD[d]	36.6 (20)	39.1 (22)	39.6 (22.6)	42.5 (21.3)
Emotional function				
COPD	65.2 (22.8)	70.4 (20.8)	69.4 (20.9)	67.2 (19.4)
Coping skills				
COPD	66.8 (21.7)	72.2 (20.1)	73.5 (23.8)	72.6 (18.4)
Treatment satisfaction				
COPD	66.7 (18.8)	73.9 (13.8)	74.5 (16.2)	68.8 (18.4)
EQ-5D				
Index				
HF	0.69 (0.18)	0.71 (0.22)	0.69 (0.19)	0.69 (0.19)
COPD	0.70 (0.19)	0.68 (0.24)	0.70 (0.16)	0.68 (0.16)
VAS[e]				
HF	55.6 (19.9)	56.9 (18.6)	54.7 (17.7)	55.4 (15.6)
COPD	65 (19)	59.4 (18.1)	57.4 (17.8)	55.1 (17.9)
SF-12[f]				
PCS[g]				
HF	32.4 (9.8)	36.2 (11.5)	34.4 (10.4)	33.9 (11.3)
COPD	33.8 (9.2)	34.5 (11.4)	33.3 (10.6)	35.6 (9.9)
MCS[h]				
HF	47.8 (9.2)	47.9 (9.6)	49.5 (7.6)	50.0 (6.5)
COPD	49.3 (10.4)	48.3 (9.7)	48.3 (9.5)	47.6 (9.3)
SES[i]				
HF	6.2 (2.0)	6.3 (1.8)	6.3 (1.8)	6.0 (1.8)
COPD	6.7 (2.1)	6.2 (1.7)	6.2 (1.7)	6.1 (1.9)
TMPQ[j]				
HF	62.1 (5.2)	64.6 (7.2)	64.7 (7.0)	61.7 (5.4)
COPD	62.8 (4.6)	65.5 (6.3)	65.9 (6.4)	62.9 (3.6)
CSQ[k]				
HF	13.6 (2.1)	13.9 (2.2)	14 (2.1)	13.3 (2.1)
COPD	14.1 (1.7)	14.5 (1.5)	14.5 (1.6)	13.8 (1.8)
MCSI[l]				

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Instrument, domain, and diagnosis	Baseline, mean (SD)	Month 3, mean (SD)	Month 6, mean (SD)	Month 12, mean (SD)
Caregiver strain	10.7 (6.2)	11.3 (6.4)	11.5 (6.3)	10.3 (5.9)
NSQ[m]				
Nurse satisfaction	6.7 (1.5)	N/A[n]	N/A	N/A
Quality of care	6.1 (0.5)	N/A	N/A	N/A

[a]MLHF: Minnesota Living with Heart Failure.
[b]HF: heart failure.
[c]SOLD: Seattle Obstructive Lung Disease Questionnaire.
[d]COPD: chronic obstructive pulmonary disease.
[e]VAS: visual analog scale.
[f]SF-12: Short-Form-12.
[g]PCS: physical component score.
[h]MCS: mental component score.
[i]SES: Self Efficacy Scales.
[j]TMPQ: Telemedicine Perception Questionnaire.
[k]CSQ: Client Satisfaction Questionnaire.
[l]MCSI: Modified Caregiver Strain Index.
[m]NSQ: Nurse Satisfaction Questionnaire.
[n]N/A: not applicable.

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Table 4. Estimated change over time for survey domains.

Instrument, domain, and variable	Baseline	Month 3	Month 6	Month 12
	Estimate (*P* value)	Estimate (*P* value)	Estimate (*P* value)	Estimate (*P* value)
MLHF[a]				
Overall (n=115)				
Age	–0.08 (.58)	N/A[b]	N/A	N/A
Time	N/A	–8.87 (.005)	–11.68 (<.001)	–18.37 (<.001)
Gender	10.80 (.01)	N/A	N/A	N/A
Time × gender	N/A	N/A	N/A	–9.53 (.03)
Physical (n=115)				
Age	0.02 (.73)	N/A	N/A	N/A
Time	N/A	–3.35 (.03)	–4.54 (.004)	–5.77 (<.001)
Gender	4.40 (0.02)	N/A	N/A	N/A
Time × gender	N/A	N/A	N/A	–5.42 (.01)
Emotional (n=115)				
Age	–0.03 (.48)	N/A	N/A	N/A
Gender	2.03 (.07)	N/A	N/A	N/A
Time	N/A	–3.91 (<.001)	–4.93 (<.001)	–6.63 (<.001)
SOLD[c]				
Treatment satisfaction (n=76)				
Age	–0.02 (.94)	N/A	N/A	N/A
Gender	6.80 (.10)	N/A	N/A	N/A
Time	N/A	9.50 (.01)	11.22 (.004)	N/A
Physical (n=76)				
Time	N/A	–0.85 (.83)	–0.01 (.99)	6.11 (.14)
Age	–0.16 (.56)	N/A	N/A	N/A
Gender	–6.81 (.16)	N/A	N/A	N/A
Coping (n=76)				
Time	N/A	0.32 (.94)	1.33 (.78)	5.88 (.23)
Age	0.20 (.45)	N/A	N/A	N/A
Gender	–1.79 (.72)	N/A	N/A	N/A
EQ-5D				
VAS[d] **(n=190)**				
Age	–0.14 (.17)	N/A	N/A	N/A
Gender	–1.59 (.48)	N/A	N/A	N/A
Diagnosis	9.47 (.001)	N/A	N/A	N/A
Time × diagnosis	N/A	–7.20 (.04)	–6.54 (.08)	–9.78 (.005)
SF-12[e]				
PCS[f] **(n=190)**				
Age	–0.06 (.33)	N/A	N/A	N/A
Gender	–1.67 (.22)	N/A	N/A	N/A
Time	N/A	3.86 (<.001)	2.69 (.02)	2.01 (.06)
Time × diagnosis	N/A	–3.24 (.05)	–2.24 (.21)	0.08 (.96)

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Instrument, domain, and variable	Baseline	Month 3	Month 6	Month 12
	Estimate (*P* value)	Estimate (*P* value)	Estimate (*P* value)	Estimate (*P* value)
MCS[g] (n=190)				
Age	0.03 (.68)	N/A	N/A	N/A
Time	N/A	N/A	N/A	2.25 (.05)
Gender	–13.89 (.05)	N/A	N/A	N/A
Time × diagnosis	N/A	–1.06 (.55)	–2.68 (.16)	–3.53 (.05)
TMPQ[h]				
Telehomecare perception (n=186)				
Time	N/A	2.50 (<.001)	2.80 (<.001)	N/A
Age	–0.10 (.002)	N/A	N/A	N/A
Gender	0.08 (.91)	N/A	N/A	N/A
Time × diagnosis	N/A	–0.12 (.92)	0.42 (.72)	–0.29 (.80)
CSQ[i]				
Client satisfaction (n=185)				
Time	N/A	N/A	N/A	–0.44 (.05)
Age	–0.04 (.002)	N/A	N/A	N/A
Gender	–0.14 (.59)	N/A	N/A	N/A
Time × diagnosis	N/A	–0.03 (.92)	–0.04 (.90)	0.15 (.67)

[a]MLHF: Minnesota Living with Heart Failure.

[b]N/A: not applicable.

[c]SOLD: Seattle Obstructive Lung Disease Questionnaire.

[d]VAS: visual analog scale.

[e]SF-12: Short-Form-12.

[f]PCS: physical component score.

[g]MCS: mental component score.

[h]TMPQ: Telemedicine Perception Questionnaire.

[i]CSQ: Client Satisfaction Questionnaire.

SOLD

A total of 77 patients with COPD completed the SOLD, contributing 209 observations across all timepoints. From baseline to month 12 SOLD physical function scores varied between 36.6 (SD 20) to 42.5 (SD 21.3), emotional function scores from 65.2 (SD 22.8) to 67.2 (SD 19.4), coping skills scores from 66.8 (SD 21.7) to 72.6 (SD 18.4), and treatment satisfaction scores from 66.7 (SD 18.8) to 68.8 (SD 18.4), indicating an improved (higher) score over time in each domain (Table 3). Considering all covariates (time, age, and gender) within each SOLD domain, only treatment satisfaction at months 3 and 6 was statistically significant (*P*=.01; *P*=.004, respectively), indicating higher satisfaction with treatments while enrolled in telehomecare. MCIDs were observed in the physical function and coping skills dimensions over the 12-month follow-up, as well as at months 3 and 6 of the treatment satisfaction dimensions (Table 4).

EQ-5D

HF index scores remained consistent from baseline to month 12, whereas COPD index scores declined over the same period. Index scores from baseline to month 12 ranged from 0.69 (SD 0.18) to 0.69 (SD 0.19) for patients with HF and 0.70 (SD 0.19) to 0.68 (SD 0.16) for patients with COPD (Table 3). From baseline to month 12 the mean unadjusted VAS scores ranged from 55.6 (SD 19.9) to 55.4 (SD 15.6) for patients with HF and 65 (SD 19) to 55.1 (SD 17.9) for patients with COPD. HF VAS scores remained consistent from baseline to month 12, with COPD VAS scores declining during that time. In relation to the VAS, patients with COPD had significantly higher scores than patients with HF (*P*=.001). After adjusting for time, age, and gender patients with COPD had significantly lower EQ-5D VAS scores in comparison to patients with HF at month 3 and month 12 (–7.20, *P*=.03; –9.78, *P*=.005), respectively. There were no significant differences between the index scores of patients with COPD and those with HF when adjusting for time, gender, and age (Table 4).

SF-12

A total of 193 patients responded completely to the SF-12 questionnaires, contributing a total of 532 administrations at all timepoints. From baseline to month 12, the mean unadjusted PCS scores ranged from 32.4 (SD 9.8) to 33.9 (SD 11.3) for

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patients with HF and 33.8 (SD 9.2) to 35.6 (SD 9.9) for patients with COPD, indicating an improved (higher) score over time for both conditions. MCS scores varied from 47.8 (SD 9.2) to 50.0 (SD 6.5) for patients with HF and 49.3 (SD 10.4) to 47.6 (SD 9.3) for patients with COPD. HF MCS scores improved from baseline to month 12; however, COPD MCS scores declined during that time (Table 3). In relation to the PCS, there was an improvement in scores at month 3 and month 6 ($P<.001$; $P=.02$). However, at month 3, patients with COPD were shown to have significantly lower scores (worse health) than patients with HF (–3.24, $P=.05$). Within the MCS there was an improvement in scores at month 12 ($P=.05$), and patients with COPD at month 12 were shown to have significantly lower scores (worse health) than patients with HF (–3.53, $P=.05$). Women were also shown to have significantly lower MCS scores than men, regardless of condition (–13.89, $P=.05$). MCIDs were achieved in the HF PCS scores across each timepoint, indicating a clinical improvement in the health of patients with HF (Table 4).

Chronic Disease SES Questionnaire

Patient self-management scores were consistently high throughout the program and did not improve over time after adjusting for age, gender, and diagnosis. Additionally, patients with HF and those with COPD did not express any significant differences in their ability to self-manage disease symptoms.

TMPQ

Throughout all timepoints, patients reported high levels of satisfaction with telehomecare as reported on the TMPQ summary scores (Table 3). The perception of telehomecare improved at month 3 and month 6; however, it is important to note that patients were no longer on the program at month 12. The age of patients may have a role to play in their perception of telehomecare. We observed that as patients' ages increased in years, scores of the TMPQ were significantly lower (–0.10, $P=.002$; Table 4).

CSQ

CSQ scores were shown to significantly decline at month 12, likely due to patients not being on the program since month 6. The age of patients may have a role to play in their satisfaction with telehomecare services. Our results indicated that as patients' age increased in years, scores on the TMPQ and CSQ were significantly lower (–0.04, $P=.002$; Table 4).

MCSI

A total of 62 caregivers provided 180 observations across all timepoints for the MCSI, and unadjusted scores from baseline to month 12 were 10.7 (SD 6.2) to 10.3 (SD 5.9), indicating a reduction in caregiver strain. Overall, caregivers had relatively low strain scores across all timepoints and did not improve over time after adjusting for age, gender, and diagnosis.

NSQ

Nurses reported moderate levels of satisfaction and perceived quality of care with telehomecare across all LHINs, with an overall mean of 6.7 (SD 1.5) and 6.1 (SD 0.5), respectively. A complete breakdown of the NSQ results can be found in the Multimedia Appendix 1.

Discussion

Principal Results

In this study, participation in telehomecare was shown to significantly improve perceived HRQoL of patients with HF across all timepoints using the MLHF. An MCID was observed in each domain of the MLHF, inferring a clinical improvement in HRQoL of patients with HF. Additionally, MCIDs were observed in the SOLD, indicating that patients with COPD experienced clinical improvements in physical, coping, and treatment satisfaction function. Results from the EQ-5D indicated that patients with COPD had significantly higher VAS scores than patients with HF. Furthermore, MCIDs were detected in the SF-12 HF PCS scores, indicating a clinical improvement in the health of patients with HF. Using the SES instrument, patients reported being confident in self-managing their diseases throughout the entire study duration, and satisfaction with telehomecare was consistently positive using both the TMPQ and CSQ. Patients who were involved in telehomecare perceived it to be important, but once they completed the program and upon follow-up, their perception of telehomecare was understandably lower. While satisfaction and perception of telehomecare were highly rated at months 3 and 6, as time went on, lower scores were reported by older patients. This could be due to the older patients in the program being in poorer health and having a more difficult time self-managing their comorbid conditions.

Comparison With Prior Work

There are only a few studies which provide patient-reported outcomes as a primary measure or as well-explored secondary outcomes within the literature. The literature surrounding the use of telehealth interventions and their ability to impact patients' HRQoL is inconsistent in definitively proving its value in patients with HF and those with COPD. A review examining telemonitoring in patients with HF and those with COPD further identified conflicting results on telehomecare's impact on HRQoL [14].

Telemedicine's Impact on Patients With HF

Conclusions from the Telemedicine for Heart study identified in the review indicated that patients with HF who received telemonitoring improved their quality of life as measured by the Short-Form-36 (SF-36) [14,45]. Conversely, upon further review of the study, both groups' scores were not significantly different from one another, SF-36 data were not reported completely, and some telemedicine group scores were worse than controls. Therefore, the conclusion that HRQoL was improved in patients with HF could not be supported in the Telemedicine for Heart study [45]. The Telemedicine for Heart study population (mean age 65.2, SD 9.9 years; 233/281, 83% men) varied from this telehomecare study as participants were, on average, younger and their study population was less diverse with only 48 (17%) women [45]. The BEAT-HF 180-day MLHF score (28.50), closely reflects the month 6 score observed in this telehomecare study (29.1, SD 21.4). Additionally, the BEAT-HF telehomecare intervention and patient population were similar to this study with a median age of 73 (range 62-84) years and 46.6% (664/1437) female participants. However, the

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BEAT-HF trial did not provide HRQoL data in full (no baseline data) or report any measures of dispersion, limiting the generalizability of this study's findings [46]. The Medly telemonitoring intervention reported improvements in MLHF scores of patients with HF in comparison to controls over 6 months. The telemonitoring group was predominately men (78%) and was significantly younger (mean age 58, SD 15.5 years) than the telehomecare patient group. Additionally, based on the baseline MLHF overall domain scores of the telemonitoring group (53.2, SD 26.3), these patients had worse symptoms than those enrolled in telehomecare (44.6, SD 23.8) [47].

A Cochrane review of 11 telemonitoring studies that measured HRQoL in patients with HF stated that only 5 studies reported statistically significant improvements in HRQoL outcomes [48]. Among the studies that reported improvements in HRQoL of patients with HF, there are a few caveats to take into consideration. Antonicelli et al [49] reported improvements only in the SF-36 health perception subscale, but component scores remained nonsignificant. The Medicare Coordinated Care Demonstration (MCCD) Project improved SF-36 PCS, MCS, and MLHF overall, physical, and emotional domains of patients with HF. However, these improvements were not significantly different from the results seen in the control group [50]. MCCD patients received a similar remote monitoring program as those in telehomecare. However, their patients with HF were older (mean age 73, SD 8 years) than those enrolled in telehomecare and were predominately male (71/101, 70%). The MCCD MLHF domain scores at baseline, month 6, and after 1 year were also compared to MLHF scores observed in this study [50]. The TIM-HF study reported improvements in SF-36 physical functioning scores in the intervention group versus the control group at 12- and 24-month follow-up after receiving remote patient monitoring. The TIM-HF study patient population was younger than telehomecare, with a mean age of 66.9 (SD 10.8) years, and was less diverse, with primarily men (81%) enrolled [51]. Subsequently, the TIM-HF II study, with a mean age of 70 (SD 11) years, like telehomecare, reported no statistical differences in MLHF scores between remote patient monitoring and usual care from baseline to 12 months [52].

Impact of Telemedicine on Patients With COPD

Two Cochrane reviews examining patients with COPD with a history of admissions for exacerbations concluded that telemonitoring provided inconclusive evidence of a benefit and did not improve patients' quality of life compared to usual care [53,54]. The review of tele–health care interventions for COPD by McLean et al [55] identified only 2 studies which reported HRQoL using validated instruments. The meta-analysis in this review reported an imprecise pooled estimate, which indicated insufficient evidence to demonstrate a clear benefit of tele–health care interventions for patients with COPD. The included studies contained patients aged 69.4 (SD 6.5) years and those aged 70 (SD 9) years, which closely related to the telehomecare population [56,57]. The TeleCare North study was a large-scale trial aimed at establishing evidence of HRQoL in patients with COPD receiving tele–health care in Denmark and closely resembling telehomecare. TeleCare North reported nonsignificant differences between intervention and control groups when looking at SF-12 PCS and MCS scores over 12 months. Interestingly, the findings of the TeleCare North study suggest that tele–health care interventions may provide a psychological benefit and work to slow the deterioration of mental health in patients with COPD [58]. In comparing the unadjusted MCS scores from baseline to month 12 for patients with COPD, a similar reduction in change scores was observed (telehomecare, –1.7 vs TeleCare North, –1.5).

HRQoL and Remote Patient Monitoring

These results reinforce the inconsistencies in the literature regarding telemonitoring improving HRQoL among patients with HF and those with COPD [58,59]. Using a disease-specific measure such as the MLHF may be more appropriate than the SF-12 or SF-36 in capturing significant changes in the health of patients with HF over time, while a more responsive disease-specific measure may need to be identified for longitudinal use in patients with COPD. Additionally, a greater emphasis may need to be placed on the MCID of HRQoL for patients with HF and those with COPD receiving telehomecare. Telehomecare seems to be well received by the majority of patients, but home telemonitoring may have more significant benefits to the HRQoL of patients with HF and those with COPD in mild to moderate disease states than those whose health has already begun to deteriorate [60]. These results provide more credence to the use of a risk stratification framework to identify patients with mild to moderate risk of hospitalization who should be directed to telehomecare [61,62]. Future research should focus on using disease-specific measures to assess HRQoL in patients and assessing change using validated MCIDs to identify meaningful change.

Clinician and Caregiver Involvement in Telemedicine

For telehomecare to be readily accepted and implemented, health care providers must be on board and believe it brings tangible benefits to their patients. Engagement and collaboration from clinicians may be critical success factors for telehomecare, as clinicians are at the forefront of the care provided to patients, and they should be a part of designing the program. Additionally, telehealth interventions should be integrated into the clinician's workflow, creating an environment that is conducive to the use of the equipment [62-64]. El-Dassouki et al [65] report how a telemedicine intervention can reduce uncertainty, reduce caregiver strain by easing their workload, and mitigate clinical knowledge requirements.

Strengths and Limitations

A vital strength of the longitudinal surveys was the use of validated generic and disease-specific measures, which provided us with the opportunity to compare important changes in patient's health over time. Using the MLHF and SOLD questionnaires allowed us to measure fundamental changes that patients deemed as important to their health status regarding their condition. The length of follow-up (12 months) was also an asset for the study because we were able to evaluate patients' self-management skills and perception of telehomecare after being off the program for a considerable amount of time. This study has limitations, which warrant discussion. First, this study was a part of a comprehensive program evaluation, which did

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not have a control group to evaluate the impact of telehomecare compared to usual care. Second, we were unable to gain access to a proportion of the patient's demographic information due to the migration of OTN telehomecare databases during this study' period. Third, there was no longitudinal follow-up for the NSQ; scores were cross-sectional. Fourth, we were not notified each time a patient passed away within the program; consequently, not every patient death was explicitly documented. When a participant was found to have died, their status was recorded as a withdrawal. Lastly, we were unable to recruit a reasonable number of physicians to take part in the study and gain their perceptions of telehomecare, which is critically important in understanding its adoption by health care providers.

Conclusion

Telehomecare was created to improve access to quality care and reduce health care use by delivering health care at a distance and providing tailored feedback. The OTN telehomecare program has demonstrated an ability to improve the HRQoL of patients with HF and those with COPD. However, the long-term sustainability of HRQoL improvements requires further investigation. Additionally, telehomecare has been shown to decrease informal caregiver perceived strain, and telehomecare nurses described moderate levels of satisfaction and perceived quality of care with telehomecare. Telehomecare seems to be well received by most patients with HF and those with COPD, but more research is needed into home telemonitoring to determine its value in improving HRQoL.

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Authors' Contributions

VER, TF, AS, and NS led the design of this study. TF, SM, AS, and NS were involved in the acquisition of survey data. TF, AS, and VER were involved in the analysis, interpretation of data, and drafting of the manuscript. All authors have read and approved the final version of the manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Description of survey instruments and nurse satisfaction questionnaire.
[DOCX File , 31 KB - formative_v10i1e70809_app1.docx]

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Abbreviations

COPD: chronic obstructive pulmonary disease
CSQ-4: Client Satisfaction Questionnaire–4
HF: heart failure
HRQoL: health-related quality of life
LHIN: local health integration network
MCCD: Medicare Coordinated Care Demonstration
MCID: minimal clinically important difference
MCS: mental component score
MCSI: Modified Caregiver Strain Index
MLHF: Minnesota Living with Heart Failure
NSQ: Nurse Satisfaction Questionnaire
OTN: Ontario Telemedicine Network
PCS: physical component score
SES: Self Efficacy Scales
SF-12: Short-Form-12
SF-36: Short-Form-36
SOLD: Seattle Obstructive Lung Disease Questionnaire
STROBE: Strengthening the Reporting of Observational Studies in Epidemiology
TMPQ: Telemedicine Perception Questionnaire
VAS: visual analog scale

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Original Paper

Uptake of Large Language Models by London Medical Students: Exploratory Qualitative Interview Study

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Abstract

Background: The popularity of large language models (LLMs) has grown exponentially across health care. Despite the wealth of literature on proposed applications in medical education, there remains a critical gap regarding their real-world use, benefits, and challenges as experienced by medical students themselves.

Objective: We aimed to explore qualitatively and characterize the perceived benefits, facilitators, and barriers associated with the use of LLMs among a cohort of London-based medical students.

Methods: Semistructured interviews were conducted with 15 medical students from preclinical and clinical stages at London-based medical schools. Guided by the technology acceptance model, interview transcripts underwent an inductive thematic analysis to identify themes on actual system use, perceived usefulness, ease of use, and attitudes toward LLMs.

Results: All participants reported frequent use of ChatGPT for concise topic summarization, clarification of complex concepts, generation of examination-style questions, and summarization of research. Students described LLMs as a complementary tool to traditional materials, valuing their immediacy ("Instead of getting a textbook, I can ask ChatGPT to summarise something in X words and read it in under a minute") and ease of use. Peer demonstration and device-agnostic accessibility emerged as key facilitators. Of note, wider applications such as simulating clinical interviews were discovered through peers rather than through formal teaching. Significant barriers were reported. Hallucinations, fabricated references, and outdated information led to loss of trust, with more junior students finding inaccurate outputs difficult to detect ("I stopped using it because I found it to be inaccurate, and I don't want to be learning the wrong things"). Half of the participants interviewed reported a sense of overreliance, defaulting to its use for answers with a perceived loss of critical thinking ability. Students noted inequalities in access to advanced features and voiced concerns about privacy when using LLMs in clinical scenarios.

Conclusions: LLMs have been widely adopted by medical students. While students perceived the efficiency, flexibility, and conversational interface of LLMs as beneficial, substantial reservations remain regarding their reliability, potential de-skilling, and the loss of academic integrity. These findings underpin the urgent need for curricula to both support safe LLM use and also adapt assessment and teaching strategies for artificial intelligence–augmented student practice. Future research should broaden geographical representation, investigate applications in low-resource settings, and integrate educators' perspectives to establish future curricular guidance in an artificial intelligence era.

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KEYWORDS

large language models; artificial intelligence; AI; generative artificial intelligence; undergraduate medical education

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Introduction

Artificial intelligence (AI) has become increasingly prevalent in the modern world. In November 2022, the release of ChatGPT by OpenAI marked a pivotal moment in the evolution of large language models (LLMs). Its success was not solely due to demonstrating exceptional generative abilities and maintaining humanlike conversational interactions but arguably even more significantly due to bridging the technological divide and making this advanced technology accessible to the public. Specifically in health care, LLMs have been demonstrated to encode significant clinical knowledge [1], and potential uses within clinical care include their use in emergency department triage, automation of clinical documentation [2], and patient chatbots [3].

While these use cases have been hypothesized to have significant clinical impact, the risks of implementing LLMs in real-world clinical practice are significant. Hallucinations, where LLMs output plausible but incorrect responses, could have profound consequences for patient safety, and existing health technology regulations remain behind the curve with these dynamic systems that do not have a singular defined use case. Medical education represents a potentially high-impact but low-risk application and has been no exception to the growing influence of LLMs. LLMs have been widely publicized to be able to pass both undergraduate and postgraduate medical examinations [4,5]. While impressive, the real benefits of these models lie in how users can use them to gain knowledge more readily rather than in the information encoded within these models themselves. The existing literature surrounding LLMs has proposed multiple use cases for medical education, including generation of topic explanations and summaries [6], simulated and interactive physician-patient interactions [7], and generating high-quality examination questions [8].

Despite these advances, there remains a significant gap in the development of comprehensive curriculum frameworks for AI and LLMs in undergraduate medicine, and reviews have found heterogeneity in learning objectives and evaluation methods and limited standardization across programs [9,10]. Against a backdrop of rapid uptake of LLMs by students and clinicians, this lack of structured education and guidance creates an immediate skill gap for safe and effective use of LLMs in training and practice. Existing cross-sectional surveys report that many medical students are already experimenting with generative AI while receiving minimal structured training or guidance, highlighting a gap between adoption and pedagogy [11,12]. One survey of US medical students, for example, found that only 8.8% had received any resources to explore AI in medicine despite over 90% agreeing that its inclusion in the curriculum would benefit their future career [13]. Multiple institutional and regional surveys similarly show high familiarity and growing use but inconsistent formal teaching, suggesting that independent student use has outpaced curriculum development and assessment [14]. Analyses of curriculum frameworks and programs have concluded on the need for clearer delivery models and assessment strategies to evaluate skills such as appraisal of AI outputs, safe prompt practices, and documentation of learning outcomes [10]. These surveys show that students and clinicians report positive attitudes toward integrating AI although they have concerns about ethics and reliability with use cases, including writing support, exam preparation, and quick explanations rather than structured learning pathways [11].

While these often single-institutional cross-sectional studies do capture valuable insights, they are often based on self-reported data and rarely probe into real-world practice, such as verification behaviors and how uncertainty is handled. To address these gaps in the literature, we conducted a qualitative interview study among medical students at London medical schools to complement the existing breadth of the survey literature with depth on actual practices. Therefore, this survey explored, first, how LLMs are currently used in real-world educational settings; second, the perceived benefits of, barriers to, and facilitators of adoption; and, finally, the implications for future curriculum and policy design. We aimed to report findings that will provide valuable insights for educators and regulators to allow for the safe and effective integration of LLMs into undergraduate medical training.

Methods

Study Design and Rationale

We selected semistructured interviews for data collection as they allowed for in-depth exploration of participants' attitudes, beliefs, and behaviors regarding LLM use. These are objectives not easily achieved using structured interviews. The flexibility of the semistructured format enabled the interviewer to probe participant responses, clarify ambiguities, and follow lines of inquiry, therefore allowing for richer and more context-dependent responses. The semistructured interview approach is particularly well suited to exploring complex or emerging phenomena, such as the adoption of novel technologies in education, and is endorsed by qualitative research best practices for trustworthiness and depth [15]. A limitation of this approach is the potential for reduced consistency across interviews and increased reliance on interviewer skill, which we mitigated through a standardized topic guide (Multimedia Appendix 1).

Interview Topic Guide Development

The standardized topic guide was created based on themes identified from the current literature regarding the use of LLMs and medical education. This was structured around the technology acceptance model (TAM), a widely applied model of user acceptance and use of technology [16]. The TAM is structured around the perceived ease of use and perceived usefulness of a new technology, which describe the effect of these on attitude toward using and actual system use of the technology (Figure 1). By structuring the topic guide around the TAM, the questions focused on specific use cases of LLMs within medical education, their perceived usefulness in medical education, and the ease of use and attitudes toward use.

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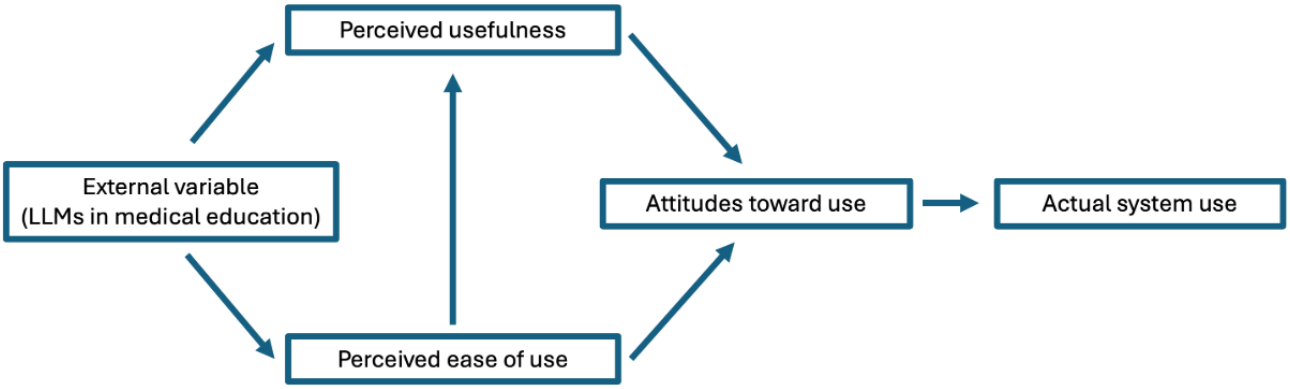
Figure 1. Components of the technology acceptance model (TAM) and relationship between variables. LLM: large language model.



Participant Recruitment and Sampling

Recruitment was conducted through open advertising to all London medical students via university mailing lists and posters (Multimedia Appendix 1). Any medical student at any stage of training was eligible for inclusion, with no strict exclusion criteria. As such, this approach constituted convenience sampling. No sample size was set a priori in line with other qualitative studies. Interviews were conducted until thematic saturation was achieved (no new prominent themes were observed).

Data Collection

All interviews were conducted by one female researcher (MA) over Microsoft Teams, where they were also recorded and transcribed. The lead interviewer (MA) is both a medical student and a researcher with an interest in LLMs and digital education. While this enabled her to understand the context of narratives, this also introduced the potential for shared biases (eg, assumptions about the value or risks of LLM adoption). To mitigate these risks, the interviewer adhered to a prespecified semistructured interview guide, taking field notes before and after interviews, and regularly discussed analytic decisions and coding with a coresearcher (KL) who also independently validated the codes. Participants were not known to the interviewer. The interviewer introduced the study and the rationale for the study to the participants. The interviewer also intentionally adopted a neutral stance, used open-ended questioning, and explicitly invited participants to discuss negative experiences and skepticism regarding LLMs. This approach aimed to ensure that a full range of perspectives were actively solicited and represented in the final analysis.

Data Analysis

Data were analyzed using an inductive thematic analysis methodology guided by the TAM as a deductive thematic framework. The analytic approach began with repeated reading of transcripts and listening back to recordings to ensure immersion and familiarization with the data while noting initial impressions. The first author (MA) then undertook line-by-line open coding of all transcripts, assigning short, descriptive labels to segments of text to capture participants' reported behaviors and perceptions and experiences of LLM use without imposing preexisting categories. Codes were then iteratively refined, grouped, and compared across transcripts and organized into candidate themes. These themes were subsequently mapped onto domains of the TAM (system use, ease of use, perceived usefulness, and attitudes toward use), with the codebook and thematic structure independently checked and refined by a second researcher (KL; Multimedia Appendix 1).

Ethical Considerations

As a low-risk undergraduate project, this study was deemed exempt from ethics approval by the research ethics committee at Imperial College London and was approved at the departmental level [17]. Therefore, the project was not formally reviewed by an ethics committee but was reviewed and approved by the head of department. All participants gave informed consent before taking part in the study. All interview transcripts and subsequent analyses were anonymized to safeguard participant information. Participants were not compensated for taking part.

Results

Overview

A total of 15 medical students from all years were interviewed across 2 London medical schools, comprising 7 (46.7%) preclinical students and 8 (53.3%) clinical students (Table 1), with an average interview length of 19.4 (SD 4.2) minutes. Thematic analysis was mapped to the TAM, and each subtheme was mapped to the study aims of benefit, barrier, or facilitator. Table 2 provides frequencies and illustrative quotes. All proportions and percentages presented are based on our qualitative, nonrandom sample of 15 students and serve as descriptive indicators of this specific group. No statistical inference or generalization beyond the study population was intended, and the findings should be interpreted as illustrative of this cohort rather than representative of the broader medical student population.

Despite the availability of other LLMs, all interviewees spontaneously described the use of ChatGPT, with none routinely using alternative LLMs. As such, our results focus primarily on ChatGPT as the representative LLM. This is reflective of the dominant adoption pattern in UK medical education at the time of data collection in line with surveys in the literature.

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Table 1. Demographic characteristics of the participants (N=15).

Demographic and category	Values
Age (y), mean (SD; range)	20.3 (1.4; 18-23)
Stage of study, n (%)	
Preclinical	7 (46.7)
Clinical	8 (53.3)
Sex, n (%)	
Female	11 (73.3)
Male	4 (26.7)
Race or ethnicity, n (%)	
Arab	4 (26.7)
Asian	6 (40)
White	5 (33.3)

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Table 2. Thematic analysis of interviews with themes based on the structure of the technology acceptance model (TAM) and subthemes mapped to benefits, facilitators, and barriers with example quotes (N=15).

TAM theme and subtheme	Prevalence, n (%)	Aim mapping	Example quote
Actual system use			
Topic summarization	15 (100)	Benefit	"Instead of getting a textbook, I can ask ChatGPT to summarise something for me in X words and read it under a minute or two."
Google or search engine replacement	13 (86.7)	Benefit	"It's just better than Googling it."
Quiz or exam question creation	6 (40)	Benefit and facilitator	"I give it a topic...and say 'make some test questions,' and I specify the difficulty and style as well."
History taking role-play	5 (33.3)	Benefit and facilitator	"It's a nice environment to test out sentences or questions before a real patient."
Email drafting or administrative tasks	3 (20)	Benefit	"I've used it for writing emails and admin tasks like that."
Article or research summary	7 (46.7)	Benefit	"It enabled me to spend less time reading tons of papers to find an answer."
Perceived usefulness			
Efficiency and time saving	13 (86.7)	Benefit	"It's more of a natural conversation as opposed to Google, where you have to scroll through lots of sites."
Clarifying difficult concepts	5 (33.3)	Benefit	"If there's a difficult concept, I ask ChatGPT to summarise it in simple terms."
Mnemonic or flash card generation	3 (20)	Benefit	"It can come up with mnemonics and memory aids—though they're not always very good."
Change in educational assessment needs	10 (66.7)	Facilitator and barrier	"If everyone is using ChatGPT to study, assessments may need to be adjusted..."
Perceived ease of use			
Device flexibility	6 (40)	Facilitator	"It fits into my revision routine because I can use it on my phone in clinic."
Technical simplicity and low learning curve	7 (46.7)	Facilitator	"You just type your question and it gives you what you want."
Attitudes toward use			
Overreliance	8 (53.3)	Barrier	"It's almost like an addiction...outsourcing every little bit of thinking instead of working something out."
Collaborative learning via peer demonstration	9 (60)	Facilitator	"After my friend showed me, I started using it for new things."
Lack of awareness of large language model features	8 (53.3)	Barrier and facilitator	"That would be useful, but I've never used it for that before."
Hallucinations or inaccurate answers	15 (100)	Barrier	"I stopped using it...because I found it to be inaccurate, and I don't want to be learning the wrong things."
Generation of fake or nonexistent references	8 (53.3)	Barrier	"It almost makes up sources out of thin air. You paste the reference in a browser, and it doesn't exist."
Difficulty trusting without prior knowledge	9 (60)	Barrier	"I think you need to have a bit of an understanding already to make sure what you're being told is right."
Privacy and data concerns	5 (33.3)	Barrier	"I'm wary of using ChatGPT in research because I don't understand all the copyright implications."
Out-of-context output	6 (40)	Barrier	"Sometimes the information is just out of context, so you have to clarify...get more specific with prompts."
Preference for official or older resources	7 (46.7)	Barrier	"I have access to sources which are more reliable than ChatGPT, like older years' notes or textbooks."
Inadequate for guideline or recommendation queries	9 (60)	Barrier	"I don't think I'd use it for treatment guidelines. Easier to get it from NICE or textbooks."

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Perceived Benefits

Students consistently described how ChatGPT had changed their learning practices, accelerated knowledge acquisition, and improved their study efficiency. Use cases reported by participants included use of ChatGPT for concise topic summarization, clarification of complex concepts, and supplementing traditional learning materials such as textbooks. ChatGPT was reported by participants as complementary to textbooks and peer notes, allowing students to obtain information on demand, with one student reporting the following:

> *Instead of getting a textbook, I can ask ChatGPT to summarise something in X words and read it in under a minute.*

Wider uses of ChatGPT within a medical education context included 40% (6/15) of the students using the technology to generate replica exam-style questions and immediate answer explanations, with students reporting its value for reinforcing knowledge and identifying gaps. A total of 20% (3/15) of the students asked ChatGPT to create mnemonics, flash cards, or analogies to aid memorization, although the quality of system outputs was acknowledged to be variable. Almost half (7/15, 46.7%) of the participants reported that ChatGPT was integrated within their learning workflow particularly in research and essay preparation as it could provide summaries of academic papers and structure long-form writing:

> *It enabled me to spend less time reading tons of papers to find an answer.*

Participants also reported turning to ChatGPT when traditional search engines failed to provide adequate answers. In total, 33.3% (5/15) of the students reported that ChatGPT provided answers for academic queries that they felt that Google or standard resources were unable to solve. Within clinical education settings, 33.3% (5/15) of the students described using ChatGPT to simulate history taking and patient role-play scenarios. They valued its ability to offer feedback on question phrasing and clinical reasoning before performing these tasks on real patients. Of note, participants did not trust LLMs to output appropriate treatment guidelines and consistently expressed a preference for official sources such as the National Institute for Health and Care Excellence. Finally, beyond allowing for gains in efficiency, participants reported that the conversational interface of ChatGPT allowed them to clarify concepts in real time, supporting a shift from pure factual recall toward inquisitive, analytical learning.

Facilitators

A key facilitator identified by participants was peer demonstration and collaborative exploration. Over half (9/15, 60%) of the students were introduced to use cases and wider applications through friends (“After my friend showed me, I started using it for new things”). The ease of using the platform combined with device flexibility (ie, ChatGPT can be used across laptops, desktop computers, and smartphones) was also identified as a key facilitator to widespread adoption and allowed it to be integrated into study routines regardless of location (“It fits into my revision routine because I can use it on my phone in clinic”).

For students who were anxious about live clinical encounters, the ability to simulate history-taking scenarios was a valued educational facilitator. Participants commented that the safe and unpressed environment of ChatGPT was beneficial for rehearsing questioning techniques and receiving unbiased feedback, allowing them to develop their skillsets. Students also commented positively on how the tool was instantly accessible, the lack of institutional gatekeeping, and the lack of learning curve to use.

However, students did broadly acknowledge that the widespread use of LLMs among students would mean that assessment strategies would have to be reformed and that examination styles would have to shift toward more critical thinking approaches.

Barriers

While broadly there was enthusiasm toward ChatGPT’s utility among participants, there were significant reservations regarding its reliability. All interviewees were able to recount experiences in which outputs were either outdated or hallucinated. Many noted that ChatGPT often seemed plausible when incorrect, which made detecting errors challenging when students lacked deeper subject knowledge. This led to students avoiding the use of ChatGPT when trying to grasp the foundations of a topic, with one student explaining the following:

> *I stopped using it…because I found it to be inaccurate, and I don’t want to be learning the wrong things.*

A total of 53.3% (8/15) of the students highlighted how ChatGPT hallucinated research references, encountering fabricated citations that could not be traced to real sources. Therefore, this led to participants perceiving the need for rigorous manual verification when using ChatGPT for academic projects, recognizing its inability to perform critical appraisal typical of research:

> *LLMs skip through this critical appraisal when giving you the information.*

Themes of overreliance and cognitive outsourcing also emerged among students, with participants describing an increasing tendency to default to ChatGPT for problem-solving and academic tasks that previously required more effort and perceiving that this could risk the erosion of traditional skills. Some students even felt a self-perceived addiction, with a fear that the ability to instantly receive answers could diminish perseverance and engagement with more complex material.

Other barriers noted included frustration with out-of-context outputs, requiring multiple prompts to obtain clinically usable or relevant information. Several participants also cited privacy and data concerns, with anxieties about copyright implications and uncertainty regarding data security. Awareness of broader functionalities of ChatGPT was uneven. While some students were simply unaware that ChatGPT could have broader applications such as custom question generation, others deliberately limited use out of concern for output reliability.

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Discussion

Key Findings in Context

This qualitative study is, to our knowledge, the first to explore how medical students are adopting, using, and perceiving LLMs for education using in-depth semistructured interviews. By mapping the TAM to user behaviors, this analysis offers an account of both the facilitators of and barriers to real-world LLM adoption in undergraduate medicine. This work contributes a qualitative account of how and why medical students are using LLMs, mapping not only the applications of LLMs within medical education but also the drivers of their uptake.

Our study shows the widespread and largely self-directed uptake of LLMs among medical students. There is an emerging shift toward these tools, replacing long-standing educational tools, including web searches or traditional textbooks, in favor of LLMs due to their capabilities of rapid summarization; conversational clarification; and device-agnostic, on-demand engagement. This signals a shift within medical education toward AI-augmented learning in which efficient, personalized, and readily accessible tools are perceived as an improvement over traditional materials.

While many of the proposed use cases for LLMs in medical education have been reported in the literature, our findings suggest that most students have not adopted the full spectrum of capabilities reported by conceptual work. Instead, real-world adoption remains focused on a relatively narrow set of functions. One survey of 443 medical students found that "a sizeable portion of students lack knowledge about ChatGPT's various functions and limitations" [18]. Complementary analyses in the literature have also highlighted a critical distinction between technology adoption and technological literacy. While institutions are rapidly introducing AI tools, medical curricula have lagged in providing structured training for responsible use, creating a gap between tool uptake and competency development [19]. Digital health frameworks have also emphasized that competence with tools such as LLMs should be developed longitudinally across the curriculum rather than acquired informally through peer networks [20]. Our observation that students discovered advanced use cases predominantly through peers rather than formal teaching demonstrates this pedagogical gap and highlights the need for AI literacy training at an undergraduate level.

Such a gap poses significant problems. First, there is an opportunity gap in which students may lack the awareness of how LLMs can be widely used. Second, and perhaps more importantly, students may not be aware of the limitations of LLMs, trusting potentially inaccurate outputs that could be applied in a clinical setting. Efforts to solve these issues have already been made with the recent publication of the digital health competencies in medical education framework [21]. While this is a vital first step to grapple with the challenges previously discussed, generative AI continues to evolve on a weekly basis with growing capabilities, and educational leaders must also decide how to ensure that the education of students does not lag behind the innovation curve.

We also demonstrated that enthusiasm about LLMs is also met with concerns. Hallucinations, nonexistent references, and out-of-date information were reported by all participants, with comments including "I stopped using it to help give answers to questions because I found it to be inaccurate, and I don't want to be learning the wrong things" and "It does a very good job of making it seem like everything is conducive to each other, but sometimes it says things that were probably true at one point but aren't true anymore." These have been widely documented as critical limitations in the literature [22,23]. These reliability concerns are especially critical for more junior students who may lack the knowledge to critically assess outputs and are most at risk of "accepting what ChatGPT tells you" at face value. Recent work has validated these students' experiences. When ChatGPT was prompted to generate academic references, approximately 1 in 5 citations was entirely fabricated, and over half of all citations contained at least one substantive error [24]. Strategies to mitigate LLM hallucinations, such as via prompt engineering, have been found to be only partially successful, with some prompting strategies even increasing major errors [25,26]. Current LLMs may also lack mechanisms to signal uncertainty and, together with frequently fabricated citations, this limits users' ability to appraise reliability at the point of use [27]. Therefore, such limitations demand that students possess at least a basic skillset in assessing AI outputs.

Finally, over half of the students interviewed acknowledged overreliance on LLMs, with both reduced incentives to use trusted sources and a feeling of reduced problem-solving abilities. We demonstrated that perceived overreliance and addiction to these tools, which have been previously theorized in the literature, may already exist in real-world practice [28]. Recent commentary has proposed potential mechanisms underpinning this pattern, including automation bias, cognitive off-loading, and genuine de-skilling of foundational clinical and academic skills in novice learners. Proposed countermeasures include reform in assessment approaches and explicit requirements for learners to interrogate, justify, and potentially reject AI-generated suggestions using primary sources [29].

Uptake of LLMs Requires Training and Assessment Reform

Facilitators of effective LLM adoption included social and peer-led dynamics. Broader use cases of LLMs, including custom question generation and history taking simulation, were discovered informally through friends and peers rather than formally taught. This demonstrates that peer-led learning rather than formal curricula is driving LLM adoption. Although these patterns may drive adoption and innovation, they may also propagate unsafe or suboptimal practices in the absence of formal oversight. In the context of potential LLM use in clinical settings, there is an urgent need for formalized training to be implemented to address safe and responsible use.

Our findings demonstrate that students are aware that the growing uptake of LLMs will likely require reform in assessment strategies. Participants, in line with the literature, anticipated that assessments will move away from factual recall and toward higher-order reasoning, critical appraisal, and digital

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literacy [30]. Recent conceptual work has begun to propose strategies for such reform, including "process-focused"grading that evaluates students explicitly assuming that AI tools may have been used rather than judging only the final answer [29]. Other proposals include "AI-resistant" question formats and assessment models in which learners are presented with a mixture of accurate and flawed AI-generated responses and required to accept, modify, or reject them with justification from primary evidence [19]. Embedding these approaches within competency-based curricula could protect academic integrity while simultaneously cultivating the skills needed to work safely with LLMs.

Ethical Considerations of LLM Use

Although LLMs were recognized to be readily accessible, the existence of the "freemium" model means that certain advanced features may only be available through paid versions of LLMs (such as ChatGPT Plus) or through institutional arrangements. This access gap has potential consequences surrounding fairness and opportunity and may drive a digital divide leading to inequalities in medical education whereby students may be disadvantaged as they cannot afford to pay for a premium LLM. This concern reflects broader evidence on digital inequity in health care education. A recent systematic review has highlighted that disparities in technology access represent a fundamental barrier to health equity, which particularly affects students from lower socioeconomic backgrounds [31]. Moreover, medical education that adopts AI without universal access mechanisms risks exacerbating existing inequalities and biases encoded in AI training data, which typically originate from high-income settings and underrepresent marginalized populations [32].

As LLM use becomes increasingly mainstream, particularly in clinical education, it also poses risks to patient privacy and confidentiality. Current regulatory frameworks provide general data protection guidance, but implementation strategies specific to generative AI remain underdeveloped [33]. When students input clinical details into commercial LLMs, they risk inadvertently introducing identifiable patient information into systems with unclear data governance.

Addressing the interconnected concerns of access, bias, and privacy requires that medical schools implement equity and privacy impact assessments before adopting LLMs, ensure institutional provision of secure access for all students, and develop curricula that ensure critical awareness of algorithmic bias and data governance alongside AI literacy.

Limitations and Future Work

This study has several limitations. First, all participants were recruited from only 2 medical schools located in London, and therefore, the findings of this study should be interpreted as locally specific and exploratory. Due to the convenience sample and restriction to a single metropolitan area, our results cannot be generalized beyond the surveyed London cohort, and we acknowledge that claims of saturation may be limited to this cohort.

The sample may also be subject to selection bias, potentially overrepresenting students who are early adopters, more digitally engaged, or have a preexisting interest in LLMs and AI, particularly given the use of open advertising to recruit participants. Broader studies are required to establish the generality of these patterns in other geographic and curricular settings as geographical diversity could lead to different experiences, perceptions, and use patterns of LLMs.

Furthermore, the impacts and potential utility of LLMs in low-resource setting medical schools remain unexplored. Medical students in these environments may derive distinct benefits from LLMs due to differing digital infrastructures, educational resources, and availability of teaching staff [34]. Further work should also extend to investigate the application and acceptability of LLMs in international and lower-resource contexts to ascertain whether LLMs could effectively bridge educational disparities.

Finally, this study did not explore the perspectives of educators or curriculum developers, who play crucial roles in incorporating AI into medical education. Understanding educators' and curriculum designers' views on what should be included in AI-related medical education and how these competencies should be evaluated and continuously updated is critical.

Therefore, future research will engage these stakeholders to inform comprehensive curricular frameworks that ensure that students are adequately prepared for responsible and effective use of LLMs in their future clinical practice. Further work will also aim to assess longitudinal impacts of LLM use on educational outcomes, clinical reasoning skills, and competencies over time. Investigating longitudinal changes in students' critical thinking and problem-solving capabilities may provide valuable insights into whether and how educational assessments should evolve to reflect the realities of LLM use. Finally, ethical considerations, including privacy, data protection, and academic integrity, should be taken into account, and pathways should be created to address differences in access and bridge digital divides.

Conclusions

This study provides a qualitative exploration into the real-world use, perceived benefits, and barriers regarding LLMs among a cohort of London-based medical students. LLMs have been widely adopted by medical students largely due to their ease of use, conversational interactions, and efficiency compared to traditional educational resources. However, there is a significant disparity between real-world use cases and those proposed in the literature. Significant concerns also remain regarding reliability, accuracy, and the risk of overreliance on these tools, potentially impacting critical thinking and clinical decision-making skills. These findings underscore the urgent need for structured education surrounding AI itself, as well as the broader implications of AI technologies on medical education delivery, curriculum design, and assessment methods. LLMs are likely here to stay, and we should be responsive adapting ahead of this adoption curve. Therefore, future educational initiatives not only should focus on developing AI competencies but also must adapt assessments to prioritize higher-order skills such as evaluation, critical thinking, and clinical reasoning, ensuring that medical students remain proficient practitioners in an era increasingly shaped by

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generative AI. Further research is necessary to explore geographic diversity, implications in low-resource contexts, and educators' perspectives to comprehensively inform curriculum development and ensure the effective integration of these technologies.

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Data Availability

The datasets generated or analyzed during this study are available from the corresponding author on reasonable request.

Authors' Contributions

Conceptualization: KL
Data curation: MA
Formal analysis: MA and KL
Investigation: MA and KL
Methodology: MA and KL
Project administration: MA and KL
Supervision: KL
Writing—original draft: MA and KL
Writing—review and editing: MA and KL

Conflicts of Interest

None declared.

Multimedia Appendix 1
Topic guide, codebook, and recruitment poster.
[DOCX File , 495 KB - formative_v10i1e82828_app1.docx]

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Abbreviations

AI: artificial intelligence
LLM: large language model
TAM: technology acceptance model

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Original Paper

Self-Perceived Preparedness Needs Among Caregivers of Veterans With and Without Dementia: An Exploratory Study Using Open-Ended Survey Data

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Abstract

Background: Caregivers' self-perceived preparedness for caregiving influences care recipients' and caregivers' emotional health, and care recipients' aging in place. Dementia's unique, long, and progressive nature compared to other age-related illnesses, along with associated behavioral symptoms and personality changes, may cause caregivers' preparedness to vary significantly from that of those caring for patients with other chronic conditions.

Objective: This study aimed to describe and compare specific domains and tasks in which family caregivers of veterans with and without dementia reported wanting to be better prepared.

Methods: Using the Veterans Affairs' HERO CARE (Home Excellence Resource Outcome Center to Advance, Redefine, and Evaluate Non-Institutional Care) Survey data, we analyzed caregivers' responses to one open-ended question: "Out of all the tasks that you help the veteran with, is there anything specific you would like to be better prepared for?" Response themes were deductively coded into 9 domains, and differences in reported domains between caregivers of care recipients with and without dementia were compared.

Results: A total of 732 caregivers were included: 301 (41.1%) caregivers of veterans with dementia and 431 (58.9%) without. Caregivers of veterans with and without dementia, respectively, were similar except in age, being spousal caregivers, working

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at least part-time, hours of care provision per week, and proportion with a high burden. Veterans with dementia, versus without, were older and had higher frailty and risk scores. Preparedness concerns among caregivers (N=732) included care coordination (n=164, 22.4%), emotional and social support (n=145, 19.8%), advance planning (n=116, 15.8%), nursing and health monitoring (n=94, 12.8%), personal care (n=65, 8.9%), mobility (n=79, 10.8%), household (n=58, 7.9%), caregiver self-care (n=36, 4.9%), and emergent situations (n=28, 3.8%). The commonest tasks caregivers expressed needs for included managing emotional and behavioral symptoms (n=74, 10.1%), recognizing and responding to significant changes in the veterans' condition (n=66, 9.0%), seeking medical information relevant to the veterans' needs (n=54, 7.4%), handling financial and legal matters (n=52, 7.1%), and advocating for services (n=49, 6.7%). Similar proportions of caregivers of veterans with and without dementia reported preparedness needs in all domains and tasks.

Conclusions: The preparedness needs of caregivers of veterans with and without dementia were mostly similar in most domains and tasks. The commonest preparedness gaps were in the domains of care coordination, emotional and social support, and advance planning. The findings can inform interventions to prepare all caregivers to support aging in place.

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KEYWORDS

caregiver preparedness; dementia; caregiver; veterans; survey; caregiver burden; unmet needs; care coordination

Introduction

Persons with complex chronic illnesses, including dementia, experience a wide range of functionally limiting needs, many of which are met by family caregivers. Caregivers are defined here as friends and family members who are involved in the care of patients in community-based settings. Family caregivers support their care recipients in many ways and are critical to their safe aging at home. These caregivers often manage their care recipients' needs and tasks, related to self-care, monitoring medical conditions, and providing emotional and social support [1].

Caregiver preparedness is defined as "how ready caregivers believe they are for the tasks and stresses of caregiving" [2-4]. It includes caregivers' perceived ability to meet the physical and emotional needs, care coordination, and emergency needs of their care recipients [5]. Prior studies have shown that better caregiver preparedness is associated with improved outcomes for the dyad: caregivers who feel more prepared have lower burden, strain, and depression [6-8], and have better self-care [9]. Care recipients, in return, have decreased risks of hospital readmission [10], higher quality of life [11], better recovery [12], and lower caregivers' desire to institutionalize their care recipient [13]. Therefore, caregiver preparedness is a critical area of concern in health care systems, since prepared caregivers can positively impact the health of both their care recipients and caregivers. While dyadic outcomes can improve with better preparedness, many caregivers do not receive training for their role [14]. The "Home Alone" study found that more than 60% of caregivers learn how to manage medical and nursing tasks on their own, with 47% never receiving training from any source [15]. In the report "Caregiving in the U.S. 2015," more than 40% of the caregivers reported performing medical or nursing tasks without any preparation, and only 14% reported having received some preparation [16].

While the onset and progression of the caregiving roles vary widely depending on the type and cause of disability, tasks and responsibilities generally are grouped into several broad themes such as household, nursing and medical tasks, advocacy, and care coordination. Several studies have categorized family caregiving tasks in general [1,17-19] and of caregivers caring for care recipients with dementia [20-22]. Caregivers of people with dementia, as a subgroup, garner special attention for several reasons: first, one-third of family and unpaid caregivers for noninstitutionalized older adults care for care recipients with dementia; second, dementia often demands more intensive support over extended periods of time compared to caring for care recipients without dementia [22,23] and involves assisting not only with physical health needs, but also managing behavioral symptoms and change in personality [24]; third, studies show disproportionately higher levels of burden among caregivers caring for care recipients with dementia compared to other conditions [25-28]; and forth, due to the progressive, evolving nature of dementia [25], caregivers may experience a significant lack of preparedness leading to care recipients' poor health outcomes and higher likelihood of early institutionalization and mortality [29].

Therefore, caregiving for care recipients with dementia is often considered intrinsically different from other chronic diseases, and caregivers caring for veterans with dementia may have different preparedness needs compared to other caregivers. Yet, to our knowledge, no studies have examined the differences in preparedness gaps between family caregivers of veterans with and without dementia.

This study aimed to describe specific domains and tasks in which family caregivers want to be better prepared and to compare preparedness gaps of caregivers caring for veterans with and without dementia. We hypothesized that caregivers of veterans with dementia would express a greater need for preparedness in domains related to managing behavioral symptoms, advance planning, and caregiver self-care.

Methods

Ethical Considerations

This project was classified as a nonresearch project by the Miami Veterans Affairs Healthcare System Human Studies Subcommittee because the findings were intended to inform VA (Veteran Affairs) operations and were therefore exempt from institutional review board review in compliance with VA

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Handbook 1058.05i. A waiver of documentation of authorization and informed consent was obtained. No compensation was provided to veterans for participation. To ensure privacy, efforts were taken to protect the identity of participants and ensure that data were kept confidential. Identifiable information will only be maintained on a VA server; documentation of the procedure used to code the data will remain within the VA. All identifiers collected as part of this project will be destroyed as per the records control schedule (RCS 10-1) of the Veterans Health Administration. Electronic files will be stored in folders with restricted access on a protected computer shared drive behind the VA firewall in a secure server. Data will not be transmitted as an attachment to unprotected email messages. The data will be accessible only to personnel involved in the study. All staff were trained to avoid breaches of confidentiality.

Study Design and Participants

We used cross-sectional data from the Veterans Affairs' HERO CARE (Home Excellence Resource Outcome Center to Advance, Redefine, and Evaluate Non-Institutional Care) Caregiver survey, administered from July 2021 to January 2022. The caregiver survey was included in a veteran survey packet mailed to 20,000 veterans across 4 VA sites (Miami, FL; Palo Alto, CA; Salt Lake City, UT; San Antonio, TX), and 1 Veteran Integrated Service Network (VISN 8). We oversampled veterans with a higher predicted 2-year long-term institutional care risk [30]. Detailed survey methods have been previously delineated [31].

Here, we specifically looked at responses to the open-ended question: "Is there anything specific you would like to be better prepared for?" Participants included caregivers (1) who had responded to the open-ended question and (2) who cared for a veteran for whom the VA had a Geriatrics and Extended Care Data Analysis Center Core Files (GCF) [32] electronic medical record that allowed classifying their dementia status. Using responses to this open-ended question, we identified tasks for which family caregivers felt insufficiently prepared for, grouping them by the veterans' dementia status.

Data Collection

We linked caregiver surveys to their Veterans' GCF [32,33]. The GCF provides information on the veterans' demographics, risk scores, comorbidities, and health care utilization. Veterans' dementia status was pulled from VA electronic health record data using the Hierarchical Condition Category (HCC) codes HCC-51 (dementia with complications) and HCC-52 (dementia without complications). Veteran data regarding age, JEN Frailty Index (JFI) [34], and HCC count [35] were also similarly extracted.

Caregiver's sociodemographic data were collected from the HERO CARE Caregiver survey responses and included many domains: age, race and ethnicity, sex, preferred language, marital status, education level, health literacy [36], employment, and financial insecurity [37]. Low health literacy was defined by responses of "somewhat," "a little," or "not at all" to confidence in filling medical forms [36]. Financial security was a 1-item assessment asking, "Without giving exact dollars, how would you describe your household's financial situation right now?" [37].

Caregiving characteristics included whether the caregiver was the veteran's spouse, the primary, secondary, or shared caregiver, the veteran's power of attorney, along with caregiving duration, and hours of care per week. Caregiver burden was measured using the measured using the 4-item Zarit Burden Interview screen, with scores summed across all four items for a total score ranging. "High" caregiver burden was attributed to a score of at least 8, per the scoring instructions [38,39].

Analysis

We report descriptive statistics for caregiver sociodemographic characteristics and health measures overall, by veterans' dementia status. Frequencies and percentages are reported for categorical variables using chi-square tests and means and SDs for continuous variables using independent *t* tests.

Qualitative content analysis from the open-ended survey responses consisted of deductively coding and organizing responses from all caregivers into broad themes representing domains such as mobility or personal care, and subthemes representing tasks within a domain such as assisting with dressing and bathing or with toileting, etc. The coding was first done by two authors (RS and SL) independently, and discrepancies were resolved by a third author (DR), with further discussion and modifications with the rest of the team until agreement was reached. If a caregiver reported preparedness needs in more than one domain, they were documented and counted in both domains [40]. If they reported preparedness needs for more than one task in a specific domain, we documented both tasks, but the caregiver was only counted once in that domain, to try to accurately reflect the number of caregivers who had needs in a specific domain.

After classifying responses under each domain (theme) and subdomain (tasks), we summed them and grouped them by veterans' dementia status. Frequency and percentages of responses by dementia status of veterans were reported by domain and tasks [40].

Caregiver Preparedness Framework

After a preliminary review of the emerging themes, we decided to sort them into predefined domains from the University of California Davis (UC Davis) Health's Family Caregiver Domains of Preparedness, since that framework captured most of the themes and subthemes we identified [3]. It consists of 9 broad domains of activities that characterize family caregiving, and each domain comprises several tasks. After a preliminary review of the emerging themes from the survey responses, we modified this existing framework in the following ways. We combined health monitoring with nursing and management of behavioral symptoms with emotional and social support. We also created two new categories: (1) emergent situations, to recognize and respond to significant changes in the veterans' medical condition and medical situations related to weather, and (2) advance planning, combining shared decision-making with concerns regarding end-of-life. The domains in our study included household tasks, personal care, mobility, emotional and social support, care coordination, nursing and health

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monitoring, advance planning, emergent situations, and caregiver self-care. Domains and subdomains or tasks are shown in Textbox 1.

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Textbox 1. Domains and tasks in each domain for which caregivers wanted to be better prepared.

Care coordination

- Navigate and communicate within the health care system (doctors, nurses, social workers, pharmacists, and other health care and long-term services and supports).
- Seek medical information relevant to the care recipient's needs
- Participate in treatment decisions
- Advocate for services
- Locate and arrange resources for cash, food, and transportation

Personal care

- Assist with bathing, dressing, feeding, grooming, and personal hygiene
- Assist with toileting (eg, getting to and from the toilet, managing incontinence episodes, and maintaining continence)
- Arrange and manage in-home help

Mobility

- Assist the care recipient to safely transfer in or out of bed, chair, wheelchair, toilet, and tub or shower
- Home modifications
- Manage assistive devices such as walkers, canes, or wheelchairs
- Assist with appropriate mobility and strengthening exercises

Emotional and social support

- Provide support in managing stressful situations
- Manage emotional and behavioral symptoms

Advance planning

- Participate advance planning (long-term care placement "future")
- End of lifecare hospice, palliative
- Handle financial and legal matters

Nursing and health monitoring tasks

- Support treatment adherence
- Administer medications including oral, topical, and injectable
- Provide wound care
- Manage healthy sleep hygiene
- Manage physical symptoms (eg, nausea, pain, and constipation)
- Use medical devices to monitor patients' condition (eg, blood pressure cuff and pulse oximeter)
- Manage hearing or vision deficits
- Access training resources (nursing training, certified nursing assistant, cardiopulmonary resuscitation, health monitoring, fall prevention, and equipment use)

Household tasks

- Assist with paying bills and managing finances
- Manage laundry, prepare meals, perform shopping, and run errands
- Perform or coordinate home maintenance activities, including odd jobs

Caregiver self-care

- Engage in activities that support caregivers' own mental, emotional, and physical well-being
- Ask for and accept assistance (eg, respite care)

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Emergent situations

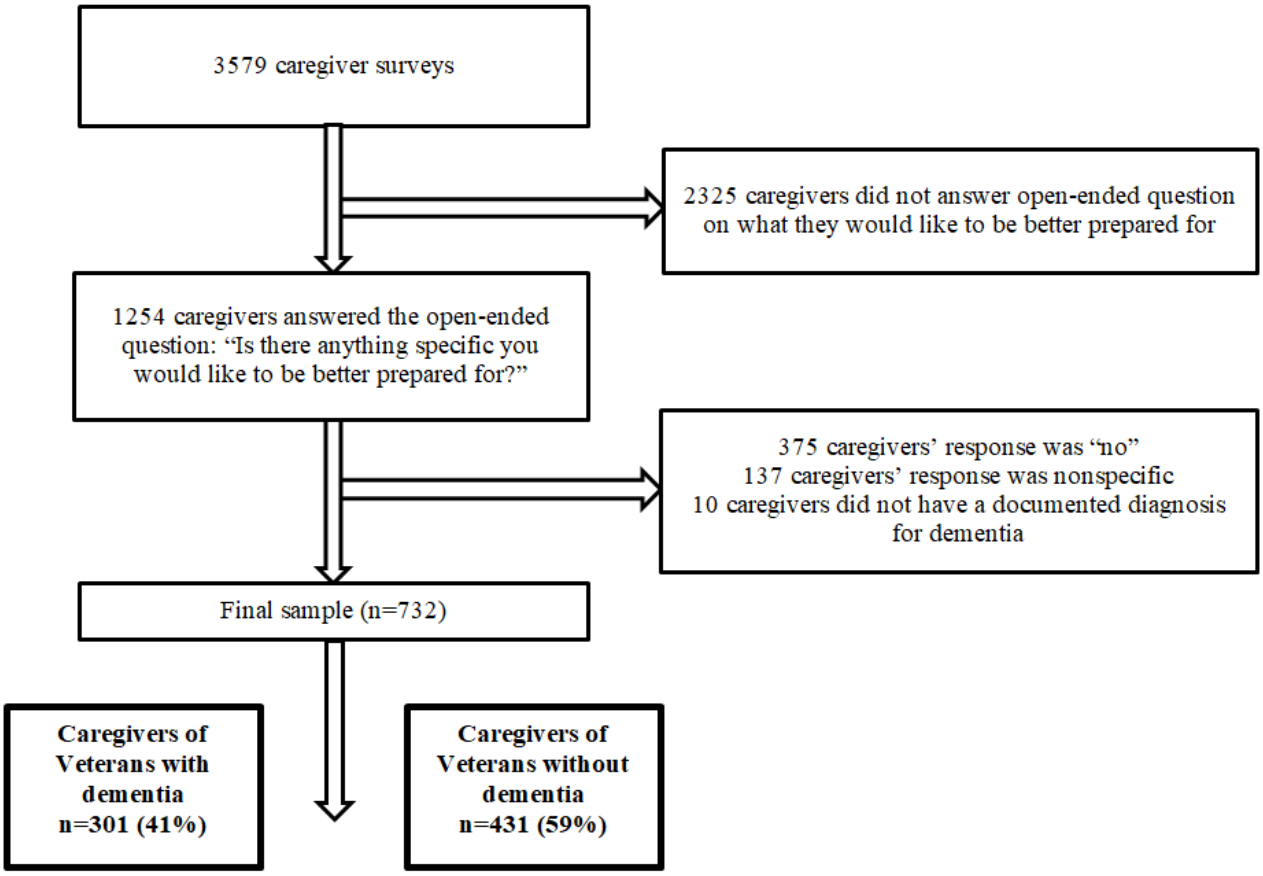
- Medical emergencies
- Weather-related emergencies (hurricanes and power outages)

Results

Final Sample

Of the 3579 caregivers who responded to the HERO CARE Caregiver survey, 1254 caregivers answered the open-ended question: "Is there anything specific you would like to be better prepared for?" We excluded caregivers whose response was a "no" (n=375) or was nonspecific (n=137). We also excluded caregivers whose veterans did not have positive or negative documentation for a dementia diagnosis (n=10). Our final sample consisted of 732 caregivers: 301 (41.9%) caregivers of veterans with dementia and 431 (58.9%) caregivers of veterans without dementia (Figure 1).

Figure 1. CONSORT (Consolidated Standards of Reporting Trials) flow diagram.



Veteran and Caregiver Characteristics

The sociodemographic characteristics of the caregivers and veterans overall, and by veterans' dementia status, are given in Table 1. Caregivers of veterans with (n=301) and without (n=431) dementia, respectively, were similar except in age (71 vs 66 years; *P*<.001), being spousal caregivers (203/301, 67.4% vs 242/431, 56.1%; *P*=.004), working at least part-time (47/301, 15.6% vs 98/431, 22.7%; *P*=.003), hours of care provision per week (mean 94.2, SD 65.9 vs mean 75.0, SD 63.1; *P*<.002), and proportion with a high burden (162/301, 53.8% vs 170/431, 39.9%; *P*<.001) based on a Zarit Burden Interview score of ≥8 [39]. Veterans with dementia versus without, respectively, were older (mean 82.4, SD 7.8 vs mean 78.4, SD 10.7 years; *P*<.001), had higher US Centers for Medicare & Medicaid Services' HCC risk scores (mean 2.6, SD 1.6 vs mean 2.2, SD 1.5; *P*<.001), and higher JFI (mean 6.4, SD 2.2 vs mean 5.3, SD 2.4; *P*<.001).

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Table 1. Sociodemographic characteristics overall and by veterans' dementia status[a].

	Overall (N=732)	Veterans with dementia (n=301)	Veterans without dementia (n=431)	*P* value
Caregiver characteristics				
Age in years, mean (SD)	68.1 (12.5)	71.0 (11.0)	66.0 (13.0)	<.001
Respondent, n (%)				.34
Caregiver (self)	556 (76.0)	230 (76.4)	326 (75.6)	
Caregiver with help	60 (8.2)	21 (7.0)	39 (9.0)	
Race and ethnicity, n (%)				.25
Non-Hispanic White	508 (69.4)	220 (73.1)	288 (68.8)	
Non-Hispanic Black	59 (8.1)	19 (6.3)	40 (9.3)	
Hispanic	107 (14.6)	41 (13.6)	66 (15.3)	
Other	41 (5.6)	14 (4.7)	27 (6.3)	
Sex, n (%)				.99
Female	631 (86.2)	260 (86.4)	371 (86.1)	
Male	91 (12.4)	37 (12.3)	54 (12.5)	
English as preferred language, n (%)				.04
Yes	696 (95.1)	279 (92.7)	417 (96.8)	
Other	33 (4.5)	20 (6.6)	13 (3.0)	
Marital status, n (%)				<.001
Married, in a civil union or domestic partnership, or living with a partner	570 (77.9)	259 (86.0)	311 (72.2)	
Not married	144 (19.7)	39 (13.0)	105 (24.4)	
Education, n (%)				.54
High school graduate, general education development certification or less	181 (24.7)	72 (23.9)	109 (25.3)	
Associate's degree or small college credit	290 (39.6)	117 (38.9)	173 (40.1)	
Bachelor's degree or graduate school	220 (30.1)	98 (32.6)	122 (28.3)	
Low health literacy, n (%)				.74
Yes	624 (85.2)	259 (86.0)	365 (84.7)	
No	103 (14.1)	41 (13.6)	62 (14.4)	
Caregiver employment, n (%)				.003
Working at least part-time	145 (19.8)	47 (15.6)	98 (22.7)	
Not working	67 (9.2)	19 (6.3)	48 (11.1)	
Homemaker	84 (11.5)	30 (10.0)	54 (12.5)	
Retired	299 (40.8)	143 (47.5)	156 (36.2)	
Other	47 (6.4)	21 (7.0)	26 (6.0)	
Caregiver employment changed, n (%)				.31
No	334 (45.6)	138 (45.8)	196 (45.5)	
Yes	266 (36.3)	99 (32.9)	167 (38.7)	
Income, n (%)				.06
After paying the bills, you still have enough money for special things that you want	254 (34.7)	109 (36.2)	145 (33.6)	
You have enough money to pay the bills, but little spare money to buy extra or special things	232 (31.7)	99 (32.9)	133 (30.9)	

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	Overall (N=732)	Veterans with dementia (n=301)	Veterans without dementia (n=431)	*P* value
You have money to pay the bills, but only because you have to cut back on things	112 (15.3)	40 (13.3)	72 (16.7)	
You are having difficulty paying the bills, no matter what you do	46 (6.3)	11 (3.7)	35 (8.1)	
Caregiver-veteran relationship, n (%)				.004
Spousal	445 (60.8)	203 (67.4)	242 (56.1)	
Other	259 (35.4)	89 (29.6)	170 (39.4)	
Caregiver as primary caregiver, n (%)				.45
Yes	620 (84.7)	254 (84.4)	366 (84.9)	
Someone else is the primary	25 (3.4)	13 (4.3)	12 (2.8)	
Share caregiving equally	66 (9.0)	28 (9.3)	38 (8.8)	
Hours of care provision per week, mean (SD)				.002
Caregiver hours of care/week	83.0 (64.9)	94.2 (65.9)	75.0 (63.1)	
Caregiving length of time, n (%)				.13
Less than 6 months	18 (2.5)	4 (1.3)	14 (3.2)	
6-11 months	35 (4.8)	11 (3.7)	24 (5.6)	
1-2 years	108 (21.3)	41 (13.6)	67 (15.5)	
3-5 years	156 (21.3)	75 (24.9)	81 (18.8)	
More than 5 years	391 (53.4)	158 (52.5)	233 (54.1)	
Zarit Caregiver Burden[b]				.002
Zarit Caregiver Burden Score, mean (SD)	7.0 (4.1)	7.8 (4.2)	6.4 (3.9)	<.001
Low to Moderate Caregiver Burden (0-7), n (%)	398 (54.4)	139 (46.2)	259 (60.1)	—[c]
High Caregiver Burden (8-16), n (%)	334 (45.6)	162 (53.8)	170 (39.9)	—
Veteran characteristics, mean (SD)				
Age in years	80.1(9.8)	82.4 (7.8)	78.4 (10.7)	<.001
CMS-HCC risk score[d]	2.4 (1.6)	2.6 (1.6)	2.2 (1.5)	<.001
JFI[e]	5.8(2.4)	6.4 (2.2)	5.3 (2.4)	<.001
Nosos	2.3 (2.3)	2.5 (2.3)	2.2 (2.3)	.05

[a]Percents do not include missing. Missingness is as follows: respondent type (n=116), race and ethnicity (n=17), sex (n=10), preferred language (n=3), marital status (n=18), education (n=41), heath literacy (n=5), caregiver employment (n=90), change in employment (n=132), income (n=88), caregiver-veteran relationship (n=28), primary caregiver status (n=21), caregiving length of time (n=24).

[b]Caregiver Burden Measured by the Zarit 4-item scale (scores of ≥8 indicate High Caregiver Burden) [39,40].

[c]Not applicable.

[d]CMS: U.S. Centers for Medicare & Medicaid Services; HCC: Hierarchical Condition Category. The CMS-HCC risk-adjusted score is the sum of the score or weight attributed to each of the demographic factors and HCCs used in the scoring model. The CMS-HCC model is normalized to 1.0, meaning veterans would be considered relatively healthy, and therefore less costly, with a risk score less than 1.0. HCCs are a risk-adjustment model used to estimate future health care costs for patients [35].

[e]The JFI or JEN Frailty Index (range 0-13) is calculated using 13 categories of ICD-9/10 (International Classification of Diseases) diagnostic codes representing geriatric syndromes, functional deficits, and multimorbidity clusters to predict the risk of nursing home admission [34].

Qualitative Results for Caregiver Preparedness Needs

Overview of Emergent Themes and Domains

Below, we present the 9 domains derived from the themes that emerged from qualitative content analysis of open-ended responses and share a representative quote for each domain for a caregiver, each providing care to a veteran with and without dementia. Both sets of caregivers seemed to have similar preparedness needs across domains, and both often handled complex tasks spanning multiple domains and multiple tasks in one domain.

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Care Coordination

The commonest concern expressed by caregivers was the need to learn how to arrange care and advocate for services and supports to make sure veterans got appropriate, timely help. They wanted to learn to navigate and communicate within the health care system and to participate in treatment decisions. They also wanted to understand how to coordinate services between different health care systems and to gather relevant information about available resources.

> *Working through getting services from the VA and coordination with PHI (private health insurance) and Medicare and long-term care insurance.* [64-year-old non-Hispanic White, American Indian, or Alaska Native male caregiver of veteran with dementia]
>
> *Sometimes paperwork, claims, or trying to get him at a higher percentage disability through system as there are no records of what my dad hauled/transported.* [45-year-old Hispanic Asian or Asian American female caregiver of veteran without dementia]

Emotional and Social Support

Family caregivers of both persons with and without dementia would benefit from more training to handle emotional outbursts, fluctuating mood, and agitation in the veterans, and provide support in managing stressful situations.

> *Dealing with his progressive fluctuating vascular dementia, dementia agitation and hostile combativeness on occasion.* [54-year-old non-Hispanic White female caregiver of veteran with dementia]
>
> *I need more training about how to deal with post-traumatic stress disorder, which my veteran husband has.* [69-year-old Hispanic, some other race, or origin female caregiver of veteran without dementia]

Advance Planning

Caregivers wanted to know how to keep the veterans at home for as long as possible, and how to arrange the needed long-term care for the veterans as their health, or that of the caregivers, declined. A common need was learning how to better handle financial and legal matters. Caregivers expressed worry about handling death and a desire to learn how to manage care at the end of life.

> *He and I don't want him to go to a nursing home. How would I handle death alone at home?* [78-year-old non-Hispanic White female caregiver of veteran with dementia]
>
> *Long-term care when I can no longer lift him.* [76-year-old non-Hispanic White female caregiver of veteran without dementia]

Nursing and Health Monitoring Tasks

Caregivers wanted to learn how to properly administer oral, topical, and injectable medications, provide wound care, and support treatment adherence. They also wanted to know how to use medical devices to monitor the veterans' condition (eg, blood pressure cuff and pulse oximeter), manage healthy sleep hygiene, and physical symptoms (eg, nausea, pain, and constipation). Some also expressed an interest in accessing various training courses, for example, nursing, nurse assistant, cardiopulmonary resuscitation, health monitoring, fall prevention, and equipment use.

> *Medical needs, medication management. Talking to the veteran about taking medicines/very poor compliance. Blood sugar dysregulated.* [48-year-old non-Hispanic White male caregiver of veteran with dementia]
>
> *Wound care, physical therapy, diapering, transfers. Not comfortable with the more medical issues...* [58-year-old non-Hispanic White female caregiver of veteran without dementia]

Household Tasks

Caregivers wanted to be better prepared to assist with household tasks like laundry, preparing meals, shopping, and performing or coordinating home maintenance activities, including odd jobs. They also wanted to be better prepared for assisting with paying bills and managing finances.

> *At my age (88) and having physical limitations, it is difficult to do all the cooking, driving, and laundry sometimes.* [88-year-old non-Hispanic White female caregiver of veteran with dementia]
>
> *I wish I were a superwoman so that I'll be able to do all the household chores while taking care of my husband!* [61-year-old non-Hispanic Asian or Asian American female caregiver of veteran without dementia]

Personal Care

Caregivers wanted to learn how to better assist the veterans with personal care tasks like bathing, dressing, feeding, grooming, personal hygiene, toileting (including getting to and from the toilet), maintaining continence, and managing incontinence. They also wanted to know how to arrange and manage in-home help.

> *The emotional toll of caring for a bed-bound, urinary and bowel incontinent adult male. Even with a "hospital bed" I am not strong enough to turn him and move him to clean his bottom. The emotional stress of tube feeding. His inability to communicate effectively. Needing to make decisions for him.* [68-year-old non-Hispanic White female caregiver of veteran with dementia]
>
> *Toileting in bed, getting in and out of bed and chairs.* [77-year-old non-Hispanic White female caregiver of veteran without dementia]

Mobility

Caregivers wanted to be better prepared to assist the veterans with moving around inside or outside the home, and to safely transfer in or out of bed, wheelchair, toilet, and tub or shower, and prevent falls. They wanted to assist with appropriate mobility and strengthening exercises, and manage assistive

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devices such as walkers, canes, and wheelchairs, and access resources to make needed home modifications for safety. Caregivers wanted to learn how to maintain proper and safe body mechanics while assisting the veterans, to avoid injuring themselves.

> *Pulling and lifting, my wife injured her arm. Pulled tendons loose in her right arm.* [76-year-old (unknown ethnicity) White male caregiver of veteran with dementia]
>
> *How to make it easier for her to walk, sit, etc., without her being in so much pain and maybe falling. She can't use her legs or hands good.* [49-year-old non-Hispanic White female caregiver of veteran without dementia]

Caregiver Self-Care

Caregiving tasks exact an extreme emotional toll on caregivers. Several caregivers reported feeling overwhelmed and needing emotional support and some time for themselves. They expressed interest in learning to engage in activities that support their own mental, emotional, and physical well-being. They wanted to learn how to ask for and accept assistance and access resources to get an occasional break, for example, respite care.

> *I can help at all things but wish I had a little time for me.* [79-year-old non-Hispanic White female caregiver of veteran with dementia]
>
> *I am needing assistance with an "adult (babysitter)." Someone to come in for weekend for about 4hrs a NEED day.* [64-year-old non-Hispanic White female caregiver of veteran without dementia]

Emergent Situations

Caregivers expressed concern about not being prepared for medical and weather-related emergencies and disasters (eg, hurricanes and power outages) and expressed a desire to proactively formulate plans for needed care and access to resources, equipment, and supplies during such times.

> *In the event of an emergency, to be able to get right help. If I am ill, to have proper care during my recovery.* [85-year-old Hispanic White female caregiver of veteran with dementia]
>
> *Would like to have a defibrillator machine at home.* [49-year-old Hispanic White female caregiver of veteran without dementia]

These results show that family caregivers often provide care for veterans with substantial impairments who need 24/7 nursing home-level care and require the caregivers to have skills in several domains and significant endurance. However, caregivers caring for veterans with and without dementia had similar preparedness needs.

Quantitative Results for Caregiver Preparedness Needs

Overall Gaps in Caregiver Preparedness

The number and proportion of all caregivers (n=732) who expressed preparedness needs by domain were care coordination 164 (22.4%), emotional and social support 145 (19.8%), advance planning 116 (15.8%), nursing and health monitoring tasks 94 (12.8%), mobility 79 (10.8%), personal care 65 (8.9%), household tasks 58 (7.9%), caregiver self-care 36 (4.9%), and emergent situations 28 (3.8%), and are shown in Figure 2.

Figure 2. Preparedness needs by domain for all caregivers (N=732).

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Domains and Tasks for Which Caregivers Reported Preparedness Needs, by Veterans' Dementia Status

The number and proportion of caregivers reporting preparedness needs were tabulated next for each domain for caregivers of veterans with dementia (n=301) versus caregivers of veterans without dementia (n=431), respectively, and were as follows: care coordination: 67 (22.3%) versus 97 (22.5%); mobility: 30 (10%) versus 49 (11.4%); personal care: 34 (11.3%) versus 31 (7.2%); emotional and social support: 56 (18.6%) versus 89 (20.6%); advance planning: 49 (16.3%) versus 67 (15.5%); nursing and health monitoring: 34 (11.3%) versus 60 (13.9%); household tasks: 30 (10%) versus 28 (6.5%); caregiver self-care: 23 (7.6%) versus 13 (3%); and emergent situations: 6 (2%) versus 22 (5.1%). The comparisons are shown in Figure 3, with details in Multimedia Appendix 1. The tasks within each domain that caregivers wanted to be better prepared for, by dementia status, are shown in Figure 4. The commonest tasks caregivers overall (N=732) expressed needs for included managing emotional and behavioral symptoms 74 (10.1%), recognizing and responding to significant changes in the veterans" condition 66 (9.1%), seeking medical information relevant to the veterans' needs 54 (7.4%), handling financial and legal matters 52 (7.1%), and advocating for services 49 (6.7%) (Table 2). Both Figures 3 and 4 show the overall similarity in the patterns of preparedness needs between caregivers of veterans with and without dementia.

Figure 3. Preparedness needs of caregivers of veterans with and without dementia by domain.

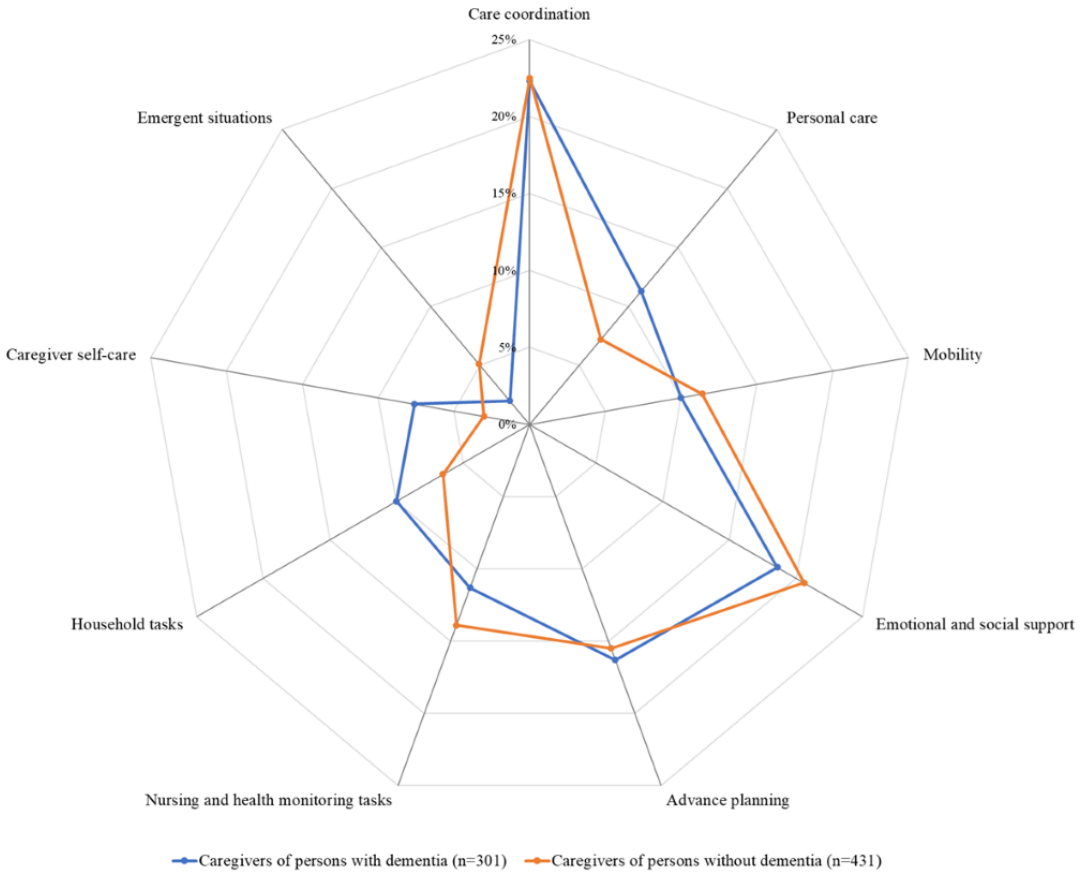

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Figure 4. Preparedness needs for various tasks in each domain by dementia status. The tasks are organized by domains, with each number group representing a different domain. 1: coordination; 2: personal care; 3: mobility; 4: emotional and social support; 5: advance planning; 6: nursing and health monitoring tasks; 7: household tasks; 8: caregiver self-care; 9: emergent situations.

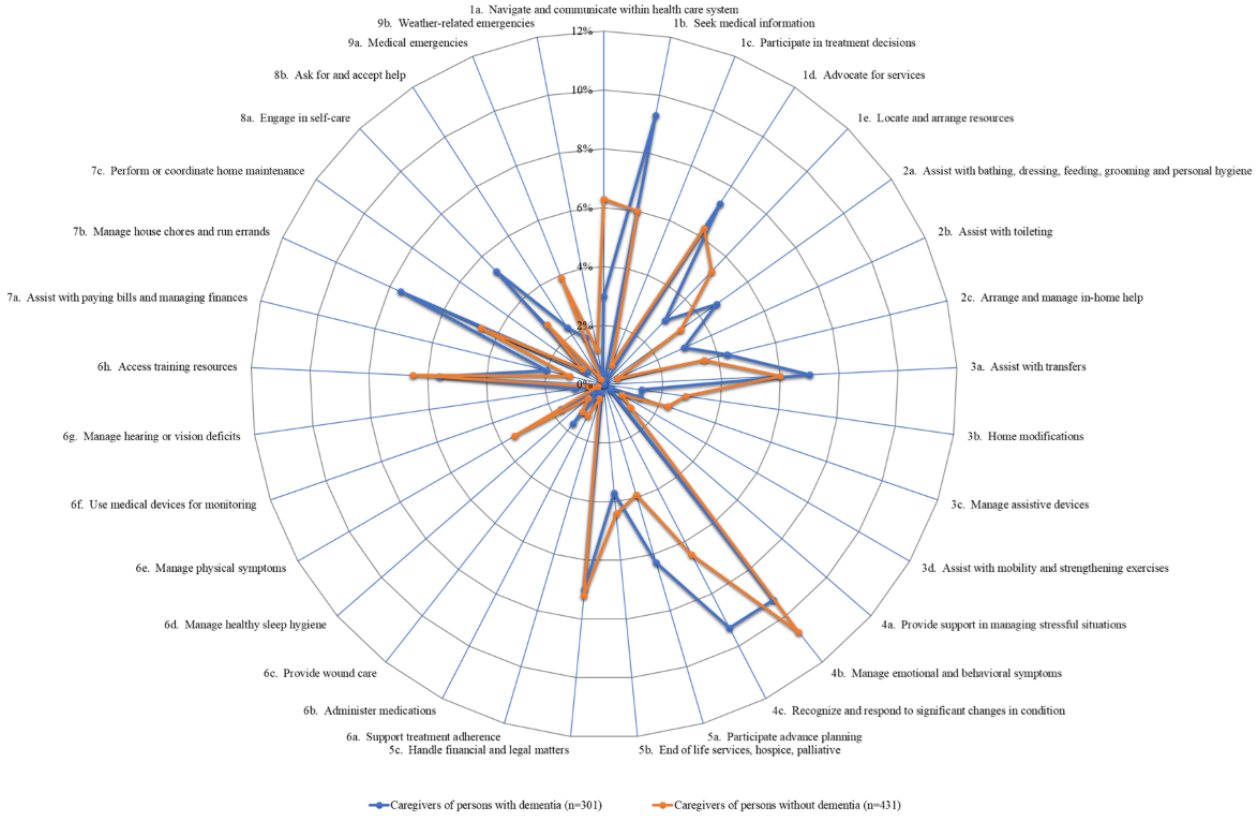

Table 2. Commonest tasks caregivers want to be better prepared for overall and by veterans' dementia status.

	Overall (N=732), n (%)	Caregivers of veterans with dementia (n=301), n (%)	Caregivers of veterans without dementia (n=431), n (%)
Manage emotional and behavioral symptoms	74 (10.1)	28 (9.3)	46 (10.7)
Recognize and respond to significant changes in the care recipient's condition	66 (9)	28 (9.3)	28 (6.5)
Seek information relevant to the care recipient's needs (medical knowledge)	54 (7.4)	28 (9.3)	26 (6)
Handle financial and legal matters	52 (7.1)	21 (7)	31 (7.2)
Advocate for services	49 (6.7)	22 (7.3)	27 (6.3)
Assist the care recipient to safely transfer in/out of bed, chair wheelchair, toilet and tub/shower	47 (6.4)	21 (7)	26 (6)
Access training resources (nursing training, certified nursing assistant, cardiopulmonary resuscitation, health monitoring, fall prevention, and equipment use)	45 (6.1)	17 (5.6)	28 (6.5)
Manage laundry, prepare meals, perform shopping, and run errands	43 (5.9)	23 (7.6)	20 (4.6)

Discussion

Our study included a large sample of diverse caregivers who identified common domains and tasks in which they felt inadequately prepared for caregiving tasks and situations. We identified key gaps in caregiver preparedness while exploring similarities and differences between the preparedness concerns of those caring for veterans with versus without dementia. Our findings are quite remarkable. Both groups of caregivers, whether caring for veterans with or without dementia, were very similar in the percentages reporting needs in most domains and tasks. The commonest preparedness gaps were in care coordination, emotional and social support, and advance planning, followed by nursing and health monitoring, personal care, mobility, and household domains.

Caregivers of veterans with dementia in our study were older, provided more hours of care, and were more likely to report high caregiver burden, compared to caregivers of veterans without dementia; this is consistent with current literature [41]. Our results are supported by previous reports showing that

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veterans with 2 or more self-care needs are similar to veterans with dementia in the high level of care needed and in the type of tasks they need help with [14]. Prior studies have also shown that caregivers of care recipients with dementia report more caregiver strain and less time for social participation [42]. This is supported by our data, in which caregivers of veterans with dementia, versus caregivers of veterans without, were more likely to perceive high caregiver burden, and be interested in strategies to take care of their own well-being [43]. Some potential explanations may be that all veterans are challenging to care for, regardless of their diagnosis. Another explanation is that caregiving, no matter for whom, just has some gaps that caregivers do not feel prepared for. A third possibility might be that the VA does a better job of preparing dementia caregivers, because some caregiver support programs in the VA are more targeted to dementia; for example, Resources for Enhancing All Caregivers' Health (REACH) VA was initially built for dementia caregivers, even though it has now expanded to other conditions.

Although each caregiver's path is unique and varies in onset and intensity, the caregiving journey has a somewhat typical trajectory [4,40]. It usually starts with a need for intermittent assistance from caregivers with tasks like transportation, medical appointments, and communicating with medical providers. This evolves over time into a more regular need for assistance with tasks like managing medications and coordinating care, followed by personal care tasks like help with bathing and dressing, and finally, with end-of-life care. Caregiving tasks are not driven by a specific diagnosis but rather by tasks in which caregivers aid with, and are influenced by, the care recipients' functional capacity, need, and behavioral problems. Therefore, the concept of caregiver preparedness for older adults is complex and evolves with time and changing context. Additionally, since caring for patients with dementia often requires more intensive support over extended periods of time compared to caring for non-dementia patients [22,23], it is perceived to lead to higher levels of burden [26-28] and unmet needs compared to caregivers of other age-related illnesses [27,28]. Yet, our data suggest that the tasks and skills they need over their caregiving journey are somewhat similar, even though the frequency and amount with which a particular skill may be applied may vary.

Caregiver preparedness has been proposed as a prospective target and a potential therapeutic mechanism by which caregiver-focused interventions lead to positive outcomes [3,44]. Prior studies have shown that caregiver preparedness can be modified with interventions that prepare caregivers to take care of their care recipients and themselves. The Department of Veterans Affairs has several programs like the Caregiver Support Program, Building Better Caregivers, and Caregivers FIRST (Finding Important Resources, Support, and Training) [45] that provide support, information, and training to caregivers. These programs also help caregivers navigate the health care system, learn stress and mood management techniques, and teach them skills needed to take care of their veterans. They prepare caregivers and potentially alleviate caregiver stress and burden, which leads to more prosocial outcomes for both caregivers and veterans. Similar programs are also available outside the VA through clinics and other health care systems through agencies like the American Association of Retired Persons, Administration for Community Living, and National Alliance for Caregiving. Yet, data suggest that many caregivers are unaware of these programs [46]. Our results also underscore that while the disease stages, progression, and some expected symptoms may vary by disease and disease types, some crucial elements of caregivers' preparedness, regardless of the specific condition, include knowledge about caregiver resources, support services, self-care, financial, medical, and legal information.

This study reinforces findings relevant to programs and interventions designed to improve family caregiving competency. First, caregiver intervention programs should focus on direct care and advocacy and coordination. Structured approaches should be used to identify gaps in caregiver preparedness, grouped by domains and tasks, and offer targeted caregiver skills training and information about resources that augment caregiver preparedness, contextualized to their needs, since not all caregiver interventions are the same. Second, programs and interventions to prepare caregivers may gain economies of scale by developing content that covers broad topics relevant to all caregivers, and supplement that by creating diagnosis-specific modules that address disease-specific information and resources. This is a strategy that caregiver interventions have adopted: examples are the RESCUE (Resources & Education for Stroke Caregivers' Understanding & Empowerment) program [47], which was initially designed to empower caregivers of veterans with stroke, and then expanded to caregivers of veterans postamputation, by adding relevant content, and the REACH VA program which was initially developed for dementia caregivers and is now offered to all caregivers [4,48]. Programs built and accessible on a modular basis per need may increase timely access to more caregivers. Third, while there are available caregiver training programs in the VA and community, there is a lack of awareness of and access to these programs. Large-scale campaigns are needed to amplify awareness regarding these programs and make them more easily available. Health care systems should routinely identify all caregivers at every contact. They should establish standardized processes to identify current and anticipated caregiver preparedness gaps, at a minimum, during changes in care recipients' care site or health status [5]. They should then provide caregiver outreach with information about available services and assist them in gaining access to caregiver training programs.

Our study has several limitations. First, we defined the dementia status via HCC-51 and HCC-52 codes and treated dementia as a simple yes/no variable, and did not analyze information by dementia subtype, severity, or cognitive/behavioral staging, even though those features heavily shape caregiving tasks and perceived preparedness. Therefore, our results may mask important gradients in needs among caregivers of veterans with mild versus advanced dementia and limit the clinical specificity of the implications for tailoring interventions. However, our objective for this manuscript was to compare preparedness needs of caregivers of dementia versus non-dementia care recipients, rather than by dementia severity. Second, we analyzed short open-ended responses, and not interviews, to classify preparedness gaps into domains. In some instances, it was hard

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to tease out whether the response expressed a preparedness gap or an unmet need. As an example, the quotes regarding caregiver self-care may be related to the caregivers' emotional problems or maybe an "objective" call for more assistance and time (unmet need). Third, about two-thirds of the caregivers did not respond to the question we analyzed, and among those who responded, a third simply wrote "no." Therefore, nonresponse and bias could distort both the reported prevalence and pattern of preparedness gaps we report. We also did not compare the responders to nonresponders, and among the responders, caregivers who reported preparedness needs to those who did not, to test if there is something fundamentally different about those who reported needing help versus those who did not. This would be a future endeavor since it could help us to target those who are likely to need help. Fourth, our sample consists largely of older, mostly female, mostly White, predominantly spousal caregivers of US veterans who are already engaged with the VA system and who responded to a mailed survey. Preparedness needs and needs gaps may look very different for younger caregivers, non-veteran populations, non–English speakers, or families outside integrated health systems. A strength of our study is the large number of caregivers whose responses were tabulated and compared, comprising both caregivers of veterans with and without dementia.

Our study provides evidence for the National Strategy to Support Family Caregivers' goal to strengthen services and supports [49]. Attention to caregivers' self-perceived preparedness for caregiving may positively influence dyadic outcomes and aging in place. Future research should include a longitudinal examination of outcomes associated with the level and gaps of caregiver preparedness and the need for long-term institutional care.

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Data Availability

The Veterans Affairs (VA) is committed to making data publicly available through its Open Data platform, in accordance with the Open Data Act. Most datasets are accessible; however, personally identifiable information will be protected, and access to sensitive data may require prior approval. For further information regarding data access or specific data requests, please contact the VA Office of Information and Technology.

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Authors' Contributions

RS designed the concept of this study, analyzed the data, and wrote and revised the manuscript. RS, SL, and DR performed the thematic analyses of the open-ended responses. SGD, RM, PT, and MD supervised and reviewed the analytic strategy, edited the manuscript, and approved its final version. LL, EB, LN, and the Elizabeth Center of Excellence for Veteran and Caregiver Research Team reviewed, edited, and approved the manuscript. All authors have read and agreed to the published version of the manuscript.

Conflicts of Interest

Authors SGD, RM DR, PT, ER, LN, MD, and LL are federal employees and this work was created as part of our duties for the US government.

Multimedia Appendix 1
Domains and tasks for which caregivers wanted to be better prepared, by dementia status.
[DOCX File , 27 KB - formative_v10i1e83493_app1.docx]

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Abbreviations

FIRST: Finding Important Resources, Support, and Training
GCF: Geriatrics and Extended Care Data Analysis Center Core Files
HCC: Hierarchical Condition Category
HERO CARE: Home Excellence Resource Outcome Center to Advance, Redefine, and Evaluate Non-Institutional Care
JFI: JEN Frailty Index
REACH: Resources for Enhancing All Caregivers' Health
RESCUE: Resources & Education for Stroke Caregivers' Understanding & Empowerment
VA: Veteran Affairs
VISN: Veteran Integrated Service Network

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Original Paper

Patient-Provider Matching, Engagement, and Outcomes of a Digital Mental Health Treatment Platform: Real-World Retrospective Cohort Study

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Abstract

Background: Technology-enabled mental health platforms that incorporate user-driven patient-provider matching may offer a novel way to personalize and optimize outcomes. We conducted this study because little is known about the engagement and clinical symptom changes of these newer types of mental health platforms and whether patient-driven selection of their provider's characteristics is associated with either engagement or clinical outcomes.

Objective: This study aimed to determine the levels of engagement and clinical symptom changes associated with the use of a technology-enabled mental health platform that allows patients to select preferred provider characteristics and to explore whether the selection of a provider characteristic was associated with engagement and clinical outcomes.

Methods: We conducted a real-world, retrospective cohort study using deidentified electronic health data from adult Grow Therapy patients aged 18 years or older with clinically elevated depressive or anxiety symptoms at baseline (PHQ-9 [Patient Health Questionnaire-9] > 9 or GAD-7 [Generalized Anxiety Disorder-7] > 9). Inclusion required 1 provider visit (intent-to-treat cohort) for engagement analyses; clinical outcome analyses required 2 or more provider visits (complete case cohort). Engagement with the platform was measured by the number of provider visits. Clinical outcomes were measured using changes in PHQ-9 and GAD-7 scores and defined as meeting a minimal clinically important difference (MCID). Bivariate associations between selection of provider characteristics and outcomes were measured using chi-square tests, and adjusted associations were modeled using logistic regression (P<.05).

Results: Among 159,448 patients with elevated depressive symptoms and 167,356 patients with elevated anxiety symptoms, engagement was high, with 69.4% (95% CI 69.2%-69.7%) and 69.3% (95% CI 69.1%-69.5%) having 3 or more visits, respectively. In the complete case cohort, symptom reductions were significant; 58.9% (95% CI 58.5%-59.2%) met depressive symptom MCID criteria, and 63% (95% CI 62.6%-63.3%) met anxiety symptom MCID criteria after engagement. Although only ≈35% of patients selected a provider specialty and ≈5% selected a provider identity before enrollment, those selecting a provider specialty experienced significantly better outcomes, and those selecting a provider identity engaged significantly more frequently as compared to those who did not select each characteristic. Sensitivity analyses confirmed these findings.

Conclusions: This exploratory, real-world, uncontrolled study provides early evidence that allowing patients to select provider characteristics within a technology-enabled mental health platform may support both engagement and meaningful symptom improvement. The investigation of the relationship between mental telehealth provider selection characteristics and both engagement and clinical outcomes is a novel addition to the peer-reviewed literature. Findings highlight how user-driven, scalable matching features may personalize mental health care in ways that differ from traditional assignment-based models and underscore the need for more rigorous, controlled studies to demonstrate efficacy and test causality and mechanisms.

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KEYWORDS

internet; psychotherapy; provider selection; anxiety; depression

Introduction

Despite major advances in mental health care delivery over the past several decades, effectiveness rates have remained modest [1-4]. Few interventions have enabled patients to sustainably engage [5-7], despite the development of web-based tools that have improved access. Nonetheless, the increased demand for flexible and scalable types of psychological support has enabled digital mental health platforms to rapidly expand their reach [8,9].

Some of these platforms offer patients greater choice than is typically available in traditional care settings, such as the option to select providers based on specific personal or professional characteristics. At the same time, however, there is growing recognition that engagement remains one of the most persistent challenges in digital mental health care, with many users disengaging early or never initiating care at all [6,7,10]. Whether the selection of provider characteristics by patients is associated with engagement or clinical outcomes, however, has yet to be reported. Prior research suggests that aspects of provider-patient concordance, such as shared cultural background, language, gender identity, or therapeutic orientation, have the potential to influence therapeutic alliance, treatment satisfaction, and engagement [11,12]. Accordingly, a randomized controlled trial (RCT) found that matching patients to providers based on therapists' performance strengths can improve mental health outcomes [13]. Previous studies, however, mostly come from traditional psychotherapy contexts that have limited generalizability to digital environments. These shifts highlight the urgent need to better understand how patients make choices within digital ecosystems and whether those choices relate meaningfully to engagement or clinical benefit.

With the growth of digital and hybrid care models, reimbursement for telehealth services, and direct-to-consumer platforms, understanding how patients make provider choices and how these choices relate to the course of treatment becomes increasingly important [14-16]. Technology-enabled platforms that incorporate user-driven matching may offer a novel way to personalize and optimize engagement between users and providers [17]. Some of these platforms, such as Grow Therapy, further empower patients to self-select preferred characteristics of their provider, but little is known about these selections and their associations with engagement and clinical outcomes.

Findings of prior studies that have investigated similar relationships, such as whether patients who visit providers with the same gender or race/ethnicity experience improved outcomes, have had mixed findings [18], with little clarity regarding whether the match characteristics were a random occurrence or patients actually had the choice to select provider characteristics. Fortunately, digital platforms now operate at sizes large enough to evaluate naturally occurring behaviors and outcomes using real-world data, offering an opportunity to study how the autonomy of patients to select their own providers may influence their care trajectories. As such, this study addresses a key gap in the literature by examining a modern digital platform in which patients, rather than systems, have better control over the selection of their provider-matching experience, given that typical access barriers, such as the availability of providers in a particular location, are removed.

Despite the noted benefits of personalization and patient choice central to web-based mental health models [19], empirical evidence on how users navigate provider-selection tools is remarkably sparse. Existing work has largely focused on algorithmic matching systems or high-level engagement metrics, leaving major questions unanswered regarding the real-world behaviors of users who manually browse and select providers [20-22]. Moreover, no web-based mental health care studies to date have examined whether specific provider characteristics, such as clinical expertise, demographics, or therapeutic style chosen by patients, are associated with subsequent engagement patterns or symptom change.

Understanding these patterns is particularly critical given the current emphasis on equity-centered care and culturally responsive provider matching [23,24]. Without foundational descriptive data on how patients actually use these features, platforms lack evidence to guide interface design, optimize provider profiles, or enhance matching systems in ways that support adherence and therapeutic outcomes. This study addresses this gap by offering an empirical examination of provider-selection behaviors and downstream engagement within a large, diverse sample of real-world digital mental health users. Understanding whether selecting specific provider characteristics is meaningfully associated with patient engagement or clinical improvement can clarify how digital platforms might guide patients toward choices that optimize therapeutic fit, strengthen the care experience, and ultimately improve engagement and clinical outcomes.

The specific aims of this study were to (1) describe age, gender, and clinical characteristics of patients enrolled in one such technology-enabled platform created to connect patients to care (Grow Therapy) and (2) determine patients' levels of engagement (primary) and clinical outcomes (secondary), namely changes in symptoms of depression and anxiety between the first and last visit in this real-world, retrospective cohort study while recognizing the sources of potential biases in interpretation of the findings. A third, exploratory aim was to determine whether there were significant associations between 2 types of provider selection (selection of a provider's specialty and selection of a provider's identity characteristic) and meaningful (1) engagement and (2) clinical outcomes that may serve as preliminary signals that can suggest the conduct of additional research studies with more rigorous, hypothesis-testing designs. These additional studies could be used to more definitively determine whether patient selection of provider characteristics, an emerging, scalable feature of digital platforms, can improve engagement or influence clinical outcomes.

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Methods

Study Design

This study used a real-world, retrospective cohort design leveraging deidentified electronic health record data from Grow Therapy, a technology-enabled mental health platform, reported in accordance with STROBE (Strengthening the Reporting of Observational Studies in Epidemiology) guidance for observational studies [25]. Adults aged 18 years or older with a first provider visit between January 1, 2022, and April 30, 2024, were eligible for inclusion. Patients were included in the intent-to-treat cohorts if they had clinically elevated symptoms at intake (PHQ-9 [Patient Health Questionnaire-9 item]>9 for the depressive symptom cohort; GAD-7 [Generalized Anxiety Disorder]>9 for the anxiety symptom cohort). Clinical outcome analyses used complete case cohorts requiring at least 2 completed PHQ-9 or GAD-7 assessments. Sample size was determined by the available population meeting these criteria, consistent with retrospective observational designs. Data included patient demographics, preferred provider characteristics selected during the matching process (specialty and identity attributes), number of completed visits, and routinely collected symptom assessments. All symptom data originated from standardized, validated electronic instruments integrated into the platform and administered at intake and approximately every third visit. No new data were collected for research purposes. Participants self-selected providers via a predefined interface, and all data used in this study were originally collected as part of routine clinical care.

Ethical Considerations

This study was reviewed by Western Institutional Review Board Copernicus Group and deemed exempt under 45 Code of Federal Regulations §46.104(d)(4) (Confirmation ID 45689720), which covers secondary research using identifiable private information or biospecimens when data are recorded in a manner that no longer allows subjects to be identified. All individuals agreed to Grow Therapy's privacy policy and informed consent procedures at intake, which permitted the use of deidentified data for research purposes. As this study involved secondary analyses of deidentified data, additional participant consent was not required. All data were extracted in deidentified form, with direct identifiers removed before analysis. Data were stored in HIPAA (Health Insurance Portability and Accountability Act)-compliant secure databases, and only aggregated results are reported. No compensation was provided to individuals whose clinical data were included in this secondary analysis. No images or materials containing individually identifiable patient information are included in this paper or supplementary materials. All analyses were conducted on deidentified data, which precluded the identification of individual participants.

Study Design and Sample Identification

Data on all adult patients (18 years or older) with a first Grow Therapy visit between January 1, 2022, and April 30, 2024, were included in this study's sample, which was further broken down into 2 cohorts. The first cohort consisted of patients who had elevated levels of depressive symptoms, and the second cohort consisted of patients who had elevated levels of anxiety symptoms as described below. Data included preferred provider characteristics endorsed by the patient when seeking to find a new provider affiliated with Grow Therapy and deidentified clinical data collected as part of treatment engagement with a provider, as well as the total number of visits between the patient and provider. Data collected through April 30, 2025, were included in analyses to allow all patients to have at least 12 full months of follow-up.

Variables of Interest

Patient Demographic Characteristics

Patient age at the time of appointment was examined continuously and also categorized into age groups (18-24, 25-34, 35-44, 45-54, 55-64, and 65+ years). Patient self-reported gender was coded into 3 groups as male, female, or other/nonbinary/preferred not to answer.

Patient Selection of Provider Characteristics

Types of provider selection characteristics selected by patients included (1) provider specialty (eg, clinical issues such as depression or anxiety, trauma, family conflict, etc), and (2) provider identity (eg, race/ethnicity, religious affiliation, and sexual orientation). Provider identity characteristics refer to self-reported demographic or cultural attributes made visible to patients during the provider selection process. Both of these characteristics were coded as yes or no to indicate whether the patient had chosen a provider specialty or provider identity, respectively, before engaging in a Grow Therapy patient-provider relationship. Patients selected from a standardized list of provider characteristics presented through the Grow Therapy matching interface during intake. These options were not free-text but offered as predefined identity and specialty attributes of each provider.

Engagement

The total number of individual, couples, or family outpatient psychotherapy, medication evaluation, or medication management noncancelled visits (ie, number of visits) was quantified and then dichotomized into 2 variables for analyses. First, a variable for having 3 or more visits was used as a reasonable benchmark by which to establish an initial relationship between patient and provider with peak therapeutic alliance that has been shown to lead to better outcomes [26], and, second, a variable quantifying having 12 or more visits benchmarked the length of a typical cognitive behavioral therapy (CBT) intervention.

Clinical Outcomes

Symptoms of Depression

The PHQ-9, a validated and reliable measure of symptoms of depression (Cronbach α=0.86-0.89) [27], was administered electronically to patients at the start of treatment as well as before every third visit or at the provider's discretion. Scores were classified by severity: minimal (0-4), mild (5-9), moderate (10-14), moderately severe (15-19), and severe (20+) [27]. The depressive symptom cohort had baseline PHQ-9 scores of 10 or higher, which prior work validated against a trained interviewer's assessments with 88% sensitivity and specificity

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[27]. Changes in symptoms between the first visit's assessment and the last visit's assessment were calculated and reported continuously as well as categorized as a minimal clinically important difference (MCID) defined as a reduction in symptoms of 5 or more points among those starting with a score of 10 or higher [28,29].

Symptoms of Anxiety

The GAD-7, a validated and reliable measure of symptoms of anxiety (Cronbach α=0.92) [30], was administered to patients upon intake at the start of treatment as well as at every third visit or at the provider's discretion. Scores were classified by severity as previously validated: minimal (0-4), mild (5-9), moderate (10-14), and severe (15+) [30]. The anxiety symptom cohort had baseline GAD-7 scores of 10 or higher, which prior work validated against a trained interviewer's assessments with 88% sensitivity and 82% specificity [31]. Changes in symptoms between the first visit's assessment and the last visit's assessment were calculated and reported continuously as well as categorized as an MCID (reduction in symptoms of 4 or more points) among those starting with a score of 10 or higher on the GAD-7 [31].

Statistical Analyses and Reporting

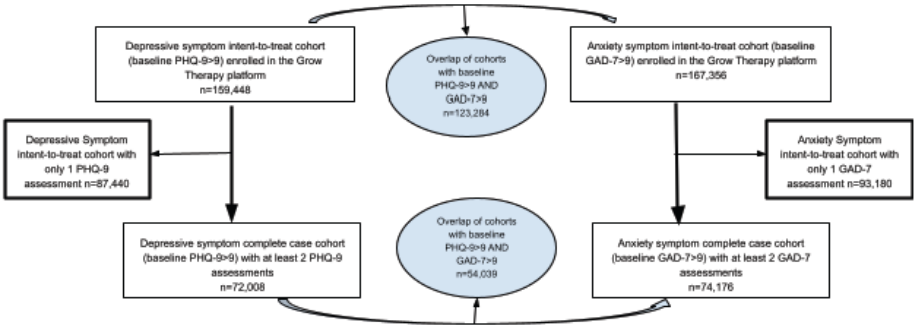
Statistical analysis was performed in May 2025. Frequency counts and percentages are reported for all categorical data, and means and SDs are reported for continuous data. Bivariate (unadjusted) associations were examined via chi-square tests to determine differences between provider characteristics selected by patients and outcomes of interest, including number of visits dichotomized into 3 or more provider visits (yes or no) in the intent-to-treat populations and change in symptom of depression and anxiety scores on the PHQ-9 and the GAD-7 quantified as having an MCID (yes or no), respectively, in the complete case populations (subsets of the intent-to-treat populations with at least 2 completed PHQ-9 or GAD-7 assessments, respectively) using chi-square tests. Logistic regression models to test associations between selected provider characteristic and each outcome of interest were run adjusted for baseline demographic (age and gender) and clinical characteristics (baseline depression or anxiety symptom scores) based on theory, prior research findings, and significant variables identified in analyses that compared those in the intent-to-treat populations who were, vs those who were not, included in the complete case populations. The primary outcome of interest was having at least 3 provider visits in each intent-to-treat population (depressive symptom and anxiety symptom cohorts), and the secondary outcomes included achieving a depressive and anxiety symptom MCID in the depressive symptom complete case cohort and anxiety symptom complete case cohort, respectively. To address the potential for selection bias, sensitivity analyses were performed using the last observation carried forward method for missing clinical outcome data. Logistic regression models were expressed as odds ratios (ORs) and 95% CI of each OR. A 2-sided $P \leq .05$ was considered indicative of statistical significance. All analyses were performed using R software (version 4.2; R Project for Statistical Computing).

Results

Sample

The intent-to-treat depressive symptom and anxiety symptom cohorts used for engagement and sensitivity analyses consisted of 159,448 and 167,356 adult Grow Therapy patients aged 18 years or older, respectively, with elevated symptoms at baseline (PHQ-9>9 and GAD-7>9, respectively) who had a first provider visit between January 2022 and April 2024. There was a sizable overlap in the 2 intent-to-treat cohorts, with 123,284/159,448 (77.3%) of the clinically elevated depressive symptom intent-to-treat cohort also having clinically elevated anxiety symptoms, and 123,284/167,356 (73.7%) of the clinically elevated anxiety symptom intent-to-treat cohort also having clinically elevated depressive symptoms at baseline. The complete case samples used for clinical symptom analyses required at least 2 PHQ-9 or 2 GAD-7 assessments to enable the computation of a change score and included 72,008 patients in the depressive symptom cohort (72,008/159,448, 45.2% of the corresponding intent-to-treat sample) and 74,176 patients in the anxiety symptom cohort (74,176/167,356, 44.3% of the corresponding intent-to-treat sample). Again, there was a sizable overlap in the 2 intent-to-treat cohorts, with 54,039/72,008 (75%) of the clinically elevated depressive symptom complete case cohort also having clinically elevated anxiety symptoms and 54,039/74,176 (72.9%) of the clinically elevated anxiety symptom complete case cohort also having clinically elevated depressive symptoms at baseline (Figure 1).

Figure 1. Patients with a first Grow Therapy visit in January 2022 to April 2024 with elevated baseline depressive or anxiety symptoms. GAD-7: Generalized Anxiety Disorder-7 item; PHQ-9: Patient Health Questionnaire-9 item.



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Baseline Patient Characteristics, Provider Selection, and Differences Between the Intent-to-Treat and Complete Case Cohorts

In the intent-to-treat cohorts, females comprised the majority of patients (about 75% in each cohort), and patients had a mean age of 33.3 (SD 11.2) years and 33.0 (SD 10.8) years in the depressive and anxiety symptom cohorts, respectively. Provider specialty was selected by approximately 35% of both cohorts, and about 5% of both cohorts selected a provider identity before the first visit (Table 1). Those in the complete case sample were overrepresented by females, had a higher mean age, and had slightly more severe depressive symptoms but slightly less severe anxiety symptoms at baseline, although the differences were not clinically significant (depressive symptom cohort completers mean baseline PHQ-9 of 15.2, SD 4.1, vs noncompleters mean baseline PHQ-9 of 15.3, SD 4.2, and anxiety symptom cohort completers mean baseline GAD-7 of 14.9, SD 3.4, vs noncompleters mean baseline GAD-7 of 15.0, SD 3.4, $P<.001$ for each comparison).

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Table 1. Baseline characteristics and provider selections made among Grow Therapy adult patients entering in January 2022 to April 2024.

Variable	Intent-to-treat clinically elevated depressive symptom cohort (n=159,448)	Complete case clinically elevated depressive symptom cohort (n=72,008)	Intent-to-treat clinically elevated anxiety symptom cohort (n=167,356)	Complete case of clinically elevated anxiety symptom cohort (n=74,176)
Baseline sociodemographic characteristics				
Gender, n (%)				
Female	117,229 (73.5)	54,334 (75.5)	124,884 (74.6)	56,857 (76.7)
Male	41,108 (25.8)	17,167 (23.8)	41,422 (24.8)	16,855 (22.7)
Other	1111 (0.7)	507 (0.7)	1050 (0.6)	464 (0.6)
Age (years), mean (SD)	33.3 (11.2)	34.2 (11.8)	33.0 (10.8)	33.8 (11.4)
Age group (years), n (%)				
18-24	36,191 (22.7)	15,122 (21)	37,456 (22.4)	15,520 (20.9)
25-34	65,783 (41.3)	28,641 (39.8)	70,888 (42.4)	30,386 (41)
35-44	33,570 (21.1)	15,691 (21.8)	35,691 (21.3)	16,315 (22)
45-54	14,365 (9)	7226 (10)	14,505 (8.7)	7087 (9.6)
55-64	6639 (4.2)	3624 (5)	6268 (3.7)	3355 (4.5)
65+	2900 (1.8)	1704 (2.4)	2548 (1.5)	1513 (2)
Provider characteristic selected by patient, n (%)				
Clinical specialty	56,094 (35.2)	25,982 (36.1)	59,573 (35.6)	27,121 (36.6)
Identity	8279 (5.2)	4005 (5.6)	8652 (5.2)	4069 (5.5)
Baseline clinical outcomes				
Clinical outcome: depressive symptoms				
Initial depressive symptom score (PHQ-9), mean (SD)	15.3 (4.2)	15.2 (4.1)	13.6 (5.6)	13.5 (5.5)
Initial depressive symptom (PHQ-9) severity category, n (%)				
Minimal (0-4)	0 (0)	0 (0)	7255 (4.4)	3217 (4.4)
Mild (5-9)	0 (0)	0 (0)	35,133 (21.2)	15,500 (21)
Moderate (10-14)	79,762 (50)	36,437 (50.6)	52,782 (31.9)	23,828 (32.3)
Moderately severe (15-19)	51,446 (32.3)	23,255 (32.3)	43,856 (26.5)	19,640 (26.7)
Severe (20-27)	28,240 (17.7)	12,316 (17.1)	26,647 (16.1)	11,499 (15.6)
Unknown	0 (0)	0 (0)	1683 (1)	492 (0.6)
Clinical outcome: anxiety symptoms				
First anxiety symptom score (GAD-7), mean (SD)	13.6 (4.8)	13.5 (4.8)	14.9 (3.4)	14.9 (3.4)
First anxiety symptom (GAD-7) severity category, n (%)				
Minimal (0-4)	5288 (3.3)	2420 (3.4)	0 (0)	0 (0)
Mild (5-9)	29,697 (18.8)	13,644 (19.1)	0 (0)	0 (0)
Moderate (10-14)	50,978 (32.2)	23,466 (32.8)	81,818 (48.9)	36,698 (49.5)
Severe (15-21)	72,308 (45.7)	32,067 (44.8)	85,538 (51.1)	37,478 (50.5)
Unknown	1,177 (0.7)	411 (0.5)	0 (0)	0 (0)

The intent-to-treat samples included all adult Grow Therapy patients aged 18 years or older with a first provider visit in January 2022 through April 2024 who had clinically elevated depressive symptoms at baseline (PHQ-9 of 10-27; baseline depressive symptom cohort) or who had clinically elevated anxiety symptoms at baseline (GAD-7 of 10-21; baseline anxiety symptom cohort) as indicated.

A total of 123,284/159,448 (77.3%) of the clinically elevated depressive symptom intent-to-treat cohort also had clinically

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elevated anxiety symptoms and are included in both intent-to-treat cohorts.

A total of 123,284/167,356 (73.7%) of the clinically elevated anxiety symptom intent-to-treat cohort also had clinically elevated depressive symptoms at baseline and are included in both intent-to-treat cohorts.

The complete case samples included patients in each intent-to-treat sample who also had at least 2 completed PHQ-9 (baseline depressive symptom cohort) or GAD-7 assessments (baseline anxiety symptom cohort).

A total of 54,039/72,008 (75%) of the clinically elevated depressive symptom complete case cohort also had clinically elevated anxiety symptoms and are included in both complete case cohorts.

A total of 54,039/74,176 (72.9%) of the clinically elevated anxiety symptom complete case cohort also had clinically elevated depressive symptoms at baseline and are included in both complete case cohorts.

Engagement Variables

The mean number of provider visits in the intent-to-treat depressive and anxiety symptom cohorts was 11.4 (SD 16.0) and 11.3 (SD 15.7), respectively. In the depressive symptom cohort, 69.4% had at least 3 provider visits, and 28.7% had at least 12 provider visits. In the anxiety symptom cohort, 69.3% had at least 3 provider visits, and 28.6% had at least 12 provider visits. As expected, the complete case cohorts had higher levels of engagement metrics than the intent-to-treat cohorts (Table 2).

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Table 2. Engagement and clinical outcomes among Grow Therapy adult patients entering in January 2022 to April 2024 with at least 2 clinical outcome assessments (complete case cohorts).

Variable	Complete case clinically elevated depressive symptom cohort[a] (n=72,008)	Complete case clinically elevated anxiety symptom cohort[b] (n=74,176)
Engagement, n (%)		
At least 3 provider visits	68,520 (95.2)	70,771 (95.4)
At least 12 provider visits	37,173 (51.6)	38,325 (51.7)
Clinical outcome: depression symptoms, mean (SD)		
Last depression symptom score (PHQ-9[c])	9.1 (6.1)	8.3 (6.1)
Last depression (PHQ-9) severity category, n (%)		
Minimal (0-4)	19,511 (27.1)	23,731 (32.8)
Mild (5-9)	20,875 (29)	21,192 (29.3)
Moderate (10-14)	17,519 (24.3)	15,133 (20.9)
Moderately severe (15-19)	9427 (13.1)	8153 (11.3)
Severe (20-27)	4676 (6.5)	4170 (5.8)
Unknown	N/A[d]	1797
Depression symptom improvement (PHQ-9), mean (SD)	6.1 (6.1)	5.2 (6.2)
Depression symptom MCID[e,f], n (%)	42,392 (58.9)	32,714 (60.5)
Clinical outcome: anxiety symptoms		
Last anxiety symptom score (GAD-7[g]), mean (SD)	8.8 (5.8)[b]	9.1 (5.7)
Last anxiety (GAD-7) severity category, n (%)		
Minimal (0-4)	19,087 (27.4)	18,496 (24.9)
Mild (5-9)	21,379 (30.7)	22,552 (30.4)
Moderate (10-14)	16,034 (23)	18,074 (24.4)
Severe (15-21)	13,117 (18.8)	15,054 (20.3)
Unknown	2391	N/A
Anxiety symptom improvement (GAD-7), mean (SD)	4.7 (5.9)[b]	5.8 (5.7)
Anxiety symptom MCID[f], n (%)	33,705 (55.2)[b]	46,715 (63)

[a]In the depression cohort, 71,602 had a valid GAD-7 assessment at the first (ie, baseline) visit and 69,618 had a valid GAD-7 assessment at the last (ie, second or later) visit. A total of 54,046 had a GAD-7 at baseline of 10 or greater and a valid last GAD-7 assessment to enable calculation of minimal clinically important difference.

[b]In the anxiety cohort, 73,684 had a valid PHQ-9 assessment at the first (ie, baseline) visit, and 72,379 had a valid PHQ-9 assessment at the last (ie, second or later) visit. A total of 54,040 had a PHQ-9 at baseline of 10 or greater and a valid last PHQ-9 assessment to enable calculation of the minimal clinically important difference.

[c]PHQ-9: Patient Health Questionnaire-9 item scale.

[d]N/A: not applicable.

[e]MCID: minimal clinically important difference.

[f]Minimal clinically important difference is defined as a reduction of at least 5 points on the PHQ-9 or at least 4 points on the GAD-7 between first and last Grow Therapy visit, and calculated only among those with a baseline score of 10 or greater in each cohort.

[g]GAD-7: Generalized Anxiety Disorder-7 item scale.

The intent-to-treat samples included all adult Grow Therapy patients aged 18 years or older with a first provider visit in January 2022 through April 2024 who had clinically elevated depressive symptoms at baseline (PHQ-9 of 10-27; baseline depressive symptom cohort) or who had clinically elevated anxiety symptoms at baseline (GAD-7 of 10-21; baseline anxiety symptom cohort) as indicated.

A total of 123,284/159,448 (77.3%) of the clinically elevated depressive symptom intent-to-treat cohort also had clinically

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elevated anxiety symptoms and are included in both intent-to-treat cohorts.

A total of 123,284/167,356 (73.7%) of the clinically elevated anxiety symptom intent-to-treat cohort also had clinically elevated depressive symptoms at baseline and are included in both intent-to-treat cohorts.

The complete case samples included patients in each intent-to-treat sample who also had at least 2 completed PHQ-9 (baseline depressive symptom cohort) or GAD-7 assessments (baseline anxiety symptom cohort).

A total of 54,039/72,008 (75%) of the clinically elevated depressive symptom complete case cohort also had clinically elevated anxiety symptoms and are included in both complete case cohorts.

A total of 54,039/74,176 (72.9%) of the clinically elevated anxiety symptom complete case cohort also had clinically elevated depressive symptoms at baseline and are included in both complete case cohorts.

Clinical Outcomes in the Complete Case Cohorts

In the complete case depressive symptom cohort, mean PHQ-9 declined from 15.2 (SD 4.1) to 9.1 (SD 6.1) from baseline to last assessment (average change of 6.1, SD 6.1, points; Table 2). In this cohort, 58.9% (95% CI 58.5%-59.2%) of patients had a PHQ-9 depressive symptom MCID. In the complete case anxiety symptom cohort, mean GAD-7 declined from 14.9 (SD 3.4) to 9.1 (SD 5.7) from baseline to last assessment (average change of 5.8, SD 5.7, points). In this cohort, 63% (95% CI 62.6%-63.3%) of patients had a GAD-7 anxiety symptom MCID. We did not use multiple imputation (MI) because greater than 50% of eligible adults had missing outcomes data, which also was not missing at random. Prior research indicates MI is unreliable when missingness exceeds 30% and the missing-at-random assumption is violated [32,33].

Relationship of Patient Self-Selection of a Provider Specialty to Engagement (in the Intent-to-Treat Cohorts) and Clinical Outcomes (in the Complete Case Cohorts)

Unadjusted chi-square and adjusted logistic regression models indicated no significant associations between provider specialty selection and having at least 3 provider visits in both the depressive and anxiety symptom cohorts (Table 3). Patients in the depressive symptom cohort who did select a provider specialty, however, were about 8% more likely to have a depressive symptom MCID than those who did not (59.9% vs 58.3%, OR 1.08, 95% CI 1.04-1.11). Similarly, patients in the anxiety symptom cohort who selected a provider specialty were about 4% more likely to have an anxiety symptom MCID than those who did not (63.4% vs 62.7%, OR 1.04, 95% CI 1.01-1.07), although this association was only significant at $P<.05$ in the adjusted regression analysis ($P<.001$) and not the chi-square unadjusted analysis ($P=.07$).

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Table 3. Unadjusted and adjusted analyses predicting having at least 3 provider visits, MCID[a] change in depressive symptoms, and MCID change in anxiety symptoms from the type of provider selection among Grow Therapy adult patients entering in January 2022 to April 2024.

	Value, n (%)	*P* value	Adjusted logistic regression β (95% CI)
Model 1: at least 3 provider visits among patients with elevated baseline depressive symptom intent-to-treat cohort (n=159,448)			
Selected provider specialty		.67	0.99 (0.97-1.01)
Yes	38,992/56,094 (69.5)		
No	71,736/103,354 (69.4)		
Selected provider identity		<.001	1.14 (1.08-1.20)
Yes	5966/8279 (72.1)		
No	104,762/151,169 (69.3)		
Model 2: depressive symptom MCID among the elevated baseline depressive symptom complete case cohort (n=72,008)			
Selected provider specialty		<.001	1.08 (1.04-1.11)
Yes	15,553/25,982 (59.9)		
No	26,839/46,026 (58.3)		
Selected provider identity		.57	0.98 (0.92-1.05)
Yes	2340/4005 (58.4)		
No	40,052/68,003 (58.9)		
Model 3: at least 3 provider visits among Grow Therapy patients with elevated baseline anxiety symptom cohort (n=167,356)			
Selected provider specialty		.63	1.00 (0.97-1.02)
Yes	41,334/59,573 (69.4)		
No	74,659/107,783 (69.3)		
Selected provider identity		.001	1.11 (1.06-1.17)
Yes	6196/8652 (71.6)		
No	109,797/158,704 (69.2)		
Model 4: anxiety symptom MCID among elevated baseline anxiety symptom complete case cohort (n=74,176)			
Selected provider specialty		.07	1.04 (1.01-1.07)
Yes	17,197/27,121 (63.4)		
No	29,518/47,055 (62.7)		
Selected provider identity		.07	0.95 (0.89-1.01)
Yes	2508/4069 (61.6)		
No	44,207/70,107 (63.1)		

[a]MCID: minimal clinically important difference.

The intent-to-treat samples used for the engagement models (models 1 and 3) included all adult Grow Therapy patients aged 18 years or older with a first provider visit in January 2022 through April 2024 who had clinically elevated depressive symptoms at baseline (PHQ-9 of 10-27; baseline depressive symptom cohort) or who had clinically elevated anxiety symptoms at baseline (GAD-7 of 10-21; baseline anxiety symptom cohort) as indicated.

A total of 123,284/159,448 (77.3%) of the clinically elevated depressive symptom intent-to-treat cohort also had clinically elevated anxiety symptoms and are included in both intent-to-treat cohorts.

A total of 123,284/167,356 (73.7%) of the clinically elevated anxiety symptom intent-to-treat cohort also had clinically elevated depressive symptoms at baseline and are included in both intent-to-treat cohorts.

The complete case samples used for the clinical symptom models (models 2, 3, 5, and 6) included patients in each intent-to-treat sample who also had at least 2 completed PHQ-9 (baseline depressive symptom cohort) or GAD-7 assessments (baseline anxiety symptom cohort).

A total of 54,039/72,008 (75%) of the clinically elevated depressive symptom complete case cohort also had clinically elevated anxiety symptoms and are included in both complete case cohorts.

A total of 54,039/74,176 (72.9%) of the clinically elevated anxiety symptom complete case cohort also had clinically

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elevated depressive symptoms at baseline and are included in both complete case cohorts.

Models adjusted for patient age (all models), gender (all models), baseline depression symptoms (all models), baseline anxiety symptoms (all models), and number of visits (models 2 and 4).

Unadjusted comparisons were done via chi-square tests.

Relationship of Patient Self-Selection of a Provider Identity to Engagement (in the Intent-to-Treat cohorts) and Clinical Outcomes (in the Complete Case Cohorts)

Unadjusted chi-square and adjusted logistic regression models indicated that patients in both the depressive and anxiety symptom cohorts who selected a provider identity characteristic before the first visit were 14% and 11% more likely, respectively, to have at least 3 provider visits (72.1% vs 69.3%, OR 1.14, 95% CI 1.08-1.20, in the depressive symptom cohort and 71.6% vs 69.2%, OR 1.11, 95% CI 1.06-1.17) as compared to patients who did not select a provider identity characteristics. There were no significant unadjusted or adjusted associations, however, between the selection of a provider identity characteristic and having a depressive or anxiety symptom MCID in either cohort (Table 3).

Sensitivity Analyses

Sensitivity analyses using the last observation carried forward for clinical outcomes in the intent-to-treat cohorts confirmed our main findings with a few exceptions. In unadjusted analyses, patients who selected both specialty and identity provider characteristics before enrollment were more likely to have a depressive symptom MCID in the depressive symptom cohort and an anxiety symptom MCID in the anxiety symptom cohort (P<.01 in each instance). These findings differed from the unadjusted main analyses which just found significant unadjusted associations between choosing the specialty of the provider and depressive symptom MCID in the depressive symptom cohort. The significance of the adjusted analyses, however, remained the same, with only those who selected a provider specialty, but not a provider identity, characteristic having a significantly greater likelihood of having a depressive symptom and an anxiety symptom MCID in the depressive symptom and anxiety symptom cohorts, respectively.

Discussion

Principal Results

In this study, a little over a third of adult patients in each cohort selected a provider specialty, and about 5% of each cohort selected a provider identity characteristic. Secondary, exploratory analyses, however, indicated that a patient's self-selection of each provider characteristic option was associated with engagement or clinical outcomes (see Table 4 for a summary of significant findings). These findings suggest the potential value of a patient self-selecting their desired provider characteristics in order to improve their therapeutic experience and subsequent outcomes. In this study, patients who selected a provider specialty were more likely to have a change in symptoms meeting the MCID criteria in both the depressive and anxiety symptom cohorts. These findings, while preliminary and exploratory, suggest that patients who knew their presenting issues and requested targeted help from providers might have been able to experience significantly better clinical outcomes by selecting providers based on self-awareness of their treatment needs. Furthermore, patients who selected a provider identity characteristic were more likely to have at least 3 provider visits than those who did not. Selecting a provider identity characteristic was not, however, associated with clinical outcomes in either the depressive or anxiety symptom cohort. Future studies with more rigorous designs that include an appropriate control group should seek to understand the impact of extended treatment beyond PHQ-9 and GAD-7 measures, including quantifying improvements in quality of life and the role of therapeutic alliance in the observed associations.

Table 4. Summary of significant associations between type of provider selection and outcomes of interest (engagement and changes in clinical outcomes) in adjusted analyses confirmed by sensitivity analyses.

	Cohort and outcome			
	Elevated depressive symptom cohort		Elevated anxiety symptom cohort	
Type of provider selection	Elevated depressive symptom cohort, engagement outcomes	Elevated depressive symptom cohort, depressive symptom changes	Elevated anxiety symptom cohort, engagement outcomes	Elevated anxiety symptom cohort, anxiety symptom changes
Provider specialty	—	✓	—	✓
Provider identity	✓	—	✓	—

Comparison With Prior Work

This is the first study of its kind to report engagement and clinical outcomes of a technology-enabled platform where patients have the choice and autonomy to select characteristics of the mental health provider treating them. Likewise, it is the first study to begin to explore the ability of patients to select provider characteristics as related to the levels of engagement and clinical outcomes found. Despite prior literature that has suggested the importance of patient choice in facilitating beneficial outcomes [18], little is known about this topic specifically related to technology-enabled platforms that provide this option.

Nonetheless, prior work examining digital mental health interventions has consistently noted low engagement rates and only modest levels of efficacy [6,7,10]. Levels of patient engagement in mental health care found in the current study, however, were quite high in comparison to even the prior recommendations from systematic reviews reported in the

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literature; for example, despite lower levels of actual engagement, 1 meta-analysis found that a typical internet-based CBT program recommends 5-9 visits per patient [34]. The present study's findings are notable in this context as the proportion of patients engaging in Grow Therapy care with at least 3 provider visits (≈69%) and meeting depressive and anxiety symptom MCID criteria (≈59%-63%) is similar or higher than those reported in typical structured digital CBT programs that often have high rates of drop-out. In general, these proportions of those meeting criteria for an MCID of each outcome appeared to be similar or slightly higher than interventions previously described in the literature, especially supported digital mental health interventions delivered over the internet or via an app [23,35]. It is important to note, however, that the present analyses were conducted on a real-world sample with at least enough provider visits to capture at least 2 relevant outcome assessments, and no control group was included to enable group-level comparisons. Additional studies using more rigorous designs, such as a pragmatic RCT or using a real-world synthetic control group, that also adjust for other potential confounders of the explored associations (eg, personality characteristics, education, or other factors related to both the exposure and outcome of interest), are needed to confirm these preliminary findings.

Most previously published work has focused on naturally occurring concordance rather than patient selections of provider attributes, so our findings might not generalize to these instances. The current study examines behaviors somewhat unique to digital settings where patients can intentionally select provider characteristics unconstrained by in-person geographic location or appointment availability. This type of investigation is novel as compared to earlier concordance studies that often relied on clinic assignment, administrative matching, or geographic convenience instead of the ability to freely choose provider characteristics [11,12]. A growing body of research, however, has examined hybrid or digital care systems that have used performance-based or algorithmic matching; for example, Constantino et al [13] conducted an RCT and determined that matching patients to providers based on therapist strengths improved outcomes. The present study differs because patients could choose preferred provider characteristics, some of which they might have thought were beneficial to their care, rather than an algorithmic assignment. This distinction is important, as choice-based matching may promote early therapeutic alliance, autonomy, and expectancy effects, each of which has been linked to improved engagement and treatment success [26,36,37].

Our findings also extend recent work on digital personalization frameworks that have suggested that the inclusion of tailored content, therapist profiles, and culturally responsive design may bolster outcomes when integrated into digital mental health services [38]. While personalization in previous studies has typically involved system-driven tailoring, provider selection in this study reflects a patient-driven personalization strategy, representing an underexamined but potentially scalable approach.

Finally, few large-scale naturalistic studies have examined associations between provider-selection behaviors and clinical outcomes in digital care settings at a real-world scale. This study's sample size exceeds most published digital mental health cohorts' sizes and provides one of the strongest empirical demonstrations to date of how patient choice operates within commercially deployed teletherapy platforms. These findings thus contribute new evidence that scalable matching systems, when embedded within a flexible platform, may relate meaningfully to both engagement and symptom change.

Clinical Implications

Although this study's design limits definitive conclusions, the exploratory findings provide preliminary evidence that a web-based platform that promotes patient selection of their provider could contribute to patient engagement and favorable clinical outcomes. Specifically, selecting a provider specialty was associated with significantly achieving MCID-level improvements in depressive and anxiety symptoms. Thus, the findings suggest that encouraging patients to select a provider specialty may positively impact clinical outcomes by ensuring a more targeted fit to the expertise of the provider. In addition, selecting a provider identity characteristic was associated with having 3 or more provider visits. This pattern aligns with theoretical models proposing that autonomy, personal relevance, and therapeutic fit enhance treatment continuation [26,36,38]. The significant association between selecting a provider identity and increased patient engagement may have resulted from patients feeling more comfortable from the onset of the patient-provider relationship due to the therapeutic alliance formed between the patient and provider, promoting cultural safety and trust [11,39]. It is somewhat surprising, however, that we did not find a significant association between the selection of provider identity and changes in clinical outcomes, potentially because of the small sample size of those selecting a provider identity or perhaps due to the current study's design itself.

Additional studies that include control groups of patients who do not select provider characteristics and that adjust for more potential confounders would lead to a greater understanding of the preliminary signals found by these exploratory analyses. These findings suggest that scalable, technology-enabled patient-provider matching systems, particularly those that allow patients to filter by provider specialty or identity, may offer a feasible way to improve engagement and outcomes at scale. As platforms such as Grow Therapy expand, this approach could be further developed to support systems–level innovation in care delivery, particularly by personalizing access in ways that are difficult to replicate in traditional models of mental health referral and triage.

Although causality cannot be inferred, these findings underscore opportunities for designing more effective digital matching interfaces. For instance, platforms may consider highlighting evidence-based specialty tags, guiding patients toward providers with relevant expertise, or using A/B testing to evaluate which provider profiles maximize engagement. Similar approaches are increasingly used in digital triage and hybrid care systems [14,40].

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Future Research Needs

In addition to the aforementioned need for more rigorous study designs to confirm these initial findings, future studies, such as pragmatic randomized or quasi-experimental studies, could also explore other potential reasons for the levels of engagement and clinical outcome success experienced by patients included in this study. For example, additional work is needed to explore potential reasons for the levels of engagement and clinical outcomes other than the selection of provider characteristics of specialty and identity. Further research is also needed to ensure that levels of outcomes are similar across different patient subgroups other than those defined by age, gender, and baseline symptomatology. These groups could be created based on social determinants of health or other vulnerable populations to ensure the equitable delivery, receipt, and experience of mental health care.

Additional work should also examine the mechanisms by which provider-selection behaviors and symptom changes are associated, perhaps via improved engagement or therapeutic alliance. Prior studies suggest that early engagement and therapeutic alliance can shape downstream clinical trajectories [28]. Research should also explore more granular subtypes of specialty and identity selection, such as having a culturally aligned provider, and whether this impacts findings. Greater attention to equity-centered matching is critical, especially as digital platforms expand access to diverse populations [23]. The current findings suggest the potential benefit of such alignment, but small sample sizes limited its evaluation. More robust investigations with larger sample sizes are needed to confirm these initial findings and to further explore more nuanced specialty and identity selections (eg, specific specialties or identity characteristics) in relation to longer-term engagement and outcomes.

Limitations

This study has several limitations. First, our clinical outcome analyses relied on complete case data rather than using MI, which introduces potential selection bias. We deemed MI inappropriate because of substantial missing data (>50%) and nonrandom missingness after considering the evidence that MI can be invalid under these conditions [32,33]. Thus, clinical outcome findings may be generalizable only to patients who completed at least 2 PHQ-9 or GAD-7 assessments. Sensitivity analyses using last observation carried forward, however, yielded similar adjusted findings, increasing confidence in the robustness of observed associations. As reasons for missingness were not captured, we could not determine whether those lost to follow-up were dissatisfied with their treatment, realized early symptom improvement so did not “need” treatment anymore (“happy abandonment” [41]), or if some other, unobserved factors were in play.

Second, due to limited sample sizes for hundreds of possible provider specialty and identity combinations, this study examined only binary selections rather than specific match types (eg, trauma specialty; Black/African American identity). Future research with larger subgroup samples may explore more granular associations. Additional limitations include reliance on observational data without a control group, lack of adjustment for unmeasured confounders such as socioeconomic status or provider experience, and potential overlap between depressive and anxiety symptom cohorts. We also did not examine how engagement and outcomes relate to each other mechanistically; future studies should test whether engagement mediates clinical change. Additional studies to determine the amount and types of engagement needed to achieve beneficial outcomes, including whether engagement mediates the associations with clinical outcomes, will provide a better understanding of the findings of this study. Finally, because analyses did not adjust for multiple comparisons, findings should be interpreted as exploratory.

Third, a majority of the sample was in both elevated baseline symptoms of depression and anxiety cohorts, given the high prevalence of comorbid baseline symptoms, rendering the engagement analyses somewhat duplicative. The reported regression analyses, however, did report associations adjusted for both baseline depressive and anxiety symptoms. We did not, however, have access to other potentially confounding variables such as socioeconomic status, education, or provider experience to further adjust the models. These factors should be included in future research. Additionally, we did not adjust the analyses for multiple comparisons, given the exploratory nature of this study. Most reported significant associations, however, were at the $P<.001$ level of significance that would have remained significant even after adjustment.

Fourth, although this study examined the patient-driven selection of providers, the Grow Therapy platform’s interface, available provider pool, and algorithmic ordering of provider profiles may influence what options users see and select. These platform-level design factors were not examined but may partially explain patterns of selection and should be considered in future research [42].

Fifth, this study did not evaluate therapist characteristics beyond those made available to patients for selection (eg, provider experience, caseload, and therapeutic fidelity). Prior work suggests that therapist effects can meaningfully influence outcomes and unmeasured provider-level variability may confound associations [43].

Finally, measures of patient preference strength (eg, how strongly a patient valued a specific attribute) were not collected. Prior meta-analytic work suggests that preference strength, rather than preference presence alone, may predict outcomes [17].

More recent quality improvement initiatives targeting measurement-informed care, which promotes the completion and use of routine outcome monitoring as part of the treatment relationship between a provider and a patient [44], have improved clinical symptom measure completion rates at Grow Therapy since the sample’s inclusion of earlier data periods (2022-2024). Future outcome analyses that include these more robust samples will thus serve to enhance the generalizability of findings, as would the use of a study design that includes an appropriate control group.

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Conclusions

In this large-scale real-world analysis, patients who selected provider characteristics before initiating care demonstrated meaningful differences in both engagement and clinical outcomes. While exploratory, these findings contribute new evidence that patient autonomy in selecting provider attributes, a feature uniquely enabled by digital mental health platforms, may play an important role in shaping therapeutic trajectories. This is likely the first real-world study of the associations between different types of provider selections and engagement and clinical symptom changes in a digital mental health platform for patients with elevated symptoms of depression or anxiety. Further research using more rigorous controlled designs is needed to confirm these preliminary findings and better understand how types of and more nuanced provider selection variables, such as specialty (eg, depression, anxiety, trauma, etc) and identity (Black/African American, Muslim, etc), are associated with engagement or clinical symptom outcomes. As the field continues to evolve toward more personalized models of digital care [19], understanding how patients navigate matching tools and how these behaviors relate to outcomes will be critical for developing scalable, equitable, and effective mental health services.

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Data Availability

The datasets generated or analyzed during this study are available from the corresponding author on reasonable request.

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Authors' Contributions

VLF-H and MK conceptualized this study; EH, AG, and MC provided the data; VLF-H performed the data analyses and wrote the draft paper and revisions; all authors reviewed this paper and approved the submission.

Conflicts of Interest

Authors EH, MK, AG, MC, and CG are all employees of Grow Therapy and receive salary and equity from the company. Author VLF-H is a consultant to Grow Therapy and receives compensation for her services.

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Abbreviations

CBT: cognitive behavioral therapy
GAD-7: Generalized Anxiety Disorder-7 item
HIPAA: Health Insurance Portability and Accountability Act
MCID: minimal clinically important difference
MI: multiple imputation
OR: odds ratio
PHQ-9: Patient Health Questionnaire-9 item
RCT: randomized controlled trial
STROBE: Strengthening the Reporting of Observational Studies in Epidemiology

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Original Paper

Creative Arts to Enhance Cervical Cancer Awareness Using Art-Based Messages From a Nigerian Crowdsourcing Open Call: Qualitative Thematic Analysis

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Abstract

Background: Cervical cancer is a leading cause of cancer deaths among women in Nigeria, yet awareness is low. Historically, art has served as a medium for processing emotions and sharing experiences, which can be effective in promoting health and behavior change.

Objective: This study aimed to examine art submissions and social media engagement from a Nigerian crowdsourcing open call to inform co-designed strategies for cervical cancer prevention among women.

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Methods: This study reported following the SRQR (Standard Reporting for Qualitative Research) guideline. From October to November 2023, we launched an open call for art on social media, inviting adult women to submit artwork that raises awareness about cervical cancer prevention. Participants' submissions were anonymized and reviewed by an independent panel of judges. A total of 6 finalists were selected to participate in a social media contest during Cervical Cancer Elimination Week, and 3 winners were identified based on total social media likes and comments, as well as grading rubric scores. We analyzed participants' art entries through thematic analysis in six steps: (1) familiarization, (2) creating categories, (3) identifying themes, (4) reviewing themes, (5) defining themes, and (6) discussing findings. The emerging themes included using art to express emotions, to convey health-related content, and to use art as a form of self-regulation, which were further analyzed using the Relationships and Expectations domain of the PEN-3 (perceptions, enablers, and nurturers) cultural model.

Results: A total of 43 entries from participants aged 18-27 (mean 22.2, SD 2.6) years were analyzed. The entries included visuals (n=14), audiovisual (n=14), text (n=14), and audio (n=1). Most entries (42/43, 97.6%) focused on cervical cancer and human papillomavirus, covering definitions, risk factors, treatment, and prevention. Using the PEN-3 cultural model's Relationships and Expectations domain for analysis, 62.8% (27/43) addressed "perceptions" of art as a means of mental and emotional expression, reflecting feelings such as humor, sadness, hope, faith, unity, and fear related to cervical cancer prevention. A majority (34/43, 79.1%) aimed to promote human papillomavirus screening and vaccination and were categorized as "enablers," viewing art as a tool for health awareness, including educational resources. Additionally, 7% (3/43) included "nurturers," representing self-regulation addressing stresses linked to having relatives with cervical cancer. Six finalist entries were shared on social media to promote cervical cancer awareness, reaching 8685 individual Instagram accounts and generating 2727 likes and 782 comments.

Conclusions: This study used art to increase awareness about cervical cancer on social media. Art can serve as a tool for promoting health by incorporating visual, emotional, and contextual messages to influence the target audience's behavior.

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KEYWORDS

art; cancer prevention; cervical cancer; education; HPV vaccines; social media

Introduction

Invasive cervical cancer is a leading cause of death among women, resulting in about 350,000 deaths yearly [1]. The burden of cervical cancer is highest in low- and middle-income countries [2], with the majority of the cases and deaths occurring in sub-Saharan Africa, Central America, and Southeast Asia [1]. Regional disparities in cervical cancer incidence are linked to unequal access to vaccination, screening, and treatment services, as well as risk factors that include HIV prevalence, social barriers, gender biases, and poverty [2]. In Nigeria, cervical cancer is the second leading cause of female cancer mortality in women aged 15-44 years [3]. About 12,000 cases and 8000 deaths are reported annually, with an incidence rate of 18.4 per 100,000 women [4]. Sociodemographic characteristics, including low levels of education, limited knowledge, and low levels of health-seeking behavior, are linked with a higher incidence and mortality rate of cervical cancer in Nigeria [5]. These issues arise from misconceptions, stigma, and fear, resulting in delays in seeking screening and care that lead to late presentation and worsened outcomes [5].

Cervical cancer is largely attributed to persistent high-risk human papillomavirus (HPV) infection, which is linked to about 99% of cervical cancer cases in women [6]. Thirteen types of high-risk HPV cause cervical cancer, with types 16 and 18 being the most common and responsible for approximately 70% of cervical cancer cases. HPV infection is the most common sexually transmitted infection, with the peak age of infection being 25 years [7]. The average age for global cervical cancer diagnosis is 59 years [8]. Studies have demonstrated that HPV vaccination is highly effective in preventing cervical cancer, particularly cancers caused by vaccine-associated HPV types 16, 18, 31, 33, 52, 58, 72, and 78 [6,9].

In 2020, the World Health Assembly launched a global initiative aimed at eliminating cervical cancer by 2030. The goal is to achieve an incidence rate of fewer than 4 cases per 100,000 people globally, alongside the 90-70-90 targets: vaccinating 90% of girls by age 15, screening 70% of women at least twice by 35 and 45 years, and treating 90% of women diagnosed with cervical cancer premalignant lesions [10]. This approach emphasizes the importance of HPV vaccination and screening in the fight against cervical cancer [11]. However, in some parts of Nigeria, there is a lack of awareness and knowledge about HPV vaccination and cervical cancer. A study in Lagos found that just about 12% of female participants aged 15-49 years were aware of cervical cancer, its risk factors, and modalities of prevention [12].

Additionally, research among women of reproductive age in Kwara State, Nigeria, found that only 39% were well-informed, and just 6.9% had undergone screening [13]. Similarly, in a study conducted in Taraba, Nigeria, among 978 women of reproductive age, religion, especially those who identified as Muslims, were less likely to know about cervical cancer and the practices of cervical cancer screening [14]. Adequate knowledge and awareness of HPV vaccination and cervical cancer screening have been shown to result in a higher uptake of these preventive services [15]. Furthermore, cultural values and beliefs have been shown to influence the use of health services among women in Nigeria [16]. Culture shapes beliefs, values, norms, and behaviors, influencing the type of health information an individual encounters while seeking health services.

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Historically, art has been used to process emotions and convey experiences that can promote health, increase health awareness and advocacy, and potentially change behavior [17]. Bunn et al [18] reported that art-based approaches have been used in sub-Saharan African countries to raise awareness of infectious diseases such as HIV/AIDS, malaria, and Ebola. However, the potential of using art as a method to address cervical cancer morbidities and mortalities has not been fully explored. In response, we organized an art contest to increase awareness of cervical cancer in Nigeria, using a participatory action research framework, especially a crowdsourcing open call aimed at soliciting artwork among adult women to raise awareness and knowledge and ultimately reduce cervical cancer mortalities and morbidities. A crowdsourcing open call involves inviting a group of people, such as adult women impacted by cervical cancer, to solve a problem and share selected solutions with the public [19]. This research examines how art uses cultural contexts to enhance health education and promotion, specifically regarding perceptions of HPV vaccination and screening in Nigeria. We analyzed textual data from participants' art submissions and social media interactions collected during an open art contest aimed at raising cervical cancer awareness among Nigerian women.

Methods

Study Design and Recruitment

Our approach is guided by a participatory action research framework that prioritizes integrating participation and action to understand and address societal issues, such as cervical cancer incidence and mortality [20,21]. We adhered to the SRQR (Standard Reporting for Qualitative Research) guideline [22].

Crowdsourcing Open Call

An open call for artwork to promote cervical cancer awareness was launched on social media between October 3, 2023, and November 5, 2023. The artwork submitted included drawings, video art, animation, illustrations, poetry, drama, and more. We developed a range of promotional materials to provide information about the art contest, its benefits, and application links. These materials were shared on the 4 Girls and Women social media platforms (Instagram, X, LinkedIn, and WhatsApp) and distributed through health influencers. We also disseminated the open call through networks of girls and women who participated in the HPV Designathon in Nigeria. An informational webinar was hosted to guide interested applicants.

Study Setting and Participants

This study includes women aged 18-65 years residing in Nigeria who submitted artwork in response to the open call. This was a purposive sampling approach targeting artists and creatives in Nigeria.

Crowdsourcing Open Call Submissions

Submissions were made through Google Forms, email, or WhatsApp. We collected a range of sociodemographic data points, such as name, age, and sex, and submission-specific information, including the submission title and a brief synopsis. At the end of the open call, the entries received were anonymized and screened for eligibility by an independent panel of judges. These data elements helped to categorize participants' submissions based on both content and demographic details.

Entry Selections

Judges reviewed and evaluated 43 eligible entries using a grading rubric that included the level of innovation demonstrated in the submission, the clarity and effectiveness of expression, the originality and creativity of the content, the overall appeal and engagement factor of the submission, and its relevance and significance to public health. Each criterion was graded on a point scale from 0 to 5. Five judges evaluated each submission, and an overall score was recorded. Following this evaluation process, we shortlisted the entries that ranked in the top 10. To ensure the accuracy and reliability of the health-related information presented in these submissions, we then shared them with a panel of public health experts for further review [23]. Following this review of the top 10 entries, 6 finalists were shortlisted.

Social Media Contest

From December 15 to 17, 2023, six finalists were shortlisted for the second phase of the social media contest. The contest was conducted on Instagram, Nigeria's third most-used social media platform, following WhatsApp and Facebook [24]. Instagram is also the preferred social media platform for sharing images and videos. Its robust algorithms effectively promote content to target audiences through features such as hashtags [25]. The artwork from each of the 6 finalists was posted on the 4 Girls and Women account, in collaboration with the participants' accounts, with a synopsis as the caption. The network among participants promoted the posts to drive engagement (views, likes, and comments) while educating users about cervical cancer. Three winners were determined based on their level of engagement on social media and the judge's overall score, using the same judging rubric as in the first round. The winners were announced during an Instagram Live session on December 17, 2023, and were awarded cash prizes of NGN 200,000 (US $200), NGN 150,000 (US $150), and NGN 100,000 (US $100) for first, second, and third place, respectively. The 3 winning artworks are provided in references [26-28] and will also be featured in an international art magazine on health promotion.

Data Analysis

A descriptive analysis examined the participants' characteristics, including age, gender, ethnicity, and educational level. Additionally, the level of engagement with participants' social media posts (eg, likes, shares, and comments) was analyzed, yielding valuable insights into digital reach and interactions.

For qualitative analysis, we adopted an inductive-deductive approach, categorizing submitted artwork into text-based, visual, audiovisual, and audio types. Following Lakh et al [29], our study used thematic analysis to identify emerging themes in the art submissions and to explore the underlying experiences and perspectives. Direct observation and interpretation of the submissions were also used to draw conclusions. Two researchers independently reviewed the submissions and resolved discrepancies; a third researcher was involved when

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discrepancies persisted, including an assessment of the credibility and accuracy of the two researchers' reviews. For the thematic analysis, we used the 6-step process [30], which included (1) researchers' familiarization with the submitted arts and accompanying texts, audios, or visuals, including identification of relevant items to the research question; (2) creation of categories based on the identified relevant items and comparing them back to the art entries; (3) identification of emerging themes, while comparing the art entries and the categories; (4) review of emerged themes while comparing the themes with the art entries, and the texts, audios, or visuals to ensure they were relevant to the research question, including refining, splitting, combining, and discarding some themes during this step; (5) naming and giving definition to the emerged themes, including organizing the themes; and (6) writing the findings, and discussion, while referring to the literature. The entire process involved referring to the initial art entries [29]. By following the 6 steps, themes emerged that outlined the key areas where art intersects with medicine and classified participants' responses into the following three emerging themes: (1) art as an avenue for mental and emotional expression, (2) art as a vehicle for raising awareness of health-related content, and (3) art as a means of self-regulation. These themes were further analyzed using the Relationships and Expectations domain of the PEN-3 (perceptions, enablers, and nurturers) cultural model [31], which includes 3 essential domains: Cultural Identity, Relationships and Expectations, and Cultural Empowerment. Our research explicitly focused on the Relationships and Expectations domain of the PEN-3 model. This involved the following three themes: (1) how the artwork depicts or perceives cervical cancer (perceptions), (2) societal or health system resources that promote cervical cancer prevention (enablers), and (3) the influence of family or relations in decision making in accessing cervical cancer prevention or management (nurturers) [32]. This model has previously been used to deepen understanding of how culture and environment influence health behavior interventions [32].

Ethical Consideration

This contest was organized as part of the Actions for Collaborative Community Engaged Strategies for HPV (ACCESS-HPV; R01CA271033). Ethical approval was obtained from the Institutional Review Board of the Nigerian Institute of Medical Research (ethics approval number IRB/23/108). Participants were informed about the possibility of using data collected for research purposes. Only participants who consented by selecting "Yes" were included in the study. The collected data were anonymized by removing identifiers such as name and email address and replacing them with a unique ID. Only participants who emerged as winners were compensated.

Results

Overview

We received a total of 43 entries (Multimedia Appendix 1). Participants were aged 18-27 (mean 22.2, SD 2.6) years, and all identified as women. The art entries included visual (n=14), audiovisual (n=14), text-based (n=14), and audio (n=1) pieces (Multimedia Appendix 1). Most participants' entries (42/43, 97.6%) focused on cervical cancer and HPV, including definitions, risk factors, treatment, and prevention. Using the framework from Lakh et al [29] and the Relationships and Expectations domain of the PEN-3 cultural model for thematic analysis, we categorized participants' entries into 3 emerged themes: perceptions, enablers, and nurturers.

Art as an Avenue for Mental and Emotional Expression (Perception)

Over two-thirds (27/43, 62.8%) of participants' entries focused on "perceptions" related to art as a means of emotional expression, encompassing feelings such as humor, sadness, hope, faith, unity, and fear in the context of cervical cancer and its prevention (Table 1). Hope was the most recurring emotion (n=10), as described by one of the participants (entry #01): "Making a difference is not a superpower, and it is not a privilege only to the people who we think can. Sometimes, if we can feel a little bit more and allow our hearts to get stirred, it can lead our feet to where change resides." The green color was also used to symbolize hope, as explained in the synopsis of entry #08: "I also used the green color to write HOPE because green depicts growth and hope itself, and it is part of our Nigerian color." Entries also depicted the "fear of death" and "pain" of loss attributed to cervical cancer (entry #04) as a means of emphasizing the need for cervical cancer prevention, "She reminisces about her life before cervical cancer. Then she tells us about the struggles of being a person with cervical cancer patient ..." Other emotions expressed include faith (entry #02), where "women who are metaphorized as "lilies," "roses," more than rubies that should take proper care." Other perceptions reported are those of susceptibility and awareness regarding cervical cancer and its prevention (entry #09), highlighting the crucial role of awareness and early detection and promoting regular screenings and HPV vaccination. One of our entries (#40) also depicted perceptions of unity in the face of diversity to prevent cervical cancer by demonstrating "Nigerian women, who, regardless of age, status, tribe or religion, are susceptible to and share the bane that is cervical cancer."

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Table 1. Thematic analysis of the art contest submissions using the Relationships and Expectations domain of the PEN-3 (perceptions, enablers, and nurturers) cultural model.

PEN-3 domain, themes (total entries), and subthemes	Mentions per subthemes, n
Perceptions	
Art as an outlet for emotional expression	
Fear and anxiety	4
Humor	1
Sadness	1
Hope	10
Faith	2
Others	9
Enablers	
Art as a medium for expressing awareness on health-related content	
Definition, pathophysiology and epidemiology	7
Signs and symptoms, eg, abnormal vaginal bleeding, pelvic discomfort, pain, foul smelling, headache, weight loss, painful urination, diarrhea	10
Cause, eg, HPV[a], unprotected sexual intercourse	5
Risk factors	1
Treatment, eg, chemotherapy, psychosocial therapy	6
Prevention, eg, HPV vaccination, screening, and early detection	34
Nurtures	
Art expressed as a form of self-regulation	3

[a]HPV: human papillomavirus.

Art as a Vehicle of Awareness for Health-Related Content (Enabler)

A significant portion (34/43, 79.1%) of entries aimed to promote HPV screening and vaccination. These were classified as "enablers" that highlighted art as a means to foster health awareness, including educational materials and information about cervical cancer. The entries featured infographics, illustrations, poems, drama, explainer videos, and graphics covering definition, epidemiology, signs and symptoms, causes, risk factors, and the treatment and prevention of cervical cancer. Out of the 34 entries, most provided details on preventing cervical cancer, including HPV vaccination, Pap smear tests, HPV screening, and the importance of early detection and management. Common signs and symptoms identified were abnormal vaginal bleeding, pelvic pain, unpleasant odors, weight loss, and headaches. Participants noted that HPV infections might not show symptoms, stating that (entry #16) "most infections with HPV resolve and cause no symptoms." In addition, artistic entries creatively used symbols to raise awareness about cervical cancer. For example, a syringe represented HPV vaccination (entries #14 and #17), a flower depicted the female reproductive system (entries #20 and #38), and a monster, along with a masked villain, symbolized HPV (entries #21 and #34; Table 1).

Art as a Form of Self-Regulation (Nurturers)

Finally, entries (3/43, 7%) also included "nurturers" through art, depicted as a form of self-regulation that addresses stress and challenges associated with having relatives with cervical cancer. For instance, entry #15 "portrays the mother's pains and struggles to protect her daughter and others from the same pain." The cervical cancer story was also used to encourage people in the community to embrace prevention. The story shared by entry #29 discusses "her personal battle with the disease" and "encourages her community to take proactive steps toward preventing cervical cancer" (Table 1).

Social Media Promotion and Awareness

The 6 finalists were promoted on social media for 48 hours to enhance awareness of cervical cancer, reaching 8685 accounts and generating 3509 engagements (likes=2727 and comments=782) on Instagram (average likes=454.5). Entry #40, named "Connected in Hope," attracted the highest engagement (likes=745 and comments=291), whereas entry #43 had the broadest account reach (total=2291), as presented in Table 2. Three winners were determined based on their level of social media engagement and their overall rubric score. The artworks of the 3 winners are provided in reference [26-28].

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Table 2. Social media engagements and data analytics of the 6 finalist submissions.

Entry number	Title	Likes, n	Comments, n	Total engagement (likes and comment), n	Accounts reached, n
#43	A fighting chance	697	98	795	2291
#19	The Tale of Aunty	432	61	493	692
#41	"it"	125	19	144	1343
#40	Connected in Hope	745	291	1036	1573
#18	Hope	173	78	251	881
#21	"Guardian of the Cervix: The battle against sneaky villain"	555	235	790	1905
Total	__[a]	2727	782	3509	8685

[a]Not applicable.

Discussion

Overview

We advance the current literature by illustrating the importance of social media and art in promoting cervical cancer awareness. By using a participatory approach, we demonstrate how engaging art submissions can resonate with audiences, fostering emotional connections and encouraging proactive health measures. This innovative method enhances outreach efforts and empowers women by transforming them into advocates for their health. Such integration of contemporary communication strategies represents a significant contribution to public health discourse, particularly in contexts with limited awareness and resources, such as Nigeria. This study investigated how art can serve as a cultural backdrop for health promotion to eliminate cervical cancer through participatory activities, such as an open call and a social media contest. By using the PEN-3 cultural model, 3 overarching themes emerged.

Most of the entries included themes related to art as a mental and emotional expression regarding cervical cancer and its prevention. Emotion is a physiological experience that occurs in response to an external stimulus and influences an individual's learning process and behavior [33]. Educational materials that integrate emotional expression can significantly impact individuals and their behaviors [33]. Hope emerged as the most frequent emotional expression in the entries. Hope therapy has proven beneficial in enhancing the quality of life for patients with cancer, though it should be accompanied by evidence-based management and realistic treatment expectations [34]. Research indicates a connection between culture and emotional expression; while certain cultural groups tend to be more expressive regarding their emotions, others may show the opposite behavior [35,36]. Moreover, art has been recognized globally as a means of promoting awareness of cervical cancer. Art as a vehicle of awareness for health-related content (enabler) was expressed in a majority (34/43, 79.1%) of entries, including content promoting HPV screening and vaccination. In India, art illustration was adopted by the Indian Cancer Society to educate the public on cervical cancer [33]. For instance, ancient Kerala Mural arts were used to educate Indian women on self-breast examination [37,38]. Additionally, the illustration of women in the traditional dress of the target population can enhance effective communication and the acceptability of the information.

Art contributes to health education by fostering empathy and creativity, influencing public behavior through cultural context. The submitted artworks reflected societal norms and local languages, enhancing the health message and promoting the intervention's sustainability. Vickhoff et al [39] noted art's appeal to cultural values, such as drawing characters in the local dress of the target population. Entry #40 illustrated women wearing attire from the 3 major ethnic groups in Nigeria to promote diversity and inclusion in eliminating cervical cancer. Additionally, entries #20 and #38 used flowers to symbolize the female reproductive system, addressing the cultural stigma around cervical cancer and female sexual health in Nigeria [35,36]. This imagery counteracts the shame associated with cervical cancer, emphasizing the importance of discussing it openly. Entries #21 and #34 depicted HPV as a monster to highlight the virus's danger and the urgency of prevention. Misconceptions in Africa often link cervical cancer to spiritual beliefs, so these entries symbolize HPV as the "devil" [40,41]. Entry #15 featured the Ibibio word (Ima meaning "love") in a letter promoting cervical cancer prevention.

Finally, 3 entries used art as a tool for self-regulation and shared experiences to advocate for cervical cancer prevention. A systematic review by Fadlallah et al [42] examined the impact of storytelling on policy advocacy and public awareness. A personal account or story from a cancer survivor or family can attract greater public attention and drive change. Such narratives can positively impact health education, encourage the use of preventive services, and promote engagement for an improved health system that ensures equitable access to services [43]. Using art entries to share the personal experiences of cervical cancer survivors or their loved ones can encourage HPV vaccination among girls and motivate women to undergo regular cervical screenings.

The Role of Art in Health Empowerment and Communication Through Social Media

Our art contest also showed the potential of art in women's health empowerment and communication through social media. First, participants expressed creativity through text-based, visual, and audiovisual entries. Although art in public health promotion

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is relatively new, it has been found to increase engagement compared to other "traditional" methods. Within 48 hours, the 6 finalists reached 8685 social media accounts, generating 2727 likes (455 on average) and 782 comments. This illustrates the potential of social media platforms to enhance the dissemination of educational messages, thus making them more accessible to a broader audience, especially younger women and remote communities.

In contrast, using traditional media for health promotion—such as newspapers, billboards, and television—can be more costly and reach fewer target groups. Moreover, unlike offline media, social media content remains continuously available without extra costs. However, increasing engagement on social media necessitates specific strategies, as not all individuals use social media platforms. A study from Brazil that examined Instagram posts about cervical cancer found an average of 153 likes per post [44]. This variation may stem from the art contest being part of a campaign focused on the cervical elimination day of action. Salako et al [45] noted that social media engagement regarding cancer tends to be greater during global campaigns than before or after those events.

The art contest was open only to females, thereby empowering girls and women to lead change. The art contest not only informed social media users about cervical cancer but also empowered women to act by leading change as health creatives, inspiring girls and women to get screened, vaccinated, or share information within their networks. For instance, entry #01 shared a story of a young woman who initiated community-based awareness and likened this to a "superpower" by saying, "Making a difference is not a superpower, and it is not a privilege only for those we think can." Entry #06 also centered on empowering girls and women to take charge of their health. One major cultural challenge of cervical cancer vaccination and screening in low- and middle-income countries is the inability of girls and women to make health decisions independently, as men often hold decision-making power. The entry was described as "The girl, a central figure, symbolizes empowerment, and her skin showcases words like 'Screening' and 'Survivor.'" This visual manifesto encourages self-awareness, urges women to take charge of their health, and fosters community solidarity." Art and social media also helped break down cultural stigmas and misconceptions surrounding cervical cancer and HPV in different communities. Some of the common misconceptions in Nigeria include the association of cervical cancer with promiscuous women, ignorance of risk, and fear of contracting sexually transmitted infections from screening [46].

Additionally, entry #41, titled "it," used spoken words to creatively lend a voice to the need to discuss cervical cancer publicly without stigmatization, "... what does the silence really do but hurt us? ... all it takes is to break the silence with one person, and maybe our vagina (it) will not worsen." Lastly, social media promotes peer-to-peer education through the "share" feature. Other social media users shared finalist entries multiple times to drive health conversations on their pages, thereby increasing the reach and impact of the artworks. It also supports the ownership and sustainability of the intervention.

Implications for Future Public Health Campaigns

The 3 winning art entries [26-28] are currently being used to raise awareness about cervical cancer and vaccination on print and social media. Specifically, the first-place visual was printed and branded on T-shirts and a magazine to raise cancer and vaccination awareness.

As digital engagement continues to expand, leveraging social media will become increasingly vital in increasing the reach of health information, particularly among younger populations. Moreover, incorporating arts and creativity into health communication strategies will be essential for driving more effective health-seeking behaviors. Future initiatives should prioritize people-centered artistic approaches, tailoring content to diverse age groups, cultural backgrounds, and educational levels. By doing so, health messaging can become more inclusive, engaging, and impactful, ultimately fostering a more informed and proactive society in addressing health challenges.

Study Limitations

Art contests on social media can promote health, but they have some limitations. Although internet access is growing in Nigeria and sub-Saharan Africa, many people, particularly in rural areas, still struggle to access mobile phones and the internet. Older individuals may also be left out of health promotion initiatives because most social media users are younger. Moreover, art interpretation is inherently subjective, influenced by context, culture, and personal perspectives. Consequently, some health messages might not be easily understood without an artist's explanation.

Additionally, there is potential for bias in the judging of art submissions. Although established judging criteria were designed and 5 independent judges evaluated the entries to minimize bias, the final entries were partly assessed based on social media engagement, which can also be subjective and favors participants with large followings. However, we mitigated this bias by grading the initial submissions solely on quality and by ensuring that the 6 finalists were equally deserving of selection as winners. Nonetheless, this approach enhances the accessibility of art for educating social media users. Lastly, the exclusion of men might have affected the campaign's reach in educating men to support cervical cancer prevention. This was to adhere to the ACCESS-HPV study protocol. Subsequent art contest or program will explore contributions of men in cervical cancer prevention.

Conclusion

In conclusion, this study shows the potential of using art and social media to empower women through cervical cancer prevention and screening education. It demonstrates the integration of cultural context in creativity to drive health promotion and increase impact. We encourage health organizations to adopt similar approaches to other women's health issues, especially those affecting young women, by leveraging creative and culturally relevant tools to increase awareness and promote health equity.

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Data Availability

All data generated or analyzed during this study are not publicly available due to the intellectual property of art owners. Only the winning entries were included with the artists' approval. Other datasets generated are available from the corresponding author on reasonable request.

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Authors' Contributions

Conceptualization: AOB, EK, JI
Data curation: AOB, EK
Formal analysis: AOB, OAO
Writing: AOB, EK, OAO, PK
Review & editing: OAO, AEW, TG, TO, UN, COJ, OA, FTA, HX, JSS, KOA, JJO, BNA, COA, JDT, OCE, JI
Funding acquisition: JI, OCE, JDT, COA
All authors reviewed the final draft and approved it for submission.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Age, type, title, overview, and total scores of the art contest crowdsourcing open call submissions.
[DOCX File , 34 KB - formative_v10i1e76240_app1.docx]

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Abbreviations

ACCESS-HPV: Actions for Collaborative Community Engaged Strategies for HPV
HPV: human papillomavirus
PEN-3: perceptions, enablers, and nurturers
SRQR: Standard Reporting for Qualitative Research

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Original Paper

An Integrated Multilevel Mental Health Support System for University Students: 4-Year Longitudinal Observational Study

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Abstract

Background: University students, in the life stage of emerging adulthood, struggle with a number of mental health problems around the world, mostly due to difficulties related to their studies and social relations. Though most students are aware of their problems, health-seeking behavior tends to lag behind. The COVID-19 pandemic aggravated mental health problems among students. In response, the University of Debrecen developed an integrated, multilevel model system aimed at the screening, prevention, and treatment of students' mental health problems.

Objective: This paper describes the testing of the integrated, multilevel model system aimed at the screening, prevention, and treatment of students' mental health problems.

Methods: The new system consists of data collection and intervention or service functions with 2 levels of informal digital, and 3 with partly digital, partly personal service modalities. Students access the system through a dedicated smartphone app that offers other university-related functions requiring personal login. One function of the app involves a mood report with 3 categories (awful, acceptable, and good), of which one per day can be submitted by students. Based on this report, further services are offered. According to the weekly patterns of the mood report, responding students may be directed to the second level, at which screening for depression or willingness to participate in peer groups is assessed. Depending on the responses, students are referred to personal (face-to-face) services at the secondary level for intervention. Aggregated reporting for leadership on the use of functions is available at all levels, which can be used to make decisions regarding the expansion of services or creating new ones.

Results: The model was launched in September 2020 and was tested for 45 months. After an initial increase in use, approximately 29% (8673/29,045) of all students provided mood reports (the University of Debrecen student population on October 15, 2024, was 29,045 students; the student population using the mobile app mood report was 8673 students). The percentage of students reporting a bad mood varied between 8.9% (26,465/297,372) and 12.2% (36,280/297,372) in the test period, while 50% (151,548/297,372 reports) of students reported being in a good mood. There was a marked pattern of increased use of mood reporting during the fall and spring study periods, while usage prominently decreased during the examination period and summer recess.

Conclusions: The 4-year trial period demonstrated that the mood report embedded in the mobile app can identify students with a potentially increased risk of mental health problems in need of support without stigmatization. The unique feature of our model seems to be its app-based screening at the first level and its hierarchy integrating digital and personal services. The system provides an easy-to-follow path from digital to personal services, along with time-specific data on the mental health of students for university leadership to facilitate the development of new services.

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KEYWORDS

mental health; digital health services; college students; student; university; higher education; undergraduate; counselling; young adult; young adults; health-seeking; mood; mHealth; mobile health; app; digital health; smartphone; eHealth; telehealth

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Introduction

University students represent a particular social group of youth that may be considered privileged since they are on their way to becoming part of the educational minority with the highest educational attainment. They are also an educational minority in their own age group, as they pursue tertiary education. 41% of 20- to 24-year-olds in Organization for Economic Co-operation and Development (OECD) countries and 35% in Hungary pursued university studies in 2020 [1].

Despite being young, university students face a range of mental health conditions. According to a survey conducted in the United States in 2001 and 2002, almost half of college-age youth had a psychiatric diagnosis; 11.9% had some degree of anxiety disorder, but less than 25% of those with a diagnosis received treatment [2]. The risk of depression was also found to be a significant problem with a prevalence of 17.3% among US college students [3]. In addition to anxiety and depressive conditions, substance use also represents a considerable problem, and although there are effective pharmacological and other methods to treat all of these conditions, the pattern of help-seeking in this group was below the level of need [4]. Studying outside their home country further increases the risk of stress [5].

A significant number of problems associated with young people in higher education have also been experienced by their peers outside the educational system. This specific period was defined by Arnett [6] as that of "emerging adulthood," a period of life that marks the transition from adolescence to adulthood with or without the period spent in higher education. Problems of this time of life inspired extensive further research since the beginning of the 21st century, and the World Mental Health Surveys [7], coordinated by the World Health Organization (WHO), established an international network to assess the mental health of students in higher education. Its first survey, conducted between 2014 and 2017 using a standardized methodology, involved students from 19 higher education institutions in 8 countries. According to the results, 35% of respondents had at least one mental disorder at some point in their lives, and 31% had at least one of the most common mental disorders (depression, mania, anxiety disorder, panic disorder, alcohol abuse, and drug abuse) in the preceding year [8]. However, despite common mental health problems, just under a quarter of respondents (24.6%) said they would seek help; they preferred to solve their problems alone or with friends and relatives [9].

The COVID-19 pandemic only worsened the mental situation of students. A survey including students from 41 European countries commissioned by the European Students' Union (ESU) in April and May 2020 found that 12.9% of respondents had a mental health problem, their emotional well-being had declined, and 7% of students had no one to turn to for emotional support [10]. A large-scale online survey of 350,000 students at 373 universities in the United States, carried out in 2020-2021 using standard screening questionnaires, found that more than 60% of students were identified as having one or more mental health problems, an increase of nearly 50% compared to 2013. The prevalence of various problems and patterns of health-service use also varied across students of different racial groups by self-definition, but help-seeking remained below need in all groups [11]. A follow-up study found that the proportion of students at high risk of anxiety and/or depression remained unchanged from fall 2020 to spring 2021 [12].

The latest results of a survey of UK undergraduates show that while 6% of students in 2017 had a mental health problem, this figure almost tripled to 16% by 2023. The same survey found that 29% of students considered dropping out, and of the 18 factors mentioned as potential reasons, mental health was by far the most frequently selected by the respondents [13].

A German survey completed in 2020 found that 24.7% of students always or almost always felt depressed, and 31% thought they were isolated from their peers.

The unfavorable impact of the pandemic on the mental health of college students was also confirmed in Australia [14], China [15], Bangladesh [16], and India [17].

Similar patterns were identified among Hungarian students before the pandemic. One-fifth of medical students at the University of Debrecen in Hungary had abnormal levels of psychological distress assessed by the 12-item General Health Questionnaire (GHQ-12). Using the same tool, it was shown that students in teacher training in 6 Hungarian higher education institutions were significantly worse off than the same age group of the general population in the first decade of the 21st century [18]. Using the 9-item version of the Beck Depression Inventory (BDI), Lisznyai et al [19] found that depression scores were significantly higher among students completing a master's degree; higher levels of anxiety were found among 18- to 19- and 24- to 26-year-olds using the STAI questionnaire.

Hungarian research on the impact of the pandemic provided contradictory results. Researchers using a validated mental health tool (Mental Health Test) [20] at the largest medical university in Hungary found no difference in student performance compared to the national average in April 2021[21].

The Association for Counselling in Higher Education (ACHE) invited students from all Hungarian higher education institutions to participate in an online survey in the fall of 2021, in which more than 10,000 students from 47 institutions participated. A total of 10.2% of respondents had been prescribed medication for a mental health problem, of whom 6.2% were also taking medication at the time of responding. The current mental status was assessed by a 45-item screening questionnaire (OQ-45), the mean of which in the Hungarian sample exceeded the clinical threshold established in US studies. According to the shortened version of the BDI, 36% of respondents were at risk of mild and 5.2% of moderate depression; 6.6% of respondents often had suicidal thoughts, 3.4% had those almost always [22]. In total, 70% of respondents were negatively affected by the pandemic, but there was no discussion of how the pandemic changed mental health compared to previous years.

The ACHE carried out a new study in November 2023 involving more than 15,000 students from 43 higher education institutions in Hungary. Furthermore, 44.6% of respondents had moderate or moderately severe depressive symptoms, 16.3% had severe

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depressive symptoms; 36% often or always felt lonely; 41.4% had a crisis that negatively affected their mental state at the time of the survey, and 3.7% of students had a mental illness at the time of responding [23].

Youth in higher education face significant mental health challenges for complex reasons. The main causes are related to their studies, the extent of knowledge to be acquired in their discipline, which is associated with high expectations, and the time spent on studying. The duration of learning has a positive impact on academic progress but a negative impact on other activities. Academic expectations, including examinations, are a significant part of the stress load for students [24]. Insufficient previous knowledge of the chosen profession or discipline can also be a risk factor that may lead to a decrease or lack of motivation [25]. Other well-known risk factors include insufficient peer support and subsequent social isolation, which may also be related to family problems; conflicts with parents or lack of friends, while a low socioeconomic status and/or financial difficulties may cause livelihood problems. Part-time work can alleviate financial issues, but at the cost of time available for learning. A common risk factor is the overuse of psychoactive substances, partly related to recreational social situations and to the misconception that this can be a solution to mental difficulties [24]. Age, gender, sexual orientation, gender identity, and ethnicity also affect students' mental health [26], as does any preexisting mental disorder [8,23].

Despite their problems, college students do not take full advantage of support services available due to reasons summarized in a recent systematic analysis of 44 publications [27]. The proportion of students who used any mental health services varied between 13.7% and 68.6%, and between 2.6% and 75% when outpatient service use was estimated. This significant variability could not be explained by the type of services but was related to the size of the at-risk population: a higher number of students with mental health problems was related to a higher rate of service use. The lowest rates of service use were found among students who studied outside their home country. Based on the aggregated data from the articles included in the review, 21% of students used mental health services (95% CI 3%-72%).

Data on mental health service use in Hungary were collected in ACHE surveys. These studies found that 4.4% of students used psychological support services provided by higher education institutions in 2021 [22], and this increased to 7.4% in 2023 [23].

Overall, the mental health of students in higher education institutions is a growing concern across countries and institutions, albeit to varying degrees. Many institutions of tertiary education make considerable efforts to improve the overall health of their students, including mental health, as recommended by the Health Promoting University concept of the WHO [28], based on which specific projects are launched [29].

Digital services offer one type of solution for the reduction of the gap between health care needs and supportive care and services. Based on a review of 89 relevant studies published in 2019, US authors found that 80% of digital interventions were delivered through an internet portal, and a third of these included human contact and support. The majority of programs were either fully or partially effective in achieving positive change in the psychological outcome variables identified for evaluation [30]. A meta-review of 7 meta-analyses published in 2020 found equivocal results in terms of quality of evidence, and small to medium effects for randomized controlled trials investigating stand-alone applications and apps with guidance. It is worth noting that most RCTs included less than 1000 participants, the highest number in the intervention group being 3639 persons [31].

The effectiveness of delivering interventions to improve mental well-being via social media was investigated by Plackett et al [32] in a systematic review based on relevant papers published between 2004 and 2022. Improvements were shown in 39% of the studies, but the rest of the papers—the great majority being of poor quality—found mixed effects or none at all [32]. On the other hand, mindfulness meditation helped by mobile devices, including smartphones and apps, was found to be more effective than control groups in decreasing stress and anxiety [33].

A recent systematic review of 6 studies on treatment apps, 4 studies on self-monitoring apps, and 21 papers on multipurpose smartphone apps for mental disorders found that they were acceptable and effective, but their use declined over time. The authors specifically recommended, among others, that apps provide feedback to patients and clinicians, and even be integrated with patient electronic health records [34].

There are a number of other digital modalities that show promising results among youngsters such as digital platform with chatbot for schoolchildren that helps improve social-emotional learning and self-help [35], smartphone app for helping delinquent adolescents to be more aware of their emotions [36], and family-based telehealth interventions for youngsters in foster care to facilitate their integration [37], but these modalities have not yet been tested among college students.

The University of Debrecen developed a mobile app (Studyversity) to help its students navigate their student life. It can be downloaded from Google Play and Apple Play in both English and Hungarian and is compatible with all mobile platforms. It has a simple graphical user interface design with separate items for each available function. The app contains class schedules of enrolled courses, registered examinations, and individualized academic data such as examination results or financial balances. Class schedules and examination dates are synchronised with the phone's calendar. A location guide is available to help students find appropriate classroom buildings. Information about academic divisions and their office hours is updated in real time based on information from the Registrar's Office, along with information on available scholarships. Another function of the app is the University of Debrecen Community Space, which allows students to find companions for various leisure activities—from dog walking to theatre visits. Students are instantly informed about university news and important updates through push notifications, even without launching the app.

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All Hungarian universities are legally obliged to protect and promote the mental health of their students. The University, by virtue of monitoring the mental health of its students [25] and maintaining various personal helping services for them that contribute to this legal obligation, acquired experience with such systems. Based on these precedents, the leadership of the University of Debrecen, together with its Students' Union, decided to expand the Studyversity app with a "mood report" function using a 3-item visual analog smiley face scale to report mood (awful, alright, and great). Its use is incentivized by the opportunity to win university-branded merchandise after submitting a certain number of reports. The mood report was integrated into a multilevel approach to the prevention and treatment of mental health problems among students.

The concept of the system was taken from the foundational concepts for the delivery of mental health care services as described by the WHO [38], along with experiences with the aforementioned services. This paper aims to present the composition and levels of this new service model, investigate the feasibility of its operation, and present data about the use of the digital levels obtained during the test period of 45 months.

Methods

Description of the Integrated Multilevel Model of Mental Health Services

The identification of students with mental health needs and finding a way to engage them to seek help while minimizing stigmatization represents a key challenge. Since nowadays each student has a mobile phone that they consider an indispensable tool in their lives, it was decided that a dedicated smartphone app would be used at the informal digital level in a hierarchy of services. The next, also digital level would be designed to engage those who are at a high risk in terms of mental health problems. In terms of screening for depression, the most frequent mental health problem among students, the scientific consensus on screening principles was taken into account [39].

Information for faculty leadership about the number of students in need of help could be provided, and resource-intensive, that is, in-person services would be offered starting at the level of formal health care services. Reporting on the use of services to the leadership of the university would enable them to expand existing or develop new services and interventions should such a need arise. Table 1 provides an overview of all (existing and newly developed) informal and formal levels of the system, along with the means of data collection, provision of interventions and services, and reporting to leadership.

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Table 1. Organizational levels of providing mental health services at the University of Debrecen.

Type, level according to WHO[a], and how students can access it	Available service	Data collection		Reporting to leadership[b,c]	
		Description	Type	Description	Type
Informal					
Self-care					
Dedicated online platform	Written, audio, and video materials related to mental health.	• Number of users. • Time spent at the platform.	• Digital	• Aggregated data	• Table
Community care					
Dedicated online platform	Individual consultation (online or in-person), peer groups for study and support (in-person).	• Number of consultations. • Number of groups. • Number of sessions.	• Analog	• Aggregated data	• Table
Self-care					
Mobile app	Mood report (3-item visual analog scale with smiley faces).	• Number of mood reports. • Number of "awful" moods if the number of "awful" moods = 10 in 10 days.	• Digital • Digital	• Aggregated data • Aggregated data	• Table • Table
Formal					
Primary					
Mobile app	If the risk of depression is elevated, referral to the Centre of Clinical Psychology (CCP).	• Screening test offered for depression.	• Digital	• Aggregated data	• Dashboard
Primary care physician	Primary care (in-person), if needed: referral to CCP.	• Health care system	• Digital	• Aggregated data	• Table
Secondary					
Appointment by phone or email	Individual psychological service (outpatient and in-person, referral-based).	• Health care system	• Digital	• Aggregated data	• Dashboard
Referral	Group psychological service (outpatient and in-person).	• Health care system	• Digital	—[d]	—
Tertiary					
Referral	Psychiatric service (inpatient and in-person).	• Health care system	• Digital	• Aggregated data	• Dashboard

[a]WHO: World Health Organization.

[b]Availability of the reports is guided by the right of access to data as specified in the University by-laws.

[c]New functions developed within the Studyversity app are marked with an asterisk.

[d]Not applicable.

Transitions between digital and in-person services are implemented through structured referral pathways across levels of care.

Digital Mental Health Services

Our service model was implemented by creating a mobile app for students called UD Studyversity (UDSV). The first version of the UDSV was available for download in September 2020. The free app, available in both Hungarian and English, provided information about a range of student services (educational, administrative, etc.) available at the university as well as a number of functions that the university developed in-house to meet the needs of students (eg, community space for incoming students, display of educational data). Some functions of the UDSV (mostly information also available online on the university website) can be accessed without logging in, while other functions are available after authentication using their unique student ID.

The first new element of the model of mental health care at the informal level is a so-called "mood report," one of the

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personalized functions of UDSV that helps identify students at risk for mental health problems. After an authenticated login, students can report their current mood at any time but only once per day by selecting one of three categories (“awful” is bad, “alright” is acceptable, and “great” is good). After sending the mood report, the student receives a positive message to acknowledge receipt of the report in the form of a motivational quote or a short entertaining video, which is not related to the mood report, only rewards the fact that the student submitted it. At the suggestion of the SU, one more feature was added to the mood report to encourage the use of UDSV: points can be earned by those who report their mood consistently every day. Students earning different scores can receive gifts, tickets to university events, or free and discounted university services (sports, meals, etc). These rewards are preselected for each level (score).

Based on consistently submitted mood reports, it is possible to identify students at risk at the informal level. Specifically, students who reported an “awful” mood on a preset number of consecutive days receive a validated online questionnaire to screen for depression, in which the student also gives permission for being contacted by clinical psychologists of the university for further services if his or her screening score reflects an increased risk.

Students who submit “great” mood reports at the informal level on a predefined number of consecutive days receive a questionnaire in which they can declare whether they would like to participate in mentoring peers to help them manage university life in a group setting.

Personal Mental Health Services

Individual Care

Students identified as high risk based on the mood reports may be contacted by clinical psychologists at the formal level, as described above, to offer further personal care. This form of care may take the form of counselling or psychotherapy. Since both of these interventions entail more than one session, it is only appropriate for high-risk students who may be clinically depressed, in crisis, or at risk of suicide. Those in need of this type of care should be diagnosed and treated in person by clinical psychologists or psychotherapists working in the Clinical Center of the university.

Group Care

Students who are identified as at risk by the mood report function of UDSV and screened by the questionnaire are offered—depending on the severity of their condition—the opportunity to join groups of 8-12 students. These groups would also include 3-4 students per group who submitted positive mood reports and signed up to be volunteer peer supporters. Groups are organized 4 times a month for 3-hour sessions. These groups serve multiple purposes, such as the provision of peer support and “healthy” feedback from peers, to increase self-awareness and identify common problems and find helpful solutions.

Secondary and tertiary health care are the highest organizational levels at which the leadership of the university would be provided with summary data about the mental health needs of students, along with provided and accessed services, in order to facilitate systemic evaluation and interventions.

Promotion, Data Collection, and Statistical Analysis in the Test Period

The UDSV was introduced in September 2020 and was actively promoted among students until the end of the fall semester (mid-December, altogether 4 months). Subsequently, there was no active promotion. The reward system was restructured in February 2024, after which the app was promoted for one month. The test period ended in May 2024, after 45 months.

As it was described above, mood reports can be filled out and submitted after authentication with a unique student ID and password. No special registration is required to use the application itself. With the consent of students, the mood reports are uploaded into the electronic database of the Management Information System (MIS) of the University of Debrecen. The database collecting the mood reports stores the unique student ID, the faculty at which they study, the mood category, and the date and time of the report.

The aggregated data is processed in Microsoft Power BI and used to create summary dashboards for management. There is an interface between the application and the Power BI to ensure an up-to-date data flow. After data processing, various summary evaluations can be created and displayed as dashboards, such as the number of users, the number of mood reports, their categorical distribution by day or by longer time intervals (eg, study period and examination period), or as time-series charts. University and faculty leaders have access to summary dashboards according to their level of authorization.

Ethical Considerations

The Hungarian Act on Higher Education (Act CCIV of 2011) [40] obliges all institutions of higher education to provide information and consultation for students to facilitate their progress and completion of studies, particulary those with disabilities; and institutions must also provide opportunities and services for promoting health while legal obligations related to data protection and information freedom must also be fulfilled [41]. Therefore, the newly created mobile app and digital screening test are completely separate from the digital educational system of the University, the use of which is mandatory for the students to monitor their educational performance. The application by which mood reports are collected was developed by the University of Debrecen, is the property of the University, and is available only to its registered students. All students of the University who can use smartphones and computers can access the system for the designated purposes. Students with special needs are served by another center of the University that has been established and operated specifically for these students. In order to enter the app, students have to supply their unique student ID, by which they consent to their data being collected by the university. A statement about this must be read and approved by the students upon entering the app. However, the self-reporting of mood and filling out the depression screening test within the app are voluntary, and this is detailed in a statement that must be approved upon entering.

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Students are not compensated for the use of the app, but small tokens (eg, a t-shirt, paper notes, a pen with the logo of the University) are offered to those who regularly report their mood for at least ten weeks. Participation in the mood reporting and screening functions was entirely voluntary and not linked to any academic requirements or benefits.

The app and digital screening test are parts of the USDV system that is operated by a division independent from any faculty, reporting directly to the Chancellor of the University. Data accessibility for staff members in this division is guided by a written protocol. All persons who can access data of this system bear criminal culpability for misuse of data.

The Regional and Institutional Ethics Committee of the University of Debrecen (2./2025 RKEB), after reading the present manuscript, issued a retrospective Institutional Review Board exemption for this study.

The full database of the system is only available to the head manager of the system and the chancellor of the University. Summary data from the system can be requested in writing by persons in leadership positions (deans of faculties, vice-rectors, and rector) of the university from the head manager. Summary reports are offered in dashboard format with no backtracking to individuals. Others requesting data must submit a research plan specifying the purpose and types of data that are requested. The plan must be approved by the head manager and the chancellor. Upon approval of the plan, deidentified data are provided, and the final results of the analysis must be submitted to the chancellor.

Results

After the development of the model and the alpha-test phase of the application (mood report and reward system), pilot testing was conducted between September 1, 2020, and May 31, 2024 (45 months), during which time the mood report function was used by 8673 students who provided approximately 297372 mood reports. According to Google Analytics, the mood report was the second most used feature of UDSV, only surpassed by the timetable function linked to the educational administrative system of the University.

The percentage of users of the mood report function out of all students somewhat decreased from almost 8% (2291/29,045 users) during the introductory first 4 months to 6% (1693/28,418 users) in the first full year, but subsequently almost doubled and remained at around 11% (3146/29,021 users) of the active students in the test period (Table 2).

Figure 1 shows a 1.47-fold increase in the number of mood reporters compared to all students and a 35% decrease in the number of submitted reports during the entire length of the test period. The reward system was restructured in February 2024, after which user numbers increased significantly, as seen in Figure 1.

Table 2. The percentage of students compared to all registered students who reported their mood by the smartphone app in the specified time intervals during the test period of the system.

Characteristic	2020: September 1 to December 31	2021: January 1 to December 31	2022: January 1 to December 31	2023: January 1 to December 31	2024: January 1 to May 31
Months, n	4	12	12	12	5
UD[a] students, n	29,045	28,418	28,414	29,021	28,244
Students who submitted mood reports out of all students, n (%)	2292 (7.9)	1695 (6)	3210 (11.3)	3232 (11.1)	3381 (12)

[a]UD: University of Debrecen.

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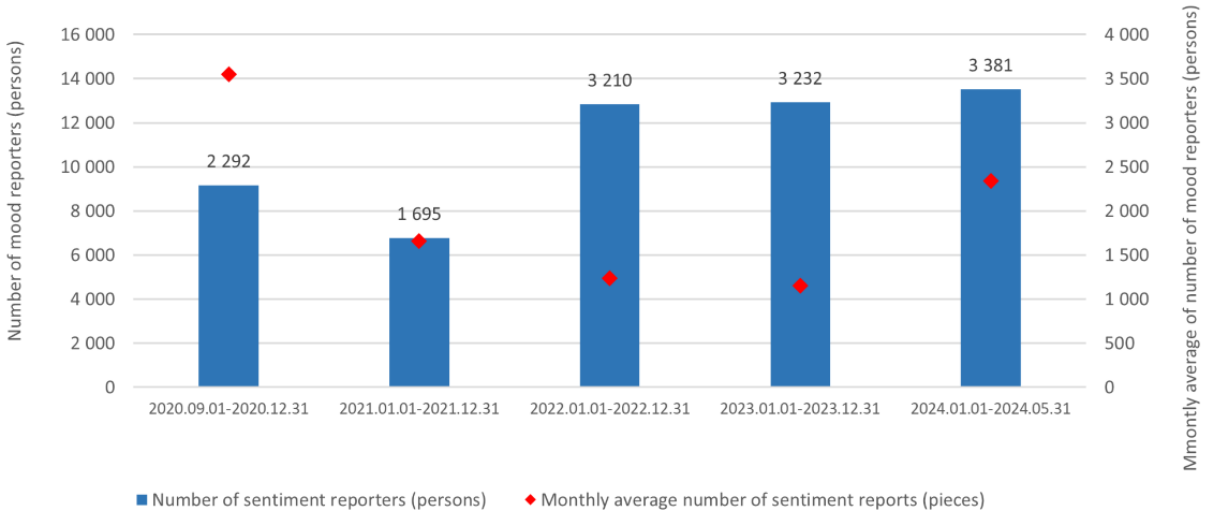
Figure 1. Number of mood reporters and mood reports collected by the smartphone app in the specified time intervals during the test period of the system.

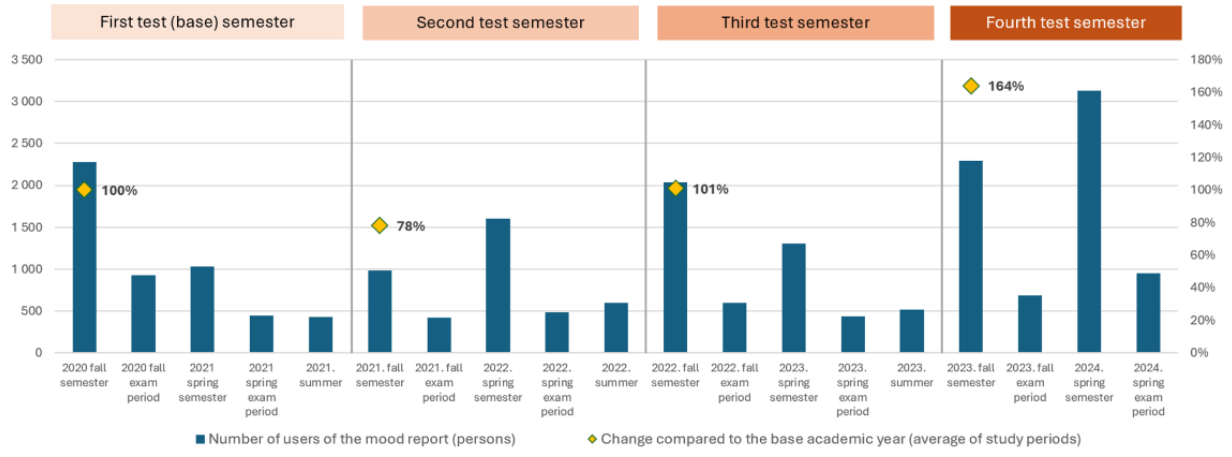


We also analyzed the use of mood reports in the specific study periods of the academic year, that is, during the fall and spring semesters, as well as the winter and summer examination periods, since most functions of UDSV are more useful during the semesters with higher expected usage. At the same time, examination periods tend to be more stressful for students with a negative or wavering impact on their mood.

After the launch of the UDSV until the end of the promotion period, the number of users of the feature as a percentage of the active students exceeded 10% (3382/33,820 users). In the following year, when the app was not promoted, the number of UDSV users more than halved. From 2024, with the promotion of the app that included new functions, UDSV use increased again.

In terms of the above-specified study periods, the UDSV and its mood reporting function were most frequently used during the semesters, and least used in the examination periods and during the summer vacation (summer; Figure 2).

Figure 2. Number of students reporting their mood by academic study periods during the test period of the system.



The distribution of the categories of the mood reports showed that the majority of students felt “alright” or “great”. The mean percent of “awful” reports was 11.6% (35,846/309,017 reports) during the full test period, 12.2% (27,379/224,418 reports) during the semesters, 12% (7158/59,650 reports) in the examination periods, and 8.9% (1309/14,708 reports) during the summer break. There was no significant difference in the proportion of “awful” mood reports during semesters and examination periods (P=.64; Figure 3).

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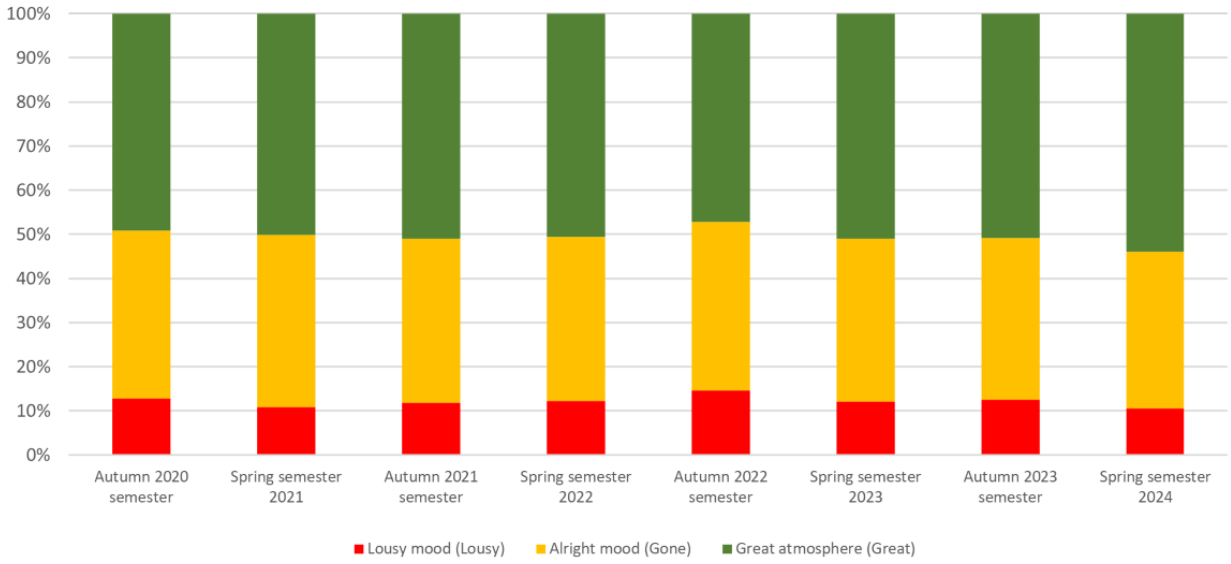
Figure 3. Distribution of the categories of mood reports by academic study periods during the test period of the system.



Discussion

This paper describes an integrated multilevel system newly developed by the University of Debrecen that provides mental help for its students, and reports on its 45-month test period between September 2020 and May 2024. There was a positive reception by students; approximately one-tenth of them used its mood report function at the first level of the system in the last half of the test period. More than 88% (261,957/297,678 reports) of students' reports were acceptable ("alright") or good ("great") moods, and only approximately 12% (35,415/295,125 reports) were "awful" moods. Token rewards increased the number of users, as supported by the fact that from the launch of its introduction (February 2024), user numbers exceeded those of the previous years.

Based on 4 years of testing, the mood report embedded in the UDSV mobile app proved to be capable of identifying those students who are at an increased risk of having a mental health problem and are in need of support.

The benefits of using a mobile app include its all-time availability and easy reporting on their mood without stigmatization, whereas the university receives personalized and time-specific estimates on the mental health of students, which allows the identification of those at high risk of mental health problems and enables the provision of further screening based on which tailored suggestions for personal help can be delivered. A similar app assessing other functions can be used as a tool of needs assessment to organize and operate direct and efficient provision of health care in case of health emergencies, such as an epidemic.

Mobile phone penetration worldwide underwent an enormous, 1177-fold increase from 1999 to 2009 [42], and as of 2023, the global smartphone penetration rate was estimated at 69% [43]. Smartphone ownership at this mass scale enabled fundamental changes in the access and use of health care services with a shift to participatory direction [44]. Furthermore, 99% of Generation Z or Zoomers (youngsters, including college students, born after 1997) own a smartphone, and 98% of them use it to connect to the internet [45], so they are the most appropriate group to target with new information technologies.

As of now, evidence has already been available for the effectiveness of digital mental health interventions, most of them based on cognitive behavioural therapy [46] for university students for enhancing well-being [47] and improving the symptoms of depression and anxiety [30]. However, most of the studies were carried out as randomized experimental studies, not as campus-wide implementation studies. The majority of the interventions were delivered through a website, most commonly offering cognitive behavioral therapy with or without human support. Only a few studies examined the feasibility of campus-wide implementation. In one, students had to personally attend a clinic where they were screened, and if eligible, offered online treatment [48]. Another implementation study also recruited students from counseling centers that required personal attendance and screening, subsequent to which students could choose from one of three internet-delivered cognitive behavioral therapies [49]. App-based first-line screening seems to be a unique feature of our model. Its advantage is that its first means of encounter (the mood report) is offered to all students on a voluntary basis, and its use provides the information that enables the personalized invitation of those who report sustained bad mood.

The identification and recruitment of persons at increased risk of mental health problems remains a challenge, as has recently been pointed out by Fitzpatrick et al [50]. Extensive resources have been dedicated to developing digital mental health interventions, and though they represent scalable, low-cost solutions, their perceived lower desirability and credibility result in their underuse. This may be slightly different among students who showed interest in online self-help materials in varied forms and duration [51].

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As to the future development of the system, including its mobile app, the authors of the most recent systematic review of smartphone apps made a number of recommendations that we agree with [34]. Among these are the multiplatform compatibility of apps, provision of feedback to clients and helpers, data protection, and involvement of users, including those with mental problems, during development. The greatest challenge is presented by the integration of smartphone apps with health care services, which is primarily ethical rather than operational. Respecting client autonomy and strict protocol for access to health care data for developers and system managers may or may not fully solve all these challenges.

One of the limitations of our system is related to the fact that two years (2020-2021) out of the full test period were markedly different from previous and subsequent years due to the pandemic that shifted most activities of the university to the online space, and also had an impact on students' attention. This is reflected by the rather extensive swings in the number of mood reports and reporters between the first and the second half of the test period. The test period was quite long, so that usage well after the end of the pandemic could be assessed. Another limitation was due to the fact that the new app was promoted only two times: after its launch for 4 months, and in 2024 for 1 month, and these had a considerable impact on use. Still another limitation may be that students with preexisting mental conditions or having severe mental problems (eg, depression) may not use the app at all, for a lack of motivation or not having the willingness to report their mood in any form. A related additional challenge may be that students who use the application at Level 1 and are identified as at high risk of depression may not be willing to get in personal touch with helpers at Level 2, even if they are recommended to do so. This is in line with the underuse of health services by university students found by a large number of studies [27].

We developed an integrated multilevel model for improving the mental health of students at the University of Debrecen. We reported the testing of the first two digital levels of the model to assess the proportion of students for whom mental help should be offered. Campus-wide easy access and entry to the system were considered a basic condition, which required going beyond the traditional, face-to-face forms of mental health support. Therefore, a mood report function was developed and embedded into the general student support app of the university UD StudyVersity), which is available for all students on a smartphone to give self-reports in a nonstigmatizing manner. The mood report was proven to be capable of identifying students likely in need of further support. Approximately one-tenth of the students could be considered at high risk and will be invited for further screening and support. The development of digital services in a hierarchical manner that extends from an easy-to-use digital platform to other, more resource- and time-intensive services provided by trained professionals will be necessary to address the worldwide phenomenon of overwhelmed and distressed college students. However, such systems need continuous feedback, improvement, and promotion in order to reach all or most students for whom such a system would be of greatest use.

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No generative artificial intelligence was used in any portion before or during the writing of the manuscript.

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Data Availability

The datasets analyzed in this study are not publicly available due to the primacy of protecting students' privacy in line with Act CXII of 2012 of Hungary. Specific reasonable requests regarding the data should be sent to the first and last authors of this paper, who serve as the head manager of the system and chancellor, respectively.

Authors' Contributions

Conceptualization: SV, AB, ZB
Methodology: SV, AB
Software: SV
Formal analysis: SV, KK
Data curation: SV
Investigation: SV, KK
Supervision: AB, ZB
Project administration: SV
Validation: SV
Funding: ZB
Resources: ZB
Writing – original draft: SV
Writing – review & editing: SV, AB, KK, ZB

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Conflicts of Interest

None declared

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Abbreviations

ACHE: Association for Counselling in Higher Education
BDI: Beck Depression Inventory
ESU: European Students' Union
GHQ-12: 12-item General Health Questionnaire
MIS: Management Information System
OECD: Organization for Economic Co-operation and Development
OQ-45: Outcome Questionnaire–45
UDSV: UD Studyversity
WHO: World Health Organization

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Original Paper

Early Evaluation of IMAGINATOR 2.0 Intervention Targeting Self-Harm in Young People: Single-Arm Feasibility Trial

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Abstract

Background: Self-harm (SH) affects around 20% of all young people in the United Kingdom. Treatment options for SH remain limited and those available are long and costly and may not suit all young people. There is an urgent need to develop new scalable interventions to address this gap. IMAGINATOR is a novel imagery-based intervention targeting SH initially developed for individuals aged 16 to 25 years. It is a blended digital intervention delivering functional imagery training via therapy sessions and a smartphone app.

Objective: This study aimed to pilot a new version of the app, IMAGINATOR 2.0, extended to adolescents from the age of 12 years and coproduced with a diverse group of young people with lived experience. Our aim was also to test the feasibility and acceptability of delivering IMAGINATOR 2.0 in secondary mental health services.

Methods: A total of 4 co-design workshops were conducted online with UK-based lived-experience co-designers aged 14-25 years to develop the IMAGINATOR 2.0 app. The intervention was then piloted with participants recruited from West London NHS Trust Tier 2 Child and Adolescent Mental Health Services and adult Mental Health Integrated Network Teams. Participants received 3 face-to-face functional imagery training sessions in which the app was introduced and 5 brief phone support sessions. Outcome assessments were conducted after completing therapy, approximately 3 months post baseline. Two focus groups gathered the therapists' perspectives on IMAGINATOR 2.0's acceptability and means of improvement. For quantitative data, descriptives are reported. Qualitative data were analyzed using a coproduced thematic analysis method with young people with lived experiences.

Results: Overall, 83 participants were referred, and 29 (gender: n=28 women, n=1 transgender; mean age 18.9, SD 3.74 years) were eligible and completed screening. Of the 27 participants who started, 59% (n=16) completed therapy per protocol, while only 15 (55.6%) completed the quantitative outcome assessment. There was an overall reduction in the number of SH episodes over 3 months from pre- to postintervention (baseline: median 7, IQR 3.5-21.5 months; postintervention: median 0, IQR 0-7 months; median difference=–6.5; r=0.69). Six themes were identified through thematic analysis of therapists' feedback, including mental imagery's potential and boundaries, therapy expectations, experience and effectiveness, accessibility of digital support,

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and adaptation of the IMAGINATOR 2.0 app to complement care pathways. The app was valued by therapists who highlighted the need for an intervention like IMAGINATOR 2.0 in their services.

Conclusions: IMAGINATOR 2.0 shows initial promise as an acceptable brief intervention targeting SH in young people under adolescent and adult mental health services. Challenges with attrition need to be addressed for a definitive randomized controlled trial to test the intervention efficacy.

Trial Registration: ClinicalTrials.gov NCT06311084; https://clinicaltrials.gov/study/NCT06311084

(JMIR Form Res 2026;10:e79496) doi:10.2196/79496

KEYWORDS

self-harm; intervention; digital; mental imagery; young people; adolescents; co-production

Introduction

Self-harm (SH) is defined as the "intentional act of self-poisoning or self-injury, irrespective of the motivation" [1]. It is an expression of emotional distress that typically begins in early adolescence and peaks in frequency around the age of 16 years [2]. SH prevalence has increased over the past 20 years [2], with approximately 20% of individuals aged 16-25 years reporting having self-harmed at some point in their life [2-4]. SH is associated with poor health and functional outcomes, including risk of suicide [5]. Despite the impact on young people's functioning, available targeted interventions are inadequate to address the high level of need [6,7]. Interventions with the strongest evidence support (such as cognitive behavioral therapy [CBT] [8] or dialectic behavioral therapy [9]) are either limited to adults or have long duration and high cost and require a high level of commitment. Therefore, we lack a stepped care model for SH [10], starting with a brief early intervention for SH in young people prior to long, complex treatments. Digital solutions could be crucial to bridge this gap and show promise in reducing the high prevalence of SH [11] by providing early support to large numbers of young people [12]. Young people are open to digital interventions for SH, especially if they provide coping strategies, but not as a substitute for human support [13]. However, despite their acceptability, challenges such as reduced app usage over time have been noted [14], while only a handful of app or web-based interventions for SH focus on and were co-designed with young people and have been adequately tested [15-17].

SH cognitions are often experienced in the form of mental imagery: vivid, realistic mental representations that can entail re- or pre-experiencing the same emotional and physiological reactions as the actual act [18]. SH mental imagery has been identified in clinical and student populations (84% and 73% prevalence, respectively) [19,20] and has been shown to increase the urge and likelihood of future SH [21-23]. Nevertheless, mental imagery of adaptive actions can promote engagement in adaptive behavior [24]. Interventions including mental imagery techniques, either transforming unhelpful mental images or promoting helpful ones, have shown growing potential in conditions related to SH, including depression [25], emotion dysregulation [26], suicidal ideation in students [27], and SH itself in adolescents [26].

Studies show that mental imagery interventions such as functional imagery training (FIT) can be more effective than motivational interviewing at promoting change of problematic behaviors [28-30]. FIT [31] involves training and rehearsal of motivational imagery to enhance the desire to reach adaptive goals [32]. For example, it has been shown to promote weight loss [30] and reduce alcohol consumption [29], suggesting it could help individuals in identifying and implementing alternative strategies to replace SH. IMAGINATOR is an imagery-based intervention delivering FIT to target SH via a combination of face-to-face therapy sessions and a smartphone app. The proposed therapeutic ingredient is personalized, positive, future-oriented imagery to support behavioral control. During FIT, individuals develop a personal imagery plan (like a movie to play in one's mind) of an adaptive behavior to put in place when and where the urge to SH occurs. In a proof-of-concept study, we showed that IMAGINATOR reduced SH after 3 months, which was maintained at 6 months in young people aged 16-25 years [33].

Building on these results, we co-designed a new version of the app for adolescents and young adults aged 12-25 years (IMAGINATOR 2.0). In this paper, we will refer to this age group as "young people." Our study aimed to assess the feasibility, acceptability, and safety of IMAGINATOR 2.0, in particular, piloting the use of the new app and the intervention delivery in children, adolescents, and adult secondary mental health services. Secondary objectives were to examine change in key outcomes, such as the number of SH episodes, SH urges' intensity and SH mental imagery characteristics, other mental health symptomatology, and explore clinicians' perspectives in delivering IMAGINATOR 2.0. Examining changes in SH outcomes provides preliminary insight into potential intervention effects to inform future trials. Young people's views are reported in a separate qualitative paper [34].

Methods

Design

This was a single-arm study delivering FIT as a low-intensity intervention alongside standard care in a sequential sample of young people under the care of West London NHS Trust. The study was registered with ClinicalTrials.gov (NCT06311084) prior to participant enrollment.

Patient and Public Involvement

A Young Person Advisory Group of 4 young people with lived experience of SH was involved in the funding application, design, recruitment, data collection, data analysis, interpretation

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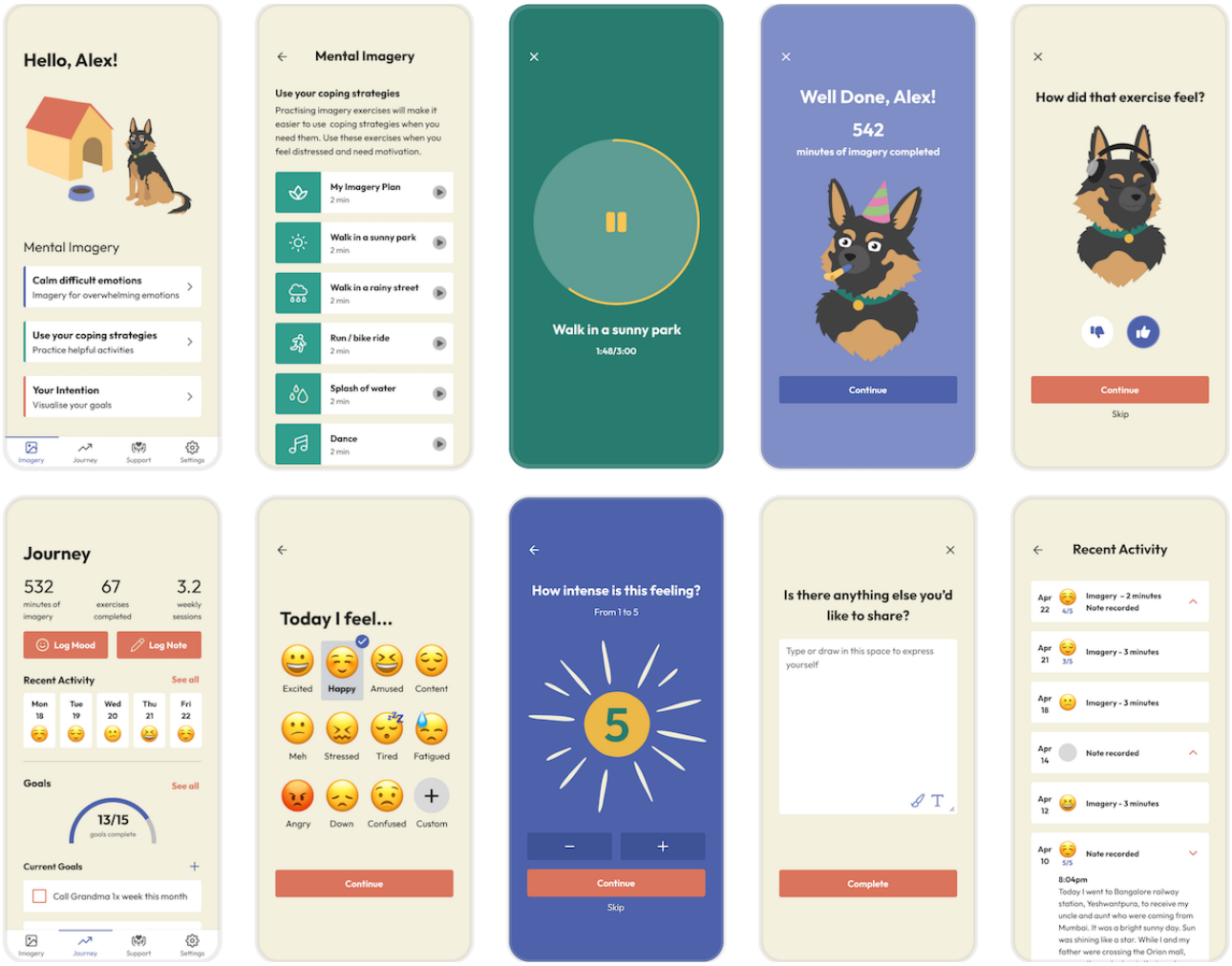
of results, and dissemination. Details on the group's involvement are reported elsewhere [34]. Three members (SM, AM, and NC) took part in the final stages of the thematic analysis reported here. They revised codes and generated themes together with the rest of the research team in 2 online meetings in April 2024.

Co-Design of the IMAGINATOR 2.0 App

We co-designed a new app with a diverse group of 14 young people with lived experience of SH recruited via social media across the United Kingdom. Details of the co-design process are reported elsewhere (case study [35] and Rodrigues et al., in preparation). Key functionalities selected for the final app (shown in Figure 1) included a degree of personalization, segmentation, inclusivity, and modularity (eg, a mascot to facilitate engagement, a goals tracker, a mood tracker, and a journal).

Figure 1. Main pages and appearance of the IMAGINATOR 2.0 app. The top panel shows the main imagery dashboard with all imagery audios for young people to practice (top left) and the user journey to selecting a subgroup of imagery audios ("coping strategies"), a specific audio to listen to ("walk in sunny park"), the mascot support, and giving feedback on the imagery exercise. The bottom panel illustrates the Journey tab, where the young people can track mood, notes, and goals, and the mood rating functionality: from selecting an emoji, to rating the feeling intensity, adding notes, and reviewing activities and mood. Additional tabs included Support, with crisis support resources, where young people can also add personal phones from people in their contacts, and Settings, where young people have the option to enable reminders for practicing mental imagery and logging mood.



Participants and Recruitment

Participants were recruited from Child and Adolescent Mental Health Services Tier 2 services and Mental Health Integrated Network Teams (adult community) in West London NHS Trust. Potential participants were identified and initially approached by their treating clinicians. Participants were eligible if they had experienced at least 2 SH episodes (an occurrence of SH perceived as distinct in time, precipitants, motives, initiation, and conclusion) in their life with at least 1 SH episode in the past month, or at least 5 SH episodes in the past year and currently reporting SH urges (self-report of wanting to engage in SH); had a smartphone; were fluent in English; and were willing to provide informed consent. Participants were excluded if they had a severe learning disability or pervasive developmental disorder, a current acute psychotic episode, current substance dependence, high risk of suicide or harm to others (based on clinicians' risk assessment), or were taking part in concurrent treatment studies for SH or in concurrent psychological therapy.

Procedures

Recruitment took place over 9 months from November 2022 to September 2023. Potential participants completed a baseline screening either in person or via Microsoft Teams video call (depending on participant preference), including assent or

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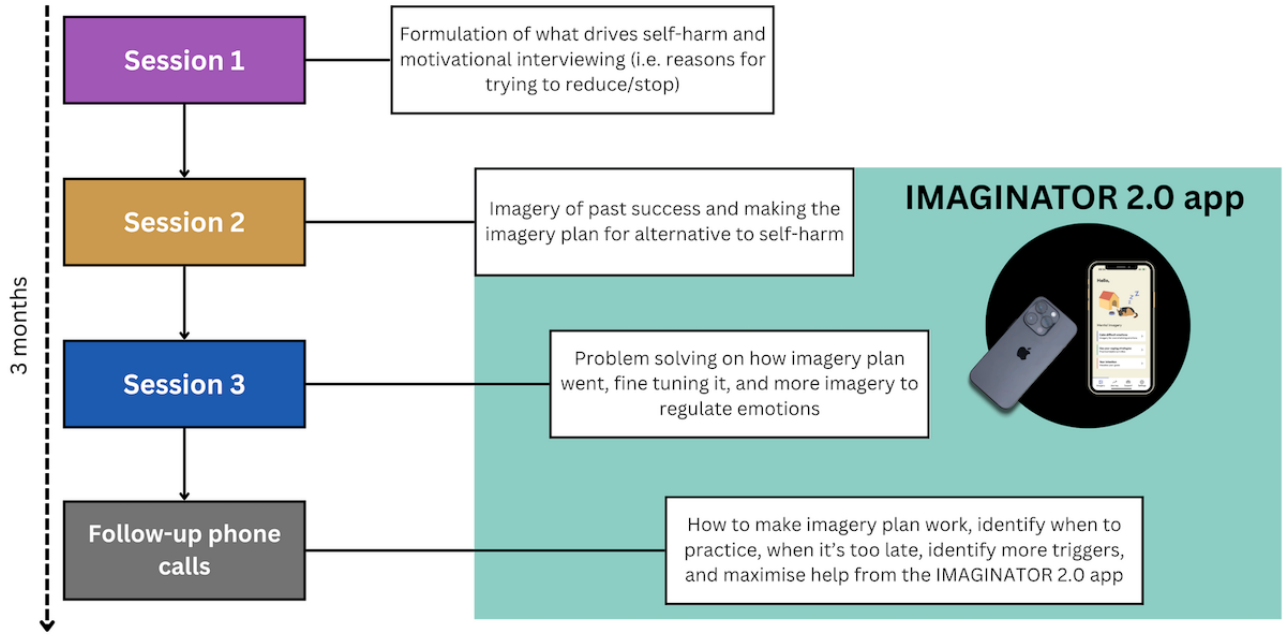
consent taking, sociodemographic characteristics (age, gender, ethnicity, sexual orientation, education, employment, and socioeconomic status), and the measures listed below using Qualtrics online surveys.

Intervention

Eligible participants were assigned a therapist from the referring team (clinical psychologists, children and well-being practitioners, clinical assistant psychology therapists, or graduate mental health workers). These are psychology or mental health graduates with varying levels of postgraduate training (from none, graduate mental health workers, to 1-year CBT training, children and well-being practitioners, to 2 years' Master's-level training, clinical assistant psychology therapists, to clinical doctorate for the clinical psychologist). IMAGINATOR 2.0 consisted of the co-designed IMAGINATOR 2.0 app, three 1-hour FIT sessions in person or via Microsoft Teams once a week, and five 15- to 30-minute support phone calls fortnightly delivered after the three 1-hour FIT sessions. FIT comprised three main sessions: (1) session 1 completes an individualized formulation of personal drivers of SH behavior and a motivational interview on SH reduction combined with mental imagery techniques. (2) Session 2 starts with a mental imagery exercise of a past achievement to increase self-efficacy. This is followed by setting personal smart goals that include both directly targeting SH (eg, engaging in a desired behavior incompatible with or alternative to SH) and targeting other processes or symptoms that have been linked to SH in the formulation (eg, engaging in a behavior that reduces anxiety or rumination). Finally, a functional imagery plan is developed to achieve the goals. (3) Session 3 practices and refines the functional imagery and problem solves any challenges. The IMAGINATOR 2.0 app was introduced in session 2. The app's key feature is mental imagery audios to support practicing the functional imagery plan at home, alongside affect and goal-tracking functions. Therapists encourage exploring which audios to use when tailored to individual needs (eg, different audios for different affect states). Follow-up phone calls focused on refining functional imagery practice, problem-solving, motivational encouragement, and personalization of the app use (Figure 2). The therapist also conducted a risk assessment at the beginning of each session or call.

Figure 2. Overview of IMAGINATOR 2.0 intervention FIT sessions.



Therapists were trained in the delivery of IMAGINATOR 2.0 over 2 workshops (1.5 days in total), provided with a manual, and supported via weekly group supervision over Microsoft Teams with the study principal investigator (MDS) and the research assistant (AS). During supervision, therapists illustrated individual cases and were guided by MDS to maintain adherence to the treatment protocol. Therapists also discussed strategies to address emerging challenges, including how to adapt and tailor FIT around each individual's needs and maintain engagement with the app.

Outcome Assessments

Participants completed the outcome assessment after the final phone session (approximately 3 months from baseline) via Microsoft Teams video call and followed the same procedures and measures as the baseline assessment. All were then invited to further expand on their answers in a semistructured interview about their experience using IMAGINATOR 2.0 [34].

Focus Groups

Given the absence of previous qualitative studies on using a digital imagery–based intervention for SH and the heterogeneity of therapists (different training and service lines), we chose a focus group format so that therapists could share and reflect on their experiences and be exposed to different viewpoints, facilitating a broader exploration of themes and depth of discussion. Therapists were invited to discuss their experience in delivering IMAGINATOR 2.0 across 2 parallel focus groups that took place in person in a private room on December 8, 2023, and December 13, 2023, respectively, on a university

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campus. They took approximately 2 hours and were cofacilitated by the principal investigator (MDS) and 2 other researchers (AS and EGB). A semistructured interview guide with open-ended questions was coproduced with the Young Person Advisory Group and used to guide discussions (Multimedia Appendix 1). Topics included barriers to adopting the intervention, perceived benefits, and suggestions for improvement. The sessions were audio-recorded with therapists' consent, transcribed verbatim, and anonymized. Field notes were also taken by the assisting researchers (AS and EGB) to capture nonverbal cues and group dynamics.

Measures

The primary outcome was feasibility and acceptability. Feasibility was measured by attrition rate (percentage of enrolled eligible participants completing outcome assessment) and treatment adherence (percentage of participants completing intervention per protocol, ie, 5/8 sessions). Acceptability was captured using the Client Satisfaction Questionnaire [36] and the User Experience Questionnaire [37] (Multimedia Appendix 2). Adverse events, defined as any untoward medical occurrence in a participant, were recorded at each assessment and therapy session. Serious adverse events were immediately reported by research assistants or therapists to the principal investigator (MDS), who discussed relatedness to the study procedures with the relevant clinical team.

Secondary outcomes included change in SH frequency and severity over the past 3 months, assessed as per the following measures:

1. SH frequency over the past 3 months: SH frequency was measured via the Timeline Follow-Back interview [33,38]. In this interview, the researcher reconstructs together with the participant the number of discrete SH episodes using calendar cues. The scale records the total number of SH episodes within a specified timeframe. The minimum number of episodes is 0, and the maximum number of episodes that can be reported for the 3 months is every day (around 90, depending on the number of days of the month). It has been successfully used in previous research measuring behavioral outcomes, such as in addiction studies and our proof-of-concept study [33]. We selected the Timeline Follow-Back technique, as the calendar-cued method aids better precision in recollecting SH retrospectively than a simple self-report questionnaire.
2. SH severity over the past 3 months: SH severity was measured using a Visual Analog Scale, severity criteria used in the nonsuicidal self-injury disorder in the *DSM-5 (Diagnostic and Statistical Manual of Mental Disorders* [Fifth Edition]) [39] and the number of different SH methods used (also termed SH versatility), elicited via these open questions: "In the last three months, how severe was the worst injury that you inflicted to yourself? Can you list all the ways that you have used to harm yourself in the last three months?" This method was advised by the Young Person Advisory Group to avoid scales listing numerous SH methods, which could be triggering or enabling.

Other secondary outcomes were the (1) Self-Harm Imagery Interview adapted from Di Simplicio et al [33] and Hales et al [40], the State Motivation for Reducing Self-Harm scale [41], the Craving Experience Questionnaire for Self-Harm, adapted from Craving Experience Questionnaire [42], the Revised Children's Anxiety and Depression Scale [43] for participants aged 12-17 years and via the Depression, Anxiety and Stress Scale [44] for participants aged 18-25 years, the Warwick-Edinburgh Mental Well-being Scale [45], the Difficulties in Emotion Regulation Scale-Short Form [39], the 11-item behavior supplement to the Borderline Symptom List [46], the Alcohol Use Disorders Identification Test [47], and the Cannabis Use Disorder Identification Test Revised [48]. Rationale and description of full scales are reported in Multimedia Appendix 2.

Analysis

Quantitative Data

Given the feasibility nature of the study, all quantitative data are reported as descriptive statistics with median values and IQRs, as data were not normally distributed. Effect sizes were calculated as r=z/N [49]. The interpretation of effect sizes was guided by Cohen *d* rule of thumb, where 0.2 denotes small, 0.5 medium, and 0.8 a large effect size [50].

Attrition, adherence to therapy per protocol, and number of therapy sessions completed are reported as counts and percentages. To explore the relationship between adherence to therapy and various demographic variables, we conducted a Mann-Whitney *U* test comparing the average number of therapy sessions completed between age, ethnicity, and sexual orientation groups.

Due to the small sample size, missing data were tolerated, and we assumed that the data were missing completely at random. Pairwise deletion was used to handle missing data. Out of 15 participants who completed the outcome assessment, data were missing from 1 participant over 5 measures (11-item behavior supplement to the Borderline Symptom List, Revised Children's Anxiety and Depression Scale, Alcohol Use Disorders Identification Test, Cannabis Use Disorder Identification Test, and Difficulties in Emotion Regulation Scale-Short Form), 1 participant in 1 measure (State Motivation for Reducing Self-Harm scale), and 1 participant in another measure (Warwick-Edinburgh Mental Well-being Scale), due to surveys not being correctly saved on Qualtrics.

Qualitative Data

Qualitative data from the focus groups were analyzed using a coproduced reflexive thematic analysis approach guided by Braun and Clarke [51] and Dewa et al [52]. More details on reflexivity are reported in Multimedia Appendix 2. First, 2 researchers (AS and EG) familiarized themselves with the transcripts by reading and rereading them. Then, these 2 researchers coded the transcripts line by line independently. A Trello board was used to collate the initial codes separately added by both researchers, so that all team members could review these. Codes were then incorporated into a coding framework. The research team (MDS, LD, AS, and EG-B) and the coresearchers (SM, AMD, and NC) met twice online in April 2024 to review, refine, and finalize codes. We grouped codes based on shared meanings and continuously combined

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them until subthemes were formed with no repetitions. We then assigned provisional theme names and connected them to the subthemes. Once all themes and subthemes were finalized, we transferred them into Miro (RealtimeBoard, Inc) and reviewed them in isolation until we formed one final thematic map.

Ethical Considerations

The study was approved by the West of Scotland Research Ethics Committee (Research Ethics Committee reference number 22/WS/0087) and the Health Research Authority. In accordance with UK legislation, participants aged 16 years and older provided informed consent prior to participation after a full explanation was given. For those aged 12-15 years, assent was obtained alongside parental or guardian consent. All participants were free to withdraw from the study at any point without giving reasons. All data processing procedures were in compliance with the UK Data Protection Act 2018. Data were pseudonymized. Participants received GBP £10 (US $13.49) per hour reimbursement in electronic vouchers for the outcome assessments and feedback interview (GBP £30 [US $40.48] overall).

Results

Sample

Sample demographics are reported in Table 1. Clinical characteristics are reported in Tables S1 and S2 in Multimedia Appendix 3. Among all participants (N=29), 21 (72.41%) reported experiencing suicidal ideation in the past month (assessed on the Columbia-Suicide Severity Rating Scale [53]) with 15 (51.72%) reporting active suicidal thoughts, 3 (10.34%) a specific plan and intent to act on the plan, and 3 (10.34%) suicidal attempts in the past month. Two participants had missing data on the Columbia-Suicide Severity Rating Scale during baseline.

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Table 1. Demographic characteristics of eligible participants at baseline assessment (N=29).

Characteristics	Values
Age (years), mean (SD[a])	18.86 (3.74)
Gender, n (%)	
Woman	28 (96.55)
Transgender	1 (3.45)
Sexual orientation, n (%)	
Heterosexual	12 (41.38)
Other	12 (41.38)
LGBTQ+[a]	3 (10.34)
Not sure	2 (6.90)
Ethnicity, n (%)	
White	17 (58.62)
Black, African, Caribbean, or Black British	4 (13.79)
Mixed or multiple ethnic groups	3 (10.34)
Other ethnic group	3 (10.34)
Asian of Asian British	2 (6.90)
Household income (GBP[b]), n (%)	
<50,000	18 (62.07)
50,000-100,000	9 (31.03)
100,000-150,000	1 (3.45)
150,000-200,000	1 (3.45)
Highest level of education completed, n (%)	
Secondary education	13 (44.83)
Primary education	8 (27.59)
Higher education	7 (24.14)
Postgraduate education	1 (3.45)
Currently in education training, n (%)	
No	15 (51.72)
Yes	14 (48.28)
Currently employed, n (%)	
No	15 (51.72)
Yes	14 (48.28)

[a]LGBTQ+: lesbian, gay, bisexual, transgender, queer or questioning, and other sexual and gender minority persons.

[b]1 GBP=US $1.35.

Feasibility and Acceptability

Overall, 83 patients were referred to the study, of which 29 (34.94%) were both eligible and completed baseline screening (Figure 3). Out of these 29 patients, 27 (93.10%) started therapy. Out of the 27 who started therapy, 16 (59.3%) adhered to therapy per-protocol (all face-to-face sessions and at least 2 phone calls), 19 (70%) completed all face-to-face therapy sessions, and 9 (33.3%) completed all 5 follow-up phone calls. On average, the waiting time to start the intervention (see “Allocation”; Figure 3) was 4 (SD 2; range 0.7-9) weeks, while the average intervention duration was 21.3 (SD 6.9; range 9.7-36) weeks. Out of the 27 participants who started therapy, only 15 (55.6%) completed the follow-up outcome assessment.

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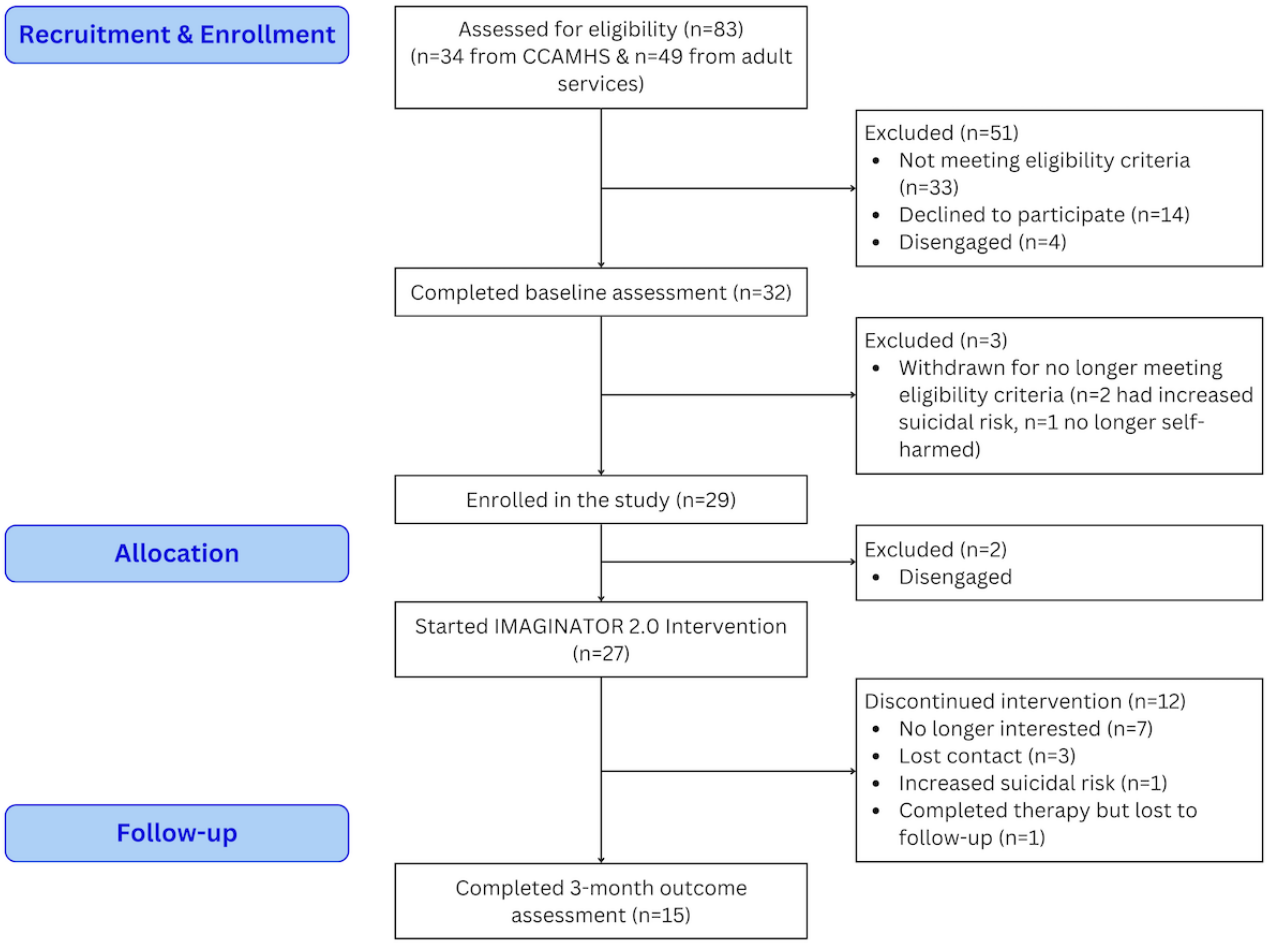
Figure 3. Flow diagram of participants in the IMAGINATOR 2.0 study. CAMHS: Child and Adolescent Mental Health Services.



The average number of therapy sessions completed out of the 3 face-to-face sessions and 5 follow-up phone calls (8 sessions total) was 4.93 (SD 2.80) and it significantly differed by sexual orientation with lesbian, gay, bisexual, transgender, queer or questioning, and other sexual and gender minority participants completing a higher number of sessions compared to heterosexual participants (Mann-Whitney *U* test=39.5; *P*=.01). No other demographic variable such as age or ethnicity differentiated therapy adherence.

Participants reported a median score of 25 (IQR 22-27.5) on the Client Satisfaction Questionnaire, indicating a very good satisfaction with the intervention received. Ratings on the User Experience Questionnaire referring to the app indicated good levels of perspicuity (median 1, IQR 0.5-2) and dependency (median 1.25, IQR 0.38-2), acceptable levels of attractiveness (median 1, IQR 0.25-1.83), but low levels of efficiency (median 1.25, IQR –0.13 to 1.5), stimulation (median 0.75, IQR –0.38 to 1.13), and novelty (median 0, IQR –0.5 to 1.13).

Secondary Outcomes

SH episodes reduced from a median of 7 (IQR 3.5-21.5) over the past 3 months at baseline to a median of 0 (IQR 0-7) over the past 3 months after IMAGINATOR 2.0 across all participants (effect size [*r*] 0.69, medium). Figure 4 shows participants categorized by age group.

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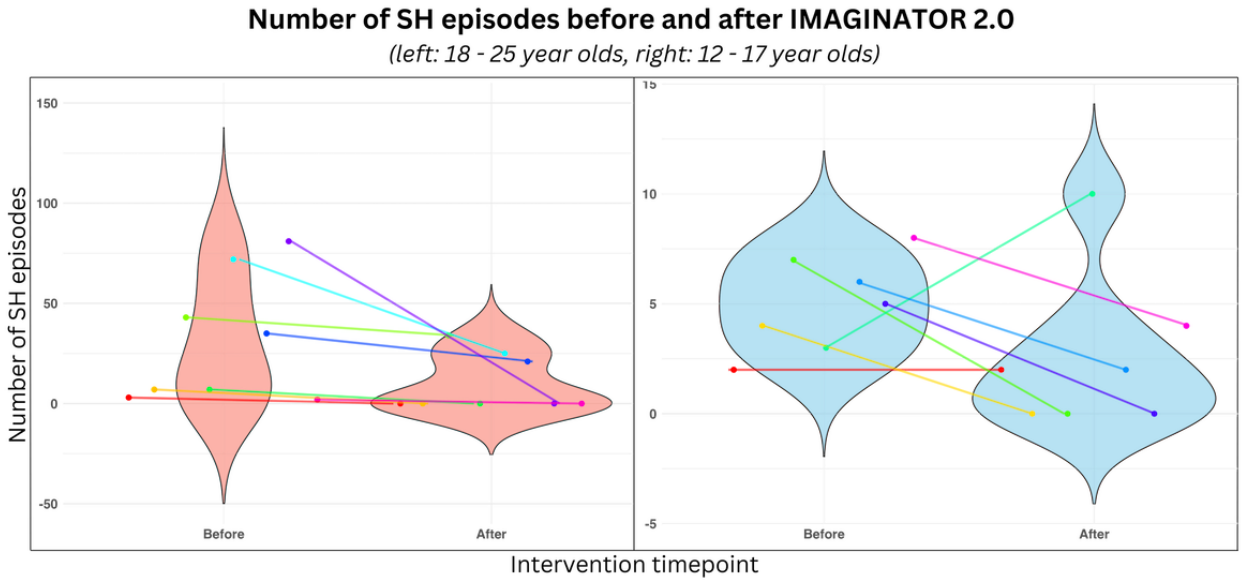
Figure 4. Number of SH episodes pre- and postintervention in 15 participants who completed both baseline and outcome assessments, grouped by age into Child and Adolescent Mental Health Services (<18 years old) and Mental health Integrated Network Teams (≥18 years old). Each participant was color-coded.



Changes in clinical secondary outcomes are reported in Tables S1 and S2 (Multimedia Appendix 3), showing a reduction in craving for SH and an increase in participants' motivation to reduce SH. Depression, anxiety, and stress also reduced in participants aged 18 years or older, while well-being and emotion regulation skills scores increased. Two participants reported increased suicidal risk between the baseline assessment and the start of the therapy sessions and were referred to a more intensive support team and consequently withdrew from the study. There were 98 adverse events during the study duration, corresponding to the number of SH episodes reported from baseline to the 3-month outcome assessment. One participant reported an increase in the number of SH episodes from baseline to outcome assessment (Figure 4). There were no serious adverse events, and no other adverse events were reported during the study.

Qualitative Analysis From Focus Groups

Overview

All 8 therapists took part in feedback focus groups: 2 clinical assistant psychology therapists, 2 graduate mental health workers, 1 assistant psychologist from adults services, 2 children and well-being practitioners, and 1 clinical psychologist from adolescent services. Thematic analysis identified six themes: (1) shifting self-perception through guided mental imagery, (2) empowering autonomy through accessible digital support, (3) balancing the potential and boundaries of mental imagery, (4) facilitating effective therapy through professional guidance, (5) adapting technology to complement care pathways, and (6) bridging expectations and experience for meaningful impact. Connections between themes and subthemes are conceptualized in a coproduced thematic map (Figure 5).

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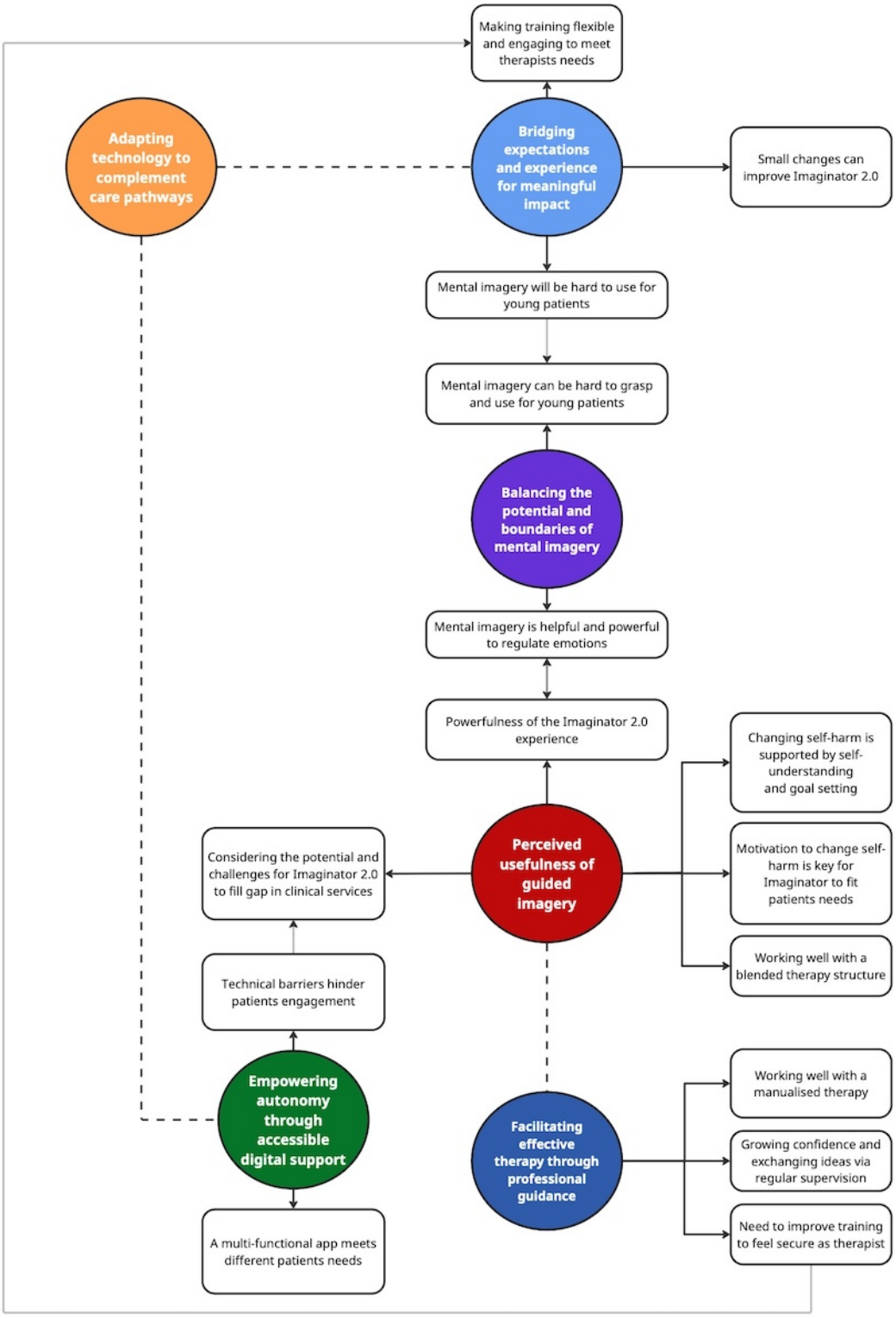
Figure 5. Coproduced thematic map of therapist focus group feedback. Solid arrows indicate the relations between each main theme and its corresponding subthemes, dashed lines represent conceptual links between main themes, and dotted arrows illustrate connections between subthemes across themes.



Perceived Usefulness of Guided Imagery

All 8 therapists reported that IMAGINATOR 2.0 was a powerful experience for patients that gave them an opportunity to understand SH beyond just risk assessments. For example, many therapists reported that it filled a critical gap in service provision, offering a needed short-term intervention targeting SH for young people that could reduce waiting times for this group. Many therapists commented that IMAGINATOR 2.0 equipped young people with coping skills to manage their SH and prevent escalation, and this could also help while waiting for more intensive therapy. Therapists also expressed that, preferably, there should not be a wait for IMAGINATOR 2.0 itself.

> *I think IMAGINATOR 2.0 was a really brilliant experience [..] Having [a] kind of a short-term therapy to reduce self-harm has been really helpful*

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> *for my participants and they said they found it really useful.* [Therapist ID: 6]
>
> *Self-harm can escalate even though people are involved with [mental health services]. So, participants need something to just sort of contain the self-harm and IMAGINATOR 2.0 can do that quite well.* [Therapist ID: 1]

Most therapists agreed that patients referred to IMAGINATOR 2.0 should have the primary goal to change their SH behavior, or they may disengage from the intervention. Some felt that offering IMAGINATOR 2.0 to young people older than 14 years is preferable to younger children to make the concept of mental imagery easier to grasp. Others suggested that a longer history of SH could facilitate self-awareness and engagement. Understanding SH and goal setting were viewed as the key components of the therapy by almost all therapists.

> *I think understanding the self-harm and goal setting [are key components of the therapy] because that is what is going on and for them that was a big problem. Understanding what would be helpful for them.* [Therapist ID: 3]
>
> *If the self-harm was not such a big issue for them, they may not be as engaged and benefit from it as much, I guess.* [Therapist ID: 5]

Most therapists found the blended therapy approach (in-person, app, and calls) a good structure catering for patients' different needs. However, some therapists reported patients were often distracted during phone calls and these sessions were not as efficient as face-to-face.

> *Overall, I sort of like the structure. I think it's sort of slowing down and basically having a repeated structure towards the end makes sort of the ending easier.* [Therapist ID: 2]
>
> *It's just chaotic because you can hear in the background, they are playing video games or they're doing something else […] So I think that's a normal experience of phone calls with young people. And I think that's probably not as helpful for IMAGINATOR 2.0.* [Therapist ID: 1]

Balancing the Potential and Boundaries of Mental Imagery

All therapists highlighted that mental imagery was a powerful tool to regulate emotions and target the personalized goals set by young people. This was despite some young people finding it difficult to grasp and practice, and it had a mixed impact on SH for young people. Other key strengths of mental imagery reported across therapists included having the freedom to practice it anywhere at any time, the collaborative process of trial-and-error with the patient to identify the most helpful adaptive image, and the likelihood of them adopting mental imagery techniques in their future routine sessions with patients. A few therapists noted that mental imagery could elicit negative emotions, which occasionally led to other distressing or negative imagery.

> *One young person's goals had more to do with social anxiety. They seemed to find it very useful to picture themselves in situations that they expected to find challenging and to actually vividly imagine themselves coping and having worked out what they would do in these situations. They found that helpful. It was a very collaborative process.* [Therapist ID: 8]
>
> *One of my participants sometimes found it hard to kind of stay on the image that she wanted. And her mind started to wander. And it started to go to negative places.* [Therapist ID: 7]
>
> *So even though they felt like mental imagery wasn't something that they like […], I think it just highlighted to them that if they set a goal, they can actually solve it, you know, work towards that goal, which I think was really helpful as well.* [Therapist ID: 4]

Bridging Expectations and Experience for Meaningful Impact

Most therapists expressed initial hesitation about using mental imagery as a tool to reduce SH in their patients. There was also some skepticism around how best to explain mental imagery and how it would work, and concern about the young age of patients being a barrier to understanding and using mental imagery techniques. For most, these negative expectations had dropped by the end of the intervention based on young people's positive response to using imagery.

> *At the beginning, I was slightly sceptical, and I didn't understand everything about the research. I was just wondering how helpful it could be and thinking in terms of imagery and how it would work. But then, after working with my first participant and recognising how she enjoyed it and how it was really working for her, I kind of changed the opinion I had initially.* [Therapist ID: 7]
>
> *So, the idea of using imagery seemed quite a compelling approach but I did find it quite challenging to deliver. Which I think was connected with the age group that I was working with.* [Therapist ID: 8]

Some therapists highlighted the need to focus on regulating emotions more directly, in addition to indirect approaches, to deal with SH urges. One therapist suggested integrating IMAGINATOR 2.0 as part of routine safety planning and training more people from the team to deliver it as an SH relapse prevention measure.

> *Using mental imagery as more than just an ad hoc tool for managing self-harm during my therapy sessions, has actually been quite effective with young people [outside IMAGINATOR 2.0]. When doing our routine safety plan, we discuss how they can use imagery. This could be part of our toolkit that we use in safety planning maybe.* [Therapist ID: 1]
>
> *Maybe first they do the managing emotions group to learn how to deal with difficult emotions and then if self-harm is still an issue put them on IMAGINATOR 2.0.* [Therapist ID: 5]

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Facilitating Effective Therapy Through Professional Guidance

All therapists found the manual practical and a useful tool to prepare for sessions. They also found regular supervision sessions helpful, a safe space, and a learning session via hearing other people's experiences. When faced with a challenge, supervision allowed for identifying alternative routes to approach a patient.

> *It was nice to have that sort of side [the manual] and the sense of knowing what direction to take to session. Sometimes with my client I found that we followed the manual a little bit but it's flexible in the sense that we don't have to sort of stick to the manual exactly. So, it's quite helpful to have it there.* [Therapist ID: 5]

Most therapists found the 1-day workshop training informative, but were left with uncertainty around what the actual therapy was going to look like. For example, some reported that they only understood aspects of the training when they finally conducted their first therapy session, whereas others found the information to be overwhelming without sufficient previous therapy experience. Most therapists suggested improvements, such as splitting the training over 2 days, increasing role-plays, practicing mental imagery techniques, and having video resources to refresh information.

> *I really enjoyed the training. The little consolidation training we did closer at the time, was really helpful because it was like more role play. So, seeing how you would actually use the app and having like visual example of that and how conversation could go even though we had the scripts, it was just easier to kind of see how it would be like in an actual session. That I found that really helpful.* [Therapist ID: 7]

Empowering Autonomy Through Accessible Digital Support

Most therapists reported that the IMAGINATOR 2.0 app was user-friendly and age-appropriate. The audios were the most frequently accessed app feature, while mood logging was also useful for young people. Therapists valued the app to have multiple components, but opinions varied around which component should be defined as the key one: guided imagery audios, the support section, or the goal section.

> *The participant... had quite a positive reaction to the app, and she used it between sessions as well. I think for her it was quite helpful because it reminded her to use imagery even outside of our sessions...I think she found the box audio quite helpful. Mood logging was helpful. She was able to see that she had more good days than she actually thought.* [Therapist ID: 5]

> *The audios were the most helpful for one of my participants. She didn't use the app much, but she found audios helpful. So, the safe bubble and the other ones she did explore them in her free time a few times. I wouldn't say it was regular, but she did listen to them.* [Therapist ID: 6]

Therapists noted that a few young people were excited to use the app. However, they reported that the young people felt a major challenge was technical difficulties, which prevented young people from engaging further with the app outside therapy sessions, and a few patients abandoned the app because of these. For example, the screen goes black, and young people need to uninstall and reinstall the app a couple of times. Few therapists believed that the app should have more personalization to address patients' needs, as individual preferences could hinder engagement. For example, some patients found the voices or accents in the audios to be jarring, which led them to stop using them.

Adapting Technology to Complement Care Pathways

Most therapists highlighted that the app needs to be more actively integrated within therapy sessions, which may help participants associate the in-session use and independence practice, potentially enhancing engagement and use outside of sessions: this could be done by having one more dedicated face-to-face session to guide patients through the app and reinforce its use.

> *We should sit down and see things together because sometimes they don't do it on their own or they have difficulties with tracking mood etc. My young person was excited to use the app. Even though their initial reaction was positive, exploring it on their own did not work.* [Therapist ID: 3]

> *I think it would be easier to start using the app or have things to do in the app from all the face-to-face sessions because it kind of consolidates it every week. So, if there's some activity or task to do on the first session, in the second session, and then in the third session, and having them recording it, kind of sets them up for when they're going off by themselves, and then we can consolidate it further when we're doing the phone calls. I think it would make it a lot easier for them to not forget the app and actually kind of integrate it more into the module. Whereas right now it kind of feels like two separate things.* [Therapist ID: 7]

A few therapists thought that using an incentive system could encourage patients to use the app more. For example, making the app visible and accessible on the patient's phone was important; improving the prompts or notifications system, and for the therapist to record audios were other suggestions.

> *Thinking about just different avatars for themselves. So, people having their own kind of avatar that they could create, you know? As you would in a game with different codes and hair and all of that, that would be a fun option. Make it more personal to them...* [Therapist ID: 6]

Discussion

Summary of Findings

This study extends our previous proof-of-concept trial [33] of an imagery-based intervention in young people who SH. Our study shows that FIT is, in principle, acceptable and safe. FIT

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also has potential at reducing SH behaviors in young people via a blended digital therapy approach. Therapists reported that IMAGINATOR 2.0 overall had a positive impact on young people's coping skills to manage SH. They assessed mental imagery as a helpful technique, although some young people may find it difficult. Therapists also valued the app as a useful tool but suggested various areas for improvement. These results should be treated with caution, given key limitations in our study, such as the small sample size and absence of a comparator intervention. Areas of uncertainty around acceptability also remain, as our results may have been biased by participants who disliked the intervention dropping out of the study. We also highlight feasibility challenges that need addressing in future studies.

Feasibility of IMAGINATOR 2.0

We replicated the recruitment rate of our previous study [33], consistent with other blended digital [54] and SH [16,55] interventions, and consistent with therapists' views that IMAGINATOR 2.0 fills a gap in available interventions to support the high presentation of young people who SH [56]. In line with our previous study [33] and other brief CBT interventions for SH, adherence to face-to-face therapy was satisfactory (70%) [57,58]. Instead, the attrition rate (48.3%) was higher than expected and higher than that reported for other fully digital interventions for SH, which showed lower dropout rates (15% and 28%, respectively) [16,17]. Most dropouts happened after the completion of the 3 face-to-face sessions, possibly suggesting that participants might have perceived phone call sessions as less beneficial or engaging compared to face-to-face interactions. Therapists emphasized how phone calls can be distracting for both participants and them, which is consistent with previous literature, suggesting a lack of control of the environment during phone calls [59]. A few dropouts occurred early after session 1, perhaps as the motivational interview selected those still in a contemplative phase of behavior change [60]. We also observed that a few participants dropped out prior to starting therapy. Importantly, long waiting times between enrollment and starting the therapy sessions (due to the lack of promptly available therapists in the service) might have led to a change in needs [61,62]. For example, some young people declined starting therapy as they had not self-harmed since the baseline assessment, whereas 2 adolescents experienced increased suicidal risk while waiting for therapy and were moved to a different team. As emphasized by our therapists, SH has to be the patient's main concern. Previous literature suggests that ambivalence around reducing SH is often present while not necessarily overt [57], and this ambivalence could persist during long waiting periods or emerge after the first therapy session. Consideration of how motivation is better explored in screening suitable participants should be included in future studies. Objective markers of motivation to stop self-harming (eg, cognitive tasks) not relying on self-report may bypass the risk that young people start therapy because they feel that "they have to," and lead to more personalized approaches [63].

High attrition could be explained by the fact that participants disengaging from therapy after a few sessions were also lost to outcome assessment: a common occurrence in psychological interventions' research [64,65]. As in other studies, the overlap between attrition and poor treatment adherence hindered our efforts to understand the reasons behind dropouts. Over the study duration, we noted that consistency in the research team conducting assessments and keeping in touch with participants during the intervention with brief messages improved retention. A highly variable duration of the intervention (between 9.7 and 36 weeks), with some participants experiencing several weeks' gap between sessions, may also have facilitated disengagement.

Finally, it is important to note that IMAGINATOR 2.0 was delivered by clinicians trained in low-intensity therapies rather than highly specialized psychologists (except one), which increases its feasibility in the context of low-resource availability in mental health services.

Acceptability of IMAGINATOR 2.0

The absence of serious adverse events and only one case of SH deterioration suggests that IMAGINATOR 2.0 is a safe intervention for young people who SH but have a low-to-moderate risk profile at the point of enrollment. Both participants' quantitative satisfaction ratings and therapists' views indicate that our intervention was acceptable and well-received. Adherence rates also indicate good acceptability of the therapy sessions, while engagement dropped for follow-up calls, suggesting these could be reduced or made optional. Overall, the IMAGINATOR 2.0 app was reported to be reliable, intuitive to understand, and attractive to both by young people and therapists. Young people's low ratings of apps' stimulation were reflected in some therapists' suggestions around adding gamification or further personalization. Overall, this supports the idea that an app can enhance control and autonomy over one's own care, which appears key in learning to manage SH behaviors [66]. Integrating therapists' suggestions in future app versions could improve this by sustaining engagement with the app.

Therapists strongly supported our blended digital approach to reduce SH in young people but recommended a more structured integration of the app in the therapy sessions. Importantly, the need for better integration was also shared by young people [34]. This possibly reflects an ongoing challenge in maximizing the potential of academic-led digital technology for therapeutic interventions, with apps failing to show superior efficacy to standard care so far [17].

Mental Imagery

Therapists perceived IMAGINATOR 2.0 as impactful and mental imagery as a useful tool to target young people's goals, although our study was not able to test a causal link between the two. Our findings of reduced emotional dysregulation scores, reduced craving to SH, and higher motivation to stop self-harming support that mental imagery could be a cognitive process able to regulate emotions and motivation away from maladaptive and toward adaptive behaviors [67]. However, in the absence of a control arm, these psychopathology improvements cannot be attributed to the intervention. In the context of growing evidence on the efficacy of targeting distressing involuntary imagery or harnessing the power of helpful imagery in anxiety and depression [68], further testing

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of IMAGINATOR 2.0 should be conducted. Importantly, therapists' view of the intervention and imagery also matches young people's subjective experience that IMAGINATOR 2.0 produces an emotional and behavioral change [34].

The mechanism by which FIT may reduce SH remains to be tested. It is possible that FIT's personalized imagery plan simulating a way out of distress may work by diminishing the sense of entrapment, a recognized motivational factor in SH [69]. Alternatively, FIT could work by offsetting SH mental imagery [22]. Another advantage of our approach is that the content of functional imagery is highly personalized to each individual's formulation of their idiosyncratic SH functions, from "reducing distress" to "feeling something" [70,71]. Importantly, this personalization reflects recent guidance to approach SH in a more individualized way [15]. Interestingly, therapists felt that key elements that made the intervention "work" were young people understanding their own SH formulation and improving goal-setting ability, in keeping with the importance of personalization and including positive values in interventions [72]. They also described that the most used feature of the app was mental imagery audios.

Importantly, therapists initially anticipated that mental imagery would be difficult to implement, especially in younger participants, as they would find abstract concepts difficult. This was true in reality with those younger than 14 years. In fact, research suggests that vividness in mental imagery relies on both long-term and working memory, which may not be fully developed before the age of 14 years [73,74]. This may explain why younger individuals struggled more with controlling and altering mental images consistent with their cognitive and emotional developmental stage [75]. However, mental imagery techniques have been found effective in participants as young as 14 years [76,77].

Therapists stressed the importance of regular rehearsal of the mental imagery plan via the app. A better integration between app and therapy may address this by specifically setting exercises that boost mental imagery's motivational elements, and via repeated pre-experiencing of positive emotions and desired outcomes. This would ensure participants enhance their ability to manage distress via imagery before reaching a crisis point [78]. Finally, therapists suggested that more direct targeting of emotion regulation, per se, would improve IMAGINATOR 2.0. This suggestion reflects young people wanting to target underlying difficulties, for instance, emotional dysregulation, rather than caring about reducing SH [79]. A focus on emotion regulation is also supported by the recent evidence on the efficacy of ERITA, a web-based emotion regulation program, at reducing SH episodes [16]. On the other hand, other factors may contribute to SH, and emotional dysregulation only explains parts of SH's persistence [80,81], favoring IMAGINATOR 2.0's individualized approach.

Limitations

The small sample and absence of a comparator arm limit the interpretation of our findings. In the absence of a control arm, a reduction in SH behavior could be secondary to passage of time, concurrent interventions such as medication, or nonspecific factors such as additional human contact provided by the study participation rather than the intervention content. The study was conducted in a single location, and mostly had participants identifying as females, which also limits generalizability. As most participants who stopped therapy early did not complete the outcome assessment, we have poor insight into barriers to engaging in IMAGINATOR 2.0. Other limitations include the absence of a specific adverse effects measure and the lack of a formal assessment of therapists' adherence to the treatment protocol.

Future Directions

Notwithstanding its limitations, this early evaluation combines the strength of both qualitative and quantitative methodology, a strong lived experience input, and a manualized treatment delivered by multiple staff across routine services. Future studies should now test the efficacy of IMAGINATOR 2.0 in a randomized controlled trial after considering design changes to improve feasibility and acceptability, such as higher monetary incentives and more continuous research staff contact to encourage participation in outcome assessments; therapists employed as trial staff to avoid delays in therapy start, an additional face-to-face session but less follow-up sessions, or follow-up video instead of phone calls to better maintain the therapeutic connection [82]. Another strength is the development and evaluation of IMAGINATOR 2.0 based on the epidemiology of SH (mean age of onset at 14 years old, and peak prevalence at 16-25 years old) rather than the traditional 18 years cutoff, in line with the new framework of youth mental health [83]. If future randomized controlled trial confirms that age is not associated with outcomes, this may ease the future implementation and access to IMAGINATOR 2.0, overcoming the limitation of services' age constraints. However, certain adjustments by age should be first implemented in the IMAGINATOR 2.0 app, so that visual and engagement aspects are suitable for both young adolescents and young adults [34]. The intervention should also be tested in different community settings where young people initially seek help, such as schools, general practitioners, and nonstatutory services. As mental imagery–based techniques appear to be underused by children and adolescent therapists, in particular, it will be important to develop more training, including videos and interactive resources. The intervention manual should include more structured session-by-session guidance on when and how to facilitate use of the app.

It is also crucial to investigate IMAGINATOR 2.0's mechanisms of action: for example, testing if the intervention works by reducing SH mental imagery, if outcomes are influenced by individual cognitive characteristics (impulsivity or compulsivity) [84,85], and what app components directly influence treatment response. This will enable refining and personalizing the app design. Finally, given its general focus on emotion regulation and behavior change strategies, IMAGINATOR 2.0 could be adapted as an early intervention targeting a variety of dysregulated behaviors.

Conclusion

In summary, IMAGINATOR 2.0 is the first blended digital intervention developed with and for young people who experience SH behavior, in line with National Institute for

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Health and Care Excellence guidelines on the long-term management of SH [1]. Together with our previous findings [33], we provide initial evidence that IMAGINATOR 2.0 is safe and supported by clinicians to fill the current treatment gap for young people with SH in mental health services. Its brevity and low clinician input could make IMAGINATOR 2.0 highly scalable across a variety of health services, highlighting the potential impact of future efficacy testing. However, design adaptations are needed to conduct a successful randomized controlled trial.

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Data Availability

The datasets generated or analyzed during this study are available from the corresponding author on reasonable request.

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Writing - review & editing: AS (equal), MDS (equal), SM (supporting), AM (supporting), NC (supporting), RR (supporting), BA (supporting), NVZ (supporting), AH (supporting), LHD (supporting)

Conflicts of Interest

None declared.

Multimedia Appendix 1
Methods.
[DOCX File , 28 KB - formative_v10i1e79496_app1.docx]

Multimedia Appendix 2
Focus Groups Topic Guide.
[DOCX File , 20 KB - formative_v10i1e79496_app2.docx]

Multimedia Appendix 3
Results.
[DOCX File , 20 KB - formative_v10i1e79496_app3.docx]

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Abbreviations

CBT: cognitive behavioral therapy
DSM-5: Diagnostic and Statistical Manual of Mental Disorders (Fifth Edition)
FIT: functional imagery training
SH: self-harm

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Original Paper

Feasibility and User Experience of an AI-Supported mHealth Intervention for Remote Life Goal Setting Based on Flow Theory: Exploratory Within-Participant Study

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Abstract

Background: Life goal setting contributes substantially to well-being and quality of life, particularly among middle-aged and older adults. However, delivering remote goal-setting support remains challenging due to limited professional resources and accessibility barriers. Recent advancements in mobile health (mHealth) technologies, telemedicine, and generative artificial intelligence (AI) present new opportunities for scalable, personalized health behavior interventions. Nevertheless, few studies have compared AI-driven life goal interventions with conventional human-facilitated approaches in real-world settings.

Objective: This study aimed to evaluate the feasibility and user experience of an AI-supported mHealth intervention for remote life goal setting based on flow theory. We compared the AI-supported approach to occupational therapist (OT)–facilitated support and explored the differential characteristics of AI-guided and human-guided interventions for self-management and motivation enhancement.

Methods: An exploratory, within-participant, 2-condition comparison with a counterbalanced order was conducted among 28 community-dwelling adults (aged between 20 and 76 years) who were smartphone users. Each participant selected 2 personal life goals and completed remote adjusting the challenge-skill balance (R-ACS) sessions, a structured telemedicine process based on flow theory. One goal was supported by an OT, while the other was facilitated by a generative AI chatbot integrated into an mHealth platform. Following each session, participants completed a 4-item rubric-based questionnaire (5-point Likert scale), assessing the quantity and quality of questions, appropriateness of suggestions, and perceived contribution to goal attainment. Free-text feedback was also collected. Quantitative data were analyzed using Wilcoxon signed-rank tests with effect size calculations and Benjamini-Hochberg correction for multiple comparisons. Qualitative differences were explored using text mining (term frequency–inverse document frequency analysis) and sentiment evaluation.

Results: Both AI-supported and OT-facilitated R-ACS sessions were feasible and successfully delivered tailored suggestions for all participants. AI-supported sessions received higher scores on all rubric items than OT-facilitated sessions, with a statistically significant difference in suggestion appropriateness (z score=3.13; P=.002; r=0.418; false discovery rate–adjusted P=.008). Term frequency–inverse document frequency analysis of free-text comments revealed that AI-supported sessions emphasized actionability, motivation, and immediacy, while OT-facilitated sessions highlighted reflection, self-understanding, and emotional safety. Participants expressed high acceptance of both intervention types, with AI-supported interactions perceived as particularly accessible and conducive to health behavior change.

Conclusions: AI-supported mHealth interventions for remote life goal setting based on flow theory are feasible, well accepted, and offer potential advantages in immediacy, motivation enhancement, and action-oriented support. OT-facilitated support provides complementary strengths by fostering reflection and psychological safety. A hybrid R-ACS model that integrates both AI and human expertise may optimize personalized, scalable self-management support for life goal setting. Future randomized

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controlled trials are warranted to further investigate the long-term impact of AI-driven mHealth interventions on health behavior, well-being, and quality of life.

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KEYWORDS

mobile health; mHealth; artificial intelligence; AI; self-management; motivation; occupational therapy; telemedicine; health behavior

Introduction

Maintaining and improving the quality of life (QOL) among middle-aged and older adults is a critical issue in an aging society. In particular, having a sense of purpose and life goals has been reported to positively affect the physical and mental well-being of older adults [1-3]. For example, a cohort study by Goto et al [4] showed that older adults without a sense of purpose had significantly higher mortality risks than those with a sense of purpose, and having a sense of purpose also reduced the risk of future physical function decline. Thus, having life goals and a sense of purpose is closely associated with healthy longevity and QOL in middle-aged and older adults [4-6]. Against this background, comprehensive programs that address physical and psychosocial aspects have been explored as suitable interventions to prevent functional decline and improve QOL in older adults [7-9].

Currently, most preventive care programs focus on individual elements, such as exercise, nutrition, and cognitive function, and often combine these elements. However, these approaches make it difficult to comprehensively address the diverse life contexts of older adults and provide personalized support, and their effectiveness requires further examination. In this regard, occupational therapy emphasizes promoting participation in meaningful daily activities as a way to enhance health and well-being. For example, the Lifestyle Redesign program developed in the United States demonstrated significant effects on physical and mental health, occupational function, and life satisfaction among older adults through large-scale randomized controlled trials [10]. The success of Lifestyle Redesign suggests that enhancing engagement in activities and fostering a sense of purpose in life can contribute to older adults' health. In Japan, Yuri et al [11] conducted an intervention in which life goal–setting support was added to conventional exercise-based preventive care programs for community-dwelling frail older adults and found that the group receiving life goal support showed significantly greater improvements. The study demonstrates that life goal support is a promising intervention for preventing frailty progression and maintaining independence among older adults.

Thus, preventive approaches incorporating life goal–setting support have been suggested to promote not only physical and mental health but also motivate older adults to actively engage in activities. To advance such initiatives further, it is essential to focus on the psychological processes that motivate older adults to engage in health-promoting behaviors. Flow theory [12,13] provides an effective framework for this purpose. Flow theory describes a psychological state in which individuals are deeply immersed in an activity and experience an optimal state in which time seems to fly. This state occurs when perceived challenges and skills are balanced. Flow experience enhances intrinsic motivation, well-being, and self-efficacy [13,14]. Studies in occupational therapy have also emphasized the importance of flow in daily activities for promoting health and quality of life [15-19]. In recent years, such approaches have been increasingly incorporated into digital health and mobile health (mHealth) interventions aimed at behavior change.

The authors also developed the adjusting the challenge-skill balance (ACS) process [20], which evaluates and adjusts the balance between perceived challenges and skills in relation to activities and goals, and reported its effectiveness [20-23]. These findings suggest that ACS based on flow theory can reduce negative experiences during activities and improve QOL among older adults. However, among participants who underwent the ACS process, QOL improvements tended to decline after the follow-up period [23], indicating that the effects may have been limited to direct intervention. Therefore, it is necessary to develop support methods that promote ongoing engagement in life tasks and goals and enhance health literacy and self-management among older adults [24].

To deliver such preventive interventions, the use of information and communication technology, including mHealth and telemedicine approaches, has attracted attention. In recent years, the potential of remote rehabilitation using information and communication technology has been highlighted, and the effectiveness of online interventions in physical therapy has been demonstrated [25-27]. The importance of remote approaches in providing community-based support for older adults is increasing, particularly considering workforce shortages and geographic barriers [28,29]. However, reports on remote interventions in occupational therapy remain limited [30], and few studies have explored artificial intelligence (AI)–driven remote interventions to support life goals or foster a sense of purpose among older adults.

In addition, the use of generative AI for conversational support is gaining attention in psychological support, rehabilitation, and mHealth interventions, with increasing evidence of its effectiveness in health management and mental health [31,32]. For example, AI-based personalized counseling and automated coaching technologies have been suggested to effectively manage stress and improve mental health [33-35]. Furthermore, AI-based digital therapies have been shown to contribute to reducing anxiety and depressive symptoms and may offer new options for remote psychological support [36].

Although remote rehabilitation and generative AI hold promise, it remains unclear whether the existing ACS process (a life goal–support process based on flow theory) can be correctly

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automated and delivered via AI-supported mHealth interventions. Traditionally, the ACS process involves occupational therapy professionals evaluating the challenge and skill levels related to life tasks and integrating the client's perceptions with the therapist's perspective to support appropriate goal setting and adjustment—a process requiring individual adaptation [20,21,23]. In contrast, generative AI provides scalable support by learning patterns from input data and providing guidance based on predetermined algorithms, raising questions about whether it can match the adaptability of human experts. On the other hand, thoughtfully distributing roles between AI and human experts may enable the development of hybrid support models that combine the consistency and immediacy of AI with the flexible judgment and emotional support of professionals.

In domains such as life goal support, which are heavily influenced by personal values and context, exploring hybrid models that leverage the strengths of both AI and human experts is a significant challenge. In this study, we defined *life goals* broadly to encompass not only long-term aspirations but also meaningful daily activities (occupations) that constitute one's sense of purpose, such as household tasks, hobbies, and social interactions. Although the ultimate target population for this intervention is older adults who require preventive care or rehabilitation, this preliminary feasibility study included a broader age range of adults (age groups: 20-29 and 70-79 years). This was done to verify the usability and interaction quality of the generative AI system across varying levels of digital literacy before narrowing the focus to specific clinical populations.

Therefore, this exploratory study examined the feasibility and appropriateness of remotely delivering ACS through AI-supported mHealth interventions and human-facilitated occupational therapy. Specifically, we compared (1) remote life goal support provided by occupational therapy professionals and (2) AI-supported remote life goal support and explored the differences and usefulness of these approaches. The significance of this study lies in empirically examining the feasibility of remote ACS interventions and the potential for integrating generative AI into scalable mHealth platforms to establish new models for remote health behavior support. Furthermore, by gaining exploratory insights into the characteristics and role-sharing possibilities of AI and human experts, this study aims to provide foundational information for developing practical hybrid mHealth interventions that promote life goal attainment, self-management, and well-being among older adults.

Methods

Participants

Participants were 28 community-dwelling adults who owned smartphones, reflecting the target population for mHealth interventions. Participants were recruited through flyers distributed at community centers and social media advertisements. The inclusion criteria included being an adult, residing in the community, owning a smartphone, and using it for daily communication. The sample included 5 (18%) participants in their twenties, 6 (21%) in their thirties, 4 (14%) in their forties, 3 (11%) in their fifties, 5 (18%) in their sixties, and 5 (18%) in their seventies. Basic demographic information, including age and occupation, was also collected (Table 1).

Table 1. Participant characteristics (N=28).

Characteristics	Participants (n=28), n (%)
Age group (y)	
20-29	5 (18)
30-39	6 (21)
40-49	4 (14)
50-59	3 (11)
60-69	5 (18)
70-79	5 (18)
Occupation	
Company employee	14 (50)
Housemaker	5 (18)
Self-employed	4 (14)
Student	2 (7)
Unemployed	3 (11)

Procedure

On the basis of the previous studies [20,23], we adopted the ACS process for remote delivery, termed remote ACS (R-ACS). The R-ACS comprises the following structured steps:

1. Goal setting and goal elaboration through initial questions
2. Participant ratings of challenge and skill levels (each on a 7-point scale), along with free-text explanations of their ratings

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3. AI-provided or therapist-provided assessment of the participant's challenge-skill (CS) balance, feedback, and proposal of an adjustment task based on flow theory's 4-channel model (flow, anxiety, boredom, and apathy)

The participants completed 2 R-ACS sessions, 1 with an occupational therapist (OT) and 1 with AI support, following a within-participant, 2-condition exploratory comparison design (no washout period was implemented). Because the intervention focused on *goal setting* for 2 distinct, independent life goals rather than a physiological treatment where carryover effects are biological, a washout period was deemed unnecessary. Although a learning effect regarding the R-ACS process was possible, the order of intervention (AI first vs OT first) was randomly assigned using a computer-generated randomization sequence to counterbalance this bias across the cohort.

For the OT-supported session, participants engaged in synchronous texting with an experienced OT. To ensure consistency and comparability with the AI condition, the OT followed a strict, structured guide adhering to the same R-ACS steps (steps 1-3) described previously. The therapist used a standardized script for the initial questions and feedback structure, ensuring that the intervention focused solely on the flow theory–based framework without providing extraneous clinical therapy or counseling. Of the 28 participants, 14 (50%) received OT support first, followed by AI support, whereas the remaining 14 (50%) followed the reverse order. Participants were asked to set 2 distinct life goals (1 per session); which goal was addressed under the AI-supported versus OT-supported session depended on the randomized order. Therefore, goal domains were not controlled to be equivalent across conditions; we report the goal category distribution per condition descriptively (Table 2) and address this as a limitation.

Table 2. Goal category distribution by intervention condition.

Goal category[a]	Artificial intelligence–supported goals (n=28), n (%)	Occupational therapist–supported goals (n=28), n (%)	Total goals (N=56), n (%)
Work	4 (14)	7 (25)	11 (20)
Health	5 (18)	6 (21)	11 (20)
Hobbies	8 (28)	3 (11)	11 (20)
Family interaction	4 (14)	3 (11)	7 (12)
Lifestyle habits	4 (14)	1 (4)	5 (9)
Childcare	1 (4)	4 (14)	5 (9)
Household tasks	1 (4)	2 (7)	3 (5)
Interaction with friends	1 (4)	2 (7)	3 (5)

[a]Each participant contributed 1 goal per condition (in total 28 goals per condition).

AI-Supported mHealth Intervention

The AI-supported intervention was implemented using a customized GPT based on GPT-4o (OpenAI), designed specifically for the R-ACS process and integrated into an mHealth delivery format.

Intervention Flow

The AI guided participants through the following structured steps: (1) goal registration and elaboration (clarifying the goal), (2) CS ratings and rationale (collecting self-rated challenge and skill levels and reasons), (3) independent CS balance estimation (AI estimating the CS balance using the person-environment-occupation model—a theoretical framework commonly applied in occupational therapy [37]), and (4) feedback and adjustment (providing adjustment task suggestions based on flow theory). The AI displayed both user-assessed and AI-assessed CS ratings, prompting reflective dialogue when discrepancies were noted.

Prompt Structure and Safety

To ensure consistency and safety, the AI's behavior was governed by a strictly defined system prompt comprising the components mentioned subsequently.

The first component was fixed vs variable elements. The fixed elements included the intervention structure (R-ACS steps), the evaluation logic based on the person-environment-occupation model and flow theory, and the persona (supportive coach tone). The variable elements were limited to the specific content of feedback and goal adjustment suggestions, which the AI generated dynamically in response to each participant's unique inputs.

The second component was safety rules. Strict safety protocols were implemented within the prompt, including (1) content safety (whereby the AI was explicitly prohibited from providing medical diagnoses or clinical advice), (2) system integrity (with internal instructions and technical specifications, eg, spreadsheet links were concealed to prevent prompt leakage), and (3) privacy protection (whereby the system was instructed to interact using only nicknames and IDs).

The third component was data handling. The system transmitted and stored only the following deidentified data points: date, user ID, nickname, goal content, goal number, user-rated challenge and skill levels and reasons, AI-rated challenge and skill levels and reasons, and the AI's suggested goal adjustment. No personally identifiable information, such as real names or contact details, was sent or stored.

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To minimize potential presentation bias, the researchers reformatted the AI-generated outputs to match the standardized format used in OT-supported interventions. A detailed overview of the prompt structure and constraints is provided in Multimedia Appendix 1.

Outcome Measures

Feasibility was formally assessed based on the completion rate of the R-ACS sessions. User acceptance and perceived quality were evaluated using the 4-item rubric. After each R-ACS session (OT supported and AI supported), participants completed a 4-item rubric-based questionnaire (5-point scale) to evaluate (1) the amount of questioning, (2) the quality of questions, (3) the appropriateness of suggestions, and (4) the perceived contribution to goal attainment. Free-text comments regarding participants' experiences were also collected. The rubric was adapted from previous research on coaching skill evaluation [38].

Additionally, this study aimed to explore differences in the characteristics and potential role complementarities of AI-supported and OT-supported interventions in the context of mHealth-based goal support.

Data Analysis

For the 4 rubric items, within-participant differences (AI vs OT) were analyzed using the Wilcoxon signed-rank test, accounting for the paired nature of the within-participant, 2-condition design. The false discovery rate (FDR) was controlled using the Benjamini-Hochberg method. Effect sizes were calculated as *r*, and bootstrapped 95% CIs were estimated to assess the precision of the effect sizes. Descriptive statistics are reported as medians (IQRs) and means (SDs).

For qualitative analysis, term frequency–inverse document frequency (TF-IDF) analysis was performed to identify characteristic words in participants' free-text responses across the 2 intervention types. Sentiment analysis was also conducted to assess trends in positive and negative language, following common approaches in mHealth research.

Ethical Considerations

This study was approved by the ethics committee of Wakayama Professional University of Rehabilitation (WRPUR2024R004). All participants provided informed consent via the mHealth platform before participation. The privacy of participants was strictly protected; all data were deidentified and stored securely, and no personally identifiable information was included in the analysis or reporting. Participants received no financial compensation for their participation. This study was conducted in accordance with the Declaration of Helsinki and ethical guidelines for medical and health research involving human participants.

Results

Participants and Procedure

A within-participant, counterbalanced-order 2-condition exploratory comparison was conducted in which 14 (50%) of the 28 participants received OT-supported interventions followed by AI-supported interventions, and 14 (50%) participants received interventions in the reverse order. Each participant set 2 life goals and underwent the R-ACS process for one goal with OT support and the other with AI support, resulting in 56 life goal–setting cases.

Goal categories for 56 goals included work (n=11, 20%), health (n=11, 20%), hobbies (n=11, 20%), family interaction (n=7, 12%), lifestyle habits (n=5, 9%), childcare (n=5, 9%), household tasks (n=3, 5%), and interaction with friends (n=3, 5%). Table 2 shows the goal category distribution for each condition. Because goal domains were not matched, these distributions are reported for transparency. Although the frequency of specific categories, such as hobbies, varied, both interventions covered a broad range of life domains.

Quantitative Results

Rubric-based questionnaire results indicated that AI-supported interventions generally yielded scores higher than or comparable to OT-supported interventions. Detailed descriptive statistics, including medians and IQRs, are summarized in Table 3.

The Wilcoxon signed-rank test revealed a significant difference in the appropriateness of suggestions (z score=3.13; P=.002; FDR-adjusted P=.008). Specifically, the median score for AI support was 5.0 (IQR 4.0-5.0), which was substantially higher than the 4.0 (IQR 3.0-4.0) observed for OT support. The effect size (r) was 0.418 (95% CI 0.16-0.63), indicating a moderate effect. No statistically significant differences were observed for the other items after FDR correction. However, a small-to-moderate effect size was noted for the quality of questions (r=0.233).

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Table 3. Comparison of artificial intelligence (AI)–supported and occupational therapist (OT)–supported interventions—rubric-based questionnaire results.

Outcome item	AI support (n=28)	OT support (n=28)	*P* value[a]	False discovery rate–adjusted *P* value	Effect size[a], *r* (95% CI)
Amount of questioning			.87	.87	0.021 (–0.24 to 0.29)
Median (IQR)	3.5 (3.0-5.0)	4.0 (3.0-4.0)			
Mean (SD)	3.64 (1.13)	3.61 (0.92)			
Quality of questions			.08	.11	0.233 (–0.04 to 0.49)
Median (IQR)	5.0 (4.0-5.0)	5.0 (3.0-5.0)			
Mean (SD)	4.64 (0.62)	4.29 (0.98)			
Appropriateness of suggestions			.002	.008	0.418 (0.16 to 0.63)
Median (IQR)	5.0 (4.0-5.0)	4.0 (3.0-4.0)			
Mean (SD)	4.32 (0.94)	3.64 (0.78)			
Perceived contribution			.19	.27	0.177 (–0.09 to 0.43)
Median (IQR)	4.0 (3.8-4.0)	3.0 (3.0-4.0)			
Mean (SD)	3.89 (0.63)	3.64 (0.78)			

[a]*P* values and effect sizes were calculated using the Wilcoxon signed-rank test.

Qualitative Results

The TF-IDF analysis of free-text responses revealed distinct lexical patterns between the AI-supported and OT-supported interventions (Table 4). As summarized in Figure 1 and Table 4, AI-supported responses frequently included terms related to motivation, clarity of action, and goal visualization, such as “easy to engage”; “provided reassurance through soft expressions”; “increased motivation to take action”; “clear image of goal attainment”; and “received specific hints.” In contrast, OT-supported responses more frequently included expressions reflecting self-understanding, reflection, and emotional safety, such as “helped verbalize my thoughts”; “assisted in organizing my thinking”; “felt safe while proceeding with the conversation”; and “impressed by the empathetic attitude.”

These results suggest distinct differences in linguistic tendencies and user experiences between the AI-supported mHealth intervention and OT-facilitated goal support.

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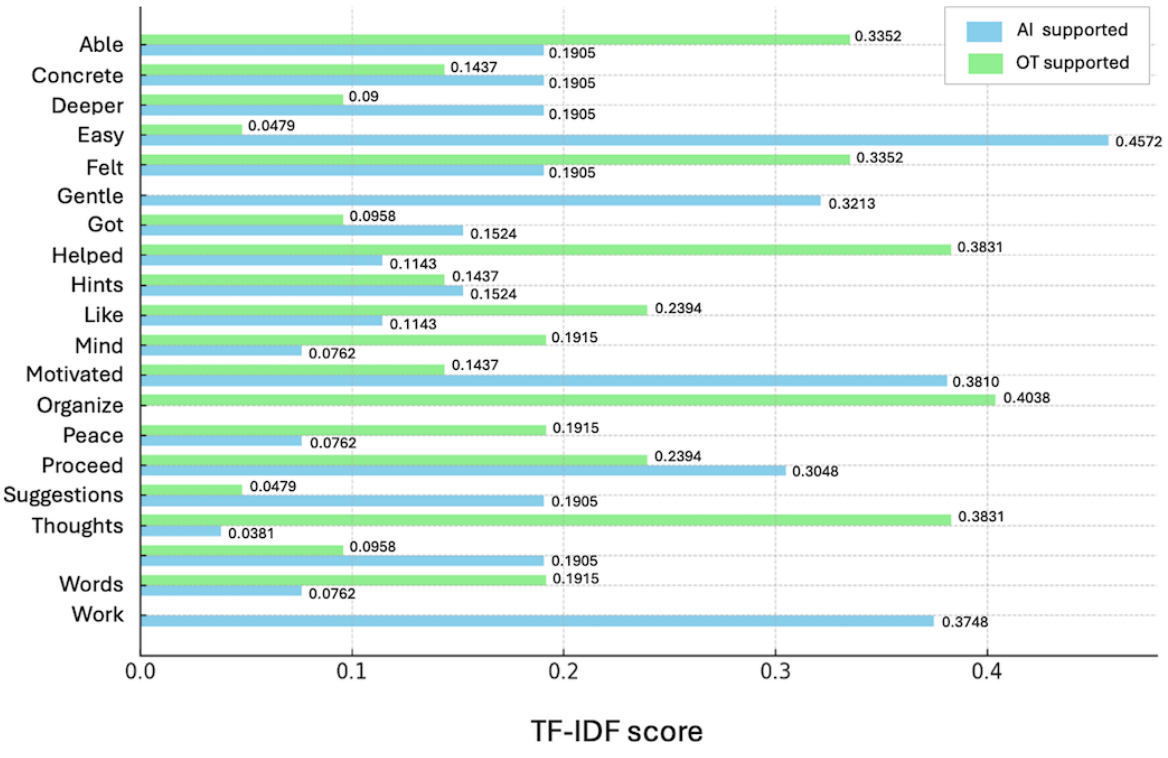
Table 4. Term frequency–inverse document frequency (TF-IDF) scores for top characteristic terms identified from free-text responses.

Term	Artificial intelligence–supported TF-IDF score	Occupational therapist–supported TF-IDF score
Able	0.1905	0.3352
Concrete	0.1905	0.1437
Deeper	0.1905	0.0958
Easy	0.4572	0.0479
Felt	0.1905	0.3352
Gentle	0.3213	0.0000
Got	0.1524	0.0958
Helped	0.1143	0.3831
Hints	0.1524	0.1437
Like	0.1143	0.2394
Mind	0.0762	0.1915
Motivated	0.3810	0.1437
Organize	0.0000	0.4038
Peace	0.0762	0.1915
Proceed	0.3048	0.2394
Suggestions	0.1905	0.0479
Thoughts	0.0381	0.3831
Understanding	0.1905	0.0958
Words	0.0762	0.1915
Work	0.3748	0.0000

Figure 1. Top characteristic terms identified through term frequency–inverse document frequency (TF-IDF) analysis of free-text responses in artificial intelligence (AI)–supported and occupational therapist (OT)–supported interventions. The bars represent TF-IDF scores, highlighting the terms characteristic of each intervention type.



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Discussion

Principal Findings

This study explored the feasibility and characteristics of remote life goal support based on flow theory by comparing OT-supported and AI-supported interventions delivered via mHealth format. The findings showed that AI-supported interventions were rated as equal to or better than OT-supported interventions across all evaluation items, with a statistically significant difference and moderate effect size in the quality of suggestions. Participants also valued the specificity, immediacy, and appropriateness of AI-generated questions and suggestions. This study evaluated the AI intervention as a stand-alone module to isolate its specific characteristics. However, we envision the clinical application of this tool not as a replacement for comprehensive care but as an adjunctive self-management module that could be integrated into broader preventive or rehabilitative programs.

These results suggest that AI can deliver highly structured and effective support within interventional processes such as the ACS, where standardized interaction sequences are beneficial for promoting self-management in remote settings.

Furthermore, to ensure a fair comparison, AI-generated outputs were reformatted by the researchers and presented to participants in a standardized format comparable to OT support, thereby minimizing potential biases related to presentation style. Therefore, the observed differences are likely attributable to the inherent characteristics of the interventions rather than formatting effects.

Comparison With Prior Work

These findings align with the growing body of evidence supporting the effectiveness of generative AI–based psychological and behavior change interventions within digital health. A recent randomized controlled trial [39] demonstrated that a generative AI chatbot significantly improved mental health outcomes. Similarly, in this study, AI-supported mHealth interventions demonstrated strengths in promoting user engagement and facilitating actionable life goal pursuit.

In addition, we conducted a TF-IDF analysis of free-text comments as an appropriate exploratory method to extract characteristic lexical patterns from participants' subjective feedback systematically. This analysis provided complementary insights into participants' perceptions and experiences of each form of support, enriching the understanding of intervention-specific characteristics.

Our results also correspond with findings from Ref-Layers, an AI-based reflection system that enhances users' metacognitive strategy use through structured dialogue [40]. The AI-supported presentation of CS balance and the guided reconsideration of reasoning in this study may have similarly contributed to participants' self-understanding and reflective thinking.

Moreover, AI-driven interactions may help reduce interpersonal anxiety and promote self-disclosure, thereby facilitating more proactive engagement in health behavior change and goal setting. Previous research [31,32] suggests that users perceive virtual agents as more confidential and less judgmental than their human counterparts, encouraging openness. Consistent with these findings, other studies [41] have reported that interactions with virtual agents can enhance perceived privacy and promote candid self-disclosure.

The immediacy of AI responses emerged as a notable advantage, particularly in remote mHealth interventions where real-time dialogue is essential. Previous studies [42,43] have reported that fast and consistent chatbot responses enhance user satisfaction and engagement. In contrast, while OT-supported interventions provide valuable, nuanced, and context-sensitive feedback, they inherently involve longer response times.

Limitations

This study has several limitations. First, participants' previous beliefs and expectations regarding AI may have influenced their evaluations. Additionally, we did not quantitatively assess participants *AI literacy* or previous familiarity with generative AI tools. Users with higher AI literacy might have navigated the AI prompts more effectively, potentially skewing satisfaction scores. Previous research has shown that priming users' beliefs about AI can alter perceptions of trustworthiness, empathy, and effectiveness [44]. Future studies should incorporate strategies to control for these effects.

Second, we did not quantitatively measure the duration of each session. However, participant feedback suggested a perception of immediacy in the AI interaction compared to the OT support.

Third, this study evaluated only a single intervention session, thereby limiting the ability to assess the long-term sustainability of AI-supported mHealth interventions. However, emerging evidence suggests that AI-based coaching can maintain its effectiveness over extended periods. For example, Terblanche et al [45] reported that AI coaching supported clients' goal attainment over a 10-month period with efficacy comparable to that of human coaching. Nevertheless, rigorous evaluation of long-term effects within life goal interventions remains essential.

Fourth, the relatively small sample size and wide age range may limit the generalizability of these findings. Future studies should examine variations in acceptance and effectiveness across different life stages and demographic groups to further validate the intervention. In addition, although the AI model used in this study effectively implemented a structured ACS process, it currently lacks the capability to fully adapt to individual users or interpret subtle psychological states and nonverbal cues—areas where human-facilitated support remains superior. Further advancements in natural language processing and integration of multimodal data are needed to enhance the adaptability of AI-supported mHealth interventions.

Finally, several methodological limitations regarding the study design and authorship must be acknowledged. Because participants set different life goals for the AI and OT conditions, and goals were not matched for domain or perceived difficulty, the observed between-condition differences may be partly attributable to goal characteristics rather than the support modality alone. To improve transparency, we report the goal category distribution per condition (Table 2); however, we did

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not formally test distributional differences due to the exploratory design. Future studies should match goal domains across conditions or adjust for goal characteristics (eg, baseline challenge and skill ratings). Additionally, the primary investigator (IY) was involved in both system development and study evaluation. Although financial conflicts of interest were absent, this concentration of roles introduces a potential risk of developer bias. Future large-scale trials should use independent evaluators and randomized goal allocation to mitigate these biases.

Conclusions and Future Directions

This study clarified the distinct strengths and limitations of AI-supported and OT-supported ACS interventions delivered via remote formats. The ability of AI to deliver structured, consistent, and immediate support makes it a promising model for scalable mHealth interventions, particularly in settings with limited human resources or geographic barriers. Conversely, personalized adaptation, emotional support, and nuanced judgment provided by occupational therapy remain indispensable in contexts where human-facilitated care is essential.

The development and evaluation of a hybrid R-ACS model that integrates the complementary strengths of both approaches is warranted. One potential model could involve OT involvement during the initial goal-setting and assessment phases, followed by AI-supported mHealth interventions providing ongoing self-monitoring, feedback, and behavior change support. Periodic OT interactions could be used to reassess and recalibrate goals and strategies, ensuring both adaptability and intervention consistency.

Such hybrid approaches may maximize the benefits of AI and human support, leading to more effective, scalable, and sustainable remote interventions for promoting life goal attainment, self-management, and well-being. Future research, including randomized controlled trials, should rigorously evaluate these hybrid models, explore improvements in AI adaptability and OT-AI collaboration interfaces, and advance the development of innovative digital health services that support personalized goal setting.

Flow theory has also been widely applied to analyze user experiences in digital health interventions, including AI-driven chatbot interactions, as it helps explain user immersion, motivation, and satisfaction [46]. Leveraging this theoretical framework may further enhance the design and effectiveness of AI-supported mHealth interventions aimed at promoting personalized goal setting and health behavior change.

Acknowledgments

The author thanks all study participants for their valuable contributions. The artificial intelligence–supported intervention was developed by the author using a customized GPT based on GPT-4o (OpenAI), designed explicitly for adjusting the challenge-skill balance process.

In the preparation of this manuscript, generative artificial intelligence tools (GPT-4o) were used for English language editing and refining clarity. The author reviewed and edited the content as needed and takes full responsibility for the content of the publication. Ippei Yoshida was affiliated with Wakayama Professional University of Rehabilitation at the time of the study and is currently affiliated with the Medical School, Department of Health Sciences, Nagoya City University (effective April 2026).

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Data Availability

The datasets generated or analyzed during this study are not publicly available due to participant privacy protection policies but are available from the corresponding author on reasonable request.

Authors' Contributions

IY was responsible for the study design, development of the artificial intelligence–supported intervention, data collection and analysis, manuscript drafting, and approving the final version of the manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Artificial intelligence system instructions for the remote adjusting the challenge-skill balance process.
[DOCX File , 22 KB - formative_v10i1e78717_app1.docx]

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Abbreviations

ACS: adjusting the challenge-skill balance
AI: artificial intelligence
CS: challenge skill
FDR: false discovery rate
mHealth: mobile health
OT: occupational therapist
QOL: quality of life
R-ACS: remote adjusting the challenge-skill balance
TF-IDF: term frequency–inverse document frequency

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Original Paper

Implementation of Web-Based Respondent-Driven Sampling to Recruit Users of Electronic Nicotine Delivery Systems in Brazil: Cross-Sectional Survey

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Abstract

Background: The marketing of electronic nicotine delivery systems (ENDSs) has been prohibited in Brazil since 2009, and their regular use is less prevalent than in countries where these devices are not banned. To monitor the presence of ENDSs, it is important to prevent the development of a new generation of nicotine-dependent individuals. However, traditional surveys are costly for accessing rare populations. Therefore, to reach ENDS users aged ≥15 years, we used the online version of the respondent-driven sampling method (web-RDS), a peer chain recruitment method for contacting hard-to-reach groups.

Objective: This paper aims to provide information on the implementation of the first web-RDS study in Brazil to recruit ENDS users.

Methods: This study was conducted in Rio de Janeiro, the second largest city in Brazil. After a formative phase using qualitative in-depth interviews, we selected the first participants ("seeds") to complete an online quantitative questionnaire on the profile of their own ENDS use and the size of their contact network of ENDS users. Participants received 3 coupons to invite eligible peers. For participation and recruitment, each participant received a gift card worth approximately US $4. The target sample size was 300 ENDS users based on a conservative estimate and adjusted for design effect.

Results: From August 2022 to May 2023, of the 12 seeds included, 508 attempts at access were recorded in the data collection system, of which 330 (65%) were eligible. Duplicate or ineligible attempts were identified and removed through automated and manual checks. Recruitment was initially slow due to the low monetary incentive, but it improved after the amount was increased. We found that 43.1% (75/174) of recruiters recruited only 1 eligible participant, 34.5% (60/174) recruited 2 eligible participants, and 22.4% (39/174) recruited 3 participants. Web-RDS was able to reach individuals in different areas of the city. Convergence was reached for target variables (ie, age and age at first use of electronic cigarettes). The median time to complete the questionnaire was 12 (IQR 8-17) minutes. Half (154/324, 47.5%) of the respondents reported that they knew up to 5 other ENDS users.

Conclusions: The web-RDS methodology proved to be a feasible approach for accessing the population of ENDS users in Brazil. Incentives for participation and recruitment emerged as a determining factor in the data collection process. However, researchers needed to be aware of individuals attempting to circumvent the system by participating without being eligible or participating multiple times. Implications for optimizing web-RDS are discussed. On the basis of the method's performance in this study, web-RDS shows potential to support future repeated data collection processes that could help monitor changes in the profiles of ENDS users over time, supporting the implementation of ongoing measures from Brazil's National Tobacco Control Policy.

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KEYWORDS

respondent-driven sampling; electronic nicotine delivery systems; web-based surveys; online respondent-driven sampling; web-RDS; hard-to-reach populations

Introduction

Electronic nicotine delivery systems (ENDSs), among which the most widely known are electronic cigarettes, have been used by the tobacco industry to replace (and possibly expand) the consumer base of nicotine-dependent individuals. This is because a global decline in cigarette consumption has been observed as a result of various tobacco control measures based on unequivocal evidence of the diseases and deaths caused by tobacco products [1,2].

When ENDSs were first introduced into the market, the tobacco industry promoted them on the grounds of harm reduction properties for people's health, supplying nicotine safely to individuals during smoking cessation [3,4]. However, there is no evidence to support this claim because electronic cigarettes cause serious lung damage [5]. In addition, the odds of developing cardiovascular disease, stroke, and metabolic dysfunction are similar between users of conventional vs electronic cigarettes [6]. Moreover, several studies indicate that switching from conventional cigarettes to ENDSs does not lead to smoking cessation, as it merely satisfies nicotine dependence, now administered in a different form.

The sale of ENDSs has been prohibited in Brazil since 2009, and the ban was reinforced by a new 2024 resolution from the Brazilian Health Regulatory Agency [7]. Current use is relatively rare as a result. According to the latest available nationwide data from the 2019 National Health Survey, prevalence of current ENDS use among Brazilians aged ≥15 years was 0.6% [8]. The most recent data from the Surveillance System of Risk and Protective Factors for Chronic Diseases via Telephone Survey conducted among adults living in Brazilian state capitals showed a downward trend in point estimates for the proportion of current ENDS use (from 2.5% in 2020 to 2.1% in 2023) [9]. However, these data are neither informative nor generalizable to the vast network of municipalities that are not state capitals (more than 5500 municipalities home to approximately 80% of Brazil's population, according to the 2022 census), for which recent trends are unknown.

ENDSs have been widely promoted through illegal online advertisements, mainly via social media and digital influencers, which mainly target young people and may encourage smoking initiation [10]. Not surprisingly, in the age group most affected by the tobacco industry's marketing (15 to 24 years), prevalence of ever use of electronic cigarettes is significant (5.4%), and prevalence of current use is 2.4% [8].

Large nationwide surveys in Brazil such as the Brazilian National Health Survey and Surveillance System of Risk and Protective Factors for Chronic Diseases via Telephone Survey do not provide the necessary details to understand the patterns of ENDS use, consumer behaviors, motivations for use, and methods of access to these devices. In addition, population-based household or telephone surveys would require large numbers of participants to reach ENDS users, who represent less than 1% of the general population in Brazil and are not proportionally distributed according to the general population's demographic profile.

Thus, specific methodologies are needed to access hard-to-reach or rare populations. The implementation of these methods is necessary to identify and quantify such populations and inform public policies and political and administrative decisions, such as those made by the Brazilian Health Regulatory Agency. One such methodology is respondent-driven sampling (RDS), initially developed to access more vulnerable populations at risk of key infections such as HIV and other sexually transmitted infections, and among injecting drug users [11]. However, RDS has since been applied to different contexts and groups, such as migrant populations, Indigenous people, drug users, female sex workers, and men who have sex with men [12].

In RDS, an initial group of participants, known as seeds, is purposely selected by the researchers. From there, each participant recruits a predetermined number of other eligible participants, and this process continues until the intended sample size is reached. This method can be viewed as asymptotically probabilistic [13] as it allows for the calculation of selection probabilities and sampling weights with a reasonable degree of approximation and acceptable error [14,15]. Estimation in RDS relies on participants' self-reported personal network size, which reflects the number of eligible peers they know. This information is used to calculate each participant's likelihood of selection and compute sampling weights, allowing for less biased population estimates. However, it cannot reach people who are not connected to contact networks, as they have zero probability of selection, and the accuracy of the probability of selection and its estimation depends on the structure of community geography and underlying contact networks [16]. For participation and recruitment, participants usually receive monetary incentives [12].

RDS traditionally uses face-to-face interviews. However, a new modality of RDS has been proposed more recently, where individuals are recruited by their peers but, rather than participating in person, they complete an online questionnaire. This modality has been called web-RDS [17]. It offers several advantages over traditional RDS, such as easier and anonymous access to participants in addition to enabling faster, less expensive, and more logistically efficient data collection [18]. The method naturally depends on the target population's digital connectivity, which is especially high among Brazilian youth across all social classes, with only minor inequalities affecting low-income groups [19,20].

A review article identified 18 studies published from 2000 to 2019 that used web-RDS conducted in 8 countries [18]. Other more recent studies have also used this methodology [21-23]. Web-RDS has been used in these studies for population size estimation, health interventions, and the study of contact network characteristics (eg, mapping the spread of infections or diseases). However, the distribution of complex behaviors

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still lacks an appropriate methodology for surveys beyond experimental studies [24] and across various types of populations. There are currently no records of this methodology's use in Brazil.

This paper aims to provide information on the implementation of a web-RDS study to recruit users of ENDSs. This is the first study in Brazil with this target population and methodology. We also aimed to gather insights to support the scalability of this methodology, with a view toward its simultaneous use in various sites across the country for comparison among different subgroups of ENDS users.

Methods

Study Design and Target Population

A cross-sectional study was conducted using web-RDS to collect data online, recruiting ENDS users in the city of Rio de Janeiro. This study was intentionally limited to 1 city as an implementation test for feasibility, recruitment dynamics, and system functionality before considering possible multicity expansion.

Eligibility criteria for participation in the study were having used ENDSs in the previous 12 months, age of ≥15 years, and residence in the city of Rio de Janeiro. This study considered the use of electronic cigarettes, heated tobacco, or vaporizers for tobacco consumption regardless of frequency of use in the 12 months before participating in the study.

Formative Phase

A formative study using qualitative methodology was conducted, as research suggests that this can be a key factor for RDS studies' ability to achieve their objectives [25]. The formative phase is important because it allows researchers to verify whether the target population is indeed connected in a way that enables chain recruitment. It also supports the selection of seeds (ideally well-connected, motivated, and heterogeneous individuals vis-à-vis socioeconomic status and location) to initiate the data collection process in RDS. It further facilitates the choice of the most effective primary and secondary incentives for online recruitment and can help refine the questionnaire [25].

Two pilot interviews were conducted to assess comprehensibility, acceptability, and feasibility based on implementation science criteria [26]. After these interviews, necessary adjustments were made to the scripts to improve the flow of the interviews. These 2 interviews were not included in the final set for analysis.

In-depth interviews were conducted from July 2022 to September 2022 with 14 individuals who met the eligibility criteria. These individuals were recruited using a combination of purposeful and snowball sampling. The researchers issued online invitations to key informants within their contact networks. These informants, in turn, passed the invitation on to potential participants or others in their networks who could recommend additional participants. Upon confirming the individuals' interest in participating, the researchers checked their eligibility before conducting the interviews. The interviews followed a semistructured script with guiding questions divided into thematic sections: general sociodemographic and behavioral characteristics, experience with ENDSs, experience with traditional cigarettes, legislation, and the ENDS users' contact networks. The qualitative interviews lasted 20 to 40 minutes and were recorded and transcribed in full for analysis.

Sampling Plan

To determine the sample size for the quantitative phase, a conservative estimate of 50% was used for the sample calculation (as it maximizes variance and yields the largest required sample size, providing adequate precision across a range of possible true prevalence values), with an SE of 0.05. Considering a design effect of 2.5 [27], the minimum sample size was calculated as 250 individuals. To account for potential data losses, especially common in studies involving stigmatized and/or criminalized behaviors [28], the sample size was increased by 20%. Therefore, the target sample size for this study was 300 ENDS users.

Seed Selection and Recruitment

Seeds were initially selected from individuals who participated in the qualitative phase of the study. The first 7 seeds were contacted in August 2022 and invited to complete an online questionnaire through a link provided via email. A dedicated email account was created for the study through which invitations were sent to the seeds. This email account was also used as the official communication channel for participants, including for inquiries.

During the data collection period, it became necessary to include additional seeds to reach the intended sample size and increase the network's diversity, thereby minimizing the effects of homophily or the tendency for participants to recruit others with similar characteristics [13,15]. A total of 15 seeds were contacted, comprising individuals who participated in the formative phase or others they indicated. However, of these 15 seeds, 3 (20%) failed to complete the questionnaire. Thus, this study included 12 valid seeds distributed across the city of Rio de Janeiro as follows: 6 (50%) from the south zone, 4 (33.3%) from the north zone, 1 (8.3%) from the west zone, and 1 (8.3%) from the city center. There were 75% (9/12) men and 25% (3/12) women aged 21 to 48 years, with 25% (3/12) of the participants aged ≤24 years, 33.3% (4/12) aged 25 to 34 years, and 41.7% (5/12) aged ≥35 years. All reported having used ENDSs for more than 2 years. After completing the questionnaire, each seed was given 3 unique codes to invite eligible friends to participate.

Data Collection System

Data collection was designed so that the questionnaire could be completed on a computer or cellphone, with the option to pause and resume completion later.

To begin the questionnaire, after reading and providing consent, participants had to enter their invitation code, email address, and date of birth. This information was used to verify duplicate participation. Participants then completed a self-administered online eligibility questionnaire. To address potential duplicate or fraudulent entries, especially in the context of an

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incentive-driven web survey, we implemented a multistep verification process combining automated and manual checks. First, the system automatically blocked repeated attempts using the same invitation code, email address, or date of birth. Second, manual validation was conducted to detect patterns consistent with the same individual attempting to participate multiple times, such as highly similar email structures (eg, inversions of first and last names and numerical variants of the same basic username) or different email addresses associated with an identical or implausibly similar date of birth. Attempts exhibiting any of these characteristics were classified as invalid and excluded from the sample for analysis. Additionally, cases in which different email addresses matched the recruiter's own date of birth were removed as this indicated possible self-recruitment. Fraud detection methods cannot guarantee full elimination of invalid entries, but they substantially increase confidence that the data included in the analysis come from verified and legitimate participants.

Upon meeting the study inclusion criteria, participants were allowed to proceed to the formal study questionnaire, which contained modules with questions on sociodemographic characteristics and use of conventional cigarettes, electronic cigarettes, heated tobacco products, dry herb vaporizers, hookahs, other tobacco products, and alcohol. For ENDSs, the questions addressed use patterns and frequency, age of initiation, access methods, and motivations for use. Participants were also asked about their knowledge of legislation regarding ENDS advertising and use in public places. Additionally, the questionnaire included questions about the participants' contact networks, as required by the RDS methodology, to assess their networks and allow for calculation of sampling weights and population estimates.

Three invitation codes were generated automatically at the end of the questionnaire. Coupons or codes were electronic, generated automatically by the system, and consisted of alphanumeric codes assigned randomly without reuse. These codes could be shared directly via WhatsApp or email by clicking on specific links or copied and sent manually through social media apps, for example. Codes had no expiration date but became inactive after use by an individual. In addition, the data collection system only remained active until the target sample size was reached, after which no additional enrollments could be made.

Individual and Public Involvement

Upon completing the questionnaire, each participant received 3 new unique codes to invite friends to participate based on the eligibility criteria. Thus, participants also acted as recruiters, following the RDS methodology.

Management of Invitations and Incentives

iFood gift cards were purchased to use as the primary incentive (for participation) and secondary incentive (for recruiting other participants). Initially, the vouchers were worth BRL 10 each (slightly less than US $2). However, this amount had to be increased to BRL 20 (slightly less than US $4 at the time) to encourage recruitment. This adjustment was made after seeds reported that the low amount of the incentive was the main reason for the lack of recruitment and participation by invitees.

Email messages containing primary and secondary incentive gift card information were sent manually by the study coordinator to each participant using the email address provided by the participant when completing the questionnaire. Email messages were also sent to participants to encourage them to invite friends to join when their codes had not been used after an extended period. These email messages also informed participants that the gift card could not be provided if evidence of duplicate participation was detected manually by the research team. They were also sent in response to inquiries. Approximately 700 email messages were sent during the study period.

Contact Network Size

The size of each participant's contact network was measured using the following 2 questions: "How many people do you know who have used ENDS in the last 12 months and live in the city of Rio de Janeiro?" and "How many of these people are 15 years or older?" (the latter being the operative network size for weighting). This information's validity was important for estimating the probability of inclusion in the study and for obtaining reliable weighted estimates [29]. Therefore, the consistency of these data was verified, and deterministic imputation was applied for implausible responses to the question defining the probability of inclusion in the study. When the reported network size in the second question was zero or smaller than the number of individuals connected to the respondent in the recruitment tree (ie, including both the recruiter and the recruits [13 cases]), we imputed the value provided in the first question. Conversely, when the first question also yielded 0 or an implausibly small value relative to the observed recruitment ties (7 cases), the network size was replaced by the mean of the valid network sizes observed in the sample. This approach follows conservative recommendations in the RDS literature by avoiding artificially small degrees, which would otherwise generate disproportionately large sampling weights. Imputation was applied to approximately 6% of the responses. The distribution of the contact network size variable was presented in box plots and histograms.

Analyses

The analyses were conducted using the R programming language (version 4.3.1; R Foundation for Statistical Computing) [30]. Because our analyses in this implementation study were limited to unweighted descriptive summaries of the obtained sample, no RDS estimator was applied; population inference will be addressed in future analyses [31]. Convergence was assessed visually using cumulative sample proportion plots for selected target variables.

Ethical Considerations

This study was approved by the institutional review board of the Brazilian National Cancer Institute (33280320.3.0000.5274). Consent to participate in the qualitative interviews was obtained from participants and recorded at the beginning of each interview after they were informed about the study's objectives, methods, risks, and benefits. Similarly, before completing the

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questionnaire in the quantitative phase, individuals were required to consent to participate by clicking on a specific field in the online questionnaire. As described in the Management of Invitations and Incentives section, participants received a primary incentive for participation (a BRL 20 [US $4] gift card) and a secondary incentive for each successful peer recruitment (a BRL 20 [US $4] gift card, limited to 3 recruits, for a maximum total of BRL 60 [US $12]). To ensure privacy and confidentiality, only minimal personal information was collected, solely to prevent duplicate responses and to enable incentive distribution. All data were stored in secure databases, and participants' personal information was not shared with third parties and was accessible only to the study coordinator.

Results

During data collection (August 2022 to May 2023), 508 attempts at access were recorded in the online system for participation in the study. However, 30.7% (n=156) of these were deemed ineligible (including manually identified duplicates, ie, people attempting to respond more than once while bypassing the automatic filter system). An additional 4.3% (n=22) of the participants failed to complete the questionnaire. Thus, the final study sample consisted of 330 individuals, with recruitment chains reaching a maximum depth of 21 waves (Figure 1); 5 seeds did not recruit any participants.

Database consistency analysis showed that 1.8% (6/330) of the individuals, although reporting previous use of ENDSs in the eligibility questionnaire, failed to provide valid or consistent information on the use of electronic cigarettes, heated tobacco cigarettes, or vaporizers for tobacco use. Thus, they were excluded from the analyses presented in this paper and future analyses (but will be retained for generating the recruitment network).

The sample consisted of 38.3% (124/324) individuals aged 16 to 24 years and 41.7% (135/324) individuals aged 25 to 34 years. Female individuals accounted for 43.8% (142/324) of the sample, and male individuals accounted for 56.2% (182/324). Most respondents (263/324, 81.2%) reported ever having smoked conventional cigarettes, and 68.1% (179/263) of these respondents were current smokers. Nearly the entire sample (317/324, 97.8%) reported having ever used electronic cigarettes, whereas experimentation with heated tobacco and vaporizers was reported by approximately one-third of the participants (109/324, 33.6% and 106/324, 32.7%, respectively; results not shown in table format). These descriptive characteristics provide a basic overview of the individuals captured through the recruitment chains using web-RDS.

The sample obtained using web-RDS included individuals in different areas of Rio de Janeiro, although the seeds were limited to a small number of neighborhoods in a city with more than 6 million inhabitants (Figure 2).

Figure 3 shows the distribution of participants by date of questionnaire completion. The initial weeks had the fewest participants, as this was when data collection began with the seeds' participation in August 2022 and September 2022. There was a delay in participation by the seeds' invitees, who were reluctant to participate because they considered the gift card value too low (BRL 10 [US $2] at the time). Therefore, starting in October 2022, the amount was increased to BRL 20 (US $4). None of the seeds generated valid recruits before the increase in the incentive value. Following this change, and with email messages sent to encourage participation and peer recruitment, the chain recruitment gained the necessary momentum starting in November 2022.

There was a plateau in participation from January 2023 to April 2023 (Figure 3), indicating that few interviews were completed during this period. This may have been due to a bureaucratic issue in early January 2023 that delayed the purchase of new gift cards, which could not be completed within the 7-day time frame promised to participants in the informed consent form and the invitations. Given the restrictions on the number of gift cards, we decided to maintain the primary incentive, whereas the secondary incentive was resumed in the latter half of February 2023. Even with email messages encouraging participants to recruit, there was no proactive and swift response as before. Thus, to reach the target sample size, and following the suspension of restrictions on gift cards, new seeds were included in late April 2023, leading to a gradual increase in the sample size at a rate consistent with that of the previous period.

Importantly, although each participant received a maximum of 3 invitation codes, in the final valid sample, we found that 43.1% (75/174) of recruiters enrolled only 1 eligible participant, 34.5% (60/174) recruited 2 eligible participants, and 22.4% (39/174) successfully recruited 3 participants (data not shown in table format). Considering the 508 individuals reached by the study (regardless of potential duplications), we found that approximately half (113/218, 51.8%) used all 3 invitations (data not shown in table format).

Figure 4 shows the distribution of contact network size among study participants (ie, the number of ENDS users aged ≥15 years residing in Rio de Janeiro that the respondents reported knowing). Half (154/324, 47.5%) of the respondents reported that they knew up to 5 other ENDS users (this number corresponds to the mode of the self-reported contact networks). Only 25.6% (83/324) of the participants reported having a contact network with more than 10 eligible individuals (the maximum reported number was 99).

The median time for completion of the questionnaire was 12 (IQR 8-17) minutes.

As shown in Figure 5, different participant characteristics exhibited distinct convergence trajectories, sometimes reinforcing the presence of homophily, other times showing chain referral processes that followed other patterns. Convergence was reached for target variables (ie, age and age at first use of electronic cigarettes).

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Figure 1. Recruitment tree of electronic nicotine delivery system users participating in the study (Rio de Janeiro, 2022-2023).

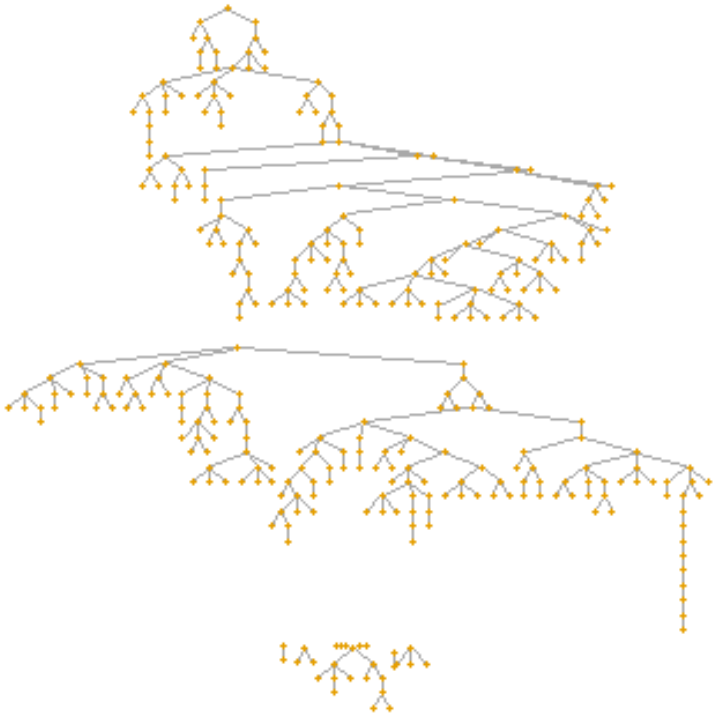

Figure 2. Neighborhood of residence of seeds (A) and total sample (B) of electronic nicotine delivery system users participating in the study (Rio de Janeiro, 2022-2023).

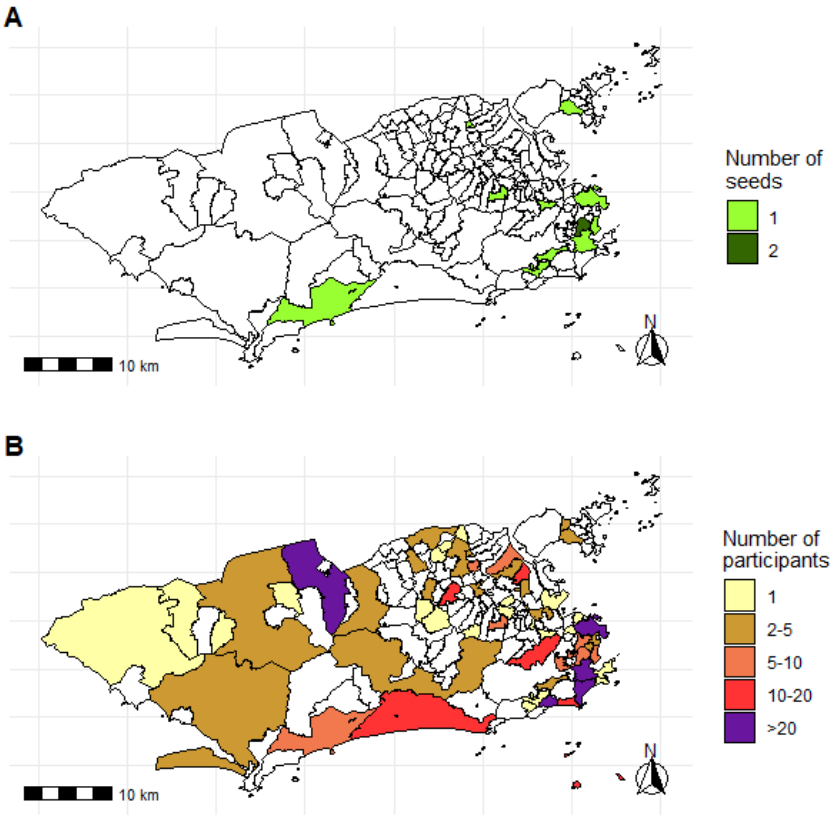

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Figure 3. Number of electronic nicotine delivery system users participating in the study by date (Rio de Janeiro, 2022-2023).

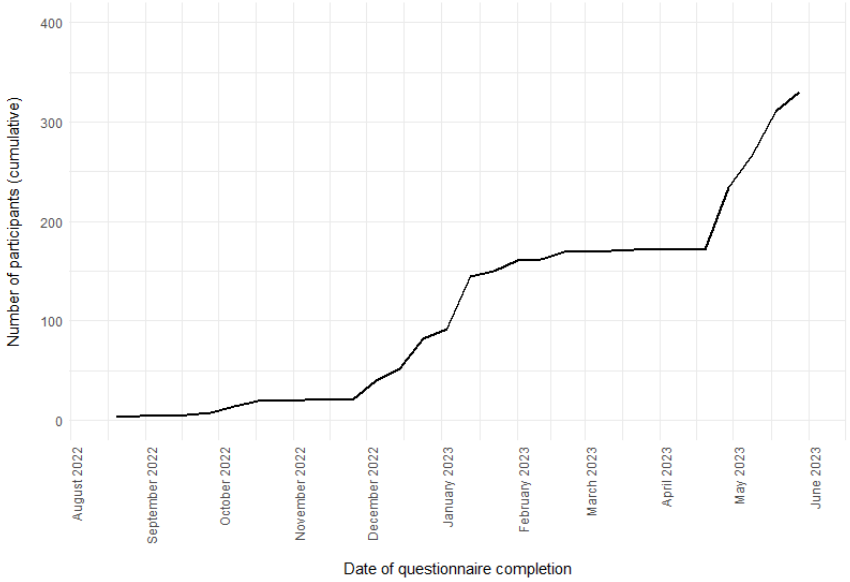

Figure 4. Boxplot (A) and histogram (B) of contact network size of electronic nicotine delivery system users participating in the study (Rio de Janeiro, 2022-2023).

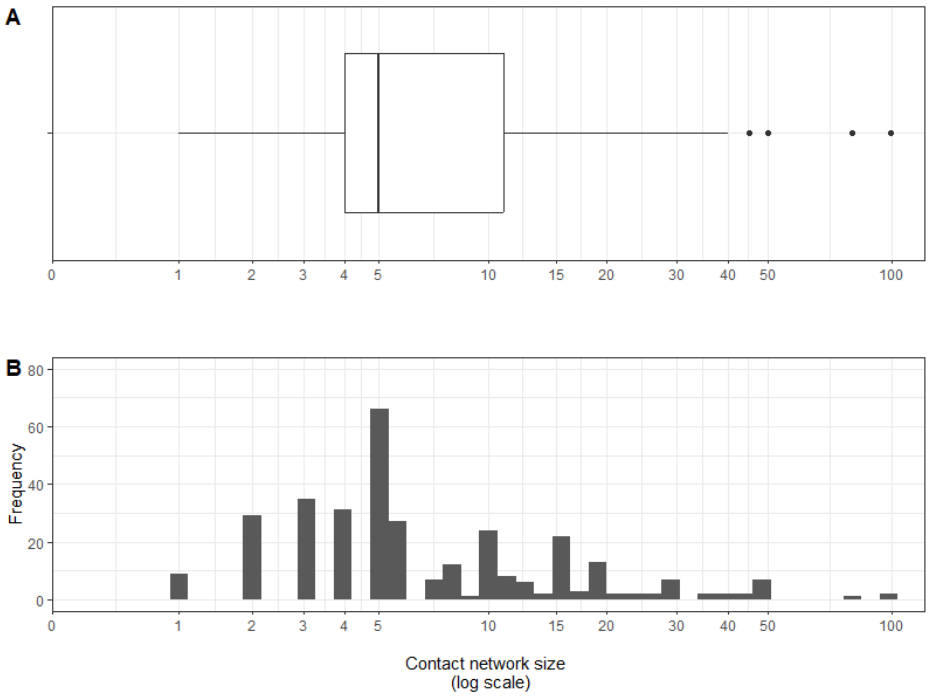

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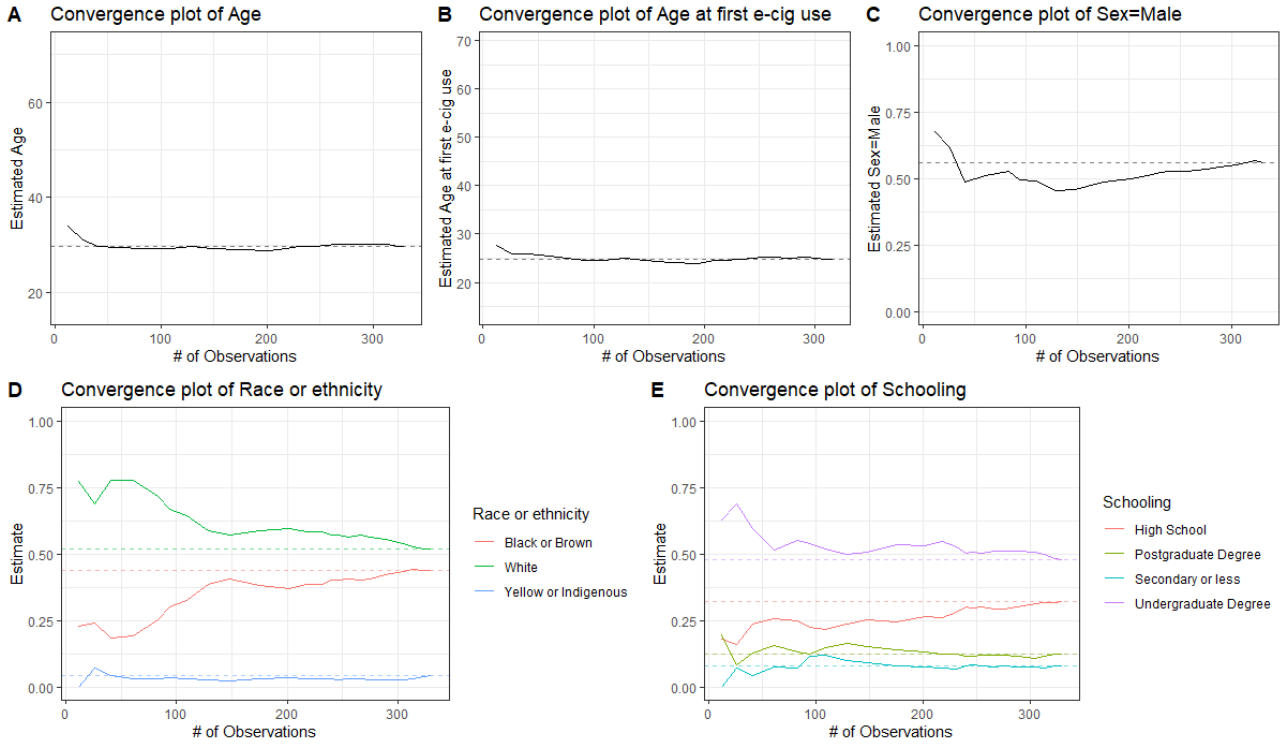
Figure 5. Convergence plots for selected variables of electronic nicotine delivery system users participating in the study (Rio de Janeiro, 2022-2023).



Discussion

Principal Findings

Web-RDS proved to be a feasible method for accessing the population of ENDS users, reaching participants in nearly all areas of the city of Rio de Janeiro. Although RDS has been used in several other studies in Brazil, ours was the first to use web-RDS and the first to use this methodology to access ENDS users. Our results are important for implementing web-RDS to ensure more effective data collection, as outlined in the following paragraphs.

Incentives for participation and recruitment emerged as a determining factor in the data collection process, consistent with findings in the international literature [18]. Recruitment chains only initiated after the primary incentive was increased, indicating that early recruitment failure was primarily related to insufficient incentive rather than to lack of network connectivity. Therefore, ensuring that there is no shortage of incentives and that they are provided as quickly as possible after completing the questionnaire can improve the effectiveness of data collection given the motivation to participate and to invite others [32]. In many settings (but not in Brazil), the legislation allows for cash compensation and incentives for participation in such studies; however, this requires a logistics system that may be unavailable in many countries. Double incentives are an intrinsic feature of studies using RDS [11]. Although several studies have attempted to quantify the influence of referral bias associated with illicit procedures or strategic participation, such efforts face a fundamental limitation: the impossibility of fully and consistently quantifying human decision-making under ethical and contextual constraints [33]. While strategic decisions may improve respondent-driven studies, they do not constitute rigorous conceptual or mathematical solutions for disentangling the combined influence of all underlying factors.

Researchers should be aware of attempts by individuals to circumvent the system by participating without being eligible or participating multiple times. This disadvantage of offering incentives for participation has also been observed in other studies with various populations [18], but it can be mitigated by using different methods, both automated and manual, to check for duplicate participation. A verification system such as one using genetic or evolutionary algorithms to track each web connection might be feasible [34]; however, it would jeopardize the study's confidentiality and violate its ethical assumptions. This concern is not exclusive to web-RDS studies, but it is a recurring issue in online research in general, particularly when pecuniary compensation is involved [35]. In our study, whenever fraudulent attempts were detected, respondents received an email message explaining that they were only allowed to participate once and that they would not be compensated (their invitations were also blocked). Such strategies have been used in other studies [21] and can deter attempts at multiple participation.

The use of web-RDS to collect large or multicenter samples requires even more automated systems, but this does not eliminate the need for manual validation. Fraud is still possible even with more advanced systems or the use of mobile phone numbers as participant identifiers [21]. Using different strategies helps minimize this problem while preserving the ethical research principles. The number of invitations distributed per participant was sufficient in our study, and there was no need for more than 3, as less than one-fourth of the participants (39/174, 22.4%) successfully recruited 3 eligible participants. In addition, half (154/324, 47.5%) of the users reported networks of up to 5 individuals. However, when a participant recruited

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an ineligible individual, the code became invalid and could not be reused to invite others. Approximately one-third of the invitations (178/508, 35.0%) were used by ineligible individuals, highlighting the importance of reinforcing the eligibility criteria with participants when recruiting their peers.

The upper limit of contact network size in our study is consistent with Dunbar's number, which theoretically represents the cognitive limit on the number of stable relationships a person can maintain [36]. However, this point deserves special attention due to the ongoing debate regarding the validity of Dunbar's number [37]. Respondents in our study tended to report their network size as a multiple of 5 (for networks larger than 5 individuals), as reported in other studies [38]. Therefore, the use of such strategies for estimating weights should be addressed, as there is a risk of bias, particularly when accessing consecutive samples. While larger samples would reduce uncertainties regarding the size of contact networks (degree) [29], they would not eliminate them given the persistent challenge of bottlenecks in any nomination network. There are strategies to minimize the negative impact of bottlenecks on recruitment processes, but bottlenecks cannot be entirely ignored [39]. Additionally, several methods for correcting or weighting samples obtained through RDS have been discussed [40,41], even the nonuse of weights for regression models [42].

Homophily is a permanent challenge for chain referral processes to recruit diverse samples rather than being trapped by "clonal dominance." The latter is quite common in biology [43] and has been extrapolated to social processes, with observable consequences [44] (ie, biasing the recruiting process). The seminal paper by Goel and Salganik [45] shows that RDS can follow a more complex process than originally conceived (as a first-order Markov process). Viewing RDS as a Markov chain Monte Carlo not only helps us understand "the effects of community structure and the recruitment procedure on the variance of RDS estimates," as stated by the authors, but also explains our study's findings. Homophily exists but is not the norm or an inevitable finding of RDS studies. The pervasive idea of "six degrees of separation" (frequently understood as a metaphor rather than a sound mathematical framework or a concrete empirical finding) suggests that most individuals can be reached within 6 intermediaries, which inspires the use of chain referral methods to access hidden populations [46]. However, this theory refers to network reach, not the specific statistical condition of sample equilibrium required for unbiased population estimates in RDS analysis.

Limitations

This study used email to communicate with participants (for motivation and to distribute incentives); however, through contact with the "seeds," we found that younger participants used email less frequently and preferred to be contacted via WhatsApp. Other studies have used cellphone numbers both as identifiers and to contact participants [21]; however, the automated use of WhatsApp is more complex and should be evaluated in light of the study's objectives [22].

Although this study used automated and manual verification procedures, additional antifraud tools (eg, one-time passwords sent to phone numbers, geolocation checks, or IP-based detection) may further reduce duplicate attempts at participation, but they were not used in this study. These methods involve trade-offs related to privacy, cost, and system complexity. Previous evidence [47] has shown that no single measure is fully effective in incentive-based online surveys and that in-depth verification remains essential.

Another limitation of the method is that it obviously cannot reach populations that lack internet access. However, this does not appear to be an issue when applying web-RDS to users of electronic smoking devices, as studies in Brazil indicate that this group enjoys high income and schooling levels [48]. According to the Brazilian census bureau, the entire educated population in Brazil has internet access [20]. If the use of ENDSs spreads to less privileged population groups, as is often the case with technological innovations [49], digital exclusion could introduce selection biases. It is also true that internet access is expanding across different population strata in Brazil [20]. Importantly, this study was only performed in the city of Rio de Janeiro, so the findings should not be generalized to the entire population of Brazilian ENDS users. However, the web-RDS procedures tested in this study provide insights into the feasibility of broader recruitment of ENDS users in Brazil.

The processes and outcomes in RDS studies have still not achieved the full application of implementation science concepts and methods. This limitation should be addressed by future studies inspired by new approaches to RDS methods and implementation science [26].

Conclusions

The web-RDS methodology proved capable of reaching ENDS users in different neighborhoods of Brazil's second largest city within a short period and at a relatively low cost. These characteristics could allow for the replication of the study at short intervals and on a larger scale for recruiting ENDS users across Brazil as a whole. Thus, web-RDS would enable monitoring the profile of ENDS users and potential changes over time, as well as methods for acquiring such products in different social and geographic contexts, thereby supporting the implementation of ongoing measures from Brazil's National Tobacco Control Policy.

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Data Availability

The datasets generated or analyzed during this study are not publicly available due to anonymity and confidentiality but are available from the corresponding author on reasonable request.

Authors' Contributions

NB conceptualized the study, analyzed the data, wrote the first draft, and revised the manuscript. ASS and FIB wrote and critically revised the manuscript. All 3 authors have read and approved the final manuscript.

Conflicts of Interest

None declared.

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Abbreviations

ENDS: electronic nicotine delivery system
RDS: respondent-driven sampling
Web-RDS: web-based respondent-driven sampling

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Original Paper

Assessment of Physician Preferences for Large Language Model–Generated Responses Across Geographic Regions and Clinical Experience Levels: Preliminary Survey Study

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Abstract

Background: Large language models (LLMs) have demonstrated increasing capabilities in generating clinically coherent and accurate responses to patient questions, in some cases outperforming physicians in terms of accuracy and empathy. However, little is known about how physicians across geographic regions and levels of clinical experience evaluate these artificial intelligence (AI)–generated responses compared to those authored by human clinicians.

Objective: This study examined physician evaluations of LLM-generated versus physician-authored responses to real-world patient questions, comparing preference patterns across geographic regions and years in clinical practice.

Methods: We conducted a cross-sectional online survey between March and May 2025 among licensed physicians recruited internationally. Participants reviewed anonymized medical responses from 2 LLMs (GPT-4.0 and Meta AI) and verified physicians to questions sourced from Reddit's r/AskDocs forum. Each participant ranked 3 responses per question (1=most preferred; 3=least preferred) according to accuracy and responsiveness. Mean ranks, pairwise win proportions, and full rank distributions were analyzed descriptively and stratified by geographic region and years in practice.

Results: Overall, LLM-generated responses were strongly preferred. GPT-4.0 achieved the best mean rank (1.63, SD 0.68; 95% CI 1.52-1.74), followed by Meta AI (1.83, SD 0.72; 95% CI 1.71-1.94), while verified physician-authored responses were least preferred (2.53, SD 0.76; 95% CI 2.40-2.65). In pairwise analyses, responses generated by GPT-4.0 won 78% (118/150) of the head-to-head comparisons versus physician-authored responses and 57% (86/150) versus Meta AI responses. Preference for GPT-4.0 was most pronounced in Africa (mean 1.59, SD 0.72), Asia (mean 1.91, SD 0.83), and North America (mean 1.55, SD 0.60), while Meta AI slightly led in Europe (mean 1.33, SD 0.57) and the Americas (mean 1.75). Across experience levels, physicians with less than 5 years in practice (28/52, 54%) ranked GPT-4.0 most favorably (mean 1.58, SD 0.63), followed by those with 10 to 15 years of experience (mean 1.56, SD 0.72). Even among physicians with more than 15 years in practice (9/52, 17%), AI-generated responses outperformed physician-authored responses (mean 1.75 vs 2.62). Across all subgroups, human-authored responses were ranked lowest.

Conclusions: This exploratory study demonstrates that physicians across diverse regions and experience levels generally prefer LLM-generated responses to human-authored ones. The consistency of this finding across continents and practice durations underscores growing professional acceptance of AI as a viable tool for patient communication. These results suggest that modern LLMs, particularly GPT-4.0, may provide clinically acceptable, contextually relevant, and user-trusted health information, with potential to augment physician workflows and patient education.

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(JMIR Form Res 2026;10:e82487) doi:10.2196/82487

KEYWORDS

artificial intelligence; AI; large language model; physician; health communication; global health

Introduction

The ability of artificial intelligence (AI) and large language models (LLMs) to analyze large volumes of health data and generate clinically accurate, context-aware responses presents a transformational opportunity to improve health care [1]. The adoption of LLMs in patient-facing clinical roles has progressed more slowly than in other areas, largely because of concerns about bias and diagnostic errors in previous models [2]. Methodological advancements, such as instruction tuning, retrieval-augmented generation, and multistep reasoning, have demonstrated significant improvements in both diagnostic accuracy and clinical utility of LLMs [3-5]. However, despite these advances, reactions within the medical community remain mixed. Surveys reveal a mixture of optimism and caution among physicians regarding the integration of LLMs into clinical and research practice [6,7].

Over the past 2 years, LLMs such as ChatGPT (OpenAI), Med-PaLM, and Claude have demonstrated increasing capability in performing complex clinical reasoning tasks, generating accurate discharge summaries, and offering patient-centered explanations comparable to those of human clinicians [8,9]. This progress has sparked active investigation into the safe and effective incorporation of generative AI into health communication workflows. Recent systematic reviews indicate that LLMs achieve high factual accuracy across common medical tasks but continue to exhibit variability depending on clinical specialty, input prompt quality, and language localization [10,11].

Understanding how physicians perceive the accuracy, appropriateness, and usefulness of LLM outputs is essential not only for assessing clinical accuracy but also for building trust in these models. Many studies have conducted physician evaluations of LLM-generated responses to patient questions, which play a crucial role in shaping broader perceptions and offer insight into both clinical utility and professional acceptance. Some studies have found that physicians rated LLM-generated responses more favorably than those authored by human clinicians [12,13]. However, previous research has been based primarily in North America and Europe, offering limited insight into how regional or experiential factors shape physicians' evaluations of AI in clinical communication. Given that cultural context, health system infrastructure, and training experiences can influence technology acceptance, understanding global variation in physician attitudes toward AI is critical for equitable integration**.** In contrast, other studies, including those in specialized therapeutic areas such as rheumatology, have found that physicians rated LLM-generated responses more favorably than those authored by human clinicians [14]. These mixed results underscore the need for more refined evaluations of LLM performance in medical question-and-answer tasks.

As the capabilities of LLMs expand, their potential integration into clinical communication raises important questions about reliability, professional trust, and cross-cultural acceptance [15]. Although technical benchmarks and validation studies have demonstrated impressive gains in diagnostic reasoning and accuracy, these metrics alone do not capture how clinicians, those ultimately responsible for patient care, perceive the credibility and usefulness of AI-generated information [16]. Physician attitudes toward LLMs are likely shaped not only by individual experience but also by broader contextual factors, such as regional practice norms, health system maturity, and exposure to digital technologies [17,18]. Trust and adoption are influenced not only by technical performance but also by explainability, ethical transparency, and alignment with professional communication norms. For instance, studies have shown that even when LLMs outperform humans in accuracy, physicians may still perceive AI-generated responses as impersonal or lacking contextual depth [19]. Understanding these contextual dynamics is essential because perceptions of AI competence and safety directly influence the adoption and integration of AI into clinical workflows. Thus, beyond measuring algorithmic accuracy, evaluating how physicians from different regions and stages of clinical practice interpret and rank AI-generated medical responses provides a more nuanced view of the readiness of global medical communities to engage with generative AI in patient-facing roles.

This study extends existing research by comparing physician evaluations of LLM-generated versus human-authored medical responses across multiple geographic regions and levels of clinical experience. Specifically, we surveyed an international sample of physicians to assess anonymized responses from verified physicians and 2 general-purpose LLMs based on accuracy and responsiveness. By capturing perspectives from diverse settings, this work aims to identify how geographic and professional contexts influence physicians' trust, preference, and acceptance of AI-generated communication in health care. Our preliminary findings demonstrate how contextual factors and professional experience shape evaluations of LLM-generated content, highlighting the need for larger, adequately powered studies to rigorously assess these differences.

Methods

Study Design and Participant Recruitment

We conducted a cross-sectional survey between March and May 2025. Eligible participants were licensed physicians and equivalent medical professionals recruited through institutional contacts, professional networks, and physician email distribution lists to ensure global representation. The recruitment email invited physicians to participate in a study comparing the accuracy and quality of responses to online medical consultations provided by physicians and by AI systems. Although the study topic was mentioned, invitations were

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distributed broadly and were not limited to networks or groups with a specific interest in digital health or AI.

No formal sample size calculation was performed because this exploratory study was designed to assess physician preferences rather than test a specific statistical hypothesis. The target sample size was determined pragmatically based on anticipated response rates from professional networks and similar physician survey studies, with the aim of obtaining at least 50 fully completed surveys to allow descriptive and subgroup analyses. Participants were asked to review and rank-order anonymized answers generated by 2 LLMs: GPT-4.0 (accessed via the ChatGPT Plus web interface [20]) and Meta AI.

Medical questions and physician-authored responses were sourced from Reddit's r/AskDocs forum, one of the largest public repositories of health-related queries, with more than 689,000 members as of April 2025 [21]. This subreddit features responses from verified medical professionals, who are credentialed through moderator verification (eg, submission of a medical ID or a diploma). No custom or pretested prompts were developed for this study. As the original physician responses were written for patients within the Reddit forum, all model prompts replicated this patient-style question format verbatim to preserve contextual equivalence. Each medical question was copied verbatim from the Reddit r/AskDocs forum and entered directly into GPT-4.0 and Meta AI through their publicly available web interfaces without any editing, rephrasing, or contextual modification. Thus, both AI systems and physicians responded to the same patient-oriented questions, minimizing but not entirely eliminating task-framing differences. The exact question texts and corresponding model responses are provided in Multimedia Appendix 1.

A total of 86 question-answer pairs (from 300 of the most recent and highly rated physician-authored responses) were selected based on clarity, generalizability, and the absence of identifiable information. From this subset, 20 question-answer pairs were randomly selected using numbergenerator.org. All data collection procedures adhered to Reddit's terms of service.

Finally, for each of the 20 selected medical question-answer pairs, new responses were generated using GPT-4.0 and Meta AI in isolated sessions to avoid contextual contamination. Consequently, each question had 3 responses: 1 from a verified physician, 1 from GPT-4.0, and 1 from Meta AI. No custom or pretested prompts were developed for this study. This approach preserved the authenticity and linguistic characteristics of real-world patient questions while ensuring that all model responses reflected genuine, unaltered interactions.

Survey Content and Administration

The survey was constructed and administered using Qualtrics. Participants were recruited using a purposive sampling approach initiated through verified physicians within professional networks. Physicians were invited to complete the survey and share the invitation with other licensed colleagues who met the inclusion criteria. This approach facilitated recruitment of a diverse group of practicing physicians across multiple regions while maintaining respondent authenticity and professional verification.

Participants were asked to provide information about their primary specialty of practice, years in clinical practice, current level of practice, age, sex, and primary geographic region of practice. Participants were also asked to indicate their current reliance on AI in routine clinical practice. Each respondent was then presented with 3 anonymized responses (GPT-4.0, Meta AI, or a verified physician) to 3 randomly selected medical questions drawn from a bank of 30 and was asked to rank each based on perceived accuracy and responsiveness (1=most preferred; 3=least preferred). Specifically, respondents were presented with the following instruction:

> *For each of the following set of questions, you will be provided with 3 responses. Carefully consider the responses and rank (using the radio buttons on the right side of the answers) in order of which most appropriately answers the question: First button—most preferred; Second button—moderately preferred; Third button—least preferred There is no right or wrong order.*

The order of the responses was randomized to reduce potential ordering bias, and all sources were anonymized to prevent identification.

Statistical Analysis

Only complete survey responses were included in the analysis, and the survey design required all ranking and demographic questions to be answered before submission. Our primary outcome was the mean rank assigned to each system (1=most preferred; 3=least preferred) across all evaluation tasks. To examine subgroup variation, we compared mean ranks for each response type (ChatGPT, Meta AI, and verified physician) across categories of years in clinical practice and geographic region. To assess robustness, we conducted two sensitivity analyses: (1) the proportion of wins in pairwise comparisons between systems and (2) full rank distribution visualizations. Given the limited sample sizes within subgroups, no formal statistical comparisons were performed. Because the survey aimed to capture individual subjective preferences, no interrater reliability statistic was calculated. Rankings were treated as independent observations reflecting personal judgments rather than measures of rater agreement. All statistical analyses were conducted using R software (version 4.1.2; R Foundation for Statistical Computing).

Ethical Considerations

This study was reviewed and approved by the institutional review board of the Morehouse School of Medicine (2276674-1) and determined to be exempt from full review because of its minimal risk, survey-based design. Participation was entirely voluntary, and informed consent was obtained electronically before respondents began the survey. All data were collected anonymously via Qualtrics, with no collection of IP addresses or other identifiable information, and were stored securely on access-restricted institutional servers. Results were analyzed in aggregate to ensure confidentiality. No monetary or nonmonetary compensation was provided.

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Results

A total of 52 physicians completed the survey, with nearly half (n=25, 48%) based in North America and the rest distributed primarily across Africa (n=13, 25%) and Asia (n=8, 15%). Most respondents were young, with more than half (n=28, 54%) aged between 25 and 34 years, and had less than 5 years of clinical experience (n=28, 54%). The sample was predominantly male (n=41, 79%). In terms of specialty, surgery was the most common (n=14, 27%), followed by family medicine (n=9, 17%) and anesthesiology (n=9, 17%). Other specialties were less represented (Table 1). On average, physicians reported integrating AI into approximately 19.1% (SD 19.6%) of their routine clinical practice, indicating varied but limited current adoption across the sample.

Table 1. Demographic and professional characteristics of physicians who participated in this global cross-sectional survey evaluating artificial intelligence–generated and physician-authored medical responses (N=52).

Variable	Participants, n (%)
Age (y)	
25-34	28 (54)
35-44	14 (27)
45-54	5 (10)
55-64	4 (8)
≥65	1 (2)
Sex	
Male	41 (79)
Female	11 (21)
Specialty	
General	2 (4)
Surgery	14 (27)
Family medicine	9 (17)
Internal medicine	5 (10)
Anesthesiology	9 (17)
Emergency medicine	3 (6)
Pediatrics	2 (4)
Psychiatry	3 (6)
Other	5 (10)
Duration of clinical practice (y)	
10-15	6 (12)
5-10	9 (17)
<5	28 (54)
>15	9 (17)
Geographic region	
Africa	13 (25)
Americas	1 (2)
Asia	8 (15)
Asia-Pacific	3 (6)
Europe	1 (2)
North America	25 (48)
Other	1 (2)

Table 2 displays the mean rank assigned to each response type across all physician evaluations, with lower scores indicating greater preference. Overall, responses generated by GPT-4.0 received the most favorable ratings, with a mean rank of 1.63 (SD 0.68; 95% CI 1.52-1.74). Meta AI responses followed, with a mean rank of 1.83 (SD 0.72; 95% CI 1.71-1.94), whereas

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verified physician-authored responses were ranked least favorably, with a mean of 2.53 (SD 0.76; 95% CI 2.40-2.65). These results suggest a clear overall preference among surveyed physicians for LLM-generated responses over those authored by verified physicians. In pairwise analyses, responses generated by GPT-4.0 won 78% (118/150) of the head-to-head comparisons versus physician-authored responses and 57% (86/150) versus Meta AI responses.

Table 2. Mean rankings of responses generated by GPT-4.0, Meta AI, and physicians by global physician respondents in a cross-sectional survey (n=150).

Response type	Rank, mean (SD)	SE	95% CI
ChatGPT-4.0	1.63 (0.68)	0.06	1.52-1.74
Meta AI	1.83 (0.72)	0.06	1.71-1.94
Physician	2.53 (0.76)	0.06	2.40-2.65

Figure 1 presents the mean ranking of each response type, stratified by geographic region, along with associated error bars. Across all 6 regions, responses generated by GPT-4.0 and Meta AI were consistently ranked more favorably than physician-authored responses. Preference for GPT-4.0 was most pronounced in Africa (mean 1.59, SD 0.72), Asia (mean 1.91, SD 0.83), and North America (mean 1.55, SD 0.60), while Meta AI slightly led in Europe (mean 1.67, SD 0.57) and the Americas (mean 1.67, SD 0.57). In the Americas and Europe, Meta AI slightly outperformed GPT-4.0; however, both LLMs were clearly preferred over human-authored responses. Physician-authored responses received the highest (least preferred) rankings in every region, with particularly low ratings in the Americas and Europe. Although the overall preference for LLM-generated content was consistent, small regional differences in the relative performance of GPT-4.0 and Meta AI suggest some variation in how physicians across different regions evaluate AI-generated responses.

Figure 1. Mean ranking of GPT-4.0, Meta AI, and physician-authored medical responses by global geographic region among physician respondents.

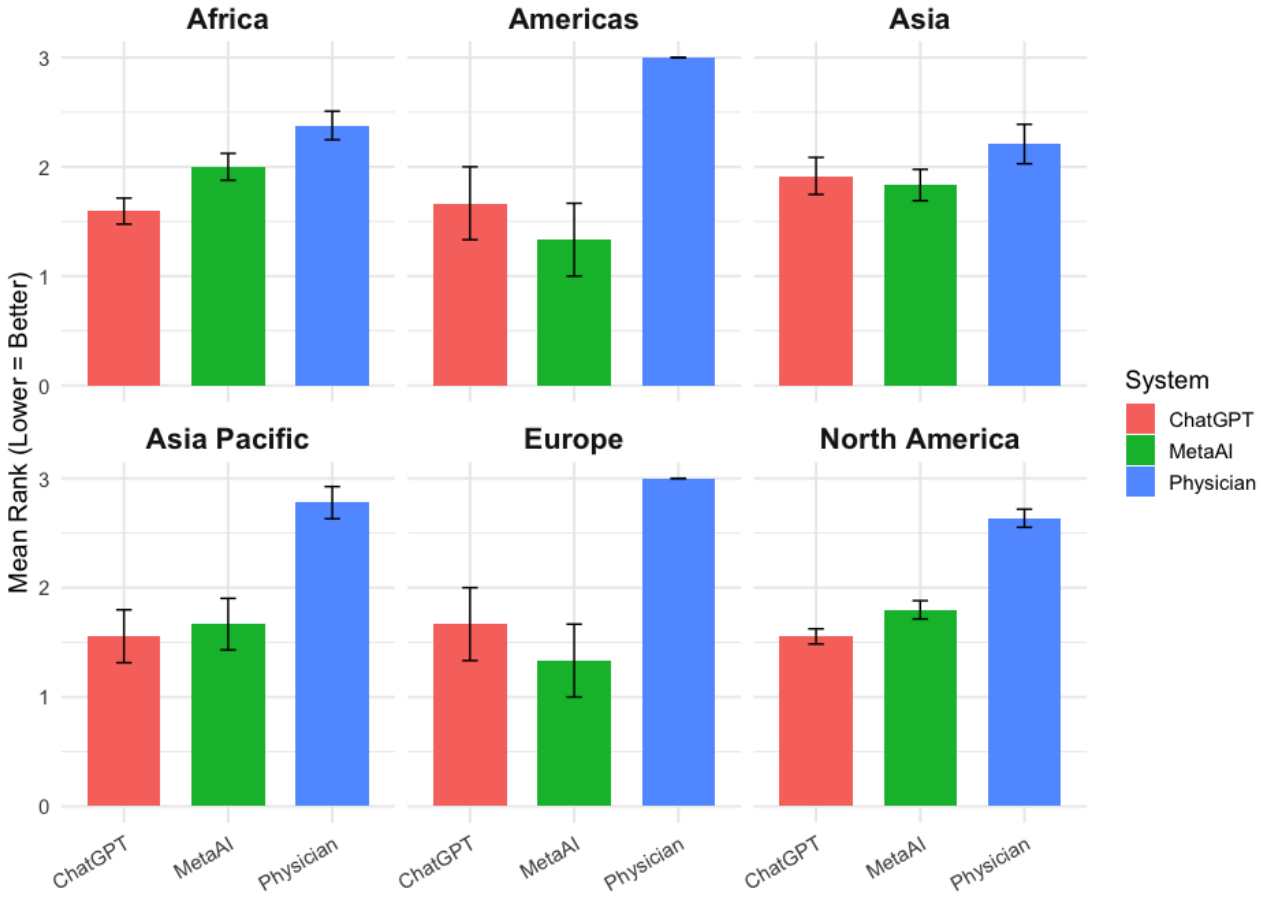

Figure 2 displays the mean ranking of each response type stratified by years in clinical practice, with lower values indicating greater preference. Across all experience levels, physician-authored responses consistently received the least favorable rankings. Across experience levels, physicians with less than 5 years in practice (28/52, 54%) ranked GPT-4.0 most favorably (mean 1.58, SD 0.63), followed by those with 10 to 15 years of experience (mean 1.56, SD 0.72). Even among physicians with more than 15 years in practice (9/52, 17%), AI-generated responses outperformed physician-authored

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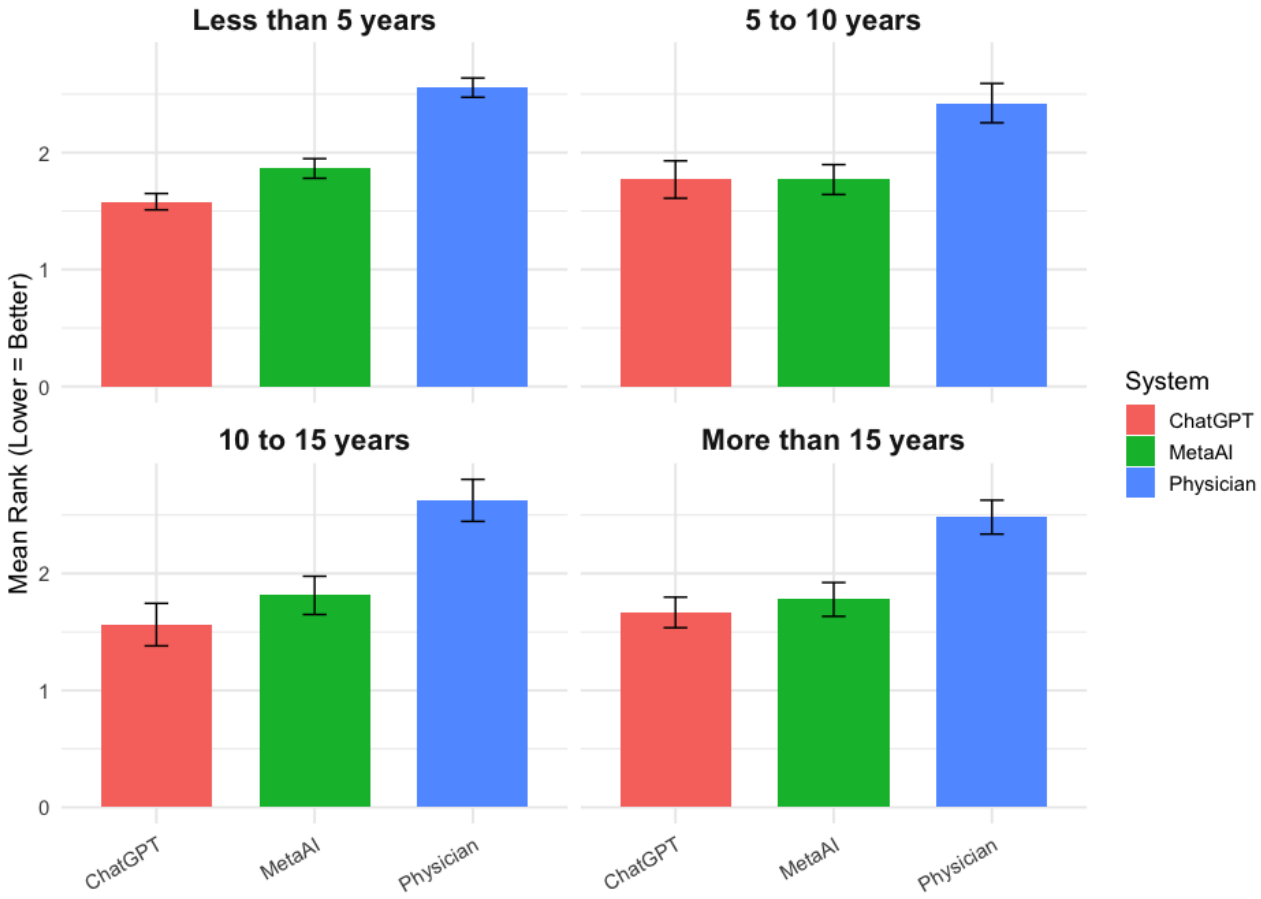
responses (mean 1.75 vs 2.62). Across all subgroups, human-authored responses were ranked lowest. Notably, the relative advantage of GPT-4.0 over Meta AI was most pronounced among those with 10 to 15 years of experience. Results were consistent across sensitivity analyses. Pairwise comparisons confirmed the relative ordering of systems, and rank distributions revealed moderate variability across subgroups.

Figure 2. Mean ranking of GPT-4.0, Meta AI, and physician-authored medical responses by years of clinical practice among physician respondents worldwide.



Discussion

In this exploratory study, we demonstrated that LLM-generated responses were consistently preferred over those authored by verified human physicians. Overall, responses generated by GPT-4.0 received the most favorable mean rankings, followed by those generated by Meta AI, with physician-authored answers ranking lowest. This pattern held across geographic regions and years in clinical practice, with particularly strong preferences for GPT-4.0 in Africa, Asia Pacific, and North America, and for Meta AI in the Americas and Europe. Similarly, regardless of clinical experience level, both LLMs outperformed physician-authored responses, with GPT-4.0 maintaining a consistent advantage. Sensitivity analyses confirmed the robustness of these findings, supporting the overall conclusion that physicians generally favored LLM-generated medical responses.

The findings of this study both confirm and extend previous research on physician evaluations of LLM-generated versus physician-authored responses to medical questions. Consistent with existing work, we found that physicians generally preferred responses produced by LLMs such as GPT-4.0 and Meta AI over those authored by clinicians [12,13]. This trend was observed across all examined subgroups. However, not all previous studies found a clear preference for LLM-generated responses. Some studies have shown that ChatGPT's medical answers can be incomplete, inaccurate, or misleading when compared to clinician responses [14,22,23]. Others have found a significant performance gap in non–English language medical question answering, including an 18% drop in correctness, a 29% decrease in consistency, and a 13% decrease in verifiability, highlighting substantial limitations in the reliability and quality of LLM-generated health information across languages [24]. Altogether, the mixed results highlight the context-dependent and variable nature of LLM performance and physician evaluations.

The observed preference for LLM-generated responses across diverse regions and experience levels suggests that physicians increasingly perceive these systems as credible and clinically useful sources of information. This aligns with previous studies showing that ChatGPT and similar LLMs often produce responses rated higher in empathy, readability, and completeness

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than those authored by human clinicians, particularly in general medical advice contexts [8-10]. However, unlike previous studies conducted within single-country or specialty-specific samples, our findings extend this evidence globally, demonstrating that favorable perceptions of LLM-generated content are not confined to technologically advanced regions. The consistency of physician preferences across geographic and professional subgroups indicates a growing normalization of AI-generated communication within medical culture. At the same time, slightly higher rankings of LLM responses among early-career physicians may reflect greater exposure to digital technologies and openness to innovation, a pattern previously noted in studies of clinical AI adoption [11,12]. These results underscore the potential for LLMs to serve as scalable adjuncts for patient education, triage support, and clinician-patient communication, especially in settings with limited physician capacity. Nevertheless, while high favorability ratings suggest strong perceived accuracy and usefulness, they also emphasize the need for robust oversight, continuous validation, and clear governance frameworks to prevent overreliance on unverified AI outputs. Collectively, this study contributes new cross-regional evidence supporting the cautious but promising integration of generative AI into medical communication workflows.

The consistent preference for AI-generated responses may reflect their greater linguistic fluency, organization, and visual formatting compared to physician-authored replies, which were often less structured or more conversational in tone. Previous studies have shown that LLM outputs tend to emphasize empathy, completeness, and readability, characteristics that may enhance perceived quality even when clinical accuracy is comparable [15]. These stylistic and communicative advantages could make AI-generated responses more appealing to readers evaluating them for clarity and responsiveness, particularly in online, text-based contexts, when compared to real-world physician responses.

This study has several limitations that should be considered when interpreting the findings. First, the relatively small sample size limited statistical power, especially for subgroup comparisons by geographic regions and years in practice. As a result, observed differences in preferences should be interpreted as descriptive rather than inferential. This is especially true for physician-authored responses from Europe and the Americas, each of which included only 1 respondent. Second, the convenience sampling approach and voluntary participation may have introduced selection bias, as physicians with stronger opinions or greater familiarity with (and interest in) AI tools may have been more likely to respond. Third, although the use of real-world patient questions from Reddit's r/AskDocs forum enhances ecological validity, the specific platform and format may not fully reflect the complexity of clinical communication in real-world practice nor are physician responses to questions on social media. Finally, the nonspecific construct of "preference" may have introduced variability in interpretation across respondents. Although rankings were analyzed as independent judgments, differences in how individual physicians conceptualized "preference" (eg, prioritizing accuracy versus clarity) could have contributed to interrater variability. Future studies with larger and more diverse samples should use mixed methods designs and incorporate standardized rating criteria or interrater reliability analyses to validate and extend these preliminary findings [12-14,22-24].

Although exploratory, this study contributes valuable evidence to the expanding literature, indicating that LLM-generated medical responses can be considered clinically acceptable by physicians. This suggests potential for LLMs to assist in patient education and clinical decision support when deployed under appropriate conditions. Our findings also underscore that physician perceptions of LLM-generated responses are not uniform but rather nuanced and influenced by various demographic factors (eg, geographic region) and professional characteristics (eg, years of clinical experience). These moderating factors may shape how clinicians evaluate the comprehensiveness, accuracy, readability, and overall usefulness of AI-generated outputs. Such variability highlights the importance of tailoring AI integration strategies to specific user groups and clinical contexts rather than assuming broad or universal acceptance. Therefore, while supporting the growing enthusiasm regarding the promise of LLMs, our study calls for continued, rigorous evaluation of AI systems across subgroups and by extension settings to ensure safe, effective, and responsible adoption.

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Data Availability

The datasets generated or analyzed during this study are available from the corresponding author on reasonable request.

Authors' Contributions

JSB contributed to the conceptualization and methodology of this study, managed data curation, and participated in reviewing and editing the manuscript. PKB contributed to data curation and reviewing and editing the manuscript. RAC and TO were

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involved in data curation. AR contributed to the conceptualization of the study. MYI played a leading role in conceptualization and methodology, contributed to reviewing and editing the manuscript, and secured funding for the project.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Sampled patient questions obtained from the r/AskDocs forum and evaluated in this study.
[PDF File (Adobe PDF File), 391 KB - formative_v10i1e82487_app1.pdf]

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Abbreviations

AI: artificial intelligence
LLM: large language model

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Original Paper

Understanding Behavioral Influences on Eating Disorders and App Engagement to Inform Eating Disorder App Development: Qualitative Online Focus Groups With Adults With Lived Experience

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Abstract

Background: Eating disorders (EDs) are severe mental health conditions driven by psychological, social, and emotional factors and have the highest mortality rate of any psychiatric disorder. Although evidence-based, theory-driven behavior change interventions are the gold standard, access to treatment remains limited. Digital interventions, such as apps, may offer accessible support for individuals with mild to moderate EDs; however, their development has rarely been guided by systematic behavior change frameworks. Consequently, many interventions inadequately target the mechanisms underlying ED behaviors and commonly lack involvement of people with lived experience.

Objective: This study aimed to identify priority behavioral change targets for ED apps by capturing lived experience perspectives on the psychological, behavioral, and contextual factors maintaining disordered eating and driving app engagement. Using the capability, opportunity, motivation—behavior (COM-B) and theoretical domains framework (TDF), we mapped these determinants to identify where and how apps can most effectively enhance capability, opportunity, and motivation.

Methods: In total, 6 small focus groups (2-5 participants per group) were conducted with 13 female and 5 male adults, including minority ethnic backgrounds, living in the United Kingdom with lived experience of an ED. Discussions explored (1) the psychological, social, and environmental determinants underpinning participants' disordered eating behaviors and (2) the behavioral and contextual mechanisms influencing engagement with an ED app. A hybrid deductive-inductive thematic analysis was performed using the COM-B model and the TDF. Themes were mapped onto evidence-based behavior change techniques using the Theory and Techniques Tool.

Results: This study identified clear behavior change targets for digital ED interventions, identifying requirements in 5 of 6 (83%) COM-B domains and 13 of 14 (93%) associated TDF domains for changing maladaptive ED behaviors and 5 of 6 (83%) COM-B and 12 of 14 (86%) TDF domains for sustaining app engagement. Although social support and emotional regulation were key influences, less commonly targeted domains, such as social or professional role and identity and belief in capabilities, emerged as powerful drivers in this population. Crucially, it demonstrated that effectiveness depended not only on which behavior change techniques were included but also on how they were implemented, as poorly delivered techniques can undermine engagement and exacerbate symptoms. Sex and cultural background moderated almost every domain, highlighting the necessity of personalized, adaptive delivery and the inadequacy of one-size-fits-all approaches.

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Conclusions: As the first study to apply the COM-B and TDF frameworks to both disordered eating behaviors and app engagement, it identifies previously overlooked behavioral mechanisms and design pitfalls, including how poorly delivered techniques can undermine recovery. It provides a practical blueprint for developing safer, more personalized, and behaviorally effective ED apps. Significant work is needed to advance apps in line with these recommendations, supported by ongoing collaboration with diverse people with lived experience.

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KEYWORDS

eating disorders; mobile apps; digital health; behavior change; COM-B model; capability, opportunity, motivation—behavior; lived experience; qualitative research

Introduction

Background

Eating disorders (EDs) are severe mental health conditions with the highest mortality rate of any psychiatric disorder [1] and are associated with significant psychological, physical, and emotional consequences [2]. Globally, EDs are estimated to affect up to 70 million people, with prevalence rates rising over recent years [3]. Despite the substantial burden of disease on individuals [4] and the health care system [5], access to treatment remains a significant challenge [6]. A US study revealed that 85.9% of individuals who had screened positive for an ED never received treatment [7]. As EDs rarely resolve spontaneously and often worsen over time, early intervention is essential [8]. EDs affect people of both sexes and all ages, ethnicities, and backgrounds, with similar prevalence rates of disordered eating in male and female individuals and in minority ethnic groups compared to White individuals [9,10]; yet, these groups experience more limited access to treatment [11,12].

Understanding the behavioral mechanisms that underpin EDs is critical for developing digital interventions, such as apps, that can effectively modify these behaviors. Existing research has highlighted key mechanisms contributing to ED behaviors, including rigid cognitive control, affect regulation difficulties, perfectionism, and negative body image [13-15]. However, it remains unclear how these mechanisms translate into the specific capabilities, opportunities, and motivations that drive restricting, bingeing, or purging in everyday life. Studies exploring these behavioral determinants through in-depth discussions with people with lived experience remain limited, and most have focused on predominantly White, female samples [16], overlooking potentially distinct influences affecting male individuals and individuals from minority ethnic groups [17,18]. To date, no study has systematically mapped these behaviors using behavior change frameworks such as capability, opportunity, motivation—behavior (COM-B) [19] and the theoretical domains framework (TDF) [20], leaving digital intervention development without a clear, theory-informed basis for targeting the behaviors that need to change [21,22].

Despite the proliferation of digital ED interventions, systematic reviews have consistently highlighted a significant gap in the incorporation of evidence-based behavior change strategies. Most commercially available apps offer minimal content, such as basic mood or food tracking and generic motivational messages, with little structured cognitive or behavioral support [23-27]. Even among research-based apps [28,29], key domains, including structured social support, environmental restructuring, and culturally tailored resources, remain underdeveloped. Usability issues [30] such as those surrounding food logging [16,31] suggest that the way behavior change components are implemented can undermine engagement. Importantly, while some usability challenges mirror those seen in broader mental health apps (eg, lack of personalization), others are unique to ED interventions, such as food tracking or numeric logging that can exacerbate perfectionism and shame [32]. These gaps highlight the need for systematic, theory-driven app development that maps behavioral mechanisms to intervention features and involvement of people with lived experience in the design process [33].

Digital interventions, particularly apps, offer accessible, flexible, and anonymous support, making them particularly suitable for individuals who might not otherwise seek help [34]. Systematic reviews suggest that digital ED intervention can be effective [27,35-37]; however, engagement (defined as uptake, sustained use, and attrition) remains a significant barrier to realizing this potential [26,36,38]. Existing self-guided apps often lack technological sophistication, meaningful interactivity, personalization, or social components, and no specific design features have been consistently associated with lower dropout [39]. Techniques effective in face-to-face therapy may require careful adaptation to maintain engagement in self-guided digital interventions. Qualitative research has shown that poor usability, perceived irrelevance, and lack of personalization are key drivers of early disengagement [16,40]. Although previous research has provided valuable insights into general usability issues and surface-level preferences, no prior study has comprehensively applied a theory-driven (COM-B or TDF) framework to map the behavioral determinants that drive sustained engagement with ED-specific apps from the perspective of people with lived experience. This gap is especially pronounced for underrepresented groups, including male individuals [41] and individuals from minority ethnic backgrounds [11,12], whose needs are frequently overlooked in the design of both traditional [42] and digital ED interventions [16]. Addressing these gaps is essential not only for inclusivity but also to ensure that digital ED interventions are acceptable, effective, and equitable across diverse populations.

Theoretical Framework

Behavioral models such as the COM-B model [19] and the TDF [20] provide a systematic approach to understanding the drivers of behavior and informing the design of effective interventions. The COM-B posits that behavior change depends on the

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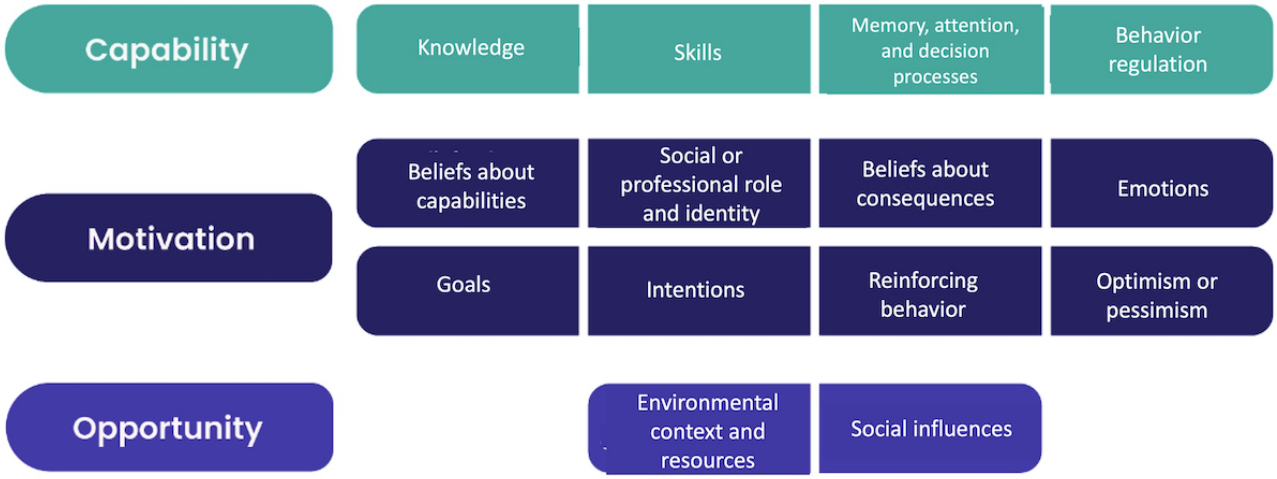
interaction of 3 factors: capability, opportunity, and motivation. The TDF is a comprehensive framework that consolidates 14 domains (eg, knowledge, skills, beliefs about capabilities, and social influences) to identify barriers and facilitators of behavior change, drawing from various psychological and behavioral theories [22]. It is closely related to the COM-B model, providing a detailed breakdown of the components within capability, opportunity, and motivation (Figure 1) [37], allowing for a more granular analysis of the factors influencing behavior. This connection enables the TDF to operationalize COM-B by offering specific constructs that can be targeted when designing interventions to address identified behavioral determinants. This methodology is a crucial step toward designing useful interventions [43].

Figure 1. The capability, motivation, and opportunity model and the theoretical domains framework.



These frameworks have been applied in various health contexts, including physical activity and smoking cessation [22,44,45], to identify the underlying mechanisms of behaviors and design interventions targeting these mechanisms. No systematic analysis has applied the COM-B model and TDF to identify specific behavioral domains in EDs, which has limited the development of targeted ED interventions [19,20].

Rationale and Study Aims

Incorporating behavior change theory into app development has been shown to improve user effectiveness and engagement [46]. While systematic reviews highlight the value of specific behavior change techniques (BCTs) [27], there is limited evidence regarding how these techniques align with the behavioral influences driving restrictive, bingeing, or purging behaviors or how they can be operationalized in digital contexts.

This study addressed this gap by exploring the behavioral influences underlying maladaptive ED behaviors and app engagement among people with lived experience, using the COM-B and TDF frameworks, and systematically mapping these influences to BCTs via the BCT Taxonomy v1 [47]. The study aimed to inform the design of theory-driven, user-informed digital interventions that are effective, inclusive, engaging, and responsive to diverse needs.

The objectives of this study were to identify the key behavioral, psychological, and contextual factors maintaining maladaptive ED behaviors; capture perspectives from male and female adults across different ethnic backgrounds to ensure inclusivity; identify the behavioral and contextual determinants of engagement with ED apps; and map identified behavioral influences to BCTs and consider how they can be prioritized and implemented sensitively in digital contexts.

Methods

Study Design

Small focus groups (FGs) of people with lived experience of EDs ensured that all had the opportunity to share their perspectives while fostering a “safer” and more intimate setting that encouraged active and meaningful contributions [48]. The number of sessions was informed by the point of data saturation of the key themes [48]. The use of online FGs allowed for the inclusion of diverse voices from geographically dispersed participants, which was relevant, given the goal to make treatment more widely accessible.

The COREQ (Consolidated Criteria for Reporting Qualitative Research) checklist [49] ensured that the procedures, analysis, and interpretation were rigorous (Multimedia Appendix 1).

Recruitment

The primary recruitment channel was First Steps ED, a specialist ED support service, which accessed individuals with relevant lived experience. This was supplemented by targeted advertisements posted on social media platforms, specifically Facebook and X (formerly known as Twitter). Since most apps are targeted mainly at the Western female population, we explicitly aimed to recruit a diverse sample, including a range of ages, male participants, and individuals from minority ethnic backgrounds.

In response to inauthentic or bot-generated responses, a structured screening protocol was developed in consultation with a second qualitative researcher (PB) and university IT support to ensure genuine, eligible participants. Of 95 emailed expressions of interest, 75 were excluded due to suspected inauthentic responses (eg, verbatim or near-verbatim responses and timestamp clustering; Multimedia Appendix 2). Flagged

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cases were independently reviewed by 2 researchers (PCT and PB), with exclusion requiring consensus.

The remaining 20 respondents were sent a screening form to assess eligibility by detailing their ED history, including self-reported diagnosis (if any), treatment history, and current or recent ED behaviors (eg, binge eating, purging, or restriction ≥1 time per week for ≥3 months, per *DSM-5* (*Diagnostic and Statistical Manual of Mental Disorders* [Fifth Edition]) subthreshold criteria). A formal diagnosis was not required, aligning with the study's focus on lived experience. Interested individuals were emailed, and those meeting the inclusion and exclusion criteria (Textbox 1) were sent study information and consent materials. A sample of 20 was considered adequate to provide thematic depth and diversity in perspectives, appropriate for the study's qualitative co-design approach [50]. Recruitment materials (advertisements, consent forms, and screening survey) were provided in English only, reflecting the UK-based sample and the FG language.

Textbox 1. Inclusion and exclusion criteria for online focus groups with people with lived experience.

Inclusion criteria

- Adults with eating disorders or eating disorder behaviors or symptoms (aged 18 years and older).
- Adults who were interested in getting support for their eating disorder or disordered eating problems.
- Adults who had experienced an eating disorder or disordered eating and were in recovery.

Exclusion criteria

- Receiving treatment for eating disorders at the time of the study.
- Had been hospitalized for an eating disorder within the last 3 years.
- Underweight at the time of the study (classified as a BMI less than 18.0 kg/m^2).
- Did not feel or present in a fit mental state to participate.

FG Procedure

A semistructured topic guide was designed to cover key behavioral domains relevant to intervention development. The structure and content were developed and piloted with Patient and Public Involvement from First Steps ED. It was structured into 3 sections: ED experiences and digital tools, influences on ED behaviors (subdivided into psychological and emotional factors, social and environmental influences, and motivational factors), and engagement with support apps (Multimedia Appendix 3).

FGs took place in January and February 2024 and were held online in the evening. While participants had no prior relationship with the researcher, rapport was established through presession email exchanges that included session outlines and answered queries. Participants were aware of the researcher's role and the study's aim to inform the development of a supportive ED app.

Reflexivity Statement

The lead researcher (PCT), a female PhD candidate trained in qualitative methods, conducted and analyzed the online FGs. She remained reflexive about potential biases, including a belief in the value of digital tools for addressing service gaps, which could influence questioning, coding, or interpretation. To mitigate this, she actively explored diverse views, including critical perspectives on ED apps. Coding and analysis were regularly discussed with the second supervisor (PB), who provided independent input and supported the development of balanced, grounded themes through ongoing analytical debriefing.

Ethical Considerations

This study received ethics approval from University College London Research Ethics Committee (UCL Ethics: 23943/001). The research adhered to ethical guidelines for qualitative studies involving human participants. Eligible participants who met the inclusion criteria received a detailed participant information sheet outlining the study's purpose, procedures, potential risks, and the voluntary nature of participation. Informed consent and baseline demographic data were collected via REDCap (Research Electronic Data Capture) [51], a secure, web-based platform hosted by University College London. Participant data were stored on encrypted, password-protected systems accessible only to the research team. All transcripts were fully anonymized, with identifying information removed prior to analysis. During FGs, participants used first names only to reduce identifiability. Quotations presented in this manuscript were reviewed to ensure anonymity with no personally identifiable details. To address the sensitive nature of EDs, safeguarding measures were implemented. Interview questions were piloted with a Patient and Public Involvement committee to ensure sensitivity and relevance. The primary researcher (PCT) was a trained facilitator with experience in motivational interviewing and previous volunteering with an ED charity. Immediate safeguarding support was available during and after sessions by an on-call safeguarding lead at First Steps ED. In line with Health Research Authority guidance [52], participants received a US $34 voucher as compensation for their time and input, ensuring fairness without undue inducement.

Data Analysis

All FG discussions were video recorded and automatically transcribed using Microsoft Teams, with transcripts subsequently checked for accuracy and anonymized. Transcripts were

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imported into NVivo (version 14; Lumivero) for analysis. A hybrid deductive-inductive thematic analysis was conducted using the COM-B model and the TDF as the primary organizing structure. All transcripts were first deductively coded line-by-line in NVivo (version 14) by the first reviewer (PCT) using COM-B components and the 14 TDF domains. To calibrate coding and enhance reliability, 2 researchers (PCT and RP), both trained in behavioral science, independently coded the first transcript together, refining code definitions through discussion. The second researcher (RP) then independently deductively coded 100% of the transcripts using the same framework. Discrepancies and emerging interpretations were documented in a Microsoft Excel spreadsheet and resolved in an iterative consensus meeting. A third reviewer (KC) was available to adjudicate unresolved disagreements. Final agreed inductive codes were grouped into subthemes.

Following the COM-B and TDF-informed analysis, the identified domains (eg, social or professional role and identity and emotions) were systematically mapped to corresponding BCTs using the BCT Taxonomy v1 [47]. This mapping process was primarily guided by the Theory and Techniques Tool [53], which provided evidence-based links between theoretical domains and BCTs in published intervention studies and indicated the strength of the evidence of each link. Where the Theory and Techniques Tool indicated strong or promising evidence for a link, the corresponding BCT was prioritized. In cases of conflicting evidence, weak evidence, or where multiple BCTs were plausible, final selection was determined by expert consensus within the multidisciplinary project team. Decisions were further refined to ensure contextual fit with study findings regarding day-to-day influences on ED behaviors and app engagement and the technical and design constraints of an app.

Results

Overview

Of the 95 initial recruitment responses, 75 inauthentic responses were excluded (Multimedia Appendix 2), and 2 withdrew prior to data collection due to conflicting commitments, resulting in 18 participants. In total, 6 online FGs (labeled FG A-F) were conducted, with an average of 3 participants (range 2-5) per group. FGs had a mean duration of 58.1 (SD 3.8; range 53.9-64.0) minutes.

Participant Characteristics

In total, 13 of 18 (72%) adult female participants and 5 of 18 (18%) adult male participants took part, a ratio closely representative of the ED population [8]. A majority of 13 of 18 (72%) participants were White, and 5 of 18 (28%) were non-White including 2 of 18 (11%) Asian and 3 of 18 (11%) Black. In terms of age, 5 of 18 (28%) participants were aged 36 years or older, with the remaining 13 of 18 (72%) younger than 35 years.

Of the 18 participants, 14 (78%) reported engaging in dietary restriction, 10 (56%) reported overexercise as a symptom, 7 (39%) reported binge eating, and 6 (33%) reported purging. In total, 12 of 18 (67%) participants had received outpatient treatment, and 6 of 18 (33%) had received inpatient care. At the time of the study, 1 of 18 (6%) male participants was on a waiting list for treatment but was in a stable condition. A total of 5 of 18 (28%) participants reported never having received any form of treatment (Multimedia Appendix 4).

Objective 1: Understanding Disordered Eating Behaviors

Overview

When discussing their ED behaviors, participants described behavioral influences across 5 of 6 COM-B domains (all domains excluding physical capability). There was consistency in the types of behavioral influences described; however, the relative importance of specific influences varied between individuals. These findings mapped to all areas of the COM-B, except for physical capability, which was not discussed, and to 13 of 14 (93%) TDF domains.

Psychological Capability

Overview

Results identified key psychological capability factors influencing disordered eating behavior, captured as themes and subthemes across COM-B and TDF domains with corresponding behavior change techniques (Table 1).

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Table 1. Psychological capability factors influencing disordered eating behavior: capability, opportunity, motivation—behavior (COM-B) and theoretical domains framework (TDF) analysis.

COM-B domain	TDF domain	Subthemes	Behavior change technique
Psychological capability	Knowledge	• Understanding eating disorder condition • Importance of nutrition • Connection between food and weight • Relapses in recovery	• 4.1 Instructions on how to perform a behavior • 4.2 Information about antecedents • 5.1 Information about health consequences • 5.3 Information about social and environmental consequences
Psychological capability	Skills	• Cognitive skills (challenging negative thoughts) • Need for coping skills (to manage urges) • Interpersonal skills • Meal planning	• 8.1 Behavioral practice or rehearsal • 8.2 Behavior substitution • 12.4 Distraction
Psychological capability	Behavioral regulation	• Regulating eating • Self-monitoring	• 2.3 Self-monitoring of behavior • 2.4 Self-monitoring of outcomes of behavior • 4.2 Information about antecedents • 8.2 Behavior substitution
Psychological capability	Memory, attention, decision-making	• Planning regular eating	• 1.4 Action planning • 12.4 Distraction • 13.2 Framing or reframing • 11.3 Conserve mental resources

Knowledge

Participants often described a limited understanding of the triggers and consequences of their disordered eating, contributed to delayed recognition of symptoms, and reduced help-seeking. This lack of insight was accompanied by confusion, uncertainty, and a sense of helplessness about their experiences. As one participant explained, understanding the mechanisms underlying their behavior and what EDs really were “might have helped me recognize the problem earlier” (FG A, Participant 1).

Understanding and being able to recognize how emotional triggers contributed to disordered eating behaviors and perpetuated cycles was seen as crucial. The knowledge that relapse was a normal part of recovery was viewed as key to maintaining motivation and self-compassion. One participant reflected that reassurance about these “cycles” of recovery and relapse could help individuals feel less discouraged when setbacks occurred (FG B, Participant 1).

There was a common gap in understanding of the relationship between EDs and nutrition, including the importance of nutrition for proper bodily function. For some, acquiring nutritional knowledge empowered some to broaden their food choices and challenge avoidance behaviors: “I didn’t know that my body needed all of that different things and how it helps you function in different ways” (FG A, Participant 3).

Learning through experience about the relationship between food intake and weight stability helped participants re-evaluate previously held fears around eating. Realizing that weight remained stable after eating previously avoided foods was often described as a turning point in recovery:

> *When I started to eat and realize everything was OK, this really surprized me. After years of not ... I ate a sandwich, and nothing happened.* [FG F, Participant 1]

Skills

All 6 FGs identified deficits across cognitive, emotional, and interpersonal skill domains. Cognitive deficits manifested as rigid, binary food rules, with participants describing thoughts such as “all negative, catastrophizing ... this is good, this is bad” (FG A, Participant 2). These judgments drove daily food avoidance and ritualistic behaviors, reinforcing disordered patterns.

Distraction and mindfulness were applied to break automatic patterns. A self-taught urge-delay strategy, beginning with seconds and progressing to minutes, emerged as a critical step in disrupting immediate enactment: “I used to try and delay [the urge to purge] for a few seconds at first ... then longer and longer” (FG B, Participant 1).

While effective at building tolerance, this approach was effortful, and success was inconsistent, with one participant describing it as “white knuckling it” (FG C, Participant 2). This strategy frequently bridged to emotional regulation, often conceptualized via a “wave-riding” metaphor: “Until you learn to ride the wave of your emotions, it’s really hard to get further” (FG E, Participant 2).

The recurrence of this metaphor across 3 groups highlighted a common experiential model. Participants emphasized the importance of practical, in-the-moment tools, framing these skills as both recovery and prevention mechanisms: “I think if I had learned specific techniques for dealing with binge urges

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earlier, it could have prevented a lot of spiralling" (FG C, Participant 3).

Interpersonal skills focused on disclosure and boundary-setting. Participants requested scripted tools to support conversations with family members, noting that without such guidance, they tended to internalize distress, creating relational barriers that worsened symptoms: "Discussing it with someone ... eventually made it easier to explain what I was going through" (FG C, Participant 3).

Practical skills, including meal planning and preparation, were highly valued for structuring eating, reducing decision fatigue, and promoting regular intake. Meal planning emerged as the most requested skill, reducing food preoccupation and supporting consistent eating patterns.

Participants frequently described skill failure as a trigger for rapid symptom escalation. A single lapse, due to unavailable or unpracticed skills, could prompt shame, erode confidence, and lead to re-engagement with disordered behaviors: "I gave up for weeks because it felt pointless" (FG B, Participant 1).

This pattern highlighted the importance of structured skill development and real-time prompts to support adaptive behaviors at moments of need.

Behavioral Regulation

Participants commonly described difficulties with self-monitoring and behavioral regulation, particularly when using digital tools that framed tracking in quantitative or performance-driven terms. Features such as calorie or BMI logging and rigid tracking often intensified preoccupation with numbers and control, amplifying rather than reducing disordered cognitions and behaviors:

> *Logging food just makes me obsess over calories and numbers. It's not helpful; it makes things worse.* [FG E, Participant 2]

A constant focus on metrics and inflexible reporting of food intake heightened anxiety and self-criticism, reducing perceived autonomy and self-efficacy. Conversely, participants viewed more reflective forms of self-monitoring, such as journaling emotional states or identifying behavioral patterns, as safer, more supportive approaches. These features were described as increasing insights, emotional awareness, and self-compassion, enabling participants to regulate their behaviors in a more flexible and supportive manner.

Memory, Attention, and Decision-Making Processes

Practical organizational skills such as meal planning, shopping routines, and simple food preparation were key enablers for regular eating and reduced avoidance. Establishing a basic structure around eating was described as especially helpful for regaining consistency after periods of restriction:

> *Planning meals in a very simple way ... because I was skipping meals ... starting with that to make sure I had something for breakfast, then at a coffee or something as a snack, then a meal for lunch, then a snack, and then a dinner.* [FG A, Participant 2]

Opportunity (Environmental and Social)

Overview

Results identified key environmental and social opportunity factors influencing disordered eating behavior, captured as themes and subthemes across COM-B and TDF domains with corresponding behavior change techniques (Table 2).

Table 2. Environmental and social opportunity factors influencing disordered eating behavior: capability, opportunity, motivation—behavior (COM-B) and theoretical domains framework (TDF) analysis.

COM-B domain	TDF domain	Subthemes	Behavior change technique
Environmental opportunity	Environmental context and resources	• Unstructured mealtimes • Access to trigger foods • Cultural norms around body image and food	• 12.1 Restructuring the physical environment • 7.1 Prompts or cues • 5.3 Information about social and environmental consequences • 13.2 Framing or reframing
Social opportunity	Social influences	• Befriending or peer support (advice, role models) • Community or opportunity to share experiences • Trusted people to talk to • Negative impact of social pressures (family, peers, society)	• 2.2 Feedback on behavior • 3.1 Social support [unspecified] • 3.2 Social support (practical) • 10.4 Social reward • 11.2 Reduce negative emotions

Environmental Context and Resources

Easy access to highly palatable or "trigger" foods, coupled with the absence of a meal structure, heightened vulnerability to binge eating. Major life transitions and high-pressure home environments, especially those emphasizing achievement or appearance, were seen as amplifying these vulnerabilities. Participants noted that family members often underestimated how such environmental cues could contribute to symptom escalation: "If certain foods are in the house, it's like I can't stop myself- they just feel too tempting" (FG B, Participant 2).

Family dynamics and expectations played a critical role in shaping disordered patterns. For some, distancing from high-pressure environments provided temporary relief and space for recovery. Although many participants valued the structure and accountability that family meals offered, these situations

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were also commonly experienced as pressurizing. Expectation around portion size, pace of eating, or food type frequently triggered conflict and, in some cases, intensified ED behaviors.

Social Influences

Participants emphasized the powerful role of social influences in shaping their eating behaviors, spanning both protective and detrimental effects. Supportive relationships with peers, family, and professionals who understood their experiences were viewed as critical in reducing isolation and fostering accountability, illustrating how social understanding could reinforce recovery motivation:

> *Having someone who understood what I was going through made a huge difference. It gave me the strength to keep going.* [FG B, Participant 1]

Online communities generated mixed experiences. While some participants valued the sense of belonging they provided, others described difficulties in maintaining safe boundaries and moderating harmful content: "If they share it [a negative eating episode] in a group chat, it may be a trigger for others getting worse, not better" (FG B, Participant 2).

Beyond interpersonal influences, exposure to idealized or contradictory nutrition content on social media was described as particularly harmful, shaping unrealistic self-comparisons and reinforcing internalized dietary norms. One participant rued: "Looking at dieting stuff and following people who I admired when I should not have admired them" (FG F, Participant 2).

Reflective and Automatic Motivation

Overview

Key reflective and automatic motivation factors influencing disordered eating behavior are summarized as themes, subthemes, and mapped behavior change techniques across COM-B and TDF domains (Table 3).

Table 3. Reflective and automatic motivation factors influencing disordered eating behavior: capability, opportunity, motivation—behavior (COM-B) and theoretical domains framework (TDF) analysis.

COM-B domain	TDF domain	Subthemes	Behavior change technique
Reflective motivation	Beliefs about capabilities	• Low confidence that can break the cycle of eating disorder (ED) • Lack of self-belief, not good enough • Reflecting on successes, self-belief	• 1.2 Problem-solving • 13.4 Valued self-identity • 15.1 Verbal persuasion about capability • 15.4 Focus on past success
Reflective motivation	Beliefs about consequences	• Beliefs about the challenges posed by giving up	• 5.6 Information about social and emotional consequences • 11.2 Reduce negative emotions
Reflective motivation	Goals	• Action planning • Goals or milestones (within app)	• 1.1. Goal setting (behavior) • 1.3 Goal setting (outcome) • 1.4 Action Planning • 5.3 Information about social and environmental consequences • 9.3 Comparative imagining of future outcomes
Reflective motivation	Optimism	• Hearing recovery stories • Positive role models	• 6.2 Social comparison
Reflective motivation	Social or professional role and identify	• Identity • Self-esteem	• 13.1 Identity associated with changed behavior • 13.4 Valued self-identity
Automatic motivation	Emotions	• Anxiety or fear • Overwhelming feelings • Guilt, shame, and anger • Low self-esteem • Feeling isolated	• 11.2 Reduce negative emotions
Automatic motivation	Reinforcement	• Habits or breaking habits • ED behaviors reinforce themselves (a "vicious" cycle) • Positive reinforcement	• 8.1 Prompts or cues • 8.4 Habit reversal • 10.4 Social reward • 10.7 Self-incentive • 10.8 Incentive (outcome) • 10.9 Self-reward

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Beliefs About Capabilities

Participants described a pervasive sense of helplessness and self-doubt that undermined confidence in their ability to recover. Past unsuccessful attempts reinforced beliefs that change was unattainable, often leading to withdrawal from help-seeking: "I tried all sorts of different things, and I just thought, you know, this is just gonna be my life forever" (FG A, Participant 3).

For some, recognizing the limits of self-management represented a turning point. Acknowledging that recovery required professional or external support transformed feelings of defeat into a new form of motivation: "I tried to get over it myself, but I think I got to a point where I was like, you know, I can't do this by myself" (FG C, Participant 3).

Building self-efficacy and challenging entrenched beliefs of inadequacy were described as essential to sustaining recovery. Structured therapeutic activities that encouraged reflection on sources of self-worth beyond appearance supported this process: "(if) you had to split up a pie chart into where you got your self-esteem from ... all these things would still be here, even if you gained weight ... you'd still be clever" (FG B, Participant 1).

Beliefs About Consequences

Participants demonstrated clear awareness of the emotional and physical harms linked to their ED behaviors, but often failed to translate this to behavioral change, reflecting an ongoing tension between awareness and action. Fear of the challenges associated with recovery, particularly the perceived loss of a familiar coping mechanism, was frequently described as a key barrier to change: "I know bingeing makes me feel terrible afterward, but the idea of stopping feels impossible sometimes" (FG E, Participant 1).

Goals

Setting short-term, achievable goals, such as planning meals or managing specific triggers, helped participants reintroduce structure and experience a sense of progress in their recovery. These goals were most effective when integrated into daily routines and aligned with personal values, as this reinforced agency, motivation, and ownership of their recovery process: "It was about setting goals that fit within my life ... it made me feel fulfilled and motivated to pursue more" (FG C, Participant 2).

Social and Professional Role and Identity

Participants described profound challenges in reconciling their sense of self, including their personal and professional identities, with their disordered eating behaviors. This identity conflict often created internal tension that undermined recovery efforts: "It was hard to distinguish me and the eating disorder in a way" (FG E, Participant 1).

The internalization of ED thoughts was frequently described as an "ED voice," illustrating the extent to which the disorder became entangled with their identity. Learning to externalize this "voice," and recognize it as separate from the self, was viewed as a critical step in reclaiming agency and distinguishing authentic identity from disordered cognition:

> *recognizing that this is like an actual disorder that's trying to make me do these things like this isn't me. I'm not the ED.* [FG F, Participant 2]

Social and professional roles also influenced help-seeking. Expectations of competence and self-sufficiency intensified the stigma and reluctance to seek support:

> *Admitting I had an eating disorder felt like a personal failure. It was hard to align my professional identity with seeking help.* [FG A, Participant 3]

Optimism

Optimism was a key driver, with participants expressing how positive role models and hearing recovery stories, particularly from individuals they could personally relate to, strengthened belief in the possibility of change and reinforced hope for recovery: "If you can show me that this has worked for people like me, I'll believe it's possible" (FG F, Participant 2).

Emotions

Emotional regulation was significant with stress, anxiety, and boredom commonly described as triggers for both binge eating and restrictive behaviors. These functioned as antecedents to maladaptive coping strategies, offering momentary distraction or relief, but ultimately perpetuating a cycle of distress fuelled by guilt and shame:

> *When I feel stressed, I eat to distract myself. It's like a temporary fix, but it always makes me feel worse afterward.* [FG E, Participant 1]

Over time, these self-regulatory behaviors became deeply ingrained, making them a more automatic response to emotional discomfort and a barrier to developing healthier coping strategies. One participant reflected on emotional resilience: "Until you learn to ride the wave of your emotions, it's really hard to get further because you're still retreating to that coping mechanism" (FG B, Participant 1).

Awareness of the harms associated with disordered eating was common, but insufficient to motivate change. Usually, it was fear, associated with a pivotal moment such as a health scare, which motivated individuals to seek help: "I was so scared by the symptoms that I was having that I felt I had to do something about it" (FG A, Participant 1).

Reinforcing Behavior

Disordered eating patterns were often described as habitual responses to distress, reinforced by their short-term soothing effects. Participants emphasized the importance of shifting these ingrained behaviors by introducing more constructive and compassionate coping strategies. Reframing from punishment to positive reinforcement was seen as key to breaking the cycle and enabling more sustainable change: "When I started focusing on rewarding myself for healthy habits, instead of punishing myself for slip-ups, it really helped" (FG B, Participant 3).

Encouragement, both internal and external, played a vital role in reinforcing healthier behaviors. Conversely, the absence of positive feedback could undermine progress and deepen feelings of failure: "You feel rubbish and that just perpetuates the disorder" (FG A, Participant 1).

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Demographic Differences

Male Perspectives

Although many experiences overlapped across both sexes, male participants identified distinct influences on their EDs, shaped by societal expectations, stigma, and masculine identity norms that often inhibited help-seeking: "Masculinity plays such a big role, it's hard to even admit you're struggling with something like this" (FG D, Participant 1).

Cultural ideals of the "ideal male body" were described as emphasizing leanness and muscularity rather than thinness, leading to restrictive eating and compulsive exercise. This pursuit of muscularity was reinforced by comparison with others in fitness environments and online spaces, heightening dissatisfaction and reinforcing unhelpful behaviors:

> *When you're constantly seeing guys at the gym who are shredded, it makes you feel like you're not good enough. You start to think you have to eat and train in a certain way to get there.* [FG D, Participant 3]

These pressures led to rigid control over diet and exercise, including avoiding foods perceived as "unhealthy" and obsessively monitoring calories. Limited understanding from family members often left male population bottling up struggles, increasing shame and isolation. A related challenge was the lack of male representation in ED discourse, which left participants feeling invisible and reinforced the perception that EDs were a "female issue." This invisibility was compounded by experiences of seeking support, which were often delayed or met with misunderstanding:

> *You feel like eating disorders are seen as a "female issue." When men reach out, it's often too late, or they're misunderstood.* [FG D, Participant 4]

Despite these barriers, male participants identified adaptive coping strategies, including grounding techniques, engaging in hobbies, and goal setting. Distraction and hobbies were helpful: "I focus on grounding myself, thinking about the bigger picture, and using distractions like video games or my favorite music" (FG D, Participant 1).

The value of peer connection, particularly with other male participants, was emphasized as a powerful way to normalize experiences and promote recovery-oriented conversations: "knowing there are other guys out there going through the same thing ... it makes you feel like you're not alone in this" (FG D, Participant 4).

Ethnic Minority Perspectives

Ethnicity emerged as a significant factor influencing ED experiences across both male and female participants, although the impact of cultural norms varied by sex. Participants from non-Western cultural backgrounds described strict societal standards regarding body weight and appearance. These pressures were often more pronounced for female participants, with body size and weight being closely tied to social value:

> *I wear a medium size in the UK, but in China, I wear XXL. It makes girls feel like they're fat even when they're not.* [FG E, Participant 2]
>
> *Big girls are seen as less likely to get married.* [FG E, Participant 2]

Cultural practices, such as food-oriented community events (eg, Chinese New Year), were described as intensifying disordered eating behaviors:

> *During holidays, it's all about food, and they keep asking me to eat, eat, eat. It's very hard for someone trying to manage their eating.* [FG B, Participant 2]

Limited family understanding of EDs was reported across participants. However, female participants more frequently highlighted the direct impact of family comments on self-esteem and body image, whereas male participants emphasized the challenge of navigating EDs within culturally normative and family context. Cultural stigma posed barriers for both male and female participants but manifested differently. Female participants described cultural attitudes that trivialized EDs as vanity, while male participants encountered stigma framing these conditions as inherently feminine or a sign of weakness, impeding recognition and help-seeking: "Mental health issues are often ignored in my culture, and eating disorders for men aren't even seen as a real thing" (FG D, Participant 5).

Participants noted tension between Western beauty ideals and their cultural norms, with exposure to unattainable media-driven body standards contributing to heightened body dissatisfaction: "The media promotes certain body types that are unattainable for most of us, especially people from different ethnic backgrounds" (FG D, Participant 3).

Objective 2: Influences on App Engagement

Overview

The analysis of app engagement against the COM-B and TDF revealed that all COM-B components, except physical capability, played a significant role in influencing app engagement. These components aligned with 12 of 14 (86%) TDF domains, highlighting key mechanisms of change and implications for app design.

Psychological Capability

Overview

Key psychological capability factors influencing app engagement were identified, with associated themes, subthemes, and behavior change techniques across COM-B and TDF domains (Table 4).

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Table 4. Psychological capability factors influencing app engagement behavior: capability, opportunity, motivation—behavior (COM-B) and theoretical domains framework (TDF) analysis.

COM-B domain	TDF domain	Subthemes	Behavior change technique
Psychological capability	Knowledge	• Knowing the benefits or how will it help me?	• 4.1 Instructions on how to perform a behavior
Psychological capability	Behavior regulation	• Reminders to use specific features in an app • Set and review goals related to app use	• 1.5 Review behavior goals • 7.1 Prompts or cues
Psychological capability	Memory, attention, and decision-making processes	• Reduce cognitive overload	• 11.3 Conserving mental resources

Knowledge

Participants displayed variable understanding of how apps functioned and how they could support recovery. Those earlier in their recovery journey generally had lower familiarity of ED apps.

Some participants identified the potential for an app to learn about their condition and enhance self-awareness. Psychoeducational content relating to EDs, coping strategies, and recovery principles was consistently regarded as essential to support engagement and inform decision-making around recovery:

> *When I first started, I didn't even know what eating disorders were. If an app had explained what I was experiencing and why, it might have helped.* [FG F, Participant 1]

Participants expressed that apps should clearly communicate their purpose, instructions, and benefits. Many expressed confusion about how existing apps should be used and questioned how certain features, such as food and thought logging, would aid their recovery: "The main reasons that I don't like using it is because ... it didn't really give me a very clear idea about why I am doing this" (FG B, Participant 2).

Behavior Regulation

Participants sought consistent engagement through behavioral prompts and tools that promote habit formation. Reminders were frequently cited as helpful:

> *I need reminders to log things. Otherwise, I just forget or don't prioritize it.* [FG F, Participant 1]

However, overreliance on self-monitoring features, such as logging every action or thought, could make apps feel burdensome rather than supportive. Logging calories, food intake, and exercise could be unhelpful or harmful in the context of EDs: "it makes me obsessed with the calorie counting" (FG E, Participant 2).

Any self-monitoring had to avoid numbers to prevent obsessive behaviors: "Not something to measure, something to kind of beat yourself up about" (FG C, Participant 3).

Memory, Attention, and Decision Processes

Many participants described cognitive barriers to engaging with ED apps, noting that complex interfaces, hard-to-use "unclear" interfaces, and confusing navigation imposed demands on them beyond simply knowledge requirements. Many reported downloading apps but failing to open them or use them consistently, suggesting that early impressions strongly influenced sustained engagement:

> *Some apps have so many options and buttons that I don't even know where to start. If it's not obvious, I won't use it.* [FG A, Participant 1]

Simplicity and intuitive design were highly valued, with participants avoiding ED apps with too "much stuff" on them and preferring apps that were more straightforward and easily navigable. Overly cluttered apps were abandoned, while streamlined interfaces enhanced usability and ongoing engagement: "Laying things out, so things are easier to find ... you don't have to go searching for things and forget where it was the next time you go back to the app and CBT" (FG C, Participant 2).

Several participants suggested that delivering interactive content such as "videos, activities, and tutorials" could further support attention, comprehension, and engagement, while providing an improved user experience (UX).

Environmental and Social Opportunity

Overview

Results identified key environmental and social opportunity factors influencing app engagement, captured as themes and subthemes across COM-B and TDF domains with corresponding behavior change techniques (Table 5).

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Table 5. Environmental and social factors influencing app engagement: capability, opportunity, motivation—behavior (COM-B) and theoretical domains framework (TDF) analysis.

COM-B domain	TDF domain	Subthemes	Behavior change technique
Environmental opportunity	Environment, context, resources	• Overwhelming app "environment" • Remove barriers to accessibility • Avoid advertisements or pop-ups	• 11.3 Conserving mental resources • 12.1 Restructuring the physical environment • 12.4 Distraction
Social opportunity	Social influences	• Befriending or peer support within the app • Community or opportunity to share experiences • Role models (within app) • Involve professionals	• 3.1 Social support (unspecified) • 6.1 Demonstration of the behavior • 9.1 Credible source • 10.4 Social reward

Environmental Context and Resources

Participants highlighted a lack of accessible support across the recovery journey and viewed the potential for an app to provide continuous, reliable guidance as highly valuable. Ease of access was central to engagement; participants preferred tools that integrated smoothly into their daily environments (eg, calendars) and could be opened quickly without friction: "I use my phone all the time, so if the app is easy to open and doesn't require a lot of setup, I'd use it more" (FG E, Participant 1).

Apps were also seen as a way to bridge gaps in formal care, particularly for those who were excluded from services due to diagnostic thresholds or limited National Health Service availability. Early access through an app was considered a crucial resource for preventing symptom escalation and entrenchment of behaviors:

> *I wasn't able to get help through the NHS because my BMI wasn't low enough. If an app could offer support earlier, it would make a big difference.* [FG F, Participant 2]

Social Influences

Peer support was a consistent facilitator of app engagement. Many participants suggested that apps providing opportunities for social interaction, such as moderated support groups, could offer a sense of community and shared understanding. Connecting with others who had similar lived experiences offered companionship that professional support alone did not always provide, reducing isolation and reinforcing motivation:

> *When I was recovering, I didn't feel like I had anyone to talk to who understood. An app that provided that connection would have helped so much.* [FG B, Participant 1]

Participants also emphasized the motivational role of seeing others' recovery journeys. Exposure to peers' experiences and strategies was perceived as inspiring, and it helped users to feel less isolated and able to envision positive change:

> *Just kind of their stories and what had helped them would help me in seeing how someone could go from this to being this person and being happy with themselves.* [FG F, Participant 1]

However, while social interaction was valued, moderation was viewed as essential to maintain safety and constructive engagement. Unmoderated spaces were viewed as potentially triggering or unhelpful, highlighting the need for structured guidance within peer features:

> *Moderation made a huge difference. In a structured group, you're less likely to worry about things spiralling out of control.* [FG B, Participant 1]

Reflective and Automatic Motivation

Overview

Results identified key reflective and automatic motivational factors influencing app engagement, captured as themes and subthemes across COM-B and TDF domains with corresponding behavior change techniques (Table 6).

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Table 6. Reflective and automatic motivation factors influencing app engagement: capability, opportunity, motivation—behavior (COM-B) and theoretical domains framework (TDF) analysis.

COM-B domain	TDF domain	Subthemes	Behavior change technique
Reflective motivation	Beliefs about capabilities	• Ability to use app effectively	• 15.1 Verbal persuasion about capability • 8.2 Focus on past success
Reflective motivation	Beliefs about consequences	• App will not help • Negative consequences of engagement (eg, obsessive behaviors) • Frame the app as nonjudgment and supportive resource • Normalize setbacks, missed logins, incomplete activities	• 5.2 Information about health consequences • 5.3 Information about social and environmental consequences • 11.2 Reduce negative emotions • 11.4 Paradoxical instructions
Reflective motivation	Intentions	• Support self-monitoring of behaviors	• 4.1 Instruction on how to perform behavior • 1.1 Goal setting (behavior) • 10.8 Incentive (outcome)
Reflective motivation	Optimism	• Potential for positive outcomes	• 5.1 Information about health consequences • 5.3 Information about social and environmental consequences
Automatic motivation	Emotions	• Avoid negative emotional triggers • Enable positive emotional responses via the app	• 10.4 Social reward • 11.2 Reduce negative emotions
Automatic motivation	Reinforcing behavior	• Positive reinforcement • Minimize risk of perfectionism or fear of failure	• 8.1 Prompts or cues • 10.3 Nonspecific reward • 10.4 Social reward • 10.6 Nonspecific incentive • 10.9 Self-reward • 10.7 Self-incentive • 10.8 Incentive (outcome)

Reflective Motivation

Beliefs About Capabilities

Participants' sense of confidence in their ability to engage with an ED app was a major determinant of whether they persisted with it. Rather than reflecting simple usability issues, uncertainty often stemmed from a deeper belief that they may not be able to use an app "properly" or benefit from it without structured support. Several participants described feeling uncertain when features lacked clear guidance or progress was difficult to track, with some questioning their own competence and disengaged as a result. Explicit guidance and opportunities for early success were described as crucial for building a sense of capability and reducing anxiety:

> *If the app had step-by-step instructions or guided prompts, I'd have felt more confident using it. Instead, I felt lost.* [FG E, Participant 1]

Beliefs About Consequences

Beliefs about the potential consequences of using apps significantly shaped participants' willingness to engage. Concerns centered on data privacy and confidentiality, with fears about misuse or excessive collection of personal information creating hesitation and distrust. For some, these concerns raised questions about whether any potential benefits outweighed the risks, with "intrusive" setup questions as a barrier to use:

> *I'm worried about how my data will be used. Will it be sold or shared without me knowing?* [FG F, Participant 2]

Some expressed doubts about professional endorsement and evidence-based content, which further shaped their willingness to engage. Participants questioned whether app guidance was reliable, highlighting the importance of transparent evidence or clinical involvement:

> *I just don't know if these apps are really supported by professionals. It makes you wonder if the advice is even valid.* [FG C, Participant 2]

Previous negative experiences with digital tools also contributed to disengagement. For some, unmet expectations led them to abandon app use or stop searching for suitable interventions:

> *What's the point of using an app if it won't really help? I don't want to waste time on something that doesn't make a difference.* [FG D, Participant 3]

Optimism

Although some users expressed initial skepticism about existing apps, there was cautious optimism that thoughtfully designed apps could provide meaningful support. Avoiding common

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pitfalls, such as calorie tracking, and emphasizing positive habits were seen as essential to success. One user suggested that providing evidence of positive outcomes from previous users' experiences could enhance confidence in the app's effectiveness and motivate continued use:

> *If you are able to work on using this app till day 30, you will be able to see 50% of people will be able to do "whatever like" positive outcomes. Then this makes me feel more hopeful.* [FG B, Participant 1]

Intentions

Participants' intentions to engage with apps were shaped by the extent to which its features aligned with their recovery goals, personal values, and emotional needs. Certain features, particularly food tracking, were frequently described as intrusive or triggering due to associations with past disordered behaviors and often discouraged ongoing use:

> *When I've used apps that have any relation to having to log food, it's really, really a no-no for me. I really don't like it.* [FG A, Participant 2]

In contrast, some participants expressed a preference for alternative journaling options that allowed them to track thoughts or emotions. These approaches felt safer, more meaningful, and supportive of self-reflection, enabling users to identify patterns in their experiences without exacerbating disordered behaviors: "I'd rather track my thoughts or feelings than food—it feels less triggering but still helpful to see patterns" (FG A, Participant 1).

Automatic Motivation

Emotions

Emotions were pivotal in shaping participants' engagement with apps, influencing both initial uptake and sustained use. Positive emotions, such as feelings of accomplishment, motivation, and connection, acted as key drivers of app engagement and could be achieved through supportive features within the app, helping participants feel recognized and reinforced within the app:

> *The milestones and rewards made me feel like I was actually making progress. Even small wins felt good and gave me a reason to come back to the app.* [FG D, Participant 1]

Negative emotions could act as barriers. Participants reported that features emphasizing rigid expectations or highlighting perceived failures often triggered anxiety, guilt, or frustration, reducing willingness to continue: "Missing a day felt like I'd failed, and it was really hard to come back to the app after that" (FG B, Participant 2).

Similarly, overly frequent or intrusive notifications and advertisements were described as frustrating and disengaging. Social features were perceived as emotionally supportive, helping reduced feelings of isolation and sustain motivation. Connecting with peers and observing others' recovery journeys provided reassurance and hope:

> *The community aspect made me feel like I wasn't alone. Reading about others' experiences gave me hope and encouraged me to keep going.* [FG B, Participant 1]

Reinforcement

Participants identified the potential for apps to support the replacement of harmful ED habits with healthier, substituted behaviors, such as establishing regular eating patterns or engaging in alternative activities. Opportunities to engage in varied activities that allowed users to explore different aspects of themselves were seen as particularly valuable. Providing positive reinforcement, such as reminders of achievements, motivational quotes, or visual cues of progress, was highlighted as a key mechanism to sustain engagement especially during challenging times:

> *Whether that's in forms of quotes, pictures of yourself that you have uploaded ... like almost being overwhelmed with the reminders of the good that is in your life in those moments of bad.* [FG C, Participant 3]

Mixed responses to generic motivational elements like milestones, badges, or standard quotes suggested that tailoring feedback to individual preferences and experiences would enhance both acceptability and effectiveness.

Demographic Differences

Male Perspectives

Male participants raised concerns about gendered design and content as a barrier to engagement. Much of the existing material within apps appeared exclusively targeted primarily at the female population:

> *A lot of the content seems aimed at women, like talking about menstruation or things that don't apply to me. It makes you feel like it's not really for you, even though you're going through the same thing.* [FG D, Participant 3]

The language, visuals, and overall tone of apps were perceived as stereotypically female-centric approaches, limiting their appeal for male users. Incorporating gender-neutral design elements was suggested as a way to increase inclusivity and engagement. Their feature preferences differed from female users, with some male users highlighting the appeal of gamification and progress tracking to sustain motivation:

> *I loved apps that gamified progress—it kept me coming back. Milestones and achievements make a big difference.* [FG D, Participant 1]

Given the specific stigma surrounding EDs in the male population, participants emphasized the importance of dedicated spaces for male users. Peer support in a male-specific context was seen as reducing isolation and normalizing help-seeking:

> *As a guy, it's not something you really talk about. Having a space where other men are going through the same thing makes it feel less isolating, like you're not the only one dealing with this.* [FG D, Participant 3]

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Ethnic Perspectives

Both male and female participants described available apps as often culturally irrelevant or overly Westernized, which reduced their perceived accessibility and effectiveness. The lack of diverse representation in imagery, language, and case scenarios diminished an app's relatability, reducing the likelihood of sustained engagement:

> *A lot of apps feel very Western in their focus. They don't reflect the food I eat or the challenges I face culturally.* [FG E, Participant 2]

Apps were also seen as insufficiently responsive to the ways cultural norms shape eating behaviors and recovery experiences. They stressed the need for diversity not only in imagery but in the perspectives and assumptions embedded in the app's guidance:

> *It would help if the app showed more diversity, not just in visuals, but in the way it talks about food and eating habits. It should feel like it's for everyone, not just one group.* [FG D, Participant 5]

Cultural stigma surrounding EDs was a significant barrier to help-seeking and engagement. Participants described family or community taboos around discussing EDs, emphasizing the need for apps to offer culturally sensitive approaches that normalize help-seeking: "An app that normalizes eating disorders for men [in my culture] would make it easier to reach out for help" (FG D, Participant 5).

Cultural influences shaped coping strategies and recovery needs in nuanced ways. Female participants put a greater emphasis on needing family education and support, as family expectations often directly influenced their disordered eating behaviors. Male participants highlighted the need for culturally sensitive tools that validated their experiences and helped normalize EDs for the male population, making it easier for them to open up.

Discussion

Key Findings

This study advanced the design of digital interventions for EDs by providing the first systematic application of the COM-B model and TDF to both the mechanisms driving maladaptive ED behaviors and app engagement. The combined analysis mapped identified behavioral determinants to 32 BCTs across 13 of the 14 TDF domains. Many of these BCTs, such as self-monitoring, feedback on behavior, and problem-solving, aligned were consistent with prior digital ED interventions [27]; however, gaps and recommendations for future development were identified (Table 7). This study extended prior work by revealing how BCT implementation was experienced by people with lived experience in digital contexts, providing insight into why theoretically sound techniques sometimes fail [39] or even have adverse effects if implemented without sensitivity to user needs. It elucidated how interactive tools, such as food logging, reminders, and progress tracking, frequently trigger shame, perfectionism, obsessive tendencies, or cognitive overload eroding reflective and automatic motivation, leading to reduced engagement and poorer treatment outcomes [39].

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Table 7. Summary of behavior change technique coverage across capability, opportunity, motivation—behavior (COM-B) and theoretical domains framework in research-developed eating disorder (ED) apps.

COM-B domain	Coverage in commercial ED apps [25,26,54]	Coverage in evidence-based research apps [26,27,55,56]	Positive recommendations for future ED apps
Psychological capability	Very limited, mostly basic mood logging or generic tips. Little structured psychoeducation or cognitive work.	Strong. Psychoeducation, self-monitoring, reframing, goal-setting, and action-planning are well represented.	• Include psychoeducation on less common or atypical EDs (eg, ARFID[a]). • Avoid stereotyped or diagnosis-specific content that may not reflect individual experiences. • Stage-of-change and early recovery–matched psychoeducation (especially "what is an ED?" and normalizing relapse cycles). • Explicit teaching that short-term fear-food exposure does not cause large or permanent weight gain. • Cognitive skills delivered via simple, nonoverwhelming formats. • Qualitative or pattern-based (nonnumeric) self-monitoring only. • Structured interpersonal or assertiveness scripts for disclosure and boundary-setting.
Environmental Opportunity	Almost absent, dominated by calorie or weight tracking. No environmental restructuring.	Very limited. Restricted to basic reminders or prompts.	• Simple meal-planning and grocery tools. • Advance planning for high-risk meals or social eating events. • Stimulus-control prompts (eg, removing binge triggers). • Culturally tailored food libraries. • Adding in-app tools or resources (meal planners, coping cards).
Social opportunity	Rare. Occasional unmoderated forums, predominantly solitary use.	Moderate. Peer affirmations and communities exist, but practical support is minimal, and moderation could be improved.	• Heavily moderated, expert-facilitated peer support, and recovery role-model content. • Structured peer-mentoring or buddy systems. • Guided disclosure or boundary-setting exercises. • Zero tolerance for body or weight or food talk in community spaces.
Reflective motivation	Very limited. Occasional motivational quotes, no systematic identity or values work.	Strong. Goal-setting, progress review, and cognitive techniques are common.	• Explicit externalization of the "ED voice" exercises. • Value clarification and nonappearance-based self-esteem modules (eg, pie-chart exercises). • Exposure to longer-term recovery narratives. • Removal of streak counters and any visible "failure" metrics. • Normalization of incomplete progress and missed days.
Automatic motivation	Limited. Mostly streak badges and generic encouragement.	Moderate. Emotion regulation, distraction, habit reversal, and social reward are frequently used.	• Timer-based urge-surfing tools with progressive delay ("ride the wave" framing). • Rapid-relief grounding or breathing exercises triggered by mood check-ins. • Noncomparative, nonperformance-based rewards only. • Graded fear-food exposure hierarchies. • Shame-reducing messages after lapses or low activity.

[a]ARFID: avoidant or restrictive food intake disorder.

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Psychological, social, and motivational influences on ED behaviors, such as self-esteem, identity struggles, and social isolation, emerged as central behavioral determinants, although they are often underrepresented in existing digital interventions [27]. Participants expressed a strong desire for moderated peer connection and exposure to recovery role models to reduce the intense feelings of isolation common in EDs, but only under strict moderation. This was a heightened concern in this population, reflecting the elevated risk of behavioral contagion and competitive symptom reinforcement in EDs [57]. Moderated peer support has supported engagement in digital interventions for other severe mental illnesses [58], suggesting that carefully implemented social support features could similarly enhance adherence and therapeutic benefit in ED apps. Grounding these factors within COM-B and TDF provided a structured, theory-driven framework to translate these lived experience determinants of behavior into actionable design guidance. This approach was built on previous work [38,59,60] with an ED-specific, experience-informed perspective, which was crucial, given the complex needs and vulnerability of this population.

Among strategies participants identified as interrupting disordered eating, 2 patient-generated approaches stood out: behavioral experiments in which eating previously feared foods led to the realization that weight remained stable and self-taught urge delay tactics consistently framed as “ride the wave” metaphor. Despite their therapeutic potential, these techniques remain largely absent from existing ED apps. The “ride the wave” approach has been implemented in an evidence-based app for self-harm [61], with preliminary efficacy in reducing impulsive harmful behaviors, supporting the feasibility and likely value of translating these features into ED apps.

The established importance of interface simplicity, usability, and intuitive navigation for early engagement and cognitive-load reduction was reinforced in this study, converging with existing qualitative syntheses of user preferences [16,40] and broader digital mental health engagement research [38,59,60]. However, interface simplicity was seen as a crucial requirement for this population, beyond the level typically emphasized in other mental health conditions [38,59]. This likely reflects ED-specific neuropsychological and personality traits including cognitive rigidity, impaired set-shifting [62], detail-focused processing biases [63], and clinical perfectionism [64]. A complex or unclear interface was also experienced by some as a direct threat to their self-esteem, undermining users’ confidence in their ability to use the app effectively. Perfectionism-driven shame around perceived failure within the app (eg, missing food logs or breaking streaks) further intensified disengagement.

Feeling personally understood and represented emerged as a prerequisite for engagement, particularly for male and minority ethnic participants, who often found existing apps exclusionary or irrelevant. Whereas “perceived fit” has been described as a moderator of engagement in broader digital mental health research [59], the present findings elevate it to a primary determinant of disengagement in EDs. Given that male participants comprise up to 25% of ED cases [65] and minority ethnic groups show comparable prevalence [9,66], future apps should integrate culturally specific content, reduce stigma-related barriers, and provide support spaces that are accessible and welcoming to underrepresented groups.

By delineating these ED-specific mechanisms within an established behavioral framework, this study provided actionable, ED-specific guidance for designing digital tools that are not only more engaging but also safer for individuals with EDs. Perceived safety consistently outweighed perceived benefit as a determinant of uptake and sustained use, a pattern corroborated by ED therapists in our related study [67], making the identification and mitigation of harm an overriding priority for use.

Current ED App Landscape and Future Directions

The vast majority (>95%) of commercially available ED apps contain minimal or no evidence-based BCTs and may even promote harm (eg, unguided calorie tracking) [25,26,54,55], with few research-developed ED apps available (eg, Recovery Record and Break Binge Eating) [56]. Table 7 illustrates the extent to which commercially available and evidence-based ED apps cover the BCTs and associated COM-B and TDF domains identified in this study. Coverage is strongest for psychological capability, with automatic motivation and physical opportunity being less frequently addressed, representing target areas for strengthening ED apps.

Implementation Sensitivity of BCTs

BCTs are not inherently beneficial: their effectiveness depends on how they are implemented. Participants described how self-monitoring and reinforcement could either support or undermine recovery depending on framing and flexibility. Rigid numeric tracking and achievement-based rewards increased compulsivity, whereas reflective journaling, pattern recognition, and intrinsic encouragement promoted autonomy and self-regulation. These insights emphasized the need for app developers to prioritize how BCTs are delivered, not just which techniques are included. Current ED apps almost universally deliver these techniques in a fixed, one-size-fits-all format. This approach is inadequate and potentially harmful, given that the same BCT can be helpful for one person yet trigger shame, obsessive preoccupation, or disengagement in another, depending on individual profile, stage of illness, cultural context, and momentary state.

Transitioning from static to adaptive delivery is crucial and increasingly feasible with existing technology [68]. By securely analyzing in-app behavioral data (eg, logging patterns, mood ratings, journal content, feature use, and timing), future apps can dynamically tailor how each BCT is presented, for example, switching from quantitative to qualitative monitoring when risk of compulsivity is detected, moderating frequency of reminders and prompts, or adapting language, case examples, and community support spaces to better reflect male or minority ethnic experiences [69]. Such responsive, data-driven personalization directly addresses the safety and engagement barriers identified and offers a practical pathway to interventions that are both more effective and substantially safer across diverse users. Robust privacy protections, transparent decision rules, and rigorous ethical oversight remain essential prerequisites before any implementation of these approaches [70].

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Strengths

As one of the first studies to apply behavior change theory, including the COM-B model and the TDF to EDs, this research bridged behavior change science with the complex challenges of designing ED interventions. This approach provided a systematic and theory-driven method for identifying relevant BCTs while ensuring that the identified techniques were rooted in an understanding of the key drivers of disordered eating behaviors. This study contributed to filling an important gap in the literature, offering a more structured and theory-informed basis for intervention development.

The inclusion of a relatively diverse sample (sex, age, ethnicity, and ED condition) enhanced the ecological validity and relevance of the findings. By engaging people in recovery, it provided a unique lens on what has been effective and meaningful in their own journeys, offering practical insights to inform intervention development. The co-design process promoted the design of interventions that are likely to be acceptable and engaging to a broad range of users as well as empowering participants as "experts by experience."

Limitations

The sampling strategy and size, while sufficient for qualitative exploration and reaching a point of saturation, may have only partially captured the diversity of experiences within this population despite efforts to broaden reach and inclusivity. The inclusion of self-reported data from participants in recovery could introduce recall bias; however, their reflections were used alongside individuals still struggling with ED behaviors. Our form-based screening relied on participants' self-reported diagnosis, treatment history, and ED behaviors, as a formal clinical diagnosis was not required. While this approach was consistent with our aim to center lived experience, it introduced the possibility of inaccuracies in participants' diagnostic status.

An unexpected limitation of our recruitment was including a public study email address in social media advertisements, which likely increased bot submissions (~79% exclusion rate). We recommend that future studies avoid listing email addresses in recruitment materials, instead using secure, anonymized survey links (eg, REDCap and Qualtrics). Additionally, we suggest incorporating attention-check or instruction-following items (eg, "Begin your response with 'selected codeword'") within screening forms to further enhance data quality in online qualitative research.

Finally, the identification of BCTs in this study reflected a focus on subjective preferences and perceptions of effectiveness. It is important to evaluate the efficacy of the identified BCTs in changing ED-related behaviors at a later stage.

Further Research

A critical next step involves effectively translating the shortlisted BCTs into an intervention design that resonates with users (Table 7) and is validated by therapists. Co-design with individuals with lived experience of EDs is fundamental, ensuring that the intervention is both relevant and accessible to a range of users. Future research should evaluate the effectiveness, acceptability, and usability of digital apps, which integrate these BCTs and offer a personalized UX. Exploration of how BCTs can be tailored to diverse user profiles, considering variations in symptomatology, age, sex, cultural background, as well as comorbidities, is also required. Developers should work collaboratively with diverse people with lived experience to test and refine how BCTs are implemented, such that self-monitoring tools or rewards do not inadvertently exacerbate stress, anxiety, or ED symptoms [16,31,62].

Evaluation will require the use of mixed methods studies to capture both quantitative measures of efficacy and qualitative feedback on UX. These BCTs should be evaluated in randomized controlled trials, exploring how their integration with cognitive behavioral therapy–based therapy impacts ED recovery rates and user engagement.

Finally, research should focus on exploring innovative personalization strategies, such as just-in-time adaptive interventions and artificial intelligence (AI), while ensuring ethical and user-centered design [70]. This includes the co-design and development of user-facing and backend AI tools to support personalization of the user journey. The potential of blended approaches that combine digital tools with therapist involvement could be explored to address deeper psychological and identity-related challenges.

Conclusions

This study delivered the first COM-B or TDF-mapped blueprint of the psychological, social, environmental, and motivational drivers of maladaptive ED behaviors and sustained app engagement derived from people with lived experience. By emphasizing which BCTs to include and understanding how their implementation determines whether they support or undermine recovery, this study provided updated guidance for co-designing engaging, emotionally safe, and effective apps. Future interventions must integrate behavioral science, trauma-informed UX, ethical AI, and clinical expertise with ongoing involvement of diverse people with lived experience to create digital tools that are effective, engaging, and equitable across sex and ethnicity.

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Data Availability

The datasets generated or analyzed during this study are not publicly available to protect participant confidentiality, but are available from the corresponding author on reasonable request.

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Authors' Contributions

PCT conceptualized the study, developed the methodology in consultation with SR, PB, and KC, acquired funding with support from SR, led the investigation, performed formal analysis and capability, opportunity, motivation—behavior or theoretical domains framework coding together with RP, validated the findings with RP, curated the data, and wrote the manuscript. SR provided primary supervision and contributed to conceptualization, methodology, funding acquisition, and review of the manuscript. PB provided secondary supervision and contributed to conceptualization, methodology, review, and editing. KC contributed to conceptualization and methodology. RP contributed to formal analysis, validation, and data curation. All authors reviewed and approved the final manuscript and have agreed to be accountable for all aspects of the work.

Conflicts of Interest

None declared.

Multimedia Appendix 1
COREQ checklist.
[DOCX File , 42 KB - formative_v10i1e79328_app1.docx]

Multimedia Appendix 2
Bot-detection protocol and exclusion breakdown.
[DOCX File , 25 KB - formative_v10i1e79328_app2.docx]

Multimedia Appendix 3
Discussion guide for focus groups.
[DOCX File , 731 KB - formative_v10i1e79328_app3.docx]

Multimedia Appendix 4
Baseline characteristics.
[DOCX File , 25 KB - formative_v10i1e79328_app4.docx]

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Abbreviations

AI: artificial intelligence
BCT: behavior change technique
COM-B: capability, opportunity, motivation—behavior
COREQ: Consolidated Criteria for Reporting Qualitative Research
DSM-5: Diagnostic and Statistical Manual of Mental Disorders (Fifth Edition)
ED: eating disorder
FG: focus group
REDCap: Research Electronic Data Capture
TDF: theoretical domains framework
UX: user experience

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Original Paper

A Culturally Tailored Diabetes Self-Management Education Program With Mobile Health Integration for Chinese Americans With Type 2 Diabetes: Development and Pilot Evaluation Study

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Abstract

Background: Although progress has been made in improving the efficacy of Diabetes Self-Management Education (DSME) programs, there remains a dearth of research on culturally adapted, evidence-based DSMEs for Chinese Americans (CAs) with type 2 diabetes.

Objective: Through collaborative partnerships with 2 large community recreation centers and the AHMC Hospital Network in San Gabriel Valley, California, we developed and pilot-tested a culturally tailored DSME program with integrated mobile health (mHealth) technology, entitled Culturally Appropriate Strategies for Chinese Americans with Diabetes (CASCADe).

Methods: The CASCADe program utilized a combined, theoretically driven, and community-participatory approach and was developed based on information gleaned from focus groups, semistructured interviews, and a questionnaire survey conducted among CA patients with diabetes, physicians, and nurses, as well as from extensive literature reviews of evidence-based program curricula. A single-group pre- and posttest design with a 3-month study period was then employed to assess the program's preliminary efficacy. The study protocols were registered on ClinicalTrials.gov.

Results: The CASCADe program consisted of (1) a home visit in the first month for training in monitoring device use and WeChat app (a mobile instant-messaging platform widely used in the Chinese population) usage, as well as for acquiring family support; (2) 8 weekly sessions over the following 2 months, delivered in a combined format of group classes, games, group exercises, videos, and discussions; and (3) WeChat follow-up involving education tips, monitoring data summaries, and group discussions after each of the 8 weekly sessions. Topics covered in the weekly sessions included recognition of diabetes and its complications, risk factors, nutrition knowledge, dietary practices, exercise, behavioral self-monitoring, medication adherence, and stress management. The monitoring system used a smartphone to coordinate cloud-based data transmission from a set of wireless devices to capture daily monitoring data on physical activity, body weight, blood pressure, and blood glucose levels. Behavioral self-monitoring was further facilitated by the WeChat app, which provided daily messages related to the diabetes education curriculum; weekly summary reports of monitoring data; feedback; bidirectional 1-on-1 communication between intervention providers and participants; and group discussions among participants regarding readings and the implications of

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monitoring results. The pre- and postcomparison from the 3-month pilot trial showed a significant reduction in glycated hemoglobin (HbA1c; 7.48 vs 7.09, *P*=.03), with all but 1 participant demonstrating a reduction and 7 out of 12 (58%) achieving a >0.5 decrease in HbA1c. Significant improvements were also observed in self-efficacy in diabetes management (6.59 vs 8.01, *P*=.003), quality of life (3.21 vs 3.69, *P*=.005), and stress-coping skills (3.18 vs 3.74, *P*=.01) at 3 months after baseline among CA patients with type 2 diabetes.

Conclusions: Our pilot study demonstrated the feasibility of implementing the CASCADe program among CAs to improve diabetes self-management skills and yielded promising results, warranting further evaluation in a larger randomized trial.

Trial Registration: ClinicalTrials.gov NCT04737499; https://clinicaltrials.gov/ct2/show/NCT04737499

(JMIR Form Res 2026;10:e77372) doi:10.2196/77372

KEYWORDS

Chinese Americans; type 2 diabetes self-management; mobile technology; WeChat; cultural tailoring

Introduction

Background

Asian Americans are proportionately the fastest-growing group in the United States, with Chinese Americans (CAs) representing the largest ethnic subgroup [1]. A report from the Diabetes Study of Northern California (DISTANCE) revealed that 104,000 (8.2%) out of 1.3 million CAs were diagnosed with type 2 diabetes mellitus (T2DM) [2]. CAs have less access to self-management education for diabetes compared with other ethnic groups [3,4], due to barriers such as language, difficulty with lifestyle transitions, financial constraints, and lack of health insurance [5-7]. A Pew Research Center [8] analysis of the American Community Survey reported that only 42% of foreign-born CAs could speak and write English well. Even when self-management programs are translated into Chinese, most are based on Western culture and lifestyle, including food choices [9]. CAs have found it difficult to manage their disease in the US context due to cultural and dietary differences [7,10]. Efforts to culturally adapt Diabetes Self-Management Education (DSME)—a key component in achieving effective glycemic control and an important part of clinical management [11]—have shown promising results in improving glycemic control and reducing cardiovascular morbidity and mortality among Whites, Latinos, and African Americans [12]. However, very limited efforts to culturally adapt evidence-based DSME programs have been made for CAs with T2DM [13-15], leading to scientifically untested assumptions that existing diabetes programs will be equally effective for CAs as for other ethnic groups.

One of the most important components of all DSME programs is patients' self-monitoring of blood glucose levels, use of antidiabetic medications, and other lifestyle changes, such as diet and exercise. Traditional tools (eg, paper and pencil) used for diabetes self-monitoring and tracking lifestyle changes have low compliance, which affects the sustainability of intervention effects. To better support daily diabetes management, mobile health (mHealth) technologies (eg, SMS text messaging, phone calls, smartphone apps, and wearable devices) provide a convenient and effective platform for promoting healthy behaviors and improving blood glucose control [16-18]. Moreover, mHealth can facilitate active collaboration between patients and health care providers.

Objectives

To address these gaps in the field, our research team undertook a 2-phase process to develop and pilot test a culturally tailored DSME program integrating mHealth technology, entitled Culturally Appropriate Strategies for Chinese Americans With Diabetes (CASCADe). Phase I used a mixed methods approach involving focus groups, semistructured interviews, and a questionnaire survey among CA patients with T2DM and health care providers (physicians and nurses), as well as extensive literature reviews of evidence-based DSME curricula. Information collected in phase I was used to inform the development of the CASCADe program curriculum. In phase II, a single-group pre- and posttest design with a 3-month study period was employed to pilot test the program's preliminary efficacy. We hypothesized that participants receiving the CASCADe intervention would show a significant reduction in glycated hemoglobin (HbA_{1c}) and significant improvements in self-efficacy, quality of life, and stress-coping skills for diabetes self-management at the end of 3 months, compared with their pretest levels.

Methods

Ethical Considerations

All study protocols for sample recruitment, data collection, intervention delivery, and evaluation were reviewed and approved by the Institutional Review Board of Claremont Graduate University (Institutional Review Board approval numbers 2522 and 2523). The protocol for the CASCADe intervention delivery and evaluation (ie, phase II study) was also registered on ClinicalTrials.gov (NCT04737499). We used active informed consent for both phase I and phase II studies. Participants were provided with an informed consent form that included information about the study purpose and background, procedures, risks or discomforts, extent of confidentiality (eg, each participant was provided with a unique study ID and study data were deidentified), benefits, incentives, and contact information for the primary investigator and the Claremont Graduate University Institutional Review Board. Each participant in phase I and phase II received US $10 as an incentive for participation. Phase II participants received an additional US $40 (US $5 for each of the 8 group-class sessions) for their time and travel. Compensation was provided as gift cards from 99 Ranch Market, the most popular Chinese grocery

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store in Los Angeles. In addition, various small gifts were offered as incentives during the education sessions. These gifts, such as a foot inspection mirror, measuring spoon, food scale, and resistance bands, were low in monetary value but served as strong motivators for participants to attend sessions and apply what they learned at home.

Community Engagement

We established collaborative partnerships with 2 local senior recreation centers (ie, Langley Senior Citizen Center in Monterey Park City and Joslyn Adult Recreation Center in Alhambra City) and AHMC Healthcare Inc. Each recreation center serves over 800 seniors, the majority of whom are CAs. These centers regularly provide a variety of recreational, social, educational, and cultural services and programs (eg, daily lunch programs, fitness programs, free health screenings, and case management services) to seniors in the local communities. AHMC Healthcare Inc is a hospital corporation based in the Greater San Gabriel Valley, California, with a mission to provide health care services across primary and tertiary care. It is one of Southern California's premier health care systems and operates a network of 6 hospitals, treating over 200,000 patients annually across more than 1100 beds. AHMC has a patient education center that includes classrooms, a large kitchen, and a laboratory. The Langley Center has classrooms, a computer laboratory, a large kitchen, and a gym with exercise facilities. The Joslyn Center has conference rooms and classrooms. Both centers and the AHMC Hospital Network helped recruit participants by distributing recruitment flyers, referring patients to the project, and providing space (eg, classrooms) and facilities for data collection and intervention delivery. AHMC Healthcare Inc also helped recruit physicians and nurses for interviews during the formative research phase and provided funds through its affiliated AHMC Health Foundation to support community diabetes screenings. Partial funding for our pilot program came from the AHMC Healthcare Foundation, which was deeply invested in the program.

Participant Recruitment

The cities of Monterey Park and Alhambra, located in the San Gabriel Valley, each have a CA population of over 35% of their total residents on average. The AHMC Hospital Network provided us with T2DM statistics from its patient information database in 2017. Therefore, in both phase I and phase II studies, we recruited participants through clinic referrals within the AHMC Hospital Network and by distributing flyers at Chinese New Year events and senior recreation centers in Monterey Park and Alhambra.

For phase I formative research, 23 CA patients with T2DM were recruited through flyers distributed at AHMC Healthcare–affiliated clinics and at Chinese New Year events. All patients were (1) previously diagnosed with T2DM and managing their diabetes through diet, oral hypoglycemic agents, insulin, or a combination of these; (2) residents of the San Gabriel Valley; and (3) Mandarin speakers. None had other self-reported or clinically diagnosed physical or mental illnesses (eg, cardiac conditions, cancer, or major depression). In addition, 3 physicians and 3 nurses from AHMC Healthcare–affiliated clinics participated in the semistructured interviews.

For phase II (pilot test of the CASCADe program curriculum), we screened and recruited participants at AHMC-affiliated clinics, Chinese New Year events, and senior centers in Monterey Park and Alhambra, CA. Eligible criteria for participation included (1) diagnosis of T2DM; (2) managing diabetes with diet, oral hypoglycemic agents, insulin, or a combination of these; (3) confirmed HbA_{1c} level ≥6.5% and <10% (HbA_{1c}≥10% indicating complicated diabetes requiring extensive medication); (4) 21-75 years old; (5) residents of the San Gabriel Valley; (6) Mandarin speakers; and (7) willing to use the smartphone-based monitoring devices provided by the study. Exclusion criteria included individuals who were unable or unwilling to give informed consent; planned to move out of the area within the study period; were pregnant, planning pregnancy, or breastfeeding within the next 6 months; had conditions that inhibited movement (eg, unable to walk unaided or unable to walk a quarter mile without stopping); or had significant physical disability or conditions that prevented in-person participation. Fourteen participants were enrolled in the study from 2017 to 2018.

Measures in Phase I and Phase II of the Study

Focus Group Discussions and Semistructured Interviews in Phase I of the Study

The goals of the focus group discussions with CA patients with T2DM were to gather their experiences and opinions on diabetes care practices (eg, dietary and physical activity behaviors, glucose monitoring, and medication compliance), and to assess the feasibility of smartphone use, text and picture messaging patterns, and perceived benefits of such technologies in enhancing diabetes management. Focus group discussions were conducted in Mandarin and included semistructured, open-ended questions designed to promote reflection and discussion, beginning with general topics and gradually moving to more specific issues. Semistructured interviews were also conducted with 3 physicians and 3 nurses/health educators to understand usual patient care, and the challenges and barriers faced when working with CA patients with T2DM. Interviews were conducted in either Mandarin or English, depending on participant preference, and followed the same structure as the focus groups, using open-ended questions progressing from general to specific topics. Audio recording consent was obtained from all participants before the sessions.

Questionnaire Surveys in Both Phase I and Phase II of the Study

In both phase I and phase II, participants completed a questionnaire developed based on our literature review. Detailed information on psychosocial and behavioral measures is provided in Table 1. A comprehensive translation and back-translation process was used for existing questionnaires that had not been previously translated into Chinese. The questionnaire was administered using Qualtrics, LLC.

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Table 1. Psychosocial and behavioral measures.

Instrument/standardized measure	Scale information	Sample item
Diabetes Quality of Life [19]	15 items (1-5 Likert Scale[a]); α=.85	How satisfied are you with your current diabetes treatment?
Diabetes Distress Assessment [20-22]	15 items (1-6 Likert Scale[b]); α=.902	I feel that diabetes is taking up too much of my mental and physical energy every day.
Diabetes Management Self-Efficacy Scale [23]	8 items (1-10 Likert Scale[c]); α=.93	I am able to choose different foods and maintain a healthy eating plan when I am eating out or at a party.
Diabetes Knowledge Test [24,25]	14 items (multiple choices); α=.62	Which of the following is highest in carbohydrate? a. Baked chicken b. Swiss cheese c. Baked potato d. Peanut butter.

[a]For the Diabetes Quality of Life Scale, the original response options ranged from 1 to 5, representing very satisfied, moderately satisfied, neither satisfied nor dissatisfied, moderately dissatisfied, and very dissatisfied. The scale was reverse-coded to range from 5 to 0, with higher scores indicating a higher quality of life.

[b]For the Diabetes Distress Assessment Scale, the original response options ranged from 1 to 6, corresponding to not a problem (1-2), moderate problem (3-4), and serious problem (5-6). The scale was reverse-coded to range from 5 to 0, with higher scores indicating greater stress-coping skills.

[c]For the Diabetes Management Self-Efficacy Scale, responses ranged from 1 to 10, representing not at all confident to totally confident, with higher scores indicating greater self-efficacy.

Measures to Assess the Preliminary Efficacy of the CASCADe Program in Phase II of the Study

The primary outcome used to evaluate the preliminary efficacy of the CASCADe program curriculum in phase II was HbA_{1c} level, assessed using the A1CNow+ point-of-care assay with a finger-prick blood sample collected by trained research assistants. This assessment method has demonstrated excellent accuracy (99% on average) in validation studies comparing A1CNow+ results with National Glycohemoglobin Standardization Program–certified laboratory reference results. HbA_{1c} assessment using finger-prick sampling has also been employed in other clinical trials evaluating diabetes treatment outcomes [14,26,27]. As suggested by the American Diabetes Association, HbA_{1c} reflects mean blood glucose concentrations over approximately the previous 8-12 weeks and provides a better indication of long-term glycemic control than fasting blood glucose [28,29]. Secondary outcomes included psychosocial and behavioral measures (listed in Table 1), as well as blood pressure, body weight, height, and waist circumference, which were measured by research assistants following standard protocols. Both primary and secondary outcomes were assessed at baseline (pretest) and at the end of the 3-month intervention (posttest).

In addition, participants' medical history, including years since diagnosis of T2DM, medication use, and diabetes complications (ie, eye problems; loss or decrease of sensation in the feet or legs; kidney problems; heart failure, angina, or heart attack; foot ulcer or infection; stroke; amputation; sexual problems; and symptoms of hypoglycemia), was self-reported. Research assistants also reviewed the use of any oral or injectable antidiabetic medications for each participant. Finally, to assess the acceptability of the CASCADe program curriculum, study dropout and intervention retention (eg, group class attendance, self-monitoring completion rate) were evaluated.

Data Analysis

Recordings of focus groups and semistructured interviews were transcribed and analyzed. An inductive thematic analysis was employed, allowing themes to emerge from the data rather than being fitted into a preexisting coding frame. This approach provided rich, detailed insights into patients' and health professionals' experiences and perspectives. Transcripts were repeatedly reviewed, coded iteratively, and grouped into major and minor themes by 2 independent student research assistants (ZN and XL), and were further reviewed and finalized by supervised researchers (ie, YWL and WCH), both of whom have extensive expertise and experience in qualitative data analysis. Discrepancies were resolved through discussion and consensus. Participants were not involved in reviewing the transcriptions or final qualitative results. SAS (version 9.4; SAS Institute) was used to manage and analyze all quantitative data. Descriptive analyses were conducted for means, SDs, frequencies, and proportions. Paired *t* tests (1-tailed) and the nonparametric Wilcoxon signed rank test were used to evaluate the preliminary efficacy of the CASCADe program for both primary and secondary outcomes.

Results

Phase I Formative Research

We conducted 5 focus group discussions with 23 patients (14 females and 9 males, aged 55-83 years) with T2DM living in the San Gabriel Valley. The discussions highlighted several challenges CAs encountered in diabetes management, including inadequate communication with physicians or other health practitioners (eg, clinical dietitians), insufficient culturally appropriate health education and materials, and limited access to training to optimize diabetes self-management. The most significant challenges reported were dietary control and blood glucose monitoring. Most patients described usual primary care as consisting mainly of medications and occasional educational brochures or pamphlets provided by clinics or community centers. Some had attended health fairs or occasional health seminars hosted by the city government, community centers, or hospitals. Although some patients sought diabetes self-management advice from health care providers, many reported learning diabetes care tips primarily from social media, friends, and family members, who may be misinformed and provide ineffective recommendations (eg, "eating less food and drinking more water").

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Table 2 presents general sample characteristics and diabetes-related psychosocial measures. On average, participants had a diabetes history of 18 years, and all were first-generation immigrants—17 (74%) originally from mainland China, with the remainder from Taiwan, Hong Kong, and Vietnam. Participants reported an average sum score of 9.96 (SD 2.18) out of 14 on diabetes knowledge questions, an average score of 2.93 (SD 1.17) on a 1-6 Likert Scale for diabetes distress, 2.61 (SD 0.70) on a 1-5 Likert Scale for diabetes quality of life, and 6.73 (SD 1.82) on a 1-10 Likert Scale for diabetes self-efficacy. These results indicated a need to improve diabetes knowledge and to address the psychological impact of diabetes on CAs.

In addition, we interviewed 3 physicians and 3 nurses/health educators regarding the usual care patients received and the challenges and barriers encountered when working with CA patients with T2DM. Clinician interviews reaffirmed the needs identified by patients and further highlighted frustrations faced by health professionals—particularly the lack of culturally appropriate diabetes educational materials available for CA patients.

Our formative research highlighted the needs and directions for developing a culturally tailored DSME program for CAs. Such programs have the potential to improve diabetes self-management by enhancing communication, cultural awareness, and competencies, as well as by changing dietary and behavioral practices. Feedback from the focus group discussions and the questionnaire survey provided valuable insights into target areas for our culturally responsive curriculum and the benefits of integrating smartphone technology to support self-management.

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Table 2. General sample characteristics (N=23).

Characteristics	Values
Age (years), mean (SD)	69.43 (8.35)
Gender, male, n (%)	9 (39)
Place of birth, n (%)	
Mainland China	17 (74)
Taiwan	3 (13)
Hong Kong	1 (4)
Other places outside the United States	2 (9)
Length of stay in the United States (years), mean (SD)	21.79 (15.10)
Educational attendance, n (%)	
Elementary/middle school	4 (17)
High/alternative high school	8 (35)
Some college	3 (13)
College	5 (22)
Graduate	3 (13)
BMI (kg/m^2), mean (SD)	
Female	23.71 (2.80)
Male	26.56 (2.60)
Age (years) at diagnosis, mean (SD)	51.64 (13.12)
Years with diabetes, mean (SD)	17.18 (15.53)
Using insulin (yes), n (%)	4 (17)
Using medications (yes), n (%)	21 (91)
Family history (yes), n (%)	16 (70)
Hypertension (yes), n (%)	17 (74)
Smartphone (yes), n (%)	14 (61)
WeChat account (yes), n (%)	7 (30)
Diabetes knowledge, mean (SD)	9.96 (2.18)
Diabetes stress, mean (SD)	
Overall	2.93 (1.17)
Emotional burden	2.90 (1.27)
Physical distress	3.08 (1.46)
Regimen distress	3.19 (1.21)
Interpersonal distress	2.38 (1.37)
Diabetes—quality of life, mean (SD)	39.22 (10.43)
Diabetes—self-efficacy, mean (SD)	6.73 (1.82)
Diabetes support, mean (SD)	
Emotional support	17.15 (5.64)
Advice support	17.40 (7.16)
Information support	17.56 (6.51)
Acculturation, mean (SD)	
Overall	1.85 (0.38)
Language	1.35 (0.57)
Identity	2.09 (0.58)

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Characteristics	Values
Friendships	1.39 (0.53)
Behavior	1.91 (0.58)
Generation	1.10 (0.35)
Attitudes	2.17 (1.11)
Brief symptoms inventory, mean (SD)	
Somatic	1.80 (0.63)
Obsessive compulsive	2.09 (0.52)
Interpersonal sensitivity	1.70 (0.58)
Depression	1.58 (0.48)
Anxiety	1.54 (0.54)
Hostility	1.70 (0.60)
Phobic anxiety	1.47 (0.48)
Paranoid ideation	1.91 (0.77)
Psychoticism	1.37 (0.36)

Phase I CASCADe Program Curriculum

Besides the mixed methods of focus groups, semistructured interviews, and a questionnaire survey, we conducted an extensive and comprehensive review of the literature on both nonculturally tailored and culturally tailored diabetes self-management programs to evaluate the strengths and weaknesses of extant evidence-based interventions, as well as to inform the creation of a bank of psychosocial and behavioral measurements. After this extensive evaluation, we decided to adapt the CASCADe program prototypes from the evidence-based curricula recommended by the American Diabetes Association [30] and the International Diabetes Federation [31]. Rather than focusing on surface-structure adaptations (eg, translation of materials and delivery in Mandarin Chinese), our program used a community-participatory framework (eg, focus groups with patients and providers) to identify areas for deep structural adaptations (eg, incorporation of cultural beliefs, barriers, values, communication styles, relationship building and support, understanding of Traditional Chinese Medicine and its impact on adherence, and culturally syntonic health and dietary behaviors and practices) [32,33]. The curriculum design was closely aligned with a theoretical framework comprising behavioral strategies and skills (eg, goal setting, self-efficacy, positive reinforcement, and peer support) drawn from the Planned Behavior Theory [34], the Social Cognitive Theory, the Social Learning Theory [35,36], and the Self-Regulation Theory [37]. The CASCADe curriculum started with a home visit in the first month to provide training on the use of monitoring devices and the WeChat (Tencent Holdings Limited) app, as well as to acquire family support. We acknowledge that participants' educational background and technological experience would help understand their overall responses to the questions and evaluations, as individuals' technical expertise can affect the adoption and integration of this program. In the following 2 months, 8 sessions (90 minutes each) using a combined format of group classes, educational games, group exercises, educational video viewing, and discussions were implemented. Throughout the entire study period, participants were instructed to use the monitoring devices for behavioral self-monitoring and to receive WeChat follow-ups, including educational tips, summaries and feedback on monitoring data, bidirectional 1-on-1 discussions between intervention providers and participants, as well as group discussions among participants.

Topics of the culturally adapted education sessions included recognition of diabetes and its complications, risk factors, dietary practices, exercise, behavioral self-monitoring, medication adherence, and stress management. Highlights of the session content are outlined in Table 3. The group-class format, as a major intervention delivery approach, has been widely used in other DSME programs for American adults [15] and is considered culturally syntonic for CAs from a collectivistic cultural background who value education. During the education sessions, we adopted this approach to enhance participants' learning by better attaching shared meaning to their experiences [38] and practice [39]. Session activities included class lectures with presentations, case studies, watching short video episodes and clips, storytelling of personal experiences (eg, stress coping), playing games (eg, ordering a meal plan through a mock dining-out experience at a Chinese restaurant), sharing tips on healthy cooking and smart grocery shopping, and reading food labels. At the beginning of each group session, participants were invited to follow an instructional video we created for a 15-minute workout using stretching bands, followed by a short video case study introducing the topic of that session. For example, the video episode for group session 1 included 2 cases addressing symptoms and diagnosis of T2DM and methods for checking complications. At the end of each group session, a factsheet summarizing key concepts in bullet points was reviewed, and participants were quizzed on the material covered in that session. We developed 2 bilingual handbooks, 1 for health educators and 1 for participants.

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Table 3. Outline of the CASCADe[a] program by session.

Session topics	Highlights of the session
Group session 1: Recognition of Diabetes and Complications	• Icebreaker game • Understand the basics of diabetes in both Traditional Chinese Medicine and Western Medicine (eg, diagnosis, symptoms, complications) context • Identify organs affected by diabetes complications using anatomy graphs • Sharing personal experience and goal setting • Discuss the pros and cons of Chinese norms, beliefs, and attitudes toward diabetes and treatment
Group session 2: Diabetes Risk Factors	• Understand diabetes-related risk factors (eg, poor diet, physical inactivity, family history, obesity, hyperlipidemia, hypertension, smoking) and guidelines and assessments • Measurement demonstration (eg, BMI, blood pressure, blood glucose) and interpretation • Information on sources for health services
Group sessions 3 and 4: Nutrition and Dietary Practice	• Nutrition misconceptions and food myths in the Chinese American community and social media • Create daily carbohydrate gram goals • Glycemic index, glycemic load, and identify high and low glycemic foods • Nutrition labels • Mock dining at restaurants • Tips on healthy cooking and smart grocery shopping • Portion size guides and healthy eating guidelines • Set diet-related goals, self-monitoring, and self-reinforcement
Group session 5: Exercise	• Physical activity guidelines • Misconceptions and myths of physical activity • Chinese norms and beliefs of exercise and diabetes • Introduce popular Chinese exercises (eg, Tai-Chi, square dancing) • Incorporate exercise into daily routine life • Discuss the benefits, safety, and barriers of exercising • Set physical activity goals and self-monitoring reinforcement
Group session 6: Self-Monitoring	• Importance of self-monitoring blood glucose, body weight, blood pressure, culturally syntonic physical activity, and eating practices • How to read and interpret results, how factors may affect results, and how to keep adequate and appropriate monitoring records • Importance of reinforcement, peer and family support, and use of technology on self-monitoring adherence
Group session 7: Medication Adherence	• Discuss types of commonly used antidiabetic medicine such as sulfonylureas, metformin, rosiglitazone, pioglitazone, or insulin, or any combination; safety on dosage change; side effects of common antidiabetic medications, including hypoglycemia episodes; recognizing typical symptoms of hypoglycemia and self-management; and Chinese herbal medicine and myths of alternative medicine (eg, Qigong and acupuncture) • Importance of antidiabetic medication adherence • Read the prescription label • Review medication adherence-related goals, self-monitoring, and self-reinforcement
Group session 8: Stress Management and Social Support	• How to assess stress, anxiety, and depression • Tips on culturally effective stress-coping strategies • Understand the importance of social support, assess the availability of support and service resources, build a support network, balance support and obligation, and navigate a cultural minefield in seeking and receiving support

[a]CASCADe: Culturally Appropriate Strategies for Chinese Americans with Diabetes.

During the 3-month study intervention period, each participant was provided with a mobile technology–assisted self-monitoring system, which was a smartphone-based, integrated health monitoring system with clinically validated devices manufactured by iHealth Labs Inc [40,41]. The system consisted of a smartphone and a set of Bluetooth-enabled wireless devices that provided continuous cloud-based data synchronization, including (1) a glucose meter for monitoring glucose levels; (2) a blood pressure cuff for assessing blood pressure and heart rate; (3) a smart weight scale for measuring body weight and BMI; and (4) a wrist band for tracking daily activity and sleep patterns (Figure 1). The iHealth MyVitals app, a central mobile phone–based platform, connected all devices via Bluetooth and automatically uploaded users' data to a secure cloud environment, allowing access by authorized personnel (eg, lifestyle coach, researcher). In addition, the WeChat app, a mobile instant messaging platform widely used in the Chinese population, was used to facilitate behavioral self-monitoring by delivering daily messages, educational tips, and supplementary readings related to the diabetes education sessions, as well as

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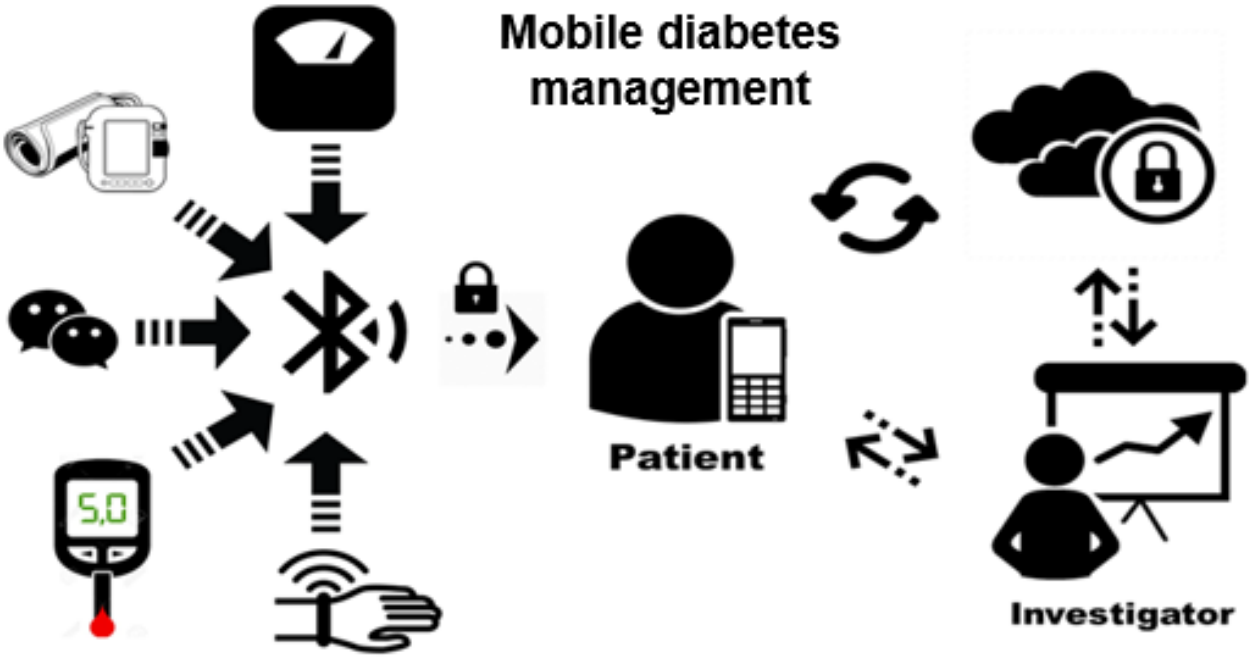
weekly summary reports of monitoring data. The instant messaging function also supported bidirectional 1-on-1 discussions between each participant and the health educator regarding the implications of monitoring results and reinforcement strategies, as well as online peer-based group discussions and social networking among participants to reinforce lifestyle changes and provide peer support. We also created a bank of WeChat articles corresponding to each classroom instruction session, along with an SMS text message bank (including graphs and short video clips) containing motivational messages on various diabetes management topics. Comprehensive training on the use of smartphones, the WeChat app, and Bluetooth-enabled behavioral self-monitoring devices, as well as privacy protection, was provided during the first home visit, with ongoing support (eg, Q&A and troubleshooting) offered by trained personnel and a hotline throughout the study period. In this pilot study, self-monitoring devices and smartphones were provided to participants. The smartphones were preloaded with all required apps, including WeChat and iHealth MyVitals, to support daily communication and self-monitoring data management. To further facilitate participants' use of mHealth technology, the phones were also preloaded with short instructional videos demonstrating the procedures for using each self-monitoring device, as well as a 15-minute stretching band exercise video used in the group class sessions. In addition to technology instruction guides, a color-illustrated, step-by-step, laminated guide was provided to assist participants in learning and using the mobile technologies. This was supplemented by a short instructional video clip accessible through participants' WeChat accounts. For data acquired through the mobile self-monitoring system (eg, body weight, blood pressure, average pulse rate, blood glucose, and physical activity measured as walking steps and calculated minutes of moderate-vigorous and vigorous activity), descriptive analysis algorithms (eg, means, SDs, frequencies, and proportions presented in tables and charts) were developed to generate weekly summary reports for both participants and investigators. All program content, technical interventions, and clinical discussions were conducted in Mandarin.

To compensate intervention participants for their time and travel, we provided incentives in the form of a US $10 gift card for each class session and an additional US $5 for WeChat and group chat participation. In addition, training tools (eg, a foot inspection mirror, measuring spoon sets, a pocket-size food scale, a stretching band, and educational posters) used during the class sessions were provided as small gifts to incentivize attendance and participation.

Figure 1. Mobile diabetes monitoring and management system.



Preliminary Efficacy of the CASCADe Program

We recruited 14 participants to join the program; however, 2 dropped out (1 returned to mainland China and the other was unavailable during the scheduled class sessions). Of the remaining 12 participants, 7 (58%) were female, and 5 (42%) were male. The mean age was 65 years (range 54-72 years). Half of the participants were born in Mainland China, 4 were from Taiwan, and 2 were from other locations outside the United States. A total of 5 (42%) participants had completed elementary or middle school, 3 (25%) had completed high school, 1 (8%) had graduated from a 4-year college or university, and 3 (25%) had attended some graduate or professional school. The average duration since diabetes diagnosis was 15 years. One participant had been diagnosed for less than 10 years, 9 had been diagnosed for 10-20 years, and 2 had been diagnosed for 20 years or more. Most participants had hypertension (n=9, 75%); 2 (17%) had cancer, and 1 had no physical disease. None of the participants had a mental disease.

A summary of pre- and posttest results for biomarkers and psychological indicators is presented in Table 4. Preliminary pre-post comparisons among participants showed significant

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improvements in HbA_{1c} levels (7.48 vs 7.09, *P*=.03; all but 3 participants reduced HbA_{1c} levels without changes in antidiabetic medication, and 7/12, 58%, participants achieved a >0.5 reduction), diabetes knowledge (7.67 vs 9.0, *P*=.04), self-efficacy (6.59 vs 8.01, *P*=.003), and quality of life (3.21 vs 3.69, *P*<.001) at 3 months after baseline (Table 4). A significant improvement was also observed in the average score for stress-coping skills (3.18 vs 3.74, *P*=.01), which was measured using a reverse-coded Diabetes Distress Scale (ie, the original Likert Scale of 1-6 was reverse coded to 5-0, with higher scores indicating better stress-coping skills). No significant changes were observed in body weight (*P*=.45) or BMI (*P*=.50).

Table 4. Summary of pre-post test results on biomarker and psychological indicators.

Outcome	Pretest, mean (SD)	Posttest, mean (SD)	Pre-post difference, mean (SE)	*P* value (1-tailed)
HbA_{1c}[a]	7.48 (0.69)	7.09 (1.25)	–0.38 (0.19)	.03
BMI	26.51 (1.82)	26.51 (1.84)	–0.0006 (0.25)	.50
Waist circumference	96.02 (7.40)	93.87 (5.73)	–2.16 (1.20)	.05
Stress coping[b]	3.18 (1.38)	3.74 (0.91)	0.56 (0.22)	.01
Self-efficacy	6.59 (1.76)	8.01 (1.37)	1.37 (0.46)	.007
Quality of life	3.21 (0.77)	3.69 (0.55)	0.48 (0.14)	.002
Diabetes knowledge	7.67 (2.27)	9.0 (1.81)	1.33 (0.71)	.04

[a]HbA_{1c}: glycated hemoglobin.

[b]The Stress-Coping Scale was the reverse-coded Diabetes Distress Scale (ie, the original Likert Scale of 1-6 was reverse-coded to 5 to 0, with a higher score indicating a higher level of stress coping skills).

Tables 5 and 6 present a summary of the evaluation of the intervention program components and adherence. All but 3 participants attended all 8 group class sessions, and those 3 missed only 1 session during the study period. All participants used smartphones, WeChat, and mHealth devices for self-monitoring. All participants reported being “very satisfied” with the CASCADe program, regarded the program as “very culturally responsive to (their) needs,” were adherent to self-monitoring using the smartphone-based mobile monitoring system, and indicated that WeChat was “very helpful” or “helpful” for engaging in group discussions; posting and receiving health tips, reminders, and reinforcements; and reading daily articles and personal weekly summary reports of behavior monitoring; 9 out of 11 (82%) participants endorsed the smartphone-based self-monitoring system as “acceptable,” “easy to use,” or “very easy to use.” The only complaint related to familiarity with participants’ own glucose meters, as some were less enthusiastic about using the new glucose meter provided, which was integrated into the smartphone-based mobile monitoring system via Bluetooth. An example of a biweekly self-monitoring chart from one participant is illustrated in Figure 2.

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Table 5. Summary of the evaluation of the intervention program.

Evaluation components	Positive feedback[a]
Overall intervention, n (%)	11 (100)
Class sessions, n (%)	
Health educational video	11 (100)
Resistance band exercise	11 (100)
Instruction delivery	11 (100)
Quiz	10 (91)
Self-monitoring instruments, n (%)	6 (55)
Weight scale	
Glucometer	6 (55)
Sphygmomanometer	7 (58)
Activity tracker	7 (58)
WeChat, n (%)	
Daily tweets	10 (91)
Personal weekly report	11 (100)
WeChat group discussion	9 (82)

[a]n=11, 1 out of 12 participants did not attend the last course to complete the evaluation survey. Positive feedback: combination of “good” and “very good,” “helpful” and “very helpful,” “satisfied” or “like.”

Table 6. Summary of intervention adherence.

Intervention adherence	Participation rate[a]
Class sessions, n/N (average percentage)	
Class attendance	91/96 (95)
In-class quiz	93/96 (97)
Home visits, n (%)	12 (100)
WeChat article-related quiz, average percentage (SD)	Round 1: 0.87 (0.20); round 2: 0.65 (0.45); and average percentage: 0.79 (0.31)
Self-monitoring instrument, average percentage (SD)	
Weight scale	0.46 (0.33)
Glucometer	0.67 (0.46)
Sphygmomanometer	0.70 (0.32)
Activity tracker	0.65 (0.31)

[a]The participation rates between class attendance and in-class quizzes differed among 12 participants. The reason is that some participants who missed the course learned the material on their own at home and made up the previous quiz when they attended the next class session. Both participation rates were calculated as the number of class attendance or in-class quizzes divided by the product of 12 participants by the total number of class sessions (8 sessions) or in-class quizzes. The means and SDs were provided for adherence to the WeChat article-related quizzes and the self-monitoring instrument.

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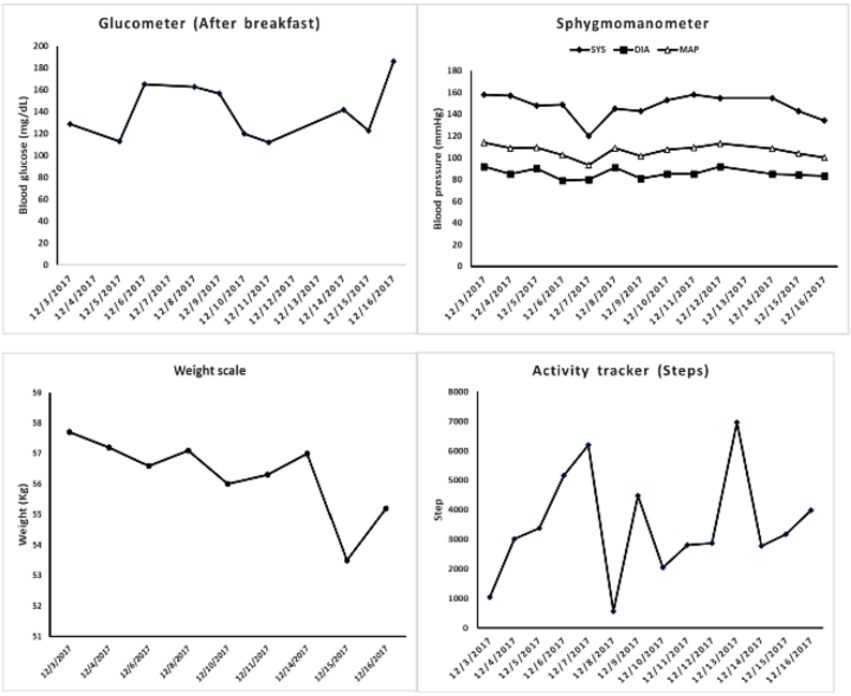
Figure 2. Fig 2. Bi-Weekly Self-Monitoring Chart for One Participant.



Discussion

Principal Findings

Through collaborative partnerships with 2 large community recreation centers and the AHMC Hospital Network in San Gabriel Valley, California, we developed and pilot-tested a culturally tailored DSME program with integrated mHealth technology, entitled CASCADe. Preliminary results from the pilot trial demonstrated a significant reduction in HbA_{1c}, along with improvements in diabetes management knowledge, self-efficacy, quality of life, and stress-coping skills among CA patients with type 2 diabetes.

Although progress has been made in improving the efficacy of DSME programs, there remains a dearth of research on culturally adapted, evidence-based DSMEs for CAs with T2DM. Our research efforts are expected to help address the growing needs of CAs with T2DM by advancing knowledge of best practices in T2DM self-management. This is particularly important given the rapidly increasing prevalence of T2DM among CAs [2-4], making investment in such efforts more urgent than ever.

The CASCADe program used a combined, theoretically driven, and community-participatory approach to develop an evidence-based curriculum comprising 8 weekly sessions of health education and diabetes management. The monitoring system employed a smartphone to coordinate cloud-based data transmission from a set of wireless devices to capture daily monitoring data on physical activity, body weight, blood pressure, and blood glucose levels. The WeChat app was used to facilitate behavioral self-monitoring by delivering daily messages aligned with the diabetes education curriculum, weekly summary reports of monitoring data, reinforcement messages, and group discussions on readings and the implications of monitoring results. The CASCADe program was successfully piloted, and preliminary results indicated a significant reduction in HbA_{1c}, along with improvements in diabetes management knowledge, self-efficacy, quality of life, and stress-coping skills among CA patients with type 2 diabetes.

Our study found results comparable to prior research on diabetes education programs for CAs. Culturally adapted programs for CAs reported in a recent systematic review included 2 conducted in San Francisco [13,14], 1 in Hawaii [15], and another that tested a linguistically and culturally tailored Diabetes Prevention Program among CAs with prediabetes in New York City [42]. All of these programs demonstrated improved treatment outcomes, including self-efficacy, diabetes knowledge, family support, diabetes distress, and quality of life. A significant reduction in HbA_{1c} was reported in all studies except 1 [13]. The preliminary efficacy observed in our study was similar to that of these diabetes educational interventions for CAs [13-15] and for other minority populations in the United States [43-45]. A key innovation of our intervention was the use of a culturally practical and integrative mHealth technology to enhance self-monitoring. The Bluetooth-enabled devices increased participants' willingness to engage in diabetes self-management monitoring by automatically uploading tracking data to a secure cloud, rather than requiring maintenance of monitoring logs and manual data entry. This approach enabled investigators to provide immediate, personalized feedback to participants upon receipt of the data [46,47]. In addition, the use of a widely adopted CA social media platform, WeChat, expedited bidirectional communication between participants and researchers and fostered a peer-supported community that connected participants and facilitated mutual support [46,47]. Although the pilot nature of the study limited the sample size and relied on a less rigorous single-group pre-post

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quasi-experimental design, the feasibility and preliminary efficacy findings are promising.

Limitations

Given the pilot nature of our study, several limitations should be considered when interpreting the findings. These include limited statistical power due to the small sample size; potential selection bias (eg, volunteer bias) arising from recruitment strategies that relied primarily on referrals through the AHMC Healthcare Network and participation via flyers distributed at senior centers and Lunar New Year events; and the use of a single-group pre- and posttest design for the preliminary evaluation of program efficacy. Future work would benefit from incorporating in-depth interviews with phase II participants to better understand the mechanisms through which the intervention produced its effects. In particular, such qualitative data could elucidate how psychological factors (eg, self-efficacy and stress-coping skills) shaped behavioral changes, as well as how cultural values and adaptations were perceived and integrated by participants during the intervention.

Implications for Diabetes Education

Lastly, our pilot study demonstrated the feasibility of implementing the CASCADe program among CAs to improve diabetes self-management skills. The study yielded promising results and warrants testing in a larger randomized trial. We expect to maintain our research collaborations, continue providing health screenings and the CASCADe program to the community, and expand this translational research model—which integrates academic research with community health services—to other ethnic minority populations.

Conclusions

Our pilot study demonstrated the feasibility of implementing a culturally tailored intervention program with mHealth integration among CAs to improve diabetes self-management skills.

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Data Availability

The datasets generated and analyzed during this study are available from the corresponding author (BX) upon reasonable request.

Authors' Contributions

Conceptualization: BX (lead, equal), YWL (lead, equal), WCH, YM
Data curation: ZN, XL, RY, YL, TF
Formal analysis: BX (lead), XL, RY, TF (supporting)
Funding acquisition: BX, YWL, and WCH
Investigation: BX, YWL, WCH, ZN
Methodology: BX, YWL, WCH, YM
Project administration: BX (lead, equal), YWL (lead, equal), ZN, XL, YL (supporting)
Resources: BX, YWL
Supervision: BX, YWL, WCH
Writing – original draft: BX (lead), XL, RY, TF
Writing – review & editing: BX (lead), YWL, WCH, YM, ZN, XL, YL, RY, TF

Conflicts of Interest

None declared.

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Abbreviations

CA: Chinese American
CASCADe: Culturally Appropriate Strategies for Chinese Americans with Diabetes
DISTANCE: Diabetes Study of Northern California
DSME: Diabetes Self-Management Education
HbA1c: glycated hemoglobin
mHealth: mobile health
T2DM: type 2 diabetes mellitus

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Original Paper

An Explanation User Interface for Artificial Intelligence–Supported Mechanical Ventilation Optimization for Clinicians: User-Centered Design and Formative Usability Study

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Abstract

Background: The integration of artificial intelligence (AI) into clinical decision support systems (CDSSs) for mechanical ventilation in intensive care units (ICUs) holds great potential. However, the lack of transparency and explainability hinders the adoption of opaque AI models in clinical practice. Explanation user interfaces (XUIs), incorporating explainable AI algorithms, are considered a key solution to enhance trust and usability. Despite growing research on explainable AI in health care, little is known about how clinicians perceive and interact with such explanation interfaces in high-stakes environments such as the ICU. Addressing this gap is essential to ensure that AI-supported CDSS are not only accurate but also trusted, interpretable, and seamlessly integrated into clinical workflows.

Objective: This study aimed to evaluate the first iteration of the design and evaluation phase of an XUI for an AI-based CDSS intended to optimize mechanical ventilation in the ICU. Specifically, it explores how different user groups—ICU nurses and physicians—perceive and prioritize explanation concepts, providing the empirical foundation for subsequent refinement iterations.

Methods: A midfidelity prototype was developed using the prototyping software Justinmind, based on existing guidelines, scientific literature, and insights from previous user-centered design (UCD) phases. The design process followed ISO (International Organization for Standardization) 9241-210 principles for UCD and combined qualitative and quantitative feedback to identify usability strengths, design challenges, and role-specific explanation needs. The prototype was evaluated formatively through 2 usability walkthroughs (walkthrough 1: 4 resident physicians and walkthrough 2: 4 ICU nurses), which included guided group discussions and Likert-scale assessments of explanation concepts in terms of understandability, suitability, and visual appeal.

Results: The XUI was structured into 2 levels: a first level displaying high-level explanations (outlier warning and output certainty) alongside the CDSS output, and a second level offering more detailed explanations (available input, feature importance, and rule-based explanation) for users seeking deeper insight. While both user groups appreciated the first level, physicians found the second level of the XUI useful, whereas ICU nurses found it overly detailed. Thus, the structure was able to address the differing needs for explanations. The layered design helped balance transparency and information overload by providing initially concise explanations and more detailed ones on demand. The evaluation further strengthened evidence for role-dependent explanation needs, suggesting that nurses prefer actionable, concise insights, whereas physicians benefit from more granular transparency information.

Conclusions: This study underscores the importance of UCD in designing XUIs for CDSS. It highlights the differing information needs of physicians and ICU nurses, emphasizing the value of involving users early in the development of suitable XUIs. The findings provide practical guidance for designing layered, role-sensitive explanation interfaces in critical care and form the basis for future iterative evaluations and experimental studies assessing their impact on decision-making and clinician trust.

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(JMIR Form Res 2026;10:e77481) doi:10.2196/77481

KEYWORDS

CDSS; clinical decision support system; XAI; explanation user interface; XUI; usability; formative evaluation; intensive care unit; ICU; explainable artificial intelligence

Introduction

Background

Artificial intelligence (AI) is expected to benefit the medical domain with improvements in patient care and reduced workload for medical personnel. AI models are increasingly proposed as a knowledge or inference base of clinical decision support systems (CDSSs) to achieve this. These AI-based CDSS are considered well-suited for use in the intensive care unit (ICU) due to the amount of available documented data in the ICU, but the transfer of these systems into clinical practice is still lacking [1]. AI models for which it is impossible to directly infer why they generate an output due to their complexity are called black-box models. The black-box nature of these models poses a barrier to adoption in the medical domain, as it makes it difficult for health care providers to understand, trust, or accept these models [2-4]. According to the EU (European Union) AI Act, AI-based CDSS are classified as high-risk AI systems [5]. For high-risk AI systems, the act requires the possibility of human oversight and the provision of appropriate interfaces for this supervision (EU AI Act, Chapter III, Article 13 and 14) [6]. Approaches from the field of explainable AI (XAI) are a solution to these barriers [7-11]. XAI provides additional information to the output of an AI model to make model reasoning more transparent through explanation user interfaces (XUIs). In the medical domain, XAI has been shown to influence users' trust [12,13], the perceived usefulness [14] or value [13] of a system, the medical professionals' confidence in decisions [14], and decision-making [15]. XAI research focuses on creating, optimizing, and evaluating XAI algorithms. Explanations are often designed to meet the needs of (X)AI developers while neglecting the needs of clinical end users [16]. Recently, calls for a user-centered design (UCD) of XUIs have been raised in the medical informatics domain [16-20].

The objective of this paper was to conduct the initial design and evaluation phases of the UCD process for an XUI of an AI-based CDSS intended for use in the ICU. As a use case, we selected the provision of recommendations for ventilation parameter settings in patients receiving mechanical ventilation in the ICU. Patients may undergo mechanical ventilation using ventilators—machines that assist breathing by delivering air into the lungs when they cannot breathe adequately. Another form of life support is extracorporeal membrane oxygenation, which bypasses the lungs—and sometimes the heart—by circulating the patient's blood through an external machine that oxygenates the blood and extracts carbon dioxide from it. To enable the continuous optimization of a patient's ventilation, a CDSS must be able to recommend a range of parameters. In mechanical ventilation, these include, for example, the ventilator mode, which defines the overall strategy and level of mechanical support; tidal volume, which specifies the amount of air delivered per breath; and respiratory rate, which determines the number of breaths per minute.

The development of such AI-based CDSS is being carried out within the IntelliLung project, a European Union–funded initiative aimed at improving ventilatory care and reducing the workload of clinical staff [21]. The CDSS will generate recommendations for both mechanical ventilation and extracorporeal membrane oxygenation settings. The research presented in this paper used the IntelliLung CDSS as a real-world use case to anchor the design in clinical practice. However, the design is independent of any project-specific AI algorithm decisions and instead focuses conceptually on XUI design for such a CDSS. As Mohseni et al [22] proposed, this type of research can be conducted before selecting and developing the AI algorithms and corresponding XAI methods.

State of the Art

Although much research on XAI focuses on the health care domain [23], to the authors' knowledge, no paper explicitly addresses the UCD of XUIs for AI-based CDSS aimed at optimizing continuous mechanical ventilation in the ICU. Several papers report on the use of AI algorithms and XAI methods from a technical perspective, for example, to predict the ventilation duration for patients with acute respiratory distress syndrome [24], to predict the disease progression of patients with acute respiratory distress syndrome [25], to predict the ventilator support for patients with COVID-19 [26], and to generate ventilator setting recommendations [27]. Hughes et al [28] report on the context and work process analysis for CDSS supporting the weaning process in the ICU to inform the overall CDSS design for weaning support, but do not focus on optimizing continuous ventilation or designing XUIs for the CDSS.

A limited number of papers address the UCD of XUIs in the ICU [14,29-31]. A preprint by Clark et al [29], published after this study concluded, investigates user requirements for using XAI in CDSS, without focusing on a specific ICU use case. Nagendran et al [30] demonstrated the feasibility of eye-tracking analysis to assess physicians' interactions with an XUI for an AI-based CDSS, although not focused on ventilation, in a simulated ICU setting. Barda et al [31] designed and evaluated an XUI for an AI-based CDSS that predicts mortality risk in a pediatric ICU. The acceptance of an XUI for a sepsis treatment CDSS by ICU clinicians was investigated by Sivaraman et al [14]. Outside the ICU setting, Schoonderwoerd et al [32] investigated pediatricians' perspectives on different explanation concepts for a diagnostic CDSS.

Previous Research

The UCD process was conducted in accordance with DIN (Deutsches Institut für Normung) EN (Europäische Norm) ISO (International Organization for Standardization) 9241-210 [33]

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to design the XUI for an AI-based CDSS that recommends ventilator settings. This paper focuses exclusively on the first iteration of the design and evaluation phases of the UCD process. These phases rely on the results of the context analysis and the specification of user requirements. The results of the first 2 phases of the UCD process are summarized to provide the necessary context.

During the context analysis, the intended use characteristics of the CDSS were defined as (1) a stand-alone CDSS, which should not replace the ventilation monitor, and (2) a CDSS that would be displayed on a stationary tablet next to the ventilation monitor of an individual patient. The identified main user groups of this CDSS were resident physicians and ICU nurses with the authority to change the patient's ventilator settings. An initial investigation into user requirements revealed conflicting opinions among future users about the importance of explanations [34]. These results led to a follow-up investigation into users' preferences for explanation, to identify which explanations to include in a first design iteration. Seventeen explanation concepts, ranging from less complex ones such as available input information to more sophisticated ones such as counterfactual explanations, were presented to the users as low-fidelity mockups in a questionnaire. This step was performed before this study to attain a manageable number of explanation concepts for the first design iteration and a formative evaluation. The selection of explanation concepts for this first iteration of the XUI was based solely on user preferences, rather than on commonly used explanation concepts. Users selected the explanation concepts, output certainty, and outlier warning to be displayed alongside the CDSS recommendations. The output certainty concept informs users about the CDSS's confidence level in its recommendation. The outlier warning alerts users if one or more input parameter values are highly unusual. Three additional explanation concepts were selected but were not designated to appear directly next to the CDSS output: available input, feature importance, and rule-based explanation. The available input explanation concept informs the user which parameter values were available when generating the recommendation. The feature importance explanation concept shows users how each parameter influenced the recommendation. The rule-based explanation concept presents simplified rules in text or decision tree format, approximating how the recommendation was calculated. These findings served as the foundation for the XUI design phase.

Study Scope and Research Question

Overview

The underlying research aim of this paper is threefold to (1) design midfidelity mockups of the XUI, focusing on its overall structure and different design variants for the explanation concepts, (2) give users an impression of the XUI without fully designing each explanation concept in detail, and (3) gather early formative feedback from future users to support iterative refinement of the XUI in subsequent design phases. Therefore, this study does not aim to deliver a finalized XUI design, nor does it seek to conduct a comprehensive summative evaluation of the XUI, as this will be the focus of future iterations.

The following research questions, aligned with the design and evaluation phases, were developed to guide the investigation.

Design Phase

The design phase focused on generating design options for the XUI, with the following research question:

- RQ1: How should the XUI of an AI-based CDSS for mechanical ventilation optimization in the ICU be designed?

Evaluation Phase

The evaluation phase focused on collecting early user feedback from clinicians, with the following research questions:

- RQ2: What are clinicians' perceptions of the proposed XUI of the AI-based CDSS for mechanical ventilation optimization?
- RQ3: What XUI design improvements should be addressed in subsequent design iterations?

Methods

Figure 1 provides an overview of the methods used in each XUI development phase.

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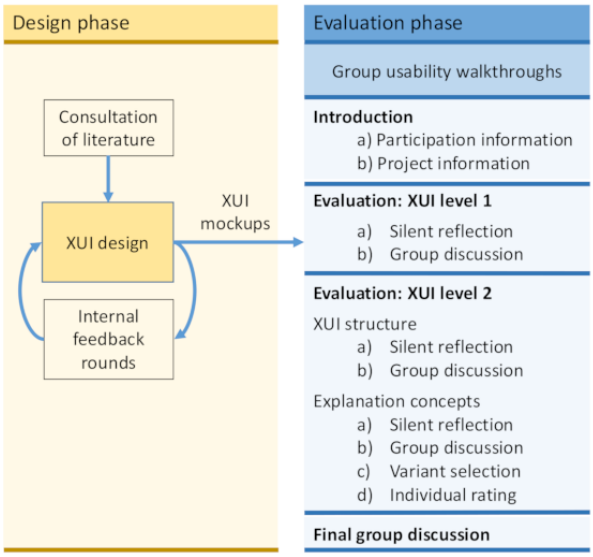
Figure 1. Overview of the methods used during the first iteration of the design and evaluation phases of the explanation user interface (XUI).



XUI Design Phase

The design phase began with the development of a foundational knowledge base for the XUI. Relevant literature, such as norms and design guidelines, was reviewed. For this purpose, the ISO 9241 standard series on human-system interaction and human-centered design was reviewed. This foundation was expanded through a scoping review and the development of design recommendations for the user-centered XUI design for CDSS [35]. Searches for research papers related to the topic of XUIs for AI-based CDSS for the ventilation of patients in the ICU found no relevant results before the design of the XUI.

Midfidelity XUI mockups were developed using the Justinmind [36] prototyping software, based on the knowledge foundation. The design of the mockups was intended to direct users' attention to elements relevant to RQ2 and RQ3 and to prevent users from focusing on aesthetic aspects such as the color of the XUI. Therefore, mockups were designed with the following characteristics: (1) realistic variable names and content to support user familiarity; (2) realistic-looking data, for which synthetic data points were generated for each displayed input variable with a large language model (Claude Sonnet 3.5 [37]); (3) minimal use of color, used selectively to highlight system functionality; and (4) simple interactions (eg, navigation between interface levels).

A main screen for the CDSS was designed to present the XUI within its intended system context and to help users envision the future context of use for the XUI. The basic structure of the XUI and the design variants for the explanation concepts were developed based on the list of selected explanation concepts and their intended level within the XUI, which had been defined during the requirements specification phase of the UCD process. The mockups were designed iteratively: the first author created initial drafts, and members of the author team with usability expertise provided verbal feedback for improvements during multiple group meetings.

The design of the individual explanation concepts was oriented toward typical design elements used for these explanation concepts in the XAI literature. This decision was made to provide the users with a realistic representation of common explanation concepts and to keep the focus on the goal of this first evaluation iteration. We opted not to apply a more elaborate design strategy to the explanation concepts in this iteration; this will be addressed in later iterations, which typically focus on aesthetics and detailed design.

XUI Evaluation Phase

In the evaluation phase, formative feedback was gathered from ICU physicians and nurses, focusing on the XUI's structure and explanation concepts. A formative evaluation was chosen to collect insights for improving the CDSS and understanding users' initial impressions of the CDSS. Given resource constraints—such as limited availability of clinical experts and their high workload—a pragmatic approach was taken. This evaluation is reported according to the STARE-HI (Statement on the Reporting of Evaluation studies in Health Informatics) guidelines to ensure consistency and standardization [38]). For the STARE-HI reporting checklist, refer to Multimedia Appendix 1 and [39].

Study Design

As a formative evaluation, 2 group usability walkthroughs were conducted—1 for each main user group (physicians and ICU nurses). A semistructured approach was followed, guided by a predefined protocol. Each walkthrough included (1) a presentation of the XUI, (2) individual reflection time, (3) guided group discussions, and (4) a quantitative assessment (QA) of the explanation concepts.

The walkthrough groups were separated by user group. This separation accounted for differing levels of project involvement and aimed to minimize hierarchical bias, particularly the risk of physicians influencing ICU nurses during discussions. The walkthroughs were moderated by a researcher with usability expertise, who introduced the mockup, guided the discussion

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using predefined questions focused on information retrieval, overall interaction, and the structure of the XUI, and asked follow-up questions where necessary. A second researcher took notes to ensure thorough documentation.

Sample Size and Recruiting Process

The target was to recruit 4 to 5 participants per user group, as small sample sizes are considered acceptable for formative evaluations in medical informatics [40], and sample size requirements can be adjusted based on system-specific characteristics [41].

Participants were recruited using convenience sampling. For the physician group, invitation emails were sent to 5 physicians in the same research group, which was involved in the IntelliLung project. Four physicians accepted the invitation. To increase the chances of successful recruitment of ICU nurses, 1 of the cooperating physicians identified an interested contact person among the nursing staff in 1 of the ICUs at the same hospital. The contact person informally inquired about his or her peers' interest in participating in the study. After the nurses were recruited, the contact person shared the contact details with the researchers. To be eligible to participate in the study, all participants were required to have at least 3 months of ventilation experience (demonstrated through working experience in the ICU or research activity in the field of mechanical ventilation). No compensation was paid for participation in the group usability walkthrough.

Walkthrough Process

The details of the physician walkthrough are described in this section. Any predefined process deviations for the nurse walkthrough are reported in the section "Deviations for the Nurse Group Usability Walkthrough."

At the start, participants received in-depth information about their rights and the purpose of the usability walkthrough. Afterward, the moderator presented the CDSS use case and the main screen of the CDSS. The XUI mockup evaluation then began. The 2 XUI levels were evaluated sequentially, reflecting their hierarchical structure.

The evaluation began with the main CDSS screen, which included XUI level 1, displayed on a monitor. The moderator provided a verbal introduction. Participants were then given time to observe and reflect on XUI level 1 silently. The reflection was followed by a group discussion guided by the question: "Is the presentation of outlier warning and system certainty on the main screen sufficient?"

The XUI level 2, a subordinate screen providing additional explanation concepts, was evaluated in 2 steps. In the first step, the participants assessed the overall structure of the level. The XUI level 2 was shown, and the participants silently analyzed it. Afterward, the group briefly discussed and then collectively answered the following questions: "In which part of the interface do you find explanations for the recommendation?" and "How do you switch between the explanations?"

In a second step, the individual explanation concepts in XUI level 2 were assessed using the following steps:

- The initial version of the explanation concept was shown, and the participants silently observed and analyzed each explanation concept.
- The group discussed the explanation concept and then provided a collective answer to the questions (Table 1). Whether the group answered the questions correctly was documented.
- Alternative design variants of each explanation concept were presented. The group discussed these variants and selected their preferred variant.
- Each participant then individually assessed the selected version on Likert scales regarding the following 3 dimensions (ie, QA-1, QA-2, and QA-3) with the following anchors:
- QA-1 (ease of understandability): "I find this explanation concept easy to understand."
- QA-2 (suitability): "I find this explanation concept suitable for everyday clinical work."
- QA-3 (appealingness): "I find this explanation concept appealingly visualized."
- Strongly Disagree, Disagree, Neutral, Agree, and Strongly Agree
- Additional options: no answer and free-text comments

Table 1. List of questions and items used to evaluate each explanation concept.

Explanation concept	Group discussion questions
Available input (AI)	• AI-1: What information do you get from this view? • AI-2: In which sections were not all values available when the recommendation was generated? • AI-3: How would you get more detailed information on input values? • AI- 4: How should the sections be sorted in the "available input" area? • Version A (static order): (1) in the presented order and (2) in a different order. • Version B (dynamic order): areas with missing values at the top? • If Version A was selected, would you prefer (1) or (2)?
Feature importance (FI)	• FI-1: What information do you get from this view? • FI-2: Which parameter had an importance of 80% for generating the recommendation? • FI-3: Where would you have to click to display the importance of more parameters?
Rule-based explanation (R)	• R-1: What information do you get from this view?

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The complete version of the instrument is provided in Multimedia Appendix 2.

The group usability walkthrough concluded with a general discussion focusing on the following guiding questions: "Should there be more or fewer explanation concepts presented?" and "Are there any missing explanation concepts?" (The physicians had access to previous presentations of other explanation concepts before the group usability walkthrough).

Deviations for the Nurse Group Usability Walkthrough

To accommodate the ICU nurses' limited previous exposure to the project, the walkthrough session was adapted to include a more comprehensive introduction to CDSS and AI concepts. Insights from the physician group informed minor refinements to the mockups. Elements that had proven consistently irrelevant or confusing across previous sessions were excluded to maintain focus, while still allowing nurses to contribute unique, user-specific feedback.

Furthermore, in the final group discussion, the nurses were verbally introduced to the possibility of additional explanation concepts (since they had not previously been exposed to other types, such as counterfactual explanations). They were also asked whether the information presented in level 1 of the XUI was sufficient.

Analysis Approach

Qualitative Analysis of Group Discussions

After each group usability walkthrough, the first author combined the notes from both researchers. The second researcher reviewed the merged version, and any disagreements were discussed and resolved jointly. The first author then categorized the notes by XUI level and discussion questions and organized them by content. No predefined coding scheme was used; categories emerged inductively based on the content of the group discussions. Summarizing bullet points were translated into English, as both group usability walkthroughs had been conducted in German, the participants' native language. The second researcher reviewed the final summary. No verbatim quotes were recorded during documentation of the group usability walkthroughs.

Quantitative Data Analysis

The QAs (QA-1, QA-2, and QA-3) of each explanation concept were analyzed purely descriptively due to the limited number of responses per user group. For each explanation concept and user group combination of the QAs (QA-1, QA-2, and QA-3), the number of responses, the number of "No Answer," the median, and the IQR are reported. In addition, all responses for the items are presented visually as horizontally oriented stacked bar plots.

Ethical Considerations

This study was conducted in accordance with ethical research principles. It involved low-risk, formative group usability walkthroughs as a qualitative survey or interview method in which clinician participants were shown interface mockups and asked structured questions about usability, understandability, and suitability. No medical interventions were performed, no patient data were collected, and the study did not constitute epidemiological research. In line with the institutional guidance of the Ethics Committee of TU Dresden for such non-interventional survey or interview studies, no IRB or REB approval was sought [42]. All procedures were carried out in accordance with the principles of the Declaration of Helsinki. Informed consent was obtained from all participants after they received detailed information about the study purpose, the walkthrough procedure, data handling, and their rights. Participation was voluntary, and participants could withdraw at any time without consequences. Participants were not compensated for their participation. Privacy and confidentiality were safeguarded by collecting and storing data in pseudonymized form; only non-sensitive, profession-related participant information was collected, no identifying information is reported, and access to raw data was limited to the research team.

Results

XUI Design Phase: Structure of the XUI

The design phase produced a 2-level XUI structure (XUI level 1 and XUI level 2). XUI level 1 is positioned on the main screen of the CDSS, adjacent to the system's recommendations. Figure 2 shows the mockup for the CDSS main screen, which contains a header with basic patient information (A in Figure 2), the recommendation (B in Figure 2), XUI level 1 (C in Figure 2), and a trend view of important parameters (D in Figure 2). XUI level 1 includes the explanation concept outlier warning (E in Figure 2), consisting of an icon with a header (H in Figure 2) and an information text (I in Figure 2); the explanation concept certainty information (F in Figure 2), for which the certainty level is presented as a traffic light (J in Figure 2), a number, and a category label (K in Figure 2); and a button (G in Figure 2) that links to XUI level 2.

Figure 3 shows XUI level 2, which includes a header with basic patient information, the CDSS recommendation, a repetition of the explanation concepts from level 1, and an expanded panel on the right side for displaying explanation concepts in more detail, one explanation concept at a time. The following explanation concepts were used in level 2: available input, feature importance, and rule-based explanation. The users can switch between explanation concepts in the expanded section using tabs.

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Figure 2. Main screen of the clinical decision support system (CDSS), showing level 1 of the explanation user interface (XUI) in the top-right section. Two versions are shown: the left screen includes the outlier warning, and the right screen does not.

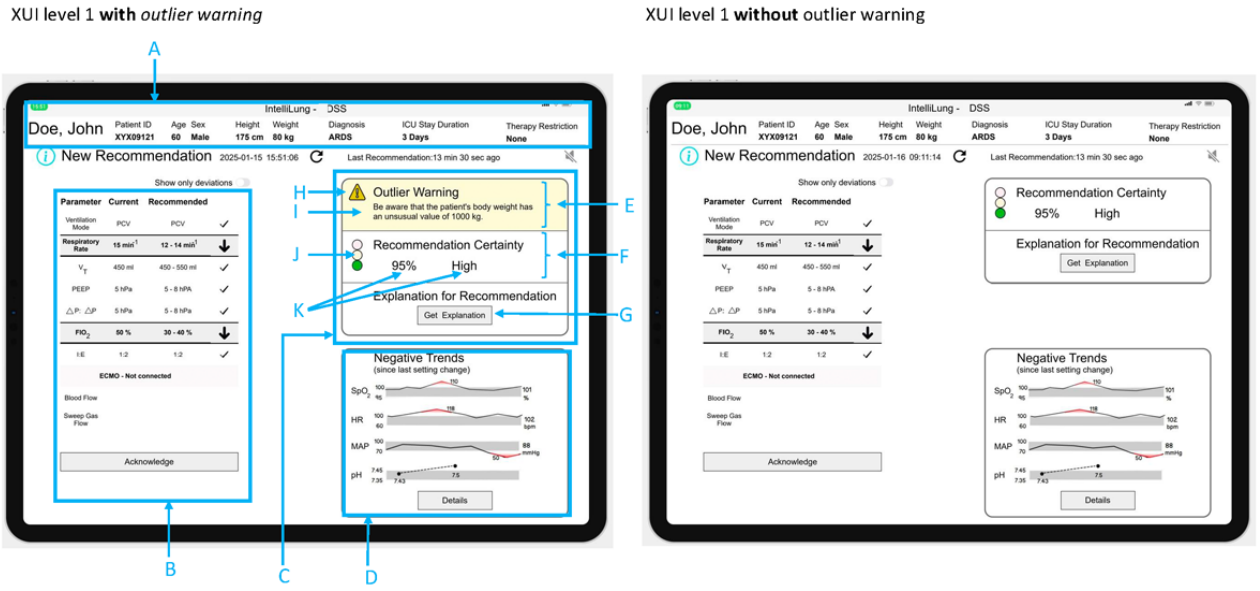
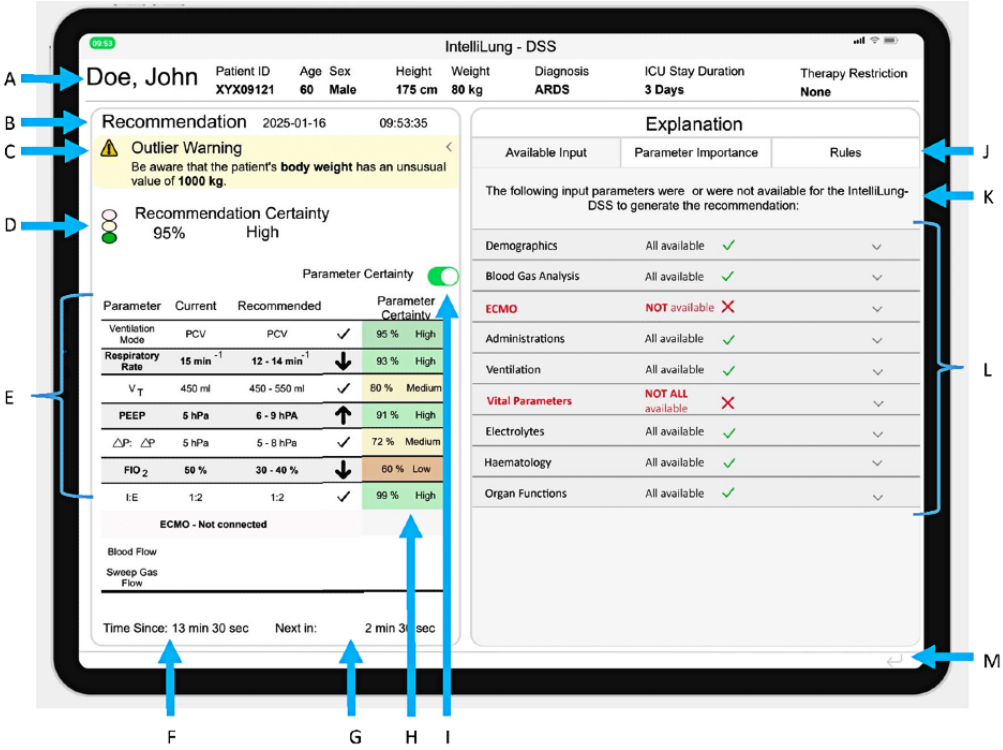


Figure 3. Level 2 of the explanation user interface (XUI) with a description of its content. A: header with basic patient information; B: identification information for the recommendation; C and D: repetition of explainable artificial intelligence (XAI) concepts from the first level; E: repetition of the clinical decision support system (CDSS) recommendation for ventilator setting; F and G: information on when the last recommendation was generated and when the subsequent recommendation will be generated; H: certainty information for each recommended ventilator setting; I: toggle button to show or hide H; J: section for the presentation of explanation concepts, with tabs for selecting specific explanation concepts; K: short sentence introducing the explanation concept; L: space for the specific explanation concepts; M: link to the first level of the XUI. ARDS: acute respiratory distress syndrome; DSS: decision support system; ECMO: extracorporeal membrane oxygenation; FIO2: fraction of inspired oxygen; ICU: intensive care unit; PCV: pressure-controlled ventilation; PEEP: positive end-expiratory pressure; VT: tidal volume; ΔP: driving pressure.



Design of Explanation Concepts

Outlier Warning

In XUI level 1, the outlier warning explanation is positioned at the top (E in Figure 2). If an outlier is detected in the input variables, a yellow warning triangle containing an exclamation mark is presented next to the heading "outlier warning." The heading is followed by text naming the parameter and value that triggered the outlier warning. When an outlier is detected, the background of the outlier warning section is highlighted in yellow. Two options were created for the case that the outlier warning was not triggered: one that hides the outlier warning

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section entirely, and another that displays the message "No Outlier Warning." The outlier detection logic was intentionally left undefined at this stage, as the study focused on evaluating conceptual explanation designs within the XUI. The specific detection mechanism will be developed and validated in subsequent iterations.

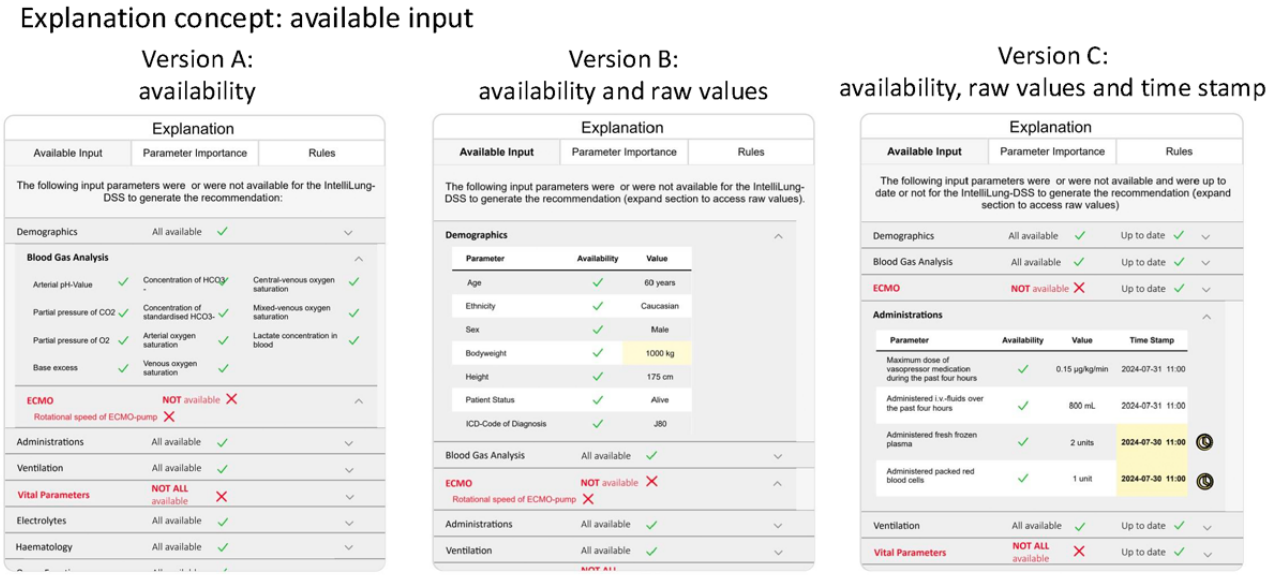
Output Certainty

Below the outlier warning section, the XUI presents the output certainty (F in Figure 2). On the left side of the output certainty section, a traffic light icon indicates the system's certainty level. This is followed by a percentage value and a categorical label representing the system's certainty.

Available Input

Figure 4 provides 3 design versions of the available input explanation concept. The versions vary in how much detail they present to the user.

Figure 4. Three versions of the available input explanation concept. Version A: availability information organized in categories. Version B: availability information extended with the values of the parameters. Version C: availability information and parameter values extended with a time stamp for parameter value collection. CO2: carbon dioxide; DSS: decision support system; ECMO: extracorporeal membrane oxygenation; HCO3: bicarbonate; ICD: International Classification of Diseases; O2: oxygen; pH: potential of hydrogen.



The input parameters are organized into categories in Version A (Figure 4). Each category is displayed as an expandable section with a labeled heading. Within each category, parameter names are displayed in a matrix format, each accompanied by an icon indicating availability (a green checkmark for available parameters; a red cross for unavailable ones). Unavailable parameters were also highlighted in red text. If any parameters in a category (eg, "Vital Parameters") were missing, the category heading appeared in bold red text, and a red cross icon with explanatory text was added to the top of the category section.

Version B (Figure 4) extends Version A by including the values of all available parameters. Each category is presented as a table with 3 columns: parameter name, availability status, and parameter value. Cells containing values that triggered an outlier warning are highlighted in yellow.

Version C (Figure 4) further builds on Version B. Each table is expanded with a fourth column displaying the time stamp of when the parameter value was recorded. If the recorded time stamp falls outside a predefined range, the cell is highlighted in yellow, and a yellow clock icon appears next to the row to indicate outdated data.

Feature Importance

Figure 5 provides 3 versions of the feature importance explanation concept. In the mockup, the explanation concept is labeled as "Parameter Importance" to avoid the necessity of pre-existing knowledge of the term feature in the context of AI for clinicians. This change in the name did not influence the information presented in the explanation concept. The 3 versions differ in the level of detail they provide.

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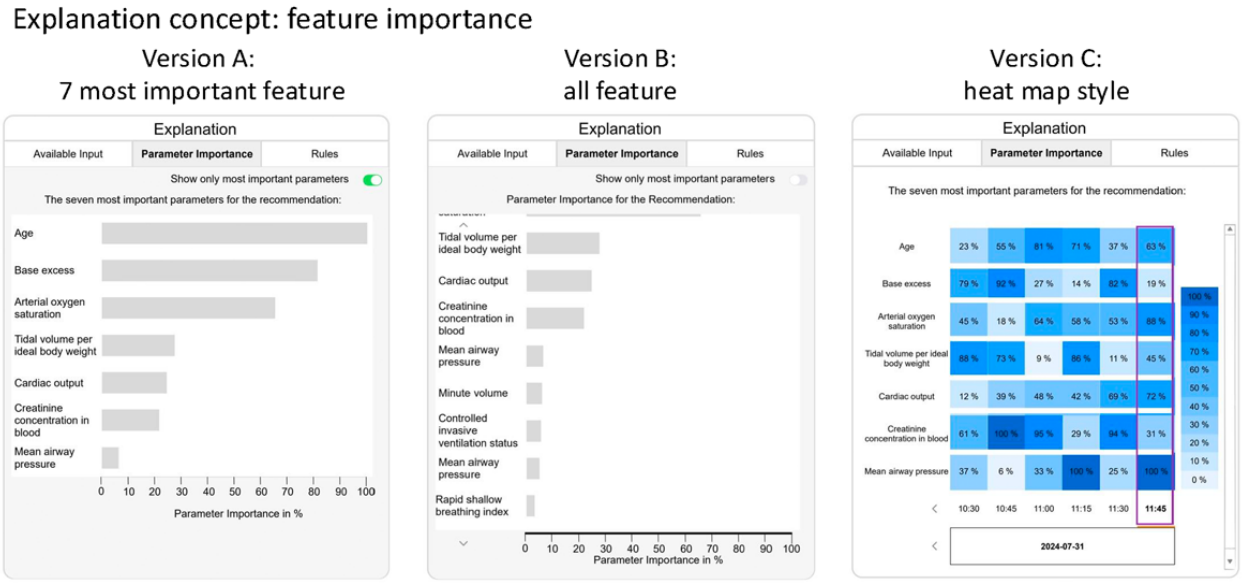
Figure 5. Three versions of the "feature importance" explanation concept. Version A: vertical bar plot of the 7 most important features. Version B: vertical bar plot showing the feature importance of all features. Version C: feature importance displayed as a heat map–style history in table format.



Version A (Figure 5) displays the top 7 features in a vertical bar plot, ranked by importance.

Version B (Figure 5) uses the same bar plot format but includes all available features. The user can scroll through the bar plot vertically and toggle between Versions A and B.

Version C (Figure 5) provides the 7 most important features of the current recommendation in a heat map history, which is designed as a table. The rightmost column contains the feature importance values for the current recommendation. The cell background color corresponds to the value of the feature importance presented in the legend. The preceding columns represent the feature importance for previous recommendations. Clicking on a column updates the recommendation displayed in the left-side panel of the XUI (B in Figure 3).

Rule-Based Explanation

Two versions of the rule-based explanation concept were designed (Figure 6).

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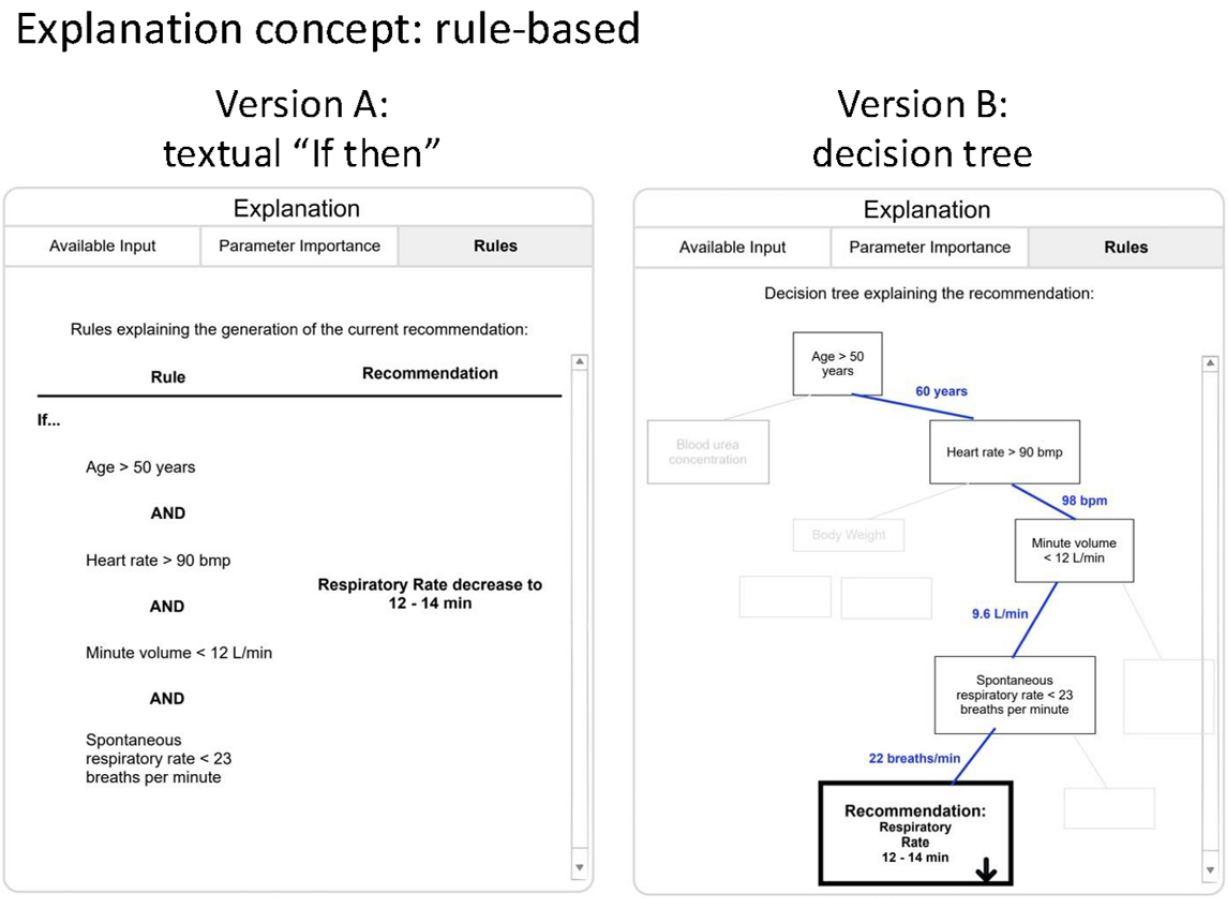
Figure 6. Different versions of the rule-based explanation concept. Version A: textual representation as an "if-then" phrase. Version B: graphical representation as a decision tree.



Version A (Figure 6) provides the explanation concept as an "if-then" rule in text format. Version B (Figure 6) uses a visual decision tree to convey the same logic. The decision tree highlights the path to the recommendation with blue lines.

XUI Evaluation Phase

Participants Description

The group usability walkthroughs were conducted with 8 health care professionals from a German university hospital, including 4 ICU physicians (4 male) and 4 ICU nurses (3 male and 1 female). All physicians participated in the preceding UCD process phases of the IntelliLung CDSS interface. In contrast, the recruited ICU nurses had no previous exposure to the IntelliLung CDSS. The recruited physicians were all anesthesiology residents with clinical and research experience in mechanical ventilation. The ICU nurses had at least 9 years of experience working in the ICU. All nurses answered a question describing their experience selecting ventilator settings for patients as "a lot" and a question regarding their experience with AI-based CDSS as "non" (n=1) and "little" (n=3) on 4-point scales with the following answer options: "non," "little," "moderate," "a lot." The physicians were not formally asked about their AI knowledge, but some degree of knowledge can be assumed due to their participation as clinical experts in the development of the IntelliLung AI model.

Evaluation: XUI Level 1

Both user groups appreciated the content in XUI level 1 and favored a concise presentation format. However, the groups differed in their preferences regarding how the information should be presented. Table 2 provides a detailed summary of findings.

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Table 2. Insights explanation user interface (XUI[a]) level 1 evaluation.

XUI part	Physician walkthrough	Nurse walkthrough
Overall assessment (level 1 XUI)	• Preferred a simple presentation with minimal content.	• Found the information on level 1 important.
Outlier warning	• Terminology improvement: suggested renaming the concept to "Input Warning" to avoid confusion with clinical outliers (ie, abnormal values). • Navigation: clicking the warning should lead users to a section containing similar information to the available input explanation concept (Version C). • In the absence of a warning, the section should contain the text "No Input Warning"; the section should not be empty. • Presentation of the exact values of the parameter triggering the warning is not important.	• Appreciated the explanation concept. • Navigation: clicking on the warning should lead directly to a section where raw values are displayed. • Requested a mechanism to acknowledge the warning and a clear distinction between new and acknowledged warnings. • Presentation of the exact values of the parameter triggering the warning is important. • Interaction: requested the ability to correct erroneous input values manually. • In the absence of a warning, the section should be empty.
Available input	• Structure: The explanation concept should be presented in an individual section of the interface and not at XUI level 2.	—

[a]XUI: explanation user interface.

Evaluation: XUI Level 2

Qualitative Analysis of Group Discussions

Overall, for the second level of the XUI, both the physician group and the nurse group had no problem identifying where the explanation concepts were presented and how to switch between them. However, 1 ICU nurse thought clicking on the recommendation would show an explanation text containing a detailed description of that specific recommended parameter.

The explanation concepts organize the following group discussion results.

Available Input

The nurses and physicians answered the questions AI-1, AI-2, and AI-3 correctly. Both groups correctly understood that the explanation concept informs which input parameters were available to the CDSS when it generated its recommendation (AI-1), identified in which sections input parameters were missing (AI-2), and could describe how to access more detailed information about the input values (AI-3). The physicians generally preferred more detail, while nurses favored a more concise presentation, which was expressed in the group discussions, the free-text answers, and the selection of variants.

For question AI-4, which addressed parameter ordering, the physician group expressed a unanimous preference for the static ordering used in the mockup. To avoid redundancy and reduce cognitive load, this question was omitted from the nurse session—while still ensuring space for user-specific feedback. Detailed findings are provided in Table 3.

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Table 3. Summary of usability walkthrough insights for the "available input" explanation concept.

Question	Physician walkthrough	Nurse walkthrough
AI[a]-4	• Preferred the static ordering of categories and parameters as presented in the mockup.	• Not discussed
Selected version	• Version C (most information).	• Version A (most concise)
Discussed insights	• Physicians should be deciding whether the values are outdated or not, and not the CDSS[b] • The value of the parameter triggering an "outlier warning" should be highlighted.	• The other versions were seen as containing too much information. • Preferred less information on the screens.
Free-text answers	• None.	• "Minimalize not important, not relevant data, or information." [P5] • "Deviations should be made visible." [P5] • "More is less." [P5] • "Too much information at once —> just the current errors —> one should be able to think that only the most recent blood gas analysis results would be considered [P6] • Red for highlighting is okay." [P6] • "Too much information." [P7] • "Not too much information! Keep it simple." [P8]

[a]AI-4: item 4 for group discussion of the available input explanation, as provided in Table 1.

[b]CDSS: clinical decision support system.

Feature Importance

The nurse and physician groups correctly answered questions—FI-1, FI-2, and FI-3—corresponding to the feature importance explanation concept. They correctly noted that the explanation concept presented the most influential factors for the recommendation (FI-1), identified which parameter had an importance of 80% (FI-2), and recognized where to click to display more parameters in the explanation (FI-3). Both groups selected Version A as their favorite. The nurses mentioned that the nursing staff would likely not use this explanation concept in clinical practice. Detailed insights for this explanation concept are provided in Table 4.

Table 4. Insights from both group usability walkthroughs for the explanation concept: feature importance.

Question	Physician walkthrough	Nurse walkthrough
Selected version	• Version A.	• Version A.
Discussed insights	• Version C was viewed as beneficial for research, but not appropriate for daily clinical workflows. • X-axis labels: What format would be most intuitive for clinicians? • X-Axis labels: the group suggested empty labels; exact values were deemed less relevant than the relative differences between features. • Participants questioned how the explanation would be interpreted or acted upon in clinical practice.	• Version C would not be interesting for the nursing staff. • Suspected feature importance would not be used in daily clinical practice.
Free-text answers	• "Importance is not clear. Which consequences should be drawn?" [P3]	• "Only if someone would like to see complete information, not to be shown as default information, only shown on demand." [P5] • "Not relevant for the daily clinical working process." [P6]

Rule-Based

The physicians unanimously voiced strong concerns about this explanation concept. They feared the concept would lead to an oversimplified perception of the AI model and might mislead nonexperts. They recommended excluding this explanation from the final XUI design. Due to the physicians' strong objections, the explanation concept was not shown to the nurses. Notes from the discussion are reported in Table 5.

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Table 5. Insights from both group usability walkthroughs for the explanation concept: rule-based.

Question	Physician walkthrough
R-1	• Correct answer.
Selected version	• Version A.
Discussed insights	• Group consensus: the explanation concept should not be part of the XUI[a] for this specific CDSS[b] for the following reasons: (1) would suggest to the user a too simple model of the system; (2) users with a low level of expertise could learn rules from the system that are not correct or clinically validated, without knowing this; and (3) an explanation that the rules, are a approximation of the system, would occupy additional resources.
Free-text answers	• "Leave [this concept] out." [P1] • "False security." [P2] • "Relationships from the menu cannot be established in this way. Possibly conveys false security, false or unproven connections." [P3] • "Creates a 'false' sense of security or being able to understand the model, but only represents it incompletely." [P4]

[a]XUI: explanation user interface.

[b]CDSS: clinical decision support system.

Final Group Discussions of the XUI

In the final group discussion, both groups agreed that no explanation concepts should be added to the XUI. The nurse group reiterated their preference for using only the first level of the XUI, suggesting that users with greater interest could optionally access Level 2. The nurses emphasized that the interface should minimize screen space usage.

Quantitative Data Analysis

Figure 7 provides the QA results (QA-1 to QA-3) for the available input and feature importance concepts.

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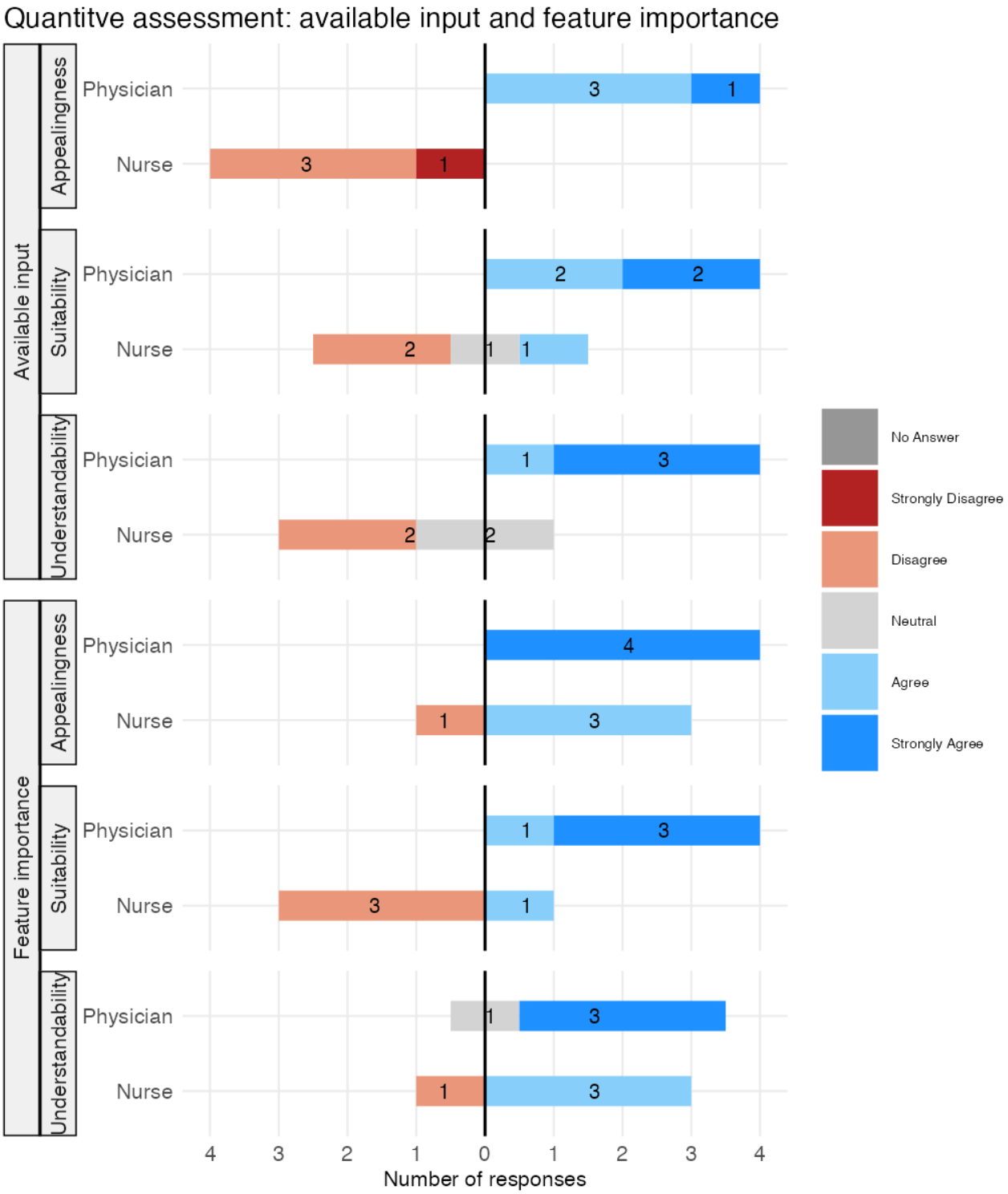
Figure 7. Results of quantitative assessments (QA-1 to QA-3) for the explanation concepts: available input and feature importance.



As shown in the top half of Figure 7, the physicians agreed or strongly agreed that the available input concept was understandable, suitable for clinical work, and visually appealing. The nurses mostly disagreed or responded neutrally regarding the concept's suitability and understandability, and found the visualization aesthetically unappealing. The nurses' and physicians' ratings, therefore, differ across all assessed dimensions, with nurses being more critical overall.

The QA results for the feature importance explanation concept are shown in the bottom half of Figure 7. Most physicians strongly agreed that the feature importance concept was appealing, suitable, and easy to understand. The nurses mostly agreed with its understandability and appeal, but tended to disagree with its suitability for clinical work. Both user groups, therefore, rate the understandability and visual appeal of the explanation concepts positively. However, the user groups differ in their assessment of the suitability for their clinical work, with a positive assessment by the physicians and a negative assessment by the nurses.

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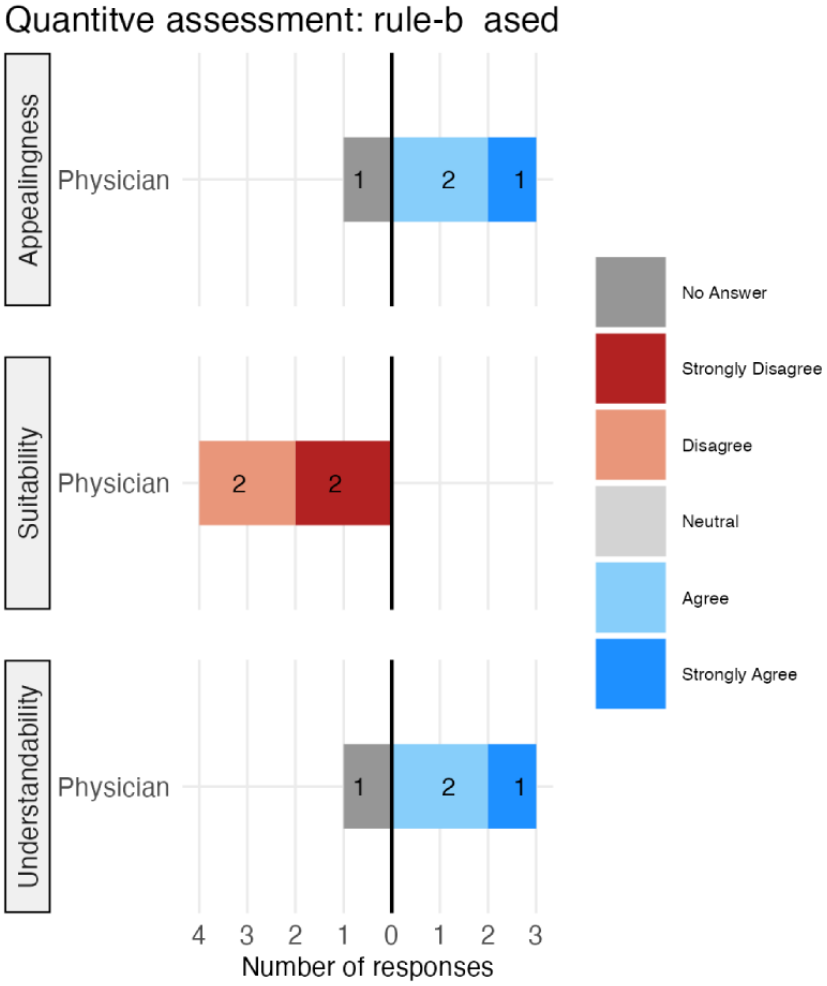
Figure 8 provides the QA results for the rule-based explanation concept. Three physicians strongly agreed or agreed with its appeal and understandability; one chose the "no answer" option. All 4 physicians disagreed or strongly disagreed with its suitability for clinical practice.

The calculated descriptive statistics for each QA for all 3 explanation concepts on the second level are provided in Multimedia Appendix 3. The descriptive statistics mirror the results visible in Figures 7 and 8.

Figure 8. Quantitative assessment results of the rule-based explanation concept.



Discussion

Principal Findings

This paper provides findings from the first design and formative evaluation phase of an XUI for an AI-based CDSS aimed at optimizing mechanical ventilation in the ICU.

The design led to an XUI with 2 levels. Level 1 of the XUI, positioned next to the CDSS recommendations on the main screen, includes the output certainty and outlier warning concepts. Level 2 of the XUI provides on-demand access to additional explanation concepts: available input, feature importance, and rule-based explanation. Multiple versions of the explanation concepts on the second level have been designed and evaluated.

The initial evaluation consisted of 2 group usability walkthroughs with ICU physicians and nurses. Both user groups liked the first level of the XUI. The physicians were satisfied with XUI level 2 but provided valuable feedback for improving it. The nurses were skeptical about whether they would use level 2 of the XUI in clinical practice.

XUI Design Phase

For the design phase, the following research question was investigated: RQ1: "How should the XUI of an AI-based CDSS for mechanical ventilation optimization in the ICU be designed?"

To address this research question, the first focus was on the XUI structure. The 2-level structure of the XUI allowed the provision of easy-to-grasp explanation concepts next to the CDSS recommendation and more complex and more detailed explanation concepts on the second level, on demand. This structure was based on the input of the previous UCD design phases and current design recommendations [35]. This design choice aligns with new recommendations published as a preprint after the work reported in this paper was concluded. The preprint recommends multiple levels with increasing detail for XUIs for the ICU [29].

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After the structure of the XUI was created, the investigation addressed the presentation of the explanation concepts themselves. The individual visualizations for the explanation concepts are comparable to typical visualizations found for XUIs in the medical domain [43,44]. The explanation concepts were kept in line with the design of XUIs to provide clinicians with an impression of the possibility of explanations at the current state of the art of research in the field.

The different versions of the explanation concepts in level 2 of the XUI varied in the level of detail presented to determine users' preferred level of detail for this CDSS. Based on the literature, this is considered an important design decision [29,35]. Minor adaptations were made to incorporate design recommendations for the UCD of XUIs; for example, the explanation concept of feature importance was presented to the user under the term "parameter importance," as the term feature importance was assumed not to be self-explanatory for non-AI experts. In addition, to add some variety to the different presented explanation concepts, the typical bar plot visualization for the feature importance explanation concept was extended by a version inspired by the works of Bienefeld et al [45], which created a heat map–style feature importance history in an XUI.

XUI Evaluation Phase

During the evaluation phase, the following research question, RQ2, was investigated: "What are clinicians' perceptions of the proposed XUI of the AI-based CDSS for mechanical ventilation optimization?"

The users' first impression of the 2-level structure of the XUI suggests that this structure is the right approach for this CDSS. Both groups were content with level 1 of the XUI, and the physician group was satisfied with level 2 of the XUI, while the nurses were more skeptical of their intentions to use level 2. No concerns were raised by either group about the general structure. The structure allows both user groups to access the information they prefer while preventing information clutter on the main screen of the CDSS.

The combined results from group discussions, concept selection, QAs, and free-text responses indicate that ICU nurses and physicians had noticeably different preferences regarding the level of detail and complexity in the XUI. The nurses preferred less complex explanation concepts, such as output certainty and outlier warning, explicitly requested a lower level of detail for the explained concepts, and rated the suitability of the explanation concepts on level 2 lower than the physicians. The literature supports this, as it has been reported that nurses wished for clear and concise explanations, outputs, and actionable information when dealing with AI [31,46]. In contrast, the physicians were satisfied with both XUI levels, which allowed them to consult low-detail and less complex information on level 1 and more detailed and complex explanation concepts on level 2 of the XUI. This implies that the explanation needs and preferences between the nurses and physicians differ, with physicians having a higher need for more complex and detailed explanations than the ICU nurses. The work from Barda et al [31] found a similar insight. Current research supports this by showing that different health care provider groups can have different explanation preferences [15] or that different stakeholders have different explanation needs [47]. The observed differences may reflect role-specific workflows in ventilator care. ICU nurses typically operate in fast-paced bedside routines with frequent monitoring and rapid adjustments, which may favor concise, immediately actionable explanations. Physicians, in contrast, often integrate XAI outputs into broader diagnostic reasoning and decision validation, which may increase the perceived value of more detailed, mechanism-oriented explanations provided on level 2.

Notably, divergence between groups was most consistent for clinical suitability rather than for understandability or visual appeal (Figure 7). This suggests that acceptance may not only be a matter of whether clinicians can comprehend an explanation and perceive it as visually appealing, but also whether it fits their real-world task context and decision-making responsibilities. Therefore, suitability should be treated as a primary design target in XUI development, alongside clarity and aesthetics.

These results emphasize the need for a rigorous application of the UCD process when an XUI is developed for different health care providers. In the XUI developed and evaluated in this study, the 2-level solution appears to meet the differing explanation needs and preferences of the user groups. Future iterations should evaluate whether this approach remains sufficient or if separate XUIs are needed. It should be kept in mind that ICU nurses will probably not consult level 2 of the XUI in future iterations. Therefore, presenting potentially necessary and valuable information only on level 2 should be avoided. Clinical role alone may not fully explain the differences; AI literacy and ventilator-care experience likely act as moderators that shape how much explanation depth is perceived as useful versus burdensome. Future work should disentangle professional role effects from training- and experience-related factors, for example, by stratifying participants accordingly.

Interestingly, both groups were skeptical about their peers' adaptations of the explanation concepts in the clinical daily routine, which was voiced during the group discussions and in the free-text answers. The nurse group voiced more skepticism than the physician group, and their skepticism increased with the level of detail and complexity of the explanation concepts. The physicians were mainly satisfied with the proposed explanation concepts, apart from the rule-based explanation concept. However, they stressed that the complexity of the explanation concepts should not exceed that used in the XUI. These results explain why both groups had no interest in more complex explanation concepts, such as a counterfactual explanation. This result contrasts with the results of a study by Jung et al [48], in which clinicians had a positive perception of counterfactual explanations.

The physician group positively assessed the explanation concepts on level 2 of the XUI, apart from the suitability of the rule-based explanations. The understandability ratings for the explanation concepts are similar to previous research, showing that physicians can understand the selected concepts [32]. The positive assessment of the feature importance explanation concept for the physician group is in line with other research efforts [14,15]. Due to the overall positive assessment by the

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physicians of both levels of the XUI and nurses' positive perception of level 1 of the XUI, it seems that the results of the first design phase were a step in the right direction. However, the evaluation also revealed some improvement opportunities.

Second, the evaluation phase investigated research question RQ-3: "What XUI design improvements should be addressed in subsequent design iterations?"

Based on the results of the evaluation, all the explanation concepts should be revised, keeping the nurses' preferences for a low level of detail and complexity for the explanation concept, and their perception of the explanation concept as having too much detail in mind. In the following design iteration, all the explanation concept versions should be provided with a lower level of detail or complexity as a default version. From these default versions, the more interested user should be able to access a more detailed version on demand. This approach has to be balanced so that the more interested users are not burdened while accessing the explanation concepts with the current level of detail and complexity for which they provided positive feedback in the evaluation.

For the feature importance explanation concept, the evaluation revealed that further research is needed for the design of the x-axis. The x-axis should be redesigned to be understandable for physicians and nurses and to transport the appropriate amount of information without overwhelming them. As raised in the physician group walkthrough, one option could be an empty x-axis; the suitability of such a version should be tested in comparison to other typical variants of the x-axis for this explanation concept. As the question about the actionability of the information provided in the feature importance explanation concept arose in the physician group, it should be investigated whether incorporating information about how to act on the explanation concept would be valuable. For the outlier warning explanation concept, the evaluation revealed different preferences for the case in which no outlier would be detected. It should be investigated how the user groups would react to the version they did not prefer when interacting with a version of the XUI.

An increased effort should be put into the design of level 1 of the XUI. No alternative versions had been designed for the explanation concepts on level 1 for this initial prototype to reduce complexity. These should be a primary focus for the next design iteration, as both user groups saw them as valuable. While refining these explanation concepts, an emphasis should be placed on concise information visualizations and effortless information retention from both user groups.

Limitations

This first iteration of the design and evaluation phase of the UCD process for the XUI of a CDSS has some limitations that influence the generalizability of the results and should be carefully considered when interpreting the results of this study. A pragmatic group usability walkthrough was selected for the evaluation phase due to the limited number of available and suitable participants per user group. Nonetheless, this pragmatic approach proved valuable as it allowed for the receipt of early feedback from subject matter experts on mechanical ventilation with real-world and research experience. Their experience might have biased their assessment of the XUI, as they might not have had to rely on the CDSS in the first place due to their extensive experience. However, their knowledge allowed them to focus on the XUI design and incorporate extensive practical knowledge and expertise in their feedback and assessment of the XUI. The small group size of only 4 participants per group usability walkthrough might be seen as a limitation, but this group size allowed for a lively discussion between participants, and smaller sample sizes are in line with early evaluation iterations [40,41]. In addition, the group walkthrough allowed for the collection of feedback in a condensed amount of time, which was necessary due to resource restrictions. Nonetheless, these points limit the generalizability to the clinical population that should be addressed in the following design iterations.

Furthermore, the changes for the nurse walkthrough limit the comparability between the 2 walkthrough groups. The walkthrough had to be adjusted to avoid overwhelming the participants. Despite the minor adjustments, the collected insights allow for a preliminary assessment of the difference between the user groups. No actual data or patient vignettes were used to promote deeper engagement or trigger demand for an explanation from the CDSS, which limits the comparability of the assessment of XUI in real-world situations. The current state of the XUI mockup was sufficient to spark extensive discussions while preventing the participants from focusing on the medical validity of the situation or mockup content. In this initial iteration of the UCD, only subjective assessments of the XUIs were elicited. This may not provide a complete picture, as it has been shown for XUIs in the ICU that subjective assessments might not transfer to the use or influence of the XUI during the medical decision-making process [30,49]. Nevertheless, the amount of valuable insights generated through subjective assessments of the XUI in this study shows that this type of feedback is helpful during such an early design phase. These limitations should be addressed in future evaluation iterations.

Future Research

Based on this research, the XUI mockup should be improved. The improvements should address the identified opportunities for enhancement in the XUI, making it more suitable for both user groups without drastically altering it, as physicians were already satisfied with the current design. A higher focus should be placed on level 1 of the XUI, as this is likely the most used part. In addition, feedback should be sought from the AI and XAI algorithm developer and incorporated into the mockup to enhance the realism of the XUI for the next iteration. An improved and extended XUI mockup would be a suitable basis for a more elaborate evaluation. The enhanced mockup could be accompanied by different vignettes of patients and situations that might trigger the need for an explanation from the user. Future evaluation rounds should have a higher experimental character to avoid the potential shortcomings of subjective assessments of an XUI in the ICU and allow the users to interact with the XUI directly. The proposed evaluation iterations should aim for a higher sample size and a diversified participant pool concerning their ventilation experience, AI literacy, and clinical center to foster generalizability and reflectiveness of the

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clinician population. To this end, a remote experimental study could be conducted in which the user directly interacts with the CDSS based on presented patient vignettes. During such an evaluation, participants reflecting a broad base of clinical users should be recruited from multiple institutions.

Conclusion

To the best of our knowledge, this paper is the first to report on the UCD and formative evaluation of an XUI for an AI-based CDSS aimed at optimizing continuous mechanical ventilation in the ICU. The findings indicate that a 2-level XUI structure can effectively address the distinct explanation needs of ICU clinicians. Nurses' information needs were largely met through concise, high-level explanations such as outlier warning and output certainty, presented alongside CDSS recommendations, whereas physicians preferred access to more detailed explanations—such as available input and feature importance—on a secondary level. These results provide empirical evidence that explanation needs differ by professional role and underscore the necessity of user-centered, iterative design processes in the development of XAI systems for critical care. Future work should refine these explanation concepts and evaluate their impact on clinical decision-making, user trust, and system adoption.

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The authors are grateful to the IntelliLung project team for their productive cooperation and to the participants of the evaluation phase for contributing their time and feedback. The authors declare that generative AI (GAI) tools were used in the research and writing process. According to the GAIDeT taxonomy (2025), tasks delegated to GAI tools under full human supervision included proofreading, editing, and translation. The GAI tools used in this work were ChatGPT-4o (OpenAI) [50], ChatGPT-5 (OpenAI), and Grammarly (Grammarly, Inc). Responsibility for the final manuscript remains entirely with the authors. GAI tools were not listed as authors and do not bear responsibility for the content or outcomes of this work. In addition, Claude Sonnet 3.5 (Anthropic) [37] was used to generate syntactic data points for the parameters displayed in the mockups, as described in the "Methods" section. The declaration was submitted by ICJ.

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Authors' Contributions

ICJ contributed to the conceptualization, methodology, and investigation, and was responsible for writing the original draft, reviewing and editing the manuscript, and creating the visualization. MZ and KS contributed to the Investigation and assisted with manuscript review and editing. MS and BS contributed to the manuscript review and editing, and were responsible for supervision and funding acquisition.

Conflicts of Interest

None declared.

Multimedia Appendix 1
STARE-HI checklist.
[PDF File (Adobe PDF File), 77 KB - formative_v10i1e77481_app1.pdf]

Multimedia Appendix 2
Quantitative assessment sheet.
[PDF File (Adobe PDF File), 87 KB - formative_v10i1e77481_app2.pdf]

Multimedia Appendix 3
Descriptive statistics for quantitative assessments of each explanation per user group.
[DOCX File , 18 KB - formative_v10i1e77481_app3.docx]

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Abbreviations

AI: artificial intelligence
CDSS: clinical decision support system
DIN: Deutsches Institut für Normung
EN: Europäische Norm
EU: European Union
FI: feature importance
ICU: intensive care unit
ISO: International Organization for Standardization
QA: quantitative assessment
STARE-HI: Statement on the Reporting of Evaluation studies in Health Informatics
UCD: user-centered design
XAI: explainable artificial intelligence
XUI: explanation user interface

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Original Paper

Clinical Decision Support Tool for Early Pancreatic Cancer Detection in Primary Care: Simulation Study

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Abstract

Background: Early detection in primary care could improve pancreatic cancer survival, but diagnosis is often delayed due to the low prevalence of the disease, the nonspecific nature of early symptoms, and the broad range of conditions and volume of consultations managed by general practitioners (GPs). In Australia, improving pancreatic cancer outcomes, including via earlier diagnosis, is a priority being progressed under the National Pancreatic Cancer Roadmap developed by Cancer Australia. Computerized clinical decision support systems (CDSSs) have shown promise in aiding timely cancer diagnosis; however, barriers to adopting CDSS such as mistrust of the recommendations or not being embedded in the clinical workflow remain. Simulation techniques, which offer flexible and cost-effective ways to evaluate digital health interventions, can be used to test CDSS before real-world implementation.

Objective: This study aims to assess the acceptability and feasibility of identifying patients with symptoms associated with pancreatic cancer through a CDSS within a simulated environment.

Methods: We developed a CDSS that interacted with an electronic health record used in general practice to identify patients with symptoms, which may indicate pancreatic cancer (unintended weight loss or new-onset diabetes), in a simulation laboratory for digital interventions. We tested it by inviting GPs (n=11) to use the CDSS, with patient actors simulating specific clinical

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scenarios. We then interviewed GPs about the interaction to assess the acceptability and feasibility of the CDSS in their clinical practice. We used thematic analysis and 2 relevant frameworks to analyze the data.

Results: GPs found the CDSS easy to use, unobstructive, and effective as a prompt to consider investigations for people with risk factors for pancreatic cancer. However, they expressed concerns about possible overtesting, financial costs, and the potential for anxiety in patients with a very low probability of having cancer.

Conclusions: While GPs found the tool useful and compatible with their workflow, concerns about overtesting, lack of evidence, and cost-effectiveness were identified as barriers. GPs favored a stepwise approach to investigations rather than immediate imaging. Despite the overall acceptability of the tool, additional evidence to underpin clinical recommendations is necessary before implementing a CDSS with these specific recommendations for pancreatic cancer in primary care.

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KEYWORDS

digital health; general practice; simulation; clinical decision support; early detection; cancer

Introduction

According to the World Health Organization, cancer was responsible for 10 million deaths in 2020 [1]. This striking figure underscores the magnitude of the global health burden created by the disease. Early cancer detection has the potential to improve patient survival and quality of life. In addition, timely diagnosis can reduce the need for aggressive treatments and lessen the overall burden on health care systems [2-4].

The World Health Organization recommends screening for cervical, breast, and colorectal cancers [5,6] with lung cancer screening being introduced in some high-income countries [7]. There are also some country-specific screening programs for cancers where the incidence is high (eg, screening for gastric cancer in Japan) [8]. For most other types of cancer, detection relies on patients presenting with symptoms in the health care system [9].

Most patients with cancer with symptoms first consult in primary care, and delays in diagnosis may occur due to the nonspecific nature of these symptoms, the high number of conditions managed, and the low incidence of cancer in primary care [10,11]. Clinical guidelines provide information about investigations in patients with symptoms suggestive of cancer [12]; however, they are not always adhered to [13] and timely access to this information at the point of care may support their implementation [14].

Clinical decision support systems (CDSSs) can be an efficient way of bringing evidence-based information to practice and facilitating cancer diagnosis. A recent systematic review of CDSS designed to improve cancer diagnosis in primary care showed their potential to optimize the quality of cancer referrals and reduce time to diagnosis. However, there are multiple barriers to implementation, such as poor integration into the practice workflow, lack of general practitioner (GP) time to consider the information, and distrust in the recommendations [15,16].

CDSSs have been developed in the United Kingdom, using symptoms and test results to calculate the likelihood of undiagnosed pancreatic cancer [17-19]. However, these tools face significant challenges:

1. Limited access and adoption: Research indicates that only 36% of clinics have access to these tools, with usage rates even lower at 16%. Time constraints and lack of awareness in clinical settings are the primary reasons cited for this low adoption [20].
2. Lack of specific follow-up recommendations: These tools do not provide standardized guidance at point of care on how to proceed based on the risk assessment results. Consequently, GPs are left to determine the appropriate course of action when presented with a patient's calculated risk of pancreatic cancer, without specific recommendations for follow-up care.

Clinical decision support tools are being developed in Australia to incorporate current guidelines. However, they face similar challenges in implementation and adoption, highlighting the need for user-centered design and robust evaluation to ensure their effectiveness in real-world clinical settings [21-23].

Pancreatic cancer, although relatively infrequent, is the sixth most common cause of cancer death worldwide, accounting for more than 460,000 deaths in 2022 [24]. Approximately 80% of pancreatic cancer cases are diagnosed when they are not amenable to surgical resection, and this is the primary driver of the poor survival [25]. In Australia, pancreatic cancer has become a health priority, as it was the third most common cause of cancer death in 2024 [26].

The National Pancreatic Cancer Roadmap was developed by Cancer Australia to reduce the burden of pancreatic cancer in a range of ways, including improving primary health care professional recognition of signs and symptoms for pancreatic cancer [27]. As part of this initiative, a working group was established by The University of Queensland in collaboration with The University of Melbourne and Cancer Australia to identify the need for, and characteristics of, a potential CDSS for pancreatic cancer in primary care.

The working group included clinical professionals (medical specialists including GPs, gastroenterologists, hepatobiliary surgeons, endocrinologists, and oncologists), public health specialists, epidemiologists, cancer policy experts, and consumer representatives. Acknowledging the limitations of existing literature regarding predictive value of unspecific symptoms, the working group agreed that "unintended weight loss" and "new-onset diabetes" could be used as flags to potentially alert

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GPs about the possibility of pancreatic cancer. The choice of these 2 flags and their recommendations was based on evidence of their association with pancreatic cancer.

Studies have shown that patients with pancreatic cancer are approximately 8 times more likely to have been diagnosed with diabetes within the past 12 months [28], and pancreatic cancer is the underlying cause of new-onset diabetes in up to 1% of patients aged 50 years [29,30]. Failure to respond to initial antidiabetic therapy is a potential indicator of pancreatic cancer as the cause of the diabetes [23]. These associations are not commonly recognized by GPs, likely because diabetes occurs commonly, and pancreatic cancer is rare and not usually highlighted in diabetes guidelines for general practice [31].

Unintended weight loss is a red flag for cancer, but it can be caused by most cancer types and is commonly attributed to other underlying conditions [32-34]. A systematic review showed that primary care patients with unintended weight loss were 12.5 times more likely to be diagnosed with pancreatic cancer than control patients [35]. Providing information to GPs about when to prioritize investigations of the pancreas in patients with unintended weight loss was thought to be of value [16].

One way to identify and potentially address barriers related to acceptability and usability before implementation of such a CDSS, is to test it in a simulated environment [36]. We chose a simulation approach to identify barriers related to the acceptability and usability of the CDSS before its implementation. Simulation in this particular case offered several advantages [37,38]:

1. Addressing rarity of symptoms: Unintended weight loss, an indicator for pancreatic cancer, is rare in primary care (1% prevalence). A randomized controlled trial would require substantial time and resources; simulations enable efficient investigation of these infrequent events without waiting for real-world occurrences.
2. Ethical considerations and evidence gap: Due to the nonspecific symptoms of pancreatic cancer, there is little consensus on the evidence supporting a trial for the CDSS. Simulations provide a safe alternative for testing without prematurely implementing the solution in clinical settings.
3. Flexibility and efficiency: Simulation allows for rapid testing of various scenarios, making it more cost-effective and quicker than large-scale clinical trial [39]. This method identifies potential issues early and informs necessary improvements, ultimately bridging the gap between development and real-world evaluation of digital health solutions.

We aimed to conduct an initial investigation of the potential use of including 2 flags into a CDSS for pancreatic cancer detection in a simulated environment: unintended weight loss and new-onset diabetes in the GP electronic health record (EHR).

The insights gained from the simulation will provide essential guidance for the subsequent empirical phase. These findings will help refine the study's methodology and strengthen its overall design. Consequently, the transition to real-world application can be more seamless and effective.

Methods

Study Design

We conducted a simulation study of a CDSS embedded in general practice EHR to identify patients with new-onset diabetes and unexplained weight loss at risk of cancer, where GPs trialed the tool in simulated consultations and were interviewed about their perceptions. An overview of the process is depicted in Figure 1.

We describe the process and each of their components below.

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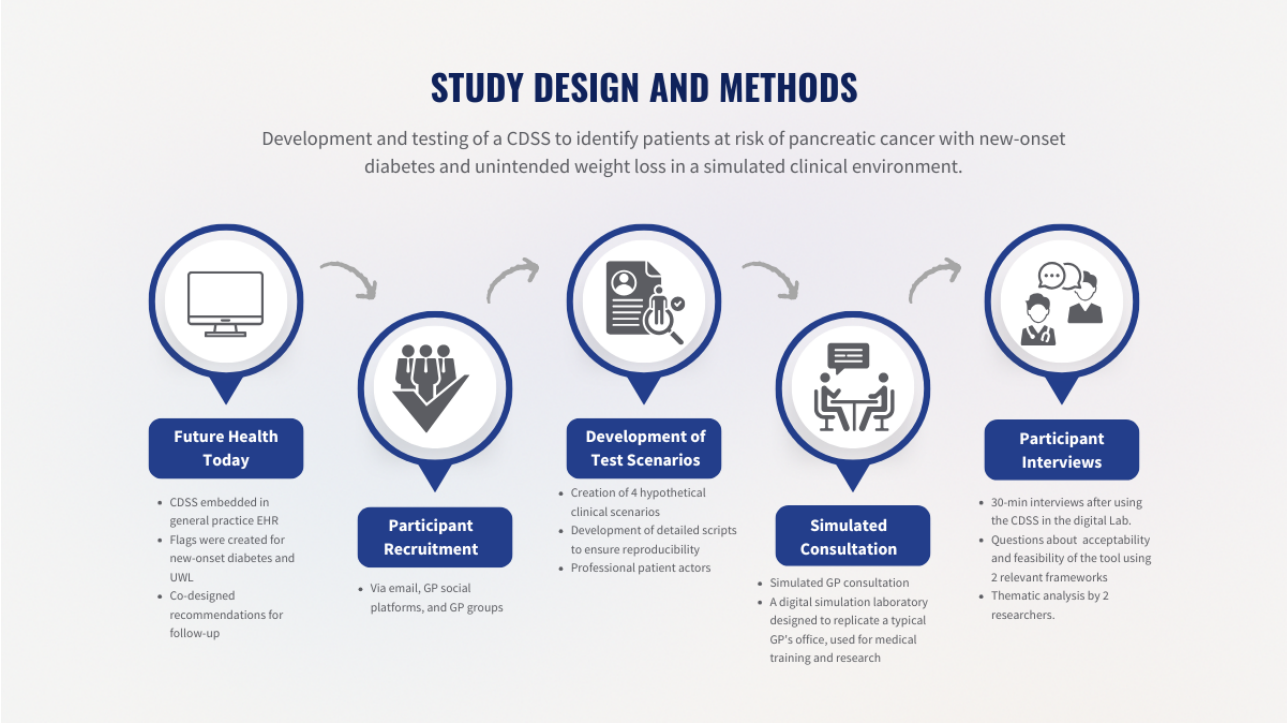
Figure 1. Study design and methods. CDSS: clinical decision support systems; GP: general practitioner; UWL: unintentional weight loss.



CDSS: Future Health Today

We used the Future Health Today (FHT) software (University of Melbourne) [40], a CDSS designed by the Department of General Practice and Primary Care at The University of Melbourne to assist general practices in identifying and managing health conditions. FHT was co-designed with clinicians working in general practice and consumers; it is embedded into a practice's EHR and offers recommendations at the point of care [41]. It also includes links to complete relevant clinical guidelines and resources. This system is an active, asynchronous CDSS. Active means it proactively generates recommendations based on EHR data without requiring the GP to input specific information. Asynchronous indicates that the algorithms run once daily, analyzing newly available data. However, because the information is not processed in real time during a patient visit, the recommendations appear only the next time the GP accesses the EHR.

We embedded flags for unintended weight loss and new-onset diabetes with recommendation for follow-up and included links to the clinical guidance developed by the working group. A snapshot of the pancreatic cancer recommendations, as they were displayed in the EHR, can be seen in Figure 2.

The alert message with recommendations was displayed at the bottom right-hand corner of the screen in the EHR. This alert pops up as the clinician opens the EHR of a patient with unexpected weight loss. GPs could hover over or click on the screen to get information about the reasons for the alert and access resources (the information displayed here does not belong to a real patient). Example of wording:

Unexpected weight loss detected:

1. In women aged 60-79 years, prioritize testing for thyroid function and screening for depression while considering cancer investigation.
2. Consider abdominal computed tomography (CT) if persistent midthoracic back pain, upper abdominal pain, nausea, or change in bowel habits.
3. Consider pancreatic protocol CT if (1) a family history of pancreatic cancer or a genetic mutation that increases risk, (2) a history of chronic pancreatitis, or (3) diabetes diagnosed in the previous 6 months.

The recommendations are described in the subsequent sections.

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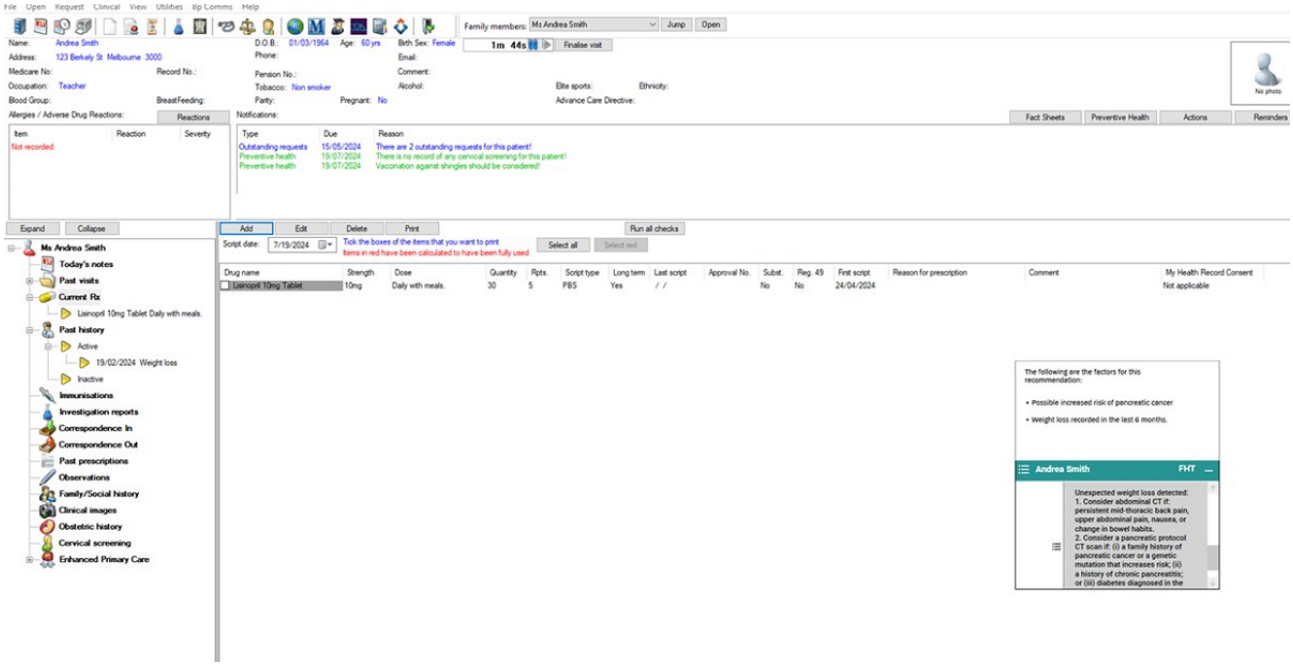
Figure 2. Recommendations for a patient with unexpected weight loss, as displayed in the electronic medical record.



Unintended Weight Loss

For patients with unintended weight loss, GPs were advised to consider common differential diagnoses based on age and sex [42], and consider referring patients for an abdominal or pancreatic protocol CT if additional risk factors were present (ie, persistent midthoracic back pain, upper abdominal pain, nausea, or change in bowel habits).

New-Onset Diabetes

For patients with new-onset diabetes, two categories of advice were provided: (1) *Urgent investigation*: For patients with specific risk factors or symptoms (chronic pancreatitis, family history of pancreatic cancer, or who have had persistent midthoracic back pain or upper abdominal pain), GPs were advised to consider urgent CT using a pancreatic protocol. (2) *Nonurgent investigation*: In patients with new-onset diabetes but no other symptoms or risk factors, GPs were advised to retest the hemoglobin A_{1c} (HbA_{1c}) 3 months after commencing medication and, if the HbA_{1c} had not responded in accordance with expectations and no cause could be identified (eg, medication noncompliance), to consider a pancreatic protocol CT. These recommendations were developed using GP and expert input, current guidelines [22], and best evidence available at the time [21,23,28,30,35,42-44].

Recruitment

We emailed a convenience sample of 72 GPs from a database available at the Department of General Practice, focusing on those with current connections to the department, as they needed to attend the simulation laboratory, and posted on social media platforms and groups associated with the University. We excluded from our invitation GPs who had participated in similar studies to avoid potential bias from their acquired "expertise" in simulated scenarios. We recruited all GPs who responded to our initial recruitment invitation, distributed via email and social media groups, and were able to attend the simulation laboratory.

Simulation Experience

The "Digital Health Validitron" at The University of Melbourne, hosted by the Centre for Digital Transformation of Health, comprises a simulation laboratory for designing, developing, validating, and evaluating digital health solutions [45,46]. The laboratory includes a physical recreation of a general practice clinic and a virtual "sandbox" (a virtual machine used to run software in a testing environment) hosting an EHR that, together, allowed our CDSS to be tested in a controlled environment.

Four hypothetical patient scenarios were created (2 for unintended weight loss, and 2 for new-onset diabetes; 1 female and 1 male patient for each condition). The cases were designed to reflect varied clinical scenarios. New-onset diabetes was included as relevant background in the EHR and simulated patient's history, with patients presenting with nonspecific symptoms such as fatigue and abdominal pain as their main reason for visit. For unintended weight loss, in 1 case it was included as background information from a previous visit, while in the other, it was the main presenting symptom. The cases were developed with input from GPs in our advisory group to ensure real-world fidelity and each script provided a detailed description of the case including behavioral cues (eg, patient looks fatigued; do not provide this information unless asked, etc). The scenarios were played by professional simulated patient actors from the Department of Medical Education at The University of Melbourne (Multimedia Appendix 1).

We invited GPs to test the scenarios in a simulated consultation, with CDSS recommendations appearing in the EHR. We informed participating GPs that they were testing a CDSS designed to identify and assist with the investigation of nonspecific symptoms in primary care. They were not made aware that the study focused specifically on pancreatic cancer. A plain language statement describing the study was provided to all participants and GPs and patient actors–signed consent forms were collected prior to the simulation session. Each

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session took 10-15 minutes, consistent with consultation times in Australian general practice, and was observed, filmed, and audio recorded by the researchers through a one-way mirror. Before the simulation session, the GPs were introduced to the CDSS and given the option to review the patients' EHR prior to the consultation, mirroring usual practice in primary care. Each GP was presented with 2 patient scenarios, determined by the gender of the available patient actor at the time of the session.

Interviews

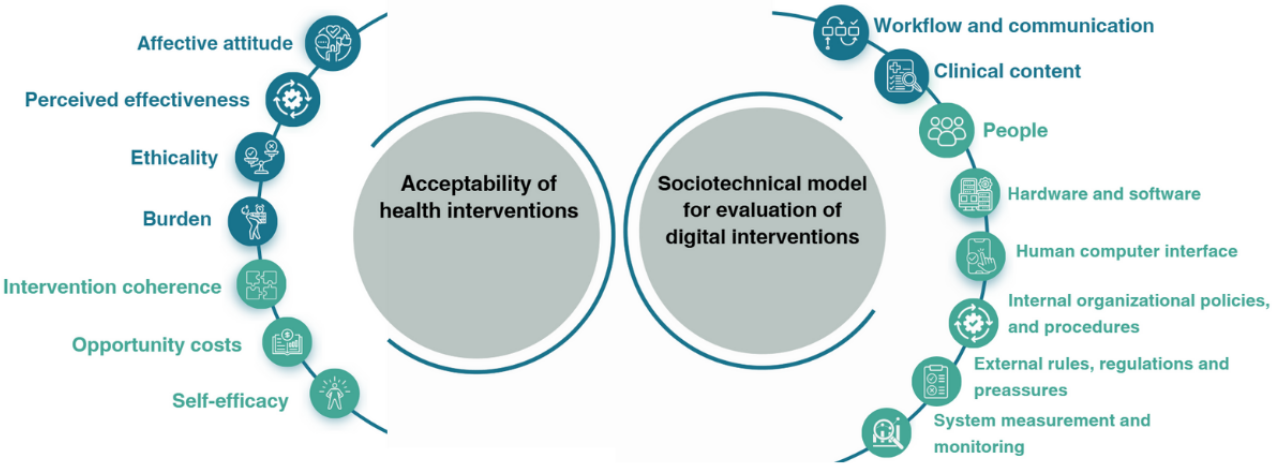
Following completion of the simulated consultations, the GPs participated in a single semistructured interview on site (Multimedia Appendix 2), assessing the acceptability, feasibility of the CDSS, and its impact on workflow. There were no external people to the study present during the simulation or the interviews. The interview guides were developed using relevant dimensions of two published frameworks: (1) sociotechnical model for evaluation of digital interventions by Sittig and Singh [47,48], and (2) the acceptability of health care interventions by Sekhon et al [49]. A depiction of the 2 frameworks and their dimensions can be found in Figure 3 [47-49].

We selected these 2 frameworks over other well-established models as our research required a broad scope that encompassed the technical aspects and the wider contextual and human factors involved in implementing a CDSS in primary care. These frameworks also not only focus on general technology use and acceptance but, particularly important, they are health care specific. Both chosen frameworks are relatively recent developments in the field, which incorporate learnings from earlier models while addressing some of their previous limitations. The Theoretical Framework of Acceptability by Sekhon et al [49] uses a multidimensional approach to assess the acceptability of health interventions in general. Its 7 dimensions—affective attitude, burden, ethicality, intervention coherence, opportunity costs, perceived effectiveness, and self-efficacy—offer a rich understanding of how interventions are perceived from the user's perspective.

In contrast, the sociotechnical model is specifically tailored for evaluating digital interventions. It provides a comprehensive lens that incorporates both technical aspects (eg, hardware, software infrastructure, and human-computer interface) and user, procedural, and contextual dimensions (eg, people, workflow and communication, internal organizational policies, procedures, and culture).

By using these 2 frameworks together, we were able to comprehensively explore and identify a wide range of barriers and facilitators to implementing and testing the CDSS in a safe and controlled environment. A description of each category can be found in Table S1 in Multimedia Appendix 3). Interviews lasted approximately 30-45 minutes.

Figure 3. Frameworks used and their dimensions (adapted from Sittig and Singh [47,48] and Sekhon et al [49]).



Data Analysis

The Sittig and Singh [47,48] and Sekhon et al [49] frameworks were systematically integrated into our thematic analysis process as follows:

1. *Framework integration*: Each dimension from both frameworks was used as an overarching theme in our codebook. This approach ensured a comprehensive and structured analysis aligned with established theoretical concepts.
2. *Coding process*: JMG and KS independently coded the transcribed interviews using NVivo (version 14; Lumivero). We systematically categorized each code under the relevant themes derived from our theoretical frameworks, ensuring a consistent application of the frameworks' components.
3. *Interrater reliability*: To maintain interrater reliability, both coders adhered strictly to the descriptions of the framework dimensions provided in Table S1 in Multimedia Appendix 3. We discussed meaning and interpretations of codes through the process. This standardized approach ensured consistency in interpretation and application of the frameworks across coders.
4. *Consensus building*: Any disagreements in coding or categorization were resolved through discussion between JMG and KS until consensus was reached. This process further enhanced the reliability and validity of our analysis.

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5. *Synthesis and quote selection*: Following the initial coding, we conducted a comprehensive analysis of the categorized codes, synthesizing findings within each theme. Representative quotes were carefully selected to illustrate key concepts and insights from each category, ensuring a clear link between raw data and our theoretical frameworks.

We used reflexive thematic analysis, which conceptualizes meaning as constructed through the researcher's interpretative process rather than inherent in the data. This approach recognizes that new meanings are always theoretically possible, as analysis is a situated, reflexive, and theoretically embedded practice of knowledge generation. Consequently, the concept of data saturation, which assumes a point where no new information emerges, was not suited to our study. Instead, our sampling strategy focused on recruiting participants who could provide rich, relevant information to address our research questions. This approach ensured that we captured a range of perspectives from those willing and able to participate, rather than aiming for a predetermined point of "informational redundancy" [50].

Interview participants were not asked to provide feedback on the transcripts, nor the findings and no repeat interviews were conducted. Field notes were not developed during or after the interviews. We followed the COREQ (Consolidated Criteria for Reporting Qualitative Research) checklist (Multimedia Appendix 4) to present our findings [51].

Researcher Characteristics

JMG was the lead investigator for this study and was assisted by KS. JMG is a trained GP and PhD candidate at the Department of General Practice and Primary Care, The University of Melbourne. KS, a researcher in the Department, holds an MPhil, and has been actively involved in primary care research since completing postgraduate studies. They are both females, experienced in qualitative research, and together they bring a complementary blend of clinical expertise and research experience to the study. Neither had an established relationship with study participants.

Ethical Considerations

Ethics approval for this study was obtained from The University of Melbourne Human Research Ethics Committee LNR 4D (approval ID: 2024-29048-51715-3). All participants provided written informed consent prior to or on the day of the simulation and were reminded that they could withdraw at any time. Audio recordings and transcripts were stored securely on an institutional, password-protected server, with all personal identifiers removed to ensure confidentiality. GPs received reimbursement for their participation (Aus $150 [approximately US $98]), and actors were compensated according to The University of Melbourne's standard pay scale. No other information was provided regarding personal goals or reasons for doing the research.

Results

Overview

Of the 72 GPs invited, 12 responded and 11 participated (1 GP was not available at the time of the simulation sessions). Approximately half of the GPs encountered female patient scenarios. The demographic characteristics of the participants are described in Table 1. Seven GPs were aged in their thirties and had fewer than 10 years in practice, 8 were female, and 7 were Australian born. Most GPs practiced in metropolitan practices, 1 had experience in rural practices, and 2 worked in an Aboriginal Medical Service.

We reported relevant themes based on 2 key criteria: the volume of information obtained, and their assessed relevance for implementation, as determined by our research team. While we acknowledge that themes may be interrelated across frameworks, we made a deliberate choice to report them separately for the sake of clarity and to avoid overcomplicating distinct aspects of our analysis.

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Table 1. Demographic characteristics of general practitioner participants (N=11).

GP[a] characteristics	Participants, n
Age (years)	
30-39	7
40-49	2
50+	2
Sex	
Male	3
Female	8
Years of experience	
1-10	7
11-20	2
21-30	2
Practice setting	
Urban	8
Regional	1
Aboriginal Medical Service	2
Country of birth	
Australia	7
Overseas	4

[a]GP: general practitioner.

Theoretical Framework of Acceptability

The key aspects of the framework related to "affective attitude" toward the flag, its "perceived effectiveness," its "burden," and any "ethical concerns" related to implementing the recommendations. Feedback on the intervention's acceptability highlighted GPs' "self-efficacy," reflecting their confidence in using the tool to benefit both their practice and their patients.

Affective Attitude, Perceived Effectiveness, and Ethicality

Overall, participants appreciated the recommendations, viewing them as helpful reminders and safety nets to ensure that they did not overlook important aspects of patient care (regardless of the condition with which a patient presents) in typically busy general practice. In general, GPs with fewer years in practice thought that a CDSS like this would be very effective at identifying patients at risk of cancer, given their own lack of experience diagnosing patients with cancer, whereas more experienced GPs, while liking the idea of a reminder, thought that they would trust their clinical experience and would not radically change their approach.

> *So, it's an interesting tool. But it'll just augment your thinking, and just remind you of things, which is always useful when you're busy and tired.* [GP9]

Collectively, the GPs valued the gentle language of the recommendations and resources provided by the CDSS for further reading.

> *I normally hate flow charts..., But this is pretty straightforward.* [GP2]

While they collectively agreed that the point-of-care recommendations served as gentle reminders, some GPs also expressed concerns that it might prompt them to focus solely on pancreatic cancer, potentially overlooking other possible diagnoses, for patients with unintended weight loss and new-onset diabetes.

> *But it did kind of push me towards focusing on that. ...And even though I guess it's really important to know about pancreatic cancer, would it make me forget about other diagnoses.* [GP2]

Some GPs highlighted the possibility that the flags would increase the risk of overdiagnosis and lead to too many computed tomographic scans being ordered.

> *Yeah, if I take it literally, I'd be doing CT scans on a huge number of people.* [GP4]

Half of the GPs were concerned that recommendation to do CT might influence junior GPs to follow point-of-care recommendations without considering the patient history as a whole, due to the medicolegal risk if they did not engage with the recommendations.

> *I think if you are prompted to look for a condition and then you personalise the decision and don't look for the condition, and it turns out, the patient does have the condition you're potentially legally in a bit of a pickle.* [GP1]

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Self-Efficacy

More than half of the GPs expressed their confidence using the resources provided by the recommendations to enhance their knowledge regarding pancreatic cancer and at the same time confidently communicate to their patients that their suggestions for further testing are based on recent evidence.

> *That's good. So, if it does that, then I think in the long run, it would improve my safety, it would teach me a few things like the relationship between diabetes and pancreatic cancer, which I think is not in as much in my mind as it should be. So, it's a good one to be setting as an example, I'm sure that's why you chose it.* [GP2]

Burden

Although the use of the tool did not represent a burden in itself, most GPs highlighted that they would think twice before following the recommendation to consider a CT, given the time and financial burden on their patients.

> *...I like to have some sort of baseline something before sending people off to potentially expensive and time-consuming tech.* [GP4]

Sociotechnical Framework

This framework focuses on factors and processes necessary to implement a digital health intervention. The qualitative data heavily reflected how the clinicians integrated the intervention into their existing workflows and communication strategies, as well as their concerns when discussing recommendations with patients. They also shared their expectations about clinical content to encourage more frequent use of the recommendations.

Workflow and Communication

This was the second most dominant theme arising from the interview data. Fitting the point-of-care recommendations into the workflow was easy, GPs found it nonintrusive, and almost all preferred looking at the recommendations prior to patients' arrival for consultation as their routine practice.

> *I'm someone that looks at the patient's file before I see them, always. So, I'd already sort of looked at the tool and thought about if it needed, if anything needed to be incorporated. So, then I just did the consult as normal once the patient was there.* [GP6]

Most GPs reflected that they prioritize communicating effectively to patients about their decision-making and recommending new tests without causing the patient undue alarm. GPs felt that this was a particular concern for patients with new-onset diabetes, resulting in a potential communication barrier.

> *Yeah, it's hard...because...you want the patient to know that it's important...because it could be something serious. But how do you communicate that without making them panic?* [GP3]

Clinical Content

Almost all GPs suggested that they would value statistical evidence about the incidence of pancreatic cancer in patients with the symptoms flagged to further guide their decision-making.

> *But I would love to...(have) the overall incidence or prevalence of pancreatic cancer...what the likelihood of that person actually having pancreatic cancer would be because that would change my decision making.* [GP7]

Some GPs expressed the importance of HbA_{1c} profiling for new-onset diabetes to better understand whether it was a gradual increase in the reading or sudden spike to be able to justify their clinical decision in suggesting a CT.

> *I guess it's because...we're talking about HbA1c that's high enough, rather than a very gentle creep over many years.* [GP5]

A summary of the major themes and further quotations is shown in Table 2.

A summary of each GP's opinions and thought processes for the entire simulation, along with their respective quotations, can be found in Table S1 in Multimedia Appendix 5.

Although the overall attitude toward a CDSS for pancreatic cancer was positive, there were important concerns and barriers that would need to be addressed for implementation. A major concern was the risk of overtesting, which not only poses a financial burden but also heightens patient anxiety due to the uncertainty of a potential cancer diagnosis. Textbox 1 provides a summary of the facilitators, barriers, and concerns identified.

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Table 2. Examples of quotations from main relevant themes.

Relevant themes	Representative quotes
Framework: Acceptability for Health Interventions [49]	
Affective attitude	• "I like it, I think patients don't tell you what they need. Sometimes, with symptoms you can be, you can become really siloed in which direction you're headed. So being made or being reminded of those rare but not to miss things is useful." [GP1] • "It's still your judgment, isn't it? But it's not I know; it's not trying to replace your clinical job. It's just trying to prompt you to think of things. So, it's saying yeah, consider, I mean, I think that's, that's fair enough. Yeah. There'd be some people who maybe, particularly if there were other risk factors, I guess it would be good to think about. Yeah, I think that's why it's very concise and clear." [GP3]
Perceived effectiveness	• "Yeah, it's a quite a non-intrusive tool, you know, you can look at it there for guidance if you need to. But you can also have sort of your own clinical judgment guiding the consult. And you get better at that, I think at first, it can be distracting and can perhaps derail you, or perhaps make you over investigate or second guess your own approach to a presenting complaint. But I think now that I've used, I've seen and seen and used this a couple of times, you get better at rationalising what you're doing, and knowing where to look for the justification, you know, double checking guidelines if you want to, and then making it work for you." [GP8]
Ethicality	• "But maybe for doctors who are a bit newer in training are more anxious or nervous or maybe new to Australian healthcare system and our learning language and how things work. It may... I think that just need to be trained to not use that as a, 'this is what you should be doing' tool. Because I've had registrars who have done something like that before they've seen something like this and being like I have to screen everyone for pancreatic cancer. That's the only thing I can think of as a drawback." [GP9] • "But the risk in that is also that you might over call things and you don't know where to stop. And I certainly have colleagues who can over investigate everything and refer everything to specialists just because there's a minor abnormality." [GP11]
Self-efficacy	• "I mean, they're gentle in their language, because it says consider. You know what I mean, it still sort of leaves it with you." [GP8] • "I would read over this, the first time I've come across this because this is new information to me. Not everyone would, particularly because of the length of it (resource document). And I think it depends on your patient, I think the newer age patients are often coming to you with some information themselves. So, they often or particularly stronger use around investigation. So, you, I think you need to be better informed yourself. So, this is where like for a patient who, who, you know, was particularly hesitant to go and have screening, they might be asking me, well, can you give me more information? And so, I pull up that guideline and say, well, someone's actually looked into this, and that evidence shows is that, you know, there's some increased risk with these issues and lesser risk with these issues." [GP1]
Burden	• "But again, if this guideline said any unexplained bloating, goes straight to pelvic CT, I probably would follow what the future health today told me as long as the patient was happy with it. And I guess you will say you making all these other decisions aren't cheap." [GP2]
Framework: Sociotechnical for digital interventions [48]	
Communication and workflow	• "Simply because if you were just asking risk factors, and then she didn't have any, that might be okay. But then she comes up with another risk factor, then you actually have to address that, and then you have to deal and because you've said the word cancer, then you usually have to deal with the fact that they've heard cancer and then are stressed about it." [GP7]
Clinical content	• "I would probably like...the probabilities so that...I would be less worried if I knew it's just,...the risk goes from 1% to 2%. That's a completely different conversation than if the risk goes from 1% to 50%, isn't it?" [GP2] • "I really think it is because I think if you have doctors that are like, I'm quite confused by this, and I want to learn more, or I'm quite surprised by these recommendations. I want to learn more. It's good that you direct them to what you want them to look at. Or where they can find more. That's a good resource." [GP5] • "I think consider a CT scan leads me to where I was before, which is that I wouldn't order, this is a very soft recommendation. So I guess again, that...statistics or something to justify. And, I mean, I like numbers. So, weight loss of X percent or X amount." [GP6]

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Textbox 1. Key facilitators, barriers, and concerns identified.

Facilitators

- Resources provided through point of care, especially the flowcharts.
- Gentle language of the recommendation gives flexibility to clinical discretion.
- Seamless fit into workflow via point of care.
- Useful as safety net and reminder in a busy general practice.

Barriers

- Lack of statistical evidence on pancreatic cancer risk in patients with these presentations.
- Need for hemoglobin A_{1c} profiling for patients with new-onset diabetes.
- Longer consultation time to action the recommendation.
- Several consultations needed to gradually introduce the recommendation for patients with new-onset diabetes.
- Time and cost of computed tomography.
- Perception of potential alarm in patients if the topic of cancer is addressed.
- Potential medicolegal risk of not actioning or actioning the recommendations.
- Concerns
- Potential bias in targeted diagnosis and fear of missing other conditions.
- Overtesting and reduced threshold for computed tomography in patients.

Discussion

Principal Findings

This simulation study aimed to assess the acceptability and feasibility of a CDSS to prompt GPs to consider investigations for potential pancreatic cancer in people with unintended weight loss or new-onset diabetes. Testing the CDSS in a simulated environment was valuable, revealing the potential benefits while highlighting barriers to implementing the recommendations in real-life settings.

Most patients with cancer have multiple GP consultations before diagnosis. A Victorian study found that 34% of Australian patients with cancer had 3 or more GP visits before being referred to a specialist. The delays varied by cancer type; for instance, patients with pancreatic cancer or myeloma, who typically present with nonspecific symptoms such as abdominal or back pain, were more likely to have had multiple GP visits than those with breast cancer or melanoma [9]. This highlights the need for tools to aid early cancer detection, in particular, for cancers, including pancreatic cancer, that are rare and frequently present with nonspecific symptoms. In line with international literature on CDSS for early cancer detection [16], our study identified both facilitators and barriers to implementing a pancreatic cancer CDSS. Our CDSS was acceptable and unobstructive and provided easy-to-read resources for GPs. A systematic review examined studies that used CDSS for skin, colorectal, and other gastrointestinal cancers (not pancreatic). It identified three key barriers to implementation: (1) Mistrust in the tool: this stemmed from ambiguity in the underlying guidelines or discrepancies between the tool's recommendations and clinicians' own assessments. (2) The GP's role as a gatekeeper: GPs were concerned about overreferral, fearing that the tool could overload health care systems with unnecessary referrals due to the low prevalence of cancer in primary care. (3) Impact on workflow: GPs highlighted the potential burden these systems could impose, further straining their already busy schedules [16]. Our results were concordant with these observations, reinforcing the international relevance of these challenges. Specifically, regarding mistrust, years of clinical experience emerged as the sole participant characteristic that notably influenced opinions, particularly regarding both system usability and trust. We observed that junior GPs generally demonstrated greater trust on CDSS and were more willing to accept and follow its recommendations. In contrast, their more experienced colleagues tended to prefer relying on their own clinical acumen.

Our analysis did not reveal any distinct differences in opinions when considering other participant characteristics such as age or gender. This finding suggests that while experience level may play a significant role in CDSS adoption and utilization, other demographic factors had less impact on participants' views and experiences in our study. It is important to note that given our relatively small sample size, which is appropriate for an in-depth qualitative study, we are cautious about drawing definitive conclusions based on demographic subgroups. The observed differences related to clinical experience provide valuable insights, but further research with larger, more diverse samples would be necessary to confirm and expand upon these findings.

The gatekeeper role was similarly reflected in our findings, with GPs voicing apprehension about the potential for increased referrals and the associated strain on specialist services. Moreover, GPs also highlighted the impact of time constraints during regular consultations, making it challenging to talk about a very unlikely potential cancer diagnosis. This reluctance aligns with global findings [52], emphasizing the universal nature of

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these implementation barriers across different health care systems and geographical contexts.

However, recommendations based on unintended weight loss were more readily accepted than the recommendation for new-onset diabetes, although there was some concern about the focus on pancreatic cancer that would cause other conditions to be missed. Although most GPs felt that they would follow up patients with unintended weight loss even without the recommendation, previous research shows that unintended weight loss can be challenging to identify in primary care settings. A study conducted in a retrospective cohort in the United States found that primary care clinicians identified only 21% of all cases of unintended weight loss in a 2-year period [53], so a technological solution to both flag weight loss and then prompt GPs to consider cancer (including pancreatic cancer) may be needed.

Despite growing evidence linking new-onset diabetes and pancreatic cancer [29,44], GPs were hesitant to follow recommendations for early CT in patients with newly diagnosed diabetes. There was an overarching concern about the potential for overreferral and overtesting, with associated costs and the potential for harm. Additional barriers included insufficient evidence or knowledge about the association and practical limitations such as cost and availability of CT in rural or remote areas [16,52].

GPs also expressed the need for more information on how to order a pancreatic protocol CT, specific Medicare coverage (Australia's universal health insurance scheme that provides reimbursement for some investigations), and evidence regarding the incidence of pancreatic cancer among people with new-onset diabetes, as well as the cost-effectiveness of widespread case-finding approaches. Some of this information could be provided through education resources, but there is currently little evidence about whether systematically investigating people with new-onset diabetes with CT would have net benefit, or the costs of this activity. A recent systematic review published in 2025 found that pancreatic cancer screening in high-risk populations can be cost-effective. High-risk populations were defined as those with a lifetime risk greater than 5%, including individuals with a family history of pancreatic cancer, relevant genetic mutations, or new-onset diabetes within the past 3 years. The review analyzed 10 studies: 6 from the United States, 2 from Japan, 1 from Denmark, and 1 from Sweden. Three studies focused specifically on patients with new-onset diabetes. Two of these stratified patients aged 50 years and older into high- or low-risk groups based on factors such as age, sex, and abnormal test results; in one, high-risk patients underwent contrast CT. The third study assessed the cost-effectiveness of microRNA compared with CA 19-9, various imaging tests, and no screening in patients with diabetes. Across all studies, the proposed screening strategies were effective at varying thresholds of risk [54]. These findings highlight the need to carefully analyze and communicate risk information to GPs in a way that reduces barriers to implementation. GPs also mentioned the challenges of discussing an unlikely cancer diagnosis and the unnecessary anxiety this may cause to patients. Digital tools can be leveraged to enhance clinician-patient interactions, and we will use this knowledge to inform the design of a feasibility trial currently in process. Research indicates that CDSS can aid communication and shared decision-making when they use non–clinical language and consider individual patient factors [55,56]. Educational material was developed for this purpose as well as focusing on CDSS functionality and coherence, workflow integration, and up-to-date guidelines.

Our study showed that to implement an effective CDSS for pancreatic cancer, it is crucial to first integrate evidence-based resources that highlight the association between pancreatic cancer, symptoms, and new-onset diabetes. It is important that this tool provides comprehensive guidelines on relevant testing, including imaging modalities, to ensure timely and accurate diagnosis. Research has shown that guidelines are more likely to be adopted if they are easy to understand, do not require specific training, are disseminated via multiple channels and have multiple components (reminders, resources, etc), and align with the clinicians' values [14]. These guidelines should be succinctly and clearly summarized into flowcharts or other visual resources. These features have all been incorporated to the CDSS in accordance with our findings. Incorporating cost-effectiveness analyses can help prioritize testing strategies that maximize patient outcomes while minimizing financial burden. Overtesting and cost have been highlighted by the participants as crucial, and more research is needed to clarify these questions before a CDSS can be widely implemented in general practice. In addition, the tool should offer patient resources, such as educational materials on managing symptoms and accessing support services, to empower patients and enhance their overall care experience. By leveraging these elements, health care providers can make informed decisions, potentially improving early detection rates and optimizing diagnostic pathways for patients with pancreatic cancer.

The Australian Primary Health Care 10-Year Plan (2022-2032) places digital transformation at the center of a "future-focused" primary care system, highlighting telehealth, data-driven insights, and precision medicine as key priorities [57]. CDSSs are central to this vision, enabling more personalized and higher-quality care. Our CDSS for pancreatic cancer has the potential to support GPs by promoting guideline adherence, standardizing referrals, and prompting timely follow-up, helping overcome barriers such as limited time and access to specialist resources. As digital-native generations increasingly expect seamless, technology-enabled health care, this tool can help demonstrate how digital innovation can strengthen primary care and improve early risk detection.

Current "Optimal Care Guidelines for Pancreatic Cancer" [22] in Australia, while available, lack several key features identified in our study. These guidelines are not readily available at point of care, do not incorporate sufficient visual aids and summaries, and fail to provide easily accessible resources for clinicians and patients. Our CDSS offers evidence-based recommendations aligned with current guidelines while incorporating features specifically requested by GPs. These tailored functionalities can enhance clinical decision-making and streamline workflow in primary care settings

Our research, involving the simulation of a CDSS for pancreatic cancer and collaboration with expert working groups, has

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informed the development of a new set of guidelines. These guidelines include GP requirements highlighted in this study, offering point-of-care accessibility, comprehensive visual aids and summaries, and resources for both clinicians and patients. This enhanced guideline package has been submitted to Cancer Australia for distribution, aiming to improve early detection rates and optimize diagnostic pathways for patients with pancreatic cancer in alignment with Cancer Australia's National Pancreatic Cancer Roadmap.

Strengths and Limitations

We used a simulation approach, which allowed for the controlled testing of a CDSS designed to identify individuals with symptoms that may be indicative of undiagnosed pancreatic cancer. Simulation enabled the exploration of various clinical scenarios, ensuring that the CDSS was evaluated under diverse and realistic conditions without putting actual patients at risk. In addition, it provided valuable insights about barriers and facilitators for the implementation of a tool for early cancer detection, which if successfully implemented, could lead to better patient outcomes and more efficient health care resource utilization [16]. In this setting, simulation effectively fulfilled dual roles. It allowed direct modeling or observation of practical issues relating to usability and workflow. Separately, it provided "priming" to enable practitioners to give rich feedback about the CDSS approach.

Our study has limitations; one being limited geographic diversity. We were able to obtain perceptions toward the tool from male and female participants, junior and senior GPs, and GPs born overseas and in Australia. We could not, however, recruit participants from rural practices. This geographical constraint was unavoidable, as participants needed to attend the simulation laboratory to test the CDSS. Consequently, our findings may not be generalizable to rural or remote health care settings. The metropolitan-only sample potentially introduces bias toward urban health care challenges, resources, and patient demographics, while limiting insights into rural-specific needs and constraints. These factors may impact the applicability of our results to nonmetropolitan environments and hinder the study's replicability in rural or remote practices. Although evidence-based recommendations for pancreatic cancer follow-up and investigations can support clinical decision-making for GPs in rural and remote areas, challenges such as overtesting, high costs, and limited access to advanced imaging are likely to present significant barriers to implementation in these settings. As with all simulation studies, it is important to note that there is an inherent gap between them and real-world clinical practice. Simulations, while valuable for training and research, may not fully capture the complexities and nuances of actual patient care. These include provider decision-making processes, patient compliance issues, and unforeseen variables in clinical settings. The lack of real diagnostic consequences in simulations could alter the decision-making process of health care providers, potentially leading to choices that may not reflect real-world practices where the stakes are considerably higher. Although we aimed to minimize variability in actor performance by providing detailed scripts, this factor can introduce inconsistencies in the simulated scenarios, potentially skewing results [58]. Actors may not always accurately portray the nuanced symptoms or behaviors of actual patients, which could impact the validity of the simulation. Furthermore, the potential Hawthorne effect, where participants' behavior may be altered simply by their awareness of being observed, can introduce bias into the simulation results [59]. This effect might lead to artificially improved performance or decision-making that does not accurately represent typical clinical practice, thus potentially overestimating the effectiveness of the simulated intervention.

Our CDSS relied on data recorded in the EHR to identify patients with relevant symptoms and its performance was therefore linked to the quality of data recorded in GP practices. The recommendations were delivered asynchronously, meaning they appeared in the patient's EHR only at the time of their next appointment. While asynchronous reminders can serve as safety-netting tools by prompting GPs to inquire about specific symptoms during subsequent visits, this approach carries the risk of missed opportunities for real-time investigation. A significant gap may occur between appointments, or the patient may not return at all, potentially delaying critical care. To address this and provide practices with a proactive solution, FHT includes an additional feature not covered in this study. This feature allows health care providers to create lists or cohorts of patients with specific conditions, enabling the clinic to actively recall these patients for follow-up.

Emerging technologies such as artificial intelligence and natural language processing of clinical notes may help identify these patients more effectively and in real time. Furthermore, the outcomes of a simulation may not accurately predict the long-term clinical impact, including how well the tool integrates with existing systems or how health care providers respond to its recommendations in practice.

Conclusions

We aimed to assess feasibility and acceptability of a CDSS for patients at risk of pancreatic cancer. Our simulation of a CDSS for identifying individuals with unintended weight loss and new-onset diabetes demonstrated that clinicians appreciated the concept of a reminder to consider pancreatic cancer in these patients. However, concerns were raised mainly regarding the potential for overtesting and the associated costs. These findings highlight the need for further research to provide a robust evidence base to support the net benefits of early imaging in patients with potential symptoms of pancreatic cancer.

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Grogan (chair), Michael Tam, Anna Fleming, Brent Venning, Andrew Metz, Rajvinder Singh, Bradley Kendall, Jong K Chin, Andrew StJohn, Daniel Croagh, Emma Scott, Dagmara Propawski, Judi Adams, Milton Kirkwood, and Chris Baggoley. Generative artificial intelligence was not used in the study design, analysis, or development of the initial draft of the manuscript. The University of Melbourne's Spark AI was used for copyediting of the revised manuscript.

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Data Availability

Unidentified transcriptions and qualitative coded data can be made available upon request secondary to ethics approval. Qualitative codes were developed in an iterative process by the 2 researchers (JMG and SC). They were uploaded to NVivo version 14. They can be shared upon request.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Patient scenarios.
[DOCX File , 14 KB - formative_v10i1e79209_app1.docx]

Multimedia Appendix 2
Interview schedule.
[DOCX File , 12 KB - formative_v10i1e79209_app2.docx]

Multimedia Appendix 3
Description of framework dimensions.
[DOCX File , 11 KB - formative_v10i1e79209_app3.docx]

Multimedia Appendix 4
COREQ (Consolidated Criteria for Reporting Qualitative Research) checklist.
[PDF File (Adobe PDF File), 268 KB - formative_v10i1e79209_app4.pdf]

Multimedia Appendix 5
General practitioner thought process for decision-making.
[DOCX File , 17 KB - formative_v10i1e79209_app5.docx]

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Abbreviations

CDSS: clinical decision support systems
COREQ: Consolidated Criteria for Reporting Qualitative Research
CT: computed tomography
EHR: electronic health record
FHT: Future Health Today
GP: general practitioner
HbA1c: hemoglobin A1c

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Original Paper

Human Papillomavirus Vaccine Perceptions Among Noncollege Young Adults and TikTok Influencers: Qualitative Study

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Abstract

Background: Human papillomavirus (HPV) vaccination is a proven and effective tool for preventing several types of cancers, yet vaccination rates among young adults remain suboptimal, particularly among those not enrolled in 4-year colleges. This population can be more difficult to reach due to fewer established institutional touchpoints, limited engagement with campus-based health services, and greater variability in access to preventive care. At the same time, social media has become a dominant source of information for young adults, with TikTok (ByteDance) emerging as one of the most widely used platforms. Approximately 41% of TikTok's users are between the ages of 16 and 24 years, making it a potentially important channel for public health communication. However, little is known about how noncollege young adults perceive HPV-related content on TikTok, or how influencers themselves view their role in communicating about vaccination.

Objective: This study explored the perspectives of young adults and TikTok influencers regarding the dissemination and reception of HPV vaccine information on TikTok. The goal was to assess the potential of leveraging influencers as trusted messengers for this hard-to-reach population.

Methods: Researchers conducted 5 focus groups with noncollege young adults, stratified by gender and vaccination status. Each group included 5-8 participants, resulting in a total of 34 individuals. Participants who reported being extremely hesitant about the HPV vaccine were excluded to focus on those more receptive to information. In parallel, researchers recruited 9 TikTok influencers who reached audiences aged 18-25 years and conducted in-depth individual interviews. Influencers represented a diverse mix of identities, follower counts, and content genres, providing varied perspectives on engagement with health-related topics.

Results: Across the focus groups, young adults described regularly encountering or actively seeking health-related information online, with TikTok emerging as a primary or supplementary source for some. However, very few participants reported seeing content specifically related to HPV vaccination. Despite this gap, most expressed openness to such content if it was delivered in a relatable, authentic manner and included concise, relevant facts. Influencers echoed the importance of authenticity, emphasizing that their credibility is grounded in genuine connections with their audiences. Many described frequent, meaningful exchanges with followers about sensitive issues, suggesting comfort in addressing health topics. Influencers noted that they would be willing to share HPV-related content under certain conditions, including alignment with existing content, personal relevance, or participation in a structured campaign or partnership.

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Conclusions: Findings suggest that TikTok may be a promising platform to engage noncollege young adults in HPV vaccination messaging. The strong parasocial relationships influencers maintain with their audiences could position them as effective messengers on sensitive health topics. Strategic collaborations with influencers, coupled with carefully crafted, authentic content, may help bridge communication gaps and support increased awareness of HPV vaccination in this underserved population.

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KEYWORDS

human papillomavirus; HPV; immunization; vaccine hesitancy; TikTok; young adults; non-college; social media influencers

Introduction

Background

In 2019, the World Health Organization identified vaccine resistance and hesitancy as a top threat to global health [1]. Vaccine hesitancy, defined as patient-level reluctance to receive vaccines, can be conceived on a spectrum that spans from cautious acceptors to outright deniers [2]. Hesitancy is often fueled by concerns about vaccine safety and efficacy, which can be undermined by widespread circulating disinformation and misinformation [3]. Furthermore, vaccine hesitancy is rooted in medical mistrust, which is higher among historically marginalized communities due to generations of systemic and institutional racism, health inequities, and misrepresentation in research [4].

The historic public health crisis resulting from the SARS-CoV-2 (COVID-19) pandemic resulted in significant morbidity and mortality in the United States and around the world, disproportionately impacting racial and ethnic minority communities [5,6]. Similarly, it caused disruptions to many essential health services, including the provision of routine immunizations [7]. Recent data reveal how the human papillomavirus (HPV) vaccination can prevent cervical cancer by 97% [8], but such a disruption to routine HPV vaccination could lead to a reversal of this trend [9,10] and, without an aggressive effort to get vaccination back on track, a rise in cervical and other cancers. Recent studies have shown that there was a decrease in coverage of HPV vaccination programs during the COVID-19 pandemic [10].

Moreover, young adults aged 18-26 years have been less likely to complete the series [11]. A recent population-based study of 18- to 26-year-olds found that men, those with a high-school diploma or less education, and those born outside the United States were less likely to initiate and complete the HPV vaccine series [12]. Now, with the delays in vaccination that have resulted from the COVID-19 pandemic, this group has less time to obtain catch-up vaccinations, which are encouraged up to an age of 45 years, but are most effective when administered at a younger age [13].

Despite this, most HPV vaccination research focuses on adolescents, and the research that has been conducted with young adults has focused on college students and taken place in college and university settings [14-16]. This is partly due to the concentration of this age cohort on college or university campuses and easier access through these networks and systems, the ease of access to the vaccine through university health services, and the fact that most colleges require students to have health insurance to be on campus. Despite having health insurance and proximal easy access to the vaccine, only 41% of 18- to 24-year-olds were enrolled in college in 2019 [17], which means that a majority of this age group—which also needs to receive HPV vaccine messages—is not reachable through these channels. Thus, less is known about 18- to 26-year-olds, particularly those not enrolled in higher education.

Complicating matters is the fact that this cohort may also be less receptive to such messages, and early evidence indicates that decision-making roles about vaccination may be shifting as they increasingly go online for health information and make their own health decisions [18-20], with young adults more likely than adolescents to seek health information online and to make their own health decisions, rather than parents [21,22].

Growth in social media platforms and channels has dramatically changed the nature of communication. There are currently 4.95 billion social media users globally [23], and upwards of 90% of Americans use social media to connect with one another, engage with news content, and share information [24]. Today, there is near-equal participation on social media by age, race, gender, education, and income levels [25], which ensures a wide range and diversity of experiences, opinions, and discourse. Content posted on social media may not undergo scientific vetting, therefore representing a more complex mixture of evidence and personal opinion that can result in misinformation [26,27].

TikTok (ByteDance) became the most downloaded social media app in the country shortly after its official launch in the United States in 2018 and is considered one of the fastest-growing social media platforms, seeing its largest jump in users between 2021 and 2023 [28]. TikTok currently has 1.5 billion monthly active users and was considered one of the fastest-growing platforms in 2025 [29]. Moreover, it is most popular among users younger than 25 years, with 41% of its userbase aged 16-24 years [30]. Many of these users gravitate to the app for its storytelling format, most of which feels relatable and organic versus its more polished and professional counterparts, such as Instagram (Meta). Furthermore, users have been turning to TikTok for more than just entertainment. At least 2 in 5 Americans, especially Gen Z populations, use TikTok as a search engine [31] to look up informative, entertaining, and easily digestible content [32].

An aspect of social media that has emerged in recent years is “online influencers,” which are “everyday people who are incredibly influential within their online social networks” [33]. While millions of people post content to social media, online influencers have established online profiles, talk about a topic

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or set of topics they are familiar with, and have a cohort of followers who trust their thoughts, opinions, and perspectives. They often garner large followings on social media, which increases the likelihood of engagement with their posts, which, in turn, amplifies the visibility of their content [34].

TikTok's ability to entertain and build community also paved the way for a new kind of user, one that had the ability to amass large followings and create connections with audiences. Particularly during the COVID-19 pandemic, when people craved connections with others and glimpses into the daily lives of those willing to share them, there was a substantial growth of TikTok influencers [35]. With over 100,000 influencers creating content on the app, its potential impact is hard to ignore [32]. While the growth of influencers on the TikTok platform is lagging behind its competitors, such as Instagram, with its 64 million influencers, there are key aspects of the TikTok platform that may make these influencers more appealing to young users. First, TikTok influencers share content that feels more organic and homemade, likely due to the higher odds of going viral on TikTok, which opens up the opportunity for the everyday user to grow their following and become an influencer [36]. By comparison, Instagram, which emerged nearly a decade before TikTok, is a bit more polished and refined. When considering the importance of connecting with audiences in a way that feels natural and authentic, TikTok appears to have the advantage despite having an overall smaller number of influencers.

For years, social media influencers have been recruited to disseminate information and encourage consumer behaviors [37-39], as they are viewed as highly credible and trustworthy messengers [40]. More recently, health communication and behavioral scientists have begun to shift their attention to partnering with online influencers to spread credible health messages [41-43].

The rise of social media has democratized the ability for many voices, including lay consumers, to share their knowledge about and experiences with vaccination, in both positively and negatively framed messages. The nature of the medium to enable the unfettered dissemination of any kind of content means that both accurate and inaccurate information can easily and quickly be disseminated. In the context of COVID-19, for example, previous studies have found social media to be a major channel contributing to the spread of misinformation, which is often tied to vaccine hesitancy [44].

In fact, much of the misinformation across social media has been vaccine-related. To date, a variety of studies have shown that antivaccine messages receive more attention across social media platforms than provaccine messages [45-49]. On Twitter (subsequently rebranded as X), studies have found a higher percentage of antivaccine messages compared with provaccine messages, and users on YouTube (Google) were also more likely to encounter negative messaging around vaccines [44]. Furthermore, social media enables users to share content with others and contribute to its virality, regardless of whether that content is accurate or originates from a reputable source.

As it relates to TikTok, researchers have found that the algorithm has favored vaccine conspiracy theories, misinformation, and false narratives around the COVID-19 vaccine, likely due to the highly sensationalized and shocking nature of that content, which generates high engagement and interaction from users [50]. Research also shows that social media may impact vaccine knowledge, awareness, and attitudes among people who read this information and may be influential in vaccine uptake [51]. Influencers themselves may either serve to combat misinformation or contribute to its spread. For example, wellness influencers urged their followers to steer clear of the COVID-19 vaccine, stating that homeopathic methods were more effective and safe [52]. That said, influencers who are equipped with evidence-based information and encourage their followers to get vaccinated have been proven to increase vaccination rates [53]. As the field of social media research continues to grow, greater insight into the impact of these messages and messengers on behavior must be better understood.

Objective

It is within this context that the National Opinion Research Center (NORC), also known as NORC at the University of Chicago, and Thomas Jefferson University (referred to as "the study team" throughout this paper) collaborated to design this study. Guided by the theory of planned behavior (TPB), which has been used to understand and predict HPV vaccination intentions and uptake of young adults enrolled in higher education [54,55], this study sought to better understand the knowledge, attitudes, and beliefs about HPV vaccination as well as TikTok use among 18- to 26-year-old noncollege young adults. As well, the study aimed to understand TikTok influencers' creative process, relationship with their followers, and their perceptions of the vaccine, and willingness to share HPV vaccination information via TikTok. This paper describes the methods and results of this formative study, as well as implications for policy and practice.

Theoretical Foundation

This study is guided by the TPB, which posits that behavioral intentions—and ultimately behaviors—are shaped by individuals' attitudes toward the behavior, perceived social norms, and perceived behavioral control [56]. Applied to HPV vaccination, young adults' intentions to initiate or complete the vaccine series are influenced by their beliefs about the vaccine's benefits and risks (attitudes), their perceptions of what peers or trusted figures think they should do (subjective norms), and their sense of ease or difficulty in obtaining the vaccine (perceived behavioral control). Social media platforms like TikTok may shape these determinants by exposing users to normative cues and persuasive messages from influencers, who often serve as relatable and trusted sources for young adult audiences. By examining the knowledge, attitudes, and beliefs of noncollege young adults, as well as influencers' perceptions and willingness to share HPV-related content, this study provides insights into how the components of TPB may operate within digital spaces to influence vaccination behaviors.

Research Questions

This study identified four key research questions (RQ):

- RQ1: How do 18- to 26-year-old noncollege young adults think about the HPV vaccine?

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- RQ2: How do 18- to 26-year-old noncollege young adults use TikTok?
- RQ3: How do TikTok influencers engage with their followers on TikTok?
- RQ4: What are TikTok influencers' perspectives about sharing HPV vaccination messages on TikTok?

Methods

The study team conducted this study from January 2023 to May 2023, collecting qualitative data from two main sources: (1) interviews with select TikTok influencers, and (2) focus groups with noncollege young adults aged 18-26 years.

Ethical Considerations

Both Thomas Jefferson University and NORC's Institutional Review Boards reviewed and approved the study's procedures and protocols (23-01-1132 and 22-03-701, respectively). All participants provided informed consent before participation in the study. To protect privacy and confidentiality, no identifying information was included in the study data and no identifying information is included in this paper or supplementary material. All data were stored securely, accessible only to the research team, and are reported in aggregate to ensure anonymity of participants. As noted below, incentive payments ranging between US $1200 and US $2000 each were provided to influencers via electronic funds deposit, and incentive payments in the form of US $100 e-gift cards were provided to focus group participants.

Study Administration and Implementation

Study Team

The study team consisted of public health communication researchers and qualitative analysts with previous experience in conducting vaccine-related studies and working with online influencers. Several team members had backgrounds in health communication, social media research, and qualitative methods, which informed study design and interpretation. We acknowledge that our professional expertise in vaccine promotion may have shaped the study focus and data interpretation. To minimize bias, we used standardized interview and focus group guides and engaged multiple coders to ensure diverse perspectives were represented during analysis.

Instrument and Material Development

The study team created a package of materials for the study, which included (1) influencer recruitment email (Multimedia Appendix 1), (2) screening questions for influencer recruitment (Multimedia Appendix 2), (3) verbal consent statement for telephone interview (Multimedia Appendix 3), (4) influencer interview guide (Multimedia Appendix 4), (5) noncollege young adult focus group screener (Multimedia Appendix 5), and (6) noncollege young adult focus group guide (Multimedia Appendix 6).

All data collection occurred virtually between January and May 2023. The online setting was chosen to facilitate participation across diverse US regions and to mirror the digital environments where participants regularly encounter health content. The following sections describe the methods used for collecting data from 2 distinct sources: TikTok influencers and noncollege young adults.

Influencer Interviews

Study Participant Screening Criteria

The study team sought to include culturally diverse TikTok influencers who reported having an audience that includes or is largely made up of young adults aged 18-26 years, who have completed no more than 1 year of higher education, and who are based in the United States. Given that the purpose of the study was to explore areas of opportunity to promote the HPV vaccine on TikTok, engaging with individuals who have very strong views against the vaccine would not have been productive. Those who responded "strongly disagree" to the following question were excluded: "Rate your level of agreement with this statement: Getting vaccines is a good and safe way to protect you and others from disease." Given the nature of one of our populations of study, for example, social media influencers, the team identified additional criteria for inclusion to ensure that the influencers were actively participating online by posting content regularly and engaging with their online communities. These were (1) influencers had to have at least a 6% engagement rate (ER) and a minimum of 100,000 followers, and (2) they had to have posted once within the last 3 months.

For this study, ER was defined as the sum of likes, comments, and shares on TikTok posts divided by the number of followers at the time of the campaign, expressed as a percentage. This metric is standard in influencer marketing research and practice, where ER is often used as a proxy for audience connection and authenticity. We applied the ≥6% threshold because influencer marketing benchmarks suggest that TikTok influencers with ERs above 5%-6% are considered to have "high engagement" compared with industry averages of 3%-5% for creators with ≥100,000 followers [57,58]. Using a ≥6% cutoff ensured that influencers selected for this study were highly engaged with their audiences, an important criterion given the exploratory nature of testing receptivity to health communication messages. Follower counts and engagement rates were provided by Brilla Media.

Study Participant Recruitment

For this study, 9 influencers were recruited to be participants in this study. We implemented purposive sampling to ensure representation across demographics, and recruitment continued until sufficient variation in perspectives was observed across groups and no new major themes emerged, suggesting thematic saturation. The study team worked with Brilla Media, a multicultural influencer marketing agency, to identify these. To do this, Brilla Media initially sent an alert to their network of over 100 multicultural influencers about the opportunity to participate in a new social media program (Multimedia Appendix 1); this contained general information about the project. In addition to this initial call, Brilla Media also reached out to influencers with whom they had existing relationships, worked before on similar campaigns, or found by searching their network, and reviewing their online profiles for relevance to the project criteria.

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Participant Screening and Confirmation

Brilla Media compiled a list of all influencers that met the study criteria for review. This included links to social platforms, followers or reach, and any other notes or insights from Brilla Media. The study team then reviewed and approved the influencers who would formally be invited to participate. Influencers were prioritized if their content featured health topics, news, advice, lifestyle, or their personal lives, and therefore, a potential fit for sharing HPV information in a future public health campaign. Upon approval, Brilla Media sent a follow-up email with additional details (Multimedia Appendix 5) about the project, including timing and compensation, to confirm influencer participation in the project. Influencers who were interested signed up using a screening form (Multimedia Appendix 2) to express interest.

Influencer Interviews

Each influencer participated in individual virtual interviews, which lasted between 25 and 45 minutes. One research staff member conducted each interview one-on-one using the Zoom platform (Zoom Communications). Per request, 2 interviewees had their agent sit in on the call, but they did not participate in the interview. Interviews were recorded after the influencer gave consent (Multimedia Appendix 3). The research staff members all used the same interview guide to conduct the interview (Multimedia Appendix 4). Interview recordings were securely sent to the Ubiqus transcription service for transcription. As Brilla Media negotiated rates with each interviewee individually and confidentially, after the research team confirmed that an influencer had participated in their interview, Brilla Media issued the previously agreed payment amount (ranging between US $1200 and US $2000, each) to them via electronic funds deposit.

18- to 26-Year-Old Noncollege Young Adult Focus Groups

Study Participant Screening Criteria

Participants in the focus groups were included if they met the following criteria: (1) aged 18-26 years, and (2) not enrolled in a 4-year university degree program, or had not attained a 4-year university degree.

Study Participant Recruitment

The research team partnered with a third-party market research firm, PRC Global Market Research, to recruit participants for the virtual focus groups. PRC recruited these participants through their nationwide database of respondents, reaching out to potential participants with a short description of the project and time commitment needed via email and/or phone to determine their eligibility if interested. Up to 10 participants were recruited for each group, with a goal to seat 8, which allowed for 2 alternates in case of no shows.

Participant Screening and Confirmation

PRC recruited a total of 34 participants using the focus group screener (Multimedia Appendix 5) to determine eligibility. Similar to the influencers, individuals who responded “strongly disagree” to the following question were excluded: “Rate your level of agreement with this statement: Getting vaccines is a good and safe way to protect you and others from disease.”

Focus Groups

PRC conducted tech checks with participants ahead of the groups, which were held on Zoom, and joined at the start of each group to troubleshoot any tech issues and take attendance. Each group had between 5 and 8 participants and was organized by gender and/or vaccination status, both of which were self-reported by the participants. Furthermore, 2 member teams of the research team (EC, KM, and ERS) administered each group: a notetaker and the interviewer, who used the focus group discussion guide (Multimedia Appendix 6). A subject matter expert with experience in conducting qualitative research with members of the LGBTQ+ (lesbian, gay, bisexual, transgender, queer/questioning, plus [others]) community, who was not part of the main project team, conducted the focus group with transgender and nonbinary participants. Following each focus group, PRC issued the incentive payment of US $100 to each participant via e-gift card. Focus group recordings were securely sent to the Ubiqus transcription service for transcription.

Analytical Process

Codebook Development

After the interviews were completed, the same team that conducted the interviews collaborated on creating two codebooks: (1) interview analysis codebook, and (2) focus group analysis codebook.

These were developed both inductively and deductively—drawing from the literature as well as based on key themes that naturally emerged from the influencer interviews and posts. Previous research on vaccine discourse and message framing across social media platforms, as well as studies on how online influencers disseminate health information and shape audience perceptions [37,43], provided a basis for identifying relevant inductive and deductive codes. Drawing on this literature, the team identified initial themes, such as trust in messengers, credibility of online sources, and peer influence, which were subsequently refined and expanded through an inductive review of the transcripts.

The full project team contributed to codebook development. The team went through several rounds of review of the codebooks to ensure that the team aligned on the codes and scope of the codebooks, therefore ensuring that they were appropriate tools for analysis. Additionally, a sample of content (Interview 1 and Focus T&NB-V Group) was analyzed by 2 independent coders and then compared for analysis. The study team met to review coding discrepancies, resolve these differences through consensus, and make final adjustments to the codebooks. κ scores ranged from 0.42 to 0.86.

Coding and Cleaning Data

All focus groups and interviews were then imported into NVivo (version 1.6.1; Lumivero), and the study team used the 2 final codebooks to code the remaining interview and focus group transcripts, with 1 coder assigned to each document. Furthermore, 4 team members (DA, EC, KM, and ERS) who had conducted interviews and focus groups also coded the

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transcripts. After coding was complete, the coded files were merged among reviewers and exported. In addition, 1 member (EC) of the team then cleaned these exported files to remove duplicate codes.

Thematic Analysis of Coded Data

After coded files had been cleaned, the team reviewed the files separately, drawing out key themes that each saw emerging in the data. They then met for an inductive brainstorming session to solidify the key themes and learnings that emerged from the coded files. Through this process, the final primary themes were identified in each of the coded files (interviews and posts) as well as across both of them; they were confirmed through team consensus.

Results

Demographic Characteristics of Study Participants

A total of 9 influencers participated in interviews, and 34 young adults participated in focus groups. The demographic characteristics of these influencers and young adults, including gender, race, ethnicity, education, and income, are presented in Table 1.

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Table 1. Demographic characteristics of study participants.

Characteristic	Influencers (N=9), n (%)	Young adults (N=34), n (%)
Gender		
Cis-female	5 (56)	15 (44)
Cis-male	2 (22)	14 (41)
Transgender	1 (11)	2 (6)
Nonbinary	0 (0)	3 (9)
Two Spirit	1 (11)	0 (0)
Race		
Caucasian or White	3 (33)	11 (32)
African American or Black	2 (22)	9 (26)
Indigenous	2 (22)	0 (0)
Multiracial	1 (11)	6 (18)
Hispanic or Latino	1 (11)	4 (12)
Asian	0 (0)	4 (12)
Ethnicity		
Non-Hispanic	4 (44)	28 (82)
Hispanic	3 (33)	6 (18)
Other: Indigenous	2 (22)	0 (0)
Marital status		
Married or common law married	4 (44)	6 (18)
Single	5 (56)	28 (82)
Education level		
Less than high-school diploma	1 (11)	0 (0)
High-school diploma	1 (11)	12 (35)
Associate degree or some college	2 (22)	22 (65)
College degree	4 (44)	0 (0)
Graduate school or graduate degree	1 (11)	0 (0)
Income (US $)		
Less than 20,000	1 (11)	2 (6)
20,000 to <30,000	0 (0)	7 (21)
30,000 to <40,000	0 (0)	9 (26)
40,000 to <50,000	1 (11)	6 (18)
50,000 to <75,000	1 (11)	5 (15)
75,000 to <100,000	2 (22)	4 (12)
100,000 or more	1 (33)	2 (6)
Prefer not to say	1 (11)	0 (0)
Geographic residence		
Rural	0 (0)	—[a]
Suburban	2 (22)	—
Urban	7 (78)	—
Served in US armed forces, reserves, or national guard		
No	—	31 (91)
Yes, but I am not on active service	—	2 (6)

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Characteristic	Influencers (N=9), n (%)	Young adults (N=34), n (%)
Yes, I am active service	—	1 (3)
HPV[b] vaccination status		
Vaccinated, 2 shots	__[c]	14 (41)
Vaccinated, 1 shot	__[c]	3 (9)
Not vaccinated	__[c]	17 (50)

[a]Not applicable.

[b]HPV: human papillomavirus.

[c]A diverse sample of influencers were recruited to ensure a mix of perspectives about HPV vaccination. While we excluded those who reported being strongly antivaccine in order to assess opportunities for HPV vaccination communication, participants were not required to disclose their own HPV vaccination status.

Demographic Characteristics of Influencers

A diverse range of 9 total influencers participated in interviews. Of the total, 5 interviewees were cis-female, 2 were cis-male, 1 was transgender male, and 1 was Two Spirit. Their ages ranged from 21 to 33 years, with the median age being 28 (IQR 23-30) years. Furthermore, 3 interviewees identified as White, 2 as African American or Black, 2 as Indigenous, 1 as Multiracial, and 1 as Mexican. Moreover, 3 of the interviewees identified as Hispanic, Latino, and Latina. Influencers had a diverse range of incomes, with the highest being US $380,000 and the lowest being less than US $20,000 annually. Similarly, there was a wide range of influencers' highest level of education, with 1 having less than a high-school diploma, 1 with a high-school diploma, 1 with some college, 1 with an associate's degree, 3 with bachelor's degrees, 1 with a bachelor's degree and some graduate school, and 1 with a postgraduate degree. In addition, 4 interviewees were married or common law married, and 5 were single. Of the total, 7 influencers reported residing in urban areas, while 2 reported residing in suburban areas (Table 1).

Demographic Characteristics of Young Adults

A diverse range of 34 participants took part in 5 focus groups. The groups were stratified according to gender and/or vaccination status:

1. Female, vaccinated group
2. Male, vaccinated group
3. Female, unvaccinated group
4. Male, unvaccinated group
5. Transgender and nonbinary, vaccinated group (T&NB-V; while not required to be vaccinated to participate, all who ended up in the group happened to be vaccinated)

The median age of participants was 22. In total, 32% (11/34) of participants identified as White, 26% (9/34) as Black or African American, 18% (6/34) as Multiracial, 12% (4/34) as Hispanic or Latino, and 12% (4/34) as Asian. Furthermore, 47% (16/34) of participants had an annual household income of US $20,000-US $60,000. Moreover, 65% (22/34) had an associate's degree, trade school, or some college, while 35% (12/34) had completed high school or a GED. In addition, 82% (28/34) of participants had never been married, while 18% (6/34) were married (Table 1).

Perspectives on the HPV Vaccine Among Noncollege Young Adults

All groups had some general awareness of HPV being a sexually transmitted infection that can lead to cervical cancer, which is somewhat common, but they reported not hearing a lot of information or news about it. There also appeared to be some confusion about how the disease affects females and males, as well as recommended age groups for vaccination. Generally, people did not feel that they had a lot of knowledge about HPV beyond these basic things.

Related to the HPV vaccine, they generally had heard about it, knew that one existed, and that it helps prevent certain cancers or infections that cause cancers:

> *Is it to help prevent any type of certain cancers, like, in the future? That's, like, so far what I know.*

They also knew that children should get it, but tended to think that it was for children aged 9 and 10 years. Recommended vaccination for other ages was less well known. As one stated,

> *I know that I think you get it around age, basically, as a kid, maybe ten or nine, something like that, if I can remember.*

Both unvaccinated groups felt like they lacked information about the vaccine and needed to do more research, while the vaccinated groups all reported not needing more information. One participant from the male (unvaccinated group) said,

> *I just remember that it's another vaccine to help prevent, but I was kind of confused exactly what it's exactly preventing, so, that's something that I'm trying to figure out. I didn't know if it was more of just, like, a sexually transmitted vaccine that's preventing everything so you don't have to use protection, or exactly how it works.*

In terms of the safety of the vaccine, some participants thought that the vaccine was safe, but that came more from the vaccine having been around for a while:

> *It's been out there a long time. So I took it when I was younger. So it had to have been out there a long time. I'm pretty sure it's trusted and tested.*

Notably, most appeared to have heard of side effects and injuries caused by vaccines, including the HPV vaccine:

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> *The HPV one and Covid one, like [participant] was saying, in particular, I have heard of people getting reactions to it. Like, with the HPV vaccine in particular, I've heard people not feeling well or passing out after it. But again, that's just people on Facebook I hear talking about it, so I don't know if that's actually a thing, or if people are just trying to avoid other people getting it. I do think the polio, TDAP, those, like, the childhood ones are what I usually generally always consider safe, like, I've gotten those for my kids. But HPV, Covid, and flu I'm just kind of on the fence about.*

Many participants who were vaccinated obtained their vaccines as children because of their parents' decision or a recommendation from their doctor, while others mentioned school requirements as a primary motivator for getting the vaccine. As one participant stated,

> *I got it for school, and everyone was recommending to take it, along with a bunch of other vaccines.*

Noncollege Young Adults' Use of TikTok for Health Information

Participants tended to all agree that they heard about information more generally, and health information specifically, on social media first:

> *I think I for sure hear about a lot of major things from social media first, just because social media has a tendency to spread things like wildfire.*

Almost all of them reported that checking sources was important to them, because there was a general understanding that not everything in social media could be believed:

> *It's kind of like the good and the bad of social media, it can be really garbage and it can be really good, and how trustworthy it is is kind of up to how much effort you're putting into using it responsibly.*

Checking sources did not necessarily translate to looking for academic or scientific sources to verify the information, though. Rather, they reported that often they are looking for verification from others:

> *I use comments or refer to comments to sort of verify whether or not the information in the video is correct. Because if people, if the general population thinks that what someone is saying is incorrect, then they're obviously gonna comment on that, to turn it down. So I usually look at it just to verify if information is right or not… Yeah, yeah. I'm seeing how many people like that comment, which is why they're probably on the top in the first place. I don't really click on their profile, I just see the interactions within the comments. So people always respond to the top comments, and I sort of read that whole conversation and see what people say on either side.*

And this leads to a lot of codiagnosing, of the act of trying to diagnose someone's symptoms together:

> *And then I'll notice it on, like, people posted forums, they'll compare each other's symptoms and kind of find out what it could be, together. And from there, it could lead me to a credible article that one of them posted, like, as a credible source that they're saying, "Oh, it could be this. Take a look at this. I have these same symptoms."*

Moreover, they noted learning a lot by reading other people's comments, and they also remarked that reading the comments helped to validate their thoughts or reactions to the online information they were seeing:

> *And then, looking at the comments, I feel like, is also another big thing for me, like, on videos like that, I then look at the comments. 'Cause a lot of other people then will share, in the comments, [crosstalk] counter experiences or kind of reaffirm that person's experience, which I feel like can be helpful to see how reliable it actually is, if you have a lot of people agreeing or not... I'm not looking for a specific thing, I just feel like some people are, like, "Oh, yeah, I had the same experience," or, "Oh, my daughter, my friend, or whoever, had these same things." But also, then there are sometimes people who are, like, "Oh, this was not the case for me, at all. I had this and I had a totally different experience." So, just keep in mind not everyone has the same experience. There's always people who kind of like have that in the comments, as well, which is good.*

As it relates to TikTok specifically, participants tended to think of TikTok as "human," "transparent," and "democratic":

> *So I think it's always good to get a human understanding of what's going on, even if you approach it with hesitation, or you run that and then you verify it again with a more educated source, I think social media is great for looking at what's actually happening in people's lives regarding these medical things. Such as, you know, like I said, on the one half of how the medical industry can poorly treat people who have maybe more invisible issues like chronic pain, or how it could clear up my skepticism of Covid by showing me a hospital filled with Covid patients, you know? So I think social media can be really good, just seeing how people in real-life are dealing with the consequences of these things.*

Because of this, they perceived the platform as a trusted source that could be used to verify information that was being shared through more mainstream channels:

> *Yeah, it's not the fact that TikTok is super reliable, but I think it's the ease of searching up something and getting videos that answer your questions, you know? So, that's why I like to use TikTok as a social media platform is because, whenever I have a question, I could just type it in, and then the results that populate are usually informative of that question. But for other social media apps like Instagram, I can't really type in a question. So, I don't really get that same search response, which is why I like using TikTok specifically.*

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Participants also commented on whether they saw HPV and HPV vaccination information–related information on TikTok. Most of them reported not seeing much or not being able to recall seeing anything. A few noted some content that they did remember seeing:

> *I actually have seen one or two TikToks in, like, the past year, about them, which is why earlier when I said I've been thinking about them again, that's, honestly, why. But then, like, your "for you" page is what TikTok thinks you want to see, right? So, that also dictates a lot of that for me… one of them was about - so, again, in TikTok, you know, people usually talk about these extreme cases. So one was about a girl who had never gotten the vaccine, and it was just, like, she got cancer as a result, and she was just kind of tracking how it led to that and how preventing it could've been useful for her. Hers was very much informational, it wasn't very, like, "Oh, my god, I got cancer and I'm gonna die. Get your HPV vaccine." It was just, like, "This is kind of what happened to me, like, just keep in mind." And she also threw in points that her doctor herself told her, too.*

Despite this, participants reported that they would be open to seeing this kind of content on TikTok but had recommendations for what they would like to see in terms of that kind of content. Most mentioned wanting natural, unbranded, unscripted content that felt authentic. They notably said that they would want the video made with a phone to give it a more personal quality. They also noted that they wanted to hear personal stories:

> *I would be more inclined to watch a video that was describing somebody's personal experience.*

Some mentioned that hearing statistics or health care providers talking about the disease and the vaccine would be interesting, but that they *"don't know if [they would] watch the whole thing, but… [they] would feel like it's good that it's out there."* They did note that they would want videos to include *"more background about what this disease is, how people get it, and if there's a cure or not, what the vaccine does to help prevent HPV."* For both vaccinated and nonvaccinated, they said that they would like to see this kind of information shared via influencers, people with personal experience, and "s*omebody, like, my age who I didn't know, if they sounded confident and enthusiastic*." Only vaccinated participants said that they would like to see influencers and doctors talking about this topic together.

Influencer-Follower Engagement on TikTok

TikTok influencers noticeably reported having very close relationships with their followers, perhaps some of the closest of any social media platform. One noted,

> *I go live a lot, so I get to talk to my followers in real time and thoroughly get to know them, because for me, I don't believe in I'm here and they're here. For me, I like to personally get to know my followers, so I can name them by name, I can come into a live and be like, "Oh, I've missed you. What have you been up to?" I follow some of my followers back just to get to know them, because I know so many of them are following me on this journey.*

They referred to these relationships as "familial," like an "older sister," "aunt," or "uncle," and reported "knowing their followers by name." One participant who shared that her followers say that she's relatable and that they see her as an "older sister" described being vulnerable with her audience, which is why she thinks she has been able to connect with her audience so much:

> *I would say that my relationship with my followers is that of like being an auntie or an uncle. Somebody who travels a lot, who gets a lot of really unique experiences, who has a lot of life experience, who's done a lot of different things.*

Participants reported that these relationships result in personal and deep conversations with their followers:

> *I feel like I'm speaking to my friends and my parents, is sort of how I address it. Friends who are not necessarily technical - my parents are not technical. So, that's how I - I kind of feel like loose friends with my audience, even though I obviously haven't met more than a handful of them.*

They also noted that they were often asked for their advice on topics and for their help answering questions:

> *A lot of my followers will tag me in videos that are really controversial. Videos from members of the community, of the Indigenous community. Even legislation or like some crises that are happening in different communities. They'll tag me and say, "Hi, [NAME]. Like, what are your thoughts on this?" or "You know, are there any words of like wisdom or advice you can give for people going through this?"*

One participant noted how his followers messaged him for advice on being transgender, struggling with their identity, or their environment (meaning, friends and family). He noted that he would try to respond in ways that were supportive and helpful:

> *He had messaged me years ago about questioning his identity, and I gave him some advice back then. Then he messaged me again like a week ago and he was like, "I finally came out and you've helped me." I like to be able to be somebody that people can look up to and see that it's okay and it's normal. I don't know, like somebody that I wish I had when I was younger to know. I feel like I would know more.*

Finally, the participants noted that one of the main ways those one-on-one conversations happen is via personal direct messages on TikTok. As one noted,

> *I get messages, at least like a dozen messages every single day. I guess we live in this time where people are surprised that I respond back to them and I try to respond back to every single person that messages me with more than just a, "Hey, thank you." You know ask, if they ask questions try to give responses back and everything. So, I have a pretty close relationship with my followers. I think they feel*

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> *comfortable with me. I think that's one of the big things that makes me a good content creator I guess, is that I'm able to be approachable, that people are able to talk to me and I respond back to them with a comment to their messages. So I would say it's a pretty cool relationship with them.*"

Because of these kinds of relationships and conversations, TikTok influencers, in particular, feel that they are helping to build community and can be incredibly persuasive with their followers:

> *A lot of people just end up commenting and saying, "Oh my God, wow, I'm so happy that you brought this up because I'm dealing with this" and it just becomes a big community.*

One participant noted how many of her indigenous followers follow to connect with their heritage, learn, and/or support her as an influencer. She also noted, however, how she had a following of non-Indigenous people, and they seemed to follow her to learn more about her and her culture. The influencers felt that this kind of community-building often leads to conversations that were not traditionally held openly or freely, which present learning opportunities:

> *I feel like for the non-Indigenous people it's just to learn… That's what I get usually in my messages when people are like… "I never really learned a lot about Indigenous culture." [or] "they don't teach it so, like, that's why I follow you." And for the Indigenous people some of them are reconnecting. So, I would say the reasons [for indigenous folks] are kind of the same as the non-Indigenous folks. But some… Indigenous people just follow me because I'm Indigenous and, you know, just to show their support I would say.*

TikTok Influencers' Perspectives on Sharing HPV Vaccine Messages

Influencers varied in the level of health information they shared on their platforms. Some had platforms that focused on health subjects, while others said that while they had not yet posted any health-related content, they would consider doing so in the future. One noted,

> *I don't think I have ever done it myself just 'cause it doesn't fall into like my category of stuff that I do.*

When asked whether they had posted about vaccines on their platforms, the influencers were split—about half had, while the other half had not. The respiratory syncytial virus and COVID-19 vaccines were popular topics to post about. The HPV vaccine tended to be talked about less often than other vaccines, but for those who had posted about it, they sought to tailor their content to address certain misconceptions about the vaccine:

> *There's a lot of misinformation about what types of injuries may result from HPV vaccination, and the VAERS system. So, it changes a little bit depending on what I think are the public's main issues with each of the vaccines.*

Overall, it appeared that TikTok influencers were not talking about the HPV vaccine but were open to it.

Discussion

Findings

This study aimed to better understand the knowledge, attitudes, and beliefs about HPV vaccination, as well as TikTok use, among 18- to 26-year-old noncollege young adults. In addition, it sought to explore TikTok influencers' creative processes, relationships with their followers, and their perceptions of the HPV vaccine, including their willingness to share vaccine-related information via TikTok. Findings indicate that while few young adults reported seeing HPV vaccine content on the platform, many were receptive to receiving such information if it was presented authentically and included clear, relevant facts. Influencers emphasized the importance of their close, trust-based connections with followers and expressed a willingness to post about HPV vaccination when it aligned with their content or personal experiences. Together, these results suggest that TikTok, and the influencers who engage audiences on the platform, may offer a promising avenue for reaching noncollege young adults with HPV vaccination messaging. The findings highlight the critical roles of authenticity, audience connection, and strategic content integration in designing effective social media interventions for this population.

The TPB links people's attitudes toward a behavior with their intentions to engage in said behavior [56] and seeks to contextualize those beliefs and behaviors within larger social contexts and take into consideration how people perceive what others (eg, peers and people of importance) think about engaging in the behavior. This study extends previous work related to the TPB by identifying ways in which young adults' health-related attitudes and decision-making may be influenced by peer-to-peer interactions on TikTok. Notably, across both unvaccinated and vaccinated young adults, participants assessed the credibility of health information they were exposed to—online and offline—and made decisions about how to think about those health topics based on popular comments on TikTok posts and interactions with TikTok influencers, whom they trust.

Moreover, our findings further align with and extend existing literature about social media and vaccine communication. Previous studies have shown that social media can shape vaccine knowledge, awareness, and attitudes, particularly among young adults who seek health information online [51]. Moreover, our finding that influencers' authenticity and relatability make them trusted messengers complements other studies that have found that partnering with social media influencers increased positive attitudes toward vaccination [37]. Our results also echo previous studies showing that narrative storytelling is an effective approach for addressing HPV vaccine hesitancy, as demonstrated by our findings that TikTok users prefer personal and unscripted stories [59]. Taken together, our results contribute to this growing body of research by highlighting TikTok's unique combination of participatory culture, peer validation through comments, and influencer-follower intimacy as potential mechanisms for strengthening HPV vaccine communication efforts.

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Related to HPV and the HPV vaccine, this study elucidates that there appears to be both a lack of knowledge, especially among the unvaccinated groups, as well as a lack of HPV vaccine content on TikTok. Thus, our findings underscore the critical role that a lack of knowledge may play in attitudes toward the HPV vaccine and decision-making about it. Skepticism can be attributed to a lack of knowledge [60], and many study participants, particularly in the unvaccinated groups, expressed having a lack of information or knowledge on the topic and a need to do more research about it. To address this gap in knowledge, some participants expressed searching for information on TikTok given its accessible, short-form content. Yet, little to no HPV vaccine-related content exists on the platform. Thus, the mismatch between need and availability may be contributing to the lack of knowledge, awareness, and decision-making around the vaccine.

Given this lack of knowledge about HPV among this audience, particularly among those who are nonvaccinated (as well as the lack of such information on this channel), strategies focused on addressing these knowledge and information gaps are critical. Noncollege adults have less access to information about the HPV vaccine as well as reduced access to health care services compared with those in college or university systems. It is therefore worth exploring ways in which TikTok may be leveraged to reach this audience with this kind of information, especially since these individuals commonly access this platform.

Related, the unique aspect of storytelling and personal narratives on TikTok is important to consider when it comes to understanding the role that these influencers may play in sharing such information with their followers and the impact that may have on their followers' HPV vaccine-related behaviors. It is well-documented in the literature that personal narratives create space for the acceptance of new information and have been well-documented as a communication approach that can effectively lead to higher HPV vaccination rates [59]. Many participants expressed a preference for receiving health information in authentic and unscripted formats and wanted to hear about people's real experiences with a health condition like HPV and getting the HPV vaccine. Matched with TikTok influencers' positions as deeply trusted sources and their willingness to share such information, under the appropriate conditions, there is an opportunity and need to further explore this channel and this set of messengers as potentially powerful conveyers of the HPV vaccination information that this age cohort is seeking—and how this might drive changes in HPV vaccine-related behaviors.

Ultimately, these findings offer guidance for communicators in terms of messaging about HPV and the HPV vaccine. Public health communicators should consider how to work with TikTok influencers to share their messages, especially about the HPV vaccine, taking advantage of their position of influencer and empowering them to tailor and personalize HPV vaccine messages as only they can—in authentic and personal ways. Their storytelling approaches, combining narrative and didactic content, can help amplify public health and immunization messages and begin to address knowledge and awareness gaps that remain strikingly persistent—even nearly 20 years after the vaccine was approved in the United States.

Limitations

This study is not without limitations. First, the study did not compare results with those of college-educated young adults, but rather explored the opinions of a diverse set of young adults who were not enrolled in higher education. It is therefore possible that some confounding variables may exist that could contribute to the differences or similarities between these 2 groups. Second, this study was exploratory in nature and therefore did not explore the effects of HPV vaccination messaging shared by influencers on noncollege young adults that could otherwise be observed through an intervention-based or longitudinal study. Finally, the study had a small sample size to represent a large portion of the population, and therefore, these results are not generalizable.

Conclusions

Noncollege young adults aged 18-26 years' experience substantial challenges accessing vital information about HPV and the HPV vaccine. This has resulted in lower vaccination rates and higher rates of related infections and cancers. Novel strategic approaches are needed to directly engage young adults with timely and relevant HPV vaccine information. This study's findings suggest that the power of narrative storytelling combined with the trusted relationships that exist between an influencer and their followers—as only exists on TikTok—may be helpful and persuasive to this audience.

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Data Availability

The datasets generated or analyzed during this study are available from the corresponding author on reasonable request.

Authors' Contributions

Conceptualization: AB-G (lead), AL (equal)
Data curation: AB-G, DA, EC, KM, AS-R, ERS, AL (equal)

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Formal analysis: AB-G, DA, EC, KM, AS-R, ERS, AL (equal)
Funding acquisition: AB-G (lead), AL (equal)
Investigation: AB-G (lead), AL (equal)
Methodology: AB-G, DA, EC, KM, AS-R, ERS, AL (equal)
Project administration: AB-G (lead); AL (equal)
Resources: AB-G (lead), AL (equal)
Supervision: AB-G (lead), AL (equal)
Validation: AB-G, DA, EC, KM, AS-R, ERS, AL (equal)
Visualization: AB-G, DA, EC, KM, AS-R, ERS, AL (equal)
Writing - original draft: AB-G, DA, EC, KM, AS-R, ERS, AL (equal)
Writing - review & editing:AB-G, DA, EC, KM, AS-R, ERS, AL (equal)

Conflicts of Interest

None declared.

Multimedia Appendix 1
Influencer recruitment email.
[DOCX File , 34 KB - formative_v10i1e80783_app1.docx]

Multimedia Appendix 2
Screening questions for influencer recruitment.
[DOCX File , 32 KB - formative_v10i1e80783_app2.docx]

Multimedia Appendix 3
Verbal consent statement for telephone interview.
[DOCX File , 23 KB - formative_v10i1e80783_app3.docx]

Multimedia Appendix 4
Influencer interview guide.
[DOCX File , 44 KB - formative_v10i1e80783_app4.docx]

Multimedia Appendix 5
Noncollege young adult focus group screener.
[DOCX File , 30 KB - formative_v10i1e80783_app5.docx]

Multimedia Appendix 6
Noncollege young adult focus group guide.
[DOCX File , 40 KB - formative_v10i1e80783_app6.docx]

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Abbreviations

HPV: human papillomavirus
LGBTQ+: lesbian, gay, bisexual, transgender, queer/questioning, plus (others)
NORC: National Opinion Research Center
RQ: research question
TPB: theory of planned behavior

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Original Paper

Challenges for a Maternal-Care Health Recommender System in Indonesia: Formative Preimplementation Qualitative Study

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Abstract

Background: Maternal evaluation during routine antenatal care visits may reduce maternal morbidity and mortality by identifying and addressing issues early on. A health recommender system could help health professionals and pregnant women monitor daily health parameters, provide tailored recommendations, and support timely antenatal care.

Objective: This study aims to qualitatively analyze challenges in the preimplementation of health recommender system for maternal care in Indonesia as perceived by multiple stakeholders, including health care providers, patients, health system managers, government officers, and technology vendors.

Methods: The methodology used a qualitative approach, where qualitative data were obtained from interviews of 37 respondents from multiple stakeholders, consisting of 15 health workers and 15 patients from private and government health care facilities, 4 officers from government health offices, 2 directors of health application vendors, and 1 manager from a private health clinic. These semistructured interview results were analyzed using thematic analysis.

Results: This qualitative study identifies key challenges in implementing a health recommender system for maternal care in Indonesia across the people, process, infrastructure, and policy dimensions. Intercoder reliability for the coding process demonstrated almost perfect agreement (Cohen κ=0.90), supporting the consistency of the coding process. Six major challenges were revealed, mostly regarding skill, accuracy, completeness, timeliness, cost, and standardization. These 6 major challenges were mentioned 96 times, accounting for 64.43% of all codes extracted from the interviews. These findings emphasize the value of user involvement in system design to meet health care professionals' and patients' needs, technical advancements to foster trust and support effective decision-making, as well as enhanced data accuracy, reliable and timely service delivery, cost management, and clear regulatory standards.

Conclusions: This formative, preimplementation qualitative study highlights the importance of involving users in system design and future implementation to meet the needs of health care professionals and patients. Reducing input errors and improving system reliability are critical to building trust and supporting effective point-of-care decision-making and, in later phases, facility-level monitoring as part of public health surveillance. Adherence to regulatory standards and the establishment of standardized guidelines will be key to enabling broader implementation. Further usability, feasibility, and pilot studies are required before any evaluation of effectiveness.

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KEYWORDS

health recommender system; maternal care; antenatal care; public health surveillance; health information systems; preimplementation;

Introduction

Overview

The global maternal mortality ratio is expected to be <70 per 100,000 live births by 2030, according to the Sustainable Development Goals [1]. The World Health Organization (WHO) report on maternal mortality, however, shows that while the rate of maternal deaths has dramatically declined, a sizeable gap needs to be closed before this goal is met, and progress varies among nations [2].

Timely and sufficient antenatal care (ANC) visits are known to reduce maternal mortality [3]. Among the major causes of maternal mortality, hypertensive disorders during pregnancy are the leading cause following postpartum hemorrhage [4,5]. Although a few of these problems might have been present before getting pregnant, most complications happen during pregnancy and can be prevented with routine ANC visits [6]. Maternal evaluations during ANC visits may help identify and address issues early on, reducing risks of morbidity and death for both the mother and the unborn child [7]. Critical illness in pregnancy, like hypertensive disorders, is often diagnosed during pregnancy at prenatal visits, as prenatal care affords the opportunity for prevention, early diagnosis, management, and treatment of hypertensive disorders [8]. Therefore, the WHO released recommendations to ensure an adequate number of ANC contacts, improve continuity of care, promote healthy behaviors, provide dietary supplements, and encourage both community involvement and home visits for ANC [9].

In Indonesia, ANC activities face challenges regarding health facility access and quality, the availability of health workers, and socioeconomic barriers such as cost limitations and education gaps [10]. Maternal mortality remains high in Indonesia, and the reduction in the maternal mortality ratio is among the slowest in Southeast Asia, even though most women attend the recommended number of ANC visits and give birth with a skilled birth attendant [11]. Baharuddin et al [12] also found that the major causes of maternal deaths were preventable, and factors that contribute were commonly health worker–oriented and related to quality of care in hospitals. Indonesia also faces urban-rural disparities in health care services with a mixed public-private delivery system and uneven digital-health uptake [13,14]. Studying this context provides transferable insights for low- and middle-income countries facing similar constraints in digital health adoption.

Using technology to monitor daily health parameters in a normal, everyday environment can help reduce hospitalization and lower medical expenses [15]. Noninvasive sensor technologies can be used to track user behavior, providing insights into how daily lifestyle choices influence health [15]. Additionally, recommender systems in health care have the ability to provide patients and physicians with tools and support, assisting in the ongoing observation and diagnosis of chronic illnesses [15].

ANC activities include not only health education and promotion but also the detection, prevention, and treatment of complications based on measurements taken during regular visits [7]. A health recommender system (HRS) for maternal care could use mobile sensors and portable diagnostic devices to automatically collect these measurements [16-18]. The data required for generating recommendations could be obtained from user inputs, the patient's health records, and connected medical devices [16,19-29].

Studies by Etemadi et al [30], Croon et al [31], Tran et al [32], and Pincay et al [33] offer insights into the methods and techniques used in HRS and the areas where HRS can be applied. Tran et al [32] explore the types of users who could benefit from different kinds of recommendations provided by HRS and examine user satisfaction with those recommendations. Furthermore, Croon et al [31] and Pincay et al [33] discuss how recommendations should be delivered to users and propose design principles that can be applied to HRS research. While these studies [30-33] address some of the challenges faced by HRS, there is still a gap in the literature regarding a comprehensive exploration of implementation challenges from multiple stakeholder perspectives, such as health care professionals, patients, app developers, and government health officers [30-33]. Existing research predominantly focuses on technical aspects, system evaluation, or specific user groups, like patients or medical experts in general, without sufficiently addressing the broader challenges faced by key stakeholders in maternal care delivery. Additionally, these studies often lack consideration of domain-specific health constructs, such as asthma, pregnancy, and iron deficiency.

HRS for Maternal Care

An HRS can be defined as a system designed to assist health professionals or patients in decision-making and personalized health care by filtering through large amounts of data and generating meaningful recommendations [15]. These systems could learn user behaviors and adapt their recommendations depending on the domain and the characteristics of available health records [15]. An HRS should be sensitive to patient needs, attitudes, and the specific context of health and disease management to ensure its effectiveness [15]. Such systems accommodate 2 main types of end users: health professionals, who can access additional resources like research articles or clinical guidelines, and patients, who receive high-quality, evidence-based content [15]. Recommendations can be generated based on users' previous interactions or explicit preferences using methods like collaborative filtering, content-based analysis, and knowledge-based analysis, with many systems integrating multiple techniques and incorporating additional data types, such as time, location, and social information, to optimize performance [32]. According to Saha et al [15], HRS can be categorized into 2 types: one that continuously monitors and diagnoses chronic diseases to support doctors and patients with advice and predictions, and a content-based system that helps users explore conditions related

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to their illness through semantic analysis. While most HRS use graphical user interfaces, some distribute information via mobile apps or web-based mobile interfaces [17,23-25,27,34,35]. Alternatively, other systems present recommendations through web interfaces [31].

The WHO recommendation for pregnancy care includes regular checkups and routine screenings to maintain wellness, detect complications early, and prevent conditions that complicate delivery [9]. The HRS aids in diagnosing and monitoring patients over time by using personal health records gathered from measurements taken by health care providers or the patients themselves [15]. Using HRS for maternal care, pregnant individuals can receive recommendations on diet, exercise, medication, or consultations [16,18,23,24,28]. These systems may incorporate portable diagnostic tools and mobile sensors to enable automatic measurements [16,18,26]. Data from connected medical devices, along with user input in patient health records, can be used to provide recommendations that assist with diagnosis and monitoring during ANC [16,19-29]. While previous studies highlight the potential of HRS to monitor pregnancies and mitigate risks, challenges in implementation, particularly from physicians' perspectives, have also been explored [36].

Conceptual Model of Research

SERVQUAL (Service Quality) is one of the widely used and accepted methods for service quality measurement [37]. The quality of health care service, as assessed by the SERVQUAL model, can be determined by examining the gap between desirable and current conditions based on 5 dimensions: tangibles, reliability, responsiveness, assurance, and empathy [38]. Furthermore, the HEALTHQUAL (Healthcare Service Quality) model expands these dimensions by including health care–specific aspects like safety, efficiency, and patient outcomes [39]. Additionally, Nemati et al [40] highlight availability, affordability, and caring as essential factors to consider in assessing health care quality. Together, these elements support a comprehensive approach to measuring care quality from the perspective of both patients and health workers [39].

In analyzing the challenges of implementing HRS in Indonesia, the framework from Handayani et al [41] also provides valuable insights. The study by Handayani et al [41] on strategic hospital services quality in Indonesia identifies key dimensions necessary for improving health care services, including human resources, processes, policy, and infrastructure. Each of these dimensions plays a crucial role in the successful implementation of health care systems, including HRS for maternal care. In the analysis, we used the model to orient coding while allowing inductive themes to emerge.

The people or human resources dimension refers to the quality and professionalism of health care staff, emphasizing empathy, communication, and skills, which are critical in building trust and patient satisfaction [41]. Health care professionals are expected to possess the necessary technical skills, medical knowledge, and expertise, while also being empathetic, compassionate, and trustworthy [42]. Empathy in health care is reflected in the ability of medical staff to understand and acknowledge the patient's situation during treatment, demonstrating personal concern for each individual [39]. It is further expressed through prioritizing patient needs, offering personalized care, showing courtesy to both patients and their families, and providing emotional support [37].

The process dimension focuses on the responsiveness and reliability of service delivery, including timely, accurate, and efficient health care operations [41]. Reliability refers to the ability to deliver consistent, dependable services, characterized by timely health care, transparent processes, and standardized treatments and procedures [37]. Responsiveness involves having quick, efficient, and customer-focused systems, such as an effective triage system for rapid emergency response and clear communication [37]. Efficiency in health care quality relates to the extent to which processes and operations are optimized to deliver effective services [39].

The policy dimension in health care involves establishing clear guidelines and standards that govern practices and ensure compliance with regulations, providing assurance to both patients and staff [41]. A significant challenge in this context is the cost-effective implementation of proven clinical interventions, with common barriers such as limited time and staffing resources [43]. Safety quality aspects further emphasize maintaining high staff qualifications, fostering confidence in service delivery, and ensuring a safe environment for both patients and employees [39].

Lastly, the infrastructure dimension pertains to the availability and quality of physical and technological resources, such as medical equipment and hospital facilities, which support the delivery of high-quality care [41]. Advanced medical equipment and technology are central to tangible quality aspects, ensuring high standards in health care alongside the best medical staff [39]. The equipment used in health care services also defines tangibles, referring to both the physical facilities and the condition of the tools used in delivering care [37].

Objective

In this study, an HRS refers to patient-facing and clinician-supporting features embedded in routine ANC workflows that generate patient-specific, actionable suggestions for pregnant women and/or clinicians, using guideline-based and/or machine learning–driven approaches. We exclude general health information systems and stand-alone prediction tools that do not produce actionable recommendations. Thus, the aim of this study was to identify implementation challenges of maternal-care HRS in Indonesia from the perspectives of multiple stakeholders. Accordingly, we addressed the following research question: What are the key challenges in implementing a maternal-care HRS in Indonesia, as perceived by multiple stakeholders? The findings of this study are expected to inform stakeholder-aligned design and implementation strategies to support adoption within routine ANC workflows.

Methods

Study Design

This formative, preimplementation qualitative study used a purposive sampling method to select respondents and elicit

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stakeholder perspectives on anticipated barriers, enablers, and surveillance-relevant requirements for future implementation; no HRS was deployed or tested in practice. This study followed the COREQ (Consolidated Criteria for Reporting Qualitative Research) guidelines as a comprehensive checklist to ensure complete reporting of key components of qualitative research (Multimedia Appendix 1) [44]. We used purposive, iterative sampling with concurrent analysis. Recruitment proceeded interview-by-interview and ceased when additional interviews yielded no substantively new codes (thematic saturation). A total of 37 participants from 32 organizations were interviewed. Among the respondents were 12 medical doctors, who were all specialists in obstetrics and gynecology, and 3 midwives. Those medical doctors and midwives worked in public hospitals (4 participants), private hospitals (11 participants), and private clinics (4 participants). It is important to note that in Indonesia, a medical doctor can work in more than one health care facility. Additionally, we interviewed 15 pregnant women who were patients at private clinics (12 participants) and community health care centers (3 participants). Four participants from government agencies represented regulatory bodies, while 2 participants with IT backgrounds, holding director positions at health application development companies, provided insights into the technological aspects. The remaining participant was part of the management team of a private mother and child health clinic.

In terms of demographics, the group consisted of 31 females and 6 males. Most participants lived or worked in Banten province (29 participants) in a region in the greater Jakarta area, characterized by urban infrastructure with well-developed health, communication, and transportation systems. The remaining participants worked in Jakarta province (6 participants) and West Java province (2 participants), which are also near the greater Jakarta area. To complement this urban perspective, we additionally interviewed representatives from government offices, such as the Ministry of Health and public health offices, whose system-level viewpoints provided a counterbalance to facility-level experiences. Table 1 shows the summary of the participant characteristics.

Table 1. Participant characteristics in a formative, preimplementation qualitative study of a maternal health recommender system in Indonesia (n=37).

Characteristics of participants	Participants, n
Respondent group	
Regulator	4
Specialist	12
Midwife	3
Health app developer	2
Clinic management	1
Patient	15
Sex	
Male	6
Female	31
Province	
Banten	29
Jakarta	6
Jawa Barat	2
Type of organization	
Ministry of Health (DTO[a])	1
Health office	2
Community health center (Puskesmas)	4
Government hospital	4
Private hospitals	11
Private clinic	4
Professional associations	4
Health app vendors	2

[a]DTO: Digital Transformation Office.

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Ethical Considerations

Ethical approval for this study was obtained from the Faculty of Computer Science at the University of Indonesia (approval number S-15/UN2.F11.D1.5/PPM.00.00/2024). Additional approval for data collection in Tangerang Selatan was provided by the local government health office (letter number 400.14.5.4/1560/SDK). All participants received information about the study purpose, procedures, voluntary nature of participation, and their right to withdraw at any time. Written or verbal consent was obtained before each interview. To ensure confidentiality, transcripts were anonymized and deidentified prior to analysis, with access restricted to the research team. Participants received no financial compensation or transportation allowance. No identifiable images or personal information are included in this manuscript or supplementary materials; all quotations are anonymized.

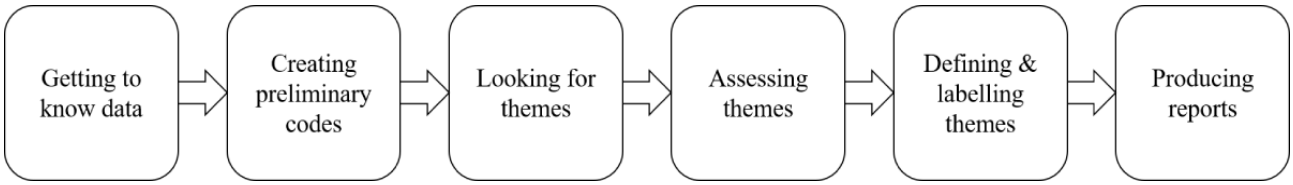
Data Collection

Semistructured interviews were used to gather data between August 23, 2024, and November 13, 2024. The interview was conducted via phone call, Zoom meeting (Zoom Communications), or face-to-face dialogue following the availability or the preference of each participant. Each interview lasted between 30 and 60 minutes and was recorded after acquiring the participant's verbal consent, witnessed by the interviewer. The recordings were transcribed, then translated, and the resulting data were anonymized. The interview questions were created to investigate the preimplementation of an HRS for maternal care, focusing on the dimensions of people, processes, infrastructure, and policy to ensure a comprehensive understanding of the challenges and opportunities (the interview questions are available in Multimedia Appendix 2).

Data Analysis

To examine different perspectives from research participants, thematic analysis was used to analyze interview data in QDA Miner Lite (Provalis Research). The 6 steps of a thematic analysis as described in Harahap et al [45] are as follows: getting to know the data, creating preliminary codes, looking for themes, assessing themes, defining and labeling themes, and producing reports (Figure 1).

Figure 1. Data analysis workflow for a formative, preimplementation qualitative study of a maternal health recommender system. Semistructured interview transcripts (n=37; regulators, clinicians, midwives, patients, app vendors, clinic manager) were analyzed in QDA Miner Lite using a 6-step thematic analysis (familiarization, initial coding, searching themes, reviewing themes, defining/naming themes, and reporting).



We first read the interview transcripts several times to become acquainted with the meanings of the data in order to become familiar with them. Every transcript file has a name that corresponds to the case and the original creation date. Second, we used QDA Miner Lite to arrange the dataset before creating the programs. All of the first codes that were discovered were noted, along with short notes and quote samples. Third, we categorized codes into subthemes and then categorized the subthemes into themes inductively. The research framework was used to help search for themes and generate initial themes from codes. When appropriate, the research framework deductively guided the organization of candidate themes without forcing fit, and we iteratively refined the structure to maintain coherence with the data. Subthemes were then derived from the coded data and represented as child nodes. In QDA Miner Lite, the themes were shown as parent nodes, and the codes and subthemes were shown as child nodes. A codebook was used to maintain the evolution and categorization of codes and subthemes. To support coding rigor, one researcher initially developed the preliminary codes and subthemes, which were subsequently reviewed by another researcher. The 2 researchers then discussed and refined the coding framework until agreement was reached on code definitions and theme boundaries. To quantitatively assess coding consistency, intercoder reliability was calculated using Cohen κ. This hybrid approach, where collaborative validation was combined with quantitative agreement testing, ensured interpretive consistency, minimized bias in theme development, and provided transparency regarding coding reliability in this formative qualitative study [46]. To limit confirmatory bias, we organized themes without forcing fit, retained nonaligned inductive codes as emergent/cross-cutting, held consensus meetings to reconcile coding differences, used constant comparison across transcripts, and actively looked for negative/variant cases to revise themes or mark their boundary conditions. Fourth, we evaluated the transcripts to make sure the chosen quotes or coded data fit the subtheme and went over the codes for each subtheme to assess their relevance. Subthemes were then examined alongside themes by the authors. Examining and contrasting earlier research was another step that complemented the process of connecting themes, subthemes, and codes. Fifth, we verified the themes and classification after writing in-depth analyses for each theme in order to refine, define, and name them. Finally, we created the report's Discussion section, which compares the findings with earlier research that supports our interpretation, and presents the report's themes, subthemes, and selected quotes. Although we calculated the frequency of each code to indicate the relative prominence of themes across stakeholder groups, these counts were interpreted descriptively rather than statistically. We analyzed the qualitative data until we did not find other themes or reached data saturation. The purpose of reporting frequencies was to illustrate thematic salience and identify the most commonly discussed issues, not to imply quantitative significance or apply statistical normalization.

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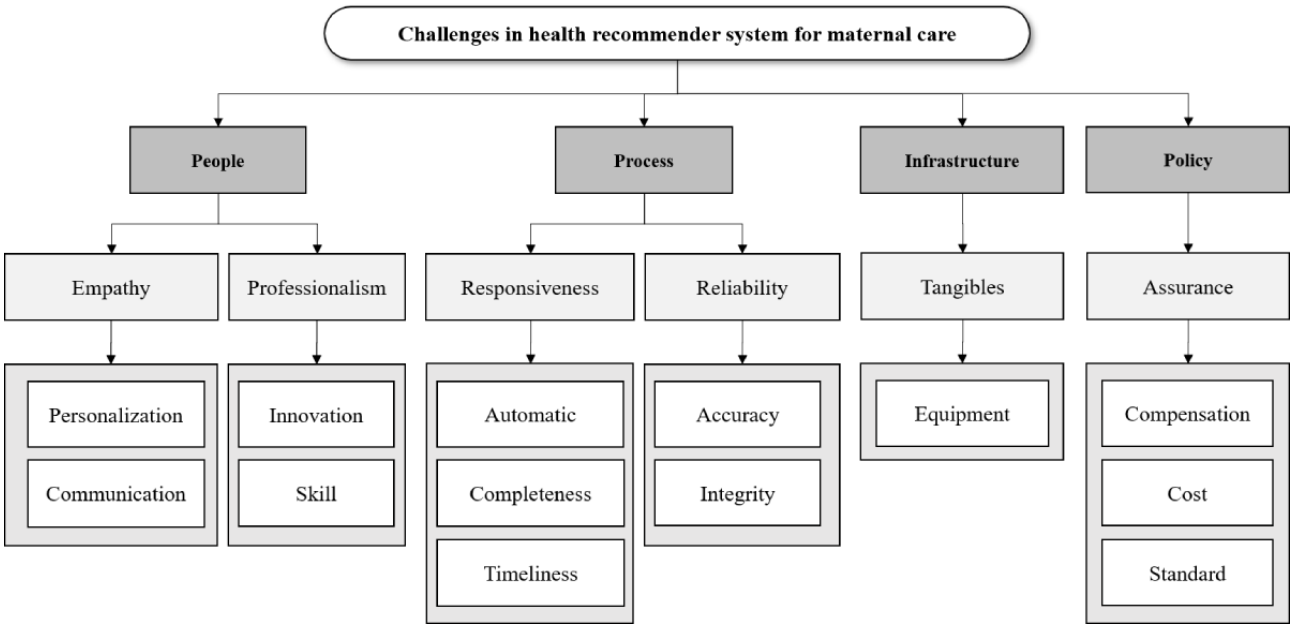
Results

Overview

We discovered 13 challenges that were represented by codes, where each code was mapped to 6 subthemes and 4 themes thereafter. People, process, infrastructure, and policy are the 4 dimensions reflecting themes. The people dimension has empathy and professionalism as subthemes and 4 codes under each subtheme. Process dimension has responsiveness and with 3 codes and reliability with 2 codes underneath. The infrastructure dimension only has tangible as a subtheme with only 1 code. Lastly, the policy dimension has assurance as a subtheme and 3 codes. These relationships are illustrated in a thematic map in Figure 2.

Figure 2. Thematic map of challenges identified from 37 stakeholder interviews on a maternal health recommender system.



The frequency of occurrences of the codes in the transcripts was calculated as shown in Table 2 and illustrated in Figure 3. These frequencies are presented to demonstrate which themes were most salient across participants; however, they should be interpreted descriptively. The counts reflect emphasis in participant discussions rather than normalized or statistically analyzed values. Intercoder reliability for the coded subset demonstrated almost perfect agreement between the 2 researchers, with Cohen κ=0.90, indicating high consistency in the application of the coding framework. Notably, professionalism, particularly the skill subtheme, is emphasized by health workers (12 occurrences) and patients (8 occurrences), indicating the importance of competence in using the system. Similarly, accuracy under reliability is a significant concern for health facility management and patients, highlighting the need for precise system outputs. The completeness of information in responsiveness is a critical issue for health workers and patients, underscoring the need for comprehensive data in the system. Additionally, financial concerns such as cost and compensation are primarily noted by health facility management and regulators, reflecting broader concerns about the system's affordability and sustainability. Timeliness is also crucial, particularly for health facility management, who emphasize the importance of efficient service delivery.

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Table 2. Frequency of qualitative codes by stakeholder group in a formative, preimplementation study of a maternal health recommender system (n=37 interviews).

Theme, subtheme, and code	Health facility management (n=1), n	Health worker (n=15), n	Patient (n=15), n	Regulator (n=4), n	Health application vendor (n=2), n	Total, n
People						
Empathy						
Personalization	0	2	4	0	0	6
Communication	0	4	2	1	0	7
Professionalism						
Innovation	0	2	0	2	1	5
Skill	0	11	7	1	0	19
Process						
Reliability						
Accuracy	0	10	5	2	2	19
Integrity	0	3	3	1	1	8
Responsiveness						
Automatic	1	5	2	1	0	9
Completeness	1	8	6	2	1	18
Timeliness	0	9	2	3	1	15
Infrastructure						
Tangible						
Equipment	0	3	0	1	1	5
Policy						
Assurance						
Compensation	0	5	2	1	1	9
Cost	0	7	4	2	2	15
Standard	0	8	2	2	2	14

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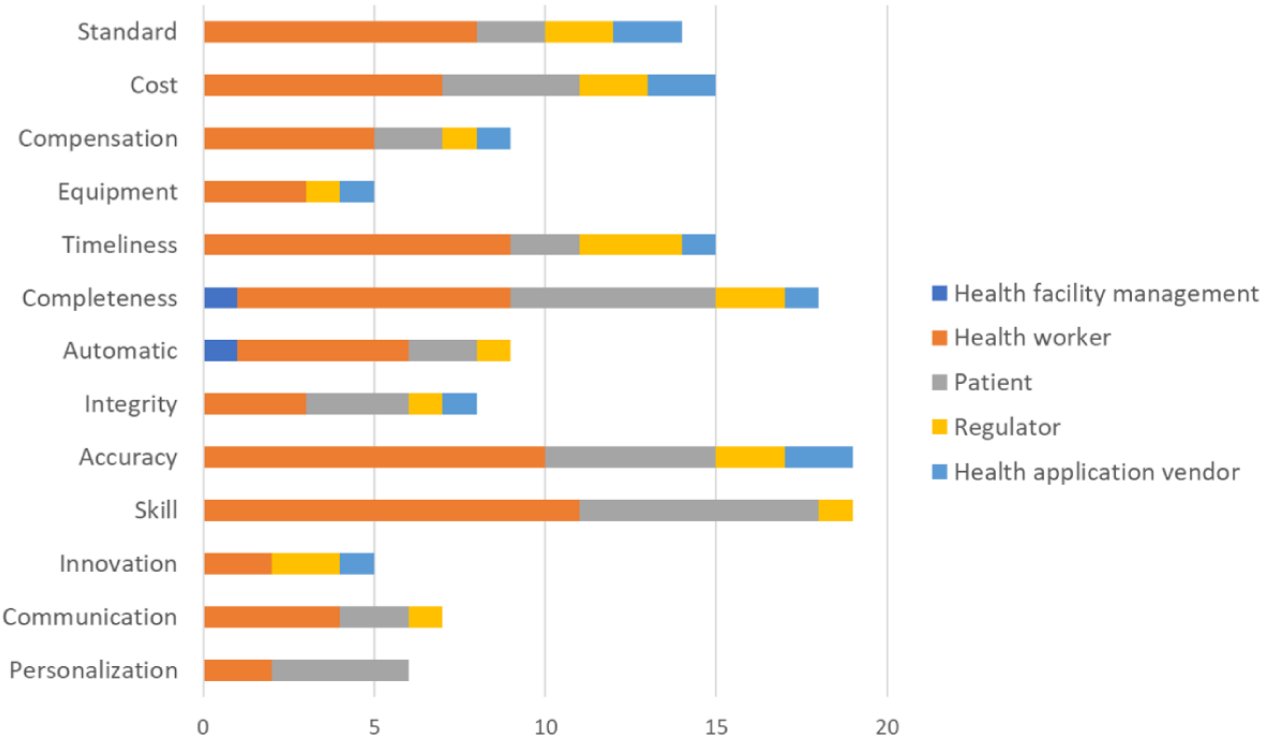
Figure 3. Distribution of code frequencies across stakeholder groups for preimplementation challenges of a maternal health recommender system (n=37 interviews). Higher bars indicate more frequent mentions. Consistent with Table 2, the 6 most-cited challenges (skill, accuracy, completeness, timeliness, standards/standardization, reliability) account for 96 references (64.43% of all coded instances).



People

The people dimension covers the needs and challenges of both health care providers and patients. Through qualitative analysis of interviews, several key themes emerged that reflect the human factors influencing the system's adoption and functionality. These themes include empathy and professionalism concerns, illustrating the importance of tailored information, interactive communication, and the delivery of new technology, as well as individual factors.

Empathy

Personalization (Need for Individualized and Specific Maternal Information)

General apps rarely meet specific maternal needs, offering only basic advice and leaving concerns unresolved. The current maternal health book offers very basic advice, such as directing users to see a doctor in case of danger signs, but it lacks detailed recommendations. A more personalized solution (eg, app or chatbot) could guide symptom causes and provide tailored recommendations.

> *Not everyone has the same problem. An application is for, for the general population, it's like saying, actually it's for the general population, right, and everyone has a different individual function.* [DR1]

Communication (Interactive Communication)

Patients need direct interaction with doctors to build trust and gain clarity, but constant personal contact can overwhelm doctors. A potential solution is an app that schedules and manages communication, ensuring patients get guidance without overburdening doctors.

> *They love it when they can have direct contact with us. On the other hand, when we give out our contact information, it can sometimes be disruptive.* [DR3]

Some patients feel a maternal HRS is unnecessary because they already have easy access to health workers and facilities. For those near health centers, face-to-face education is faster and more convenient than using an app, and comprehensive apps are hard to find; direct access to doctors is often enough.

> *Because the neighborhood is close, for their education, it's faster to came here. They are also more focused, right. That's why it may not be really necessary to have an application.* [GO3]

Professionalism

Innovation (Time and Effort in New Tech Delivery)

Many developers struggle to reach product-market fit because solutions do not align with clinicians' workflows or pregnant women's needs, leading to low interest.

> *Maybe there is something that we still miss ... As long s we haven't found a product market fit or product solution fit, this can't continue more massively.* [VD2]

Adoption also slows due to the need to train users (providers and patients). During transition, old systems run in parallel until the new one embeds in daily work, and technological/infrastructure gaps add friction.

> *The Satu Sehat platform [Indonesia's integrated health data platform], the main goal is actually*

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> *initially reducing such applications. But during this transition period, they are still input in their respective applications.* [GO2]

Skill (Individual Factor)

Applications in health care should be designed to be easy to use, with information that is simple to understand, provided to both health care providers and patients. Some users may find traditional methods, like writing in a book, more straightforward, leading to more complete and detailed notes. However, others prefer the convenience of digital tools, finding it easier to access information through gadgets or by searching online. The system must also consider user preferences for different types of interaction with the application, ensuring that it is intuitive and adaptable to individual needs. Moreover, patients should be equipped with the necessary knowledge to accurately measure health indicators at home and correctly interpret the results.

> *Sometimes there are patients who don't understand, but it turns out that it is already written by the doctor, so it is more, I rely more of a book than that, for example, sometimes it is also more complicated to work than to write, so sometimes it is even more complete what is written, which is in a book than what is typed.* [DR2]

Process

The process dimension addresses issues related to reliability and responsiveness. The challenges identified within this dimension include issues related to the accuracy of data input, quality of output, and data integrity. Additionally, there are concerns about the need for automated processes, the lack of data integration, and incomplete information provided to users. Timeliness is another key concern, particularly in terms of ensuring continuity of service, delivery time of service, and improving time efficiency in patient handling.

Reliability

Accuracy

Incorrect Input

Reliability in the implementation of a health care information system is dependent on the accuracy of the data input. Manual data entry, while sometimes necessary, is prone to human error, leading to inaccuracies that can compromise patient care. To mitigate these issues, an application could use a guided form within the system that can help standardize input and reduce the risk of mistakes. Otherwise, as some users point out, the process to avoid inaccuracies requires careful checking and rechecking, and if errors are found, it may require redoing the entire examination, which is time-consuming and frustrating.

> *I think there's always some manual input involved, like entering lab results, which is probably done manually. Because the lab system isn't connected to the Satu Sehat, so the lab staff have to enter it manually. Hopefully, there won't be any human error during the entry.* [DR7]

Technical issues within the application could lead to input errors. Such errors can result in data that are either inaccurately recorded or, in some cases, completely unreadable. This not only disrupts the continuity of care but also poses significant risks to patient safety, as health care providers may be unable to access crucial information when needed. These technical glitches undermine trust in the system, making it imperative to address them proactively.

> *The problem is that the delivery of the results doesn't come in even though it's been sent. It seems like we have updated the patients as of today, right, but we can't read it later.* [GO4]

For the system to function effectively, diagnostic devices must be routinely calibrated to ensure they deliver precise measurements. Without regular calibration, there is a risk of inaccurate readings, which could lead to incorrect diagnoses or treatment plans. Additionally, there is a valid concern regarding the sensitivity of diagnostic devices; if a device is not sensitive enough, it may fail to detect subtle but crucial changes in a patient's condition, further compromising the accuracy of the information within the system.

> *The better the device, the more sensitive the tool is, right. I'm afraid that for example, like a sports watch, if the sensitivity for the pulse track will also be different, so it will be different from the sensitivity.* [DR2]

Quality of Output

The accuracy of a health care information system for maternal care is not only determined by the correct input and processing of data but also by ensuring that the data are delivered to the right person. If the information reaches the wrong individual, it could lead to significant errors in patient care, including incorrect diagnoses, inappropriate treatments, or delays in critical interventions.

Additionally, another significant challenge is the potential for misinterpretation or the generation of inaccurate recommendations, which can occur if the system's data are not correctly analyzed or presented. For instance, if the system displays inaccurate information, it can lead to misinterpretation by health care providers or patients, resulting in misguided decisions or actions. Furthermore, discrepancies in critical calculations, such as due date estimates, can cause confusion and erode trust in the system, especially when the simulations provided are significantly off-target.

> *Last time the simulation was very far from the ... what ... from menstrual tracking. Also when entered into the application. The estimated due date is like a month different.* [PS10]

There is often an assumption that health apps may not provide all the necessary information about a patient's condition, leading to a lack of motivation to use them. Some patients may not be aware of the importance of monitoring their health, or they may lack support from those around them to do so. Moreover, health apps are frequently deprioritized in favor of entertainment or social media unless their use is mandatory. For patients experiencing a second pregnancy, there may be a perception that they already know everything they need to, making them less inclined to use the app.

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> *Even if we make an application, if from the mother herself, her desire to monitor herself is lacking, it is still less useful.* [DR8]

Partial Availability of Required Data

For the system to provide precise and reliable guidance, it must have access to all necessary data inputs, which typically require contributions from both the patient and the physician. It is good that patients understand what data should be available in the system, but examination results from physicians are needed to create recommendations. If any required data are missing or incomplete, the algorithm within the system cannot produce an accurate recommendation, leading to potentially flawed advice that could impact patient care. Therefore, it is important to ensure that both patients and health care providers understand their roles in data input to maintain the system's accuracy and overall effectiveness.

> *If the results are patient-based, only based on what the patient knows or experience, maybe the recommendations will not be very accurate.* [DR6]

Integrity (Data Integrity and System Reliability)

Clear accountability for data entry/management builds trust. Users need assurance that data are accurate and protected end-to-end, with strong technical and operational security and not just policies on paper. Many still fear cloud risks.

> *What is clear to me is a safety issue. Data safety, right. That the cloud is not safe. Yes, I think so. Because this cloud has data everywhere. If someone hacks like that, it's really troublesome.* [DR1]

Reliability issues such as crashes and poor connectivity, especially in weak-network areas, undermine confidence and make users hesitate to rely on the system.

> *Some people are still in trouble if the network is not very strong.* [GO4]

Responsiveness

Automatic

Need of Automated Process

Linked data can trigger reminders and follow-ups automatically, improving responsiveness for providers and patients. But overcomplex automation is hard to build and maintain and can cause delays/errors.

> *It's a bit difficult if it's a bit complex, if it's simple, it's already automatic in our hospital.* [DR5]

Repetitive Action by User

Users often reenter the same data across apps. Interoperability with medical records would allow automatic data pull, reducing manual entry and frustration.

> *We write everything manually, so we can't directly pull the data …. If it was already entered into the system, the data could be pulled right away. So, if you want to connect that, that's how it should work.* [DR2]

Completeness

Lack of Data Integration

Users, both patients and health care providers, express a strong preference for an all-in-one solution that consolidates various functions and data sources. Patients, for example, desire the ability to view ultrasound results and track fetal development directly within their app, without having to switch between multiple platforms. The absence of integration between different applications often leads to inefficiencies and complications, making it difficult to manage health care processes smoothly. When systems are not interconnected, simple tasks like managing schedules, setting reminders, or sharing data become cumbersome, requiring multiple actions that could be streamlined through a unified system.

> *Yes, if you can have one application that covers everything. So there is no need to double record, and there is no need to repeat it.* [BD2]

When an app is fully integrated with medical records, it can automatically generate reminders and recommendations that are personalized and timely, directly benefiting patient care. However, a common challenge arises when health facility apps are not connected to other applications and are used merely for data collection. This lack of integration limits the system's ability to provide actionable insights, as it cannot leverage the full spectrum of patient information.

> *If there could be an app that acts like a personal doctor, reminding you, "Hey, your weight has reached this point," that would be great. But the issue is that it's not integrated with medical records.* [DR1]

Partial Information

When only partial information is accessible, it limits the effectiveness of both patient care and health care management. For instance, teleconsultation has inherent limitations because it cannot perform physical examinations, which are vital for accurate diagnosis and treatment. Additionally, patients often find themselves with access to only a portion of their medical information, which can hinder their understanding and engagement in their own care. On the other side, doctors may struggle to obtain comprehensive data on their patients, particularly regarding treatments received elsewhere, leading to gaps in care continuity. Moreover, relying solely on traditional methods, such as paper records, fails to provide a clear view of a patient's medical history and risk factors, which are essential for informed decision-making.

> *They don't see the previous pattern, so they only look at the examination at that time. Meanwhile, when we combine it with some historical data, or indeed the use of this application has been carried out from the beginning of pregnancy, there will be patterns of what risk factors the mother has.* [VD1]

Another key aspect in the completeness of information is the ease of data recording that digital applications provide. Unlike physical books, which can be easily lost, forgotten, or suffer from scattered and unreadable notes, apps offer a secure and organized way to store important health data. This digital approach reduces the risk of losing critical information and

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ensures that records are always accessible when needed. However, despite this convenience, it is important to recognize that patients may still struggle to interpret their own health data accurately. Even with easy access to stored information, they often rely on a doctor's expertise to draw conclusions and make informed decisions about their care.

> *Yes, I mean, reading is fine, but I don't want to make assumptions on my own. Sure, for example, with hypertension, you're supposed to do this and that. That's the theory. In practice, we need to ask the doctor directly. We can't conclude on our own. Because it is still, even if you want to take action, you must have the doctor's approval. Like in my case, I have gestational diabetes, that's a warning, I can't decide on my own what to do. I'd be clueless.* [PS15]

Timeliness

Continuity of Maternal Care

Health workers need the flexibility to input data into the system while on the move, allowing patients to immediately view results and follow up on their care. This seamless integration is vital for maintaining a continuous workflow. However, the experience is often disrupted when the application crashes, is inaccessible, or lags, especially during critical moments like home visits when access to data is urgently needed.

> *It would be better if there was already a system that was used when they served while go around, they immediately input at the system and allows the patient to see the results and later in the future so they will be better at following up.* [GO1]

A maternal care system must not only detect and diagnose problems in a timely manner but also ensure that appropriate follow-up actions are seamlessly integrated into the care process. This means that the system should be designed to automatically prompt and schedule follow-up appointments, reminders, and any necessary additional tests or treatments, ensuring that patients receive continuous care without gaps.

> *So, with any health-related app, the difficult part is the follow-up. Because in my opinion, these online apps are helpful for initial emergencies, but after that, there's no follow-up. You can't just contact the same number or even the same doctor again. It's unlikely that you'll be connected to the same doctor again after using the app the first time.* [DR5]

Delivery Time of Service in Maternal Care

Physicians need to take action at the right moment to ensure effective treatment, and early detection of health issues is essential for preventing complications. To support this, the system must be capable of delivering necessary services and information to the right stakeholders exactly when needed. For instance, using instant messages sent directly from the system can significantly enhance awareness and prompt action, especially since stakeholders may not be checking the app regularly.

> *If they have to open the application every time, there's a concern that they might miss it. And we also don't just remind in emails, but we also make interactions in emails.* [VD1]

Time Efficiency in Patient Handling

In a setting where the number of patients is high and time is limited, improving time efficiency becomes essential. A health care information system that optimizes time management allows health care providers to handle more patients effectively without compromising the quality of care. By streamlining processes, reducing unnecessary delays, and automating routine tasks, the system can free up valuable time for health care professionals, enabling them to focus on direct patient care.

> *There are many pregnant women as patients, as you can see right now, there are 30. And my time is limited, right, so for one patient we need fast.* [DR10]

Infrastructure

Overview

The infrastructure dimension highlights the tangible challenges related to equipment availability/performance and access to technical support. Key challenges within this dimension were identified, including the availability of required equipment and infrastructure, as well as the difficulty in accessing technical support. For instance, there is a significant gap in network quality and availability between different areas, hindering the system's effectiveness; in such settings, offline capture-and-sync strategies are used to ensure data transmission. Additionally, the lack of easy-to-reach technical support further complicates the smooth operation and maintenance of the system. Where connectivity issues affect the timing of care or reminders, we discuss implications under process timeliness.

Tangible (Equipment)

Availability of Required Equipment and Infrastructure

In many cases, the necessary equipment and infrastructure are not uniformly available, leading to significant disparities in health care delivery. The gap between urban centers and suburban or rural areas is often substantial, even within the same region. While downtown areas might have advanced technology and reliable network connectivity, many suburban and rural regions face challenges such as poor network access and inadequate infrastructure. These communication access issues are particularly problematic in health care, where a strong and consistent network is essential for the timely transmission of data, remote consultations, and other critical services.

> *Yes, that's why I said because this technology has the obstacle, right, not all regions have a good network, right, that's why there is offline data transmission. When it is downloaded, it enters like that, so there are various strategies.* [DR4]

Lack of Technical Support

A lack of accessible and timely technical support can lead to frustration, decreased trust in the system, and ultimately, reduced usage. An app provided by the government nationwide could have centralized support that can be difficult to reach. This is especially critical in health care, where delays or difficulties in

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accessing information can have serious implications for patient care.

> *No, we usually can't directly contact the technical support, because that's the program from the Health Office.* [BD2]

Policy

Overview

The policy dimension covers the guidelines, regulations, and resources that shape how such systems are developed and applied. Several challenges were identified within this dimension, particularly concerning compensation, cost, and standardization. Key challenges include the lack of alternatives for patient monitoring, budget limitations, and the disparity between costs and perceived benefits. Additionally, the need for standardized application development and strict regulatory compliance is emphasized to ensure that health facilities and developers follow government regulations and medical practice standards. Budget limitations pose a significant challenge, particularly for health facilities with restricted resources, which may hinder the system's full implementation. Additionally, the balance between cost and benefit is a concern, with potential cost burdens on patients that could diminish the system's perceived value.

Assurance

Compensation (Absence of Alternatives for Patient Monitoring)

Clinicians still keep paper records because digital systems are error-prone or go down; paper becomes the source of truth, and outages force providers to reconfirm info with patients. Without a manual backup, progress cannot be tracked during downtime.

> *They have manual records ... So they have a record if they are going to get around, they have data on which one they want to visit.* [GO3]

A fragmented app ecosystem also persists: facilities build their own tools due to limited guidance, leading to poor integration. What is needed is a unified, interoperable platform rather than many siloed apps; government support often stops at web resources.

> *If we're talking on a national level, why should every health care facility have to create its own app, right? Ideally, they should just be able to integrate.* [DR12]

Cost

Budget Limitation in App Implementation

While large hospitals can make significant investments in IT infrastructure, the cost of developing and maintaining health care apps can be prohibitively expensive for smaller institutions. These primary and regional facilities often operate on limited budgets, and local governments, which are responsible for funding these centers, also face financial constraints. The Ministry of Health may not allocate sufficient funding for health care IT, leaving these institutions with inadequate resources to implement and sustain these systems. As a result, even if an app is developed, its long-term viability is at risk if funding stops.

> *I have also made an application for pregnant women ... but the cooperation was only 3 years, and now it can no longer be accessed.* [GO1]

While there may be abundant ideas for innovative solutions, the in-house IT teams are often focused solely on managing daily operations and maintaining existing infrastructure, leaving no capacity for the development of new applications. This creates a significant gap, as organizations must then rely on third-party developers to build and implement the system. However, contracting with external developers can be costly, especially for smaller health facilities with limited budgets. This reliance on third-party services further strains financial resources, making it difficult to invest in the necessary IT infrastructure.

> *The logic in the application can be used, for example, to make recommendations and others whose data has been entered but we're still limited in resources that the person who works on it also does not available.* [GO2]

Inequal Benefit Compared to Cost

For many patients, the cost burden of using health care technology can be a significant barrier. The technology must be affordable, accessible, and easy to use to encourage widespread adoption. If an app requires payment, subscription fees, or is cluttered with advertisements, patients are often reluctant to engage with it, preferring alternatives that are free or less intrusive.

> *Number one, of course, the most important thing later is that this technology must be cheap, right? It has to be cheap, anyone can buy it, right?* [DR4]

Many stakeholders may feel that the high costs associated with developing, deploying, and maintaining such a system are not justified by the benefits it provides. This sentiment is particularly strong when the perceived needs are not fully met by the system, leading to dissatisfaction and reluctance to invest. Additionally, the recent release of a government-backed app can worsen these concerns, as users may question the necessity of investing in a separate system when a potentially more cost-effective or widely supported alternative is available.

> *It seems that the price is also not bad. Then the hospital may also feel that it is not too necessary because there is no interest either. Maybe it would be very useful if the model was in remote areas like that might be more useful.* [DR3]

Standard

Standardization in Application Development

Currently, patients who visit multiple facilities often encounter a variety of record-keeping formats, leading to confusion and difficulty in managing their medical history. This lack of uniformity can be particularly problematic when there are many parties involved in a patient's care, raising questions about who is responsible for data input and how the information should be

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managed. Moreover, a standard for connecting medical devices is needed, as each device may operate under different protocols.

> *So it's tricky and sometimes because of the custom protocol, they have updates, in the previous backend so that the integration of the device needs efforts and there is no standard.* [VD2]

Regulatory Compliance

Health care providers are required to adhere to strict data privacy regulations, reflecting widespread concerns among patients and providers about the safety and confidentiality of medical data. According to regulations, medical data must remain confidential. However, there is a particular fear that connecting an app to an electronic medical record system could expose sensitive data to risks such as hacking, loss, or tampering. This skepticism is often heightened by concerns over user negligence, as users frequently fail to keep their credentials secure, making them vulnerable to data leaks. In other cases, storing patient data within an application is not allowed by law, yet practical challenges, such as signal problems, can delay the immediate transmission of data, complicating compliance.

> *We refer to the old law, the old health law, so applications like this are very, very comply. So there is no data at all that can be stored in the application, on a cell phone. Because this medical data is sensitive, and there is a legal impact, if we refer to the old law, all the data must not be stored in ... we couldn't save in ... save first, in the cache or here in the application or in the cell phone, all data is sent immediately.* [VD1]

The WHO provides standards and guidelines for medical practice; yet, not all applications easily comply, even with these guidelines in place. Hospitals often face lengthy bureaucratic processes that can hinder the implementation of such systems, while clinics may exhibit more flexibility. Despite the push for connectivity and standardization, there are still a few implementations that successfully send data to a unified platform, and not all vendors possess the capability to ensure seamless connectivity.

> *So the behavior is somewhat different between hospitals and clinics. We used to fit into the hospital and it is true that they are difficult to change, the bureaucracy is long, one feature can take a long time. But for clinics, they actually tend to be more flexible. The problem is that we can say that this regulation must require this.* [VD2]

Table 3 summarizes the 6 major challenges with operational definitions, exemplar quotes, and associated actors (patients, clinicians, midwives, vendors, managers, regulators). We include a concise map here for readability; the expanded map with all subthemes and additional examples appears in Multimedia Appendix 3.

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Table 3. Major challenges to implementing a maternal-care health recommender system (HRS) with operational definitions, exemplar quotes, and primary actors.

Major challenge and indicator	Operational definition	Exemplar quote	Primary actors
People			
Skill			
Individual factor	Counts when users lack the skill/confidence to navigate the HRS, find and understand needed information, or enter data so they are shifting to paper or other workarounds; excludes technical/device failures.	"Sometimes it is even more complete what is written, which is in a book than what is typed." [DR2]	BD, DR, GO, PS
Process			
Accuracy			
Incorrect input	Counts when recorded values are factually wrong at entry or later corrupted (manual entry, device miscalibration, app-induced loss); excludes missing/late data.	"Lab system isn't connected; staff enter results manually; risk of human error." [DR7]	BD, DR, GO, PS, VD
Quality of output	Counts when recommendation content or routing is incorrect/ambiguous/misdirected and causing misinterpretation; excludes correct but late (timeliness) or incomplete-input cases.	"Estimated due date in the app was about a month off." [PS10]	DR, PS, VD
Partial availability of required data	Counts when only a subset of required inputs is available, preventing accurate computation; excludes wrong values.	"If only patient-reported data are available, recommendations may be inaccurate." [DR6]	DR
Completeness			
Lack of data integration	Counts when required data sources (medical records/registers/devices/government apps) are not linked, causing fragmented records or duplicate entry; excludes wrong values (accuracy) or late arrival (timeliness).	"The issue is it's not integrated with medical records." [DR1]	BD, DR, GO, MG, PS
Partial information	Counts when only a subset of required fields or longitudinal history is available at the point of use, limiting recommendations; excludes integrated but incorrect data.	"They don't see previous patterns; combining history reveals risk factors." [VD1]	BD, DR, MG, PS, VD
Timeliness			
Continuity of maternal care	Counts when ANC service continuity is interrupted because the app/system is unavailable/unstable or lacks timely follow-up mechanisms; excludes accuracy/completeness issues.	"Online apps help initially, but there's no follow-up with the same doctor." [DR5]	BD, GO
Delivery time of service in maternal care	Counts when ANC services, alerts, or information are delivered after recommended clinical windows or too late to act; excludes misrouted/incorrect content (accuracy) or missing inputs (completeness).	"If they must open the app each time, they might miss it." [VD1]	BD, DR, GO, PS, VD
Time efficiency in patient handling	Counts when HRS-related steps cause avoidable delays (eg, slow loading, manual entry, multi-screen navigation) that reduce throughput; excludes staffing/scheduling delays unrelated to the HRS.	"There are many patients and limited time so we need to be fast." [DR10]	DR
Policy			
Cost			
Budget limitation in app implementation	Counts when budget/capacity for development, maintenance, integration, or platform compliance prevents deployment or continuity; excludes standards/regulatory issues (see Standard).	"Access stopped after three years; maintenance and cooperation were constrained." [GO1]	DR, GO, VD
Perceived benefit does not justify cost	Counts when stakeholders judge benefits do not justify costs for patients/providers/organizations, reducing willingness to adopt or pay; excludes provider-side budget limits (see row above).	"This technology must be cheap ... anyone should be able to buy it." [DR4]	PS, DR, GO, VD
Standard			
Standardization in application development	Counts when lack/inconsistency of shared technical standards or device protocols makes integration or development hard; excludes pure budget issues.	"Because of the custom protocols and no standard, when there's updates the device integration needs extra efforts." [VD2]	BD, DR, GO, PS, VD

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Major challenge and indicator	Operational definition	Exemplar quote	Primary actors
Regulatory compliance	Counts when legal or institutional requirements constrain data storage/processing or delay adoption; excludes technical-standard gaps.	"Old law required no data stored on the phone; everything must be sent immediately." [VD1]	DR, GO, PS, VD

Discussion

Principal Findings

The HRS is equipped with the features needed to assist medical professionals in their current roles and the patients they serve [15]. This system provides users with a variety of recommendations that support individuals in taking charge of their health and help medical professionals make the best choices [15]. This study investigated anticipated challenges and requirements for implementing an HRS for maternity care in Indonesia. We found 6 major challenges regarding skill, accuracy, completeness, timeliness, cost, and standardization, which primarily lie within the people and process dimensions. These 6 major challenges were mentioned 96 times, or 64.43% of all the codes extracted from the interviews. Our analysis of stakeholder interviews suggests a primary focus on real-time, individual-level recommendations, while surveillance applications remain conceptual at this stage.

HRS can be used by both health care professionals and patients, where health care professionals use the system to access supplementary information while patients use the system to receive health-related content that is based on evidence [15]. Additionally, these systems allow patients not only to browse relevant content but also to receive alerts, notifications, risk predictions, and other actionable guidance through the application [32]. Our study shows that one of the major challenges identified is the varying skill levels of users interacting with the HRS. Users, including health care professionals and patients, may struggle with navigating, understanding, and accessing the correct information in the application. This is combined with difficulties in adding or updating new information. If the system is not user-friendly or intuitive, there is a high risk that users may become frustrated or disengage, which would ultimately affect the quality of care and the overall effectiveness of the system. Poor usability in health information systems can lead to negative outcomes such as medical errors, clinician burnout, and patient disengagement [47]. Improving health IT usability is not possible without actively involving users in the design, testing, and implementation stages to ensure the system aligns with their real-world practices and enhances their work rather than creating additional challenges [47]. Priambodo et al [36] discovered that simplicity is a key factor in implementing HRS for maternal care. The app should deliver information quickly, raise awareness, and be user-friendly. Although a significant amount of information needs to be entered, the data recording process should remain simple and clear to ensure that important messages are not missed, enabling both patients and doctors to make informed decisions [48]. Meanwhile, Abejirinde et al [26] found that, despite the perceived usefulness and motivation of users, individual factors such as low technological self-efficacy and limited knowledge hindered the use of the system.

Second, our study shows that accuracy in data entry and processing is a critical concern. Manual input by health care professionals or patients may lead to errors, creating biases or discrepancies in the data. These inaccuracies can arise from technical issues within the application, such as failure to properly record data or rendering previously entered data unreadable. Ensuring that the devices used for data input are properly calibrated is crucial, as this ensures that the system can capture and process data accurately, particularly for sensitive health measurements. Wang and Preininger [49] also found that errors in measurements from various devices can impact the accuracy and reliability of results. Therefore, it is crucial to develop methods that can effectively model and minimize these measurement errors to ensure accurate physiological data analysis. Technical problems during data entry, such as the inability to correct errors and frequent software malfunctions, could lead to further inconsistencies [50]. Additionally, Shiferaw et al [51] identified instances where data were accidentally deleted, memory cards failed, resulting in data loss, and phones became dysfunctional, rendering them unusable when required. Abejirinde et al [52] also found that a malfunction caused incorrect dates to appear in numerous records from one of the facilities, illustrating how system malfunctions can affect the accuracy of health data. Perceived reliability is essential for user satisfaction and the intention to use interactive IT, as it demonstrates the technology's ability to deliver services consistently, securely, and accurately as promised [53]. These examples highlight the importance of addressing both manual and technical issues to ensure the accuracy, reliability, and overall user trust in health data systems.

Our study also found that the quality of the recommendations generated by the system is just as important as the accuracy of the input. The recommendations must reach the correct person, specifically the individual responsible for taking action based on the health information. Misinterpretations or inaccurate recommendations can lead to confusion, potentially putting patients at risk. This issue is further compounded when patients feel that the system fails to provide adequate information about their maternal health, which undermines the system's credibility and trustworthiness. Carlisle et al [54] identified usability issues with the app, including the misinterpretation of obstetric definitions within the app's fields, which aligns with our findings. Furthermore, Lobach [55] reported that ensuring effective nationwide implementation of clinical decision support systems and knowledge management systems requires more than simply delivering the correct information to the right individual. Lobach [55] also found that a deeper understanding of what constitutes the correct information, and when and how it should be delivered, is necessary to expand the reach of clinical decision support beyond isolated, well-established institutions. This underscores the importance of both the quality and timing of recommendations in maintaining system reliability and patient trust.

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In some cases, HRS may not have access to all the necessary data required to generate accurate recommendations, which limits their ability to provide comprehensive and actionable suggestions, ultimately affecting the quality of maternal care. Ensuring that all relevant data are captured and integrated is critical for the system's effectiveness. The data sources for these systems can include user input or information directly obtained from measurement devices [56]. However, even when the suggested diagnoses are generally adequate, the top recommendation's accuracy can be compromised by ineffective information collection and the system's inability to capture subtle clinical clues recognized by health care professionals, making the recommendations less useful and more time-consuming [57]. Reengineering workflows to better integrate eHealth solutions is crucial for enhancing efficiency, optimizing task distribution, ensuring patient safety, and improving the completeness and quality of data collected from patients [58].

Third, our study shows that a significant challenge with current HRS is the lack of integration across various data sources. Ideally, these systems should integrate data from multiple platforms, such as medical records and government databases, enabling both health care professionals and patients to access all necessary information through a single application. However, current systems often only support data collection, lacking alerts, reminders, or actionable recommendations due to limited integration, which reduces their overall effectiveness. A typical HRS framework gathers information about a patient's health status from sources like electronic medical records or electronic health records through secure network protocols to create personal health records [59]. Clinicians found such systems less useful when they were not integrated with other systems, like pharmaceutical databases that provide information on available medications, leading to recommendations that were not helpful when the prescribed medications were unavailable [57].

Another related challenge identified in this preimplementation study of HRS for maternal care is the incomplete information provided by the system. Both patients and health care workers have noted that the information offered is often insufficient to meet their needs. While the system may simplify data recording, users are not receiving the full range of information required to make informed decisions regarding maternal care. Uncertainty in HRS is also associated with potential risks, such as inaccurate predictions due to user preferences not being fully captured, or difficulties in identifying optimal patterns because of incomplete data [32]. Enhancing the system's capacity to provide comprehensive, detailed data will be essential for improving maternal care outcomes.

Fourth, our study shows that the continuity of maternal care is essential, and disruptions in the HRS can interrupt health care workers' ability to provide consistent care. If the application is unavailable or disrupted, it hinders the ability of health care providers to follow up with patients and ensure continuous service. To support uninterrupted care, the system needs to be highly reliable and accessible at all times. DeLone and McLean [60] identified reliability, completeness, and accuracy as key metrics for assessing information quality in an information system. Consequently, hospitals must ensure timely operation and delivery of promised services, implement automated processes, and provide all necessary services to meet patients' needs, thereby offering excellent public service [41].

Timely service delivery is crucial in maternal care, where delays can have significant consequences for both the mother and child. The system must ensure that health care services and recommendations are delivered promptly to address any immediate health concerns, thereby enhancing the overall quality of care. Saha et al [50] found that clinicians faced difficulties using the application offline when it required internet connectivity to manage beneficiaries' details. Shiferaw et al [51] also found that while the system generally operated well, disruptions may occur due to poor network connectivity or power outages. Ensuring reliable connectivity was challenging during implementation in low- and middle-income countries [61].

Another benefit of improving the timeliness of the HRS is the potential for greater time efficiency in patient handling. With faster and more accurate data processing, health care providers could manage more patients within the same time frame, leading to improved health care efficiency and the ability to serve a larger population. These systems are designed to reduce the time and effort involved in the health care decision-making process, thereby lowering the overall costs [32].

Fifth, our study shows that the cost of developing and implementing HRS in health care facilities is a major concern. Developing these systems requires specialized resources, and many health facilities face budgetary limitations that prevent them from implementing comprehensive and functional solutions. This financial barrier can slow the adoption of such technologies, particularly in resource-constrained settings.

There is also a concern about the perceived cost-benefit ratio of using the system. Some users, particularly patients, feel that the financial burden of adopting the system does not justify the benefits they receive from it. If the system is seen as expensive but ineffective or difficult to use, this perception will act as a deterrent to widespread adoption. Ensuring that the benefits clearly outweigh the costs will be essential for driving the success of the system.

Sixth, our study shows that a lack of standardization in the development of HRS poses a significant challenge. Without standardized guidelines, it is difficult to ensure that these applications are developed in a way that makes them user-friendly, reliable, and compatible across different platforms. Developing and enforcing standards will streamline the development process, ensuring that applications meet the necessary quality and usability benchmarks. For the long-term viability of scaling up, it is vital to develop standards for the mobile health ecosystem that account for service integration and interoperability [51].

Regulatory compliance is another important challenge. HRS must adhere to government regulations and medical practice standards, ensuring that they align with the legal requirements for health care applications. Health facilities and application developers are obligated to follow these regulations, and failure to comply could result in legal issues, reduced system credibility,

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and potential harm to patients. Therefore, compliance with regulatory standards is a critical consideration for successful implementation. Adhering to standards ensures that health care services are delivered consistently and meet patients' needs and expectations [62]. Among various dimensions, the policy dimension is the most crucial and should be clearly defined first to ensure that all hospital activities comply with standards related to personnel, processes, and infrastructure. Without a well-defined and standardized policy, the dimensions of human resources and processes cannot function effectively. To enhance patient trust and offer affordable services, the policy dimension should also include guarantees aligned with fairness principles, as well as compensation or warranties for patients who encounter issues.

The findings of this formative, preimplementation study have significant implications for the implementation of HRS in maternal care. Practically, improving the user interface is essential, as some users struggle to navigate and update information; a simpler, more intuitive design will help both patients and health care providers access and input data more easily. Ensuring that devices used for data input are properly calibrated is also crucial for collecting accurate health data, which is vital for generating reliable, actionable recommendations. Additionally, the system should be reliable and accessible at all times to support continuous care, enabling health care providers to respond to real-time health needs and manage more patients efficiently. At the implementation level, the study underscores the importance of evaluating usability, feasibility, and cost implications, especially in resource-constrained settings, to inform adoption. Furthermore, adherence to regulatory standards and the establishment of standardized guidelines are key to ensuring system quality, safety, and trustworthiness across diverse health care environments.

Consistent with the WHO Global Strategy on Digital Health 2020-2025, these findings highlight the need for interoperable, sustainable, and people-centered digital health systems that strengthen public health surveillance and data-driven maternal care [63]. Similarly, the WHO Classification of Digital Interventions, Services, and Applications in Health (second edition) identifies core digital functions such as client's health tracking, health care provider decision support, and data collection management that align closely with the capabilities of the maternal HRS examined in this study [64].

Although infrastructure challenges were not among the most frequently cited issues in this formative study, participants noted that reliable connectivity, compatible devices, and system interoperability are essential prerequisites for sustained system performance and adoption. These considerations also align with the WHO Global Strategy on Digital Health 2020-2025, where accessibility and interoperability are identified as strategic objectives for developing scalable and equitable digital technologies for global health [63]. Aligning the design and implementation of the maternal HRS with these global frameworks can therefore enhance scalability, interoperability, and equitable integration into national health information systems, ultimately contributing to improved maternal health outcomes.

Limitations

This study has several limitations that should be considered when interpreting the findings. First, the sample size distribution among stakeholder roles was uneven, with some groups being more represented than others, potentially limiting the diversity of perspectives captured. Additionally, most patients interviewed were from private clinics, with only a few from government-run community health centers, which may lead to findings that primarily reflect experiences typical of private health care settings. Furthermore, all participants lived or worked in the Greater Jakarta area, where IT infrastructure is sufficient, health care facilities are accessible, and quality medical care is affordable. This urban-centric sampling approach may limit the transferability of our findings to rural or resource-limited settings, where differences in health care access and infrastructure could affect how HRS are implemented. We did not design or evaluate aggregation or data feeds for facility- or population-level surveillance; these implications remain conceptual and require future development and testing. Future research should aim for a more balanced sample and include perspectives from rural or underserved areas to provide a broader understanding of these challenges.

Additionally, usability, feasibility, and pilot studies are needed prior to any effectiveness evaluation. Developing an architecture for maternal HRS based on user needs would be valuable for enhancing system relevance and usability. Beyond cross-stakeholder triangulation, future studies should also integrate regulatory documents and cost data to strengthen confirmability and economic interpretation. In this study, we conducted a limited document review (program guidelines and internal standard operating procedure excerpts) to contextualize perceived barriers.

Conclusions

This formative, preimplementation qualitative study highlights 6 major, stakeholder-perceived challenges to implementing an HRS for maternal care in Indonesia: skills, data accuracy, data completeness, data timeliness, cost/sustainability, and standardization/interoperability. These challenges, primarily within the people and process dimensions, present significant barriers to the successful implementation of the system. Addressing these issues will require a multifaceted approach, including enhancing user training and system usability, ensuring data accuracy and integration, improving the reliability and timeliness of services, managing costs effectively, and establishing clear regulatory standards.

The findings of this research underline the importance of user involvement throughout the system's design and implementation process to ensure that it meets the needs of both health care professionals and patients. Moreover, technical improvements, such as reducing manual input errors and enhancing system reliability, will be critical for building trust and ensuring that the system supports effective decision-making. Finally, ensuring regulatory compliance and developing standardized guidelines will be essential for facilitating broader implementation and ensuring the system's long-term success in improving maternal care outcomes in Indonesia.

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Acknowledgments

Generative artificial intelligence tools were not used to generate scientific content, data interpretation, or analysis. ChatGPT was used to assist with language editing and improving readability, and all text and references were reviewed and verified by the authors to ensure accuracy and originality.

Data Availability

The datasets generated or analyzed during this study are available from the corresponding author on reasonable request.

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Conflicts of Interest

None declared.

Multimedia Appendix 1
COREQ checklist.
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Multimedia Appendix 2
Interview questions.
[DOCX File , 22 KB - formative_v10i1e73726_app2.docx]

Multimedia Appendix 3
Summary of challenges.
[DOCX File , 24 KB - formative_v10i1e73726_app3.docx]

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Abbreviations

ANC: antenatal care
COREQ: Consolidated Criteria for Reporting Qualitative Research
HEALTHQUAL: Healthcare Service Quality
HRS: health recommender system
SERVQUAL: Service Quality
WHO: World Health Organization

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Original Paper

Gaming-Based Community Intervention for Loneliness in Adult Gamers: Longitudinal Observational Study

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Abstract

Background: Loneliness is a form of psychological distress associated with increased risk of depression, anxiety, and adverse health outcomes across the life span. This study evaluates an online gaming-based community intervention that combines professionally facilitated groups, commercial video games, and skills-focused workshops for adults who play video games.

Objective: This study aimed to examine the feasibility of this health-supporting gaming community and to characterize 30- and 60-day changes in depression, anxiety, psychological well-being, and psychological flexibility, as well as heterogeneous trajectories of depressive symptoms.

Methods: In a longitudinal observational study, adults in the United States self-enrolled in a gaming therapeutics community hosted on Discord. Participants completed baseline, 30-day, and 60-day assessments including the Patient Health Questionnaire-9 (PHQ-9), Generalized Anxiety Disorder-7 Scale, World Health Organization-5 Well-Being Index, and Psychological Flexibility Scale (Psy-Flex). Of 438 participants with 30-day data, 403 met inclusion criteria for longitudinal analyses and 157 (35.6%) completed the 60-day survey. Within-person change scores and standardized mean differences were calculated, and latent growth mixture modeling was used to identify depressive-symptom trajectories and baseline predictors of nonresponse versus improvement.

Results: At baseline, mean PHQ-9 score was 13.37 (SD 6.04), decreasing to 10.27 (SD 5.80) at 60 days (Cohen *d*=0.52). Mean Generalized Anxiety Disorder-7 scores decreased from 11.23 (SD 5.24) to 8.25 (SD 4.22) (Cohen *d*=0.60). Psy-Flex scores increased from 11.51 (SD 4.30) to 12.55 (SD 4.37; Cohen *d*=0.24), and World Health Organization-5 Well-Being Index scores increased from 7.86 (SD 3.82) to 8.08 (SD 4.44; Cohen *d*=0.24). Latent growth mixture modeling identified 3 depressive-symptom trajectories: a low group (229/438, 52.3%; baseline PHQ-9 mean 8.80 (SD 3.67); 60-day mean 7.64, SD 3.87), a chronic group (118/438, 26.9%; baseline mean 18.30 (SD 4.03); 60-day mean 16.78, SD 4.10), and an improvers group (91/438, 20.8%; baseline mean 18.52, SD 3.13; 60-day mean 7.42, SD 4.27). In logistic regression among participants with moderate-to-severe baseline depression, a gender identity other than woman was associated with lower odds of belonging to the Improvers versus Chronic group (odds ratio 0.42, 95% CI 0.19-0.94). Post hoc analyses indicated lower odds of improvement for nonbinary participants compared with women (odds ratio 0.25, 95% CI 0.10-0.59). No other baseline characteristics significantly distinguished chronic versus improving trajectories.

Conclusions: A professionally moderated, gaming-based community intervention was feasible to deliver, engaged a diverse sample of adult gamers, and was associated with medium-sized reductions in depressive and anxiety symptoms and small improvements in well-being and psychological flexibility over 60 days. A subgroup moved from moderate-to-severe symptoms to subthreshold depressive symptoms. These findings support further controlled evaluation of health-supporting gaming communities as a scalable support and potential preventive context for adult gamers experiencing distress.

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KEYWORDS

gaming interventions; video games; adult gamers; discord; loneliness

Introduction

Loneliness is a form of psychological distress that has been linked with increased risk of several serious medical conditions like diabetes, stroke, heart disease, dementia, depression, anxiety, suicide, and self-harm [1-6]. By the age of 25 years, almost 80% of individuals will have experienced loneliness at some point in their life, along with the associated health risks like depression, anxiety, suicidal ideation and self-harm, and will likely experience it again as they age [4,7,8]. Due to the increased risk of several severe diseases and mental health risks, loneliness is being identified by large health organizations, such as the Centers for Disease Control and Prevention, World Health Organization, and American Psychological Association, as a critical point of intervention for increasing health and wellness of individuals [1,7,9,10].

Importantly, while increasing prosocial behavior and interaction with a community is commonly proposed, increased social contact is insufficient to decrease loneliness on its own [11]. Conditions such as social anxiety, social skills, self-esteem, and personal distress can all decrease the likelihood that connection with community improves experiences of loneliness [12,13]. This is especially true for marginalized populations, including individuals that are neurodivergent, LGBTQIA+ (lesbian, gay, bisexual, transgender, queer or questioning, intersex, asexual, and others), or Black, Indigenous, and People of Color (BIPOC) that find it difficult to navigate social situations where connection and welcomeness may be ambiguous [14].

Online communal servers and chat services often provide a sense of community and virtual relationships [15], but these communities are often not designed specifically for connection or mental health. Online video game communities can be hostile or "toxic," which does not promote meaningful connection that improves mental health [16-18]. Additionally, gaming has ambivalent attention within the mental health community, given concerns about addiction and social withdrawal [19-21]. Due to this, many have steered away from the potential of using video games, when appropriately designed and supported, to build social connections, community and to combat loneliness. In contrast to these largely unstructured and sometimes "toxic" gaming spaces, the present intervention was intentionally designed as a health-supporting community. It uses explicit community guidelines, structured channels and events, active professional moderation, and therapist-facilitated groups to promote supportive interactions and reduce exposure to harassment, discrimination, and other harmful content.

Research on the mental health of video game players reveals that the gaming community is often distressed, with low physical, social, and mental health reported [22-24]. However, a common belief is that problematic video game use is a cause or catalyst to lower well-being, research suggests that problematic use is a coping strategy for distress rather than the cause [12,19,25,26]. Recent research further highlighted the moderating role that meaningful relationships, especially parent-child relationships have on problematic video game usage and aggressive behavior linked to violent video games [27-30]. This perspective suggests using a systemic lens to evaluate the promises and perils of video games for supporting well-being and community cohesion. Furthermore, video games have been associated with a number of cognitive and mental health benefits, both in the absence of and in addition to traditional treatment options [31-38].

The interpersonal structure of online communities and the documented benefits of gaming suggest an opportunity to reimagine gaming platforms as accessible digital settings for challenging loneliness and promoting well-being. However, given the complex relationship between gaming, online toxicity, and mental health, there is a critical gap in understanding how gaming environments might serve as therapeutic environments. To fill this gap, in this study we investigate whether a communal gaming environment intentionally designed to promote mental health is a feasible and acceptable intervention for improving well-being at 30 days and 60 days. This approach was designed to leverage the unique characteristics of gaming communities and of their online environment to expand individual capabilities combined with group and community interventions that offer new, supportive opportunities to build relationships are essential for breaking self-sustaining feedback cycles that contribute to ill health.

Methods

Setting and Participants

This study is a proof-of-concept feasibility study of a health-supporting online community using a longitudinal observational design. Participants consisted of self-referred users of an online community. Recruitment occurred via targeted social media posts on platforms frequented by gamers (eg, Discord [Discord Inc.], X [X Corp], and Reddit [Advance Publications]), outreach to existing gaming communities, and word-of-mouth referrals from current participants. The structure and reporting of this paper follow the guidelines of the STROBE (Strengthening the Reporting of Observational Studies in Epidemiology) Statement for observational research (Multimedia Appendix 1). Sample selection was nonrandom with primarily purposive and snowball sampling methods. Sample size was based on the feasibility of the program's first phase rather than an a priori calculation. Participants of this group model were included if they were older than 18 years and had access to discord. Participants were excluded from participation if, at sign up, the participant was evaluated to have a condition unsuitable for a subclinical service, such as active suicidality or homicidality, active psychotic symptoms, or ongoing substance use disorders. The final sample consisted of 438 participants.

Program Procedures of Health-Supporting Communities

Systems theory is a useful framework for understanding how patterns in couples, families, groups, and in this case, broader

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communities shape individual thoughts, emotions, and behavior [39-42]. Rather than focusing only on one-to-one treatment, systems theory highlights opportunities to relieve distress by changing the social contexts people inhabit, in ways that complement but do not replace individual care [40,43-45]. Guided by this systems-theory perspective, the gaming community was intentionally structured to address both internal systems of the self (eg, beliefs, emotion-regulation, and interpersonal skills) and external social systems (eg, patterns of interaction in the Discord server and journey groups). In the following sections we give an overview of the theoretical basis, programs, and models we use that were developed with both external and internal system perspectives in mind. The online nature of this program does present potential risks including emotional discomfort or distress due to the discussions in group meetings on discord, the inherent risk of negative interactions from peers in an online community and group setting, as well as possible disclosure of personal issues by peers in groups or communities in a way the individual does not desire. For all of these, efforts were made to reduce risks through online moderation, discussion and reminders of confidentiality in every group meeting, and journey guides (or group leaders) that are trained mental health professionals.

Building Health-Supporting Communities

Peer Relationship Building: Discord Communities

Discord is a platform for social networks, primarily used by gamers, to communicate and build community around a specific topic or game. We organized several "servers" or subcommunities around shared gaming interests. Each server is overseen by moderators and staff, and offers text and voice channels, read-only resources, event spaces, and community rules to encourage and preserve supportive interactions. These online communities are designed to aid in meaningful and health-promoting connections between members [46]. Careful, active moderation of this community facilitates the intended purpose of reinforcing social skills and preserving safety of all parties [13,47]. While the interactions are inherently unstructured, each participant reads and acknowledges the rules of the discord server which are moderated and enforced. These moderation rules are listed in Appendix 4.

Journey Sessions

In addition to Discord communities, weekly group sessions are facilitated by group leaders with counseling or clinical training. A group setting has been selected because group settings have long been found to be effective for providing social support to individuals experiencing distress [48-51] and can be a suitable setting for teaching self-care, social and emotion regulation skills, and offers a practical setting for practicing these skills [48].

This intervention is designed to position peer support as a complement to, rather than a replacement for, trained clinical guidance. Peer-based group interactions, facilitated through cooperative video game play, offer unique benefits, including normalization of social struggles, opportunities for mutual identification, and repeated exposure to low-stakes social engagement that can reduce loneliness through increased belonging and shared purpose [52,53]. However, peer communities alone may be limited in their ability to systematically target maladaptive social cognitions, address avoidance patterns, or scaffold skill acquisition in an appropriate manner. Trained facilitators and structured psychoeducational components can address these gaps by providing evidence-based frameworks (eg, behavioral activation, social skills training, and cognitive models of loneliness), providing psychological safety, and guiding reflection that links in-game social experiences to real-world interpersonal functioning [54,55]. Journey guides (group facilitators) shape norms, reinforce adaptive behaviors, and translate emergent peer interactions into durable skills and insights. In this structure, peers provide authenticity, immediacy, and belonging, while journey guides aid groups in adhering to mechanisms of change and mitigating known risks of unguided peer support [56]. Journey session structure is outlined in Appendix 2.

Commercial video game play (ie, *Minecraft*, *Animal crossing*, etc) is reported to accelerate group cohesion and bonding through shared interests [46], and provides opportunities to explore individual and group dynamics, as well as practice learned skills [57]. Socio-emotional skills are drawn from well-validated interventions such as Dialectical Behavior Therapy [58,59] and Acceptance and Commitment Therapy [60]. Group members are connected in a text channel on Discord that is accessible only by that particular group to foster connection and support throughout the week in between sessions. Group meetings provide a context of support [61,62], accountability, and normalization of challenges and setbacks as skills are learned and practiced [63-65].

Working With Imminent Risk

Protocols were designed and followed for imminent risk within this subclinical, online support program. Guides were not acting as treating clinicians and contact with journeyers occurred in an online environment. These protocols included the following steps. The first step is a crisis-resource channel in the discord. Journeyers were advised frequently throughout participation about the resources within this page. Participants were also instructed how to use the crisis-resource page which included numbers to centers and hotlines. The protocol for addressing imminent threat is included in Appendix 3.

Gaming Therapeutics

Gaming therapeutics use readily available commercial games to further practice skills through preconstructed situations akin to an interactive worksheet set in the game world. They are especially helpful for emotion regulation, executive functions, problem solving, decision-making, and social collaboration [15,48,57,66]. Games like *Minecraft*, *Roblox*, *Skyrim*, and *D&D* have a developer mode that allows designers to create scenarios for specific skill building exercises.

Weekly Session Facilitators

We had a sample of 36 facilitators for these groups. Of these, 11 (31%) reported social work training, 9 (25%) reported art therapy training, 1 (3%) reported a Doctor of Psychology, 8 (22%) reported marriage and family therapy training, 7 (19%) reported mental health clinician training. The average age of

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these facilitators was 32 (SD 4.56). They collectively represent 25 different geographic states in the United States with the most common states being New York, Florida, and Texas. Regarding gender, 28 (78%) facilitators identified as women, 4 (11%) as men, and 4 (11%) non-cis-gendered. All weekly journey groups were led by "journey guides," who were licensed or prelicensed mental health professionals (eg, social work training, marriage and family therapy training, mental health clinician training, art therapy, and Doctor of Psychology) contracted by the program. Before leading groups, guides completed a structured onboarding that included asynchronous training modules on the program model, Discord community guidelines, group structure, and crisis-escalation procedures, followed by live role-play sessions and observation of at least 1 full group cycle. Guides were provided with written session outlines (check-in prompts, group agreements, theme-setting questions, and closing prompts) to support consistent delivery while allowing flexibility to respond to group needs, and they used standardized protocols for moderating chat, handling rule violations, and escalating risk concerns. Throughout the program, guides attended regularly scheduled group supervision meetings (biweekly) with the Director of Clinical Operations and could request ad-hoc consultation for complex cases, including any incidents involving crisis-resource referrals or duty-to-warn decisions.

Measures

Demographic Questions

Participants completed demographic questions including gender identity, race and ethnicity, and self-reported neurodivergent status. These questions were asked during onboarding.

Patient Health Questionnaire-9

We administered the Patient Health Questionnaire-9 (PHQ-9) at entrance to the program and again at 30 days and 60 days via survey. The PHQ-9 is a self-report screener of depression symptoms and severity that has been evaluated as a reliable and valid measure for several populations. There are 9 questions with answers ranging from 0=Not at all to 3=Nearly every day. Symptoms measured include: "Little interest or pleasure in doing things" or "Trouble concentrating on things, such as reading the newspaper or watching television." Due to its relatively short length and sensitivity to change over time [67], it is an ideal measure for gauging distress over time.

Generalized Anxiety Disorder-7 Scale

We also used the Generalized Anxiety Disorder-7 Scale (GAD-7) to measure anxiety symptoms and severity [68]. Like the PHQ-9, this was administered via survey at the start of the program, and then again at 30 and 60 days. This was a 7 item questionnaire that measured symptoms over the last 2 weeks. Each item could be answered from 0=Not at all to 3=Nearly every day. Items include: "Trouble Relaxing" and "Feeling afraid, as if something awful might happen." The GAD-7 was also selected for its length, reliability, validity, and sensitivity to change [69].

World Health Organization-5 Well-Being Index

The World Health Organization-5 Well-Being Index (WHO-5) is a brief, 5-item self-report measure of subjective psychological well-being developed by the World Health Organization [70]. Items assess positive mood, vitality, and general interest over the past 2 weeks (eg, "I have felt cheerful and in good spirits"), with responses scored from 0 ("at no time") to 5 ("all of the time"). Item scores are summed to yield a total score from 0 to 25, which is then multiplied by 4 to produce a 0-100 index, where higher scores indicate better well-being. The WHO-5 is widely used as a generic measure of mental well-being and has demonstrated good reliability and construct validity across clinical and non-clinical populations, including digital mental health and community samples. In this study, the WHO-5 was administered at baseline, 30 days, and 60 days to index changes in positive well-being alongside symptom measures.

Psychological Flexibility Scale Inventory

The Psychological Flexibility Scale (Psy-Flex) was also administered at baseline, 30 days and 60 days [71]. This is a 6 question assessment of psychological flexibility. Statements are measured over the last 2 weeks and include items such as: "Even if I am somewhere else with my thoughts, I can focus on what's going on in important moments." and "I can look at hindering thoughts from a distance without letting them control me." Scores for each question range from 1 to 5 and total scores are summed. This measure was chosen for its short length as well as its connection to the psychological flexibility literature, in which greater psychological flexibility is associated with reduced symptoms and better functioning across a range of mental health concerns. In this study, psychological flexibility was examined as a candidate process through which participation in skills-focused groups and community activities might support improvements in depression, anxiety, and well-being [71].

Data Analysis

Data were pulled from the program in January of 2024. Demographic data were gathered for participants who responded to an invitation to complete measures about their experience in the program. Only those who had at least 2 time points were included in the analysis. Participants were then separated into 2 groups based on their baseline scores for the GAD-7 or PHQ-9.

To model changes in depressive symptoms following enrollment, we conducted Latent Growth Mixture Modeling (LGMM) to identify distinct subgroups characterized by different PHQ-9 symptom trajectories over 60 days in the subclinical support program. We focused trajectory modeling on PHQ-9 scores given the higher comorbidity between loneliness and depression [1] as well as sample size considerations. We used an intent-to-treat approach for the LGMM by including all participants and handling missingness through full information maximum likelihood. We modeled nested unconditional LGMMs with increasing numbers of trajectories (1-4). All models included random effects for the intercept and slope parameters and a fixed quadratic growth factor to capture potential nonlinear change patterns in depressive symptoms over time. The best fitting model was determined using a combination of fit indices and theoretical considerations [72]. Examined criteria included Bayesian information criterion, sample-size adjusted Bayesian information

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criterion, Akaike information criterion, relative entropy, and statistical significance of the Lo-Mendell-Rubin likelihood ratio test and the bootstrap likelihood ratio test. Additionally, we considered parsimony, class interpretability, and clinical relevance when selecting the final model [72]. After determining the best fitting LGMM solution, we conducted logistic regression analyses to identify baseline participants' characteristics that distinguished between trajectories with higher baseline symptoms showing nonresponse versus improving PHQ-9 patterns. Variables included in the analysis consisted of race (identifying as non-Hispanic White and BIPOC), gender (identifying as woman, man, or other), baseline PHQ-9, WHO-5, and GAD-7 scores, and psychosocial flexibility assessed at baseline (ie, Psy-Flex score).

Ethical Considerations

Participants were recruited prior to joining a group and the discord community. They agreed via the service terms of use and a separate informed consent process to their data being collected for research purposes in a de-identified, aggregated fashion. Research on the feasibility of this support model followed ethical guidelines for human research. Data intended for research use was stripped of identifying information (ie, names, Discord handles, contacts, dates, and account numbers) and were linked across datasets based on anonymized IDs. Regarding data from discord, the server is private (invite-only) and only designated staff and moderators have access to nonanonymized logs. Researchers were only able to access deidentified exports of these. Study analytic procedures were approved as exempt by the NYU School of Medicine Institutional Review Board (i24-00822). Group members were compensated via free sessions for a month. Participants were free to leave the group at any time.

Results

Participants and Demographics

A total of 438 participants that provided follow-up data at their 30-day mark were included in this analysis. Of these, 157 (35.61%) also completed the 60-day survey at exactly 60 days. There was a portion who completed the 60-day survey more than 10 days after the 60-day mark (n=34) or earlier than 20 days before the 60-day mark (n=1). These 35 were dropped from change analyses and demographics. The LGMM analysis was performed with all 438 participants. The demographic and longitudinal change scores were analyzed with n= 403.Of those in the clinically elevated group, 98 (28.91%) completed the 60 day survey. In the subclinical group, 24 (27.90%) completed the 60-day follow-up.

Community demographics reveal an incredibly diverse population with 29.38% (118/403) identifying as BIPOC, 48.64% (196/403) neurodivergent (eg, autism and attention-deficit/hyperactivity disorder), and 25.27% (102/403) noncisgender gender identities. Overall, 45.92% (180/403) of participants identified as women and 28.83% (113/403) identified as men (Table 1). These counts surpass the latest US census demographics (82,862,320/331,449,281, 25% BIPOC, 66,289,856/331,449,281, 20% neurodivergent, and 39,773,914/331,449,281 12% gender minorities), highlighting the diversity of video game communities. Demographic information by grouping is reported in Table 2.

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Table 1. Baseline demographic characteristics of adult gamers (n=403) in a longitudinal online gaming community intervention for loneliness (United States, 2023-2024) compared to 2020 US census population.

Demographic categories[a]	Hero Journey Club participants, (n=403), n (%)	US census 2020 (n=331,449,281), n (%)
BIPOC[b]	118 (29.38)	(82,862,320 (25%)
Indigenous	2 (0.52)	—[c]
Asian	14 (3.61)	—
Hispanic	22 (5.67)	—
Black	15 (3.87)	—
Multirace	47 (12.11)	—
Others	2 (0.52)	—
Non-Hispanic White	274 (70.62)	—
Neurodivergent	196 (48.64)	66,289,856 (20)
Gender identity	125 (31)	39,773,914 (12)
Transgender woman	11 (2.81)	—
Transgender man	15 (3.83)	—
Nonbinary	68 (17.35)	—
System	5 (1.28)	—
Men	113 (28.83)	165,724,640 (50)
Women	180 (45.92)	165,724,640 (50)

[a]Baseline demographic data collected from 403 adult participants enrolled in the Hero Journey Club online gaming community intervention targeting loneliness. Percentages reflect the diversity of the sample compared to general population estimates from the 2020 US Census.

[b]BIPOC: Black, Indigenous, and People of Color.

[c]Not applicable.

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Table 2. Longitudinal changes in anxiety (Generalized Anxiety Disorder-7 Scale), depression (Patient Health Questionnaire-9), well-being (World Health Organization-5 Well-Being Index), and psychological flexibility among adult gamers in online gaming community intervention for loneliness at baseline, 30-day, and 60-day follow-up (United States, n=403).

Statistics	Baseline	30 days	60 days
GAD-7[a]			
Mean (SD)	11.23 (5.24)	9.03 (4.99)	8.25 (4.22)
Cohen *d*[b]	—[c]	0.43	0.60
t test (*df*) between time points[d]	—	6.3863 (874)[e]	1.7260 (593)
PHQ-9[f]			
Mean (SD)	13.37 (6.04)	11.01 (6.15)	10.27 (5.80)
Cohen *d*	—	0.39	0.52
t test (*df*) between time points	—	5.7492 (874)[e]	1.3001 (593)
WHO-5[g]			
Mean (SD)	7.86 (3.82)	8.22 (4.03)	8.08 (4.44)
Cohen *d*	—	–0.092	–0.24
t test (*df*) between time points	—	–1.3593 (874)	–1.5132 (593)
Psy-Flex[h]			
Mean (SD)	11.51 (4.30)	11.87 (4.41)	12.55 (4.37)
Cohen *d*	—	–0.08	–0.24
t test (*df*) between time points	—	–1.2327 (874)	–1.6497 (593)

[a]GAD-7: Generalized Anxiety Disorder-7.

[b]Effect sizes (Cohen *d*) compare baseline scores to each follow-up time point.

[c]Not applicable.

[d]*t* tests compare consecutive time points.

[e]*P*<.001.

[f]PHQ-9: Patient Health Questionnaire-9.

[g]WHO-5: World Health Organization-5 Well-Being Index.

[h]Psy-Flex: Psychological Flexibility Scale.

Change in Anxiety and Depression

Results for Anxiety and Depression at 60 days are reported in Table 2. At baseline, the average PHQ-9 score was 13.37 (SD 6.04), which falls in the high moderate severity range. At the 60-day follow-up, the average score was low moderate at 10.27 (SD 5.80), with a medium Cohen *d* effect size of 0.52. The average baseline GAD-7 score was 11.23 (SD 5.24), in the low moderate range, and 8.25 (SD 4.22), a high mild, subthreshold score at the 60-day follow-up, with a medium Cohen *d* effect size of 0.60. Psy-Flex and WHO-5 results at 60 days are similarly reported in Table 2. Average baseline scores were 11.51 (SD 4.30) for the Psy-Flex with an average of 12.55 (SD 4.37) at 60 days. The WHO-5 average baseline was 7.86 (SD 3.82) with an average 60-day score of 8.08 (SD 4.44). Cohen *d* for Psy-Flex at 60 days was –0.24 and the WHO-5 Cohen *d* was also –0.24.

Heterogeneous trajectories of depressive symptoms change were estimated using LGMMs. The tree class solution was identified as optimal, with model fit indices reported in the Multimedia Appendices 2-4. Sensitivity analyses suggested no significant differences in likelihood of trajectory membership between survey completer and noncompleters at 30 days ($^2_2$= 0.71 (n=438); *P*=.70) and 60 days ($^2_2$=1.53 (n=438); *P*=.47). The 3 identified trajectories showed distinct patterns of depressive symptom change over 60 days of engagement with the subclinical support program (Figure 1).

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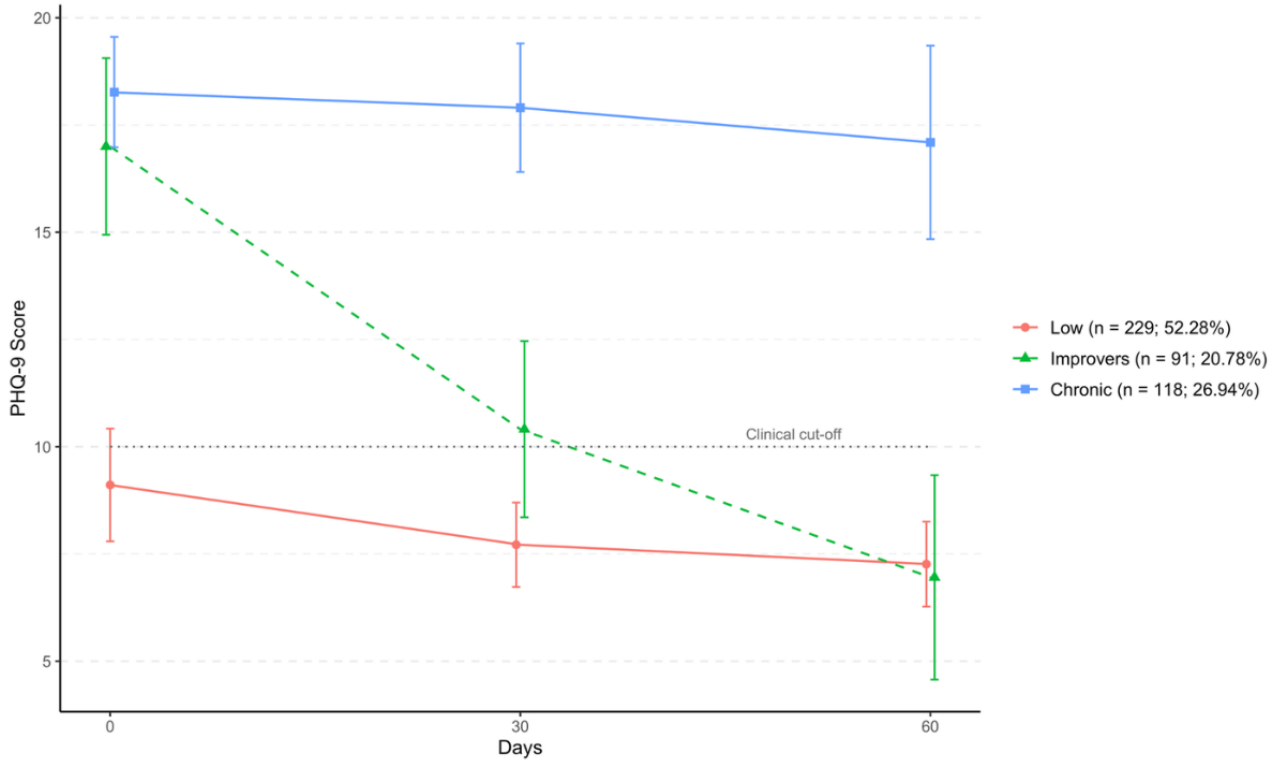
Figure 1. Three heterogeneous trajectories of depressive symptoms (Patient Health Questionnaire-9) over 60 days among adult gamers in online gaming community intervention for loneliness using latent growth mixture modeling (United States, n=438).



The modal trajectory ("Low"; n=229, 52.28%) was characterized by baseline mild to moderate symptoms (baseline PHQ-9 score: mean 8.8, SD 3.67) with a slight decreasing slope over 60 days (60 days PHQ-9 score: mean 7.64, SD 3.87). The second largest heterogeneous subgroup ("Chronic"; n=118, 26.94%) was characterized by baseline moderate to severe symptoms (Baseline PHQ-9 score: mean 18.3, SD 4.03) with no significant change over time (60 days PHQ-9 score: mean 16.78, SD 4.10). The third largest trajectory ("Improvers"; n=91, 20.78%) was characterized by initial baseline moderate to severe PHQ-9 scores (baseline PHQ-9 score: mean 18.52, SD 3.13), which improved to moderate depression levels at 30 days (30 days PHQ-9 score: mean 10.17, SD 4.01) and below the clinical cutoff following 60 days (60 days PHQ-9 score: mean 7.42, SD 4.27).

To identify baseline characteristics that distinguished between participants with moderate to severe baseline depression (n=209) and who exhibited nonresponse versus those who showed symptom improvement, we conducted a logistic regression examining predictors of trajectory membership in the Chronic versus Improvers groups. Results from the analysis indicated that a gender identity other than "woman" was more likely associated with nonimprovement in PHQ-9 scores (odds ratio [OR] 0.42, 95% CI 0.19-0.94; *P*=.04). We further examined potential differences between specific gender identities in post hoc analyses. We conducted multiple pairwise logistic regressions with women as the reference group for each other gender category. Bonferroni correction was applied for 4 pairwise comparisons (α=0.0125). Findings from the post hoc analyses indicated that non-binary individuals (n=68) had significantly lower odds of Improving compared to women (OR 0.25, 95% CI 0.10-0.59; corrected *P*=.009). No significant differences were observed for men, trans women, or trans men compared to women. No other baseline factors significantly distinguished between Chronic and Improvers trajectories. Results are reported in Table 3.

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Table 3. Baseline predictors of Chronic Elevated Symptoms versus Improvers trajectory membership using logistic regression among adult gamers with moderate-to-severe baseline depression in online gaming community intervention for loneliness (US, n=209).

Variables	Elevated Symptoms Improvers[a]	
	OR[b] (95% CI)	*P* value
Baseline PHQ-9[c]	1.03 (0.94-1.13)	.49
Baseline GAD-7[d]	0.94 (0.87-1.01)	.10
Baseline WHO-5[e]	0.95 (0.85-1.07)	.40
Baseline PsyFlex[f]	0.93 (0.86-1.00)	.05
Race (non-White)	1.337 (0.70-2.54)	.38
Sex (female)[g]	1.46 (0.72-2.95)	.30
Sex (other)[g]	0.42 (0.19-0.94)	.04

[a]Logistic regression examining baseline demographic and clinical predictors distinguishing participants with persistent elevated depressive symptoms (Chronic trajectory) from those showing symptom improvement (Improvers trajectory) over 60 days. Analysis restricted to participants with moderate-to-severe baseline depression (PHQ-9 ≥10).

[b]OR: odds ratio.

[c]PHQ-9: Patient Health Questionnaire-9.

[d]GAD-7: Generalized Anxiety Disorder-7.

[e]WHO-5: World Health Organization Well-Being Index.

[f]Psy-Flex: Psychological Flexibility Scale.

[g]Reference category: Sex (male).

Sensitivity Analysis

Sensitivity analyses indicated no significant differences in terms of baseline characteristics between participants who completed all surveys or showed survey nonadherence at 30 and 60 days. Results are reported in the supplementary materials.

Discussion

Main Findings

In this longitudinal proof-of-concept study, we examined the feasibility and both 30- and 60-day changes among adults participating in an online gaming therapeutics community. Retention to 60 days was relatively strong for a remote, subclinical program, but this may partly reflect the fact that participants were receiving paid services, which could increase motivation to remain engaged compared with fully free or purely research-based interventions. Overall, participants showed significant improvements in depressive symptoms, anxiety symptoms, psychological well-being, and increases in psychological flexibility over 60 days. LGMM identified 3 depressive-symptom trajectories (Low, Chronic, and Improvers), with an Improvers group showing clinically meaningful reductions in PHQ-9 scores. The sample was also notably diverse in terms of race, gender, and neurodivergence compared with typical psychotherapy samples, consistent with the program's aim to reach underserved gamers. Exploratory post hoc analyses further indicated that, among participants with moderate-to-severe baseline depression, non-binary participants were significantly less likely than women to follow the Improvers trajectory, whereas men and binary trans participants did not differ from women. This pattern suggests that, even within a community that is intentionally structured to be inclusive and affirming, some gender minorities may face additional barriers to symptom improvement that require more tailored support.

In this study, depressive and anxiety symptoms were indexed by the PHQ-9 and GAD-7, whereas the WHO-5 captured broader well-being, including positive mood, vitality, and general life satisfaction. Loneliness functions as a transdiagnostic risk factor that is associated with increased symptoms and poorer social and role functioning across both clinical and nonclinical populations, making it a relevant target for gamers regardless of formal diagnosis. Health-supporting communities such as the one studied here are hypothesized to reduce loneliness and increase perceived connection, which may in turn support reductions in distress and improvements in subjective well-being and everyday functioning

Although this intervention took place in an online gaming community, it differs in important ways from the largely unstructured and sometimes toxic gaming spaces described in prior work. The server was intentionally organized as a health-supporting community, with explicit behavioral guidelines, structured channels and events, and active professional moderation to reduce harassment, discrimination, and other harmful content. These design features likely constrained some of the spontaneity of naturalistic communities but were intended to create conditions in which distressed gamers could safely form relationships and practice new skills.

Loneliness is a rising epidemic in the United States [4,7,8] that has far reaching impacts on physical and mental health [1-6]. Health-supporting communities are designed to alleviate loneliness and the ill health effects associated with loneliness by cultivating individual skill development related to fostering

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more enduring social connections. These communities are not a replacement for clinical treatment, but work hand-in-hand with existing mental health care, and appear to deliver clinically meaningful results over 60 days. The 30-day and 60-day findings for anxiety, depression, and overall wellness show a positive change in participants' reported functioning.

Importantly, health-supporting communities appear to be acceptable to a diverse set of populations that tend to underuse traditional mental health care. These are all populations that have found it difficult to find meaningful community connection and tend to underuse mental health care [73-77]. In total, 28.83% (113/403) of participants in our program identify as men and 45.92% (18/403) identify as women. Typical demographics rates of mental health care reported ~70% female, ~15% male, and 30% report as BIPOC [78-80]. Demographics beyond these are rarely reported [81]. When compared to typical attendance demographics for psychotherapy, this health-supporting communities for gamers seem to attract a more diverse population. At the same time, our trajectory analyses suggest that some minoritized gender groups, particularly non-binary participants, may be less likely to experience large symptom reductions over 60 days than women, underscoring that designing “for diverse gamers” requires not only successful recruitment and retention but also ongoing adaptation of content and support structures to address the distinct stressors faced by marginalized identities in gaming spaces.

Video games have historically carried a stigma of harming mental and physical health. Recent research has begun highlighting the potentially health-reinforcing opportunities of video games and their associated communities. This includes physical health as well as for mental health support, such as combating loneliness and the accompanying symptoms of anxiety and depression. Furthermore, some clinicians have demonstrated that using commercial video games as part of treatment can be impactful for clients [32,36]. By incorporating video games as a central part of community and supportive settings, there is potential to assist populations that have often felt uninterested in mental health care services.

LGMM results also reported change over 60 days for 3 distinct groups. While all groups showed improvement over the 60 days, the Improvers group (about 20% 91/438 of the population) showed significant improvement moving from well above clinical cutoff to below clinical cutoff. The only significant difference between the 2 groups that had elevated PHQ scores was gender identity other than male or female. This could be linked to the higher levels of loneliness and depression experienced in these demographics [82].

The post hoc analysis of this LGMM demonstrated that non-binary participants were less likely to be in the Improvers group when compared to women. These results align with current research regarding non-binary individuals reporting poorer mental health conditions when compared to binary individuals (whether trans or cis) [83].

Importantly, the largest group of participants identified by the LGMM reported near threshold depression that was maintained at subthreshold levels for 60 days. The prevention of depression is identified as a longstanding major global concern [84] with psychological and social intervention identified as promising mechanisms of prevention [85]. Social prescribing is likewise a growing area of research for ameliorating and preventing depression episodes [86], though it is still in its infancy and is limited by a lack of robust designs [87]. In person communities and services are often hard to access for some individuals, and a remote option that involves an area of strong interest for some, like video games, could offer an accessible and attractive option for accomplishing the aims of depression prevention.

Research Positionality and Reflexivity

Members of the research and program team include individuals who identify as gamers, as mental health professionals, and as people with lived experience of mental health challenges. These shared identities likely shaped decisions about program design (eg, emphasis on safety, inclusivity, and subclinical support) and interpretation of findings (eg, attention to both promise and risks of gaming communities). Additionally, the team’s investment in gaming as a potential health-supporting context may have influenced interpretations of the data.

Limitations

This data represents a proof-of-concept evaluation of a novel intervention type and is therefore limited in several ways. First, given the longitudinal and real-world nature of this study, survey nonresponse was a primary limitation of the study, with only a reported 30% (157/438) completing the full 60-day observation This limits the ability to fully evaluate longitudinal change. Our LGMM method attempts to estimate for and correct this missingness, but may still over- or underestimate the effects of the intervention.

Future research should include direct measures of loneliness such as the University of California, Los Angeles (UCLA) Loneliness Scale [88,89]. Similarly, our statistical findings were restricted to essential clinical metrics of change over time. Latent structure, clustering and linear models analyses may be warranted in future research with larger samples to better characterize for whom this kind of supportive community is most beneficial. Randomized controlled and decomposition studies would further isolate the relative contribution of program features to promote further program development and efficacy. Future studies should also incorporate systematically collected engagement and platform-usage data (eg, Discord participation metrics, session attendance, and in-community behavior markers) that can be securely linked to survey measures to clarify how patterns of engagement relate to symptom and well-being trajectories over time. There are also opportunities to leverage platform usage data and other rich sources of passive data to understand engagement with the services and community and the impact of that engagement on outcomes that were prevented by privacy concerns related to the platforms being used and limitations on anonymization of platform data, but that could be corrected in future studies. Finally, because participants were enrolled in a paid program and, in some cases, received free sessions as compensation, retention patterns and engagement may differ from what would be observed in unfunded or purely research-driven implementations, which limits generalizability of the observed retention rates.

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Conclusions

Health-supporting communities that intentionally combine commercial video games, professionally facilitated groups, and structured online spaces appear to be a promising way to support adults experiencing elevated distress while helping others sustain subthreshold symptom levels. In this proof-of-concept study, a substantial subgroup of participants with initially moderate-to-severe depressive symptoms followed an 'Improvers' trajectory over 60 days, while the largest subgroup maintained mild, subthreshold symptoms, suggesting that such communities may function both as subclinical support and as a potentially preventative context. At the same time, the presence of a Chronic group underscores that this approach will not be sufficient for all participants and highlights the importance of clear positioning as an adjunct or alternative for those who are not ready, able, or willing to engage in traditional psychotherapy.

More broadly, the combination of high levels of racial, gender, and neurodivergent diversity in this sample and the observed changes in symptoms and well-being suggest that moderated, game-based communities may help address gaps in reach and relevance for groups that underuse health services. By embedding psychological flexibility processes, social skills practice, and health-supporting norms within familiar gaming environments and online community structures, this model offers one concrete method of how subclinical supports might complement existing mental health services. Future controlled trials and mechanistic studies will be needed to clarify for whom and under what conditions health-supporting gaming communities are most beneficial and how they can be integrated into broader prevention and care ecosystems.

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Generative artificial intelligence was used for proofreading, review, and suggesting structural improvements to the manuscript. All artificial intelligence use was thoroughly reviewed, edited, and approved by the authors.

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Conflicts of Interest

None declared.

Multimedia Appendix 1
STROBE checklist.
[PDF File (Adobe PDF File), 189 KB - formative_v10i1e82428_app1.pdf]

Multimedia Appendix 2
A: Moderation rules agreed to by participants of the Discord community.
[DOCX File , 8 KB - formative_v10i1e82428_app2.docx]

Multimedia Appendix 3
B: Journey session structure.
[DOCX File , 8 KB - formative_v10i1e82428_app3.docx]

Multimedia Appendix 4
Imminent risk protocol.
[DOCX File , 1643 KB - formative_v10i1e82428_app4.docx]

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Abbreviations

BIPOC: Black, Indigenous, and People of Color
GAD-7: Generalized Anxiety Disorder-7 Scale
LGBTQIA+: lesbian, gay, bisexual, transgender, queer or questioning, intersex, asexual, and others
LGMM: Latent Growth Mixture Modeling
OR: odds ratio
PHQ-9: Patient Health Questionnaire-9
Psy-Flex: Psychological Flexibility Scale
STROBE: Strengthening the Reporting of Observational Studies in Epidemiology
UCLA: University of California, Los Angeles
WHO-5: World Health Organization-5 Well-Being Index

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Original Paper

Predictive Modeling of Preoperative Sleep Disorder Risk in Older Adults by Using Data From Wearable Monitoring Devices: Prospective Cohort Study

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Abstract

Background: Sleep disorders are common among older adults undergoing surgery and contribute significantly to postoperative complications, delayed recovery, and higher health care costs. The combined effects of age-related physiological changes and surgical stress further disrupt sleep in this vulnerable group. However, current tools for predicting surgical risk rarely account for the specific physiological, clinical, and psychological factors that affect older patients. While wearable devices are used to monitor sleep, most prediction models focus on general sleep quality in nonsurgical populations, leaving a gap in forecasting preoperative sleep disorders in older surgical candidates. Therefore, we developed and validated a tailored risk prediction model that integrates objective sleep data from wearable devices with comprehensive clinical and psychosocial evaluations for older adults preparing for surgery.

Objective: We aimed to develop and validate a risk prediction model for preoperative sleep disorders in older adult surgical patients by using data from smart wearable devices and clinical assessments, thereby facilitating early identification of the influencing factors and providing a scientific basis for personalized care planning.

Methods: We conducted a prospective study at the Second Affiliated Hospital of Zunyi Medical University. A cohort of 242 older surgical patients was monitored using smart rings on the night before surgery. We simultaneously collected data on sociodemographic factors, cognition, and psychological status. As per preoperative sleep assessments, patients were classified into sleep disorder and non–sleep disorder groups. Independent predictors of sleep disorders were identified using univariable and multivariable logistic regression. These predictors were used to build a risk prediction model, which was internally validated with 1000 bootstrap samples. The model's performance was evaluated by its ability to discriminate between groups (using receiver operating characteristic curves), its calibration, and its clinical usefulness (via decision curve analysis).

Results: Multifactorial logistic regression analysis showed that Hospital Anxiety and Depression Scale score (odds ratio [OR] 3.21, 95% CI 1.54-6.69; P=.002), number of awakenings (OR 3.33, 95% CI 1.82-6.12; P<.001), duration of rapid eye movement sleep (OR 0.96, 95% CI 0.93-0.99; P=.04), and duration of light sleep (OR 0.98, 95% CI 0.96-0.99; P=.01) were independent risk factors for preoperative sleep disturbances in older adults (P<.05). The receiver operating characteristic curve showed an area under the curve of 0.92, and the calibration curve indicated good model calibration. Decision curve analysis showed that the model improved the maximum net benefit across risk thresholds ranging from 0.2 to 0.8, indicating high clinical utility.

Conclusions: The risk prediction model developed using smart ring–derived data effectively identifies older adult surgical patients at elevated risk of preoperative sleep disturbances, thereby facilitating timely and individualized interventions. This advancement provides a robust scientific foundation for delivering personalized perioperative care, with the potential to improve postoperative outcomes and alleviate the health care burden in this vulnerable population.

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KEYWORDS

preoperative sleep disorder; older adults; smart wearable devices; risk prediction model; logistic regression

Introduction

Background

Sleep disorders, characterized by disruptions in sleep duration, sleep quality, and circadian rhythm [1], are frequently accompanied by anxiety, depression, and cognitive impairment, collectively exerting detrimental effects on patients' perceptions and behaviors [2]. With advancing age, older adults typically exhibit characteristic alterations in sleep architecture, including prolonged sleep latency, reduced total sleep time, and increased sleep fragmentation [3]; perioperative factors may further exacerbate these disturbances [4]. Intraoperative administration of anesthetics and analgesics can disrupt neurotransmitter homeostasis—particularly involving dopamine, norepinephrine, and γ-aminobutyric acid (GABA)—in older adults, resulting in heightened sensitivity to external stimuli and increased nocturnal arousals [5-7].

With the global population aging at an unprecedented rate, the demand for geriatric surgical procedures continues to grow annually. According to the World Health Organization, individuals older than 65 years now account for more than 40% of all surgical interventions worldwide [8]. This demographic is typically marked by physiological aging, multisystem functional deterioration, and a substantial burden of comorbidities, which collectively lead to increased perioperative vulnerability and a postoperative complication rate 2 to 3 times higher than that observed in younger cohorts [9]. Notably, sleep disturbances constitute a critical factor influencing postoperative recovery in older adults [2]. The reported incidence of perioperative sleep disturbances in older adults ranges from 15% to 84% [10,11]. Approximately 23% of the patients experience postoperative sleep disorders that may persist for up to 4 days, and by postoperative day 15, approximately 25% continue to exhibit pronounced symptoms of sleep deprivation. A subset of these patients still requires pharmacological intervention to maintain sleep continuity [12].

Perioperative sleep disturbances in older adults not only elevate the risk of postoperative delirium [13] but are also linked to a spectrum of adverse outcomes, including an increased risk of stroke, compromised immune function, elevated obesity risk, and higher morbidity and mortality rates [14,15]. Specific disturbances such as insomnia and circadian rhythm disruption during the perioperative period can result in daytime fatigue and a heightened risk of falls in older adults, thereby delaying wound healing, prolonging hospitalization, and contributing to increased health care expenditures and elevated mortality risk [13,16,17]. One survey indicated that, over a 6-month period, health care costs were approximately US $1100 higher for older adults who developed sleep disorders than for those without such conditions [17]. The economic burden of sleep disorders is substantial, amounting to 0.7% of Australia's gross domestic product, while nonfinancial costs account for an additional 3.2% of the national disease burden [18]. The presence of perioperative sleep disorders in older adults not only impairs sleep quality, physical health, and postoperative recovery but also exerts a profound impact on long-term quality of life [19]. Therefore, early identification and timely management of sleep disturbances in older adult surgical patients are crucial for improving clinical outcomes and alleviating the broader societal health care burden.

With the rapid advancement of information technology, smart wearable devices—such as smart bracelets and smartwatches—have demonstrated significant potential in monitoring individual sleep patterns. Evidence suggests that smart wearable devices yield measurements comparable to polysomnography in terms of total sleep time, nocturnal awakenings, and sleep efficiency [20]. Furthermore, sleep metrics obtained from smart rings exhibit good concordance with assessments derived from the Pittsburgh Sleep Quality Index (PSQI) [21]. Smart rings detect micromovements via a triaxial accelerometer and demonstrate high sensitivity and specificity in tracking parameters such as sleep onset latency, wake time, total sleep duration, rapid eye movement (REM) sleep, and the number of nocturnal awakenings [22].

Risk prediction models are designed to estimate the likelihood of future clinical events, such as the onset of a specific disease in a given patient population [23]. The identification and management of sleep disturbances in surgical settings can enhance perioperative care, reduce postoperative complications and associated health care expenditures, and improve patient throughput efficiency [24]. Although several risk prediction models for sleep disorders in older adults have been proposed [24,25], their predictive performance remains inconsistent, and none has been specifically designed for older adults undergoing surgery. Moreover, although recent studies have begun to use smart wearable devices for sleep monitoring—for example, machine learning–based approaches that forecast sleep efficiency hours before bedtime [26]—these efforts have largely focused on general sleep quality metrics in nonsurgical populations. Building on this work, this study extends the application of wearable technology by developing a targeted risk prediction model for preoperative sleep disorders in older adults undergoing surgery. By integrating high-resolution, objective sleep architecture data captured by a smart ring with key clinical and psychological assessments, the model addresses the distinct physiological and psychological vulnerabilities of this patient population. This approach represents a substantial advance beyond simple sleep efficiency forecasting, enabling proactive identification of clinically meaningful sleep disorders in the high-risk perioperative setting.

Objective

This study aimed to construct a predictive nomogram by integrating sleep-related data collected via smart wearable devices from older adult surgical patients to estimate the risk

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of postoperative sleep disturbances and support the early identification and management of high-risk individuals.

Methods

This study was designed and executed in accordance with the Transparent Reporting of a Multivariable Prediction Model for Individual Prognosis or Diagnosis (TRIPOD) guidelines [27,28].

Study Design and Participants

This prospective cohort study enrolled older adults who underwent elective surgical procedures between August 1, 2023, and January 30, 2024, at the Second Affiliated Hospital of Zunyi Medical University, China. Inclusion criteria were as follows: (1) aged between 60 and 80 years, (2) scheduled for elective surgery, (3) had an American Society of Anesthesiologists physical status of I to III, (4) fully conscious and capable of effective communication, and (5) had no documented history of sleep disorders. Exclusion criteria were as follows: (1) presence of central nervous system diseases or psychiatric disorders, (2) a history of sedative or hypnotic medication use, (3) undergoing daytime surgery or neurosurgical procedures, (4) New York Heart Association class IV heart failure, and (5) planned postoperative admission to the intensive care unit.

Data Collection

Patient clinical data were extracted from electronic medical records and included variables such as age, sex, diagnosis, BMI, and surgical specialty department. Additionally, sleep-related parameters were acquired via wearable monitoring devices, encompassing sleep onset time, wake-up time, total sleep time, durations of deep and light sleep, REM sleep duration, and the number of awakenings. Furthermore, several validated instruments were administered, including the PSQI, Hospital Anxiety and Depression Scale (HADS), Mini-Mental State Examination (MMSE), and Numerical Rating Scale (NRS) for pain assessment.

Biochemical markers were also obtained, including white blood cell count; neutrophil count; red blood cell count; hemoglobin; hematocrit; platelet count; prothrombin time; activated partial thromboplastin time; fibrinogen, serum potassium, sodium, and calcium levels; alanine aminotransferase; aspartate aminotransferase; prealbumin; blood urea nitrogen; creatinine; blood glucose; total protein; cholinesterase; high-sensitivity C-reactive protein; and creatine kinase and its isoenzymes.

In this study, the PSQI was used to evaluate the sleep quality of older adults on the night preceding surgery. Concurrently, a smart ring (Figure 1; SRing2; Shenzhen Century Modern Technology Development Co, Ltd) was used to monitor sleep parameters in real time, including sleep onset time, wake-up time, total sleep duration, REM sleep duration, durations of light and deep sleep, and the number of awakenings. The implementation procedure was as follows: the smart ring was uniformly fitted on each patient by the researcher before 10:00 PM on the night before surgery and removed upon waking up the following morning. Thus, this smart ring–based monitoring technology provided more objective and comprehensive sleep data.

Figure 1. SRing2 smart ring.

Sleep Quality Grouping

On the basis of the PSQI scores and sleep data collected via the smart ring, in conjunction with established diagnostic criteria for sleep disorders, 242 older adults were classified into 2 groups: the sleep disorder group, defined by PSQI scores of 7 points or more [29] and total sleep duration of less than 6.5 hours [30], and the non–sleep disorder group, characterized by

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PSQI scores of 7 points or less and total sleep duration of 6.5 hours or more.

Ethical Considerations

This study was approved by the ethics committee of the Second Affiliated Hospital of Zunyi Medical University (KYLL-2023-012). Written informed consent was obtained from all participants before enrollment. Participants were informed of their right to withdraw from the study at any time without penalty. All personal data collected from the devices were deidentified before analysis. The research data are encrypted and stored on secure servers, accessible only to members of the research team. No financial compensation was provided to the participants.

Statistical Analysis

All statistical analyses were conducted using R (version 4.4.1; R Foundation for Statistical Computing). Normally distributed continuous variables were summarized as means (SDs) and compared between groups using Student *t* test (2-tailed). Nonnormally distributed variables were presented as medians (IQRs) and compared using the Mann-Whitney U test. Categorical variables were expressed as frequencies and percentages and compared using the chi-square test or Fisher exact test, as appropriate.

Candidate predictors included sociodemographic characteristics (age, sex, and BMI), comorbidities, surgical specialty, biochemical markers, psychometric scale scores (PSQI, HADS, MMSE, and NRS), and sleep parameters derived from the smart ring (including total sleep time, REM sleep duration, light sleep duration, and the number of awakenings). Variable selection was conducted using the least absolute shrinkage and selection operator regression with 10-fold cross validation. Variables with nonzero coefficients in the least absolute shrinkage and selection operator model, together with variables with $P<.10$ in univariable logistic regression or judged to be clinically relevant, were entered into a multivariable logistic regression model. The final model was constructed using backward stepwise selection based on the Akaike information criterion, identifying the HADS score, number of awakenings, REM sleep duration, and light sleep duration as independent predictors. These predictors were incorporated into the nomogram.

Model performance was evaluated using receiver operating characteristic (ROC) curves, calibration plots, and decision curve analysis (DCA). Internal validation was conducted using 1000 bootstrap resamples to estimate optimism-corrected performance metrics (eg, area under the curve [AUC]) and assess the stability of the variable selection process. A 2-sided P value of <0.05 was considered statistically significant.

Model Evaluation

The predictive performance of the model was evaluated using ROC curve analysis, with the AUC representing the model's discriminatory ability [31]. DCA was used to assess the clinical utility and effectiveness of the model. DCA quantifies the net benefit of a predictive model by incorporating threshold probabilities that balance the relative harms of false-positive and false-negative classifications. In recent years, DCA has gained recognition as a superior approach to ROC curve analysis for evaluating the clinical value of predictive models [32]. Therefore, this study used DCA to evaluate the clinical benefit of the model.

Results

General Characteristics

A total of 242 older adults were enrolled in this study, comprising 129 (53.3%) female individuals and 113 (46.7%) male individuals. The mean age was 67.45 (SD 6.23) years, and the mean BMI was 23.34 (SD 3.69) kg/m^2. Regarding ward accommodation, 204 patients (84.3%) were admitted to multioccupancy rooms, while 38 (15.7%) patients stayed in single-occupancy rooms. The average length of hospitalization was 12.52 (SD 5.99) days. Additional details are presented in Table 1.

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Table 1. Baseline characteristics of older adults (N=242)a.

Variable	Total patients (N=242)	Patients in the non–sleep disorder group (n=202)	Patients in the sleep disorder group (n=40)	Statistics	*P* value
Age (y), mean (SD)	67.45 (6.23)	67.40 (6.25)	67.70 (6.22)	–0.28[b]	.78
S ex , n (%)				0.21[c]	.65
Female	129 (53.3)	109 (54)	20 (50)		
Male	113 (46.7)	93 (46)	20 (50)		
BMI (kg/m^2), mean (SD)	23.34 (3.69)	23.31 (3.63)	23.47 (4.06)	–0.24[b]	.81
Wardroom type, n (%)				6.31[d]	.01
Multioccupancy room	204 (84.3)	165 (81.7)	39 (97.5)		
Single-occupancy room	38 (15.7)	37 (18.3)	1 (2.5)		
Length of hospital stay (d), mean (SD)	12.52 (5.99)	12.65 (6.16)	11.82 (5.04)	0.80[b]	.43
Residence, n (%)				2.82[c]	.09
Urban	128 (52.9)	102 (50.5)	26 (65)		
Rural	114 (47.1)	100 (49.5)	14 (35)		
Smoking history, n (%)				2.57[c]	.11
No	154 (63.6)	133 (65.8)	21 (52.5)		
Yes	88 (36.4)	69 (34.2)	19 (47.5)		
Drinking history, n (%)				1.13[c]	.29
No	174 (71.9)	148 (73.3)	26 (65)		
Yes	68 (28.1)	54 (26.7)	14 (35)		
Diabetes, n (%)				0.20[c]	.66
No	216 (89.3)	179 (88.6)	37 (92.5)		
Yes	26 (10.7)	23 (11.4)	3 (7.5)		
Hypertension, n (%)				1.34[c]	.25
No	169 (69.8)	138 (68.3)	31 (77.5)		
Yes	73 (30.2)	64 (31.7)	9 (22.5)		

[a]Continuous variables are presented as mean (SD), while categorical variables are expressed as counts and percentages (n, %).

[b]Independent 2-sample *t* test.

[c]Chi-square test.

[d]Fisher exact test.

Clinical and Sleep-Related Characteristics

Among the 242 older adults enrolled in this study, the mean PSQI score was 7.31 (SD 2.38), the HADS score was 7.21 (SD 1.84), the NRS score for pain was 1.83 (SD 1.07), and the MMSE score was 20.45 (SD 4.65). Sleep parameters included total sleep duration (mean 473.36, SD 146.06 min), REM sleep duration (mean 84.25, SD 39.42 min), deep sleep duration (mean 128.50, SD 59.70 min), light sleep duration (mean 262.57, SD 92.63 min), and the number of awakenings (mean 2.68, SD 1.77; see Multimedia Appendix 1).

Factors Associated With Sleep Disorders

Univariable Analysis

On the basis of the clinical data, older adults' preoperative sleep status was classified into 2 groups: those with and those without sleep disorders. One-way ANOVA revealed statistically significant differences between the 2 groups in terms of wardroom type, HADS score, NRS score, number of awakenings, total sleep duration, REM sleep duration, deep sleep duration, and light sleep duration (all $P<.05$; Table 2).

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Table 2. Univariable logistic regression analysis.

Variable	β coefficient (SE)	*z* score	*P* value[a]	Odds ratio (95% CI)
Wardroom type				
Multioccupancy room	2.17 (1.03)	2.11	.04	8.75 (1.16-65.71)
Single-occupancy room	—[b]	—	—	1.00 (reference)
Psychometric scale scores				
Hospital Anxiety and Depression Scale score	1.00 (0.16)	6.35	<.001	2.72 (2.00-3.70)
Numerical Rating Scale score	1.22 (0.21)	5.80	<.001	3.38 (2.24-5.11)
Sleep parameters				
Number of awakenings	0.72 (0.12)	6.01	<.001	2.06 (1.63-2.60)
Total sleep duration (min)	–0.02 (0.00)	–6.32	<.001	0.98 (0.97-0.98)
Rapid eye movement sleep duration (min)	–0.04 (0.01)	–5.32	<.001	0.96 (0.94-0.97)
Deep sleep duration (min)	–0.02 (0.00)	–5.21	<.001	0.98 (0.97-0.99)
Light sleep duration (min)	–0.03 (0.00)	–6.10	<.001	0.97 (0.96-0.98)

[a]*P*<.05 denotes statistical significance.

[b]Not applicable (because this category serves as the reference for comparison).

Multivariable Analysis

Multivariable logistic regression was conducted with the presence of sleep disorders as the dependent variable and variables found to be statistically significant in the univariable analysis as independent predictors. The results demonstrated that HADS score (odds ratio [OR] 3.21, 95% CI 1.54-6.69), number of awakenings (OR 3.33, 95% CI 1.82-6.12), duration of REM sleep (OR 0.96, 95% CI 0.93-0.99), and duration of light sleep (OR 0.98, 95% CI 0.96-0.99) were independent predictors of preoperative sleep disorders in older surgical adult patients (all *P*<.05; Table 3).

Table 3. Multivariable logistic regression analysis.

Variable	β coefficient (SE)	*z* score	*P* value	Odds ratio (95% CI)
Hospital Anxiety and Depression Scale score	1.17 (0.38)	3.10	.002	3.21 (1.54-6.69)
Number of awakenings	1.20 (0.31)	3.89	<.001	3.33 (1.82-6.12)
Rapid eye movement sleep duration	–0.04 (0.02)	–2.10	.04	0.96 (0.93-0.99)
Light sleep duration	–0.02 (0.01)	–2.52	.01	0.98 (0.96-0.99)

Development and Validation of the Nomogram-Based Prediction Model

Construction of the Nomogram Prediction Model

A nomogram was developed based on the results of multivariable logistic regression analysis. As illustrated in Figure 2, each predictor variable is assigned a corresponding point value by projecting vertically onto the scoring axis. The sum of these values yields a total score, which is then mapped onto the total score axis. The final projected value on the risk axis indicates the estimated probability of preoperative sleep disorders in older adult surgical patients.

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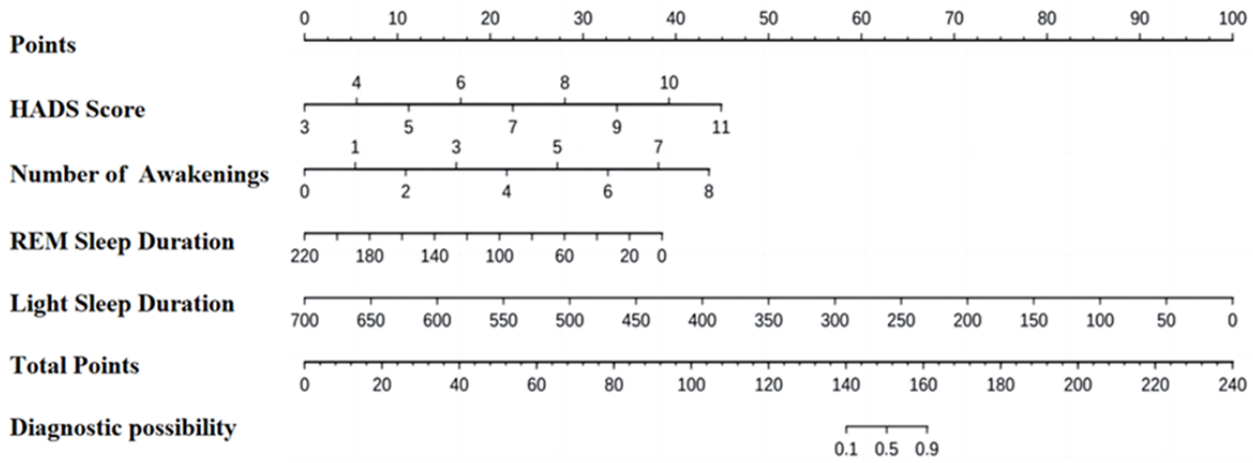
Figure 2. Nomogram for predicting the risk of sleep disorders in older adults undergoing elective surgery. HADS: Hospital Anxiety and Depression Scale; REM: rapid eye movement.



Evaluation of the Predictive Performance of the Nomogram Model

The predictive performance of the nomogram model was evaluated using discrimination, calibration, and DCAs, as mentioned subsequently.

First, internal validation of the nomogram model was conducted using 1000 bootstrap resamples, resulting in an area under the ROC curve of 0.92 (95% CI 0.88-0.96), indicating excellent discriminative ability of the model (Figure 3).

Second, calibration curves were used to evaluate the agreement between predicted and observed probabilities of sleep disorder onset. The model's predicted probabilities exhibited minimal deviation from the observed outcomes, indicating good calibration and strong predictive performance (Figure 4).

Third, DCA was performed to evaluate the clinical utility of the model by quantifying the net benefit across a range of risk thresholds, in comparison to the default strategies of treating all patients (gray line: "all") or treating none (black line: "none"). The DCA curve lay above both the "none" and "all" lines across most threshold probabilities, indicating superior predictive performance. The model achieved the greatest net benefit within a threshold probability range of 0.2 to 0.8 (Figure 5).

Figure 3. Receiver operating characteristic curves for the prediction model of preoperative sleep disorders in older adults. AUC: area under the curve.

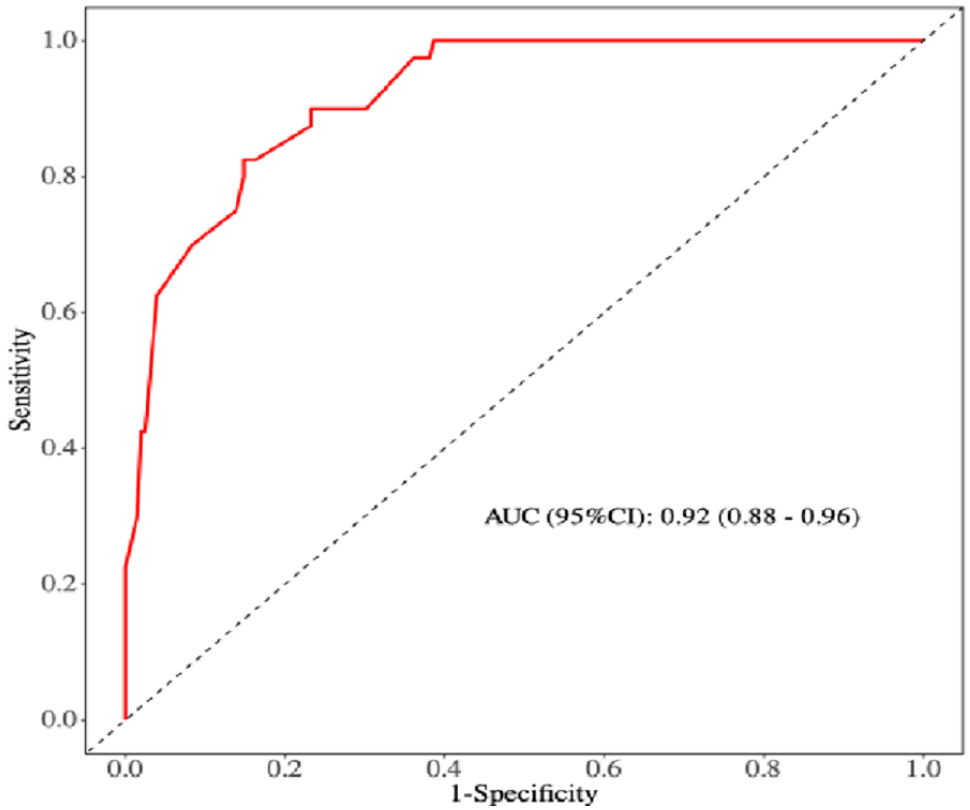


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Figure 4. Calibration curve for the risk prediction model of preoperative sleep disorders in older adults.

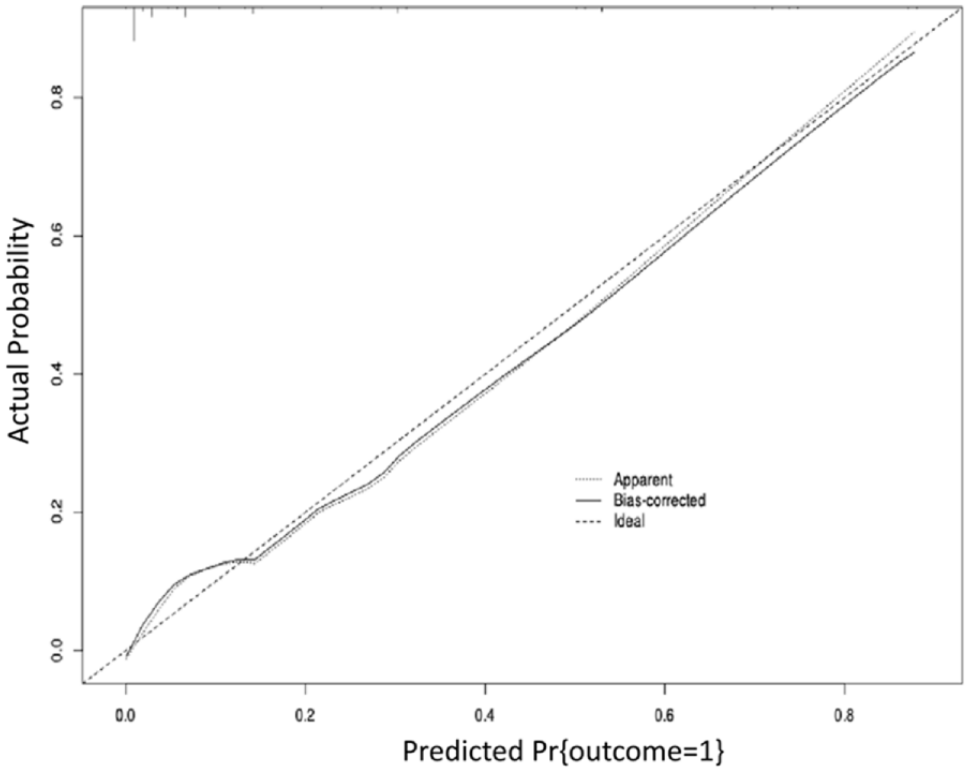
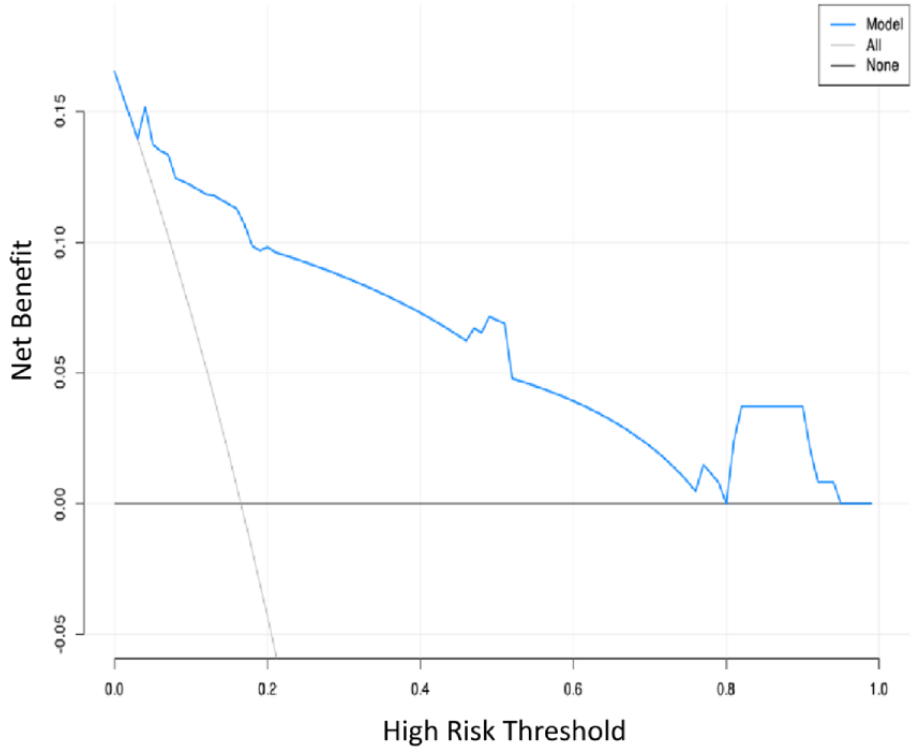


Figure 5. Decision curve analysis of the prediction model for preoperative sleep disorder risk in older adults.



Discussion

Significance of the Prospective Study Design

The prospective design of this study establishes a methodologically robust framework for investigating sleep disorders in the preoperative setting. By systematically assessing key predictors—encompassing psychological state (via HADS scores) and objective sleep architecture parameters (such as the frequency of nocturnal awakenings and the durations of REM and light sleep)—before surgical intervention, this methodology

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delineates a clear temporal sequence, thereby strengthening causal inference. This design effectively mitigates recall bias and substantiates the role of these factors as antecedent risk determinants rather than mere correlates of postoperative sleep disturbance. Therefore, this design was crucial to accurately quantify the independent contribution of each predictor and reliably construct the subsequent multivariate predictive model.

Analysis of Factors Affecting Preoperative Sleep Disorders in Older Adults

Anxiety and depression are common in older adult surgical patients, often linked to factors such as previous medical history, changes in the sleep environment, levels of family support, and personal coping styles [33,34]. A strong link exists between these mood states and sleep; 70% to 90% of the patients with anxiety or depression report sleep disturbances [35], a prevalence that is particularly high in older populations [36]. Our results indicate that each 1-unit increase in HADS score was associated with a 3.21-fold higher risk of preoperative sleep disorders in older adults, consistent with previous findings [37,38]. Anxiety and depressive mood have been shown to dysregulate neurotransmitter systems, including serotonin and norepinephrine, in older adults, thereby disrupting sleep-wake regulation and promoting sleep disorders [39]. Critically, anxiety, depression, and poor sleep engage in a bidirectional, vicious cycle, wherein each worsens the others [40]. A state of hyperarousal, driven by dysregulation of neurotransmitters such as GABA and acetylcholine, is a shared pathological feature of both anxiety and sleep disorders [41]. Older adult surgical patients with anxiety and depression exhibit elevated levels of adrenocorticotropic hormone–releasing hormone, which promotes amyloid-β aggregation and accumulation in the brain, thereby exacerbating both mood and sleep disturbances as part of a deleterious feedback loop [42]. Conversely, poor sleep itself chronically activates the hypothalamic-pituitary-adrenal axis. This leads to glucocorticoid resistance, increased sympathetic nervous system activity, and higher circulating catecholamine levels, all of which exacerbate anxiety and depression [43].

The number of awakenings is a critical indicator for evaluating sleep quality [30]. In older adults, frequent awakenings not only disrupt sleep architecture but also contribute to daytime fatigue, cognitive decline, and mood fluctuations [19]. Our findings revealed that each additional awakening was associated with a 3.33-fold increase in the risk of preoperative sleep disorders among older adults, consistent with previous research [44]. Awakenings in the surgical context differ from those in chronic illness. Perioperative awakenings are often more abrupt and intense, driven by acute physiological stress and the direct effects of anesthetic and analgesic drugs [4,5]. These medications disrupt normal sleep architecture. Anesthetics, for instance, act on key neurotransmitter systems (eg, GABA, norepinephrine, and dopamine), which can dysregulate sleep-wake circuits and heighten neural sensitivity to stimuli, predisposing patients to more frequent awakenings [6,7]. This vulnerability continues after surgery, when pain, discomfort, and the hospital environment itself become primary drivers of sleep fragmentation [45,46]. Specifically, routine hospital disturbances such as nighttime noise and light can significantly impair sleep. Nocturnal light exposure is particularly disruptive, as it stimulates specialized retinal cells that signal the brain to promote arousal, thereby worsening sleep disturbances [47].

REM sleep is a critical phase, typically making up 20% to 25% of total sleep [48]. It is essential for key functions, such as memory consolidation, emotional processing, and neural recovery, helping to maintain neurotransmitter balance [49]. Our results demonstrated that each 1-unit increase in REM sleep duration corresponded to a 4% reduction in the risk of preoperative sleep disorders among older adults. Alterations in sleep architecture frequently occur with advancing age, characterized by reductions in slow-wave and REM sleep alongside increased nocturnal awakenings [3]. Older adults are predisposed to heightened anxiety and depression during hospitalization, attributable to altered sleep environments, the absence of familial support, and surgery-related psychological stress [50]. These emotional disturbances and sleep disorders interact bidirectionally, forming a vicious cycle in which anxiety and depression diminish sleep quality, which in turn exacerbates these psychological symptoms [51]. REM sleep mitigates anxiety and depression by promoting cerebral processing of emotional experiences, thereby indirectly enhancing sleep quality in older adults [52].

Light sleep typically encompasses non-REM stage 1 (N1) and non-REM stage 2 (N2) of non-REM sleep. Stage N1 represents the transitional phase from wakefulness to sleep, comprising approximately 5% to 10% of total sleep duration. In contrast, stage N2 constitutes 45% to 55% of total sleep time and represents the largest proportion of the sleep cycle [53]. Our findings indicate that each unit increase in light sleep duration corresponds to a 2% reduction in the risk of preoperative sleep disorders in older adults. During light sleep, synchronized neuronal activity facilitates the reorganization of neural networks and information processing, thereby sustaining stable brainwave patterns and enhancing cerebral sensitivity and adaptability [54]. These stages contribute distinct functions. N1 sleep, involving neurotransmitters such as dopamine, aids in processing emotional memories and can ease the transition to sleep. N2 sleep is characterized by specific brainwave patterns (sharp-wave ripples) and hippocampal reactivation, which consolidate memory by strengthening relevant neural pathways and pruning weaker ones. N2 also supports overall sleep stability, thermoregulation, and energy restoration [55]. Therefore, light sleep is not merely a structural component of sleep but a physiologically active period critical for cognitive function and emotional regulation.

Value of a Risk Prediction Model for Preoperative Sleep Disorders in Older Adults

Clinical prediction modeling uses multifactorial models to estimate the likelihood of disease onset or the occurrence of future outcome events [56]. Wang et al [57] incorporated 9 predictors in developing a postoperative sleep disorder risk prediction model for patients undergoing arthroplasty, including preoperative sleep disorder status upon admission, wardroom type, BMI, and smoking status. Similarly, Renmei et al [58] incorporated 9 predictors, including anxiety, depression, tracheotomy, and posttraumatic stress disorder, into a risk

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prediction model for sleep disorders in patients discharged from the intensive care unit.

In contrast, our model is uniquely tailored to older adults in the preoperative period, a population at heightened risk due to age-related physiological changes, multimorbidity, and complex interactions between mental health and sleep [44,52]. Our model integrates 4 key predictors relevant to this group: HADS score, number of nocturnal awakenings, REM sleep duration, and light sleep duration. This selection aligns with the emphasis on psychological and sleep-architectural factors seen in previous research [24,58].

Multivariable logistic regression confirmed these as independent predictors: HADS score (OR 3.21, 95% CI 1.54-6.69), number of awakenings (OR 3.33, 95% CI 1.82-6.12), REM sleep duration (OR 0.96, 95% CI 0.93-0.99), and light sleep duration (OR 0.98, 95% CI 0.96-0.99). By incorporating objective sleep metrics, the model specifically addresses the distinct vulnerabilities of older surgical patients [59]. Calibration was strong, with close agreement between predicted probabilities and observed outcomes. DCA confirmed substantial clinical utility, showing the model provides a net benefit across a wide range of risk thresholds [32]. In summary, this model provides a novel, evidence-based tool for the early identification of older surgical patients at high risk of sleep disorders. It validates the critical role of sleep architecture and psychological state in preoperative risk. By enabling targeted interventions before surgery, it offers a proactive strategy to improve patient outcomes and potentially mitigate postoperative complications.

In clinical practice, caregivers should actively monitor the sleep health of older adults by implementing psychological interventions, such as cognitive behavioral therapy and positive thinking training; promoting family involvement; and optimizing the sleep environment and pharmacological treatments, including short-acting sedatives and anxiolytics, to enhance sleep quality and overall health [60].

For patients with severe sleep disorders, short-acting hypnotics or nonbenzodiazepine agents may be cautiously administered under clinical supervision to minimize the risk of dependence and adverse effects. On the basis of this predictive model, caregivers can devise individualized nursing interventions aimed at alleviating sleep-onset difficulties and fragmentation in older adults undergoing surgery, thereby mitigating the incidence of sleep disorders.

Limitations

First, although the prospective cohort design of this study enhances the robustness of temporal inferences, the potential for residual or unmeasured confounding cannot be excluded. Second, the study cohort was recruited from a single tertiary hospital, which constrains the sample size and may limit the generalizability of the results to broader populations. Third, this study's focus was confined to the immediate preoperative period, without extending follow-up into the postoperative phase. Consequently, although the model identifies presurgical risk factors, it cannot assess the temporal stability of these predictors or their longitudinal association with critical postoperative outcomes, including delirium and functional recovery. Therefore, future research should prioritize external validation across diverse clinical settings, investigation of additional potential confounders, and longitudinal assessments to elucidate how the preoperative sleep disorder risk identified by this model influences tangible postoperative outcomes.

Conclusions

The preoperative sleep disorder risk prediction model developed for older adults in this study achieved an AUC of 0.92 (95% CI 0.88-0.96), demonstrating excellent discriminatory performance. The calibration curve indicated minimal deviation between the predicted probabilities and the observed outcomes, reflecting strong model calibration. DCA further demonstrated that the model improved net clinical benefit across risk thresholds ranging from 0.2 to 0.8, indicating high clinical utility. By integrating the quantitative relationships among HADS score, wakefulness duration, REM sleep duration, light sleep duration, and sleep disorders, the model provides a scientific foundation for the early identification and intervention of preoperative sleep disorders in older adults.

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Data Availability

The datasets generated or analyzed during this study are not publicly available due to restrictions related to the source data (originating from an ongoing master's thesis research project) but are available from the corresponding author on reasonable request.

Conflicts of Interest

None declared.

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Multimedia Appendix 1
Clinical disease profiles of older adults.
[DOCX File , 13 KB - formative_v10i1e79008_app1.docx]

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Abbreviations

AUC: area under the curve
DCA: decision curve analysis
GABA: γ-aminobutyric acid
HADS: Hospital Anxiety and Depression Scale
MMSE: Mini-Mental State Examination
N1: non–rapid eye movement stage 1
N2: non–rapid eye movement stage 2
NRS: Numerical Rating Scale
OR: odds ratio
PSQI: Pittsburgh Sleep Quality Index
REM: rapid eye movement

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ROC: receiver operating characteristic
TRIPOD: Transparent Reporting of a Multivariable Prediction Model for Individual Prognosis or Diagnosis

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Original Paper

Real-World Use of a Mental Health AI Companion: Multiple Methods Study

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Abstract

Background: The rapid acceleration of large language models (LLMs) creates opportunities to expand the accessibility of mental health support; however, general artificial intelligence (AI) tools lack safety guardrails, evidence-based practices, and medical regulation compliance, which may result in misinformation and failing to escalate care in crises. In contrast, Ebb, Headspace's conversational AI tool (CAI tool), was purpose-built by clinical psychologists and research experts using motivational interviewing techniques for subclinical guidance, incorporating clinically backed safety mechanisms.

Objective: This study aimed to (1) understand Headspace members' sentiment toward AI and expectations for a mental health CAI tool, (2) evaluate real-world use of Headspace's CAI tool, and (3) understand how members perceive a CAI tool fitting into their mental health journey.

Methods: This was a multiple method study using three data sources including Headspace members: (1) cross-sectional survey (n=482) assessing demographics, AI use, and the Artificial Intelligence Attitude Scale-4 (AIAS-4); (2) real-world engagement descriptive analysis (n=393,969) assessing session and message counts, retention, and conversation themes; and (3) diary study (n=15) exploring the CAI tool's role within members' mental health journey. App engagement was compared between CAI tool 1.0 and CAI tool 2.0, where CAI tool 2.0 featured enhanced LLM conversational prompts, comprehensive memory, woven content recommendations, and more robust safety detection.

Results: While the majority of survey respondents used and would continue to use general AI tools, overall attitudes toward AI remained neutral (AIAS-4 mean 5.7, SD 2.2, range 1-10). Survey results suggest that members viewed the CAI tool as a guide to navigate to mental health resources and Headspace content and provide in-the-moment support. Members emphasized the need for data safety and ethics transparency, clinical guidelines structure, and for the CAI tool to be a resource in addition to human-delivered mental health care, not a replacement. Real-world CAI tool use showed strong engagement across 393,969 Headspace members. The product evolution to CAI tool 2.0 led to increased retention (77,894/153,249, 50.8% completed 2 sessions within 7 days vs 68,701/240,720, 28.5% for CAI tool 1.0) and higher positive conversation ratings (37,819/40,449, 93.5% vs 94,308/104,323, 90.4%). Retained CAI tool 2.0 users showed greater retention (6.1 sessions per user) compared to all CAI tool 2.0 users (2.9 sessions per user) and CAI tool 1.0 (2.4 sessions per user). Diary study results suggest that members imagined using the CAI tool when feeling stress or anxiety and during morning routines, commutes, or while winding down at night.

Conclusions: Results emphasize the necessity of research-backed, purpose-built mental health AI products with minimum viable safeguards, including (1) transparent labeling of intended use, benefits, and limitations; (2) safety by design principles to monitor for overuse, detect risk, and flag needs for escalation; and (3) child and adolescent safeguards.

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KEYWORDS

mental health; AI; artificial intelligence; digital mental health; Headspace; mental health chatbot

Introduction

The recent boom in artificial intelligence (AI), accelerated by advancements in large language models (LLMs), has opened new opportunities in mental health as AI-powered tools are being developed to expand access to and accessibility of mental health support. Research suggests that 48.7% of individuals used a general LLM, such as ChatGPT, for mental health support in the past year, with 73.3% seeking help for anxiety, 63% personal advice, and 59.7% depression [1]. Furthermore, a recent Harvard Business Review report identified therapy and companionship as the leading AI use case in 2025, with finding purpose ranked third [2]. This analysis also highlights the shift in AI use for emotional support and personal development, as therapy and companionship rose from the second use case in 2024, and finding purpose was not identified in the top 100 use cases that year [2]. While recent studies from OpenAI and Anthropic report that smaller percentages of messages are exclusively for mental health support, they still imply hundreds of millions of mental health–related messages are being exchanged with ChatGPT and Claude each day [3,4].

Although AI tools are available 24/7 to provide support in a timely, accessible manner and initial research suggests that AI-based conversational agents may improve anxiety and depression symptoms [5], general AI tools are not designed using evidence-based practices or with the safety guardrails necessary for mental health use. Specifically, general LLMs may provide misinformation or hallucinate, perpetuate inequalities and stigma around mental health disparities, not store and protect personal data and information in accordance with HIPAA (Health Insurance Portability and Accountability Act) and standard medical regulations, provide inaccurate or inconsistent responses, not escalate care when a patient is indicating serious mental illness or self-harm, and fail to respond to crises [6,7]. Furthermore, general LLMs are designed to maximize engagement and create dependence [8], continuously asking the user more questions to keep them in the conversation, whereas mental health treatment is designed to provide patients with tools and skills that extend beyond care to promote personal growth, autonomy, and long-term well-being [9]. AI tools offer great promise for improving the accessibility of mental health support; however, it is imperative to design tools built specifically for mental health by experts that include informed consent, evidence-based practices, safety mechanisms, regulation compliance, and rigorous research and testing.

Headspace [10] is a commercial digital mental health platform that offers a spectrum of mental health care options including mindfulness, meditation, and sleep content; cognitive behavioral therapy-based clinical programs; human-delivered care including coaching, therapy, psychiatry; and Ebb [11], a unique offering within the Headspace app that is an empathetic conversational artificial intelligence tool (CAI tool) designed to process thoughts and emotions and guide members to relevant Headspace content. Specifically, the CAI tool was designed, built, and tested by clinical psychologists and research experts for subclinical guidance using motivational interviewing techniques and clinically backed safety mechanisms (eg, safety escalation, high acuity safety message flagging and review, and AI risk detection). At Ebb's launch in October 2024, early pilot data suggested that Headspace members used the CAI tool as a self-reflection tool for emotional support, with top conversation topics including relationship and social support, work or career frustration, and sleep challenges. Between launch and July 2025, the CAI tool was consistently monitored and updated to improve safety, usability, and LLM accuracy. Additionally, since its launch, the CAI tool has become available for more members, and its LLM was expanded to include more conversational prompts, Headspace content recommendations, more detailed memory knowledge (to previous conversations with the CAI tool and overall Headspace content consumption), and a more robust approach to safety risk detection.

As AI technologies and their applications in mental health rapidly evolve, it is critical to understand what individuals expect from these tools, how they are using them in real-world settings, and how they envision such tools fitting into their overall mental health journey. Therefore, the purpose of this study was to (1) understand the overall sentiment toward AI and expectations for a mental health CAI tool, (2) descriptively evaluate real-world use of the CAI tool, and (3) understand how Headspace members perceive the CAI tool fitting into their broader mental health journey.

Methods

Overview

This study used three data sources: (1) member survey: cross-sectional, mixed methods survey to understand general sentiment toward AI and expectations for t a mental health CAI tool; (2) app engagement data: real-world engagement analysis using in-app Headspace data to understand how Headspace members are using the CAI tool; and (3) diary study: qualitative study to understand how Headspace members perceive the CAI tool fitting into their broader mental health journey. Details on each data source are outlined below and identified in Table 1. Results are reported in accordance with STROBE (Strengthening the Reporting of Observational Studies in Epidemiology) reporting guidelines (Multimedia Appendix 1).

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Table 1. Data sources used in this study.

Sources	Research questions	Description	Sample	Date	Outcomes
Member survey	What is the overall sentiment toward AI[a], and what do Headspace members want from a mental health CAI[b] tool?	Cross-sectional survey sent via Qualtrics	482 Headspace members who sent at least 1 message to the CAI tool	April 2025	Demographics, general AI use, AI attitudes (AIAS-4[c]), and CAI tools' role in their mental health journey
App engagement data	How are Headspace members using the CAI tool?	In-app engagement metrics collected via the Headspace app	393,969 Headspace members who used the CAI tool	October 2024 to October 2025 (focus on engagement from July 25, 2025, to October 1, 2025)	Number of users, sessions, messages sent, messages received, session rating, and conversation themes
Diary study	How do Headspace members perceive a CAI tool fitting into their broader mental health journey?	Qualitative diary study conducted via Dscout	15 Headspace members	October 2025	Themes and topics from qualitative data focused on how a CAI tool fits within a daily routine, Headspace CAI tool vs. general AI tools, and barriers to engagement

[a]AI: artificial intelligence.

[b]CAI: conversational artificial intelligence.

[c]AIAS-4: Artificial Intelligence Attitude Scale-4.

Member Survey: What Is the General Sentiment Toward AI, and What do Headspace Members Want From a Mental Health CAI Tool?

Data Collection

A cross-sectional survey was conducted to understand Headspace members' general sentiment toward AI and their expectations for a mental health CAI tool. Eligible participants were US-based Headspace members aged 18 years or older who sent at least 1 message to the CAI tool. The survey was sent in April 2025 via Qualtrics [12] to Headspace members' email addresses collected during Headspace onboarding. Questions included demographics (age, gender, and race), general AI use, attitudes toward AI measured using the AI Attitude Scale [AIAS-4, 4 questions on a scale from 1-10 with a total score as a mean of the 4 items (range 1-10, higher scores indicating more positive attitudes toward AI use)] [13], and how members want a CAI tool to play a role in their mental health journey. The full member survey is reported in Multimedia Appendix 2.

Data Analysis

Survey responses are reported descriptively with demographics, general AI use, and CAI tool expectations reported as frequencies and percentages; means and standard deviations reporting AIAS-4 individual items and total; and qualitative analysis for open-ended questions on the CAI tool's role.

App Engagement Data: How Are Headspace Members Using the CAI Tool?

Data Collection

Headspace app engagement data were collected from members who used the CAI tool from October 1, 2024, to October 1, 2025.

Data Analysis

To evaluate detailed engagement, metrics were calculated for three groups: (1) CAI tool 1.0: members who used the CAI tool from October 1, 2024, to July 24, 2025; (2) CAI tool 2.0: members who used the CAI tool from July 25, 2025, to October 1, 2025 as the CAI tool became available for more members and its LLM was expanded to include more conversational prompts, Headspace content recommendations, detailed memory knowledge (to previous conversations with the CAI tool and overall Headspace content consumption), and a more robust approach to safety risk detection; and (3) CAI tool 2.0 retained users: a subset of CAI tool 2.0 members who returned to the CAI tool twice within a week at least once during the study period (between July 25, 2025, and October 1, 2025). Detailed differences between CAI tool 1.0 and CAI tool 2.0 can be found in Table 2. To characterize the overall engagement funnel in all 3 groups, frequencies were reported for the total number of members who have used the CAI tool, total number of sessions, and total number of messages (sent and received). Mean (SD) values, and ranges (minimum to maximum) were reported for the number of sessions and messages per user and number of messages (sent and received) per session. To assess retention, mean (SD) values and ranges were reported for average monthly active users (MAU), weekly active users (WAU), and daily active users (DAU), and frequencies and percentages were reported for users who return within 7 days and return within 30 days. Frequencies and percentages were reported for postconversation thumbs-up ratings. In CAI tool 2.0, users with >1 conversation with the CAI tool, key conversation topics were pulled from conversation histories, with frequencies and percentages indicating the top 15 conversation topics.

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Table 2. Updates made to the Headspace conversational artificial intelligence tool, differentiating CAI tool 1.0 and CAI tool 2.0.

Key updates	CAI[a] tool 1.0	CAI tool 2.0
Study dates	October 1, 2024, to July 24, 2025	July 25, 2025, to October 1, 2025
LLM[b] infrastructure	Turn-based prompting (ie, the CAI tool is able to ask a question or reflect throughout the session)	General conversation prompt, allowing a more flexible conversation
Memory	Reference to previous conversations at the start of a new session	Comprehensive memory of all previous conversations and more recent content plays
Content recommendations	End of session button prompted the option for a content recommendation	Content recommendations are woven into the conversation based on the LLM's decision-making
Safety	In-house proprietary safety system (safety escalation, high acuity safety message flagging and review, AI[c] risk detection)	Expanded in-house safety system with clearer clinical boundaries, reduced out-of-scope and sycophantic behavior, improved de-identification, evaluation of AI-related risks (eg, parasocial relationships), and continued expansion of safety flagging with clinician oversight

[a]CAI: conversational artificial intelligence.

[b]LLM: large language model.

[c]AI: artificial intelligence.

Diary Study: How do Headspace Members Perceive a CAI Tool Fitting Into Their Broader Mental Health Journey?

Data Collection

A qualitative diary study was conducted with 15 Headspace members to understand how members perceive the CAI tool fitting into their broader mental health journey. Participants engaged in a 7-day diary study conducted via Dscout [14], where they shared their baseline comfort and usage of AI tools, reflected on their CAI tool engagement, and provided in-the-moment insights into their experiences using the CAI tool. Data from the diary study's baseline assessment were used for the present analyses. Participants were recruited through Dscout's research platform using a screener that confirmed Headspace membership and active CAI tool use. Baseline questions included feedback prompts focused on understanding members' baseline routines and initial perceptions of the CAI tool, including broad questions such as what a typical day looks like, what tools they use to manage stress, and their use of and attitudes toward general AI tools. CAI tool-specific questions included first impressions, how the CAI tool fits into their current routine, and how their use of the Headspace CAI tool differs from general AI tools. Data were collected using a mix of video, open-ended text, close-ended questions, and photo entries to capture in-the-moment reflections on their CAI tool engagement and how their use fits into their typical day. All data were captured within the Dscout platform and were reviewed by the Headspace research team to ensure data accuracy and participant compliance.

Data Analysis

Data were analyzed using a mixed-methods approach. Quantitatively, close-ended responses were transformed into categorical attributes to enable grouping and comparison of participant insights. Open-ended text and video transcriptions were also processed using LLM-assisted analysis to support theme identification. Qualitative data were analyzed using reflexive thematic analysis to identify patterns in how members perceive a CAI tool within their mental health journeys [15]. An inductive, data-driven approach was used, with codes generated from participants' accounts and iteratively refined through repeated engagement with the data. Themes captured the primary topics participants discussed regarding their use of Headspace, including when and how they used the tool, perceived benefits, and areas of friction. Throughout the process, analytic decisions were documented through memoing and reflexive note-taking."

Ethical Considerations

Participation for all studies was entirely optional, and the studies operated under Headspace's umbrella Institutional Review Board protocol, which covers research use of app data and associated research activities (Pro00078213). Member survey participants provided consent for their data to be used in this study as a part of the survey, members agreed to the use of their in-app data for research purposes when acknowledging the Headspace terms and conditions [16] and privacy policy [17], and diary study participants completed informed consent through Dscout when signing up for the service and prior to the start of the study. Participants for the diary study received US $60 in compensation upon completing all diary entries. All data were analyzed in aggregate form, and deidentification procedures were applied to ensure participant privacy and confidentiality in alignment with ethical standards for research involving human participants.

Results

Member Survey

Attitudes Toward AI

Overall, 482 Headspace members completed the member survey via Qualtrics and were included in these analyses (full survey results are reported in Table 3). The majority of survey respondents were women (321/475, 67.6%) and identified their race as White (414/475, 87.2%). Most respondents used AI tools outside of the Headspace CAI tool (272/475, 57.3%), with the top types of AI-powered tools reported as AI-generated

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content (246/304, 81.0%), virtual assistants (237/306, 77.7%), AI chatbots for customer service (202/304, 66.2%), and AI-powered recommendation systems (175/305, 57.4%). While the majority of respondents reported using general AI tools, only a small percentage (12.5%) reported using other AI tools for mental health support or self-reflection outside of the Headspace CAI tool. Most people agreed that they would use AI in the future, but overall attitudes toward AI (ie, perception of impact on life, work, and humanity) were neutral (AIAS-4 mean 5.7, SD 2.2, range 1-10).

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Table 3. Member survey quantitative results highlighting member demographics, artificial intelligence (AI) use, and attitudes toward AI (AIAS-4[a]).

Characteristics	Values
Age (years), n (%)	
18-24	9 (1.9)
25-34	53 (11.1)
35-44	101 (21.2)
45-54	109 (22.9)
55-64	108 (22.7)
65-74	79 (16.6)
75 and older	17 (3.6)
Gender, n (%)	
Woman	321 (67.6)
Man	144 (30.3)
Nonbinary	5 (1.1)
Prefer to self-describe	2 (0.4)
Prefer not to answer	3 (0.6)
Race and ethnicity (choose all that apply), n (%)	
White or Caucasian	414 (87.2)
Hispanic or Latino	27 (5.7)
Asian	17 (3.6)
Black or African American	12 (2.5)
Native Hawaiian or Pacific Islander	4 (0.8)
Native American or Alaskan Native	3 (0.6)
Middle Eastern or North African	3 (0.6)
Other	5 (1.1)
Prefer not to answer	11 (2.3)
Outside of Ebb, have you ever used an AI-powered tool or service?, n (%)	
Yes	272 (57.3)
No	169 (36.6)
Maybe	34 (7.2)
What types of AI-powered tools have you used? Select all that apply (n=272, those who responded yes to using AI tools), n (%)	
AI-generated content	247 (81.0)
Virtual assistants	237 (77.7)
AI chatbots for customer service	202 (66.2)
AI-powered recommendation systems	175 (57.4)
AI-powered mental health or wellness tools	175 (57.4)
AI image or video generators	64 (21.0)
Other	19 (6.2)
Outside of Ebb, have you used any other AI tools for mental health support or self-reflection?, n (%)	
Yes	59 (12.5)
No	414 (87.5)
AIAS-4[b] (range 1-10), mean (SD)	
I believe that AI will improve my life.	5.6 (2.4)

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Characteristics	Values
I believe that AI will improve my work.	5.7 (2.7)
I think I will use AI technology in the future.	7.2 (2.6)
I think AI technology is positive for humanity.	5.1 (2.3)
Total	5.1 (2.3)

[a]AIAS-4: Artificial Intelligence Attitude Scale-4.

Perceptions of a Mental Health CAI Tool

When asked what role members would want a CAI tool to play in their mental health journey, top responses included tool or assistant to be more efficient (n=147, 35%), guide to navigate to mental health resources (n=138, 33%), and a coach to help set and achieve goals (n=125, 30%). Qualitative themes, topics, and quotes from the open-ended questions are reported in Multimedia Appendix 3. Members used the CAI tool as an interactive self-reflection tool to vent and reflect, appreciating the feedback and reflection it provides. Specifically, 1 member indicated that, "I use [Ebb] as a form of journaling and as a way to cope with anxious overthinking." While members use the CAI tool to guide them toward content within the Headspace app, they emphasized the need for more personalized content recommendations. Results suggest that members also use the CAI tool as an interim support between other forms of care, want it to be an adjunct to their therapy, and requested direct connection to human-delivered care within Headspace – with 1 member indicating that, "Ebb provides support for the tough moments between seeing my mental health providers." Finally, members voiced their concerns about trusting AI for mental health care, emphasizing the need for transparency in data safety and ethics, structure around clinical guidelines, and for CAI tools to be a resource in addition to human-delivered mental health care, not as a replacement. Additionally, members were hesitant to anthropomorphize a CAI tool, wanting it to be clearly identified as an AI tool. Members specifically said, "I would like to know what the confidentiality and security level is there," and, "Ebb is not a therapist or real human, but I appreciate Ebb listening and providing feedback and recommendations. Ebb is more of a guide who points me to the direction I want to go."

App Engagement Data

CAI Tool 1.0

Real-world CAI tool use showed strong engagement across 393,969 unique members, with the overall CAI tool engagement funnel outlined in Figure 1 and the full app engagement data reported in Table 4. Overall, 240,720 Headspace members engaged with CAI Tool 1.0 (users from October 1, 2024, to July 24, 2025), exchanging 6,775,167 messages. Across the study period, 75,557 (25.8%) completed 2 sessions within 30 days, and 62,054 (25.8%) completed 2 sessions within 7 days. On average, 14.6% (mean 35,022.2, SD 17,435.9) are MAUs, and 3.9% (mean 9449.3, SD 5007.9) are WAUs, and members engaged in a total of 2.4 (SD 14.1) sessions, sent a total of 12.8 (SD 129.1) messages to the CAI tool, and received 15.3 (SD 168.3) messages from the CAI tool.

Figure 1. Engagement funnel from CAI tool 1.0 and CAI tool 2.0 (overall and retained users). CAI tool 1.0 and 2.0 users are mutually exclusive, with CAI tool 2.0 retained users being a subset of CAI tool 2.0. CAI: conversational artificial intelligence; MAU: monthly active user; WAU: weekly active user.

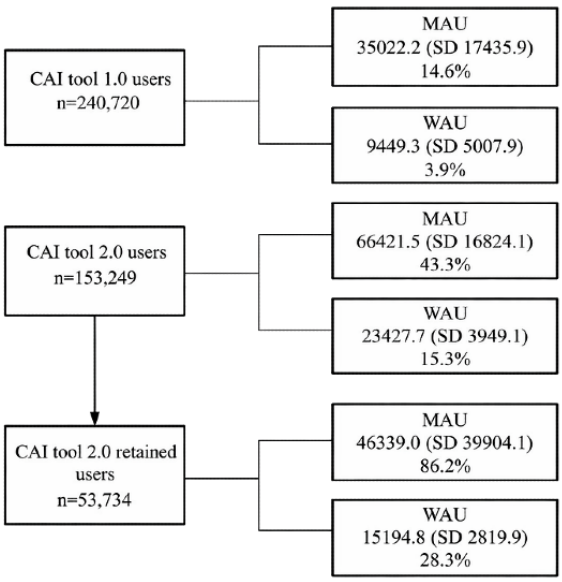

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Table 4. In-app conversational artificial intelligence tool engagement data for Headspace members from October 1, 2024, to October 1, 2025.

Engagement	CAI tool 1.0 users[a]	CAI tool 2.0 users[b]	CAI tool 2.0 retained users[c]
Total number of users, N	240,720	153,249	53,734
Total sessions, N	568,611	436,104	326,178
Total messages sent, N	3,026,387	2,526,894	1,991,025
Total messages received, N	3,610,066	2,925,353	2,282,652
2 CAI[d] tool sessions within 7 days, n (%)	68,701 (28.5)	77,894 (50.8)	53,734 (100)
2 CAI tool sessions within 30 days, n (%)	80,973 (33.6)	82,392 (53.8)	—[e]
Positive conversation rating (thumbs up)[f], n (%)	94,308 (90.4)	37,819 (93.5)	46,935 (93.4)
Duration of session (minutes), mean (SD), range	6.7 (23.7), 0.1-4679.6	6.9 (12.6), 0.1-1173.6	7.6 (13.7), 0.1-1173.6
Monthly active users, mean (SD), range	35,022.2 (17435.9), 10,825-59,247	66,421.5 (16,824.1), 50,220-87,579	46,339.0 (39,904.1), 5860-88,062
Weekly active users, mean (SD), range	9449.3 (5007.9), 2433-17,640	23,427.7 (3949.1), 16,536-30,094	15,194.8 (2819.9), 10,879-20,389
Daily active users, mean (SD), range	1623.5 (950.9), 305-3867	4619.2 (963.5), 2373-7131	3432.8 (763.4), 1596-5152
Sessions per user, mean (SD), range	2.4 (5.9), 1-947	2.9 (9.1), 1-1107	6.1 (14.8), 1-1107
Messages sent per user, mean (SD), range	12.6 (44), 1-10,870	16.5 (75.8), 1-9183	37.1 (125.3), 2-9183
Messages received per user, mean (SD), range	15.0 (48.4), 0-11,569	19.1 (81.1), 0-9447	42.5 (133.7), 2-9447
Messages sent per session, mean (SD), range	5.3 (5.4), 1-274	5.8 (6.3), 1-460	6.1 (6.9), 1-460
Messages received per session, mean (SD), range	6.3 (5.6), 0-287	6.7 (6.4), 0-465	7 (7), 0-465

[a]Engagement from October 1, 2024, to July 24, 2025.

[b]Engagement from July 25, 2025, to October 1, 2025.

[c]Engagement from July 25, 2025, to October 1, 2025: a subset of conversational artificial intelligence tool 2.0 users who used the tool ≥2 days over a 7-day period.

[d]CAI: conversational artificial intelligence.

[e]Not available.

[f]Thumbs up rating was calculated based on those who rated their conversation with Ebb as a thumbs up or down (icons presented at the bottom of a conversation). Sample sizes are as follows: CAI tool 1.0 users n=106,008, CAI tool 2.0 users n=79,240, and CAI tool 2.0 retained users n=50,262.

CAI Tool 2.0

Since the launch of CAI tool 2.0 (July 25, 2025, to October 1, 2025), 153,249 members engaged with CAI tool 2.0, with 31,498 (20.6%) completing 2 sessions within 30 days and 53,734 (35.1%) completing 2 sessions within 7 days. On average, 43.3% (mean 66,421, SD 16,824.1) are MAUs and 15.3% (mean 23,427.7, SD 3,949.1) are WAUs. On average, members engaged in a total of 2.9 (SD 9.1) sessions, sent a total of 16.5 (SD 75.8) messages to the CAI tool, and received 19.1 (SD 81.1) messages from the CAI tool. Key conversation topics included Headspace app use and navigation, health and well-being, relationships, productivity, work and career, and anxiety and stress (Multimedia Appendix 4). Overall, 93.5% (37,819//40,449) of CAI tool users rated their conversation positively.

CAI Tool 2.0 Retained Users

In CAI tool 2.0, retained users (subset of CAI tool 2.0 members, those who engaged in at least 2 CAI tool sessions within 7 days anytime in the study period, n=53,734), on average, 86.2% are MAUs and 28.3% are WAUs. CAI tool 2.0 retained users engaged in a total of 326,178 sessions and exchanged 4,273,677 messages with the CAI tool, with 6.1 (SD 14.8) sessions per user, 37.1 (SD 125.8) messages sent per user, and 42.5 (SD 133.7) messages received per user. CAI tool 2.0 retained users who completed more conversations over time (Figure 2). Overall, 93.4% (46,935/50,250) of CAI tool retained users rated their conversation positively.

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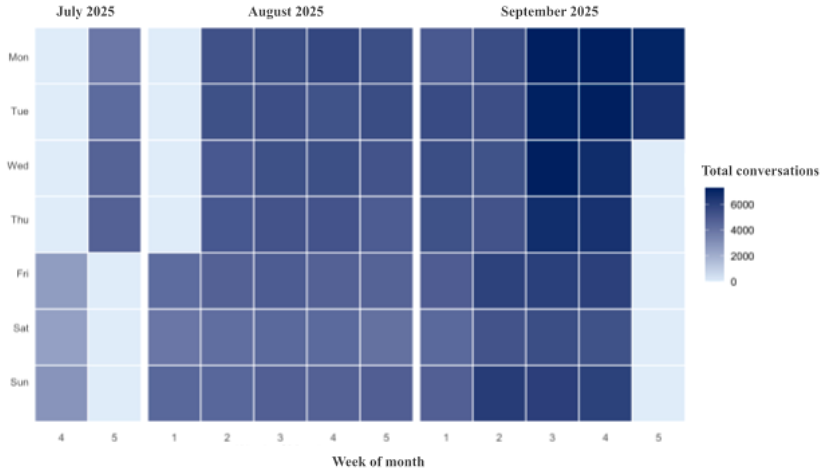
Figure 2. Total conversations across the study timeframe (July 25, 2025, to October 1, 2025) for CAI tool 2.0 retained users (2 sessions within 7 days).



Diary Study

Overall, 15 Headspace members completed the diary study baseline assessment, providing 1 Dscout entry each that combined open-ended reflections with several multiple-choice questions about their familiarity with AI tools, early impressions of the CAI tool, and anticipated use contexts. Overall, participants represented a highly engaged and technologically fluent sample; 73.3% (n=11) reported using AI tools such as ChatGPT (OpenAI), Google Gemini, or Copilot multiple times per day, and 13.3% reported using tools about once per day. Most (n=13, 86.7%) had already experimented with AI for health or wellness purposes, including stress management, exercise, or learning about symptoms, suggesting strong readiness to adopt CAI in a well-being context.

All participants were current Headspace users, and 73.3% (n=11/15) had used the CAI tool at least once. Overall, 66.7% (n=1015) described their first impression of the CAI tool as positive, with 46.7% (n=715) rating it somewhat positive and 20% very positive. A single participant expressed a somewhat negative view, with follow-up questions suggesting this participant is hesitant to share their feelings with AI in general. Participants generally found the CAI tool approachable and supportive, often describing it as a quick way to check in emotionally or regain focus, though several remained uncertain about how personalized or trustworthy its responses might be compared with other AI tools.

When asked when they imagined using the CAI tool throughout the week, participants most frequently selected moments of heightened emotion or daily transition. Overall, 80% (12/15) anticipated using the CAI tool when feeling anxious or overwhelmed, 60% (9/15) during stressful moments, and 46.7% (7/15) during morning routines, commutes, or while winding down at night. Overall, 33.3% (5/15) expected to use it during work or study breaks.

Open-ended responses and video transcriptions across the prompts reinforced the quantitative trends and revealed six inductive themes: (1) stress and anxiety coping, with members using the CAI tool to ground, reframe, and normalize emotions; (2) work/career focus, using the CAI tool to reset between meetings or during pressure; (3) interactive self-reflection, treating the CAI tool as a responsive diary; (4) sleep and nighttime routines, using the CAI tool to wind down and process the day; (5) content recommendations and navigation, valuing guidance to relevant meditations and courses; and (6) trust, privacy, and accuracy expectations, requesting transparency on data handling and more personalized guidance. Collectively, entries situate the CAI tool as an adjunct, between-session support that complements members' broader mental-health toolkit rather than replacing human care. Members contrasted the CAI tool's mental-health framing and content routing with general-purpose AI tools, and they emphasized opportunities to increase personalization and clarify privacy and safety. Key quotes for the open-ended response themes are reported in Multimedia Appendix 5.

Discussion

Principal Findings

The purpose of this study was to understand Headspace members' overall sentiment toward AI and expectations for a mental health CAI tool, evaluate real-world use of the CAI tool, and understand how Headspace members perceive a CAI tool fitting into their broader mental health journey. Results from this study are imperative to the field of digital mental health, where AI is rapidly evolving, but limited insights exist on the details of real-world engagement and use cases. Despite reporting overall neutral attitudes toward AI, the majority of members reported using general AI tools. Members viewed the CAI tool as a valuable tool to process thoughts and reflect, connect to relevant Headspace content, and provide support in between other forms of care (eg, therapy). A substantial number of Headspace members interacted with the CAI tool during the study period, and iterative product improvements led to higher retention, greater engagement, and deeper conversations. Diary study results further highlight the CAI tool's role as an accessible form of support that naturally integrates into moments of stress, transition, or reflection.

While our findings and broader AI engagement data indicate widespread adoption of generative AI tools [18], attitudes toward AI remain neutral to negative, and skepticism persists [19]. These results underscore the critical need for transparency in AI-driven mental health products. Although members expressed

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trust in Headspace, they emphasized the importance of understanding the confidentiality and security measures governing the data they share with the CAI tool. Members also requested that the CAI tool be clearly labeled as an AI tool to differentiate it from human-delivered care (eg, text-based mental health coaching or therapy). As the regulatory landscape evolves to catch up with AI advancements, it is important for companies developing mental health AI tools to enact minimum viable safeguards including: (1) transparent consumer labeling of intended use, benefits, and limitations; (2) safety by design principles to monitor for overuse, detect risk, and flag needs for escalation; and (3) child and adolescent safeguards to account for developmental differences in users. Beyond regulation, as AI adoption and attitudes continue to evolve, it will be essential to regularly assess how members perceive AI's role in their mental health care experiences, particularly in relation to professional, human-delivered care.

In contrast to other mental health AI tools developed for therapeutic or clinical applications, the Headspace CAI tool was designed for subclinical support to help maintain mental wellness by fostering regular reflection and mindfulness. It is not a substitute for human-delivered care and does not provide clinical mental health services [11]. Member perceptions were consistent with the CAI tool's intended subclinical use case, describing the CAI tool as a tool that promotes self-reflection, enables brief emotional resets and reflective pauses, guides them toward relevant Headspace mental health content and resources, and provides in-the-moment support between additional care, such as therapy sessions. Findings from the diary study further reinforce this view, with members seeing the CAI tool as a complementary aid that naturally fits within their daily routines and broader mental health ecosystem. Notably, members often turned to the CAI tool during moments of heightened emotion or during daily transitional periods (eg, commutes, work or study breaks, or while winding down at night). These patterns highlight an opportunity for mental health AI tools to engage people in real time during moments of activation—when stress, frustration, or sadness are high enough to spark openness to change, but not so high as to overwhelm [20]. While therapy and other traditional forms of support often focus on reflection after the fact, AI interventions like CAI tools can offer assistance in the moment, when the mind may be most receptive. Additionally, the CAI tool's connection to Headspace's extensive evidence-based content library allows for dynamic recommendation of the right mindfulness exercises, meditations, and/or cognitive-behavioral tools based on a member's needs. Improving the CAI tool's ability to more seamlessly navigate to licensed professionals when higher levels of support are needed, including coaches, therapists, and psychiatrists within the Headspace network, can ensure that members receive the right level of care at the right time. An integrated system of AI, content, and human care creates a safe, clinically informed continuum of support compared to stand-alone mental health AI tools.

The rapid evolution of general-purpose AI and related technologies creates new opportunities for the continued advancement of purpose-built mental health AI. In just over a year since launch, the CAI tool has undergone significant updates. Notably, its LLM was expanded to include more conversational prompts, Headspace content recommendations, enhanced memory capabilities (capturing prior conversations and Headspace content engagement), and a more robust approach to safety risk detection. These improvements aimed to increase personalization, strengthen safety mechanisms (eg, escalation pathways, high-acuity flagging, and AI-based risk detection), and foster deeper engagement with Headspace app content. Comparative engagement data between CAI tool 1.0 (preupdate) and CAI tool 2.0 (postupdate) reflect these enhancements. Descriptive results indicate higher retention, greater weekly activity, and more positive conversation ratings. Although the average number of sessions per user remained similar, the CAI tool 2.0 cohort exchanged more messages, suggesting increased conversational depth. Among retained CAI tool 2.0 users (those with 2+ sessions within 7 days), weekly retention continued to rise. Moreover, these retained users averaged more than twice as many sessions as those in the CAI tool 1.0 and the general CAI tool 2.0 cohort. Overall, this study's engagement data suggests that enhanced memory, personalization, conversational depth, and tailored content recommendations contributed to stronger user retention, indicating that members are finding meaningful support and returning to the CAI tool more frequently. As users engage with AI more regularly, conversations likely become increasingly personalized, deepening user comfort and connection with the tool. Furthermore, as AI adoption and familiarity grow more broadly, individuals may become more open to engaging with mental health AI products, potentially leading to new patterns of real-world engagement over time.

Strengths, Limitations, and Future Directions

A key strength of this study lies in its use of large-scale, real-world engagement data drawn from a widely used commercial mental health app. The multiple methods design integrating multiple data sources with both quantitative and qualitative as well as survey and real-world data, offers a nuanced understanding of how Headspace members engage with the CAI tool and provides valuable insight into how AI tools can be safely and effectively designed for mental health support.

While this study contributes important findings to the emerging field of AI in mental health, several limitations should be acknowledged. The data analyzed reflect Headspace members who used the CAI tool during its first year of availability, which may introduce selection bias toward individuals who are already comfortable using digital tools for mental health or who are early adopters of AI-based support. Additionally, data suggest that this study skewed toward a highly engaged and technologically fluent sample, which may limit generalizability. These analyses focus on descriptive surveys, engagement, and qualitative data. Although these descriptive findings help bridge an important knowledge gap in understanding real-world use of AI within digital mental health contexts, future research should aim to link engagement patterns with clinical outcomes to more fully assess the efficacy and impact of AI-driven mental health tools.

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Headspace's future product development for mental health CAI will focus on deeper integration across Headspace's full spectrum of mental health resources, enabling members to use the CAI tool not only to access mindfulness and meditation content, but also to more seamlessly connect with licensed professionals. Additional advancements include the development of single-session interventions and conversation pathways designed to provide tailored, in-the-moment support. Continued development of all mental health AI tools should include transparent consumer labeling, safety by design principles, and child and adolescent safeguards in addition to continued advancements to expand memory, personalization, conversation depth, and coping skill development. Future research will expand beyond descriptive and feasibility studies to examine clinical efficacy and outcomes, exploring how the CAI's ongoing evolution influences engagement, care adherence, clinical outcomes, and individual differences that may moderate these effects.

Conclusions

AI tools offer tremendous promise for expanding access to mental health care; however, it is essential that such tools are purpose-built for mental health by experts with minimum viable safeguards including (1) transparent consumer labeling of intended use, benefits, and limitations; (2) safety by design principles to monitor for overuse, detect risk, and flag needs for escalation; and (3) child and adolescent safeguards to account for developmental differences in users. Ebb, Headspace's empathetic CAI tool, was developed by clinical psychologists using motivational interviewing techniques and clinically informed safety systems to help members process thoughts and emotions while guiding them toward relevant content within the Headspace app. Findings from this study reveal that, despite generally neutral to negative attitudes toward AI, members are using AI tools and plan to continue use. Members viewed the CAI tool as a complementary mental health resource, fitting naturally into their broader system of care by connecting them to helpful content within the app and supporting reflection. Engagement patterns have evolved over time, with product updates leading to higher retention, greater engagement, and deeper conversations. Future development will focus on further integration with Headspace's full spectrum of mental health services, while upcoming research will evaluate the CAI tool's impact on clinical outcomes and care adherence. Continued, clinically informed innovation in AI for mental health is essential to ensure that these tools remain safe, effective, and supportive for individuals seeking accessible mental health care.

Acknowledgments

NotebookLM was used to support the member survey qualitative analyses; specifically, open-ended responses from the member survey and diary study were uploaded and analyzed for common themes and topics. Authors then reviewed the common themes suggested by NotebookLM and created the themes and topics for the analyses, working off the initial themes indicated by NotebookLM. Authors then pulled direct quotes into categories to finalize the themes and topics. ChatGPT was used to edit and format the paper.

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Authors' Contributions

C Callahan contributed to conceptualization, data curation, formal analysis, investigation, methodology, and writing (original draft, reviewing, and editing). LT contributed to data curation, formal analysis, methodology, and writing (reviewing and editing). C Coe contributed to data curation, formal analysis, investigation, methodology, and writing (original draft, reviewing, and editing). MD contributed to conceptualization, resources, and writing (reviewing and editing). JG contributed to conceptualization, supervision, and writing (reviewing and editing). EB contributed to conceptualization, resources, and writing (reviewing and editing). KS contributed to supervision, conceptualization, resources, and writing (reviewing and editing). KU contributed to supervision, conceptualization, resources, and writing (reviewing and editing). MC contributed to conceptualization, resources, and writing (reviewing and editing). SK contributed to conceptualization, methodology, supervision, and writing (original draft, reviewing, and editing).

Conflicts of Interest

C Callahan, LT, C Coe, JG, EB, KS, KU, and SK are paid employees of Headspace. MD and MC were paid employees of Headspace at the time of the study.

Multimedia Appendix 1
STROBE checklist.
[PDF File (Adobe PDF File), 90 KB - formative_v10i1e86904_app1.pdf]

Multimedia Appendix 2

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Member survey questions to understand overall sentiment toward AI and what do Headspace members want from a mental health AI tool.
[PDF File (Adobe PDF File), 83 KB - formative_v10i1e86904_app2.pdf]

Multimedia Appendix 3
Member survey qualitative results highlighting themes, topics, and key quotes from open-ended survey questions.
[PDF File (Adobe PDF File), 65 KB - formative_v10i1e86904_app3.pdf]

Multimedia Appendix 4
CAI tool 2.0 conversation topics synthesized via in app data collection.
[PDF File (Adobe PDF File), 88 KB - formative_v10i1e86904_app4.pdf]

Multimedia Appendix 5
Key themes and CAI tool use cases from the diary study open-ended questions.
[PDF File (Adobe PDF File), 61 KB - formative_v10i1e86904_app5.pdf]

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Abbreviations

AI: artificial intelligence
AIAS-4: Artificial Intelligence Attitude Scale-4
CAI: conversational artificial intelligence
DAU: daily active user
HIPAA: Health Insurance Portability and Accountability Act
LLM: large language model
MAU: monthly active user
STROBE: Strengthening the Reporting of Observational Studies in Epidemiology
WAU: weekly active user

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Original Paper

Exploring Strategies for a Digital Tool to Support Medication Adherence Among Adolescents and Young Adults Undergoing Hematopoietic Stem Cell Transplant and Their Care Partners: Qualitative Formative Study

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Abstract

Background: Allogeneic hematopoietic stem cell transplant (HCT) is a complex but essential treatment for malignant and nonmalignant conditions, requiring strict posttransplant adherence to immunosuppressant medications to prevent complications such as graft-versus-host disease. Adolescents and young adults undergoing HCT face unique challenges, including balancing growing independence with ongoing reliance on care partners, often parents. Medication adherence in this group is often suboptimal, and few interventions address adolescent and young adult–care partner dyads. To address this gap, we aim to develop a mobile health (mHealth) app that engages both the patients and care partner to improve adherence.

Objective: As formative research for early-stage intervention development, this study aimed to (1) explore current HCT medication adherence strategies and challenges; (2) understand attitudes toward digital technology, including dyadic perspectives on app use to support adherence; and (3) assess adolescent and young adult–care partner relationships, including views on care partner involvement. This process was intended to inform the design of a relevant, user-centered mHealth app.

Methods: Eligible participants included adolescents and young adult patients aged 12-39 years and primary care partners, such as parents, involved in medication management. Participants were recruited from a large academic medical center through direct outreach and electronic health records. Data collection involved 2 focus groups (6 dyads and 2 additional adolescents and young adults), 4 individual interviews (2 patients and 2 care partners), and 6 dyadic interviews. Semistructured sessions (in person or virtual) gathered feedback on medication adherence practices and app design preferences. All sessions were audio recorded with consent and professionally transcribed. Qualitative data were analyzed systematically: transcripts were deidentified, coded using both inductive and deductive strategies, and themes were refined through team consensus. Patterns were organized into major themes, and representative quotations were selected to illustrate findings. Data management was facilitated by NVivo (version 13; Lumivero) software.

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Results: We included 28 participants (15 adolescents and young adults and 13 care partners). The median age of adolescents and young adults was 18 (range 13-39) years and 53% (8/15) were female. Adolescents and young adults were 47% (7/15) White, 40% (6/15) Black, and 13% (2/15) mixed race. Care partners' median age was 48 (range 36-72) years, with 92% (12/13) female and 77% (10/13) White. Three principal themes emerged: (1) existing reminders and organizational tools are often insufficient for consistent adherence; (2) adherence barriers are multifaceted, often involving autonomy vs care partner support; and (3) both adolescents and young adults and care partners showed strong interest in a dyadic digital health intervention to foster collaboration and support shared adherence goals.

Conclusions: This formative study highlights the complex dynamics of medication adherence in adolescent and young adult–care partner dyads and supports the need for a dyadic mHealth app to enhance adherence, collaboration, and relationship quality.

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KEYWORDS

adherence; adolescent; family caregiver; family relations; hematopoietic stem cell transplant; medication; mHealth; mobile health; young adult

Introduction

Allogeneic hematopoietic stem cell transplant (HCT) is a potentially lifesaving treatment for malignant and nonmalignant conditions, such as aplastic anemia and sickle cell disease [1]. This procedure requires intensive radiotherapy and/or chemotherapy to achieve adequate immunosuppression, enabling successful engraftment of healthy donor stem cells [2]. Adolescents and young adults undergoing HCT face unique challenges, including disruptions in peer and family relationships, concerns about cancer care quality, and difficulties maintaining treatment-related health behaviors [3]. Adherence to immunosuppressant regimens (eg, tacrolimus and cyclosporine) is essential to prevent and treat potentially life-threatening posttransplant complications, such as acute graft-versus-host disease (GVHD) [4], with even minor deviations associated with poor clinical outcomes in transplant recipients [4]. Despite this, to our knowledge, no evidence-based interventions are available to support adolescents and young adults and their care partners, often parents, in medication adherence [5].

GVHD remains a leading cause of transplant-related morbidity and mortality among HCT recipients [6]. GVHD arises from a "cytokine storm" following host tissue injury, eventually resulting in target end-organ damage [7]. This complication can lead to cognitive decline, diminished health-related quality of life (HRQoL), and challenges reintegrating into society as a long-term survivor [8]. Thus, interventions aimed at improving adherence to prophylactic immunosuppressant medications could be especially beneficial for this population. This is especially relevant among adolescents and young adults, who show lower medication adherence than younger children across various conditions, including cancer [9], and who must navigate illness during a critical developmental stage [10].

In this population, we define medication adherence primarily as the success rate at which someone takes their prescribed medication. Of equal importance is the timing of the medication, 9 AM and 9 PM, for example, as the medication is most useful when taken at specified times (12 hours apart). Subsequent dimensions, such as routine formation, autonomy of medication taking, and collaboration with a care partner, also contribute to our definition. Medication adherence rates in the adolescent and young adult HCT population are suboptimal, estimated at 52%-72% [11]. Although understanding the specific risk factors and barriers to nonadherence is crucial, it remains significantly understudied in this group [11]. Existing research points to multiple reasons for missed doses, including medication refusal, resistance to care partner involvement, forgetfulness, side effects, and interference with usual activities such as socializing [11,12]. Adolescents and young adults have also expressed a desire for resources and tools, such as medication reminder systems, to support adherence [12].

Our prior research has shown that adolescents and young adults undergoing cancer treatment often rely on, or share, medication management responsibilities with their care partners [13,14]. Although adolescent and young adult years are characterized by increasing autonomy, many adolescents and young adults benefit from continued support due to the complexity of their treatments and associated side effects. It is also normative for adolescent and young adult-care partner dyads to experience relational strain during these years, as family roles and responsibilities are renegotiated to support the developmental strivings of adolescence (eg, peer affiliation and greater independence). While such challenges are often temporary, disruptions in family functioning can hinder medication adherence. A meta-analysis found that greater family conflict, lower cohesion, and poorer problem-solving were all associated with reduced adherence to medical regimens in children and adolescents with chronic health conditions [15].

Because HCT medication management typically requires active involvement from both the adolescent or young adult and care partner, the bidirectional relationship within the dyad is critical to consider [16]. The experiences and psychological well-being of both members are closely linked, and addressing them cohesively can improve medication adherence and related outcomes, such as HRQoL [17,18]. Interventions that engage care partners or focus on family functioning have been shown to improve medication adherence in pediatric and adolescent populations [19]. Dyadic models emphasize joint problem-solving and treating health care as a team effort [17], with interventions often incorporating behavioral strategies (eg, reminders and incentives), cognitive approaches (eg, shaping attitudes toward adherence), and collaborative problem-solving [19,20]. Thus, developing a digital intervention that targets the

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dyadic unit, rather than focusing solely on the patient or care partner, may yield a more effective approach [17].

This study is part of a multiphase research project to guide the early-stage development of a mobile health (mHealth) app delivering a dyadic just-in-time adaptive intervention (JITAI) for adolescent and young adult HCT recipients and their care partners. Traditionally, JITAIs provide timely, tailored support to individuals based on dynamic needs and contexts [21]; for example, offering medication reminders when an adolescent or young adult is away from home and at higher risk of forgetting. Mobile platforms are ideally suited for these interventions, enabling real-time personalization through continuous assessment of temporal contexts through sensors and brief surveys. Our proposed JITAI is uniquely designed to address the needs of both members of the adolescent and young adult–care partner dyad, supporting shared challenges and leveraging their interdependent experiences to promote medication adherence and well-being.

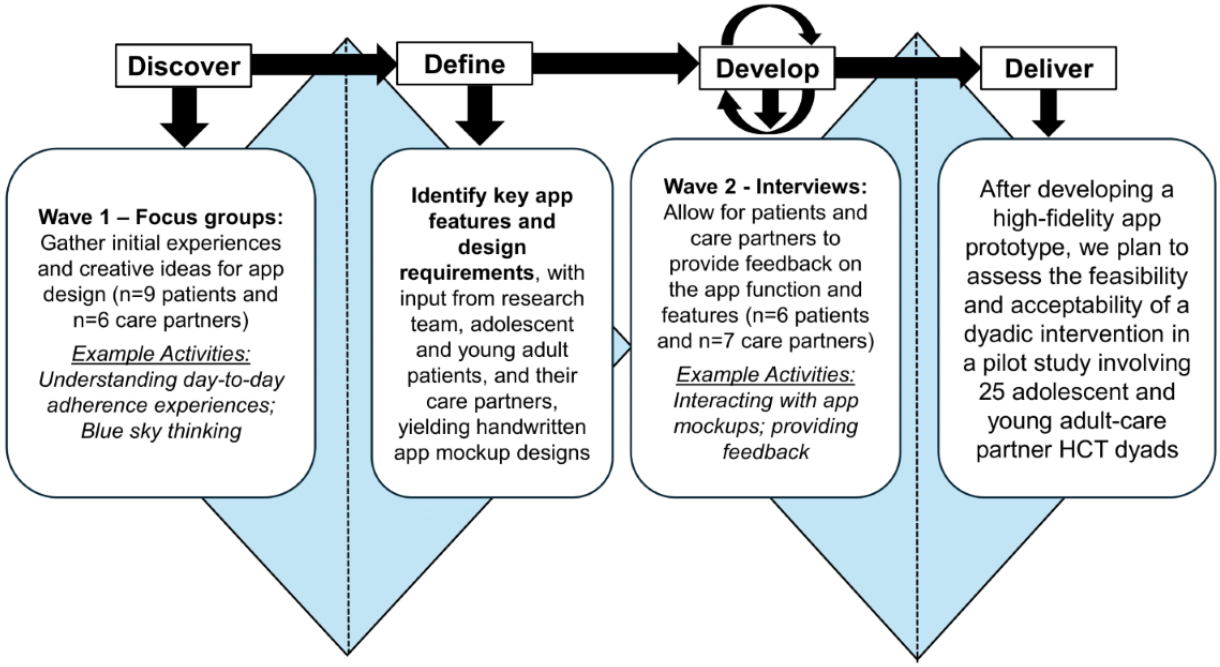
As formative research to inform app development, this study reports on findings from qualitative interviews and focus groups conducted with adolescent and young adult–care partner dyads. The semistructured sessions focused on three primary objectives: (1) exploring current HCT adherence and medication management strategies and challenges; (2) understanding attitudes toward digital technology, including dyadic perspectives on using an app together to support adherence; and (3) assessing adolescent and young adult–care partner relationships, including adolescents' and young adults' attitudes about care partner involvement in medication management. These sessions also incorporated a think-aloud approach [22] with hand-drawn mock-ups, enabling participants to provide feedback and co-design suggestions for the app's features, layout, and design.

Methods

Study Design and Setting

The study was conducted at a large, tertiary academic center in the Midwest (Michigan Medicine in Ann Arbor, Michigan, United States). Our methods were guided by the Double Diamond Framework (Figure 1), a widely used, human-centered design framework that incorporates both divergent (free-flowing and creative ideation, ie, the widening of the diamond) and convergent thinking (identifying concrete solutions, ie, the narrowing of the diamond) to co-create desirable and usable interventions with users [23,24].

Figure 1. Double Diamond Framework. The "Discover" step is connected to Wave 1 focus group findings; the "Define" step is connected to identifying key app features and design requirements; the "Develop" step is connected to patient and care partner feedback that informs app development; and the "Deliver" step is connected to the planned future pilot study. HCT: hematopoietic stem cell transplant.



Recruitment and Enrollment

Eligible patients were aged 12-39 years, received care from a Michigan Medicine provider in the Pediatric Hematology/Oncology and Blood and Marrow Transplant and Cellular Therapy Unit, and were currently prescribed daily immunosuppressant medications, such as tacrolimus or cyclosporine. While the typical adolescent and young adult age range is 15-39 years, as defined by organizations such as the National Cancer Institute and the American Cancer Society, eligibility was extended to include patients as young as 12 years, as they commonly own smartphones and are of assenting age. Care partners were eligible if they were aged 18 years or older and identified by the patient as a primary care partner. All participants were required to speak English. Eligibility was determined through Michigan Medicine's electronic health record, Epic (MiChart). Recruitment methods included flyers

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placed in clinic rooms, outreach in the clinics, as well as direct phone calls and emails. Informed consent (or assent for minors) approved by the University of Michigan Medical School Institutional Review Board was obtained from all participants using either traditional paper forms or electronic platforms. Recruitment continued until thematic saturation was reached, as indicated by the absence of new information or emerging themes [25].

Focus Groups and Interviews

The study consisted of focus groups and semistructured qualitative interviews, conducted either in conference rooms at Michigan Medicine or through password-secured Zoom (Zoom Video Communications, Inc), involving 28 participants (15 adolescents and young adults and 13 care partners). Data collection included 2 focus groups, comprising 6 patient–care partner dyads and 2 additional adolescents and young adults, 4 individual interviews (2 patients and 2 care partners), and 6 dyadic interviews. Sessions were facilitated by trained research staff (GS and SWC) using standardized Moderator Scripts (Multimedia Appendix 1), which was initially developed by GS and then iteratively refined after each round of focus groups or interviews. Before the commencement of the interviews, GS and SWC explained to participants the motivations and primary goals for the interview sessions (Multimedia Appendix 1).

In Wave 1, focus groups and 2 individual interviews explored initial experiences and generated ideas; in Wave 2, a total of 6 patient–care partner dyadic interviews and 1 individual interview were conducted to gather usability feedback on app mock-ups (Figure 1). All sessions followed open-ended questions designed to elicit detailed discussion about medication adherence experiences, strategies, reasons for missed doses, patient–care partner interactions and collaboration, attitudes toward technology, and desired app features to support collaboration and relationship building.

A think-aloud procedure [22] using hand-drawn app mock-ups was used to collect in-depth feedback about app design, layout, and features. Focus groups lasted approximately 45 minutes, individual interviews approximately 25 minutes, and dyadic interviews approximately 60 minutes. Participants received US $20 compensation on completion. Sociodemographic data (eg, age, sex, disease name, and date of birth) were collected with permission through the electronic health record. All sessions were audio recorded and professionally transcribed verbatim by Babbletype Inc (Philadelphia) with permission; a second note-taker (GR and ZB) was present during the focus groups and interviews. All data were deidentified, and participants were assigned a unique code to maintain anonymity (deidentified transcripts are available upon request from the corresponding author).

Thematic Analysis

Guided by the Double Diamond Framework [23,24], data were analyzed using a thematic approach [26], with ongoing integration between data collection and analysis. The codebook was developed by ZB and GR under the supervision of SWC. Initial coding was open-ended and conducted independently by both coders to identify broad patterns, using line-by-line or paragraph-level review of transcripts in NVivo 13 (QSR International). This stage focused on qualitative content analysis [27] and allowed for the generation of new codes as significant concepts and themes emerged. The team then compared and discussed their codes, collaboratively organizing them into an initial codebook (Multimedia Appendix 2). Notably, divergence in participant perspectives allowed refinement of the coding framework by expanding and clarifying code definitions. Convergence, in which similar patterns or themes emerged, helped prioritize and emphasize core themes in the analysis, allowing focus on commonly shared needs and concerns expressed by participants.

Analysis followed established phases of thematic analysis: familiarization with the data, generation of initial codes, searching for themes, reviewing themes, defining and naming themes, and producing the final report. As subsequent transcripts were analyzed, the codebook was iteratively refined, and new codes were added as warranted. Emerging patterns and subthemes were grouped into overarching themes, with short codes assigned to representative quotations. Each transcript was reviewed by at least 2 research team members (ZB, GR, or SS), and discrepancies in coding or theme interpretation were resolved by a third reviewer as needed. The final synthesis and interpretation of codes and themes were completed by ZB and GR and reviewed by the broader study team (SS, AP, MR, GS, and SWC). This iterative approach ensured that consistent, hierarchically organized themes were confirmed by later interviews and represented the key patterns across the dataset.

Reflexivity

We are an interdisciplinary research team based at a tertiary academic medical institution in the Midwest, bringing diverse expertise grounded in biomedical sciences. Our research team is composed of a variety of racial and ethnic backgrounds, sexes, ages, and training levels. As noted in the Authors' Contributions section, the research scientists hold PhD degrees in strategy (GS), behavioral and management sciences (IBNS), statistics (SM and ZX), and psychology (AP), with tenure-track appointments at academic institutions across the Midwest, South, and Northeast. The research assistants (GR, ZB, and SS) and lab manager (MR) have all been trained in qualitative research in the biomedical setting primarily by an MD physician-scientist with expertise in cancer and HCT research (SWC). Our team developed expertise in qualitative research through interdisciplinary programs and research projects. Our team's collective experience shaped this research project, bringing together different and diverse perspectives and training. The moderator scripts were developed by GS, who has expertise in human factors research. Thus, the interpretation of the study findings is informed by our team's clinical and scientific training, which shapes our perspective on medication adherence and digital health research. We acknowledge that our biomedical orientation influences how we frame, analyze, and contextualize the results.

Ethical Considerations

The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). Ethics approval for the study was obtained from the University of Michigan Medical School

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Institutional Review Board (HUM00224785). Participants did not have any prior relationship with the research staff before consenting and completing the interview. All study participants provided informed consent by signing and returning an institutional review board–approved consent document. Each participant received US $20 compensation after completing the interview. Each participant was assigned a unique study ID to protect their identities, and all transcripts were deidentified prior to analysis. Data generated in this study were secured in a password-protected, HIPAA (Health Insurance Portability and Accountability Act)-compliant database. The authors take full accountability for the work, ensuring that the study was conducted with full integrity and that all questions or concerns related to the study were thoroughly investigated and addressed.

Results

Wave 1 Insights on Adherence Challenges and App Design Feedback

Table 1 summarizes the goals, major themes, participant quotations, and subsequent design decisions from Wave 1 of the study. It highlights current adherence challenges, attitudes toward technology, and patient–care partner collaboration, linking user insights to medication adherence strategies.

Table 1. Wave 1 goals, major themes, participant quotations, and Wave 2 feedback.

Theme	Wave 1: goals	Wave 1: major themes	Wave 1: quotes	Wave 2: design decisions and initial feedback
Theme 1 (correlation with medication adherence dimensions): strategies, such as pill boxes, phone alarms, and reminders, correlate with dose-taking and dose-timing dimensions of medication adherence.	Goal 1: current adherence challenges and strategies	• Challenges: getting out of routine, sleeping in or staying out late, and living the life of a teenager (eg, spending time with friends). • Strategies: pill boxes, phone alarms, or reminders.	• "Reminders on my phone. I have an alarm clock as well" [MA-20 AYA] • "I pair my medicine with a daily activity" [MA-06 AYA] • "Life in general. A busy work schedule, other activities." [MA-14 Care Partner] • "Morning is a struggle." [MA-17 Care Partner] • "I'd usually be out socializing" [MA-02 AYA]	• Patients self-reporting a dose being taken empowers autonomy and reduces direct care partner oversight. • Adaptive daily reminders to play a game that implicitly reminds the patient to take their dose. • Patients and care partners felt that these types of reminders would not be a burden.
Theme 2 (correlation with medication adherence dimensions): attitudes toward using technology, such as allowing patients to keep track of their medication on their own, correlate with medication-taking, routine, and habit formation, and autonomy surrounding medication adherence.	Goal 2: attitudes toward using technology	• Technology would help adherence. • The app should be visually appealing. • It would make life easier. • It allows patients to keep track of medication on their own.	• "I think it's better than having somebody…remind you…you still have that feeling of autonomy." [MA-05 AYA] • "I would feel like if the app is more eye-catching and attention catching, it would help." [MA-06 AYA] • "The value, to me, is that one, I can see it, but then she is also learning to be more independent with it, so when she is on her own, it'll become a better habit that she'll continue." [MA-07 Care Partner]	• A simple, user-friendly interface with bright colors. • A calendar view available to both the patient and care partner provides some oversight while fostering adolescent and young adult independence.
Theme 3 (correlation with medication adherence dimensions): positive feelings from both patients and care partners toward collaborating in an app correlate with routine and habit formation and collaboration with a care partner.	Goal 3: attitudes toward patient and care partner collaboration in an app	• Liking the idea of collaborating in an app. • Believing it would be useful for the parent and patient to use the same app. • Various levels of collaboration would work at different patient ages.	• "I think that's good, because that can, in some ways, push you to do better." [MA-02 AYA] • "I feel like that would help both of us get an understanding of what needs to happen." [MA-06 AYA] • "You don't get too many times to sit there and collaborate on things too much." [MA-10 AYA]	• A collaborative word game that requires input from both patient and care partner. • This feature leads to improved management of the dyadic unit, focusing on a common goal of completing the task. • It takes dyadic communication focus away from medication and toward a collaborative pursuit.

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Demographics of Study Participants

The median age of the adolescents and young adult patients was 18 (range 13-39) years, with a balanced sex distribution of females (8/15, 53%) and males (7/15, 47%). Their racial distribution included 47% (7/15) White, 40% (6/15) Black, and 13% (2/15) mixed race. Among the care partners, the median age was 48 (range 36-72) years, with the majority being female (12/13, 92%). Racial distribution among care partners was 77% (10/13) White and 23% (3/13) Black. A detailed distribution of participants by focus groups and interviews is provided in Multimedia Appendices 3 and 4, respectively.

Table 2 summarizes demographic characteristics of the study participants, including gender, age, race, and ethnicity, for both patients and care partners.

Table 2. Patient and care partner demographic information.

Characteristic	Patients (n=15)	Care partners (n=13)	Total (N=28)
Sex			
Male	7 (47%)	1 (8%)	8
Female	8 (53%)	12 (92%)	20
Age (years), median (range)	21 (13-39)	48 (36-72)	33 (13-72)
Race			
Black or African American	6 (40%)	3 (23%)	9
White	7 (47%)	10 (77%)	17
Mixed race	2 (13%)	0 (0%)	2
Ethnicity			
Hispanic or Latino	0 (0%)	0 (0%)	0
Non-Hispanic or Latino	15 (100%)	13 (100%)	28

Focus Group and Interview Findings

Overview

The focus groups and interviews revealed key insights into the challenges, relationship dynamics, and strategies used by adolescents and young adults and their care partners in managing medication adherence, as well as their use of technology and preferences for an mHealth app. Major themes related to adherence barriers and challenges, as reported by patients, care partners, and dyads, are summarized below and illustrated in the schematic presented in Figure 2.

Adolescents and young adults perspective: patients commonly identified forgetfulness, medication side effects, and a sense of being constantly monitored by care partners (often parents) as barriers, leading to an increased desire for autonomy and agency.

Care partner (parent) perspective: care partners focused on ensuring medication adherence while also supporting the patient's development of autonomy and self-management skills.

Dyadic perspective: both adolescents and young adults and care partners shared the goal of promoting adolescent and young adult autonomy and agency, highlighting the importance of balancing support with independence.

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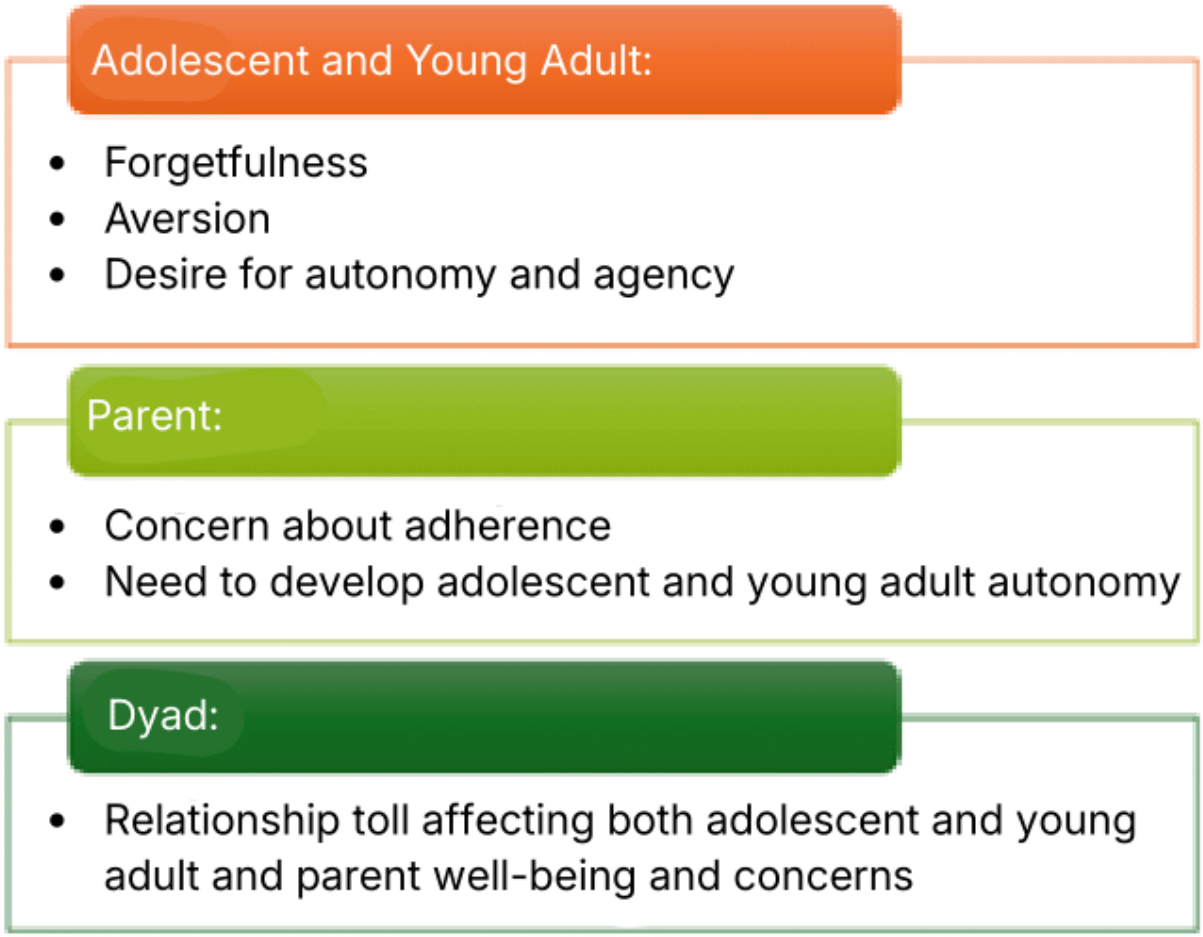
Figure 2. Key findings from focus groups and interviews.



Medication Adherence Challenges

Adolescents and young adults consistently reported difficulties maintaining their medication regimen, with the most significant barrier being disruption of routines typical in this developmental stage. Common scenarios included staying out late with friends or sleeping in, which often resulted in missed or late doses.

> *For me, I'd usually be out socializing, so an event at a friend's house or something, and then 9:00 rolls around and… I don't have my [medication].* [MA-03 AYA]

Adolescents and young adults acknowledged that irregular schedules posed ongoing challenges to adherence, particularly for morning doses.

> *One big reason that I miss a dose is sleeping in. I like to sleep in. A lot of the time, I sleep in past 12:00 p.m., so I'll miss that morning dose, but I typically won't miss the evening dose.* [MA-20 AYA]

Their care partners also recognized that routines can be disrupted by staying up late and sleeping in.

> *I don't know if it's because he felt…It's more or less just forgetting and being busy, the busier he is. If he is out with his friends or he is at work or something, it just slips his mind.…We haven't taken the tacrolimus yet. He's done Xarelto like that though where he had the blood clots. He had to take that on a regimented basis. There were times when he just completely missed a dose. You'd be like, "Why?" He was just, "Oh, I forgot," or, "I slept in," or, "I wasn't here and I didn't have the pill with me." That's another big one is it's time to take it and not having it with them.* [MA-02 Care Partner]

Existing Strategies for Medication Adherence

Patients and care partners described several strategies used to support adherence, including setting phone alarms, using reminder and calendar apps, and organizing medications in pill boxes. These tools helped automate reminders and allowed care partners to discreetly monitor adherence, reducing the need to directly prompt the patient.

> *Timers are really good to help remembering to take your meds…I have an iPhone, but the Reminders app is okay. Then, what I will also do, sometimes, is input events in my Calendar app on my phone. It will pop up, and you can set it to remind you every day or every week or whatever the case may be. Those are three helpful things electronically.* [MA-05 AYA]

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> *I do like the pillbox though because then I can always double check, you did, in fact, take it, without having to bug her constantly.* [MA-06 Care Partner]

Despite these efforts, both adolescents and young adults and care partners shared that busy schedules, forgetfulness, and the desire to avoid being constantly reminded still contributed to suboptimal adherence.

> *No, they're just like, 'No big deal.' We're the ones hovering over the bedside, watching them suffer, and they're knocked out. They don't remember half of it.* [MA-04 Care Partner]

> *I'll say if I'm having a really busy day and I don't keep track of everything that I'm doing or everything I need to do, I forget that I have to take my medicine. I'm like, 'Oh, I forgot to take my medicine today'.* [MA-06 AYA]

Views on Technology and Tools to Promote Medication Adherence

Attitudes Toward Using an App to Assist With Adherence

Care partners expressed enthusiasm for the potential of an app to support medication adherence.

> *Oh my God, you guys can help so many, so many patients.* [MA-12 Care Partner]

Care partners highlighted the value of verifying dose completion without direct verbal reminders.

> *Just as a point that we can make sure they've taken it without having to constantly call them or text them or bug them about it, is where I see the value in it more.* [MA-07 Care Partner]

Adolescents and young adults shared this interest, particularly appreciating features that could foster a greater sense of autonomy.

> *I think it's better than having somebody, like family or friend, remind you, only because, if it's a reminder that you set up yourself, you still have that feeling of autonomy. You did yourself, it's you reminding yourself, instead of somebody else.* [MA-05 AYA]

> *"It'd probably be better if it was an app or an inanimate object yelling at me, rather than my own mom. It'd be easier to deal with.* [MA-02 AYA]

Potential Concerns About App Features

Adolescents and young adults and care partners agreed that complex or time-consuming apps would be burdensome. Preferred features included a shared calendar for medication tracking, notification reminders, and optional shared activities, such as a simple and engaging game that could be completed in under 5-minutes. An interviewer asked adolescent and young adult participants and a care partner about the ideal length of a game within the app

> *Interviewer: How long do you guys think would be a good amount of time to have the game take?*

MA-06 AYA: No more than five minutes.

MA-18 Care Partner: I know every person's situation is different, but I work full-time. My husband works full-time, so adding this on top of all of the other responsibilities. Maybe it's an optional game within the app.

Overall Suggestions for App

Care partners expressed developing routines and strategies early in the transplant process.

> *[My daughter] has been on it since she was five, so it was easier when she was younger, because I felt more responsible for it, but now that she's older, and I'm trying to get her gear, it has been a little bit difficult.* [MA-06 Care Partner]

Care partners valued the ability to send reminders through the app, reducing the need for direct prompting and supporting the adolescents and young adults' autonomy.

> *If we can go in the app and have the app send them a notification. Like, 'Check and see if she took her meds today.' I think that would be something.* [MA-06 Care Partner]

Both adolescents and young adults and care partners responded positively to a built-in reward system to help motivate and help support the patient's continued, consistent medication adherence.

> *They get a streak or they get to a certain point and they get a little gift or they can send a postcard to their friends or whatever.*" [MA-02 Care Partner]

> *I would say that's nice because, yes, we've taken it all our lives, but I feel like being rewarded for something makes you want to do something even more.* [MA-06 AYA]

The app could also facilitate community-building among adolescents and young adults and care partners with similar medical conditions, providing an additional source of support and relatability that families may not have previously experienced. An interviewer asked an adolescent and young adult participant about the possibility of connecting with others who have a similar disease.

> *Interviewer: Then maybe you could connect with other people who have a similar disease to you or something like that?*

MA-06 AYA: Yes.

Additionally, participants suggested including a feature that allows adolescents and young adults to record reasons for missed doses (eg, an "other" or "why" box), enabling them to note why a dose was not taken. This could help adolescents and young adults identify patterns, such as specific activities or times of day when doses are missed, ultimately supporting improved adherence.

> *I feel like maybe there should be a fourth, like a "other" in there, just in case for some weird reason those three don't actually sum up what it is and you can actually type out what your "other" is.* [MA-18 AYA]

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Patient–Care Partner Dyadic Relationship Quality

Adolescents and young adults frequently described tense or frustrating interactions with care partners, often centered on medication reminders. Care partners similarly expressed reluctance to repeatedly prompt adolescents and young adults but felt their involvement was vital for successful medication management during the transplant process. The desire for increased autonomy and agency was a recurring theme for adolescents and young adults.

> *...sometimes when your parents are on you a lot, it can be annoying. It's like when you're young and you go to do the dishes. You're on the way to the dishes, but while you're on the way there, your parent says, "Go do the dishes," and you don't want to do the dishes.* [MA-05 AYA]

Care partners expressed similar feelings, noting a reluctance to repeatedly remind adolescents and young adults about medication adherence. Nonetheless, they viewed their support, including providing reminders, as essential for successfully navigating the transplant process.

> *It's your medicine. I'm just here giving you a little helping and a little nudging, little kick butting. If there's anything you think will work better, so we don't have to go through this dance, you just throw it out there and let's talk about it.* [MA-04 Care Partner]

Patient's Desire for Autonomy and Agency

Adolescents and young adults expressed a strong desire for autonomy and independence in managing their lives and reported frustration with frequent reminders from care partners about medication adherence.

> *She wanted to feel like she was in control of her life, not that the cancer took control of her life, so many times even if she took a dose she didn't want us to know that she took a dose.* [MA-12 Care Partner]
>
> *Sometimes my mom will get on me about taking it. That makes me actually want to take it less, because I find it annoying, but that's not always the case. Sometimes I have legitimately forgotten, while other times it's usually just a matter of being a kid and having a parent tell me what to do.* [MA-02 AYA]

Care Partner Perspectives on Facilitating Medication Adherence

Care partners shared a range of emotions related to supporting medication adherence, from maintaining a positive outlook to experiencing fatigue, worry, and anxiety.

> *Her health, her staying alive, her fighting through this, her getting through the whole process, and she's my baby. I love her. I don't want anything bad to be happening to her.* [MA-09 Care Partner]
>
> *How I felt? Very worried, very anxious. (Laughs.) Yes. I actually personally had to go to my primary doctor and I asked for help and I had to take some Lexapro.* [MA-12 Care Partner]

Perspectives About Using an App Focused on the Dyadic Relationship

Both adolescents and young adults and care partners responded positively to the idea of an app designed for use by both members of the dyad. They saw potential for the app to support adolescents and young adults' autonomy as well as connection within the relationship through shared or collaborative management of the patient's health.

> *The value, to me, is that one, I can see it, but then she is also learning to be more independent with it, so when she is on her own, it'll become a better habit that she'll continue.* [MA-07 Care Partner]
>
> *I feel like that would help both of us get an understanding of what needs to happen.* [MA-06 AYA]

App Mock-Up Design Interviews

Findings from the focus groups and interviews informed the design of low-fidelity, paper-based mock-ups of the app intended for dyadic use (Multimedia Appendix 5). Participants expressed interest in a shared calendar view, in which adolescents and young adults could log their medication intake and care partners could view, but not edit, these entries. This could facilitate information flow between adolescents and young adults and care partners while maintaining adolescents and young adults' autonomy. This approach centers medication management with adolescents and young adults, allowing them to update their logs while providing care partners with oversight through viewing access only (ie, care partners cannot enter themselves; rather, medications are managed by adolescents and young adults; Table 3).

Table 3. Medication log feedback.

Interviewer-asked question	Participant quotes
"How do you feel about using one of those apps with a care [giver] or parent?"	"I think that would be really helpful because as much as I'm in control of mostly everything I take, it would feel even better if I could just log it myself without making it more of a pressure for my parents to log.' [MA-17 AYA]
"...and then you would be able to see the exact time she took it because she'll click that she took it at that time and it'll log the time that she took the medication."	"Oh my god, you guys can help so many, so many patients ... .Oh, this is really good, 'Medication Log' I think it looks good, yes." [MA-12 Care Partner]
"Describe what you see from top to bottom. What pops up to you as something that you notice?"	"I think the medication log is really cool, just to keep track of what medication you take on whatever day, or how much you have to take, or just even the messages." [MA-2 Care Partner]

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Adolescents and young adults and care partners agreed that working together or collaborating on a shared game within the app could enhance their relationship quality and provide a positive distraction from illness management and related stressors. Participants emphasized that the game should require minimal time commitment, as adolescents and young adults often experience attention and cognitive fatigue, especially over extended periods (Table 4).

Table 4. General game feedback.

Interviewer-asked question	Participant quotes
"What did you like about it (the game)?"	• "I like the idea. The game draws in the parent and the child, tracking. You go into it to play the game, but you also are tracking your medicine." [MA-14 Care Partner] • "I think it's a mind distraction too. Instead of me, 'Come on, [AYA], take the meds, take the meds,' it's, 'Okay, as she's taking the meds, we're playing a game.' We're doing something more interactive." [MA-17 Care Partner] • "Yes, mm-mmm (agreement)." [MA-17 AYA]

The design goals included creating a low-effort, collaborative game for adolescents and young adults and care partners; for example, a word-solving activity in which each member of the dyad (eg, adolescent or young adult and care partner) is assigned specific words within the phrase. Importantly, this collaborative opportunity would take place outside of medication management. The game is intended to be noncompetitive, fostering mutual benefit and possibly strengthening the dyadic relationship by engaging in a shared activity they are doing together (Table 5).

Table 5. Collaborative game feedback.

Interviewer-asked question	Participant quotes
"You have your own word that you can solve…behind the scenes you can meet up together and solve both words together."	• "I like it. I just was wondering. It's intriguing. I think it's fun…Even if they're too young to have the app themselves, they can do it on their parent's phone and they can input, by just touching the screen and the parents can talk over it and say, 'Okay, we're going to input your dose. I'll help you input it.' I like it!" [MA-15 Care Partner] • "If they're just constantly being reminded to take pills, that's (the game) maybe another way that can make you…maybe just a little bit more fun instead of just being like, 'Oh, it's time to take this.'" [MA-2 AYA] • "You don't feel like you're nagging as much because I feel like I nag, but that's my job, so that's what I do (laughs)." [MA-2 Care Partner]

Discussion

Principal Findings

This qualitative study showed that adolescents and young adults and their care partners face significant challenges in maintaining adherence to their immunosuppressant regimens, despite the essential role of these medications in preventing serious posttransplant complications. Although adolescents and young adults strongly desired autonomy and agency in managing their medications, our findings indicate that when left to self-manage, they frequently missed doses due to disrupted routines, oversleeping, forgetfulness, side effects, and competing priorities typical of this developmental stage, such social activities. These findings are consistent with recent studies reporting lifestyle (ie, adjusting to new social and family dynamics) and sleep as common post-HCT challenges [28-30]. In adapting to these challenges, both adolescents and young adults and care partners relied on strategies like pill boxes, phone alarms, and reminder systems. However, these tools often failed to fully overcome barriers such as busy schedules and shifting routines (eg, clinic appointments, transfusions, and other infusions). Eventually, adoption of strategies could help build habit formation, which was similarly discussed in another qualitative study among patients living with acute GVHD: "transitioning from an external obligation to a habit" [31].

When specifically asked, participants viewed technology positively, expressing enthusiasm for a simple, user-friendly app that both adolescents and young adults and care partners could use to support medication tracking, offer visual confirmation of adherence, and provide motivational features, such as rewards or messages. These findings align with recent digitally-delivered interventions reported in similar, though not exclusively HCT, patient populations with cancer [32-35]. Adolescents and young adults preferred app-based reminders over direct prompts from care partners, suggesting that technology may serve as a neutral facilitator of adherence, supporting their need for autonomy and agency, a central developmental goal for this age group [29,36]. Lastly, using low-fidelity mock-up designs, both adolescents and young adults and care partners valued features that balanced oversight with independence, such as a shared medication calendar, optional reminders, and collaborative, low-effort activities (eg, brief games) to support adherence and strengthen their relationship. These insights have collectively informed the initial co-design of a dyadic mHealth app with shared features and activities that both adolescents and young adults and care partners could use to promote medication adherence. This intervention is intended to mainly impact dose-taking and dose-timing, with additional improvements in patient autonomy, routine and habit formation, and collaboration with care partners.

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Comparisons and Contrasts With Previous Research

Our findings support previous research indicating that medication nonadherence remains a significant concern among HCT recipients. A literature review of 5 studies on medication adherence in the HCT population reported rates of adherence ranging widely from 33% to 94% across pediatric and adult populations, with a trend toward declining adherence over time [30]. More recent studies further highlight this issue: a prospective survey of 200 adult allogeneic HCT recipients found that nearly 38% reported medication nonadherence to oral immunosuppressants, and 51% had nonadherence to nonimmunosuppressants closely linked to complex regimens, frequent medication adjustments, younger age, polypharmacy, fatigue, and psychological distress [37,38]. Similarly, a cross-sectional study of 203 adult and 39 pediatric allogeneic HCT recipients reported a nonadherence rate of 75% to cyclosporine [39]. Among long-term survivors, another report identified 69% nonadherence to immunosuppressants, highlighting the persistence of adherence challenges even among those without active GVHD or even with mild chronic GVHD (62%), as well as those with more severe presentations (80%) [40]. Taken together with our qualitative formative research, these studies provide strong rationale for addressing critical gaps through design strategies and behavioral interventions to support medication adherence.

Indeed, our own data reinforce concerns about nonadherence, identifying barriers such as oversleeping, busy routines, side effects, and, particularly relevant for adolescents and young adults, ongoing negotiation between care partner oversight and adolescents and young adults' desire for autonomy. These challenges support established literature [41]. Care partners play an essential but often stressful role, trying to balance support with allowing for adolescents and young adults' independence. A recent mHealth app (BMT4me) was developed with this in mind to promote adherence to immunosuppressant medication and track symptoms in children following HCT [35,42]. In their recent pilot study, the authors reported that care partners found the app helpful in organizing medications, setting reminders, tracking symptoms, and emphasized the value of digital support during an overwhelming phase of early post-HCT care (ie, the first 100 days). However, they noted the challenge of maintaining sustained app engagement over time, with some users never logging in after the initial onboarding [35].

Unique Contributions of This Qualitative Study

Studies by Amonoo et al [38] and Kochashvili et al [35] highlight the crucial role of care partners in posttransplant care, especially in medication management during the early acute postdischarge phase when patients are often fatigued, cognitively taxed, and psychologically distressed. Their findings show that care partner involvement is vital for establishing and sustaining medication routines, as supported by representative qualitative quotes from both studies. While the recent BMT4me app study demonstrates the impact of a digital app specifically for care partners of patients aged 2-18 years, showing user satisfaction, usefulness of reminders, and establishing new habits posttransplant, our qualitative research extends this work in several unique ways. Our findings emphasize the dyadic relationship [16] and support the design of an intervention that targets the dyadic unit, engaging both adolescents and young adults and care partners as active participants [43]. Accordingly, we included both members of the dyad in focus groups and interviews, including input from both in the co-design of using low-fidelity app mock-ups. Our participants clearly articulated a desire for features that promoted both autonomy and relational connection. Our emphasis on strengthening the dyad, not only in practical management (eg, adolescents and young adults self-reporting), but also through relationship-building features (eg, shared calendar and games), is an innovation. Our formative research specifically identified the value of simple, brief, noncompetitive, collaborative games as both a motivator for app use and a means for shifting care partner communication toward positive, goal-directed interactions, moving away from framing medication as a source of "nagging" or conflict. This concept of gamification aligns with recent findings of Tran et al [44] in their scoping review, which synthesized support on the role of incentive- and game-based features in mHealth adherence apps. Their work indicated the importance of early and meaningful involvements of patients in app design phases. This study directly responds to this recommendation by engaging both adolescents and young adults and care partners in the formative research and design process (ie, co-design) to ensure that gamification features and engagement are meaningful, developmentally appropriate, and tailored to the unique needs and daily lives of posttransplant dyads. For example, our participants provided input on features that could motivate continued app interaction and emphasized the point of brief games (ie, 5-minutes or less), as highlighted in the review by Tran et al [44].

Proposed Dyadic Just-In-Time Adaptive Intervention Components

Based on our formative qualitative interviews and established literature on JITAIs [21], we anticipate that our dyadic JITAI will incorporate the following elements. Decision points are times when the intervention delivery can be adapted based on the participant's current state or context. For our dyadic intervention, decision points could be based on scheduled dose time (ie, morning/evening dose windows selected by the adolescents and young adults) or missed self-report detection (ie, failure to log a dose within a set time frame).

Potential tailoring variables are characteristics or real-time contextual features used to personalize the intervention. These may include previous medication adherence trends or patterns, such as logged dose status of "taken," "missed," or "paused" in the previous window, or average self-report missing rate in the past week; self-reported barriers, including "forgot," "busy," "out with friends," "sleeping in," "side effects," or typed open-text reasons in an "other" box; dyad mood, physical illness, and relationship quality (ie, through in-app daily assessment or diary); or app engagement (ie, time and frequency of app use).

Potential intervention options include positively framed messages near scheduled medication dose times (ie, in lieu of actual medication reminders), game-focused reminders that engage the dyads in interacting with one another around scheduled medication times, or context-specific messaging. For

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example, when certain barriers are reported (eg, “forgot” or “busy”), motivational messages or tips (eg, “pair meds with your evening routine!”) could be sent. Additional options include dyadic support prompts; if low mood is detected, additional prompts could be sent that encourage or lift mood; rewards for consecutive adherence, delivered as shared app features (eg, unlock new game levels and send congratulatory postcards); or care partner engagement or information prompts. The care partner will be able to view the calendar (but not edit) to see whether repeated adherence lapses occur, with encouragement to use the collaborative game feature.

Thus, adaptation may occur based on time, if doses are consistently missed at a certain time (eg, morning), intervening with adjusted reminders or routine-change suggestions; context, if social activity, tiredness, or side effect reporting is high in a given period, adapting messaging or interventions accordingly; adherence behavior, whereby the app could increase support for dyads with declining adherence (eg, motivational messaging); dyadic interaction, whereby low engagement with the collaborative app features triggers prompts to remind dyad of benefits or to schedule shared activities. Thus, the initial intervention may rely on scheduled reminders, but as the app learns the individual’s barriers and the dyad’s engagement patterns with the game, it will provide contextually relevant supports, such as encouraging collaborative game play after missed doses and offering motivational, agency-preserving messages for adolescents and young adults when repeated “nagging” is detected as a source of friction. The proposed variables are founded in the JITAI principles described by Nahum-Shani et al [21] and the emergent findings of this formative qualitative study. They will be iteratively refined in a future pilot as more data are collected and may be further improved during a study on the fly through an optimization algorithm.

Study Limitations

This study had several limitations. The sample size was relatively small and was drawn from a single academic institution, which may limit the generalizability of our findings to a broader and more diverse population of adolescents and young adults undergoing HCT. Participation was limited to English-speaking individuals, excluding non–English speakers who may face distinct adherence barriers and whose experiences are not reflected in this analysis. In addition, participants were compensated and tended to have favorable attitudes toward research, the health care system, and the health care being provided, which may have introduced selection or response bias. Our sample included adolescents and young adults with both cancer and noncancer hematologic conditions at various stages in their treatment trajectory, rather than focusing specifically on those within the acute period (first 100 days) posttransplant. As a result, our findings may not fully capture the unique challenges and experiences faced by adolescents and young adults during the most critical early phase following transplant. Future research should aim to include larger, more diverse, and geographically varied cohorts, as well as specifically study participants during the acute posttransplant period to enhance the relevance and applicability of findings. Developmental variability may have impacted the interpretation of our findings and potential applicability to a broader population.

Conclusions

In summary, our findings highlight the need for innovative, dyadic interventions that actively engage both adolescents and young adults and their care partners as a dyadic unit in efforts to improve medication adherence. Despite decades of research documenting adherence challenges in the HCT population, existing interventions have often been limited in scope and struggled with low engagement, leaving adolescents and young adults especially underserved during this developmental stage. In this study, both adolescents and young adults and care partners showed strong interest and willingness to explore new approaches, expressing particular enthusiasm for digital health technologies to support medication management. By fostering autonomy in adolescents and young adults and strengthening collaboration within the dyad, a well-designed mHealth app has the potential not only to enhance medication adherence but also to improve HRQoL, well-being, communication, and overall outcomes for both adolescents and young adults and care partners. The formative insights presented herein provide a solid foundation for our upcoming pilot study using an mHealth app, which will test JITAIs delivering individualized and dyadic messages, as well as interactive, relationship-building activities such as brief games. Our goal is to promote sustained medication adherence and support dyadic relationship quality by actively involving both the patient and care partner in the intervention.

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Data Availability

The study protocol and data generated or analyzed (ie, anonymized interview transcripts) during this study are available from the corresponding author on reasonable request. The codebook is available in Multimedia Appendix 2.

Authors' Contributions

ZB (female research assistant) and GR (male research assistant) drafted the manuscript, organized the data, and created figures and tables under the supervision of SWC (female professor, physician-scientist). ZB and GR performed the data cleaning, processing, and analyses under the supervision of SWC. GS (male scientist) helped design the study and developed the moderator script and the low-fidelity app mock-ups. MR (female project manager), GR, ZB, and SS (female research assistant) coordinated the study, recruited study participants, provided informed consent, and onboarded participants under the supervision of SWC. GS and SWC performed the focus groups and interviews and organized and reviewed the professionally transcribed qualitative data. MR critically reviewed and edited the manuscript and handled all regulatory aspects of the study. SAM (female professor, statistician and computer scientist), IBNS (female professor, behavioral scientist), ZX (male, postdoctoral fellow, computer scientist), and AP (female, assistant professor, behavior scientist) provided input on study design and critically reviewed and edited the manuscript. GS and SWC designed the study, curated study resources, oversaw study operations, and critically reviewed and edited the manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Moderator scripts.
[DOCX File , 44 KB - formative_v10i1e82356_app1.docx]

Multimedia Appendix 2
Medication adherence focus group and interview codebook.
[DOCX File , 48 KB - formative_v10i1e82356_app2.docx]

Multimedia Appendix 3
Patient and care partner demographic information–focus groups.
[DOCX File , 14 KB - formative_v10i1e82356_app3.docx]

Multimedia Appendix 4
Patient and care partner demographic information–individual and dyadic interviews.
[DOCX File , 14 KB - formative_v10i1e82356_app4.docx]

Multimedia Appendix 5
Low-fidelity, paper-based app mock-ups.
[DOCX File , 280 KB - formative_v10i1e82356_app5.docx]

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Abbreviations

GVHD: graft-versus-host disease
HCT: hematopoietic stem cell transplant
HIPAA: Health Insurance Portability and Accountability Act
HRQoL: health-related quality of life
JITAI: just-in-time adaptive intervention
mHealth: mobile health

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Original Paper

Smartphone-Based Contingency Management for Patients Who Use Methamphetamine: Qualitative Analysis of Patient and Clinician Perspectives

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Abstract

Background: Methamphetamine use disorder is a growing public health crisis with limited access to effective treatment. Contingency management (CM) has demonstrated efficacy for stimulant use disorders, but is typically delivered in person. Smartphone-based CM may overcome barriers such as limited access, but its effectiveness and real-world application remain understudied. This study explores patient and clinician experiences with a fully remote, smartphone-based CM intervention for methamphetamine use.

Objective: This exploratory, descriptive qualitative study analyzes interviews with patients and clinicians involved in a previously published single-arm trial in which smartphone-based CM was offered to individuals using methamphetamine through primary care or specialty addiction treatment clinics within a large health system. The study aims to identify and describe key facilitators, barriers, and perspectives related to engagement of both groups with the intervention, providing actionable insights to inform optimization and implementation of digital CM in health care settings.

Methods: We conducted a qualitative analysis of semistructured interviews with 14 patients and 14 clinicians from a prior pilot study of a fully remote, smartphone-based CM intervention for methamphetamine use. Interviews were analyzed using grounded theory in a 5-step process: transcript review, codebook development, coding, thematic reduction, and generation of overarching themes. The analysis focused on a priori themes related to facilitators, barriers, and suggestions for improvement.

Results: Patients and clinicians identified many benefits, viewing the program as valuable for individuals using methamphetamine. Patients appreciated the flexibility, accessibility, and motivational incentives. Clinicians saw CM as a low-risk, evidence-based strategy that could enhance engagement, especially among patients less responsive to traditional approaches. Common challenges included technological issues such as problems with video-based testing, app navigation, and internet access. Patients had mixed views about educational modules and described difficulty with correct substance test procedures and a lack of human connection. Clinicians expressed concerns for patients with significant psychosocial instability. Differences emerged in the types of concerns raised: patients focused on day-to-day engagement, while clinicians emphasized broader themes of equity, sustainability, and a preference for models rewarding improvement even without full abstinence.

Conclusions: Smartphone-based CM shows promise for addressing methamphetamine use disorder, especially in settings lacking traditional treatment access. However, optimizing implementation requires addressing challenges related to technology, accessibility, and equity. Recommendations include integrating CM with clinical infrastructure, expanding rewardable behaviors beyond abstinence, enhancing user experience, and improving technological access. Future research should explore flexible models that incorporate broader recovery goals and strengthen both technical and human support.

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KEYWORDS

contingency management; DynamiCare; methamphetamine use disorder; mHealth; mobile health; motivational incentives; primary care; qualitative study; stimulant use disorder

Introduction

Methamphetamine use disorder (MUD) is an escalating public health issue in the United States, where methamphetamine-involved drug overdose deaths have risen more than 5-fold from 2015-2022 [1]. To combat the significant impact of MUD, more efforts are needed to increase the availability and accessibility of treatments for methamphetamine use.

Currently, the MUD treatment with the strongest evidence base is contingency management (CM), a behavioral intervention in which motivational incentives (eg, financial rewards) are administered to patients when they provide objective evidence of a target behavior (eg, objective evidence of recent methamphetamine abstinence as verified by a substance toxicology test) [2,3]. Recent guidelines jointly issued by the American Society of Addiction Medicine and the American Academy of Addiction Psychiatry identify CM as the intervention with the best evidence of effectiveness for the treatment of stimulant use disorders and state that CM should represent the current standard of care for treatment of stimulant use disorders [4]. However, despite the efficacy of CM, there have been major challenges to implementing it in health care settings, and it is almost never available in more general medical settings like primary care. Limited access to CM is due to multiple implementation barriers, including intervention cost, regulatory policies, stakeholder buy-in, and clinical staffing and resource barriers related to collecting urine/saliva samples and delivering rewards several times per week [5,6].

While digital CM approaches have begun to show feasibility and efficacy in broad substance use disorder (SUD) and opioid use disorder (OUD) populations, very few studies have examined these methods in the specific context of MUD. Given the unique features of MUD (eg, lack of approved pharmacotherapies), this represents an important gap in the evidence base [4].

Smartphone-based CM interventions may also help address many of the structural and logistical barriers that have limited access to traditional, clinic-based CM. By allowing patients to complete substance tests and receive incentives remotely, these digital platforms can reduce the burden of frequent in-person visits, lessen demands on clinic staff, and facilitate implementation in primary care and other settings without specialized CM infrastructure. The use of mobile technology may therefore extend the reach of this evidence-based intervention to individuals and health care systems previously unable to offer or access CM.

Several studies have demonstrated that CM can be offered digitally using mobile devices [7,8]. For example, using smartphones or other devices, patients can complete the essential components of CM interventions by videorecording themselves taking saliva-based substance toxicology tests, which program staff review to verify methamphetamine abstinence and disburse financial incentives through reloadable debit cards [9-11]. This approach could help make CM more accessible by allowing patients to engage with CM from any location (ie, not needing to come into the clinic to complete substance tests or receive financial incentives) and potentially making CM available in clinical settings that otherwise would not have the capacity to maintain a CM program.

During the COVID-19 pandemic, which posed significant barriers to in-person clinical services, our team studied the feasibility and usability of a commercially available mobile health (mHealth) CM intervention as part of an effort to increase the availability of CM in primary care and addiction treatment clinics [12]. The pilot study found that smartphone-based CM was feasible to deliver to patients who used methamphetamine and who were receiving treatment within clinical settings that lacked CM programs. However, despite patients' satisfaction with the intervention, there was limited engagement with core intervention components (eg, participants completed 35% of substance tests requested) and limited rates of verified methamphetamine abstinence (eg, verified methamphetamine abstinence on 31% of substance tests completed).

Considering these findings, there is a need to better understand factors that could influence engagement with and the success of smartphone-based CM interventions. This study was designed as a descriptive, exploratory investigation aimed at identifying potential barriers, facilitators, and ideas for improving the mHealth-based CM intervention offered in the pilot study. To achieve this, we conducted qualitative analyses of interviews with both patients who received the intervention and clinicians involved in offering it to them, capturing multiple perspectives on its implementation and usability. We hope that these findings, in turn, could be used to provide actionable insights to help guide the future development and implementation of mHealth-based CM interventions.

Methods

Participants and Procedures

As previously described [12], patients receiving treatment from 7 primary care clinics or 1 specialty SUD clinic were invited to participate in a single-arm pilot study in which they would receive access to the mHealth CM intervention for up to 3 months. Patient eligibility criteria included (1) receiving care from a participating clinic, (2) self-reported methamphetamine use for at least 5 out of the past 30 days, (3) a self-reported goal of reducing or abstaining from methamphetamine use, (4) age 18 years or older, and (5) ability to read and communicate in English per self-report. Patients without smartphones who met eligibility criteria could receive a smartphone to use through the study. The study recruitment period was from September

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2021 to July 2022. Clinic staff were provided with information about the study and flyers that they could distribute to patients they thought might benefit from CM; patients could also self-refer by calling the phone number listed on the flyers that had been posted in public clinical spaces.

Ethical Considerations

The study procedures were approved by the University of Washington Institutional Review Board (STUDY00013066). All research activities were conducted in accordance with institutional and national ethical standards, as well as the principles of the Declaration of Helsinki. Participants provided informed consent prior to participation, and all data were collected and stored to maintain privacy and confidentiality. Research procedures were completed remotely via telephone, videoconference, SMS text message, and the smartphone app. Participants were not financially compensated beyond the incentives provided as part of the intervention itself.

Intervention Description

The DynamiCare Health intervention (Boston, Massachusetts) was adapted and used as the intervention for the separately published pilot study. While previously evaluated for nicotine, alcohol, and OUDs [9-11,13-16], this study was the first to our awareness to apply the DynamiCare Health intervention specifically to methamphetamine use. The intervention's components were tailored to suit the study's needs, including intervention duration, reward structures, and specific cognitive behavioral therapy (CBT) modules. Onboarding procedures were modified based on clinician input obtained prior to the study, with the goal of minimizing workflow disruptions.

After enrolling in the study, participants entered a "welcome phase" in which they were required to download the smartphone app, receive testing supplies and a reloadable debit card by mail, and complete 2 instructional video calls in which they were provided opportunities to become familiar with the platform. During the welcome phase, participants also needed to perform 2 "practice" substance tests within 6 hours of being prompted by the app to verify their ability to complete this core intervention component. DynamiCare staff reviewed these recordings to verify participant identity, proper test administration, and result visibility. Participants earned US $10 per video call and US $5 per practice test.

Upon completing the welcome phase, participants received access to the 12-week intervention. The app randomly prompted saliva-based substance testing twice weekly, offering an US $8.42 incentive for methamphetamine and amphetamine abstinence (rewards were not contingent on abstinence from other substances). Reward values increased, and testing frequency decreased with consecutive negative tests. Participants received OralTox Oral Fluid Drug Tests (Premier Biotech) by mail, which tested for multiple substances and included separate panels for methamphetamine (cutoff of 50 ng/mL) and other amphetamines (cutoff of 50 ng/mL; only methamphetamine and amphetamine results were factored into the financial incentive structure).

The intervention included access to 35 brief, self-paced CBT modules, with participants earning US $1 per completed module. Up to 9 surveys were prompted through the app, rewarding US $1 or US $2 per completion. Participants had access to a CM guide with a lived recovery experience who provided encouragement and support with completing the intervention components. Weekly meetings with the CM guide initially were not incentivized, then later incentivized to boost engagement (US $20 for the first meeting and US $10 for each meeting thereafter). Participants could earn up to US $45 more for completing research assessments at baseline, 6 weeks, and 12 weeks. Total potential earnings varied based on enrollment timing. Participants completing the welcome phase before March 2022 (before CM guide meetings were incentivized) could earn up to US $325, while those enrolling later could earn up to US $465, including research assessment compensation. Referring clinicians were not actively involved in the intervention but could access a web-based dashboard to monitor patient progress and received monthly secure message updates summarizing their patients' participation.

Qualitative Data Collection

Patients who completed the welcome phase were invited to participate in semistructured interviews via telephone halfway through the intervention period (ie, after the sixth week of the 12-week intervention). Clinicians who referred patients to the intervention or who were identified as providing SUD or other behavioral health care services to study participants were identified by reviewing participants' electronic health records, and these clinicians were also invited to participate in semistructured interviews via Zoom (Zoom Communications) shortly after the completion of the trial.

Patient interview questions solicited information about both positive aspects (facilitators) and negative aspects (barriers) of the intervention—what they found most or least helpful, what made the intervention easy or difficult to use, how participation with the intervention affected their substance use—as well as suggestions on how to improve the intervention and how to advertise the intervention to other patients. Clinician interview questions also focused on facilitators and barriers related to their experience with the intervention—how it was helpful to their patients, how it fit into their clinical workflow, considerations about implementing such an intervention in their clinics—and similarly asked for suggestions on how the intervention might be improved both in its current form and if the intervention were to be implemented in their clinical setting in a longer-term manner (ie, beyond the scope of this small pilot study). Patient interviews were transcribed near-verbatim in real time with occasional summarization; clinician interviews were audio recorded and transcribed verbatim.

Analytic Plan

Two members of the research team (YMC and ACK, both psychiatry residents at the time of coding) conducted a qualitative analysis of the transcribed interviews with guidance from a third team member (KAH, academic psychologist). Analyses proceeded according to a 5-step plan (outlined below) based on grounded theory, which aims to generate themes grounded in the data, as described by Felner and Henderson [17]. This analytic framework was selected because it reflects

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a rigorous, iterative approach to deriving themes from transcripts that still fit the timeline available to the investigative team.

First, all transcripts were reviewed, and analytic memos (informal analytic notes about the data and theoretical connections) were applied to specific segments or excerpts to better understand the range of participants' thoughts. These memos were then compiled, and a codebook of inductive codes grounded in the data was developed, with each code fitting under 3 a priori themes aligning with the focus of topics addressed in each interview: facilitators or benefits of the intervention, barriers or drawbacks, and ideas for improving it. Codes were then applied to discrete segments of the text. Next, all coded text segments associated with a single code were grouped and reduced by writing narrative summaries for each code. Finally, themes were generated by systematic analytic engagement with the data, including discussions among the investigative team looking for patterns that emerged from the data. Concurrently, thematic networks were developed to visually connect ideas between themes and codes.

This multistep process was completed iteratively; that is, earlier steps were repeated and clarified to achieve a more granular understanding of the data as the researchers' experience with the data grew and became more refined. Dedoose (Los Angeles, California), a software used for codifying and analyzing qualitative and mixed methods research, was used to organize the approach, to house the codebooks, and to facilitate coding and analysis of the transcripts.

The authors selected 6 transcripts to be coded independently by both coders. These transcripts were then reviewed in consultation with the senior researcher to identify areas of concordance and divergence in code application. Discussions from this review were used to refine code definitions, clarify boundaries between similar codes, and ensure shared understanding of analytic concepts. Once an agreement in interpretive approach was established, the remaining transcripts were coded by a single coder. Because the analytic framework used was grounded in interpretive, inductive qualitative methodology and focused on latent meaning rather than surface-level semantic features, formal quantitative intercoder agreement statistics were not calculated, as such measures are not always appropriate or meaningful for interpretive qualitative approaches and may conflict with underlying epistemological assumptions [18]. Throughout the process, reflexive discussion among the coding team was used to promote analytic consistency, consider alternative interpretations, and enhance the credibility of the final themes.

Results

Description of Patient Sample

Overview

A total of 28 patients consented to enroll in the pilot trial, of whom 15 completed an initial welcome phase and received access to the intervention. Of these, 14 participants completed semistructured interviews at the midtreatment research assessment and were included in this study. Characteristics of these participants are shown in Table 1. In brief, patients were predominantly male, half were White or Caucasian, and the other half were from other racial and ethnic groups. Just under half were members of a sexual minority group. Most reported using methamphetamine on 15 or more days out of the past 30, and most expressed a goal of abstinence from methamphetamine use (as opposed to nonabstinent reduction in use). Half also received medications for OUD, most had another cooccurring nonamphetamine SUD documented in the electronic health record, and all had a cooccurring mental health disorder. Housing insecurity, financial insecurity, unemployment, and a lack of transportation were common. Themes identified from analyses of patient interviews are discussed in the sections below and are also summarized in Table 2, which includes a summary of each theme, example quotes, and the number of patients whose transcripts had any codes related to each identified theme.

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Table 1. Characteristics of patient participants who completed qualitative interviews (n=14).

Characteristics	Value, n (%)
Age (years)	
18-29	4 (29)
30-45	5 (36)
46-64	5 (36)
Sex	
Female	4 (29)
Male	10 (71)
Race	
Black or African American	3 (21)
Hispanic, Latinx, or Spanish origin	1 (7)
Middle Eastern or North African	1 (7)
White or Caucasian	7 (50)
More than 1 race	2 (14)
Member of a sexual minority group	
Yes	6 (43)
No	8 (57)
Past 30-day methamphetamine use	
5-9 days	1 (7)
10-14 days	0 (0)
15-20 days	7 (50)
21-30 days	6 (43)
Methamphetamine use goal	
Abstinence	10 (71)
Nonabstinent reduction	4 (29)
Prescribed medications for opioid use disorder	7 (50)
Cooccurring nonamphetamine SUD[a] (per EHR[b])	11 (79)
Cooccurring mental health disorder (per EHR)	14 (100)
Benefits	
Medicaid	11 (85)
Disability	3 (23)
Social Security	4 (31)
Welfare	2 (15)
Supplemental Nutrition Assistance Program	9 (69)
Unhoused or in temporary or transitional housing (n=13)[c]	1 (8)
Housing insecurity (n=12)[c]	4 (33)
Employed (n=11)[c]	2 (18)
Lack of transportation (n=13)[c]	7 (54)
Financial insecurity (n=13)[c,d]	7 (54)
Past-year jail or criminal legal involvement (n=13)[c]	2 (15)

[a]SUD: substance use disorder.

[b]EHR: electronic health record.

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[c]There was 1 participant who did not provide information about housing status, transportation, financial insecurity, or past-year jail or criminal legal involvement; 2 participants who did not provide information about housing insecurity; and 3 participants who did not provide information about employment.

[d]Financial insecurity was defined by the self-reported inability to pay for at least 2 of the following things when needed in the past year: food, clothing, utilities, childcare, medicine/health care, phone, or other.

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Table 2. Summary of themes identified by patients.

Theme	Summary	Example quotes	Patients, n
Facilitators (patients)			
Testing was helpful	Substance testing was seen as helpful for several reasons, including the ability to see test results in real time, the randomness of testing, the good feeling associated with passing a drug test, feeling encouraged to complete a drug test even after using substances, the flexible window for testing, the ability to show family that the patient has been compliant, and the ability to see what substances are present.	"I do like the structure of having random saliva tests, because that has motivated me. Like when I was about to relapse, I was like 'I don't want to not get paid for that and I don't want to risk having a nonpositive test."	8
Modules were helpful	Educational modules were seen as helpful for at least 2 reasons, including learning from the modules and enjoying completing the modules.	"I really enjoy reading the CBT modules and it's nice and pleasant way of refreshing my head what's wrong, what's right, how to deal with things without really stressing out over things that aren't in my control."	6
Incentives were helpful	Patients expressed positive opinions about financial incentives, including having a reason to want to be in the program, benefit to daily life, the value of the financial incentive being enough, efficient delivery of incentives, and limits on what the card can be used to purchase.	"I liked the fact that it was a reward, an incentive with money. I like money quite a bit, just like everyone else does. And also just to see if that was enough to make me quit, so I was interested in trying it out." "I think [the incentive values] were completely fair with today's prices. I think it's pretty spot on. It's well done, calculated."	11
Intervention fits into the landscape of other treatment services	Patients felt that the intervention complemented their overall treatment, including that it was a treatment option where there has otherwise been a lack of treatment options, was a more palatable alternative to rehabilitation, enhanced engagement with other mental health treatments, and did not interfere with or detract from other treatments.	"When you're in my position, signing up for rehab seems like climbing Mount Everest times ten. And with DynamiCare it's just the perfect amount of help for someone like me in my position."	12
Technology / remote delivery	Patients appreciated technological aspects of the intervention, including not needing to travel to the clinic to participate in the intervention; helpful reminders; and a user-friendly interface.	"I thought it was very convenient, it comes in handy ... I thought it was great. It's not like you needed to catch a bus to meet with you all, everything was done online."	12
Accountability, helpfulness, and overall benefit of the intervention	Patients found the overall intervention helpful in several ways, including reducing substance use and promoting harm reduction, providing accountability, noticing more benefits with more time spent in the intervention, wanting to do or be "better," meeting or exceeding patient expectations, and finding all parts of the intervention helpful.	"It's a great program, it's helped me stay sober and helped me in times of cravings and emotional vulnerability." "Overall, I would say that it's set up in a nice way. I can't see anything I would add to benefit the program. It's easy enough, understandable enough, it's good."	14
Human connection	Patients expressed a sense of human connection despite receiving care remotely, including that intervention staff were helpful and quick to respond, appreciating that the CM[a] guide was also in recovery, feeling good talking to the CM guide, having access to the CM guide several times per week and after hours, and the CM guide being helpful and motivating the patient.	"I identified with [my CM guide's] story and a bit about himself. The fact he was able to stay clean for this long and have the job he does. I was impressed by that." "I thought it was just going to be a very corporate type of meeting, like once a month. But it's very personalized ... you can be vulnerable ... and it's a judgment free zone. I wasn't expecting that level of support from this app."	12
Intervention embedded within a research study	Patients appreciated being able to contribute to research.	"I've been addicted for so long, I feel like I have the ability to give back to others. So I was hoping that I'd be able to help other people that are struggling at this time."	2
Barriers (patients)			

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Theme	Summary	Example quotes	Patients, n
Testing problems and challenges	Patients expressed frustration with the substance testing process, including difficulty performing the test correctly, the need to have test equipment with you at all times, not having enough time to complete the test, feeling that test results were sometimes inaccurate, running out of test supplies, test kits being too big and bulky, and taking too long to get replacement supplies.	"I took one with my camera, my photo roll, so that was invalid. Another one my saliva didn't go into all the panels so it was defective." "If the tests themselves were smaller sized and you could carry them in your backpack or something more portable. Even with the size of these, I need to keep them at home, which means that at work or wherever I am, I have to go home to take the test."	14
Module problems and challenges	Patients found some aspects of the educational modules unhelpful, including difficulty understanding due to typographical errors, feeling like homework, being too complicated, being too long, and not having enough content.	"The questionnaires were fine, but those questionnaires, I don't know, I could've been completely positive I was picking the right selection when you're reading different learning sessions but maybe ones that are a little easier comprehension -- maybe I'm just not up to par on my education -- some were easier and some were a lot harder."	5
Incentive problems and challenges	Patients expressed negative opinions regarding the incentive structure, including incentives taking too long to be added to the card, the value of incentives being too low, and feeling that debit card restrictions were too limiting.	"I know I'm not going to get much from this reward, and the thought of using ignites me more."	6
Challenges due to psychiatric comorbidity	Patients struggled to use the intervention due to psychiatric comorbidity.	"Ever since I've been on Klonopin my short-term memory has been really bad."	5
Technology / remote delivery challenges	Patients struggled to use the intervention or connect remotely, including not liking the remoteness of the intervention, difficulty with onboarding, engagement being limited by the phone being broken, being unsure who to talk to about problems with the intervention, difficulty communicating using the app, difficulty connecting to Zoom, difficulty recording the drug test video, inconsistent Zoom meeting number and timing, reminders being unhelpful (too many, content overbearing, etc), the timer on the phone interrupting filming of the drug test, and the timing of prompts to complete a drug test.	"And the Zoom part, I majorly didn't like that because you have to start out with Zoom, and I'm sitting there looking at the lady and I can't hear her, I didn't like that part." "I'd wake up at 9 or 10 and it had prompted me at like 8am in East coast time and it had only given me a 2-hour window." "The only thing I can think of is when I try to reach out for help, it makes me text through the app, and then I get a response back through my iPhone's text messages, so it's hard to keep track of what's been sent and what was responded."	10
Lack of human connection	Patients expressed a lack of human connection, including the CM guide having unhelpful advice or not being a good match, bad timing of calls with CM guides, and the time commitment being greater than expected.	"Basically, I was clear to [my CM guide] with 'Hey, this approach is not a good one for me and we are not a good match' and I was hoping that somehow it would work out. But when you disagree with something and participate in these talks and debates after a while it gets frustrating."	4
Suggestions for Improvement (patients)			
Drug testing	Patients suggested improving the drug testing experience, including allowing more time to complete tests, allowing patients to request replacement drug test kits through the app, providing test kit supplies more quickly and/or automatically when appropriate, and making drug test kits smaller and easier to use.	"If the tests themselves were smaller sized and you could carry them in your backpack or something more portable ... I need to keep them at home, which means that at work or wherever I am, I have to go home to take the test."	4
Educational modules	Patients suggested improving the educational modules, including adding more modules; making modules shorter, more entertaining, more personalized, and easier to understand; and encouraging patients to start modules early.	"Maybe have more of those CBT modules to educate yourself." "Maybe I'm just not up to par on my education -- some were easier and some were a lot harder."	6
Incentives	Patients suggested increasing the financial incentives for the drug tests and educational modules.	"For me, the reward should be very substantial in order for me not to use."	2

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Theme	Summary	Example quotes	Patients, n
Improving fit into other treatment services	Patients suggested that the intervention could better integrate with the landscape of other treatment services, including advertising Alcoholics Anonymous and Narcotics Anonymous sooner, helping with transportation to appointments, integrating the intervention with clinic visits, providing education about substances and how they affect the brain, and providing additional therapy resources.	"I think it could integrate better with the addictions clinic here. I know they get copies of everything I'm doing, but they don't mention it. If there's more, we heard from [my CM guide], there's more person-to-person accountability, I think that would be help."	4
Onboarding	Patients suggested that the onboarding process could be improved, including explaining all features of the intervention more completely, providing more detailed instructions on how to use the tests, and offering one-on-one orientation.	"Financial incentives will be the main reason people hook up to the program. But also, we need to explain to them that it's a big commitment program. It's not just about getting money on the debit card, but it's a lot of work and accountability that comes with it."	4
Advertising and outreach	Patients suggested that the intervention be advertised to other patients, including developing an outreach intervention to recruit people who are not engaged with the health care system, emphasizing financial incentives, emphasizing that CM guides are in recovery, using flyers to advertise the intervention, and using positive feedback to advertise the intervention.	"I know that I learned about this through my primary care physician, that's how I found out about this study. I'd only had a [primary care physician] for about a year before that. A lot of people I was using with definitely weren't seeing doctors, so I don't know if there's any type of outreach program that could talk to the homeless or people on the streets to have something available for them."	8

[a]CM: contingency management.

Facilitators (Patients)

Patients highlighted a range of perceived benefits, with many participants appreciating the value of testing, educational modules, financial incentives, technological convenience, integration with existing care, and the strong sense of human connection offered by the remote format.

The Role of Testing

Most patients found substance testing to be a valuable component of the intervention. The ability to see real-time test results provided immediate feedback, reinforcing their efforts to reduce substance use. Many appreciated the randomness of testing, which added an element of accountability, and the flexible window for completing tests made participation more manageable. Even after using substances, some patients still felt encouraged to complete tests rather than avoid them. Additionally, testing allowed patients to demonstrate compliance to family members and to see what substances were present in their system. Passing a drug test often provided a sense of accomplishment, further motivating engagement with the intervention.

Helpfulness of Educational Modules

Many patients found the educational modules to be both engaging and informative. Many enjoyed completing them and felt they learned valuable skills that supported their recovery. The modules provided structured content that reinforced healthy behaviors, making them a meaningful part of the intervention.

Impact of Financial Incentives

The financial incentives were widely regarded as a beneficial aspect of the intervention. Patients felt that the incentives were a good reason to stay engaged, had a meaningful impact on their daily lives, and were delivered efficiently. Most agreed that the value of the incentives was sufficient and appreciated that the intervention placed limits on what incentive funds could be used to purchase, ensuring they were spent on appropriate items.

Integration Into Existing Treatment Services

Nearly all patients noted that the intervention complemented their existing treatment rather than interfering with or detracting from it. Some saw it as a valuable option in an area where treatment services for methamphetamine use were otherwise lacking. Others found it to be a more acceptable alternative to other treatments (eg, inpatient or residential rehabilitation). Several patients noted that participating in the intervention helped them stay engaged with their other mental health treatment.

Benefits of Technology and Remote Delivery

The technological aspect of the intervention was well received by patients. Many appreciated the remote nature of the intervention, which allowed them to engage from the comfort of their own environment while maintaining confidentiality. Several reported that the intervention's reminders helped them stay on track and that the user-friendliness of the interface made it easy to navigate and complete tasks.

Accountability and Overall Intervention Benefit

Patients found the intervention helpful in promoting accountability and supporting recovery. Many reported that it helped them reduce their substance use. The structured support from the intervention was reported as helpful by some for working toward self-improvement.

Human Connection in a Remote Setting

Despite being a remote intervention, many patients reported feeling a strong sense of human connection. One participant noted, "It's very personalized, it's that third-party observer you can be vulnerable with, and it's a judgment-free zone ... I wasn't expecting that level of support from this app." Many patients

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appreciated the responsiveness and helpfulness of the intervention staff and found it valuable that their CM guides were also in recovery. Many felt a positive connection with their CM guide, had frequent access to them—including after hours—and found their support to be motivating.

Research Study Context

Some patients appreciated the opportunity to contribute to research by participating in the intervention. While not a primary focus of their experience, those who acknowledged this aspect felt that their involvement had a broader impact on improving treatment options for others.

Barriers (Patients)

Patients described a variety of challenges to engagement, including difficulties with testing logistics, the design of educational modules, incentive structures, psychiatric comorbidities, technology access, and limits in building supportive human connections.

Challenges With Substance Testing

Many patients experienced difficulties with the substance testing process. Some found it challenging to perform the tests correctly, while others questioned the accuracy of the results. The need to carry testing supplies at all times (due to the random timing of testing prompts) was seen as inconvenient by many, and some struggled to complete tests within the allotted time. Running out of supplies and waiting too long for replacements often created further frustration. Additionally, some patients found the test kits too large or bulky to carry easily. The timing of test prompts was also a concern, as it did not always align with their schedules.

Limitations of Intervention Modules

Patients expressed mixed opinions about the educational modules, with some finding them too long, complicated, or difficult to understand. Others felt that the modules resembled homework, making them less engaging. At the same time, a few participants thought there were not enough modules to complete over the course of the intervention.

Concerns About Financial Incentives

While incentives were generally seen as a benefit, some patients found aspects of the incentive structure frustrating. Delays in funds being added to the debit card were a common complaint, and some felt that the value of the incentives was too low. Others found the spending restrictions on the card too limiting, making it difficult to use the funds as they had hoped.

Impact of Psychiatric Comorbidities

Some patients reported struggling to engage with the intervention due to cooccurring psychiatric conditions (eg, memory lapses attributed to psychiatric symptoms or medication side effects). These challenges made it harder for them to consistently participate in testing, complete intervention modules, or attend sessions with CM guides.

Difficulties With Remote Access and Technology

Some patients found the remote nature of the intervention to be a barrier. Some struggled with onboarding, while others had difficulty knowing who to contact for help with technical or intervention-related issues. Broken phones or unreliable internet access limited participation for some individuals. Issues with the app, communication difficulties, and trouble connecting to Zoom for videoconference calls during the welcome period further complicated engagement. Many patients had difficulty recording the drug test video due to interruptions from other phone apps, which caused them to lose progress. Others encountered inconsistencies with Zoom meeting numbers and scheduling issues, making it difficult to attend sessions. Some found the reminders to be excessive or overbearing, while others were frustrated by the timing of test prompts, which did not always align with their availability. These technical difficulties made it harder for patients to stay engaged and complete intervention-related tasks.

Limits in Making Human Connection

While some patients reported positive interactions with their CM guides, others found the experience less helpful. Some felt that their CM guide was not a good match or that the advice given was not useful. Scheduling was also a challenge, with some participants finding that calls with CM guides were poorly timed or that the overall time commitment was greater than expected.

Suggestions for Improvement (Patients)

Patients recommended multiple enhancements for the intervention, such as making testing more convenient, redesigning educational modules, adjusting incentives, improving alignment with other services, offering clearer onboarding, and strengthening outreach efforts.

Suggestions for Substance Testing

Patients suggested several ways to improve the substance testing process. Many wanted more time to complete tests to better accommodate their schedules. Some recommended the ability to request replacement test kits directly through the app, while others suggested that supplies be provided more quickly or automatically when needed. Several patients felt that the test kits should be made smaller and more portable to make it easier to complete tests when away from home.

Suggestions for Educational Modules

To improve the educational modules, patients suggested adding more content to provide deeper education while also making the modules shorter, more engaging, and easier to understand. Some felt that modules should be more personalized to individual needs, and others recommended encouraging participants to begin working on the modules earlier in the intervention.

Suggestions for Incentives

A few patients suggested increasing the financial incentives for demonstrating methamphetamine abstinence and for completing educational modules to further enhance motivation.

Improving Fit With Other Treatment Services

Patients offered several suggestions to help integrate the intervention more effectively with other addiction treatment services. Some wanted earlier promotion of Alcoholics Anonymous and Narcotics Anonymous meetings, while others

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suggested assistance with transportation to treatment appointments. Additional recommendations included integrating the intervention with clinic visits, providing more education about substances and their effects on the brain, and offering additional therapy resources to support recovery.

Suggestions for Onboarding

To improve the onboarding process, patients recommended clearer explanations of all intervention features and more detailed instructions on how to use the substance tests. Some felt that onboarding should be conducted one-on-one rather than in a group setting to provide more individualized support.

Suggestions for Advertising and Outreach

Patients suggested several ways to expand awareness of the intervention and reach more individuals who could benefit from the intervention. Some recommended developing an outreach intervention specifically targeting people with SUDs who are not currently engaged with the health care system. Others felt that advertising should emphasize key intervention benefits, such as financial incentives and the fact that CM guides were themselves in recovery. Suggestions for outreach strategies included distributing flyers and using positive participant feedback as a promotional tool. One patient reflected on the potential impact of greater outreach, saying, “I know a lot of people who aren’t seeing doctors but could benefit from this intervention. Maybe an outreach intervention could reach those people.”

Description of Clinician Sample

Overview

Of 28 clinicians who were identified as providing substance use or other behavioral health services to study participants, 24 were still employed within the health system at the conclusion of the trial and were invited to participate in research interviews. Of these, 13 clinicians completed semistructured interviews and were included in this study. The professional roles of these participants are shown in Table 3. Just under half were primary care providers, while the remainder were psychiatrists, case managers, or nurse care managers. Just over half worked in primary care clinics, with the remainder working in a specialty addiction clinic. Subsequent sections also describe themes from clinician interviews, which are summarized in Table 4.

Table 3. Professional roles and settings for clinician participants who completed qualitative interviews (n=13).

Roles and settings	Value, n (%)
Professional role	
Primary care provider	6 (46)
Psychiatrist	5 (38)
Case manager	1 (8)
Nurse care manager	1 (8)
Setting	
Primary care	8 (62)
Specialty addiction clinic	5 (38)

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Table 4. Summary of themes identified by clinicians.

Theme	Summary	Example quote(s)	Clinicians, n
Facilitators (clinicians)			
Benefit to therapeutic alliance	The intervention benefited the therapeutic alliance between clinician and patient, including engagement with the intervention providing an opportunity to build a therapeutic alliance, a perceived low risk of harm to patients from the intervention, the intervention serving as a source of additional income, patient-reported ease of use of the intervention, and an unexpected benefit to the therapeutic alliance.	"I thought the CM program was really nice and I think it was nice for my patient to be able to come in and process his experience as well and share how he felt about it, if it was working or not."	11
Patient factors (which patients might benefit from the intervention)	Clinicians considered individual-level patient factors when deciding to offer CM[a], including that treatment should align with patient goals, the impact of environmental stability, perceived interest from patients in using CM, patients being connected to the clinic and attending appointments regularly, and smartphone-based CM as an alternative approach to reach patients who were unwilling or unable to engage with conventional treatments.	"The other thing might be, what does the patient's environment look like? Are they homeless? Are they in a supportive environment? Are they living on their own? Are they living with multiple people? Is it hard to find space for that [CM intervention] on their own? What are some of those micro interactions? What would that look like in their environment and having that conversation? But that's probably where I would start."	7
Clinician factors (perception of CM being clinically helpful or effective)	Clinicians wanted to use CM for multiple reasons, including the desire to address the need for treatment of methamphetamine use, understanding the treatment's value and effectiveness and the need to optimize treatment, patient reports of benefit from CM, and benefit to community and public health.	"I think it did provide some patients with maybe an effective treatment as was designed. So, contingency management was helpful. And for others, even if methamphetamine use persisted, it felt like maybe they were able to reduce their use. And then there are folks who explicitly said that their contact with and their relationship with their [CM guides] was really key. That daily engagement with the app and the prompting and notifications was an opportunity to be reminded of, and maybe even reinforce their own recovery goals, and make that kind of a part of their day-to-day life in the midst of what was often otherwise, a lot of other kind of chaos. There's a sense of being kind of connected to some kind of support, when they weren't in clinic or weren't otherwise engaged in a network that was healthy and supportive of them, if they even had such a thing in their lives."	11
Ease of use	Clinicians described systems-level factors that facilitated the use of CM, including a self-sufficient intervention that did not rely on clinicians, receiving updates from the program, ease of the referral process, availability of technical support and troubleshooting, and more than one modality of treatment.	"So having what seemed like it'd be a self-contained, almost like kind of plug-and-play contingency management intervention as an option that we could offer folks was really, really exciting. And I did wonder if things would be maybe quite as smooth or as effective as advertised, but was still really, really intrigued to try it out."	12
Barriers (clinicians)			
Equity issues	Clinicians expressed concerns that the intervention may exacerbate inequities, including complex patient factors, issues of equity, accessibility, and accidentally or inadvertently forgoing access to other treatments due to CM accessibility.	"I think we talked about accessibility. So is this something that the patients are actually going to be able to engage with? But for this study, they had to have easy access to internet for this app. So I mean, even that sometimes is a barrier for folks that don't have phones. Does it fit well with other interventions that are offered in the clinic?"	8

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Theme	Summary	Example quote(s)	Clinicians, n
Technology, workflow, and usability	Clinicians were concerned about usability and workflow, including adding to clinician work burden, technological challenges experienced by patients, low clinician familiarity, a lengthy onboarding process for patients, difficulties with enrollment of patients, and technological challenges for clinicians.	"If there had been some additional coaching about what I as a provider could be doing to help build the [patients'] motivation and momentum, and then sustain it as they get onboarded [to the intervention], that may have had an effect. But outside of that, because we kind of treated it as maybe more of a medication or an external referral where you just wash your hands of it and just assume everything's going to fall into place, it didn't have any change. So I think that is a missed opportunity that we did not consider needing to pursue."	10
Effectiveness concerns	Some clinicians had concerns about how well CM works in the real world and factors that would negatively impact its effectiveness, including sustainability, effectiveness, cost-effectiveness, and quality of life; a perceived lack of impact on patient methamphetamine use; a lack of clarity about the appropriate length of the intervention or how to handle repeat intervention episodes; patients being falsely reassured; the incentive structure; variability of experiences with CM guides; and perceived low engagement of patients.	"Well, I think ... is it effective is probably the first thing we should consider. Does it help patients? And then is it cost effective? What's the cost? And especially what's the cost to the patient? Because many of our patients don't have high incomes and couldn't take on extra costs for care."	12
Privacy and monitoring concerns	There were concerns related to privacy, surveillance, and monitoring of people who use drugs, including psychosocial treatment being offered or controlled by a company outside of the clinic's health care system and patients not wanting to participate in research.	"Very, very broadly, from a 30,000-feet view. I worry about the level at which people who use drugs are surveilled. Because I think there was a video component where people swab and I just worry about that, ongoing surveillance of people who use drugs."	3
Integration with other clinical services	Clinicians felt that CM could have been better integrated into the clinical work setting, citing limited capacity to integrate new workflows, disconnect or lack of alignment of the CM intervention with in-clinic visits, limited clinician involvement with the intervention, and perceived clinician disconnectedness.	"Building out a new kind of intervention and clinical offering like this always takes a lot of time. And doing a research project where people are going to have three months of active intervention and the whole thing may last a year and a half or so, that just may not be enough time for it to really take hold and become fully integrated into the clinic's way of thinking and doing things. And it's hard. And with anything new, I mean it's obviously hard to do that in general. It takes a lot of coaching, and meetings, and so forth, and that is just hard to do. The other thing is there's lots of interventions, and providers' focus is pulled in lots of different directions, and so that also makes building something like this difficult."	11
Suggestions for improvement (clinicians)			
Education	Clinicians suggested focusing on education when implementing CM, including establishing clear rules and expectations for patients who participate, promoting clinician buy-in by showing data on the need for such interventions, educating clinicians about the nature of the intervention, creating a patient-specific pamphlet, and incorporating the intervention into medical education.	"I think any buy-in from the provider side is extremely important. And so, understanding how many patients that you see on a daily basis actually do have issues with stimulant use disorder or substance use disorder in general. That is kind of a question that when asked is generally a little surprising. And I think that helps to facilitate buy-in to say, 'Yeah, this is an issue that we need to have more resources or ways to address, and maybe I'm not doing enough to understand the community that I'm serving and their need for that resource.'"	6

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Theme	Summary	Example quote(s)	Clinicians, n
Engagement	Clinicians suggested improving engagement from patients and clinicians by designing the intervention to encourage person-to-person interactions and social connections and keeping clinicians more engaged with the intervention and informed about the intervention rollout.	"Some of the things that I really like for studies like this would be to get an update on how the project's going. So a newsletter is kind of cool to get once in a while, which could be in the form of an email that just says, 'Here's the progress, don't forget about us. These are the key things. Here's a link to a website with more details. Here's who you should contact.' Things like that. And that is coming monthly or quarterly, depending on recruitment."	2
Collaboration using existing resources	Clinicians suggested using existing resources to improve collaboration when implementing CM, including integrating the intervention into existing clinical workflows, having an intervention superuser in the clinic, collaborating and using existing support, and obtaining input from relevant stakeholders.	"If you're working in a neighborhood clinic with maybe primarily Amazon employees, that's going to be a different group with different needs than someone that who, 'The average patient,' whatever that looks like at [county safety net mental health center]. And I guess what would be good is, part of implementation would be getting some input and buy-in from clinicians and staff, and even administrators locally. And if there are opportunities to get input from patient advisory boards, or members of governing boards that have, or folks with lived experience, that would actually be super awesome. And we didn't have as much opportunity. We tried to involve some of our peer specialists early on, but doing that more vigorously would be helpful."	11
Alignment with existing clinical structure	Clinicians felt that the intervention could be better aligned with other clinical structures and practices, including leveraging or synergizing patients' experiences with the CM intervention in coordination with other clinical interventions.	"I think something that would've helped me be aware and reminded me of it would've been useful. Ideally a patient coming in and having it somehow be associated with the visit. If there was a patient on my schedule with methamphetamine history or with current methamphetamine use as a diagnosis and saying, 'Hey, this person is eligible, potentially don't forget about meth use ...' That would've been great. And that's where the way we're working toward with clinical care, which those are the workflows that fit into with research stuff, is to tie in with whatever decision support on treatment options that really integrate it into those workflows. That would've been the most useful for me."	3
Reward more outcomes that don't require abstinence	Clinicians expressed a desire for the intervention to be more thoughtful about incentivizing outcomes that are not inherently abstinence-based.	"When you look into the contingency management literature, at least what I see, it's heavily focused on abstinence. And the people who are participating are people who say, 'I want abstinence.' But even in our patient population, when people are talking about abstinence, it comes and goes. Even with my one patient who I got into the [CM intervention], he goes back and forth on that a lot. Sometimes he wants abstinence ... I don't know, I'm curious about contingency management being done in a harm- reduction model more."	2

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Theme	Summary	Example quote(s)	Clinicians, n
Develop infrastructures	Clinicians suggested developing infrastructure to support programmatic implementation, including promoting more holistic treatment, strengthening workforce engagement, supporting targeted patient population or panel management, and identifying effectiveness markers.	"Do we have a population that would benefit from it? And I think in this urban setting, absolutely. Do we have the engagement of the majority of providers? Are we going to put it out there and have providers that are willing to engage patients and attempt to use the program? And then the capture rate, do we have enough patients? Can we get to enough patients to start to work up towards that success rate, and how are we to measure that? And the resources just to be issuing phones and incentives, and making it reasonably accommodating for a patient to show up, give test samples, things like that. How can we work through some barriers that may make a person less likely to continue? Because once they miss one session, it's easier to miss a second and a third. So reducing barriers on the clinic side, the patient's side, and do we just have the resources to continue that?"	8

[a]CM: contingency management.

Facilitators (Clinicians)

Several positive themes emerged from the clinician interviews, with most clinicians endorsing a perception that CM is an effective treatment, believing that the intervention would be helpful for patients with certain characteristics, and expressing a positive view of the intervention operating as a self-contained program.

Benefit to Therapeutic Alliance

Most clinicians expressed positive sentiments toward CM as an opportunity to build greater therapeutic targets/alliance via a modality with low perceived risk of harm to patients that could also generate additional income for patients.

Interest in Patient Selection/Optimization

Most clinicians appreciated CM as a potentially effective treatment that is in alignment with patient goals and expressed particular interest in optimizing patient selection. They reported that patients with relatively intact living environments and those who demonstrated upfront interest in the intervention may be most receptive and most likely to benefit from smartphone-based CM. They further noted that for some patients who were unwilling or unable to engage with conventional treatments, mHealth represented a potentially attractive alternative therapeutic modality.

Perception of CM Being Effective

Clinicians appreciated having CM as a treatment option when no other evidence-based interventions were available. Several clinicians appreciated that CM was evidence-based and noted that patients reported benefiting from it. Some clinicians proposed that the impact of CM may extend to benefit the patient's greater community.

Ease of Use

The intervention was perceived by many clinicians to be self-sufficient, and they felt it did not result in increased clinical workloads. Many appreciated the updates they received from the intervention and the ease of the referral process. Many also expressed positive sentiments about the availability of technical support.

Barriers (Clinicians)

Perceived barriers to CM uptake also emerged from the clinician interviews, with several clinicians identifying equity, accessibility, usability, and workflow concerns.

Equity and Accessibility

Some clinicians discussed equity-related concerns—for example, that clinicians might preferentially offer CM to patients who engage more frequently with in-person treatments. Similarly, clinicians expressed concerns about inadvertently not offering other non-CM treatments due to the perceived accessibility of CM. Several clinicians also expressed worry that a lack of access to mobile phones could create inequities in who has access to smartphone-based interventions. Several clinicians described the difficulties of enrolling or engaging patients in this clinical population, noting that complex and challenging psychosocial factors may impede engagement. For example, 1 clinician stated, "We saw, a lot of the patients that we had, had multiple cooccurring issues ... chronic diseases, medical issues, multiple substance use, mental health diagnoses ... which definitely makes for a very challenging population to reach."

Usability

Clinicians expressed several concerns about usability issues hindering patient engagement. For example, some clinicians were concerned that patients could have problems navigating the smartphone app. One stated, "I think my patient had trouble uploading videos and kind of got frustrated and gave up." Similarly, some clinicians also expressed not being familiar with how to use available tools for tracking their patients' progress with the intervention. Several clinicians also described concerns that it took too long for patients to complete onboarding. One clinician stated, "On the sort of less helpful side, obviously, some [patients] really struggled to get in, and remain engaged in the intervention. The long timeline was really frustrating, and didn't allow us to strike while the iron was hot." Other clinicians agreed that the enrollment process of getting

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their patients into the CM intervention was too complicated and required additional effort and time from the clinician.

Effectiveness

Clinicians were particularly concerned about the effectiveness of the intervention for specific patient populations, especially those with comorbid serious mental illness. Several expressed concerns about the lack of evidence for the appropriate length of CM. Others agreed that they would not know how to approach the issue of repeating treatment for patients who require multiple courses of CM, including how costs and financial incentives would be handled for these patients. Clinicians raised a number of concerns related to sustainability as well. They questioned how to support their patients' recovery goals once treatment ended, including one who stated, "One of the things that I really feel guilty about not spending more time thinking about with individual patients is that regardless of the duration of treatment, treatment comes to an end. And with contingency management, cessation of treatment, it's associated with return to use at higher levels than it would be for others like CBT for substance use disorders, because contingency management isn't skill-based." Furthermore, clinicians were concerned that their patients might be misinformed or falsely reassured that CM alone (without other interventions) would be sufficient for treating their methamphetamine use, potentially leading some patients to forego other treatment options. Another challenge that clinicians noted was the variability of patients' experiences with CM coaches, and hearing from patients who perceived their CM coach to be unsupportive. A few clinicians also thought the financial incentives were not adequate. Additionally, several clinicians highlighted the delay in the treatment effect of CM when compared to some pharmacologic interventions, which led to decreased interest and motivation. For example, one stated, "In what ways was it not helpful? Getting excited about a treatment or excitement is probably not the right word, but when you're talking with people and talking through treatment options and then agreeing on a specific treatment, it's helpful to move on that quickly and to start things going in that direction as soon as possible. And that's a huge reason why everybody likes medications because you can start it today, you can start doing something today, and it's probably a reason why some people get disappointed with therapy because it could be months out that you actually start to notice anything."

Ethics

Clinicians noted a few ethical dilemmas that were barriers to implementing the CM intervention. Some expressed concerns about intrusion into patient privacy, given that patients recorded themselves when conducting saliva-based drug tests. Others noted the difficulties of getting patients who use methamphetamine to engage with a smartphone-based CM intervention, due to potential concerns of their substance use being monitored. Similarly, another clinician expressed negative sentiments toward the intervention being offered by a private company outside of the clinic's health care system.

Integration With Other Clinical Services

Clinicians raised a number of organizational and capacity issues that would prevent the successful integration of smartphone-based CM into their clinical practice. Many clinicians expressed worry that integrating smartphone-based CM in their clinics in a more sustainable manner (ie, beyond the scope of this small pilot study) could add to their already heavy clinical workloads. Some felt that the intervention's content and timeline could have been better aligned with the timing of their patients' clinical visits. Some were additionally concerned about the fit of the intervention content with other interventions they used. While many clinicians enjoyed having a stand-alone CM intervention, some also felt disconnected and wanted to have a better understanding of their patients' experiences with it. Consequently, a few clinicians reported they were not very engaged with the intervention, which hampered their ability to support patients' involvement with it.

Suggestions for Improvement (Clinicians)

In addition to the facilitators and barriers identified by the clinicians in our study, they expressed specific recommendations that could enhance the clinical delivery and implementation of smartphone-based CM.

Education and Engagement

Clinicians emphasized the importance of having education and training for all clinical staff to collaborate effectively when integrating the mHealth CM intervention into their clinics. Clinicians also described the importance of having buy-in from all staff members. Another suggested creating more opportunities for interpersonal interactions and social connections in the clinic as a way to increase clinician engagement and also improve future implementation.

Collaboration and Alignment With the Existing Clinical Environment

Clinicians suggested that mHealth CM interventions should provide robust technological support, limit the number of administrative tasks, and continue to optimize usability for clinicians, ancillary staff, and patients. Additionally, they expressed interest in having a CM intervention that is better aligned with their existing clinical structure and visits.

Non–Abstinence-Based Outcomes

Many clinicians expressed a desire for the intervention to be tailored to the needs of their patient populations and clinical approaches, which often emphasized harm reduction rather than abstinence.

Development of Clinical Infrastructure

In addition to ensuring that there is appropriate infrastructure to support a CM intervention in the clinical environment, clinicians also expressed the need to have feasible "effectiveness markers" to help monitor and track their patients' progress with the intervention. Finally, they felt that the initial duration of the CM intervention should be more individualized and discussed in advance with patients, leaving open the possibility of repeat enrollment when appropriate, in order to ease transitioning from CM to other treatment modalities.

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Discussion

Principal Findings

This study provides important insights into patient and clinician experiences and perspectives related to a smartphone-based CM intervention that was offered to patients who use methamphetamine. Together, these findings enhance our understanding of the opportunities and limitations associated with smartphone-based CM models and highlight practical recommendations for the implementation of such interventions in clinical settings.

Across both patient and clinician groups, there was a shared recognition that CM fills a critical treatment gap, especially due to the lack of widely available evidence-based interventions for patients who use methamphetamine. Both groups perceived the financial incentives offered by the CM intervention to be a valuable and safe strategy to increase motivation for engagement and recovery. Patients found the educational modules useful and often found the CM guides to be helpful. Clinicians viewed CM as a research-supported treatment that provided an opportunity to strengthen their therapeutic alliance with patients and meaningfully engage those who might otherwise not respond to other available approaches.

Technological challenges emerged as a common barrier for both groups. Patients reported difficulties with video-based substance testing, app navigation, and access to reliable internet service. Clinicians expressed concerns about potential technology-related barriers, especially for patients with more profound social and socioeconomic barriers. These underscore the importance of designing CM platforms that are accessible, easy to use, and responsive to the needs of individuals with varying levels of digital literacy.

There were also some notable differences in the scope of concerns raised by each group. Patients tended to focus more on the immediate, concrete features of the intervention, such as the helpfulness of the educational modules, the timeliness of financial incentives, and the perceived support from CM coaches. In contrast, clinician responses were more focused on broader systems-level factors, raising issues related to equity, clinical integration, long-term sustainability, and ethical use of the intervention. Clinicians highlighted concerns about how factors related to socioeconomic status could impact which patients they select to offer CM. They also questioned the traditional abstinence-based model of CM, including its long-term impact on recovery, its alignment with other ongoing treatments, and whether a non–skill-based approach could sustain benefits once the intervention ended.

These findings highlight relational and systemic factors underlying patient and clinician perspectives. Patients' emphasis on perceived support from CM coaches aligns with clinicians' discussion of the intervention's potential to strengthen therapeutic alliance [12]. Both groups recognized that better integration with existing clinical services could improve engagement and outcomes, emphasizing that the intervention's effectiveness is enhanced when it is embedded within broader care and when patients feel connected to supportive clinicians. Clinicians' focus on equity and sustainability further underscores systemic challenges, including resource allocation, staffing, and broader social determinants of health [5,6].

Moreover, our findings extend existing research on digital CM by explicitly examining both patient and clinician perspectives. While prior studies have quantitatively evaluated smartphone-based CM for various substance use populations [7-11], few qualitative studies have explored the experiences of both patients and providers concurrently, and none have focused specifically on methamphetamine use [12]. This dual perspective allows identification of points of convergence and divergence, such as shared recognition of CM's motivational benefits and technology-related barriers, as well as differences in how immediate versus systemic issues are prioritized. Recognizing these complementary perspectives can inform the design of future digital CM interventions, emphasizing both user-centered usability and system-level feasibility.

These results must be interpreted within the broader context of health care delivery during the COVID-19 pandemic. Clinics that participated in this study were dealing with high clinical demand, staffing shortages, and other COVID-19–related clinical care adjustments. The CM intervention used in the pilot study was designed to be fully remote to minimize potential additional burdens to an already strained system. As a result, clinician involvement in and engagement with the intervention were limited.

Social determinants of health (eg, poverty, housing instability, and limited access to technology) further shaped patients' experiences. Some individuals struggled with remote onboarding, video-based testing, and the use of mobile apps. These challenges were even more difficult among patients with cooccurring psychiatric conditions or unstable living environments. These challenges underscore the importance of designing CM interventions that are both flexible and responsive to real-world barriers.

Unlike prior studies on CM, which often focused on other substances or used more integrated in-person models (eg, onsite onboarding or supervised substance testing), this CM intervention was fully remote and targeted methamphetamine use. While remote delivery increased accessibility for some patients, it also introduced unique challenges related to patient engagement, technology use, and delayed reinforcement. Compared to in-person CM, which often provides more immediate and structured rewards, the digital format may have resulted in lower motivation for some patients.

Clinical Implications and Recommendations

Based on these findings, several practical recommendations can guide future implementation of smartphone-based CM interventions.

First, greater integration with existing clinical services may help bridge the gap between stand-alone digital tools and routine clinical care. Clinics can use specific operational steps, such as providing in-person onboarding, completing a brief app demonstration, and ensuring that patients are able to successfully submit a test video before independent use. Identifying a clinic point-person to monitor CM progress and embedding

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CM-related reminders into the electronic health record can further support workflow integration and sustainability.

Second, CM interventions may benefit from a broader set of rewardable behaviors, beyond strict abstinence from methamphetamine (or other substances). Incorporating financial rewards for harm reduction outcomes, such as reduced use, therapy attendance, or other prorecovery behaviors that do not require abstinence, could support individuals who are at various phases of their recovery journey or who have difficulty with abstinence. Additionally, rewarding the completion of substance tests, regardless of result, may help improve engagement with substance testing among all patients. These strategies align with clinical approaches that emphasize reinforcing small, achievable steps to promote sustained behavior change.

Third, app-specific factors should be considered to optimize user experience. More immediate access to rewards, larger and more celebratory notifications for negative test results, and stronger integration with support networks (eg, involving family or referring clinicians) could boost patient motivation to engage with the intervention and reduce methamphetamine use. Offering portable "travel testing kits" may be helpful for some individuals who would otherwise miss tests due to the inconvenience of keeping supplies on hand.

Finally, continued attention to equity and digital accessibility is essential. Ensuring that patients have reliable access to technology, minimizing onboarding complexity, and providing personalized support when needed will be critical for the success of smartphone-based CM interventions in real-world settings.

Limitations

Several limitations should be considered when interpreting the findings of this study. The original pilot study was conducted within a single multisite academic health system and included patient participants with high rates of cooccurring substance use and mental health conditions. As a result, the sample represents a population with complex treatment needs, and the findings may not be generalizable to other clinical settings or patient populations. Patient participants included those who completed initial onboarding steps required to be exposed to the smartphone-based CM intervention, and thus the sample does not include perspectives of patients who were not capable of completing those initial onboarding steps. The clinician participants often had little direct involvement with the CM intervention, and their perspectives may have been primarily influenced by information they heard from their patients or from periodic updates about their patients. Some clinicians provided input regarding how the intervention should be modified and offered to patients for the pilot, which may have also influenced how they responded to some questions during the qualitative interviews. The sample did not include clinicians who may have lacked the interest or time required to participate in research. The sample size used in this formative research was based primarily on the number of patients and clinicians who were eligible and willing to participate during the study period rather than a sample size designed to ensure thematic saturation; thus, it is possible that additional benefits, drawbacks, and ideas for improvement could emerge with future studies that use larger or more diverse samples.

While qualitative methods provide rich insights into participant experiences, they are inherently subjective and rely on self-reported data, which can be influenced by recall bias or social desirability. Future studies could address these limitations by integrating multimodal data collection, combining qualitative interviews with quantitative measures such as app usage logs, substance use outcomes, and clinician-reported outcomes, to supplement and validate self-reported experiences and to better capture the benefits, drawbacks, and opportunities for improvement of smartphone-based CM interventions. Recruiting a broader and more diverse sample of both patients and clinicians, including those who face challenges completing onboarding or who may be less engaged with research, could improve generalizability and capture a wider range of perspectives. Additionally, longitudinal follow-up or repeated interviews may help reduce recall bias and capture evolving experiences with the interventions over time. The version of the intervention that was tested in the pilot study was tailored by the research team in an effort to focus specifically on methamphetamine use and to improve fit with the clinical settings where it was used; therefore, the experiences of participants in this study may not reflect experiences that others may have with the same digital health program if it was focused on use of other substances or customized for other settings.

Conclusions

Smartphone-based CM interventions represent a promising approach to addressing methamphetamine use, particularly in settings where traditional in-person CM is difficult to implement. While both patient and clinician groups reported clear benefits of remotely delivered CM, successful use in clinical practice will require integration with existing services, simplified onboarding, and supports that address equity and digital accessibility.

At a policy level, our findings highlight the importance of establishing reimbursement pathways, promoting digital equity, and developing guidance for expanding CM for broader recovery-oriented outcomes.

Future studies should evaluate hybrid delivery models, test broader rewardable behaviors, incorporate objective and longitudinal data, and recruit more diverse patient and clinician samples. These efforts will help clarify how smartphone-based CM can be optimized to meet the needs of patients and health systems in real-world settings.

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Data Availability

The datasets generated or analyzed during this study are not publicly available due to restrictions in the informed consent provided by participants. Deidentified data may be made available from the corresponding author upon reasonable request.

Authors' Contributions

Conceptualization: KAH (lead), MHD, MDI, AJS
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Project administration: YMC, ACK, KAH
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Validation: YMC, ACK, KAH
Writing – original draft: YMC, ACK, KAH
Writing – review & editing: YMC, ACK, KAH, MHD, MDI, AJS

Conflicts of Interest

None declared.

Multimedia Appendix 1
Guide used to interview patients.
[DOCX File , 16 KB - formative_v10i1e80808_app1.docx]

Multimedia Appendix 2
Guide used to interview clinicians.
[DOCX File , 16 KB - formative_v10i1e80808_app2.docx]

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Abbreviations

CBT: cognitive behavioral therapy
CM: contingency management
mHealth: mobile health
MUD: methamphetamine use disorder
OUD: opioid use disorder
SUD: substance use disorder

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Original Paper

Autonomous Motivation Trajectory Following Adoption of a Team-Based Gamification App Among Adults With Diabetes: 1-Year Formative Longitudinal Study

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Abstract

Background: Autonomous motivation, grounded in self-determination theory, is important for sustaining diabetes self-care behaviors. Although mobile health interventions, gamification, and peer support are increasingly used to enhance motivation in diabetes care, evidence on how motivation evolves over time remains limited. Specifically, it is unclear whether motivational change follows a linear pattern or a nonlinear trajectory, such as an initial increase followed by a subsequent decline. Clarifying these temporal patterns is critical for informing the design of adaptive diabetes self-care interventions.

Objective: The objective of this study was to characterize the 1-year developmental trajectory of autonomous motivation following the real-world introduction of a commercially available team-based gamification app.

Methods: This prospective, single-arm longitudinal study involved adults with diabetes (predominantly type 2) recruited from outpatient clinics in Japan. Participants were instructed to use a team-based gamification app designed to promote desirable habits through peer support and social comparison for at least 7 days. The primary outcome, autonomous motivation, was assessed using the Treatment Self-Regulation Questionnaire–Autonomous Motivation subscale (TSRQ-AM; score range 7-49) at baseline, 6 weeks, 6 months, and 1 year. Secondary measures included hemoglobin A_{1c} (HbA_{1c}), body weight, triglycerides, and psychological scales (eg, Self-Efficacy Scale for Diabetes Self-Care, Summary of Diabetes Self-Care Activities, Problem Areas in Diabetes scale, and World Health Organization–Five Well-Being Index). To analyze the trajectory, we used linear mixed-effects models with random intercepts for participants. The final model included fixed effects for time (as both linear and quadratic terms), age, sex, employment status, family structure, baseline BMI, and baseline HbA_{1c}.

Results: Of 32 consenting participants, 29 (90.6%) were included in the primary analysis; clinical data at 1 year were available for 26 (81.3%) participants. In exploratory analyses, mean TSRQ-AM scores increased from baseline (37.4, SD 7.9) to 6 months (39.5, SD 7.4; Cohen d=0.47). Over the 1-year period, body weight decreased significantly (b=−0.39; P=.01), whereas HbA_{1c} (P=.40) and triglycerides (P=.14) showed no significant changes. The TSRQ-AM score showed a significant nonlinear change over time. A model including a quadratic time term fit significantly better than a linear-only model (χ^2_1=4.1; P=.04), with a significant quadratic effect (b=−7.26; P=.045), indicating an inverted U-shaped trajectory peaking at 6 months. Higher baseline BMI was associated with lower TSRQ-AM scores (b=−1.00; P=.001).

Conclusions: This formative study provides preliminary evidence of a nonlinear, 1-year trajectory of autonomous motivation following the introduction of a team-based app. The observed curvilinear pattern suggests that autonomous motivation during

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the intervention may peak at around 6 months, underscoring the importance of adaptive intervention designs to maintain engagement over time. The accompanying reduction in body weight suggests potential physiological relevance that warrants further investigation in controlled studies.

Trial Registration: UMIN Clinical Trials Registry UMIN000044874; https://tinyurl.com/59bzb68k

(JMIR Form Res 2026;10:e87236) doi:10.2196/87236

KEYWORDS

smartphone; health apps; eHealth; diabetes mellitus; digital health; social support; self-care; gamification; patient participation; consumer health information

Introduction

Autonomous motivation is a critical determinant of sustained diabetes self-care, and its importance has been emphasized in numerous studies [1-3]. According to self-determination theory (SDT) [4], autonomous motivation—engaging in behaviors out of personal interest or values—is linked to better long-term adherence, whereas controlled motivation (pressure or obligation) is less sustainable. Therefore, fostering autonomous motivation is a key goal in diabetes self-care interventions [3,4].

Both peer support and mobile health (mHealth) interventions have been proposed as ways to enhance patient motivation [5,6]. For instance, some peer support programs have been shown to have a positive impact on self-care and psychological well-being [7,8], but they often encounter logistical challenges that restrict widespread access [9]. In contrast, mHealth interventions can provide support regardless of time and place. Studies have found mHealth to have an independent effect on hemoglobin A_{1c} (HbA_{1c}) and self-care behaviors [10,11]. The use of mHealth in diabetes care continues to expand. In particular, gamification approaches are expected to sustain motivation by leveraging social comparison and reward mechanisms [12]. However, the long-term motivational effects of prescribing such apps as part of routine diabetes care remain unclear. Furthermore, the temporal trajectory of these motivational changes beyond a few weeks is largely unknown. It is unclear whether psychological outcomes improve linearly or follow a more complex, nonlinear path (eg, peaking and then declining). Understanding this pattern is critical for designing interventions that can sustain engagement.

In a prior report, we introduced a commercially available team-based habit-forming app that incorporates gamification as a means to integrate peer support and mHealth [13]. A preliminary qualitative analysis conducted at 6 weeks revealed that approximately 80% of participants found the app helpful for self-care, while some also reported mixed experiences. Importantly, some participants expressed negative impressions stemming from conflicts within their teams. These findings indicate preliminary signs of early benefits, but it is not yet clear whether such motivational gains can be maintained over the long term.

Building on these findings, the purpose of this study was to investigate the 1-year developmental trajectory of autonomous motivation following the implementation of a team-based gamification app, with the hypothesis that autonomous motivation would increase over time. To reflect real-world conditions, participants were only instructed to try the app for at least 7 days and were free to discontinue thereafter. The primary outcome of interest was autonomous motivation, a key psychological factor for sustaining diabetes self-care.

Methods

Research Design and Participants

This prospective, single-arm, hypothesis-generating longitudinal study was conducted between 2022 and 2023. Participants were adults with type 1 or type 2 diabetes who voluntarily responded to recruitment posters displayed at outpatient clinics.

Intervention

Participants were instructed to download and use Minchalle (A10 Lab Inc), a commercially available team-based gamification app designed to promote the formation of desirable habits. Grounded in social cognitive theory, the app facilitates behavior change through small anonymous groups (up to 5 members) that foster social support, social comparison, and accountability. The app has been widely adopted, with more than 1.6 million downloads. Users share daily progress via photos on team chats, provide mutual feedback, and receive in-app rewards such as coins and badges for task completion, reinforcing sustained engagement. Inactive members are automatically removed, emphasizing active participation and shared responsibility.

Participants were required to join a team and try using the app for at least 7 days; thereafter, continued use was optional. Teams were selected according to personal preference (eg, exercise-oriented or daily weight–tracking teams), and no diabetes-specific team assignment was mandated. To ensure that all participants could meet the initial 7-day requirement under equal conditions, they were provided with researcher-funded access to the app's premium features at no cost. Detailed app features have been described in our previous study [13].

Measures

The primary outcome was autonomous motivation, assessed using the Treatment Self-Regulation Questionnaire–Autonomous Motivation subscale (TSRQ-AM) in Japanese (score range 7-49, higher scores indicate greater autonomous motivation) [14].

Secondary outcomes included key physiological measures such as HbA_{1c}, triglycerides, and body weight obtained during routine clinic visits. In addition, several psychological scales were administered for exploratory purposes: the Treatment

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Self-Regulation Questionnaire–Controlled Motivation subscale, Perceived Competence for Diabetes Scale [3], Japanese Summary of Diabetes Self-Care Activities [15], Self-Efficacy Scale for Diabetes Self-Care [16], Problem Areas in Diabetes scale [17], and World Health Organization–Five Well-Being Index [18].

Assessments were conducted at baseline, 6 weeks, 6 months, and 1 year after app implementation.

Although both self-reported continuation and objective use data were potentially available, these were intentionally excluded from the analysis. Our aim was to evaluate the impact of the implementation of such an app under real-world conditions rather than to establish a dose-response relationship. Therefore, we focused on outcomes irrespective of actual use intensity to avoid the tautological conclusion that those who used the app more frequently achieved greater improvements.

Statistical Analysis

All statistical analyses were performed in R (version 4.5.1; R Foundation for Statistical Computing) using the *lme4* and *lmerTest* packages. Analyses were conducted with a four-step sequence:

First, we conducted a descriptive analysis of participant characteristics and each outcome at all time points.

Second, we created a visualization of time-course data for all psychological and physiological measures.

Third, we performed an exploratory trend analyses with linear mixed models (LMMs) to evaluate general trends in secondary psychological, behavioral, and clinical outcomes across the 4 assessment time points. The time variable was entered as an ordinal variable (0=baseline, 1=6 weeks, 2=6 months, and 3=1 year) to test for linear trends.

Fourth, we used longitudinal modeling of the primary outcome with a linear mixed-effects model to examine changes in TSRQ-AM scores over time, with random intercepts for participants to account for baseline differences. In the primary analysis, time was modeled as a continuous variable representing the actual months elapsed from baseline (coded as 0, 1.5, 6, and 12). Fixed effects included time (linear and quadratic terms), age, sex, employment status, family structure, baseline BMI, and baseline HbA_{1c}. To capture potential nonlinear patterns, such as an inverted U-shaped trajectory (initial increase followed by a decline), both linear and quadratic time terms were included. Linear vs quadratic models were compared using likelihood ratio tests, and the final model retained both terms to capture potential nonlinear patterns such as peaks and declines. Marginal and conditional R^2 values were calculated to quantify model fit. To verify the robustness of the findings against different time specifications, a sensitivity analysis was conducted in which time was treated as an ordinal numeric variable.

Ethical Considerations

This study was conducted in accordance with the Declaration of Helsinki and approved by the ethical committee of Kobe City College of Nursing (approval 21,104-10). The study protocol was registered with the UMIN Clinical Trials Registry (UMIN000044874).

All participants provided written informed consent in person before enrollment and any study procedures. During the consent process, participants were informed of the study purpose, procedures, their right to withdraw at any time without penalty, and data confidentiality measures. Written consent for the publication of anonymized data was also obtained. Participants received a JP ¥3000 (US $25.50) reward for using the app for 7 days and JP ¥1000 (US $8.50) for each completed questionnaire.

To protect participant privacy, individuals were assigned unique study identification numbers, and their data were pseudonymized. The reidentification key was securely maintained and accessible only to the principal investigator. The anonymized research dataset used for analysis was stored in a password-protected environment and managed on password-secured systems to ensure data security.

Results

Participants

A total of 32 individuals with diabetes provided consent. Of these 32 participants, 2 (6.3%) did not join a team, and 1 (3.1%) withdrew from the study after the 6-week assessment, leaving 29 (90.6%) participants for the main analysis. Due to clinic transfers or missing laboratory assessments at the 1-year follow-up, HbA_{1c} and other laboratory data were available for 89.7% (26/29) of the participants and used in the subanalysis. The participant flow is shown in Figure 1.

Baseline characteristics are summarized in Table 1. The mean age was 61 (SD 10) years, and the mean HbA_{1c} at baseline was 6.96% (SD 0.51%).

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Figure 1. Flowchart of participant enrollment, allocation, follow-up, and analysis.

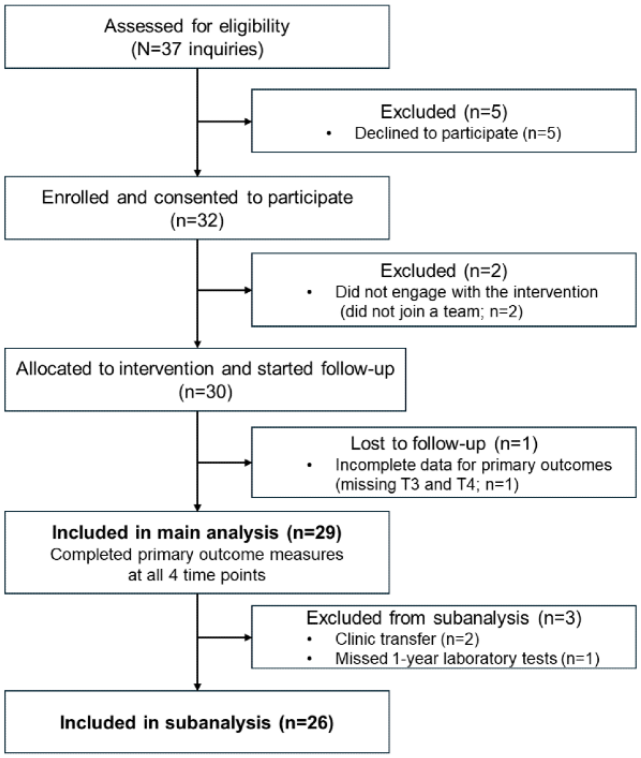

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Table 1. Baseline characteristics of study participants (N=29).

Characteristic	Values
Continuous variables, mean (SD)	
Age (years)	61 (10)
BMI (kg/m^2)	25.7 (5.2)
Hemoglobin A_{1c} (%)	6.96 (0.51)
Duration of diabetes (years)	11.8 (9.1)
Categorical variables, n (%)	
Sex	
Male	19 (65.5)
Female	10 (34.5)
Type of diabetes	
Type 2	28 (96.6)
Type 1	1 (3.4)
Diabetic complications	
Present	7 (24.1)
Absent	22 (75.9)
Employment status	
Full-time job	9 (31.0)
Part-time job	8 (27.6)
Homemaker	2 (6.9)
Unemployed	10 (34.5)
Living arrangements	
Living alone	6 (20.7)
Living with spouse	17 (58.6)
Living with children or parents	4 (13.8)
Other	2 (6.9)

Changes in Psychological, Behavioral, and Clinical Outcomes

Table 2 summarizes the descriptive statistics for all outcomes across the 4 assessment points. Figure 2 shows changes in group average values and 95% CIs for psychological and physiological measurements, whereas the spaghetti plot visualizing individual differences is shown in Multimedia Appendix 1.

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Table 2. Changes in psychological, behavioral, and clinical measures across the 4 assessment points (baseline, 6 weeks, 6 months, and 1 year)[a].

Measure and time point	Values, mean (SD)	Values, median (IQR)
Autonomous motivation (TSRQ[b]; range 7-49)		
Baseline	37.4 (7.9)	38 (34-43)
6 weeks	39.3 (8.4)	40 (36-46)
6 months	39.5 (7.4)	40 (37-44)
1 year	38.5 (8.2)	41 (35-44)
Controlled motivation (TSRQ; range 7-49)		
Baseline	21.0 (9.3)	22 (13-28)
6 weeks	23.1 (9.4)	24 (16-30)
6 months	21.4 (7.7)	23 (16-27)
1 year	20.8 (8.6)	21 (14-27)
PCDS[c] (range 4-28)		
Baseline	18.3 (5.8)	20 (15-22)
6 weeks	18.4 (6.2)	18 (13-24)
6 months	19.1 (4.9)	19 (16-24)
1 year	18.7 (5.5)	19 (16-22)
Self-efficacy (SESD[d]; range 8-32)		
Baseline	22.2 (3.9)	23 (18-25)
6 weeks	23.1 (4.2)	23 (21-26)
6 months	23.2 (4.1)	23 (20-26)
1 year	23.4 (3.4)	23 (22-25)
PAID-5[e] (range 0-20)		
Baseline	9.3 (4.6)	9 (6-13)
6 weeks	10.1 (4.9)	10 (6-14)
6 months	9.1 (5.3)	10 (4-12)
1 year	9.4 (5.2)	9 (6-13)
WHO-5[f] (range 0-25)		
Baseline	16.4 (4.0)	17 (14-19)
6 weeks	16.5 (2.9)	17 (15-18)
6 months	16.0 (4.8)	16 (14-19)
1 year	16.3 (4.4)	16 (14-19)
General diet (SDSCA[g]; range 0-7)		
Baseline	3.9 (1.9)	4 (3-5)
6 weeks	4.5 (2.0)	5 (3-6)
6 months	4.5 (2.0)	5 (3-6)
1 year	4.5 (1.7)	4.5 (3-6)
Special diet (SDSCA; range 0-7)		
Baseline	4.3 (1.6)	4.5 (3.5-5.5)
6 weeks	4.6 (1.5)	5 (4-6)
6 months	4.6 (1.5)	5 (4-5.5)
1 year	4.5 (1.4)	4.5 (4-5.5)
Exercise (SDSCA; range 0-7)		

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Measure and time point	Values, mean (SD)	Values, median (IQR)
Baseline	3.1 (2.2)	3 (1-5)
6 weeks	3.6 (2.2)	3.5 (2-5.5)
6 months	3.4 (2.4)	3.5 (1-5)
1 year	3.4 (2.0)	3 (2-4.5)
HbA_{1c}[h] (%)		
Baseline	7.0 (0.5)	6.9 (6.7-7.4)
6 weeks	7.1 (0.6)	7.1 (6.7-7.3)
6 months	7.0 (0.6)	6.9 (6.7-7.2)
1 year	7.0 (0.7)	6.9 (6.5-7.2)
Triglycerides (mg/dL)		
Baseline	133.3 (70.7)	125 (86.8-157.8)
6 weeks	134.7 (71.8)	123 (92-163)
6 months	123.2 (49.7)	118 (90-136.3)
1 year	167.1 (86.3)	136 (108-195)
Body weight (kg)		
Baseline	70.7 (15.5)	66.7 (60.8-80)
6 weeks	70.4 (15.5)	66 (60.3-77)
6 months	69.4 (16.3)	65.3 (60.2-76.8)
1 year	69.6 (15.3)	68 (59-78)

[a]Clinical outcomes (hemoglobin A_{1c}, triglycerides, and body weight) were available for 26 participants.

[b]TSRQ: Treatment Self-Regulation Questionnaire.

[c]PCDS: Perceived Competence for Diabetes Scale.

[d]SESD: Self-Efficacy Scale for Diabetes Self-Care.

[e]PAID-5: Problem Areas in Diabetes scale (short form).

[f]WHO-5: World Health Organization–Five Well-Being Index.

[g]SDSCA: Summary of Diabetes Self-Care Activities.

[h]HbA_{1c}: hemoglobin A_{1c}.

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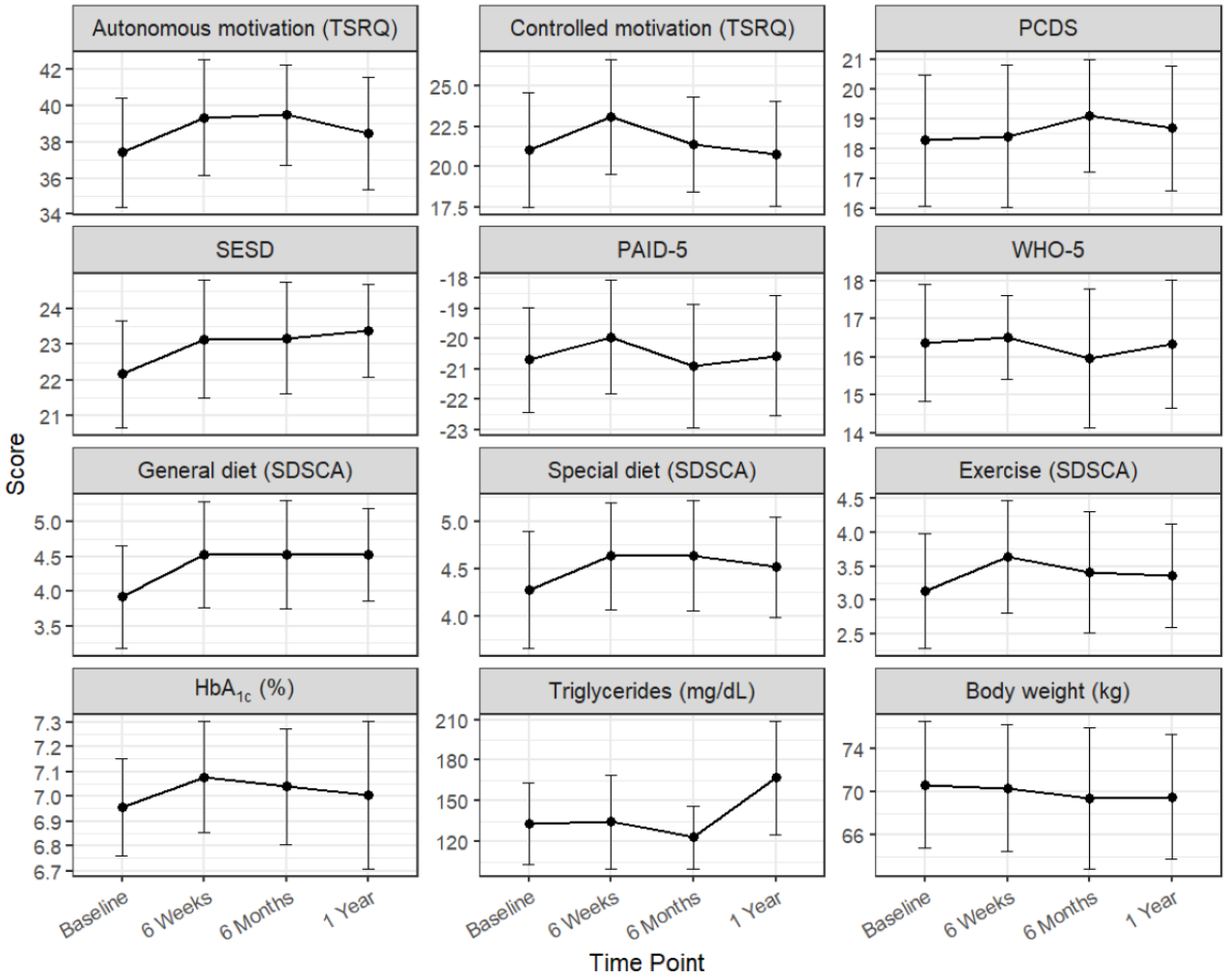
Figure 2. Mean changes in psychological, behavioral, and clinical outcomes over 4 assessment points. Dots represent estimated marginal means, and error bars indicate SEs. Refer to Table 2 for detailed descriptive statistics. HbA1c: glycated hemoglobin; PAID-5: Problem Areas in Diabetes scale; PCDS: Perceived Competence for Diabetes Scale; SDSCA: Summary of Diabetes Self-Care Activities; SESD: Self-Efficacy Scale for Diabetes Self-Care; TSRQ: Treatment Self-Regulation Questionnaire; WHO-5: World Health Organization–Five Well-Being Index.



Exploratory trend analyses using LMMs revealed significant longitudinal improvements in specific outcomes (Table 3). Regarding psychological outcomes, self-efficacy for diabetes self-care increased significantly over the 1-year period (b=0.38; P=.02). Other psychological measures, including controlled motivation, did not show significant linear trends. Regarding behavioral outcomes, no significant linear trends were observed in self-care activities such as general and special diets or exercise habits. Regarding clinical outcomes, a significant reduction in body weight was observed (b=−0.39; P=.01), demonstrating a consistent weight loss trend throughout the study despite the lack of significant changes in HbA_{1c} (P=.40) or triglycerides (P=.14).

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Table 3. Results of linear mixed models assessing time trends in psychological, behavioral, and clinical outcomes[a].

Outcome	Unstandardized coefficient, B (SE; 95% CI)	*P* value
Psychological outcomes		
Autonomous motivation (TSRQ[b])	0.33 (0.3; –0.26 to 0.93)	.27
Controlled motivation (TSRQ)	−0.24 (0.39; –1.02 to 0.54)	.55
PCDS[c]	0.19 (0.26; –0.32 to 0.71)	.46
Self-efficacy (SESD[d])	0.38 (0.16; 0.07 to 0.69)	*.02* [e]
PAID-5[f]	−0.06 (0.19; –0.43 to 0.32)	.77
WHO-5[g]	−0.07 (0.2; –0.46 to 0.33)	.74
Self-care activities (SDSCA[h])		
General diet	0.18 (0.11; –0.04 to 0.41)	.11
Special diet	0.07 (0.06; –0.04 to 0.19)	.22
Exercise	0.04 (0.13; –0.21 to 0.3)	.73
Clinical outcomes		
HbA_{1c}[i] (%)	0.03 (0.03; –0.04 to 0.1)	.40
Triglycerides (mg/dL)	6.91 (4.62; –2.34 to 16.16)	.14
Body weight (kg)	−0.39 (0.16; –0.70 to –0.08)	*.01* [e]

[a]Time was coded as an ordinal variable (0=baseline, 1=6 weeks, 2=6 months, and 3=1 years).

[b]TSRQ: Treatment Self-Regulation Questionnaire.

[c]PCDS: Perceived Competence for Diabetes Scale.

[d]SESD: Self-Efficacy Scale for Diabetes Self-Care.

[e]Statistical significance ($P<.05$).

[f]PAID-5: Problem Areas in Diabetes scale (5 items).

[g]WHO-5: World Health Organization–Five Well-Being Index.

[h]SDSCA: Summary of Diabetes Self-Care Activities.

[i]HbA_{1c}: hemoglobin A_{1c}.

Longitudinal Trajectories of Autonomous Motivation (Primary Outcome)

A model comparison indicated that including a quadratic term for time provided a significantly better fit than a linear-only specification ($\chi^2_1=4.1$; $P=.04$). Consequently, the quadratic model was adopted as the primary analysis.

As shown in Table 4, the linear effect of time was not statistically significant ($P=.60$), whereas there was a significant quadratic effect of time ($b=-7.26$; $P=.045$). This indicates an inverted curvilinear trajectory consistent with the pattern depicted in Figure 3, where autonomous motivation increased initially and then plateaued or declined. Descriptively, the mean score peaked at 6 months (39.5 vs 37.4 at baseline), representing an effect size of Cohen $d=0.47$. A sensitivity analysis treating time as ordinally coded time points (0-3) yielded consistent results, confirming a significant quadratic effect (Multimedia Appendix 2).

The fixed effects accounted for 46% of the variance in TSRQ-AM scores (marginal $R^2=0.46$), whereas the full model including random intercepts explained 83% of the variance (conditional $R^2=0.83$). Substantial between-participant variability was observed in baseline levels (mean random intercept variance 27.77, SD 5.27), with an intraclass correlation coefficient of 0.69, indicating that approximately 69% of the total variance was attributable to stable individual differences.

Among the covariates, higher baseline BMI was significantly associated with lower TSRQ-AM scores across time ($b=-1.00$; $P=.001$). No other demographic or clinical covariates reached statistical significance.

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Table 4. Fixed-effects estimates from the linear mixed-effects model predicting autonomous motivation scores over 1 year[a].

Variable	Coefficient (95% CI)	*P* value
Intercept	30.68 (–20.69 to 82.04)	.20
Time—linear	1.98 (–5.12 to 9.07)	.60
Time—quadratic	−7.26 (–14.36 to –0.16)	*.045* [b]
Age	0.11 (–0.26 to 0.48)	.50
Sex: female	−3.88 (–10.33 to 2.58)	.20
Job: part-time	−1.36 (–8.93 to 6.21)	.70
Job: homemaker	−0.99 (–16.3 to 14.32)	.90
Job: unemployed	1.81 (–4.74 to 8.35)	.60
Baseline BMI	−1.00 (–1.55 to –0.46)	*.001* [b]
Baseline HbA_{1c}[c]	3.46 (–2.35 to 9.26)	.20
Family: living with spouse	5.71 (–1.74 to 13.16)	.12
Family: living with children or parents	3.56 (–5.5 to 12.62)	.40
Family: other	2.97 (–9.16 to 15.1)	.60

[a]Time was coded as a continuous variable representing actual months (0, 1.5, 6, and 12) and modeled using orthogonal polynomials to avoid multicollinearity. Consequently, the coefficients for linear and quadratic terms represent orthogonal contrasts rather than raw monthly changes. Employment status and family structure were treated as categorical variables, with “full-time employment” and “living alone” as reference categories, respectively. The estimates shown are fixed effects; random intercepts (not shown) account for individual baseline differences in Treatment Self-Regulation Questionnaire–Autonomous Motivation score.

[b]Statistical significance ($P<.05$).

[c]HbA_{1c}: hemoglobin A_{1c}.

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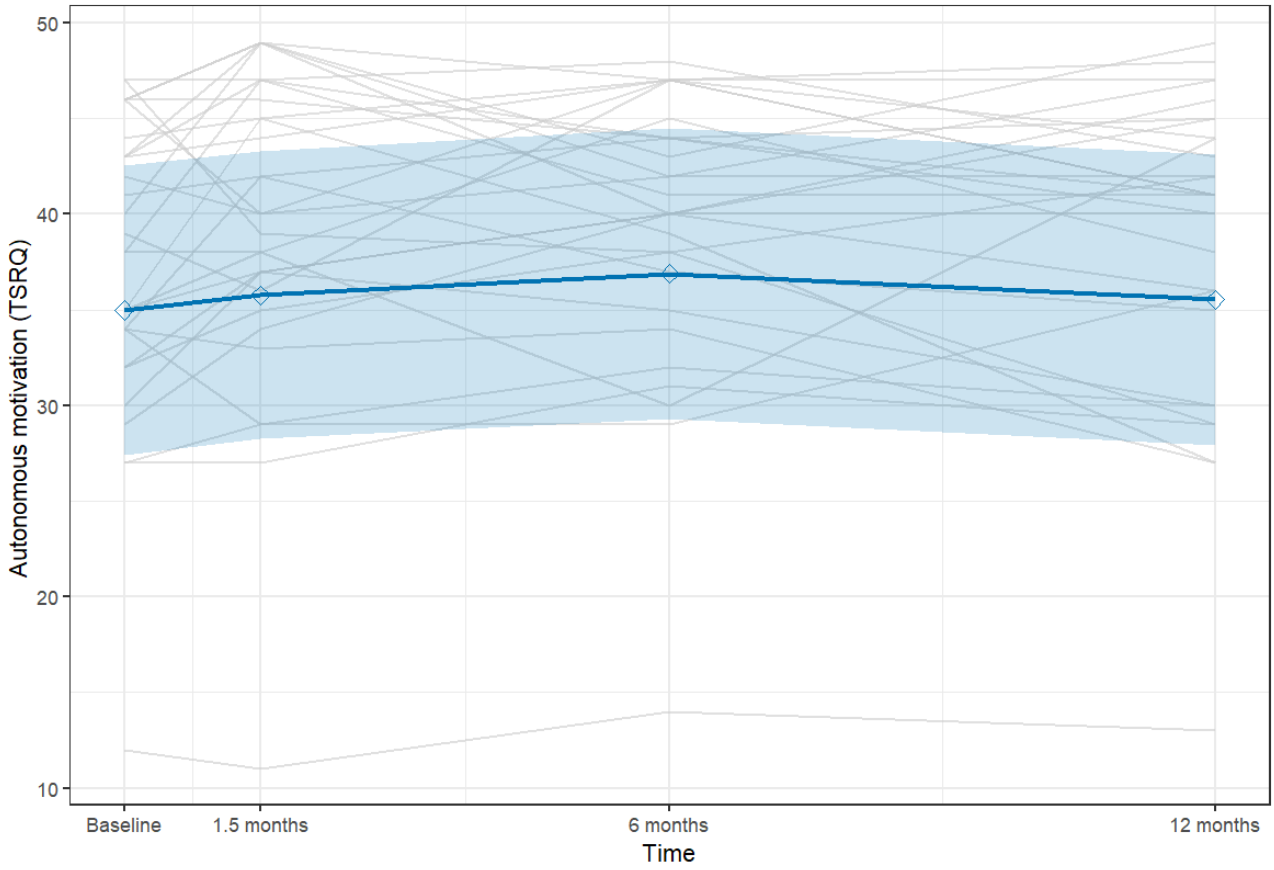
Figure 3. Model-estimated trajectories of Treatment Self-Regulation Questionnaire (TSRQ) scores on the autonomous motivation subscale across 4 assessment points (baseline, 6 weeks, 6 months, and 1 year). The solid line represents the estimated mean trajectory derived from a linear mixed-effects model, with the shaded area indicating the 95% CI. The gray lines depict individual participant trajectories.



Discussion

Principal Findings

The primary finding of this study was the curvilinear trajectory of autonomous motivation, which peaked at 6 months and then declined, although it remained above baseline after 1 year of implementing use of a commercially available, team-based gamification app. There was no significant change in HbA_{1c}, suggesting that psychological benefits may occur independently of physiological improvements.

Motivational Trajectories and Individual Variability

The observed trajectories of motivation can be interpreted within the framework of SDT [4]. Autonomous motivation, in particular, followed a curvilinear trajectory, increasing substantially and persisting above baseline even after 1 year. This pattern underscores the unique role of autonomous motivation in sustaining health behaviors and is consistent with prior SDT-based studies linking autonomous forms of regulation with long-term adherence to self-care [2,3,19]. However, our findings extend this literature by identifying a significant nonlinear, curvilinear pattern (P=.045) that peaked at 6 months before modestly declining, providing a novel and critical insight into the temporal dynamics of app-supported motivation. In contrast, descriptive data suggested that controlled motivation increased at 6 weeks but returned to baseline levels thereafter. This transient elevation likely reflects a temporary sense of pressure to meet team expectations—an external regulatory process [20] that is, by nature, short-lived. However, no significant deterioration in psychological well-being (World Health Organization–Five Well-Being Index) or diabetes-related distress (Problem Areas in Diabetes scale) was observed during this period. This suggests that the initial social pressure did not result in psychological harm. Few mHealth or gamification studies have tracked motivational processes over a full year, making these findings valuable in extending evidence beyond the short-term effects typically reported.

At the same time, the mixed-effects model revealed substantial variability in baseline autonomous motivation (mean random intercept variance 27.8, SD 5.3). Further inspection of individual trajectories highlighted considerable heterogeneity: some participants showed early declines, whereas others maintained or even enhanced their motivation. A plausible contributor is differential engagement [21] with the app, such as frequency of log-ins or postings. We intentionally did not systematically assess this engagement factor in this study to avoid the tautological conclusion that patients who used the app more frequently achieved better outcomes. Instead, our aim was to examine the outcomes when the app was merely implemented, regardless of how intensively participants used it. Participants were only asked to download and try the app for at least 7 days, with the option to discontinue thereafter. Even under these conditions, the overall trend still indicated psychological benefits for many participants, suggesting that peer presence and social comparison [13] may exert influence even without intensive

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engagement. It is also possible that the act of prescribing the app or the decision to accept it itself fostered a sense of autonomy. This raises the possibility that digital tools may offer psychological benefits through the very act of adoption, not solely through intensive use.

Comparison With In-Person Peer Support

Our findings are consistent with those of previous research on the distinct effects of peer support on behavioral and physiological outcomes. While some real-world peer support initiatives have demonstrated modest HbA_{1c} reductions [7,22], others, particularly those involving participants with well-controlled baseline glycemic levels, have not observed significant metabolic improvements despite behavioral gains [23]. For instance, Yin et al [24] demonstrated that patients with well-controlled blood glucose can improve self-management behaviors through peer support without necessarily altering glycemic control. Our study corroborates this pattern, suggesting that while enhancing autonomous motivation is critical for adherence, its independent impact on HbA_{1c} may be modest relative to pharmacological therapy [25], especially in a population with a mean baseline HbA_{1c} of 6.96% (SD 0.51%).

However, unlike traditional in-person peer support, which faces logistical barriers [6,9], the digital nature of the intervention in this study allowed for the preservation of emotional connection and practical assistance independent of time and place. This flexibility in changing teams was a feature valued by participants in our prior qualitative work [13].

With regard to secondary outcomes, while enhancements in self-reported diet and exercise were not statistically significant, our longitudinal analysis confirmed a substantial reduction in body weight. This discrepancy suggests that participants may have incorporated subtle yet effective lifestyle modifications that were not consciously perceived as major behavior changes. This finding is consistent with previous research indicating that mHealth and peer support interventions are particularly effective in promoting simple, sustainable lifestyle modifications [11,26].

Clinical Implications

The findings of this study offer several practical insights for integrating digital health tools into diabetes care.

First, in terms of the magnitude of the effect, the observed increase in autonomous motivation (1-2 points on the TSRQ-AM) should be considered within the context of behavioral science and cost-effectiveness. Although meta-analyses suggest that the effect sizes of health behavior interventions are usually modest, approximately d=0.64 [27], this study achieved a Cohen d of approximately 0.47 at the 6-month follow-up. While this represents a small to medium effect size, it is consistent with the range reported in other studies [27-29]. The clinical significance of this finding is further emphasized by the fact that the intervention was delivered at no cost and without the direct involvement of health care providers. Thus, even the modest motivational gains make this a valuable, scalable solution for long-term health behavior management when viewed from a population health perspective.

Second, our findings identify the 6-month mark as a critical opportunity for re-engagement. Engagement peaked at this point and then gradually declined, suggesting that clinicians should schedule a brief “motivational check-in.” If engagement is waning, this moment is well suited for proposing “team reorganization” as joining a new team may refresh social dynamics and restore a sense of novelty.

Finally, interindividual variability in this study indicated that lower motivation among patients with higher baseline BMI identifies a group needing additional support. This inverse association is consistent with evidence linking higher BMI to attrition and poor adherence, potentially due to reduced reward sensitivity [30] and greater reliance on less sustainable, externally driven motivation [31]. For these patients, clinicians should consider a hybrid strategy that combines the app with regular face-to-face counseling rather than relying on the digital tool alone [32,33].

Limitations and Future Research Directions

Several limitations of this study should be acknowledged.

First, the single-arm, pretest-posttest design without a control group limits causal inference. The observed changes may be attributable not only to the intervention but also to natural maturation, testing effects, or regression to the mean. Second, the small sample size (N=29), which predominantly comprised older adults with type 2 diabetes, reduces statistical power and limits the generalizability of the findings. However, we note that the use of LMMs with 4 repeated measures allowed for the estimation of individual trajectories, providing preliminary evidence on the significant quadratic trend in our primary psychological outcome (TSRQ-AM score). Participants were also volunteers, potentially introducing selection bias toward individuals with greater baseline motivation or digital literacy. Third, psychological outcomes were assessed solely through self-report questionnaires, which may be susceptible to social desirability or recall bias. Finally, the intervention included multiple components (team structure, peer support, social comparison, and gamification rewards), making it difficult to disentangle which elements were most responsible for the observed changes. Further research with larger, randomized samples and process evaluations is needed to elucidate causal mechanisms and optimize intervention design.

Conclusions

In conclusion, this formative longitudinal study provides preliminary evidence on the 1-year nonlinear trajectory of autonomous motivation following the introduction of a team-based gamification app. The observed curvilinear pattern suggests that motivation may peak at around 6 months, underscoring the importance of adaptive intervention designs to maintain engagement over time. Furthermore, this study demonstrated a significant reduction in body weight, suggesting potential physiological benefits.

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Acknowledgments

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Data Availability

The datasets generated or analyzed during this study are not publicly available due to participant privacy and ethical restrictions but are available from the corresponding author on reasonable request.

Authors' Contributions

SI conceived the study. All authors contributed to the study design. SI conducted the screening and data extraction as part of the data collection process. Data analysis was performed by SI and KK. All authors critically assessed the adequacy of the data analysis. SI drafted the manuscript, and HY and KK provided critical revisions. All authors approved the final version of the manuscript and agreed to its submission. SI is the guarantor of the study and is responsible for the integrity of the data and the accuracy of the data analysis.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Changes in psychological, behavioral, and clinical outcomes over 1 year.
[PDF File (Adobe PDF File), 193 KB - formative_v10i1e87236_app1.pdf]

Multimedia Appendix 2
Sensitivity analysis using ordinally coded time points (0-3): multivariable linear mixed-effects model of autonomous motivation (Treatment Self-Regulation Questionnaire–Autonomous Motivation subscale) over 1 year.
[PDF File (Adobe PDF File), 113 KB - formative_v10i1e87236_app2.pdf]

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Abbreviations

HbA_{1c}: hemoglobin A_{1c}
LMM: linear mixed model
mHealth: mobile health
SDT: self-determination theory
TSRQ-AM: Treatment Self-Regulation Questionnaire–Autonomous Motivation subscale

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Original Paper

Screening by Health Care Systems for Barriers to Patient Engagement With Digital Health Care: Cross-Sectional Survey Study

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Abstract

Background: Digital health tools, including patient portals, telemedicine, and mobile health apps, are increasingly a core part of health care. Digital readiness, encompassing both digital access and literacy, is crucial for enabling patients to effectively engage with the increasing number of digital health tools. Despite growing recognition of digital readiness as a health-related social need, little is known about digital readiness screening practices.

Objective: We aimed to assess the extent of digital readiness screening and the organizational factors associated with screening.

Methods: From January to May 2024, we administered an online survey to a convenience sample of clinicians or informatics leaders from US health care systems. Our primary outcome was whether the respondent reported that their organization screened for digital readiness (yes vs no), and the secondary outcome was self-reported barriers to screening. We asked respondents to report characteristics related to their health system, including health system type, geographic area, payers accepted, patient

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population characteristics, screening practices for health-related social needs (eg, screening for food insecurity), and awareness of digital inclusion policies and programs. Using bivariate logistic regression models, we examined organizational characteristics associated with screening for digital readiness.

Results: Of 144 total respondents, 64 (44%) reported screening patients for digital readiness. Organizations serving uninsured patients had lower odds of screening (odds ratio [OR] 0.32, 95% CI 0.14-0.72). Less than half of respondents to the digital readiness survey (47/99, 47%) were familiar with any digital readiness–related policy, but screening was more likely when respondents were familiar with at least one policy or program promoting equitable digital readiness (OR 6.6, 95% CI 2.4-20.6). Screening for other health-related social needs was not associated with digital readiness screening. The most frequently cited barriers to screening for digital readiness were lack of resources to address digital access (n=45, 45%), lack of resources to implement screening (n=42, 42%), and lack of time (n=41, 41%).

Conclusions: Digital readiness screening has had limited adoption in US health care systems, particularly in settings serving the populations most likely to experience challenges with digital access or literacy. The limited adoption of digital readiness screening likely reflects lower awareness of digital readiness as a social need and a lack of infrastructure to support its uptake, such as standardized screening questions or a workforce trained on how to screen for and intervene on barriers to digital readiness. Low awareness of digital equity policies that might incentivize digital readiness screening further hinders adoption. Without increased adoption of digital readiness screening and/or interventions to mitigate barriers to digital readiness, digital health tools are unlikely to be accessible to or benefit all populations. Multilevel interventions, including policy changes and workforce training, are likely necessary to increase the adoption of digital readiness screening and mitigation efforts that address barriers to digital exclusion.

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KEYWORDS

health equity; telemedicine; health care disparities; health information technology; social drivers of health

Introduction

Digital inclusion is the availability of digital technology and the ability to use it [1]. As health care systems increasingly use patient portals, telehealth, and remote monitoring, digital inclusion has become essential for equitable access to care and patient engagement [2,3]. It has also been identified as a "super social determinant of health," due to its influence on other key determinants, such as education and employment [4,5]. Consequently, barriers to patient engagement with digital tools, including limited device availability, internet connectivity, and digital literacy, threaten health equity [6,7].

To support digital inclusion, several policies and programs (eg, the Affordable Connectivity Program) have aimed to increase broadband infrastructure, access to devices, and systematic assessment and mitigation of digital inclusion barriers. These programs align with broader trends to intervene on health-related social needs (HRSNs) [8]. Efforts to "screen-and-intervene" on HRSNs have mostly been directed toward areas such as food and housing insecurity and have aimed to improve health outcomes by linking patients with resources [9]. However, these efforts have largely excluded screening for barriers to patient engagement with digital health tools, referred to here as "digital readiness," which encompasses some but not all elements of digital inclusion (eg, technical support and inclusive tool design). Digital readiness screening includes identifying barriers to engagement with digital health tools, such as access (device ownership and internet access) and literacy (digital skills and confidence) [10-13], and serves as a critical first step toward equitable digital health use.

Despite the increasing importance of digital health tools, little is known about digital readiness screening in US health care systems. To address this gap, we surveyed health care institutions to assess the extent of digital readiness screening and the organizational factors associated with screening.

Methods

Study Design and Recruitment

We conducted a cross-sectional survey using a convenience sample of health system leaders, clinicians, staff, and informatics personnel working in ambulatory care in the United States. From January to May 2024, we disseminated a Qualtrics survey. We emailed ambulatory practice–based research networks identified on the Agency for Healthcare Research and Quality's Practice-based Research Networks Registry website [14] to ask if they would distribute our survey. We also disseminated the survey link through social media and professional societies (such as those for medical informatics, general internists, and family physicians). We included individuals who could report their organization's ambulatory digital readiness screening practices and excluded invalid responses (eg, duplicate or bot-generated responses). We collaborated with another study team to include our digital readiness questions in the digital navigation survey (the supplementary survey) distributed to California safety-net systems. As a result, our sample included responses collected by their study and our own. (Details of the supplementary survey were previously published [15].) Additional methodological details appear in Multimedia Appendix 1.

Ethical Considerations

The University of California, San Francisco Institutional Review Board approved our study (23-39284) with a waiver of informed consent. We stored data on secure institutional servers and

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deidentified the data for reporting. Participants received a US $10 gift card upon completing the survey.

Survey Development

Our survey (Multimedia Appendix 1) assessed digital readiness screening practices, barriers to screening, and factors associated with screening. Questions were adapted from validated surveys [16,17] combined with newly developed questions tailored to our study objectives.

Variables

The primary outcome was whether the organization screened for digital readiness, dichotomized as “yes” vs “no” (“no” collapsed the responses “no,” “don’t know,” and “not currently but planning to”). As a secondary outcome, we assessed self-reported barriers to screening, a variable captured only in our digital readiness survey and not in the digital navigation survey.

Organizational characteristics were used as predictor variables and included health system type (academic, not-for-profit, for-profit, nonfederal governmental, federally qualified health center [FQHC], or Veterans Affairs); geographic area (rural, suburban, or urban); accepted payers (Medicaid, traditional Medicare, Medicare Advantage [MA], commercial insurance, city or county safety-net insurance, and uninsured or self-pay); and patient population characteristics, including the proportion of patients with limited English proficiency (LEP) (0% to <25%, 25% to <50%, or ≥50%) and the proportion identifying as racial and ethnic minorities (0% to <25%, 25% to <50%, or ≥50%).

In our digital readiness survey, we captured 2 additional sets of predictor variables: HRSN screening practices and awareness of digital inclusion policies and programs. We asked whether the organization screened for HRSNs (similarly to the primary outcome, responses were dichotomized as yes vs no), which of 9 HRSNs they screened for, and their awareness of the following policies and programs: the Affordable Connectivity Program (ACP) of the Federal Communications Commission (FCC) [18,19], Healthy People 2030 health literacy objectives [20], Joint Commission requirements for reducing disparities,[21] MA digital literacy screening requirements [22], Digital Equity Act [23], and Medicare Payment for Community Health Workers [24]. Policy awareness was dichotomized as familiar vs not familiar (collapsed the responses “have heard of it but not familiar” and “have not heard of it”).

Statistical Analysis

Associations between each predictor variable (organizational characteristics, HRSN screening, and policy awareness) and the primary outcome were assessed using chi-square analyses and unadjusted bivariate logistic regression models. For each association, we calculated the odds ratio (OR) and corresponding 95% CI, with significance defined as $P<.05$. We conducted a sensitivity analysis using an alternative grouping for the outcome variable (“yes” or “not currently but planning to” vs “no” or “don’t know”).

Results

Organization Characteristics

Our total sample included 144 respondents (Table 1), of which 99 were from our digital readiness survey and 45 from the supplementary survey. The most common organization types were not-for-profit (31%), academic (29%), and FQHCs (28%). Most respondents served urban areas (67%) and patient populations where <25% had LEP (40%). More than one-third (35%) reported that a majority of their patients identified as racial/ethnic minorities. There was payer diversity, with strong representation from organizations that cared for Medicaid-insured (72%), uninsured or self-pay (61%), and city or county safety-net insured patients (41%). Most (60%) organizations accepted MA. Respondents represented organizations from all 50 states.

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Table 1. Characteristics of screening among overall sample (N=144). Overall, 64 of 144 (44%) respondents currently screened for digital readiness.

Characteristic	Respondents[a], n/N (%)	Respondents that currently screened for digital readiness, n/N (%)
Type of health system		
Not-for-profit	45/144 (31)	19/45 (42)
Academic	42/144 (29)	16/42 (38)
Federally qualified health center	40/144 (28)	14/40 (35)
Nonfederal governmental (eg, state or county funded)	19/144 (13)	7/19 (37)
For-profit	18/144 (13)	11/18 (61)
Veteran Affairs (VA)	6/144 (4)	5/6 (83)
Other	5/144 (4)	2/5 (40)
Location		
Urban	96/144 (67)	41/96 (43)
Suburban	52/144 (36)	20/52 (39)
Rural	33/144 (23)	13/33 (39)
Payers accepted		
Medicaid	104/144 (72)	39/104 (38)
Traditional Medicare	101/144 (70)	37/101 (37)
Commercial insurance plan	90/144 (63)	32/90 (36)
Uninsured/self-pay[b]	88/144 (61)	29/88 (33)
Medicare Advantage plan	87/144 (60)	37/87 (43)
City or county safety-net insurance	59/144 (41)	19/59 (32)
Other	10/144 (7)	3/10 (30)
Don’t know	3/144 (2)	0/3 (0)
Patients with limited English language proficiency (%)		
0 to <25	58/144 (40)	23/58 (40)
25 to <50	29/144 (20)	13/29 (45)
≥50	24/144 (17)	9/24 (38)
Unsure/don’t know	8/144 (6)	3/8 (38)
Patients that identify as racial/ethnic minority individuals (%)		
0 to <25%	40/144 (28)	17/40 (43)
25 to <50%	21/144 (15)	9/21 (43)
≥50%	50/144 (35)	21/50 (42)
Unsure/don’t know	8/144 (6)	1/8 (13)

[a]Percentages are calculated using the full sample of 144 respondents. Missing responses ranged from 19 to 25 across variables: health system type (n=19), location (n=21), accepted payers (n=23), and patient demographics (n=25). Categories within health system type, location, and payers accepted were not mutually exclusive, so sum of counts may exceed the total sample size.

[b]$P<.05$ for association with screening in bivariate analysis.

Digital Readiness Screening and Organizational Predictors of Screening

Among the 144 respondents, 64 (44%) reported that their organization screened for barriers to digital readiness. Organizations serving uninsured patients had lower odds of screening compared to those that did not (OR 0.32, 95% CI 0.14-0.72). Digital readiness screening was not associated with health system type, location, or patient population characteristics (ie, LEP or racial/ethnic minority status).

HRSN Screening, Digital Inclusion Policy Awareness, and Association With Digital Readiness Screening

Among the 99 digital readiness survey respondents asked about HRSN screening practices and policy awareness, 57 (58%) reported screening for at least one HRSN (Table 2). These organizations most frequently screened for food (51/57, 89%)

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and housing (48/57, 84%) insecurity. Almost half (47/99, 47%) of all organizations were familiar with any digital readiness–related policy. The greatest familiarity was with the FCC's ACP (24%) and the least with the MA digital literacy screening requirements and the Digital Equity Act (17%). Among the 56 respondents whose organizations accepted MA, only 12 (21%) were familiar with the MA digital literacy screening requirement.

HRSN screening was not associated with digital readiness screening. Familiarity with any of the 6 policies was associated with screening (OR 6.6, 95% CI 2.4-20.6). Familiarity with the following individual policies was associated with screening: the FCC's ACP (OR 5.6, 95% CI 2.0-16.8), Joint Commission disparities requirement (OR 3.5, 95% CI 1.2-10.5), MA screening requirement (OR 3.2, 95% CI 1.1-10.4), and the Digital Equity Act (OR 4.5, 95% CI 1.5-15.6).

Sensitivity analyses yielded similar results (Multimedia Appendix 1, Tables S1 and S2), with additional associations between utility screening and Healthy People 2030 familiarity and digital readiness screening. Caring for commercially insured patients was associated with lower odds of screening.

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Table 2. Characteristics of health-related social need (HRSN) screening and familiarity with digital readiness policy (N=99). Overall, 47 of 99 (48%) respondents currently screened for digital readiness.

Characteristic	Respondents[a], n/N (%)	Respondents that currently screened for digital readiness, n/N (%)
Currently screening for HRSNs		
Yes	57/99 (58)	29/57 (51)
No	17/99 (17)	6/17 (35)
Screening for other HRSN items[b]		
Food insecurity or hunger	51/57 (89)	24/51 (47)
Housing (instability, quality, or financing)	48/57 (84)	23/48 (48)
Interpersonal violence	46/57 (81)	21/46 (46)
Transportation	39/57 (68)	18/39 (46)
Employment and income	35/57 (61)	17/35 (49)
Social isolation (lack of family and social support)	31/57 (54)	16/31 (52)
Education	29/57 (51)	13/29 (45)
Utility needs	29/57 (51)	17/29 (59)
Other	3/57 (5)	2/3 (67)
Level of familiarity with any of the 6 digital inclusion policies		
Familiar with any policy details[c]	47/99 (47)	28/47 (60)
Not familiar with any policy details	33/99 (33)	6/33 (18)
Level of familiarity with the Federal Communications Commission's Affordable Connectivity Program		
Familiar with the policy details[c]	24/99 (24)	17/24 (71)
Not familiar with the policy details	56/99 (57)	17/56 (30)
Level of familiarity with the Joint Commission requirements to reduce health care disparities		
Familiar with the policy details[c]	20/99 (20)	13/20 (65)
Not familiar with the policy details	60/99 (61)	21/60 (35)
Level of familiarity with the Medicare Physician Fee Schedule payment for community health integration services by community health workers		
Familiar with the policy details	20/99 (20)	10/20 (50)
Not familiar with the policy details	60/99 (61)	24/60 (40)
Level of familiarity with the Healthy People 2030 health literacy objectives focused on health communication and information technology		
Familiar with the policy details	18/99 (18)	11/18 (61)
Not familiar with the policy details	62/99 (63)	23/62 (37)
Level of familiarity with the Digital Equity Act		
Familiar with the policy details[c]	17/99 (17)	12/17 (71)
Not familiar with the policy details	63/99 (64)	22/63 (35)
Level of familiarity with the Medicare Advantage digital literacy screening requirements		
Familiar with the policy details[c]	17/99 (17)	11/17 (65)
Not familiar with the policy details	63/99 (64)	23/63 (37)

[a]Percentages are calculated using all 99 respondents who received these questions. Missing data ranged from 19 to 25 across items: policy familiarity (n=19) and HRSN screening behaviors (n=25). HRSN screening categories were not mutually exclusive; the sum of counts may exceed the number of respondents who reported any HRSN screening (n=57).

[b]Of 57 respondents who were screening for at least one HRSN.

[c]$P<.05$ for association with screening in bivariate analysis.

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Barriers to Screening

Among the 99 digital readiness survey respondents who were asked about perceived barriers to screening (Multimedia Appendix 1, Table S3), the most frequently cited challenges were lack of resources to address digital access (n=45, 45%), lack of resources to implement screening (n=42, 42%), and lack of time (n=41, 41%).

Discussion

Principal Findings

In this study on digital readiness screening, only 44% of respondents reported that their organizations screened for barriers to patient engagement with digital health tools. This is lower than the 58% who reported screening for other HRSNs in our sample and the 79% seen in a study of approximately 3000 US hospitals [25]. This gap may reflect a stronger infrastructure and policy focus on other HRSNs, particularly following the 2019 National Academies of Sciences, Engineering, and Medicine report on integrating social care into health care delivery [26]. For example, the Center for Medicare and Medicaid Services incentivizes HRSN screening but excludes digital readiness, reflecting the failure to recognize digital access as a social need and potentially limiting reimbursement and thereby exploration and awareness of strategies to address patients' digital access and literacy challenges. Digital readiness was not associated with HRSN screening, suggesting that even organizations already engaged in social risk screening have not yet adopted digital readiness screening.

Given health care's increasing reliance on patient portals, telehealth, and remote monitoring—and known disparities in adoption of digital health tools [27-30]—equity advocates worry that digitization intended to increase access may instead worsen disparities in access, engagement, and outcomes [31]. This screening gap represents a missed opportunity for health care organizations to address a barrier that directly impacts other HRSNs that are increasingly managed through digital platforms, such as access to food, housing, or transportation resources [32]. Moreover, without routine digital readiness screening, health systems and policymakers lack the data needed to quantify the scope of digital access barriers or track progress toward digital equity over time.

Organizations serving uninsured patients—populations most vulnerable to digital exclusion—were significantly less likely to screen for digital readiness. This highlights a critical paradox: organizations caring for patients most likely to face digital readiness barriers may also lack the resources or awareness needed to screen for them, as reflected by the frequently reported barriers to screening in our study (lack of resources to address needs, limited infrastructure for screening, and inadequate staff training). Current federal digital readiness policies do not target safety-net systems or address these operational challenges, reflecting a broader pattern of structural underinvestment in organizations that disproportionately serve patients at the highest risk for digital exclusion (ie, patients with LEP or lower income, or those in underconnected areas) [30,33-36]. Resource constraints (lower reimbursement rates, understaffing) limit capacity to train staff, implement screening, and build referral networks [37,38]. Addressing these disparities will require targeted policies that provide sustainable funding for digital access programs, reimbursement for screening and navigation, and investment in workforce training tailored to safety-net settings. Developing standardized digital readiness screening tools for integration into electronic health records, like those for other HRSNs, may reduce implementation barriers. Embedding digital screening into existing reimbursable activities and incorporating equity-focused metrics into value-based payment models could further promote adoption [39]. Additionally, health care systems could leverage existing reimbursement codes and build partnerships with community-based digital readiness organizations that provide skills training, device access, and connectivity support. Community health workers may also represent a mechanism to support digital readiness screening, although sustainable funding is lacking [40].

Awareness of digital equity policies was significantly associated with screening. However, overall awareness was low, with fewer than a quarter of respondents familiar with each of the 6 policies. Even among organizations accepting MA, only a minority were aware of the MA digital literacy screening requirement. These findings suggest that policy changes without dissemination, financial support, and institutional prioritization may be insufficient to drive adoption. There are similar gaps in policy dissemination to individual patients; in 2023, nearly 50% of eligible households were not aware of the ACP [41]. Ultimately, improved policy visibility, organizational engagement, and stable federal investment are necessary to promote digital readiness. However, ongoing policy uncertainties, including failure to ensure sustained availability of affordable internet service [22] and the cancellation of the Digital Equity Act [42], present threats to progress toward digital equity [43].

Limitations

The use of convenience sampling may have limited generalizability, as organizations with a greater interest in digital access or HRSN screening may have been more likely to respond (eg, academic health systems and FQHCs). The causality of identified associations also cannot be determined from our observational data. While our survey specified that respondents should be able to comment on digital screening practices, we did not vet the individual qualifications to answer all survey questions. Therefore, as with any self-reported measures, there may have been unreliable responses. Despite these limitations, our study is strengthened by being one of the first assessments evaluating how health care systems are screening for digital readiness, with representation from a breadth of clinical care settings.

Conclusion

This national survey found that digital readiness screening is not routinely conducted in US health care settings, especially among organizations serving populations most at risk for digital exclusion. Without intervention, patients already facing barriers to care risk being left further behind, exacerbating health disparities. As HRSN screening demonstrates, creating standardized and integrated digital readiness screening is

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feasible, but awareness and prioritization are lacking. Policy solutions that support safety-net systems, such as broadband subsidies, increasing device access, and improving digital navigation, may drive broader screening and intervention. Increasing awareness of existing digital equity initiatives is also needed to sustain progress and advocate for policy development. By identifying low policy awareness, associations between policy familiarity and screening, and implementation barriers, our findings offer actionable insights for those seeking to advance digital readiness screening.

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Data Availability

The datasets generated or analyzed during this study are available in the openICPSR repository [44].

Conflicts of Interest

KHN holds an advisory role with AstraZeneca. All other authors declare no conflicts of interest.

Multimedia Appendix 1
Additional details on methods, Digital Inclusion Screening Survey Instrument, and Tables S1-S3.
[DOCX File , 79 KB - formative_v10i1e85205_app1.docx]

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Abbreviations

ACP: Affordable Connectivity Program
FCC: Federal Communications Commission
FQHC: federally qualified health center
HRSN: health-related social need
LEP: limited English proficiency
MA: Medicare Advantage
OR: odds ratio
UCSF: University of California, San Francisco

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Original Paper

Effects of a Semantically Irrelevant Virtual Reality Experience on Memory and Emotion After Watching a Traumatic Event: Randomized Controlled Experimental Study

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Abstract

Background: First responders, such as firefighters, experience significant mental health issues due to the high-stress nature of their work. Existing mental health interventions, such as meditation and debriefing, despite their benefits, do not target cognitive processing of traumatic events such as memory and emotion.

Objective: This work aims to examine effects of semantically irrelevant virtual reality (VR) content to intervene in the retrieval of an adverse event memory and its associated emotions. Cognitive models of posttraumatic stress disorder posit that exposure to stimuli that are similar to a previous trauma acts as a trigger for retrieval of the associated memory and bodily reaction (eg, elevated heart rate). This work uses semantically irrelevant VR as an intervention to interrupt the retrieval of the traumatic memory by placing a participant in a VR environment that has a distant semantic connection to the trauma.

Methods: A total of 107 participants recruited from a large public university in Texas were randomly assigned to 1 of 3 groups: control (n=33), comparison (n=37), and intervention (n=37). In stage 1, participants in all groups watched a short video of an actual severe house fire to create a traumatic event memory. In stage 2, the control group stayed seated without doing anything, the comparison group read a paragraph about the Red Sea as semantically irrelevant follow-up information, and the intervention group watched a 360° VR video of the Red Sea that featured opposite attributes to the fire (eg, blue water vs red fire, cool water vs hot fire). The Positive and Negative Affect Schedule, which has 10 items for positive emotions (eg, attentive and excited) and 10 items for negative emotions (eg, scared and distressed), was administered after each of the two stages. In stage 3, the memory accuracy of the house fire video was assessed using a forced recognition test of 15 pairs of a true image and a fake image generated by artificial intelligence software.

Results: A 1-way ANOVA revealed no difference in memory accuracy between the three groups (P=.48). Mean memory accuracy was 0.714 (SD 0.125) for the control group, 0.732 (SD 0.117) for the comparison group, and 0.694 (SD 0.155) for the intervention group. However, a repeated-measures ANOVA found that the semantically irrelevant VR experience significantly boosted positive emotions among the intervention group participants (P=.04) and reduced negative feelings among participants in all groups (P<.001).

Conclusions: Our findings suggest that semantically irrelevant VR was effective in changing the emotional states of participants. This implies that a semantically irrelevant VR experience can serve as a quick and affordable way to address psychological reactions after watching a traumatic event. Future research is required to design semantically irrelevant VR content to produce the memory suppression effect.

Trial Registration: ClinicalTrials.gov NCT07393776; https://clinicaltrials.gov/study/NCT07393776

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(JMIR Form Res 2026;10:e75848) doi:10.2196/75848

KEYWORDS

mental health; virtual reality; memory; emotion; firefighter

Introduction

Emergency response is a high-risk task that places severe stress on first responders. An intense burden is incurred by witnessing human death and suffering, risking harm, overwhelming workloads due to physically demanding tasks and long work hours, and making life and death decisions under time pressure [1].

The harsh nature of emergency response leads to serious health issues among first responders. Occupational injuries and illnesses among US firefighters occur at more than 3 times the rate observed across all other occupations [2]. Particularly, first responders' mental health issues are at an alarming level. Nearly 50% of police officers who responded to the 9/11 terrorist attack experienced severe depression, anxiety, and posttraumatic stress disorder (PTSD) [3]. More than 20% of medical responders to the Great East Japan Earthquake were diagnosed with clinical depression [4]. Astonishingly, 50% of US firefighters have had suicidal ideation or attempts in their careers [5].

To tackle mental health issues among first responders, several psychological interventions are available. Critical incident stress debriefing has been used to enable them to share their reactions and emotions after witnessing a traumatic event [6,7]. Nonetheless, the effectiveness of critical incident stress debriefing has been either insignificant or weak [8]. Mindfulness meditation aims to slow racing and negative thoughts [9]. However, the psychological effects of mindfulness meditation are not sustained over the long term [10]. In addition, Difede et al [11] provided first responders to the 9/11 terrorist attack with cognitive behavioral therapy (CBT), including psychoeducation, breathing exercises, imaginal exposure, and relapse prevention. Results showed significantly lower depression and PTSD survey scores compared with the non-CBT group. Essar et al [12] administered pretraumatic vaccination (PTV) for search and rescue personnel to prepare for anticipated traumatic events (eg, warfare) and found that those who received PTV reported lower levels of distress.

Despite the benefits of existing mental health treatments, limitations exist. Therapeutic techniques such as CBT and PTV are focused on increasing individuals' general coping capacity for future traumatic events; therefore, they do not target specific causes of mental health symptoms or account for the psychological processes leading from causes to symptoms [13]. For example, deep breathing is intended to control autonomic nervous system functions, resulting in reduced heart rate and oxygen consumption [14]. Thus, the breathing technique has little to do with the individual's prior traumatic experience. In addition, existing interventions generate transient effects after the interventions [15]. The effectiveness of psychological techniques such as debriefing and mindful meditation greatly depends on the recipient's commitment toward the interventions [8]. In this regard, knowledge regarding human cognitive processes involving the memory and emotion of a traumatic event remains limited. Our study aims to bridge this research gap by providing semantically irrelevant virtual reality (VR) content to suppress the retrieval of the memory of a traumatic event and to alter its associated emotions.

Cognitive models of mental disorders posit that repeated re-experiencing of a traumatic event leads to negative symptoms such as hyperarousal, anxiety, and depression [16,17]. A traumatic event is perceived via multiple sensory channels (eg, visual and auditory) and stored in one's memory. The cognitive processing of the traumatic event is influenced by different factors such as the event characteristics (eg, severity and uniqueness) and the individual's prior experiences, beliefs, and coping behaviors related to the event—both positive (relaxation, meditation, or counseling) and negative (avoidance, anger, violent behavior, or use of alcohol).

Once the memory of the traumatic event is created, re-experiencing the trauma can occur when current threats emerge as matching triggers. Matching triggers are the cues associated with the nature of the trauma, such as similar situations, lights, and sounds. For example, if an individual experienced a severe fire event, exposure to other fires or bright lights may trigger the memory of the prior fire. Perception of similar threats causes retrieval of the traumatic memory and accompanying strong emotional reactions, such as hyperarousal, fear, and anxiety [17]. Psychological reaction to the re-experience is also influenced by coping strategies, either positive or negative. When an individual relies on negative coping strategies, emotional symptoms may progress to more severe mental health disorders, such as depression and PTSD [18].

Given that the re-experience of a traumatic event is closely connected to the retrieval of an associated memory, it is anticipated that if memory retrieval gets suppressed, then the negative appraisal of the previous trauma and its associated emotional reaction will be lessened. To generate the "memory suppression effect," we used semantically irrelevant information as a follow-up intervention after an individual experiences a traumatic incident directly or indirectly.

Semantically irrelevant information refers to visual and auditory cues that are meaningfully distant from an initial experience of the trauma. Semantically relevant information is widely used to produce the "misinformation effect," which indicates the integration of false follow-up information into the memory of an initial experience. As a seminal work, Loftus et al [19] discovered that participants' initial memory of a car accident occurring near a yield sign was partially altered, when compared to that of an accident occurring near a stop sign, due to the subsequent false information that was semantically relevant. Following this work, numerous studies have examined the malleability of human memory, which allows for the integration of an initial memory and subsequent false information when

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the two are semantically related [20]. Misinformation effect brought remarkable impacts on forensics and criminal justice where the truthfulness of one's memory determines the guilt of crimes or offenses. Nevertheless, there is little knowledge regarding the effects of semantically irrelevant information, especially regarding its role in suppressing the initial memory of a traumatic event and assuaging associated emotions.

There are several categories of semantical relationships between concepts [21]. In this study, the antonymic or opposite relationships were used to achieve semantical irrelevance. For example, a residential house fire, a common emergency handled by first responders, has several representative attributes, such as fire, red, hot, and artificial structure. Thus, semantically irrelevant content should have opposite qualities, such as water, blue, cool, and natural environment, which are commonly available in tropical oceans.

VR offers an excellent environment that enables an immersive experience of the semantically irrelevant content, compared with a 2D computer monitor. Indeed, previous research showed the effectiveness of VR in reducing psychological symptoms [22,23]. Nonetheless, the effects of semantically irrelevant VR environments on memory and emotion related to a previous adverse event have been seldom reported in the literature.

In addition to the "memory suppression effect" of semantically irrelevant VR experiences, our study examines the "virtual getaway effect" of a VR-based trip that relieves negative emotions induced from traumatic events. Previous studies found that traveling has a positive impact on reducing stress and depressive symptoms [24,25]. Considering the cost and time required for physical travel, VR-based trips have emerged as an easy, accessible way of taking a virtual getaway [26,27].

To this end, the objective of this study was to investigate the memory suppression and the virtual getaway effects of semantically irrelevant VR experiences as an intervention for mental health challenges commonly faced by first responders after they were exposed to a traumatic event.

Methods

Overview

This study followed the CONSORT (Consolidated Standards of Reporting Trials) guidelines (Multimedia Appendix 1) and used a randomized controlled experimental design with 3 groups: a control group, a comparison group, and an intervention group. After eligibility screening, we recruited 156 participants from a large public state university in Texas between June 2023 and August 2023. The recruitment ended when the required sample size was attained. The sample size was determined based on a power analysis wtih with α=.05, power=0.90, effect size=0.25, and correlation among repeated measures=0.50. The participants were randomly allocated to 1 of the 3 experimental conditions in a 1:1:1 allocation ratio (ie, 52 in each group). Random assignment was conducted by one of the authors (KP) using Microsoft Excel using the RAND() function. Participant codes, initially listed by group (eg, control group from S001 to S052, comparison group from S053 to S104, and intervention group from S105 to S156),) were sorted in ascending order of the generated random numbers. After excluding participants who did not show up or acted as pilot-testers of the research protocol, the remaining participants received no intervention (control: n=33), alternative intervention (comparison: n=37), or target intervention (intervention: n=37). Figure 1 shows the CONSORT diagram of participant flow in this study. No restrictions such as blocking or stratification were applied during randomization. Allocation was not concealed from the researchers assigning participants to the experimental conditions due to the nature of the interventions; however, participants were not informed of alternative conditions or study hypotheses at the time of assignment. The university enrolls a diverse student body of more than 44,000 undergraduate and graduate students, providing access to a broad and representative sample of young adults. Recruitment was conducted using TechAnnounce, the institution's official campus-wide electronic announcement platform, which distributes daily bulletins to all enrolled students, faculty, and staff via email.

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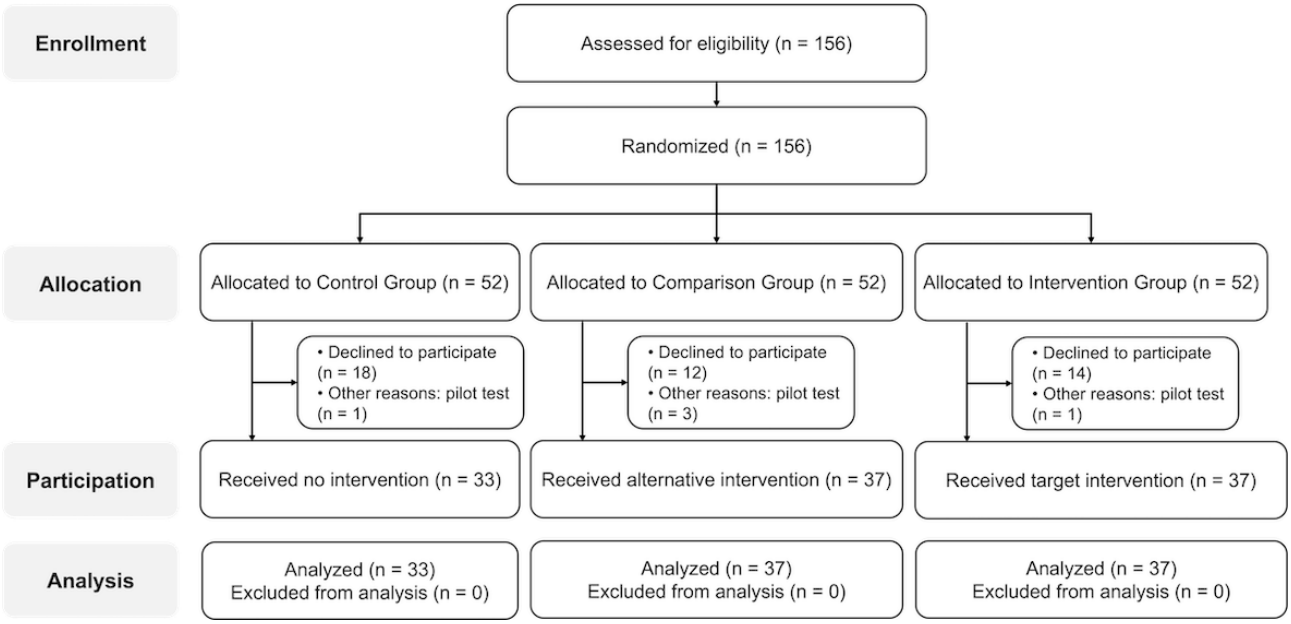
Figure 1. CONSORT (Consolidated Standards of Reporting Trials) flow diagram of participant randomization in this study.



To ensure consistency and broad visibility, the recruitment message was posted once per week during the recruitment window. Each announcement contained a standardized description of the study purpose, eligibility criteria, and a hyperlink to an online sign-up sheet. Interested students who clicked the link were directed to a screening form that assessed the inclusion and exclusion criteria.

The eligibility criteria required participants to be aged at least 18 years and currently enrolled at the university. To control for previous exposure to atypical emergency experiences and the baseline emotional state, individuals who currently worked or had previously worked as first responders were excluded, as were those who self-reported a history of depression, PTSD, or other serious mental health concerns. Additionally, students who indicated a fear of water or a tendency toward motion sickness with VR applications were excluded to minimize the risk of adverse reactions during the experiment.

The mean age of the participants was 25 (SD 6.00; range 18-50) years. There was no significant age difference among participants across the three groups ($F_{2,104}$=0.214; P=.81).

Participants followed a 3-stage experimental protocol (Figure 2). In stage 1, participants in all groups watched a 3-minute video of a real house fire that occurred in a residential area in the United States. A large TV monitor (65-inch type) was used to display the video, enhancing the realism of indirectly witnessing the fire. The video was recorded by a local fire department in 2019 and posted on YouTube (Alphabet Inc) shortly after. Figure 3 shows different snapshots of the house fire video. The fire ruined most of the house and spread to a neighboring house.

Figure 2. A 3-stage experimental procedure. Participants were randomly assigned to 1 of 3 groups: control, comparison, and intervention. In stage 1, all participants watched a short video clip of a severe house fire. In stage 2, the control group stayed seated doing nothing, the comparison group read a paragraph describing the Red Sea, and the intervention group watched a 360° virtual reality (VR) video. The Positive and Negative Affect Schedule (PANAS) surveys were administered after stages 1 and 2. Finally, a forced recognition memory test was conducted to assess memory accuracy of the house fire. SI: semantically irrelevant.

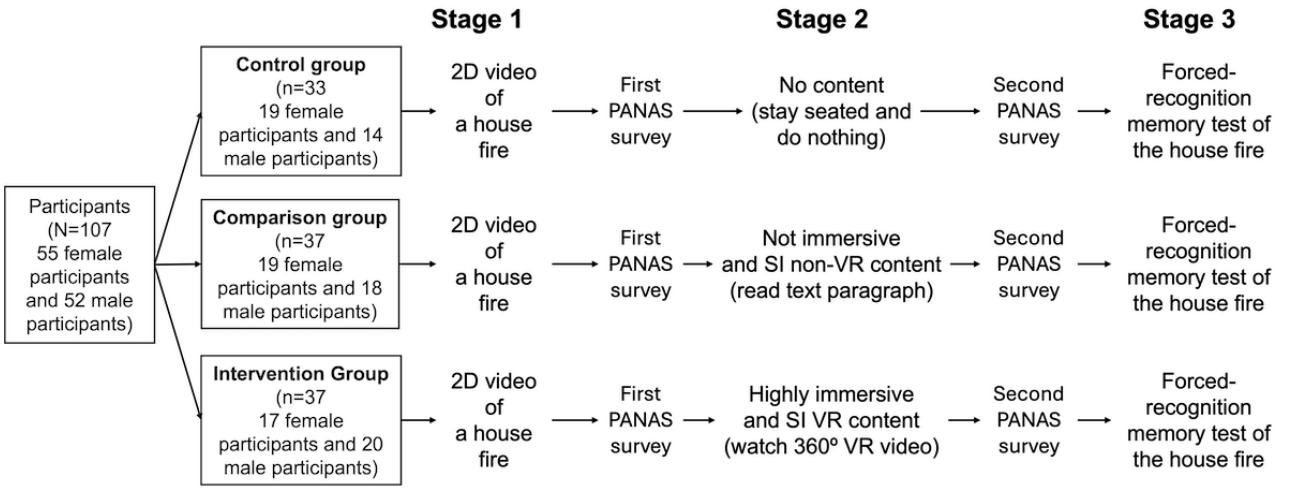


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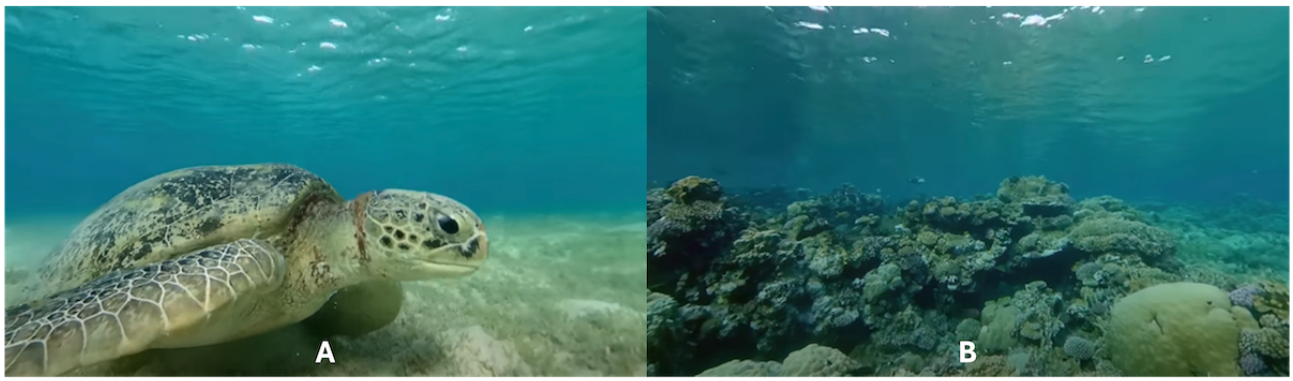
Figure 3. Snapshots of the 2D video of a real house fire; the picture on the left is from the front side of the house, and the picture on the right is from the back side.

In stage 2, each group was exposed to different treatments. Control group participants did not do any task while staying seated for 3 minutes. Participants in the comparison group read a paragraph describing the Red Sea. The length of the text was adjusted so that it would take approximately 3 minutes to read. Excerpts from the paragraph are as follows:

> *Egypt is an interesting destination in many ways: history and culture buffs can explore its ancient civilization, and beach vacationers can relax in its many resorts. One of them, Marsa Alam, is considered the best place in the country for snorkeling.... Its water area is rich in coral, fish and other underwater life.... Coral reefs are turtles' favorite environment: not only do they provide turtles with food, but also protect them from bad weather. Barely hatched from the egg, a baby turtle gains strength by eating jellyfish, sponges, and fish.*

Participants in the intervention group watched a 3-minute 360° VR video of the Red Sea that shows similar natural scenes to those described in the paragraph. Figure 4 shows snapshots of the VR video (source: AirPano). This VR video provides a live recording of underwater nature that contains sea animals and coral reefs. The choice of the Red Sea as semantically irrelevant VR content was based on the opposite attributes of the underwater nature to the house fire in several representative aspects: red versus blue (color), fire versus water (element), hot versus cold (temperature), and artificial structure versus underwater nature (environment).

Figure 4. Snapshots of the 360° virtual reality video of the Red Sea. Participants turned their heads to view different elements under water, such as a turtle (left) and coral reefs (right).



In stage 3, a forced recognition test was conducted to assess the memory accuracy of the house fire that participants in all three groups watched in stage 1. A forced recognition memory test was used, in which participants are required to choose 1 image from multiple options that they believe they have seen previously. The forced recognition test is widely used in memory testing studies [28,29].

To make fake images of the house fire video, we used Adobe Firefly (Adobe Inc) [30], an image-generating artificial intelligence (AI) program available to the public. This generative AI program has multiple features, such as generative fill. An example of the fake images used in the forced recognition test is shown in Figure 5.

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Figure 5. An example of a true and a fake image of a house fire. The image on the left is a true snapshot from the house fire video, and the image on the right is a modified (fake) one using a generative artificial intelligence software. In the fake image, the fire and smoke near the house were replaced with a small car that showed no signs of fire damage.

A total of 15 pairs of a true image and a fake image were used in the forced recognition test. Memory accuracy was calculated using the following equation:

In addition to the memory accuracy, the participant's emotions were assessed each after the first and second stage, using the Positive and Negative Affect Schedule (PANAS) survey [31]. The PANAS survey has 20 items, consisting of 10 positive emotion types (eg, interested or enthusiastic) and 10 negative emotion types (eg, distressed or upset), rated on a 5-point Likert scale (1=not at all to 5=extremely). The positive PANAS score was obtained by summing the scores for items 1, 3, 5, 9, 10, 12, 14, 16, 17, and 19. Thus, a positive PANAS score can range from 10 to 50, with a higher score representing a higher level of positive affect. The negative PANAS score was the sum of the scores for items 2, 4, 6, 7, 8, 11, 13, 15, 18, and 20. Hence, a negative PANAS score can range from 10 to 50, with a lower score representing a lower level of negative affect. Cronbach α for positive and negative PANAS items was 0.915 for positive affect items and 0.808 for negative affect items, indicating good to excellent internal reliability of the items [32]. The PANAS survey was widely used in previous studies as an instrument to assess the participants' emotional state [33,34].

Memory accuracy was analyzed using a 1-way independent ANOVA across groups. Before conducting the analysis, the assumptions of normality and homogeneity of variances were examined. The data satisfied the assumption of normality, and the Levene test indicated equal variances across groups ($F_{2,104}$=2.348; P=.10). This result confirmed that the homogeneity of variance assumption was not violated, supporting the validity of using ANOVA for group comparisons [35,36]. Following a significant main effect, post hoc analyses were conducted using the Tukey honestly significant difference test to identify specific group differences while controlling for family-wise error rates [37]. ANOVA was chosen because it provides a robust method for testing mean differences among more than two independent groups when assumptions are satisfied [38].

To assess differences in positive and negative affects across groups and stages, a 2-way mixed factor repeated-measures ANOVA was performed on the PANAS survey data. Study groups (ie, control, comparison, and intervention) served as the between-subjects factor, while study stages served as the within-subjects factor. The mixed factor design was appropriate for this dataset, as it allows for the simultaneous evaluation of between-group differences and within-subject changes over time [39]. A significance level of α=.05 was adopted for all statistical tests. Repeated-measures ANOVA is particularly advantageous in this context because it accounts for correlations between repeated observations among the same participants, thereby increasing statistical power compared with independent designs [40]. For all statistical tests, JASP (version 0.18.3; JASP Team, 2024) was used.

Ethical Considerations

This study was conducted in accordance with a research protocol approved by the Texas Tech University's institutional review board (institutional review board number 2022-966). Written informed consent was obtained from all participants before their participation, covering both their voluntary participation in this study and the publication of data collected from the research.

Results

For memory accuracy, there was no significant difference between the three groups ($F_{2,104}$=0.748; P=.48). Mean memory accuracy was 0.714 (SD 0.125) for the control group, 0.732 (SD 0.117) for the comparison group, and 0.694 (SD 0.155) for the intervention group.

Regarding positive emotion, Table 1 presents descriptive statistics for the mixed factors repeated-measures ANOVA for the positive PANAS scores, and Figure 6 illustrates changes in positive emotion of the participants along the first two stages between groups.

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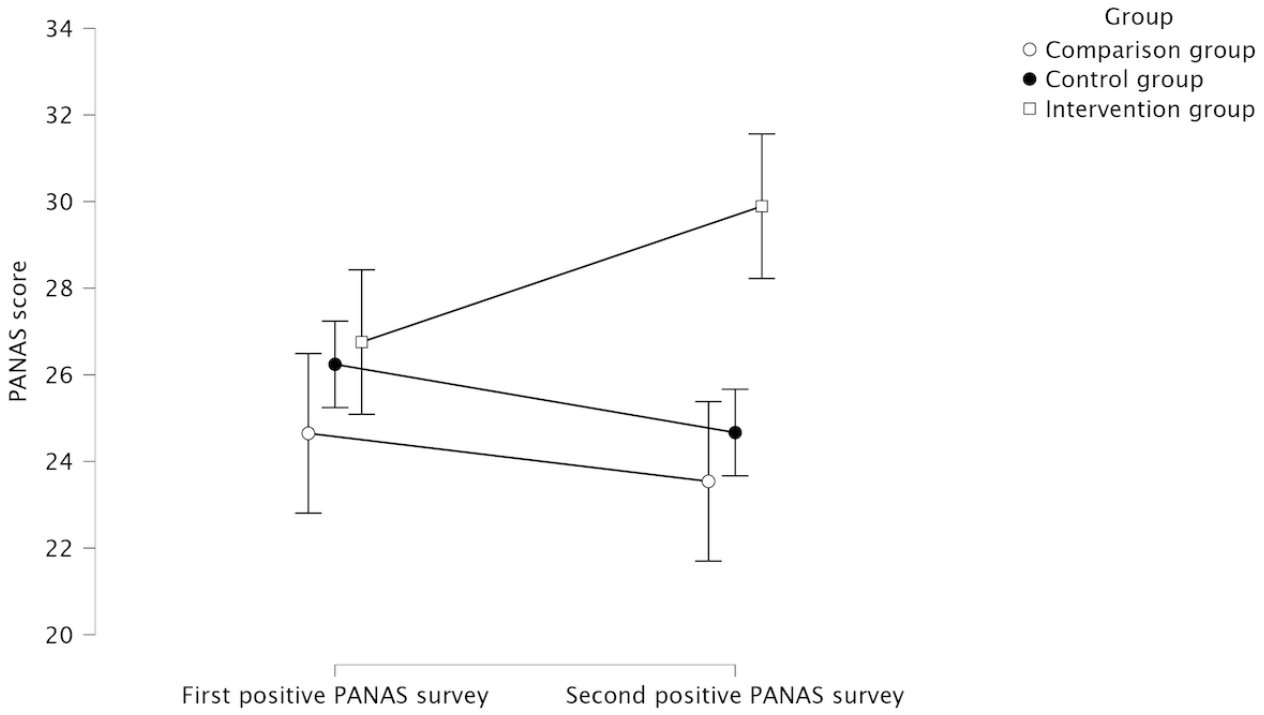
Table 1. Descriptive statistics of the positive affect survey scores (N=107).

Stage and group	Participants, n (%)	Scores, mean (SD)
Positive PANAS[a] survey after stage 1		
Control group	33 (30.8)	24.649 (7.595)
Comparison group	37 (34.6)	26.242 (8.972)
Intervention group	37 (34.6)	26.757 (9.124)
Positive PANAS survey after stage 2		
Control group	33 (30.8)	23.541 (8.726)
Comparison group	37 (34.6)	24.667 (9.816)
Intervention group	37 (34.6)	29.892 (11.007)

[a]PANAS: Positive and Negative Affect Schedule.

Figure 6. Mean positive affect survey scores between groups at the first and second stages, with 95% CI. PANAS: Positive and Negative Affect Schedule.



Regarding positive PANAS scores, there was no significant difference between the groups ($F_{2,104}$=2.296; P=.11) and between the two stages ($F_{1,104}$=0.056; P=.81). However, we found a significant interaction effect between the groups and stages ($F_{2,104}$=5.610; P=.005; η^2=0.013). The post hoc analysis revealed that positive PANAS scores significantly increased only in the intervention group between the two stages (P=.051) and that the second positive PANAS score of the intervention group was significantly higher than that of the comparison group (P=.04). All other interactions were not statistically significant.

Table 2 shows descriptive statistics of negative PANAS scores, and Figure 7 illustrates the changes along the first two stages between groups. Results showed a significant change between the stages ($F_{1,104}$=68.213; P<.001). No significant main effect was found for the groups. In addition, no significant interaction effect between the groups and the stages was found. Negative PANAS scores significantly decreased in the comparison group (P<.001) and intervention group (P<.001). No other significant differences were found.

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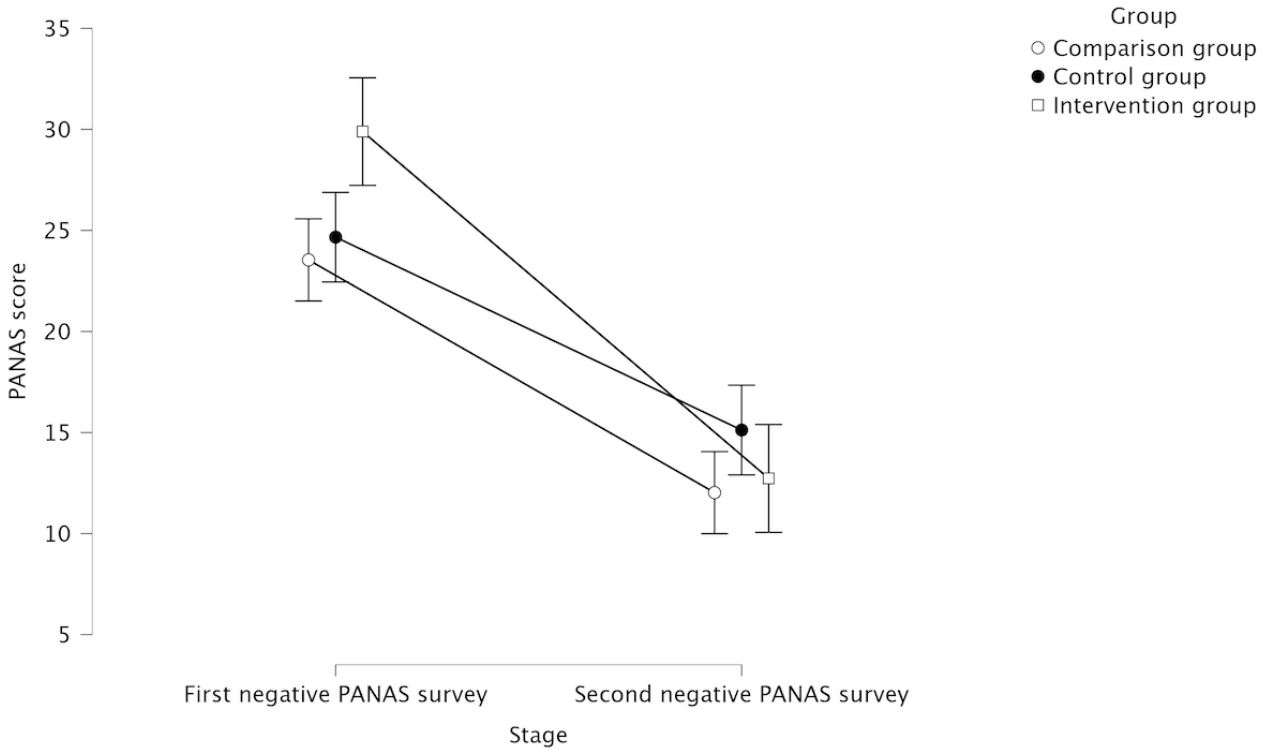
Table 2. Descriptive statistics of the negative affect survey scores (N=107).

Stage and group	Participants, n (%)	Scores, mean (SD)
Negative PANAS[a] survey after stage 1		
Control group	33 (30.8)	18.242 (6.778)
Comparison group	37 (34.6)	18.892 (6.798)
Intervention group	37 (34.6)	18.108 (6.790)
Negative PANAS survey after stage 2		
Control group	33 (30.8)	15.121 (3.050)
Comparison group	37 (34.6)	12.027 (5.781)
Intervention group	37 (34.6)	12.730 (4.350)

[a]PANAS: Positive and Negative Affect Schedule.

Figure 7. Mean negative affect survey scores between groups at the first and second stages, with 95% CI. PANAS: Positive and Negative Affect Schedule.



Discussion

Principal Findings

Findings from this study showed that a semantically irrelevant VR experience (diving in the Red Sea) boosted positive emotion and lessened negative mood after indirectly witnessing an adverse event (ie, watching a residential house fire). Specifically, participants' positive affect improved only with the semantically irrelevant VR experience, whereas negative emotions were mitigated by watching a wall (control group), reading a text (comparison group), and watching a VR video (intervention group). Nevertheless, there was no difference in memory accuracy between the groups. These results indicate that the semantically irrelevant VR experience of this study (ie, watching an immersive VR video) did not affect the memory of the house fire. However, regardless of how accurately participants remembered the details of the previous traumatic event (ie, the house fire), providing the semantically irrelevant VR experiences such as doing virtual scuba diving and reading a paragraph about a tropical sea helped participants adjust their emotional states.

These findings show the promise of VR technology as an alternative tool to address chronic mental health problems among first responders. Given that existing mental health interventions, such as postincident debriefing, mindfulness meditation, and CBT, require professional support and long-term commitment, semantically irrelevant VR experiences represent a more accessible solution.

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Implications of Study Findings and Comparison to Previous Work

This study's findings corroborate the remedial effects of a virtual trip, or "a virtual getaway effect," derived from immersive VR environments [24,25]. Interestingly, reading a paragraph describing the Red Sea also helped reduce negative emotions, whereas participants in the control group did not report any substantial changes in positive emotions. The latter signifies the needs for mental health support in any form, ranging from simple guided imagery training [41,42] to more interactive solutions such as VR experiences [43]. Thus, semantically irrelevant VR experiences can act as an alternative and complementary approach, compatible with the unique cultural traits of first responders, due to their high accessibility. As highlighted in a review of VR solutions for mental health [44], VR-based interventions can be useful in treating a variety of mental health issues, such as eating disorders and depression, especially if VR is integrated with other advanced technologies such as large language models and gamification.

It is also noteworthy that even a brief virtual getaway (3 min) produced substantial changes in participants' emotional states. In contrast, taking an actual vacation requires considerable time and expense. Moreover, the temporal gap between a traumatic event and a real trip may be long, potentially reducing the remedial effects of the vacation. Thus, a virtual getaway using the semantically irrelevant VR experience offers a quick and affordable way to alleviate negative emotions following exposure to traumatic events. Additionally, our findings corroborate the stress-reducing effects of immersing oneself in natural environments (eg, forests and mountains) [45,46]. In future studies, diverse VR apps such as virtual concerts and sports events [47] can be considered as options to personalize the VR experience as a psychological aid.

Strengths, Limitations, and Future Directions

One methodological implication of this study is the use of an image-generating AI program (Adobe Firefly). Previous studies used simple drawings, photos, and verbal narratives to examine the malleability of human memory [48,49]. Owing to advanced AI technology, it now takes only a few mouse clicks to create a fake image that looks genuine. To our knowledge, this is the first study to use a generative AI tool to create fake images for a memory test. Considering the rapid development of generative AI applications, the methodology established in this study will inform future experiments that necessitate AI-generated artifacts. Nevertheless, the AI-generated images were not validated for their realism against a separate and independent sample. Thus, future studies need to assess the perceived level of fakeness of AI-generated images when they are used in recognition-based memory tests.

Despite the novel benefits of the semantically irrelevant VR experience on emotions, our study could not reveal the memory suppression effect, given the nonsignificant difference in memory accuracy. Therefore, the relationship between the adverse event memory and its associated emotions remains inconclusive. We suspect several reasons behind this lack of evidence.

First, the forced recognition test may not be the best way to assess the memory accuracy of an initial event (ie, a house fire). As shown in Figure 5, only a limited number of items were modified (eg, a lawn under fire to a small car). In the house fire video, there are numerous elements that a participant could potentially catch or miss (eg, flames, adjacent trees, firefighters, and houses). Thus, there was no guarantee that the participants observed the items that were modified in the fake images. If the participants did not observe such items, the recognition-based test becomes a binary choice with random chance. To address this issue, alternative methods for assessing an individual's memory should be considered, such as a recall-based memory test, which has been used in previous memory research [29].

Second, it is unclear whether watching a house fire created sufficiently negative emotions. Experiencing a house fire directly can cause immense stress and suffering. However, watching a house fire on a computer screen without any severe injuries and damages may not feel as traumatic, which may have weakened the memory suppression effect of the subsequent semantically irrelevant VR experience. In future studies, a stronger dosage of a traumatic event needs to be considered to create more distressing emotions. Alternatively, future studies may consider recruiting those with traumatic memories associated with a fire to see how the same semantically irrelevant VR experience influences their emotions. Relatedly, we did not assess the pre-experiment emotional state, leading to a limited manipulation check to see whether the house fire video made sufficient changes in the viewers' emotions. Thus, future studies require a prestudy assessment of the participants' emotional state. In addition to self-reported surveys such as the PANAS survey [31], we recommend that physiological measures, such as heart rate, skin conductance, or eye-tracking metrics, be collected to find associations with self-reported survey results.

Third, our study used a passive VR experience that only required participants to watch. Therefore, watching the VR video (Red Sea) may not have consumed much cognitive resources for attention and perception. It is speculated that if a participant uses more cognitive resources in a VR environment, the memory suppression effect and the psychologically remedial effect would be stronger, making it more difficult to retrieve the memory of a previous traumatic event. Indeed, previous studies report that active VR requiring psychomotor activities consumed more cognitive resources [50,51]. Moreover, this study did not reveal whether the changes in emotions occurred due to either the semantically irrelevant experience or the immersive environment afforded by the VR. Thus, future research needs to consider using active VR that consumes more cognitive and physical resources. Furthermore, it is recommended to vary the VR modality (2D experience vs 3D experience) while keeping the semantically irrelevant content constant.

Additionally, longitudinal studies with multiple follow-up assessments are recommended to examine the long-term effects of semantically irrelevant VR on memory and emotions, as this study examined only immediate effects.

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Conclusions

Our work showed the promise of immersive semantically irrelevant VR as a novel solution to addressing mental health issues faced by first responders. Although semantically irrelevant VR did not result in a memory suppression effect, this study found that a virtual trip had substantial effects on both positive and negative emotions after individuals indirectly witnessed an adverse event. Considering the prevalence of severe mental health issues among first responders and the paucity of mental health support for them, findings from this study can inform quicker and more accessible VR solutions for psychological issues, in combination with existing mental health interventions.

Acknowledgments

The authors used the generative artificial intelligence tool Adobe Firefly [52] to create images, which were used for a recognition-based memory test in this study.

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Data Availability

The datasets generated or analyzed during this study are available from the corresponding author on reasonable request.

Authors' Contributions

Conceptualization: CS
Data curation: CS, KP, MJ
Formal analysis: CS
Investigation: CS, KP, MJ
Methodology: CS, KP, MJ
Project administration: CS
Resources: CS
Software: CS
Supervision: CS
Visualization: CS
Writing—original draft: CS
Writing—review and editing: CS, KP, MJ

Conflicts of Interest

None declared.

Multimedia Appendix 1
CONSORT-eHEALTH checklist (V 1.6.2).
[PDF File (Adobe PDF File), 94 KB - formative_v10i1e75848_app1.pdf]

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Abbreviations

AI: artificial intelligence
CBT: cognitive behavioral therapy
PANAS: Positive and Negative Affect Schedule
PTSD: posttraumatic stress disorder
PTV: pretraumatic vaccination
VR: virtual reality

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Original Paper

Web-Based Acceptance and Commitment Therapy Tobacco Cessation Program for Veterans With Mental Health Disorders: Adaptation and Usability Testing

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Abstract

Background: US veterans with mental health disorders have high rates of smoking and low rates of smoking cessation.

Objective: This study aims to focus on an adaptation of a web-based acceptance and commitment therapy (ACT) tobacco cessation intervention (Vet WebQuit) for veterans with mental health disorders who use tobacco and used a qualitative approach to test its usability (n=16).

Methods: Participants were asked to walk through the site during laboratory-based usability testing and "think aloud" about the features of the intervention. A trained facilitator used semistructured interview questions to assess participants' experiences with Vet WebQuit and obtain feedback on their impressions of the site. Qualitative analyses identified themes regarding participants' experiences with the intervention, usability concerns, and recommendations for improving Vet WebQuit.

Results: Overall, veterans found that the Vet WebQuit layout was simple and easy to navigate and use. Veterans reported that several features of the program were useful, including the quit plan, identification of triggers, content that targets mental health concerns (eg, dealing with anger), information on the health effects of smoking, tools for managing triggers (eg, urge surfing), and involving others in their quit plan. Veterans reported that particular features of the ACT approach for tobacco cessation were appealing to them, including the distinction between internal and external smoking triggers, the inclusion of the serenity prayer, and mindfulness exercises, which they could use as a tool reduce the intensity of cravings. Veterans reported wanting more information on the health aspects of smoking (ie, effects on breathing and lung capacity) as a way to motivate them to quit smoking. In addition, they suggested targeting specific mental health concerns that serve as triggers for smoking, including nightmares, boredom, and social isolation.

Conclusions: Overall, results from this project identified important elements of ACT digital tobacco cessation interventions for veterans with mental health disorders.

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KEYWORDS

tobacco cessation; smoking; veterans; mental health disorders; acceptance; mindfulness; acceptance and commitment therapy

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Introduction

Smoking is significantly more common among veterans relative to nonveterans [1], and veterans with co-occurring mental health diagnoses carry an even heavier burden, with high rates of smoking (32%-68% vs 15% in the general population) and low lifetime quit rates (17-33% vs 43% in the general population) [2-4]. Individuals with mental health disorders have less successful quit attempts [5-7], increasing the chances of experiencing serious medical consequences, including myocardial infarctions, stroke, and cancer [8] and an average of 25 years of potential life lost [9]. Challenges with quitting smoking are often directly related to mental health symptoms [6,7,10,11]. People with tobacco use and co-occurring mental health disorders frequently report smoking to manage their psychiatric symptoms [12-14]. This is a critical challenge, as smoking does reduce anxiety and improve mood in the short-term [15], but with deleterious long-term effects on mental health [16,17] and worse outcomes of treatment for co-occurring conditions [18,19]. Further, mental health symptom severity predicts heavier smoking for veterans with common co-occurring conditions, including posttraumatic stress disorder (PTSD) [20]. Despite the role of psychiatric symptoms as a key barrier to quitting [10,11], they are not a major focus of most current treatments.

Standard tobacco cessation treatments typically use a cognitive-behavioral therapy (CBT) approach [21], which teaches people to avoid tobacco triggers, change routines, and alter thoughts about smoking. These treatments often do not focus on the mental health concerns that make it difficult for veterans with mental health disorders to quit, and existing population-level tobacco treatments (eg, the Veterans Healthcare Administration [VHA] National Quitline) for veterans are provided by cessation counselors for whom mental health symptoms are outside their scope of competence. The most widely studied tobacco cessation treatment for veterans with mental health disorders showed that integrating standard tobacco cessation techniques into PTSD treatment modestly improved cessation outcomes compared to traditional treatment (14% vs 8% at 3 months) [22]. Another trial of concurrent PTSD and standard tobacco treatment found that participants significantly decreased their cigarette use during treatment, but had not quit smoking [23].

Acceptance and commitment therapy (ACT) for smoking cessation is an evidence-based approach with great potential to help veterans with co-occurring mental health disorders. ACT fosters psychological flexibility (ie, the ability to act in the service of personally meaningful values while remaining open to internal experiences [eg, thoughts, feelings, and sensations]). ACT does this by targeting 6 interrelated psychological processes: acceptance, cognitive defusion (ie, learning to see thoughts as passing mental events), present-moment awareness, self-as-context (ie, cultivating a perspective of self as the observer of experiences rather than being defined by them), values clarification, and committed action [24]. ACT uses mindfulness (ie, focus on the present moment with a nonjudgmental attitude) to help individuals accept aversive internal experiences (eg, smoking cravings and nicotine withdrawal symptoms), rather than trying to control or change them. Empirical support for ACT for smoking cessation comes from several randomized controlled trials demonstrating the efficacy of ACT versus pharmacotherapy and CBT-based treatments [25,26].

There is increasing interest in adapting these interventions for people who smoke and have co-occurring psychiatric disorders due to ACT's demonstrated efficacy for both smoking [26-31] and mental health disorders [24,32-37]. A targeted ACT approach offers advantages over traditional tobacco treatment, which typically uses a CBT approach [21]. One major issue with a CBT approach to tobacco cessation is that avoiding triggers may not be possible, particularly "internal" triggers, which include affective, physical (eg, pain), and cognitive triggers for smoking. In addition, these treatments often do not focus on the mental health obstacles to quitting. In contrast, ACT tobacco cessation treatment helps individuals pursue what is important to them (ie, quitting smoking) by increasing willingness to experience affective, physical, and cognitive triggers for smoking (eg, mental health symptoms).

A novel, web-based delivery method increases the availability of needed tobacco treatment and addresses key barriers to smoking cessation care for veterans. First, lack of clinician training in tobacco treatment is a major barrier to the accessibility of treatment in mental health care settings [38-40]. Self-guided, web-based interventions provide a referral option that requires no knowledge of tobacco treatment. Second, veterans report limited appointment hours and long waitlists as key barriers to tobacco cessation treatments [41], both of which are addressed by the accessibility and flexibility of web-based interventions. Additional benefits include the cost-effectiveness and ease of disseminating web-based interventions [42]. Finally, web-based treatments have high potential reach, as 76-80% of veterans use the internet at home or on mobile devices [43,44] (somewhat lower for rural veterans at 53% [45]), including 70% of veterans with serious mental illness (SMI) [38], and 56-76% of veterans are interested in using VHA health-related programs [43,44].

There is good evidence to support a web-based ACT intervention for smoking cessation, WebQuit, with a nonveteran population [39,40]. In this first study, participants were randomized to either the ACT intervention (WebQuit; n=111) or the National Cancer Institute's Smokefree.gov web page, the current standard for web-based smoking cessation interventions (n=111). WebQuit [40] was more efficacious than the standard web-based smoking cessation intervention for people who smoke in the general population (23% vs 10% at 3 months). A subsequent larger randomized controlled trial also showed that WebQuit was as effective as CBT (24% vs 26%) [39], and WebQuit was highly acceptable to people who smoke with clinically significant symptoms of PTSD [46].

Building on this promising evidence, we developed Vet WebQuit, a targeted intervention that has strong potential to improve the efficacy and accessibility of tobacco treatment for veterans with mental health disorders. As part of the development process, our team conducted work to examine the usability of this adaptation, or the extent to which a website can

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be easily navigated and understood by users. Usability is a critical outcome of a web-based program development process, as low usability can undermine engagement with the intervention [47] as well as its potential efficacy for smoking cessation [48]. While the original version of WebQuit underwent usability testing as part of its development, additional testing was needed to examine the veteran-specific elements of the Vet WebQuit program. This was particularly crucial given our focus on co-occurring mental health conditions, as there is evidence of wide-ranging usability problems in existing smoking cessation websites for individuals with SMI [49]. Further, some mental health disorders (eg, psychotic disorders and PTSD) are associated with neurocognitive impairments, including executive functioning, attention, and verbal memory and learning [50-52], all of which could influence usability. This study evaluated interview data from veterans about the usability of the Vet WebQuit website, focused on key usability areas [53] to identify the most and least favored aspects of the site, review usability challenges, gather feedback on ideas for improving the site's usability, and understand overall satisfaction with the site.

Methods

Recruitment

Inclusion criteria were (1) current *DSM-5* (*Diagnostic and Statistical Manual of Mental Disorders* [Fifth Edition]) mental health disorder, (2) regular smoking for at least 3 years, (3) currently smoking at least 5 cigarettes per day, (4) competent to provide written informed consent, (5) at least weekly access to a high-speed internet connection, (6) willing and able to read in English, and (7) age 18 years and older. Exclusion criteria included (1) current or recent (within 1 month of study entry) moderate or severe *DSM-5* alcohol or drug use disorder, (2) cognitive impairment that would interfere with participation, (3) suicidal behavior or severe suicidal ideation within the past 3 months, and (4) a psychiatric hospitalization within the past month.

Participants were first prescreened by phone, then invited to attend a more comprehensive virtual screening. At the beginning of the screening, participants were provided with detailed information about the study, and informed consent was obtained. Following informed consent, participants completed study assessments, including the *Structured Clinical Interview for DSM-5 Research Version (SCID-5-RV)* [54], a semistructured interview guide for making mental health diagnoses, and the Smoking History Questionnaire [55], which is a measure of smoking history and patterns. Participants who remained eligible following the virtual screening were enrolled in the usability testing procedure. No participants were ruled out based on virtual screening (n=20), 4 were lost to follow-up after screening, before completing usability testing, for a total sample of 16. Participant numbers in the Results section will range from 1 to 20 based on the number of participants who were originally consented. We chose to interview 16 veterans since the average number of participants needed to reach saturation for usability testing is 10 (SD 2) [56], and we added 4 more interviews beyond the upper limit of the recommendation to ensure saturation. All eligible participants were provided with smoking cessation resources after the usability testing procedure.

Vet WebQuit Program

The Vet WebQuit program is a veteran-focused adaptation of the evidence-based WebQuit program. The goals of the intervention are to (1) develop acceptance-related skills for dealing with internal smoking cues while (2) enhancing commitment to quit smoking and making improvements in life functioning [31]. Participants are encouraged to make behavioral choices guided by valued life goals, rather than modifying or alleviating certain sensations, emotions, and thoughts. To this end, the intervention focuses on ACT's core interdependent processes: acceptance and commitment. In ACT for smoking cessation, acceptance refers to allowing oneself to have, without defense, the sensations, emotions, and thoughts that cue smoking [27,29-31]. The process of commitment in ACT means committing to taking actions to quit smoking, even in the presence of smoking cues.

The original WebQuit program has 4 parts. Part 1, make a plan, allows users to develop a personalized quit plan, consider smoking triggers, learn about cessation medications, and upload a photo of what inspires them to quit (ACT processes: values and committed action). Part 2, be aware, contains ACT exercises to illustrate the problems with trying to control thoughts, feelings, and physical sensations rather than allowing them to come and go (ACT process: acceptance). Part 3, Be Willing, contains a series of ACT exercises designed to help the user practice by allowing uncomfortable thoughts, feelings, and physical sensations to be present, without trying to change them by smoking or using some other means of control (ACT processes: acceptance, being present, and cognitive defusion). Part 4, Be Inspired, contains ACT exercises to connect deeply held values to the user's motivation for quitting and to exercise self-compassion in response to difficult experiences, including smoking lapses (ACT processes: values and self-as-context). The program also prompts users to track smoking, use of cessation medications, and practice of ACT skills. To increase interactivity and personalization, tracking results are displayed graphically as progress reports on the home screen, along with the user's inspiration for quitting and badges earned for program use.

Vet WebQuit is built on the content of the original WebQuit program by incorporating ACT exercises that specifically address challenges to quitting for veterans with mental health disorders. This includes specific content on managing common co-occurring emotional challenges for veterans (ie, anxiety, anger, trauma, and substance use) as triggers for tobacco use. Veterans are encouraged to identify their values and activities that they can accomplish to help them quit smoking, improve their management of psychiatric symptoms, and increase their quality of life. The new content (Table 1) also specifically addresses the culture among veterans that encourages smoking and asks veterans to choose to quit based on their values and not on social pressure to smoke (eg, mentioning that smoking often started in the military, that it was social and common, and often used as a reward). Veterans Affairs (VA) tobacco cessation resources are embedded in the adapted program (eg, VA tobacco

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cessation information, links to online VA resources and programs). Veteran-specific quit stories based on real veterans were included with a focus on co-occurring substance use, PTSD, and anxiety to help veterans with mental health disorders feel inspired by other veterans in their journey to stop smoking.

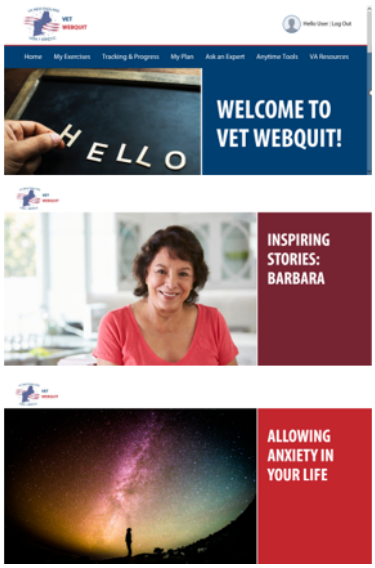
Table 1. Vet WebQuit content tailored for veterans with mental health disorders.

Purpose	Description
New Content for Vet WebQuit	
Increase motivation to make life changes	Values clarification exercise to motivate veterans to quit smoking and identify other life goals (eg, social and community involvement) that are connected to values.
Identify new coping skills to improve functioning	More committed action exercises to help veterans identify activities to improve mood, replace smoking, and improve quality of life.
Reduce anxiety over making life changes	More exercises focused on increasing willingness to experience uncomfortable thoughts and feelings about quitting and making life changes for the sake of living one's values.
Specific Content for Veterans with Mental Health Disorders	
Veteran-specific content	Imagery and exercises are tailored to veterans (eg, veteran-specific images, stories, and exercises), and address the veteran culture of smoking.
Embed VA[a] resources	VA tobacco cessation resources are embedded (eg, VA tobacco cessation information, links to online VA resources and programs).
Target mental health symptoms as triggers	Specific content on how to manage common co-occurring symptoms for veterans who smoke (eg, anxiety and anger) as triggers for tobacco use.

[a]VA: Veterans Affairs.

Images for the program (Figure 1) were chosen by veterans based on how close they felt the image represented a particular ACT concept (eg, a person with open arms representing acceptance). In development work leading up to the creation of the Vet WebQuit program, veterans indicated that they did not prefer military-specific images (eg, helicopters and jets), but did like images of nature and the American flag. These images were embedded in the Vet WebQuit program, and the VA-approved color scheme was used throughout the program.

Figure 1. Vet WebQuit images.



Usability Testing Procedures

Eligible veterans participated virtually over VA-approved video conferencing software. Each recorded usability testing session took about 1.5-2 hours to complete. A trained facilitator used semistructured interview questions to assess participants' experiences with Vet WebQuit and obtained feedback on impressions of the site. Participants were asked to interact with the Vet WebQuit program and complete 4 tasks: setting up a quit plan, tracking progress, viewing progress, and completing an ACT exercise. At the beginning of the usability testing session, a trained facilitator provided the following instructions:

> *In a few minutes I'm going to show you the Vet WebQuit website. I'm going to ask you to try things out. As you're trying them out, think aloud—whatever comes to mind as you're seeing the program for the first time.*

Facilitators indicated that they wanted participants' honest opinions about what they experienced. The facilitator guided

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participants through the usability testing procedure but did not intervene or disrupt the thinking-aloud process. The facilitator provided instructions on how to navigate to each task (ie, since tasks were spread throughout the program), but the participant was asked to navigate to the task themselves and complete it on their own.

We asked participants if they had challenges with using the site, their most and least favorite aspects of the intervention, and any recommendations they had for improving the site. We assessed Vet WebQuit's usability along the following dimensions that are recommended for usability testing by the US government [57]: (1) intuitive design: understanding the setup and navigation of the site; (2) ease of learning: how fast a user can learn to accomplish basic tasks on the site; (3) efficiency of use: how fast a user can accomplish basic tasks for the site; (4) memorability: the ability of the user to remember the site in order to effectively use in in future visits; (5) error frequency and severity: how often users make errors when using the site, the severity of the errors, and how users recover from the errors; and (6) satisfaction: the users' feelings and opinions about the website. Two additional dimensions were assessed: (7) usefulness and (8) visual appeal. These usability testing procedures are consistent with best practices and procedures used for other popular tobacco cessation websites (eg, Smokefree.gov) [53].

Data Analysis

The audio recordings from the usability sessions were transcribed. Selective coding [58] was used to identify participant comments on chosen areas of usability: intuitive design, ease of learning, efficiency of use, memorability, error frequency and severity, satisfaction, usefulness, and visual appeal. Selective coding involves identifying central categories and other categories that are systematically linked to it, producing a coherent explanation of the phenomenon under study. Structured codes were developed to guide the selective coding process. These codes were iteratively refined through team discussions and consensus coding, ensuring consistent application of codes across the dataset. Two members of the research team (MK and AD) reviewed the transcripts. An iterative process was used to map interview comments onto each usability area. Discrepancies between reviewers were resolved through discussion. Notes were used to clarify any potentially confusing content from transcripts. In addition, notes made about participants' performance during usability testing, including types of errors made and requests for help, were used to identify usability issues.

Ethical Considerations

Ethical approval for this study (#1598749) was obtained from the Institutional Review Board of the VA Bedford Healthcare System, Bedford, Massachusetts. Participants were US veterans recruited from the Tobacco Cessation Program and from flyers at the VA Bedford Healthcare System in Bedford, Massachusetts. There was a complete discussion of the study with potential participants, and all participants provided written informed consent to participate in the study. Veterans were informed that refusal to participate will be accepted without hesitation at any time and would not change their eligibility for VA services, treatment, disability payments, or other related VA benefits. To protect participants' confidentiality, identifiable information collected as part of the study screening and enrollment procedures was stored in a VA shared drive that was not accessible to anyone outside the research team, and each participant was assigned a code that linked all of their data. The participants were compensated up to US $100 to complete all study assessments and usability testing. Compensation was not linked to the completion of study activities.

Results

Sample Description

Veterans were aged an average of 52.4 (SD 12.3) years. They reported smoking for 28.7 (SD 13.4) years on average, with smoking an average of 11.1 (SD 4.5) cigarettes per day. Additional demographic information is provided below (Table 2).

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Table 2. Demographic characteristics of study participants (N=16).

Sample characteristics	Values, n (%)
Gender, n (%)	
Men	10 (62.5)
Women	6 (37.5)
Race, n (%)	
White	12 (75)
Black	4 (25)
Asian	0 (0)
Native Hawaiian or Pacific Islander	0 (0)
American Indian or Alaska Native	0 (0)
Ethnicity, n (%)	
Non-Hispanic or Latino	16 (100)
Hispanic or Latino	0 (0)
Mental health diagnoses[a], n (%)	
Depressive disorders	14 (87.5)
PTSD[b]	13 (81.3)
Anxiety disorders	7 (43.8)
Bipolar disorder	1 (6.3)
Schizophrenia and other psychotic spectrum disorders	1 (6.3)

[a]Categories not mutually exclusive and may not equal 100%.

[b]PTSD: posttraumatic stress disorder.

Qualitative Feedback: Usability Areas

Intuitive Design

Most participants indicated that the Vet WebQuit layout was easy to navigate and use (n=15, 94%). They stated that they liked the structure, which was self-explanatory and user-friendly. Participants reported liking how the program explained material and that they could find what they needed. Participants indicated that they liked the step structure of the program and the ability to access the anytime tools at the top of the program.

> *Takes you through the steps, step at a time -- finds things to motivate you, get support, place to go.* [Participant 1]

> *It was very easy. When I first saw the page and read across, liked how 'my exercises' was next to 'home.'* [Participant 13]

Some participants also highlighted a few features that were less intuitive. One veteran indicated that he did not like how the program initially did not include lines or another color to distinguish hyperlinks, so he did not realize that there was additional material that could be helpful to him. Similarly, it was noted by one veteran that audio mindfulness exercises should be highlighted to allow users to understand that they should be clicked on to be used and to provide information on how long these exercises are before they start them.

> *Make links red. They are important and are getting swallowed by the black. Wanted to click on them but didn't realize they were hyperlinks.* [Participant 10]

> *Point to the audio exercise! Decorate the audio exercise. Give people a heads up that it is six minutes.* [Participant 16]

Two veterans also indicated that they preferred more exercises with less information and less scrolling, so that the material was not overwhelming.

> *Is there any way to condense all that information? Right now, no mechanism for it. It's informative. People will scroll up and down and take what they need. They can always come back to it.* [Participant 10]

> *Some pages are colorful and attention-grabbing but need not a huge scroll down of words. Finish reading one section and click next.* [Participant 20]

Ease of Learning

Two veterans indicated that they were not as tech-savvy, particularly as older veterans, and that working with a web-based program made it more difficult for them.

> *I'm not a computer guy. People who like computers would learn more. I just don't like computers.* [Participant 7]

> *A lot of older people won't be able to run this website. I can see some older friends say, "F this" and get out*

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> *of the website completely. For the younger generation, it's pretty easy.* [Participant 10]

However, Participant 10 indicated that even though he was not as tech-savvy, the program was easy to learn.

> *Once you figure it out, it's pretty easy.* [Participant 10]

One veteran reported feeling unsure of what the next steps were for the program, which interfered with their ability to learn more about how the program worked.

> *I am a little confused by the 1-3 days for each step. I need to keep moving to figure out how it works.* [Participant 20]

Efficiency of Use

Two veterans indicated that they could move through tasks quickly, highlighting the quick login and fast-paced nature of the program.

> *Short login.* [Participant 1]
>
> *I didn't have anything in if I didn't want to. It was click to play. There wasn't too much stuff. Not a huge commitment.* [Participant 8]

However, Participant 8 also indicated that he did not want any login to make the program even quicker.

> *I need something that doesn't involve logging in. I need something quick and easy that I can hit in the moment. If I have to invest a lot of time, I won't do it.* [Participant 8]

These 2 veterans indicated that they also liked how concise the information was in the program.

> *The quit plan – it was simple. The questions weren't repetitive, they were to the point.* [Participant 1]
>
> *Nice to have short sections and click to play.* [Participant 8]

Memorability

Three veterans indicated that the program captured their attention so that they would remember to use it effectively in future visits.

> *The program piques my curiosity and learning. I want to read on.* [Participant 3]
>
> *The way it is formatted – it keeps my attention. It makes me want to learn more. It keeps me wanting to learn.* [Participant 4]

Error Frequency and Severity

Two veterans (Participants 1 and 13) encountered server errors when they were going through the program, including one time after finishing the quit plan and one time after a veteran clicked on a response. In both instances, veterans were able to move through the program.

Two veterans (Participants 9 and 19) had difficulty logging into the program. One instance was because of mistyping the domain name, and another instance included difficulties getting the program web page up. In both instances, the veterans were still able to able to login in and progress through the remaining areas of the program.

Overall Satisfaction

All veterans (n=16, 100%) reported finding the information in the program to be helpful.

> *A lot of things in the website give me hope. This is a different website than anything I have seen before. Not just about urges, but letting them go is so different.* [Participant 13]

Veterans were particularly satisfied with certain content in the program, including internal vs external triggers, the serenity prayer, and mindfulness.

> *I think it's good. It is steering people to do more inside work. That's a good thing.* [Participant 4]
>
> *The serenity prayer is more for alcoholics, but smoking – I like it.* [Participant 17]
>
> *I like the serenity prayer. It's filled with wisdom.* [Participant 20]
>
> *It's perfect. Reading this is an hour's worth of therapy. It took me 2 minutes to read it. Put me in a mindful spot.* [Participant 17]

Overall, all veterans (n=16, 100%) reported that they liked the program and that they planned to use it.

> *One of the most motivating websites for quitting smoking. I want to get into it. I will definitely use this.* [Participant 4]
>
> *I like it just the way it is, especially the reasons to quit and the good stuff. Secondhand smoke too – how it affects my family. Being African American, it affects us even more.* [Participant 11]

Usefulness

Most veterans (n=14, 88%) indicated that the program was useful to them as a tool to quit smoking.

> *I don't have to make an appointment to see a doctor. This is right at my fingertips. It's great for introverts or people who don't like people.* [Participant 10]
>
> *At one point during the survey, I was thinking about having a cigarette. I came from outside to get it accomplished. The craving subsided. Reading all the material, I got caught up. So, it changed my thought process.* [Participant 12]
>
> *I like interacting with the Vet WebQuit plan and part of the study. I've had some impulses to smoke, so this can help to stay quit.* [Participant 13]
>
> *I would use it anytime. I would come back because it's informative and everything is at your fingertips.* [Participant 20]

Veterans reported that several features of the program were useful. Specific examples of features that were mentioned as helpful included the quit plan, identifying triggers, dealing with anger, preventing relapse, mindfulness, urge surfing, involving others in their quit plan, anytime tools, and information on the physical and health effects of smoking were very helpful to

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them. Veterans also indicated that they liked having other resources embedded in the program.

Visual Appeal

Most veterans (n=14, 88%) reported liking the overall layout.

> *Simple. Not complicated and not busy.* [Participant 1]
>
> *I like that it is lowkey and not jumping at me too much. It is really focused on tracking and progress. Nice scenery, friendly, organized, but laidback.* [Participant 6]

Veterans had mixed reactions about the font and spacing included in the program. Two veterans reported difficulties with these elements when viewed on a mobile phone.

> *I think to begin with, that font can be a tiny bit bigger. Shorten the space at the top if you can. A lot of people will have trouble. I tried in horizontal and didn't like it.* [Participant 10]
>
> *Some was fine print and italic that was small on the phone screen.* [Participant 17]

Three veterans reported that the font size was fine.

> *Spaced well. Good sized text.* [Participant 1]
>
> *I like that the writing is big.* [Participant 6]
>
> *Fonts are fine.* [Participant 20]

Several veterans (n=6, 38%) specifically reported that they liked the colors of the program, which were based in the VA style guide.

> *Color is important. Looking at positivity, colors are lowkey, pretty, subdued.* [Participant 6]
>
> *I like the colors, pictures, layout, everything. I want to congratulate the team that put this together.* [Participant 11]

However, 2 veterans didn't like the darker images that were included.

> *Pictures that are darker ones are ominous. Stay clear of doom and gloom.* [Participant 1]
>
> *I don't like the picture of water – it looks like everything is gray, so it doesn't standout.* [Participant 9]

Most veterans (n=12, 75%) also reported liking the pictures that were selected, including the inspirational, friendly, and relaxing characteristics of the images.

> *Friendly pictures.* [Participant 6]
>
> *Did a good job. Each picture goes with each resource.* [Participant 7]
>
> *The pictures were vibrant.* [Participant 9]

Several veterans (n=7, 44%) specifically reported that they felt like the program was veteran-centric.

> *Photos are awesome. Vet forward. Red, white, and blue.* [Participant 3]
>
> *Veteran-sensitive. A lot of veterans would benefit from it, especially those with PTSD. Looks good.* [Participant 4]
>
> *I think it is very veteran-centric. You don't really see people in uniform. That doesn't matter.* [Participant 8]

Participant Recommendations

Veterans mentioned specific recommendations for the program, including wanting more information on the health aspects of smoking as a way to motivate them to quit smoking. Specifically, they were concerned about their breathing and lung capacity, and how that was affected by smoking. Similarly, veterans were interested in more facts about the effects of smoking (eg, nicotine) and were interested in including them in the program. In addition, they suggested mentioning specific mental health concerns that could be targeted in the program since they served as triggers for smoking, including nightmares, boredom, and social isolation.

Discussion

Principal Results

Usability testing is an important process in digital intervention development, since it can assess how well users can perform needed tasks in the intervention. In this study, we interviewed participants to understand their reactions to the Vet WebQuit intervention, how well they could navigate and use the web-based program, and their satisfaction with the content and design. Overall, veterans found the Vet WebQuit layout was simple and easy to navigate and use. This feedback is consistent with other digital intervention research for veterans with mental health disorders that indicates that they prefer simple and straightforward digital intervention designs [59]. Furthermore, individuals with SMI have also reported that if digital interventions are not simple to use, they experience increased stress [60], reinforcing the need to ensure that digital smoking cessation interventions have simple layouts that are easy to navigate. Supporting this, veterans liked having both the content of the program clearly broken down into steps that they could progress through, as well as content that they could easily access at any time (ie, anytime tools). They preferred features in the program that could help them to navigate (eg, audio buttons and clearly distinguished hyperlinks). They also preferred having succinct content that they could easily understand and digest.

Since most veterans who smoke and use VA tobacco cessation services are older [61], and this is reflected in our sample, we received several comments on concerns about computer literacy among older veterans and being able to use the program. However, most veterans who used the program found that they were easily able to use the program and learn how to use the features. This supports previous research on WebQuit showing that older adults in the general population were more engaged with the program and quit smoking at the same rate as middle-aged and younger adults [62], which is contrary to the popular myth that older adults have difficulty with technology [63]. If veterans encountered errors, they mostly found them in logging in to the program, highlighting the need to make the

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program as easy to access as possible. However, they did prefer knowing what the next steps for the program were going to be, so having that clearly laid out for them ahead of time was a preferred feature.

The present sample of veterans also reported liking having an easily accessible program that they could use at any time of the day, since they could easily log in to read over information and get help for cravings as they occurred in their day-to-day life. Since few veterans with mental health disorders engage in tobacco cessation counseling in a given year [6%, [61]], having an accessible tobacco cessation program is important to increase the chances that veterans with mental health disorders will engage in care. Furthermore, veterans with mental health disorders often face other challenges to accessing health care services (eg, transportation, remembering appointments, and responding to personal crises) [64]. In addition, often services for tobacco cessation will be offered weekly or less, and having a web-based tobacco cessation program at their "fingertips" was a widely reported positive aspect of the self-management–focused Vet WebQuit program. However, although the Vet WebQuit program is designed as a self-management digital intervention program, veterans indicated that they also liked having information on other resources that they could use for more support, such as information on counseling programs. This supports our other study on digital interventions for tobacco cessation for veterans, where veterans reported wanting to have a digital self-management program, but with someone they could also talk to for additional support [65]. Having clinician support can also boost the low rates of use of digital interventions for veterans [59]. Future work on self-management tobacco cessation programs for veterans would benefit from evaluating the use and acceptability of clinician-supported digital interventions and the best models for implementing this type of care in VA health care settings.

This sample of veterans reported that several features of the program were useful, including the quit plan, identification of triggers, content that targets mental health concerns (eg, dealing with anger), information on the health effects of smoking, tools for managing triggers (eg, mindfulness and urge surfing), and involving others in their quit plan. More information is needed, using a broader sample of veterans with mental health disorders, on the usefulness of these and other features of Vet WebQuit.

These veterans also reported that particular features of the ACT approach for tobacco cessation were appealing to them. They reported liking the distinction in the program between internal and external triggers. Consistent with this, they mentioned liking the inclusion of the serenity prayer, which helps users to understand how to manage internal triggers ("grant me the serenity to accept the things I cannot change") and external triggers ("courage to change the things I can") and the importance of distinguishing between these 2 types of triggers ("and the wisdom to know the difference"). They also reported especially liking the mindfulness exercises, which they could use as a tool to help them manage their cravings by not pushing the craving away but acknowledging it, and then putting their attention to something else, thereby reducing the intensity of the craving. This finding is consistent with other literature that shows that users of digital smoking cessation interventions prefer having information in these interventions on how to cope with negative emotions like anxiety [66]. However, these needs are even more heightened for veterans with mental health disorders since they are coping with more frequent and intense emotions that trigger smoking [6]. Therefore, having increased and detailed ACT-focused content on how to manage emotions such as anger and anxiety using acceptance and mindfulness, and making the distinction between internal triggers and external triggers, provides important guidance that veterans with mental health disorders find particularly useful. Overall, ACT digital interventions for smoking cessation show high satisfaction, user engagement, and efficacy for people with mental disorders [67].

Finally, participants recommended including more information on the health aspects of smoking. This recommendation is in line with more general feedback from users of smoking cessation digital interventions, with users indicating that they want to have information on what they could gain and lose through smoking cessation [68].

Limitations

This study had several strengths and limitations. A strength of this study was the qualitative approach, with a more intensive "think-aloud" procedure that had veterans work with the program and provide feedback in the moment as they used it. Using qualitative data to understand how to make digital health interventions more acceptable to the user is a core process in the development of these programs.

The limitations of this study include the small sample of 16 veterans from one medical center. There may be varying feedback depending on the geographical location, digital literacy, and demographic characteristics of veterans (eg, rurality, race, and ethnicity). For instance, obtaining feedback from more rural users may be helpful to determine if the acceptability is the same for people who are not as close to VA health care locations and have fewer resources in the community. Therefore, the conclusions of this particular study should be tempered. In addition, this study did not focus on evaluating the effectiveness of the intervention, only on usability and acceptability. Future research is needed to understand the effectiveness of the Vet WebQuit intervention for veterans with mental health disorders.

Conclusions

Overall, veterans with mental health disorders are in need of accessible and engaging digital tobacco cessation interventions. Veterans with mental health disorders found that the Vet WebQuit program was easy to navigate and use, and liked particular features, such as the quit plan, identification of triggers, targeted mental health content, information on the health effects of smoking, and ACT-focused skills and strategies for managing smoking triggers (eg, internal vs external triggers and mindfulness exercises). Overall, this study demonstrated that Vet WebQuit was acceptable to veterans and they found it useful. Future research should focus on the effectiveness of this program for veterans with mental health disorders. However, given the positive responses to the Vet WebQuit program, our study demonstrates that this program may fill an important gap

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in accessible smoking cessation services targeted at mental health obstacles to quitting smoking.

Data Availability

The datasets generated and analyzed during this study are not publicly available due to the security requirements of the Department of Veterans Affairs, but are available from the corresponding author on reasonable request. The authors will consider reasonable requests on a case-by-case basis, subject to compliance with the Department of Veterans Affairs data sharing agreements.

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Authors' Contributions

MK, JB, JH, and KQ contributed to study conception and design. Vet WebQuit program intervention content was created by MK, JB, JH, KQ, ER, and BAP. Data analyses were performed by MK and AD. The first draft of the article was written by MK and VA, and all authors contributed to subsequent versions of the article. All authors have read and approved the final article.

Conflicts of Interest

MK receives royalties from New Harbinger Publications for a book on Acceptance and Commitment Therapy for cravings and addictions.

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Abbreviations

ACT: acceptance and commitment therapy
CBT: cognitive behavioral therapy
DSM-5: Diagnostic and Statistical Manual of Mental Disorders (Fifth Edition)
PTSD: posttraumatic stress disorder
SCID-5-RV: Structured Clinical Interview for DSM-5 Research Version
SMI: serious mental illness
VA: Veterans Affairs
VHA: Veterans Healthcare Administration

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Original Paper

Draw-Care, a Co-Designed Multilingual Digital Intervention for Family Carers of People Living With Dementia From Ethnically Diverse Communities: User-Testing Study

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Abstract

Background: Technology can deliver culturally and linguistically appropriate resources to support ethnically diverse family carers (hereafter referred to as carers) of people living with dementia. However, carers' involvement in research on the development and evaluation of such digital health interventions is limited.

Objective: This study aims to user-test the co-designed Draw-Care multilingual, web-based dementia resource with and for carers.

Methods: We evaluated the web-based resource through observation sessions to collect carer feedback, using a mixed methods approach. This comprised the online, validated eHealth Literacy Scale and survey questions assessing the perceived usefulness and importance of the internet for health-related decision-making and access to health resources. In addition, "think-aloud" website navigation sessions were conducted, and Hotjar analytics were used to capture participants' behavior on the website. Quantitative and analytics data were analyzed descriptively, and qualitative data were analyzed using instant data analysis, followed by thematic analysis.

Results: Between March and April 2023, a total of 30 carers participated in the user-testing sessions (women, n=20, 67%; mean age 61, SD 13.5 years). The mean eHealth Literacy Scale score was 30 (SD 6.1). Overall, 18 (60%) participants perceived the internet as useful, and laptops and tablets were the most commonly used devices for accessing resources, each used by 9 (30%) participants. Vietnamese (n=5, 17%), Mandarin (n=5, 17%), and English (n=5, 17%) were the top 3 languages the resource was accessed in. A total of 28 (93%) participants could navigate and log in to the website with little to no support. Qualitative results

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showed that overall, the Draw-Care web-based resource was acceptable, culturally responsive, engaging, and usable. However, navigation was more complicated for those using smaller screens (eg, smartphones and tablets). There were linguistic discrepancies arising from translation issues in Vietnamese and Mandarin, and 14 (46%) participants found it difficult to identify and use the chatbot (ie, virtual helper interface). Issues identified with the prototype Draw-Care website and the proposed improvements included eliminating the virtual helper, simplifying the rating scale from a 5-point smiling emoticon scale to a 3-star rating scale, improving the visibility of the feedback button, and ensuring translation accuracy.

Conclusions: To our knowledge, this is the first study to evaluate a bespoke multilingual website delivering a novel, co-designed, and culturally adapted digital intervention in 10 languages for ethnically diverse family carers of people living with dementia. Findings from this user-testing study undertaken with carers uncovered usability issues requiring remediation and emphasized the importance of inclusive, accessible, culturally sensitive, engaging, and beneficial content and design. Key revisions were implemented before the randomized controlled trial commenced.

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KEYWORDS

carer; co-design; dementia; digital intervention; ethnically diverse

Introduction

Ethnically diverse communities experience a disproportionately high and growing burden of dementia [1-3]; however, they continue to face substantial barriers to accessing timely, culturally and linguistically appropriate support [4,5]. Family members of people with dementia from ethnically diverse backgrounds often provide care alone, which adversely affects their health and economic well-being [6]. They report limited awareness of available services, difficulty navigating complex care systems, language barriers, culturally insensitive service models, and a lack of translated or tailored information [5,7-9]. These unmet needs contribute to higher psychological distress, greater social isolation, and reduced care continuity for ethnically diverse carers and people living with dementia [10,11].

Digital technologies can partially address some of these inequities by providing flexible and accessible support that improves carers' psychological health, self-efficacy, caregiving skills, and problem-solving abilities [11]. The World Health Organization's iSupport program is one such digital intervention [12]; although it has been adapted in more than 40 countries, no comparable work has been completed for iSupport Lite (a simplified version of iSupport that includes 6 visual messages to support carers) [13]. Research to include ethnically diverse family carers (hereafter referred to as carers) of people living with dementia in the development and testing of culturally responsive digital media resources remains limited [14,15]. Existing adaptations often require substantial localization to reflect cultural norms, family structures, and beliefs about dementia. In addition, many digital resources for culturally and linguistically diverse carers provide only translated information without meaningful cultural tailoring, which may contribute to low uptake and engagement [16-18]. To advance health equity through technology [19], further research is needed to explore technology's potential to bridge gaps in caregiving provision [15,19,20].

Addressing these gaps, the Draw-Care study culturally adapted the iSupport Lite dementia carer online support messages with carers and service providers and co-designed a multilingual, culturally responsive website [21]. The co-designed prototype intervention comprised 6 short, animated films and tips sheets hosted on the website, along with a virtual helper, delivered in 10 languages: Arabic, Cantonese, Greek, Hindi, Italian, Mandarin, Spanish, Tamil, Vietnamese, and English [17].

Before testing the intervention's clinical and economic effectiveness in a parallel, 12-week waitlist randomized controlled trial (RCT), user testing was undertaken to refine the intervention with ethnically diverse carers to examine its usability and acceptability. This paper reports the findings from the user-testing component. The specific study aims were to assess the website's usability, accessibility, and ease of navigation across the aforementioned 10 languages and to identify any refinements required before RCT implementation to test the intervention. The specific research questions guiding the user testing were as follows: how usable, accessible, and easy to navigate is the website for ethnically diverse carers from the aforementioned linguistic backgrounds? What modifications, if any, are needed to optimize the website for broader implementation and rigorous testing in a future RCT?

Methods

Study Setting and Participants

Before the RCT, the Draw-Care study comprised the co-design and development of the Draw-Care digital intervention, including member checking and user testing of the web-based resource. Between March and April 2023, a total of 65 ethnically diverse carers from our existing networks and previous studies [22], across all 10 language groups, were invited to evaluate the co-designed Draw-Care intervention. Member checking was undertaken with participants from the co-design phase (ie, health care providers and current carers) to ensure that the prototype reflected the feedback gathered during the co-design of the resources. Details of this have been published elsewhere [21].

User-testing sessions with the intended end users were subsequently conducted as part of the co-design, development, and refinement of the intervention before the trial. Unlike the member-checking step, eligibility criteria for participants in the

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user-testing sessions included being a current or former carer of a person living with dementia; aged >18 years; not having participated in the co-design of Draw-Care; having access to the internet and a device (eg, computer, phone, or tablet); and being from an Arabic-, Cantonese-, Greek-, Hindi-, Italian-, Mandarin-, Spanish-, Tamil-, or Vietnamese-speaking background. These 9 languages are among the top 10 non-English languages spoken by people aged >65 years in Australia, and English is the official language of Australia [21]. The sample size for online user-testing sessions was estimated to be between 27 to 45 eligible participants, based on enrolling 3 to 5 carers for each language group (excluding English).

Ethical Considerations

The Draw-Care study was approved by the Human Research Ethics Committee of Curtin University, Australia (HRE2022-0004) and the National Ageing Research Institute Research Governance Office. The trial was prospectively registered on the Australian New Zealand Clinical Trials Registry (trial registration numbers ACTRN12622000382774 and ACTRN12622000358741). All participants provided written informed consent and received a US $30 gift card for their time. Participants were able to opt out of the study prior to their data being de-identified, aggregated, and analysed.

Procedure

Using REDCap (Research Electronic Data Capture) [23], all participants completed a sociodemographic questionnaire. The questionnaire included a question to self-report their English proficiency level with the following response options: none or no proficiency, basic or simple proficiency, conversational proficiency (ie, can carry a conversation but is not fluent), professional or high-level proficiency (but not at the level of a native speaker), and native speaker (highest level of fluency and proficiency).

Participants also completed the 8-item eHealth Literacy Scale (eHEALS) [24] and questions on the perceived usefulness and importance of the internet for health-related decision-making and access to health resources (Multimedia Appendix 1). Although the psychometric properties of the validated eHEALS can vary across populations and translations, there is agreement in scientific literature that it is a reliable and robust measure of perceived eHealth literacy, demonstrating strong internal consistency (measured by Cronbach α with values ranging from 0.84 to 0.97) and significant correlations with related measures that support its validity [25,26]. Designed to measure an individual's confidence in their ability to locate and evaluate online health information, eHEALS has been widely used and tested across diverse populations [27,28].

Subsequently, via an online "think-aloud" interview, the researchers (AT and THD) conducted a user-testing session with each participant. A log-in code was emailed to each participant to access the website. Codes were activated when the session started and remained active after capturing user behavior analytics using embedded Hotjar (Contentsquare) [29]. Each session lasted 20 to 30 minutes. The researchers asked participants to complete sequential, representative website tasks and provide feedback while "thinking-aloud" and screen sharing (Multimedia Appendix 2). Participants were asked to select their preferred language for navigating the site, log in to the website using the code provided, follow the website prompts to the home page titled "Films and More Information," and then commence the sequential tasks with the researcher (Multimedia Appendices 2 and 3). All participants completed each component. Sessions were not recorded; therefore, the researchers took extensive notes.

Analysis

Survey data were analyzed descriptively using SPSS (version 28.0; IBM Corp) [30]. The sample size limited subgroup analyses by language group; therefore, these analyses were not conducted. An eHEALS score was calculated for each participant, and the aggregated mean score was reported. Higher scores (range 8-40) indicate greater self-perceived skills in finding, evaluating, and using electronic information to make decisions about individual health.

Issues, frustrations, and comments made by the participants during the "think-aloud" sessions were recorded by AT or THD in an Excel (Microsoft) spreadsheet and analyzed to identify and rank website usability issues using instant data analysis (IDA) [31]. At the end of each interview, they listed the usability issues observed. The issues were ranked as critical (participant unable to complete the task), severe (significant delay or frustration in completing the task), or cosmetic (minor issues). Each issue was annotated with precise references to the website, alongside supplementary notes detailing the nature of the problem and participants' reactions [31]. This detailed annotation process helped identify when data saturation, (ie, no new usability issues) had occurred.

After all the sessions were completed, the identified usability issues were aggregated into broader themes using a thematic analysis approach [32]. As we assumed that participants' accounts reflected and were mediated through their real-world experiences, a postpositivist thematic analysis was conducted to analyze the entire dataset and identify key themes through a comparative and iterative process [32]. During this stage, AT and THD independently coded the data, met to create consensus, resolved discrepancies, and developed themes. BB checked the final codes and themes and moderated where there were conflicts. Attention was paid to comparing findings across linguistic groups. Thus, the use of multiple coders and consensus-based coding ensured data triangulation and robust interpretation, enhanced thematic and coding reliability, and minimized researcher bias [32]. Combining IDA and thematic analysis generated a consolidated list of usability issues and proposed modifications to overcome them, an approach successfully applied in previous digital health intervention studies [33,34].

Analytics data were aggregated to generate visual heat maps of the overall website, individual pages, and elements of a page that participants did or did not engage with. Screenshots of the website's feedback feature and samples of user feedback and visual heat maps are shown in Figures 1, 2, and 3, respectively.

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Figure 1. Screenshot of the Draw-Care website's "Films and Tips" home page showing the location of the feedback button (top right-hand side) covered by a red heat map.

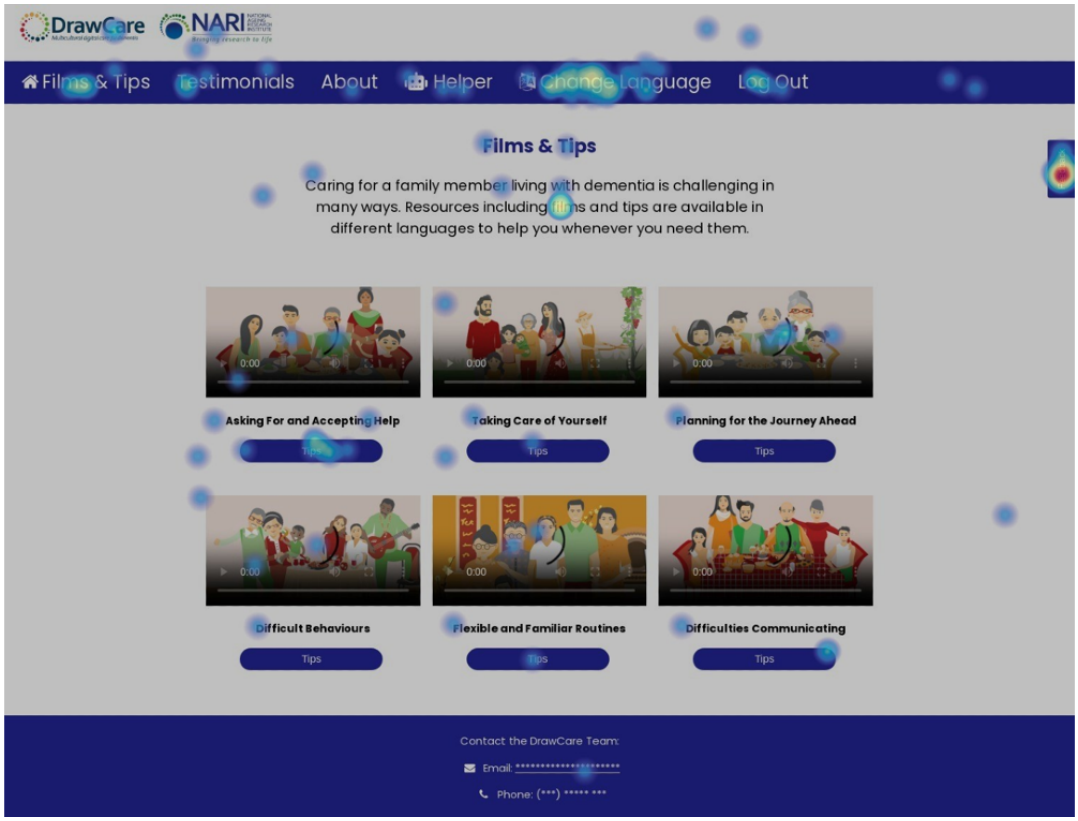

Figure 2. A sample of the feedback and film ratings captured from participants who used the feedback feature and the 5-point emoticon rating scale on the Draw-Care website.

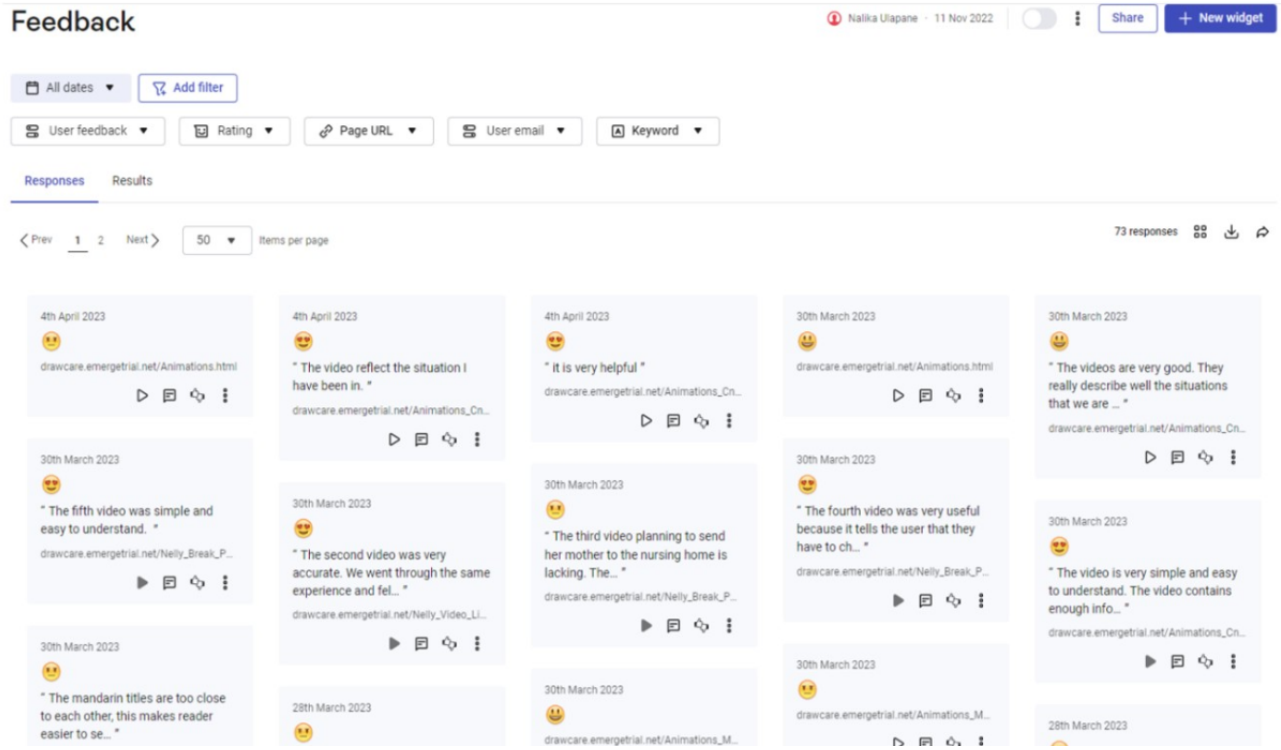

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Figure 3. Screenshot of the Draw-Care website's "Films and Tips" home page with a heat map recording showing user movements by color coding (blue=less activity and red=more activity).

Results

Participant Characteristics

A total of 30 carers participated in the study (with a 46% response rate), comprising mainly women (n=20, 67%). Participants' mean age was 61 (SD 13.5) years, and they were related to the person living with dementia as a daughter (n=15, 50%), wife (n=4, 13%), daughter-in-law (n=3, 10%), son (n=3, 10%), husband (n=2, 6%), or granddaughter (n=1, 3%). Mean duration of caregiving was 7.1 (SD 3.5) years. Most participants were born overseas (n=22, 73%), and the mean duration of residence in Australia was 43 (SD 11.7) years. All participants were either Australian citizens (n=26, 87%) or permanent residents (n=4, 13%). A total of 26 (87%) participants spoke a language other than English at home, including Chinese (n=6, 20%), Vietnamese (n=5, 17%), Hindi (n=5, 17%), Greek (n=5, 17%), Italian (n=3, 10%), Arabic (n=1, 3%) and Spanish (n=1, 3%). Few only spoke English at home (n=2, 7%) and data was missing for 2 (7%) participants (Table 1).

From the IDA and thematic analysis, website issues were inductively analyzed into two themes: (1) acceptability and (2) usability. Table 2 describes how the themes, codes, and IDA findings were grouped. Website issues are detailed and supported by illustrative quotes, labeled with deidentified participant ID number, age (years), gender, and preferred language. Where relevant, descriptive quantitative data are integrated to provide further context.

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Table 1. Sociodemographic characteristics of the participants (N=30).

Characteristics	Participants, n (%)
Marital status	
Married	20 (67)
Single[a]	10 (33)
Living circumstances	
Lives with others	19 (63)
Lives alone	11 (37)
Work status	
Employed	
Full time	6 (20)
Part time	3 (10)
Casual	5 (17)
Retired	14 (47)
Unemployed	2 (7)
Highest education level	
Primary	1 (3)
Secondary	10 (33)
Tertiary	19 (63)
Self-reported English proficiency level[b]	
None	1 (3)
Basic	6 (20)
Conversational	5 (17)
Professional	10 (33)
Native	8 (27)

[a]Single includes the following response options: single, never married, and divorced or separated.

[b]Response options were adapted from the International English Language Testing System categories: none=no proficiency, basic=simple proficiency, conversational=can carry a conversation but not fluent, professional=high level of proficiency but not at native speaker level, and native=highest level of fluency and proficiency.

Table 2. Summary of thematic analysis and instant data analysis (IDA).

Theme and code	Issues identified in IDA
Website acceptability	
Presentation	• First impressions and overall look and feel of the website
Navigation	• Ease of navigation varied depending on the device used
Understanding	• Linguistic discrepancies (human translation)
Website usability	
Interface interaction	• Chatbot interface (technology-related issues)
Satisfaction	• Use of emoticons • Cultural misunderstanding of emoticons
Accessibility	• Monolingual feedback button • Cultural misunderstanding of feedback request

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Website Acceptability

Participants perceived themselves to be relatively adept at finding, evaluating, and using online health information, with the mean eHEALS score being 30 (SD 6.1). Most participants perceived the internet as *useful* (n=18, 60%) or *very useful* (n=6, 20%), and only 6 (20%) were unsure. Most participants rated the internet as *important* (*n*=13, 43.3%) or *very important* (*n*=12, 40%), with 3 (10%) unsure and 2 (7%) rating it as *not important* or *not important at all*.

Consistent with their high eHEALS score, a diverse array of devices was used to access the website, including laptops (n=9, 30%), tablets (n=9, 30%), PCs (n=7, 23%), and smartphones (n=5, 17%). The most common languages the website was accessed in were Vietnamese (n=5, 17%), Mandarin (n=5, 17%), English (n=5, 17%), Cantonese (n=4, 13%), Greek (n=4, 13%), Hindi (n=3, 10%), Italian (n=2, 7%), Spanish (n=1, 3%), and Arabic (n=1, 3%).

In terms of website navigation, 28 (93%) participants identified the log-in box, entered the code, and located the home page and menu bar (Multimedia Appendix 3). Most carers (n=25, 83%) located the films and tips sheets, watched an animation, and read the tips sheets without researcher's instruction. Qualitative feedback regarding acceptability was positive. The presentation and first impressions indicated that a clear color branding was used, text size and fonts across all languages were clear and readable, and the film content and tips sheets were cohesive and informative:

> *Chinese writing, strokes, and characters are good in subtitles and on the website.* [ID 21, woman, aged 60 years, Mandarin]
>
> *Good, informative, and clear. The animation was consistent with the message [in the accompanying tips sheet].* [ID 1, woman, aged 60 years, Spanish]

However, locating the menu bar on the home page depended on the device used and screen size. On Mac laptops and smaller screens (eg, tablets and smartphones), the website layout changed, and some participants struggled to navigate it on these devices:

> *The horizontal menu becomes vertical with the three short bars on the top-right. Not everyone knows that they need to click on this bar to find the menu.* [ID 7, woman, aged 63 years, Hindi]

Linguistic translations of "tips" in Vietnamese and "dementia" in Mandarin were also found to be unacceptable. The intended use of "tips" was to denote a brief, useful piece of information accompanying each film's theme, but in Vietnamese, the term meant a gratuity. The translation of "Dementia" to Mandarin was incorrect and outdated, with some terms overly technical or difficult to understand:

> *The video is very good and helpful. Just a suggestion...some of the medical terms in Chinese is difficult...e.g. the medical term [for] "Alzheimer"...* [Deidentified user ID 49]

Website Usability

Overview

When prompted to locate and use the virtual helper to select 1 of the 6 films, 16 (53%) participants completed this task without further instruction. Most participants (n=20, 67%) correctly located and used the film rating scale. Heat map recordings were captured to visually track how users interacted with the website, with interaction intensity ranging from red=busy interactions to blue=fewer active interactions. An example of an aggregated heat map is shown in Figures 1 and 3.

Data were captured through user movements such as clicks or page scrolls. There were 199 aggregated user movements and heat map recordings, which on average suggested low user frustration, based on the low proportion of rage clicks, and high website engagement, based on movements patterns such as landing mostly on the films and tips page. User movements on average indicated about 28 minutes spent scrolling on this page, which is the core of the intervention. According to user feedback from the think-aloud sessions and heat map recordings, three features were unclear: (1) the virtual helper; (2) the 5-point emoticon or smiley face film rating scale; and (3) the feedback button. These features are discussed in the subsequent sections.

Virtual Helper

The "helper"—a simple, non–artificial intelligence chatbot—was denoted by a smiling robot icon intended to help users locate which short films addressed their needs. Clicking on the icon revealed a list of problematic caring scenarios that the films then addressed. A total of 14 (47%) of the 30 participants required instruction to locate and use the helper, as the icon did not prompt users to click on this function. On smaller screens, the icon was too small to view clearly and was difficult to locate on the menu bar. The word "helper," when translated into other languages, was also unclear. For example, the Italian translation was perceived as a helper who assists in caring for a person living with dementia. Feedback to improve usability included changing the icon to a question mark symbol to indicate help-seeking and adding short multilingual "pop-up" explanations about its purpose.

Five-Point Emoticon Rating Scale

The 5-point emoticon rating scale used smiley faces ranging from a very happy face to a very sad face. Emoticons appeared after watching a film to capture an optional rating of likability and satisfaction of the film. However, the emoticons were culturally incongruent and frequently misinterpreted. Participants selected an emoticon that described their emotional state as a carer rather than a rating of satisfaction or dissatisfaction with the film itself. Feedback to improve usability included replacing emoticons with stars and reducing the options from 5 to 3:

> *[A] star icon is better than "emotion" icon because the emotion can be understood differently in different cultures.* [ID 2, man, aged 62 years, Cantonese, and Mandarin]

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Feedback Button

The "feedback" button was designed to capture users' optional, deidentified website feedback by easily clicking on the button to enable a gray pop-up text box with the phrase "Tell us about your experience" (Figure 2). Due to software limitations, it was not possible to translate this phrase, which remained in English, unlike the remaining website text. Consequently, some participants were unable to provide feedback because they could not type in English and in their preferred language. Participants who located the feedback button provided feedback that was overall positive (Figures 1 and 2). However, several carers misinterpreted the feedback request as referring to their caregiving experiences rather than their experience using the website:

> *In the "feedback," it asked about the user's experience. It is not clear for carers: their experience in using the website or in care work.* [ID 3, woman, aged 57 years, Vietnamese]

User testing further revealed that the feedback button's appearance and position were also too small and hidden on devices with smaller screens. Repositioning the button as a discreet tab on the main menu bar was recommended to improve visibility and usability.

After collating the feedback, several changes were made to improve the website's acceptability and usability. These revisions are detailed in Textbox 1.

Textbox 1. Acceptability and usability issues identified from user testing and proposed revisions to improve the Draw-Care intervention (before testing the intervention's effectiveness in a randomized controlled trial [RCT]).

Key usability and acceptability issues identified from user testing of the prototype Draw-Care website

- Ease of access to the nonpublic prototype website was hindered by the case sensitivity of the log-in code.
- Poor visibility of resources made the animations and tips sheets difficult to locate on smaller screens.
- Positioning of film titles under image windows was not user-friendly or intuitive, thus requiring users to scroll down the page.
- Virtual helper feature: the purpose and terminology translated from English to other languages lacked clarity, the feature was not easily located, and the robot icon that visually symbolizes "help" was not intuitively obvious.
- Feedback button and text box pop-up: the purpose, location, and size were unclear and only usable in English text.
- The function and purpose of the 5-point emoticon-based optional film rating scale were unclear and culturally incongruent.
- Linguistic discrepancies in key terms:
  - Dementia (Mandarin only)
  - Tips (all languages)

Proposed revisions to improve the acceptability and usability of the prototype Draw-Care website (before commencement of the RCT)

- Written instructions will be provided to RCT participants to streamline website access, noting the case sensitivity of the log-in code.
- Film titles will be repositioned above the animated images.
- A "Read" button will be added to direct users to information sheets.
- The color of the buttons for "Watch" and "Read" will change as users hover over these options to indicate that clicking on each will play the film or direct the user to the information sheet.
- Font size of the text will be increased, and text will be repositioned to improve optimization on screens of all devices.
- The virtual helper function will be removed; therefore, the term "helper" in all languages will be removed from all website text.
- The feedback button and text box pop-up will be removed.
- Emoticons will be replaced with an optional 3-star rating scale at the end of each film.
- Revisions and retranslations will be conducted where required, including the following:
  - Replacing the outdated terminology of dementia with the correct version in all Mandarin resources.
  - Changing the title "Tips" to "More Information" and consequently changing the title "Films and Tips" to "Films and More Information."
- One round of review of revised resources will be conducted with selected users.

Discussion

Principal Findings

To our knowledge, this is the first study to evaluate a bespoke multilingual website that hosts a novel, co-designed, culturally adapted digital intervention in 10 languages, including English, for ethnically diverse family carers of a person living with dementia. On the basis of feedback, film ratings, and aggregated Hotjar data analytics, the website design, layout, and content, including films and information sheets, were culturally acceptable and engaging. The information was useful and aligned with the corresponding film messages; however, the

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purpose and positioning of the virtual helper, the film rating scale, and the feedback button were not intuitive. Linguistic discrepancies occurred despite an extensive co-design process and professional translation of the text and resources. For example, linguistic translations for “helper” and “tips” did not help users understand their function in all the languages, which created confusion. Similarly, the translation of dementia from English to Mandarin (ie, 痴呆症), while a clinical term, can also connote “stupidity.” During the user-testing phase (within 12 months of co-design and website development), this terminology was considered outdated, with emerging nomenclature favoring more neutral and less stigmatizing terms (ie, 失智症, meaning “loss of cognition”) [18].

Access to the nonpublic prototype website was occasionally hindered by the case-sensitive log-in code, which some participants found difficult to enter correctly. o streamline access in the RCT, written instructions were provided to all participants, explicitly highlighting the case sensitivity of the log-in code and offering clear, step-by-step guidance for logging in.

These findings underscore the importance of engaging end users to ensure digital interventions function as intended and are understood clearly before proceeding to the RCT and the rollout of a web-based intervention, particularly when the primary focus is on ensuring that resources are culturally responsive beyond language translation alone [35]. Such steps are necessary, albeit expensive and time consuming, even when the resources are co-designed with end users.

Study strengths include the use of a mixed methods approach, experienced bilingual researchers (with lived experience of dementia care), and rapid inductive analysis to revise the web-based resource before undertaking the RCT to test its effectiveness with carers from ethnically diverse backgrounds who had not participated in the co-design phase, which is likely to encourage unbiased feedback related to usability.

Limitations

Despite achieving a sample size within the estimated range (n=27 to 45), not all 10 language groups targeted by the prototype intervention were represented (eg, Tamil-speaking carers). Most participants had a moderately high level of eHealth literacy, and all participants were within a category of Australian residence that enabled access to government-subsidized services. Results might have been different if participants had lower eHEALS scores and limited access to publicly subsidized services.

Conclusions

The Draw-Care study is one of the first to investigate how to make digital interventions more ethnically inclusive, thereby better supporting ethnically diverse family carers of people living with dementia. Prioritizing a user-testing component with carers increases the likelihood of refining and improving the usability of an intervention that is culturally appropriate, user centered, and lays the foundation for a subsequent RCT to test its effectiveness.

Acknowledgments

The authors thank the family carers for their feedback on the Draw-Care website and the Australian ethnic-specific community organizations that supported participant recruitment and user-testing sessions. They acknowledge their study partners: the Department of Mental Health and Substance Abuse, the World Health Organization (WHO), Dementia Australia, the Federation of Ethnic Communities’ Councils of Australia, and Advance Care Planning Australia. The co-designed Draw-Care web-based resources were based on the WHO’s iSupport Lite online dementia carer support messages, with input from the Australian iSupport for Dementia Program modules shared by researchers from Flinders University, Australia.

The authors declare the use of generative artificial intelligence (GAI) for the final version. According to the GAI Delegation Taxonomy (2025), the following tasks were delegated to GAI tools under full human supervision: proofreading and editing. The GAI tool used was Grammarly Free (Superhuman). Responsibility for the final manuscript lies entirely with the authors. GAI tools are not listed as authors and do not bear responsibility for the final outcomes. This declaration is submitted under collective responsibility.

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Data Availability

The datasets generated and analyzed during this study are available from the corresponding author on reasonable request.

Authors' Contributions

AT and THD coordinated and facilitated the website user-testing sessions and completed the data analysis. AT, BB, NW, and THD developed the first draft. Feedback was provided by AT, BB, NW, THD, NU, DM, CC, BD, LDX, and TN. AT, THD, and BB reviewed the final manuscript, and AT prepared it for submission. All authors approved the final version.

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Conflicts of Interest

None declared.

Multimedia Appendix 1
Online surveys completed by user-testing participants using REDCap (Research Electronic Data Capture).
[DOCX File , 17 KB - formative_v10i1e81128_app1.docx]

Multimedia Appendix 2
Sequential website tasks completed by user-test participants.
[DOCX File , 15 KB - formative_v10i1e81128_app2.docx]

Multimedia Appendix 3
Screenshots of the Draw-Care website showing (1) the language selection page, (2) the log-in page, and (3) a sample of the main home page.
[DOCX File , 460 KB - formative_v10i1e81128_app3.docx]

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Abbreviations

eHEALS: eHealth Literacy Scale
GAI: generative artificial intelligence
IDA: instant data analysis
RCT: randomized controlled trial

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REDCap: Research Electronic Data Capture
WHO: World Health Organization

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Original Paper

Smartphone-Based Ecological Momentary Assessment of Pain in Older Adults Undergoing Auricular Point Acupressure for Chronic Low Back Pain: Secondary Analysis of a Randomized Controlled Trial

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Abstract

Background: Chronic low back pain (cLBP) is a prevalent and disabling condition in older adults. Auricular point acupressure (APA), a nonpharmacologic intervention, has shown promise in managing cLBP. However, its impact on daily symptom fluctuations remains unclear. Ecological momentary assessment (EMA), which collects real-time data, offers a method to capture these fluctuations.

Objective: This secondary analysis evaluated the effects of APA on EMA-reported pain intensity and pain interference among older adults with cLBP and examined associations among APA practice patterns, recall-based assessments, and EMA engagement.

Methods: Data were drawn from a published 3-arm randomized controlled trial of 272 adults aged ≥60 years with cLBP, randomized to targeted auricular point acupressure (T-APA), nontargeted auricular point acupressure (NT-APA), or education control. For this analysis, only participants who completed at least one EMA entry during the 4-week intervention were included. A total of 61 participants were excluded due to missing EMA data, resulting in a final analytic sample of 211 (T-APA: 72; NT-APA: 74; and control: 65). EMA-reported pain intensity and interference were collected using a smartphone app 3 times daily over 29 days. Linear mixed-effects models assessed the effects of group assignment and APA practice behaviors on EMA outcomes, adjusting for demographics, smoking, opioid use, and baseline recall-based pain. Spearman correlations assessed associations between EMA and 7-day recall measures.

Results: The overall compliance rate was 44.8%, with an attrition rate of 54%. There were no significant differences in compliance or attrition across treatment groups. Older participants showed significantly lower compliance, though attrition was not associated with age. Pain intensity reported via EMA was significantly lower than recall-based pain, while EMA-reported pain interference was higher. EMA and 7-day recall pain outcomes were strongly correlated (Spearman =0.53–0.95; P<.001). Both T-APA and NT-APA, analyzed as separate randomized groups, significantly reduced EMA-reported pain and interference compared to the control. T-APA reduced worst pain (β=–0.98, SE 0.33; P<.001), average pain (β=–0.93, SE 0.30; P<.001), and current pain

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(β=–1.01, SE 0.36; *P*=.006). NT-APA also reduced worst (β=–0.74, SE 0.12; *P*<.001), average (β=–1.02, SE 0.30; *P*=.001), and current pain (β=–1.26, SE 0.37; *P*=.001). For interference, T-APA significantly reduced interference with enjoyment of life (β=–1.72, SE 0.37; *P*<.001) and daily activity (β=–1.41, SE 0.34; *P*=.001), with similar reductions seen in NT-APA.

Conclusions: APA significantly reduced daily pain and interference among older adults with cLBP. EMA provided valuable insights into treatment response and symptom variability. Future research should enhance EMA adherence and explore sustained APA use for self-management.

Trial Registration: ClinicalTrials.gov NCT03589703; https://clinicaltrials.gov/study/NCT03589703

International Registered Report Identifier (IRRID): RR2-10.1186/s13063-019-4016-x

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KEYWORDS

ecological momentary assessment; auricular point acupressure; chronic low back pain; randomized controlled trial; pain

Introduction

Chronic low back pain (cLBP) is a common and debilitating condition affecting approximately 20.5% of older adults in the United States [1]. It contributes to substantial physical disability, reduced quality of life, and elevated risks of depression and social isolation [2]. As pharmacologic treatments may pose safety risks in this population, there is growing interest in nonpharmacologic approaches that support self-management [3,4]. Auricular point acupressure (APA), a low-cost and noninvasive technique rooted in traditional Chinese medicine, involves applying small seeds to specific points on the ear corresponding to body regions to relieve pain. APA is safe, easy to administer, and can be integrated into daily routines. To evaluate its effectiveness, we conducted a 3-arm randomized controlled trial (RCT) of 272 older adults with cLBP. Participants were randomized to receive either targeted auricular point acupressure (T-APA; ear points related to low back), nontargeted auricular point acupressure (NT-APA; ear points unrelated to low back), or an educational control. The study demonstrated that both APA groups reported significantly greater improvements in self-reported pain intensity and physical function compared to the control group. Details of the study protocol and primary outcomes have been published previously [5,6].

While these findings support the clinical benefits of APA, the interpretation of self-reported outcomes is limited by reliance on retrospective patient-reported outcome measures, such as weekly or monthly recall of pain. These traditional assessments are susceptible to memory bias and may not capture the moment-to-moment variability of pain—particularly in older adults [7]. Chronic pain is increasingly recognized as a fluctuating and context-dependent experience, with substantial within-day and day-to-day variability that is poorly characterized by summary recall measures alone [8,9]. Ecological momentary assessment (EMA), which prompts participants to report symptoms in real time using smartphones, has been increasingly used in chronic pain research to address these limitations. EMA reduces recall bias, improves ecological validity, and enables the examination of intraindividual pain variability and symptom dynamics that are not captured by conventional patient-reported outcome measures [7,10]. EMA studies in chronic pain populations have demonstrated that pain intensity varies substantially within individuals, that such variability is stable over time yet heterogeneous across patients, and that variability metrics may be independently associated with quality of life, emotional functioning, and pain-related interference beyond mean pain levels [8,9,11].

For older adults, EMA may offer additional advantages by accommodating mobility limitations and supporting more accurate symptom reporting in daily life by addressing common challenges in pain assessment, such as memory lapses and difficulty recalling pain episodes. EMA has also been shown to be feasible and acceptable in chronic pain populations when thoughtfully designed, although adherence remains a challenge in studies requiring frequent prompts over extended periods [12,13]. Emerging work further suggests that EMA is uniquely suited to examine modifiable psychosocial and behavioral processes relevant to pain, including emotion regulation, pain catastrophizing, substance use, and treatment engagement, which may explain on a momentary timescale [9,14,15].

Despite growing use of EMA in chronic pain research, its application in evaluating nonpharmacologic, self-administered interventions, such as APA, remains limited. To assess the feasibility of integrating EMA into a pain management and APA trial, we conducted a pilot study involving a 4-week APA intervention among older adults with cLBP [12]. Among 18 participants, adherence to EMA prompts was high (87%), usability ratings were favorable, and there were significant positive correlations between EMA and recall-based pain scores. These findings supported the integration of EMA into the larger RCT to enhance symptom assessment accuracy and better capture real-time treatment responses.

Building on these pilot findings, we incorporated EMA into our larger RCT evaluating the effectiveness of APA for managing cLBP in older adults. The study protocol was published [5], and primary outcomes demonstrating significant improvements in pain and physical function were reported [6]. In addition to standard retrospective self-reported measures, the trial prospectively integrated EMA via a smartphone app to capture real-time pain experiences and monitor adherence to APA practice. This approach allowed for examination of both average treatment effects and daily symptom trajectories, addressing recent calls to move beyond static pain outcomes toward dynamic, patient-centered measures in chronic pain research [16,17].

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The purpose of this secondary analysis was to examine EMA-reported pain outcomes collected via a smartphone-based (EarAPA) app (developed by Chi-Chih Chen) and explore the relationship between APA practice patterns and daily fluctuations in pain intensity and interference.

Methods

Design

This study is a secondary analysis of EMA data collected as part of a previously published RCT evaluating APA for older adults with cLBP. The parent study protocol and primary outcomes have been reported elsewhere [5,6]. The original trial was registered at ClinicalTrials.gov (NCT03589703). This analysis focused on examining real-time pain intensity and interference captured via EMA and exploring their associations with APA practice patterns. The study is reported in accordance with the CONSORT-EHEALTH (Consolidated Standards of Reporting Trials of Electronic and Mobile Health Applications and Online Telehealth) checklist (version 1.6.1) in Multimedia Appendix 1 [18].

Participants

This secondary analysis used data from a previously published RCT that evaluated the effectiveness of APA for managing cLBP in older adults [5,6]. The parent trial enrolled 272 participants who were randomized to T-APA (n=92), NT-APA (n=91), or an education control group (n=89). Recruitment occurred in 2 phases, from March 1, 2019, to March 13, 2020, and from June 12, 2021, to November 18, 2021, with follow-up completed by December 1, 2022.

For this analysis, inclusion was limited to individuals who had at least one EMA data point during the 4-week intervention period. Because the analytic aim was to examine real-time pain outcomes and their associations with APA practice, 61 participants without EMA data were excluded. The final analytic sample consisted of 211 participants with 72 in the T-APA group, 74 in the NT-APA group, and 65 in the control group.

Recruitment

This secondary analysis used data from a previously conducted RCT evaluating APA for cLBP in older adults. Recruitment procedures, eligibility criteria, and informed consent processes have been detailed in the published protocol [5] and primary outcomes paper. Participants were recruited from outpatient clinical sites (eg, pain management, geriatrics, and internal medicine), community outreach, an aging research registry, social media platforms (including Craigslist), and ClinicalTrials.gov.

Randomization and Intervention

This secondary analysis used data from an RCT in which participants were originally assigned to one of 3 study arms in a 1:1:1 ratio: T-APA, NT-APA, or education control. Randomization procedures, including using a computer-generated allocation sequence and block randomization, are described in detail in the published protocol [5]. In the parent trial, participants in the APA arms were blinded to their group assignment, and blinding was maintained for investigators, data collectors, and analysts.

The APA intervention protocol is described previously [5]. Participants in the groups were instructed to apply small seeds to designated auricular points 3 times daily, pressing each point for 3 minutes per session. All auricular points were selected based on standardized Chinese ear acupuncture maps, which correspond to specific regions of the ear to particular body parts and organ systems. The T-APA group received acupressure at points associated with cLBP (eg, lower back, nervous subcortex, sympathetic, and Shenmen), while the NT-APA group received acupressure at auricular points that were strategically selected to be unrelated to the low back (eg, mouth, stomach, duodenum, internal ear, and tonsil) [19,20]. Although NT-APA was described as a placebo control in the original trial design, it involved active auricular stimulation and was therefore retained as a distinct intervention arm in this secondary analysis to reflect its procedural characteristics while maintaining consistency with the parent RCT. The education control group received a booklet outlining evidence-based strategies for managing chronic back pain. All participants attended weekly sessions over 4 weeks to receive new seeds (APA groups) or review educational materials (control). A smartphone app (EarAPA) was used to collect real-time pain data and monitor adherence to the APA protocol.

Smartphone EMA (EarAPA App)

Participants received a study smartphone (HTC Desire 612; HTC Corporation) with the EarAPA app preinstalled, along with a charger. The EarAPA app, adapted from the previously developed Earpress app [12], originally delivered educational materials and symptom surveys. For this study, the app was further customized to support EMA and to enhance usability for older adults by incorporating features, such as adjustable volume and larger font size [21]. Although the app was available on Android and iOS platforms, access was restricted to enrolled participants.

This EarAPA app was used to deliver EMA prompts and surveys over a 29-day period to facilitate real-time symptom tracking. Two types of EMA surveys were administered: (1) random EMA, issued once daily during waking hours, included 4 brief questions assessing momentary pain intensity and interference with enjoyment of life and daily activities; and (2) time-contingent EMA, prompted twice daily based on participants' routines, captured information on pain, APA adherence, and analgesic use. The random EMA surveys took approximately 1 minute to complete, while time-contingent surveys took less than 2 minutes. All data were automatically uploaded to a secure, cloud-based server in real time, allowing research staff to monitor participation and follow up as needed.

Measurement

Baseline Characteristics

This analysis used data collected as part of the parent RCT of APA for cLBP in older adults. Baseline characteristics, including age, sex, race or ethnicity, education level, employment status, income, BMI, smoking status, and opioid use, were collected before intervention initiation.

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Pain Measures

Recall-Based Pain Intensity and Interference

Recall-based pain intensity worst pain and average pain) and interference (overall pain interference with daily activity and overall pain interference with enjoyment in life) were assessed weekly using items from the Brief Pain Inventory–Short Form (BPI-SF). All items used a 0-10 numeric rating scale, where 0 indicated “no pain” or “does not interfere” and 10 indicated “pain as bad as you can imagine” or “completely interferes.” The BPI-SF has been validated in various populations and demonstrates strong internal consistency, with Cronbach α ranging from 0.82 to 0.95 [22].

EMA-Based Pain Intensity and Interference

Real-time pain intensity and pain interference were assessed using EMA surveys delivered via the EarAPA smartphone app. EMA assessments were administered 3 times daily over a 29-day period, allowing for repeated measurement of pain experiences in participants’ natural environments. During daytime assessments, current pain intensity was reported using a 0-10 numeric rating scale, where 0 indicated “no pain” and 10 indicated “pain as bad as you can imagine.” Evening assessments measured the worst and average pain experienced that day, as well as pain interference using the same 0-10 scale, with 0 indicating “does not interfere” and 10 indicating “completely interferes.”

Both recall-based pain and EMA-based pain assessments were collected concurrently during the intervention period to enable direct comparison between retrospective weekly reports and real-time, momentary pain outcomes within the same time frame.

APA Practice and Analgesic Use

Daily self-report of APA practice behaviors, including frequency of pressing the taped seeds, minutes per pressing, and total pressing time, was collected via the evening EMA survey. Participants also reported daily analgesic use, including medication name, dosage, and frequency of use, via evening EMA assessment.

Analysis

Data from the EarAPA smartphone app were analyzed using our published EMA analytic methods [12]. The analytic window included EMA data collected during the first month of treatment, defined as days 0 through 28 following baseline assessment. Descriptive statistics were used to summarize demographic characteristics, EMA compliance, and attrition. EMA compliance was defined as the proportion of completed EMA assessments relative to the total number of scheduled assessments (87 assessments per participant: 29 days×3 times per day). EMA attrition was defined as discontinuation of EMA participation during the intervention period.

Two-tailed paired *t* tests were used to compare weekly mean EMA-reported pain intensity and pain interference with corresponding 7-day recall-based assessments. Longitudinal associations between intervention assignment, APA practice behaviors, and pain outcomes were examined using linear mixed-effects models with repeated EMA measures nested within individuals to account for within-person correlation over time. Fixed effects included treatment group (T-APA, NT-APA, and education control), APA practice variables (pressing frequency, minutes per pressing, and total pressing time), analgesic use, day since baseline, and relevant covariates (age, sex, race, smoking status, employment status, baseline opioid use, baseline pain measures, and pain interference ratings). Random effects included participant-specific intercepts and slopes for APA practice and analgesic use, with temporal autocorrelation modeled using a first-order autoregressive covariance structure. All inferential analyses preserved the 3 original randomized groups. The 2 APA arms were not pooled for any statistical comparisons. Linear mixed-effects models were selected instead of ANOVA to accommodate repeated, unequally spaced EMA measurements and varying numbers of assessments per participant.

Because EMA data are inherently unbalanced due to variable response patterns across participants and time points, mixed-effects models allowed inclusion of all available observations without imputing missing values under the missing-at-random assumption. Total daily pressing time was calculated as the product of daily pressing frequency and minutes per pressing and was treated as a time-varying predictor. The analytic sample size was determined by the number of participants with available EMA data from the parent RCT. No a priori sample size calculation was performed for this secondary analysis. All analyses were conducted using R version 4.3.1 (R Foundation for Statistical Computing).

Ethical Considerations

The parent RCT [5,6] was approved by the Johns Hopkins Medicine Institutional Review Board (IRB00175409). This secondary analysis used data collected under this original approval and did not require additional ethics review because all data were deidentified prior to analysis. Informed consent was obtained before enrollment, including consent for the collection of real-time symptom data using a smartphone-based EMA app. A copy of the consent form is available in Multimedia Appendix 1, following CONSORT-EHEALTH recommendations. To ensure privacy and confidentiality, EMA and survey data were transmitted securely and stored on encrypted, password-protected servers accessible only to authorized research staff of the parent study, with all identifying information removed before secondary analyses were conducted. Compensation was provided as part of the parent trial in accordance with the approved protocol. No additional compensation was offered for this secondary analysis, which involved only previously collected data.

Results

Demographics and Baseline Characteristics

This secondary analysis included 211 participants from a previously published RCT. As detailed in the Methods (Participants and Recruitment Sections), participants were included in this analysis if they had at least one EMA entry recorded during the 4-week intervention period. The final analytic sample comprised 72 participants in the T-APA group,

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74 in the NT-APA group, and 65 in the education control group (Figure 1).

The analytic sample was generally balanced across the 3 study arms in terms of age, sex, race or ethnicity, education level, employment status, BMI, smoking status, and opioid use at baseline (Table 1). Overall, the sample had a mean age of 69.4 (SD 6.70) years and was predominantly female (135/211, 64%), with 63.5% (134/211) identifying as Black or African American. Most participants were retired or unemployed (181/211, 85.8%), and approximately 46% (97/211) reported current or recent opioid use.

Figure 1. CONSORT (Consolidated Standards of Reporting Trials) diagram of the parent randomized controlled trial and eligibility for the ecological momentary assessment secondary analysis. EMA: ecological momentary assessment; NT-APA: nontargeted auricular point acupressure; T-APA: targeted auricular point acupressure.

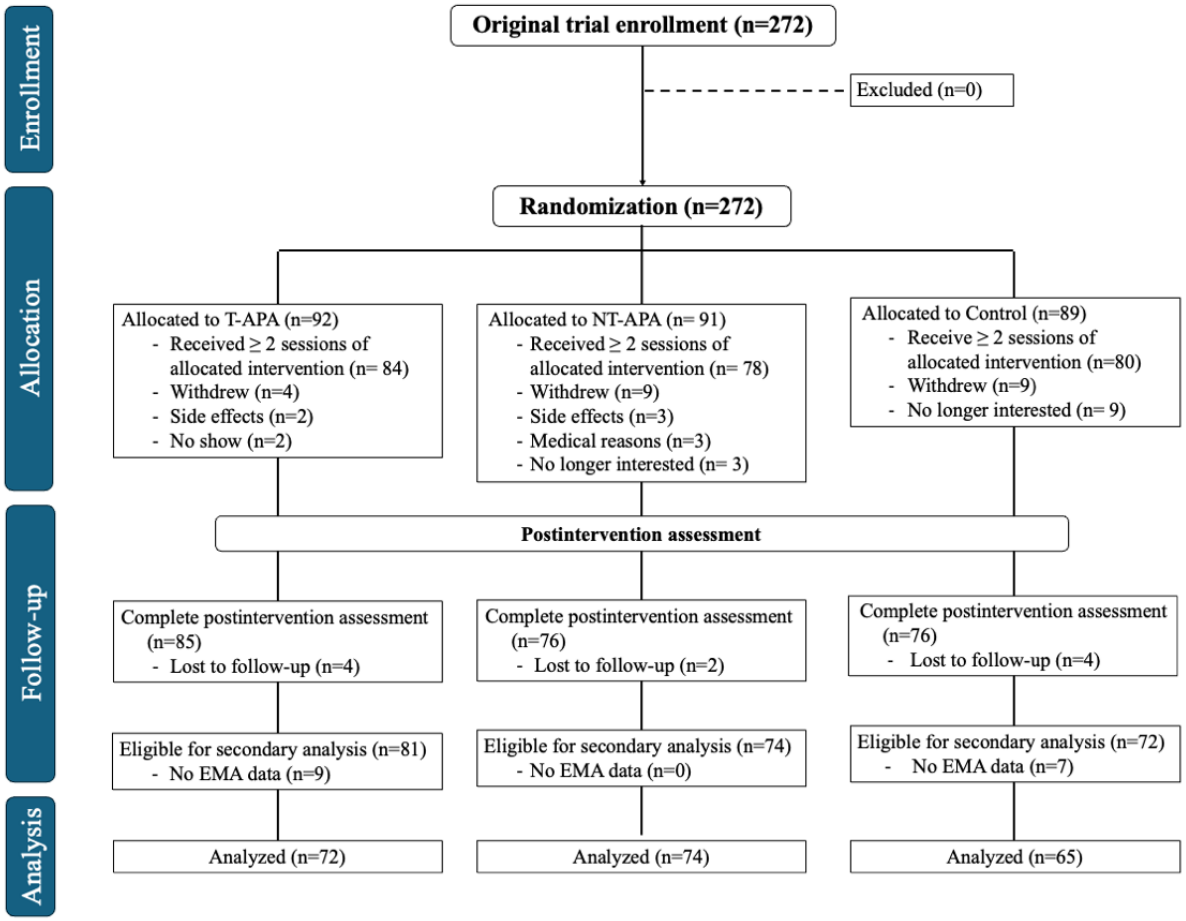

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Table 1. Demographics and baseline characteristics of all the participants who had ecological momentary assessment data (N=211).

Characteristic	T-APA[a] (n=72)	NT-APA[b] (n=74)	Control (n=65)	Overall (N=211)
Age (years), mean (SD; range)	69.6 (6.28; 60.0-87.0)	67.9 (6.93; 60.0-87.0)	70.7 (6.76; (60.0-91.0)	69.4 (6.70; 60.0-91.0)
Sex, n (%)				
Female	46 (63.9)	46 (62.2)	43 (66.2)	135 (64)
Male	25 (34.7)	28 (37.8)	21 (32.3)	74 (35.1)
Unspecified	1 (1.4)	0 (0)	1 (1.5)	2 (0.9)
Race, n (%)				
American Indian or Alaska Native	0 (0)	0 (0)	2 (3.1)	2 (0.9)
Asian	0 (0)	1 (1.4)	0 (0)	1 (0.5)
Black or African American	41 (56.9)	49 (66.2)	44 (67.7)	134 (63.5)
White	29 (40.3)	21 (28.4)	18 (27.7)	68 (32.2)
Native Hawaiian or Pacific Islander	0 (0)	1 (1.4)	0 (0)	1 (0.5)
More than one race	1 (1.4)	2 (2.7)	0 (0)	3 (1.4)
Unknown or not reported	1 (1.4)	0 (0)	1 (1.5)	2 (1)
Ethnicity, n (%)				
Hispanic or Latino	1 (1.4)	0 (0)	2 (3.1)	3 (1.4)
Non-Hispanic or Latino	66 (91.7)	57 (77)	49 (75.4)	172 (81.5)
Unknown or not reported	5 (7)	17 (23)	14 (21.5)	36 (17.1)
BMI (kg/m^2), mean (SD)	30.8 (8.34)	31.2 (7.50)	30.6 (6.63)	30.9 (7.56)
Education level, n (%)				
High school or less[c]	24 (33.3)	28 (37.8)	24 (36.9)	76 (36)
Some college[d]	17 (23.6)	20 (27)	11 (16.9)	48 (22.6)
College or higher[e]	28 (38.9)	24 (32.4)	27 (41.5)	79 (37.4)
Unknown[f]	3 (4.2)	2 (2.7)	3 (4.6)	8 (3.8)
Employment status, n (%)				
Employed	7 (9.7)	9 (12.2)	10 (15.4)	26 (12.3)
Unemployed or retired	63 (87.5)	64 (86.5)	54 (83)	181 (85.8)
Unknown	2 (2.8)	1 (1.4)	1 (1.5)	4 (1.9)
Smoking status, n (%)				
Current smoker	14 (19.4)	19 (25.7)	9 (13.9)	42 (19.9)
Never smoked	30 (41.7)	18 (24.3)	28 (43.1)	76 (36)
Previously smoked	28 (38.9)	37 (50)	28 (43.1)	93 (44.1)
Opioid use, n (%)				
No	32 (44.4)	36 (48.7)	35 (53.9)	103 (48.8)
Yes	36 (50)	36 (48.7)	25 (38.5)	97 (46)
Not sure	4 (5.6)	2 (2.7)	5 (7.7)	11 (5.2)
Baseline recall pain severity, mean (SD)				
Worst pain	7.43 (1.71)	7.04 (1.76)	7.03 (1.53)	7.18 (1.67)
Average pain	6.00 (1.83)	6.14 (2.00)	6.03 (1.61)	6.07 (1.82)
Current pain	4.81 (2.73)	4.93 (2.71)	4.22 (2.85)	4.68 (2.77)
Baseline recall pain interference, mean (SD)				

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Characteristic	T-APA[a] (n=72)	NT-APA[b] (n=74)	Control (n=65)	Overall (N=211)
Interfere with enjoyment of life	4.71 (3.05)	4.86 (3.05)	4.62 (2.94)	4.76 (3.00)
Interfere with daily general activities	5.35 (2.70)	5.47 (2.44)	4.74 (2.26)	5.22 (2.48)

[a]T-APA: nontargeted auricular point acupressure.

[b]NT-APA: targeted auricular point acupressure.

[c]High school or less includes participants with no high school diploma or who graduated from high school or obtained a high school equivalency (General Educational Development).

[d]Some college includes those who attended an occupational, technical, or vocational program or completed some college without obtaining a degree.

[e]College or higher includes participants with an associate degree, bachelor's degree, master's degree, doctoral degree, or professional school degree.

[f]Unknown represents participants who did not report their education level.

A comparison of participants with versus without EMA data (Multimedia Appendix 2) revealed that those without EMA data were significantly older (mean age 72.15, SD 7.41 vs 69.36, SD 6.70 years; *P*=.01) and reported significantly lower pain interference with enjoyment of life at baseline (mean 3.80, SD 3.42) vs 4.74, SD 3.00; *P*=.04). No other baseline characteristics showed statistically significant between-groups differences.

EMA Compliance and Attrition

Based on the study design, EMA measurements were scheduled 3 times daily from baseline (day 0) through day 28 of the intervention period, for a total of 87 potential assessments over 29 days. The compliance analysis excluded 61 participants who did not respond to any EMA prompts. Among the remaining 211 participants, the overall compliance rate was 44.8%, and the attrition rate was 54%. Participant-level EMA compliance rates varied widely across individuals (Multimedia Appendix 3). There were no significant differences in compliance or attrition rates across the 3 treatment arms. Sex, race, analgesic use, opioid use, and baseline pain measurements were not significantly associated with compliance or attrition. However, age was significantly associated with compliance, with older participants exhibiting lower compliance rates ($F_{1,209}$=6.96; *P*=.009), though age was not significantly related to attrition (*P*=.19).

Patterns of EMA-Reported Pain Intensity and Pain Interference

Figure 2 shows the patterns of EMA-reported pain intensity, which were analyzed by examining the daily average scores of worst pain (Figure 2A), average pain (Figure 2B), and current pain (Figure 2C) over the 28-day intervention period across the 3 study arms, including T-APA, NT-APA, and education control. Both APA groups demonstrated a decreasing trend in worst and average pain over time, with consistently lower intensity levels compared to the control group. Although EMA-reported current pain scores showed some day-to-day variability, they remained generally lower in the APA groups throughout the intervention. These patterns suggest potential benefits of both APA interventions in reducing daily pain intensity.

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Figure 2. Patterns of ecological momentary assessment–reported pain intensity over the 4-week intervention period by treatment arm: worst pain (A), average pain (B), and current pain (C). NT-APA: nontargeted auricular point acupressure; T-APA: targeted auricular point acupressure.

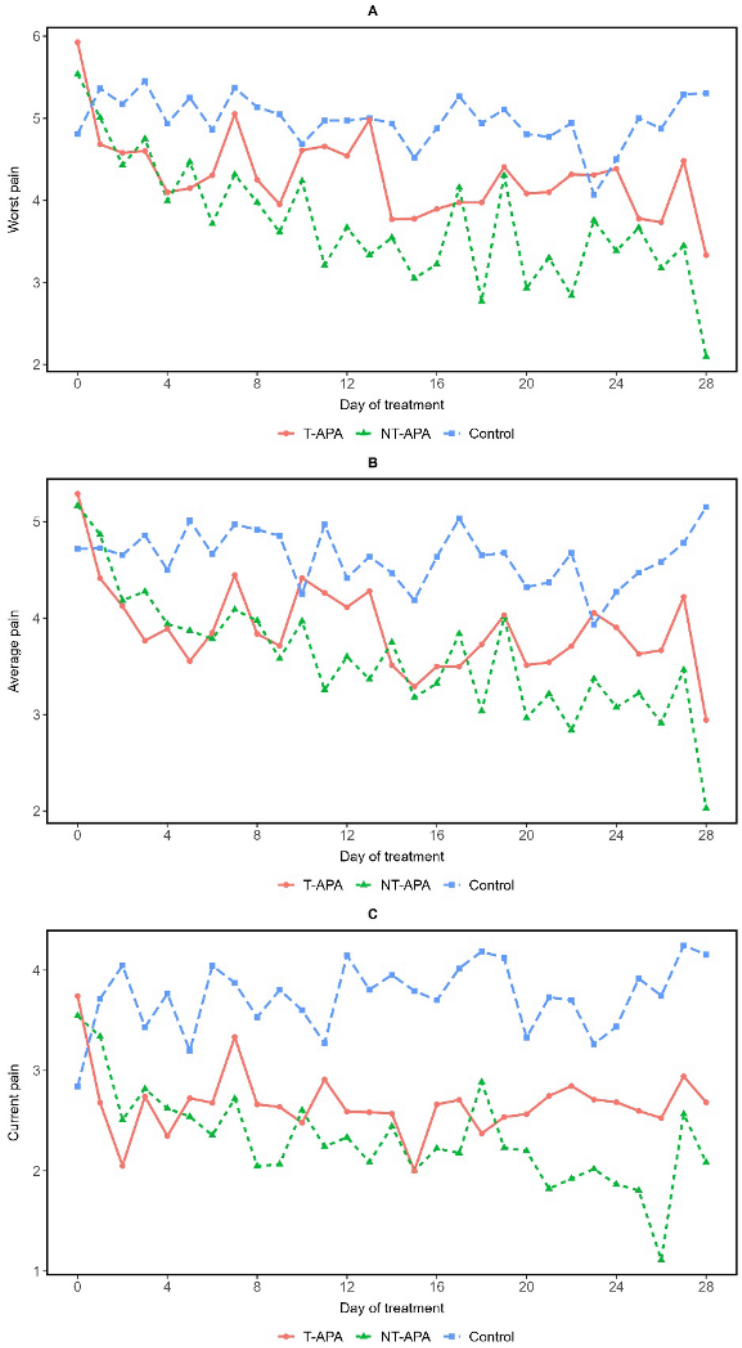

Figure 3 shows the EMA-reported overall pain interference. Daily average scores of overall pain interference with enjoyment in life (Figure 3A) and overall pain interference with daily activity (Figure 3B) over the 28-day period showed a decreasing trend in both the T-APA and NT-APA groups, with generally lower scores compared to the control group. Similar patterns were observed for EMA-reported current pain interference with enjoyment in life (Figure 3C) and current pain interference with daily activity (Figure 3D), suggesting that participants receiving APA experienced less disruption in daily functioning and enjoyment in life due to pain.

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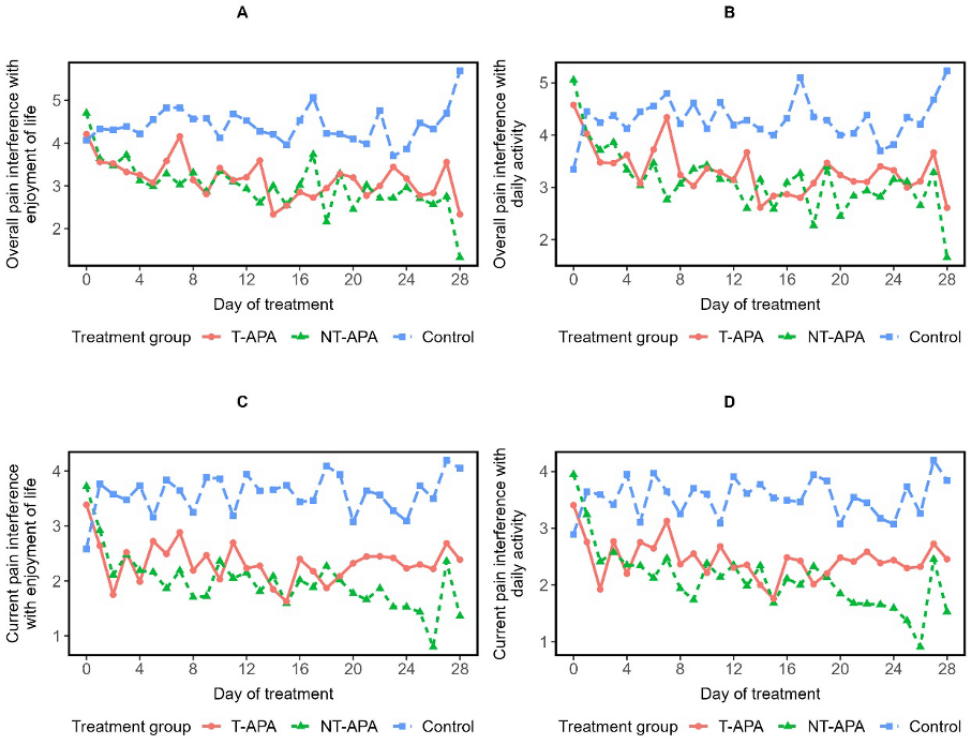
Figure 3. Patterns of ecological momentary assessment–reported overall pain interference with enjoyment of life (A) and daily activity (B), and current pain interference with enjoyment of life (C) and daily activity (D) over the 4-week auricular point acupressure by treatment arms. NT-APA: nontargeted auricular point acupressure; T-APA: targeted auricular point acupressure.



Comparison of Pain Intensity and Pain Interference Outcomes Between EMA and 7-Day Recall

Weekly average EMA scores for pain intensity and interference were compared with corresponding weekly 7-day recall scores. Across all 4 weeks, EMA mean scores were consistently lower than recall-based ratings for worst and average pain (all $P<.001$). In contrast, EMA mean scores for interference with daily activity were significantly higher than recall scores across all weeks (all $P\leq.01$). For interference with enjoyment of life, the recall data were collected only at Week 4, at which no significant difference was observed at that time point ($P=.77$; Table 2).

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Table 2. Comparison of pain intensity and pain Interference between ecological momentary assessment (EMA) and 7-day recall using a 2-tailed paired *t* test.

Time	EMA, mean (SD)	7-day recalled, mean (SD)	*P* value
Worst pain			
Week 1	4.81 (2.20)	6.45 (2.40)	<.001
Week 2	4.44 (2.45)	6.24 (2.68)	<.001
Week 3	4.21 (2.51)	6.23 (2.64)	<.001
Week 4	4.09 (2.71)	5.81 (2.49)	<.001
Average pain			
Week 1	4.39 (2.02)	4.91 (2.24)	<.001
Week 2	4.17 (2.34)	4.66 (2.41)	<.001
Week 3	3.89 (2.44)	4.65 (2.48)	<.001
Week 4	3.75 (2.60)	4.33 (2.39)	<.001
Overall pain interference with daily activity			
Week 1	3.93 (2.45)	2.82 (1.04)	<.001
Week 2	3.63 (2.62)	2.76 (1.04)	<.001
Week 3	3.44 (2.65)	2.84 (1.07)	.002
Week 4	3.45 (2.77)	2.86 (1.06)	.01
Overall pain interference with enjoyment of life			
Week 1	3.86 (2.45)	—[a]	—
Week 2	3.59 (2.72)	—	—
Week 3	3.39 (2.76)	—	—
Week 4	3.40 (2.84)	3.58 (3.18)	.77

[a]Not applicable.

Across the intervention period, EMA and 7-day recall ratings were highly correlated for both pain intensity and pain interference outcomes. Spearman correlation coefficients demonstrated strong associations between EMA and 7-day recall ratings across all 4 weeks of the intervention. For both worst and average pain, correlations between EMA and recall scores remained consistently high (ranging from 0.73 to 0.95, all *P*<.001; Table 3). Similarly, overall pain interference with daily activity showed moderate to strong correlations between EMA and recall across the weeks (ranging from 0.66 to 0.80, all *P*<.001). In Week 4, when recall data for overall pain interference with enjoyment of life were available, correlations with EMA were also moderate (=0.59 for recall and 0.56 for EMA, both *P*<.001; Table 3).

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Table 3. Spearman correlation coefficients of pain intensity and pain interference between ecological momentary assessment (EMA) and 7-day recall for every week throughout the intervention period.

Pain measures and week	Worst pain		Average pain		Overall pain interference with daily activity		Overall pain interference with enjoyment of life	
	Recall	EMA	Recall	EMA	Recall	EMA	Recall	EMA
Week 1: worst pain								
Recall	—[a]	0.61	0.74[b]	0.62[b]	0.53[b]	0.56[b]	—	—
EMA	0.61[b]	—	0.73[b]	0.90[b]	0.56[b]	0.83[b]	—	—
Week 2: worst pain								
Recall	—	0.80[b]	0.90[b]	0.76[b]	0.71[b]	0.79[b]	—	—
EMA	0.80[b]	—	0.86[b]	0.92[b]	0.70[b]	0.89[b]	—	—
Week 3: worst pain								
Recall	—	0.75[b]	0.80[b]	0.72[b]	0.53[b]	0.71[b]	—	—
EMA	0.75[b]	—	0.85[b]	0.92[b]	0.60[b]	0.88[b]	—	—
Week 4: worst pain								
Recall	—	0.74[b]	0.79[b]	0.74[b]	0.62[b]	0.70[b]	0.58[b]	0.68[b]
EMA	0.74[b]	—	0.78[b]	0.95[b]	0.62[b]	0.89[b]	0.53[b]	0.87[b]
Week 1: average pain								
Recall	0.74[b]	0.62[b]	—	0.78[b]	0.56[b]	0.73[b]	—	—
EMA	0.73[b]	0.90[b]	0.78[b]	—	0.56[b]	0.89[b]	—	—
Week 2: average pain								
Recall	0.90[b]	0.86[b]	—	0.86[b]	0.74[b]	0.86[b]	—	—
EMA	0.76[b]	0.92[b]	0.86[b]	—	0.67[b]	0.78[b]	—	—
Week 3: average pain								
Recall	0.80[b]	0.85[b]	—	0.84[b]	0.66[b]	0.84[b]	—	—
EMA	0.72[b]	0.92[b]	0.84[b]	—	0.64[b]	0.93[b]	—	—
Week 4: average pain								
Recall	0.79[b]	0.78[b]	—	0.82[b]	0.69[b]	0.81[b]	0.59[b]	0.79[b]
EMA	0.74[b]	0.95[b]	0.78[b]	—	0.62[b]	0.94[b]	0.56[b]	0.92[b]
Week 1: overall pain interference with daily activity								
Recall	0.53[b]	0.56[b]	0.56[b]	0.56[b]	—	0.66[b]	—	—
EMA	0.56[b]	0.83[b]	0.83[b]	0.73[b]	0.66[b]	—	—	—
Week 2: overall pain interference with daily activity								
Recall	0.71[b]	0.70[b]	0.74[b]	0.67[b]	—	0.78[b]	—	—
EMA	0.79[b]	0.89[b]	0.86[b]	0.91[b]	0.78[b]	—	—	—
Week 3: overall pain interference with daily activity								
Recall	0.53[b]	0.60[b]	0.66[b]	0.64[b]	—	0.80[b]	—	—
EMA	0.71[b]	0.88[b]	0.84[b]	0.93[b]	0.70[b]	—	—	—
Week 4: overall pain interference with daily activity								
Recall	0.62[b]	0.62[b]	0.69[b]	0.62[b]	—	0.72[b]	0.64[b]	0.69[b]

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Pain measures and week	Worst pain		Average pain		Overall pain interference with daily activity		Overall pain interference with enjoyment of life	
	Recall	EMA	Recall	EMA	Recall	EMA	Recall	EMA
EMA	0.70[b]	0.89[b]	0.81[b]	0.94[b]	0.72[b]	—	0.62[b]	0.95[b]

[a]Not applicable.

[b]*P*<.001.

The Effects of APA Practice and Medication Use on EMA-Reported Pain Intensity

Both T-APA and NT-APA interventions significantly reduced EMA-reported pain intensity across 3 specific variables, including worst pain, average pain, and current pain. As shown in Table 4, participants in the T-APA group experienced significant reductions in EMA-reported worst pain (β=–0.98, SE 0.33; *P*<.001), EMA-reported average pain (β=–0.93, SE 0.30; *P*<.001), and EMA-reported current pain (β=–1.01, SE 0.36; *P*=.006; Table 4). Similarly, the NT-APA group showed significant reductions in EMA-reported worst pain (β=–0.74, SE 0.12; *P*<.001), EMA-reported average pain (β=–1.02, SE 0.30; *P*=.001), and EMA-reported current pain (β=–1.26, SE 0.37; *P*=.001) compared to the control group. When comparing T-APA and NT-APA directly, there were no statistically significant differences in any of the momentary pain outcomes, suggesting comparable efficacy between the 2 APA protocols.

Adherence to APA practice was variably associated with EMA pain outcomes. Longer pressing time per session (more than 3 minutes) was significantly associated with reduced EMA-reported current pain (β=–0.28, SE 0.13; *P*=.02). In contrast, pressing more than 3 times per day was unexpectedly linked with increased EMA-reported worst pain (β=0.29, SE 0.15; *P*=.04) and EMA-reported average pain (β=0.32, SE 0.13; *P*=.01). Total daily pressing time greater than 9 minutes was not significantly associated with changes in any EMA-reported pain variable, indicating that pressing duration per instance may be more relevant than cumulative daily time.

Baseline pain characteristics, measured by a 7-day recall self-report questionnaire, also predicted EMA-reported pain outcomes. Use of analgesic medications was associated with increased EMA-reported pain across all domains, including worst pain (β=0.74, SE 0.12; *P*<.001), average pain (β=0.47, SE 0.11; *P*<.001), and current pain (β=0.74, SE 0.14; *P*<.001). Higher baseline recall of worst pain was associated with greater levels of all EMA-reported pain outcomes, such as worst pain (β=0.51, SE 0.09; *P*<.001), average pain (β=0.31, SE 0.10, *P*=.003), and current pain (β=0.27, SE 0.11; *P*=.02). Similarly, higher baseline recall of pain interference with daily activities was associated with increased EMA-reported worst pain (β=0.20, SE 0.06, *P*=.001) and EMA-reported average pain (β=0.19, SE 0.06, *P*=.001). Furthermore, baseline recall, average pain, and current pain were significant predictors of their corresponding EMA-reported pain outcomes.

Among demographic variables, age was the only significant factor associated with EMA-reported pain outcomes. Older age was linked with reduced EMA-reported worst pain (β=–0.07, SE 0.02; *P*=.001) and EMA-reported average pain (β=–0.06, SE 0.02; *P*=.001), though it was not significantly related to EMA-reported current pain. Other demographic and clinical characteristics—including sex, race, employment status, smoking status, opioid use, and baseline pain interference with enjoyment of life—were not significantly associated with any EMA-reported pain outcomes.

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Table 4. The estimated coefficients and SEs of the main effects on EMA-reported pain intensity.

EMA-reported pain intensity	Worst pain		Average pain		Current pain	
	Estimate (SE)	*P* value	Estimate (SE)	*P* value	Estimate (SE)	*P* value
Group (control as a comparison group)						
T-APA[a]	–0.98 (0.33)	<.001[b]	–0.93 (0.30)	<.001[b]	–1.01 (0.36)	.006[b]
NT-APA[c]	–0.74 (0.12)	<.001[b]	–1.02 (0.30)	.001[b]	–1.26 (0.37)	.001[b]
Control	Ref	Ref	Ref	Ref	Ref	Ref
Group (NT-APA as a comparison group)						
T-APA	0.28 (0.29)	.34	0.09 (0.27)	.74	0.25 (0.34)	.47
NT-APA	Ref	Ref	Ref	Ref	Ref	Ref
Control	1.25 (0.34)	<.001[b]	1.02 (0.30)	<.001[b]	1.26 (0.37)	<.001[b]
Pressing frequency (times/day)						
≥3	0.29 (0.15)	.04[b]	0.32 (0.13)	.01[b]	—[d]	—
<3	Ref	Ref	Ref	Ref	—	—
Minutes per pressing						
≥3	–0.25 (0.17)	.14	–0.22 (0.15)	.12	–0.28 (0.13)	.02[b]
<3	Ref	Ref	Ref	Ref	Ref	Ref
Total pressing time (minutes)						
≥9	—	—	—	—	—	—
<9	—	—	—	—	—	—
Analgesic use (confounding)						
Yes	0.74 (0.12)	<.001[b]	0.47 (0.11)	<.001[b]	0.74 (0.14)	<.001[b]
No	Ref	Ref	Ref	Ref	Ref	Ref
Day of treatment	–0.04 (0.00)	<.001[b]	–0.03 (0.00)	<.001[b]	–0.01 (0.00)	.001[b]
Covariates [e]						
Age	–0.07 (0.02)	.001[b]	–0.06 (0.02)	.001[b]	—	—
Recall worst pain	0.51 (0.09)	<.001[b]	0.31 (0.10)	.003[b]	0.27 (0.11)	.02[b]
Recall average pain	—	—	0.27 (0.09)	.002[b]	—	—
Recall current pain	—	—	—	—	0.36 (0.07)	<.001[b]
Recall pain interference with daily activities	0.20 (0.06)	.001[b]	0.19 (0.06)	.001[b]	—	—

[a]T-APA: targeted auricular point acupressure.

[b]*P*<.05.

[c]NT-APA: nontargeted auricular point acupressure.

[d]Variable not selected for the final model due to lack of statistical significance or contribution to model fit.

[e]Models adjusted for baseline demographics (age, sex, race, employment, smoking, and opioid use) and baseline recall pain variables (intensity and interference).

The Effects of APA Practice and Medication Use on EMA-Reported Pain Interference

Linear mixed-effects models showed that both APA interventions were significantly associated with reductions in EMA-reported pain interference outcomes compared to the control group. T-APA significantly reduced EMA-reported overall pain interference with enjoyment of life (β=–1.72, SE 0.37; *P*<.001), overall pain interference with daily activity (β=–1.41, SE 0.34; *P*=.001), current pain interference with enjoyment of life (β=–1.28, SE 0.40; *P*=.003), and current pain interference with daily activity (β=–1.27, SE 0.37; *P*=.001). NT-APA produced similar reductions in all EMA-reported pain interference outcomes, with effect sizes ranging from β=–1.21 to –1.50 (all *P*≤.002; Table 5).

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Table 5. The estimated coefficients and SEs of the main effects on pain interference.

	EMA[a]-reported overall pain interference				EMA-reported current pain interference			
	Enjoyment of life		Daily activity		Enjoyment of life		Daily activity	
	Estimate (SE)	*P* value	Estimate (SE)	*P* value	Estimate (SE)	*P* value	Estimate (SE)	*P* value
Group								
T-APA[b]	–1.72 (0.37)	<.001[c]	–1.41 (0.34)	.001[c]	–1.28 (0.40)	.003[c]	–1.27 (0.37)	.001[c]
NT-APA[d]	–1.21 (0.37)	.002[c]	–1.10 (0.34)	.002[c]	–1.45 (0.41)	<.001[c]	–1.50 (0.38)	<.001[c]
Control	Ref	Ref	Ref	Ref	Ref	Ref	Ref	Ref
Pressing frequency (times/day)								
≥3	0.44 (0.14)	.002[c]	—[e]	—	—	—	—	—
<3	Ref	Ref	—	—	—	—	—	—
Minutes per pressing								
≥3	–0.28 (0.14)	.04[c]	—	—	–0.21 (0.10)	.03[c]	–0.20 (0.10)	.047[c]
<3	Ref	Ref	—	—	Ref	Ref	Ref	Ref
Total pressing time (minutes)								
≥9	—	—	0.33 (0.13)	.009[c]	—	—	—	—
<9	—	—	Ref	Ref	—	—	—	—
Analgesic use								
Yes	0.68 (0.14)	<.001[c]	0.76 (0.14)	<.001[c]	0.58 (0.14)	<.001[c]	0.65 (0.13)	<.001[c]
No	Ref	Ref	Ref	Ref	Ref	Ref	Ref	Ref
Day of treatment	–0.02 (0.00)	<.001[c]	–0.02 (0.00)	<.001[c]	–0.02 (0.00)	<.001[c]	–0.02 (0.00)	<.001[c]
Covariates [f]								
Age	—	—	—	—	—	—	—	—
Recall worst pain	0.53 (0.10)	<.001[c]	0.46 (0.10)	<.001[c]	—	—	—	—
Recall average pain	—	—	—	—	—	—	—	—
Recall current pain	—	—	—	—	0.34 (0.07)	<.001[c]	0.33 (0.06)	<.001* [c]
Recall pain interference with enjoyment of life	0.35 (0.07)	<.001[c]	—	—	0.23 (0.06)	<.001[c]	—	—
Recall pain interference with daily activities	—	—	0.27 (0.05)	<.001[c]	—	—	0.30 (0.07)	<.001[c]

[a]EMA: ecological momentary assessment.

[b]T-APA: targeted auricular point acupressure.

[c]*P*<.05.

[d]NT-APA: nontargeted auricular point acupressure.

[e]Variable not selected.

[f]Models adjusted for baseline demographics (age, sex, race, employment, smoking, and opioid use) and baseline recall pain variables (intensity and interference).

APA practice behaviors were variably associated with EMA-reported pain interference outcomes. Longer pressing duration (more than 3 minutes per session) was significantly associated with lower EMA-reported pain interference in several domains. Participants with longer pressing time reported reduced EMA-reported overall pain interference with enjoyment of life (β=–0.28, SE 0.17; *P*=.04), current pain interference with enjoyment of life (β=—0.21, SE 0.10; *P*=.03), and current pain interference with daily activity (β=—0.20, SE 0.10; *P*=.047), but not with overall pain interference with daily activity. However, pressing more than 3 times daily was associated with greater EMA-reported overall pain interference with enjoyment

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of life (β=0.44, SE 0.14; *P*=.002), and total pressing time greater than 9 minutes per day was linked to greater EMA-reported overall pain interference with daily activity (β=0.33, SE 0.13; *P*=.009; Table 5).

Analgesic use was consistently associated with increased EMA-reported pain interference across all outcomes (β=0.58-0.76, all *P*<.001). Higher baseline recall pain interference scores predicted greater EMA-reported interference during the intervention. Specifically, baseline recall pain interference with enjoyment of life was associated with greater EMA-reported overall (β=0.35, SE 0.07; *P*<.001) and current (β=0.23, SE 0.06; *P*<.001) pain interference with enjoyment in life. Similarly, baseline recall pain interference with daily activities predicted greater EMA-reported overall (β=0.27, SE 0.05; *P*<.001) and current (β=0.30, SE 0.07; *P*<.001) pain interference with daily activity (Table 5).

Baseline recall of pain intensity was significantly associated with EMA-reported pain interference outcomes. Higher baseline recall of worst pain was associated with greater EMA-reported overall pain interference with enjoyment of life (β=0.53, SE 0.10; *P*<.001) and daily activity (β=0.46, SE 0.10; *P*<.001). Higher baseline recall of current pain was significantly associated with both EMA-reported current pain interference with enjoyment of life and daily activity (β=0.33-0.34, both *P*<.001). No significant associations were observed for age, sex, race, smoking status, employment, baseline opioid use, or baseline recall of average pain (Table 5).

Discussion

Principal Findings

This secondary analysis of EMA data from an RCT supports the real-time effectiveness of APA in managing cLBP among older adults. Our results build on the original trial's finding [6], demonstrating sustained improvements in self-reported pain and function while uncovering the dynamic relationship between APA practice and day-to-day symptom trajectories.

A key contribution of this study is the use of EMA to capture real-time symptom fluctuations. Compared to traditional 7-day recall measures, EMA consistently recorded lower pain intensity but higher pain interference scores. These findings align with prior research suggesting that retrospective methods may overestimate pain severity due to memory distortion and underestimate real-time disruptions to daily life [10,12,23,24]. This discrepancy may reflect the tendency of individuals to experience more interference in the moment but recall less of it afterward [25]. However, measuring interference with EMA remains methodologically complex; a prior study has found that interference ratings may be more variable and less reliable than intensity ratings in real-time formats [26]. Further research should evaluate the psychometric stability of EMA-based interference items to inform appropriate use in future trials.

This study was built on previous research by Yeh et al [27] and Lin et al [12], but with a larger sample size. EMA compliance in this study was lower (44.8%) compared to 87% in previous reports [12], and the attrition rate was higher (54% vs 17%-32%) [27]. Age was a significant predictor of lower compliance, suggesting potential barriers to EMA participation among older adults. While previous meta-analyses have found that younger participants may show quicker declines in EMA adherence over time [28], older adults may face distinct challenges, such as fatigue, cognitive burden, or technological limitations. A study recommends limiting EMA to 1 week to reduce the burden [29]; such an approach may hinder the ability to observe longitudinal treatment effects. An alternative strategy involves EMA burst designs, which collect intensive real-time data over brief intervals (eg, several days), repeated periodically over the course of an intervention [30,31]. This design may offer a compromise between detailed data tracking and participant burden, particularly for older adults or those with limited digital literacy.

The study also examined APA practice behaviors and their associations with pain outcomes. Pressing for more than 3 minutes per session was associated with reduced EMA-reported pain outcomes, including lower current pain intensity and reduced interference across several domains, consistent with prior APA dosing recommendations [27]. These findings support the importance of adequate per-session stimulation time. In contrast, more frequent pressing (≥3 times/day) was associated with higher EMA-reported worst and average pain intensity, as well as greater overall interference with enjoyment of life. Additionally, total daily pressing time over 9 minutes was linked to greater interference with daily activity, though it was not associated with pain intensity. These associations may reflect reverse causality, where individuals experiencing more severe symptoms press more frequently or for longer durations to manage discomfort. Prior studies have suggested that greater APA frequency improves recall outcomes [12,27], but this discrepancy highlights the importance of real-time assessment and individualized dosing. Taken together, these results suggest that per-session duration may be more influential than cumulative daily time and that optimal APA dosing strategies may vary across individuals and symptom profiles.

Exploratory analyses of baseline characteristics revealed that higher baseline recall worst, and average pain levels, which were associated with higher EMA-reported pain intensity and interference during the intervention, consistent with patterns observed in systematic reviews of cLBP populations [32]. Analgesic use was also associated with increased symptom burden, possibly reflecting higher baseline severity and treatment-seeking behaviors. Interestingly, older age was associated with lower EMA-reported pain intensity, suggesting potential differences in pain perception or response to APA in older individuals. These results underscore the importance of personalized APA strategies that take into account symptom severity, medication use, and age.

While these findings support the promise of dynamic, personalized interventions, real-world apps will require adjustments to the delivery infrastructure. In the RCT, participants received automated reminders, technical support, and weekly reinforcement—all of which would be difficult to replicate in standard care. Participants also used uniform smartphones and a simplified app. In practice, device variability, digital literacy, and lack of support may hinder EMA engagement [33]. Prior studies have shown that technological burden, lack of training, and inconsistent access to compatible

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devices are common barriers to sustained EMA use in older adult and chronic pain populations [34,35]. Future adaptations should prioritize user-friendly design, embedded prompts, automated troubleshooting, and brief onboarding to support participation across diverse settings.

Finally, the integration of EMA into APA trials opens the door to future development of just-in-time adaptive approaches that dynamically tailor support based on real- time symptom data. By detecting periods of elevated pain or interference in real time, these systems could prompt users to engage in APA or other self-management strategies at moments of greatest need. While not tested in this study, our findings support the feasibility of capturing real-time pain dynamics—a critical step toward implementing adaptive, personalized digital interventions [36-38]. Incorporating the features of just-in-time adaptive interventions into mobile platforms may further optimize APA delivery by enabling real-time behavioral support, especially for populations managing fluctuating symptoms.

Limitations

This study has several limitations that should be acknowledged. First, as a secondary analysis of an RCT, the inclusion criterion of having at least one EMA entry led to the exclusion of 61 participants, who were significantly older and had lower baseline pain interference scores. This introduces potential selection bias and limits generalizability to older adults with lower digital literacy or more advanced physical or cognitive limitations. Second, despite promising findings in a prior pilot study, EMA compliance in this trial was modest (44.8%), and attrition was high (54%), particularly among older participants. This may have affected the completeness and representativeness of real-time data and reduced statistical power to detect more nuanced effects. The high frequency of EMA prompts (up to 3 times daily for 4 weeks) may have contributed to measurement fatigue and burden, which are known challenges in older adult populations using mobile health tools [33-35]. Moreover, while the use of EMA allowed for rich, real-time data, the act of frequent self-monitoring may itself influence behavior or symptom reporting, a phenomenon known as EMA reactivity, which was not assessed in this study [39].

Additionally, pressing behaviors were self-reported and not objectively verified, which may introduce recall or social desirability bias, particularly in reporting APA adherence. The study's relatively short intervention duration (4 weeks) also limited the ability to assess long-term outcomes or sustained benefits. Although the use of standardized smartphones and technical support ensured uniformity during the trial, these supports may not be available in real-world practice, where diverse device use, technical variability, and digital inequity may pose barriers to implementation [30,31,38]. Finally, both T-APA and NT-APA protocols showed similar effects, which may limit the interpretation of treatment specificity and suggest the need for further mechanistic research to understand the role of point selection.

Conclusions

This study provides evidence that APA effectively reduces pain intensity and improves daily functioning and quality of life in older adults with cLBP. The use of EMA offers a valuable method for capturing real-time pain experiences, mitigating recall bias, and providing a more accurate assessment of treatment effects. However, challenges related to EMA compliance highlight the need for refined intervention protocols. Future research should focus on optimizing APA regimens, extending intervention duration, and improving EMA adherence to enhance its applicability in clinical practice. By addressing these considerations, APA has the potential to serve as a widely accessible and effective self-management strategy for chronic pain relief.

Acknowledgments

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Data Availability

The datasets analyzed will be available from the corresponding author on request.

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Conflicts of Interest

None declared.

Multimedia Appendix 1
CONSORT-eHEALTH checklist (V 1.6.1).
[PDF File (Adobe PDF File), 1218 KB - formative_v10i1e79612_app1.pdf]

Multimedia Appendix 2
Demographics and participants' characteristics.
[DOCX File , 28 KB - formative_v10i1e79612_app2.docx]

Multimedia Appendix 3
Distribution of individual EMA compliance rates among participants.
[DOCX File , 148 KB - formative_v10i1e79612_app3.docx]

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Abbreviations

APA: auricular point acupressure
BPI-SF: Brief Pain Inventory–Short Form
cLBP: chronic low back pain
CONSORT-EHEALTH: Consolidated Standards of Reporting Trials of Electronic and Mobile Health Applications and Online Telehealth
EMA: ecological momentary assessment
NT-APA: nontargeted auricular point acupressure
RCT: randomized controlled trial
T-APA: targeted auricular point acupressure

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Original Paper

School and Community Stakeholder Perceptions of a Free, Confidential Digital Mental Health Platform (Soluna): Mixed Methods Study Examining Barriers and Facilitators to Real-World Implementation at Scale and Early Impact

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Abstract

Background: Mental health disorders are common among adolescents worldwide; yet, access to preventive and early intervention services remains limited. Digital mental health platforms may help bridge this gap, but little is known about how these platforms are perceived, implemented, and adopted by school and community stakeholders during early stages of rollout in real-world youth-serving settings.

Objective: This study aimed to examine school and community stakeholders' perceptions of a new, free, confidential digital mental health platform for youth (Soluna by Kooth Digital Health) in its first year of rollout, focusing on its features, barriers, and facilitators to early implementation and adoption, and early stakeholder perceptions of its perceived impact on youth mental health.

Methods: Surveys were distributed to 77 stakeholders (54 school staff and 23 community staff) in California from February to April 2025. Eligible participants were frontline staff directly engaging with youth in settings where the platform was offered. Following the survey, 17 stakeholders (12 school and 5 community) participated in semistructured interviews via Zoom (Zoom Communications). Survey data were analyzed descriptively to summarize perceptions and experiences, while interview data were analyzed using inductive-deductive reflexive thematic analysis to explore themes related to implementation, facilitators, and barriers.

Results: Most stakeholders (71.4%) agreed that the platform positively contributed to youth well-being, and 89.6% felt comfortable referring youth to it, indicating good acceptability. Free access (91%), availability during nontraditional hours (45%), and ease of use (42%) were identified by stakeholders as the most valuable features for youth. Facilitators of adoption included digital accessibility (87%), confidential peer support (84.1%), and youth choice in engagement (85.7%). Key barriers included stigma around mental health (64.7%) and lack of awareness of the platform's benefits (61%). Qualitative findings revealed three main categories: (1) perceived impact, including support for youth from diverse backgrounds and use as a supplemental resource when traditional services are limited; (2) facilitators to implementation and adoption, such as direct referrals, peer promotion, accessible framing focused on coping and life skills, supportive materials, and engagement from platform staff; and (3) barriers to implementation and adoption, including stigma and phone or internet access challenges in school settings. Stakeholders also emphasized the importance of practical resources and ongoing support to build confidence in using and recommending the platform.

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Conclusions: Stakeholders viewed the platform as a valuable and accessible tool to support youth mental health, particularly in underserved communities. Findings suggest that digital mental health platforms should address external barriers to adoption, including stigma around mental health, while also increasing awareness of available resources. Providing tailored implementation support demonstrates progress in these areas and can further strengthen adoption and engagement. These findings offer actionable recommendations for improving the design and delivery of digital mental health platforms in real-world youth-serving settings.

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KEYWORDS

adolescent mental health; digital mental health; mobile health; app; implementation science; stakeholder perspectives; schools; community organizations

Introduction

Mental health disorders affect 15.2% of children and adolescents aged 10-19 years globally, with anxiety disorders most prevalent (4.9%), followed by depressive disorders (2.4%) [1]. In the United States, rates are substantially higher, with 31.9% of adolescents aged 13-18 years experiencing anxiety disorders and 14.3% experiencing mood disorders [2]. These disorders contribute to significant morbidity and mortality, with suicide ranking as the second leading cause of death among adolescents aged 15-19 years [3]. Multiple risk factors, including untreated mental disorders, family dysfunction, and acute psychosocial stressors, interact in complex ways to increase vulnerability, making early prevention efforts critical [3]. However, accessing preventive and early intervention services remains challenging. Shortages of licensed mental health care professionals, long wait times, and financial barriers limit timely access to care [4]. These challenges are especially pronounced in geographically underserved areas, such as rural communities, where psychological support may be scarce or entirely unavailable [5].

Adolescents and young adults are turning to mobile apps as a means of supporting their mental health and wellness more frequently [6]. However, many existing digital mental health services are accessible only through paid subscriptions or insurance-based models [7]. Insurance-based models in digital mental health services are those that can only be accessed when the cost is covered through a formal health care system, meaning individuals must qualify for coverage through their country's health services or employment benefits rather than being able to access the service freely and independently. These financial hurdles can lead to lower user engagement; adolescents and young adults report that they expect mental health apps to be free and are often reluctant to download apps that require payment when free alternatives are available [8-11].

The stigma surrounding mental health can deter adolescents from seeking help through traditional channels. For example, traditional mental health services (eg, outpatient clinics or private therapy sessions) may seem intimidating and overly clinical to adolescents, while parent involvement can amplify concerns about privacy and stigma [12]. Given that schools and community programs are central to how young people learn about and engage with mental health and wellness services [12-14], it is essential to provide mental health tools through these accessible, familiar avenues. In addition, digital mental health platforms that offer round-the-clock access to mental health support are crucial for those who face barriers to accessing face-to-face services (eg, geographically diverse areas and areas with shortages of licensed therapists) [5,15].

Given the rapid expansion of the digital health marketplace, now comprising over 350,000 mobile health apps worldwide [16], it is important to explore which aspects of real-world implementation are successful and scalable to ensure these platforms are sustained. In this context, a platform is defined as a multicomponent digital mental health system that integrates multiple services within a single digital environment, which may be accessed via a mobile app. Insights from established companies with successful platform rollouts can help identify key barriers and facilitators of scalable implementation, informing the launch of new platforms across diverse regions. Criteria for a successful rollout include effective adoption and sustained use across settings, consistent with implementation science frameworks [17]. Exploring this process in the first year of a platform's rollout provides an opportunity to capture early stakeholder-identified impacts, including potential systemic ripple effects that may not be easily quantifiable in broader health or education datasets.

The purpose of this paper is to provide a nuanced understanding of how school and community stakeholders view the offering of a free, confidential digital mental health platform for youth in their schools and communities during its first year of rollout. Guided by implementation science frameworks, including the Consolidated Framework for Implementation Research (CFIR) and Reach, Effectiveness, Adoption, Implementation, and Maintenance (RE-AIM) frameworks [18,19], this mixed methods study addresses the following aims:

1. Examine stakeholders' views of the platform's perceived impact on youth mental health and well-being as well as school or organizational contexts;
2. Identify barriers and facilitators influencing early implementation and adoption in real-world school and community settings; and
3. Explore downstream or distal effects of platform implementation, including perceived changes in staff workload and youth engagement in school and community settings.

Methods

Overview

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Throughout this paper, adolescents and young adults are collectively referred to as "youth." This terminology is used because the platform is available to those aged 13-25 years, and stakeholders in school and community settings provided general observations about youth in their settings, rather than reporting on specific individual users.

Soluna Platform

Kooth Digital Health has a longstanding history of scaled implementation in education and health care settings across the United Kingdom [20]. Building on this experience, the Soluna platform was launched by Kooth Digital Health, a commercial digital mental health company, at the start of 2024 [21]. Soluna is a free, confidential digital mental health and well-being platform designed to expand access to preventive and early intervention support for youth aged 13-25 years. Accounts can only be created by individuals within this age range, although demonstration versions are available for training and outreach purposes. The rollout of Soluna applies implementation processes used in previous settings to a new geographic context (the United States), creating an opportunity to examine early barriers, facilitators, and perceived impacts as observed by frontline stakeholders in youth-serving settings.

During Soluna's rollout, the platform was, and at the time of writing remains, available to all youth (aged 13-25 years) across California in a population-level approach [22-24], at no cost and without referral, insurance, diagnosis, immigration disclosure, or parental consent. Youth learned about Soluna through routine outreach and promotion efforts, including schools, community-based organizations, in-person events, digital media, and word of mouth. Youth could access Soluna by downloading the mobile app and independently registering using either a guest or a full account. Guest registration provided access to self-guided tools and content, while full registration enabled access to moderated peer support, one-to-one coaching with trained professionals, and care navigation services. Soluna is deployed statewide as part of the California Youth Behavioral Health Initiative [25]. This initiative aims to expand access to mental health services for youth throughout the state, particularly in underserved communities, and the Soluna platform plays a key role in supporting the California Youth Behavioral Health Initiative's goal of providing accessible, scalable mental health resources to California's youth population [26,27].

Soluna is free, eliminating financial and administrative barriers to participation and ensuring that young people can access routine mental health support anytime and anywhere. Users can search a repository for local clinical and nonclinical support, while the contact center provides translation services and technical assistance. The platform enables personalized, one-to-one support with trained professionals through live chat, telephone, or video sessions and offers coaching either on a drop-in basis or by scheduled appointment. In addition, users can journal, set and track progress on goals, and contribute to a human-moderated peer community to ensure safety and content appropriateness. The Soluna platform also includes robust care navigation services; highly trained care coordinators assist users in locating resources beyond the platform, such as services providing food, housing, and wider health needs, supporting access to behavioral health care and other critical services. Coordinators help users understand their insurance coverage, find network providers, assist with scheduling appointments, and provide access to services.

Soluna Implementation and Outreach

As part of Soluna's rollout in California, implementation included free promotional materials provided to schools and community organizations to support awareness and youth engagement. These materials were informed by early usability testing and feedback on terminology used in outreach and engagement efforts, with attention to accessible, nonclinical language where appropriate.

Materials included posters and flyers displaying QR codes linking directly to the platform, wallet-sized cards that youth could discreetly take with them, stickers, and phone "pop-its" (small, silicone, tactile phone accessories that attach to the back of a smartphone). Soluna staff were actively involved in implementation efforts, including hosting informational presentations and trainings for staff, participating in school- and community-based events, and conducting in-person outreach activities, such as tabling at community events and school sites.

This study focused on stakeholders' perceptions of Soluna's implementation in their settings and their observations of how the platform impacted youth and their schools or organizations. Because Soluna accounts were designed for youth aged 13-25 years, staff did not have user access to the platform and were not expected to provide direct user experience data; however, demonstration versions were available to support training, outreach, and stakeholders' understanding of the platform.

Recruitment and Participants

Participants were recruited via convenience sampling. Recruitment procedures did not differ across stakeholder groups; all contacts were emailed using the same process. Surveys were distributed via email in February and April 2025 to key stakeholders whose contact information was already held by the Soluna implementation team through previous engagement and communication. The distribution list included representatives from K-12 schools, community-based organizations, higher education institutions, mental health care providers, and other youth-facing entities.

The initial survey invitation was sent to 5539 California-based contacts, with a 25.17% open rate and a 7.96% click-through rate to the survey link. A second email was sent to 1300 individuals who opened the initial invitation but did not click through to access the survey; this follow-up email had a 72.31% open rate and a 7.13% click-through rate. No additional emails were sent to individuals who did not open the initial invitation.

All recipients received the same survey invitation and study information. The survey link directed respondents to a single instrument that branched automatically based on whether they identified as school- or community-based stakeholders. A total of 91 individuals completed the survey; 14 were deemed ineligible based on the eligibility screener. Interview participation was open to all eligible survey respondents who volunteered. Interviews were scheduled on a first-come,

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first-served basis, and recruitment concluded once thematic saturation was reached.

Data Collection

Before accessing the survey, participants completed screening questions to confirm eligibility: they had to be at least 18 years of age, reside in the United States, be able to read and write in English, and serve as frontline staff (directly interacting with youth) at a school- or community-based organization where the Soluna platform is offered. Eligible participants then completed the survey and indicated their willingness to provide further feedback via an interview. Those who expressed interest were invited to participate in one-on-one semistructured interviews conducted via a virtual video meeting (Zoom Communications). Interviews were conducted between February and April 2025 and were audio recorded and transcribed for analysis. Transcripts were deidentified and assigned unique study IDs before coding. These interviews lasted up to 30 minutes, and questions were tailored to the stakeholders' context; for example, the interview protocol was slightly adapted for school-based stakeholders (focusing on youth within their schools) vs community-based stakeholders (focusing on youth engagement in their organization).

Interviews were conducted by the lead author, a female research scientist with a PhD and formal training in qualitative research. At the time of the study, she was working as a research scientist. No previous relationships existed between the interviewer and participants before study commencement, and no nonparticipants were present during interviews. Participants were informed that the interviewer was a research scientist conducting the study on behalf of Soluna to understand school- and community-stakeholder perspectives on implementation, adoption, and perceived impact of the platform. The interviewer approached the analysis reflexively. While professional interest in digital mental health research may have shaped analytic attention, no a priori assumptions about expected findings were imposed, and themes were grounded in participants' accounts through iterative engagement with the data and memo writing. Field notes were taken during and immediately after each interview and reviewed following each interview to support analytic reflection.

Measures

The cross-sectional survey was investigator-developed by the study team and informed by the CFIR and RE-AIM frameworks [18,19] to capture both implementation factors and stakeholder perceptions of the Soluna platform. Questions included participant demographics, stakeholder roles, perceptions of the platform's impact on youth well-being and school or community environments, and the importance of various facilitators and barriers to adoption. Items were adapted for school- and community-based contexts to reflect stakeholders' direct experiences. The survey was administered via Google Forms. Multimedia Appendix 1 provides the exact survey items and response options.

Semistructured interview questions (Textbox 1) were developed by the study team to expand on survey findings and to elicit in-depth perspectives on implementation experiences. The interview guide was informed by CFIR and RE-AIM domains and designed to explore perceived impact, adoption, facilitators and barriers, and implementation needs in real-world settings [18,19]. The guide was reviewed internally by researchers with qualitative and implementation science expertise and refined through informal pretesting and team-based review before data collection. Minor adaptations were made to tailor questions for school- vs community-based stakeholders, while maintaining consistency in core domains across interviews.

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Textbox 1. Semistructured interview guide used with school- and community-based stakeholders.

Introduction:

- What is your role at the school or organization, and how do you interact with students or youth?

Facilitators:

- What school-wide or community organization–wide factors have supported Soluna's integration?
- Which Soluna features have been most effective for student or youth engagement and mental health?
- How has Soluna influenced engagement across different student or youth demographics?

Barriers:

- What challenges prevent students or youth from effectively using Soluna?
- Can you identify particular challenges faced by different student or youth demographics (eg, grade level, gender, ethnicity, or socioeconomic status) that hinder their engagement with Soluna?
- What school-wide or community organization–wide barriers make it harder to integrate Soluna?
- If you could improve one aspect of Soluna's implementation, what would it be?

Perceptions and feedback:

- What are your overall thoughts on Soluna and its impact on school or community organization culture?
- What feedback have you heard from students or youth about Soluna?

Personal experience and support:

- Have you explored Soluna yourself?
- Would additional training help you support students or youth?
- How has Soluna affected your workload?

Closing:

- Any final thoughts on Soluna's impact, challenges, or successes?

Data Analysis

Survey Data

Survey responses were analyzed in SPSS (version 29; IBM Corp [28]). Descriptive statistics summarized stakeholder perceptions of the Soluna platform. Frequencies and percentages were computed for categorical variables, while means and SDs were calculated for continuous variables.

Qualitative Interview Data

Qualitative analyses were conducted in Dedoose (SocioCultural Research Consultants, LLC [29]). The lead author analyzed semistructured interview transcripts using inductive-deductive reflexive thematic analysis [30,31]. As coding was conducted by a single researcher, rigor was supported through reflective practices (eg, memo writing and iterative engagement with the data), grounding theme development in participant quotations, and discussing emerging themes with a coauthor. The interview questions (Textbox 1) guided the initial coding phase, while additional codes were developed based on themes that emerged from the interviews. Survey and interview data were analyzed separately and then triangulated during interpretation by examining how qualitative themes aligned with or contextualized survey findings. The lead author read each transcript in its entirety, applied descriptive labels to key excerpts, and then organized similar codes into broader categories that captured stakeholder perspectives on barriers, facilitators, and implementation of the Soluna platform. From these categories, high-level findings were extracted that directly addressed the research aims and highlighted the key factors influencing the platform's real-world adoption.

Ethical Considerations

This study was approved by the BRANY Institutional Review Board (protocol no 24-086-1708). All participants provided informed consent electronically. Before accessing any survey items, individuals were required to read an online consent form and select "I agree to participate" to proceed. Survey responses were anonymous, and identifying information was not collected within the survey. To receive compensation, participants were routed to a separate, unlinked form to provide their email address, ensuring that contact information could not be connected to survey data. Participants who volunteered for an interview had already received information in the consent form about the interview procedures, including that interviews would be audio recorded and that recordings would be deleted after transcription, with identifying details removed. Verbal consent was reconfirmed at the start of each interview. All data were stored on a secure, encrypted drive to protect confidentiality. Participants received a US $10 Amazon gift card for completing the survey and a US $25 gift card for participating in an interview.

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Results

Participants

Seventy-seven stakeholders completed the survey: 54 school staff and 23 community staff. School respondents were primarily counselors or support personnel, while community respondents most often served as outreach workers or program directors. Overall, 83.1% of participants identified as women, and 50.6% identified as Hispanic or Latino(a). Stakeholder demographics are outlined in Table 1. Regarding implementation, Soluna had been offered at nearly half (49.4%) of schools and community organizations for 4-11 months. Following the survey, 17 stakeholders (12 school and 5 community) completed follow-up qualitative semistructured individual interviews.

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Table 1. Demographic characteristics of school and community stakeholders participating in the Soluna study (N=77).

Demographic characteristic	Value, n (%)
Current role	
School stakeholders (n=54)	
Other school staff (eg, behavioral health therapist, support coordinator, mental health counselor, social worker, and wellness coach)	36 (66.70)
Guidance counselor	12 (22.20)
Teacher	3 (5.60)
Principal	2 (3.70)
School nurse	1 (1.90)
Outreach staff	6 (26.10)
Director or assistant director	5 (21.70)
Community stakeholders (n=23)	
Other (eg, program coordinator and social service worker)	4 (17.40)
Counselor or therapist	2 (8.70)
Manager or supervisor	2 (8.70)
Peer specialist	2 (8.70)
Case manager	1 (4.30)
Administrative support staff	1 (4.30)
Years working as school or community staff (years)	
0-2	11 (14.50)
3-5	23 (30.30)
6-9	15 (19.70)
≥10	27 (35.50)
Length of time Soluna has been offered at the school or community organization	
1-3 months	5 (6.50)
4-6 months	16 (20.80)
6-11 months	22 (28.60)
1 year	17 (22)
>1 year	17 (22.10)
Gender	
Women	64 (83.10)
Men	12 (15.60)
Nonbinary or nonconforming	1 (1.30)
Race or ethnicity	
Hispanic, Latino, or Latina(a)	39 (50.60)
White	22 (28.60)
Multiple races	10 (13)
Black or African American	2 (2.60)
Asian	1 (1.30)
Native Hawaiian or Pacific Islander	1 (1.30)
Native American or Alaska Native	0 (0)
Age (years), mean (SD; range)	37.45 (10.30; 22-60)

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Quantitative Survey Findings

Stakeholder Perceptions of Impact

Quantitative survey results offer insight into stakeholder perspectives on Soluna's implementation and impact. Table 2 summarizes the proportion of respondents who agreed with each survey statement. Overall, survey responses reflected strong stakeholder endorsement of Soluna. Most stakeholders reported feeling comfortable referring youth to the platform (89.6%). The majority also agreed that the platform contributes positively to youth well-being (71.4%), addresses general mental health needs (76.6%), and is a safe and confidential resource (84.1%). While fewer stakeholders agreed that Soluna facilitates communication between youth and staff about mental health (62.2%) or supports a positive climate and culture (56.9%), these findings still indicate a favorable perception of the platform's impact across schools and communities.

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Table 2. Survey responses from school and community stakeholders on Soluna's early implementation and impact (N=77).

Construct	Overall agreement (agree and strongly agree), n (%)
Stakeholder perspectives of Soluna and its impact	
Positive well-being impact	55 (71.40)
Referral comfort	69 (89.60)
Positive climate and culture impact	44 (56.90)
Positive behavior change	38 (49.30)
Develop better emotional regulation skills	46 (59.70)
Positive youth interactions with each other (community) and positive academic impact (school)	26 (33.50)
Facilitate communication about mental well-being between youth and staff	48 (62.20)
Effective addressing the mental health needs of youth	59 (76.60)
Effective addressing the mental health needs of youth from racial or ethnic minority backgrounds	50 (64.90)
Effective addressing the mental health needs of youth from gender minority backgrounds	49 (63.30)
Confidence in the privacy and security of Soluna	59 (76)
Effective in addressing or reducing bullying	22 (28.50)
Contributed to the reduction in absenteeism	20 (26.60)
Confidence Soluna safe platform to receive mental health support	65 (84.10)
Top 3 features most valuable to youth[a]	
No cost	70 (91)
Access during hours when traditional mental well-being supports are not available	35 (45)
Easy to access	32 (42)
No formal referrals needed	23 (30)
No waiting list for professional support	18 (23)
Reduced stigma around accessing anonymous support	14 (18)
Safe place to receive mental health support	12 (16)
Addresses a variety of mental health issues	5 (6)
Facilitators of youth's use of Soluna services	
Positive feedback from youth	57 (73.90)
Strong support from school and community staff	44 (57.10)
Engagement initiatives (workshops and information sessions)	37 (47.50)
Accessible resources and training	57 (74)
Ability to access mental health support through digital apps	67 (87)
Confidential peer support	65 (84.10)
Youth choice in what they engage in	66 (85.70)
Youth need to understand what help they can get	65 (84.10)
Barriers to youth's use of Soluna services	
Lack of internet access	30 (39)
Lack of time for use during school or in the community	34 (44.30)
Stigma around mental health	50 (64.70)
Lack of understanding of the platform	39 (50.80)
Lack of awareness of the benefits of the platform	47 (61)
Reluctance to engage with services	33 (42.30)
Resistance from parents or guardians	28 (36.40)

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Construct	Overall agreement (agree and strongly agree), n (%)
Privacy or confidentiality concerns	22 (28.60)
Overall thoughts of Soluna	
On a scale from 1 to 5, how likely are you to recommend Soluna to other schools or organizations for students or youth? Answered “4” or “5”	73 (94.60)
Have you directly referred any of the youth in your community to Soluna? (community) Answered “Yes”	65 (84.20)
Have you directly referred any of your students to Soluna? (school) Answered “Yes”	65 (84.20)
Overall, how pleased have you been with Soluna in terms of the goal to increase access to mental well-being support at your school or organization? Answered “Quite pleased” or “Very pleased”	67 (86.90)
How confident are you that Soluna benefits school staff or organization staff in their role supporting students’ or youth mental well-being? Answered “Confident” or “Very confident”	64 (83.10)
Do you think Soluna has helped to increase students’ engagement and concentration in school, and ultimately their academic outcomes? (school) Answered “Somewhat” or “Yes”	64 (88.70)
Do you think Soluna has helped increase youths’ engagement in community-based programs? (community) Answered “Somewhat” or “Yes”	74 (95.70)
Soluna implementation and integration	
Soluna presentation or event attendance: Answered “Yes”	57 (73.90)
Reason for absence at Soluna presentation or event attendance	
Answered: “Not Aware”	15 (19.50)
Answered: “Time Conflict”	3 (3.90)
Answered: “Not Applicable”	25 (32.50)
Received an email from Soluna about the offering at the school or organization. Answered “Yes”	65 (84.40)
Read email: Answered “Yes”	63 (81.80)
Reason for not reading the email: Answered “Not Applicable”	43 (55.80)
School has signage (posters, fliers, etc) about Soluna: Answered “Yes”	60 (78)
Signage appropriately placed for maximum visibility: Answered “Yes”	50 (65)
Soluna implementation and integration	
The presentation or event was useful to me for understanding all that Soluna offers to students.	
Answered: “Agree”	54 (70.70)
Answered: “Not Applicable”	13 (16.90)
The email about Soluna was useful for me in understanding all that Soluna offers to students.	
Answered: “Agree”	62 (80.20)
Answered: “Not Applicable”	4 (5.20)
The Soluna posters and signage around the school are useful for students to learn about Soluna.	
Answered: “Agree”	55 (71.40)
Answered: “Not Applicable”	13 (16.90)
I feel confident in knowing when to refer a student to Soluna.	
Answered: “Agree”	62 (80.40)
Answered: “Not Applicable”	7 (9.10)
Having Soluna has contributed to a decrease in my workload.	
Answered: “Agree”	22 (28.60)
Answered: “Not Applicable”	7 (9.10)

[a]The results are not mutually exclusive. Stakeholders selected up to 3 features they considered most valuable.

Each construct corresponds to a parallel survey item; for example, “Soluna has positively contributed to the overall

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well-being of our students" (school) and "Soluna has positively contributed to the overall well-being of youth in our community" (community).

Top Features

Across all stakeholders, the feature most frequently identified as most valuable for youth was Soluna's free access (91%, n=70). This was followed by access during nontraditional hours (45%, n=35) and ease of access (42%). Other features stakeholders identified as valuable to youth included "no formal referral needed" (30%, n=23), "no waiting list for professional support" (23%, n=18), and "reduced stigma around accessing anonymous support" (18%, n=14). In addition, 16% (n=12) selected "a safe place to receive mental health support," and 6% (n=5) selected "the platform treats a variety of issues" as a top feature. Because respondents could choose only up to 3 most valued features, percentages for some items are lower, and totals exceed 100%, but this does not necessarily indicate low perceived value for those features.

Facilitators and Barriers

Stakeholders identified several key facilitators of youth's use of Soluna in their school or community (Table 2). The most widely endorsed was the ability to access mental health support through digital apps (87%, n=67). High agreement was also reported for the value of confidential peer support (84.1%, n=65) and providing youth with choice in what they engage in (85.7%, n=66). In addition, 74% of stakeholders agreed that accessible resources and staff training facilitated youth engagement with Soluna services. Stakeholder engagement initiatives, such as workshops and information sessions, were less frequently endorsed as facilitators (47.5%, n=37).

Stakeholders identified several common barriers to youth use of Soluna in their school or community. The most frequent barriers endorsed were stigma around mental health (64.7%, n=50) and lack of awareness of the platform's benefits (61%, n=47). Nearly half (44.3%, n=34) reported that lack of time for youth's use, either during school hours or at their community organization, was a barrier, and 39% (n=30) identified internet access issues as a limiting factor.

Overall Adoption and Satisfaction

Nearly all stakeholders reported they would recommend Soluna (94.6%, n=73) and had already referred to youth (84.2%, n=65). Overall satisfaction with Soluna was high (86.9%, n=67), and 83.1% (n=64) were confident that Soluna benefits staff in supporting student or youth mental well-being. The study also explored potential downstream effects on youth concentration and engagement. The majority of stakeholders perceived that Soluna had improved youth concentration in school (88.7%, n=64 indicated somewhat or yes) and engagement in community-based programs (95.7%, n=74 indicated somewhat or yes).

Implementation and Integration

Most stakeholders had attended a Soluna presentation or event (73.9%, n=57), received (84.4%, n=65), and read (81.8%, n=63) related emails, and reported visible poster signage in their schools or communities (78%, n=60). The majority found these communication channels useful for understanding Soluna (presentations: 70.7%, n=54 and emails: 80.2%, n=62) and felt confident in knowing when to refer youth to Soluna (80.4%, n=62). A more distal impact examined was staff workload, and 28.6% (n=22) of stakeholders reported that Soluna had already begun to reduce their workload during early implementation.

Qualitative Interview Findings

Qualitative analysis of 17 stakeholder interviews revealed three main categories with associated themes: (1) early impact, (2) facilitators to successful real-world implementation and adoption, and (3) barriers to successful real-world implementation and adoption. Themes are presented in order of frequency (n), with full counts and example quotes available in Multimedia Appendix 2.

Early Impact

Platform Impact on Youth From Diverse Backgrounds

Stakeholders reported that Soluna had a positive impact on youth, noting that it was especially important for those from diverse contexts, including minoritized, rural, and low-income communities, where access to mental health resources was limited or conversations about mental health were often stigmatized.

> *We don't have resources out here for our students. So, having something literally at their fingertips has been very beneficial. It's a small community, and it's on the outskirts of the county. So apps, like Soluna, are just so important.* [School Stakeholder #3, Female]

Platform Impact on Stakeholder Workload

Stakeholders shared that they appreciated the platform as a valuable resource for supporting youth, particularly during times of staff shortages or high demand, even though it did not directly reduce their broader workload. Stakeholders appreciated that the platform allowed them to continue offering youth a form of support during times of high demand.

> *I think, for us it hasn't necessarily changed our workload, but it's an added service that we can't provide…with Soluna they have that option to still reach out to somebody. It's been an added benefit to what we're already doing.* [School Stakeholder #2, Female]

> *I feel like it's just helpful to offer another option. We have around 1,200 students and there's only four of us that get to speak with students. Our students' needs are very high. So it's nice to offer something else for the students.* [School Stakeholder #10, Female]

Facilitators to Successful Real-World Implementation and Adoption

Materials and Merchandise From Soluna

Stakeholders noted that Soluna's promotional materials, such as stickers, pop-its, and posters, helped raise awareness and pique the youth's interest in the platform. These materials served as tangible reminders to explore the platform, with stickers and

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pop-its being especially effective in catching youth attention and sparking curiosity.

> *Things that I think connected them was when we had the stickers and little phone pop things that they had that they could put on their phone. Those kind of things. Kids like free swag. And they were like, 'okay, free stuff. We're cool with that.' But then, when they realized it was free stuff that had kind of a meaning behind it.* [Community Stakeholder #11, Female]

> *I was giving out stickers, and then a month later I was talking to a student about something, and she said, 'Oh, yeah, I use that tool from the app you told me about.' I'm like 'Oh!' And at that point we hadn't really dove deep into it. And she was like 'You were giving out free stickers on the picture day', and she had taken it upon herself, downloaded the app and was using the toolkit.* [School Stakeholder #4, Female]

Stakeholders highlighted the value of the promotional materials provided by Soluna, noting that having ready-to-use resources supported outreach efforts and made it easier to introduce the platform to youth. Materials such as posters, flyers, QR codes, and other take-home items were described as practical tools that could be easily distributed during events or during one-on-one interactions. Stakeholders also emphasized the importance of having materials available in Spanish, which supported outreach in communities with large Spanish-speaking populations.

> *They've given us all the material. So all you have to do is either print it out, and they'll give us flyers, so we just print them out in English and Spanish, and when we go do outreach with what they've given us, the youth coloring pages. So we take those to our events.* [School Stakeholder #3, Female]

> *It's been great with like the merch. I think it really helps just having something physical, tangible that I can give to students. You're like, "Hey, remember, Soluna, is this great app?"* [School Stakeholder #10, Female]

Platform-Specific Factors

Stakeholders highlighted several platform features that made it attractive to youth. The platform's confidentiality was a major influence, as stakeholders expressed that youth valued the ability to access mental health resources anonymously.

> *I did have a learner say that they've used it a couple of times, so they really liked it. They like the privacy, being anonymous, not having any trail left back to them. [School Stakeholder #9, Male] Another stakeholder shared: They love the confidentiality.* [School Stakeholder #2, Female]

In addition, the platform's digital format, offering 24/7 access, was crucial for youth who might not have access to mental health services outside of school hours.

> *The app and all of the features. They can use it, you know, at night time, when they need to.* [School Stakeholder #17, Female]

Stakeholders emphasized the platform's free nature, noting that youth were often surprised by the range of features available at no cost.

> *It was easy to use and it was really just accessible. And she [student] was just really surprised of how much you guys were able to offer through a free app.* [School Stakeholder #6, Male]

Stakeholders emphasized that youth aged 13 years and older could access Soluna without parental permission, which they viewed as a significant advantage over other services that require signed parental release forms. They felt this reduced a barrier for youth who might otherwise hesitate to seek support due to concerns about parental resistance.

> *So I know for sure Hazel Health is telehealth, and it's therapy. And the students need to have a parent release form while Soluna doesn't. So that's a big advantage. For the students to access services without parent permission. Especially if they are 13 and older.* [Community Stakeholder #2, Female]

Referrals

Stakeholders frequently referred youth to the platform, particularly in situations where mental health resources were constrained, such as during school session breaks or in areas with high demand for mental health services. Referrals were particularly effective in getting youth to explore the platform during times when other support options were limited.

> *Even trying to find, therapy places, clinics, there are not a lot of options close for our community. So I have been telling the students that they can use the app to chat with a coach.* [School Stakeholder #9, Female]

> *Because of the difficulty and access to care, I end up with a lot of teenagers who didn't have a therapist who was a good fit, or didn't really get the coping skills they were looking for. So once Soluna was offered, I do the same, vetting like I do with any other outside community resources.* [Community Stakeholder#8, Female]

Stakeholder Presentation of Soluna

Stakeholders described their role in presenting the platform to youth as a crucial factor in its adoption. They found that emphasizing Soluna's practical benefits, such as coping skills or solutions to specific challenges, including bullying or academic stress, was more effective than using clinical mental health terminology.

> *Sometimes I refer to it [Soluna] as a coping skills app. As a distraction, tool. And that has been received better. Because when I do say 'mental health app', students are like, 'well, my mental health is fine' or like, 'I don't want to work on my mental health.' So when I reframe it, it definitely does help.* [School Stakeholder #13, Female]

> *When I say life skills training then there is a different kind of opening.* [Community Stakeholder #2, Female]

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Soluna Engagement Team

The involvement of Soluna representatives in providing training, presentations, and support was considered a significant facilitator in promoting the platform. Stakeholders appreciated the direct engagement and expressed a desire for continued support from representatives to help with ongoing adoption efforts.

> *I think what really helped in terms of getting youth involved with Soluna, and how we were able to really incorporate was the help from the Soluna ambassador. She just was really helpful and passionate about getting our students involved in Soluna.* [Community Stakeholder #6, Male]

> *In a perfect world, it would be great to have an actual human that we know is our person. We know it's helpful, and we know that students have liked it in the past. So if there was funding, resources to be able to have a representative here.* [School Stakeholder #13, Female]

One-on-One Instruction

Another key factor in promoting adoption was one-on-one instruction. Stakeholders reported that walking the youth through the platform, explaining its features, and demonstrating its benefits helped the youth feel more comfortable downloading and using the platform.

> *They [youth] like me walking through it, cause I also know…just this population you have to put it in front of them for them to even recall that it's there. So I'm intentionally like, 'we're gonna look at this one and this one. And I'm gonna show you like, this is a multi-purpose app.'* [Community Stakeholder #7, Female]

Hear From Other Youth

Several stakeholders pointed to the importance of peer recommendations in encouraging youth to use the platform. Stakeholders explained that youth who had used the platform and found it helpful often shared their experiences with peers, motivating others to explore the platform.

> *I know that they've [youth] been mentioning Soluna as a resource in their workshops that they run at lunchtime and activities. And so it's obviously beneficial. If students are the ones talking about the app and not just adults. So I think that is key… I think that's really powerful when other youth see youth sharing something that's engaging to them, and helpful.* [School Stakeholder #6, Female]

> *She [teacher] had two girls who were having issues like bullies and things like that, and one of the girls was like, 'well, here, download this on your phone.'* [Community Stakeholder #15, Female]

Barriers to Successful Real-World Implementation and Adoption

Lack of Instructions

Several stakeholders mentioned that the lack of detailed instructions on the platform's features and resources was a significant barrier to adoption.

> *I can't use it. Like telling someone 'these are the steps you're gonna do' is very different than actually doing it.* [School Stakeholder #2, Female]

> *I think we're in an era where kids look up everything on TikTok and so like just having very basic videos on like this is how you access this. This is how you set up a meeting would be super helpful for them just to feel like extremely confident in what they're doing, what they're setting up. I think that it is a lot of the anxiety of starting something new and doing this. So I definitely think videos or like just tutorials would help them a lot.* [School Stakeholder #1, Female]

Stakeholder Desire for Local Usage Data

Stakeholders expressed strong interest in understanding how many youth are using Soluna and the reasons behind their engagement. They felt this information would help them better facilitate adoption.

> *The biggest thing would be a count of like people that have downloaded it or used it, or something. You know, in my position I push a lot of information out to them, but to us, knowing that they are using it or seeing like if there's an influx going on would be helpful.* [School Stakeholder #10, Male]

Phone Restrictions (Parental and School Policies)

Stakeholders frequently cited restrictions on phone use both at home and at school as significant barriers to the platform's use. Parental limits on screen time, along with youth being grounded or having limited phone access, often prevented them from using the platform when needed.

> *Now we're like a completely cell phone-free school. And so the students don't have access to put those things on their phone at school.* [School Stakeholder #7, Female]

> *I do know that certain students, especially when they get in trouble they get their phone taken away. But there's this underlying mental health issue. But now they can't access it.* [School Stakeholder #9, Female]

Lack of Awareness

A common barrier identified by stakeholders was a general lack of awareness among youth about the platform's existence and its potential benefits. Stakeholders noted that youth are often inundated with numerous other apps and digital tools. Stakeholders also noted that some youth were skeptical about the platform being truly free, as they are typically accustomed to encountering hidden costs in digital apps.

> *It doesn't get recognized enough where on the app you're able to talk with a professional. It just seems*

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> *relatively a little bit confusing to me, cause I was like 'is it free'? It is a free option. I feel like that needs to be expressed a little bit more, because I feel like that's one of the biggest selling points of the Soluna app.* [Community Stakeholder #6, Male]

> *I just feel like everybody's kind of inundated with apps and there's an oversaturation, I guess, in the market of similar products. So I think a lot of students and families, especially think that there's some sort of catch, you know.* [School Stakeholder #7, Female]

Mental Health Stigma

Stakeholders reported that mental health stigma was a barrier to youth engagement. This included stigma at the community and cultural level, as well as the youths' own discomfort with seeking help or participating in practices such as counseling, meditation, or breathing exercises. Stakeholders shared that this stigma often deterred some youth from seeking help or using mental health tools, including the platform.

> *I think the main barrier is the stigma of needing someone to talk to, or needing to speak to a counselor or that kind of stuff. There's so many youth we have, particularly in lower-income communities where it's still a stigma and seen as a weakness…You know, because in the Hispanic community things like depression and anxiety, we don't talk about those things. That's just not something that we do.* [Community Stakeholder #12, Female]

Discussion

Overview of Findings

The purpose of this mixed methods study was to (1) examine stakeholders' views of the platform's perceived impact on youth mental health and well-being and on school or organizational contexts, (2) identify barriers and facilitators influencing early implementation and adoption in real-world school and community settings, and (3) explore downstream or distal effects of platform implementation, including perceived changes in staff workload and youth engagement in school and community settings. Both quantitative and qualitative data revealed important barriers and facilitators to the platform's implementation and adoption in the first year of the platform's launch in California, along with valuable suggestions for implementation strategies for similar digital well-being platforms. These insights contribute to a deeper understanding of how digital mental health platforms can be more effectively integrated into youth support systems, ensuring broader engagement and sustained use. Many stakeholders perceived the platform as positively impacting youth well-being and supporting youth mental health. These findings can be used to inform future research and guide practical strategies for the sustainable integration of digital mental health tools into everyday settings for youth, ultimately enhancing overall youth wellness and support.

Perceived Benefits for Youth Mental Health and Well-Being

Both the quantitative survey and qualitative interviews highlighted that stakeholders felt the platform was a valuable tool for addressing youth mental health needs. The survey responses suggested that the platform contributed positively to youth well-being, while the qualitative interviews further elaborated on how the platform provided a critical resource, especially for youth in underserved or low-resource settings. Stakeholders perceived the Soluna platform as having a positive impact on youth mental health.

Impact

While the stakeholder survey assessed specific perceived impacts on youth well-being, mental health, and staff workload, the qualitative interviews relied on a single open-ended question, capturing where stakeholders perceived Soluna had an impact but not necessarily the full range of possible impacts. Stakeholders felt that Soluna had a significant impact on youth from diverse backgrounds, particularly in underserved areas, where stakeholders said it filled a crucial gap in mental health services. For underresourced communities, digital mental health platforms can be crucial in bridging gaps in mental health services, offering accessible, confidential, and free support where traditional resources are lacking [32]. To maximize their impact, digital mental health companies should focus on partnerships with local organizations and explore funding opportunities to ensure these platforms reach the communities that need them most while maintaining financial sustainability. Soluna's approach of working closely with schools and community organizations during early implementation shows that such collaboration is critical for driving adoption and increasing reach.

Our findings suggest that digital mental health platforms can play a critical role in supporting school and organizational staff by providing an accessible way to extend mental health support to youth, especially in environments where resources are scarce. Although stakeholder workload was not a primary outcome, it was examined as an exploratory indicator of potential distal effects of platform implementation. While roughly one-third of stakeholders reported a perceived reduction in workload in the quantitative survey, qualitative findings suggested early ripple effects of implementation in school and community settings.

Facilitators to Successful Real-World Implementation and Adoption

Stakeholders identified promotional materials as critical to Soluna's successful implementation. Free resources such as posters, QR codes, and cards raised awareness in classrooms and offices, while cards provided a discreet way for youth to access information without directly asking for help. Spanish-language versions further expanded reach in diverse communities. Digital mental health platforms seeking broader adoption should consider a similar approach, offering free promotional materials to schools and community organizations. Branded items such as stickers and pop-its were also effective in sparking curiosity and increasing awareness of the platform. Studies suggest that extrinsic incentives can help spark initial

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interest in mental health tools, especially when the tools are seen as personally relevant and useful [33]. For digital mental health companies, stakeholders identified that branded items may offer an approachable entry point that helps normalize mental health conversations and raise awareness, making them a worthwhile strategy to consider for encouraging early engagement.

Platform-specific features also supported adoption. Stakeholders emphasized confidentiality, anonymity, 24/7 access, no cost, and no requirement for caregiver permission as central factors influencing youth engagement. These findings are consistent with evidence that cost and parental consent remain major barriers to care [33,34]. Ensuring platforms remain free and self-accessible is therefore essential to reaching youth who may otherwise go without support.

Direct referrals further strengthened adoption, particularly during times when traditional services were less available, such as school breaks or in high-demand settings. Youth were also likely to recommend the platform to peers, creating additional pathways for engagement. This aligns with evidence that peer influence strongly motivates youth to engage with mental health resources [35], and research suggests direct referrals are associated with lower dropout from digital mental health tools [36]. Ohio's youth peer advocate initiative trains young people with lived experience to share resources and guide peers toward mental health support, helping to build awareness and trust [37]. Adapting similar peer referral models for digital platforms may offer a promising strategy to boost youth engagement and sustained use. Soluna is applying a similar approach through its Youth Ambassador Program and upcoming peer-to-peer content-sharing features. Future research should evaluate the impact of these initiatives on stakeholder perceptions, as well as on real-world engagement and retention with the platform.

Stakeholders found that using language that emphasized the practical benefits of the platform, such as coping skills and solutions to specific challenges, such as academic stress or bullying, resonated more effectively with youth than framing the platform purely as a mental health tool. Research suggests that stigma often discourages youth from seeking mental health support, and that they prefer tools offering immediate, tangible benefits such as symptom relief, mood improvement, and self-reflection [10,38]. Using nonclinical language and emphasizing real-world relevance may help digital mental health platforms feel more approachable and meaningful in young people's daily lives [12].

Personalized support to schools and community organizations at multiple levels was key to successful implementation and engagement with the Soluna platform. Training, presentations, and continued engagement from Soluna staff equipped school and community partners to introduce the platform effectively. One-on-one instruction during initial use was especially influential in helping youth feel comfortable returning to the platform. These findings reinforce the importance of ongoing professional support to sustain the integration of digital mental health tools [39]. Digital mental health companies should consider investing in ongoing, personalized support through trained individuals, either in person or through digital channels, who can provide instruction, presentations, and direct engagement with schools and community organizations. Experience from Soluna in California suggests that combining low-barrier access to digital platforms with sustained, meaningful in-person engagement and localized partnerships is central to achieving reach, adoption, and maintenance [19].

Barriers to Successful Real-World Implementation

Several barriers to the real-world implementation of the Soluna platform were identified. Stakeholders expressed a need for clear instructions surrounding the platform features and resources, along with a demo mode to allow both youth and staff to explore the platform before committing to use. Stakeholders expressed that without a way to fully experience the platform's features, it was difficult for them to promote it effectively to youth. Ensuring sufficient onboarding support is essential to enable broader user engagement and facilitate the wider implementation of digital mental health interventions. For instance, a systematic review identified that technical issues are common barriers to user engagement with digital mental health interventions [40]. In addition, program usability, including clear instructions and accessible design, significantly influences young people's engagement with web-based mental health interventions [10]. Incorporating comprehensive onboarding processes, such as interactive demos and clear instructional materials, could facilitate the adoption and sustained use of digital mental health platforms among youth [41]. Learning from early implementation and how users engage with the digital tools can also provide a feedback loop to adapt and improve engagement materials and onboarding flows.

Several stakeholders desired metrics on how many youth were using the platform at their schools or organizations. Without this data, it was difficult for stakeholders to assess whether their efforts were successful or to determine how effectively the platform was being used. This lack of insight also made it challenging for stakeholders to identify patterns or adjust their strategies to improve engagement. However, data sharing is complicated by the platform's confidential nature, as users are not linked to a specific school, and there are limitations on sharing ZIP code–level data due to privacy concerns. As a potential solution, digital mental health companies could implement QR code tracking or in-app self-report features to help identify referral sources while preserving user anonymity. Companies can also share aggregate, non–school-specific reports with schools and organizations that include actionable recommendations based on overall data trends to inform outreach and implementation strategies. Such sharing should be coordinated with the contract payer to determine what engagement data can be appropriately shared.

There were also logistical barriers identified by stakeholders, such as phone restrictions imposed by schools, which further hindered platform engagement. These findings underscore the need to address external constraints, such as school policies, limited access to devices, and the importance of educating parents about the platform when implementing digital mental health platforms for youth. Meta-analytic evidence shows that school-based mental health interventions are most effective when delivered frequently and integrated into the school day,

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highlighting the value of allowing structured access to digital platforms during designated periods [42]. Schools should consider integrating structured access to digital mental health platforms during designated periods. In addition, schools could offer virtual or social media–based parent education to increase awareness of how digital mental health tools support youth and encourage access during times of distress. Such efforts can build shared understanding and reduce barriers to help-seeking [43].

Low awareness among youth was another barrier during the first year of launch. Some youth were unaware of Soluna's availability or benefits, which limited early adoption. As with many digital platforms, an initial adoption period is expected, during which awareness and trust build over time [44]. One option to help promote awareness is to involve trusted adults, such as school or library staff, in sharing information about the platform. For example, public libraries often conduct weekly school outreach, youth-focused events, and partnerships with schools, park districts, and mental health clinics to promote programs and connect youth to resources [45]. These strategies can help make digital tools more visible and accessible to youth in familiar, supportive environments.

Finally, stigma remained a significant barrier, especially in communities where mental health is not openly discussed. Stakeholders from certain cultural communities noted that stigma discouraged youth from seeking help. This is consistent with research showing that stigma disproportionately affects youth from racial and ethnic minority backgrounds [46]. Schools and community organizations should collaborate with digital platforms providing well-being or mental health services on education-based, culturally tailored interventions led by trained facilitators to reduce stigma and normalize mental health discussions among youth [47].

Recommendations for Mental Health Companies and Industry Professionals

Based on the findings from this study, we make several recommendations for digital mental health companies developing platforms for youth and for researchers involved in their evaluation. These recommendations aim to bridge the gap between research insights and real-world implementation challenges, ultimately improving the design and effectiveness of digital mental health tools for youth. Table 3 outlines key issues identified in the study and provides tailored recommendations for both digital mental health companies and industry professionals (eg, behavioral scientists and product engineers).

Table 3. Recommendations for digital mental health companies and industry professionals informed by stakeholder interviews.

Issue or topic	Recommendation for industry professionals	Recommendation for digital mental health companies
Stigma and mental health framing	Collaborate with product teams to develop and test messaging that focuses on coping skills and well-being to reduce stigma.	Frame the platform in terms of skills building (eg, coping strategies and emotional regulation) and mental well-being rather than focusing on clinical mental health language; develop culturally tailored campaigns that normalize mental health support.
Low awareness among youth	Partner with communications and IT teams to integrate platform promotions into student portals, learning systems, and routine announcements.	Invest in youth-led, peer-to-peer, and influencer-driven campaigns; build social media toolkits co-designed with youth to increase reach and relatability.
Lack of usage data for stakeholders	Use QR codes and in-app self-report prompts to track referral sources while preserving anonymity.	Share aggregate, non–school-specific reports with schools and organizations that include actionable recommendations based on overall data trends to guide outreach and implementation.
Importance of direct support and training	Coordinate with program managers to establish a cadence of representative-led orientations and refreshers throughout the year.	Fund and train a team of community engagement specialists to deliver school-based and community training sessions (live or virtual) and build local relationships.
Promotional materials and visibility	Coordinate with outreach and development teams to distribute merchandise (eg, stickers and QR codes) during events or in high-traffic areas.	Create bundled outreach kits with tiered options (free for low-resource settings and discounted for others); include multilingual and culturally relevant assets.
Effective messaging to youth	Test and deploy notifications and content that emphasize solving everyday challenges (eg, bullying and academic stress) instead of mental health–focused language.	Conduct A/B testing on notifications and content that center on daily life skills and reframes help-seeking as a strength and self-improvement.
Referral as a key facilitator to adoption	Support and equip peers to share digital mental health tools, and encourage trusted adults (eg, educators, counselors, and youth program staff) to actively promote them.	Streamline referral pathways through digital tools, QR codes, and cobranded materials; consider referral incentive programs.
Logistical barriers (eg, phone restrictions)	Collaborate with product engineers to explore ways to expand access to the platform through shared devices (eg, Chromebooks) in schools, libraries, or community centers.	Explore partnerships with schools to ensure that the platform is accessible through shared devices in classrooms or school libraries.
Need for demo mode and onboarding support.	Work with product engineers to create real-time support systems (eg, live chat and interactive tutorials) that cater to individual needs.	Develop an interactive demo version or sandbox mode to showcase key features.

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Limitations

This study has limitations that should be considered. First, the findings are based on stakeholder reports, and youth perspectives were not directly included in the data collection. This may influence interpretation by misrepresenting youths' actual experiences of the platform, particularly in ways that are not readily observable by adult staff. While outside the scope of this study, future research should complement stakeholder perspectives by directly assessing youth experiences and examining changes in youth mental health outcomes to more fully understand the platform's effectiveness. In addition, the study relied on self-reported data from stakeholders, which could introduce bias, such as social desirability or recall bias. Another limitation is the self-selection bias in participant recruitment, which could influence interpretation by making implementation appear more feasible or less challenging than it may be in settings facing greater barriers. Furthermore, the surveys and interviews were conducted between February and April 2025. Engagement initiatives related to the platform evolved after this period, although overarching implementation strategies remained similar. These changes in engagement efforts and promotional strategies over the first year of implementation may not be reflected in the results, and future research should consider these updates when assessing the platform's impact. In addition, interview data were coded by a single researcher, which did not allow for intercoder comparison, though qualitative findings were interpreted alongside survey results to support analytic rigor. The study focused on a specific platform deployed in California, limiting the generalizability of the results to other regions or platforms. Future research should aim to include a broader range of stakeholders, incorporate youth feedback, and consider longitudinal studies to evaluate the long-term effectiveness of digital mental health platforms.

Conclusions

This study provides valuable insights into how key stakeholders from schools and community organizations perceive the impact, implementation, and adoption of a free, confidential digital mental health platform for youth in California during its first year of implementation. These insights contribute to the implementation of digital mental health tools and can help guide future efforts to better meet the perceived needs of both youth and the organizations that serve them, particularly in underresourced settings. In addition, the findings inform product development, marketing, and customer support teams within digital mental health companies, offering suggestions for practical ways to improve platform features, outreach strategies, and support systems to facilitate broader adoption and successful implementation, learning from a real-world example of a scaling digital mental health platform.

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Data Availability

The datasets generated and analyzed during this study are not publicly available due to proprietary restrictions and confidentiality agreements. However, aggregated and anonymized data are available from the corresponding author upon reasonable request.

Authors' Contributions

JY contributed to the conceptualization of the study and was responsible for data curation, formal analysis, investigation, methodology, project administration, and writing of the original draft, as well as reviewing and editing the paper. JH contributed to study conceptualization, paper review and editing, and supervision. RM contributed to the paper review and editing. LS contributed to study conceptualization, paper review and editing, and supervision.

Conflicts of Interest

JH is a consultant for Kooth, and JY is employed by JH. RG was employed by Kooth Digital Health at the time of the data collection and analysis, but is no longer used by Kooth Digital Health at the time of publishing. LS is employed by Kooth Digital Health, receives an honorarium from Kooth Digital Health, and shares in Kooth on an annual basis; however, these are not contingent on study performance or scientific outputs. LS is also an honorary Senior Research Fellow at the University of Manchester, UK. To mitigate potential conflicts of interest, data collection, analysis, and interpretation were led by authors not employed by Kooth Digital Health; the analysis plan was prespecified, and results were interpreted collaboratively to support objectivity. All conflicts of interest have been fully disclosed, and no author's salary or employment status is dependent upon the study findings.

Multimedia Appendix 1
School and community stakeholder quantitative survey items.
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Multimedia Appendix 2

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Themes and example quotes.
[DOCX File , 1647 KB - formative_v10i1e82864_app2.docx]

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Abbreviations

CFIR: Consolidated Framework for Implementation Research
RE-AIM: Reach, Effectiveness, Adoption, Implementation, and Maintenance

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Original Paper

Prediction of Aspiration Risk by Using Vocal Biomarkers: Machine Learning Development and Validation Study

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Abstract

Background: Aspiration causes or aggravates a variety of respiratory diseases. Subjective bedside evaluations of aspiration are limited by poor interrater and intrarater reliability, while gold standard diagnostic tests for aspiration, such as video fluoroscopic swallow study and fiberoptic endoscopic evaluation of swallowing, are cumbersome or invasive and health care resource-intensive.

Objective: This study aims to develop and validate a novel machine learning (ML) algorithm that can analyze simple vowel phonations to aid in predicting aspiration risk.

Methods: Recorded [i] phonations during routine nasal endoscopy from 163 unique patients were retrospectively analyzed for acoustic features, including pitch, jitter, shimmer, harmonic to noise ratio, and others. Supervised ML was performed on the vowel phonations of those at high-risk for aspiration versus those at low-risk for aspiration. Ground truth of aspiration risk classification for model development was established using a video fluoroscopic swallow study. The performance of the ML model was tested on an independent, external cohort of patient voice samples. The performance of trained speech language pathologists to categorize high versus low-risk aspirators by listening to phonations was compared against the ML model.

Results: Mean ML risk score for those with the ground truth of high versus low aspiration risk was 0.530 (SD 0.310) vs 0.243 (SD 0.249), which was a significant difference (0.287, 95% CI 0.192-0.381; P<.001). In the development cohort, the model showed an area under the curve for the receiver operator characteristic of 0.76 (0.67-0.84) with specificity of 0.76 and F_1-score of 0.63. The performance of the model in an external testing cohort was comparable, with an area under the curve of 0.70 (0.52-0.88), a specificity of 0.81, and an F_1-score of 0.67. The ML model had comparable accuracy, sensitivity, specificity, negative, and positive predictive values compared to trained speech language pathologists in classifying aspiration risk by evaluating vowel phonations.

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Conclusions: Otolaryngology (ear, nose, and throat) patients at high risk for aspiration have quantifiable voice characteristics that significantly differ from those who are at a low risk for aspiration, as detected by an ML model trained to analyze sustained phonation and tested on an independent cohort.

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KEYWORDS

aspiration; voice; speech; artificial intelligence; ARDS; acute respiratory distress syndrome; lung transplant; ILD; interstitial lung disease

Introduction

Abnormalities of the oropharynx or larynx can cause clinically relevant aspiration of oropharyngeal or gastrointestinal contents into the lungs [1]. Such abnormalities include tumor bulk, resection or radiation injury, pathological or age-related deterioration of nerves or muscles of the upper airways, esophageal abnormalities, and altered sensorium. Acute aspiration can cause significant injuries leading to pneumonias and acute respiratory distress syndrome [1,2]. Chronic aspiration of gastrointestinal contents can aggravate airway and parenchymal lung diseases, such as chronic lipoid pneumonia, bronchiectasis, obliterative bronchiolitis, refractory asthma, and pulmonary fibrosis [3], and is a major risk factor for transplanted lung rejection [4,5].

Aspiration is common but is often undetected and usually only suspected after significant pulmonary damage has occurred. Despite its high prevalence in ambulatory and hospitalized patients [6-8], proactively detecting aspiration risk to prevent downstream sequelae is challenging. The most widely used hospital-based screening method to rule out anterograde aspiration (aspiration that occurs during swallowing) is nursing or speech-language pathologist (SLP) administered bedside swallowing evaluations (BSEs). BSEs vary across institutions but often include listening for a wet cough or wet voice quality after patients swallow varying amounts of liquid. Due to interrater and intrarater reliability issues inherent with these subjective assessments [9], the sensitivity for BSEs ranges from 27% to 85%, with specificities ranging from 50-80% [10], and poor predictive values [11]. BSE results inform referral decisions for gold standard confirmatory testing, including a video fluoroscopic swallow study (VFSS) [12] and fiberoptic endoscopic evaluation of swallowing (FEES) [13]. The VFSS exposes patients to radiation, requires coordinated participation, and can be challenging if patients are acutely ill, delirious, or have mobility issues, for example, in intensive care units. FEES is an invasive and uncomfortable evaluation where a scope is inserted through the nose and oropharynx to visualize the larynx during swallowing. Both VFSS and FEES are resource-intensive, requiring specialized equipment and the expertise of radiologists, laryngologists, and SLPs for administration and proper interpretation, limiting wide-scale deployment as screening tests. Consequently, there is an unmet need for an objective bedside screening test that is easily administered and provides a valid indication of aspiration risk to support decisions regarding referral for VFSS or FEES.

Aspiration involves contact of gastrointestinal/or oropharyngeal contents with the vocal folds as they move through the airway and into the lungs. While perceptual-acoustic studies of postprandial phonation have shown some limited evidence of acute aspiration immediately after a swallow [14-16], chronic exposure to gastrointestinal or oropharyngeal contents is likely to degrade the mucosal surfaces in ways that manifest as changes to the vocal folds' vibratory and acoustic characteristics. Exposure to gastrointestinal contents can induce histopathological changes to the vibratory margins of the vocal folds, leading to changes in vocal quality [17]. We therefore anticipate that aspirators will exhibit changes in vocal quality relative to non-aspirators either due to underlying pathophysiology or as a consequence of chronic aspiration. In this study, we evaluated voice samples available from Mayo Clinic's Otolaryngology clinical practices to develop, validate, and externally test a machine learning (ML) algorithm that analyzes voice to predict aspiration risk. We hypothesize that increased risk of aspiration may be associated with changes in human voice quality that can be detected by ML approaches for the objective prediction of aspiration risk.

Methods

Voice Data Collection

Voice recordings collected during laryngoscopy exams at Mayo Clinic Arizona (MCA), Otolaryngology clinics were extracted. All voice samples had been originally recorded during routine clinical workflow, using the lapel microphone (of the Pentax Laryngeal Strobe system) clipped near the clavicle. Endoscopy and VFSS databases from January 2020 to July 2021 were curated to identify patients with VFSS, an endoscopy exam, and voice recordings to identify 332 consecutive patients with both VFSS and voice recordings that were within 1 year of each other. Notably, since this is a retrospective study, voice sample collections were not specifically protocolled as would be done in a prospective study. Three SLPs (15 years combined experience) screened and manually excluded (Audacity 3.1.3) recordings with background noise, overlapping sounds (eg, multiple speakers and machine sounds), or low volume. The samples were discarded if SLPs were unable to reliably tag and label the individual samples, per the protocol below. Robust recordings were analyzed without computerized preprocessing to avoid artifacts from being introduced into the signal analysis pipeline. These samples were exported as .wav files, and PRAAT (version 6.2.15) was used to tag the samples with specific labels, including sustained vowel phonation, cued speech, reading, and spontaneous speech. To maximize the number of participants used for training, only [i] vowel phonations were analyzed, as these were most consistently collected across all patients, during routine clinical practice.

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Focusing on a single vowel type also reduced variability arising from differences in speech elicitation, dialect, or other idiosyncratic speech characteristics. Reducing variability ensures that observed differences in acoustic features reflect true underlying vocal characteristics rather than differences in speaking style or task conditions. Of 772 voice recording sessions from 332 patients, 283 recordings (with each recording containing one to several sustained [i] phonations) from 163 patients were analyzed. An average of 3 clips of the [i] vowel phonations lasting a minimum of 0.5 seconds from the central portion of each recording per patient were used to develop the ML model. These clips were treated as repeated measurements from the same patient rather than independent samples. The patient was defined as the fundamental unit of analysis for both model training and evaluation. All vowel clips from a given patient were always kept together and assigned to the same fold during cross-validation. No clips from the same patient were ever split across training, validation, or test folds.

Clinical Data Collection

Clinical data extracted included aspiration risk factors, such as upper airway involvement (vocal fold disease, head and/or neck surgery, radiation exposures), esophageal diseases (strictures, impaired motility, GERD), neurological compromise (stroke, neuromuscular, neurodegenerative, or peripheral nerve disease), BMI, and obstructive sleep apnea.

The Rosenbek Penetration-Aspiration Scale (PAS) [18], a well validated and widely used clinical standard [19,20], was used to classify patients VFSS exams as high-risk for aspiration (PAS scores of 6-8, materials into the lower airways); moderate-risk (PAS 3-5 (materials in laryngeal vestibule and/or on vocal folds without being ejecting); and low-risk (PAS 1-2, no penetration or ejected out of airway). PAS measurements are collected as part of routine clinical SLP practice at Mayo Clinic, as is the case in most major medical centers. The moderate aspiration risk group was not included in the test set, as the goal of testing is to observe if this model developed on retrospective voice data can discriminate between high and low risk aspirators. Notably, sustained /i/ phonations were recorded separately from the VFSS on different days. As such, the [i] phonations performed by patients were not influenced by simultaneous VFSS testing.

Data Preprocessing, ML, and Statistical Analysis

All recordings were processed using a standardized pipeline prior to feature extraction to reduce sensitivity to recording conditions. Audio was converted to mono and resampled to 16 kHz (16-bit pulse-code modulation). A band-pass filter (70-8,000 Hz; 4th-order Butterworth) was applied to reduce low-frequency, handling noise and high-frequency hiss. The retained phonation segment was amplitude-normalized to a fixed level (eg, peak normalization to −1 dBFS [decibels relative to full scale] or root mean square normalization to −20 dBFS). Traditional acoustic features were computed using short-time analysis with 25 ms Hamming windows and 10 ms hop, and summary statistics were aggregated across frames to obtain per-recording feature values.

In our initial model development and training, traditional voice features including pitch, jitter, shimmer, harmonics-to-noise ratio (HNR), cepstral peak prominence (CPP), and relative average perturbation (RAP) were extracted from tagged /i/ samples using audio processing toolboxes PRAAT (GNU General Public License Version 3, 29 June 2007) and Collaborative Voice Analysis Repository for Speech Technologies (COVAREP) [21].

Acoustic features were aggregated at the participant level (by averaging repeated vowel clips) to ensure independence of observations. Group differences between high- and low-risk aspirators were evaluated using 2-sample parametric 2-sided *t* tests. Although the 2-sided *t* test assumes approximate normality, it is generally robust to moderate departures from this assumption when applied to participant-level summaries. Feature distributions were therefore examined for gross irregularities (eg, extreme skewness or outliers), and no violations severe enough to invalidate mean-based comparisons were observed; accordingly, 2-sided *t* tests were used as a univariate screening analysis.

Since multiple acoustic features were evaluated, false discovery rate–adjusted q-values were computed using the Benjamini–Hochberg procedure to account for multiplicity. Raw *P* values are retained in the main text for comparability with prior studies, while the complete set of false discovery rate-adjusted q-values is reported in Multimedia Appendix 1 to guide interpretation under multiple testing.

Comparisons of demographics and clinical characteristics between the groups were performed with the Fisher exact test for categorical variables and the Kruskal-Wallis rank sum test for continuous variables. These analyses were performed with the arsenal package (R4.2.2; R Foundation for Statistical Computing). 0.05 was chosen as the cut-off criterion for statistical significance.

Neural additive models (NAM) [22] were used to classify the voice data and analyze the [i] phonation data of 163 patients. The following dependencies were used for ML coding in Python3: PyTorch, numPy, and sciPy. For NAM, we included 33 features that are well described to have validity in characterizing pathological voice states [23-25].

The patient was defined as the unit of analysis. Five-fold patient-level cross-validation was used for model development and internal validation. All modeling steps, including feature selection, oversampling, hyperparameter tuning, and calibration, were performed exclusively within the training data of each fold, with no information from validation folds used during model fitting or selection.

Recursive feature addition (RFA) [26,27] was nested within the cross-validation framework to avoid optimistic selection bias. Within each training fold, features were added sequentially based on improvement in cross-validated area under the receiver operator characteristic curve (AUC). Feature addition was terminated when performance reached a plateau. To ensure robustness and stability, the final feature subset was defined as the intersection of selected features across cross-validation folds, and validation performance was evaluated using only the feature subset determined from the corresponding training fold.

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Hyperparameter tuning for the NAM, including the learning rate and number of training epochs, was conducted using a grid search within each training fold, with performance assessed via an inner validation split.

Class imbalance was addressed during training using random oversampling of the minority class to achieve full class balance, applied only to the training portion of each fold. No oversampling was applied to validation data.

Model calibration was evaluated to assess the reliability of predicted risks. Because uncalibrated NAM outputs exhibited overconfident probability estimates, post-hoc logistic recalibration was applied. Calibration intercept and slope were estimated using predictions from the training folds and then applied to the corresponding held-out validation folds to obtain out-of-sample calibrated probabilities. Calibration performance was summarized using the calibration intercept, calibration slope, and the Brier score.

Model development, internal validation, feature selection, and calibration procedures were conducted and reported in accordance with the TRIPOD-AI (Transparent Reporting of a multivariable Prediction model for Individual Prognosis or Diagnosis-Artificial Intelligence) guidelines for multivariable prediction models using artificial intelligence.

Independent Model Testing

The development NAM model was trained on voice data from MCA, while independent validation of the model was performed with voice data of patients from another distinct Mayo Clinic site: Mayo Clinic in Rochester. The clinicians, recordings, equipment, rooms, geographic location, and patient demographics of the external testing cohort (Mayo Clinic in Rochester) were independent of the training cohort (MCA). These differences naturally introduced a domain shift, meaning that the distribution of test samples differed from that of the training samples. Evaluating the model under this shift allowed us to assess its out-of-distribution generalizability, ensuring that its predictions reflect aspiration-related signals rather than site-specific confounders. The selection, extraction, tagging, and processing of these externally collected voice samples used the same methodology as described previously for the development cohort. The recording systems in both sites were similar (ie, Pentax systems). ML risk score for each patient in the testing cohort was calculated in a blinded fashion by the model by analyzing [i] phonation clips in the context of the patient's age and sex. The gold standard designation (ie, aspiration risk category based on VFSS) or clinical information was not known to the investigators running the ML code. Statistical analyses, including sensitivity, specificity, and receiver operator characteristics (ROC), were calculated to assess the model's performance on both the testing and development cohorts.

Comparing Human Raters With ML Model

Overall, 4 SLPs, from the 2 medical centers (40 years combined experience), blinded to medical history and aspiration risk, classified patients as at high- or low-risk for aspiration based on perceptual judgements of the [i] phonation clips. This is identical to the information that was provided to the ML model in testing. Notably, the moderate aspiration risk group is not included in the test set, as the goal of testing is to observe if this model developed on retrospective voice data can discriminate between high and low risk aspirators. The interrater reliability for the human raters was assessed using pairwise Cohen kappa. The sensitivity, specificity, positive and negative predictive values, and accuracy of the human raters and the ML model for predicting high versus low-risk aspirators were calculated.

Ethical Considerations

This study was performed in accordance with the Declaration of Helsinki. This human study was approved by Mayo Clinic Institutional Review Board (approval 21-008975). As part of routine clinical care at Mayo clinic, patients can opt out of having their retrospective clinical data used for research purposes. Patients were not paid for this retrospective study. However, no individual patient's identifiable information can be found in any part of this manuscript or any of its appendices, ensuring patient privacy. The workflow for voice data curation, ML model development, and validation is shown in Figure 1.

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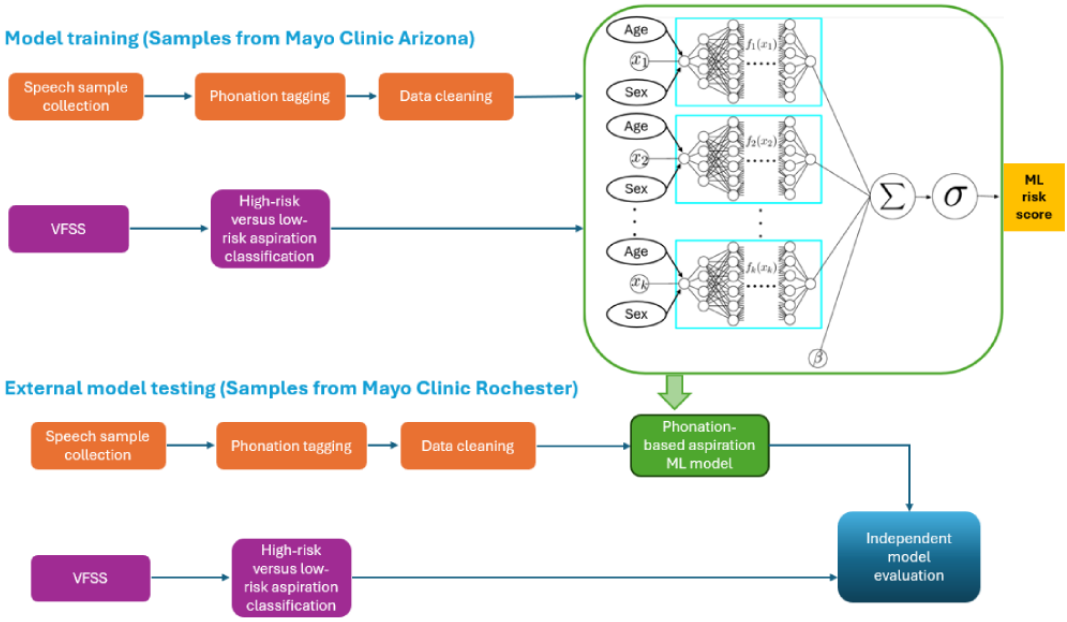
Figure 1. A graphical representation summarizing the workflow for this study from voice sample collection, phonation tagging, and subsequent machine learning model development based on gold standard testing (video fluoroscopic swallow study, determined aspiration risk). Subsequently, independent model evaluation was performed wherein the aspiration risk category based on the video fluoroscopic swallow study was unknown to the model. Contained within the green box is a schematic of the neural additive model [23] trained to estimate risk of aspiration using 33 voice features, in the full cohort (N=163), while adjusting for age and sex, the main confounders between the groups. Σ: summation of all subfeature network outputs and learnable offset β; σ: represent the sigmoid function σ(x)=1/(1+e^(-x)); β: learnable offset of neural additive model. ML: machine learning; VFSS: video fluoroscopic swallow study.

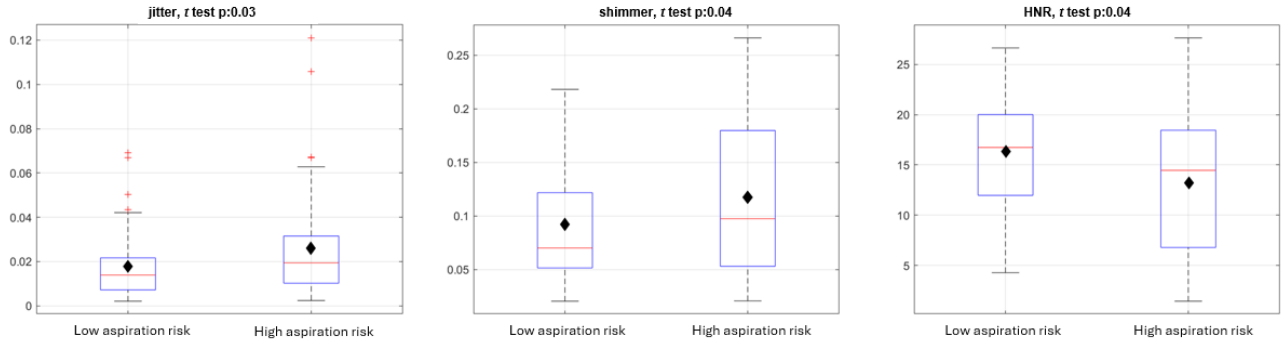


Results

Feature Analysis

We initially analyzed retrospective samples from 87 patients (19 high-risk aspirators, 10 medium-risk aspirators, and 58 low-risk aspirators) with an average of approximately 2 voice files per patient. Nonparametric analysis of variance of demographic and clinically relevant risks of aspiration in the pilot data revealed that only age and sex were different among the groups. On age and sex-matching prior to analysis, 17 high-risk aspirators were found to be age- and sex-matched to 17 low-risk aspirators in our exploratory cohort. Of the traditional voice features that were explored, high-risk aspirators were found to have higher jitter and shimmer but lower harmonics richness factor than low-risk aspirators (Figure 2).

Figure 2. Pilot data of 17 age- and sex-matched aspirators with 17 nonaspirators reveal that aspirators had a higher mean jitter (mean difference 0.0085, 95% CI 0.000756-0.0161), shimmer (mean difference 0.0266, 95% CI 0.00228-0.0506), and lower harmonics-to-noise ratio (mean difference 3.1, 95% CI 0.603-5.6). Means represented by black diamonds. Shimmer is the cycle-to-cycle variability in amplitude, while jitter is the cycle-to-cycle variability in frequency. HNR: harmonics-to-noise ratio.



Development of ML Model and Internal Cross-Validation

Our primary ML model development and training cohort evaluated 163 patients within the 3 groups (47 high-risk aspirators, 17 moderate-risk aspirators, and 99 low-risk aspirators) that significantly differed by sex, age, and BMI (with high-risk aspirators having a lower BMI than low-risk aspirators). Additional differences included more reported solid and liquid dysphagia symptoms and a higher frequency of structural changes to head and neck anatomy in the high-risk group than in the low-risk group, as expected in an otolaryngology population (Table 1).

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Table 1. Baseline characteristics of the training cohort.

Characteristics	High aspiration risk (n=47)	Low aspiration risk (n=99)	Moderate aspiration risk (n=17)	*P* value
Sex, n (%)				<.001[a]
Male	39 (83)	45 (45.5)	9 (52.9)	
Female	8 (17)	54 (54.5)	8 (47.1)	
Age at scope examination				<.001[b]
Mean (SD)	72.3 (9.9)	62.9 (12.6)	75.1 (9)	
Median (IQR)	73 (67-78)	61 (55-72)	77 (65-82)	
Range	40-88	31-90	62-89	
BMI (kg/m^2)				.009[b]
Mean (SD)	24.1 (3.2)	27.0 (5.3)	26.4 (7.7)	
Median (IQR)	23.8 (22-26.1)	26.8 (23.4-29.7)	25.3 (21.3-29.4)	
Range	18.7-31.2	17-44.2	16-48.9	
Dysphagia, n (%)				.06[a]
No	4 (8.5)	25 (25.25)	2 (11.8)	
Yes	40 (85.1)	72 (72.7)	14 (82.4)	
NA[c]	3 (6.4)	2 (2)	1 (5.9)	
Esophageal disease group, n (%)				.55[a]
Clinical GERD[d]	23 (48.9)	46 (46.5)	5 (29.4)	
Other esophageal disease	3 (6.4)	6 (6.1)	0 (0)	
Multiple esophageal diseases	2 (4.3)	3 (3)	1 (5.9)	
GERD on impedance or manometry studies	1 (2.1)	0 (0)	0 (0)	
No esophageal disease	9 (19.1)	24 (24.2)	4 (23.5)	
NA	9 (19.1)	20 (20.2)	7 (41.2)	
OSA[e], n (%)				.87[a]
Compliant with CPAP[f]	8 (17)	19 (19.2)	1 (5.9)	
Not compliant with CPAP	2 (4.3)	5 (5.1)	1 (5.9)	
Compliance not reported	2 (4.3)	4 (4)	0 (0)	
No OSA	35 (74.5)	71 (71.7)	15 (88.2)	
Neurological illness, n (%)				.14[a]
CVA[g] without any deficit	1 (2.1)	4 (4)	0 (0)	
ALS[h]	0 (0)	1 (1)	0 (0)	
Neuromuscular diseases	3 (6.4)	0 (0)	0 (0)	
CVA with dysphagia only	1 (2.1)	0 (0)	0 (0)	
CVA with residual neuro deficit	1 (2.1)	0 (0)	0 (0)	
None	41 (87.2)	94 (94.9)	17 (100)	
Vocal fold disease, n (%)				.34[g]
Yes	23 (48.9)	35 (35.4)	8 (47.1)	
No	22 (46.8)	62 (62.6)	9 (52.9)	
NA	2 (4.3)	2 (2)	0 (0)	

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Characteristics	High aspiration risk (n=47)	Low aspiration risk (n=99)	Moderate aspiration risk (n=17)	*P* value
Head and neck anatomical disease, n (%)				.01[g]
Surgery	6 (12.8)	13 (13.1)	2 (11.8)	
Cancer	1 (2.1)	1 (1)	0 (0)	
Radiation	0 (0)	2 (2)	0 (0)	
Multiple head and neck anatomical diseases	25 (53.2)	22 (22.2)	5 (29.4)	
None	15 (31.9)	61 (61.6)	10 (58.8)	

[a]Fisher exact test for count data.

[b]Kruskal-Wallis rank sum test.

[c]NA: not reported by patient or not found in chart review.

[d]GERD: gastroesophageal reflux disease.

[e]OSA: obstructive sleep apnea.

[f]CPAP: continuous positive airway pressure.

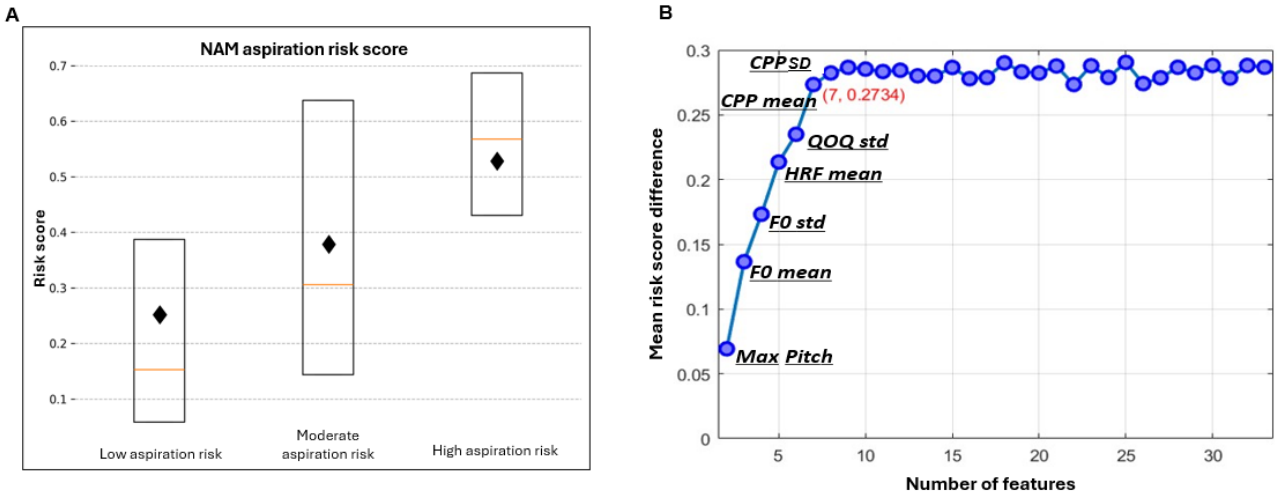
[g]CVA: cerebrovascular accident.

[h]ALS: amyotrophic lateral sclerosis.

Baseline characteristics for the age- and sex-matched cohort of 36 high-risk aspirators and 36 low-risk aspirators (N=72) showed that BMI and incidence of head and neck disease were different between the groups (Multimedia Appendix 2).

Because age and sex influence voice, and were different between the groups, they were controlled for in the NAM (Figure 1). The model used 33 extracted features to differentiate between aspirators and controls (Multimedia Appendix 3). Each subnetwork within the model processed a single extracted voice feature along with the corresponding sample sex and age as inputs (Figure 1). The subnetwork output was a single scalar reflecting the adjustments made for age and sex within the feature. The whole NAM output for aspiration risk was a scalar ranging from 0 to 1. High- and low-risk aspirators were clearly distinguished: high-risk aspirator score=0.530 (SD 0.310) versus low-risk aspirator risk score of 0.243 (SD 0.249); mean risk difference between groups was 0.287 (95% CI 0.192-0.381; *P*<.001; Figure 3A). Moderate-risk aspirators had a risk score between high-risk aspirators and low-risk aspirators, although this difference when compared to the other groups was not significant. RFA showed an elbow point at 7 features (Figure 3B), revealing that the most significant voice features adding to the model's discriminability were the average fundamental frequency and SD (F0_mean; importance=0.45 and F0_std [SD]; 0.29), the maximum fundamental frequency during phonation (Max Pitch; 0.57), the SD of the quai-open quotient that measures the proportion of the glottal cycle when the glottis is open (QOQ_std; 0.04), the average of the harmonic richness factor (HRF_mean; 0.18), the average of the CPP (CPP_mean; 0.07), and the SD of the CPP (CPP_std; 0.04). Feature importance was quantified as the average absolute weights of the corresponding feature-specific subnetworks in the NAM, reflecting each feature's relative contribution to the model's overall discriminative performance at a global level.

Figure 3. (A) High-risk aspirator neural additive model risk score mean 0.530 (SD 0.31) versus low-risk aspirator risk score of mean 0.243 (SD 0.249); Mean risk difference between groups 0.287 (95% CI 0.192-0.381; *P*<.001). Means represented by black diamonds. Moderate-risk aspirators' score fell between high- and low-risk aspirators. (B) The recursive feature addition method was used to identify the minimal set of features required to effectively distinguish between high and low-risk aspirators. This method initiates with a single feature and iteratively adds the voice feature that enhances the performance of the existing set. The key metric used to assess the performance of the feature set is the mean risk score difference. CPP: cepstral peak prominence; HRF: harmonic richness factor; NAM: neural additive model; RFA: recursive feature addition.



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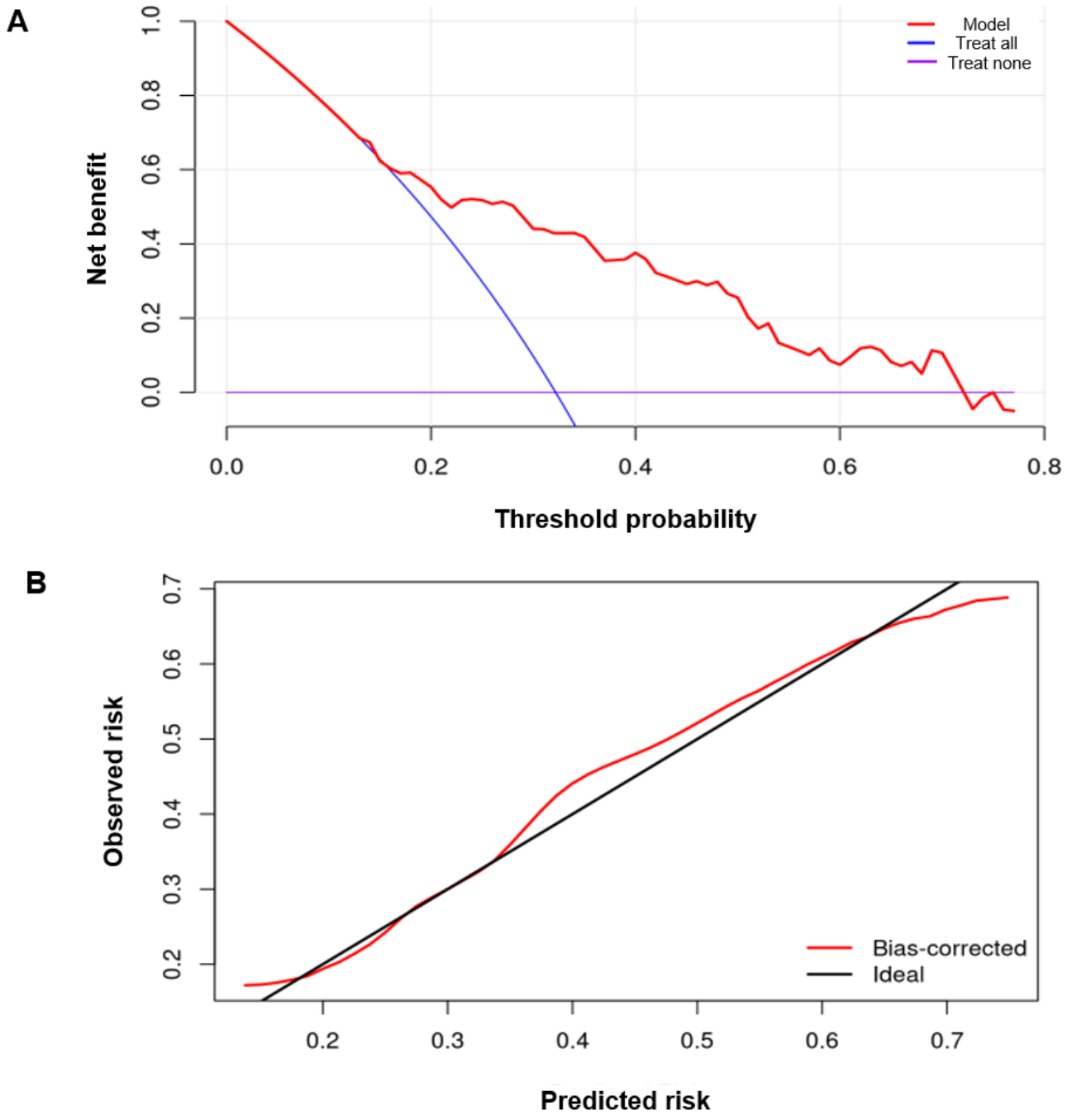
A description of these features and the other 33 features analyzed in the NAM is in Multimedia Appendix 3. After cross-validated recalibration, the model demonstrated good calibration, with a calibration intercept of –0.06 and a calibration slope of 0.89, indicating minimal global bias and substantially reduced overconfidence. The Brier score improved to 0.189.

Estimation of Model Performance

Decision curve analysis performed on the model showed that using ML risk score for prediction provided more benefit than binary strategies of "Treating all" versus "Treating None". This was true over a wide range of thresholding probabilities (Figure 4A). Additionally, a bootstrapped bias-corrected calibration analysis showed good agreement between predicted and observed probabilities (Figure 4B).

Figure 4. (A) Machine learning risk score to predict aspirators consistently provided higher net benefit than both the "Treat All" and "Treat Non" strategies across a wide range of threshold probabilities (approximately 0 to 0.75). (B) Bootstrap bias-corrected calibration curve closely followed the ideal 45° reference line across the central range of predicted risks.



External Testing of the ML Model

The external cohort contained 19 high- and 16 low-risk aspirators based on VFSS, which totaled 24% of the sample size of high and low-risk aspirators in the development cohort. The mean ML risk score output for the high-risk aspirators was significantly higher than the low-risk aspirators (mean 0.469, SD 0.327 vs mean 0.245, SD 0.265; *P*=.047; Figure 5A). The

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optimal ML risk score cut-off to distinguish high- from low-risk aspirators by analyzing the training cohort was 0.35 based on the Youden index (which is calculated as sensitivity+specificity–1 and determines the optimal cutoff for balancing sensitivity and specificity). The demographics between the training and testing cohorts were different. (Figure 5B). The AUC for the ROC for the testing cohort was 0.697 (0.517-0.878) compared to the AUC of 0.755 (0.666-0.843) for the training cohort (Figure 5B). The precision, recall, F_1-score, and specificity of the model for the testing cohort were 0.79, 0.57, 0.67, and 0.81, respectively (Table 2). There was not a significant drop in AUC despite the demographic differences between the training and testing cohorts (Table 3). For example, the testing cohort had a higher proportion of female high-risk aspirators (20% vs 5.5%), and a lower proportion of male low-risk aspirators (8.6% vs 30.8%; *P*=.005). The testing cohort was also older (mean age 70.3, SD 13.4 years vs mean 65.9, SD 12.6 years; *P*=.03).

Figure 5. (A) Box plot of machine learning risk score for training versus the external testing cohort. (B) Receiver operator curve for development versus the external testing cohort. AUC: area under the curve; ML: machine learning.

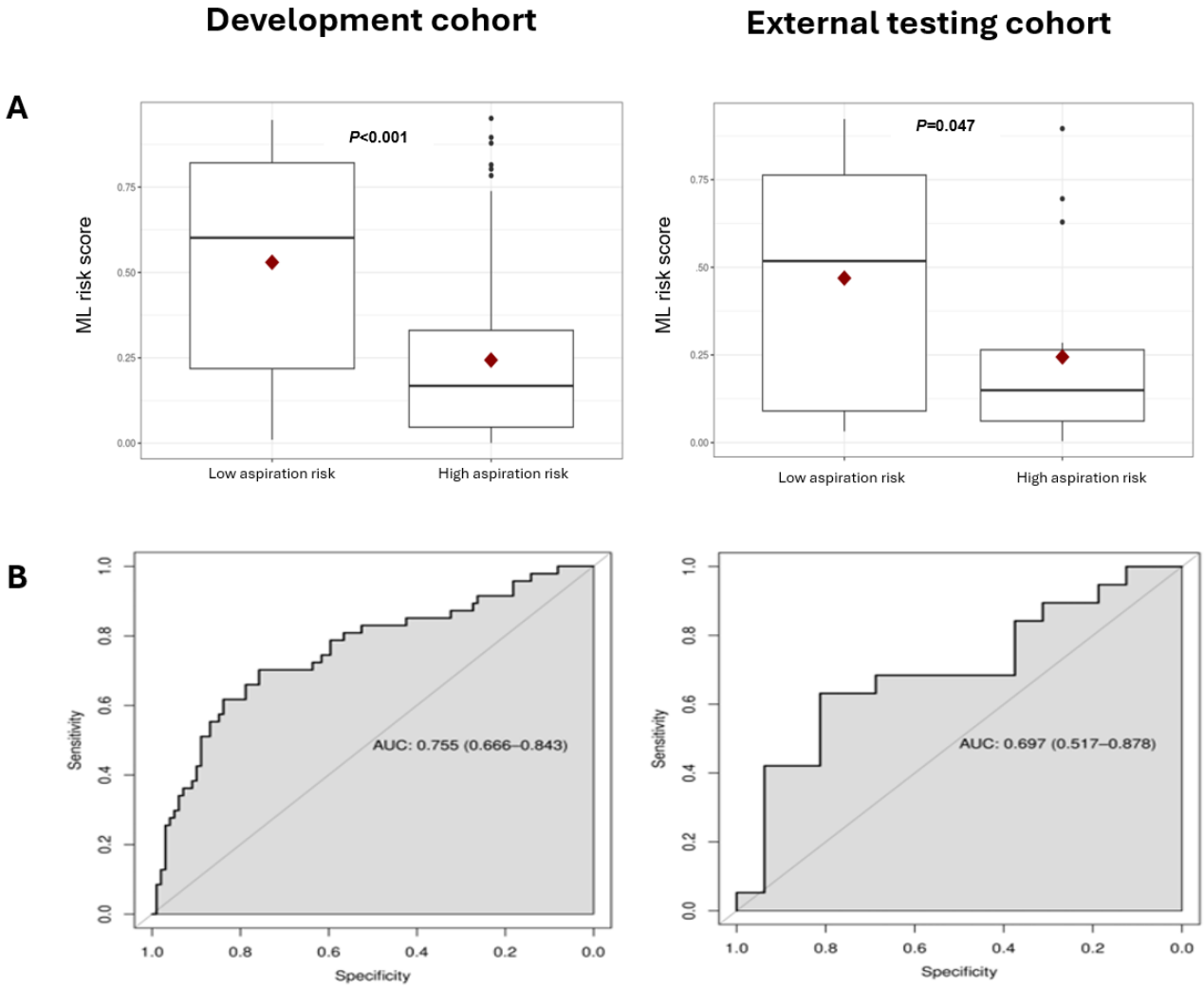

Table 2. Analyses evaluating the performance of the model on training versus validation cohort, where F1-score= 2*Precision*Recall/ (Precision + Recall).

Cohorts	Precision	Recall	F_1-score	Specificity
Development	0.58	0.70	0.63	0.76
External testing	0.79	0.58	0.67	0.81

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Table 3. Illustration of demographic differences between the development and testing cohorts, especially in factors like sex that significantly influence voice.

Aspiration risk	Female	Male
High, n (%)		
Development cohort (%)	8 (5)	39 (26.7)
Testing cohort	7 (20)	12 (34.3)
Low, n (%)		
Development cohort	54 (37)	45 (30.8)
Testing cohort	13 (37.1)	3 (8.6)

Human Raters vs ML Model

Other than 2 raters that had very good agreement (pairwise Cohen Kappa of 0.8), the rest had fair agreement (Cohen κ range 0.34-0.59; Table 4). In classifying patients as a high- or low-risk aspirator by analyzing [i] phonations, the ML model had comparable accuracy to human raters' range (69% vs 46-60%), sensitivity (58% vs 32-47%) PPV (79% vs 50-78%) and NPV (62% vs 41%-54%; Table 5). The ML model also had comparable specificity to human raters (81% vs 44%-88%). No statistically significant differences were found while comparing the ML model's performance metrics to the performance of human raters using the McNemar or DeLong test.

Table 4. Interrater reliability pairwise κ coefficient between human speech language pathologists' raters. In parenthesis, interrater reliability between raters is mentioned, as they made predictions of high-risk versus low-risk aspirators.

SLP[a] raters	Rater 1	Rater 2	Rater 3
Rater 2	0.590 (0.774/0.200)	—[b]	—
Rater 3	0.508 (0.573/0.412)	0.397 (0.573/0.2)	—
Rater 4	0.801 (0.650/1)	0.505 (0.650/0.2)	0.343 (0.249/0.412)

[a]SLP: speech language pathologist.

[b]Not applicable.

Table 5. Blinded human (raters 1-4) and machine (rater 5) raters' ability to predict aspiration risk by listening to phonations against the ground truth (based on video fluoroscopic swallow study).

Reader	Sensitivity, % (95% CI)	Specificity, % (95% CI)	PPV[a], % (95% CI)	NPV[b], % (95% CI)	Overall accuracy, % (95% CI)
Rater 1	36.8 (17.2-61.4)	75 (47.4-91.7%)	63.6 (31.6-87.6)	50 (31.4-68.6)	54.3 (36.9-70.8)
Rater 2	36.8 (17.2-61.4)	87.5 (60.4-97.8)	77.8 (40.2-96.1)	53.8 (33.7-72.9)	60 (42.2-75.6)
Rater 3	47.4 (25.2- 70.5)	43.8 (20.8-69.4)	50 (29-71)	41.2 (19.4-66.5)	45.7 (29.2-63.1)
Rater 4	31.6 (13.6-56.5)	75 (47.4-91.7)	60 (27.4-86.3)	48 (28.3-68.2)	51.4 (34.3-68.3)
Rater 5 (machine)	57.9 (34-78.9)	81.2 (53.7-95)	78.6 (48.8-94.3)	61.9 (38.7-81)	68.6 (50.6-82.6)

[a]PPV: positive predictive value.

[b]NPV: negative predictive value.

Discussion

Study Strengths

While acutely or chronically having ingested materials enter the larynx alters the quality of voice, human judgment of voice changes [28,29] or even validated tools for perceptual assessments are unreliable screening methods to detect aspiration risk [30,31]. There is a need for tools to objectively quantify aspiration-related voice changes in patients [14-16]. In a study of 93 patients, RAP combined with HNR increased the sensitivity of detecting aspiration in the 5 voice features analyzed [14]. A similar study of 165 patients demonstrated that of 8 voice features evaluated, RAP was the most distinguishing measure between aspirators and non-aspirators [15]. Recently, a study of 198 patients used ML to detect aspiration by analyzing postprandial voice [16]. However, all these studies were single-center studies without an external testing cohort. The focus of these studies was on the effects of anterograde aspiration on voice as ingested materials contact the vocal folds in real time. However, current bedside swallow evaluations also screen for aspiration by making the patient swallow. There are no available tests to objectively detect aspiration risk without having the patient swallow liquids or solids. This can be a limitation for patients who are frail, immobile, and experiencing delirium, who are already at considerable risk for aspiration. An objective screening test for aspiration risk that only requires simple phonation could be useful in these scenarios. Such a method could facilitate frequent

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longitudinal testing, refining referral for confirmatory testing with VFSS or FEES.

While our model's performance based on metrics like AUC, F_1-score, and decision curve analysis showed reasonable performance (Figures 4-5), unlike other studies in this space, we also tested the performance of our model in an independent external testing cohort. Previous work has shown that external testing of voice models is critical, as it can be difficult to train clinical speech models that generalize [32-34]. Our testing cohort was from a geographically distinct clinic where retrospective voice samples were collected from patients who were demographically different from our training cohort. Despite these differences, the model's performance did not change significantly (Tables 2-3 and Figure 5), suggesting that the model is not fragile. Fragile models that are over-fitted in development cohorts tend to perform poorly in external cohorts and therefore can seldom be used effectively in clinical practice. Finally, we explored whether the ML tool added value as a preliminary test to predict aspiration risk by comparing its performance to SLPs. We found that the inter-rater reliability among our SLP raters was only "fair," similar to reports in the literature for other perceptual evaluations.

There is an inherent tradeoff between purely data-driven model development and approaches that incorporate domain expertise. While deep learning models typically require very large datasets to automatically learn relevant features, simpler supervised ML methods can achieve strong performance with smaller sample sizes when domain experts guide the feature selection and validation process [35]. One of the benefits of NAM used in this evaluation is the sequential way in which features can be considered and confounding variables controlled, thereby improving the explainability of the model [22]. While simpler models like logistic regression can classify by accounting for basic covariates such as age and sex, they are limited in capturing non-linear relationships and feature-specific interactions. The NAM's feature-specific networks capture complex, nonlinear interactions while controlling for relevant patient characteristics.

Study Limitations and Future Directions

This study has several limitations. The relationship between voice and aspiration is likely a complex bidirectional relationship that cannot be fully elucidated with a retrospective analysis. Our population of ear, nose, and throat (ENT) patients has other reasons related or unrelated to aspiration for their voice to be altered (eg, radiation-induced vocal fold scarring). We controlled for age and sex (predictors known to covary with voice) using our NAM. However, other clinical factors like BMI and anatomical head and neck disease are known to covary with aspiration (the response variable) either as a cause or an effect and therefore cannot be easily controlled by generalized regression models in a retrospective analysis. Also, we also focused on anterograde aspiration as confirmed by VFSS. It is possible in our cohorts that participants experienced retrograde aspiration, wherein micro-aspiration of gastrointestinal contents occurs typically during sleep in the context of gastroesophageal reflux disease [3]. Because it can occur in the absence of any structural or functional abnormalities, VFSS or FEES are not sensitive diagnostics. This may have resulted in false positive high-risk errors in both SLP and ML classifications. The inclusion of indirect (reflux symptoms or esophageal impedance testing) and direct indicators of retrograde aspiration (eg, pepsin and bile in bronchoalveolar lavage) in our model may further refine model performance beyond the AUC of .70 range. Additional fine-tuning may be achieved by including measures from connected speech and increasing the diversity of clinical settings. While constrained by the retrospective voice data, this formative study motivates a prospective multi-site voice collection trial to better characterize voice and its relationship to aspiration.

The elbow point in the cross-validation analysis (Figure 3B) was attained at 7 features (relevant features highlighted in Multimedia Appendix 3). These features and interactions were the most predictive of aspiration risk, but only in the specific sample we evaluated, namely ENT patients, while performing the vowel phonation task. We expect that as we expand our databases to include more diverse patient samples from different clinical settings, other voice features may emerge as significant predictors. Our categorization of "high" and "low" aspiration risk was based on VFSS at one point in time. It could be claimed that this is not reflective of the patient's true longitudinal aspiration status. This is why we were careful to label the categories in terms of "risk" rather than absolute diagnoses. Those categorized as high aspiration "risk" were widely separated from the low aspiration "risk" (PAS 6-8 vs PAS 1-2), and crossovers between these categories in our ENT practice, although possible is unlikely. Since PAS scores were obtained from retrospective clinical data and not from a prospective research protocol, interrater reliability of the PAS within our clinical ENT practice cannot be easily calculated. Nevertheless, since the PAS is a well-established and widely used clinical method of estimating aspiration risk, we used this scoring system to define the labels for our cohorts. The performance of the model was only tested for binary discrimination of high-risk versus low-risk aspirators. Aspirators in the moderate group were not tested due to paucity in available retrospective data. However, we recognize that this is an important clinical group that needs to be the focus of future prospective research. It should be noted that SLPs do not make decisions about aspiration risk based on sustained phonations alone. However, this study highlights the potential benefit of ML to complement informed clinical decision-making by experts. Finally, we do not claim that this ML tool can be used as a confirmatory diagnostic test like VFSS or FEES. Rather, the goal of this study was to develop and validate a tool that can potentially serve as an easily deployable screening test used by bedside nurses and SLPs to more objectively screen for anterograde aspiration risk.

Conclusions

Otolaryngology (ear, nose, and throat) patients at high risk for aspiration have quantifiable voice characteristics that significantly differ from those who are at a low risk for aspiration, as detected by an ML model trained to analyze sustained phonation and tested on an independent cohort. This study uses ML techniques to quantify the quality of voice to estimate aspiration risk without performing a simultaneous swallow evaluation. Future research could include collecting

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voice samples (including connected speech) from a variety of clinical settings, including intensive care units, hospital wards, and ambulatory clinics, to facilitate model fine-tuning so that it is more generalizable.

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Authors' Contributions

Conceptualization, supervision, funding acquisition, project administration, resources, investigation, methodology, formal analysis, visualization, validation, data curation, writing – original draft, writing – review and editing: CV
Software, methodology, formal analysis, visualization, validation, data curation, writing – review and editing: JZ
Investigation, methodology, formal analysis, visualization, validation, data curation, writing – review and editing: SC
Methodology, formal analysis, visualization, validation, data curation, writing – review and editing: AAA, ER
Methodology, visualization, validation, data curation, writing – review and editing: SH, AB, HS
Investigation, methodology, formal analysis, visualization, validation, data curation, writing – review and editing: MKH
Investigation, supervision, methodology, formal analysis, visualization, validation, data curation, writing – review and editing: JL
Software, formal analysis, visualization, validation, data curation, writing – review and editing: NZ
Validation, data curation, writing – review and editing: DO, RLP, LR
Investigation, supervision, methodology, formal analysis, writing – review, and editing: VO, DL
Conceptualization, supervision, resources, investigation, methodology, formal analysis, visualization, validation, writing – review and editing: VB

Conflicts of Interest

None declared.

Multimedia Appendix 1
Raw *P* values from univariate 2-sided *t* tests comparing acoustic features between high-risk and low-risk aspirators, along with corresponding Benjamini-Hochberg false discovery rate (FDR)-adjusted q-values. Q-values are provided to assess the robustness of univariate screening results under multiple testing and were not used to modify primary analyses or figures.
[DOCX File , 15 KB - formative_v10i1e86069_app1.docx]

Multimedia Appendix 2
Baseline characteristics of training cohort when high-risk and low-risk aspirators were age and sex-matched.
[DOCX File , 17 KB - formative_v10i1e86069_app2.docx]

Multimedia Appendix 3
List of 33 voice features that were used for machine learning organized in clinically meaningful domains. The seven features that contributed most to the model's discriminability are bolded. Importance score is the average absolute weights of the corresponding feature-specific subnetworks in the neural additive model, reflecting each feature's relative contribution to the model's overall discriminative performance.
[DOCX File , 17 KB - formative_v10i1e86069_app3.docx]

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Abbreviations

AUC: area under the curve
CPP: cepstral peak prominence
ENT: ear, nose, and throat
FEES: fiberoptic endoscopic evaluation of swallowing
HNR: harmonic-to-noise ratio
MCA: Mayo Clinic Arizona
ML: machine learning
NAM: neural additive model
PAS: Penetration Aspiration Scale
RAP: relative average perturbation
ROC: receiver operator characteristic
SLP: speech language pathologist
TRIPOD-AI: Transparent Reporting of a multivariable Prediction model for Individual Prognosis Or Diagnosis-Artificial Intelligence
VFSS: video fluoroscopic swallow study

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Original Paper

Enhancing Workplace Outcomes Through Digital Behavioral Health Programs: Retrospective Real-World Study

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Abstract

Background: Modern workplaces create increasing demands on employees, often leading to stress, burnout, and reduced functional capacity. These challenges contribute to significant functionality losses, with absenteeism and presenteeism posing economic burdens. Mindfulness-based workplace interventions have been shown to improve mental health, yet their effects on specific work-related performance outcomes such as concentration difficulties, mistakes, and procrastination over time are less explored.

Objective: This study aimed to evaluate self-reported workplace function changes for a 10-week period among users of a digital behavioral health program.

Methods: This retrospective analysis used real-world data from users of the Dario Health behavioral health app. Participants were required to complete at least 2 workplace functionality assessments, including one at week 1 as a baseline. The assessment comprised 3 items measuring concentration difficulties, mistakes at work, and procrastination, each rated on a 0 (“not at all”) to 3 (“a lot”) scale. Users who initially scored 2 (“often”) or 3 (“a lot”) on each respective measure formed the cohorts for analysis. Longitudinal changes were examined using piecewise linear mixed-effects models. Cut points were selected empirically through sensitivity analyses comparing alternative cut points (weeks 2-7) using Akaike and Bayesian information criteria to identify the best-fitting model for each outcome.

Results: Sensitivity analyses identified optimal cut points at week 6 for concentration difficulties and procrastination and at week 5 for mistakes at work. Among users reporting baseline concentration difficulties (n=1254), significant reductions were observed during weeks 1 to 6 (B=−0.02; *P*<.001), with larger reductions during weeks 6 to 10 (B=−0.08; *P*<.001). For mistakes at work (n=167), a significant decrease occurred during weeks 1 to 5 (B=−0.05; *P*=.02), followed by a more pronounced reduction during weeks 5 to 10 (B=−0.22; *P*<.001). Among users reporting baseline procrastination (n=1004), significant improvements were observed during weeks 1 to 6 (B=−0.02; *P*<.001), with greater reductions during weeks 6 to 10 (B=−0.08; *P*<.001).

Conclusions: Use of the digital behavioral health platform was associated with improvements in workplace function, particularly among users with sustained use beyond 4 weeks. The observed outcomes suggest that continued participation in such digital behavioral health programs may be linked to favorable changes in mental health and cognitive functioning over time and may support employee well-being. Long-term engagement appears essential to maximize benefits, warranting further research into sustained impacts and optimization strategies for workplace productivity.

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KEYWORDS

workplace well-being; burnout; evaluation; digital health; behavioral health

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Introduction

In today's fast-paced work environment, employees are facing escalating demands that can negatively impact their well-being. The increasing demands in the workplace can have adverse effects, leading to work-related stress, exhaustion, burnout, and other health issues [1]. These challenges contribute to significant functional impairments, with absenteeism and presenteeism representing major economic burdens in industrialized countries [2]. Therefore, employers are increasingly implementing health promotion strategies [3], recognizing that employee health and well-being are vital for sustaining functional capacity and ensuring organizational success [4].

Previous studies have shown that mindfulness-based workplace interventions have demonstrated significant benefits in mental health outcomes [5,6]. These programs offer employees accessible and flexible ways to manage stress through mindfulness practices, such as meditation and deep breathing exercises. By integrating these practices into daily routines, employees can develop greater self-awareness and emotional regulation, which help them navigate workplace challenges more effectively. Mindfulness-based interventions have been linked to reductions in symptoms of anxiety, depression, and burnout [7], while improving cognitive functions like attention, memory, and decision-making [8]. As employees feel more supported in managing their mental health, they are better equipped to engage in their work, ultimately benefiting both the individual and the organization.

Workplace mental health has become a critical priority for employers due to its strong association with productivity, absenteeism, presenteeism, and overall organizational performance. While digital behavioral health programs have demonstrated effectiveness in reducing symptoms of depression and anxiety, there remains a limited body of real-world evidence examining their association with functional workplace outcomes, such as concentration, task completion, and error reduction. Digital health measures provide a unique opportunity to evaluate real-world outcomes in workplace function over time and at scale. The objective of this study was therefore to assess changes in user-reported workplace function outcomes over a 10-week period among individuals using the platform in routine practice.

Methods

Platform

The Dario Health behavioral health app (DarioHealth Corp) is a modular tool delivering emotion-focused support designed to address a range of mental health conditions. Members generally have access to the Dario Health behavioral health platform as part of their employee or health plan benefits. A clinically based screening tool assesses each person's needs and guides users to the most efficient support. The app provides several cognitive behavioral therapy programs, including depression, anxiety, anger, stress, and substance use, and can be used as a self-guided intervention or with the help of a certified coach. The structure of each program includes conceptual videos, textual skills, breathing exercises, and progress monitoring tools. These features are designed to address common drivers of workplace impairment, including stress-related attentional difficulties, executive function challenges, emotional dysregulation, and avoidance behaviors that contribute to procrastination. Through repeated skill practice, self-monitoring, and adaptive content delivery, users are supported in building sustainable cognitive and behavioral strategies that may improve concentration, reduce errors, and enhance task completion over time. This study focuses on tracking cohorts of users with work functionality scores measured by their responses to the questionnaire.

Measures

Workplace functionality levels were tracked for 10 weeks using a 3-item assessment designed to evaluate user-reported issues related to concentration difficulties, mistakes at work, and procrastination (Table 1). The assessment is scored from 0 (not at all) to 3 (a lot).

Internal consistency reliability of the workplace function measure was assessed using Cronbach α. Cronbach α was calculated at baseline assessment, yielding a coefficient of 0.70, indicating acceptable internal consistency. In addition, internal consistency was examined across repeated assessment waves with sufficient sample sizes to assess the stability of the measure over time.

Table 1. The components of the assessments and their corresponding answers.

Title	Questionnaire	Scoring
Concentration difficulties	I have not been able to concentrate	• 0="not at all" • 1="sometimes" • 2="often" • 3="a lot"
Mistakes at work	I have made avoidable or costly mistakes at work	• 0="not at all" • 1="sometimes" • 2="often" • 3="a lot"
Procrastination	I have procrastinated on important work tasks because I just couldn't get started	• 0="not at all" • 1="sometimes" • 2="often" • 3="a lot"

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Ethical Considerations

This study was a retrospective, real-world analysis of an existing database collected in the digital platform. All data were fully anonymized and deidentified before extraction for this study. No identifiable personal information was accessed, and no direct interaction with users occurred for the purposes of this research. In accordance with institutional policies and applicable regulations, the Ethical and Independent Review Services [9], a professional review board, issued the institutional review board exemption for this study (21235-01#).

In accordance with institutional policies and applicable regulations, analyses of fully anonymized retrospective datasets did not constitute human subjects research and therefore did not require institutional review board approval or informed consent. All data were processed in compliance with relevant data protection, privacy, and security standards.

Study Design

This study used a single-arm, real-world retrospective analysis based on data from users of the behavioral health app. Users included in this analysis were required to have completed at least 2 assessments, including one from week 1. Work productivity outcomes were sorted into 3 different item categories.

Statistical Analysis

Piecewise linear mixed-effects models were used to examine longitudinal changes in workplace functioning outcomes (concentration difficulties, mistakes at work, and procrastination). This approach was selected to allow for different rates of change across distinct periods, which is appropriate when change is not expected to be uniform over the entire follow-up. Piecewise modeling enables estimation of separate linear slopes before and after a change point, providing a flexible and interpretable framework for analyzing longitudinal trajectories [10]. In the present context, this framework enables evaluation of whether changes in workplace functioning differ between the initial period following baseline and a later period, rather than assuming a single linear trajectory over time. For each outcome, separate models were fitted with time (in weeks since baseline) specified as 2 linear segments divided by a cut point. Models included a random intercept for participants to account for within-subject correlation due to repeated measurements.

To empirically determine the most appropriate cut point, sensitivity analyses were conducted by systematically testing alternative cut points ranging from weeks 2 to 7 for each outcome. For each cut point, models with identical fixed and random effects structures were fitted, differing only in the location of the breakpoint. Model fit was evaluated using the Akaike information criterion (AIC) and Bayesian information criterion (BIC), with lower values indicating better fit. The cut point yielding the lowest AIC and BIC was selected as the optimal cut point for the primary analyses.

Fixed-effect estimates were reported as regression coefficients (B) with 95% CIs and corresponding *P* values. Statistical significance was assessed using 2-sided tests with an α level of .05. All statistical analyses were conducted using R software (R Foundation for Statistical Computing) in RStudio (version 2024.09.0; Posit PBC).

Results

Sensitivity Analysis of Piecewise Cut Point Selection

Sensitivity analyses were conducted to evaluate the robustness of the piecewise mixed-effects models to the choice of cut point. Alternative cut points from weeks 2 to 7 were systematically tested for each outcome, with model fit compared using AIC and BIC. These analyses identified week 6 as the optimal cut point for concentration difficulties and procrastination and week 5 as the optimal cut point for mistakes at work, based on minimum AIC and BIC values. Models using these cut points provided the best overall fit to the data.

Concentration Difficulties

The concentration difficulties cohort included 1254 users who reported concentration difficulties (score of 2 [“often”] or 3 [“a lot”]) at baseline. On the basis of model fit criteria, a piecewise mixed-effects model with a cut point at week 6 was selected. The model showed a significant decrease during the first segment (weeks 1-6: B=−0.02, 95% CI −0.02 to −0.01; *P*<.001), followed by a larger and highly significant decrease during the second segment (weeks 6-10: B=−0.08, 95% CI −0.10 to −0.06; *P*<.001; Figure 1). The fitted model predicts a 0.43-point reduction in concentration difficulties scores over 10 weeks.

Mean concentration difficulties scores decreased from 2.33 (SD 0.47) at week 1 to 2.05 (SD 0.72) at week 10, corresponding to an absolute reduction of 0.27 points on the 0 to 3 scale (11.8% decrease).

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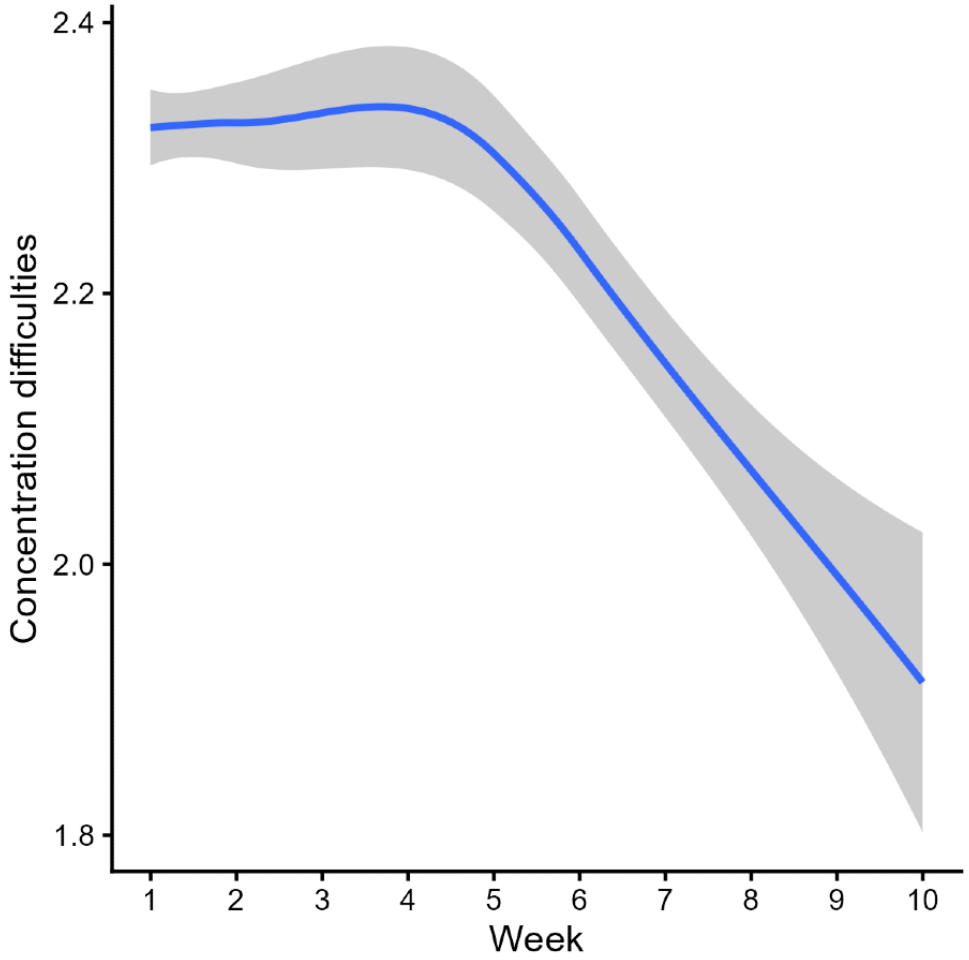
Figure 1. Fluctuation in concentration difficulties over 10 weeks of app use. The blue line represents a smoothing of concentration levels over time. The gray area around the line represents the 95% CI.



Mistakes at Work

The mistakes cohort comprised 167 users who reported frequent work-related mistakes (scores of 2 [“often”] or 3 [“a lot”]) at baseline. Model comparison identified week 5 as the optimal cut point. The piecewise mixed-effects model demonstrated a significant decrease during the first segment (weeks 1-5: B=−0.05, 95% CI −0.09 to −0.007; *P*=.02), followed by a more pronounced decrease during the second segment (weeks 5-10: B=−0.22, 95% CI −0.30 to −0.14; *P*<.001; Figure 2). The fitted model predicted a 1.31-point reduction in mistakes at work scores over 10 weeks.

Mean mistake scores decreased from 2.33 (SD 0.47) at week 1 to 1.93 (SD 1.28) at week 10, corresponding to an absolute reduction of 0.40 points on the 0 to 3 scale (17.1% decrease).

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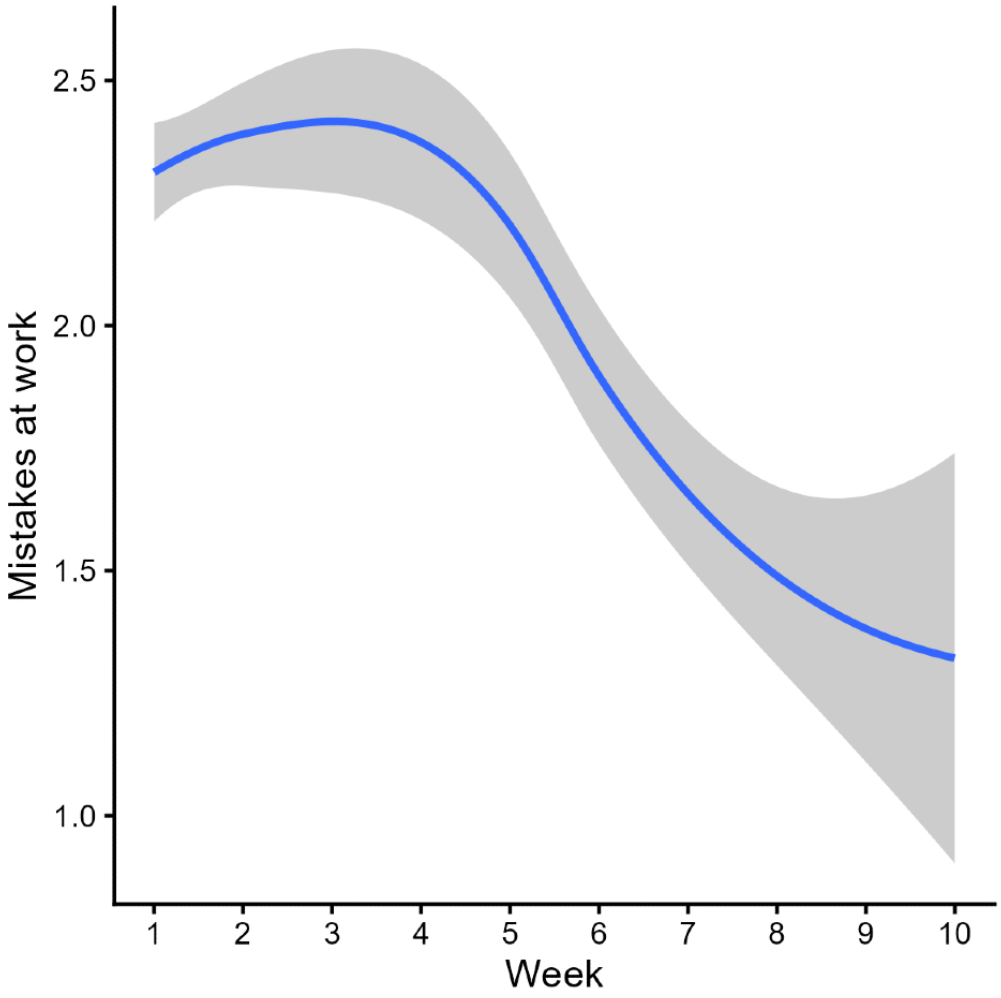
Figure 2. Fluctuation in mistakes at work over 10 weeks of app use. The blue line represents a smoothing of mistakes at work levels over time. The gray area around the line represents the 95% CI.



Procrastination

The procrastination cohort included 1004 users who reported frequent procrastination (scores of 2 [“often”] or 3 [“a lot”]) at baseline. A cut point at week 6 provided the best model fit. The piecewise mixed-effects model revealed a significant decrease during the first segment (weeks 1-6: B=−0.02, 95% CI −0.02 to −0.01; *P*<.001), followed by a larger decrease during the second segment (weeks 6-10: B=−0.08, 95% CI −0.11 to −0.06; *P*<.001; Figure 3). The fitted model predicts a 0.44-point reduction in procrastination scores over 10 weeks.

Mean procrastination scores decreased from 2.39 (SD 0.49) at week 1 to 2.01 (SD 0.83) at week 10, corresponding to an absolute reduction of 0.37 points on the 0 to 3 scale (15.7% decrease).

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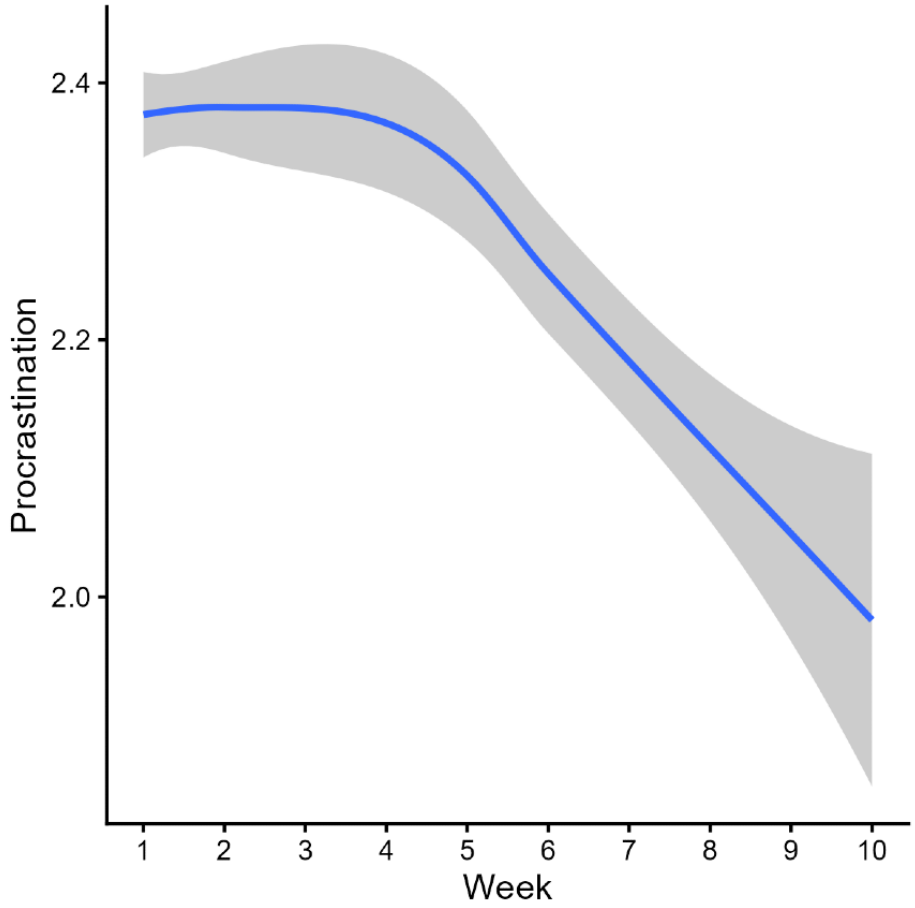
Figure 3. Fluctuation in procrastination over 10 weeks of app use. The blue line represents a smoothing of procrastination levels over time. The gray area around the line represents the 95% CI.



Discussion

Principal Findings

The results of this study provide valuable insights into the association between use of the Dario Health digital behavioral health program and improvements in key aspects of workplace function. Achieving significant improvements in workplace functioning is important.

The observed reductions in workplace function outcomes are clinically meaningful when interpreted in the context of established behavioral health symptom scales. At baseline, mean scores across concentration difficulties, mistakes at work, and procrastination ranged from 2.33 to 2.39 on a 0 to 3 frequency scale, corresponding to symptom levels reported as occurring "often" to "a lot." By week 10, these scores declined to approximately 1.9 to 2.0, reflecting a shift toward lower symptom frequency and functional impairment. Specifically, mean concentration difficulties scores decreased from 2.33 to 2.05 (absolute reduction: 0.27 points; 11.8% decrease), mistakes at work declined from 2.33 to 1.93 (absolute reduction: 0.40 points; 17.1% decrease), and procrastination decreased from 2.39 to 2.01 (absolute reduction: 0.37 points; 15.7% decrease). These magnitudes are comparable to reductions reported in prior digital behavioral health interventions targeting behavioral health conditions, such as depression and anxiety, where symptom improvements of similar relative scale have been associated with meaningful functional recovery and improved daily performance [11-13].

Taken together, these findings suggest that improvements in mental health symptom burden previously demonstrated in our behavioral health programs may translate into parallel gains in cognitive functioning and work-related performance domains, including concentration, task completion, and error reduction.

Following onboarding, users complete an initial assessment of stress, mood, and functional well-being, which informs content recommendations. The platform suggests relevant mindfulness and attention-training activities. Mindfulness content is also available in the app's content library, allowing members to freely explore and self-select sessions according to their preferences and needs. The mindfulness training itself is delivered through short, structured, evidence-based exercises grounded in mindfulness-based stress reduction and cognitive behavioral therapy principles. These include guided breathing practices, grounding techniques, attention-focusing exercises, and brief meditations designed to support stress regulation, emotional awareness, and cognitive control. Importantly, this study does not evaluate a targeted mindfulness intervention. Rather, it reflects real-world use of a multimodal digital behavioral health platform in which mindfulness is one of several therapeutic modalities available to members. Therefore, engagement with mindfulness practices represents naturalistic, self-directed use within the broader digital care experience.

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The delay in the self-observed improvements in workplace function can be attributed to the gradual nature of behavioral interventions. These interventions primarily target mental health outcomes, such as stress reduction and enhanced emotional regulation, which in turn influence cognitive functions such as attention and working memory. The cognitive improvements potentially assist employees in developing better focus, reducing procrastination, and making fewer mistakes. However, the full impact on work-related performance takes time to emerge, as individuals first need to internalize these practices into their routines. This gradual process is consistent with findings in prior research, which showed that improvements in cognitive functions, particularly attention and working memory, were most apparent after completing the full course of mindfulness training [8]. Additionally, another study found that substantial improvements in absenteeism and presenteeism were observed at 8 weeks, compared with the 4-week results [14], suggesting that longer-term engagement with behavioral health interventions leads to more significant reductions in functional impairments.

Workplace productivity is a complex outcome influenced by both mental health and cognitive factors. In this context, the observed improvements in concentration difficulties, decision-making, and overall performance are consistent with the potential benefits of behavioral interventions delivered through a digital health platform [15,16]. These findings also suggest that consistent engagement is essential for employees to report meaningful improvements in their work performance over time.

Limitations

We noted several limitations in this study. First, as with all retrospective, single-arm, real-world data analyses, groups were not randomly assigned and treatment protocols were not prescribed, creating challenges for drawing causal inferences. Unmeasured confounding factors, such as baseline symptom severity, concurrent mental health treatment, coaching use, job type, work setting, or major life and work-related events, may have influenced changes in workplace function independently of program engagement. Second, participant-level demographic, geographic, and employer-sector characteristics were not available for inclusion, limiting the ability to assess subgroup effects across different workforce populations. In addition, the study relied on self-reported measures of workplace functioning, which are subject to recall bias and social desirability bias. Although self-reported outcomes are highly relevant for subjective experiences such as concentration difficulties and procrastination, they may not fully reflect objective work performance or productivity.

Conclusions

This retrospective, single-arm, real-world analysis observed improvements in workplace function among users of the Dario Health digital behavioral health program over time. By targeting mental health outcomes first and gradually improving cognitive functions, digital behavioral health programs offer employees a valuable tool for enhancing workplace performance. The findings suggest that sustained engagement with a digital behavioral health platform is associated with favorable outcomes in work-related functioning and mental health outcomes. Future controlled and comparative research should continue to explore the long-term effects of such interventions, further refining strategies for optimizing workplace functionality, productivity, and well-being.

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Data Availability

The datasets generated or analyzed during this study are not publicly available due to the company’s privacy policy but are available from the corresponding author on reasonable request, subject to company policies.

Authors' Contributions

Conceptualization: DLH, OM, YF-H
Data curation: IBA
Formal analysis: IBA
Investigation: IBA, YF-H
Methodology: IBA, YF-H
Resources: YF-H
Supervision: YF-H
Writing – original draft: IBA, YF-H
Writing – review and editing: DLH, OM

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Conflicts of Interest

IBA, OM, and YF-H are employees of DarioHealth Corp. DLH serves as a DarioHealth scientific advisory board member.

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Abbreviations

AIC: Akaike information criterion
BIC: Bayesian information criterion

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Original Paper

Automated Annotation of Pain Chronicity in Patients With Back Pain by Using Electronic Health Records: Retrospective Study

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Abstract

Background: Chronic back pain is a severe health condition with underlying biopsychosocial factors that make diagnosis difficult, and pain chronicity has been shown to be an important variable for studying patient outcomes. Due to the absence of standardized criteria, pain chronicity needs to be manually annotated by clinicians in electronic health records (EHRs), which is not only time consuming but also has the potential to introduce variability in analysis and interpretation among practitioners.

Objective: Pain chronicity is not typically recorded in EHRs and currently needs to be manually annotated by experts. Using a dataset from an interdisciplinary spine clinic consisting of 386 patients manually annotated for pain chronicity by clinical experts, this study has two objectives: (1) to examine the relationship between expert-annotated chronicity and social determinant variables present in EHRs and (2) to evaluate the feasibility of extracting pain chronicity from the EHR without expert annotation.

Methods: We used a supervised machine learning model, specifically univariate regression, to examine associations between clinician-annotated pain chronicity values and the structured variables present in EHRs. Next, we trained a random forest model to predict pain chronicity by using both structured and unstructured data extracted by clinical Text Analysis and Knowledge Extraction System, a natural language processing (NLP) tool. The features extracted included clinical keywords; duration of pain reported; and the International Classification of Diseases, Tenth Revision codes. The model was assessed using the Pearson correlation coefficient and mean absolute error (MAE).

Results: The study analyzed 386 patients (mean age 60.2 years, SD 16.1 years and median age 62.0 years, IQR 48.8-72.0 years) from the San Francisco Bay Area, with 62.7% (n=242) identifying as women. Our univariate regression analysis identified structured EHR variables associated with pain chronicity, which include pain severity before the last visit (P=.006), number of imaging orders (P=.006), number of visits to the neurology department (P=.01), and Medi-Cal insurance coverage (P=.03). Our random forest model using structured data showed a strong correlation of 0.887 (P<.001) with an MAE of 18.45 between predicted and observed chronicity, whereas our model that used the NLP tool to extract information from unstructured clinical notes and structured data showed a slightly higher correlation of 0.968 (P<.001) with an MAE of 10.87 between predicted and observed chronicity.

Conclusions: Our study indicates that pain chronicity from EHR data could be used to study more topics on larger datasets in the future without the need for manual annotation and that using NLP tools to automate prediction is feasible.

(JMIR Form Res 2026;10:e63198) doi:10.2196/63198

KEYWORDS

chronic back pain; phenotyping; machine learning; electronic health records; prediction; algorithms; medical informatics; time series analysis; longitudinal data; clinical decision support; machine annotation

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Introduction

While there is no singular cause, chronic back pain often stems from conditions such as sciatica or spinal stenosis [1]. Chronic back pain is already the most prevalent source of chronic pain, which cost the United States an estimated US$134.5 billion in 2016 alone, and is projected to increase by 36.4% in total cases globally by 2050 [2-4]. A characteristic of back pain is that it is often subjective in nature [5,6]. Individuals who experience pain for a prolonged period are considered to have chronic back pain. Pain is influenced by a complex mixture of biopsychosocial factors [7], and there has been increased interest in understanding how pain negatively affects an individual's objective function. However, much work needs to be done to better understand the multifaceted approach required for treating back pain that considers the complex interplay between biological, psychological, and social factors.

Recent wide-scale adoption of electronic health records (EHRs) indicates that the health care field is evolving toward large databases of patient information. EHRs make the entry, storage, and sharing of patient information among the multiple health care providers seamless. The adoption of EHR systems opens new avenues for research and innovation in health care. As clinicians use EHR systems to document findings, this documentation provides an opportunity to study recorded data and develop automated systems for extracting information from the EHR. The automation of data extraction processes from EHRs can significantly alleviate the burden on clinicians, who would otherwise spend countless hours manually reviewing patient charts [8,9].

Particularly for back pain, although a very important variable for patient diagnosis and treatment, pain chronicity is often difficult to ascertain from structured EHR fields. Due to the absence of standardized criteria, pain chronicity needs to be manually annotated by clinicians in EHRs, which is not only time consuming but also has the potential to introduce variability in analysis and interpretation among practitioners. Clinical documents, such as clinician notes, diagnosis codes, laboratory reports, procedures, and hospital visits, can be inputted into models using natural language processing (NLP) [10]. NLP with machine learning of clinical documents in the EHRs may enable automated injury scoring [9]. This is a major impediment to back pain research because the duration of symptoms plays a crucial role in predicting the progression of back pain over time.

The automation of data extraction processes from EHRs can significantly alleviate the burden on clinicians, who would otherwise spend countless hours manually reviewing patient charts [8,9]. We hypothesize that pain chronicity can be automatically extracted from the EHR using statistical and NLP techniques, thus making the information available for research in large EHR databases. These techniques have the potential to extend to larger EHR databases in the future, such as the Observational Health Data Sciences and Informatics network, which includes data from more than 810 million individuals [11].

Methods

Study Design

This was an observational cohort study with data retrospectively collected from EHRs of patients who visited a specialty spine clinic, the Integrated Spine Services at the University of California, San Francisco, from December 2017 to March 2020. The Integrated Spine Service is a multidisciplinary program focused on improving the quality of care delivered to patients with spinal (cervical, thoracic, or lumbar) pain [12]. Our dataset consisted of outpatient EHRs, which included information on social determinants of health and clinical notes.

The study included patients aged 25 to 97 years with chronic back pain who had been diagnosed by a clinician using an *International Classification of Diseases, 10th Revision* (ICD-10) code ranging between M54.0 and M54.9 [13], had a documented history of pain lasting more than 3 months, and had complete EHRs, including social determinants of health information. Patients were excluded if their files were not annotated with "chronic back pain" or the corresponding ICD-10 code or if their EHR was incomplete or missing. The overall goal of the study was to examine the relationship between expert-annotated pain chronicity and various factors and to evaluate the feasibility of automating the annotation of pain in the EHR of patients with chronic back pain.

Ethical Considerations

This study received institutional review board approval from the University of California, San Francisco (20-31733). The institutional review board determined that the study qualifies as non–human subjects research, as it involved a retrospective analysis of fully deidentified EHR data collected as part of a clinical quality initiative. Therefore, informed consent was not required. All patient data used in this study were deidentified before analysis and are available upon institutional review. Identifiers such as names, dates, addresses, and medical record numbers were removed in accordance with the Health Insurance Portability and Accountability Act (HIPAA) Safe Harbor guidelines and institutional policy. The research team did not have access to the key linking codes to reidentify the data. There was no direct interaction with participants, and no patients were contacted or compensated for the purposes of this study. No identifiable images or other personally identifying information were included in the manuscript.

Primary Outcome and Features

The primary outcome of interest was pain chronicity, which was assessed by its duration in months and recorded by clinicians. Pain chronicity was manually annotated by clinicians based on the duration of chronic back pain (Multimedia Appendix 1). The scale ranged from 0 months to decades, which was determined by clinicians based on their assessment of the EHRs. For modeling, chronicity was capped at 66 months (≥5.5 years), as this was determined to be sufficient for research or predictive modeling and matched the maximum amount of time available in the EHR. This information was captured retrospectively from the electronic medical records by reviewing the ICD-10 codes assigned during visits and clinical notes.

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ICD-10 codes ranging from M54 to M54.9 were used, as each value corresponds to a specific diagnosis. Features that were consolidated into the model were retrospectively collected from the EHR system. The data included age (years), sex (male or female), clinical notes (physician observations and diagnoses), BMI (kg/m^2), height (cm), race, ethnicity, insurance details, smoking status, first visit date, last visit date, STarT Back risk level, Patient-Reported Outcomes Measurement Information System scores, Area Deprivation Index information, hospital visits to the neurology department, hospital visits to the orthopedic department, and imaging tests (eg, magnetic resonance imaging, computed tomography, and x-ray). These features were included, as they were determined to be relevant to the incidence of chronic back pain based on clinical judgment and previous research.

Statistical Analysis

RStudio (version 2023.09.1; RStudio PBC) was used for all statistical analyses. Our aim is to explore the relationship between pain-related diagnosis and patient characteristics. To understand the sample, we conducted univariate regression analysis to explore the relationship between annotated pain chronicity—our dependent variable—and a range of potential predictors. These predictors encompassed demographic factors, such as age, sex, and race and ethnicity, as well as clinical indicators, including anxiety; depression; and various medical conditions such as heart disease, high blood pressure, and diabetes. In addition, lifestyle factors such as smoking status and opioid use were considered. The analysis also incorporated the presence of specific ailments such as asthma, migraine, and rheumatoid arthritis, among others. All features were included in the model, and their associations with the outcome were evaluated based on their respective estimates, SEs, test statistics, and *P* values.

Natural Language Processing

Our study Our study used Apache cTAKES (Clinical Text Analysis and Knowledge Extraction System), which is a powerful open-source NLP model. The cTAKES builds on existing open-source technologies—the Unstructured Information Management Architecture framework and OpenNLP NLP toolkit. Its components, specifically trained for the clinical domain, create rich linguistic and semantic annotations [14]. After processing the clinical notes using cTAKES, the extracted diagnosis codes can be used in the same manner as the structured diagnosis codes.

Machine Learning Model

The caret package in R (R Foundation for Statistical Computing) was used to train a random forest model [15]. Pain chronicity was used as the outcome variable, and predictors were constructed using structured and unstructured EHR data collected before the last visit date. To train the model, performed a 10-fold cross-validation with 1 repetition. To compare, we trained one random forest model using only structured data and another model using both structured data and NLP results from the unstructured clinical notes. Only NLP-extracted information related to pain diagnosis codes was used and included in the "pain counts before last visit" variable. We used the Pearson correlation coefficient and the mean absolute error (MAE) to assess model performance.

Results

Our cohort consisted of 1295 patients with orthopedic pain. Within this cohort, our extracted sample size included 394 patients who met criteria for specific variables of interest, including, but not limited to, diagnosis codes (ICD-10: M54.0 to M54.9), free-text notes, patient visit history, and imaging tests related to chronic back pain. Before conducting a demographic analysis specific to our sample size, we conducted a manual check and found 8 instances where the first visit date of the patient was missing.

Thus, our final sample included 386 patients who were residents of the San Francisco Bay Area, with 70.2% (n=271) residing in urban areas, 12.4% (n=48) in predominantly suburban areas, 10.6% (n=41) in upscale suburban areas, and 3.9% (n=15) in the San Francisco Peninsula. The median age of the sample was 62.0 (IQR 48.8-72.0) years, and the mean age was 60.2 (SD 16.1) years. Our sample comprised 62.7% (242/386) of patients who identified as women and 37.3% (144/386) who identified as men. Race was predominantly defined by 3 categories (ie, 189/386, 49% White; 85/386, 22% Asian; 56/386, 14.5% Black or African American), and 9.1% (35/386) of the patients identified as Hispanic or Latinx. The sample had 3 insurances: Medicare (125/386, 32.4%), commercial insurance (37/386, 9.6%) and Medi-Cal Managed care (31/386, 8%; Table 1).

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Table 1. Demographic characteristics of patients with chronic back pain, identified by International Classification of Diseases, 10th Revision, codes in the electronic health records, who visited the Interdisciplinary Spine Clinic at the University of California, San Francisco, between December 2017 and March 2020 (N=386).

Variable	Values, n (%)
Sex	
Female	242 (62.7)
Male	144 (37.3)
Race	
American Indian or Alaska Native	1 (0.3)
Asian	85 (22)
Black or African American	56 (14.5)
Native Hawaiian or other Pacific Islander	4 (1)
Other Pacific Islander	1 (0.3)
White	189 (49)
Other	44 (11.4)
Declined	6 (1.6)
Ethnicity	
Hispanic or Latino	35 (9.1)
Not Hispanic or Latino	342 (88.6)
Declined	8 (2.1)
Unknown	1 (0.3)
Bay Area region	
San Francisco city	271 (70.2)
East Bay	48 (12.4)
North Bay	41 (10.6)
San Francisco Peninsula	15 (3.9)
Missing	11 (2.8)

The information in the EHRs from the spine clinic consisted of multiple variables. First, we conducted a univariate regression analysis to ascertain each variable's individual association with chronic pain severity. The analysis indicated a positive relationship between the pain severity before the last visit, the number of prior imaging orders (P<.001), the number of prior visits to the neurology department (P=.01), Medi-Cal insurance (P=.02), prior opioid antagonist prescriptions (P=.08), and a negative relationship with commercial insurance (P=.05). Table 2, ordered by ascending P values, highlights the most influential predictors of chronic pain severity based on their association strength.

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Table 2. Top 10 variables from the structured electronic health records associated with manually annotated pain chronicity levels in patients with chronic back pain who visited the integrated spine clinic at the University of California, San Francisco, between December 2017 and March 2020.

Variable	Estimate (SE)	Coefficient	*P* value
Pain counts before the last visit	6.2289928 (1.2429963)	5.0112722	<.001
Number of prior imaging orders (MRI[a], CT[b], or X-ray)	0.4973738 (0.1671713)	2.9752338	.003
Number of prior visits to the neurology department (spine)	0.6731830 (0.2472161)	2.7230548	.007
Insurance type (Medi-Cal)	7.8438835 (3.8850542)	2.0189895	.04
BMI	0.4714030 (0.2693194)	1.7503493	.08
Number of prior visits to the orthopedic department	0.2661974 (0.1650582)	1.6127484	.11
All clinical notes	0.0635035 (0.0462438)	1.3732308	.17
ADI[c] rank (state)	1.3598764 (1.0230850)	1.3291920	.18
Number of prior visits to the neurosurgery department	0.6092814 (0.4744465)	1.2841941	.19
Number of hospital or ED[d] visits	−0.2283034 (0.2096801)	−1.0888178	.28

[a]MRI: magnetic resonance imaging.

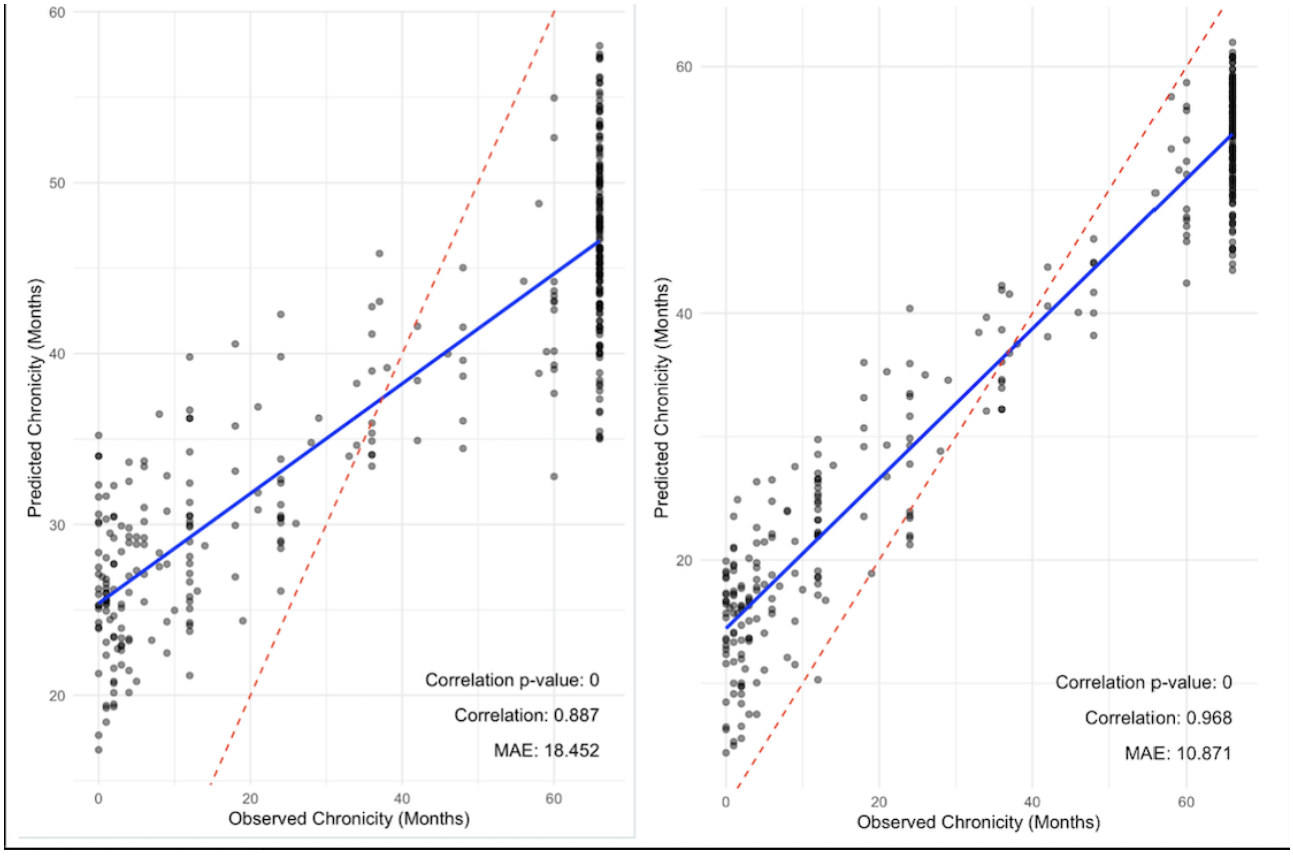
[b]CT: computed tomography.

[c]ADI: area deprivation index.

[d]ED: emergency department.

Univariate regressions were performed to assess the association of structured EHR variables with the manually annotated pain chronicity. The results are sorted by *P* value, and only the top 10 variables are included. Next, we used the random forest machine learning model to assess the performance of extracting pain chronicity from the EHR. For the model using only structured data (Figure 1A), a strong correlation was observed between predicted and observed chronicity values, with a correlation coefficient of 0.887 and an MAE of 18.45 (correlation *P* value =0).

Figure 1. (A) Accuracy of prediction of pain chronicity levels using structured electronic health record data without utilization of natural language processing tools. (B) Accuracy of prediction of pain chronicity levels using unstructured electronic health record data with utilization of natural language processing tool. MAE: mean absolute error.



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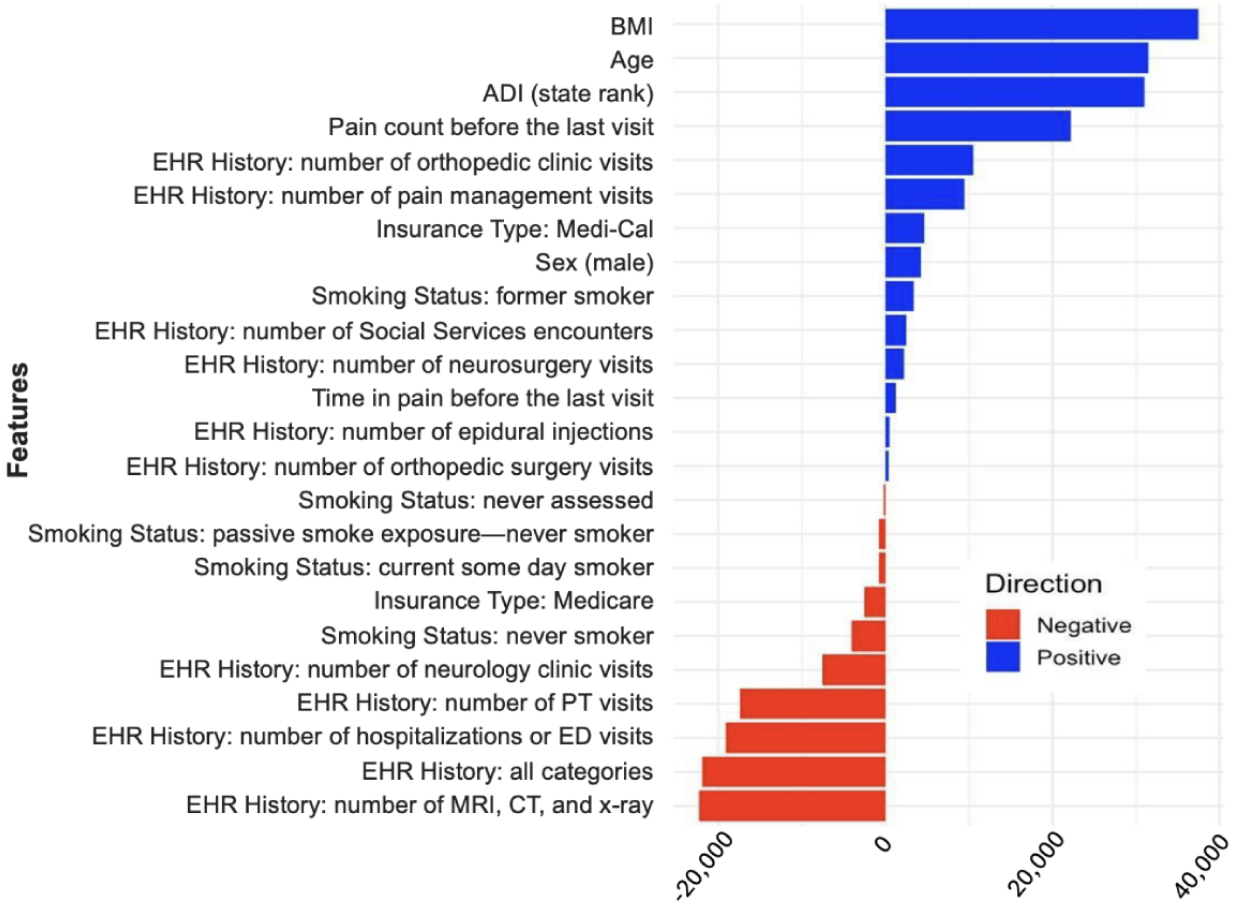
However, when using NLP tools to extract information from unstructured data (Figure 1B), the correlation coefficient increased to 0.968, with an MAE of 10.87. This suggested improved accuracy in predicting chronicity when using NLP tools compared to the model without NLP tools. Both approaches demonstrated strong correlations (structured model: r=0.887, P<.001; NLP-enhanced model: r=0.968, P<.001) between predicted and observed chronicity values, with predictions showing a lower MAE. The use of NLP tools resulted in more accurate predictions with lower MAE. Overall, the most important features for predicting pain chronicity in the NLP model (Figure 2) were BMI, age, area deprivation index, and pain count before the last visit predicted by the model to increase the chronicity of pain, whereas EHR visit history and smoking status (never smoker) were used by the model to predict decreased pain chronicity.

Figure 2. Feature importance ranked by mean decrease in Gini from a random forest model, which is predicting pain chronicity levels from electronic health records of patients with chronic back pain. ADI: area deprivation index; CT: computed tomography; EHR: electronic health record; MRI: magnetic resonance imaging; PT: physiotherapy.



Discussion

Principal Findings

Our study successfully demonstrated the feasibility of automatic extraction of pain chronicity from EHRs using a combination of structured data and NLP techniques on unstructured clinical notes. Our findings support our initial hypothesis that automation of this process is feasible, which reduces the need for manual chart review by clinicians. Our results highlight the potential for application of this method to larger EHR databases, which would enable expansive chronic pain research. The initial univariate regression analysis identified several variables significantly associated with chronic pain severity. A positive relationship was observed with the number of pain diagnoses before the last visit, prior imaging orders, prior visits to the neurology department, Medi-Cal insurance, and prior opioid antagonist prescriptions, while a negative relationship was noted with commercial insurance. Furthermore, we used a random forest machine learning model and used an NLP tool to compare the accuracy between the use of just structured EHR data versus the use of structured EHR data and the information extracted from unstructured clinical notes with the help of the cTAKES tool. As evidenced by a lower MAE of 10.87, the model that used both structured data and unstructured information extracted by the NLP tool had superior performance.

The use of EHRs to develop a predictive model for lower back pain outcomes is not a novel concept. In an observational study to identify acute low back pain in primary care practice from clinical notes [16], the researchers noticed that due to a lack of distinguishing codes, both chronic and acute low back pain are coded in the EHRs with the same ICD-10 code and can only be differentiated by retrospective chart reviews. The objective of their study was to evaluate the feasibility of automatically distinguishing acute low back pain by analyzing free-text clinical

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notes. A dataset of 17,409 clinical notes from different primary care practices was used, of which 891 documents were manually annotated as acute low back pain and 2,973 were generally associated with low back pain based on the recorded ICD-10 code.

Published studies have reported that the use of machine learning models on EHR data has been successful in the extraction of predictors of pain. In a retrospective study that used EHR data from UConn Health John Dempsey Hospital applied NLP technology to an EHR dataset as part of a pilot study to capture pain information from clinical notes and prove its feasibility as an efficient method. Their pain extraction model created using the NLP tool was successful in extracting granular pain parameters from the clinical notes. The model identified back pain as the most commonly reported pain location, with 40,369 term frequencies. In identifying body location, the model has a precision value of 0.78 and a recall value of 1, resulting in an *F* score of 0.87. In identifying co-occurring symptoms within the clinical note, the model has a precision value of 1 and a recall value of 1, resulting in an *F* score of 1 [17].

Different supervised and unsupervised strategies were used for automated identification, such as keyword search, topic modeling, logistic regression with bag-of-n-grams and manual features, and deep learning models (a convolutional neural network [ConvNet]–based architecture). They trained the models using either manual annotations or ICD-10 codes as positive labels. The results showed that the ConvNet trained using manual annotations obtained the best results, with an area under the receiver operating characteristic curve of 0.98 and an *F* score of 0.70. ConvNet's results were also robust to reductions in the number of manually annotated documents. It was also seen that in the absence of manual annotations, topic models performed better than methods trained using ICD-10 codes, which were unsatisfactory for identifying low back pain acuity [16]. This study uses clinical notes to analyze and understand different therapeutic treatments, guidelines for billing, and management options for acute low back pain. Similarly, we leveraged information in EHRs to automate the extraction of pain chronicity and used both machine learning and NLP methods.

Limitations

We worked with retrospective data, which come with their own drawbacks, such as conscious or unconscious bias and lack of control toward confounding factors. Due to this, assessment of chronicity of back pain was subjected to biased interpretation of symptoms by clinicians based on their experiences and the subjective nature of patient reporting, which can often be influenced by health literacy and social determinants, potentially leading to misdiagnosis. Our sample size is left skewed, with most of the patients having long-standing back pain (ie, for ≥5 years), which makes generalization of our results difficult. As our data source is from the EHR, there is a high likelihood of incomplete notes, which poses a significant challenge because accurate information is required to provide successful patient care. This issue is highlighted when essential information is missing, which can hamper the accuracy of our model. Communication barriers resulting in misinterpretation of patient conditions, redundant tests, and absence of visit dates are some of the common gaps that can compromise patient safety, which may be misinterpreted by the machine learning model, resulting in inaccurate results.

Defining chronic pain (chronicity) is also a challenge because there is an absence of a precise definition due to the complexity of its nature. In this study, we classified it as an ailment lasting beyond a certain time frame, with a minimum duration of 3 months.

Future Research

The observations of our study strongly suggest that the analysis of pain chronicity using EHR data holds promise for exploring a broader range of topics on larger datasets in the future, eliminating the necessity for manual annotation.

Conclusions

By leveraging the information in EHRs using machine learning models, which contain information on patient health over time, we can potentially delve into various aspects related to chronic pain without the labor-intensive process of manual annotation. This approach not only offers adaptability but also opens doors to uncovering insights into the progression, management, and impact of chronic pain on individuals and populations. In addition, the use of larger datasets can enhance statistical power and allow for more robust analyses, enabling researchers to explore nuanced relationships and trends related to chronic pain with greater accuracy and confidence. Consequently, our study underscores the potential of leveraging clinical data to advance our understanding of pain chronicity and its broader implications for health care and research, which can pave the way for future investigations into this critical area without the constraints of manual annotation.

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Data Availability

The data analyzed in this study were derived from electronic health records and contain protected health information. For this reason, the data are not publicly available. Deidentified data may be made available from the corresponding author on reasonable request, subject to approval by the appropriate institutional review board and in accordance with institutional policies and applicable data use agreements.

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Conflicts of Interest

None declared.

Multimedia Appendix 1

Frequency distribution of manually annotated pain chronicity (in months) by clinicians in the electronic health records (EHRs) of patients was collected at the interdisciplinary spine clinic at University of California, San Francisco, between December 2017 and March 2020. The study population included patients from the San Francisco Bay Area aged between 25 and 97 years. Pain chronicity levels were manually annotated through EHR review, with a focus on the number of visits in this retrospective observational study.

[PNG File , 16 KB - formative_v10i1e63198_app1.png]

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Abbreviations

cTAKES: clinical Text Analysis and Knowledge Extraction System
EHR: electronic health record

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HIPAA: Health Insurance Portability and Accountability Act
ICD-10: International Classification of Diseases, 10th Revision
MAE: mean absolute error
NLP: natural language processing

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Original Paper

Health-Related Quality of Life Before and After Sobriety in Combination With an Adjunctive Journaling App in Patients With Alcohol-Related Liver Disease: Prospective Single-Arm Study

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Abstract

Background: Alcohol-related liver disease (ALD) is a global health concern, and harmful alcohol use negatively affects clinical outcomes and health-related quality of life (HRQOL). Previous studies have demonstrated impaired HRQOL in chronic liver disease, including ALD; however, evidence remains limited regarding whether hepatologist-delivered abstinence support in outpatient practice can improve HRQOL. Digital interventions such as smartphone journaling apps may support behavior change, but their effectiveness in hepatology-led care settings has not been well established.

Objective: This study aimed to prospectively evaluate changes in HRQOL over time among patients with ALD receiving routine hepatologist-led abstinence support supplemented by a smartphone-based journaling app.

Methods: This was a prospective single-arm observational study. Eligibility criteria included a diagnosis of ALD, outpatient follow-up in hepatology, advice to abstain from alcohol, and written informed consent; patients were excluded if they reported abstinence for >1 year, had no intention to reduce or abstain from alcohol, or declined medical follow-up. In total, 21 outpatients with ALD (mean age 51, SD 3 years; men: n=12, 57.1%) were enrolled from a gastroenterology and hepatology outpatient clinic between August 2021 and July 2023 (convenience sampling). Participants attended scheduled visits at 4, 8, 12, and 24 weeks and received brief abstinence counseling by hepatologists while using a journaling app. HRQOL was assessed using the Japanese version of the 36-Item Short Form Health Survey version 2 at entry, week 8, and week 24. Changes in subscale and summary scores were analyzed using paired *t* tests (2-sided α=.05) with 95% CIs; when normality assumptions were not met, Wilcoxon signed-rank tests were applied.

Results: From entry to week 8, significant improvements were observed in physical functioning (mean difference [MD] +4.70, 95% CI 1.62-7.78; *P*=.005), role physical (MD +7.87, 95% CI 1.05-14.70; *P*=.02), general health (MD +5.82, 95% CI 1.74-9.88; *P*=.007), and role emotional (MD +7.85, 95% CI 0.29-15.41; *P*=.04). The Physical Component Summary score also improved (MD +4.78, 95% CI 1.22-8.34; *P*=.01). These findings were consistent in sensitivity analysis using the Wilcoxon signed-rank test. No significant changes were observed in mental or social HRQOL domains. In subgroup analyses, patients who maintained abstinence during the first 8 weeks (7/21, 33.3%) showed continued improvement in physical HRQOL up to 24 weeks, whereas those who continued drinking (11/21, 52.4%) did not exhibit meaningful change.

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Conclusions: In this exploratory observational study, hepatologist-led abstinence support supplemented by a smartphone-based journaling app was associated with improvements in physical HRQOL. Unlike previous studies that have focused on addiction specialist–led interventions, this study evaluated abstinence support delivered by hepatologists in routine outpatient practice, providing a real-world assessment of a digitally supported approach. These findings suggest that hepatologist-led, digitally supported care may be a feasible strategy in clinical settings with limited access to specialized addiction services.

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KEYWORDS

alcohol-related liver disease; health-related quality of life; patient-reported outcome; smartphone journaling app; SF-36

Introduction

Alcohol-Related Liver Disease and the Clinical Relevance for Abstinence Support

Alcohol-related liver disease (ALD) is a major and growing global health problem, with increasing prevalence and disease burden worldwide, including in Japan [1-4]. The World Health Organization adopted a global strategy to reduce the harmful use of alcohol in 2010 and, more recently, reinforced the urgency of this issue through the Global Alcohol Action Plan 2022-2030, underscoring that harmful alcohol use remains a major global priority [1]. Recent epidemiological data indicate that the prevalence and impact of ALD continue to rise worldwide, including in Japan [2-4].

ALD encompasses a wide spectrum of diseases, ranging from simple steatosis to cirrhosis and hepatocellular carcinoma, and ongoing alcohol consumption plays a central role in disease progression [5]. Observational studies have consistently reported associations between abstinence and favorable liver-related outcomes, positioning interventions targeting drinking behavior as a core component of ALD management [5-7].

Early identification of harmful drinking and timely intervention are therefore essential components of ALD management. Screening tools such as the Alcohol Use Disorders Identification Test are widely used in clinical practice [8,9], and brief interventions that encourage self-monitoring of alcohol consumption have been shown to reduce alcohol intake [10]. While such identification and early intervention are ideal, most patients with alcohol use disorder (AUD) have not received intervention or been referred to specialists [11]. A recent survey of hepatologists and gastroenterologists reported that although AUD screening was nearly universal, many clinicians reported low comfort with and low rates of prescribing AUD pharmacotherapy due to insufficient training and perceived knowledge gaps [12]. Collaboration with a multidisciplinary team may improve interventions for AUD [13]. Although evidence remains limited, recent randomized controlled trials have demonstrated that digital tools, including smartphone apps, can contribute to reductions in alcohol consumption [14].

Evidence for Digital Interventions in Alcohol Use

Systematic reviews of mobile health interventions for alcohol use have reported that many mobile apps and digital strategies are associated with reductions in alcohol consumption or related behaviors, although evidence regarding optimal design and outcomes remains heterogeneous [15]. In addition, systematic reviews of telehealth and digitally delivered cognitive behavioral therapy for AUD suggest that digital tools can decrease drinking behavior and may offer sustained benefits when used longitudinally [16]. Despite this growing evidence, most digital alcohol interventions have been evaluated under controlled research conditions or in general populations rather than within routine hepatology outpatient practice [14,15]. Taken together, these studies suggest that digital tools are feasible and potentially effective for alcohol reduction, but evidence remains limited regarding their impact on patient-centered outcomes, such as health-related quality of life (HRQOL) in routine hepatology care.

Preliminary studies in patients with alcohol-associated liver disease have demonstrated the feasibility and potential utility of digital therapeutics that combine smartphone apps with behavior change techniques, reporting associations with reduced alcohol use and increased abstinence in open-label settings [17]. Furthermore, a multicenter randomized controlled trial protocol has been published to evaluate the real-world effectiveness and cost-effectiveness of such smartphone-based digital therapeutics in patients with ALD, highlighting a growing focus on real-world implementation [18]. A usability study also indicates that patients with ALD generally perceive mobile health tools as accessible and acceptable for supporting alcohol cessation, supporting their integration into routine care [19]. Self-monitoring of alcohol intake is a core component of many behavioral change interventions and has been associated with increased awareness of drinking patterns and motivation to reduce consumption [15]. In this context, we previously developed a smartphone-based journaling app designed to support abstinence through patient self-monitoring and hepatologist review. In our pilot study conducted in a hepatology outpatient clinic, this approach was associated with reduced alcohol consumption and improved liver function over an 8-week period [20]. However, the broader impact of such abstinence support on patient-centered outcomes remains unclear.

HRQOL in ALD: Evidence Gaps in Routine Outpatient Care

Beyond biochemical and clinical outcomes, ALD substantially impairs patients' quality of life (QOL). Harmful alcohol use is associated with multidimensional burdens affecting physical, psychological, and social functioning, and HRQOL is commonly evaluated using generic instruments such as the 36-Item Short Form Health Survey (SF-36) and EQ-5D [21-23]. Previous studies have shown that HRQOL is impaired in patients with chronic liver disease regardless of etiology [23] and that ongoing

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alcohol use in cirrhosis is associated with further deterioration in QOL [24].

More recent evidence from studies in patients with alcoholic hepatitis has further highlighted the prognostic and clinical relevance of HRQOL [25]. In these highly selected populations with advanced disease severity and poor short-term prognosis (90-day mortality was approximately 15%), lower baseline mental and physical component scores were associated with increased mortality, and patients who achieved sustained abstinence over 180 days demonstrated greater recovery in both mental and physical HRQOL compared with those who continued drinking [25].

However, these findings were derived from patients with advanced disease in inpatient or specialist settings. It remains unclear whether similar changes in HRQOL can be observed in routine hepatology outpatient practice, where patients with ALD are often managed by hepatologists rather than addiction specialists and where disease severity is generally less advanced.

Study Rationale and Aim

In routine hepatology outpatient practice, hepatologists frequently provide abstinence guidance as part of longitudinal ALD management [5,26], yet the impact of such care on HRQOL has not been well characterized. Moreover, evidence remains limited regarding whether a simple, feasible digital tool—such as a journaling app integrated into routine visits—is associated with longitudinal changes in HRQOL in real-world hepatology settings. Understanding these effects is essential to optimize patient-centered care and to inform the integration of digital tools into routine hepatology practice. Therefore, we prospectively evaluated changes in HRQOL over time among patients with ALD receiving hepatologist-led abstinence support supplemented by a smartphone-based journaling app.

Methods

Inclusion and Exclusion Criteria

Patients were eligible if they (1) had a diagnosis of ALD, (2) were outpatients attending the gastroenterology and hepatology clinic, (3) had been advised to abstain from alcohol, and (4) provided written informed consent. Patients were excluded if they self-reported having already maintained abstinence for more than 1 year, reported no intention to reduce or abstain from alcohol intake, or declined medical follow-up.

Participant Characteristics

A total of 21 adult outpatients with ALD were enrolled. The mean age was 51 years, and 57.1% (n=12) of the patients were men. All participants were receiving routine hepatology outpatient care and had been advised to abstain from alcohol.

Sampling Procedures

Participants were recruited consecutively during routine outpatient clinic visits (convenience sampling) between August 2021 and July 2023. No randomization or stratification procedures were applied. During the recruitment period, 31 patients who were considered eligible were approached. Of these 31 patients, 21 (67.7%) provided written informed consent and were enrolled. In total, 10 (10/31, 32.3%) patients were not enrolled because 7 (70%) reported no intention to reduce or abstain from alcohol use and 3 (30%) declined medical follow-up. Patients attended scheduled outpatient visits at 4, 8, 12, and 24 weeks. All participants received brief abstinence counseling by hepatologists and used a journaling app; app use was required until the 8-week visit and voluntary thereafter.

Sample Size, Power, and Precision

As HRQOL assessment was an exploratory outcome in this observational study, no a priori sample size or power calculation was performed. The sample size was therefore determined by the number of eligible patients who consented during the study period, and the analyses were intended to be descriptive and hypothesis generating rather than confirmatory. All analyses were conducted after completion of follow-up for all participants.

Measures and Covariates

HRQOL was assessed as the primary outcome using the Japanese version of the SF-36 version 2 (SF-36v2) at entry, week 8, and week 24. Achieved abstinence was defined as self-reported alcohol intake of 0 throughout the observation period.

No additional covariates were prespecified, and all analyses were conducted descriptively.

Data Collection

HRQOL data were collected using a self-administered questionnaire. Participants completed the Japanese version of the SF-36v2 independently at the outpatient clinic at entry, week 8, and week 24.

Quality of Measurements

To enhance data quality, trained research staff reviewed the completed questionnaires at each visit to check for missing responses or duplicate entries. When incomplete or unclear responses were identified, participants were asked to confirm or complete the items at the same visit.

Instrumentation

A smartphone-based journaling app with basic logging and clinician review functions was used [20]. App engagement metrics were not assessed because the primary outcome was HRQOL. HRQOL was assessed using the Japanese version of the SF-36v2 [27,28]. The SF-36 measures 8 health domains: physical functioning (PF), role physical (RP), bodily pain, general health (GH), vitality, social functioning, role emotional (RE), and mental health [29]. Three summary scores were derived from these subscales: the Physical Component Summary, Mental Component Summary (MCS), and Role/Social Component Summary (RCS). Scores were calculated using the official Japanese scoring system (web based) and expressed on a 0- to 100-point scale with norm-based scoring, standardized to a national mean of 50 (SD 10) based on the 2017 Japanese population norms [30].

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Masking

No masking or blinding procedures were implemented, as this was an observational study conducted during routine outpatient care.

Psychometrics

The SF-36v2 is a widely used and validated generic measure of HRQOL [29,31]. The Japanese version has demonstrated good internal consistency, with Cronbach α coefficients generally ranging from 0.72 to 0.90 across subscales, and acceptable test-retest reliability (intraclass correlation coefficients approximately 0.65-0.85) [27]. Construct validity has been supported by expected correlations with clinical status and by known-group differences between patients with chronic diseases and the general population [28,30]. Factor analyses have also confirmed a 2-component structure corresponding to the Physical and Mental Component summaries, consistent with the original US version [28]. Norm-based scoring is standardized to a national mean of 50 (SD 10) based on representative Japanese population data [30]. Given the prior validation of this instrument, no additional psychometric validation was performed in this study.

Conditions and Design

This study used a prospective, single-arm observational design. Participants were drawn from patients who had participated in a previously reported interventional study using a smartphone-based journaling app [20].

Data Diagnostics

Descriptive statistics were used to summarize patient characteristics at entry, including counts, means, medians, SD, ranges, minimum, and maximum for continuous variables and percentages for categorical variables. Missingness patterns were evaluated using the Little missing completely at random (MCAR) test, applied only to variables with missing data. Normality of continuous variables was assessed using the Shapiro-Wilk test.

Analytic Strategy

Changes in HRQOL scores were analyzed using paired *t* tests for each observed case, with mean differences and 95% CIs reported. For variables in which normality was rejected, the Wilcoxon signed-rank test was additionally performed. For subgroup analyses, due to the small number of participants, only the Wilcoxon signed-rank test was used. Between-group comparisons for characteristics at entry were conducted using Student *t* tests for normally distributed variables and the Wilcoxon rank sum test for nonparametric data. Categorical variables were compared using chi-square tests or Fisher exact tests, as appropriate. Summary scores were compared at entry, 8 weeks, and 24 weeks. A 2-sided *P* value of <.05 was considered statistically significant. All analyses were performed using STATA 18 (StataCorp LLC).

Reporting Standards

This paper was written in accordance with the *American Psychological Association* (*APA*) style, including the *Journal Article Reporting Standards for Quantitative Research* (*JARS-Quan*) [32].

Ethical Considerations

This study was registered with the University Hospital Medical Information Network Clinical Trials Registry (UMIN000045285). This study was approved by the Ethics Review Center of Kansai Medical University (2020252) and conducted in accordance with the Declaration of Helsinki. Written informed consent was obtained from all participants before enrollment. All data were deidentified before analysis, and no personally identifiable information was collected or stored. No compensation was provided to participants. The manuscript and supplementary materials contain no images or information that could identify individual participants.

Results

Patient Characteristics

Patient characteristics at entry are summarized in Table 1. The mean age was 51 (SD 3) years. Of the 21 patients, 12 (57.1%) were men, and 9 (42.9%) were women. The average BMI was 24.3 (SD 4.5) kg/m^2. In total, 52.4% (n=11) of the patients were married, and 66.7% (n=14) were employed; 38.1% (n=8) had coexisting mental disorders, and 66.7% (n=14) were smokers. Regarding drinking history, the average age at onset of drinking was 19 (SD 1) years, with an average drinking duration of 28 (SD 10) years and a daily alcohol consumption of 112 (SD 72) g. The mean Alcohol Use Disorders Identification Test score was 20 (SD 9).

Of the 21 patients enrolled, 18 (85.7%) remained in follow-up at 8 weeks, and 15 (71.4%) remained in follow-up at 24 weeks. Patient flow is shown in Figure 1. At 8 weeks, of the 18 patients, 7 (38.9%) who abstained were classified as the abstinence group, and 11 (61.1%) who continued drinking were classified as the nonabstinence group. At 24 weeks, 20% (3/15) of the patients remained abstinent. Here, the achieved abstinence was based on the self-reported alcohol intake of zero during the observation period.

Background factors are presented in Multimedia Appendix 1 by patient drinking status at 8 weeks. Patients who continued abstinence for 8 weeks had more liver cirrhosis than others (7/7, 100% vs 5/14, 35.7%; Fisher exact test *P*=.007). Similarly, more patients who continued abstinence for 8 weeks were hospitalized for liver-related complications (5/7, 71.4% vs 1/14, 7.1%; risk difference=−64.3%, 95% CI −100.4% to −28.2%; *P*=.002) and had a prolonged international normalized ratio (mean difference 0.55, 95% CI 0.26-0.84; *P*<.001) and lower hemoglobin (mean difference −2.58 g/dL, 95% CI −3.93 to −1.23; *P*<.001) and albumin (mean difference −1.1 g/dL, 95% CI −1.84 to −0.42; *P*=.004) than others.

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Table 1. Patient characteristics at entry of 21 patients with alcohol-related liver disease enrolled in a prospective single-arm study.

Factor	Values
Age (y), mean (SD)	51 (3)
Male sex, n (%)	12 (57)
BMI[a] (kg/m^2), mean (SD)	24.3 (4.5)
Married or coresiding with others[a], n (%)	11 (52.3)
Employed, n (%)	14 (66.6)
Mental illness comorbidity, n (%)	8 (38.1)
Alcohol use disorder	2 (9.5)
Alcohol use disorder and depression	2 (9.5)
Depression	1 (4.7)
Panic disorder	1 (4.7)
Eating disorder	1 (4.7)
Depression and eating disorder	1 (4.7)
Smoking[a] , n (%)	
Current smoker	14 (66.6)
Former smoker	3 (14.2)
Nonsmoker	3 (14.2)
Unknown	1 (4.7)
Age of starting drinking (y), median (IQR)	20 (16-20)
Drinking duration (y), mean (SD)	28 (10)
Daily alcohol consumption (ethanol equivalent; g), mean (SD)	112 (72)
AUDIT[b] score at entry, mean (SD)	20 (9)

[a]Missing values were observed for BMI (n=1), cohabitation status (n=1), and smoking status (n=1).
[b]AUDIT: Alcohol Use Disorders Identification Test.

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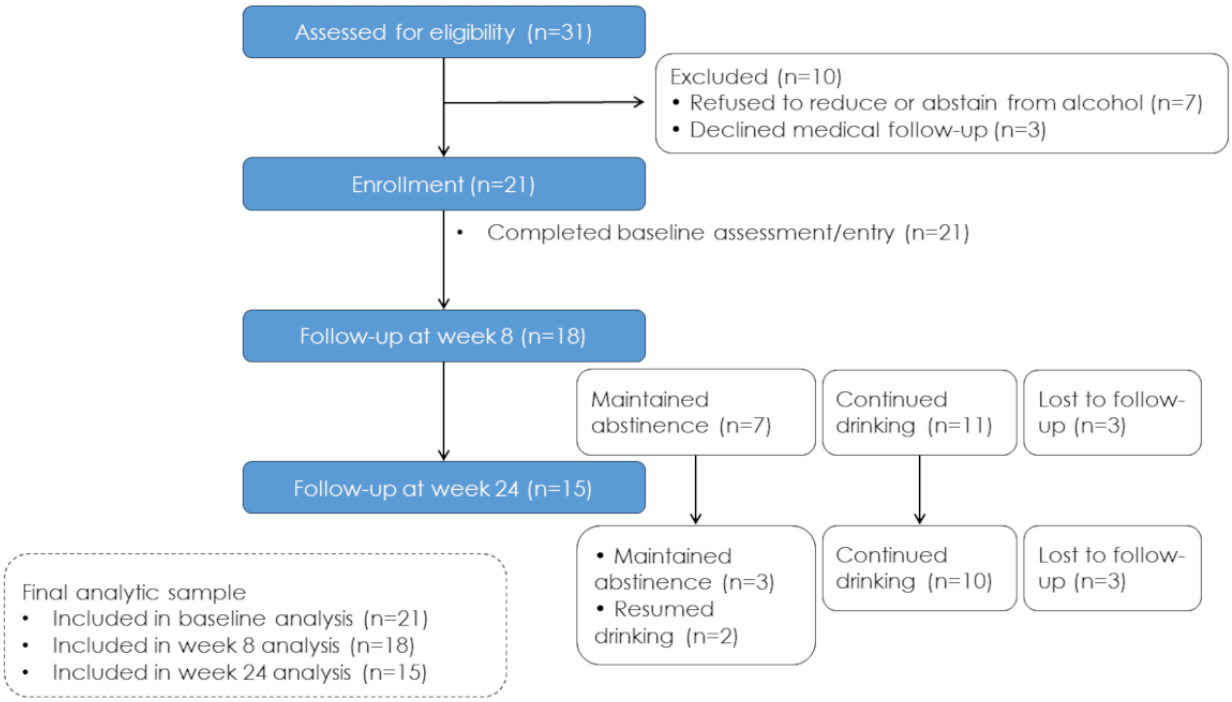
Figure 1. Participant flow diagram. In total, 31 patients were assessed for eligibility, of whom 21 were enrolled. Follow-up attendance included 18 patients at week 8 and 15 patients at week 24. At week 8, participants were classified into abstinence and nonabstinence groups based on self-reported alcohol intake.



Missing Data and MCAR Assessment

A small amount of missing data was present among the variables at entry: BMI (kg/m^2; 1/21, 4.8%), cohabitation status (1/21, 4.8%), and smoking status (1/21, 4.8%). The Little MCAR test yielded χ^2_6=10.8 (P=.09), indicating that the pattern of missingness was consistent with MCAR.

HRQOL Scores at Entry

The average scores of the 8 subscales assessed with SF-36v2 at entry are shown in Figure 2 (Multimedia Appendix 2). Patients enrolled in this study had lower HRQOL scores in all 8 subscales compared with the Japanese population norms (mean 50, SD 10 points).

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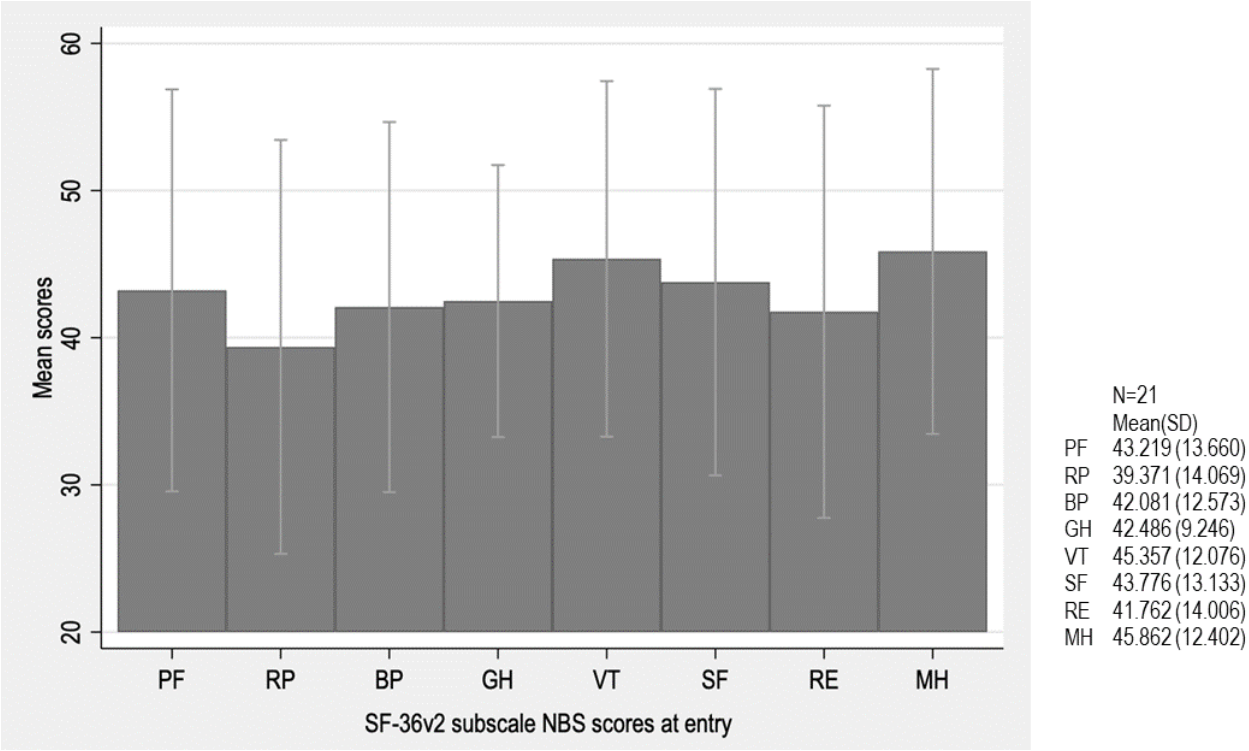
Figure 2. Mean scores of the 8 SF-36v2 subscales at entry, expressed using norm-based scoring (NBS). Scores are standardized to the Japanese population norm (mean 50, SD 10). Error bars indicate SD. Participants demonstrated lower scores across all 8 subscales compared with the Japanese population norms. BP: bodily pain; GH: general health; MH: mental health; PF: physical functioning; RE: role emotional; RP: role physical; SF: social functioning; VT: vitality.



Changes in HRQOL Scores

The results of pairwise comparison of each subscale and summary scores are shown in Figures 3 and 4. At the subscale level, PF increased by 4.70 points (95% CI 1.62-7.78; *P*=.005), RP increased by 7.87 points (95% CI 1.05-14.70; *P*=.02), GH increased by 5.82 points (95% CI 1.74-9.88; *P*=.007), and RE increased by 7.85 points (95% CI 0.29-15.41; *P*=.04) after 8 weeks (Figure 3). These results were consistent in a sensitivity analysis using the Wilcoxon signed-rank test (PF: *P*=.005; RP: *P*=.01; GH: *P*=.01; RE: *P*=.04). No significant changes were observed for bodily pain, vitality, social functioning, mental health, MCS, or RCS. The PCS score increased by 4.78 points (95% CI 1.22-8.34; *P*=.01), which was similarly supported by the Wilcoxon signed-rank test (*P*=.03; Figure 4). Changes in MCS and RCS were not significant on either test. From entry to week 24, RP showed a significant improvement, increasing by 7.90 points (95% CI 2.23-13.57; *P*=.009), which was consistent with the Wilcoxon signed-rank test (*P*=.02). In contrast, no other subscale or summary score showed significant changes from entry to week 24 or from week 8 to week 24 on 2-tailed paired *t* tests (all *P*>.14), and similar nonsignificant results were obtained using Wilcoxon signed-rank tests.

Further subgroup analysis revealed that patients in the abstinence group demonstrated significant improvements in PF (*P*=.02), GH (*P*=.02), and RE (*P*=.049) from entry to week 8 (Multimedia Appendix 3), whereas the nonabstinence group showed no appreciable improvement or deterioration (Multimedia Appendix 4). While overall pre-post changes in the entire cohort were analyzed using paired *t* tests, the subgroup comparisons were conducted using Wilcoxon signed-rank tests owing to the small sample size and deviation from normality.

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Figure 3. Changes in mean SF-36v2 subscale scores at entry, week 8, and week 24, expressed using norm-based scoring (NBS). Error bars indicate SD. Physical functioning (PF) increased by 4.70 points (95% CI 1.62-7.78; *P*=.005), role physical (RP) increased by 7.87 points (95% CI 1.05-14.70; *P*=.02), general health (GH) increased by 5.82 points (95% CI 1.74-9.88; *P*=.007), and role emotional (RE) increased by 7.85 points (95% CI 0.29-15.41; *P*=.04) after 8 weeks. BP: bodily pain; MH: mental health; SF: social functioning; VT: vitality. **P*<.01; ***P*<.05.

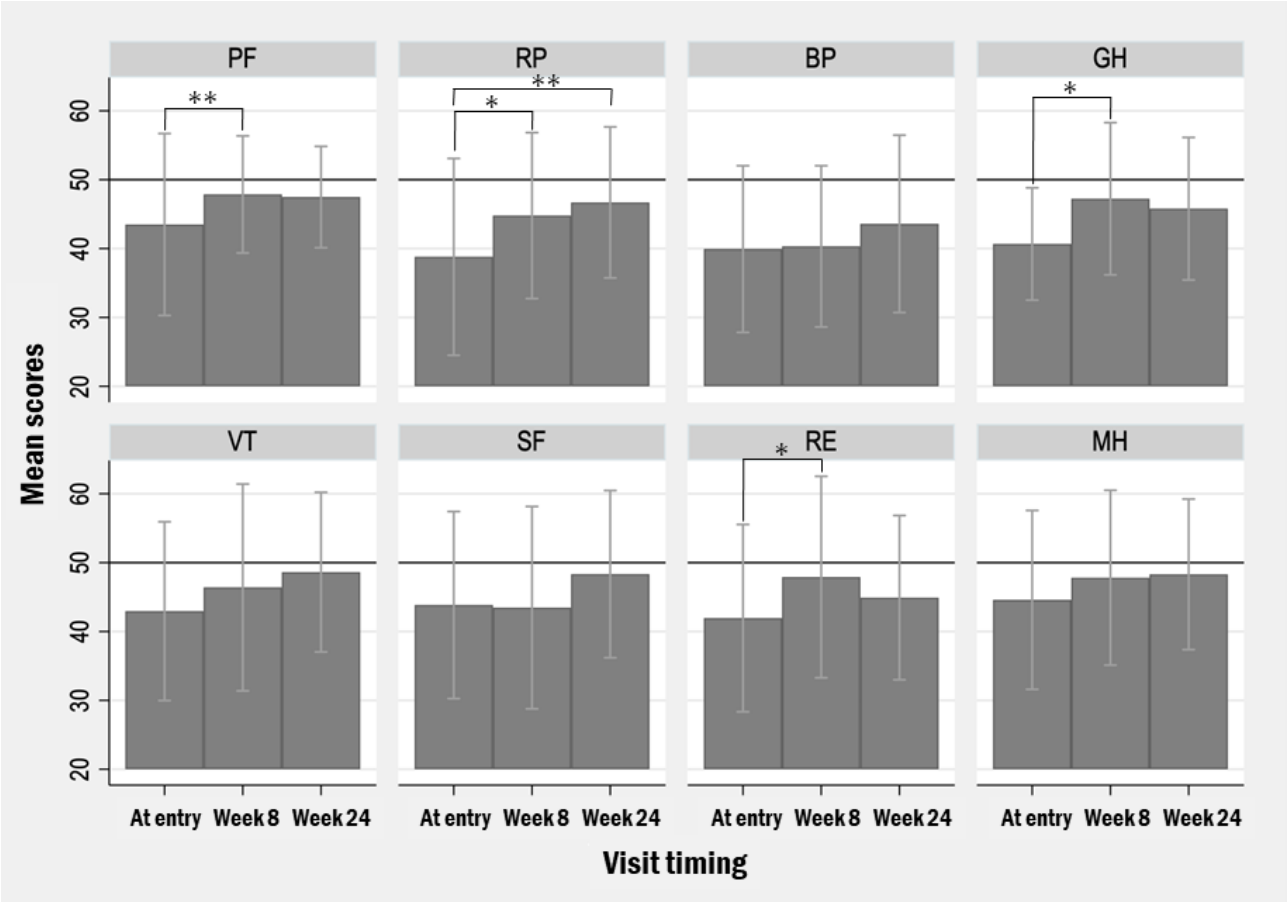
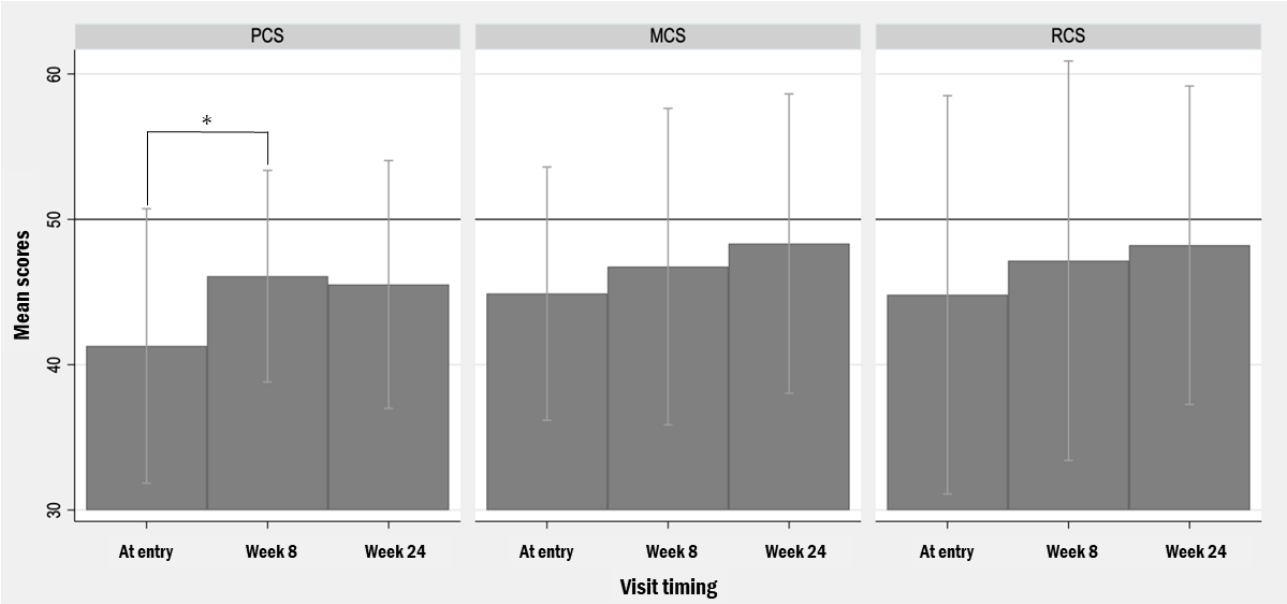


Figure 4. Changes in mean SF-36v2 component summary scores (physical, mental, and role or social) over time at entry, week 8, and week 24. Scores are presented using norm-based scoring (NBS). Error bars indicate SD. MCS: Mental Component Summary; PCS: Physical Component Summary; RCS: Role/Social Component Summary. **P*<.05.



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Discussion

Principal Findings

In this study, we aimed to evaluate changes in HRQOL over time among patients with ALD receiving routine outpatient care by hepatologists supplemented by the use of a journaling app. Consistent with this objective, we observed that physical HRQOL improved over the follow-up period, particularly among patients who maintained abstinence, whereas mental and social HRQOL domains showed no meaningful change. These findings provide an overview of how HRQOL evolves in this cohort when hepatologists address abstinence in routine outpatient care and suggest which HRQOL domains tend to change over time.

Previous studies have consistently shown that the severity of liver cirrhosis is inversely associated with QOL, particularly in the physical domain [31], and that individuals who develop liver cirrhosis at a younger age tend to experience a greater decline in HRQOL [33]. In this study, HRQOL scores across all 8 SF-36v2 subscales were lower than the Japanese population norms at entry, which is likely explained by the fact that more than half (12/21, 57.1%) of the participants had cirrhosis. This finding is consistent with prior reports demonstrating substantially impaired HRQOL among patients with advanced liver disease or cirrhosis-related complications [23,24,34]. When HRQOL trajectories were examined over time, patients who maintained abstinence showed gradual improvement in physical aspects of HRQOL, whereas no meaningful improvement was observed among those who continued drinking. Notably, the abstinent group had lower HRQOL scores at entry and included a higher proportion of patients with cirrhosis or a history of recent hospitalization. This baseline imbalance represents a potential confounding factor, limiting the extent to which subsequent differences in HRQOL trajectories can be attributed solely to abstinence or the intervention itself. Although causal mechanisms cannot be determined in this observational study, one possible explanation is that patients with more advanced disease or recent symptoms may have had greater awareness of their impaired health status, which could have strengthened their motivation to abstain from alcohol. A previous study has reported that recently hospitalized patients with ALD showed increased motivation to reduce their alcohol consumption [35]. In contrast, patients who continued drinking or who dropped out may have perceived less immediate impact of their disease on daily functioning, potentially limiting both abstinence motivation and observable HRQOL improvement. In our previous report using the same cohort, abstinent patients demonstrated improvements in liver function during the early follow-up period [20]. Taken together, these findings may suggest that recovery of liver function associated with abstinence may contribute to subsequent improvements in physical aspects of HRQOL, even among patients with impaired baseline liver function. Although the foregoing interpretation remains speculative, the observed pattern is not inconsistent with previous reports linking disease severity, abstinence, and physical HRQOL in chronic liver disease [22-24,31].

Whether changes in HRQOL during abstinence interventions are clinically meaningful has not been well characterized in previous studies. A recent observational study focusing on patients with alcoholic hepatitis reported comparable findings in a population with more severe liver dysfunction [25]. In that study, patients with alcoholic hepatitis exhibited substantially lower physical HRQOL scores at baseline than heavy drinkers without hepatitis, reflecting advanced disease severity. Importantly, lower baseline HRQOL was associated with poor prognosis independently of the Model for End-Stage Liver Disease score, and improvements in HRQOL were linked to both abstinence and improvement in liver function [25]. This study shares several key features with these findings, including the coexistence of impaired baseline liver reserve and reduced HRQOL, as well as the association between sustained abstinence and subsequent improvement in physical HRQOL. However, the population studied by Madathanapalli et al [25] consisted of patients with a very high short-term mortality risk. This represents a substantially more severe disease spectrum than that typically encountered in routine outpatient hepatology practice. Although limited by sample size, our study extends these observations by demonstrating similar HRQOL trajectories in a real-world outpatient cohort of patients with ALD, many of whom had cirrhosis but were clinically stable enough to be managed in an ambulatory setting. This suggests that the relationship between abstinence, liver function recovery, and improvement in physical HRQOL may also be relevant in less severely ill patients routinely followed by hepatologists.

In this outpatient setting, abstinence support was provided by hepatologists through regular clinical follow-up combined with review of patients' entries in the journaling app. The important role of hepatologists in the identification and management of AUD among patients with ALD has been emphasized in current clinical practice guidelines [5,26]. Although all participating hepatologists had completed e-learning modules on the diagnosis and management of alcohol dependence, they were not psychiatric or addiction specialists. Accordingly, the association observed between hepatologist-led follow-up and changes in HRQOL should be interpreted with caution. Nevertheless, regular outpatient contact and structured review of self-reported alcohol-related behaviors may have facilitated sustained patient engagement in abstinence efforts, which could have contributed to the observed stabilization and improvement of physical HRQOL. This interpretation is consistent with previous studies demonstrating that brief interventions delivered in general medical settings can positively influence alcohol use behaviors, even when provided by nonspecialists [10,14]. In contrast, improvements in mental and social domains of HRQOL were limited in this study. Previous studies have reported that psychological distress, stigmatization, and social isolation often persist in patients with alcohol-related conditions despite improvements in physical health and may not be sufficiently addressed by brief medical interventions alone [23]. This finding suggests that while hepatologist-led abstinence support may be sufficient to influence physical aspects of HRQOL, broader improvements in psychological and social well-being may require more comprehensive psychosocial or psychiatric interventions beyond the scope of routine hepatology outpatient care.

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Limitations

This study has several limitations. First, the small sample size and the absence of a control group limit the generalizability of the findings and preclude causal inference; therefore, the findings should be interpreted as exploratory. Baseline disease severity differed between the abstinent and nonabstinent groups, with the abstinent group showing more advanced liver disease at entry. This imbalance represents a potential confounding factor and limits causal interpretation, as observed improvements in HRQOL may partly reflect regression to the mean or greater potential for recovery rather than the effect of abstinence support alone. In addition, participant attrition was substantial, with only 85.7% (18/21) of the enrolled participants remaining in follow-up at 8 weeks and 71.4% (15/21) remaining in follow-up at 24 weeks, which may introduce attrition bias and further limit the robustness of longitudinal comparisons. Multiple statistical tests were performed without formal correction for multiple comparisons, which increases the risk of type 1 error. Therefore, statistically significant findings should be interpreted with caution. Second, engagement metrics for the journaling app (such as frequency or duration of use) were not collected or analyzed, as the primary outcome of this study was health-related QOL; thus, the relationship between intensity of app use and outcomes could not be evaluated. Third, because only the generic SF-36v2 was used, disease-specific psychosocial domains such as sleep disturbance, stigma, and social isolation may not have been fully captured.

The proposed app has the potential to evolve into a form of personal health record that integrates artificial intelligence functions to enhance patient motivation. However, legal guidelines defining safe feedback to patients remain unclear. Therefore, the app is currently limited to simple functions. Furthermore, the digital divide remains a serious concern, as older individuals or those with visual impairment may not be able to use the app, which may limit the broader applicability of this approach.

Conclusions

In conclusion, hepatologist-led review of entries from a smartphone-based journaling app during routine outpatient visits was associated with improvements in the physical component of HRQOL among patients with ALD who achieved and maintained abstinence.

Unlike previous studies that have primarily examined abstinence interventions delivered by addiction specialists, this study evaluated an abstinence support approach integrated into routine hepatology practice and supplemented by a simple digital tool, an area in which evidence has been limited. By focusing on HRQOL outcomes, this study provides preliminary evidence that hepatologist-led, digitally supported abstinence care may contribute to improving physical well-being in patients with ALD.

From a broader perspective, these findings suggest that such an approach may represent a feasible real-world strategy in clinical settings where access to specialized addiction services is limited. Although further controlled and comparative studies are required, hepatologist-led, digitally supported abstinence support may help address existing care gaps in routine practice, while improvements in mental and social HRQOL likely require additional psychosocial or psychiatric interventions.

Acknowledgments

The authors declare the use of generative artificial intelligence (GenAI) in the research and writing process. According to the Generative Artificial Intelligence Delegation Taxonomy (2025), the following tasks were delegated to GenAI tools under full human supervision: proofreading and editing, adapting and adjusting emotional tone, translation, and reformatting. The GenAI tool used was ChatGPT-5 (OpenAI). Responsibility for the final manuscript lies entirely with the authors. GenAI tools are not listed as authors and do not bear responsibility for the final outcomes. Parts of the study protocol and primary outcomes related to alcohol consumption have been previously reported in a pilot interventional study using the same journaling app (Yamashiki et al [20]; *JMIR Formative Research*). This analysis focuses specifically on longitudinal changes in health-related quality of life and does not duplicate the outcomes reported in the previous publication.

Funding

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Data Availability

The data supporting the findings of this study are not publicly available due to ethical and privacy restrictions but are available from the corresponding author upon reasonable request.

Authors' Contributions

NY and NK are co-first authors and jointly wrote the manuscript. NY, MM, SI, H Yoshii, and H Yamada were responsible for the clinical study and data collection. NK, KK, and TF contributed to study management and coordination. EA and MN supervised the study. Final data analysis and manuscript preparation were performed by NY and NK. All authors reviewed and approved the final manuscript.

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Conflicts of Interest

None declared.

Multimedia Appendix 1
Patient background characteristics stratified by drinking status at 8 weeks. Patients who maintained abstinence at week 8 had a higher prevalence of liver cirrhosis compared with those who continued drinking.
[DOCX File , 24 KB - formative_v10i1e80421_app1.docx]

Multimedia Appendix 2
Mean 36-Item Short Form Health Survey version 2 (SF-36v2) subscale scores at entry. At study entry, participants demonstrated lower health-related quality of life scores across all 8 subscales compared with Japanese population norms.
[DOCX File , 23 KB - formative_v10i1e80421_app2.docx]

Multimedia Appendix 3
Changes in mean 36-Item Short Form Health Survey version 2 (SF-36v2) subscale scores at entry, week 8, and week 24 in the abstinence group, expressed using norm-based scoring (NBS). Error bars indicate SD. Subgroup comparisons were performed using Wilcoxon signed-rank tests because of the small sample size and nonnormal distribution.
[DOCX File , 65 KB - formative_v10i1e80421_app3.docx]

Multimedia Appendix 4
Changes in mean 36-Item Short Form Health Survey version 2 (SF-36v2) subscale scores at entry, week 8, and week 24 in the nonabstinence group, expressed using norm-based scoring (NBS). Error bars indicate SD. The nonabstinence group showed no appreciable improvement or deterioration. The subgroup comparisons were conducted using Wilcoxon signed-rank tests owing to the small sample size and deviation from normality.
[DOCX File , 66 KB - formative_v10i1e80421_app4.docx]

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Abbreviations

ALD: alcohol-related liver disease
APA: American Psychological Association
AUD: alcohol use disorder
GH: general health
HRQOL: health-related quality of life
JARS-Quan: Journal Article Reporting Standards for Quantitative Research
MCAR: missing completely at random
MCS: Mental Component Summary
MD: mean difference
PF: physical functioning
QOL: quality of life
RCS: Role/Social Component Summary
RE: role emotional
RP: role physical
SF-36: 36-Item Short Form Health Survey
SF-36v2: 36-Item Short Form Health Survey version 2

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Original Paper

Medical Student Experiences With ChatGPT: National Cross-Sectional Study

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Abstract

Background: Artificial intelligence (AI) is increasingly influencing medical student education, with AI-driven chatbots, such as ChatGPT, emerging as powerful study tools. While these technologies offer numerous benefits, they also pose challenges that warrant the adaptation of medical school curricula.

Objective: This study examines medical students' perceptions and use of ChatGPT. We hypothesize that ChatGPT is widely used for academic support, but concerns remain regarding reliability and academic integrity.

Methods: We conducted a cross-sectional study from August 25 to December 10, 2024, in the United States. Students in all years of medical training who were enrolled in accredited allopathic or osteopathic medical schools were eligible to participate. Data were collected using an anonymous online questionnaire, which was distributed through institutional mailing lists. Overall, 188 schools were reached, of which 14 (7.4%) responded and agreed to distribute the survey. A total of 177 participants completed the survey. Survey items consisted primarily of Likert-scale and multiple-choice questions. Primary outcome measures included self-reported frequency of ChatGPT use, perceived usefulness of ChatGPT, and ChatGPT use habits.

Results: Overall, 98.9% (175/177) of participants had heard of ChatGPT, with 88.7% (157/177) reporting having used it; 62.7% (111/177) identified as female, and 52% (92/177) had completed at least 1 block of clinical rotations. Medical students most often used ChatGPT to understand complex medical concepts, prepare for exams, and generate study materials. Moreover, 46.5% (73/157) used it to help complete medical school assignments. Medical students also reported using it clinically, with the most common use being to generate differential diagnoses. Notably, 21.0% (33/157) of participants responded having used ChatGPT to help write clinical notes. Moreover, 73.9% (116/157) reported that their experience with ChatGPT improved their overall perception of AI's potential to assist in medical practice, and 86.6% (135/157) believed that having ChatGPT as a resource would make them more effective physicians. Statistical analyses were performed using the Pearson chi-square test with α=.05. Students who reported moderate or advanced baseline understanding of AI were more likely to practice conscientious use habits, such as cross-checking (odds ratio [OR] 2.31, 95% CI 1.08-4.97) and editing (OR 2.45, 95% CI 1.05-5.71) ChatGPT output before using it, than those who reported a basic or limited understanding.

Conclusions: Our study is among the few to examine medical student perceptions of ChatGPT at a national level. We examined responsible use habits to identify areas in which reliance on this technology may lead users astray. We found that ChatGPT is being used to complete academic assignments and write clinical notes, raising concerns about information verification, AI literacy, patient confidentiality, and ethical use. Together, these findings highlight the need for structured AI education to help students leverage these technologies effectively while mitigating risks associated with misinformation and overreliance on AI.

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KEYWORDS

ChatGPT; large language model; medical student; medical education; artificial intelligence; AI

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Introduction

Problem

Artificial intelligence (AI) is progressing rapidly, with increasing applications in health care, including medical education. Among AI-driven technologies, chatbots powered by large language models (LLMs) have gained significant attention for their potential to support learning, clinical decision-making, and research. These chatbots can generate humanlike responses based on complex pattern recognition and statistical synthesis of massive datasets comprising papers, books, websites, and other written text [1]. Perhaps the most prominent example of such technology is ChatGPT, an LLM-based chatbot that was launched by OpenAI in November 2022.

ChatGPT was likely one of the fastest-growing user applications in internet history, with nearly 100 million users as of January 2023 and approximately 1.8 billion website visitors monthly [2]. In the context of the medical field, it is reasonable to expect that both medical providers and patients have interfaced with and used such technology. ChatGPT and other LLMs have already influenced medical education, providing medical students with a powerful tool for education while also raising new issues regarding academic dishonesty, plagiarism, and ethics [3].

As medical students seek efficient ways to enhance their education, the integration of AI-powered tools raises important questions about their usefulness, reliability, and impact on learning. Understanding medical students' perceptions of these technologies is crucial for assessing their role in medical training and future clinical practice. Moreover, this integration raises important questions about the necessity of adapting medical curricula in the United States to address the increasing use of AI, as well as to establish policies regarding academic integrity and the ethical use of AI in patient care to protect patient confidentiality and critical thinking skills.

Review of Relevant Scholarship

There have been few studies examining medical student perceptions and use of AI chatbots, such as ChatGPT; moreover, many of these studies were conducted at single institutions or overseas. A single-institution study in Thailand found that medical students had begun using AI-based chatbots with generally positive perceptions [4]. A 2023 cross-sectional study in Germany, Austria, and Switzerland found that more than one-third of medical students had already used an AI-based chatbot, such as ChatGPT, but the majority had not been exposed to formal AI or AI ethics curricula [5]. However, there have been few studies examining the use habits associated with such technology and the resulting ethical concerns. A cross-sectional study in Jordan found that younger students and those with lower AI proficiency used ChatGPT more frequently [6]. In our previous single-institution study of medical students' use of LLM-based chatbots, we found that medical students were already integrating these technologies into their academics and even patient care [7]. Moreover, having a baseline exposure or knowledge of AI was associated with more conscientious technology use habits such as double-checking information obtained [7]. A 2023 cross-sectional study in the United States found that medical students identified HIPAA (Health Insurance Portability and Accountability Act)–compliance concerns with ChatGPT and endorsed clearer guidelines for its use [8]. Despite this, many medical schools are still unprepared, with a recent survey of US osteopathic medical schools finding that many lacked formal policies for the integration of generative AI [9].

Hypothesis, Aims, and Objectives

In this study, we examined perceptions of ChatGPT across various medical schools spanning different geographic locations nationwide. The goal of our study was to explore how current medical students are using ChatGPT on a national level and to identify what students find most useful for augmenting learning and productivity. Importantly, this study aimed to identify pitfalls or risks of use as well as opportunities for targeted educational support to improve medical education. On the basis of previous research, we hypothesize that ChatGPT is widely used among students primarily for academic study support and writing tasks, but concerns remain regarding reliability and academic integrity.

Methods

Inclusion and Exclusion Criteria

Students in all years of medical training in the United States who were enrolled in either accredited allopathic or osteopathic medical schools during the study period were eligible to participate.

Sampling Procedure and Recruitment

We used a nonprobability referral sampling design, recruiting participants through institutional mailing lists distributed by deans of student affairs and student representatives at US medical schools.

Email addresses of the deans of student affairs were collected by reviewing publicly available information on medical school websites. One senior coauthor subsequently sent out email requests to the deans to survey their respective medical student populations, reaching a total of 188 allopathic and osteopathic medical schools in the United States from August 25, 2024, to December 10, 2024. If permission was granted by the dean, a link to the online survey was distributed to their schools' respective mailing lists of currently enrolled medical students across all years of training. If no response was received from the deans, a follow-up email was sent 1 week later by the same senior coauthor.

One senior coauthor also contacted members from the Organization of Student Representatives using social media to similarly distribute the survey link to their student bodies via email listserv. Participants were given a 4-week deadline from the date the survey link was distributed to complete the survey. The institutions included in this study were those that responded and agreed to distribute the survey to the email addresses of their medical students. A total of 14 schools responded and agreed to participate.

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Survey Design

The open survey consisted of 28 questions (Multimedia Appendix 1). Participants were queried on their use of ChatGPT in the domains of academic use, research, and patient care. Participants were also queried, with Likert-scale response options, about their perception of ChatGPT and about AI in general. The final section of the survey collected demographic information. Those who responded that they had not heard of or used ChatGPT were automatically directed to the end of the survey, which contained the AI perception and demographic sections. The survey was developed from a single-institution pilot study. In addition, it was piloted among 7 students to test the functionality of the survey and to obtain a time-to-completion estimate for survey distribution.

Instrumentation

The online questionnaire was administered using Qualtrics (Qualtrics LLC), a secure web-based survey platform. Cookies and IP addresses were automatically detected by Qualtrics to prevent duplicate submissions. Overall, the online questionnaire was designed and distributed in accordance with the CHERRIES (Checklist for Reporting Results of Internet E-Surveys) checklist [10]. This manuscript was written and organized according to the JARS quantitative reporting standards [11].

Data Diagnostics

Likert-scale categories showed complete separation of data in many instances, so we collapsed the items into binary indicators to permit stable model estimation. Some response variable combinations contained zero observations or very few observations (<5), which did not permit other forms of regression models. For questions in which answer choices were reported as frequencies (0%, 25%, 50%, 75%, and 100%), frequencies of 50% and below were considered infrequent and reclassified as such, whereas those above 50% were classified as “frequent.” We dichotomized at this point because it provided a straightforward, practical interpretation. Given the data separation, higher-order Likert categories could not be modeled. Incomplete responses referred to questions in which one or more items were left unanswered. Although these surveys were retained, only completed cases were included for statistical analysis. Missing data were not imputed, as all data summaries and analyses were conducted using only observed responses.

Analytic Strategy

Statistical analyses were conducted using JMP Pro (version 18; JMP Statistical Discovery LLC), with the significance level set at $P<.05$. The Pearson chi-square test was used to determine associations between survey responses.

Ethical Considerations

This study was determined to be exempt from review by the University of Florida Institutional Review Board (ET00042341) because it involved an anonymous online survey with minimal risk to participants. However, all participants were presented with a one-page description of the study before participating, including the purpose of the study, time required, research benefits, risks, confidentiality, data storage procedures, contact information of the principal investigator, and notice of voluntary participation. The study was anonymous, and no personal information was collected from the Qualtrics platform; however, it was up to the participants’ discretion to list which medical school they attended. No identifying data were collected or presented in this manuscript. Participants were not compensated, and participation was completely voluntary.

Results

User Statistics

A total of 188 schools were contacted, of which 14 (7.4%) responded and agreed to distribute the survey. There were 228 total responses, of which 177 (77.6%) were completed survey responses. While the true response rate is unknown, we conservatively estimate a response rate of 2.3% (228/10,017), with the denominator based on publicly available data on the total class sizes of the schools that participated in the survey. The following schools were represented:

- Carle Illinois College of Medicine
- Kansas City University College of Osteopathic Medicine
- The Joe R & Teresa Lozano Long School of Medicine
- NYU Grossman School of Medicine
- Perelman School of Medicine at the University of Pennsylvania
- The Texas College of Osteopathic Medicine
- The Warren Alpert Medical School of Brown University
- The University of Florida College of Medicine
- The University of the Incarnate Word School of Osteopathic Medicine
- The University of Central Florida College of Medicine
- Wayne State University School of Medicine
- The Western Michigan University Homer Stryker MD School of Medicine
- Western University College of Osteopathic Medicine of the Pacific
- William Carey University College of Osteopathic Medicine

In total, 98.9% (175/177) of the participants responded that they had heard of ChatGPT, and 88.7% (157/177) reported having ever used ChatGPT. The demographics of respondents are shown in Table 1. Moreover, 27.7% (49/177) of respondents reported having only a limited or basic understanding of AI, whereas the majority (128/177, 72.3%) reported having a moderate or higher understanding (Table 2). Additionally, 31.6% (56/177) of respondents reported having been exposed to AI integration or education in their medical curriculum.

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Table 1. Self-reported demographics of participants[a].

Demographics	Medical students, n (%)
Age (years)	
<20	0 (0.0)
20-24	62 (35.0)
25-30	101 (57.1)
>30	14 (7.9)
Sex	
Female	111 (62.7)
Male	63 (35.6)
Other	1 (0.6)
Prefer not to answer	2 (1.1)
How do you self-identify?	
American Indian or Alaska Native	4 (2.3)
Asian	40 (22.6)
Black or African American	10 (5.6)
Hispanic, Latino, or Spanish origin	14 (7.9)
Native Hawaiian or other Pacific Islander	1 (0.6)
White	95 (53.7)
Other	8 (4.5)
Prefer not to answer	5 (2.8)
Year of medical school	
First	51 (28.8)
Second	46 (26.0)
Third	34 (19.2)
Fourth	44 (24.9)
Fifth or beyond	2 (1.1)
Completed at least 1 block of clinical rotations	
No	92 (52.0)
Yes	85 (48.0)

[a]Cross-sectional study of medical student perceptions of ChatGPT in the United States from August 25, 2024, to December 10, 2024.

Table 2. Self-reported baseline understanding of artificial intelligence (AI) among participants[a].

How would you describe your current understanding of AI?	Medical students, n (%)
No understanding: “I have never heard of AI.”	0 (0.0)
Limited understanding: “I have heard of the terminology but do not understand how it works.”	6 (3.4)
Basic understanding: “I understand that AI involves machines performing tasks that typically require human intelligence, but I am not familiar with its applications.”	43 (24.3)
Moderate understanding: “I have a general understanding of the key principles of AI and its common applications.”	119 (67.2)
Advanced understanding: “I possess a comprehensive understanding of AI principles, including deep learning, neural networks, and their complex implementations in real-world scenarios.”	9 (5.1)

[a]Cross-sectional study of medical student perceptions of ChatGPT in the United States from August 25, 2024, to December 10, 2024.

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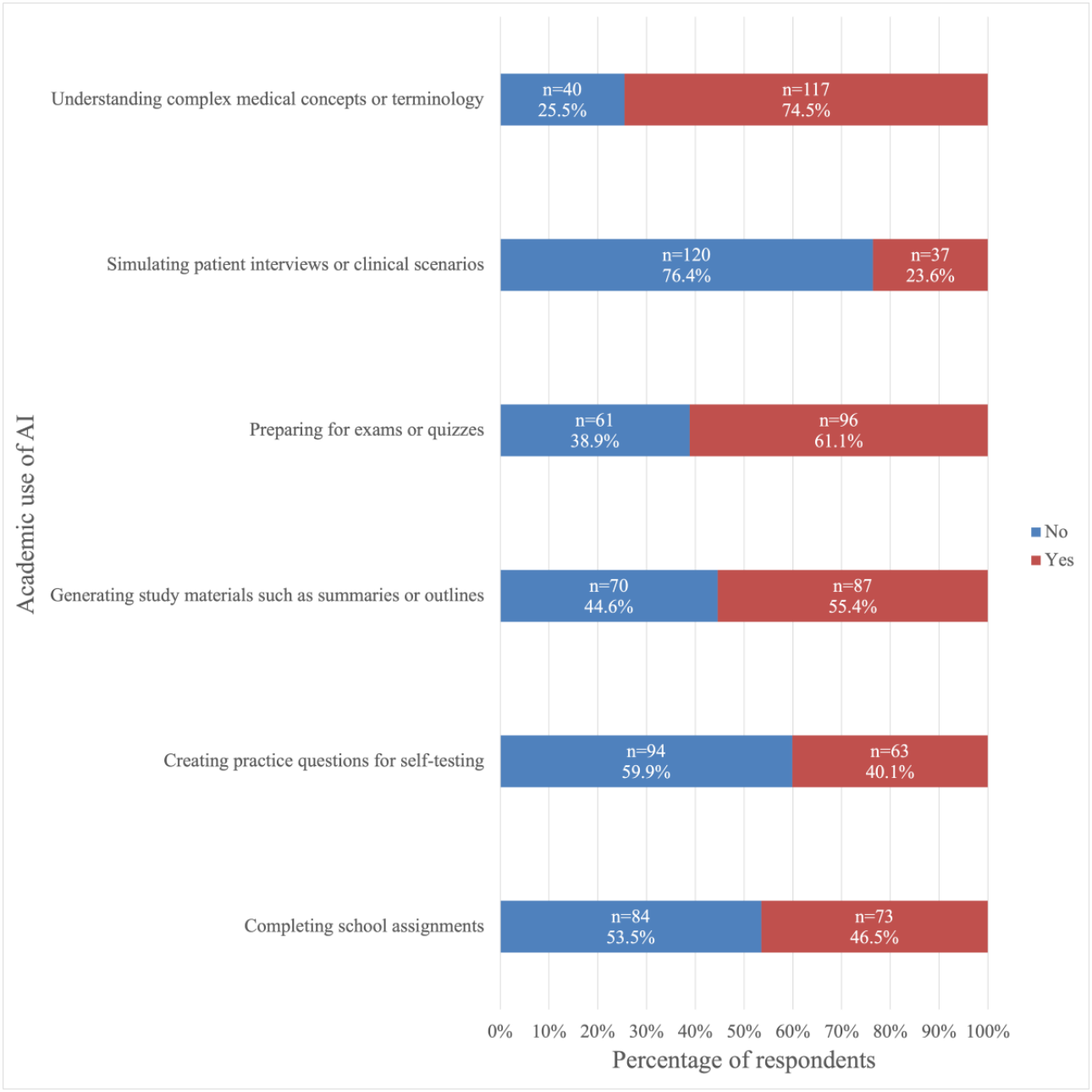
Statistics and Data Analysis

We examined whether participants had used ChatGPT for academic, clinical, or research purposes. For each category, we developed specific use cases that were representative of each educational area and asked participants to indicate whether they had used the tool for those purposes. The results are shown in Figures 1-3.

Figure 1. Frequency of use of ChatGPT among medical students in the United States (August 25 to December 10, 2024) for academic-related purposes in medical school. AI: artificial intelligence.



Among students who used ChatGPT for medical school-related purposes, the most common academic use cases were helping understand complex medical concepts or terminology (117/157, 74.5%), followed by preparing for exams or quizzes (96/157, 61.1%), and generating study materials such as summaries or outlines (87/157, 55.4%; Figure 1). Additionally, 46.5% (73/157) reported having used ChatGPT to help complete medical school assignments (Figure 1). The most common clinical use cases of ChatGPT were generating differential diagnoses (67/157, 42.7%) and reviewing pharmacological information (56/157, 35.7%; Figure 2). Furthermore, 21.0% (33/157) had used it to help write clinical notes (Figure 2). Moreover, 57.6% (19/33) of these students reported that they were in the first or second year of medical school. The most common research-related use case was summarizing research papers or studies (70/157, 44.6%; Figure 3). Additionally, 24.8% (39/157) had used it to draft research manuscripts (Figure 3).

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Figure 2. Frequency of use of ChatGPT among medical students in the United States (August 25 to December 10, 2024) for clinical-related purposes in medical school. AI: artificial intelligence.

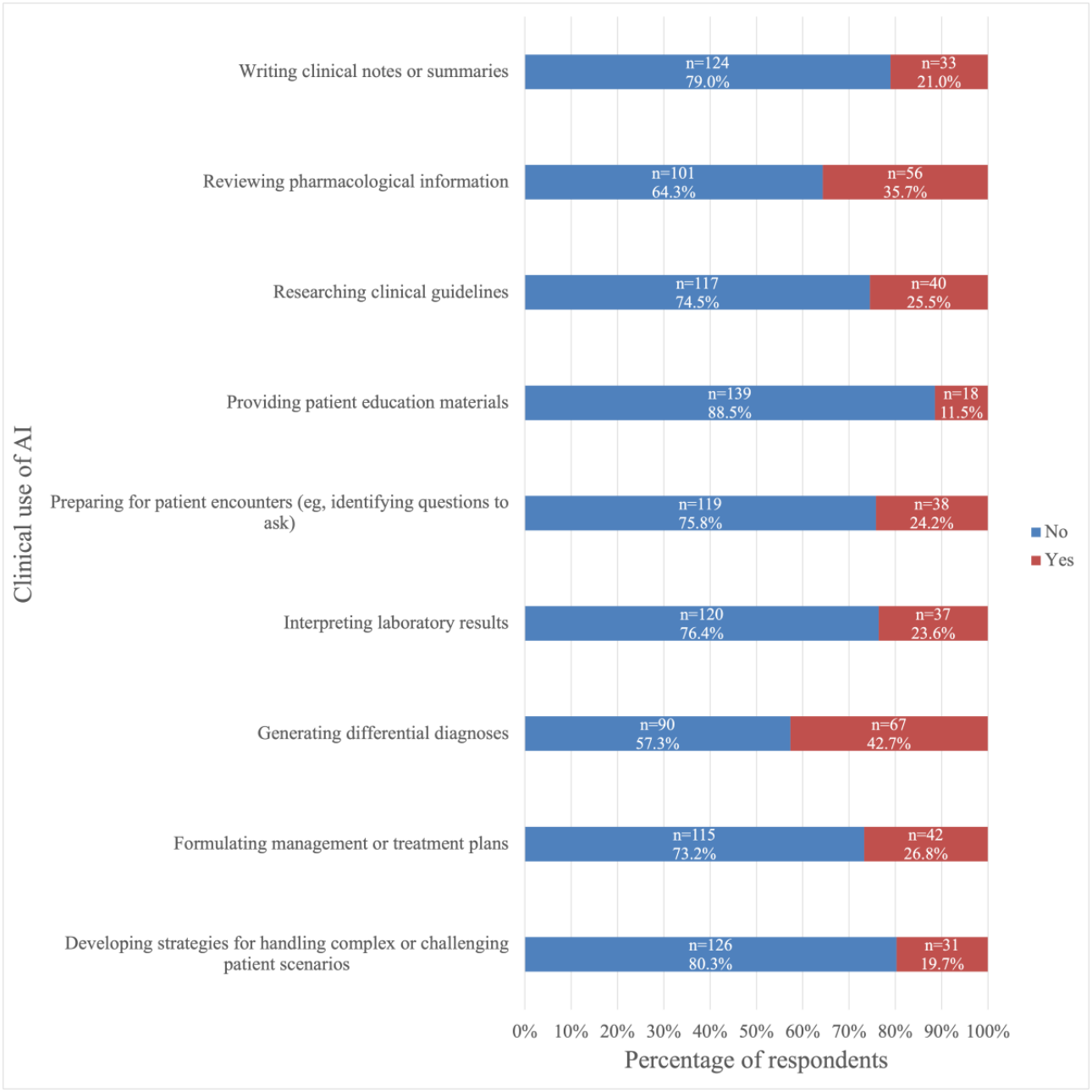

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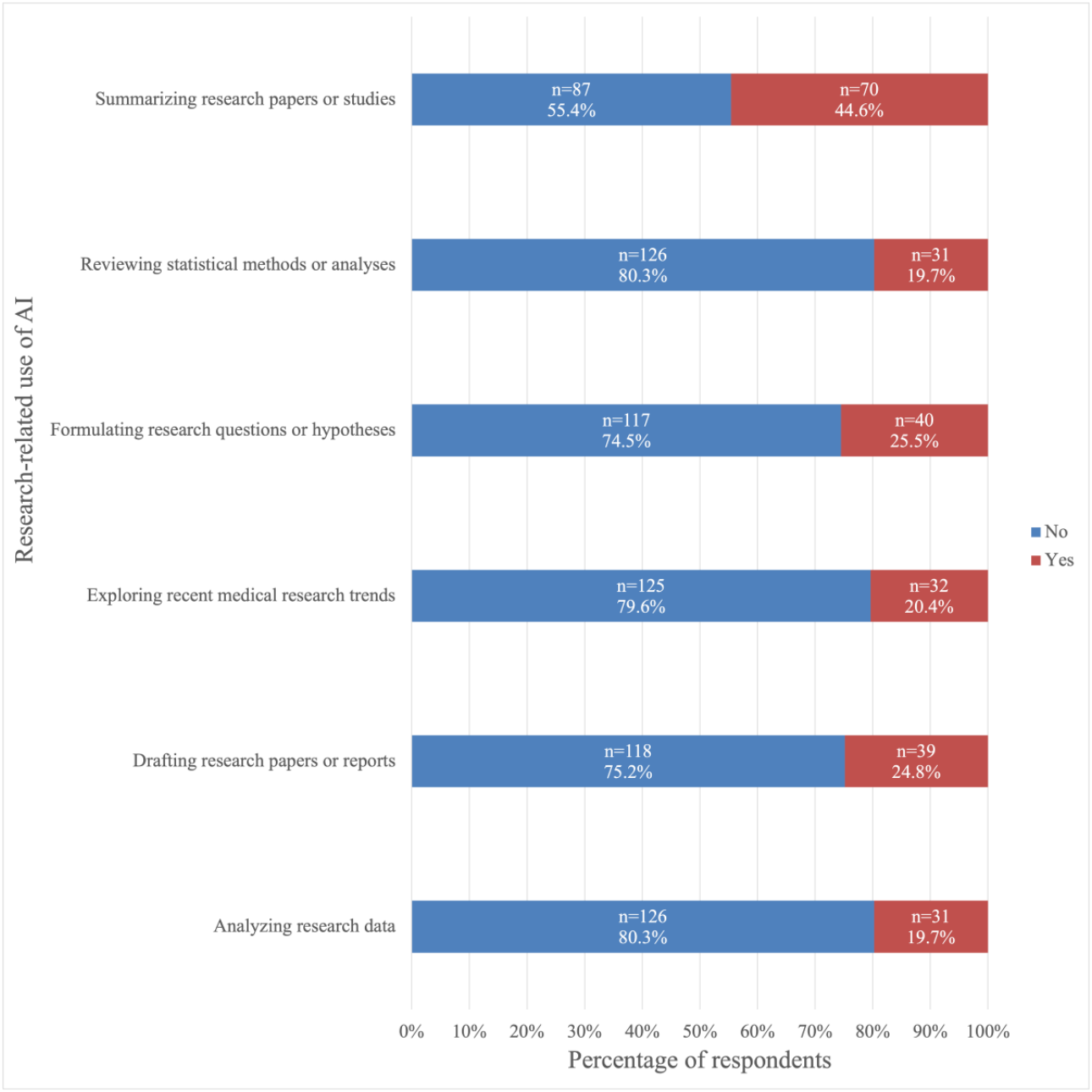
Figure 3. Frequency of use of ChatGPT among medical students in the United States (August 25 to December 10, 2024) for research-related purposes in medical school. AI: artificial intelligence.



Participants were queried on their perception of the accuracy and usefulness of ChatGPT. In total, 75.2% (118/157) of respondents reported that the information provided by ChatGPT was more accurate than not, and 90.4% (142/157) agreed that ChatGPT's responses were useful for their medical-related queries (Table 3). Moreover, 73.9% (116/157) reported that their experience with ChatGPT improved their overall perception of AI's potential to assist in medical practice, and 86.6% (136/157) believed that having ChatGPT as a resource would help them better manage patient care and make them more effective physicians (Table 3). Additionally, 86.0% (135/157) believed that they would continue to use ChatGPT or similar AI chatbots in their future medical practice.

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Table 3. Participants' overall perceptions of ChatGPT for medical-related purposes[a].

Questions	Medical students, n (%)
When using ChatGPT for medical-related queries, how would you rate the accuracy of the information given?	
Very inaccurate: consistently gives incorrect information	0 (0.0)
Inaccurate: more often gives incorrect information	1 (0.6)
Somewhat inaccurate or accurate: gives a similar frequency of incorrect and correct information	29 (18.5)
Accurate: more often gives correct information	97 (61.8)
Very accurate: consistently gives correct information	21 (13.4)
N/A[b]: "I have not used ChatGPT in this context."	9 (5.7)
Overall, the responses provided by ChatGPT were useful for your medical school–related queries.	
Strongly disagree	2 (1.3)
Disagree	4 (2.6)
Agree	88 (56.0)
Strongly agree	54 (34.4)
N/A: "I have not used ChatGPT in this context."	9 (5.7)
How has your experience with ChatGPT influenced your overall perception of AI's potential to assist in medical practice?	
Somewhat worsened	8 (5.1)
No change	33 (21.0)
Somewhat improved	82 (52.2)
Significantly improved	34 (21.7)
To what extent do you agree that having ChatGPT as a resource would help you better manage patient care and make you a more effective physician?	
Strongly disagree	2 (1.3)
Disagree	19 (12.1)
Agree	98 (62.4)
Strongly agree	38 (24.2)

[a]Cross-sectional study of medical student perceptions of ChatGPT in the United States from August 25, 2024, to December 10, 2024.

[b]N/A: not applicable.

Respondents were asked if they verified the accuracy of ChatGPT responses and how often they did so. In total, 46.5% (73/157) of students reported cross-checking or double-checking the responses they received 50% of the time or less (Table 4). Moreover, 21.0% (33/157) reported editing or refining ChatGPT's output before using it 50% of the time or less (Table 4).

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Table 4. Participant responses regarding ChatGPT use habits for medical purposes[a].

Questions	Medical students, n (%)
When using ChatGPT for medical school–related queries, how often do you cross-check or double-check the responses you receive?	
Almost never: about 0% of the time	9 (5.7)
Occasionally: about 25% of the time	24 (15.3)
Sometimes: about 50% of the time	42 (26.8)
Frequently: about 75% of the time	40 (25.5)
Almost always: almost 100% of the time	31 (19.8)
N/A[b]: "I have not used ChatGPT in this context."	11 (7.0)
When using ChatGPT for medical school–related purposes, how often do you edit or refine ChatGPT's output before using it?	
Almost never: about 0% of the time	8 (5.1)
Occasionally: about 25% of the time	8 (5.1)
Sometimes: about 50% of the time	17 (10.8)
Frequently: about 75% of the time	30 (19.1)
Almost always: almost 100% of the time	66 (42.0)
N/A: "I have not used ChatGPT in this context."	28 (17.8)

[a]Cross-sectional study of medical student perceptions of ChatGPT in the United States from August 25, 2024, to December 10, 2024.

[b]N/A: not applicable.

We conducted a chi-square analysis to examine the association between baseline understanding of AI and frequency of cross-checking and editing information obtained from ChatGPT. "Limited" and "basic" understanding of AI were categorized into one group, and "moderate" and "advanced" understanding were categorized into another. Frequencies of 50% or less were categorized as "infrequent," and those above 50% were categorized as "frequent." We found that those with moderate or advanced baseline understanding of AI were more likely to cross-check (odds ratio [OR] 2.31, 95% CI 1.08-4.97) and more likely to edit the output (OR 2.45, 95% CI 1.05-5.71) from ChatGPT before using it than those with a basic or limited understanding (Table 5).

Table 5. Statistical analysis of participant baseline understanding of artificial intelligence (AI) and the likelihood of responsible AI use habits[a].

Responsible AI use habit	*P* value	Odds ratio (95% CI)
Moderate or advanced baseline understanding of AI and the frequency of cross-checking information obtained from ChatGPT	.03	2.31 (1.08-4.97)
Moderate or advanced baseline understanding of AI and the frequency of editing output from ChatGPT	.04	2.45 (1.05-5.71)

[a]Pearson chi-square was performed with an α=.05. Data were dichotomized to compare those with self-reported moderate or advanced baseline understanding of AI vs basic or limited understanding. Cross-sectional study of medical student perceptions of ChatGPT in the United States from August 25, 2024, to December 10, 2024.

We queried participants on their perception of AI in health care and medical education. In total, 80.2% (142/177) of the respondents believed that concepts of AI should be taught in medical school. Respondents were most comfortable with AI assisting in completing administrative tasks such as handling billing and scheduling appointments (151/177, 85.3%), writing medical notes (133/177, 75.1%), and organizing the flow of a patient visit (131/177, 74.0%). However, respondents were less comfortable with AI assisting in diagnosis and management decision-making (Figure 4).

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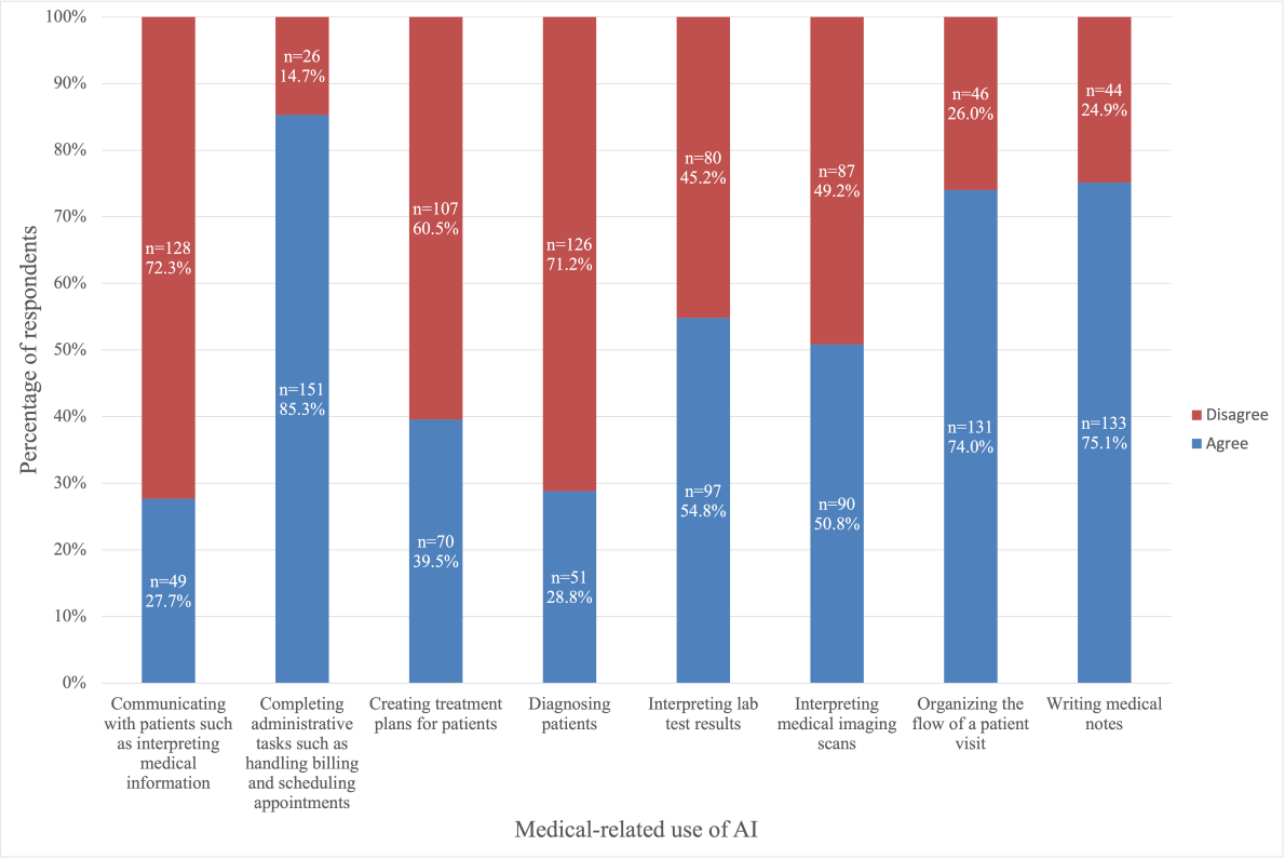
Figure 4. Participant comfort with artificial intelligence (AI) performing various medical-related tasks. Cross-sectional study of medical student perceptions of ChatGPT in the United States from August 25 to December 10, 2024.



Moreover, we surveyed medical students' overall outlook of AI's impact on health care. Most respondents believed that AI would reduce time spent on administrative tasks, expand access to health care services, enhance the overall quality of patient care, and improve the speed and accuracy of diagnoses and treatments. However, 35.6% (63/177) of participants believed it would lead to a reduction in physician jobs, 53.7% (95/177) believed it would reduce clinical reasoning skills, and 39.0% (69/177) believed it would reduce physician decision-making autonomy (Figure 5).

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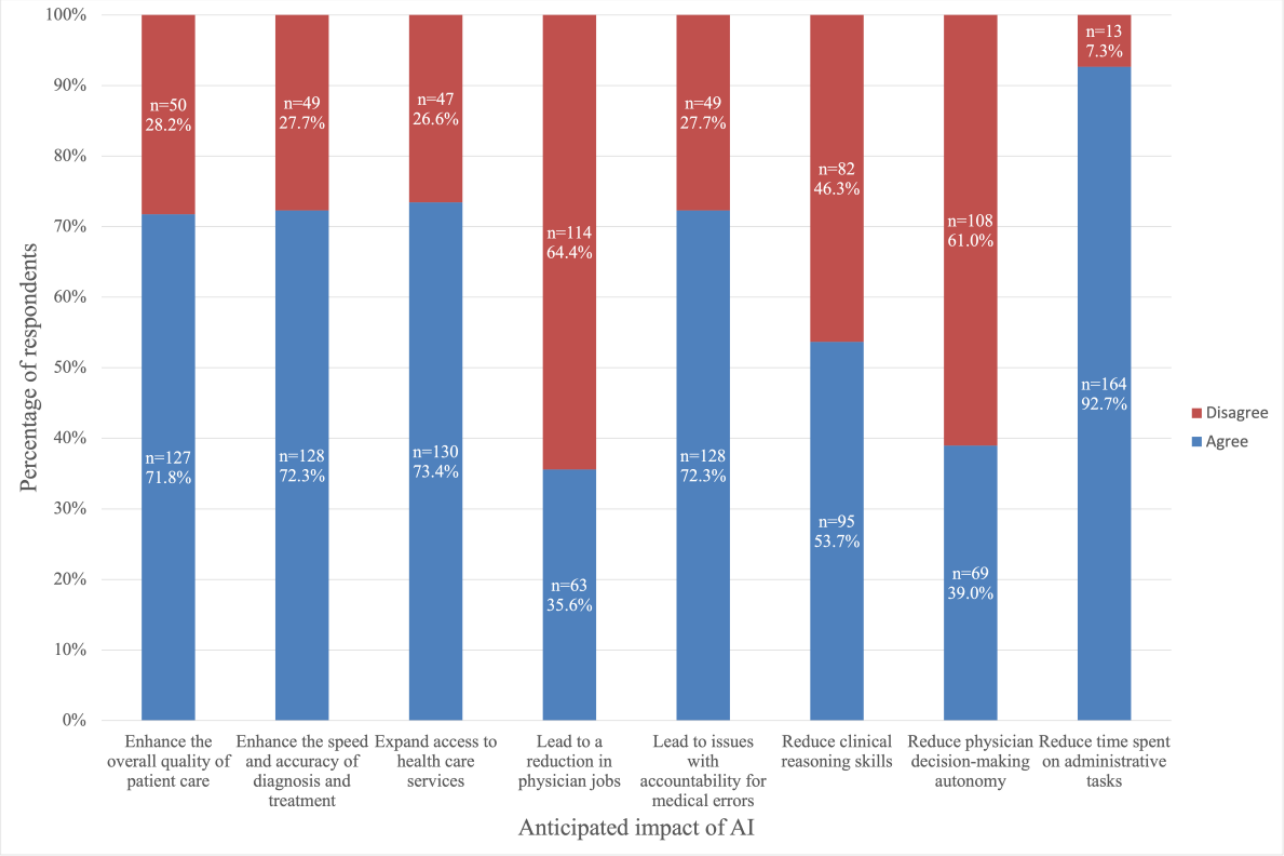
Figure 5. Participant opinions on artificial intelligences (AI) future impact on health care. Cross-sectional study of medical student perceptions of ChatGPT in the United States from August 25 to December 10, 2024.



Discussion

Support of Original Hypotheses

Our findings support the hypothesis that medical students across the United States are actively incorporating ChatGPT as a support tool in medical education. Our previous single-institution study found that students were frequently using ChatGPT for clinical, academic, and research purposes [7]. This study further corroborates those results and elucidates specific use cases within these categories. Moreover, our findings suggest that there are concerns around the ethical and safe use of such technology, with students who have higher baseline AI knowledge being more likely to practice conscientious AI use habits. Overall, these findings warrant additional educational and policy interventions.

Interpretation

Previous literature has highlighted the hypothetical utility of LLM-based tools in augmenting academic writing, generating practice questions with detailed answers, creating patient-physician simulations, suggesting new ideas for research, and creating personalized study materials [12,13]. Our results demonstrate that students are already using ChatGPT for these purposes. Although less common than academic applications, students also used ChatGPT in clinical practice, most frequently to generate differential diagnoses. Studies indicate a high rate of correct diagnosis within the differential list generated by ChatGPT. One study reported an accuracy exceeding 80% with ChatGPT [14]. Another study evaluating its accuracy using clinical notes recorded within the first 24 hours of emergency department admission found that ChatGPT had high accuracy in diagnosing common presentations but lower accuracy in diagnosing infrequent conditions or conditions with subtler clinical presentation, likely due to poorer representation in training data [15].

However, the clinical utility that LLM-based tools bring to the table may extend beyond merely providing a correct diagnosis. Another study suggested that it may increase confidence in diagnosis by bringing up other potential differential diagnoses or offering suggestions similar to those of specialists, which may help diagnostic workflow in lower-resource settings [16]. In certain institutions with student-run clinics for underinsured or uninsured patients, this may directly translate to improved patient care. Overall, this feature of LLM-based tools such as ChatGPT may help medical students perform better on clinical rotations by performing more comprehensive histories and assessments and developing more thorough plans.

Respondents also generally had a positive attitude toward ChatGPT. The majority reported that the information reported by ChatGPT was accurate and agreed that it was useful for their medical-related queries. Respondents indicated that they were likely to continue using ChatGPT or similar tools in their future medical practice (ie, as resident or attending physicians). Respondents also reported that their experience with ChatGPT improved their overall perception of AI's potential to assist in medical practice. Many also responded that having ChatGPT as a resource would facilitate better patient care and enhance their effectiveness as physicians, further emphasizing the

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probable continued integration of AI technology into medical practice.

However, there are emerging challenges related to ensuring academic integrity, stopping the spread of misinformation, and preventing the erosion of independent clinical reasoning skills with the more widespread adoption of this technology [12]. We found that almost half of the respondents had used ChatGPT to help complete medical school assignments. Owing to ChatGPT's access to a huge knowledge base and its ability to generate novel and detailed content, it is not surprising that students may use this tool to help answer open-ended questions in assignments or draft essays. This raises concerns about students relying on AI-generated text without critically engaging with the material. If students increasingly use ChatGPT as a shortcut rather than a supplementary tool, it risks diminishing analytic skills, weakening foundational medical knowledge, and promoting plagiarism.

There are also patient privacy and safety concerns associated with inputting sensitive patient information into ChatGPT. Whether using ChatGPT to generate a differential diagnosis list or to formulate a management plan, medical students and physicians must take caution to deidentify data and protect patient information. Respondents were not asked about the degree to which the information to input was deidentified; however, some respondents had reported using ChatGPT for writing clinical notes. Notably, many of these students who answered "yes" reported that they were in the first or second year of medical school, indicating that it may have been perceived as a theoretical use, given that most clinical rotations begin in years 3 and 4. It is also important to note that when this survey was sent out, there was little guidance or formal educational policies regarding the ethical use of AI in clinical practice. Nevertheless, this finding does present an opportunity for more formal education for both medical students and physicians alike on the importance of deidentifying patient data for future AI technologies.

Additionally, ChatGPT's potential to generate inaccurate or misleading information means that students who do not critically evaluate its outputs may internalize incorrect medical knowledge. Although we did not explicitly ask our participants this, it is possible that ChatGPT could be used to answer multiple-choice or open-ended questions on take-home quizzes and examinations. This poses a challenge for medical education institutions to adapt their academic policies and assessment methods to ensure that students develop essential critical thinking skills and problem-solving skills.

Another issue is the well-known tendency of LLM-based chatbots to fabricate data, or "hallucinate," in a manner where the generated responses appear convincing and correct, which can lead to medical error if users do not cross-check the information or exercise their own clinical judgment [17-20]. The latter is more likely to affect those with less experience, such as medical students or junior physicians. As such, it is crucial to adopt a conscientious approach to the use of these AI tools and for educational systems to deliberately engage future physicians in this practice early in training. We found that many participants infrequently cross-checked or double-checked the responses or edited the output before using it. Infrequency was defined as double-checking or editing 50% or less of the time. We did not specifically ask participants to identify or define what resources students use to cross-check information; while this may reflect the superior accuracy and quality of the output provided by ChatGPT, we used it as a metric of awareness of the need to critically evaluate AI-provided information, acknowledging its fallibility. We found that those who reported a stronger baseline understanding of AI were more likely to double-check and refine the output from ChatGPT before using it. This likely reflects a greater appreciation for the limitations of these AI tools, and such practice should be encouraged in the future to avoid medical error and underreliance on clinical judgment. This further emphasizes the need, at an institutional level, to educate future physicians about the limitations of AI tools they will inevitably encounter in clinical practice to ensure their most effective and responsible use. The quality of the output of LLM-based chatbots is also highly dependent on the user input or prompt provided. "Prompt engineering," which involves thoughtfully designing prompts to optimize and tailor the output of AI tools, may become an integral part of medical education as we teach future physicians how to get the most out of their AI tools.

Similarity of Results

Several survey studies from international medical institutions have examined medical students' perception of LLM-based chatbots. A 2023 cross-sectional study conducted among graduated medical students at a medical center in the United Arab Emirates found that most students had not begun using ChatGPT during medical school at that time [21]. However, previous AI experience was strongly linked to a positive perception of AI's role in patient care, reducing medical errors, and improving diagnostic accuracy [21]. Another cross-sectional study at the Faculty of Medicine of the University of Porto found that 16% of students were using ChatGPT daily, with 92% expressing satisfaction with the responses generated [22]. We previously conducted a pilot study of medical students' perceptions of LLM chatbots locally at our institution, the University of Florida. We found that 69% of respondents had already been using LLM chatbots, such as ChatGPT, for medical-related purposes at least once a month or more [7]. We also found that those who had a baseline understanding of AI and exposure to AI in medical school were more likely to practice conscientious use of these chatbots, such as cross-checking the information obtained [7]. Those who were exposed to AI in medical school were also more likely to trust AI with clinical decision-making [7]. Our results are consistent with cross-sectional studies performed at other institutions, in which students overall demonstrate positive attitudes and an optimistic outlook toward LLM-based tools and AI in general. However, our study adds important insights regarding the ethical and safe use of AI technologies, underscoring the need for formal generative AI policies in medical schools and, potentially, the development of a dedicated AI curriculum.

Limitations

A limitation of this study is the low survey response rate, which limits the generalizability of the survey results. Low response

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rate in our survey may be related to the length or complexity of the survey, as it included 28 questions, as well as competing time demands during medical education and a lack of perceived benefit from completing the survey. Additionally, email surveys may have lower response rates than more traditional methods, and given the abundance of phishing attempts, there may have been a reluctance to open an email from an unfamiliar sender. Low response rate among medical learners in general is common, given the large number of medical learners in US medical schools [23]. In addition, there is an increasing survey burnout among medical students, and there is a trend to limit the number of surveys medical students receive, which may have affected the delivery mode and response rate [24]. Despite the low response rate, our sample was diverse, with broad geographic representation and participation from both osteopathic and allopathic institutions.

Our survey was voluntary and self-reported; therefore, the survey results may be biased due to inaccurate self-reporting, nonresponse, and selection bias. There may be an overrepresentation of participants familiar with ChatGPT. Due to the different structure of medical education internationally, the results may be less generalizable outside of the United States. Another limitation is that we limited responses on use of ChatGPT to those who had been previously reported in the literature; our survey did not include free-response items, and thus, we may have missed novel potential applications of ChatGPT for academic, clinical, or research purposes that students are using it for.

Implications

Future directions include examining resident and attending physicians' use of AI tools, such as LLMs, to understand the attitudes and perceptions of those currently providing direct clinical care. A cross-sectional study by the Prince of Songkla University surveying both medical students and physicians found that graduated physicians tended to have less favorable perceptions of ChatGPT for clinical practice and medical education compared to medical students [4]. This may reflect that LLMs are less clinically useful as physicians develop more expertise, as participants listed concerns that ChatGPT lacks patient-specific treatment plans, provides superficial responses, and does not incorporate updated evidence [4]. As AI models evolve, with use specifically tailored toward medical queries, it will be interesting to examine how clinicians' perspectives might change.

Conclusions

This study highlights the current adoption of ChatGPT among medical students throughout the United States and underscores its perceived utility in academic, clinical, and research settings. A significant majority of students in our survey reported using ChatGPT to enhance their learning experience, with notable use cases including understanding complex medical concepts, preparing for exams, and generating study materials. Clinical and research applications were also prevalent, particularly in generating differential diagnoses, reviewing pharmacological information, and summarizing research papers.

Despite its benefits, our findings raise concerns regarding information verification, ethical use for academic activities, and AI literacy. A substantial proportion of students reported infrequent cross-checking or editing of ChatGPT-generated responses, which poses a real risk of misinformation in medical training. This emphasizes the need for improved education on AI's limitations and potential biases. Notably, students with a higher baseline understanding of AI were more likely to verify and refine ChatGPT's output, reinforcing the importance of integrating AI education into medical training. Moreover, the use of ChatGPT for completing assignments may undermine learning outcomes, highlighting the need for updated academic integrity policies in medical education. Finally, the use of ChatGPT in patient care also raises HIPAA-compliance concerns, further emphasizing the need for updated policies to deliver the safest and most effective patient care.

Given the rapid evolution of AI-powered tools, medical educators should consider incorporating structured AI literacy programs to equip students with the skills necessary to use these technologies responsibly and effectively. Guidance on the use of AI in medical schools may be further standardized by collaborating with national accrediting bodies and medical education organizations. Ultimately, more research is needed to explore best practices for AI integration in medical education and to assess the long-term impact of AI-assisted learning on clinical decision-making and patient care.

Data Availability

The datasets generated or analyzed during this study are available from the corresponding author on reasonable request.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Survey questionnaire.
[DOCX File , 26 KB - formative_v10i1e76838_app1.docx]

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Abbreviations

AI: artificial intelligence
CHERRIES: Checklist for Reporting Results of Internet E-Surveys
HIPAA: Health Insurance Portability and Accountability Act
LLM: large language model
OR: odds ratio

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Original Paper

Comparing Pregnant and Postpartum Client and Provider Feedback on a Digital Health Intervention for Substance Use Recovery: User-Centered Design Approach

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Abstract

Background: Mobile health (mHealth) interventions can expand access to and engagement in lifesaving treatment for pregnant and postpartum people with a substance use disorder. Yet, many people with lived experience and substance use providers alike are often excluded from mHealth intervention development, limiting opportunities to provide feedback on critical design components such as usability, cultural relevance, and compatibility with real-world practice.

Objective: The study engaged pregnant and postpartum people and substance use providers in a formative evaluation to refine an mHealth intervention designed to support recovery.

Methods: Pregnant and postpartum participants (n=11) and providers working in recovery settings (n=13) across Missouri reviewed the same mHealth intervention. Participants completed a survey and semistructured qualitative questions on usability and compatibility after reviewing the same mHealth intervention. Survey responses and qualitative themes were compared across groups. Post hoc analyses examined differences between pregnant and postpartum participants who had used the app and those who had not (n=8) to identify barriers to participation.

Results: Both participant groups reported similar themes related to the usability and compatibility of the mHealth intervention, including a need for simplified navigation and greater personalization of app content. The e-coaching feature and directory of recovery-focused resources were viewed as valuable by both groups. Uniquely, pregnant and postpartum participants emphasized the need for app content addressing craving management, emotional triggers, and parenting stress. These participants also requested more frequent communication with the e-coach than providers recommended. Nonapp users differed from app users by race, education, and household characteristics, underscoring structural barriers to engagement.

Conclusions: Engaging both pregnant and postpartum people and providers in formative evaluation reveals overlapping and distinct priorities for mHealth design. Findings highlight that user-informed development is essential for improving usability, engagement, and recovery outcomes, including reaching those least likely to engage with traditional or digital treatment supports.

(JMIR Form Res 2026;10:e86255) doi:10.2196/86255

KEYWORDS

pregnant people; substance use disorders; user-centered design; mHealth; mobile health; postpartum

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Introduction

Background

Substance use and related overdoses remain leading causes of perinatal death in the United States [1], particularly during the postpartum period [2,3]. Most deaths among people with substance use disorder (SUD) involve the use of opioids and stimulants [4]. Initiation of substance-use recovery-focused perinatal care is the optimal strategy to reduce fatal outcomes related to substance use [5]. Through treatment, individuals can learn about the impact of substance use on themselves and their baby and can receive prescriptions for medications such as buprenorphine and methadone to reduce cravings and symptoms [6]. Despite the availability of current evidence-based interventions, pregnant and postpartum people with SUD face multiple barriers to accessing and staying on SUD treatment. These include unavailability of treatment services, limited access to specialized care, lack of social support to support recovery [7], and comorbid mental health conditions related to substance use. These can decrease rates of treatment retention and usually exacerbate SUD symptoms [8]. Pregnant and postpartum people may also prioritize the health of their baby and have less time to consider treatment for their own health and recovery [9]. Furthermore, stigma, criminalization, and the threat of child-protective services can deter individuals from seeking care in the first place [10].

Mobile health (mHealth) can potentially help pregnant and postpartum people access and stay engaged in treatment. mHealth is the use of social media, phones, and other technology (eg, app-based interventions) to measure and improve health outcomes [11]. mHealth tools can bridge gaps in treatment linkage and use by providing reminders for upcoming appointments, sending notifications for medications, and helping to provide “between appointment” support. The use of mHealth tools has also been shown to have great potential for supporting health care providers [12]. For example, mHealth interventions may help to alleviate the burden of a high caseload for health care providers by sharing or taking on tasks such as education and resource dissemination or providing emotional and social support. There is also the potential for health care providers to receive updates about their clients’ well-being and progress through remote strategies, versus only at in-person appointments, using mHealth tools [13].

Health care providers who are at the frontline of clinical care can play an important role in mHealth development and refinement and are considered integral to the user-centered mHealth design process. User-centered design is a process that refers to how key informants and end users including clients and health care providers influence the design of a tool through involvement in the design process [14]. The involvement of both health care providers and SUD clients in the user-centered design process is key to ensure that a final product actually meets the needs of clients and can be easily integrated into pathways of care by providers. Reliance on the feedback of one key informant group could hinder the success of the final product (eg, increasing access to SUD and prenatal care), especially as providers and clients may not always be aligned in their preferences and priorities for care. Yet, there is a critical gap in mHealth interventions for pregnant and postpartum people with SUD that includes input from people with lived experience [15,16], providers, or both [17] in the design process.

Usability and compatibility are key areas of user experience and technology adaptation. Usability explores how an mHealth tool is technically effective (desired outcomes or goals are achieved), efficient (can be used easily and quickly), and satisfactory (is likable and meets expectations) [18,19]. Compatibility assesses how an mHealth tool fits the targeted end user, such as if the tool is appropriate for the user’s stage in recovery and daily life as a pregnant person or new parent with SUD [20]. Applying user-centered design and mHealth testing can reveal unasked but necessary questions about how to support this specific population and provide insight into current changes in the local recovery landscape. Leveraging user-centered design approaches could greatly enhance the translation of evidence-based practices from research to tailored mHealth supports for pregnant and postpartum people with SUD [14].

This Study

The study sought to engage pregnant and postpartum people and health care providers in formative evaluation, including usability testing, to guide further mHealth app refinement and to support recovery from SUD. Our primary questions were as follows: (1) What are the perceptions of pregnant and/or postpartum clients regarding an mHealth intervention developed to support their SUD recovery during the pre- and postnatal stages? (2) What are health care provider perceptions of an mHealth intervention to support clients with SUD during pregnancy and the postpartum period? (3) How are client and provider perceptions about an mHealth intervention and barriers to care similar or different? To triangulate key informant perspectives, we conducted post hoc analyses of the barriers to participation reported by pregnant and postpartum clients who did not use the app. Findings contribute to the needed literature on feedback from multiple key informants, particularly people with lived experience, in the design and refinement of digital health interventions for SUD.

Methods

Overview

This study examines the usability and acceptability of an mHealth intervention (uMAT-R) among pregnant and postpartum people after 1 week of app use and is part of a larger, ongoing intervention. uMAT-R is pronounced as “you matter” and is based on the acronym for medication-assisted treatment. Please see Eswaran et al [21] and Szlyk et al [22] for more information about the parent intervention project, including intervention effectiveness and participant recovery outcomes. uMAT-R is a mobile app with features originally designed to educate people who use opioids and/or stimulants and includes tailored content to support recovery during pregnancy and the postpartum period (Multimedia Appendix 1). Over the past few years, the research team has conducted an iterative user-centered design program of research to increase uptake and continued engagement with the uMAT-R app. The app contains

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educational content (a course library) that is designed to counter misconceptions and deficits in medication for opioid use disorder knowledge and to support a healthy pregnancy, postpartum recovery, and overall recovery capital (eg, employment and housing) [23]. In the app, participants have access to a recovery e-coach that follows a motivational interviewing model [24]. Participants have access to the e-coach during weekdays and general workday hours (eg, 8 AM-6 PM) for approximately 1 month. e-Coaches serve as an additional support to clients and are trained in person-centered therapy techniques and crisis intervention. e-Coaches help clients set goals and provide information on community resources. Pregnant and postpartum participants can also set their own goals, create reminders, and use a sober day tracker within the uMAT-R app. Finally, the uMAT-R app contains a resource directory with information on where to find support with housing, food, clothing, employment, and specific services for pregnant and postpartum women and people and their families. The following sections describe the specific enrollment and consenting processes conducted with each participant group as part of this formative work.

Pregnant and Postpartum Clients

Eligible client participants (these individuals will be referred to as "clients" throughout this paper) included those who were aged 18 years or older, had a history of opioid or stimulant use, were receiving treatment at a consenting treatment facility and/or referred from other participants or a community partner, were pregnant (second or third trimester) or postpartum within the past 3 years, were US residents, and owned a smartphone with an iOS or Android operating system. Eligible clients were invited to provide initial feedback after using the uMAT-R app for 1 week. Data collection occurred from July 2022 through December 2024. Clients were asked to complete a (1) baseline survey and (2) open-ended app usability questions at week 1. Initially, clients were asked to complete the week 1 questions via a phone or Zoom (Zoom Video Communications) interview. After having trouble with scheduling and completing the interviews using this approach, the research team decided to send clients the open-ended questions in a survey format via REDCap (Research Electronic Data Capture; Vanderbilt University). This strategy appeared to better suit the needs of the clients, as they balanced recovery and family life.

In total, 16 clients logged on to the app and initiated the open-ended questions; 11 of these clients completed the 31 open-ended questions at week 1. Clients who logged into the app took between 10 and 30 minutes to complete all the questions as indicated by the REDCap time stamp. An additional 8 clients did not log on to the app and completed 11 open-ended questions about app use in general and identified barriers to using this app. Time spent completing the questions ranged from 3 to 10 minutes. Our main analysis will focus on the 11 clients who logged on and answered open-ended questions. Our post hoc analysis includes the 8 clients who answered the open-ended questions about barriers to app use but did not log into the app.

Health Care Providers

Providers from regional treatment facilities in both Missouri and neighboring Illinois were recruited via email or telephone for enrollment. Additional providers were recruited via study announcements circulated through regional and state-specific listservs for health care providers and researchers who support individuals in recovery from SUD, including during pregnancy and/or the postpartum period. One listserv included a regional network of health care providers and staff who receive funding through the same Substance Abuse and Mental Health Services Administration grant. Some providers were recruited via snowball sampling (eg, referrals to our study). Individuals who expressed interest in participating were sent up to 3 email reminders about the study and next steps for enrollment.

In total, 22 health care providers responded to the study flyers and expressed interest in the study. Of those individuals, 16 providers agreed to participate in the study and provided consent. Overall, 16 providers completed the brief survey; 13 completed the follow-up interview.

Ethical Considerations

The Washington University Institutional Review Board (IRB) approved the study (IRB study ID: 2021022070). Quantitative surveys, including open-ended written questions, were recorded using the REDCap survey tool, which is a secure, web-based application designed to support data capture for research studies that are approved by the IRB. Interview audio and transcripts were stored on the secure platform, Box, which is also approved for storage of human subjects' data by the IRB. All study participants were granted a study ID, which was used to label participants' survey responses and interviews. The study log including the participants' identifiable information was stored separately from the raw data, also on Box. Only study personnel had access to the study data and study log. These procedures assisted the study team in upholding participant privacy and confidentiality. Clients provided written, informed consent when they were enrolled in person at recruitment activities that took place at participating treatment facilities. If a client contacted the study team at the laboratory phone number, the participant received the study information over the phone and could provide consent verbally. Clients were compensated US $20 for completing the baseline survey and US $10 for completing the open-ended survey questions. Participating providers gave verbal consent to participate in the study, including to be interviewed and recorded (audio and video). Enrollment was designed to be brief and less intrusive for the standard 9-5 workday (eg, a 15-minute phone call at participants' desired time). Participants were compensated with a US $20 e-gift card after completing a brief survey and a 30- to 45-minute feedback interview.

Qualitative Data Collection

Open-ended questions, either completed via survey or interview, were conducted among clients and health care providers approximately 1 week after participants engaged with the mHealth intervention. Providers could interview in person, via telephone, or via Zoom, and interviews lasted approximately 30-45 minutes. Following a user-centered design approach, the questions assessed characteristics of usability (efficiency,

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technical effectiveness, and satisfaction) and compatibility (eg, the app's suitability of the daily schedule as a pregnant person or new parent and the recovery status of the user) of uMAT-R, informed by the International Organization for Standardization [25]. The questions assessed participants' engagement with the app (or barriers to engagement) and their recommendations for mHealth use to treat SUD. Open-ended survey questions were collected in REDCap. Each interview was audio-recorded and transcribed. A team member completed interview summaries after each interview to provide an audit trail of the qualitative research process and to ensure fidelity to the interview guide [26]. The interview summaries documented characteristics of the interview, including rapport and whether any interviewer biases emerged. Interview summaries were not returned to participants.

Data Analysis

Qualitative Data Coding and Analysis

The primary coders (including coauthor EM) were members of a clinical research team, who support the larger parent study. Using an iterative process of content analysis [27], the 2 pairs of team members coded transcribed interviews and survey responses using a codebook based on question domains from the original interview guide. Since both participant groups were asked the same questions, a single codebook was developed for the study. Example codes included "education videos," "preferred format," and "use of goals features" (for clients). Microsoft Excel software was used for coding. Meaningful units or quotes [28] from each case were pasted under each code's column. Next, the team consolidated initial codes into broader categories that more accurately explained the data (eg, "what to change within the app" and "motivators to use the app"), and the 2 team members recoded condensed units of text using this updated codebook. In total, 3 coders could not continue with the project (eg, left the laboratory to continue graduate education), and 3 additional team members took their place to support the analyses. The new coders (including coauthors JP, LM, and LP) were able to view how their past teammates had coded the text within the Excel spreadsheets, including disagreements about codes. The 2 new pairs (one pair assigned to provider transcripts; the second pair assigned to pregnant and postpartum participant transcripts) met periodically to discuss differences in coding. The principal investigator (HS) served as the third coder for both teams to help identify areas of coding inconsistency. The 2 pairs of coders and the principal investigator (HS) met to review inconsistencies and resolve discrepancies until 100% consensus was obtained [29].

Multimedia Appendix 2 shows how the full team evaluated study decisions by each of the 4 criteria for trustworthiness based on the work of Lincoln and Guba [30]: credibility, transferability, dependability, and confirmability. To further enhance the trustworthiness of the findings, the analytical team identified and examined 2 negative cases. Negative cases are defined as those that deviate from the main themes identified in a study [31], and their presence can help to better understand the potential limitations and variability of findings and their application. Only 1 client suggested that the mobile app should be more colorful, and this same client shared that they would not like to use the app to track recovery goals, as they preferred to write down this type of information in a journal. Another client reported that they would have been more motivated to use the app if they had been in an earlier phase in their recovery, when they would have needed more guidance and support. Potential implications in the context of the main findings are explored in the Discussion section.

Quantitative Analysis

Quantitative survey data and demographic data were summarized by group using descriptive statistics. Both clients and providers completed questions via a REDCap survey about personal sociodemographics and barriers to care at the beginning of the study. Items about barriers to care were slightly different between the 2 groups. Clients were asked to select reasons for missing any SUD treatment or recovery service appointments in the past month. This question was adapted from an earlier study that examined barriers to treatment among Mexican American and European American women with eating disorders [32]. The constructs and response options featured closely resemble that of the SUD treatment barrier question from the National Survey on Drug Use and Health [33]. Similarly, providers were asked to identify significant barriers to care that their clients face. This question was developed by the authors' research laboratory as part of an alternative project to assess the experience of SUD treatment providers during COVID-19 [34]. Post hoc, survey data from clients who were inactive in the app were analyzed to determine any demographic differences between these clients and those who were able to use the app.

Results

Survey Results

Active Pregnant and Postpartum Clients

In total, 11 pregnant and postpartum client participants engaged with the uMAT-R app and completed the baseline survey (Table 1). At the time of the study, 6 participants were pregnant, and 5 were postpartum. A total of 10 clients identified as women; 1 client identified as gender nonconforming or nonbinary. Of these clients, 1 identified as Black or African American, 1 identified as Hispanic, 6 identified as White, and 3 belonged to other racial or ethnic groups. The highest level of education achieved for over half of the clients was a General Educational Development test or a high school diploma. Most of the clients (8/11) were unemployed and covered by Medicaid. In the past 12 months, 8 clients reported having more than 1 phone. Most clients (10/11) reported currently being in treatment for SUD, and 6 clients reported having missed appointments in the past month. In total, 5 clients were in recovery from opioid use, 5 were in recovery from dual opioid and stimulant use, and 1 client was in recovery from stimulant use only. Only 3 clients reported being prescribed medication for opioid use disorder (MOUD). When asked about reasons for missed appointments in the past month, the top response was not having transportation (3/11).

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Table 1. Pregnant and postpartum active participant demographics (n=11).

	Values, n (%)
Age range (years)	
18-30	8 (72.7)
31-50	3 (27.3)
Gender identity	
Women	10 (90.9)
Nonbinary	1 (9.1)
Race or ethnicity	
Black or African American	1 (9.1)
Hispanic	1 (9.1)
White	6 (54.5)
Other	3 (37.3)
Education level	
GED[a] or high school diploma	6 (54.5)
Some college or higher	5 (45.5)
Employment status	
Employed full-time	2 (18.2)
Employed part-time	1 (9.1)
Unemployed	8 (72.7)
Pregnant or postpartum	
Pregnant	6 (54.5)
Postpartum	5 (45.5)
Substance use	
Opioids	5 (45.5)
Stimulants	1 (9.1)
Opioids and stimulants	5 (45.5)
MOUD[b]	
Prescribed MOUD?[c]	3 (27.3)
Buprenorphine or suboxone	1 (9.1)
Methadone	2 (18.2)
Health insurance	
Medicaid	8 (72.7)
Private health insurance	1 (9.1)
No insurance	2 (18.2)
Number of children	
1	5 (45.5)
2	3 (27.3)
3	2 (18.2)
4+	1 (9.1)
Number of phones in the past 12 months	
1	3 (27.3)
2	4 (36.4)

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	Values, n (%)
3+	4 (36.4)
Number of phone numbers in the past 12 months	
1	3 (27.3)
2	5 (45.5)
3+	3 (27.3)
Treatment status	
Currently in treatment	10 (90.9)
Not currently in treatment	1 (9.1)
Any missed appointments in the past month	
Yes	6 (54.5)
No	5 (45.5)

[a]GED: General Educational Development test.

[b]MOUD: medication for opioid use disorder.

[c]Only 3 participants responded to this question.

Health Care Providers

In total, 13 providers completed both the survey and the interview (Table 2). Of these providers, 9 were identified as women. Only 1 was American Indian, 2 were Black or African American, 9 providers were White, and 1 identified as belonging to another racial or ethnic group. A total of 3 individuals worked as peer providers, 2 as community health workers, 3 as program administrators, 2 as medical doctors, and 3 as behavioral health technicians. Nearly half (6/13) of the providers reported being in recovery from SUD themselves.

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Table 2. Health care provider demographics (n=13).

Characteristic	Values, n (%)
Age range (years)	
18-30	2 (15.4)
31-50	9 (69.2)
51+	2 (15.4)
Gender	
Women	9 (69.2)
Men	3 (23.1)
Genderqueer	1 (7.7)
Race	
American Indian	1 (7.7)
Black or African American	2 (15.4)
White	9 (69.2)
Other	1 (7.7)
Ethnicity	
Non-Hispanic or Latino	12 (92.3)
Hispanic or Latino	1 (7.7)
Education	
GED[a] or high school diploma	4 (30.8)
Some college credit	2 (15.4)
Bachelor degree	4 (30.8)
Master degree	1 (7.7)
Role at work	
Peer	3 (23.1)
Community health worker	2 (15.4)
Administrator	3 (23.1)
Medical doctor or psychiatrist	2 (15.4)
Behavioral health technician	3 (23.1)
Place of work	
Recovery community center	7 (53.8)
Hospital-based setting	3 (23.1)
Other	3 (23.1)
In recovery themselves	
Yes	6 (46.2)
No	7 (53.8)

[a]GED: General Educational Development test.

When asked about barriers to treatment for pregnant and postpartum clients (Table 3), the top reasons reported by providers included lack of transportation (12/13), low motivation to stay in recovery (12/13), a lack of childcare (11/13), feelings of stigma from others (11/13), relapse (10/13), and fears of being reported to social services (9/13).

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Table 3. Barriers to care for people in treatment for opioid use disorder during the postpartum period based on health care provider perspectives (n=13).

Barriers to care	Values, n (%)
Lack of transportation	
Yes	12 (92.3)
No	1 (7.7)
Lack of appropriate technology	
Yes	6 (46.2)
No	7 (53.8)
Does not like sessions	
Yes	3 (23.1)
No	10 (76.9)
Has relapsed	
Yes	10 (76.9)
No	3 (23.1)
Low motivation to stay in recovery	
Yes	12 (92.3)
No	1 (7.7)
Lack of childcare	
Yes	11 (84.6)
No	2 (15.4)
Cost of appointment	
Yes	5 (38.5)
No	8 (61.5)
Length of appointment	
Yes	2 (15.4)
No	11 (84.6)
Lack of health insurance	
Yes	4 (30.8)
No	9 (69.2)
Fear of being reported to social services	
Yes	9 (69.2)
No	4 (30.8)
Feelings of stigma from others	
Yes	11 (84.6)
No	2 (15.4)
Having to work[a]	
Yes	8 (61.5)
No	4 (30.8)

[a]One participant did not answer this question. Two participants responded to an additional question about which barriers were missed. They suggested a lack of scheduling skills, a lack of drug-free housing, and a shortage of treatment.

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Qualitative Results

Overview

The themes and minor themes for both key informant groups per category are described below, with representative quotes for both providers and clients shown in Tables 4 and 5.

Table 4. Themes: uMAT-R feedback from providers and clients.

Categories	Theme and quote	
	Provider	Client
What to change within the app	• Streamline content and information: "But there is a lot, yeah. It's a lot of information, and if you're trying to make it more simple for people to wanna go to" [ID 07, office manager at an RCC[a]] • More personalization and person-centered: "... but you can look at doing patient-centered language. As opposed to domestic violence or MAT, you could frame it as the—'I'm not safe in my living environment' or 'I'm trying to get clean.'" [ID 12, physician at a hospital-based clinic]. • Need for more specialized content: "... talking about concentration of medication and breastfeeding, I think that was a topic. I can't remember if I read about that when I scrolled through. Moms ask, 'Is this safe?'" [ID 16, instructor at a hospital-based clinic].	• More educational content on how to manage triggers and cravings: "Maybe keeping track of how many triggers we have a day. If we have a bunch of cravings then we might need to change our surrounding" [ID32]. • Easier navigation of app and ability to personalize content: "... curated information. directly linked resources curated to the individual. [For example], I click on the link fill out the assessment or forms and the app notifies me when the agency responds or at least reminds me to check my email for that response" [ID18]. • More content and resources specific to pregnancy and parenting: "Medications that could help with stimulant usage during pregnancy" [ID44].
Favorite uMAT-R feature	• Personalized features: "I definitely like the homepage. This is the how many days sober, and how many days of treatment? It walks you through. It gives you ... something extraneous of yourself that you can look at, 'Okay, how am I doing? How long have I been in this process?'" [ID 11, behavioral health technician at an RCC]. • Information about treatment and medication: "I did like the videos. I liked putting a face to the story. I did like the information about MAT ... it's nice that they can get the information that MAT does work and it is a positive and not a negative" [ID01, certified peer support specialist at a hospital-based clinic for people in treatment for opioid use disorder during the postpartum period].	• In-app messaging to e-coach: "Texting with counselor" [ID41] and "Messaging" [ID43]. • Interactive features (eg, sober day tracker, in-app assessments): "Also, they had the days sober. I also like they had that on there too because I've been doing the track of how many days I've been sober" [ID09]. • Educational and motivational information: "Motivational quotes and the simplicity of the lessons" [ID13].

[a]RCC: recovery community centers.

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Table 5. Themes: e-coaching conversations and motivations for app use.

Categories	Theme and quote	
	Provider	Client
e-Coach conversations	• Support to manage emotions and behavior: "When the baby's screaming, you're overwhelmed, you're finding you're getting evicted from your apartment, you've just lost your job, recently, you don't have enough—when all of these stressors are compounding on you, what are you gonna do in that moment? [ID16, physician at a hospital-based clinic for people in treatment for opioid use disorder during the postpartum period]. • Meeting basic needs: "Cause I think recovery is a really multifaceted goal, and for a lot of people the recovery part of that is ... just learning how to take care of themselves, and where to find good, affordable food ..." [ID06, coordinator at an RCC[a]]. • Taking care of baby: "Well, lots of things. I can think of 100 things right now. If they have any extra resources. Does this spot on my baby look worrisome? Is it too cold to take him outside with a light blanket" [ID10, community outreach specialist at an RCC]. • Weekly check-ins with e-coach: "It would probably be each week. A lot of my clients say they're busy. They got things going on in their lives, so each week would be, preferably" [ID15, community health worker at agency for postpartum people and babies]. • Frequency of messages depends on clientb: "I mean, everybody's journey is different. One person may not utilize the messaging which the next person may utilize that strongly ..." [ID04, recovery coach at an RCC].	• Setting and monitoring progress toward recovery goals: "about my progress, goals, or life concerns ..." [ID35]. • Support with daily concerns (eg, substance use, mental health, and services): "About how to go certain ways with getting help that I need with my ADHD that I don't get prescribed medicine for due to my past drug usage" [ID44]. • At least weekly messages with e-coach: "maybe every 3 days, to serve as a reminder someone is always there to help or talk" [ID29].
Motivation to use uMAT-R	• Receive emotional support: "[Speaking of the e-coach), 'Oh, this is someone that hasn't seen me, met me. They haven't judged me on any preliminary things. They're just someone here to listen and get to know me.' That might even be a motivating factor" [ID11, behavioral health technician at an RCC]. • Access to tools to reduce recovery barriers: "More resources and more tools you have to help [the better], especially with everybody on their phones, that's why I kinda liked how [this app] is" [ID07, office manager at an RCC].	• Access to resources about recovery and parenting: "This app helps me with all of these things cause I get to do surveys and answer questions about these things honestly, I love that I have endless resources to learn and read about that are specifically about my recovery" [ID37]. • Flexible support and accountability from e-coach: "Coaching has helped" [ID41] and "Staying motivated and knowing that there's always someone who is willing to help" [ID13]. • Access to personalized features and educational content: "It motivates and educates me on this subject to stay clean & I already know about MAT and I study and discuss triggers in my daily groups" [ID13]. • Personal goal of recovery and sobriety: "This pregnancy is my motivation I have to stay sober I do not want to lose my baby" [ID14]. • Compensation for participating in study activitiesb: "Well right now it is the gift cards that's motivating me because I don't have a job currently so the money is helping me with baby food / supplies" [ID44].

[a]RCC: recovery community centers.

[b]Denotes minor theme.

Favorite uMAT-R Feature

Clients liked the in-app messaging feature, which allowed them to connect with the e-coach. Clients also enjoyed the interactive features of the app, such as the sober day tracker and the in-app assessments of current SUD symptoms and confidence in meeting basic needs. Clients liked the variety of information offered in the app, including the educational courses and daily motivational quotes that would appear on the app homepage.

Providers especially liked features that already seemed interactive and personalized for clients. These included the sober day tracker, the in-app messenger that allowed specialized support from the e-coach, and daily assessments about well-being and substance use. Providers conveyed satisfaction with the information about treatment and medication available in the app.

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e-Coach Conversations

Clients shared that they had used the in-app messaging feature to receive help from the e-coach with setting and monitoring progress toward substance use recovery goals. Clients also contacted the e-coaches for support as daily concerns emerged, often related to their substance use and mental health and on how to engage with local recovery resources. Clients wanted to be able to converse with their e-coach at least once weekly, as many clients reported that they would prefer multiple check-ins per week.

Providers recommended certain topics of conversation that could occur between a client and an e-coach. Major themes included how e-coaches could help clients manage emotions and behavior, meet basic needs through accessing resources, and provide education to help care for their baby. Providers noted the key role of the e-coach in helping clients access resources to support basic needs, take care of their babies, and manage everyday stressors. Weekly check-ins were endorsed by providers as the ideal frequency for e-coaches to check in on their clients; the frequency of messages being dependent on the client and their stage in recovery was identified as a minor theme.

Motivation to Use uMAT-R

Clients were motivated to use the app, as it provided them with access to local resources for recovery, parenting, and managing a family. Clients appreciated that the e-coaching feature allowed them to benefit from flexible support that fits their schedule and that the e-coach provided motivation to continue working toward recovery. Personal goals of achieving recovery for themselves and their loved ones also served as motivation to use the app. Finally, receiving compensation for participation in the app and the related study was a minor theme among clients, as gift cards could be used to purchase items for their baby and family.

Two major themes that providers noted as motivators for clients to use the uMAT-R app included emotional support available through the e-coach and access to tools to reduce recovery barriers. An in-app directory of recovery resources and services, educational content, and information were cited by providers as motivating factors for app use. Most providers felt that their clients would use the app and felt that the app offered important features that could help facilitate recovery.

What to Change Within the App

Clients voiced a need for an app that was easy to navigate, such as being able to "skip" through content, and to have options for personalization of content (eg, access to more assessments once completed). Clients also mentioned wanting extensive educational content in the app about how to manage triggers and cravings related to substance use and content and resources that were specific to being pregnant and being a parent—both in the context of SUD recovery and in general. For example, clients wanted more information on how to handle potential issues with child custody and local resources for childcare. A minor theme included being able to use the messaging feature to connect with other people who were working toward recovery, not just the e-coaches.

Similarly, providers agreed that the app content could be more streamlined (eg, having courses better organized to support ease of use among clients) and be tailored to use more person-centered language. Suggestions such as building a separate directory for this population, being mindful of the use of clinical and potentially stigmatizing jargon, involving the e-coach in the curation of content, and including topics such as breastfeeding while taking MOUD were all provided as ways to improve the app. Pairing of the goals feature with e-coaching support was a minor theme identified to better support clients.

Post Hoc Analysis

We analyzed the demographic characteristics of clients who completed surveys but did not log into the app (Multimedia Appendix 3).

Discussion

Principal Findings

This study contributes to needed research on formative evaluations that include both pregnant and postpartum people and substance use providers' perspectives on mHealth as part of substance use recovery while also addressing gaps in key informant representation in addiction science research. This study sought to include underserved and high-need client populations in user-centered design for digital interventions [35,36] (eg, unemployed and less formal education) [37] and less often represented health care providers, such as peers, community health workers, and behavioral health technicians. Additionally, this study sought to identify similarities and differences in feedback on the proposed mHealth tool among these high-need clients and their providers to better address the diverse needs of the pregnant and postpartum recovery community. The perspectives provided by both groups aligned on themes related to the usability and compatibility of the uMAT-R app for SUD recovery, particularly emphasizing the utility of the app's messaging feature, which facilitated supportive and knowledgeable conversations with an e-coach. They also mirrored each other's praise for the inclusion of interactive features, such as a sober day tracker and an extensive psychoeducational library, which allowed for personalization. Themes from the pregnant and postpartum clients provided a more nuanced understanding of the app's compatibility with their specific needs, and they provided suggestions for more content on parenting and new capabilities to message with peers within the app. Meanwhile, the health care providers offered multifaceted insights on the mHealth intervention, not only informed by their professional practices with diverse client bases but often also their own personal backgrounds as people with lived experience in recovery.

The e-coaching modality was one of the most liked features of the mobile app. This finding contrasts with common perceptions that communication only via text may jeopardize trust and rapport and reduce app engagement [38,39]. Additionally, both provider and client findings suggest that mHealth interventions, such as uMAT-R, may be especially useful in providing readily available daily support and recovery-related problem-solving to clients and help to facilitate linkage to community-based resources. These findings also align with transportation being

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reported by both groups as a major barrier to health care appointments. This is in line with general sentiments within the broader addiction research community that digital interventions can improve overall access to care for SUDs [40].

With respect to the usability of the mobile app, both clients and providers requested that content be easier to search through and find specific information of interest. Ease of navigation is a central aspect of app usability. Similar to prior qualitative studies [41,42], findings from both the providers and clients also highlighted the importance of intervention personalization, as we continue to iterate versions of the app. For example, in the future, we may be able to add more tailored features such as providing automated or coach-curated educational content based on the client's assessment responses or on conversation topics with the e-coach.

In terms of compatibility with the mobile app, both clients and providers shared that regular support with daily recovery stressors and parenting and access to resources are key motivators to using the app. Clients reported that gift card compensation for participation was an additional motivator. One client wanted more educational content that was not tied directly to being in recovery from SUD. This comment aligns with previous research that found that many individuals viewed their recovery as an opportunity to also return to "normalcy" [43]. End users may appreciate a mobile app that focuses on their other life roles (eg, parent, spouse, and employee) and builds leisure skills. Indirectly, this comment may also align with a theme from the providers that language within the app be updated to be more person-centered versus clinical.

Negative cases identified during analyses (as mentioned in the Methods section) provided insight into how mobile app preferences can be very personal. For some, writing by hand may be a more multisensory and emotional experience preferred to typing with a digital tool. Additionally, an mHealth app may be more useful for people at the beginning of their SUD recovery when they may have fewer supports and resources than for individuals who are at later stages in their recovery. Available literature suggests that people earlier in recovery benefit from more intensive and structured support compared to those later in recovery who may have already developed long-standing support systems [44]. Future iterations of this study may explore how to personalize mobile app content and programming to better suit individual factors, such as stage in recovery.

Study findings may have valuable implications for sustaining engagement among high-need and at-risk pregnant and postpartum clients in digital interventions and SUD treatment. The active client subgroup reported various barriers to treatment continuation and recovery, such as missing at least 1 appointment in the past month and having more than 1 phone in the past year (a proxy for interruption in communication with providers and, thus, care). At the same time, this subgroup included individuals with overdose risk factors (eg, in treatment for opioid and/or stimulant and no MOUD prescription use among the majority in treatment for opioids), further emphasizing the potential value of the participants' perspectives. Additionally, the inclusion of providers with lived experience of SUD and recovery, and who work at different stages in the continuum of care, may have provided diverse perspectives, which studies that only include one provider discipline may miss [45].

Post hoc, the authorship team decided to analyze the survey responses of the inactive clients to better understand potential gaps in app use (Multimedia Appendix 3). Our subsample of active clients was predominantly White, while, among those who were inactive in the app (n=8), there was a higher proportion of Black individuals. Additionally, fewer inactive clients had formal education beyond a high school diploma or a General Educational Development test, and more had families of multiple children. These findings suggest that the racial and educational disparities often observed in in-person care for SUD may also translate to digital interventions and tools [40]. Thus, mHealth and substance use treatment scholars need to identify strategies that can ameliorate socioecological barriers. Mobile app content may need to be updated to be more inclusive and appropriate for different levels of learning (eg, reading level) and households (eg, shorter lessons and assessments for busy parents and use of videos versus only PDFs and PPTs for providing psychoeducation). Some individuals may need additional support with addressing gaps in digital literacy skills (eg, using the mobile app features) and digital access (eg, purchasing cellular data and locating public Wi-Fi). Across participant groups, transportation stood out as a crucial barrier to receiving SUD treatment.

Including providers' perspectives when developing and refining mHealth tools such as uMAT-R can validate the ideas and reported needs of pregnant and postpartum participants. A strength of our study is that nearly half of the providers shared that they were in recovery from SUD themselves; these individuals could speak to lived experience as both a client and a provider. Synergy between mHealth development teams and providers is also important for establishing a united front when using mHealth in the real world. Trusted providers can often serve as models or gatekeepers for what resources and tools "work" or "do not work" in the eyes of clients. Providers can offer insight on mHealth tools informed by their experience serving adults with SUD and bridge the gap between active, long-term mHealth use and passive, short-term app engagement.

Limitations

Our study's findings should be interpreted within the limitations of its design. The transferability of the findings may be limited by the sociodemographic profile of the clients and providers. The subsamples of clients and providers predominantly identified as cisgender and White. Reflecting the nature of the pilot study, the sample size was small and was solicited across one region of the Midwest. Pregnant clients were also only in the second and third trimesters, as these specific clients and those who were postpartum were more likely to seek care at the participating recruitment sites.

Additionally, we acknowledge changes to the study research team through the course of the study and the need to pivot from a "live" interview to an open-ended survey to best suit participants' schedules and needs. Changes to study methods always have the potential to impact the dependability and the confirmability of the research findings. To mitigate these risks,

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all interviewers provided an audit via an interview summary after each interview, and the coders clearly documented their coding process in Excel.

Conclusions

This study included qualitative responses from pregnant and postpartum people and SUD providers. Both groups of key informants were asked questions about the usability and compatibility of an mHealth intervention to support SUD recovery. While both groups described similar themes, pregnant and postpartum participants described specific nuances in their preferences for the mHealth intervention that were not shared by the providers. e-Coaching and interactive features were the most well-received components, and navigability and personalization of the mHealth intervention were highlighted as key aspects to explore in future work to increase the uptake and impact of such digital tools. Additionally, baseline data from participants who did not use the app offered insight into potential barriers to use (eg, structural racism in health care, less formal education, and taking care of family and other children), reinforcing that pregnancy and the postpartum period is a high-need time, in which innovative approaches to outreach, engagement, and retention in care (both digital and in person) are needed. Overall, both participants' and providers' feedback suggest the feasibility of using mHealth to support SUD recovery among pregnant and postpartum parents, and the usability and compatibility factors identified in this study should be considered when designing and refining mHealth interventions to meet the unique needs of this population.

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Data Availability

The datasets generated or analyzed during this study are not publicly available due to the sensitive nature of the data and to protect participant confidentiality and privacy. Data are available from the corresponding author on reasonable request.

Authors' Contributions

Conceptualization: HS (lead)
Data curation: HS (lead)
Formal analysis: HS (lead), LP (supporting), LM (supporting), JP (supporting), EM (supporting)
Funding acquisition: HS (lead), PC-R (equal)
Investigation: HS (lead)
Methodology: HS (lead)
Project administration: HS (lead)
Resources: HS (lead)
Supervision: HS (lead)
Validation: HS (lead), LP (supporting), LM (supporting), JP (supporting), EW (supporting), EM (supporting), KK (validation)
Visualization: HS (lead)
Writing—original draft: HS (lead), EW (supporting), EM (supporting), EK (supporting), CL (supporting), PC-R (supporting)
Writing—review and editing: HS (lead), LP (supporting), LM (supporting), JP (supporting), EW (supporting), EM (supporting), EK (supporting), AR (supporting), KK (supporting), PC-R (supporting)

Conflicts of Interest

None declared.

Multimedia Appendix 1
uMAT-R app, including home page, course library, and messaging feature, respectively.
[DOCX File , 704 KB - formative_v10i1e86255_app1.docx]

Multimedia Appendix 2
Pregnant and postpartum inactive participant demographics (n=8).
[DOCX File , 21 KB - formative_v10i1e86255_app2.docx]

Multimedia Appendix 3

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Evaluation of study quality and rigor.
[DOCX File , 22 KB - formative_v10i1e86255_app3.docx]

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Abbreviations

IRB: institutional review board
mHealth: mobile health
MOUD: medication for opioid use disorder
REDCap: Research Electronic Data Capture
SUD: substance use disorder

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Original Paper

Clinical and Behavioral Outcomes During 4 Weeks of Home-Based Self-Administered Transcranial Direct Current Stimulation in Perinatal Women With Depressive Symptoms: Open-Label Exploratory Pilot Study

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Abstract

Background: Depression during the perinatal period poses significant risks to both maternal and infant health. Although transcranial direct current stimulation (tDCS) has shown promise as a safe and well-tolerated intervention for perinatal depression, empirical evidence remains limited, and no prior study has integrated clinical outcomes with continuous objective behavioral monitoring.

Objective: This pilot study aimed to evaluate the feasibility and preliminary effects of home-based tDCS combined with wearable monitoring in women with perinatal depression and to explore the correlation between behavioral and clinical measures.

Methods: In total, 38 perinatal women completed a 4-week self-administered tDCS protocol targeting the left dorsolateral prefrontal cortex (DLPFC) with 30-minute daily sessions. Participants continuously wore a wrist device (Fitbit Inspire 2) that passively collected data on the step count, distance traveled, calorie expenditure, and heart rate. Depressive symptoms were assessed at baseline (week 0), midintervention (week 2), and postintervention (week 4) using the Montgomery-Åsberg Depression Rating Scale (MADRS) and the Beck Depression Inventory (BDI). Linear mixed models (LMMs) and nonparametric tests were used to evaluate changes over time, and correlations between behavioral and clinical variables were analyzed.

Results: Significant reductions were observed in depressive symptoms from baseline to postintervention. Mean MADRS scores decreased from 21.3 (SD 5.2) at baseline to 12.3 (SD 8.5) at week 4 (P<.001), and mean BDI scores decreased from 24.8 (SD 11.4) at baseline to 16.1 (SD 11.2) at week 4 (P<.001). Physical activity markers increased significantly: from baseline to week 4, the mean daily step count increased from 2366.8 (SD 2293.0) to 6278.7 (SD 5026.8) steps (P<.001), the mean distance traveled daily increased from 1564.6 (SD 1528.4) to 4105.9 (SD 3117.6) m (P<.001), and the mean daily calorie expenditure increased from 1130.6 (SD 759.9) to 1834.9 (SD 458.1) kcal (P<.001). However, the mean resting heart rate decreased from 85.9 (SD 9.0) to 80.4 (SD 7.0) bpm (P<.01). Exploratory correlation analyses revealed that BDI score reductions, but not MADRS changes,

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correlated significantly with increases in physical activity indicators (step count: r=0.401, P=.02 at week 2; r=0.351, P=.04 at week 4).

Conclusions: Results showed that 4 weeks of home-based, self-administered tDCS are feasible, well tolerated, and associated with improvements in depressive symptoms and objective behavioral activity among perinatal women. Self-reported symptom changes show stronger correlations with behavioral outcomes compared to clinician-rated scores. Although the lack of a control group precludes causal inference, these findings support the feasibility of integrating wearable monitoring with tDCS protocols and warrant further validation in randomized sham-controlled trials.

(JMIR Form Res 2026;10:e56454) doi:10.2196/56454

KEYWORDS

transcranial direct current stimulation; tDCS; perinatal depression; wearable devices; digital phenotyping; behavioral activation; pilot study

Introduction

Perinatal depression, encompassing both antenatal and postpartum periods, is among the most prevalent mental health conditions affecting women during childbearing years [1]. Studies estimate that 15%-20% of women experience clinically significant depressive symptoms during this period, often extending for months if left untreated [2]. These mental health difficulties not only affect maternal emotional well-being but are also associated with increased risk for obstetric complications, such as preeclampsia, preterm birth, and low birth weight, as well as disruptions in maternal-infant bonding and adverse long-term outcomes in child development [3-6].

Despite the high prevalence and clinical relevance of perinatal depression, access to appropriate care remains limited [7]. Pregnant and postpartum women often face significant barriers to seeking mental health treatment, including stigma, limited service availability, and safety concerns about pharmacotherapy [7,8]. Psychological interventions, such as cognitive behavioral therapy and interpersonal therapy, are effective but require intensive time commitments and access to trained professionals. These requirements may be difficult to meet during pregnancy or early motherhood, when competing demands are substantial [8,9]. These challenges have driven increasing interest in developing nonpharmacological and more accessible interventions, particularly those that can be delivered safely at home during the perinatal period [10].

Transcranial direct current stimulation (tDCS) is a noninvasive brain stimulation method that applies weak electrical currents through scalp electrodes to modulate cortical excitability and induce neuroplastic changes [11]. A substantial body of evidence across psychiatric and neurological populations indicates that tDCS is generally well tolerated, with adverse event (AE) and dropout rates comparable to sham stimulation [12,13]. Importantly, early clinical investigations suggest that tDCS may also be feasible and safe in perinatal populations. In one pilot randomized controlled trial [14], symptom reductions were observed in pregnant women with major depressive disorder (MDD), with no major maternal or neonatal complications. Another open-label study during pregnancy [15] demonstrated similar improvements, and a case report [16] described successful tDCS monotherapy in a perinatal patient. A systematic review [17] further concluded that noninvasive neurostimulation appears promising and well tolerated during pregnancy. Collectively, these studies indicate that tDCS represents a feasible, safe, and potentially effective treatment option for perinatal depression.

Most prior studies have focused on symptom reduction using validated clinician-rated or self-reported measures, such as the Montgomery-Åsberg Depression Rating Scale (MADRS), the Hamilton Depression Rating Scale (HAMD), or the Beck Depression Inventory (BDI) [18,19]. Although these tools are essential for evaluating depression severity, they may offer limited insight into functional changes in everyday behavior [19,20]. Real-world functioning, including physical activity, sleep, and physiological regulation, is increasingly recognized as an important dimension of treatment response, particularly in perinatal populations where the ability to maintain activity and caregiving responsibilities is directly linked to maternal and infant health [21,22].

Wearable devices and digital phenotyping methods, involving moment-by-moment quantification of individual-level behavioral patterns using data from personal devices, now provide opportunities to objectively measure such outcomes [23]. Recent studies on depression have demonstrated that wearable-derived metrics, such as the step count, distance traveled, and heart rate, are associated with self-reported mood and stress, offering ecologically valid markers of behavioral and physiological change [23-26]. However, to the best of our knowledge, no prior study has simultaneously evaluated associations between tDCS and both clinical symptom scales and wearable-based behavioral indicators in perinatal women [27].

In summary, although emerging evidence supports the feasibility and safety of tDCS for depressive symptoms during pregnancy, little is known about its integration with real-world behavioral monitoring or its applicability in home-based settings. To address these gaps, we conducted an open-label exploratory pilot study designed to primarily evaluate feasibility and exploratory associations, combining 4 weeks of daily tDCS with continuous wearable monitoring and standardized clinical assessments in perinatal women. This study primarily evaluated the feasibility and preliminary effects of home-based, self-administered tDCS on depressive symptoms and wearable-derived behavioral outcomes and further explored the association of clinician-rated (MADRS) and self-reported (BDI) symptom measures with behavioral indicators. Ultimately, the

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findings may inform the development of integrated digital neuromodulation platforms for perinatal depression.

Methods

Trial Design

This study was a 4-week, open-label, multicenter pilot trial conducted across four medical centers in South Korea to assess the feasibility, safety, and preliminary associations between home-based self-administered tDCS and clinical and behavioral outcomes in perinatal women with depressive symptoms. Trial registration was not applicable as this was an exploratory pilot study. Participants were recruited on a rolling basis without a formal sample size calculation, as the study was designed to evaluate feasibility and inform power estimates for future trials.

Participants

In total, 38 participants were enrolled during the pilot phase, of whom 36 (95%) completed follow-up to week 4 and provided analyzable data. Participants were recruited through internet-based advertisements and onsite recruitment at four medical centers in South Korea: the Seoul National University Hospital (Seoul), the Yongin Severance Hospital (Yongin), the CHA University Bundang Medical Center (Seongnam), and the Ilsan CHA Hospital (Goyang-si). Recruitment occurred from November 2023 to March 2025 through outpatient clinics in obstetrics and psychiatry.

The target population included perinatal women aged 19-49 years, encompassing those with infertility, planning pregnancy, currently pregnant, or in the postpartum period. Inclusion criteria were as follows:

- Mild-to-moderate MDD, defined as meeting the diagnostic criteria for unipolar, nonpsychotic MDD according to the *Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition* (DSM-5), with severity indicated by a BDI-II score of 18-28 or a MADRS score of 14-34
- Current MDD episode confirmed by the Mini International Neuropsychiatric Interview (MINI)
- Sufficient proficiency in Korean to understand study procedures and complete questionnaires
- Ability to provide informed consent
- Access to a smartphone compatible with the study app
- Willingness and ability to comply with the 4-week intervention protocol

Exclusion criteria were as follows:

- History of psychiatric comorbidities, including post-traumatic stress disorder or obsessive-compulsive disorder
- Diagnosis of bipolar or psychotic MDD
- History of seizure disorder or neurological conditions associated with increased risk for seizures that would make participation unsafe, as judged by the investigator
- MADRS item 10 (suicidal thoughts) score≥5 or suicide attempt within 6 months prior to screening
- Imminent suicide risk requiring psychiatric hospitalization, as judged by the investigator
- Scalp abnormalities, inflammatory reactions, or dermatological conditions preventing proper electrode placement
- Contraindications to noninvasive brain stimulation (eg, metal implants in the head, cardiac pacemakers, implantable cardioverter-defibrillators, or other implanted medical devices)
- Clinically significant cardiovascular, gastrointestinal, respiratory, endocrine, or central nervous system disorders interfering with device application or efficacy assessment
- Participation in another clinical trial within 30 days prior to screening
- Receipt of tDCS within 6 months prior to screening
- Any other clinically significant finding deemed inappropriate for study participation by the investigator

At visit 1 (V1; baseline, week 0), eligible participants completed demographic and clinical assessments. Follow-up evaluations were conducted at visit 2 (V2; week 2) and visit 3 (V3; week 4).

Ethical Considerations

This study was approved by the Institutional Review Boards (IRBs) of the Seoul National University Hospital (IRB #2307-135-1452); the Yongin Severance Hospital (IRB #2023-07-004); the CHA Bundang Medical Center, CHA University College of Medicine (IRB #2023-08-024); and the Ilsan CHA Hospital (IRB #2023-07-004). All participants provided written informed consent before enrollment. Participants were fully informed about the study's purpose, procedures, and potential risks, as well as their right to withdraw at any time without consequence. All study procedures complied with the principles of the Declaration of Helsinki and local ethical guidelines. To ensure privacy and confidentiality, all data were deidentified before analysis and securely stored on encrypted servers, accessible only to authorized research staff. Participants received a financial compensation of Korean Republic Won (KRW) 20,000 (~US $14) per visit (V1, V2, and V3).

Transcranial Direct Current Stimulation Intervention

Participants self-administered active tDCS once per calendar day for 4 weeks in an open-label design. There were no restrictions on the time of day, but multiple sessions within the same day were not permitted. Stimulation was delivered using a Conformité Européenne (CE)-certified portable stimulator (YMS-201B+/201BS+, MINDD STIM+; Ybrain Inc), which is classified as a class III medical device (psychotherapy brain electrical stimulator) approved by the Ministry of Food and Drug Safety (MFDS, Korea; product classification code A16180.02). The anode was positioned over the left dorsolateral prefrontal cortex (DLPFC; F3 according to the 10-20 electroencephalogram [EEG] system) and the cathode over the right DLPFC (F4), corresponding to Brodmann areas 9 and 46.

Each stimulation session lasted 30 minutes, consisting of a 30-second ramp-up phase, 29 minutes of active stimulation, and a 30-second ramp-down phase. Current intensity was set to either 2 or 1.5 mA, depending on participant tolerability. If participants demonstrated sensitivity to the 2 mA current during

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the initial sessions, the stimulation intensity was reduced to a minimum of 1.5 mA, and such adjustments were documented in the case report form.

Participants were instructed to complete one session per day, with a minimum of five and up to seven sessions per week. Thus, over the 4-week intervention period, participants could complete between 20 and 28 sessions. Saline-soaked sponge electrodes were used to ensure stable conductivity and to minimize skin irritation. No concomitant interventions were introduced during the study, and concomitant medications were permitted if clinically indicated and recorded in the case report form.

All participants attended an initial training session with study staff to ensure correct electrode placement, proper device handling, and safe operation. Written instructions and pictorial guides were provided for home use. Participants were instructed to synchronize the stimulation device with a dedicated smartphone app, which recorded adherence and sent automated reminders. Device logs and transmitted data ensured objective monitoring of compliance throughout the study.

Safety was monitored throughout the intervention period. Study staff asked participants about any adverse sensations or symptoms after each session, and investigators reviewed these reports weekly to identify potential AEs. All events were documented in the case report form and evaluated for seriousness and relatedness to the stimulation.

Behavioral Assessments

Behavioral outcomes were continuously assessed using a wrist-wearable device (Fitbit Inspire 2, Fitbit Inc). Four indicators were monitored: daily step count, distance traveled, calorie expenditure, and average heart rate. All wearable-derived variables were obtained from data collected via the Fitbit application programming interface (API) and aggregated by the investigators into daily mean values for analysis.

The step count, distance traveled, and calorie expenditure were derived from the Fitbit activity intraday endpoints, which provide minute-level measures of physical activity recorded while the device is worn. Distance traveled estimates were calculated by the device based on step counts and user-specific stride length parameters. Calorie expenditure reflects the total energy expenditure, including periods of physical activity as well as resting metabolic processes, as defined by the manufacturer.

Heart rate data were obtained from the Fitbit activities-heart-intraday endpoint, which provides minute-level heart rate values derived from photoplethysmography-based measurements. These intraday heart rate values represent physiological measurements collected while the device is worn and were summarized as the daily mean heart rate for each participant.

Baseline behavioral data were collected from the screening visit for the baseline assessment (1-3 days), whereas week 2 and week 4 data represented approximately 2-week collection periods preceding each assessment. Devices were worn continuously throughout the 4-week intervention period, and data were automatically uploaded to the study database through the Fitbit API. These measures provided objective and ecologically valid indices of participants' daily physical activity and physiological state [28]. Detailed definitions of wearable-derived features, corresponding Fitbit API endpoints, temporal resolution, and aggregation procedures are provided in Multimedia Appendix 1.

Clinical Assessments

Clinical outcomes were evaluated at baseline (week 0), midintervention (week 2), and postintervention (week 4). Depressive symptoms were assessed using two validated instruments. MADRS is a clinician-administered measure consisting of 10 items rated on a scale from 0 to 6 (total range 0-60), with higher scores indicating more severe depressive symptoms [29,30]. The Korean version of the Beck Depression Inventory-II (K-BDI-II) is a 21-item self-report questionnaire scored on a scale of 0 to 3 per item (total range 0-63), with higher scores reflecting greater depression severity [31,32]. Both scales have been validated for use in clinical and research settings and are sensitive to changes in depressive symptomatology over short time intervals.

Demographic and clinical background information, including obstetric status, psychiatric history, medical history, and medication use, were collected at baseline through structured questionnaires. Perinatal status was recorded in detail, including pregnancy trimester or postpartum duration, to allow stratification of participants according to the reproductive stage.

Data Analysis

All statistical analyses were performed using Python 3 (Python Software Foundation) with the *pandas*, *stats models*, and *scipy* packages. Descriptive statistics were used to summarize baseline sociodemographic and clinical characteristics. Continuous variables were presented as means (SDs) and categorical variables as frequencies and percentages. Missing data were handled using available-case analysis. For heart rate, missing values occurred primarily due to device removal or loose fit during sleep, which we considered to represent missing at random with respect to treatment response. Heart rate data were assumed to be missing at random for analytical purposes; however, no formal statistical test was conducted to verify this assumption. The number of valid observations is reported for each analysis.

For clinical outcomes, changes across time points (weeks 0, 2, and 4) were analyzed using linear mixed models (LMMs), with participant-level random intercepts and time as a fixed effect [33]. Results are reported as regression coefficients (β), SEs, 95% CIs, and *P* values.

For behavioral outcomes (step count, distance traveled, calorie expenditure, and heart rate), both LMMs and nonparametric tests were applied. Friedman tests were conducted to examine overall time effects, followed by pairwise Wilcoxon signed-rank tests. For these post hoc comparisons, *P* values were adjusted using Bonferroni correction to control for multiple testing. Effect sizes were calculated as Cohen d for descriptive purposes. It should be noted that effect sizes in within-subject pre-post designs may overestimate treatment-related effects in the

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absence of a control group and, thus, should be interpreted cautiously.

LMMs were applied to examine changes over time, with time as a fixed effect and participant as a random effect. Covariates were not included in the primary models; age-adjusted models were conducted as sensitivity analyses and are presented in Multimedia Appendix 2.

Associations between changes in clinical outcomes and behavioral indicators were assessed using Spearman rank correlation coefficients (r) with corresponding *P* values. Change scores were calculated for three intervals: week 2 vs week 0, week 4 vs week 0, and week 4 vs week 2.

To further account for multiple testing, false discovery rate (FDR) correction was explored for overall nonparametric analyses (Friedman tests); however, the main results are presented with Bonferroni-adjusted values for pairwise comparisons. All statistical results, including test statistics, *P* values, effect sizes, and 95% CIs, are reported.

Results

Participant Enrollment

A total of 38 perinatal women were enrolled in the study, of which 2 (5%) were excluded from the analyses: 1 (50%) participant did not provide any behavioral data, and 1 (50%) participant had no data available after week 2. Accordingly, the data of 36 (95%) participants were included in subsequent analyses.

Baseline Characteristics

Baseline demographic and clinical characteristics were assessed for all 38 (100%) participants. The mean age was 34.8 (SD 4.3) years, and the mean height was 163.2 (SD 6.2) cm. The majority of participants were married (35/38, 92%). In terms of occupation, 14 (37%) participants were homemakers, 10 (26%) were professionals, and 8 (21%) were white-collar workers, with smaller proportions engaged in services (2/38, 5%), self-employment (2/38, 5%), technical work (1/38, 3%), or as students (1/38, 3%).

The mean systolic and diastolic blood pressures were 116.1 (SD 13.4) and 70.0 (SD 11.5) mmHg, respectively. The mean pre-pregnancy weight and BMI were 60.9 (SD 10.1) kg and 22.9 (SD 4.2), whereas the current weight and BMI at baseline were 66.0 (SD 13.4) kg and 24.8 (SD 5.1). All 38 (100%) participants were nonsmokers, and 2 (5%) reported current alcohol use.

Regarding perinatal status, 11 (29%) participants were postpartum, 20 (53%) were pregnant (n=9, 45%, in the first trimester, n=8, 40%, in the second trimester, and n=3, 15%, in the third trimester), and 7 (18%) either had infertility or were planning pregnancy. The mean gestational age at participation among pregnant participants was 16 weeks and 6 days (SD 70.7 days). The postpartum period was defined as within 12 months after delivery and was, on average, 47.2 (SD 36.0) days after delivery.

These baseline characteristics are summarized in Tables 1 and 2.

Table 1. Baseline demographic characteristics of study participants (N=38).

Characteristics	Value
Age, years, mean (SD)	34.8 (4.3)
Occupation, n (%)	
Homemakers	14 (37)
White-collar workers	8 (21)
Services	2 (5)
Professionals	10 (26)
Technical jobs	1 (3)
Students	1 (3)
Self-employed	2 (5)
Marital status, n (%)	
Married	35 (92)
Divorced	1 (3)
Single mother	2 (5)
Number of offspring, mean (SD)	1.6 (0.8)[a]

[a]Data of 37 (97%) participants.

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Table 2. Baseline clinical characteristics of study participants (N=38).

Characteristics	Participants, n (%)	Mean (SD)
Physical characteristics		
Systolic blood pressure (mmHg)	37 (97)	116.1 (13.4)
Diastolic blood pressure (mmHg)	37 (97)	70.0 (11.5)
Pre-pregnancy weight (kg)	32 (84)	60.9 (10.1)
Weight (kg)	37 (97)	66.0 (13.4)
Height (cm)	38 (100)	163.2 (6.2)
Pre-pregnancy BMI	32 (84)	22.9 (4.2)
Current BMI	33 (87)	24.8 (5.1)
Smoking		
Yes	0	—[a]
No	38 (100)	—
Alcohol use		
Yes	2 (5)	—
No	36 (95)	—
Gestational status		
Planning pregnancy	2 (5)	—
First trimester (weeks 0-13)	9 (24)	—
Second trimester (weeks 14-28)	8 (21)	—
Third trimester (weeks 29-42)	3 (8)	—
Postpartum	11 (29)	—
Infertility	5 (13)	—

[a]Not applicable.

Descriptive Statistics

Table 3 shows descriptive statistics for all behavioral and clinical outcomes at baseline, week 2, and week 4. Baseline behavioral data represented 1-3 days of monitoring from screening to baseline assessment, whereas week 2 and week 4 data represented approximately 2-week collection periods. For the step count, distance traveled, and calorie expenditure, baseline (week 0) data were available for 36 (95%), week 2 data for 34 (90%), and week 4 data for 35 (92%) participants. The mean daily step count increased from 2366.8 (SD 2293.0) steps at baseline to 6278.7 (SD 5026.8) steps (P<.001) at week 4. The mean distance traveled daily increased from 1564.6 (SD 1528.4) m at baseline to 4105.9 (SD 3117.6) m (P<.001) at week 4. The mean daily calorie expenditure increased from 1130.6 kcal (SD 759.9) kcal at baseline to 1834.9 (SD 458.1) kcal (P<.001) at week 4. The mean resting heart rate decreased from 85.9 (SD 9.0) bpm at baseline to 80.4 (SD 7.0) bpm (P<.01) at week 4. Heart rate data were not available for all participants; the device measures the resting heart rate during sleep periods, but some participants removed the device during sleep or because it had a loose fit. Furthermore, for 36 (95%) participants, mean MADRS scores decreased from 21.3 (SD 5.2) at baseline to 12.3 (SD 8.5) at week 4, and mean BDI scores decreased from 24.8 (SD 11.4) at baseline to 16.1 (SD 11.2) at week 4.

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Table 3. Descriptive statistics of clinical and behavioral outcomes at each visit.

Variables	Week 0 (baseline)			Week 2 (midintervention)			Week 4 (postintervention)		
	Mean (SD)	Median (IQR)	Participants, n (%)	Mean (SD)	Median (IQR)	Participants, n (%)	Mean (SD)	Median (IQR)	Participants, n (%)
Clinical outcomes									
MADRS[a]	21.3 (5.2)	20.5 (7.8)	36 (95)	14.6 (7.0)	14.0 (8.0)	36 (95)	12.3 (8.5)	12.0 (10.0)	36 (95)
BDI[b]	24.8 (11.4)	21.0 (12.8)	36 (95)	18.3 (11.9)	17.0 (16.0)	36 (95)	16.1 (11.2)	13.5 (19.3)	36 (95)
Behavioral outcomes									
Step count	2366.8 (2293.0)	1977.0 (3158.8)	36 (95)	6099.3 (4611.9)	5475.0 (5506.0)	34 (90)	6278.7 (5026.8)	5218.0 (5247.0)	35 (92)
Distance traveled	1564.6 (1528.4)	1294.0 (2079.8)	36 (95)	4021.3 (3048.6)	3556.0 (3663.3)	34 (90)	4105.9 (3117.6)	3387.0 (3459.0)	35 (92)
Calorie expenditure	1130.6 (759.9)	1568.0 (1335.8)	36 (95)	1771.5 (520.3)	1821.0 (252.8)	34 (90)	1834.9 (458.1)	1790 (317.5)	35 (92)
Resting heart rate	85.9 (9.0)	84.7 (8.2)	27 (71)	82.6 (8.2)	80.8 (9.9)	28 (74)	80.4 (7.0)	82.5 (7.1)	27 (71)

[a]MADRS: Montgomery-Åsberg Depression Rating Scale.

[b]BDI: Beck Depression Inventory.

Clinical Outcomes: Model-Based Analyses

Table 4 presents results from the LMM analyses of clinical scales. Results indicated significant reductions in clinical scales over time. MADRS scores decreased at week 2 (β=−6.51, *P*<.001, 95% CI −7.59 to −5.44) and at week 4 (β=−8.80, *P*<.001, 95% CI −9.88 to −7.72) compared with baseline. Similarly, BDI scores decreased at week 2 (β=−6.60, *P*<.001, 95% CI −8.01 to −5.19) and at week 4 (β=−8.64, *P*<.001, 95% CI −10.05 to −7.22) compared with baseline.

Table 4. Clinical outcomes analyzed with LMMs[a].

Variable and comparisons	Regression coefficient β (SE)	95% CI	Effect size (Cohen d)	*P* value
MADRS[b]				
Week 2 vs week 0	–6.51 (0.55)	–7.59 to –5.44	1.33	<.001
Week 4 vs week 0	–8.80 (0.55)	–9.88 to –7.72	1.8	<.001
BDI[c]				
Week 2 vs week 0	–6.60 (0.721)	–8.01 to –5.19	0.95	<.001
Week 4 vs week 0	–8.64 (0.721)	–10.05 to –7.22	1.2	<.001

[a]LMM: linear mixed model.

[b]MADRS: Montgomery-Åsberg Depression Rating Scale.

[c]BDI: Beck Depression Inventory.

Behavioral Outcomes: Model-Based and Nonparametric Analyses

Figure 1 illustrates the model-estimated temporal trajectories of behavioral outcomes across the three assessment points. LMM analyses confirmed significant time effects for all behavioral indicators. Compared to baseline, the step count increased at week 2 (β=3735.98, *P*<.001, 95% CI 2089.65-5382.32) and week 4 (β=3938.59, *P*<.001, 95% CI 2306.69-5570.48), the distance traveled increased at week 2 (β=2458.66, *P*<.001, 95% CI 1412.46-3504.86) and week 4 (β=2559.28, *P*<.001, 95% CI 1522.32-3596.24), and calorie expenditure increased at week 2 (β=643.18, *P*<.001, 95% CI 380.08-906.28) and week 4 (β=705.99, *P*<.001, 95% CI 445.01-966.97). In contrast, heart rate decreased at week 2 (β=−3.39, *P*=.013, 95% CI −6.06 to −0.71) and week 4 (β=−5.61, *P*<.001, 95% CI −8.33 to −2.90).

Complementary nonparametric analysis results are summarized in Table 5. Friedman tests showed significant effects of time on the step count (χ^2_2=24.76, *P*<.001), distance traveled (χ^2_2=24.64, *P*<.001), calorie expenditure (χ^2_2=22.53, *P*<.001), and heart rate (χ^2_2=7.90, *P*=.019). Post hoc Wilcoxon signed-rank tests showed significant changes from baseline to week 2 and from baseline to week 4 for the step count, distance traveled, and calorie expenditure (all *P*<.001), but we observed no significant changes between weeks 2 and 4 (step count: *P*=.75; distance traveled: *P*=.77; calorie expenditure: *P*=.97). Heart rate decreased significantly from baseline to week 2 (*P*=.02) and from baseline to week 4 (*P*=.004), with no

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significant change between weeks 2 and 4 (P=.35). Effect sizes ranged from 0.74 to 0.86 for the step count, from 0.74 to 0.90 for the distance traveled, and from 0.76 to 0.86 for calorie expenditure. For heart rate, effect sizes were −0.57 at week 2 and −0.73 at week 4 compared with baseline.

Figure 1. Changes in behavioral outcomes over 4 weeks of the tDCS intervention. Data are presented as the mean (SD). Statistical significance between time points was assessed using Wilcoxon signed-rank tests with Bonferroni correction. *P<.05, **P<.01, ***P<.001. Error bars represent the SD. n=34-36 (89%-95%) for steps, distance, and calories; n=27-28 (71%-74%) for heart rate due to device removal or loose fit during sleep. tDCS: transcranial direct current stimulation.

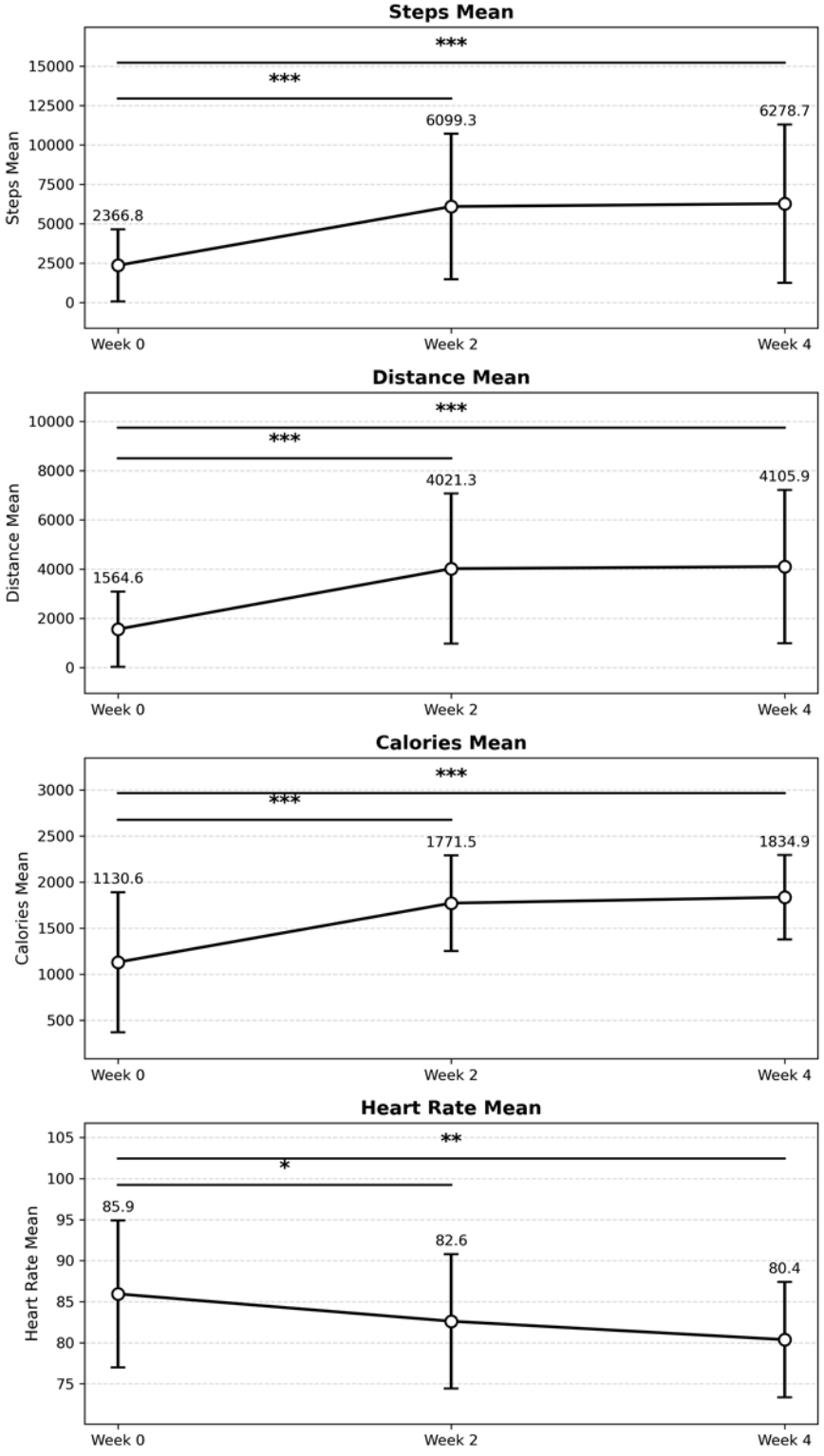

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Table 5. Behavioral outcomes across time points (nonparametric tests and effect sizes).[a]

Variable and comparisons	Friedman *P*	Wilcoxon *P*	Cohen d
Step count			
Week 0 vs week 2	<.001	<.001	0.74
Week 0 vs week 4	<.001	<.001	0.86
Week 2 vs week 4	.75	.75	0.06
Distance traveled			
Week 0 vs week 2	<.001	<.001	0.74
Week 0 vs week 4	<.001	<.001	0.9
Week 2 vs week 4	.77	.77	0.05
Calorie expenditure			
Week 0 vs week 2	<.001	<.001	0.76
Week 0 vs week 4	<.001	<.001	0.86
Week 2 vs week 4	.97	.97	0.11
Heart rate			
Week 0 vs week 2	.02	.02	–0.57
Week 0 vs week 4	.02	.004	–0.73
Week 2 vs week 4	.35	.35	–0.29

[a]Wilcoxon signed-rank tests were conducted for pairwise comparisons following a significant Friedman test. All *P* values were adjusted for multiple comparisons using Bonferroni correction.

Correlations Between Clinical and Behavioral Changes

Associations between changes in clinical scales and behavioral indicators are displayed in Table 6. No significant correlations were observed between changes in MADRS scores and behavioral measures across week 0 vs week 2, week 0 vs week 4, or week 2 vs week 4. However, significant correlations were identified for BDI scores, indicating that reductions in BDI scores are associated with increases in behavioral activity. Between baseline and week 2, decreases in BDI scores were correlated with increases in the step count (r=0.401, *P*=.02) and distance traveled (r=0.387, *P*=.02). Between baseline and week 4, similar correlations were observed for the step count (r=0.351, *P*=.04) and distance traveled (r=0.338, *P*=.05). Between weeks 2 and 4, changes in BDI scores were correlated with changes in heart rate (r=0.525, *P*=.01), whereas associations with the step count (r=0.295, *P*=.09) and distance traveled (r=0.293, *P*=.09) were not statistically significant.

Table 6. Correlations between changes in clinical scales (MADRS[a], BDI[b]) and behavioral indicators.

Scale and comparison	Step count		Distance traveled		Calorie expenditure		Heart rate	
	Correlation coefficient r	*P* value	Correlation coefficient r	*P* value	Correlation coefficient r	*P* value	Correlation coefficient r	*P* value
MADRS[a]								
Week 2 vs week 0	0.057	.75	0.034	.85	–0.126	.48	0.007	.98
Week 4 vs week 0	0.261	.13	0.249	.15	0.114	.52	–0.232	.30
Week 4 vs week 2	0.159	.37	0.125	.48	0.095	.60	0.228	.28
BDI[b]								
Week 2 vs week 0	0.401	.02	0.387	.02	0.149	.40	0.182	.41
Week 4 vs week 0	0.351	.04	0.338	.05	0.169	.33	–0.235	.29
Week 4 vs week 2	0.295	.09	0.293	.09	0.278	.11	0.525	.01

[a]MADRS: Montgomery-Åsberg Depression Rating Scale.

[b]BDI: Beck Depression Inventory.

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Adherence to Intervention

Overall adherence to the tDCS protocol was favorable across sites. Among the 38 participants, the mean completion rate was 68.9% (SD 28.3%) when considering full sessions only and 73.3% (SD 26.3%) when partial sessions were also included.

When adherence was examined based on the number of completed full sessions (out of 28 scheduled sessions), 22 (58%) participants completed at least 20 (71%) sessions, 10 (26%) participants completed 10-19 (36%-68%) sessions, and 6 (16%) participants completed fewer than 10 (<36%) sessions. Using a threshold of ≥70% adherence, 22 (58%) participants met this criterion based on full sessions only, and 25 (66%) participants met the same threshold when partial sessions were included.

Site-level adherence results and detailed distributions are summarized in Multimedia Appendix 3.

Safety and Tolerability

The tDCS intervention was generally well tolerated. A total of 10 (26%) participants experienced AEs during the 4-week intervention, most of which were mild to moderate in severity.

The most frequent AEs were skin and subcutaneous tissue disorders, including pruritus (n=1, 3%), skin irritation (n=5, 13%), and rash (n=1, 3%). Nervous system disorders were reported in 3 (8%) participants, all including mild headaches. Importantly, one serious adverse event (SAE) occurred, corresponding to a single case of skin irritation that met the criteria for seriousness (investigator-judged as requiring temporary medical attention but without hospitalization or lasting sequelae).

All other events were nonserious and transient, and no participants discontinued treatment due to AEs. Details of the AE profile are summarized in Table 7.

Table 7. Summary of reported AEs[a] during the 4-week tDCS[b] intervention.

Symptom category and reported symptom	Participants with AEs, n (%)	Participants, n (%)	
		Non-SAE[c]	SAE
Skin and subcutaneous tissue disorders			
Pruritus	1 (3)	1 (3)	0
Skin irritation	5 (13)	4 (11)	1 (3)
Rash	1 (3)	1 (3)	0
Nervous system disorders			
Headache	3 (8)	3 (8)	0
Total participants	10 (26)	9 (24)	1 (3)

[a]AE: adverse event.

[b]tDCS: transcranial direct current stimulation.

[c]SAE: serious adverse event.

Discussion

Principal Findings

To the best of our knowledge, this is the first study to combine self-administrated tDCS and continuous wearable data in perinatal women. This pilot study investigated associations between 4 weeks of daily tDCS and changes in depressive symptoms and wearable-derived behavioral outcomes in perinatal women. We observed concurrent reductions in depressive symptoms, increases in physical activity markers, and decreases in heart rate during the intervention period. Notably, reductions in self-reported BDI scores were correlated with changes in behavioral indicators, while clinician-rated MADRS scores were not, suggesting differential patterns in how these assessment modalities relate to real-world behavioral changes. These findings demonstrate the feasibility of integrating wearable monitoring with tDCS protocols across a heterogeneous perinatal population and provide preliminary evidence supporting further investigation in randomized controlled trials.

Both MADRS and BDI scores improved significantly across the study period, indicating meaningful symptom reduction. These results are consistent with prior evidence for tDCS in perinatal women. Previous randomized controlled trials have reported reductions in depressive symptoms among pregnant women without major maternal or neonatal complications [14]. Open-label studies during pregnancy have similarly demonstrated substantial improvements in depressive symptoms, with no obstetric or neonatal adverse outcomes [15]. Furthermore, systematic reviews of noninvasive brain stimulation during pregnancy have highlighted the promise and tolerability of tDCS in this population [17]. Together, these findings strengthen the evidence base that tDCS may be considered a safe and potentially beneficial intervention for perinatal depression, and our results extend prior work by demonstrating consistent improvements across both clinician-rated (MADRS) and self-reported (BDI) scales in a single study cohort.

Wearable-derived outcomes showed significant increases in step counts, distances traveled, and calorie expenditure, accompanied by decreases in heart rate. These improvements were evident by week 2 and were sustained through week 4. Such objective data provide an ecologically valid complement to traditional symptom ratings by reflecting day-to-day functioning in real-world contexts [22]. In neurological

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populations, repeated sessions of tDCS have been associated with cumulative improvements in motor and functional outcomes, suggesting that stimulation can enhance behavioral performance, in addition to potentially reducing symptoms [34]. In this study, the improvements in wearable-based outcomes paralleled the symptom reductions, underscoring the added value of integrating digital phenotyping into clinical trials. However, the findings reflect exploratory associations, and further work is needed to determine how wearable-derived measures can be systematically evaluated and applied within clinical trial frameworks. Digital phenotyping research has further shown that wearable-based indicators are sensitive to concurrent changes in self-reported mood and stress, reinforcing their utility as objective proxies of functional improvement [24,25].

It should be noted that baseline activity levels were particularly low, with a mean of approximately 2400 steps/day. Although this may partly reflect the shorter baseline collection period (1-3 days vs 2 weeks at follow-up), it also aligns with prior evidence that perinatal depression commonly presents with marked reductions in physical activity and behavioral activation. The substantial increases observed by week 2 and sustained through week 4 suggest that tDCS may be associated with behavioral activation in this population, although the uncontrolled design precludes definitive causal inference [35,36].

Exploratory analyses revealed that reductions in BDI scores, but not MADRS scores, were significantly associated with increases in step counts and distances traveled, as well as with decreases in heart rate. This pattern suggests that self-reported symptoms may capture subjective experiences that align more directly with daily activity patterns, whereas clinician-administered assessments may reflect broader, standardized clinical constructs with different relationships to real-world behavioral changes. This interpretation is supported by recent digital health research, which has shown that self-reported measures collected via mobile platforms are more strongly associated with wearable-derived indicators of activity than clinician-rated assessments [24]. Our findings add to this growing body of evidence, suggesting that patient-reported outcomes, when combined with objective wearable monitoring, may provide a more ecologically valid picture of functional change. From a clinical perspective, this highlights the importance of considering multiple outcome modalities to capture both symptom severity and functional change in perinatal populations. However, given the exploratory nature of these analyses and the number of comparisons conducted, these findings should be interpreted cautiously and require replication in larger controlled samples.

The intervention was well tolerated, and only 1 participant experienced an SAE (skin irritation requiring brief medical attention), with no treatment discontinuations or long-term effects. This observation is consistent with previous trials, in which tDCS during pregnancy or postpartum was associated with good tolerability and an absence of major maternal or neonatal complications [14-16]. A Cochrane review of tDCS across various populations similarly concluded that the rate of AEs and treatment discontinuation was comparable to sham stimulation, providing broader evidence of the safety of this intervention [12]. Recent trials of home-based or remotely supervised tDCS for depression have also demonstrated that this modality is both feasible and acceptable, further supporting the scalability of tDCS interventions in routine practice [37]. Our results contribute to this literature by showing that wearable monitoring can be effectively combined with stimulation in perinatal women, adding an additional layer of feasibility for future trials and demonstrating the potential for integrated digital health approaches in this population. Home-based, self-administered tDCS may represent a scalable intervention approach that could help address behavioral health provider shortages in perinatal care settings, pending validation in controlled trials.

Limitations

Several limitations should be acknowledged. First, and most importantly, the absence of a sham control group is a critical limitation of this pilot study. Without a control condition, observed changes cannot be attributed specifically to tDCS, as they may reflect placebo effects, natural symptom fluctuation, regression to the mean, or the effects of increased monitoring and supportive contact. Perinatal depression is known to improve spontaneously in some cases, particularly when women receive regular attention and support [38]. Therefore, no causal claims can be made from the findings, and results should be interpreted as preliminary associations that require validation in randomized sham-controlled trials to establish whether tDCS causally improves symptoms and functioning.

Second, several measurement challenges affected the wearable monitoring data. Baseline behavioral data were collected over a shorter period (1-3 days) compared to follow-up assessments (approximately 2 weeks), which may have contributed to artificially low baseline activity values and limits interpretation of the magnitude of behavioral changes. Additionally, heart rate data had substantial missingness due to device removal during sleep or loose device fit. Because no formal statistical test was performed to confirm the missing-at-random assumption, heart rate findings should be interpreted as exploratory. Although we considered this to represent missing at random with respect to treatment response, the representativeness of these data remains uncertain, and the Fitbit device measures the resting heart rate primarily during sleep periods, which represents a specific physiological state. Future studies should use consistent measurement periods across all time points and optimize device-wearing protocols to minimize data loss.

Third, the relatively small sample size limited statistical power and precluded meaningful subgroup analyses. The sample was heterogeneous, including women experiencing infertility, women across different pregnancy trimesters, and postpartum women, which limits interpretability regarding perinatal stage–specific effects. These groups may differ in their baseline characteristics, symptom profiles, and responses to intervention. However, the pilot design could not adequately address such differences. Future larger trials should consider stratification by perinatal status to examine potential differential effects.

Fourth, the exploratory correlation analyses involved multiple comparisons. Although we applied Bonferroni corrections to

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pairwise Wilcoxon tests, several significant correlations between BDI changes and behavioral indicators had *P* values near the significance threshold (eg, .04, .05). These findings should be interpreted cautiously and require replication in independent samples before firm conclusions can be drawn about differential sensitivity of assessment modalities.

Fifth, the study was limited to a 4-week intervention period, and therefore, the durability of the observed symptom reductions and behavioral improvements remains unknown. Longer-term follow-up is needed to determine whether benefits are maintained after treatment discontinuation. Additionally, wearable-derived measures, although ecologically valid, may be influenced by contextual factors, such as caregiving responsibilities, occupational demands, or lifestyle variations, which were not systematically controlled in this study.

Finally, effect sizes reported for within-subject pre-post comparisons should be interpreted as descriptive rather than definitive estimates of treatment effects. In the absence of a control group, such effect sizes may be inflated and do not necessarily reflect the true magnitude of tDCS-specific effects. These values are reported primarily to facilitate comparison with future controlled studies.

Conclusion

In summary, this pilot study provides preliminary evidence that 4 weeks of daily tDCS in perinatal women is associated with significant reductions in depressive symptoms, improvements in daily activity, and decreases in heart rate. Improvements emerge early and can be sustained through the intervention period. Self-reported outcomes (BDI) show stronger associations with wearable-based behavioral indicators compared to clinician-rated outcomes (MADRS), suggesting that patient-reported measures may be particularly sensitive to ecologically valid changes in functioning. The intervention is safe, feasible, and well tolerated, consistent with previous evidence from perinatal and broader clinical populations.

However, the open-label design without a sham control group is a fundamental limitation that precludes causal inference. Rather than prioritizing a single wearable-derived measure, future trials may benefit from evaluating multiple complementary indicators of activity and physiology, with stepwise validation focusing on reproducibility, sensitivity to change, and clinical relevance. The observed changes may reflect tDCS effects but could also result from placebo responses, natural symptom fluctuation, or increased monitoring. Therefore, these findings should be considered hypothesis-generating rather than confirmatory.

These results support the integration of wearable-based monitoring into tDCS trials as a strategy to capture multidimensional outcomes and emphasize the importance of combining clinician-rated, self-reported, and objective measures. Larger randomized sham-controlled trials with consistent measurement periods across time points, adequate statistical power for subgroup analyses, extended follow-up to assess the durability of effects, and stratification by perinatal status (eg, pregnancy trimester, postpartum period) are essential to validate these preliminary associations and establish whether tDCS causally improves symptoms and functioning in perinatal depression. Such trials should continue to incorporate multiple outcome modalities to comprehensively evaluate treatment effects and inform clinical implementation.

Acknowledgments

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Data Availability

The datasets generated and/or analyzed during this study are not publicly available because of restrictions containing information that could compromise the privacy of study participants but are available from the corresponding author upon reasonable request.

Authors' Contributions

SP conducted all statistical analyses, interpreted the results, and drafted the entire manuscript. GD, JP, MK, SJ, HK, and HYC contributed to the conceptualization and design of the study. JP, MK, SJ, and HK collected and organized the data and verified data accuracy. HYC supervised the overall study, contributed to data interpretation, and critically reviewed and revised the manuscript for important intellectual content.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Definition of wearable-derived behavioral features.
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Multimedia Appendix 2
Sensitivity analyses: age-adjusted LMMs. LMM: linear mixed model.
[DOCX File , 18 KB - formative_v10i1e56454_app2.docx]

Multimedia Appendix 3
Site-specific adherence to the tDCS intervention. tDCS: transcranial direct current stimulation.
[DOCX File , 115 KB - formative_v10i1e56454_app3.docx]

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Abbreviations

AE: adverse event
API: application programming interface
BDI: Beck Depression Inventory
DLPFC: dorsolateral prefrontal cortex
HAMD: Hamilton Depression Rating Scale
IRB: Institutional Review Board
LMM: linear mixed model
MADRS: Montgomery-Åsberg Depression Rating Scale
MDD: major depressive disorder
SAE: serious adverse event
tDCS: transcranial direct current stimulation

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Original Paper

Using a Wearable-Based Animated Patient Avatar to Improve Patients' Perception of Vital Signs: Multicenter Computer-Based Study

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Abstract

Background: Visual patient avatars are an innovative patient monitoring technology that can be used to translate numerical and waveform data into intuitive, avatar-based representations of patient conditions. Previous research indicates that this technology improves health care providers' situational awareness compared to conventional monitoring methods. As patient-worn continuous vital sign monitoring continues to evolve, we introduce the Visual Patient Wearable device to provide avatar-based visualization tailored to this application.

Objective: This study aimed to evaluate whether a wearable-based animated patient avatar can improve patients' perception and recall of simulated vital sign deviations compared to conventional monitoring methods, and to assess the usability and acceptance of this avatar-based visualization.

Methods: This computer-based study included 67 patients from 3 academic hospitals in Central Europe. Participants were randomly assigned to a Visual Patient Wearable group or a conventional monitoring group and viewed a standardized instructional video for their allocated method. They then completed 4 randomized clinical scenarios, each displayed for 6 seconds to simulate glance-based assessment. Accuracy in recalling vital sign deviations was measured, and Visual Patient Wearable participants additionally gave user feedback on Likert scales.

Results: The Visual Patient Wearable system was associated with higher detection accuracy of vital sign deviations compared with standard monitoring layouts, increasing from a median correctness of 46% (IQR 33%-63%) with conventional monitoring to a median of 67% (IQR 49%-79%) with the Visual Patient Wearable system (P<.001). This corresponded to a risk ratio of 1.34 (95% CI 1.23%-1.47%). The magnitude of this association varied across signals, with the largest relative improvement observed for heart rhythm (137% improvement, 95% CI 85%-209%), followed by oxygen saturation (SpO_2; 64% improvement, 95% CI 30%-108%) and temperature (30% improvement, 95% CI 5%-60%). No statistically significant reductions in risk were observed for heart rate, respiratory rate, or blood pressure. User experience ratings based on Likert scale assessments indicated high levels of satisfaction across all 6 vital sign categories (median score 4, IQR 4-5 on a 5-point scale).

Conclusions: This computer-based study suggests that Visual Patient Wearable visualizations enhance patients' ability to detect and recall simulated vital sign deviations. Participants found the system intuitive, easy to learn, and reassuring. The Visual Patient Wearable system provides an at-a-glance interface that may support patients' understanding of their vital signs and could facilitate

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communication of relevant information to clinical staff, thereby potentially contributing to informed patient engagement. The next step is to develop a software prototype for wearable devices and test it in a clinical study.

(JMIR Form Res 2026;10:e84130) doi:10.2196/84130

KEYWORDS

diagnosis; patient avatars; patient monitoring; situation awareness; vital sign information; usability; wearable

Introduction

Background

Visual patient avatars were first introduced in 2018 as a novel approach to presenting vital sign data by transforming traditional numerical and waveform information into an animated, avatar-based display [1]. This intuitive design improves the comprehensibility of vital signs, making physiological changes easier to interpret at a glance [2]. The development of visual patient avatars was grounded in the principles of situational awareness [3], which is recognized as critical for safe and effective decision-making in anesthesia and critical care settings [4,5]. Studies have demonstrated that avatar-based visualization enables clinicians to detect vital sign deviations more quickly and with greater confidence than standard displays, while also reducing cognitive workload [6,7]. Further investigations have demonstrated the robustness of the avatar concept across various clinical scenarios, including (simulated) high-stress environments [8,9], peripheral viewing conditions [10], and monitoring at a distance [11]. Visual patient avatars have since been applied successfully in operating rooms and acute care settings, including intensive care [12,13] and pediatric anesthesia [14].

Despite these advances in intraoperative and critical care monitoring, there remains a significant gap in continuous vital sign awareness on general hospital wards, where patients are typically monitored only intermittently [15]. Many adverse events, such as hypotensive episodes or desaturation events, occur in the perioperative setting and remain undetected for multiple hours [16,17]. The European Surgical Outcomes Study reported that 73% of patients who died after surgery were never admitted to critical care at any point [18]. Similarly, national audits from the United Kingdom indicate that more than half of in-hospital cardiac arrests occur on regular wards, often without prior warning [19].

Emerging technologies such as wireless wearable sensors promise continuous, real-time surveillance of vital signs on the ward [20]. These systems have been associated with reductions in desaturation episodes, intensive care unit transfers, and postoperative complications when compared to traditional intermittent monitoring [21]. However, current solutions predominantly rely on passive data collection and alarm-based alerts, offering limited patient involvement [22].

To address this gap, we introduce Visual Patient Wearable device, a patient-worn, avatar-based system that translates vital sign data into an intuitive format. Unlike conventional monitors, the Visual Patient Wearable system is designed for direct patient use, promoting engagement and supporting the concept of patient-centered precision care [23,24]. Conceptually, the Visual Patient Wearable system targets the first link in an intervention-outcome chain. By enabling patients to detect vital sign deviations early, it may support timely actions by patients or notified clinicians, potentially improving process measures such as response times and, over time, may contribute to a reduction in adverse outcomes such as desaturation episodes, intensive care unit transfers, and postoperative complications.

Objectives

This study aimed to investigate whether an animated patient avatar displayed on a wearable device (the Visual Patient Wearable system) can enhance patients' perception of their vital signs. Specifically, we aimed to determine (1) whether avatar-based visualization of vital sign data enhances patients' ability to detect early deviations and (2) how patients perceive the learnability and utility of the Visual Patient Wearable system.

Methods

Ethical Considerations

The study received a declaration of nonjurisdiction (exemption from ethics approval) from the Cantonal Ethics Commission of Zurich, Switzerland (Req-2024-00286), as no personal health data were collected. In addition, the study obtained positive ethics approval from both participating sites in Germany (Bonn: 2024-209-BO; Frankfurt: 2024-1759). The study was conducted in accordance with the principles of the Declaration of Helsinki. All participants provided written informed consent before participation and were free to withdraw at any time without consequences. Nonparticipation or withdrawal did not affect patients or their subsequent medical treatment. No personal or identifiable data were collected. Participants were tested experimentally using arbitrary vital parameters. Individual medical parameters, medical history, diagnoses, or therapies were neither collected, manipulated, nor stored. All data were fully anonymized at the time of collection and stored securely on password-protected systems accessible only to the study researchers. Participants did not receive any financial or other compensation for participation. Reporting followed the Guidelines for Health Care Simulation Research and extensions to the CONSORT (Consolidated Standards of Reporting Trials) and STROBE (Strengthening the Reporting of Observational Studies in Epidemiology) statements [25].

Study Design

This computer-based study compared patients' ability to correctly identify simulated vital sign deviations (respiratory rate, oxygen saturation [SpO_2], temperature, blood pressure, heart rate, and heart rhythm) presented on a wearable device using two visualization methods: (1) a conventional numeric

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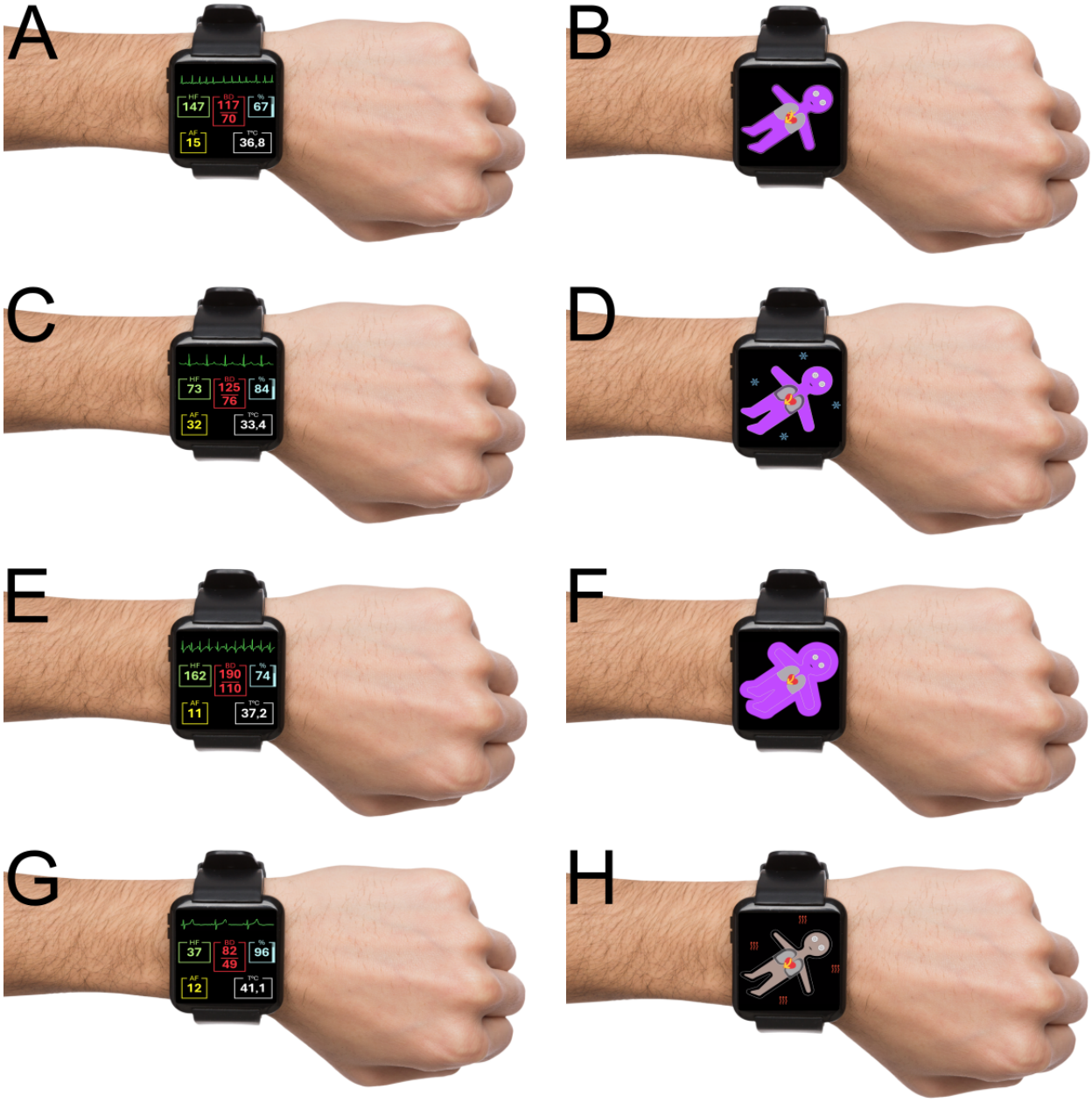
display with 1-lead electrocardiogram and (2) an animated patient-avatar display based on existing visual patient avatars.

Figure 1 shows a side-by-side comparison of both digital visualizations. Figure S1 in Multimedia Appendix 1 shows the flowchart of the study design. Table S1 in Multimedia Appendix 1 shows the vital sign deviations and cutoff values.

Figure 1. Visualizations for conventional monitoring (A, C, E, and G) and the Visual Patient Wearable system (B, D, F, and H), showcasing the same pathologies (scenarios 1 to 4).



Participants were approached directly on the ward and invited to participate, resulting in a convenience sample of readily available and willing patients. They first completed an assessment of general knowledge of vital signs, based on conventional monitoring values and alarm thresholds. Participants were then randomly assigned to either a Visual Patient Wearable group or a conventional monitoring group using a computer-generated random number sequence [26]. Before testing, each participant individually viewed a standardized instructional video corresponding to their assigned visualization method (refer to Multimedia Appendix 2 for the Visual Patient Wearable system and Multimedia Appendix 3 for conventional monitoring). Subsequently, participants were exposed to 4 standardized scenarios (Figure 1) presented in an individually randomized order, again determined using a computer-generated random number sequence from 1 to 4 [26]. Each scenario was displayed for 6 seconds to simulate a glance-based assessment (eg, following an alarm). After each display, participants were required to recall the status of each vital sign (too low, normal, or too high). Participants allocated to the Visual Patient Wearable group subsequently completed a questionnaire consisting of 6 statements addressing the design and applicability of the Visual Patient Wearable system (Textbox 1).

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Textbox 1. Questionnaire assessing participants' perceptions of the Visual Patient Wearable system.

- Question 1: "I would consider the avatar a useful addition to a wearable device such as a smartwatch."
- Question 2: "Using the avatar would improve my perception of the vital signs."
- Question 3: "Using the patient avatar would improve my ability to manage my health."
- Question 4: "The patient avatar was clear and understandable."
- Question 5: "The patient avatar would be easy for me to use."
- Question 6: "Learning to understand and use the patient avatar would be easy for me."

These statements were rated on a 5-point Likert scale from 1 (strongly disagree) to 5 (completely agree).

Overall, 46% (31/67) of the participants underwent surgery. Among them, 23% (7/31) reported experiencing visual patient avatars during their procedure, accounting for 10% (7/67) of all participants. These participants subsequently completed 6 additional questions, rated on a 7-point Likert scale ranging from 1 (strongly disagree) to 7 (completely agree; Textbox 2).

Finally, demographic data (sex, age, and study center) were collected.

Textbox 2. Additional questionnaire assessing participants' perceptions of the visual patient avatar system.

- Question 1: "The visual patient avatar confused me."
- Question 2: "The visual patient avatar cheered me up."
- Question 3: "The visual patient avatar scared me."
- Question 4: "The visual patient avatar seemed unprofessional."
- Question 5: "The visual patient avatar made me feel well-monitored."
- Question 6: "The visual patient avatar gave me a positive impression."

Data Collection

The study assessed the suitability of the experimental technology solely for its intended patient user group. Participants' medical history, current illness, or treatment data were neither collected, stored, nor influenced. Data were collected digitally using offline-capable software (Harvest Your Data) together with a single instructor. Testing lasted approximately 30 minutes per participant. No data could be traced back to individual participants. The following data were recorded: recall of vital signs; pretesting knowledge of conventional monitoring aspects (physiological thresholds of vital signs); answers from Likert rating scales; and demographics, including age (in years), sex (male or female), chronic illness (yes or no), surgery (yes or no), and experience with visual patient avatars in the operating room (yes or no).

Study Centers

This study was conducted at 3 academic medical centers: the University Hospital Zurich, Switzerland; the University Hospital Bonn, Germany; and the University Hospital Frankfurt am Main, Germany.

Study Participants

Patients were approached on general wards at participating centers and informed about the study. All participants received written information about the study procedures and data handling and provided written informed consent before participating. We defined the following inclusion criteria: adults (≥18years) hospitalized on a general ward, fluent in German, and fully conscious (Glasgow Coma Scale=15). Exclusion criteria were as follows: admission to intermediate or intensive care units, any cognitive impairments (eg, dementia, intellectual disability, delirium, or language barrier), thought disorders, inability or unwillingness to provide informed consent, uncorrected visual impairment (unable to read a newspaper), or acute psychological or physical distress.

Statistical Analysis

For the a priori sample size calculation, we assumed a clinically relevant difference of 2 correctly identified vital signs between groups. On the basis of this assumption, with a power of 80% and a significance level of $P<.05$, 31 participants per group (62 in total) would be required. This estimate was based on the expected performance with the conventional monitoring device and the anticipated improvement using the Visual Patient Wearable system. All analyses were performed at the participant level. For each participant, responses were first aggregated across all scenarios to yield a single summary value per vital sign as well as 1 overall correctness value, ensuring that each participant contributed only 1 observation to the final analyses. Descriptive statistics were reported as medians with IQRs (Q1-Q3) for continuous variables and as counts and percentages for categorical variables. The primary outcome was the number of correctly identified vital sign deviations, reported both per signal (respiratory rate, SpO_2, temperature, blood pressure, heart rate, and heart rhythm) and overall. Comparisons between the 2 modalities (Visual Patient Wearable vs conventional monitoring) were performed using the Wilcoxon rank sum test for independent samples (MATLAB function *ranksum*), applied separately for each vital sign and for the overall mean score. To quantify relative performance, risk ratios with 95% CIs (2.5th and 97.5th percentiles) were calculated using nonparametric

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bootstrapping (10,000 iterations). The risk ratio was defined as the proportion of correct identifications in the Visual Patient Wearable condition relative to the conventional condition, calculated both per signal and overall. To evaluate potential influences of participant demographics or study center, we conducted nonparametric analyses. Center effects were assessed using the Kruskal-Wallis test on overall correctness. Age effects were evaluated using Spearman correlation, and sex differences were assessed with the Wilcoxon rank sum test. To confirm the robustness of the primary Visual Patient Wearable vs the conventional effect, sensitivity analyses were performed, stratified by age (median split) and center, comparing each stratum using Wilcoxon rank sum tests. In addition, to assess potential familiarity effects, overall correctness was compared between participants with and without previous exposure using Wilcoxon rank sum tests, analyzed separately for each study arm. All statistical analyses and visualizations were performed in MATLAB R2023a (update 8, MathWorks).

Creation of Visual Patient Wearable System

The Visual Patient Wearable system uses an animated patient-avatar display based on existing visual patient avatars [27], which represent numerical vital signs in an animated format. Only minor modifications, regarding the size of thoracic organs, were made for the Visual Patient Wearable system to better fit the smaller screen. It visualized 6 vital signs: respiratory rate, SpO_2, temperature, blood pressure, heart rate, and heart rhythm, which most wearable devices can measure. Respiratory rate was indicated by the speed of lung movements (slow=low and fast=high). Oxygen saturation was represented by skin color (brown ≥92% and purple or cyanotic <92%). Temperature was indicated by the presence of ice crystals or heat waves surrounding the avatar; the absence of these showed a normal temperature. Blood pressure was conveyed by the overall filling of the avatar (thin=low and thick=high). Heart rate was displayed via the speed of electrical excitation, visualized as a yellow arrow in the heart. Heart rhythm was represented by the excitation pattern: regular propagation from atrium to ventricle indicated sinus rhythm, whereas irregular atrial discharges, shown as lightning flashes near the sinus node, indicated atrial fibrillation.

Animated examples of the Visual Patient Wearable system are provided in Multimedia Appendix 2, and cutoff values for low, normal, and high readings are listed in Table S1 in Multimedia Appendix 1.

For comparison, the conventional numerical display presented the same 6 vital signs in standard formats, with values, waveforms (electrocardiogram), and colors, reflecting normal or abnormal ranges. The corresponding conventional display of the 6 vital signs is detailed in Multimedia Appendix 3. The Visual Patient Wearable system's display and conventional displays conveyed equivalent information content, allowing observed differences in user performance to be attributed to the mode of visualization rather than differences in data availability or labeling.

Results

Overview

A total of 67 patients were recruited into the study. There were no dropouts, and all data (1584 responses, 792 per arm) were included in the analysis. Demographic and baseline characteristics of the participants are presented in Table 1. The median overall percentage of correct responses was 66.7% (IQR 49%-79.2%) in the Visual Patient Wearable group and 45.8% (IQR 33.3%-62.5%; $P<.001$) in the conventional group. Baseline knowledge of physiological threshold values for vital signs (heart rate, respiratory rate, systolic and diastolic blood pressure, SpO_2, and body temperature) was moderate across the study population, and there were no statistically significant differences between groups (Figure S2 in Multimedia Appendix 1; $P=.74$). The age of participants was not significantly different between the Visual Patient Wearable and conventional monitoring groups (Visual Patient Wearable group: median age 36 [IQR 23-48] years; conventional group: median age 45 [IQR 30-55] years; $P=.15$). Correctness differed significantly across centers (Kruskal-Wallis; $P<.001$), indicating some heterogeneity in performance. Nevertheless, within each center, the Visual Patient Wearable group still consistently achieved significantly higher correctness than the conventional group (Table S2 in Multimedia Appendix 1). Age was also significantly associated with correctness, exhibiting a moderate negative correlation (Spearman rho=–0.374; $P<.001$). However, in age-stratified analyses, the Visual Patient Wearable group outperformed the conventional group in both younger participants (conventional group: median 50%, IQR 50%-67% vs Visual Patient Wearable group: median 67%, IQR 50%-83%; $P<.001$) and in older participants (conventional group: median 33%, IQR 17%-50% vs Visual Patient Wearable group: median 50%, IQR 33%-67%; $P=.015$). No significant differences in performance were observed between female and male participants, independent of center ($P=.70$). Within the Visual Patient Wearable group, participants with previous Visual patient avatar experience (13/67, 19%) achieved higher overall correctness than those without experience (54/67, 81%; median 83.3%, IQR 67%-92% vs median 66.7%, IQR 50%-83%; $P=.02$), indicating a benefit of familiarity. In contrast, in the conventional group, performance was similar regardless of previous exposure (median 50%, IQR 50%-67% vs median 50%, IQR 42%-67%; $P=.80$).

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Table 1. Study participants' demographics (N=67).

Parameter	Visual Patient Wearable group (n=34)	Conventional group (n=33)
Location, n (%)		
University Hospital Bonn	10 (29)	10 (30)
University Hospital Frankfurt	11 (32)	10 (30)
University Hospital Zurich	13 (38)	13 (39)
Age (years), median (IQR)	36 (23-48)	45 (30-55)
Female sex, n (%)	20 (59)	12 (36)
Prior surgery at the center, n (%)	17 (50)	15 (45)
Any chronic illness, n (%)	9 (26)	12 (36)
Previous visual patient avatar exposure, n (%)	7 (21)	6 (18)

Primary Outcome: Correct Identification

The Visual Patient Wearable system improved correct identification across all 4 scenarios:

1. Conventional group (median 50%, IQR 16.7%-54.2%) vs Visual Patient Wearable group (median 66.7%, IQR 50%-83.3%; *P*=.004)
2. Conventional group (median 50%, IQR 33.3%-66.7%) vs Visual Patient Wearable group (median 66.7%, 50%-83.3%; *P*=.041)
3. Conventional group (median 50%, IQR 29.2%-66.7%) vs Visual Patient Wearable group (median 66.7%, IQR 50%-83.3%; *P*=.005)
4. Conventional group (median 50%, IQR 33.3%-70.8%) vs Visual Patient Wearable group (median 66.7%, IQR 50%-83.3%; *P*=.032; Figure S3 in Multimedia Appendix 1)

This was reflected in the overall increase in correct responses from a median of 45.8% (IQR 33%-63%) with the conventional group to a median of 66.7% (IQR 49%-79%) with the Visual Patient Wearable group (*P*<.001). Relative risk estimates indicated an overall 34% (95% CI 23%-47%) higher probability of a correct response when the Visual Patient Wearable system was used. The magnitude of this effect varied across signals, with the most considerable improvement observed for heart rhythm (137%, 95% CI 85%-209%), followed by SpO_2 (64%, 95% CI 30%-108%) and temperature (30%, 95% CI 5%-60%). Heart rate, respiratory rate, and blood pressure showed no significant change in risk ratios. For a complete statistical analysis of all vital sign parameters, refer to Figure 2 and Table 2.

Figure 2. Primary outcome (correctness) comparing the Visual Patient Wearable system and conventional monitoring. (A) Bar chart displaying the percentage of correct identifications of vital sign deviations across all 4 scenarios for 6 parameters. (B) Log-scaled risk ratios per vital sign. The risk ratios were considered significant when the 95% CI did not include 1. ABP: arterial blood pressure; SpO2: oxygen saturation; Temp: temperature; RR: respiratory rate; HR: heart rate.

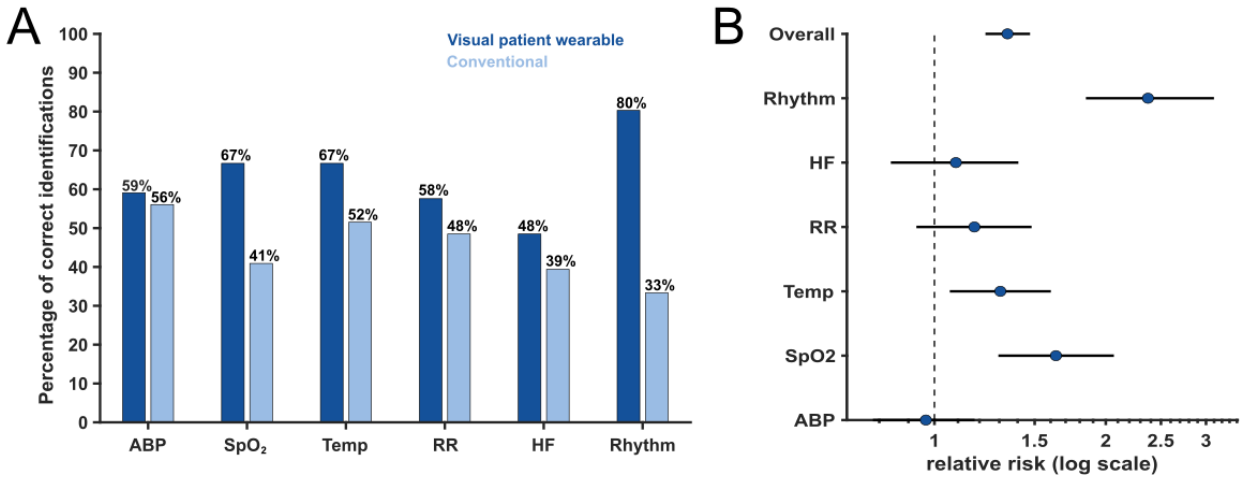

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Table 2. Statistical overview of percentages of correctly identified vital signs over 4 scenarios (N=67).

Signal	Visual Patient Wearable (%), median (IQR)	Conventional (%), median (IQR)	Risk ratio (95% CI)	Benefit of the Visual Patient Wearable system
Arterial blood pressure	50 (50-75)	50 (50-75)	0.97 (0.79-1.18)	None
Oxygen saturation	75 (44-100)	25 (25-75)	1.64 (1.30-2.08)	Moderate
Temperature	75 (25-100)	50 (25-50)	1.30 (1.05-1.60)	Moderate
Respiratory rate	50 (50-75)	50 (50-75)	1.18 (0.93-1.48)	None
Heart rate	50 (25-75)	50 (25-75)	1.09 (0.84-1.40)	None
Rhythm	75 (70-100)	25 (25-50)	2.37 (1.85-3.09)	Strong
Overall	66.7 (49-79)	45.8 (33-63)	1.34 (1.23-1.47)	Moderate

User Experience and Feedback

We conducted 2 separate evaluations of the Visual Patient Wearable system. The first focused on general user impressions and was based on a 5-point Likert scale. Participants rated various aspects of the system as follows: visualization had a median score of 4 (IQR 4-5), organization had a median score of 4 (IQR 3-5), usefulness had a median score of 4 (IQR 4-5), learnability had a median score of 4 (IQR 4-5), understandability had a median score of 4 (IQR 3.75-5), and usability had a median score of 4.18 (IQR 4-5; Figure S4 in Multimedia Appendix 1). These results indicate that all evaluated aspects were judged positively, with particularly strong ratings for learnability, usability, and visualization.

In a separate analysis, we evaluated feedback from participants who had personally experienced visual patient avatars in the operating room, using a 7-point Likert scale (with higher scores indicating more favorable ratings, except for negative aspects such as fear, confusion, and untrustworthy appearance). These participants reported an overall positive impression, with a median score of 5 (IQR 4.5-6), and felt well monitored, with a median score of 5 (IQR 4.75-6). The visual patient avatars were also perceived as somewhat cheerful, with a median of 5 (IQR 4-6.25). The ratings for negative aspects were consistently low: fear was rated at 1 (IQR 1-2), confusion at 2 (IQR 1-2.5), and untrustworthy appearance at 2 (IQR 1-2.5). Participants who encountered visual patient avatars in clinical practice experienced them positively, with minimal negative perceptions (Figure S5 in Multimedia Appendix 1).

Discussion

Principal Findings

In this simulation study conducted on a general ward patient cohort, the Visual Patient Wearable system was associated with higher accuracy in detecting vital sign deviations compared to conventional monitoring visualizations. The greatest improvements were seen for heart rhythm, followed by SpO_2 and temperature. Heart rate, respiratory rate, and blood pressure showed nonsignificant variability in favor of better detection with the Visual Patient Wearable system. Qualitative assessments indicated that patients perceived the Visual Patient Wearable system as understandable and easy to learn and believed it had potential value for future real-world clinical use.

Our primary outcome was the detection and recall of changes in simulated vital signs, averaging across all 6 parameters, to assess the overall effect of the avatar. The effect varied across parameters for 2 main reasons. First, some vital signs were more visually prominent on the wearable device. For example, SpO_2 changes were clearly indicated by a color shift in the avatar's skin, making them noticeable even on a small display. In contrast, parameters such as respiratory rate and heart rate were represented only on the avatar's thorax, appearing smaller and less visually prominent when shown on a small screen. Second, participants' general knowledge of common vital signs may have influenced detection. Blood pressure was generally well recognized, whereas electrocardiogram signals and heart rhythm, typically reserved for medical professionals, were difficult to interpret with conventional displays. However, the simplified Visual Patient Wearable visualization allowed participants to correctly identify the heart rhythm much more reliably.

Continuous vital sign monitoring has gained increasing attention for its potential to improve patient safety and clinical outcomes, particularly in anesthesiology, where perioperative care is crucial for preventing morbidity and mortality [28-30]. Continuous monitoring has been shown to detect critical events more quickly and reduce adverse events, such as clinical deterioration and cardiac arrests, compared to intermittent monitoring [31,32]. Advances in sensor technology [22] and machine learning [33] further highlight the growing interest in continuous ward monitoring. Unlike sensor- or algorithm-specific solutions, our Visual Patient Wearable visualization prioritizes patient comprehension, offering an intuitive and co-designed interface with the goal of enhancing usability, relevance, and acceptance [34]. The Visual Patient Wearable system aims to empower patients to actively engage in monitoring their health, supporting early detection of deviations and potentially mitigating risks associated with delayed intervention [35]. This study specifically focused on the first link in the intervention-outcome chain: patient detection of vital sign deviations. Subsequent steps, such as alerting clinicians, process measures such as response time or escalation, and ultimate clinical outcomes, were not assessed and will be addressed in future clinical trials to evaluate the full impact of the Visual Patient Wearable system on clinical workflows and patient care, as this study had no influence on real clinical behavior or outcomes. The next step will be to conduct a feasibility study on ward patients using a Visual Patient Wearable prototype, explicitly considering real-world conditions such as variations in lighting, background noise,

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alarms, and typical workflow interruptions. Practical end points will include patient adherence, time-to-notice of vital sign deviations, usability, and satisfaction. The study will also explore how the Visual Patient Wearable system can be integrated into standard patient monitoring routines, notifying staff when necessary, without disrupting care, and providing critical insights into its feasibility and potential application in clinical practice. In addition, integrating machine learning algorithms and optimizing data flow to the responsible health care professional into the Visual Patient Wearable system could further enhance its predictive capabilities [36,37].

Situational Awareness and Visual Patient Avatar Design

Visualization plays a crucial role in presenting complex data in an intuitive manner, thereby reducing cognitive load for clinicians and patients. The Philips visual patient avatar integrates multiple vital signs into a single animated figure [38]. Simulation studies indicate that user-centered displays, using color, shape, and motion, assist anesthetists in swiftly identifying clinical deteriorations, increasing diagnostic confidence, and reducing workload [1,8,9]. These visuals are designed to leverage innate human abilities in color and motion recognition, offering a rapid overview of multiple vital sign data [39].

While visual patient avatars were initially developed for clinical professionals, the same design principles may also apply to patient-facing systems. In particular, presenting physiological information in a simplified and intuitive visual form may help patients better understand their own health data. Improved comprehension of physiological information through accessible visualizations may increase engagement with health-related information and self-care, with potential benefits for both mental and physical health. Support for this concept can be found in previous work on adaptive digital health interventions. For example, a psychoeducational mobile health program for parents expecting a fetus classified as small for gestational age demonstrated that providing tailored, understandable health information during pregnancy was associated not only with improved emotional support for the mother but also with higher birth weights in the intervention group compared with controls [40]. This suggests that improved comprehension and engagement with health information may have downstream effects beyond psychological well-being.

Limitations

This study has several limitations. The sample size was limited, and the cohort was relatively young. Participants were recruited as a convenience sample, which inherently restricts the generalizability of the findings. While inclusion of participants from 3 academic centers in different countries increased heterogeneity, performance differences were observed between centers and age groups, underscoring the potential influence of local training environments and demographic factors. Group allocation and scenario order were randomized, and no significant differences in age or previous knowledge of vital sign thresholds were present between groups. Using short, 6-second video scenarios to simulate clinical scenarios may not fully reflect the complexity of real-world decision-making for patients to alert health care providers. A future clinical study using a functional prototype is warranted. Previous exposure to the Visual Patient Wearable system was limited to a short instructional video, and participants may not have reached full proficiency before testing. Thus, their performance may not reflect actual use after more extended training or repeated use. In addition, we were unable to assess participants' long-term learning or retention, as repeated sessions and follow-up assessments were not feasible in this study. Consequently, the results may not capture potential improvements in detection accuracy or usability that could occur with extended exposure and repeated use over time. The evaluation of the Visual Patient Wearable system included self-reported ratings based on hypothetical use scenarios, which may not accurately predict behavior or acceptance in real clinical environments. The subset of participants who experienced visual patient avatars as surgical patients was small (approximately 7/67, 10%), and retrospective recall of emotional reactions may be prone to bias. There were challenges related to the Visual Patient Wearable system, such as data security concerns, patient acceptance, and usability issues among older or technologically inexperienced populations [41]. Addressing these challenges is crucial for ensuring the widespread adoption and effective implementation of the Visual Patient Wearable system in routine clinical practice.

Conclusions

This computer-based study evaluated Visual Patient Wearable visualizations for continuous monitoring of vital signs in patients. Our findings indicate that the Visual Patient Wearable system may improve the recognition of simulated vital sign deviations, even in complex scenarios. Participants generally found the system intuitive, learnable, and reassuring, with minimal negative emotional responses. These results suggest that the Visual Patient Wearable system could help patients better understand their vital sign data and communicate relevant information to staff, although our study was not based on real clinical outcomes. Conventional monitoring systems are primarily designed for health care professionals and often present information that is not easily comprehensible to patients. The Visual Patient Wearable system addresses this gap by providing an intuitive, at a glance interface that enables patients to engage with their monitoring. The next step should be to refine the visualization for small screens, develop a software prototype compatible with common wearable devices, and evaluate its impact in a clinical study using patients' data.

Acknowledgments

During the preparation of this work, the authors used GPT 3.5 and 4.0 (OpenAI) [42] and DeepL (DeepL SE) [43] to improve the linguistic quality of the manuscript. After using these tools and services, the authors reviewed and edited the content as needed and take full responsibility for the content of the published manuscript.

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Data Availability

The datasets generated or analyzed during this study are available from the corresponding author on reasonable request.

Authors' Contributions

Conceptualization: JK, ME, DWT, TRR
Data collection: JK, CAH, AR, GM, AD, FP, FJR, KZ, DWT, TRR
Formal analysis: ME
Investigation: JK, ME, DWT, TRR
Methodology: JK, ME, TRR
Project administration: DWT
Resources: DWT, KZ
Software (technology development, Visual Patient Wearable): JK, DWT, TRR
Supervision: DWT (University Hospital Zurich), KZ (University Hospital Frankfurt), GM (University Hospital Bonn), TRR
Visualization: ME
Writing – original draft: ME, TRR
Writing – review and editing: (all authors) JK, ME, DWT, CAH, AR, AD, FP, FJR, KZ, GM, TRR

Conflicts of Interest

TRR is an inventor of Visual Patient Predictive and Visual Blood, with intellectual property held by the University of Zurich and Philips. TRR receives research funding, honoraria, and travel support through joint development and licensing agreements with Philips. ME and CAH are registered inventors of Visual Patient Heart. DWT is an inventor of Visual Patient, Visual Patient Predictive, Visual Blood, Visual Clot, Visual Hemofilter, and Visual Patient Heart, with intellectual property held by Philips and the University of Zurich. DWT receives research funding, honoraria, royalties, and travel support through joint development and licensing agreements. Instrumentation Laboratory-Werfen, the Swiss Foundation for Anesthesia Research, and the International Symposium on Intensive Care and Emergency Medicine have provided additional honoraria and travel support. DWT serves on the Philips Patient Safety Advisory Board. All other authors declare no other conflicts of interest. Philips provided no funding for the development of the Visual Patient Wearable and had no role in this study’s design, conduct, or reporting.

Multimedia Appendix 1
Study flowchart and additional figures illustrating the study outcomes.
[DOCX File , 538 KB - formative_v10i1e84130_app1.docx]

Multimedia Appendix 2
Standardized training video for the Visual Patient Wearable.
[MP4 File (MP4 Video), 143160 KB - formative_v10i1e84130_app2.mp4]

Multimedia Appendix 3
Standardized training video for conventional monitoring.
[MP4 File (MP4 Video), 70762 KB - formative_v10i1e84130_app3.mp4]

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Abbreviations

CONSORT: Consolidated Standards of Reporting Trials
SpO2: oxygen saturation
STROBE: Strengthening the Reporting of Observational Studies in Epidemiology

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Original Paper

Strategic Governance of Artificial Intelligence–Enabled Clinical Algorithm Development: Formative Evaluation of the Semiautomatic Clinical Algorithm Development Framework

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Abstract

Background: Health care leaders face a strategic dilemma: traditional expert-led content development ensures safety but is too slow for digital innovation, whereas artificial intelligence (AI) automation offers speed but introduces risks from hallucinations. Resolving this tension requires governance frameworks that balance operational efficiency with rigorous accountability for patient safety.

Objective: This study describes the development process and conducts a formative evaluation of the Semiautomatic Clinical Algorithm Development (S-ACAD) framework as an industry-driven implementation strategy. We aimed to assess the feasibility of this "human-in-the-loop" governance model in balancing the need for operational efficiency with the rigorous safety standards required for pediatric emergency guidance.

Methods: We conducted a prospective, single-day proof-of-concept case study focusing on pediatric febrile seizures. A single physician expert executed a 4-phase workflow: (1) parallel data collection using multiple AI agents, (2) AI-assisted synthesis, (3) iterative refinement via "AI sparring," and (4) final clinical validation. The resulting algorithm was reviewed by 2 independent external pediatric specialists. We benchmarked this process against a fully automated system (Fully Autonomous Clinical Algorithm Development [F-ACAD]) to illustrate comparative efficiency and safety trade-offs.

Results: In this single execution, the S-ACAD framework produced a parent-actionable febrile seizure algorithm in approximately 245 minutes. Two independent pediatric specialists (N=2) reviewed the output and did not identify medically inaccurate sections or critical safety errors requiring mandatory correction, and both rated overall clinical validity highly (9.0 and 9.5 out of 10). During the workflow, 19 human expert interventions were recorded, with clinical judgment (n=8, 42.1%) and safety review (n=5, 26.3%) as the most frequent categories in an exploratory post hoc analysis. By comparison, the fully automated approach (F-ACAD) completed the task in approximately 68 minutes, but its own AI critics identified 17 issues (9 high-priority), including concerns related to emergency response clarity and standard-of-care alignment.

Conclusions: These preliminary findings suggest that the S-ACAD framework may offer a potential pathway for "active governance" in AI-assisted clinical content development. In this proof-of-concept case, the framework combined rapid AI-assisted drafting with continuous expert oversight and independent clinical review, suggesting the potential to reduce turnaround time while maintaining safety safeguards. However, these results are based on a single expert applying the workflow to a single clinical topic, and validation across multiple experts, topics, and institutional contexts is needed before generalizability can be established.

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KEYWORDS

AI-enabled uncertainty; strategic governance; digital health management; health care leadership; human-in-the-loop; organizational implementation; clinical algorithm development; human-AI collaboration; decision-making frameworks; learning health systems

Introduction

Digital health organizations face a strategic paradox when deploying artificial intelligence (AI) for clinical content development. Traditional expert-led methods protect clinical safety, but they can take weeks to months, creating a knowledge translation gap that delays updated guidance [1,2]. AI can synthesize quickly, yet hallucinations can produce plausible but medically inaccurate advice, creating unacceptable liability for leaders accountable for patient safety [3,4]. Managing this speed-safety trade-off has become a core executive challenge. Recent evidence suggests that successful AI transformation requires multidimensional leadership that balances technological opportunities with stakeholder needs [5]. The emergence of multiagent AI systems and autonomous workflows has further intensified this challenge, as organizations must now govern not just individual AI tools but also complex, interacting systems of AI agents [6,7]. This study addresses strategic decision-making under AI-related uncertainty and introduces an actionable governance workflow for health care leaders.

This strategic dilemma is particularly acute in high-stakes clinical scenarios. Consider pediatric febrile seizures—the most common convulsive disorder in childhood, affecting 2%-5% of children between ages 6 months and 5 years [8-10]. Although most febrile seizures are benign and do not cause long-term neurological sequelae [11,12], witnessing one's child suddenly lose consciousness, stiffen, and tremble is a shocking experience that causes extreme anxiety and fear for parents. In such a high-stress situation, parents need an answer to 1 urgent question: "What do I do right now?"

While professional clinical practice guidelines from organizations such as the American Academy of Pediatrics (AAP) and the National Institute for Health and Care Excellence (NICE) exist [12,13], they are designed for clinicians and do not directly provide actionable guidance for a layperson in a crisis. For instance, a guideline might state, "consider neurodiagnostic evaluation for a child with a complex febrile seizure." What a parent needs is "clinical guidance": clear, actionable instructions such as "call 911 immediately if the seizure lasts longer than 15 minutes" or "lay the child on their side." This gap between expert knowledge and parent-actionable guidance represents a critical challenge in pediatric emergency care.

The traditional process of translating complex medical guidelines into simple, actionable algorithms is resource-intensive, typically requiring multidisciplinary teams working over several weeks to months [14,15]. This knowledge translation bottleneck delays the delivery of potentially life-saving information to families who need it most. As medical evidence evolves, these manually developed materials can quickly become outdated, creating a perpetual cycle of revisions. Recent analyses of clinical practice guideline development timelines have confirmed that the process often takes between 1 and 3 years from conceptualization to publication [16].

Recent advances in large language models (LLMs) have demonstrated significant potential for accelerating medical knowledge synthesis [17]. Their direct application in creating clinical guidance, however, faces a critical challenge: the risk of "hallucination," where an AI confidently generates plausible but medically inaccurate information [3]. Recent studies document hallucination rates of 1.47% in AI-generated clinical notes, with 44% of these constituting major errors affecting diagnosis or management [18]. While this rate may appear low, in the context of high-stakes pediatric emergencies, where zero tolerance for error is required, even a single such error could have life-threatening consequences. For that reason, deterministic, rule-based algorithms with clear evidence traceability remain essential for ensuring safety [3]. Several recent frameworks have proposed structured approaches to evaluating and mitigating AI-generated clinical content risks, emphasizing the need for systematic human oversight rather than post hoc review [19,20].

For digital health leaders, hallucination risk translates into organizational uncertainty and a critical barrier to adoption. The challenge is strategic: harness AI's speed without outsourcing accountability for patient safety.

This study describes the development process and formatively evaluates Semiautomatic Clinical Algorithm Development (S-ACAD), an organizational governance framework that positions continuous human oversight as the core management strategy for navigating AI-enabled uncertainty. S-ACAD leverages AI for rapid data collection and synthesis, freeing the expert to focus on high-stakes clinical validation and safety assurance. To explore the feasibility of this approach and make the speed-safety trade-offs explicit, we prospectively applied S-ACAD to pediatric febrile seizures and benchmarked it against a fully automated variant (Fully Autonomous Clinical Algorithm Development [F-ACAD]), providing leaders with preliminary evidence for this strategic choice.

Methods

Study Design and Data Sources

This prospective, single-day case study was conducted on July 25, 2025, to execute and document the S-ACAD workflow for developing pediatric febrile seizure guidance (Figure 1). The entire process was designed to be transparent and reproducible, with all artifacts documented in Multimedia Appendices 1-8. This study was informed by the SQUIRE 2.0 (Standards for Quality Improvement Reporting Excellence) reporting guidelines [21], adapted for the formative evaluation of a health care quality improvement workflow (Multimedia Appendix 9).

Data were collected using the "deep research" modes of Gemini 2.5 Pro (Google LLC; accessed July 25, 2025), ChatGPT (model o3; OpenAI; accessed July 25, 2025), Perplexity Pro (Perplexity

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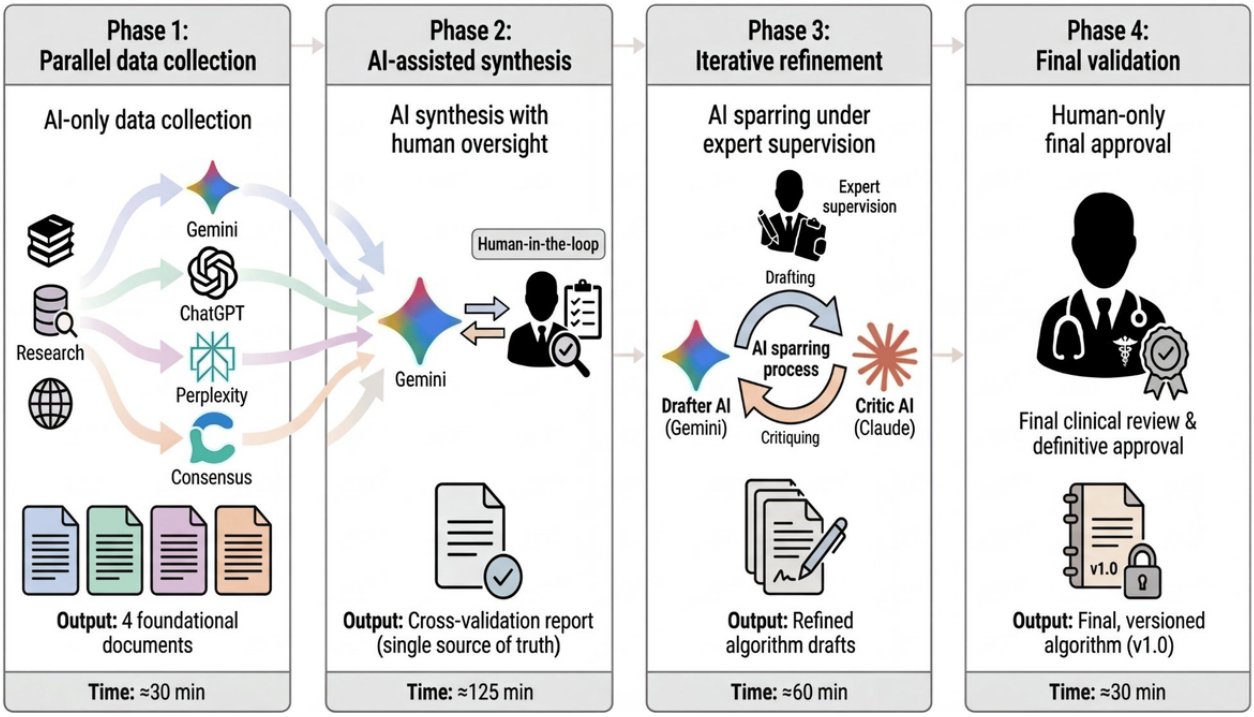
AI, Inc; accessed July 25, 2025), and Consensus (Consensus; accessed July 25, 2025). The critical review in phase 3 was performed in the "deep thinking" mode of Claude Opus 4 (Anthropic PBC; accessed July 25, 2025). All AI systems were accessed via subscription-based web interfaces with default configurations on the specified date.

Figure 1. Overview of the Semiautomatic Clinical Algorithm Development framework workflow. AI: artificial intelligence.



Phase 1: Parallel Foundation Data Collection Using Multiple AIs

To rapidly build a comprehensive and multifaceted information base on pediatric febrile seizures, 4 AI services with different strengths were used in parallel. This strategy was designed to compensate for the potential biases of a single AI model and to secure both the breadth and depth of information simultaneously. To maximize the capabilities of each AI model, customized prompts were designed. The prompts were standardized to include the following elements: a clear role definition (eg, "You are a medical information specialist..."), specification of a concrete output format, key information categories to be included, and a request to specify the level of evidence. Detailed prompts are provided in Multimedia Appendix 1. These 4 services were specifically chosen for their distinct strengths: Gemini and ChatGPT for generating comprehensive foundational text; Perplexity for its focus on citing recent academic literature and guidelines; and Consensus for its ability to extract findings from systematic reviews. Conceptually, this parallel, multimodel querying aligns with the "LLM Council" practice—posing the same prompt to multiple LLMs and comparing their outputs—to surface disagreement early and reduce single-model bias [22].

Phase 2: Expert-Led, AI-Assisted Cross-Validation

The role of the "human expert" throughout the S-ACAD workflow was performed by the first author (SHA), a board-certified physician with more than 10 years of clinical and medical informatics experience. It is important to acknowledge that SHA is also the originator of the S-ACAD methodology, which introduces the potential for researcher bias. This limitation is further discussed in the "Discussion" and "Conflicts of Interest" sections.

The expert-led cross-validation process began with the human expert conducting a primary review of the 4 AI-generated outputs from phase 1 to check for clinical appropriateness and obvious errors. Subsequently, all 4 documents were fed into an LLM (Gemini), which was instructed to automatically identify points of consensus, conflict, and unique information among the sources and to assign reliability tags, generating a "Cross-Validation Synthesis Report." This report served as the *single source of truth* in the subsequent phases.

Phase 3: AI-Human Collaborative Algorithm Generation and Refinement

An initial draft of the algorithm was developed through a cyclical refinement process of "AI generation → AI critique → human revision." A draft was generated in a decision-tree format by inputting the 5 documents created up to phase 2 into the Gemini model. The resulting draft was then presented to a second AI model (Claude), known for its strengths in critical analysis, to generate a "critical review report" that identified logical flaws, user experience (UX) issues, and missing scenarios (AI sparring). In S-ACAD, we operationalize this idea as a structured drafter-critic pattern (Gemini as drafter; Claude as critic), with the licensed clinician retaining final accountability as the human-in-the-loop. This reframes multimodel comparison as an internal governance control rather than an ad hoc model ensemble. This approach was designed not only to compensate for the potential biases of a single AI model, but also to serve as an internal quality-assurance

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mechanism that challenges the human expert's assumptions. The critique was then fed back into Gemini, and during this process, the human expert served as the "human-in-the-loop," making final clinical judgments, directly revising safety-related content, and adjusting prompts to iteratively refine the algorithm. Claude was selected for the critic role because of its recognized strengths in nuanced reasoning and critical analysis, providing a robust challenge to the initial draft generated by Gemini.

Phase 4: Final Expert Review

The human expert conducted a final review of the algorithm draft completed in phase 3, verifying the accuracy of all decision pathways, action guidelines, and evidence-level notations, and approved the content as clinically reasonable and safe for parent-facing use, finalizing version 1.0.

Data Collection and Metrics

By the prospective study design, the following metrics were recorded in real time: time spent on each phase (in minutes), number of AI prompt iterations (AI calls), number and type of human expert interventions, volume of information generated (word count and number of references), and time spent resolving information conflicts. Human expert interventions were logged in real time. Following the experiment, these 19 interventions were retrospectively coded and categorized by the first author (SHA) into 4 predefined categories: (1) clinical judgment (modifying medical logic or content), (2) safety review (adding warnings or conservative pathways), (3) UX optimization (improving clarity or simplicity for the parent user), and (4) prompt adjustment (refining instructions to the AI). The authors acknowledge that retrospective coding by the originator of the methodology, without independent verification (eg, interrater reliability [IRR] assessment), is a limitation and carries a significant risk of interpretation bias. The resulting distribution of intervention types (see panel B in Multimedia Appendix 10) should therefore be interpreted as an exploratory descriptive analysis rather than validated measurements. However, given the complex medical reasoning required to distinguish between categories such as clinical judgment (eg, resolving conflicting evidence) and safety review, expert clinician involvement was deemed essential for accurate categorization.

Independent Expert Review

Following completion of the algorithm (version 1.0), we commissioned an independent expert review to assess its clinical validity, safety, and completeness. The algorithm was sent for review to 2 board-certified pediatric specialists who were not involved in the study: 1 primary care pediatrician and 1 pediatric emergency medicine physician. These 2 specialties were deliberately chosen to ensure that the algorithm was evaluated from both a primary care perspective (representing routine management and parent education) and an emergency medicine perspective (representing acute, high-stakes situations). A structured survey instrument was used for the review. The instrument included quantitative assessments on a 5-point Likert scale across 4 domains (clinical accuracy, completeness, safety, and usability for parents), as well as qualitative feedback sections for in-depth comments. Reviewers' identities were known to the author for the purpose of solicitation; however, all ratings and comments were deidentified before analysis and reporting, and no personal identifiers are presented in the manuscript or its multimedia appendices. The primary objective of this review was not statistical generalization but to obtain in-depth qualitative insights and assess whether any critical safety errors requiring mandatory correction were present.

Comparative Analysis With a Fully Automated Approach

Following S-ACAD completion, an identical task was performed using F-ACAD via Genspark's multiagent system. It is important to note that F-ACAD represents an experimental baseline configuration constructed on a specific platform to illustrate the risks of ungoverned automation, rather than a definitive representation of all fully automated approaches. The system autonomously deployed 14 specialized AI agents for data collection, validation, algorithm generation, and refinement, without human intervention beyond the initial task specification. The same clinical objective and scope were provided to ensure a fair comparison. Metrics collected included total time, number of agents deployed, sources reviewed, and critical issues identified by the system's own AI critics.

AI Model Parameters and Reproducibility

All AI interactions used subscription-based web interfaces with default configurations, as these platforms do not offer user-controllable sampling parameters (eg, temperature and top-p). No random seeds were set, limiting exact output replication. As these interfaces do not provide persistent build identifiers, we report model names and access dates rather than internal version numbers. However, the workflow structure and human intervention patterns remain reproducible. Hardware specifications are not applicable because all computations occurred on cloud-based services. Complete prompts, outputs, and development logs are provided in Multimedia Appendices 1-4 to support methodological transparency. Given the rapid evolution of AI models, the specific model versions used in this July 2025 study may perform differently or be unavailable in the future. Future applications of S-ACAD should document exact model versions and reevaluate model selection accordingly.

Generative AI Disclosure

In accordance with JMIR's policy on generative AI use, we disclose that multiple LLMs were used as integral components of the S-ACAD methodology under evaluation. Specifically, Gemini 2.5 Pro was used for cross-validation synthesis and primary algorithm drafting; ChatGPT (model o3) contributed to foundational data collection during phase 1; Perplexity Pro and Consensus supported literature synthesis; and Claude Opus 4 performed critical review (AI sparring).

To ensure scientific rigor and accountability, human oversight was strictly enforced at every stage (Textbox 1).

Complete prompts and AI-generated outputs are provided in Multimedia Appendices 1-4 to support methodological transparency.

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Textbox 1. Application of artificial intelligence in this study.

1. Research design and experimental protocols

The study design, that is, the Semiautomatic Clinical Algorithm Development (S-ACAD) framework architecture, and all experimental protocols were conceived and developed entirely by the human authors without artificial intelligence (AI) assistance. The AI tools were used solely as functional agents to execute these human-defined protocols.

2. Data collection and literature synthesis

AI agents performed data retrieval and summarization based on strict, predefined prompts designed by the human expert (see Multimedia Appendix 1). All retrieved sources and synthesized findings were verified against the original documents by the human author (phase 2).

3. Text generation and algorithm drafting

While AI models generated the initial text drafts and decision tree structures, every decision node was subject to human review. The human expert retained full editorial control, directly revising safety-critical content and finalizing the algorithm (phases 3 and 4).

4. Manuscript preparation

Generative AI tools assisted with manuscript drafting and English-language editing. However, all AI-assisted content was reviewed, verified, and finalized by the human author, who takes full responsibility for the final manuscript.

Ethical Considerations

This study did not involve patients or patient-level data and used only publicly available medical information for algorithm drafting. To ensure methodological rigor and establish content validity, the algorithm underwent cross-verification by 2 external physicians. No sensitive personal data were collected for research purposes, and reviewer feedback was deidentified before analysis and reporting. Given the absence of patient data and the minimal-risk nature of deidentified expert feedback, formal institutional review board review was not sought. Any future deployment of the algorithm would require appropriate institutional review and regulatory oversight to ensure patient safety.

Results

Overview

For decision makers, 3 findings stand out: (1) the workflow's time profile and where effort concentrates, (2) where human oversight remained nonnegotiable, and (3) what happens when automation is left unguided. The detailed workflow metrics are described below.

Quantitative Results

The S-ACAD framework was completed in approximately 245 minutes (4 hours and 5 minutes) in a single end-to-end execution, during which 8 AI calls and 19 distinct human interventions were recorded. Table 1 summarizes the phase-level resource use. These time values should be interpreted as single-run operational estimates from 1 complete execution by 1 expert, intended to characterize where effort concentrates across phases rather than as generalizable performance benchmarks. The outcome is inherently dependent on the specific expert's clinical experience and familiarity with AI tools, as well as the performance characteristics of the AI models used at the time of execution. Notably, phase 2 (cross-validation) accounted for the largest share of time (approximately 125 minutes), highlighting that expert validation and reconciliation of multisource AI output—rather than raw drafting—was the dominant workload in this case. This finding underscores the importance and complexity of synthesizing the vast amount of information generated by multiple AIs through a single AI and having a human expert carefully review and validate the results. By contrast, phase 3 (algorithm generation) had the most human interventions (7 instances), indicating intensive collaboration in which the expert refined the logic and enhanced the safety of the AI-generated draft.

In this representative execution of the workflow, each AI model demonstrated distinct strengths and played a complementary role (Table 2). The web-search–based Perplexity cited the most recent literature with 147 references, making a significant contribution to ensuring the timeliness of the evidence. Gemini generated the most words (n=8420), showing strength in systematically structuring information, while ChatGPT provided a comprehensive overview summarizing the key content. This suggests that a strategy of using multiple AIs in parallel may be effective for securing the quantity, quality, and timeliness of information simultaneously.

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Table 1. Time and resource consumption by the S-ACAD[a] workflow phase.[b]

Phase	Time (single-run estimate), minutes	Number of artificial intelligence calls, n	Number of human interventions, n
Phase 1: data collection	≈30	4	4
Phase 2: cross-validation	≈125	1	3
Phase 3: algorithm development	≈60	3	7
Phase 4: final review	≈30	0	5
Total	≈245	8	19

[a]S-ACAD: Semiautomatic Clinical Algorithm Development.

[b]Time values are approximate single-run estimates recorded during 1 complete execution of the S-ACAD framework (July 25, 2025). They are reported to describe the relative workflow burden across phases, not to provide generalizable duration benchmarks. A different expert or clinical topic may yield different time profiles.

Table 2. Quantitative characteristics of information generated by each artificial intelligence model in phase 1 (data collection).[a]

Artificial intelligence model	Generated word count, n	Number of cited references, n	Primary contribution
Gemini	8420	81	Structured information
ChatGPT	6890	25	Comprehensive overview
Perplexity	4250	147	Latest guidelines
Consensus	7100	50	Academic evidence

[a]The generated word count was calculated based on the body text of each artificial intelligence's output. The number of cited references was verified and corrected based on the initial development log and the unique sources specified in each artificial intelligence's output.

Algorithm Structure and Characteristics

The final developed algorithm is a rule-based decision tree that operates on personalized information and is easy for caregivers to follow. The algorithm's flow begins at node 0, where the user's initial information (eg, child's age, medical history) is entered, and then guides the user through 6 core decision nodes (nodes 1-6; Figure 2). This structure logically progresses from immediately identifying an emergency situation, to managing the seizure as it occurs, to observing after the seizure, and finally to determining the appropriate level of hospital visit required.

The main features of the algorithm are as follows: a total of 6 main decision nodes (excluding initial screening); 23 specific action guidelines; 12 red flag warnings; and pathways optimized to reach a final action within an average of 3-5 steps.

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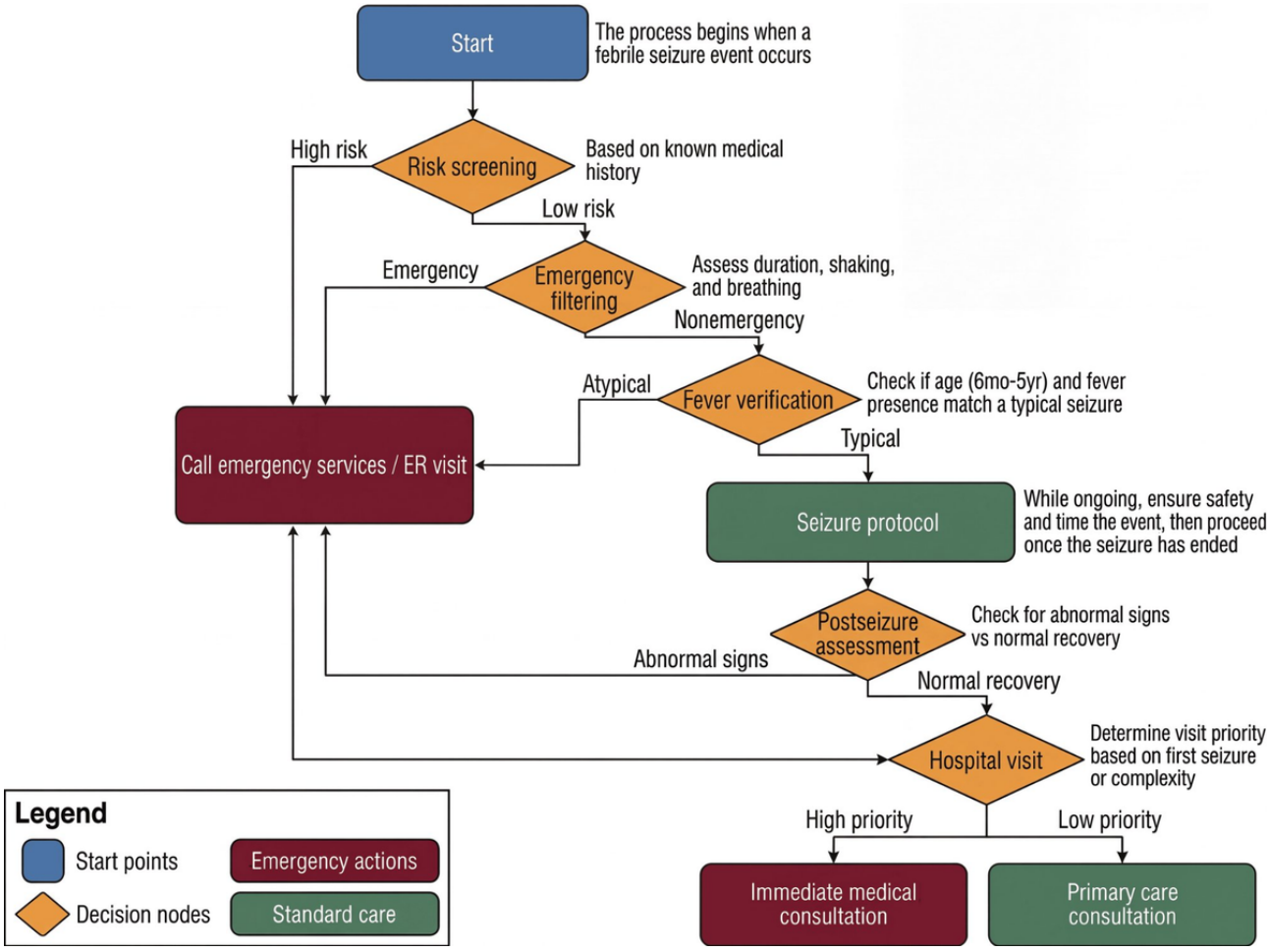
Figure 2. Simplified clinical decision flowchart of the febrile seizure guidance algorithm (version 1.0) developed using the Semiautomatic Clinical Algorithm Development framework. The flowchart guides caregivers through 6 core decision nodes, from initial risk screening to determining the appropriate level of hospital visit. ER: emergency room.



Evidence Tagging Analysis

To ensure the reliability of the algorithm, all 23 action guidelines were tagged with their level of evidence. The analysis confirmed that 18 (78%) guidelines were based on a "high consensus level (A)," which is consistently recommended across multiple guidelines (Table 3). This indicates that the core content of the algorithm is based on robust medical consensus. There were 4 guidelines (17%) with a "medium consensus level (B)" and 1 (4%) with a "conservative recommendation (C)," which represented a case where the expert made a direct judgment to recommend the safest course of action when evidence was insufficient or conflicting. This transparent evidence labeling not only increases the algorithm's reliability but also helps clearly identify areas for modification when evidence is updated in the future.

Table 3. Distribution of evidence levels within the algorithm.

Level of evidence	Values, n (%)
A (high consensus)	18 (78)
B (medium consensus)	4 (17)
C (conservative recommendation)	1 (4)

AI Sparring Effectiveness Analysis

The AI sparring phase, a core component of phase 3, appeared to contribute to improving the draft's quality in this single-case execution. The Claude model, tasked with critical review, identified a total of 16 improvement suggestions for the draft generated by Gemini. Of these, 14 (88%) were adopted into the final algorithm after expert review. The specific improvement suggestions included the following: logic gaps (3, all adopted); UX improvement suggestions (7, 5 adopted); missing scenarios (4, all adopted); and safety enhancements (2, all adopted). These results suggest that AI sparring may serve as a valuable internal quality-assurance mechanism, extending beyond simple error detection to support the algorithm's completeness, user-friendliness, and safety.

Analysis of Human Interventions

The descriptive analysis of the 19 human interventions, as categorized retrospectively by the first author (SHA), indicated that clinical judgment (8/19, 42%) and safety review (5/19,

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26%) were the most frequent types of input (see panel B in Multimedia Appendix 10). UX optimization accounted for 3 out of 19 (16%) and prompt adjustment for 2 out of 19 (11%). Although these findings are specific to a single case study and are subject to potential interpretation bias due to the lack of independent coding verification (see the "Limitations" section), they highlight the areas in which expert oversight appeared to concentrate during the workflow. Future multiexpert studies with IRR assessment will be necessary to validate these exploratory categorizations.

Expert Review Results

Independent Specialist Validation

The final algorithm underwent a formal review by 2 independent, board-certified pediatric specialists—a pediatric emergency physician (reviewer A) and a primary care pediatrician (reviewer B)—both with 15 years of clinical experience.

Safety Review

Crucially, neither reviewer independently identified medically inaccurate sections or critical safety errors requiring mandatory correction. This review served as a vital safety check against potential oversights by the single developer.

Qualitative Feedback

The qualitative feedback strongly supported the algorithm's utility (Multimedia Appendix 7). Reviewer A (emergency physician) stated that the algorithm's greatest strength was that "it provides comprehensive and accurate guidance...especially for situations requiring attention." Reviewer B (primary care pediatrician) noted that it "allows caregivers to respond safely at home...which can provide reassurance." Both rated the algorithm as "much better" than existing educational materials and recommended it as "usable after minor revisions" for a parent-facing service, pending successful usability testing.

Quantitative Overview

Although not intended for statistical generalization, given the small sample size (N=2), quantitative assessments were also conducted (Multimedia Appendix 6). Both reviewers strongly agreed (providing the highest possible rating) on all items within the clinical accuracy and safety domains. Although ratings for completeness and usability were generally high, reviewer A noted a concern regarding the "practical executability" of certain guidelines under stress (scoring 3/5 on item 4-2). Overall, the reviewers assigned high ratings for the algorithm's clinical validity (9.0/10 and 9.5/10 by reviewers A and B, respectively). Full raw data are available in Multimedia Appendix 8.

Comparative Analysis: S-ACAD Versus F-ACAD

The F-ACAD system, powered by the Genspark Super Agent, completed the entire algorithm development task in 67 minutes and 58 seconds—approximately 3.6 times faster than S-ACAD's 245 minutes. However, this substantial reduction in time was accompanied by notable quality trade-offs. Table 4 summarizes the key differences between the 2 approaches.

Although F-ACAD reviewed more sources and produced a more complex algorithm, its own AI critics identified 17 issues requiring correction, including 9 high-priority concerns related to US standard-of-care compliance, emergency-response clarity, and parent-friendly communication. These were precisely the areas in which S-ACAD's 19 human interventions appeared most relevant.

To directly compare the shortcomings of the fully automated approach with the contributions of the human expert, the 17 issues identified by F-ACAD's critics were mapped to the categories of the 19 human interventions performed in S-ACAD. The analysis suggests a correspondence between F-ACAD's weaknesses and the areas in which human clinical judgment and safety oversight were most needed (Table 5).

Table 4. Comparison of S-ACAD[a] and F-ACAD[b] approaches.

Characteristic	S-ACAD	F-ACAD
Total time (minutes)	≈245	≈68
Human interventions, n	19	1 (initial task specification only)
AI[c] calls/agents, n	8 AI calls	14 autonomous agents
Sources reviewed, n	18	25
Algorithm nodes, n	22	25
Critical issues identified, n	N/A[d] (addressed by human in-process)	17 (9 high and 8 medium)

[a]S-ACAD: Semiautomatic Clinical Algorithm Development.

[b]F-ACAD: Fully Autonomous Clinical Algorithm Development.

[c]AI: artificial intelligence.

[d]N/A: not applicable.

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Table 5. Mapping of high-priority issues in F-ACAD[a] to human intervention types in S-ACAD[b].

F-ACAD high-priority issue category	Example issue identified by F-ACAD critics	Corresponding human intervention type in S-ACAD
Clinical accuracy	Inadequate differentiation between emergency room and primary care physician visits	Clinical judgment (8/19, 42%)
Safety and emergency response	Inconsistent emergency response timing (3-5-minute ambiguity)	Safety review (5/19, 26%)
Parent-centric communication	Complex medical terminology without lay explanations	User experience optimization (3/19, 16%)
Logical completeness	Missing age-specific nuances for children <12 months	Clinical judgment (8/19, 42%)

[a]F-ACAD: Fully Autonomous Clinical Algorithm Development.

[b]S-ACAD: Semiautomatic Clinical Algorithm Development.

Discussion

Summary of Findings

This proof-of-concept study set out to describe and formatively evaluate the S-ACAD framework as a governance approach for AI-assisted clinical algorithm development. The primary objectives were to assess the feasibility of the "Human-in-the-Loop" model and to explore the speed-safety trade-off relative to full automation. In this single-case execution, the S-ACAD framework produced a parent-actionable febrile seizure algorithm in approximately 245 minutes. Two independent pediatric specialists did not identify critical safety errors requiring mandatory correction, and both recommended the algorithm as usable with minor revisions. The fully automated comparator (F-ACAD), although approximately 3.6 times faster, generated 17 issues (9 high priority) that overlapped with the categories in which human oversight was concentrated in S-ACAD. These findings, although preliminary and specific to this single case, suggest that continuous expert governance may help mitigate the safety risks associated with fully automated approaches.

Interpretation and Implications

Active Governance as a Management Strategy for Navigating AI-Enabled Uncertainty

A central challenge for digital health leadership is managing AI-enabled uncertainty. S-ACAD addresses this challenge by redefining the human-in-the-loop. Rather than serving merely as a passive final reviewer, the human expert engages in "active governance"—directing the AI, applying critical clinical judgment, and enforcing ethical oversight and safety throughout the development lifecycle. In this study, the 19 documented interventions (see the "Analysis of Human Interventions" section and Multimedia Appendix 10) illustrate what this governance looked like in practice and appear to map to the safety and nuance failures observed under full automation (F-ACAD).

The exploratory analysis of the 19 human interventions, as categorized by the first author, indicated that clinical judgment (8/19, 42%) and safety review (5/19, 26%) constituted the majority of interventions (see panel B in Multimedia Appendix 10). Although this categorization requires independent validation, it suggests that AI may currently lack the nuanced understanding of clinical context, ethical considerations, and patient safety required for reliable guidance [17]. S-ACAD leverages this dynamic, elevating the expert from a data collector to an augmented "clinical strategist" and "safety guarantor."

A critical example illustrates the potential importance of this governance. In phase 3, the AI initially generated a protocol allowing parents to directly administer prescribed emergency medication (eg, diazepam) if a seizure lasted more than 5 minutes. The human expert intervened to modify this pathway, mandating that parents call 911 for real-time instructions before administration (Multimedia Appendix 4). This intervention, driven by considerations of liability, situational stress, and the need for professional guidance during medication use, exemplifies a safety-critical judgment that the automated system failed to make.

Other key interventions included providing nuanced guidance on antipyretics based on conflicting evidence [23,24] and adding specific pathways for atypical presentations (eg, first seizure over age 5). These examples suggest that human-in-the-loop may be essential for mitigating AI limitations, managing uncertainty, and ensuring that the final product is clinically sound and safe. The quantitative impact of such oversight is supported by recent literature: a controlled study reported that diagnostic accuracy among the best-performing clinicians decreased when AI advice was introduced (from 87.3% to 77.1%), highlighting how AI-related "false conflict" can negatively affect expert performance and underscoring the need for structured human oversight [25]. This provides external context for the potential value of S-ACAD's human interventions.

Efficiency Considerations

In this proof-of-concept case, S-ACAD produced a clinically reviewed draft in just over 4 hours. Relative to published descriptions of traditional manual synthesis timelines—often reported in weeks and involving 60-200 person-hours of multidisciplinary team effort [14,15]—this suggests the potential for a reduction in turnaround time, although the magnitude remains illustrative in the absence of a concurrent traditional control. As we did not conduct a parallel traditional control process on the same topic, the magnitude of any efficiency gain should be interpreted as illustrative rather than definitive. The 245-minute figure reflects a single execution by 1 expert, who

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was also the methodology's originator and therefore had extensive familiarity with the workflow; a different expert or a different clinical topic might require more or less time.

A potential strategic advantage of S-ACAD is its capacity to support "perpetual updates" of clinical guidance. In the current evidence ecosystem, there is often a substantial lag between the publication of new evidence and its incorporation into patient-facing materials—the knowledge translation gap [14]. If the efficiency observed in this case generalizes to other contexts, S-ACAD's accelerated timeline could help reduce this gap, keeping guidance aligned with the latest evidence and strengthening patient safety. This capability also aligns with learning health systems, in which the continuous integration of new evidence into clinical practice is a core operational principle [26].

The efficiency gains appear to arise from restructuring the development workflow. Traditional methods are often slowed by sequential reviews and delayed committee consensus. S-ACAD uses parallel AI processing and "AI sparring" (phase 3) to convert a linear peer-review cycle into rapid iteration, potentially reducing waiting times associated with sequential review cycles.

Notably, the AI-assisted synthesis phase took the longest (125 minutes), reflecting the intensive work required for expert validation of AI-generated sources. This finding underscores a critical distinction: S-ACAD may improve efficiency not by removing the human expert, but by reallocating effort away from laborious data collection and toward high-value validation and synthesis. This "cognitive reallocation" may represent the methodology's core strategic advantage. For digital health management, it suggests a potential talent realignment in which expert roles shift from routine data collection to high-stakes validation and governance. Although this expert validation remains the rate-limiting step, it is also the methodology's most critical safety feature.

Generalizability of the Methodology

The core elements of the S-ACAD framework show potential applicability, particularly in clinical areas in which clear guidelines exist [13,27], logical expression in a decision tree is feasible, and the level of evidence is well established. This makes the methodology potentially suitable for developing parent-actionable guidance for acute pediatric emergencies commonly encountered at home, extending well beyond febrile seizures.

For example, other acute pediatric conditions with well-defined clinical guidelines and clear decision logic—such as anaphylaxis management or minor head injury triage—may be amenable to this workflow, although this remains to be empirically tested.

By contrast, there are areas in which the application of this methodology may face significant challenges. For topics involving rapidly advancing treatments or emerging technologies, there may be a lack of consensus evidence, meaning that the data available for AI synthesis are themselves limited. Furthermore, in areas such as mental health, where cultural context and the therapeutic relationship are central, or in chronic disease management, where long-term lifestyle and personal preferences have substantial influence, it is difficult to create comprehensive guidance based solely on text-based evidence. In these contexts, S-ACAD should be used as an initial data-collection and structuring tool, but expert qualitative judgment and user-participation processes must be further strengthened. Consistently, agent benchmarks (eg, SWE-Bench Pro, GAIA) demonstrate sharp performance degradation as tasks require multistep reasoning, tool use, and cross-source synthesis—conditions intrinsic to clinical algorithm development [28,29].

Strategic Choice: Comparing Governance Models Across the Automation Spectrum

Strategic decision-making under AI-related uncertainty requires digital health leaders to select a governance model that balances efficiency and rigor. Our comparative analysis of 3 approaches—traditional (human-only), F-ACAD (AI-only), and S-ACAD (hybrid)—provides a preliminary decision framework to inform this management choice.

Traditional methods (human-only) prioritize rigor, involving extensive literature review and expert consensus. However, this approach is characterized by low efficiency, often taking weeks or months [13,14], which can lead to outdated guidance and delayed knowledge translation.

The fully automated approach (F-ACAD, AI-only) was fast, completing the task in approximately 68 minutes. However, that speed was accompanied by a clear governance gap. Although F-ACAD reviewed a larger volume of sources (25 vs 18 in S-ACAD), this recall-oriented capacity did not translate into clinical precision. The system generated 17 critical issues, including 9 high-priority concerns related to clinical safety, nuance, and communication (Table 5). Many of these issues overlapped with the areas in which human intervention was most frequent in S-ACAD, providing some triangulation for the identified intervention categories despite the limitation of single-researcher coding. This pattern is consistent with broader benchmarks suggesting that fully autonomous agents continue to struggle with end-to-end, real-world tasks; the Remote Labor Index [30] reported an autonomous completion rate of only 2.5% across 240 freelance tasks. Taken together, the 17 critical issues appear less like an isolated failure and more like a predictable consequence of generating patient-facing guidance without continuous human governance.

S-ACAD represents a deliberate strategic choice: a hybrid governance model that integrates AI for speed while embedding human expertise to manage uncertainty and ensure safety. For digital health leaders, this comparison clarifies the stakes: fully automated approaches (F-ACAD) offer speed but may introduce unacceptable clinical risk, whereas traditional approaches offer safety but may not keep pace with rapidly evolving evidence. These preliminary findings suggest that a redesigned workflow, in which human expertise is strategically allocated to governance and validation, may achieve both the efficiency required for the digital age and the rigor essential for patient care.

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Strategic Implications for Digital Health Management

Organizational Implementation Strategy

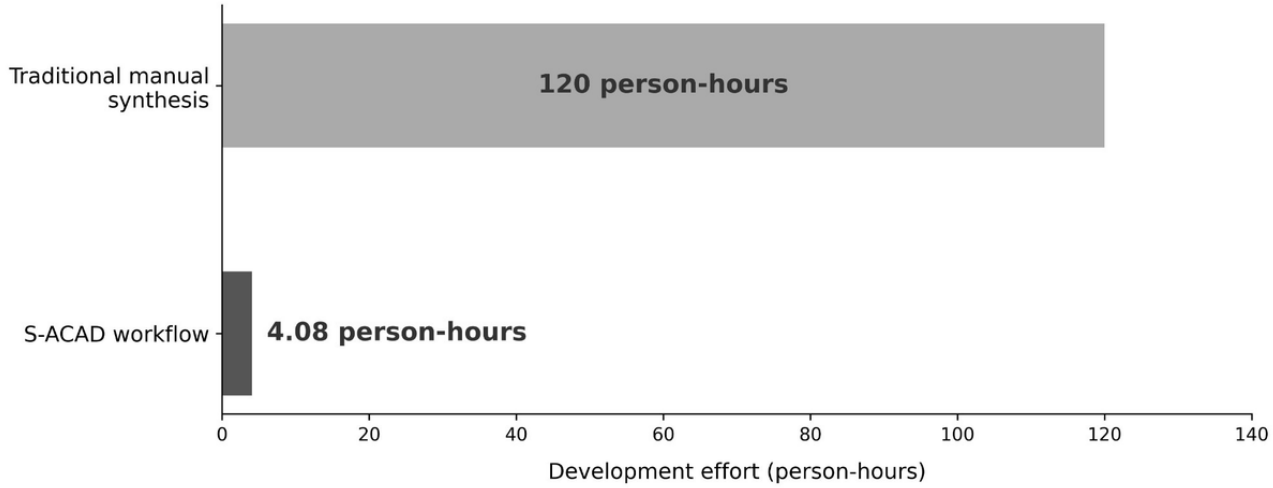
Adoption of S-ACAD requires strategic changes in workforce structure and resource allocation. Organizations implementing this framework should consider the following:

- Talent realignment: Shifting expert roles from routine data collection to high-stakes validation and governance.
- Infrastructure requirements: Ensuring access to multiple AI platforms, version-control systems, and transparent documentation workflows.
- Training and change management: Preparing clinical experts to direct AI rather than compete with it.
- Pilot implementation: Beginning with low-risk clinical topics before scaling to high-stakes applications.

Preliminary Resource and Implementation Considerations

Although this single-case study cannot provide a formal economic evaluation, the observed time profile offers an illustrative resource comparison (Figure 3). Traditional guideline translation typically requires multidisciplinary teams (2-5 clinical experts, medical writers, and editors) working 60-200 person-hours over several weeks [14,15], whereas S-ACAD in this case achieved same-day completion by a single expert in approximately 4 hours, alongside subscription access to multiple AI platforms. However, organizational resource implications would also depend on initial setup costs, AI subscription expenses, quality-assurance overhead, and long-term maintenance. Multisite implementation studies with prospective time tracking and cost accounting are needed to quantify the organizational value proposition across diverse institutional contexts.

Figure 3. Comparison of development effort between traditional manual synthesis (120 person-hours) and the Semiautomatic Clinical Algorithm Development (S-ACAD) workflow (4.08 person-hours). Traditional estimates are based on published literature [14,15]. S-ACAD time was empirically measured during a single execution. S-ACAD: Semiautomatic Clinical Algorithm Development.



Decision Framework for Leaders

Our case suggests 3 potentially "nondelegable" checkpoints: (1) evidence traceability before synthesis becomes a single source of truth; (2) safety-first review during decision-node generation; and (3) independent clinical review before deployment. In practice, leaders can separate "speed layers" (parallel collection and drafting) from "accountability layers" (validation, safety, and external review) to capture efficiency without transferring clinical risk to automation.

Anticipated Implementation Barriers

Despite its potential advantages, organizational adoption of S-ACAD may face several practical barriers:

- Clinical expert resistance: A traditional culture of slow, deliberative peer review may perceive S-ACAD's speed as "cutting corners."
- IT and infrastructure gaps: Adoption requires organizational access to multiple AI platforms and version-control systems.
- Regulatory and liability uncertainty: Although S-ACAD's human governance and transparent documentation are designed to mitigate risk, legal frameworks for AI-assisted content generation are still evolving.
- ROI measurement challenges: The primary benefits, such as closing the knowledge translation gap, are often intangible and more difficult to quantify than direct cost savings.

Beyond Accuracy: Practical Executability, Ethical Considerations, and the Need for User-Centered Design

The strategic implications of this work extend beyond development efficiency to implementation readiness. Although S-ACAD may produce clinically accurate guidance, accuracy alone is insufficient for real-world effectiveness. This mirrors the implementation gap widely reported in health care AI: many initiatives demonstrate high laboratory accuracy yet fail to scale beyond pilot settings in practice, often because of challenges related to usability, governance, and workflow integration [28]. By embedding governance considerations and workflow compatibility during development rather than addressing them post hoc, the S-ACAD framework represents a proposed strategy to mitigate these systemic risks.

A critical insight from the expert review highlights this challenge. Reviewer A questioned the feasibility of the "wait for 5 minutes" rule, noting that caregivers, under extreme stress, might be unable or unwilling to wait, regardless of the guideline

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(Multimedia Appendix 7). This observation underscores a gap that S-ACAD, as an evidence-synthesis methodology, cannot bridge on its own.

These findings confirm that S-ACAD is intended as a development tool, not a deployment solution. Even a clinically validated algorithm requires a rigorous subsequent phase of user-centered design—including usability testing with diverse caregivers, cultural adaptation, and attention to health literacy and equity considerations—before it can be responsibly deployed.

Limitations

Overview

This study, as a proof-of-concept, has several important limitations that should be considered when interpreting the results.

Single-Case Study Design

This is an "n-of-1" study: a single expert applied the workflow to a single clinical topic. The time profile reported here (approximately 245 minutes) reflects a single-run operational measurement from 1 complete execution by 1 expert and cannot characterize variability across topics, teams, or organizational settings. It is unclear whether this time represents a best-, average-, or worst-case scenario. The 245-minute figure may have been influenced by the expert's familiarity with the methodology (as its originator) and by the clinical topic's suitability for decision-tree structuring. Different experts—particularly those less familiar with AI tools or the S-ACAD workflow—might require substantially more time. Similarly, clinical topics with less clearly defined guidelines or more complex decision logic might yield different results. We therefore present the timing primarily to describe the relative distribution of effort across phases rather than to claim generalizable efficiency benchmarks. A more rigorous approach would involve multiple experts applying the workflow to multiple clinical topics to establish variability and generalizability.

Researcher Bias

A substantial potential for researcher bias exists, encompassing both execution bias (during development) and interpretation bias (during analysis). The first author (SHA) is both the originator of the S-ACAD methodology and the human expert who executed the workflow, which inevitably influenced workflow execution. The retrospective coding of the 19 human interventions (see panel B in Multimedia Appendix 10) was performed solely by SHA, without independent verification through IRR assessment. The resulting distribution of intervention types (eg, clinical judgment, 8/19, 42%, or safety review, 5/19, 26%) therefore reflects the first author's interpretation and may be influenced by confirmation bias. These proportions should be interpreted as exploratory rather than as objective measurements. This single-expert dependency also means that the final algorithm reflects both the S-ACAD framework and the expert's individual clinical judgments; a different expert might intervene differently, leading to different outputs and development timelines.

To partially mitigate these bias risks, 2 design features were intentionally embedded (Textbox 2).

Textbox 2. Design features embedded.

1. Artificial intelligence sparring as a bias-challenge mechanism

Phase 3's artificial intelligence (AI) sparring was specifically designed to provide algorithmic critique independent of the developer's assumptions. The high adoption rate (14/16, 88%) indicates that AI-generated critiques were frequently incorporated after expert review, which may reflect the mechanism's capacity to challenge and refine initial decisions.

2. Independent blinded validation

The external expert review by 2 board-certified pediatricians, conducted blind to the development process, served as a safety check. Neither reviewer identified critical safety errors requiring mandatory correction, providing some reassurance that execution bias did not compromise clinical safety in this single-case run. Although these mechanisms cannot eliminate bias entirely, they represent a deliberate methodological strategy to bound its impact. Future multiexpert implementations should include interrater reliability data to more fully characterize the role of individual expert variation.

Lack of Concurrent Traditional Comparison

The comparison with traditional methods is based on literature estimates (60-200 person-hours) rather than on a concurrently conducted traditional process [14,15]. Without a direct comparison using the same topic and comparable expertise, the efficiency implications remain illustrative rather than empirically validated. No specific percentage efficiency gain should be inferred from this proof-of-concept. Similarly, the comparison with F-ACAD highlights potential risks associated with inadequate governance but does not establish the optimal level or method of human oversight.

Reproducibility Challenges

All AI interactions were conducted using subscription-based web interfaces with default configurations, as these platforms do not provide user-controllable sampling parameters. No random seeds were set, limiting exact output replication. The rapid evolution of AI models presents an additional challenge; the specific model versions used in this July 2025 study may perform differently or may be unavailable in the future. Future applications of S-ACAD should document the exact model versions used and reevaluate model selection as platforms evolve.

External Validation Limitations

The external review was conducted by only 2 reviewers, which lacks sufficient statistical power for generalization. The resulting scores should therefore be interpreted as qualitative indicators within this proof-of-concept study rather than as statistically validated metrics.

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Contextual Limitations

The algorithm developed in this study reflects US-centric emergency response protocols (eg, "911" as the emergency number and specific medication availability). Health care systems vary substantially across countries in emergency services, medication regulations, and clinical practice norms. Organizations implementing S-ACAD in different contexts should incorporate an explicit localization phase.

Scope of Conclusions

Finally, although this proof-of-concept suggests the feasibility and safety of S-ACAD as a governance framework for algorithm development, it does not constitute validation of its effectiveness as an organizational management strategy. The strategic implications discussed—including talent realignment, resource considerations, and organizational adoption—are derived from this single case and require empirical testing through multiinstitutional implementation studies. Decision makers considering the adoption of S-ACAD should view this work as providing a structured framework and preliminary evidence, rather than definitive proof of organizational benefit.

Future Research Directions and Broader Implications

To address these limitations and advance the field of AI-assisted clinical content governance, several key directions emerge:

First, *empirical validation with end users* is the most critical next step. Simulation-based usability testing with actual caregivers is essential to evaluate the algorithm's safety and effectiveness for its target audience and to address sociocultural barriers to adherence.

Second, *multicenter, multiexpert, multitopic validation* is needed. S-ACAD should be applied repeatedly to diverse clinical topics by multiple experts across different institutions. By systematically collecting development time data (using predefined time-tracking procedures) and comparing results against traditional methods as a control, a more robust statistical foundation for the methodology's efficiency can be established, including CIs.

Third, *rigorous comparative studies and exploration of the automation spectrum* are warranted. Different hybrid human-AI configurations—including hypothesized intermediate models between S-ACAD and F-ACAD—should be systematically evaluated to define the optimal balance between automation and expert oversight.

Fourth, *implementation science and organizational studies* are required to validate S-ACAD as a management strategy. This includes multiinstitutional implementation studies assessing adoption barriers and stakeholder acceptance, cost analyses and economic evaluations from a health system perspective, and longitudinal studies evaluating sustainability and scalability.

More broadly, the findings of this study contribute to a growing body of evidence that governance of AI in health care cannot be reduced to a binary choice between human-only and AI-only approaches. Instead, effective governance requires deliberate, continuous alignment of human expertise with AI capabilities—what we have termed "active governance." As AI systems become increasingly capable, the role of the human expert is not diminished but elevated to a higher-order function: ensuring that AI-generated outputs meet the safety, ethical, and contextual standards that patients and families deserve. The S-ACAD framework, although requiring further validation, offers an operationalizable model for this governance approach that health care organizations can adapt and test within their own institutional contexts.

Conclusions

In this single prospective case study, the S-ACAD framework produced a parent-actionable febrile seizure algorithm in just over 4 hours while preserving evidence traceability and incorporating independent clinical review. Two independent pediatric specialists did not identify critical safety errors requiring mandatory correction, suggesting that continuous expert governance during AI-assisted development may help maintain clinical safety standards. Although limited to a single expert and clinical topic, these preliminary findings suggest a practical governance pathway for digital health teams that require speed but cannot outsource accountability.

The key insight from this formative evaluation is not the time metric itself, but the redistribution of expert effort: S-ACAD assigns AI to rapid collection and drafting while reserving expert effort for validation, governance, and safety—areas in which human judgment appeared most consequential. Critical next steps include multiinstitutional implementation studies to evaluate S-ACAD as an organizational strategy across diverse health care settings, clinical domains, and institutional contexts. More broadly, the "active governance" paradigm demonstrated here—embedding continuous human oversight within AI-accelerated workflows rather than relying on post hoc review—may offer a generalizable model as health care organizations navigate emerging regulatory frameworks for AI-assisted clinical tools. As both the EU AI Act and Food and Drug Administration (FDA) guidance on AI/machine learning–based Software as a Medical Device increasingly emphasize human oversight and algorithmic transparency, governance approaches such as S-ACAD that operationalize these principles during development, rather than retrofitting them after deployment, may become essential components of responsible digital health innovation.

Acknowledgments

The authors thank the 2 independent pediatric specialists for their time and expert feedback during the external clinical review of the algorithm. The authors also acknowledge the artificial intelligence models used in the Semiautomatic Clinical Algorithm Development (S-ACAD) workflow and the Genspark platform used for the Fully Autonomous Clinical Algorithm Development (F-ACAD) comparative experiment. In accordance with JMIR's policy on generative artificial intelligence (GAI) use and guided

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by the GAIDeT (Generative AI Delegation Taxonomy) framework [31], we disclose the following use of GAI tools in this study: For S-ACAD workflow execution (July 25, 2025), Gemini 2.5 Pro (Google; accessed July 25, 2025) was used for cross-validation synthesis and primary algorithm drafting (phases 2 and 3); ChatGPT (model o3; OpenAI; accessed July 25, 2025) for foundational data collection (phase 1); Perplexity Pro (Perplexity AI; accessed July 25, 2025) and Consensus (Consensus; accessed July 25, 2025) for literature search and systematization (phase 1); and Claude Opus 4 (Anthropic PBC; accessed July 25, 2025) for critical quality review via "AI sparring" (phase 3). For the F-ACAD comparative experiment, Genspark (Genspark; accessed July 25, 2025) was used for fully autonomous algorithm generation as a comparative benchmark (the "Comparative Analysis With a Fully Automated Approach" section). The authors declare the use of GAI in the research and writing process. According to the GAIDeT framework, the following tasks were delegated to GAI tools under full human supervision: literature search and systematization, data collection, text generation, proofreading and editing, and quality assessment. The GAI tools used were Claude (Anthropic PBC), Gemini (Google LLC), and ChatGPT (OpenAI). Responsibility for the final manuscript lies entirely with the authors. GAI tools are not listed as authors and do not bear responsibility for the final outcomes. All AI models were accessed via subscription-based web interfaces with default configurations. All AI-generated outputs were reviewed, verified, and finalized by the human authors. All intellectual content, study design, data collection, analysis, and final interpretations are the sole responsibility of the authors. For a detailed disclosure of human oversight procedures across all study phases, see the "AI Model Parameters and Reproducibility" and "Generative AI Disclosure" sections. Complete prompts and AI outputs are provided in Multimedia Appendices 1-4.

Funding

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Data Availability

All data generated and analyzed during this study are included in this manuscript and its multimedia appendices. The detailed prompts used for each artificial intelligence (AI) model (Multimedia Appendix 1), the full cross-validation synthesis report (Multimedia Appendix 2), the complete algorithm flowchart (Multimedia Appendix 3), the detailed AI sparring and development process log (Multimedia Appendix 4), the Fully Autonomous Clinical Algorithm Development (F-ACAD) comparative analysis data (Multimedia Appendix 5), the expert evaluation form (Multimedia Appendix 6), anonymized qualitative feedback (Multimedia Appendix 7), and quantitative review scores (Multimedia Appendix 8) are provided as multimedia appendices to ensure transparency and support reproducibility of the described workflow.

Authors' Contributions

Conceptualization: SHA
Data curation: SHA
Formal analysis: SHA
Investigation: SHA
Methodology: SHA
Project administration: SHA
Supervision: JK
Validation: JK
Visualization: SHA
Writing – original draft: SHA
Writing – review & editing: JK

Conflicts of Interest

SHA is the originator of the Semiautomatic Clinical Algorithm Development (S-ACAD) methodology proposed in this study and currently serves as the Medical Algorithm Director at MoDoc AI, a company that develops commercial medical algorithms. Although this study was conducted as academic research, the findings may inform future commercial applications. For transparency, the authors note that S-ACAD may be applied in the FeverCoach app to create additional guidance modules; however, no implementation has occurred to date. The study received no commercial funding, and commercial partners had no role in the study design, execution, analysis, or decision to publish. JK declares no conflicts of interest. All methods and findings are reported transparently to enable independent evaluation and replication.

Multimedia Appendix 1
Detailed prompts used for each artificial intelligence model.
[DOCX File , 20 KB - formative_v10i1e90273_app1.docx]

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Multimedia Appendix 2
Full text of the cross-validation synthesis report.
[DOCX File , 18 KB - formative_v10i1e90273_app2.docx]

Multimedia Appendix 3
Complete flowchart of the final algorithm (version 1.0).
[DOCX File , 23 KB - formative_v10i1e90273_app3.docx]

Multimedia Appendix 4
Detailed log of the artificial intelligence sparring and iterative development process.
[DOCX File , 21 KB - formative_v10i1e90273_app4.docx]

Multimedia Appendix 5
Comparative analysis of the Fully Autonomous Clinical Algorithm Development methodology and results.
[DOCX File , 22 KB - formative_v10i1e90273_app5.docx]

Multimedia Appendix 6
The expert evaluation form.
[DOCX File , 20 KB - formative_v10i1e90273_app6.docx]

Multimedia Appendix 7
Anonymized qualitative feedback from external experts.
[DOCX File , 15 KB - formative_v10i1e90273_app7.docx]

Multimedia Appendix 8
External review raw data (quantitative scores).
[DOCX File , 1913 KB - formative_v10i1e90273_app8.docx]

Multimedia Appendix 9
The SQUIRE (Standards for Quality Improvement Reporting Excellence) 2.0 reporting checklist.
[PDF File (Adobe PDF File), 165 KB - formative_v10i1e90273_app9.pdf]

Multimedia Appendix 10
Artificial intelligence sparring effectiveness and human intervention analysis. Panel A presents the number of issues identified by the artificial intelligence critic versus the number adopted after expert review, by category. Panel B shows the distribution of all 19 human expert interventions recorded across the Semiautomatic Clinical Algorithm Development workflow.
[PNG File , 620 KB - formative_v10i1e90273_app10.png]

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Abbreviations

AAP: American Academy of Pediatrics
AI: artificial intelligence

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F-ACAD: Fully Autonomous Clinical Algorithm Development
FDA: Food and Drug Administration
GAIDeT: Generative AI Delegation Taxonomy
IRR: interrater reliability
LLM: large language model
NICE: National Institute for Health and Care Excellence
S-ACAD: Semiautomatic Clinical Algorithm Development
SQUIRE: Standards for Quality Improvement Reporting Excellence
UX: user experience

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Original Paper

Digital Phenotyping of Pain Modulation and Associations Among Personality, Attachment, and Behavioral Signatures: Cross-Sectional Study

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Abstract

Background: The transition from acute to chronic pain often reflects a persistent dissociation between physical tissue damage and subjective reports. In alignment with the 2020 International Association for the Study of Pain definition, pain is a personal experience filtered through a latent "susceptibility architecture." While clinical assessment currently relies on static, text-based questionnaires, these are often confounded by linguistic interpretation bias and cognitive literacy. We hypothesized that an individual's internal psychological substrate—traditionally captured via text—can be characterized through real-time behavioral signatures during physical challenge.

Objective: This study aimed to demonstrate that the "pain-prone" phenotype can be identified through high-frequency digital assessment of pain ratings. By correlating established psychometric traits with dynamic behavioral signatures, we sought to establish a foundation for "digital phenotyping" that moves beyond the limitations of linguistic self-reports.

Methods: A cohort of 534 healthy volunteers (mean age 38.62, SD 22.35 years; n=336, 62.9% male and n=198, 37.1% female) underwent a controlled thermal stimulation protocol (36 °C, 44 °C, 46 °C, and 48 °C). Continuous pain intensity was recorded via a high-frequency (1000 Hz) digital visual analog scale (VAS). To establish a psychological baseline, participants were profiled using the Revised NEO Personality Inventory (NEO PI-R) and the Relationship Questionnaire. Two behavioral indexes were then derived from the digital VAS: the temporal augmentation index (TAI), reflecting within-stimulus physiological sensitization, and the cognitive contrast effect (evaluative instability). Statistical significance was adjusted using the false discovery rate.

Results: Repeated-measure multivariate ANOVA confirmed a highly significant main effect of time for all noxious conditions (P<.001; 46 °C: t_{533}=27.69). Perceived intensity at 46 °C was significantly lower following 48 °C (mean VAS 12.31; SD 15.55) than following 36 °C (mean VAS 30.45; SD 22.38; t_{533}=−25.76; P<.001). Crucially, vulnerability (facet N6 of the NEO PI-R) was significantly associated with contrast magnitude (q=.03) and showed a trend for the TAI (q=.09), whereas self-discipline (facet C5) showed a significant negative association with the TAI (q=.048) and a trend for contrast magnitude (q=.09). Mediation analysis identified 2 distinct pathways: (1) a "stabilization path" where secure attachment fully mediated the inhibitory effect of facet C5 on evaluative instability (direct effect c'=−0.25; P=.11) and (2) an "instability path" where facet N6 exerted a direct amplifying effect on instability (c'=0.34; P=.03).

Conclusions: Subjective pain evaluation is governed by a stable internal psychological substrate. By shifting the assessment modality from linguistic self-reports to dynamic behavioral signatures, we provide a framework for "digital phenotyping." These evaluation patterns serve as an objective behavioral marker, enabling the identification of latent susceptibility before chronification and offering a novel foundation for personalized precision pain management.

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(JMIR Form Res 2026;10:e91540) doi:10.2196/91540

KEYWORDS

pain modulation; personality; attachment; digital phenotyping; precision management; susceptibility

Introduction

The Subjectivity of Pain and the Evolution of the Clinician's Paradox

The transition from acute to chronic pain remains one of the most formidable frontiers in modern clinical medicine [1]. Traditionally, pain was viewed through a Cartesian, dualistic lens, assuming a linear, proportional relationship between noxious input and perceived intensity. In this classic biomedical model, pain was considered a direct symptom of tissue damage, much like a ringing bell signals a pull on a cord. However, clinical reality has long presented a striking paradox: many patients experience debilitating chronic pain in the absolute absence of identifiable pathology, whereas others recover fully from severe physical trauma without developing long-lasting sensitivity [2-4]. This "clinician's paradox" suggests that the nervous system is not a passive conduit but an active and plastic interpreter of sensory signals.

In 2020, the International Association for the Study of Pain formalized the shift away from the biomedical model by revising the definition of pain to "an unpleasant sensory and emotional experience associated with, or resembling that associated with, actual or potential tissue damage" [2]. A pivotal aspect of this revision is the explicit recognition that pain is "always a personal experience," influenced to varying degrees by a complex and dynamic interplay of biological, psychological, and social factors [5,6]. This suggests that pain is an "emergent property" of the brain's integrative processes rather than a mere sensory readout [7,8]. From this perspective, the initial physical insult serves merely as a "triggering event," whereas the eventual trajectory toward chronicity is largely governed by the individual's inherent susceptibility—the "pain-prone" phenotype [9,10].

Personality and Attachment as Latent Psychological Filters

In accordance with the diathesis-stress model, preexisting psychological architectures function as a latent "vulnerability filter" that determines how raw sensory signals are processed, interpreted, and emotionally modulated [11,12]. Personality traits, particularly those elucidated by the five-factor model, provide a high-resolution map of this temperament. Previous research has consistently demonstrated that individuals with high levels of neuroticism exhibit heightened pain hypersensitivity and a greater predisposition toward maladaptive catastrophizing [4,10,13-15]. Conversely, traits such as conscientiousness and self-discipline appear to foster adaptive coping strategies and higher self-efficacy, potentially acting as a neurocognitive buffer against the amplification of pain signals [16,17].

Furthermore, these traits are deeply intertwined with "internal working models" (IWMs) of attachment. Attachment theory offers a fundamental developmental framework for understanding how early relationship experiences shape a person's cognitive and emotional templates for regulating distress in response to threat [18-20]. These IWMs act as the brain's "operating system" for managing physical and psychological pain, serving as a "cognitive calibrator." Secure attachment provides a stable foundation for the accurate appraisal of threat and the efficient downregulation of distress. In contrast, insecure attachment styles are associated with the hyperactivation of the stress response, causing individuals to exhibit greater fluctuations and evaluative instability in their pain reports [21,22]. We hypothesize that this IWM is the critical nexus through which personality traits are translated into sensory experiences.

Mechanistic Pathways: Physiological Sensitization vs Cognitive Calibration

To move toward the clinical ideal of "precision pain management," it is essential to identify the precise mechanisms—both bottom-up and top-down—through which these inherent traits modulate the pain experience. This study focused on 2 distinct behavioral indexes: the temporal augmentation index (TAI) and the cognitive contrast effect. The TAI, conceptually linked to central sensitization, reflects the progressive, time-dependent amplification of nociceptive signaling within the central nervous system during sustained, tonic noxious stimulation [14,23]. This process primarily reflects physiological sensitization at the spinal and supraspinal levels and is a clinical hallmark of the "sensitization-prone" phenotype [23].

Simultaneously, we examined the cognitive contrast effect—a phenomenon where the evaluation of a current noxious stimulus is significantly skewed by the intensity of the preceding sensory context. This effect reflects higher-order cognitive judgments and the stability (or instability) of subjective perception. This process is deeply rooted in the predictive coding framework, which suggests that the brain is an "inference machine" that constantly compares incoming nociceptive input against predicted internal mental models [24,25]. Identifying whether psychological susceptibility primarily modulates "physiological sensitization" (TAI) or "cognitive calibration" (contrast effect) is a critical step for the proactive stratification of patients who are at risk of pain chronification [5,26].

Beyond Linguistic Modalities: From Text to Behavioral Signatures

Despite the critical role of psychological factors, current clinical assessment relies almost exclusively on traditional, text-based self-report questionnaires. However, these psychometric instruments possess inherent limitations that may significantly compromise the accuracy of patient profiling. The validity of self-reports is frequently confounded by variations in linguistic comprehension, cognitive literacy, and the subjective interpretation of descriptive items [27]. Research in psychometrics has highlighted that individuals may interpret

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the same written prompt in vastly different ways based on their cognitive load or personal semantics, leading to "common method bias" and a failure to accurately capture the latent psychological construct [28]. It must be acknowledged that visual analog scales (VASs), while providing a continuous metric, are also susceptible to individual interpretational variability similarly to linguistic prompts. However, this study aimed to move beyond treating this variability as "noise" and, instead, treat the dynamic, high-frequency evaluation pattern itself as a characteristic behavioral signature.

To overcome these fundamental limitations, this study proposes a paradigm shift in assessment modality: from linguistic self-reports to dynamic behavioral evaluation. By analyzing the real-time "behavioral signature" of pain ratings during controlled physical stimulation, we aimed to bridge the gap between abstract psychological constructs and observable neurobehavioral reactions. We hypothesized that stable personality facets—previously captured only through text—can be characterized more accurately through the unique ways in which an individual's pain ratings fluctuate and augment in response to noxious input. This transition from "what the patient says" to "how the patient reacts to a stimulus" allows for a multimodal understanding of human nature, redefining psychological traits not just as abstract descriptions but as specific patterns of behavioral reaction. This approach provides a robust foundation for "digital phenotyping" in pain medicine [29-31]. The primary aim of this study was to demonstrate that dynamic behavioral signatures of pain evaluation reflect an individual's latent psychological substrates. We hypothesized that (1) personality traits such as vulnerability (facet N6 of the Revised NEO Personality Inventory [NEO PI-R]) would amplify both physiological sensitization (the TAI) and cognitive evaluative instability (the contrast effect) and (2) this instability can be explained through 2 distinct psychological pathways—a "stabilization path" and an "instability path"—mediated by IWMs of attachment.

Methods

Ethical Considerations

This study was approved by the Research Ethics Committee of the Graduate School of Frontier Biosciences, Osaka University (approval FBS2020-13 and FBS2021-10), and was conducted in strict accordance with the Declaration of Helsinki. All participants provided written informed consent before participation. To ensure participant privacy and confidentiality, all data were pseudonymized (symbolized) using identification numbers, and the correspondence table between personal information and these numbers was strictly managed by the research team. Data processed on external cloud servers contained no personally identifiable information. Participants were compensated for their time with a payment of JP ¥1000 (US $7.28) per hour.

Recruitment and Procedures

Participants were recruited through 2 primary channels to ensure a diverse age distribution: (1) KOAN, an internal online bulletin board for students and staff at Osaka University; and (2) the Toyonaka City Silver Human Resources Center targeting community-dwelling older adults. The recruitment advertisements specified that participants must be aged at least 18 years and in good physical and mental health.

To ensure participant safety and data validity, we applied strict exclusion criteria. Individuals were ineligible if they had (1) known neurological disorders or a history of brain-related conditions (eg, epilepsy, stroke, or organic brain disease), (2) a clinical diagnosis of chronic pain or current use of narcotic analgesics, (3) electronic implants such as cardiac pacemakers, or (4) severe visual impairment that would interfere with using the digital tablet for pain assessment. Additionally, candidates were informed that thermal stimulation might cause temporary skin redness; those who did not consent to this potential effect were excluded.

The systematic screening followed a 3-step process. First, applicants contacted the research team via email and completed a health screening questionnaire based on the above criteria. Second, a researcher verified their eligibility. Third, for eligible candidates, a research assistant coordinated the experimental sessions via email. All experiments were conducted in a dedicated laboratory at Osaka University (Japan Registry of Clinical Trials jRCT1090220286).

A total of 538 healthy volunteers were initially recruited through these systematic procedures. Of the initial cohort of 538 participants, 4 (0.7%) were excluded due to a significant discrepancy between their real-time VAS ratings and postexperimental verbal reports (numeric rating scale), suggesting equipment misuse or measurement error. The final analytical sample consisted of 534 participants (mean age 38.62, SD 22.35 years; n=336, 62.9% male and n=198, 37.1% female). For multivariate analyses involving psychological inventories, the effective sample size ranged from 522 to 530 due to minor missing data.

Psychological Profiling

Before the thermal stimulation trials, participants' psychological architectures were profiled using 2 validated instruments. The first, the NEO PI-R (Japanese version), is a 240-item questionnaire assesses the "big five" domains (neuroticism, extraversion, openness, agreeableness, and conscientiousness) and their 30 constituent facets. The Japanese version has demonstrated high reliability and validity across diverse demographic groups [21,27]. The second was the Relationship Questionnaire, an instrument that measures adult attachment styles—secure, dismissing, preoccupied, and fearful—based on mental models of the self and others. Participants provide self-ratings on a 7-point Likert scale for each of the 4 prototypes, allowing for both categorical and dimensional analyses of their IWMs [22,28,32].

Thermal Stimulation Protocol

Thermal stimuli were delivered via a computer-controlled PATHWAY system (Medoc - Advanced Medical Systems Ltd) using a contact advanced thermal stimulator probe (30 × 30 mm) attached to the medial aspect of the left forearm. The Medoc PATHWAY system is a gold-standard device in quantitative sensory testing (QST) research capable of precise temperature delivery with a 0.1 °C resolution.

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The experimental program consisted of 20 tonic heat stimuli, each lasting 30 seconds at a target temperature, with an interstimulus interval of 30 seconds at a baseline of 35 °C to avoid excessive cumulative skin heating. The target temperatures included 1 nonnoxious control (36 °C) and 3 noxious conditions (44 °C, 46 °C, and 48 °C). The stimuli were presented in a fixed pseudorandomized sequence (36, 44, 48, 46, 46, 44, 36, 48, 46, 48, 36, 44, 48, 44, 36, 46, 36, 44, 48, and 46) to control for order effects while specifically enabling the assessment of temperature-dependent contrast effects on the 46 °C target. Each stimulus ramped from baseline to the target temperature at a rate of 1 °C per second and returned to baseline at the same rate. The heating ramp of 1 °C per second preferentially activates unmyelinated C-fibers, which are known to contribute to slow, burning pain and temporal summation phenomena.

Real-Time Pain Assessment

Participants were instructed to rate their pain intensity continuously throughout the stimulation period using a sliding-lever VAS device (Intercross-210; Intercross Corporation). The VAS was anchored at 0 (“no pain”) and 100 (“maximum imaginable pain”). The digital output was sampled at a high frequency (1000 Hz) to ensure high-fidelity data acquisition and facilitate effective noise reduction during subsequent signal processing.

Derivation of Modulation Indexes

Two distinct modulation indexes were calculated for each participant.

First, the TAI: the 30-second stimulation period was divided into three 10-second epochs (time A: 0-10 seconds; time B: 10-20 seconds; time C: 20-30 seconds). After preliminary examination of all possible increments between the intervals (B – A, C – B, and C – A), the C – A index (the difference in mean VAS between the terminal and initial phases) was adopted as the primary measure of within-stimulus pain augmentation as it most clearly and robustly reflected the overall progression of pain intensity. It should be noted that, while the ratio-based windup index (VAS[C]/VAS[A]) is frequently used in clinical populations, it was not used in our primary analyses. Because our cohort consisted of healthy volunteers, initial pain ratings (time A) were often near 0, creating mathematical instability and artificially inflated ratios. Thus, the absolute difference (C – A) was adopted for mathematical robustness.

Second, the cognitive contrast effect: this index quantified the influence of preceding thermal context on the evaluation of the 46 °C target stimulus. The “magnitude of the contrast effect” was defined as the difference in VAS scores between the low-contrast condition (preceded by 36 °C) and the high-contrast condition (preceded by 48 °C).

Statistical Analysis

All analyses were conducted using JMP (version 14.2.0; JMP Statistical Discovery LLC). Data distribution was assessed using the Shapiro-Wilk test, which revealed significant nonnormality for most behavioral indexes (P<.05). Consequently, the Spearman rank correlation coefficient (ρ) was used to evaluate associations between psychological facets and pain modulation indexes. To control for the inflation of type I error rate due to multiple comparisons across personality facets and attachment prototypes, the false discovery rate (FDR) using the Benjamini-Hochberg procedure was applied, with q values (FDR-adjusted P values) of <.05 considered statistically significant. Repeated-measure multivariate ANOVA was configured as a 4 (temperature: 36 °C, 44 °C, 46 °C, and 48 °C) × 3 (time: epoch A, B, and C) factorial design, where 36 °C served as the non-noxious control condition. Greenhouse-Geisser corrections were applied to the df across all temperature levels to adjust for violations of sphericity when evaluating time-dependent changes in VAS scores across these temperature conditions. Evaluation instability was operationally defined as the magnitude of the cognitive contrast effect. Additionally, participants were categorized into low- and high-sensitivity groups via a median split based on their average VAS score at 46 °C to investigate group-level differences in temporal augmentation. Finally, a mediation analysis was performed following the standard criteria of Baron and Kenny [33]. The indirect effects were further validated using the Sobel test to ensure statistical robustness. For all analyses not involving multiple comparisons (eg, multivariate ANOVA and mediation), significance was defined as P<.05. All t tests were 2-tailed.

Results

Time-Dependent Modulation of Pain

The model confirmed a highly significant main effect of time for all noxious conditions (44 °C, 46 °C, and 48 °C; P<.001 in all cases). For the 44 °C condition, the mean VAS increased from 7.52 (SD 9.76) at time A to 12.20 (SE 0.62) at time C (P<.001). For the 46 °C target stimulus, univariate results revealed a linear progression of pain intensity over the 30-second window. Significant increases were observed between time A and B (t_{533}=27.69; P<.001), time A and C (t_{533}=26.88; P<.001), and time B and C (t_{533}=12.33; P<.001). For the 48 °C condition, a more pronounced augmentation was observed, rising from 24.62 (SE 0.68) at time A to 62.73 (SE 1.07) at time C (P<.001). Overall, these results demonstrate a robust and sustained temporal augmentation (TAI; Figure 1). In contrast, the 36 °C control condition showed no significant variation across the 3 epochs even within this factorial framework ($F_{1.31, 695.56}$=2.43; P=.11). This confirms that the observed augmentation reflects specific nociceptive temporal integration rather than generalized response fatigue or habituation.

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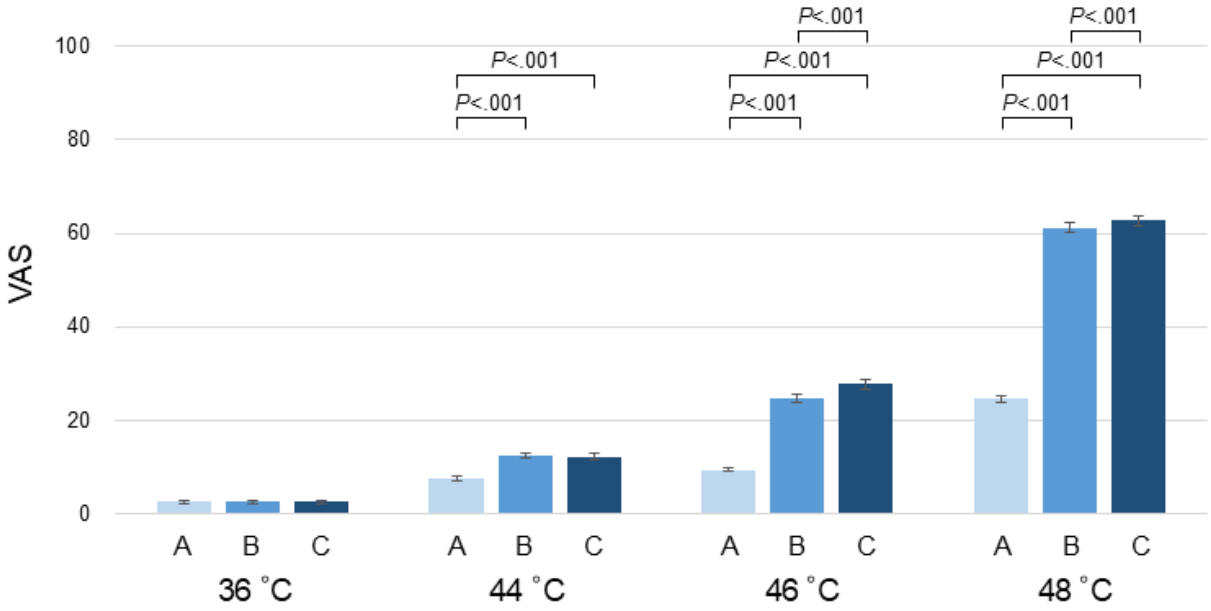
Figure 1. Time course of pain intensity ratings within the 30-second heat stimulation period. The 30-second period is divided into 10-second intervals (epochs A, B, and C). The temporal augmentation index is calculated as C – A. Significant main effects of time were observed for all noxious conditions (*P*<.001). Data are presented as mean and SE (n=534).



Context-Dependent Modulation (Contrast Effect)

A paired *t* test revealed a powerful contrast effect on the 46 °C target stimulus (t_{533}=−25.76; *P*<.001). Perceived intensity for the 46 °C stimulus was significantly lower in the high-contrast condition (following 48 °C; mean VAS 12.31, SD 15.55) than in the low-contrast condition (following 36 °C; mean VAS 30.45, SD 22.38). This confirms that subjective pain evaluation is not an absolute readout of temperature but a relative judgment influenced by immediate sensory history and the brain's contextual predictive model.

Correlation Analysis With Personality and Attachment

Correlation analysis using the Spearman ρ and the FDR following the Benjamini-Hochberg procedure revealed that self-discipline (C5) was significantly negatively associated with the TAI at 46 °C (Figure 2A; ρ=−0.14; *q*=.048). Vulnerability (facet N6 of the NEO PI-R) and dutifulness (facet C3) were observed as trends within the FDR-adjusted framework (N6: ρ=0.12 and *q*=.09; C3: ρ=−0.12 and *q*=.07). The broad domain of neuroticism was not significantly associated with the 46 °C TAI (ρ=0.06; *q*=.27). In contrast, N6 showed significant positive correlations with average pain intensity in the low-contrast condition (Figure 3A; ρ=0.14; *q*=.04) and with the magnitude of the contrast effect (Figure 4A; ρ=0.15; *q*=.03). Notably, the associations for N6 with these indexes remained significant after FDR correction, whereas the broad domain of neuroticism was not significantly associated with these indexes after correction (low contrast: ρ=0.09 and *q*=.12; contrast effect: ρ=0.09 and *q*=.18). However, the association between C5 and the contrast effect was observed as a trend (ρ=−0.11; *q*=.09). Additionally, at the highest temperature of 48 °C, excitement seeking (facet E5) exhibited a significant negative association with TAI after FDR correction (ρ=−0.14; *q*=.03).

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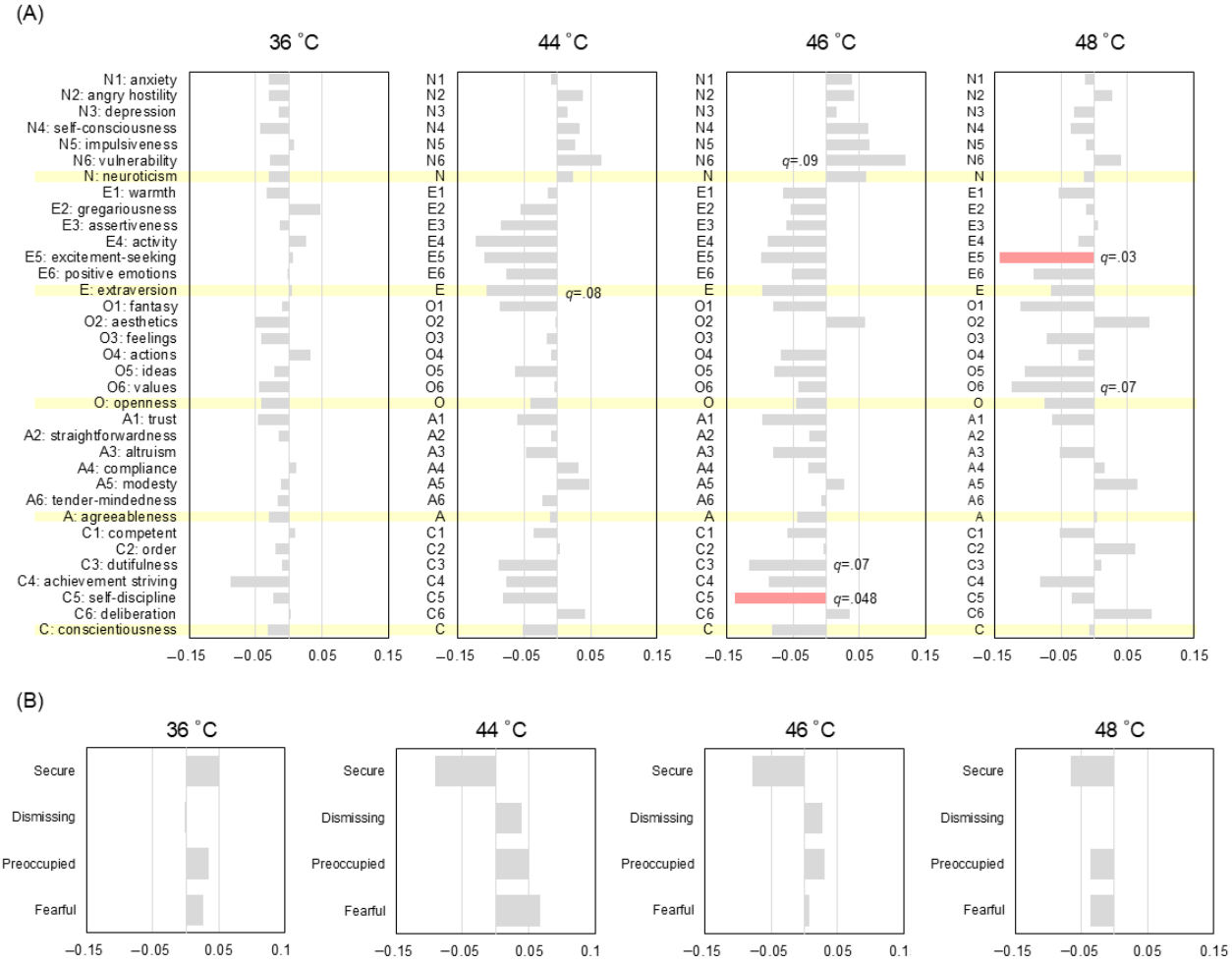
Figure 2. Correlations among personality traits, attachment styles, and intrastimulus changes in pain ratings (C – A) across stimulus temperatures. (A) Spearman rank correlation coefficients (ρ) between the "big five" personality facets and the temporal augmentation index (TAI; defined as epoch C – epoch A). Rightward and leftward bars indicate positive and negative correlations, respectively; shaded rows highlight the 5 main domains. Significance was adjusted using the Benjamini-Hochberg false discovery rate procedure (n=523). (B) Correlations between attachment styles and the TAI (n=530).



Regarding attachment styles, no prototypes were directly correlated with the TAI (q>.05 in all cases; Figure 2B), suggesting that temporal augmentation may be governed by more rudimentary neurobiological sensitization paths. However, IWMs were significantly linked to evaluative stability. The secure attachment style showed a negative correlation with pain intensity in the low-contrast condition, appearing as a trend (Figure 3B; ρ=−0.10; q=.07). Furthermore, the magnitude of the contrast effect was associated with the preoccupied prototype as a trend (Figure 4B; ρ=0.09; q=.09), whereas the association with the secure prototype did not maintain significance within the FDR framework (ρ=−0.09; q=.13). These relationships were further supported by significant correlations between attachment styles and personality domains (Figure 5; with many associations reaching q<.001); for instance, the secure style was negatively associated with neuroticism (ρ=−0.30; q<.001) and positively associated with extraversion (ρ=0.41; q<.001), whereas the preoccupied style was linked to high neuroticism (ρ=0.40; q<.001).

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Figure 3. Correlations among personality traits, attachment styles, and average pain intensity at 46 °C in low- and high-contrast conditions. (A) Spearman rank correlation coefficients (ρ) between the "big five" personality facets and average pain intensity in the low-and high-contrast condition. Significance was adjusted using the Benjamini-Hochberg false discovery rate procedure (n=523). (B) Correlations between attachment styles and average pain intensity in the low-and high-contrast condition (n=530).

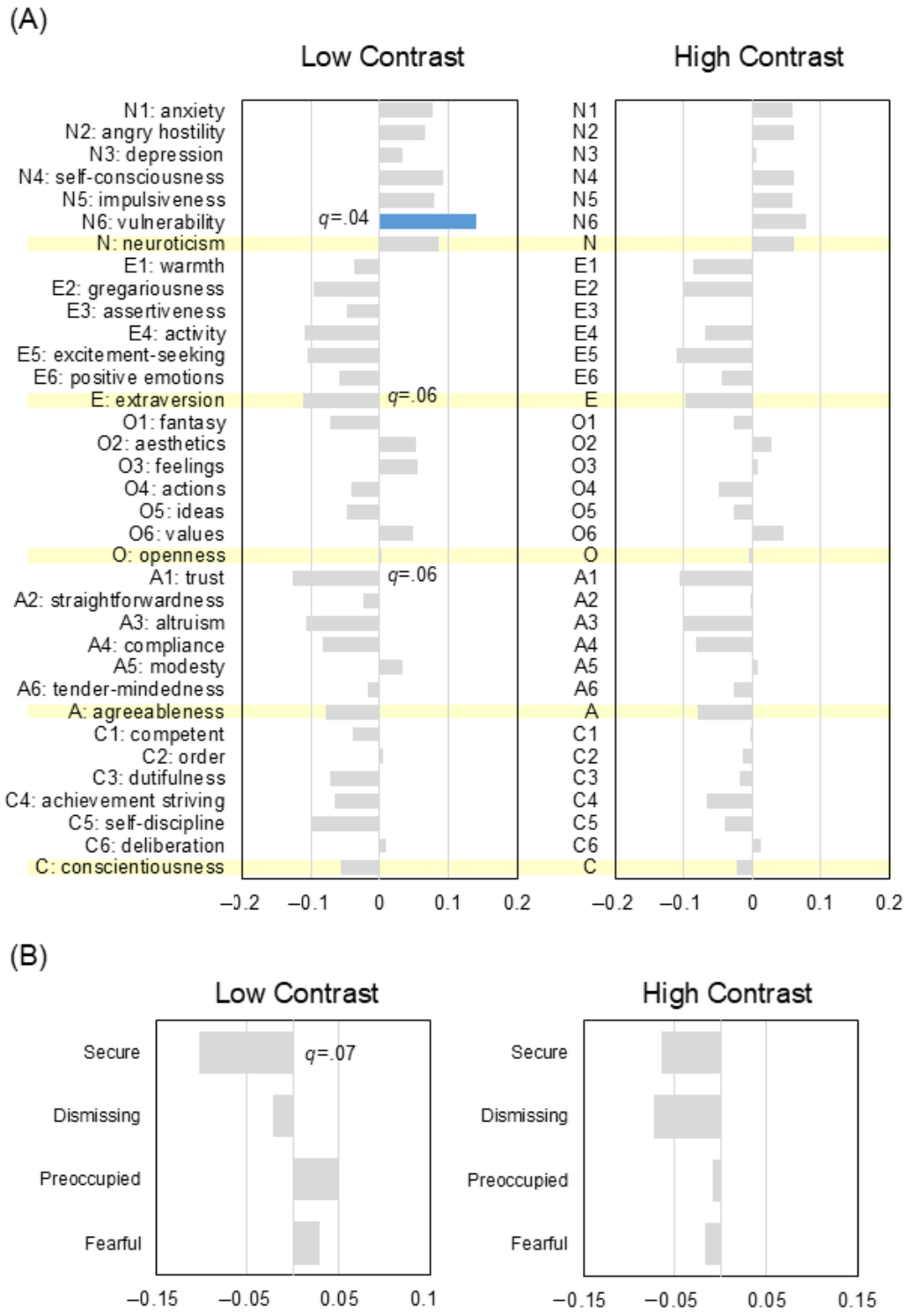

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Figure 4. Correlations among personality traits, attachment styles, and the magnitude of the contrast effect at 46 °C. (A) Spearman rank correlation coefficients (ρ) between the "big five" personality facets and the magnitude of the contrast effect (defined as the difference in average visual analog scale scores between low- and high-contrast conditions). Significance was adjusted using the Benjamini-Hochberg false discovery rate procedure (n=523). (B) Correlations between attachment styles and the contrast effect (n=530).

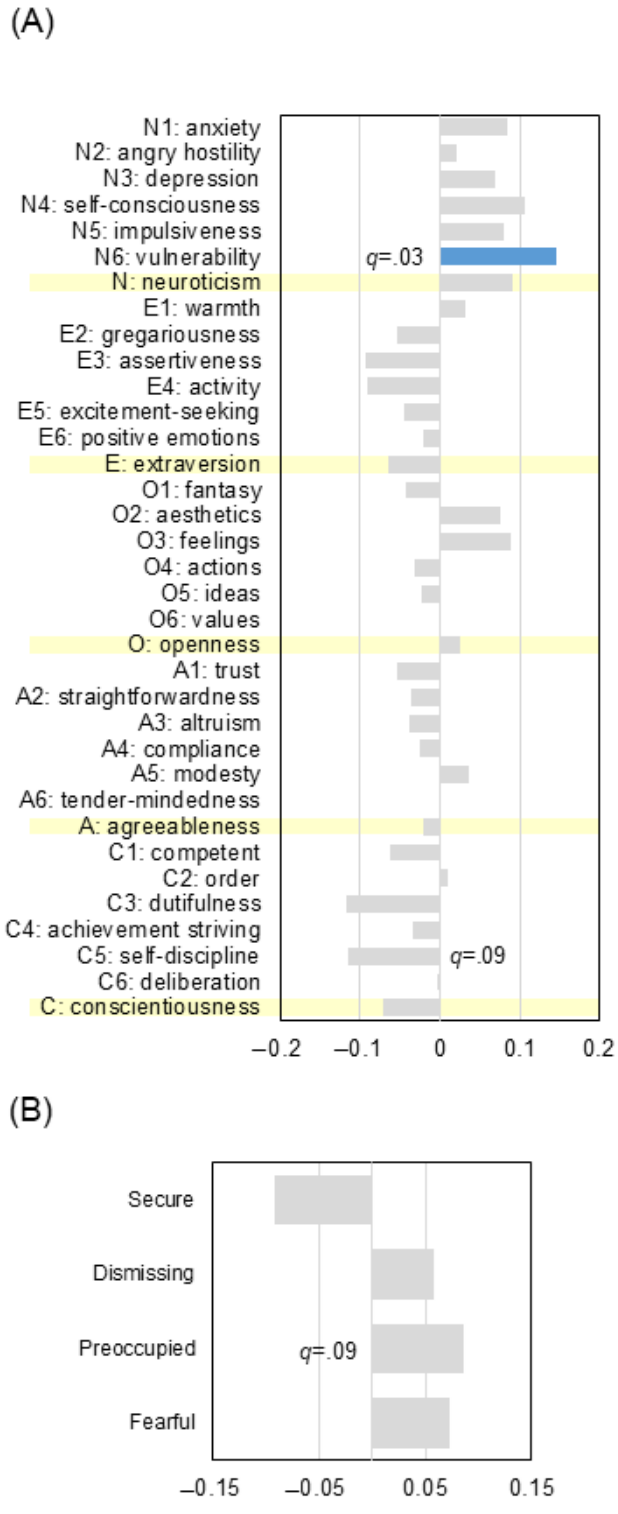

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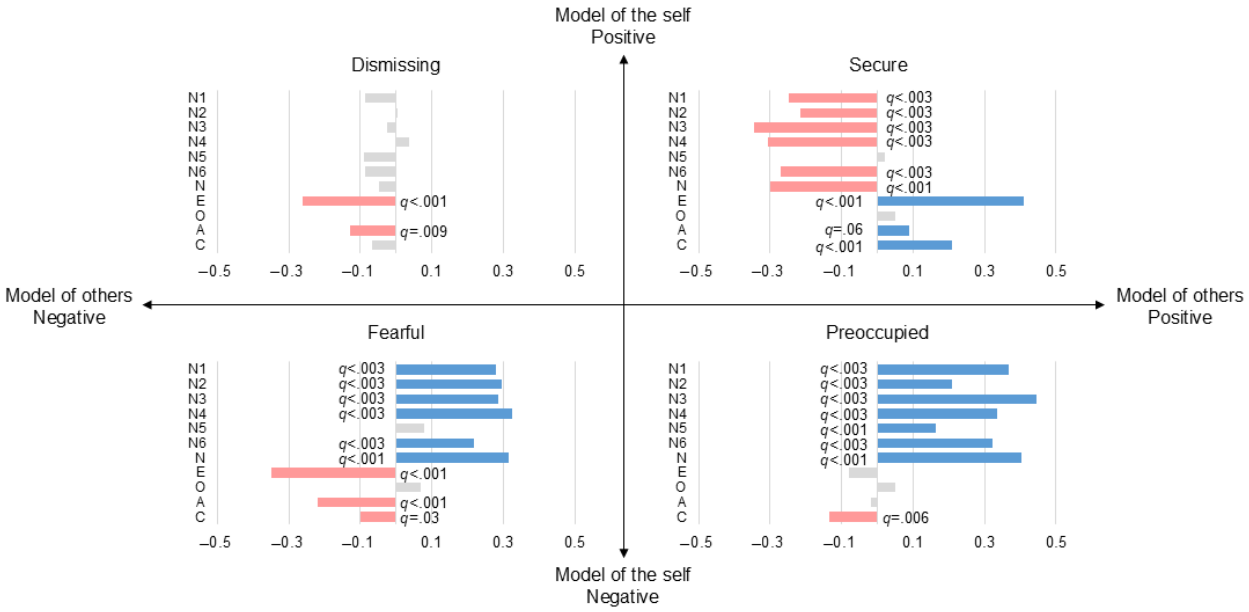
Figure 5. Correlations between attachment styles and personality traits based on the mental models of the self and others. The matrix displays Spearman rank correlation coefficients (ρ) between the 4 attachment prototypes and the "big five" personality domains. The prototypes are organized according to the internal working models of the self (horizontal axis) and others (vertical axis). Significance was adjusted using the Benjamini-Hochberg false discovery rate procedure (n=522).



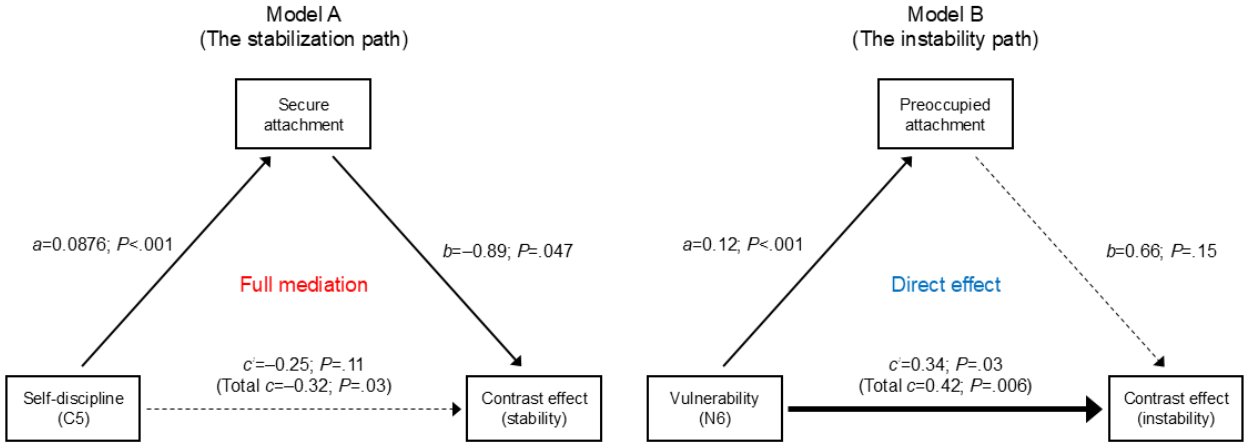
Mediation Analysis: Stabilization vs Instability

The mediation findings provided the deepest insight into the psychological architecture of pain evaluation (Figure 6):

Model A, the stabilization path: the inhibitory effect of self-discipline (facet C5) on evaluation instability was fully mediated by secure attachment. The direct effect of C5 became nonsignificant ($c'=-0.25$; $P=.11$) when the mediator was included. This implies that discipline promotes stability primarily by fostering a secure internal mental framework.

Model B, the instability path: the amplifying effect of vulnerability (N6) on evaluation instability remained a direct effect ($c'=0.34$; $P=.03$). Although N6 strongly predicted preoccupied attachment, the attachment style itself did not significantly influence the contrast effect in this specific model, suggesting a direct temperamental "destabilization" in vulnerable individuals.

Figure 6. Path models of the effects of personality traits and attachment styles on the magnitude of the contrast effect. The path diagrams illustrate 2 distinct psychological mechanisms governing the stability of pain evaluation (model A: stabilization path; model B: instability path). Numbers on the paths represent unstandardized coefficients (B), with values in parentheses indicating the total effect. Solid and dashed arrows denote significant and nonsignificant paths, respectively. Highlighted labels denote significant negative (suppression) and positive (amplification) impacts on the contrast effect. Significant paths were defined at $P<.05$ (n=522).



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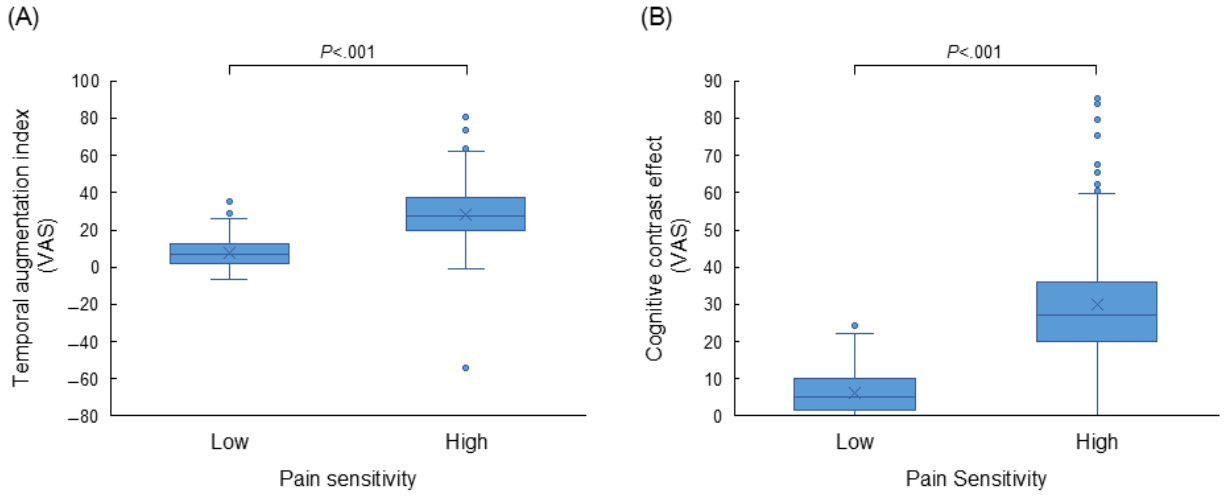
Impact of Baseline Pain Sensitivity on Temporal Augmentation and Contrast Effect

To further elucidate the clinical relevance of our findings, participants were stratified into low– and high–pain sensitivity groups based on a median split of their average VAS scores at 46 °C. Nonparametric comparisons using the Wilcoxon rank sum test revealed that the high-sensitivity group exhibited a significantly larger TAI (mean 28.52, SD 15.10) than the low-sensitivity group (mean 7.92, SD 7.11; z=16.25; P<.001). Furthermore, the cognitive contrast effect was also significantly greater in the high-sensitivity group (mean 30.13, SD 14.70) than in the low-sensitivity group (mean 6.15, SD 5.13; z=19.09; P<.001). These results indicate that individuals with inherently higher pain sensitivity are more susceptible to both temporal sensitization (windup) and context-dependent evaluation instability (Figure 7).

Figure 7. Comparison of pain modulation indexes between groups with different baseline pain sensitivity. Participants were stratified into low- and high-sensitivity groups based on a median split of average visual analog scale (VAS) scores at 46 °C. The panels represent (A) the temporal augmentation index and (B) the cognitive contrast effect. Box plots indicate the median, IQR, and range, with individual data points overlaid. Significance was determined using the Wilcoxon rank sum test (N=534).



Discussion

Principal Findings

In this cross-sectional study of 534 healthy adults, we demonstrated that specific personality facets were selectively associated with dynamic behavioral signatures of pain modulation under standardized tonic heat stimulation. Vulnerability (facet N6 of the NEO PI-R) was associated with greater evaluative instability, whereas self-discipline (facet C5) was associated with reduced temporal augmentation. Importantly, these associations were observed at the facet level rather than uniformly across broader personality domains, suggesting selective mechanistic relationships rather than a generalized negative affect effect [4,10,13,14].

The Subjectivity of Pain: The Observer as the Primary Architect

The findings of this study provide empirical evidence that the "observer" plays a critical role in shaping the pain experience, extending beyond a purely Cartesian view of nociception [2]. By standardizing the physical input (46 °C) while observing substantial interindividual variation in both the TAI and the cognitive contrast effect, we demonstrated that pain is not merely a passive sensory readout but reflects integrative brain processes [5,6,16,34].

Specifically, the TAI used in this study is conceptually linked to the clinical phenomenon of temporal summation [23], which has been described as a behavioral correlate of central sensitization [14,23]. Temporal summation reflects activity-dependent amplification of nociceptive signaling within the central nervous system and has been extensively characterized in experimental and clinical research [14,23]. The positive correlation between vulnerability (N6) and TAI suggests that this trait may be associated with increased sensitivity to sustained nociceptive input.

However, although the TAI was conceptually linked to central sensitization, we did not directly measure neurophysiological markers such as conditioned pain modulation or spinal nociceptive reflexes [35,36]. Therefore, our behavioral indexes should be interpreted as indirect proxies rather than definitive measures of central sensitization.

Pain, as an emergent property of consciousness, is not solely a reflection of peripheral input but is shaped by latent psychological architecture. Even under identical physical conditions, the perceived intensity and its temporal dynamics varied substantially across individuals.

Inherent Susceptibility: Vulnerability (N6) and Sensitization Processes

A central pillar of our findings is the susceptibility hypothesis, which proposes that individual differences in psychological architecture are associated with variability in nociceptive modulation. Vulnerability reflects a temperamental disposition characterized by emotional reactivity and perceived difficulty coping with stress. Individuals with higher N6 scores exhibited

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greater temporal augmentation and evaluative instability during sustained stimulation.

While this pattern is conceptually consistent with models of central sensitization [14,23], this study cannot establish causal or longitudinal risk relationships. Therefore, the observed associations should be interpreted as correlational markers of susceptibility rather than determinants of future chronification [9,26,37].

The Stabilization Path: Attachment as a Cognitive Calibrator

We identified a stabilization pathway in which secure attachment mediates the relationship between self-discipline (C5) and evaluative stability.

According to attachment theory, IWMs regulate threat appraisal and distress tolerance [18-20,38]. Secure attachment has been associated with adaptive emotion regulation and reduced pain-related distress [21,22]. Our mediation findings extend this literature by suggesting that attachment-related internal models may influence not only pain intensity but also the stability of pain evaluation across contextual changes.

Mechanistic Implications: Predictive Coding and Evaluative Noise

The contrast effect observed in our results aligns with predictive coding frameworks in which perception reflects the integration of sensory input and prior expectations [24,25]. Therefore, pain is evaluated relative to contextual history rather than as an absolute signal.

Individuals high in vulnerability (N6) exhibited larger contrast effects, suggesting increased contextual sensitivity. Within predictive processing models, this may reflect heightened responsiveness to prediction error [39]. These findings support the view that psychological architecture influences the stability of evaluative processes during nociceptive challenge [40].

Modality Shift: From Text-Based Introspection to Behavioral Signatures

This study proposes a complementary assessment modality that integrates dynamic behavioral evaluation with established psychometric measures [29,30].

QST has long been a cornerstone of pain phenotyping [23,41,42]. Rather than replacing QST, our approach links dynamic QST-derived indexes to latent psychological traits within a large cohort.

By focusing on within-subject temporal change (C – A) and contextual contrast, we aimed to minimize reliance on absolute VAS magnitude, which is known to vary across individuals due to interpretational and response-style differences [27,28]. In this sense, dynamic evaluation patterns may serve as behavioral expressions of psychological structure.

Limitations

Several limitations should be acknowledged. First, while the five-factor model is widely used, it does not fully capture the dynamic and context-sensitive nature of personality. Alternative dimensional models (eg, the HEXACO model [43] or hierarchical models of affect regulation) may offer complementary perspectives. Second, although temporal augmentation was conceptually linked to central sensitization [14,23], we did not directly measure neurophysiological markers (eg, conditioned pain modulation [35,42,44,45] or spinal reflexes). Therefore, our behavioral indexes should be interpreted as proxies rather than definitive measures of central sensitization. Third, because the heating rate was 1 °C per second, the stimulation predominantly engaged C-fiber–mediated nociception [14,23]. Therefore, the findings may not generalize to A-delta fiber–mediated sharp pain paradigms. Fourth, as this was a cross-sectional study of healthy volunteers, longitudinal prediction of chronic pain development cannot be inferred [9,26,37]. Finally, although statistically significant, the observed effect sizes were modest, reflecting the multifactorial nature of pain modulation [5,6].

Conclusions

In conclusion, the findings suggest that dynamic pain evaluation patterns are associated with stable psychological substrates. By integrating personality facets, attachment models, and behavioral indexes derived from standardized experimental stimulation, this study contributes to the development of multimodal pain phenotyping frameworks [17,46,47].

Future longitudinal studies will be necessary to determine whether these behavioral signatures have predictive value for pain chronification [9,44]. These results provide a foundation for further investigation into how psychological architecture relates to dynamic nociceptive processing.

Acknowledgments

The authors acknowledge the support of the participants who took part in this study. Their invaluable time and contribution are greatly appreciated. This acknowledgment is made while strictly ensuring the anonymity of all individuals involved. Portions of this work, specifically the data presented under the Time-Dependent Modulation of Pain subheading in the Results section, were previously presented at the Japan Pain Week - Joint Conference (the 47th Japanese Association for the Study of Pain conference, 18th Japanese Association for the Study of Musculoskeletal Pain conference, 29th Japanese Association for the Study of Pain Rehabilitation conference, and 30th Japanese Society of Orofacial Pain conference) held from December 4 to 6, 2025, in Tokyo, Japan. The authors declare the use of generative artificial intelligence in the research and writing process. According to the Generative Artificial Intelligence Delegation Taxonomy (2025), the following tasks were delegated to generative artificial intelligence tools under full human supervision: (1) proofreading and editing and (2) translation and style adjustment. Gemini

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(Google) was used for these purposes. Responsibility for the final manuscript lies entirely with the authors. Generative artificial intelligence tools are not listed as authors and do not bear responsibility for the final outcomes.

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Data Availability

The datasets generated or analyzed during this study are not publicly available to ensure participant confidentiality and comply with ethical restrictions. However, they may be available from the corresponding author on reasonable request.

Authors' Contributions

Study conception and design and material preparation were performed by AN. Data collection and analysis were performed by CK. Data extraction was performed by HMB-O. The first draft of the manuscript was written by CK, and all authors commented on previous versions of the manuscript. All authors read and approved the final manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1
STROBE checklist.
[DOCX File , 29 KB - formative_v10i1e91540_app1.docx]

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Abbreviations

FDR: false discovery rate
IWM: internal working model
NEO PI-R: Revised NEO Personality Inventory
QST: quantitative sensory testing
TAI: temporal augmentation index
VAS: visual analog scale

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Original Paper

Mental Health Needs of Families of Patients in Intensive Care Units and the Role of Mobile Health: Survey Study

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Abstract

Background: The experiences of patients with COVID-19 and their families manifested the most devastating effects of family separation since the 1918 Spanish influenza pandemic and, with it, a call for solutions to patient isolation and its effect on family mental health.

Objective: This study examined the recent experiences of families of critical care (intensive care unit; ICU) patients related to anxiety and depression (AD), satisfaction with clinician-family communication, and counseling from mental health and social services. This study explored correlations between these factors and family interest in mobile health (mHealth) designed to improve information flow and communication from patient bedside to remote families.

Methods: Using a 36-question quantitative survey, we collected 97 responses over 6 months. We selected participants by using a convenience sampling strategy. To analyze data, we applied descriptive and inferential statistics. Participants represented a spectrum of ages, relationships to patients, and races (n=78, 80% White; n=17, 18% Black; n=2, 2% other races). Approximately 17% (n=16) of the patients were admitted for cancer, 13% (n=13) were admitted for COVID-19, and 21% (n=20) were admitted for other conditions.

Results: The mean score for remote families' satisfaction with patient health updates from the bedside and mental health services was 2.94 (SD 1.31), whereas that for phone communication was lower on average. The mean scores of family AD levels were elevated, and levels were higher among family members during the ICU stay than after discharge. These findings confirmed evidence of a negative correlation between transportation difficulties and satisfaction with the frequency of information provided (r=−0.284; P=.005), suggesting that, with the increase in transportation challenges, families become less satisfied with the frequency of patient health information. Family members expressed strong interest in using mHealth information and communication services (mean 8.34, SD 1.98) and having easy access to social workers to manage AD (mean 8.29, SD 2.03). Families experiencing higher levels of anxiety during patients' ICU stays had significantly greater interest in the use of an mHealth app that would provide direct access to social workers (r=0.326; P<.001), in using an mHealth videoconferencing app (r=0.319; P=.002), and in overall mHealth app use (r=0.322; P<.001).

Conclusions: Family members experienced high levels of AD during patient ICU admission, as well as after discharge even though their mental health challenges were reduced. Families were highly dissatisfied with the frequency of health updates, with lower satisfaction reported among those who faced difficulties arranging transportation or lived further from the hospital. Modest but statistically significant correlations were observed between family members' reported mental health status during ICU stays and an interest in an mHealth app that could provide access to real-time bedside information, facilitate communication with bedside nurses, and support connections with social workers.

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KEYWORDS

mental health; intensive care unit; ICU; communication; mobile health; COVID-19; health equity; health technology; digital tools; eHealth

Introduction

The experiences of patients with COVID-19 and their families in the intensive care unit (ICU) brought to the fore the most devastating effects of family (or caregiver) separation since the 1918 H1N1 Spanish influenza pandemic [1]. Today, even under the best of conditions, ICU patients and their families often experience uncertainty and heightened levels of confusion that inevitably produce increased psychological burden [2]. The ICU is a critical care facility dedicated to patients who need constant specialized bedside care [3], a situation in which the family members of patients develop high levels of anxiety and depression (AD).

Multiple studies show that this is due in part to a lack of timely medical updates and staff communication, especially if family members live in locations far from the point of care [4-6]. In particular, studies demonstrate that family members are more likely to develop anxiety, depression, posttraumatic stress disorder [7-9], and disruptions to family relationships [10,11] because of challenges surrounding less than optimal information flow from bedside to family members [12].

Other key factors impacting the mental health of family members of ICU patients include isolation from the patient [13-20], socioeconomic inequalities [21-23], and increased transportation needs due to interhospital transfers [24-26]. For example, during the COVID-19 pandemic [27], families encountered the suspension of ICU visitation rights and, as a result, experienced a high prevalence and severity of acute stress disorder even 3 months after patient discharge [8]. Researchers have argued that “during times of healthcare crises and the restriction of the physical presence of families, family support is more, not less, important” [28,29]. As a result, there is a need for increased communication between the ICU care team and family members, adopting “family-centered tools” that address restrictions on family access to patient health updates and communication [30-33].

Such tools might include family-centered digital solutions that provide relevant and easily accessible information from the bedside for family members. Research suggests that convenient ways to support families in their understanding of the real-time health status of patients might include mobile apps (mobile health; mHealth). Such interventional support would be specifically designed to safely and securely communicate patient health and wellness information to families, providing them with the greatest benefit to their mental health [34-36].

Researchers further argue that health care providers should explore mHealth as part of standardized care for patient families [37]. To address these challenges, digital communication interventions are one possible solution [38,39] to reduce the psychological burden on family members [40,41] with a loved one in the ICU. In support of this view, it is well documented in prior studies that particular mHealth apps have the potential to significantly reduce AD. For example, in one systematic review and meta-analysis, researchers observed 15 studies that reported on the positive effects of mHealth interventions on AD symptoms in patients with cancer, with the mHealth intervention group demonstrating a statistically significant improvement in AD compared to the control groups. The researchers concluded that their meta-analysis demonstrated the potential of mHealth interventions to significantly improve anxiety, depression, and quality of life in patients with cancer [42].

A second systematic review addressing the effects of mHealth, web-based, or virtual reality platforms on depression, anxiety, and enhancement of psychological well-being among college students found that the vast majority of studies reported that digital interventions were either effective or partially effective in producing beneficial changes in the main psychological outcome among students. The effectiveness of the intervention did not appear to substantially vary by type of digital mental health technology used, indicating that all held the potential for improving mental health on college campuses [43].

Another scoping study of 8 studies demonstrated the positive effect of mHealth to reduce mental health burdens among family members. The results showed decreased depression scores, with strong satisfaction with the accessibility and flexibility of mHealth combined with peer support features [44].

These well-documented studies suggest that mHealth has the potential to support higher patient and family satisfaction and the lowering of family member AD [45]. To this end, we designed this study to provide additional insight into the needs of families of critical care patients. Hence, the broad objective of this study was to assess to what degree increased access to ICU patient health information via mHealth or other forms of digital communication may serve as a strategic intervention to reduce AD among patients’ family members.

We present the current experiences of family members of ICU patients; gauged their interest in alternative communication solutions that would help lower their experiences of AD; and explored any associations among family interests in increased communication, family AD, and family satisfaction with current communication systems within the health care system.

This study was designed to answer the following 5 specific research questions (RQs):

- RQ 1: to what extent are family members satisfied with patient health information communicated by ICU medical staff?
- RQ 2: what is the prevalence of AD among family members during the patients’ stay in the ICU and after discharge?
- RQ 3: is there any relationship between the difficulty in arranging transport to and from the hospital and family

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members' level of satisfaction with the frequency of communication (RQ 3a) and AD (RQ 3b)?
- RQ 4: how interested are families in the use of a mobile app that sends patient health updates and allows for communication with nurses, social workers, and/or mental health counselors via SMS text message and/or video about the patients' health status?
- RQ 5: is there a correlation between family members' AD and their satisfaction with current communication with the critical care team?

Methods

Study Design

We collected quantitative data using a 36-question survey divided into six categories: (1) demographics (multiple choice; questions 1-2); (2) patient and family background, such as location and medical history (multiple choice; questions 6-15); (3) degree of AD and general mental health (sliding scale; questions 16-23); (4) quality and quantity of health care services and communication (sliding scale; questions 24-30); (5) degree of health inequity experienced while in the hospital (sliding scale; questions 31-33); and (6) degree of interest in the use of mHealth to facilitate better communication with the clinical staff (sliding scale; questions 34-36).

The Family Inpatient Communication Survey [46,47] and senior technology acceptance model survey [48], along with other published papers addressing family-centered care of patients [20,49-51], provided guidance in the development of our research instrument. After institutional review board approval, we prepared the questionnaire in the REDCap (Research Electronic Data Capture; Vanderbilt University) survey platform. The overall reliability of the scales used was assessed using the Cronbach α, yielding a coefficient of 0.758, indicating acceptable internal consistency.

All self-reported psychological constructs within the survey, such as anxiety, depression, satisfaction, and mental health, were left to each participant's interpretation based on their subjective experience of the terms. For example, one question asks the following: "How would you rate your anxiety after your family member was in the ICU?" Next to the question is a sliding scale with no numbers, ranging from "no anxiety" on the left to "highly anxious" on the right. Such terms were not operationalized or linked to existing standardized psychometric tools such as the Hospital Anxiety and Depression Scale or the Beck Anxiety Inventory [52].

Recruitment

For participant enrollment, we posted our survey aims and invitation with a URL on 16 social networking websites and Facebook community groups related to critical care and family-centered care. We also displayed posters at selected clinical sites on the University of Kentucky medical campus (Lexington, Kentucky) for further recruitment. Individuals were eligible to participate if they were (1) adults (aged ≥18 years) and (2) self-identified family members of critical care patients (in cardiac, pediatric, COVID-19, and cancer ICUs) admitted within the previous 2 years. Data collection lasted 6 months.

Sample Size

This research project was originally designed as a proof-of-concept study, where a limited sample would be sufficient to achieve our intended goals. Moreover, we experienced extraordinary challenges in obtaining responses. As such, we set the sample size at 100 using a convenience sampling method for participant recruitment. A post hoc sensitivity analysis was performed using G*Power (version 3.1). With a sample size of 100, an α level of .05, and statistical power set at 80%, the analysis demonstrated sufficient capacity to detect a medium effect size of r=0.28 (2 tailed). This indicates that the study was appropriately powered to identify moderate or stronger associations, aligning with the objectives of this pilot investigation. We received 97 responses in the end.

Data Analysis

We analyzed the data using the open-source statistical software Jamovi (version 2.7.9) [53]. Jamovi is a statistical software built on R (R Foundation for Statistical Computing). Standard significance levels were used throughout the analysis, with α=.05 as the threshold for statistical significance unless otherwise specified. To analyze the data, first, we examined the extent and pattern of missingness across variables. Jamovi excludes any row (case) that has missing data for one or more variables used in the analysis. The analysis was set to Jamovi's handling of missing data as the default. In addition to reporting descriptive statistics (eg, means, SDs, and frequencies), we conducted inferential statistical analyses to explore relationships and differences among variables.

We applied a paired-sample 2-tailed t test to identify differences in AD between ICU admission and postdischarge. Furthermore, correlation analyses were conducted to determine the strength and direction of relationships among transportation difficulties, satisfaction with the frequency of patient updates, mental health indicators (reported AD status), and family interest in mHealth solutions. However, because the data did not meet the assumptions of normality, nonparametric tests were used to assess differences (Wilcoxon W) and relationships (Spearman ρ) among variables. Further analysis details are provided in the Results section.

Ethical Considerations

This study was reviewed and approved by the institutional review board (approval 83549) at the University of Kentucky, Lexington, Kentucky, United States, in accordance with the principles of the Declaration of Helsinki. The participant population was from both within and outside the University of Kentucky. Outside populations were recruited through REDCap advertising networks and through the list of websites that specialize in participant recruitment. Researchers obtained an institutional review board waiver of documentation for the informed consent process. All participation was on a voluntary basis, with no compensation offered. Research presented no more than minimal risk to the participant because it involved only survey and interview questions and obtaining consent would increase the risk related to confidentiality based on the consent document being the only link to any personal health information.

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Results

Demographics

We used a nonprobability sampling technique, necessitating the collection of demographic information from family member participants. Patients spanned various age groups, with a notable concentration of those aged ≥31 years. The 97 individuals who responded to the survey represented a spectrum of ages, races, ICU patient disease types, and relationships to patients. The data showed a balance of both male and female patients. Race identification among family members was 80% (n=78) White, 18% (n=17) Black, and 2% (n=2) other races.

Regarding medical reasons for patient admission to the ICU, the percentage breakdown of the sample included cancer (n=16, 17%) and COVID-19 (n=13, 13%) as the most frequent, followed by pneumonia or infections (n=9, 9%), myocarditis (n=7, 7%), stroke (n=7, 7%), sepsis (n=7, 7%), accidents or injuries (falls, burns, cuts, or gunshot wounds; n=7, 7%), overdose or substance abuse (n=6, 6%), diabetes (n=3, 3%), meningitis (n=2, 2%), and other conditions (n=20, 21%). The largest group of patient relatives who spent time at the bedside were parents or guardians (n=34, 35%), followed by spouses (n=14, 14%), grandparents (n=12, 12%), and other relatives (n=37, 39%).

Normality of Data

We analyzed the normality of the data by using skewness and kurtosis tests for all dependent variables. Table 1 shows how the data were normally distributed. Values were within the threshold range for both skewness (–1 to +1) and kurtosis (–3 to +3) [54]. We supplemented the skewness and kurtosis statistics with formal normality tests, specifically the Shapiro-Wilk test, which is more appropriate for small to moderate sample sizes. To further support our assessment, we generated *Q-Q* plots for the main continuous variables used in parametric analyses. These plots were examined to identify deviations from normality that may not be evident in statistical tests alone. The Shapiro-Wilk test results and *Q-Q* plots showed deviation from normality; therefore, nonparametric tests were applied for inferential statistics. Figures 1-4 provide the *Q-Q* plots illustrating the data.

Figure 1. Q-Q plots of anxiety (A) and depression (B) during the patients' stay.

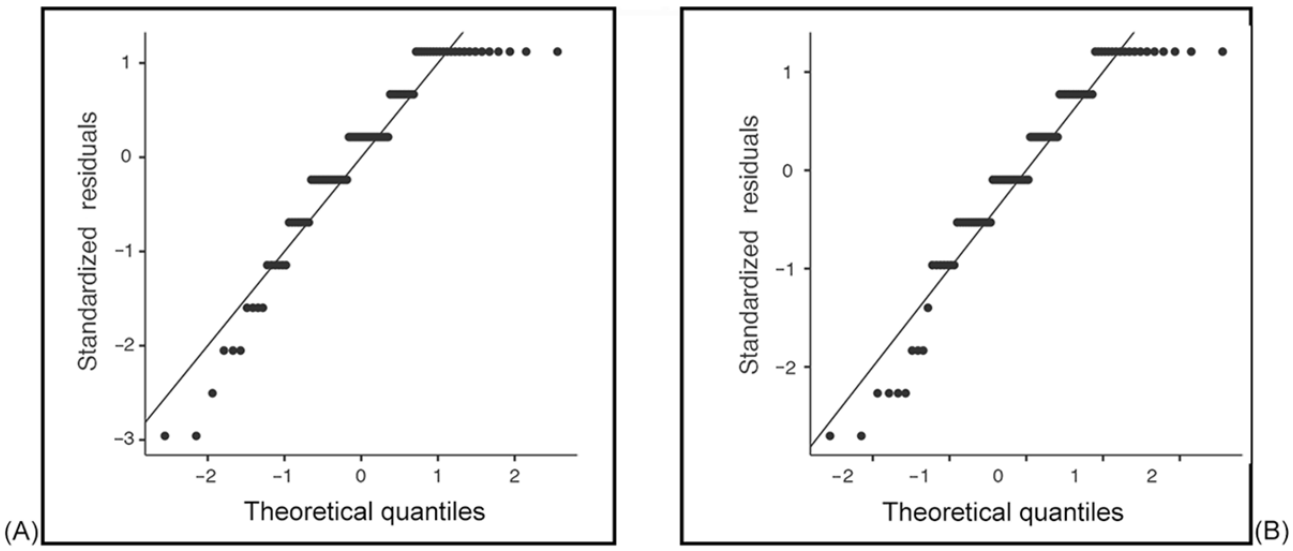

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Figure 2. Q-Q plots of satisfaction with the frequency of communication of medical information via telephone (A) and verbally (B) while families are in the intensive care unit.

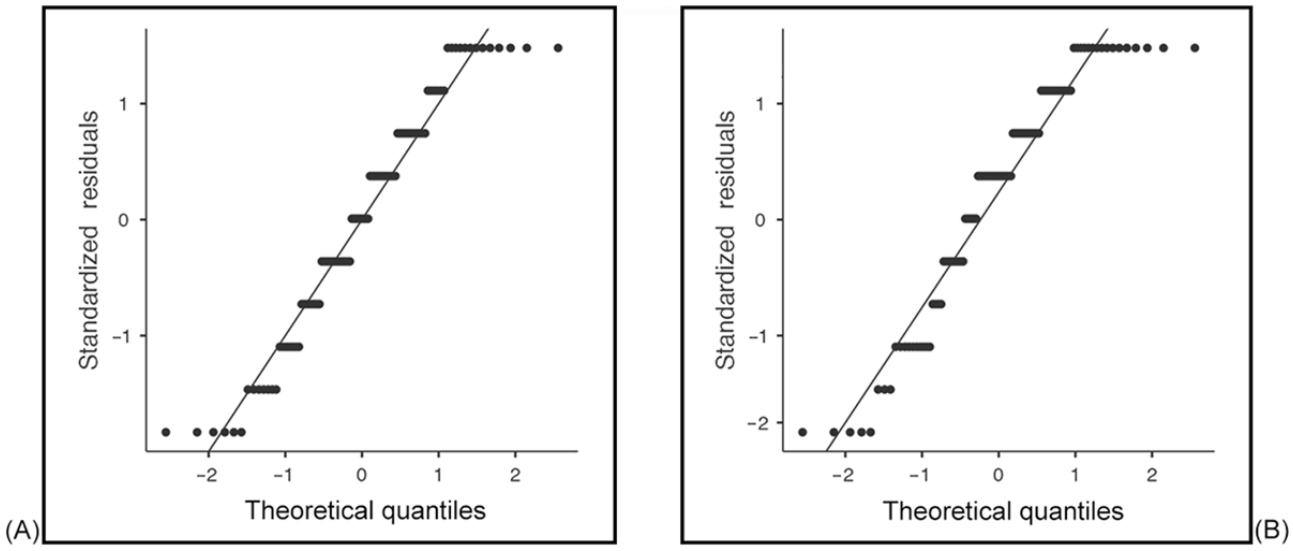

Figure 3. Q-Q plots of general interest in the use of mobile health (mHealth; A), an mHealth videoconferencing app (B), and an mHealth feature that connects family members with a social worker (C).

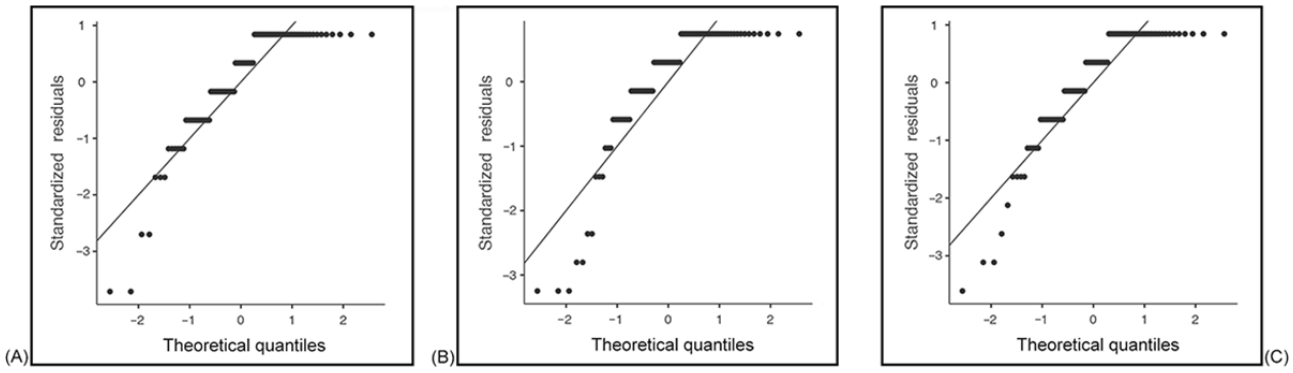

Figure 4. Q-Q plots of anxiety (A) and depression (B) after discharge.

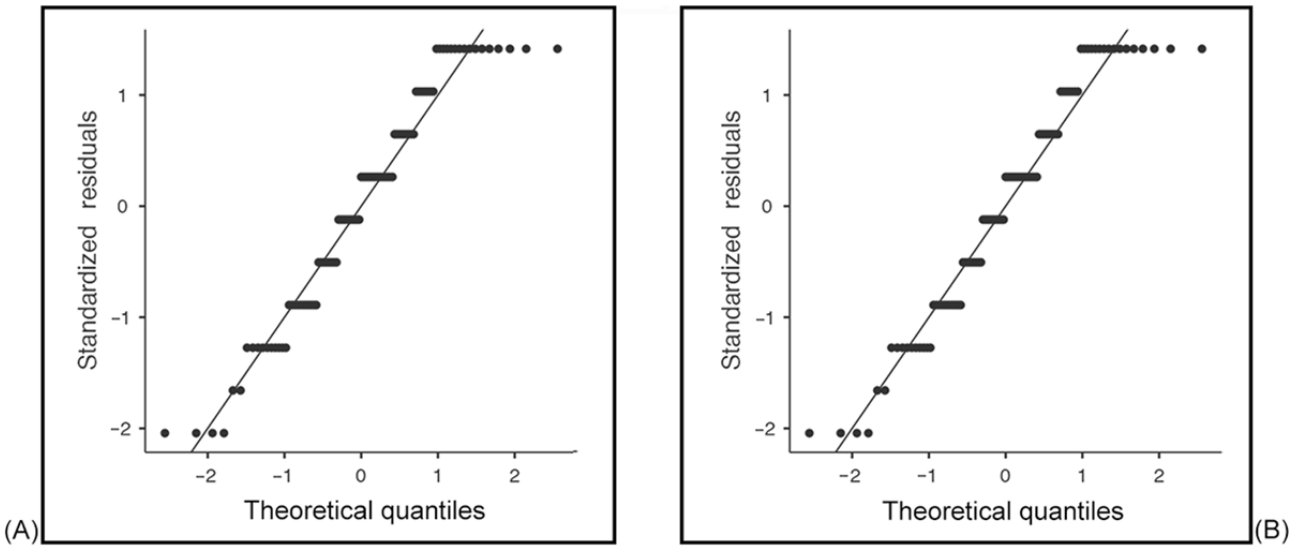

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Table 1. Data normality.

	Descriptive statistics		Skewness (SE)	Kurtosis (SE)	Shapiro-Wilk test	
	Participants (n)	Score (1-10), mean (SD)			Wilcoxon *W*	*P* value
Depression during the patients' stay in the ICU[a]	95	7.22 (2.30)	−0.84 (0.24)	0.31 (0.49)	0.91	<.001
Anxiety during the patients' stay in the ICU	95	7.53 (2.21)	−0.93 (0.24)	0.55 (0.49)	0.89	<.001
Depression after the patients' ICU discharge	95	6.32 (2.60)	−0.18 (0.24)	−0.92 (0.49)	0.94	<.001
Anxiety after the patients' discharge from the ICU	95	6.68 (2.38)	−0.48 (0.24)	−0.55 (0.49)	0.93	<.001
Satisfaction with the frequency of telephone medical information communication	95	5.98 (2.72)	−0.17 (0.24)	−0.96 (0.49)	0.94	<.001
Satisfaction with the frequency of medical information communication	95	6.62 (2.70)	−0.53 (0.24)	−0.77 (0.49)	0.92	<.001
Overall mHealth[b] app interest	95	8.34 (1.98)	−1.60 (0.24)	3.07 (0.49)	0.79	<.001
Interest in mHealth videoconferencing app	96	8.32 (2.25)	−1.84 (0.24)	3.07 (0.48)	0.74	<.001
Interest in mHealth app to connect with social workers	96	8.29 (2.02)	−1.50 (0.24)	2.32 (0.48)	0.81	<.001

[a]ICU: intensive care unit.

[b]mHealth: mobile health.

RQ 1 Results

RQ 1 addresses the degree to which family members were satisfied with available health information and communication provided by ICU clinical staff. The mean score of 2.94 (SD 1.31) on a scale from 1 to 6 shows that, on average, family members received updates once every 7 to 12 hours when away from the hospital (Table 2). Regarding the satisfaction level with the overall frequency of communication with the patients' family members, we observed a mean score of nearly 7 on average (mean 6.62, SD 2.70) on a scale from 1 to 10. Conversely, phone communication was lower on average. Furthermore, satisfaction with the mental health services provided by the hospital for family members was at a midpoint on a scale from 1 to 10 on average (mean 4.97, SD 2.90). Mental health services as defined in the survey included mental health counseling, social services, and clinical psychologists available to family members on request (Table 2).

Table 2. Scores for frequency of patient information communicated and satisfaction with the available patient information communicated, combined with the mental health services provided to the patients' family members.

Mental health services	Score, mean (SD)
Frequency of patient information communicated (n=97) [a]	
"How often were you updated by the ICU staff regarding your loved one (family member) health status when you were away from the hospital?"	2.94 (1.31)
Satisfaction with the available patient information communicated, combined with the mental health services provided to the patients' family members (n=95)[b]	
"How satisfied were you with the frequency of medical information being shared by the ICU nurses or doctors about your family member?"	6.62 (2.70)
"How satisfied were you with the frequency of phone communication the nurses had with your family while your family member was in the ICU?"	5.98 (2.72)
"Rate your satisfaction with the mental health services available to your family, when your family member was in the ICU, e.g., mental health counseling, social services, clinical psychologists?"	4.97 (2.90)

[a]Scale: 1="never," 2="once every 1-6 hours," 3="once every 7-12 hours," 4="once every 13-24 hours," 5="once every 25-48 hours," and 6="after more than 48 hours."

[b]Scale: 1="not satisfied"; 10="highly satisfied."

RQ 2 Results

RQ 2 addresses the level of AD among family members while their loved ones were in the ICU, as well as after discharge. Table 3 shows that the mean scores for AD were elevated (scale from 1-10). Anxiety was consistently higher than depression in both periods (Table 3). Levels of AD were higher among family members during the ICU stay than after discharge. To determine whether this difference was statistically significant, we conducted a paired-sample *t* test using the Wilcoxon *W*. The

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results confirmed a significant difference between AD levels of family members during the ICU stay and after discharge (Table 4).

Table 3. Mental health status of the family members during admission of their loved ones to the intensive care unit and after discharge.

	During admission, mean (SD)[a]	After discharge, mean (SD)[a]
Depression level	7.22 (2.30)	6.32 (2.60)
Anxiety level	7.53 (2.21)	6.68 (2.38)

[a]Scale: 1=low; 10=high.

Table 4. Comparison of anxiety and depression levels among family members during the intensive care unit stay and after patient dischargea.

	Wilcoxon *W*	*P* value	Effect size—rank biserial correlation
Anxiety during admission and after discharge	1479[b]	<.001	0.52
Depression during admission and after discharge	1844[c]	.001	0.44

[a]The alternative hypothesis states that the mean of measure 1 differs from the mean of measure 2 (ie, there is a nonzero difference between the 2 measurements).

[b]33 pairs of values were tied.

[c]24 pairs of values were tied.

RQ 3 Results

Prior research has established that there is difficulty in arranging transportation for family members to ICU clinical sites, which impacts their satisfaction level and frequency of receiving patient information, phone communication, and mental health services [55].

For RQ 3, we examined the correlation between difficulty arranging transportation and satisfaction with the frequency of shared information. Our findings confirmed evidence of a negative relationship between transportation difficulties and satisfaction with the frequency of information provided (r=−0.284; P=.005). This suggests that, as transportation challenges increase, families become less satisfied with the frequency of patient health information. The lack of frequent visits due to transportation issues may also suggest a heightening of AD and, subsequently, a stronger desire for more frequent updates to compensate for family members' inability to regularly visit the ICU.

RQ 3b examined the correlation between difficulty in arranging transportation and AD. As performing multiple correlation analyses increases the risk of type I error, the Benjamini-Hochberg procedure was applied to control the false discovery rate at α=.05. As all raw P values were identical and very small (P=.001), the Benjamini-Hochberg–adjusted P values were uniformly .002, which is well below the threshold. Therefore, all tests remained significant after false discovery rate correction, indicating strong evidence against the null hypotheses (Multimedia Appendix 1).

Unlike the correlation observed with satisfaction regarding communication of patient information, we found no significant correlation between transportation difficulties and anxiety (P=.15) and depression during the patients' ICU stay (P=.71). However, there was a positive correlation between anxiety levels and depression levels during the patients' ICU stay (r=0.550; P=.001). Additionally, AD levels experienced during the ICU stay were significantly and positively correlated with AD levels after patient discharge (Table 5).

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Table 5. Correlations among family members' anxiety and depression during patients' intensive care unit (ICU) stay and after patient discharge.

	Depression during the patients' stay in the ICU	Anxiety during the patients' stay in the ICU	Depression after the patients' discharge from the ICU	Anxiety after the patients' discharge from the ICU
Depression during the patients' stay in the ICU				
r	1	0.550	0.468	0.417
P value	—[a]	<.001	<.001	<.001
Anxiety during the patients' stay in the ICU				
r	0.550	1	0.528	0.528
P value	<.001	—	<.001	<.001
Depression after the patients' discharge from the ICU				
r	0.468	0.528	1	0.692
P value	<.001	<.001	—	<.001
Anxiety after the patients' discharge from the ICU				
r	0.417	0.528	0.692	1
P value	<.001	<.001	<.001	—

[a]Not applicable.

RQ 4 Results

Regarding RQ 4, we surveyed family members about their interest in new forms of mobile technology designed to improve information flow and communication from the ICU bedside to the family's location regarding their loved ones' health status. Table 6 presents data indicating that family members expressed strong interest in using such a service (mean 8.34, SD 1.98), connecting with bedside nurses via SMS text message and videoconferencing (mean 8.32, SD 2.25), and having easy access to social workers to help manage their AD (mean 8.29, SD 2.03; 1=least interest; 10=high interest).

Table 6. Interest in patient information communicated using a new mobile health appa.

	Participants (n)	Score, mean (SD)
"How interested would you be in a mobile app that provides better information and communication for families by sending regular patient health and wellness updates, while their loved one is in a critical care facility?"	95	8.34 (1.98)
"How interested would you be in a communication mobile app that gives families the ability to text or videoconference with the bedside nurse, while their loved one is in the ICU or another in-patient facility?"	96	8.32 (2.25)
"How much would you be interested in a communication mobile app that allows families the ability to connect directly to a social worker or mental health counselor, while their loved one is in the ICU or another in-patient facility?"	96	8.29 (2.02)

[a]Scale: 1=least interest; 10=high interest.

RQ 5 Results

RQ 5 explored the correlation among satisfaction with communicated patient information, AD experienced by family members, and interest in using an mHealth app. As performing multiple correlation analyses increases the risk of type I error, we applied the Benjamini-Hochberg false discovery rate correction (α=.05) to adjust for multiple comparisons. Adjusted *P* values (*q* values) are reported, and correlations with $q<0.05$ were considered statistically significant. Thus, we found it reliable to proceed with a multiple correlation analysis (Multimedia Appendix 2).

Spearman ρ outcomes revealed significant positive correlations among these variables ($P<.05$; Table 7). We discovered that families experienced higher levels of anxiety during patients' ICU stays and had significantly greater interest in the use of a mobile app that would provide direct access to social workers ($r=0.326$; $P<.001$), in using an mHealth videoconferencing app ($r=0.319$; $P=.002$), and in overall mHealth app use ($r=0.322$; $P=.001$). We also observed that family members who experienced higher levels of depression during ICU stays had significantly greater interest in SMS text message and videoconferencing communication with the bedside nurse ($r=0.297$; $P=.003$) and an app to connect with social workers ($r=0.214$; $P=.04$). Figure 5 provides a graphic review of the findings.

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Figure 5. Correlation among 3 variable groups. ICU: intensive care unit; mHealth: mobile health. *P<.05; **P<.01; ***P<.001.

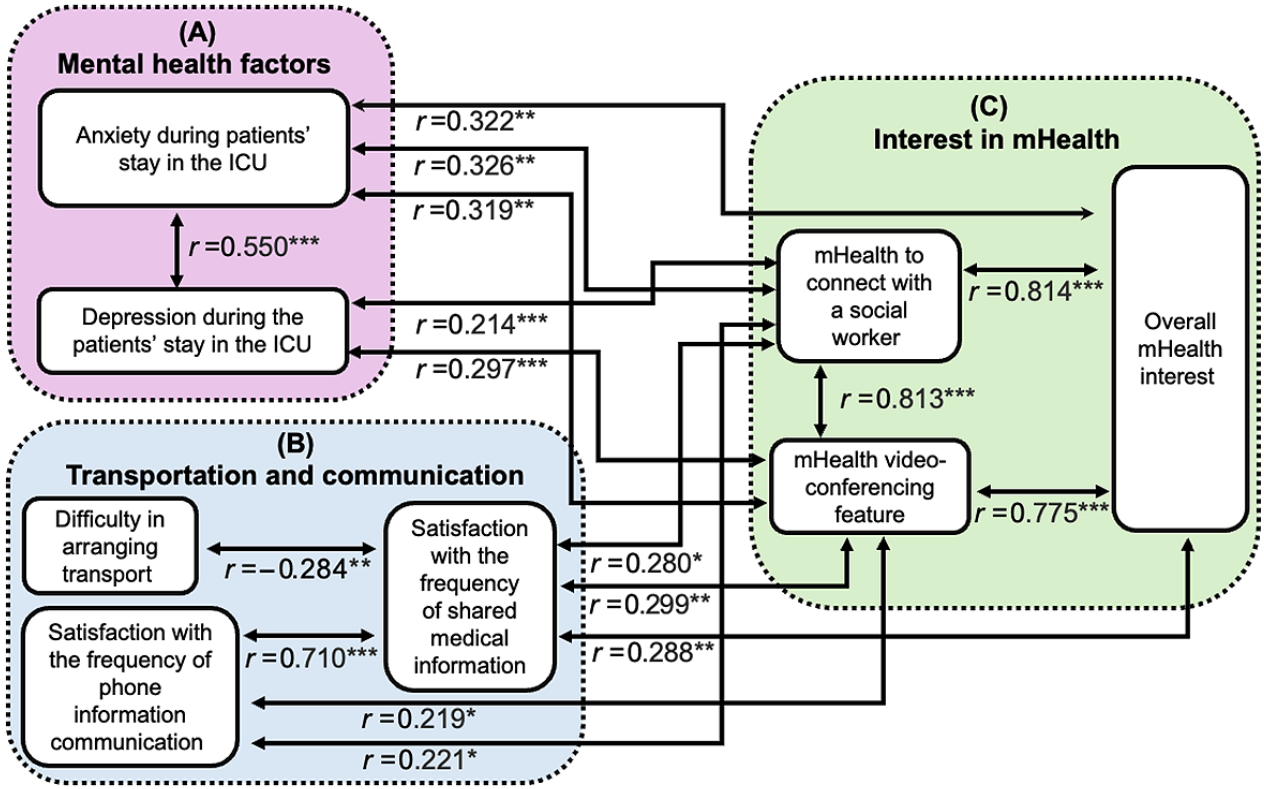

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Table 7. Correlation matrix of family members' anxiety and depression during patients' intensive care unit (ICU) stay, satisfaction with frequency of medical information communication, and interest in mobile health (mHealth) apps (n=93).

	Anxiety during the patients' stay in the ICU	Depression during the patients' stay in the ICU	Interest in app to connect with social workers	Interest in SMS text messaging or videoconferencing app communication	Overall mHealth app interest	Satisfaction with the frequency of telephone medical information communication	Satisfaction with the frequency of medical information communication
Anxiety during the patients' stay in the ICU							
r	1	0.550[a]	0.326[b]	0.319[b]	0.322[b]	0.024	0.064
P value	—	<.001	.001	.002	.001	.82	.54
Depression during the patients' stay in the ICU							
r	0.550[a]	1	0.214[c]	0.297[b]	0.196	−0.058	0.107
P value	<.001	—	.04	.003	.06	.58	.30
Interest in app to connect with social workers							
r	0.326[b]	0.214[c]	1	0.813[a]	0.814[a]	0.221[c]	0.280[b]
P value	.001	.04	—	<.001	<.001	.03	.006
Interest in SMS text messaging or videoconferencing app communication							
r	0.319[b]	0.297[b]	0.813[a]	1	0.775[a]	0.219[c]	0.299[b]
P value	.002	.003	<.001	—	<.001	.03	.003
Overall mHealth app interest							
r	0.322[b]	0.196	0.814[a]	0.775[a]	1	0.174	0.288[b]
P value	.001	.06	<.001	<.001	—	.09	.005
Satisfaction with the frequency of telephone medical information communication							
r	0.024	−0.058	0.221[c]	0.219[c]	0.174	1	0.710[a]
P value	.82	.578	.03	.03	.09	—	<.001
Satisfaction with the frequency of medical information communication							
r	0.064	0.107	0.280[b]	0.299[b]	0.288[b]	0.710[a]	1
P value	.54	.30	.006	.003	.005	<.001	—

[a]*P*<.001.

[b]*P*<.01.

[c]*P*<.05.

Similarly, we observed that satisfaction with phone communication from clinicians was positively correlated with direct access to social workers through mHealth (r=0.221; P=.03), use of an mHealth videoconferencing app (r=0.219; P=.03), and satisfaction with the frequency of medical information shared by the staff (r=0.710; P<.001).

We further confirmed that participants' interest in an mHealth videoconferencing app was significantly and positively correlated with overall mHealth app interest (r=0.775; P<.001). Interest in mHealth to connect with social workers was significantly and positively correlated with interest in an mHealth videoconferencing app (r=0.813; P<.001) and overall mHealth app use (r=0.814; P=.001). However, there was no correlation between satisfaction with health information communicated and AD.

Finally, our results indicate a positive correlation between satisfaction with the frequency of health information received and satisfaction with phone communication from medical staff (r=0.710; P<.001). The results further indicate that family members who were more satisfied with the frequency of communication were more interested in using an mHealth videoconferencing app for frequent updates (r=0.299; P=.003), using an app to connect with social workers (r=0.280; P=.006), and using an mHealth app for updates about their family members (r=0.288; P=.005).

Discussion

Principal Findings

Our findings confirm that family members experienced high levels of AD both during their loved ones' ICU stay and after discharge. Notably, AD levels were more pronounced while patients were in the ICU compared to after discharge. This heightened stress was especially evident during the first year of the COVID-19 pandemic, when many ICU patients died

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without a family member present, leading to increased stress levels among relatives [56]. Although AD can be significant during an ICU stay, the persistence of these issues after discharge, as reported in this study, raises serious concerns. This finding is further confirmed by another recent study reporting that family members exhibited symptoms of posttraumatic stress disorder for up to a year after their loved ones were discharged from the ICU [57].

We emphasize COVID-19 as a primary context for the issues raised due to the recent global impact it had on millions of families. While cancer as a reason for admission to the ICU was noted in 17% (n=16) of cases (COVID-19 constituting n=13, 13% of cases), there are over 200 types of cancer, with the National Cancer Institute identifying breast cancer, lung cancer, prostate cancer, colorectal cancer, bladder cancer, and melanoma as the most common. Due to the noncommunicable nature of these diseases, families do not experience the same types of mental health issues because they are often not isolated from their loved ones. Conversely, COVID-19, within a short period, brought to the fore the severe challenges of family-clinician communication and its impact on the mental health of families.

Our study indicated a maximum mean satisfaction level of only 6.62 (SD 2.70) on a scale from 1 to 10, reflecting a generally low level of satisfaction among family members regarding real-time communication. Difficulties in arranging transportation significantly affected their dissatisfaction with the frequency of updates. This difficulty may be attributed to the challenges of traveling to hospitals from remote areas. This finding aligns with those of previous research that suggests that the psychosocial status of family members can influence their satisfaction with communication.

Satisfaction with existing communication between clinical staff and family members of ICU patients led participants to express interest in a digital solution that could more readily provide real-time bedside health updates, as well as the ability to text and conduct videoconferences. This need was also highlighted during the COVID-19 pandemic, when visitation restrictions underscored the necessity of having alternative means of connecting family members with their loved ones. Virtual visitation via videoconferencing has been proposed as a solution, addressing the challenges faced by family members who struggled with the distance and time constraints associated with in-person visits [56,58].

Additionally, our study found that family members were not satisfied with the adequacy and availability of mental health counseling and social services provided by hospitals. This dissatisfaction further underscores an interest from families in an mHealth solution that facilitates virtual communication with social workers or mental health counseling, particularly for families of critical care patients.

In summary, our findings suggest that families were highly dissatisfied with the frequency of health updates provided by clinical staff, with lower satisfaction reported among those who faced difficulties arranging transportation or lived further from the hospital. Family members experienced high levels of AD during their loved ones' ICU admission as well as after discharge even though their mental health challenges were reduced.

In this study, modest but statistically significant correlations were observed between family members' reported mental health status (AD) during the patients' ICU stay and their interest in using an mHealth app. A similar association was found between participants' satisfaction with medical communication and their interest in a mobile app. Additionally, difficulty arranging transportation was negatively correlated with family members' satisfaction with the frequency of medical information sharing. Overall, family members expressed interest in a digital tool that could provide access to real-time bedside information, facilitate communication with bedside nurses, and support connections with social workers.

It is important to note that these findings are based on a nonrandom sample and reflect moderate correlations; therefore, they should be interpreted with caution. Rather than indicating strong evidence of effectiveness, the results suggest potential associations that warrant further investigation. Nonetheless, when considered alongside prior research emphasizing the value of structured interprofessional frameworks in hospital and ICU settings—particularly those using standardized digital tools and empathic communication strategies [59]—the findings highlight directions for future work.

Moreover, prior studies suggest that interventions aimed at mitigating the negative psychological impacts of hospitalization may be beneficial when initiated early during ICU admission. Remote or technology-mediated approaches may improve reach and engagement, whereas individuals with greater needs may benefit from longer or in-person interventions to ensure adequate support and reduce the risk of discontinuation [60].

Building on these insights, we propose that future research explore the development and evaluation of an mHealth intervention designed to support communication between family members and ICU bedside staff. Such an app could offer timely clinical updates and secure messaging or video communication within a HIPAA (Health Insurance Portability and Accountability Act)-compliant platform. Importantly, rather than replicating the limited access often associated with existing mobile electronic medical record services, a family-centered design could acknowledge the central role of family members in patient recovery. However, rigorous studies using randomized designs are needed to assess feasibility, effectiveness, and ethical considerations before such interventions can be recommended for widespread implementation.

Limitations of the Study

This study has several important limitations that should be considered when interpreting the results. First, our self-selecting sampling strategy may have introduced bias, potentially overrepresenting family members who were more comfortable with technology and, thereby, inflating interest in mHealth apps. Second, the sample size was limited due to the uniqueness of the population studied and the sensitivity of the topic (ie, family members may have found it difficult to fill out the survey due to the need to revisit a prior family event that was psychologically painful). Third, mental health status (AD) was

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self-reported and was not assessed using standardized scales. Considering these limitations, the findings may be interpreted as exploratory and may not be generalizable to all ICU family populations. Nevertheless, this study offers valuable insights into this important issue and identifies directions for future research.

Future Research

In parallel with this study, we recently completed a quasi-experimental pilot study that investigated the feasibility, usability, and efficacy of a newly developed mHealth app to reduce the AD of family members of critical care patients with cancer, with a focus on those living in rural Kentucky. This study recruited family members of patients in the Markey Cancer Center, Blood & Marrow Transplant and Cellular Therapy Program, University of Kentucky. As such, our ongoing research includes further mHealth app design, development, and clinical testing of this intervention in both critical care and other long-term health facilities (eg, nursing homes). The aim of this translational research is to provide bedside support to family members living in remote locations throughout Kentucky and Ohio.

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Data Availability

The datasets generated or analyzed during this study are available from the corresponding author on reasonable request.

Authors' Contributions

AF and SS conceived and developed the survey and the original manuscript, whereas AF, SS, and ZH refined and enhanced the final manuscript, with ZH providing his insights and expertise in critical care services and patient and family support. AF provided internal funding for data collection and obtained institutional review board approval. AF and SS developed the survey instrument, whereas SS reviewed and enhanced the instrument. AF and SS participated in data collection with the support of 2 student research assistants. SS conducted the data analysis. All authors have reviewed and agreed to the final version of the manuscript for submission.

Conflicts of Interest

None declared.

Multimedia Appendix 1

P values adjusted for multiple comparisons using the Benjamini-Hochberg procedure: correlation between difficulty in arranging transportation and anxiety and depression.

[DOCX File , 16 KB - formative_v10i1e75461_app1.docx]

Multimedia Appendix 2

P values adjusted for multiple comparisons using the Benjamini-Hochberg procedure: correlation among satisfaction with communicated patient information, anxiety and depression experienced by family members, and interest in using an mHealth app.

[DOCX File , 17 KB - formative_v10i1e75461_app2.docx]

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Abbreviations

AD: anxiety and depression
HIPAA: Health Insurance Portability and Accountability Act
ICU: intensive care unit
mHealth: mobile health
REDCap: Research Electronic Data Capture
RQ: research question

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Original Paper

Scaling Multimodal Agentic AI in Medical Education: Multisite Cross-Sectional Study of Simulation Effectiveness in Primary Care

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Abstract

Background: Conversational artificial intelligence (AI) systems offer potential solutions to traditional constraints in medical consultation skills training, including high costs, scheduling difficulties, and varied standardization. There is limited evidence evaluating medical professionals' perceptions of AI-generated patient interactions across multiple fidelity dimensions and assessing the educational value of conversational AI for consultation skills training.

Objective: This study aimed to evaluate perceptions of conversational AI patient simulations in primary care consultation training, examining functional fidelity, conversational realism, educational value, and implementation readiness.

Methods: A cross-sectional evaluation study at a UK medical school (medical students and general practitioners) yielded 47 grouped and individual responses. Participants completed standardized clinical scenarios using the SimFlow conversational AI system, a conversational AI system, followed by a multidomain questionnaire evaluating AI realism, medical content, educational value, feedback, and usability. Data were analyzed using the Wilcoxon signed rank test, Spearman correlation, and Firth logistic regression to assess domain performance and participant characteristics.

Results: Medical content received the highest ratings (median 4.5, IQR 4.0-5.0), with 97.8% (45/46) rating clinical plausibility highly. Educational value was rated positively (median 4.0, IQR 3.0-4.0), although AI realism received moderate scores (median 3.0, IQR 2.0-4.0). Participants with prior AI experience gave significantly higher ratings for AI realism than those without prior experience (mean 3.81, SD 0.63 vs 3.07, SD 0.72; P=.03). Concordance analysis demonstrated moderate-to-strong agreement between individual- and group-level domain rankings (mean Spearman ρ=0.685), supporting consistency between collaborative and individual survey evaluations. Qualitative analysis revealed 4 themes: clinical authenticity, interactional limitations, educational potential, and implementation considerations.

Conclusions: Conversational AI demonstrates strong capabilities in functional fidelity (clinical accuracy) despite limitations in conversational fidelity (realism). The technology shows promise as a supplementary tool for clinical skills training rather than higher-stakes assessment, with future development needed in dialogue naturalness and feedback capabilities.

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KEYWORDS

artificial intelligence; AI: medical; conversational; education; realism; clinical

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Introduction

Artificial intelligence (AI) is widely regarded as the suite of technologies that allow computers to perform tasks that resemble human abilities, including pattern recognition, decision-making, and content generation [1]. It has shown considerable promise in health care applications over recent years, with prospects for continued development in medical training contexts [2]. The integration of AI into medical education represents a significant development in health care training approaches, as traditional consultation skills training has long relied on human standardized patients and role-playing exercises. While these conventional methods remain valuable, they face notable constraints, including high costs, scheduling difficulties, and limited standardization across encounters [3].

Large language models (LLMs) and conversational AI systems have demonstrated notable capabilities across health care applications. These systems have shown the ability to pass standardized medical examinations such as the United States Medical Licensing Examination with performance levels approaching human benchmarks [4]. More sophisticated domain-specific models such as Med-PaLM2 have achieved expert-level performance on complex medical questions, indicating their potential for specialized health care applications [5,6]. These capabilities translate effectively into virtual patient simulations, where LLM-sourced avatars can provide authentic and professional patient scenario dialogue flows that enable realistic clinical interactions through large data–resourced models [7]. Multimodal technologies have quickly updated from basic text generation to systems capable of processing voice, text, and visual inputs.

Conversational AI using multimodal agentic systems designed for medical training offer several advantages over traditional methods of simulating patient interactions. They provide continuous availability, enabling students to practice consultation skills without the logistical constraints of coordinating with human actors. These systems can deliver standardized case presentations, ensuring learners encounter consistent scenarios and receive uniform training experiences. The scalability allows multiple simultaneous interactions, addressing resource limitations that have historically restricted access to hands-on practice opportunities [8]. Recent studies have demonstrated the practical application of these technologies, with research showing that medical students can effectively use readily available AI tools such as GPT-4o Advanced Voice Mode for challenging communication skills practice, finding the technology both useful and acceptable for supplementing traditional training methods [9]. Models can be developed for feedback that provides insights into clinical reasoning, language use, and response effectiveness [10]. Furthermore, AI-created feedback offers potential advantages over human supervisor feedback by providing detailed, criterion-based assessments with multiple verbatim quotations from transcribed clinical interactions, enabling personalized learning conversations [11].

Simulation fidelity encompasses multiple dimensions beyond visual and auditory realism, including psychological fidelity and functional fidelity that support specific learning objectives [12]. Understanding these different dimensions of fidelity is important for developing effective AI-based training systems, as research suggests that functional fidelity, the degree to which a simulation evokes targeted cognitive processes, may be more significant for learning outcomes than perfect physical or conversational realism [13]. The conceptual framework for how users interact with immersive technologies encompasses multiple interconnected domains, including engagement, system usability, and cognitive processes, that together influence the overall user experience and educational effectiveness [14].

Recent work has explored how AI can benefit simulation-based training through advanced assessment capabilities and adaptive learning approaches [15,16]. Current research on AI in medical education has primarily focused on knowledge assessment and content generation rather than interpersonal skills training through experiential learning approaches, though systematic reviews indicate growing evidence of AI's broader educational impact across health professions [17,18]. While studies have examined medical students' interactions with AI tutoring systems and assessment tools, there is growing recognition of AI's potential for supporting communication skills training in health care education, though limited research has evaluated how different dimensions of simulation fidelity impact learning outcomes in conversational AI applications for consultation skills development [19]. Training effectiveness and optimizing learning outcomes are becoming apparent, though questions remain about their readiness for widespread implementation [20].

The specific aims of this research were to (1) evaluate how medical professionals perceive the realism and clinical authenticity of AI-generated patient interactions across multiple fidelity dimensions, distinguishing between functional fidelity (clinical accuracy and medical content) and conversational fidelity (realism and flow); (2) assess the educational value of conversational AI for experiential learning in consultation skills training; (3) identify factors that influence user acceptance and perceived simulation effectiveness, particularly regarding the relationship between technical realism and functional educational outcomes; and (4) determine current readiness and implementation considerations for AI-constructed patient simulation in medical education curricula.

Methods

Study Design and Participants

We conducted a cross-sectional evaluation study of a conversational AI system designed for patient consultation training. Participants were recruited from a single UK university medical school incorporating 70 general practice sites using a census sampling approach. All medical students in their third year of study and general practitioners within these settings were invited to participate via email invitation during March 2025. Invitations were distributed by administrative education teams and included study information, participation instructions, and survey links. A retrospective protocol for this study, including the full methodology, questionnaire, and analysis

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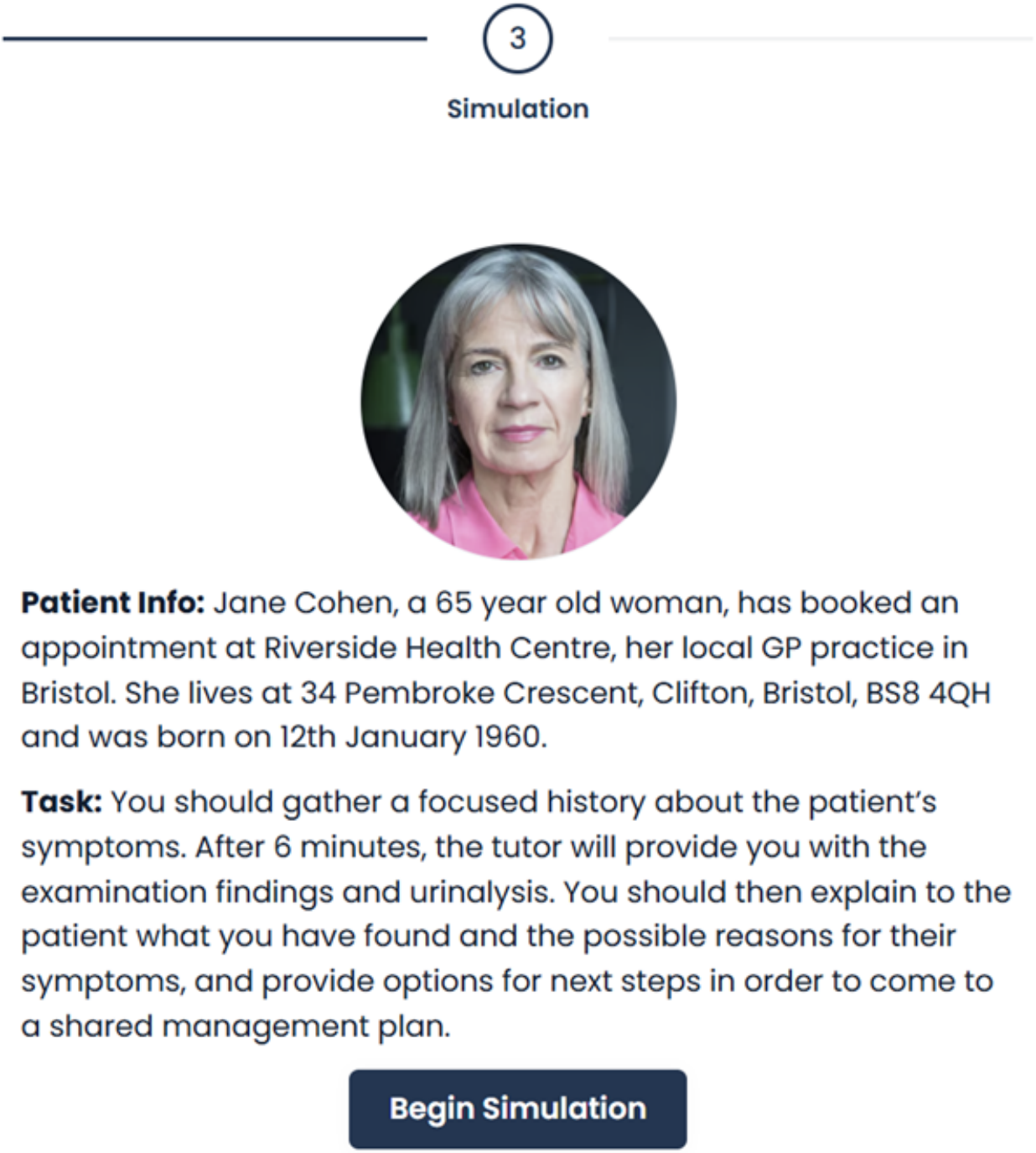
plan, was registered on the Open Science Framework prior to journal submission [21].

Procedure

Participants completed a standardized clinical scenario with a conversational AI system during a scheduled primary care training day. The simulation was delivered through the SimFlow.ai web-hosted platform (Figure 1), which operates within an institutional firewall-protected environment using single-stage authentication. The platform was accessed simultaneously by more than 70 participating teaching practices during a single morning session.

Figure 1. Screenshot of the SimFlow web-hosted conversational artificial intelligence patient simulation platform used during standardized primary care consultation training sessions across UK teaching practices (March 2025).



The simulated patient was powered by a proprietary fine-tuned OpenAI GPT model accessed via the OpenAI application programming interface. The deployed model configuration remained constant throughout the evaluation period (February to March 2025). Scenario-specific instructions and application-layer prompt engineering were applied to maintain a consistent simulated patient role and constrain responses within the intended educational context.

Inference parameters were fixed across all users. Temperature (model configuration parameter) was set to 0.7, and maximum response length was configured using a per–simulated patient character baseline cap to support different communication styles

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(eg, more reserved vs more talkative), with an average maximum of approximately 120 tokens. In addition, the deployment included a sentiment-adaptive dialogue component that monitored conversational cues and modulated response verbosity turn-by-turn within the character's configured bounds, supporting realistic variability across interactions. The system did not have access to internet browsing or external tools during consultations and relied solely on the current conversation context window acting as memory, with no external retrieval.

A synthetic voice engine generated an age-appropriate female voice matched to the demographic profile of the virtual patient. The AI operated in a one-way configuration in which user inputs were not stored or transmitted externally beyond the secure hosting environment. All sites undertook the same scenario, involving a primary care consultation with a woman in her 60s presenting with a first episode of visible hematuria. Learners were instructed to conduct the consultation as they would in routine clinical practice, including eliciting the history, identifying relevant red flag symptoms, and discussing appropriate investigation and management options.

The underlying prompt design was developed from a summarized version of the case-based learning materials used in the teaching session and mapped closely to the intended learning outcomes. This ensured that the virtual patient's history, symptom cues, and conversational structure aligned with established clinical reasoning expectations and supported the educational aims of the activity.

Prior to deployment, the scenario underwent face validity testing with practicing clinicians, medical educators, and individuals experienced in simulation design. Feedback from this process informed iterative refinements to the prompt, including clearer symptom cues, improved clinical accuracy, and more coherent conversational flow. Supporting materials for students and facilitators, including case notes, learning points, and debriefing guidance, were also reviewed for accuracy and curricular alignment.

The simulation was delivered in a facilitated training setting. Members of the academic team were present across participating sites remotely to support implementation and oversight. The simulated patient was constrained via scenario- and role-specific prompts, including separate guardrail instructions, to ensure responses remained within the simulation context. Outputs were monitored during the session, and transcripts were reviewable post hoc, enabling sessions to be paused and reviewed if required. No safety concerns were reported during deployment, and no clinically inappropriate outputs were observed during facilitator observation or post hoc transcript review.

Platform safeguards included role-based access controls, audit logging, and encryption in transit and at rest. OpenAI was used as a subprocessor under contractual safeguards, and user data were not used for model training within the service.

Data Collection

Following the consultation, participants completed a structured questionnaire evaluating the system across 5 domains (Multimedia Appendix 1): AI realism (6 items), medical content (2 items), educational value (3 items), feedback (2 items), and usability (2 items). Each item was rated on a 5-point Likert scale (1=strongly disagree to 5=strongly agree). A total of 3 open-ended questions captured qualitative feedback on the system's most realistic aspects, areas for improvement, and suitability for assessment purposes such as objective structured clinical examinations. Domains relating to engagement and system usability abridged from immersive technology in medical education measure (Immersive Technology Evaluation Measure) [22]. Furthermore, the working group pilot-tested for construct validity check. The overall questionnaire demonstrated excellent internal consistency (Cronbach α=0.92). Factor analysis supported the 5-domain structure, with internal consistency ranging from good (user experience: α=0.753) to excellent (feedback: Cronbach α=0.954 and learning value: Cronbach α=0.935), confirming the validity of the theoretical framework for evaluating conversational AI acceptability in medical education. Survey methods are reported using the Checklist for Reporting of Survey Studies checklist [23] (Multimedia Appendix).

Demographic information collected included professional role, years of clinical experience, and prior experience with conversational AI systems for medical training.

Data Analysis Plan

Quantitative data analysis was performed on 47 unique questionnaire responses, representing a mix of individual submissions and group consensus submissions. The unit of analysis was defined a priori as the completed survey instrument rather than the individual respondent. Surveys were completed either by individual participants or collaboratively by groups; where surveys were completed jointly, each group-completed survey was treated as a single data point. This approach reflects the level at which data were generated and avoids inappropriate assumptions of independence among contributors to group responses.

As this was an exploratory feasibility study, aggregated group responses were retained for analysis. The implications of this analytic decision, including limitations related to inference at the individual level, are acknowledged in the Discussion section.

Data cleaning and statistical analysis were conducted using R statistical software (R Foundation for Statistical Computing). Internal consistency of the questionnaire domains was assessed using Cronbach α. One-sample Wilcoxon signed-rank tests were used to determine if domain scores differed significantly from a neutral median of 3.0. Mann-Whitney *U* tests were used to evaluate subgroup differences based on professional role and prior AI experience. For odds ratio (OR) calculations comparing high ratings (≥4) between groups with and without prior AI experience, we used Firth penalized logistic regression. All statistical tests were 2-tailed, and a P value <.05 was considered statistically significant.

Qualitative analysis of open-ended survey responses was conducted using reflexive thematic analysis following the framework of Braun and Clarke [24]. A total of 2 researchers independently familiarized themselves with the data and generated initial codes. These codes were iteratively reviewed and collated into overarching themes regarding clinical

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authenticity, interactional limitations, and educational potential. Qualitative findings were triangulated with quantitative results to provide context for statistical trends, specifically regarding the divergence between medical content accuracy and conversational realism.

Patient and Public Involvement

Health care professionals and students were interviewed in the design process of the Immersive Technology Evaluation Measure survey [14,25]. During the evaluation, patients in 1 primary care practice were asked for their views on this training method. No objections were raised regarding the use of agentic AI to simulate conversations. Medical actors (n=34) were consulted about using AI in simulation, with 30 (88%) expressing a positive attitude toward involvement in future research on agentic AI.

Ethical Considerations

This study was approved by the Swindon Academy Medical Education and Ethics Committee Institutional Review Board (CJ062023). All participants provided voluntary informed consent after receiving a comprehensive explanation of the study. Data were anonymized, deidentified, and stored on a secure server. No compensation was provided for participating in the study.

Results

Participant Characteristics

From the eligible population of 305 health care professionals (n=245, 80.3% medical students and n=60, 19.7% general practitioners), the adjusted response rate was 61.3% (n=179). The final sample included evaluations from medical students (27/47, 57.4%), general practitioners (18/47, 38.3%), and specialist doctors (1/47, 2.1%). Most participants had clinical experience of either 1 to 2 years (17/47, 36.2%) or >11 years (14/47, 29.8%), with fewer in intermediate experience categories (3-5 years: 10/47, 21.3% and 5-10 years: 6/47, 12.8%). Only 12.8% (6/47) reported prior experience with conversational AI for medical training.

Quantitative Findings

Domain-Level Evaluation

Table 1 presents descriptive statistics for the 5 evaluation domains (additionally in Figure 2). Medical content received the highest ratings (median 4.5, IQR 4.0-5.0), with nearly all participants (45/46, 97.8%) rating the medical plausibility of the AI system highly. Educational value was also rated positively (median 4.0, IQR 3.0-4.0), though with greater variability in responses. AI realism received moderate ratings (median 3.0, IQR 2.0-4.0), with voice quality (median 4.0) scoring higher than other realism aspects (median 3.0). Feedback capabilities received the lowest consistent ratings (median 3.0, IQR 2.0-3.0).

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Figure 2. Domain-level participant ratings of conversational artificial intelligence (AI) simulation across fidelity and usability domains among medical students and general practitioners following participation in a standardized hematuria consultation scenario in UK primary care training settings (March 2025).

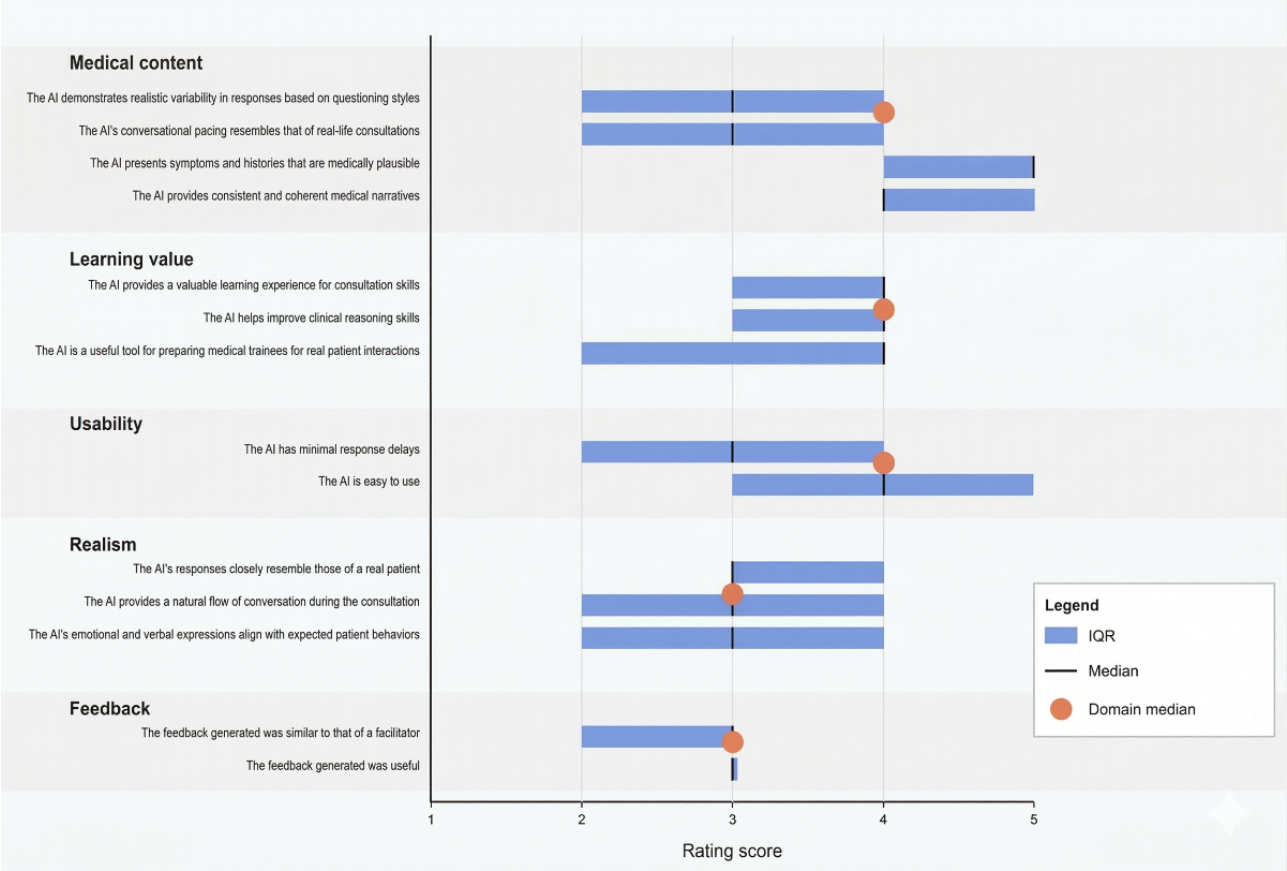

Table 1. Domain-level participant ratings of conversational artificial intelligence (AI) patient simulation across fidelity, usability, and educational value domains among medical students and general practitioners following completion of a standardized hematuria consultation scenario in UK primary care teaching practices (March 2025).

Domain	Value, median (IQR)	Value, range
Medical content	4.0 (4.0-5.0)	3-5
Learning value	4.0 (3.0-4.0)	1-5
User experience (usability)	4.0 (3.0-5.0)	2-5
AI realism	3.0 (2.0-4.0)	1-5
Feedback	3.0 (2.0-3.0)	1-5

On the basis of individual-level concordance analysis, 46.8% (22/47) of participants demonstrated high or very high agreement with the group findings (≥3 exact domain rank matches), with an additional 25.5% (17/47) showing moderate concordance (2 exact matches), and an average Spearman correlation of 0.685 (moderate-to-strong agreement; Figure 3).

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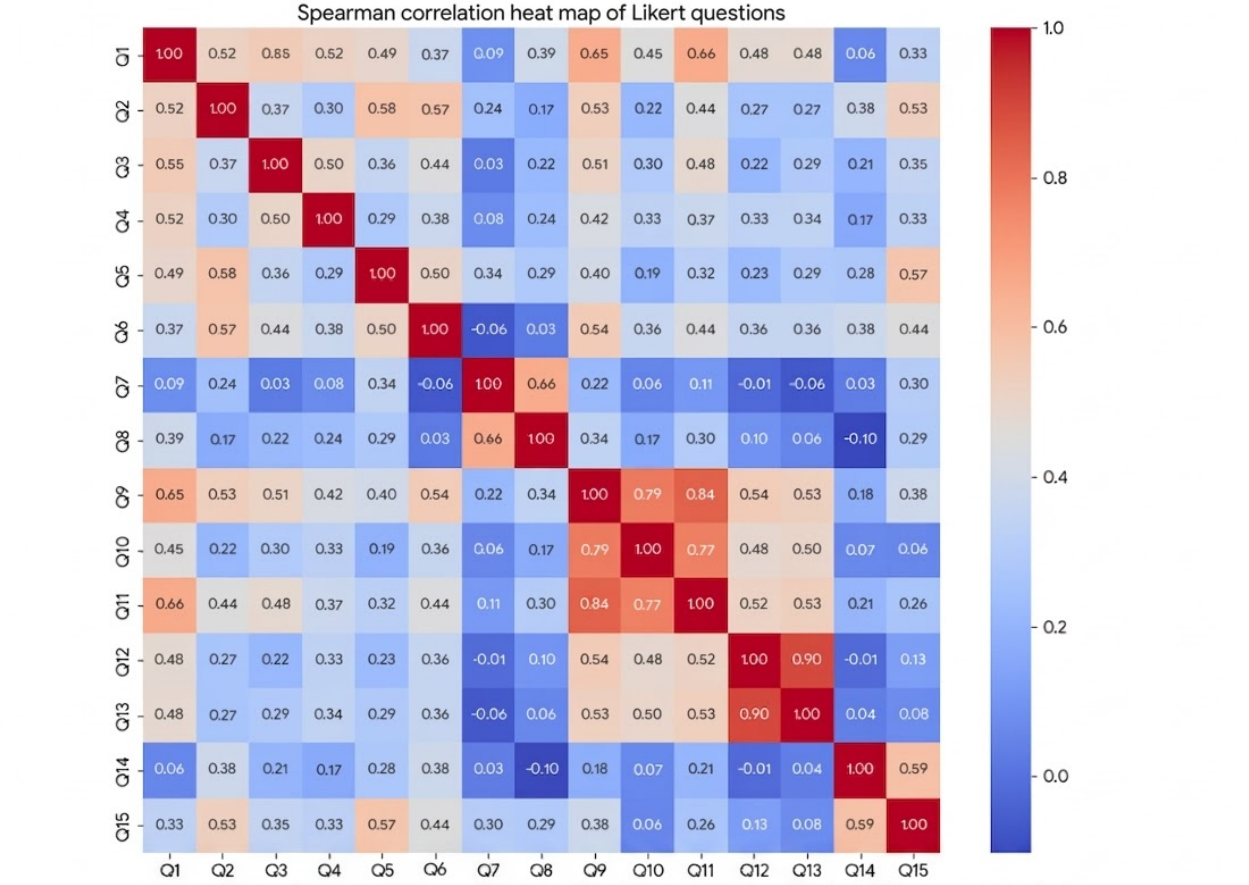
Figure 3. Heat map demonstrating correlation strength between questionnaire items evaluating conversational artificial intelligence simulation fidelity, usability, and educational value among medical students and general practitioners following participation in a standardized hematuria consultation training scenario in UK primary care teaching settings (March 2025).



Q1, AI responses resemble a real patient; Q2, natural conversation flow; Q3, emotional/verbal alignment; Q4, realistic response variability; Q5, voice sounds natural; Q6, conversational pacing; Q7, medically plausible symptoms; Q8, consistent/coherent narratives; Q9, valuable learning experience; Q10, improves clinical reasoning; Q11, useful preparation tool; Q12, feedback similar to a facilitator; Q13, feedback was useful; Q14, minimal response delays; Q15, easy to use.

Effect of Participant Characteristics

Prior AI experience (*expectation effect*) was associated with higher ratings for AI realism when analyzing mean scores (with experience: 3.81, SD 0.63; without experience: 3.07, SD 0.72; difference: 0.74; t_7=2.63; *P*=.03), as seen in Figure 4. In the OR analysis, participants with prior AI experience were more likely to give high ratings (≥4) for AI realism (OR 3.69, 95% CI 0.54-21.89) and user experience (OR 2.29, 95% CI 0.45-14.35), though these CIs included 1.0 (Table 2). For medical content, where near-ceiling effects were observed (100% vs 97.6% with high ratings), the OR was 0.48 (95% CI 0.02-73.37), with the wide CI reflecting the small sample size among participants with prior AI experience and limited variability in this domain.

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Figure 4. Logistic regression model demonstrating association between prior conversational artificial intelligence (AI) experience and probability of assigning high realism ratings to conversational AI patient simulation among medical students and general practitioners participating in a standardized hematuria consultation scenario in UK primary care training settings (March 2025). OR: odds ratio.

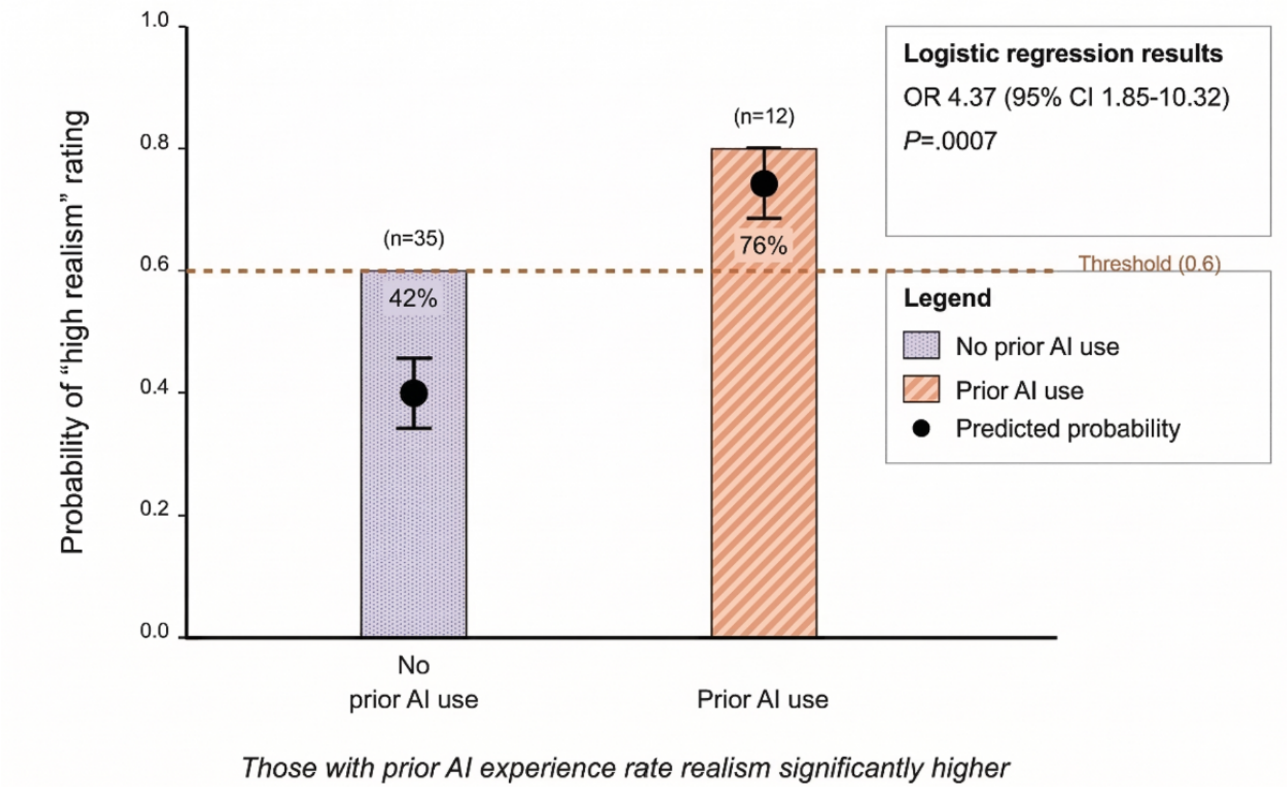

Table 2. Impact of prior artificial intelligence (AI) experience on domain scores among participants evaluating conversational AI patient simulation during a standardized primary care hematuria consultation training exercise in UK teaching practices (March 2025).

Domain	High ratings with AI experience (n=6), n (%)	High ratings without AI experience (n=41), n (%)	Odds ratio[a] (95% CI)
AI realism	2 (33.3)	5 (12.2)	3.60 (0.52-21.89)
User experience	4 (66.7)	18 (43.9)	2.56 (0.42-14.35)
Educational value	3 (50.0)	20 (48.8)	1.05 (0.19-5.50)
Feedback	1 (16.7)	7 (17.1)	0.97 (0.10-9.65)
Medical content	6 (100.0)	40 (97.6)	0.30 (0.02-73.37)

[a]Odds ratios derived using Firth penalized logistic regression.

Question-Level Analysis

The highest-rated individual item was "The AI presents symptoms and histories that are medically plausible" (median 5.0, IQR 4.0-5.0), followed by "The AI provides consistent and coherent medical narratives" (median 4.0, IQR 4.0-5.0). "Is easy to use" also received high ratings (median 4.0, IQR 3.0-5.0). The lowest-rated items were "The feedback generated was similar to facilitator" (median 3.0, IQR 2.0-3.0) and "has minimal response delays" (median 3.0, IQR 2.0-4.0). Table 3 and Figure 2 summarize these item results against a neutral baseline.

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Table 3. Item-level participant ratings of conversational artificial intelligence (AI) simulation fidelity, usability, and educational utility following participation in a standardized hematuria consultation scenario in UK primary care teaching settings (March 2025)a.

Domain or item	Value, median (IQR)	*P* value
Medical content (functional fidelity)		
Medically plausible symptoms (Q7[b])	5.0 (4.0-5.0)	<.001
Consistent or coherent narratives (Q8[c])	4.0 (4.0-5.0)	<.001
AI realism (conversational fidelity)		
Voice sounds natural (Q5[d])	4.0 (3.0-4.0)	.001
Responses resemble a real patient (Q1[e])	3.0 (3.0-4.0)	.43
Natural flow of conversation (Q2[f])	3.0 (2.0-4.0)	.76
Emotional or verbal alignment (Q3[g])	3.0 (2.0-4.0)	.58
Realistic response variability (Q4[h])	3.0 (2.5-4.0)	.33
Conversational pacing (Q6[i])	3.0 (2.0-4.0)	.89
Educational value		
Valuable learning experience (Q9[j])	4.0 (3.0-4.0)	.01
Improves clinical reasoning (Q10[k])	4.0 (3.0-4.0)	.02
Useful preparation tool (Q11[l])	4.0 (2.0-4.0)	.11
Feedback and usability		
Easy to use (Q15[m])	4.0 (3.5-5.0)	<.001
Feedback similar to a facilitator (Q12[n])	3.0 (2.25-3.0)	.17
Feedback was useful (Q13[o])	3.0 (3.0-3.0)	.21

[a]Statistical significance determined using 1-sample Wilcoxon signed-rank testing against a neutral midpoint rating of 3.0.
[b]Q7: medically plausible symptoms.
[c]Q8: consistent or coherent narratives.
[d]Q5: voice sounds natural.
[e]Q1: AI responses resemble a real patient.
[f]Q2: natural conversation flow.
[g]Q3: emotional or verbal alignment.
[h]Q4: realistic response variability.
[i]Q6: conversational pacing.
[j]Q9: valuable learning experience.
[k]Q10: improves clinical reasoning.
[l]Q11: useful preparation tool.
[m]Q15: easy to use.
[n]Q12: feedback similar to a facilitator.
[o]Q13: feedback was useful.

Qualitative Findings

Thematic analysis of open-ended responses revealed 4 key themes: clinical authenticity, interactional limitations, educational potential, and implementation considerations. Figure 5 summarizes the key themes and subthemes related to response.

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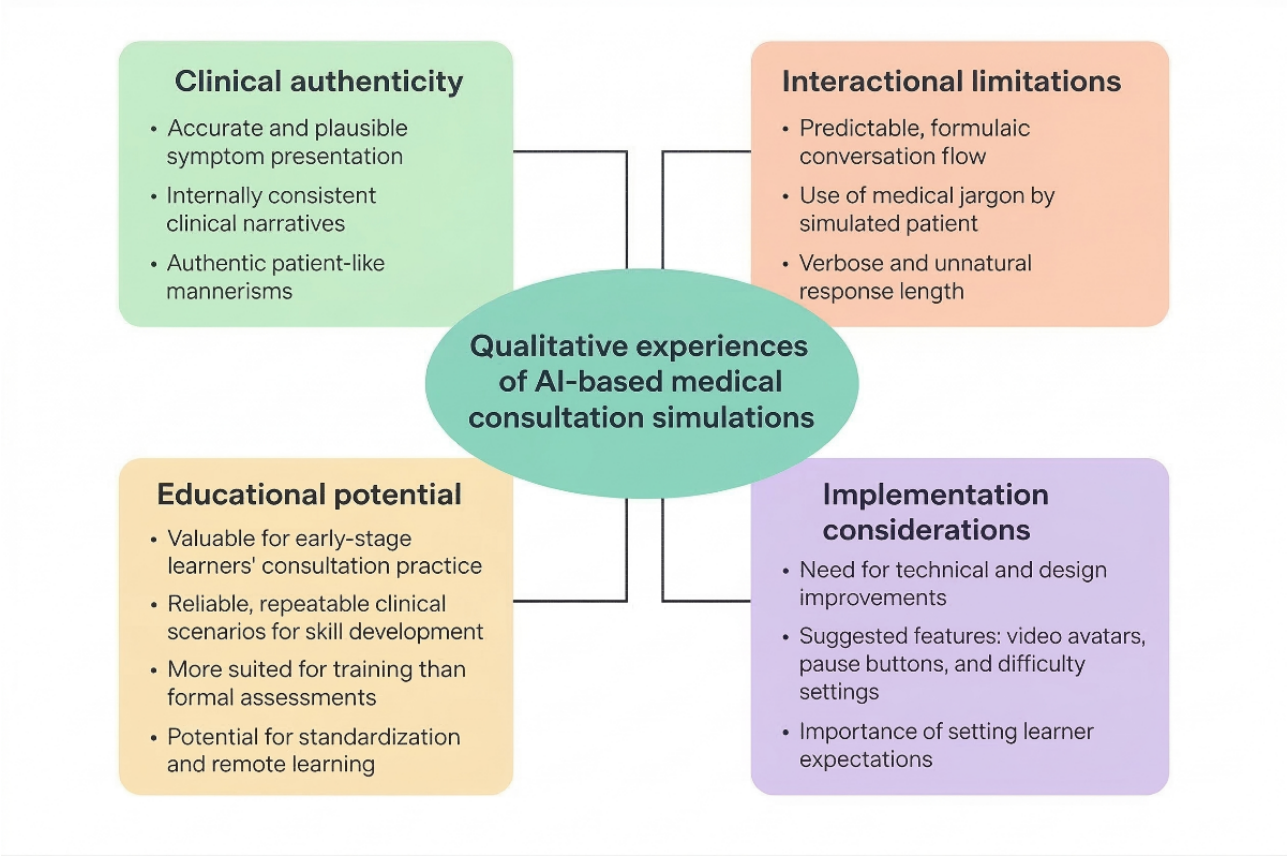
Figure 5. Thematic map illustrating qualitative themes identified from participant feedback regarding conversational artificial intelligence (AI) patient simulation following completion of a standardized hematuria consultation scenario in UK primary care teaching settings (March 2025).



Clinical Authenticity

This clinical reliability was frequently noted as the system's greatest strength, even when other aspects were criticized:

> *Mannerisms sounded human, plausible responses, given good history. Responding well to questions asked. Patient sounded appreciative and positive.* [Participant #18]

Many participants observed that the authenticity of clinical content partially compensated for conversational limitations, suggesting that strong medical accuracy might be more important than perfect conversational flow for educational applications.

Interactional Limitations

Participants frequently identified unnatural conversational patterns that diminished the realism of the consultation experience:

> *The AI answered almost every question with a question which disrupted the flow of the consultation. Almost every answer was followed by "is that what you'd expect"/"does that rule anything out" which became a bit repetitive and did not feel natural.* [Participant #1]

Educational Potential

Despite limitations, participants recognized significant training value, particularly for early-stage learners who need practice with basic consultation skills and clinical reasoning before engaging with real patients. The system's ability to provide consistent scenarios with reliable clinical presentations was seen as valuable for skill development:

> *Consultation skills—her answers were life like, as if talking to a real patient.* [Participant #25]

Implementation Considerations

Participants identified specific technical and design improvements needed before wider deployment, focusing on both technological limitations and pedagogical design elements that would enhance the educational experience:

> *1. Monologue 2. Information given too readily 3. Knew what question would be 4. Less prompt based and more response based.* [Participant #22]

Triangulation of Findings

Quantitative and qualitative findings showed strong convergence. The high ratings for medical content aligned with qualitative praise for clinical plausibility. Similarly, the moderate ratings for conversational aspects corresponded with qualitative feedback about unnatural dialogue patterns. The statistically significant difference showing that participants with prior AI experience gave higher realism ratings (t =2.63; P=.03) aligns with qualitative comments suggesting expectations influence perception of the system's capabilities.

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Discussion

Principal Findings

The system demonstrated high functional fidelity, with "medical plausibility" scoring significantly above the neutral baseline (median 5.0; $P<.001$). This confirms that current LLM-based simulations can effectively replicate the "medical logic" of a patient encounter. However, conversational fidelity (realism) remained statistically neutral (median 3.0). Participants did not actively reject the realism but perceived it as average, supporting the hypothesis that while the voice was excellent (median 4.0), the emotional and conversational flow lagged behind.

Qualitative analysis identified 4 key themes: clinical authenticity, interactional limitations, educational potential, and implementation considerations. Participants consistently praised the system's medical knowledge base and clinically accurate presentations, which partially compensated for conversational limitations.

Notably, prior experience with AI technology significantly influenced perception of system realism ($P<.05$), with experienced users rating realism higher (mean 3.60) than those without prior exposure (mean 3.07), highlighting a potential expectation effect.

Comparison With Other Studies

Our findings align with previous research on AI virtual patient simulation in health care education. Systematic reviews of LLM applications in medical training have similarly found that clinical accuracy and educational utility were rated more favorably than conversational ability in relation to human interaction [26]. The challenge of creating natural dialogue patterns in AI systems has been identified as a technical hurdle despite advances in foundation models [5,27].

The high ratings for medical content accuracy in our study correspond with findings from performance analyses of AI in adopting large datasets, which have documented capabilities in representing detailed information while highlighting limitations in naturalistic conversation [28]. Our findings regarding the high ratings for clinical content accuracy despite lower ratings for conversational realism reinforce important principles about simulation fidelity in health care education. Effective simulation does not require faithful replication of reality but rather accurate representation of essential cues and stimuli [12]. In our study, participants clearly distinguished between clinical plausibility and conversational authenticity, however, they still found significant educational value in the AI simulation. This supports that learning outcomes can be achieved without perfect fidelity in all dimensions [29,30]. Aspects of fidelity significantly hinge on the learners' perceived realism of the context of the learning episode as opposed to any one particular element.

LLM can perpetuate and amplify existing biases in datasets, which may explain our participants' observations of the AI's tendency toward medically precise but conversationally unnatural responses. Research shows that LLMs are primarily optimized for generating accurate informational content rather than simulating natural human conversation patterns [31]. This optimization bias helps explain our qualitative findings, in which participants noted that the AI system often answered questions with questions and produced verbose responses when simpler answers would have been more natural. This tendency to provide excessively detailed information reflects what has been described as a fundamental characteristic of current LLMs, which prioritize comprehensive information delivery over conversational naturalness. For medical education specifically, our participants' tolerance of these conversational limitations suggests that the educational value of accurate clinical content may outweigh the need for perfect conversational simulation. In a pilot study, similar conversational limitations in their virtual patient system were noted, including unusually formal language, repetitive answers, excessively long responses, and consistently polite demeanor. Latency is an ongoing limitation with current AI technology that incorporates humanlike voice [32], which is due to multiple systems working in tandem to provide the necessary computational steps from text transcription to voice creation [33,34].

There has been significant progress in the ability of LLM to accurately assess a wide range of clinical material [35-37]. Furthermore, the computational capacity exists to analyze the conversation transcription against a chosen framework or rubric [38]. Our findings on conversational AI feedback capabilities align with research on AI-generated educational feedback. In a study using a custom prompt for GPT-4 demonstrated how LLMs can be specifically tailored to educational objectives when guided by established pedagogical frameworks [39]. Similar to our results showing moderate feedback ratings (median 3.0, IQR 2.0-3.0), their study revealed variability in AI performance across different feedback dimensions. This suggests that while current AI systems can successfully incorporate elements of effective feedback principles, they still require refinement in consistently providing high-quality information about learner performance.

The "expectation effect" we observed, where prior AI experience influenced system perception, can be interpreted as technological readiness [40]. This phenomena may have influenced the perception of the conversation AI. In particular, our findings suggest improved realism with prior experience. Users with prior AI exposure develop more realistic expectations about system capabilities and limitations, leading them to evaluate performance relative to known technological constraints rather than human interaction standards [30]. Given the cross-sectional nature of the study and the potential influence of unmeasured factors such as digital literacy or baseline attitudes toward AI, these findings should be interpreted as associative and hypothesis generating.

Implications for Training

Our findings suggest several tentative implications for medical education. Conversational AI systems may have a role as supplementary, low-stakes tools for early-stage communication skills practice, offering consistent and accessible rehearsal opportunities prior to, or alongside, patient contact. While ratings for medical content and educational value were favorable, these should be interpreted in the context of moderate realism and limitations in conversational flow, indicating that current systems are not substitutes for human interaction.

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For medical educators, these systems may partially mitigate challenges in standardizing training experiences and providing equitable access to practice opportunities, particularly in settings with limited standardized patient resources or during disruptions to in-person teaching [3]. The ability to deploy multiple simultaneous interfaces (>70 in this study) demonstrates technical scalability, though its educational effectiveness at scale requires further evaluation before broader curricular adoption [41].

Content may compensate for realism despite the neutral ratings for conversational flow; the educational value remained significantly positive (median 4.0, IQR 3.0-4.0). This supports the theory that functional fidelity (the accuracy of the case) is more critical for clinical reasoning training than conversational fidelity (perfect chat flow). Learners appear willing to tolerate some *robotic* conversational traits provided that the medical signs, symptoms, and history are robust.

However, participants' distinction between the system's utility for practice vs assessment (noted in qualitative feedback) suggests caution in higher-stakes implementation. Recent commentary on AI assessment tools in health care education emphasizes that technology-enhanced learning tools should complement human instruction and assessment as an adjunct rather than replace them [42]. Transparency and disclosure of the fundamental nature of AI interactions help avoid misrepresentation of technological capabilities and cultivate an ethical approach and awareness of system biases [43].

Strengths

The study's unique methodology allowed for simultaneous testing with more than 70 AI interfaces in a single time window, demonstrating the system's scalability for large group teaching sessions.

The study also achieved a relatively high adjusted response rate (179/292, 61.3%), suggesting good engagement with the evaluation process [44]. The systematic evaluation across multiple domains using a structured questionnaire built upon validated measures provides a reliable framework for future studies in this area.

Limitations and Future Research

Several limitations warrant consideration. First, the study was conducted at a single institution that potentially limits generalizability. The uneven distribution of clinical experience among participants (bimodal distribution toward either 1-2 years or >11 years) may have influenced overall ratings. Importantly, surveys completed collaboratively may reflect group dynamics such as dominant voices, social desirability, or facilitation effects; although these responses were analyzed as single data points to avoid nonindependence, they may not be fully equivalent to individually completed surveys, and this could have influenced domain scores and subgroup comparisons. The cross-sectional design provides only a snapshot evaluation rather than longitudinal assessment of the technology's impact on learning outcomes or skill development.

The design and evaluation of AI-driven virtual platforms that focus on communication skills would benefit from greater stakeholder participation throughout the development process. Including input from diverse user groups, subject matter experts, educators, and industry professionals can provide valuable perspectives that enhance the relevance and effectiveness of these systems. Educational effectiveness can be explored with controlled studies that expand from co-designed learning approach. This collaboration ensures that the resulting platforms address actual communication challenges while incorporating real-world contexts and expectations that might otherwise be overlooked in purely technical development environments [8].

Building on the findings and these methodological limitations identified in this study, our research group is undertaking a prospectively registered program of work to further evaluate conversational AI–based simulation using analytically robust, prespecified methods [45]. The protocol accounts for the structure of simulation-based education, in which learners contribute repeated responses across multiple clinical scenarios and simulation modalities. Quantitative outcomes will be summarized with group-level comparisons (eg, AI-simulated patients vs actor-based simulation; medical students vs general practitioner educators). To address repeated measures and clustering, mixed-effects models were specified a priori, incorporating identifiers as random intercept and adjusting for station or scenario as a fixed effect. This modeling strategy is intended to preserve within-participant correlation, reduce bias arising from clustered educational delivery, and allow more precise attribution of observed differences to simulation modality rather than contextual variation. By embedding this statistical analysis plan within a prospectively defined research protocol, , the study aims to address the limitations of this study, improve reproducibility, and support scalable multisite evaluation of conversational AI in medical education.

Conclusions

This evaluation demonstrates that conversational AI systems for patient consultation skills training show promising capabilities in providing clinically accurate scenarios with educational value, despite limitations in conversational authenticity. The technology appears particularly suited for supplementary training in clinical skills development rather than high-stakes assessment. Future refinements for large-scale randomized studies should focus on enhancing dialogue naturalness and feedback capabilities while maintaining the strong medical content accuracy that participants valued most highly.

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for image generation of Figure 1. The GenAI tool used was GPT-4. Responsibility for the final manuscript lies entirely with the authors. GenAI tools are not listed as authors and do not bear responsibility for the final outcomes.

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There were no sources of funding for this study other than the free use of the web-based platform for the purposes of the study.

Data Availability

Anonymized data are in the Multimedia Appendix 1.

Authors' Contributions

Conceptualization: CJ
Data curation: CJ
Formal analysis: CJ, HJ
Investigation: CJ, RJ, TT, KB
Methodology: CJ, HJ
Project administration: KB
Resources: CJ, HJ
Software: CJ, HJ
Supervision: RJ, TT
Validation: CJ, HJ
Visualization: CJ
Writing – original draft: CJ
Writing – review and editing: CJ, RJ, TT, KB, HJ

Conflicts of Interest

Authors have no financial relationship with SimFlow.ai but received nonfinancial support in the form of platform access; the developers did not have access to any data collected and were not involved in analysis.

Multimedia Appendix 1
Anonymized data.
[XLSX File (Microsoft Excel File), 12 KB - formative_v10i1e88905_app1.xlsx]

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Abbreviations

AI: artificial intelligence
LLM: large language model
OR: odds ratio

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Original Paper

Trends in Internet Infrastructure Development and Online Health Use in China: 10-Year Descriptive Longitudinal Study

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Abstract

Background: Despite the rapid expansion of internet infrastructure and digital health initiatives in China, there remains a lack of longitudinal, nationally representative analyses that track the concurrent development of general internet access and the specific adoption of online health services over the past decade. Understanding these parallel trends is crucial for evaluating the reach and equity of the ongoing digital health transformation.

Objective: The aim of this study was to describe decade-long trends in internet infrastructure development and online health service adoption in China through a comprehensive secondary analysis of nationally representative, publicly available survey data from 2014 to 2025.

Methods: Data were retrieved from the official website of the China Internet Network Information Center for the period from June 2014 to June 2025. The study was conducted in 31 provinces, autonomous regions, and municipalities, excluding Hong Kong, Macau, and Taiwan. The participants were citizens aged 6 years and older who had a telephone or mobile phone. The China Internet Network Information Center conducted a stratified 2-stage sampling survey using a computer-aided telephone access system.

Results: From 2014 to 2025, an increasing trend was observed in the number of internet users and the internet penetration rate in China. It also showed an upward trend in the number of internet users, both in urban and rural areas. A consistent increasing trend was detected in the number of mobile internet users. In contrast, desktops and laptops showed a declining trend. The number of online health users in China showed a V-shaped change from 2020 to 2025. In June 2025, the total number of online medical users reached approximately 393 million, representing 35% of all internet users.

Conclusions: This decade-long observational study demonstrates sustained and significant growth in internet access across China, accompanied by a substantial rise in online health service adoption. A notable V-shaped trajectory in online health use emerged after 2020, indicative of a rapid COVID-19 pandemic–driven acceleration followed by market consolidation. The converging trends of near-universal smartphone-based access and the massive popularity of mobile-centric services, such as short videos, have fundamentally reshaped the digital landscape. Consequently, the findings suggest that for digital health strategies to achieve broad impact, policymakers and health care providers could consider prioritizing the integration of health promotion and services into existing high-penetration mobile platforms and communication formats that the population already uses daily.

(JMIR Form Res 2026;10:e86714) doi:10.2196/86714

KEYWORDS

internet; internet trends; online health; online health users; China

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Introduction

With the rapid development of the economy and internet technology in China, the internet has become deeply embedded in the social fabric, serving as a vital platform for diverse activities. At the end of 2022, there were 3.53 billion mobile Internet of Things terminal connections in China, reflecting the extensive infrastructure supporting the Internet of Things [1]. Concurrently, the health care sector has undergone a significant digital transformation. Following the formal regulation of internet hospitals by the National Health Commission in 2018, these platforms have proliferated, providing essential services for consultation, chronic disease management, and health education [2,3]. This transformation aligns with global trends in digital health integration and has been accelerated by specific national policies aimed at promoting "internet and health care" [4]. Research has begun to document the positive impacts of such digital health interventions, including improved patient self-management and clinical outcomes in conditions such as diabetes [5,6].

However, existing literature often examines internet development and digital health adoption separately. Studies on national internet penetration typically focus on access disparities and device use [7,8], while evaluations of online health services are frequently confined to specific clinical settings, patient groups, or short-term periods following policy changes [5,6,9]. A comprehensive, longitudinal perspective that links the foundational trends of general internet accessibility and use with the emergent trajectory of population-level online health service adoption remains lacking. This disparity restricts the capacity of policymakers and health care providers to formulate strategies according to how the development of digital infrastructure directly facilitates or restricts digital health equity and accessibility.

Therefore, to bridge this gap, this study aimed to conduct an integrated 10-year observational analysis (2014-2025) to describe the parallel trends of internet development—encompassing penetration rates, urban and rural distribution, and access devices—and the adoption of online health services among the general population in China.

Methods

Data Source

Data were obtained from the official website of the China Internet Network Information Center (CNNIC) from June 2014 to June 2025. This study was conducted in 31 provinces, autonomous regions, and municipalities, excluding the Hong Kong Special Administrative Region, Macao Special Administrative Region, and the province of Taiwan. This study was a secondary analysis of data from the Statistical Survey Report on Internet Development in China, published semiannually by the CNNIC. The CNNIC survey was designed to measure internet access and use patterns among the Chinese population aged 6 years and above. It used a stratified 2-stage random sampling method via computer-assisted telephone interviewing. The survey measured (1) basic internet access (penetration), (2) devices used for access (eg, smartphones and computers), (3) purposes of internet use (including communication, video, online payment, and since 2020, online health services), and (4) user demographics (urban or rural, age, etc). The data were weighted to represent national and provincial estimates.

Ethical Considerations

This study used data exclusively from the publicly released Statistical Report on Internet Development in China by CNNIC. The data were aggregated and anonymized without any personally identifiable information. The research did not involve direct interaction with human participants and interventions or the collection of sensitive personal information. In accordance with the policies of the institutional review board of Ningbo Medical Center Li Huili Hospital, secondary analysis of publicly available, fully anonymized data are exempt from ethical review (KY2023ML047).

Definitions

In this study, an internet user was defined as a resident aged 6 years and older who had used the internet in the past 6 months.

The internet penetration rate is defined as the number of internet users divided by the total resident population of the corresponding region (national, urban, or rural), expressed as a percentage.

Rural and urban users refer to internet users who have mainly lived in rural or urban areas of China in the past 6 months.

Data for specific devices (smartphones, desktops, etc) and services (instant messaging, short video, etc) were extracted directly from CNNIC reports.

Online health users were defined as individuals who prefer to search for health care–related activities via the internet. These activities primarily include online medical and follow-up consultations, medication delivery, health management, and health education.

Statistical Analysis

We conducted a longitudinal descriptive analysis of national aggregated data. All data on user numbers were extracted directly from CNNIC reports without modification. Calculated indicators, specifically internet penetration rates (derived from user numbers and corresponding population estimates), were presented rounded to 1 decimal place. Core variables included total users, penetration rates, and urban-rural distributions from 2014 to 2025. All data were analyzed using descriptive statistics and visualized through time-series plots.

Annual growth rates were calculated as the percentage change in numbers between consecutive time points, using the following formula:

Where N_t represents the number of users at time t.

Urban-rural disparity was quantified using both absolute and relative measures:

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Absolute gap = urban penetration rate – rural penetration rate **(2)**

Relative gap = urban penetration rate / rural penetration rate **(3)**

The V-shaped trend in online health users (2020-2025) was characterized by comparing user counts at 3 key points—initial (2020), nadir (2023), and final (2025)—and calculating the percentage change between these points. All analyses were performed using R software (version 4.2.1; R Foundation for Statistical Computing) and RStudio (version 2023.06.1; Posit Software, PBC).

Results

Trends in Internet Development in China

From 2014 to 2025, an increasing trend was observed in the number of internet users and the internet penetration rate in China. As of June 2025, 1123 million individuals had access to the internet in China, with an internet penetration rate of 79.7% (Table 1).

Table 1. Development of the internet in China from 2014 to 2025.

Month and year	Internet users (million), n	Internet penetration rate (%)
June 2014	632	46.9
December 2014	649	47.9
June 2015	668	48.8
December 2015	688	50.3
June 2016	710	51.7
December 2016	731	53.2
June 2017	751	54.3
December 2017	772	55.8
June 2018	802	57.7
December 2018	829	59.6
June 2019	854	61.2
March 2020	904	65.4
June 2020	940	67.0
December 2020	989	70.4
June 2021	1011	71.6
December 2021	1032	73.0
June 2022	1051	74.4
December 2022	1067	75.6
June 2023	1079	76.4
December 2023	1092	77.5
June 2024	1099	78.0
December 2024	1108	78.6
June 2025	1123	79.7

Internet Users in Urban and Rural Regions

In China, the number of internet users has shown an upward trend over the past decade, both in urban and rural areas. By June 2025, there were 801 million internet users in urban areas, corresponding to a penetration rate of 84.9%. The number of internet users in rural areas stood at 322 million, which is less than that in urban areas. Rural areas had a penetration rate of 69.2%. Although there was an obvious disparity in the internet penetration rate between the urban and rural regions, the gap gradually narrowed over time (Figure 1).

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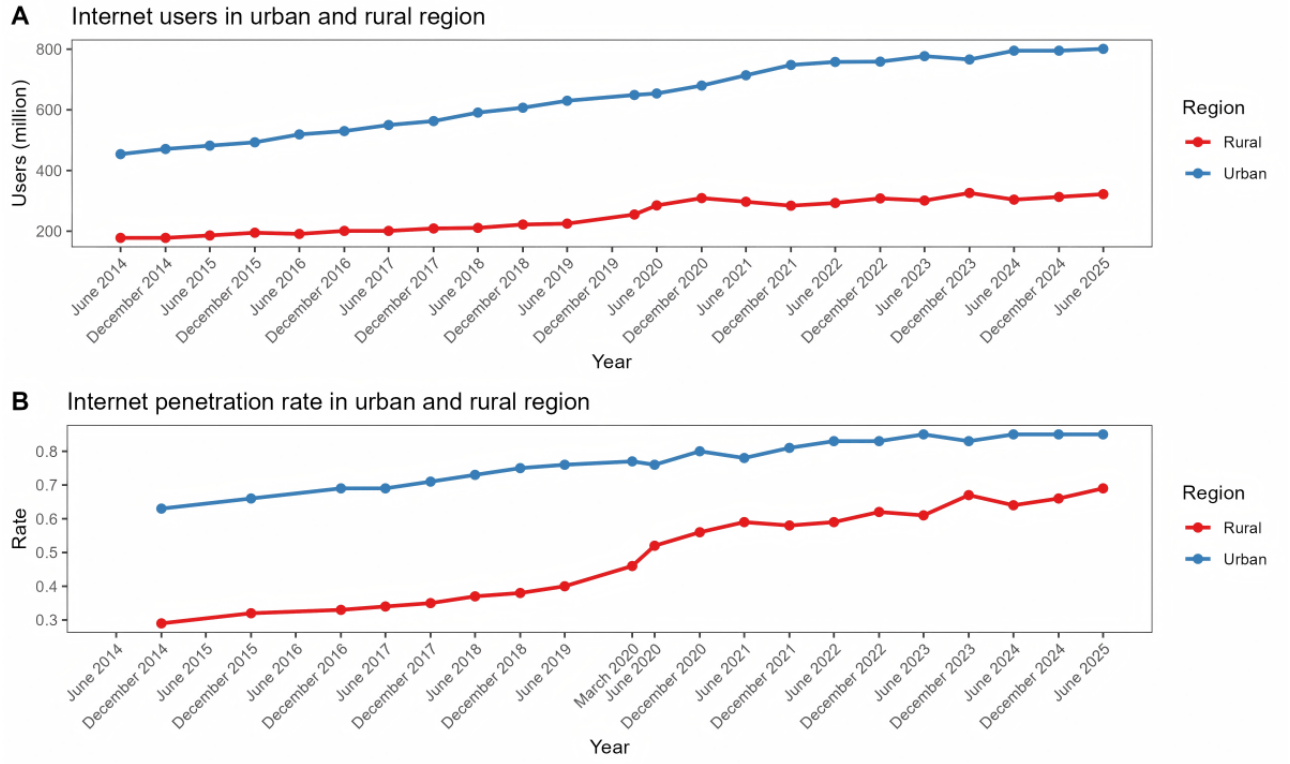
Figure 1. Internet users and the internet penetration rate in urban and rural regions.



Devices for Internet Access Among Chinese Residents

In China, internet users access the internet via various devices, mainly mobile phones, televisions, desktops, and laptops. From 2014 to 2025, a consistently increasing trend was detected in the number of mobile internet users. In June 2025, smartphones were used by almost all internet users for access. In contrast, desktops and laptops showed an overall declining trend. The use rate of accessing the internet through televisions initially increased and then declined gradually after 2019 (Table 2).

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Table 2. The penetration rate of different internet access devices in China.

Month and year	Mobile phone (%)	Television (%)	Desktop (%)	Laptop (%)
June 2014	83.4	__[a]	69.6	43.7
December 2014	85.8	15.6	70.8	43.2
June 2015	88.9	16.0	68.4	42.5
December 2015	90.1	17.9	67.6	38.7
June 2016	92.5	21.1	64.6	38.5
December 2016	95.1	25.0	60.1	36.8
June 2017	96.3	26.7	55.0	36.5
December 2017	97.5	28.2	53.0	35.8
June 2018	98.3	29.7	48.9	34.5
December 2018	98.6	31.0	48.0	35.9
June 2019	99.1	33.1	46.2	36.1
March 2020	99.3	32.0	42.7	35.1
June 2020	99.2	28.6	37.3	31.8
December 2020	99.7	24.0	32.8	28.2
June 2021	99.6	25.6	34.6	30.8
December 2021	99.7	28.1	35.0	33.0
June 2022	99.6	26.7	33.3	32.6
December 2022	99.8	25.9	34.2	32.8
June 2023	99.8	26.8	34.4	32.4
December 2023	99.9	22.5	33.9	30.3
June 2024	99.7	25.2	34.2	32.4
December 2024	99.7	25.1	36.2	32.0
June 2025	99.4	24.5	32.3	30.9

[a]Not available.

Online Services in China

In China, most residents use the internet for communication via instant messaging, browsing videos, short videos, and online payment (Table 3). There has been a substantial rise in user engagement in these activities from 2014 to 2025. Daily communication is the predominant internet service.

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Table 3. Number of internet users engaging in specific online services in China (2014-2025).

Month and year	Instant message (million), n	Internet video (million), n	Short video (million), n	Online payment (million), n
June 2014	564	439	294	292
December 2014	588	433	313	304
June 2015	606	461	354	359
December 2015	624	504	405	416
June 2016	642	514	440	455
December 2016	666	545	500	475
June 2017	692	565	525	511
December 2017	720	579	549	531
June 2018	756	609	594	569
December 2018	792	612	648	600
June 2019	825	759	648	633
March 2020	896	850	773	768
June 2020	931	888	818	805
December 2020	981	927	873	854
June 2021	983	944	888	872
December 2021	1007	975	934	904
June 2022	1027	995	962	904
December 2022	1038	1031	1012	911
June 2023	1047	1044	1026	943
December 2023	1060	1067	1053	954
June 2024	1078	1068	1050	969
December 2024	1081	1070	1040	1029
June 2025	1093	1085	1068	1022

Trends in Online Health Use in China

On the basis of data available from 2020 to 2025, online health use in China exhibited a V-shaped pattern during this period. Following a significant increase during the COVID-19 pandemic (2020-2022), user numbers experienced a slight contraction in the first half of 2024 and then rose again toward 2025 (Figure 2).

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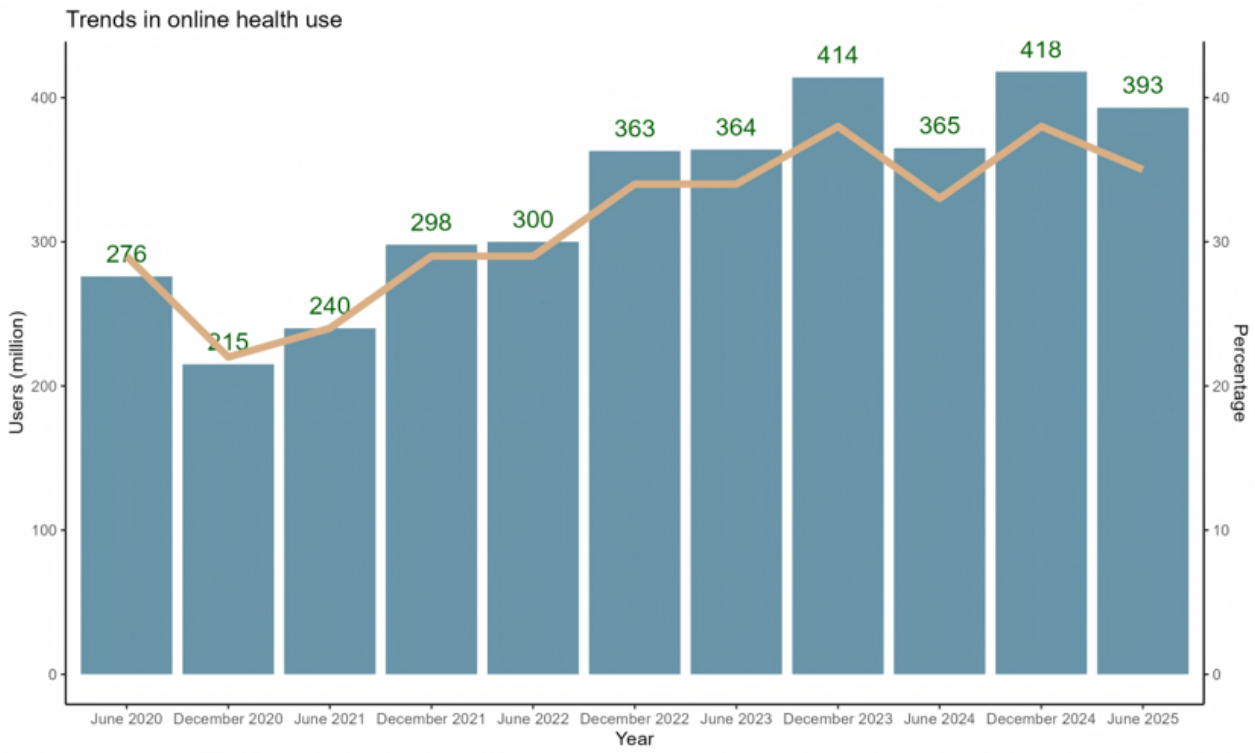
Figure 2. The number of online health-seeking users from 2020 to 2025 in China.



Discussion

Principal Findings

In June 2025, there were 1.123 billion internet users in China. The number of internet users increased dramatically from 2014 to 2025. The number of internet users showed an upward trend in both urban and rural areas in the past decades. Although the gap in internet penetration rate has narrowed between urban and rural areas, it still persists, highlighting the ongoing challenge of the digital divide in China. However, recent research suggests that nationwide investments in information infrastructure, such as the "Broadband China" strategy referenced in our study, can generate a significant "catching-up effect" in rural areas. Specifically, improving information infrastructure has been shown to increase household income more substantially in rural regions, thereby contributing to the reduction of the urban-rural development gap [9]. Empirical studies confirm that improved broadband infrastructure directly stimulates online health service adoption in rural communities, contributing to narrowing the health access gap [10]. This suggests that targeted digital infrastructure policies could be of critical importance for attaining equitable digital inclusion, even when disparities in baseline access continue to exist.

A longitudinal analysis of the penetration rates reveals a trend of convergence. While the absolute gap in internet penetration between urban and rural areas was 40% in 2014, it decreased to 15.7% by June 2025. This narrowing of the penetration rates occurred alongside a period of significant national policy focus on rural digital infrastructure (eg, the "Broadband China" strategy), suggesting that these efforts had a measurable mitigating effect on the digital divide, even as a disparity persists.

After the Chinese socioeconomic reforms, reports focused on the rural-urban disparity in health care [11]. Along with the urban-rural income gap, economic development causes a health care resource gap and health inequality. Ecological and individual-level studies elsewhere have suggested that internet use may be associated with reduced health inequality by promoting health awareness [12]. For instance, evidence suggests that the use of the internet influences mental health inequalities between urban and rural areas [13]. More attention should be paid to older adults. Although their adoption of the internet has witnessed a significant increase, they still constitute a crucial demographic affected by the digital divide. Understanding their use patterns is also crucial for inclusive digital health strategies [14]. Regarding the access devices, smartphones have remained the primary choice, showing a continuous increase in use over the past decade. In contrast to other devices, smartphones have become increasingly popular and affordable. In China, the government launched a series of internet infrastructure projects to lower the threshold for the use of smart terminals [9].

These policy measures have been associated with accelerated internet adoption in rural areas. First, as shown in our results, this contributed to a narrowing of the urban-rural penetration gap over the study period. However, a substantive gap remains (urban: 84.9%; rural: 69.2%) between the regions in June 2025, indicating that continued and targeted efforts are necessary to achieve equitable digital access. Second, smartphones are convenient to carry and provide improved internet capabilities

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compared with desktop computers and televisions. We will consider "health code" as an example. It was a widely used smartphone-based app to provide precise health protection from 2020 to 2025 nationwide [15]. Third, the government has improved the internet environment by supporting mobile internet access and reducing barriers and costs. The integration of mobile payment platforms (such as Alipay and WeChat Pay) has further eliminated transactional obstacles, rendering online health consumption seamless and more accessible [16]. Finally, the accessibility of diverse mobile internet apps has heightened the inclination to use these services and incorporate them into daily life, appealing to users from conventional industries.

Instant messaging is the predominant form of online digital media use in China. Communication was highly popular among residents across multiple domains, such as the social, occupational, and educational spheres. DingTalk and WeChat are 2 prevalent social media platforms, with WeChat being among the top. DingDing provides official collaboration and organizational management modules. Moreover, large institutions have increased their adoption of enterprise instant messaging, forming partnerships with platforms such as DingDing [17]. QQ can also be used in China, and studies have shown that the use of instant messaging tools, such as QQ, could improve teaching quality in medical imaging technology courses [18]. In addition to instant messaging, internet users of the other 3 types have increased dramatically in the last 10 years, with short videos increasing the most. Several factors could explain these changes. First, there is a strong desire to showcase the achievements of the new era through diverse forms of online audiovisual content, focusing on producing high-quality programs that capture the essence of this era. Additionally, online video platforms are expanding their offerings, including mobile cinema experiences in cars and providing entertainment for people while they travel. For example, Mango TV has partnered with more than 10 car brands to offer video entertainment services on in-vehicle screens, allowing users to enjoy popular programs through the Mango TV client [19]. The dominance of major short video platforms, such as TikTok and Kuaishou, has also led to a differentiated competitive advantage. These platforms have a significantly larger user population than other short video apps, and their respective ecosystems have contributed to increased market concentration. Furthermore, the integration of short video content into e-commerce has improved the e-commerce industry. These platforms have evolved into significant channels for disseminating health information and conducting public health campaigns, particularly influencing health behaviors among younger and middle-aged users [20]. Platforms such as TikTok and Kuaishou actively promote e-commerce marketing and accelerate the integration of online payment services, creating a short video e-commerce ecosystem.

By the end of June 2025, there were 393 million online medical users in China. Among them, most Chinese residents sought medical assistance from an internet hospital. In 2015, the internet hospital emerged in China as a new approach to provide health services and outpatient services, particularly through internet technology [21]. Initially, internet hospitals did not enjoy a high level of public recognition. After the COVID-19 outbreak, the demand for the use of internet medical care reached a peak when offline treatment channels were obstructed. The observed V-shaped trajectory, characterized by a surge during the COVID-19 pandemic peak (2020-2022), a decline in 2024, and a subsequent recovery, reflects the market's adjustment to a new equilibrium. This pattern aligns with national survey data, which reveals a continuous growth in the use of telemedicine after the COVID-19 pandemic. This indicates a fundamental shift in behavior rather than a temporary surge [22]. The specific and transient decline noted in mid-2024 (June 2024) during this recovery period can potentially be ascribed to multiple converging factors. First, it might indicate a postexpansion consolidation phase. During this phase, the initial high-frequency users from the COVID-19 pandemic period stabilized their use patterns, and the growth resulting from new user acquisition temporarily decelerated. Second, potential alterations in the reimbursement policies for specific types of online consultations by national or regional health care insurers at that time may have temporarily influenced user engagement. The development of national digital health policies has been demonstrated to substantially affect the scale, quality, and user acceptance of internet hospitals over time [23]. Third, by the end of 2023, the COVID-19 pandemic monitoring was not a mandatory requirement; therefore, the use of the internet for scanning codes to monitor SARS-CoV-2 saw a significant decline. Finally, this period coincided with a phase where the market was digesting the initial rapid influx of internet hospitals, and user preferences may have shifted toward more integrated or specialized platforms. This short-term decline underscores that the adoption of digital health services is dynamic and influenced by policy, market maturity, and user behavior, even within a strong positive long-term trend. To further understand the drivers behind these adoption trends, recent syntheses have highlighted a complex interplay of factors influencing digital health uptake in China. Beyond infrastructure access, key determinants include perceived usefulness and ease of use of the platforms, trust in online health information and health care providers, and individuals' digital literacy and health needs [24]. According to official Chinese data, the number of internet hospitals increased from 1400 in 2018 to 2700 in 2020. Apart from internet hospitals, online medical services and research are still underway. Research has shown that the application of the Internet of Medical Things to patients with interstitial lung disease can enhance individually targeted treatment [25]. Moreover, integrated online-to-offline chronic disease management models, facilitated by these platforms, have demonstrated effectiveness in improving clinical outcomes in primary care settings [26]. Yeh et al [25] suggested that web-based diabetes prevention programs can delay the onset of type 2 diabetes, providing culturally and linguistically appropriate interventions for Chinese Americans. It should also be noted that although access is on the rise, inequalities in the capacity to proficiently use digital tools for health purposes (the "second-level digital divide") persist. These inequalities are manifested in and may intensify the preexisting socioeconomic and spatial disparities in the actual use and perceived quality of online health services, as demonstrated by studies on internet hospitals [27].

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It is important to acknowledge a key limitation inherent in the aggregate CNNIC data used in this analysis—while they capture whether individuals used online health services within the past 6 months, they cannot distinguish between frequent, infrequent, or 1-time users. This lack of granularity regarding use intensity and user retention influences the interpretation of the observed V-shaped trend. For instance, the post-2023 rebound might reflect a consolidation toward a core group of repeat users who have integrated online health services into their regular care routines rather than a broad re-engagement of the general population. Conversely, the 2023 dip could represent a shedding of less-engaged or trial users while a stable base of dedicated users persisted. Therefore, while the trend indicates overall adoption dynamics, it does not elucidate whether growth is driven by deepening engagement among existing users or expansion to new ones. Future studies incorporating individual-level longitudinal data on use frequency and continuity are needed to disentangle these patterns and better understand the maturation of the digital health market in China.

This study still has other limitations. First, while aggregate internet use trends are based on complete data (2014-2025), detailed metrics on online health users are only available from 2020 onward, which restricts our long-term trend analysis for this specific sector. We have addressed this by clearly framing the online health analysis within the 2020 to 2025 period and by performing sensitivity analyses on the core internet adoption trends to confirm their robustness. Second, as an ecological study using aggregate administrative data, it cannot account for individual-level confounding factors or establish causality between internet development and health service adoption. The observed trends, while nationally representative, should be interpreted as descriptive associations that generate hypotheses for future causal investigation. Despite these limitations, this analysis provides a comprehensive and robust overview of the 10-year evolution of internet infrastructure and adoption patterns in China, establishing a reliable baseline for future investigations.

Conclusions

This study demonstrates that the internet in China continued to develop significantly and steadily from 2014 to 2025, with an increasing number of internet and online medical users in both urban and rural areas. Smartphones remained the primary device for accessing the internet. The internet and short videos increased significantly, nearly surpassing instant messaging in user numbers. Notably, the observed V-shaped trajectory of online health adoption—marked by a COVID-19 pandemic–driven surge followed by consolidation and recovery—suggests that the digital health market is maturing through a phase of user-base stabilization. In light of this finding, we recommend that policymakers and health care providers focus not only on promoting initial adoption but also on developing mechanisms to retain users and ensure consistent service quality. Strategies should be made, including integrating health services into highly engaging platforms (such as short-video apps), improving user experience, and cultivating trust in online care, which may contribute to consolidating the recovery phase of the V-shaped trajectory and averting future downturns. To maximize the impact, such strategies should be based on a comprehensive understanding of the evolving digital health ecosystem, which includes infrastructure, user behavior, and policy enablers, as synthesized in recent national-level analyses [28].

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Data Availability

The datasets generated or analyzed during this study are available from the corresponding author on reasonable request.

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Authors' Contributions

YQ contributed to the conception and design of this manuscript and critically revised it for intellectual content. CW performed the data analyses and wrote the manuscript. Both authors have read and approved the final manuscript.

Conflicts of Interest

None declared.

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Abbreviations

CNNIC: China Internet Network Information Center

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Original Paper

Virtual Reality–Based Avatar Intervention for Eating Disorders: Mixed Methods Feasibility Study

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Abstract

Background: There is a growing interest in developing novel psychological interventions for eating disorders, with an emphasis on targeting maintaining factors. One hypothesized mechanism underlying illness maintenance is the experience of an "inner eating disorder voice," which reinforces maladaptive thoughts, emotions, and behaviors. Preliminary studies suggest that the eating disorder voice is common among patients and is linked to greater illness severity.

Objective: This single-arm, mixed methods pilot feasibility study aimed to evaluate a novel virtual reality (VR)–based therapy targeting the eating disorder voice. The intervention was adapted from AVATAR therapy for psychosis and was examined as an adjunct to treatment as usual in individuals with eating disorders. In this adaptation, participants engaged with a therapist-controlled avatar representing their inner eating disorder voice in VR. The primary objectives were to assess the feasibility, acceptability, and safety of the intervention and to provide preliminary estimates of its clinical efficacy.

Methods: Adults with anorexia nervosa (9/10, 90%) or bulimia nervosa (1/10, 10%) took part in a 7-session VR-based therapy course at the Mental Health Centre Copenhagen, Copenhagen University Hospital, Denmark, alongside their treatment as usual. Quantitative measures of feasibility (recruitment, retention rates, and satisfaction scores), safety, and eating disorder–related outcomes were collected at baseline and after treatment between June 2023 and January 2024. Qualitative interviews conducted after the intervention (October 2023 to November 2023) explored participants' experiences. Descriptive statistics, paired *t* tests, and thematic analysis were conducted, and the analyses were finalized in October 2025.

Results: Recruitment targets were met: 14 individuals were referred, and 11 provided consent well within the prespecified time frame. Treatment completion rate was 80% (8/10; 95% CI 44%-97%), and no serious adverse events occurred. Participants reported high satisfaction (7/10, 70%; mean 9, SD 1.15 on a 10-point Likert scale; median 9, IQR 8.5-10.0; range 7-10), and qualitative data (8/10, 80%) suggested that they valued the immersive virtual representation of their eating disorder voice. Exploratory analyses indicated improvements in eating disorder symptoms (Hedges g=−0.99, 95% CI −1.74 to −0.24; P=.01), power dynamics associated with the eating disorder voice (Hedges g=−1.63, 95% CI −2.59 to −0.67; P=.002), and emotion regulation via cognitive reappraisal (Hedges g=0.87, 95% CI 0.08-1.66; P=.04).

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Conclusions: The VR-based avatar intervention for eating disorders was feasible, acceptable, and safe, with preliminary signals of clinical improvement. These findings support further development and evaluation of the intervention in a randomized clinical trial.

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KEYWORDS

Virtual reality-assisted therapy; eating disorders; anorexia nervosa; bulimia nervosa; eating disorder voice; anorexic voice; externalization techniques; narrative therapy; relational therapy

Introduction

Eating disorders involve harmful eating behaviors and an excessive focus on weight and body shape in one's self-evaluation [1]. These illnesses impact at least 7% of the global population [2] and impose severe physical and psychological consequences, including an elevated risk of early mortality [3-5]. Additionally, eating disorders impose substantial economic burdens, including health care expenditures, reduced employment rates, and productivity losses, with overall costs exceeding those associated with anxiety and depression [6].

Psychological therapies are recommended as first-line treatments for eating disorders [7], although their effectiveness, particularly for anorexia nervosa, remains suboptimal [8-10]. Approximately 30% of adult patients who complete treatment relapse within a year of treatment completion [11,12], and dropout rates ranging from 20% to 70% have been reported [13,14]. Long-term recovery rates remain low, especially for anorexia nervosa [15], while barriers to initiating treatment remain high [16,17]. These challenges underscore the need for innovative and engaging therapeutic approaches that target core maintaining mechanisms of eating disorder psychopathology and enhance treatment engagement.

An estimated 94% of individuals with an eating disorder report experiencing an internal "eating disorder voice," often described as an inner self-critical commentary or self-talk focused on weight, eating, and self-worth [18,19]. While this voice may be perceived as supportive at first, it typically becomes increasingly critical and controlling, reinforcing harmful eating behaviors [19]. Qualitative research indicates that this shift can feel like a division between the disorder and the self, with the eating disorder voice becoming a dominant, dissociated part of the self that often overrides personal values and leaves individuals feeling powerless [20,21].

A stronger eating disorder voice is associated with more frequent compensatory behaviors (eg, fasting, vomiting, laxative misuse, and compensatory exercise) and longer illness duration [22]. Accordingly, research suggests that an individual's subordinate stance toward the eating disorder voice may play a significant role in maintaining eating disorder symptoms and hindering treatment engagement [22]. Despite its clinical significance, the everyday experience of the eating disorder voice and the individual's dialogue with it are rarely addressed directly in therapy. Most treatment programs aim to reduce the disorder's dominance over identity and behavior; however, specifically targeting the eating disorder voice in a relational manner may further empower patients to reclaim agency and develop a self-concept not defined by the disorder [19,21,23,24].

Similar relational dynamics are observed in individuals with psychosis who hear distressing voices, inspiring adaptations of relational approaches such as "voice dialogue" for eating disorders. Preliminary qualitative work has used chair work techniques to facilitate dialogue between patients and their eating disorder voice [21,24].

AVATAR therapy, a digital intervention initially developed for psychosis, uses computer-generated avatars to embody distressing voices and enable structured dialogue. It has demonstrated efficacy in reducing voice severity in 2 fully powered randomized clinical trials [25-27]. A proof-of-concept study and a recent feasibility study adapting AVATAR therapy for anorexia nervosa suggest that this approach is feasible, acceptable, and potentially effective for shifting power dynamics, enhancing self-compassion, and reducing symptoms of stress and anxiety in individuals with anorexia nervosa [14,23].

The previous adaptation of AVATAR therapy for anorexia nervosa was delivered on a standard desktop screen [14,23]. This study is the first to evaluate a virtual reality (VR)–based format, providing a fully immersive environment that may enhance therapeutic engagement through increased presence and exposure to emotionally salient content [28]. Although most studies on the eating disorder voice focus on anorexia nervosa, qualitative findings suggest that individuals with bulimia nervosa report similar inner voices [29]. Additionally, to test the intervention more broadly, the target population was extended to include patients with bulimia nervosa. The primary aim was to assess the feasibility, acceptability, and safety of this novel VR-based avatar intervention while collecting exploratory data on its potential clinical effects. Qualitative interviews were incorporated to capture participant experiences, refine the intervention, and inform the design of a future randomized clinical trial.

Methods

Trial Design

The study was a single-arm pilot feasibility trial enrolling 10 participants with anorexia nervosa or bulimia nervosa. All participants received the VR-based avatar intervention alongside their ongoing standard treatment, which consisted of long-term weekly psychodynamic therapy sessions with a psychologist and, for some, additional dietary guidance, focused on symptom management rather than full recovery. The research team conducted assessments of eating disorder–related outcomes and

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quality of life at baseline and after the treatment (12 weeks after baseline) and completed semistructured qualitative interviews after the intervention. The therapist monitored safety throughout the study. The therapy sessions, assessments, and qualitative interviews were conducted at the Mental Health Centre Copenhagen, Copenhagen University Hospital, Denmark, between June 2023 and January 2024. The study is reported in accordance with the CONSORT (Consolidated Standards of Reporting Trials) extension for pilot and feasibility trials, the TIDieR (Template for Intervention Description and Replication) guidelines, and the SRQR (Standards for Reporting Qualitative Research). Completed checklists are provided in Multimedia Appendices 1-3.

Ethical Considerations

The study was approved by the Committee on Health Research Ethics of the Capital Region of Denmark (H-22067692) and the Danish Data Agency (P-2022-932). Participants received oral and written information about the study and provided written informed consent before enrollment. Study data were deidentified before analysis and stored on secure, password-protected servers in accordance with the requirements of the Danish Data Agency. No compensation was provided to participants in accordance with Danish legislation restricting financial or material compensation for patient participation.

Recruitment

Participants were recruited from a specialist service within the Mental Health Services of Copenhagen, which provides a multidisciplinary treatment program including individual or group psychotherapy, dietetic support, and social work services for patients with long-standing eating disorders. Between May 2023 and October 2023, clinical staff from the specialist service identified potential participants who met the inclusion criteria and approached them with study information. All study materials were reviewed by a patient with lived experience and revised accordingly. With participants' consent, clinicians forwarded their contact information to the research group via a secure email system. Members of the research team then contacted potential participants by telephone to assess eligibility. Individuals who met the inclusion criteria and expressed interest were invited to a baseline interview, during which written informed consent was obtained.

Inclusion criteria were (1) age of 18 years or above, (2) an ICD-10 diagnosis of anorexia nervosa or bulimia nervosa (ICD-10 codes F50.0, F50.1, F50.2, and F50.3) [30], (3) self-reported recognition of an internal eating disorder voice, and (4) proficiency in Danish or English. Individuals with a diagnosis of psychosis and/or those at risk of suicidal behavior were excluded. Eligibility criteria remained unchanged after trial commencement.

Sample Size

The study involved 10 participants, consistent with pilot and feasibility guidance prioritizing procedures, refinement, and parameter estimation over efficacy [31]. This sample size was adequate to assess recruitment and retention, acceptability, and safety and to generate preliminary data for a larger randomized controlled trial.

Intervention

This study adapted a previously validated 3D VR-based avatar intervention for psychosis (the "Challenge" trial) [26] to target eating disorder psychopathology. The adaptation involved collaboration with 8 individuals with lived experience of eating disorders, whose input informed the VR content and the therapy manual to ensure clinical relevance and acceptability prior to commencement of the pilot study.

Participants received 7 weekly individual VR-based avatar sessions alongside their ongoing standard treatment. The VR-based avatar intervention was delivered by a psychologist with clinical experience in the treatment of eating disorders and formal training in avatar-based therapy acquired through our previous psychosis trial. All VR-based avatar therapy sessions were conducted face-to-face in a dedicated therapy room.

In the initial session, participants worked with the therapist to identify key distressing verbal content and characteristics of the eating disorder voice. They then designed a computer-generated avatar to embody their voice, with options to customize sex, age, facial features, body size, skin color, and hair color. A voice modulation program was used to adjust the therapist's voice to match the tone and pitch of the participant's imagined eating disorder voice.

In subsequent sessions, participants wore a VR headset and noise-canceling headphones while engaging in dialogue with the avatar. Each session lasted 60 minutes, including approximately 15 minutes spent interacting in VR with the avatar, with the remainder dedicated to preparation and reflection.

In the virtual environment, participants were placed in a living room setting facing the avatar. The therapist was not visible in VR but was present in the therapy room, controlling the avatar and facilitating the interaction by alternating between speaking as the avatar and as a supportive therapist (Figure 1). When speaking as the avatar, the therapist used a transformed voice, and the avatar's mouth movements were synchronized with the speech to represent the participant's eating disorder voice.

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Figure 1. Photograph of the therapy setup and virtual reality (VR) equipment used in a single-arm feasibility study of VR-based avatar therapy for eating disorders conducted at the Mental Health Centre Copenhagen, Copenhagen University Hospital, Denmark, between June 2023 and January 2024.

Participants were encouraged to confront the avatar and assert their beliefs, values, and wishes, with the aim of gaining increased control over their eating disorder voice. Early sessions followed a structured format with prescripted dialogue, gradually progressing to more spontaneous exchanges to increase immersion. The therapist continuously monitored the participants' distress levels and adjusted the intensity of interactions as needed.

To promote skill consolidation, participants were provided with a picture of their avatar and audio recordings of avatar dialogues for between-session review. The recordings aimed to reinforce participants' sense of control and motivation for change; maintain therapeutic gains; and support discussions with family members, peers, or other treatment providers.

Outcome Measures

Primary Outcomes: Feasibility, Acceptability, and Safety

Primary outcomes included feasibility and acceptability of the therapy, operationalized as recruitment of 80% or more of the target sample (N=10) in 12 months, 80% or higher retention to the study protocol at cessation of therapy (7 sessions), and 80% (8/10) or more of the participants reporting a satisfaction rating of 7 or higher on a Likert scale from 1 to 10. Acceptability was further assessed using the Client Satisfaction Questionnaire (CSQ) [32].

The Negative Effects Questionnaire was applied as a participant-reported, exploratory measure of negative effects, including a broad scope of psychosocial, emotional, and cognitive effects attributed to the treatment [33].

Safety was monitored by the therapist at each session through systematic recording of adverse events related or unrelated to participation in the study (eg, death, suicide attempts, hospital admissions, and complaints about the therapy). Any adverse events were reported to the Danish Health Research Ethics Committee, which oversaw the study and had the authority to recommend pausing or terminating the study.

Exploratory Clinical Outcomes

Given the novelty of the intervention, we adopted an exploratory approach to outcome measures to identify potential areas of therapeutic impact. Preliminary indications of efficacy were assessed using the following measures obtained at baseline and at the end of treatment (12 weeks after baseline): (1) Eating Disorder Examination Questionnaire (EDE-Q) global score [34] to assess eating disorder symptoms, (2) Modified Psychotic Symptoms Rating Scale–Auditory Hallucinations subscale total score [35] to assess eating disorder voice characteristics and the distress it evokes, (3) Body Shape Questionnaire–34 total score [36] to assess body dissatisfaction, (4) Eating Disorder Quality of Life Scale (EDQLS) total score [37] to assess quality of life, (5) Self-Compassion Scale (SCS) total score [38] to assess self-compassion, (6) Revised Beliefs About Voices Questionnaire subscale scores (for omnipotence, malevolent beliefs, affective engagement, benevolent beliefs, behavioral engagement, affective resistance, and behavioral resistance)

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[39] to assess engagement with the eating disorder voice, (7) Voices Power Differential Scale total score [40] to assess voice power, (8) Voices Acceptance and Action Scale (VAAS) total acceptance score [41] to assess acceptance and action toward the eating disorder voice, (9) Hospital Anxiety and Depression Scale total scores [42] to assess anxiety and depression symptoms, (10) General Self-Efficacy Scale total score to assess self-efficacy [43], (11) Emotion Regulation Questionnaire subscale scores for Cognitive Reappraisal and Expressive Suppression [44] to assess emotion regulation, (12) Identity and Eating Disorder Questionnaire (IDEA) total score [45] to assess identification with the eating disorder and sense of embodiment, and (13) Behavior Rating Inventory of Executive Function global score [46] to assess executive functioning.

Statistical Analysis

Feasibility, acceptability, and safety outcomes were summarized descriptively [31,47]. Recruitment, retention, and follow-up rates were reported as proportions with Clopper-Pearson 95% CIs. Acceptability was assessed with patient satisfaction scores (Likert scale 1-10), with a mean score of 7 or higher reported by 80% (8/10) of more of the participants indicating acceptability. Safety was described using frequencies of adverse events. Exploratory efficacy analyses used 2-tailed paired *t* tests (α=.05) comparing baseline and posttreatment scores. For each measure, mean differences, SDs, medians, IQRs, *P* values, and Hedges g with CIs were stated. Due to a REDCap (Research Electronic Data Capture) error, 1 item from the IDEA questionnaire and the first 12 items of the EDQLS were missing at baseline for 9 participants. To ensure comparability across time points, analyses excluded these items from both baseline and follow-up calculations. No data were excluded.

Qualitative Analysis

Semistructured interviews were conducted to explore participants' experiences regarding barriers and facilitators to engagement, with the aim of informing intervention acceptability and refinement [31,47]. A total of 8 interviews were conducted by 2 members of the research group between October 2023 and November 2023. The interviews followed a flexible guide based on the study aims but allowed participants to highlight their own perspectives. Data were analyzed thematically using the framework by Braun and Clarke [48], with a hybrid deductive-inductive approach: predefined codes reflected study objectives, while additional codes and themes emerged inductively from the data. To enhance rigor, the 2 researchers independently coded the transcripts, discussed discrepancies, and agreed on the final coding structure. To address potential bias, given that interviewers were members of the research team, reflexivity practices were applied throughout. NVivo (version 15.3.1; Lumivero) software was used to support coding and data management.

Results

Participant Characteristics

A total of 14 eligible patients were referred, of whom 3 (21%) declined participation. In total, 79% (11/14; 95% CI 49%-95%) consented and completed the baseline assessment. Another participant (1/14, 7%) was excluded after baseline due to discontinuation of standard care. Consequently, 71% (10/14) of the participants referred received the intervention as planned (Figure 2). After study commencement, 10% (1/10) of the participants were identified as having nonorganic psychosis, characterized by a single persistent auditory hallucination without other psychotic features. Given the symptom profile, the participant remained in the study, and the data were included in the analyses.

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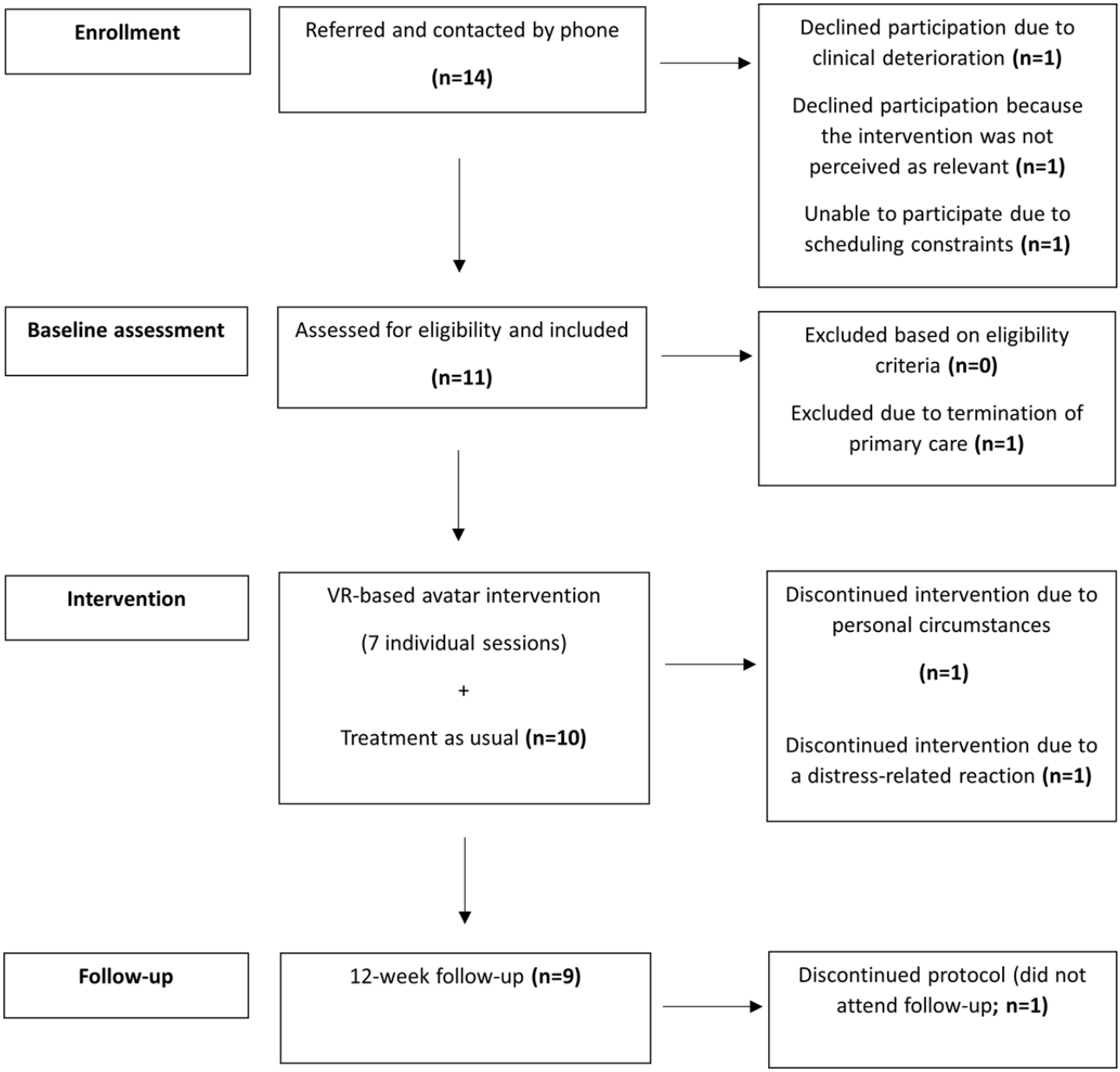
Figure 2. CONSORT (Consolidated Standards of Reporting Trials) flow diagram of participant (N=10) enrollment, intervention, and follow-up in a single-arm feasibility study of a virtual reality (VR)–based avatar therapy for eating disorders conducted at the Mental Health Centre Copenhagen, Copenhagen University Hospital, Denmark, between June 2023 and January 2024.



A total of 10 participants (all female) were enrolled in the study, with a median age of 35.7 (IQR 26.2-40.8; range 23.0-55.0; mean 35.1, SD 9.8) years. Of the 10 participants, 1 (10%) had bulimia nervosa, whereas the remaining 9 (90%) had anorexia nervosa. The median illness duration was 16.5 (IQR 11.3-19.8; range 7.0-45.0; mean 17.8, SD 10.7) years. Eating disorder severity, measured using the EDE-Q global score, averaged 3.44 (SD 1.56; median 3.9, IQR 2.9-4.1; range 0.3-5.2), reflecting symptoms in the mild to moderate range. The mean BMI was 19.4 (SD 1.6; median 19.1, IQR 18.7-20.2; range 16.6-21.7) kg/m^2. A total of 90% (n=9) of the participants reported psychiatric comorbidity (ie, generalized anxiety, nonorganic psychosis, autism spectrum disorder, posttraumatic stress disorder, panic attacks, attention-deficit/hyperactivity disorder, personality disorder, bipolar disorder, and obsessive-compulsive disorder) and all were receiving psychiatric medication (Table 1).

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Table 1. Baseline characteristics of participants enrolled in a single-arm feasibility study of virtual reality–based avatar therapy for eating disorders conducted at the Mental Health Centre Copenhagen, Copenhagen University Hospital, Denmark, between June 2023 and January 2024 (N=10).

Characteristics	Value
Age (y)	
Mean (SD)	35.1 (9.8)
Range	23.0-55.0
Median (IQR)	35.7 (26.2-40.8)
Sex, n (%)	
Female	10 (100)
Diagnosis of eating disorder, n (%)	
Anorexia nervosa	9 (90)
Bulimia nervosa	1 (10)
Illness duration (y)	
Mean (SD)	17.8 (10.7)
Range	7.0-45.0
Median (IQR)	16.5 (11.3-19.8)
Eating disorder severity (Eating Disorder Examination Questionnaire total score)	
Mean (SD)	3.4 (1.6)
Range	0.3-5.2
Median (IQR)	3.9 (2.9-4.1)
BMI (kg/m^2)	
Mean (SD)	19.4 (1.6)
Range	16.6-21.7
Median (IQR)	19.1 (18.7-20.2)
Comorbidity, n (%)	9 (90)
Generalized anxiety	1 (10)
Nonorganic psychosis and other	1 (10)
Phobic anxiety	1 (10)
Posttraumatic stress disorder	3 (30)
Attention-deficit/hyperactivity disorder	2 (20)
Bipolar mood disorder	1 (10)
Obsessive-compulsive disorder	1 (10)
Autism spectrum disorder	1 (10)
Personality disorder	1 (10)
Psychotropic medication, n (%)	9 (90)
Antidepressants	6 (60)
Antipsychotics	4 (40)
Mood stabilizers	1 (10)
Benzodiazepines	2 (20)

Evaluation Outcomes

Feasibility

Recruitment of the target sample was completed in 5.5 months, within the prespecified 12-month time frame. Of the 10 participants, 8 (80%; 95% CI 44%-97%) completed all 7 therapy sessions. In total, 10% (1/10) of the participants withdrew after 2 sessions due to emotional distress triggered by the avatar dialogues in the context of previous trauma, and 10% (1/10) of the participants discontinued participation after 3 sessions due to personal stressors. The end-of-intervention assessment was

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completed by 90% (9/10; 95% CI 55%-99.7%) of the participants, although 22% (2/9) provided partial data, leaving a total of 70% (7/10) of the participants who completed the full assessment battery (Multimedia Appendix 4 shows an overview of the participants per outcome measure). In total, 80% (8/10) of the participants took part in qualitative interviews, including 10% (1/10) who had discontinued therapy early due to emotional distress.

Safety

No serious adverse events occurred during the intervention period (eg, deaths, suicide attempts, serious violent incidents, formal complaints, crisis referrals, or hospital admissions). One nonserious adverse event was recorded: emotional distress leading to early withdrawal.

Acceptability: Quantitative Analysis

The overall satisfaction rate was high, with a mean of 9 out of 10 (SD 1.15; median 9.0, IQR 8.5-10.0; range 7.0-10.0; 7/10, 70%) on a 10-point Likert scale. This aligned with a high mean score of 30.7 out of 32.0 (SD 3.5; median 28, IQR 25-29; range 22.0-30.7; 7/10, 70%) on the CSQ, measuring client satisfaction. However, responses were missing from the 2 participants who terminated therapy prematurely and from 1 participant who only partially completed the end-of-treatment assessment and did not respond to the satisfaction scale or the CSQ.

On broader self-reported negative effects, participants reported an average of 5.3 (SD 6.0; range 0-15) negative effects on the Negative Effects Questionnaire, most commonly distress-related experiences (eg, stress and sadness) and concerns about treatment quality (eg, misunderstanding of treatment and unmet expectations). The mean perceived severity was 1.2 (SD 0.9; range 0-2.2) on a 0 to 4 scale, indicating a mild overall impact.

Preliminary Efficacy

Regarding exploratory clinical outcomes, participants showed improvements in eating disorder symptoms and key psychological processes related to the eating disorder. The EDE-Q global score demonstrated a reduction in disordered eating behaviors (Hedges g=−0.99, 95% CI −1.74 to −0.24; median preintervention score=3.98, IQR 2.98-4.13; median postintervention score=2.89, IQR 2.51-3.46; P=.01). The Voice Power Differential Scale indicated a substantial shift in the perceived power balance between the participant and the eating disorder voice (Hedges g=−1.63, 95% CI −2.59 to −0.67; median preintervention score=23.0, IQR 17.75-25.75 median postintervention score=18.0, IQR 15.00-19.00; P=.002). Emotional engagement with the eating disorder voice, measured by the Revised Beliefs about Voices Questionnaire engagement affective subscale, decreased significantly (Hedges g=−0.98, 95% CI −1.80 to −0.16; median preintervention score=5.5, IQR 4.25-7.50; median postintervention score=3.0, IQR 1.00-5.50; P=.02). Cognitive reappraisal (eg, the ability to think differently to alter emotional states), as measured by the Emotion Regulation Questionnaire, also improved significantly (Hedges g=0.87, 95% CI 0.08-1.66; median preintervention score=4.1, IQR 2.67-4.50; median postintervention score=4.5, IQR 4.33-5.42; P=.04).

In contrast, 3 Self-Compassion Scale subscales—self-judgment (P<.001), isolation (P=.03), and overidentification (P<.001)—showed significant negative change, whereas 3 Self-Compassion Scale subscales—self-kindness, common humanity, and mindfulness—showed positive, nonsignificant change.

Acceptance of the eating disorder voice (measured using VAAS) decreased slightly but not significantly (P=.12). No significant change was observed in disease-specific quality of life (P=.76). Multimedia Appendix 4 displays all exploratory outcome findings.

Acceptability: Qualitative Analysis

Overview

Four main themes captured participants' experiences of the VR-based avatar intervention. The themes reflected both the intensity of confronting the eating disorder voice and the potential therapeutic value of that intensity. Further qualitative findings will be reported in a separate paper currently in preparation.

Theme 1: Real-Time Visual and Auditory Externalization–Enabled Resistance

Participants described how the avatar dialogue helped externalize the eating disorder voice, making it feel more concrete, as 1 participant noted:

> *It's not just thoughts flying around in my head.... It's something that's really being said to me.* [Participant 1]

This shift in perception facilitated resistance:

> *If it's this avatar saying to me, "You look fat," then it's easier to say, "You're not going to talk to my body like that."* [Participant 1]

In general, the participants stressed that the avatar created psychological distance from the eating disorder thoughts, making it easier to challenge them.

Theme 2: Empowerment

Across participants, the avatar dialogue fostered a sense of empowerment, described in three ways: (1) increased control over eating disorder thoughts and behaviors, (2) enhanced motivation for change, and (3) new insights and greater self-acceptance. One participant explained the following:

> *It felt like being in dialogue with something I previously wasn't able to control.* [Participant 6]

These subjective accounts aligned with quantitative findings of increased perceived power and reduced eating disorder symptoms.

Theme 3: Intensity as Catalyst and Challenge

The heightened realism of thought content intensified emotions, sometimes experienced as overwhelming or anxiety-provoking, yet was generally regarded as therapeutically meaningful:

> *If it affected me as much as it did, then it must have an effect.* [Participant 6]

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For manual refinement, some participants suggested preparatory psychoeducation and postsession cooldown periods to better manage the emotional load. The participant with a trauma history highlighted the need for tailored pacing and support.

Theme 4: Barriers and Suggested Improvements

Technical issues (eg, sound disruptions and heavy VR goggles) and limited avatar customization reduced immersion. Several participants also recommended extending the number of sessions, noting that initial meetings were often spent acclimating, while later sessions felt more impactful and natural.

Discussion

Principal Findings

This mixed methods pilot feasibility study explored a novel VR-based avatar intervention used alongside treatment as usual for individuals with anorexia nervosa and bulimia nervosa. The intervention proved feasible, with a 100% recruitment rate achieved in less than 6 months, well ahead of the 12-month target, and 80% treatment adherence, meeting predefined feasibility criteria. Acceptability was high, although incomplete response rates introduce some uncertainty. Safety monitoring identified no serious adverse events; however, 1 participant discontinued due to distress triggered by the avatar dialogue, highlighting the need for individualized pacing. Participants reported a modest number of negative therapy-related events, indicating that negative experiences were present but not highly frequent across the sample. Events were generally rated as mild and most often involved distress (eg, experiencing stress or sadness from therapy). However, 1 clinician reported symptom deterioration in a patient 7 months after discontinuing treatment, for which a potential association with the intervention could not be ruled out.

The coexistence of high satisfaction and mild to moderate negative effects suggests that participants valued the intervention overall, despite experiencing some transient distress. Qualitative findings supported this interpretation, describing the avatar dialogue as meaningful and immersive, helping participants externalize and concretize the eating disorder voice, thereby making it easier to foster resistance and regain a sense of control. At the same time, the realism and intensity of the dialogues could be overwhelming, particularly early in treatment. This duality underscores the importance of preparatory psychoeducation, postsession processing, and tailored pacing. Careful assessment of potential triggers and a slower pace of exposure might be of particular importance for patients with trauma histories. Participants also recommended improving technical reliability, enhancing avatar customization, and extending the number of sessions to maximize therapeutic benefit, consistent with findings from previous feasibility research on computer-based AVATAR therapy for anorexia nervosa [23]. Further research into avatar customization options is warranted, as enhancing personalization may be important for improving therapeutic engagement in future interventions.

Despite the small sample, exploratory analyses suggested potential for clinical change across several domains, including large effect sizes for perceived power shifts in the eating disorder voice and reduced emotional engagement with the voice. In contrast to the previous AVATAR feasibility study [14], participants also reported reductions in disordered eating behaviors, and cognitive reappraisal abilities improved significantly, indicating enhanced flexibility in managing emotional responses. A nonsignificant decline in “voice acceptance” was also observed, which may represent a therapeutic shift toward greater psychological distance from the eating disorder voice.

Unexpectedly, 3 self-compassion subscales (self-judgment, isolation, and overidentification) worsened, whereas self-kindness, common humanity, and mindfulness showed nonsignificant gains. Follow-up interviews with participants showing the largest negative changes suggested that the intervention increased awareness of self-critical thinking patterns, leading to more self-critical ratings after treatment, despite no subjective worsening. This interpretation is consistent with qualitative reports of heightened insight. While these findings differ from positive self-compassion changes reported in previous AVATAR feasibility work [14], both studies are underpowered, and these discrepancies underscore the need for larger, controlled trials. Overall, the intervention appears to target core maintaining mechanisms of eating disorders, including identity fusion with the eating disorder and affect regulation difficulties.

Limitations

The small sample size is typical of feasibility studies [31,49], and while it enabled qualitative exploration, it limits generalizability and likely inflates effect sizes. Results on clinical outcomes should be interpreted cautiously, given that participants continued to receive standard treatment alongside the VR intervention; therefore, any observed changes cannot be definitively attributed to the VR intervention. A further limitation was missing data caused by REDCap entry errors, resulting in incomplete IDEA and EDQLS scores. Additionally, small sample sizes for certain VAAS subscales limited the interpretation of the action subscale. Only 1 participant had a diagnosis of bulimia nervosa, and no male participants took part in the study, limiting the generalizability of acceptability and feasibility findings to a broader population with eating disorders; the results primarily reflect female individuals with anorexia nervosa.

Conclusions

This study provides early evidence that VR-based avatar therapy is a feasible and acceptable approach as an add-on to treatment as usual for patients with long-standing eating disorders, complementing traditional cognitive and imagery-based methods [50,51] by virtually externalizing the eating disorder voice and facilitating direct, immersive confrontation. Potentially, immersive VR delivery may enhance realism and emotional engagement. The intervention may be particularly valuable for patients with entrenched symptomatology, for whom existing therapies yield limited gains.

On the basis of these findings, a full-scale randomized controlled trial is underway to evaluate efficacy, with additional attention to optimizing safety protocols, session structure, and technical

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reliability [52]. Future work should also investigate individual predictors of tolerance to exposure intensity and explore the potential for adaptive pacing.

Acknowledgments

The authors declare the use of generative artificial intelligence (GAI) in the research and writing process. According to the GAIDeT (Generative Artificial Intelligence Delegation Taxonomy; 2025), the following tasks were delegated to GAI tools under full human supervision: code generation, data cleaning, translation, proofreading, and editing. The GAI tool used was ChatGPT (version 5.3; OpenAI). Responsibility for the final manuscript lies entirely with the authors. GAI tools are not listed as authors and do not bear responsibility for the final outcomes.

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Data Availability

The datasets generated or analyzed during this study are not publicly available due to the small sample size and the resulting risk of participant re-identification but are available from the corresponding author on reasonable request.

Authors' Contributions

Conceptualization: NKH, ESR, LBG
Data curation: NKH
Formal analysis: NKH, KR
Funding acquisition: LBG
Investigation: NKH, KR
Methodology: NKH, ESR, KR, CH, AB, NM, LBG
Project administration: NKH, LBG
Resources: AB, NM, LBG
Supervision: VC, CH, TW, LBG
Visualization: NKH
Writing—original draft: NKH
Writing—review and editing: ESR, KR, VC, AB, CH, NM, TW, LBG
All authors read, commented, and approved the final manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1
CONSORT checklist extension for pilot and feasibility trials.
[PDF File (Adobe PDF File), 313 KB - formative_v10i1e88445_app1.pdf]

Multimedia Appendix 2
TIDieR checklist.
[PDF File (Adobe PDF File), 297 KB - formative_v10i1e88445_app2.pdf]

Multimedia Appendix 3
SRQR checklist.
[PDF File (Adobe PDF File), 228 KB - formative_v10i1e88445_app3.pdf]

Multimedia Appendix 4
Exploratory outcome findings.
[PDF File (Adobe PDF File), 400 KB - formative_v10i1e88445_app4.pdf]

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Abbreviations

CONSORT: Consolidated Standards of Reporting Trials
CSQ: Client Satisfaction Questionnaire
EDE-Q: Eating Disorder Examination Questionnaire
EDQLS: Eating Disorder Quality of Life Scale
IDEA: Identity and Eating Disorder Questionnaire
REDCap: Research Electronic Data Capture
SCS: Self-Compassion Scale
SRQR: Standards for Reporting Qualitative Research
TIDieR: Template for Intervention Description and Replication
VAAS: Voices Acceptance and Action Scale
VR: virtual reality

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Original Paper

Development of a Culturally Adapted Smartphone App (IndigeQuit) Designed to Help American Indian and Alaska Native People Quit Commercial Cigarettes: User-Centered Mixed Methods Study

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Abstract

Background: Due to the colonization of tobacco plants by European settlers and the subsequent intensive marketing of commercial tobacco products to American Indian and Alaska Native (AI/AN) communities in the United States, commercial cigarette smoking accounts for half of all deaths among AI/AN people. Limited awareness, access to treatment, and the absence of culturally relevant, effective smoking cessation interventions contribute to these high death rates.

Objective: This study aims to culturally adapt iCanQuit, a smartphone smoking cessation app proven efficacious for the general population, for AI/AN people.

Methods: A user-centered and community-based participatory research (CBPR) mixed methods approach was applied to culturally adapt iCanQuit for AI/AN people in collaboration with a community advisory board (CAB) of AI/AN individuals using a 3-step process. Step 1 identified ways to culturally adapt the iCanQuit for AI/AN people through 1-on-1 qualitative interviews with 8 prior iCanQuit AI/AN participants. Step 2 involved developing prototypes of cultural refinements identified in step 1 through regular biweekly meetings of the CAB, research, and app development teams. The prototypes were then evaluated with a separate group of 4 prior iCanQuit AI/AN participants through 1-on-1 qualitative interviews. Step 3 involved beta testing the

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app through a 6-day diary study followed by 1-on-1 qualitative interviews with a nationally recruited group of 7 AI/AN adults who smoke commercial cigarettes. The development work associated with step 3 was further informed by the CAB and the research and app development teams.

Results: Key findings identified 5 cultural refinements that informed subsequent app development and testing: (1) stories featuring AI/AN adults and elders emphasizing culture, spirituality, family, and community; (2) honoring the Earth as a motivator for cessation; (3) a guide character representative of AI/AN people; (4) clear distinction between ceremonial and commercial tobacco use; and (5) use of earth tones in visual design. In Step 3, all 7 (100%) diary study participants rated the beta version of the app as excellent or good/meets expectations (5/7, 71%, and 2/7, 29%, respectively) and that it felt made for them. They suggested 6 modifications which were incorporated into the final version of the app: (1) include vaping frequently asked questions, (2) feature motivation icons more prominently, (3) increase notification frequency, (4) track today's cigarettes rather than yesterday's, (5) allow users to update how much they spend per pack of cigarettes; and (6) rename the medications tool to reflect the inclusion of AI/AN traditional healing modalities.

Conclusions: A user-centered and CBPR development process yielded IndigeQuit—one of the first known apps developed specifically to help AI/AN adults quit commercial cigarette smoking.

Trial Registration: ClinicalTrials.gov NCT06145763; https://clinicaltrials.gov/ct2/show/NCT06145763

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KEYWORDS

American Indian; Alaska Native; ceremonial tobacco; commercial cigarettes; cultural adaptation; iCanQuit; Indigenous; IndigeQuit; Native; smartphone apps; smoking cessation; tailoring; Tribal communities

Introduction

Background

Due to the appropriation of tobacco plants by European settlers and the subsequent intensive marketing of chemically engineered commercial tobacco products by the tobacco industry to American Indian and Alaska Native (AI/AN) populations in the United States, AI/AN communities have a commercial cigarette smoking rate 3 times higher than that of the general population (36.5% vs 11.5%) [1-12]. For instance, research analyses of secret tobacco industry documents by Lempert and Glantz et al [9] revealed specific promotional strategies used to exploit Native imagery and target these populations, thereby contributing to the higher-than-average rates of commercial cigarette smoking among AI/AN people compared with any other race in the United States. Consequently, AI/AN communities have 6 times higher rates of smoking-related cancers, as well as smoking-related respiratory and heart disease [13-15], and are only half as likely to quit smoking as other races and ethnicities [16,17]. The result is that commercial cigarette smoking now accounts for half of all deaths among AI/AN communities nationwide [13,18,19].

There are complex historical, social, and cultural factors that have contributed to these longstanding inequities in rates of commercial smoking and related deaths. For instance, due to federal policies that forbade cultural ceremonial practices, the use of ceremonial tobacco has become infrequent and has largely been replaced by commercial cigarette smoking [1-8]. Decades-long predatory marketing by the tobacco industry has further exacerbated smoking rate inequities among AI/AN communities [8-10]. Examples include the use of advertising with Native imagery in tobacco products and the sponsorship of cultural events targeting marginalized populations, including racial and ethnic minorities, people of low socioeconomic status, and youth. Additionally, historical trauma, racism, and discrimination have fostered mistrust of and fear of the health care system among AI/AN communities, resulting in limited access to efficacious smoking cessation treatment [20-24]. The inaccessibility of treatment is further compounded by lack of insurance coverage and lack of systems for universal assessment, referral, and integration of services into routine care for these communities [25-29].

One method for AI/AN communities to access evidence-based smoking cessation treatments is via smartphone-based smoking cessation apps [30,31]. Smartphone apps can deliver all the smoking cessation content now found on websites and SMS text messaging interventions—other common digital intervention delivery modalities [30-33]. Apps are an important technological advance over these modalities because they do not always require internet access and have more engaging features than websites and SMS text messaging interventions [34-42]. These apps can reduce smoking inequities because they do not require interaction with the health care system, can be freely accessed through an app store, and are available anytime at the convenience of the user. The reach of smoking cessation apps for AI/AN adults who smoke is climbing rapidly, greatly aided by growing smartphone ownership in Native communities [43-45].

To help address the reach of digital smoking cessation treatments for all adults who smoke in the United States, our team developed iCanQuit, a smoking cessation smartphone app based on the principles of acceptance and commitment therapy (ACT) [46]. ACT for smoking cessation teaches skills for allowing cravings to pass without smoking and motivates individuals to quit by appealing to deeply held personal values, such as family, community, cultural traditions, and health [47-51]. iCanQuit is the only app proven efficacious for smoking cessation in a randomized controlled trial (RCT) with long-term 12-month follow-up among 2415 adults recruited from all 50 US states. Compared with participants using the National Cancer Institute

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(NCI) QuitGuide app based on the US Clinical Practice Guidelines (USCPG) for smoking cessation, iCanQuit participants had 1.5 times higher odds of quitting smoking at 12 months (28% vs 21% quit rate; odds ratio [OR] 1.49, 95% CI 1.22-1.83; *P*<.001) [46].

A subsequent secondary analysis of the iCanQuit RCT among the subsample of AI/AN adults (N=165) recruited from 32 US states (25% residing on Tribal land) showed very encouraging results. AI/AN participants assigned to iCanQuit had 2.6 times higher odds of quitting smoking compared with AI/AN participants assigned to QuitGuide at 6 months (25% vs 11%; OR 2.62, 95% CI 1.06-6.45; *P*=.04) and correspondingly higher odds of quitting smoking at 12 months (30% vs 18%; OR 1.96, 95% CI 0.90-4.26; *P*=.09) [52]. Treatment engagement (number of sessions, 32.4 vs 8.5; *P*<.001) and satisfaction with the assigned app (92% vs 65%; *P*<.001) were also significantly higher among AI/AN participants using iCanQuit compared with those using QuitGuide [52]. Changes in the ACT-based process of accepting bodily sensations, emotions, and thoughts that cue smoking significantly mediated the effect of iCanQuit on cessation outcomes compared with QuitGuide (all *P*<.01).

Objectives

Although encouraging, iCanQuit was not developed specifically to help AI/AN adults quit commercial cigarette smoking. To better support AI/AN adults quitting commercial cigarette smoking, we implemented a user-centered and community-based participatory research (CBPR) development process to culturally adapt iCanQuit and make the app-based smoking cessation intervention more relevant, inclusive, and meaningful for AI/AN communities. Here, we report the details of the 3-step iterative development process grounded in CBPR principles, AI/AN cultures, and an ACT-based behavioral approach for smoking cessation that resulted in the IndigeQuit app—one of the first known apps developed specifically for AI/AN adults quitting commercial cigarette smoking. The IndigeQuit app is currently being tested against QuitGuide in a full-scale randomized trial among 776 nationally recruited AI/AN adults who smoke commercial cigarettes and want to quit.

Methods

IndigeQuit Trial Overview

The cultural adaptation of iCanQuit for AI/AN communities preceded the launch of a large-scale RCT currently testing the efficacy of the culturally adapted smartphone app for commercial cigarette smoking cessation, named IndigeQuit, against the NCI-developed USCPG-based smartphone app (QuitGuide).

Ethical Considerations

Study procedures were approved by the Institutional Review Board at Fred Hutchinson Cancer Center (protocol number FHIRB0020279/RG1123796; ClinicalTrials.gov: NCT06145763). Written and verbal informed consent was obtained from participants. To protect participants' privacy and confidentiality, all collected data were deidentified and stored in a password-protected format.

Community Advisory Board

Formation

The IndigeQuit RCT is being implemented by a multidisciplinary community advisory board (CAB) and research team consisting of AI/AN and non-AI/AN investigators. We partnered with AI/AN community members to culturally adapt the intervention through a collaborative and iterative process following CBPR principles [53]. To form the CAB, AI/AN investigators extended invitations to AI/AN community members within their networks who had an interest in improving the health of AI/AN people by reducing commercial tobacco use in their communities. Prior AI/AN participants in the iCanQuit parent RCT who had agreed to be contacted for future research were also recruited for CAB participation by study staff. Others were identified by active CAB members.

Ten individuals accepted the invitation via email. Study staff then followed up with an official invitation letter and a CAB agreement outlining the study aims and expectations, as well as the CAB members' roles and responsibilities. Each CAB member was asked to read and sign the CAB agreement before joining, which included a 1-year minimum commitment. The first meeting was conducted in June 2024, and the CAB has met biweekly to the present day. In early meetings, facilitators highlighted the value of input from the community and introduced details about the parent RCT, including the background and significance of the work ahead. CAB members are compensated US $100/hour for their time.

CAB Members

CAB members hold a wide variety of roles and perspectives, including current and former commercial cigarette users, prior iCanQuit RCT participants, family members of people who smoke, tobacco treatment specialists, physicians, public health professionals, and leaders of health organizations that serve the AI/AN community, as well as national AI/AN leaders in the campaign for cessation of commercial tobacco within Tribal Nations. CAB members represent diverse Tribal affiliations across North America, including Cherokee, Lakota, Navajo, Coast Salish, and Seneca, as well as geographic residences in Arizona, California, Kansas, New Mexico, New York, Oklahoma, South Dakota, and Washington.

User-Centered and CBPR Development Process

Overview

The mixed methods research for culturally adapting iCanQuit for AI/AN communities followed a 3-step development process consistent with user-centered design and CBPR principles. The steps were further informed by the CAB, research team, and app development team through regular biweekly meetings between June 2024 and July 2025. Each step in the iterative development process is described below.

Step 1: Needed Changes

Overview

Step 1 aimed to identify changes needed to make the iCanQuit app more culturally relevant, acceptable, and inclusive for AI/AN people through 1-on-1 semistructured qualitative

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interviews with prior AI/AN participants in the iCanQuit parent RCT.

Participants

iCanQuit RCT participants who (1) self-identified as AI/AN; (2) received the iCanQuit app; (3) agreed to be recontacted in the future; and (4) were willing and able to participate in a 60-minute video call were invited to participate. The full inclusion criteria for the iCanQuit RCT have been previously published [46,52]. Briefly, these included smoking 5 or more commercial cigarettes per day in the past year and wanting to quit.

Recruitment

The recruitment process started with an email invitation to randomly selected prior iCanQuit RCT AI/AN participants who met the eligibility criteria. If a participant expressed interest, study staff asked about their availability, access to a device for a video call, and willingness to be interviewed and recorded. Of the participants contacted, 19 individuals expressed interest in participating, 9 were available and scheduled for an interview, and 8 completed the interviews. Thematic saturation was not used as a stopping criterion. Rather, the number of interviews was dependent on prior iCanQuit AI/AN participants' availability, logistical constraints (eg, time, budget, personnel), and our limited goal of producing actionable cultural refinements to the iCanQuit app.

Interviews

The interview guide was developed collaboratively by AI/AN and non-AI/AN investigators with expertise in behavioral interventions, digital health, and commercial tobacco cessation. The semistructured interview guide included open-ended questions that began with participants' overall experiences with the iCanQuit app, followed by more specific questions about how each section of the iCanQuit app–based intervention could be made more culturally relevant, acceptable, and inclusive of AI/AN people (Multimedia Appendix 1). All interviews were conducted via a Health Insurance Portability and Accountability Act (HIPAA)–compliant video call, and verbal consent was obtained from each participant before the interview. Data were collected in September 2022. Participants were compensated US $100 for their time.

Step 2: Prototype Iterative Development

Overview

Building on the qualitative findings from step 1, we engaged in an iterative process of adaptation and development in collaboration with the study CAB from June 2024 to August 2025. We co-developed prototype versions of the refinements, which were then evaluated by a separate group of 4 prior iCanQuit RCT AI/AN participants through 1-on-1 qualitative interviews conducted in November 2024. The results of these interviews were shared with the CAB, research team, and app development team, and suggested edits were incorporated. The CAB continued to provide input through biweekly meetings, generating additional refinements to strengthen culturally appropriate contextual fit. Results from the 6-day diary study and qualitative interviews conducted in June 2025 and described in step 3 were also presented to the CAB, which provided final feedback. This 14-month process culminated in August 2025 with the CAB's review and final approval of the app.

CAB Meetings

Three investigators (2 of whom self-identify as AI/AN and 1 non-AI/AN) jointly led the biweekly meetings with the CAB (n=10), research team (n=10), and app development team (n=3), which served as a collaborative forum to review app features and provide feedback. Meetings were held virtually via a HIPAA-compliant, passcode-enabled Zoom room (Zoom Communications). Each meeting lasted approximately 1.5 hours. Throughout these meetings, the app development team used CAB feedback to iterate on new app designs and features, which were subsequently brought back to the group for additional review. In parallel, app content was iteratively reviewed, and additional feedback was solicited to ensure the tone, language, and messaging resonated with AI/AN users. Over the course of 25 virtual meetings and a 2-day in-person retreat in February 2025, 8 design iterations of the app were generated, yielding the beta version of the app, which was subsequently tested in the 6-day diary study described in step 3.

Interviews

Midway through the prototype development with the CAB, qualitative interviews were conducted with a separate group of 4 prior iCanQuit RCT AI/AN participants. The purpose of these interviews was to collect feedback on the new prototype designs for the app (ie, home screen, avatar "guide" persona, motivational values, and images) and to identify any further refinements needed for clarity, relevance, relatability, and usefulness. The eligibility criteria, recruitment, and enrollment process were identical to step 1. Of the 87 participants contacted, 9 individuals expressed interest in participating, 8 were eligible and scheduled for an interview, and 4 completed the interviews. For this step, a more structured interview guide was implemented that included open-ended questions focusing on the evaluation of the prototypes developed in step 2 (Multimedia Appendix 2). Data were collected in November 2024. Participants were compensated US $100 for their time.

Step 3: Beta Testing

Overview

Step 3 involved a 6-day diary study followed by 1-on-1, semistructured 45-minute qualitative interviews. The purpose of the diary study was to test the beta version of the app with a nationally recruited group of AI/AN adults who smoke commercial cigarettes and had no prior experience with the iCanQuit app. Throughout the diary study, participants provided daily ratings for each app feature via online surveys assessing clarity, relevance, relatability, and usefulness. At the end of the diary study, 1-on-1 qualitative interviews explored participants' experiences with the app in greater depth.

Participants

Eligibility criteria were as follows: (1) self-identify as AI/AN, either alone or in combination with other races; (2) age 18 years or older; (3) have smoked commercial cigarettes in the past 30 days; (4) have daily access to their own Android or iPhone; (5)

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be able to download a smartphone app; (6) be willing and able to read English; and (7) have no other household or family member participating.

Recruitment and Enrollment

Guided by the CAB, social media ads featuring images of IndigeQuit AI/AN testimonial characters were designed to refer AI/AN individuals to the screening survey. Interests associated with AI/AN communities were selected for ad targeting. These included Native languages; hobbies such as beading, woodworking, leatherworking, and rodeo; and areas of study such as Native American studies and herbalism.

Those who were eligible were contacted for phone screening and then scheduled for onboarding interviews, during which participants verbally provided informed consent and received instructions for completing diary entries and downloading the beta version of the culturally adapted app. Of the 31 eligible participants identified through online screening, 13 completed phone screening, and 10 remained eligible. Eight completed onboarding interviews, and 7 completed the diary study. Data were collected in June 2025. Participants were compensated US $30 for the onboarding interview, US $15 for each completed daily survey, and US $50 for completing the exit interview.

Six-Day Diary Study

For 6 consecutive days, participants were asked to complete an online survey that combined closed- and open-ended prompts to evaluate user experience ratings, perceived usefulness, and engagement with the app. Daily surveys focused on specific app features. Across the 6 days, the surveys collected data through (1) usage checks (eg, “Did you set a quit date?”); (2) Likert-type ratings on a 5-point scale to measure perceived experience and app feature value (eg, rating the value of audio exercises from “1=not very valuable” to “5=very valuable”); and (3) ranking tasks (eg, “Please rank the following types of notifications from 1=most liked to 5=least liked”). Open-ended items (eg, “Please tell us why you chose that rating. We’d like you to be as detailed as possible”) helped supplement the insights provided during the 1-on-1 interviews.

Interviews

Both the diary surveys and interview guide were collaboratively developed by the CAB and research team. The semistructured interview guide included open-ended questions about the participant’s overall experience with the app, followed by more specific questions on how each section of the app was perceived (Multimedia Appendix 3).

Coding and Analysis

Audio recordings of the 1-on-1 interviews in steps 1-3 were professionally transcribed and inductively coded according to a thematic analysis paradigm [54]. Participants’ write-in responses to daily diary prompts in step 3 were treated in a similar manner. Inductive thematic analysis was selected to aid in hypothesis generation on actionable cultural refinements to the app. It also allowed us to identify and characterize patterns across participants’ recommendations and CAB members’ input to make the iCanQuit app more culturally relevant, acceptable, and inclusive of AI/AN people.

Authors CAF and ARK conducted the analysis. After familiarizing themselves with the data, they independently applied line-by-line open coding to identify preliminary themes that described participants’ experiences with the app and their recommendations for how it could be improved. Both are long-term members of the research group and have contributed to various smoking cessation and weight loss clinical trials, including qualitative fidelity coding of hundreds of telephone-based counseling sessions. ARK has coordinated multiple smoking cessation trials. CAF holds a master’s degree in experimental psychology and has led multiple qualitative research projects. The 2 coders then met and collaboratively developed, reviewed, and defined a final set of themes and recommendations. For each step, results were presented to the CAB to ensure credibility of the findings through member checking and to stimulate additional conversation about how participant feedback could be incorporated into the app.

Results

Step 1: Needed Changes

Participant Characteristics

The 8 iCanQuit parent RCT interview participants were from 7 US states (Florida, Kansas, North Carolina, Nevada, Oklahoma, Texas, and Washington). On average, participants were 40.5 (13.7) years old, including 5 women and 3 men. There were 5 Tribal affiliations represented: Cherokee, Cree, Creek, Lakota Sioux, and Tsimshian. According to participants’ ZIP codes linked to federally recognized Tribal lands, 1 of the 8 participants was residing on Tribal land. Regarding smoking status at the time of the interviews, 5 had quit commercial cigarette smoking, 2 were in the process of quitting, and 1 was currently smoking commercial cigarettes.

Summary of Results

Content Analysis

Content analysis revealed the number of times concepts were mentioned during the interviews (from most to least mentioned): (1) stories from elders; (2) importance of nature; (3) more detailed information about commercial smoking cessation medications; (4) voice recordings or testimonials from Natives; (5) differences between traditional and commercial tobacco use and the lack of education regarding commercial tobacco use; (6) inclusion of appropriate and relevant Tribal symbols; (7) importance of family and community; and (8) changes to the color palette and the addition of imagery of AI/AN people clothed in Native fashion or styles. Four additional interpretive themes emerged from the analysis.

Theme 1: Nature, Elders, and Storytelling Are Important

Although participants came from different Tribes with varying traditions, most talked about connecting with Mother Earth, the importance of elders, and the significance of sharing stories and traditions. Across Tribes, storytelling is a traditional and highly respected means of passing down wisdom from generation to generation. Many stories include themes about being connected

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to one's community and the earth. Some participants said these cultural stories may be a way to share messages about commercial smoking. One participant explained that Indigenous people have a particular cadence and way of speaking, suggesting that including the voices of people telling their stories may create additional opportunities to build trust and connectedness with the app.

Theme 2: Medications Are Commonly Misunderstood

A lack of trust in commercial smoking cessation medications was a common theme across individuals interviewed. Participants reported a lack of trust, a lack of education, and limited access to health care as major barriers to using medications to quit commercial smoking. Several participants also stated that trust could be built by including direct statements about medication. Instead of just listing medications, the app could state what the medications do and how they work. One participant shared: "I was chewing gum and smoking a cigarette thinking it was gum. I was like no, it doesn't work like that. This is medication that's actually trying to help you."

Theme 3: Culture and Connectedness

Participants commonly mentioned Mother Earth, elders, family, and community, and described Mother Earth and family as positive ways to connect with AI/AN culture. In Indigenous cultures, Mother Earth refers to the Earth as a nurturing and life-giving entity. Adding stories about how quitting commercial smoking benefits the environment and community may be a way to incorporate AI/AN culture. Example quote: "Honoring Mother Earth by not ruining the ground with filters that are filled with chemicals...The plastic and cigarette butts will be here long after we are."

Theme 4: Distinction Between Traditional and Commercial Tobacco

Several participants stated that their Tribes did not actively educate members about the difference between traditional ceremonial tobacco use and commercial tobacco use, with one noting that traditional tobacco is no longer used in their Tribe. One participant explained how the ceremonial context makes a key distinction: "If I go to a ceremonial situation where there's going to be a tobacco pipe used,...if it's part of the tradition, I can participate in that and then walk away from it because I'm doing it as a religious observation. It's just like if you go to church and take communion, you're not going to immediately go out and chug a bottle of wine."

Step 2: Prototype Development

Cultural Refinements to the iCanQuit App

The themes identified in step 1 informed 5 specific cultural refinements to the iCanQuit app that served as the starting point for discussion and design iterations in collaboration with the CAB in step 2: (1) modify the app's stories to feature AI/AN adults and elders who quit commercial smoking, emphasizing the values of spirituality, family, and community as motivators; (2) add honoring the Earth as a motivator to quit smoking; (3) make the appearance of the app's "guide" character more representative of AI/AN people; (4) add information distinguishing ceremonial and commercial tobacco; and (5) use earth tones in the app's colors. The suggested cultural refinements were incorporated through changes to the app's visual design and content.

Iterative Cultural Adaptation of Visual Design

The visual design of the app was culturally adapted to include Native imagery, symbolism, and color palettes. The app home screen, icons for values-based motivations, and the appearance of the avatar characters were the most heavily revised visuals (Figure 1). The original landing home screen page in iCanQuit was updated to feature the Medicine Wheel, a circular symbol divided into 4 quadrants that signifies living in balance for Indigenous populations, and it was used as the central image and navigation menu (Figure 1A). While interpretations of the Medicine Wheel may vary across Tribes, such as the 4 Directions (East, South, West, and North) or aspects of life (spiritual, emotional, mental, and physical), it is a powerful image representing wellness for Native people [55]. Bright earth-tone colors were incorporated throughout the app, echoing colors commonly seen in ceremonial regalia.

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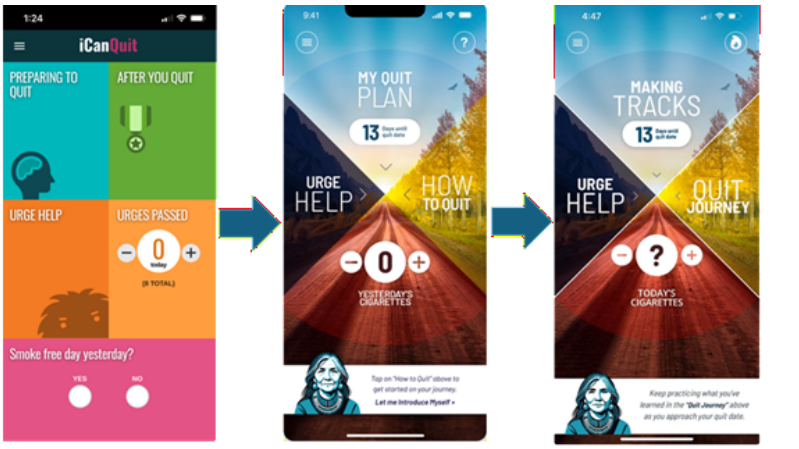
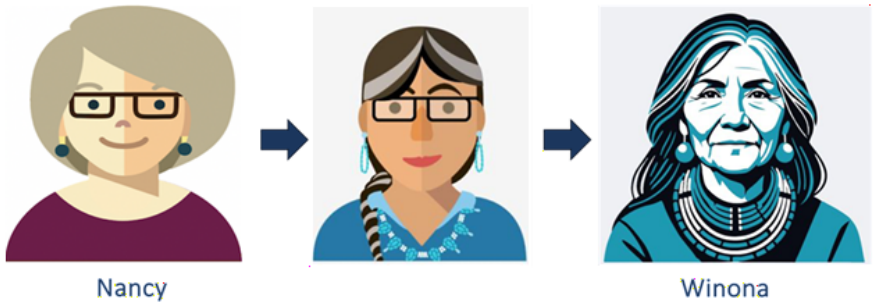
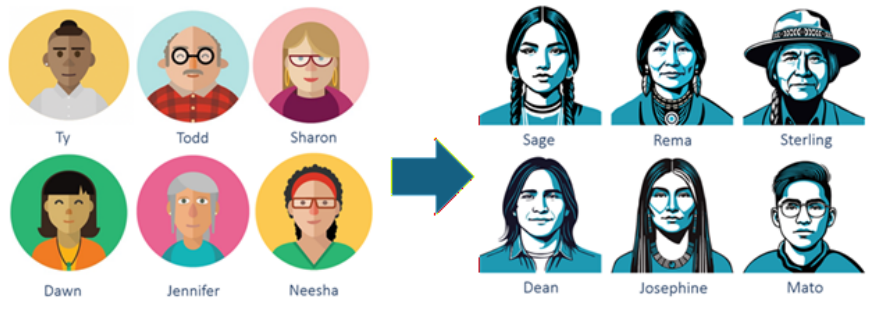
Figure 1. Iterative visual design updates used to create step 2 prototypes. (A) (Home screen) This sequence illustrates the evolution of the app's home screen across design iterations. The left image shows the original iCanQuit home screen. The middle image reflects an early revision informed by participant and community advisory board (CAB) feedback, featuring the Medicine Wheel—a circular symbol divided into 4 quadrants that represents wellness for many Native people—as the central image and navigation menu. The right image shows the final revised design. (B) (What's Inspiring Me to Quit?) An interactive feature in which users select 1 or more personal motivations for quitting smoking from a set of illustrated, values-based icons. The iconography was updated to include Native symbols. The "Caring for the Earth" icon, shown here, emphasizes connections between smoking cessation and honoring the earth as part of supporting balance, health, and responsibility to future generations. Selected inspirations are displayed back to users to reinforce motivation during their quit journey. (C) (Guide avatar) The original iCanQuit guide avatar, "Nancy" (left), was redesigned as "Winona" (right), a Native-named elder intended to feel more familiar to Native users and to serve as a source of wisdom and support. The sequence illustrates the evolution of Nancy across design iterations leading to the final Winona design. (D) (Additional avatars) The left image shows the original iCanQuit set of additional avatars. The right image shows the revised set developed through iterative design informed by participant and CAB feedback to reflect Native features, hairstyles, and names.







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Nature motifs were incorporated throughout to reflect user feedback that the nature theme should be represented in both the visual design and the app content. For instance, the values-based motivation iconography was updated to include Native symbols such as the Medicine Wheel to represent wellness and a mountain to represent spirituality. The "Caring for the Earth" motivation icon was designed to emphasize honoring nature through connections between smoking cessation and stewardship of the land, respect for natural elements, and the role of honoring the Earth in supporting balance, health, and responsibility to future generations. Motivational icons (eg, "Caring for the Earth") were included within the app feature "What's Inspiring Me to Quit?," where users select their top inspirations for quitting smoking (Figure 1B). Regarding the app content, illustrations of an "urge monster" that had been used to indicate the strength of a craving were replaced with a water metaphor, prompting users to select the strength of their urge, ranging from a drop to a flood.

Finally, the avatars that share their quitting journeys were completely redesigned to have Native features (eg, defined nasolabial folds), hairstyles (eg, traditional braids as well as contemporary styles), accessories (eg, silver jewelry), and names (eg, Sterling or Dean, after 1 of the CAB members). Extra attention was given to redesigning "Nancy," the original iCanQuit guide avatar, into "Winona," a Native-named elder who would feel more familiar to Native users and be viewed as a source of wisdom and support (Figure 1C and D).

Mid-Way External Evaluation of Prototype Designs: Qualitative Interviews

Participant Characteristics

Four participants were recruited from 4 US states (Oklahoma, Tennessee, Texas, and Washington). On average, participants were 38.3 (7.8) years old, and 3 of the 4 were women. There were 5 Tribal affiliations represented: Cherokee, Chiricahua Apache, Creek, Lakota, and Zapotec. At the time of the interviews, all 4 participants reported living off-reservation, and 3 had quit commercial cigarette smoking.

Summary of Results

Participants provided feedback on the new prototype designs for the app home screen, lessons menu, avatars, and motivation icons. Participants found the home screen attractive and easy to navigate, and the lessons menu layout seemed intuitive. They liked the earth tones and the avatar designs. Participants viewed the guide as strong yet approachable, and 3 associated the image with their own grandmother or community elder. All participants felt the values and associated icons made sense and looked good overall, although revisions were suggested for the family and health icons. Three additional themes emerged during the interviews.

Theme 1: Opportunity for Community Building

Multiple participants viewed the app not only as a tool to quit commercial cigarette smoking, but also as an opportunity to connect with their community and alleviate feelings of isolation while quitting. One participant described: "My cousins were smoking. My dad's still smoking. My aunt's smoking. Everybody's smoking...So that was the hardest part. It still is sometimes. Everybody else goes out and smokes and has the little break and then you're just trapped inside." This participant suggested the app could be strengthened by allowing users to connect: "It would be really cool to have a community to be able to interact with other users...because you build that community and you know that somebody else is suffering with you at certain points."

Theme 2: Connecting to Native Culture Enhances Motivation

Participants overall provided positive feedback about aspects of the app that had been adapted to better fit Native users, and 2 emphasized that connecting to Native culture can be a motivating force in quitting commercial cigarettes. One participant suggested capturing this with an additional value icon: "...preserving yourself as a person and as a body for your culture's sake. That could be a motivation because it's like being extinct or endangered species."

Theme 3: The Importance of Indigenous Contributions and Authenticity

Participants emphasized the importance of Indigenous people being involved in the creation of the app and the smoking-cessation intervention more generally. They also expressed concern that a lack of Indigenous voices in the app's development could affect its credibility among potential users. One participant said, "I think just knowing that the representation that they worked with Native communities would be more appealing. Just even if it's a fictional character, but a quote from someone within communities that we worked on this app would be something that would make it more attractive."

The themes identified through this process of external evaluation of the prototype designs informed additional cultural refinements to the IndigeQuit app: (1) incorporating a social component into the app and its content that normalizes and alleviates feelings of shame or isolation associated with trying to quit; (2) adding a new motivation icon to capture the desire to engage in cultural preservation by caring for one's body; and (3) clearly indicating that Native people were involved in developing and adapting the app. These suggestions were discussed with the CAB and stimulated additional content iterations described below.

Iterative Cultural Adaptation of App Content

Modifications to Original iCanQuit Content

App content was also culturally adapted. The name of the app was changed from iCanQuit to IndigeQuit, and language throughout was adapted to better resemble the way Indigenous people speak and interact with one another. For example, to begin their quit journey, users now select a button labeled "Skoden," a common abbreviation of the phrase "let's go then" in reservation (rez) slang. Additionally, Lakota language phrases such as *Mitakuye Oyasin* (all my relations) were added to boost the familiarity and credibility of the guide avatar, Winona. Daily push notifications to increase app engagement were interspersed with inspiring quotes from Native leaders and poets that reinforce the ACT principles of acceptance, willingness, and living in line with one's values.

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Further elaboration about Winona's backstory was added to her introduction in response to feedback that, in Native communities, it is common to provide an informal recap of one's Tribal or Clan affiliation and familial relations when meeting someone new. Winona grew up on a Lakota reservation and now lives in an urban area to increase the credibility of her wisdom among people with diverse backgrounds and life experiences. To further develop Winona's character and legitimacy, a Lakota actress voiced passages that Winona presents throughout the app, giving users the option to read along or listen to the content.

iCanQuit's central "Urge Monster" metaphor was overhauled for IndigeQuit. Urge Monster is a classic ACT metaphor that suggests "dropping the rope" when you find yourself in a tug-of-war with a strong craving imagined as an urge monster. CAB members felt it too closely resembled colonial propaganda and demonizing language that had historically been used to oppress Native people, and evoked terrifying mythological creatures in Navajo culture called skin walkers. It was replaced with a new metaphor collaboratively developed by ACT clinicians and CAB members—Dropping Anchor. In this metaphor, resisting an urge is compared to rowing a boat against a river current. Rather than fighting the inevitable flow of nature to the point of exhaustion, the exercise suggests dropping the boat's anchor and letting one's urges come and go on their own.

New Content Additions

From the beginning of the redesign process, supported by step 1 findings, the distinction between commercial and ceremonial tobacco was considered a necessary change for cultural adaptation. A goal of IndigeQuit was to honor the ceremonial role of sacred tobacco and support the reclaiming of Indigenous practices through its use. A new section on ceremonial tobacco was added to the app and included an explanation of how it differs from commercial tobacco, the federal prohibition of its use until 1978 [5,8], and its roles in Indigenous culture as offerings, for healing, prayer, and ceremonies. In response to the suggested cultural refinements from step 2 interviews, a new "Preserving Traditions" motivation icon was designed and incorporated into the app, and all advertisement materials and app onboarding highlight that the app was created by *Natives for Natives.*

Feedback obtained through the step 2 interviews also urged the inclusion of a feature that facilitates connection between users. Members of the CAB strongly agreed and collaborated on creating a social component named Fireside Chat: a moderated message board where users post questions and share their quitting stories. CAB members noted this would particularly resonate in Indigenous cultures, where the pervasiveness of commercial smoking makes it common to feel alienated for deciding to quit. This feature might also help users enact their values of strengthening community and cultivating their Native identity, both of which IndigeQuit identifies as possible motivations that could bolster users' resolve to quit. CAB members volunteered to moderate the Fireside Chat feature and were trained to respond to questions as Winona, providing intervention-consistent content and screening user stories for appropriateness before posting them for others to see. Users also have the option to message Winona (ie, study staff or CAB members) privately through the Fireside Chat feature, facilitating another layer of connection between app users and study staff.

Additional resources to support Native users were added on the recommendation of the CAB. These include links to a documentary on reclaiming sacred tobacco; information about the ways that commercial tobacco harms the environment; a powwow dancing video as an alternative form of exercise; an online resource that identifies whose ancestral homelands one resides on; and links to the American Foundation for Suicide Prevention and Mind Mental Health Support: Coping with Trauma. The CAB emphasized the prevalence of trauma among Indigenous communities and how it contributes to commercial tobacco use and addiction more broadly.

CAB members advocated that non-Western healing practices be presented alongside pharmaceutical support for commercial smoking cessation. Ceremony, prayer, reconnecting with nature, and sweat lodges were added to the Medications Tool and presented above pharmaceutical options, based on feedback that Indigenous people are more likely to gravitate toward traditional ways of healing than Western pharmacotherapy (Figure 2). The CAB felt it would be refreshing for Native users to see that their non-Western healing practices were treated as legitimate medicines alongside options such as nicotine replacement therapy, among others.

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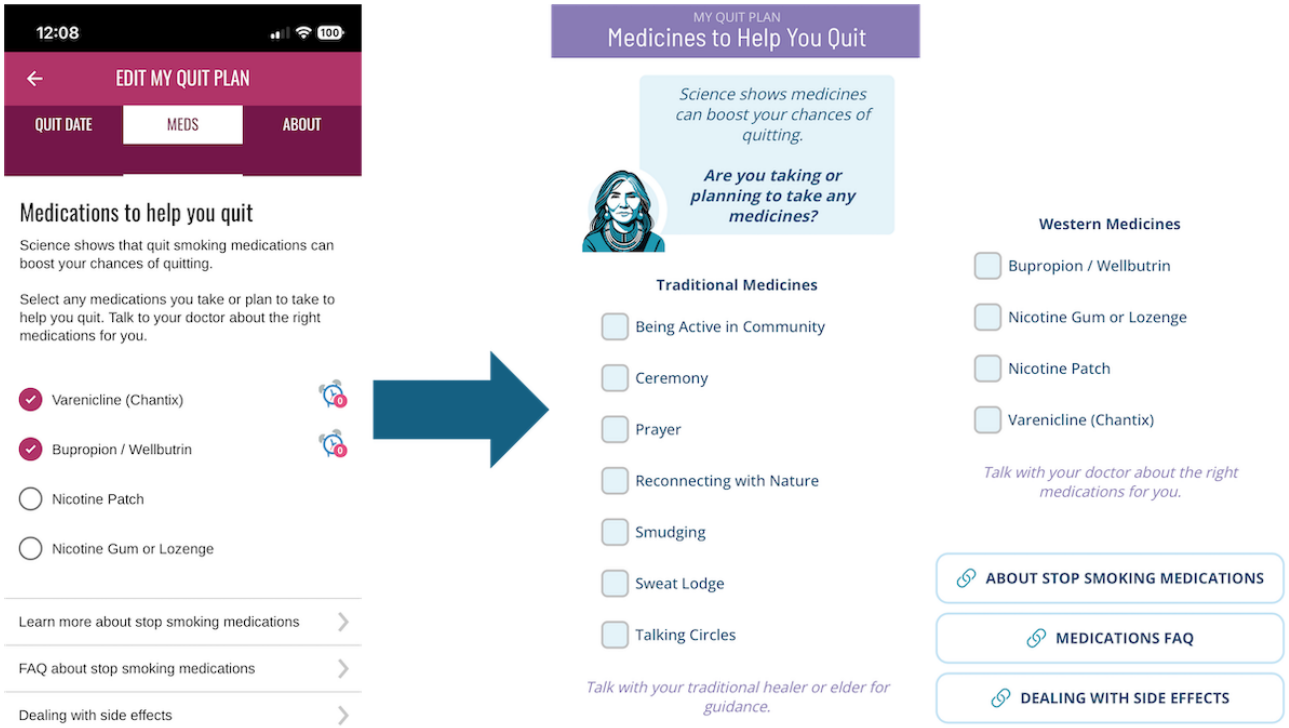
Figure 2. Medicines Tool. The left panel shows the original iCanQuit medication selection screen, which focused exclusively on Western pharmacologic smoking cessation treatments. The right panel shows the revised design, informed by participant and community advisory board feedback, which distinguishes between Western medicines (eg, nicotine replacement therapy, bupropion, varenicline) and traditional approaches to healing (eg, ceremony, prayer, reconnecting with nature, smudging, talking circles).



Step 3: Beta Testing

Participant Characteristics

Seven participants were recruited from 6 US states (Alabama, Arizona, Minnesota, North Carolina, Oklahoma, and Washington). On average, participants were 42.6 (11.0) years old, and 2 (29%) were men. There were 6 Tribal affiliations represented: Choctaw, Lumbee, Navajo, Quapaw, Tsimshian, and White Earth Chippewa. At the time of the interview, all participants were currently smoking commercial cigarettes. Five participants completed all 6 daily diary entries, 1 participant completed 5 of 6 entries, and 1 participant completed 4 of 6 entries.

Summary of Results

Participants reported that the app was user-friendly and convenient to use. All participants expressed strongly positive views about the look and feel of the app and did not report any negative or critical feedback on this aspect. They praised the Native artistic touches, the user-friendly layout, and the app's modern and refreshing feel. Participants also noted that the app was clearly tailored to their culture, citing elements such as the Medicine Wheel imagery, the use of Native lingo, and Winona (the guide avatar). Finally, participants appreciated the notifications with inspirational quotes and reminders to stay smoke-free throughout the day. Participant perceptions of each app feature from diary entries are presented in Table 1, along with representative quotes from 1-on-1 interviews.

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Table 1. Quantitative rating summary and representative quotes for each app feature reviewed[a].

App feature	Example question	Rating scale (1 to 5)	Ratings summary	Representative quote
Overall Experience	How would you rate your experience with the IndigeQuit app?	Poor to excellent	• 5 of 7 participants gave an experience rating of 5 across all or almost all entries, with 1 participant giving a rating of 4 on 1 day. • 1 of 7 participants gave an experience rating of 4 across almost all entries, giving a rating of 3 on 1 day. • 1 of 7 participants gave a mix of experience ratings between 3 and 5, giving a rating of 3 on 2 days, 4 on 3 days, and 5 on 1 day.	"There's something special about this app that, for Natives, will make it better than any other."
Information About Ceremonial Versus Commercial Tobacco	If you read about Ceremonial Versus Commercial Tobacco, what is the value of this information?	Not very to very valuable	• 3 of 4 participants gave a value rating of 5. • 1 of 4 participants gave a value rating of 4.	"Having that historical information in there I think is good, especially for those that maybe don't know about ceremonial tobacco use to know that it's not the same. I know I've definitely been around Natives where we're off praying and it's like, 'All right, who's got a cigarette?' And we're just going to pop some tobacco out of a cigarette off on the side of a mountain or whatever…I know there's been a couple of us making jokes like, 'Yeah, we're going to go smudge our lungs.' Oh my god, that's so bad, but it's so common. So having that distinction in there I think is really good."
Character Testimonials	How valuable are these stories?	Not very to very valuable	• 6 of 7 participants gave a value rating of 5. • 1 of 7 participants gave a value rating of 3.	"It actually made it sink in a little bit more too, because after growing up being Native and everything, hearing stories is one of the best ways to learn."
Tracking smoking, urges, and smoke-free days	How likely are you to continue tracking?	Not likely to very likely to continue tracking	• 5 of 7 participants gave a likelihood rating of 5. • 2 of 7 participants gave a likelihood rating of 4.	"That was really helpful, especially giving me little quotes and little tips to actually, like little to-do techniques or tools to use…It's just a moment or at a moment's notice and you just let that moment just pass and you'll be okay."
Push Notifications	How valuable are the notifications?	Not very to very valuable	• 4 of 7 participants gave a value rating of 5. • 2 of 7 participants gave a value rating of 4. • 1 of 7 participants gave a value rating of 3.	"When I got up in the morning, or when it was like a phrase or something, then I'd take a look inside the app, see where I was at…that was pretty cool. I liked that. It kind of got me up in the mornings."
Track My Progress & Calendar Tracking	What is the overall ease of use of tracking your smoking and urges?	Not easy to very easy to use	• 2 of 5 participants gave an ease-of-use rating of 5. • 2 of 5 participants gave an ease-of-use rating of 4. • 1 of 5 participants gave an ease-of-use rating of 3.	"I liked it. I liked it, because it shows progress, and it shows the effort that I've made. That definitely, progress is very important for me, because I like to know how far I have come along, since I have implemented an app that is able to help me quit smoking."
Journey Statistics & My Quit Plan	How valuable is this information?	Not very to very valuable	• 3 of 4 participants gave a value rating of 5. • 1 of 4 participants gave a value rating of 4.	"I like how it was set up with the amount of money saved. I'm on a 6-day plan just for the testing. The milestone medals were pretty neat, just kind of keeps me busy. It kind of keeps my mind off of the urges and going out and smoking basically." [edited for clarity]

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App feature	Example question	Rating scale (1 to 5)	Ratings summary	Representative quote
Audio exercises	If you have listened to audio exercises, how valuable is the information given in the exercise?	Not very to very valuable	• 2 of 4 participants gave a value rating of 5. • 2 of 4 participants gave a value rating of 4.	"You could just hit play and close your eyes and think that somebody's sitting there with you and is from your community and is talking to you, which is nice. I liked that."
Fireside Chat	If you used Fireside Chat, what is the value of this feature?	Not very to very valuable	• 2 of 2 participants gave a value rating of 5.	"It's nice to hear from other people from other Nations to express their journey on a smoke-free life and using the app and everything.
Medication Tool	How useful was this information and reminder system?	Not very to very useful	• 4 of 5 participants gave a usefulness rating of 5. • 1 of 5 participants gave a usefulness rating of 2.	"My favorite part has actually been the medications. To see prayer included and to see community included is crazy to me not because it's crazy but because it's unheard of to see those things considered in any journey surrounding something like stopping smoking, drinking, or even mental health with apps like these. It's such a good thing to acknowledge these because I know for me, having tried other apps and the patches before, that at one point prayer and community was all I had but it felt like it wasn't enough for these apps when documenting information because it isn't gum or a medication physically. If it's encouraging to me to get credit for these things I know it will be to others and if that's all they have? To be credited for it can go a long way."

[a]For summaries of ratings with fewer than 7 total participants, the remaining participants either did not complete the diary entry in which the question was included, had not yet encountered the app feature at the time the question was asked, or had their response excluded due to their rating explanation indicating they had thought the question was asking about a different app feature.

Positive Response to Cultural Tailoring

Participants unanimously felt that the app was designed for them and pointed to several culturally tailored features as the reason. These included the following: (1) stories from testimonial characters, which they found relatable and inspiring and which fostered a sense of community; (2) culturally tailored resources, such as information about ceremonial versus commercial tobacco, which they found informative and engaging; (3) character designs and the app's inviting interface, which reinforced the sense that the app was truly created for them; and (4) the medicines tool's recognition of prayer, ceremony, and community engagement as aids to quitting smoking. One participant said: "Right off the bat they're including prayer and ceremony and community. That's not something that you see with the other apps. I really like that, because it felt like being seen and that recognition is there for something that typically isn't recognized...It goes a long way."

Many participants also identified the guide character, Winona, as a key example of cultural tailoring. Responses to Winona were overwhelmingly positive. Participants described receiving guidance from her as feeling similar to being spoken to by an elder or older relative, particularly a grandmother. This association was viewed entirely positively and was often described as meaningful and cherished. One participant shared: "My grandma was kind of the same way. She told stuff in stories. She never got really angry. She just always knew the right time to talk and say certain things. So, it was pretty neat. The way I felt about it was getting up in the morning, having breakfast, drinking coffee, and sitting with her and talking. That's the way it felt to me." Participants were enthusiastic about Winona's visual appearance, which they felt conveyed wisdom and healthy aging. They also found her storytelling humanizing and inspiring, making the content feel more authentic and helping them connect it to their own lives.

Quantitative content analysis of diary entries and 1-on-1 interviews with diary study participants generated 20 suggested changes to the app, summarized in Table 2. These results were presented to the CAB and stimulated discussion of additional adaptations. Suggestions supported by 3 or more diary study participants or strongly endorsed by CAB members were prioritized. The remaining suggestions were not implemented because of feasibility and budget constraints. The following changes were deemed both appropriate and feasible and were incorporated into the final version of the app: (1) content on vaping was added to the frequently asked questions (FAQ) section; (2) motivation icons were incorporated into My Quit Plan, and a link to update these motivations was added to the hamburger menu (Figure 3); (3) the number of daily push notifications was increased to 4, including additional content encouraging users to check in on urges; (4) tracking on the home screen was changed from "Yesterday's Cigarettes" to "Today's Cigarettes," and a link to calendar tracking was added to the hamburger menu; (5) a field was added to the Quit Plan where

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users can update how much they spend on a pack of cigarettes; and (6) the Medications Tool was renamed the "Medicines Tool."

Table 2. Suggested changes based on diary study participant feedback.

Number of participants endorsing each change, n	Suggested change
4	• Include vaping frequently asked questions addressing the dangers of vaping and its health impact, how it compares to smoking cigarettes, and how vape nicotine is also commercial. • Feature the motivations icons selected by the user more prominently and allow users to edit their list more easily. • Increase standard to 4 push notifications per day. If feasible, allow the user to customize the number and time of notifications.
3	• Change "Yesterday's Cigarettes" counter to "Today's Cigarettes." • Include more push notifications that prompt the user to check in on their urges. • Explicitly state that IndigeQuit tools can also be used to quit/reduce other substances, especially alcohol.
2	• Ensure more variety in the tips offered in the Urge Help feature. • Have a location in the app where users can find the quotes provided in push notifications. • Provide more organization in Fireside Chat, such as topic categories or a search bar for key terms. • Prepopulate Fireside Chat with quitting stories. • Include a Tools menu in the hamburger menu to help users locate specific tools after they are introduced. • Include an editable field for price per pack next to "Money Saved" in "My Quit Plan".
1	• Rename the medications tool so it doesn't discourage people who are not taking medications from interacting with it. • Address how marijuana (including edibles) is often used as a replacement behavior. • Allow a customizable write-in option under the existing "Additional Support" list (eg, ceremony, prayer, being active in community, other: ____). • Add "time of day" to the list of trigger options in Urge Help. • Add a new motivation icon called "Community." • Make a full monthly calendar option (or show at least 2 weeks at a time) to better see progress and potentially include more information about urges and triggers tracked in Urge Help. • Rename "On the Path" to make it clearer that this menu item refers to content after your quit date. • Add visuals to accompany the Leaves on a Stream exercise.

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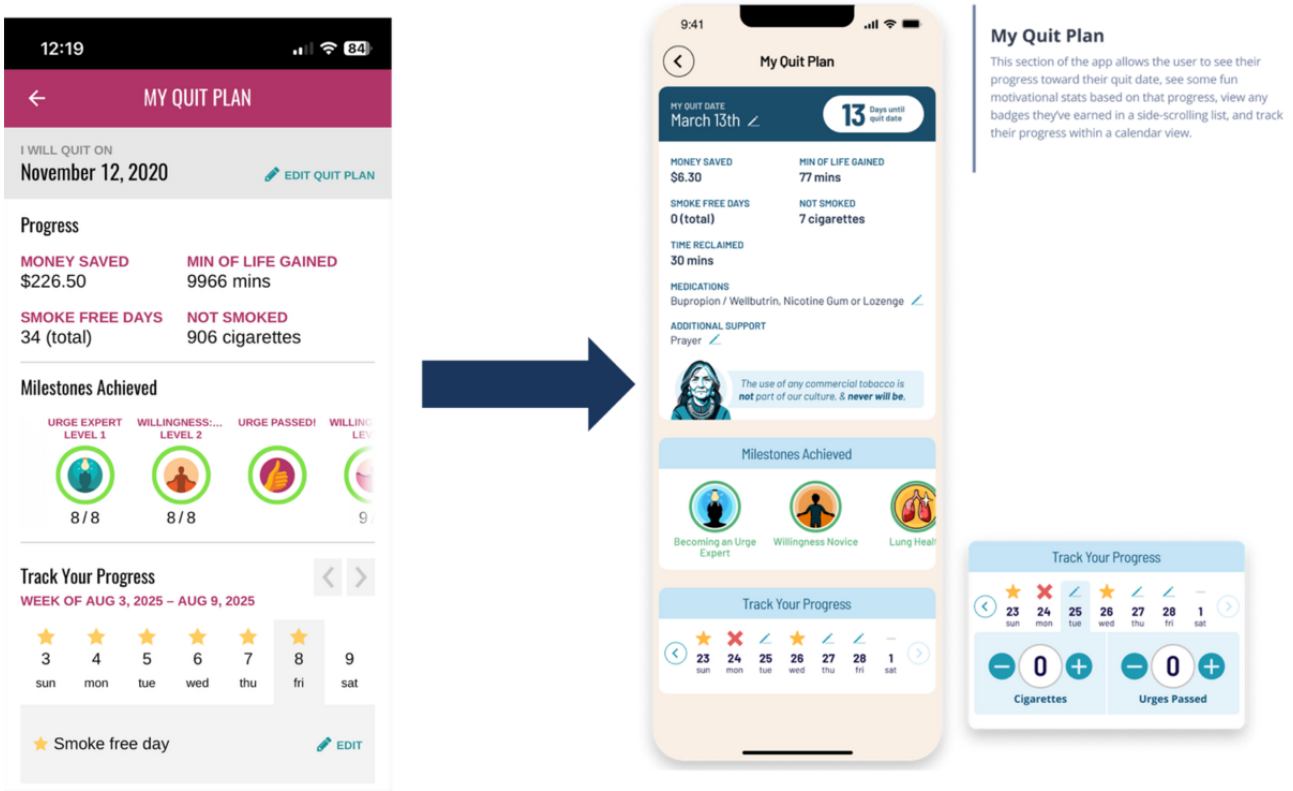
Figure 3. My Quit Plan. The left panel shows the original iCanQuit My Quit Plan feature, which summarizes quit progress using smoking cessation–related metrics (eg, smoke-free days, money saved, cigarettes not smoked) and calendar-based tracking. The right panel shows the redesigned version, which integrates supportive messages from the guide avatar, Winona, to reinforce motivation and engagement.



Discussion

Principal Findings

This study used a 3-step, user-centered CBPR approach to culturally adapt the iCanQuit app in collaboration with a CAB of AI/AN members, resulting in the development of the IndigeQuit app to help AI/AN communities quit commercial cigarette smoking. Principal findings indicated that honoring the Earth and nature, family and community, and cultural connectedness emerged as key themes throughout the iterative process and therefore became the focus of the app's cultural refinements.

The main cultural adaptations included AI/AN imagery, refinements to avatar testimonials and intervention content (eg, incorporating "rez" phrases), and the development of new features and tools. New imagery features avatars representative of AI/AN community members, including the guide avatar Winona, who resembles a community elder, and the use of the Medicine Wheel as the basis for the home screen design. Culturally tailored content includes information on the distinction between ceremonial and commercial tobacco, resources and external links to support Native users (eg, a powwow sweat dancing exercise video and an online resource identifying whose ancestral homelands one resides on), a vaping FAQ, and messaging in recruitment and onboarding materials emphasizing that the app was developed by Natives for Natives. New functions include Fireside Chat to facilitate connection between users and a revised Medicines Tool that tracks both Traditional (eg, community engagement, ceremony, prayer) and Western medicines (eg, bupropion, nicotine patch).

The beta testing of the app, which included a 6-day diary study followed by 1-on-1 interviews with a nationally recruited sample of AI/AN adults who smoke commercial cigarettes, indicated that all participants responded positively to the app's design, praising its Native modern, user-friendly layout and cultural tailoring through Native imagery, language, and the Winona avatar. Participants especially valued the inspirational quote notifications and reminders, with some intentionally keeping them on their home screens for continued motivation.

Comparison to Prior Work

Digital interventions for smoking cessation are now ubiquitous. However, only a few studies have reported on the cultural adaptation of smoking cessation interventions developed specifically to meet the unique needs of historically underserved AI/AN communities [56-59]. Specific to digital smoking cessation interventions, Carroll et al [60] developed and pilot-tested a cultural adaptation of the NCI smoking cessation app "QuitGuide" for AI adults who smoke commercial cigarettes and want to quit, named "QuitGuide for Natives." Their cultural adaptation process also included qualitative interviews with the sample population and a second set of interviews with tobacco treatment specialists and public health professionals working in AI community settings in Minnesota and at a Tribal health clinic in Wisconsin.

Importantly, while both the IndigeQuit and QuitGuide for Natives apps were culturally tailored to AI/AN communities, the key distinction is that IndigeQuit is based on ACT [47], whereas QuitGuide for Natives is based on the USCPG [61]. ACT for smoking cessation focuses on the acceptance of

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cravings to smoke, which is conceptually distinct from standard USCPG approaches that teach avoidance of cravings. In fact, the IndigeQuit RCT is currently testing the efficacy of IndigeQuit in comparison with QuitGuide.

Nonetheless, the suggested cultural adaptations in our study aligned closely with those identified in the qualitative study by Carroll et al [60]. For instance, the importance of ceremonial use of tobacco, being in community, and practicing cultural traditions emerged as important intervention components. Additionally, the portrayal of the Medicine Wheel in the app imagery was suggested in that study, along with highlighting that the app had been developed by Natives for Natives. While in our study we found that caring for the Earth and community were main motivators to quit, in the Carroll et al [60] study, legacy and heritage emerged as the most important reasons for wanting to quit.

One main distinction between the qualitative findings of Carroll et al [60] and ours was that grief emerged as the primary theme with regard to important triggers for smoking. The authors noted that a sense of historical trauma and oppression was related to the concept of grief. While grief, specifically, did not emerge as a theme in the qualitative interviews we conducted, the concept of historical trauma did emerge during our discussions with the study CAB. The CAB emphasized the prevalence of trauma among AI/AN communities and how it contributes to commercial tobacco use and addictive behaviors more broadly. We addressed this emergent theme by adding a link to Mind Mental Health Support: Coping with Trauma in the newly developed Resources Tool in the app.

Community Impact

The findings from the study that we consider particularly important relate to the use of CBPR principles and the community impact that was integral to the entire process. The incorporation of CBPR principles to collaborate with AI/AN community members in their roles as the study CAB was crucial, given the team's focus on culturally adapting the intervention to be more relevant, acceptable, and inclusive of AI/AN communities. This goal was achieved through qualitative feedback from nationally recruited AI/AN community members and CAB-driven adaptations.

The importance of building partnerships with community members and stakeholders cannot be overstated. Collaborating with the CAB provided us with constructive suggestions and helped establish a bottom-up approach to community participatory planning by prompting useful modifications to the suggested refinements in step 1. Their input, grounded in lived and professional experiences from diverse Tribal communities, ensured that the app was culturally tailored for AI/AN people broadly, increasing its relevance across Tribal communities. This helped us develop the suggested refinements to more effectively meet the unique needs of AI/AN communities. In the next phase of the study, we are currently implementing the IndigeQuit RCT in strong collaboration with the CAB throughout the duration of the trial and beyond.

Strengths and Limitations

This study has the potential to advance research on the development of culturally tailored interventions for AI/AN populations. First, the use of CBPR principles within a transdisciplinary research and community team provided contextual relevance and helped address the unique needs of the priority population. Second, the comprehensive 3-step process and the use of both quantitative and qualitative data offer a practical example for future cultural adaptation studies. Third, the inclusion of a geographically diverse group of AI/AN individuals who smoke or formerly smoked commercial cigarettes, in addition to CAB members and AI/AN investigators representing diverse Tribal affiliations, provided diverse perspectives on Indigenous customs, traditions, and viewpoints. Despite the study's strength in incorporating diverse perspectives, several limitations should be noted. As with all qualitative research, the findings are not intended to be generalizable to other populations and do not represent the full diversity of the 574 federally recognized AI/AN Tribes in the United States. Accordingly, the results should be interpreted as informing culturally grounded design rather than representing all AI/AN experiences.

Second, the findings should be considered in the context of the convenience sampling approach used in steps 1 and 2, which included prior iCanQuit RCT participants. This approach may have introduced selection or social desirability biases. However, these participants' direct, in-depth experience with the original app uniquely positioned them to identify which elements required cultural adaptation to enhance relevance for AI/AN users.

Third, the study was not designed to prospectively assess thematic saturation, as the interviews were intended to elicit targeted, actionable feedback on specific cultural adaptation elements, and responses were largely consistent across participants. Although saturation was not prospectively assessed in steps 2 and 3, substantial thematic overlap was observed. Given the study's narrow aims, high-quality and time-intensive diary data, and confirmatory analytic focus, the concept of information power supports the sufficiency of the sample despite limited generalizability [62,63].

Finally, step 1 interviews were conducted in September 2022, whereas the primary 3-step development process occurred between June 2024 and August 2025. This time gap reflects the iterative nature of culturally grounded intervention development, including securing funding, establishing the CAB, and conducting subsequent qualitative work. Importantly, findings from 2022 were reexamined and confirmed through later CAB engagement and diary studies and remained relevant because they reflected enduring AI/AN values and practices, such as the central role of culture, spirituality, family, and community as motivators; the importance of a representative guide character; and the distinction between ceremonial and commercial tobacco use.

Conclusions

The user-centered and CBPR development process yielded a comprehensive and culturally tailored app called IndigeQuit.

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The iterative development process led to improvements in app imagery, design, content, and features, enabling users to connect more deeply with the program. Our next step is to test IndigeQuit against QuitGuide in an RCT among 776 nationally recruited AI/AN adults who smoke commercial cigarettes and want to quit.

The principles of cultural adaptation, community engagement, and value-based motivation—while grounded in AI/AN cultural contexts—may inform the design of smoking cessation and digital health interventions for other demographic groups.

The processes presented here provide a guide for developing culturally tailored commercial smoking cessation interventions designed to meet the unique needs of priority populations experiencing tobacco-related health inequities.

Acknowledgments

We extend our heartfelt gratitude to all the participants who generously contributed their time and insights to this study. We also thank the members of our community advisory board for their invaluable guidance and feedback throughout the project. Finally, we are deeply grateful to all members of the study team and Moby Inc., whose dedication and collaboration made the cultural adaptation of the smartphone app possible.

Data Availability

The data will be shared on a reasonable request to JBB (jbricker@fredhutch.org).

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Conflicts of Interest

None declared.

Multimedia Appendix 1
Step 1 interview guide.
[DOCX File , 4010 KB - formative_v10i1e88768_app1.docx]

Multimedia Appendix 2
Step 2 interview guide.
[DOCX File , 3237 KB - formative_v10i1e88768_app2.docx]

Multimedia Appendix 3
Step 3 interview guide.
[PDF File (Adobe PDF File), 1759 KB - formative_v10i1e88768_app3.pdf]

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Abbreviations

ACT: acceptance and commitment therapy
AI: American Indian
AN: Alaska Native
CAB: community advisory board
CBPR: community-based participatory research
FAQ: frequently asked questions
HIPAA: Health Insurance Portability and Accountability Act
NCI: National Cancer Institute
OR: odds ratio
RCT: randomized controlled trial
USCPG: US Clinical Practice Guidelines

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Original Paper

Evaluating the Preliminary Outcomes and Acceptability of a Virtual Adaptation of Acceptance and Commitment Training for Caregivers of People With Disabilities ("I Am Not Alone"): Mixed Methods Study

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Abstract

Background: Family caregivers of children and youth with neurodevelopmental disabilities report higher levels of stress, anxiety, and depression than other caregivers, yet few evidence-based mental health services are available to support them. Our previous research demonstrated that caregivers benefitted from our in-person group-based acceptance and commitment training (ACT) workshop, which increased their psychological flexibility and improved their mental well-being. During the COVID-19 pandemic, we adapted this intervention to be delivered virtually.

Objective: In this study, we evaluated the program's impact on caregivers' psychological flexibility and mental well-being, as well as the acceptability of the virtual program.

Methods: A total of 205 family caregivers of neurodivergent people or people with disabilities who registered for a virtual, group-based ACT intervention (10-12 hours across 5 or 6 weeks) from 1 of 27 teams across Canada participated in this research. ACT process (measured via the Cognitive Fusion Questionnaire, Acceptance and Action Questionnaire, Self-Compassion Scale–Short Form, and Valued Living Questionnaire) and mental well-being outcomes (measured through the Patient Health Questionnaire, Parenting Stress Index, Multi-System Model of Resilience Inventory, and Short Warwick-Edinburgh Mental Well-being Scale) were measured before and after the intervention and again at an 8-week follow-up. An acceptability survey was completed after the intervention, including items on satisfaction with virtual aspects of the intervention.

Results: There was high intervention acceptability related to the virtual format (at least >80% satisfaction) despite variability in individual preferences (preferred in-person format: 28/91, 31%; preferred virtual format: 37/91, 41%; no preference: 26/91, 29%). Significant improvements were found for most ACT processes (fusion: $F_{2,279}$=63.96; psychological flexibility: $F_{2,264}$=38.81;

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values: $F_{2,244}$=8.32; self-compassion: $F_{2,170}$=33.59; P<.001 in all cases) and mental well-being measures (parental stress: $F_{2,236}$=20.27; well-being: $F_{2,137}$=22.89; mood: $F_{2,15}$=23.12; resilience: $F_{2,17}$=32.83; P<.001 in all cases). Pairwise comparisons between preintervention and follow-up showed maintenance of ACT skills (P<.001 in all cases; η_p^2 ranged from 0.09 to 0.40) and well-being improvement (P<.001 in all cases; η_p^2 ranged from 0.19 to 0.37). Direct content analysis of participants' qualitative survey responses revealed that cognitive defusion, mindfulness, and acceptance were the most helpful ACT processes. We received feedback for modifications to formatting, pacing, content, and duration of the group to support a wider range of caregiver needs.

Conclusions: The virtual, group-based ACT intervention was acceptable and led to positive changes in psychological flexibility and mental well-being among family caregivers of people with disabilities or neurodivergent people, similar to outcomes observed with in-person delivery of the intervention. Further comparison and contrast with in-person programming is needed to ensure accessibility and sustainability of this program.

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KEYWORDS

neurodivergent; family caregivers; clinicians; acceptance and commitment training; virtual adaptations

Introduction

Family caregivers caring for children and youth with disabilities, including those with medical conditions (eg, epilepsy and diabetes) and/or neurodevelopmental conditions (eg, autism, intellectual disability, cerebral palsy, and fetal alcohol spectrum disorder), hereinafter referred to as caregivers of people with disabilities, experience both rewards and challenges. These caregivers are often balancing the needs of their family member with a disability, while attending to their own physical and mental well-being [1-5]. As a result, caregivers often face more stress and decreased well-being compared to caregivers of children without disabilities [6-8]. With heightened strain on the family system, caregivers may engage in avoidance strategies to cope [9]. While avoidance coping may offer short-term relief, it is linked to heightened stress and long-term challenges with mental well-being [10].

Interventions directly addressing caregiver well-being have been underprioritized, with most efforts focused on training caregivers to support their family member with a disability [11,12]. Among the limited research exploring caregiver-focused interventions, mindfulness- and acceptance-based approaches have received attention for enhancing caregivers' mental well-being, with most studies focusing on adaptations of mindfulness-based stress reduction [13-15]. Another third-wave intervention, acceptance and commitment training (ACT), has also recently gained traction, highlighting the potential benefits of increasing psychological acceptance and value-driven behaviors, in addition to providing training on the principles of mindfulness. (For this manuscript, we used the term "acceptance and commitment training" rather than "therapy." Our program focuses on providing ACT skills to a nonclinical population outside of a psychotherapeutic setting, so we chose to use "training" to align with previous studies of a similar nature [16].) Preliminary research exploring ACT, including multiple randomized controlled trials [17-20], has shown promising results in supporting the mental well-being of caregivers of people with disabilities [12,21-25].

ACT aims to increase psychological flexibility by opening up, being present, and doing what matters [21,26-28]. It acknowledges that life experiences evoke negative emotions and proposes that accepting and distancing from internal experiences can reduce long-term distress [27]. In offering an alternative way to engage with internal experiences, ACT can support caregivers to examine their values and commit to them through action, including prioritizing their well-being, often overlooked amid the pressures of caregiving.

Self-compassion is also a key factor in reducing caregiver stress. For caregivers of individuals with disabilities, greater self-compassion has been linked to lower levels of stress and depression as well as improved resilience [29]. A meta-analysis of 15 studies highlighted that self-compassion had moderate to large effects on parental stress, anxiety, and well-being [30]. ACT, with its focus on acceptance and values, has also been effective at improving self-compassion among mothers of children with neurodevelopmental disabilities [31] and people managing chronic pain [32]. Furthermore, in a randomized controlled trial of a single-session ACT workshop, psychological flexibility was found to be a mediator of self-compassion [33].

Consistent with the growing evidence demonstrating the benefits of caregiver-focused interventions led or supported by peer mentors [34-37], our model of ACT intervention is cofacilitated by teams of trained caregivers of people with disabilities and clinicians [22,38]. Caregivers' insights contribute invaluable perspectives, while their presence fosters a supportive environment where participants feel validated, facilitating open dialogue and promoting mutual learning [16]. This collaborative approach enriches both the intervention experience and provides a sense of community among participants and facilitators.

The COVID-19 pandemic necessitated the transition from in-person interventions to virtual formats. Continuing to offer virtual support from that time has enabled health care providers to reach a broader audience of caregivers, including those who may prefer or require remote access to care due to a variety of reasons (eg, childcare responsibilities, geographical restrictions, and financial costs) [39].

Although in-person ACT has shown effectiveness for caregivers [22,39] and other virtual interventions are acceptable and effective [40], no research has examined the preliminary outcomes of a group-based virtual ACT for caregivers. Group-based virtual ACT has been found to be effective in

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addressing other concerns during the pandemic, including mental health for women [41], depression [42], and early psychosis [43]. This study aims to fill this gap by examining acceptability and preliminary outcomes of a virtual, group-based ACT intervention cofacilitated by caregivers and clinicians. Given previous evaluations of the main content, we hypothesized replication of good acceptability (with variations in accessibility due to virtual implementation), improvement in mental health outcomes, and increased ACT-related skills.

Methods

Overall Design

The study used a within-participants preintervention, postintervention, 8-week follow-up design to evaluate the acceptability and preliminary outcomes of a virtual ACT group intervention aimed at improving specific ACT processes and the mental well-being of caregivers of people with neurodevelopmental disabilities. Acceptability was examined through a Likert scale measuring intervention satisfaction and accessibility. Preliminary outcomes were evaluated through standardized measures of mental well-being and ACT-related process outcomes. Directed content analysis was used to examine participants' postintervention responses to open-ended questions about program takeaways and suggestions for improving the intervention.

Procedure

Participant Recruitment and Research Participation

Eligible participants included English-speaking caregivers of people with disabilities with internet access and a private space for the virtual intervention. Participants were recruited at 12 organizations serving people with disabilities and their families across Canada through digital flyers. Recruited participants of the ACT intervention were invited to take part in the research evaluation, which was not mandatory. ACT groups were run between 2020 and 2024. Consenting participants completed an online survey 1 to 2 weeks prior to the start of the intervention (preintervention time point), immediately after the intervention (postintervention time point), and again 8 weeks after the final session (follow-up time point). All study data were collected and managed using Research Electronic Data Capture (REDCap; Vanderbilt University) electronic data capture tools. Given the focus on implementation and delivery of services to partnering agencies, no previous sample size analysis was calculated; instead, the full dataset of individuals recruited during a grant period was analyzed.

Ethical Considerations

Participants were compensated with CAD $50 (US $37) for their time. This project received ethics approval from the Centre for Addiction and Mental Health Research (037-2017). Written informed consent was obtained from participants. Data were deidentified after data collection to safeguard participant information.

ACT Intervention Description

The ACT intervention consisted of 90-minute weekly virtual group sessions conducted via platforms (eg, Zoom or Webex) over 5 or 6 weeks (ie, modified longer version used by some organizations). The intervention was designed to accommodate groups of up to 15 participants, depending on site capacity. Each session was cofacilitated by at least 1 caregiver and 1 clinician, both of whom completed formal ACT facilitator training, including coaching sessions with experienced caregiver facilitators. The intervention was structured using a combination of didactic teaching, experiential activities, and small group sharing, with each session focused on learning about 1 or 2 specific ACT processes [22,38]. Facilitators implemented the intervention with high fidelity (84.7%) based on an internally designed fidelity measure where facilitators reported on whether they completed, partially completed, or did not complete specific exercises.

Measures

Acceptability

Participants completed 7 items pertaining to their satisfaction with the intervention (eg, intervention relevancy, helpfulness, and usefulness). Seven items were measured on a 5-point Likert scale (1=strongly disagree and 5=strongly agree).

Well-Being Measures

Parenting Stress Index–Fourth Edition

The 6-item isolation and the 5-item health subscales of the Parenting Stress Index–Fourth Edition [44] were summed to reflect participants' perceived social isolation and physical health in relation to parenting. Items are rated on a 5-point scale (1="strongly agree" to 5="strongly disagree"), with higher scores indicating more overall parental stress. The internal consistency was acceptable in this sample (Cronbach α=0.78 altogether; Cronbach α=0.64 for the Parenting Isolation subscale alone; Cronbach α=0.75 for the Parenting Health subscale alone).

The Short Warwick-Edinburgh Mental Well-Being Scale

The Short Warwick-Edinburgh Mental Well-being Scale (SWEMWBS) [45] is a 7-item measure designed to assess mental well-being. Items are rated on a 5-point scale (1="none of the time" to 5="all of the time"), with higher scores reflecting increased mental well-being. The internal consistency was good (Cronbach α=0.85).

Patient Health Questionnaire–4

The Patient Health Questionnaire–4 (PHQ-4) [46] is a valid ultrabrief measure for capturing anxiety and depressive symptoms. Total possible scores on the PHQ-4 can range from 0 to 12, with higher scores indicating greater challenges to mental well-being related to anxiety and/or depression. The internal consistency was good (Cronbach α=0.87).

Multi-System Model of Resilience Inventory

The Multi-System Model of Resilience Inventory (MSMR-I) [47] is a 27-item tool to measure resilience. The items examine 3 systems of resilience resources, including internal resources; external resources; and values, pursuits, and coping. Questions are scored on a 4-point Likert-type scale (0="not at all like me" and 3="very much like me"), with higher scores indicating

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greater resilience. The internal consistency was good (Cronbach α=0.81).

ACT Process Measures

Cognitive Fusion Questionnaire

The Cognitive Fusion Questionnaire (CFQ) [48] is a 7-item measure used to assess cognitive fusion vs defusion (ie, not relating to thoughts based on their literal content or having more psychological distance from one's thoughts). Participants rate statements related to their struggle with their thoughts on a 7-point Likert scale (1="never true" and 7="always true"), with higher scores indicating greater fusion with thoughts and lower scores indicating greater defusion. The internal consistency was excellent (Cronbach α=0.92).

Acceptance and Action Questionnaire: Intellectual Disability Parent Version

The Acceptance and Action Questionnaire–Intellectual Disability Parent Version (AAQ-ID) [49] assesses psychological flexibility in relation to parenting a child with a disability. Participants rated 8 statements that were adapted to refer to a "child with a disability" (rather than "child with fetal alcohol syndrome" in its original form) using a 7-point scale (1="never true" and 7="always true"). Higher scores indicate less flexibility, while lower scores indicate more flexibility. The internal consistency was good (Cronbach α=0.83).

Valued Living Questionnaire

The Valued Living Questionnaire (VLQ) [50] is a two-part instrument used to assess (1) the perceived importance of values across 10 different areas of life (eg, work, family, and friends) on a 10-point scale and (2) the consistency of one's actions with regard to their own values in each of these areas on the same scale. VLQ scores are calculated by the sum of the products of each pair of items (importance × consistency) across the 10 domains. Higher scores indicate greater alignment with values. The internal consistency was good (Cronbach α=0.82).

The Self-Compassion Scale–Short Form

The Self-Compassion Scale–Short Form (SCS-SF) [51] is a 12-item measure that assesses the ability to demonstrate care and kindness toward oneself and acceptance of one's own imperfections. Responses are recorded using a 5-point Likert scale (1="almost never" to 5="almost always"), yielding a total score between 12 and 60, with higher scores indicating greater self-compassion. The internal consistency was good (Cronbach α=0.88).

Data Analysis

Preintervention, Postintervention, and Follow-Up Quantitative Comparisons

A within-participants repeated measures ANOVA was conducted using SPSS (IBM Corp) to evaluate changes in mental well-being and ACT process outcomes (psychological flexibility, fusion, and values) across the 3 time points: preintervention, postintervention, and follow-up. Assumptions for repeated measures ANOVA were assessed by checking normality and the absence of outliers. Normality was evaluated using skewness, kurtosis z values, and *QQ* plots, while boxplots were examined visually for outliers. Violations of normality and outlier assumptions were noted for a couple mental well-being measures; specifically, 2 influential outliers were removed for the SWEMWBS and 3 for the PHQ-4. Moreover, sphericity was assessed using the Mauchly test, and when this assumption was violated, results were adjusted using the Greenhouse-Geisser correction. To account for multiple comparisons, Bonferroni correction was applied to post hoc contrasts, setting the significance threshold at P=.02 (ie, P=.05/3). When significant results were found, pairwise comparisons were performed for preintervention to postintervention, preintervention to follow-up, and postintervention to follow-up, with Bonferroni corrections applied. The analyses included data only from participants who completed the relevant measure at all 3 time points. Effect sizes were explored using partial eta squared (η_p^2) to assess the magnitude of the observed effects. To handle missing data, if 80% or more of the individual items were completed, the total score was calculated; otherwise, the data were considered missing. Only data with all 3 time points were included. The SCS-SF, SWEMWBS, PHQ-4, and MSMR-I were added in later cycles, resulting in smaller sample sizes for those analyses.

Content Analysis

Directed content analysis [52] was used to identify common concepts across three open-ended questions relating to participants' experience with the intervention: (1) key intervention takeaways (n=96 completed responses), (2) suggestions for ways to improve the intervention (n=84 completed responses), and (3) most helpful ACT processes (n=70 completed responses). A mixture of deductive (ie, theory-driven codes about ACT processes [22] and self-compassion [53,54]) and inductive coding (ie, identified from the data) was used [52]. Open-ended responses were reviewed, and a codebook was codeveloped (LM and HD) and cocoded. Overarching category structure and interpretation were reviewed with a caregiver advocate (LS). After initial review, we found that the "key intervention takeaways" section had codes that were consistent with existing frameworks (eg, the self-compassion framework by Neff [53] and ACT processes), supporting the use of a directed content analysis approach [52]. Due to the brevity of other responses, we analyzed ways to improve the intervention and the most helpful ACT processes using summative content analysis.

Results

Demographics

A total of 219 caregiver participants of people with disabilities from 27 virtual ACT intervention cohorts across Canada consented to participate in the research study between 2020 and 2024, of whom 205 (93.6%) proceeded to complete the demographics section. The participant flowchart is shown in Figure 1. Caregiver participants were aged between 19 and 78 (mean 47, SD 3) years. Approximately three-quarters of participants (170/205, 82.9%) identified as women, 12.2% (25/205) identified as men, 0.5% (1/205) identified as genderfluid, and 4.4% (9/205) did not report their gender. In total, 33.5% (70/209) of the participants obtained a postgraduate

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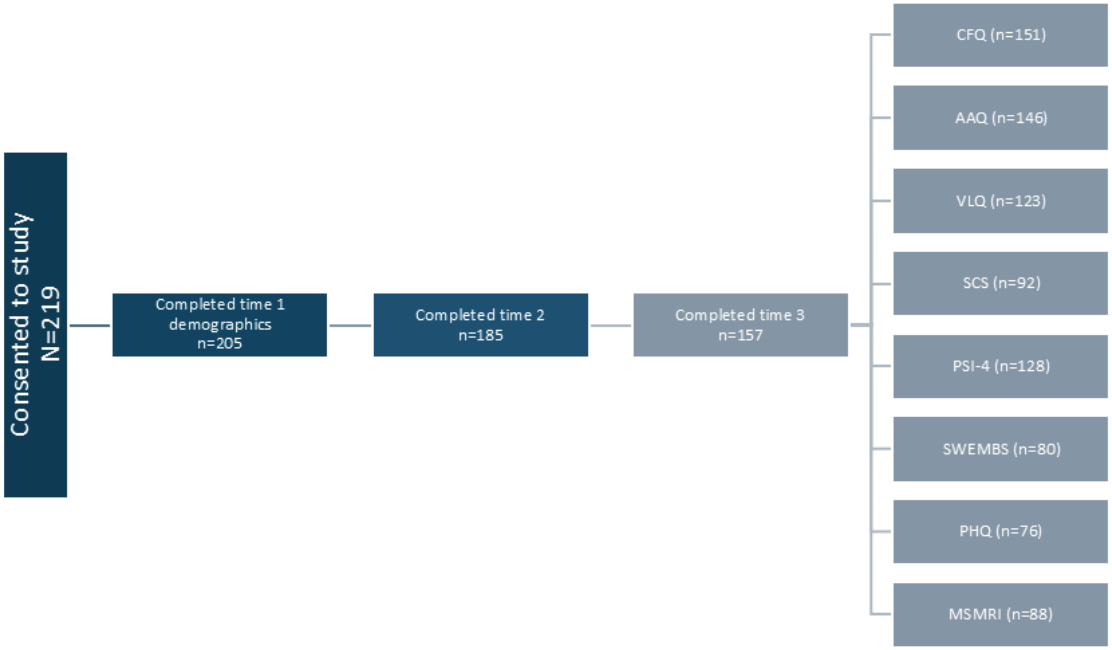
degree, 61.2% (128/209) attended or graduated from college or university, and 4.8% (10/209) attended high school equivalent or less (with 1 person declining to answer).

Figure 1. Participant flowchart showing the number of participants who consented and completed each of the 3 time points (preintervention, postintervention, and 8-week follow-up), as well as the number of complete datasets for each measure. AAQ-ID: Acceptance and Action Questionnaire–Intellectual Disability Parent Version; CFQ: Cognitive Fusion Questionnaire; MSMR-I: Multi-System Model of Resilience Inventory; PHQ-4: Patient Health Questionnaire–4; PSI-4: Parenting Stress Index–Fourth Edition; SCS-SF: Self-Compassion Scale–Short Form; SWEMWBS: Short Warwick-Edinburgh Mental Well-Being Scale; VLQ: Valued Living Questionnaire.



The age of participants' family members with a disability ranged from 1 to 69 (mean 19, SD 1) years. The reported gender of 209 family members with disability indicated that 63.6% (n=133) were cisgender boys or men, 31.1% (n=65) were cisgender girls or women, 2.4% (n=5) were gender diverse (these included 1 each of transgender man, transgender woman, two-spirit, nonbinary, or gender neutral), and 2.9% (n=6) had missing data or preferred not to disclose. In terms of the 202 participants' relationship with their family member with a disability, 59% (n=131) identified as biological parents; 14% (n=32) identified as adoptive parents; 13.4% (n=30) identified as siblings; and the remainder (n=9, 3%) identified as stepparents, grandparents, or step-grandparents. Table S1 in Multimedia Appendix 1 provides a breakdown of family members' diagnoses.

Quantitative Analyses

Acceptability of Virtual Delivery

Almost all participants reported that the web-conferencing software was easy to use (87/91, 95.6%), that they did not encounter technological issues (83/91, 91.2%), and that they were able to find a quiet environment to participate (85/90, 94.4%). Most participants (80/91, 87.9%) also felt connected in the virtual space. In terms of the format of the intervention, 30.7% (28/91) would have preferred an in-person intervention, 40.7% (37/91) preferred a virtual intervention, and 28.6% (26/91) did not have a preference for virtual or in-person intervention, highlighting that there were different preferences for both formats of this intervention.

Mental Well-Being

Table 1 presents the means, SDs, and the ANOVA results related to mental well-being variables at preintervention, postintervention, and follow-up. The ANOVA results revealed that time (ie, preintervention, postintervention, and follow-up) had a significant and large effect across measures of mental well-being.

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Table 1. Repeated measures ANOVA comparing self-reported ratings of mental well-being at preintervention, postintervention, and 8-week follow-up.

	n	Preintervention, mean (SD)	Postintervention, mean (SD)	Follow-up, mean (SD)	*F* test (*df*)	*P* value	η_p^2
Parenting Stress Index–Fourth Edition	128	39.16 (8.22)	36.40 (8.49)	36.02 (8.07)	20.27 (2, 236.25)[a]	<. 001	0.14
Short Warwick-Edinburgh Mental Well-being Scale	80	19.35 (2.69)	20.84 (2.96)	21.36 (2.95)	22.89 (2, 137.72)[a]	<.001	0.23
Patient Health Questionnaire–4	76	5.13 (3.32)	3.59 (2.83)	3.12 (2.23)	23.12 (2, 15)	<.001	0.24
Multi-System Model of Resilience Inventory	88	41.50 (13.7)	47.52 (13.13)	49.86 (12.12)	32.83 (2, 17)	<.001	0.27

[a]Greenhouse-Geisser correction applied.

Paired comparisons with Bonferroni correction applied for the mental well-being outcome measures are detailed in Table 2. Contrasts revealed that scores on the Parenting Stress Index–Fourth Edition, PHQ-4, SWEMWBS, and MSMR-I significantly reduced from preintervention to postintervention and preintervention to follow-up, with no significant difference from postintervention to follow-up.

Table 2. Pairwise comparisons from preintervention to postintervention, postintervention to follow-up, and preintervention to follow-up assessments on mental well-being measures.

	F test (*df*)	*P* value	η_p^2
Parenting Stress Index–Fourth Edition			
Preintervention to postintervention	23.08 (1, 127)	<.001	0.15
Postintervention to follow-up	0.70 (1, 127)	.41	0.01
Preintervention to follow-up	29.96 (1, 127)	<.001	0.19
Short Warwick-Edinburgh Mental Well-being Scale			
Preintervention to postintervention	19.23 (1, 79)	<.001	0.20
Postintervention to follow-up	4.60 (1, 79)	.04[a]	0.06
Preintervention to follow-up	36.38 (1, 79)	<.001	0.32
Patient Health Questionnaire–4			
Preintervention to postintervention	23.42 (1, 75)	<.001	0.24
Postintervention to follow-up	3.16 (1, 75)	.08	0.04
Preintervention to follow-up	35.16 (1, 75)	<.001	0.32
Multi-System Model of Resilience Inventory			
Preintervention to postintervention	34.31 (1, 87)	<.001	0.28
Postintervention to follow-up	5.50 (1, 87)	.02[a]	0.06
Preintervention to follow-up	51.85 (1, 87)	<.001	0.37

[a]Not significant after adjusting for multiple comparisons.

ACT Processes

Table 3 presents the mean, SD, and ANOVA results related to the ACT process variables at preintervention, postintervention, and follow-up. Overall, time had a significant effect across measures of ACT processes, with large effect sizes (ie, η_p^2>0.14) for CFQ, AAQ-ID, and SCS-SF scores and a medium effect size (ie, η_p^2>0.06) for VLQ scores.

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Table 3. Repeated measures ANOVA comparing self-reported ratings of acceptance and commitment training processes at preintervention, postintervention, and 8-week follow-up.

	n	Preintervention, mean (SD)	Postintervention, mean (SD)	Follow-up, mean (SD)	*F* test (*df*)	*P* value	η_p^2
Cognitive Fusion Questionnaire	151	29.11 (8.45)	24.87 (7.54)	22.46 (8.83)	63.96 (2, 279.40)[a]	<.001	0.30
Acceptance and Action Questionnaire–Internalized Dysfunction	146	27.25 (8.47)	23.27 (8.28)	22.36 (7.90)	38.81 (2, 264.70)[a]	<.001	0.21
Valued Living Questionnaire	123	476.56 (155.02)	516.74 (147.65)	519.76 (146.83)	8.32 (2, 244)	<.001	0.06
Self-Compassion Scale–Short Form	92	31.89 (8.45)	37.09 (8.13)	38.21 (8.13)	33.59 (2, 170.04)[a]	<.001	0.27

[a]Greenhouse-Geisser correction applied.

As shown in Table 4, paired comparisons with Bonferroni correction applied revealed a significant reduction in CFQ scores preintervention to postintervention, postintervention to follow-up, and preintervention to follow-up. For the AAQ-ID, VLQ, and SCS-SF, there was a significant reduction in scores from preintervention to postintervention and preintervention to follow-up, with no significant difference between postintervention and follow-up.

Table 4. Pairwise comparisons from preintervention to postintervention, postintervention to follow-up, and preintervention to follow-up for acceptance and commitment training process measures.

	F test (*df*)	*P* value	η_p^2
Cognitive Fusion Questionnaire			
Preintervention to postintervention	51.77 (1, 150)	<.001	0.26
Postintervention to follow-up	21.14 (1, 150)	<.001	0.12
Preintervention to follow-up	100.23 (1, 150)	<.001	0.40
Acceptance and Action Questionnaire–Internalized Dysfunction			
Preintervention to postintervention	40.14 (1, 145)	<.001	0.22
Postintervention to follow-up	3.43 (1, 145)	.07	0.02
Preintervention to follow-up	58.35 (1, 145)	<.001	0.29
Valued Living Questionnaire			
Preintervention to postintervention	11.96 (1, 122)	<.001	0.09
Postintervention to follow-up	0.07 (1, 122)	.90	<0.01
Preintervention to follow-up	12.13 (1, 122)	<.001	0.09
Self-Compassion Scale–Short Form			
Preintervention to postintervention	32.98 (1, 91)	<.001	0.27
Postintervention to follow-up	2.46 (1, 91)	.12	0.03
Preintervention to follow-up	57.04 (1, 91)	<.001	0.30

Qualitative Analysis

Directed content analysis was used to identify (1) key takeaways from the intervention, (2) ways to improve the intervention, and (3) the ACT processes that were most helpful.

Key Takeaways From the Intervention

We applied two different frameworks to guide the organization of key takeaways (categories are italicized) from the intervention: (1) core ACT processes and (2) the self-compassion model by Neff [53].

Participants *described building psychological flexibility by integrating ACT processes*. Participants spoke about embodying *cognitive defusion*, often naming the leaves on the stream exercise as a core takeaway. This exercise involves visualizing each thought placed on a leaf floating down a stream, with the goal of visualizing a different relationship with thoughts (ie, defusion). Others described *acceptance*, primarily around making room for positive and negative feelings. Among *values*, participants detailed a sense of reestablishing a value for self-care and prioritizing their own needs, putting them into *committed action*. *Mindfulness* was also often described in the context of specific meditation exercises that were helpful.

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Finally, 1 respondent shared about how *perspective-taking* and *self-as-context* had been helpful. Altogether, this demonstrated that participants were learning and applying ACT principles in their daily life in a meaningful way.

We identified 3 categories based on the self-compassion framework by Neff [53], including *self-kindness*, *common humanity*, and *mindfulness* (ie, overlapping with ACT processes). *Common humanity*, often phrased as "I am not alone," appeared often as the most commonly reported takeaway.

Finally, some respondents shared about *learning other skills* that were not specific to the ACT intervention but which may have emerged from debriefing discussions. Examples are provided in Multimedia Appendix 1.

Most Helpful ACT Processes

Finally, participants were asked which ACT processes were most helpful. *Cognitive defusion* was named most frequently, followed by mindfulness and acceptance (refer to Multimedia Appendix 1 for frequencies and examples).

Ways to Improve the Intervention

When asked what changes they would make to the intervention, most participants reported *no changes*; however, a few provided feedback on *formatting*, *pacing*, *content*, and *duration* (refer to Multimedia Appendix 1 for examples). Formatting, pacing, and content changes included more opportunities to connect with group members and more time to review concepts. Others preferred a hybrid or in-person format. Duration-related changes included having additional sessions, shorter sessions, and offering the intervention at different times.

Discussion

Principal Findings

The virtual ACT intervention was designed as a rapid response to pandemic-related restrictions and evaluated across agencies for acceptability and preliminary outcomes. This program had strong acceptability and preliminary outcomes, with improvements in well-being and ACT processes, as discussed below. We found significant improvements postintervention across ACT processes and well-being outcomes, similar to the original in-person program [12,22]. Postintervention improvements were maintained for all well-being measures (ie, parental stress, mental well-being, low mood, and resilience) and all ACT processes (ie, defusion, psychological flexibility, values-oriented living, and self-compassion). This study is the largest study to date to examine mental health, well-being, and ACT process outcomes for a virtual ACT program for caregivers [17,20,55]. Critically, we were able to demonstrate improvement in preliminary outcomes of this program for caregivers beyond mothers-only [12,22] or parents-only groups [17,20,55], supporting a subset of siblings who may take over the role of caretaking as parents age. While previous studies targeted caregivers of autistic children, adolescents, or young adults [17,20-22,29,55], our sample included caregivers of adults with diverse neurodevelopmental disorders (eg, intellectual disability and fetal alcohol spectrum disorder).

Acceptability

For this virtual adaptation, there was high acceptability related to the virtual format (>80% satisfaction) despite variability in individual preferences. Although previous studies focused on ACT programs for caregivers collected acceptability measures indirectly through dropout rates [20,21] and Likert ratings [12,24], this is the first large-scale study to examine qualitative feedback in depth. Participants provided suggestions for improving the intervention that may also highlight their diverse needs to enhance acceptability. Examples included offering the program at different times, providing shorter or longer versions, allowing for more time for connection, and adding visual or material supports (eg, workbooks) to accommodate different learning styles.

The pandemic gave rise to a number of virtual and telepsychology programs, particularly for family caregivers of people with disabilities [56-58]. In addition to supporting families during pandemic restrictions, virtual programs have met needs that in-person programs were not able to meet (eg, childcare, travel, and geographic restrictions) [56,58]. Importantly, when family caregivers in this study were polled after completing the intervention around future preferences for programming modality, the proportion of family caregivers who wanted the virtual or in-person format or had no preference was roughly the same (in-person format: 28/91, 31%; virtual format: 37/91, 41%; no preference: 26/91, 29%). This highlighted that both in-person and virtual adaptations of this program may exist to serve different needs. Offering both in-person and virtual adaptations may help address barriers relating to time, income, and childcare support [11,59,60]. Consequently, the virtual adaptation of the ACT program may broaden opportunities for people who are unable to attend in-person programs, with potential suggestions for adaptations to continue evolving to meet more diverse needs. However, considerations regarding how virtual programs may be less accessible to people without technology or a stable internet connection (eg, rural or remote communities) should be considered.

The current synchronous virtual adaptation may have relative advantages over asynchronous adaptations. There have been few studies on virtual asynchronous studies for family caregivers of people with neurodevelopmental disabilities. One meta-analysis of asynchronous (eg, websites, apps, and computer-based interventions) programs focused on parent-mediated interventions for autistic children demonstrated that asynchronous interventions may not produce any changes in outcome [61]. This could suggest that virtual asynchronous modalities alone may not be as effective as virtual synchronous modalities, but this possibility requires further evaluation. This virtual synchronous program may provide family caregivers with a sense of building connection and fostering common humanity [53] that is similar to the in-person format without the cost and barriers associated with an in-person group. Hybrid psychoeducational programs, such as the Healthy Mothers Healthy Families program, which involves asynchronous modules and synchronous training on physical health needs, were found to foster a sense of not being alone while providing mothers with time flexibility in their daily routine [56]. Altogether, this virtual adaptation of ACT for caregivers

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supported participants in feeling connected and empowered to follow their values, providing a possible relative advantage to asynchronous virtual modalities by building a real-time shared connection.

Well-Being

We found significant improvements in postintervention well-being outcomes, consistent with previous in-person workshops [12,22]. Parental stress and depression symptoms were both reduced by the end of the program and maintained. Importantly, well-being and resilience also improved and were maintained. This suggests that a virtual adaptation of this program may help address the service gap for caregivers who experience higher levels of stress compared with those caring for children without disabilities [6-8]. This augments an array of existing programs that show reductions in caregiver stress [12,22,24] and improvements in mental well-being [17,20,21]. Notably, this is the first virtual adaptation of ACT for caregivers that has examined well-being outcomes, such as overall mental well-being and resilience factors, highlighting that virtual modality can be helpful for improving well-being for caregivers in need.

ACT Processes

Finally, this caregiver study is the largest to date that examines ACT processes commonly examined, such as cognitive flexibility [20,21] and defusion [22], while also including additional processes such as self-compassion and values. We found significant improvements postintervention in all 4 ACT processes measured, including a reduction in cognitive fusion and psychological inflexibility and improvements in values-oriented living and self-compassion. Not only were the results maintained, but cognitive defusion continued to improve at the 8-week follow-up relative to the end of the program. This result may suggest that caregivers were continuing to deepen their practice of this skill beyond the program. This suggests that improvements in well-being may be related to the adoption of core ACT skills. When participants were asked about their core takeaways and the most helpful ACT processes from the group, participants regularly named cognitive defusion and provided examples (eg, list of cognitive defusion techniques). This provided further context for our finding that participants continued to increase their cognitive defusion skills by the 8-week follow-up, perhaps due to the concreteness of using this skill.

Participants additionally provided qualitative takeaways that matched the model of self-compassion by Neff [53], highlighting areas of self-kindness, common humanity, and mindfulness [54]. In particular, common humanity in the form of “I am not alone” was the most commonly provided answer as key takeaways from the program. This may be related to the cofacilitated model of our program, where caregivers with lived experience share their own personal examples and barriers, shifting the discussion from clinical professionals providing advice to more tangible, real-world examples. Altogether, participants demonstrated improvement across all ACT core processes and provided positive qualitative feedback on how these ACT processes continue to affect their lives after completion of the program.

Limitations and Future Directions

Without a control group, it is not known whether changes reported here are instead attributable to the passage of time, although a previous randomized control trial of the in-person version of this program did suggest treatment effects [20]. Moreover, only 209 people consented to participate in the study (76-151 completing all measures), which may not represent those who could not access a virtual program (eg, due to internet or technology accessibility), who dropped out, or who did not consent to research. Future replication and comparison across modalities are needed to understand accessibility of virtual vs in-person programs.

Another limitation may be the differential impacts of caregivers with different training experiences, baseline ACT-related characteristics, and disability status. Future research is underway to examine how baseline fusion, psychological flexibility, caregiver experience, and the disability status of the person they care for influence outcomes of ACT.

Conclusions

The virtual adaptation of ACT for family caregivers was found to be acceptable and fostered a sense of shared humanity, resulting in improved well-being and greater practice of defusion, psychological flexibility, and values alignment. This builds on the literature that highlights the rising need for virtual, synchronous programs that address family caregiver well-being, as well as the continued need for program modifications to address diverse needs.

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Data Availability

The datasets generated or analyzed during this study are not publicly available due to research participants not consenting to data sharing at the time of data collection but are available from the corresponding author on reasonable request.

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Authors' Contributions

Conceptualization, funding acquisition, and methodology were completed by LS, YL, AP, JS, NB, BR, KT, MP, JW, JL, and KF. JS and LS provided lived experience perspectives in conceptualization. Data curation was completed by SM. Formal analysis and writing of the original draft were completed by LLYM, HD, SM, and CM. All authors were involved in review and editing. Supervision was jointly provided by KPLF and JL.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Supplementary tables describing frequencies and percentages of family members' diagnoses, participant quotes on key takeaways, participant quotes on suggested changes, and participant quotes on the most helpful acceptance and commitment training processes.
[DOCX File , 23 KB - formative_v10i1e86205_app1.docx]

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Abbreviations

AAQ-ID: Acceptance and Action Questionnaire–Intellectual Disability Parent Version
ACT: acceptance and commitment training
CFQ: Cognitive Fusion Questionnaire
MSMR-I: Multi-System Model of Resilience Inventory
PHQ-4: Patient Health Questionnaire–4
REDCap: Research Electronic Data Capture
SCS-SF: Self-Compassion Scale–Short Form
VLQ: Valued Living Questionnaire

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Original Paper

Development of a Tailored Online Video-Based Assistant to Support Prenatal Screening Decisions in Couples With Limited Health Literacy: User-Centered Design Approach

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Abstract

Background: Up to 25% of pregnant couples in the Netherlands do not make an informed decision about prenatal screening: their decisions are value-inconsistent or based on insufficient knowledge and deliberation. More than one-third (36%) of the population in the Netherlands has limited health literacy skills, with the majority being individuals with lower levels of education or a migration background. They experience serious problems in understanding health information and taking an active role in decision-making. Therefore, the Dutch Health Council recommends improving decision support for pregnant couples.

Objective: This study aimed to describe the rationale and systematic design of an online, interactive, and tailored video-based assistant to support pregnant couples with limited health literacy skills in decision-making on prenatal screening.

Methods: The intervention mapping framework was used for the iterative user-centered development of the decision aid prenatal screening. This includes the following steps: (1) a needs assessment among the target group (ie, pregnant couples and counselors), (2) defining change objectives based on the needs assessment, (3) selection of theoretical methods, (4) program production and prototype testing, (5) implementation planning, and (6) preparation for evaluation. Three prototypes of the decision aid were iteratively tested among pregnant couples (with low literacy), counselors, and stakeholders relevant for future implementation. This paper describes steps 1 to 4 of the decision aid development.

Results: We developed a decision aid guided by a virtual assistant to promote informed decision-making among pregnant couples (with low health literacy) on prenatal screening. To comply with users' needs, it includes the following four interactive modules: (1) Other people's experiences, (2) Information about the tests (and anomalies), (3) Help me decide, and (4) Further questions. To increase accessibility, it features a menu that allows for adapting the speed of speech, making use of subtitles, and is offered in 3 different languages. To increase implementation and future use of the decision aid, an e-learning tool was developed. The decision aid can be used either as a stand-alone tool by pregnant couples or in combination with a counselor during counseling sessions.

Conclusions: By describing the systematic development of a prenatal screening decision aid designed to support pregnant couples with low health literacy in making well-informed choices, we aimed to contribute to systematic reporting and transparent intervention design.

Trial Registration: International Standard Randomised Controlled Trial Registry ISRCTN18016226; https://www.isrctn.com/ISRCTN18016226

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KEYWORDS

tailored video intervention; shared decision-making; informed decision-making; prenatal screening; health literacy; counseling aid; decision aid; vulnerable individuals

Introduction

Prenatal screening is routinely offered in the first trimester to support prospective parents in autonomous reproductive decision-making. These screenings empower pregnant couples to make informed decisions about preparing for a child with anomalies or considering pregnancy termination. In the Netherlands, two types of prenatal screening are offered: (1) a noninvasive prenatal testing (NIPT), which is a blood test available from 10 weeks of pregnancy that screens for chromosomal anomalies, such as Down syndrome, Edwards' syndrome, and Patau syndrome. This test may also reveal incidental findings. (2) Ultrasound scans at 13 and 20 weeks to screen for structural fetal anomalies [1]. The screening is centrally regulated via the Dutch Center for Population Screening. Unique to the Dutch program is the training provided to counselors in nondirective, value-sensitive counseling, enabling prospective parents to make decisions aligned with their own norms and values. In contrast to other Western countries—where prenatal screening is either not offered on a nationwide level (including Germany, Spain, or England) or is offered only to women at intermediate to high risk based on combined first-trimester screening (including France, Italy, and Sweden)—the Netherlands offers NIPT to all pregnant couples [2]. Prospective parents receive counseling about the option of prenatal screening, after which they must decide whether to accept or reject the screening. Besides empowering couples to make autonomous reproductive decisions, prenatal screenings can also increase anxiety and stress related to deciding whether to undergo testing, interpreting test results, concerns about the health of the baby, and the potential consequences for the baby and the family. At the time of the study, NIPT was not yet reimbursed, whereas ultrasounds were. This may explain why the uptake of NIPT screening has generally been lower in the Netherlands than in countries such as Denmark, where NIPT has been integrated into the national guidelines on prenatal screening since 2017 [3].

The current decision support for pregnant couples in the Netherlands consists of individual counseling by a trained professional, usually a midwife, along with universal information provided through a leaflet and an online questionnaire designed to prompt reflection on feelings and thoughts about prenatal screenings. For counselors, it consists of skills training, skills examination every 2 years, a counseling aid, and an e-learning tool. However, this seems insufficient for all pregnant couples to make an informed decision.

Despite the availability of counseling and informational materials, between 25% to 45% of pregnant couples in the Netherlands do not make an informed decision about prenatal screening: their decisions are value-inconsistent or based on insufficient knowledge and deliberation [4,5]. Counselors have difficulty tailoring their decision support to the needs of pregnant couples, especially those with limited health literacy skills [6-9]. More than one-third (36%) of the population in the Netherlands has limited health literacy skills, with the majority being individuals with lower levels of education or a migration background [10,11]. They have difficulty in understanding health information and in taking an active role in decision-making [12]. To overcome this gap, the Dutch Health Council—an independent advisory council that provides the Dutch government with evidence-based advice on public health and health care policy, including medical screening programs like prenatal screening—recommends more inclusive decision support [13]. Suggested strategies include (1) providing information materials that are accessible to individuals with low literacy, and (2) educating counselors to understand the challenges faced by vulnerable pregnant couples and how to address them effectively [14]. This can be achieved by using plain language, using (audio)visual rather than textual information (eg, icons, graphics, videos, and animation), and stimulating interaction via signposting (ie, framing of information in tangible actions) and tailoring (ie, presenting personally relevant information to avoid distraction) [15]. However, decision support that fits the needs of counselors and pregnant couples was not available for prenatal screening [9,16,17].

This paper describes the systematic development of the online, interactive, virtual assistant–based "Decision Aid Prenatal Screening" (in the following "decision aid") designed to overcome this gap, and to support pregnant couples with low health literacy in making informed choices about prenatal screening.

Online, interactive, and tailored video-based decision aids have shown promise in enhancing comprehension, counseling, and informed decision-making [18-20]. A possible way to improve communication is to use video-based assistants, which offer the following advantages: they are easily accessible tools with audio-visual elements and a talking avatar who interacts with the user in a structured way. The assistant asks for user input to provide personalized information and advice, while explaining complex topics in a human-like conversation or counseling session. The key strengths of these tools are that they improve attention, comprehension, and information processing (ie, active learning): (1) the use of video promotes vividness of the information (narrative) and ease of understanding [21], (2) tailoring ensures relevance and fit to the needs of users [22], and (3) the interactive part enables scenario-based learning of the pros and cons of different screening choices [23]. Online, interactive, and tailored video-based assistants can furthermore improve provider-patient communication and informed decision-making and reduce decisional conflict [18,20,24,25]. In the paper, the online, interactive, and tailored video-based assistant will be referred to as "the decision aid."

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Methods

Design

This study applied a user-centered, iterative design approach guided by the Intervention Mapping (IM) framework [26,27]. User-centered design is an approach in which experiences of end users and their interaction with the intervention are central in all steps of intervention development to increase usability and effectiveness [26]. The IM framework consists of 6 steps that provide a systematic and evidence-based approach to develop, implement, and evaluate health-promoting interventions. The first 4 steps—(1) needs assessment, (2) defining change objectives, (3) selecting theoretical methods, and (4) program production—are described in this paper. Implementation (step 5) and evaluation (step 6) will be addressed in the effect evaluation (randomized controlled trial; see trial registration number ISRCTN18016226).

Participants

Needs Assessment

Participants included both end users (ie, pregnant couples, including those with limited health literacy) and health care professionals (HCPs, ie, counselors). Inclusion criteria for counselors were at least 5 counselors with varying levels of experience in prenatal screening counseling, working in practices located in low socioeconomic status (SES) or disadvantaged neighborhoods. They may also include obstetric care providers, including gynecologists, with experience in prenatal screening and counseling. Inclusion criteria for end users were pregnant women from the second trimester onward (after the 20-week ultrasound) who had already made a decision regarding the NIPT, combined test, or 20-week ultrasound, and their partners. We strived to include a minimum of 18 participants, including 4 partners, 4 highly educated individuals, 1 temporary emigrant, and 9 individuals with low education (secondary vocational education level 1 or lower) or migration background (Eastern European, refugee, Turkish, or Moroccan).

Prototype Testing

Participants in prototype testing included individuals with limited health literacy, pregnant individuals, and partners of pregnant individuals, as well as counselors.

Recruitment

Participants were recruited in lower SES neighborhoods via midwifery practices, “Pharos” (the Dutch center of expertise on health inequalities), and “Stichting ABC” (a volunteer organization of and for individuals with low literacy). The selection specifically targeted people with low health literacy or limited literacy (reading, writing, and digital skills). Recruitment materials were designed in a personal style with simple words (for details, refer to [28]). Participants of the needs assessment were recruited in April and June 2020, and participants for prototype testing were recruited between February 2021 and January 2022 for various rounds of prototype testing.

Advisory Board

To anticipate implementation of the decision aid, an advisory board was set up at the start of the project, comprising obstetric care providers, midwives, gynecologists, counselors, researchers, and health literacy experts. Moreover, members of the working group of the program committee, Prenatal Screening of the National Institute for Public Health and the Environment (RIVM), were part of the advisory board. This working group consisted of researchers, gynecologists, and midwives who advise RIVM and the program committee on communication strategies and the promotion of professionalization in prenatal screening in the Netherlands [29]. Their role was to provide ongoing content-related feedback to ensure that the decision aid would be in line with Dutch prenatal screening standards.

Ethical Considerations

The study and intervention research were approved by the ethical board of the Netherlands Organisation for Applied Scientific Research (Institutional Review Board 2020-035). All participants who took part in the research studies received oral and written information, including information about the possibility to opt out, and provided informed consent. Participation in the interview was confidential. This means that no personal details of participants were stored or reported, and therefore could not be traced back to participants. The information was used solely for this study. Participants received gift vouchers for participation. End users were compensated with a 25€ (US $29.41) coupon. HCPs were compensated with 65€ (US $76.47). The trial is registered at the International Standard Randomised Controlled Trial Registry with registration number ISRCTN18016226. Data were summarized and stored anonymously in a protected SharePoint vault that only the researchers could access and will be deleted after 15 years.

Materials

Materials included interview protocols for counselors and pregnant individuals for needs assessments and testing schemes for prototype testing.

Procedure

Development of the decision aid followed the IM steps [27] listed below.

Step 1

A needs assessment was conducted using semistructured interviews with end users (ie, pregnant individuals) and HCPs (ie, counselors) to identify experiences with counseling on prenatal screening and needs and wishes related to informed decision-making for prenatal screening.

Interviews with end users focused on (1) participants’ experiences with decision-making about prenatal screening, (2) the use and evaluation of decision aids and other tools such as brochures and websites, and (3) preferences for a new tool. The latter was evaluated using A/B testing (also known as split testing), a user experience method to assess performance against a specific goal (such as acceptance or functionality). A/B testing comprised providing participants with 5 different options of interactive digital tools, including diverse behavior change strategies [30]. Interviews with end users took 60 minutes. The

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translated interview scheme can be found in Multimedia Appendix 1.

Interviews with HCPs focused on three main topics: (1) supporting pregnant couples (with low health literacy) in prenatal screening, including challenges and a reflection on their role as counselor; (2) tools they currently use, including usability, and needs for extra tools to use before, during, and after counseling; and (3) needs and wishes for the new decision aid, including content and functionalities. Interviews with HCPs took 90 minutes. The translated interview scheme can be found in Multimedia Appendix 2.

Interviews took place online via Skype.

Step 2

Based on the outcomes of the needs assessment, behavior objectives were formulated for the decision aid targeting the key behavioral determinants (eg, knowledge and attitude). These were formulated into change objectives in line with the needs assessment (eg, preferences based on A/B tests), literature [30], and consensus among the project group through discussion.

Step 3

Theoretical methods were selected based on the determinants and translated into practical applications (functionalities within the decision aid), taking into account requirements for use. These were based on input retrieved during steps 1 and 2, literature, and consensus among the project group.

Step 4

A prototype was iteratively developed following a program plan. This included the script and functionalities of the decision aid. The prototype was iteratively tested with users and relevant stakeholders (ie, the advisory board and RIVM working group). The testing assessed the (1) concept of the decision aid, (2) information provided in the decision aid, and (3) functionalities. Prototype testing took place individually and was carried out by project members with expertise in health inequality. Detailed information on recruitment and testing procedures, including test methods appropriate for individuals with low health literacy, is thoroughly described elsewhere [28]. These included presenting figures and pictures to assess inferred meaning and comprehensiveness, asking participants to read-aloud and describe the information in their own words (“teach-back method”) to uncover difficult words or unclear pieces of information, giving participants assignments (such as navigating to a certain piece of information), and asking participants to provide their opinion and advice for improvement. Testing with end users took 90 minutes and was compensated with a 25€ (US $29.41) coupon. Testing took place online via Skype. All participants provided informed consent. Data was summarized and stored anonymously in a protected SharePoint vault that only the researchers can access. To anticipate implementation and use of the decision aid, an e-learning for counselors was developed, which will be briefly described.

Data Collection

Data collection during the needs assessment entailed qualitative data through individual semistructured interviews and a focus group interview. During prototype testing (including usability testing), participants provided feedback on content clarity, usability, cultural sensitivity, and perceived usefulness collected through individual semistructured interviews. Interviews were recorded and transcribed.

Data Processing and Analysis

Data from interviews were thematically analyzed to identify user needs and wishes, usability issues, and content gaps. Iterative refinements were made based on user input that was tested again among the end users and HCPs.

Results

IM Step 1: Needs Assessment

Participants

From the semistructured interviews with potential users (n=22), we gathered information on needs and wishes. These included (1) individual interviews with 6 counselors (mean age 39, SD 12.21 years) with an average counseling experience of 15.5 (SD 12.28) years; (2) interviews with 4 pregnant individuals with an average age of 29.75 (SD 4.11) years, who were generally higher educated (average 18.38, SD 4.27 years of education), had medical backgrounds, and represented diverse countries of origin for themselves and their partners, including in the Netherlands, Suriname, Ethiopia, Poland and Greece; and (3) a focus group interview with 12 pregnant individuals with limited health literacy due to the language barriers, who were participating in group care for Eritrean individuals (described in [28]). Interviews were conducted between July 2020 and September 2020.

Needs and Wishes of Pregnant Women and Counselors

The findings revealed overarching themes relating to clarity, cultural sensitivity, accessibility, expectation management, and informed decision-making.

1. False security: Both pregnant women and HCPs report that it is essential to address the so-called “false sense of security,” which may arise when screenings show no anomalies:
   [The screenings] provide a false security, you only pick up 3 possible anomalies with it but there are up to the 1000 more possible anomalies. [Counselor]
   The tool should thus emphasize that the screenings cannot guarantee the baby to be free of health problems beyond what was screened for.
2. Incidental findings: Pregnant women and HCPs expressed a need to explain incidental findings. These are unexpected results unrelated to the primary screening purpose:
   Incidental findings are very difficult to grasp. What kind of incidental findings are there and what can come out of [the results] and what does that mean [Counselor]
3. Structured information: pregnant women specifically preferred clear, concise, and well-structured information. Counselors requested the decision aid to help verify comprehension (a checklist to see if it really comes across and do they understand) or to be used during counseling.
4. Accessibility: individuals with a migrant background highlighted the importance of receiving the information in

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their native language, as misunderstandings caused anxiety and uncertainty about the purpose and procedure of the screenings. Many were unaware that screening is optional and "not used to receiving such screenings." In line with end users, counselors asked for a multilingual decision aid that allows the counselor to follow along in Dutch:

In people with moderate language skills [it is difficult to] convey the details well with proper nuances, you need to make it more manageable; A double card with the same information and the left and right in both Dutch and the another language.

5. Cultural sensitivity: Additionally, they favored culturally sensitive information, in spoken form rather than written text.

   Less writing but more spoken text [End user]

6. Belief: participants with religious beliefs reported to generally declining screening due to their belief:

   "[we] *accept anything God has planned*", a sentiment echoed by counselors who had similar experiences with non-Dutch couples.

7. Preparation: Most pregnant women favored using the decision aid digitally, especially on their mobile phone, to prepare for the counseling (together with their partner) or the birth of a child with anomalies:

   Preparation for possible child with anomalies and you know where you stand, can arrange things and get information about it [End user]

8. Informed decision-making: counselors emphasized the need to make pregnant couples aware that undergoing screening is a personal choice, and clarify its implications:

   Making them aware that they have their own choice and what do they choose if they choose [to undergo the screening]

9. Expectation management: counselors also emphasized the need to make pregnant couples aware that undergoing screening is a personal choice and clarify its implications

   Making them aware that they have their own choice and what do they choose if they choose [to undergo the screening]

   They reported the observation of couples misunderstanding the purpose of screenings, such as assuming that ultrasounds are to determine the baby's sex:

   Sometimes people assume that [at the ultrasound] they just get to know the sex. Then they point out that there may also be findings such as a heart defect so that people are prepared and aware of it.

   Expectation management may prepare pregnant couples for potential bad news relating to fetal anomalies uncovered during the ultrasounds.

IM Step 2: Change Objectives

The intervention's goal was to promote informed decision-making among pregnant couples prior to the decision regarding prenatal screening [31,32]. We formulated subgoals to be addressed by means of the decision aid, based on the needs assessment and literature (see Table 1 for an overview of the different goals). Definite change objectives were derived by consensus forming among the project group, in line with relevant literature. Project group members included researchers, a professor of midwifery, a former midwife and teacher in midwifery, and experts on health inequalities.

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Table 1. Definition of program objectives and selection of change methods for the decision aid for pregnant couples.

Key objectives	Key determinants	Change objectives	Method: practical application
Actively review information regarding prenatal screening, health conditions, and anomalies	Knowledge	• Are able to explain what health conditions and anomalies entail and what these mean for the life of the baby itself and the family • Are able to explain what the prenatal screenings entail and how they are carried out • Recognize that opting for or against prenatal screening is a personal choice that they are involved in	• Consciousness-raising [33,34]: Factual information concerning (1) the screening (aim, procedure, and implications), (2) diseases and anomalies (probabilities, implications for life of baby and family, certainty and false sense of security of test results), and (3) freedom of choice that fully lies with the pregnant couples, including potential consequences of opting and not opting for the screenings • Chunking [35]: Providing small pieces of information, aggregated in logical groups (eg, "What is Down Syndrome?", "How is it for your child?" "How is it for your family?"; see Multimedia Appendix 3) • Tailoring [36,37]: Tailoring by (1) allowing the user to navigate to the most relevant information, split in logical chunks by means of information routing, and (2) providing users with personalized summaries and insights in the Modules "Help me decide" and "Further questions" • Teach-back method [38,39]: Chunk "Did I explain it well?" to repeat the most essential information (without users experiencing text anxiety)
Weigh the pros and cons of screening and possible results	Attitude	• Are able to explain what the benefits and disadvantages of undergoing prenatal screening are for themselves • Are able to elaborate on the benefits and disadvantages of potential pregnancy termination in their personal situation	• Value clarification [40,41]: Unbiased decisional balance sheet in module "Help me Decide": users are prompted to weigh pros and cons to consider relevant aspects within their decision, for example, "I want to have the option to terminate the pregnancy if my baby has a serious anomaly" or "I want to be able to prepare for life with a child with a serious anomaly" • Narrative information and role model stories [23]: Provision of various audio-visual scenarios depicting a variety of situations, perspectives, and respective implications
Discuss questions with significant others (eg, partner, midwife) in case information is unclear, or there are questions with regard to the personal situation, prior to the decision	Self-efficacy	• Express confidence in discussing (remaining) questions with significant others (eg, partner, midwife)	• Facilitation [42,43]: Facilitation through (1) module "Remaining questions": stimulating users to think about remaining questions they might have, such as "Why does testing not guarantee that my baby is healthy?" or "What can I do if my partner does not agree with my decision?" and to bring these questions to their counselor for further discussion. (2) Module "Help me decide": preparing pregnant couples to discuss important values, thoughts, and concerns regarding prenatal screening with each other, and the counselor
Make a decision for or against the different screenings in agreement with their partner	Self-efficacy	• Express confidence in making a well-informed choice based on knowledge and attitude about using the screening tests, in agreement with each other	• Value clarification [40,41,44]: Unbiased decisional balance sheet in module "Help me decide"; see above

IM Step 3: Program Design

Theoretical Methods and Practical Applications

In line with the outcomes of the needs assessment, the set of objectives was translated into a content script and functionalities. We aimed for an online, interactive, and tailored video-based decision aid for pregnant couples that they can use to prepare for the consultation. The content of the decision aid was based on the behavioral determinants (defined in Table 1) and a selection of appropriate methods fitting these targeted determinants. Appropriate methods were chosen based on the literature and consensus forming among the project group. A first draft of the script of the decision aid and functionalities was written by the project group members. This included information on the prenatal screening tests, the fetal anomalies, and the consequences for the baby and the family. The script

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also included relevant and frequent considerations to support the user in decision-making and frequently asked questions. The script was iteratively reviewed by the project group and the advisory board, including the RIVM working group, and tested with end users. Adaptations were made based on feedback from the professionals, in line with input from user testing (as described in step 4). The script was then implemented as a spoken version to be tested in the prototype.

We followed International Patient Decision Aid Standards criteria for decision aids [42], (1) ensuring information provision of all options, (2) presenting information about outcomes in an unbiased and understandable way, (3) providing methods for clarifying patient values, and (4) including guidance for deliberation and communication (Table 1). Below, we discuss several examples of methods and strategies applied to address the change objectives derived from steps 1 and 2.

Examples for Methods and Strategies Used

As an example, to target knowledge, we used consciousness-raising [33,34] about the (1) screenings including their aim, procedure, and implications (including false sense of security); (2) the fetal anomalies, what these entail, and what the life of a child and family with the former may look like; and (3) freedom of choice that fully lies with the pregnant couple, encompassing potential consequences when opting in or out of the screening. This incorporated factual knowledge concerning, among others, probabilities of anomalies, certainty of test results, and difficulties that children or (grown up) individuals and families with the anomalies may face.

Attitude formation was promoted by stimulating value clarification, for which we used an unbiased decisional balance sheet (eg, [40,41,44]) in the "Help me decide" module. This neutral method for weighing pros and cons of (not) acting on a certain kind of choice stimulates decision-making readiness and lowers decisional ambivalence or conflict. Users are therefore required to think of which aspects of the choice regarding prenatal screening matter to them (eg, knowing as soon as possible if their baby has an anomaly). Value clarification was further supported using information regarding screening procedures and potential outcomes (ie, how does screening work and what is it like for the child and family).

Self-efficacy to communicate with a counselor or a partner was enhanced by stimulating users to think about remaining questions they might have in the "Further questions" module, such as "Why does testing not guarantee that my baby is healthy?" or "What can I do if my partner does not agree with my decision?" and pose these questions to their counselor or partner. Moreover, the "Help me decide" module encourages users to consider relevant aspects within their decision, for example, "I want to have the option to terminate the pregnancy if my baby has a serious anomaly," or "I want to be able to prepare for life with a child with a serious anomaly" to prepare them for a conversation with their partner and counselor. Additionally, self-efficacy was tackled by narratives, which can increase self-efficacy and engagement [45].

To increase the overall accessibility of the decision aid, it was important to limit the amount of information, offer the content in various languages, and present it audiovisually [21]. We therefore opted for an avatar to verbally explain the use of the decision aid and to guide users through the information, using additional visual aids such as pictures (eg, of a vitality ultrasound) and video scenarios (eg, of role model experiences). Using avatars in digital interventions offers various benefits such as increased information recall and improved learning compared to static content [25,46,47]. Besides, avatars have previously been shown to increase behavior change and literacy [25,48-50] alongside making the user experience more engaging and enjoyable [25,49,51,52]. Moreover, avatars have previously been shown to promote a feeling of connectedness and support (eg, by providing more personalized feedback) [53-57] and have the potential for increasing the effectiveness of an intervention [25,48,49,58]. To enhance information processing and retrieval, and to make the decision aid quick to go through, as requested, we applied chunking throughout the decision aid by grouping information into logical chunks of information [35]. The "Help me decide" module and "Further questions" module make use of interaction to stimulate scenario-based and active learning [23]. The use of narratives by means of personal stories in the module "Experiences of others" was meant to promote greater engagement with information, as these may be especially useful for people with limited literacy skills. A complete overview of the final decision aid sections can be found in Figure 1.

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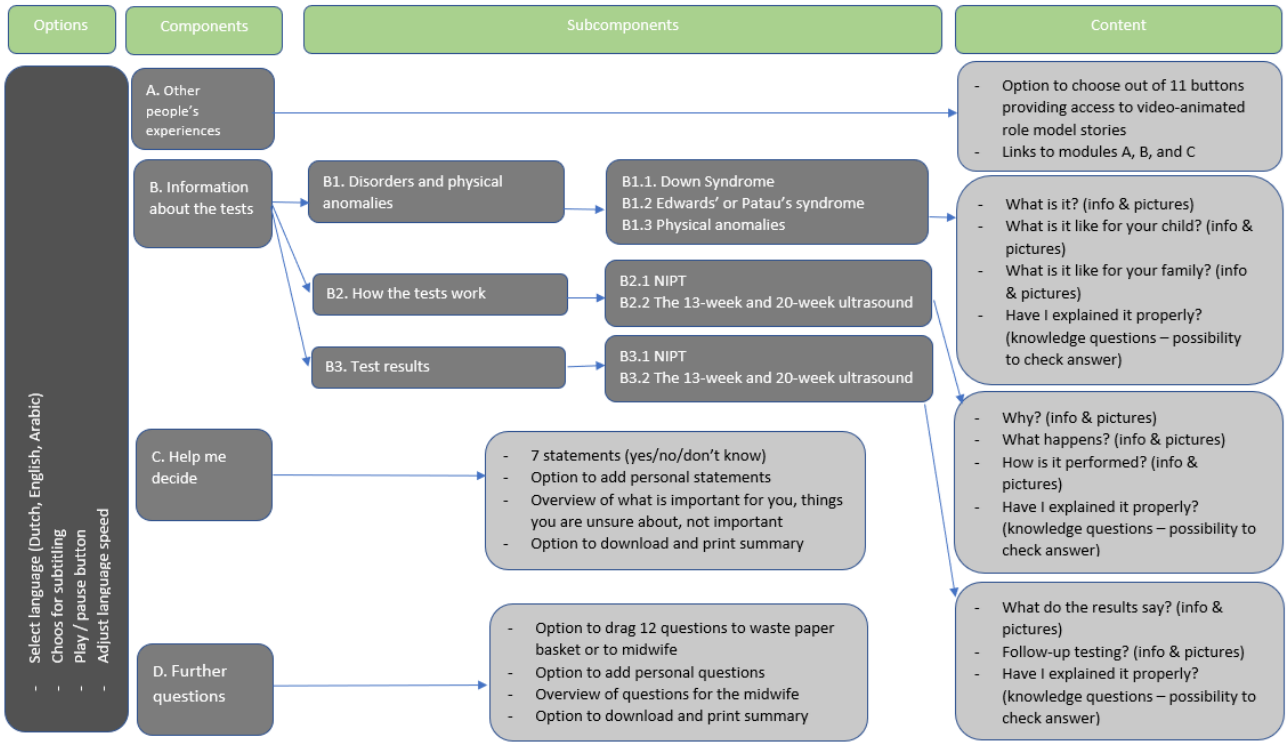
Figure 1. Blueprint of the decision aid for prenatal screening. NIPT: noninvasive prenatal testing.



IM Step 4: Prototype Testing and Program Production

The decision aid was created using user-centered design and iterative testing with ongoing involvement of potential end users, counselors, and relevant stakeholders for implementation. In this step, we will describe the final decision aid (see Multimedia Appendix 3 for screenshots of the decision aid). As part of step 4, we evaluated 3 prototype versions in different stages of development with potential end users (ie, pregnant couples) and intermediate users (ie, counselors).

Prototype Testing

Three prototypes were iteratively tested between March 2021 and July 2022 among individuals with limited health literacy skills (n=4), (pregnant) women (n=6), and fathers (n=2) from lower SES neighborhoods, and counselors (n=4). Additionally, the advisory board and the working group provided ongoing feedback. Table 2 provides an overview of prototype testing rounds, including the aim, sample, methods used, results, and adaptations.

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Table 2. Overview of iterative development phases of the decision aid, including feedback provided by various target users and adaptations.

Round	Aim	Sample	Methods used	Results	Adaptations
1	Testing the goal, ease of use, sound clips, and overall impression. Thereby assessing: homepage, main menu, information provided by the avatar about the screening pictures, and reading aloud functionality	3 individuals with former limited literacy, 1 pregnant woman	Teach-back method, tasks and recommendations, open questions	• Goal of the decision aid is unclear[a] • Lack of essential navigation features • Sound fragments are too long • Pictures are distracting and do not match the text well[a] • Generally, no difficult words[a] • Request for multilanguage decision aid[a] • (Role of) Avatar unclear[a]	• Introduction of the decision aid, including the goal and functionalities • Play and pause button added • Pictures were changed or removed • Decision aid translated into English and Arabic • Avatar introduces herself and the decision aid
2	Testing the information module in written format, the name of the decision aid, and the knowledge test	3 pregnant women, one mother with former limited literacy	Teach-back method, recommendations, read-aloud, open questions	• Information too long[a] • Too negatively framed (including terms “illness” and “handicap”)[a] • Change words like “tests” to “control” or “examination”[a] • Quiz questions are valuable, but can also put pressure on users • Attention for emotion regulation and how to discuss this[a]	• Information fragments shortened • More neutral framing of information, removal of diminutives • Use of teach-back questions per information fragment
3	Home screen, ‘Help me decide’ module, ‘Further questions’ module	4 midwives or counselors, 4 potential users (1 pregnant woman, 1 mother, 2 fathers)	Teach-back method, recommendations, read-aloud, open questions, think-aloud, questions regarding acceptance and future use	• Expectation of added value of the decision aid for future use in practice[b] • Mention and involve the partner explicitly, earlier and more often in the decision aid[a,b] • Use more visual support[a] • Help me decide is appreciated, but response options require reframing[a] • Name of the decision aid is unclear[a] • Missing experiences of others[a]	• Addition of consideration for the nonpregnant partner and naming the partner more explicitly throughout the decision aid • Response options in the “Help me decide” module reframed • Change of name • Addition of others’ experiences

[a]Input provided by participants with (former) low literacy.

[b]Input provided by counselors.

Most Important Adaptations

To improve clarity, cultural sensitivity, emotional relevance, and accessibility, several adaptations were made to the decision aid, based on user feedback:

1. Title revision: the name of the decision aid was revised from “Do you want to get free tests to see if your baby is healthy?” to “Decision Aid prenatal screening: support in choosing whether to test for conditions or anomalies in your unborn baby” to better reflect its purpose.
2. Avatar redesign: the design was adapted to resemble an end user's recognizable counselor, wearing a clinical white uniform.

Put on midwife’s clothes. White uniform [End user]

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This conflicted with advisory board feedback, which favored a more realistic and approachable appearance. To clarify its role, the avatar now introduces herself and explains the tool's purpose and navigation options (eg, language and speech settings).

3. Visual and textual adjustments: Images depicting advanced pregnancy stages were replaced to better reflect the early phase of prenatal screening, in order to improve recognition. *We are at the beginning of the examinations. She has such a big belly. It looks like she's going into labor, that's not right* [End user]
   Text fragments were shortened for clarity.
4. Neutral language: In the "Help me decide" module, complex or emotionally charged statements were simplified to neutral, single-sentence considerations (eg, "A life with a child with Down syndrome would be too heavy for me, I therefore would like to undergo screening" to "Living with a child with a serious anomaly seems too hard for me"). Earlier versions were perceived as overly negative or steering by end users:
   It is a sensitive topic and therefore it is important not to make judgments about the choices and severity of the anomalies [End user]
   Revised content presents information objectively while acknowledging potential challenges. Diminutives (eg, "kiddo") were replaced with more neutral terms (eg, "child").
5. Inclusion of personal narratives: As requested by end users ("*I miss experiences, the feelings* […] [End user]"), personal experiences of others deciding for and against prenatal screening to help them reflect and put their emotions into perspective, were added as an extra module: Experiences of others. This module features animated scenarios based on real-life narratives that illustrate diverse perspectives (including perceived barriers, positive, and negative experiences) and decisions around the screenings.
6. Partner involvement: Both counselors and male participants emphasized the importance of involving the nonpregnant partner more explicitly, earlier, and more often in the decision aid.
   Involving dads is very important to me [Male end user]
   The decision aid now includes references to partners in tailored content, considerations, and remaining questions that reflect shared decision-making (eg, scenario "In my mind, I was already a father – until my girlfriend called" or consideration "What can I do if my partner wants something different than me?").
7. Replacement of knowledge test by a teach-back module: To prevent test anxiety, the original Test your knowledge module was removed to prevent test anxiety. It was replaced with the teach-back prompts in each section, allowing users to confirm understanding without feeling tested.

The Final Decision Aid

Overview

The decision aid prenatal screening is a tailored, online, and interactive virtual assistant–based tool [59] featuring virtual assistant Anna. It can be used before, during, or after counseling and contains 48 minutes and 58 seconds of optional content that users can engage with depending on their needs and preferences. The decision aid comprises four modules: (1) Other people's experiences, (2) Information about the tests, (3) Help me decide, and (4) Further questions (refer to Figure 1 for a blueprint of the decision aid content).

Module 1

"Other people's experiences" offers the user 11 different audiovisual scenarios, each lasting between 9 and 45 seconds. These depict other parents' decisions over prenatal screening, including experiences relating to child loss, reasons for undergoing or declining screening, and choices about continuing or terminating the pregnancy. Characters and stories reflect (cultural) diversity.

Module 2

"Information about the tests" is organized into three sections: (1) "Disorders and physical anomalies," (2) "How the tests work," and (3) "Test results." The first section explains Down syndrome, Edwards', or Patau syndrome, and physical anomalies, with details about the disorder or anomaly, and its impact on the child and family. These information chunks are combined with the teach-back question "Have I explained everything properly?" where Anna asks questions and provides answers to reinforce understanding. The second section covers the NIPT and ultrasounds, explaining what they are, why they are performed, and how they are conducted. It also includes "incidental finding" (NIPT) and "What happens at the ultrasounds?" (ultrasounds), concluding with the teach-back question. The third section explains test results (NIPT and ultrasounds), including what the results mean and potential follow-up steps, concluding with the teach-back question. All content is based on RIVM brochures and counselor experiences.

Module 3

In the "Help me decide" module, users are guided through 7 different reasons that may influence their decision, such as accepting a child with an anomaly, preparing for life with a child with a serious anomaly, or feeling unable to cope with such a situation. Users are informed they can choose to participate in some, all, or none of the screenings. They can then select which reasons are important for their decision, and add their own additional reasons. Users are then presented with a summary that can be printed and brought to their counseling session. The module allows for cultural sensitivity, accommodating considerations fitting various cultures (including accepting the child as it is vs. choosing to abort), and the option to add one's additional reasons.

Module 4

"Further questions" supports users in identifying remaining questions that they would like to discuss with their counselor. Users are presented with 12 questions, which they can discard or save by dragging them to the trash can or avatar. The avatar reads each question aloud when it appears on the screen. Again, relevant questions are summarized. Examples include "What can I do if something is wrong with my baby?" or "Why does testing not guarantee that my baby is healthy?"

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Accessibility Features

To support users with limited health literacy, the decision aid includes features such as audio narration by the avatar and adjustable speed of speech. To further allow for cultural sensitivity, it is available in Dutch, English, and Arabic, with optional Dutch subtitles to assist counselors when couples use the aid together during a counseling session, in another spoken language.

Implementation Strategy: e-Learning for Counselors

To anticipate the implementation of the decision aid and to conform with the needs and wishes of the counselors, an e-learning tool for counselors was iteratively developed and tested alongside the decision aid. The e-learning tool supports counselors in recognizing signs of potential health illiteracy and strategies on how to counsel individuals with low health literacy. Furthermore, the e-learning tool informs counselors how they can deploy the decision aid as educational material to be used before, during, or after the counseling. An overview of modules and content of the e-learning tool can be found in Multimedia Appendix 4.

Discussion

Principal Findings

In line with our objective to support informed decision-making among pregnant couples with low health literacy, we systematically developed and iteratively refined a tailored, video-based decision aid. Our findings demonstrate that systematically involving end-users and counselors throughout the development process contributed to building an acceptable and accessible tool that fits a diversity of needs. These include demand for clear, culturally sensitive, and accessible information, which is delivered digitally and in multiple languages to support informed, realistic decision-making about prenatal screening. The final decision aid was designed to be used during counseling, as preparation before counseling, or as a means for reflection afterwards. It includes factual information, experiences of others, support in decision-making, and formulating remaining questions. The decision aid stimulates users to think about personally relevant questions to promote active participation in the counseling, facilitate shared decision-making, and ensure an informed choice is made. Prototype testing indicated high acceptability and usability among both pregnant couples and counselors, suggesting the decision aid's potential to fill a critical gap in current prenatal screening support. By describing the systematic design, we aimed to contribute to calls for improving the quality of reporting of the content and design rationale of interventions, to ensure reliable implementation and replication [60,61].

Strengths

To begin with, the decision aid was developed to support pregnant couples with low literacy in making an informed decision about prenatal screening. Easily accessible and understandable information for this often underserved group is especially needed to overcome health inequalities [62]. Including individuals with limited health literacy skills in both developing and testing the decision aid enabled us to fully accommodate the design and functionalities to their needs, and to improve accessibility in general. The iterative, participatory approach resulted in the selection and application of strategies to address health literacy challenges, such as features such as audio-visual content, the teach-back strategy, and chunking. The needs assessment highlighted the importance of explicitly including partners and stories of others. First, the inclusion of partners could foster shared decision-making. Moreover, the desire for stories of others aligns with findings elsewhere, where narratives not only improve knowledge and confidence but also improve the perceived relevance and supportiveness of health information [63]. By directly involving end-users in prototype testing, we were able to identify and address barriers related to language, cultural beliefs, and digital skills. The user-centered approach and design principles allowed for meeting the needs and wishes of both pregnant couples and counselors. Iterative development and testing, moreover, contributed to increased user acceptance and overall usability, underscoring the importance of participatory design [64].

The Intervention Mapping approach ensured the intervention was grounded in behavioral theory and evidence by means of a structured, systematic approach, which increases the likelihood of addressing the most important determinants of informed decision-making [27]. Moreover, IM facilitated the integration of the perspectives of end users and counselors in every stage. Also, IM made the development process transparent and replicable. Finally, the IM approach encourages the consideration of implementation factors, such as the counselor's e-learning. The involvement of the advisory board, counselors, and the RIVM working group enabled us to anticipate future implementation of the decision aid in practice. Whether the decision aid also contributes to more effective informed decision-making remains to be seen.

Limitations

A first limitation of the decision aid and its design approach includes the difficulty of fitting the sometimes opposing needs and wishes of both the users (ie, pregnant couples), counselors, and advisory board, such as relating to the visual appearance of the avatar. In line with the decision aid's aim to support pregnant couples, their wish for the avatar to be better recognizable as a counselor was followed, which means that the avatar got a rather clinical look. Second, due to the development taking place during the COVID-19 pandemic, all research activities, including the needs assessment with low-literacy individuals, had to take place online, which was expressed to be a challenge by this group. To mitigate its impact, we invited a facilitator and translator who knew the participants, if necessary, to make the participants feel more comfortable, and took extra time to get to know each other, explaining the research and testing the decision aid. Thirdly, another limitation is the fact that the functionality to drag and drop questions to the midwife or wastepaper basket in the 'Further questions' module was not usable on iPhones, due to technical issues that could not be repaired. To facilitate users to still use this module if desired, they were referred to the browser version of the decision aid: "Unfortunately, this section does not work on iPhone. You can use this section on your desktop."

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Practical Implications and Future Directions

The decision aid can be integrated into routine counseling, potentially improving informed choice rates and reducing decisional conflict. Its design aligns with national recommendations for inclusive, low-literacy-friendly health communication and supports the broader goal of reducing health inequalities. The methodology—combining Intervention Mapping with user-centered design—serves as a model for developing other digital health tools targeting vulnerable groups. Early consideration of implementation factors increases the likelihood of successful adoption and sustained use in practice [64].

Regarding future research, we suggest that the final decision aid should be pretested as a whole instead of its parts and functionalities, and that it will be tested in practice. In theory, the decision aid aligns with the user group as tested during the iterations; however, it should also be tested by both pregnant couples and their counselor in a real-life setting, instead of an online setting, that is, before, during, and after the counseling. It would further be interesting to assess which of the modules are necessary for users to make an informed decision as the 'most essential elements' of the decision aid. Lastly, the effect of the decision aid on behavioral determinants such as knowledge, attitude, and informed decision-making should be researched. The effects of this trial will be described in a following article.

Conclusion

This study presented the systematic, user-centered development of a decision aid designed to support pregnant couples with low health literacy in making well-informed choices about prenatal screening. By integrating evidence-based techniques and tailoring the tool to the needs of underserved populations, the decision aid could contribute to reducing health inequalities and promoting shared decision-making in prenatal care. The development process, grounded in Intervention Mapping, demonstrates how structured, iterative design can enhance usability, accessibility, and stakeholder engagement. Ultimately, this work contributes to the broader goal of equitable health care by offering a replicable model for designing inclusive decision support tools that align with the needs of diverse populations.

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Data Availability

The datasets generated or analyzed during this study are not publicly available due to privacy protection, but are available from the corresponding author on reasonable request.

Authors' Contributions

Conceptualization, Investigation, Methodology, Writing – original draft, Writing – review & editing: KP
Conceptualization, Funding acquisition, Methodology, Supervision, Validation, Writing – original draft, Writing – review & editing: HvK
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Investigation, Validation, Writing – review & editing: AW
Conceptualization, Funding acquisition, Methodology, Validation, Writing – review & editing: MN
Investigation, Validation, Writing – review & editing: NA
Conceptualization, Funding acquisition, Methodology, Project administration, Validation, Writing – original draft, Writing – review & editing: PvE

Conflicts of Interest

None declared.

Multimedia Appendix 1
Interview scheme needs-assessment pregnant women.
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Multimedia Appendix 2
Interview scheme needs-assessment HCPs.
[DOCX File , 40 KB - formative_v10i1e75391_app2.docx]

Multimedia Appendix 3
Screenshots of the decision aid.
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Multimedia Appendix 4
Table 3. Overview of modules and learning goals of the e-Learning.
[DOCX File , 64 KB - formative_v10i1e75391_app4.docx]

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Abbreviations

HCP: health care professional
IM: Intervention Mapping
NIPT: noninvasive prenatal testing
RIVM: National Institute for Public Health and the Environment
SES: socioeconomic status
ZonMw: Care Research Netherlands and Medical Sciences

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Original Paper

Emotional and Psychosocial Correlates of Problematic Social Media Use Among Adults: Cross-Sectional Study

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Abstract

Background: Social media platforms have become integral to daily life, particularly among younger users. While they offer opportunities for connection, they also introduce new psychological stressors. Prior research has often relied on simplistic metrics such as screen time, failing to capture complex emotional and behavioral dimensions of digital engagement. There is a growing need to understand how design features and user experiences contribute to problematic social media use (PSMU), especially in adult populations.

Objective: This study aims to assess the psychosocial dimensions of social media use and their associations with problematic use in an adult population, with particular attention to emotional fatigue, avoidance, and interface-induced stress.

Methods: A cross-sectional online survey was completed by 402 participants, of whom 393 completed the entire questionnaire (response rate 97.8%). Recruitment was conducted through targeted advertisements on major social media platforms. Participants self-reported demographic information and completed a modified version of the CAGE-AID (Cut down, Annoyed, Guilty, Eye-opener–Adapted to Include Drugs) screener, adapted to detect PSMU. They also responded to 49 Likert scale items measuring 7 thematic psychosocial dimensions: empathic fatigue, silent stressors, identity fragmentation, pressure for visibility, algorithmic influence, digital detox behaviors, and nostalgia-linked affective responses. Descriptive and correlational statistics were used to analyze data. CAGE-AID positivity was defined as 1 or more affirmative responses.

Results: Among 393 respondents (mean age 32.7, SD 10.8 years; 257/393, 65.4% women), younger age was significantly associated with PSMU as measured by modified CAGE-AID positivity (χ^2_5=27.0; *P*<.001; Spearman ρ=−0.160; *P*<.001). Lower education level (χ^2_4=11.6; *P*=.02) and employment status (χ^2_6=13.5; *P*=.04) were also significantly associated with PSMU. Emotional fatigue items, including reduced empathy following online emotional exposure, showed moderate correlations with PSMU (ρ=0.19-0.22; all *P*<.001). Silent interface stressors, particularly pressure to respond due to “seen” indicators, were positively associated with PSMU (ρ=0.124-0.153; *P*=.013). Online identity curation demonstrated the strongest association (ρ=0.280; *P*<.001). Digital detox behaviors, including guilt and sleep disruption, were also significantly correlated with PSMU (ρ=187-0.200; *P*<.001).

Conclusions: PSMU in adults is closely tied to emotional fatigue, interface-related stress, and avoidance. Younger users appear particularly susceptible to emotional saturation and compulsive engagement. These findings highlight the need to consider

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psychological and design-related mechanisms in public health responses to digital overuse. Interventions should move beyond screen time to address emotional reactivity and structural stressors embedded in platform design.

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KEYWORDS

affective avoidance; digital mental health; digital stress; emotional fatigue; interface design; mental health; online behavior; problematic social media use; psychology; psychosocial correlates

Introduction

Social media has emerged as a dominant force in contemporary digital culture, reshaping communication, identity formation, and emotional expression. As of 2023, over 60% of the global population actively uses social media, with daily usage averaging more than 2 hours per person [1,2]. Platforms like Instagram, TikTok, Facebook, Snapchat, and X (formerly known as Twitter) are not merely channels for information and entertainment: they have become integral to how people present themselves, maintain relationships, and engage with the world [3]. These digital spaces operate on feedback loops that amplify emotional content and favor visibility, governed by algorithms that personalize content based on user behavior [4]. As users become increasingly immersed in these environments, the psychological dynamics of social interaction, social comparison, and impression management have shifted from offline to online domains, introducing new cognitive and affective demands [5,6].

Literature increasingly demonstrates that social media use is associated with both salutary and adverse mental health outcomes, with effects varying according to context of use, platform architecture, and individual vulnerability profiles [7-9]. On one hand, digital environments may facilitate social connectedness, identity exploration, community belonging, and rapid access to health-related information. On the other, a substantial body of evidence links heavy or maladaptive engagement to elevated symptoms of depression, anxiety, sleep disruption, diminished self-esteem, and broader psychological distress [10-13]. Importantly, these associations are not merely functions of time spent online but appear to be mediated by specific psychosocial mechanisms. Upward social comparison processes, repeated exposure to emotionally arousing or polarizing content shaped by algorithmic amplification, and fear of missing out have all been identified as pathways through which digital engagement may exacerbate emotional vulnerability [14,15].

Beyond these mechanisms, emerging constructs further underscore the complexity of digital mental health dynamics. Prolonged exposure to emotionally charged or traumatic content may contribute to emotional exhaustion and desensitization, sometimes conceptualized as “digital empathic fatigue,” reflecting a form of affective overload unique to high-volume online environments [16]. Concurrently, the sustained management of one’s online persona (balancing authenticity, audience expectations, and performance metrics) can generate chronic self-monitoring and identity strain [17]. Together, these findings suggest that the psychological impact of social media is best understood as multidimensional, shaped by interacting emotional, cognitive, and structural features of digital platforms rather than by exposure alone.

Despite increasing interest in the psychological consequences of social media use, the literature still faces several limitations. Many studies rely on simplistic measures such as screen time or general frequency of use, which fail to capture the complexity of users’ emotional and cognitive experiences online [18,19]. The specific effects of platform design features (such as algorithmic feeds, read receipts, viral metrics, or digital memory functions) remain underexplored, even though these features may subtly reinforce compulsive behavior or emotional dysregulation [20-22]. Furthermore, most existing research has been conducted in adolescent samples, with less attention to adult populations who may experience different forms of psychosocial stress in digital environments [23,24]. There is a pressing need for more multidimensional analyses that account for the psychological nuances of digital engagement and move beyond correlational metrics to consider the lived experiences and emerging stressors associated with social media.

The primary objective of this study is to explore the perceived effects of social media use on the mental health of adult users by analyzing quantitative data from thematic scales. Through this approach, the study attempts to better understand how specific platform features (such as algorithms, viral content dynamics, memory notifications, and read receipts) may influence psychological well-being. In parallel, this study aims to assess the intensity of various psychosocial dimensions linked to social media use, identify user profiles at greater risk of emotional distress based on sociodemographic and behavioral variables, and uncover recurring themes within participants’ lived experiences. This research intends to provide a more nuanced and integrated understanding of how digital practices intersect with mental health. Finally, we aim to highlight the mechanisms underlying social media–related distress and to inform more targeted strategies for prevention and intervention.

Methods

Ethical Considerations

This study was approved by the Research Ethics Committee in Education and Psychology of the Université de Montréal (approval number 2025-6867). Participants were presented with an information letter outlining the purpose and procedures of the study and were required to provide informed consent prior to participation. All data were collected anonymously, and no identifying information was retained. Participants did not receive any form of compensation for their involvement in the study.

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Study Design

This study used a cross-sectional design using a survey approach. Data were collected through an online survey created and administered via LimeSurvey, accessible in both French and English. The survey aimed to assess psychosocial factors associated with social media use in the general adult population. All responses were anonymous and collected over an 8-week period. The choice of an online format was appropriate given the digital literacy of the target population and the thematic focus on social media use. We followed the STROBE (Strengthening the Reporting of Observational Studies in Epidemiology) checklist (Multimedia Appendix 1) to strengthen the reporting of this observational cross-sectional study [25].

Participants and Recruitment

Participants were recruited through organic (nonpaid) postings on popular social media platforms, including Facebook, Instagram, Reddit, and TikTok. A standardized study invitation describing a research project on social media habits and emotional experiences was publicly shared on these platforms and within selected online communities. No paid advertising or algorithmic demographic targeting was used; participation relied entirely on voluntary self-selection by individuals who encountered the post and chose to access the survey link.

Individuals who clicked the link were redirected to a secure LimeSurvey platform hosted on institutional servers. Inclusion criteria were (1) age of 18 years or older (self-attested), (2) regular use of at least 1 social media platform, and (3) provision of informed digital consent prior to participation. Exclusion criteria included reporting no social media use or submitting incomplete questionnaires. Because the survey was fully anonymous and did not collect identifying information, eligibility criteria such as age were based on participant self-report.

The target sample size ranged between 300 and 500 participants. This range was informed by comparable cross-sectional digital health surveys and supported by an a priori power analysis conducted using G*Power (version 3.1.9.7), which indicated that a minimum sample of 385 participants would provide adequate statistical power (95% confidence level, 5% margin of error) to detect small-to-moderate correlational effects [26].

Data Collection

Sociodemographic variables collected included age, sex assigned at birth, country of residence, living environment (urban, rural, or other), current employment status, highest level of education attained, and estimated daily time spent on social media (in hours). These variables were selected for their relevance to previous literature on digital media use and mental health risk factors.

To assess problematic or compulsive social media use, the study adapted the CAGE-AID (Cut down, Annoyed, Guilty, Eye-opener–Adapted to Include Drugs), a validated 4-item screener commonly used for alcohol use disorders and substance abuse [27]. In this adaptation, items were reworded to target digital behaviors and emotional responses rather than substance use. For instance, questions assessed participants' desire to reduce social media use, emotional discomfort when criticized about their usage, feelings of guilt about time spent online, and compulsive checking behavior, such as opening social media immediately upon waking. Each item had a binary response format (yes/no), and a score of 1 or more "yes" responses was interpreted as a positive screen, consistent with established usage of the original tool. The rationale for this adaptation lies in the emerging consensus that behavioral addictions, such as problematic social media use (PSMU), share features with substance use disorders (including impaired control, emotional salience, and functional impairment), making the CAGE-AID a reasonable, if preliminary, proxy for identifying at-risk individuals in population surveys [28].

Beyond the screener, participants completed a series of Likert-type items related to 7 thematic psychosocial dimensions of social media use: empathic fatigue, silent stressors (eg, read receipts and typing indicators), identity fragmentation, pressure for visibility and virality, algorithmic influence, digital detox behaviors, and nostalgia-related emotional responses. Each dimension was explored using a standardized set of 7 statements, rated on a 5-point Likert scale ranging from "strongly disagree" to "strongly agree." These items were developed from a synthesis of emerging literature and pilot feedback and aimed to capture the subjective intensity of each experience. The full questionnaire is available in French and in English in Multimedia Appendix 2.

Statistical Analysis

All quantitative analyses were conducted using Python (version 3.11) and the scikit-learn library [29]. Descriptive statistics were computed to characterize the sample and provide means for each psychosocial dimension. Associations between sociodemographic variables and CAGE-AID positivity were examined using chi-square tests for categorical variables and Spearman's ρ for ordinal or nonnormally distributed continuous variables. The threshold for statistical significance was set at $P<.05$ for all tests. Data were screened for missingness and outliers prior to analysis, and appropriate assumptions for each test were verified.

Results

Sociodemographic Characteristics of the Respondents

The surveyed population was composed of a diverse sociodemographic cohort of 402 respondents, of whom 393 completed the questionnaire. Participants ranged across various age groups, with a larger representation from younger adults (particularly those aged 18-34 years). The gender distribution included both male and female respondents, with an overrepresentation of women, which is common in mental health–oriented surveys [30]. Most participants resided in urban or suburban environments, and the majority were either employed full-time or students. A high level of education was observed in the sample, with many respondents holding university degrees, including graduate-level qualifications. Daily time spent on social media varied, but several participants reported spending 3 or more hours per day, which may reflect the integration of digital platforms into daily routines. The sample skewed toward a digitally connected, educated, and

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professionally active population. The main characteristics of the population and correlations with the CAGE-AID are presented in Table 1.

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Table 1. Sociodemographic characteristics and associations with problematic social media use (modified CAGE-AID [Cut down, Annoyed, Guilty, Eye-opener–Adapted to Include Drugs] ≥1) in a cross-sectional online survey of adult social media users (aged 18 years or older) recruited via organic social media postings over an 8-week period. Associations were tested using chi-square and Spearman rank correlation (ρ) analyses.

Variable and subgroup	Total, n	CAGE-AID (modified) positive, n	Positive, %	*P* value (chi-square test)	Spearman rank correlation, ρ	*P* value (Spearman rank correlation)
Age group (years)						
18-24	108	104	96.3	<.001	–0.126	.01
25-34	129	123	95.3	<.001	–0.126	.01
35-44	58	56	96.6	<.001	–0.126	.01
45-54	48	43	89.6	<.001	–0.126	.01
55-64	41	38	92.7	<.001	–0.126	.01
65 and above	9	5	55.6	<.001	–0.126	.01
Gender						
Female	312	295	94.6	.49	–0.053	.30
Male	79	72	91.1	.49	–0.053	.30
Other	2	2	100	.49	–0.053	.30
Country						
Algeria	3	3	100	>.99	–0.034	.51
Canada	353	332	94.1	>.99	–0.034	.51
France	14	13	92.9	>.99	–0.034	.51
India	1	1	100	>.99	–0.034	.51
Netherlands	2	2	100	>.99	–0.034	.51
Norway	1	1	100	>.99	–0.034	.51
Philippines	1	1	100	>.99	–0.034	.51
Portugal	1	1	100	>.99	–0.034	.51
Russia	1	1	100	>.99	–0.034	.51
United Kingdom	2	2	100	>.99	–0.034	.51
United States of America	14	12	85.7	>.99	–0.034	.51
Living environment						
Suburb	161	148	91.9	.12	0.091	.07
Rural	39	35	89.7	.12	0.091	.07
Urban	193	186	96.4	.12	0.091	.07
Employment						
Other	7	6	85.7	.04	0.091	.07
Full-time	175	162	92.6	.04	0.091	.07
Part-time	25	23	92	.04	0.091	.07
Retired	19	15	78.9	.04	0.091	.07
None	5	5	100	.04	0.091	.07
Self-employed	37	37	100	.04	0.091	.07
Student	125	121	96.8	.04	0.091	.07
Education						
Other	11	11	100	.02	–0.104	.04
Masters or Doctorate (including professional doctorates)	145	139	95.9	.02	–0.104	.04
Bachelor’s degree	137	128	93.4	.02	–0.104	.04

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Variable and subgroup	Total, n	CAGE-AID (modified) positive, n	Positive, %	*P* value (chi-square test)	Spearman rank correlation, ρ	*P* value (Spearman rank correlation)
Vocational training or technical degree	69	66	95.7	.02	–0.104	.04
Highschool or less	31	25	8.6	.02	–0.104	.04
Time on social media, hours/day						
1-2	143	131	91.6	.002	–0.006	.91
3-4	176	172	97.7	<.001	–0.006	.91
5-6	40	39	97.5	<.001	–0.006	.91
7	10	9	90	<.001	–0.006	.91
<1	24	18	75	<.001	–0.006	.91

Main Findings on CAGE-AID and Sociodemographic Correlates

Analysis of the adapted CAGE-AID screener for PSMU revealed meaningful associations with several sociodemographic factors. Younger age groups demonstrated a significantly higher likelihood of screening positive on the CAGE-AID, with the highest positivity rate observed among those aged 18 to 24 years. This trend was statistically supported by both a significant chi-square result (χ^2_5=27.0; *P*<.001) and a negative Spearman correlation (ρ=–0.160; *P*<.001), suggesting an inverse relationship between age and problematic use. Similarly, lower levels of education were associated with increased CAGE-AID positivity, reinforcing the possibility that educational attainment may act as a protective factor (χ^2_4=11.6; *P*=.02; ρ=–0.121). Employment status also emerged as a relevant factor, with higher positivity rates among students and those in less stable employment (χ^2_6=13.5; *P*=.04). While time spent on social media showed a significant global association (χ^2_4=21.9; *P*<.001), the corresponding Spearman rank correlation was weak (ρ=–0.097), suggesting that the quantity of use alone may be less informative than the psychological relationship with these platforms. No significant associations were observed for gender, country of residence, or living environment, indicating these variables may not independently predict PSMU in this sample.

Fatigue Empathy Linked to Social Media Usage

Emotional fatigue and empathy erosion in relation to prolonged social media use responses are presented in Figure 1. Mean scores indicate that the most endorsed items were “Emotional posts exhaust me” mean 3.35 (SD 1.10) and “I avoid emotional engagement because it’s overwhelming” mean 3.20 (SD 1.12), highlighting a prevalent sense of emotional saturation online. Conversely, statements reflecting emotional detachment, such as “Social media made me indifferent to emotional hardship” mean 2.30 (SD 0.77), were less strongly endorsed.

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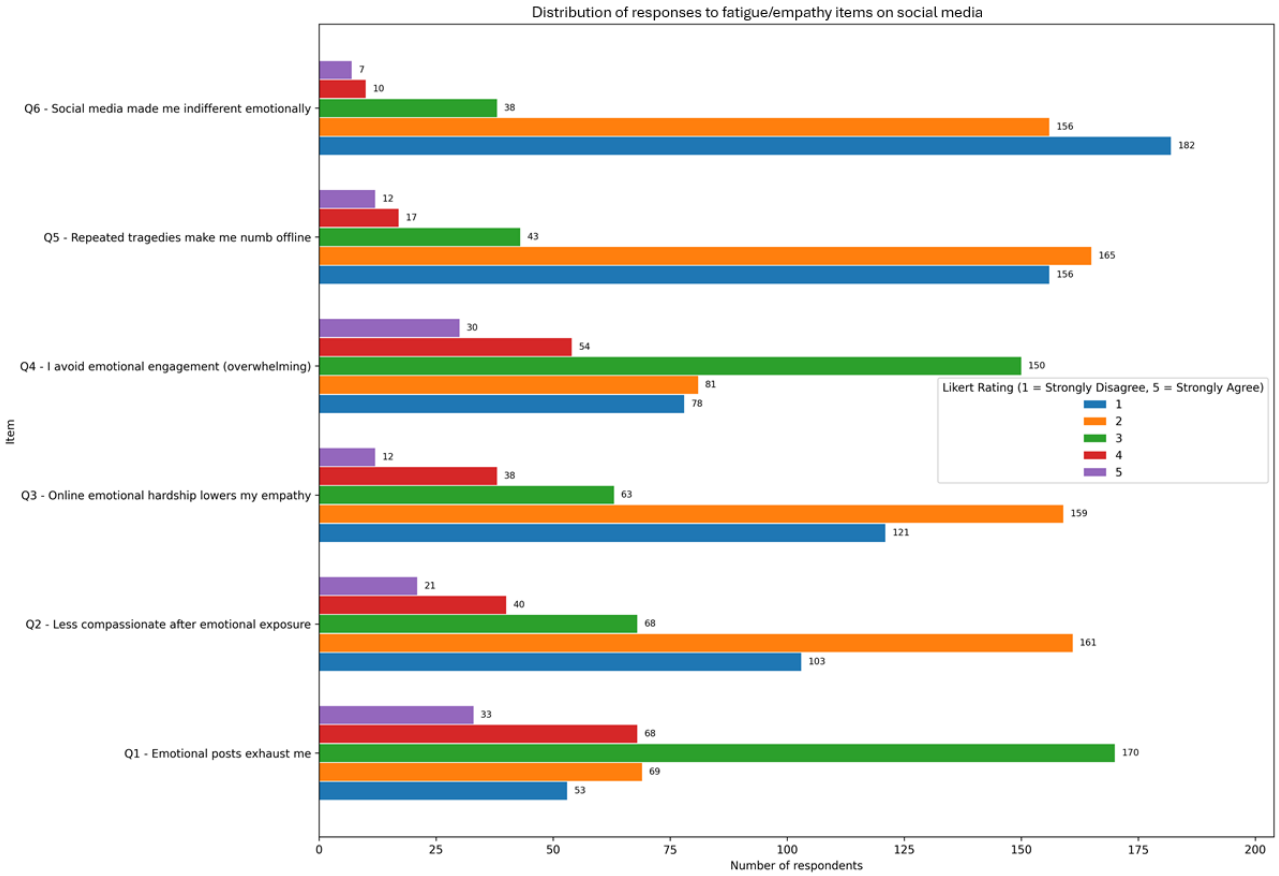
Figure 1. Mean Likert scale endorsement (1-5) of emotional fatigue and empathy-related experiences among adult social media users in a cross-sectional online survey conducted over 8 weeks. Associations with problematic social media use were examined using Spearman rank correlations.



In terms of correlations with PSMU (defined as 1 or more positive responses on the adapted CAGE-AID), the strongest association emerged for the item "Online emotional hardship lowers my empathy" (ρ=0.22; *P*<.001), suggesting a potential link between emotional desensitization and maladaptive usage patterns. Other items such as "Less compassionate after emotional exposure" and "I avoid emotional engagement" also showed significant positive correlations with PSMU (ρ=0.20; *P*<.001 and ρ=0.19; *P*<.001, respectively).

Subgroup analyses revealed that younger age groups, particularly those aged 18 to 24 years, tended to report higher agreement with emotionally fatiguing statements, with scores gradually decreasing in older cohorts. This suggests that emotional saturation and disengagement may disproportionately affect younger users, who are also more likely to be heavy social media users and more susceptible to CAGE-AID positivity.

Psychosocial Impact of Silent Factors in Social Media

The "silent factors" explored in this survey (such as read receipts, typing indicators, and perceived delays in replies) emerge as subtle but significant sources of digital stress. Responses of the respondents are presented in Figure 2. The items most frequently endorsed were "I feel pressured to reply quickly due to 'seen' indicators" mean 3.44 (SD 1.08) and "I delay reading messages due to read receipts" mean 3.16 (SD 1.12), suggesting that interface cues in messaging apps may generate a sense of urgency and avoidance behaviors. In contrast, items like "Typing indicators cause me stress" mean 2.23 (SD 1.05) and "Read receipts worsen my mood" mean 2.26 (SD 1.03) were endorsed less frequently, indicating more individualized reactions to these features.

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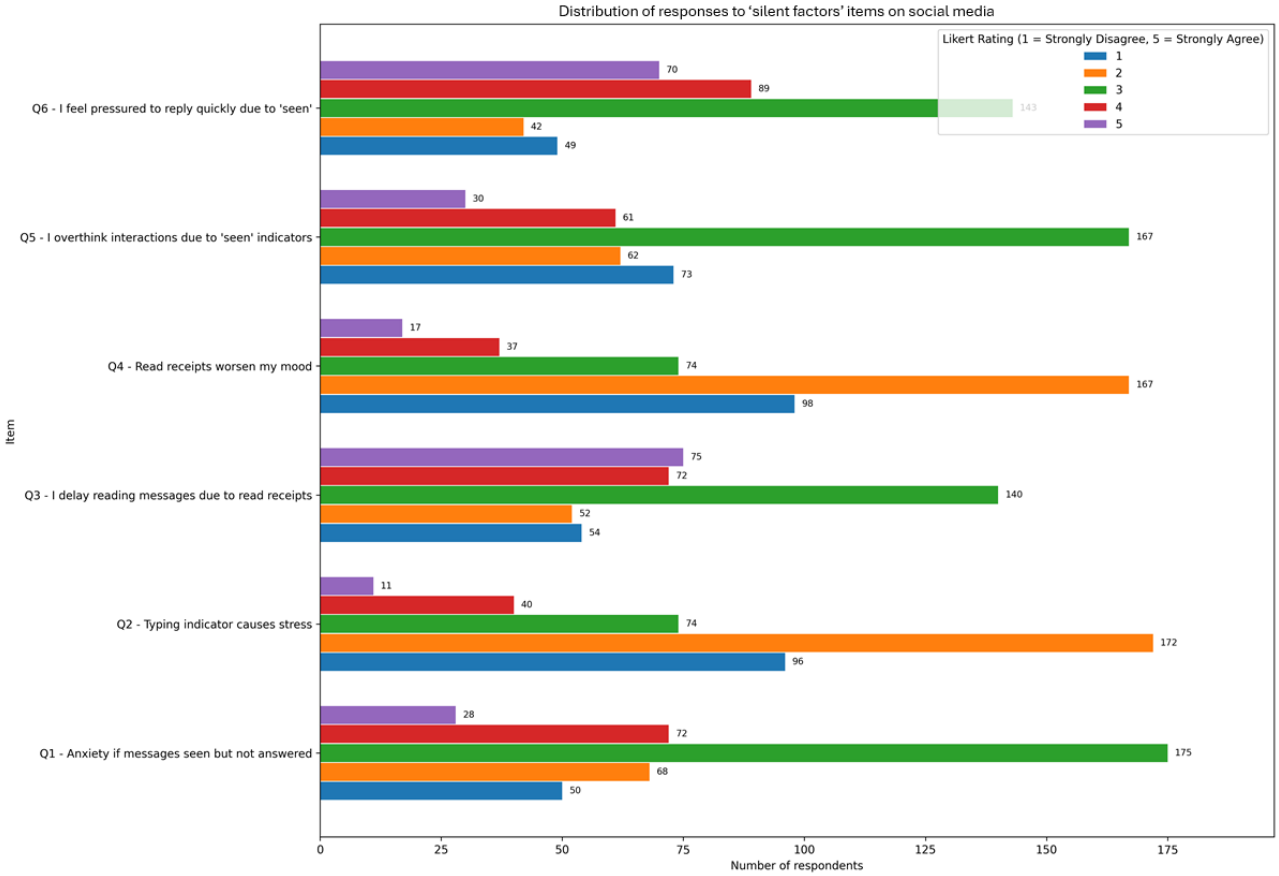
Figure 2. Mean endorsement (1-5 Likert scale) of stress related to messaging interface features (eg, read receipts and typing indicators) in adult social media users from a cross-sectional online survey (8-week recruitment period).



Correlational analyses showed that several items had modest but statistically significant associations with CAGE-AID positivity, indicating potential links between digital communication stress and PSMU. Specifically, "I delay reading messages due to read receipts" and "I overthink interactions due to 'seen' indicators" both correlated significantly with CAGE-AID scores (ρ=0.153 and ρ=0.146, respectively; *P*<.001), while "Feeling pressured to reply quickly" also showed a positive association (ρ=0.124; *P*=.01). These findings suggest that users who internalize social expectations embedded in app features may be more likely to report problematic patterns of use.

Subgroup analysis by age revealed that younger respondents reported higher levels of stress and reactivity across nearly all silent factor items. For example, participants aged 18 to 24 years averaged a higher agreement with statements as "I feel anxious if messages are seen but not answered" mean 2.90 (SD 1.07) and "I overthink interactions due to 'seen' indicators" mean 2.78 (SD 1.05). This pattern reinforces prior observations that digital social stressors disproportionately affect younger users, possibly due to greater online social dependence, peer validation needs, and digital communication intensity. Therefore, these results highlight that messaging app design may unintentionally contribute to psychological strain, especially in vulnerable populations.

Online Identity Fragmentation and Its Psychological Implications

Responses to the Online Identity scale reveal nuanced tensions between self-presentation and authenticity in digital spaces and are presented in Figure 3. The most endorsed items were "I show a more idealized version of myself online" mean 1.95 (SD 0.92) and "I feel pressure to curate my digital identity" mean 1.84 (SD 0.90), indicating that many participants (though not strongly) experience subtle pressures to maintain a carefully crafted online image. Other items such as "I manage multiple versions of myself online" and "I use social media to escape my offline self" had lower endorsement (means ranging from 1.2 to 1.5), suggesting that these behaviors may be more specific to certain users rather than generalized across the sample.

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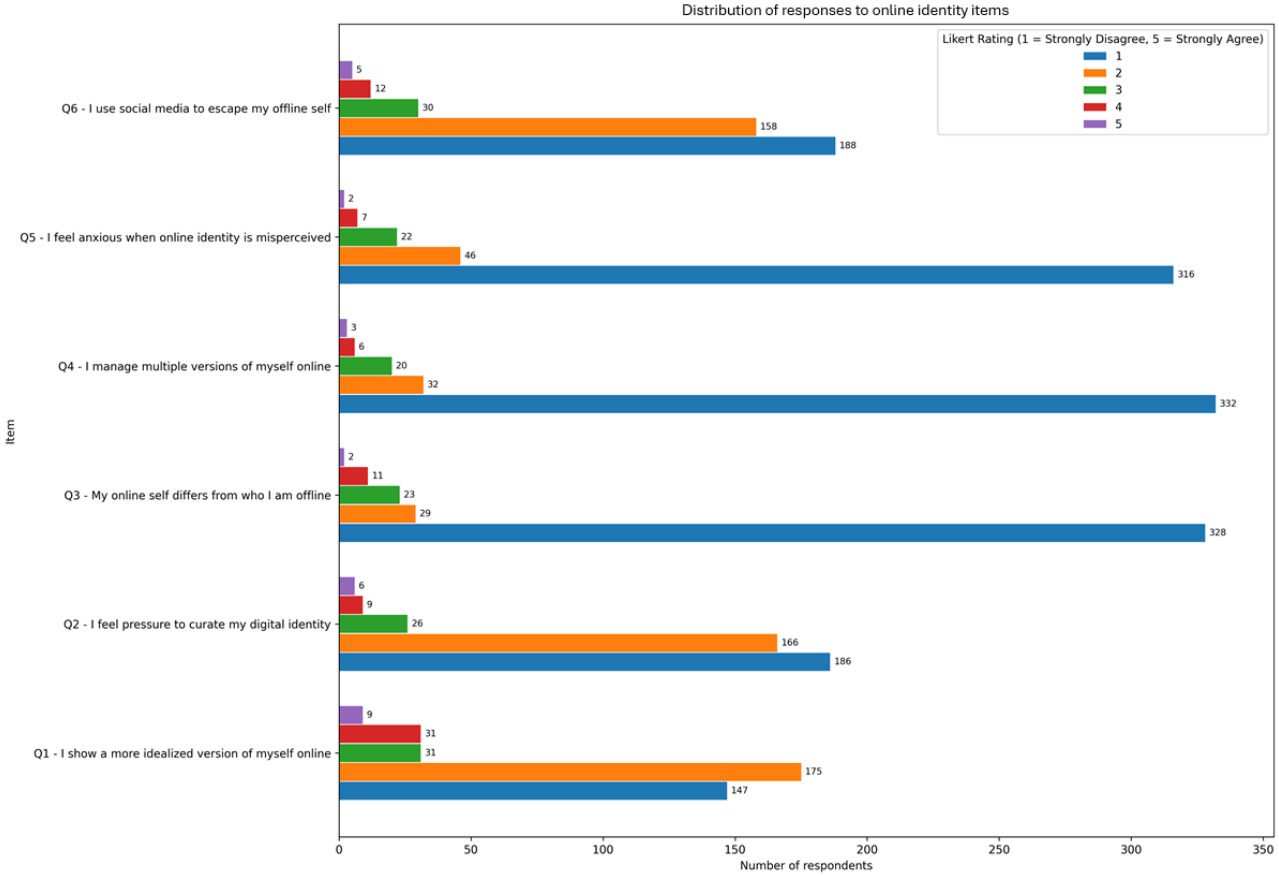
Figure 3. Mean endorsement (1-5 Likert scale) of online identity–related pressures (eg, idealization and curation) among adult social media users in a cross-sectional online study conducted over 8 weeks.



Correlational analyses with CAGE-AID positivity highlight a significant relationship between online identity manipulation and PSMU. The item “I feel pressure to curate my digital identity” showed the strongest correlation with CAGE-AID scores (ρ=0.280; *P*<.001), followed by “I show a more idealized version of myself online” (ρ=0.234; *P*<.001). These findings suggest that individuals who invest more in crafting or controlling their online persona may be more likely to engage in maladaptive social media behaviors. Lesser but still significant correlations were observed for items related to anxiety over misrepresentation (ρ=0.132; *P*=.009) and using social media for escapism (ρ=0.117; *P*=.02).

Subgroup analysis by age revealed a clear downward trend: younger participants (aged 18-34 years) reported higher mean scores on nearly all identity-related items compared to older groups. For example, the group of respondents aged 18 to 24 years had the highest mean for “I show a more idealized version of myself” mean 1.99 (SD 0.93) and “I feel pressure to curate” mean 1.74 (SD 0.90), whereas respondents aged 55 years or older consistently reported means below 1.5 across all items. This trend suggests that digital identity tension is especially prominent in younger adults, potentially driven by increased social media exposure, peer comparison, and developmental identity work.

Online Viral Presence: Motivations, Validation, and Age-Sensitive Trends

Participant responses on viral presence and engagement-related behaviors reveal a low-to-moderate overall endorsement, with nuanced psychological implications. They are presented in Figure 4. The most endorsed items included “I compare my engagement to others” mean 2.06 (SD 1.00) and “I dream of going viral on social media” mean 1.88 (SD 0.95), reflecting some aspirational and comparative tendencies related to online visibility. Meanwhile, items reflecting emotional reactivity such as “I feel disappointed when posts don’t perform well” mean 1.30 (SD 0.85) had the lowest mean, suggesting that for most users, personal validation is not entirely contingent on digital metrics.

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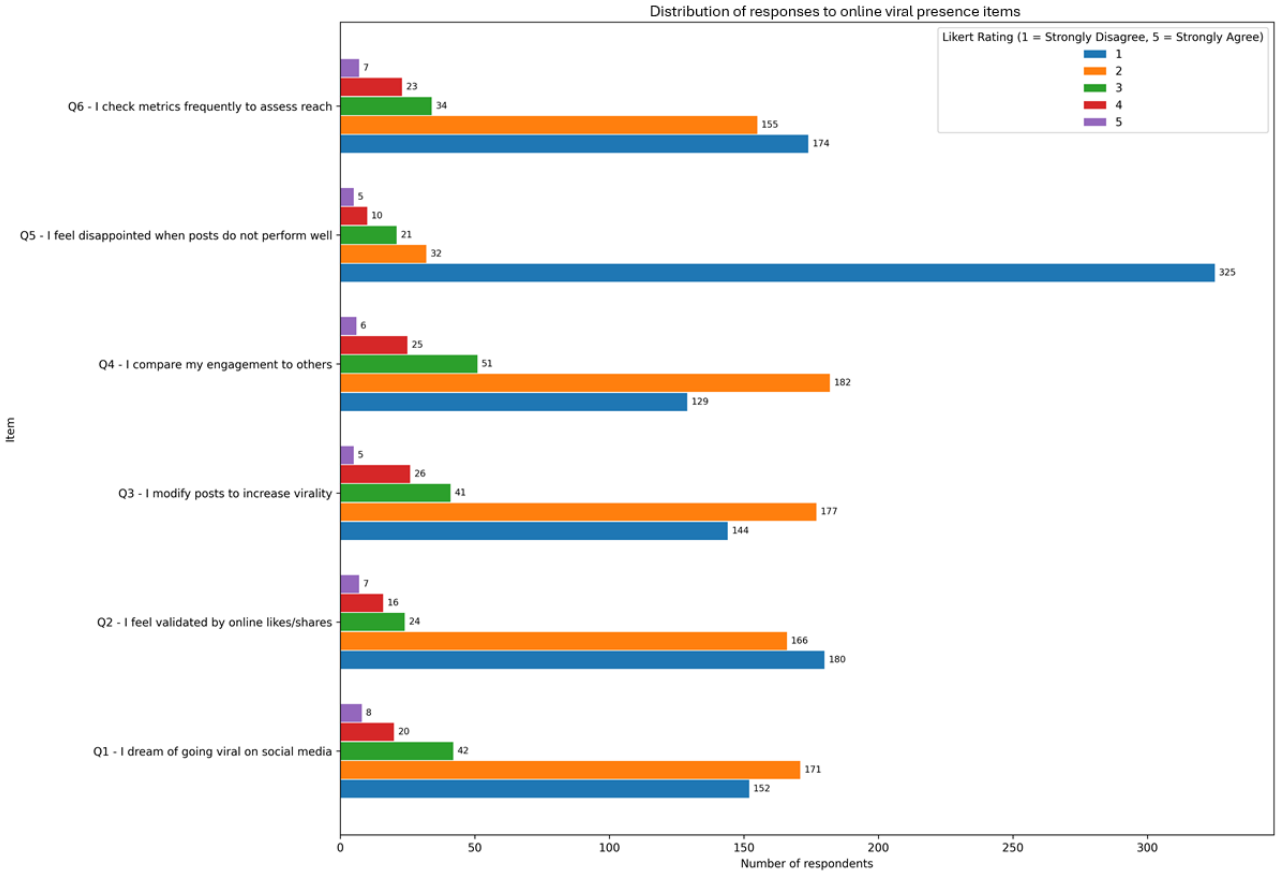
Figure 4. Mean endorsement (1-5 Likert scale) of perceived algorithmic influence among adult social media users in a cross-sectional online survey conducted over 8 weeks.



Correlational analysis identified significant, though modest, associations between several viral presence items and CAGE-AID positivity. The strongest were “I compare my engagement to others” (ρ=0.134; *P*=.008) and “I modify posts to increase virality” (ρ=0.130; *P*=.01), suggesting that a performance-oriented approach to content curation may be linked to PSMU. Other items like “I feel validated by likes/shares” and “I check metrics frequently” showed weaker, nonsignificant correlations, reinforcing that not all engagement behaviors are inherently maladaptive.

Subgroup analysis by age revealed a consistent trend: younger age groups (aged 18-24 years and 25-34 years) reported higher agreement with nearly all items, particularly for “dreaming of going viral” mean 2.02 (SD 0.98) in those aged 18-24 years and “comparing engagement” mean 2.11 (SD 1.02). These ratings declined with age, reaching the lowest levels among those aged 55 years or older. This pattern underscores the generational dynamics of social media use, with younger users potentially more invested in visibility, peer comparison, and digital identity performance. The findings suggest that engagement-oriented and comparative behaviors (hallmarks of viral motivation) may serve as subtle contributors to compulsive social media habits, especially in younger populations navigating online validation pressures.

Algorithmic Influence: Perception, Resistance, and Associations With Social Media Overuse

Participants’ responses indicate a nuanced awareness of the role algorithms play in shaping online experiences, accompanied by varying degrees of psychological impact and are presented in Figure 5. The highest rated item was “I feel trapped in algorithmic echo chambers” mean 2.99 (SD 1.10), followed by “Algorithms impact my emotional state” mean 2.31 (SD 1.05), suggesting that while participants acknowledge the emotional and cognitive influence of algorithmic filtering, their active concern or resistance remains moderate. Other items, such as “I try to resist algorithmic influence” mean 2.10 (SD 1.02) and “I’m concerned about algorithmic manipulation” mean 2.00 (SD 1.00), received lower endorsement, indicating that the internalization of algorithmic impact is more cognitive than behavioral for most users.

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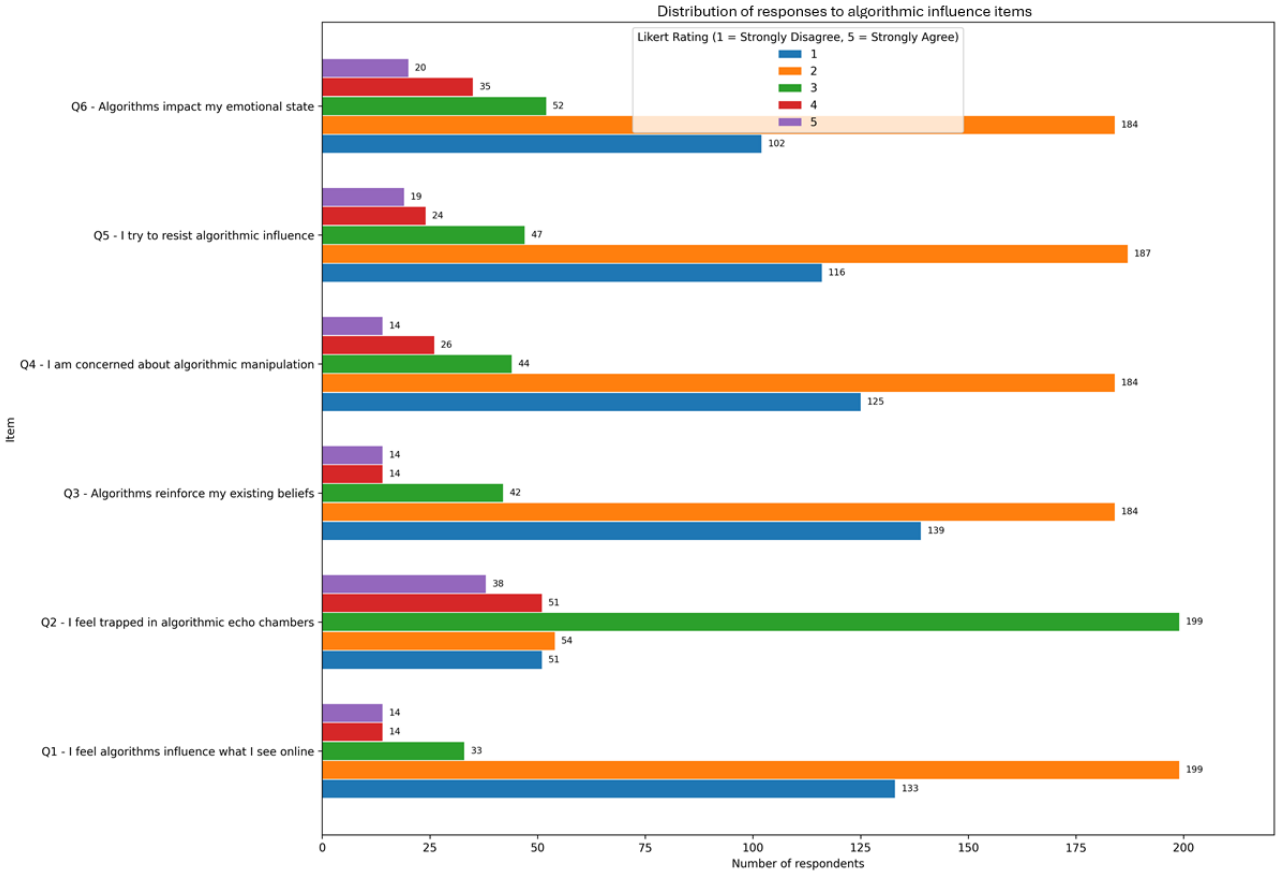
Figure 5. Mean endorsement (1-5 Likert scale) of perceived algorithmic influence among adult social media users in a cross-sectional online survey conducted over 8 weeks.



Correlational analysis revealed several significant associations with PSMU as indexed by the CAGE-AID. The strongest relationship was observed for “I try to resist algorithmic influence” (ρ=0.155; *P*=.002), followed by “Algorithms reinforce my existing beliefs” (ρ=0.149; *P*=.003) and “Algorithms impact my emotional state” (ρ=0.139; *P*=.006). These results suggest that individuals who are more attuned to or concerned about algorithmic shaping of their feeds may also be more vulnerable to patterns of compulsive or dysregulated use. Interestingly, feeling trapped in echo chambers did not reach statistical significance (ρ=0.075; *P*=.14), possibly reflecting a broader but less emotionally salient experience.

Age-based subgroup analyses showed modest differences. Younger participants (aged 18-34 years) tended to report slightly higher algorithm awareness and concern, with average scores of approximately 2.00 to 2.13 for items such as “Algorithms influence what I see online” and “I’m concerned about algorithmic manipulation.” The oldest group (aged 65 years or older), however, reported lower levels of perceived influence mean 1.22 (SD 0.80) and concern mean 1.56 (SD 0.90),consistent with possible generational gaps in algorithmic literacy or engagement intensity. Nevertheless, feelings of being trapped in echo chambers remained relatively elevated across all age groups, suggesting that algorithmic filtering may be broadly recognized regardless of demographic background.

Digital Detox Behaviors: Coping Strategies and Associations With Problematic Use

Survey responses indicate that digital detox behaviors (such as taking breaks, deleting apps, or attempting challenges) are moderately common among participants and presented in Figure 6. The most frequently endorsed item was “I feel guilty after long time on social media” mean 2.31 (SD 1.05), followed by “I delete apps to limit my usage” mean 2.26 (SD 1.03) and “I take breaks from social media to feel better” mean 2.15 (SD 1.02; μ=2.15). These results suggest a notable level of self-awareness and adaptive attempts at behavioral regulation. Less frequently endorsed behaviors included “I try detox challenges or fasts” mean 1.83 (SD 0.95) and “I re-download apps after deleting them” (μ=1.99), which reflect more intermittent or ambivalent strategies.

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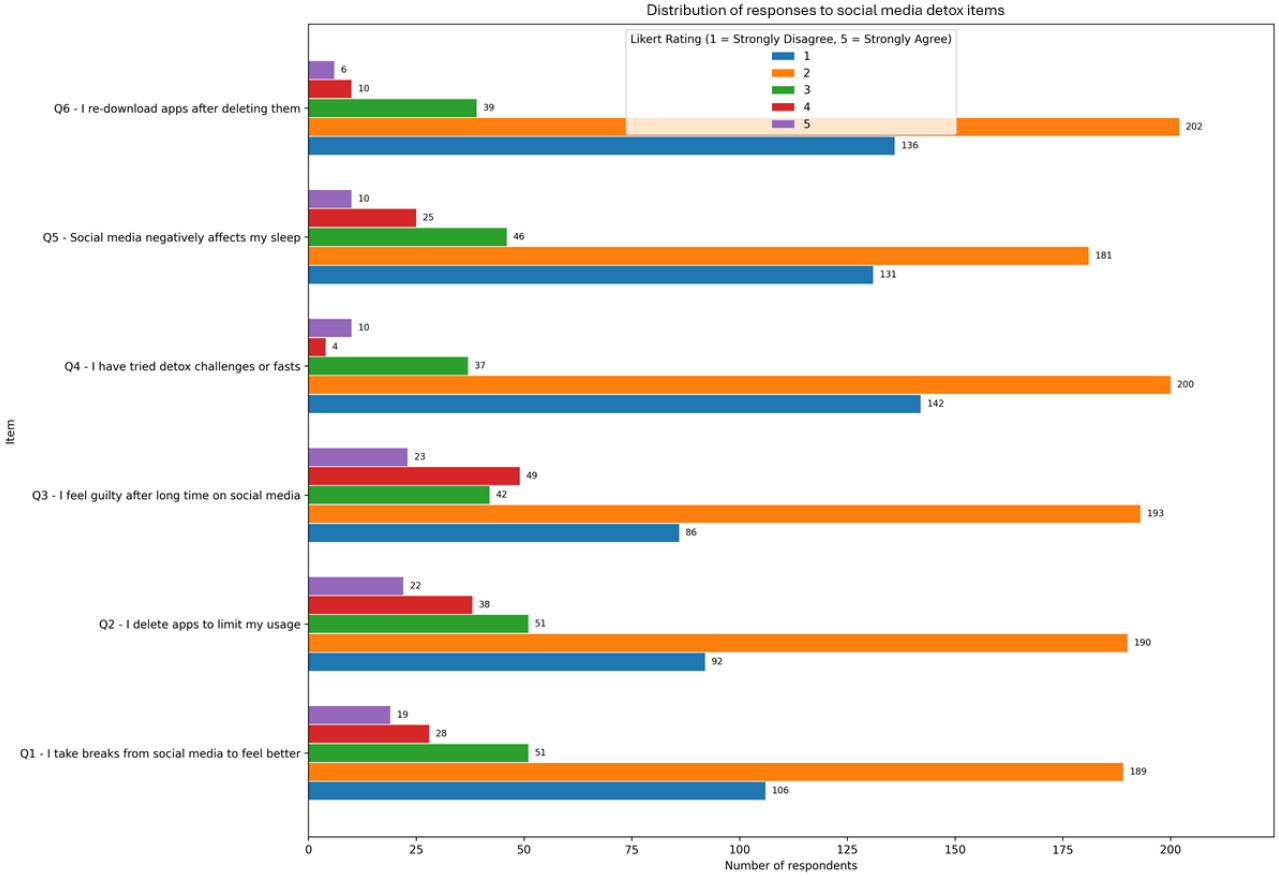
Figure 6. Mean endorsement (1-5 Likert scale) of digital detox behaviors among adult social media users in a cross-sectional online survey (8-week recruitment period).



Importantly, several detox behaviors showed statistically significant positive correlations with CAGE-AID positivity, suggesting a link between attempts to regulate use and potential problematic engagement. The strongest associations were observed for “I feel guilty after long time on social media” (ρ=0.200; *P*<.001) and “Social media negatively affects my sleep” (ρ=0.187; *P*<.001), underscoring emotional and physiological consequences of excessive use. Other significant associations included app deletion (ρ=0.159; *P*=.002) and taking breaks (ρ=0.138; *P*=.006). These results suggest that individuals engaging in detox behaviors may already recognize maladaptive patterns and are attempting to restore control, but with varying success.

Subgroup analysis by age revealed that younger users were more likely to engage in detox-related behaviors, particularly in deleting apps and expressing guilt. Mean scores for app deletion, guilt, and perceived sleep impacts all hovered around 2.25 to 2.31, while older adults consistently scored lower on these items. This age gradient suggests that younger individuals (potentially more embedded in digital environments) may also be more prone to cyclical disengagement strategies as a form of digital self-care or reactive control. These findings highlight a tension between awareness and effectiveness of digital detox strategies. While users, particularly younger ones, are actively attempting to regulate their consumption, the correlations with CAGE-AID positivity suggest that detox behaviors often arise in response to distress rather than prevention, reinforcing the need for proactive and sustainable digital well-being interventions.

Nostalgia and Reminders: Emotional Reactions and Coping Mechanisms in the Digital Archive

Participant responses to nostalgia-related items reveal that emotional engagement with past digital content is common but nuanced and are presented in Figure 7. The most endorsed items were “Old memories triggered by social media make me emotional” mean 2.05 (SD 1.00) and “I get sad when reminded of past posts or people” mean 1.87 (SD 0.95), suggesting that while the emotional impact is present, it is generally moderate. Other items, such as “I revisit past posts/photos frequently” mean 1.76 (SD 0.92) and “I use reminders as a way to cope” mean 1.79 (SD 0.93), highlight the potential dual function of nostalgic content—as both a stressor and a source of comfort. Interestingly, “Social media nostalgia is mostly positive” had the lowest endorsement mean 1.70 (SD 0.90), indicating a slightly negative or ambivalent emotional valence overall.

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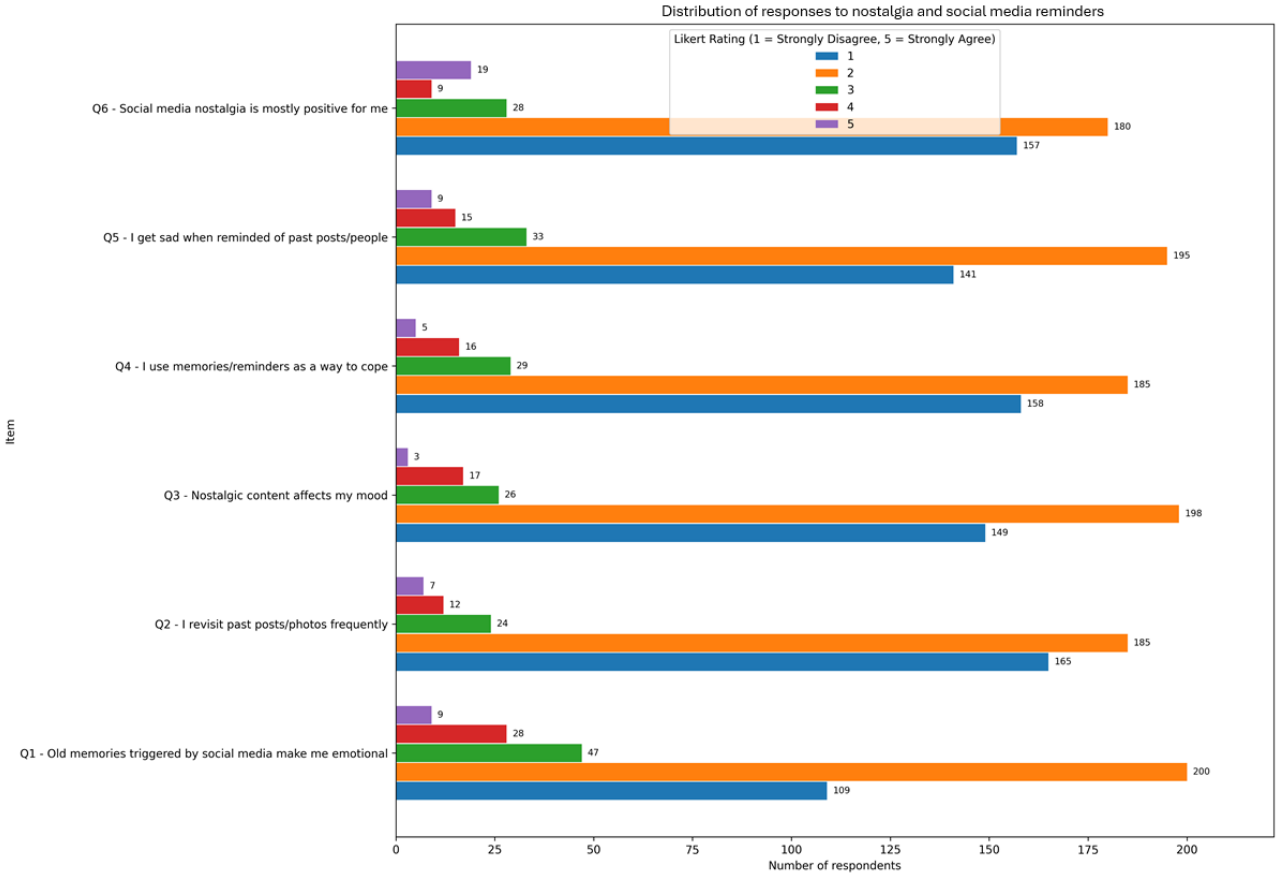
Figure 7. Mean endorsement (1-5 Likert scale) of nostalgia-related emotional responses to social media memories in adult users from a cross-sectional online study conducted over 8 weeks.



Correlational analyses showed modest but significant associations with CAGE-AID positivity, especially for items reflecting emotional reactivity. The strongest association was observed for "I use memories/reminders as a way to cope" (ρ=0.122; *P*=.02), followed by "Old memories make me emotional" (ρ=0.111; *P*=.03), and "Nostalgic content affects my mood" (ρ=0.104; *P*=.04). These findings suggest that users who respond more intensely to digital memories may also be more susceptible to PSMU (perhaps due to underlying affective vulnerabilities or rumination tendencies).

Age subgroup analysis showed that younger participants reported slightly higher emotional resonance with nostalgic content. In the subgroup with a positive CAGE-AID result, average scores hovered between 1.70 and 2.05 for all items. Although these means are modest, the consistent pattern across items supports the idea that social media nostalgia is a cross-cutting but variably experienced emotional phenomenon, more pronounced in individuals who engage frequently and emotionally with their digital history.

The responses of the survey are available in Multimedia Appendix 3.

Translating Findings Into Practical Guidance

Overview

Although this study is cross-sectional in design and thus cannot infer causality, the patterns observed across nearly 400 participants offer meaningful insights into the psychological impact of everyday social media use. The consistency of associations between self-reported distress and specific digital behaviors highlights the need for more considerate digital well-being strategies. While further longitudinal and experimental research is required to validate these associations, the current findings offer a useful baseline from which preliminary guidance can be drawn. The following recommendations are intended for the general public and reflect trends observed in our dataset. They aim to support healthier and more mindful engagement with social media platforms, especially in an era where digital interactions are deeply embedded in daily life.

Be Mindful of How Social Media Affects Your Emotions

If you often feel drained, anxious, or self-critical after spending time online, it is worth pausing to reflect on which types of content or which platform features may be contributing to this. Recognizing these emotional patterns is a first step toward more conscious digital habits.

Set Gentle But Clear Boundaries Around Your Usage

Turn off unnecessary notifications, hide "read" receipts, or put your phone away during meals or bedtime. These small adjustments can significantly reduce feelings of pressure, improve sleep, and help restore a sense of control over your digital life.

Understand How Your Feed Is Shaped

Algorithms are designed to keep you engaged, often by prioritizing emotionally charged or repetitive content. Learning

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to recognize when your attention is being hijacked, and choosing to scroll more intentionally, can reduce stress and prevent compulsive behaviors.

Take Breaks Before You Burn Out

Rather than waiting until you feel overwhelmed, try scheduling short breaks from social media regularly. Unplugging periodically (even for a few hours) can reduce fatigue and help you reconnect with activities that restore your mental focus.

It Is Okay to Feel Conflicted About Social Media

Many people experience both positive and negative emotions online. Feeling nostalgic, left out, overwhelmed, or even manipulated by digital platforms is not a personal failing: it is a reflection of how these tools are designed. Being aware of this can help you navigate your digital life with more self-compassion and intention.

Discussion

Principal Results

In this study, we investigated the psychosocial effects of social media use among adults, focusing on how specific features of digital platforms relate to emotional well-being. One of the most important findings was the remarkably high proportion of respondents who screened positive on the adapted CAGE-AID tool for PSMU, particularly among younger adults, those with lower educational attainment, and those spending more time online. Emotional fatigue and empathic desensitization emerged as dominant experiences, with participants reporting avoidance of emotional content and feelings of overwhelm. Features embedded in messaging platforms (such as read receipts and typing indicators) were associated with elevated stress levels and compulsive checking behaviors. Respondents also expressed moderate internal conflict related to online self-presentation, with younger users more likely to curate idealized versions of themselves. Engagement-driven behaviors such as comparing metrics or aspiring to virality were modestly endorsed but nonetheless correlated with problematic use. Finally, awareness of algorithmic filtering and digital detox attempts reflected a self-perceived need for behavioral regulation, while nostalgic digital content elicited mixed emotional reactions, serving both as sources of comfort and distress. These findings highlight the complex interplay between platform design, individual vulnerabilities, and psychological strain.

Comparison With Prior Work

The association between emotional exhaustion and PSMU aligns with existing work suggesting that constant exposure to emotionally charged or traumatic content can lead to "compassion fatigue" or emotional burnout [31,32]. Emotional avoidance and decreased empathy, as reported in our sample, echo findings from Elhai [33], who documented emotional desensitization among heavy users. These patterns may be exacerbated by the algorithmic amplification of emotionally provocative content, which can prolong emotional arousal and disrupt emotional regulation [34]. Similarly, our findings on silent stressors resonate with studies showing that even minor interface cues can provoke anxiety, compulsive checking, and performance-related pressure [35]. These stressors, often dismissed as trivial, may accumulate to create chronic low-grade distress, particularly in users already prone to digital overuse or social sensitivity.

Our observations regarding online identity support prior research emphasizing the psychological toll of managing multiple selves online. This is similar to the findings of Marwick and Boyd [36] who described the "context collapse" effect, wherein individuals navigate overlapping social audiences and expectations, leading to increased self-monitoring and anxiety. Younger participants in this study showed greater pressure to idealize their online image, consistent with the literature that adolescents and young adults are particularly vulnerable to appearance-based social comparisons [37,38]. Likewise, engagement with virality (though not universally endorsed) was linked to greater emotional investment in likes, shares, and public validation. This is in line with Yang and Robinson's [39] work on "quantified self-worth," wherein digital metrics become a proxy for self-esteem. Even among adults, our findings suggest that the aspiration to "go viral" or modify content for maximum reach is not uncommon and may contribute to a cycle of compulsive posting and performance anxiety.

The study also highlights algorithmic awareness as a psychosocial construct in its own right. Although participants expressed feeling emotionally affected by curated feeds and filter bubbles, only a minority reported actively resisting algorithmic influence suggesting a cognitive dissonance between perceived manipulation and behavioral response. This reflects Roth's [40] notion of algorithmic disturbances where users feel that digital environments shape their behaviors beyond their control. Moreover, our findings on digital detox behaviors provide important insight into the limits of self-regulation. While many participants reported deleting apps, taking breaks, or experiencing guilt, these behaviors were also associated with higher modified CAGE-AID scores, which implies that detox efforts may often be reactive, triggered by distress rather than preventive. This echoes observations by Roberts and David [41], who found that digital disconnection is frequently short-lived and emotionally ambivalent. Lastly, the role of digital nostalgia as both a coping mechanism and a source of sadness has been underexplored in the literature. Our findings suggest that reminders of past posts and memories can evoke emotional turbulence, particularly in individuals already prone to compulsive engagement, and this should be further studied.

Limitations

Amongst its limitations, the cross-sectional nature of the design precludes causal inferences, and the reliance on self-reported data may introduce biases such as social desirability or recall distortion. The adapted CAGE-AID, while grounded in conceptual analogies to behavioral addiction, has not yet been psychometrically validated for digital contexts, which limits its diagnostic utility. Additionally, the sample was not representative of the general population, with an overrepresentation of younger, urban, and educated respondents. These factors limit generalizability and suggest the need for replication in more diverse cohorts.

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Conclusions

This study offers a portrait of the psychological impacts of social media use among adults, emphasizing the interplay between digital platform features, emotional regulation, and self-perception. By investigating dimensions such as empathic fatigue, identity fragmentation, algorithmic distress, and digital nostalgia, the findings move beyond simplistic metrics like screen time to reveal the complex emotional and cognitive terrain of online engagement. A significant proportion of participants screened positive for PSMU, particularly among younger and more digitally immersed users. Subtle design elements, such as read receipts, algorithmic feeds, and visibility metrics, emerged as meaningful contributors to digital stress and are often overlooked in public discourse. This underscores the need to reconceptualize digital well-being not just as a function of usage duration, but of platform architecture and emotional exposure. As social media becomes increasingly embedded in daily life, mental health professionals, educators, and platform designers must collaboratively develop strategies to mitigate its more insidious effects. Future research should build on these findings to create validated tools for digital distress screening and intervention. In conclusion, designing healthier digital habits will require a more empathetic and evidence-informed understanding of how people navigate these emotionally charged environments.

Acknowledgments

The authors declare the use of generative AI in the research and writing process. According to the GAIDeT taxonomy (2025), proofreading and editing tasks were delegated to GAI tools under full human supervision. The tool used was ChatGPT 5.1 (OpenAI). Responsibility for the final manuscript lies entirely with the authors, and GAI tools are neither listed as authors nor held accountable for the final outcomes. This declaration is submitted under collective responsibility.

Data Availability

All data generated or analyzed during this study are included in this published article as Multimedia Appendix 3.

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Authors' Contributions

AH conceived, designed, and supervised the study and was responsible for project administration, methodology, and overall manuscript preparation. All authors (AH, EP, MD, SC, CB, ML, ALB, LAA, LH, and EL) contributed to data collection and data analysis. All authors participated in drafting and revising the manuscript, approved the final version, and agree to be accountable for all aspects of the work.

Conflicts of Interest

None declared.

Multimedia Appendix 1
STROBE checklist.
[PDF File (Adobe PDF File), 158 KB - formative_v10i1e82098_app1.pdf]

Multimedia Appendix 2
French and English full questionnaires.
[PDF File (Adobe PDF File), 456 KB - formative_v10i1e82098_app2.pdf]

Multimedia Appendix 3
Full dataset of the answers of the respondents.
[XLSX File (Microsoft Excel File), 89 KB - formative_v10i1e82098_app3.xlsx]

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Abbreviations

CAGE-AID: Cut down, Annoyed, Guilty, Eye-opener–Adapted to Include Drugs
PSMU: problematic social media use
STROBE: Strengthening the Reporting of Observational Studies in Epidemiology

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Original Paper

Screening the Digital Skills of Patients in Geriatric Rehabilitation: Multicenter Cross-Sectional Study

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Abstract

Background: Digitalization in geriatric rehabilitation presents unique challenges, making it essential to align eHealth solutions with patients' digital skills. The Quickscan Digital Skills (QDS) is a tool designed to help health care professionals match eHealth interventions to individual skill levels.

Objective: This study aimed to explore the applicability of QDS by comparing it to self-reported digital skills and to gain insight into the digital skills of patients in geriatric rehabilitation.

Methods: In this multicenter cross-sectional study, participants from 13 geriatric rehabilitation centers in the Netherlands completed a survey, including demographic questions, QDS, and a numeric rating scale (NRS) for self-reported digital skills. Participants were categorized into 3 skill levels (beginner, intermediate, and experienced) based on the cutoff points in QDS scores. Cutoff points were predetermined, guided by the information provided on QDS. Descriptive statistics for median age and frequencies for skill levels were calculated. Comparative analysis using a Kruskal-Wallis test assessed differences between QDS and NRS within these groups, and Spearman rank-order correlation examined the relationship between the two measures. To gain more insight into the different skill levels between groups, data were visualized and associations among age, gender, and digital skill levels were examined using ordinal logistic regression analysis.

Results: A total of 463 patients (median age 78, IQR 12 years; 282/463, 60.9% female) participated in this study. Based on QDS scores, 42.1% (195/463) were classified as beginners, 19.4% (90/463) as intermediates, and 38.4% (178/463) as experienced users. A moderate positive correlation was found between QDS and NRS scores. Digital skills generally declined with age: 69.8% (37/53) of participants younger than 65 years were experienced users compared to only 13.2% (5/38) of those older than 91 years. A logistic regression analysis showed that increasing age was significantly associated with lower digital skill levels (odds ratio 0.93, 95% CI 0.92-0.95; P<.001). The association between age and digital skills does not differ between males and females.

Conclusions: This study suggests that QDS is a promising and practical screening tool for assessing digital skills in patients in geriatric rehabilitation. Self-reported digital skills with an NRS do not capture the differentiation in the assessed abilities by QDS. QDS could be a practical tool for identifying digital skill levels in patients in geriatric rehabilitation and can support more personalized eHealth implementation. Further research should explore the parametric properties of QDS and how the scores relate to actual eHealth use.

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KEYWORDS

older adults; telehealth; telerehabilitation; rehabilitation; digital health; digital proficiency; assessment

Introduction

eHealth is becoming increasingly important in geriatric rehabilitation and has been found to be effective as long as it aligns with the digital skills and needs of the patient [1]. Within geriatric rehabilitation, digitalization presents unique challenges, particularly given the diversity in life experiences and backgrounds of older adults [2]. These challenges are compounded by age-related barriers such as impaired vision, dexterity issues that result in difficulties with touch screens, or cognitive limitations [3,4].

The World Health Organization has emphasized the importance of eHealth aligning with the users' digital health literacy and skills in its global strategy on digital health [5]. Digital health literacy is defined as the ability to seek, find, understand, and appraise health information from electronic sources and apply the knowledge gained to address or solve a health problem. When there is a mismatch between digital health literacy and the skills of the users and the rate at which society is digitalized, existing health inequalities (eg, access to the internet and the skills to use the internet) can increase [6]. As a result of the digitalization of society, people could end up receiving inadequate care, which could increase health inequalities even more.

Despite the Netherlands having a notably high percentage of daily internet users compared to other European countries (91.4% among adults aged 65-75 years), it remains unclear what their digital health literacy and skills are. Usage among those aged 75 years and older declines to 66.3%, which is a major demographic in geriatric rehabilitation [7]. Promoting a positive culture around digital technology use is essential to ensure older adults maintain engagement, even when their digital health literacy is limited [8,9].

eHealth inequalities experienced by older adults can be exacerbated by societal and self-directed ageism [3,8]. Self-ageism refers to internalized age-based discrimination [10,11], which may lead older adults to perceive themselves as less digitally capable and therefore avoid learning new digital skills [3]. By avoiding these negative experiences, older adults decrease their digital technology use, which poses extra challenges to the digitalization of health care systems that focus on treating older adults. Societal ageism is present among health care professionals who tend to assume older adults are less digitally skilled and, therefore, exclude the option of eHealth from the start [12-14]. Therefore, the assessment of the fit with the individual patient's skill level, needs, and physical capabilities cannot solely depend on the judgment of the health care professional. Similarly, self-assessment by older adults introduces its own limitations, as individuals may inaccurately estimate their abilities due to internalized biases or limited reference frameworks [15]. Therefore, an assessment of the digital skills of a patient at the start of geriatric rehabilitation could aid health care professionals in their decision to offer a care pathway utilizing eHealth effectively [16].

To our knowledge, there is no digital skills assessment specifically for geriatric rehabilitation. Therefore, there is a need to look into related fields such as hospital care. Recently, a scoping review on digital health literacy in a hospital setting found limited results on the inclusion of digital skills within these assessments, with only 8 out of 44 assessments having any form of digital skills included [16]. One of the assessments, the eHealth Literacy Questionnaire, has been studied and validated but is intended to be used by policymakers, eHealth developers, and researchers [17]. A more performance-based instrument is the Digital Literacy Instrument, which consists of 21 self-report items with a 4-point Likert scale, which is still quite extensive with 21 items [18]. The shortest assessment is the eHealth Literacy Scale (eHEALS), which includes 8 items answered on a 5-point Likert scale [19]. However, the eHEALS has been previously discussed as being outdated in its questions since its development in 2006 [20,21].

Pharos, the Dutch Centre of Expertise on Health Disparities, developed the Quickscan Digital Skills (QDS) [22]. QDS was developed as a practical digital skills assessment tool for health care professionals, consisting of 6 items. What sets QDS apart from the other assessments is that, in its conclusion, it tells you what kind of support is necessary when eHealth is used and which types of eHealth might fit [22]. However, QDS has not yet been scientifically validated and is not being used regularly in geriatric rehabilitation.

This study has two main objectives: first, to explore the applicability of QDS by comparing it to self-reported digital skills, and second, to examine how digital skills vary among patients in geriatric rehabilitation based on demographic factors.

Methods

This multicenter cross-sectional study used a survey. Data were collected from October 2023 to April 2024 by trained occupational therapy students in a face-to-face, interview-like setting.

Patient Recruitment

Patients were recruited from 13 geriatric rehabilitation centers in the Netherlands, both urban and rural. All the participating centers were affiliated with a university network (UNC ZH, UNO Amsterdam, UKON [23-25]), and they were approached through these networks for participation. Patients could also be excluded during data collection due to insufficient physical or cognitive capacity. Reasons for exclusion were registered.

Ethical Considerations

The non-Dutch Medical Research Involving Human Subjects Act (WMO) review board of the Leiden University Medical Center (one of the institutional review boards) declared this study outside the scope of the Dutch Medical Research Involving Human Subjects Act and issued a certificate of no objection (reference 23-3072) [26]. All patients in the geriatric rehabilitation ward of the participating rehabilitation centers

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were eligible for inclusion unless the staff excluded them beforehand if they were known to receive palliative care or did not speak Dutch. Informed consent was obtained verbally and registered before continuing with the survey. All patients had the option to opt out of the study without any consequences. All data were collected anonymously and could not be traced back to the participant. No compensation was given to participants.

Data Collection

Patient Characteristics

Demographic data, including age, gender, and rehabilitation diagnosis, were collected. Rehabilitation diagnoses were categorized into 4 nationally recognized groups: stroke, orthopedics and trauma, amputation, and others. The rehabilitation center where the patient resided was also recorded. For comparison with national data, age was categorized in 5-year increments. Participants were asked to rate their digital skills on a numeric rating scale (NRS), with scores ranging from 1 to 10, with higher scores indicating higher digital skills. To make sure participants understood the NRS and what they were rating, it was pilot tested. The NRS was accompanied by the explanation that 1 means no digital skills and 10 means high digital skills. All data were collected in a face-to-face interview-like setting by occupational therapy students who received a thorough explanation of the questions and data collection system. All data were entered directly and anonymously into Castor EDC [27].

QDS Tool

The digital skills were assessed using QDS [22]. It was developed as a practical assessment for health care professionals to decide what kind of support is needed when eHealth is used according to the patient's skill level. The QDS contains 6 questions (Table 1), which can all be answered with No, With help, or Yes. The QDS guides assessors in interpreting the digital skill level of the participant based on their responses: if the participant answered mostly “No” and “With help,” they are seen as not digitally skilled or beginners who need help with the use of the internet and applications. If they answered equal amounts of “With help” and “Yes,” the conclusion was drawn that they are of intermediate skill level and that these people need help sometimes. When they answered mostly “Yes,” they were classified as experienced: they can largely use the internet and applications independently. In this study, the responses were quantified to allow for standardized analysis. The following scoring system was applied: No=0, With help=1, and Yes=2. Adding the scores on all the answers results in a total Quickscan score ranging from 0 to 12. To then determine the digital skill level, cutoff points were set at “not digitally skilled or beginner = ≤6,” “intermediate = 7-9,” and “experienced = ≥10.” These scores were based on the interpretation guideline provided by QDS.

Table 1. The translated questions of the Pharos Quickscan Digital Skills tool.

	No	With help	Yes
Do you have a computer, phone, tablet with internet?			
Do you ever look for information (about health and diseases) on the internet?			
Are you using email so I can send you a link?			
Do you ever use an app?			
Can you download an app yourself?			
Do you use your DigiD to view your patient data, for example?			

Data Analysis

Following data cleaning, descriptive analyses were performed on the demographics by using mean (SD) for normally distributed data, median (IQR) for nonnormally distributed data, and frequencies with percentages for categorical variables. Several comparative analyses were performed to determine if there were significant differences between the digital skill level and NRS. First, the distribution of the total QDS scores in relation to NRS was visualized with a bubble plot. Second, a Kruskal Wallis test was conducted to compare NRS with the 3 digital skill levels, and post-hoc analyses, using Dunn's (1964) procedure with a Bonferroni correction for multiple comparisons, were applied when necessary. Third, Spearman rank-order correlation was used to explore the association between the categorical digital skill level and the NRS scores in greater detail. To gain more insight into the digital skills of the participants, differences between groups based on gender, age, and diagnosis groups were visualized and described with frequencies and percentages. Associations between demographic characteristics (age and gender) and digital skill levels were examined using ordinal logistic regression analysis. Model assumptions, including the proportional odds assumption, were evaluated using the test of parallel lines.

Results

Study Participants

A total of 724 patients from 13 distinct geriatric rehabilitation centers were approached for participation. Of these, 167 individuals were excluded by the staff due to various reasons, including cognitive impairments, language barriers, palliative care, illness, or other factors. Among the remaining 557 eligible patients, 42 declined to provide consent, resulting in 515 consenting participants. During data collection, 52 patients were excluded by the researchers because they noticed a language barrier, a lack of understanding of the questions due to cognitive problems, illness, or other reasons. Consequently, the final sample comprised 463 participants, yielding an inclusion rate

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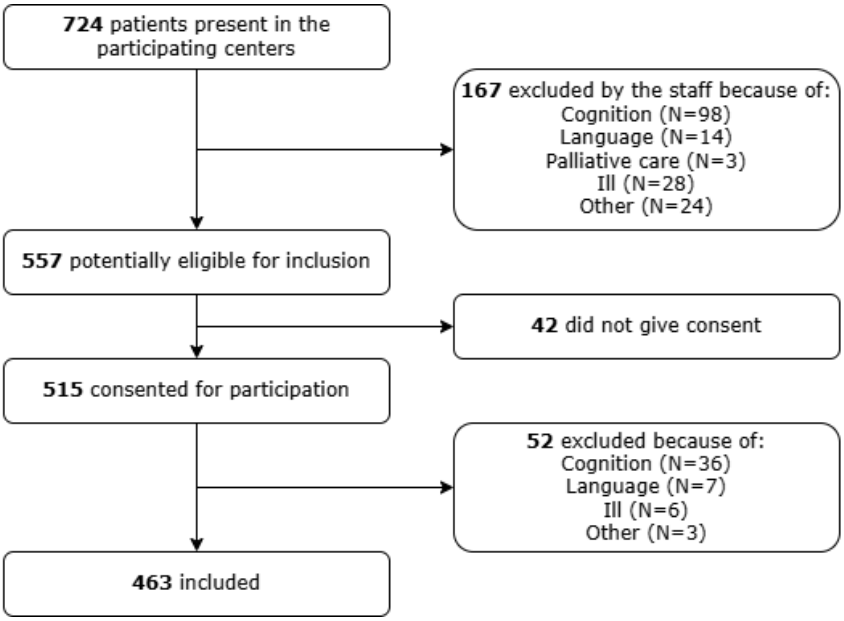
of 64% (463/724). Detailed participant inclusion and exclusion are shown in Figure 1.

Figure 1. Flowchart of the inclusion and exclusion of participants.



Demographics

The sample was predominantly female (282/463, 60.9%), with a median age of 78 (IQR 12) years. Most participants were aged between 76 and 80 years (116/462, 25.1%), while the smallest group comprised those aged 91 years and older (38/462, 8.2%). The most common diagnosis for rehabilitation was orthopedics and trauma (200/463, 43.2%), followed by other diagnoses (144/463, 31.1%) and stroke (77/463, 16.6%). Overall, digital skill levels as measured with QDS were nondigitally skilled or beginners (195/463, 42.1%), intermediate (90/463, 19.4%), and experienced (178/463, 38.4%) users. For a complete overview of the demographics, see Table 2.

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Table 2. Overall demographics of the participants classified by digital skill levels.

	Total, n (%)	Nondigitally skilled and beginners, n (%)	Intermediate, n (%)	Experienced, n (%)
Overall	463 (100)	195 (42.1)	90 (19.4)	178 (38.4)
Sex				
Male	181 (39.1)	67 (37)	33 (18.2)	81 (44.8)
Female	282 (60.9)	128 (45.4)	57 (20.2)	97 (34.4)
Age (y)				
<65	53 (11.5)	8 (15.1)	8 (15.1)	37 (69.8)
66-70	47 (10.2)	14 (29.8)	14 (29.8)	19 (40.4)
71-75	78 (16.9)	25 (32.1)	17 (21.8)	36 (46.2)
76-80	116 (25.1)	48 (41.4)	19 (21.1)	49 (42.2)
81-85	79 (17.1)	41 (51.9)	15 (19)	23 (29.1)
86-90	51 (11)	31 (60.8)	11 (21.6)	9 (17.6)
>91	38 (8.2)	27 (71.1)	6 (15.8)	5 (13.2)
Missing	1 (0.002)	—[a]	—	—
Diagnosis				
Stroke	77 (16.6)	30 (39)	18 (23.4)	29 (37.7)
Orthopedics and trauma	200 (43.2)	90 (45)	37 (18.5)	73 (36.5)
Amputation	18 (3.9)	10 (55.6)	0 (0)	8 (44.4)
Other	144 (31.1)	52 (36.1)	27 (18.8)	65 (45.1)
Unknown	24 (5.2)	13 (54.2)	8 (33.3)	3 (12.5)

[a]Not applicable.

Applicability of QDS vs NRS

A bubble plot (Figure 2) illustrates the distribution and frequency of total QDS scores in relation to the NRS values. The bubble plot shows a considerable variation in each digital skill group with various frequencies. The mean ranks of NRS scores were statistically significantly different between groups (χ^2_2=126.8; *P*<.001). Post-hoc analyses revealed statistically significant differences in mean rank NRS scores between the beginners and the experienced groups (*P*<.001) and the intermediates and the experienced (*P*<.001) but not between the beginners and intermediates (*P*=.045). There was a statistically significant, moderate positive correlation between the total QDS and NRS (r_s(460)=0.554, 95% CI 0.485-0.616; *P*<.001) scores.

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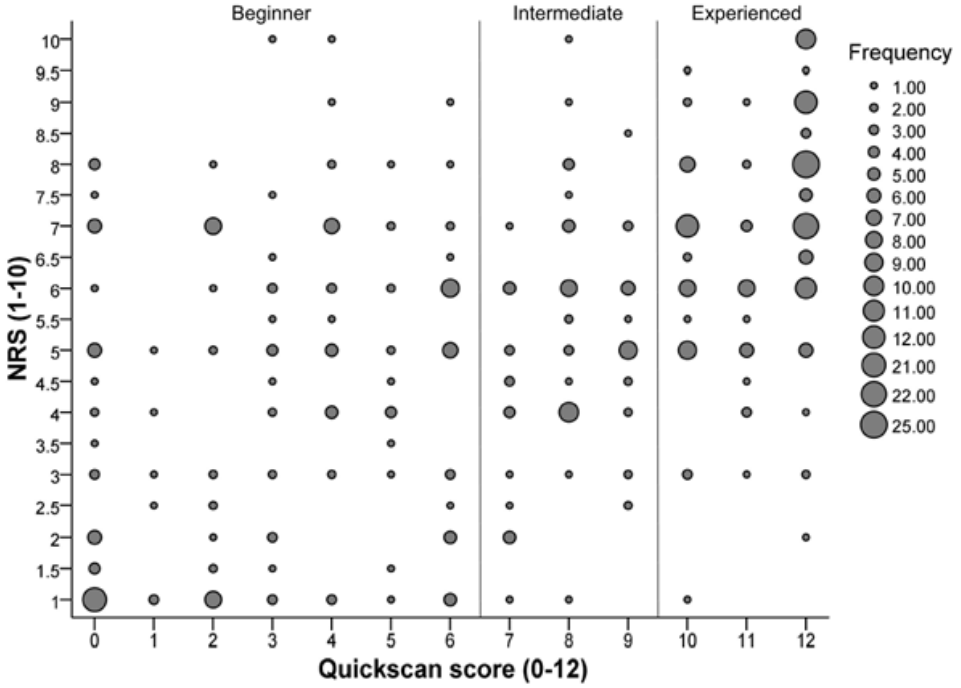
Figure 2. Bubble plot of the Quickscan digital skills scores vs numeric rating scale (NRS) scores and their frequencies.



Insight in Digital Skills

Skill levels differed between male and female participants. Most male participants were experienced users (81/181, 44.8%), whereas the largest proportion of female participants were nondigitally skilled or beginners (128/282, 45.4%) (Figure 3). There was a similar distribution between the diagnosis groups and the overall group, except for the amputation and the other groups, which both had a higher percentage of beginners (10/18, 55.6% and 13/24, 54.2%, respectively) as can be seen in Figure 4.

Figure 3. Visualization of skill level distribution by gender.

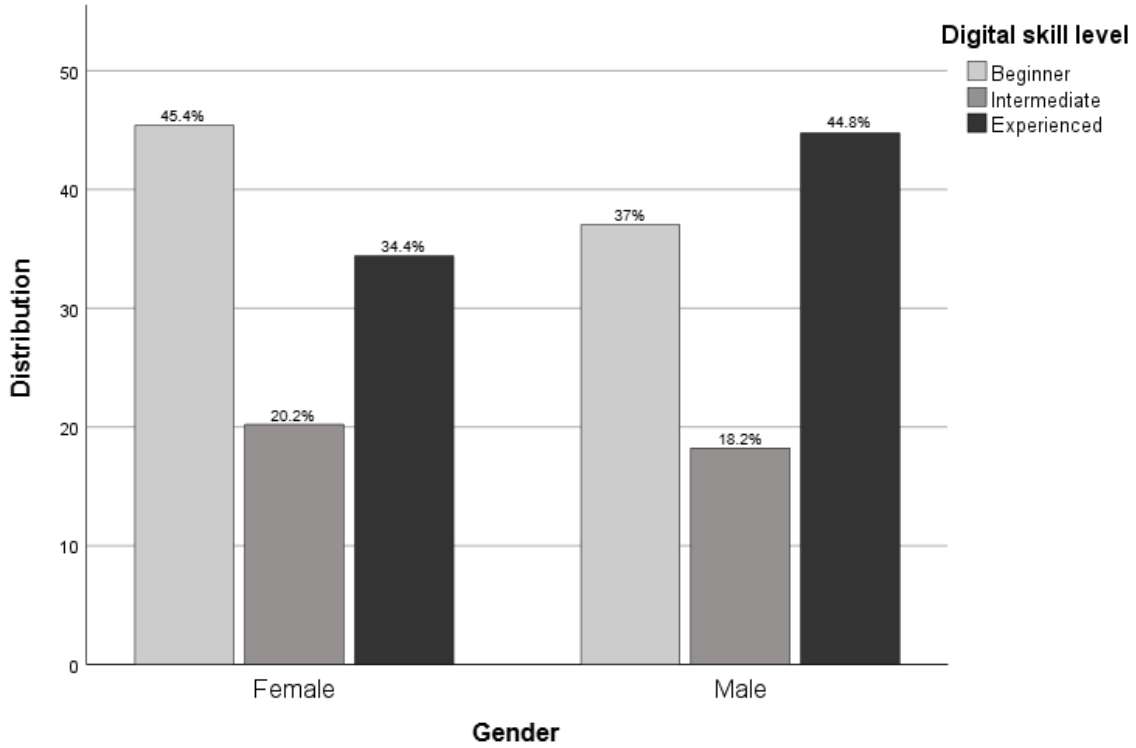


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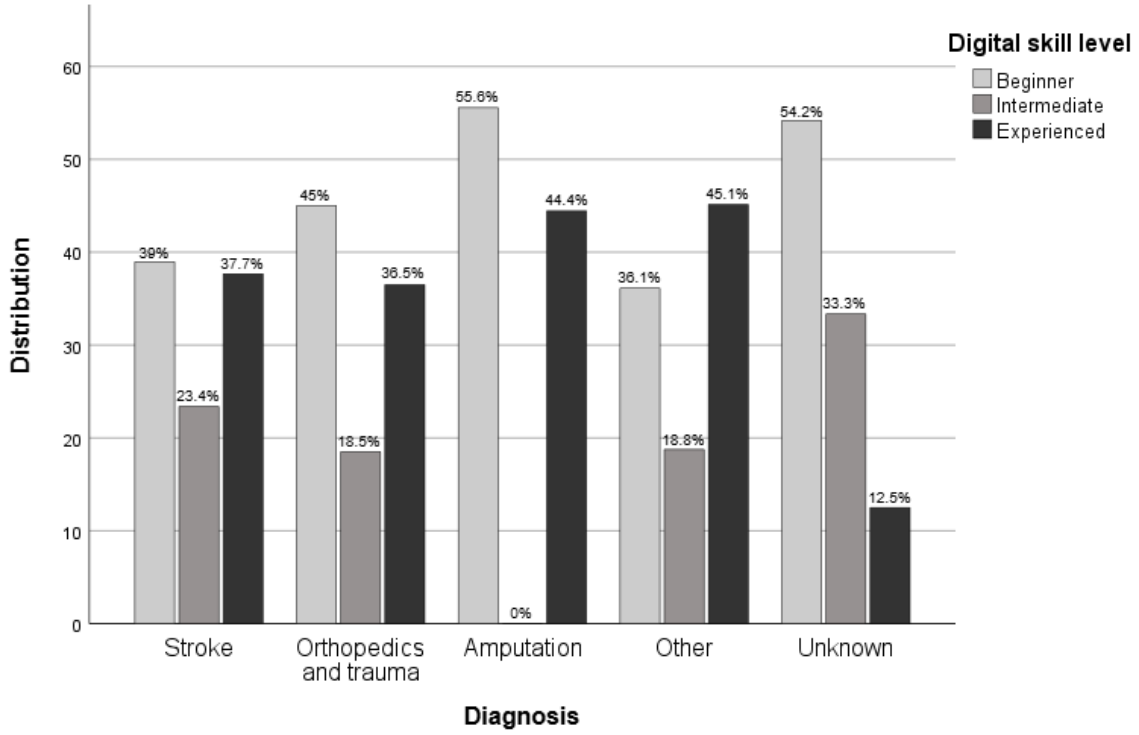
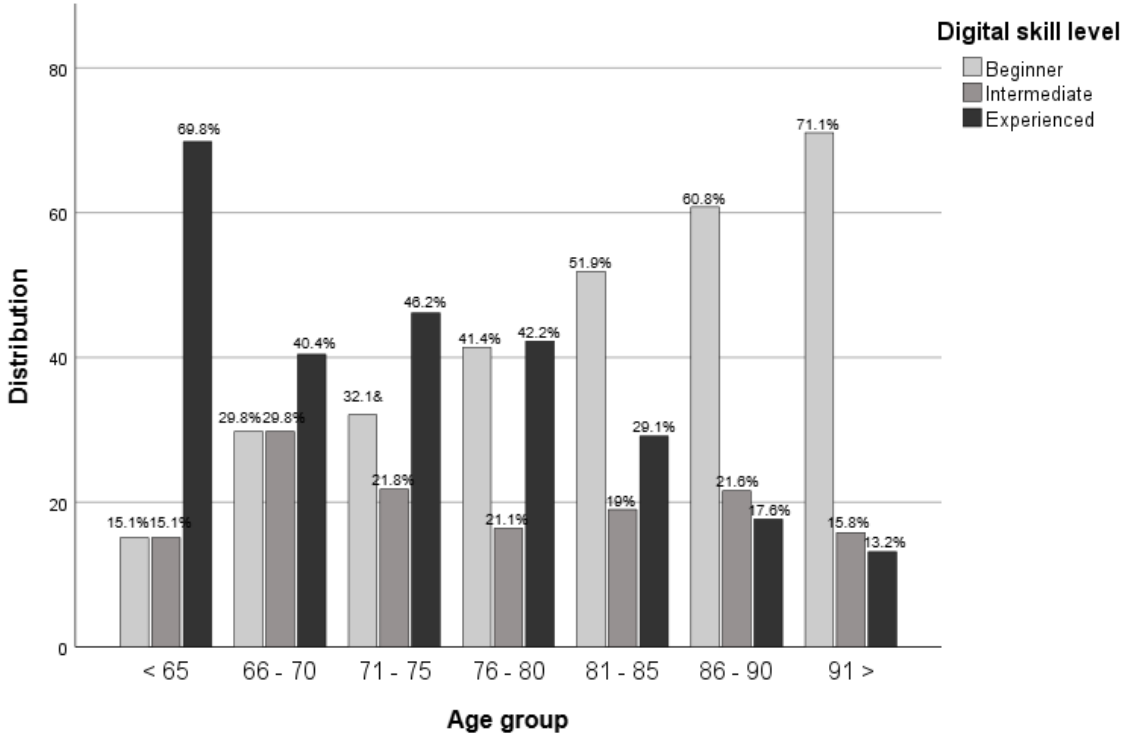
Figure 4. Visualization of skill level distribution by diagnosis.



The digital skill level for each age group showed a decrease in skill level with age, with 69.8% (37/53) of those younger than 65 years in the experienced group compared to 13.2% (5/38) in those who older than 91 years (Figure 5). Conversely, the proportion of nondigitally skilled or beginners steadily increased with age, from 15.1% (8/53) in the <65 years age group toward 71.1% (27/38) in the >91 years age group. The proportions of the intermediate users remained relatively stable at approximately 20% across all age groups.

Figure 5. Visualization of skill level distribution by age.



Due to the observed differences in gender and age, an ordinal logistic regression analysis was done to examine whether gender differences in digital skill level were independent of age. Increasing age was significantly associated with lower digital skill levels (odds ratio 0.93, 95% CI 0.92-0.95; *P*<.001). After adjusting for age, gender was no longer significantly associated

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with digital skill level (P=.15). Furthermore, the age × gender interaction term was not significant (P=.49), indicating that the association between age and digital skills does not differ between males and females.

Discussion

Principal Findings

This study aimed to explore the applicability of QDS as a tool for screening digital skills in patients in geriatric rehabilitation by comparing it with a self-reported NRS and to gain insight into the digital skill levels of patients undergoing geriatric rehabilitation.

The study demonstrated notable discrepancies between QDS and NRS, highlighting the practical use of QDS as an objective screening tool. QDS differentiated patients into 3 distinct skill categories: nondigitally skilled or beginner, intermediate, and experienced. Notably, the majority of patients were classified as having intermediate or experienced digital skill levels. Interestingly, while increasing age was significantly associated with a decline in digital skills, the data revealed exceptions with some individuals aged older than 91 years demonstrating high skill levels and others younger than 65 years showing low levels of digital competencies. This shows that assuming low digital skills solely based on age is not accurate.

The moderate correlation between QDS and NRS, combined with clear discrepancies in individual scores, highlights important limitations of self-assessment. Some patients scored themselves highly on NRS, yet were classified as having low digital skills on QDS and vice versa. These inconsistencies may reflect the subjective nature of a self-evaluation with it being difficult to score oneself if not familiar with the topic at hand [28]. This results in a different reference framework used by each person, and though unknown to the assessor, will influence the scores given [29]. For example, participants may have compared themselves to either highly skilled individuals or others with minimal digital exposure. The reference frameworks could be influenced by the person's self-perception and therefore be a result of self-directed ageism [11].

These subjective evaluations suggest that while NRS may capture participants' motivation and openness toward eHealth, QDS offers a more structured and objective assessment of digital skills. This distinction is critical, as prior research has shown that older adults' self-reported eHealth literacy often does not align with their actual ability to use digital tools effectively [30]. This could again be related to personal beliefs and self-perception, the continuum of digital literacy, and the contextual barriers and facilitators to technology adoption [31].

Although QDS is not yet a validated or standardized instrument, it provides a replicable and systematic approach for assessing digital skills in clinical practice. Its quantified design minimizes interpretative variability during administration, offering a key advantage over subjective self-rating scales. While this study was not intended to establish the psychometric properties of QDS, the findings offer preliminary support for its practical utility. This underscores the importance of having reliable tools to identify individuals who may be less likely to benefit from digital health interventions [32].

Strengths and Limitations

The first strength of this study is its sample size and how it compares to national and international data, showing its representativeness of the population. Our study sample aligns with national data on geriatric rehabilitation, with 60.9% (282/463) females in this study compared to 59.6% (36,015/60,450) nationally [33]. Diagnoses such as stroke showed identical prevalence, while orthopedics and trauma were similar. For age, it seems the population in this study was a bit younger, with a median age of 78 years compared to the estimated European mean age of 80 years [34].

Another strength lies in the quantification of QDS, which minimizes interpretive variability during data collection, even though the reliability of QDS has not been studied [35]. Nonetheless, quantifying QDS was not without limitations. Participants who answered 4 questions with "Yes," one "With help," and one "No" ended up being classified as intermediate skill level. The interpretation guideline by Pharos mentions someone should be experienced if they answer mostly "Yes" [22]. For this study, the research group argued that anyone who answers a question with "No" should not be classified as experienced and was therefore used as the upper threshold for intermediate classification. There was also no possibility of comparing QDS with a gold standard, since there currently is none [16].

A limitation of this study is that QDS has not yet been formally validated. Although the instrument was developed as a practical screening tool, its psychometric properties have not been formally evaluated. This may have resulted in measurement imprecision or misclassification of digital skill levels, particularly within intermediate categories. Nevertheless, this study provides preliminary empirical insight into the clinical applicability of QDS and highlights the need for formal validation studies in geriatric rehabilitation.

Despite the relatively large sample, another limitation is the fact that some patients either did not consent to participation or were excluded in advance by the health care professionals. The potential impact of these nonparticipants remains unknown and has been a known problem in eHealth research [36-38]. In particular, the applicability of QDS for those who were excluded by the staff based on cognition remains unknown. An underrepresentation of people with cognitive problems could result in overlooking flaws in the questions of QDS that could not be found with their participating counterparts.

Implications for Geriatric Rehabilitation and eHealth

Our findings suggest that QDS may serve as a valuable tool for tailoring eHealth interventions to older adults' skill levels. It offers health care professionals practical insight into patients' digital abilities and can help guide decisions about the level of support required. QDS could therefore be an eHealth readiness indicator for the patient that helps with shared decision-making. Due to its observed short administration time, integration into current workflows seems feasible. However, QDS was not originally developed for the geriatric rehabilitation context.

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Future studies should evaluate whether QDS validly measures digital skills and clarify how scores translate into actionable care decisions before widespread adoption in clinical practice.

Conclusions

This study suggests that QDS is a promising and practical screening tool for assessing digital skills in patients in geriatric rehabilitation. QDS seems to be applicable as a screening tool when compared to self-reported digital skills on an NRS, since it revealed a differentiation in skill levels not captured by self-reported NRS scores. Even though QDS is not a gold standard, it could provide practical guidance to health care professionals when they want to use eHealth with a patient. QDS showed a differentiation into 3 skill levels and gives examples of what to offer for each skill level and what kind of help these people would need. However, the examples are not specifically designed for patients in geriatric rehabilitation, underscoring the need for further research to validate its practical applications within this field. Furthermore, future studies should focus on assessing the digital skills of patients in geriatric rehabilitation and on linking the results of QDS with practical skills and help needed with eHealth use in geriatric rehabilitation.

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Data Availability

Data can be made available upon request to the corresponding author.

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Authors' Contributions

Conceptualization: MBGZ, MCP, WPA, and EFvDvI
Data curation: MBGZ
Formal analysis: MBGZ, MJK
Investigation: MBGZ
Methodology: MBGZ, MCP, and EFvDvI
Project administration: MBGZ
Supervision: EFvDvI and WPA
Visualization: MBGZ, MCP, and MJK
Writing – original draft: MBGZ, MCP
Writing – review & editing: MBGZ, MCP, MJK, WPA, EFvDvI

Conflicts of Interest

None declared.

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Abbreviations

eHEALS: eHealth literacy scale
NRS: numeric rating scale
QDS: Quickscan digital skills

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Original Paper

Performance of DeepSeek V3, DeepSeek R1, ChatGPT 4o, and ChatGPT o1 on the National Health Professional and Technical Qualification Examination (Intermediate Level) in China: Comparative Analysis

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Abstract

Background: In recent years, large language models (LLMs) have undergone swift cycles of refinement and iteration. However, in the realm of clinical medicine, different LLMs' capability of logical reasoning and disease diagnosis needs further investigation.

Objective: The aim of our study was to evaluate the performance of 4 different LLMs in the National Health Professional and Technical Qualification Examination in China.

Methods: A total of 398 multiple-choice questions of 5 different question types were integrated within the examination with respect to the diagnosis or care of cases. These questions were categorized into different cardiology subspecialties and different clinical disciplines. DeepSeek V3 and R1 were accessed through an application programming interface, while ChatGPT 4o and o1 were queried via its public chat-based interface. We offered the same prompts instructing LLMs to assume the role of a physician and provide answers with explanations at the beginning of each conversation. We assessed different LLMs' performance by the accuracy in the responses to the multiple-choice questions. For the first 3 examination sections, McNemar test was used to compare the accuracy among the models, with post hoc pairwise comparisons performed using partitions of chi-square method and Bonferroni correction (significance set at $P<.008$). For the fourth section involving partially credit scoring, one-way ANOVA was performed to compare the mean scores among the models, with statistical significance set at $P<.05$.

Results: Both DeepSeek V3 and R1 showed superior performance in the first 3 sections of the Chinese National Health Professional and Technical Qualification Examination, achieving an overall performance of 93% and 93.6%, respectively. ChatGPT 4o and o1 achieved accuracies of 73.3% and 69%, respectively (all $P<.001$ compared with DeepSeek V3). For the fourth section, the performance of all 4 LLMs markedly declined compared to their results in the preceding sections. Particularly, in the section of gastroenterology and hematology, DeepSeek V3 achieved the highest accuracy, while R1 ranked first in cardiology and neurology. ChatGPT o1 achieved the highest accuracy in the topic of coronary artery disease, with no statistical significance.

Conclusions: DeepSeek V3 and R1 showed remarkable potential in facilitating clinical decision-making in the Chinese professional examination, with both outperforming ChatGPT 4o and o1. Nonetheless, future research should continue evaluating their economic efficiency and susceptibility to hallucination.

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KEYWORDS

large language models; DeepSeek; ChatGPT; support clinical decision-making; cardiology

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Introduction

In recent years, large language models (LLMs) such as Anthropic 2024, Google Gemini 2024 [1], and OpenAI 2024 [2] have undergone swift refinement and iteration. Since their launch by OpenAI, ChatGPT holds significant potential across various facets of the medical field, including medical documentation, scientific writing, and medical education [3-5]. Numerous studies have demonstrated its potential applications in health care, particularly in cardiology, due to its ability to advance the management of long-term heart conditions [6], provide medical advice on acute cardiac events [7], answer clinical cardiac questions [8], interpret cardiac diagnostics tests [9], and design an individualized therapeutic strategy [10]. Specifically, Wang et al [11] revealed that ChatGPT was proficient in specific medical tasks such as discharge summarization and group learning within the Chinese linguistic paradigm. Another investigation showed that both ChatGPT-3.5 and GPT-4 can successfully achieve average scores that exceed the admission benchmark on the master's degree entrance examination in clinical medicine [12] only, with an accuracy of 48% and 68% respectively. However, Sarangi et al [13] illustrated that ChatGPT-4 has limitations in processing radiology anatomy. While these studies suggest that ChatGPT may have potential proficiency in logical reasoning and disease diagnosis, considering its financial cost and underperformance on image-based questions, its performance warrants further evaluation.

In addition to proprietary systems, open-source frameworks are achieving substantial breakthroughs in capability development, actively narrowing the performance divide with their closed-source counterparts such as the newly published DeepSeek MoE. Launched in January 2025, DeepSeek's DeepThink (R1), an open-source LLM [14], is different from proprietary models as it fosters a sustained learning environment by integrating publicly accessible open-source datasets, which may in turn improve its ability to adapt to the continuously evolving domains of medical expertise and scientific analysis [15,16]. Moreover, compared to proprietary LLMs, DeepSeek R1 offered free-tier access and reduced financial costs, making artificial intelligence more accessible for smaller institutions [17-20]. In terms of performance on mathematics and science problems, DeepSeek-R1 demonstrates proficiency rivaling that of the ChatGPT-o1 model, released in September by OpenAI, whose reasoning models were considered industry leaders [21]. However, in the clinical medicine domain, DeepSeek-R1's capabilities of logical reasoning and disease diagnosis warrants further investigation.

The National Health Professional and Technical Qualification Examination (intermediate level) in China is a government-organized assessment, and passing the examination demonstrates the requisite competence to assume corresponding levels of professional and technical responsibilities. This examination is designed to evaluate the clinical acumen, depth of knowledge, diagnostic competence, and clinical decision-making expertise of resident physicians who have chosen cardiology as their practice area and are aiming at the promotion to fellows. The examination consists of 5 types of questions, namely, A1 (knowledge-based multiple choice), A2 (case-based multiple choice), A3/A4 (case-group-based multiple choice), B (matching), and X (multiple choice), totaling 398 multiple-choice questions (MCQs) distributed across 4 parts: basic concepts, relevant expertise, foundational professional knowledge, and professional practical skills. In the sections of basic concepts and relevant expertise, the examination encompasses several distinct branches of internal medicine covering the foundational concepts and standard clinical practices in medicine, such as respiratory medicine, cardiology, gastroenterology, hematology, nephrology, infectious diseases, neurology, rheumatology and immunology, endocrinology, and emergency medicine. In the section on foundational professional knowledge, a comprehensive overview of 10 prevalent cardiac conditions is provided, covering in-depth, cardiology-specific expertise in heart failure, arrhythmias, cardiac arrest and sudden cardiac death, congenital cardiovascular diseases, hypertension, coronary artery disease, valvular heart disease, infective endocarditis, myocardial diseases, and pericardial disorders. For the section on professional practical skills, a series of multiple-answer questions is set within a simulated clinical scenario. To eliminate the need for analyzing pictures or other visual forms, we established a dataset comprising questions and options only in text format.

In this study, we aimed to investigate whether different types or fields of questions would influence LLMs' performance in the Chinese linguistic paradigm. Delving deeper, we aimed to evaluate the efficacy and reliability of different LLMs' decision-making ability, offering insights and practical recommendations of their possible role in facilitating clinical decision-making. We selected the most recent LLMs, GPT-4o and GPT-o1 in the GPT family of models, as they represent the proprietary systems that were released in May 2024 and September 2024, respectively. In contrast to GPT's proprietary framework, we selected the open-access models DeepSeek V3 and R1 [14,22] launched in January 2025 to compare their accuracy, robustness, and limitations.

Methods

Chinese National Health Professional and Technical Qualification Examination (Intermediate Level) Knowledge Datasets

We created an examination dataset of the National Health Professional and Technical Qualification Examination (intermediate level) containing questions extracted from the book *Cardiovascular Medicine: Synchronized Exercises and Comprehensive Mock Examinations* [23] to test the performance of different LLMs (Figure 1). We randomly selected 398 queries from the dataset across various medical fields (Multimedia Appendix 1) under 4 different types: A1 (knowledge-based multiple choice), A2 (case-based multiple choice), A3/A4 (case-group-based multiple choice), B (matching), and X (multiple choice). The composition of these four sections is presented in Table 1. Except for the X-type questions, each question presented 5 answer options, with only 1 correct answer. Meanwhile, for the X-type questions, there were 5-11 options

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across various questions. All questions were composed and presented in Chinese, with no English inclusion or explanation.

Figure 1. Workflow illustration of this study.

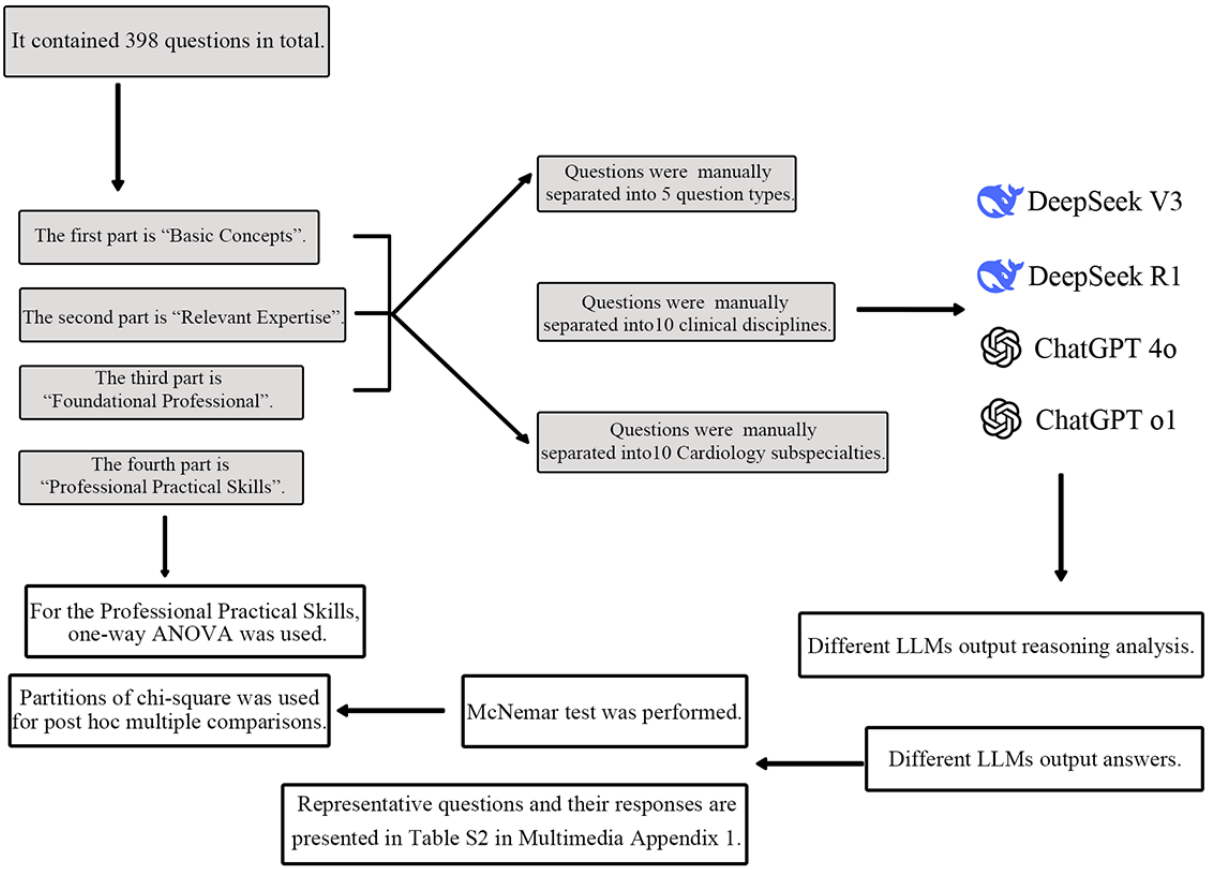

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Table 1. Dataset of the National Health Professional and Technical Qualification Examination in China.

	Questions, n
Parts of the examination (N=398)	
Basic Concepts	100
Relevant Expertise	100
Foundational Professional Knowledge	100
Professional Practical Skills	98
Format of the examination (N=398)	
A1-type	89
A2-type	78
A3/A4-type	88
B-type	45
X-type	98
Clinical disciplines in the section of Basic Concepts and Relevant Expertise (n=200)	
Respiratory Medicine	34
Cardiology	32
Gastroenterology	24
Hematology	17
Nephrology	10
Infectious diseases	31
Neurology	19
Rheumatology and immunology	8
Endocrinology	15
Emergency medicine	10
Cardiology subspecialties in the section of Foundational Professional Knowledge (n=100)	
Heart failure	10
Arrhythmias	25
Cardiac arrest and sudden cardiac death	1
Congenital cardiovascular diseases	1
Hypertension	12
Coronary artery disease	17
Valvular heart disease	3
Infective endocarditis	3
Myocardial diseases	15
Pericardial disorders	13

LLM Testing

In this comparative study, we tested 398 MCQs selected from the dataset with 4 different LLMs, namely, DeepSeek V3, DeepSeek R1, ChatGPT 4o, and ChatGPT o1 by manually entering the questions. To assess the performance of DeepSeek V3 and R1, we used the application programming interface (API) provided by SiliconFlow [24], a cloud service platform, due to usage limitations on the official server. For the evaluation of ChatGPT 4o and o1, we obtained them through the official chat user interface (UI). Temperature settings are crucial in the usage of LLMs, as this directly influences the randomness of the generated content. In this study, the temperature for DeepSeek V3 and R1 was set typically at 0.7. Regarding the ChatGPT chat UI, we were unable to find the direct control over temperature settings; thus, these 2 models were evaluated under default configurations, which could have introduced variability in systematic bias. The responses were generated by different LLMs between February 21 and February 28, 2025.

Questions were run independently without additional instructions during the conversation. To enhance contextual connections capabilities, we offered the same prompts

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instructing LLMs to assume the role of a physician and provide answers with explanations at the beginning of each conversation [25,26] (Table S1 of Multimedia Appendix 1). Answers and explanations generated by LLMs were meticulously documented using Word and cross-referenced with the correct answers to ensure precise evaluation of examination performance.

For the first three parts (basic concepts, relevant expertise, foundational professional knowledge), we evaluated different models' performance by calculating the accuracy rates (percentage of correct answers out of the total). For the final part of professional practical skills, each question was assigned one point; correct answers received full credit, while incorrect ones received none. For partially correct responses, scores were awarded proportionally based on the number of accurate options selected. To compare the performance of different models in various types or fields of questions, the questions from the first three sections were categorized into different segments based on their types and subject domains, as mentioned before, and then analyzed.

Cost-Effectiveness Analysis

For DeepSeek V3 and R1, costs were calculated on a pay-per-token basis using the official pricing published on the SiliconFlow website (as of February 2025): ¥2 per million input tokens and ¥8 per million output tokens for DeepSeek V3; ¥4 per million input tokens and ¥16 per million output tokens for DeepSeek R1 [24]. During the study, the applicable exchange rate was US $1=¥7.52. Total input and output tokens for each model were obtained from the API response logs.

For ChatGPT 4o and o1, both models were queried via the public chat UI. We estimated expenditure based on the monthly subscription fee required for o1 access (ChatGPT Plus, US $20 per month, approximately ¥150.59), which includes up to 50 o1 prompts per month according to OpenAI's policy at the time of the study. ChatGPT 4o is included in the same subscription tier with no separate prompt limit.

Data Analysis

All data for this study were collected using Microsoft Excel for Mac 16.95, and the accuracy was analyzed using SPSS software (version 30.0; IBM Corp). For the first three sections, that is, basic concepts, relevant expertise and foundational professional knowledge, we performed the McNemar test to examine the performance among the models. For post hoc multiple comparisons of accuracy rates across multiple groups, we used partitions of chi-square method. To control the risk of type I error, statistical significance was set at $P<.008$ according to the Bonferroni correction $\alpha' = \alpha/(k*(k-1)/2)$. For the professional practical skills, one-way ANOVA was used to compare the performance of the 4 LLMs in processing real-world clinical cases, with statistical significance set at $P<.05$.

Ethical Considerations

As this study was limited to medical state examination questions and publicly available results, no research involving human participants was conducted. Ethics approval was therefore not required.

Results

Overview of Different LLMs' Performance in the Examination

As illustrated in the Table 2 and Figure 2A, for the first three parts of the examination, DeepSeek V3, DeepSeek R1, ChatGPT 4o, and ChatGPT o1 showed accuracy of 93%, 93.6%, 73.3%, and 69%, respectively ($\chi^2_3=102.9$; $P<.001$). Compared with ChatGPT 4o and ChatGPT o1, DeepSeek R1 demonstrated better performance (DeepSeek R1 vs ChatGPT 4o, $\chi^2_1=45.1$, $P<.001$; DeepSeek R1 vs ChatGPT o1, $\chi^2_1= 60.1$; $P<.001$) among the 4 LLMs, and DeepSeek V3 ranked second (DeepSeek V3 vs ChatGPT 4o $\chi^2_1=41.4$; $P<.001$; DeepSeek V3 vs ChatGPT o1 $\chi^2_1=56.1$; $P<.001$), with no statistically significant differences between R1 and V3 ($\chi^2_1=0.1$; $P=.74$).

Regarding each individual section, both in basic concepts and relevant expertise sections, ChatGPT 4o and o1 showed lower accuracy of 66% and 58% for the basic concepts part and 71% and 66% for the relevant expertise part, respectively—all with statistical significance compared with 2 models of DeepSeek ($P<.008$). In the section of foundational professional knowledge, the two models of ChatGPT, 4o and o1, showed a moderate increase of accuracy of 82% and 83%, respectively, compared with the first two sections, and showed no statistical significance when the 4 models compared with each other ($\chi^2_3=11.3$; $P=.01$).

Additionally, for the section on professional practical skills, as illustrated in the Table 2 and Figure 2B, although the two DeepSeek's models achieved worse performance as they did in the first three sections, DeepSeek V3 and R1 ranked first and second respectively, with scores of 64.63 and 64.3, respectively, while the two models of ChatGPT ranked third and last, with 4o's score at 47.98 and o1's at 46.29. This is also of statistical significance compared with DeepSeek V3 ($P=.003$; $P<.001$) and DeepSeek R1 ($P=.003$; $P<.001$), respectively.

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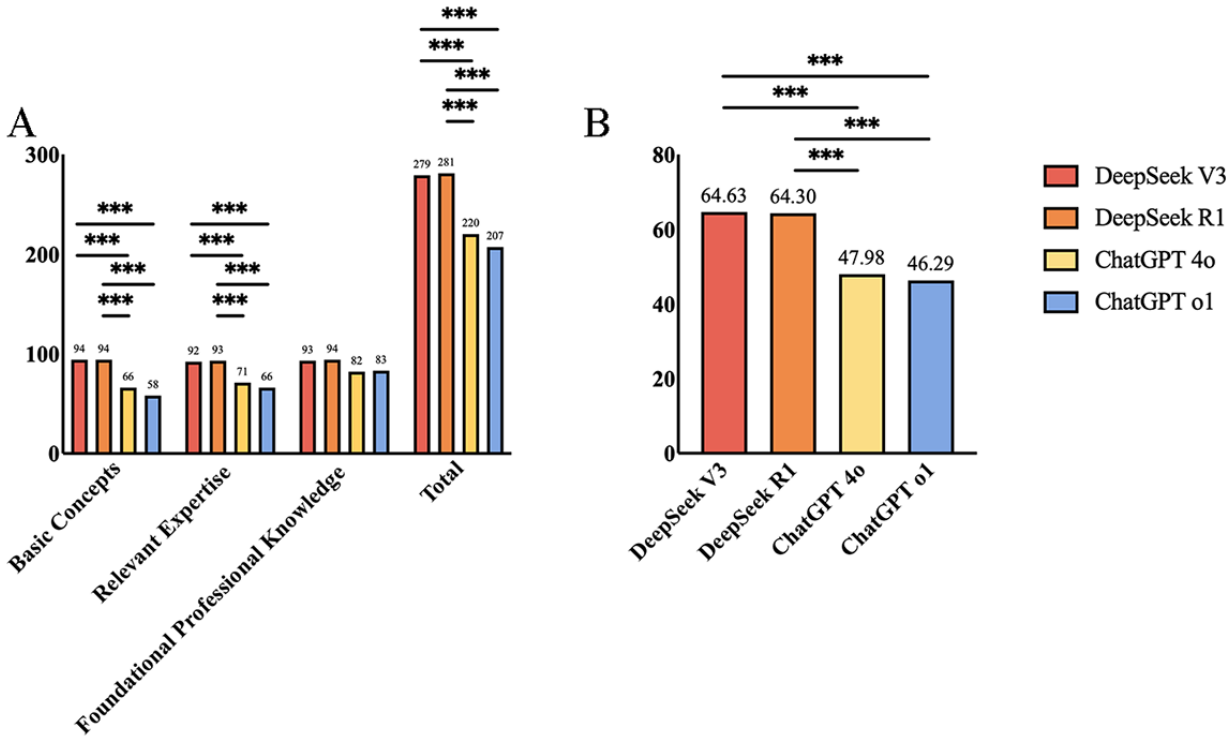
Table 2. Performance of the different large language models in the examination.

	DeepSeek V3	DeepSeek R1	ChatGPT 4o	ChatGPT o1
Correct answers in the first 3 sections, n (%)				
Basic Concepts (n=100)	94 (94)	94 (94)	66 (66)	58 (58)
Relevant Expertise (n=100)	92 (92)	93 (93)	71 (71)	66 (66)
Foundational Professional Knowledge (n=100)	93 (93)	94 (94)	82 (82)	83 (83)
Total (n=300)	279 (93)	281 (93.6)	220 (73.3)	207 (69)
Mean scores on the fourth section (n=98, each scored 0-1 point with partial credit)				
Professional Practical Skills	64.63	64.3	47.98	46.29

Figure 2. Comparisons among DeepSeek V3, DeepSeek R1, ChatGPT 4o, and ChatGPT o1. (A) Performance on the first three sections. Pairwise model comparisons were performed using McNemar test with Bonferroni correction. (**P<.008; ***P<.001). (B) Performance on the fourth section of the multiple choice questions. Pairwise model comparisons were performed using one-way ANOVA (***P<.001).



Performance of LLMs in Various Topics

Table 3 presents the percentage of correct answers for each field for each question answered by various LLMs. The topics in Table 3 were manually sorted into 10 clinical disciplines, which contained different branches of internal medicine. Among these topics, DeepSeek-V3 achieved the highest accuracy in two topics, that is, gastroenterology (91.7%) and hematology (94.1%), with no statistical significance compared with DeepSeek R1 (χ^2_1=1.3; P=.26; χ^2_1=0.4; P=.54). DeepSeek R1 achieved the highest accuracy in cardiology (96.9%) and neurology (100%). In the topics of gastroenterology, hematology, nephrology, neurology, rheumatology, immunology, endocrinology, and emergency medicine, the performance of the 4 LLMs did not illustrate statistically significant differences (χ^2_1=9.4, P=.02; χ^2_1=1.1, P=.77; χ^2_1=3.9, P=.27; χ^2_1=11.4, P=.01; P>.99; χ^2_1=2.5, P=.48; χ^2_1=2.3, P=.50, respectively). Besides, statistical significance was observed when ChatGPT 4o was compared with DeepSeek V3 and R1 in the fields of respiratory medicine (χ^2_1=14.8, P<.001; χ^2_1=11.6, P<.001), cardiology (χ^2_1=9.1, P=.002; χ^2_1=11.7, P<.001), and infectious diseases (χ^2_1=14.8, P<.001; χ^2_1=14.8, P<.001). As for ChatGPT-o1, statistical significance was observed also in respiratory medicine (χ^2_1=14.8, P<.001; χ^2_1=11.6, P<.001), cardiology (χ^2_1=15.8, P<.001; χ^2_1=18.8, P<.001), and infectious diseases (χ^2_1=14.9, P<.001; χ^2_1=14.9, P<.001) in comparison with DeepSeek V3 and R1 (Figures 3A-C).

Meanwhile, for the third section of foundational professional knowledge, 100 questions were categorized into 10 prevalent cardiology subspecialties. As presented in Table 3 and Figures 3B-D, the performance of ChatGPT 4o and o1, in the field of arrhythmias, hypertension, myocardial diseases and pericardial

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disorders, was poorer than that of DeepSeek V3 and R1, while it was of no statistical significance (χ^2_1=9.3, *P*=.03; χ^2_1=1.5, *P*=.68; χ^2_1=4.3, *P*=.23; χ^2_1=2.1, *P*=.56). Particularly, it is noteworthy that in the field of coronary artery disease, the accuracy of ChatGPT o1 was 88.2% and ranked the highest even when no statistical significance was observed compared with DeepSeek V3 and R1 (χ^2_1=0.8, *P*=.37; χ^2_1=0.2, *P*=.63).

Table 3. Correct answers by clinical discipline in the Basic Concepts and Relevant Expertise section and by cardiology subspecialty in the Foundational Professional Knowledge section.

	DeepSeek V3, n (%)	DeepSeek R1, n (%)	ChatGPT 4o, n (%)	ChatGPT o1, n (%)
Basic Concepts and Relevant Expertise section (n=200)				
Respiratory medicine (n=34)	30 (88.2)	30 (88.2)	17 (50)	17 (50)
Cardiology (n=32)	30 (93.6)	31 (96.9)	20 (62.5)	16 (50)
Gastroenterology (n=24)	22 (91.7)	21 (87.5)	18 (75)	14 (58.3)
Hematology (n=17)	16 (94.1)	15 (88.2)	14 (82.3)	15 (88.2)
Nephrology (n=10)	9 (90)	9 (90)	8 (80)	7 (70)
Infectious diseases (n=31)	30 (96.8)	30 (96.8)	17 (54.8)	17 (54.8)
Neurology (n=19)	18 (94.7)	19 (100)	13 (68.4)	13 (68.4)
Rheumatology and immunology (n=8)	8 (100)	8 (100)	8 (100)	8 (100)
Endocrinology (n=15)	13 (86.7)	13 (86.7)	12 (80)	10 (66.7)
Emergency medicine (n=10)	9 (90)	9 (90)	9 (90)	7 (70)
Cardiology subspecialty in the Foundational Professional Knowledge section (n=100)				
Heart failure (n=10)	10 (100)	10 (100)	10 (100)	8 (80)
Arrhythmias (n=25)	24 (96)	25 (100)	19 (76)	21 (84)
Congenital cardiovascular diseases (n=1)	1 (100)	1 (100)	1 (100)	1 (100)
Cardiac arrest and sudden cardiac death (n=1)	1 (100)	1 (100)	1 (100)	1 (100)
Hypertension (n=12)	10 (83.3)	10 (83.3)	10 (83.3)	8 (66.7)
Coronary artery disease (n=17)	13 (76.5)	14 (82.4)	12 (70.6)	15 (88.2)
Valvular heart disease (n=3)	3 (100)	3 (100)	3 (100)	3 (100)
Infective endocarditis (n=3)	3 (100)	3 (100)	3 (100)	3 (100)
Myocardial diseases (n=15)	14 (93.3)	14 (93.3)	11 (73.3)	11 (73.3)
Pericardial disorders (n=13)	13 (100)	13 (100)	12 (92.3)	12 (92.3)

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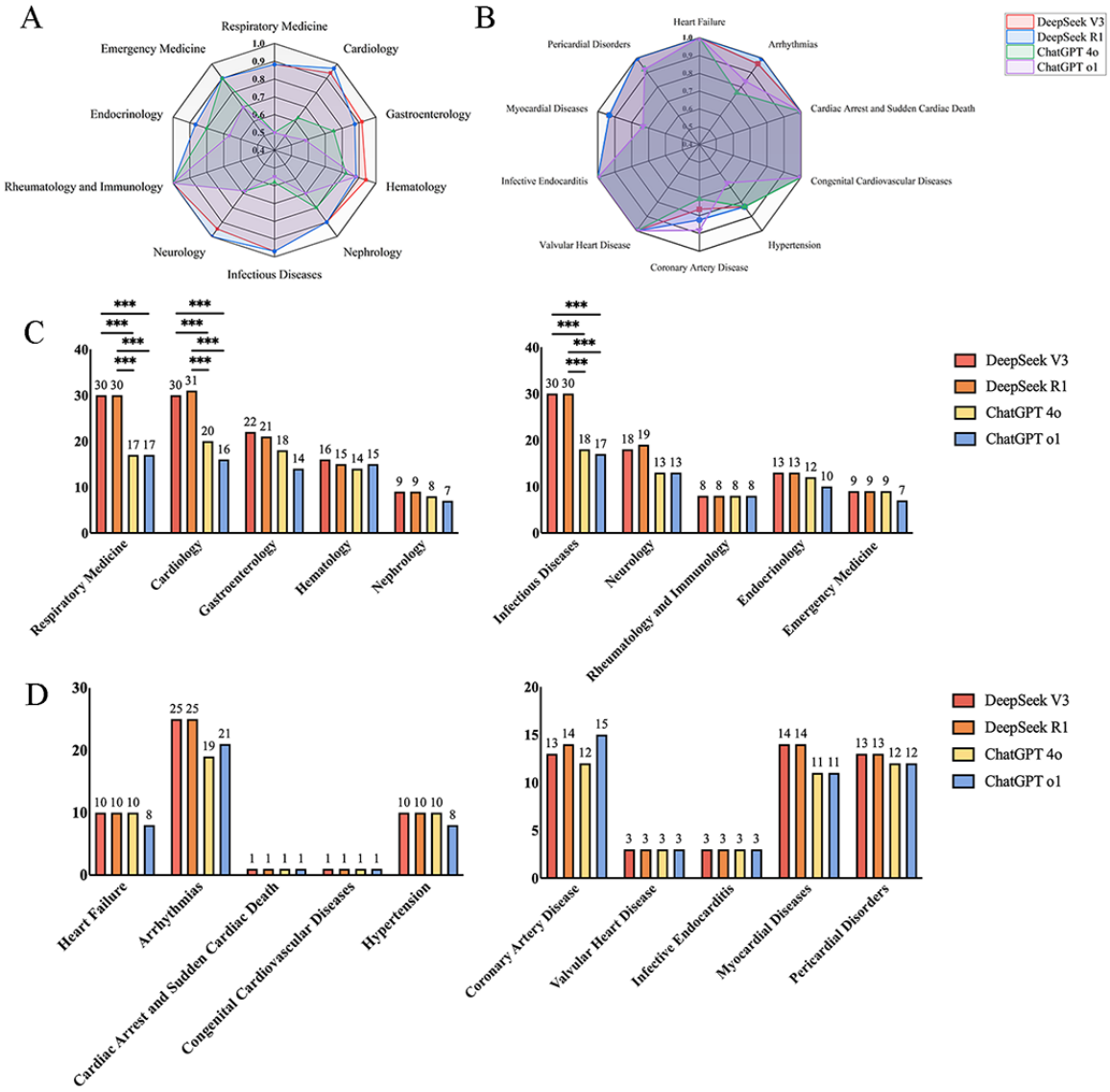
Figure 3. Comparisons among DeepSeek V3, DeepSeek R1, ChatGPT 4o, and ChatGPT o1. (A) and (C) show the performance on the topics of clinical disciplines, and (B) and (D) show the performance on the topics of cardiology subspecialties. Pairwise model comparisons were performed using McNemar test with Bonferroni correction (***P*<.008; ****P*<.001).



Performance of LLMs in Different Question Types

As mentioned before, questions in basic concepts, relevant expertise, and foundational professional knowledge were separated into 4 types, namely, A1 (knowledge-based multiple choice), A2 (case-based multiple choice), A3/A4 (case-group-based multiple choice), and B (matching). As illustrated in Table 4 and Figure 4, DeepSeek V3 and R1 showed distinct capability in answering various question types, even though they did not show a comparable difference (χ^2_1=0.06, *P*=.80; χ^2_1=0.09, *P*=.75; χ^2_1=0.2, *P*=.70; *P*>.99). Specifically, DeepSeek R1 ranked the highest in A1-type (91%) and A3/4-type (96.6%), while DeepSeek V3 ranked first in A2 (93.6%). Except for A1 type questions (ChatGPT 4o vs DeepSeek V3 χ^2_1=6.6; *P*=.01), ChatGPT 4o and o1 demonstrated an equal weakness in other 3 question types, with statistically significant differences compared with DeepSeek V3 and R1 (*P*<.001).

To make it more transparent and demonstrate the performance differences among models, the representative questions and their responses made by the LLMs were chosen and are presented in Table S2 in Multimedia Appendix 1.

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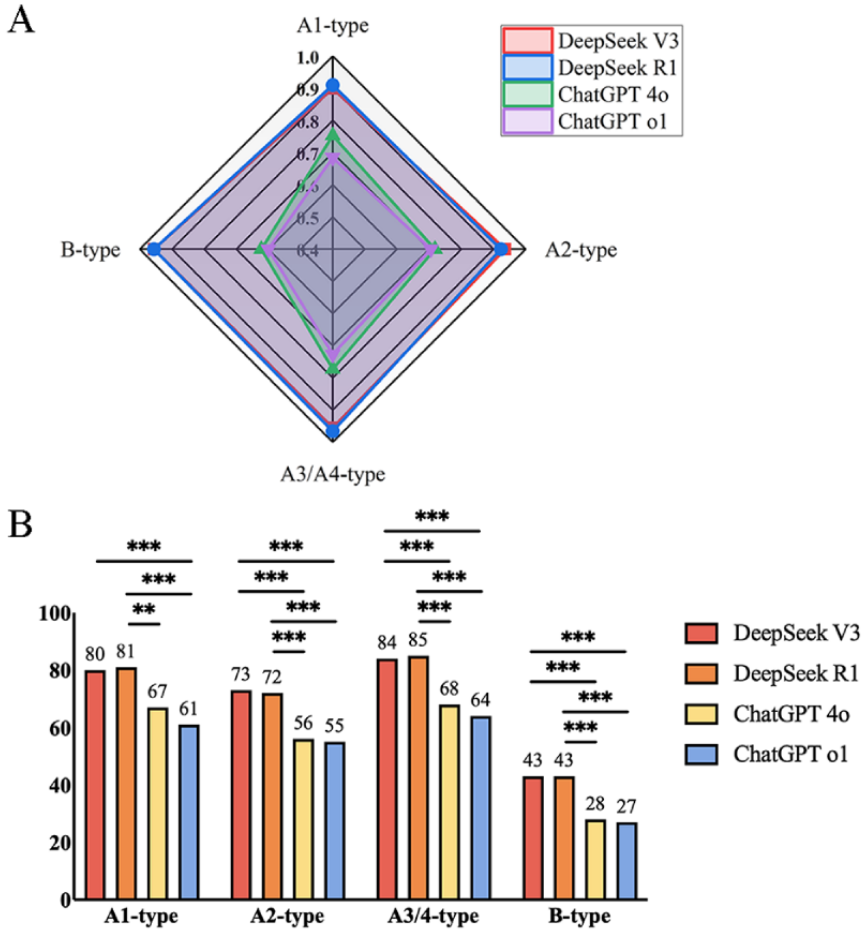
Table 4. Performance of the 4 large language models by question format in the first 3 sections.

Question format	DeepSeek V3, n (%)	DeepSeek R1, n (%)	ChatGPT 4o, n (%)	ChatGPT o1, n (%)
A1-type (n=89)	80 (89.9)	81 (91)	67 (75.3)	61 (68.5)
A2-type (n=78)	73 (93.6)	72 (92.3)	56 (71.8)	55 (70.5)
A3/4-type (n=88)	84 (95.5)	85 (96.6)	68 (77.3)	64 (72.7)
B-type (n=45)	43 (95.6)	43 (95.6)	28 (62.2)	27 (60)

Figure 4. Comparisons among DeepSeek V3, DeepSeek R1, ChatGPT 4o, and ChatGPT o1. (A) and (B) show the performance on the topics of different question types. Pairwise model comparisons were performed using McNemar test with Bonferroni correction (**P<.008; ***P<.001).



Cost-Effectiveness

In total, there were approximately 251,190 input tokens used to prompt DeepSeek V3 and R1. The responses made by DeepSeek V3 contained 22,530 output tokens, while for R1, there were about 48,575 output tokens when compiling all the responses. Based on the token counts recorded during API queries, the total cost for DeepSeek V3 was approximately ¥0.68, and for DeepSeek R1 ¥1.78. For ChatGPT 4o and o1, the estimated cost using the monthly subscription model was ¥37.65 for the 8-day data collection period. Under these specific access conditions, the expense of using ChatGPT models was approximately 55-fold higher than using DeepSeek V3 and 21-fold higher than using DeepSeek R1.

Discussion

Our study aimed to evaluate and compare the performance of four LLMs—DeepSeek V3, DeepSeek R1, ChatGPT 4o, and ChatGPT o1—in answering medical questions within a Chinese-language context. As demonstrated above, our findings indicated that DeepSeek V3 and R1 showed comparable and superior overall performance compared to both ChatGPT models across multiple question types and clinical disciplines. In the first 3 sections, DeepSeek R1 achieved the best performance, slightly exceeding DeepSeek V3. Additionally, DeepSeek V3 and R1 achieved the highest accuracy in the greatest number of clinical topics. Regarding performance across different question types, DeepSeek R1 performed exceptionally well on A1 and A3/4 types, while DeepSeek V3 performed better on A2 type. Notably, ChatGPT o1, which was thought to be comparable on reasoning tasks to DeepSeek R1 and better than ChatGPT 4o,

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performed the poorest across most question types among the 4 LLMs. However, all models showed a notable performance decline in realistic clinical case simulations (professional practical skills section).

Our findings demonstrated substantial accordance with previous research. Xu et al [27] reported that in ophthalmology, DeepSeek R1, with overall accuracy of 86.2% on Chinese MCQs, showed superior performance in Chinese complex reasoning tasks compared to Gemini 2.0 Pro, OpenAI o1 and o3-mini. Similarly, Mikhail et al [28] illustrated that DeepSeek R1 had comparable performance with ChatGPT o1 at reduced cost. However, DeepSeek R1 outperformed ChatGPT-4 on pediatric MCQs [19]. Integrating previous research outcomes with our new evidence, LLMs, in particular, DeepSeek V3 and R1, show extensive medical knowledge under the given settings.

However, both in our research and prior studies [19,27,28], LLMs demonstrated exceptional performance primarily in MCQs. Although these questions were designed to assess examinees' mastery of clinical knowledge, most can be effortlessly answered through mere memorization. MCQs failed to mirror the complexity and depth inherent in real-world clinical judgments, which require gathering and evaluating diverse data to reach evidence-based clinical decisions. To assess the usage of LLMs in an autonomous, real-world context, rigorous testing with authentic data and within practical, real-life conditions is essential [29]. Hence, the fourth section of professional practical skills was designed simulate a real-world clinical case. As evidenced in our study, all 4 LLMs showed marked performance decline compared to their results in the preceding three sections, highlighting their evident limitations in confronting with X-type questions (multiple choices) involving real-world clinical case analyses. Tordjman et al [30] reported that for text-based cases without answer choices, DeepSeek R1 (0.36) preformed similarly as ChatGPT o1 (0.32), reflecting the underperformance of the LLMs on open-ended questions. Consequently, while we firmly believe that LLMs have immense potential to revolutionize clinical decision-making in the future, their limitations in more realistic clinical contexts make us skeptical about their suitability at this stage.

Synthesizing the findings from previous research with the outcomes of our study, we raised the following inquiry: what factors enable DeepSeek to surpass ChatGPT in examinations within a Chinese linguistic framework? The DeepSeek team reported in their article [14] that to train a user-friendly model that can produce clear and coherent chains of thought, they designed a pipeline constructed in 4 stages. These 4 stages incorporate the following components: cold start, reasoning-oriented reinforcement learning, rejection sampling, and supervision of fine-tuning and reinforcement learning for all scenarios [14]. These 4 unique stages may be the elements that set DeepSeek R1 apart from the multitude of LLMs in reasoning tasks, elevating it to a distinct level of excellence. Moreover, despite the absence of publicly available details regarding the precise proportion of Chinese and English corpora used in DeepSeek R1’s training process, we found that in its early version DeepSeek V2, it contained 1.12 times more Chinese tokens than English data [31]. It is reasonable to infer that DeepSeek, a Chinese company, likely prioritizes Chinese corpora over English materials in training its LLMs; thus, the superior performance of DeepSeek V3 and R1 in the examination can be partly attributed to this factor.

Beyond the aforementioned discussion, we found several limitations requiring attention. First, in this study, costs of different LLMs were not calculated precisely, and we are yet to establish a comprehensive framework to assess the costs associated with different models. This may contribute to the underestimation of the actual token usage and associated costs. Second, during the interaction process, we provided a prompt requesting each LLM to furnish a detailed analysis for each question. Nonetheless, we were unable to devise a suitable methodology to thoroughly examine these analyses, which warranted further in-depth investigation. Third, as previously reported, LLMs may generate nonsensical or untrue content in relation to certain sources, which is called hallucinations [32]. The occurrence of such inaccuracies in clinical applications may lead to significant economic repercussions and, more gravely, the loss of life [33]. Additionally, we encompassed only one question referring to the image-based questions. However, as illustrated by Sarangi et al [34,35], even the performance of 4 LLMs, that is, Bing, Claude, ChatGPT, and Perplexity, varied in responding to MCQs based on radiology cases, while all failed to perform remarkably well when compared with residents. Meanwhile, even we compiled our own question database to avoid the risk of dataset contamination noted in prior studies (eg, Mikhail et al [28]), we cannot exclude the possibility that this material was included in the training corpora of the evaluated LLMs. Consequently, high accuracy in this study should not be equated with robust clinical decision-making ability. Last, the temperature for DeepSeek V3 and R1 was set to 0.7, while ChatGPT 4o and o1 were evaluated under default configuration. Thus, the comparison between models accessed via API and those evaluated through chat-based interfaces would have introduced systematic bias in output variability and accuracy [12]. Therefore, we have to admit that our findings reflect comparative performance under these specific experimental conditions rather than inherent model superiority.

In the future, we will concentrate on addressing the limitations mentioned above to further evaluate the disparities in the economic efficiency and the dissemination of erroneous information among various LLMs.

On these 398 questions comprising 5 different question types and 10 fields of different clinic disciplines, DeepSeek V3 and R1 demonstrated comparable performance, both surpassing ChatGPT 4o and o1 within the Chinese linguistic environment under the chosen experimental conditions. Consequently, they showed remarkable potential in facilitating clinical decision-making. Nonetheless, continued research is needed to evaluate their economic efficiency and hallucination.

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Data Availability

The datasets generated or analyzed during this study are available from the corresponding author on reasonable request.

Authors' Contributions

JX and QW contributed to overall study design and manuscript preparation. JX and SW contributed to technical support and data analysis. JX, QW, and JS contributed to manuscript writing, preparation, review, revision, and submission and approved the final manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Questions and representative answers given by different large language models.
[DOCX File , 542 KB - formative_v10i1e90673_app1.docx]

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Abbreviations

API: application programming interface
LLM: large language model
MCQ: multiple-choice question
UI: user interface

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Original Paper

Willingness of Patients With Mental Disorders to Engage in Online Psychotherapy: Multicenter Cross-Sectional Survey

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Abstract

Background: China faces a high prevalence of mental disorders but low treatment uptake, a gap driven by limited awareness and unevenly distributed mental health resources. While online psychotherapy has the potential to expand access, patient willingness remains insufficiently explored.

Objective: This study aimed to investigate the willingness of Chinese patients with mental disorders to engage in online psychotherapy and to identify associated factors.

Methods: A multicenter, cross-sectional survey was conducted using a structured questionnaire to assess the attitudes and willingness of patients with mental disorders in China to engage in online psychotherapy. Willingness to engage in online psychotherapy was assessed using a 0 to 100 rating scale, with higher scores indicating greater willingness. Univariate analysis, correlation analysis, and multivariate linear regression analyses were used to identify factors influencing willingness.

Results: Among 361 eligible participants, the mean willingness score for online psychotherapy was 70 (SD 28.56). In total, 86.4% (n=312) of participants preferred short-term therapy (1 to 10 sessions), while 92.5% (n=334) expected the cost per session to remain less than CNY ¥400 (US $55.50). Participants most preferred therapist-guided online individual therapy (n=142, 39.3%). Convenience (124/361, 34.3%) and perceived anonymity ("no one will know about the illness"; 119/361, 33.0%) were the 2 most commonly reported perceived benefits of online psychotherapy. The leading barrier was concerns about data security and privacy (108/303, 35.6%), followed by difficulty in establishing therapeutic rapport (60/303, 19.8%). The regression analysis revealed that age, self-stigma, satisfaction with current psychiatric medications, and satisfaction with previous online psychotherapy significantly influenced patients' willingness to seek online psychotherapy.

Conclusions: This multicenter study reveals a high level of willingness to engage in online psychotherapy among Chinese patients, with self-stigma as a key barrier. These findings support the development of tailored services, stigma reduction interventions, and infrastructure investment to enhance mental health care delivery.

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KEYWORDS

mental disorders; online psychotherapy; willingness; attitude; stigma

Introduction

Ranked as the second leading cause of disease burden worldwide, mental disorders present a major challenge to global health [1]. However, progress toward universal health coverage is significantly impeded by disparities in mental health services [2]. In China, although the lifetime prevalence of mental disorders among adults is 16.6% [3], the service use rates of mental health services are very low. For example, among individuals with depression, merely 9.5% seek professional help and only 0.5% receive adequate treatment. [4]. This treatment gap is often attributed to factors such as low mental health awareness, social stigma, inequitable resource distribution, and barriers to in-person care [2,4,5].

Driven by digital advances and the COVID-19 pandemic, online mental health services have become mainstream, with a 71% acceptance rate among patients [6]. Online psychotherapy, or telepsychology, includes interventions delivered via video calls, SMS text messaging, and apps, using methods such as cognitive behavioral therapy, dialectical behavior therapy, and mindfulness-based interventions [7,8]. Evidence indicates that online psychotherapy is as effective as in-person therapy for depression, anxiety disorders, posttraumatic stress disorder, and obsessive-compulsive disorder [9]. However, adoption faces barriers such as technical issues, privacy concerns, and challenges in establishing a therapeutic alliance [10-12].

Online psychotherapy presents a valuable opportunity to expand mental health service coverage. However, its implementation in China must consider local cultural contexts and patient-specific needs. Previous studies have focused on single cities, with little data from nationwide, multicenter surveys [13,14]. Previous research has found that age and sex may influence willingness to undergo psychotherapy, while the level of self-stigma is negatively correlated with the intention to seek psychological help [4,15,16]. Further studies have revealed that self-stigma may interfere with the formation of the therapeutic alliance during treatment [17]. Previous experiences with psychotherapy, whether online or in person, may also be significant factors influencing future willingness to engage in online psychological treatment.

In this study, we aimed to conduct a multicenter cross-sectional survey to assess the willingness to engage in online psychotherapy among Chinese patients with mental disorders and to identify the key factors associated with their willingness to use such services. We hypothesize that higher levels of self-stigma and previous negative experiences with psychotherapy are associated with lower willingness to engage in online psychotherapy.

Methods

Study Design and Sample

This study is a cross-sectional, multicenter survey using a structured questionnaire to assess the attitudes and willingness of patients with mental disorders in China to engage in online psychotherapy. We collected data during a 2-month period from February through March 2025. Eight medical institutions across China were involved: 4 specialized psychiatric hospitals—Peking University Sixth Hospital in Beijing, the Second Affiliated Hospital of Xinxiang Medical University in Henan province, the Third People's Hospital of Lincang in Yunnan province, and Ji'ao Brain Hospital of Siping in Jilin province—and 4 general hospitals with psychiatry departments—Zhongshan Hospital (Xiamen), Fudan University in Fujian province, First Hospital of Hebei Medical University in Hebei province, Shaanxi Nuclear Industry 215 Hospital in Shaanxi province, and Heping Hospital Affiliated to Changzhi Medical College in Shanxi province.

These institutions covered provinces spanning eastern (Beijing, Fujian, and Hebei), central (Henan and Shanxi), western (Yunnan), and northeastern (Jilin and Shaanxi) regions, including megacities (Beijing), medium-sized cities (Shijiazhuang), and peripheral cities (Lincang), ensuring representation of urban and rural populations and socioeconomic diversity. Attending physicians approached potential participants, and if a patient met the diagnostic criteria for a psychiatric disorder according to the *International Classification of Diseases, Tenth Revision*, they could be recommended to participate in the study. Specifically, the inclusion criteria were individuals who (1) were aged ≥10 years, (2) had a diagnosis of a mental disorder according to the International Classification of Diseases (tenth revision) criteria, (3) were able to read and complete the questionnaire, and (4) provided voluntary consent to participate in this survey. At each site, researchers distributed the structured questionnaire via quick response codes generated on the Wenjuanxing platform, which outpatients or inpatients scanned to complete the survey on their mobile phones.

On the basis of previous research [18], we assumed a 65% preference rate for online psychotherapy and calculated a minimum sample size of 350 participants (Z=1.96; E=0.05; P=.65) using standard proportion sampling methodology as follows:

To account for invalid questionnaires (approximately 10%), we increased the sample size to 385 participants.

Ethical Considerations

This study was approved by the Ethics Committee of Peking University Sixth Hospital. The approval number is 2025-1-9-1 (rapid review). Informed consent was obtained from all participants prior to enrollment, and participants were informed that their responses would be kept confidential. Parental or guardian consent was mandatory for all participants aged <18 years, in addition to the minor's assent. To protect privacy, all data were anonymized, and no personally identifiable information was collected or stored. Data were stored on a secure, password-protected server accessible only to the research

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team. Participants received CNY ¥10 (US $1.40) as compensation for their time and participation.

Measures

Demographics

Sex, age, educational attainment, occupational status, marital status, and socioeconomic status were collected in the survey. The exchange rate used for currency conversion during the study period was US $1=CNY ¥7.2.

Use Patterns of Internet-Enabled Devices

Participants indicated their primary internet access devices (eg, computer, tablet, and smartphone) as well as their frequency of internet use and their frequency of using video or voice call functions through multiple-choice or single-choice questions in the questionnaire.

Current Psychiatric Diagnoses and Treatment Experiences

Participants provided information regarding their diagnosis and treatment status by selecting the options that best matched their situation. The questionnaire covered several dimensions, including current diagnosis, pharmacotherapy (encompassing use, satisfaction, and disease improvement), and online psychotherapy (encompassing history of receiving treatment and satisfaction with it).

Willingness to Engage in Online Psychotherapy

Willingness refers to an individual's conscious intent or readiness to engage in a specific future behavior, given the opportunity. It is a subjective probability judgment about one's likelihood to act, positioned as a direct antecedent and key predictor of actual behavior [19]. In this study, "willingness to engage in online psychotherapy" was operationalized as participants' self-reported likelihood of initiating or participating in this intervention in the future, assessed before any direct experience with it. We measured this construct using a digitized, single-item visual analogue scale, presented as an interactive horizontal slider ranging from 0 ("absolutely unwilling") to 100 ("extremely willing"). A draggable indicator was initially placed at the midpoint (50). Participants were instructed to drag the indicator to the position that best reflected their current willingness. The web-based survey platform automatically recorded the corresponding numeric value (range 0-100) with 1 decimal place precision upon page submission.

Perceived Benefits and Barriers

Perceived benefits and barriers of online psychotherapy were assessed using 2 separate interactive drag-and-drop ranking tasks. One task listed 6 potential advantages, and the other listed 7 potential barriers to online psychotherapy. For each task, participants viewed all items in a randomized initial order. The instruction read: "please rank the following items in order of their importance to you, from the most important (1) to the least important (6 or 7), by dragging and dropping them into your preferred order."

Preferences

We assessed preferences for various online psychotherapy modalities (eg, individual, group, or virtual reality therapy) by asking participants to rank them from most to least preferred. Participant preferences in relation to the per-session fee and the desired therapy frequency were captured via single-choice selection of the most preferred option for each item.

Stigma

We used the Self-Stigma of Seeking Help Scale (SSOSH) to assess help-seeking stigma and explore its association with online psychotherapy willingness [20]. The SSOSH scale is a 10-item self-report measure assessing the internalized stigma associated with seeking psychological help. Items (eg, "I would feel inadequate if I went to a therapist for psychological help") are rated on a 5-point Likert scale ranging from 1 (strongly disagree) to 5 (strongly agree). The total score can range from 10 to 50, with higher scores indicating greater levels of self-stigma. The scale has demonstrated good reliability and validity in various populations [21]. Zuo and Ai [22] translated and revised the Chinese version of the SSOSH, with an internal consistency coefficient ranging from 0.86 to 0.90. In our study, the internal consistency coefficient (Cronbach α) for the SSOSH was 0.70, which is acceptable for a multi-item scale in this context. The questionnaire used in this study is provided in Multimedia Appendix 1.

Statistical Analysis

Descriptive analyses included means with SDs for normally distributed continuous variables and counts with percentages for categorical variables. On the basis of the city information obtained from patients' questionnaire responses, we classified the cities into 3 tiers according to urban hierarchy classification standards: large cities (urban resident population >1 million), medium-sized cities (urban resident population 500,000-1,000,000), and small cities (urban resident population <500,000) [23].

In the analysis of factors influencing online psychotherapy willingness, we used both univariate and correlation analyses.

Categorical variables were analyzed using the chi-square test. For continuous variables, normality was assessed using the Shapiro-Wilk test and visual inspection of quantile-quantile plots. Normally distributed data were analyzed using independent *t* tests (2 groups) or 1-way ANOVA (≥3 groups), with Fisher least significant difference post hoc tests applied if ANOVA was significant ($P<.05$). Nonnormal data were compared using Mann-Whitney *U* tests (2 groups) or Kruskal-Wallis tests (≥3 groups), followed by Dunn tests if overall differences existed ($P<.05$).

Spearman correlation analysis was used to examine relationships between continuous variables (age and SSOSH scores) and willingness to engage in online psychotherapy.

Multivariate linear regression analyses were used to identify independent factors associated with willingness to engage in online psychotherapy. Variables with statistical significance in the univariate analyses were entered into the regression model.

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All analyses were performed using SPSS (version 26.0; IBM Corp). $P<.05$ was considered statistically significant based on 2-tailed *t* tests.

Results

Participant Characteristics

A total of 390 questionnaires were collected. Following a rigorous review process, 29 duplicate submissions (characterized by identical IP addresses and fully consistent questionnaire content) were excluded. Consequently, 361 valid questionnaires were retained for the final analysis.

In the total sample, females accounted for 65.1% (235/361), with a mean age of 32.1 (SD 11.9) years. Individuals with a primary or secondary education level constituted 40.4% (146/361), while married participants represented 39.9% (144/361). Those holding full-time or part-time employment accounted for 48.2% (174/361). In total, 51.8% (187/361) had an annual income below CNY ¥50,000 (US $6944.40). The participants' addresses indicated residence in large, medium, and small cities at rates of 29.6% (107/361), 43.8% (158/361), and 26.6% (96/361), respectively. The smartphone use rate was 98.1% (354/361), and 78.1% (282/361) of participants used video platforms at least once a week. Among them, 65.4% (236/361) received outpatient psychiatric treatment, 62.3% (225/361) were diagnosed with anxiety or depression, and 69.0% (249/361) were on medication (details are provided in Table 1).

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Table 1. Descriptive characteristic of the whole sample (N=361).

Variables	Values
Sex, n (%)	
Female	235 (65.1)
Male	114 (31.6)
Other	1 (0.3)
Prefer not to disclose	11 (3.0)
Age[a] (years), mean (SD)	32.1 (11.9)
Educational level, n (%)	
Primary school	24 (6.6)
Junior high school	79 (21.9)
Senior high school	43 (11.9)
Higher vocational education	58 (16.1)
Bachelor degree	127 (35.2)
Master degree	26 (7.2)
Doctoral degree	4 (1.1)
Occupational status, n (%)	
Full time	133 (36.8)
Part time	41 (11.4)
Unemployed	51 (14.1)
Retired	11 (3.0)
Other	125 (34.6)
Marital status, n (%)	
Married	144 (39.9)
Unmarried, divorced, or widowed	217 (60.1)
Annual income[b] (¥), n (%)	
≤10,000	107 (29.6)
10,001-50,000	80 (22.2)
50,001-100,000	36 (10.0)
100,001-200,000	33 (9.1)
200,001-500,000	11 (3.0)
>500,000	2 (0.6)
Prefer not to disclose	92 (25.5)
City of residence, n (%)	
Large city	107 (29.6)
Medium-sized city	158 (43.8)
Small city	96 (26.6)
Devices used, n (%)	
Smartphones	354 (98.1)
Laptops	168 (46.5)
Tablets	132 (36.6)
Desktop computers	65 (18.0)
Internet use frequency, n (%)	

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Variables	Values
Almost always	227 (62.9)
Several times a day	95 (26.3)
About once a day	12 (3.3)
Several times a week	13 (3.6)
Once a week	5 (1.4)
Less than once a week	1 (0.3)
Never	8 (2.2)
Video platform use frequency, n (%)	
Almost always	78 (21.6)
Several times a day	71 (19.7)
About once a day	32 (8.9)
Several times a week	78 (21.6)
Once a week	23 (6.4)
Less than once a week	56 (15.5)
Never	23 (6.4)
Current psychiatric diagnoses, n (%)	
Anxiety disorder	127 (35.2)
Depressive disorder	98 (27.1)
Bipolar disorder	43 (11.9)
Sleep disorder	34 (9.4)
Psychotic disorder	22 (6.1)
Obsessive-compulsive disorder	21 (5.8)
Substance dependence–related disorder	3 (0.8)
Trauma-related disorder	2 (0.6)
Other	11 (3.1)
Illness duration (months), n (%)	
<6	96 (26.6)
6-24	91 (25.2)
>24	174 (48.2)
Currently taking psychiatric medications, n (%)	
Currently taking	249 (69.0)
Not taking	112 (31.0)
Current treatment setting, n (%)	
Outpatient care	236 (65.4)
Inpatient care	95 (26.3)
Partial hospitalization	9 (2.5)
Other	21 (5.8)
Previous experience with online psychotherapy, n (%)	
Had experience	90 (24.9)
No experience	271 (75.1)
Willingness to engage in online psychotherapy, mean (SD)	70 (28.56)
Acceptable cost per session for online psychotherapy (¥), n (%)	
≤200	285 (78.9)

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Variables	Values
201-400	49 (13.6)
401-600	13 (3.6)
>600	14 (3.9)
Preferred number of sessions for online psychotherapy, n (%)	
1-5	212 (58.7)
6-10	100 (27.7)
11-15	32 (8.9)
>15	17 (4.7)
Self-Stigma of Seeking Help Scale scores, mean (SD)	25.04 (5.56)

[a]n=354 participants.

[b]Exchange rate during the study period: US $1=CNY ¥7.2.

Online Psychotherapy Willingness, Perceived Benefits, and Barriers

In our study, the mean willingness score for engaging in online psychotherapy was 70 (SD 28.56). In total, 86.4% (312/361) of participants preferred short-term therapy (1-10 sessions), while 92.5% (334/361) expected the cost per session to remain less than ¥400 (details are provided in Table 1). Regarding the formats of psychotherapy, participants most preferred therapist-guided online individual therapy (142/361, 39.3%), which was higher than face-to-face individual therapy, whereas technology-assisted formats (artificial intelligence, virtual reality, and self-guided) showed modest acceptance (68/361,18.8%). Face-to-face group therapy ranked lowest (12/361, 3.3%; Figure 1).

Figure 2 shows participants' perceived benefits and barriers of online psychotherapy. We found that convenience (124/361, 34.3%) and perceived anonymity ("no one will know about the illness"; 119/361, 33.0%) were the 2 most commonly perceived benefits of online psychotherapy. Concerns about data security and privacy (108/303, 35.6%) emerged as the most significant barrier, followed by difficulty in establishing therapeutic rapport (60/303, 19.8%).

Figure 1. Ranking of preferences for different forms of psychotherapy.

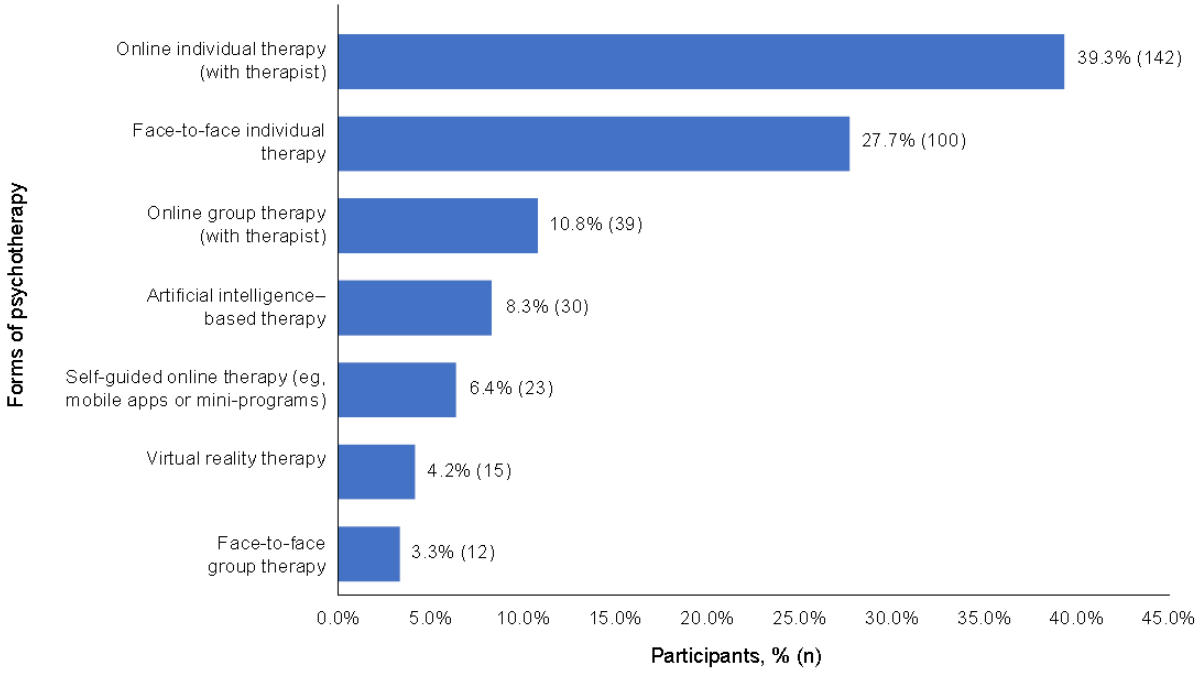

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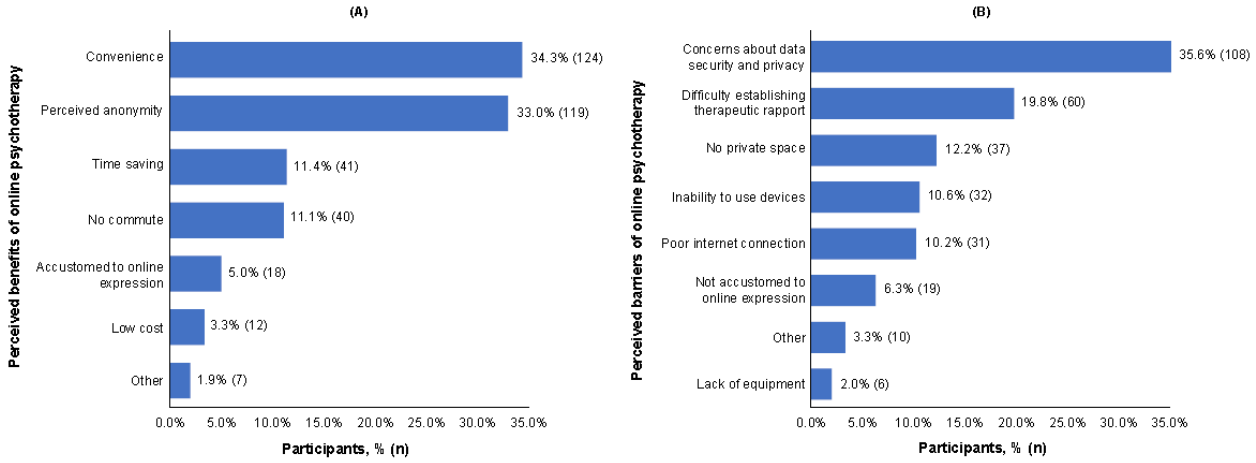
Figure 2. Perceived benefits and barriers of online psychotherapy, ranked from 1 (most important) to 6 (least important). (A) What are the benefits of online psychotherapy (n=361)? and (B) What stops you from trying online psychotherapy (n=303)?



Factors Associated With Online Psychotherapy Willingness

Univariate analyses revealed several factors significantly associated with willingness to engage in online psychotherapy, as shown in Table 2.

Some of the key factors from Table 2 are geographic variation, treatment status, and previous experience. For geographic variation, participants from small cities demonstrated significantly higher willingness than those from medium or large cities. For treatment status, individuals currently using psychiatric medications showed a higher willingness than those not using medications. Those reporting being “very satisfied” with pharmacotherapy were more willing than those in other satisfaction categories. Individuals with previous online psychotherapy experience exhibited greater willingness than those without such experience. Participants who were satisfied with past online psychotherapy were more willing than those who were neutral or dissatisfied.

Spearman rank correlation revealed a weak but statistically significant positive association (ρ=0.17; *P*=.001) between age and online psychotherapy willingness. A statistically significant negative correlation of comparable magnitude was observed (ρ=−0.17; *P*=.002) between total SSOSH score and online psychotherapy willingness. We found that participants preferring online psychotherapy had significantly higher SSOSH scores than those preferring face-to-face sessions (mean 25.53, SD 5.31 vs mean 23.96, SD 5.96; *P*=.01). The regression model incorporated all statistically significant variables as independent variables (including age, city size, use of psychiatric medications, satisfaction with pharmacotherapy, previous online psychotherapy experience, satisfaction with previous online psychotherapy, and SSOSH scores), with willingness to engage in online psychotherapy as the dependent variable. The regression analysis revealed that age, total SSOSH score, satisfaction with current psychiatric medications, and satisfaction with previous online psychotherapy significantly influenced patients’ willingness to seek online psychotherapy (*P*<.05; details are provided in Table 3). The model demonstrated good explanatory power, with an R^2 =0.518 and adjusted R^2=0.475. Additionally, diagnostic checks revealed that the residuals were normally distributed (Shapiro-Wilk *P*=.18), exhibited homoscedasticity, and showed no issues with multicollinearity (variance inflation factor<2.5).

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Table 2. Univariate analysis of factors associated with willingness to seek online psychotherapy (N=361).

Variables	Participants, n (%)	Willingness score, mean (SD)	*F* value (*df*)	*t* value (*df*)	*P* value[a]	η^2	Cohen *d*
Sex[c]			0.577 (2)	—[b]	.56	0.003	—
Female	235 (65.1)	70.43 (28.63)					
Male	114 (31.6)	70.03 (29.01)					
Age[d] (years)			2.628 (5)	—	*.02*	0.036	—
<20	42 (11.9)	64.26 (28.77)					
20-29	143 (40.4)	68.68 (26.99)					
30-39	90 (25.4)	69.34 (26.37)					
40-49	45 (12.7)	76.51 (31.55)					
50-59	26 (7.3)	83.27 (28.52)					
≥60	8 (2.3)	53.00 (44.44)					
City size[e]			2.872 (2)	—	.06	0.016	—
Large	107 (29.6)	67.22 (29.45)					
Medium	158 (43.8)	68.28 (26.12)					
Small	96 (26.6)	75.91 (30.79)					
Occupation			0.645 (4)	—	.63	0.007	—
Full time	133 (36.8)	70.22 (27.94)					
Part time	41 (11.4)	73.12 (26.68)					
Unemployed	51 (14.1)	73.84 (25.85)					
Retired	11 (3.0)	65.73 (37.31)					
Others	125 (34.6)	67.54 (30.15)					
Education level			1.768 (5)	—	.12	0.024	—
Primary school	24 (6.6)	69.50 (34.58)					
Junior high school	79 (21.9)	73.65 (30.10)					
Senior high school	43 (11.9)	72.58 (30.42)					
Higher vocational education	58 (16.1)	63.24 (30.60)					
Bachelor degree	127 (35.2)	67.85 (26.07)					
Graduate degree (master or doctoral)	30 (8.3)	79.23 (19.04)					
Annual income[f] (¥)			1.427 (5)	—	.21	0.020	—
<10,000	107 (29.6)	68.36 (28.94)					
10,001-50,000	80 (22.2)	75.28 (27.71)					
50,001-100,000	36 (10.0)	69.39 (28.33)					
100,001-200,000	33 (9.1)	73.12 (27.37)					
>200,000	13 (3.6)	78.23 (19.41)					
Prefer not to disclose	92 (25.5)	65.27 (30.00)					
Illness duration (months)			0.827 (2)	—	.44	0.005	—
<6	96 (26.6)	67.14 (27.34)					
6-24	91 (25.2)	69.62 (26.30)					
>24	174 (48.2)	71.78 (30.32)					
Currently taking psychiatric medication			—	3.082 (359)	*.002*	—	0.351

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Variables	Participants, n (%)	Willingness score, mean (SD)	*F* value (*df*)	*t* value (*df*)	*P* value[a]	η^2	Cohen *d*
Currently taking	249 (69.0)	73.07 (28.01)					
Not taking	112 (31.0)	63.17 (28.72)					
Satisfaction with psychiatric medication[g]			11.853 (4)	—	*<.001*	0.155	—
Very satisfied	77 (30.9)	89.27 (18.64)					
Somewhat satisfied	115 (46.2)	66.95 (27.39)					
Neutral	51 (20.5)	64.45 (29.56)					
Somewhat dissatisfied	5 (2.0)	62.80 (42.69)					
Very dissatisfied	1 (0.4)	20.00[h]					
Previous experience with online psychotherapy			—	3.478 (359)	*.001*	—	0.423
Experienced	90 (24.9)	78.93 (25.09)					
Not experienced	271 (75.1)	67.03 (29.07)					
Satisfaction with previous online psychotherapy[i]			7.633 (4)	—	*<.001*	0.264	—
Very satisfied	13 (14.4)	88.38 (27.40)					
Somewhat satisfied	35 (38.9)	91.20 (14.76)					
Neutral	25 (27.8)	67.60 (22.90)					
Somewhat dissatisfied	10 (11.1)	57.00 (27.62)					
Very dissatisfied	7 (7.8)	71.86 (29.84)					

[a]Not applicable.

[b]Italicized values indicate variables with statistically significant differences (*P*<.05).

[c]n=349; 12 participants did not disclose their gender or entered "other."

[d]n=354 participants; post hoc comparisons (Fisher least significant differences test or Dunn test) showed higher willingness scores among participants aged 50-59 years than those aged <20, 20-29, 30-39, and ≥60 years, and among those aged 40-49 years than those aged <20 and ≥60 years.

[e]Post hoc comparisons showed higher willingness scores among participants from small cities than those from large and medium cities.

[f]Exchange rate during the study period: US $1=CNY ¥7.2.

[g]n=249.

[h]n=1, SD not applicable.

[i]n=90, post hoc comparisons showed higher willingness scores among participants who were somewhat satisfied than those who were neutral, somewhat dissatisfied, or very dissatisfied, and among those who were very satisfied than those who were neutral and very dissatisfied.

Table 3. Multiple linear regression predicting willingness to seek online psychotherapy.

Variables	B (SE)	β	*t* test (*df*)	*P* value
Age	0.465 (0.176)	0.276	2.642 (67)	.01
Total Self-Stigma of Seeking Help Scale score	−0.815 (0.407)	−0.205	−2.004 (67)	.049
Satisfaction with psychiatric medication	11.193 (3.008)	0.369	3.721 (67)	<.001
Satisfaction with previous online psychotherapy	6.250 (1.960)	0.303	3.189 (67)	.002

Discussion

This study is a nationwide, multicenter, cross-sectional survey, and participants come from both specialized psychiatric hospitals and general hospitals with psychiatric departments in China. Our findings indicate a moderate level of willingness to engage in online psychotherapy, with a preference for short-term, affordable, therapist-guided individual formats. Convenience and perceived anonymity were key perceived benefits, while data security concerns and challenges in establishing therapeutic rapport were major barriers. Importantly, age, satisfaction with pharmacotherapy, previous positive experiences with online psychotherapy, and levels of self-stigma (SSOSH scores) independently predicted patients' willingness, highlighting critical leverage points for expanding access to digital mental health services.

Our study reveals that Chinese patients with mental disorders exhibit moderate-to-high willingness to engage in online psychotherapy, indicating promising prospects for its application in China. Previous studies have found that fewer than 10% of

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individuals with mental disorders seek professional help, which is associated with China's vast territory, uneven distribution of mental health resources, and concentration of psychotherapy services primarily in major cities [24,25]. In response, the National Health Commission has launched a 3-year initiative (2025-2027) to strengthen pediatric and mental health services (National Health Commission of the People's Republic of China, 2025). Online psychotherapy—with its advantages in convenience, privacy, and cost and time efficiency—aligns well with patients' treatment needs. Expanding such services may provide an important avenue for improving the accessibility of mental health care delivery in China.

Regarding factors influencing willingness to engage in online psychotherapy, univariate analysis revealed that (1) age was positively correlated with willingness, (2) participants from small cities demonstrated significantly higher willingness than those from medium or large cities, (3) individuals satisfied with their current psychopharmacological treatment or with previous online psychotherapy experience exhibited greater willingness, and (4) the total SSOSH score showed a negative association with online psychotherapy willingness. Multivariate analysis revealed that age, satisfaction with current medication, and satisfaction with previous psychotherapy exerted positive effects on willingness, while the total SSOSH score showed a negative association. Previous studies indicate age-related differences in online mental health resource use: tech-savvy younger individuals show greater adoption, while middle-aged users prefer traditional authoritative sources. Older adults' use is often limited by digital barriers and physical or cognitive constraints [14,26]. However, in our study, we found that middle-aged patients demonstrated a higher willingness for online psychotherapy than younger patients. One possible explanation for this age-related difference is that middle-aged individuals often face compounded work and family responsibilities, which may heighten their sensitivity to the flexibility and efficiency offered by online modalities. Although these underlying factors (such as perceived time pressure or convenience needs) were not directly assessed in our study, they represent a plausible interpretation grounded in the existing literature on midlife developmental tasks [27,28]. Future studies should incorporate direct measurements of these psychological and practical barriers to empirically test the mediating mechanisms driving the relationship between age and willingness to use online psychotherapy. Mental health resources in China are unevenly distributed, with in-person psychotherapy services being more accessible in large cities but significantly scarcer in smaller urban areas [25]. Online psychotherapy effectively breaks down geographic barriers, enabling patients from smaller cities to access higher-quality services typically concentrated in major metropolitan areas. This may explain why residents of smaller cities exhibit greater willingness to adopt online psychotherapy than those in medium-sized and large cities. Participants satisfied with pharmacotherapy and previous psychotherapy exhibited greater willingness to pursue online psychotherapy. This suggests that effective medication treatment may serve as a gateway to psychological interventions, as symptom improvement motivates patients to seek further quality-of-life enhancements. For clinically indicated patients with low treatment motivation, successful pharmacotherapy demonstrates dual benefits: not only relieving symptoms but also facilitating potential long-term engagement in psychotherapy. Finally, stigma remains a significant barrier to treatment seeking among patients, with higher stigma levels correlating with lower treatment willingness [29]. However, online psychotherapy may present a preferable alternative for highly stigmatized individuals due to its enhanced privacy and convenience. Previous studies have shown that patients with higher stigma scores tend to prefer online psychotherapy over face-to-face therapy [30]. Our study yielded similar findings: stigma scores negatively correlated with willingness to pursue psychotherapy overall; however, among treatment format preferences, patients who preferred online psychotherapy exhibited higher stigma scores than those favoring face-to-face therapy.

Regarding the formats and settings of online psychotherapy, we found that participants preferred therapist-guided, individual online psychotherapy, particularly short-term interventions (1-10 sessions) priced <¥400 per session. Therapist-guided psychotherapy remained participants' preferred choice, suggesting that even when integrating technologies such as virtual reality, artificial intelligence, or self-help applications, maintaining a therapeutic role for clinicians remains essential. To enhance accessibility and engagement, future online psychotherapy services could adopt modular, short-term treatment plans with flexible themes and phases, allowing patients greater autonomy in tailoring their therapeutic journey. These adaptations could make online psychotherapy more accessible and sustainable.

The primary obstacles preventing patients from seeking online psychotherapy were concerns about data security and privacy, followed by difficulties in establishing therapeutic relationships. Other obstacles include the absence of a private space suitable for online psychotherapy, difficulty using devices, or poor internet connection, illustrated in Figure 2. These findings are largely consistent with previous research [25,31,32]. To address these barriers, it is essential to enhance data security and privacy protection to mitigate the risk of information breaches. It will be helpful to provide specialized training for therapists to develop therapeutic relationships in virtual environments, thereby reducing difficulties in establishing rapport. Additional improvement measures include offering pretherapy guidance on the use of digital devices to minimize technical barriers and their negative impact. Future efforts should focus on further refining the standards for online psychotherapy to comprehensively enhance its accessibility and effectiveness.

Our study has some limitations. First, patients with anxiety and depression accounted for 62.3% (225/361) of the sample. Although other disorders were less represented, the study still covered common mental health conditions such as bipolar disorder, sleep disorders, obsessive-compulsive disorder, trauma-related disorders, substance dependence, and psychotic disorders. Future studies should investigate specific patient populations to provide tailored references for implementing online psychotherapy for patients with different disorders. Second, our sample was recruited from hospital settings, which ensured that all participants had clinically confirmed mental disorders; however, it may have introduced selection bias toward higher treatment-seeking motivation and consequently elevated

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willingness to engage in online psychotherapy. Consequently, the overall willingness reported in this study may be overestimated compared to community-dwelling or untreated populations, which limits the generalizability of our findings to broader, non–treatment-seeking groups. Future studies should include community-based samples to improve external validity and allow for more comprehensive comparisons across different subgroups. Third, while we included sociodemographic and treatment variables in the regression analysis, factors such as illness severity may also shape willingness. Future studies need to consider other potential influencing factors.

In conclusion, this study provides novel evidence from a multicenter clinical sample of Chinese patients with mental disorders, revealing not only a relatively high willingness to engage in online psychotherapy but also distinct preferences for specific treatment formats. Furthermore, we identified self-stigma (measured by the SSOSH) as an independent negative predictor of willingness. These findings have several practical implications. First, online psychotherapy services should be tailored to patient preferences by offering flexible modality options. Second, targeted interventions aimed at reducing self-stigma could be integrated into digital platforms to lower psychological barriers, particularly for patients in smaller cities where access to traditional mental health services is limited but there is a high willingness to engage in online psychotherapy. Finally, policymakers and health care administrators should consider investing in infrastructure and training programs that support the scalable implementation of online psychotherapy, thereby strengthening the reach and resilience of mental health care delivery in China.

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Conflicts of Interest

None declared.

Multimedia Appendix 1
Self-Stigma of Seeking Help (SSOSH) scale.
[DOCX File , 15 KB - formative_v10i1e83299_app1.docx]

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Abbreviations

SSOSH: Self-Stigma of Seeking Help Scale

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Original Paper

Real-World Data From a Group Parent Management Training Program Enhanced Using Artificial Intelligence: Qualitative Study

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Abstract

Background: Parent management training (PMT) is an evidence-based intervention for children with disruptive behavior problems. However, access to care is often limited by cost, availability of clinicians, scheduling, and transportation barriers. Integrating artificial intelligence (AI) into group PMT may improve accessibility, personalization, and adherence, while preserving therapeutic quality.

Objective: This study explored caregivers' experiences with a hybrid PMT program that combined live therapist-led group sessions with asynchronous support from Pat, an AI conversational agent designed to augment the therapists' support to caregivers.

Methods: A total of 88 caregivers of children aged 3-14 years (mean 7.98, SD 2.45 years) from Argentina and Paraguay participated in eight weekly online group sessions led by human therapists and supplemented by Pat. Caregivers were asked to provide the net promoter score (NPS) and their perceived contribution of their experience in remote group sessions and with Pat. Caregiver perspectives were analyzed using thematic analysis by multiple coders with consensus and interrater reliability assessment.

Results: The average NPS was 76.92, indicating excellent satisfaction. Regarding participants' perceptions of the overall program, the most frequent theme was useful strategies (73/202, 36.1%), reflecting the value placed on clear, structured, and practical tools to address everyday parenting challenges. Most comments about Pat were positive (156/164, 95.1%), particularly highlighting its 24/7 accessibility and constant availability (69/164, 42.1%). Recommendations for improvement mainly focused on enhancing the user experience and incorporating additional functionalities. Regarding perceived contribution to progress, caregivers attributed, on average, 61% to Pat and 46% to the group sessions.

Conclusions: Combining therapist-led PMT group sessions with AI support appears feasible, acceptable, and valued by caregivers and may expand reach without sacrificing quality. Overall, caregivers valued the useful strategies and the professional and peer support and reported positive changes. Regarding Pat, the most valued aspect is the constant and immediate support. This model integrates human expertise with the accessibility and continuity provided by AI, reducing barriers, such as time, cost, and clinician availability.

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(JMIR Form Res 2026;10:e91841) doi:10.2196/91841

KEYWORDS

artificial intelligence; conversational agent; parent management training; disruptive behavior; hybrid intervention

Introduction

Worldwide, approximately 15% of children and adolescents (10-19 years old) experience a mental health condition, with behavioral disorders being the most prevalent [1]. Untreated behavioral problems are often associated with poor long-term outcomes, including early high school dropout, criminal justice system involvement, lower life satisfaction, and emotional difficulties [2]. Parenting interventions can make a difference in reducing child behavior problems. For example, parent management training (PMT) in individual or group format leads to significant reductions in child behavior problems, improvements in parent mental health and positive parenting skills, and reductions in negative or harsh parenting practices [3-11].

More specifically, group-based PMTs are associated with reducing children's behavioral problems, having a positive effect on parents' expectations, and improving social competence, as reported by teachers [12]. PMTs can also decrease both behavioral and clinically significant problems in children, as well as increase positive or effective parenting practices [8]. Furthermore, a recent meta-analysis showed that overall group parenting programs enhance child behavior management, reduce parenting stress, and decrease parental depressive symptoms [13]. Although both group-based and individual parenting programs improve child behavior and reduced parent stress, only group-based programs significantly reduce parental depressive symptoms [13]. However, access to care remains a substantial barrier, with only a limited number of children in need of mental health services having access to effective interventions, such as behavioral parenting interventions [14], because of barriers, such as childcare, time constraints, and transportation [15]. As such, there is a critical need for more accessible, efficient, and reliable tools to support caregivers and improve child outcomes.

There are three potential ways of reducing these barriers: group format to reduce cost, teletherapy sessions to reduce transportation, and digital interventions to increase accessibility. For example, group parent training programs delivered through teletherapy show similar results in reducing disruptive behavioral problems in children as in-person therapy [16]. Digital parenting interventions (eg, apps, websites) have yielded comparable outcomes to traditional parenting programs [17]. Further, group programs combined with technology have yielded positive outcomes. For example, Jones et al [18] found that families engaged in a parent training program with enhanced technology (a mobile app monitored by a therapist via a web portal to customize content for parents) display increased homework compliance and participate in more phone calls than those without technology. A randomized controlled trial (RCT) comparing a behavioral parent training program to the same program with enhanced technology found improvements in parenting skills and child behavior postintervention for both groups; however, only the group with the enhanced technology was able to maintain these improvements at 6-month follow-up [19]. Technological means may fill the support gap that occurs between sessions and eventually lead to better treatment progress and satisfaction.

Furthermore, an RCT by Yang et al [20] found that a technology-enhanced parent training program is more effective in reducing child behavior intensity than a parent training program without enhanced technology. A recent study [21] reported that increased app use as an adjunct to a traditional behavioral parent training reduces the time needed for parents to achieve mastery of skills. In addition, a study [22] that compared the use of artificial intelligence (AI) support with cognitive behavioral therapy (CBT) exercises and no AI support for adults with depression and anxiety found that the AI group attained greater improvement and recovery rates as well as higher attendance and lower dropouts. Although these studies show the potential benefits of integrating digital resources and AI into group settings, there are no studies on the use of AI integrated into group PMT.

A study [23] on an AI rule-based conversational agent (CA) delivering a parenting intervention found that delivering parenting skills (ie, how to praise) through CA is feasible, acceptable, well retained, and associated with high user satisfaction; however, symptom outcomes are limited. Parents who were taught praising skills using a rule-based CA microintervention delivered through a PMT intervention demonstrated high completion rates and skill retention, strong engagement, and willingness to recommend the program to other parents [23]. In a subsequent RCT using a modified version of the microintervention, Entenberg et al [24] found high parental engagement with the CA (as measured by the number of text messages sent). Furthermore, parents were satisfied, felt comfortable with the intervention, found the skills learned useful, and reported they would recommend it to other parents [24]. These studies delivered interventions in a self-guided format (not group) and tested only a short intervention [25] rather than more complete interventions that address multiple components of effective parenting skills [26]. In addition, they relied on rule-based CAs, which is a much limited technology compared to the new models of generative AI, which allow for more personalization and complexity [27] compared to rule-based technologies.

To the best of our knowledge, there is only one study on PMT using generative AI [28]. The study [28] examined the delivery of PMT via a digital platform (ParenteAI [29]) with an AI agent (Pat) in a combination of live sessions with a human therapist. The therapist facilitated the conversations with Pat to deliver half of the PMT modules, and Pat independently delivered the other half of the modules. This uncontrolled study [28] reported significant improvements in the children's externalizing and internalizing symptoms, as well as significant reductions in parental depression, anxiety, and stress [28]. Although these

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outcomes are promising, PMT was delivered in a one-on-one format, and more research is needed to understand how a group format, in combination with AI performs can enhance human support.

Although overall prior studies on PMT groups have shown positive outcomes [18], caregivers might feel the need for more individualized support that a group format can provide. Given that AI agents can adjust to specific users, integrating AI into such groups can complement the work of the group sessions by providing more personalized support in between sessions. Although Rivera-Cepeda et al [28] showed promising outcomes using AI as a complement to therapy, the one-on-one intervention was not evaluated in a group context. Moreover, most studies relied primarily on quantitative outcomes and offered limited insight into parents' lived experiences.

In this study, we propose that caregiver groups led by human experts can be supported and enhanced using generative agents (eg, Pat). By combining the expertise of human facilitators with the scalability and adaptability of AI, caregivers may receive support that is not only scalable but also safe and personalized. Importantly, when AI is used to augment digital therapeutics (DTx), tools should be dynamic and customizable, support real-time decision-making, deliver personalized experiences, provide automated assistance and adherence support, and adapt to ongoing user feedback [30].

Given the growing demand for accessible, evidence-based parenting interventions, hybrid models combining live group sessions with AI platforms may offer a flexible, scalable, and personalized way to support families. In this study, we aimed to understand how caregivers perceive a novel implementation of group PMT combined with an AI platform. PMT was delivered through weekly online group meetings via Zoom led by a therapist and supplemented by Pat, an AI-based CA between sessions. Our primary goal was to understand how caregivers perceive this hybrid approach. Specifically, we analyzed their (1) ratings of the overall program using a net promoter score (NPS) as well as qualitative feedback on their experiences, (2) perceptions of the overall hybrid intervention, (3) impressions of their interactions with and the value of Pat, and (4) perspectives on how the live group sessions influenced their child's progress compared to their work with Pat. By centering caregiver perspectives, our findings aim to inform future models of care that leverage both human expertise and scalable digital support.

Methods

Recruitment

Caregivers in Argentina and Paraguay were recruited online through targeted online advertisements and the social media channels of two mental health professionals (one from each country). Recruitment and group participation ran from January to November 2025. The advertisements stated that the program was designed specifically for caregivers of children between the ages of 3 and 12 years who exhibited disruptive behaviors, such as frequent tantrums, defiance, aggression, rule breaking, and difficulty following instructions. Interested caregivers were directed to a website to learn more about the program and complete registration. Registration and payment were conducted entirely online. Upon registration, caregivers received access to the ParenteAI platform. In addition to the digital platform, participants were enrolled in a live therapist-led parenting group session that met weekly via Zoom. The first three cohorts participated in 12 weekly sessions, but the seven subsequent cohorts received an 8-week group format. The group length was reduced to make it more manageable for the caregivers and because Pat was able to provide information about the remaining modules. Surveys were administered twice, once at week 4 (midintervention) and again at week 8 (the final session). Four children who were slightly over the age of 12 years were admitted with the caregivers' understanding that the program was aimed at younger children and that adaptations were going to be discussed with them.

Parent Management Training Groups Combining a Human Expert and AI

The intervention consisted of a hybrid model that combined live group meetings with a digital platform (ParenteAI) with an AI-based CA (Pat).

ParenteAI With Pat

ParenteAI is a digital platform designed to facilitate and support the delivery of behavioral parenting interventions by a therapist to caregivers of children with behavioral problems (Figure 1). It is designed to enhance the work of the therapists. Caregivers access the platform only through an invitation from a mental health professional. ParenteAI is a Health Insurance Portability and Accountability Act (HIPAA)–compliant platform to be used by clinicians. Pat chats with caregivers as a parenting coach, and the therapist can review all the conversations between Pat and the caregivers. Pat has three main functions for caregivers:

- To deliver 20 PMT modules teaching specific skills, with each module lasting between 20 and 40 minutes in different languages, including Spanish
- To provide caregivers with in-the-moment support, where they can ask Pat questions about how to manage behavioral problems, and responses are generated using a curated knowledge base to deliver a safe, effective, and engaging experience
- To deliver personalized reminders based on the conversations that caregivers have with Pat

ParenteAI stores all conversations and provides conversation summaries to both caregivers and therapists. Therapists use these summaries to monitor interactions and to inform and facilitate therapeutic interactions.

ParenteAI's architecture is designed to enhance engagement, efficiency, and personalization, while reducing errors [29]. Unlike general-purpose AI (eg, ChatGPT) that provides quick responses to user input, Pat is designed to gather context before providing responses, to collaborate on setting goals, and to guide users throughout the PMT modules. To improve response accuracy, the system uses retrieval-augmented generation (RAG) with a curated knowledge base developed by mental health professionals, minimizing risks of inaccurate or inappropriate outputs [29]. Further, Pat has a series of guardrails to restrict

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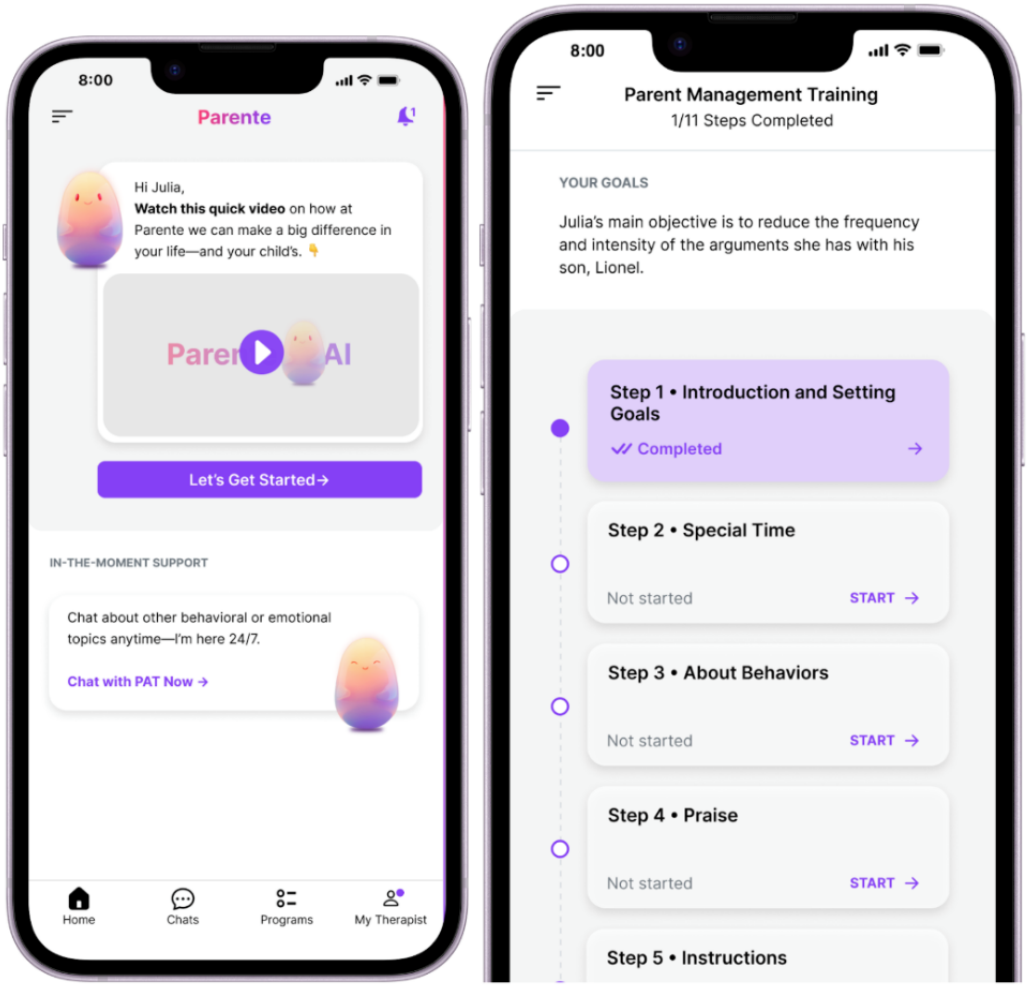
responses to evidence-based material and limit conversations to caregiver strategies. Additionally, agentic architecture allows Pat to maintain treatment fidelity throughout multiweek modules. Recognizing the risks inherent to novel technologies, ParenteAI was designed to allow human therapists to supervise and review all parent interactions with Pat to ensure safety and fidelity.

Figure 1. Screenshots of the ParenteAI platform. (Left) Home screen where caregivers can go to the PMT or select in-the-moment support. (Right) Sample of the modules covered in the PMT. PMT: parent management training.



Zoom Group Meetings Integrating Pat

The intervention consisted of eight live meetings conducted over Zoom delivered by two therapists. The therapists delivered the PMT core concepts and assigned caregivers specific activities to be completed with Pat. This hybrid model is designed to complement the work of the live meetings with the work with Pat.

In PMT, therapists teach caregivers to change reinforcement patterns and use consistent consequences to improve child behavior [31-34]. The caregivers engaged with Pat between sessions to support the acquisition and implementation of parenting skills through personalized and interactive dialogue and to obtain in-the-moment support.

During the live meetings, nine core PMT topics were covered: focus on goal setting, understanding why misbehavior occurs, special time (ie, to improve the parent-child relationship), how to praise, reward systems, effective instructions, active ignoring, timeout, school behavior, and behavior in public places. Pat covered these nine topics plus several other PMT modules that caregivers could complete at their own pace, if interested: emotional regulation for parents, the de-escalation for explosive kids, understanding screen time, screen time, parental screen use, using reprimands effectively, reflecting on their parenting style, handling low-rate but serious behaviors, compromising strategies for resolving conflicts, and understanding and using consequences effectively.

During the first Zoom group meeting, the therapists taught caregivers how to use and navigate Pat and encouraged them to do so throughout the course of subsequent meetings. Live sessions aimed to be interactive and were guided by a slide deck that included triggers for the topics discussed.

During the live sessions, the therapists focused on three main tasks: (1) review and provide feedback on the work caregivers did with Pat during the week, (2) troubleshoot and/or role-play the implementation of the skills learned with Pat, and (3) assign a new module for the caregivers to complete during the week. The therapists reviewed caregivers' interactions with Pat to

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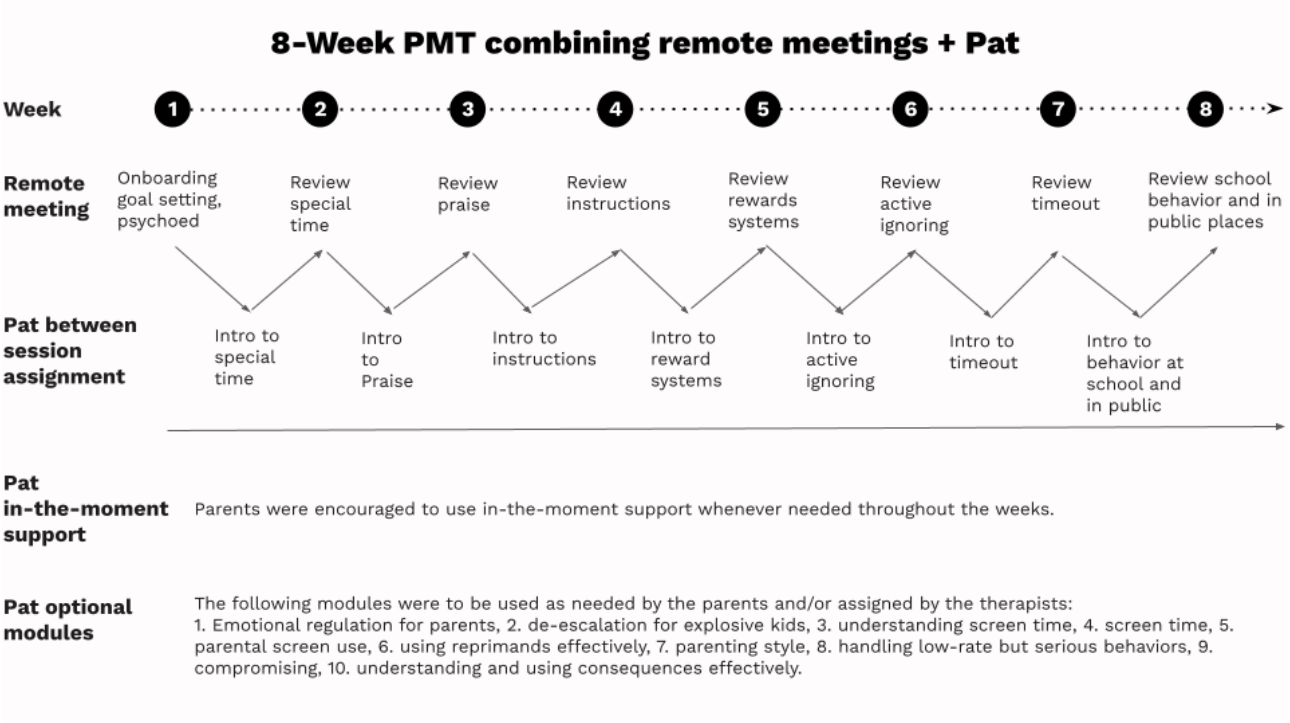
inform the discussions during live sessions, clarify content, and provide feedback during the subsequent live session. Here are example questions the therapists asked for the "how to praise" topic:

- We saw you completed the conversation on praise. What do you remember about it?
- What are your thoughts about it?
- Were you able to put it into practice? How did it go?
- Do you have any additional questions about how to praise your child?

In all meetings, the therapists engaged in a brief role-play about the topic covered and provided extra feedback to the caregivers. At the end of each live session, the therapists assigned a new module for the caregivers to complete independently with Pat before the subsequent live session and encouraged caregivers to interact with Pat in between sessions as much as they desired. See Figure 2 for an illustration of the interventions.

Figure 2. Representation of the PMT program combining remote meetings over Zoom and asynchronous use of Pat in the ParenteAI platform. PMT: parent management training.



Caregiver Measures

Net Promoter Score

Caregivers were administered a survey asking their willingness to recommend the intervention on a Likert scale ranging from 1 (strongly disagree) to 10 (strongly agree). Based on the scores, caregivers were categorized as promoters (9-10), passives (7-8), or detractors (0-6). Furthermore, they were asked for the reasons for their score. The NPS was calculated by subtracting the percentage of detractors from the percentage of promoters, resulting in a score between –100 and 100. The NPS has been proposed as a measure to evaluate the overall impression of a digital product [35] and has been widely used in other CA studies [36]. General guidelines for interpreting the score are as follows: negative score (<0), more detractors than promoters; 0-30, good; 30-70, great; and 70-100. excellent or world-class tier.

The survey included two open-ended questions:

- What are the things you liked the most about the program?
- What would you recommend to improve?

Relative Contribution of Intervention Components

To assess the perceived impact of each component of the intervention, caregivers were asked to estimate the relative contribution of the ParenteAI platform versus the live group sessions to their children's progress. Specifically, they were prompted with the following instructions:

> *We are interested in understanding how helpful each part of the program was for you. Please estimate what percentage of your child's progress you attribute to the live group sessions (with professionals and other parents), and what percentage you attribute to your conversations with Pat (the ParenteAI platform). Please make sure the two percentages add up to 100%.*

The system did not add the percentages up to 100 by default. The caregivers were then asked to explain their reasoning.

Ethical Considerations

This study was approved by the Institutional Review Board of the Universidad Santo Tomás in Chile (approval #23136643/2023). The analysis was conducted using secondary deidentified data collected as part of the original ParenteAI program implementation. At the time of registration, caregivers

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agreed to the ParenteAI Terms of Service, which included a clause stating that anonymized data could be used for research purposes. Additional informed consent was obtained at the time of survey completion. Participants were not compensated and could withdraw at any time.

Data Analysis

This study was a secondary analysis of real-world data. Descriptive statistics were used to report NPSs and the relative contribution of the intervention components. A thematic analysis of participants' responses was conducted following the steps proposed by Braun and Clarke [37]: (1) familiarization with the data, (2) generation of initial codes, (3) searching for themes, (4) reviewing themes, (5) defining and naming themes, and (6) producing a report. Responses to the NPS question ("Why did you provide this rating?") and the question regarding positive aspects were combined. With respect to the open-ended questions on the relative contribution of the intervention components, participants' responses were grouped into three categories based on (1) attributing change to interactions with Pat, (2) attributing change to participation in the group, and (3) complementarity of the interventions.

AI was used as a supportive tool to generate an initial set of proposed codes based on participants' responses. This proposal was thoroughly reviewed by three of the paper's authors, who evaluated its conceptual relevance, refined operational definitions, removed redundancies, deepened analytical nuances, verified the relevance of potential themes, and generated the final list of themes.

In addition, following the guidelines of the coding reliability approach described by Boyatzis [38] and later operationalized and further developed in applied research contexts by Guest et al [39], participants' responses were independently analyzed by two evaluators. Code frequencies and interrater reliability (IRR) were calculated using the Cohen κ coefficient. Discrepancies were discussed and resolved by consensus among the three authors. All themes were initially developed in Spanish and subsequently translated into English by the authors.

Results

Participant Details

In total, 88 primary caregivers participated in the study. They were mostly female (n=76, 86%), aged 34-65 years (mean 44.31, SD 5.73), and had a child between 3 and 14 years old (mean age 7.98, SD 2.45 years). The children were 80% (n=70) male and 20% (n=18) female. Only 3% (n=3) of the caregivers identified as Indigenous or belonging to Native people, while 84% (n=74) identified as White or of European descent. More than half of the caregivers reported being married (n=49, 56%). Furthermore, 38% (n=33) had a university degree, while 42% (n=37) had a postgraduate degree. See Table 1 for participants' demographic characteristics.

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Table 1. Participants' demographic characteristics (N=88).

Characteristics	Value
Age (years), mean (SD; range)	44.31 (5.73; 34.00-65.00)
Gender, n (%)	
Female	76 (86)
Male	12 (14)
Ethnic identification, n (%)	
White/European descent	74 (84)
Other	9 (10)
Indigenous/Native people	3 (3)
Missing	3 (3)
Marital status, n (%)	
Married	49 (56)
Cohabiting (civil/de facto union)	15 (17)
Single	8 (9)
Divorced	8 (9)
Separated	7 (8)
Missing	1 (1)
Educational level, n (%)	
Postgraduate education (specialization, master's, or doctorate)	37 (42)
University degree	33 (38)
Technical/nonuniversity studies	13 (15)
Secondary education	4 (4)
Did not complete primary school	1 (1)
Missing	0

Net Promoter Score

The mean NPS was 9.32 (SD 1.31; range 2-10), and the majority of caregivers were promoters (Figure 3). The NPS was calculated as the percentage of promoters (scores 9-10) minus the percentage of detractors (scores 0-6), following standard NPS methodology. Of 117 responses, 94 (80.3%) were classified as promoters (scores 9-10), 19 (16.2%) as passives (scores 7-8), and 4 (3.4%) as detractors (scores 0-6). The resulting mean NPS was 76.92 (range 80.34-3.42), which is considered excellent. When asked why they provided such NPSs, most responses (n=211, 56.3%) were about the intervention in general (which included group sessions and the platform), and a considerable portion (n=164, 43.7%) were specific to Pat. The IRR for the overall program or Pat was 0.87.

Overall, caregivers' responses revealed a positive sentiment about combining therapists with Pat. As shown in Table 2, the sentiment of the majority of responses was positive (172/181, 95.0%), a small portion of responses were neutral (8/181, 4.4%), and only 1 response was coded as negative (1/181, 0.6%). A total of 10 themes emerged, and the IRR was 0.90.After assessing the IRR, discrepancies between raters were resolved through consensus, resulting in a final set of themes.

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Figure 3. NPSs for all responses. Labels above the bars indicate the frequency (n) and percentage of responses. Dashed vertical lines indicate standard NPS cutoffs (1-6: detractors; 7-8: passives; 9-10: promoters). NPS: net promoter score.

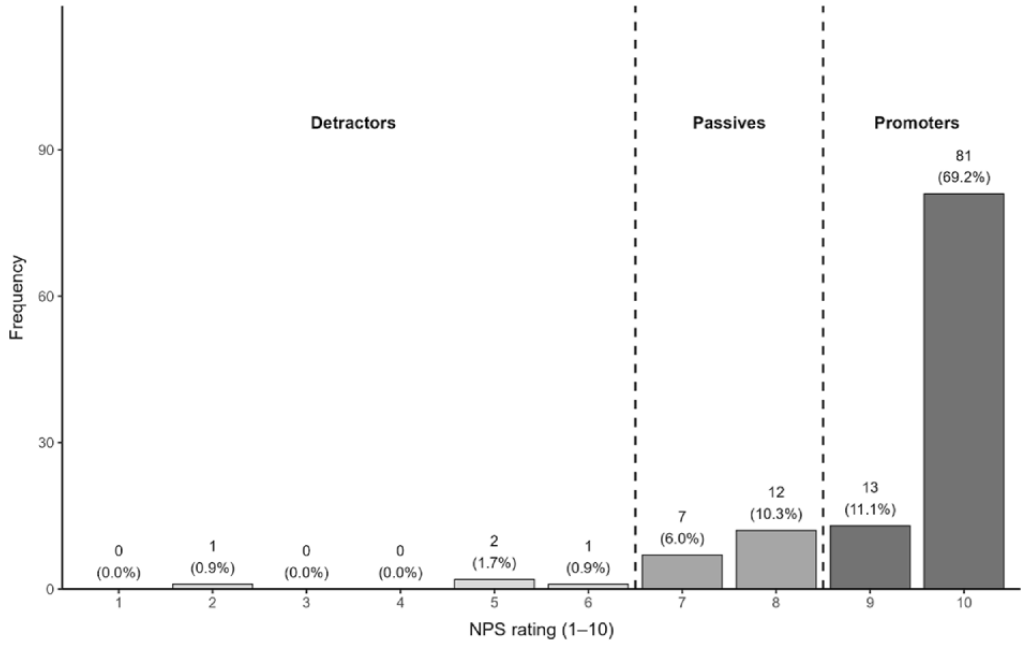

Table 2. Summary of attribution and sentiment.

Attribution or sentiment	Frequency, n/N (%)
Attribution	
Overall program (group sessions + Pat)	211/375 (56.3)
Pat (AI[a])	164/375 (43.7)
Sentiment	
Positive	172/181 (95.0)
Neutral	8/181 (4.4)
Negative	1/181 (0.6)

[a]AI: artificial intelligence.

Themes About the Overall Program

There were 202 coded segments in total. Regarding participants' perceptions of the overall program, four major themes emerged (Table 3): useful strategies (73/202, 36.1%), professional and peer support (65/202, 32.2%), positive changes (52/202, 25.7%), and overall satisfaction and recommendation (12/202, 5.9%). The most frequent theme was "useful strategies," highlighting the value placed on PMT strategies and participants' appreciation for clear, structured, and applicable tools to address daily parenting challenges. For example, one caregiver noted:

> *The most innovative contribution of this program is that it is a setup plan, with a goal, step by step, where they not only tell us what to do but, most importantly, how and why.*

The "professional and peer support" theme highlighted the value placed on ongoing guidance from professionals and shared experiences with other caregivers. The "positive changes" theme captured caregivers' reports of improvements in family communication, reflection, and their children's behavior, as reflected in statements such as:

> *It made me think, it stopped me, and it turned what could have been a fight into a coffee chat and a reunion with my daughter.*

Finally, the "overall satisfaction and recommendation" theme reflected caregivers' general endorsement of the program.

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Table 3. Themes about the overall program (group sessions plus Pat; positive sentiment).

Theme	Definition	Subcategories (if any) and example quotation; partial frequency (if any), n/N (%)	Total frequency (N=202), n (%)
Useful strategies	Appreciation of the clear tools and guidance offered by the program, perceived as useful, applicable, and effective for facing everyday parenting challenges, along with recognition of a structured step-by-step guide.	• "The tools I acquired gave me the security and confidence to handle situations that previously overwhelmed me."	73 (36.1)
Professional and peer support	Participants' perception of the technical and human quality of the professional team, as well as the horizontal support between parents.	• "The program offers daily support and guidance from professionals, in addition to meetings where we could share with other parents who are experiencing the same difficulties."	65 (32.2)
Positive changes	A process through which parents develop a greater awareness of their role, practices, and priorities, adopting a more reflective and committed approach to raising children. This process translates into concrete changes in children's behavior and strengthens relationships within the family unit, improving dialogue, empathy, and coordination among its members.	• "Parental reflection" subcategory: "It made me think, it calmed me down, and that is how what could have been a fight turned into a coffee chat and a reunion with my daughter."; 29/52 (56) • "Family atmosphere and communication" subcategory: "Because it changed our climate, our family life, and I would really like more families to experience the same."; 22/52 (42) • "Son's behavior" subcategory: "Because I see that the program really works, I am already starting to see changes and better results in my son."; 1/52 (2)	52 (25.7)
Overall satisfaction and recommendation	Expressions of general pleasure with the program, overall satisfaction with the experience, and willingness to recommend it to other families.	• "I have already recommended the program to two friends. I think it is very useful."	12 (5.9)

Themes Specific to Pat

Participants were asked about Pat, and most comments were positive in nature (Table 4). The most frequent positive theme was "24/7 accessibility" (69/164, 42.1%), reflecting users' appreciation for the constant availability of the platform. The second-most common positive theme was "useful strategies" (54/164, 32.9%), emphasizing that Pat provides concrete, evidence-based tools for managing parenting challenges. The third positive theme, "emotional support and containment" (33/164, 20.1%), captured caregivers' sense of empathy and understanding from Pat.

Neutral comments accounted for a smaller portion of the responses. The most frequent neutral theme was "preference for human accompaniment" (6/164, 3.7%), with some caregivers expressing that live professional meetings felt more personal and specific. Another neutral theme, "limitations at critical moments" (1/164, 0.6%), reflected the perspective of a user who found it difficult to access help from the platform, when needed.

Finally, the only negative theme, "difficulty trusting the app" (1/164, 0.6%), captured skepticism or hesitation toward relying on Pat compared to human professionals. For example, one participant said:

> *I have not yet fully established myself with an app that gives me answers and more clarity than a professional evaluating my son and the family.*

Themes on Recommendations for Improvement

Regarding participants' recommendations for improvement, four main themes emerged: user experience and technological functionalities (56/122, 45.9%), overall satisfaction without recommendations (29/122, 23.8%), content adaptation (26/122, 21.3%), and resources and support materials (11/122, 9.0 %). The IRR was 0.84.

The "user experience and technological functionalities" theme included suggestions to enhance accessibility, usability, and interactivity. For instance, caregivers said:

> *It would be more convenient if there was an app.*
>
> *Having Pat have a voice would be great.*

Such features were incorporated for the final cohorts, but initially, the web app supported only text.

The "overall satisfaction without recommendations" theme reflected participants' approval of the program without suggesting changes.

> *Everything was excellent! I recommend it! It changes families' lives.*

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The "content adaptation" theme included recommendations to tailor Pat's content to caregivers' specific contexts, children's developmental stages, and family dynamics. Suggestions included each parent having a unique username when both parents of a child participated so that Pat could understand the unique dynamics of each parent and provide tailored guidance.

The "resources and support materials" theme captured requests for complementary resources and printable materials to support learning and follow-up, such as adding visual resources.

Table 4. Themes specific to Pat.

Sentiment and topics	Definition	Example quotation	Total frequency (N=164), n (%)
Positive sentiment			
24/7 Accessibility	Constant availability of the platform, valued for being able to access it at any time of day, even outside of professional business hours.	"Because it is like having a therapist at home 24/7. It is comforting."	69 (42.1)
Useful strategies	Providing practical, applicable, and effective tools for addressing complex parenting situations, backed by a solid professional and academic foundation that guarantees their quality and relevance. The approach is perceived as novel and innovative, incorporating distinctive approaches and formats that enrich the user experience.	"It gives me concrete tools to help my son, which have brought objective and positive results for him and our family."	54 (32.9)
Emotional support and containment of Pat	A feeling of being emotionally supported through the platform, especially during times of high emotional demand, generating relief, understanding, and containment.	"...that she understands me and that I can express everything that is happening to me...and for a while with Pat, when I have time, I can talk without rushing...and she always gives me a solution and support for everything."	33 (20.1)
Neutral sentiment			
Preference for human support	Explicit preference for human contact (meetings with professionals) over the use of technological tools, valuing the direct link as more effective or meaningful.	"I found the work in meetings with professionals more interesting and specific."	6 (3.7)
Limitations at critical moments	Difficulties expressed by users when trying to access or receive help from the platform at critical moments, where a more immediate or decisive response was expected.	"There are times, especially in times of crisis, when it is difficult to consult at the moment."	1 (0.6)
Negative sentiment			
Difficulty trusting the app	Accounts that express doubts, skepticism, or difficulty in establishing a relationship of trust with the app, especially when compared to human professional judgment.	"I still have a hard time trusting an app can give me more accurate answers than a professional who evaluates my son and the family group."	1 (0.6)

Relative Contribution to Progress

Caregivers reported attributing, on average, 61% of the progress to Pat and 46% to the group sessions. When asked to estimate what percentage of their child's progress they attributed to Pat compared to the live group sessions (see Multimedia Appendix 1 for a graphical representation), percentages exceeded 100% because several caregivers assigned overlapping credit to both components. Their qualitative explanations for these attributions revealed three main categories: (1) favor Pat, (2) favor group sessions, and (3) favor a combination of both Pat and group sessions (Table 5). The largest proportion of responses favored Pat (45/106, 42.5%), primarily due to its practical tools and specific strategies, its emotional support and personalization, and its constant accessibility. The caregivers were satisfied with the group experience, but the accessibility and immediacy of Pat were valued even more:

> *The professionals are excellent, and the parent group sessions are great too, but I cannot always participate because of my busy daily routine with the kids. Pat, however, is available 24/7; even if problems come up at any time of the day or night, I can ask for its help.*

A second group of caregivers (44/106, 41.5%) emphasized the importance of the group sessions, highlighting the clear and reliable professional support and shared learning with other caregivers they provided. Caregivers expressed they most valued the presence of the therapists, as well as the value in interacting with and listening to other caregivers, which they found reinforced theories learned. Finally, a smaller subset (17/106, 16%) of caregivers emphasized the complementarity between both delivery approaches, describing how the combination of Pat and live group sessions yielded the greatest benefit, as they were able to learn from Pat and then discuss and expand what was learned in the group.

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Table 5. Themes about the preference for Pat, group, or Pat plus group sessions.

Preference and topics	Definition	Example quotations	Partial frequency, n (%)
Preference for Pat (total frequency: 45/106, 42.5%)			
Constant availability and accessibility	Assessment of immediate and continuous access: 24/7 support, consultation, or emotional release in critical moments.	• "Pat helps you put out those fires in critical moments." • "With Pat available 24/7, you feel supported at all times." • "Pat's daily contact allowed for a more personal connection to our difficulties."	18 (40)
Practical tools and strategies	Pat is perceived as a resource that provides clear, applicable guidelines.	• "Pat helps us with specific questions about how to talk to the child or how to handle specific situations." • "I found it very helpful to read and complete the online module with Pat."	18 (40)
Emotional support and personalization	Pat offers not only strategies but also support, closeness, and a sense of individualized accompaniment.	• "The daily contact with Pat allowed for a more personal understanding of our difficulties." • "It allows me to elaborate more on my daughter's specific needs and behaviors."	9 (20)
Preference for group sessions (total frequency: 44/106, 41.5%)			
Clear and reliable professional support	The meetings are valued for their technical clarity and the warmth of the professionals, who provide structure, practical guidance, and security in the process.	• "I think you are very clear and engaging." • "What I value most is the presence of the professionals." • "The interaction with the specialists is very enriching."	14 (32)
Shared learning with other parents	Interaction and exchange with other families are perceived as opportunities for learning, personal relief, and normalization of parenting difficulties.	• "Seeing that there are other realities that are the same or even worse made us feel less bad." • "Interacting with and listening to others; the group reinforced theoretical aspects."	13 (30)
Emotional support and a sense of belonging	The emotional support received during the meetings is noteworthy, as it generates calm, validation, and a feeling of not being alone in the parenting process.	• "Sharing with other parents… helps keep you grounded." • "Group discussions give you peace of mind."	12 (27)
In-depth analysis and theoretical framework	The meetings allow for a more reflective approach, with theoretical explanations that enrich the understanding of difficulties and provide a solid conceptual framework.	• "The meetings helped me stay focused and try to stick to the treatment."	5 (11)
Preference for Pat + group sessions (total frequency: 17/106, 16.0%)			
Synergy between Pat and group sessions	The greatest benefit arises from using both modalities together: Pat provides immediate and personalized support, while the meetings provide containment and a human framework.	• "Pat complements very well what we are guided by and discussed in the groups." • "Both options complement each other and are essential."	17 (100)

Discussion

Principal Findings

This study aimed to understand caregivers' experiences with a hybrid PMT program that combined live, therapist-led group sessions with asynchronous support from Pat, an AI-based CA. Overall, caregivers reported high satisfaction, reflected in an NPS of 76.92, which is considered excellent. Qualitative analyses revealed overwhelmingly positive feedback about the program overall and specifically about Pat. Regarding the overall program, caregivers highlighted its practical tools, the support and sense of community fostered by the group format, and positive changes observed. Comments specific to Pat emphasized its constant availability; its sense of empathy, containment, and companionship; and the useful strategies it taught.

Caregivers reported more benefits from Pat than from the live sessions, with approximately 61% of the improvement being

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assigned to Pat and 46% to the live group sessions. These percentages suggest that both components played significant and overlapping roles in promoting change. However, caregivers leaned more toward Pat, and most responses highlighted the importance of the in-the-moment support provided by Pat. Although these findings should be considered with caution as this was a survey, taken together, the findings highlight the positive acceptance of caregivers of the hybrid model and the complementary benefits of incorporating AI to enhance the support provided to caregivers of children with disruptive behaviors.

Themes About the Overall Program

Caregivers reported highly positive experiences with the hybrid PMT program (56.3%), and a considerable portion of the positive comments were specific to Pat (43.7%), emphasizing the value of both the live group sessions and the AI support. The most frequent theme caregivers reported appreciation for was professional and peer support. The comments on the benefits of the live group sessions emphasize the important role of a human connection in PMT. Caregivers valued the professional guidance, empathy, and validation provided by therapists, as well as how sharing with other caregivers going through the same difficulties helped them feel less alone and more supported. These findings align with prior research showing that the relational and collaborative aspects of group-based interventions enhance motivation, accountability, and learning through social modeling [3,13]. Other major themes were useful strategies (clear tools and guidance offered) and the positive changes observed by the caregivers. Given the well-established evidence on the efficacy of PMT, these themes are not surprising. However, delivering PMT in group format through videoconferencing with AI to provide extra support is a novel way of delivering parenting skills, and these findings provide preliminary support to the use of AI as a complement to traditional parenting programs delivered online.

Themes Specific to Pat

Caregivers revealed several aspects of Pat that were particularly valued and that align with prior research on CAs in mental health care. The most frequently valued theme was constant accessibility and usefulness. Caregivers appreciated having immediate access to guidance and strategies that could be applied when needed, filling the support gap between sessions; something that traditional therapist-only formats cannot provide. This accessibility may play a critical role in increasing adherence, skill generalization, and caregivers' sense of self-efficacy. The second-most frequent theme was the emotional support and containment perceived by caregivers from Pat. Caregivers reported that they felt understood and accompanied, even during difficult moments. These perceptions suggest the emergence of a working alliance with AI, an experience that has also been observed in several studies on CA [36,40,41]. Collectively, these findings suggest that when AI systems are carefully designed and embedded within a human-supervised framework, they can provide not only practical guidance but also a sense of emotional presence that supports caregiver engagement and adherence to the program. Caregivers also valued the practical tools given by Pat, reflecting that Pat's support represented not just emotional support but also a practical resource in moments of need. The themes seem to indicate patterns observed in prior studies showing that CAs are acceptable and capable of sustaining user satisfaction over time [25,28].

Caregivers' improvement recommendations highlighted opportunities to enhance technological functionalities, such as adding a mobile app or a voice interface for Pat (which was included only for the final cohorts). Suggestions for content adaptation emphasized tailoring examples and guidance to each family's context and each child's developmental stage, while requests for additional resources pointed to the value of complementary materials to support practice at home. Overall, these recommendations suggest that ongoing improvements in personalization, accessibility, and usability could further strengthen caregivers' experience and sustained engagement with the program.

Progress due to Pat With Group Sessions

Caregivers' reflections on the relative contribution of Pat and the live group sessions, in the context of a combined model, further illustrate the complementary nature of this hybrid approach. Although caregivers attributed a considerable portion of the progress to both Pat and the group sessions, contrary to our expectations, caregivers attributed more progress to Pat than to their participation in the group sessions with professionals and other caregivers. This finding was unexpected, who anticipated that caregivers would report the support of the professionals and other caregivers as the most valued aspect. Again, this finding should be considered in the context of both elements (chats with Pat and group participation) being used together, and it does not mean that one element is better than the other. Professionals in the group setting prompted the use of Pat, and without this human support, parents might not have engaged with Pat. Thus, the contribution of each element depends on each other. When asked why they attributed the progress to Pat, caregivers again specified the companionship, constant accessibility, practical tools, and individualized guidance from Pat as reasons. The caregivers who preferred the group sessions emphasized the professional expertise and shared learning from other caregivers. A smaller group described the synergy between both elements, noting that Pat helped them apply what was discussed during live meetings. Together, these findings suggest that combining continuous, AI-based support with human-led group interaction can optimize learning, adherence, and confidence in implementing parenting strategies. Again, these findings should not be interpreted as a preference for an AI versus a therapist, as this question was implemented in a context in which both resources were designed to help each other in a group setting.

Practical and Clinical Implications

The findings of this preliminary study have several implications for clinicians, program developers, and health systems. For clinicians, hybrid models that combine live PMT through videoconferencing with AI support can enhance scalability and continuity of care, allowing families to receive personalized guidance from their homes and receive support between sessions without increasing therapist workload. AI tools, such as Pat,

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can function as engagement boosters (ie, reminding, reinforcing, and tracking caregivers' use of skills). Although this study did not analyze engagement, other studies on group interventions with adults with depression have shown that AI could enhance the engagement with the treatment and improve outcomes [22]. For developers, including accessible resources (eg, apps) and voice features to avoid typing will be essential to ensure smoother engagement with the CAs. Finally, for health systems, integrating AI-supported interventions could lead to greater accessibility and cost efficiency, reducing logistical barriers, such as time, transportation, and provider shortages, that often limit families' participation in evidence-based parenting programs.

Limitations and Future Directions

Several limitations should be considered when interpreting the findings reported here. First, the study relied on real-world, cross-sectional, and self-report data, which may be influenced by recall or social desirability biases. Second, there was no control group or pre-/postmeasurement of child behavior change, preventing conclusions about child behavior outcomes or causal effects. Third, the sample likely reflects a degree of selection bias, as participating caregivers were digitally literate, motivated, and had consistent internet access, and we do not know the impressions of those who did not complete the surveys. Additionally, the percentages attributed to Pat and the live sessions represent subjective perceptions rather than objective estimates of causal contribution. Finally, because the study was conducted in Argentina and Paraguay, findings may be context bound and not fully generalizable to other cultural or health care settings. To note, most evidence-based parenting interventions (including PMT) have been developed and tested primarily in high-income, English-speaking contexts, often with non-Hispanic White samples [42]. This study provides a unique contribution to the field by including a Latin American population that often lacks mental health resources and is understudied.

Future research should build on these findings by using RCT designs to examine the causal effects of hybrid, AI-supported PMT compared to traditional formats. A key next step is to quantify the therapeutic alliance that may develop between caregivers and AI agents, given caregivers' reports of empathy and support from Pat. Finally, future evaluations should incorporate child-level outcomes (eg, behavioral improvements) and family-level outcomes (eg, reductions in parenting stress and improvements in family functioning) to determine the broader impact of this approach on both caregivers and children.

Conclusion

In this preliminary investigation, caregivers reported positive experiences with a hybrid program combining live videoconferencing group PMT sessions plus an AI. Delivering PMT in group format and through videoconferencing increases the scalability of the workforce and increases accessibility to the resources. Furthermore, the integration of AI (Pat) expanded the benefits of traditional PMT by continuing the delivery of skills and providing personalized, on-demand support between sessions. Caregivers valued Pat's immediacy and practicality, noting that "Pat helps us with specific questions about how to talk to our child or how to handle situations," as well as its constant availability, sharing that "having Pat 24/7 makes you feel supported at all times." Together, these components created a synergistic model in which human expertise and empathy were complemented by AI-driven accessibility and continuity, reducing barriers, such as time, cost, and clinician availability. This hybrid approach appears to make PMT more flexible, scalable, and sustainable without sacrificing the relational quality that remains central to therapeutic success.

Acknowledgments

ChatGPT 4.0 was used to draft some sections of the initial manuscript based on an outline provided by the authors. In addition, ChatGPT 4.0 was used to translate qualitative responses from Spanish to English.

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Data Availability

The datasets generated or analyzed during this study are not publicly available due to difficulty in anonymizing qualitative messages but are available from the corresponding author upon reasonable request.

Authors' Contributions

The authors reviewed and edited several subsequent versions and take full responsibility for this manuscript's originality, content, and validity.

Conflicts of Interest

ELB is the CEO, cofounder, and stock owner of ParenteAI. AYH is a scientific advisor, cofounder, and stock owner of ParenteAI. No part of the research reported here was completed at Stanford University.

Multimedia Appendix 1

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Graphical representation of the relative contribution of Pat or group sessions to the caregiver's child's progress.
[PDF File (Adobe PDF File), 27 KB - formative_v10i1e91841_app1.pdf]

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Abbreviations

AI: artificial intelligence
CA: conversational agent
IRR: interrater reliability
NPS: net promoter score
PMT: parent management training
RCT: randomized controlled trial

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Original Paper

Co-Design of a Depression Self-Management Tool for Adolescent and Young Adult Cancer Survivors: Rapid Qualitative Analysis of Interview Feedback on a Prototype

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Abstract

Background: Over 2.1 million adolescent and young adult cancer survivors (AYACS) live in the United States. Recent estimates suggest that up to one-third of AYACS experience major depressive disorder. Although several efficacious evidence-based interventions are available to manage symptoms of depression, these interventions are often inaccessible to AYACS who have many competing commitments. Digital mental health tools hold promise for this population; however, only a few have been tailored to meet the unique needs of AYACS, and findings to date have yielded mixed results.

Objective: This study aims to obtain feedback from AYACS on a mid-fidelity prototype of a depression self-management tool being tailored for AYACS.

Methods: Individuals with a history of cancer diagnosed at age 12 or older who were between the ages of 15 and 39 and had completed primary treatment were identified through a review of medical records from a comprehensive cancer center in the Southeastern United States. Potentially eligible participants were contacted by study staff to conduct additional screening and obtain informed consent via REDCap (Research Electronic Data Capture; Vanderbilt University). Upon enrollment, participants provided demographic and clinical information, as well as their availability for an interview. The principal investigator (KMI) conducted semistructured individual interviews with consented AYACS. Most of the interview was dedicated to showing participants the mid-fidelity prototype of the tool, explaining how the prototype might work, and requesting targeted feedback. Demographic and clinical characteristics, as well as some aspects of feedback on the prototype, were summarized using descriptive statistics. Interviews were audio- and video-recorded and transcribed. The transcriptions underwent rapid qualitative analysis guided by the Rigorous and Accelerated Data Reduction technique.

Results: A total of 14 AYACS (n=9, 64%, female; n=9, 64%, white; ages 15-38) completed an individual interview. Participant preferences for mood tracking, content presentation, user input, and duration of use were captured qualitatively but analyzed quantitatively. For example, most participants (n=10, 71%) indicated that they preferred a mood-tracking option that included emojis and would be willing to track their mood at least once per day (n=11, 79%). Participant preferences captured qualitatively

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fell into 4 themes: (1) features to promote user engagement (eg, the use of gamification); (2) tailored content presentation (eg, authenticity in the portrayal of the cancer experience); (3) perceived usability (eg, simplifying user input); and (4) interface design (eg, implementing a coherent design theme and color scheme).

Conclusions: Findings indicated that AYACS highly value personalization, flexibility, and peer support in digital interventions. Based on insights obtained during individual interviews, a working prototype was developed by reprogramming an existing digital tool. Qualitative and quantitative findings informed modifications to the existing digital tool. The working prototype will next undergo evaluation as part of a pilot full-factorial trial.

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KEYWORDS

adolescent and young adult; cancer survivorship; depressive symptoms; self-management; individual interviews; user-centered design; rapid qualitative analysis; intervention tailoring; digital mental health

Introduction

As of 2020, around 2.1 million adolescent and young adult (AYA; ages 15-39) cancer survivors (AYACS) live in the United States, with this number projected to grow as the incidence of cancer in this age group rises. Additionally, nearly 90,000 AYAs receive a cancer diagnosis each year in the United States [1,2]. Given the complexities of an AYACS' life, significant disruptions to personal milestones (eg, career establishment, family development, and financial stability) may cause elevated depressive symptoms [3].

Indeed, it is estimated that AYACS are 1.3-fold more likely to experience depression than older cancer survivors or cancer-free counterparts [4]. Increased depressive symptoms can result in poorer quality of life, lower adherence to medical recommendations, increased health care costs, and elevated mortality risks [5]. Unlike other factors that contribute to these problematic outcomes (eg, genetics), symptoms of depression are treatable and represent an ideal target for behavioral interventions. AYACS are estimated to have a prevalence of major depressive disorder of 25%-32% [6].

The American Psychological Association clinical practice guidelines recommend cognitive behavioral therapy (CBT) as an effective method for treating depressive symptoms [7]. CBT is well documented as an effective treatment for managing depressive symptoms in patients with cancer and cancer survivors [8-10]. Patients who experience depressive symptoms can utilize CBT to identify and alter negative automatic thoughts and maladaptive behaviors through the practice of cognitive restructuring and behavioral activation [11]. Expanding on CBT, mindfulness-based CBT integrates principles of mindfulness-based stress reduction, which encourages individuals to develop a different relationship with their thoughts and emotions [7,12]. This added focus on mindfulness may further enhance the effectiveness of treating depression by promoting greater acceptance and awareness of one's mental state. In addition to these evidence-based therapies, a growing body of literature highlights the use of positive psychology interventions to improve mental health outcomes in individuals with severe and chronic illnesses. Recent systematic reviews and meta-analyses of positive psychology interventions found a small-to-moderate effect on depressive symptoms and suggest that these interventions may be more effective than other interventions targeting depression [13,14]. Overall, several efficacious evidence-based interventions (EBIs) are available to manage symptoms of depression. AYACS face a heightened risk of depression, yet the accessibility of EBIs for managing depression remains uncertain. Findings from the AYA Health Outcomes & Patient Experience study revealed that 56%-75% of AYACS reported unmet psychosocial support needs 1 year after diagnosis [15].

Providing accessible psychosocial interventions to support the AYACS population is critical for managing and treating depressive symptoms [16]. Barriers to accessing psychosocial interventions for AYACS are limited access to in-person services and difficulties fitting therapy sessions into their schedules, as many are offered only during standard business hours [16]. Digital mental health interventions offer numerous benefits that enhance the accessibility of mental health care for busy AYACS. Digital tools provide a convenient way to access support and resources, allowing individuals to seek help from the comfort of their homes. Furthermore, digital mental health solutions can reach underserved populations in remote or low-income areas [17]. EBIs can be provided remotely through smartphone technology, which is widely accessible to most AYACS, enabling broad scalability [18,19]. Research has shown that digital tools can effectively support AYACS in managing physical symptoms [20]. Additionally, psychosocial interventions have been successfully adapted for digital formats, demonstrating their effectiveness in healthy AYA populations [21-24]. Despite this progress, there is limited research assessing the impact of digital interventions that specifically assist AYACS with depression. For instance, a recent meta-analysis of online mental health interventions targeting pediatric and AYACS revealed a small pooled effect size (g=0.17, 95% CI –0.40 to 0.74) with significant heterogeneity (I^2=71%) and no significant differences between intervention and control groups (Z=0.59, P=.55) [25]. This finding highlights the overall limited and inconsistent efficacy of current interventions for managing depressive symptoms in AYACS. As such, there is a critical need to develop efficacious interventions to manage depressive symptoms in AYACS.

This study is part of a larger, 5-year project that follows the Multiphase Optimization Strategy framework [26]. The framework comprises 3 distinct phases. The preparation phase sets the groundwork for the intervention's development, involving the selection of a guiding conceptual model, the identification of potential intervention components, and the

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completion of formative and pilot research. The optimization phase uses a factorial experiment to assess which components most effectively meet the criteria for improving the intervention [26,27]. Lastly, the evaluation phase tests the efficacy of the optimized intervention. Our work to date addresses tasks within the preparation phase, gathering formative data that will shape the design and functionality of the digital tool [28]. This work has been informed by the user-centered design process proposed by McCurdie et al [29]. This process begins with concept generation and ideation involving the user. To achieve this step, we previously conducted co-design workshops to tailor a digital self-management tool for AYACS experiencing depressive symptoms [30]. We then engaged in initial prototype design, the second step of the user-centered design process. The resulting mid-fidelity prototype is a mock-up of the tool, which is planned to include features such as mood tracking, psychoeducation about depression and cancer, and adaptations of evidence-based care (eg, behavioral activation, cognitive restructuring, mindfulness training, and positive psychology). In this study, we engaged in the evaluation step of this process by conducting individual interviews with AYACS to collect targeted feedback on the mid-fidelity prototype. Finally, we returned to the second step of the user-centered design process by designing and developing a working prototype.

Methods

Overview

AYACS provided feedback on the mid-fidelity prototype during individual interviews. Individual interviews were conducted via Cisco Webex by KMI. KMI is a female researcher with a PhD in Clinical Psychology and extensive training in qualitative data collection methods, including a certificate in user-centered design. At the time of the study, KMI was an Instructor at the Wake Forest University School of Medicine. She did not have a relationship with study participants before study commencement, although some participants had previously engaged in co-design workshops with KMI as part of the larger study. Participants were informed that the primary purpose of the interviews was to inform the development of a digital tool to help AYACS better manage symptoms of depression. Each interview lasted approximately 1 hour. Transcripts of the individual interviews underwent rapid qualitative analysis to determine what changes should be made to the mid-fidelity prototype. The findings informed the design of a working prototype.

Recruitment and Enrollment

Potentially eligible AYACS were identified through electronic medical record review at a large academic medical center in the Southeastern United States with a National Cancer Institute–designated comprehensive cancer center. At the time this study was conducted, this center served over 1300 AYACS annually. Based on the surrounding county demographics, the average minority distribution of AYACS was estimated to be approximately 13% African American, 2% Asian/Pacific Islander, 13% other/non-White, and 8% Hispanic/Latinx.

Potentially eligible participants were identified from the electronic medical record if they met the following criteria: (1) currently between the ages of 15 and 39; (2) diagnosed with cancer between 12 and 39 years of age; and (3) between 1 month and 5 years after completion of primary treatment for their cancer. Study staff contacted potentially eligible patients or their parents/guardians (for adolescents) by sending a message about the study through the electronic patient portal. Follow-up calls or emails were sent within 2 weeks to nonresponders. Across all modes of contact, we attempted to reach potentially eligible participants no more than 3 times before receiving a response. Recruitment materials directed interested individuals or their parents/guardians to a REDCap (Research Electronic Data Capture; Vanderbilt University) [31] screening form to confirm their eligibility for the study. In addition to evaluating the criteria described above, this form was also used to ensure that the patient (1) was fluent in spoken and written English; (2) owned a smartphone with a data plan; (3) had access to a computer with internet access, a webcam, and a microphone that could be used to participate in the interview; and (4) did not have a current diagnosis of a severe or persistent mental illness. Eligible patients and, in the case of adolescents, their parents/guardians were automatically directed to complete digital assent/consent forms. If eligibility could not be determined based on the screening form alone, study staff contacted the participant to make a final determination regarding eligibility for the study and, if eligible, manually sent the participant the digital assent/consent forms.

Upon providing assent/consent, AYACS were asked to provide demographic and clinical information, along with their availability to participate in study procedures. Study staff then contacted the participant to schedule the interview.

Ethical Considerations

All study procedures were reviewed and approved by the Wake Forest University Health Sciences Institutional Review Board (IRB00075887). Participants provided informed consent or assent before engaging in the interview by reviewing and signing a REDCap form. This REDCap form included a brief overview of the study, information about study procedures, details regarding the risk level of the study (minimal risk), potential risks (eg, breach of confidentiality) and benefits (eg, helping others), compensation information, and ways to contact the principal investigator and Institutional Review Board. For adolescents, parents were initially contacted and asked to provide permission for the adolescent to participate. Study staff contacted adolescents directly only after parental permission was provided.

All data were collected remotely using platforms designated as compliant with the Health Insurance Portability and Accountability Act (HIPAA) and stored on secure, password-protected servers accessible only to study staff. Individual interview recordings were transcribed and deidentified for analysis. All information linking participants to their data will be deleted upon publication of the primary study outcomes.

To compensate participants for their time, a US $40 digital gift card was emailed to the participant following the interview.

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Individual Interviews

All interviews were conducted via Cisco Webex. Participants were asked to complete the interview in a quiet, private space. Only KMI and the participant were present during the interview. At the beginning of each interview, KMI provided context regarding the project goals and the work completed thus far (ie, co-design workshops with AYACS and providers). Most of the interview was dedicated to showing participants the mid-fidelity prototype of the tool, explaining how each page of the prototype might work, and requesting targeted feedback (see Multimedia Appendix 1 for example interview questions and associated slides; questions were not pilot-tested before study commencement). At the end of the interview, participants were also asked to provide any additional feedback that had not been shared during the interview.

Data Processing and Analysis

Individual interviews were recorded and auto-transcribed using Cisco Webex software. Given these recordings, field notes were not made by KMI, and transcripts were not returned to participants for comment or correction. Transcripts were cleaned by study staff. The original audio/video recordings were consulted as needed for clarification. Our sample size of 14 is within the recommended number of interviews needed to reach saturation in qualitative research [32] and in other work focused on developing digital interventions for young cancer survivors [33].

Guided by the Rigorous and Accelerated Data Reduction technique for rapid qualitative analysis [34], we derived themes from the data. Interview transcripts were organized by interviewee, aspect of the digital tool in question, and specific interview questions in an Excel spreadsheet (Microsoft Corporation) to serve as the phase 1 data table. Next, 2 coders (KMI and GW) collectively brainstormed an overarching question to determine which responses would be included in the reduced phase 2 data table: What changes do we need to make to this prototype to more fully integrate AYA needs and preferences for a digital tool to help them manage depressive symptoms? A response was included in the coding process only if it answered this question directly. The coders independently determined whether each response met this criterion. They then compared and discussed their decisions to form a final list of responses to be included in the coding process. During this process, the coders also identified data they believed would be best captured quantitatively. This approach was most often warranted when the interviewer presented the interviewee with options from which to choose, allowing the interviewee to express a preference. For example, participants were shown several options for what the mood rating scale might look like and were asked how often they would be willing to track their mood. Choosing to capture data quantitatively did not preclude including associated context in the qualitative coding process. Quantitative data were summarized using descriptive statistics.

Next, the coders individually developed preliminary codes for the first 3 interviewees' responses. They then compared and discussed these code ideas to determine the final codes for each response. Throughout this process, the coders attempted to use as much of the interviewees' original language as possible to carry forward the interviewees' sentiment. The coders then repeated this process with the next 3 interviewees' responses, creating and adding new codes as needed until all interviewees' responses were coded.

Following the application of codes to all interviewee responses, the coders reviewed the codes and began organizing them into themes and subthemes. Themes and subthemes were derived both empirically, based on the interview transcripts, and a priori using existing coding schemes from related work [35,36]. Coders applied themes and subthemes independently, then compared and discussed them to determine the final themes for each code, returning to the response data as needed. A final version of the data table was created to assist with the identification of major codes and illustrative quotes that helped define, refine, and illustrate the identified themes. Participants were not offered the opportunity to provide feedback on the findings.

Design and Development of a Working Prototype

Based on feedback and recommendations from the interviews, revisions to the prototype were identified by the study team. BrightOutcome provided reprogramming of an existing digital tool (EMPOWER) [37-39] to meet the technical, functional, and aesthetic preferences of end users based on our co-design process.

Specifically, for each property of a subtheme identified through qualitative analysis, a determination was made as to (1) whether a change was needed (eg, no feature addressing a property already existed within the prototype, the existing tool being adapted, or both; the change aligned with best practices for design); (2) what change should be made (eg, the study team's recommendation for how to best address a property through a specific adaptation); and (3) whether the change was feasible within the constraints of the budget and timeline of the current project. At times, feasibility also informed decision-making (eg, if an existing feature of EMPOWER addressed a property of the subtheme, additional features were not added). Changes that were deemed ideal by the study team but were not feasible were retained as potential future changes.

Adaptation of Evidence-Based Interventions for Depression

In conjunction with developing the digital platform through which content would be delivered, we adapted 4 EBIs for depression (behavioral activation, cognitive restructuring, mindfulness training, and positive psychology interventions) for digital delivery to AYACS in accordance with the first 3 steps of the planned adaptation approach [40]: (1) examine the theory of change; (2) identify population differences; and (3) adapt program content in a manner that retains the core functions of the intervention (eg, for behavioral activation, increasing engagement in enjoyable activities) while allowing for tailoring (eg, using examples and stories to demonstrate how core functions such as engagement in enjoyable activities might look different for AYACS than for their noncancer peers).

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Results

Participants

Fourteen AYACS participated in the individual interviews. At the time of the interview, AYACS ranged in age from 15 to 38 years (mean 25.7, SD 9.14 years). AYACS were diagnosed with cancer between the ages of 13 and 37 (mean 23.4 years, SD 8.9 years) and were between 1 and 55 months posttreatment (mean 23.7 months, SD 16.1 months). The majority of AYACS identified as non-Hispanic White, female, and heterosexual (see Table 1 for additional details).

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Table 1. Demographic and clinical characteristics of adolescent and young adult cancer survivors who participated in individual interviews (N=14).

Characteristic	
Group	Values, n (%)
Sex	
Female	9 (64)
Male	5 (36)
Race	
Black/African American	2 (14)
Native American/Alaska Native	1 (7)
White/Caucasian	9 (64)
Mixed racial background	1 (7)
Other race	1 (7)
Ethnicity	
Hispanic	1 (7)
Non-Hispanic	13 (93)
Level of education	
Some high school	3 (21)
High school diploma or equivalent	2 (14)
Some college	2 (14)
College graduate	4 (29)
Graduate degree	2 (14)
Sexual orientation	
Heterosexual	13 (93)
Prefer not to answer	1 (7)
Cancer type[a]	
Bone	2 (14)
Brain	1 (7)
Breast	2 (14)
Gastrointestinal stromal tumor	1 (7)
Leukemia	1 (7)
Non-Hodgkin lymphoma	3 (21)
Sarcoma	1 (7)
Testicular	1 (7)
Thyroid	3 (21)
Marital status	
Single, never married	8 (57)
Married	6 (43)
Have children	
Yes	4 (29)
No	10 (71)
Household income (US $)	
Less than 25,000	0 (0)
25,000 to 34,999	2 (14)
35,000 to 49,999	0 (0)

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Characteristic	
Group	Values, n (%)
50,000 to 74,999	2 (14)
75,000 to 99,999	2 (14)
100,000 to 124,999	2 (14)
125,000 or more	1 (7)
Do not know/prefer not to answer	4 (29)
Health insurance	
Private	9 (64)
Public	4 (29)
None	2 (14)

[a]Percentages add up to >100% because 1 participant reported being diagnosed with both bone cancer and non-Hodgkin lymphoma.

Quantitative Outcomes

Overview of Themes

Participant preferences captured quantitatively fell into 4 key areas: (1) mood tracking; (2) content presentation; (3) user input; and (4) duration of use.

Mood Tracking

To evaluate preferences for mood tracking, participants were asked what format they would prefer for the response options for mood tracking, how often they would want to track their mood, and how mood data should be displayed. The majority of participants (n=10, 71%) indicated that they preferred an option that included emojis and would be willing to track their mood at least once per day (n=11, 79%). Users preferred to be able to review a month's worth of data (n=7, 50%) via a calendar display that showed their mood each day using an emoji (n=8, 57%).

Content Presentation

Regarding content presentation, participants indicated that they would want to view stories of the experiences of other AYACS as live-action videos (n=12, 86%), with a slight preference for AYACS themselves sharing their stories (n=7) rather than actors (n=5). However, for educational information, participants suggested that presenting the content in multiple formats (ie, a combination of video, audio, and text) would be preferred (n=12, 86%). There was no clear consensus on whether live-action or animated videos would be preferred for educational information.

User Input

More participants reported that mood and activity tracking should be conducted using multiple-choice questions (n=7, 50%) rather than free-text response boxes (n=3, 21%) or a chatbot (n=4, 29%). In this context, 5 participants also suggested including an "Other" option that allows for free-text responses. Half of the participants indicated that they would be willing to complete a practice activity at least once per day (n=7, 50%). Participants suggested that multiple-choice questions should also be used when reflecting on the stories of other AYACS (n=11, 79%), whereas free-text responses were preferred for reflecting on their own experiences (n=10, 71%).

Duration of Use

When asked how long participants would want to spend completing a lesson like the one presented in the example, responses ranged from less than 5 to 90 minutes, with most responses (n=8, 57%) falling between 5 and 30 minutes. When asked how long they could see themselves using a tool like this, responses ranged from 1 month to several years, with many participants suggesting that it would depend on factors such as whether they found the tool helpful, how they were doing medically and psychologically, and whether they had developed relationships with other users.

Qualitative Outcomes

Overview of Themes

Participant preferences captured qualitatively fell into 4 themes: (1) features to promote user engagement; (2) tailored content presentation; (3) perceived usability; and (4) interface design.

Theme 1: Features to Promote User Engagement

Overview of Subthemes

Participants provided feedback regarding potential changes to existing features included in the prototype and suggested the addition of new features to help ensure that users remain engaged with the digital tool. Within this theme, 4 subthemes were identified: communication, options, reinforcement, and value.

Subtheme 1.1: Communication

Participants emphasized that the opportunity to connect with other cancer survivors around their age would increase their engagement with the tool. They suggested that AYACS would be more interested in conversations about the unique experience of being an AYACS rather than in conversations tied directly to the content presented through the tool (see the "Subtheme 4.3: Organization" section).

> *Interviewer: What would make cancer survivors your age want to use this tool?*
>
> *Participant: Being able to interact and connect with other people who have gone through the same thing.* [16-year-old female bone cancer survivor]

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> *If I was having a conversation or if there was a discussion board and everyone was really engaged in it, that might be really fun, and I might do that for a while. So, I'd maybe spend 5 minutes on it but then there's also like other stuff going on in the app that's more fun.* [25-year-old female sarcoma survivor]

Furthermore, participants expressed a desire for the tool to provide opportunities to connect with providers. They suggested that knowing a provider would review their responses would increase the likelihood that they would complete activities within the tool.

> *If I was using this tool for this reason, I would only spend time completing it and giving it attention if I knew that someone on the other side was going to take it and use it somehow. If it's going to help form a conversation with a provider next week. But if I'm just doing it because someone who created an app think it's helpful, I'm probably not going to put effort into it. ...But if you were my provider and I knew we had a quarterly meeting, then I would type something in because then I would anticipate that they would view it prior to our meeting.* [34-year-old male non-Hodgkin lymphoma survivor]

However, privacy also emerged as an important consideration; some participants felt it would be helpful to reflect on and process their experiences in a space that could not be viewed by others.

> *I don't want everyone to see what I'm doing. I know we're going through similar situations, but sometimes I like to keep stuff to myself.* [20-year-old female leukemia survivor]

Subtheme 1.2: Options

Participants thought that users should be allowed to view content in whatever order they choose. Having the option to access content as needed would allow them to tailor what they access to their needs in the moment.

> *Especially for me, with my cancer that I went through, I didn't really feel the depression at first. I felt like I needed more support so if you're not feeling like a certain way and that's the beginning, I think it wouldn't explain a lot of it until you get into it. So, I think if you could click at the point where you're at, it'll help you a bit more.* [32-year-old female thyroid cancer survivor]

Some participants were concerned that having the option to view any of the content they would like might be overwhelming, and recognized that there are individual differences in preferences for the level of autonomy.

> *I always appreciate freedom, but I know that most of my students, they get panicked when they have freedom. So, my preference is certainly not a universal preference.* [35-year-old male non-Hodgkin lymphoma survivor]

Participants also suggested that any practice activities in the tool should be optional.

> *I would like to be able to go try it and wait before I come back to it. Because I want to be able to implement those skills. But you might have people wanting to go straight through. So maybe give me the option. Maybe have a pop up notification that says you can choose to try it that week or you can go straight through.* [20-year-old female leukemia survivor]

Subtheme 1.3: Reinforcement

The most common recommendation from participants regarding how to ensure engagement with the tool was the use of gamification. Most AYACS felt that gamification could make the tool more interesting and fun, whereas others felt it might be inappropriate given the subject matter of the tool.

> *If it were to be something where you could accumulate points or something like that, you could redeem those points later on. And it would make it more interesting and more fun for them to answer those questions and put a little bit more effort into it.* [32-year-old female thyroid cancer survivor]

In addition to gamification broadly, participants suggested various reinforcement features that they had found helpful in other tools to ensure engagement, including the use of streaks, reminders, and a progress bar.

> *A lot of other apps use this, but you could use a streak, like how many days you've used it in a row, it could be on the calendar. That motivates people to keep doing it cause they don't want to lose their streak.* [15-year-old male gastrointestinal stromal tumor survivor]

> *I could just set it to where it goes off on my phone. I just click on it and choose how I'm feeling at that moment. So having a reminder notification to do it would be helpful.* [25-year-old female sarcoma survivor]

> *Interviewer: What would make it more likely that you would complete a session like this?*

> *Participant: A progress bar that shows how far you are within all the modules.* [16-year-old female bone cancer survivor]

However, participants also emphasized that it would be important to be able to turn off or manage the frequency of these engagement-promoting features because a variety of factors outside the tool may affect their use of it (eg, cancer trajectory, severity of disease, daily activities, and personal preferences).

> *I don't know if it's possible for the user to set their own settings or to mute it for the day or something like that. So they're not randomly being prompted to check in on the days that they're not doing well. That might be a good option. [later, in response to another question] I'm in a weird spot right now. I've had active treatment for 3 years so that was a very big part of my life. And now I don't have active treatment and there are days when I'm doing quite well and then there are days when things surface and I can make sense of them and then there are days when things*

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> *surface and I just can't make sense of it. I would like to not have the constant reminder. When I'm doing well, just let me do well. And when things are difficult, it would be nice to have a resource.* [35-year-old male non-Hodgkin lymphoma survivor]

Subtheme 1.4: Value

Some participants struggled to see the value of the tool for themselves and suggested that providing education about why they might find the tool useful early on would increase the likelihood that they would engage with it.

> *Not to diminish the tool, I just don't see the value for me personally. That's why I wouldn't spend a lot of time on it. Maybe if I was educated on the value it can provide for someone like you, maybe. But I don't think getting tokens or stars is going to change my mind.* [34-year-old male non-Hodgkin lymphoma survivor]

Additionally, participants noted that if they found the tool helpful, they would be more likely to use it in the long term.

> *If I feel like the app is working, I'm more likely to use it long term. If I feel like it's not doing anything, I'm more likely to delete it and just go on without it.* [20-year-old female leukemia survivor]

Theme 2: Tailored Content Presentation

Overview of Subthemes

Participants provided feedback regarding how to best tailor content to this target population. Within this theme, 7 subthemes were identified: accessibility of activities, authenticity, avoiding discouragement, duration, maturity level, normalization, and use of multimedia.

Subtheme 2.1: Accessibility of Activities

Participants expressed concern that certain activities, such as a walking meditation, might be difficult for some AYACS to complete. They suggested including modifications for these activities if they are incorporated into the final tool.

> *With mindful movement, there could be modifications in case someone can't do what they're doing in the video.* [15-year-old male gastrointestinal stromal tumor survivor]

Subtheme 2.2: Authenticity

Participants emphasized the importance of authenticity in the portrayal of information, as well as in the portrayal of AYACS in images throughout the tool. They also noted the importance of experts truly being experts rather than actors performing a role.

> *Hearing it come from an actual person would feel more understanding and it feels more human.* [16-year-old male brain cancer survivor]

Similarly, they desired imagery that conveyed the authentic, messy experience of having cancer as a young person rather than "branded cancer."

> *A lot of health care and cancer imagery is very much not like the experience. Even though I had people on my side, at no point was there someone just casually over my shoulder, holding my hand, and we were wistfully looking off into the distances with two cups of coffee...I just feel like my cancer experience was way more messy than this. So removing the image would be helpful here. If you actually do real interviews with real people and have a real photograph, then maybe that gets past it. But this is branded cancer - I bet that person doesn't have cancer. They just have a nice scarf on their head.* [35-year-old male non-Hodgkin lymphoma survivor]

Subtheme 2.3: Avoiding Discouragement

Throughout the tool, AYACS emphasized that users should not find the content discouraging. This concern was evident in their considerations of how mood data should be displayed over time, as well as how incorrect answers to multiple-choice questions should be addressed.

> *If you're going through a slump and it [the line graph] just keeps going lower and lower, that can be discouraging.* [21-year-old female non-Hodgkin lymphoma survivor]

> *I think it's okay cause they can go back and reflect on it and figure out what actually was the issue. Maybe after 2 wrong guesses, just kind of give them the correct answers so they're not just sitting there. They might get frustrated after a couple times. Younger people might not get what is actually starting the event of them getting depressed and it helps them reflect on it but then also not getting frustrated after 1 or 2 guesses.* [36-year-old female breast cancer survivor]

Subtheme 2.4: Duration

AYACS indicated that it would be preferable to have variation in lesson duration. They suggested that this would make the tool feel less "sterile" and allow them to choose a lesson based on its duration.

> *I would probably appreciate them being different lengths so that I can pick based on the amount of time that I'm either emotionally or physically able to invest.* [35-year-old male non-Hodgkin lymphoma survivor]

AYACS also noted that the duration of practice activities would affect the frequency with which they were willing to complete them and suggested that longer activities should be required less frequently than shorter activities.

> *If you ask them to do it every day, I'd keep it shorter, like 5 minutes. Or if they're longer, you could do 3 times a week or twice a week.* [15-year-old male gastrointestinal stromal tumor survivor]

Finally, there was no clear consensus on how long users might want to engage with the tool. While some felt that it might be most helpful years after the completion of treatment, when less support is available, others felt that the duration of their use

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would depend on their health, implying that it might be more helpful if their cancer recurred.

> *I think it would need to be available to people for a long time. In my case, it was a couple of years until I realized the trauma I'd been through and needed help getting through it. And at that point, I wasn't even seeing a doctor anymore. I didn't have any support.* [37-year-old male testicular cancer survivor]
>
> *Interviewer: How long can you see yourself using a tool like this?*
>
> *Participant: I think it would depend on how I'm doing medically.* [25-year-old female sarcoma survivor]

Subtheme 2.5: Maturity Level

AYACS recognized that preferences for content delivery may vary across the wide age range targeted by the tool. However, participants most consistently cautioned against presenting the content in a manner that would be perceived as juvenile.

> *A lot of the people you'll be dealing with are going to be very emotional because of what they're dealing with or have dealt with, but they've also matured in ways that their peers haven't. So, for me personally, I would disengage if it was too juvenile in nature.* [35-year-old male non-Hodgkin lymphoma survivor]

Subtheme 2.6: Normalization

It was important to AYACS that the tool normalize their experience, particularly regarding the impact of cancer on one's mental health.

> *Sometimes you may worry you're not normal during this time. So maybe listening to a psychologist talk about it, cause a lot of people don't like to ask for help.* [36-year-old female breast cancer survivor]
>
> *If there was a multiple choice and then you click on the choice. "Explain an event" - is it family, school, friends, social, financial, whatever. Then let's say you click "financial" and then it pops up a bubble that affirms that's a normal thought to have, or studies show that coming out, you may feel less motivated in your career. That makes sense to me. Even if it's a robot, at least someone is listening.... Just a blurb that affirms that you're not crazy.* [34-year-old male non-Hodgkin lymphoma survivor]

Subtheme 2.7: Use of Multimedia

AYACS suggested that using animation throughout the tool would make it more engaging, interactive, and fun. Additionally, AYACS felt that using animation to convey information about mental health could reduce stigma around mental health concerns and make the information easier to understand.

> *I like animated stuff. I think that's more engaging than a psychologist going through something.* [15-year-old male gastrointestinal stromal tumor survivor]
>
> *You go through different employer trainings. When something is animated, it takes the taboo or the stigma off of certain topics. It makes it more easy to understand. As opposed to reading it or having a formal psychologist reading it.* [34-year-old male non-Hodgkin lymphoma survivor]

While each participant expressed preferences for content presentation, they often suggested presenting content in multiple formats because of individual differences in how people prefer to consume information.

> *I know for myself, I like to read things. I don't like when someone else is reading to me, but everybody's different.* [20-year-old female thyroid cancer survivor]

Theme 3: Perceived Usability

Overview of Subthemes

Participants suggested strategies to enhance the perceived usability of the tool. Within this theme, 4 subthemes were identified: accessibility, clarity, navigation, and user input.

Subtheme 3.1: Accessibility

Participants recognized the importance of ensuring that content would be accessible to all users. In particular, they emphasized that it would be helpful to present information in multiple formats (ie, text and video or audio) and that text should be easy to read.

> *Having the transcript is good. You never know when you're going to be somewhere where you can't hear or watch, and it's good for accessibility too.* [37-year-old male testicular cancer survivor]
>
> *I think that the white color of the words could be hard to see. Because it's so light in the green.* [25-year-old female sarcoma survivor]

Subtheme 3.2: Clarity

Participants expressed a desire for greater clarity from the tool in several areas, most notably the name of the tool, the module overview, and how the tool would work. Specifically, participants expressed concerns about the use of the acronym "AYA" in the name of the tool.

> *iManageAYA would definitely make me curious, but maybe it should be explained more, like what AYA is.* [20-year-old female thyroid cancer survivor]

With regard to the module overview page, participants suggested using names that were more clearly distinct from one another and adding a description for each module. This would help users better understand which module they may want to engage with.

> *The Doing & Feeling, Thinking & Feeling, and Being & Feeling, maybe I'm not very educated in this space, but I don't understand how those are very different. Why would I click on one versus the other?...I can't distinguish between those three.* [34-year-old male non-Hodgkin lymphoma survivor]
>
> *I think it would be helpful to have descriptions of what they are rather than just those little snippets of Doing & Feeling and Being & Feeling. Especially if it was somebody who was a lot younger, because they might not have heard of those things before....it should be something a little bit more so that you know exactly what you're clicking on or even if you do keep the*

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> *titles, put something under it in parentheses that kind of sums up what that particular section is.* [38-year-old female breast cancer survivor]

Finally, participants noted that it would be helpful to include more information about how the tool's features work to prevent confusion.

> *Maybe you could have a note that says that once you complete a session, it will unlock the next one. That way people don't think that they can't get into it and that there's something wrong with the app.* [32-year-old female thyroid cancer survivor]

Subtheme 3.3: Navigation

Participants indicated that it would be important for users to be able to leave the tool and easily return to where they left off. Suggested strategies to achieve this included ensuring an easy log-in process and adding a bookmark feature.

> *Because I have a million passwords and it's hard to keep up with all of them. So having an easy log in process is key.* [32-year-old female thyroid cancer survivor]
>
> *I would definitely use [a bookmark feature] because I'm not as consistent as I'd like to be. So I can look at it for like 2 or 3 days consistently, and then I get busy and then I would like to remember where I can come back to.* [2-year-old female leukemia survivor]

Participants also requested enhancements to the daily check-in question, such that additional questions would be asked of the user. Participants suggested that these questions could be added to all check-in questions as an optional addition, asked only if a pattern of negative emotions is detected, or asked at predetermined intervals.

> *Another option would be...after you click one [an emoji], you can write a bit about exactly how you're feeling. But the writing would be optional.* [16-year-old male brain cancer survivor]
>
> *But if somebody is interested and struggling through the emotions post-treatment and it's just a quick notification, you could just click it once a day or something like that. If the trend starts, or if somebody consistently does a certain emotion, then maybe it can dig deeper after a week or two and maybe a deeper dive monthly.* [34-year-old male non-Hodgkin lymphoma survivor]

Finally, participants suggested making modifications to the bottom navigation menu of the tool, including removing the text and reorganizing it depending on where users are in the tool.

> *Something about the dashboard, ldlearn, discuss, connect, something just looks a little off. Maybe if you just use the logos there, cause you can infer from the logos what it'd be.* [15-year-old male gastrointestinal stromal tumor survivor]
>
> *I think once you click on a Learn module, the anchor (Dashboard, Learn, Discuss, Connect) could all be reorganized to be specific to what is being engaged with in that Learn module. And then you could keep the Dashboard. But if I'm in a Learn module, I don't really need to see my Inbox.* [35-year-old male non-Hodgkin lymphoma survivor]

Subtheme 3.5: User Input

Overall, participants reported preferring simplicity over complexity for user input, particularly when the goal is for users to engage in reflection about the content rather than to collect back-end data. Yet, participants recognized that there are benefits and limitations to both free-text and multiple-choice responses.

> *If it's just about the person checking in with themselves, then just keep it simple. Whereas, if you're actually trying to collect data, then you need to get into the nuance. Like you can be angry and happy at the same time.* [35-year-old male non-Hodgkin lymphoma survivor]
>
> *I like the multiple choice, but then I realize that it would be hard to put all the different emotions that you would have in...I feel like it would be harder to sit there and write out everything and people may not have the time. Versus if they could just choose something, they're more likely to do it cause it's quicker and faster. So I like a way that they can quickly choose something, but like I said, I don't know how you would do that cause that would be hard with so many different emotions. But I do feel like if you did a lot of text, people would not engage in it just because of the time that it would take to sit there and write all that out.* [36-year-old female breast cancer survivor]

Participants emphasized that it would be useful to have multiple options for inputting responses to free-text questions, as this would allow for more accurate expression of an individual's experience.

> *I also like the different words because sometimes you struggle to find a certain word for pain or how you're feeling and sometimes you're empty, like you don't have an emotion for some reason and so it's more than just feeling terrible. You just kind of feel numb...I know it's a lot, but when you have a lot of options to express yourself, you're more likely to convey how you're actually feeling...Maybe even having the option to put a picture there so you can look back on it and remember how you were feeling.* [25-year-old female sarcoma survivor]
>
> *I've been playing with the idea of how to get students to engage with their personal thought life. I have found that there is resistance to typing with your thumbs. But, as soon as I remind them that most phones now have voice activation auto-text, I get a lot more written responses simply because they remember that they can push the microphone and it will type for them. So maybe having a reminder like that would be good. People will think differently and record their thoughts differently. So since this is for them, I would give them options. Maybe they hand*

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> *write it out on paper and take a photograph and upload it. Or record an audio clip. But I think those sorts of accommodations, if it's possible to achieve, I think it would make for a more personal experience than, you know, type a minimum of 150 words.* [35-year-old male non-Hodgkin lymphoma survivor]

Theme 4: Interface Design

Overview of Subthemes

Participants provided suggestions on how to improve the design of the user interface. Within this theme, 4 subthemes were identified: coherent theme, color scheme, organization, and text.

Subtheme 4.1: Coherent Theme

Participants indicated that they would like the tool to have a consistent look and feel, with continuity across images.

> *Aesthetically, the continuity isn't there between each image. It looks like different artists are making each of them. I personally don't care about branding, but it does make it a little bit disjointed. It's like, in one you're at a Trader Joe's and another you're at Kroger. I would tidy those up. The first one has hardly any facial features and then the last one, Thinking & Feeling, it's emphasizing facial features, but in a very cartoon-y way.* [35-year-old male non-Hodgkin lymphoma survivor]

Subtheme 4.2: Color Scheme

Participants suggested incorporating brighter colors into the design of the tool and allowing users to customize the color scheme according to their preferences.

> *They're more neutral colors. It wasn't anything that really popped out. So maybe I would incorporate bright colors as well.* [38-year-old female breast cancer survivor]

> *I think it would be nice to be able to customize the theme or the colors, so it's the person's favorite color.* [21-year-old female non-Hodgkin lymphoma survivor]

Subtheme 4.3: Organization

Participants indicated that they would prefer discussion boards to be organized by survivor groups (eg, specific cancer diagnosis, treatment type) rather than having a discussion board for each content area.

> *People would always have questions, so I don't know that you're going to have a problem with people interacting. Cause people always worry about their health, especially afterwards. I feel like I worry all the time and I don't know if it's normal. So I would get on there and read to see if I'm the only one going through this. I feel like a discussion board where they can talk about anything rather than ones specific to the content would be more useful to people...Maybe the different types of cancers so that you can have somebody that's going through what you have, some of the same treatments and stuff like that. I would rather connect with somebody that went through breast cancer just like I did rather than somebody with a different kind of cancer where we went through two different treatments.* [36-year-old female breast cancer survivor]

Subtheme 4.4: Text

Participants requested that information presented in text be visually appealing.

> *I think it's [the transcript] very bland. I would add a different font because I feel like I'm just reading a paragraph of text. Maybe add some colors too.* [20-year-old female thyroid cancer survivor]

Design and Development of a Working Prototype

Based on insights obtained during individual interviews, a working prototype was developed by reprogramming an existing digital tool (EMPOWER) [37-39] by BrightOutcome, a health care technology company. While much of the working prototype aligned with the design of the mid-fidelity prototype and EMPOWER, modifications were informed by quantitative findings and themes identified in the individual interviews. To promote user engagement, we decided to provide AYACS with daily SMS text message reminders that use an encouraging tone (sent only if the user does not engage with the tool by early evening) and to provide graphical feedback on fluctuations in their mood. Regarding tailored content presentation, AYACS emphasized that content should be authentic and age-appropriate. As such, we partnered with 2 nonprofit organizations (Elephants and Tea and Cancer Rebellion) to integrate real stories from AYACS into the tool in both blog and video formats. Further, we worked with a professional animator to create age-appropriate animated psychoeducational videos. To enhance the perceived usability and accessibility of the tool, all videos include transcripts or closed captioning. We also modified the names of modules and added descriptions to provide users with a clearer understanding of what each module entails. Finally, we worked with a professional designer to improve the design of the user interface by implementing a consistent and coherent theme and using brighter colors throughout the tool. We also included artwork throughout the tool created by a professional artist who is an AYACS. Screenshots of the working prototype, now called ASCENT (which stands for the AYA Survivors' Coping and Emotional Needs Toolkit), are presented in Figure 1.

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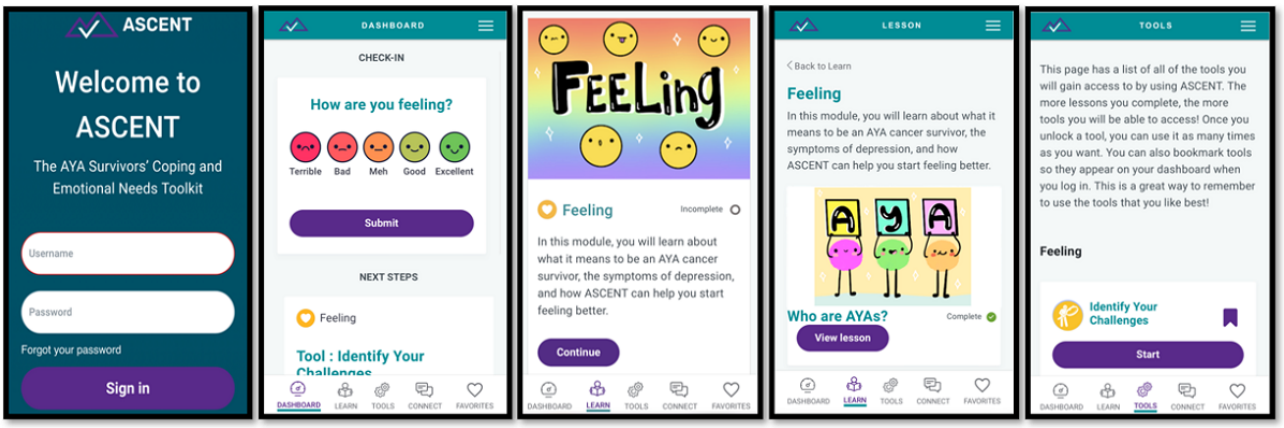
Figure 1. Screenshots of the ASCENT (AYA Survivors' Coping and Emotional Needs Toolkit) working prototype.



Adaptation of Evidence-Based Interventions

In addition to reprogramming the EMPOWER platform based on this feedback, we also adapted 4 EBIs for digital delivery. Consistent with our theoretically and empirically derived conceptual model [30], EBIs were adapted for delivery via 5 modules. Core elements of 4 EBIs (behavioral activation, cognitive restructuring, mindfulness training, and positive psychology interventions) were identified by reviewing established clinical treatment manuals, existing digital tools, and prior empirical findings. Population differences requiring adaptation were identified as the experience of having cancer, age or maturity level, and delivery via a self-guided digital platform. Intervention content was adapted to address these differences while preserving core elements and ensuring that there was no overlap between modules. The Feeling module includes 6 sequential lessons that provide general psychoeducational content about AYACS and depression, resources for identifying and managing a mental health crisis, and an introduction to how the tool's discussion boards can be used for peer support. Each adapted EBI was included as a separate module of 6 sequential lessons based on established treatment protocols: Doing (behavioral activation), Thinking (cognitive restructuring), Being (mindfulness training), and Positivity (positive psychology interventions). Within lessons, text-based psychoeducational content was adapted into scripts for brief, educational animated videos. Interactive exercises such as Socratic questioning and goal-setting were modified for digital delivery. The content was tailored to AYACS by incorporating stories from other AYACS, using age-appropriate language and design, and incorporating features to promote engagement with the tool that were informed by user-centered design with AYACS. Table 2 provides a more detailed description of current and potential future changes to the tool based on individual interview feedback and the planned adaptation process.

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Table 2. Current and potential future changes to the digital depression self-management informed by themes identified through qualitative analysis of individual interviews with AYACS[a].

Theme, subtheme, and property	Working prototype	Potential future changes
Theme 1: Features to promote user engagement		
Communication		
Opportunities to interact with other AYACS using the tool would increase engagement.	• A discussion board will be included for each content area of the tool[b,c].	N/A[d]
The tool should allow patients to connect with a mental health provider.	• Information about crisis management will be provided as part of the psychoeducational module[e].	Add the ability to connect with local providers.
While users wanted opportunities to engage with others through the tool, they also wanted some aspects of it to be private.	• Users will be provided with the option to share their responses to open-ended questions to the relevant discussion board[c].	N/A
Options		
Participants felt that users should be able to choose in what order they view content unless it needs to be presented sequentially.	• Users will be able to complete modules in any order at their own pace; however, within modules, content will be presented sequentially[b].	N/A
Participants expressed concerns that receiving all content at once may be overwhelming.	• Users will only have access to 1 new lesson per module at a time[b].	N/A
Allowing users to choose the order in which they view content allows them to tailor it to what they need in the moment.	• Users will be able to complete modules in any order at their own pace[b].	N/A
Completion of questions, practice activities, etc throughout the tool should be optional.	• N/A	Consider making only certain practice activities that are essential for the benefit required; this will require additional empirical information.
Reinforcement		
Gamification could make the tool more interesting and fun, but it may be inappropriate given the nature of the content.	• Gamification tactics shown to be efficacious in and appropriate for health behavior change interventions will be used (eg, motivational messages)[e].	N/A
Participants suggested including various features to increase user engagement: motivational messages, streaks, rewards, progress bar, and reminders.	• Daily reminders to use the tool will be sent using a motivational tone[e].	Consider adding features such as streaks, progress bars, and rewards.
A variety of factors impact the frequency at which users want reminders to track their mood and activities. These include cancer trajectory, severity of disease, daily activities, and personal preference.	• Reminders will be provided once daily[e].	Additional tailoring/personalization of reminder frequency.
Users should have the option to turn features meant to promote engagement on or off.	• N/A	Consider providing an option for users to turn reminders off; this will require additional empirical information.
Value		
Education on the value of the tool will increase AYACS motivation to engage with it.	• N/A	Provide education on the value of the tool once supported by empirical data.
Experiencing improvements in symptoms will increase the duration of use.	• Users will receive graphical feedback on how their mood has fluctuated each time they track it in the tool[c].	N/A

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Theme, subtheme, and property	Working prototype	Potential future changes
Theme 2: Tailored Content Presentation		
Accessibility of activities		
Certain activities may be difficult for some survivors to complete (eg, walking meditation); modifications should be provided if these activities are included.	• A curated group of activities was chosen to ensure individuals of all physical abilities would be able to complete them[e].	N/A
Authenticity		
Experts and AYACS should be portrayed in an authentic manner.	• Information about the expertise of the team involved in the development of the tool will be provided[c]. • Real stories from AYACS will be integrated to illustrate concepts[e].	N/A
Avoiding discouragement		
Information should not be presented in a manner that could be considered discouraging or demotivating.	• An encouraging and supportive tone will be used throughout the tool and in all reminders[e].	N/A
Duration		
Lesson duration should be variable.	• While all lessons include similar parts, the length of time to complete each part will be variable[e].	N/A
The duration of practice activities should influence the frequency of required completion.	• Longer practice activities will require fewer repetitions before unlocking additional content[e].	N/A
Preferred duration and timing of use are variable.	• Users will be asked to engage with the tool for 6 weeks, as each module has 6 lessons[b].	Modify the duration of the study if needed to ensure users can complete all content.
Maturity level		
Content should not be presented in a manner that could be considered juvenile.	• A professional designer and an artist will assist with ensuring visuals are age-appropriate[e].	N/A
Normalization		
The tool should provide normalization regarding the impact of cancer on AYACS mental health.	• A lesson focused on the relationship between cancer and depressive symptoms in AYACS will be included in the psychoeducational module[b].	N/A
Use of multimedia		
Using animations will make the tool more engaging, interactive, and fun, as well as reducing stigma and enhancing comprehension.	• Psychoeducational information will be provided via animated videos[e].	N/A
Content should be presented in multiple formats to account for individual differences.	• All video content will include transcripts and closed captions[e].	N/A
Theme 3: Perceived Usability		
Accessibility		

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Theme, subtheme, and property	Working prototype	Potential future changes
Information should be presented in multiple formats.	• All video content will include transcripts and closed captions[e].	N/A
Text should be easy to read.	• A professional designer will ensure the tool uses fonts and colors that are easy to read and visually appealing[e].	N/A
Clarity		
Potential users may not know what AYA[f] in the name iManage AYA stands for.	• The tool was re-named ASCENT[g], which stands for the AYA survivors coping and emotional needs toolkit; the meaning of AYA will be described in the first lesson of the psychoeducational module[e].	N/A
Rename modules to allow for clearer differentiation between topics; include brief descriptions of each module.	• Modules were renamed to provide additional clarity[e]. • A brief description was added for each module[e].	N/A
Include more information about how the practice activities work to prevent confusion regarding lack of access.	• As part of research studies, users will be required to complete an orientation call in which they learn how to use the tool[e].	Provide potential users with a manual or introductory video, or both, that describes how to use the tool.
Navigation		
Users should be able to leave the tool and easily come back to where they left off.	• Users will be able to ask the tool to remember their log-in information[c]. • Features such as bookmarks and favorites will support ease of navigation within the tool[e].	N/A
Include additional questions in the daily check-in.	• N/A	Add questions to the daily check-in at either predetermined intervals or based on consistent low mood.
Remove text from the navigational menu.	• N/A (not in alignment with best practices for web design).	N/A
Reorganize the navigational menu depending on where the user is in the tool.	• N/A (not in alignment with best practices for web design).	N/A
User input		
User input should be as simple as possible, particularly when the goal is for users to engage in reflection on content.	• Multiple choice questions will be prioritized as much as is feasible to ensure ease of input[e].	N/A
Users should have multiple options for inputting responses to free-text questions.	• The web-based application is compatible with native talk-to-text features[c].	Add photo upload, use of GIFs, etc as response options for open-ended questions.
Theme 4: Interface Design		
Coherent theme		
The tool should have a consistent look and feel with continuity between images.	• A consistent icon set, color scheme, and artistic style will be used throughout the tool[e].	N/A
Color scheme		

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Theme, subtheme, and property	Working prototype	Potential future changes
Incorporate brighter colors into the design.	• Brighter colors will be incorporated into the design of the working prototype[e].	N/A
Allow users to customize the color scheme of the tool.	• N/A	Allow users to customize the color scheme of the tool.
Organization		
The discussion board should be organized by disease or treatment characteristics rather than content area.	• N/A (not appropriate for planned full factorial trial in which it is necessary to prevent cross-contamination between conditions).	Reorganize discussion boards in the optimized version of the tool.
Text		
Text should be visually appealing.	• A professional designer will ensure the tool uses fonts and colors that are easy to read and visually appealing[c].	N/A

[a]AYACS: adolescent and young adult cancer survivors.

[b]Existing feature of the mid-fidelity prototype.

[c]Existing feature of EMPOWER.

[d]N/A: not applicable.

[e]Change based on interview feedback.

[f]AYA: adolescent and young adult.

[g]ASCENT: AYA Survivors' Coping and Emotional Needs Toolkit.

Discussion

Principal Findings

This study aimed to explore the preferences of AYACS for the design and content of a digital self-management tool for depressive symptoms. The findings indicate that AYACS highly value personalization, flexibility, and peer support in digital interventions. Specifically, participants emphasized the importance of tailored content that resonates with AYACS' lived experiences of cancer survivorship, opportunities for interaction with peers facing similar challenges, and features that allow flexible engagement with the tool. These preferences underscore the need for a tool that is uniquely tailored to the needs of AYACS.

Comparison With Prior Work

This study provided key insights into the unique needs and preferences of AYACS for digital mental health interventions. First, the findings will inform the development of a working prototype of the digital tool being developed by our team and have broader implications for researchers seeking to develop interventions tailored to this population.

A second strength of this study is the use of user-centered design methods with AYACS. User-centered design has been increasingly recognized as an important strategy for informing the development of digital mental health interventions in the general population [41]. Further, user-centered design methods have been successfully used with young people with cancer to inform the development of health care transition and symptom self-management interventions [42-44]. However, such methods have not explicitly been used to develop digital mental health interventions for AYACS [37,45,46], although AYACS have provided input that has guided the development of these tools. By relying on established methods from the field of human-centered design to guide the inclusion of AYACS in informing the design of our tool, we have gained valuable insights into AYACS' needs, motivations, and preferences for digital mental health tools. Ultimately, we believe that integrating these insights into our tool will help ensure that AYACS engage with it.

The findings of this study also underscore several important considerations for the development of digital tools for AYACS. Tailoring emerged as a key theme, with participants expressing a strong preference for content that reflects their individual cancer experiences. This aligns with findings from our prior work [30], as well as those from other groups that have identified the importance of relevant, cancer-specific content and peer stories in engaging cancer survivors in digital interventions [47,48]. AYACS' strong preference for tailored content underscores the necessity of providing not just general mental health advice but contextually relevant information that resonates with the unique challenges of this population.

Another important finding is the need for flexibility in the tool's design. AYACS expressed a preference for content that can be accessed at their own pace, with variation in the duration and frequency of interaction. While prior work has indicated that AYACS broadly prefer on-demand interventions [16], our findings suggest a broader desire for flexibility. Specifically, AYACS emphasized that it is important for users to be able to access the content most relevant to them at the moment when they are most ready to engage. One question this raises is how best to help AYACS make decisions about what content to access and when. Future research on digital tools should consider using adaptive trial designs such as the sequential

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multiple assignment randomized trial [27] to determine which interventions may be most effective for which AYACS and at what time, ultimately informing the development of a just-in-time adaptive intervention [49].

The study also highlighted the significance of peer support. Participants emphasized that having the opportunity to connect with others who have experienced similar challenges would be an important feature of the digital tool. This is consistent with prior research suggesting that AYACS place a high value on support from peers who have had cancer. Prior research indicates that peer interactions can reduce feelings of isolation and provide valuable emotional support for cancer survivors [47]. Incorporating social features, such as forums or shared experiences from other survivors, could enhance AYACS' sense of community and support.

Finally, participants raised important ethical concerns regarding privacy when using the digital tool. In accordance with best practices for digital mental health tools, the working prototype of ASCENT was developed on a HIPAA-compliant platform with several technical safeguards in place to protect participant data. Further, participants are never required to share their personal information or responses with other users on the platform; rather, this is an optional part of ASCENT. While participants did not explicitly raise other concerns regarding the potential risks of ASCENT, this remains an important consideration in the development of such tools. Prior research suggests that while digital mental health interventions are generally considered relatively safe, the occurrence, frequency, and methods for safety data collection vary widely, making it difficult to validate this claim [50]. A recent qualitative study provided recommendations for improving the safety of interventions such as ASCENT, including acknowledging the lack of personalization, providing genuine crisis support, and anticipating and supporting deterioration [51]. Such recommendations will be critical in informing future evaluations of the effectiveness and safety of ASCENT.

Limitations

While this study provides several important insights, it is not without limitations. Despite efforts to recruit a diverse group of participants by identifying individuals from varied backgrounds during our review of medical records, our sample does not fully reflect the broader population of AYACS in terms of race, ethnicity, gender, and sexual orientation. Future research aimed at tailoring digital health interventions for this population should seek to recruit diverse samples of AYACS via targeted recruitment strategies to ensure the generalizability of findings across diverse AYACS. However, it is worth noting that the sample was broadly representative of the typical age range and common cancer types found among AYACS. Further, while our sample size of 14 was sufficient for the planned qualitative approach, future studies are needed to test the generalizability of these findings in a larger sample of AYACS. This could occur through a stand-alone study (eg, a questionnaire designed to validate AYACS' preferences for digital self-management tools) or as an adjunct to future trials of such tools. The qualitative methodology of this study could also have been more rigorous. For example, it is best practice to pilot-test interview guides before beginning recruitment. Further, it would have been ideal to obtain participant feedback on transcripts and identified themes and subthemes before finalizing our insights and design decisions, as well as to conduct follow-up focus groups.

Conclusions

This study highlights the key features that AYACS value in digital self-management tools: personalization, flexibility, and peer support. These preferences underscore the need for digital interventions that are not only tailored to individual cancer experiences but also flexible in design to meet the evolving needs of AYACS over time. The broader implication of these findings is that digital health tools, when designed with these elements in mind, have the potential to improve mental health outcomes and AYACS' overall quality of life. By offering a more personalized, flexible, and socially connected experience, digital interventions can play a crucial role in supporting this often-overlooked group of cancer survivors. Future research should continue to evaluate the impact of integrating AYACS' preferences into digital tools on promoting sustained engagement with digital interventions, which may ultimately lead to improved health outcomes. For example, in our pilot feasibility study of procedures for a full factorial trial of ASCENT, we will collect data regarding usability, engagement, actual usage, and safety (ie, occurrence of adverse events, deterioration). Further, participants will be asked to provide feedback on the working prototype via exit interviews [52].

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Data Availability

An all-inclusive table of raw data from the transcripts is available online [53].

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Conflicts of Interest

None declared.

Multimedia Appendix 1
Slides presented to participants during individual interviews.
[PPTX File , 3602 KB - formative_v10i1e77994_app1.pptx]

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Abbreviations

AYA: adolescent and young adult
AYACS: adolescent and young adult cancer survivors
CBT: cognitive behavioral therapy
EBI: evidence-based intervention
HIPAA: Health Insurance Portability and Accountability Act
REDCap: Research Electronic Data Capture; Vanderbilt University

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Original Paper

Community Health Worker Feedback on an mHealth Intervention for Hypertension in Rural Guatemala: Mixed Methods Formative Study

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Abstract

Background: Hypertension remains a leading global health challenge, particularly in low- and middle-income countries (LMICs), where limited health care infrastructure and resources restrict effective management. Community health workers (CHWs) are critical in delivering care in these settings, and when equipped with mobile health (mHealth) apps, they can greatly enhance chronic disease management. Involving CHWs in the design and development at all stages is essential for the success of such programs. However, relatively little research discusses CHW feedback on mHealth interventions.

Objective: This study aims to evaluate CHW feedback on a hypertension program using a novel tablet-based mHealth tool designed for CHW hypertension diagnosis and management in rural Guatemala.

Methods: We conducted a mixed-methods analysis as part of a pilot study in San Lucas Tolimán, Guatemala, involving 6 CHWs over a 6-month period. Quantitative data were collected using the System Usability Scale and Likert-scale surveys before and after study completion. Qualitative data were gathered through written surveys and focus group interviews conducted in Spanish by bilingual team members. These methods assessed the app's ease of use, workflow integration, and cultural appropriateness. CHWs provided detailed perspectives on technical challenges, training adequacy, and patient engagement, which guided iterative refinements to both the mHealth app and the hypertension management program.

Results: The mHealth app was generally well-received. Average System Usability Scale scores exceeded 70, surpassing established usability thresholds. Likert scale data revealed CHWs found the app to be useful and easy to use, but identified training protocols as areas for improvement. Qualitative analysis of focus groups and written surveys revealed 3 dominant themes. First, CHWs identified practical short-term needs, including slower and more comprehensive training sessions, simplified medication dosing regimens to reduce pill burden, and streamlined survey questions to shorten patient visit times. Second, CHWs raised larger structural concerns, including retention challenges related to financial compensation and misalignment between required clinical data collection and the cultural appropriateness of certain app questions. Third, CHWs highlighted program benefits, including improved patient care and hypertension management, empowerment through educational tools, and increased pride and community trust associated with the program.

Conclusions: Our findings suggest that iteratively integrating user feedback into the development of mHealth interventions is key to improve usability, cultural appropriateness, and overall effectiveness of chronic disease management in resource-constrained

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settings. Due to the small number of CHW participants, as well as a reliance on self-reported perceptions, these findings should be interpreted as exploratory and hypothesis-generating rather than generalizable. This study contributes to the growing literature on mHealth apps for noncommunicable diseases in LMICs and provides insights into CHW experiences. Addressing the technical barriers and systemic challenges identified in this study can help improve future implementations of mHealth-enabled chronic disease programs in LMICs.

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KEYWORDS

hypertension management; mHealth app; mobile health; community health workers; Guatemala; digital health; rural health; noncommunicable diseases

Introduction

Hypertension is the leading risk factor for death globally, and a major cause of premature death worldwide [1]. Of the estimated 1.4 billion adults worldwide living with hypertension, two-thirds live in low- and middle-income countries (LMICs) [2]. Despite the high prevalence of hypertension, estimates suggest that globally 44% of adults with hypertension are unaware of their condition [2]. Moreover, only 44% are diagnosed and treated, with just 23% having hypertension that qualifies as controlled [2]. Awareness, treatment, and control rates are notably higher in urban than rural areas in LMICs [3].

Limited health care infrastructure, low physician-to-patient ratios, and lack of access to medicines are among the key challenges disproportionately faced by LMICs, further contributing to the burden of hypertension [4]. To help address these health care inequities, community health worker (CHW) programs have been widely implemented, often enhancing health system capacity for both acute and chronic conditions by supporting tasks traditionally performed by physicians [5,6]. The use of mobile health (mHealth) technologies by CHWs has emerged as promising for health care delivery in LMICs across various contexts, including the management of noncommunicable diseases [7-10].

Our team developed a novel mHealth app as part of a larger hypertension program aimed at facilitating the diagnosis and management of hypertension by CHWs in San Lucas Tolimán, a rural municipality in Guatemala. The details of the program, training, and app's feasibility have been discussed, tested, and published previously [11], but to provide context for this study, here is a summary. The program equips CHWs with a tablet running the app using a platform called CommCare (Dimagi), enabling them to enroll patients, record medical and lifestyle history, and track relevant blood pressure measurements. At the end of the patient visit, the app provides both diagnostic guidance and hypertensive treatment recommendations (Multimedia Appendix 1). An ongoing clinical trial (ClinicalTrials.gov NCT06444308) seeks to compare the CHW intervention incorporating the app with that of a physician, the traditionally accepted standard of care [12].

This study focuses on the structured feedback system used to iteratively evaluate and refine the implementation of this hypertension program. In this phase of the study, 6 trained CHWs helped implement the pilot as members of the study team; they also provided feedback, which we analyzed here. We present our experience using multimodal feedback to identify implementation barriers, training gaps, and workflow inefficiencies. We accomplished this by collecting quantitative and qualitative feedback from CHWs through System Usability Surveys (SUS), written surveys, and focus group discussions. By centering CHWs as active contributors to the program, this study highlights a feedback-driven approach that can inform the design and adaptation of mHealth-supported chronic disease programs in resource-limited settings.

In LMICs, where access to health care technology is still evolving, adoption and implementation challenges are significant [13], and studies focusing on how implementation challenges are identified, communicated, and addressed remain limited [14,15]. Iterative feedback at all steps of the design and implementation process is crucial for ensuring that the intervention is functional, culturally sensitive, and adaptable to the specific needs of the community. This study addresses this gap by evaluating the feedback of CHWs in rural Guatemala on the use of one mHealth app.

Methods

Study Design

Our group recently conducted a pilot study to evaluate the feasibility and effectiveness of a CHW-led, mHealth-supported hypertension management program in rural Guatemala. The mHealth app used for the study was developed through regular consultations with CHWs and community members to ensure that the app considered challenges commonly faced in rural health care delivery [16]. Our research team consists of male and female physicians, medical students, graduate students, undergraduate students, and health care administrators. Some team members live in Guatemala, and others in the United States. Approximately half of the team members were born and continue to live in rural Guatemala. All members speak Spanish; 2 learned Spanish as children and are fluent speakers, while the rest of the team are native Spanish speakers. About one-half of the team speaks Kaqchikel, the Indigenous Mayan language spoken by many in San Lucas Tolimán.

Data collection for the study presented here focused on the app's ease of use, workflow challenges, and the overall impact of the program on the CHWs' ability to provide care, as these factors are key facilitators for the sustainability of digital health interventions in LMICs [17]. Our goal was to identify areas of success and where improvement was needed in the app workflow, study protocol, and overall hypertension program.

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In accordance with this framework, one component of this study focused on technical usability in introducing CHWs to digital tools largely unfamiliar to them. The other examined how well the mHealth solution aligned with local practices, cultural norms, and its impact on CHW-patient interactions, which are critical for cultural and contextual adaptation [18].

Study Setting

The study took place in San Lucas Tolimán, a municipality in Guatemala's Western Highlands with a population of just over 30,000 people, most of whom identify as Kaqchikel Maya. Approximately half of the residents reside in the 19 rural villages that surround the main town [19]. Guatemala has the second-highest poverty rate in Latin America, with rural regions disproportionately affected. It is estimated that 80% of Guatemala's rural population lives in such conditions [20]. Socioeconomic barriers like inequitable investments in infrastructure, education, and sanitation contribute to significant health disparities. Additionally, many villages are remote with few transportation options, further restricting access to formal health care services [21]. Notably, many disparities stem from histories of colonialism and genocide, including post–civil war divestment in rural infrastructure and health care, leaving many Indigenous communities in rural Guatemala with inadequate services and economic opportunities [22].

Participants

The study examined feedback from 6 CHWs, known locally as *promotores de salud*. They are a part of a health program managed by the San Lucas Mission, a nonprofit organization with which we partner that provides health care and social services to local residents.

For the purposes of this feedback study, participants were drawn from the cohort of CHWs already enrolled in the larger pilot program. Their recruitment for the pilot occurred in-person during routine program meetings and was conducted by members of the study team in collaboration with San Lucas Mission leadership. From this group, we used purposive sampling to invite CHWs to participate in the current feedback study. All 6 eligible CHWs agreed to participate in the additional feedback activities.

During the pilot, the 6 CHWs used our mHealth app during routine patient visits supporting hypertensive care. This participation informed the perspectives discussed in this study. All participants completed a structured training program to partake in the pilot study, including instruction in hypertension management and app use (Multimedia Appendix 2). This training ensured a mutual baseline of technical competency, which allowed the feedback collected to focus on experiential, cultural, and structural considerations rather than basic operational challenges.

Data Collection

Data collection aimed to capture both the technical and cultural dimensions of the program. This was accomplished using three complementary methods:

1. SUS: usability was assessed using the SUS, a validated 10-item questionnaire that measures perceived ease of use and system functionality (Multimedia Appendix 3). Widely used in technology and health care research, the SUS helps evaluate user experience across various digital tools, from mobile apps to medical devices [23]. Each item was rated on a 5-point Likert scale (1=Strongly Disagree and 5=Strongly Agree). Negatively worded SUS items (Q2, Q4, Q6, Q8, and Q10) were reverse-coded prior to score calculation so that higher values consistently reflected better usability. Five CHWs completed the survey, administered at month 0 and month 6, to evaluate changes in CHWs' perceptions of the mHealth app over time.
2. Written surveys: 5 CHWs completed written surveys with open-ended questions to provide qualitative feedback on the app's strengths, challenges, and areas for improvement (Multimedia Appendix 3).
3. Focus group interviews: two 1-hour focus group interviews were conducted, one at the end of the pilot study and another 4 months post study, to gather in-depth insights on 6 CHWs' experiences. These discussions were conducted in Spanish, led by 2 (first group) or 1 (second group) of 3 bilingual team members. Interviewers used a guide to ensure that key topics were discussed, including usability, training adequacy, and broader program challenges (Multimedia Appendix 4).

Qualitative data saturation was reached after written surveys and 2 focus group interviews. Many themes were repeated across surveys and focus groups, and these conversations ended with time to spare. Additionally, we had interviewed and requested surveys from every CHW who participated as a study member in this pilot study.

Data Analysis

For our limited quantitative analysis, SUS scores were analyzed following the method described by Bangor et al [24]. Scores on the 5-point Likert scale were summed and multiplied by 2.5 to scale the final SUS score to a 0-100 range. Given the low sample size of the study (n=5), we did not conduct statistical analysis by demographics.

For the qualitative data, focus group interviews were audio-recorded in Spanish, transcribed verbatim, and translated into English by 2 bilingual members of the research team. Both members used a memoing approach, annotating the document directly before translating to English. This was completed independently, and then discrepancies were resolved to minimize interpretive bias. Both translators have experience working with CHWs directly, which helped them interpret local terminology. These 2 members did not conduct the interviews themselves, potentially reducing the possibility of translation biases due to interviewer-participant dynamics. Still, we understand that any translation, in this case from Kaqchikel-influenced Spanish to English, carries the risk of shifting nuance, and this may affect interpretation.

We reported the qualitative components of this study in accordance with the COREQ (Consolidated Criteria for Reporting Qualitative Research) checklist, which was completed and supplied for editorial review. Analyses were made using an inductive coding approach. This meant that, rather than imposing codes from a predefined framework, we allowed

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CHWs' language to shape the analytical results. This approach is well-suited to exploratory qualitative analysis, where explanations are derived from the data, rather than testing preexisting theories [25]. We identified themes primarily based on immediate usefulness to our study implementation. These were organized into 3 categories: "Practical short-term needs," "Larger structural concerns," and "Program Benefits." We then selected specific participant quotes to illustrate key insights.

Ethical Considerations

Ethics Approval

This set of studies was approved by the University of Wisconsin Institutional Review Board (ID # 2022-0794) as well as the San Lucas Healthcare Committee, an interdisciplinary, international group that provides local ethics oversight to health care projects. The overarching hypertension program, including earlier feasibility phases, was also registered with ClinicalTrials.gov (ID NCT05479097). This substudy was exempt from additional institutional review board review because the CHW study participants were, in fact, researchers on the study themselves.

Informed Consent

CHWs signed documentation to take part in the overarching hypertension pilot study as study team members, and these specific CHWs provided verbal consent to participate in focus groups, written surveys, and usability assessments included in this substudy.

Privacy and Confidentiality

Since the CHWs were actively involved in the pilot study, complete anonymity during data collection was not feasible. However, all qualitative and quantitative data were deidentified prior to analysis, and no personally identifiable information was included in analytic datasets or reported in the results. Audio recordings and transcripts were stored on secure, password-protected servers accessible only to authorized study personnel.

Participant Compensation

CHWs did not receive additional compensation specifically for participation in this feedback substudy beyond their standard stipends for program-related activities at the time of the pilot.

Results

Participant Demographics

In total, 6 CHWs participated in the pilot study. At the onset of the study, the 6 participating CHWs had an average age of 42.2 (SD 8.09) years. Five were female, while 1 was male. Four had completed elementary school, one had attended middle school, and one had obtained an associate's degree. All CHWs reported using a smartphone daily.

System Usability Survey Scoring

At the beginning of the pilot, the average system usability score (SUS) was 72.5 out of 100, which decreased marginally to 71.25 by the end of the 6-month period. Specific results of the survey are seen in Table 1.

Table 1. Analysis of System Usability Scale responses before and after the pilot study.

Items	Questions	Before, mean (SD)	After, mean (SD)
Q1	I think I'd like to use the app frequently.	4.75 (0.43)	5 (0)
Q2	The app is unnecessarily complicated.	5 (0)	4 (0)
Q3	I find the app easy to use.	4 (1.73)	4.25 (0.43)
Q4	I believe I'd need help from a technician to use the app.	2.50 (1.50)	3.25 (1.30)
Q5	The different functions of the app are well integrated.	4.50 (0.50)	3.25 (0.83)
Q6	I find the app confusing.	5 (0)	4.25 (0.83)
Q7	I imagine most people would learn to use this app very quickly.	2.25 (1.30)	3.50 (1.12)
Q8	I find the app very difficult to use.	4.75 (0.43)	4.75 (0.43)
Q9	I feel confident using the app.	4.25 (0.83)	5 (0)
Q10	I needed to learn many things about this app before I could use it.	1.50 (0.50)	2 (1.23)

Categorized Qualitative Feedback

We categorized qualitative data from written surveys into 3 main themes: practical short-term needs, larger structural concerns, and program benefits. We organized the themes in this way to be the most useful in ongoing project implementation, reflecting the pragmatic aims of the work, a method grounded in established qualitative research practices [25]. Table 2 provides a summary of these key insights, offering concrete examples of CHWs' experiences with the mHealth app and highlighting specific areas for improvement and success.

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Table 2. Key insights for improvement from community health workers' focus groups.

Categories	Quotes	Interpretation
Practical short-term needs	• "Patients say they need to take too many pills, but we feel like the medication doses are just too low." • "Trainings to learn about hypertension could be taught a bit more slowly." • "Questions in the app seem to repeat. These repetitions make using the app quite slow."	• Highlights tension between algorithm dosing and actual pill burden. Suggests either needing a clearer CHW[a]-facing explanation of dosing rationale or adjusting pill dosages. • Indicates that training pace may be a barrier to effective adoption. Emphasizes the importance of longitudinal training models. • Reveals app workflow inefficiencies. Suggests shortening survey questions to shorten visit length and improve patient and CHW satisfaction.
Larger structural concerns	• "For us working here, is there going to be more compensation?" • "It is often hard because in our culture we are not used to asking women how many times they urinate; this is not normal for us Indigenous people." • "It may be common for women in other countries to drink [alcohol] often, but here in Guatemala they don't tend to, and if you ask them, they get offended."	• Signals a potential retention and motivation issue. This challenge is a common barrier to long-term CHW program implementation, where compensation is often limited due to financial constraints. Suggests shifting financial priority toward workers. • Demonstrates a cultural mismatch between standardized clinical questions and local norms. Indicates the necessity of culturally adapted questions, although many times it is difficult to align, since changes or omissions may affect the validity and reliability of clinical trial outcome measures.
Program benefits	• "The program benefits many people in our communities since receiving care is often hard to get, but they can with the program." • "Our educational flip book helps make patients aware, specifically the objectives of the program and causes of hypertension." • "The patients look for us because they trust us. They know we can help them and that we are here for them."	• Emphasizes the importance of improved access to care, reinforcing program value and motivation. • Identifies educational material as key for facilitating patient engagement and understanding. • Highlights trust as a central mechanism through which CHWs enable hypertension management.

[a]CHW: community health worker.

Practical Short-Term Needs

CHWs identified several practical and readily implementable strategies to improve the management of hypertension in rural settings.

CHWs reported that many patients were frustrated by the need to take multiple pills daily, which they perceived as increasing regimen complexity and undermining adherence. To address this, CHWs recommended reducing pill burden by using higher-dose formulations when clinically appropriate, emphasizing regimen simplification as a practical strategy to support adherence. CHWs also emphasized the need for greater transparency in treatment protocols, explaining they wanted to better understand the reasoning behind the app's recommendations and workflow design.

Several CHWs acknowledged that fasting for laboratory testing—required twice over the pilot period, at enrollment and at 6 months—helps ensure reliable results for patient care purposes and scientific rigor, even though they felt it could inconvenience patients and potentially reduce attendance. In addition, CHWs advocated for a slower, more comprehensive training process; while they stated appreciating their training and education on hypertension, they said that additional reinforcement could deepen their understanding and improve patient management.

Finally, CHWs mentioned multiple times that the app contained survey questions they found both burdensome and redundant. CHWs expressed awareness, due to the use of this and previous apps during multiple phases of development, that additional questions, on average, made mHealth apps work more slowly. They acknowledged the importance of being thorough and adhering to guidelines for diagnosis and treatment. However, they suggested that reducing the number of questions would make the process easier for patients and CHWs themselves.

Larger Structural Concerns

CHWs raised challenges that we categorized as more difficult to implement due to cultural and structural barriers. One significant issue was the cultural sensitivity of certain questions within the app, such as those related to alcohol consumption and urination frequency. CHWs shared that these topics are rarely discussed in their communities, and that they sensed that these questions often made patients feel uncomfortable (Table 2).

CHWs also stressed the need for better compensation and incentives for their own participation, as they felt the financial support for their work at the time was insufficient, given the demands of their role. They further highlighted the difficulty of reaching patients in remote or difficult-to-access areas.

Program Benefits

Enhanced Patient Care and Hypertension Management

Although the focus group interview guide focused on areas of potential improvement, CHWs also shared positive feedback on the program. They emphasized its positive impact on patient

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care and how it increased their ability to deliver critical health care services to their communities. They noted that, in their opinions, the mHealth app itself contributed to improved hypertension management, enabling patients to access care that had previously been difficult to obtain.

Empowerment Through Educational Tools

CHWs approved of the program tools for patient education. They found that the mHealth app, along with supplementary materials such as several educational flip books, helped them educate patients on hypertension. These resources helped patients understand their condition and increased CHWs' own medical knowledge. CHWs explained how these educational tools made them feel more confident, particularly when explaining medication adherence and lifestyle changes to patients.

Pride and Community Trust

Finally, CHWs expressed pride and satisfaction in their work, recognizing their contributions to improving health and well-being in their communities. They valued the relationships they built with community members, specifically the trust they described as having fostered through their consistent presence and support. Their dedication to continuous learning and skill development further reinforced their motivation, as they saw tangible improvements in both their abilities and the well-being of their patients.

Discussion

Summary of Principal Findings

This study aimed to characterize CHW feedback on the usability, cultural fit, and implementation challenges of a tablet-based mHealth app supporting hypertension care in rural Guatemala. Analysis of quantitative and qualitative feedback indicated that CHWs generally perceived the app as usable and acceptable within their routine work and reported that the program supported hypertension care in communities with limited access to formal health services.

In addition to these perceived benefits, CHWs identified several implementation challenges and areas for improvement. These included workflow inefficiencies driven by survey burden and repetitive questions that lengthened patient visits; the need for more comprehensive and slower-paced training, including additional practice scenarios and guidance on how to explain hypertension and treatment recommendations to patients; and medication-related concerns, particularly the complexity of pill dosing regimens and perceptions of pill burden. CHWs raised concerns about the cultural appropriateness of certain intake questions. They also identified broader structural constraints, including compensation and retention challenges. At the same time, CHWs described meaningful program benefits, including increased confidence in delivering hypertension care, enhanced capacity to educate patients, empowerment through educational tools, and strengthened trust and pride within their communities.

Interpretation and Implications

Together, these findings highlight both the feasibility of CHW-led, mHealth-supported hypertension care in this setting and the importance of incorporating frontline feedback to guide ongoing program refinement. Encouraging CHWs to critically examine the intervention secured insights from its primary users, which informed iterative improvements to the program and app.

Likert Scale Usability Surveys

Likert scale data showed overall SUS scores averaging above 70, suggesting the app's general acceptability and functionality in one town in rural Guatemala in this small pilot sample. These scores surpassed the threshold of acceptability as defined by Bangor et al [24], indicating that the app was generally perceived as well-received by the CHWs and aligned with their capabilities and expectations.

CHWs who took both pre and post surveys rated different usability questions on the app differently. Two questions with relatively low scores included Q4 and Q10, related to potential technician help for app use and prior knowledge needed before using the app, respectively. Given the small sample size, these patterns are interpreted descriptively rather than as statistically meaningful differences. This result suggests areas for further attention, particularly regarding technical support and adequate training when implementing an app with complicated clinical functions such as ours.

Study team members felt that CHW participants' comfort in expressing their opinions increased over the pilot period. We observed more extensive written responses on the 6-month surveys, attributed to both deeper CHW understanding of the app's functionality and workflow improvements, and to increased trust that led to more open communication and honest, constructive feedback.

Cultural and Contextual Adaptation

Program and app development occurred with continuous feedback from CHW coordinators, building on over 5 years of prior work in these same communities with similar mHealth apps. Yet, despite these efforts, CHWs perceived some cultural barriers and discomfort in using the novel tool within this specific program context, raising the key question of why these issues persisted.

Previous scholars have highlighted the importance of cultural sensitivity in designing and implementing global health interventions, including mHealth tools [26-28]. In our study, CHWs highlighted that certain questions, such as those related to alcohol consumption and urination frequency, were uncomfortable to ask and for patients to answer in their communities. CHWs explained explicitly that in their own communities, social norms and health conversations may differ from places where other team members are from. Our findings build upon established literature by illustrating, within this specific setting, that cultural alignment enhances usability and trust between CHWs and patients, an important factor for the long-term success of mHealth tools alongside their technical functionality. Our study aligns with conclusions from those who emphasize the importance of iterative cultural adaptation in the design process [29-31]. Adapting mHealth tools is a dynamic process: once new content is introduced, unanticipated challenges may arise. Ongoing dialogue and iterative tool

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improvement can help apps like ours remain culturally appropriate for end users over time.

Training

While the mHealth tool was designed to minimize training burden by offering user-friendly interfaces and decision-support tools, CHWs expressed a need for deeper training on both hypertension management and the app's use. This highlights a common challenge in digital health interventions: while such tools can streamline tasks, they require strong training programs to ensure users feel capable and confident [32].

In our specific context, CHWs have decades of expert knowledge about their communities, but some struggle with literacy. Our own in-house training may be some of the first formal instructions they have received on using digital tools. At the same time, all CHWs use smartphones, so many have intuitive understandings of technology use that they bring to their mHealth work. Additionally, all CHWs who participated in the pilot study had worked with earlier mHealth tools from our team [33-35]. To address diverse training needs, we used iterative, case-by-case reinforcement, particularly for CHWs with literacy challenges or gaps in understanding hypertension management. Training alternated among group discussions, one-on-one support, and practical case-based scenarios tailored to individual strengths. The feedback CHWs provided gave us better insight – training should go slower, cover more scenarios, and train CHWs specifically on how to explain health concerns to patients. This aligns with our group's participatory experience that traditional, classroom-style didactics were less well received than one-on-one or small-group practical and case-based learning.

Workflow Optimization

A key distinction between research protocols and routine clinical care helps contextualize some CHW feedback on the app's perceived slowness. In our research context, the decision support system was designed to capture additional data for our own research purposes—data that, while valuable, is not strictly necessary for everyday clinical care. This included survey questions that CHWs found repetitive and burdensome but that were required as part of the study protocol. Rather than simply eliminating these questions, we refined technical features to increase app speed: we restructured the forms, reduced redundancies when appropriate, used faster-processing tablets, and divided forms into multiple sections that still operate as a single cohesive interface for the CHWs. These changes have significantly improved performance while preserving certain research elements that differentiate our study from routine clinical practice [36]. This highlights a broader tension between the data requirements of research protocols and the efficiency in digital health research.

Compensation and Structural Barriers

The study also revealed structural challenges beyond the usability of the mHealth tool, specifically around compensation for CHWs within the program. Many CHWs at the time of the study were essentially unpaid volunteers, who only received a small stipend on days they were asked to work. This lack of reliable financial support raised significant concerns about the sustainability of CHW-led health programs. Notably, after this study was completed but before submission of the manuscript, the local nongovernmental organization (NGO) and its American funders overhauled CHW compensation to achieve parity with other hospital employees. This process, while it involved administrative challenges outside of the scope of this study, introduced reliable income and benefits to a cadre of workers that had never experienced this type of labor support. In a country like Guatemala, where most employment does not meet this level of formality or security, this represented a meaningful programmatic change. Indeed, the program team's efforts to support the employment overhaul were informed by CHW feedback we present in this study. Our experiences working with CHWs in LMICs yield an important lesson for researchers: while mHealth technologies can support health care delivery, technologies' successes are closely tied to the well-being and motivation of the workers using them. Providing fair compensation is important to ensure the long-term viability and scalability of CHW programs in LMICs. Therefore, future interventions should focus not only on technological aspects but also on providing adequate compensation, training, and institutional support to create sustainable health care programs in low-resource settings.

Limitations

The small sample size of 6 CHWs and the relatively short 6-month duration of the pilot limit the extent to which these results can be applied to other settings. We nonetheless feel our findings are useful and contribute to the state of knowledge in the field. We benefited from the capacity to quickly evaluate and iterate on our initial results, including those presented in this study.

The SUS, as a measure of usability, provides valuable insights but cannot capture the full complexity of user experiences. Since only 5 CHWs completed both the pre- and post surveys, our SUS analysis was additionally limited. Future studies from our team could benefit from a more comprehensive quantitative evaluation framework that incorporates a wider range of usability metrics and long-term follow-up data. Additional constraints in our limited quantitative data include the ambiguity of Likert-scale scoring, which we are exploring in future research, and inconsistencies in how users interpret and rate their experiences [37]. The assumption that ordinal SUS scores behave linearly can also introduce variability, complicating direct comparisons.

Additionally, qualitative findings are subject to limitations inherent to translation. Although focus groups were conducted in Spanish and translated by bilingual team members familiar with local terminology, participants' speech was often influenced by Kaqchikel, and translation into English may have shifted nuance or meaning, potentially affecting interpretation. Just like the quantitative data, our qualitative data were pulled from a small sample, and our interview guide was quite programmatic, not designed to pull de novo theory regarding health care delivery. Nonetheless, we believe our qualitative data was rich and helpful in our project's formative phase.

The scalability of our findings is limited by the nature of our partnership with a local NGO rather than working within the

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national health system. Our work with the NGO allowed us to develop a more nuanced, adaptable tool. However, we recognize that this model is not directly transferable to national health systems, which often operate on larger scales where reaching research agreements can take years, limiting the capacity for quick iteration. Nonetheless, we demonstrate how learning directly from CHWs can inform the design of mHealth tools that can later be modified to fit broader contexts.

Conclusions

The implications of this study extend beyond rural Guatemala. The methods outlined in this study provide a context-informed model for the evaluation and iterative refinement of similar mHealth solutions in other LMIC settings, including at the level of small pilot studies. More broadly, this work demonstrates the value of formative, CHW-centered evaluation in identifying factors such as training, workflow, cultural alignment, and structural supports that shape the real-world implementation of digital health interventions. Researchers developing novel interventions like mHealth tools should ensure their use is driven by the specific needs and expectations of the communities in which they work. By integrating community feedback and attending to cultural sensitivity during an iterative design process, we provide practical guidance for how future mHealth initiatives can enhance usability and impact.

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The authors used the generative artificial intelligence tool ChatGPT (OpenAI; GPT-4 and GPT-5 models) to assist with language editing and clarity during manuscript preparation. The tool was not used to generate original research content, perform data analysis, conduct literature searches, interpret results, or draft substantive sections of the manuscript. All artificial intelligence-assisted text was reviewed and edited by the authors, who remain fully responsible for the accuracy, integrity, and originality of the manuscript.

Data Availability

The data generated during this study are not publicly available due to ethical and confidentiality considerations related to the small sample size and the inclusion of qualitative interview data. Requests for access to deidentified data can be directed to the corresponding author and will be considered on a case-by-case basis.

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Authors' Contributions

ABC and PNP contributed to study design, mHealth (mobile health) app development, project implementation—excluding data collection—and assisted with manuscript drafting and editing. SD assumed the lead role in study design, clinical algorithm development, and project oversight and contributed to manuscript review and editing. TMV directed study planning and data collection, supervised data analysis, and contributed to manuscript drafting, review, and editing. AC led mHealth app development and data collection and contributed to manuscript review and editing. IA contributed to study planning, manuscript review, and program implementation. RT and YLL contributed to study design, project implementation, and contributed to manuscript review and editing. CP contributed to study design, app development, project implementation, data collection, and contributed to manuscript review and editing.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Diagram of the mHealth Application Workflow.
[PDF File (Adobe PDF File), 111 KB - formative_v10i1e75471_app1.pdf]

Multimedia Appendix 2

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Community health worker training PowerPoint.
[PDF File (Adobe PDF File), 5895 KB - formative_v10i1e75471_app2.pdf]

Multimedia Appendix 3
Likert scale survey template and written survey questions.
[PDF File (Adobe PDF File), 67 KB - formative_v10i1e75471_app3.pdf]

Multimedia Appendix 4
Focus group interview question guide.
[PDF File (Adobe PDF File), 43 KB - formative_v10i1e75471_app4.pdf]

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Abbreviations

CHW: community health worker
COREQ: Consolidated Criteria for Reporting Qualitative Research
LMIC: low- and middle-income country
mHealth: mobile health
NGO: nongovernmental organization

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SUS: System Usability Scale

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Original Paper

Involving Health Care Professionals in the Human-Centered Design of a Digital Platform for Work-Focused Health Care: Lessons From a Mixed Methods Study

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Abstract

Background: Effective collaboration throughout the full cycle of care is essential for value-based health care. In the Netherlands, occupational health care and curative health care traditionally operate as 2 separate sectors. As a consequence, effective communication and robust collaboration between professionals working in these sectors are lacking. Digital collaborative care platforms (ie, digital systems that facilitate communication and collaboration between health care professionals) are recognized as a promising solution to address the fragmentation of work-focused health care (health care that supports people on long-term sick leave in staying at or returning to work). A human-centered design (HCD) approach can help ensure that such platforms align with professionals' needs by involving them throughout the design process.

Objective: This study examines the experiences of (work-focused) health care professionals, including occupational physicians, insurance physicians, medical specialists, and general practitioners, during the design phase of a real-world HCD process for developing a digital platform to support collaborative care. The study specifically focused on understanding how these professionals perceive this collaborative approach.

Methods: A mixed method study design was employed, combining observations of 17 design sessions with semistructured interviews with health care professionals as intended users of the platform. Observational data captured session dynamics, while interview data provided deeper insights into professionals' experiences with the participatory HCD approach.

Results: Health care professionals were generally motivated to contribute, driven by professional interest, social encouragement, or a desire to improve practice. They valued the open and informal atmosphere of the design sessions and described their role as actively sharing practical experiences and identifying bottlenecks in current practice. Participants emphasized the importance of clear goals, good preparation, and iterative involvement for meaningful engagement. Barriers identified included limited session time, constraints of virtual interaction, and uncertainty about the commercial context of the platform. Some professionals felt unsure about the relevance of their input or experienced limited interaction, especially when the session's purpose was unclear. Others noted that the use of a mock-up platform as a conversational foundation, familiarity with similar system interfaces, and well-guided, structured discussions facilitated their input. Positive experiences included a sense of impact through involvement in the design process, note-taking as part of active user engagement, and a safe environment for open and constructive feedback. Participants recommended a clearer explanation of the platform's broader aims in advance, enhanced participant preparation, and opportunities for multidisciplinary co-creation in future sessions.

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Conclusions: Health care professionals valued being part of the collaborative design process, but their engagement and perceived contribution were highly dependent on how the design sessions were facilitated. Structuring design sessions with clear expectations, preparatory tools, and opportunities for follow-up can support more effective, foundational co-creation in digital platform development for collaboration among professionals providing work-focused health care.

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KEYWORDS

human-centered design; work-focused health care; networked-care platforms; end-user involvement; co-creation; digital platform development

Introduction

A major challenge in health care is the fragmentation between work-focused health care and curative health care. In the Netherlands, these sectors function as 2 separate entities that collaborate suboptimally [1,2]. Work-focused health care refers to the system and professionals, including occupational physicians, insurance physicians, and labor experts, who are responsible for work-focused health guidance, return-to-work (RTW) support, and work disability assessment, as regulated by the Dutch Gatekeeper Improvement Act and the social insurance system. Curative health care refers to medical care provided by general practitioners and medical specialists, aimed at diagnosing, treating, and curing diseases. Organizational and operational structures for direct referral, reimbursement, and multidisciplinary consultation and collaboration are insufficient or lacking [3,4]. Furthermore, communication between professionals operating within these 2 distinct health care entities is inadequate and inefficient [5]. This lack of coordination has significant implications for work-focused health care, particularly in addressing key challenges such as an aging workforce and the increasing prevalence of chronic diseases within the working population [6]. Inefficient collaboration between occupational and curative health care can lead to delays in RTW processes, increased administrative burden, and suboptimal support for employees with complex or long-term health conditions [6,7]. Therefore, there is a clear need for a digital infrastructure to enhance communication and collaboration between the work-focused and curative care sectors [5]. Digital platforms have the potential to directly address these inefficiencies by facilitating real-time information exchange, enabling seamless multidisciplinary consultation, and integrating care pathways across occupational and curative health care sectors [8]. By breaking down silos and supporting coordinated action, such platforms can reduce administrative burden, minimize delays in RTW processes, and improve outcomes for workers with complex or long-term health conditions [2,9].

A promising strategy to address these problems is to establish regional work-focused collaborative care networks in which all relevant health care professionals—from both work-focused and curative care (ie, medical specialists, general practitioners, occupational health physicians, and insurance physicians)—work together throughout the full cycle of care surrounding the sick worker [5]. Such collaborative care networks could contribute to sustainable employability. To operate effectively and efficiently, these networks should ideally be supported by digital platforms for information sharing, care planning, and digital multidisciplinary consultation [5]. Although regional collaborative care via digital platforms is endorsed by governmental authorities [10] in the Netherlands, insights into the design and implementation of such platforms across sectors are still lacking. To ensure sustainable implementation and use, it is highly important to align the platform with the functional and technical requirements of all users and stakeholders involved [11].

In this context, human-centered design (HCD) has gained prominence as an essential approach for integrated health care innovations, as it helps ensure that interventions are tailored to the real needs of patients, caregivers, and health care providers [11]. HCD is a person-focused methodology that aims to create intuitive, effective, and meaningful interventions by involving key professionals throughout the development process [11,12]. While user-centered design focuses on optimizing usability for end users, HCD adopts a broader, more holistic approach that considers the needs, values, and context of all people involved, including professionals, patients, and other stakeholders. The goal of HCD is to align human needs with complex environments such as work-focused care and curative care [11,13,14]. A fundamental principle of HCD is the initial assessment of the target population's needs, ensuring that solutions are tailored to the intended users [11,15]. A common HCD approach is the 4-phased double-diamond approach—(1) discover, (2) define, (3) design, and (4) validate—which enables iterative development through continuous stakeholder engagement [11,16]. The (1) discover phase aims to comprehensively understand the problem, informing the (2) define phase to clarify the actual problem. The (3) design phase employs participatory methods, such as co-creation, to address the defined problem. Finally, in the (4) validate phase, small-scale testing is conducted on different interventions to identify the most suitable one. These phases are often framed in a double-diamond model to reflect the iterative nature of exploring various solution options before narrowing down to the most suitable solution [11]. HCD adopts a holistic approach, considering a system of interacting and interdependent stakeholders rather than a single group [11]. In health care, HCD is widely applied in health technology innovation [14], especially in integrated care where multiprofessional collaboration is essential. Health challenges such as chronic diseases, aging populations, and mental health issues require multistakeholder input from patients, care providers, policy makers, and IT developers to co-create context-aware innovations that enhance usability and practical implementation [17]. Additionally, health care technologies often face resistance

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due to usability or workflow issues [8], but involving end users in co-design fosters engagement, co-ownership, acceptance, and trust [8]. In this way, HCD-driven development helps address implementation challenges, especially in networked care models that rely on interoperability, data sharing, and coordinated workflows [11].

This study explores how health care professionals perceive their involvement and the value they attribute to participating in the design of a platform aimed at enhancing interprofessional collaboration to facilitate a collaborative care network for work-focused health care. By addressing these objectives, the study provides insights into the practical use of collaborative design sessions in health care technology development and offers recommendations to optimize user involvement in the design and implementation of digital platforms that support collaboration between work-focused health care and curative care.

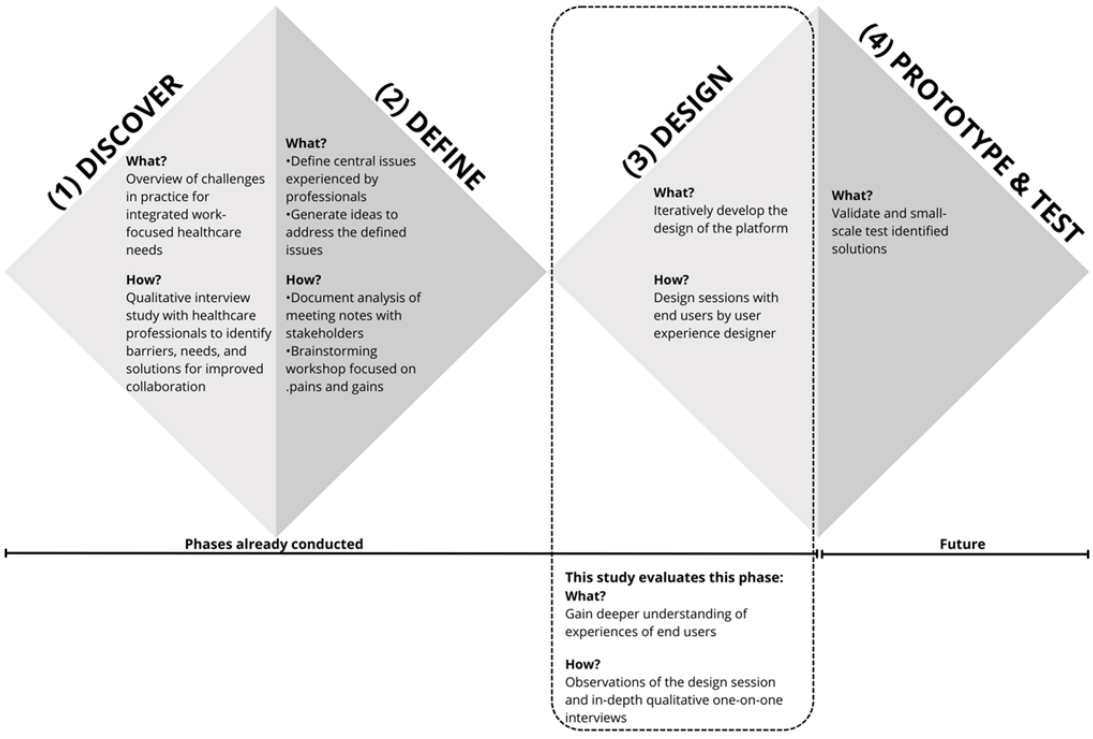
Methods

Study Design and Setting

The study used a mixed method design, combining qualitative observations of design sessions with semistructured in-depth interviews to gain insight into the experiences of health care professionals as intended users of the platform. Observations were used to inform and tailor the subsequent interviews. This study adhered to the COREQ (Consolidated Criteria for Reporting Qualitative Research) checklist to ensure comprehensive and transparent reporting of qualitative research methods and findings. The completed COREQ checklist is provided in Multimedia Appendix 1.

This study specifically evaluates (work-focused) health care professionals' experiences during a design session in the development of a digital platform, as part of a broader design process (Figure 1). While design processes using an HCD approach may involve a diverse range of stakeholders, including decision makers, policy makers, and insurers, this study focuses exclusively on health care professionals, aiming to gain a deeper understanding of their experiences and to ensure the platform's relevance to their daily practices. The first 2 phases, discover and define, were part of earlier studies that examined both patients' and professionals' perspectives [1,2,18]. In the discover phase, qualitative interviews and patient journey mapping were used to explore the experiences, needs, and barriers of workers living with cardiovascular disease, as well as the perspectives of health care professionals involved in work-focused health care [1,2]. Key findings from these studies highlighted persistent fragmentation and suboptimal communication between occupational and curative health care, insufficient multidisciplinary collaboration, and a lack of digital infrastructure to support RTW processes. Both patients and professionals expressed a need for better information exchange, clearer role definitions, and more integrated care pathways [1,2,18]. The involvement of people with lived experience (patients and professionals) was central to these phases, ensuring that the design constraints and priorities reflected real-world practice. The detailed results of these phases are published elsewhere [1,2,18]. The study setting was embedded within the Value@WORK research project, which focuses on implementing value-based health care and promoting collaboration in a work-focused collaborative care network for patients with cardiovascular disease who experience work-related problems.

Figure 1. Overview of the person-centered design approach and the focus of the current mixed-methods study evaluating experiences of healthcare professional during the design phase of a digital platform for work-focused healthcare in the Netherlands based on Melles et al. [10, 15].



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Phase (3) Design: Setup Design Sessions

The design sessions were led by a company specializing in the development of digital infrastructure for health care professionals, specifically a digital platform that supports interprofessional communication and collaboration among professionals [19]. A user experience (UX) designer from this company, who was responsible for developing the digital platform, facilitated the sessions. In these one-on-one sessions, the designer presented mock-up versions of a potential platform (ie, a static representation of the envisioned digital interface) and invited health care professionals to provide feedback. In addition, a platform developer was present in each session to explain the platform's goals and to ensure maximal learning. The researchers were involved as independent observers, capturing the experiences of health care professionals as intended users of the platform throughout the process. To support an unbiased evaluation, clear agreements were established regarding data governance, confidentiality, and independent analysis of the findings. The researchers had full autonomy in conducting the evaluation and interpreting the data, separate from the platform developers. The design session format (see also Table 1) followed these steps: (1) an introduction to the broader context and purpose of the platform, (2) presentation of a mock-up version of the platform, (3) an interactive discussion with the participant, and (4) a general wrap-up of key insights and next steps. All design sessions were held online via Microsoft Teams and lasted approximately 1 hour. The sessions were conducted using the same design, which did not change during this phase. Although the design sessions were intended as co-design activities, in practice they often focused on idea generation and feedback on a mock-up rather than fully participatory co-creation. This distinction is important for interpreting the level of user involvement and the rigor of the HCD process in this study.

Table 1. Format of the one-on-one design session conducted with 17 health care professionals as part of a mixed methods study on the development of a digital platform for work-focused health care in the Netherlands.

Step in the design session format	Explanation of this step
1. Introduction	A typical session began with the platform developers providing an overview of the broader context of integrated work-focused health care and the platform's purpose. The UX[a] designer then explained the process and set the framework for the design sessions. Depending on the participant's familiarity with the goals of the design, this step ranged from brief to more detailed.
2. Presentation of the platform mock-up	The UX designer shared their screen via Microsoft Teams to present a static mock-up of the platform. Key features, such as a timeline, document-sharing tools, agenda functionalities, and user permissions, were demonstrated. During this step, participants observed but did not interact directly with the mock-up.
3. Interactive discussion with participants	During this step, open, high-level questions invited participants to share their thoughts on the platform's overall design, usability, and alignment with their professional needs. The UX designer clarified participants' questions and elaborated on specific features of the mock-up version of the platform. The platform developers provided additional context, particularly in areas related to business considerations, finance, and future implementation. The discussion focused on general impressions, perceived usefulness, and potential barriers or facilitators for implementation rather than on detailed workflow or task-based usability testing. Participants did not interact directly with the mock-up; instead, they provided feedback based on the demonstration and their professional experience. Discussions often addressed workflow inefficiencies, privacy concerns, and role-specific requirements, ensuring that the feedback was relevant and actionable.
4. General wrap-up	The design sessions concluded with a summary of the key points discussed and requests for further participation in future iterations of the platform.

[a]UX: user experience.

Participants and Recruitment

The study included 17 health care professionals who each participated in an individual design session as intended users of the platform under development. Each participant was involved in a single design session. These participants represented both work-focused health care professionals (ie, occupational health physicians and social insurance physicians) and curative care professionals (ie, medical specialists and general practitioners). Participants took part in the design sessions, as described above, and were also included in the evaluation of the HCD process. This ensured that all professionals who engaged with the mock-up during the (3) design phase also provided feedback on their experiences.

The study involved health care professionals for whom the new platform is intended to be used, including 3 insurance physicians working with the Dutch social security agency, 1 policy advisor from the same agency with a focus on digital technology development, 1 reintegration counselor from the Dutch social security agency, 1 private insurance physician, 5 occupational physicians, 2 cardiologists, 2 general practitioners, 1 physiotherapist, and 1 clinical psychologist. These professionals were selected because they are involved in providing both work-focused and curative care, as identified by patients in an earlier study [1]. Participants were recruited using a combination of convenience and snowball sampling from the networks of the researchers and the developers. While the platform developers led the organization of the design sessions, recruitment was a shared effort based on a jointly defined overview of professionals involved in work-focused health care, informed by earlier studies [1,2]. Notably, the evaluation of the experiences of professionals intended to use the platform was initiated independently by the researchers and agreed upon in advance. All health care professionals who participated in a design session were also invited and agreed to take part in the interviews for the purpose of this study.

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Data Collection and Analysis

Data were collected from (1) observations of the one-on-one design sessions and (2) one-on-one semistructured interviews with participants after their participation in the design session. All data were collected between June and September 2023. Both the design sessions and the one-on-one interviews were conducted online via Microsoft Teams. The design sessions were observed by the first author (NZ), who also conducted the one-on-one interviews.

Observations

As part of the data collection process, all design sessions conducted in phase 3 were systematically observed using a structured observation checklist to gain deeper insights into UX with the participatory HCD approach during platform development. This checklist was developed for the study and included predefined categories related to session structure, participant and UX designer behavior, and the use of supporting materials. Particular attention was given to nonverbal cues, hesitations, and spontaneous feedback, providing a deeper understanding of how professionals experienced their involvement in the design session. The approach was primarily deductive, but notes were also taken on any additional relevant behaviors or events that emerged during the sessions. The detailed observation checklist is presented in Multimedia Appendix 2.

The insights from these observations were used to structure and refine the subsequent semistructured interviews, ensuring that questions addressed key aspects of the collaborative approach during the design session, such as users' perceptions of collaboration, their sense of influence over design decisions, and their overall engagement in the process. By identifying patterns in user responses and areas of uncertainty or enthusiasm, the observations helped guide a more in-depth exploration of health care professionals' experiences, leading to a richer understanding of the impact of the participatory HCD approach. The observational data were primarily used to contextualize the results and to inform the development and focus of the subsequent qualitative interviews, thereby enhancing the relevance and depth of the insights gathered.

Semistructured Interviews

To gain a deeper understanding of the experiences of the involved health care professionals, qualitative semistructured interviews were conducted with all participants following the design session. An interview guide was developed to gain insights into participants' motivations for joining the session and their experiences. It included questions about their expectations for participating in the design session, their overall experience, their perceived role, the extent to which they felt prepared, their experience with the materials used, their communication with the UX designers, and their envisioned future role after participating in the design session. The interview guide served as a memory aid during the interviews. The detailed interview guide is presented in Multimedia Appendix 3. Interviews were conducted individually following the design session and lasted approximately 30 minutes. All interviews were audio-recorded with participants' consent and later transcribed verbatim. The data were then analyzed using thematic analysis, which involved coding the transcripts to identify key themes and patterns. Thematic analysis of the interview data was primarily inductive, with codes and themes developed from the data. However, the structuring and interpretation of themes were guided by the "4 E's of HCD participation" framework, providing a deductive lens for organizing the findings [12]. This method allowed for a systematic analysis of the structure, process, experiences, perceptions, and feedback shared by participants [12]. To guide the structuring and interpretation of themes, the "4 E's of HCD participation" framework was used: *engage*, *elicit*, *elaborate*, and *evaluate* [12]. *Engage* refers to the process of actively involving participants in the design process, ensuring they are invested in and committed to the development of the platform. *Elicit* involves gathering input from participants to understand their needs, challenges, and expectations regarding the platform. *Elaborate* entails refining and expanding on the gathered input, allowing for deeper discussion and clarification of participants' perspectives. *Evaluate* focuses on assessing the effectiveness of the design, ensuring that the platform aligns with users' needs and improves their work-focused practices. All data were analyzed in MAXQDA.

Role of the Researchers

The first (NZ) and second (MEH) authors are full-time researchers with demonstrated expertise in qualitative research methods. The fourth author (MMM), in addition to being a full-time researcher with expertise in qualitative research methods, provided expertise in HCD and user involvement in the development process. The other authors (BEC and SJvdBV) are experienced researchers with knowledge of both the curative care sector and the work-focused care sector, contributing to the relevance of this study. Notably, none of the authors were involved in the design of the design sessions. While this independent position may limit the ability to fully assess certain aspects of the design process, it also allowed for an unbiased observation and evaluation of participant experiences. However, it may have limited the ability to fully capture the rationale behind certain design choices or the nuances of the facilitation process.

Ethical Considerations

This study was reviewed by the Medical Ethics Committee of the Amsterdam University Medical Center, which determined that it did not fall under the scope of the Medical Research Involving Human Subjects Act (Reference 2023.0463). Therefore, formal ethics approval was not required according to institutional and national guidelines. All participants provided informed consent for the researcher to observe the sessions and conduct interviews before participation. Participation was voluntary, and participants could withdraw at any time without consequence. To ensure privacy and confidentiality, all data were anonymized and deidentified before analysis. Audio recordings were transcribed verbatim, and any identifying information was removed. Data were stored securely and were accessible only to the research team. No compensation was provided to participants for their involvement in the study.

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Results

Overview

In total, 17 individual one-on-one sessions focusing on the same design were conducted, each followed by a one-on-one interview to explore participants' experiences with the session. The section below presents the findings, structured along the 4 E's of HCD participation: *engage, elicit, elaborate,* and *evaluate* [12].

Engage: Motivations and Preconditions for Participation

Participants described various reasons that shaped their motivation for joining the design sessions. These motivations reflected both intrinsic professional drivers and contextual conditions that enabled or constrained engagement. Some professionals indicated that they were driven by a desire to "contribute to improving the quality of the profession," aiming to enhance their field of practice. Others appreciated that "participation provides variety in work" and viewed the design sessions as a welcome change from routine tasks. Additionally, professionals reported being "motivated for change," particularly in addressing long-standing communication barriers. Curiosity also played a role, especially among those with "prior exposure to digital innovations" or a "professional expertise and interest in technology." As one insurance physician explained:

> *...through my work, I deal with aspects like medical confidentiality and GDPR. Data sharing is part of my portfolio, and I am also involved in the IT side of things. I am not an IT professional, but whenever an IT system is being developed, they involve me. So, for that reason, I do have some interest, and I felt this fit well with that. I enjoy seeing a bit of development and wondering, "Where is this going?"* [Insurance physician, female]

Engagement was also influenced by "social proof and personalized recruitment." Professionals reported that they were more inclined to join the HCD process after a colleague had personally recommended participation or confirmed that the process was worthwhile. This collegial endorsement provided reassurance and fostered trust, thereby encouraging participation.

While many professionals expressed motivation to contribute, engagement was also shaped by "uncertainties regarding the commercial character of the design sessions." This ambiguity created hesitancy for some, who questioned the intentions of the organizing party and whether their input aligned with professional values or scientific interests. One participant stated:

> *Well, I do not know that company [organizing the design session], so why would I help this company with its commercial product? Whereas if it were different—let's say you wanted to develop this product from an academic perspective—then I probably would have said, "Oh, sure, I will help, you know?" But that makes it different for me. If you know that research is involved, or that we are going to look at whether this actually has an effect in an evidence-based way, then I find that more valuable to contribute to than just helping another commercial company put its product on the market.* [Occupational physician, female]

Elicit: Health Care Professional Input and Interaction During the Design Session

Health care professionals described their roles during the design sessions as "being a brainstormer" on the topic, appreciating the open space and using the opportunity to think aloud and provide relevant feedback and input for the platform's development. They experienced the sessions as a space to "share experiences and bottlenecks from practice," with the expectation that these insights would help shape a collaborative care network platform that is better aligned with the complexities of work-focused health care. As one participant explained:

> *Well, I hoped, so to speak, that I was able to provide a lot of information. A lot of information that can actually be used, something that is useful. That was my own idea of it—just share as much as possible, examples from practice. So that the people working on a problem, to come to a solution, can use all that information to reach a resolution.* [Insurance physician private, female]

Some professionals noted that "minimal presession preparation" lowered the threshold for participation and made it easier to join the session. Looking ahead, several professionals stated that, once the platform becomes more concrete, they could see themselves "sharing the platform's existence" among colleagues, especially if the platform evolves into a usable form. One professional remarked:

> *I would briefly talk about [the platform], particularly with colleagues who are more involved in the IT side and data exchange. I would definitely mention it to them. [The platform] is already a bit more concrete than it was before. But I think that as I attend more sessions in the future, the more concrete it becomes, the more I will have to share -that is what I mean....Because for now, I would probably only say that this is something being worked on but that it is still in the early stages.*" [Insurance physician, female]

Alongside positive experiences, participants also noted barriers affecting interaction during the design session. Some professionals reported that it was "unclear what the platform's purpose and personal relevance is" and that they received "limited information on the aim of the design session," making it challenging to provide focused input. Several professionals indicated that a "defensive response by the session moderator" obstructed open dialogue and made them feel that their input was not taken seriously. Others reported "limited interaction during the design session," resulting in one-sided exchanges. As one professional reflected:

> *Well, I think I mainly gave my input somewhat freely and did not give them much opportunity to speak, or ask many questions, so to speak. The time was up so quickly, and afterwards, I thought: Oh dear, I mostly just shared my own perspective. That was it. There might have been too little of a real conversation, you*

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> *know—a bit one-sided, perhaps.* [Clinical psychologist, female]

Some professionals expressed that they could provide only "limited input due to a perceived lack of professional expertise," as they did not see themselves as experts in medical information exchange or the development of digital tools. Differences in session pacing also influenced active interaction and input: some participants found the "duration of the session too short," while others felt that the "duration of the session was long enough." Practical barriers were frequently related to the virtual format. Several professionals described "challenges of a virtual design session," such as delayed turn-taking or audio issues, as one professional expressed:

> *The only thing that was perhaps a bit less smooth was that, because it was on Teams, there were moments where you wonder, "Am I interrupting when I speak?" And there was one moment when I could not hear him properly. Those kinds of small things. But that was it—live, it might have been a bit easier.* [Insurance physician, female]

Additionally, presenting a "mockup platform as a conversational foundation to facilitate concrete understanding" helped guide professionals through the session. One professional noted:

> *I think it is the combination [of presenting a static mockup and interviewing]. The platform is the foundation, and the questions around it, which were clarified, make you provide answers. But the platform is definitely the foundation that guides the conversation.* [Occupational physiotherapist, female]

Professionals noted that, for the mock-up to be helpful, "good explanation while showing the design" was essential. Additional facilitators included "familiarity with similar system interfaces," which made it easier to provide feedback, and the use of "clear and specific open questions," which prompted more targeted input. Overall, many described the session as a "well-guided, structured discussion." Several professionals also expressed that their contribution had an "impact due to involvement in human-centered design." One professional shared:

> *Well, it definitely makes a difference, because you are involved, so you also feel like there is really an effort to listen to those who will actually work with it. What I often see in health care is managers, or other roles, who come in but are never on the work floor. They do not know how the process works, and then suddenly a process is rolled out that you are expected to implement. And we sometimes think, "Goodness, who came up with this? How is this even possible?" Not all steps are necessarily bad, but the process often hits a snag, and you think, "But this is a critical point where it fails." You really need to involve the people who will actually work with it or, if it is for the work floor, those who will use it. That way, you know what you are doing with such a system and whether it is implementable for those who have to work with it. So, that is really nice. I truly believe that in this way, we can definitely contribute.* [Medical specialist, cardiologist, female]

Professionals also appreciated when the moderator (the UX developer of the platform) engaged directly in note-taking, describing this as "active user engagement," which increased their sense of being taken seriously. Moreover, many reported experiencing a "safe environment for open and constructive feedback," especially when explicitly invited to interrupt, comment, or raise concerns. One professional said:

> *Yes, he [the interviewer] offered that right at the start of the conversation: "You can interrupt me, or if you see something you want to comment on, feel free to do so." And that is nice, because sometimes in these kinds of conversations, they only want questions one to ten answered, and then I might have something in my mind like, "Oh, but this does not look right, but I cannot say anything about it because that is not what the conversation is about." But now, I could. It is then up to him, or the organisation, whether they do something with it, but at least I was able to express what my concerns or potential risks are.* [Private insurance physician, female]

Elaborate: Reflection and Value of Participation

Health care professionals reported mixed expectations before participating in the design sessions. Some indicated that they had "no expectations prior to the design session," while others anticipated a degree of interactivity and were "expecting a user interface mockup" based on previous experiences with digital design activities. As one professional explained:

> *I did indeed expect that we would navigate through some kind of product. I participated in something similar once before, which involved navigating a website where I had to search for items and see if I could find them. So, I thought maybe I would get assignments or something. Or they [the facilitator and designer] would show me something, to see if it looked good and if it was practical.* [General practitioner, female]

Professionals acknowledged the potential added value of participation and expressed a "positive experience with user involvement," although some hesitated due to a "perceived unfavorable time trade-off" relative to their patient care responsibilities, offering them limited personal benefit. The "importance of designs" was recognized, with participants noting that even simple versions can reveal issues before further development. Furthermore, the "value of various backgrounds in co-creation" was highlighted, as professionals appreciated multiperspective engagement and the opportunity to hear diverse input, which they felt enriched the feedback process. For some, participation also contributed to personal learning. They described the session as providing "gaining more insight into rules and regulations," particularly regarding data protection. Others mentioned "insight into progression in new developments," expressing enthusiasm about moving from discussions on improving collaborative work-focused health care to actual implementation. One professional said:

> *For me personally, what was the added value: Well, I enjoyed it because I was kind of triggered with ideas.*

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> *So, it also gave me a broader perspective on this issue, so to speak, on what it is for. And maybe I did not have such a clear picture myself of this particular solution direction, for example.* [Private insurance physician, female]

Several professionals highlighted that their participation in the session provided a glimpse into the future of more collaborative work-focused health care and helped them understand the platform's potential value.

Evaluate: Recommendations for Future End-User Involvement

Health care professionals provided multiple recommendations for future end-user involvement in the development of the communication platform. They emphasized the "need for a clear explanation of the platform's broader aim in advance" and requested "clear and concise communication beforehand" regarding the platform's goals. As one professional remarked:

> *When you are explaining something more complex or outside of what people already know, yes, then you really need to inform them beforehand. Otherwise, I would have needed the entire hour just to understand it, without even being able to give my reaction.* [Private insurance physician, female]

Others pointed to a "need for a clearer explanation of the development process," particularly regarding the co-creation concept, which was unfamiliar to some professionals. To improve session effectiveness, participants recommended a "clearer introduction during the design session" and "enhanced participant preparation," for example, through materials or examples provided in advance. One professional described the challenge of providing targeted feedback without sufficient prior context or familiarity. One professional said:

> *For us, as the audience, it is the first time....Sometimes it can catch you off guard a bit, putting you in a different mindset, like, "Whoa, hold on." But without me meaning that negatively. For the person presenting, they are already familiar with it, but for us, it is new. So, take that into account—think about how you can make us a kind of co-owner of what is being presented. Because that will make you look at it differently. It might also make it easier to come up with suggestions for improvement—I do not want to call it criticism, but suggestions for improvement or changes—if you are more engaged with it.* [Insurance physician, female]

Professionals recommended including "illustrative examples," such as user stories showing how a patient or professional would move through the platform, and offering a "demo for pretesting the platform" to help end users quickly understand its functionality. Some mentioned the value of "being able to autonomously navigate through the prototype platform," even if it meant using a simple clickable mock-up. Others expressed a "need for feedback on their input," seeking reassurance that their time investment had an impact and that their contributions were valued. To improve the session, professionals also mentioned a "need for reflection time," noting that insights often emerged only as the session progressed or afterward. One professional noted:

> *But then I think the improvement point, if I may call it that, is that there should perhaps be an option to revisit it afterwards, to take the time to reflect calmly on the whole process. I also noticed during the conversation itself that as we progressed, I started thinking, "Oh, that is important too, and so is that, and that as well." So, you kind of need to get into it, as it were.* [Occupational physician, male]

To enhance diversity and foster cross-pollination of ideas and input in the design process, professionals suggested "inviting a broader range of participants, including those without prior affinity for the topic," and expressed a "desire for discussion with other professionals." Finally, many professionals emphasized the value of moving toward "co-creation in multidisciplinary groups," viewing cross-professional dialogue as essential for advancing and refining the platform in future development stages. As one participant described:

> *And I think it is very important to do this with more people. So, involve more professionals from different perspectives. It is not a problem at all if they come from different environments. Include a cardiologist, an occupational physician, an insurance physician, a general practitioner. Maybe even a client, if you can manage that. Then sit together, have the conversation, and look at how this can help us and what could be different or better....Because you also stimulate each other at some point. In those discussions, in those conversations, a dynamic emerges where you encourage and challenge each other to think beyond boundaries and share broader experiences. And you sometimes need that input to move forward.* [Insurance physician, female]

Discussion

Principal Findings

This mixed method study explored how health care professionals experienced their involvement in the development of a digital platform for more collaborative, work-focused health care. Using the 4 E's of HCD participation framework (engage, elicit, elaborate, and evaluate), we gained insight into professionals' motivations, roles, reflections, and recommendations for participating in design sessions. The findings show that, while professionals were generally motivated to contribute, their level of engagement and perceived value of the session were strongly influenced by how the process was introduced, facilitated, and followed up.

A key finding was that motivation to participate was often tied to a personal interest in the topic or innovation, a sense of professional responsibility, or social encouragement from colleagues. Previous research has examined the involvement of end users and distinguished between intrinsic motivation, where individuals engage in design processes because they find them personally meaningful or aligned with their professional identity, and extrinsic motivation, which is driven by external rewards

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or expectations [20]. In HCD in health care, intrinsic motivation has been shown to contribute to deeper engagement, stronger ownership, and more context-relevant input from professionals [14]. The distinction between intrinsic and extrinsic motivation for engagement is in line with our findings that professionals were most engaged when they saw a clear link between their professional expertise and the development goals of the platform. In our study, health care professionals expressed frustration when the purpose or ownership remained unclear. This was also highlighted in a previous narrative review, which showed that transparency about the design context and expected outcomes is essential to sustain trust and active contribution in HCD processes [14]. Additionally, our findings indicate that the perceived intentions and background of the organizing party (eg, commercial company vs academic institution) can influence professionals' willingness to participate. Some participants expressed hesitancy when the design process was led by a commercial organization, associating academic or public initiatives more strongly with the public good and evidence-based development. However, literature suggests that commercial organizations can also be committed to public benefit and rigorous, human-centered innovation, especially when transparency and shared values are emphasized [8,17]. In terms of interaction, health care professionals in our study described their role during the sessions as "brainstormers," suggesting that a generally open and safe environment for sharing ideas was created. This reflects a key principle in HCD: enabling participants to contribute freely [11]. However, design researchers in health care often face challenges in managing a dual role of both enabling open dialogue and directing discussions toward actionable outcomes [21]. This is also supported by our findings, where professionals appreciated the opportunity to share their ideas but also expressed a need for clearer preparation and guidance, particularly before the session. HCD offers a wide range of techniques to prepare and guide professionals, such as the use of sensitizing tools to prime participants and enhance engagement by encouraging reflection before an interview session [11,22]. Previous research argues that generative tools not only contribute to creativity but also empower participants to contribute more meaningfully [23]. In our study, professionals expressed the need for more context and clearer expectations before the session, which could potentially be addressed by such tools. Notably, some participants indicated that they were still unclear about the overall purpose and direction of the platform during the design sessions, describing the project as being "in the early stages" and difficult to communicate concretely to colleagues. This finding is concerning, as a core principle of HCD is to involve end users meaningfully from the outset, with clear communication about the goals and intended impact of the intervention. Lack of clarity at this stage may limit the depth and relevance of user input and could undermine engagement and ownership. This highlights the importance of providing participants with sufficient background information, context, and a clear articulation of the project's aims before and during co-creation activities. Approaches such as shadowing have been shown to layer engagement strategies, allowing researchers to integrate various perspectives and better tailor design interventions to real-world complexity [24]. Applying similar preparatory methods in our setting could have helped balance the openness of idea sharing with more structured, context-informed discussion.

In addition, practical aspects such as the short duration of 1-hour sessions and the limitations of virtual interaction via video calls influenced professionals' ability to contribute fully. This aligns with earlier findings that design researchers often face time constraints and infrastructural limitations, which can restrict the depth of user engagement [21]. To improve future co-creation efforts in digital health innovation, especially within complex environments such as cross-domain care settings, researchers and developers should consider allocating more time and resources [2]. Alternatively, using preparatory tools such as informational or instructional videos can help clarify key concepts and expectations in advance, allowing the actual session to remain concise while maximizing efficiency and user input.

The experiences of professionals also revealed a desire for more iterative involvement. Professionals expressed that they felt their participation was limited to a single design consultation, rather than being part of an ongoing development process. This underlines the importance of designing HCD processes that not only collect feedback on a single occasion but also show how user input informs development and offer opportunities for continued engagement. Iterative participation enhances a sense of co-ownership and contributes to better alignment between user needs and final interventions [11]. A central strength of HCD is that it directly involves those who will ultimately use or implement the intervention, ensuring that their practical knowledge and needs shape the outcome [11]. This was strongly reflected in our findings, as participants emphasized that active engagement in the design process increased their sense of being heard and contributed to the development of interventions that are more likely to be practical, relevant, and accepted in daily practice. Such involvement stands in contrast to top-down approaches, which often result in solutions that are less attuned to real-world workflows and may face resistance during implementation [25].

A core value of co-creation is the inclusion of diverse, interdisciplinary perspectives to enrich the design process and stimulate creative solutions. This was strongly reflected in our findings, as participants emphasized the importance of involving a broad range of professionals, and even patients, in collaborative sessions. This perspective is well supported in the literature, which shows that interdisciplinary co-design sessions foster creativity, mutual learning, and more contextually relevant and implementable interventions [11]. Interprofessional collaboration and the inclusion of diverse stakeholders, including patients, are recognized as best practices in HCD, as they help ensure that interventions are robust, acceptable, and sustainable in real-world settings [26]. While our findings reaffirm core HCD principles, such as the importance of user engagement and iterative feedback, this study uniquely highlights how the context of cross-domain health care and the nature of session facilitation (commercial vs academic) influence participant motivation and the effectiveness of co-design. These insights extend the current literature by illustrating practical challenges

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and opportunities for HCD in complex, real-world health care settings.

Limitations

Although this study offers valuable insights into health care professionals' experiences with HCD in the context of work-focused health care, several limitations should be acknowledged. First, the sample of health care professionals consisted mainly, though not exclusively, of individuals already interested in integrated care or digital innovation. This may limit the transferability and representativeness of the findings to less engaged individuals or those who are hesitant about digital interventions. Second, all design sessions were conducted online. While virtual formats offer convenience and accessibility, they may reduce the depth of interaction by limiting nonverbal communication. Third, participants were involved in a single design session during the design phase. A more continuous and iterative approach, with repeated engagement across phases, could have provided deeper insights into how professionals' perceptions evolve and how feedback is integrated into the final product over time. Fourth, the authors were not involved in the design or facilitation of the design sessions. While this independent position reduced the risk of bias in our observations and analysis, it may have limited our ability to fully capture the rationale behind certain design choices or to assess the nuances of the facilitation process. Future studies may benefit from closer collaboration between evaluators and designers or from including multiple perspectives in the evaluation process.

Implications for Practice

The findings of this study highlight the importance of a carefully structured and transparently communicated HCD approach, particularly in complex, cross-domain care settings. Developers of digital care platforms should invest in clear engagement strategies, such as using short videos or visuals to explain the goal, scope, and co-ownership of the platform. Sensitizing tools, such as brief presession assignments or opportunities for reflection, may further enhance user engagement. Facilitators of design sessions should carefully balance fostering open dialogue with providing structured guidance to ensure that the input gathered is both meaningful and actionable. Furthermore, timely follow-up communication that informs professionals involved in the design phase how their input has been incorporated can strengthen engagement, foster a sense of co-ownership, and ultimately contribute to more successful implementation. In addition, our findings highlight the importance of skilled facilitation in person-centered design sessions. Defensive or dismissive responses from session facilitators can undermine open dialogue and participant trust. Therefore, organizations leading co-creation or design sessions should invest in facilitator training focused on active listening, openness to feedback, and creating a safe, inclusive environment. Well-prepared facilitators are essential to ensure that all participants feel valued and that their contributions are genuinely considered in the design process.

Implications for Research

This study adds to the literature on HCD in health care by applying the 4 E's framework to examine the experiences of health care professionals as intended users of a digital platform in a real-world design phase. Our findings highlight the importance of aligning facilitation methods with the intended level of user participation. For rigorous person-centered design, it is essential to move beyond idea generation and feedback and to actively involve users in all stages of the design process through true co-creation. Future research could explore a more longitudinal and iterative participation approach and how this affects platform adoption. Additionally, perspectives from other stakeholders, such as patients, policy makers, and IT developers from other disciplines, would help build a more comprehensive understanding of suitable interventions in collaborative, work-focused health care.

Conclusions

This study contributes to a deeper understanding of how to meaningfully involve health care professionals in the design of digital health innovations. Applying the 4 E's of HCD participation revealed that motivation, quality of interaction, and iterative involvement are critical for effective co-creation, reinforcing and contributing to the existing body of literature on person-centered design in health care. To enhance future HCD efforts, clear communication, preparatory tools, and ongoing involvement should be prioritized, especially in complex, cross-domain care settings such as work-focused health care.

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Data Availability

The data that support the findings of this study are available on request from the corresponding author (NZ).

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Authors' Contributions

Conceptualization: NZ (lead), MM (supporting), EC (supporting), SJvdB-V (equal)
Formal analysis: NZ (lead), MH (equal), MM (supporting), SJvdB-V (supporting)
Investigation: NZ (lead)
Methodology: NZ (lead), MM (supporting), SJvdB-V (equal)
Supervision: MM (supporting), EC (supporting), SJvdB-V (lead)
Validation: MM (lead), SJvdB-V (lead)
Writing – original draft: NZ (lead), MH (supporting)
Writing – review & editing: NZ (equal), MM (equal), EC (equal), SJvdB-V (equal), MH (equal)

Conflicts of Interest

None declared.

Multimedia Appendix 1
COREQ (Consolidated Criteria for Reporting Qualitative Research) checklist.
[PDF File (Adobe PDF File), 485 KB - formative_v10i1e83212_app1.pdf]

Multimedia Appendix 2
Observation checklist.
[DOCX File , 24 KB - formative_v10i1e83212_app2.docx]

Multimedia Appendix 3
Interview guide.
[DOCX File , 24 KB - formative_v10i1e83212_app3.docx]

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Abbreviations

COREQ: Consolidated Criteria for Reporting Qualitative Research
HCD: human-centered design
RTW: return-to-work
UX: user experience

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Original Paper

Preliminary Usability Assessment of a Rule-Based Digital Self-Monitoring Platform for Patients With Brain Tumors Toward Digital Early Warning Systems: Pilot Feasibility Study

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Abstract

Background: Postoperative follow-up after brain tumor surgery is typically limited to intermittent clinic visits, leaving subtle neurological or general deterioration between visits underrecognized. Digital self-monitoring platforms may help fill this gap, but evidence in neuro-oncology is scarce, particularly regarding how patient-reported symptom trajectories can feed into future data-driven early warning systems.

Objective: This study aimed to evaluate the feasibility, use patterns, and preliminary usability of a smartphone or web-based self-monitoring system for patients after brain tumor surgery and to explore simple rule-based digital alerts as a first step toward an advanced digital early warning framework.

Methods: We conducted a single-center prospective pilot study including adults discharged after brain tumor surgery who had access to a smartphone and could use a web app. Participants completed brief symptom surveys consisting of 51 binary items across 7 symptom domains, with an automatically calculated daily total score and score history visualization. Feasibility was assessed by enrollment, retention, submission counts, and submission rates. A total of 4 interpretable alert rules based on current score, short-term worsening, new-onset symptom combinations, and persistence across domains were evaluated using each patient's last 3 submissions as the analytic unit. Clinical deterioration was defined a priori as objective decline in performance status, new neurological deficit, radiologic progression, or clinically significant laboratory changes. Rule performance metrics and bootstrap CIs were computed. Usability and acceptability were evaluated using the System Usability Scale and additional adherence-related items.

Results: Of 64 enrolled patients, 30 (47%) with ≥3 submissions formed the analysis cohort (median age 57, IQR 47.2–64.5 years; n=12.9, 43% malignant tumors); 6 (20%) experienced clinical deterioration during follow-up. Patients contributed a median of 8.5 submissions (mean 19.03, SD 30.12) at 1.7 surveys per week on average, indicating sustained but heterogeneous engagement. The best-performing rule, based on net short-term score increase, achieved an area under the receiver operating characteristic of 0.88, with sensitivity 0.83, specificity 0.92, and accuracy 0.90 on the last-window dataset, outperforming rules based solely on current score or multidomain persistence. Among 23 app users who completed the System Usability Scale, the mean score was 84.0, reflecting high perceived usability; higher-frequency users reported stronger perceived usefulness and habit-driven use.

Conclusions: This pilot study demonstrates that a smartphone or web-based self-monitoring platform for patients with brain tumor is feasible and well accepted and that simple, transparent rules applied to longitudinal symptom scores show potential to capture early signals of clinical deterioration. However, given the small sample size, these predictive metrics are preliminary and require rigorous validation in larger, independent cohorts. These findings support further development of integrated digital early

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warning systems that combine patient-reported trajectories with clinical and physiological data to enhance postoperative neurosurgical care.

(JMIR Form Res 2026;10:e87928) doi:10.2196/87928

KEYWORDS

brain tumor; neurosurgery; mobile health; self-monitoring; early warning systems

Introduction

Advances in neurosurgical techniques have markedly improved survival and functional outcomes in patients with brain tumors [1,2]; however, postoperative management remains one of the most complex challenges in in the field of neurosurgery [3,4]. After neurological surgery, patients often experience fluctuating symptoms such as headache, fatigue, cognitive decline, or subtle sensorimotor changes that may precede significant clinical deterioration [2,5-7]. Despite these risks, most follow-up systems still rely on intermittent hospital visits and subjective recall, leaving a critical gap in the continuous monitoring of patients' neurological and general well-being [8,9].

The expansion of digital health technologies, particularly smartphone apps and wearable devices such as smartwatches and smart rings, has created new possibilities for personalized and remote patient care [10-13]. Nevertheless, tools specifically designed for patient self-care remain scarce, and most existing digital monitoring systems are generalized, without the sensitivity required to detect subtle neurological changes. Patients with brain tumors constitute a rare and highly specialized group [14]. Because most specialists are concentrated in tertiary medical centers, and their number is limited, a considerable gap persists between apparent and actual accessibility to specialized care [15,16]. As a result, many patients struggle to receive timely evaluation and guidance for minor symptoms at primary or secondary health care institutions [17,18]. This imbalance often leads to 2 extremes: some patients with mild or nonspecific symptoms seek tertiary care unnecessarily out of anxiety or uncertainty, while others with neurological deficits delay seeking medical attention until substantial deterioration has occurred [8,19].

This study was designed to address these challenges by developing a self-report-based symptom monitoring system that incorporates simple rule-based alert algorithms. The system aims to support patients in managing mild symptoms independently, while providing early alerts for those showing signs of deterioration. To assess the practical feasibility of this approach, we designed and implemented a smartphone app to collect longitudinal patient-reported symptom data after brain tumor surgery. This pilot study evaluates the feasibility, usability, and preliminary applicability of the system as an initial step toward establishing a robust digital early warning framework for postoperative neurological risk detection. The findings from this work are expected to provide essential evidence for future large-scale integration of clinical, biological, and physiological data into a comprehensive digital ecosystem for continuous brain health monitoring.

Methods

Study Design and Setting

We conducted a single-center, prospective pilot cohort study to evaluate the feasibility and usability of a smartphone or web-based self-monitoring system for patients after brain tumor surgery during outpatient follow-up.

Ethical Considerations

The study protocol was approved by the institutional review board of Korea University Guro Hospital (2025GR0177). Written informed consent was obtained from all participants prior to study enrollment. To ensure privacy and confidentiality, all collected data were rigorously deidentified, and patient-level information was stored on a secure, encrypted clinical research server accessible only to authorized personnel. Participants did not receive any financial compensation for their involvement in this study.

Participants and Recruitment

Eligible participants were adults discharged after brain tumor surgery at our institution between April 2025 and October 2025. The participant eligibility criteria are presented in Textbox 1.

Textbox 1. Participant eligibility criteria.

Inclusion criteria

- Aged ≥19 years
- Consent to use the study app
- Access to a smartphone or PC
- Korean language proficiency

Exclusion criteria

- Severe cognitive impairment
- Life expectancy <6 months
- Investigator judgment of inability to participate

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Of 100 patients approached, 64 (64%) enrolled; after excluding those with <3 total submissions due to access issues (eg, older devices and unstable connections) and 2 midstudy withdrawals, 30 (30%) participants completed the study. Baseline characteristics (enrollment, attrition, sex, and diagnosis) are summarized in Figure 1 and Table 1.

Figure 1. Selection and inclusion of patients.

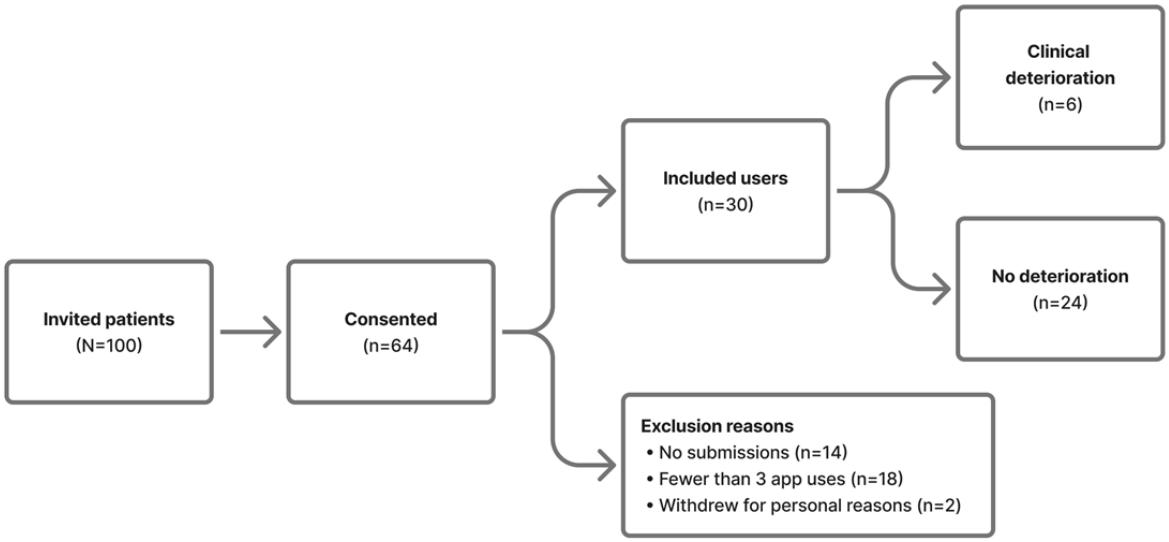

Table 1. Baseline characteristics of the patients who used the brain tumor self-monitoring app (N=30).

	Values
Age (years), median (range)	57 (16-78)
Gender, n (%)	
Male	19 (63)
Female	11 (37)
Diagnosis category, n (%)	
Malignant brain tumor	13 (43)
Benign brain tumor	11 (37)
Intracranial hemorrhage	4 (13)
Primary headache disorder	1 (3)
Head trauma	1 (3)
Clinical deterioration, n (%)	
Yes	6 (20)
No	24 (80)

Outcomes or Definitions

"Clinical deterioration" during follow-up was a composite clinical end point, met when any of the following objective criteria were observed: (1) a decline of ≥20 points in the Karnofsky Performance Status Scale [20,21], (2) new or progressive neurological deficits verified on clinical examination, (3) radiographic progression of intracranial lesions on serial neuroimaging, or (4) clinically significant abnormalities in hematologic or biochemical laboratory results indicating disease progression or systemic decline. Events were ascertained only when patients visited the outpatient clinic or were admitted to the emergency room and were verified by the treating neurosurgeon. To prevent information bias, the treating neurosurgeon adjudicating the clinical deterioration was strictly blinded to the patients' app-submitted symptom scores. The adjudication relied solely on objective electronic medical records, neuroimaging reports, and standardized clinical examinations obtained during these hospital visits. The "deterioration day" was strictly defined as the date of the patient visit (outpatient or emergency room) during which the objective end point was confirmed and recorded by the physician, rather than a retrospectively estimated date of symptom onset based

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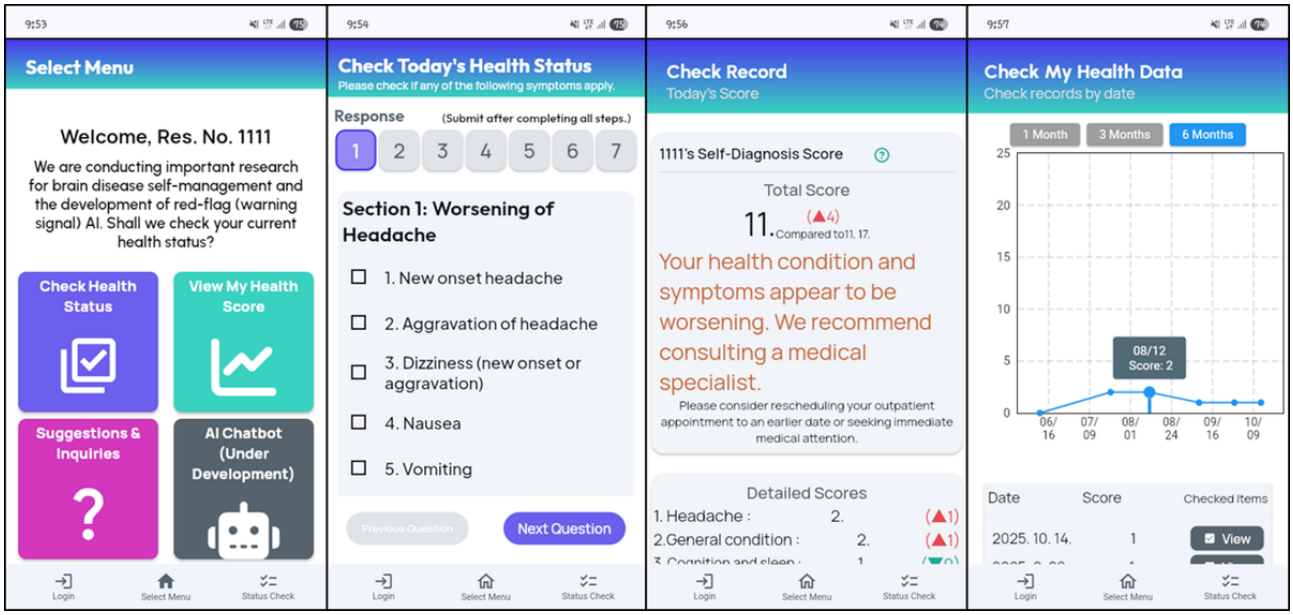
on patient recall. The remaining participants were classified as having no deterioration over the observation period.

Intervention: Rule-Based Digital Self-Monitoring Web App

Participants accessed a secure, credentialed web application providing three core functions: (1) *Daily symptom check*—7 sequential pages of brain-disease–related yes or no items (4-10 items per page), with an automatically computed same-day score based on the number of checked items; (2) "My score"—a time-series visualization of daily scores to support self-tracking; and (3) Free-text inquiries—patient-entered concerns routed to the attending neurosurgeon for in-app responses. The overall user interface and task flow are shown in Figure 2.

Figure 2. Screenshots of the brain tumor self-monitoring web app (English user interface) function overview. Screen 1 (menu after log-in): 4 tiles—Daily symptom check, View my score trend, Ask my doctor, and artificial intelligence chatbot. Screen 2 (Daily symptom check): 7 symptom categories relevant to neuro-oncology; each category presents 4 to 8 yes or no checkbox items with a step indicator (1-7) and a Next button. Screen 3 (Today's result): automatically computed daily score with brief interpretation and side-by-side comparison to the most recent prior submission. Screen 4 (My data): time-series plot of cumulative daily scores with tabbed views (graph or table) to review longitudinal trends. The application was originally designed in the Korean language. The figure displays an English-translated version that preserves the same layout and content.



Procedures

At discharge, a research coordinator provided onboarding (log-in, tutorial, and practice submission). Ongoing user support was provided through KakaoTalk (Kakao Corp), a widely used mobile instant-messaging app in South Korea [22,23]. Participants were encouraged to complete at least 1 survey per week beginning the day after discharge. One SMS text message reminder was sent weekly (Monday or Tuesday). Outpatient visits proceeded per standard care; no clinical management changes were mandated beyond app use.

App-Derived Features and Candidate Rules for Deterioration

Each daily submission comprised 51 binary items (checked=1 and unchecked=0). The total score on day t was defined as follows:

We also computed 7 subcategory subscores as within-category sums. A clinically curated set of "core" items, C = {6,8,12,13,14,22,23,26,29,30,32,33,34,49}, was prespecified as higher-risk symptoms. The complete list of the 51 symptom items, their category assignments, and whether each item was flagged as "higher risk" is provided in Table S1 in Multimedia Appendix 1.

The higher-risk symptoms (eg, confusion and seizures) were designated a priori as red-flag signs. These symptoms were defined as highly objective indicators of acute neurological deterioration that may pose an immediate threat to patient safety if not evaluated promptly. Although the rule-based alert algorithm is still under development, these red-flag signs were predefined as conditions requiring immediate clinical attention, even in the absence of other symptomatic changes. Clinically, these red-flag signs are operationalized to completely bypass the standard cumulative score rules (R1-R4). If a patient endorses any red-flag item, the system is designed to trigger an immediate on-screen warning instructing the patient to seek urgent medical care (eg, visiting the emergency room), independent of the rule-based thresholds. This red-flag designation is orthogonal to the core set C and was used to guide urgent clinical triage.

To reduce within-patient correlation and address class imbalance, the unit of analysis was each patient's last 3 consecutive submissions ("last-window": with most recent). For patients with adjudicated clinical deterioration, submissions up to "deterioration day" +1 were retained, and the last window was labeled positive (deterioration=1); otherwise, the window was labeled negative (deterioration=0). Patients with <3 submissions were excluded from rule analysis.

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We evaluated 4 simple, interpretable rule families as candidate digital alerts:

- R1: current total score threshold—alert if the current total score is greater than or equal to a fixed threshold T_1 (ie, $x_{i2} \geq T_1$)
- R2: net-increase sum threshold (Δ)—alert if the cumulative nonnegative increase in total score over the last 2 intervals meets or exceeds, that is, if
- R3: new-onset combo (core and noncore)—alert if at least C_{min} "core" symptoms and at least N_{min} "noncore" symptoms newly appear between the previous and current windows (ie, items with).
- R4: number of increasing categories—alert if at least K of the 7 category subscores have increased compared with the immediately preceding window (ie, if the count of domains with higher subscore in the current window is $\geq K$).

Threshold Tuning and Model Selection

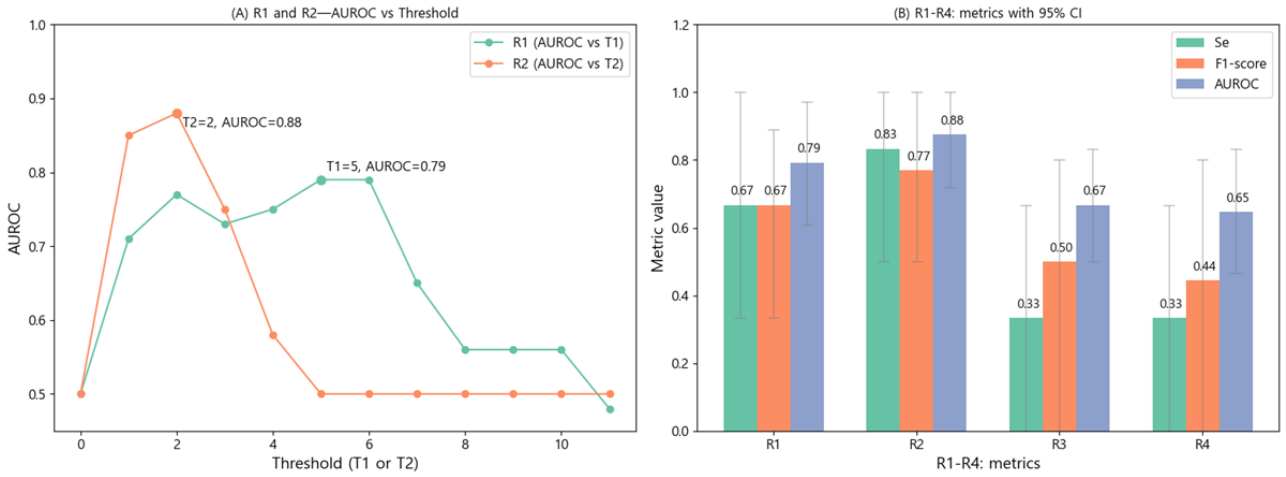
Thresholds were tuned on observed, discrete values in the last-window dataset using grid search: (1) R1: T_1 over empirical integer of x_{i2}, (2) R2: T_2 over empirical integer of , (3) R3: $(c_{min}, n_{min}) \in \{(1,0),(1,1),(1,2),(2,0)\}$, and (4) R4: $K \in \{2,3,4\}$.

The primary selection criterion was area under the receiver operating characteristic (AUROC); ties were broken by F_1-score and then by the positive predictive value (PPV). Final tuned parameters for each rule are reported in Table 2, with performance summarized in Figure 3.

Table 2. Candidate rule definitions for digital alerts.

Rule name	Inputs	Calculation	Optimized parameters
R1: current total score threshold	x_{i2}	Positive if $x_{i2} \geq T_1$	T_1=6
R2: net-increase sum threshold	x_{i0}, x_{i1}, x_{i2}		T_2=2
R3: new-onset combo (core and noncore)	$y_j(i1)$, $y_j(i2)$, C		c_{min}=1, n_{min}=1
R4: number of increasing categories			K=2

Figure 3. Threshold tuning and rule-wise performance. (A) Area under the receiver operating characteristic (AUROC) vs threshold for R1 (current total score) and R2 (net increase); optima at T_1 =5 (AUROC 0.79) and T_2 =2 (AUROC 0.88). (B) Comparison of sensitivity (Se), F1-score, and AUROC for R1-R4 at optimized settings, with 95% CIs shown.



Statistical Analysis

For each rule, we computed sensitivity, specificity, PPV, negative predictive value, F_1-score, accuracy, AUROC, and area under the precision-recall curve using the binary rule outputs on the last-window sample. Uncertainty was quantified with patient-level bootstrap resampling (5000 replicates) and percentile 95% CIs for each metric. Because our analytic approach restricted the dataset to a single "last-window" observation per patient (ie, analyzing only the final interval before an event or the end of follow-up), each participant contributed exactly 1 independent data point to the evaluation dataset. Consequently, within-patient clustering was inherently avoided in this analysis. Analyses focused on discrimination and precision-recall trade-offs appropriate for rare adverse events in small pilot cohorts. The Python code used for these analyses is available in Multimedia Appendix 2.

To address the missing data resulting from study attrition, we used a complete-case analysis approach for evaluating the alert rules. Because the primary objective of this pilot study was to establish initial technical feasibility and conduct rule-based parameter tuning rather than population-level causal inference, imputation of missing longitudinal submissions was not performed. To assess potential selection bias, baseline demographic and clinical characteristics were compared between the included participants (≥3 submissions) and excluded

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participants (<3 submissions) using the Mann-Whitney *U* test for continuous variables and chi-square or Fisher exact tests for categorical variables as appropriate. Because the entire last-window cohort was used for both threshold optimization (grid search) and performance evaluation without an independent holdout test set, the reported metrics represent resubstitution (apparent) performance.

Usability and Satisfaction Instruments

We administered a brief questionnaire, including the System Usability Scale (SUS) and additional items on use frequency and initiation triggers. The survey link was distributed via KakaoTalk; responses were anonymized. A total of 27 responses were received; after excluding 4 respondents who reported never using the app, 23 responses were analyzed. SUS scoring followed standard procedures and is reported alongside satisfaction ratings.

Results

App Use and Adherence

Among patients with ≥3 total submissions (analysis cohort; N=30), the mean weekly submission rate was 1.70 surveys per week (range 0.32-6.90); individuals contributed a median of 8.5 (IQR 3-143) submissions over the observation period. The interval between the last 2 submissions (i1→i2) had a median of 17.5 (IQR 15.75; mean 18.4; range 1-105) days, indicating substantial variability and a tendency toward longer gaps near the end of follow-up for some participants. The most recent total score averaged 2.43 points (median 1; range 0-11), and the patient-level mean total score across all submissions averaged 2.21 points (median 1.11; range 0-12.5). Descriptive statistics for use and scores are summarized in Table 3.

A comparison of baseline characteristics between the 30 included participants (completers) and the 34 excluded participants (noncompleters) is presented in Table S2 in Multimedia Appendix 1. There were no statistically significant differences between the 2 groups in terms of age (*P*=.08), sex (*P*=.19), or diagnosis categories (*P*=.36). This lack of significant difference suggests that the initial study attrition was primarily driven by external technological or access issues rather than distinct clinical severity or tumor phenotypes. However, the excluded cohort was significantly older than the included cohort, with a median age of 63.0 years compared to 57.0 years (*P*=.04). There were no significant differences between the two groups in terms of sex (*P*=.19) or diagnosis categories (*P*=.36).

Table 3. Descriptive statistics of app use and scores (per patient).

Metric (unit)	Mean (SD)	Min-Max	Median (IQR)
Total submissions per patient (n)	19.03 (30.12)	3-143	8.5 (6-13)
Submission rate (surveys/week)	1.7 (1.7)	0.32-6.9	0.84 (0.53-2.25)
Days between the last 2 submissions: i1→i2 (days)	18.4 (21.25)	1-105	17.5 (4.5-20.0)
Most recent total score: (points)	2.43 (3.06)	0-11	1 (0.0-3.25)
Patient-level mean total score across submissions	2.21 (2.76)	0-12.5	1.11 (0.29-3.47)

Feature Discovery and Threshold Optimization

We conducted grid searches to tune thresholds for the 4 prespecified rule families (R1-R4) defined in the Methods section. The optimized parameters are reported in Table 2. For visualization, AUROC was plotted against the candidate thresholds for R1 (current total score, T_1) and R2 (net increase, T_2); both curves showed clear internal maxima, with peak performance at T_1=5 and T_1=2, respectively (Figure 3A). These findings support the face-valid expectation that (1) a moderately elevated current score and (2) short-horizon net worsening each contribute usefully to discrimination.

Rule-Wise Performance Comparison

At the optimized settings, R2 (net increase) showed the best overall balance (AUROC 0.875; sensitivity 0.833; specificity 0.917; PPV 0.714; negative predictive value 0.957; F_1-score 0.769; accuracy 0.900), outperforming other rules on discrimination and F_1-score while preserving high specificity (Figure 3B; Table 4). R1 performed second best (AUROC 0.792; F_1-score 0.667; accuracy 0.867), while R3 and R4 traded sensitivity for specificity (R3: specificity 1.000; sensitivity 0.333; AUROC 0.667 and R4: specificity 0.958; sensitivity 0.333; AUROC 0.646), indicating more conservative alerting with reduced case finding. Bootstrap 95% CIs for sensitivity, F_1-score, and AUROC are shown as error bars in Figure 3B. It is important to note that due to the small sample size and the low number of clinical deterioration events (n=6), these CIs are wide. This indicates that the point estimates (eg, the AUROC of 0.88 for R2) are statistically unstable and should be interpreted with caution. Nevertheless, the point estimates for R2 remain consistently highest across metrics, supporting the value of short-horizon worsening (change from the immediately prior submission) as a digital signal of deterioration.

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Table 4. Performance of candidate alert rules (R1-R4) on the last-window dataset at optimized thresholds.

Rule[a]	Sensitivity	Specificity	PPV[b]	NPV[c]	F_1-score	Accuracy	AUROC[d]
R1	0.667 (0.33-1.00)	0.917 (0.85-1.00)	0.667 (0.33-1.00)	0.917 (0.85-1.00)	0.667 (0.33-0.90)	0.867 (0.78-0.95)	0.792 (0.61-0.97)
R2	0.833 (0.50-1.00)	0.917 (0.85-1.00)	0.714 (0.33-1.00)	0.957 (0.92-1.00)	0.769 (0.50-1.00)	0.900 (0.83-1.00)	0.875 (0.72-1.00)
R3	0.333 (0.00-0.67)	1.000 (1.00-1.00)	1.000 (1.00-1.00)	0.857 (0.77-0.95)	0.500 (0.00-0.80)	0.867 (0.78-0.95)	0.667 (0.50-0.83)
R4	0.333 (0.00-0.67)	0.958 (0.92-1.00)	0.667 (0.00-1.00)	0.852 (0.75-0.95)	0.444 (0.00-0.80)	0.833 (0.74-0.94)	0.646 (0.47-0.83)

[a]Data are presented as point estimates with 95% bootstrap CIs in parentheses.

[b]PPV: positive predictive value.

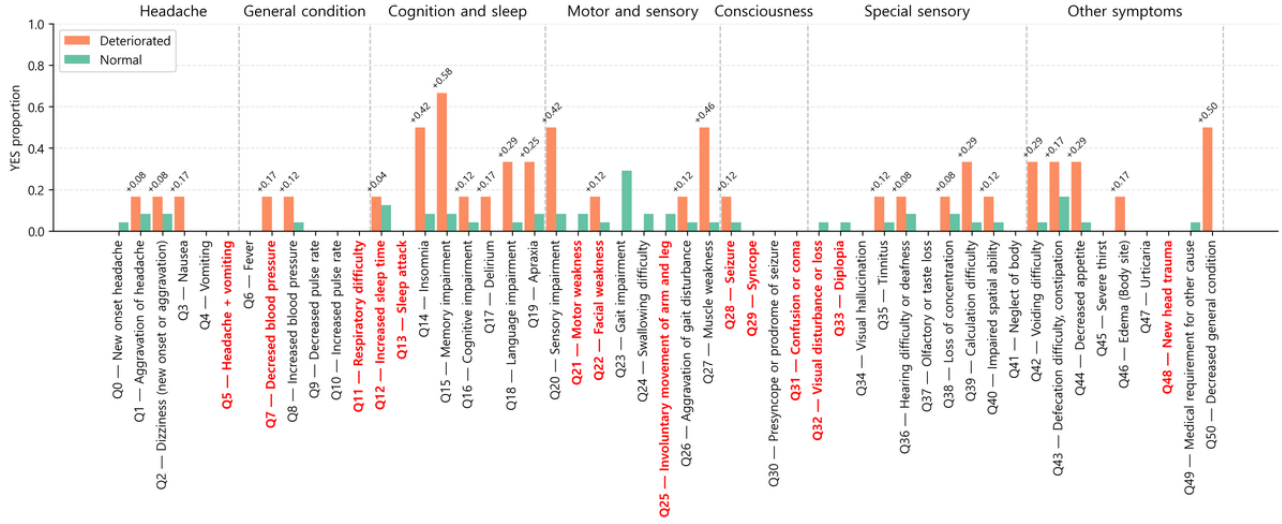
[c]NPV: negative predictive value.

[d]AUROC: area under the receiver operating characteristic.

Item-Level Response Differences

Item-wise yes-response rates were contrasted between patients with adjudicated deterioration and those without (Figure 4). When grouped by the 7 symptom categories, the "cognition and sleep" and "other symptoms" domains showed notably higher affirmative rates in the deterioration group. At the item level, "memory impairment," "decreased general condition," and "muscle weakness" ranked among the largest between-group differences. Conversely, several items predesignated as "core" due to presumed clinical severity were infrequently endorsed in both groups, limiting their utility as direct triggers in this dataset. Taken together, these patterns indicate that comparatively *softer* but commonly reported symptoms may carry earlier signal for deterioration than rarer, high-severity items.

Figure 4. Item-level yes-response proportions by symptom category (7 domains) comparing deteriorated (orange) vs normal (green) windows. Dashed lines mark category boundaries, and red labels denote prespecified core items. Numbers above bars denote the between-group proportion difference (deteriorated−normal). Larger between-group differences are notable in the sleep and cognition and other symptoms domains.



Usability (SUS)

Of 27 questionnaire respondents, 23 (85%) reported at least 1 instance of app use and were included in the SUS analysis. The SUS total score distribution is shown in Figure 5A (mean 84.0, median 90.0), indicating generally favorable perceived usability. Participants with only 1 submission exhibited a lower SUS distribution than those with ≥2 submissions, consistent with lower adherence among users reporting poorer usability. To probe domain-level patterns, item means were compared between the 1-submission and ≥2-submission groups (Figure 5B): differences were modest for standard (odd-numbered) items, while reverse-scored (even-numbered) items were more negative in the single-submission group. This indicates that infrequent users tend to perceive higher complexity or lower consistency in relation to app use.

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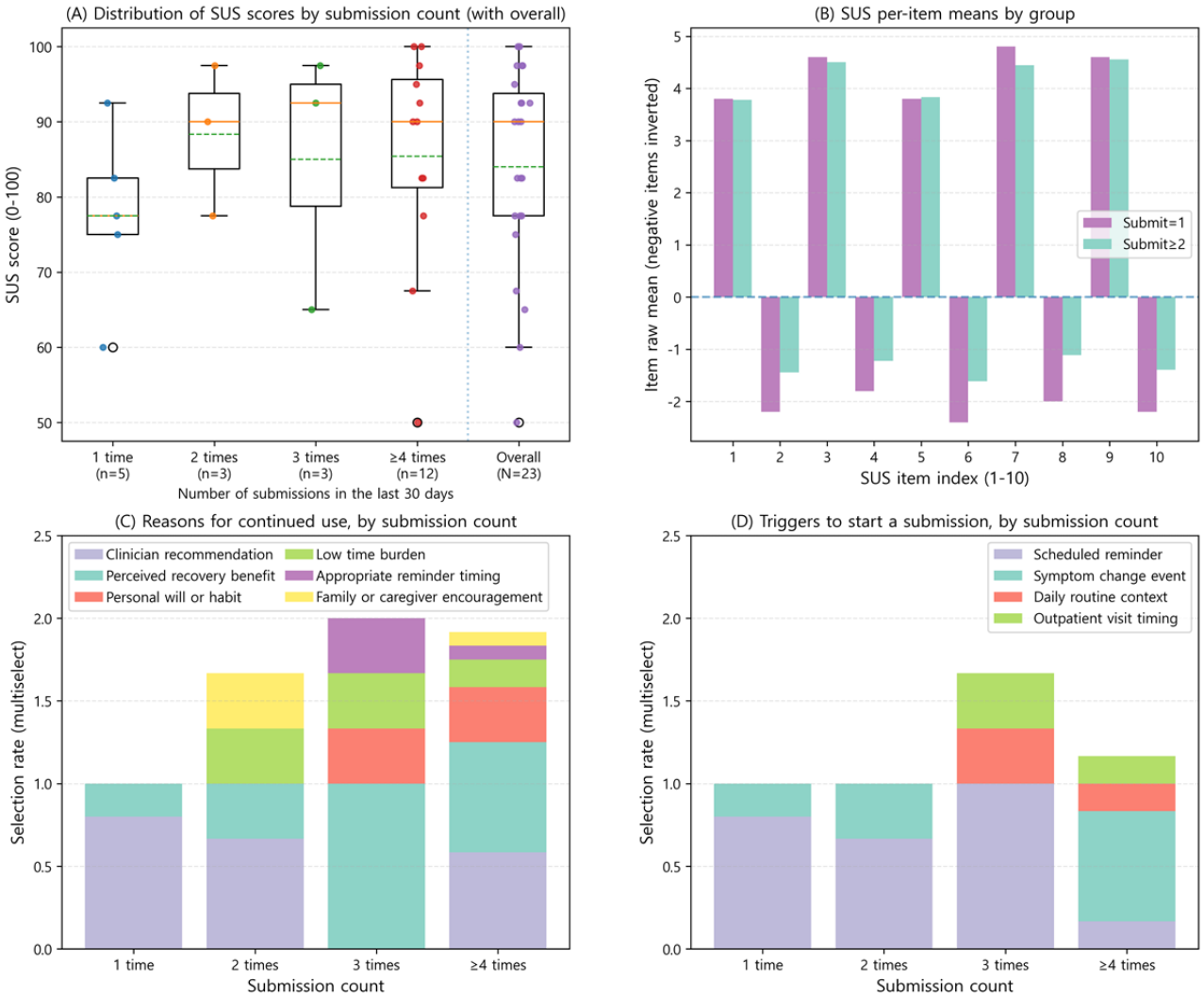
Figure 5. Usability and adherence-related survey results. (A) System Usability Scale (SUS) total score distributions (0-100) by submission-count group and overall (boxplots with individual points; N=23 app users). (B) Mean SUS item scores by group (1 submission vs ≥2 submissions); reverse-scored items appear below 0 after centering. (C) Reasons for continued use (multiresponse) by submission-count group—stacked proportions. (D) Triggers to start a submission (multiresponse) by submission-count group—stacked proportions.



Adherence-Related Survey Findings

Multiresponse questions on (1) reasons for continued use and (2) triggers to initiate a submission are summarized in Figures 5C and 5D. Participants with higher submission counts more frequently selected "personal will or habit" and "perceived recovery benefit" as reasons for sustained use. For initiation triggers, higher-adherence users more often endorsed cues embedded in daily routines. Together, these findings imply that emphasizing perceived clinical usefulness and integrating reminders into routine time points (eg, after lunch) may enhance adherence in future iterations of the intervention.

Discussion

Principal Findings

This preliminary study demonstrated the feasibility and patient acceptability of a rule-based smartphone and web application for self-monitoring in individuals recovering from brain tumor surgery. Following major neurosurgical procedures, even minor physical or neurological changes can provoke significant anxiety [24]. By providing a structured, medically validated alternative to unverified online information, this platform supports objective symptom tracking and bridges the gap between intermittent in-person clinic visits [25-29]. The high usability scores (mean SUS 84.0) suggest that patients are willing to engage with digital health tools during the vulnerable postoperative period, a willingness likely bolstered by the personalized oversight of their treating neurosurgeon. Furthermore, our evaluation of simple heuristic rules, particularly the short-horizon worsening rule (R2), demonstrated preliminary discriminative potential for capturing early signals of clinical deterioration.

Clinical Implications and Workflow Integration

While the technical performance of these heuristic rules demonstrates initial feasibility, excellent technical accuracy alone is insufficient for a viable clinical decision support system. A critical challenge for real-world implementation is the risk of alert fatigue. Generating an excessive number of false alarms can easily overwhelm clinical staff and disrupt workflows. Therefore, future deployments of this system will use a structured, tiered triage protocol. Rather than directly interrupting the attending neurosurgeon, a breached cumulative

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threshold could trigger an automated recommendation for the patient to reschedule a clinic visit or route the alert to a specialized triage nurse for preliminary review. Conversely, prespecified "red-flag" symptoms (eg, seizures) are operationalized as distinct medical emergencies; endorsing these items bypasses the cumulative score rules entirely to provide instantaneous safety instructions, ensuring critically urgent cases receive immediate attention.

From a technical standpoint, the current platform evaluates simple, prespecified threshold rules, which serve merely as a foundational step. The long-term vision of this project is to establish an advanced artificial intelligence–driven early warning framework [8,30,31]. By aggregating longitudinal patient-reported symptom trajectories and eventually integrating continuous physiological data from wearable devices [32-35], future machine learning algorithms could autonomously identify subtle, multivariate deviations. This transition represents a paradigm shift from a passive, provider-centered framework to an active, patient-engaged model of postoperative neurosurgical care [36-40].

Limitations

As with all pilot studies, several limitations should be acknowledged. First, the small sample size (N=30) and the low number of clinical deterioration events (n=6) mean that the discriminative performance metrics—including the high AUROC observed for R2—are statistically unstable and exhibit wide CIs. These results must be interpreted strictly as preliminary feasibility signals rather than definitive validations. Additionally, to accommodate data sparsity during this pilot phase, we used a simplified "last-window" heuristic and a complete-case analysis. This approach does not fully leverage the longitudinal nature of the data or account for within-patient correlation. Future investigations must address these analytical limitations by using advanced longitudinal methodologies, such as mixed-effects models or time-series machine learning algorithms, in larger independent cohorts. Furthermore, defining the clinical event by the actual hospital visit date introduces potential lead-time bias. Because patients may delay seeking care despite experiencing worsening symptoms, the observed interval between an app threshold breach and the clinical event may overestimate the system's true early warning capability. Additionally, our threshold parameters were optimized and evaluated on the exact same dataset. Consequently, our findings represent apparent (or resubstitution) performance that is inherently subject to optimistic bias. These rule thresholds must be rigorously evaluated and calibrated on independent, external test sets in future larger-scale studies.

Second, the substantial attrition rate (34/64, 53%) introduces potential selection bias. Although baseline clinical characteristics did not differ significantly between completers and noncompleters, the dropout group tended to be older (median 63.0 vs 57.0 years; P=.04). The platform currently targets patients with mild symptoms capable of independent daily activities, and the high usability scores likely reflect a technologically adept subgroup. However, patients with brain tumors frequently experience postoperative cognitive deficits, visual impairments, or motor limitations that hinder standard smartphone interaction. To address these significant digital literacy and physical barriers, future iterations will incorporate tailored adaptations, including caregiver proxy-reporting functionalities and natural conversational (chatbot) interfaces currently under development. Advanced statistical methods such as multiple imputation should also be used to handle missing data robustly.

Finally, this study was conducted at a single tertiary medical center in South Korea, an environment with exceptionally high smartphone penetration, reliable digital infrastructure, and specific health care follow-up protocols. Consequently, the high engagement rates and feasibility observed may not directly translate to other global health care systems or populations with different socioeconomic constraints. Multicenter validations across diverse geographic contexts are required to externally validate these digital self-monitoring tools.

Conclusions

Our preliminary report provides early evidence that smartphone-based self-monitoring systems are both feasible and acceptable among patients with brain tumors. Beyond usability, this research lays the groundwork for the next phase of development—building predictive, artificial intelligence–powered early warning algorithms that can autonomously identify high-risk symptom patterns and deliver timely alerts. Such an approach has the potential to redefine postoperative neurosurgical care, enhance digital health care accessibility, and ultimately improve patient safety and long-term outcomes.

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Data Availability

The datasets generated or analyzed during this study are available from the corresponding author on reasonable request.

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Authors' Contributions

YL and JB were responsible for data collection and processing. YL conducted the statistical analysis. HS and JB interpreted the results. YL and JB drafted the initial version of the manuscript, which was further developed by HS and JB. All authors reviewed and approved the final version of the manuscript for submission.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Daily self-monitoring questionnaire items and baseline patient characteristics.
[DOCX File , 22 KB - formative_v10i1e87928_app1.docx]

Multimedia Appendix 2
Python source code for statistical analysis, bootstrap CI estimation, rule-based alert evaluation, and figure generation.
[TXT File , 14 KB - formative_v10i1e87928_app2.txt]

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Abbreviations

AUROC: area under the receiver operating characteristic
PPV: positive predictive value
SUS: System Usability Scale

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Original Paper

Safe@Campus Virtual Reality Training for Campus Shooting Preparedness: Prototype Development and Usability Study

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Abstract

Background: Campus shootings, though infrequent, result in significant loss of life, psychological trauma, and disruption to university communities. Traditional preparedness programs developed for K-12 settings do not translate well to university environments. Virtual reality (VR) offers an immersive and engaging method to enhance situational awareness and decision-making during high-stress events.

Objective: This study aimed to develop the Safe@Campus prototype, a theory-informed, stakeholder-engaged VR-based prototype designed to prepare university students to recognize and respond to campus shooting threats, and to evaluate its initial usability and feasibility among undergraduate students.

Methods: We followed a 2-phase, user-centered design process. Phase I (stakeholder-informed feasibility assessment and prototype refinement): through interviews with campus safety experts, firearm safety practitioners, school safety specialists, and students, we identified key content, scenario requirements, and implementation considerations. A 360-degree video–based VR prototype depicting an active shooter incident in a university classroom was developed using Unity3D, incorporating branching decision points aligned with the "run, hide, or fight" framework. Expert and user feedback guided iterative refinements. Phase II (student usability and acceptability testing): 2 focus groups with undergraduates at The Ohio State University (N=17) viewed a VR scenario and then participated in guided discussions about prior training experiences, the acceptability of VR, and recommendations for improvement. Transcripts were analyzed using constant comparative methods in ATLAS.ti (version 25).

Results: The first focus group comprised 8 students (n=5, 63% female; n=3, 38% White, n=4, 50% Asian/Asian American), and the second comprised 9 students (n=6, 67% female; n=6, 67% White). Across both groups, 82% (14/17) reported participating in active shooter drills during K-12 schooling, yet many felt these experiences did not adequately prepare them for the complexity of university environments. The following four major themes emerged: (1) prior experience with active shooter drills: K-12 drills varied widely in realism and left students uncertain about appropriate actions in university settings; (2) need for university-specific training: participants noted substantial gaps in preparedness and expressed strong support for required, standardized training; (3) perceived usefulness of VR: students found VR highly engaging, realistic, and effective for reinforcing situational awareness and decision-making; and (4) recommendations for prototype improvement: students suggested increasing interactivity, adding time-pressured decisions, expanding scenarios to diverse campus spaces, and integrating the program into required university activities such as orientation.

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Conclusions: Safe@Campus is a feasible, acceptable, and engaging VR-based approach to campus shooting preparedness. Students viewed the immersive, decision-driven format as an effective way to build practical skills not addressed by traditional training. Future development should expand scenario diversity, increase interactivity, and evaluate program effectiveness in larger trials.

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KEYWORDS

active shooter events; firearm violence; firearms; students; virtual reality

Introduction

Firearm injuries kill over 48,000 people annually in the United States, equivalent to approximately 132 deaths per day [1]. Approximately 85,000 more individuals are shot and wounded annually [1]. Campus shootings represent a small but highly tragic and publicized portion of firearm injuries and deaths in the United States. Since the 2007 campus shooting at Virginia Tech, high-profile incidents at the University of Nevada, Las Vegas, and Michigan State in 2023 and, more recently, at Florida State University, the University of New Mexico, and Brown University in 2025, have heightened national concern [2-4]. Between 2013 and 2025, at least 418 incidents of gunfire occurred on university campuses across 44 states, resulting in 114 deaths and 312 serious injuries [5]. These events disrupt educational environments, strain emergency response systems, and generate lasting psychological trauma for survivors, bystanders, and surrounding communities [4,6-13]. Even indirect exposure to campus gun violence erodes feelings of safety, with recent surveys reporting that 65% of current and prospective college students worry about potential campus shootings [14-17].

Despite this widespread concern, few evidence-based, theory-informed interventions exist to help university students recognize, prevent, and respond to active shooter threats [18,19]. Active shooter drills are mandated in over 40 states and implemented in 95% of K-12 schools [20-24], but these programs have not been effectively adapted for use in university settings. One potential reason for the lack of adaptation is the nature of university campuses, which differ significantly from typical K-12 settings. University campuses are generally more open, cover larger geographic areas, contain diverse and sometimes nonlockable facilities, and serve a more independent adult population than K-12 settings [25]. Given the prevalence and profound impact of campus shooting events, there is a critical need to develop an effective firearm injury prevention program for use in university settings.

Virtual reality (VR) offers a promising strategy for such firearm injury prevention programs. VR simulations provide immersive, engaging, and interactive environments that enhance learning, accelerate skill acquisition, and increase knowledge retention [26-28]. VR has been widely used in education and injury prevention [29-31], including in law enforcement training for active shooter response [32,33]. It can help students recognize concerning situations and behaviors and reinforce the best ways to report possible threats [25]. Using this evidence, we developed and evaluated a prototype of Safe@Campus, a VR-based intervention. Unlike traditional K-12 active shooter drills, the fully-developed Safe@Campus program will address both the prevention of and response to campus shootings by providing guidance on how to recognize behavioral warning signs and report potential threats before violence occurs, as well as practical strategies for responding effectively during an active shooter incident [34-38]. Through immersive VR scenarios, students will practice systematic threat observation to recognize potentially dangerous environments, situations, and individuals. They will also rehearse rapid, critical decision-making based on the “run, hide, or fight” framework [39] and build confidence to act under stress, skills that extend beyond campus and can be applied in other public settings.

The aims of this study were to develop a prototype of the Safe@Campus program, a theory-informed, stakeholder-engaged VR-based prototype designed to prepare university students to recognize and respond to campus shooting threats, and to evaluate its initial usability and feasibility among undergraduate students. As an early step in this line of research, this study focuses on the development and usability testing of a single VR prototype scenario rather than an evaluation of effectiveness. These findings provide the foundation for future studies, including randomized clinical trials, to rigorously assess the intervention’s impact on behavioral and preparedness outcomes.

Methods

Theoretical Framework and Conceptual Model of Safe@Campus VR Intervention

Safe@Campus is a semi-immersive VR educational app that immerses users in realistic, risk-adjusted settings such as dormitory, classroom, and outdoor campus area environments, with the goal of enhancing situational awareness and response skills. Proximity-based decision-making and stress inoculation are emphasized to help students build coping skills and confidence in high-stress situations. All virtual stimuli are delivered through a commercially available VR headset (Pico Neo 3 Eye), providing an immersive 360-degree video experience with synchronized spatial audio.

Safe@Campus is underpinned by the theoretical constructs of both the experiential learning model [40-42], which emphasizes “learning by doing,” and the theory of planned behavior (TPB) [43,44], which highlights the role of intention in performing behaviors.

Conceptually, Safe@Campus aims to enhance university students’ ability to recognize, report, and respond to campus shooting threats, boost their self-efficacy to engage in these actions, and increase their perceived preparedness.

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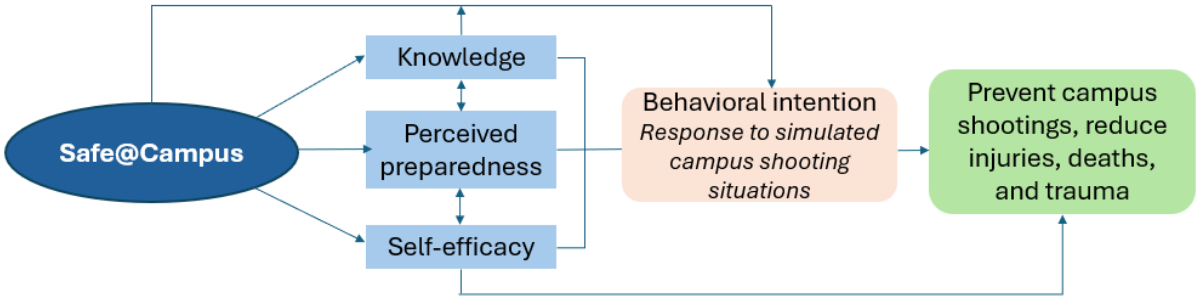
Improvements in these abilities are hypothesized to lead to safer behavioral response intentions in simulated campus shooting situations, preventing future campus shootings, and reducing associated injuries and deaths (Figure 1).

Figure 1. Conceptual model.



Development of the Safe@Campus VR Prototype

Platform Selection and Technical Implementation

VR training experiences are typically created in one of two ways. The first involves building a digital environment where users can navigate and interact, similar to a fully immersive video game. The second uses 360-degree video captured with a specialized camera, allowing users to view scenarios unfolding in real-world settings. Although 360-degree video offers fewer options for interactive elements than some alternatives, it presents several key advantages: it is significantly more cost-effective to produce, provides a consistent experience across all users, and places users in familiar environments with a high degree of realism [45].

The prototype tested in this study used a VR headset to immerse users in a 360-degree video environment, allowing them to rotate their bodies and view the scene from any direction. The scene unfolds around the user, guided by dialogue from an on-screen actor. While the companion's lines are delivered verbally, often while making direct eye contact with the camera, the user's responses are presented as scripted dialog boxes.

The prototype was developed in the Unity3D game engine, which enabled the creation of interactive interface elements prompting users to make decisions. These decisions impact the outcome of the scene. Multiple videotapes were filmed to account for the branching of the scenario. For example, if a user chose to hide, a corresponding video sequence showed the actor asking where to hide next. The user was then prompted to find a suitable hiding place from highlighted options around the room, and the actor responded to each choice by explaining why it was appropriate or inadequate.

Scenario Design and Instructional Structure

While the full Safe@Campus intervention is designed to address both the prevention of and response to campus shooting situations, the prototype evaluated in this study consisted of a single scenario focused specifically on response during an active shooter incident in a classroom building setting. The experience begins with the immersed user and their virtual companion leaving a classroom, casually discussing a difficult exam, and making plans to meet friends for tacos. This light, relatable interaction is abruptly interrupted by the sound of gunshots. Initially, both characters are unsure whether the noises were gunfire or something less serious. However, moments later, their phones buzz with an emergency alert, confirming that an active shooter is present on campus. The atmosphere quickly shifts from light and relatable dialogue to background noises filled with the sounds of panic, yelling, and running. At this point, the user is prompted by the program to make a critical decision: run, hide, or fight. Each selection leads to a short scenario illustrating key safety strategies and lessons:

- Run: the user evacuates using the stairs, leaving their belongings behind.
- Hide: the user seeks secure cover nearby, in a janitor's closet.
- Fight: the program discourages this, with the companion advising against it.

The simulation concludes with an expert message reinforcing that running is the safest and preferred option, hiding is a viable secondary option, and fighting should be considered only as a last resort. In this early-stage prototype, prompts and highlighted options were intentionally included to reinforce the "run, hide, or fight" framework. Future iterations may introduce more advanced, open-ended scenarios that better reflect real-world conditions and require users to identify response options independently.

User-Centered Development: Feasibility and Usability Test of the Safe@Campus Prototype

The Safe@Campus prototype was refined and tested through a collaborative, user-centered design process. As outlined below and shown in Figure 2, the refinement and testing occurred in two phases: (1) stakeholder-informed feasibility assessment and prototype refinement, and (2) student usability and acceptability testing.

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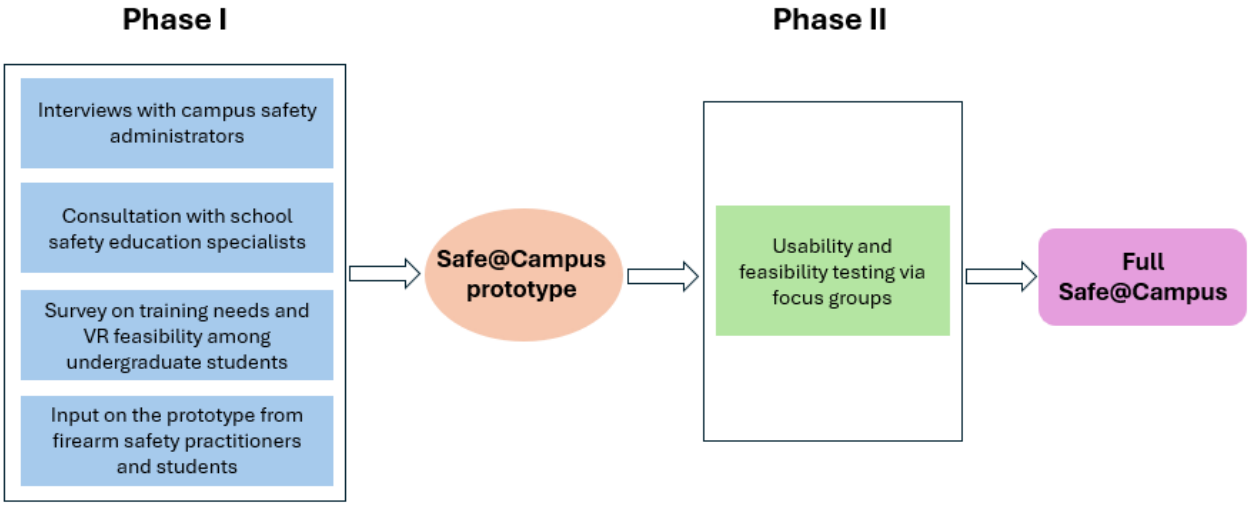
Figure 2. Process of developing and testing the Safe@Campus prototype. VR: virtual reality.



Phase I: Stakeholder-Informed Feasibility Assessment and Prototype Refinement

Overview

Phase I assessed the feasibility of the Safe@Campus prototype and refined its design through structured input from key stakeholders. We consulted experts in digital health design, campus safety education, firearm safety research, and campus safety administration and law enforcement, as well as university students. These interviews had three primary objectives: (1) assess the prototype's appropriateness for college students and its relevance to campus firearm safety; (2) gather stakeholder recommendations on visual and sensory design, content, and scenarios; and (3) obtain guidance on optimal implementation, including when, where, how, and under what conditions the intervention should be delivered. End users were engaged early and throughout the refinement process to ensure the prototype's relevance, realism, and practical feasibility.

Interviews With Campus Safety Leaders and Law Enforcement

In February 2024, we conducted individual interviews with campus safety experts, including leaders from public safety at The Ohio State University (OSU), the University of Alabama at Birmingham, and the Regional Gun Violence Research Consortium in New York State, as well as a detective from the OSU Police Department specializing in campus shooting threats and safety education. These interviews explored the national landscape of campus emergency preparedness, opportunities for institutional partnerships, design considerations for VR-based training, the effectiveness and unintended consequences of existing active shooter preparedness programs, and the specific needs of college students. Experts emphasized that training should prepare students to respond not only on campus but also in public settings such as concert venues and shopping malls, underscoring the importance of practical self-defense and transferable skills across environments and scenarios. They also endorsed VR as an engaging and effective medium for student learning. Collectively, these consultations highlighted key programmatic gaps, institutional needs, and opportunities for collaboration.

Consultation With School Safety Education Specialists

In August 2024, we met with the leadership team and school safety education specialists from the Ohio School Safety Center (OSSC), including the director and the school policy and compliance manager. Established in 2019, OSSC employs 53 staff who support firearm safety training across both K-12 and higher education institutions. As part of our effort to gather feedback on the Safe@Campus prototype, we sought OSSC staff's insights from their experience in campus firearm safety education and discussed the potential of VR to enhance situational awareness and decision-making during emergencies. They recommended tailoring "run, hide, or fight" scenarios to the unique features of university campuses, such as open layouts, diverse environments, and a student population more mature than at K-12 schools. Staff also noted that funding for firearm safety initiatives is more limited in higher education than in K-12 settings, highlighting the need for additional resources.

Undergraduate Survey on Training Needs and VR Feasibility

To assess student perspectives on training needs and VR feasibility, we conducted an anonymous online survey among undergraduates enrolled in a health sciences course at OSU. Among 45 respondents, 87% (n=39) rated active shooter training as "very" or "extremely important," and 87% (n=39) considered VR-based training "feasible" or "very feasible." These results demonstrate strong student support for VR as an engaging and acceptable approach to campus safety training.

Prototype Feedback From Firearm Safety Practitioners and Students

Based on initial feedback, we refined scripts and scenarios, recruited an actor, and filmed 360-degree videos for a Safe@Campus prototype. After multiple rounds of internal testing and refinement of the prototype, we conducted a focus group to gather information about the prototype with OSU campus police officers and 8 OSU student interns specializing in campus safety. Participants reviewed the prototype, evaluating its features, active shooter simulations, and scenario design. They reflected on their user experience, including what they

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"liked most" and "liked least." A trained qualitative researcher facilitated the discussions.

Key recommendations for the prototype included (1) incorporating quicker decision-making options, (2) gradually escalating threat levels with appropriate trigger warnings, (3) ensuring institutional buy-in and coordination, and (4) expanding the intended audience to include faculty, staff, and administrators. These insights provided critical guidance for refining the Safe@Campus prototype to enhance its relevance, usability, and institutional feasibility. We incorporated this feedback into the final prototype version prepared for Phase II usability and feasibility testing.

Phase II: Student Usability Testing of the Safe@Campus Prototype

Phase II aimed to evaluate the usability and acceptability of the Safe@Campus prototype through 2 focus groups with OSU undergraduate students.

Focus Group Guide

The focus group guide was developed based on the theoretical frameworks of the experiential learning model [40-42], the TPB [43,44], and existing literature on campus shooting prevention and response [15-18,36,46,47]. It was pilot tested and refined based on feedback from the research team and external collaborators, including firearm safety experts and qualitative researchers.

For this study, we concentrated on questions related to student perspectives and experiences in four areas: (1) prior active shooter training (eg, "What personal experience do you have with active shooter training? When and where did you have the experience?"), (2) the need for active shooter training for college students (eg, "What are your thoughts about conducting active shooter training in college campus or among college students?"), (3) the usefulness of the VR-based training approach and feedback on the Safe@Campus prototype (eg, "Do you feel like it is an important issue in college campus? Why or why not?"), and (4) facilitators and barriers to implementing VR active shooter safety training in university settings (eg, "What barriers might prevent us from developing the VR active shooter safety training for college students?").

Participants

Participants were undergraduate students. Eligible students were aged 18-25 years and enrolled at the OSU Columbus campus, English-speaking, and provided informed consent.

Study Procedure

A convenience sample of undergraduate students from OSU was recruited for 2 focus groups held in an OSU classroom in October and November 2024. Study information was shared with potential participants through word of mouth. Interested students contacted the research coordinator to be screened for eligibility and, if eligible, to schedule a focus group. Two focus groups were scheduled and conducted. At the start of each session, a trained researcher (HPS) reviewed the study purpose and procedure, answered questions, and then obtained written consent from participants.

Each student then participated in a single in-person session with 8-10 participants (n=8 in Group 1 and n=9 in Group 2). After brief introductions and safety instructions, including a content warning and a reminder that students could stop participation at any time due to motion sickness, emotional discomfort, or any other reason, students independently engaged in the VR Safe@Campus prototype. The simulation placed users in a university classroom scenario that was disrupted by the sound of gunfire and a campus emergency alert indicating an active shooter. Participants were prompted to choose whether to run, hide, or fight, with each option illustrating key safety strategies. The simulation concluded with a police officer reinforcing the "run, hide, or fight" framework.

Following the VR experience, students participated in a semistructured focus group facilitated by 2 experienced qualitative social science researchers (HPS and LS) trained on the study protocol. A discussion guide was used to ensure consistency across groups while allowing flexibility to probe emerging themes. Participants were asked about their prior active shooter training, perspectives on implementing such training in university settings, and reactions to VR as a training tool. They also provided feedback on the prototype's storyline, tone, dialogue, and character representation. Each focus group lasted 30-45 minutes. Sessions were audio-recorded with participant consent and transcribed verbatim by an institutional review board–approved transcription service for analysis.

Data Analysis

Transcribed focus group data were analyzed using the constant comparative method [48,49] through an iterative and systematic process. Two research team members (HPS and JY) independently read each transcript in full to familiarize themselves with the data and document initial impressions. Using an inductive approach, they conducted line-by-line coding of meaningful text segments, generating open codes grounded in participants' language. Codes were continuously compared within and across transcripts to identify similarities, differences, and recurring concepts, and were refined as analysis progressed. Related codes were grouped into broader categories and synthesized into higher-order themes and subthemes. Both categorizing and connecting strategies were used to organize themes by shared meaning and examine relationships across themes, contexts, and focus groups. ATLAS.ti (version 25; ATLAS.ti Scientific Software Development GmbH) was used to manage transcripts and coding. To enhance rigor, both coders independently coded all transcripts and met regularly to reconcile discrepancies through discussion and consensus with the broader research team. Analytic decisions and codebook revisions were documented throughout the process to ensure transparency and consistency.

Ethical Considerations

All aspects of the study were approved by the institutional review board at Nationwide Children's Hospital (IRB STUDY00004155). Written informed consent was obtained from each student participant prior to the study procedures. All participant data were deidentified to ensure the privacy and anonymity of participants. Participants were compensated with

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a US $20 ClinCard (Greenphire Inc) upon completion of the focus group.

Results

Participant Demographics

The first group comprised 8 participants (n=5, 63% female, n=3, 38% White, n=4, 50% Asian or Asian American, n=6, 75% junior- or senior-year students), and the second group comprised 9 participants (n=6, 67% female, n=6, 67% White, n=7, 88% junior- or senior-year students). More than 82% (14/17) reported having participated in active shooter drills during their K-12 education. All students had reviewed a required active shooter video training as part of the new student university orientation.

Themes and Subthemes

Overview

The following four major themes and relevant subthemes were identified, as presented in Textbox 1 along with associated quotations: (1) prior experience with active shooter drills—defined as students' past exposure to K-12 drills and related training activities; (2) need for university-specific training—which referred to students' perceived gaps between K-12 preparation and the unique risks and demands of a large, diverse campus environment; (3) perceived usefulness of VR—representing students' perceptions of VR as an immersive tool for situational awareness and decision-making; and (4) recommendations for prototype improvement—which referred to students' suggestions to improve the VR training content, scenarios, and how to integrate the intervention into required university programs. Theme 4 comprised 3 subthemes: VR content, VR scenarios and design, and VR delivery.

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Textbox 1. Theme, subtheme, quotation, and data source.

Theme 1. Prior experience with active shooter drills

- "Most of the time, we just barricaded our classroom to just prepare. In some cases, depending on where the expected shooter was, we would evacuate the school in its entirety, but in other cases, we would just barricade up." (Group 1)
- "It was called a lockdown drill, and it was probably three or four times a year.... I did it in elementary school through high school, but we would act it out. We'd sit really, really quiet and all the lights would go out and we'd have to hide in the corner away from the door and then someone would walk around and make sure they couldn't see people and then if they could see people, they'd send an email and make sure that they fixed it." (Group 1)
- "We did a lot of barricade drills where we'd have to put stuff in front of the door, and then they would try and open it, and then if they couldn't open it, then we passed. But then, if they could open it, then it was a failure, and then the class had to talk about what to do better. And then I know some teachers had weapons that they could use or tell us where they were. It was not a real weapon, but just stuff that we could use to throw, and then they would tell us where that was." (Group 2)
- "In high school, they had it very realistic...they would just make an announcement over the PA system and say where it was located. And then based off that, the teachers were supposed to react and have a plan set in place, whether it was run, hide, or fight. And then also, I know the teachers had a separate training day for active shootings outside of when students were in the building." (Group 2)

Theme 2. Need for university-specific training

- "I feel like it's needed because I remember thinking a few months ago when there was a shooting...if we're in class and it happens, I'm just thinking does everyone know what to do? ...some of us are also like you don't remember every single protocol and I just feel like it should be a mandatory thing in college too because if anything a shooter would have more free rein and more I feel like could go on rather than in a high school in one location." (Group 1)
- "After coming to [university], there's been multiple shooters that actually have been on campus. And honestly, I have no idea what to do other than run. And we've never actually been through a professional procedure, so I feel like it would be good if we did." (Group 1)
- "I think they definitely need to prepare. In my perspective, coming from a really small high school, I never felt like in K-12 that an active shooter situation was a direct risk. But coming to [university], I feel like there have been shootings nearby or I've gotten an alert on my phone about people on campus with guns before. So, I feel like the preparation that I had in K-12 doesn't carry over to college, and it does not prepare me for an active shooter situation in college." (Group 2)
- "I feel like that's a good thing to implement, but it's also hard that you don't want your students to know always 100% what your active shooter procedure may be just because if your shooter is a student then it's like well then they know what you're going to do and that aspect of making sure that everyone can still stay safe. But I think it is important that everyone should be aware in the scenario, like, okay, we do need to lock down the area, and instead of just feeling like you're trapped, like no, they're doing something here and need to figure it out." (Group 2)

Theme 3. Perceived usefulness of Virtual Reality (VR)

- "I really thought it brought out situational awareness, and it made you feel like in the place at that moment. Like, what would you actually do? And I really liked how there were multiple exits, so you got to choose, and it would correct you and tell you if your decisions were right or wrong because this could be a real scenario as well. You don't want to make the wrong decision when it actually happens." (Group 1)
- "I feel like VR is a unique way.... Because it's made to make you feel like you're in that situation. So, I've never done anything like that, but it was cool to actually have to look around the room, think about nearest, furthest exits. Like, actually hear where the gunshots are in relation to you." (Group 1)
- "It's good to get a visualization of what that situation would be like without having to, like we said in our elementary schools and high schools and stuff, they actually went through and had everyone do it, but in college, there was not really an opportunity for that." (Group 2)
- "I ran through all three scenarios of the run, fight, and hide, and I liked that after everyone, it explained why this was the best option, or fighting, it was like this is your worst case, don't ever do this. And I think it's good [it was] explaining why that was the correct choice just so that if you're ever in a stressful situation, you can kind of break it down a little bit and be like, okay, well I know this, and then I can kind of think through it a little bit more logically." (Group 2)

Theme 4. Recommendations for prototype improvement

- Subtheme 4.1: VR content
  - "People who were feeling different things. The girl we're interacting with was kind of calm in the situation, and I wouldn't expect it. I think the only thing she did was lower her voice after the shooting. Probably having other people who react differently." (Group 1)
  - "I feel like there should also be a timer associated with your decisions to have more chaos. Because in a real event, you won't actually have infinite time to choose. I feel like having a time rule like, oh I have this set of time, I have to make an option right now.' And then that'll also train people to make the right decision when that actually does happen." (Group 1)
  - "I would've liked to see more options as far as where to hide or where to run, and just to visualize why the option I chose is incorrect instead of having it be explained. I think being able to see it for yourself would also be more helpful." (Group 2)
  - "I feel like it'd be nice if they had someone telling you this, ...a campus resource officer or something like that, or a police officer saying think this was the best option, good job, or that was the worst option." (Group 2)

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- Subtheme 4.2: VR scenarios and design
  - "I think a lot of the training focuses on indoors. Maybe if you're walking out of the student union, you're like wait, there's a huge lawn space. If I'm running, I'm going to be seen, where would I go? I think outside is a whole different thing." (Group 1)
  - "Just like the areas like the student union. It could be literally in the student union, where are your exits, where can you go." (Group 1)
  - "The library." (Group 2)
  - "I feel like a dining hall." (Group 2)
- Subtheme 4.3: VR delivery setting
  - "Maybe you would have the option if you're a freshman, you would take it in that [freshmen] class because it's in class, people must go to it. And then for a transfer when they have their orientation to do it." (Group 1)
  - "If you're at the student union or something a day and you go and if you put this VR thing on.... If you're an outside, it'd probably work better. Then you get free food." (Group 1)
  - "I would say it should be something that could be a grade for a student or something implemented at orientation that you kind of can't avoid because personally I'm not going to go out of my way in the student union to do an active shooter thing." (Group 2)
  - "Most students are required to live in a dorm their first and second year, [so] making it a part of an RA task and looking at it, and every month you could do a different floor of the dorm.... So that way it still keeps it in a small group." (Group 2)

Theme 1: Prior Experience With Active Shooter Drills

Participants recalled extensive exposure to active shooter drills in K-12 schools, most of which emphasized lockdowns, barricades, and real-world simulated scenarios. While these experiences fostered familiarity with basic safety actions, the approaches varied in realism and thoroughness. Some recalled routine lockdowns in which "we'd sit really, really quiet and all the lights would go out and we'd have to hide in the corner away from the door" (Group 1). Others described more interactive drills that evaluated their responses, such as "put[ting] stuff in front of the door...and then if they couldn't open it, we passed" (Group 2). Several remembered creative training formats, like a video with an "Alice in Wonderland" theme where letters stood for different actions, or teachers pointing out improvised objects to throw if necessary. Still, the depth of practice ranged; while some schools practiced evacuations, others focused exclusively on barricading. This left participants with mixed impressions of preparedness.

Theme 2: Need for University-Specific Training

Students emphasized that earlier training did not adequately prepare them for the risks they now face on a large university campus. Many noted that while their K-12 environments felt relatively secure, universities posed different challenges, such as larger, open campuses and a multitude of diverse buildings. One participant reflected, "Coming to [university], I feel like there have been shootings nearby...the preparation I had in K through 12 doesn't carry over to college" (Group 2). Others stressed the importance of coordinated strategies, given the diverse backgrounds and experiences of the student body: "Everybody comes from so many different places...it'll be important just to implement some kind of strategy" (Group 2). Students also raised concerns about the lack of professional, standardized training, with 1 admitting, "After coming [to university], there's been multiple shooters...and honestly I have no idea what to do other than run" (Group 1). Some even worried about balancing safety with security, noting that while procedures should be clear, they must also be designed so that potential shooters who are students themselves cannot exploit the knowledge of planned responses.

Theme 3: Perceived Usefulness of VR

Students viewed 360-degree video VR training as a highly engaging and memorable approach, noting that this approach was preferred over traditional videos or lectures. Many valued how VR immersed them in realistic scenarios and required them to engage and make active decisions. One participant shared, "I really thought it brought out situational awareness, and it made you feel like [you were] in the place at that moment" (Group 1). Others appreciated the ability to learn through reinforcement; 1 noted, "I liked that after every scenario it explained why this was the best option...so that if you're ever in a stressful situation you can think through it more logically" (Group 2). For some, the novelty of VR heightened its impact: "I've only used VR three times in my life, so it's definitely more impactful. I'd definitely pick up some cues if it were to happen from the VR" (Group 1). Overall, students felt that VR helped bridge the gap between abstract preparation and practical readiness.

Theme 4: Recommendations for Prototype Improvement

This theme comprised 3 subthemes: VR content, VR scenarios and design, and VR delivery setting.

Subtheme 4.1: VR Content

While VR was seen as effective, students called for greater interactivity and realism to strengthen its training value. They wanted to "see more options as far as where to hide or run" (Group 2) and even visualize why certain choices were incorrect. Others suggested sensory enhancements, such as louder sound, vibrations, or simulated chaos to mirror the stress of real events: "I want to feel like vibrations...if there were more people in the room then it'd be more immersing" (Group 2). The addition of timed choices was another common request, with 1 participant explaining, "In a real event, you won't actually have infinite time to choose...[a timer] will also train people to make the right decision when that actually does happen" (Group 1).

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Subtheme 4.2: VR Scenarios and Design

Students suggested that VR scenarios should extend beyond classrooms to encompass a wider range of campus-specific spaces they encounter in their daily routines. Locations like “the student union...the library...[and] a dining hall” (Group 2) were highlighted as critical areas where preparedness would be just as important as in classrooms. They also emphasized the need to incorporate outdoor environments, noting that most current training focuses on indoor settings: “Maybe if you are walking out of the student union, there’s a huge lawn space. If I’m running, I’m going to be seen, where would I go? Outside is a whole different thing” (Group 1). Students felt that practicing in realistic-feeling, recognizable simulated spaces, both indoors and outdoors, would make the training more relevant and effective.

Subtheme 4.3: VR Delivery Setting

Finally, students emphasized the importance of how the training is delivered and who participates. They felt voluntary participation would be inadequate and recommended integrating VR training into university-required programs such as orientations, first-year courses, or residence life activities. One student explained, “requiring at orientation...because there was a lot of incoming freshmen where we just kind of did nothing with their peer leader.” (Group 1), while another added, “If it is required, more students would get it done” (Group 2). Others suggested enforcement strategies such as course requirements, account holds, or resident assistant led dorm sessions. Overall, students viewed embedding VR training within existing academic curriculum or residential structures as the most effective way to ensure participation and maximize its impact.

Discussion

Brief Summary of Main Findings Relative to Study Aims

This study describes the development of Safe@Campus, a theory-informed, stakeholder-engaged VR-based program designed to prepare university students to recognize and respond to campus shooting threats. Specifically, the study evaluated the initial usability and feasibility of a Safe@Campus prototype among undergraduate students. Consistent with our aims, findings indicate that the prototype is feasible to implement and highly acceptable to students. Although most participants had prior K-12 active shooter training, they reported feeling unprepared for the scale and complexity of university settings. Students perceived VR-based training as immersive and more engaging than traditional video- or lecture-based approaches. They also offered specific recommendations to enhance realism, interactivity, and campus relevance, directly informing the next phase of refinement and evaluation. The results support continued development of Safe@Campus and evaluation of the program in continuing research studies, including randomized clinical trials.

Interpretation of Findings, Implications, and Comparison to Existing Literature

Gaps in Preparedness From K-12 to University Settings

A key finding was a clear disconnect between prior K-12 active shooter drills and students' perceived readiness in university settings. This perception aligns with prior research demonstrating that preparedness strategies developed for K-12 settings do not seamlessly translate into higher-education environments [10,50,51]. University campuses are larger, more open, and more diverse in building types and populations, making standardized lockdown procedures and coordinated response more complex [25,38,47,52]. The students are older, more mature, and more independent. Our findings provide qualitative evidence that drills focused on confined classroom settings may not prepare students to navigate the spatial and organizational complexity of university campuses. Participants also emphasized the need for coordinated and standardized training that reaches the entire student body, reflecting recommendations for institution-wide prevention and response frameworks in higher education [10,38,52]. Moreover, students highlighted the challenges of balancing transparency with security, recognizing that while clear procedures are necessary, overly detailed protocols could potentially be exploited. This tension mirrors concerns raised in the campus threat management literature [36,47,53].

Experiential Learning and the Role of VR

Students consistently described VR as immersive, memorable, and more engaging than traditional didactic formats. These findings concord with experiential learning theory, which emphasizes active engagement and reflection as drivers of skill acquisition [40-42]. The Safe@Campus prototype required participants to assess environmental cues, interpret auditory signals, and make rapid decisions under simulated stress, elements that align with experiential learning principles and the TPB framework guiding the intervention [43,44]. Previous evidence supports the effectiveness of VR for enhancing knowledge retention and situational awareness across educational and safety contexts [26,31,33,54,55], including law enforcement and emergency response training [32,33]. Our findings suggest similar potential for university firearm injury prevention. Participants particularly valued the structured feedback explaining why specific choices aligned, or did not align, with the “run, hide, or fight” framework [39]. Such feedback may strengthen perceived behavioral control and self-efficacy, key constructs within TPB [43,44].

Integrating Prevention and Response Within a Public Health Framework

The Safe@Campus prototype evaluated in this study focused on response to an active shooter incident. When fully developed, Safe@Campus is conceptually designed to integrate prevention (recognition and reporting of warning signs) along with response strategies. This approach aligns with public health models emphasizing upstream identification of warning behaviors alongside crisis response planning [34-38,46]. Research on leakage warning behaviors and threat assessment underscores the importance of empowering individuals to recognize and

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report concerning behaviors before violence occurs [36,37]. By combining recognition, reporting, and response within an immersive platform, the conceptualized Safe@Campus aligns with comprehensive campus violence prevention frameworks [10,38,52].

Implementation and Policy Implications

Students strongly supported embedding VR training within required university programming, such as orientation, first-year seminars, or residence life activities. This recommendation is consistent with existing research suggesting that campus safety initiatives are most effective when standardized, required, and institutionally integrated rather than voluntary [10,38,52]. Given persistent student concern about campus safety [14-17], scalable and engaging training models may help address both student preparedness and perceived safety.

Compared with resource-intensive live drills, VR-based programs may offer a more feasible and potentially cost-effective alternative, particularly in university settings where funding for firearm safety initiatives is limited [56]. Partnerships among universities, campus police, state school safety centers, and public health agencies may enhance sustainable implementation.

An important consideration for broader dissemination is generalizability across campuses with different physical layouts and resources. The Safe@Campus prototype reflects a typical university classroom setting that students at a wide range of universities might relate to. Future research should confirm that well-designed generic environments can achieve a similar impact across the wide diversity of college campuses and student populations across the country. Balancing realism and scalability will be critical to achieve a program appropriate for wide implementation.

Finally, consistent with research on the psychological impact of active shooter drills [57-59], implementation of VR-based training must be trauma-informed and include appropriate content warnings and opt-out options to minimize potential distress among users.

Study Limitations

Several limitations of this study should be acknowledged. First, the study was conducted with a convenience sample of undergraduate students from a single large public university. Eligibility was limited to students aged 18-25 years, capturing prototypical undergraduate students but excluding perspectives from nontraditional or graduate students, as well as other campus community members such as faculty and staff. Given that just 2 focus groups were conducted, our findings may limit generalizability to other institutional types and student populations. Second, findings are based on self-reported perceptions of usability and acceptability rather than objective measures of learning, behavioral intention, or performance. Designed as a usability and feasibility study, it did not assess behavioral outcomes such as threat recognition, reporting behaviors, or simulated response effectiveness. Future research should incorporate those measures. Third, the Safe@Campus prototype included only 1 classroom-based scenario. Additional scenarios, such as outdoor spaces, residence halls, student unions, and dining facilities, will be incorporated into the final design of the program and may yield different usability considerations. Fourth, although stakeholder input informed development, broader multisite validation is needed to assess scalability and implementation feasibility across diverse campus infrastructures. Finally, immersive simulations addressing violence may evoke emotional distress. Although safeguards were in place, future research should rigorously assess psychological impact and incorporate trauma-informed best practices consistent with the emergency preparedness literature [57-59].

Conclusions and Future Directions

This study provides foundational evidence supporting the feasibility and acceptability of Safe@Campus, a VR-based campus shooting preparedness intervention tailored to university settings. Findings also suggest that immersive technologies may bridge the gap between passive awareness and actionable preparedness for firearm injury prevention in university settings.

As firearm-related violence continues to affect university communities [2-4], institutions face increasing demand for effective, developmentally appropriate training. Safe@Campus represents a shift from passive informational approaches toward interactive, skill-based learning grounded in behavioral theory and public health principles. By allowing students to rehearse rapid decision-making in realistic campus environments, VR may enhance situational awareness, perceived behavioral control, and preparedness intentions consistent with TPB constructs [43,44].

Future research should continue to develop Safe@Campus and then evaluate its effectiveness through rigorous trials, including randomized clinical trials, which assess knowledge retention, self-efficacy, behavioral intentions, threat reporting, and simulated response performance. They should also rigorously assess the mental health aspects of exposure to the program. Longitudinal studies will be necessary to determine sustained impact. Expanding scenario diversity, increasing interactivity, and integrating prevention-focused modules aligned with threat assessment research will further strengthen ecological validity. If effective at scale, Safe@Campus may provide a scalable model for experiential firearm injury prevention in university settings, contributing to comprehensive campus safety and broader public health strategies to reduce violence-related harm.

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Data Availability

The datasets used and/or analyzed during this study are available from the corresponding author, JY, upon reasonable request. JY had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis. JY will be responsible for providing access to research data requested by third parties as freely and timely as possible unless a legal obligation restricts access to the data (eg, nondisclosure agreement), intellectual property protection, ethical approval requirements, ethical or security reasons, or other legitimate reasons.

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Authors' Contributions

JY and DCS participated in the study conceptualization, supervision, and methodology. JW and BA participated in providing the resources and software. JY, HPS, LS, and KKW participated in project administration and study investigation procedures. JY, HPS, and KKW participated in data curation and formal analysis. JY and DCS drafted the initial manuscript. All authors critically reviewed and revised the manuscript.

Conflicts of Interest

None declared.

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Abbreviations

OSSC: Ohio School Safety Center
OSU: The Ohio State University
TPB: theory of planned behavior
VR: virtual reality

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Original Paper

Autoencoder-Enhanced Convolutional Neural Networks for Plantar Pressure–Based Gait Pattern Recognition: Model Development and Cross-Validated Evaluation Study

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Abstract

Background: Plantar pressure imaging is a stable modality that reflects gait-related biomechanical characteristics and has been used increasingly for gait assessment and recognition. However, plantar pressure images are high dimensional and nonlinear, making manual feature engineering and conventional machine learning insufficient to capture discriminative patterns.

Objective: This study aimed to develop a gait pattern recognition model based on plantar pressure using an autoencoder (AE)-enhanced convolutional neural network (CNN) and to evaluate its performance against baseline deep learning and classical machine learning approaches.

Methods: A total of 13 healthy volunteers (aged 18-24 years) were recruited. Plantar pressure data were collected during treadmill walking using an in-shoe pressure measurement system and converted into frame-wise plantar pressure images. We compared a lightweight CNN (Light CNN), an AE-CNN cascade model, and an encoder-augmented CNN with an additional bottleneck layer. Model development used participant-wise data partitioning, and performance was evaluated using accuracy, precision, recall, and F_1-score.

Results: The proposed encoder-augmented CNN achieved the best overall performance (F_1-score=96.20%), outperforming the Light CNN (F_1-score=94.44%) and AE-CNN cascade (F_1-score=92.45%). Confusion matrices and learning curves further indicated stable training behavior and consistent classification performance across gait patterns.

Conclusions: Integrating representation learning (AE-based compression) with CNN-based classification improved the recognition of gait patterns from plantar pressure images. This pilot study included only healthy participants. Future work should validate generalizability in larger and clinically diverse cohorts and further investigate participant-level evaluation and model interpretability, as well as deployment feasibility.

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KEYWORDS

plantar pressure; gait; convolutional neural networks; autoencoder; wearable sensors; deep learning; machine learning; biomedical engineering

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Introduction

With the rapid development of smart health care and artificial intelligence, the analysis of physiological signals has become increasingly important in fields such as disease diagnosis, rehabilitation monitoring, and identity verification. Among these signals, plantar pressure imaging is a stable method that reflects the posture of the individual, the characteristics of the gait, and foot functionality. Due to its ease of collection and visualization, plantar pressure imaging has been widely used for behavioral analysis, clinical evaluation, and biometric recognition. Gait is a fundamental human activity that represents the coordinated movement of the lower limbs. Although often overlooked because of its automaticity, gait involves complex and synchronized interactions between the musculoskeletal system and neural control. Understanding gait dynamics is important to assess gait alterations and support rehabilitation planning. Previous studies have investigated gait analysis using deep spatiotemporal learning and machine learning, including pathological gait classification, gait phase detection, pilot gait classification studies, and deep learning–based gait trajectory modeling [1-4]. Typically, the gait cycle can be described by the stance and swing phases, and more detailed phase characterization may provide additional functional information [2,4].

Traditional gait and plantar pressure analysis relied on manual feature extraction and classical machine learning algorithms. However, plantar pressure data are typically high dimensional and nonlinear, making it difficult for handcrafted features to capture informative patterns consistently. In recent years, deep learning, particularly convolutional neural networks (CNNs), has shown superior performance in automatically extracting features and improving classification accuracy. Autoencoder (AE) techniques have also been used to reduce dimensionality and alleviate redundancy, improving representation compactness and computational efficiency for high-dimensional inputs. Previous research has explored plantar pressure–based assessment in health-related applications. Deschamps et al [5] analyzed plantar pressure distribution patterns in people with diabetes, and Amemiya et al [6] investigated the relationships between elevated plantar pressure and gait characteristics in patients with diabetes. Wang et al [7] developed an insole-based gait monitoring technique to recognize gait patterns associated with knee osteoarthritis. These studies highlight the value of plantar pressure analysis to quantify lower limb loading characteristics and support gait-related assessment. Other researchers have investigated computational models for gait recognition. Nguyen et al [8] used smart shoes to classify ambulatory activities and proposed statistical characteristics combined with conventional classifiers, and Jeong et al [9] studied the classification of activity with respect to stairs using plantar pressure sensors. Jun et al [10] further proposed a hybrid deep learning framework that integrates plantar pressure images and 3D skeletal data, indicating that multimodal fusion can improve the recognition of abnormal gait patterns compared to pressure-only inputs. Beyond classification, related gait evaluation studies have compared optimization strategies for sensory data classification using deep neural networks [11] and evaluated machine learning algorithms for electromyography pattern classification in gait disorders [12], underscoring the broader demand for robust learning pipelines. To address the need for portable, real-time applications, Cho [13] developed a deep learning approach using plantar pressure signals to estimate walking speed and gait-related classification tasks. Chhoeum et al [14] applied CNN-based regression to estimate knee joint angles using foot pressure mapping images. Ling et al [15] introduced an AE-CNN–based multisource data fusion framework to estimate the step length of the gait motion, illustrating the practical value of representation learning when handling high-dimensional gait-related data. Ardhianto et al [16] formulated the estimation of the foot progression angle as an object detection task on plantar pressure images using YOLO (You Only Look Once)-based models, demonstrating the feasibility of computer vision–style pipelines on pressure maps. From a system-level perspective, Zhou et al [17] developed a gait detection and plantar pressure analysis system using a flexible triboelectric pressure sensor array and deep learning, highlighting the direction of continuous wearable gait monitoring under real-world constraints. Collectively, these studies suggest that plantar pressure imaging is advantageous due to its stability, visualization quality, and strong correspondence with gait cycles. Building on these advances, there remains a need for pressure-only deep learning frameworks that can learn discriminative representations from high-dimensional plantar pressure images, reduce redundancy via representation learning (eg, AEs), and maintain computational efficiency. Importantly, clinical claims should be supported by validation in clinically diverse cohorts; therefore, model development and evaluation in controlled settings should be clearly distinguished from future clinical verification.

Methods

Study Design and Workflow

The general workflow of this study is illustrated in Figure 1. The experimental design consisted of 3 major components. The first component involved the collection of plantar pressure response data required to generate plantar pressure images. The second component focused on the application of machine learning classifiers and a deep learning model based on a CNN. The third component addressed the AE, which was further investigated as a core part of this study. In the final stage of the experiments, the CNN and AE frameworks were integrated to perform classification and performance evaluation.

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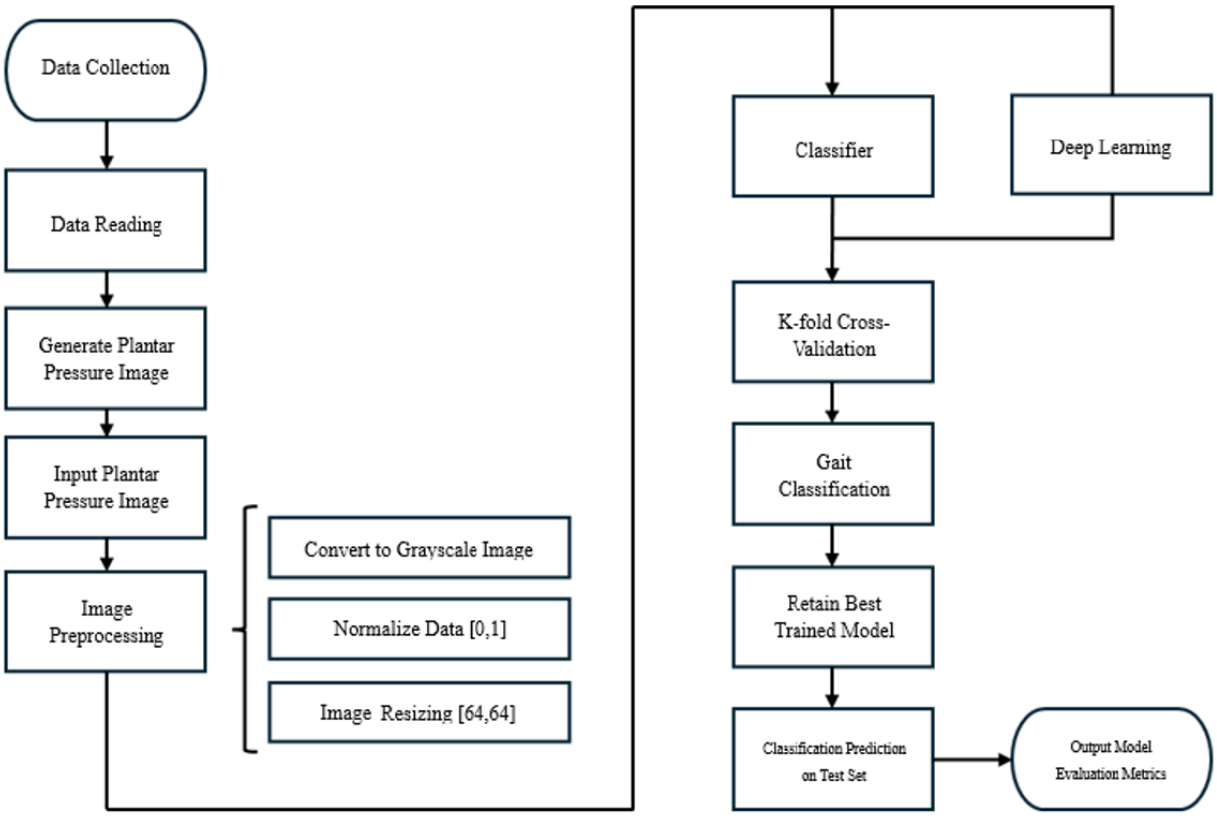
Figure 1. Overall workflow of the proposed plantar pressure–based recognition system.



As shown in Figure 1, the experimental workflow highlights the sequential architecture of the study. In particular, the second component, which encompasses both classifiers and CNN-based models, is presented in separate blocks. The detailed structures of these blocks are illustrated in Figures 2 and 3.

Figure 2. Model development framework that includes the autoencoder (AE)–convolutional neural network (CNN) pipeline and traditional classifiers. AE: autoencoder; AE-CNN: autoencoder convolutional neural network; KNN: k-nearest neighbors; SVM: support vector machine.

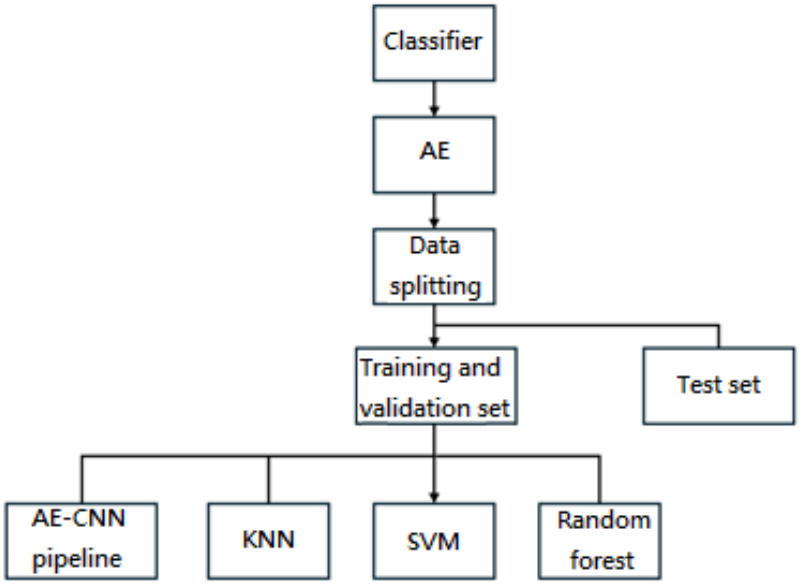


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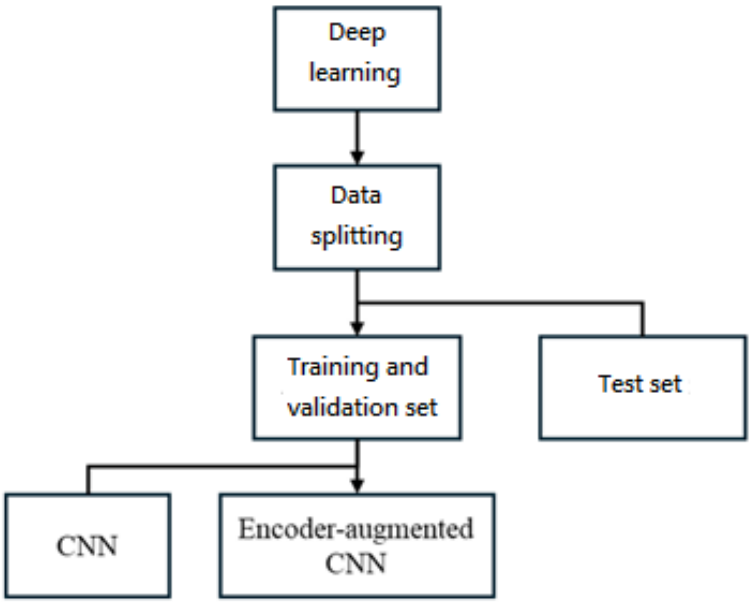
Figure 3. Architectures of the convolutional neural network (CNN) and encoder-augmented CNN models.



In the classifier block diagram, the AE-CNN cascade is defined as an AE in which compressed data are modularized and sequentially integrated with a CNN. This design enables the model to be trained in a staged manner, thereby forming the AE-CNN cascade. Furthermore, because its data processing pathway resembles that of conventional classifiers, the AE-CNN cascade was grouped within the classifier block for consistency in experimental design.

In the deep learning block diagram, the encoder-augmented CNN is defined as a hybrid model in which the encoder component of the AE is directly integrated into the CNN classifier. This design enables end-to-end training, allowing the encoder and CNN to fuse into a unified framework. By adopting this hybrid strategy, the model is trained as an integrated architecture, which is referred to as encoder-augmented CNN.

Participants and Experimental Setup

A total of 13 healthy university student volunteers (aged 18-24 years) were recruited for this study. Exclusion criteria included current or previous foot ulcers, diabetes, vascular disease, hypertension, inability to walk independently for at least 10 minutes, and continued use of medications that could affect gait. Only participants who met all eligibility criteria were enrolled.

Ethical Considerations

This study was approved by the Central Regional Research Ethics Committee of China Medical University, Taichung, Taiwan (approval CRREC-112-130). All participants received a full explanation of the study procedures and provided their written informed consent prior to participation. The data were deidentified for analysis and reporting. No financial compensation was provided to participants in this study.

Plantar Pressure Measurement

Plantar pressure data were acquired using the Tekscan F-Scan in-shoe pressure measurement system (Figure 4 [18]). The F-Scan provides high-resolution plantar pressure distribution with real-time acquisition via a dedicated data cable, making it suitable for gait analysis, sports science, insole design, and clinical applications. The key functions adopted in this study are summarized in Table 1. In particular, the system's real-time recording capability and high spatial resolution enabled the capture of subtle pressure changes, thereby improving the fidelity of the experimental dataset.

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Figure 4. F-Scan plantar pressure sensor: (A) data collection wearing mode and (B) pressure sensing sheet [18].

Table 1. Main functions of the F-Scan plantar pressure sensor.

Item	Explanation	Application
Plantar pressure measurement	Unit: kPa	Measurement of plantar pressure distribution
Gait analysis	Analysis of step length, step frequency, and gait cycle	Walking, running, and abnormal gait
High-resolution sensor	0.5 cm^2 per sensing unit; visualization of subtle pressure variations	Detailed plantar pressure analysis
Calibration function	Three calibration methods: walking, gait, and point modes	Normal gait analysis, abnormal gait analysis, and plantar pressure distribution while standing

Foot Pressure Data Acquisition

Plantar pressure responses were recorded using the Tekscan F-Scan in-shoe system while participants walked on a treadmill at a fixed speed. Each trial began with a 1-minute familiarization period to stabilize gait at the target speed. The F-Scan microsensors sampled plantar pressure at 25 Hz, and instantaneous pressures were stored as matrix-valued frames and exported in CSV format for downstream processing.

Frame selection was based on gait cycles, each consisting of a stance phase and a swing phase (Figure 5). The pressure value at each time point was calculated as the sum of pressure readings across all sensing elements (kPa) as an overall loading indicator. In Figure 5, the green bracket denotes 10 gait cycles, blue markers indicate frames within the stance phase, and red markers denote the swing phase. As the plantar load is negligible during swing, the sensors yield near-zero readings. Therefore, to enable frame-wise classification of gait patterns and only the stance-phase frames of the 10 cycles were retained for analysis.

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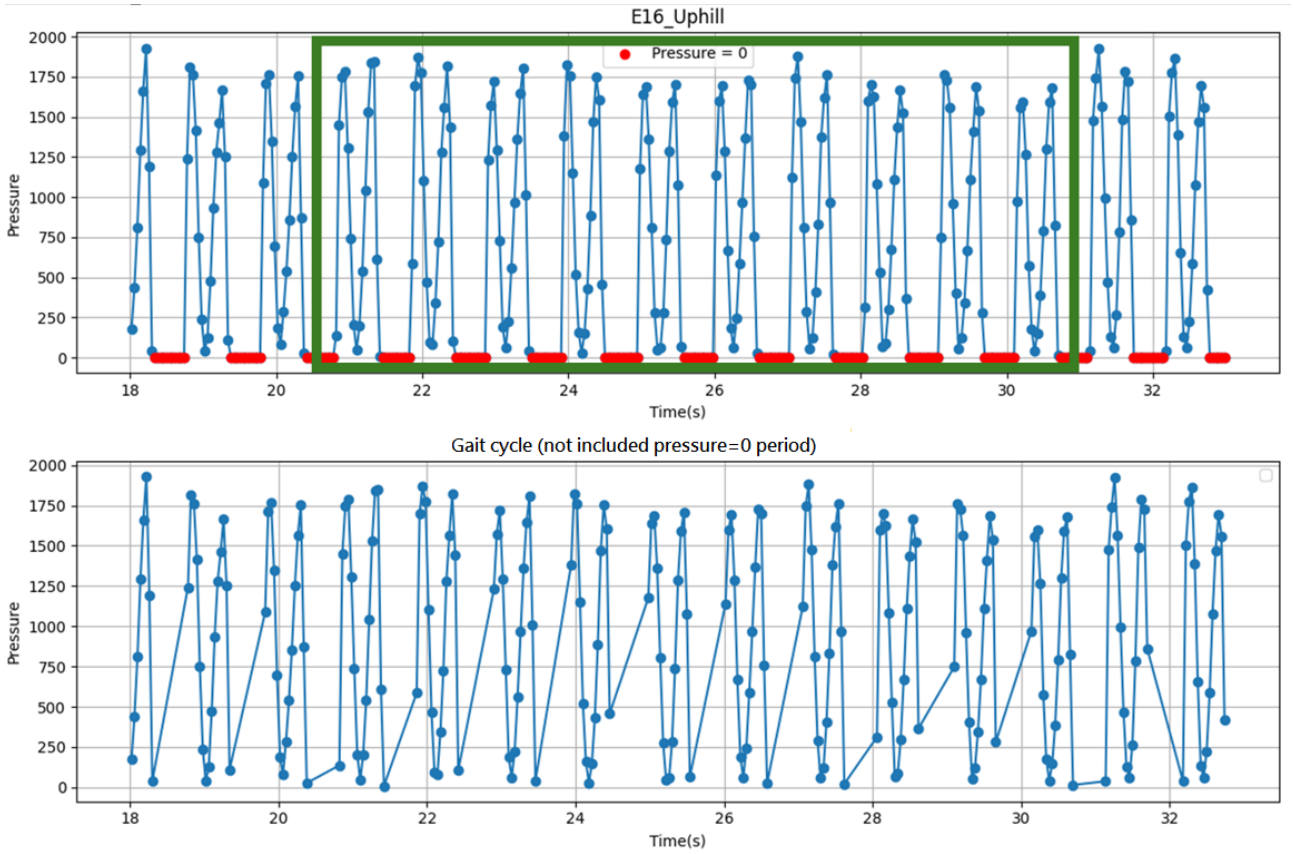
Figure 5. Example of the plantar pressure response across gait cycles: the green bracket indicates 10 gait cycles, blue markers denote stance-phase frames, and red markers denote swing-phase frames.



The final dataset comprised 6994 frames in 3 gait patterns: slow walking (2590 frames), fast walking (2162 frames), and uphill walking (2242 frames). These frames served as input to the proposed models for training and evaluation.

Image Preprocessing

Matrix-form plantar pressure signals exported by the F-Scan system were converted into frame-wise instantaneous plantar pressure matrices using Python 3.10.12 (Python Software Foundation) to enable deep learning. Each frame-wise matrix was normalized to the range (0, 1) using min-max normalization and rendered directly as a grayscale intensity image, in which pixel intensity represents normalized pressure magnitude. For visualization (Figure 6A), we additionally rendered the same normalized matrices as pseudocolor pressure maps using the perceptually uniform viridis colormap. The viridis colormap was used for visualization only. The grayscale images were resized to 64×64 pixels to ensure consistency across samples, and Gaussian noise was injected as a lightweight augmentation to improve noise robustness and mitigate overfitting. After preprocessing, the resulting input tensor for model training and evaluation had the shape (6994, 64, 64, 1).

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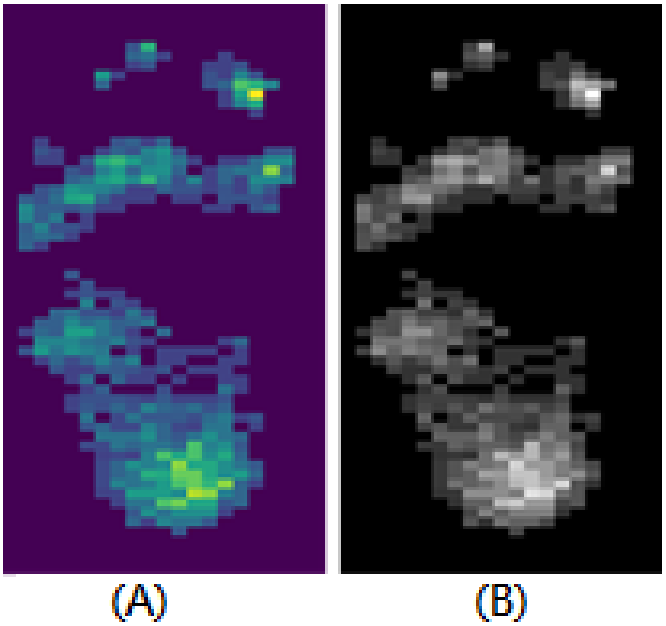
Figure 6. (A) Example of an image of plantar pressure distribution rendered with a perceptually uniform viridis colormap. (B) The corresponding grayscale image used as the model input after preprocessing.



Model Architecture

In this study, 3 deep learning architectures were developed to address plantar pressure image classification, each designed with distinct structural characteristics. The first was a lightweight CNN (Light CNN), which served as the baseline model. It was constructed with 3 convolutional layers, each followed by max-pooling to progressively reduce dimensionality while preserving salient spatial features. Batch normalization was incorporated to stabilize the training process, while dropout layers were used to mitigate overfitting. A fully connected layer and a final softmax classifier were used to output the probabilities of the 3 gait categories, namely, slow walking, fast walking, and uphill walking. The structural design of this network is summarized in Table 2, which establishes the baseline framework for subsequent comparisons.

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Table 2. Light convolutional neural network model architecture.

Tasks	Structural parameters		Training parameters (activation function)
	Layer	Detailed parameters	
Feature extraction	Input image	(64, 64, 1)	—[a]
Feature extraction	Conv2D_1	32,(3, 3), padding="same"; L2 regularization (λ=0.0005)	Leaky ReLU
Feature extraction	MaxPool2D	(2, 2), padding="same"	—
Feature extraction	Conv2D_2	64,(3, 3), padding="same"; L2 regularization (λ=0.0005)	Leaky ReLU
Feature extraction	MaxPool2D	(2, 2), padding="same"	—
Feature extraction	Conv2D_3	128,(3, 3), padding="same"; L2 regularization (λ=0.0005)	Leaky ReLU
Feature extraction	MaxPool2D	(2, 2), padding="same"	—
Feature extraction	Dropout (0.2)	—	—
Multiclass classification	Dense	90	—
Multiclass classification	Dense	60	—
Multiclass classification	Dense	3	Softmax
Other parameters	K-fold	9	—
Other parameters	Batch size	64	—
Other parameters	Epochs	100	—
Other parameters	Loss function	categorical_crossentropy	—
Other parameters	Optimizer	Adam (learning rate=0.0005)	—
Other parameters	Metrics	accuracy	—

[a]Not applicable.

The second model was the AE-CNN cascade, which modularized the integration of an AE and a CNN classifier. In this design, the encoder of the AE first compressed the high-dimensional plantar pressure matrices into a compact latent representation, while the decoder simultaneously ensured that essential structural information could be reconstructed. The compressed latent features were then transferred to a CNN classifier for further convolutional processing and final classification. This staged cascade design effectively separated feature compression from classification, improving both the stability and the interpretability of the learning process. The encoder architecture used in the AE-CNN cascade is presented in Table 3, illustrating how feature reduction and classification were sequentially integrated.

Table 3. Autoencoder encoder model architecture.

Task	Structural parameters		Training parameters (activation function)
	Layer	Detailed parameters	
Encoded	Input image	(64, 64, 1)	—[a]
Encoded	Conv2D_1	32, (3, 3), padding="same"	Leaky ReLU
Encoded	MaxPool2D	(2, 2), padding="same"	—
Encoded	Conv2D_2	64, (3, 3), padding="same"	Leaky ReLU
Encoded	MaxPool2D	(2, 2), padding="same"	—
Encoded	Conv2D_3	128, (3,3), padding="same"	Leaky ReLU
Encoded	MaxPool2D	(2, 2), padding="same"	—
Encoded	Flatten	—	—
Encoded	Dense	128	—

[a]Not applicable.

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To evaluate generalization while reducing the risk of information leakage from correlated frame-wise samples, data partitioning was performed at the participant level. Participants (n=13) were first split into a development set (n=10, 76.9%) and an independent held-out test set (n=3, 23.1%). Within the development set, a participant-wise grouped 9-fold cross-validation procedure was applied for model selection and stability assessment. In each fold, all frame-wise samples from participants in the training folds were used for model fitting, and all samples from participants in the held-out fold were used for validation. As 10 is not evenly divisible by 9, fold sizes differed by at most 1 participant (8 folds contained 1 participant and 1 fold contained 2 participants). After cross-validation, the final model configuration was retrained on the full development set and evaluated once on the held-out test set. Performance was reported using accuracy, precision, recall, and F_1-score.

The third architecture was the encoder-augmented CNN, which further extended the integration of AE and CNN by embedding the encoder directly into the CNN pipeline. Unlike the cascade structure, this hybrid design adopted an end-to-end framework, where the encoder served as the initial feature extractor and its outputs were directly connected to the subsequent CNN layers. This approach allowed the encoder and CNN to be jointly optimized, combining compact representation learning with the discriminative power of deep convolutional layers. The architectural layout of this model is summarized in Table 4, highlighting its streamlined structure and enhanced learning efficiency.

Table 4. Encoder-augmented convolutional neural network model architecture.

Task	Structural parameters		Training parameters (activation function)
	Layer	Detailed parameters	
Spatial and feature compression	Input image	(64, 64, 1)	__[a]
Spatial and feature compression	Conv2D_1	32,(3, 3), padding="same"; L2 regularization (λ=0.0005)	—
Spatial and feature compression	Batch normalization	—	Leaky ReLU
Spatial and feature compression	MaxPool2D	(2, 2), padding="same"	—
Spatial and feature compression	Conv2D_2	64,(3, 3), padding="same"; L2 regularization (λ=0.0005)	Leaky ReLU
Spatial and feature compression	MaxPool2D	(2, 2), padding="same"	—
Spatial and feature compression	Conv2D_3	128,(3, 3), padding="same"; L2 regularization (λ=0.0005)	Leaky ReLU
Spatial and feature compression	MaxPool2D	(2, 2), padding="same"	—
Spatial and feature compression	Dropout(0.2)	—	—
Spatial and feature compression	Flatten	—	—
Spatial and feature compression	Dense (bottleneck)	128	—
Multiclass classification	Dense	90	—
Multiclass classification	Dense	60	—
Multiclass classification	Dense	3	Softmax
Other parameters	K-fold,	9	—
Other parameters	Batch size	64	—
Other parameters	Epochs	100	—
Other parameters	Loss function	categorical_crossentropy	—
Other parameters	Optimizer	Adam (learning rate=0.0005)	—
Other parameters	Metrics	accuracy	—

[a]Not applicable.

Evaluation Metrics

Model performance was assessed using accuracy, precision, recall (sensitivity), F_1-score, and confusion matrix:

- The accuracy reflects the overall proportion of correctly classified samples in all classes.
- Precision quantifies the reliability of positive predictions for a given class by indicating how many predicted positives are correct.
- Recall (sensitivity) measures the model's ability to correctly identify true instances of a given class.

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- The F_1-score provides a balanced summary of precision and recall, particularly useful when both false positives and false negatives matter.
- The confusion matrix offers a class-by-class view of predictions vs ground truth, enabling identification of error patterns (eg, which gait classes are most frequently confused). For the 3-class setting in this study (slow walking, fast walking, and uphill walking), a 3×3 matrix was used to summarize the results per class and general trends.

All metrics were computed on the designated evaluation split without using any evaluation data for parameter updating. Unless stated otherwise, results are reported at the overall level to facilitate comparison among the baseline CNN, the AE-CNN cascade, the encoder-augmented CNN, and traditional classifiers; confusion matrices are additionally provided to illustrate class-wise error patterns. To reduce optimistic bias due to correlated frame-wise samples, all data splitting was performed at the participant level. Specifically, all stance-phase frames from the same participant were assigned to a single fold during cross-validation, ensuring that no participant's frames appeared in both the training and validation sets within any iteration. Model performance was summarized using accuracy, precision, recall, and F_1-score.

Reporting Guidelines

This model development and evaluation study was reported with reference to the CREMLS (Consolidated Reporting of Machine Learning Studies) checklist. The completed checklist is provided in Multimedia Appendix 1.

Results

Overview

This section summarizes the main comparative findings from the deep learning and classical machine learning models evaluated. Detailed training curves, optimization experiments, and hyperparameter tuning results are provided in Multimedia Appendix 2.

Among the baseline deep learning models, the Light CNN achieved an F_1-score of 94.44% on the held-out test set, whereas the AE-CNN cascade achieved an F_1-score of 92.45%.

Additional optimization analyses of the encoder-augmented CNN, including comparisons of downsampling strategies, batch normalization configurations, and bottleneck layer inclusion, supported the final model design reported here (Multimedia Appendix 2).

For the classical machine learning models trained on AE-derived features, support vector machine (SVM) with a radial basis function kernel performed best (F_1-score=93.76%), followed by k-nearest neighbors (F_1-score=91.73%) and random forest (F_1-score=88.54%).

Principal Findings

The primary finding of this study is that the proposed encoder-augmented CNN architecture achieves superior performance (F_1-score=96.20%) in classifying dynamic gait patterns from plantar pressure images compared to both baseline deep learning models and classical machine learning classifiers (Figure 7; Table 5). This result supported the hypothesis that an integrated deep learning architecture, combining the feature extraction and dimensionality reduction capabilities of an AE with the classification power of a CNN, is highly effective for this task.

Figure 7. Overall performance comparison of all models. AE-CNN: autoencoder convolutional neural network; KNN: k-nearest neighbors; SVM-RBF: support vector machine-radial basis function.

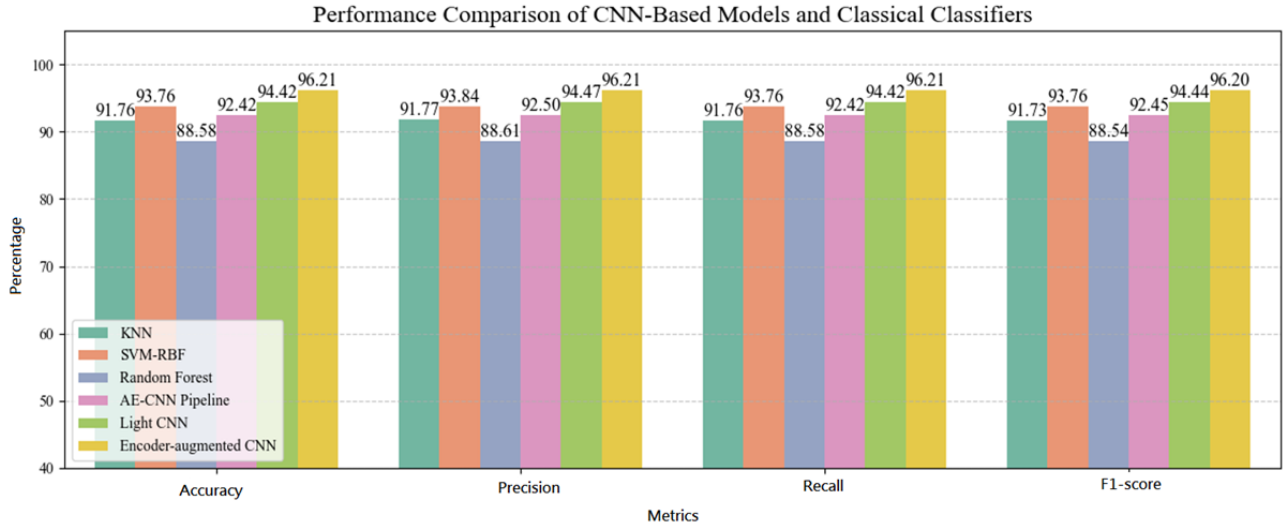

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Table 5. Overall performance in the held-out test set.

Model	Accuracy	Precision	Recall	F_1-score
KNN[a]	91.76	91.77	91.76	91.73
SVM[b]-RBF[c]	93.76	93.84	93.76	93.76
Random forest	88.58	88.61	88.58	88.54
AE[d]-CNN[e] cascade	92.42	92.50	92.42	92.45
Light CNN	94.42	94.47	94.42	94.44
Encoder-augmented CNN	96.21	96.21	96.21	96.20

[a]KNN: k-nearest neighbors.

[b]SVM: support vector machine.

[c]RBF: radial basis function.

[d]AE: autoencoder.

[e]CNN: convolutional neural network.

Discussion

Overview

This model development and evaluation study demonstrates that the integration of AE-based representation learning with CNN architectures can achieve accurate recognition of gait patterns based on plantar pressure in a pilot dataset of healthy participants. Future work should validate generalization across broader demographics and clinical populations, evaluate robustness to real-world variability (eg, footwear, sensor noise, and speed fluctuations), and further strengthen interpretability and deployment feasibility for wearable or embedded applications. The performance of the Light CNN (F_1-score=94.44%) also demonstrated that even a lightweight, stand-alone CNN can effectively learn discriminative features from plantar pressure data. Among the classical methods, the **support vector machine**–RBF classifier proved to be the most robust, outperforming **k-nearest neighbors** and random forest, which aligns with its known strengths in handling high-dimensional feature spaces.

The study also highlights the importance of architectural choices in model optimization. Supplementary analyses of downsampling strategy, batch normalization placement, and bottleneck layer inclusion are provided in Multimedia Appendix 2. These experiments supported the final selection of the encoder-augmented CNN configuration reported in the main manuscript.

Interpretation of Results and Gait Feature Analysis

A notable and consistent finding in multiple models was the confusion between “fast walking” and “uphill walking” gaits (Figure 8). The encoder-augmented CNN, for example, misclassified 23 “uphill” instances as “fast walking.” This suggests that at similar walking speeds, the plantar pressure distributions for these 2 activities share substantial similarities. The primary differentiator may lie in subtle temporal features or pressure shifts related to gravitational resistance during uphill walking, which current spatial feature–focused models may not fully capture. In contrast, “slow walking” was classified with very high precision, indicating that variations in walking speed produce more distinct plantar pressure patterns than variations in surface uphill.

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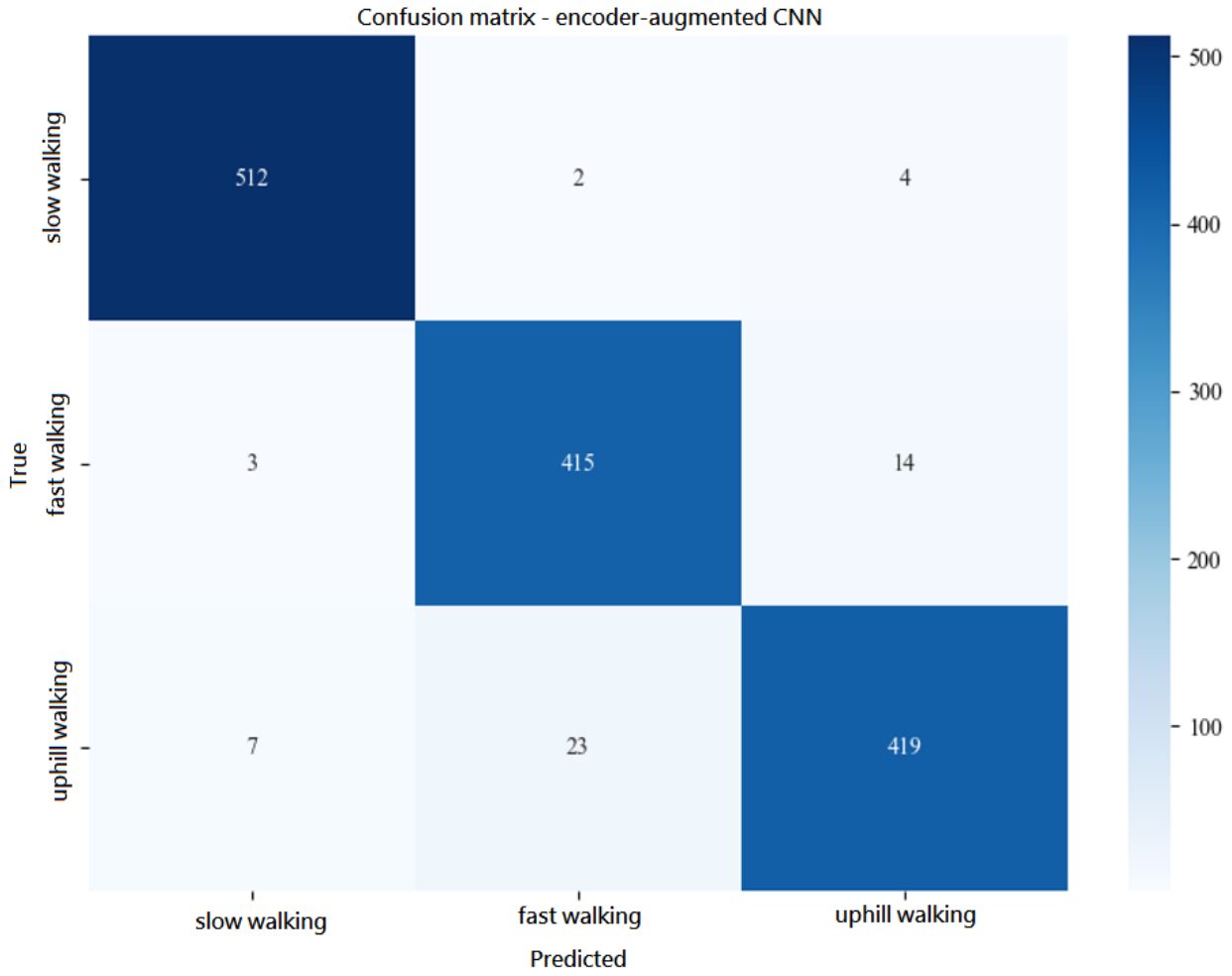
Figure 8. Confusion matrix for the encoder-augmented convolutional neural network (CNN).



Comparison With Prior Work

The use of deep learning, particularly CNNs, for plantar pressure analysis is consistent with recent trends in biomechanics and clinical research. Although many studies have successfully used CNNs for static pressure images (eg, for disease diagnosis), this research extends their application to dynamic gait classification. The accuracy achieved by the encoder-augmented CNN (96.21%) is competitive with or exceeds that reported in other studies using different sensor modalities or classification algorithms for similar tasks. The finding that an integrated AE-CNN architecture outperforms a standard CNN suggests that explicit feature learning and dimensionality reduction prior to classification can be a beneficial strategy for complex, high-variance data such as plantar pressure sequences. Clinical and translational implications should be interpreted with caution. This pilot study included only healthy young adults under controlled treadmill conditions and did not include participants with pathological gaits (eg, diabetes-related gait alteration). Therefore, while plantar pressure imaging is clinically relevant and the proposed framework shows technical promise, clinical screening performance has not been empirically validated here and requires future studies in clinical cohorts and real-world environments. In addition, our current approach performs frame-wise classification of stance-phase plantar pressure maps and does not explicitly model temporal dynamics across gait cycles; future work could incorporate sequence models (eg, temporal CNNs or long short-term memory) to better capture temporal gait signatures.

Limitations

Although this study has yielded promising results, several limitations should be considered:

1. Single data source—plantar pressure data in this study were collected from a limited number of participants in a controlled laboratory environment. Whether the model's generalization ability can be extended to populations with different ages, genders, weights, or specific pathological gaits (eg, flat feet and diabetic foot) requires further validation.

2. Model interpretability—compared to classical machine learning models, deep learning models are often regarded as "black boxes," with less transparent decision-making processes. Although this study validated the effectiveness of the model, it did not explore which specific regions or features of plantar pressure images the model used for classification.

3. Limited gait types—the study only covered 3 specific dynamic gaits. The applicability of the model to more complex daily activities, such as walking downhill, turning, or climbing stairs, has yet to be determined.

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In addition, the evaluation in this study was reported primarily at the frame level. Although frame-wise metrics are useful for model comparison, participant-level performance (eg, aggregating frame-level predictions to participant-level decisions) should be reported in future studies to better reflect real-world use. Moreover, statistical uncertainty (eg, CIs via bootstrapping) and systematic robustness tests under controlled perturbations (eg, varying noise intensity or sensor shift) were not performed in this study and remain important directions for future work.

Conclusions

This study developed and evaluated a deep learning architecture named encoder-augmented CNN for gait classification using plantar pressure images. The model combines the feature extraction capabilities of an AE with the classification strengths of a CNN. Through systematic structural optimization, it ultimately achieved an accuracy of 96.21% in the 3-class dynamic-gait recognition task, outperforming classical machine learning methods and other deep learning variants in this study.

On the basis of the findings and limitations of this research, future studies could proceed in the following directions:

- Database expansion and model generalization—recruit a more diverse range of participants and collect data in settings closer to real-life scenarios to validate and enhance the model's generalization ability. Future clinical studies could explore whether this framework can assist in the assessment of pathological gaits.
- Enhancing the interpretability of the model—introduce visualization techniques (eg, gradient-weighted class activation mapping) to analyze the plantar pressure heat maps that the model focuses on during classification decisions. This would improve understanding of the basis for the model's decisions and could potentially lead to the discovery of new biomechanical indicators.
- Multimodal data fusion—to address the confusion between fast walking and uphill walking, future work could attempt to fuse data from other sensors (such as gyroscopes and accelerometers) to build a multimodal gait recognition system, with the aim of achieving higher classification accuracy.
- Model lightweighting and real-time application—explore techniques such as model pruning or knowledge distillation to further reduce the computational complexity of the encoder-augmented CNN. This would enable its deployment on wearable devices or embedded systems for real-time gait monitoring and feedback.

Acknowledgments

No generative artificial intelligence tools were used in the writing or editing of this manuscript.

Data Availability

The datasets generated or analyzed during this study are not publicly available due to privacy and ethical restrictions but are available from the corresponding author on reasonable request. Access to deidentified data may be subject to institutional approval and a data use agreement, where applicable. Requests for data access may be directed to the corresponding author at byliau@fcu.edu.tw.

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Authors' Contributions

Conceptualization: CCC, BYL
Formal analysis: CCC
Investigation: CCC
Methodology: CCC, BYL, CWL, YKJ
Resources: CCC, BYL
Writing – original draft: CWL, YKJ, BYL
Writing – review & editing: CWL, YKJ, QQL, YYW, YSC, BYL
All authors have read and agreed to the published version of the manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1
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Multimedia Appendix 2

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Supporting optimization analyses, training curves, and hyperparameter tuning results.
[DOCX File , 554 KB - formative_v10i1e88488_app2.docx]

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Abbreviations

AE: autoencoder
CNN: convolutional neural network
CREMLS: Consolidated Reporting of Machine Learning Studies

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Original Paper

Understanding Collaborative CT and MRI Utilization Through Network Analysis: Retrospective Study Using Administrative Claims Data

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Abstract

Background: Japan has one of the highest densities of computed tomography (CT) and magnetic resonance imaging (MRI) scanners globally, yet efficient resource allocation remains a challenge amid demographic shifts and regional health care disparities.

Objective: This study aimed to develop an analytic framework using network analysis techniques to understand the collaborative use of CT and MRI devices across health care facilities in a Japanese prefecture.

Methods: A retrospective observational study was conducted using outpatient receipt data from Japan's National Health Insurance and the Late-Stage Elderly Medical System, covering fiscal years 2016 to 2019. Network analysis techniques were used to identify patterns of shared use among medical institutions. Network graphs with community detection were developed to visualize collaborative relationships, and density and reciprocity metrics were calculated to assess interinstitutional cooperation.

Results: CT examinations increased from 287,782 (2016) to 307,029 (2019), while MRI examinations increased from 107,876 to 115,929 over the same period. Collaborative examinations also increased for both modalities. Network density remained relatively stable (CT: 3.10-3.50×10^{-3}; MRI: 3.20-3.70×10^{-3}), while reciprocity decreased (CT: 9.74×10^{-2} to 7.79×10^{-2}; MRI: 2.82×10^{-2} to 1.56×10^{-2}). Community detection analysis showed differences in the distribution of medical institutions across clusters over time.

Conclusions: Network analysis revealed structural changes in collaborative CT and MRI use patterns, including declining reciprocity, which suggests a shift toward more unidirectional referral patterns. This analytic framework provides a method for health care planners to assess interinstitutional collaboration and inform resource allocation strategies for shared diagnostic equipment.

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KEYWORDS

network analysis; administrative data; diagnostic imaging; computed tomography; magnetic resonance imaging; health care resource management; interinstitutional cooperation; shared use

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Introduction

Background

Japan has one of the highest densities of computed tomography (CT) and magnetic resonance imaging (MRI) scanners per capita in the world, significantly surpassing other resource-limited countries such as the United States and European nations. According to the Organisation for Economic Co-operation and Development (OECD) data, Japan's health care system has more than 153 CT scanners and 57 MRI units per million population [1]. These figures are more than twice the OECD average. This high density is attributed to factors such as an aging population, strong demand for advanced diagnostic imaging, and policies that facilitate investment in medical technology. However, despite the abundance of these devices, disparities in access and underutilization in certain regions persist, highlighting the need for an efficient resource allocation strategy. In Japan, given the anticipated population decline [2], the government has been implementing policies to encourage the shared use of CT and MRI equipment among regional medical facilities and patient referrals [3,4].

In Japan, prefectural governments are mandated under the Medical Care Act to develop strategic plans for the shared use of diagnostic devices to optimize the allocation of expensive medical equipment [5]. The efficient sharing of such devices among medical facilities is crucial for enhancing health care accessibility and reducing health care costs. Formulating effective plans requires a comprehensive understanding of the current cooperation among health care facilities. Unfortunately, publicly available statistical data offer limited insights into the current actual shared-use patterns and interinstitutional collaborations related to diagnostic devices.

Formulating effective plans for shared equipment use requires empirical evidence on current collaborative patterns among health care facilities. Without systematic data on how facilities actually share diagnostic imaging resources, prefectural governments must rely on incomplete information when making equipment allocation decisions. This information gap can lead to imbalances in the distribution of resources, ultimately affecting patient access to timely diagnostic services. An analytic framework that can quantify and visualize interinstitutional collaboration patterns would therefore provide an evidence base for health care resource planning.

Literature Review

Some recent studies have suggested the potential benefits of shared use of high-cost diagnostic equipment such as CT and MRI in health care systems. Some research indicates that increased use of CT and MRI correlates with hospital cost inefficiency [6]. The strategic sharing of these devices within regional health care networks can lead to significant cost savings and improvements in service delivery [7]. In medium to large hospitals, the introduction of CT and MRI contributes to improved quality and resource efficiency, but in smaller clinics, the use of diagnostic imaging may not contribute to these improvements [8]. Therefore, appropriate allocation of medical equipment, considering hospital volume and establishing a coordinated method of shared use, could improve cost efficiency.

To accurately depict real-world scenarios using empirical data and to formulate evidence-based policies, there remains a notable absence of studies addressing analytic methods for collaborative medical equipment use.

The aim of this study was to propose an analytic framework for understanding the collaborative use of CT and MRI devices across health care facilities of diverse scales. Specifically, we used network analysis techniques—including network graph visualization, density and reciprocity metrics, and community detection—to characterize the sharing dynamics of CT and MRI equipment within a regional health care network. Through analysis of longitudinal administrative claims data, we aimed to describe patterns of collaborative use that may inform resource allocation decisions.

Methods

Data Sources

This study used an outpatient receipt database from the National Health Insurance and Health Insurance System for people aged 75 years and older in a Japanese prefecture [9]. Receipt databases provide detailed records of health care services, including the history of imaging examinations, patient demographics, and medical institution identifiers, which could be used as a resource for analyzing interinstitutional collaboration. Our analysis covered the fiscal years 2016 to 2019 to capture longitudinal changes and identify potential factors influencing collaboration.

This study used a retrospective observational design to examine the trends and patterns in diagnostic device sharing. The procedure in this study involved five key processes: (1) extracting the study population from receipt data, (2) identifying the shared use of CT and MRI for these patients, (3) identifying the relationship between collaborative medical facilities engaged in shared use, (4) constructing network graphs of collaboration based on a network analysis method, and (5) evaluating the collaborative structure by calculating network measurements.

Study Population

The targeted patients were covered by the National Health Insurance and the Late-Stage Elderly Healthcare System and underwent CT and MRI examinations between fiscal years 2016 and 2019. The inclusion criteria required patients to have undergone at least one CT or MRI scan, maintained continuous insurance coverage throughout the survey period, and had sufficient outpatient consultation records for tracking health care use patterns. Patients who discontinued insurance during the period of shared equipment use or failed to follow medical advice regarding facility visits were excluded from the study population.

Analyzing Methods

Network analysis is beginning to be recognized as an important approach for understanding and improving large-scale health system operations, with its full potential yet to be established [10,11]. Previous research using the same regional claims

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database demonstrated the use of network analysis for evaluating patient-sharing structures among medical facilities [12]. Traditional analytic approaches, such as descriptive statistics and regression analyses, typically treat medical facilities as independent units, limiting their ability to capture interinstitutional relationships [13,14]. Network analysis addresses this limitation by enabling the examination of relational structures among health care providers [15]. Network metrics, such as density and reciprocity, quantify connectivity patterns, while community detection algorithms can identify clusters of collaborating facilities [16,17].

This approach is used to evaluate the types and structures of interactions between medical facilities and network indicators to identify the real-world correlations of these network indicators [18]. In this study, the networks were analyzed using adjacency matrices, where nodes represent medical facilities and directed edges indicate the relationships for the shared use of diagnostic equipment.

In this study, we defined "shared use" medical cooperation as follows:

- Condition 1: a medical facility conducts only a single diagnostic imaging visit within a continuous 3-month period
- Condition 2: another medical facility conducts multiple visits within a continuous 6-month period
- Condition 3: the date of the diagnostic imaging examination at the medical facility in condition 1 falls within the period of visits at the medical facility specified in condition 2.

This study identified medical facilities meeting the specified conditions solely for conducting examinations as a "target facility," while those not conducting examinations but identified as requesting them were categorized as a "source facility."

We organized consecutive medical consultations meeting these criteria chronologically, identified the originating and receiving medical facilities, and constructed an adjacency matrix. Subsequently, we performed network analysis using this matrix, where medical facilities were nodes and shared-use relationships were represented as directed edges. We depicted network graphs to visualize relationships between medical facilities with the Fruchterman-Reingold algorithm, which is commonly used to enhance the understanding of structural patterns [19]. We performed community detection using the Louvain algorithm, which optimizes modularity to identify densely connected groups of facilities within the broader network [18]. This algorithm iteratively assigns nodes to communities in a manner that maximizes the density of connections within communities relative to connections between communities. The resulting cluster groups represent naturally occurring collaborative communities—groups of medical facilities that share patients more frequently with each other than with facilities outside the cluster.

Measurements

The key evaluation metrics used in this study were network density, reciprocity, and collaboration count (the number of shared use cases between facilities).

Network density and reciprocity were calculated using the following formulas:

Here, *n* represents the total number of medical facilities (nodes) in the network, and m denotes the total number of shared-use relationships (edges) between facilities. Density represents the proportion of actual referral connections relative to all possible connections among facilities [11,20].

For the reciprocity formula, *a* denotes the number of bidirectional edges, where both facility A refers patients to facility B and facility B refers patients to facility A for shared imaging examinations within the same fiscal year. The terms *b* and *c* represent unidirectional edges: *b* denotes edges where only facility A refers to facility B and *c* denotes edges where only facility B refers to facility A [21]. Higher reciprocity indicates that facilities mutually refer patients to each other, while lower reciprocity indicates unidirectional referral patterns where patients are sent to specific facilities without reciprocal referrals.

These metrics are relative values; in this study, we focused on temporal changes in these indicators, using reciprocity to supplement the interpretation of changes in network density. Differences in facility characteristics (fiscal years 2016-2019) were compared using the Kruskal-Wallis test, while CT and MRI modalities were compared via the Mann-Whitney *U* test (2-sided $P<.05$). The analysis was conducted using R software (version 4.3.2; R Foundation for Statistical Computing) with specialized libraries for network analysis (igraph, networkD3, and ggraph).

Ethical Considerations

Our study was approved by the Ethics Committee of the Institute for Health Economics and Policy (approval R4-010). The requirement for informed consent was waived because of the anonymized nature of the data in the database. Patient confidentiality was maintained throughout, and no compensation was provided to participants, as this was a retrospective analysis of existing administrative claims data.

Results

Figure 1 depicts a network diagram illustrating the coordination of CT and MRI use. Table 1 summarizes annual statistics for CT examinations, coordinated CT examinations, and the proportion of coordinated CT use from fiscal years 2016 to 2019, with data provided for MRI in a similar manner.

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Figure 1. Computed tomography (CT) and magnetic resonance imaging (MRI) shared-use network graph (2016 to 2019).

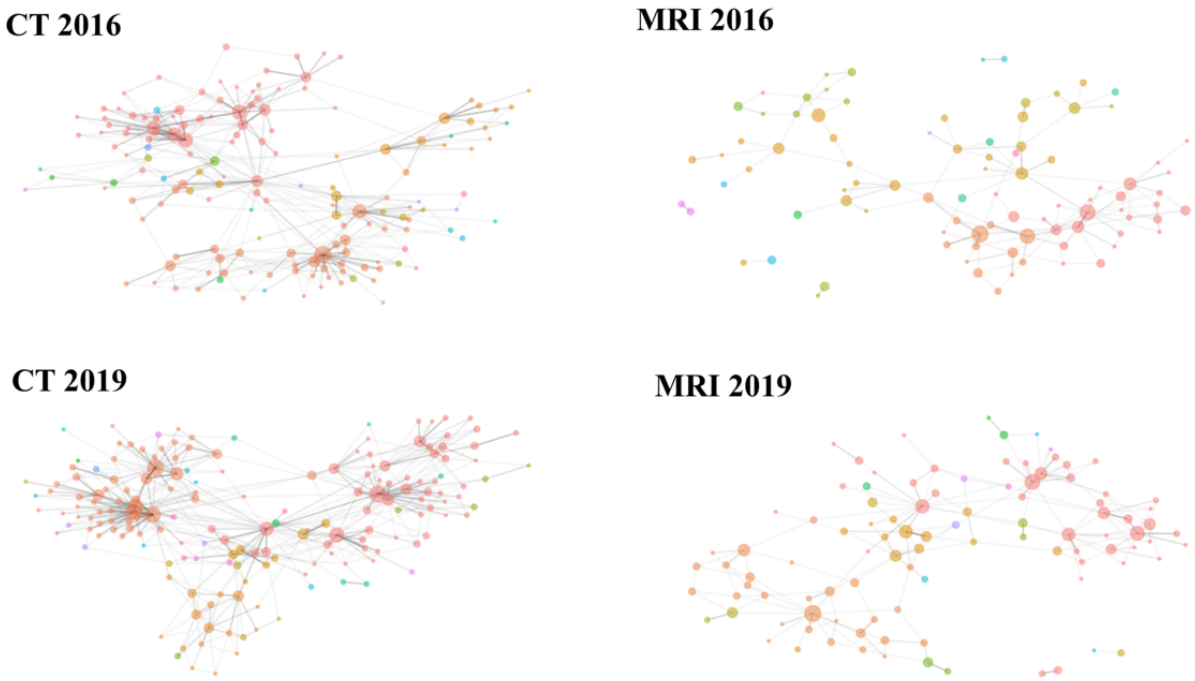

Table 1. Trends in computed tomography (CT) and magnetic resonance imaging (MRI) examinations and collaborative use.

Year	CT examinations, n	Shared CT examination, n	Proportion of collaborative shared use	MRI examinations, n	Shared MRI examinations, n	Proportion of shared MRI use
2016	287,782	1507	0.524	107,876	537	0.498
2017	298,755	1665	0.557	112,018	560	0.500
2018	304,322	1580	0.519	114,528	574	0.501
2019	307,029	1774	0.578	115,929	612	0.528

From 2016 to 2019, CT examinations increased from 287,782 in 2016 to 307,029 in 2019. Collaborative CT examinations also increased from 1507 to 1774 over the same period, with the proportion of collaborative CT use ranging between 0.52 and 0.58. Similarly, MRI examinations increased from 107,876 in 2016 to 115,929 in 2019. Collaborative MRI examinations also increased from 537 to 612, with the proportion of collaborative MRI use ranging between 0.50 and 0.53.

The edges observed in Figure 1 compared with CT correspond to the count of source and target medical facilities in Table 2. CT requests and MRI requests are aggregated separately, focusing on both the number of requests made and received per medical facility. *P* values were calculated using the Kruskal-Wallis test for comparisons of facility characteristics across fiscal years 2016 to 2019.

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Table 2. Trends in requests and requests received for shared use by source and target medical facilities from 2016 to 2019.

	2016	2017	2018	2019	*P* value
Source medical facilities (CT[a])	531	529	530	530	—[b]
Number of CT requests, mean (SD)	2.47 (3.06)	2.70 (3.43)	2.63 (3.54)	2.73 (3.72)	.61
Number of beds, mean (SD)	32.87 (100.48)	31.89 (98.16)	36.06 (105.02)	32.88 (101.62)	.92
Target medical facilities (CT)	134	129	119	122	—
Number of CT requests received, mean (SD)	9.79 (18.81)	10.88 (18.45)	11.02 (19.37)	11.39 (20.99)	.92
Number of beds, mean (SD)	126.24 (168.52)	128.84 (169.54)	131.20 (169.85)	131.52 (173.42)	.99
Source medical facilities (MRI[c])	281	279	281	283	—
Number of MRI requests, mean (SD)	1.61 (1.66)	1.71 (1.89)	1.75 (1.86)	1.74 (1.81)	.81
Number of beds, mean (SD)	30.86 (103.43)	39.22 (117.50)	38.60 (116.32)	37.88 (112.25)	.81
Target medical facilities (MRI)	75	72	65	66	—
Number of MRI requests received, mean (SD)	6.97 (6.98)	6.31 (7.23)	6.12 (7.27)	6.30 (7.47)	.92
Number of beds, mean (SD)	171.63 (179.47)	175.80 (172.87)	167.46 (174.59)	174.15 (175.92)	.99

[a]CT: computed tomography.

[b]Not applicable.

[c]MRI: magnetic resonance imaging.

Across the years from 2016 to 2019, facility-level characteristics showed no statistically significant year-to-year variation for CT (requests: *P*=.61; beds: *P*=.92) or MRI (requests: *P*=.81; beds: *P*=.81). The mean number of requests received per medical facility was higher for CT than for MRI. No statistically significant differences were observed in the mean number of hospital beds across years for either modality. Network density values for MRI were lower, approximately 2.50×10^{3}, 2.45×10^{3}, and 2.40×10^{3}, indicating a less connected network. Similarly, reciprocity declined slightly, with values around 7.50×10^{2}, 7.45×10^{2}, and 7.20×10^{2} over the 3-year period, reflecting a weaker bidirectional collaboration compared with CT.

Table 3 shows the metrics for CT and MRI shared-use networks presented annually from 2016 to 2019. For CT networks, density showed slight variations year to year, ranging from 3.20×10^{-3} in 2017 to 3.50×10^{-3} in 2018. Reciprocity decreased over the years from 9.74×10^{-2} in 2016 to 7.79×10^{-2} in 2019. MRI networks exhibited different patterns. The density remained relatively stable, with values ranging from 3.40×10^{-3} to 3.20×10^{-3} across the years. Reciprocity declined from 2.82×10^{-2} in 2016 to 1.56×10^{-2} in 2019.

Table 3. The metrics for computed tomography (CT) and magnetic resonance imaging (MRI) shared-use networks from 2016 to 2019.

Year	CT network metrics		MRI network metrics	
	Density	Reciprocity	Density	Reciprocity
2016	3.30×10^{-3}	9.74×10^{-2}	3.40×10−3	2.82×10^{-2}
2017	3.20×10^{-3}	9.80×10^{-2}	3.60×10^{-3}	2.15×10^{-2}
2018	3.50×10^{-3}	8.78×10^{-2}	3.70×10^{-3}	1.77×10^{-2}
2019	3.10×10^{-3}	7.79×10^{-2}	3.20×10^{-3}	1.56×10^{-2}

Figures 2 and 3 illustrate the network of medical institutions categorized by clusters based on the Louvain community detection algorithm. These communities were visually distinguished using different colors in the network diagrams. The cluster numbers (1-8) are arbitrary identifiers assigned by the algorithm; however, the spatial arrangement in the figures reflects the relative strength of connections between facilities, with more closely positioned facilities demonstrating stronger collaborative relationships. The distribution of medical institutions across clusters has shown changes from 2016 to 2019, indicating a concentration of institutions within specific clusters.

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Figure 2. Clustered network graph of computed tomography (CT) shared use from 2016 to 2019 (with numerical IDs for each cluster group).

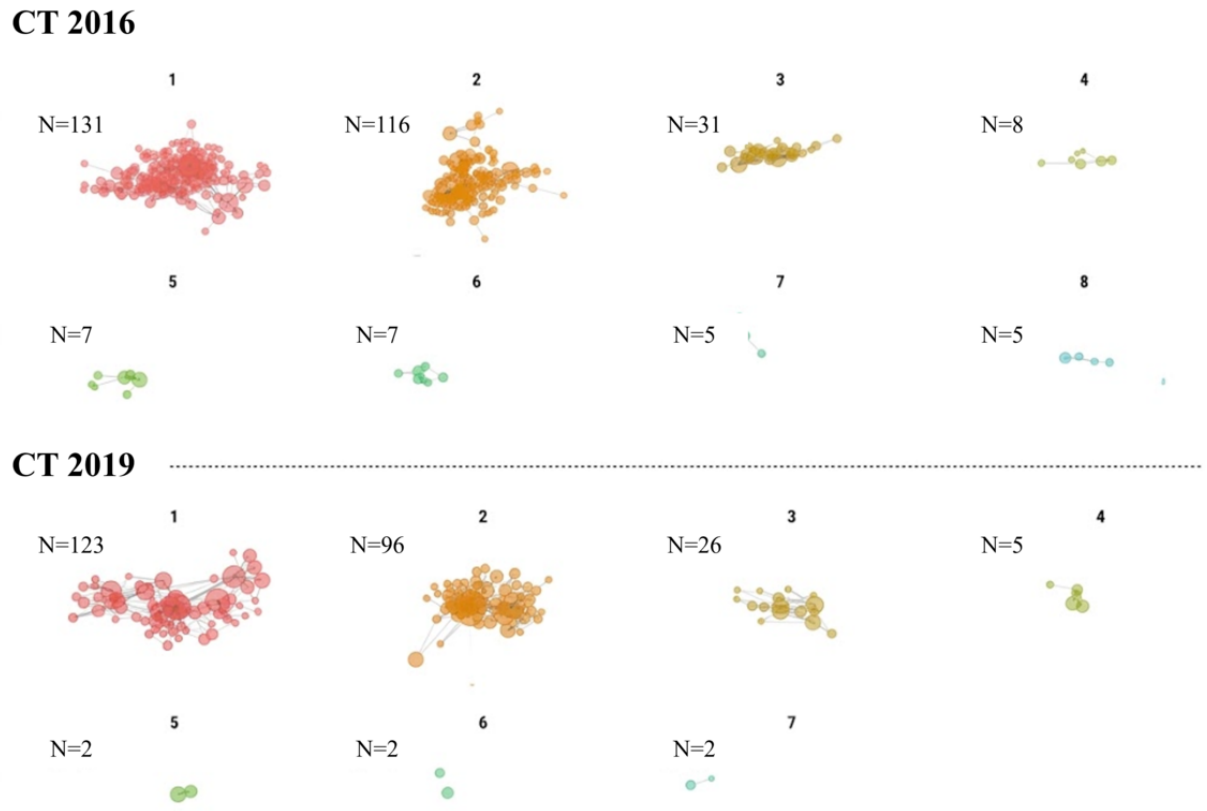
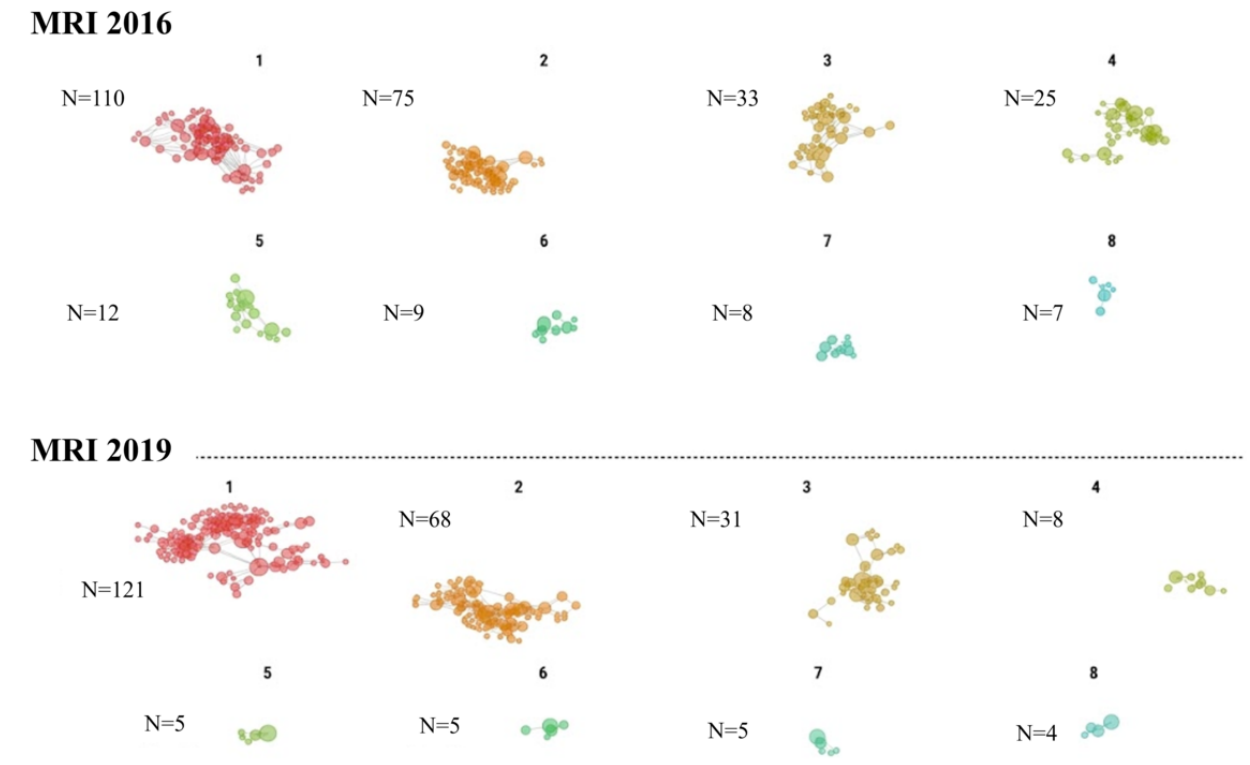


Figure 3. Clustered network graph of magnetic resonance imaging (MRI) shared use from 2016 to 2019 (with numerical IDs for each cluster group).



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Discussion

Principal Findings

This study investigated the collaborative use patterns of CT and MRI within a regional health care network from 2016 to 2019. The annual trends in examination volumes and collaborative use proportions were analyzed to provide insights into the operational dynamics of these diagnostic modalities.

CT examinations increased from 287,782 in 2016 to 307,029 in 2019. Collaborative CT examinations also increased from 1507 to 1774, with the proportion of collaborative CT use ranging between 0.524 and 0.578 over the study period. Similarly, MRI examinations increased from 107,876 in 2016 to 115,929 in 2019. Collaborative MRI examinations increased from 537 to 612, with the proportion of collaborative MRI use ranging from 0.498 to 0.528. The network structural characteristics of this shared use are examined in the following paragraphs.

The analytic framework used in this study demonstrates the value of network analysis for health care resource management research. Prior studies examining medical equipment use have primarily relied on facility-level statistical analyses, which cannot reveal the structural patterns of interinstitutional collaboration [13,14]. Our network-based approach addresses this limitation by enabling systematic assessment of how shared-use relationships form, evolve, and concentrate over time [15,16].

Simple counts of collaborative examinations (Table 1) indicate increasing collaborative activity; however, network metrics (Table 3) reveal that this growth occurs within an increasingly concentrated network structure characterized by declining reciprocity. This pattern would not be apparent from traditional analytic approaches that do not account for the relational nature of health care collaboration.

Our findings illustrate how network analysis can provide information relevant to resource allocation planning. The decreasing reciprocity observed for both CT and MRI networks, combined with changes in cluster composition identified through community detection, describes an evolving pattern of collaborative use that would not be captured by conventional facility-level statistics. For health care planners developing prefectural strategic plans for shared equipment use, these network metrics can serve as supplementary information sources: density measurements can describe the extent of collaborative relationships within a region, reciprocity can indicate the directionality of referral patterns, and community detection can identify naturally occurring collaborative groupings that may inform the geographic planning of equipment investment.

Our findings provide several insights into the collaborative CT and MRI use patterns through a network-based analytic framework, offering perspectives that extend beyond traditional use statistics. Examination volumes increased for both modalities over the study period, possibly reflecting changing demand and access to diagnostic imaging services. The proportion of collaborative CT and MRI examinations also increased, suggesting evolving coordination and resource sharing among medical facilities. This aspect underscores the strength of our study in quantifying collaborative practices, which are crucial for optimizing resource allocation and enhancing diagnostic efficiency.

There were no significant changes in the number of source medical facilities for either CT or MRI use. Conversely, target medical facilities exhibited a decrease. This suggests a potential concentration of diagnostic imaging functions within facilities that perform these examinations. The clustering of medical facilities into specific clusters as depicted in Figure 2 supports this pattern of unidirectional referral within the network.

The stable facility-level characteristics (Table 2; all $P>.05$) suggest that collaborative use practices remained within a stable institutional environment over the study period. However, it is important to note that the rate of shared use remains relatively small compared to the total number of tests conducted. This indicates the potential for expansion and further integration of shared imaging services in the future. The higher mean number of CT requests received per facility, compared with MRI, may reflect the broader clinical indications and versatility of CT imaging in routine clinical practice.

The network metrics reveal distinctive patterns between CT and MRI networks, particularly in terms of density and reciprocity, indicating differing levels of interconnectivity and collaborative interaction within the health care network. Reciprocity, which measures bidirectional referrals between medical facilities, decreased in both CT and MRI networks from 2016 to 2019. This decrease suggests a shift toward more unidirectional referral patterns, possibly influenced by evolving clinical practices or logistical challenges specific to each imaging modality. The lower reciprocity in MRI networks, despite relatively stable densities, might indicate a less symmetrical exchange of referrals compared with CT. This asymmetry could stem from specialized clinical needs or operational factors unique to MRI, such as availability, cost considerations, or specific clinical indications.

While our empirical findings are specific to the Japanese health care context, the analytic framework itself has broader international applicability. The network analysis methods we used—including density calculation, reciprocity measurement, and community detection—are methodologically universal and can be applied to any health care system with appropriate administrative data on patient referrals or facility use. Several contextual factors specific to Japan should be considered when interpreting our findings or adapting this framework to other settings. Japan maintains an exceptionally high density of CT and MRI equipment, approximately 4 times the OECD average [1]. This high density creates an environment where shared-use networks can form extensively, as numerous facilities possess equipment that could function as either referral sources or referral destinations. Health care systems with lower equipment density would likely demonstrate different network structures, potentially showing higher concentration from the outset. Japan's universal health insurance system and comprehensive claims database (National Database of Health Insurance Claims) provide the detailed use records that enable this type of analysis.

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Countries with similar insurance-based systems and administrative databases—such as Germany, South Korea, Taiwan, and France—could readily adapt this methodology. However, health care systems with fragmented insurance coverage or limited administrative data infrastructure may face challenges in constructing comparable datasets. Additionally, Japan's relatively unrestricted patient access to health care facilities (free access system) influences referral patterns differently than countries with formal gatekeeping systems. In systems requiring primary care referrals for specialist services, network structures would inherently show more hierarchical patterns. Despite these contextual variations, the core analytic approach—using network metrics to quantify interinstitutional collaboration and identify structural changes over time—provides a transferable framework for health care system analysis across diverse national contexts.

While our study provides valuable insights, it is important to acknowledge several limitations. First, our results are specific to a single prefecture in Japan where CT and MRI facilities are densely concentrated. This geographic specificity may restrict the generalizability of our findings to regions with different health care infrastructures and resource distributions.

Second, the data used in this study are derived from insurance reimbursement records, reflecting actual clinical use but potentially excluding examinations conducted outside insurance claims (eg, health screenings and private pay services). This limitation implies that our findings may not fully capture the comprehensive use of CT and MRI services in the region.

Third, the identification of shared use is based on specific criteria applied in this study. Variations in these criteria could potentially impact the results, influencing the interpretation of collaborative patterns and the efficiency of resource allocation across medical institutions. Fourth, our network analysis captures structural relationships but cannot directly assess causality or the quality of care delivered through these collaborative arrangements. In summary, these limitations are acknowledged; however, our study's approach supports the development of methodological approaches without compromising the interpretation of collaborative health care practices and resource management.

Conclusions

Using the receipt database from 2016 to 2019, our analysis showed increases in both CT and MRI examinations, accompanied by increases in shared use. Network analysis revealed decreasing reciprocity in both CT and MRI networks, suggesting a shift toward more unidirectional referral patterns. Moreover, we observed a concentration of shared-use requests among specific medical institutions within the shared-use network structure. These findings enabled us to propose an analytic framework grounded in network analysis theory for assessing the practical dynamics of resource sharing, including medical equipment, across health care settings. This framework may inform prefectural strategic plans for shared equipment use as mandated under the Medical Care Act.

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Data Availability

The data are not publicly available due to restrictions imposed by the regional insurers and local governments. The dataset was provided under contractual agreements prohibiting third-party sharing. Requests for access may be directed to the corresponding author.

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Authors' Contributions

Conceptualization: TI, NM
Data curation: JS, KG
Formal analysis: TI
Funding acquisition: NM
Investigation: TI
Methodology: TI, YM, KO
Project administration: KG
Resources: MK, KG
Software: JS
Supervision: MK, NM
Validation: JS
Visualization: TI

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Writing—original draft: TI
Writing—review and editing: YM, KO, NM
All authors read and approved the final version of the manuscript.

Conflicts of Interest

None declared.

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Abbreviations

CT: computed tomography
MRI: magnetic resonance imaging
OECD: Organisation for Economic Co-operation and Development

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Original Paper

Prepregnancy Lifestyle Risk Factors in Women Seeking Digital Fertility Services: Cross-Sectional Descriptive Study

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Abstract

Background: Approximately 1 in 3 pregnancies in the United States are complicated by one or more adverse pregnancy outcomes. This high prevalence contributes to the elevated rates of maternal and infant mortality in the United States. Modifiable prepregnancy or preconception lifestyle factors have been associated with adverse pregnancy outcomes in observational studies, which underscores the importance of preconception care.

Objective: This cross-sectional descriptive study aimed to (1) estimate the prevalence of preconception lifestyle risk factors among women seeking services from a digital fertility platform, (2) characterize the study population and present relevant reference data, and (3) examine the distribution of prepregnancy lifestyle scores across demographic and clinical subgroups.

Methods: The digital health company, Doveras Fertility, has built a prepregnancy digital health platform for individuals and couples seeking to optimize their fertility potential. Targeting users prior to initiation of pregnancy, the platform facilitates the assessment of baseline lifestyle risk factors. This paper reports on 396 adult women who sought the platform's services in a 1-month period between May and June 2024 by completing a digital fertility questionnaire. Self-reported data were analyzed for 6 healthy prepregnancy lifestyle factors known to be associated with maternal health outcomes in prior observational studies, and each participant was given a composite score between 0 to 6 to represent the number of these healthy behaviors reported. The 6 healthy prepregnancy lifestyle factors include a BMI of 18.5 to 24.9 kg/m^2, not currently smoking, ≥150 min/week of moderate to vigorous physical activity, healthy eating, no daily alcohol intake, and use of a prenatal multivitamin.

Results: The study population was racially and ethnically diverse, with a mean age of 32.9 (SD 6.3) years. Most (235/396, 59%) participants received a composite score of 3 factors or fewer, and less than 5% (19/396) scored 6 out of 6. For context, this cohort had higher proportions of participants with unhealthy BMI and dietary patterns than those in the reference data. Regarding fertility, 46% (182/396) met the clinical definition of infertility (≥1 year trying to conceive), with the prevalence of infertility ranging from 16% (3/19) among those with the highest lifestyle scores to 59% (17/29) among those with the lowest.

Conclusions: Most women seeking services from this digital fertility platform exhibited multiple lifestyle factors that have been previously associated with adverse pregnancy outcomes in observational studies. These results suggest that nearly all survey participants have potential risk factors for adverse maternal outcomes and therefore the potential to adopt at least one improvement in their lifestyle behavior. A digital platform may offer an accessible mechanism for identifying and characterizing preconception risk factors; however, future longitudinal studies are needed to evaluate whether platform-based interventions can effectively support behavior change and improve maternal health outcomes.

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KEYWORDS

prepregnancy lifestyle; digital health; maternal health; fertility; preconception care

Introduction

The United States has witnessed a critically worsening maternal mortality rate—one that is several times higher than that of other industrialized and high-income countries and adversely affects the overall quality of health care in the United States [1]. The real-world experience for the American woman is that she is more than twice as likely to die from complications related to pregnancy or childbirth than a woman in another high-income nation [1]. Intervention during the prepregnancy period may help reduce not only the incidence of maternal health risks but also the associated costs for payers: every US $1 invested in prepregnancy care may save up to US $5 on infant and maternal health costs [2]. There are multiple approaches that may reverse the worsening maternal mortality rate in the United States and improve maternal health outcomes overall [3].

Evidence supporting the impact of preconception lifestyle factors continues to grow. For example, the Nurses' Health Study II, a large longitudinal cohort study run by Harvard Medical School, Brigham and Women's Hospital, and Harvard TH Chan School of Public Health, showed that women with the highest adherence to a *prepregnancy healthy lifestyle* had a substantially lower risk of adverse pregnancy outcomes and suggested that these lifestyle factors could be targeted as an effective intervention for the prevention of adverse pregnancy outcomes [4]. The benefits of a prepregnancy healthy lifestyle extend beyond the mother to the infants as well. A study from the Pregnancy Environment and Lifestyle Study cohort found that a healthy diet, healthy weight, and low levels of stress during the preconception period were associated with reduced risk of preterm birth [5], and a meta-analysis of 17 clinical trials found that micronutrient supplementation during the preconception period reduced the risk of having an infant with low birth weight [6]. However, more intervention studies are needed to effectively demonstrate that lifestyle interventions during this critical preconception period can significantly reduce both maternal and infant health risks.

Given the high-quality evidence for the importance of lifestyle factors in the preconception window for maternal health outcomes, numerous public health bodies encourage women trying to conceive to engage in preconception counseling. According to the American College of Obstetricians and Gynecologists, "the goal of prepregnancy care is to reduce the risk of adverse health effects by optimizing health and addressing modifiable risk factors" [7]. The World Health Organization has emphasized preconception care as a public health priority, and the International Federation of Gynecology and Obstetrics (FIGO) has released comprehensive recommendations highlighting the importance of optimizing maternal health before conception [8]. Despite this recognition, significant barriers to preconception care delivery persist, including lack of awareness among both patients and clinicians, socioeconomic factors limiting health care access, and competing health care priorities [9,10].

Given these barriers, it is likely that the opportunity for preconception intervention to reduce adverse maternal health risks is not being well captured by the current health system [10-13]. More effective and widespread intervention might be possible through a digital health solution. By capturing those at the high engagement point of trying to conceive, interventions might be able to target people in the important preconception window to assess a user's potential risks and deliver personalized intervention in an accessible and affordable way.

The aim of this cross-sectional descriptive study was to (1) estimate the prevalence of preconception lifestyle risk factors among women seeking services from a digital fertility platform, (2) characterize the study population and present relevant reference data, and (3) examine the distribution of prepregnancy lifestyle scores across demographic and clinical subgroups. We hypothesized that this population would exhibit modifiable lifestyle factors that have been previously associated with adverse pregnancy outcomes in observational studies.

Methods

Study Design and Setting

This was a cross-sectional descriptive study analyzing anonymized data from individuals who sought services from the Doveras digital health platform. Doveras has designed and developed preconception lifestyle and behavioral intervention programs, delivered through its digital health platform, for individuals and couples to improve various end points along the reproductive health journey. These personalized interventions are based on relevant data from existing clinical studies on preconception lifestyle factors and their impacts on various reproductive health end points. The platform (1) facilitates the assessment of baseline lifestyle risk factors, (2) identifies modifiable behavior opportunities and potential adverse fertility and maternal health risks to mitigate, and (3) delivers personalized programming to help users sustain simple behavior changes that target their unique risk to improve their overall reproductive health outcomes.

Participants

This study evaluated the anonymized data of nearly 400 verified participants who sought services from the Doveras digital health platform during a 1-month period (mid-May to mid-June 2024). These participants were directed to the Doveras website through their engagement with social media advertisements (including platforms such as Facebook and Instagram) to improve fertility potential with personalized, data-driven lifestyle interventions. Enrollment criteria entailed completion of a digital fertility questionnaire encompassing self-reported personal demographics and various lifestyle and behavioral characteristics. The included participants were aged 18 years or older, who self-reported as female, and were attempting to conceive via sexual intercourse with a male partner. Individuals who reported they were using or planning to use assisted reproduction technologies to conceive were excluded. This

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exclusion was applied because participants using assisted reproductive technologies would likely receive specialized medical care that could confound assessment of lifestyle risks. During the enrollment period, 441 individuals completed the questionnaire. Of these, 45 (10.2%) were excluded for not meeting eligibility criteria (eg, n=41, 9.3% not attempting to conceive via sexual intercourse or n=4, 1% incomplete data), yielding 396 (89.8%) eligible participants included in the analysis.

Data Collection and Measures

For the purposes of this study, self-reported behavioral and demographic data from these participants were analyzed using the maternal health risk framework developed through the Nurses' Health Study II's definition of a participant's healthy prepregnancy lifestyle factor score [4]. This framework observed 15,509 women and 27,135 pregnancies and identified 6 healthy prepregnancy lifestyle factors associated with a lower risk of adverse maternal health outcomes. These factors included (1) healthy BMI of 18.5 to 24.9 kg/m^2, (2) not currently smoking (cigarettes or e-cigarettes), (3) 150 min/wk or more of moderate to vigorous physical activity, (4) healthy eating, (5) <15 g/d alcohol, and (6) use of a prenatal multivitamin.

Participants answered questions on these and other topics as part of a single time point survey. Following the method from the Nurses' Health Study II, self-reported behaviors of this study cohort were analyzed according to each of these 6 variables. These 6 variables were coded as binary (0 or 1) and summed for each participant to compute their total healthy prepregnancy lifestyle score. Regarding diet, participants who reported "I would say I mostly eat healthy" received a score of "1," while those who answered, "I have some healthy habits" or "I would say my diet needs a lot of help to be considered healthy" received a score of "0." For the smoking variable, participants who reported that they were a "social smoker" received a "1" as not regular smokers. For the alcohol variable, those who reported "no" to the question of whether they drink daily received a "1," and those who responded "yes—1 drink daily" or "yes—2+ drinks daily" received a score of "0." Participants also self-reported data on reproductive and clinical history.

Statistical Analysis

Descriptive statistics are presented as means with SDs for normally distributed continuous variables, medians with IQRs for nonnormally distributed variables, and frequencies with percentages for categorical variables. A 1-way ANOVA was used to test for differences in mean values of continuous variables across the 6 groups of healthy lifestyle scores, while a chi-square test (or a Fisher test for low cell count values) was used to assess the association between categorical variables and these 6 groups. Effect sizes are reported as η^2 (eta-squared) for continuous variables and Cramér V for categorical variables. A *P* value of <.05 was considered statistically significant. All analyses were conducted using R (version 4.4.0, R Foundation for Statistical Computing). Missing data were minimal (<1% for any single variable); analyses included only participants with complete data for all variables. No formal sample size calculation was performed, as this was a descriptive study designed to characterize the population seeking services from the platform during the study period; all eligible participants were included.

Ethical Considerations

The study met the criteria for human subject research exemption as determined by the Salus Institutional Review Board (protocol number 24072). The exemption was granted because the research involved the analysis of existing, anonymized data collected during routine platform operations under a Terms of Use and a privacy policy that disclosed the use of deidentified data for research. All data were deidentified prior to analysis, with no direct identifiers included in the research dataset. No monetary compensation was provided for questionnaire completion. Participants were offered a promotional discount for the platform's services, consistent with standard onboarding procedures for all new users at that time.

Results

Participant Characteristics

The analysis included 396 female-identifying participants, with a mean age of 32.9 (SD 6.3) years and 50% (198/396) of participants identified as non-Hispanic White.

Assessment of Healthy Prepregnancy Lifestyle Factors

Among survey participants, the median number of the 6 healthy prepregnancy lifestyle factors was 3.0 (IQR 2.0-4.0), with 59% (235/396) scoring 3 or below and 86% (340/396) scoring 4 or below (Table 1).

Table 1. Distribution of healthy prepregnancy lifestyle scores among survey participants (N=396).

Healthy prepregnancy lifestyle score	Participants, n (%)
0 or 1	29 (7.3)
2	83 (21)
3	123 (31.1)
4	105 (26.5)
5	37 (9.3)
6	19 (4.8)

The average participant had a median BMI of 31.9 (IQR 26.5-38.0), with 82% (325/396) of participants outside of a BMI range defined as healthy (18.5-24.9 kg/m^2). There were significant differences in the mean BMI of participants across

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the different healthy prepregnancy lifestyle scores ($F_{5,390}$=17.6; P<.001; η^2=0.18), demonstrating that participants with lower healthy prepregnancy lifestyle scores had higher average BMI levels. Using the Nurses' Health Study II and nationally representative samples from the National Health and Nutrition Examination Survey (NHANES) as references [4], the Doveras cohort had a greater proportion of respondents with unhealthy BMI and unhealthy diets (Table 2). However, the Doveras cohort's smoking, physical activity, and alcohol intake were similar to those of these populations. These comparisons should be interpreted as contextual only, given differences in populations, periods, and measurement approaches across the studies.

Table 2. Presence of healthy prepregnancy lifestyle factors in Doveras cohort (2024), Nurses' Health Study II (2005), and from nationally representative samples of women aged 18 to 44 years (National Health and Nutrition Examination Survey, NHANES; 2017-2018).

Healthy lifestyle factors	Doveras (2024; %)	Nurses' Health Study II (2005; %)	NHANES (2017-2018; %)
BMI (18.5-24.9 kg/m^2)	17.7	52.1	32.2
Current nonsmoker	88.4	94.3	81.4
Moderate to vigorous exercise (≥150 min/wk)	51.0	33.9	54.3
Healthy diet	21.2	38.6	40.0
Alcohol intake (0-15 g/d)	92.7	93.5	92.9
Multivitamin use	55.8	48.4	19.4

A total of 5% (19/396) of participants received the highest healthy prepregnancy lifestyle score of 6. Within this group, most participants were White (15/19, 79%).

Unsurprisingly, regarding behavioral characteristics, it was generally observed that participants with lower healthy prepregnancy lifestyle scores had lower proportions of healthy behavior. For example, among participants who said they rarely or never exercised (n=63), 83% (52/63) had a healthy prepregnancy lifestyle score of 3 or lower. As for diet, 25% (100/396) of participants felt their diet "needs a lot of work to be considered healthy." In a similar pattern, 97% (109/112) of people who scored 2 or lower (n=112) believe they could use help with their diet. Furthermore, 44% (175/396) of all participants did not report taking prenatal vitamins.

However, there were certain healthy behaviors that most of the respondents reported. For example, 92% (367/396) of participants did not report daily alcohol use and 77% (306/396) did not report currently smoking. Although among those who did report drinking one or more drinks daily, 55% (16/29) had a healthy prepregnancy lifestyle score of 2 or lower suggesting that individuals who drink daily are more likely to lack other healthy lifestyle behaviors as well.

Associated Health History

The survey also assessed self-reported past medical and fertility history (Table 3). Among 396 survey participants, 61 (15%) reported they had been diagnosed with prediabetes or diabetes, and 98 (25%) reported a close family member had been diagnosed with diabetes. Among participants who reported having diabetes or prediabetes (n=61), only 1 (2%) had a healthy prepregnancy lifestyle score of 5 or 6, suggesting individuals with these health conditions are at higher risk for adverse maternal health outcomes and would benefit from improvements in healthy behaviors.

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Table 3. Participant characteristics by healthy prepregnancy lifestyle score.

	Healthy prepregnancy lifestyle score						*P* value	Effect size (V)[a]
	0 or 1	2	3	4	5	6		
Participants, n	29	83	123	105	37	19		
Demographic characteristics								
Race or ethnicity, n (%)							.01	0.09
American Indian or Alaskan native	0 (0)	2 (2.4)	2 (1.6)	1 (1)	0 (0)	0 (0)		
Asian	0 (0)	2 (2.4)	5 (4)	6 (5.7)	2 (5.4)	1 (5.3)		
Black or African American	11 (38)	31 (37)	23 (19)	23 (22)	2 (5.4)	0 (0)		
Hispanic or Latino	2 (6.9)	11 (13)	16 (13)	14 (13)	7 (19)	1 (5.3)		
Mixed Race	1 (3.4)	6 (7.2)	4 (3.3)	5 (4.8)	1 (2.7)	1 (5.3)		
Prefer not to say	3 (10)	0 (0)	5 (4.1)	3 (2.9)	1 (2.7)	0 (0)		
Race not listed	0 (0)	0 (0)	1 (0.8)	3 (2.9)	1 (2.7)	1 (5.2)		
White	12 (41)	31 (37)	67 (55)	50 (48)	23 (62)	15 (79)		
Age (years), mean (SD)	32.2 (6.5)	33.6 (6.5)	32.4 (6.3)	32.8 (6.3)	32.6 (5.6)	34.8 (5.7)	.55	
Healthy prepregnancy lifestyle factors								
BMI, median (IQR)	33.2 (30.0-41.8)	35.3 (29.7-41.7)	33.4 (26.9-40.5)	30.0 (24.5-36.5)	25.4 (22.3-31.4)	21.0 (20.2-22.2)	<.001	
Smoking, n (%)							<.001	0.32
Yes	18 (62)	18 (22)	6 (4.9)	4 (3.8)	0 (0)	0 (0)		
Social smoker	7 (24)	5 (6)	4 (3.3)	0 (0)	0 (0)	0 (0)		
Former	1 (3.4)	7 (8.4)	3 (2.4)	14 (13)	2 (5.4)	1 (5.3)		
No	3 (10)	53 (64)	110 (89)	87 (83)	35 (95)	18 (95)		
Physical activity, n (%)							<.001	0.26
I rarely or never work out	15 (52)	16 (19)	21 (28)	10 (9.5)	1 (2.7)	0 (0)		
Approximately 0.5 h/wk	5 (17)	19 (23)	7 (5.7)	8 (7.6)	0 (0)	0 (0)		
Approximately 1 h/wk	3 (10)	9 (11)	12 (9.8)	1 (0.95)	1 (2.7)	0 (0)		
Approximately 1.5 h/wk	3 (10)	8 (9.6)	9 (7.3)	5 (4.8)	2 (5.4)	0 (0)		
Approximately 2 h/wk	3 (10)	18 (22)	13 (11)	5 (4.8)	0 (0)	0 (0)		
Approximately 2.5 h/wk	0 (0)	2 (2.4)	5 (4.1)	9 (8.6)	4 (11)	3 (16)		
>3 h/wk	0 (0)	11 (13)	56 (46)	67 (64)	29 (78)	16 (84)		
Alcohol use, n (%)							.63	0.11
No	22 (76)	74 (89)	116 (94)	100 (95)	36 (97)	19 (100)		
Yes—1 drink daily	5 (17)	7 (8.4)	5 (4)	5 (4.7)	1 (2.7)	0 (0)		
Yes—>2 drinks daily	2 (6.8)	2 (2.4)	2 (1.6)	0 (0)	0 (0)	0 (0)		
Diet, n (%)							<.001	0.50
I would say I mostly eat healthy	0 (0)	3 (3.6)	4 (3.3)	29 (28)	29 (89)	19 (100)		
I have some healthy habits	15 (52)	48 (58)	83 (67)	59 (56)	7 (19)	0 (0)		
My diet needs a lot of work to be considered healthy	14 (48)	32 (39)	36 (29)	17 (16)	1 (2.7)	0 (0)		
Prenatal vitamin, n (%)							<.001	0.62
No	28 (97)	70 (84)	57 (46)	17 (16)	3 (8.1)	0 (0)		

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	Healthy prepregnancy lifestyle score						*P* value	Effect size (V)[a]
	0 or 1	2	3	4	5	6		
Yes	1 (3.4)	13 (16)	66 (54)	88 (84)	34 (92)	19 (100)		
Reproductive and clinical history								
Clinical definition of infertility[b], n (%)	17 (59)	39 (47)	65 (53)	45 (43)	13 (35)	3 (16)	.04	0.16
Previous birth, n (%)	7 (24)	36 (43)	59 (48)	51 (49)	11 (30)	3 (16)	.01	0.18
Hormone imbalance[c], n (%)	20 (69)	57 (69)	78 (63)	69 (66)	28 (76)	16 (84)	.37	0.10
Diabetes or prediabetes, n (%)	9 (31)	12 (15)	17 (14)	22 (21)	1 (2.7)	0 (0)	.01	0.18
Endometriosis, n (%)	6 (21)	7 (8.4)	12 (9.8)	13 (13)	2 (5.4)	2 (11)	.51	0.11

[a]η^2 for continuous variables are: <0.01 for age, 0.18 for BMI.

[b]Defined as self-reported duration of attempting to conceive for 12 months or longer.

[c]Self-reported diagnosis of any hormonal condition (eg, polycystic ovary syndrome, thyroid disorder, and luteal phase defect).

Regarding fertility, 46% (182/396) met the clinical definition of infertility (≥1 year trying to conceive), with the prevalence of infertility ranging from 16% (3/19) among those with the highest lifestyle scores to 59% (17/29) among those with the lowest. This high proportion of participants meeting criteria for infertility is notable given that individuals using or planning to use assisted reproductive technologies were excluded; this suggests the cohort may represent individuals in the intermediary period: those who have been trying to conceive for more than a year but have not yet initiated or decided to pursue assisted reproductive technology. Among those who reported giving birth prior to the program (n=167), 56% (10/18) of individuals with a prepregnancy healthy lifestyle score of 0 or 1 (n=18) took >1 year to conceive. In contrast, 15% (2/13) of those with a score of 6 (n=13) took the same amount of time to conceive.

Discussion

Principal Findings

This cross-sectional descriptive study characterized the prevalence of preconception lifestyle risk factors among 396 women seeking services from a digital fertility platform. The principal findings were that (1) most (n=235, 59%) of participants received a composite score of 3 factors or fewer and less than 5% scored 6 out of 6, (2) for context, this cohort had higher proportions of participants with unhealthy BMI and dietary patterns than those in the reference data, and (3) regarding fertility, 46% (n=182) met the clinical definition of infertility (≥1 year trying to conceive), with prevalence of infertility ranging from 16% (3/19) among those with the highest lifestyle scores to 59% (17/29) among those with the lowest.

Comparison With Prior Work

Overview

The population of people seeking Doveras' services presented, before joining the platform, with considerably lower healthy prepregnancy lifestyle factor scores than those reported in the Nurses' Health Study. Since the Doveras preconception platform is marketed for its fertility benefits, this research may have oversampled individuals who are having trouble conceiving, which could contribute to why this cohort represents a particularly at-risk group for adverse pregnancy outcomes. The Doveras cohort is also demographically diverse, roughly matching the general population in racial and ethnic composition, though not necessarily in other characteristics, such as socioeconomic status or geographical distribution, which were not assessed. The unique lifestyle and demographic baseline of this cohort point to a few avenues of significance and areas for future research, discussed subsequently.

Prevalence of Modifiable Risk Factors

These results suggest that most people seeking preconception services during this period from Doveras have the potential to adopt additional healthy behaviors that have been associated with lower risk of adverse pregnancy outcomes in observational studies.

The lifestyle factor gaps exhibited in these participants during the preconception window have been shown to be associated with various adverse pregnancy outcomes in prior observational research. For example, a prospective cohort of 2449 women as part of the Pregnancy Environment and Lifestyle Study found that modifiable lifestyle factors such as healthy weight, high-quality diet, and low levels of stress were associated with a reduced risk of preterm birth by 42%, 32%, and 40%, respectively [5]. Additionally, a meta-analysis of 17 trials encompassing 137,791 women found that taking multiple micronutrient supplements resulted in reduced risk of having a newborn infant with low birth weight [6]. The Nurses' Health Study II, which used the same 6 healthy prepregnancy lifestyle factors as this study, shows similar associations between prepregnancy adherence to these lifestyle factors and adverse outcomes. This research reported that approximately 1 in 3 pregnancies (9702/27,135, 36%) in the cohort were complicated by one or more adverse pregnancy outcomes. The researchers found that these 6 specific low-risk factors were inversely associated with risk of adverse pregnancy outcomes—including miscarriage, gestational hypertension, preeclampsia, gestational diabetes, preterm birth, and low birthweight—in a dose-dependent manner. Compared with women who had 0 or 1 healthy prepregnancy lifestyle factor, those with 6 had a 37%

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lower risk of adverse pregnancy outcomes, driven primarily by lower risks of gestational diabetes, gestational hypertension, and low birth weight.

A digital health platform may offer a mechanism for identifying these lifestyle risk factors and characterizing the preconception health status of individuals seeking fertility services. The Nurses' Health Study researchers concluded that if the observed relationships between the studied behaviors and adverse maternal health outcomes were causal, 19% of adverse pregnancy outcomes could have been prevented by the adoption of all 6 healthy prepregnancy lifestyle factors [4]. However, as that study and this study are observational, causality cannot be established, and intervention studies are needed to determine whether promoting adoption of these factors will in fact reduce adverse outcomes.

Given that the Doveras cohort presents with lower healthy lifestyle (ie, less healthy) scores than the Nurses' Health Study cohort, this population may represent a group with particularly high prevalence of modifiable risk factors. If the associations observed in prior research are causal, interventions targeting this population could potentially have meaningful effects.

Lifestyle Factors With Highest Prevalence of Unhealthy Patterns

This descriptive analysis also highlights which lifestyle factors showed the highest prevalence of unhealthy patterns in this cohort. Specifically, the Doveras population overindexed on the lack of these specific healthy factors: BMI, healthy diet, physical activity, and taking a prenatal vitamin, in that order. Among the Doveras participants, 82% (325/396) reported a high BMI (≥25 kg/m^2), which has been associated with gestational hypertension, preeclampsia, gestational diabetes, and miscarriage in data from the Nurses' Health Study II [4]. Similarly, 44% (175/396) of the study participants reported that they were not currently taking prenatal vitamins, which has been associated with higher rates of miscarriage and having infants with low birth weight [4].

The Nurses' Health Study II also reported that the prepregnancy healthy lifestyle factors screened for, except avoiding harmful alcohol consumption and regular physical activity, were independently associated with lower risk of adverse pregnancy outcomes after mutual adjustment for each other. Healthy BMI, high-quality diet, and multivitamin supplementation showed the strongest inverse associations with adverse pregnancy outcomes.

Given the high prevalence of elevated BMI and suboptimal dietary patterns in this cohort, these lifestyle factors may represent particularly relevant targets for future intervention development and testing.

Digital Health Platforms for Preconception Care

A critical question is whether a digital intervention can facilitate sustained behavior change, and if so, whether such an intervention can decrease adverse pregnancy outcomes. Previous studies have suggested that lifestyle interventions deployed electronically during the preconception period can be feasible and may promote short-term behavior change [14-16]. A 2023 systematic review of mobile phone apps for preconception behavior change found growing interest in this area, although the limited number of studies and heterogeneity in outcomes precluded firm conclusions about effectiveness [15]. Smith et al [16] showed that nudging behavior change during prepregnancy digital interventions to encourage pregnancy preparation is feasible. These studies show the feasibility of digital platforms for delivering preconception health information and behavior change support. Future studies should validate the platform's usability and behavior change capabilities.

Limitations

This study has several important limitations. The cross-sectional descriptive design precludes causal inference; we only report associations and prevalence estimates.

The self-selection of the program is an inherent limitation that limits the generalizability. The Doveras cohort may not be fully representative of all individuals trying to conceive, as participants who opt into this product might be more likely to be experiencing fertility challenges or have a higher motivation to improve their lifestyle behaviors. Indeed, 46% (182/396) of participants met the clinical definition of infertility, despite the exclusion of those using or planning to use assisted reproductive technologies. This high proportion suggests the cohort may overrepresent individuals experiencing fertility challenges. Participants were recruited through social media advertisements for a commercial platform, which may select for individuals with internet access, engagement with fertility-related content, and motivation to improve fertility. The study did not include LGBTQ+ (lesbian, gay, bisexual, transgender, and queer) individuals, single women attempting to conceive through donor insemination, or those using assisted reproductive technologies, limiting applicability to these populations. Information on geographical location, income, and other socioeconomic factors was not studied, precluding assessment of representativeness along these dimensions.

Several measurement limitations should be noted. Key constructs such as diet quality, smoking status, and alcohol intake were measured using single self-reported items with dichotomized definitions that deviate from validated instruments used in prior studies. For example, our diet assessment relied on a single question about perceived diet quality rather than validated dietary assessment tools such as food frequency questionnaires. Future studies should incorporate validated instruments for key constructs such as diet quality and physical activity. Furthermore, as with all self-reported data, the potential for recall error is another concern.

Finally, comparisons with the Nurses' Health Study II and NHANES should be interpreted with caution. These comparisons are indirect and unadjusted, involving different populations, periods, recruitment methods, and measurement tools. These comparisons are provided for contextual purposes only and do not represent direct statistical comparisons.

Conclusions

This cross-sectional descriptive study found that most women seeking services from a digital fertility platform exhibited multiple lifestyle factors that have been previously associated

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with adverse pregnancy outcomes in observational studies, including high BMI (325/396, 82% outside healthy range), suboptimal dietary patterns (312/396, 79%), and lack of prenatal vitamin use (175/396, 44%). At least 86% (340/396) of people seeking fertility services from the Doveras digital health platform exhibited 2 or more known lifestyle risk factors that have been associated with adverse maternal health outcomes in prior research.

These findings suggest that a digital platform may offer an accessible mechanism for identifying and characterizing preconception risk factors among individuals seeking fertility services. Future longitudinal and intervention studies are needed to determine whether digital platform–based preconception interventions can effectively support sustained lifestyle modification and, ultimately, reduce adverse pregnancy outcomes.

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Data Availability

The datasets generated and analyzed during this study are not publicly available due to privacy considerations and proprietary platform data restrictions but are available from the corresponding author on reasonable request and with appropriate data use agreements.

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Authors' Contributions

Conceptualization: NL, JC
Data curation: NL, EM
Formal analysis: TS
Methodology: NL, JC, AJG, PNS
Project administration: EM
Supervision: NL
Writing—original draft: TS
Writing—review and editing: NL, JC, AJG, EM, PNS

Conflicts of Interest

NL is the founder and CEO of Doveras Fertility Inc. JC, AJG, PNS, EM, and TS are advisers for Doveras Fertility Inc.

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Abbreviations

FIGO: International Federation of Gynecology and Obstetrics
LGBTQ+: lesbian, gay, bisexual, transgender, and queer
NHANES: National Health and Nutrition Examination Survey

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The Comprehensive Assessment of Social Media Use: Development and Validation Study

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Abstract

Background: Nearly all youth use the internet daily, with many maintaining several social media accounts. As increasing numbers of young people engage online and the ways we communicate fundamentally change, it is increasingly important to ask: how do these shifts influence youth mental health? To better understand how social media may affect mental health, researchers require validated tools that capture young people's heterogeneous experiences with social media. However, few available measures evaluate the full range of positive and negative behaviors associated with its use, limiting our ability to meaningfully advance interventions promoting online hygiene.

Objective: This study aims to develop and validate the Comprehensive Assessment of Social Media Use (CASM). The CASM is a self-report survey measure that moves beyond simple duration or frequency of use and captures how young people engage with social media. Importantly, the CASM assesses both the positive and negative dimensions of social media engagement.

Methods: Two studies are outlined in this paper. Study 1 outlines the process of item generation and exploratory factor analysis. Study 2 outlines confirmatory factor analysis and validity testing. Both studies were conducted online and enrolled a convenience sample of college-aged young adults. Study 1 enrolled 260 participants (mean age 19.73, SD 2.91; n=172, 66.2% female; n=164, 63.1% White; n=38, 14.6% lesbian, gay, bisexual, transgender/transsexual, and queer [LGBTQ]). Study 2 enrolled 508 participants (mean age 18.99, SD 1.17; n=323, 63.6% female; n=272, 53.5% White; n=58, 11.4% LGBTQ).

Results: Exploratory and confirmatory factor analysis resulted in a 29-item CASM scale that assesses 7 distinct aspects of young adult social media use: self-branding, compulsive use, disruptive use, impulsive sharing, social engagement, induce negative emotions, and induce positive emotions. This model accounted for 61% of the variance in responses. The chi-squared test of model fit was significant (χ^2_{356}=941, P<.001; root mean square error of approximation=0.064; comparative fit index=0.855; Tucker-Lewis index=0.848; standardized root mean squared residual=0.060). Factor internal consistency reliability ranged from 0.699 to 0.817. Validity testing suggested moderate discriminant, convergent, and criterion validity.

Conclusions: The CASM measures a broad range of social media behaviors, enabling researchers to more effectively examine associations between online engagement and mental health outcomes. We hope the CASM will help researchers better understand how young people interact with social media, and that this knowledge will inform the development of more targeted interventions promoting healthy online habits.

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KEYWORDS

social media; young adults; scale development; survey measurement; mental health

Introduction

Social media is a ubiquitous part of life in the United States, particularly among teenagers and young adults [1]. Nearly all teenagers (96%) use the internet daily, with many reporting spending at least 4 hours on their phones [2]. Most of this time is spent on social media apps, such as YouTube, TikTok, Instagram, and Snapchat [1]. Importantly, this increased time spent online is reshaping youth friendships and social development by providing immediate connection with peers, easy access and sharing of information, and a distinct digital social environment with its own cues and customs [3,4].

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However, young people's screen use is not homogeneous. Variations across age, gender, race, and other social factors influence one's motivations to visit these digital spaces and their subsequent experiences there [5,6]. As social media continues to redefine how we interact with one another, and as increasing numbers of young people struggle to disconnect despite recognizing their excessive use [1], it is increasingly important to ask: how do these changes influence youth mental well-being and how can we best measure young people's heterogeneous experiences with social media?

A considerable amount of research has found associations between social media use and negative mental health outcomes [7,8]. Problematic social media use (ie, patterns of engagement that disrupt daily functioning) has been identified as a distinct and meaningful type of social media use associated with anxiety, attention problems, and increased risk of self-harm and suicidality [9]. Recently, surges in screen time and online social engagement during the COVID-19 pandemic [10,11] have been linked to amplified mental health risks associated with problematic social media use in the years that followed [9,12]. As such, more nuanced study of social media use patterns in the post–COVID-19 era (normative, problematic, healthy, or otherwise) is especially important.

To better understand how social media may impact mental well-being, researchers need validated measures that examine how an individual engages with these online platforms. Many studies have measured associations between social media use and mental health in terms of quantity (ie, the number of hours spent on social media), though correlations are generally weak or not significant [13-16]. Time spent online has received criticism as a stand-alone metric to measure social media use because a strictly quantitative approach does not consider the context or content of use [17]. More recent efforts examining qualitative differences in social media use (eg, posting vs browsing, seeking out frustrating content vs happy content) reveal stronger associations with indicators of mental well-being [5,18,19]. A popular dichotomy that has emerged from this research is that which differentiates passive social media use (eg, "lurking" or "scrolling") from active use (eg, creating content or directly communicating with other users) [20]. These studies generally assert that passive use is more associated with negative mental health outcomes [21-23], though null associations [24], individual differences [25], and inconsistencies across contexts [20,26] cast doubt on whether a passive-active distinction alone can predict poor outcomes from social media use.

Several instruments have been developed to assess social media use behaviors. For example, the Social Media Addiction Questionnaire [27] and the Social Media Disorder Scale [28] focus on user motivations and addictive characteristics of social media such as loss of control, tolerance, withdrawal, and conflict. Measuring social media behaviors that mirror addiction characteristics can identify unique risk factors for problematic use [29,30]. However, addiction-centric measures omit other ways in which an individual may engage with a digital environment, namely those that are healthy and adaptive [5,31]. They also overlook subjective aspects of social media, such as one's perceived social investment or emotional affect during use [3,4]. Alternatively, the Social Media Use Scale [32] analyzes functional dimensions of social media use (ie, sharing beliefs, making social comparisons, managing social image, and consuming content). The focus on broader categories of behavior is likely to more accurately capture how individuals engage with online social platforms; however, positive and prosocial dimensions of social media engagement are still absent from this measure. Further, this scale measures the frequency of specific behaviors, which may be susceptible to recall bias. To gain a more holistic understanding of social media use and its associations with mental well-being, researchers could benefit from a tool that simultaneously assesses a broad range of both positive and negative social media behaviors.

This study outlines the development and validation of the Comprehensive Assessment of Social Media Use (CASM), a survey measure that assesses several aspects of young adult social media use. Given the shortcomings of prior efforts to effectively measure social media behavior, the CASM is structured around self-appraisal, reporter agreement with items (rather than duration or frequency reports) and the integration of positive as well as negative qualities of social media use. Two studies were conducted, hereafter referred to as study 1 and study 2. Study 1 outlines the process of item generation and exploratory factor analysis. Study 2 outlines the process of confirmatory factor analysis and validity testing.

Study 1

Overview

The goal of study 1 was to first create a comprehensive list of candidate items to assess a range of social media behaviors. The authors first drafted items to assess both positive and negative aspects of social media use, including addictive characteristics (eg, *How hard is it to resist the urge to check social media?*), self-branding (eg, *How much do your profiles represent your "real life"?*), adaptive coping (eg, *How often do you turn to social media to relax?*), and positive uses (eg, *How often do you use social media for activism purposes?*). Additional candidate items were then created after reviewing previous research and measures examining social media behaviors [33-37] to ensure a representative list of survey questions. Psychology professors at a small liberal arts college from a variety of disciplines (eg, cognitive, school, and clinical) informally reviewed the items and provided feedback. Since many young people have multiple social media accounts [1,2], all items use flexible language that is not specific to one social platform's culture or cues. To respond, participants indicate the extent to which they agree with an item's statement using a Likert scale ranging from 1 (not often or not at all) to 10 (very often or very much), such that a higher score indicates greater perceived engagement in a specific social media behavior. Our item generation process created a total of 42 candidate items. We then aimed to conduct an exploratory factor analysis to identify latent variables that would guide the structure of the CASM.

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Methods

Participants

We enrolled a convenience sample of college-aged young adults. Participants were recruited from introductory psychology classes at a small liberal arts college in the Northeast United States. If applicable, individuals could be compensated for participation with research credit hours for a class requirement. Study flyers promoting the study were also shared on social media. To participate, individuals had to be between 18 and 29 years old, be fluent in English, and certify that they could provide informed consent.

Study 1 enrolled a sample of 260 participants (Table 1). Participants were predominantly female (n=172, 66.2%), White (n=164, 63.1%), and non-LGBTQ (lesbian, gay, bisexual, transgender/transsexual, and queer; n=215, 82.7%) with a mean age of 19.73 (SD 2.91) years. All participants owned at least 1 social media account (mean 4.9, SD 1.8) and reported spending an average of 5.3 (SD 4.1) hours per day on social media.

Table . Participant demographics.

Demographics	Study 1 (n=260)	Study 2 (n=508)
Age (y), mean (SD; range)	19.73 (2.9; 18 - 29)	18.99 (1.2; 18 - 24)
Gender, n (%)		
Male	85 (32.7)	182 (35.8)
Female	172 (66.2)	323 (63.6)
Identify as LGBTQ[a], n (%)		
Yes	38 (14.6)	58 (11.4)
No	215 (82.7)	438 (86.2)
Race or ethnicity, n (%)		
White	164 (63.1)	272 (53.5)
Black	28 (10.8)	73 (14.4)
Hispanic Latino	48 (18.5)	129 (25.4)
Asian	4 (1.5)	12 (2.4)
Middle Eastern	2 (0.8)	6 (1.2)
Other or unknown	13 (5)	14 (2.8)
Number of social media accounts, mean (SD; range)	4.9 (1.8; 1 - 15)	4.6 (1.5; 0 - 11)
Hours per day on social media, mean (SD; range)	5.3 (4.1; 0 - 21)	5.4 (3.7; 0 - 21)

[a]LGBTQ: lesbian, gay, bisexual, transgender/transsexual, and queer.

Procedures

Data collection occurred from April 2018 to November 2018 on the online research platform Qualtrics. After providing informed consent, participants answered a brief demographics survey. Participants then completed the 42 CASM candidate items. After completing the study measures, participants received a debriefing form with a list of local and national mental health resources.

Data Analysis

Descriptive statistics were calculated to characterize sample demographics. An exploratory factor analysis was conducted to identify item groupings for survey subscales and determine which candidate items to retain. Principal axis factoring with oblique rotation was used to allow for correlations to exist between factors. To retain an item, the following criteria were used, as recommended by Costello and Osborne [38]: (1) items must have a factor loading greater than 0.40, (2) any items that cross-loaded with a value greater than 50% of the largest factor value were eliminated, and (3) any factors with less than 3 items were removed. For all analyses, missing data were handled using listwise deletion. All statistical analyses were conducted with SPSS (IBM).

Ethical Considerations

This study received institutional review board approval from Iona College (reference number: 201718 - 22) in 2018. Before participating, individuals agreed to participation by electronically signing a consent form that outlined study aims, procedures, time requirements, potential risks, and rights for human research subjects. Individuals from special or protected groups (ie, individuals who are <18 years old, imprisoned, or cognitively impaired) with impaired ability to provide free consent were ineligible to participate. We did not screen for pregnancy, and pregnant women were considered eligible to participate.

Results

The first exploratory factor analysis produced a solution that included 12 factors that accounted for 67.5% of the variance. Using the criteria outlined above, a total of 16 items were eliminated, resulting in a 6-factor, 26-item solution. We deviated from the established cutoff criteria on 1 occasion: factors 7 and

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9 were retained as we felt they would combine into 1 factor since both contained items related to online social communication. Thus, 8 factors and 30 items were retained from the first exploratory factor analysis.

A second exploratory factor analysis was conducted to confirm the identified factors. Using the same criteria outlined by Costello and Osborne [38], the second exploratory factor analysis resulted in a 7-factor solution with 29 items that accounted for 61.1% of the variance. One minor adjustment was made to the solution: item 29 (*How often do you post to make others think you are feeling better than you actually are?*) was moved to factor 6, as it had previously loaded onto factor 6 and aligned more with its theme of inducing negative affect. The factors and their internal consistency reliability are as follows: self-branding (0.829), compulsive use (0.798), disruptive use (0.759), impulsive sharing (0.701), social engagement (0.755), induce negative emotions (0.768), and induce positive emotions (0.735). Table 2 lists all retained items and their factor loading, mean, and SD.

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Table . Factor loadings, means, and SDs for the final, 7-factor scale from study 1 exploratory factor analysis (EFA)

Factor or item	Factor loading							Mean (SD)
	1[a]	2[b]	3[c]	4[d]	5[e]	6[f]	7[g]	
Self-branding								
How much do your profiles represent an "idealized self"?	0.51	0.06	0.17	0.03	0.06	0.07	0.23	4.78 (2.66)
How often do you put a filter on pictures that you post or share?	0.51	0.19	−0.08	−0.05	−0.01	0.07	0.07	5.41 (3.16)
How important to you is the number of likes you get on a post?	0.79	−0.04	−0.09	0.09	−0.02	−0.1	0.1	4.82 (2.8)
To what extent do you post on a schedule/certain time of day, thinking people will be more likely to see your post?	0.79	−0.1	0.04	−0.16	−0.02	0.07	0.15	4.73 (3.31)
To what extent do you have a process/routine to developing your posts before sharing them?	0.64	0	0.05	−0.01	0.08	0.14	−0.02	3.71 (2.75)
How much does the number of likes you get on a post affect your mood?	0.53	0.04	0.11	0.11	0.09	0.12	0.1	3.63 (2.58)
Compulsive use								
How often do you check social media during face-to-face conversations?	−0.02	0.42	0.11	0.23	−0.08	−0.16	0.04	3.26 (1.94)
How often do you spend more time on social media than you intended to?	0.1	0.86	0	0.24	0.01	0.19	0.1	5.55 (2.59)
How often do you sleep with your phone within arm's reach?	0.05	0.48	−0.02	0.06	0.03	−0.07	0.01	8.53 (2.54)

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Factor or item	Factor loading							Mean (SD)
	1[a]	2[b]	3[c]	4[d]	5[e]	6[f]	7[g]	
How often do you stop doing other tasks (such as homework) to check social media?	0.07	0.7	0.07	−0.07	−0.07	−0.02	0.11	6.75 (2.59)
How often do you lose track of time because you get so involved in your social media activity?	−0.05	0.68	0.15	−0.17	0.08	0.08	0.08	5.32 (2.85)
Disruptive use								
How hard is it to not check social media during class?	0.11	0.15	0.46	0.08	−0.01	0.05	−0.17	4.14 (2.95)
How often has a loved one (parent, friends, etc.) told you that you are on social media too often?	−0.07	0.06	0.51	0.19	0.01	0.01	0.16	3.41 (2.54)
How often have you gotten “in trouble” in class or at work for using social media when you shouldn’t have been?	−0.16	−0.02	0.78	0.08	0.14	0.15	−0.04	2.26 (1.71)
How likely are you to use (check or post) social media accounts while driving?	0.05	0.1	0.42	0.24	0.08	0.03	0.24	2.11 (1.85)
How uncomfortable do you feel if you are away from your phone and can’t use social media for an extended period of time (i.e., one h or more)?	0.18	0.17	0.42	0.07	0	0.1	0.01	3.82 (2.57)
Impulsive sharing								

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Factor or item	Factor loading							Mean (SD)
	1[a]	2[b]	3[c]	4[d]	5[e]	6[f]	7[g]	
How often have you felt that you "over-shared" on social media?	0	−0.09	0.26	0.58	0.1	−0.08	0.01	2.6 (2.17)
How often have you posted something on a social media site and later regretted it?	0.21	−0.11	0.12	0.49	0.04	0.06	0.06	2.97 (2.13)
How often do you post on social media as a reaction to stress?	0.17	0.01	0.12	0.67	0.08	0.04	0.27	3.05 (2.76)
Social engagement								
How often do you use social media to stay connected for extracurriculars?	0.11	−0.1	0.11	−0.14	0.73	−0.13	0.05	4.56 (2.59)
How often do you use social media for information about school/academics?	0.02	0.09	0.24	0.11	0.63	0.04	0.21	4.86 (2.82)
How often do you use social media for activism purposes?	−0.1	0.15	−0.16	0.23	0.7	0.07	−0.07	3.61 (2.86)
How often do you engage in discourse about social issues/justice over social media?	−0.01	0.09	−0.13	0.34	0.53	0.02	−0.11	3.06 (2.55)
Induce negative emotions								
Do you ever spend time viewing profiles even though you know it makes you feel badly about yourself?	0.16	0.06	0.04	0.07	0	0.63	−0.08	4.35 (3.07)

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Factor or item	Factor loading							Mean (SD)
	1[a]	2[b]	3[c]	4[d]	5[e]	6[f]	7[g]	
How often do you post to make others think you are feeling better than you actually are?	0.03	−0.16	0.04	0.61	−0.07	0.29	0.17	3.83 (2.78)
How often do you look at social media pages that you know will make you feel bad/induce negative affect?	0.07	−0.04	0.09	0.1	−0.09	0.7	−0.03	2.91 (2.51)
Induce positive emotions								
How often do you turn to social media because you think it will improve your mood?	0.04	0.13	0.09	0.4	0.07	0.13	0.56	4.6 (2.95)
How often do you turn to social media to relax?	0.07	0.23	−0.13	0.17	0.03	−0.13	0.57	5.62 (2.79)
How much does your social media activity make you feel connected to others?	0.29	0.01	−0.02	0.05	0.14	−0.03	0.45	5.43 (2.55)

[a]Eigenvalue: 8.92; percentage of variance: 29.73; Cronbach α: 0.83.

[b]Eigenvalue: 2.19; percentage of variance: 7.31; Cronbach α: 0.8.

[c]Eigenvalue: 1.76; percentage of variance: 5.86; Cronbach α: 0.76.

[d]Eigenvalue: 1.68; percentage of variance: 5.61; Cronbach α: 0.7.

[e]Eigenvalue: 1.54; percentage of variance: 5.13; Cronbach α: 0.76.

[f]Eigenvalue: 1.14; percentage of variance: 3.81; Cronbach α: 0.77.

[g]Eigenvalue: 1.08; percentage of variance: 3.61; Cronbach α: 0.74.

Study 2

Overview

The goal of study 2 was to conduct a confirmatory factor analysis to evaluate the model fit of the 29-item CASM measure created in study 1 (see Multimedia Appendix 1). A secondary goal was to assess the discriminant, convergent, and criterion validity of the CASM.

Methods

Participants

We enrolled a convenience sample of college-aged young adults. Sample recruitment and inclusion criteria are identical to those outlined in study 1. Study 2 enrolled 508 participants (Table 1). Participants were predominantly female (n=323, 63.6%), White (n=272, 53.5%), and non-LGBTQ (n=438, 86.2%) with a mean age of 18.99 (SD 1.17) years. All participants used at least 1 social media account (mean 4.55, SD 1.54), and individuals reported spending an average of 5.35 hours per day on social media (SD 3.72).

Measures

Comprehensive Assessment of Social Media Use

The 29-item CASM (Multimedia Appendix 1) was produced by the exploratory factor analysis described in study 1.

Bergen Facebook Addiction Scale

The 6-item Bergen Facebook Addiction Scale (BFAS) was used to assess self-perceived levels of dependence on the social media

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platform Facebook [39]. The BFAS is a self-report measure that asks participants to rate their Facebook use over the past week. Items are scored on a 5-point Likert scale from 0 (very rarely) to 5 (very often). The BFAS demonstrates acceptable psychometric properties and has demonstrated validity in additional young adult samples [40,41].

Motivations for Electronic Interaction Scale

The Motivations for Electronic Interaction Scale (MEIS) is a 22-item self-report survey measure used to assess an individual's motivations for using electronic interactions [42]. Items are scored on a 5-point Likert scale from 1 (not at all true) to 5 (extremely true). The Motivations for Electronic Interactions Comparison and Feedback Subscale (MEIS-CF) can be used to assess an individual's motivation for using electronic interaction based on their desire to make social comparisons. The MEIS-CF was used in this study to assess an individual's comparison and feedback-seeking behaviors on social media.

Brief Fear of Negative Evaluation Scale

The 12-item Brief Fear of Negative Evaluation Scale (B-FNE) was used to measure self-perceived levels of anxiety related to being negatively evaluated by another person [43]. The B-FNE is a self-report measure that asks participants to rate how accurately a statement describes them. Items are scored on a 5-point Likert scale from 1 (not at all characteristic of me) to 5 (extremely characteristic of me). The B-FNE has demonstrated adequate psychometric properties among undergraduate students.

Depression, Anxiety, Stress Scale

The Depression, Anxiety, Stress Scale (DASS) is a 21-item self-report measure designed to assess an individual's emotional state of depression, anxiety, and stress [44]. The DASS asks participants to indicate how much a statement applied to them during the past week. Items are scored on a 4-point Likert scale from 0 (did not apply to me at all) to 3 (applied to me very much or most of the time). The DASS has strong psychometric properties and has consistently demonstrated adequate validity [45].

Measure of Verbally Expressed Emotion

The Measure of Verbally Expressed Emotion (MoVEE), a 19-item self-report measure, was used to measure an individual's comfort in verbally expressing different emotions [46]. The MoVEE asks participants to answer items relating to how comfortable they are expressing feelings to others. Items are scored on a 4-point Likert scale from 0 (strongly disagree) to 4 (strongly agree). The MoVEE demonstrates strong validity and reliability among young adults.

Procedures

Data collection occurred from December 2018 to December 2019 on the online research platform Qualtrics. After providing informed consent, participants completed a demographic survey and the 29-item CASM. Participants then completed the B-FNES, DASS, MEIS, BFAS, and MoVEE. After completing the study measures, participants received a debriefing form with a list of local and national mental health resources.

Data Analysis

Descriptive statistics were calculated to characterize sample demographics. Model fit indices calculated included root mean square error of approximation (RMSEA) [47], comparative fit index (CFI) [48], Tucker-Lewis index (TLI) [49,50], and standardized root mean square [51]. RMSEA provides an estimate of how far a hypothesized model is from a perfect model, CFI and TLI compare the performance of a hypothesized model against a null model, and standardized root mean squared residual measures the average difference between observed and predicted correlations.

Discriminant validity was examined by calculating correlations between the CASM, the MoVEE, and self-reported frequency of phone video game use. The MoVEE scale and the frequency of phone video game use question were chosen to assess discriminant validity, as both measure smartphone uses not related to social media. Construct validity was determined by calculating correlations between CASM latent factors, the BFAS, and MEIS-CF. Criterion validity was evaluated by calculating correlations between CASM latent factors and 2 indicators of well-being: fear of negative evaluation (measured by the B-FNE) and depression, anxiety, and stress (measured by the DASS).

Finally, a bivariate correlation was calculated to test whether there is a significant relationship between hours per day spent on social media and symptoms of depression, anxiety, and stress. For all analyses, missing data were handled using listwise deletion. All statistical analyses were conducted with SPSS.

Ethical Considerations

This study received institutional review board approval from Iona College (reference number: 201718 - 22) in 2018. Before participating, individuals agreed to participation by electronically signing a consent form which outlined study aims, procedures, time requirement, potential risks, and rights for human research subjects. Individuals from special or protected groups (ie, individuals who are <18 years old, imprisoned, or cognitively impaired) with impaired ability to provide free consent were ineligible to participate. We did not screen for pregnancy, and pregnant women were considered eligible to participate.

Results

Table 3 presents the standardized parameter estimates for the confirmatory factor analysis model as well as the factor loading and error variance for each item. A variety of indices of model fit were examined: the chi-squared test of model fit was significant (χ^2_{356}=941, P<.001; RMSEA=0.064; CFI=0.855; TLI=0.848; standardized root mean squared residual=0.060). The factors and their internal consistency reliability are as follows: self-branding (0.817), compulsive use (0.771), disruptive use (0.699), impulsive sharing (0.750), social engagement (0.712), induce negative emotions (0.751), and induce positive emotions (0.746). As expected, all CASM factors were positively correlated with one another but not so strongly as to suggest a single factor (Table 4). Skewness and kurtosis of all items and subscales on the CASM are reported in Multimedia Appendix 2.

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Table . Internal consistencies, factor loadings, and error variances for the final 29-item, 7-factor scale from study 2 confirmatory factor analysis (CFA).

Scale (internal consistency) and item	Factor loading	Error variance
Self-branding (0.817)		
How much do your profiles represent an "idealized self"?	0.332	0.110
How often do you put a filter on pictures that you post/share?	0.589	0.347
How important to you is the number of likes you get on a post?	0.711	0.505
To what extent do you post on a schedule/certain time of day, thinking people will be more likely to see your post?	0.710	0.504
To what extent do you have a process/routine to developing your posts before sharing them?	0.810	0.656
How much does the number of likes you get on a post affect your mood?	0.707	0.55
Compulsive use (0.771)		
How often do you check social media during face-to-face conversations?	0.523	0.274
How often do you spend more time on social media than you intended to?	0.710	0.504
How often do you sleep with your phone within arm's reach?	0.394	0.155
How often do you stop doing other tasks (such as homework) to check social media?	0.732	0.537
How often do you lose track of time because you get so involved in your social media activity?	0.771	0.594
Disruptive use (0.699)		
How hard is it to not check social media during class?	0.566	0.320
How often has a loved one (parent, friends, etc.) told you that you are on social media too often?	0.599	0.359
How often have you gotten "in trouble" in class or at work for using social media when you shouldn't have been?	0.542	0.294
How likely are you to use (check or post) social media accounts while driving?	0.453	0.206
How uncomfortable do you feel if you are away from your phone and can't use social media for an extended period of time (ie, one hour or more)?	0.537	0.289
Impulsive sharing (0.750)		
How often have you felt that you "overshared" on social media?	0.795	0.632
How often have you posted something on a social media site and later regretted it?	0.718	0.515
How often do you post on social media as a reaction to stress?	0.642	0.412
Social engagement (0.712)		
How often do you use social media to stay connected for extracurricular activities?	0.397	0.157

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Scale (internal consistency) and item	Factor loading	Error variance
How often do you use social media for information about school/academics?	0.421	0.177
How often do you use social media for activism purposes?	0.788	0.620
How often do you engage in discourse about social issues/justice over social media?	0.771	0.595
Induce negative emotions (0.751)		
Do you ever spend time viewing profiles even though you know it makes you feel badly about yourself?	0.741	0.548
How often do you post to make others think you are feeling better than you actually are?	0.673	0.453
How often do you look at social media pages that you know will make you feel bad/induce negative affect?	0.648	0.420
Induce positive emotions (0.746)		
How often do you turn to social media because you think it will improve your mood?	0.752	0.566
How often do you turn to social media to relax?	0.772	0.596
How much does your social media activity make you feel connected to others?	0.607	0.368

Table . Correlations between latent Comprehensive Assessment of Social Media Use (CASM) factors, means, and SDs of CASM factors.

	SB[a]	CU[b]	DU[c]	IS[d]	SE[e]	INE[f]	IPE[g]
SB	—[h]	0.42[i]	0.45[i]	0.51[i]	0.36[i]	0.60[i]	0.42[i]
CU	0.42[i]	—	0.55[i]	0.36[i]	0.23[i]	0.39[i]	0.46[i]
DU	0.45[i]	0.55[i]	—	0.42[i]	0.29[i]	0.39[i]	0.37[i]
IS	0.51[i]	0.36[i]	0.42[i]	—	0.31[i]	0.59[j]	0.47[i]
SE	0.36[i]	0.23[i]	0.29[i]	0.31[i]	—	0.33[i]	0.36[i]
INE	0.60[i]	0.39[i]	0.39[i]	0.59[j]	0.33[i]	—	0.44[i]
IPE	0.42[i]	0.46[i]	0.37[i]	0.47[i]	0.36[i]	0.44[i]	—
Total sample, mean (SD)	4.08 (2.09)	5.81 (1.87)	3.31 (1.65)	2.85 (1.95)	3.88 (2.00)	3.44 (2.31)	4.77 (2.25)

[a]SB: self-branding.

[b]CU: compulsive use.

[c]DU: disruptive use.

[d]IS: impulsive sharing.

[e]SE: social engagement.

[f]INE: induce negative emotions.

[g]IPE: induce positive emotions.

[h]Not applicable.

[i]$P<.01$.

[j]$P<.05$.

The results found all CASM latent factors to be weakly correlated with the MoVEE scores and frequency of phone video game use, providing initial evidence of discriminant validity (Table 5). Scores on the BFAS and MEIS-CF, which both assess social media behavior, were correlated with the CASM, providing initial evidence of construct validity (Table 5). All CASM latent factors were correlated with B-FNE scores. Moreover, all CASM latent factors were found to be correlated

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with scores on the depression, anxiety, and stress subscales from the DASS, providing initial evidence of criterion validity (Table 5). The internal consistency reliability for measures used in validity testing is as follows: MoVEE (0.385), BFAS (0.802), MEIS-CF (0.924), B-FNE (0.791), and DASS (0.937).

Finally, a bivariate correlation revealed no statistically significant association between hours per day spent on social media and symptoms of depression, anxiety, and stress (r_{397}=0.06; P=.21; R^2=0.003), where less than 1% of the variability in symptoms of depression, anxiety, and stress could be accounted for by hours per day spent on social media.

Table . Correlations between the Comprehensive Assessment of Social Media Use (CASM) and indicators of validity.

Measure of validity	Self-branding	Compulsive use	Disruptive use	Impulsive sharing	Social engagement	Induce negative emotions	Induce positive emotions
Discriminant							
MoVEE[a]	−0.04	0.02	0.02	−0.10[b]	0.01	−0.16[c]	0.04
Phone video game use	0.07	0.06	0.01	−0.01	−0.18[c]	0.04	−0.05
Convergent							
B-FAS[d]	0.35[c]	0.42[c]	0.41[c]	0.44[c]	0.28[c]	0.45[c]	0.45[c]
MEIS-CF[e]	0.54[c]	0.36[c]	0.37[c]	0.46[c]	0.27[c]	0.60[c]	0.41[c]
Criterion validity							
B-FNE[f]	0.26[c]	0.19[c]	0.15[c]	0.25[c]	0.11[c]	0.40[c]	0.21[c]
DASS[g]—depression	0.10[b]	0.10[b]	0.14[c]	0.25[c]	0.08[b]	0.41[c]	0.10[b]
DASS—anxiety	0.16[c]	0.15[c]	0.20[c]	0.26[c]	0.14[c]	0.39[c]	0.14[c]
DASS—stress	0.25[c]	0.20[c]	0.29[c]	0.34[c]	0.16[c]	0.45[c]	0.19[c]
CASM as an outcome							
Nonsuicidal self-injury	t(496)=5.10, P<.001[c]	t(496)=1.65, P=.10	t(494)=1.50, P=.14	t(486)=2.97, P<.001[c]	t(496)=1.68, P=.09	t(488)=5.50, P<.001[c]	t(496)=2.41, P=.02[b]

[a]MoVEE: Measure of Verbally Expressed Emotions.

[b]P<.05.

[c]P<.01.

[d]B-FAS: Bergen Facebook Addiction Scale.

[e]MEIS-CF: Motivations for Electronic Interactions Comparison and Feedback Subscale.

[f]B-FNE: Brief Fear of Negative Evaluation Scale.

[g]DASS: Depression Anxiety Stress Scale.

Discussion

Principal Findings

This study developed and validated the CASM. Exploratory and confirmatory factor analyses resulted in a 29-item self-report survey measure that assesses 7 distinct types of social media behavior: self-branding, compulsive use, disruptive use, impulsive sharing, social behavior, induce negative emotions, and induce positive emotions. Each factor of the CASM demonstrates good internal consistency reliability. Further, following cutoff criteria outlined by Hu and Bentler [52], the CASM demonstrates adequate model fit with moderate discriminant, convergent, and criterion validity.

To meaningfully advance research on social media use and mental health, researchers require better measurement tools to capture a range of online behaviors and engagement patterns. Encouragingly, the CASM measures a range of social media behaviors identified in prior research [53-55] that are clinically meaningful. To summarize, the self-branding subscale evaluates how often an individual engages in self-presentation strategies to manage how others perceive them and is similar to digital status–seeking behavior identified in prior research [54]. Individuals with higher scores on the branding behaviors subscale are more likely to have their own social media "brand," which they adhere to. The compulsive use subscale measures behavior that suggests an overreliance on social media, which prior research has framed as addictive social media behavior [53]. Individuals with higher scores in this category may find it hard to disconnect from social media. The disruptive use subscale measures how frequently an individual uses social media maladaptively. This factor is distinct from the addictive behavior subscale, as its items assess social media use in inappropriate contexts (eg, during class or while driving), rather than use that is excessive. The impulsive sharing subscale examines how often an individual impulsively posts on social

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media, which aligns with oversharing behavior characterized in prior research [55]. Individuals with higher scores on the impulsive posting subscale are more likely to "over-share," or post in an unedited, spontaneous manner that results in feelings of regret. The social engagement subscale examines how often an individual uses social media to communicate with others. Individuals with higher scores in this category are more likely to use social media as a tool to communicate and plan with others. The induce negative emotions subscale explores how often an individual uses social media to worsen their affect. One item in this factor evaluates upward social comparisons, a behavior examined extensively by prior research [56-58]. Individuals with higher scores in this category are more likely to use social media to lower their mood. Finally, the induce positive emotions subscale examines how often an individual uses social media to improve their affect. Individuals with higher scores in this category are more likely to use social media as a coping strategy to feel more relaxed or connected with others.

The CASM is novel in that it is one of the first validated measures to assess both positive and negative aspects of social media use simultaneously. Social media use measures have traditionally focused on overtly negative patterns of online engagement [27,28,32,41], such as addictive characteristics. The CASM extends this research by also measuring overtly positive aspects of social media use, such as social connection. This inclusion is especially relevant to advancing our understanding of social media and mental health; emerging research shows that social media may promote mental health through increased social support and peer connection [59]. However, existing evidence is still limited, emphasizing the need for improved measurement to assess potentially protective aspects of social media use.

Another advantage of the CASM is its emphasis on reporter agreement with items, rather than duration or frequency reports of social media engagement. When examining correlations between the CASM and indicators of mental well-being, self-perceived levels of depression, anxiety, and stress were significantly associated with the induce negative emotion and impulsive sharing subscales (Table 5). Notably, self-perceived levels of depression, anxiety, and stress as measured by the DASS were not associated with the self-reported hours per day spent on social media. This finding aligns with prior research showing that characterizing social media use as specific behaviors, rather than time spent online, is a better predictor of mental health [5,18,19].

Advancing our understanding of social media use is especially important for clinicians and parents tasked with promoting the well-being of young people. It is our hope that researchers will leverage the CASM's ability to measure distinct aspects of social media behavior simultaneously to identify unique "engagement profiles" that more accurately reflect how people interact with social media. With a more holistic understanding of how an individual uses social media, it may be possible to gain deeper insight into what specific patterns of use may be adaptive, neutral, or detrimental to mental health. With this information, interventions and guidance aimed at promoting online hygiene could become more targeted and personalized. To accomplish this, future research should continue to advance the measurement of social media use, incorporating additional markers, such as passive sensing, to more accurately capture youth engagement with these platforms.

Limitations

The findings from this initial validation study are important and yield ideas for further research. This study used a convenience sample of college students, limiting the generalizability of the findings beyond this population. This is especially important given demonstrable age differences in social media use [60]. Future research should examine the CASM's application and validity across different age groups. Second, the CASM is a self-report measure and is therefore susceptible to response bias. This may have resulted in skewed responses, especially on items that conveyed negative social media habits. Future research should seek novel ways to assess social media use without the use of self-report measures. Third, while the 7 categories of social media use identified in this study cover a broad range of behaviors, it is likely that there are other clinically relevant dimensions of social media use. Future research should continue to examine and identify novel ways individuals interact and use social media, especially as these platforms continue to extend into news, gaming, and entertainment ecosystems and incorporate advances in artificial intelligence. Finally, this study predates the COVID-19 pandemic. Given documented increases in social media use during the pandemic [61], the behaviors identified in this study may not reflect social media engagement in more recent populations.

Conclusions

This study led to the development of the CASM, a 29-item scale that assesses 7 distinct social media behaviors: self-branding, compulsive use, disruptive use, impulsive sharing, social engagement, induce negative emotions, and induce positive emotions. The CASM demonstrates adequate model fit with moderate discriminant, convergent, and criterion validity. The CASM is one of the first validated measures to multiple, distinct aspects of social media behavior simultaneously, enabling researchers to more effectively examine associations between social media use and mental health outcomes. With this improved measurement, researchers can better assess how individuals use social media, and how this use may impact mental well-being.

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Data Availability

The datasets generated or analyzed during this study are not publicly available due to privacy and confidentiality obligations to participants but are available from the corresponding author on reasonable request.

Authors' Contributions

NJL, RRG, and CMJ designed the study and wrote the paper. NJL and RRG collected and prepared the data. CMJ conducted the statistical analysis. All authors prepared and approved the final paper.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Comprehensive Assessment of Social Media Use (CASM).
[PDF File, 171 KB - formative_v10i1e87599_app1.pdf]

Multimedia Appendix 2
Summary of skewness and kurtosis.
[DOCX File, 19 KB - formative_v10i1e87599_app2.docx]

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Abbreviations

B-FNE: Brief Fear of Negative Evaluation Scale

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BFAS: Bergen Facebook Addiction Scale
CASM: Comprehensive Assessment of Social Media Use
CFI: comparative fit index
DASS: Depression, Anxiety, Stress Scale
LGBTQ: lesbian, gay, bisexual, transgender/transsexual, and queer
MEIS: Motivations for Electronic Interaction Scale
MEIS-CF: Motivations for Electronic Interactions Comparison and Feedback Subscale
MoVEE: Measure of Verbally Expressed Emotion
RMSEA: root mean square error of approximation
TLI: Tucker-Lewis index

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Exploring the Cultural Adaptation of an Ongoing Evidence-Based Intervention for Chinese and Korean American Dementia Caregivers: Descriptive Study

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Abstract

Background: The aging and caregiving population is becoming increasingly diverse in the United States, leading to a growing need for culturally adapted interventions to address the unique needs of underrepresented groups, such as Asian Americans. However, interventions targeting Asian Americans and exploring cultural adaptation strategies remain limited in dementia caregiving research.

Objective: This study aimed to describe the cultural adaptation process of an evidence-based intervention for Chinese and Korean American dementia caregivers, called the New York University Caregiver Intervention–Enhanced Support.

Methods: We conducted a deductive content analysis and categorized our adaptation strategies into 5 elements: content, context, relationship fidelity and core elements, engagement, and cultural competence. Timing and types of responses to each adaptation strategy were also observed. Two authors conducted the initial analysis, and additional team members finalized the synthesis through discussion. The Template for Intervention Description and Replication (TIDieR) checklist was used to guide the methodological rigor.

Results: Twenty-four major adaptations were identified and categorized. For content, we translated materials, used culturally relevant terms, incorporated ethnic-specific surveys and resources, created social media support groups on platforms widely used by the targeted population, and extended the time allocated to complete the 6 counseling sessions. Context adaptation included expanding the range of individuals eligible for family counseling sessions to include fictive kin, using online and social media apps for communication, cultural matching and training of staff, and partnerships with relevant community organizations. Relationship fidelity and core elements involved consulting with community experts, conducting focus group interviews with caregivers, having regular meetings with the developer of the original intervention and an experienced New York University Caregiver Intervention–Enhanced Support clinician as well as experts in Chinese and Korean culture, and continuing regular counseling supervision. To enhance engagement, we provided clear explanations of the study procedure, which emphasized the benefits in participants' native languages and matched participants with social workers who shared the same cultural backgrounds. We also used a step-by-step contact approach and prolonged communication, explained staff roles to build rapport, and offered participant compensation. Finally, cultural competence was reflected in tailoring counseling techniques with respect for cultural beliefs, the use of euphemistic language for taboo subjects, and culturally appropriate refreshments to show respect and build interpersonal relationships.

Conclusions: We systematically adjusted a counseling-based intervention, an approach less familiar among Asian Americans, to fit the cultural characteristics of the target population. A contribution of this study is using an integrated, theory-driven approach that combines 2 cultural adaptation frameworks while also capturing real-time adaptations informed by external feedback and

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self-reflection. This work provides a practical model for adapting evidence-based interventions to serve Chinese and Korean American dementia caregivers and may inform future adaptations for other East Asian populations.

Trial Registration: ClinicalTrial.gov NCT05461495; https://clinicaltrials.gov/study/NCT05461495

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KEYWORDS

dementia; caregivers; evidence-based intervention; program descriptions; Asian; culture

Introduction

Background

As the US caregiver population becomes increasingly diverse, including an increasing number of Asian Americans, there is a critical need to develop and implement culturally tailored interventions that address the unique values, beliefs, and needs of underrepresented groups [1,2]. The importance of cultural adaptation is underscored by findings that interventions may not be equally effective across all populations due to cultural differences [3,4]. Cultural adaptation can enhance intervention effectiveness for different groups by making them culturally relevant, reducing health disparities, and offering more comprehensive support [1,4,5]. Interventions targeting the needs of different races and cultures have recently been developed and monitored; however, Asian Americans are the least targeted group for interventions [6,7], including interventions for dementia caregivers from Asian cultures [8-10]. Culturally tailored interventions for dementia caregivers from Asian backgrounds living in the United States warrant further modification in terms of implementation guidelines, evaluation, and intervention provider training [7].

In response to this gap, we adapted the New York University Caregiver Intervention (NYUCI) for Chinese and Korean American dementia caregivers, named NYUCI-Enhanced Support (NYUCI-ES) [10,11]. The original NYUCI was developed in the 1980s to improve caregiver well-being and delay nursing home placement for individuals living with dementia [12-14]. The intervention was originally evaluated in a randomized controlled trial (RCT) and targeted spousal or partner caregivers of individuals with dementia residing in the New York City metropolitan area. Participants in the treatment group received 2 individual and 4 family counseling sessions in 4 months after baseline and were encouraged to attend community support groups and use ad hoc (on-request) counseling from their assigned counselor. The content and duration of counseling sessions varied according to participants' interests and availability. In contrast, those in the control group received ad hoc counseling and resource information based on their needs but did not participate in the 2 individual and 4 family counseling sessions provided to the treatment group; participants were evaluated every 4 months for the first year and every 6 months thereafter [12,13].

The intervention helped reduce depressive symptoms and stress among caregivers in the treatment group and improved their subjective assessment of physical health [12,15]. It also delayed nursing home placement for individuals with dementia whose caregivers were in the treatment group by a median of 557 days [13]. The intervention was later applied to the population of adult children caring for parents living with dementia and revealed similar positive outcomes [16,17]. These results contributed to its implementation across the United States and elsewhere [15,17-21]. NYUCI was also adapted to Hispanic caregivers in New York City, whose family support has a significant role in caregiving [22], similar to the Asian population [10]. The intervention has demonstrated significant reductions in caregiver burden in the Hispanic population [23].

Given the potential of the NYUCI to support a diverse population and the current lack of culturally tailored support for Asian American communities [10,11], it is important to discuss how we conducted systematic, real-time cultural adaptations made to the NYUCI model to align with Chinese and Korean cultural values and support the feasibility of the intervention in the target population (ie, NYUCI-ES). In this study, we first describe Eastern cultural perspectives on caregiving, as well as previously developed culturally adapted interventions and adaptation frameworks. We then document the cultural adaptation strategies applied to the original NYUCI procedures before and during implementation using these established frameworks. Our focus herein is on the adaptation process; participant outcomes will be reported separately at a later time following study completion.

Eastern Cultural Perspectives on Caregiving

Asian Americans are the fastest-growing ethnic group in the United States, expected to reach 46 million by 2060 [24]. Compared to other racial groups, Asian American dementia caregivers are more likely to find the consideration of cultural background in care settings important but perceive a lack of a culturally competent health care system, along with challenges in care navigation [25]. As the majority of Asian American older adults were born outside the United States [24], this racial group also tends to experience acculturative stress and family conflicts as they maintain traditional culture while assimilating into a new society [26].

Individuals originating from East Asian countries, including Chinese and Korean, account for 37% of the Asian American population [27]. Although Asian Americans exhibit high cultural heterogeneity among subgroups in terms of language, religion, and historical backgrounds [27], those from East Asian countries tend to share more similar cultural traits due to geographical proximity and historical closeness [28]. Specifically, their cultural similarities result from Confucianism, which emphasizes benevolence, integrity, propriety, morality, and trust [29]. This can also lead to cultivating oneself to be morally perfect and become part of society, prioritizing family values over personal

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ones, controlling oneself in behaviors tied to filial piety, and expressing respect and loyalty toward older adults [29,30].

These values often lead to assigning caregiver roles to family members, particularly children of the family member living with dementia [31], who feel a greater sense of filial obligation to reciprocate the previous care that they received [26]. Familism also requires individuals to follow family decisions rather than their own decision-making process, resulting in a disregard for individuals' emotions and needs [28,31]. In addition, dementia caregivers from East Asian cultures are likely to have the misconceptions that dementia symptoms are a normal part of aging or a matter of fate [32,33]. Stigma against dementia is often confounded with stigma against mental illness [26,34,35]. These perceptions can delay treatment for dementia [33], causing emotional stress, burden, and negative health status among family caregivers [36].

Existing Culturally Adapted Interventions Incorporating East Asian Culture

A few previous researchers have adapted interventions into Eastern cultural contexts to take into account differences from Western cultural norms [9,37-41]. For instance, Jang et al [9,41] adapted the Savvy Caregiver Program for Korean American dementia caregivers (K-Savvy) using the cultural adaptation process of Barrera et al [5] and the Framework for Reporting Adaptations and Modifications–Enhanced (FRAME) [42]. They translated study materials into Korean, reframed program content to align with collectivist cultural values, extended the length of sessions based on participants' needs, collaborated with multiple stakeholders, and trained staff regarding the program components and an appropriate culturally related approach [9,41]. Similar strategies were used in other adapted interventions, along with modifications to the delivery format, such as omitting phone-based sessions [37], implementing an in-home approach [39], and using a DVD delivery format [38,40].

While prior studies have incorporated cultural elements into dementia caregiver interventions, few have used a structured framework to assess adaptation strategies, which is essential for understanding the mechanisms and evaluation of the strategies [43]. In addition, most research addressed preimplementation modifications rather than exploring ongoing adaptations made during the implementation based on participants' feedback and discussions with the research team. This limits the ability to refine interventions during implementation.

Cultural Adaptation Framework for Intervention Implementation

Stirman et al [42] developed FRAME, which provides a systematic structure to assess how and why interventions are modified, improving the transparency as well as effectiveness of the adaptation. It represents an expanded version of their previous framework and incorporates pivotal components to consider during the adaptation process. These components contain intervention elements being modified, the individuals who are involved in the modification, the timing (ie, preimplementation, implementation, scale-up, and sustainment), and types of responses (ie, proactive vs reactive) to the modification, the changes in delivery methods, and the underlying reasons for modification—including cultural norms.

To narrow down the intervention type and focus more on the adaptation of intervention elements, Day et al incorporated FRAME into a systematic review of cultural adaptation frameworks for psychosocial interventions and addressed the literature gap regarding limited details on the components for cultural adaptation. They synthesized the findings using FRAME as part of their analytic structure and identified 5 core elements: *content*, *context*, *relationship fidelity and core elements*, *engagement*, *and cultural competence*. "Content" involves changes in the intervention materials and procedures, including adding or modifying original program components, changes to or translations of study materials, and adjustments in the number or intervals of the interventions. "Context" refers to modifications in the intervention's setting or personnel while preserving its core "content," such as adjusting delivery methods, providing staff training, and considering community and situational factors. "Relationship fidelity and core elements" considers how interventions lead to different intervention outcomes due to participant diversity. It emphasizes the importance of adapting the intervention to align with the target population's cultural values while preserving its core elements to maintain the effectiveness of the original intervention. "Engagement" reflects the process of building participants' relationships with researchers and the intervention. It encompasses strategies to effectively recruit and retain participants by enhancing awareness, accessibility, and trust in both the intervention and its providers. Finally, "cultural competence" describes the ability to integrate cultural norms and attitudes to implement interventions effectively in the targeted cultural settings. It also includes the capacity to provide individualized accommodations throughout the intervention [2].

The framework of Day et al [2] underscores the importance of maintaining intervention fidelity and promoting cultural relevance while adapting evidence-based psychosocial interventions across diverse populations, offering a basis for evaluating culturally adapted interventions. However, the synthesis was specific to intervention elements and did not consider the time, which could affect whether certain adaptations were feasible for participants during the implication phase. Considering time-related factors in addition to Day's 5 elements would give researchers a more concrete understanding of cultural adaptation strategies.

Study Aims

Given the gaps in knowledge and a pressing need for cultural adaptation in interventions, this study explored the process of culturally adapting an enhanced version of the original NYUCI for 2 East Asian subgroups. To be specific, this study identified the types of cultural adaptations made to the intervention for each of the targeted subgroups and described when these adaptations occurred throughout the implementation process.

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Methods

This study used a descriptive research design and used deductive content analysis. To guide the cultural adaptation process, this study drew on both the framework of Day et al [2] and the FRAME [42], as each framework addresses distinct but complementary aspects of cultural adaptation.

Parent Study: NYUCI-ES

The NYUCI-ES, an ongoing study of an evidence-based intervention using an RCT design, aimed to assess its effects on improving the physical and psychological health of Korean and Chinese American caregivers who have risk factors for cardiometabolic diseases. To be eligible, participants should be primary caregivers of a family member living with memory problems in community settings and aged 50 years or older. They should also have Chinese or Korean ancestry, live in the New York City metropolitan area, have access to the internet as well as a phone with voice and text messaging capabilities, report that they have at least one family member who can attend family counseling sessions, have sufficient proficiency in English, Chinese, or Korean, and have at least one of the self-reported medical conditions related to cardiometabolic syndrome, such as diabetes, high cholesterol, high blood pressure, obesity, and/or other related symptoms. The target was 150 Chinese American and 150 Korean American participants, with a sample size estimated to provide 80% power to detect small to moderate effect sizes (ranging from 0.22 to 0.31) in key inflammation biomarkers using an analysis of covariance model, consistent with benchmarks defined by Sawilowsky [44]. Recruitment was conducted through, but was not limited to, community organizations, including hospitals, clinics, and adult day care centers; word of mouth, community outreach and events, and media advertisements; and a research registry targeting Asian Americans, Native Hawaiians, and Pacific Islanders [45,46]. Participant recruitment began in February 2023 and was completed by September 2025.

After being deemed eligible and completing informed consent and the baseline assessment visit, participants were randomized in a 1:1 ratio to either the treatment or control group using a computer-generated allocation sequence. Participants in the treatment group received (1) a total of 6 counseling sessions—2 individual (between the participant and a social worker) and 4 family counseling sessions (among the participant, at least one family member, and a social worker)—in person, via video calls, or by phone, with flexible session lengths depending on participants' needs; (2) ad hoc counseling that is initiated at the participant's request; and (3) enhanced support through an online chat group (eg, WeChat for Chinese participants and KakaoTalk for Korean participants), which is a newly added feature to the original NYUCI. Participants completed the counseling sessions before the second visit but can continue to use ad hoc counseling sessions and join the online chat group throughout the 1-year study period. They were also recommended to join community support groups, as in the original NYUCI, to access additional supportive resources. Caregivers in the control group are not offered structured counseling sessions but may use ad hoc counseling for caregiving resources. They can also participate in an online study chat group for enhanced support throughout the study. We assessed participants' physical and psychosocial status at baseline, 6 months, and 12 months using written assessments and biometric tests, including measures of chronic disease management, stress, depression, blood pressure, BMI, and metabolic biomarkers. Detailed study information is provided in Table 1 and elsewhere [11].

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Table . Study procedure of New York University Caregiver Intervention–Enhanced Support (NYUCI-ES)

Characteristics	NYUCI-ES
Study period and design	A year-long randomized controlled trial (ongoing)
Study purpose	To assess the effects of NYUCI-ES in improving the physical and psychological health of Korean and Chinese American caregivers who have risk factors for cardiometabolic diseases
Study population (eligibility)	• Korean or Chinese Americans aged 50 years or older who live in the New York metropolitan area • Those who provide care for people living with memory problems in the community setting • Those who can access the Internet as well as phone with voice messages and text messages • Those who report that they have at least one family member who can attend family counseling sessions • Those who have sufficient proficiency in English, Chinese, or Korean • Those who have at least one cardiovascular disease risk factor (eg, obesity, diabetes, hypertension, hyperlipidemia, and other related symptoms)
Recruitment strategies	• Community organizations, word of mouth, community outreach and events, media advertisement, a research registry, and so on
Study procedure	Treatment and control groups: • Three assessment visits (baseline, 6-mo follow-up, and 12-mo follow-up) • Caregiver-initiated counseling as needed (ie, ad hoc counseling) • Participation in a social media chat group Treatment group only: • Six counseling sessions (2 individual and 4 family-based counseling sessions) (between first and second visits)
Compensation	US $150 to US $200 (US $50 per assessment visit and US $50 for completing the metabolic biomarker test during each assessment visit)

Data Collection

For the cultural adaptation, adaptations before starting the intervention phase of the study had been proposed through team discussions, focus group interviews of eligible individuals [10], and input from the community advisory board. Ongoing adaptation was a result of information from consultation sessions with community partners, weekly team meetings, meeting notes, self-reports from the staff who communicate with participants or the senior counselor, and team members' observations during follow-up interview visits and counseling sessions. The information gathered by the aforementioned sources was reviewed and summarized to identify topics and to match the categories of Day et al [2]. The community advisory board, composed of community organization staff, clinicians, and professors, provided ongoing feedback on cultural relevance throughout the preimplementation period. The modifications during the implementation period were primarily based on staff observations, experiences encountered during trial delivery, and active discussions with all study team members, including the original program developer and a senior counselor.

Data Analysis

The coding and categorization procedures described below were used to document and analyze the cultural adaptation process conducted as part of the NYUCI-ES. We used deductive content analysis to operationalize the concept of previous knowledge [47]. This analysis process began with the development of an analysis matrix, followed by data collection and categorization guided by the analysis matrix [47]. On the basis of the 5 elements of Day et al [2] and the FRAME's timing and type of response to adaptation [42], we analyzed our cultural adaptation approach. The adaptation strategies we implemented were first summarized by 2 research team members (EK and AL) who shared the same cultural backgrounds as the participants and served as frontline staff, using Microsoft Word and Excel. After gathering the strategies, they were reassessed and categorized based on the 5 elements of Day et al [2]. The coding was independently conducted. The 2 research team members participated in iterative discussions to resolve discrepancies and refine the categorization.

Following this content-based categorization of the cultural adaptation strategies, the FRAME was applied to further characterize each adaptation in terms of its implementation process. For instance, each adaptation strategy was identified by when it occurred along the implementation timeline (eg, preparation vs implementation) and whether it was planned (eg, proactive vs reactive). This analytic approach systematically identified culturally grounded adaptation strategies and characterized them using established frameworks, thereby directly addressing the aim of the study.

The other 2 team members (YP and XQ), who have a Chinese cultural background and had previously served as program

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managers for this study, reviewed the coding decisions and categorizations, resolved any unresolved disagreements, and provided suggestions if necessary. The Template for Intervention Description and Replication (TIDieR) checklist was used to ensure methodological rigor [48].

Ethical Considerations

The parent study was approved by the Institutional Review Board of New York University (i22-00615) and registered on ClinicalTrials.gov [49] on July 18, 2022. Participants in the NYUCI-ES provided informed consent before the data collection. They were informed about the study procedure, the deidentification of their data during analysis to protect privacy and confidentiality, limited access to their data within the research team, the potential benefits and risks of participation, and the contact information for the principal investigators. Participants received US $50 per visit (US $150 for 3 visits) and an additional US $50 for measuring metabolic biomarkers.

Results

We found 24 major adaptation strategies and categorized them into 5 key cultural adaptation elements as defined by Day et al [2]. We also identified the timing and types of responses to adaptation by the FRAME framework [42]. The explanation is illustrated in Table 2.

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Table . Classification of the cultural adaptation process based on key adaptation elements (Day et al) [2] and the timing and types of response to adaptations using the FRAME[a] (Stirman et al) [42].

Adaptation elements [2]	Types of adaptation [2]	Our approach	Timing of response [42]	Type of response [42]
Content: changing materials or procedures of interventions	• Changes in packaging or materials • Tailoring, tweaking, refining • Adding or removing elements • Pacing or timing	• Translating materials and providing multilingual support • Using culturally appropriate terminology, images, questionnaires, and community resources • Adding familism, stigma, and social support in surveys • Providing social media support groups using popular apps among the Chinese and Korean • Extension of the interval of each family counseling session (6 family sessions for 4-6 mo)	• Preparation and implementation • Preparation and implementation • Preparation • Preparation • Preparation	• Proactive • Proactive and reactive • Proactive • Proactive • Proactive
Context: modifying the format, setting, personnel, and target population in the intervention	• Format • Setting • Personnel • Population	• Allowing various fictive kin to join the family counseling • Contacting participants in person and online, including through popular social media apps among Chinese or Korean • Arrangement of the staff with the same cultural background • Attending training sessions about caregiving in Korean or Chinese population • Partnering with culturally tailored organizations	• Implementation • Preparation and implementation • Preparation and implementation • Preparation and implementation • Preparation and implementation	• Reactive • Proactive and reactive • Proactive • Proactive • Proactive
Relationship fidelity or core elements: ensuring fidelity while preserving key active components during adaptations	—[b]	• Having focus group interviews with caregivers who may be eligible for NYUCI-ES[c] • Consulting external community board members with expertise in cultural adaptation • Having weekly meetings with the original intervention developer and research personnel with expertise in Korean or Chinese culture • Weekly clinical supervision by a senior counselor who was involved in the original intervention	• Preimplementation • Preimplementation and implementation • Preparation and implementation • Preparation and implementation	• Proactive • Proactive • Proactive and reactive • Proactive and reactive

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Adaptation elements [2]	Types of adaptation [2]	Our approach	Timing of response [42]	Type of response [42]
Engagement: facilitate participants to be involved and remain in the study	• Awareness • Access or entry • Client or therapist relationship • Retention or completion	• Providing detailed study information in participants' preferred language and emphasizing the benefits of the intervention • Offering clear explanations for the randomization assignment to help participants better understand the study procedure and reduce hesitancy • Using a step-by-step outreach process • Prolonged, multiple communications in their preferred language • Improving credibility through the explanation of staff roles and building rapport through active engagement • Offering participant compensation	• Implementation • Implementation • Preparation and implementation • Preparation and implementation • Preparation and implementation • Preparation	• Proactive • Reactive • Proactive and reactive • Proactive • Proactive and reactive • Proactive
Cultural competence: encompassing cultural characteristics effectively in the intervention	—[b]	• Delivering culturally, individually tailored counseling • Respecting their cultural beliefs • Using euphemistic language during communication • Providing culturally appealing refreshments during visits	• Preparation and implementation • Preparation and implementation • Preparation and implementation • Implementation	• Proactive and reactive • Proactive and reactive • Proactive and reactive • Proactive and reactive

[a]FRAME: Framework for Reporting Adaptations and Modifications–Enhanced.

[b]Not applicable.

[c]NYUCI-ES: New York University Caregiver Intervention–Enhanced Support

Content

While the original NYUCI had flexibility based on participants' needs, the most important consideration regarding the content was addressing language barriers. Before implementing the study, we translated all materials, such as consent forms, flyers, and questionnaires, from English into simplified Chinese and Korean. During implementation, our team members who were fluent in Chinese and able to read and write both simplified and traditional Chinese added a traditional Chinese version of the study materials to attract participants who use traditional but not simplified Chinese (ie, individuals from Hong Kong or Taiwan). In addition to language, we also carefully considered cultural perceptions of dementia to reduce stigma while selecting wording. For example, we used softer terms, such as "memory loss" instead of "dementia" and "consulting," "meeting," "support," and "education" instead of "counseling." This linguistic adaptation aimed to make the intervention more culturally acceptable and less intimidating for participants. This was also helpful to our recruitment efforts, addressed elsewhere in relation to this intervention [11]. Additionally, culturally specific questionnaires regarding familism, affiliated stigma against dementia, and acculturation status were included to embrace caregivers' traditional culture during the preparation period.

To enhance both formal and informal support, we integrated regular online support group sessions into the original NYUCI program using social media apps (eg, WeChat for many Chinese participants and KakaoTalk for the Korean participants) that are more commonly used apps among the target population. Through this platform, we delivered weekly educational resources on dementia care, self-care strategies, and available community resources where participants could seek help from culturally competent organizations. We also facilitated peer connections through the group chats, allowing participants to share experiences and support one another. Regarding the pacing and timing, family counseling sessions were modified by extending the phase of 6 counseling sessions in the original NYUCI, from 4 to 6 months. This strategy was adapted from

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the earlier adaptation of NYUCI targeting the Hispanic population [22], and NYUCI-ES applied a similar adaptation approach to accommodate participants' availability.

Context

For family counseling sessions, we used a broad definition of family. In response to implementation-related challenges involving participants who had family members eligible to join but preferred not to include them in the family sessions, we allowed participants to invite a range of individuals who had close bonds with them (ie, fictive kin). This range included family members or relatives living in other states or overseas, friends, neighbors, and local community organization staff participants whom they frequently relied on. These individuals shared similar cultural or situational backgrounds with the participants, which made their involvement feel natural and supportive.

The NYUCI was adapted for telehealth in Virginia and, in a pre-post study, demonstrated favorable outcomes, including reductions in caregivers' burden, depressive mood, and reactions to their care recipient's symptoms [20]. Similar to this adaptation, we offered counseling sessions either in person or online, as preferred, to accommodate participants' schedules and locations and to reduce the burden of attending in person. During implementation, we also used the aforementioned culturally familiar social media apps, such as WeChat or KakaoTalk, to communicate with participants more conveniently.

Additionally, we matched frontline team members who shared the same cultural and linguistic backgrounds as the participants. Before and during implementation, bilingual social workers and research assistants who were fluent in Chinese (Mandarin and Cantonese) or Korean and had in-depth knowledge about their respective cultures were hired. Social workers also received training in caregiving approaches specific to Chinese and Korean populations, thereby enhancing the effectiveness of culturally tailored counseling. Moreover, we collaborated with and maintained partnerships with community organizations that serve these populations in New York City. This partnership was sustained through occasional meetings with community partners or community advisory members, participation in community events, and the provision of educational presentations.

Relationship Fidelity and Core Elements

While integrating Korean and Chinese cultural values into the original NYUCI program, we made efforts to maintain the core concepts. First, during the preparation period, we conducted a focus group interview with 25 caregivers of people living with dementia (14 Chinese and 11 Korean) to explore their caregiving experiences and needs that could inform the adaptation of the intervention [10]. We also received consultation from community experts, including faculty members in academic institutions, clinicians, and community partners, through occasional meetings to improve recruitment and retention and to discuss adaptation strategies.

We also held weekly meetings with key team members, including the original intervention developer, lead counselor, research staff with expertise in Chinese or Korean culture, and social workers who mainly interacted with the participants. These meetings have been continued during the preimplementation and implementation processes. During the implementation period, frontline team members shared updates on recruitment, implementation, counseling sessions, and any challenges faced while communicating with participants. All team members discussed possible solutions during meetings or through email between meetings. The original program developer and senior counselor revisited examples that reflected local family structures based on their previous applications of the intervention, compared them with this study, and confirmed that adjustment of the content of sessions to reflect the cultural context was within the spirit of the original intervention's purpose. In addition, social workers responsible for counseling also received additional weekly clinical supervision sessions from a senior counselor with expertise in the original intervention to discuss participants' concerns or needs during the intervention and provide culturally aligned counseling while preserving the values and contents of the original interventions.

Engagement

We offered detailed explanations of the study's purposes, procedures, and expected outcomes in participants' preferred language to build trust and ensure participants' understanding and adherence to the NYUCI-ES. For example, to align with the core East Asian value of family harmony, we emphasized that the primary goal of counseling was to maintain and strengthen family harmony as well as the caregivers' own capacity. We also highlighted the potential benefits of counseling sessions, which are often unfamiliar in Chinese and Korean cultures, and personalized the topics that would be addressed in the counseling sessions. This effort was reiterated throughout the screening calls, baseline interviews, and initial individual and family counseling sessions by frontline team members. We also provided detailed information about the importance of RCTs. Participants tended to have limited familiarity with research and hesitated to join the study in case they would be assigned to the treatment group, potentially leading to scheduling conflicts and perceived burden. During the initial orientation session, we emphasized that assignment to the treatment or control groups would occur by chance (eg, "through the computer") rather than by participant choice or staff preference, and that this procedure is necessary to assess how effective the intervention would be for their health and to further provide evidence-based support for other Chinese and Korean dementia caregivers. Although a few participants initially expressed concerns about the RCT procedure, these concerns were addressed through repeated clarification of the rationale for the random assignment process.

In addition, we used a step-by-step communication approach to reduce apprehension and encouraged engagement, initially contacting them through text messages or email to introduce ourselves and the study. To enhance the relationship between research staff and participants, we maintained multiple, prolonged communications during screening calls, interviews, and counseling sessions. We also emphasized transparency by clearly stating our job titles and the roles of the intervention team to help participants understand how each team member could support them. Furthermore, we provided support and

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education for all participants by actively offering them support and engagement through social media platforms to maximize their access to the resources that we could provide and to make participants feel cared for and supported, strengthening the rapport between the study team, specifically, frontline team members. Finally, we provided compensation in the form of physical gift cards, offering US $50 per data collection at baseline and at 6-month and 12-month follow-ups. This compensation was to acknowledge caregivers' time and efforts, encouraging their consistent engagement and retention in this study.

Cultural Competence

To appropriately respect and adapt the intervention to Chinese and Korean culture, social workers provided a culturally tailored approach during counseling. In family counseling sessions, we adapted our approach by prioritizing practical caregiving skills, equipping caregivers with the tools they need to provide effective care, and focusing less on emotional discussions, considering their reluctance to open up and express themselves emotionally. In addition, we connected participants with community organizations that offer linguistically appropriate services, allowing them to receive more detailed guidance from experts such as elder law attorneys and social service agency staff fluent in their languages. These efforts were intended to reduce financial and language barriers and improve access to essential services.

We also respected participants' cultural values related to health and caregiving. While providing accurate information about dementia and its care, we honored participants' cultural beliefs, acknowledging and respecting the viewpoint that dementia and memory loss are natural aspects of aging. Additionally, we respected traditional family structures and communication patterns, acknowledging that open discussions about emotional issues might not always be the preferred approach.

Along with the written materials mentioned in the *Content* section, we used euphemized language during conversations to align with East Asian cultural beliefs. Specifically, we used terms such as "memory loss" instead of "dementia," "discomfort and unhappiness" instead of "mental health," "being uncomfortable" instead of "stigma," and "gaining a few more pounds than average" instead of "obesity." Finally, we prepared culturally related refreshments during visits to express respect and build interpersonal relationships. This small gesture not only helped foster trust and rapport with participants but also contributed to participant retention by making them feel more comfortable and understood by the intervention staff.

Discussion

Principal Findings

We identified cultural adaptation strategies to an evidence-based program as classified by the 5 adaptation elements of Day et al [2] and the timing and types of responses to adaptation from the FRAME [42]. Our description underscores the importance of cultural adaptation in dementia caregiver interventions, demonstrating how and when modifications in content, context, fidelity, engagement, and cultural competence are applied to enhance accessibility and relevance for Chinese and Korean American communities.

Unlike prior culturally adapted interventions, our approach is pivotal because we systematically adjusted and implemented counseling-based interventions, an approach that is relatively unfamiliar among Asian Americans, to fit the cultural and linguistic context of Korean and Chinese American groups. Asian Americans showed lower rates of mental health service utilization, driven by language barriers, stigma toward mental illness, limited culturally sensitive therapeutic options, and relationships between clients and health professionals [50]. Documentation of this adaptation process can be extended to cultural adaptation strategies applicable to community organizations and health care professionals in the mental health field, potentially contributing to reducing the mental health access gap in Asian communities.

Moreover, the NYUCI-ES applies a structured, theory-driven approach that integrates both the cultural adaptation framework [2] and parts of FRAME [42]. The framework of Day et al [2] highlights the multifaceted content-related changes involved in culturally adapting psychosocial interventions, whereas the FRAME brings attention to how and when the intervention adaptations occur across the implementation timeline. The integrated use of these frameworks allows for a systematic documentation of cultural adaptations throughout the implementation process. It can further provide an in-depth understanding of the cultural adaptation process in the NYUCI-ES, which was based not only on participants' individual and environmental factors but also on cultural considerations.

Moreover, the NYUCI-ES embeds deeper cultural constructs, such as familism, filial piety, and stigma, into the program's design, counseling process, and engagement strategies. Beyond preimplementation adjustments, NYUCI-ES uniquely documents ongoing, real-time adaptations informed by participant and community feedback. We also added culturally unique communication platforms for peer support and recognized "fictive kin" in family sessions. This work can move the field beyond stating that cultural tailoring matters to showing how it can be systematically and sustainably achieved.

Lessons Learned From the Cultural Adaptation Process

Content and context modifications used in our adaptation were similar to those used in other culturally adapted interventions targeting East Asian cultures [9,37-41], including language translation and considerations of participants' cultural values in program components and format. Approximately half of the Korean and Chinese American population whose origins are outside of the United States revealed limited English proficiency [51,52]. Considering the language barrier, providing information translated into the participant's familiar language is essential to providing adequate support based on their needs [53]. This strategy not only creates comfort and familiarity with the intervention but also builds a foundation for trust and engagement. To provide effective support that can have a positive impact on the physical and emotional health of

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caregivers, it is essential to take into account the recipients' cultural identity.

However, our adaptation process went beyond mere language translation. For instance, participants' hesitancy toward involving family members in counseling was due to cultural beliefs about caregiving as a personal duty rather than a responsibility to be shared by their families or external resources [10]. To mitigate their reluctance, we reframed culturally sensitive wording, emphasized family harmony, and provided primary caregivers with practical support. Additionally, allowing participants to invite their fictive kin with similar cultural and situational backgrounds to the family counseling sessions could broaden their informal support network. Partnerships with community-based organizations also provided valuable insights into recruitment and retention, effective communication with the target population, and the exchange of study information and community resources, enabling us to offer participants culturally relevant resources and support.

Maintaining fidelity to the original intervention components while incorporating cultural adaptations was a key theme of our study. By involving the original intervention developer and clinical supervisor with experts in East Asian culture throughout the whole process, we ensured that core elements were preserved while making necessary cultural adjustments before and during the implementation. This balance is critical for maintaining the intervention's evidence-based foundation while enhancing its cultural relevance.

Moreover, engagement strategies took into account the culturally grounded hesitancy in seeking help or sharing dementia care experiences with others [54]. A step-by-step approach with prolonged conversations with participants and financial compensation for completing assessments mitigated barriers to participation and fostered trust between participants and the intervention team.

Considering culturally rooted beliefs and norms is also important to sustain participants' engagement. Efforts to enhance cultural competence included adjusting counseling approaches to Eastern caregiving norms and family dynamics. By prioritizing family harmony and using culturally appropriate language, we could discuss sensitive topics in a way that resonated with participants' values and beliefs. Culturally adapted strategies are essential for recruiting and retaining individuals from diverse cultures to participate in research. The flexibility of the original NYUCI allowed us to provide person-centered, culturally tailored resources in participants' preferred language during counseling sessions. As the topics of the counseling sessions were based on participants' concerns or needs, it permitted ample flexibility to offer personalized support. This approach also fostered a stronger connection with the social worker providing counseling, which may have enhanced participant engagement and is anticipated to contribute to the overall effectiveness of the intervention.

In terms of the timing and types of response to adaptation, we used cultural adaptation strategies both proactively and reactively, before and during the study implementation. However, more reactive strategies were often conducted to increase participant engagement and to address participants' cultural beliefs and viewpoints on dementia care and intervention (ie, cultural competence). Whereas cultural adaptation approaches are prepared proactively to reflect the targeted cultural content and context, ongoing reactive adjustments during the implementation period are necessary to address unexpected challenges promptly in real-world settings [42]. At the same time, these adaptations should remain the core value and components of the original intervention [42]. Day et al [2] also emphasized the pivotal role of fidelity in culturally adapting interventions and the need for consideration of fidelity at every stage of the adaptation process. Hence, there is a need to facilitate activities that can strengthen fidelity not only through observation and self-reports but also through a fidelity checklist and the examination of how modifications influence the intervention outcomes [42].

Another key lesson from our study was the limited desire for psychological support among participants. For example, caregivers in our study tended to prioritize practical caregiving strategies, such as learning symptom management and resource navigation, rather than emotional or mental health support for themselves. Additionally, some caregivers believed that counseling was solely for individuals with psychological disorders. In East Asian cultures, mental health issues are often stigmatized, sometimes perceived as a sign of personal failure or weakness [55], and dementia is often misunderstood as a mental illness. This stigma, combined with limited family support systems and language barriers, made it challenging for caregivers to access resources [9,56]. By emphasizing practical caregiving strategies during counseling and gradually incorporating emotional support, we could help caregivers feel more comfortable seeking help. Reframing counseling as a resource for both caregiving skills and caregiver well-being and providing culturally competent community resources aligning with their language and beliefs may further reduce stigma through caregivers' willingness to accept concrete assistance. Furthermore, evaluating attitudes toward dementia throughout a study such as this could also help identify the effectiveness of our culturally adapted intervention in mitigating stigma and lowering barriers to intervention engagement.

Hesitancy to share personal experiences, which was a similar challenge addressed by Jang et al, could result from privacy concerns, fear of judgment, and limited familiarity with counseling among the East Asian population [55,57]. To address this, we encouraged participants to share their expectations and provide feedback during the counseling sessions, maintained regular contact with caregivers in the study via social media apps, built rapport through multiple interactions and clear explanations of staff roles, and kept encouraging caregivers to share their concerns and questions. By structuring discussions based on participants' concerns and actively facilitating conversations, rather than expecting caregivers to initiate discussions, our approach could improve engagement and make support more accessible for caregivers from Eastern Asian cultural backgrounds.

Strengths and Limitations

One of the distinctions of our adaptation strategy compared to other cultural adaptation studies is the flexible program delivery

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method. Considering the advancement of technology, using digital tools in dementia care has become inevitable [58]. In our adaptation of the NYUCI, we offered counseling sessions in person and through video or audio calls and modified the original intervention by integrating social media group support. These modifications are intended to help participants easily access culturally tailored resources and provide continuous peer support. Another strength is the active involvement of the original NYUCI developer and senior clinician in all phases to ensure maximum fidelity to the original while respecting and considering the cultural values of the target populations. This active engagement and supervision, both before and during the implementation, helped us make necessary cultural adaptations while preserving the original evidence-based intervention's principles. In addition, instead of focusing solely on language translation or surface-level modifications, our approach combined comprehensive and theory-based adaptations. By considering multiple cultural factors while maintaining the original NYUCI's structure, our intervention not only aligned with participants' needs but also maintained the integrity of the original program. Moreover, the adaptation process went beyond individual decisions and was conducted collectively through group discussions. This collaborative process highlights the interactive decision-making process while paying close attention to the experience and response from social workers and other study personnel who directly contact participants.

There are several limitations to our observations. One key issue was the overlap among the concepts of the 5 key elements, which made it difficult to delineate specific adaptation strategies. For example, hiring personnel with the same background and training them in the culturally tailored intervention approach is one of the "context" modifications. This suggests a need for further refinement of cultural adaptation frameworks to improve their practical application in intervention design and implementation. Second, this analysis relied mostly on internal team meetings and self-reports rather than direct participant perspectives through the interview recordings, which may limit the diversity of viewpoints represented. Owing to the fact that the study is not yet complete, the effectiveness of these adaptations on implementation and outcomes has not yet been assessed. Although the achievement of our recruitment goals [11] may be indirect evidence of our success in the cultural adaptation approach, it is warranted to evaluate the strategies for cultural adaptation in future research. In addition, this study's focus on specific subgroups of Asian caregivers in the New York City metropolitan area limits its generalizability to other subgroups of Asian Americans. There is a clear need for further research on other Asian subgroups and diverse geographical locations. Finally, as this is an ongoing study, we could not yet assess the effectiveness of the culturally adapted intervention. However, our approach already provides information to inform future development of culturally tailored dementia caregiver support programs. Assessment and refinement of these strategies will continue as we move forward.

Implications for Future Culturally Adapted Interventions

A lack of culturally and linguistically competent resources can exacerbate systemic health care barriers among Asian American communities [59], indicating the need for greater cultural inclusivity [10]. Strategies to address this gap include further development and refinement of guidelines for implementing culturally sensitive support based on evidence-based interventions, training professionals in cultural competency, and integrating community-based resources in all aspects of the endeavor [53]. Flexible delivery methods, including technology use, can also support individual needs across generations and geographic distances. Currently, there are limited guidelines and frameworks for culturally adapted interventions in dementia caregiving [2]. Integrating theoretical frameworks while adapting interventions based on a specific culture is necessary to ensure cultural relevance and program fidelity. Finally, continued evaluation and refinement of cultural adaptation strategies are important. Our ongoing RCT of the NYUCI-ES targets a large sample and provides year-long support for each participant. The description of adaptation strategies in this study will contribute to the growing literature on the long-term effects of culturally adapted, evidence-based interventions.

Conclusions

This study explored cultural adaptation strategies within an ongoing dementia caregiver intervention, NYUCI-ES, tailored to Chinese and Korean cultures. This approach can improve cultural sensitivity while preserving key components of an evidence-based intervention. Our future research will focus on evaluating the effectiveness of NYUCI-ES and the influence of adaptation approaches on participant outcomes and feedback. We anticipate that these findings will help guide the development of more inclusive and responsive caregiver support programs in dementia care.

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Data Availability

The authors do not report participants' data in this manuscript, and therefore, the preregistration and data availability requirements are not applicable.

Authors' Contributions

Conceptualization: EK (lead), BW (lead), JW (equal)
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Funding acquisition: BW (lead), MSM (equal)
Investigation: EK (lead), XQ (supporting)
Methodology: EK (lead), JW (supporting), WM (supporting)
Project administration: BW (lead), MSM (lead), EK (supporting)
Resources: EK (equal), BW (supporting), ITL (equal), MSM (supporting)
Supervision: BW (lead), CE (equal), MSM (lead)
Validation: XQ (equal), YP (equal), CE (supporting), MSM (equal)
Visualization: EK
Writing – original draft: EK (lead), JW (equal), XQ (equal), ITL (equal), YP (equal), WM (equal), JS (supporting)
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Conflicts of Interest

None declared.

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Abbreviations

FRAME: Framework for Reporting Adaptations and Modifications–Enhanced
NYUCI: New York University Caregiver Intervention
NYUCI-ES: New York University Caregiver Intervention–Enhanced Support
RCT: randomized controlled trial
TIDieR: Template for Intervention Description and Replication

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Changes in Internet Search Term Popularity in Elder Mistreatment (2018-2023): Infodemiology Study of Google Trends Data

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Abstract

Background: Elder mistreatment (EM) is a significant public health problem that is frequently underdetected and underreported. Insufficient public recognition and engagement have been hypothesized as one contributor to this underreporting; however, few data sources exist to quantify public awareness or engagement with EM at the population level.

Objective: This study examined relative internet search interest in EM compared with other forms of abuse (child abuse and domestic violence) in the United States using Google Trends data.

Methods: We analyzed Google Trends data to compare the Relative Search Index (RSI) for the terms “elder abuse,” “child abuse,” and “domestic violence” in the United States from December 2018 to December 2023. RSI values reflect normalized search activity relative to the maximum search volume within the specified period.

Results: Mean RSI values for “elder abuse” were substantially lower than those for “child abuse” (11.35 vs 50.21) and “domestic violence” (6.96 vs 63.50). Ad hoc tests for stationarity indicated that RSI values for all 3 terms remained stable over the 5-year study period. During Elder Abuse Awareness Month, RSI for “elder abuse” increased relative to “child abuse” and “domestic violence” by 8.3 and 5.7 points, respectively, compared with other months of the year.

Conclusions: Relative search interest in elder abuse appears to be persistently lower than that for child abuse and domestic violence, despite modest increases during Elder Abuse Awareness Month. Although Google Trends does not provide a validated measure of public awareness, search-based metrics such as RSI may offer a scalable, low-cost complement to traditional data sources for contextualizing public engagement with EM and informing future awareness, detection, and prevention efforts.

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KEYWORDS

elder abuse; elder maltreatment; elder neglect; Google Trends; abuse reporting; reports

Introduction

Elder mistreatment (EM) is generally defined as an intentional act or failure to act by a caregiver or another person in a relationship involving an expectation of trust that causes or creates a risk of harm to an older adult [1]. In the United States, up to 14% of adults older than 70 years have experienced some form of EM [2]. Most commonly, EM takes the form of neglect,

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financial abuse, and emotional abuse but can also include physical and sexual abuse, often with dire consequences including increased mortality risks [2-6]. Furthermore, elder financial abuse is estimated to cost billions of dollars per year [7]. This figure is particularly concerning given that financial abuse (similar to many forms of EM) is considered to be grossly underreported, with an estimate of only 1 in 24 cases being reported [7-9].

One hypothesized reason for underreporting includes insufficient public awareness of EM [10]. Prior research consistently characterizes EM as a hidden and underrecognized public health problem, shaped by stigma, dependency, fear of disclosure, and limited institutional detection pathways [5,11,12]. Because EM often occurs in private settings and survivors may be reluctant or unable to seek help, few cases come to the attention of formal service systems [12]. Furthermore, prevention and response efforts are constrained by gaps in public awareness and societal recognition, limiting sustained attention and coordinated intervention [13]. Together, prior literature suggests that low public visibility of EM reflects not only prevalence or legal frameworks but also broader societal and structural barriers to recognition, providing critical context for the comparatively low levels of EM-related Google search activity examined in this study.

Despite ongoing public awareness campaigns [14-16], we are unaware of any nationally representative polls or studies that measure public awareness of EM. This lack of data is a barrier to quantifying current levels of public awareness of EM and evaluating the impact of campaigns, programs, and policies intended to increase public awareness. Although administrative data sources (eg, National Incident-Based Reporting System) might seem suitable for this purpose, existing crime and reporting systems do not comprehensively capture several of the most prevalent forms of EM, such as neglect and emotional or psychological abuse, limiting their usefulness for assessing population-level awareness or incidence. As a novel, *preliminary step* toward overcoming this barrier, we used publicly available data from Google Trends (Google LLC) to explore relative Google search volumes for EM. The objectives of these analyses are to demonstrate the use of Google Trends as a convenient, cost-effective method for establishing and comparing baseline measures of relative search interest (RSI), including in relation to other forms of abuse (ie, child abuse and domestic violence). We also aim to explore the utility of Google Trends to inform future efforts designed to increase public awareness and engagement around EM.

Methods

We used publicly available data from Google Trends [17] to explore Google search patterns related to EM. Google Trends data are accessed through a web application that allows users to specify 1 or more search terms of interest along with location information and a timeframe of interest. We queried Google Trends for data on the relative volume of Google searches in the United States each week for the term “elder abuse” during a 5-year period from December 2018 to December 2023. The term “elder abuse” was specifically used to reflect its colloquial understanding that encompasses various forms of EM, a term often favored in academia [18]. As a sensitivity analysis, we also examined Google Trends data for the term “elder mistreatment.” RSI values for this term were zero for nearly the entire study period, with the exception of 2 isolated weeks. This pattern suggests minimal public-facing search activity for “elder mistreatment.” Accordingly, we retained “elder abuse” as the primary search term to reflect common public use rather than conceptual equivalence with the broader academic construct of EM.

For a given Google Trends query, a graph similar to Figures 1 and 2 is generated that shows the relative popularity of one or more search terms in the specified location and timeframe. Each data point on the graph can be downloaded in tabular form for further analysis and reflects the number of searches for the term relative to the total number of Google searches in the same location and timeframe. Importantly, Google Trends queries do not provide the absolute number of searches for each term (eg, 4000 searches for the term “elder abuse” in week X); instead, they return a normalized relative search index (RSI) for each search term, which is an integer value that exists on a scale from 0 to 100, where each data point is divided by the highest point or 100 [19]. In other words, a value of 100 represents the term’s peak popularity within the search period but reveals nothing about total search volumes.

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Figure 1. Plot of the Google Trends Relative Search Index for the search terms “elder abuse” and “child abuse” in the United States from December 2018 to December 2023.

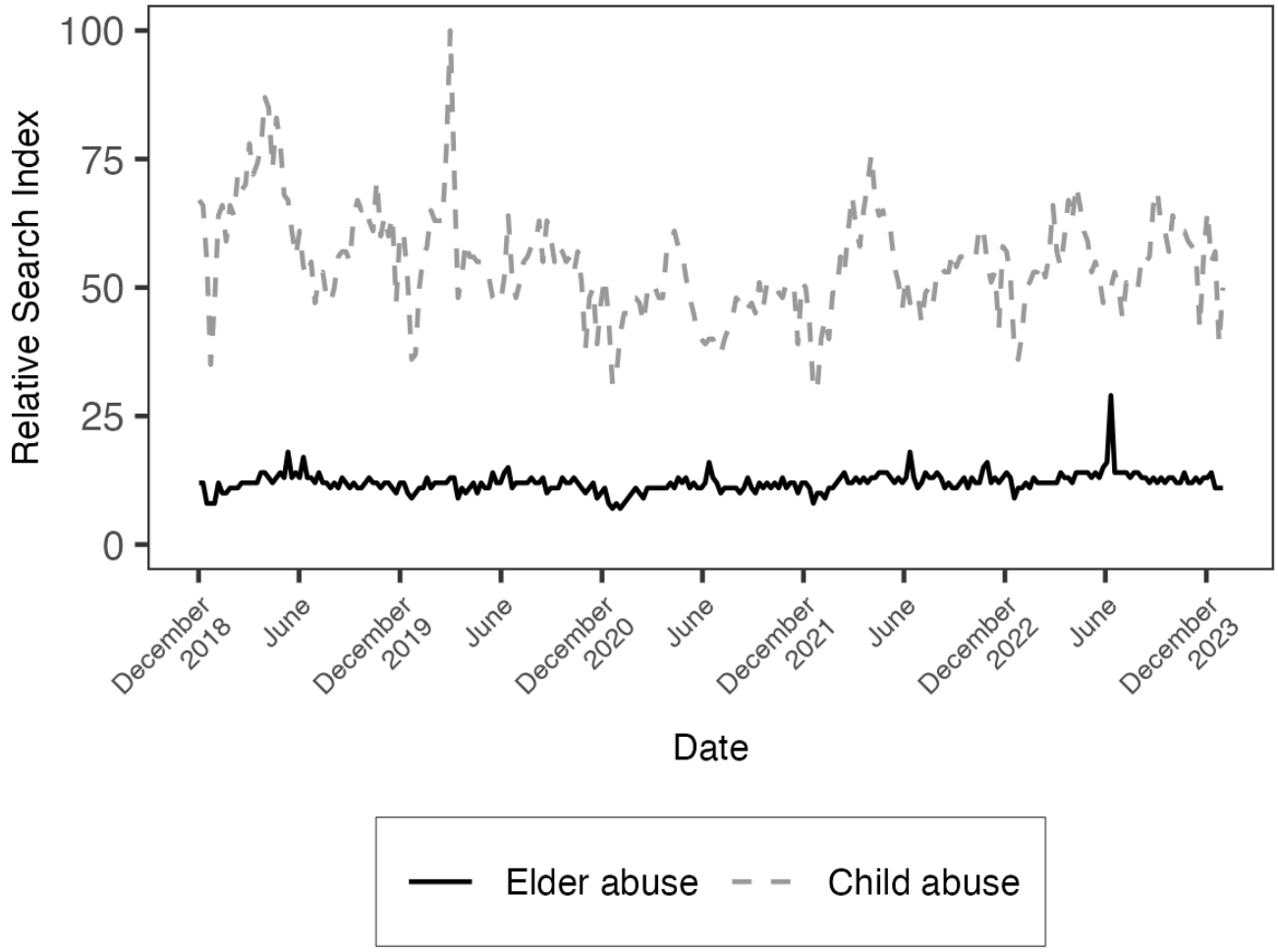

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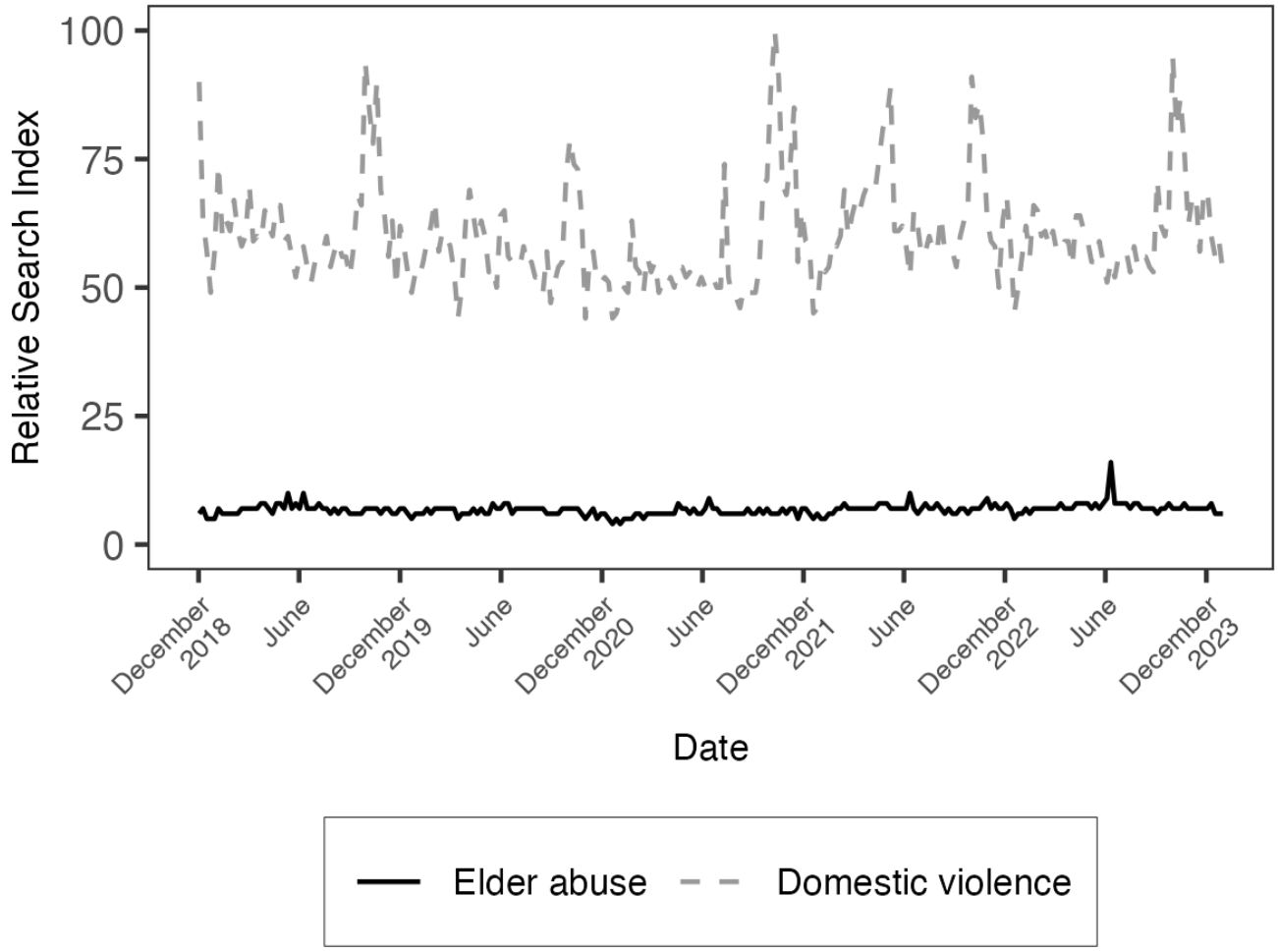
Figure 2. Plot of Google Trends Relative Search Index for the search terms "elder abuse" and "domestic violence" in the United States from December 2018 to December 2023.



It is also possible to query Google Trends data for multiple search terms simultaneously. Doing so still does not produce any information about the absolute volume of searches for either term, but it does provide information about the relative search volume of the terms, for example, that one search term is twice as popular as another search term for a given place and time. We compared the RSI of "elder abuse" to the RSIs of "child abuse" and "domestic violence" during the same timeframe. The additional context allowed us to draw conclusions about the relative search volume of elder abuse compared to other forms of abuse.

As a further exploratory step, we investigated whether the relative search popularity of elder abuse compared to other forms of abuse varied during periods of heightened awareness about elder abuse, specifically Elder Abuse Awareness Month, which happens every June. For each comparison to elder abuse, we created a long-form data set of the RSIs by week with an indicator for whether the abuse type was elder abuse or another abuse type. We additionally created an indicator for Elder Abuse Awareness month. To estimate the relative change during Elder Abuse Awareness month, we ran generalized estimating equations including the indicators of abuse type, Elder Abuse Awareness Month, their interaction, and controlling for year as a fixed effect. The coefficient for the interaction can be interpreted as the difference in RSI between elder abuse and the comparison abuse type during elder abuse month relative to the difference during other months of the year. All models clustered SEs at the year level to account for potential autocorrelation. Sensitivity analyses logging RSI values found similar results to our primary specification and are not discussed further.

Results

When comparing elder and child abuse at the national level, the search term "elder abuse" had a mean RSI of 11.35 (SD 1.91) with a peak RSI of 26.00, whereas "child abuse" had a mean RSI of 50.21 (SD 10.14) with a peak popularity of 100.00 (Figure 1). When comparing elder abuse and domestic violence, the search term "elder abuse" had a mean RSI of 6.96 (SD 1.15) with a peak popularity of 16.00, whereas "domestic violence" had a mean RSI of 63.51 (SD 8.96) with a peak popularity of 100.00 (Figure 2). While short-term fluctuations were observed, ad hoc tests for stationarity indicate that baseline search interest trends were stable throughout the 5-year study period.

The results of our exploratory analyses found statistically significant changes in the difference in RSI by abuse type during Elder Abuse Awareness Month. Compared to other months of the year, the RSI for "elder abuse" increased from an estimated 11.2 points to 13.23 points, while the RSI for "child abuse" fell from an estimated 50.7 points to 44.5 points, resulting in a net increase of 8.3 points for the RSI of "elder abuse" during Elder

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Abuse Awareness month (β=8.29, 95% CI 5.70-10.88; Z=6.27; *P*<.001). A similar pattern was observed comparing "elder abuse" to "domestic violence." Compared to other months of the year, the RSI for "elder abuse" increased from an estimated 6.9 points to 8.1 points, while the RSI for "domestic violence" fell from an estimated 63.9 points to 59.4 points, resulting in a net increase of 5.7 points for the RSI of "elder abuse" during Elder Abuse Awareness month (β=5.72, 95% CI 2.55-8.90; Z=3.54; *P*<.001). Notably, these changes were driven largely by a reduction in the relative search volumes for "child abuse" and "domestic violence," and not by the relatively small increase in RSI for "elder abuse." In both cases, the RSI for "elder abuse" remained substantially lower than its comparators.

Discussion

Principal Findings

EM is an important and pervasive public health problem that is exacerbated by chronic underdetection and underreporting. Insufficient public awareness of EM is one hypothesized reason for its underdetection and underreporting [2]. Our results provide preliminary evidence of the following: (1) Google Trends may feasibly be used to measure the RSI of EM, (2) the RSI for EM is lower than it is for child abuse and domestic violence, (3) the RSI of EM remained relatively unchanged between December 2018 and December 2023, and (4) the RSI for "elder mistreatment" was essentially zero during the study period.

Measuring Public Awareness May Be Feasible With Google Trends

Currently, there are no nationally representative polls or studies that measure public awareness of EM. This gap perpetuates barriers in assessing efforts to increase public awareness of EM and ultimately its detection, intervention, and prevention. Ideally, public awareness of EM would be rigorously measured longitudinally, at the state and national levels, in a population-representative way. However, such studies typically require significant planning, resources, and political prioritization. In the meantime, other less-rigorous measures of public awareness can serve as an important stopgap. To the best of our knowledge, this is the first study that objectively compares the RSI of EM to the RSI of other forms of abuse including child abuse and domestic violence, albeit with some important limitations.

While the technical definition of what Google Trends data measure (ie, the RSI) is clearly defined, we recognize the challenge of identifying a single term—such as "public awareness"—that accurately captures its practical meaning, particularly when attempting to distinguish "public awareness" from related constructs such as "public interest." To the best of our knowledge, empirically robust methodological evidence does not currently exist to support the claim that Google Trends RSI is a valid and reliable proxy measure of public awareness. Nonetheless, a growing number of published studies have used Google Trends data in this way [20-22]. We posit that Google Trends RSI likely reflects search activity among individuals who possess some awareness of EM *and* have sufficient interest and access to seek information using Google. However, more rigorous research, which is beyond the scope of this study, is needed to empirically evaluate this interpretation.

If one is willing to accept that Google search volume is a useful proxy measure of —or at least closely associated with—public awareness, then this study provides an example of how the public awareness of EM may feasibly be estimated by the relative popularity of related search terms over time. In fact, such methods are increasingly represented in the literature as a measure of public awareness for topics ranging from concussions in Australia following the National Brain Injury Awareness Week to rheumatic disease in relation to high-profile diagnoses among celebrities and the use of glucagon-like peptide 1 agonists such as "Ozempic" for cosmetic weight loss [23-25].

The RSI for EM Is Lower Than That for Other Forms of Abuse

In this analysis, the RSI for EM was lower than for other forms of abuse. Despite the fact that estimates of the past year prevalence of child abuse are comparable to EM (14% for child abuse [26] and 10% for EM [23], about 1.4 times higher), the public used the search term "child abuse" approximately 4 times as often as "elder abuse" during the 5-year study period. Similarly, although the estimated past year prevalence of domestic violence (7.3% of women and 6.8% of men [27]) is roughly 1.4 times lower than the past year prevalence of EM, the search term "domestic violence" was used approximately 9 times as often as "elder abuse" during the 5-year study period, as measured by Google Trends RSI. Extreme caution is warranted in interpreting these comparisons. The accuracy and comparability of these past year prevalence estimates are questionable for a number of reasons; however, the magnitude of the discrepancy between the underlying prevalence of these abuse types and their Google search volumes is consistent with the results we would expect to find if the public were indeed less aware of EM than other forms of abuse. That said, baseline differences between EM and other forms of abuse may influence public awareness and search term popularity and are worthy of inclusion in future studies exploring public awareness of EM.

RSI Remained Relatively Unchanged Over Time

The results of this study also suggest that, aside from a modest relative increase during the World Elder Abuse Awareness Month, the relative popularity of Google searches for "elder abuse" remained relatively unchanged over the study period. However, we did observe a stable, non-zero level of public awareness, which could serve as a baseline to assess future public health interventions, including changes in EM policies and the implementation of public awareness campaigns. Although Google Trends data alone do not provide information about the causes of this trend, its stability suggests that short-term or sporadic efforts may not be sufficient to sustain meaningful change, as acute events such as increased media coverage may only produce superficial short-lived spikes in searches. Instead, public policies backing sustained efforts over an extended period may be needed to shift societal attitudes about aging and increase awareness of EM. That said, RSI is a single crude measure that reveals nothing about the intentions behind an individual's search nor about their level of awareness. Future research should further explore event-driven analyses

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(eg, news stories involving celebrities, World Elder Abuse Awareness Day, and the US Postal Inspection Service campaign) to investigate how the public responds to these campaigns and events reflected by specific keyword searches (eg, financial fraud or survivor services). Analyses should also seek to determine if these increases are sustained over time. For example, future interrupted time series analyses could provide valuable insight into the short- and long-term effects of these campaigns.

Similarly, the near absence of search activity for the term "elder mistreatment," contrasted with sustained search interest in "elder abuse," may reflect a disconnect between academic terminology and public-facing language. Although "elder mistreatment" is widely used in research and policy contexts to capture a broader range of harmful experiences, the public may be more familiar with or responsive to the term "elder abuse." This observation has potential implications for the design and evaluation of public awareness campaigns, suggesting that efforts to increase recognition and engagement may benefit from careful consideration of terminology. Future research could examine how language choice influences public attention, search behavior, and engagement with prevention and reporting resources.

Limitations

Using normalized, relative search term popularity (ie, RSI) derived from Google Trends represents a novel approach for examining patterns related to EM. However, this approach has notable limitations. A clear, practical definition of what RSI measures, backed by empirical evidence, does not currently exist. Framing RSI as a more easily understood construct (eg, public awareness) is appealing and could improve the practical value of studies such as this one; however, generating the empirical evidence needed to support such a framing is beyond the scope of this study. Furthermore, Google Trends cannot tell us about people who are aware of EM but not interested, nor those who are aware and interested but lack digital literacy or internet access. It also cannot identify those who are unaware of EM, regardless of whether they might become interested if awareness were increased. Future studies that attempt to tease apart the nuances of what Google Trends data are measuring in the context of family violence may prove to be valuable to the field.

A second major limitation is that the RSI provided by Google Trends represents the relative popularity of a search term in relation to the total number of searches within a specified time and location; absolute numbers of searches are not available. Furthermore, the RSI does not include search term variations such as misspellings, synonyms, or translations into other languages, nor does it address overlap in colloquial understandings among these terms, for example, in cases where one may categorize EM as a form of domestic violence and search for that term instead. Future studies would benefit from broadening the number of related terms to better capture these contributory permutations. Moreover, integrating complementary methods of measuring public awareness of EM (social media chatter, signal detection, etc) would provide an even greater insight into how the public expresses both awareness and interest in EM.

Additionally, our comparisons of "elder abuse" to "child abuse" and "domestic violence" used mean RSIs over a 5-year period. Short-lived spikes in popularity could potentially coincide with discrete efforts to increase public awareness of EM (eg, World Elder Abuse Awareness Day), significant current events associated with increases in EM (eg, the COVID-19 pandemic), or headline news stories about allegations of EM perpetrated against celebrities such as Stan Lee, Mickey Rooney, Brooke Astor, and Richard Simmons. However, despite observing periodic spikes in popularity, we found no sustained changes for any search terms of interest throughout the study period as measured by tests for stationarity. This suggests that any potential influences on EM awareness during the study period were likely transient.

Despite these limitations, there is growing evidence that Google Trends data have the potential to serve as a useful measure of public awareness in some circumstances [28,29].

Public Health Implications

EM is a significant public health problem that remains underdetected and underreported, in part due to limited public recognition and engagement. Using Google Trends data, this study demonstrates a persistent disparity in relative search interest between EM and other forms of abuse such as child abuse and domestic violence. This methodological approach is novel in its direct comparison of internet search behavior across different forms of abuse. By directly comparing internet search behavior across these forms of abuse, this work introduces a novel, scalable approach for contextualizing public engagement with EM over time and geographic location.

Although Google Trends does not provide a validated measure of public awareness, search-based metrics such as RSI may offer a low-cost and widely accessible complement to traditional surveillance systems, particularly in settings where population-representative measures are unavailable. Over time, such approaches could help inform the targeting and evaluation of public awareness campaigns, generate hypotheses about gaps in engagement, and support broader efforts aimed at improving detection, prevention, and response to EM.

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Data Availability

The datasets generated or analyzed during this study are available from the Google Trends website [29].

Authors' Contributions

Conceptualization: MBC, ML
Data curation: MBC, ML, NS
Formal analysis: ML
Funding acquisition: MBC, ML, KL-H, JB, CEZP
Methodology: MBC, ML
Supervision: MBC, ML
Writing – original draft: NS, ML, KL-H, OO, RC, JB, CEZP, DH, MBC
Writing – review & editing: NS, ML, KL-H, OO, RC, JB, CEZP, DH, RS, MBC

Conflicts of Interest

None declared.

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Abbreviations

EM: elder mistreatment
RSI: relative search index

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Predictors of Psychiatric Emergency Department Visits Following Inpatient Discharge: Secondary Analysis of a Stepped-Wedge Cluster Randomized Trial

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Abstract

Background: The period following discharge from psychiatric inpatient care represents a critical transition phase marked by heightened vulnerability to relapse, including increased risks of emergency department (ED) utilization. Understanding the risk factors for ED utilization after hospital discharge will help identify individuals who should be targeted for enhanced follow up care in the community.

Objective: This study aimed to examine the sociodemographic and clinical factors associated with psychiatric ED utilization within six months of discharge from inpatient psychiatric care among individuals assigned to different postdischarge interventions. The goal is to identify high-risk groups to inform targeted follow up strategies and enhance transitional care planning.

Methods: This study analyzed secondary data from a pragmatic stepped-wedge cluster-randomized trial which recruited patients across ten health care sites in Alberta, Canada, from March 2022 to February 2024. For the primary study, a total of 1098 psychiatric inpatients were allocated to one of three post-discharge conditions: treatment as usual (TAU), SMS, or SMS plus peer support (SMS+ PS). Sociodemographic and clinical data were collected at discharge. ED visits 6-months postdischarge were recorded. χ^2 tests identified variables associated with ED utilization. Significant predictors were entered into a logistic regression model to determine adjusted odds ratios (ORs) and 95% CIs.

Results: Of the 1098 participants, demographic and clinical variables were examined for association with mental health ED visits at 6-months post discharge. Univariate analysis identified six significant predictors: age, ethnicity, relationship status, employment, housing status, and prior ED use. Logistic regression analysis identified several predictors of mental health ED visits 6-months postdischarge. Compared to participants under 25 years, those aged 26 - 40 was less likely to revisit the ED (OR 0.66, 95% CI 0.46 - 0.95), as were those over 40 years (OR 0.58, 95% CI 0.37 - 0.92). Individuals identifying as mixed or other ethnicity were less likely than White people to return to the ED (OR 0.52, 95% CI 0.28 - 0.96). Unemployed participants had higher odds of ED use than those employed (OR 1.66, 95% CI 1.18 - 2.34). Prior ED attendance was the strongest predictor (OR 2.45, 95% CI 1.03 - 5.80). Housing status showed varied but nonsignificant effects.

Conclusions: This study highlights key demographic and clinical factors influencing psychiatric ED use following inpatient discharge. The findings emphasize the importance of targeted transitional care interventions, particularly for high-risk groups such as younger, unemployed, and previously ED-utilizing individuals, and support the integration of scalable approaches like SMS and peer support into discharge planning.

Trial Registration: ClinicalTrials.gov NCT05133726; https://clinicaltrials.gov/study/NCT05133726

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KEYWORDS

psychiatric discharge; emergency department visits; transitional care; supportive text messaging; peer support; mental health

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Introduction

The transition period following discharge from psychiatric inpatient care is a critical and vulnerable phase in a patient's recovery journey. This timeframe is frequently associated with heightened risks of symptom relapse, increased psychiatric emergency department (ED) visits, and hospital readmissions [1,2]. Recently discharged psychiatric patients often encounter considerable difficulties, including inadequate access to appropriate outpatient mental health services, limited social support, and fluctuating symptom severity, which contribute to their increased utilization of emergency mental health care services [3-5]. In Canada, approximately 15% - 25% of psychiatric inpatients are readmitted within 30 days of discharge, and ED revisit rates approach 40% within the first year [6,7]. These repeat encounters expose patients to additional stress, disrupt recovery trajectories, and are consistently linked to poorer long-term outcomes.

Emergency department visits for mental health-related concerns have progressively increased over the past decade, creating substantial burdens on health care systems worldwide [6,7]. Frequent ED presentations not only escalate health care costs but also negatively impact the quality of life and psychological stability of patients and their families [8,9]. System-level impacts include overcrowding in EDs, resource diversion from acute medical emergencies, and increased strain on community-based mental health providers who must accommodate unplanned demand. This illustrates how rising ED visits contribute to bottlenecks across the continuum of psychiatric care. Specifically, in Alberta, provincial reports have noted rising psychiatric ED presentations and high rates of relapse following discharge, underscoring the urgency of identifying context-specific predictors that can inform local service planning [10].

Recent research has focused on identifying factors associated with increased ED utilization post discharge. Sociodemographic factors such as age, ethnicity, employment status, and housing conditions have been found to significantly influence patients' likelihood of returning to EDs. Clinical predictors include primary psychiatric diagnoses (eg, schizophrenia, personality disorders, substance use disorders), comorbid substance misuse, and high symptom burden at discharge. Social risk factors, including unemployment, unstable housing, and weak social support, also increase vulnerability [7,11,12]. Studies have consistently demonstrated that younger age, unstable housing, unemployment, and severe psychiatric conditions, particularly personality disorders and substance use disorders, are linked to higher rates of repeated ED visits [13-15]. However, despite a growing number of international studies, relatively few investigations have examined these predictors in Canadian settings, and even fewer within the province of Alberta. Given Alberta's health care delivery structures and recent adoption of digital and peer-based transitional supports, understanding predictors in this setting addresses a critical gap in the literature.

Alongside digital solutions, several nondigital transitional interventions have been trialed internationally to reduce psychiatric readmissions and ED visits. These include assertive community treatment, intensive case management, crisis residential services, and structured follow up appointments scheduled shortly after discharge [7]. While effective in some contexts, such approaches can be resource-intensive and difficult to scale, creating interest in low-cost, technology-enabled alternatives such as supportive text messaging.

To address these challenges, various transitional interventions have been developed, incorporating both technological and peer-support elements designed to enhance outpatient continuity and support [7,16]. Among these, supportive text messaging (SMS) interventions have gained traction due to their accessibility, affordability, and potential to maintain continuous engagement with patients after discharge. In this program, participants receive supportive messages designed by clinicians, containing motivational content, coping strategies, and reminders to adhere to treatment plans. Messages are automated but overseen by mental health professionals to ensure quality and appropriateness. Preliminary evidence suggests that such interventions can effectively reduce feelings of isolation, improve adherence to outpatient care plans, and potentially decrease ED presentations and hospital readmissions [17,18]. Additionally, integrating peer support alongside SMS interventions has been proposed as a promising approach, leveraging lived experiences and empathetic interactions to bolster patient engagement and enhance psychosocial recovery outcomes. In our study, peer supporters were trained individuals with lived experience of mental illness and recovery, offering empathetic, recovery-oriented support via in-person and virtual contact. Despite the promise of these innovative transitional strategies, evidence remains unclear regarding their long-term efficacy in reducing psychiatric emergency visits and promoting sustained clinical improvement. Additionally, questions persist regarding the relative efficacy of standalone SMS interventions compared to combined SMS and peer-support programs in reducing frequent ED presentations. Importantly, prior work has rarely connected the study of predictors of ED use to the context in which these transitional interventions are being implemented, leaving uncertainty about whether high-risk groups identified through predictive modeling are the same groups most likely to benefit from SMS and peer support.

The purpose of this study was to examine the sociodemographic and clinical factors that predict psychiatric ED utilization within six months following discharge from inpatient psychiatric care among participants who were assigned to different treatment groups (treatment as usual, TAU, SMS and SMS+ peer support, PS). By situating this analysis within the broader context of transitional interventions currently being tested in Alberta, the study both addresses a clear research gap and provides evidence to support refinement of local service delivery. By identifying high-risk groups for post-discharge ED visits, the study aims to support the development of targeted follow-up strategies and inform transitional care planning. Findings from this study will help health care providers and policy makers refine and optimize transitional care strategies, ultimately aiming to reduce the burden on emergency psychiatric services and improve patient-centered recovery trajectories.

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Methods

Study Setting and Design

This study analyzed secondary data from pragmatic stepped-wedge cluster-randomized controlled trial which recruited patients across ten major inpatient psychiatric units in Alberta, Canada, from March 2022 to February 2024. While the primary study is focused on cost effectiveness analysis related to the impact of supportive text messaging with and without peer support interventions on acute health services utilization for patients discharged from inpatient psychiatric hospitals, this analysis focuses solely on identifying the sociodemographic and clinical predictors of psychiatric ED visits within six months following discharge. Participants were randomized into three groups: TAU (control group, standard postdischarge care), SMS (TAU plus daily supportive text messages), and SMS+ PS (TAU plus SMS plus structured peer support). As a secondary analysis, the range of available predictors was constrained by the data collected in the parent trial. Several potentially important clinical and social variables, such as diagnose severity, comorbid substance use, treatment adherence, and outpatient service engagement were not available, limiting the ability to adjust for confounding. In addition, the stepped-wedge design, while pragmatic, introduces potential clustering and time effects (eg, site-level changes, policy shifts) that may influence outcomes independent of individual predictors. These factors should be considered when interpreting causal inferences from this analysis.

Data Collection and Inclusion Criteria

Recruitment was conducted face-to-face, and nursing managers and staff supported recruitment efforts by identifying eligible patients preparing for discharge from inpatient psychiatric units. Potential participants were provided with detailed study information, including informational leaflets. Interested patients gave written informed consent and completed a self-administered questionnaire on tablet devices. The survey, hosted on REDCap, a secure, web-based platform designed for research surveys and databases [19], collected sociodemographic data (eg, age, gender, ethnicity, relationship status, employment, education, housing status) and clinical characteristics (eg, psychiatric diagnoses at discharge, anxiety, depression, and well-being levels). All participants who consented were included in the subsequent analyses. All sociodemographic and clinical variables used in this analysis were self-reported by participants at the time of discharge; diagnostic categories were confirmed against medical discharge notes when available, and information about ED visits were collected from the records of Alberta Health Service.

Inclusion and Exclusion Criteria

Participants were required to have a diagnosed mental health condition, be preparing for discharge from an inpatient psychiatry unit, be aged 18 years or older, and possess a mobile device with an active phone number. They were also required to have the ability to receive text messages, read English texts, and provide written informed consent. Patients planning to travel out of town during the 6-months follow-up period were excluded due to the nature of one of the interventions, a peer support service, which necessitated in-person meetings to provide lived experiences shared by peer support workers. The research team collected participants' phone and health care numbers as primary identifiers. Operational definitions were applied to key variables to ensure clarity and reproducibility. Housing status was categorized as owning, renting, living with family or friends, or unstable housing (eg, shelter, street, couchsurfing, other). Employment status was grouped into employed, unemployed, student, retired, or other. Prior ED use was defined as any psychiatric ED visit in the six months prior to discharge. These categorizations align with prior studies on ED utilization [20-22].

Missing Data

We followed an intention-to-treat (ITT) approach. For participants with at least one follow-up assessment, the Last Observation Carried Forward method was used to retain them in the analysis. When later follow ups were missing, the last available data point was carried forward, thereby avoiding excessive attrition and preserving statistical power. No more complex imputation methods (eg, multiple imputation) were applied in order to maintain transparency and interpretability of results.

Ethical Considerations

This study received ethical clearance from the Health Research Ethics Board of the University of Alberta (Ref # Pro00111459) and operational approval from the regional health authority. All participants provided written informed consent prior to participation. Participants' confidentiality was protected throughout the study; all identifying information was stored separately from research data and accessible only to authorized research personnel. Participants did not receive monetary compensation for participation.

Sample Size Calculation

The sample size calculation was based on the 28,571 psychiatric discharges recorded in Alberta in 2018. Using a CI of 95% and a margin of error of ±3%, a minimum required sample size of 1036 participants was estimated. This number was rounded slightly upwards to provide a conservative estimate, ensuring adequate statistical power to detect meaningful group differences and maintain representativeness for the general psychiatric inpatient population [10].

Outcome Measures

Generalized Anxiety Disorder Scale (GAD-7)

Anxiety symptoms were assessed using the Generalized Anxiety Disorder 7-item scale (GAD-7), a validated self-report measure. This scale comprises seven items evaluating the frequency and severity of anxiety symptoms over the preceding two weeks, rated on a 4-point Likert scale (0 = "Not at all" to 3 = "Nearly every day"). Scores range from 0 to 21, with higher values indicating more severe anxiety [23]. The GAD-7 demonstrates strong psychometric validity, including a sensitivity of 89% and specificity of 82% for generalized anxiety disorder at the recommended cut-off score of 10, high test-retest reliability (intraclass correlation, ICC=0.83), and excellent internal consistency (Cronbach α=0.92) [23,24].

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Patient Health Questionnaire (PHQ-9)

Depressive symptoms were measured using the Patient Health Questionnaire-9 (PHQ-9), a self-administered scale based on Diagnostic and Statistical Manual of Mental Disorders, 4th Edition, DSM-IV criteria for major depressive disorder. It consists of nine items scored from 0 (“Never”) to 3 (“Nearly every day”), yielding total scores between 0 and 27 [25,26]. A score of ≥10 indicates clinically significant depression. Severity categories include mild (5), moderate (10), moderately severe (15), and severe (20). The PHQ-9 exhibits good internal consistency (Cronbach α=0.85), robust convergent validity with related measures, and high sensitivity and specificity (approximately 88%) at the ≥10 cut-off [25-27].

World Health Organization-Five Well-Being Index (WHO-5)

The World Health Organization-Five Well-Being Index (WHO-5) assessed participants’ overall mental well-being. Developed by the World Health Organization, this brief measure includes five positively phrased items rated from 0 (“Not at all”) to 5 (“All the time”), standardized to a 0 - 100 scale. Scores below 50 indicate poor emotional well-being and necessitate further assessment. WHO-5 shows excellent internal consistency (Cronbach α=.90), strong convergent validity with the PHQ-9 (r=–0.73), and high sensitivity (93%) and specificity (83%) for detecting depression [28,29].

Brief Resilience Scale (BRS)

Resilience, defined as the capacity to recover from stress and adversity, was assessed using the Brief Resilience Scale (BRS), a validated six-item self-report instrument. Each item measures the ability to bounce back from difficult experiences, rated on a 5-point Likert scale (1 = “Strongly disagree” to 5 = “Strongly agree”). Scores are calculated as the mean of all items, with higher scores indicating greater resilience [30]. The BRS has demonstrated solid psychometric properties, including good internal consistency (Cronbach α=0.80 - 0.91) and test-retest reliability (r=0.69 over one month). It has shown good construct validity with positive correlations with coping resources and negative correlations with perceived stress and depression, supporting its use in clinical and research contexts [30].

Statistical Analysis

Statistical analyses were performed using SPSS (version 25; IBM Corp) [31]. Initially, univariate analyses were conducted using χ^2 tests to identify demographic and clinical factors significantly associated with mental health ED visits at 6-months post-discharge. Variables that were significantly associated with ED visits were then entered into a multivariable logistic regression model to predict ED utilization at the 6-months follow-up. Model fit was evaluated using the χ^2 test, Cox and Snell R^2, and Nagelkerke R^2. Odds ratios (ORs) with 95% CIs were calculated to quantify the strength and direction of associations between predictor variables and ED visits. Statistical significance was set at P<.05. While ORs and P values provide estimates of association, the modest R^2 values signal that unmeasured variables contribute substantially to ED utilization risk, and findings should therefore be interpreted as indicative rather than determinative predictors.

Results

Univariate Analysis

Table 1 presents the findings from a univariate analysis exploring the relationship between ED visits at 6-months postdischarge and a range of demographic and clinical variables. Fourteen factors were assessed using χ^2 tests (ie, study clusters, age, gender, ethnicity, education level, relationship status, employment status, housing status, primary mental health diagnosis, GAD-7, PHQ-9, WHO-5, BRS, prior 6-month ED visits), of which six demonstrated statistically significant associations. Participants younger than 25 years were more likely to report ED visits compared to older age groups. Individuals identifying as White people had higher rates of ED utilization relative to other ethnicities. Relationship status was also significant; single participants exhibited a greater likelihood of ED visits than those who were married, separated, divorced, or widowed. Employment status emerged as a notable factor, with unemployed individuals more frequently reporting ED use than those employed, retired, in school, or in other categories. Housing status also showed a significant association, with participants living with family or friends demonstrating the highest rates of ED visits at 6-months. Additionally, prior ED use within 6-months before discharge strongly predicted subsequent utilization, reinforcing the role of historical service use in forecasting future demand.

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Table . Sociodemographic and clinical characteristics of participants at discharge from inpatient psychiatric units in Alberta, Canada.

Variables	Have had no ED[a] visits at 6-months, n (%)	Have had ED visits at 6- months, n (%)	Total participants, n (%)	χ^2	*P* value
Age (years)				8.79	.01[b]
18 - 25	253 (34.2)	142 (43.0)	395 (36.9)		
26 - 40	257 (34.7)	108 (32.7)	365 (34.1)		
>40	230 (31.1)	80 (24.2)	310 (29.0)		
Ethnicity				9.85	.04[b]
White people	458 (61.9)	203 (61.5)	661 (61.8)		
Indigenous	60 (8.1)	38 (11.5)	98 (9.2)		
Black people	86 (11.6)	30 (9.1)	116 (10.8)		
Asian	77 (10.4)	44 (13.3)	121 (11.3)		
Mixed/Other	59 (8.0)	15 (4.5)	74 (6.9)		
Relationship status				10.0	.04[b]
Married/Partnered/Common-law	232(31.4)	79 (23.9)	311 (29.1)		
Single	420 (56.8)	213 (64.5)	633 (59.2)		
Separated or divorced	60 (8.1)	23 (7.0)	83 (7.8)		
Widowed	10 (1.4)	2 (0.6)	12 (1.0)		
Prefer not to say	18 (2.4)	13 (3.9)	31 (2.9)		
Employment status				19.90	<.001[b]
Employed	239 (32.3)	78 (23.6)	317 (29.6)		
Unemployed	362 (48.9)	206 (62.4)	568 (53.1)		
Student	64 (8.6)	23 (7.0)	87 (8.1)		
Retired	52 (7.0)	11 (3.3)	63 (5.9)		
Other	23 (3.1)	12 (3.6)	35 (3.3)		
Housing status				13.14	<.001[b]
Own home	162 (21.9)	49 (14.8)	211 (19.7)		
Rented accommodation	224 (30.3)	121 (36.7)	345 (32.3)		
Live with family or friends	315 (42.6)	132 (40.0)	447 (41.8)		
Couchsurfing/Shelter/Street/Other	38 (5.1)	28 (8.5)	66 (6.2)		
Prior 6-months ED visits				17.60	<.001[b]
No	345 (45.5)	110 (32.1)	455 (41.3)		
Yes	413 (54.5)	233 (67.9)	646 (58.7)		

[a]ED: Emergency Department.

[b]Statistically significant values.

Logistic Regression Analysis Results

Six variables identified as statistically significant in the univariate analysis were included in a logistic regression model to examine predictors of ED visits 6-months post-discharge. This variable-selection strategy was chosen to maximize model parsimony and reduce the risk of overfitting, given the relatively modest sample size for regression analysis. To confirm robustness, an alternative model including all measured demographic and clinical variables was also tested. The pattern of results was consistent: age, employment, and prior ED use remained the strongest predictors, while nonsignificant

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predictors did not meaningfully improve model fit. We therefore report the more parsimonious model below. The model was statistically significant, χ^2_{31}=63.0, P<.001, indicating a good fit for distinguishing between individuals who did and did not access ED services after discharge. It accounted for 5.9% (Cox and Snell R^2) to 8.3% (Nagelkerke R^2) of the variance and correctly classified 68.1% (748/1098) participants. These values indicate that while the model improves classification compared to chance, it explains only a modest proportion of overall variance, underscoring the multifactorial and complex nature of ED utilization.

As shown in the model (Table 2), age was a significant predictor: individuals aged 26‐40 (OR 0.66, 95% CI 0.46‐0.95) and those over 40 (OR 0.58, 95% CI 0.37‐0.92) were significantly less likely to revisit the ED than those 25 and younger. The effect sizes suggest that being older reduced the odds of repeat ED use by approximately one-third to almost one-half, which is clinically meaningful given the high service burden of younger patients. Ethnicity also played a role, with participants identifying as “mixed or other” being less likely than White people to return to the ED (OR 0.52, 95% CI 0.28‐0.96). Although the overall effect was modest, this finding highlights possible protective factors among minority or mixed-ethnic groups that warrant further exploration. Employment status emerged as a strong predictor: unemployed individuals were significantly more likely to report ED visits than those employed (OR 1.66, 95% CI 1.18‐2.34). This effect size indicates that unemployment increased the likelihood of repeat ED visits by roughly two-thirds, a difference that is substantial in both clinical and policy contexts.

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Table . Logistic regression model showing predictors of psychiatric emergency department visits within six months post-discharge among patients enrolled in TAU[a], SMS, and SMS+PS[b] groups.

Variables	B	SE	Wald statistic (*W*)	*df*	*P* value	Odds ratio (95% CI 95% for EXP(B)[c])
Age (years)						
18-25	__[d]	—	6.77	2	.03[e]	—
26-40	−0.42	0.19	5.04	1	.03[e]	0.66 (0.46-0.95)
>40	−0.55	0.23	5.46	1	.02[e]	0.58 (0.37-0.92)
Ethnicity						
White people	—	—	10.292	4	.04[e]	—
Indigenous	0.11	0.24	2.89	1	.65	1.12 (0.70-1.78)
Black people	−0.41	0.24	3.07	1	.09	0.66 (0.41-1.07)
Asian	0.29	0.22	1.69	1	.19	1.33 (0.86-2.07)
Mixed/Other	−0.66	0.32	4,31	1	.04[e]	0.52 (0.28-0.96)
Employment status						
Employed			12.2	4	.02[e]	—
Unemployed	0.51	0.17	0.86	1	<.001[e]	1.66 (1.18-2.34)
Student	−0.1	0.3	0.11	1	.75	0.91 (0.50-1.64)
Retired	−0.07	0.39	0.03	1	.86	0.93 (0.43-2.02)
Other	0.09	0.47	0.03	1	.86	1.09 (0.43-2.74)
Housing status						
Own home			12,20	3	.01[e]	—
Rented accommodation	0.34	0.22	2.3	1	.13	1.41 (0.91-2.18)
Live with family or friends	−0.25	0.25	1	1	.32	0.78 (0.48-1.27)
Coach surfing/ Shelter/Street/Other	0.38	0.34	1.28	1	.26	1.46 (0.76-2.83)
Prior 6-month ED[f] visits						
Had prior 6-month ED visits	0.89	0.44	4.12	1	.04[e]	2.45 (1.03-5.80)
Constant	–1.41	0.63	4.97	1	.03[e]	0.24[d]

[a]TAU: Treatment as usual

[b]PS: peer support.

[c]EXP(B): Exponentiated coefficient (odds ratio)

[d]Not applicable.

[e]Statistically significant *P* value.

[f]ED: Emergency department.

Housing status also contributed meaningfully to the model. Compared to individuals who owned their homes, those renting (OR 1.41, 95% CI 0.91 - 2.18), living with family or friends (OR 0.78, 95% CI 0.48 - 1.27), or in unstable housing conditions such as couch surfing or homelessness (OR 1.46, 95% CI 0.76 - 2.83) showed varied but nonsignificant likelihoods of ED utilization. Although these estimates did not reach statistical significance, the directionality of effects is consistent with prior literature linking housing instability with increased ED reliance. Notably, prior ED visits in the 6-months before discharge significantly predicted future ED use (OR 2.45, 95% CI 1.03 - 5.80), indicating that individuals with previous ED use were more than twice as likely to return post discharge. This strong association reinforces prior ED utilization as a key risk marker for repeat presentations and highlights its potential utility in risk stratification tools.

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Discussion

Principal Findings

The present study evaluated factors associated with mental health emergency department visits among psychiatric patients within 6-months post discharge, emphasizing demographic and clinical predictors. The analysis revealed that age, ethnicity, employment status, housing status, and prior ED utilization significantly influenced ED revisits, offering critical insights for enhancing transitional care programs aimed at reducing recurrent ED visits among psychiatric patients.

Age was a significant predictor of ED use, with participants aged 26 - 40 and those over 40 being significantly less likely to revisit the ED compared to those under 25 years. This finding is consistent with previous literature indicating that younger adults often face increased challenges following psychiatric discharge due to limited coping mechanisms, developmental transitions, and weaker social support systems [32,33]. Specific challenges include difficulties navigating health care systems independently, greater likelihood of unstable housing or employment, and higher prevalence of comorbid substance use, all of which may exacerbate reliance on emergency services. Younger adults may also be less engaged with primary care and community follow-up, increasing vulnerability to crisis presentations. From a service-planning perspective, these findings suggest that younger patients should be proactively flagged for additional follow-up, aligning with risk stratification models increasingly promoted in mental health policy.

Regarding ethnicity, the study found that participants identifying as mixed or other ethnic groups were significantly less likely to revisit the ED within 6-months post-discharge compared to White participants. This result contrasts with some prior studies that have reported higher service utilization among minority groups due to barriers in outpatient care and stigma [34,35]. However, it aligns with other literature suggesting that cultural resilience, extended family support, or reliance on community-based coping strategies may buffer the need for acute service use [36,37]. Cultural perceptions of mental illness, such as framing psychiatric distress through spiritual or community-based lenses, may also influence patterns of help-seeking. While these factors may lower ED utilization, they also risk masking unmet needs if formal care is underutilized. Understanding these protective mechanisms could inform the design of culturally tailored outreach and transitional supports.

Employment status significantly influenced ED utilization: unemployed individuals were 1.66 times more likely to return to the ED compared to those who were employed. This result aligns with previous findings suggesting that unemployment is associated with higher psychiatric symptom burden and greater use of acute care services, likely due to financial strain, reduced access to regular health care, and lack of routine [38,39]. These findings support the integration of vocational rehabilitation and employment-focused interventions into post-discharge plans to enhance stability and reduce emergency service dependence. Embedding employment support into transitional interventions such as SMS and peer support could increase both engagement and impact, particularly among high-risk unemployed groups.

Housing status contributed to the model, but there was no significant difference between any of the housing options and home ownership. Compared to individuals living with family or friends, participants who owned their homes exhibited a slightly lower likelihood of returning to the ED (OR 0.78; 95% CI 0.48 - 1.27). In contrast, those living in rented accommodations (OR 1.41; 95% CI 0.91 - 2.18) and those in unstable housing conditions, such as shelters, couch surfing, or homelessness (OR 1.46; 95% CI 0.76 - 2.83), tended to show higher odds of ED visits within 6-months post-discharge. Although these differences did not reach statistical significance, the pattern suggests that housing stability may influence health care utilization. These findings align with existing literature indicating that insecure housing is associated with increased acute service use and mental health deterioration [20,21]. As such, future research should continue to investigate housing as a key social determinant of health and explore its potential role in discharge planning and ED prevention strategies. Housing should therefore be treated as a critical social determinant of psychiatric outcomes, and future intervention studies in Alberta should integrate housing supports alongside psychosocial care in discharge planning.

Perhaps most notably, prior mental health ED utilization strongly predicted future psychiatric ED revisits within 6-months of discharge. Participants with a history of ED attendance within the 6-months preceding their hospital discharge were significantly more likely to revisit the ED post-discharge compared to those without previous ED visits. This result aligns closely with existing literature emphasizing that previous emergency health care utilization is among the strongest indicators of subsequent ED reliance [40,41]. Frequent ED use often reflects unresolved or inadequately managed psychiatric and medical conditions, suggesting the presence of underlying chronic, complex health needs that persist despite hospitalization [6]. Addressing these unmet needs through coordinated care management and targeted intervention post-discharge is critical for reducing future emergency visits and improving overall mental health outcomes [6,35]. In practice, this supports the implementation of “high-utilizer” pathways that provide more intensive follow-up for patients with repeated ED use, a model already being piloted in some Canadian areas.

Although the logistic regression model was statistically significant and correctly classified 68.1% of cases, the amount of variance explained was modest (5.9% Cox and Snell R^2; 8.3% Nagelkerke R^2). This suggests that many important factors influencing ED use post-discharge were not captured in the model. Existing literature points to additional variables such as psychiatric diagnosis, substance use, medication adherence, co-occurring physical conditions, trauma history, and access to outpatient mental health services as critical influences on ED utilization [22,42,43]. Social determinants of health, including transportation barriers, social isolation, and stigma, may also play a significant role [44]. Rather than undermining the model, this limitation highlights the multifactorial nature of psychiatric crises and underscores the need for multi-level, biopsychosocial approaches to prediction.

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Integrating across these findings, a picture emerges of intersecting social and clinical vulnerabilities: young age, unemployment, unstable housing, and prior ED use cluster together to identify a subgroup of patients at highest risk. These overlapping factors should not be addressed in isolation but through coordinated transitional care packages that combine psychosocial support, housing assistance, vocational services, and scalable interventions such as SMS and peer support.

The study findings have several clinical and policy implications. Discharge planning should incorporate risk stratification protocols that take into account factors such as age, housing status, and prior ED use. Tailored interventions, such as job placement assistance for unemployed individuals, supported housing programs for those experiencing instability, and enhanced follow-up for frequent ED users could help reduce avoidable ED visits. Integrating low-barrier, scalable solutions like supportive text messaging (SMS) and peer support services may also contribute to improved continuity of care. Prior studies have demonstrated the feasibility and acceptability of SMS-based interventions in postdischarge mental health care, offering a low-cost approach to maintaining patient contact, monitoring well-being, and providing timely support [45,46]. Peer support, while variably effective depending on delivery and patient engagement, remains a promising adjunct when implemented with appropriate oversight [45,46]. Future research should build on these findings by: (1) incorporating additional clinical and social predictors such as diagnosis severity, substance use, and medication adherence; (2) testing predictive models within culturally diverse subgroups to explore differential effects; and (3) evaluating how SMS and peer support interventions may moderate the risks identified in high-risk groups. Structured, mixed-methods designs may be especially useful in capturing patient perspectives on these mechanisms.

Limitations

Several limitations must be acknowledged when interpreting the study findings. First, the modest variance explained by the logistic regression model (5.9% to 8.3%) suggests that additional unmeasured factors may contribute significantly to mental health ED revisits. These may include the severity of psychiatric conditions, comorbid medical disorders, medication adherence, or social determinants such as trauma history and stigma. In particular, clinical information such as symptom severity ratings, comorbid substance use, and adherence to prescribed treatments was not available in this dataset, which may have led to residual confounding and underestimation of the true strength of some predictors. Additionally, adherence and engagement with the SMS and peer support interventions were not tracked. As this was a secondary, intention-to-treat analysis, differences in exposure or participation (“dosage”) could not be assessed, which may have influenced post-discharge outcomes.

Second, our reliance on self-reported data introduces the potential for recall bias, which may affect the accuracy of participants’ responses, particularly regarding sociodemographic details and prior ED utilization. Although recall bias is difficult to quantify, prior studies suggest that retrospective reporting of service use may underestimate utilization, meaning that the observed associations with prior ED visits could in fact be conservative.

Third, although we captured a wide range of clinical and psychosocial variables, we did not assess whether participants had a regular general practitioner or how frequently they accessed primary care services. This is a critical limitation, as regular contact with a primary care provider has been shown to reduce unnecessary ED visits and support better outpatient continuity of care in psychiatric populations [47,48].

Fourth, the stepped-wedge design of the parent trial introduces potential clustering and time-related biases. Site-specific differences in resources, staffing, or policy changes occurring during the staggered rollout could have influenced both predictors and outcomes, limiting the ability to attribute findings solely to individual-level factors. While the design increased external validity by reflecting real-world conditions, it also constrained variable selection and confounder control.

Lastly, while our sample was drawn from multiple health care sites across Alberta, the generalizability of our findings may be limited to similar health care settings with comparable service delivery models and population demographics. Replication of this work in other provinces and internationally would help determine the transferability of identified predictors across health systems.

Conclusion

This study underscores the complex and multifactorial nature of emergency department utilization following discharge from psychiatric inpatient care. Key predictors of post-discharge ED visits included younger age, White ethnicity, unemployment, housing instability, and prior ED use. These findings emphasize the importance of identifying high-risk individuals and implementing tailored, evidence-based interventions during the transition from hospital to community care. At the same time, the modest variance explained by the regression model indicates that these predictors capture only part of the risk profile, and results should be interpreted with caution rather than as definitive determinants of ED use.

Proactive strategies, such as risk stratification, targeted psychosocial support, and integration of digital tools, may reduce mental health ED recidivism, improve continuity of care, and alleviate pressure on emergency services. In particular, SMS and peer support represent low-cost, scalable approaches that could be embedded into discharge planning, especially for groups identified as higher risk. While our study was not designed to evaluate intervention effects directly, situating predictors within this transitional care context strengthens the clinical and policy relevance of the findings.

It is important to emphasize that the primary aim of this secondary analysis was to identify predictors of psychiatric ED visits, not to assess intervention efficacy. Findings therefore apply to patients randomized to TAU, SMS, or SMS+ PS, and should not be generalized to all psychiatric patients presenting to EDs. As such, the results are best viewed as hypothesis-generating and useful for refining risk stratification and tailoring transitional interventions in Alberta’s mental health system.

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Given the limited predictive power of the current model and the omission of several important variables, future research should expand predictor sets to include illness severity, comorbidities, treatment adherence, and outpatient engagement. Cross-provincial and international replication will also be essential to establish generalizability beyond the Alberta health system.

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Data Availability

The datasets used or analyzed during the current study are available from the corresponding author on reasonable request.

Conflicts of Interest

None declared.

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Abbreviations

BRS: Brief Resilience Scale
ED: emergency department
GAD-7: Generalized Anxiety Disorder 7-item scale
ICC: intraclass correlation
ITT: intention-to-treat
OR: odds ratio
PHQ-9: Patient Health Questionnaire-9
PS: peer support
TAU: treatment as usual
WHO-5: World Health Organization-Five Well-Being Index

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Community Experiences of Social and Nonmedical Gender-Affirming Care: Interview Study Among Transgender and/or Nonbinary Persons

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Abstract

Background: Access to care that affirms one's entire self is essential, especially for gender-diverse individuals. Gender-affirming care includes medical, social, and nonmedical supports to affirm gender identity.

Objective: This study qualitatively examined the importance of social and nonmedical gender-affirming services as described by gender-diverse community members.

Methods: Thematic analysis was conducted on qualitative data from 5 participants (3 rural and 2 urban; 2 with doctoral-level education and 3 health professionals) with experiences accessing gender-affirming care in Nova Scotia, Canada, between October 2023 and November 2023.

Results: Participants included transgender and/or nonbinary individuals who highlighted the significance of social and nonmedical gender-affirming care over traditional medical interventions. Themes included the centrality of belonging, the use of online spaces such as TikTok for gender affirmation, and the emotional impact of barriers such as cost and safety concerns. Four of 5 participants emphasized the importance of social and nonmedical gender-affirming care over medical interventions. Participants stressed the importance of fostering a sense of belonging and accessing supportive communities, which is crucial in navigating transphobic environments without support. Many felt abandoned by public systems and resorted to passing as cisgender due to barriers such as cost in accessing gender-affirming resources. Internet platforms such as TikTok provided valuable guidance, supplementing limited access to medical gender-affirming care. Participants emphasized a crucial need for health care providers to understand basic gender-affirming care, including respect for preferred pronouns and gender identities.

Conclusions: This study found that members of the gender-diverse community significantly value social and nonmedical gender-affirming care services with respect to their well-being. The findings underscore the complex interplay among social support, health care access, and resilience in transgender and/or nonbinary individuals' lives. This work can aid in exploring how best to educate health care providers in gender-inclusive care and enable increased access to all forms of care that can help affirm an individual's gender.

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KEYWORDS

gender-affirming care; social support; health equity; rural health; inclusive health care

Introduction

Access to care that affirms an individual's gender identity is fundamental. Gender-affirming care encompasses a wide range of medical, social, and nonmedical services essential for supporting one's gender identity [1]. These services include hormone therapy, surgeries, mental health support, voice training, and other medical interventions, but they also extend to social and nonmedical supports that are equally crucial, such as gear and feelings of belonging [1,2]. It is important to recognize that what may be considered cosmetic or aesthetic for cisgender individuals can be gender-affirming and vital for gender-diverse individuals [3]. For example, clothing, hairstyling, name changes, and gender marker alterations are all powerful affirmations of identity that often carry profound psychological and social benefits for those within the gender-diverse community.

Despite the critical importance of these services, access to medical gender-affirming care is often limited by systemic barriers such as long wait times, restrictive insurance policies, and a lack of knowledgeable health care providers [1,4-6]. As a result, many gender-diverse individuals turn to social and nonmedical resources to express and validate their identities in everyday life [1]. These forms of care can offer more immediate and accessible means of gender affirmation, helping individuals

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navigate a society that may not always recognize or understand their needs.

Historically, social and nonmedical gender-affirming services have been underrecognized and undervalued by health care providers and insurance coverages, creating barriers to accessing care [1]. Without these supports, many individuals experience increased risk of mental health challenges, discrimination, and social isolation [7,8].

This study aimed to qualitatively examine the importance of social and nonmedical gender-affirming care services in supporting gender identity as experienced by members of the gender-diverse community. By uplifting the lived experiences of individuals, this research sought to highlight the impact of these services on well-being while advocating for additional inclusive policies recognizing the diverse needs of the gender-diverse community.

Methods

Study and Context

In Nova Scotia, Canada, gender-diverse individuals continue to face systemic inequities in health care access [6]. In 2021, the Statistics Canada Census of Population began collecting gender diversity data, revealing that Nova Scotia had the highest proportion of transgender and nonbinary people aged ≥15 years in the country [9]. Despite progress in provincial policies, accessing gender-affirming services such as hormones and surgery remains challenging, particularly outside urban centers. Barriers include not only discrimination and stigma but also a lack of knowledgeable health care providers and logistical hurdles such as lengthy wait times, geographic distance, and financial costs [6]. These challenges are exacerbated for individuals in rural or underserved areas, making the need for alternative support systems such as social and community-based services increasingly critical. This context underscores the importance of understanding how community-based and social supports function as vital sources of affirmation. This study aimed to explore the role of social and nonmedical services in affirming gender identity in a context in which traditional medical gender-affirming care is limited or difficult to access.

Study Design

This study used qualitative methodologies to gather in-depth insights into the experiences of individuals navigating gender-affirming care. An advisory group composed of representatives from community-based organizations that advocate for gender-diverse individuals was established to provide input throughout the research process. This group played a key role in ensuring that the study's design, recruitment strategy, and research materials were culturally sensitive and aligned with the needs of the gender-diverse community. The advisory group also assisted in refining the interview questions.

Data Collection

Five semistructured interviews were conducted using probing techniques in a conversational manner. Participants needed to have accessed gender-affirming care in Nova Scotia within the previous 5 years. Participants also had to be aged >18 years and speak and understand English. Interviews were conducted via Zoom (Zoom Video Communications) to increase accessibility in rural areas. Each interview lasted an average of 55 (SD 14) minutes and was audio recorded and transcribed verbatim. Recruitment took place between August 2023 and November 2023 in the province of Nova Scotia. Participants were recruited through snowball sampling initiated via community organizations that serve gender-diverse individuals. Recruitment notices were shared on organizational social media and on university bulletin boards. Interested individuals contacted the research team directly to ensure confidentiality. Recruitment continued until no new themes emerged from the data. Although the final sample consisted of 5 participants, this number was sufficient given the narrow focus of the study, the relative homogeneity of participant experiences, and the high information power of each interview. Consistent with qualitative guidance, information-rich samples with focused aims may reach saturation with small numbers when participants share similar contextual experiences (eg, access to gender-affirming care within the same province) [10,11]. After the fifth interview, no new codes or themes emerged, and all themes were consistently represented across participants. For these reasons, thematic saturation was considered achieved. In recognition of the potential emotional and psychological impact of discussing sensitive topics, participants were offered the opportunity to have a support person from the gender-diverse community present during the interviews to promote a sense of safety and comfort.

Data Analysis

Thematic analysis [12] was used for the data, with the NVivo software (Lumivero) facilitating the coding and organization of themes. A codebook was developed through a combination of inductive and deductive coding approaches, ensuring that themes emerged both from the data themselves and from preexisting findings in the literature. Data were analyzed solely by the author. During codebook development, the author sought consultation from 2 qualitative research experts who reviewed a subset of coded excerpts and provided feedback on code clarity, organization, and analytic coherence. Their role was advisory rather than analytic; they did not perform independent coding, conduct parallel analysis, or participate in theme generation. This consultation was used to refine the codebook and strengthen analytic rigor and transparency. Example codes included "community as safety," "passing for protection," "provider respect," and "online peer education."

Ethical Considerations

This study received ethics approval from the Dalhousie University Department of Research Ethics Board in Social Sciences in August 2023 (2023-6700). This study adhered to ethical guidelines regarding informed consent, confidentiality, and participant well-being throughout all stages of the research process. All participants provided oral informed consent before taking part, including consent for audio recording and use of anonymized quotes. Participants were fully informed of their rights, including the ability to withdraw from the study at any time without consequence. Data were anonymized and stored on encrypted, password-protected drives accessible only to the

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research team. Participants did not receive an honorarium for taking part.

Reflexivity

As a heterosexual, cisgender woman with lived experience in rural communities, the author recognizes the privileges she carries in both her gender identity and sexual orientation, which have largely aligned with societal norms and expectations. Her experiences navigating health and social systems have not been shaped by the same systemic barriers or identity-based marginalization that gender-diverse individuals often face. Growing up in a rural setting, the author has witnessed the limitations of local health care systems, particularly regarding specialized and inclusive services. However, she has not had to seek out gender-affirming care or worry that her identity might be invalidated or misunderstood in those settings. Engaging with this research required continuous reflection on these differences and a commitment to listening deeply and respectfully to participants' narratives. The author approached this work with humility, striving to center the voices and lived experiences of gender-diverse individuals and avoid imposing assumptions shaped by her own positionality.

Results

Five participants took part in semistructured individual interviews. Three participants identified as living in a rural area, whereas 2 lived in an urban area. One urban-dwelling participant also had experience accessing services in a rural location. Two participants indicated that they had a doctorate-level education, and 3 participants were trained in health care delivery (or allied health care delivery). All participants identified as transgender and/or nonbinary.

Thematic analysis identified four major themes: (1) belonging as care, (2) barriers and safety in accessing resources, (3) informal digital support networks, and (4) provider competency as affirmation. These themes were consistently represented across participants, with minor variation based on rural vs urban context.

All participants highlighted the significance of social and nonmedical aspects of gender-affirming care in supporting their identity. They discussed the significance of services such as gender-affirming gear, hair alteration, and the ability to access spaces that foster a sense of community. Participants stressed that the sense of belonging outweighs the importance of obtaining medical gender-affirming care. Participants consistently emphasized that a sense of belonging within supportive communities was the foundation of their well-being, often surpassing the importance of medical interventions. For all 5 participants, belonging operated as both a psychological anchor and a survival mechanism in contexts in which formal systems felt unsafe or exclusionary. Rural participants, in particular, described community connection as a form of "protective care" against the social isolation and transphobia of their environments. Urban participants also highlighted belonging but described it more as an avenue for identity expression and solidarity than for safety. Across participants, belonging was experienced as daily, relational affirmation—something that no prescription or surgical procedure could substitute. As one participant explained,

> *Medical care isn't going to make my life amazing—it's finding people that I can connect with that can offer circles of support where we love each other.*

Feelings of systemic abandonment were common, with 4 participants describing how limited institutional support forced them to rely on self-devised or peer-provided means of protection. "Passing" as cisgender emerged not as a cosmetic preference but as a vital survival strategy in unsafe public or work environments. Rural participants described the physical act of blending in—through clothing, binding, or padding—as a form of harm reduction in communities where visibility could invite violence or exclusion. One participant explained,

> *Just having that ability to make my pelvis appear more female, it feels important to me, just from a safety standpoint. Blending in, in environments where you're not necessarily going to be among supportive people, is important.*

This underscores how nonmedical gender-affirming gear operates at the intersection of safety, identity, and accessibility. The high cost of such gear further amplified participants' sense of inequity, reinforcing how financial and systemic barriers shape daily decisions about safety and self-expression. One participant stated,

> *It's really hard to explain to a straight person that experience of not having access to trans tape, which is not cheap.*

The emotional toll of these compromises—needing to hide to survive—was a recurring theme that participants linked to chronic anxiety and diminished well-being. Participants shared that being unable to access these resources can exacerbate feelings of dysphoria, which in turn can lead to severe mental health challenges, including suicidal ideation:

> *The amount that helps with your mental health and well-being to prevent anything from suicide to just literally living every day feeling like shit is enormous.*

Four of 5 participants, particularly those residing in rural communities or facing long wait times for specialist referrals, described turning to online spaces such as TikTok and Reddit for gender-affirming guidance. These participants noted that virtual communities compensated for geographic isolation and distrust of local health care providers. In contrast, the 2 urban participants, who had intermittent access to affirming clinicians, reported using online resources primarily for emotional validation rather than clinical information. Participants described how online platforms helped them navigate the complexities of their gender identity, find resources, and connect with others facing similar challenges. Many found that social media platforms such as TikTok played a key role in their journey. One participant shared how TikTok guided them in using nonmedical transgender tape for the first time, providing tutorials and tips that were crucial for them:

> *I just immediately went to TikTok and there's videos with tutorials with different people with different sizes*

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> *and just like, here's some tips and tricks [...] I know it's good to know because I wish someone would have told me this earlier.*

This informal support from the internet was often more useful than professional care. One participant explained how they found more helpful information about speech therapy online than from their private therapist:

> *I found out more [speech therapy techniques] doing research on the internet and following people... That was a much more useful resource for me.*

All participants emphasized that provider competency extended beyond medical expertise to include relational respect and cultural humility. While none expected every clinician to specialize in transgender health, participants unanimously stated that the absence of basic gender awareness—such as using correct pronouns or avoiding invasive curiosity—communicated a deeper message of disregard. For some, these encounters shaped whether they would seek care again. Two participants described leaving appointments feeling "invisible" or "unsafe," whereas others recounted moments of relief when a provider simply affirmed their identity without hesitation. This theme reveals that, for gender-diverse individuals, the therapeutic value of health care interactions often lies not in clinical outcomes but in the acknowledgment of personhood. Inadequate provider training was seen as a systemic issue that perpetuates mistrust and withdrawal from formal care systems, further driving reliance on informal networks.

Discussion

Principal Findings

This study reviewed the significant role of social and nonmedical gender-affirming care services in supporting the gender identity of members of the gender-diverse community. The findings suggest that informal and digital networks are not merely substitutes for unavailable formal medical services but also function as parallel systems of affirmation. Participants sought information online not only because of geographic or financial barriers but because these spaces offered identity-affirming interactions often missing in clinical encounters. Thus, the internet served as a trusted site for peer-led knowledge exchange where the authenticity and relatability of the advice outweighed formal credentialing. This illustrates how mistrust in institutional systems drives the creation of community-based health ecologies that are adaptive, resilient, and grounded in lived experience. The main findings reveal that participants highly valued social and nonmedical aspects of gender-affirming care such as gender-affirming gear, hair services, and supportive communities. These findings highlight the importance of fostering a sense of belonging and supportive communities, which are crucial in navigating transphobic environments, particularly in rural settings with limited access to traditional medical gender-affirming care. This aligns with previous research showing that social support is a critical factor in the mental health and well-being of members of the gender-diverse community. For instance, Glynn et al [13] demonstrated that social connections are protective against psychological distress. Additionally, Durwood et al [14] highlighted that social support from family and friends is associated with lower rates of internalizing symptoms such as depression and anxiety among transgender youth.

Participants in our study reported the need to build connections with other gender-diverse individuals who are going through similar experiences. Supportive networks were perceived as essential in mitigating the failures of public systems, particularly in rural areas where access to gender-affirming services is sparse. These findings align with the literature [15-17] and the gender affirmation framework [13], which posits that strong support systems can foster resilience when faced with social oppression. Participants in this study noted that being in a space in which they felt affirmed in their gender identity led to a reduced risk of experiencing suicidal ideation, illustrating the profound psychological impact of social affirmation.

Furthermore, this study sheds light on the innovative strategies used by gender-diverse individuals to access nonmedical gender-affirming care, particularly through the internet. The use of internet platforms such as TikTok was frequently mentioned as a means of seeking guidance and support, filling the gap created by the unavailability of traditional medical care in rural regions. This finding is supported by Karim et al [18], who found that online communities offer critical resources and spaces for gender affirmation. The digital world can allow individuals to create a sense of community and belonging even in the absence of physical proximity to others.

One crucial aspect of this study is the importance of health care providers having a foundational understanding of gender-affirming care, including knowledge of social and nonmedical aspects. Respect for proper pronouns and gender identities should be considered the bare minimum for creating inclusive and supportive environments. This may involve understanding the broader context of the struggles faced by gender-diverse people, especially in rural areas. Previous studies [19-21] have emphasized the need for health care systems to evolve to meet the needs of this community. Ignorance or neglect of these essential practices can further marginalize gender-diverse individuals, reinforcing the systemic barriers they face. By integrating these social and nonmedical aspects of care into standard practice, health care providers can contribute to a more inclusive and supportive environment for all gender-diverse individuals.

These findings illuminate the interplay between structural exclusion and community innovation—as formal health care systems remain inaccessible or invalidating, gender-diverse individuals generate alternative infrastructures of care through peer-to-peer support, online platforms, and social belonging.

Limitations

Appropriate acknowledgment of limitations is crucial to inform the interpretation and application of the findings. One limitation included recruitment being conducted primarily through snowball sampling within community-based organizations. Thus, individuals who do not interact with these supports may not have known about the research. As most participants shared experiences from rural access standpoints in Nova Scotia, the findings may be less representative of urban-dwelling

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individuals. However, this geographic focus aligns with the acknowledgment that access to gender-affirming care services is more challenging in rural regions, thereby providing a unique strength in understanding the challenges faced.

The small sample size is a limitation; however, the depth of narratives, focused research question, and shared sociocultural context among participants provided substantial information power. While the findings are not intended to be generalizable, the sample allowed for a rich exploration of experiences within the Nova Scotia context.

Furthermore, this research did not explore how nuanced experiences of individuals with intersecting identities, such as race, ability, or culture, shed light on the complexities faced in accessing gender-affirming care. Additional research is needed to explore this intersection.

Finally, despite efforts to emphasize the inclusion of various types of gender-affirming care services on recruitment materials, some individuals may have associated gender-affirming care solely with traditional medical services, potentially leading to the exclusion of eligible participants. Moreover, gender-diverse persons who were not comfortable discussing their gender identity may not have chosen to participate; therefore, these voices may have been missed in the findings.

Conclusions

These findings can inform health care providers' perspectives on what services are important in affirming an individual's gender identity and organizations that create policies to govern accessibility, including insurance companies and educational programs. It is recommended that policies prioritize the understanding and provision of gender-affirming care among health care providers, social service professionals, and community organizations in Nova Scotia. By conducting assessments to identify barriers to and facilitators of providing gender-affirming care, including medical and nonmedical interventions, targeted interventions, educational programs, and training initiatives can be developed to address gaps in knowledge, attitudes, and skills.

Future research directions should focus on exploring the perspectives of health care providers in nonmedical and informal gender-affirming care services to explore additional barriers to and/or facilitators of providing these services. Such work could aid in exploring how best to educate health care providers in gender-inclusive care and enable the best quality of care to be delivered to all individuals regardless of gender.

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Data Availability

The datasets generated or analyzed during this study are not publicly available to maintain the confidentiality of the participants and uphold the study's confidentiality agreement with participants.

Authors' Contributions

BB wrote the manuscript and collected and analyzed the data.

Conflicts of Interest

None declared.

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Exploring Perceived Changes to Mental Health When Restricting and Resuming Specific Adaptive Daily Actions: Longitudinal Qualitative Substudy Within a Randomized Controlled Trial

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Abstract

Background: Anxiety and depressive disorders are common and burdensome, yet many people prefer to self-manage and do not access treatment or fail to achieve meaningful improvement. Prior research indicates that the frequency of performing simple, everyday actions, namely "The Things You Do" (TYD; ie, healthy thinking, meaningful activities, having goals and plans, healthy routines, and social connection), is strongly associated with support mental health and well-being. This research has been primarily quantitative in nature, and so less is known about how people perceive and interpret changes in their mental health when engaging in or limiting these actions.

Objective: This study aims to explore participants' perceptions of mental health changes and associated insights into what most impacts their mental health, during a randomized controlled trial involving the systematic restriction and followed by the resumption of the TYD actions.

Methods: This longitudinal qualitative substudy analyzed weekly free-text comments from 70 healthy Australian adults (intervention group [IG] n=36; control group [CG] n=34). IG participants completed an 8-week randomized controlled trial comprising 3 phases: a 2-week baseline phase (Phase A), a 2-week behavior restriction phase during which they reduced the frequency of the TYD actions (Phase B), and a 4-week recovery or resumption phase during which they increased the frequency of the TYD actions back to usual levels (Phase C). CG participants were instructed to maintain usual habits and activities. The weekly free-text comments were related to what participants had noticed and learned about their mental health. These were thematically analyzed using framework methods to identify patterns in perceived changes, considering trial phase, group allocation, and participant characteristics.

Results: Analyses identified five interrelated themes around what participants reportedly learned and what most impacted their mental health: (1) rhythms of daily life and routine, (2) harnessing internal psychological resources, (3) social support and interpersonal stressors, (4) staying active and enjoying yourself, and (5) environmental and external influences. In the IG, participants reported that behavioral restriction led to subjective disruptions across all 5 themes, precipitating declines in mood, energy, and stability; resumption fostered recovery, along with increased insights into oneself and mental health, coping strategies, and a sense of agency. Compared to the IG, the CG more often emphasized environmental and external influences.

Conclusions: The findings reinforce the centrality of specific daily actions, namely the TYD, to people's subjective well-being and suggest an additional "macro-level" comprising environmental and external influences. Exposure to behavioral restriction and resumption/recovery served to highlight the importance of certain factors for mental health and appeared to improve people's sense of agency and locus of control regarding their mental health.

Trial Registration: Australian New Zealand Clinical Trials Registry ACTRN12624001491550; https://anzctr.org.au/Trial/Registration/TrialReview.aspx?id=388828

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KEYWORDS

activities of daily living; coping strategies; goals; habits; health behavior; mental health; qualitative research; self-management; social support

Introduction

Mental health disorders impose a significant and increasingly heavy burden of disease globally, with anxiety and depressive disorders being the most prevalent [1]. While a range of psychological interventions are available and effective, many people experiencing these symptoms are unable to or choose not to access treatment or do not experience meaningful improvement [2,3]. Accordingly, there has been growing interest in the role and impacts of low-intensity behavioral strategies as more accessible ways to support mental health and well-being. These strategies might include engaging in enjoyable or meaningful activities, maintaining daily routines, and fostering social connection [4-6].

Recent work by Titov and colleagues [7-10] has sought to identify the specific behavioral actions most strongly associated with reduced symptoms of depression and anxiety. This program of research has culminated in the identification of the "Things You Do" (TYD) actions, which are (1) healthy thinking (ie, maintaining realistic, balanced thoughts about yourself, others, and the future), (2) meaningful activities (ie, doing things that bring a sense of accomplishment, satisfaction, or joy), (3) having goals and plans (ie, having something to look forward to, and working toward personal goals), (4) healthy routines (ie, maintaining regular habits like sleep, healthy eating, and physical activity), and (5) social connection (ie, having regular, meaningful contact with people you care about). A series of cross-sectional, longitudinal, and experimental studies have shown that increased engagement with these actions predicts improvements in mental health outcomes, whereas reductions in these behaviors are associated with increased symptoms [7-10]. Additionally, a recent to-be-published randomized controlled trial (RCT; ACTRN12624001491550) demonstrated that systematically restricting then resuming the TYD actions led to an initial induction and a subsequent recovery of depression and anxiety symptoms in a community sample of healthy adults (n=70).

While these findings provide strong empirical support for the relevance of TYD actions to mental health, all studies to date have been quantitative in nature. Less is known about how people perceive and interpret changes in their mental health when engaging in or limiting specific adaptive actions over time, that is, longitudinally. Existing qualitative and mixed methods research using a longitudinal design has provided some relevant and important insights into people's subjective experience of changes in their mental health over time. These insights include people's awareness of changes in their mental health in response to life-changing health events (ie, depression in stroke survivors) [11] or treatment initiation (ie, ketamine for treatment-resistant depression) [12] or discontinuation (ie, antidepressant withdrawal) [13], as well as the complex meanings that people attribute to changes in their mental health beyond symptom changes alone, in terms of their identity, agency, and sense of control [11-14]. Additionally, existing research highlights the importance of longitudinal, qualitative mental health assessments to explore people's subjective experience in a more nuanced way and to mitigate difficulties in retrospective recall and inaccurate reporting [11,12,14,15]. Gaining an in-depth understanding of people's perceptions of TYD-related changes in their mental health, alongside any learnings gained during this process, can offer important insights into the acceptability, perceived mechanisms, and personal relevance of such interventions.

To address this knowledge gap in our understanding, this study aimed to explore participant views and experiences of mental health changes going through periods of reducing and increasing specific daily activities related to mental health. It is a substudy of the aforementioned RCT (ACTRN12624001491550). Specifically, the research questions guiding this study were as follows: (1) What do participants attribute any perceived changes in their mental health to during the trial? (2) What do participants report learning in response to any perceived changes? (3) To what extent, if any, are these perceived changes influenced by participant group, trial phase, and background characteristics (eg, age, gender, education, baseline symptoms of anxiety and depression, prior help-seeking for mental health)?

In answering these questions, this study sought to complement and build upon the existing quantitative findings on the TYD and mental health. To this end, this study sought to provide a comprehensive understanding of behavioral approaches to mental health, to help inform the design and delivery of the TYD and other similar low-intensity or self-guided interventions.

Methods

Study Design

This longitudinal qualitative substudy formed part of an RCT described elsewhere (ACTRN12624001491550), which evaluated the mental health impact of changes in specific daily actions linked to psychological health and well-being (ie, the aforementioned TYD) [9]. The trial employed a 2-arm, parallel-group design with participants randomly stratified by gender, age, and symptom severity and randomly allocated to either an intervention group (IG) or control group (CG). Allocation was performed by a researcher independent of recruitment (BFD), using concealed randomization until eligibility was confirmed during a structured telephone interview.

The IG followed an 8-week protocol comprising three phases, consistent with prior methodology [9]: a 2-week baseline phase (Phase A), a 2-week behavior restriction phase during which the IG was instructed to reduce the frequency of the TYD actions (Phase B), and a 4-week recovery or resumption phase during which the IG was instructed to increase the frequency of the TYD actions back to usual levels (Phase C). Both the IG and the CG completed the same questionnaires at equivalent time

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points, but the CG was instructed to maintain their usual routines and activities throughout the trial. As expected, the findings from this RCT showed significantly greater increases in symptoms of depression and anxiety for the IG during Phase B compared to the CG, while the scores on all outcome measures were similar for both groups during Phase A and Phase C. In addition, the self-reported ratings of any mental health changes corresponded to changes on the symptom measures.

This qualitative substudy explored participants' weekly subjective experiences of mental health changes and associated insights during each of the trial phases, using data collected via a purpose-designed questionnaire (see the *Materials and Measures* section).

Ethical Considerations

Ethics approval for all aspects of the research was obtained from Macquarie University Human Research Ethics Committee (Ref: 520241769358699), and the trial was prospectively registered on the Australian and New Zealand Clinical Trials Registry (ACTRN12624001491550). All participants provided informed consent prior to enrollment and were informed of the behavioral restriction component of the IG. Participants in the IG were also asked to confirm ongoing consent on a weekly basis. All participants provided informed written consent prior to enrollment and were informed of the behavioral restriction component of the IG, along with their right to withdraw at any time without consequence. Participants in the IG were also asked to confirm ongoing consent on a weekly basis. The privacy and confidentiality of participants were maintained throughout the study. In recognition of their time and effort, participants were offered gift vouchers valued at AU $25 (US $16.75) for completing the questionnaires on time each week, and an additional gift voucher valued at AU $50 (US $33.50) for completing the final set of questionnaires. As such, participants could be remunerated a total of AU $250 (US $167.54) in gift vouchers across the course of the trial. For more information, see the registered trial protocol (ACTRN12624001491550).

Participants and Setting

Participants were recruited nationally through the eCentreClinic website and social media posts (Facebook and X) and via an external recruitment agency ("Build Clinical"). The eCentreClinic is a digital mental health research clinic specializing in clinical trials across a range of mental health and physical health conditions.

The inclusion criteria for both this study and the overall trial were as follows: (1) aged 18 years or older, (2) self-reported symptoms of depression (Patient Health Questionnaire-9 item, PHQ-9 <10) [16] and anxiety (Generalized Anxiety Disorder questionnaire-7 item, GAD-7 <8) [17] in the healthy or mild range, and (3) resident of Australia. The exclusion criteria included inability to read and understand English and current engagement in psychological treatment.

Procedure

Interested individuals completed an online screening questionnaire and were invited to a structured telephone interview with a registered mental health professional (NT or AD) to confirm eligibility and review study procedures. During this call, NT or AD explained the behavioral restriction phase (Phase B) to all participants. IG participants were provided with a "Restriction Guide" and received a follow-up call before or at the start of the restriction phase to go through this guide, and confirm the start date, 2-week duration, trial purpose, and address any questions. In addition, upon starting the restriction phase, a reminder email was sent to IG participants.

Of the 103 applicants between February 3 - 21, 2025, 70 met all inclusion criteria and were randomized to the IG and the CG. All participants were monitored by NT and AD for safety and risk over the course of the trial. IG participants received weekly brief phone calls (<5 min) from week 2 onward, while CG participants were only called if there were clinical concerns or to prompt questionnaire completion. These calls followed a script and were used to confirm participants' understanding of the current trial phase (eg, restriction or recovery), reiterate key instructions for the phase, conduct a brief well-being check, and answer any questions. Participants were also reminded of how to contact the research team if needed. During these calls, NT and AD took notes of their discussion with participants, but no specific therapeutic or mental health support was offered. These notes aimed to capture information about additional comments expressed by participants in the weekly call, as well as clinical observations of those calls. Throughout the recovery phase of the trial (Phase C), IG participants were sent 1 brief SMS message each weekday (for the full 4 wk) encouraging them to do a target TYD action (eg, for healthy routines: "Healthy habits start with a good routine. Plan out your day so that you can get things done, but also have time for what makes you feel good. Routines matter").

Materials and Measures

This study draws on a subset of measures included in the overall trial. All included measures are described in the registered trial protocol (ACTRN12624001491550).

Reflections Questionnaire

The purpose-designed reflections questionnaire (RQ) was administered weekly from weeks 2 to 8, and again at posttrial (also week 8). It consisted of three items: (1) a Likert-style question assessing perceived change in mental health in the past week (from "greatly improved" to "greatly deteriorated," with "no change or normal" at the midpoint), and 2 open-ended items asking participants to (2) describe the reasons for any changes, and (3) reflect on what they had learned about their mental health. In the final administration of the questionnaire, an additional question was included with slight rewording asking participants to reflect on perceived changes and insights from across the whole trial.

Sociodemographic and Clinical Characteristics

To characterize the participant sample and their mental health trajectory during the trial and explore potential links between their responses on the RQ and background characteristics, the following information was also included: age, gender, educational attainment, symptoms of depression (PHQ-9) [16] and anxiety (GAD-7) [17], past mental health seeking (if so),

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and type of health professional seen (eg, general practitioner psychologist). With regard to the PHQ-9 and the GAD-7, higher scores correspond to more severe depression and anxiety symptomatology, respectively. Of relevance to this study of healthy adults, scores of 0 - 4 indicate minimal or no symptoms whereas scores of 5 - 9 indicate mild symptoms.

Analysis

This substudy focuses on participants' free-text responses to the open-ended items on the RQ (ie, items 2 and 3), collected weekly and at posttrial. All analyses were conducted by the lead author, AF, a postdoctoral researcher with a background in applied clinical or health psychology and expertise in qualitative research in mental health populations. All responses were analyzed thematically using framework methods [18]. This analytic approach allowed the research team to discern common patterns (subthemes or themes) in the responses of participants both within individuals across the phases of the trial (longitudinally) as well as between individuals in specific phases of the trial (cross-sectionally). Additionally, analyses sought to explore the potential qualitative links between participant responses, trial phase (Phase A, B, C, posttrial), group allocation (IG vs. CG), and background characteristics (eg, age, past help-seeking).

AF developed a set of initial codes along with a preliminary map of higher order subthemes or themes based on the responses from a randomly selected subsample of 20% (n=14) of the participants across all phases of the trial. These subthemes or themes were then discussed and refined to minimize duplication or repetition and to ensure that they were comprehensive in their coverage, sufficiently distinct, and named in a way that accurately reflected their content. AF led this process in collaboration with the other members of the multidisciplinary research team whose backgrounds included psychology, psychiatry, digital mental health, and qualitative or mixed-methods research (eg, NT, AD, LGS, BFD, ON, HDH). AF then coded all participant responses with the assistance of the NVivo software (version 15; QSR International), meeting with the team regularly to continue iterating and refining the thematic map. To explore any potential relationships between participant responses, trial phase, and group allocation, separate files were created for each phase of the trial. This meant that each participant had up to 4 files, ie, for Phase A, B, C, and posttrial. Only files containing codable data were included; files with responses such as "N/A," "no change," "nothing," and so forth were excluded from analyses.

Analyses were mainly inductive (data driven) and took a postpositivist approach, such that participant responses were taken at face value and as describing reality, with minimal interpretation [16]. This approach was chosen because participants had recorded their responses remotely and without the opportunity for a researcher to probe for more contextual detail or clarification. Once all participant responses were coded in NVivo, they were exported to a framework matrix created in Microsoft Excel [17]. At this point, AF noted any marked differences in the relative prevalence or frequency of the codes or subthemes or themes based on participant group allocation, trial phase, or background characteristics. Lastly, AF read over and synthesized the weekly clinician notes (by NT and AD), triangulating these with the identified codes or subthemes or themes and chose illustrative participants' quotes for each of the subthemes.

Results

Participant Characteristics

Participants' baseline sociodemographic and clinical characteristics will be described in a separate, forthcoming publication. Broadly speaking, the sample was aged on average in their mid-thirties (CG: mean 34.7, SD 13.2 y; IG: mean 37.4, SD 9.4 y) and predominantly female (CG: n=24, 68.6%; IG: n=26, 78.8%), with university level education (CG: n=21, 60%; IG: n=31, 93.9%). A minority of the sample had previously consulted a mental health professional (eg, GP, psychologist, and/or counselor) (CG: n=5, 14.3%, IG: n=4, 12.1%) and indicated very mild-to-mild difficulties with anxiety (CG: n=6, 17.2%; IG: n=8, 24.3%). No one indicated any difficulties with depression. There were no significant between-group differences, except for the level of education, with a significantly higher proportion of the IG having university-level education compared to the CG.

During the course of the trial, the average PHQ-9 (depression) scores ranged as follows: for Phase A weeks 1 and 2 (IG: mean 1.5 - 1.5, SD 1.4 - 1.6; CG: mean 2.1 - 2.3, SD 2.8 - 2.9), Phase B weeks 3 and 4 (IG: mean 1.8 - 7.0, SD 2.9 - 4.6; CG: mean 1.7 - 1.7, SD 2.3 - 2.6), and Phase C weeks 5-8 (IG: mean 1.2 - 6.9, SD 1.3 - 3.4; CG: mean 0.9 - 1.3, SD 1.4 - 1.9). Meanwhile, the average GAD-7 (anxiety) scores ranged as follows: for Phase A weeks 1 and 2 (IG: mean 1.1 - 1.2, SD 1.5 - 1.6; CG: mean 1.2 - 1.4, SD 1.6 - 2.1), Phase B weeks 3 and 4 (IG: mean 5.6 - 5.9, SD 3.0 - 4.3; CG: mean 1.1 - 1.2, SD 1.7 - 2.3), and Phase C weeks 5-8 (IG: mean 0.9 - 5.6, SD 1.6 - 3.0; CG: mean 0.9 - 1.0, SD 1.4 - 1.7).

Attrition was low for the parent RCT and therefore this substudy: 1 IG participant and 1 CG participant did not start, while a second IG participant withdrew in week 2 (Phase A) due to unrelated physical illness. In this substudy, a total of 231 participant files were included for qualitative analyses with similar numbers across each phase and group of the trial (Phase A: n=25 IG, n=25 CG; Phase B: n=32 IG, n=28 CG; Phase C: n=31 IG, n=31 CG; posttrial: n=30 IG, n=29 CG).

The thematic analysis identified 5 overarching themes about what participants perceived impacted their mental health, each comprising several subthemes: all of which mapped across all 4 phases of the trial and both participant groups. The themes appeared to be to some extent overlapping and interrelated; for example, when the rhythms of daily life and routine (Theme 1), social support and interpersonal stressors (Theme 3), and staying active and enjoying oneself (Theme 4) were all functioning well, these served to support one's internal psychological resources (Theme 2), while buffering against environmental and external influences (Theme 5). By contrast, when Themes 1-3 were disrupted (as was the case for the IG during the behavioral restriction phase, Phase B), they served to challenge one's internal psychological resources (Theme 2) and render

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participants more vulnerable to the negative impacts of environmental and external influences (Theme 5). As the CG was not exposed to behavioral restriction and resumption or recovery (in Phases B and C), the importance of Themes 1, 3, and 4 appeared to be less salient to them, and they had fewer opportunities to challenge and harness their internal psychological resources (Theme 2), while also more frequently describing the environmental and external influences (Theme 5) on their mental health compared to the IG.

In instances where the relative prevalence or salience of a particular theme or subtheme appears to differ according to trial phase, participant group, or background characteristics, this is noted in the following sections. Illustrative quotes for each of the subthemes or themes are provided in Table 1.

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Table . Illustrative participant quotes organized by theme and subtheme.

Theme[a]	Subtheme	Illustrative participant quote
Theme 1: Rhythms of daily life and routine	• Keeping a consistent "healthy" routine is key • Organization and scheduling to "stay on track" • Sleep as a pillar for mental health • Physiological and hormonal fluctuations	• "Changing my healthy habits...I learnt that my mental health can be improved by doing healthy habits and it has been affected by stopping these habits or restricting them." (ID29_PhaseB_Intervention) • "I have been a little more organized this week by noting down appointments, assessments, classes, work and calls to keep on track and not be surprised." (ID62_PhaseB_Control) • "Sleep…keeps me happy and improves my mental health...not being able to do that has a ripple effect on me. I get easily irritated and angry and I go in my shell...It also impacts my energy levels." (ID17_PhaseB_Intervention) • "I find that my mental health sometimes changes with my menstrual cycle." (ID32_PhaseA_Intervention)
Theme 2: Harnessing internal psychological resources	• Cognition-focused strategies for self-regulation • Emotion-focused strategies for self-regulation • Building self-awareness and insight into mental health	• "I am in control of my mental health ie, in the way I choose to frame situations and the way I choose to react to good and bad news." (ID20_PhaseA_Intervention) • "That being kind to myself is important and that to not put pressure on myself and to just do the best I can." (ID47_PhaseC_Control) • "...the disruption period was hard for me to climb out of. [It] Has taken longer time than I thought [it would]...my mental health is more fragile than I once thought..."(ID5_PhasePosttrial_Intervention)
Theme 3: Social support and interpersonal stressors	• Social support and connection for mental health • Interpersonal stressors affecting mental health	• "Catching up with friends has helped boost my mental health. Being around positive people has helped boost my happiness." (ID13_PhaseC_Intervention) • "[I'm] Feeling overwhelmed by juggling kids home on school holidays and trying to get work done in amongst it all while still trying to create memories for them and facilitate fun activities for them." (ID34_PhaseC_Intervention)
Theme 4: Staying active and enjoying yourself	• Engaging in enjoyable and purposeful activities • Role of (physical) activity in regulating mood and anxiety	• "I think having a strong sense of purpose and feeling like I'm working towards the achievement of that is really important to my sense of wellbeing." (ID33_PhaseC_Intervention) • "Exercising is important to me beyond just the act itself as it regulates my sleep, balances my schedule and improves my mood." (ID28_PhaseA_Intervention)
Theme 5: Environmental and external influences	• External stressors and demands • Your environment matters	• "I do feel that my mental health changed a little in the last week...primarily due to extra tasks and deadlines at work. I found myself needing to spend a lot more time completing things, and often bringing work home..." (ID32_PhaseC_Intervention) • "My house mess reflects my mental health. I just can't seem to keep up with housework…[it]loses out to other responsibilities." (ID55_PhaseB_Control)

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[a]Across themes, differences were evident by participant characteristics and group. Themes 1 and 2 were more salient among intervention group participants, particularly during restriction (Phase B) and resumption or recovery (Phase C), and among those reporting baseline anxiety. Themes 3 and 4 were more frequently referenced by younger participants and those without prior help-seeking, with social connection especially salient among female participants. Theme 5 was the only theme more prominent among control group participants, particularly younger and middle-aged adults with baseline anxiety. Gender differences were most apparent in Themes 2 and 3, with female participants describing a broader range of psychological and interpersonal strategies.

Theme 1: Rhythms of Daily Life and Routine

Theme 1 was highly prevalent within participant accounts (269 coded instances across the 231 participant files) and was present across both groups and all phases of the trial. This theme appeared to be especially salient among IG participants relative to CG participants during the restriction (Phase B) and resumption or recovery phases (Phase C) of the trial. Some but not all subthemes (eg, the importance of routine) within this theme appeared to be more salient among participants with some self-reported baseline anxiety compared to those without.

Many participants reported that maintaining (and in the case of the IG, also reinstating) a consistent "healthy" daily routine was a core strategy for regulating their mood, anxiety, energy, and thinking. Specifically, participants articulated the importance of regular patterns of sleep, nutrition, physical activity, and social interaction. Both the IG and the CG commonly reported disruptions to these patterns; for IG participants, these disruptions were mainly attributed to behavioral restriction (Phase B), while CG participants cited factors such as changes in health or illness, or external obligations (eg, family, work, study). Regardless of the perceived cause, disrupted routines reportedly precipitated emotional lability, a general sense of malaise and instability.

According to participants, sleep was foundational and a "pillar of mental health." As such, a lack of or "poor" sleep (often in interaction with other factors such as fatigue, illness, and stress) quickly led to worse mood and anxiety, while "good" sleep had the opposite effect. For IG participants, sleep appeared to be a primary driver of both worsened and improved mental health across the restriction (Phase B) and resumption or recovery phases (Phase C) of the trial.

Fewer participants cited organization and scheduling as helping them to "stay on track" and balance various life demands (eg, work, study, family commitments). Participants also cited the importance of being flexible and needing to accommodate and adapt to change; indeed, breaks from routine were also seen as having a positive effect on their mental health when taken in the form of holidays, days off work, and long weekends. In addition, a few participants (all women) reported that hormonal and physiological fluctuations, such as menstruation, (peri)menopause, and migraines, influenced their mood by way of disrupting their usual routine (eg, sleep, physical activity).

Theme 2: Harnessing Internal Psychological Resources

As with Theme 1, Theme 2 was also highly prevalent within the sample (278 coded instances across the 231 participant files) and was identified in both groups and across all phases of the trial. Participants, especially female participants, described a repertoire of psychological strategies to help regulate their emotional responses and navigate stressors. Participants alluded to both cognition-based and emotion-based strategies; cognition-based strategies included cognitive flexibility (reappraisal and reframing) and balancing tolerance of uncertainty with realistic expectations around their personal sense of control and influence over others. Emotion-based strategies included maintaining a positive mindset and "self-talk," along with self-compassion and taking time to emotionally remove oneself and reflect rather than react with heightened emotion.

These strategies, in particular cognitive-based strategies, were especially salient among IG participants relative to CG participants during the behavioral resumption or recovery phase of the trial (Phase C). For all participants, these strategies reportedly buffered against psychological distress and enhanced their emotional resilience.

Participants, especially female participants and those in the IG during the behavioral resumption or recovery phase (Phase C), described building self-awareness and insight into the "ups and downs" or "fragility" of their mental health, identifying personal triggers, and developing bespoke coping "toolkits," which incorporated a combination of personally relevant and useful strategies (eg, positive mindset, reframing). These participants articulated a growing sense of agency and accountability in managing their well-being, which included making a concerted effort to do more of the things known to positively impact their mental health, less of those known to negatively impact their mental health, and committing to process over outcomes.

Theme 3: Social Support and Interpersonal Stressors

Theme 3 appeared to be less prevalent within participant accounts compared to the first two (91 coded instances across the 231 participant files). That said, Theme 3 was still present across both groups and all phases of the trial, with greater predominance among female compared to male participants and younger or general age adults compared to older adults (aged 55 y and over).

Socializing and connection with loved ones (eg, friends, family, partner) as well as "positive" others (eg, colleagues, new friends, a pet) appeared to be key determinants of emotional well-being. These interactions, and for some, particularly in-person interactions, were described as vital sources of support, belonging, validation, and emotional "grounding." By contrast, negative or challenging relationship dynamics or interactions, including via social media, were associated with emotional dysregulation, heightened anxiety, and loneliness.

The bidirectional link between social withdrawal versus connection and negative versus positive mental health was especially evident in the accounts of IG participants during the behavioral restriction (Phase B) and the resumption or recovery phases of the trial (Phase C). Across both groups and all phases, a few participants also felt that heightened family demands affected their mental health, with caregiving roles especially

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taking an emotional toll (eg, young children, older adults, or sick parents).

Theme 4: Staying Active and Enjoying Yourself

As with Theme 3, Theme 4 was also less prevalent within participant accounts (109 coded instances across the 231 participant files), although still present across both groups and all phases of the trial. Participants, especially those reporting no prior help-seeking with a mental health professional, consistently emphasized the importance of staying (physically) active and engaging in activities that were enjoyable, purposeful, and meaningful. The importance of these activities appeared to be more salient in the accounts of IG participants than CG participants during the behavioral restriction phase (Phase B). Physical activity, both in the form of structured exercise and leisure-based movement (eg, walking, hiking), was described not only as mentally and physically energizing but also as central to mood regulation and a sense of well-being.

Participants also expressed that staying "purposefully busy" and pursuing personal goals, whether through work, volunteering, or personal projects, served as a positive distraction and helped to ease worry. Conversely, excessive passive activities, such as screen time or "doom-scrolling" (ie, mindlessly viewing high volumes of social media content without intending to), were seen as having a negative impact on mental health, and participants sought to limit these.

Theme 5: Environmental and External Influences

Theme 5 was the least prevalent within participant accounts (64 coded instances across the 231 participant files), although still present across both groups and all phases of the trial. This theme appeared to be more frequently described by younger and middle-aged adults (ie, younger than 45 years old), those reporting some anxiety at baseline, and those without any prior help-seeking with a mental health professional. This theme was also the only one to be more salient within the accounts of CG participants compared to IG participants. Accordingly, there did not appear to be any differences in the prevalence of this theme across the trial phases.

Within this theme, external stressors, such as work and study pressures, financial concerns, and pending major life decisions, had a negative impact on mental health. These stressors reportedly impacted daily rhythms and routines, led to emotional lability, and triggered maladaptive coping responses such as withdrawing from family and friends or working longer hours. By contrast, several participants reported that resolving or gaining clarity on major life decisions (eg, purchasing a house) or stressors (eg, a family member's diagnosis) led to improvements in their mood and anxiety.

In addition, one's immediate surrounding environment was described as a key influence on mental health. Here, participants alluded to both their physical environment as well as their experiential environment. For example, chaotic or, by contrast, calm home environments shaped and were shaped by a negative or positive mental state, while access to personal "mental" space and time outdoors and in nature was described as calming and restorative. Weather and seasonal changes also reportedly had an influence on affect for a few participants, sometimes but not always by way of changes in their behavior (eg, sleep, exercise, diet).

Weekly Clinician Notes—Confirmatory Insights Into IG Participants' Mental Health Trajectory

A review of the weekly clinician notes confirmed the above-described themes and subthemes, while also providing some additional insights into the mental health trajectory of participants in the IG. The notes revealed that, even at baseline (Phase A), the IG participants anticipated that breaking their usual routines would be challenging and detrimental to their mental health, which was realized during the behavioral restriction phase (Phase B). The impact of these breaks in routine on mood and anxiety appeared to compound over time, with the IG participants reporting increasing fatigue and emotional discomfort. That said, it was also during the behavioral restriction phase (Phase B) that some participants started developing early insight into the importance of routine for their well-being.

When starting the behavioral resumption or recovery phase (Phase C), most IG participants experienced gradual improvements in their mental health with a return to their routine, albeit with some lingering anxiety and low mood. During this phase, IG participants felt that the SMS reminders acted as a supportive mental health aide. While the pace of recovery varied, by the end of the trial, participants across both groups expressed greater self-awareness, highlighted personal learnings, and evaluated the trial experience positively.

Discussion

Overview

This study provides in-depth qualitative insights into how individuals perceive and make sense of mental health changes when engaging in or limiting simple, daily actions (ie, the "TYD"). These findings not only reinforce the importance of these behaviors to people's emotional well-being, but they also reveal the context-dependent ways in which people interpret changes to their mental health and develop strategies and self-awareness in response to behavioral restriction and resumption or recovery.

Principal Findings and Comparison With the Broader Literature

Based on the current findings, healthy adults tend to attribute perceived changes in their mental health most frequently to shifts in their daily routines and use of psychological coping strategies, followed by engagement in enjoyable and purposeful activities, the availability and quality of social support, and exposure to environmental and external stressors. Despite our sample having received no specific psychoeducation in the "TYD" until toward the end of the trial, the identified themes broadly map onto the 5 domains of healthy routines, healthy thinking, meaningful activities, goals and plans, and social connections, with the addition of responding and adapting to one's environment. This additional theme may be subsumed by the existing TYD actions, for example, one may adapt to their environment by way of healthy thinking (eg, developing realistic

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thoughts about the world) or social connections (eg, being part of a community) [7,9]. Alternatively, this additional theme may represent an expansion to the TYD model, in so far as environmental and external influences operate at a "macro" level and shape one's capacity to engage at the "micro" level, that is, regularly practice actions to improve mental health. This integration of "macro" and "micro" elements within mental health is consistent with current research focusing on the broader social and environmental determinants of psychological distress and well-being [19,20]. Also building on prior research into adaptive actions for mental health, some themes were more frequently cited within our sample, suggesting that, for healthy adults, some action domains (eg, healthy routines, healthy thinking) are seen to more strongly influence their mental health than others (eg, social connections). Future research would need to test this hypothesis in a larger, more representative community sample, as well as in adults with clinically significant mental health symptoms.

Behavioral restriction (ie, Phase B for the IG) often led to disruptions in sleep, physical activity, and social contact, precipitating declines in mood, energy, and emotional stability. Meanwhile, behavioral resumption or recovery (ie, Phase C for the IG) led to gradual improvements mostly by way of reinstating healthy daily routines and activities, which some credited to receiving the daily SMS prompts and weekly questionnaires. In the absence of any structured restriction or recovery (ie, Phases B and C for the CG), external pressures, such as work, study, finances, and home environments, appear to exert a greater influence on people's mental health. These findings suggest possible causal mechanisms between withdrawing or disengaging from certain daily activities and subsequent deteriorations in mental health. One such mechanism of key importance appears to be disrupted sleep and its resulting negative impacts on energy levels, activity, and fatigue. Aligning with our findings, other research has confirmed sleep's role as a "pillar of mental health," with positive correlations between sleep quality and mental health in the general adult population [21,22] and RCT interventions designed to improve sleep quality, also leading to improved mental health [23]. Future research would need to test this within a causal model. However, the current findings suggest that prioritizing regular sleep-wake patterns in times of significant disruptions or stressors (eg, routine changes due to illness, starting a new job, moving cities or towns, or having a baby) may help to maintain good mental health.

Based on our findings, even a relatively short period of behavioral restriction (two weeks) led to the IG gaining greater self-awareness of the factors shaping their mental health and well-being, identifying personal triggers and buffers, and making use of bespoke coping "toolkits" incorporating emotion-focused (eg, self-compassion, positive self-talk) and more often, cognitive strategies (eg, reframing, maintaining realistic expectations). Research in Western cultures has shown that cognitive strategies, such as cognitive reappraisal or reframing, promote emotion regulation and are generally more adaptive than some emotion-focused strategies, such as expressive suppression [24,25]. It is noteworthy also that these insights into one's mental health and coping were not limited to the IG; these insights were also evident, albeit to a lesser extent, in the accounts of CG participants. As a result, simply tracking one's mental health symptoms and being asked to reflect on any spontaneous changes, triggers, or learnings may be a subjectively useful intervention in and of itself [14]. This would need to be confirmed in a future study, especially considering limited and uncertain evidence on links between symptom monitoring and improvements, and the possible effect on the control arm of any RCTs [26,27].

This said, the IG's preponderance to attribute mental health changes—both deteriorations and improvements—to their own thinking, behavior, and ways of responding suggests that behavioral restriction and resumption or recovery increased their sense of agency and internal locus of control with regard to mental health. Consistent with this suggestion, the CG was more likely than the IG to cite environmental and external influences as being responsible for their mental health changes, in the absence of any behavioral restriction and resumption or recovery. A greater sense of agency and internal (mental health) locus of control may be 2 serendipitous benefits of the current ultra-light intervention in a group of healthy volunteers, as shown with more targeted psychological and health behavioral interventions [28,29]. In addition, these benefits may carry forward insofar as a more internal health locus of control is associated with less psychological distress, lower prevalence of depression and anxiety, and better health care access and outcomes [28,30]. Future research may consider measuring any specific improvements in agency, locus of control, and cognitive emotion regulation strategies as a result of engaging in the "TYD" or similar mental health promoting actions.

Not only did the prevalence or salience of some themes appear to differ by participant group and trial phase, but there was also some preliminary evidence for the influence of background characteristics. Specifically, women, adults of working or study age (ie, aged in their 20s, 30s, and 40s), those with baseline anxiety symptoms, and those without prior mental health help-seeking reported greater sensitivity to disruptions or stressors. While these findings should be treated with caution due to the relatively small number of mentions for some subthemes or themes, the non-representative sample, and the fact that analyses were exploratory, they suggest that some factors are more important to the mental health of different groups. These findings also suggest that ultralight behavioral interventions such as the "TYD" could be tailored for different groups to be maximally relevant and beneficial (eg, younger vs older adults, healthy individuals vs individuals with moderate-to-severe symptoms, first-time help seekers vs those who have completed psychological treatment). By contrast, maintaining (and for the IG, reinstating) a regular healthy routine and daily habits appeared to be universally recognized as important for mental health. In this way, a healthy routine might be promoted as a universal strategy for good mental health, as supported by research conducted during the COVID-19 pandemic [31,32].

Strengths and Limitations

The findings of this study need to be considered in light of several strengths and limitations. Strengths include the use of

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longitudinal, qualitative assessments together with weekly clinician notes to gain in-depth and detailed accounts of perceived mental health changes both over time and in response to behavioral restriction and resumption or recovery. Another strength is the low levels of attrition in the sample, ensuring that the findings accurately capture the mental health trajectories of the full sample rather than just a subsample of highly engaged participants. The limitations of the study include the nonrepresentative nature of this sample of healthy volunteers, which was predominantly female and university educated, and therefore had potentially higher levels of mental health literacy [33] compared to the general adult population. Future research would need to ascertain whether the current findings are transferrable to a larger, more representative sample, comprising more male individuals and people without university-level education. Another limitation of the study is that the free-text comments needed to be analyzed at a face level, with minimal interpretation. This was done because the free-text comments were collected remotely, without the opportunity for prompting for future explanation or contextual detail. Remote data collection may be seen as a strength, insofar as it permitted participants to reflect and respond in a self-paced and spontaneous way and may have made some participants more comfortable to disclose sensitive information. However, future research may wish to include weekly interviews to better understand how people perceive and interpret changes in their mental health.

Conclusions

This study provides novel qualitative evidence on how healthy adults perceive and interpret changes in their mental health both over time and in response to restricting and resuming specific daily actions related to mental health. The findings reinforce the relevance of the "TYD" actions to both mental health deterioration and improvements, while highlighting the potential role of environmental and external influences as an additional, "macro-level" consideration within the model. Even a brief period of behavioral restriction prompted perceived declines in well-being, often via disruptions to sleep and its associated impacts, but also fostered greater self-awareness, coping strategies, and a sense of agency. Taken together, these findings elucidate potential mechanisms of change and some unintended benefits of ultra-light behavioral interventions, such as the "TYD." While maintaining a regular routine and daily habits appear to be universally important for people's mental health, other factors may vary in terms of their perceived impact. This underscores both the broad appeal of the "TYD" as well as opportunities for tailoring to ensure it is as relevant and beneficial as possible to different groups in the population.

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Data Availability

According to current ethics approval, the data of this study cannot be made publicly available. Any requests for access to the data should be directed to the corresponding author.

Authors' Contributions

Conceptualization: AF, NT
Data curation: AF, AD, NT, BD
Formal analysis: AD, AF, BFD, HDD, LGS, NT, ON, RK
Investigation: AD, AF, BFD, HDD, LGS, NT, ON, RK
Methodology: AF, NT, BD, HDD
Project administration: AF, NT, AD, BD
Resources: BFD, NT
Supervision: NT
Writing – original draft: AF
Writing – review and editing: AD, AF, BFD, HDD, LGS, NT, ON, RK

Conflicts of Interest

None declared.

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Abbreviations

CG: control group
GAD-7: Generalized Anxiety Disorder questionnaire-7 item
IG: intervention group
PHQ-9: Patient Health Questionnaire-9 item
RCT: randomized controlled trial
RQ: reflections questionnaire
TYD: Things You Do

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First Implementation of a Point-of-Care Ultrasound Course in Undergraduate Medical Students in Peru: Mixed Methods Study

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Abstract

Background: Point-of-care ultrasound (POCUS) is a test performed by physicians, as an adjunct to physical examination, to identify the presence or absence of specific clinical findings. This skill is not currently included in undergraduate medical education in Peru.

Objective: This study aims to describe and evaluate the implementation of a POCUS course in undergraduate medical students.

Methods: A pre-experimental study, without a control or comparison group, in which a pretest and posttest were used to evaluate the same group of students. A theoretical-practical POCUS course was designed and implemented for fifth-year medical students at the Universidad Peruana Cayetano Heredia in Lima (Peru) during late 2019 and early 2020. Their prior knowledge was assessed using a pretest consisting of 10 short-answer questions. At the end of the course, a posttest consisting of 9 different questions on ultrasound image analysis and recognition was administered, and the same 10 pretest questions were also re-evaluated. Satisfaction and perception of learning were also assessed through a survey. A descriptive analysis was performed, obtaining absolute and relative frequencies. The Wilcoxon test for related samples was used to evaluate the differences between the pretest and posttest.

Results: A total of 26 students participated in the course, although only 19 completed the post-test (10 women and 9 men). The average pretest score before the course started was 4.8 (SD 2.2) points, indicating poor prior knowledge. This average increased to 18.5 (SD 1.6) points when they retested the pretest at the end of the course. The average posttest score was 12.2 (SD 3.3) points, which differed significantly from the initial pretest average (P<.001). Only 15 students responded to the satisfaction survey, with more than 50% reporting that they had fully acquired the ability to assess the inferior vena cava, bladder, free fluid in the thorax and abdomen, and right kidney. They also reported that the course met 97.5% of their prior expectations, but all considered the practical sessions with the ultrasound equipment to be essential. Although they considered that the best aspects of the course were learning how to use the ultrasound equipment and the small size of the groups, they suggested that the course could be improved by increasing its duration and the number of practical sessions, as well as by conducting the practical sessions with real patients presenting some type of pathology.

Conclusions: We have successfully created a short theoretical and practical course on POCUS and have applied it for the first time to undergraduate medical students after their clinical rotations. This course has enabled them to perceive a significant improvement in their ability to recognize certain abdominal and pelvic organs and anatomical structures using ultrasound. This course can serve as a starting point for replicating POCUS teaching in medical schools across the country.

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KEYWORDS

POCUS; point-of-care ultrasound; ultrasound; medical curriculum; curriculum; medical training; medical schools; competency-based education; undergraduate medical education

Introduction

Ultrasonography is a noninvasive, portable, cost-effective, accurate, safe, efficient, and widely used clinical diagnostic tool [1], with few contraindications and adverse effects. In addition, ultrasound equipment is increasingly available to many physicians in the emergency and hospitalization areas of various hospitals in Peru and around the world.

Point-of-care ultrasound (POCUS), unlike a routine diagnostic ultrasound study performed by radiologists and ultrasound technologists, answers a clinical question posed by surgeons [2], emergency physicians [3], family physicians [4], and, in general, by any physician who treats a patient's health problem using this procedure to solve it. POCUS is defined as an ultrasound examination provided and performed by the patient's primary care physician, usually as an adjunct to the physical

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examination, to identify the presence or absence of a limited number of specific findings [5]. It has some synonyms such as clinical ultrasound, bedside ultrasound, or focused ultrasound [6].

As early as 2014, the American Academy of Emergency Medicine stated that "ultrasound should be integrated into the undergraduate medical education curriculum." It even mentioned that there are numerous forms of introduction (teaching anatomy, physiology, physical examination, and procedures) and learning modalities, with 4 that report the best results: learning on "live" models rather than on simulators; e-learning based on cases or self-directed "podcasts" rather than lecture-based presentations; peer-to-peer practice rather than practice with the student "alone," and a doctor-patient role-play model where they learn by participating as simulated patients [7]. However, to date, the skill of performing ultrasound studies is only taught in postgraduate programs and only in some medical specialties, and its teaching is not explicitly included in undergraduate programs at the main medical schools in Peru [8]. In their pilot study, Syrpeda et al [1] reported on the teaching and learning of some ultrasound skills and techniques in a small group of second-year medical students in practical sessions of 2 hours per week, promoting self-learning with minimal teaching guidance on the subject and achieving adequate levels of competence in obtaining and interpreting some ultrasound images.

We consider it necessary to introduce POCUS teaching into the undergraduate medical programs at our universities. This could also improve learning in certain subjects, such as anatomy and physiology, and certain skills and abilities, such as physical examination and diagnostic approach. Therefore, the objective of this research was to describe and evaluate the implementation of a POCUS course in a group of undergraduate medical students.

Methods

Overview

This was a pre-experimental study without a control or comparison group, as a pre and posttest was used to evaluate the same group of students. Quantitative and qualitative data were obtained. Students who were in their fifth year of medical school at the Universidad Peruana Cayetano Heredia in 2019 were included. The sample was convenience-based, consisting of those who voluntarily agreed to take the course through an invitation sent via institutional email. Students who started but did not fully complete the course were excluded, as well as those who had already received formal training in POCUS.

Definitions

Knowledge of POCUS

This was measured using 2 assessments designed exclusively for this course. A pretest with 5 theoretical questions and 5 questions analyzing ultrasound images. A posttest with 9 questions, all analyzing images different from those used in the pretest. Each test had a minimum score of 0 and a maximum score of 20.

Perception of Achievement of Skill to Perform POCUS Studies

Students were asked about their perception of having achieved the ability to perform a POCUS study on a patient, and this was explored as a perceived percentage from 0% to 100%.

Satisfaction With the POCUS Course

To evaluate the impact on educational training at level 1 of the Kirkpatrick model [9], a satisfaction survey was conducted at the end of the course that evaluated the perceived percentage of usefulness of the course and some of its characteristics.

Procedures and Techniques

The medical degree at Universidad Peruana Cayetano Heredia lasts 7 years, of which the first 3 are preclinical, the next 2 are clinical, and the last 2 are preprofessional internships in hospitals. To date, there is no specific POCUS course in any of the 7 years [10]. Therefore, the researcher designed a 3-week theoretical-practical course from scratch to teach the skill of using ultrasound equipment to perform POCUS studies in adults, identifying some images of importance in medical teaching and learning. This course was optional and voluntary, not part of the official curriculum, and was held between October 2019 and February 2020.

The theoretical part of the course was conducted exclusively through asynchronous individual reading of certain chapters of the ultrasound manual by García and Torres [11]: gallbladder, common bile duct, liver, kidneys, bladder, abdominal aorta, portal vein, inferior vena cava, and the E-FAST (Extended Focused Abdominal Sonography for Trauma) study. Specific learning objectives were drafted and sent to students via email prior to the practical sessions (Annex S1 in Multimedia Appendix 1 [11]). To ensure that the bibliography was read, a web-based formative pretest on the learning objectives was administered prior to each practical session, the results of which were not taken into account for this research.

The practical part was face-to-face and was led by the principal investigator, who is a specialist in internal medicine with training in POCUS since 2003 and more than 10 years of experience performing general ultrasound studies at the time of the study. Groups of 3 or 4 students were formed based on their own affinities. The practical sessions were carried out in three 2-hour sessions, during which the students performed ultrasounds based on what they had read the previous week. For these face-to-face practical sessions, each student took turns participating as "patients" (those who underwent the ultrasound study) and as "sonographers" (those who performed the ultrasound study), similar to that reported by Syrpeda et al [1] in order to learn normal ultrasound images. Each group was made up exclusively of either female or male students.

The researcher first performed each POCUS study on a volunteer student at the beginning of each session to show the other students what to do in practice. This also served as a role model for each of them, so they could then perform the same actions and maneuvers as the researcher, locating all the structures that were the subject of study in each session. The roles of sonographer and patient alternated between each student. The

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researcher stood next to the student at all times and guided them in the use of the transducer or corrected certain maneuvers, if necessary. The student had to show and point out each organ for the practice to be considered adequately performed. Each group had 4 practice sessions throughout the course. During the practical sessions, we were able to describe clinical cases in which abnormal findings could be found in the organ that the students were examining (eg, shock in the study of the inferior vena cava, acute renal failure in the study of the kidneys, cholecystitis or cholangitis in the evaluation of the gallbladder and bile ducts, etc). The cases were not standardized for each group and were used to contextualize the evaluation of each organ as a teaching strategy, so they are not shown in the study.

The ultrasound equipment used in the course was the Samsung SonoAceR3 model, available in the internal medicine hospitalization 1-II ward of the Hospital Nacional Arzobispo Loayza, and a 3.5 MHz convex transducer and a 7.5 MHz linear transducer were used, depending on the type of study performed. All course materials, notices, and communications were distributed through the Edmodo web-based classroom [12], which was available free of charge on the web until 2022. In this classroom, there were opportunities for question-and-answer forums to address any questions students had about what they were reading.

Although the study was conducted over 5 months, the specific duration of the course for each student was approximately 3 to 4 weeks, as the 3 practical sessions were held once or twice a week for each group, and the theoretical learning was asynchronous during the week prior to each practical session.

To determine students' prior knowledge, the researcher designed an ad hoc pretest with 10 questions on theory and image analysis, the answers to which were to be developed and substantiated (Annex S2 in Multimedia Appendix 1 [11]). Multiple-choice questions were not used to eliminate the possibility of guessing, in case the student did not know or recognize what they were observing in the image they were asked about. If the student did not know the answer, they left it blank or wrote "I don't know" and had a score of 0 on that question. The same pretest was also given to participating students to measure knowledge retention one week after the end of the course. Some questions from the pretest were:

- Which organic structure is the most hyperechoic, and which is the most anechoic when performing ultrasounds?
- Explain the purpose of performing the FAST protocol with ultrasound.
- Describe or list the 5 locations where ultrasound is performed in the extended FAST protocol.
- Mention the levels and cuts of protocolized visualization of the abdominal aorta.

To measure the achievement of learning objectives at the end of the course, a different posttest was designed (Annex S3 in Multimedia Appendix 1 [11]), with another 9 questions to be answered (short answer type), which only assessed the analysis and recognition of ultrasound images and were completely different from those used in the initial pretest.

Some questions from the posttest were:

- In the image below (Figure 1), describe what each image corresponds to with a letter and arrowheads (there are 4 answers).
- In the following image (Figure 2), describe what each image corresponds to with a letter and what this projection is used for (there are 4 answers).

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Figure 1. Image of question 2 from the posttest.

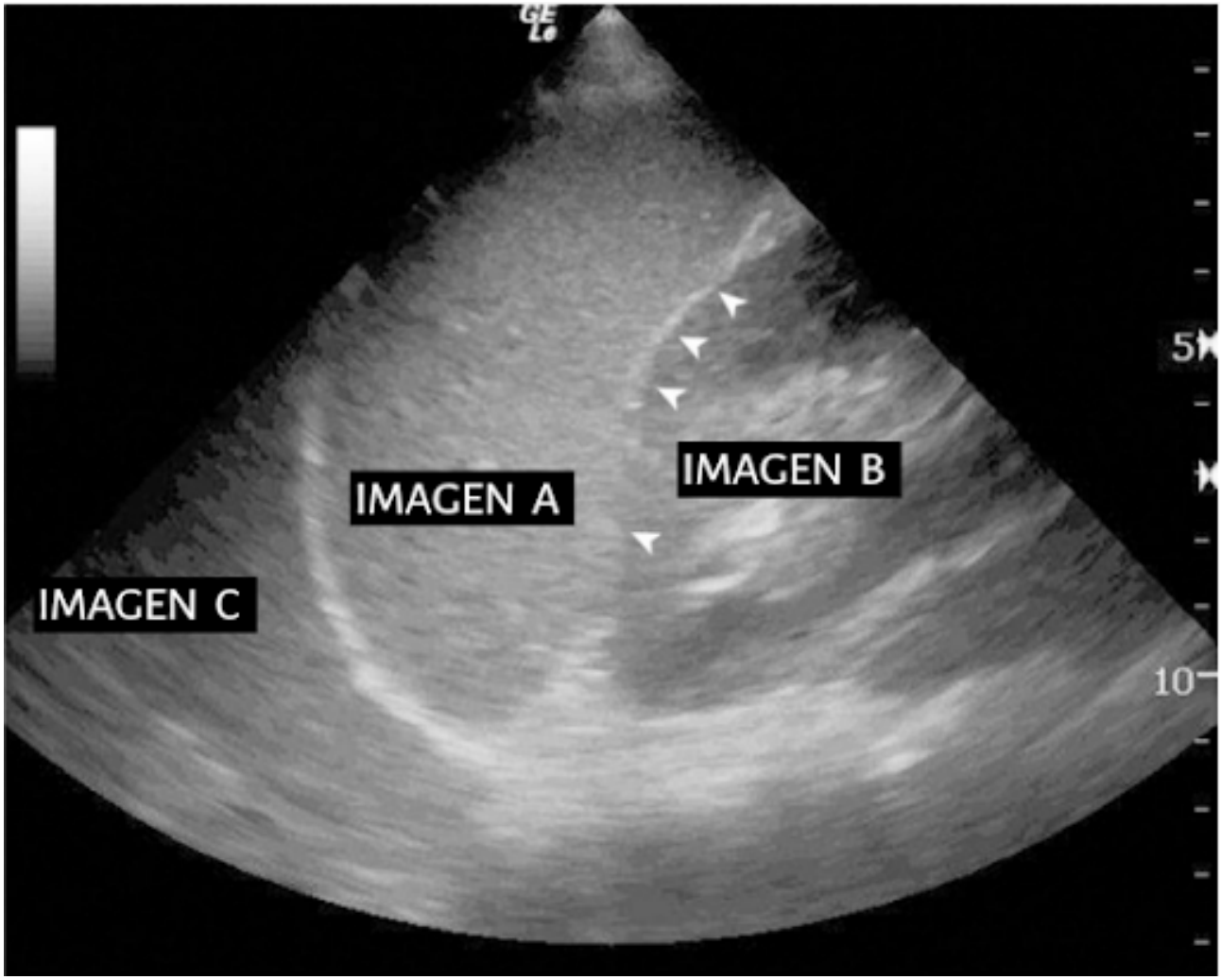

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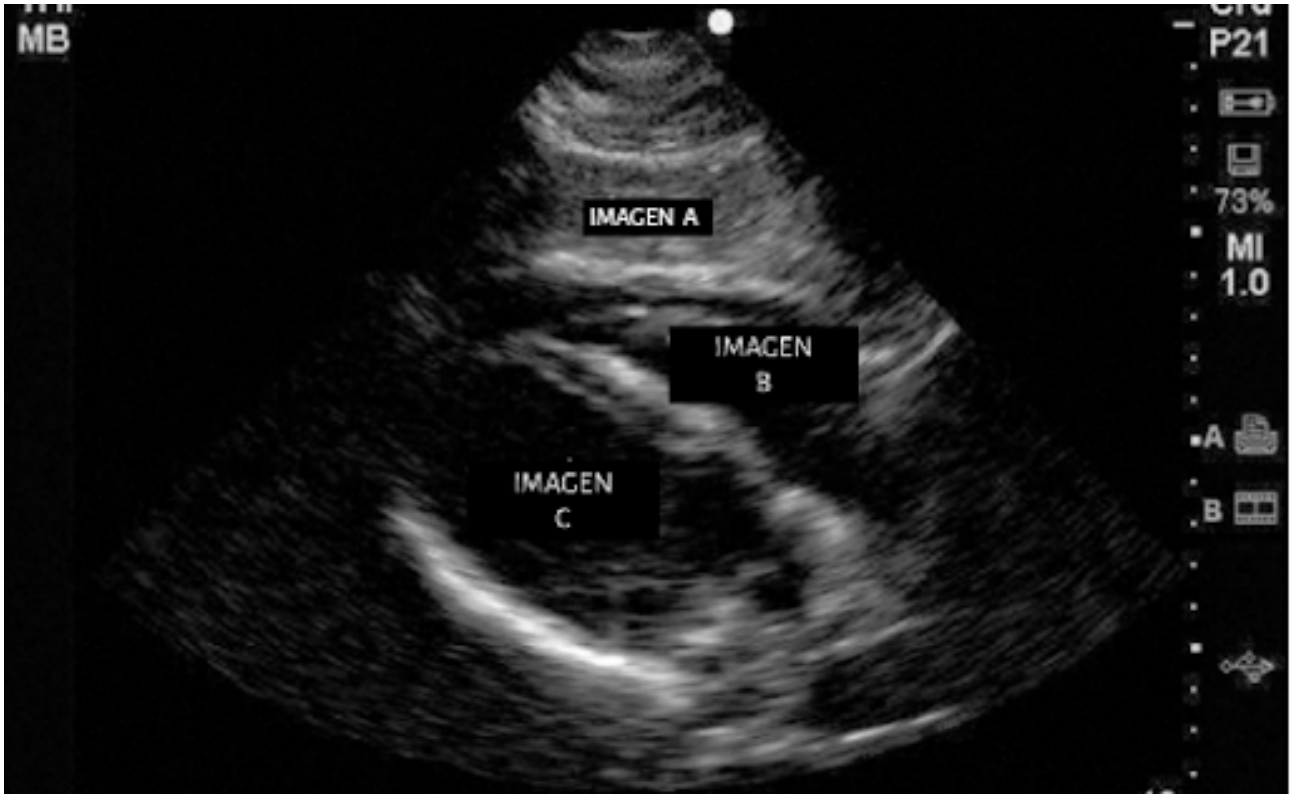
Figure 2. Image of question 3 from the posttest.



Neither the pretest nor the posttest underwent a rigorous instrument validation process, but they were tested in a pilot study conducted the previous year with similar students, who reported no problems understanding the questions or images. The tests were transcribed into Google Forms and then sent via email using a link, to be completed asynchronously by the students. All pretests and posttests were corrected by the same researcher following a scoring rubric (Annexes S2 and S3 in Multimedia Appendix 1 [11]). The maximum score for each was 20 points.

Likewise, after completing the posttest, students were sent a satisfaction survey (Annex S4 in Multimedia Appendix 1 [11]) to be completed via the SurveyMonkey platform. In this survey, the perceived usefulness of the course in general was evaluated, and students were asked to give a score from 1 to 10, which was then stratified as follows: essential (9 - 10 points), very useful (6 - 8 points), not very useful (1 - 5 points), and not at all useful (0 points). The perception of the acquisition of different skills in ultrasound was also evaluated, and students were asked to give a score from 0% to 100%, which was stratified as follows: complete ability (100%), good ability (51% - 99%), little ability (1% - 50%), and no ability (0%). Students were also asked for open-ended opinions about the course, which are presented as they were written.

Statistical Analysis Plan

A descriptive analysis was performed by obtaining the absolute and relative frequencies of the quantitative variables. The scores obtained in the pretest and posttest were subjected to calculation of averages with standard deviation and then to comparison of means using the Student t test. To evaluate the differences between pretest and posttest, the Wilcoxon test for related samples was used. A $P \leq .05$ was considered significant. Some questions that required opinions are shown verbatim in quotation marks, but opinions that were repeated or only related to the specific content of the course were not included. Excel 2021 for Windows software was used for tabulation and descriptive analysis of the data.

Ethical Considerations

The students authorized their participation by agreeing to take the course via email and by signing a written informed consent on the first day of practical sessions. The privacy and comfort of the students were respected by using an office, where only they were present in groups of 2, 3, or 4 people and the researcher; the office also had adequate ventilation and lighting. A stretcher and bedding were used to cover the parts of their bodies that were not undergoing ultrasound examination. The research did not involve any harm to any study participant, as it was an educational intervention. No student received any financial compensation for participating in the course, nor did they invest or spend any money.

This study was conducted after receiving approval from the Integrated Research, Science, and Technology Management Unit of the Faculties of Medicine, Stomatology, and Nursing, and from the Institutional Research Ethics Committee of the Universidad Peruana Cayetano Heredia with certificate number 480-20-19 dated August 27, 2019.

Results

Quantitative Results

An invitation to participate in the study was sent to 81 students; 34 enrolled, but only 26 participated in the course, although

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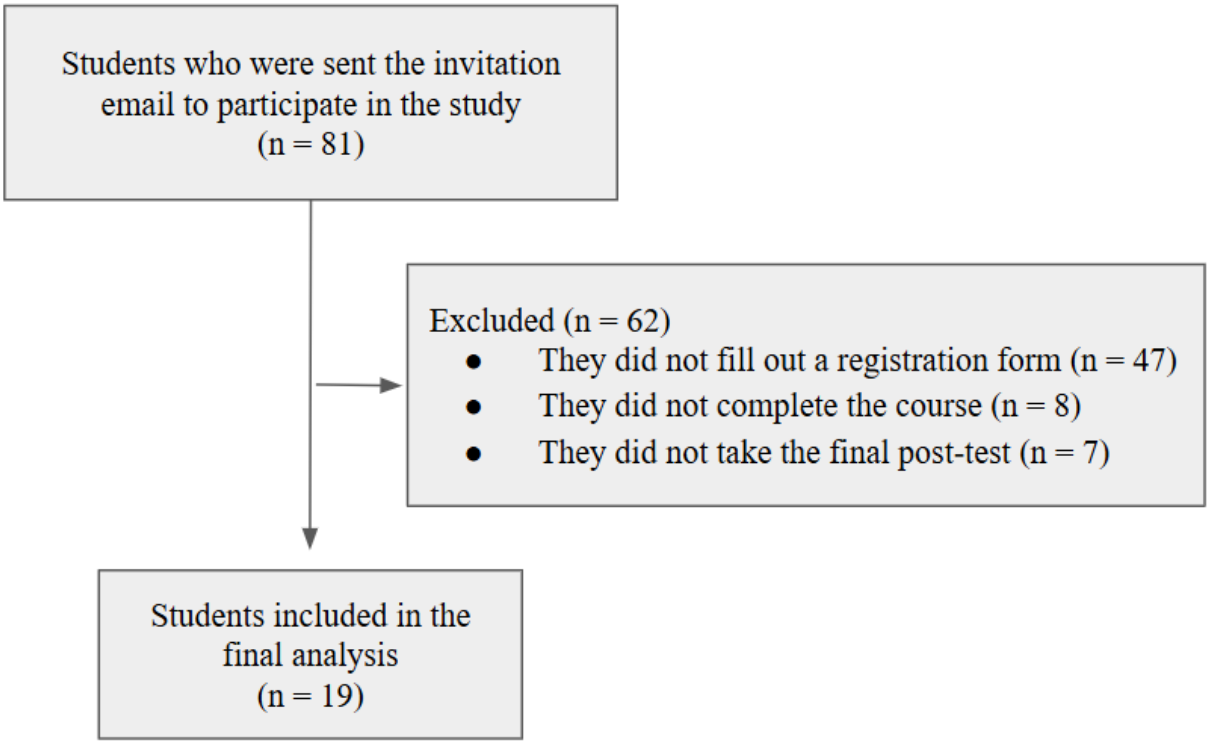
only 19 completed the posttest (10 women and 9 men). Figure 3 illustrates this. The mean age of these students was 22.2 (SD 0.8) years.

Figure 3. Flow chart of participant selection for the study.



The 26 students took the pretest before the start of the course, with an average score of 4.3 (SD 2.2) points out of a maximum of 20, but only 19 (73%) students took the posttest at the end of the course. Table 1 shows the scores of these 19 students who took the 3 assessments (precourse pretest, end-of-course pretest, and posttest) between October 2019 and February 2020. The average posttest score was 12.2 (SD 3.3) points, and the average score obtained when retaking the same initial pretest was 18.5 (SD 1.6) points. However, there were 5 students (26.3%) who scored 10 points or less on the posttest, which made the final average lower than expected. One student even scored lower on the posttest than on the pretest at the beginning of the course. Nevertheless, it was evident that the students' poor knowledge of POCUS before starting the course, with an average of 4.8 (SD 2.2) points, improved significantly in the posttest, where they obtained an average of 12.2 (SD 3.3) points, differences that were statistically significant ($P<.001$). In percentage terms, this meant an increase in precourse knowledge from 24% in the pretest to 61% in the posttest at the end of the course.

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Table . Pretest and posttest notes from medical students, Universidad Peruana Cayetano Heredia, October 2019 to February 2020 (n=19).

Student	Pretest score basal	Pretest score at the end of the course	Posttest score
E1	5	17	13.5
E2	5	18.5	13.5
E3	3	20	12.5
E4	4.5	15	7.5
E5	6.5	16	12
E6	4	19	18
E7	6.5	20	15.5
E8	7.5	16	11.5
E9	4.5	19	16.7
E10	0	18	7.5
E11	5.5	19.5	10.5
E12	3	20	10
E13	7	19.5	13
E14	9	18.5	10.5
E15	4	19	12.7
E16	4.5	20	18
E17	2.5	17	9.5
E18	7.5	19	7
E19	2	20	12
Mean qualification (SD)	4.8 (2.2)	18.5 (1.6)[a]	12.2 (3.3)[b]

[a]*P*<.001 compared with the baseline pretest.

[b]*P*<.001 compared with the baseline pretest.

The course satisfaction survey was completed by only 15 students (57.7% response rate), who reported that the course met 97.5% of their prior expectations (range 90% - 100%).

Table 2 shows the perception of acquisition of the skills taught in the course. More than 50% of students reported that they had fully acquired 5 skills by the end of the course: assessing the size of the inferior vena cava (10/15, 66.7%), the volume and characteristics of the bladder (9/15, 60%), detecting free fluid in the thorax (8/15, 53.3%) and abdomen (8/15, 53.3%), and assessing the size and characteristics of the right kidney (8/15, 53.3%). The remaining skills obtained lower percentages. However, it is noteworthy that only a third or fewer of the students who responded to the survey considered that they had fully learned how to evaluate the common bile duct, spleen, gallbladder, and liver.

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Table . Perception of acquisition of the skills taught in the course reported by medical students, Universidad Peruana Cayetano Heredia, October 2019 to February 2020 (n=15).

Perceived ability to evaluate each item	None or little, n (%)	Good, n (%)	Complete, n (%)	Total, n (%)
Size of the inferior vena cava in the study of a patient with hypotension	1 (6.7)	4 (26.7)	10 (66.7)	15 (100)
Bladder volume and characteristics	1 (6.7)	5 (33.3)	9 (60)	15 (100)
Free thoracic fluid	1 (6.7)	6 (40)	8 (53.3)	15 (100)
Free abdominal fluid	0 (0)	7 (46.7)	8 (53.3)	15 (100)
Size and characteristics of the right kidney	0 (0)	7 (46.7)	8 (53.3)	15 (100)
Pelvic free fluid	1 (6.7)	7 (46.7)	7 (46.7)	15 (100)
Free pericardial fluid	1 (6.7)	7 (46.7)	7 (46.7)	15 (100)
Size and characteristics of the left kidney	0 (0)	8 (53.3)	7 (46.7)	15 (100)
Portal vein size	1 (6.7)	7 (46.7)	7 (46.7)	15 (100)
Size and characteristics of the abdominal aorta	1 (6.7)	7 (46.7)	7 (46.7)	15 (100)
Size and characteristics of the spleen	0 (0)	10 (66.7)	5 (33.3)	15 (100)
Size of the common bile duct	2 (13.3)	8 (53.3)	5 (33.3)	15 (100)
Size and characteristics of the gallbladder	1 (6.7)	9 (60)	5 (33.3)	15 (100)
Size and characteristics of the liver	1 (6.7)	10 (66.7)	4 (26.7)	15 (100)

Table 3 shows the students' perception of the usefulness of the different aspects of the course. All of them considered the teacher (15/15, 100%) and the practical sessions with the ultrasound equipment (15/15, 100%) to be essential. Meanwhile, the teaching methodology used in the course, with an emphasis on practice and asynchronous theoretical study with periodic evaluations, was considered essential by 93.3% (14/15) of students.

Table . Perception of the usefulness of the course and its materials reported by medical students, Universidad Peruana Cayetano Heredia, October 2019 to February 2020 (n=15).

Perceived usefulness of…	Not very useful, n (%)	Very useful, n (%)	Essential, n (%)
Course teacher	0 (0)	0 (0)	15 (100)
Practice with the ultrasound scanner	0 (0)	0 (0)	15 (100)
Course methodology	0 (0)	1 (6.7)	14 (93.3)
Learning objectives	0 (0)	2 (13.3)	13 (86.7)
Course manual	0 (0)	2 (13.3)	13 (86.7)
Course pretest	0 (0)	3 (20)	12 (80)
Course posttest	1 (6.7)	3 (20)	11 (73.3)
Web-based classroom	1 (6.7)	3 (20)	11 (73.3)
Course time	1 (6.7)	5 (33.3)	9 (60)

Qualitative Results

Table 4 shows the open opinions of the students, who found that the best aspects of the course were putting theory into practice (5/15, 33.3%), learning to use the ultrasound equipment (3/15, 20%), and having few students per group (2/15, 13.3%).

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Table . Textual responses to the question "Describe the best thing about the ultrasound course you took" from some medical students, Universidad Peruana Cayetano Heredia, October 2019 to February 2020.

Student[a]	Opinions
E1	"Learning how to use the machine, performing ultrasounds with my classmates, and seeing my organs."
E2	"Using the ultrasound machine for the first time in my career, patiently and in a small group, gave me enough confidence to do the practice well."
E3	"The content of the information is very accurate."
E4	"Precise time for practice."
E5	"To practice among ourselves and be able to see what's normal."
E7	"Put into practice what we had theoretically read."
E8	"Learning to perform focused questions."
E10	"Each chapter had specific objectives to accomplish."
E11	"The teacher who always strives to ensure we effectively learn the basic concepts necessary for our careers, in addition to conveying knowledge well and seeking alternative learning methods, such as using a virtual classroom."
E11	"Practicing with the ultrasound machine among students allowed us to learn what an ultrasound machine is like and how to use it, as well as to recognize anatomically normal structures without disease."
E13	"Put into practice what you learned from the manual."
E14	"Few students in each learning session."
E14	"Do the practice based on clinical cases."

[a]Some students wrote more than one different opinion. Others did not write any opinions at all.

Table 5 shows the students' opinions on how to improve the course they took in this study. These were mainly related to having more course time and more practical sessions with the ultrasound equipment (5/15, 33.3%) and performing practical sessions on real patients with pathologies (6/15, 40%). This suggests that although students consider the course to be very valuable, it could be improved by increasing the duration of the course and the number of teaching assistants.

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Table . Textual responses to the question "Describe suggestions you consider to improve learning in the ultrasound course you took" from some medical students, Universidad Peruana Cayetano Heredia, October 2019 to February 2020.

Student[a]	Suggestions for improvement
E1	"More topics"
E2	"When we couldn't find a position for the ultrasound during practice, sometimes the doctor would help us guide the transducer, but even then, I often felt like I didn't know where it was pointing. It would have also helped to hear an anatomical reference or a verbal tip on how to locate it at that moment to remind me where to look"
E2	"Shorten the time between practices. A consistent week-to-week rhythm of these practices would seem ideal to consolidate knowledge and practice with the ultrasound"
E2	"See cases of pathologies"
E3	"More practice time"
E4	"Clinical cases in each practice, including echocardiographic studies"
E5	"It would be possible to see pathologies in real patients using ultrasound"
E7	"Having the opportunity to perform ultrasound on real patients"
E7	"Conduct more sessions on other uses of ultrasound"
E8	"Perhaps we could also practice it on a patient with a pathology related to the corresponding topic"
E9	"I think one more session would be beneficial so as not to cover so many topics in the second session"
E11	"With regard to the learning objectives, perhaps it would have been more appropriate to also mention that we review topics such as cases of biliary colic, hypotensive patients, or some cases that were seen in the pretest, because although we should have that knowledge from our previous years, it would have been important to mention them so that students could review and have an idea of how to relate the ultrasound manual to clinical aspects"
E11	"Although the central theme of the course is learning how to use ultrasound and asking focused questions, it would have been more interesting to have given us more examples so that we could ask more focused questions, because otherwise the course would only focus on learning ultrasound, but not POCUS, which would involve seeing patients or identifying pathological findings"
E11	"Time will always be a difficulty that is not necessarily the fault of the students or the teacher"
E12	"I wish I could have more days to practice"
E14	"Maybe I can practice with a patient with a certain pathology after having practiced"
E15	"I would like to be able to practice on patients with pathology"

[a]Some students wrote more than one different suggestion. Others did not write any opinions at all.

Discussion

Principal Findings

Although by 2023, 18 of 53 (31%) medical schools in the European Union [13] and, by 2020, 56 of 122 (56%) undergraduate medical schools in North America and other countries included POCUS instruction in their curricula, only 3 were from South America, specifically Brazil [14]. The theoretical and practical course that was the subject of our study was conducted between October 2019 and January 2020, at a time when there was little or no experience of using POCUS as a learning methodology in undergraduate medical studies in Peru [8]. Its design and subsequent application in a group of volunteer students before they began their preprofessional internships in hospitals showed favorable results, both in learning how to use ultrasound equipment and in knowledge of theoretical aspects and recognizing normal images in ultrasound studies in some areas of human medicine. This was reflected in the results of the postcourse evaluation, which showed significant differences with those of the precourse evaluation, indicating adequate acquisition of the knowledge and skills taught.

Our course was created from scratch following the 6 steps described by Kern and reported by Rivera Mercado et al [15], using the information we had previously obtained on the learning needs of medical students in 2018 [8]. The content and learning

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objectives of our course partially coincide with those used in a medical school in a rural area of Idaho, United States, in 2022 [16], and, although the latter was implemented in first-year medical students and lasted longer than ours, it also demonstrated a significant increase in their knowledge of POCUS. Meanwhile, in 2023, POCUS was taught from the first to the sixth year of medical school and was mandatory in some institutions in the European Union. In some of these institutions, it was even taught longitudinally over several years, although in others, it was offered transversally in subjects such as anatomy, cardiology, gastroenterology, or pulmonology [13].

At Jichi Medical University in Japan, where the medical degree lasts 6 years, ultrasound education has been provided to medical students since 1978 and is taught from the second to the final year of the degree in different courses. The 2021 curriculum also includes ultrasound training content in courses on cardiology, gastroenterology, nephrology, orthopedics, obstetrics, and emergency medicine. However, it had not yet been used for formal teaching of basic sciences or physical examination [17].

By 2022, a study in Denmark reported that 95.7% of physicians had received formal ultrasound training during medical school, although only 71.7% of their training was practical, and only 20.7% were formally evaluated in ultrasound during their medical studies [18]. The content most commonly included in the ultrasound training of these medical students was FAST, heart, lung, peripheral venous access, gallbladder, bladder, kidney, abdominal aorta, and liver, which were very similar to those taught in our course.

Comparison With Prior Work

We found only 2 studies in Latin America on POCUS teaching in undergraduate medical education in São Paulo, Brazil, and basically on E-FAST. One was developed at the University of São Paulo in 2017, where a 50-minute ultrasound course was given to 37 medical students, most of whom were in their first 4 years of study, and improvements in knowledge were found, even up to 3 months after the course ended [19]. However, this study did not evaluate the learning of practical skills. The other was conducted with 66 sixth-year medical students at Santo Amaro University in 2015 in a 5-hour program of theoretical and practical sessions, and it was shown that students improved their knowledge of E-FAST, although this was not maintained sufficiently after 3 months. However, in this study, a practical assessment was conducted at the end of the course, and it was found that 81.8% of students demonstrated skills in acquiring ultrasound images, especially of the hepatorenal and pulmonary windows [20].

In our study, although we were unable to evaluate ultrasound diagnostic imaging skills in a practical and objective manner, more than 67% of our students perceived that they had fully acquired the skills in assessing the inferior vena cava and bladder, and more than 53% of them felt that they had acquired the skills to detect pleural and ascites fluid and the right kidney after taking our course. Similarly, a study in Saudi Arabia in 2023 reported that most final-year medical students perceived that they had acquired adequate skills to detect free abdominal fluid, hepatomegaly, deep vein thrombosis, and thyroid masses, but at least 31.5% of them had received some prior POCUS training at their faculty [21]. Meanwhile, in 2021 and 2022, another theoretical-practical course for second-year medical students also reported full acquisition of skills in assessing the liver and right kidney, Morrison's space, the subxiphoid and long parasternal views of the heart, and the pleural line in Indianapolis, United States [22]. However, in the latter study, almost 40% of students also had some prior experience with POCUS. In our study, all students reported that they started their ultrasound training from scratch, although, as they were students finishing their fifth year of medical school, they may have been able to use their prior knowledge of anatomy and physiology to achieve better learning outcomes.

Meanwhile, a study conducted in Germany at the same time as ours also demonstrated a significant improvement in learning after a POCUS course focused on the liver, gallbladder, spleen, kidney, pancreas, urinary bladder, and spaces for evaluating free fluid or pleural effusion, as well as the thyroid and vascular structures, in fourth- and fifth-year medical students [23]. On the other hand, good learning in the evaluation of the spleen, right kidney, and urinary bladder was also observed in another study, which was even conducted with instructors who were peer students with experience in POCUS, and these skills could be maintained for up to 4 months after instruction of only one day of theory and one day of practice at different times [24].

The greatest contribution of our study was to show that it is possible to design a POCUS course for students in the clinical years of undergraduate medical school, implement it in a practical way in a few weeks with a single qualified instructor, and evaluate the knowledge acquired by students not in a theoretical way, but analytically, through exams requiring short answers about the analysis of POCUS images. In this regard, most studies on the implementation of POCUS courses in medicine are carried out for postgraduate students in different medical specialties (emergency medicine, internal medicine, critical care, anesthesiology, rheumatology, nephrology, pediatrics, etc) and are evaluated with multiple-choice exams, which only measure memorization [25]. However, some studies conducted in other countries, particularly the United States and Canada, have already implemented POCUS and proposed its inclusion in the medical school curriculum beyond the preclinical years (anatomy and physiology learning). For example, in Utah, United States, in 2022, a pilot course of self-directed learning was conducted with medical students in their clinical rotation with internal medicine inpatients, and they mentioned that in addition to being able to obtain adequate ultrasound images of the heart and lungs, they were able to improve their clinical reasoning, learning of pathophysiology, and medical decision-making and care for patients with cardiorespiratory pathologies [26].

Since 2021, the Medical University of South Carolina has implemented a 3-year POCUS program for its undergraduate students starting in their second year, teaching various related topics (pulmonary, cardiac, and abdominal ultrasound, studies for deep vein thrombosis) using educational videos, high-fidelity simulators, and hands-on workshops [27]. This program improved students' overall knowledge of POCUS from 50% before the program to 67% after it, which was similar to the

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61% average posttest scores achieved in our course. Although our students started with an average pretest knowledge score of 24% at the beginning of the course, the questions on our posttest were completely different from those on the pretest, and images were also used for analysis in their assessment.

At the Mayo Clinic in Minnesota, United States, an elective POCUS course was offered to medical students prior to their clinical years between 2021 and 2023. In this course, which was conducted theoretically through individual video viewing and 3 in-person practice sessions, students learned basic knowledge of POCUS, E-FAST, abdomen, etc, topics similar to those in our course. These students improved their precourse test scores from an average of 56.3% to 73.3% on the postcourse test [28]. However, the practical sessions in this course lasted 9 hours per student, while in ours they lasted 6 hours per student.

At the University of Connecticut, United States, a sustainable, vertically integrated 4-year POCUS curriculum was created, which they began to develop in 2016. During the 2021 - 2022 academic year, more than 400 medical students who took this curriculum were evaluated using a objective structured clinical exam, and it was found that the students improved their basic knowledge of ultrasound, as well as their orientation, selection of transducers and modes, and were even able to independently acquire and identify 11 of 18 anatomical structures using POCUS [29]. This demonstrates that POCUS teaching can be included not only as a stand-alone course in medical school but also longitudinally throughout all years of study.

The expectations of the students regarding our course were met in more than 97% of them, probably due to the predominance of the practical methodology of the course and teaching in small groups, which is consistent with other similar studies [16,30,31]. In fact, the main objectives of this course were captured by 2 students who commented: “Practicing with the ultrasound machine among students allowed us to learn what an ultrasound machine is like and how to use it, as well as to recognize anatomically normal structures without disease” and “Using the ultrasound machine for the first time in my career with patience and in a small group of people gave me enough confidence to do the practice well.” This improvement in confidence in the use of ultrasound was also reported by other authors in Germany, Canada, and Poland, even with only one day of instruction in POCUS [32-34].

However, there were still areas for improvement in our course, such as those related to performing ultrasound studies on patients with pathologies and, especially, having more practice time with the ultrasound equipment, as reported in other studies [18,32,33]. All suggestions for improvement could be achieved in the future by obtaining more POCUS-trained teachers and more ultrasound equipment, if teaching can be implemented in undergraduate programs and funding and logistical support can be obtained. In other countries, the use of peer teaching by students as POCUS instructors [29,31,35], and low- and high-fidelity simulation strategies have been proposed, each with several advantages, which could even complement each other to contribute to or develop other skills, such as empathy, communication, and teamwork, among others [36]. Most importantly, regardless of the duration of our course or its future voluntary or mandatory implementation in the medical school, after learning these skills, each student should continue to use POCUS in every area of the rest of their undergraduate studies and their future professional career.

Limitations

We group the limitations of our study into several types. First, those related to the development of the course itself, as the number of students who completed the course was lower than initially expected when the call for applications was made, which may have been related to the fact that they were taking regular courses that they had to pass at that time at the university and were unable to participate or complete the entire course. Other students had to travel abroad at the end of 2019, despite initially enrolling in the course. This meant that the final number of students who took the posttest was less than 20. Although this does not allow us to generalize the results obtained in our study, the large difference found between the pre- and postcourse assessments in almost all students could indicate that the course was indeed useful for learning how to perform POCUS. Another limitation was that the students voluntarily enrolled in the POCUS course, which could have positively influenced the learning of new concepts, as they were highly motivated to learn and faced a selection bias.

A second type of limitation is related to the assessment methods. On the one hand, learning was measured with image recognition and knowledge tests shortly after the course was completed. It was not possible to conduct a follow-up assessment a few months after the course ended due to circumstances arising from the COVID-19 pandemic and because contact with the students was lost, as communication with them was only through institutional email, access to which is lost upon graduation from the university. Nowadays, follow-up evaluations of the course can be carried out after a few months, as the skills and knowledge learned in the course may be forgotten if they are not continued to be practiced. On the other hand, there was no time, teachers, or resources to design and carry out practical evaluations to determine the acquisition of operational skills in the use of ultrasound equipment and transducer management to obtain images of the organs to be evaluated.

Subsequent research may also include assessments of level 3 of Miller’s pyramid, such as objective structured clinical evaluations, as performed in other countries, so that students can “show how” they perform the ultrasound study [37]. Rubrics can also be used to review video clips of the students themselves performing an ultrasound examination, with subsequent feedback [16] or direct observation of procedural skills [32,36].

Another type of limitation could be related to biases in the qualitative part of the study, as there could have been response bias, since students, even though the responses were anonymous, could have expressed favorable opinions about the course in order to look good in front of the professor or to acknowledge his effort and dedication. There could also have been a possibility that students who completed the course but did not respond to the satisfaction survey had less favorable opinions. However, this risk may have been minimal because the questions were open-ended, specific, and precise (Annex S4 in Multimedia Appendix 1 [11]), and because some students also described

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several areas for improvement in the course. Nevertheless, both types of opinions are useful to take into account for future similar research and subsequent applications of the course.

Other Relevant Aspects of the POCUS Course Implemented

Nevertheless, there are several relevant aspects to our research. One was that no real patients were needed for the practical sessions, as the students were able to perform the POCUS studies on each other. This may have created a more comfortable learning environment than in a hospital ward or health center office with real patients. Furthermore, although many medical schools in other countries include POCUS from the first year of the degree in anatomy, physiology, or physical examination courses [14], our study was conducted prior to the students' preprofessional practices, when they had already taken medical clinical courses, which may have positively influenced the learning of POCUS skills by using some prior knowledge of anatomy and physiology. However, over time, it could be implemented earlier in the degree program once certain barriers described above have been overcome, such as the lack of trained teachers, the lack of space in the current curriculum, or the lack of ultrasound equipment [14]. Another unique aspect of our study is that, unlike almost all studies on POCUS teaching in undergraduate medical education, we conducted assessments with short-answer, open-ended, or essay questions. By not using multiple-choice questions in our course assessments, we reduced the possibility of students guessing the answer by "recognizing" the correct answer rather than remembering or generating it, or using exam strategies to "eliminate incorrect alternatives" without requiring in-depth knowledge of the subject [38]. Several authors have described and demonstrated that short-answer questions have similar reliability and discrimination as multiple-choice questions [38-40]. A final important point was that at the end of the course, we only assessed the interpretation of ultrasound images and not the theoretical aspects of the subject, which is required to be competent in medical ultrasound and had been included by other authors [30,36]. This could indicate that students had also mastered the modality of acquiring some ultrasound images.

Something we noticed during the practical sessions was that some students had deficiencies in their theoretical knowledge of abdominal and vascular anatomy, and these were precisely the students who had the most difficulty recognizing some images and locating anatomical structures during abdominal ultrasound examinations. Therefore, we suggest that, if this proposed POCUS course is implemented in the undergraduate medical curriculum, it should be taken after sufficient knowledge of anatomy has been acquired, at least of the abdomen, urinary tract, and pelvis. Alternatively, a prior review of the anatomy of the organs and systems that will be covered in this course should be included.

Finally, we sought to develop several practical skills in students beyond the course: (1) the ability to apply the theoretical and practical knowledge acquired in the course to real situations, since the following year they would be treating patients in their hospital rotations, (2) the ability to solve complex cases or problems in a simulated manner, since when conducting the practical sessions with the ultrasound equipment, we told the students about clinical cases in which they might encounter an abnormal finding in the organ they were exploring, and (3) reflection on continuing to learn how to use ultrasound equipment wherever they are rotating or working in order to further develop the skills learned in this course. We even thought that in this course, we could have recruited some students to act as teachers or instructors and thus replicate the course in other groups of students later on. However, the circumstances of the pandemic prevented us from achieving this.

Conclusions

Our theoretical-practical POCUS course, conducted in small groups of undergraduate medical students after their clinical rotations, demonstrated that it was able to achieve a significant improvement in their recognition of certain organs and anatomical structures using ultrasonography. Likewise, the students who participated in the course found it very useful to learn the skill of performing POCUS to identify and interpret some normal findings in abdominal and pelvic anatomy using ultrasonography. Therefore, we suggest that it can be progressively implemented in undergraduate medical programs in Peru, as it already exists in other countries.

Funding

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Conflicts of Interest

None declared.

Multimedia Appendix 1
Course design, pretest, posttest, and satisfaction survey.
[DOCX File, 3808 KB - formative_v10i1e82717_app1.docx]

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Abbreviations

E-FAST: Extended Focused Abdominal Sonography for Trauma
POCUS: point-of-care ultrasound

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Pet Ownership, Depression, Anxiety, Well-Being, and Cognitive Functioning in Older Adults: Cross-Sectional Study

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Abstract

Background: Depression, anxiety, and cognitive decline are prevalent concerns among older adults and can negatively affect their well-being. Pet ownership has been proposed as a potential protective factor, but inconsistencies remain in the current literature.

Objective: The study aims to compare symptoms of depression, anxiety, and levels of psychological well-being between older pet owners and non–pet owners. Additionally, we compared the cognitive functioning and cognitive reserve between these 2 groups of older individuals.

Methods: This cross-sectional study included 215 community-dwelling older adults aged ≥59 years (mean 69.13, SD 6.89). Participants completed a sociodemographic questionnaire, the Modified Telephone Interview for Cognitive Status, Cognitive Reserve Index Questionnaire, Mental Health Continuum-Short Form, Geriatric Depression Scale-15, and Geriatric Anxiety Inventory. The data were collected via video calls through WhatsApp and analyzed using the JASP software. Group comparisons (pet owners vs nonowners) were conducted using the Mann-Whitney *U* test, followed by rank-biserial correlation for effect sizes (α=.05).

Results: The sample consisted of 114 (53.0%) older adults pet owners and 101 (46.9%) older adults who did not own pets. Among the pet owners, 77.2% (n=88) were female, and 57.9% (n=66) were married or in common-law marriages. In the non–pet owners' group, 71.3% (n=72) were female, and 46.5% (n=47) were married or in common-law marriages. Pet owners showed lower depression symptoms (Geriatric Depression Scale-15: mean 2.33 vs 3.00 non-owners; *U*=4714, *P*=.02; r_b=−0.18, 95% CI –0.326 to –0.028), indicating a small effect. No significant group differences were observed for anxiety (Geriatric Anxiety Inventory: mean 5.33 vs 4.92, *P*=.52), psychological well-being (Mental Health Continuum-Short Form: mean 68.21 vs 67.46, *P*=.43), cognitive performance (Modified Telephone Interview for Cognitive Status: mean 24.74 vs 24.30, *P*=.60), or cognitive reserve (Cognitive Reserve Index Questionnaire: mean 123.82 vs 123.28, *P*=.95).

Conclusions: The pet owner group presents fewer symptoms of depression in comparison to the non–pet owner group. Although no differences were observed in anxiety, well-being, cognitive functioning, or cognitive reserve, these findings suggest that pet companionship correlates with better emotional outcomes in later life. Future longitudinal studies are needed to clarify causal pathways and examine whether the frequency and quality of interactions with pets influence these outcomes.

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KEYWORDS

depression; older adults; human-animal interaction; pets; successful aging

Introduction

The global population is aging at an increasing rate. According to United Nations projections, the population aged 65 years and older is expected to exceed 2.2 billion by the end of the 2070s, and the number of people aged 80 years or older will surpass the population of infants by the mid-2030s [1]. The Brazilian population is following this trend. According to a survey by the Brazilian Institute of Geography and Statistics, life expectancy in Brazil has risen from 71.1 years in 2000 to 76.4 years in 2023 and is projected to reach 83.9 years by 2070. Over the same period, the proportion of older adults aged 60 years or more nearly doubled, increasing from 8.7% (15.2 million individuals) to 15.6% (33.0 million individuals), and approximately 37.8% of Brazil's population is expected to be aged 60 years or older by 2070 [2].

The increase in life expectancy is partly due to improvements in health conditions [2]. However, living longer does not always

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mean living better, as the aging process is associated with a decline in the individual's physical and mental capacity [3]. Furthermore, this process brings about a series of changes that can negatively impact the psychological health of older adults [4].

The mental health status of older adults presents considerable challenges. Recent evidence indicates that depression and anxiety are highly prevalent mental health conditions among older adults worldwide [5]. In Brazil, a national survey found that 13.2% of the community-dwelling individuals aged 60 years or older reported depressive symptoms [6]. Depressive symptoms in older adults are strongly associated with declines in physical health and quality of life [7,8]. Moreover, late-life depression poses a substantial public health challenge, increasing health care demands and adding to the social and economic burden of aging populations [9].

Regarding anxiety, in a sample of older adults from a city in southern Brazil, the prevalence of anxiety disorders reached 21.9% [10]. Anxiety in older adults is often underrecognized, despite its high global prevalence and its associations with comorbidity and cognitive decline [5,11].

Cognitive decline is another major challenge associated with aging and has become a growing global public health concern. Recent estimates indicate that approximately 55 million people worldwide are currently living with dementia, and this number is projected to increase to 139 million by 2050 [12]. In Brazil, a recent population−based study reported a prevalence of 5.8% for dementia and 8.1% for cognitive impairment, with projections suggesting that these figures may increase 5-fold over the next 3 decades [13].

However, not all individuals experience cognitive decline in the same way. Despite similar levels of brain pathology, some older adults maintain relatively preserved cognitive functioning, suggesting that certain factors may protect against or delay the onset of decline. One concept that helps explain these interindividual differences is cognitive reserve, which can be understood as a set of cognitive resources that an individual acquires throughout life, which can help delay declines caused by the process of healthy aging, brain damage from dementia, and slow the progression of neurodegenerative diseases [14]. Cognitive reserve has 2 theoretical models, passive and active. The passive model refers to the brain's structural characteristics, providing resilience against healthy brain aging and pathologies [15]. The active model, on the other hand, relates to external factors—activities performed throughout life that provide cognitive stimulation and lead to the strengthening or creation of new neural networks [16].

The high prevalence of depression, anxiety, and cognitive decline in later life underscores the need to identify protective factors that promote psychological and cognitive health among older adults, and the companionship of an animal could serve as a resource to achieve this goal [4]. Pets are becoming increasingly valued in society [17], and although pet ownership tends to decline as people age [18], it is possible that with the aging population, there will be more older individuals owning a companion animal [19]. According to Meier and Maurer [18], promoting pet ownership may contribute to enhancing individual well-being in older adults. Companion animals also appear to alleviate psychological symptoms in their owners, as pet ownership has been associated with fewer depressive symptoms, and regular interaction with a dog has been related to lower levels of anxiety [20,21]. Additionally, evidence suggests that pet ownership contributes to cognitive functioning in older adults and may help slow the rate of decline in executive functioning and episodic memory [22,23].

However, other studies do not support these findings. For example, the research by Hansen et al [24] found no relationship between pet ownership and psychosocial factors in adults aged 40 years and over, and another study reported no association between pet ownership and depressive symptoms among older adults [25]. Moreover, the relationship between pet ownership and better cognitive functioning in older adults is also contested [26].

Considering that symptoms of anxiety and depression are common among older adults [5] and that preventing cognitive decline is essential for healthy aging [27], it is plausible that pet ownership during this stage of life may contribute to successful aging. However, given the inconsistent findings of previous studies regarding the influence of pets on psychological health and cognition in older adults, further research is warranted. It is also noteworthy that cognitive reserve has been rarely explored in the context of human-animal interaction, underscoring the importance of including this variable in future investigations. Therefore, the aim of this study was to compare symptoms of depression, anxiety, and levels of psychological well-being between older adults who owned pets and those who did not, as well as to examine differences in cognitive functioning and cognitive reserve between these 2 groups.

Methods

Design

This is a quantitative cross-sectional observational study.

Participants

A total of 221 individuals were recruited from the general community in Brazil, primarily from the southern region. Recruitment occurred through social media platforms (Facebook and Instagram). In addition, part of the sample was recruited from existing contact lists of older adults who had previously participated in research studies conducted at the Pontifical Catholic University of Rio Grande do Sul. Posts and messages contained standardized text explaining the study objectives, eligibility criteria, and a contact link for interested participants. Individuals who expressed interest were contacted individually via WhatsApp to confirm eligibility before scheduling the interview. The participants were divided into 2 groups: 1 group consisted of participants who owned pets and the other consisted of individuals who did not own pets.

Eligible participants were community-dwelling older adults aged 59 years or older, who scored more than 14 points on the Modified Telephone Interview for Cognitive Status (TICS-M) [28], were literate, and did not have uncorrected hearing problems that could interfere with completing the instruments. All participants provided electronic informed consent before

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data collection. A total of 6 individuals who did not complete the entire questionnaire were excluded from the study. The final sample consisted of 215 participants.

Measures

The Sociodemographic Questionnaire was used to collect information regarding the sociodemographic characteristics of the sample.

The TICS-M was employed to assess the cognitive functions of the participants. The original 41-item version (TICS) was developed to identify cognitive decline through a telephone interview [29]. In its modified version (TICS-M), 2 items were altered to include a measure to assess late memory [30]. This instrument has been translated and validated for the Brazilian population in a sample of elderly stroke survivors, showing a Cronbach α coefficient of 0.93. The Brazilian version of the questionnaire identified 3 domains: working memory, recent and late memory, and orientation [28].

Cognitive Reserve Index Questionnaire (CRIq) was applied to assess the cognitive reserve of the participants. This questionnaire consists of 20 items grouped into 3 subscales (CRIq Education, CRIq WorkingActivity, and CRIq LeisureTime). The total score of the instrument is calculated by adding up the subscores of the 3 subscales. The original version of the CRIq has a Cronbach α coefficient of 0.73 [31], and this questionnaire already has a version translated into Brazilian Portuguese [32], which was used in this study.

Mental Health Continuum-Short Form (MHC-SF) was used to assess positive mental health. It consists of 14 items presented in a Likert scale format, ranging from 1 (never) to 6 (every day). The MHC-SF has 3 subscales that assess subjective or emotional well-being, psychological well-being, and social well-being [33]. In this study, we applied the translated and validated version of the MHC-SF for the Brazilian population, which shows adequate reliability with a Cronbach α of 0.96 [34].

Geriatric Depression Scale (GDS-15) was used to measure the participants' depression symptoms. The GDS is specifically designed for older adults and addresses depression symptoms experienced in the week preceding the questionnaire application. The short version consists of 15 items, with responses classified as "yes" or "no." The total score is calculated by adding up the responses selected by the respondents [35]. In this study, we used the translated and validated version for the Brazilian context, which presents adequate reliability coefficients according to the paired Wilcoxon test (z=1.60; P=.11), Spearman correlation (ρ=0.86; P<.001), and weighted kappa (κ=0.64) [36].

Geriatric Anxiety Inventory (GAI) was used to assess symptoms of anxiety. This instrument consists of 20 items in which participants indicate whether they agree or disagree with the statements, considering the week before the questionnaire was applied [37]. In this study, we used the translated and validated version for the Brazilian population, which has a Cronbach α coefficient of 0.90 and significant test-retest reliability (ρ=0.85, P<.001) [38].

Data Collection

Data collection was conducted through individual video calls using the WhatsApp messaging app. During each session, participants' responses were entered in real time into the Qualtrics platform by the researcher. All data were collected by trained psychology students who received prior instruction and supervision to ensure the standardized administration of the instruments. The data collection period extended from April to September 2023.

Ethical Considerations

The study was approved by the Research Ethics Committee of the Pontifical Catholic University of Rio Grande do Sul (approval number: 65996522.5.0000.5336) and complied with national and institutional ethical standards for research involving human participants, in accordance with Resolution No. 466/2012 of the Brazilian National Health Council and Resolution No. 016/2000 of the Federal Council of Psychology. All participants received an electronic informed consent form outlining the study's objectives, potential risks and benefits, anonymity, and voluntary nature of participation. Only those who agreed to the consent form were included in the study. Participants were assured of the confidentiality of their data and their right to withdraw from the study at any time without any consequences. Data were collected and stored anonymously, and no personally identifying information was retained or linked to participant responses. Participants did not receive financial compensation or any other form of remuneration for their participation.

Data Analysis

The data were analyzed using the JASP software (version 0.18.3.0. JASP Team). Quantitative variables were described using means and standard deviations, while categorical variables were presented in terms of absolute and relative frequency. The normality of the univariate distribution of the variables under investigation was assessed using the Shapiro-Wilk test, adopting a significance level of P<.05. Since all variables in this study violated the assumption of normality, nonparametric statistical tests were employed. To compare the groups, the Mann-Whitney U test was conducted, followed by a rank-biserial correlation (r_b) to assess the magnitude of the effect size found.

Results

The final sample of this study consisted of 215 participants, with an average age of 69.13 years (SD 6.89), ranging from 59 to 93 years. Among the participants, 160 (74.4%) were female, 188 (86.2%) resided in the state of Rio Grande do Sul, 113 (51.8%) were married or in a common-law marriage, and 80 (37.2%) had higher education. Regarding pet ownership, 114 (53.0%) were pet owners of at least 1 animal, and 101 (46.9%) did not have pets. Among the participants who reported having pets, the majority (n=88, 77.2%) were female, and the most common marital status was married or in a common-law marriage (n=66, 57.9%). Among those who did not have pets, most (n=72, 71.3%) were female, and 47 (46.5%) reported being married or in a common-law marriage. These and other sociodemographic characteristics are presented in Table 1.

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Within the group of pet owners, 18 (8.4%) only had cats, 66 (30.7%) only had dogs, and 3 (1.4%) only owned other species of animals. Additionally, 27 (12.5%) individuals reported owning both dogs and cats; 9 (4.2%) owned dogs and other species; 2 (0.9%) had cats and other species; and 4 (1.9%) were owners of dogs, cats, and other species. The most frequently mentioned other animal species were rabbits, turtles, chickens, and monk parakeets.

Using the Mann-Whitney *U* test, we found significant differences between the groups regarding the total GDS score (U=4714, P=.02), with a small effect size observed (r_b=−0.18). No significant differences were found in the other variables. The information is provided in Table 2.

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Table . Sociodemographic characteristics of older adults (≥59 y) participating in a cross-sectional study in Brazil.[a]

Variables	Total, n (%)	Pet owners, n (%)	Non–pet owners, n (%)
Gender			
Women	160 (74.4)	88 (77.2)	72 (71.3)
Male	55 (25.2)	26 (22.8)	29 (28.7)
States of the country			
Goiás	1 (0.4)	0 (0)	1 (0.9)
Minas Gerais	6 (2.7)	5 (4.4)	1 (0.9)
Paraná	3 (1.4)	2 (1.7)	1 (0.9)
Rio de Janeiro	2 (0.9)	0 (0)	2 (1.9)
Rio Grande do Sul	188 (86.2)	99 (86.8)	89 (88.1)
Santa Catarina	7 (3.2)	6 (5.2)	1 (0.9)
São Paulo	8 (3.7)	2 (1.7)	6 (5.9)
Marital status			
Married or common-law marriage	113 (51.8)	66 (57.9)	47 (46.5)
Divorced or separated	39 (17.9)	16 (14.0)	23 (22.8)
Single	25 (11.5)	15 (13.1)	10 (9.9)
Widow or widower	38 (17.4)	17 (14.9)	21 (20.8)
Education level			
Incomplete primary education (up to 4 y of study)	8 (3.7)	3 (2.6)	5 (5.0)
Incomplete secondary education (less than 11 y of study)	10 (4.7)	5 (4.4)	5 (5.0)
Complete secondary education (up to 11 y of study)	38 (17.7)	21 (18.4)	17 (16.8)
Incomplete higher education	18 (8.4)	9 (7.9)	9 (8.9)
Complete higher education	80 (37.2)	41 (36.0)	39 (38.6)
Postgraduate (specialization, master's, or doctorate)	61 (28.4)	35 (30.7)	26 (25.7)
Employment status			
Employed	15 (7.0)	9 (7.9)	6 (5.9)
Self-employed	11 (5.1)	10 (8.8)	1 (1.0)
Retired	146 (67.9)	74 (64.9)	72 (71.3)
Retired but still working	40 (18.6)	20 (17.5)	20 (19.8)
Never worked	3 (1.4)	1 (0.9)	2 (2.0)
Medication use			
Yes	175 (80.3)	89 (78.1)	86 (85.1)
No	40 (18.3)	25 (21.9)	15 (14.8)

[a]Data were collected through online interviews conducted via WhatsApp video calls between April and September 2023. The table presents the total sample and subgroup distributions for pet owners and nonowners.

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Table . Differences in depression, anxiety, well-being, and cognitive measures between pet owners and nonowners in a cross-sectional study with older adults from Brazil.[a]

Variable	Pet owners (mean)	Non–pet owners (mean)	*U*	*P* value	Effect size	SE effect size	95% CI for rank-biserial correlation	
							Lower	Upper
Orientation TICS-M[b]	6.737	6.752	5651	.75	−0.018	0.079	−0.172	0.136
Recall TICS-M	4.912	4.653	6195	.32	0.076	0.079	−0.079	0.227
Attention TICS-M	4.307	4.495	5462	.48	−0.051	0.079	−0.203	0.103
Memory TICS-M	4.807	4.772	5897	.65	0.024	0.079	−0.130	0.177
Language TICS-M	0.851	0.772	6209	.14	0.079	0.079	−0.076	0.230
Delayed Recall TICS-M	3.123	2.851	6171	.36	0.072	0.079	−0.083	0.223
Total TICS-M	24.737	24.297	5996	.598	0.042	0.079	−0.113	0.194
CRI-Education	126.658	130.059	5265	.28	−0.085	0.079	−0.236	0.069
CRI-WorkingActivity	116.711	116.772	5623	.77	−0.023	0.079	−0.176	0.131
CRI-LeisureTime	110.605	106.030	6272	.26	0.090	0.079	−0.065	0.240
Total CRIq[c]	123.816	123.277	5784	.95	0.005	0.079	−0.149	0.158
EWB[d] MHC-SF[e]	15.842	15.426	6306	.22	0.095	0.079	−0.059	0.246
SWB[f] MHC-SF	31.553	31.139	5917	.73	0.028	0.079	−0.144	0.164
PWB[g] MHC-SF	20.816	20.891	5817	.896	0.010	0.079	−0.127	0.181
Total MHC-SF	68.211	67.455	6113	.43	0.062	0.079	−0.093	0.214
Total GAI[h]	5.325	4.921	6048	.52	0.051	0.079	−0.104	0.203
Total GDS[i]	2.333	3.000	4714	.02	−0.181	0.079	−0.326	−0.028

[a]Statistical comparisons were conducted using the Mann–Whitney *U* test, with effect sizes reported as rank-biserial correlations (α=.05).

[b]TICS-M: Modified Telephone Interview for Cognitive Status.

[c]CRIq: Cognitive Reserve Index Questionnaire.

[d]EWB: emotional well-being.

[e]MHC-SF: Mental Health Continuum-Short Form.

[f]SWB: social well-being.

[g]PWB: psychological well-being.

[h]GAI: Geriatric Anxiety Inventory.

[i]GDS: Geriatric Depression Scale.

Discussion

Principal Findings

This study aimed to compare symptoms of depression, anxiety, and levels of psychological and cognitive well-being between older individuals who owned pets and those who did not. The results showed that pet owners presented fewer symptoms of depression compared to non–pet owners, whereas no significant differences were observed for anxiety, cognitive functioning, or cognitive reserve.

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The observed association between pet ownership and lower depressive symptoms aligns with previous findings, suggesting that companion animals can mitigate depression symptoms among older individuals who had experienced loss, such as a divorce or the death of a spouse [21]. Furthermore, in another study, older individuals who frequently engaged in activities with their pets reported lower levels of depression symptoms, regardless of factors such as age, gender, and education. However, this effect was not observed when considering only the presence of a pet [39].

Friedmann et al [19] proposed the biopsychosocial model as a framework to explain how companion animals may help minimize depressive symptoms in their owners. According to this perspective, pet ownership can influence health through the interaction of biological, psychological, and social factors. The presence of an animal may enhance the social dimension by providing companionship and emotional support, which can improve the psychological state through social support or other mechanisms, such as reducing depression, stress, and anxiety, and ultimately promote positive health outcomes in older adults [19].

However, not all studies have found the same association. Sharpley et al [40], in a longitudinal study, reported that older individuals with more symptoms of depression were more likely to own a dog. However, in this study, pet ownership was not associated with changes in symptoms of depression over time [40]. Similar results were observed in the study by Mueller et al [41], where pet ownership was associated with a higher likelihood of having experienced symptoms of depression over the course of life. In contrast, no relationship was found between current depression and pet ownership [41].

In another investigation, cat owners exhibited more symptoms of depression in comparison to dog owners or older individuals without pets [42]. These results were corroborated by other studies that also found no evidence of an association between having a pet and symptoms of depression in the older population [19,24,43,44].

One possible explanation for these inconsistencies is that while some older individuals may benefit from living with pets, for others, the responsibility of caring for an animal could be detrimental [24]. This may be due to the stress caused by the commitment or difficulties in meeting the pet's needs [42]. The responsibility of taking care of a pet might interfere with the individual's freedom, limiting outings and travel. Financial concerns, such as the costs of food and veterinary care, may also cause worries for some pet owners [45,46].

As for anxiety symptoms, no significant differences were found between the groups. This result also shows contradictory findings across studies. While some research has not observed differences in anxiety symptoms when comparing older individuals with and without pets [19,47], the results from Bolstad et al [48] suggest that having a pet during old age is associated with lower anxiety symptoms. Additionally, the systematic review conducted by Hughes et al [49] concluded that interaction with companion animals can alleviate anxiety symptoms in older individuals. Moreover, a study that evaluated mental health outcomes in older individuals with dogs concluded that the frequency of contact with a dog might be associated with lower anxiety levels [20].

Regarding psychological well-being, the results of this study did not indicate significant differences between the groups. This finding is consistent with previous studies that also found no differences when comparing the psychological well-being of older individuals with and without pets [19,47]. However, the study by Hui Gan et al [46] does not support these findings, highlighting the positive effect of pets on the well-being of older individuals. Furthermore, recent research suggests that owning a dog may be effective in enhancing the psychological well-being of socially isolated older individuals. However, the authors of the study highlight that this effect was not observed among cat owners [50].

As observed by Bennett et al [47], merely owning a pet may not be associated with substantial differences in the well-being of older individuals, a point also noted by studies investigating other psychological measures, such as anxiety and depression symptoms [39,47]. This observation may help explain the inconsistencies in the scientific literature that evaluated human-animal interactions [47]. Recent research conducted with adults supports this hypothesis, indicating that interactions with animals may have a protective effect against negative feelings. These studies show that tactile interactions and activities like playing with, caring for, and training the animal are associated with greater well-being among pet owners [51-53]. Thus, it may be more important to consider the frequency of contact with the pet rather than merely evaluating the presence of a pet [47].

Additionally, comparing these studies is challenging due to their methodological differences, such as the use of different instruments to assess the same constructs and the heterogeneity of their samples. It is also important to consider that mental health is influenced by various factors, and pet ownership is just 1 aspect. Therefore, it is crucial to investigate other elements that also affect mental health [54]. In this study, these sources of variability were minimized by employing validated assessment instruments and standardized procedures for data collection, as well as by including a relatively homogeneous sample in terms of education and cognitive level.

When assessing the cognitive level and cognitive reserve of the participants, no significant differences were found between the groups. An earlier study also found no association between cognitive function and pet ownership [26]. However, other studies reveal that older individuals who own pets exhibit better cognitive function compared to those who do not [22,23,43]. Furthermore, the study by McDonough et al [55], conducted with participants up to 74 years old, indicated that pet ownership was associated with higher levels of cognition and larger brain structures, especially among dog owners. Thus, we can infer from these studies that pet ownership may also be associated with a higher level of cognitive reserve.

The inconsistencies observed in these research results may be due to the different methods used to assess cognition. Additionally, evidence suggests that long-term pet ownership (more than 5 y) is what might provide cognitive benefits for older individuals [56]. Since the time spent with the pet was

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not included in the analyses of this study, and some studies did not mention whether this variable was evaluated [43,43], this may be an alternative explanation for the discrepancies found between the results.

However, the lack of significant differences between the groups regarding cognitive level and cognitive reserve reinforces the finding that indicates fewer depression symptoms among pet owners. Considering the relationship between depression symptoms and cognitive decline in older individuals [57,58], the absence of differences in cognitive levels and cognitive reserve suggests that variations in depression symptoms between groups cannot be attributed to differences in cognitive function. Instead, it is more likely a direct result of the influence of pet ownership. Thus, pet ownership may act as a protective factor against depression symptoms in the older population.

Limitations and Future Directions

These findings should be interpreted with caution due to several limitations. First, the cross-sectional design precludes causal inferences. Second, the data were based on self-reported measures, which may be subject to response bias. Additionally, the study did not assess the duration or nature of pet ownership, factors that could influence psychological outcomes. Moreover, the sample was primarily composed of highly educated older adults with preserved cognitive functioning from southern Brazil, which may limit the generalizability of the results to other populations.

Future studies should investigate the activities performed with pets to gain a better understanding of how pet ownership can influence the psychological health of older individuals. Additionally, future studies must explore this association with larger samples and use a longitudinal design to examine the effect of pet ownership on depressive symptoms over time.

Conclusions

Despite the mentioned limitations, the results of this study are relevant, as they compared groups with similar cognitive characteristics, suggesting that the differences found may be attributed to the presence of pets. Therefore, the present findings indicate that pet ownership may be associated with fewer depressive symptoms in older adults, although no significant effects were observed on cognitive reserve, cognitive functioning, anxiety, or psychological well-being. These findings highlight the potential role of companion animals as a source of emotional support in later life. Moreover, these findings have practical implications, as encouraging community initiatives that foster human-animal interaction, such as volunteer programs in shelters or animal-assisted physical activities, may help mitigate depressive symptoms in older adults while also promoting animal welfare.

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Data Availability

The datasets generated or analyzed during this study are not publicly available due to participant confidentiality but are available from the corresponding author on reasonable request.

Authors' Contributions

NSdA and TQI contributed to the conceptualization and methodology of the study. NSdA and ISK were responsible for data collection. WdLM performed the formal analysis and contributed to writing the original draft, together with NSdA and ISK. NSdA, TQI, and CM-T contributed to the writing—review and editing of the manuscript. TQI and CM-T provided supervision throughout the project. All authors have read and approved the final version of the manuscript. NSdA is the co-corresponding author of this study and can be reached via email at nathalia.albuquerque@edu.pucrs.br.

The authors declare the use of generative AI in the research and writing process. According to the GAIDeT taxonomy (2025), the following tasks were delegated to GAI tools under full human supervision:
- Proofreading and editing
- Translation
The GAI tool used was: ChatGPT-5.
Responsibility for the final manuscript lies entirely with the authors.
GAI tools are not listed as authors and do not bear responsibility for the final outcomes.
Declaration submitted by: Collective responsibility

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Conflicts of Interest

None declared.

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Abbreviations

CRIq: Cognitive Reserve Index Questionnaire
GAI: Geriatric Anxiety Inventory
MHC-SF: Mental Health Continuum-Short Form
TICS-M: Modified Telephone Interview for Cognitive Status

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Identifying the Structure and Elements of Nutritional Guidance Techniques: Cross-Sectional Analytic Hierarchy Study

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Abstract

Background: Registered dietitian nutritionists (RDNs)—referred to as registered dietitians in Japan—contribute to disease management, prevention of complications, and improvement in quality of life through individualized nutritional guidance. However, these techniques often rely on individual experience, leading to variations in quality. The nutrition care process provides a standardized framework for nutritional care, but the specific techniques used in clinical practice and their interrelationships remain unclear. Interpretive structural modeling (ISM) is a method that visualizes and hierarchically organizes interrelationships among multiple elements, making it useful for structuring complex practical skills. Therefore, clarifying the structure of nutritional guidance techniques may support the standardization of practice and the development of educational frameworks.

Objective: This study aimed to identify the elements influencing nutritional guidance techniques in clinical practice, clarify their hierarchical structure using ISM, and explore their potential applicability to the education of registered dietitians.

Methods: Three experienced RDNs participated in an expert panel. Elements influencing nutritional guidance techniques were identified through structured brainstorming and consensus-building sessions. The extracted elements were analyzed using ISM to generate a reachability matrix and derive a hierarchical structure that visualized the interrelationships among the elements.

Results: A total of 14 elements were identified and organized into a 6-level hierarchical structure. The upper levels included nutrition care process–related elements, with the “nutritional intervention plan” positioned at the top, whereas the lower levels consisted of foundational elements such as “clinical knowledge” and “understanding of patient background.”

Conclusions: This study identified 14 elements influencing nutritional guidance techniques in clinical practice and systematically visualized their interrelationships as a 6-level hierarchy using ISM. The resulting model provides an initial framework that may inform the development of clinical education curricula and competency evaluation frameworks for RDNs, and it could contribute to the advancement of standardized approaches in nutritional guidance education.

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KEYWORDS

nutrition counseling; dietitians and education; health education; educational models; decision-making; clinical competence; professional competence; medical informatics

Introduction

In clinical settings, registered dietitian nutritionists (RDNs) play a critical role in delivering individualized nutritional guidance tailored to each patient, thereby contributing to disease management, prevention of complications, and improvement in quality of life, with their effectiveness being well documented [1-5].

With the growing public interest in nutrition, the significance of RDNs is increasingly recognized. To provide systematic and evidence-based nutritional care, the nutrition care process (NCP) has been internationally standardized, and its framework is defined by the NCP model [6,7].

Although the NCP offers a standardized procedural framework for nutritional care, it does not capture the specific techniques used by dietitians in practice or the interrelationships among them. In clinical nutrition counseling, not only professional

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knowledge but also skills such as communication, patient motivation, value sharing, and understanding of the patient background are essential [8]. These elements are often dependent on the individual dietitian's experience and skill set, which can result in variability in the quality of nutritional counseling [9].

While previous studies have explored the competencies of expert dietitians [10-13] and conceptually defined their professional expertise [14], the specific components and interrelationships of nutritional guidance techniques in clinical practice remain unclear. To clarify the complex interplay among these techniques, it is necessary to move beyond anecdotal discussion and adopt a systematic and objective analytical method.

Interpretive structural modeling (ISM) [15] is a methodology designed to visualize and hierarchically structure interdependent relationships among elements. ISM has been applied in diverse fields, such as organizational theory, curriculum development, and medical informatics [16-20]. Its strength lies in structuring complex insights derived from expert knowledge, offering a valuable foundation for educational design that facilitates efficient learning for novices.

Accordingly, this study identified and visualized the hierarchical structure of elements influencing nutritional guidance techniques in clinical practice using the ISM approach. The findings are expected to contribute to the standardization of clinical nutrition counseling, the development of structured educational programs for dietitians, and the establishment of competency evaluation frameworks, ultimately enhancing the quality of clinical education.

Methods

Study Design and Participants

This study used a cross-sectional design using ISM to visualize the structural relationships among elements influencing nutritional guidance techniques in clinical practice. ISM is a methodology used to structure and analyze complex issues by leveraging expert knowledge. Because ISM derives insights from a small number of experts within a specific system, the expertise and credibility of panel members are critical.

In alignment with previous ISM studies in the health care domain [18-20] and consistent with the objective of systematizing practical knowledge in clinical settings, an expert panel of RDNs was convened at a medical institution in Japan, where the study was conducted. Participation was entirely voluntary, and eligible individuals were invited based on predefined eligibility criteria.

The eligibility criteria for the expert panel were as follows:

- At least 10 years of clinical experience as an RDN in medical institutions
- Ongoing involvement in routine nutritional counseling, with a workload of more than 10 counseling sessions per week
- Engagement in the training and education of dietetic students at accredited educational institutions

On the basis of these criteria, 3 RDNs with 19, 14, and 12 years of clinical experience participated in the study. The purpose and procedures of the study were explained in advance, and all participants voluntarily engaged in the structured consensus-building process as part of professional collaboration.

Extraction of Elements and Procedure

A structured expert consensus method was adopted to extract elements relevant to the nutritional guidance techniques. The procedure comprised the following steps:

- Brainstorming—each participant independently listed the elements they considered influential on nutritional guidance.
- Sorting and categorization—the extracted elements were written on individual sticky notes and displayed on a large board. Similar items were grouped, and category names were assigned to each group. The relationships among the groups were then visually organized using connecting lines.
- Consensus formation—under the facilitation of a moderator, the participants discussed and confirmed the validity of the groupings and interrelationships. Each step was conducted independently to minimize bias, and the final decisions were made after a third-party review.

Definition of the Elements

Each element was assigned a clear and concise definition based on the NCP to eliminate ambiguity and promote shared understanding among professionals.

Statistical Analysis

The structural relationships among the elements were analyzed in accordance with the standardized ISM procedures as follows:

- Development of the adjacency matrix—all elements were arranged in a square matrix with element i on the vertical axis and element j on the horizontal axis. If element i influenced element j, then the matrix entry a_{ij} was set to 1; otherwise, it was set to 0. This resulted in the formation of the adjacency matrix A (Table S1 in Multimedia Appendix 1).
- Derivation of the reachability matrix—the identity matrix I was added to the adjacency matrix A to obtain matrix B. By exponentiating B, the reachability matrix T was calculated (Table S2 in Multimedia Appendix 1).
- Hierarchy level determination—for each element, a reachability set (R) and an antecedent set (Q) were determined. Elements satisfying the condition $R \cap Q = R$ were assigned to the highest hierarchical level. This process was repeated to classify all elements into hierarchical levels, which were then visualized in a structured diagram.

All analyses were conducted using College Analysis (version 8.5) [21].

Independent Third-Party Review

To further enhance reproducibility and minimize bias, an independent third-party review was conducted for the ISM procedure and outputs. The reviewer was a researcher with more than 20 years of experience in the field of medical informatics who did not participate in the selection of candidates or the expert panel sessions. The review assessed (1) the

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comprehensiveness of the 14 elements and their operational definitions with reference to the NCP, (2) the audit trail from the original brainstorming records to the grouped categories and final elements, (3) the internal consistency of the pairwise comparisons and the resulting adjacency matrix, (4) the reproducibility of the reachability matrix and level assignments, and (5) the validity of the final hierarchical diagram. No major discrepancies requiring changes in element membership or hierarchy levels were identified, and only minor wording adjustments were recommended and implemented.

Ethical Considerations

The Teine Keijinkai Hospital Ethics Committee of the authors' affiliated institution determined that this study was not subject to ethical review under Japan's Ethical Guidelines for Medical and Biological Research Involving Human Subjects, as it did not involve the collection of information on individual participants (ethical review status TKH-EC No. A1-3-025298).

Results

This study identified 14 elements that influence nutritional guidance techniques and their definitions (Table 1).

Table . The 14 elements influencing nutritional guidance techniques and their definitions.

Element	Definition
Food, nutrition, and cooking knowledge	Correct recognition and understanding related to food, nutrition (including meals, snacks, enteral and parenteral nutrition, and supplements), and cooking
Clinical experience	Experience addressing nutritional problems in patients as a clinical dietitian
Learning opportunities	Time spent acquiring knowledge and skills outside of routine clinical practice
Multidisciplinary collaboration	Consulting, referring to, and coordinating with other health care professionals and institutions involved in nutritional management
Information gathering	Gathering clinical data and facts about patients whose nutritional status is presumed to be affected
Clinical knowledge	Correct recognition and understanding of clinical medicine and understanding of the patient's condition
Communication skills	Ability to build good relationships with patients and various professionals
Physical assessment	Evaluating physical signs and symptoms in patients
Nutritional diagnosis	On the basis of nutritional assessment, comprehensively determining the nutritional status of the patient and identifying nutritional issues
Understanding of patient background	Understanding and respecting the patient's social and mental conditions
Motivating	The psychological process that encourages a patient to start taking action toward a goal and reach that goal
Nutritional intervention plan	Intervention contents to improve and solve nutritional issues according to the individual needs of patients
Educational materials	Materials and media used to structure an educational curriculum aimed at facilitating mutual understanding between the dietitian and learners
Counseling techniques	Techniques used by clinical dietitians to assist patients using psychological methods from a professional standpoint

Furthermore, a 6-level hierarchical structure based on these elements was obtained (Figure 1).

The 3 upper levels consisted of NCP-related elements. At the top level (level 1) was "nutritional intervention plan," followed by "nutritional diagnosis" at level 2. Level 3 included "information gathering" and "physical assessment." "Clinical knowledge" and "motivating" were placed at level 4. Level 5 comprised "food, nutrition, and cooking knowledge," "counseling techniques," and "multidisciplinary collaboration." At the base level (level 6), "understanding of patient background," "communication skills," "clinical experience," "learning opportunities," and "educational materials" were located.

Figure 1 illustrates the 6-level hierarchical framework consisting of 14 elements that influence nutritional guidance techniques. Levels 1 to 3 represent higher-order elements related to the NCP, whereas levels 4 to 6 represent foundational elements that underpin these upper-level competencies.

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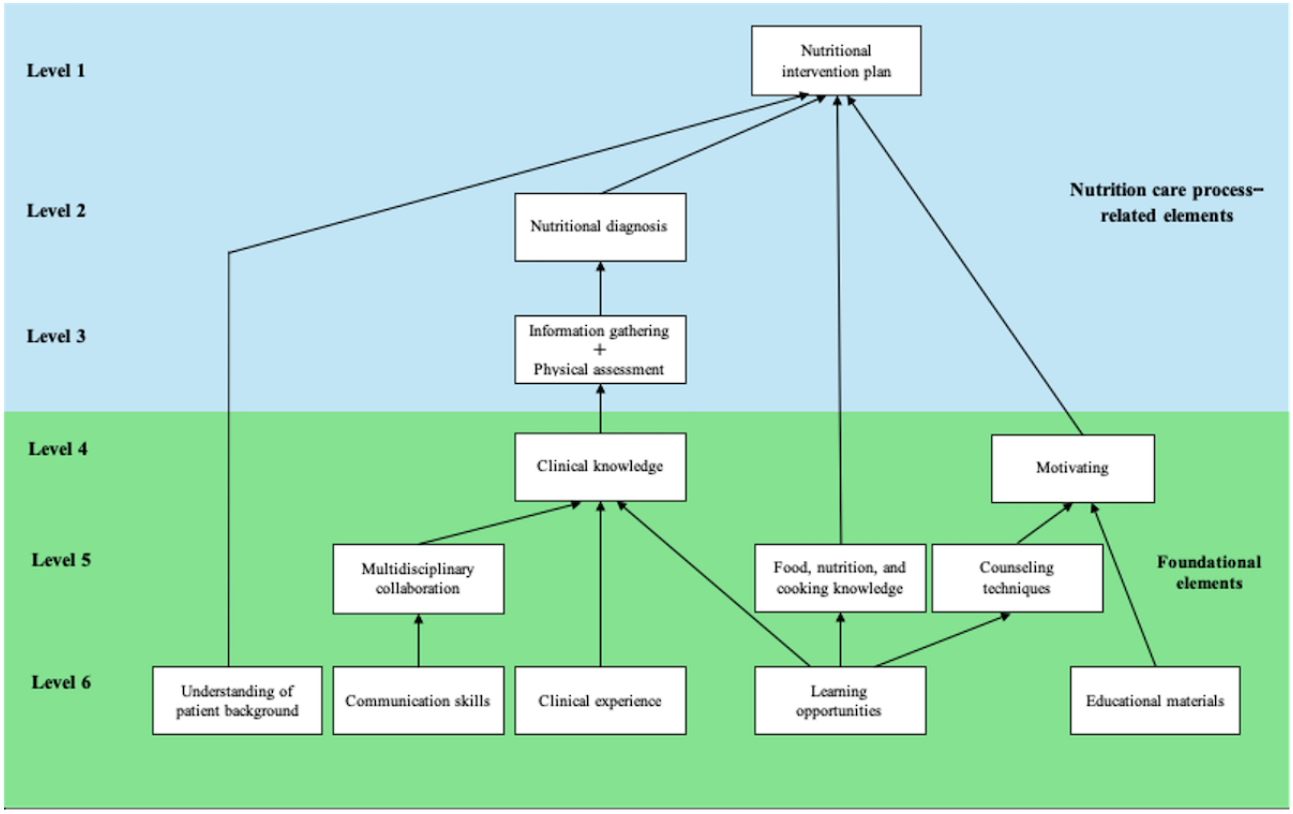
Figure 1. Hierarchical structure of 14 elements influencing nutritional guidance techniques identified using interpretive structural modeling.



Discussion

Principal Findings

This study is the first to systematically visualize both the components and the hierarchical structure of nutritional guidance techniques in clinical settings using ISM. A total of 14 elements that influence dietitians' practical skills were extracted by 3 experienced registered dietitians, and the interrelationships of these elements were structured into 6 hierarchical levels. The findings reveal that nutritional guidance is not a linear sequence of procedures but a multilayered construct formed through the integration of knowledge, clinical experience, interpersonal skills, and contextual factors.

While the NCP model offers a procedural framework focused on standardizing nutrition care [6], this study offers a new perspective by capturing the interrelationships among the technical elements underpinning nutritional guidance techniques in clinical settings.

Comparison With Previous Studies and Interpretation

All 14 elements identified in this study correspond closely to the essential competencies outlined in the most recent standards of practice and standards of professional performance (SOPP) by the Academy of Nutrition and Dietetics for RDNs [10-13], supporting the content validity of the results.

Specifically, "nutritional intervention plan," "nutritional diagnosis," "information gathering," and "physical assessment" align directly with the core components of the NCP and are described as the foundational practical skills required for all dietitians. In addition, "clinical knowledge" and "clinical experience" are recognized as crucial for advanced practice, particularly for managing complex cases and making high-level judgments. "Counseling techniques," including reflective listening and goal setting, are emphasized as behavior change strategies rooted in communication science.

The importance of "motivating" is underscored by its alignment with the principles of motivational interviewing, which aims to enhance patient engagement through individualized support. "Food, nutrition, and cooking knowledge" is fundamental for providing culturally appropriate and practical dietary advice. "Multidisciplinary collaboration" is considered a key driver of patient-centered care, requiring mutual understanding of roles across health care professionals.

"Understanding of patient background" and "communication skills" are regarded as indispensable competencies for providing support from a comprehensive perspective that encompasses cultural background, health literacy, and social factors. "Learning opportunities" are positioned in the SOPP as elements of self-development and professional growth that continuously enhance the expertise of registered dietitians, with expectations for engagement in professional certification and the training of future practitioners. Furthermore, "educational materials" are intended to facilitate patient understanding and promote behavior change. The role of RDNs is emphasized in selecting and using educational resources that are culturally and linguistically appropriate as well as visually accessible to support the delivery of patient-centered care.

The 14 elements extracted in this study corresponded closely to many of the competencies described in the standards of practice and SOPP; however, certain components, such as leadership, policy advocacy, and advanced research skills, were not included. While these skills are professionally important,

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they may be less directly observable in the context of daily clinical nutrition counseling. Ethical principles were also raised but were not retained as an independent element as they are regarded as a fundamental premise of professional practice for registered dietitians, as outlined in the code of ethics of the Japan Dietetic Association [22] and the 2018 Academy of Nutrition and Dietetics and Commission on Dietetic Registration Code of Ethics for the Nutrition and Dietetics Profession [23]. Therefore, the ISM model presented in this study does not aim to comprehensively reproduce all NCP-related competencies but, rather, to provide a practical framework focusing on the core techniques of clinical nutrition counseling.

Structural Interpretation

The hierarchical positioning of "nutritional intervention plan," "nutritional diagnosis," "information gathering," and "physical assessment" at the upper levels of the structure suggests that effective nutritional guidance is critically dependent on the proper implementation of the NCP. Among them, "nutritional intervention plan," located at the topmost level, represents the culmination of the entire process and serves as the decisive element determining the success of dietary intervention. This is consistent with the theoretical foundation of the NCP [6], which emphasizes the structured and sequential application of care processes as essential to high-quality nutrition counseling.

In contrast, the lower-level elements—including "communication skills," "clinical experience," "learning opportunities," "educational materials," and "understanding of patient background"—represent the foundational competencies that support the execution of the upper-layer techniques. These elements emerged as enabling factors, suggesting that improvements in knowledge, skills, and environmental support can exert cascading effects on the quality of higher-order nutritional practices.

Formation of Clinical Knowledge and the Role of Learning Opportunities

While prior studies have noted that nutritional guidance is influenced by the dietitian's knowledge and experience [10], our analysis further clarifies that "clinical knowledge" is shaped not only by experience but also through "multidisciplinary collaboration" and "learning opportunities." Engagement with other health care professionals provides exposure to interdisciplinary knowledge; enriches perspectives; and, ultimately, enhances clinical competence and service quality [24]. Brody et al [25] also found that advanced-level RDNs emphasize communication with patients, families, and the health care team as a core aspect of their work.

Furthermore, Dart et al [14] emphasized that interpersonal communication and lifelong learning are the central components of dietitian professionalism. In this study, "learning opportunities" was shown to influence "clinical knowledge," "food, nutrition, and cooking knowledge," and "counseling techniques," reinforcing the notion that continuing education is essential for acquiring and maintaining advanced skills in nutrition counseling.

Understanding Patient Background and Its Contribution to Person-Centered Care

Importantly, "understanding of patient background" emerged as a distinct and independent component of nutritional guidance, separate from "clinical knowledge." Lövestam et al [26] pointed out that patients' circumstances do not always fit neatly within the predefined structure of the NCP. Brody et al [27] similarly emphasized that effective practice by RDNs requires a deep understanding of patients' complex backgrounds; delivery of person-centered care; and individualized, comprehensive support. Soguel et al [28] argued that integrating contextual information into care enhances quality and bridges the gap between knowledge and practice. In alignment with this, Holdoway et al [29] demonstrated that focusing on patients' values, priorities, and needs significantly improves the outcomes of nutritional interventions. These findings reinforce the idea that understanding the social, cultural, and psychological context of patients is indispensable for delivering effective nutritional guidance.

In addition, the element "understanding of patient background" encompasses the recognition of social determinants of health. Yoshikawa et al [30] demonstrated that dietary-specific social support significantly influences eating behaviors. Accordingly, consideration of social determinants of health and related social support should be explicitly integrated when assessing patient background and planning nutritional interventions.

Technical and Environmental Elements Supporting Professional Competence

The bottom level of the structure included both technical competencies to be acquired by dietitians and contextual elements that influence practice. Specifically, "understanding of patient background," "communication skills," and "clinical experience" are competencies to be developed, whereas "learning opportunities" and "educational materials" represent environmental enablers.

Postgraduate education in clinical settings is vital for maintaining and advancing professional competencies. Both Vogelzang and Roth-Yousey [31] and Palermo et al [32] stressed the need for continuous self-development, knowledge acquisition, and technical enhancement throughout the dietitian's career. Dart et al [14] highlighted "lifelong learning" as a defining theme of professionalism in dietetics, emphasizing the importance of reflective practice—evaluating one's own performance and taking action toward improvement.

Moreover, as Lövestam et al [33] noted, support from supervisors and colleagues is also a key factor influencing clinical practice. Organizational backing is crucial, particularly in busy clinical settings, where dietitians must secure time and resources for ongoing learning and skill updates. The combination of self-directed effort and structured institutional support is essential for sustained professional growth.

Implications for Education and Practice

The hierarchical model developed in this study may serve as a practical framework for designing clinical education curricula and training programs for dietitians. For example, beginner-level

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training could prioritize foundational competencies at level 6, such as “communication skills” and “understanding of patient background.” Instruction could then gradually progress toward higher-level competencies such as “diagnosis” and “intervention planning.” This stepwise approach could enhance both comprehension and skill acquisition. Furthermore, this model may inform revisions of existing professional standards and assessment tools by offering a structured basis for evaluating clinical competence in nutrition guidance.

Limitations and Future Directions

Several limitations must be acknowledged. First, the model was developed based on insights from a limited number of expert participants, which may affect its generalizability. However, the ISM approach emphasizes depth of expertise over sample size, and expert selection in this study adhered to methodological recommendations. Future research should further validate and refine the model through Delphi methods and multisite collaboration to ensure its robustness across diverse settings.

Second, although this study was conducted at a single health care institution, the use of internationally standardized NCP elements suggests that the findings may be applicable to other contexts. Furthermore, refinement and validation of the model may contribute to the improvement of dietitian education and clinical training programs. In particular, comparing novice and expert dietitians could help clarify developmental differences in competencies and guide the systematic design of competency-based curricula.

Finally, while ISM identifies the presence or absence of relationships among elements, it does not measure the strength of those relationships. Combining ISM with other analytical approaches may yield deeper insights into interdependencies among elements and support the development of more effective educational frameworks for dietitians.

Conclusions

This study identified 14 elements influencing nutritional guidance techniques in clinical practice and systematically visualized their interrelationships as a 6-level hierarchical structure using ISM. The findings revealed that foundational competencies function as prerequisites for the development of higher-level NCP-based practice skills. The model developed in this study provides both theoretical and practical foundations for strengthening clinical education, establishing competency assessment frameworks, and standardizing nutrition counseling techniques, and it may serve as an initial framework contributing to the further advancement of nutrition guidance education.

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Data Availability

All data generated or analyzed during this study are included in this published article and its supplementary information files.

Authors' Contributions

Conceptualization: MU, MO, K Ogasawara
Formal analysis: MU, MK, RS, K Ogasawara
Methodology: MU, MO, K Ogasawara
Writing – original draft: MU
Writing – review & editing: K Ohashi, K Ogasawara

Conflicts of Interest

None declared.

Multimedia Appendix 1
The relational and reachability matrices derived from the interpretive structural modeling analysis of 14 elements influencing nutritional guidance techniques.
[DOCX File, 35 KB - formative_v10i1e83185_app1.docx]

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Abbreviations

ISM: interpretive structural modeling
NCP: nutrition care process
RDN: registered dietitian nutritionist
SOPP: standards of professional performance

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Strengthening Nonspecialist Health Care Providers' Capacity to Address Mental Health in the Context of Domestic Violence in Nepal: Pre–Post Mixed Methods Training Evaluation

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Abstract

Background: Health care providers (HCPs) in public health facilities in low- and middle-income countries, including Nepal, often lack adequate training to manage mental health problems effectively.

Objective: This study evaluated the impact of structured mental health training on the knowledge, attitudes, confidence, and psychosocial support skills of nonspecialist HCPs in Madhesh Province, Nepal.

Methods: This study is a nested substudy within a larger domestic violence (DV) intervention trial and used a mixed method, pre–post intervention design with a comparison group. A total of 46 nonspecialist HCPs were randomized into 2 groups: group 1 (n=24) received a 10-day comprehensive mental health and violence prevention training; group 2 (n=22) received a 3-day training focused on ethical considerations, the link between intimate partner violence (IPV) or DV and mental health, and available referral services. The training was based on the World Health Organization's Problem Management Plus model, with augmented modules on safety planning and psychosocial support. Changes in knowledge and attitude scores were assessed at baseline, immediately post-training, and at 3-month follow-up. In-depth interviews with participants from group 1 were thematically analyzed.

Results: At baseline, nearly 90% of nonspecialist HCPs had not received any prior formal mental health training. Both groups demonstrated significant improvements in mental health knowledge, with a greater increase observed in group 1 (mean score 41.33-48.41) compared to group 2 (41.18-44.27). Attitudes toward individuals with mental health problems also improved in both groups, reflected in reductions in social distance and perceived dangerousness scores. Thematic analysis of interviews indicated enhanced confidence and psychosocial support skills, particularly in managing mental health concerns among women experiencing IPV or DV.

Conclusions: Structured mental health training significantly improved both knowledge and attitudes among nonspecialist HCPs in public health facilities in Madhesh Province. Participants also reported increased confidence in addressing common mental health concerns. This training model has potential for scale-up in other resource-limited settings to build frontline capacity in managing mental health problems and supporting women experiencing IPV or DV.

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KEYWORDS

health care providers; mental health training; knowledge and attitudes; safety planning; Problem Management Plus; Nepal; training effectiveness

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Introduction

Globally, an estimated 1 in 8 individuals experience mental health problems, particularly anxiety and depression [1]. The burden of these conditions increased substantially during the COVID-19 pandemic [2], driven by factors such as job losses, social isolation, and mobility restrictions. These disruptions also contributed to a rise in violence against women worldwide [3]. Despite this growing burden, access to mental health services remains limited in many settings, largely due to a global shortage of trained mental health professionals [4].

Mental and physical health are closely interconnected. Individuals with mental health problems face a higher risk of developing other health problems, including HIV, tuberculosis, and noncommunicable diseases [1]. Left untreated, mental health conditions can lead to long-term disability, unemployment, substance use, and even suicide [5], which is a leading cause of death among young people [1]. Mental health problems also contribute significantly to economic losses and societal burden [6]. In many low- and middle-income countries (LMICs), mental health remains a neglected area of public health, characterized by underfunding, limited service coverage, and substantial unmet needs [7,8]. Stigma and discrimination further hinder access to care [9].

In Nepal, as in many LMICs, mental health services are underresourced [10]. Government expenditure on mental health remains below 2% of the national health budget [11], and services are largely concentrated in tertiary care settings [12]. Although Nepal's National Mental Health Strategy and Action Plan [13] advocates for the availability of psychotropic medications—such as antipsychotics, antidepressants, anxiolytics, mood stabilizers, and antiepileptics—at all health facility levels, chronic supply chain issues [14,15] and limited authority to dispense these medications at lower-tier facilities persist [14].

The mental health workforce in Nepal remains severely limited [16]. As of 2020, there were only 200 psychiatrists across the country [17]. Nepal has a single mental health hospital, 18 outpatient mental health care facilities, and 17 general or teaching hospitals with inpatient psychiatric units—all of which are based at the tertiary level [18]. With only 500 psychiatric beds nationally—approximately 1.5 beds per 100,000 people [19]—access to care is particularly limited in rural and remote areas. The 2021 Nepal Health Facility Survey found that only 25% of health facilities provided any mental health services, and this proportion was even lower outside urban centers [15]. Barriers such as stigma, poor awareness, discrimination, and logistical inaccessibility lead many people with mental health needs [20] to go untreated or to rely on informal providers, such as traditional healers [21].

To address the treatment gap, the World Health Organization's (WHO) mental health Gap Action Program has been adopted in Nepal [22], training nonspecialist health care providers (HCPs) to identify and manage priority mental health conditions such as depression, psychosis, epilepsy, and substance use disorders [22]. Other initiatives, such as the REducing Stigma among HealthcAre ProvidErs (RESHAPE) program, have targeted stigma reduction through providers' training in selected municipalities [23]. While these programs represent important progress, their implementation remains limited in scale, and they often do not address the complex mental health needs of women who have experienced intimate partner violence (IPV) or domestic violence (DV).

In Nepal, IPV is widespread. Nearly 29% of women aged 15 to 49 years reported experiencing emotional, physical, or sexual violence from an intimate partner in the previous 12 months [24]. Among those, 41% reported symptoms of anxiety, 33% reported depression, and 14% reported suicidal ideation. Yet, mental health utilization among women experiencing IPV remains low, with only 24% seeking support. Although HCPs are well positioned to identify and respond to mental health needs among IPV or DV survivors, evidence shows that most lack the necessary training and support [25]. The 2021 National Health Facility Survey found that only 27.1% of facilities offering mental health services had clinical guidelines in place, and just 16.2% of HCPs had received any form of mental health training prior to 24 months [15].

Evidence suggests that nonspecialist HCPs can play a pivotal role in early detection, psychosocial support, and referral for individuals with mental health problems, especially in low-resource settings [26,27]. Systematic reviews have shown that training nonspecialist providers in mental health care can improve their knowledge, confidence, and clinical practices, ultimately leading to better patient outcomes [26]. In Nepal, training programs targeting rural health providers have demonstrated a positive impact on managing depression and anxiety [28], with similar evidence reported from Ethiopia [27].

In response to the gap between rising mental health needs and shortage of trained professionals, particularly in underserved regions such as Madhesh Province, we implemented a structured mental health training program targeting nonspecialist HCPs. The training aimed to prepare frontline providers to identify and manage women experiencing IPV-related psychological distress. This study evaluates the impact of structured mental health training on the knowledge, attitudes, confidence, and psychosocial support skills of nonspecialist HCPs in Madhesh Province, Nepal. The findings contribute to ongoing efforts to integrate mental health and IPV/DV support into the public health system and may inform national strategies to build capacity among frontline health workers.

Methods

Study Design

This study employed a mixed methods design, combining quantitative and qualitative approaches to evaluate the impact of structured mental health training on nonspecialist HCPs. The quantitative component followed a pre- and post-test design with a comparison group to assess changes in mental health–related knowledge and attitudes. The qualitative component involved in-depth interviews with nonspecialist HCPs from group 1 (nonspecialist HCPs from the intervention sites of the parent cluster randomized trial, domestic violence intervention [DeVI]) to explore their experiences with the

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training and their perceived changes in knowledge, confidence, and psychosocial support skills.

Setting

According to the Nepal Demographic and Health Survey, more than 1 in 5 women and 1 in 10 men aged 15 to 49 years report symptoms of anxiety [20]. In Madhesh Province of Nepal, approximately 27% of health facilities report offering some form of mental health services. However, only 35 of 246 health facilities have essential psychotropic medicines available, and most services are delivered through private providers [29]. Given these constraints, the training targeted nonspecialist HCPs working in government primary health care centers (PHCCs) and public hospitals across 8 districts of Madhesh Province. Although public hospitals are not part of the first-contact primary care tier, they remain central to the public health care system and routinely serve women seeking maternal and reproductive health care. Because the intervention focused on supporting women affected by IPV, including nonspecialist HCPs from public hospitals was considered appropriate.

This study was a nested substudy within the broader DeVI trial, a cluster randomized controlled trial designed to reduce IPV and related psychological distress among women. Details of the trial design are described elsewhere [30]. The training was conducted before the implementation of the main DeVI. A total of 24 public health facilities were randomly selected and assigned to either the intervention or control arms of the DeVI trial [30]. Nonspecialist HCPs working at intervention sites formed group 1 and received the comprehensive training, whereas those at control sites (group 2) received a shorter training.

Participants

The training targeted 46 nonspecialist HCPs, including nurses and auxiliary nurse midwives (ANMs). One additional female participant serving in the role of psychosocial counselor also took part in the training and was included in the analysis.

Nurses and ANMs were selected because they are the primary providers of maternal and reproductive health services in Nepal and are often the first point of contact for women experiencing violence or mental health concerns. Furthermore, evidence suggests that women are more likely to disclose sensitive issues such as IPV to female care providers. Group 1 included 24 participants from intervention facilities, and group 2 included 22 participants from control sites.

Ethical Considerations

This study forms part of a larger trial evaluating a multicomponent intervention to reduce IPV and psychological distress among women in Nepal [30]. The larger trial was registered with ClinicalTrials.gov (NCT05426863). Ethical approval was obtained from the Nepal Health Research Council (852/2019). All procedures adhered to the 2019 National Ethical Guidelines for Health Research in Nepal [31] and to the principles of the 1964 Helsinki Declaration and its subsequent amendments.

Written informed consent was obtained from all participating HCPs for both training participation and in-depth interviews. Consent included approval for audio recording and use of deidentified data. All data were stored securely on password-protected devices accessible only to the research team. Quantitative findings were reported in aggregated form to prevent participant identification. Audio files were deleted after transcription. Personal identifiers were removed from transcripts to maintain confidentiality. Verbatims used in this manuscript are labeled with nonidentifying labels.

HCPs received a daily allowance of either 1200 or 1600 Nepalese rupees for participation in the training, in accordance with the Nepalese government's daily subsistence allowance rates, which vary based on the participant's official ranking or position. Photographs of training sessions were taken only after obtaining written informed consent from participants, who explicitly indicated no objection to the use of images in study outputs. To protect privacy, faces of training participants shown in this paper were blurred.

Training Duration

Training was conducted from May 26 to June 4, 2022, in Bardibas, Mahottari District, Madhesh Province. Nonspecialist HCPs in group 1 received a comprehensive 10-day training, whereas group 2 participants attended a 3-day training. Each training day comprised approximately 8 hours of instruction.

Training Content

The training was grounded in the WHO's Problem Management Plus framework [32], a brief psychological intervention designed for individuals experiencing distress in adversity-affected settings. Problem Management Plus has been demonstrated to be effective in LMIC contexts, including Nepal [33-35]. The intervention was further adapted to include modules on safety planning [36]. Details of the training content are provided in Textbox 1 . Nonspecialist HCPs at both sites were trained on different mental health–related topics, such as an introduction to mental health and common mental health problems, consequences of mental health problems on women, their family, and the community, and stigma associated with mental health problems. They were further trained on the role of nonspecialist HCPs in managing mental health problems and referring patients to higher health facilities, psychiatrists, or psychologists for further management. Nonspecialist HCPs were also trained in administering data collection tools. Furthermore, nonspecialist HCPs in group 1 were trained to identify patients with mental health problems, implement stress management techniques such as slow breathing exercises, apply problem identification and solving techniques, develop safety plans against IPV/DV, and manage challenging/difficult patients.

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Textbox 1. Content of the training for DeVI intervention. *Integrated multicomponent intervention refers to the DeVI intervention comprising PM+, safety planning, and mental health components. ** Group 2 nonspecialist HCPs were informed about available social support services in the community but did not receive training on guiding survivors to enhance social support

Both groups (group 1 and group 2)

- Introduction to intimate partner violence (IPV)/domestic violence (DV): types of violence, causes and effects, and their impact on women, children, and society; and common health consequences of IPV/DV
- Global, national, and provincial epidemiology of IPV/DV and mental health problems
- Introduction to mental health and different mental health problems: causes, effects, and impact on women, children, and society; and stigma and mental health
- Relationship between IPV/DV and mental health
- Social support: approaches to strengthening and practicing support**
- Ethical guidelines on human research participants: the importance of consent, privacy, and confidentiality

Group 1 only

- Role of health care settings in addressing IPV in Nepal
- Detail on the integrated multicomponent intervention*, understanding adversity, and violence
- Use of basic helping skills to build relationship with participants
- Cyclical nature of violence and its phases
- Stress management: slow breathing techniques and deep breathing exercise
- Problem management: steps for managing problems, identifying solvable and unsolvable problems, and making problem management plans for solvable problems of the women experiencing violence
- Understanding “get going, keep doing” strategy to keep the women experiencing violence active and present
- Safety planning: developing safety plans for the participants for their protection from future harm and their advantages
- Assessing safety behaviors using checklists; exploring barriers to and facilitators of using safety behaviors
- Dealing with challenging clients
- Social support; and approaches to strengthening and practicing support, including steps of strengthening social support
- These contents were developed and moderated to the participants via different approaches such as discussion on real-life lived experiences by mental health professionals demonstrating treatment success stories.
- These concepts were not only delivered theoretically but were augmented through case examples based on our formative research in Madhesh province; interactive role-plays and reflection exercises were also added by the mental health professionals.

Nonspecialist HCPs were provided with brochures containing referral sites for women with mental health problems and a training manual, in line with the WHO’s recommendations for conducting intervention research on violence against women [37].

Training Delivery

Training methods included didactic lectures, interactive group discussions, case vignettes, role plays, demonstrations, and brainstorming sessions (Figure 1). Activities were designed to maintain engagement and facilitate experiential learning. Recreational activities were incorporated to reduce fatigue during long training sessions.

Sessions were delivered in Nepali by a multidisciplinary team, including mental health professionals, public health experts, and members of the study team.

Participants demonstrated active engagement during training sessions. Role-play exercises using different scenarios were integrated into the training sessions (Figure 1). Experts demonstrated how interventions should be delivered. Nonspecialist HCPs also put forward different situations that could arise during the implementation of the intervention, which were addressed by experts via role plays. Role plays were evaluated by trainers based on predefined criteria, including confidentiality, nonjudgmental listening, and appropriate application of stress management and problem-solving techniques.

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Figure 1. Glimpses of role-play activities during the training session. Left: Participants engaging in role-play as client and patient. Right: The training facilitator (psychiatrist) observing the role-play.

Data Collection Tools and Variables

Quantitative data were collected using a self-administered questionnaire that included demographic information and 3 validated instruments.

Mental health knowledge schedule (MAKS) [38]: A 12-item tool scored on a 5-point Likert scale. The first 6 items in the scale measure the stigma-related mental health knowledge areas while the other 6 measure the knowledge on mental health problems. For positive statements, “strongly agree” is scored the highest 5 points whereas “strongly disagree” is scored 1. The points are reversed for the negative statements. Total scores are obtained by adding the scores of 12 items and higher score indicates higher participant’s knowledge in mental health.

Social Distance Scale (SDS) [39]: A 7-item scale assessing attitudes toward individuals with mental illness. Responses are rated on a 0 to 3 scale, with higher scores indicating a greater desire to distance one from the people with mental health problems. An example of an item is, “How would you feel about renting a room in your home to a person with serious mental illness?”

Perceived Dangerousness Scale [40]: An 8-item tool assessing participants’ beliefs about the dangerousness of individuals with mental health problems. Each item is scored from 0 to 5, with higher scores indicating greater perceived threat.

Although a more detailed version of SDS is available, we aimed at maintaining brevity while ensuring content validity for use in training evaluation context. All tools underwent cultural and linguistic adaptation following standard translation and back-translation procedures. A panel of Nepali mental health and public health experts reviewed the instruments for content and cultural appropriateness before finalization. It was then reviewed by a Nepali language expert to confirm cultural appropriateness and clarity. Lastly, the tools were finalized after consensus within the study team.

Qualitative data were collected using an interview guide focused on participants’ perceptions of the training, changes in knowledge, confidence, and self-reported skills. In-depth interviews were conducted only with group 1 participants due to the comprehensive nature of their training.

Data Collection Techniques

The pretest, post-test, and follow-up questionnaires were self-administered questionnaires in Nepali language and took on average 15 to 20 minutes for completion. The pretest assessment was conducted prior to the training, while the post-test assessment was conducted after completion of the training. The follow-up questionnaire was completed after 3 months of training. In-depth interviews were conducted face-to-face and were audio-recorded with written consent from nonspecialist HCPs after completion of the training.

Quantitative data were self-administered by participants. In contrast, qualitative data were collected through interviews conducted by a mix of health workers, some of whom were involved in implementing the training sessions and others who were not. This approach was employed to capture detailed and diverse perspectives on participants’ experiences.

Data Management and Analysis

Quantitative Analysis

Quantitative data were analyzed using STATA (version 14.2). Both descriptive and analytical analyses were performed. Sociodemographic characteristics are presented in the form of frequency, percentage, mean (SD), and median (IQR).

For MAKS, SDS, and Perceived Dangerousness Scale, data normality was assessed. Repeated-measures ANOVA was used for normally distributed data, and the Friedman test was used for nonnormally distributed data to compare mean scores at 3 different time points within groups [41]. Each item on MAKS was scored for each HCP. The scores obtained were then added to get the total score of each HCP. From the total score of each HCP, a mean score along with standard deviation was calculated. A similar process was conducted for the other two, perceived dangerousness of mental health patients and social distance scale as well. In both of these attitude scales, first, each item

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for individual HCP was calculated to get the total score obtained by them. As for assessing the effect of training between group 1 and group 2, one-way ANOVA for normally distributed data and the Kruskal-Wallis test for data not following normal distribution were performed [41]. The *P* value of ≤.05 was considered statistically significant.

Qualitative Analysis

Interviews were transcribed in Nepali and translated into English. Data were analyzed using thematic analysis [42]. Initial coding was based on concepts such as "first mental health training," "stress management," "confidence," and "referral." Themes were then refined through iterative discussion and mapped to the study objectives. Key themes included acquisition of new skills, changing perceptions, and increased readiness to provide psychosocial support.

The analysis focused on the mental health training component. Findings related to the IPV-focused elements of the DeVI will be presented separately due to differing timelines and follow-up periods.

Results

Participant Characteristics

Table 1 presents the sociodemographic characteristics of the 46 nonspecialist HCPs included in this study. The mean age of participants was 34.2 (SD 6.96) years, ranging from 21 to 50 years. Participants aged 21 to 30 years accounted for 39% of the sample (18/46), those aged 31 to 40 years also accounted for 39% (18/46), and participants aged 41 to 50 years constituted 22% (10/46). The majority of participants were married (38/46, 83%). More than half of participants were ANMs and senior ANMs combined (30/46, 65%), one-third were nurses (15/46, 33%), and 1 participant was a psychosocial counselor (1/46, 2%).

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Table . Sociodemographic characteristics of the training participants (nonspecialist health care providers).

Variables	Group 1, n (%)		Group 2, n (%)		Total, N (%)
	Hospital	PHCC[a]	Hospital	PHCC[a]	
Age distribution (y)					
21 - 30	6 (13)	2 (4)	1 (2)	9 (20)	18 (39)
31 - 40	7 (15)	5 (11)	1 (2)	5 (11)	18 (39)
41 - 50	3 (7)	1 (2)	0	6 (13)	10 (22)
Marital status					
Married	11 (24)	6 (13)	2 (4)	19 (41)	38 (83)
Unmarried	5 (11)	2 (4)	0	1 (2)	8 (17)
Profession within health facility					
ANM[b]	4 (9)	3 (7)	1 (2)	9 (20)	17 (37)
Nurse	8 (17)	4 (9)	1 (2)	2 (4)	15 (33)
Senior ANM	3 (7)	1 (2)	0	9 (20)	13 (28)
Psychosocial counselor	1 (2)	0	0	0	1 (2)
Level of education					
Proficiency certificate level in nursing	5 (11)	4 (9)	1 (2)	7 (15)	17 (37)
ANM	5 (11)	4 (9)	1 (2)	9 (20)	19 (41)
Bachelors	5 (11)	0	0	3 (7)	8 (17)
Master's and above	1 (2)	0	0	1 (2)	2 (4)
Duration of working in current health facility (in y)					
<1	0	0	0	3 (7)	3 (7)
1-5	8 (17)	5 (11)	2 (4)	10 (22)	25 (54)
>5	8 (17)	3 (7)	0	7 (15)	18 (39)
Number of patients attended per week					
≤50	13 (28)	2 (4)	2 (4)	8 (17)	25 (54)
>50	3 (7)	6 (13)	0	12 (26)	21 (46)
Ever received any training related to mental health					
Yes	6 (13)	0	0	0	6 (13)
No	10 (25)	8 (20)	2 (4)	20 (50)	40 (87)

[a]PHCC: primary health care center.

[b]ANM: auxiliary nurse midwife.

Over half of the nonspecialist HCPs had worked at their current health facility for 1 to 5 years (25/46, 54%), and more than one-third over 5 years of service (18/46, 39%). Just over half of the participants reported attending to 50 or fewer patients per week (25/46, 54%).

Although nonspecialist HCPs often receive in-service training, the majority (40/46, 87%) reported that this was their first exposure to training focused on mental health. Only 6 out of 46 nonspecialist HCPs (13%) stated that they had earlier received training on mental health, particularly on psychosocial counseling. None of the participants from group 2 or from primary health care facilities in group 1 had previously received training on mental health (Table 1).

The in-depth interviews highlighted the importance of mental health–related training.

Qualitative Findings From In-Depth Interviews

In-depth interviews conducted with group 1 participants revealed a range of positive changes in knowledge, confidence, and skills following the training.

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Enhanced Knowledge of Mental Health and Violence

Participants shared that the training enhanced their understanding of the interrelationship between mental health and IPV, equipping them to better identify, assess, and support affected individuals.

> *This training definitely helped me. It is because with this training I have learnt how to manage women experiencing IPV... I can make safety plans for them which will help them in stress management.* [Hospital Nursing Inspector, PHCC]

> *Before this, we never considered managing confidentiality or asking them questions... Now we understand how to ensure privacy.* [ANM, Hospital]

Shift in Attitudes Toward Mental Health and IPV Survivors

Participants reported that the training changed their understanding of mental health. They earlier believed that mental health problems could only be solved via clinical interventions, but now they consider it a social issue that can be managed by counseling and empathy.

> *We used to think that any mental illness needs medication. Now we know that it can be solved through counseling... and letting them express.* [ANM, Hospital]

> *Mental health problems were never prioritized. This training has made me realize it's a key part of our work.* [Staff Nurse, Hospital]

Positive Training Experience and Perception of Training Modules

Participants valued the structured nature of the training, particularly the sessions on problem management and safety planning.

> *Session on problem management was my favorite. We list solvable and unsolvable problems, develop a plan, and help women build routines. This helps them not feel isolated.* [Hospital Nursing Inspector, PHCC]

> *Training sessions helped identify the level of mental stress and how it could lead to suicide. These sessions were invaluable.* [Nursing Officer, PHCC]

Increased Confidence in Providing Psychosocial Support

Participants expressed that the training boosted their confidence in identifying and addressing mental health issues, even for those with no prior exposure.

> *My confidence level has improved. I became aware of data collection, counseling steps, and follow-ups.* [Staff Nurse, Hospital]

> *Now I can identify mental health problems and provide support. This was missing from our service delivery before.* [Staff Nurse, Hospital]

> *Before this I have neither worked on anything related to mental health nor received any training. This is my first experience. But now we understand that, from where we work and the position we are in, we can assist individuals with mental health problems. We have also developed confidence that we can provide psychosocial counselling to them. Additionally, we learned about the organizations where we can refer patients with mental health problems.* [Nurse, Hospital]

Perceived Improvement in Counseling and Supportive Skills

Participants shared that the training enhanced their ability to manage mental health problems, particularly in stress management. Nonspecialist HCPs reported notable improvement in supportive skills like screening, problem identification, and active listening. Some also mentioned that they are now aware of referral sites for more advanced care.

> *Earlier I did not know how to manage mental health problems. Through this training, we learned techniques like stress management, breathing exercises, and staying active. We also learned where to refer patients.* [Nurse, PHCC]

> *We learned relaxation techniques, deep breathing, and how to build rapport... Even a minor decrease in stress changes their daily life.* [Staff Nurse, Hospital]

> *Now we guide them to make their own decisions and plan for themselves. This is a skill I didn't have before.* [Nursing Officer, PHCC]

> *We learned to identify mental health problems early, screen them properly, and maintain confidentiality.* [ANM, Hospital]

Changing Perceptions

Nonspecialist HCPs emphasized that mental health is often neglected in Nepal; this training helped to fill critical gaps in awareness, empathy, and basic support strategies. They recognized that simple interventions, such as counseling and stress management, could mitigate adverse outcomes, including depression or suicidal ideation. Overall, the training was perceived as essential in equipping nonspecialist HCPs with the necessary skills to help reduce mental health problems within their communities, marking a transformative change in their perceptions and approaches to mental health care.

> *Mental health trainings are important and not common in Nepal. Most of us were unaware of how to interact with people with mental health problems, who are often stigmatized and isolated. This training showed us the impact of even small conversations and motivated us to engage with those showing signs of mental stress. We've learned we can help reduce mental health problems in our communities.* [ANM, Hospital]

> *This training has been beneficial. Before, we had limited knowledge and couldn't effectively help patients with mental health problems, who are often discriminated against. Now, I feel confident in supporting them.* [Nurse, Hospital]

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Minor issues can greatly affect mental health. If not addressed, stress can lead to depression or even suicide. By providing counseling and stress management, we can prevent these complications. [Nurse, Hospital]

Quantitative Results

Table 2 summarizes changes in outcome measures before and after the training. In group 1, MAKS scores improved significantly from pretest to post-test (mean difference [MD] 7.41, 95% CI 4.85 - 9.98) and remained elevated at 3-month follow-up (MD 7.08, 95% CI 4.28 - 9.87). Group 2 also showed modest improvements at post-test (MD 3.82, 95% CI 0.01 - 7.63) and at follow-up (MD 3.09, 95% CI 0.46 - 5.71). Attitudes, as measured by the Perceived Dangerousness Scale, declined post-training in both groups (Table 2). Group 1 showed reductions at post-test (MD 2.30, 95% CI 0.27 - 4.30) and 3 months follow-up (MD 4.67, 95% CI 2.33 - 6.99). Group 2 also improved, with reductions at post-test (MD 4.77, 95% CI 2.60 - 6.93) and 3 months follow-up (MD 6.91, 95% CI 4.17 - 9.63).

SDS scores decreased in both groups post-training. Group 1 reported reduced scores at post-test (MD 1.87, 95% CI 0.02 - 3.77) and follow-up (MD 2.87, 95% CI 0.75 - 4.99). Group 2 demonstrated similar reductions at post-test (MD 3.50, 95% CI 0.82 - 6.17) and follow-up (MD 2.45, 95% CI 0.11 - 5.02) (Table 2).

Table . Comparison of knowledge and attitude within and between groups in pre, post, and 3 months follow-up.

Scales	Time	Group 1 (n=24), mean (SD)	*P* value[a]	Group 2 (n=22), mean (SD)	*P* value[a]	Total (n=46), mean (SD)	*P* value[a]	*P* value[b]
Mental health knowledge schedule	Pretest	41 (6)	<.001	41 (7.8)	.044	41 (6.7)	<.001	.94
	Post-test	49 (3.5)		45 (7.2)		47 (5.8)		.028
	Follow-up	48 (5)		44 (7.1)		46 (6.4)		.027
Perceived dangerousness of mental health patients	Pretest	20 (5.6)	<.001	19 (5.7)	<.001	19 (5.6)	<.001	.72
	Post-test	17 (6.9)		14 (4.9)		16 (6.2)		.092
	Follow-up	15 (5.9)		12 (3.2)		14 (4.9)		.051
Social Distance Scale	Pretest	9 (5.3)	.009	8 (4.9)	.011	8 (4-11)[c]	.001[c]	.85[d]
	Post-test	8 (4.9)		4 (3.3)		4 (2-8)[c]		.059[d]
	Follow-up	6 (4.5)		5 (2.6)		5 (3-8)[c]		.96[d]

[a]Within group *P* values analyzed using repeated measures ANOVA or Friedman test.

[b]Between group *P* values analyzed using one-way ANOVA or Kruskal-Wallis test.

[c]The total score for pre, post, and 3-month follow-up in the Social Distance Scale did not follow normal distribution; thus, the Friedman test was performed, and median scores with interquartile range were reported.

[d]For between analyses, *P* value was based on Kruskal-Wallis test.

Between Group Comparisons

One-way ANOVA showed no significant pretest differences in MAKS scores between groups. However, post-test and follow-up scores were significantly higher in group 1, suggesting a stronger training effect. Similarly, for the Perceived Dangerousness Scale, significant between-group differences emerged only at the 3-month follow-up. Kruskal-Wallis tests for the SDS showed significant between-group differences post-training, but not at follow-up (Table 2).

Discussion

Principal Findings

This study found that nonspecialist HCPs had limited prior knowledge of mental health, as many were exposed to mental health–related training for the first time. This finding is consistent with previous studies indicating that individuals with mental health problems in LMICs often lack adequate care due to the limited mental health knowledge among HCPs [27,43]. Although Nepal has initiated mental health Gap Action Program-based mental health training programs through government and development partner collaborations [44], our earlier work showed that the majority of HCPs (almost 90%) had never received formal mental health training [12]. Consistent with previous research in Nepal [28] and international contexts such as Hong Kong and China [45,46], our study demonstrated an increase in mental health knowledge post-training in both groups. To help sustain knowledge gains, the study team conducted brief reviews of key training content during monthly regular monitoring visits.

In addition to improving knowledge, the training positively influenced HCPs' attitudes [27]. While mental health issues are largely associated with IPV, they are often perceived as dangerous by both the public [47] and HCPs [48]. This perception was evident in our study during the pretest but showed a positive shift following the training.

Existing literature suggests that HCPs often hold stigmatizing beliefs and maintain social distance from individuals with mental health conditions [49,50]. At baseline, nonspecialist HCPs demonstrated moderate social distance scores. After training,

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both groups showed a reduction in these scores, reflecting improved attitudes toward people with mental health problems. Notably, group 1 maintained this reduction at the 3-month follow-up, whereas the effect was not sustained in group 2. This may be attributed to the more comprehensive and intensive training to the group 1 and prior exposure to mental health training or psychosocial counseling among some of its participants. While social distance scores differed significantly between the groups immediately post-training, the difference was no longer significant at follow-up, indicating that initial effects were not sustained and highlighting the need for ongoing support or refresher training.

Interestingly, group 2 exhibited greater improvement than group 1 in some attitude-related measures such as the SDS. This could be due to informal exposure to mental health concepts through personal experiences or ongoing discussions within their health facilities or communities. Previous literature has shown that even limited, contextually relevant exposure to mental health topics can influence stigma-related attitudes [51].

HCPs' desire to distance themselves from individuals with mental health problems is influenced by their attitudes [52]. The training led to improved attitudes among nonspecialist HCPs, reducing their desire to distance themselves from those with mental health conditions. Prior to the intervention, many HCPs lacked the skills to manage mental health concerns or were unfamiliar with referral systems. The training addressed this gap, enhancing their perceived ability and self-reported readiness to identify symptoms, provide psychosocial support, demonstrate stress management techniques, and make appropriate referrals. For many, this was often their first structured training related to mental health, which helped foster a more supportive and responsive attitude toward affected individuals.

Strengths and Limitations

A key strength of this study was the inclusion of a comparison group. To our knowledge, this is among the first studies in Madhesh Province to assess mental health knowledge and attitudes among nonspecialist HCPs at different levels of health care system. The study design captured both immediate and 3-month follow-up outcomes. The training employed interactive and practical methods, including role plays, case discussions, video demonstrations, and practice interviews, which align with established criteria for effective educational interventions [53]. The target population comprised nonspecialist HCPs at public health facilities, who are expected to apply the knowledge and skills gained from the training in their daily services, which is particularly beneficial given their long-term careers within the public health system. Moreover, the training model used in this study should be integrated into routine training within the health system, especially for health workers at district and primary health care levels, to address psychological distress and to facilitate appropriate referrals when necessary.

Nonetheless, the study has limitations. It did not assess whether changes in knowledge and attitudes led to behavioral changes in clinical practice. The small, all-female sample limits generalizability, although this is justified given the nurses and ANMs predominantly provide maternal and child health services in Nepal. The findings are therefore most relevant for similar provider groups. Moreover, the study did not adjust for potential confounders such as age or experience due to the small sample size (n=46), which may result in potential residual confounding. While no validated self-efficacy scale was used to measure confidence, this was addressed through qualitative data that provided insight into perceived changes in non-specialist HCPs' confidence and practice.

Future Implications

This training could be an important intervention for managing mild to moderate psychological distress and making appropriate referrals for severe mental health problems among women experiencing IPV or DV. In the present study, both groups received training; group 1 received comprehensive 10-day training while group 2 received short 3-day training. After the training, there was improvement in mental health knowledge and a positive change in attitude of nonspecialist HCPs across both groups, although the level of improvement varied between the groups. This suggests the possibility that brief training lasting for 3 days can bring some improvement among nonspecialist HCPs regarding their mental health knowledge and perception toward people with mental health problems.

Conclusions

The structured training program significantly improved mental health knowledge among nonspecialist HCPs in Madhesh Province. At the end of the training, group 1 showed greater improvements post-training and at follow-up. Attitude toward mental health also shifted positively. Beyond improving knowledge and attitudes, the training helped equip HCPs with essential skills in counseling, stress management, problem-solving, and referrals. Such training is especially vital in settings with limited specialist services, where nonspecialist HCPs are often the first and only point of contact for individuals facing psychological distress and IPV.

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Data Availability

The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

Authors' Contributions

RK, RS, and KD conceived and designed the study. RK, RS, AL, JD, and KD contributed to data collection and data management. RK, RS, and KD contributed to data analysis. RK, RS, and KD drafted the first version of the manuscript with inputs from JD, AL, DS, and AME. All authors contributed substantially to manuscript drafting and revision and approved submission of the manuscript.

Conflicts of Interest

None declared.

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Abbreviations

ANM: auxiliary nurse midwives
DeVI: domestic violence intervention
DV: domestic violence
HCP: health care provider
IPV: intimate partner violence
LMIC: low- and middle-income countries
MAKS: mental health knowledge schedule
PHCC: primary health care center
RESHAPE: Reducing Stigma among Health Care Providers
SDS: Social Distance Scale
WHO: World Health Organization

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Attitudes of Men Who Have Sex With Men Toward HIV Functional Cure: Community-Based Study

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Abstract

Background: Investigation of community awareness of HIV functional cure has often been restricted to people living with HIV. An understanding of the attitudes of men who have sex with men (MSM) without HIV is important, as it contributes to the supportiveness of curative treatment in the community.

Objective: This study aimed to profile the attitudes toward HIV functional cure among MSM without HIV.

Methods: This is a secondary analysis of data from a community-based survey on MSM 18 years or older in Hong Kong. MSM who self-reported being HIV negative were recruited for enrollment in the study. To understand the diversity of beliefs and their association with attitudes toward functional cure, attributes under the health belief model constructs were used for delineation of the study population by latent class analysis. Factors, including identified latent class analysis, associated with each outcome variable, including awareness, high anticipation, and trial participation willingness, were examined in bivariable and multivariable logistic regression models.

Results: A total of 712 MSM were recruited between September 2021 and October 2022, a majority of whom were Chinese, single, and employed. In 541 (76%) MSM who self-reported not having tested positive for HIV, 43% (n=233) were aware of and 44% (n=236) held high anticipation toward functional cure, while 84% (n=452) indicated willingness to join clinical trials. Trial participation willingness and high anticipation were associated with indicators of higher risk sexual behavior. Four latent classes were identified. Compared with the reference group of class 4 (considered nontransmissibility as the main benefit, n=301, 56%), MSM in class 1 (selection of all perceived benefits, n=40, 7%) and class 2 (considered safety, trial duration, sites as most important, n=82, 15%) had significantly higher anticipation of functional cure, while those from class 2 were less likely to be aware of functional cure, and those from class 3 (no selection of reasons for joining trials, n=118, 22%) were less willing to participate in a trial.

Conclusions: In Hong Kong, compared with MSM living with HIV, MSM without HIV had similar awareness and trial participation willingness but lower anticipation of functional cure, probably due to lower susceptibility to HIV infection. As community awareness and understanding of the functional cure concept take time to nourish, these have to be nurtured in advance while the development of the functional cure is in progress.

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KEYWORDS

HIV functional cure; HIV remission; men who have sex with men without HIV; attitudes; latent class analysis

Introduction

Antiretroviral therapy (ART) is a potent form of treatment that can suppress viral load and effectively restore immunity in people living with HIV. Life-long maintenance of ART is required, posing risks of adverse effects, poor adherence, and loss to follow-up. To overcome the shortcomings, new therapies are being trialed, which aim at maintaining viral load suppression without long-term treatment. Functional cure is a form of HIV therapy under development, which could maintain an undetectable viral load status in the absence of ART [1]. The outcome is also referred to as ART-free remission. Instead of a sterilizing cure, which aims at eradicating the virus, a functional cure aims to achieve a state of host-mediated viral replication control. Immune-based therapies involving broadly neutralizing antibodies and vaccines are being explored to achieve a functional cure [2]. In the past decade, novel interventions have been tested in clinical trials, showing the feasibility of HIV functional cure, while a sterilizing cure of

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HIV is still far from being achievable [3]. When functional cure–based therapies are successfully developed and implemented, people living with HIV could live without ART for an extended period or even for life. As people living with HIV on ART would stop therapy when functional cure is achieved, positive attitudes toward this new form of treatment are important. Previous studies [4-7] have shown the following perceived HIV cure outcomes in people living with HIV: free from HIV-related morbidities, no risk of transmitting HIV to sex partners, no requirement of HIV medication, no HIV in the body, and reduction of stigma. In general, people living with HIV showed positive attitudes toward functional cure [4,5].

While people living with HIV may face the new therapeutic challenge of functional cure, men who have sex with men (MSM) without HIV constitute the major stakeholders. Globally, the HIV prevalence is less than 10% in most MSM communities [8], implying that MSM without HIV account for a majority of the population. Failure of functional cure in people living with HIV while not on ART might suggest additional risk of virus transmission to MSM without HIV, after years of high ART coverage with the undetectable=untransmittable state. Perception of potential risk might discourage partners' support for people living with HIV to start novel functional cure therapy. On the other hand, MSM with higher-risk sexual behavior are more likely to undergo repeat HIV testing and take pre-exposure prophylaxis (PrEP) [9,10], reflecting their higher perceived risk of HIV acquisition. In a qualitative study in the Netherlands, MSM without HIV considered reduction of HIV burden and increase of sexual freedom as the benefits of an HIV cure [11]. Their attitudes toward functional cure may be affected by their perceived susceptibility to HIV infection [11]. Their higher risk of HIV infection and the high subsequent likelihood of being introduced to functional cure make them a unique stakeholder group. Comparing the attitudes toward functional cure in different populations, a qualitative study in the Netherlands showed similar perceptions of the impact of HIV cure between people living with HIV and MSM without HIV [6]. However, in a qualitative study in China, people living with HIV ranked family, mental stress, and health as the top 3 themes of the potential benefits of HIV cure, while MSM without HIV ranked HIV and MSM stigma, sexual risk, and romantic relationship as the top themes [12]. A quantitative study suggested greater interest in functional cure research and higher frequency of information-seeking behavior in people living with HIV than people without HIV (including partners of people living with HIV and MSM) [13]. To our knowledge, no studies have quantitatively assessed the attitudes of MSM without HIV toward functional cure, except one that had not differentiated between partners of people living with HIV and MSM [13], and the limited number of studies in MSM without HIV were qualitative studies [6,11,12,14]. The attitudes toward HIV cure may be complex and varied among MSM without HIV in the community, but the potential patterns of attitudes could be explored and summarized systematically based on latent class analysis (LCA) of quantitative data. This study aimed to examine and profile the attitudes of HIV functional cure among MSM without HIV.

Methods

Study Area

Hong Kong is an international city in the Asia-Pacific region. The estimated HIV prevalence in the general population in Hong Kong in 2022 was 0.1%, but it was much higher at 6.6% in the MSM community [15]. MSM has been accounting for more than half of all new HIV diagnoses per year since 2012, the proportion of which has declined since 2018 [16].

Study Population

This is a secondary analysis of data from a community-based online survey about HIV and sexually transmitted infections in MSM [17]. MSM aged 18 years or older who normally lived in Hong Kong were recruited through gay apps, online gay forums, and nongovernmental organizations. With e-consent, participants completed a self-administered online survey and received a HKD25 (US $1=HKD $7.8) catering voucher as an incentive for survey completion. The address and phone contact information provided for the delivery of incentives were used to check for duplication. The main survey items included sociodemographics, awareness, and attitudes toward HIV functional cure, sexual behavior, and practices of HIV prevention.

Data Analysis

Characteristics of MSM who self-reported having tested negative for HIV (hereafter referred to as MSM without HIV) and those with unknown HIV status (hereafter referred to as unknown status) were compared in bivariable logistic regression. Data of MSM without HIV were then included in the main data analysis. To profile attitudes, the outcome variables were defined based on our previous study in people living with HIV [5], including dichotomized awareness of functional cure (at least knowing the idea), full score (10/10) on excitement level to reflect high anticipation, and willingness to participate in clinical trials of functional cure. Factors associated with each outcome variable were identified in bivariable and multivariable (stepwise backward) logistic regression models.

To account for the complexity of dimensions and the presence of a continuum of beliefs potentially associated with attitudes toward functional cure, LCA was applied to differentiate the patterns. LCA is a statistical model that classifies a population into unobserved groups that differ by attributes [18]. The attributes in LCA were selected based on the health belief model constructs, including perceived susceptibility, perceived severity, perceived benefits, perceived barriers and facilitators, and cues to action [19]. The variables were input in R version 4.2.2 (The R Foundation) using the poLCA package, with 4999 iterations. We tried 2 to 5 classes in LCA. Lower Bayesian information criterion (BIC), Akaike information criterion (AIC), chi-square statistics, higher entropy (at least 60%), and interpretability of identified classes were used to determine the number of classes in the model [20]. Multinomial logistic regression models were performed to compare the characteristics among the identified latent classes in SPSS. To account for the possible impact of MSM with unknown HIV status on functional cure attitudes and to test the robustness of the class structure, data of MSM

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without HIV and those with unknown status were input for sensitivity analysis in LCA. The associations between identified LCA classes and attitude variables (awareness, anticipation, and willingness to participate) were examined in bivariable and multivariable logistic regression. Complete case analyses were performed.

Ethical Considerations

Ethical approval from the Joint Chinese University of Hong Kong-New Territories East Cluster Clinical Research Ethics Committee was obtained (approval CREC2020.436). Electronic consent was obtained before the start of the online survey. Participants received a catering voucher with a face value of HK $25 (~US $3.20) after submission of the online survey. All data are password protected and only accessible by project investigators and designated research staff.

Results

Characteristics of MSM Without HIV and With Unknown HIV Status

Between September 2021 and October 2022, 541 (78%) MSM without HIV and 150 (22%) MSM with unknown status were recruited. The median age of MSM without HIV was 30 (IQR 26 - 35) years, while the median age of MSM with unknown HIV status was 30.5 (IQR 26 - 35) years. A majority of the recruited MSM were Chinese, single, employed, and had attained secondary school education level or above (Table 1). Compared with MSM without HIV, MSM with unknown HIV status were more likely to have a monthly income below HKD $50,000. They were less likely to be PrEP experienced (odds ratio [OR] 0.36, 95% CI 0.21 - 0.63), to have engaged in chemsex (OR 0.50, 95% CI 0.27 - 0.91), and to have engaged in group sex (OR 0.50, 95% CI 0.35 - 0.72), although chemsex engagement in the past 6 months was not significantly different. MSM with unknown HIV status were also less sexually active (OR 0.27, 95% CI 0.15 - 0.50) and less likely to have participated in sexual partner networking events through gay apps (OR 0.66, 95% CI 0.45 - 0.96) and social media (OR 0.68, 95% CI 0.47 - 0.99) in the past 6 months.

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Table . Characteristics of men who have sex with men self-reported without HIV or unknown HIV status.

	Latest HIV test results, n (%)		Bivariable logistic regression, OR[a] (95% CI)
	Negative (n=541)	Do not know (n=150)	
Sociodemographics			
Age group (y)			
18 - 29	245 (45)	70 (47)	1.10 (0.64 - 1.91)
30 - 39	215 (40)	59 (39)	1.06 (0.60 - 1.85)
≥40	81 (15)	21 (14)	Ref[b]
Ethnicity (n=689)			
Non-Chinese	7 (1)	1 (1)	Ref
Chinese	533 (99)	148 (99)	1.94 (0.24 - 15.92)
Marital status			
Married or civil union	17 (3)	4 (3)	Ref
Single	524 (97)	146 (97)	1.18 (0.39 - 3.57)
In employment			
No	84 (16)	29 (19)	Ref
Yes	457 (84)	121 (81)	0.77 (0.48 - 1.22)
Education level (n=690)			
Secondary	71 (13)	27 (18)	Ref
Above secondary	470 (87)	122 (82)	0.68 (0.42 - 1.11)
Monthly income (n=62; HK $[c])			
<15,000	118 (24)	32 (25)	3.25[f] (1.30 - 8.16)
15,000 - 30,000	223 (45)	66 (51)	3.55[f] (1.48 - 8.54)
30,001 - 50,000	83 (17)	26 (20)	3.76[f] (1.47 - 9.64)
≥50,000	72 (15)	6 (5)	Ref
HIV/STI[d] prevention			
PrEP[e] experience (n=682)			
Never	399 (74)	125 (89)	Ref
Ever	142 (26)	16 (11)	0.36[f] (0.21 - 0.63)
Sexual behavior			
Ever chemsex engagement			
No	454 (84)	137 (91)	Ref
Yes	87 (16)	13 (9)	0.50[f] (0.27 - 0.91)
Every group sex engagement			
No	197 (36)	80 (53)	Ref
Yes	344 (64)	70 (47)	0.50[f] (0.35 - 0.72)
STI diagnosis in the past 1 y (n=690)			
No	468 (87)	139 (93)	Ref
Yes	72 (13)	11 (7)	0.51[f] (0.27 - 0.997)
History of sex in the past 6 mo			

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	Latest HIV test results, n (%)		Bivariable logistic regression, OR[a] (95% CI)
	Negative (n=541)	Do not know (n=150)	
No	24 (4)	22 (15)	Ref
Yes	517 (96)	128 (85)	0.27[f] (0.15 - 0.50)
Chemsex engagement in the past 6 mo			
No	499 (92)	143 (95)	Ref
Yes	42 (8)	7 (5)	0.58 (0.26 - 1.32)
Sex partner networking event in the past 6 mo (not mutually exclusive)			
Gay apps	392 (72)	95 (63)	0.66[f] (0.45 - 0.96)
Social media	256 (47)	57 (38)	0.68[f] (0.47 - 0.99)
Sauna	73 (13)	18 (12)	0.87 (0.50 - 1.52)
Gay bars	20 (4)	8 (5)	1.47 (0.63 - 3.40)

[a]ORw: odds ratio.
[b]Ref: reference.
[c]US $1=HK $7.8.
[d]STI: sexually transmitted infection.
[e]PrEP: pre-exposure prophylaxis.
[f]*P*<.05.

Pattern of Beliefs Potentially Associated With Attitudes Toward Functional Cure in LCA

Among MSM without HIV, 4 latent classes were identified by LCA (BIC=9149; AIC=8878; and entropy=71.5%; Multimedia Appendix 1). A majority of *class 1 (high anticipation and willingness*) MSM (n=40, 7%) selected almost all perceived benefits of functional cure (Table 2). More than 90% of *class 2 (high anticipation but low awareness*) MSM (n=82, 15%) perceived safety and the duration of clinical trial as influencing factors for participation and considered the advice of clinical staff and studies by reputable research organizations important in encouraging them to participate. Less than 60% of *class 3 (moderate anticipation and low willingness*) MSM (n=118, 22%) perceived that these were benefits of functional cure. Only a small proportion of them selected factors that might affect their participation in functional cure trials, of which one-third selected no participation for any reason. In *class 4 (moderate anticipation and high willingness*; n=301, 56%), more than half (75%) of the MSM perceived the benefit of functional cure as the state of nontransmissibility.

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Table . Pattern of beliefs potentially associated with attitudes toward functional cure among men who have sex with men (MSM) self-reporting HIV negative test results (n=541).

LCA[a] attributes	MSM, n (%)	Latent classes[b]			
		Class 1—high anticipation and willingness[c], n (%)	Class 2—high anticipation but low awareness[d], n (%)	Class 3—moderate anticipation and low willingness[e], n (%)	Class 4—moderate anticipation and high willingness[f], n (%)
Perceived susceptibility					
Sex partner living with HIV					
None	324 (60)	18 (45)	51 (62)	70 (59)	185 (61)
At least one	41 (8)	4 (10)	5 (6)	14 (12)	18 (6)
Not sure	176 (33)	18 (45)	26 (32)	34 (29)	98 (33)
Perceived severity (indirectly from the meaning of functional cure)					
Risk of progressing to AIDS or developing other complications	251 (46)	37 (93)	37 (45)	30 (25)	147 (49)
Impairment of immune function	356 (66)	40 (100)	49 (60)	73 (62)	194 (64)
Perceived benefits					
No longer needing to take life-long medicine	287 (53)	40 (100)	44 (54)	69 (58)	134 (45)
No transmission of HIV to others	379 (70)	40 (100)	55 (67)	59 (50)	225 (75)
No more positive markers for infection	177 (33)	39 (98)	44 (54)	21 (18)	73 (24)
Feel like immune to HIV, never be infected with HIV anymore	90 (17)	27 (68)	5 (6)	29 (25)	29 (10)
No longer have to seek medical help	135 (25)	40 (100)	3 (4)	25 (21)	67 (22)
Perceived barriers and facilitators					
Safety of the treatment	419 (77)	36 (90)	77 (94)	23 (19)	283 (94)
Duration of the study	289 (53)	27 (68)	75 (91)	12 (10)	175 (58)
Support from friends and family	29 (5)	4 (10)	11 (13)	5 (4)	9 (3)
The need to stop other medicine	125 (23)	14 (35)	41 (50)	0 (0)	70 (23)
Cues to action					
Advice of clinical staff	196 (36)	24 (60)	78 (95)	29 (25)	65 (22)
Reputation of research organization	229 (42)	26 (65)	81 (99)	21 (18)	101 (34)

[a]LCA: latent class analysis.

[b]Bayesian information criterion 9149; Akaike information criterion 8878; relative entropy 71.5%.

[c]Class 1: selection of all perceived benefits (n=40, 7%).

[d]Class 2: considered safety, trial duration, and sites as most important (n=82, 15%).

[e]Class 3: no selection of reasons for joining trials (n=118, 22%).

[f]Class 4: considered nontransmissibility as the main benefit (n=301, 56%).

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When comparing the characteristics among MSM in the 4 classes, class 4 MSM were more likely to be single (OR 3.10, 95% CI 1.02 - 9.43) than class 3 MSM (Table 3). Moreover, class 2 MSM were more likely to be PrEP experienced (OR 2.14, 95% CI 1.11 - 4.12) compared with class 3 MSM. No other factors were significantly associated, although the proportion of MSM aged 18 to 29 years in class 2 was high (44/82, 54%) and the proportion of sexually transmitted infection diagnosis in the past 1 year in class 1 was high at 20% (8/40).

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Table . Factors associated with the 4 identified classes in latent class analysis.

	Class 1 (n=40), n (%)	Class 2 (n=82), n (%)	Class 3 (n=118), n (%)	Class 4 (n=301), n (%)	Multinomial logistic regression (reference: class 3[a])		
					Class 1[b], OR[c] (95% CI)	Class 2[d], OR (95% CI)	Class 4[e], OR (95% CI)
Sociodemographics							
Age group (y)							
18 - 29	17 (43)	44 (54)	55 (47)	129 (43)	0.54 (0.19 - 1.51)	1.40 (0.54 - 3.64)	0.64 (0.33 - 1.26)
30 - 39	15 (38)	30 (37)	49 (42)	121 (40)	0.54 (0.19 - 1.52)	1.07 (0.4 - 2.86)	0.68 (0.34 - 1.34)
≥40	8 (20)	8 (10)	14 (12)	51 (17)	Ref[f]	Ref	Ref
Chinese (ref: non-Chinese; n=540)	39 (98)	81 (99)	117 (99)	296 (99)	0.33 (0.02 - 5.46)	0.69 (0.04 - 11.23)	0.63 (0.07 - 5.72)
Being single (ref: married or civil union)	38 (95)	80 (98)	111 (94)	295 (98)	1.20 (0.24 - 6.02)	2.52 (0.51 - 12.46)	3.10[g] (1.02 - 9.43)
In employment (ref: no)	33 (83)	70 (85)	97 (82)	257 (85)	1.02 (0.40 - 2.62)	1.26 (0.58 - 2.74)	1.26 (0.72 - 2.24)
Above secondary education level (ref: secondary)	33 (83)	73 (89)	104 (88)	260 (86)	0.63 (0.24 - 1.70)	1.09 (0.45 - 2.66)	0.85 (0.45 - 1.63)
Monthly income (HK $[h]; n=496)							
<$15,000	6 (17)	17 (23)	28 (27)	67 (24)	0.64 (0.13 - 3.11)	0.42 (0.15 - 1.19)	0.46 (0.20 - 1.06)
$15,000 - $30,000	15 (42)	31 (42)	51 (49)	126 (45)	0.88 (0.21 - 3.68)	0.42 (0.16 - 1.10)	0.47 (0.22 - 1.04)
$30,001 - $50,000	12 (33)	13 (18)	17 (16)	41 (15)	2.12 (0.47 - 9.50)	0.53 (0.17 - 1.61)	0.46 (0.19 - 1.15)
≥$50,000	3 (8)	13 (18)	9 (9)	47 (17)	Ref	Ref	Ref
Sexual behavior and HIV prevention							
Ever group sex	24 (60)	53 (65)	69 (58)	198 (66)	1.07 (0.51 - 2.21)	1.30 (0.73 - 2.32)	1.37 (0.88 - 2.11)
Chemsex engagement in the past 6 mo	2 (5)	8 (10)	8 (7)	24 (8)	0.72 (0.15 - 3.56)	1.49 (0.53 - 4.14)	1.19 (0.52 - 2.73)
STI[i] diagnosis in the past 1 y	8 (20)	11 (14)	15 (13)	38 (13)	1.72 (0.67 - 4.42)	1.08 (0.47 - 2.49)	0.99 (0.52 - 1.88)
PrEP[j] experience	12 (30)	27 (33)	22 (19)	81 (27)	1.87 (0.82 - 4.24)	2.14[g] (1.11 - 4.12)	1.61 (0.95 - 2.73)
HIV testing in the past 1 y	33 (83)	68 (83)	98 (83)	250 (83)	0.96 (0.37 - 2.48)	0.99 (0.47 - 2.10)	1.00 (0.57 - 1.76)

[a]Class 3: no selection of reasons for joining trials.

[b]Class 1: selection of all perceived benefits.

[c]OR: odds ratio.

[d]Class 2: considered safety, trial duration, and sites as most important.

[e]Class 4: considered nontransmissibility as the main benefit.

[f]Ref: reference.

[g]*P*<.05.

[h]US $1=HK $7.8.

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[i]STI: sexually transmitted infection.

[j]PrEP: pre-exposure prophylaxis.

In the sensitivity analysis including data of MSM with unknown HIV status , 4 latent classes could be identified (BIC=11,485; AIC=11200; and entropy=69.4%; Multimedia Appendix 2). The distribution of attributes in the identified latent classes was similar to that of MSM without HIV, within a 10% difference, except for a lower proportion of class 1 and class 3 MSM who considered treatment safety and class 1 MSM who considered trial duration as the potential facilitators and barriers to participation in the sensitivity analysis (Multimedia Appendix 3).

Factors Associated With Awareness and High Anticipations of Functional Cure and Trial Participation Willingness

Among MSM without HIV, 43% (233/541) were aware of functional cure, with 84% (452/541) indicating willingness to join related clinical trials, while 44% (236/541) gave a full score for excitement level. In bivariable logistic regression, LCA classes were the only factor significantly associated with each of these outcomes (Table 4).

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Table . Factors associated with awareness and high anticipations of functional cure and trial participation willingness in men who have sex with men self-reported without HIV (n=541).

	Aware of functional cure, OR[a] (95% CI)	High anticipations (full score excitement), OR (95% CI)	Willing to participate, OR (95% CI)
Sociodemographics			
Age group (y)			
18 - 29	1.43 (0.85 - 2.40)	0.62 (0.37 - 1.02)	0.68 (0.32 - 1.43)
30 - 39	1.25 (0.74 - 2.11)	0.85 (0.51 - 1.41)	0.68 (0.32 - 1.44)
≥40	Ref[b]	Ref	Ref
Chinese (ref: non-Chinese; n=540)	1.91 (0.37 - 9.94)	0.31 (0.06 - 1.59)	—[c]
Being single (ref: married or civil union)	0.52 (0.19 - 1.38)	0.53 (0.20 - 1.42)	1.59 (0.51 - 4.99)
In employment (ref: no)	0.54[d] (0.34 - 0.86)	0.93 (0.58 - 1.48)	0.92 (0.48 - 1.74)
Above secondary education level (ref: secondary)	0.97 (0.59 - 1.61)	1.07 (0.64 - 1.77)	1.16 (0.61 - 2.23)
Monthly income (HK $[e]; n=496)			
<$15,000	1.52 (0.84 - 2.76)	1.17 (0.64 - 2.15)	0.84 (0.37 - 1.93)
$15,000 - 30,000	1.02 (0.59 - 1.77)	1.60 (0.93 - 2.77)	0.70 (0.33 - 1.47)
$30,001 - 50,000	1.33 (0.70 - 2.52)	1.36 (0.71 - 2.59)	1.18 (0.46 - 3.01)
>$50,000	Ref	Ref	Ref
Health status and sexual behavior			
HIV testing 1 y (ref: no)	1.28 (0.81 - 2.04)	1.18 (0.75 - 1.87)	1.19 (0.66 - 2.13)
STI[f] testing 1 y (ref: no)	1.18 (0.84 - 1.67)	1.03 (0.73 - 1.44)	0.88 (0.56 - 1.40)
History of STI diagnosis in the past 1 y (ref: no)	1.47 (0.89 - 2.41)	1.52 (0.93 - 2.51)	5.18[d] (1.59 - 16.84)
PrEP[g]-experienced (ref: PrEP naïve; n=527)	0.96 (0.65 - 1.41)	1.31 (0.89 - 1.93)	3.26[d] (1.64 - 6.49)
Sex partner living with HIV			
None	1.69[d] (1.15 - 2.47)	0.82 (0.57 - 1.19)	0.70 (0.42 - 1.16)
At least 1 person living with HIV	2.39[d] (1.17 - 4.86)	2.36[d] (1.13 - 4.91)	2.98 (0.67 - 13.16)
All were people living with HIV	0.97 (0.09 - 10.88)	2.46 (0.22 - 27.58)	—
Not sure	Ref	Ref	Ref
Ever chemsex engagement (ref: never)	0.87 (0.55 - 1.39)	0.90 (0.56 - 1.43)	3.72[d] (1.46 - 9.47)
Ever group sex (ref: never)	1.10 (0.77 - 1.56)	1.21 (0.85 - 1.73)	2.52[d] (1.59 - 3.99)

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	Aware of functional cure, OR[a] (95% CI)	High anticipations (full score excitement), OR (95% CI)	Willing to participate, OR (95% CI)
In the past 6 mo			
Sought new sex partners	0.88 (0.51 - 1.52)	0.84 (0.49 - 1.44)	1.34 (0.68 - 2.65)
Sex partner networking events (not mutually exclusive)			
Gay apps	1.05 (0.71 - 1.53)	0.96 (0.66 - 1.41)	1.10 (0.67 - 1.82)
Social media	0.93 (0.66 - 1.31)	0.66[d] (0.47 - 0.93)	0.95 (0.60 - 1.50)
Sauna	0.91 (0.55 - 1.50)	1.91[d] (1.16 - 3.15)	2.00 (0.89 - 4.52)
Gay bars	2.54 (0.997 - 6.47)	1.06 (0.43 - 2.60)	1.12 (0.32 - 3.91)
History of sex (ref: no)	0.89 (0.39 - 2.02)	1.09 (0.47 - 2.49)	1.74 (0.67 - 4.52)
Number of nonregular sex partners (n=514)			
0	0.98 (0.63 - 1.52)	1.24 (0.80 - 1.91)	0.40[d] (0.22 - 0.75)
1 - 4	1.03 (0.68 - 1.55)	1.05 (0.69 - 1.59)	0.57 (0.30 - 1.05)
≥5	Ref	Ref	Ref
Number of regular sex partners (n=514)			
0	0.96 (0.61 - 1.50)	0.76 (0.49 - 1.19)	0.40[d] (0.22 - 0.74)
1	0.99 (0.66 - 1.48)	0.59[d] (0.39 - 0.88)	0.48[d] (0.27 - 0.86)
≥2	Ref	Ref	Ref
At least one commercial sex partner (ref: zero; n=514)	0.96 (0.49 - 1.88)	1.31 (0.68 - 2.54)	0.43[d] (0.20 - 0.91)
Always condom usage (ref: inconsistent; n=506)	0.47[d] (0.31 - 0.71)	1.12 (0.75 - 1.65)	0.79 (0.47 - 1.32)
Chemsex engagement (ref: no)	0.99 (0.52 - 1.87)	1.07 (0.57 - 2.02)	8.78[d] (1.19 - 64.67)
Suspected to have STI (ref: no; n=523)	0.84 (0.58 - 1.24)	1.30 (0.89 - 1.89)	1.33 (0.78 - 2.27)
LCA[h] classes [i]			
Class 1[j]—high anticipation and willingness	0.87 (0.45 - 1.70)	3.57[d] (1.75 - 7.29)	1.04 (0.39 - 2.82)
Class 2[k]—high anticipation but low awareness	0.49[d] (0.29 - 0.83)	1.95[d] (1.19 - 3.20)	1.07 (0.51 - 2.25)
Class 3[l]—moderate anticipation and low willingness	1.00 (0.65 - 1.53)	0.88 (0.56 - 1.36)	0.35[d] (0.21 - 0.59)

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	Aware of functional cure, OR[a] (95% CI)	High anticipations (full score excitement), OR (95% CI)	Willing to participate, OR (95% CI)
Class 4[m]—moderate anticipation and high willingness	Ref	Ref	Ref

[a]OR: odds ratio.
[b]Ref: reference.
[c]Not applicable.
[d]$P<.05$.
[e]US $1=HK $7.8.
[f]STI: sexually transmitted infection.
[g]PrEP: pre-exposure prophylaxis.
[h]LCA: latent class analysis.
[i]Identified latent classes in Table 2.
[j]Class 1: selection of all perceived benefits.
[k]Class 2: considered safety, trial duration, and sites as most important.
[l]Class 3: no selection of reasons for not joining trials.
[m]Class 4: considered nontransmissibility as the main benefit.

In the multivariable logistic regression model, being unemployed (adjusted OR [aOR] 2.00, 95% CI 1.20 - 3.33), inconsistent condom use in the past 6 months (aOR 1.97, 95% CI 1.28 - 3.04), and reporting zero partner living with HIV (with "not sure about partners' HIV status" as reference group; aOR 1.72, 95% CI 1.14 - 2.60) were positively associated with awareness. In the same model, compared with class 4 MSM, class 2 MSM (aOR 0.52, 95% CI 0.30 - 0.90) were less likely to be aware of functional cure. In a multivariable logistic regression model for high anticipation, having at least one partner living with HIV (with "not sure about HIV status" as the reference group; aOR 2.58, 95% CI 1.16 - 5.75), having sex partner networking events in saunas (aOR 1.76, 95% CI 1.03 - 3.02) but not through social media (with "social media" as the reference group; aOR 1.54, 95% CI 1.06 - 2.23), and having at least 5 regular sex partners (1 - 4 as the reference group; aOR 1.81, 95% CI 1.18 - 2.79) in the past 6 months, and belonging to class 1 (aOR 3.41, 95% CI 1.63 - 7.15) and class 2 (aOR 1.95, 95% CI 1.16 - 3.26) were significant factors. In the model for willingness to participate in clinical trials, only group sex engagement in the past 6 months (aOR 1.81, 95% CI 1.09 - 3.03) and belonging to class 3 (with class 4 as the reference group; aOR 0.32, 95% CI 0.18 - 0.57) were significantly associated factors.

Discussion

Principal Findings

Community support is important for the successful implementation of HIV treatment among people living with HIV. This is particularly crucial for new forms of therapy such as functional cure–based treatment, the implementation of which is anticipated as the next milestone in advanced HIV therapeutics. In this study, we profiled attitudes toward functional cure in MSM without HIV in Hong Kong, a city where the coverage of ART is high among people living with HIV[21]. Compared with a previous study in MSM living with HIV in Hong Kong, a similar proportion of our study participants were aware of functional cure (42% vs 43% in this study), and most were willing to join a functional cure trial (93% vs 92% in this study), but a smaller proportion scored full excitement level (59% vs 44% in this study) [5].

In MSM without HIV, high anticipation of functional cure and willingness to participate in a functional cure trial were associated with indicators of recent practice of higher risk sexual behavior. Participants in a previous qualitative study expressed more liberal attitudes toward sexual behavior if an HIV cure can be achieved [10]. The practice of high-risk sexual behavior may result in a lower risk of acquiring HIV if most of the people living with HIV in the community achieve functional cure. This explains why they were supportive and willing to contribute to the development of an HIV functional cure despite their HIV negative status. On the other hand, a PrEP awareness study in China suggested that young MSM who had sex partner networking events in physical venues were more likely to be aware of and willing to take PrEP than those who met partners through the internet, probably due to insufficient online promotion [22]. Our study findings showed no significant differences in willingness to join HIV cure trials by types of sex partner networking events. However, the positive association of events in gay saunas and the negative association of events through social media with high anticipation of cure were in line with the observations from the previous study [22]. When there is trial recruitment, messaging at physical venues, such as gay saunas, might enable potential participants with high anticipation to be enrolled. Consistent with the previous study, those with at least one sex partner living with HIV had more positive attitudes or were more supportive [23]. On the other hand, engagement with existing biomedical prevention measures might affect attitudes toward functional cure. In our study, PrEP-experienced MSM showed higher willingness to participate in a cure trial, who might be more familiar with and more open to novel biomedical interventions.

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In this study, we delineated MSM without HIV into 4 latent classes, of which class 2 had significantly lower awareness but higher anticipation than class 4. This was consistent with the findings from a study of MSM living with HIV, suggesting a significant negative association between anticipation and awareness [5]. Promotion of the functional cure concept and related knowledge would be needed to ground the expectations of class 2 MSM. Distinguishing the concept of functional cure from that of sterilizing cure to avoid misconception is important in communicating with potential participants. MSM in class 3 (n=118, 22%) and class 4 (n=301, 56%) had similar levels of awareness and moderate anticipation of functional cure, but class 3 had significantly lower willingness to participate. Class 3 MSM could be similar to participants in a previous qualitative study, who had lower perceived susceptibility to HIV. They might not consider HIV functional cure as a therapy highly relevant to or affecting them, reflecting a perceived distance from personal benefits [11]. Community education focusing on personal relevance and then extending to the broader MSM community might be useful for targeting class 3 MSM. On the other hand, three-quarters of MSM in class 4 perceived the nontransmissibility of HIV as the main benefit of functional cure, which was consistent with the perceived benefits of reduced HIV burden and more sexual freedom shown in the previous qualitative study [11].

As a novel biomedical intervention, both the community and people living with HIV need time to comprehend the underlying concept of HIV functional cure before a future new treatment strategy is implemented. The lesson derived from the undetectable=untransmittable regarding HIV therapy is that increasing awareness [24] is necessary but not sufficient. It would be important to reduce potential misunderstanding of functional cure in the community, notably MSM without HIV but at higher risk of infection. Even among people living with HIV, knowledge of HIV cure–related research was limited, and their understanding of functional cure needs to be further enhanced [25]. In parallel with progress in the scientific development of functional cure, promotion of community awareness among people at higher risk of infection is much needed.

This study has a few limitations. We applied the same survey items from the previous local study on functional cure for people living with HIV [5], which may not be fully applicable for people without HIV, as they did not have the same concern about treatment interruption nor the perceived stigma associated with HIV status. The responses to hypothetical questions may not reflect the actual thoughts and willingness, as suggested in the previous study [26]. Misclassification in LCA might bias the findings toward the null hypothesis. Compared with the previous local community-based survey [15], our study population, regardless of HIV status (n=712) [17], was younger, with 85% (n=607) aged 18 to 39 years (vs 70% in the previous study), but had a similar proportion of Chinese ethnicity and ever having HIV testing coverage. However, we acknowledge the cultural specificity of Hong Kong, the findings and implications of which might not be extrapolated to other places. As with other surveys, recall bias in respondents' sexual behavior and potential bias in response quality caused by incentives could exist. Finally, there is no validation of participants' self-reported HIV status. Regardless of the last HIV testing time, participants' responses on their beliefs and attitudes toward functional cure should remain valid, as they were provided under the perception of being uninfected.

Conclusions

MSM without HIV are a key early audience for functional cure communication and are stakeholders of functional cure. While MSM without HIV are not direct recipients of functional cure therapies, their awareness and willingness to join a functional cure trial were similar to MSM living with HIV in a previous local study, but with lower anticipation. Overall, 4 latent classes of MSM without HIV can be differentiated, which varied by their perceived susceptibility to infection, benefits, barriers and facilitators, and cues to action. As community awareness and understanding of the functional cure concept take time to nourish, these have to be nurtured in parallel with the scientific progress of functional cure development.

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Data Availability

The data that support the findings of this study are available on request from the corresponding author. The data are not publicly available due to privacy or ethical restrictions.

Conflicts of Interest

None declared.

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Multimedia Appendix 1
Comparison on the performance of latent class analysis, 4999 iterations, for men who have sex with men without HIV (n=541).
[DOCX File, 18 KB - formative_v10i1e79631_app1.docx]

Multimedia Appendix 2
Comparison of the performance of latent class analysis, 4999 iterations, for men who have sex with men without HIV or with unknown HIV status (N=684).
[DOCX File, 16 KB - formative_v10i1e79631_app2.docx]

Multimedia Appendix 3
Latent pattern of attitude toward HIV functional cure among men who have sex with men self-reported without HIV or unknown HIV status (N=684).
[DOCX File, 20 KB - formative_v10i1e79631_app3.docx]

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Abbreviations

AIC: Akaike information criterion
aOR: adjusted odds ratio
ART: antiretroviral therapy
BIC: Bayesian information criterion
LCA: latent class analysis
MSM: men who have sex with men
OR: odds ratio
PrEP: pre-exposure prophylaxis

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Biosurveillance and the Opioid Crisis in Emergency Medicine: Qualitative Study of Physician Perspectives

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Abstract

Background: In 2017, the US Department of Health and Human Services declared a national opioid crisis. In 2022, an estimated 81,806 overdose deaths involved an opioid. Emergency departments are critical in the pathway of care for providing resources and linkages to services. Studies investigating emergency medicine (EM) physicians' perspectives on the opioid crisis have largely focused on prescribing.

Objectives: To investigate EM physicians' perspectives on response strategies to the opioid crisis of biosurveillance and linkages to care. A secondary objective was to map reported challenges and recommendations using a sequential intercept model as an actionable framework.

Methods: This is a qualitative study. Six EM physicians in an academic health care system were interviewed through semi-structured interviews. Interviews were transcribed, then thematically coded and analyzed to identify cross-sector settings and barriers to care with corresponding recommendations. Settings and recommendations were mapped as a sequential intercept model.

Results: EM physicians identified 9 key settings as crucial touch points in the opioid crisis: home setting, emergency medical services, patient care, clinically relevant data and information, prescriptions and pain management, predischarge coordination, outpatient resources, biosurveillance sample collection, and the external partner and administrative environment. Biosurveillance challenges included concerns about collecting biological materials for state and regional monitoring, as well as the time burden for sample collection. Linkage to care challenges included social determinants of health and limited outpatient care access. Recommendations were specific to each setting and included care coordination and fostering cross-sector partnerships. A patient-centered approach and better integration of community resources were emphasized.

Conclusions: The service delivery culture is of acute and episodic care but needs to more seamlessly address care across its fragmented multicomponent complex system. EM physicians face systemic challenges and provide actionable recommendations to promote comprehensive care to patients presenting to the emergency department with opioid-related complaints.

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KEYWORDS

emergency medicine; emergency department; qualitative; opioids; substance use disorder

Introduction

In 2017, the US Department of Health and Human Services declared a national opioid crisis [1]. In 2025, the public health emergency declaration was renewed [2]. This crisis has evolved from overdose deaths related primarily to prescription painkillers, to heroin, to illicitly manufactured fentanyl and other synthetic opioids [3]. Recently, opioid overdose deaths often involve polysubstance use [4]. In 2022, an estimated 81,806 overdose deaths involved an opioid [5], and 11.8% of adults reported a past substance use problem, with over 70% identifying as in recovery [6]. Despite recent declining trends in overdose mortality, fentanyl-involved nonfatal overdose emergency department (ED) visits remain high [7].

The federal public health response [8] to the opioid crisis recommended key public health and surveillance components: strengthening public health data reporting and collection to improve the timeliness and specificity of data to inform a real-time public health response; and improving access to prevention, treatment, and recovery support services to prevent the health, social, and economic consequences associated with opioid addiction while enabling individuals to achieve long-term recovery. Federal response has included using ED and emergency medical services (EMS) data to track and analyze

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morbidity trends, and building systems to facilitate better linkages to treatment, such as emergency room peer patient navigators. Central to these strategies is establishing partnerships among public health, public safety, harm reduction, and clinical and health settings.

Public health surveillance has been actualized through prescription drug monitoring programs (PDMPs) to minimize high-risk opioid prescribing. In 2022, 21 states reported 96,332 nonfatal opioid-related ED visits [9]. ED patients frequently present with chief complaints of pain, requiring emergency medicine (EM) providers to balance effective pain management with the risks associated with prescription opioids [10]. EDs are critical touchpoints for providing persons who use drugs with overdose prevention resources and linkages to care, as those who experience a nonfatal opioid overdose are at increased risk of a subsequent overdose [11].

Previous research involving EM physicians has largely focused on prescribing. ED providers expressed helplessness, sadness, and frustration toward current approaches to treating patients with opioid use disorder (OUD) [12,13]. Many felt unprepared to discuss buprenorphine (an evidence-based treatment option) with patients [12]. Providers expressed clinician- and system-level barriers to initiating buprenorphine, with recommendations for improved training opportunities, clinical protocols, and referral systems for outpatient follow-up [12]. Providers generally support opioid prescribing guidelines for EDs [14,15]; however, they described a need for increased administrative support, improved PDMP efficiency, and increased patient involvement in the opioid prescribing process [15].

Biosurveillance is the process of gathering, integrating, interpreting, and communicating essential information related to all-hazards threats or disease activity affecting human, animal, or plant health to achieve early detection and warning, contribute to overall situational awareness of the health aspects of an incident, and enable better decision-making at all levels [16]. In the context of the opioid crisis, this might include toxicology testing of drug products or individuals' biological samples (such as blood or urine) to track and monitor drug trends and overdose outbreaks [17]. Individuals admitted to the ED for an overdose would be potential candidates for testing.

While PDMPs and prescribing guidelines have been studied as response strategies to the opioid crisis, little is known about EM physicians' perspectives on biosurveillance and linkages to care, especially across the care continuum. This qualitative study analyzes data from semistructured interviews with EM physicians. Our primary objective is to investigate EM physicians' perspectives on response strategies to the opioid crisis related to biosurveillance and linkages to care. Our secondary objective is to map their reported challenges and recommendations in a sequential intercept model (SIM) as an actionable framework. SIM mapping of EM physicians' perspectives in a cross-sector model is innovative, given that historically this modeling has been used to inform community-based responses to the engagement of people with mental health conditions and substance use disorders (SUD) in the criminal justice system [18-20].

Methods

Study Design

This study is a qualitative investigation of EM physicians' perspectives on biosurveillance and linkage-to-care responses to the opioid crisis, including barriers and recommendations along the patient care continuum. A content analysis of semistructured interviews was applied to a purposive sample of EM physicians with clinical responsibilities practicing in the ED.

Setting

The setting was an academic tertiary EM department in a Midwestern community in a county of about 200,000 residents. This setting provides the only Level I trauma center and the only board-certified team of EM physicians in the region. The department has a catchment area of 30 mostly rural counties spanning 190 miles in length and 125 miles in width.

Participants

The project was announced to EM physicians during a faculty meeting, with interested participants recruited through in-person invitations. Recruitment targeted diversity in physician roles. Personal invitations included a brief summary stating that the study aimed to understand physicians' experiences in the ED, outlining that participation would involve a 30-minute semistructured interview, and emphasizing the value of their specific professional perspective. All six board-certified EM physicians invited for interviews agreed to participate. The participants were previously familiar with the interviewer (author JAWS). In addition to clinical duties, each participant maintained at least one of the following administrative foci or subspecialty board certifications: medical administration; medical student or EM resident education; EMS; pediatric EM; or academic research specializing in OUD. All participants were trained at outside residency and fellowship programs across the country, and the majority practiced as attending physicians outside of Missouri prior to their current role.

Data Collection and Interview Process

A first draft of interview questions was developed in April 2023 based on EM physician experiences in their roles, initiatives to enhance biosurveillance (eg, the Centers for Disease Control and Prevention's Enhanced State Opioid Overdose Surveillance program [8]), and their perspectives on care coordination across a broad cross-sector. Two authors (JAWS and JMK) collaborated on refining the questions with an EM physician sample in mind. Textbox 1 shows the final interview questions. Semistructured interviews occurred between July and August 2023 without incentives. One interviewer familiar with the participants (JAWS) conducted the interviews. Participants 1 and 2 volunteered to participate together given their availability; the remaining participants opted for one-on-one interviews. Participants received questions on the day of their interview. Interviews occurred in a private office. The interviewer read each question aloud, and follow-up questions were asked as the interview progressed. Interviews were completed in approximately 30 minutes (mean 32, range 25 - 47 min). In the case of the dual interview, each participant answered the

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questions individually and then was allowed to expand upon the other's responses. To confirm that the dual interviewees did not influence one another, each was independently asked later if they were satisfied with their answers, and both indicated in the affirmative. All interviews were audio recorded with permission.

Textbox 1. Focus group interview questions.

1. How is the opioid crisis affecting your job in the emergency department (ED)?
   a. Prompt with "What challenges are you facing in your day to day?"
   b. Prompt with "How has this evolved as the opioid crisis evolved, for example, inclusion of fentanyl, xylazine, etc.?"
   c. Prompt with "What solutions have you thought might work?"
2. How do you think social determinants of health affect what you see in the ED in regards to opioids?
   a. Prompt with "What resources are hard to get? For your practice and for specific patients?"
   b. Prompt with "How do you identify any gaps in care? How has the ED tried to provide wrap around services or tried to make community connections?"
3. There is interest from the state in collecting samples from overdose patients and sending them to a state laboratory for testing. Do you think our hospital would be interested in participating?
   a. Prompt with "Why do you think our hospital wouldn't want to?"
   b. Prompt with "What if it was only up to the ED staff to send in samples?"
   c. If there is robust conversation about this question, provide more context, "The state is hoping to collaborate with MHA (Missouri Hospital Association) to assist in this effort. Do you have any thoughts about that?"
4. How do you currently learn information or current data about the state of the opioid crisis? Locally? Statewide? Nationally?
   a. Prompt with "How would you like to learn about it?"
   b. Prompt with "How would you use the information?"
   c. Prompt with "How can we be a good partner to you when getting you the most up to date information?"
5. How can we best connect with first responders, correctional systems, and others?
6. What's your experience with EPICC (Engaging Patients in Care Coordination) in the ED? Is their presence helpful to patients at risk for overdose?
7. Do you know of any other acute resources that your patients can use outside of EPICC?

Data Analysis

Audio recordings of the interviews were transcribed by two authors using slowed playback. Transcripts were organized into a Microsoft Excel spreadsheet, segmented into natural conversational breakpoints by row, resulting in 191 rows of data referred to as "observations." Authors identified predominant patterns and themes through content analysis. To reduce bias, authors involved in developing initial codes and applying those codes were not the same as the author who collected the data. First, two authors (MB and JMK) independently reviewed organized transcripts to inductively develop two preliminary sets of codes. Authors' goals for interpreting the data included identifying physician perspectives related to actionable opioid response strategies and explanations of patient care touchpoints along the treatment continuum. Next, all authors discussed and reviewed these codes, drawing on their areas of expertise to create a revised coding scheme. Two authors (MB and AED) then independently applied this scheme to 10% of observations. All authors discussed the results of the 10% of coded observations to better understand how interpretation was applied and to continue the refinement of codes until final. This was accomplished with researchers tracking coding spreadsheets as they developed, discussing disagreements in person and via email to clarify coding discrepancies, and debriefing on the coding process until final agreement was reached. Two authors (MB and AED) then independently coded remaining observations for the two categories described below using final codes.

The first category of coding was the "setting," which included the context of intervention points for a person presenting with suspected overdose or suspected OUD (see Table 1). Settings were categorized into 9 areas: home setting, EMS, ED (including patient care, prescriptions/pain management, predischarge coordination, and clinically relevant data), outpatient resources, biosurveillance sample collection, and the external partner/administrative environment. Settings were grouped as 3 phases: *prehospital* (prior to entry to the ED), *ED* (the span of medical care activities in that setting), and *cross-sector partnerships* (administrative or organizational setting that includes structure, partnerships, resources, and regulations). The second category of coding was challenges and barriers (C/B) and actionable "recommendations" for intervening in those settings.

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Table . Codes and definitions.

Setting code	Definition
Home setting	Outside of the health care system, social conditions, housing, food insecurity, transportation, access to care, telehealth, geography.
Emergency medical services	Exclusively in the care of EMS[a], regardless of the location of EMS activities.
Patient care	Patients in the care of ED[b] personnel, the process of clinical treatment, clinical decision-making, Narcan-revivals, trends in diagnoses.
Clinically relevant data and information	How EM[c] providers prefer to receive information, timeline of information, geography of data disseminated, information sources, information processes.
Prescriptions/pain management	Considerations of substance use disorder potential while prescribing.
Predischarge coordination	Peer counseling, peer support, peer navigation, peer education, coaching, social work, coordinating resources, warm handoff.
Outpatient resources	Long-term medication-assisted therapy, rehabilitation, at-home Narcan resources, mental health care, discharge by EMS at the site of emergency.
Biosurveillance sample collection	Sample collection, sample testing/analysis, patient confidentiality in testing, resources needed for sampling, workflow related to samples.
External partner or administrative environment	Hospital coordinating bodies, interactions with law enforcement/justice systems/courts, rules and policies, partnership with state government.

[a]EMS: emergency medical services.

[b]ED: emergency department.

[c]EM: emergency medicine.

For confirmability of coding, Stata version 16.1 was used to assess agreement between coders. For setting, 2 authors (MB and AED) agreed on 73% of codes (κ=0.6874, substantial agreement [21]), and for C/B or recommendations, 2 authors agreed on 83% of codes (κ=0.6407, substantial agreement). A third and a fourth author separately interpreted remaining disagreements independent of prior coding, resulting in each observation having one setting and one C/B or recommendation categorization.

Observations were not weighted, with each observation carrying the same importance during analysis. The frequency of codes was tabulated to approximate how commonly a topic was discussed, suggesting participants' emphasis on that topic.

Example quotes were selected for each C/B and recommendation for each setting. Quotes were lightly edited for readability (eg, spelling corrections or removal of disfluencies) but retained their original meaning. Ellipses indicate removed text, and relevant unspoken contextual details are added in brackets.

Identified settings informed the creation of a SIM map to visually summarize the sequential span of potential intervention points and recommendations for those settings. Categorization of settings into phases was developed by all authors inductively, based on pattern emergence and interpretation from author expertise areas (ie, EM, epidemiology, behavioral neuroscience and addiction science, public policy, and program evaluation), with the goal of providing a visual representation of a potential sequence of settings and intervention points from the patient's perspective after overdose. Bullet points were added under each setting to reflect key recommendations provided by physicians. SIM mapping has previously been used to display how people move through the criminal justice system with the intention of generating considerations for interception points [18,19].

Ethical Considerations

This study was reviewed and approved by the University of Missouri Institutional Review Board (IRB 2101376). This study is a secondary analysis of previously collected, deidentified transcripts from a program evaluation and therefore did not require additional consent.

Results

Descriptive Characteristics

Table 2 reports descriptive information for coded observations. The most common setting mentioned was clinical decision support, with 46 out of 191 (24%) observations coded. The least common settings were prescriptions or pain management and EMS, each with only 4 out of 191 (2%) observations coded. Observations included more C/Bs (122/191, 64%) than recommendations for improvement (69/191, 36%). The phase with the most observations was the ED (110/191, 58%), followed by cross-sector partnerships (58/191, 30%) and preclinical (23/191, 12%). The percentages of recommendations within phases included 13% (3/23) for prehospital, 40% (44/110) for ED, and 38% (22/58) for cross-sector partnerships.

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Table . Distribution of settings, challenge/barrier, and recommendations.

Phase and setting	Setting, n/N (%)	C/B[a] and recommendations, n/N (%)
Prehospital (n=23)		
Home setting	19/191 (10%)	• C/B: 16/19 (84%) • Recommendations: 3/19 (16%)
Emergency medical services	4/191 (2%)	• C/B: 4/4 (100%) • Recommendations: 0/4 (0%)
Emergency department (n=110)		
Patient care	27/191 (14%)	• C/B: 21/27 (78%) • Recommendations: 6/27 (22%)
Clinically relevant data and information	46/191 (24%)	• C/B: 24/46 (52%) • Recommendations: 22/46 (48%)
Prescriptions/pain management	4/191 (2%)	• C/B: 4/4 (100%) • Recommendations: 0/4 (0%)
Predischarge coordination	33/191 (17%)	• C/B: 17/33 (52%) • Recommendations: 16/33 (48%)
Cross-sector partnerships (n=58)		
Outpatient resources	10/191 (5%)	• C/B: 6/10 (60%) • Recommendations: 4/10 (40%)
Biosurveillance sample collection	21/191 (11%)	• C/B: 14/21 (67%) • Recommendations: 7/21 (33%)
External partner/administrative environment	27/191 (14%)	• C/B: 16/27 (59%) • Recommendations: 11/27 (41%)
Total	191/191 (100%)	• C/B: 122/191 (64%) • Recommendations: 69/191 (36%)

[a]C/B: challenge/barrier.

Table 3 reports examples of C/Bs and recommendations in each setting. The leftmost column shows each setting, the center column shows quotes related to C/Bs, and the rightmost column shows quotes related to recommendations.

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Table . Demonstrative C/B[a] and recommendations from each setting.

Setting	ID: Example C/B	ID: Example recommendation
Home setting	• 1: From a standpoint of rural agencies, there's a lot less resources the farther out you go…There are not as many treatment centers…and a lot of those people…cannot drive 30 [minutes to] an hour to go through outpatient treatment.	• 4: It has to be a free service. A phone number that they can call and talk to someone…Everyone these days needs therapy, so probably some sort of free therapy.
EMS	• 2: I think for EMS[b], a lot of these substance abuse patients also have dual diagnoses with psychiatric complaints. So, there can be a lot of overlap and trying to figure out the primary problem for that day and sometimes those [behavioral] issues can lead to safety concerns.	• Not applicable
Patient care	• 6: I have had to call codes [as deceased and declared deceased] on people who are opiate overdosed. I've gotten people back [from death] from opioid overdose and seen their reaction. It ranges from sorrow and dismay…to annoyed and angry at me that I have taken away their high. • 5: I think that fentanyl has been an increased issue across the board.	• 3: I ask about whether they would be interested in resources for substance use treatment and whether they have a primary care doctor who they feel comfortable talking with about this subject. • 4: Usually it's asking a pretty thorough history and including those additional historical questions, like social history and past medical history. • 6: I do my very best to attempt to be an ally... I always thank people for their honesty, particularly when they tell me something shameful or taboo or whatever…it's my perception that it helps build rapport, and lets them know that my main goal is to help them from a medical perspective.
Clinically relevant data and information	• 3: But no matter which opioid you're using, if you come in overdosed to my department, I'm getting you a Narcan. • 4: I've been spammed by a whole bunch of medical email listservs that I'm somehow on now, and there's always something about [the state of the opioid crisis], but it never seems like it's related to my population. • 4: I do not feel like it's timely and I feel like I almost don't get any information. • 5: I don't know a whole lot about what's going on in the state or the county.	• 1: If a dashboard were built, even a 30-day delay would be too much to be actionable. • 2: [It would be helpful for the dashboard to show] where the event occurred, where the 911 call or where the hospital was. County level is plenty…We don't need any information about the patient themselves. • 2: I really need new data, real time information. Last year's data is interesting to know, but it's not actionable. • 6: If I'm on an email list, the odds of me actively looking at it are probably a lot lower…Honestly, I'd probably be more apt to read it if it came from our admin.
Prescriptions/pain management	• 6: I try to be judicious of like, how much [opioid] do I think [the patient] needs? And how much am I ok prescribing them? In the literature, it's like less than 10 pills is all it can take to get people addicted to opioids. • 6: I feel more people are reticent to get fentanyl when they come to see us, because they've heard about fentanyl in the media and whatever.	• Not applicable
Predischarge coordination	• 2: If you leave a pamphlet, the likelihood of somebody calling [for treatment] is small versus if you make the call yourself and set it up. But to attempt to do that in a hospital setting, time may be an issue. • 4: Our social worker has very limited hours and she is stretched thin based on what's going on in the ED.	• 2: I would like to have an ED[c] social worker that is present 24/7. • 4: It would be beneficial to have a therapist in the ED. Having a social worker available 24 hours a day would be huge too. • 6: It would be nice to have a social worker 24/7.

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Setting	ID: Example C/B	ID: Example recommendation
Outpatient resources	• 3: The other thing that is acutely available and very useful is a script for Narcan or even better, an actual dose of Narcan to take home with them from the ED. • 6: I am aware that there are detox houses. Or houses where people have some other services.	• 1: Access to some sort of treatment center, even just a hallway or one room in a local public health [organization], would be a huge benefit for a lot of these patients. Somewhere they can go locally…where they can have a social worker help, arrange for resources once they've had some medical evaluation, and get plugged into continued outpatient resources. • 3: I wish we had a detox slash treatment unit associated with our hospital.
Biosurveillance sample collection	• 2: There may be some difficulty in workflow, especially on busy days. • 3: We are already understaffed, underfunded, and overstretched in the ED. To give us one more thing to do without providing the resources to do it is not helpful. • 4: A lot of concerns for patient privacy, realistically. I think if you have more than one identifier…you can probably track that patient back.	• 4: [You could collect the] ZIP Code of where the overdose was. Just so they can see if there are pockets, or certain communities that have a higher incidence of overdose, and maybe law enforcement could look into that further. But even that's a bit dicey because they are getting information that was provided by the hospital. Yikes. • 5: If you're collecting information about the person it has to be voluntary. I don't think you have the option of obtaining information, personal information of any kind, and samples, without consent. If it's a way to collect samples so that there's no patient information, then I think that would be acceptable. • 5: I think it can be done anonymously versus having to have minimum patient information on it. • 6: Patient autonomy is a tenet of medicine.
External partner/administrative environment	• 4: I think the MHA[d] is great because it can outreach to all the hospitals in Missouri. They do some really great things on different initiatives. So, maybe they could help with legal issues, like what are the minimum necessary requirements and how can we keep hospitals and physicians safe. • 5: I don't have great insight into the system…I mean, we don't really deal with the aspect of if someone relapses. We treat them and we're going to deal with their medical problem, and then we don't really deal with the justice side. That's not really our area to take part in. • 6: As soon as I was allowed to do it, I had an X-waiver, before it became a thing you didn't have to have anymore.	• 1: I think MHA has administrative capabilities. They can run a dashboard and can probably run a dashboard better than the state. • 4: I see them as a higher-level organization. Getting the general counsel kind of things together and making sure all the labs are run the same…So if they could come up with like 1 clear protocol for everyone to use that would be beneficial to the whole state. • 6: I think MAT[e] in the correction[al] system would be great.

[a]C/B: challenge/barrier.

[b]EMS: emergency medical services.

[c]ED: emergency department.

[d]MHA: Missouri Hospital Association.

[e]MAT: medication assisted treatment.

Home Setting

Participants often mentioned social determinants of health (SDH), which included challenges such as rural geography, income, language barriers, employment, insurance, food access, and disability status. Treatment can be especially difficult to access for people with low income or no insurance.

Many treatment programs require that you pay for them and if you don't have a job with health insurance you are unlikely to be able to pay for it. And if you don't have a good leave policy at your job, you risk losing your job. So, if you have the money to pay for treatment, and if you have a good job that understands taking time off for a health issue, you're going to have

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> *a much easier time treating the problem than if you work graveyard shift at a factory or at the 7/11 and you're living paycheck to paycheck, and you can't afford to miss a single shift.* [Participant 3]

Participants recommended improving access to or offering free therapeutic community services, particularly through telehealth.

Emergency Medical Services

A call to EMS is often a first step after overdose. EMS patients can have complex needs, creating barriers to identifying the root cause of a call. Participant 1 stated, "dual diagnoses definitely are frequent with SUD if it is psychiatric disorders as well."

Patient Care

Participants reported an increase in opioid overdoses and a shift from heroin toward fentanyl. Patients' reactions after administration of naloxone varied from anger to dismay; some are open to discussing treatment, but Participant 4 noted some "are not even willing to have that conversation." Participant 4 recognized the need to involve families:

> *[The opioid epidemic] affects their family members, loved ones, or they know someone…if a patient wants to come in for withdrawal symptoms…do we have appropriate outpatient resources for the patients? And what do we do with their families and how do we refer them on?* [Participant 4]

Recommendations included offering treatment information to patients. Additionally, Participant 4 recommended improving education for medical students on SDH screening, while Participant 3 discussed screening for the trustworthiness of the drug supplier:

> *Ask "where do you live? Do you have a safe place to stay? Do you have transportation?"…We need to teach residents and physicians to just keep asking those questions, even though they might have some information in front of them because you can't always rely on what's in the computer…Sitting down at their level, not interrupting, all those things so they feel comfortable talking to you and being nonjudgmental.* [Participant 4]

> *One of the things I actually do ask people when they have a bad trip, and they're concerned that they may have been slipped something, is whether they got their [drugs] from a usual supplier that they trust, or whether it's somebody new that they have no idea how reliable they are.* [Participant 3]

Participants suggested not assuming existing information about patients in the electronic record was correct and to be diligent in gathering information to best help patients.

Clinically Relevant Data and Information

Participants wanted surveillance information disseminated about drug trends and opioid overdoses but were unsure that this would meaningfully alter clinical care and instead be useful for population-level outreach and intervention planning. Participant 3 stated, "no matter which opioid you're using, if you come in overdosed I'm getting you a Narcan."

Biosurveillance information may help if timely, relevant, and direct. Participants wanted information on local drug trends or overdoses, but it would need to be within the occurrence week to be actionable. Participant 3 reported:

> *If a dashboard were built, even a 30-day delay would be too much to be actionable. You'd almost have to have a weekly update.*

The best way to receive information is communication from their institution. Some also suggested communicating through professional association (eg, American College of Emergency Physicians) emails.

Prescriptions/Pain Management

Participant 6 spoke to the tension of judiciously prescribing opioids for managing patients' pain while also avoiding addiction potential. They also spoke to the experience of working in a state with a robust PDMP versus a state [like Missouri] with a nascent PDMP:

> *I feel more people are reticent to get fentanyl when they come to see us, because they've heard about fentanyl in the media…we're a much more controlled setting than getting your bundle off the street…fentanyl has more bad press around it and [people] don't want to use it…Pills around here are more accessible. Where I was previously, I think heroin was more accessible. I came from a state that had a strict and robust PDMP…it was much easier [in the previous state] to look up people who had been getting prescriptions.*

Only one participant offered prescription/pain management setting observations, and no one offered recommendations for that setting.

Predischarge Coordination

Patients were perceived as less likely to receive post-ED care if left to self-coordinate than if coordination was provided. This puts a burden on ED physicians, and social work resources are at capacity. An increase in dedicated care coordination resources would be beneficial. Participant 4 noted:

> *There's a lot more [treatment] resources for people to get compared to 10 - 15 years ago. Because it's more talked about, not as scary for patients to admit to it, and they're more forthcoming… So, then we can actually get them the help that they need…[If they need] medication assisted treatment [MAT]…the resources are a lot more plentiful. I love the [Engaging Patients in Care Coordination] EPICC program because it's like a peer coach. And I've had really good luck with that.*

Participants need all-hours social worker positions in the ED to assist in care coordination, which is seen as the responsibility of ancillary services. Participants spoke highly of the Missouri Hospital Association (MHA) EPICC program, based on the screening, brief intervention, and referral to treatment model that links opioid overdose survivors at a point of crisis to

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community-based care via peer outreach across institutional and community settings. Participant 6 said:

> *My experience with EPICC has been that they're an excellent resource. I appreciate that they call and/or see the person in real time.*

Outpatient Resources

Participants had limited knowledge of OUD outpatient resources in communities, such as residential treatment centers, MAT, or longer-term mental health care. Participants encouraged patients to seek and receive care and offered what their hospital had available; however, connecting to community resources for outpatient treatment was beyond their role. Participants were challenged with getting patients access to ongoing outpatient treatment. For example, Participant 5 said, "many of the places that address addiction don't take pediatric patients."

> *Primary care is so short staffed…If you come in ready to change and ready to get treatment, but it's going to be 3 months before you can see anybody, then the chances you can maintain that on your own are pretty small.* [Participant 3]

Recommendations included improved processes to connect patients to local clinical- or community-based resources. Participant 3 stated:

> *Opioid withdrawal is miserable and may make you wish you were dead but will not actually kill you, so it's very seldom that we admit somebody to the hospital for that purpose.*

However, the importance of outpatient resources was noted. Participant 1 said:

> *Sobriety centers are [something] we see a lot of in urban areas, but most of those are funded by health systems trying to divert patients out of the ED…I think something locally that enables the patient to stay there… from the standpoint of the ED, tele-psychiatry is sorely needed.*

Biosurveillance Sample Collection

Participants expressed concern about collecting biological materials and sending them to a central location for state and regional opioid use monitoring. Challenges included the time burden, a lack of clarity on whether samples would be collected via kits or tubes, and funding. Participant 1 said:

> *I think workflow is going to be huge…are we using our own equipment... is the state providing a kit…a whole kit you have to put the information in, that's a barrier.*

Participants believed ED staff roles in collecting and shipping samples should be minimized. Participants had concerns about patient privacy and consent, seeing it as inappropriate to sample and test patients without consent. Participant 6 asked, "is that a patient gets-to-decide kind of question?" and stated, "it's their body, it's their choice." Even with consent, participants reported concerns about potential law enforcement consequences; it was viewed as inappropriate to attach personal information to samples.

Participants suggested that a partnership with MHA could be beneficial if they provide staff to process samples. Participants strongly recommended obtaining patient consent for sampling and minimizing identifiable information on samples. Participants speculated that only the ZIP code and date might be needed.

External Partner/Administrative Environment

Challenges included siloing between organizations. For example, physicians or other medical professionals did not often interact with the justice system. Concurrently, there was support for modernizing opioid treatment in criminal justice systems, such as providing MAT in correctional systems. Participants also spoke of challenges with administrative red tape that created barriers to clinical practice. One participant described the importance of obtaining an X-waiver from the Drug Enforcement Agency when that authorization and registration was required.

While participants appreciated EPICC and other care coordination services, Participant 2 also acknowledged the challenge of coordinating external resources:

> *[Care coordination and referrals is] kind of scattered with programs like EPICC, the local clinic, and some of the other disorder clinics and stuff. [It's challenging]…having to coordinate several different programs that overlap and interact but are different.*

Participants viewed MHA as capable and well-positioned to provide administrative support for dissemination of biosurveillance information to Missouri hospitals.

Sequential Intercept Model

Figure 1 shows a SIM map based on the findings reported above, with summary recommendations bulleted below the corresponding setting. This SIM map summarizes and integrates the coded data from EM physicians into a visual representation of a patient's potential overdose experience across sequential settings (home through outpatient), highlighting contextual opportunities for intervention based on participant recommendations for action.

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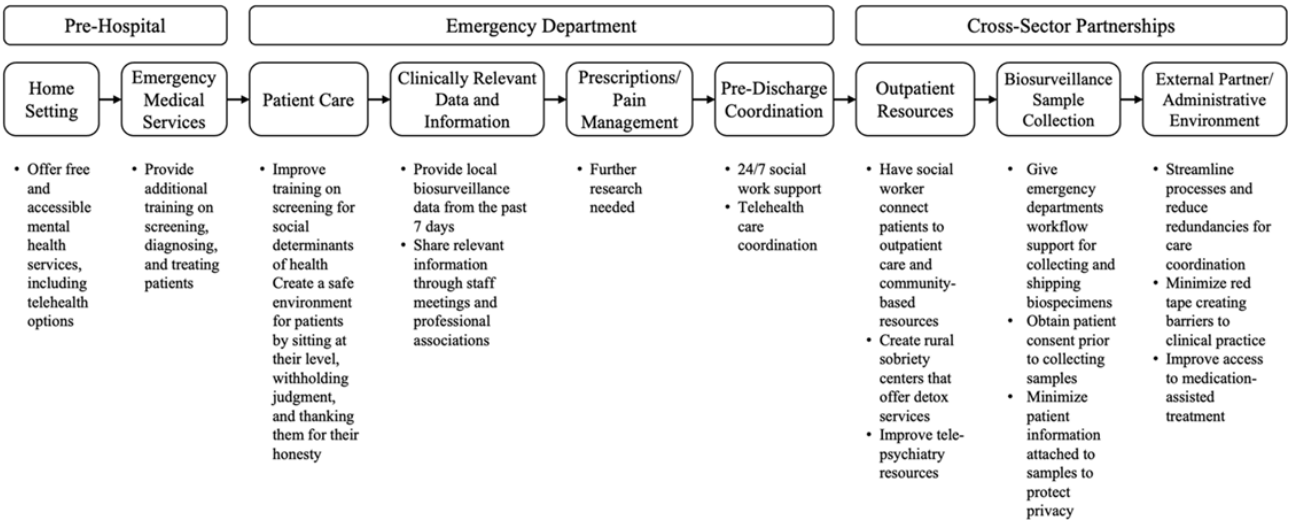
Figure 1. Sequential intercept model mapping to emergency department physicians' perspectives on the opioid crisis.



Discussion

Principal Findings

This is the first study to investigate EM physicians' perspectives on actionable response strategies to the opioid crisis of biosurveillance and linkages to care throughout the care continuum, and then to map their reported challenges and recommendations in a SIM as an actionable framework across the sequence of patient settings. Key patterns across settings include a desire for actionable, practical support with clear workflows. Workflow and implementation burden are concerns across settings given limited staffing and lack of capacity. There is also significant variability in resource availability and community infrastructure, limiting local options and creating constraints.

Regarding biosurveillance dashboards, given the acute and rapid nature of EM, with physicians making complex decisions in the absence of ideal data, dashboards are not perceived as actionable unless they are current and within a local context. New knowledge of the overdose landscape from dashboards is not likely to alter the standard of care. Participants prefer that critical information be communicated through trusted sources such as professional organizations. Participants expressed concern about privacy and patients' ability to consent to sample collection. Concerns related to patient privacy, stigma, and drug-related prosecution are common and necessitate maintaining strict confidentiality [22]. The Association of Public Health Laboratories recommends routine confidentiality training for staff, establishing data use agreements between parties involved in data sharing, using unique identifiers in place of identifiable data, and sharing aggregate data with partners [23].

Regarding linkages to care, the service delivery culture is acute and episodic care but needs to more seamlessly address care across its multicomponent complex system. Participant responses reflect fragmentation between systems (especially EMS, ED clinical care including predischarge coordination, and outpatient treatment), with weak care transitions, particularly for patients with social or behavioral health needs. Participant recommendations inform federal goals for decreasing barriers to care. Sobriety centers are needed, along with 24/7 social work support to connect patients with resources, including outpatient treatment and establishing primary care. For rural patient challenges of availability and distance to treatment, participants recommended therapy by phone or telehealth. Telehealth-delivered substance use interventions are generally shown to be effective alternatives to in-person treatment, although further research on this topic is needed [24]. Finally, participants indicated that pediatric populations are particularly challenged in accessing SUD resources.

Participant recommendations inform education and training for peers, screening patients to determine whether they have trusted primary care, and their willingness to pursue SUD resources. Key patterns mentioned across settings include stigma, judgment, and internal tension about prescribing or referring. Patient–provider interaction recommendations included creating a safe space for patients by sitting at their level, not interrupting, withholding judgment, thanking patients for their honesty, and treating patients humanely. Participants recommended updating didactics for trainees to include screening patients for SDH. Participants also acknowledged stigma and bias that other providers can hold against the OUD population and the detrimental effect this can have on learners' perspectives. Many of these recommendations align with those reported by ED patients with OUD; patients have described experiencing stigma in the ED, indicating a desire to be treated with respect and for their autonomy to be recognized [25]. To accomplish these goals, however, requires a significant level of emotional and relational labor across care settings to build rapport, create safe environments, manage patient trust, and minimize compassion fatigue.

EMS workers are important partners in addressing the opioid crisis. More research is needed in the prehospital setting to characterize the challenges of EMS providers. EMS providers would benefit from expanded clinical training to effectively respond to psychiatric calls and drug overdoses [26]. This is consistent with EM participants' perspectives on challenges with psychiatric conditions of the patients, dual diagnoses, and the safety of the EMS crew. Federal initiatives acknowledge the role of EMS, but more research is needed on their lived experience in responding to the opioid crisis.

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Strengths and Limitations

Although our findings may be limited by state-specific laws, a small sample size, and the local, single-site setting, there was surprising consistency between the views of our participants and those in another study, enhancing trustworthiness and suggesting transferability of findings to similar contexts. Specifically, findings are consistent with those from a study conducted in New Hampshire, which recommended naloxone prescriptions to those presenting with an overdose, 24-hour on-call recovery coaches, providing resources, and supporting needle syringe programs and prevention programs to address pain [13]. Still, given the limited sample size, findings should be considered exploratory. Selection bias was not present in this study, as all participants who were approached agreed to participate. Confirmability of coding was mitigated given the author conducting interviews did not also code the data and was tested with Kappa statistics. Findings represent an in-depth analysis of EM physicians' lived experiences, although the sample size was small and limited to a single site, participants' experience working in previous settings enriched the breadth of their knowledge and perspectives.

Conclusions

Prior studies have examined barriers within a single clinical environment and focused on prescribing; this study provides a rare cross-setting analysis of EM physicians' perspectives on the opioid crisis, including the home setting, EMS, ED (including pain management and predischarge coordination), outpatient resources, and external partnerships. This study provides an opportunity to hear directly from EM physicians about the challenges they face as frontline workers to the opioid crisis and offers actionable recommendations. Findings reveal system-level constraints, emotional and cognitive burdens, stigma, judgment, and the need for additional training and resources for the providers themselves. Organizing findings as a SIM map summarizes and disseminates information into a useful visual to facilitate actionable discussion with stakeholders about the end-to-end care coordination pathway and the barriers to recovery.

Data Availability

The datasets generated or analyzed during this study are not publicly available due to the risk of reidentification.

Conflicts of Interest

None declared.

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Abbreviations

ED: emergency department
EM: emergency medicine
EMS: emergency medical services
EPICC: Engaging Patients in Care Coordination
MAT: medication-assisted treatment
MHA: Missouri Hospital Association
OUD: opioid use disorder
PDMP: prescription drug monitoring program
SDH: social determinants of health
SIM: sequential intercept model
SUD: substance use disorder

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Exploring the Barriers and Opportunities for a More Predictive Data-Driven Telecare Service: Qualitative Study in Scotland

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Abstract

Background: Telecare uses technology to help people live more independently at home. When an adverse event (such as someone falling or a bath overflowing) happens, the technology reactively senses this and alerts a call center to respond. If the technology can detect a person's current (and past) states and behaviors, with machine learning, we can more proactively identify potential risks before an adverse event occurs and intervene. Despite social care organizations being data-rich, few predictive analytics are currently routinely applied. There is a need to understand current data management practices before optimizing organizational and technical readiness for proactive data-driven telecare services.

Objective: The aim of this study was to understand how specific telecare data (monitoring falls, identifying people at risk of falling, and providing services in response) are collected, managed, and used in the largest health and social care region in Scotland. The objectives were to: (1) map the community alarm data flow to understand what data were being collected, by what services, and where it was stored, linked, and managed; and (2) identify the current barriers and opportunities around staff and organizations using or applying predictive analytics routinely within telecare service provision.

Methods: This qualitative study involved interviews with health and social care professionals working in Glasgow City Council (GCC) and a telecare service provider (Tunstall). Interviews explored experiences of the systems and data access, processes for collecting and using the data, and how it might be better used to target services more proactively. Data underwent a thematic framework analysis. Descriptions of the data flow were used to develop visual representations of the sociotechnical system.

Results: A total of 14 participants at operational and managerial levels took part. A complex sociotechnical telecare system was identified, involving multiple staff roles, with data exchanged across 11 teams, using 17 systems, with 4 distinct data sources. In total, four themes highlighted key challenges that are: (1) suboptimal systems and equipment; (2) data recording inefficiencies and use; (3) specific patient population barriers and IT literacy; and (4) limited resources and support. Opportunities for more predictive telecare included: establishing a more structured and integrated approach to data management; scope for improved data organization and retrieval; better cross-platform integration and data sharing; and the use of tools or models to support insightful data analysis tailored to the users.

Conclusions: Scottish telecare data services require improved infrastructure to be managed in ways that support more predictive telecare services. This includes more structured and linked datasets and greater integration between the services and systems to allow service providers more integrated, up-to-date, and real-time connected data to build accurate and meaningful models.

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KEYWORDS

telecare; telehealth; data analytics; predictive models; preventative care

Introduction

Technology-enabled care at home services (known as telecare in the United Kingdom) collect behavioral and environmental data from sensors within a person's home or on the person to: (1) monitor and act to provide a safe environment (eg, community alarms, door alarms to signal wandering risk, and sensors to prevent flooding a bathroom), (2) provide reminders to do something or take action (eg, stand up and take medication), (3) or to look after the home and more [1]. Telecare has long been considered a means of supporting aging populations to maintain independence within their own home [2]. In Scotland, in 2021‐2022, there were an estimated 128,795 people (approximately 1 in 42 people) who used a

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telecare service or community alarm [3], and 1.8 million people across the United Kingdom accessed telecare [4]. The ability to capture data from devices such as sensors and fall detectors allows for the possibility to monitor both behaviors and outcomes in citizens, and even to predict and prevent negative outcomes, such as falls [5]. This can lead to savings in resources (eg, reduce hospital admissions or ambulance call-outs), reduced carer burden (providing more reliable remote support and reassurance services for family members), and improved citizen well-being and quality of life (allowing people to feel safe, more independent in their own homes [6], and allowing them to live longer in those homes, supported by technology [6,7]).

There is a growing need from service providers and policymakers in health and care globally to use bigger data from more diverse data streams, including from citizens, wearable and mobile technologies, as well as existing routinely collected datasets in health and care [8]. Analysis of these data through the advancement of artificial intelligence (AI) capability could lead to more predictive and proactive models for home care [2] and may have an impact on patient safety and well-being [9]. Within Scotland, for example (the context for this study), the Scottish Government has committed to transitioning the estimated 170,000 citizens in receipt of telecare to a digital service, with a view to improved access to data, future-proofing care, and helping prevent unnecessary and costly hospital admissions [10]. As part of this, telecare manufacturers are working with health and social care partnerships (HSCPs) to collate bigger and better datasets on service users to provide more preventative, rather than reactive, models of care.

Despite the promise AI and machine learning hold within this context, very little predictive analytics have been conducted in the home care setting, as reported by a review by Anderson et al [11]. The review showed much of the research to date has been small-scale and lacking proactive or predictive techniques, instead using simple models of categorizing behaviors, diagnosis of conditions being present or not, or simple anomaly detection (an adverse or undesired event occurring that should be reacted to). To progress the analytic capabilities in this domain of social care and telecare specifically, better understanding is needed of how social care and telecare data are currently being collected and managed, and also to identify how "ready" health and social care organizations are to use these data to build more predictive systems if any of the cost savings and benefits are to be more widely realized.

There are many use cases in telecare and social care more generally, such as predicting the likelihood of, and outcomes from, falls, which was the key use case for this study. Therefore, the aim of this qualitative, explorative study was to understand how data are collected and managed in the largest HSCP in Scotland. The study objectives were to: (1) map the community alarm data flow in that local context to understand the complexity of the different telecare datasets, and how data were transferred, stored, linked, and managed; and (2) identify the current barriers and opportunities around staff and organizations applying predictive analytics in their day-to-day roles within telecare service provision. The research questions are: how are community alarm data collected, managed, and then used within the Glasgow HSCP (data mapping and interviews); and what are the barriers and opportunities around staff and organizations applying predictive analytics within the telecare service in Glasgow HSCP (interviews)?

Methods

This qualitative study involved interviews with professionals working in the largest HSCP in Scotland (Glasgow City Council [GCC]) and a leading telecare service provider (Tunstall).

Research Materials

A semistructured interview schedule was developed independently by the research team (Multimedia Appendix 1) and underwent face-validity checking by 2 members of the GCC HSPC team. The schedule included questions covering participants' experiences of the systems and processes in place for collecting and using telecare data, what data they access, and how data can be better used to help them meet service user and organizational needs. We based our interview schedule on the People, Processes, Technology Framework because we were interested in staff roles and capabilities, the processes and systems for collecting, managing, and using data, and the data and the systems used to manage the data. A participant information sheet (PIS), consent, and demographics forms were developed and hosted online using Qualtrics.

Recruitment

A purposive sample of eligible participants (n=17) was identified by a member of the project team from GCC HSCP to represent the breadth of staff who might be directly interested in, or working with community and falls alarm data from across their organization and their commercial provider Tunstall. Potential participants included operational staff, including locality or referrer staff, and managerial staff, including senior management. Individuals were contacted by a GCC project team member to invite them to participate. Interested participants were contacted by a researcher via email to arrange an interview. Given the niche nature of the interview criteria seeking people working in specific roles, in a specific organization, stakeholders from GCC provided names and contact details of potential participants. The inclusion criteria were any staff member who was directly involved in, or interested in more predictive analytics usage within the telecare service, or works directly with the data (either collecting it, managing it, or acting on it to improve services). This form of sampling was deemed the most effective method. To counter any risks of bias or influence, GCC were not informed of who accepted or declined participation, nor were they involved in conducting the interviews. Participants were also assured that all comments would be anonymized and that the research team was seeking honest criticism to improve the service. A total of 17 participants were invited by the research team to take part. Of these, 2 did not respond and 1 withdrew with no stated reason, leaving 14 participants to take part in the study.

Data Collection

Once potential participants had read the online PIS and completed the consent and demographics, one-to-one semistructured interviews were conducted between August and October 2022. Interviews were conducted by a research team

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independent from GCC and Tunstall. Interviews lasted between 17 and 47 minutes and were conducted remotely using Microsoft Teams, Zoom (Zoom Communications), or telephone. Interviews were recorded via the participant's preferred platform or with a dictaphone. Participants who could not attend an interview could respond via an online questionnaire using Qualtrics which posed the same questions used during the interview with free-text response options for participants to complete. Participants were offered a copy of the interview schedule before the interview.

Data Analysis

All interviews were transcribed using an intelligent verbatim approach, using the automatic transcription on the online platform used and edited for accuracy. Free-text data from the interviews and questionnaires were combined into a single dataset and analyzed alongside the interview transcriptions by the research team, independent from the vendors (GCC). GCC did not have access to any data and were not involved in the analysis or interpretation of any data.

Development of Sociotechnical Map

Data from the interviews pertaining to the data handling and flow process, including people and systems involved, were used to develop a data flow diagram of the sociotechnical system (by DK), which was initially based on an early process diagram of the telecare system provided by the principal officer at GCC HSCP. This map was then reviewed internally by the research team continuously (DK, ML, ED, and KK) before being validated for accuracy by 3 GCC stakeholders. Data were also used to develop a comprehensive description of staff roles, systems involved, the range of service user equipment, and the data used within the sociotechnical system.

Thematic Analysis of Barriers and Facilitators

All data were analyzed inductively using Braun and Clarke's thematic analysis procedure [12] supported by the NVivo (Lumivero) analysis software, focusing on the identification of barriers and facilitators to the data handling process. Transcripts were examined for key themes and coded with labels that were then developed further by DK, ED, NW, and ML into a codebook over 3 iterations until a final codebook was agreed. This codebook was then used for validation, with 30% of the transcripts independently coded by 1 researcher (DK) plus 2 others (NW and ED), who then met and compared coding. Agreeability was high enough that the remaining transcripts were coded by 1 researcher (DK), who used the results to develop the thematic map (Multimedia Appendix 2). Data analysis occurred between November 2022 and January 2023.

Ethical Considerations

This study was granted ethical approval by the University of Strathclyde Ethics Committee (ID 1937; approved on July 20, 2022). Participants provided informed consent at each stage of the study after reading the relevant PIS and signing a consent form, based on the University of Strathclyde's standard template. The PIS and consent forms informed participants that their participation was voluntary, that their data would be anonymized, and that they would remain anonymous in the reporting of the research. Participants were informed about their freedom to refuse or withdraw their participation. Participants did not receive any compensation for taking part in the study. The Consolidated Criteria for Reporting Qualitative Research (COREQ) guidance was followed for our reporting of this study (Checklist 1).

Results

Participants

In total, 14 people participated; 12 (85.7%) people by interview and 2 (14.3%) people by questionnaire. Most were female (n=8, 57%) and aged between 28 and 66 years. The median age was 47 (IQR 42.75 - 56.25) years. Most worked in the GCC HSCP (n=11, 78.6%) and had 0 - 15 years' experience in their role, with a median of 5 (IQR 2.25-12) years' experience (Table 1).

Table . Participant demographics (N=14).

Characteristics	Value
Age (y) median (IQR; range)[a]	47 (42.75 - 56.25; 28-66)
Years' Experience (y) median (IQR; range)	5 (2.25 - 12.0; 0-15)
Gender, n (%)	
Woman	8 (57.1)
Man	6 (42.9)
Job role, n (%)	
Management	6 (42.9)
Operational	7 (50)
Not Stated	1 (7.1)

[a] N=2 participants did not disclose their age

Sociotechnical Map

Figure S1 in Multimedia Appendix 3 illustrates the full complexity of the telecare services system explored in this study, as described by participants. As illustrated in Figure S2 in Multimedia Appendix 3, data are frequently being passed between various teams (4 internal teams and 5 external teams). This typically results in the alarm service team being a

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chokepoint for data, often relaying data between systems and teams, as not all teams will have direct access to the necessary information within all systems. As illustrated in Figure S3 in Multimedia Appendix 3, most of the data are concentrated in the Care First system, which is populated by HSCP Management and used by alarm services. In total, there are 6 primary systems that share data, but these data are not automated and have to be manually updated and maintained by the various teams. This issue is compounded further by the variety and volume of data sources that feed data into these systems, as presented in Figure S4 in Multimedia Appendix 3. This provides an overview of the complexity of the sociotechnical system where many of the barriers arise, but also the opportunities to improve and streamline the data in the future.

Theme 1: Challenges for Predictive Data-Driven Approaches in Telecare

The main challenges reported in this theme are related to suboptimal systems and equipment, inefficient recording and use of data, barriers to inclusive telecare, and limited resources and support for exploiting the data.

Suboptimal Systems and Equipment

In total, 7 participants reported that there was no single standardized process or technology used in telecare, leading to significant regional variation, and there were calls for the development of a minimum dataset which could be used across Scotland (which has since been introduced). Even definitions, such as what is defined as a fall, can vary, making direct comparison between regions difficult, as what one region may record as a fall may not be recorded as such in a different region:

> *I think that platform providers should be using a defined list that should be set by either the Scottish Government, or even the UK governments…if we have these standard criteria that we're all using…we're all comparing like for like. The problem is just now, we're comparing apples, oranges, pears, and grapes…it's like every fruit there.* [Participant A10, Operational Staff]

It was reported that with new technologies and a lack of standardization, platform providers often developed technology that was only functional within single organizational ecosystems, often using stand-alone portals. This meant each technology required its own software, on which staff require specific training on how to use, often with no option to transfer the data out of the system. Participants reported this as particularly problematic, as when technology stops being supported and used, it can mean losing access to all the data contained within that portal, raising significant concerns around what happens when systems and technology are retired:

> *… if you have three different suppliers, you have three different device management portals, which is a lot to manage…what does happen when they update the portal and what happens to the data that's already on there?* [Participant A7, Operational Staff]

There was a perception by participants that the market for telecare devices may have stagnated, with 1 participant stating that the market had not changed for several decades. Systems that were designed for care settings (where staff members were typically on site and could respond quickly), as opposed to a home environment, were still common:

> *There's some real limitations about the devices we got, the devices we got have really haven't changed over the past 30 years and they were actually made to suit in a care homes or residential areas where staff are on site and they could respond to it quickly.* [Participant A3, Managerial Staff]

Inefficient Recording and Use of Data

In total, 7 participants reported that sensor and service user data are currently underused and rarely used proactively. An overreliance on free-text entry and an inability to search or filter data make retrieval difficult when manually generating reports that get used for reporting monthly activity and service user needs. The over usage of free-text entry into records, including making notes intended to be read by other team members, resulted in misunderstanding or misinterpretation of entries. Manually generated reports were described as one of the most labor-intensive and time-consuming tasks by participants, and a lot of important user data regarding service user needs may not be incorporated into monthly reports and key performance indicators (KPIs) due to volume:

> *Basically to do a desktop assessment for everybody that had door lights installed in the last 12 months… I had to go through it, every single call record individually…every time that it alerted the door sensors, I'd need to go in, record the outcome of the call and record… if they'd better management report functions from our data, if you know what I mean, so you can just get in at the top end, get the data you need.* [Participant A5, Operational Staff]

> *There's so much data that's being collected. And then if we can get a better handle and use this data, we can get far more efficient services, especially if we can implement things such as machine learning and AI to automatically analyse. And you'll find patterns and predict what times we need new equipment and that sort of things.* [Participant A1, Operational Staff]

Another concern was related to the lack of interoperability between the different systems in use. Participants reported many independent systems used throughout the telecare service; however, they are not all connected, which leads to inaccuracies and repetition of data. This was reported as particularly difficult in relation to external systems, where there are a lack of any data-sharing agreements:

> *…I think that that [one system] talking to [another system]…so the person doesn't need to give that information three or four different times…all of those services talk to each other. They would have the bigger picture on that person, which would definitely improve the care that that person receives and prevent a lot of people been admitted to hospital when they don't need to be admitted to hospital.* [Participant A7, Operational Staff]

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Staff members not having access to data also affected its use. Participants reported that communication between teams was often superfluous, as staff often had to contact people in different departments to relay necessary information to those who do not have access to certain systems. For example, due to not all staff members having access to all relevant systems, the responder team would need to contact the alarms team to relay details regarding a service user and how to support them during an incident, such as the service users' physical descriptions or impairments, the location of lock boxes containing keys for access, where the service user may have wandered, or when they may have to request details of certain medical requirements or impairments in order to support the service user during a medical incident. This was all done by staff members instead of being able to access that data directly themselves. This type of information can be vital for the responder team to know when dealing with a callout. Many participants had worked in multiple departments over time and referenced missing some of the features and data in systems they had access to in previous roles but could no longer access:

> *…looking at [the main device portal] and we are just telling them this person has a medical history of dementia. They're prone to falls, but if they were able to see that for themselves, I just think it would cut down on a lot of miscommunication…and just time doing these calls back and forth to pass on information because you could pass a job and then you forgot to tell them all you actually need to come back here to get a key to then go back to the job…technology for responders is really critical at the moment. I think we need to get them up to speed and allow them to have access to a lot more .* [Participant A1, Operational Staff]

Barriers to Inclusive Telecare

In total, 2 participants reported issues around some telecare services not reaching certain populations, which may lead to inequalities. One participant surmised there was a lack of uptake for telecare services in one ethnic minority community in the city. However, the lack of data collected on service users' ethnicity means it is not actually possible to accurately compare minority populations' needs with those of the whole community to identify and address any potential inequality:

> *For example, we are confident we see this, there's not a huge uptake in the Asian [population] in the mix, the African population in the city…so that's a challenge.* [Participant A2, Managerial Staff]

The IT literacy of some service users was also a concern, as an over-reliance on new and varied technologies can leave many service users vulnerable if they do not have people to support them with technology. Concerns were reported regarding funding and the cost of procuring and implementing new telecare equipment. Participants worried that increased costs of bespoke technologies could create a 2-tier system, resulting in inequality for service users. Not all service users can afford to have the most up-to-date or relevant technologies as others, possibly resulting in an inequality of care and service:

> *What doesn't work well is the need for IT literacy. At times reliance on new forms of technology…For those with little money or those who are not able to negotiate these systems…it is denied to them…access to a landline is prohibitive financially for many people. Passive technology is less prevalent but essential for those with incapacity who cannot engage in current forms of Telecare in operation.* [Participant C2, Managerial Staff]

Limited Resources and Support

High workload, understaffing, and recruitment problems were all raised by 4 participants as challenges:

> *They are having problems with their support services and they are either understaffed or long term sickness…There's simply too few staff within the service… some of the data that we are pulling off is evidencing that there there's a lack of staffing or short staff-ness that is impacting on the service provision that the providers are actually providing to their service users.* [Participant A9, Managerial Staff]

Furthermore, these participants felt that financial intervention from the government would be vital to continue the provision of telecare services. One particular concern, especially moving from analog to digital, was the lack of existing infrastructure required to support internet-connected devices, with limited support in the community to prioritize updating and replacing this infrastructure. One participant described how some more rural communities cannot always provide the reliable data needed to support internet-enabled devices. Older networks would still be relied upon, likely to be decommissioned soon, severely diminishing reliability, as companies may pull support for the equipment:

> *In some of our, particularly, tenement flats in Glasgow, actually getting a signal with that SIM service or whatnot through some of that thick sandstone is an issue in itself. It's issues that we're grappling with in terms of how we ensure that those who want the service can get it and get it in a reliable fashion.* [Participant A4, Managerial Staff]

> *I would also say that others have struggled with it…We did look at the Highland Project and model and it took a lot of investment, but the public didn't particularly like it. So we've got to change hearts and minds as well as this technology about what the role technology can play.* [Participant A2, Managerial Staff]

Additionally, the nonemergency use of alarms by service users affected workload, where incidents would be better dealt with by a different provider, was another issue reported by participants. One participant estimated that approximately 30% of service users may frequently trigger such alarms:

> *Now, that might be 'can you phone my son, can you phone my daughter?' That sort of thing. It might be that there's a medical emergency. It might be that they need a responder callout. It might be that they*

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just need a joiner or something like that. [Participant A10, Operational Staff]

Theme 2: Data Potential – Opportunities to Enable More Proactive Predictive Telecare Services in the Future

Several opportunities were identified in the analysis, which could help alleviate the challenges raised (refer to Theme 1): more efficient data organization and retrieval, integrated systems that share data across the service, and predictive and proactive data analysis tools.

More Efficient Data Organization and Retrieval

In total, 5 participants reported that exporting data on telecare service users into a usable format can be time-consuming. Participants suggested that data could be filtered and more easily searched if it were formatted in a more standardized way to allow for more granularity, with certain key details (such as impairments, descriptions, and particulars about a service user) separated into defined categories. Data filtering would also enable search and retrieval, allowing staff to quickly configure what is displayed, giving access to the most salient information needed. This would also allow the automatic generation of reports, but to achieve this, data standardization and adherence to data governance are required:

> *…say somebody had mental health issues. And they were kind of feeling a bit down and we get specialist mental health teams, is there a way that that person recording that data, if they agreed to it and then that getting filtered amongst the team…and then they could be some sort of follow up at the local level whether could be some sort of triage and things like that.* [Participant A5, Operational Staff]

Integrated Systems That Share Data Across the Service

In total, 7 participants reported that various pieces of information about service users and their access to different telecare and social care services were recorded in a variety of different systems, resulting in staff searching across different systems to try to get the full picture of a service user and their needs, often manually. For example, when a service user is assessed by a member of staff, or if they fall, an ambulance is called, or if they are admitted to hospital, all of this is recorded, but not necessarily in all the relevant systems. Participants reported that it is very difficult to track what happens to a service user over time across different services as a result. Participants commented that a person's Community Health Index (CHI) number (the unique health identifier all citizens have in Scotland) could be more consistently used across the various systems to enable data linkage between systems, which would result in better modeling of that service user's health and service use journey:

> *If you had that data and it was really good data…you would then inform at a national level with a business case, but what we have right now in Scotland is 32 different services…Having that where you could standardize a telecare service? And have all that data, all in the one place…some of that service that we all deliver in the same way. That would just be ideal.* [Participant A7, Operational Staff]

Furthermore, by leveraging the popularity of current technological products that some service users already have access to (eg, fitness trackers and cloud-based virtual assistants), participants felt that more diverse datasets could be explored alongside those already in use and built into future predictive models:

> *Somebody I think is far more likely than pre-pandemic to now have a smart speaker in their home to be able to connect with family and potential carers through that. I think that's one of the avenues we can leverage in the future to make telecare as a concept perhaps more palatable to service users who would be I guess more traditionally resistant to have it, not imposed on them, but the fact that they have to have a box in their home which is a signal that they are declining in health, as opposed to having an already existing technology which can be purposed to provide a telecare service.* [Participant A4, Managerial Staff]

> *As a much more a commercial offering for families who don't really need a community alarm service direct, so actively encourage them to think about the Alexa…how you can integrate technology. It's now very well used in homes to actually do the same thing.* [Participant A2, Managerial Staff]

Predictive and Proactive Data Analysis Tools

One of the most called-for changes from participants (n=7) was the ability to proactively use data for service planning. The telecare service was frequently described as reactive by participants, with a focus on *"crisis management"* [Participant A3, Managerial Staff]. Data on service users' needs across their lifespan (including their equipment and service use and needs) were seen as vital for staff members to make decisions on their care in a more proactive and personalized way. Although these data are technically available, staff must manually trawl through multiple disconnected systems, reports, and plain text fields, which is slow and lacks ambition. By making data easier to categorize and access, many processes, such as generating reports, can be streamlined or automated. With the use of predictive models, these data can be better used to identify and predict service users' needs, so resources can be focused where they are needed most:

> *We've moved away from any preventative…services now to very much crisis management. What happens now, how do we react to it…And this is a major weakness…quite often we get telecare referrals where the person is actually that close to going into care…* [Participant A3, Managerial Staff]

> *[One service user] ended up actually having some falls that the telecare service wasn't able to prevent because it was reliant on her being able to push this pendant…Currently, we don't know somebody has fallen until they push the button. I think that there is a lot of scope in how we use data in an anticipatory*

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fashion to enhance someone's care and linking that to services... [Participant A4, Managerial Staff]

Discussion

Principal Findings

This study sought to explore a real-world telecare service by mapping the sociotechnical system and exploring the barriers and opportunities to make this service more data-driven and proactive. This was conducted qualitatively (interviews, questionnaires, and systems mapping) with 14 participants from the largest HSCP in Scotland (Glasgow City, GCC). A complex sociotechnical telecare system emerged from the study, comprising diverse staff roles, service users, multiple data systems, and equipment. Key challenges to implementing predictive telecare included: suboptimal systems and equipment, underused data, barriers to inclusivity affecting specific populations and those with limited IT literacy, and constrained resources and support for being data analytics active or ready. Participants also identified substantial opportunities to advance predictive telecare through a more structured and integrated approach to data management, including enhanced data organization and retrieval, improved cross-platform interoperability, and the application of predictive analytical tools tailored to service user needs.

While technology is widely and routinely used throughout the telecare service, the entire system requires a more joined-up and organized way to manage and use the diverse and distributed data within and across organizations, which can be organizationally challenging. This has also been identified with home care data in Canadian systems [13]. Automation is limited within telecare currently, with most processes relying heavily on staff performing manual activities, such as writing case notes, updating and checking files, and cross-checking data from multiple different interactions with the service users at different points in time. The current system requires significant collaboration and communication between staff working across different departments, especially when systems are not accessible to all. One study in the Netherlands exploring social care data use identified high variation between regions in the social care data, data infrastructure, and processing of data, echoing the results of this Scotland-based study [14]. There is growing recognition that the design of social care and telecare data management systems needs to improve and could be optimized with the aid of more careful consideration of Human Factors [9,15,16]. Human Factors takes a systems approach to understanding and designing health and social care, and this can help to identify where data management changes need to be made.

Data linkage is an important factor in ensuring telecare data can be used to predict adverse events and link them to health outcomes (which are not always recorded in telecare datasets). This could result in models built to flag service users' risk factors, as well as the resource implications for different people with different levels of telecare equipment and services. A review by de Bell et al [17] identified that effective data sharing is reliant on several factors, including goal setting, interprofessional relationships, having a policy context to develop a shared vision of care, using technology as a tool for sharing data (not as an all-encompassing solution), and data users having full awareness of the various systems used. Given there is evidence to suggest that both professionals and citizens believe that their health and social care data should be shared between relevant settings for direct care purposes [18], it is recommended that HSCPs develop joint data-sharing agreements to link health and social care data. This could result in health outcomes and cost savings of telecare services being better demonstrated. However, evidence suggests that issues, such as privacy and confidentiality, appropriate use of data, sharing with relevant organizations (eg, not private companies), and unintended consequences of data-sharing (eg, raised insurance costs if other organizations find out about a health condition), are concerns of service users and patients [18], which would need to be considered in the development of data-sharing agreements.

The telecare devices of the future promise to offer more ways to actively monitor service users and their homes, as well as new ways of interacting with the systems (eg, voice and cloud-based virtual assistants) [19]. With more advanced sensing technology and interaction devices, the amount and diversity of data have the potential to increase. The ability to capture more about a person's activity, mood, sleep, diet, and exercise, as well as environmental data (eg, room temperature and time of day) and use this data to predict how well a person is and how likely they are to experience an adverse event may occur [20]. Predicting the likelihood of those events presents the possibility of building models to intervene before they happen. Steps could then be taken to avoid these events and provide services in time to minimize possible negative outcomes (eg, being injured or hospitalized).

As we move forward into a fully digital telecare service within this Scottish setting [21], it is critical that efforts are made to future-proof the data collection and management systems to make them analytics-ready. Incomplete or unstructured data can hinder the development of statistical or machine models, which can enable more preventative and predictive models of care [22,23]. A key area for consideration is the development of templates and protocols for structuring datasets to make them robust and complete, resulting in the input and outcome variables being easily identified and used in machine modeling [24]. Relevant multistakeholder training will be required to ensure that all partnership organizations agree on a minimum dataset, allowing for national consistency yet allowing room for appropriate regional variation. Without this training, the risk of inaccurate and incomplete data coding is high, possibly leading to misinterpretation of data items and data meaning. Furthermore, lack of awareness of the importance and benefits of a more consistent approach to data recording and use to the service and care that service users receive is also a risk [25].

The next steps to progress this work would require further stakeholder engagement to translate the findings into a more concrete staged roadmap, including, for example, interoperability pilots and longer-term predictive pilots both with GCC and through reaching out further to other HSPCs nationally. This might include (1) developing standardized telecare minimum datasets and promoting their utility to

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encourage return of such benchmarking data; (2) encouraging HSPCs to create better linkage between different systems that store different data that when linked could reveal predictive opportunities; (3) upskill staff on data linkage, data management, and analytics capabilities; and (4) creating usable dashboards that different levels of staff can use to generate queries and interrogate telecare data. While this study focused on falls and community alarm data, there are other use cases in telecare for more predictive services that could learn from this work, such as predicting hospital readmissions and medication adherence.

Strengths and Limitations

One of the strengths of this study is that it contributes to the distinct lack of research on the sociotechnical aspects of data prepared for future use within social care and, more specifically, telecare services. Machine learning and AI are increasingly being explored in health care settings, but data-driven social care has until now been relatively unexplored. The data collected during this study were incredibly rich, providing quality as well as a range of insights from professionals from different staff groups and with many years of experience in a field that is underrepresented in the published literature. The main limitation was that participants were sampled from only 1 geographical area in Scotland and were selected purposively by GCC based on their role, which might have led to some bias in the sample (eg, participants may have wished to present themselves or their organizations positively throughout the interviews). However, given that the interviewer had no previous relationship with the participants and did not work in this respective field, this minimizes the risk of this, and participants were explicitly informed that all comments would be anonymized and their participation would be confidential. Furthermore, the region sampled was the largest in the country. Given that participants reported huge variation in how telecare services are run and how data are collected, it would be beneficial to collect data from participants across Scotland to corroborate and add to these accounts. Finally, we did not include service users themselves as participants in this study, as the aim was to explore professionals' perspectives. This is also a rich area for future work that should be explored.

Conclusions

This study explored telecare professionals' perspectives and experiences of the data collected and used in one telecare community alarm service in Scotland. The sociotechnical system map showed that the telecare service is complex. Like other research findings, there are many separate systems for storing data about service users and their use. The data are often incomplete, disconnected, and underused, especially in relation to more predictive analytics. Future research should continue to explore the challenges and opportunities relating to data analytics readiness within telecare services at a larger, more national scale and identify ways to make organizations and systems more analytics-ready in the future. They should also strive to improve linking social care datasets with health outcome datasets to more fully realize the benefits of more predictive and proactive telecare services in Scotland, the United Kingdom, and beyond.

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Data Availability

The participants of this study did not give written consent for their data to be shared publicly, so due to the potentially sensitive nature of the research, supporting raw data is not available. Themes will be deposited in PURE (University of Strathclyde's Data Repository).

Authors' Contributions

Conceptualization: ML (lead), NW, ED, KK, and MR
Data curation: DK
Formal analysis: DK
Funding acquisition: ML
Investigation: DK
Methodology: ML, ED, and NW
Project Administration: ML (lead), DK (supporting)
Supervision: ML, ED, and NW
Validation: ED and NW
Visualization: DK
Writing-original draft: NW, ED, DK, and ML

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Writing-review and editing: NW, DK, ML, ED, KK, and MR

Conflicts of Interest

None declared.

Multimedia Appendix 1
Interview schedule.
[DOCX File, 25 KB - formative_v10i1e85056_app1.docx]

Multimedia Appendix 2
Themes diagram.
[DOCX File, 991 KB - formative_v10i1e85056_app2.docx]

Multimedia Appendix 3
Theme 1: the sociotechnical system map and tables.
[DOCX File, 985 KB - formative_v10i1e85056_app3.docx]

Checklist 1
COREQ checklist.
[DOCX File, 38 KB - formative_v10i1e85056_app4.docx]

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Abbreviations

AI: artificial intelligence
CHI: Community Health Index number
COREQ: Consolidated Criteria for Reporting Qualitative Research
GCC: Glasgow City Council
HSCP: health and social care partnership
IQR: Interquartile Range
KPI: Key Performance Indicators
PIS: participant information sheet

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Original Paper

Sustaining a Promising Clinical Practice in High-Turnover Rural Environments Through the Geriatric Referral Navigator Role: Qualitative Case Study

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Abstract

Background: Sustaining evidence-based health care programs is challenging, especially in clinical settings with high staff turnover. GRECC Connect is an evidence-based telemedicine service that provides geriatric specialty care to rural patients through a hub-and-spoke model between US Department of Veterans Affairs medical center “hubs” and community-based outpatient clinic (CBOC) “spokes.” Four geographically diverse GRECC Connect hub sites (of 19 total) volunteered to implement a “geriatric referral navigator” role to address the challenge of sustaining use of this program in rural CBOCs.

Objective: This study aimed to understand how a health care program such as GRECC Connect can design and implement a navigator role to sustain use of its services.

Methods: We conducted a longitudinal qualitative study using a case study approach. Participants were GRECC Connect hub site staff, including program directors, coordinators, and analysts from a range of disciplines, including clinical pharmacists, geriatricians, and social workers. Over one year, we conducted 31 qualitative interviews (5 to 9 “periodic reflection” meetings and 2 semistructured interviews at each of the 4 sites) focused on key tasks, skills, and characteristics of the geriatric referral navigator role along with perceptions about the role’s value. Each of the group interviews involved 2 to 4 staff members (N=10). We conducted directed content analysis using a rapid analytic approach and then shared deidentified preliminary findings at a national GRECC Connect online meeting where staff from all 19 hub sites (n=40) reflected on the role. We summarized and compared the perspectives shared during that meeting with the data we collected and analyzed from the 4 participating hub sites.

Results: Key navigator tasks included building relationships, providing education, monitoring and troubleshooting logistical and technological issues within and across CBOCs, and evaluating the appropriateness of referrals. While professional backgrounds varied, navigator traits deemed essential for success included being flexible, creative, and a problem solver with deep institutional

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knowledge. The time needed to conduct navigator tasks—between 15% and 70% of the time required of a full-time employee—was substantial. The navigator role resembles several roles described in the literature that are meant to support program implementation and service use, including internal champions, external facilitators, and clinical navigators. Navigator tasks reflected a combination of known "semivisible" implementation strategies that hub site staff considered necessary not only for *initially* implementing the program but also for *sustaining* use of GRECC Connect in rural clinical environments with high staff turnover.

Conclusions: The geriatric referral navigator role encompasses a broad array of recognized implementation strategies. It is critical to invest in supporting the types of tasks and strategies implemented by the geriatric referral navigator to maintain promising practices over time, where appropriate, to avoid the costs and burdens of implementing new, similar programs in the future.

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KEYWORDS

sustainment strategies; navigators; access; telemedicine; rural

Introduction

Implementation science literature describes numerous strategies to spread and, to a lesser extent, sustain use of evidence-based programs in clinical settings, such as the use of internal champions and external facilitators and the development and distribution of educational materials to support awareness and knowledge of programs [1-4]. However, many promising programs created to address challenges in the health care system are not sustained [5-8]. Inadequate staffing has been identified as a key challenge to achieving sustainment [8-10], which is defined by Shelton et al [11] as "the continued use of program components at sufficient intensity for the sustained achievement of desirable program goals and population outcomes." There is a call to describe approaches used to achieve sustainment in general [12], and given that the health care system in the United States is currently experiencing a protracted period of staff shortages and turnover since the start of the COVID-19 pandemic [13], there is a distinct need for approaches to support sustainment in environments with unstable staffing.

Programs implemented within the context of the US Department of Veterans Affairs (VA) rural community-based outpatient clinics (CBOCs) are particularly vulnerable to sustainment challenges posed by unstable staffing [14]. The VA's integrated health care system—the Veterans Health Administration—mandates access to care for all enrolled veterans. A large and growing proportion of the VA's patient population are older and live in rural areas [15]. Thus, the VA has developed an extensive network of CBOCs and numerous virtual and in-person programs and services to care for this population, only a few of which are on-site at the rural clinics [14,16]. CBOCs are, by definition, generally located in resource-poor areas and often struggle with high staff turnover [14,16]. Rural clinicians, many new at the clinics, find themselves in the position of being the critical link between patients and the myriad off-site services available to them through referrals [14]. Among these services is GRECC Connect, a promising practice that provides virtual geriatric specialty care to rural older adults.

GRECC Connect is a VA Office of Rural Health–funded program developed in 2014 to address the challenge of providing specialty care to older, rural veterans. GRECC Connect uses a telehealth hub-and-spoke model that provides rural patients with access to multidisciplinary geriatrics teams in larger "hub site" medical centers [17-19]. CBOC primary care providers make referrals to GRECC Connect for their older, medically complex patients. The patients, and caregivers as needed, can participate in virtual visits from a specially equipped room in the CBOC via a clinical video telehealth platform or from their home via the VA Video Connect app. While rural CBOC staff, patients, and caregivers value the service [14,20], maintaining awareness, knowledge, and consistent use of the program by its target audience can be incredibly challenging, especially given the high staff turnover in this setting and that several different geriatric consultative services may be available.

To address these challenges, as part of a pilot project, 4 GRECC Connect hub sites implemented a "geriatric referral navigator" role to maintain CBOC staff's use of GRECC Connect services and improve the appropriateness of referrals received from CBOCs. Given the unique context of VA outpatient clinics, GRECC Connect leadership predetermined that part of the role would involve assisting CBOC clinicians in navigating the complexity of referral options for rural patients. However, each hub site had flexibility to define other aspects of this role and associated strategies aimed at sustaining use of GRECC Connect services within the context of their individual sites. We used a case study approach to understand how a health care program such as GRECC Connect can design and implement a navigator role to promote sustained use of its services.

Methods

Study Design

We conducted a longitudinal qualitative study using a case study approach.

Study Team

The overall evaluation team was called the Qualitative Evaluation Core (QualEC) and consisted of 8 VA researchers with expertise in program evaluation, qualitative methods, implementation science, and geriatric medicine. The subgroup of this team that conducted interviews was led by an anthropologist (ED) with more than 25 years of experience leading qualitative research and evaluation studies and included health service researchers with substantial experience in public health and qualitative methods (LMK, LAG, and JR). The entire QualEC team guided the study design and contributed to the interpretation of the findings.

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Setting and Recruitment

In the spring of 2021, we discussed the geriatric referral navigator role during a national GRECC Connect "all-site monthly forum" online meeting with team members from all 19 hub sites in attendance and asked for volunteers to implement the role at their hub site. We then invited the clinical leads of 4 hub sites to participate in this project based on their expressed interest in implementing the navigator role, the availability of a person able to serve in the role, and the geographic diversity of their sites. All GRECC Connect hub sites work with CBOCs whose patient population is more than 50% rural or highly rural.

Participants

All GRECC Connect staff from the 4 participating hub sites, including individuals filling the geriatric referral navigator role, were invited via email to participate in group interviews and periodic reflections. The data collection activities were scheduled for times when all members of the team were available to make participation more feasible.

Data Collection

We met virtually via Microsoft Teams with each of the 4 hub site teams for an initial interview to discuss their vision for the "geriatric referral navigator" role (hereafter referred to as the "navigator role"). We continued to meet with the hub site teams every month or two over the course of the pilot year to collect "periodic reflections" [21]. Periodic reflections are a set of structured questions that ask participants to reflect on an implementation process at numerous time points throughout a project. This method enabled us to capture detailed information about participants' changing perspectives, decision-making processes, and resulting adaptations to the project over time. At each meeting, the hub site teams were asked to discuss and share the data they were collecting and reflect on current pilot program activities, what was working well, what was challenging, changes in implementation plans, and lessons learned. In addition to these periodic reflections, a final interview was conducted with each hub site team during which they shared their perspectives on the navigator role in general, including essential tasks engaged in, necessary skills or characteristics of a successful navigator, the value of the role, and lessons learned for other sites considering having a navigator. All team members were invited to participate together in each of the data collection activities, allowing them to respond to each other's reflections, thereby providing a more comprehensive view of the navigator role. Interviews and periodic reflections were audio recorded on Microsoft Teams and transcribed.

Once the periodic reflection and interview data were analyzed, we shared the deidentified findings with the GRECC Connect national team during an online meeting—the all-site monthly forum—in November 2022 and asked participants to reflect on the tasks and characteristics associated with the role, the time dedicated to it, and value of the role. This activity also provided an opportunity for member checking [22], as all team members from hub sites implementing the navigator role participated in this national meeting. The meeting was conducted and recorded on Microsoft Teams while 2 QualEC team members took notes.

Data Analysis

We conducted a directed content analysis [23] using a rapid analytic approach [24,25] to identify essential navigator tasks, beneficial navigator skills and characteristics, barriers to and facilitators of implementing the navigator role, and the perceived value of the navigator role. These approaches combine rigor with speed and were chosen to allow us to generate credible findings within our project's time frame. We started with a priori coding categories based primarily on topics of interest that were the focus of the interviews and periodic reflections and included the following: description of hub site staff; site context, including patient geographic catchment area (the area for which each hub site is responsible for providing services); key problems to be addressed by implementing the navigator role; description of the navigator role and associated tasks and activities; implementation challenges; and lessons learned. Emergent categories captured additional content relevant to the sites' implementation of the navigator role.

Consistent with a rapid approach, 3 QualEC team members (ED, JR, and LG) reviewed the transcripts and systematically organized the data into 4 structured individual site-level templates—one for each GRECC Connect hub site. The team met regularly to develop consensus about how to organize the interview and periodic reflection content among the categories within the template. We then synthesized the information within each category across the site-level templates using constant comparison to create a robust description of the navigator role and its perceived value for supporting ongoing use of the GRECC Connect services at the targeted CBOCs.

Two members of the QualEC team took detailed notes at the GRECC Connect national all-site monthly forum meeting where we shared our preliminary deidentified findings on the navigator role. We then augmented the notes with quotes from the meeting's Microsoft Teams recording. We summarized and compared the perspectives shared during that meeting with the data we collected and analyzed from the 4 participating hub sites, noting areas of alignment or divergence.

Ethical Considerations

The need for ethics approval was waived by the VA Bedford Healthcare System Institutional Review Board, which determined this program evaluation activity to be nonresearch. As a nonresearch activity, formal informed consent was not required; however, participants were informed about the project plans, including that participation was voluntary, they could opt out of being recorded, and all data collected would be deidentified for publication purposes. Under VA policy, no compensation is provided to VA staff for their participation in interviews.

Results

Hub Site Characteristics

Each hub site's catchment area differed in size, terrain, and weather conditions, which may exacerbate health care access issues. Some hub sites worked with patients across state lines, complicating service provision. The number of CBOCs affiliated with each hub site ranged from 6 to 15, and the subset of CBOCs

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initially working with each navigator ranged from 2 to 5 (Figure 1).

Figure 1. Geriatric Referral Navigator Role cross-site summary.

Goal of implementing geriatric referral navigator role: maintain awareness and use of GRECC Connect services and appropriateness of referrals received from CBOCs.

Navigator tasks: identifying CBOC contacts; reaching out to CBOC staff and initiating and maintaining contact with them; organizing and scheduling outreach and education efforts; preparing and facilitating educational presentations and handouts about GRECC Connect services, referral options, and referral processes; responding to questions about placing referrals; rerouting more clinical questions to appropriate hub site clinicians; initiating follow-up after the presentations; updating and streamlining referral template; and tracking/monitoring referrals and CBOC telehealth capacity and troubleshooting logistical and technical issues.

	Site 1	Site 2	Site 3	Site 4
Geographic location	Northeast	Midwest	West	Northwest
Catchment area description	Ranges across 3 states.	Ranges across 2 states.	Extensive and quite rural covering 4 states. The terrain, weather, and long distances make travel challenging for patients.	Covers a large population with some extremely rural communities within 1 state. Significant geographic features make travel challenging, especially during inclement weather.
Number of CBOCs targeted out of number of CBOCs in catchment area	2/15	2/10	5/11	3/6
Number of staff in the navigator role performing navigator tasks	2	3	2	1
FTE (total) devoted to navigator tasks	20%	15%	70%	50%
Background of navigator(s)	Registered nurse and program coordinator with a nutrition background	Program analyst and social worker and clinical pharmacist	Nurse practitioner and social worker	Project management (PMP) with a research background

Participant Characteristics

In total, 2 to 4 staff members from each of the 4 hub sites participated in interviews and periodic reflections (N=10). Participants included GRECC Connect program directors, coordinators, and analysts from a range of disciplines, including clinical pharmacists, geriatricians, licensed nurses, and social workers. Between June 2021 and September 2022, each site participated in 5 to 9 reflection meetings (total of 23 meetings across all sites) and 2 semistructured interviews (a total of 8 interviews across all sites). Reflections and interviews each lasted approximately 60 minutes.

Navigator Responsibilities

While each hub site was responsible for establishing their own version of the navigator role, they addressed the same barriers:

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CBOCs' limited sustained general awareness of GRECC Connect, unfamiliarity with how to make referrals to GRECC Connect, and lack of consistent champions at the CBOCs. Hub sites varied in their approach and structuring of the navigator role, but their vision for the role was the same: to maintain awareness and use of GRECC Connect services and appropriateness of referrals received from CBOCs. The effort dedicated to navigator role tasks at each hub site varied from 15% to 70% of the time required of a full-time employee, spread across 1 to 3 people.

Participants identified several key tasks performed by the navigators. The navigators spent a significant amount of time building relationships with CBOC staff—from identifying CBOC contacts to initiating and maintaining relationships, in some cases trying to cultivate GRECC Connect champions within each CBOC. They conducted educational presentations to CBOC staff on GRECC Connect referral processes, alternative geriatric referral services, and general geriatric care. Tasks related to the presentations included scheduling, facilitation, and follow-up. Other tasks included monitoring CBOC telehealth capacity, troubleshooting technological and logistical issues, and evaluating the appropriateness and completeness of referrals to identify where more education was needed.

Many of the navigator tasks were meant to address confusion regarding placing geriatric referrals. The need for this work was summed up humorously by one of the navigators as she compared clinicians placing referrals to football players engaging in a desperate effort:

> *[The CBOC clinicians] don't know which [referral they] should be choosing. So, they kind of, I don't know. I don't want to say they throw a Hail Mary, but they kind of pick one and go from there.*

To aid the educational process, navigators developed and distributed decision-making tools. These visual aids were meant to assist clinicians in making decisions about the most appropriate referral options for specific types of older patients. Additionally, they streamlined referral templates and processes, distributed marketing flyers, promoted in-service geriatric education opportunities, and responded to questions about referrals.

Hub sites varied in their implementation of each of these activities. For example, some hub site staff members traveled to the CBOCs to conduct educational presentations, whereas others conducted them over online platforms. Additionally, some navigators focused their outreach work solely on the CBOCs, whereas others also presented information to rural community-based organizations with the goal of spreading awareness of the service to community members who may inquire about it from their VA clinicians. Figure 1 provides a comprehensive cross-site summary.

Characteristics of Successful Navigators

Navigators' professional backgrounds differed across sites, with some having clinical training and others coming from research backgrounds. However, there was a set of personality characteristics that the hub sites deemed essential for the role that all navigators demonstrated. These traits included flexibility, creativity, perseverance, and being personable and a "problem-solver." One navigator described outreach to CBOCs as "a marathon, not a sprint" and went on to say the following:

> *Be diligent and don't give up if they say this is the right person—just wait. I had a spreadsheet of the contacts that I reached out to...the same people via email, via Teams, and via phone leaving messages.... Don't be afraid to ask again. If you don't hear back in a week, 2 weeks, 3 weeks, I just continue to follow up.*

They also demonstrated a social savviness in that they were keenly aware of targeting their messages to CBOC staff of a similar professional background or "level" as themselves and harnessing the help of their hub site colleagues from other health care disciplines as needed. Describing this strategy, one navigator said the following:

> *The telehealth technicians at the CBOCs are a really good way for me to get my foot in the door and then they take it to the supervisory staff and...then we get anywhere from 10 to 50 minutes at a meeting.*

Previous VA experience was also critical as institutional knowledge was needed to successfully help others navigate the VA health care system and services.

Perceived Value of the Role

Regardless of how the navigator role was implemented at each site, staff saw great value in the role because it provided protected time for connecting with rural CBOC staff and clinicians. They noted that most of these tasks had taken place to some extent since the GRECC Connect hub sites were established. However, the tasks had fallen to team members who did not always have the time to complete them as they were additive to their main job. The reality of the CBOC environment, including high staff turnover and a confusing array of referral options, meant that these tasks were never complete; there was an ongoing need to spend substantial amounts of time developing relationships and educating staff on the GRECC Connect service. The purpose of establishing the navigator role was to formalize and highlight this work, to elevate the tasks into a "role" to allow for a more systematic, intentional, and intensive focus on these tasks. Participants across all sites believed that this role, or these tasks spread out among staff members, was critical for sustaining the GRECC Connect service at their site. Uncertainty about consistent hub site staff funding was both a concern and potential barrier to maintaining the navigator role. One navigator reflected on who would do this important work if the navigator role did not exist:

> *I think that anybody on the team having a connection to the CBOC or traveling there or being willing to be humbled and outreach to people or offer services...I think is key. ...making those connections and showing up.... It's just...who has the time and ability to do that?*

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Reflections on Navigator Role From GRECC Connect National All-Site Monthly Forum

In November 2022, at GRECC Connect's national monthly forum, we presented a summary of our findings to all staff, including those from hub sites beyond the 4 participating ones, and asked them to reflect on the geriatric referral navigator role. In total, there were 40 participants representing all 19 GRECC Connect hub sites. Participants' professions included geriatricians, pharmacists, social workers, administrative staff, and data specialists.

The description of the navigator tasks and the characteristics for success strongly resonated with participants. One navigator noted the following:

> *The common theme [the pilot navigators] were talking about is being ready to put on whatever "hat" that you need to and learn about new tasks or fulfill responsibilities.... Really, anything that needs to be done to improve visibility and make sure things work and flow smoothly.... The path isn't always straightforward.*

While almost all hub site staff members participating in the forum endorsed having conducted some of the noted navigator tasks, program coordinators identified the most with the findings. They perceived that a portion of their job, too, was to increase the visibility and reach of the program. This was in addition to the time they spent as program coordinators on administrative reporting duties and connecting with veterans, families, and clinicians; scheduling telehealth appointments; and providing telehealth support before and during visits.

While many navigator tasks were done to some extent by program coordinators and others, the amount of time spent on those tasks was quite different. For example, one navigator noted sending more than 600 emails over the year to 6 CBOCs to create and maintain relationships, schedule educational sessions, and troubleshoot technical issues. Participants noted that all members of hub site staff are allotted insufficient time to create and sustain relationships with CBOCs and that having any member of staff with dedicated time for those tasks can help provide access to services that would otherwise be overlooked. One GRECC Connect hub site director said the following:

> *As others have agreed, this [the geriatric referral navigator tasks] is the glue, right? This is what makes "everything" go.*

Discussion

Principal Findings

GRECC Connect was created to provide needed geriatric specialty care services to rural patients that have limited access to them locally [17]. Within CBOC settings with high levels of staff turnover, maintaining awareness of GRECC Connect and knowledge of how to place a referral has proven challenging and threatens the sustainability of this valuable service. The navigator role was developed to address sustainability barriers faced by GRECC Connect in the rural CBOCs by intentionally carving out protected time for one or more staff members to dedicate to relationship building and education. Participants perceived the navigator tasks to be essential for maintaining the use of GRECC Connect services in dynamic CBOC environments and for ensuring that rural patients who need specialty geriatric care are connected with the right services in a timely manner. However, the time needed to implement these navigator tasks was substantial, and the role was most successful when filled by a uniquely skilled individual.

Geriatric Referral Navigators as Internal Champions and External Facilitators

The tasks performed by GRECC Connect's geriatric referral navigators, including building relationships, providing education, guiding referrals, monitoring CBOC telehealth capacities, and troubleshooting logistical and technological issues within and across CBOCs, are reflected in a combination of similar roles described in literature. The navigator exists in an interesting position in that it is "internal" to the GRECC Connect program (they are part of the GRECC Connect hub site) but "external" to the rural outpatient clinics that are the source of GRECC Connect referrals and, therefore, the focus of the implementation uptake and sustainment activities. The tasks of the role and characteristics associated with a successful navigator reflect this inside and outside position and align with at least 2 different types of implementation strategies—"site champions" and "external facilitators."

Miech et al [26] articulate the key characteristics of champions as "people who (1) are internal to an organization; (2) generally have an intrinsic interest and commitment to implementing a change; (3) work diligently and relentlessly to drive implementation forward, even if those efforts receive no formal recognition or compensation; (4) are enthusiastic, dynamic, energetic, personable, and persistent; and (5) have strength of conviction." Successful champions are also noted to be good communicators, boundary spanners, and skillful at troubleshooting problems and using data to monitor progress, as well as influencing peers as they educate and collaborate with those who are expected to implement the program [26]. These are very similar attributes to traits that were perceived to be essential for successful geriatric referral navigators in our evaluation. Not having consistent champions to work with at the CBOCs is likely a contributing factor as to why the navigators took on this role themselves.

One difference between the navigators and champions is that champions are often frontline employees that can lead by example [27]. Another difference is that this work is the focus of the navigator's role and they are being compensated and recognized for doing these tasks. In that way, they are like another key actor in the implementation "active change process" [28]: the external facilitator.

External facilitators have many of the same characteristics of champions, including good communication skills. Because external facilitators are situated outside of the local implementation context, a large part of their role is to "build relationships across organizational boundaries and levels to create a supportive environment for the program" [29]. Given their outsider role, they usually take on a more systems-level

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approach than site champions, leading and managing processes that affect multiple sites within the system while at the same time helping sites tailor the intervention to fit within their clinic environment [29]. Geriatric referral navigators similarly worked to address some of the more systemic-level challenges they saw arising across multiple CBOC sites, such as helping create easier-to-use referral templates and processes. Their higher-level institutional knowledge also helped them troubleshoot in a way that site champions may not feel they have the knowledge or authority to do, such as when working with telehealth leadership to try to ensure availability of telehealth equipment across CBOCs to support their capacity to engage in these services.

Geriatric Referral Navigators as Clinical or Triage Navigators

The geriatric referral navigator role is also similar to that of patient navigators [30] and clinical navigators [31] in that their goal is to ease the referral process for both clinicians and patients and ensure that patients get to the right services at the right time. While the "patient navigator" role may be more common and familiar, the geriatric referral navigator role is more akin to both "clinical navigators" and "triage navigators" in that it directly supports clinicians navigating the referral landscape. The VA's Referral Coordination Initiative, currently being implemented for some types of specialty care at a select number of sites, is a type of triage navigation strategy that serves clinicians [32,33]. It uses a "nurse-first" approach, meaning that referrals first go to nurses who assess and then triage them to the most appropriate services to ensure that patients receive the right care at the right time. This approach shifts tasks from specialty care clinicians to nurses with the intent of creating a more efficient process.

Navigator Tasks Are Aligned With Consolidated Framework for Implementation Research Constructs and Expert Recommendations for Implementing Change Strategies

The Consolidated Framework for Implementation Research (CFIR) [28] is a well-known implementation science framework that describes 5 domains or constructs that influence program implementation. By combining many of the functions of clinical navigators, internal champions, and external facilitators, geriatric referral navigators address several known barriers to program implementation related to the CFIR constructs of "intervention characteristics," "inner setting," and "outer setting." [28]. Specifically, through their educational efforts that include information on other types of geriatric services, they bolster the perceived "relative advantage" of GRECC Connect. By developing and sharing decision trees and working to simplify referral requirements, they reduce the perceived "complexity" of service use. Through building relationships with local staff and monitoring referrals and technical needs, they align their technical assistance and educational content with "local patient needs and resources." Finally, the ongoing nature of all the navigator tasks helps address challenges related to staff turnover, one of the most significant "structural characteristics" that impede sustainability.

Often discussed alongside the CFIR are the Expert Recommendations for Implementing Change (ERIC) [4] that were developed by a panel of implementation scientists and include 73 strategies for supporting program implementation. Geriatric referral navigator tasks overlap extensively with ERIC strategies related to educational efforts (eg, conducting educational meetings and outreach visits and developing and disseminating educational materials), monitoring (eg, conducting audits, providing feedback, and developing quality monitoring systems), relationship building (eg, building a coalition and identifying champions and early adopters), and external facilitation activities (eg, sharing local knowledge and advocating for a change in equipment and interactive problem-solving) [4]. Furthermore, as noted by Chambers et al [34] in their dynamic sustainability framework, traits identified across the navigators in this case study, including being flexible, creative problem solvers, help the program adapt as needed to support its sustainability over time. Viewed together, this broad expanse of implementation support provided by the geriatric referral navigator may help not only explain but also justify the relatively significant amount of employee effort needed to accomplish the navigator tasks in our case study.

Navigator Tasks and Semivisible Labor

It is notable that many of the tasks that were a core part of the navigator role were recognized by GRECC Connect hub site staff, including physicians, as tasks they often did in addition to their "official" work. They described these tasks, such as "ongoing relationship building," as taking a substantial amount of time, yet they were not necessarily recognized as a part of their job. In this way, these types of tasks could be characterized as "semivisible labor." Semivisible labor is described by Zogas et al [35] as "activities performed by workers that are necessary and that advance an organization's objectives, but which are often overlooked or devalued by employers, consumers, and other workers." Therefore, while critical for maintaining use of the valuable GRECC Connect services, they are not officially part of anyone's job duties. Zogas et al [35] go on to say the following when describing the efforts of clinical pharmacy practitioners to ensure that their services were used: "[the clinical pharmacy practitioners] did report a need to continue using relationship-building strategies because of turnover in leadership, clinicians, and other clinic staff," and there would be an ongoing "need for continued efforts at maintaining integration given staff and leadership turnover."

This strongly aligns with our findings and suggests that the types of tasks that were viewed as integral to the navigator role and critical to sustaining the use of GRECC Connect services are not unique to GRECC Connect. However, geriatrics may be more likely to suffer from these challenges; there may be a lack of immediate recognition of the value of geriatric consultative services given that many clinicians may care for older patients regularly and may not have had the opportunity to experience the benefits of geriatric specialty care for their patients. Ongoing educational efforts may be even more essential to support the sustained use of such services. Especially in the current health care environment with staffing turnover and shortages, it is important to acknowledge and make visible these tasks that are essential to sustaining valuable health care

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programs. Assigning these tasks to a position such as the geriatric referral navigator could improve efficiency by allowing others on the team to practice at the highest level of their training and expertise.

Our paper characterizes the role of the geriatric referral navigator, a unique approach to supporting sustainment in a context about which little has been written [12]. The tasks performed by a geriatric referral navigator are critical in an environment of high staff turnover—a situation experienced in many rural health care settings. However, when funding shifts and external funds are no longer available to support this role, this valuable service could be in danger of ending. The navigator's tasks may be more readily recognized as essential for the *initial* implementation phase of a program, not as *ongoing* activities in need of continuous dedicated support. In the context of high turnover and complex referral landscapes, the tasks performed by the navigator are needed continuously to sustain valuable services and should be considered an ongoing program cost. More work needs to be done to make these vital tasks visible and provide the necessary resources to fund them.

Limitations

This description of the navigator role as a strategy to support the sustainment of a promising practice has limitations. First, we have not yet assessed whether implementing this role does maintain or increase referrals for older patients from rural CBOCs over time. Future research will help determine this. Second, the hub sites that implemented this role were not chosen at random. Because, instead, they expressed interest in piloting this role, they likely anticipated some of the value they later ascribed to it.

Conclusions

Implementing the geriatric referral navigator role was considered by GRECC Connect hub site staff to be an important strategy to sustain service use in dynamic rural CBOC environments. It is critical to invest in such strategies to maintain promising practices over time, where appropriate, to avoid the costs and burdens of implementing new, similar programs in the future.

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Data Availability

The datasets generated or analyzed during this study are available from the corresponding author on reasonable request.

Authors' Contributions

All authors have been personally and actively involved in the substantive work leading to the preparation of this manuscript and accept joint and individual responsibility for its content.

Conflicts of Interest

None declared.

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Abbreviations

CBOC: community-based outpatient clinic
CFIR: Consolidated Framework for Implementation Research
ERIC: Expert Recommendations for Implementing Change
QualEC: Qualitative Evaluation Core
VA: United States Department of Veterans Affairs

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Original Paper

Health Beliefs and Perspectives of Parents Regarding Human Papillomavirus Vaccination in Kuwait: Qualitative Study

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Abstract

Background: After breast cancer, cervical cancer (CC) is one of the leading causes of female mortality. CC accounts for more than 7.5% of female cancer deaths worldwide. Human papillomavirus (HPV) is the most common sexually transmitted disease in women and the leading cause of CC in almost 99% of all CC cases. HPV vaccination could prevent up to 70% of HPV-related CC and 90% of genital warts. HPV vaccination is the bedrock of primary prevention and helps reduce the incidence and death rates of HPV-associated CC.

Objective: The study aimed to understand the knowledge, health beliefs, and perspectives of Kuwaiti parents regarding HPV vaccination, with the goal of developing a health promotion policy and introducing a national immunization program in Kuwait.

Methods: A total of 37 participants were evaluated using purposive sampling to select 20 (54%) participants for one-on-one semistructured interviews. We wanted to include both participants (male and female parents) with primary education (diploma or below) or secondary and higher education (bachelor's degree and above). We had four categories (male parents/guardians with a diploma or below, male parents/guardians with a bachelor's degree or above, female parents/guardians with a diploma or below, and female parents/guardians with a bachelor's degree or above) with at least 5 participants in each category, which gave us 20 participants. Semistructured interviews were based on the Health Belief Model (HBM). The data were thematically analyzed using an inductive approach, generating themes through the theoretical framework of the HBM, and theme extraction analyses were managed on a semantic level.

Results: We identified 7 main themes containing 20 subthemes. The seven themes were (1) knowledge and awareness about HPV infection and vaccination (3 subthemes); (2) perceived susceptibility, which is explained by the HPV infection effect based on sex (2 subthemes); (3) perceived barriers to HPV vaccination (8 subthemes); (4) perceived benefits (1 subtheme); (5) perceived severity (2 subthemes); (6) perceived efficacy (2 subthemes); and (7) cues to action (2 subthemes).

Conclusions: The HBM framework is beneficial for Kuwait's HPV vaccination campaign. The correlation between sexual intercourse and the HPV vaccine frequently adds complexity to the decision-making process about immunization. This study demonstrates that positive cues to action from health care practitioners and educational vaccination benefits can overcome perceived barriers among parents related to stigma and religion. It is essential to conduct more such research to guide the development of interventions aimed at promoting adoption of the HPV vaccine.

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KEYWORDS

human papillomavirus; HPV; human papillomavirus vaccine; HPV vaccine; parents; Health Belief Model

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Introduction

Background

Human papillomavirus (HPV) is the most common sexually transmitted disease worldwide and is responsible for nearly all cases of cervical cancer (CC). Moreover, anogenital cancers occur in both men and women [1,2]. HPV 16 and 18 have been implicated in 70% of all CC cases in the world [3,4]. CC is the third-most common cancer among women in high-income nations and the second-most common in medium-income countries, after breast cancer. CC, in general, causes around 12% of all cancers worldwide and 18% of cancer among women in the Middle East [5]. CC is unlike many other malignancies and has excellent potential for primary prevention with HPV vaccination and secondary prevention with CC-screening methods, such as cytology (Papanicolaou [Pap] smear) and HPV testing, which enable early detection and treatment of precancerous lesions [6-8].

In Kuwait, the HPV vaccine is not included in the national vaccination program; however, it is accessible through the private health care sector [9]. At the end of 2024, the government health care center made the HPV vaccine available as an option. One significant barrier to CC prevention in Kuwait is the lack of a nationwide HPV vaccine and cervical cancer–screening program, with cytology being the most common screening technique [10,11]. Consequently, many CC cases are diagnosed at advanced stages, which hampers treatment and increases mortality.

Despite being a high-income country, Kuwait is one of the few nations without policies on CC vaccination and screening programs. Therefore, it is critical to identify the elements necessary for successful implementation of such a policy in Kuwait. The purpose of this study was to investigate parents' perspectives, knowledge, and beliefs about HPV vaccination in Kuwait to develop an effective health promotion policy, based on analysis of data collected from semistructured interviews of 20 participants using questions based on the Health Belief Model (HBM). Each theme was analyzed based on the responses to questions on HPV and HPV vaccine knowledge and beliefs among Kuwaiti parents. The HBM was used as the theoretical basis for this study since it is a commonly used motivational framework for developing health education programs and supporting beneficial actions or behaviors that assist in lessening actual or perceived health concerns [12]. The Middle East has its own cultures and beliefs, much like the West and other parts of the world. The HBM is a framework that attempts to predict health-related behaviors based on specific belief systems (the Kuwait system).

Study Aims and Objectives

The aim was to establish a health promotion policy by assessing Kuwaiti parents' deep understanding and health beliefs regarding the HPV vaccine through an interview based on the HBM.

Toward this end, the study had the following specific objectives:

- Conduct semistructured interviews of Kuwaiti parents of children aged 12-17 years to determine what they know and believe about the HPV vaccine.
- Quantify the health beliefs and knowledge that are used to guide parents in deciding to vaccinate their children against HPV.
- To understand Kuwaiti parents' knowledge of HPV and HPV vaccination by looking for gaps and ignorance in order to develop recommendations for health promotion to vaccinate against HPV.

Methods

Study Design

This study used a qualitative approach by conducting face-to-face semistructured interviews with participants. Data collection involved open-ended questions, targeting a purposive sample of Kuwaiti parents with children aged 12-17 years. Thematic analysis was used to analyze the data.

Theoretical Framework

This study used the HBM as a theoretical framework because of its articulate, measurable constructs—perceived susceptibility, perceived severity, perceived benefits, perceived barriers, cues (to action), and self-efficacy—which can be easily mapped onto parental cognition and can be operationalized in survey and interview measures [13,14]. The interview questions were designed to align with the HBM's components, aiming to understand how parents perceive HPV vaccination in terms of perceived susceptibility (questions about HPV transmission and cancer risk), perceived severity, perceived benefits and barriers (questions about the reasons for or against vaccination), self-efficacy, and cues to action. The HBM identifies barriers to behavior change. In this study, the HBM was used to explain participants' (parents) health behavior. For example, the participant was asked about the perceived benefits of HPV: "What are the health benefits that lead you to think about getting the HPV vaccination for your child, or not, in case it is available?" (Multimedia Appendix 1).

Nevertheless, the HBM has been identified to have shortcomings: it focuses on individual cognitions, and in most instances, it explains only a modest level of behavioral variance in complex behaviors in public health [15]. We used part 1 of the framework to explore the principle of consent in this model through the interview questions.

Study Site and Sampling

Qualitative research typically uses a smaller sample size than quantitative studies, because instead of applying the findings to an entire population, it attempts to obtain deeper knowledge and meaning [16]. A purposive sampling strategy was used to select 20 parents/guardians of 12-17-year-old children from intermediate-level schools in Kuwait. Both male and female parents were eligible to participate in the study.

This study also explored the different information and themes in male responses compared to those in female responses. Both sexes were included, with primary, secondary, or higher education. The criteria used to select a sample based on maximum variation were sex and educational attainment. We had four categories (male parents/guardians with a diploma or below, male parents/guardians with a bachelor's degree or

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above, female parents/guardians with a diploma or below, and female parents/guardians with a bachelor's degree or above) with at least 5 participants in each category, resulting in at least 20 participants. Parents could opt in to the qualitative study at the end of the quantitative study [17]. Based on the aforementioned criteria, the individuals who were excluded were also sent an explanation of why they had not been included in the study.

A total of 18 schools were selected for the study, with 6 (33%) schools chosen from each of the three educational regions. Since the study focused on parents with school-age children, the sample was based on selecting participants who positively responded to the questionnaire and purposefully choosing respondents who represented the aforementioned four categories. All participants were recruited on a rolling basis. We used purposive sampling to select parents of children from the 18 schools. Purposive sampling ensures that participants selected have useful and relevant knowledge, and it is often used to optimize resource use while collecting the maximum amount of valuable data [18]. In addition, participants are chosen based on the characteristics of the population, needs, and study design. Purposive sampling is one of the most popular nonprobability sampling methods for obtaining data in a particular field and can be especially useful for qualitative research. This way researchers can focus on choosing participants who fit the research aim and are most likely to contribute to knowledge of the phenomenon in question. Purposive sampling makes sense if the information-laden cases provide nuance and insight, and qualitative studies that want to dive deeper or more complicated issues could benefit from purposive sampling.

Once identified as being eligible for the study, participants were sent an interview invitation based on their answers to the last question in the questionnaire, "Would you like to participate in an interview?"

Ethical Considerations

Ethical considerations were addressed via an official letter from the Kuwait Ministry of Health (MOH; #1345/2020) and the Ministry of Education (reference 25914), and ethical approval was also obtained from the Ethical Committee of the University of Bradford (E844). Participants who accepted the interview invitations ascertained their interest by signing a consent letter that provided them with an overview of the study, in addition to an information sheet (Multimedia Appendix 2). The information sheet clearly stated that participation in the study was for research purposes only.

To obtain the consent to participate, participants were given time (about 1 week) to make their own decision and sign the consent letter. Interviews were scheduled at convenient times and locations. Given the sensitivity of Kuwaiti culture, the interviews were audio-recorded with the participants' permission; if any participant refused to be recorded, only notes were taken. To minimize any potential misunderstanding by participants during the interviews, the researcher ensured that participants had an opportunity to elaborate on unclear points. In addition, the researcher read back the notes made during the interview to double-check their accuracy and provide the participant with an opportunity to explain or elaborate. This made the data more trustworthy and also made sure that the perspectives and opinions of the participants were captured accurately.

Data will be preserved for 5 years and archived within the University of Bradford, and no medical experiments, medicines, biopsies, or other interventional testing will be conducted in the future.

Data Collection

Research data are essential to reaching meaningful conclusions because they reveal participants' perspectives. Data collection is a process of taking actions to tackle research questions and obtain information [19]. Semistructured interviews are particularly useful in helping to get a sense of the context and what is going on with a descriptive study and understand the attitude of participants [20]. In this study, before the interviews, participants received an open-ended interview guide with questions based on parents' health beliefs regarding HPV vaccination. This protocol made sure that the discussions were still anchored in the research aim but gave room to all researchers to explore what they had learned and felt.

The interview questions were written in English and then translated into Arabic, Kuwait's official language. The interviews and data collection were conducted in Arabic and transcribed. The thematic analysis was conducted in Arabic and later translated into English by an authorized translation center to avoid losing any insight from the answers. The official translation office verified the translations. The transcripts were read and re-read to obtain a comprehensive perspective on the data; subsequently, the transcripts were compared to the original notes, and the data were presented. Cost and time elements were also obtained.

Each interview lasted 30-60 minutes, allowing participants to express their views on HPV vaccination. Once at the interview site, each participant was administered a demographic questionnaire to gather information such as age, marital status, and education level (already in the questionnaire but to ensure this information was correct). To ensure the effectiveness of the final interviews, a pilot study was conducted with 5 parents before the main data collection. This was a pretest phase to determine whether the interview questions and study resources were helpful and clear, as well as how much time was required for all the steps. The pilot study also helped detect potential difficulties that could have arisen during the interviews and let the researcher polish up the process and the quality of data collection in general.

Data Analysis

After conducting the semistructured interviews, the recordings were transcribed verbatim to accurately represent participants' answers. The data were filtered using themes from the open-ended questions. Such unravelling and corralling of data to find commonalities and patterns helped us read, explain, and understand the data [21,22].

This study used thematic analysis, a common qualitative analytical technique. It involves spotting, interpreting, and summarizing patterns or themes in qualitative data to produce

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a detailed and refined picture of the phenomenon under consideration. Deductive analysis is based on assumptions about already present theories or frameworks, while in inductive analysis, themes and codes appear spontaneously from the data. We used inductive thematic analysis to identify codes, themes, concepts, and categories within the interview data. This methodology provided us with the flexibility to ask parents about their health beliefs and knowledge regarding HPV vaccination, without having to follow set rules; this gave meaning to the data through theme selection and grouping. This process ensured a detailed and complete appreciation of participant perception, which was used to meet the study's aims [23]. We used an iterative analytical process, in which three to four transcripts were reviewed independently to identify key themes. Subsequent sets of interviews were similarly assessed to clarify core themes. We also developed and applied codes that explained the categorization of the data. The HBM was used to structure the interviews. Therefore, the interview outcomes were categorized under HBM components (perceived susceptibility, perceived severity, perceived benefits, perceived barriers, perceived self-efficacy, and cues to action). A code was created, and themes evolved because we used that as a structure to try to analyze what the parents said and the questions already focused on these components. The open coding of the transcribed interviews helped increase understanding of the data's meaning and significance. Manual open coding involved line-by-line repeated reading and coding to identify themes and subthemes. Two supervisors conducted identical evaluations to ensure the validity of this procedure. Any differences of opinion were settled by reviewing the entire thematic analysis process (codes, themes, and subthemes) and then reaching a consensus to make the final decision about the themes that evolved.

Results

Themes and Subthemes

The interview transcripts were analyzed by reading the obtained data line by line. This process continued, and 221 codes were created. The initial codes from each interview were then categorized, given new titles, and assigned to distinct themes and subthemes. These themes and subthemes were combined if duplicates were found in order to eliminate any conceptual repetition. There were 7 main themes, with a total of 20 subthemes, that explored HPV and HPV vaccine knowledge and health beliefs among Kuwaiti parents. Table 1 provides a list of the final themes and subthemes, followed by example quotations for a few subthemes.

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Table 1. Themes and subthemes identified in the study.

Theme number	Theme	Subthemes
1	Knowledge and awareness about HPV[a] infection and vaccination	• Subtheme 1: parents' knowledge and awareness about the HPV vaccine • Subtheme 2: importance of the HPV vaccine for both sexes • Subtheme 3: ways of transmitting HPV and the effects of factors
2	Perceived susceptibility	• Subtheme 1: relationship of HPV infection and sex • Subtheme 2: parents' perspectives on getting an HPV infection
3	Perceived barriers	• Subtheme 1: lifelong stigma, social customs, and negative HPV vaccine uptake • Subtheme 2: social and familial influences regarding HPV vaccination and decision-making about immunization • Subtheme 3: religious and societal influences regarding HPV and HPV vaccination on decisions • Subtheme 4: fear of complications from the vaccine • Subtheme 5: previous bad experiences with vaccines and medications • Subtheme 6: cost of the HPV vaccine • Subtheme 7: trust in the HCS[b], confidence in medical staff, and satisfaction with the vaccination • Subtheme 8: availability of authentic and reliable information about the HPV vaccine
4	Perceived benefits	• Subtheme 1: benefits of getting an HPV vaccine as protection from and prevention of the virus and related cancer
5	Perceived severity	• Subtheme 1: fear of HPV infection being a cause of cancer or severe disease • Subtheme 2: viral disease that affects the skin or appears in the form of a wart
6	Perceived efficacy	• Subtheme 1: parents' preferences and experiences influencing decisions regarding HPV vaccination • Subtheme 2: availability of the vaccine in private hospitals and lack of availability in government hospitals
7	Cues to action	• Subtheme 1: role of the government and the MOH[c] • Subtheme 2: awareness through campaigns, the media, HCPs[d], and schools

[a]HPV: human papillomavirus.

[b]HCS: health care system.

[c]MOH: Ministry of Health.

[d]HCP: health care practitioner.

We used HBM concepts in this analysis to align and extend the themes with the HBM framework. The HBM provided a theoretical framework to explore health beliefs among parents in Kuwait and the associated knowledge.

Theme 1: Knowledge and Awareness About HPV infection and Vaccination

Subtheme 1: Parents' Knowledge and Awareness About HPV and the HPV Vaccine

Some participants had some basic knowledge of HPV infection. For example, a male parent with a bachelor's degree said:

> *It is a type of viral disease that affects the skin in the form of small granules and may cause cancer.*

In contrast, other participants had no knowledge or limited knowledge of HPV infection and its vaccine. For example, a female parent with a diploma said:

> *I do not know about HPV and [have] no awareness about it. I do not know well about HPV vaccine and how it works. I have no idea. Is it for girl or boys to give it?*

Subtheme 2: Importance of the HPV Vaccine for Both Sexes

Some participants mentioned that the vaccine is essential to both sexes. A female parent with a bachelor's degree said:

> *The answer is that both sexes are the same. There is no difference between girls and boys in terms of vaccination priority.*

Subtheme 3: Ways of Transmission of HPV and the Effects of Factors

Participants highlighted that the major reason for HPV infection is illegitimate relationships with several partners. A female parent with a bachelor's degree said:

> *It is an infection transmitted through sexual intercourse.*

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Theme 1 and its subthemes revealed that participants were at different levels of knowledge regarding HPV and its vaccine regardless of their level of education or sex.

Theme 2: Perceived Susceptibility

Subtheme 1: Relationship of HPV Infection and Sex

Some participants associated HPV infection with women and girls. These participants were told that the perceived susceptibility to HPV is linked to being a woman, which would result in HPV in female individuals more than in male individuals. For example, a male parent with a diploma said:

> *A virus that infects a woman's reproductive system...*

Another female parent with a bachelor's degree said:

> *Maybe it will affect pregnancy if women take it before marriage.*

However, some participants were aware that HPV affects both sexes and may have devastating consequences for both sexes. A male participant with a doctorate said:

> *A virus that infects a woman or a man as a result of multiple illegal sexual relations...*

Subtheme 2: Parents' Perspective on Getting an HPV Infection

Some of the participants said that their children can get an HPV infection but at a lower percentage. One female parent with a high school degree said:

> *I do not know the chances because life will change a few years later, and I cannot tell you the behavior that the boy or girl will have in [the] future.*

Most of the participants said they did not know whether their children will get an HPV infection. They did not give any reasons, which was not related to the sex or education level of the parents:

> *I don't know the chance to get this virus.*

In contrast, other participants provided different reasons for why they believed that they were not at risk for HPV infection. For example, a participant with a bachelor's degree thought there was no chance of an HPV infection because he trusted his children:

> *There is none because customs and traditions dictate that you be bound to one person, and I trust my children.*

Only one female parent with a bachelor's degree believed in her children's perceived susceptibility to infection and felt the chances of getting infected are high based on many things changing these days.

> *In these days, [there] will be a high chance of being infected.*

Theme 2 and its subthemes show that some parents feel that HPV affects only female individuals, while others say it could affect both sexes. In addition, some parents mentioned that there was no chance of their children getting an HPV infection, while others felt that their children might get infected.

Theme 3: Perceived Barriers

In this study, many subthemes regarding perceived barriers fit the HBM. Parents of both sexes and all education levels reported several barriers.

Subtheme 1: Lifelong Stigma, Social Customs, and Negative HPV Vaccine Uptake

Participants highlighted that they might be reluctant to vaccinate their children against HPV because of the stigma associated with it. One female participant with a diploma refused to vaccinate her daughter, feeling that it was unnecessary because her daughter was unlikely to contract the virus due to traditions:

> *We are a conservative society with social customs and traditions, where most married people are only related to one person. It may be a lifelong stigma for her, and she will not marry after that.*

One of the male participants with a doctorate mentioned that a feeling of shame may be one of the barriers that can affect him when he decides to vaccinate his children:

> *It may negatively affect the girl's psychology in terms of her feeling ashamed, given that we are a conservative society, so they can understand that this wrong.*

Subtheme 2: Social and Familial Influences Regarding HPV Vaccination and Decision-Making About Immunization

One of the barriers discovered in this study was related to cultural and familial issues. Some participants stated that in Kuwaiti society, the decision to receive the HPV vaccine is often associated with promiscuity. A female parent with a diploma said:

> *I will worry regarding the HPV vaccine; vaccination will not be widely accepted in Kuwaiti society. Therefore, I will worry and think a lot before giving it to my daughters. It is new for Kuwaiti society, as it only exists in the West.*

Another female parent with a bachelor's degree said:

> *There are no factors that encourage me to give it [HPV vaccine] to my sons because this disease results from illegal relationships.*

Subtheme 3: Religious and Societal Influences Regarding HPV and HPV Vaccination on Decisions

Religious beliefs and the idea that Islamic norms prevent risky sexual behavior were often mentioned as reasons to consider HPV vaccination unnecessary or unsuitable. Parents commonly said that following Islamic law and local customs protects against behaviors that could cause HPV infection, so they felt the vaccine was more fitting for other communities.

One father with a master's degree expressed this opinion clearly:

> *We follow Islamic law, and our customs and traditions preserve, preserve, capture these, preserve these points. There are no illegal relationships, and there are not many homosexuals.*

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Subtheme 4: Fear of Complications From the Vaccine

Another perceived barrier identified was the fear of complications from HPV vaccination. Therefore, some of the participants hesitated to get their children vaccinated. Participants also highlighted that the HPV vaccine might have side effects. A male parent with a bachelor's degree said:

> *I am afraid of the side effects of this vaccine when I decide to vaccinate my daughters.*

Subtheme 5: Previous Bad Experiences With Vaccines and Medications

Participants highlighted that people's bad experiences with COVID-19 vaccines had made them reluctant to get their children vaccinated against HPV. A male participant with a master's degree said:

> *This vaccine could prevent [HPV], but as far as I know, the spread that happened with previous vaccines [COVID-19]...I expect this vaccine to be harmful or useless or have side effects and complications that are more [harmful] than useful.*

Subtheme 6: Cost of the HPV Vaccine

Another perceived barrier to HPV vaccination was the cost of the vaccine. A female parent with a diploma said:

> *I found it [HPV vaccine] in private hospitals, but the price of the dose is approximately 35 Kuwaiti dinar* [US $110]

Subtheme 7: Trust in the Health Care System, Confidence in Medical Staff, and Satisfaction With the Vaccination

Male parents with high school education highlighted that doctors generally do not recommend the HPV vaccine in routine clinical practice:

> *Also, it is not recommended by doctors, as I visited hospitals and polyclinics a lot for my sons, but I have yet to hear anyone speak to me about this vaccination.*

Subtheme 8: Availability of authentic and reliable information about HPV vaccine

Parents commonly noted a lack of reliable, locally relevant information concerning HPV and the HPV vaccination. This information vacuum left individuals unsure about the benefits and risks of vaccines, prompting some to rely on informal or online sources that did not fully reassure them.

A male participant with bachelor's degrees participant expressed:

> *It makes me discouraged that there is no information about this vaccination. Therefore, we do not know how effective it is, and therefore, we will not take this vaccination.*

Another father attributed his reluctance directly to the lack of existing studies:

> *It is possible that I will not give my daughters the vaccination, as there are no studies that I have read before that, especially in Kuwait.*

Theme 3 and its subthemes explain the barriers in parents' minds regarding HPV vaccine uptake.

Theme 4: Perceived Benefits

Perceived benefits of health-promoting behaviors refer to an individual's subjective perception of the beneficial effects and rewards associated with engaging in those behaviors. In this study, although some participants had a superficial knowledge of HPV or had incorrect ideas about their children's susceptibility to the virus, they noted the positive benefits of engaging in preventive actions.

Subtheme 1: Benefits of Getting an HPV Vaccine as Protection From and Prevention of HPV Infection and Related Cancer

The prevention of cancer linked to HPV is one of the HPV vaccine's main benefits. Participants highlighted that due to the perceived benefits of the HPV vaccine, they might vaccinate their children. A female participant with a bachelor's degree mentioned that if the HPV vaccine has benefits, she would vaccinate her children:

> *[It will] encourage me to vaccin[ate] my children if it has a benefit for my children.*

Male participants with high school education mentioned the prevention of cancer as a benefit:

> *The vaccine, in general, is preventing disease; maybe, anyone has this virus. But if receiv[ing] the vaccine means that will decrease cancer in the body or prevent it, this is a very positive thing.*

Theme 5: Perceived Severity

Perceived severity relates to the way in which participants believed that HPV infection may severely impact the quality of life of their children. Participants highlighted the possible severe health ramifications of HPV infection, including CC, genital warts, and skin disease.

Subtheme 1: Fear of HPV Infection Being a Cause of Cancer or Serious Disease

One male parent with a doctorate mentioned that HPV and cancer are related:

> *There is a close relationship between HPV and cancer, as it is possible, in a large percentage, for this virus to turn into cancer. Also then, it can turn into CC in women and penis cancer in men.*

One female parent with a bachelor's degree said that HPV "causes CC."

Subtheme 2: Viral Disease That Affects the Skin or Appears in the Form of a Wart

Some participants mentioned that HPV infection can affect the skin in the form of warts. A male parent with high school education said:

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> *A virus that infects humans through skin-to-skin contact, either through sexual intercourse or skin to skin*

Another male participant with a bachelor's degree said:

> *[Appears on] the skin in the form of small granules and may cause cancer*

Theme 6: Perceived Efficacy

Subtheme 1: Parents' Preferences and Experiences Influencing Decisions Regarding HPV Vaccination

Self-efficacy relates to a person's belief in their ability to change or perform a behavior effectively. Participants highlighted that parents' preferences and experiences can influence their decision to vaccinate their children. One male parent with a master's degree mentioned that he will vaccinate his children when he sees an infection among people:

> *The factors that encourage me to vaccinate my son are that I see many infections among people and that I see them with my own eyes.*

Subtheme 2: Availability of the Vaccine in Private Hospitals and Lack of Availability in Government Hospitals

A male participant with a bachelor's degree added:

> *I read that there is a vaccine for this virus but outside Kuwait, and I have not heard of it in Kuwait.*

Theme 7: Cues to Action

Subtheme 1: Role of the Government and the MOH

Cues to action are unique triggers that encourage individuals to make changes that promote their health. Participants engaged in a discussion of the significance of external cues that prompt action. They said that they would take action if health care practitioners (HCPs) strongly recommended vaccination. A male participant with a doctorate highlighted the role of the MOH and the government:

> *The factors that encourage me to take my child for vaccination: First, that this vaccination should be included in the vaccination schedule of the Kuwaiti MOH, where I will be very reassured.*

A female participant with a diploma said:

> *I do not know anything about it, and [I have] not been made aware of it by MOH, but if MOH advises us to vaccinate, I will give it to my daughter after they explain the benefits and side effects of this vaccine.*

Subtheme 2: Awareness Through Campaigns, the Media, HCPs, and Schools

Another example of cues to action is a campaign encouraging people to vaccinate against HPV. A male participant with high school education said:

> *Awareness campaigns must be made for parents to encourage them to vaccine their children. We trust MOH if they advise it.*

According to the HBM, a cue, or trigger, is necessary to encourage people to adopt health-promoting attitudes. Participants highlighted that advice and/or prescriptions from doctors can help parents decide about HPV vaccination. A female parent with high school education said:

> *It encourages me that doctors recommend it during a regular visit to a polyclinic or hospital or when asking about that HPV vaccination.*

Discussion

Principal Findings

In this study, overall, there was variability in knowledge and awareness regarding HPV. Some parents had no knowledge, while others had only basic knowledge and awareness about HPV, its transmission, and the HPV vaccine. A study [24] conducted in Indonesia showed a lack of knowledge about HPV and sexually transmitted diseases among parents regardless of sex. Another study [25] conducted in Australia also reported a lack of knowledge about HPV among parents; although the majority of parents had heard about HPV, only two had strong information about HPV and how it is transmitted [25].

This study identified many barriers to HPV vaccine uptake. The main obstacles are stigma, religion, societal influences, risk and fear of vaccine complications, cost, and the availability of authentic and reliable information about the HPV vaccine. Religious and cultural reasons were found to be some of the main barriers in a study [26] conducted among Syrian mothers in 2011; results showed that cultural influences lead mothers to perceive that their daughters are not at risk for HPV and, therefore, do not need vaccination [26].

Many studies have shown the benefits of the HPV vaccine from parents' perspectives. Parents have explored the benefits of the HPV vaccine in preventing CC and believe that it would reduce the impact of the infection [27-30]. In this study, we observed low perceived susceptibility regarding HPV infection, as half of the parents enrolled did not know whether their children can get an HPV infection. Prior studies have established that the perceived susceptibility to developing HPV infection among different communities is low. In one study [31] in Saudi Arabia, the parents said their children were not at risk for infection, so they would not vaccinate them.

Perceived severity is one of the HBM concepts that explores the seriousness of infection or disease. A different community in Indonesia mentioned that there is a relationship between HPV and cancer, but few participants noted it [24]. Another study [32] in Saudi Arabia showed that HPV infection is the main cause of cancer. Our findings reveal perceived efficacy as another HBM concept based on parents' views. Previous studies have addressed this issue; a mother mentioned that a shift in the young generation's thinking encouraged her to vaccinate her children [33]. In another study [34], a participant mentioned that her daughter was too young for the vaccine and that she would wait for her to be older.

Cues to action are another HBM concept that explains to parents how to take action for their health. Our findings showed how parents would take action to vaccinate their children against

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HPV. Previous studies have found that HCPs' recommendations can motivate parents to accept the HPV vaccine by advising them and explaining about HPV [35]. Similarly, if doctors recommend the HPV vaccine, parents can make an informed decision based on clear and trusted information [36].

Strengths and Limitations of the Study

One of the study's strengths was the use of the HBM, which has three strengths: a comprehensive framework, individual focus, and practical application. The HBM provides a comprehensive framework for understanding health-related behaviors by examining a wide range of factors that affect people's behavior. The model's simplified health-related components support ease of implementation, application, and testing. The HBM is the best model for health promotion [37]. The advantage of this qualitative research is that it can provide a comprehensive description of participants' opinions about an HPV vaccine, thereby strengthening our assessment of the reality of HPV vaccine uptake in the context of their deepest health beliefs regarding HPV infection and its vaccine [38].

One of the limitations of this study is that the interviews were unavoidably restricted to just Kuwaiti citizens because no non-Kuwaiti citizens volunteered. This limits the generalizability of the findings to the wider population residing in Kuwait. In addition, the study was conducted exclusively in government schools and did not collect data from private schools, with the majority of pupils being non-Kuwaiti residents. Therefore, these results are unlikely, given the knowledge and health beliefs of all parents in Kuwait. Furthermore, given that we examined the delicate subject of HPV and sexual health, it is plausible that the participants abstained from disclosing their experiences because of concerns regarding adhering to social standards. The findings of this research may not be applicable to the entire population of parents in Kuwait. All parents refused to permit audio-recording during the interviews. The researchers, who are Kuwaiti, realized that the participants were cautious and expected this. As a result, the researchers took notes during each interview and transcribed them. This allowed the researchers to note the most important points made by the participants, although the precise way in which the participants made those points was somewhat lost.

As the data for the study were collected during the COVID-19 pandemic or near the end stage of COVID-19, all recommended precautionary measures related to the pandemic were taken during data collection. However, the precautionary measures taken due to COVID-19 may have had some effect. For example, as the COVID-19 vaccines were new, many people hesitated to take them; similarly, participants may fear the impact of the HPV vaccine since it is new to most participants. Some complications have arisen due to the COVID-19 vaccine, which may also occur with the introduction of a new vaccine, such as the HPV vaccine.

Conclusion

Over 90% of HPV-caused cancers (mainly CC) may be avoided with the HPV vaccine. HPV vaccination serves as the principal preventive measure against CC. Positive cues to action from parents after advice from the MOH and HCPs about the benefits of vaccination can overcome perceived barriers among parents related to stigma and religion. Most parents have been motivated to protect their children and prevent disease. The correlation between sexual intercourse and the HPV vaccine frequently adds complexity to the decision-making process about immunization. National health care systems and HCPs can enhance the importance of getting the HPV vaccine and explain why vaccination is recommended by giving clear and timely information. They must alleviate parental concerns over vaccination efficacy and safety, while also considering diverse religious, social, and cultural sensitivities, as well as varying educational backgrounds. The findings from this study demonstrate the potential of using the HBM to overcome perceived barriers to HPV vaccine uptake with culturally appropriate interventions and accurate information.

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Data Availability

All supporting data are reported in the article.

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Authors' Contributions

Conceptualization, writing, editing—original draft manuscript, overall coordination, methodology, and formal analysis were handled by AA; conceptualization, review, and manuscript structure refining were handled by MSRJ; and conceptualization, review, editing, manuscript structure refining, and overall coordination were handled by CJ.

Conflicts of Interest

None declared.

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Multimedia Appendix 1
Semistructured interview questions.
[DOCX File , 17 KB - formative_v10i1e85438_app1.docx]

Multimedia Appendix 2
Consent form.
[DOCX File , 21 KB - formative_v10i1e85438_app2.docx]

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Abbreviations

CC: cervical cancer
HBM: Health Belief Model
HCP: health care practitioner
HPV: human papillomavirus
MOH: Ministry of Health

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Original Paper

Effects of a Modified Exposure Claim for an e-Cigarette on Claim Comprehension, Behavioral Intentions, and Risk Perceptions Among US Adult Tobacco Users and Nonusers: Randomized Experimental Study

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Abstract

Background: Effective communication about the relative risks of cigarettes and e-cigarettes can help increase switching away from cigarettes while minimizing unintended use.

Objective: This study examined comprehension of a proposed modified exposure claim (MEC) about an e-cigarette (IQOS VEEV, the study product [SP]) and the effects of claim exposure on SP use intentions and risk perceptions among adult tobacco users and nonusers.

Methods: Adult smokers with no intention to quit smoking (S-NIQ, n=606), adult smokers with an intention to quit smoking (S-IQ, n=600), adult e-cigarette users (ECU, n=630), adult former smokers (FS, n=619), adult tobacco and nicotine products (TNP) never-users aged 18-24 years (n=648), and adult TNP never-users aged 25 years and older (n=749; total N=3852) participated in a randomized between-groups online experimental study. Participants viewed a marketing brochure for the SP with (test condition) or without (control condition) an embedded MEC. Outcome measures included claim comprehension, intention to use the SP regularly, and perceived health risk to self from using the SP or smoking cigarettes.

Results: Most participants were female (n=2110, 54.8%), had a mean age of 40.2 (SD 14.93) years, and were equally split across the 4 US regions. S-IQ and S-NIQ were long-term, frequent cigarette smokers, while 91.4% (566/619) of FS were long-term quitters. ECU on average used e-cigarettes ≥15.2 times per day, and the majority of them (552/630, 87.6%) had started using e-cigarettes more than 12 months before. Most participants correctly understood the key elements of the claim: the SP produces lower levels of harmful chemicals compared to cigarettes (1818/1926, 94.4%), and switching completely from cigarettes to the SP reduces exposure to harmful chemicals (1832/1926, 95.1%). In both conditions, positive intention to use the SP was high among ECU (control: 238/314, 75.8% vs test: 249/315, 79%; *P*=.33), moderate among S-IQ (control: 127/299, 42.5%; test: 166/299, 55.5%; *P*<.001) and S-NIQ (control: 140/299, 46.8%; test: 166/307, 54.1%; *P*=.07), low among FS (control: 28/306, 9.2%; test: 33/312, 10.6%; *P*=.55), and very low among adult TNP never-users aged 18-24 years (control: 3/330, 0.9%; test: 8/318, 2.5%; *P*=.11), and adult TNP never-users aged 25 years and older (control: 5/373, 1.3% vs test: 12/375, 3.2%; *P*=.09). All groups understood that the SP posed a lower health risk compared to cigarettes. In all groups, claim exposure was associated with significantly lower risk perception of the SP relative to cigarettes (all comparisons, *P*<.001).

Conclusions: The tested MEC has the potential to benefit public health by simultaneously increasing already high levels of SP use intention and reducing SP risk perceptions relative to cigarettes among adult tobacco users while generating low levels of use intention among tobacco nonusers.

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KEYWORDS

cigarettes; electronic cigarettes; intentions; public health; risk perceptions; switching; tobacco

Introduction

Despite a substantial decline in adult smoking prevalence over the past several decades, 28.8 million (11.6% of all) US adults (aged ≥18 years) were current cigarette smokers in 2022 [1]. Between 50%-70% of adults who smoke are projected to die prematurely from smoking-related diseases if they continue to smoke [2,3], losing around 10 years of life relative to adults who never start smoking [3]. The best action that a person who smokes can take to protect and improve health is to completely stop all tobacco and nicotine use. Since many adults continue to smoke, reducing tobacco-related harms among this population is a public health priority.

The United States Food and Drug Administration (FDA) Center for Tobacco Products recognizes that tobacco products exist on a "continuum of risk," with combusted or "smoked" products, such as cigarettes, posing the greatest health risks, and noncombusted products, such as e-cigarettes and smokeless tobacco, generally considered to be lower risk alternatives for adults who smoke, but not risk-free [4,5]. Therefore, although complete cessation of all tobacco use is optimal, complete switching from cigarettes to a tobacco product that sits lower on the risk continuum has the potential to substantially reduce an individual's health risks and so represents the second-best option to complete cessation, and one that may be more viable and appealing to adults who are open to stopping smoking but not to stopping all nicotine use.

Absolute and relative risk perceptions are well-established as important predictors of intentions and actions to initiate, continue, and transition between cigarette smoking and e-cigarette use. Adults who smoke and perceive e-cigarettes to be equally or more harmful than cigarettes are significantly less likely to transition from exclusive cigarette smoking to exclusive e-cigarette use [6-8]. Among adults who do switch, the belief that e-cigarettes are less harmful than cigarettes reduces the likelihood of resuming smoking up to 1 year later [7]. In 2018, approximately three-quarters (22.5 million) of US adults who smoked held the belief that e-cigarettes are equally or more harmful than smoking cigarettes, of which only 3.3% completely switched to e-cigarettes in the following year [7]. The authors' analysis indicated that approximately 1.1 million more adults would likely have switched from cigarettes to e-cigarettes between 2018 and 2019 had they correctly perceived e-cigarettes to be less harmful than cigarettes. Similarly, Persoskie et al [9] estimated that an additional 370,000 adult dual users of cigarettes and e-cigarettes would have completely switched to e-cigarettes between 2013 and 2014 had they correctly perceived e-cigarettes to be less harmful than cigarettes.

Evidence of this significant population-level relationship between lower-risk perceptions of e-cigarettes and adults' likelihood of adopting and subsequently switching from cigarettes to e-cigarettes, together with evidence that a declining proportion of US adults who smoke believe that e-cigarettes are less harmful than cigarettes, suggests that misperceptions that e-cigarettes pose similar or higher health risks than cigarettes harm public health by maintaining smoking among adults who otherwise may be open to switching. Additionally, with some evidence indicating that this risk misperception is more prevalent among some minority and vulnerable populations [6], it may also contribute to health disparities associated with smoking. Population-level harm may be reduced significantly, therefore, by informing adults who smoke that completely switching to e-cigarettes may substantially lower their health risks.

Marketing e-cigarettes as having "modified" or reduced risks represents one such opportunity available to manufacturers to communicate the absolute and relative risks of using a new e-cigarette product to potential consumers. To market a new tobacco product in the United States, for use to reduce harm or risk of tobacco-related disease, the manufacturer must first submit a modified risk tobacco product (MRTP) application and obtain a marketing granted order from the FDA [10,11]. In deciding on an MRTP order, the FDA evaluates the application for evidence that potential consumers understand the modified risk/exposure claims in the context of the product's label, labeling, and marketing materials, and the impact that advertising of the new product with the proposed modified risk/exposure claims will have on tobacco use behavior of current tobacco users (eg, adoption, regular use, switching from cigarettes, dual use, and switching back to cigarettes) and nonusers (eg, initiation, reinitiation, and progression to use of more harmful products) [12].

Prospective evidence of the actual behavioral impact of exposure to modified risk/exposure claims about e-cigarettes is limited and difficult to obtain prior to receipt of an MRTP order. In the absence of direct behavioral evidence, data that characterize behavioral intentions and risk perceptions of a new e-cigarette product following exposure to marketing materials with and without presentation of a modified exposure claim (MEC) can inform estimates of the product's future population use and associated health impact. This study evaluated comprehension of an MEC for a closed-end e-cigarette (the study product [SP]) and tested the effects of exposure to marketing material containing the MEC on adult tobacco users' and nonusers' intentions to use the SP and the risk perceptions of the SP relative to cigarettes.

Methods

Study Design

A randomized, parallel, between-groups, 2-condition experimental study was conducted in 2 parts. In part 1, participants completed a self-administered online survey about their current and past tobacco and nicotine use. Responses were used to classify participants into 1 of 6 mutually exclusive

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groups according to criteria presented in Multimedia Appendix 1 [13] (described in the "Tobacco Use" section below). In part 2, participants were randomly assigned to 1 of 2 study conditions (control or test). Participants in the test condition viewed a marketing brochure for the SP, which contained an MEC for the SP. Participants in the control condition viewed a brochure for the SP without the claim. Study enrollment began on November 14, 2022; data collection ended on April 14, 2023.

Study Product

The SP under the brand name of "IQOS VEEV" is an electronic vaping device (also referred to as an e-cigarette or vaping product) that produces an aerosol for inhalation through vaporization of a nicotine-containing liquid. The SP is a closed e-cigarette comprising 2 main components: a replaceable cartridge containing e-liquid and a heating element that connects to a device containing electronics with a rechargeable battery. The marketing brochure presented the device to participants as "IQOS VEEV" and presented the disposable replaceable cartridges as "IQOS VEEV Cartridges."

Participants

The study planned to recruit a total of approximately 4320 US-based, English-speaking adults aged 18 years and older who fit the criteria for classification into one of the following six mutually exclusive groups: (1) adult smokers with no intention to quit smoking (S-NIQ), (2) adult smokers with an intention to quit smoking (S-IQ), (3) adult e-cigarette users (ECU), (4)adult former smokers (FS), (5) adult tobacco and nicotine products (TNP) never-users aged 18-24 years inclusive (TNU18-24), and (6) adult TNP never-users aged 25 years or older (TNU25+). In this study, adult smokers were stratified into 2 groups—S-NIQ and S-IQ—given that e-cigarette use intentions may vary by level of intention to quit smoking. Definitions for each group are provided in Multimedia Appendix 1. Classifications were based on participants' self-reported use of cigarettes, e-cigarettes, and other tobacco products, consistent with guidelines established by the World Health Organization [13]. Excluded individuals were those who (1) did not provide acceptable proof of age; (2) were employed in the fields of market research, public relations, journalism, the tobacco industry, or the health sector; (3) had participated in a clinical study or in research about tobacco or nicotine-containing products in the past 3 months; (4) preferred not to answer the question on sex; (5) started smoking cigarettes/using e-cigarettes within the last 30 days; (6) quit smoking cigarettes/using e-cigarettes within the last 30 days; (7) did not have access to a device appropriate for viewing the study materials; (8) did not acknowledge the informed consent form or did not provide consent to participate; and (9) did not confirm they had the opportunity to review the applicable privacy notices. Stratified randomization was performed using the permuted-block technique to balance the composition of each group on the following three demographic variables: (1) US Census region (US Census Bureau–designated region: Northeast, South, Midwest, and West), (2) sex (male or female), and (3) age (S-NIQ; S-IQ; ECU; and FS aged 21-35 years, 36-50 years, and >51 years; TNU18-24 [18-20 years and 21-24 years]; TNU25+ [25-35 years, 36-50 years, and >51 years]). Randomization of the total sample to study conditions was stratified by group (n=6), US Census region (n=4), sex (n=2), and age (n=3, except for TNU18-24, n=2). This randomization method ensured that an approximately equal number of participants in each group was assigned to each condition (planned n=360).

Recruitment

Participants were recruited from proprietary databases consisting of people who had indicated an interest in participating in consumer research studies and provided consent to receive invitations to participate. The databases included basic demographic information about potential participants, which was used to create sample frames comprising individuals likely to satisfy study eligibility criteria. Participants were also recruited through retail mall site intercepts and via digital advertising (eg, digital banner advertisements and advertisements on social media platforms). Potential participants received an email invitation to participate in the study, which provided basic information about the study, including the need to be screened for eligibility, the anticipated time to complete the survey, compensation for completion, and a hyperlink that routed to part 1 of the study survey.

Procedures

Part 1 of the survey involved completion of the screening. Participants who completed part 1 of the survey and satisfied all study eligibility criteria were qualified to continue to part 2 of the survey. Qualified participants were given a link to an appointment scheduling platform where they could schedule an appointment to complete part 2, which involved an interviewer-led interview using a videoconferencing solution, with participants reading and answering some survey questions on their own.

In part 2, participants were age-verified and randomized to the test or control condition. Participants assigned to the test condition viewed a brochure for the SP containing the MEC (Figure S1A in Multimedia Appendix 1). Participants assigned to the control condition viewed the same brochure without the MEC (Figure S1B in Multimedia Appendix 1). Each brochure was a mockup generated specifically for use in this study, in electronic form, and consisted of 3 pages. Page 1 (images of the SP device and packaging containers for SP cartridges in 2 flavor variants [tobacco and menthol]) and page 2 (description of features of the SP) were identical in all respects (ie, content, font size, colors, and positioning) for participants in both conditions.

For participants in the test condition, page 3 displayed an image of the SP with the following MEC: "IQOS VEEV produces significantly fewer and lower levels of harmful chemicals compared to cigarettes. Scientific studies have shown that switching completely from cigarettes to IQOS VEEV significantly reduces your body's exposure to harmful chemicals. Important information: IQOS VEEV is not risk-free." For participants in the control condition, the third page displayed the same image of the SP device without the MEC.

Upon opening the assigned brochure, participants were asked by the interviewer to read 1 page at a time, to carefully read all the information on each page, even if the participant did not

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feel the information applied to them, and to click "next" when they were ready to read the next page. For each page, the interviewer ensured that participants spent sufficient time viewing each page of the brochure before moving to the next page. Images of the assigned brochure were displayed to participants on screen in a manner that was broadly compatible with common devices.

Participants viewed the assigned brochure prior to answering survey questions that measured study outcomes. Questions were displayed in the same fixed order—comprehension, intention to use (ITU) the SP, and risk perceptions—for all participants, as applicable. Participants were not allowed to change their answers after moving to the next question in the survey. Prior to the comprehension assessment, participants were informed that the aim of the assessment was not to test their memory but rather to assess the effectiveness of the brochure at communicating key information about the SP. Accordingly, participants were able to reopen the assigned brochure at any time during the comprehension assessment. Instructional and factual manipulation checks were used to determine participants' attentiveness during review of the assigned brochure. Given the low proportion of participants who incorrectly answered either the attention check or manipulation check questions, all participants were included in the analysis. Upon survey completion, participants were debriefed to address any misperceptions about the SP that may have arisen from participation in the study. The debriefing script stated that the marketing brochure viewed was for research purposes only and that participants should not assume that using SP is safer than using any other tobacco or nicotine-containing product, such as cigarettes.

Measures

Eligibility

In part 1 of the study, screening questions assessed participants' eligibility to participate against study inclusion/exclusion criteria.

Demographics

Questions assessed participants' age, sex, race/ethnicity, US state of residence, highest educational attainment, and household income.

Tobacco Use

Participants were classified into 1 of 6 mutually exclusive groups based on their responses to questions that assessed their ever use, ever-established/fairly regular use, current use, and frequency/intensity of each of a spectrum of tobacco and nicotine-containing products, including cigarettes, e-cigarettes, oral smokeless tobacco, hookah tobacco, pipe tobacco, and cigars/cigarillos. Intention to quit smoking was measured by two questions based on the Stages of Change model developed by Prochaska and DiClemente [14]: (1) "Are you seriously considering quitting smoking within the next 6 months?" (yes/no) and (2) "Are you planning to quit smoking within the next 30 days?" (yes/no). This approach assessed participants' readiness to quit smoking according to the distinct stages outlined in the model.

Comprehension of the MEC

Comprehension of the key elements of the MEC was assessed by 4 questions (provided in Multimedia Appendix 1). Questions assessed participants' understanding that (1) the SP produces significantly lower levels of harmful chemicals compared to cigarettes, (2) exposure to harmful chemicals is significantly reduced when switching completely from cigarettes to the SP, (3) in order for a person to reduce his/her body's exposure to harmful chemicals, he/she should stop smoking cigarettes and only use the SP, and (4) using the SP would be associated with some risk (ie, would not be risk-free). For each question, participants selected a single response from 5 options (questions 1, 2, and 3) or 2 options (question 4; yes/no). Each question had only 1 correct response, and all questions included a "don't know/not sure" option. The comprehension question closely followed the guidance recommended by the FDA for label comprehension studies. In both the test and control conditions, 2 questions additionally assessed participants' understanding that the SP (1) is a vaping product/electronic cigarette and (2) contains nicotine [15].

ITU the SP Regularly

ITU the SP regularly was measured by a single question: "If you try IQOS VEEV and like it, how likely or unlikely would you be to use IQOS VEEV regularly?" Participants selected a single response from a 6-point Likert scale (1=Definitely not, 2=Very unlikely, 3=Somewhat unlikely, 4=Somewhat likely, 5=Very likely, and 6=Definitely). Participants were also able to select "don't know." This question was displayed only to participants who had previously indicated they were "Somewhat likely," "Very likely," or "Definitely" would try IQOS VEEV in response to the question: "Based on what you know about IQOS VEEV, how likely or unlikely are you to try IQOS VEEV?"

Risk Perception

Risk perception was measured using the Assessment of Behavioral Outcomes Related to Tobacco and Nicotine Containing Products (ABOUT)-Perceived Risk Instrument [16-18]. The ABOUT-Perceived Risk Instrument is a psychometrically validated, self-reported measurement instrument that assesses the perceived risks associated with the use of tobacco and/or nicotine containing products (eg, cigarettes, e-cigarettes, heated tobacco products, and nicotine replacement therapy products), and the perceived risks associated with the past use of tobacco and/or nicotine containing products (ie, cessation). The instrument assesses perceived risks to the individual (their personal risk) in 2 domains (perceived health risk to self and perceived addiction risk) using 2 unidimensional scales. The Perceived Health Risk Scale measures the perceived negative impact of product use on the user's physical health, starting with minor, immediate manifestations of health risk (eg, having sores of the mouth or throat) to more serious long-term manifestations (eg, having lung cancer).

In this study, the 9-item short version of the Perceived Health Risk Scale measured perceived health risk to self from use of (1) cigarettes, (2) the SP, (3) e-cigarettes, and (4) cessation [18].

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Responses were measured on a 5-point Likert scale (0=no risk, 1=low risk, 2=moderate risk, 3=high risk, and 4=very high risk) [16,17]. Participants could also select an "I don't know" option for each item. "Don't know" responses were interpreted as missing values and replaced by the mean response to other items by the same participant. Missing value imputation was only carried out for participants with ≤50% missing values. A small number of risk perception assessments were not applicable to some groups and/or tobacco-related products and so were not assessed (ie, adult TNP never-users were not assessed on risks that are perceived to remain after smoking cessation).

Statistical Analysis

All analyses were performed with SAS software (version 9.4; SAS Institute Inc; 2021). All analyses were specified a priori. Categorical outcome measures are described by the total number of participants in each group with nonmissing data and by the number and proportion of participants in each group endorsing each response option. Continuous outcome measures are described by the number of participants in each group with nonmissing score values, and by appropriate measures of central tendency and dispersion. Participant disposition is summarized. Descriptive statistics are reported for all demographic and participant characteristics (age, sex, race, ethnicity, highest educational attainment, US Census region of residence, and household income), overall and stratified by group and study condition.

Analyses of claim comprehension, ITU the SP, and risk perception outcomes included all participants who completed the survey. The number and proportion of participants in the test condition who selected the predefined correct answer and each incorrect answer in response to each measure of claim comprehension are reported separately for each group.

The number and proportion of participants who selected each response option on the 6-point ordinal scale measure of "intention to use the SP regularly" (1=Definitely not, to 6=Definitely) is reported for each group within each condition. For each group, the effect of the study condition on the ITU score between the test and control conditions was tested by the Mann-Whitney *U* test. To account for multiple comparisons, *P* values were calculated based on a Bonferroni-adjusted type I level of 0.0167. "Positive intention" to use the SP regularly was operationalized in this study as the proportion of participants who indicated they would be "Very likely" or "Definitely" to use the SP regularly (ie, response option 5 or 6 on the ITU scale). The number and proportion (unadjusted 95% CIs) of participants who expressed a positive ITU the SP regularly are reported separately for each group within each condition. For each group, a 2 × 2 chi-square test tested the association between study conditions (test vs control) and the level of ITU the SP regularly (positive intention vs nonpositive intention).

A total score was calculated for the Perceived Health Risk to Self Scale and transformed into a Rasch-derived measure on a 0 to 100 scale (where 0=no risk and 100=very high risk) in accordance with instrument scoring procedures [16]. Descriptive statistics and unadjusted 95% CIs of the perceived health risk scores are reported for each group within each condition separately for the SP, cigarettes, e-cigarettes, and cessation. The difference between transformed Rasch-derived scores for perceived health risk to self for cigarettes and the SP (calculated as SP score minus cigarettes score) was calculated for each condition. The difference between cigarettes and SP (SP minus cigarettes) was calculated for each condition and compared by group in both the test and control conditions using a 2-tailed, unpaired *t* test at the Bonferroni-adjusted type I level of 0.0167 to account for multiple comparisons.

Ethical Considerations

This study was approved by the Sterling Institutional Review Board (10288). All participants provided informed consent prior to enrollment in the study. The informed consent form included a description and purpose of the study, the duration and compensation for participating, as well as information that the findings may be published externally. Participants who completed parts 1 and 2 of the study were compensated US $50. All data analyses were conducted on deidentified datasets, with no individual data disclosed.

Results

Disposition

The CONSORT (Consolidated Standards of Reporting Trials) guidelines were used to ensure the reporting of this experimental study (Multimedia Appendix 2) [19]. Figure 1 presents the flow diagram of the study.

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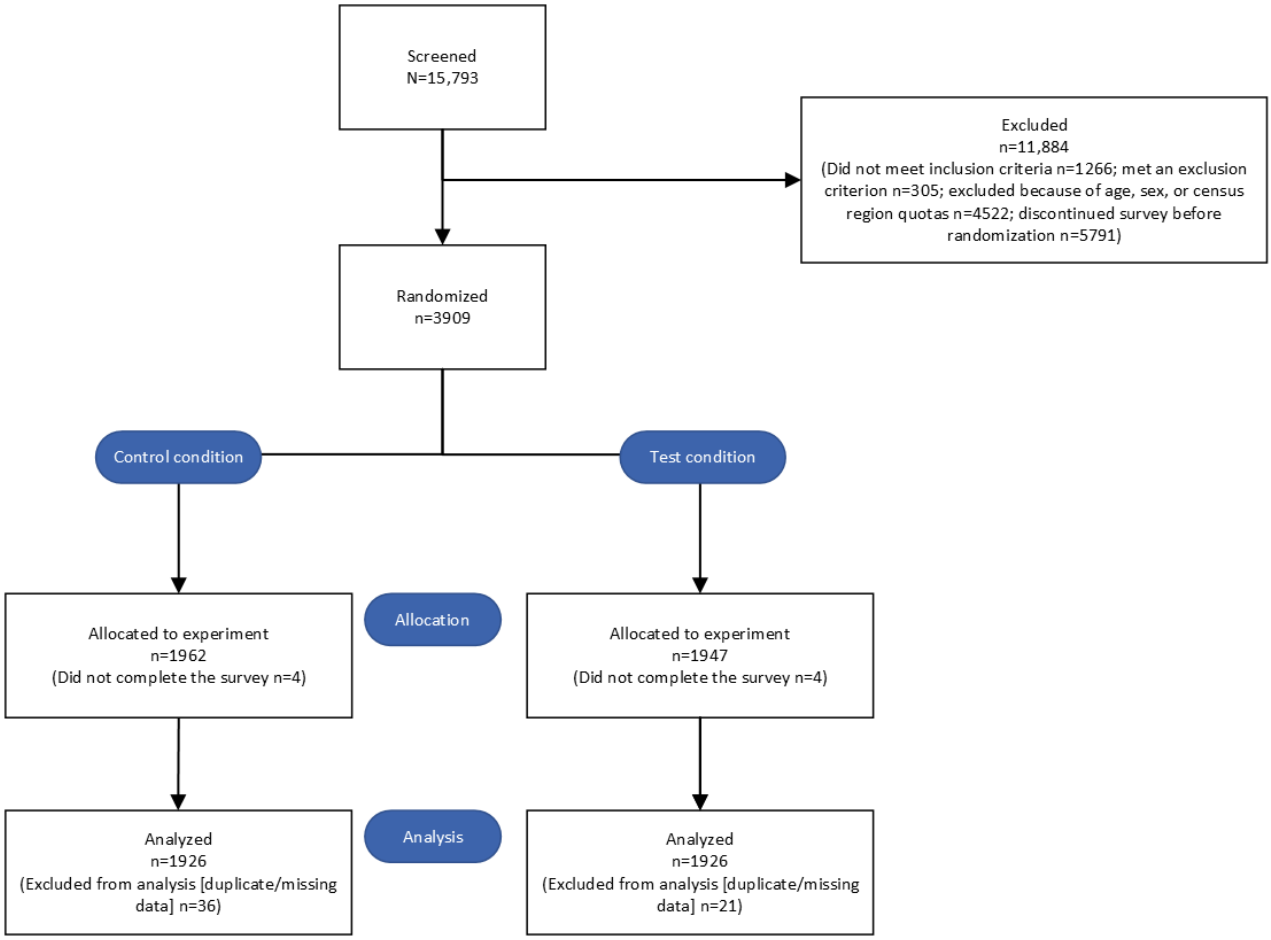
Figure 1. CONSORT (Consolidated Standards of Reporting Trials) flow diagram for a US-based, randomized, online experimental study evaluating a modified exposure claim for the study product (an e-cigarette). The diagram shows the number of participants screened, excluded, randomized, and included in analyses across test and control conditions. Study enrollment and data collection occurred between November 14, 2022, and April 14, 2023.



A total of 15,793 individuals were screened, of whom 11,884 (75.2%) were excluded (reasons for exclusion are presented in Figure S2 in Multimedia Appendix 1). A total of 1962 participants and 1947 participants were randomized to the control and test conditions, respectively. In total, 1926 participants in each condition completed the study survey. Thus, the final study sample included 3852 participants across 6 mutually exclusive groups, as shown in Table 1.

Table 1. Random assignment of participant groups to study conditions. Participants were classified into 6 mutually exclusive tobacco use groups—adult smokers with no intention to quit (S-NIQ), adult smokers intending to quit (S-IQ), adult e-cigarette users (ECU), adult former smokers (FS), and tobacco and nicotine products never-users aged 18-24 years (TNU18-24) and ≥25 years (TNU25+). Participants were randomized to view a product brochure either with (test) or without (control) a modified exposure claim for the study product (an e-cigarette).

Group	Control (n=1926), n (%)	Test (n=1926), n (%)	Total (n=3852), n (%)
S-NIQ	299 (15.5)	307 (15.9)	606 (15.7)
S-IQ	301 (15.6)	299 (15.5)	600 (15.6)
ECU	315 (16.4)	315 (16.4)	630 (16.4)
FS	307 (15.9)	312 (16.2)	619 (16.1)
TNU18-24	330 (17.1)	318 (16.5)	648 (16.8)
TNU25+	374 (19.4)	375 (19.5)	749 (19.4)

Demographic and Tobacco Use Characteristics

Participants predominantly identified as female (n=2110, 54.8%), White (n=2732, 70.9%), and not Hispanic (n=3227, 83.8%; Table 2). The final sample was approximately evenly distributed across the 4 US Census regions. The mean age was 40.3 (SD 14.97) years and 40.0 (SD 14.97) years in the test and control conditions, respectively. Participant distributions across age group, sex, US Census region, highest educational attainment, race, and ethnicity were comparable between the test and control conditions.

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Table 2. Participant demographic characteristics, stratified by study condition. Participants were randomized to view a product brochure either with (test) or without (control) a modified exposure claim for the study product (an e-cigarette). Characteristics are stratified by study condition.

Assessment	Control (n=1926)	Test (n=1926)	Total (n=3852)
Age (years), mean (SD)	40.0 (14.89)	40.3 (14.97)	40.2 (14.93)
Age group, n (%)			
18-20 years	178 (9.2)	172 (8.9)	350 (9.1)
21-24 years	228 (11.8)	207 (10.7)	435 (11.3)
25-35 years	431 (22.4)	442 (22.9)	873 (22.7)
36-50 years	572 (29.7)	583 (30.3)	1155 (30.0)
51+ years	517 (26.8)	522 (27.1)	1039 (27.0)
Sex, n (%)			
Male	872 (45.3)	870 (45.2)	1742 (45.2)
Female	1054 (54.7)	1056 (54.8)	2110 (54.8)
US Census region, n (%)			
Midwest	440 (22.8)	434 (22.5)	874 (22.7)
Northeast	480 (24.9)	481 (25.0)	961 (24.9)
South	487 (25.3)	489 (25.4)	976 (25.3)
West	519 (26.9)	522 (27.1)	1041 (27.0)
Ethnicity, n (%)			
Hispanic or Latino	255 (13.2)	253 (13.1)	508 (13.2)
Not Hispanic or Latino	1614 (83.8)	1613 (83.7)	3227 (83.8)
Prefer not to say	56 (2.9)	60 (3.1)	116 (3.0)
Missing	1 (0.1)	0 (0.0)	1 (0.0)
Race[a], n (%)			
American Indian or Alaska Native	36 (1.9)	44 (2.3)	80 (2.1)
Asian	149 (7.7)	137 (7.1)	286 (7.4)
Black or African American	335 (17.4)	370 (19.2)	705 (18.3)
Native Hawaiian or Other Pacific Islander	7 (0.4)	10 (0.5)	17 (0.4)
White	1385 (71.9)	1347 (69.9)	2732 (70.9)
Prefer not to say	89 (4.6)	92 (4.8)	181 (4.7)
Missing	1 (0.1)	0 (0.0)	1 (0.0)
Education attainment, n (%)			
Less than high school	11 (0.6)	7 (0.4)	18 (0.5)
Some high school or General Education Development	74 (3.8)	76 (3.9)	150 (3.9)
High school graduate	252 (13.1)	236 (12.3)	488 (12.7)
Some college	670 (34.8)	657 (34.1)	1327 (34.4)
College graduate	690 (35.8)	704 (36.6)	1394 (36.2)
Advanced degree	223 (11.6)	241 (12.5)	464 (12.0)
Prefer not to say	5 (0.3)	5 (0.3)	10 (0.3)
Missing	1 (0.1)	0 (0.0)	1 (0.0)

[a]Answers are not mutually exclusive. The total percentage may be higher than 100%.

More than two-thirds (834/1206, 69.2%) of S-IQ and S-NIQ in the test and control conditions smoked cigarettes "daily," with the remaining (372/1206, 30.8%) smoking cigarettes "occasionally" (Table S2 in Multimedia Appendix 1). S-IQ and S-NIQ who reported smoking cigarettes "occasionally" smoked cigarettes on approximately 10 days in the past month. In each

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of the test and control conditions, S-IQ and S-NIQ smoked approximately 13 cigarettes on average on each smoking day. Almost all S-IQ and S-NIQ (1167/1206, 96.8%) started smoking cigarettes more than 12 months ago. These results indicate that S-IQ and S-NIQ were predominantly long-term, frequent cigarette smokers. The vast majority (566/619, 91.4%) of FS were long-term quitters, having last smoked a cigarette more than 12 months ago. ECU used e-cigarettes approximately 16 times per day, on average, with most (552/630, 87.6%) having started using e-cigarettes more than 12 months ago.

Claim Comprehension

Comprehension of key elements of the MEC was high overall, highest among TNU18-24, and lowest among ECU. The difference between the lowest and highest rate of comprehension was 11.5% on each of the 4 elements of the claim across groups. Following reading of the claim, the majority of participants in each group correctly understood that (1) the SP produces lower levels of harmful chemicals compared to cigarettes (correctly understood range: 284/315, 90.2% [ECU] to 313/318, 98.4% [TNU18-24]), (2) exposure to harmful chemicals is significantly reduced when switching completely from cigarettes to the SP (correctly understood range: 291/315, 92.4% [ECU] to 310/318, 97.5% [TNU18-24]), (3) in order for a person to reduce his/her body's exposure to harmful chemicals, he/she should stop smoking cigarettes and only use the SP (correctly understood range: 262/315, 83.2% [ECU] to 300/318, 94.3% [TNU18-24]), and (4) there are some risks associated with using the SP (ie, using the SP would not be risk-free; correctly understood range: 265/315, 84.1% [ECU] to 304/318, 95.6% [TNU18-24]; Table 3). In each study condition, most participants in each group also correctly understood that the SP is a vaping product/electronic cigarette (control: 1843/1925, 95.7%; test: 1830/1926, 95%) that contains nicotine (control: 1907/1925, 99.1%; test: 1886/1926, 97.9%; Table S1 in Multimedia Appendix 1).

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Table 3. Comprehension of key elements of the modified exposure claim.

Assessment	S-NIQ[a] (n^b=307), n (%)	S-IQ[c] (n^b=299), n (%)	ECU[d] (n^b=315), n (%)	FS[e] (n^b=312), n (%)	TNU18-24[f] (n^b=318), n (%)	TNU25+[g] (n^b=375), n (%)	Total (n^b=1926), n (%)
Understanding that IQOS VEEV produces lower levels of harmful chemicals compared to cigarettes: "According to the material, what should Kelly say when asked which of the following statement best describes the amount of harmful chemicals produced by IQOS VEEV compared to cigarettes? Should Kelly say that..."							
IQOS VEEV produces higher levels of harmful chemicals than cigarettes	5 (1.6)	1 (0.3)	5 (1.6)	1 (0.3)	1 (0.3)	6 (1.6)	19 (1.0)
IQOS VEEV produces the same levels of harmful chemicals as cigarettes	6 (2.0)	10 (3.3)	13 (4.1)	5 (1.6)	4 (1.3)	6 (1.6)	44 (2.3)
IQOS VEEV produces lower levels of harmful chemicals than cigarettes (correct)	288 (93.8)	278 (93.0)	284 (90.2)	298 (95.5)	313 (98.4)	357 (95.2)	1818 (94.4)
IQOS VEEV does not produce harmful chemicals	8 (2.6)	7 (2.3)	12 (3.8)	8 (2.6)	0 (0.0)	4 (1.1)	39 (2.0)
Don't know/not sure	0 (0.0)	3 (1.0)	1 (0.3)	0 (0.0)	0 (0.0)	2 (0.5)	6 (0.3)
Understanding that the exposure to harmful chemicals is significantly reduced when switching completely from cigarettes to IQOS VEEV: "According to the material, what should Jennifer say when asked which of the following statements best describes the exposure to harmful chemicals when switching completely from cigarettes to IQOS VEEV? Should Jennifer say that the exposure to harmful chemicals..."							
Is significantly increased	4 (1.3)	2 (0.7)	4 (1.3)	0 (0.0)	1 (0.3)	6 (1.6)	17 (0.9)
Is significantly reduced (correct)	287 (93.5)	282 (94.3)	291 (92.4)	302 (96.8)	310 (97.5)	360 (96.0)	1832 (95.1)
Is eliminated	6 (2.0)	4 (1.3)	8 (2.5)	3 (1.0)	0 (0.0)	1 (0.3)	22 (1.1)
Is the same as continuing to smoke cigarettes	9 (2.9)	9 (3.0)	12 (3.8)	6 (1.9)	6 (1.9)	8 (2.1)	50 (2.6)
Don't know/not sure	1 (0.3)	2 (0.7)	0 (0.0)	1 (0.3)	1 (0.3)	0 (0.0)	5 (0.3)
Understanding that the exposure to harmful chemicals is significantly reduced when switching completely from cigarettes to IQOS VEEV: "The material states that the exposure to harmful chemicals is significantly reduced when switching completely from cigarettes to IQOS VEEV. What should Greg, who is currently smoking cigarettes, do to reduce his body's exposure to harmful chemicals? Should Greg..."							
Continue to smoke the same number of cigarettes and use IQOS VEEV	1 (0.3)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.1)
Reduce the number of cigarettes and use IQOS VEEV	29 (9.4)	28 (9.4)	50 (15.9)	26 (8.3)	18 (5.7)	23 (6.1)	174 (9.0)
Stop smoking cigarettes and only use IQOS VEEV (correct)	274 (89.3)	271 (90.6)	262 (83.2)	285 (91.3)	300 (94.3)	348 (92.8)	1740 (90.3)
Increase the number of cigarettes and use IQOS VEEV	2 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.5)	4 (0.2)
Don't know/not sure	1 (0.3)	0 (0.0)	2 (0.6)	1 (0.3)	0 (0.0)	2 (0.5)	6 (0.3)
Any risk associated with using IQOS VEEV: "According to the material, is there any risk associated with using IQOS VEEV?"							
Yes (correct)	275 (89.6)	264 (88.3)	265 (84.1)	292 (93.6)	304 (95.6)	349 (93.1)	1749 (90.8)
No	28 (9.1)	31 (10.4)	44 (14.0)	19 (6.1)	11 (3.5)	18 (4.8)	151 (7.8)
Don't know/not sure	4 (1.3)	4 (1.3)	6 (1.9)	1 (0.3)	3 (0.9)	8 (2.1)	26 (1.3)

[a]S-NIQ: adult smokers with no intention to quit.

[b]Number of participants who answered all questions required for the evaluation of this end point and were asked the respective question depending on their assigned group.

[c]S-IQ: adult smokers with an intention to quit.

[d]ECU: adult e-cigarette users.

[e]FS: adult former smokers.

[f]TNU18-24: tobacco and nicotine products never-users aged 18-24 years.

[g]TNU25+: tobacco and nicotine products never-users aged 25 years and older.

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ITU the SP Regularly

When examined on the 6-point ITU scale, ITU the SP regularly was significantly higher in the test (versus control) condition among 2 of the 6 groups: S-IQ and TNU18-24 (both *P*<.001; Table 4). S-IQ rated their ITU the SP regularly higher than the scale midpoint (rank 3.5) in both the control (mean rank 3.6, SD 1.81) and test (mean rank 4.2, SD 1.58) conditions. In contrast, although it is statistically significantly different between conditions, TNU18-24 expressed an ITU the SP regularly that was close to the scale minimum score (rank 1.0) in both the control (mean rank 1.1, SD 0.50) and test (mean rank 1.3, SD 0.88) conditions.

Table 4. Intention to use (ITU) the study product regularly, stratified by study condition among adult smokers with no intention to quit (S-NIQ), adult smokers intending to quit (S-IQ), and adult e-cigarette users (ECU) study groups.

	S-NIQ			S-IQ			ECU		
	Control (n[a]=299)	Test (n[a]=307)	*P* value	Control (n[a]=299)	Test (n[a]=299)	*P* value	Control (n[a]=314)	Test (n[a]=315)	*P* value
ITU rating[b]									
Definitely not, n (%; 95% CI)	64 (21.4; 16.8-26.5)	48 (15.6; 11.7-20.2)	N/A[c]	86 (28.8; 23.6-34.3)	40 (13.4; 9.7-17.8)	N/A	23 (7.3; 4.6-10.8)	20 (6.3; 3.9-9.7)	N/A
Very unlikely, n (%; 95% CI)	6 (2.0; 0.7-4.4)	2 (0.7; 0.0-2.4)	N/A	2 (0.7; 0.0-2.4)	4 (1.3; 0.3-3.4)	N/A	5 (1.6; 0.5-3.7)	2 (0.6; 0.0-2.3)	N/A
Somewhat unlikely, n (%; 95% CI)	10 (3.3; 1.6-6.1)	11 (3.6; 1.8-6.4)	N/A	11 (3.7; 1.8-6.5)	10 (3.3; 1.6-6.1)	N/A	6 (1.9; 0.7-4.2)	6 (1.9; 0.7-4.1)	N/A
Somewhat likely, n (%; 95% CI)	79 (26.4; 21.5-31.9)	80 (26.1; 21.2-31.4)	N/A	73 (24.4; 19.6-29.7)	79 (26.4; 21.5-31.9)	N/A	42 (13.4; 9.8-17.7)	38 (12.1; 8.6-16.2)	N/A
Very likely, n (%; 95% CI)	104 (34.8; 29.3-40.5)	112 (36.5; 31.0-42.2)	N/A	94 (31.4; 26.2-37.1)	122 (40.8; 35.1-46.7)	N/A	145 (46.2; 40.5-51.9)	147 (46.7; 41.0-52.4)	N/A
Definitely, n (%; 95% CI)	36 (12.0; 8.5-16.3)	54 (17.6; 13.4-22.4)	N/A	33 (11.0; 7.7-15.2)	44 (14.7; 10.9-19.3)	N/A	93 (29.6; 24.6-35.1)	102 (32.4; 27.2-37.9)	N/A
Mean rank sum, mean (SD; 95% CI)	3.9 (1.69; 3.7-4.1)	4.2 (1.58; 4.0-4.4)	.02[d]	3.6 (1.81; 3.4-3.8)	4.2 (1.50; 4.1-4.4)	<.001[d]	4.8 (1.33; 4.6-4.9)	4.9 (1.26; 4.8-5.0)	.30[d]
Positive ITU[e], n (%; 95% CI)	140 (46.8; 41.0-52.7)	166 (54.1; 48.3-59.8)	.07[f]	127 (42.5; 36.8-48.3)	166 (55.5; 49.6-61.3)	<.001[f]	238 (75.8; 70.6-80.5)	249 (79.0; 74.1-83.5)	.33[f]

[a]Number of participants who answered all the questions required for the evaluation of this end point.

[b]Question asked: "If you try IQOS VEEV and like it, how likely or unlikely are you to use IQOS VEEV regularly?"

[c]N/A: not applicable.

[d]Bonferroni adjusted type I level of 0.0167. *P* values were based on the Mann-Whitney *U* test calculated for 6-item Likert scales.

[e]The percentage of participants with "Definitely" or "Very likely" ITU.

[f]Chi-square 2-tailed test of independence between test vs control conditions.

When ratings on the 6-point ITU scale were dichotomized, positive ITU the SP (ie, proportion of participants selecting "Very likely" or "Definitely") was significantly higher for S-IQ only (control: 127/299, 42.5% vs test: 166/299, 55.5%; *P*<.001; Table 4). In both conditions, positive ITU the SP regularly was highest among ECU (control: 238/314, 75.8% vs test: 249/315, 79%; *P*=.33) followed by S-NIQ (control: 140/299, 46.8% vs test: 166/307, 54.1%; *P*=.07) and S-IQ (control: 127/299, 42.5%; *P*<.001 vs test: 166/299, 55.5%; *P*<.001). Positive ITU the SP regularly was lower among FS (control: 28/306, 9.2% vs test: 33/312, 10.6%; *P*=.55) and very low among TNU18-24 (control: 3/330, 0.9% vs test: 8/318, 2.5%; *P*=.11) and TNU25+ (control: 5/373, 1.3% vs test: 12/375, 3.2%; *P*=.09; Table 5).

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Table 5. Intention to use (ITU) the study product regularly, stratified by study condition—adult former smokers (FS), tobacco and nicotine products never-users aged 18-24 years (TNU18-24), and tobacco and nicotine products never-users aged 25 years and older (TNU25+) study groups.

Statistics	FS			TNU18-24			TNU25+		
	Control (n[a]=306)	Test (n[a]=312)	*P* value	Control (n[a]=330)	Test (n[a]=318)	*P* value	Control (n[a]=373)	Test (n[a]=375)	*P* value
ITU rating[b]									
Definitely not, n (%; 95% CI)	228 (74.5; 69.2-79.3)	219 (70.2; 64.7-75.3)	N/A[c]	323 (97.9; 95.6-99.2)	288 (90.6; 86.8-93.6)	N/A	345 (92.5; 89.3-95.0)	337 (89.9; 86.3-92.8)	N/A
Very unlikely, n (%; 95% CI)	4 (1.3; 0.3-3.4)	9 (2.9; 1.3-5.5)	N/A	1 (0.3; 0.0-1.7)	7 (2.2; 0.8-4.5)	N/A	1 (0.3; 0.0-1.5)	2 (0.5; 0.0-2.0)	N/A
Somewhat unlikely, n (%; 95% CI)	10 (3.3; 1.5-6.0)	8 (2.6; 1.1-5.0)	N/A	2 (0.6; 0.0-2.2)	3 (0.9; 0.1-2.8)	N/A	6 (1.6; 0.5-3.5)	6 (1.6; 0.5-3.5)	N/A
Somewhat likely, n (%; 95% CI)	36 (11.8; 8.3-16.0)	43 (13.8; 10.1-18.2)	N/A	1 (0.3; 0.0-1.7)	12 (3.8; 1.9-6.5)	N/A	16 (4.3; 2.4-6.9)	18 (4.8; 2.8-7.5)	N/A
Very likely, n (%; 95% CI)	25 (8.2; 5.3-11.9)	23 (7.4; 4.7-10.9)	N/A	1 (0.3; 0.0-1.7)	7 (2.2; 0.8-4.5)	N/A	4 (1.1; 0.2-2.8)	10 (2.7; 1.2-4.9)	N/A
Definitely, n (%; 95% CI)	3 (1.0; 0.2-2.9)	10 (3.2; 1.5-5.9)	N/A	2 (0.6; 0.0-2.2)	1 (0.3; 0.0-1.8)	N/A	1 (0.3; 0.0-1.5)	2 (0.5; 0.0-2.0)	N/A
Mean rank sum, mean (SD; 95% CI)	1.8 (1.45; 1.6-2.0)	1.9 (1.57; 1.8-2.1)	.23[d]	1.1 (0.50; 1.0-1.1)	1.3 (0.88; 1.2-1.4)	<.001[d]	1.2 (0.80; 1.1-1.3)	1.3 (0.98; 1.2-1.4)	.19[d]
Positive ITU[e], n (%; 95% CI)	28 (9.2; 6.1-13.0)	33 (10.6; 7.3-14.6)	.55[f]	3 (0.9; 0.1-2.7)	8 (2.5; 1.0-4.9)	.11[f]	5 (1.3; 0.4-3.2)	12 (3.2; 1.6-5.6)	.09[f]

[a]Number of participants who answered all the questions required for the evaluation of this end point.

[b]Question asked: "If you try IQOS VEEV and like it, how likely or unlikely are you to use IQOS VEEV regularly?"

[c]N/A: not applicable.

[d]Bonferroni adjusted type I level of 0.0167. *P* values were based on the Mann-Whitney *U* test calculated for 6-item Likert scales.

[e]The percentage of participants with "Definitely" or "Very likely" ITU.

[f]Chi-square 2-tailed test of independence between test vs control conditions.

Perceived Health Risk to Self

Overall, participants in the test condition perceived smoking cigarettes to have the highest health risk to self (mean 68.9, SD 14.67), followed by e-cigarettes (mean 53.5, SD 17.80), the SP (mean 48.2, SD 17.61), and cessation (mean 32.8, SD 17.49; Table 6). This order was observed in all groups. Again, groups consisting of FS and adult TNP never-users (FS, TNU18-24, and TNU25+) perceived health risks to self from using the SP, using e-cigarettes, and smoking cigarettes to be higher compared to groups consisting of adult current tobacco users (ECU, S-NIQ, and S-IQ). Perceived health risk to self from cessation was again similar across all groups. Perceived health risk to self among participants in the control condition followed a similar pattern. Overall, participants in the control condition perceived the health risk to self from using the SP (mean 54.4, SD 19.78) to be lower than smoking cigarettes (mean 66.1, SD 16.16), comparable to using e-cigarettes (mean 55.8, SD 19.61), and higher than cessation of all tobacco use (mean 35.9, SD 17.74).

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Table 6. Perceived health risks to self from using each tobacco product, stratified by participant group and study condition.

Group/product		Control, mean (95% CI)[a]	Test, mean (95% CI)[a]
S-NIQ[b]			
	Participants, n[c]	299	307
	Cigarettes	57.9 (55.9-59.9)	64.8 (62.9-66.6)
	e-Cigarettes	47.7 (45.7-49.8)	48.1 (46.0-50.2)
	SP	45.6 (43.4-47.7)	42.6 (40.7-44.4)
	TNP cessation	33.6 (31.6-35.5)	32.0 (29.9-34.1)
S-IQ[d]			
	Participants, n[c]	301	298
	Cigarettes	62.7 (60.8-64.5)	66.9 (65.4-68.4)
	e-Cigarettes	52.0 (49.8-54.2)	49.7 (47.9-51.6)
	SP	50.6 (48.6-52.7)	43.3 (41.6-45.0)
	TNP cessation	37.2 (35.1-39.2)	33.3 (31.3-35.2)
ECU[e]			
	Participants, n[c]	312	315
	Cigarettes	62.0 (60.1-63.8)	65.6 (63.7-67.5)
	e-Cigarettes	45.7 (43.6-47.8)	47.3 (45.2-49.3)
	SP	43.9 (41.7-46.0)	42.0 (40.1-44.0)
	TNP cessation	35.3 (33.3-37.4)	32.6 (30.5-34.7)
FS[f]			
	Participants, n[c]	306	312
	Cigarettes	66.5 (64.9-68.0)	68.2 (66.7-69.7)
	e-Cigarettes	57.5 (55.3-59.7)	53.9 (52.1-55.6)
	SP	56.6 (54.5-58.7)	49.4 (47.5-51.2)
	TNP cessation	37.6 (35.6-39.6)	33.2 (31.4-35.0)
TNU18-24[g]			
	Participants, n[c]	329	318
	Cigarettes	72.5 (71.1-73.9)	71.9 (70.7-73.1)
	e-Cigarettes	65.2 (63.4-67.0)	59.3 (57.7-61.0)
	SP	63.9 (62.1-65.7)	54.3 (52.5-56.0)
	TNP cessation	N/A[h]	N/A
TNU25+[i]			
	Participants, n[c]	374	372
	Cigarettes	73.0 (71.6-74.4)	74.7 (73.3-76.0)
	e-Cigarettes	63.8 (61.9-65.6)	60.6 (58.7-62.5)
	SP	63.1 (61.2-65.0)	55.9 (53.9-57.9)
	TNP cessation	N/A	N/A
Total			
	Participants, n[c]	1926	1926
	Cigarettes	66.1 (65.4-66.8)	68.9 (68.2-69.5)

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Group/product	Control, mean (95% CI)[a]	Test, mean (95% CI)[a]
e-Cigarettes	55.8 (54.9-56.7)	53.5 (52.6-54.3)
SP	54.4 (53.5-55.3)	48.2 (47.4-49.0)
TNP cessation	35.9 (34.9-36.9)	32.8 (31.8-33.8)

[a]Unadjusted 95% CIs.

[b]S-NIQ: adult smokers with no intention to quit.

[c]Number of participants who answered all questions required for the evaluation of the end point.

[d]S-IQ: adult smokers with an intention to quit.

[e]ECU: adult e-cigarette users.

[f]FS: adult former smokers.

[g]TNU18-24: tobacco and nicotine products never-users aged 18-24 years.

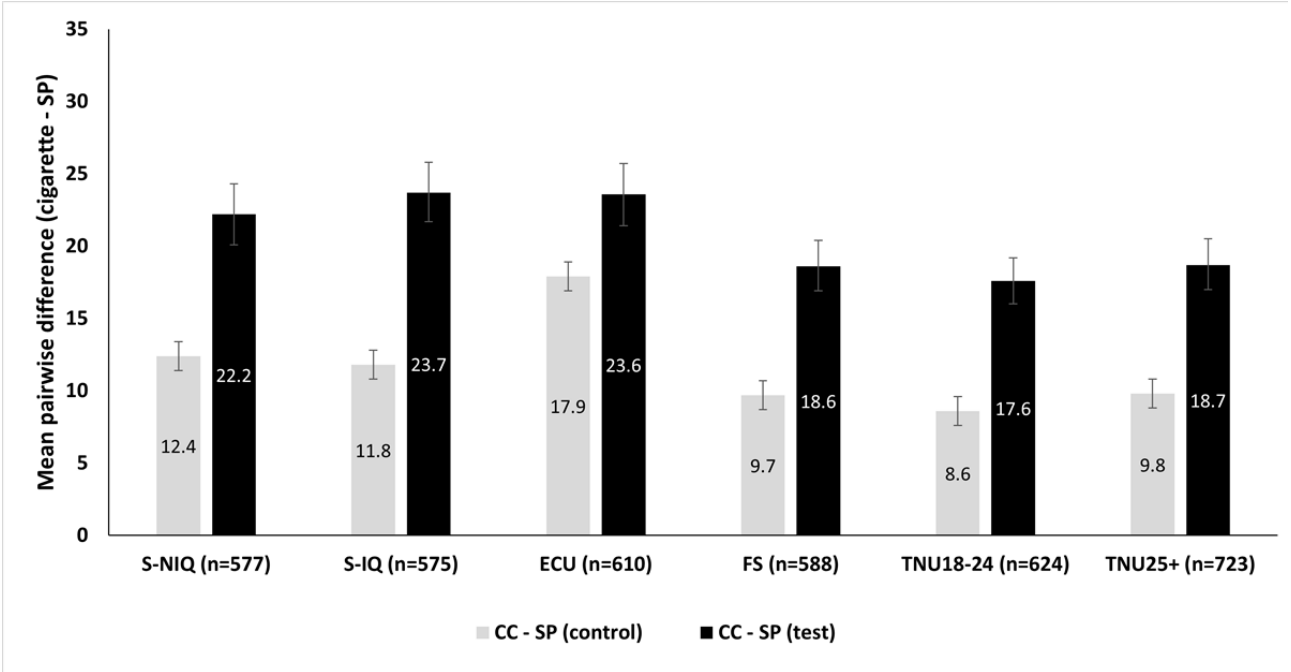
[h]N/A: not applicable.

[i]TNU25+: tobacco and nicotine products never-users aged 25 years and older.

This ordering of product use behaviors from highest (cigarettes) to lowest (cessation) health risk to self was observed in all groups. Groups consisting of adult former users and adult TNP never-users (FS, TNU18-24, and TNU25+) perceived the health risk to self from using the SP, using e-cigarettes, and smoking cigarettes to be higher compared to groups consisting of current tobacco users (ECU, S-NIQ, and S-IQ). Perceived health risks to self from cessation were similar across all groups.

Within each group, exposure to the claim (versus no claim) was associated with a significantly larger negative mean difference score for perceived risk to self from using the SP relative to smoking cigarettes (all comparisons, $P<.001$). Mean difference scores for perceived health risk to self (ie, the mean score for smoking cigarettes minus the mean score for using the SP) ranged from 8.6% (TNU18-24) to 17.9% (ECU) in the control condition, and from 17.6% (TNU18-24) to 23.7% (S-IQ) in the test condition (Figure 2). Overall, exposure to the claim increased perceived risk to self of cigarettes and decreased perceived risk to self of the SP, leading to a larger negative mean difference score.

Figure 2. Difference scores for perceived health risk to self from smoking cigarettes versus using the study product (SP). Participants were randomized to view a product brochure either with (test) or without (control) a modified exposure claim. Perceived risk was measured using the Assessment of Behavioral Outcomes Related to Tobacco and Nicotine Containing Products-Perceived Health Risk Scale and transformed to a Rasch score. All *P* values are <0.001. "n" represents the sum of test and control conditions (CC). ECU: adult e-cigarette users; FS: adult former smokers; S-IQ: adult smokers with an intention to quit; S-NIQ: adult smokers with no intention to quit; TNU18-24: tobacco and nicotine products never-users aged 18-24 years; TNU25+: tobacco and nicotine products never-users aged 25 years and older.



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Discussion

Principal Findings

e-Cigarettes typically expose users to substantially fewer and lower levels of toxicants compared to cigarettes, which likely translates into lower health risks [20]. Yet, most adults who smoke are unaware and instead believe e-cigarettes to be equally or more harmful than cigarettes [7]. Communicating e-cigarettes' lower exposure profile could help to correct smokers' misperceptions and, in turn, increase their likelihood of adopting and switching to e-cigarettes. However, an MEC could harm public health if it leads the public to believe that an e-cigarette's lower exposure means its use would pose no risk to health. For these reasons, it is important that MECs about e-cigarettes are correctly understood and that the effects of claim exposure on e-cigarette behavioral intentions among tobacco users and nonusers are assessed. This study assessed comprehension of a scientifically substantiated claim, embedded within a mocked-up marketing brochure for the SP, that switching completely from cigarettes to the SP (an e-cigarette) reduces the body's exposure to harmful chemicals. The effects of this MEC on SP behavioral intentions and risk perceptions among both adult tobacco users and nonusers were also evaluated.

Results indicated high comprehension of key elements of the claim among all groups, with comprehension exceeding the threshold of 80% that is generally accepted for label comprehension studies for all 4 claim communication objectives [21]. The vast majority of adult tobacco users and nonusers understood that the SP produces lower levels of harmful chemicals compared to cigarettes, but also that exposure to lower levels of harmful chemicals does not mean that using the SP would pose no risk. Additionally, the vast majority of adults who smoke cigarettes—the population for whom the switching message is most relevant—understood that exposure to harmful chemicals is significantly reduced when switching completely from cigarettes to the SP (566/606, 93.4%), and understood that a person who smokes would need to stop smoking cigarettes and only use the SP (ie, switch completely from cigarettes to the SP) to achieve this exposure reduction (545/606, 89.9%). These high levels of comprehension closely resemble those elicited by exposure to a very similarly worded MEC for similar e-cigarette products [21], providing evidence to suggest the tested claim may be comparably well understood in the context of a variety of e-cigarette brands and marketing materials.

A small minority (57/606, 9.4%) of adult smokers with and without an intention to quit cigarettes understood that a person who smokes could reduce exposure to harmful chemicals by reducing the number of cigarettes this person smokes while using the SP. This response is incorrect because this is not what the claim stated. However, this response may not reflect participants' interpretation of the claim, but rather may reflect their preexisting beliefs, their personal experiences of the health benefits of reducing smoking, and/or their awareness of scientific evidence that suggests reducing smoking without cessation can benefit health [22-25] and can lead to subsequent cessation [26-28].

Exposure to a marketing brochure for the SP both with and without the MEC generated moderate to high levels of positive ITU the SP on a regular basis among adults who currently smoke and/or use e-cigarettes while simultaneously generating low ITU the SP among former smokers and very low levels of positive use intention among young and older adults who have never used, or never regularly used, any tobacco or nicotine product. Results showed that claim exposure was associated with significantly higher levels of positive ITU the SP regularly in only 1 of the 6 groups: adult smokers who intend to quit cigarettes. The absolute increase in the proportion of S-IQ who reported an ITU the SP following exposure to the claim was large (+13% versus without the claim), suggesting the SP would likely interest a larger proportion of adult smokers who intend to quit smoking if marketed with the MEC. In contrast, the absolute increase in the proportion of adult tobacco nonusers (FS, TNU18-24, and TNU25+) who reported an ITU the SP following exposure to the claim was small. The overall level of positive ITU suggests that marketing the SP with or without the MEC would be unlikely to lead to any sizeable use among tobacco nonusers, particularly among adult tobacco and nicotine never-users (TNU18-24 and TNU25+). Other studies have reported that young adult nonsmokers' interest in using snus and e-cigarettes was similarly unaffected by exposure to modified risk messages for these products, particularly when the message's focus on "reducing risks by switching from smoking" made the products and the message feel less relevant to them as nonsmokers [29,30].

Consistent with this study's finding that significantly more adult smokers may adopt and use the SP as an alternative to smoking cigarettes when informed that completely switching to the SP would significantly reduce exposure to harmful chemicals, several studies have similarly reported the potential switching benefits of presenting comparative risk messages to adults who smoke. Messages that emphasize the potential benefits of switching completely from cigarettes to e-cigarettes, such as reduced exposure to harmful chemicals, have been found to increase smokers' intentions to switch completely from cigarettes to e-cigarettes [31,32]. In contrast, messages emphasizing uncertainty about e-cigarette risks (eg, focusing on unknown long-term effects) can reinforce misperceptions that e-cigarettes may be equally or more harmful than cigarettes, potentially deterring smokers from switching [33,34]. This aligns with findings from risk communication research showing that clear, actionable messages about relative risks are generally more effective for promoting harm-reducing behavior change compared to messages that emphasize scientific uncertainty or unknown risks [35,36].

Perceptions of the health risks posed by the different tobacco products and use behaviors in this study are generally aligned with the FDA's ordering of these products and use behaviors along the "continuum of risk." Tobacco users and nonusers perceived that continuing/starting to smoke cigarettes would pose the greatest risk to their health, while they perceived the lowest risk would be achieved through the cessation of all TNP use. The health risks of using the SP specifically or e-cigarettes more generally were perceived to fall between smoking cigarettes and complete cessation. Tobacco users also perceived

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cigarettes, e-cigarettes, and the SP to be riskier than did tobacco nonusers. Findings suggest the tested marketing material with MEC elicited a significantly larger difference between the perceived health risk from smoking cigarettes versus using the SP, indicating the greater effectiveness of the claim (versus no claim) in reducing risk perceptions of the SP relative to cigarettes. Given the evidence that millions more adult smokers would by now have switched completely to e-cigarettes had they correctly held lower risk perceptions of e-cigarettes relative to cigarettes [7,9], marketing the SP with the claim may be significantly more effective than "no claim" in increasing switch intentions. However, prospective, randomized studies would be needed to understand the effects of claim exposure on actual switching behavior and any mediating role of earlier switch intentions attributable to claim exposure.

Study findings should be interpreted in the context of several limitations. This study tested the effects of brief exposure to a single, online instance of marketing material containing a single MEC at a single point in time. It is possible that the use intentions and risk perceptions of the SP may change, strengthen, or weaken with repeated exposure to the same claim presented within the same or different forms of marketing materials over longer periods of time. The study did not assess actual use of the SP or any other tobacco product following exposure to the claim. No conclusions can be drawn, therefore, about the actual behavioral effects of advertising materials or of any mediation effects of this relationship by SP use intentions or risk perceptions. Exposure to actual physical products and marketing materials with claims in real-world retail settings may also elicit use intentions and risk perceptions of the SP that differ from those elicited by this study's online presentation of 2-dimensional product-related imagery. Prospective observational and interventional studies can address these limitations. In particular, regulatory assessments of the public health impact of a MEC would benefit from longitudinal examination of (1) the stability of use intentions over time following a single exposure to the claim, (2) the effects of increasing the frequency of claim exposure, (3) the effects of exposure to different claims on both behavioral intentions and actual tobacco product use and switching behavior, and (4) the extent to which SP use intentions predict subsequent use behavior. Lastly, sampling from research panels may limit the generalizability of results to the general US adult population. For example, this study recruited a higher proportion of participants who had completed at least some college education (3185/3852, 82.7%) than is found in the general US adult population (63.3%) [37], which may have yielded higher levels of claim comprehension than may be found in the general population.

Conclusion

Adult TNP users and nonusers understood the claim that switching completely from cigarettes to the SP significantly reduces exposure to harmful chemicals. Viewing marketing materials for the SP with and without the claim simultaneously generated high levels of use intention among adult tobacco users and low levels of use intention among TNP nonusers. Results suggest that marketing the SP with (versus without) the MEC may increase use intentions and reduce risk perceptions of the SP relative to cigarettes among adults who smoke, both of which are known promoters of cigarette to e-cigarette switching behavior.

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Data Availability

We are committed to transparency and will consider any requests for underlying data, provided that such data may be shared under applicable laws.

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Authors' Contributions

Conceptualization: ME, SR, PM, GK, CR
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Validation: ME, SR, PM
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Data curation: AS
Formal analysis: GK
Writing – original draft: ME, SR, PM, GK, CR
Writing – review & editing: ME, SR, PM, GK, CR

Conflicts of Interest

PM, ME, AS, and SR are employees of Philip Morris Products SA and hold stocks in Philip Morris International. GK was formerly employed by ARGUS GmbH and contracted by Philip Morris Products SA as the biostatistician for the study and contributed to writing the manuscript. This study involved products developed by the Study Sponsor, Philip Morris Products SA. CR is a director of Russell Burnett Research and Consultancy Ltd (RBRC). RBRC received funding for medical writing services from the study sponsor of the publication, Philip Morris Products SA. In the past 5 years, RBRC has received funding to provide research and/or consultancy services to tobacco and nicotine product manufacturers and contract research organizations on tobacco harm reduction and individuals' use and perceptions of noncombustible tobacco and nicotine products, including electronic nicotine delivery systems, modern oral products, and heated tobacco products.

Multimedia Appendix 1
Participant group definitions, marketing materials, claim comprehension results, disposition, use characteristics, and modified exposure claim comprehension measures.
[DOCX File , 1796 KB - formative_v10i1e85802_app1.docx]

Multimedia Appendix 2
CONSORT checklist.
[DOCX File , 45 KB - formative_v10i1e85802_app2.docx]

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Abbreviations

ABOUT: Assessment of Behavioral Outcomes Related to Tobacco and Nicotine Containing Products
CONSORT: Consolidated Standards of Reporting Trials
ECU: adult e-cigarette users
FDA: United States Food and Drug Administration
FS: adult former smokers
ITU: intention to use
MEC: modified exposure claim
MRTP: modified risk tobacco product
S-IQ: adult smokers with an intention to quit
S-NIQ: adult smokers with no intention to quit
SP: study product
TNP: tobacco and nicotine products
TNU18-24: tobacco and nicotine products never-users aged 18-24 years
TNU25+: tobacco and nicotine products never-users aged 25 years and older

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Public Perceptions of AI in Medicine and Implications for Future Medical Education: Cross-Sectional Survey

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Abstract

Background: The integration of artificial intelligence (AI) into clinical practice is contingent on public trust. This trust often depends on physician oversight, yet a significant gap exists between the need for AI-competent physicians and the current state of medical education. While the perspectives of students and experts on this gap are known, the views of the US general public remain largely unquantified.

Objective: This study aimed to assess US public perceptions regarding AI in medicine and the corresponding emergent needs for medical education. We specifically sought to quantify public trust in different diagnostic scenarios, concerns about physician overreliance on AI, support for mandatory AI education, and priorities for the future focus of medical training.

Methods: We conducted a cross-sectional, web-based survey of adults in the United States in November 2025. Participants (N=524) were recruited via SurveyMonkey Audience. We calculated descriptive statistics, frequencies, proportions (percentages), and 95% CIs for all main survey items.

Results: A total of 524 participants completed the survey. Most (n=329, 62.8%; 95% CI 58.6% - 66.9%) placed the most trust in a physician's diagnosis based on their expertise alone; only 7.8% (n=41; 95% CI 5.5% - 10.1%) trusted an AI-first diagnostic model. Trust was highly contingent on training: 93.9% (n=492) of participants rated formal physician training on AI limitations as "essential" or "very important." Widespread concern about physician overreliance on AI was reported, with 81.1% (n=425) being "very concerned" or "extremely concerned." Consequently, 85.1% (n=446) agreed or strongly agreed that training on AI use, ethics, and limitations should be mandatory in medical school. When asked about future educational priorities, 70.2% (n=368; 95% CI 66.3% - 74.1%) believed that medical education should focus on human-centered skills (eg, empathy and communication) over clinical skills.

Conclusions: The US public expressed conditional trust in medical AI, strongly preferring physician-led and critically supervised models. These findings reveal a clear public mandate for medical education reform. The public expects future physicians to be mandatorily trained to appraise AI, understand its limitations, and refocus their professional development on the human-centered skills that technology cannot replace.

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KEYWORDS

artificial intelligence; AI; medical education; public perception; survey; trust; curriculum; physician training

Introduction

The integration of artificial intelligence (AI) into clinical practice represents a significant paradigm shift in health care. While public awareness of AI in general is growing, understanding of its concrete applications in medicine, such as diagnostics or treatment, remains substantially lower [1]. As these technologies move from development to deployment, their acceptance hinges on a critical and complex challenge: patient trust.

Current evidence on patient trust presents a conflicted picture. Some US-based experiments indicate that patients may have a strong baseline preference for human-only care, demonstrating a significant AI trust gap where trust in a physician decreases when AI is used [2]. However, other large-scale US studies have found that the public is almost evenly split in their preference between a human specialist and an "AI clinic" [3].

This complex trust dynamic appears tied not to the technology itself but to its governance and the role of the human operator. Public attitudes are strongly driven by demands for high reliability and transparency [4], and qualitative studies confirm

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that "fear of insufficient human oversight" and a "need for training of end users" are key barriers to acceptance [5]. To improve patient acceptance of automated technology, recent research emphasizes the need to design for an "appropriate level of trust," ensuring that users understand how ambiguous clinical situations can challenge trust in AI outputs [6]. This places a heavy emphasis on the physician's ability to critically evaluate and safely implement AI tools, a competence that must be built through formal education.

However, a significant gap exists between this emergent need and the current state of medical training. Studies of physicians and medical students report low familiarity with AI concepts, with very few having taken any formal AI courses [7]. This gap is starkly illustrated in US medical schools, where over 91% of students believe that training on AI would be useful for their careers, yet an identical proportion (91%) either report that their schools do not offer such resources or are unsure of whether they exist [8]. This lack of formal education is systemic; in a 2025 survey of US osteopathic medical schools, 93% of deans reported having no student-focused generative AI policy, and among colleges without a policy, 79% had no formal plans for mandatory student training, and 73% had no plans for elective training [9]. Leaving students unprepared is especially risky given the dual nature of generative AI in medical education: while it can enhance learning, it also threatens to undermine cognitive autonomy if trainees internalize biased, inaccurate, or hallucinated content without expert guidance [10].

This creates a critical mismatch: the public's trust is contingent on physician oversight, yet physicians are not being systematically trained for this role. While the perspectives of students [8,11] and educational experts [2,12] on this gap are well documented, the views of the general public remain largely unquantified. It is unknown how the public perceives this training gap, whether they support educational mandates, or how they believe AI should reshape the priorities of medical education.

To address these gaps, this study was designed to assess the perceptions of the US general public regarding the intersection of AI, medicine, and medical education. Our primary objectives were to (1) assess public trust in different human-AI diagnostic scenarios, (2) quantify public concern about physician overreliance on AI, (3) measure public support for mandatory training on AI in medical schools, and (4) elicit public priorities for the future focus of medical education (human-centered vs clinical skills).

Methods

Study Design and Setting

We conducted a cross-sectional, descriptive study using a web-based survey. This study was designed to assess the perceptions of the general public in the United States regarding the role of AI in medicine and the corresponding needs for medical education. The survey was administered online in November 2025.

Participant Recruitment and Sampling

Participants were recruited from the United States using SurveyMonkey Audience (SurveyMonkey Inc), a commercial panel that provides access to a nonprobability, convenience sample of respondents. The survey was targeted at the general adult population. Inclusion criteria for participation were (1) being aged 18 years or older, (2) residing in the United States, and (3) providing digital informed consent to participate. Recruitment was systematically managed through the SurveyMonkey platform, which draws from a diverse pool of opted-in individuals who participate via partner panels or the SurveyMonkey Contribute program. On the basis of our defined inclusion criteria, the platform automatically routed eligible users to our web-based survey.

Survey Instrument

The survey instrument was a 12-item questionnaire developed by the study author comprising 7 main items and 5 demographic items. The main questions assessed several key domains: respondent trust in different diagnostic scenarios (eg, physician only and AI as a "second opinion"); perceptions on AI training and governance, including the importance of training on AI limitations, concerns about physician overreliance on AI, and mandatory AI education in medical schools; and ratings of physicians' current digital skills. The instrument also queried about opinions on the future focus of medical education (human-centered vs clinical skills) and respondents' experiences with physician reactions to patient-initiated discussions about AI-derived health information. Demographic data collected included age, gender, annual household income, and major US region. All questions were presented in a multiple-choice format.

Data Analysis

All analyses were descriptive in nature. Initial data processing and frequency calculations were performed using SurveyMonkey's built-in analysis tools. Data were then exported for further analysis. We calculated frequencies and proportions (percentages) for all categorical variables from the main survey questions and demographic items. The final analysis and data handling were conducted using Python (version 3.13; Python Software Foundation). Given the descriptive, cross-sectional design, no inferential statistical tests for causation were performed. For all proportions, 95% CIs were calculated using the normal approximation to the binomial distribution.

Ethical Considerations

This study was conducted in accordance with the Declaration of Helsinki ethical principles for research involving human participants. All participants were presented with a digital information sheet on the survey's landing page, which detailed the study's purpose, the voluntary nature of participation, and the anonymity of their responses. Consent was obtained digitally before participants could proceed to the questionnaire. No personally identifiable information was collected, ensuring participant anonymity. Participants were recruited via SurveyMonkey and compensated through the platform's standard incentive scheme.

According to the Professional Code for Physicians in Bavaria [13], research projects involving strictly anonymized data are

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not subject to mandatory ethical consultation. Consequently, this study was exempt from formal institutional review board review given the anonymous nature of the data and the minimal risk posed to participants (involving opinions rather than sensitive personal health data).

Results

Participant Demographics

A total of 524 individuals completed the main survey questions. While 99.2% (n=520) of these participants provided data on age, gender, income, and device type, slightly fewer (n=516, 98.5%) provided their US region. The participant characteristics are detailed in Table 1.

Table . Characteristics of the survey participants (n=520).

Characteristics	Participants, n (%)
Age group (y)	
18-29	23 (4.4)
30-44	196 (37.7)
45-60	210 (40.4)
>60	91 (17.5)
Sex	
Male	340 (65.4)
Female	180 (34.6)
Household income (US $)	
0-9999	24 (4.6)
10,000-24,999	26 (5.0)
25,000-49,999	56 (10.8)
50,000-74,999	47 (9.0)
75,000-99,999	33 (6.3)
100,000-124,999	52 (10.0)
125,000-149,999	77 (14.8)
150,000-174,999	55 (10.6)
175,000-199,999	79 (15.2)
≥200,000	50 (9.6)
Prefer not to answer	21 (4.0)

Most respondents (340/520, 65.4%) were male. The most common age groups were 45 to 60 years (210/520, 40.4%) and 30 to 44 years (196/520, 37.7%). Respondents were predominantly from the Pacific (190/516, 36.8%) and Mid-Atlantic (122/516, 23.6%) regions. The cohort represented a wide range of annual household incomes, with the most frequent brackets being US $175,000 to US $199,999 (79/520, 15.2%) and US $125,000 to US $149,999 (77/520, 14.8%). The vast majority of participants (499/520, 96.0%) responded via a mobile device, with Android phones or tablets being the most common (335/520, 64.4%).

Trust in Diagnostic Scenarios

Participants were first asked the following question: “If you needed a complex diagnosis, which of the following scenarios would you trust the most?”

As shown in Figure 1, the vast majority of respondents (329/524, 62.8%; 95% CI 58.6% - 66.9%) selected the option “The doctor makes the diagnosis based only on their own expertise.” The second most common response was “The doctor makes a diagnosis first, and then uses AI to confirm it (AI as a ‘second opinion’),” chosen by 26.7% (140/524; 95% CI 22.9% - 30.5%) of the participants. Substantially fewer participants opted for the inverse scenario, “The AI makes a diagnosis first, and the doctor then reviews and confirms it (Doctor as a ‘second opinion’),” at 7.8% (41/524; 95% CI 5.5% - 10.1%). A small fraction (14/524, 2.7%; 95% CI 1.3% - 4.1%) selected “I have no preference/I don’t know.”

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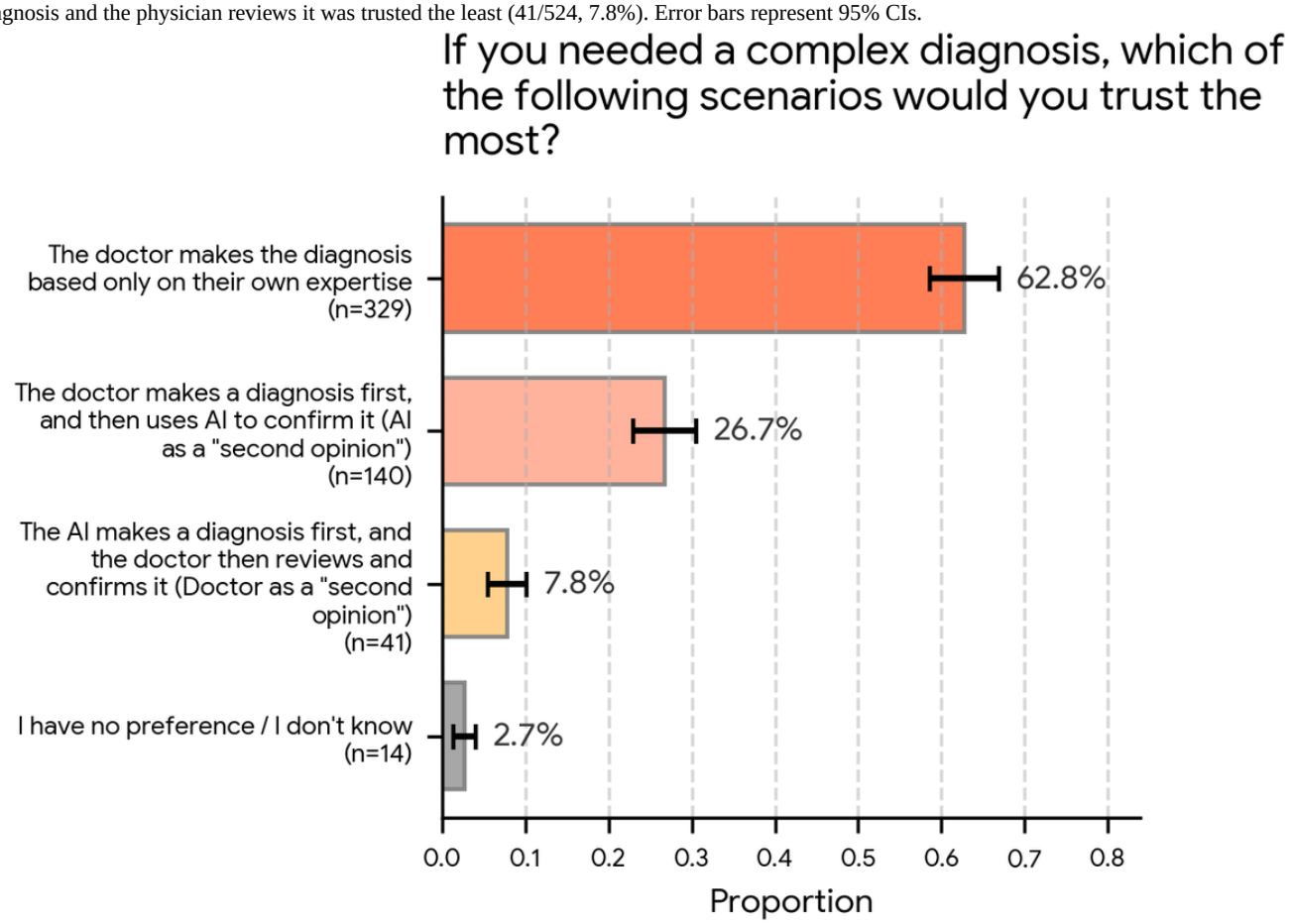
Figure 1. Public trust in different diagnostic scenarios involving physicians and artificial intelligence (AI; N=524). When asked which scenario they would trust most for a complex diagnosis, most (329/524, 62.8%) selected the physician's diagnosis based on their expertise alone. The next most trusted scenario was the physician making the diagnosis first and then using AI to confirm it (140/524, 26.7%). The scenario in which AI makes the initial diagnosis and the physician reviews it was trusted the least (41/524, 7.8%). Error bars represent 95% CIs.



Perceived Importance of Physician Training on AI Limitations

To gauge expectations regarding physician competency, participants were asked the following: "How important is it for your personal trust in a doctor's decision, to know that the doctor has been formally trained to understand the limitations and potential errors of the AI systems they use?"

The responses, detailed in Figure 2, indicate that such training is overwhelmingly viewed as critical for patient trust. A vast majority of respondents rated this training as either "essential" (311/524, 59.4%; 95% CI 55.1% - 63.6%) or "very important" (181/524, 34.5%; 95% CI 30.5% - 38.6%).

Together, 93.9% (492/524) of the participants considered this formal training to be at least "very important." In contrast, very few respondents rated it as "moderately important" (22/524, 4.2%; 95% CI 2.5% - 5.9%), "slightly important" (4/524, 0.8%; 95% CI 0.0% - 1.5%), or "not important at all" (6/524, 1.1%; 95% CI 0.2% - 2.1%).

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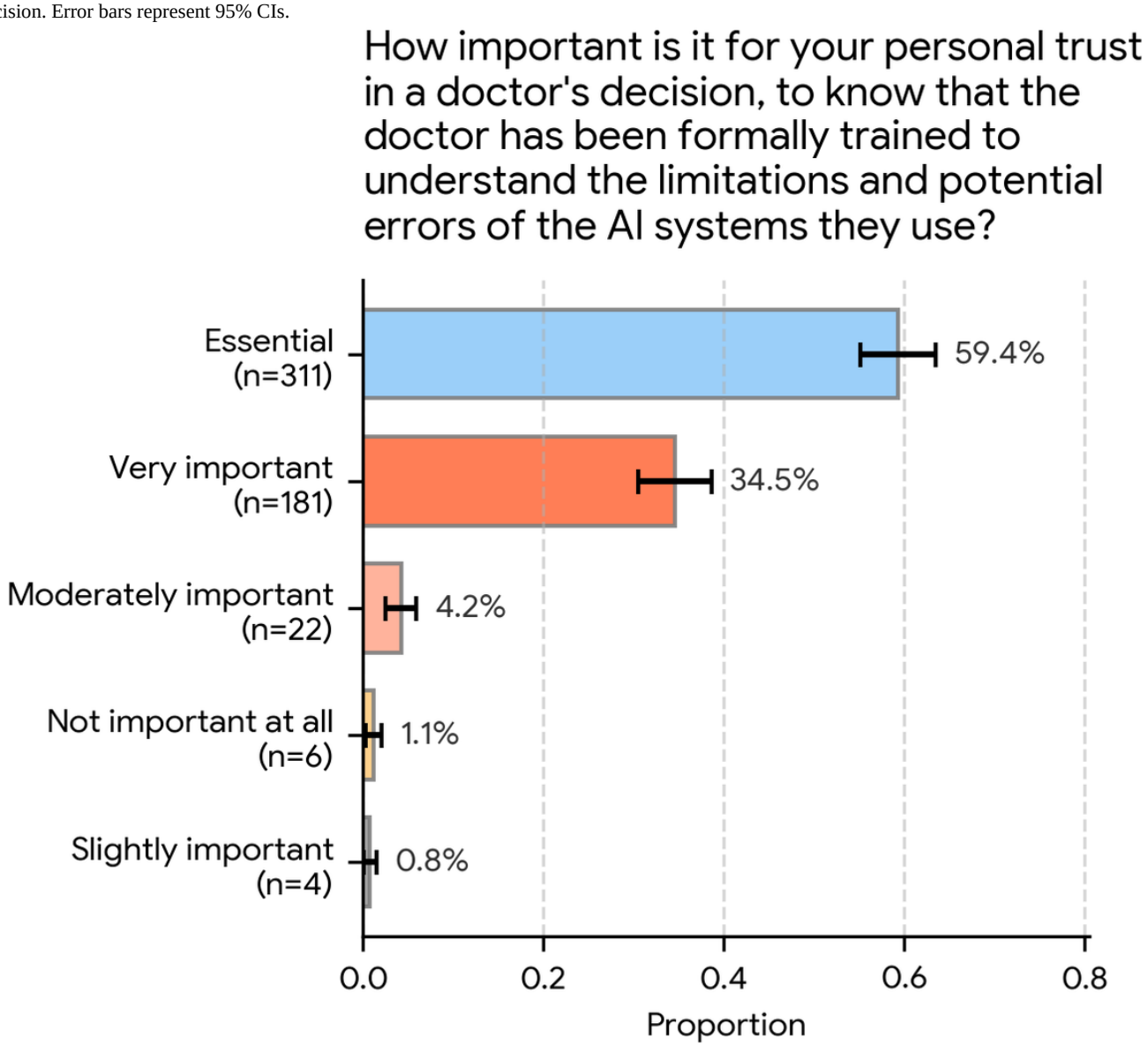
Figure 2. Perceived importance of formal physician training on artificial intelligence (AI) limitations (N=524). Respondents rated the importance of a physician being formally trained to understand the limitations and potential errors of the AI systems they use. An overwhelming cumulative majority of 93.9% (492/524) rated this training as "essential" (311/524, 59.4%) or "very important" (181/524, 34.5%) for their personal trust in the physician's decision. Error bars represent 95% CIs.



Concern About Physician Overreliance on AI

The survey also explored public concern about the potential for physician overreliance on AI. Participants were asked the following: "How concerned are you that future doctors might rely too much on AI for diagnosing patients, without critically questioning the AI's results?"

As Figure 3 illustrates, concern was widespread and strong. Most respondents (291/524, 55.5%; 95% CI 51.3% - 59.8%) reported being "extremely concerned," and another 25.6% (134/524; 95% CI 21.8% - 29.3%) reported being "very concerned."

Cumulatively, 81.1% (425/524) of the participants were "very concerned" or "extremely concerned" about this issue. A smaller group expressed moderate concern (79/524, 15.1%; 95% CI 12.0% - 18.1%), whereas very few were "slightly concerned" (14/524, 2.7%; 95% CI 1.3% - 4.1%) or "not concerned at all" (6/524, 1.1%; 95% CI 0.2% - 2.1%).

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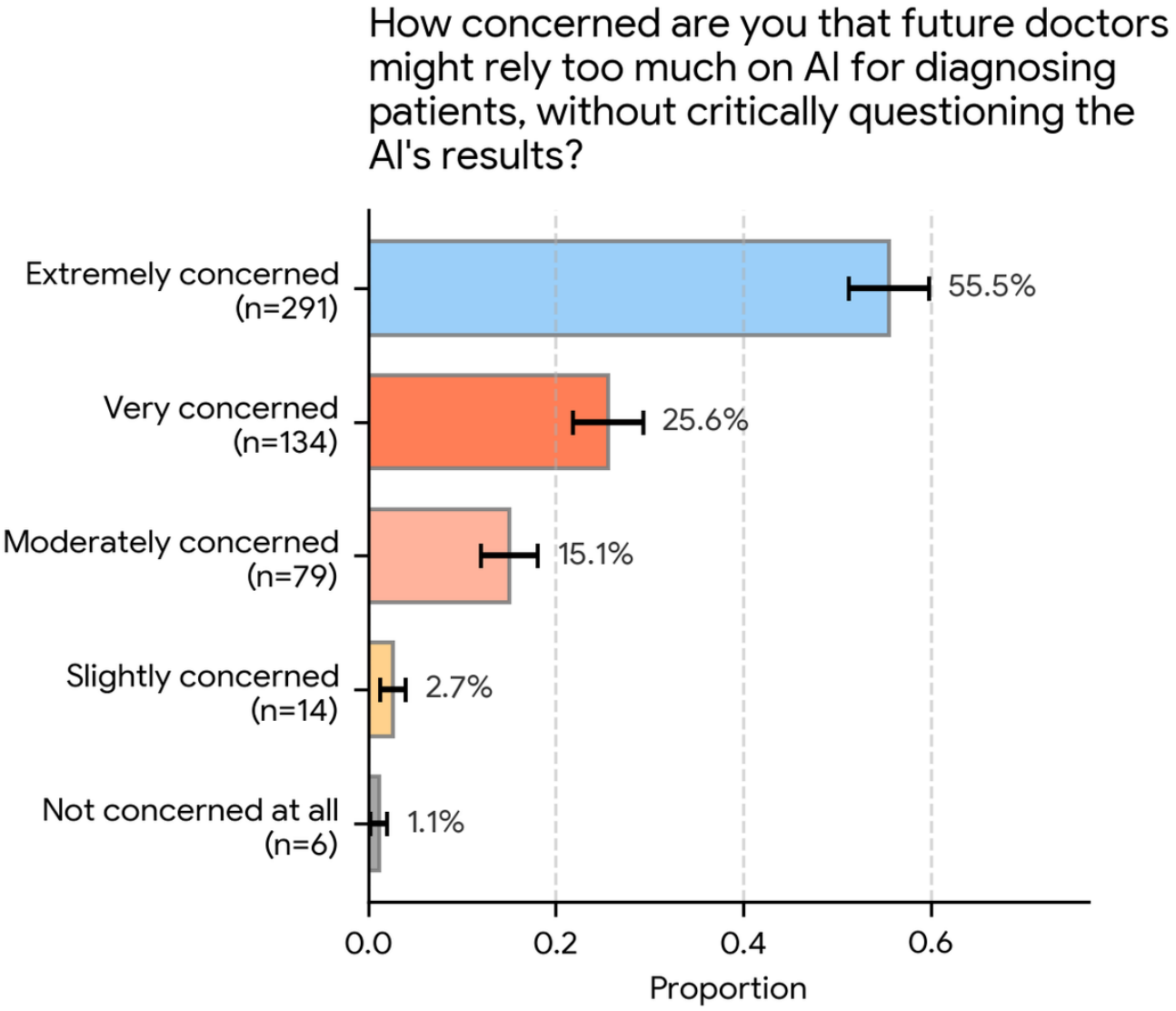
Figure 3. Public concern regarding future physician overreliance on artificial intelligence (AI; N=524). Participants rated their concern that future physicians might rely too much on AI results without critical questioning. A cumulative total of 81.1% (425/524) of the participants reported being "extremely concerned" (291/524, 55.5%) or "very concerned" (134/524, 25.6%) about this potential overreliance.



Support for Mandatory AI Education in Medical Schools

To connect public concern with actionable policy, the survey asked participants the following: "To what extent do you agree or disagree with the following statement: 'Training on the use, ethics, and limitations of Artificial Intelligence should be a mandatory (required) part of medical school education.'"

As shown in Figure 4, there was overwhelming agreement with this statement. Most participants (322/524, 61.5%; 95% CI 57.3% - 65.6%) selected "strongly agree," and an additional 23.7% (124/524; 95% CI 20.0% - 27.3%) selected "agree."

Combined, 85.1% (446/524) of all respondents agreed or strongly agreed that this training should be mandatory. A small portion remained "neutral" (52/524, 9.9%; 95% CI 7.4% - 12.5%), whereas only 5.0% (26/524) in total selected either "disagree" (13/524, 2.5%; 95% CI 1.1% - 3.8%) or "strongly disagree" (13/524, 2.5%; 95% CI 1.1% - 3.8%).

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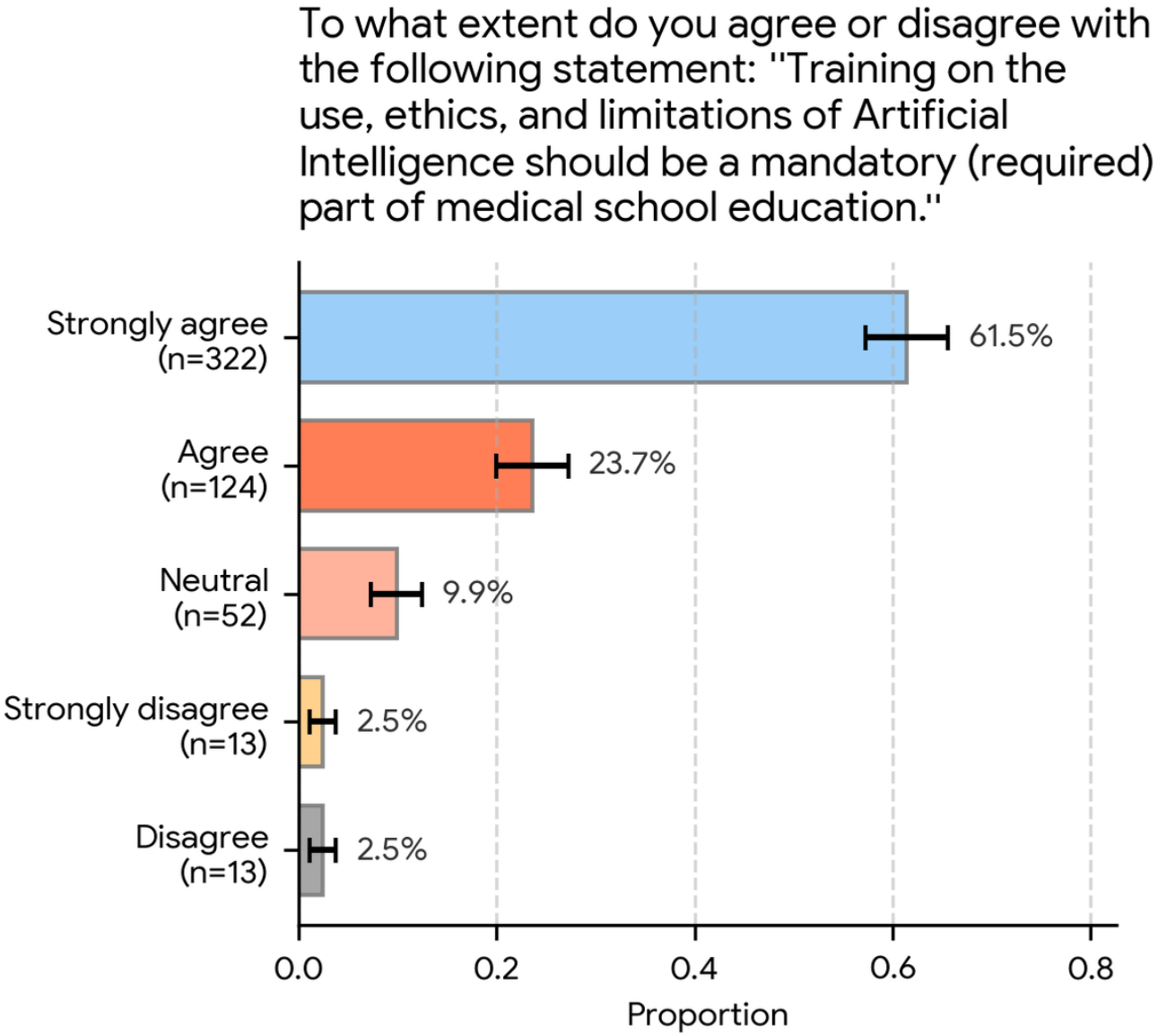
Figure 4. Support for mandatory artificial intelligence (AI) education in medical schools (N=524). Participants overwhelmingly agreed that training on the use, ethics, and limitations of AI should be a mandatory part of medical school education. A combined 85.1% (446/524) agreed or strongly agreed, with 61.5% (322/524) strongly agreeing. Error bars represent 95% CIs.



Public Perception of Physicians' Current Digital Skills

Participants were asked to rate their perception of physicians' current digital proficiency using the following question: "Based on your general experience with the healthcare system, how would you rate the current digital skills of most doctors (e.g., using electronic health records, video consultations, or patient data from apps)?"

The responses, shown in Figure 5, were generally positive. Just under half (261/524, 49.8%; 95% CI 45.5% - 54.1%) of the participants rated physicians' skills as "very good," and 29.8% (156/524; 95% CI 25.9% - 33.7%) rated them as "good."

Collectively, nearly 80% (417/524, 79.6%) of respondents held a positive view ("good" or "very good") of physicians' digital skills. A smaller group rated them as "average" (84/524, 16.0%; 95% CI 12.9% - 19.2%). Very few participants perceived these skills as "poor" (16/524, 3.1%; 95% CI 1.6% - 4.5%) or "very poor" (7/524, 1.3%; 95% CI 0.4% - 2.3%).

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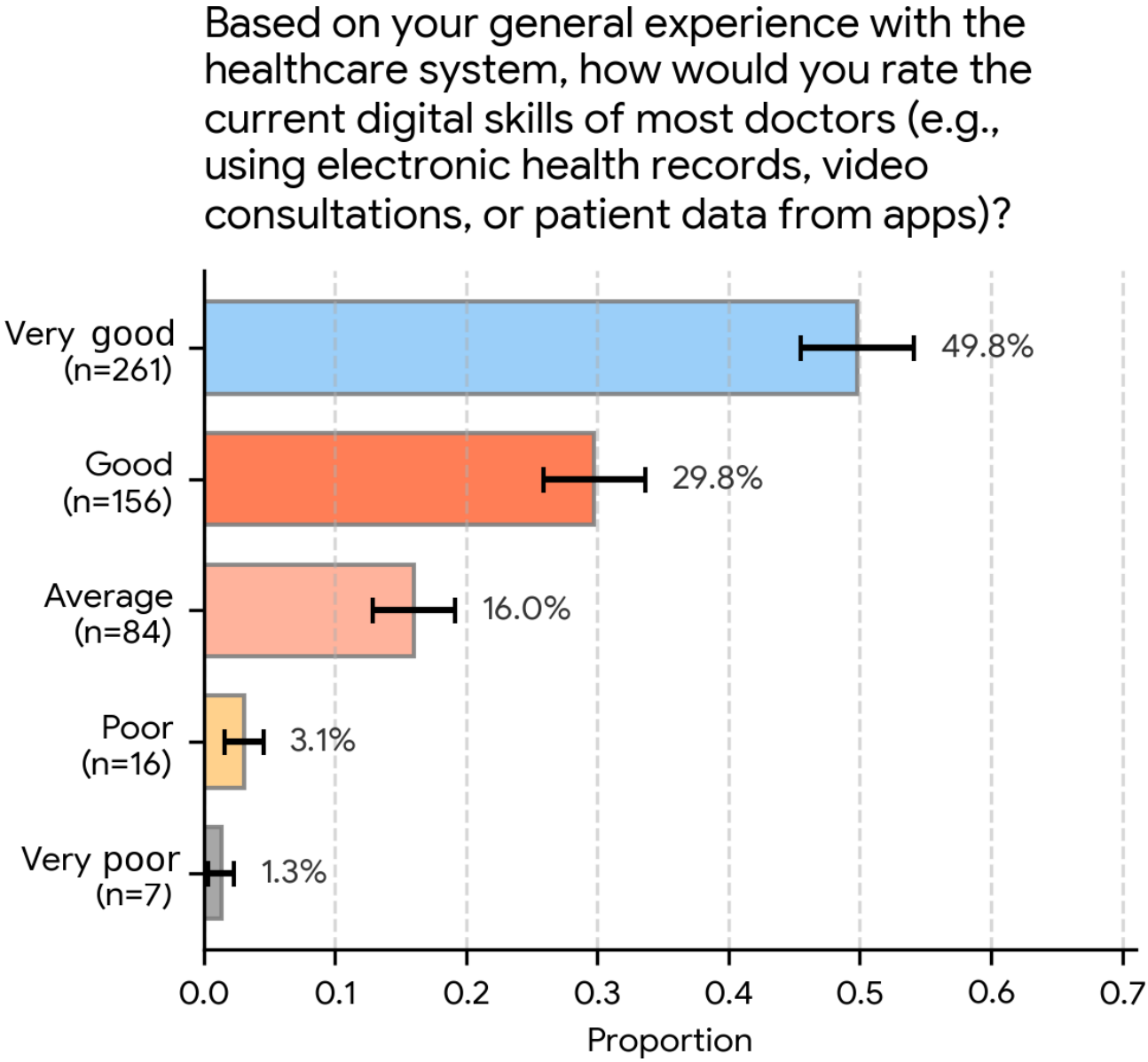
Figure 5. Public perception of the current digital skills of most physicians (N=524). Respondents rated the digital skills of most physicians (eg, using electronic health records or patient data from apps). A positive view was held by nearly 80% (417/524, 79.6%), rating physicians' skills as "very good" (261/524, 49.8%) or "good" (156/524, 29.8%). Error bars represent 95% CIs.



Future Priorities for Medical Education

Participants were asked to make a direct choice about the future focus of medical training using the following question: "Assuming AI will reliably handle more technical tasks (like analyzing scans) in the future, where should medical education place its primary focus to train better doctors?"

As Figure 6 shows, the response was a decisive, binary choice. A large majority of respondents (368/524, 70.2%; 95% CI 66.3% - 74.1%) believed that the primary focus should be "On human-centered skills (empathy, patient communication, and ethical judgment)."

Conversely, 29.8% (156/524; 95% CI 25.9% - 33.7%) believed that the focus should remain "On clinical skills (e.g., physical examination, surgery)."

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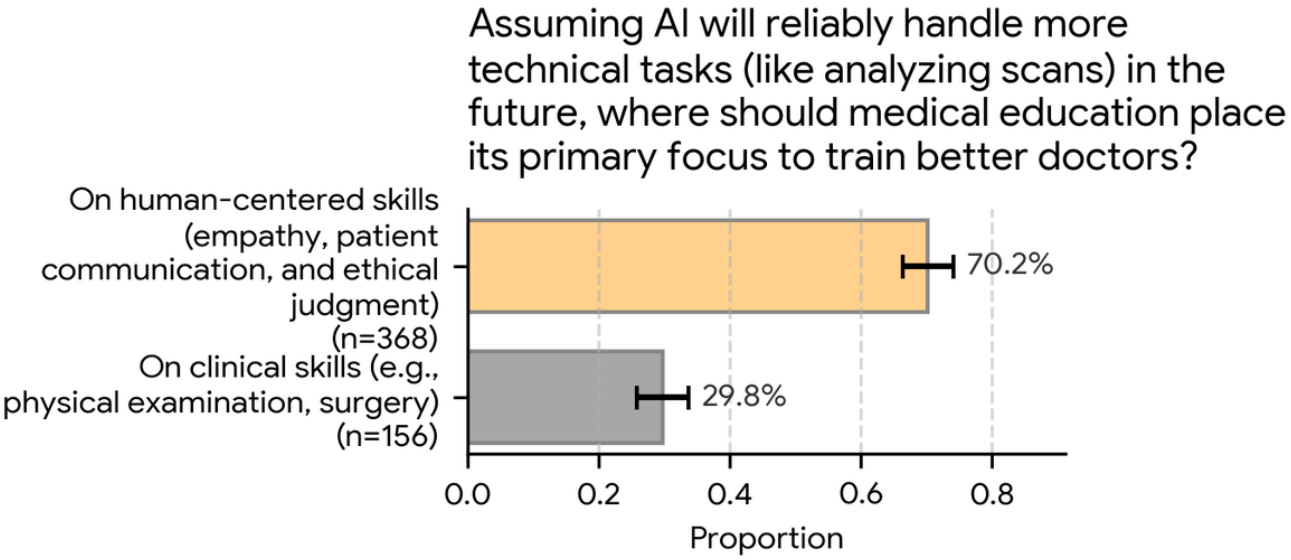
Figure 6. Priorities for future medical education focus (N=524). Assuming that artificial intelligence (AI) will reliably handle technical tasks (such as analyzing scans) in the future, participants were asked where medical education should focus. A large majority (368/524, 70.2%) prioritized "human-centered skills (empathy, patient communication, and ethical judgment)" over "clinical skills" (156/524, 29.8%). Error bars represent 95% CIs.



Patient-Reported Physician Reactions to AI-Informed Discussions

Finally, the survey assessed participants' real-world experiences by asking the following: "Thinking about that consultation when you discussed AI information on symptoms, which of the following examples best describes how your doctor reacted?"

As Figure 7 details, the most commonly reported reaction was positive. Most participants (305/524, 58.2%; 95% CI 54.0% - 62.4%) selected the "Collaborative / Positive" response, exemplified by "That's interesting, let's review this together."

The second most frequent reaction was "Neutral / Indifferent" (eg, "I see" followed by their own assessment), reported by 24.4% (128/524; 95% CI 20.7% - 28.1%). A smaller group of 9.0% (47/524; 95% CI 6.5% - 11.4%) indicated that "None of the answers" fit their experience.

Negative reactions were the least common. Only 5.7% (30/524; 95% CI 3.7% - 7.7%) reported a "Dismissive/Negative" reaction (eg, "Please don't use those tools, they are unreliable"), and 2.7% (14/524; 95% CI 1.3% - 4.1%) reported a "Defensive/Challenged" reaction.

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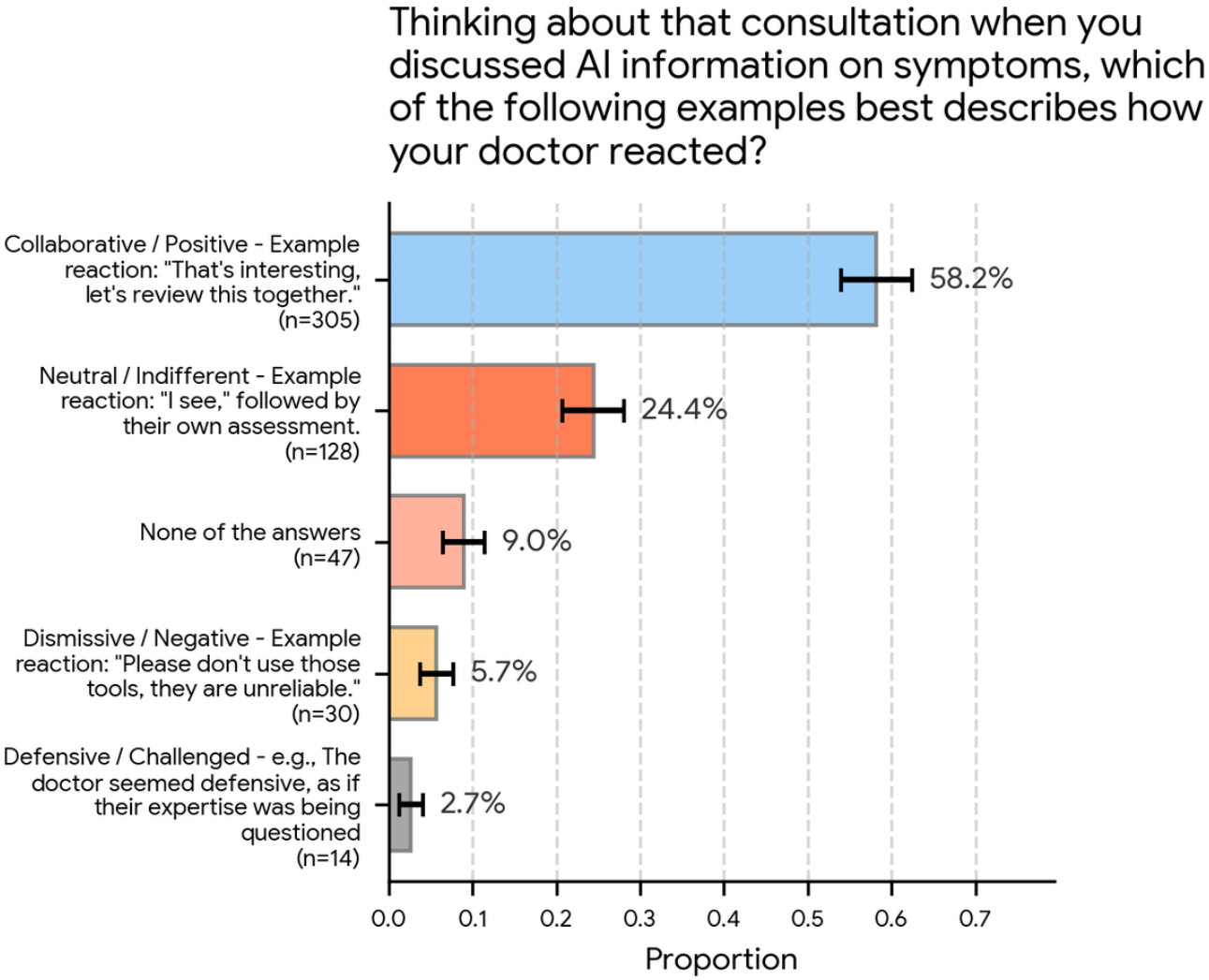
Figure 7. Patient-reported physician reactions when discussing artificial intelligence (AI) information on symptoms (N=524). Participants reported how their physician reacted during a consultation when information derived from AI regarding symptoms was discussed. The most common reaction was "Collaborative / Positive" (305/524, 58.2%), followed by a "Neutral / Indifferent" reaction (128/524, 24.4%). Negative or defensive reactions were reported by small minorities. Error bars represent 95% CIs.



Discussion

Principal Findings

In this national web-based survey of adults in the United States, respondents expressed a clear preference for physician-led diagnosis in complex clinical scenarios. Almost two-thirds (329/524, 62.8%; 95% CI 58.6% - 66.9%) indicated highest trust in a scenario in which the physician made a diagnosis based only on their own expertise. In contrast, only approximately one-quarter preferred a model where the physician made the initial diagnosis and then consulted AI as a "second opinion" (140/524, 26.7%; 95% CI 22.9% - 30.5%). Very few respondents favored AI making the first diagnosis with a physician as the checker (41/524, 7.8%; 95% CI 5.5% - 10.1%).

At the same time, trust in physicians' use of AI was strongly contingent on formal training. An overwhelming majority (492/524, 93.9%) rated training on AI limitations and potential errors as at least "very important" for their personal trust. More than four-fifths (425/524, 81.1%) reported being "very concerned" or "extremely concerned" that future physicians might rely too heavily on AI. Consequently, most respondents (446/524, 85.1%) supported mandatory AI education in medical schools. Respondents generally perceived physicians' current digital skills as "good" or "very good" (417/524, 79.6%). However, when asked where medical education should primarily focus assuming reliable AI for technical tasks, a clear majority (368/524, 70.2%; 95% CI 66.3% - 74.1%) prioritized human-centered skills such as empathy, communication, and ethical judgment. When reflecting on consultations in which they had discussed AI-derived health information, most participants recalled collaborative or positive physician reactions (305/524, 58.2%; 95% CI 54.0% - 62.4%), with overtly dismissive or defensive responses described only by a small minority.

These findings suggest that, while the public expresses significant caution and specific concerns regarding autonomous AI diagnostics, there is a clear preference for AI to be integrated as a supportive, physician-led tool rather than being rejected entirely. The data reflect a nuanced "guarded acceptance," where trust is contingent on human oversight and formal medical training.

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Public Trust in Diagnostic Scenarios and Preference for Physician-Led Care

Our diagnostic scenario findings dovetail with experimental work showing that people remain cautious about AI when it is introduced into core clinical decision-making. In a randomized online experiment with 1762 American adults, Chen and Cui [2] found that simply describing a physician as using AI assistance reduced both trust and intention to seek care compared with identical vignettes that either did not mention AI or explicitly stated that the physician did not use AI. On a scale from 0 to 1, mean trust and help-seeking scores were highest when AI was explicitly absent and lowest when AI was used "extensively," with large negative effects of AI use on intention to seek care. Previous behavioral work by Longoni et al [14] also demonstrated that patients may avoid AI even when its performance is presented as equivalent to that of a physician: in one experiment, 40% of participants enrolled when a free stress diagnosis was described as being performed by a human clinician, but only 26% enrolled when the same service was described as being provided by a computer despite identical accuracy information across conditions.

Experimental data on human-AI collaboration further support the idea that the public prefers physician-led models where AI acts as an adjunct rather than a primary decision-maker. In an online study of patients in the United States, Esmaeilzadeh et al [15] compared scenarios in which diagnoses were provided by AI alone, a physician alone, or a physician collaborating with AI. On a trust scale from 5 to 25, marginal mean trust scores were lowest for AI-only scenarios (16.0) followed by AI and physician scenarios (17.1) and were highest for physician-only scenarios (18.4). Our finding that respondents trusted a physician-only diagnosis the most (329/524, 62.8%; 95% CI 58.6% - 66.9%) followed by a physician-first-then-AI model (140/524, 26.7%; 95% CI 22.9% - 30.5%) while showing little enthusiasm for AI-first scenarios (41/524, 7.8%; 95% CI 5.5% - 10.1%) is consistent with these results.

Multinational patient surveys also show a similar structure of attitudes. In a large study of 13,806 hospital patients, Busch et al [16] reported that 57.6% of respondents held a positive view of AI in health care overall, yet less than half (43.6%) trusted AI to provide reliable diagnostic information. Only 4.4% preferred fully autonomous AI systems; in contrast, most wanted physician-led decision-making.

Expectations for Training, Governance, and Avoidance of Overreliance

Participants in this survey linked their trust in clinicians who use AI to explicit, formal training on the limitations and potential errors of AI systems. Nearly 60% (311/524, 59.4%; 95% CI 55.1% - 63.6%) rated such training as "essential," and a further 34.5% (181/524; 95% CI 30.5% - 38.6%) rated it as "very important." This demand is likely driven by the widespread concern that future physicians might rely too much on AI, with 81.1% (425/524) of our sample being "very concerned" (134/524, 25.6%; 95% CI 21.8% - 29.3%) or "extremely concerned" (291/524, 55.5%; 95% CI 51.3% - 59.8%) about this issue. These expectations mirror themes identified in qualitative work where participants stressed worries about safety and bias, emphasizing that clinicians should act as safeguards who check and contextualize AI outputs [17].

Support for Mandatory AI Education in Medical Schools

The high level of agreement in our sample regarding AI-related training aligns with expectations observed in surveys of health profession students. In Canada, Teng et al [11] found that 78.77% of students expected AI to affect their careers. A similar pattern can be found among American medical students; Liu et al [8] reported that 91.5% agreed that training on AI would be useful. However, only 8.8% indicated that their schools provided such resources, and only 8.7% had any formal training on AI.

Our survey did not ask respondents to design curricula, but the finding that 85.1% (446/524) agreed that training on AI use, ethics, and limitations should be mandatory, with 61.5% (322/524; 95% CI 57.3% - 65.6%) "strongly" agreeing and 23.7% (124/524; 95% CI 20.0% - 27.3%) agreeing, suggests that public expectations and student aspirations are aligned. This convergence suggests a shared expectation between future professionals and the public that AI topics should be formally addressed in curricula. Our findings suggest that public support for AI education is not necessarily an endorsement of AI-driven care itself but rather a demand for risk mitigation. Just as patients in acute settings, such as the emergency department, may prefer human-only care but accept technology if it improves efficiency, they demand that such use be strictly supervised. Consequently, the public views training on AI as an essential safeguard; they want physicians to be "AI literate" specifically to understand the limitations of these tools and limit potential harms. This shifts the narrative of medical education from simply "learning to use AI" to "learning to safely oversee AI." This highlights an ongoing conversation for medical educators regarding how to best integrate AI literacy without compromising existing clinical training. This does not necessarily require entirely new departments. AI can be integrated as a tool for "learning support" and "personalized learning pathways" [18]. Practical models for this implementation are already emerging. For example, a web-based, self-guided elective course for senior medical students, which focused on dataset analysis and project-based learning, demonstrated an increase in self-reported confidence in AI skills and received high qualitative satisfaction ratings from participants [12]. Such models provide a feasible blueprint for developing the critical appraisal and technical understanding that our findings show the public expects from future physicians.

Digital Skills and the Call for Human-Centered Training Priorities

Respondents in this study tended to view physicians as already reasonably digitally competent. Nearly 80% (417/524, 79.6%) rated physicians' digital skills as "good" (156/524, 29.8%; 95% CI 25.9% - 33.7%) or "very good" (261/524, 49.8%; 95% CI 45.5% - 54.1%). Nevertheless, when asked to identify where medical education should place its primary focus if AI reliably handles more technical tasks, a clear majority (368/524, 70.2%; 95% CI 66.3% - 74.1%) favored human-centered skills—empathy, patient communication, and ethical

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judgment—over core clinical procedures (156/524, 29.8%; 95% CI 25.9% - 33.7%).

This preference aligns with a systematic review that found that participants consistently voiced concerns about loss of human contact and expressed a preference for AI systems operating under human oversight [19]. Our findings suggest that the public does not see digital skills and human-centered skills as competing priorities; rather, they appear to treat digital competence as a given and want any "freed capacity" from AI to be reinvested in the human aspects of care.

Patient-Physician Interactions Regarding AI-Derived Information

An additional contribution of this study is the focus on patient-reported experiences. Among respondents who recalled such interactions, most described their physicians' reactions as collaborative or positive (305/524, 58.2%; 95% CI 54.0% - 62.4%), with roughly one-quarter (128/524, 24.4%; 95% CI 20.7% - 28.1%) describing a neutral reaction. Only small minorities reported dismissive or defensive responses. This suggests that, at least in this online US sample, many clinicians may already be engaging with AI-derived information in ways that align with patient expectations for partnership, providing a strong foundation for the human-centered model of care that our respondents prioritized.

Limitations

Several limitations must be considered. First, this study used a nonprobability convenience sample recruited via SurveyMonkey Audience and is not statistically representative of the general US population. Respondents were predominantly male (340/520, 65.4%) and more often reported higher income brackets. Additionally, the youngest adult demographic (18 - 29 years) was notably underrepresented (23/520, 4.4%), which is a relevant limitation as younger, potentially more "AI-native" populations might hold different perspectives on automated diagnostics. Finally, almost all participants completed the survey on mobile devices (499/520, 96.0%), which may indicate a group that is generally more digitally engaged.

Second, all measures were self-reported attitudes collected in hypothetical scenarios. Expressed trust, concerns, and preferences may not fully predict actual behavior. Recall of physician reactions is also subject to memory and social desirability bias.

Third, the survey instrument was intentionally concise. We did not distinguish between different types of AI systems (eg, imaging algorithms and generative chatbots) or different clinical contexts, nor did we collect qualitative data.

Specifically, we must explicitly acknowledge that certain terms used in the survey, such as "complex diagnosis," were not clinically defined. While this phrasing was intended to convey a high-stakes health scenario to a lay audience without using medical jargon, it is highly subjective. Because we do not know what specific medical scenario the respondents were imagining, their reported levels of trust must be interpreted with caution. For instance, had respondents envisioned a life-or-death emergency (eg, acute trauma), their willingness to accept AI involvement even merely as a "second opinion" might have been substantially lower than if they had imagined a chronic disease diagnostic dilemma. Additionally, public support for mandatory training on AI may be inflated as the survey did not present the zero-sum trade-offs inherent in crowded medical curricula, where adding new topics requires sacrificing existing clinical training.

Finally, the framing of specific survey items may have introduced a priming effect. For example, prefacing a question with the assumption that AI will "reliably handle more technical tasks" could have inadvertently biased respondents toward a more optimistic view of AI's capabilities, potentially influencing their responses to other items. This optimistic phrasing contrasts with the complex reality of real-world AI deployment. For instance, despite immense initial optimism regarding AI's ability to automate technical tasks such as analyzing medical imaging, comprehensive reviews have demonstrated that hundreds of predictive deep learning models developed for COVID-19 scan analysis failed clinical validation due to severe methodological flaws and lack of real-world generalizability [20]. Given these clinical realities and this rapidly evolving technological environment, our results should be interpreted as a time-bound snapshot. Replication in more diverse samples will be important.

Conclusions

Our study reveals that public acceptance of AI in medicine is not a blanket endorsement of automation but rather a "guarded acceptance" deeply contingent on human accountability. The findings suggest that, as AI becomes more prevalent, the value of the human-centered elements of care such as empathy, ethical judgment, and communication will not diminish but will likely become the primary benchmark of quality for patients.

Medical education must evolve beyond technical AI literacy. There is a clear public mandate to frame training on AI as a risk mitigation strategy, ensuring that physicians act as rigorous safeguards against algorithmic error rather than mere users. For policy and practice, this means that the integration of AI must be transparent and physician led. Any attempt to bypass human oversight in complex diagnostics may risk eroding the foundational trust of the patient-physician relationship. Ultimately, the successful deployment of AI in health care will depend less on the sophistication of the algorithms and more on the demonstrated competence of the clinicians who oversee them.

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During the preparation of this work, the author used Google Gemini primarily to check grammar and correct spelling. The author thoroughly reviewed and edited the text and takes final, sole responsibility for the content.

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Data Availability

The extracted dataset generated during this study is available from the corresponding author on reasonable request.

Conflicts of Interest

MCK is the editor of *JMIR Dermatology* at the time of this publication.

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Abbreviations

AI: artificial intelligence

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Artificial Intelligence Design for Race-Based Prostate Cancer Stage Classification With Multilayer Perceptron: Feature Selection Optimization Approach

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Abstract

Background: Prostate cancer progression exhibits significant variability influenced by biological and racial factors. DNA methylation profiling has shown potential in early cancer detection, but its integration with machine learning across racially diverse populations remains limited.

Objective: This study aimed to develop a prostate cancer stage classifier for the majority White cohort using DNA methylation data and a multilayer perceptron (MLP) model in order to classify prostate cancer stages into early (stages I-II) and late (stages III-IV) stages and assess its performance when applied to other racial groups to highlight the need for race-specific models.

Methods: Methylation and phenotype data from the TCGA-PRAD (The Cancer Genome Atlas Prostate Adenocarcinoma) dataset were processed using differentially methylated position (DMP) analysis to identify CpG sites correlated with cancer stages. These features were further refined through recursive feature elimination (RFE) and used to train MLP models. Shapley Additive Explanations (SHAP) and Local Interpretable Model-Agnostic Explanations (LIME) were used to interpret the model and identify key DNA methylation features contributing to model predictions.

Results: The best-performing model achieved 95% accuracy and up to 99% area under the curve on the majority race (White) training data using 90 selected features. However, performance declined sharply in racial minority groups, revealing the effects of sample imbalance and race-specific methylation patterns. Feature importance examination indicated strong patterns within certain CpG sites driving model predictions.

Conclusions: We propose a race-aware MLP model for prostate cancer stage classification using DNA methylation data, which has been optimized through DMP and RFE-based feature selection. SHAP and LIME confirmed the predictive relevance of selected CpG sites, supporting model transparency. The results highlight high performance within the White cohort but reveal poor generalization to racial minority groups, emphasizing the importance of race-specific modeling strategies.

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KEYWORDS

prostate cancer; multilayer perceptron; feature selection; DNA methylation; differentially methylated positions; race-aware model; explainable artificial intelligence

Introduction

Prostate cancer is one of the most frequently diagnosed cancers in men and a major cause of cancer-related deaths in the United States [1-3]. It is particularly prevalent among older individuals, with risk factors including age, family history, and lifestyle [4]. Biologically, prostate cancer is a heterogeneous disease, marked by distinct subtypes and gene expression profiles that influence prognosis and treatment outcomes [5-7]. These biological variants range in severity from slow-growing forms to aggressive and rapidly spreading types, affecting how the disease progresses and responds to therapy. This complexity poses a challenge for achieving accurate and consistent diagnosis across diverse patient populations.

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The classification of prostate cancer typically depends on the Gleason score and androgen receptor status, which inform tumor aggressiveness and therapeutic response [8]. Genetic mutations, including those involving *TMPRSS2-ERG*, *PTEN*, and *SPOP*, have also been implicated in disease progression [9-11]. Advances in sequencing and molecular profiling have enabled the discovery of new biomarkers for targeted treatment [12], yet many classification models still fail to capture the nuanced biological variation across cancer stages.

Next-generation sequencing (NGS) has seen rapid technological advancements over the years and has become central to exploring epigenetic regulation in cancer [13]. DNA methylation, an epigenetic mechanism that modifies gene expression without altering the sequence, is key to identifying biomarkers and understanding cancer development. NGS enables high-throughput, genome-wide methylation profiling, facilitating the discovery of fine-grained methylation patterns and their association with specific mutations [14-16]. However, the vast complexity of methylation data demands computational approaches that can extract clinically actionable insights, which remains a key challenge.

Methylation data analysis, especially differentially methylated position (DMP) analysis, addresses the high dimensionality of methylation profiles by identifying individual CpG sites with significant methylation differences between groups [17]. DMP analysis offers single-site resolution and is better suited for classification tasks compared with region-based methods like differentially methylated regions, especially when individual CpG sites are used as input features [18]. Statistical methods, such as *t* tests and linear models, help quantify these differences [19]. Despite their advantages, DMPs are rarely used in conjunction with machine learning models like multilayer perceptron (MLP) for stage-specific cancer classification, highlighting a gap that this research aims to address. Beyond genetic variation, accumulating evidence shows that DNA methylation profiles differ substantially between populations and racial or ethnic groups, reflecting both ancestry and the environment. Genome-wide studies have reported population-specific methylation patterns at thousands of CpG sites, with over one-third of genes showing differential methylation between African and European populations, often driven by differences in allele frequencies and gene-environment interactions. Ethnic differences in methylation have been replicated in multiple cohorts and tissues, including the blood and brain, and frequently map to loci linked to metabolic traits and other complex diseases. This indicates that epigenetic regulation is not universally shared across racial or ancestral groups but is shaped by socially patterned exposures, lifestyle, and genetic background [20-22].

MLP is a neural network model widely used for pattern recognition and classification in fields like bioinformatics, particularly cancer diagnostics [23-26]. It can effectively manage high-dimensional data, such as DNA methylation data, outperforming many traditional statistical approaches. MLP has been shown to identify cancer-specific biomarkers and classify cancer stages with high accuracy [27-29]. Beyond that, MLP also supports personalized therapy by improving diagnostic consistency. However, no prior studies have combined DMP-based feature selection with MLP for stage-specific cancer classification, making this approach a novel contribution to the field. This framework provides accurate race-based classification of prostate cancer for diagnosed individuals, offering an effective tool for rapid initial screening and preoperative assessment.

Although machine learning has significantly advanced cancer classification, current genome-based models often neglect racial disparities, particularly in DNA methylation patterns. A study by Abdollahi et al [30] introduced a radiomic-based framework for prostate cancer evaluation, utilizing machine learning techniques and magnetic resonance imaging (MRI) features to predict the treatment response, Gleason score, and cancer stage. The study involved 33 patients with prostate cancer who underwent T2-weighted (T2W) and apparent diffusion coefficient (ADC) MRI scans before and after intensity-modulated radiation therapy. Radiomic features were extracted from both image types, and univariate analysis combined with paired *t* tests identified significant features associated with treatment response. Feature selection and classification were performed using 10-fold cross-validation across various image sets, and the predictive performance of post-T2W radiomic models was the highest (area under the curve [AUC]=0.632), followed by pre-ADC models (AUC=0.626) and pre-T2W models (AUC=0.610). Additionally, T2W-based models had a mean AUC of 0.739 for Gleason score prediction, while ADC-based models performed better in stage prediction, with a mean AUC of 0.675. A study by Hartenstein et al [31] evaluated 3 convolutional neural networks (CNNs) trained to detect lymph node infiltration by prostate cancer, using contrast-enhanced computed tomography images. The models were tested against expert radiologists and achieved comparable performance. The best-performing CNN, trained on a status-balanced dataset, reached a high AUC of 0.90, primarily by learning anatomical context. In contrast, a location-balanced CNN and a segmentation-masked (xMask) CNN reached lower AUCs of 0.858 and 0.677, respectively. Random forest classifiers using only nodal volume and location performed well on status-balanced data (AUC=0.90) but poorly on location-balanced data (AUC=0.677), reinforcing that CNNs leveraged anatomical features in classification. A similar study by Eissa et al [32] utilized DNA methylation profiles to investigate the impact of feature selection in reducing the dimensionality of methylation data through metaheuristic techniques. The study was structured in 2 stages: the first stage focused on feature selection, and the second stage focused on developing a deep neural network (DNN) model to classify samples based on malignancy status and cancer type. The proposed method achieved competitive results compared with existing approaches, with strong performance in terms of recall, precision, and accuracy, along with excellent AUC values ranging from 0.85 to 0.89. While previous studies have achieved promising results using artificial neural network models, most have focused on imaging data, and the use of DNA methylation profiles as features remains relatively uncommon. Among the limited research using methylation data, few have attempted to classify malignant cancer stages, particularly in distinguishing early-stage disease from late-stage disease. Additionally, many models do not prioritize minimizing feature sets, which may

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reduce model interpretability and increase the risk of overfitting. Racial disparities in DNA methylation patterns are also often overlooked, with limited efforts to develop race-specific models despite known imbalances in publicly available datasets. Rather than attempting to learn a single model that generalizes across all racial groups, our primary objective was to build a high-performing, interpretable stage classifier within a specific race (White cohort) and then examine how its performance degrades in Asian and Black or African American patients. This design reflects a realistic scenario where models are trained in data-rich majority populations but deployed more broadly, and our findings argue for race-specific modeling and feature selection. To address these gaps, we utilized DNA methylation data and applied a combination of DMP and recursive feature elimination (RFE) to identify a minimal, high-impact set of features. We further validated the selected biomarkers using COSMIC (Catalog Of Somatic Mutations In Cancer) and cBioPortal [33] to ensure biological relevance. Our study introduced a race-aware MLP model focused on prostate cancer stage classification that specifically distinguished early stages from late stages, demonstrating the importance of both racial context and minimal feature sets in developing more accurate and equitable diagnostic tools.

Methods

Ethical Considerations

No human participants were directly involved in this study. All data were obtained from the publicly available Genomic Data Commons (GDC) TCGA-PRAD (The Cancer Genome Atlas Prostate Adenocarcinoma) dataset accessed via the University of California, Santa-Cruz (UCSC) Xena Browser (UCSC Xena compiles processed, deidentified The Cancer Genome Atlas [TCGA] files) [34,35]. The TCGA program collected specimens under institutional review board (IRB) oversight and with donor informed consent. Data made available through TCGA/GDC are deidentified and intended for secondary research use. As this work involved secondary analysis of publicly available, deidentified data, it did not require additional local IRB approval.

Study Design

This study implemented data collection, preprocessing, feature selection, and MLP modeling and evaluation, as seen in Figure 1. These methods were conducted with Python (version 3.12.3; Python Software Foundation) programming language and the necessary libraries using Visual Studio Code editor (version 1.95.3; Microsoft Corp).

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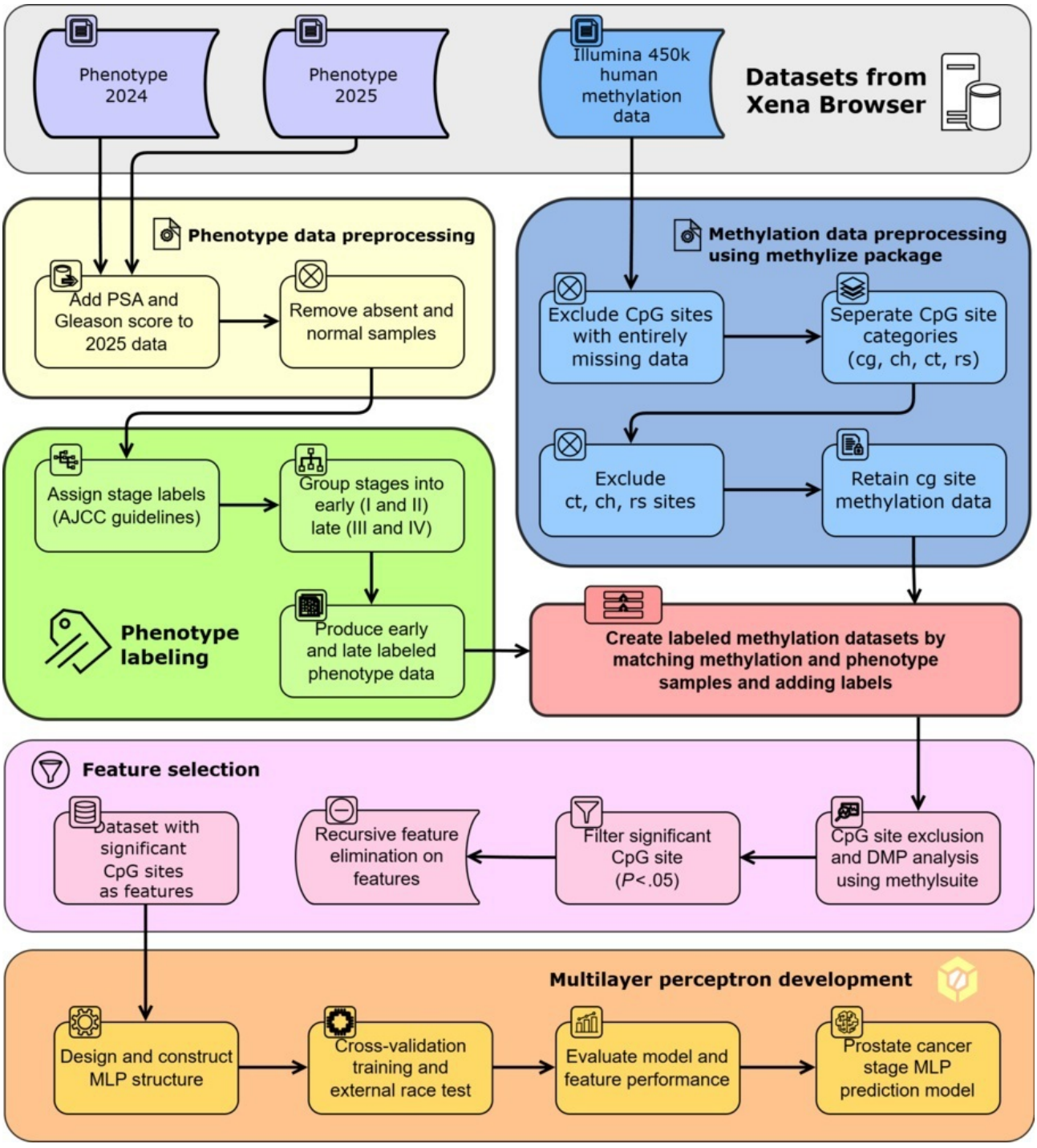
Figure 1. Datasets were sourced from Xena Browser and processed independently. Phenotype data were standardized for labeling, while Illumina 450k methylation data were preprocessed using the methylize package. CpG sites were categorized (cg, ch, ct, and rs); however, only cg sites were retained as others lacked sufficient methylation values. Phenotype samples were labeled according to AJCC 7th edition guidelines and binarized into "early" (stages I and II) and "late" (stages III and IV) groups. Following sample matching, feature selection was performed using methylsuite for differentially methylated position (DMP) analysis, followed by recursive feature elimination (RFE) to identify the most informative CpG sites. These features were used to develop a multilayer perceptron (MLP) model, featuring cross-validation and external race testing, to predict prostate cancer stages. AJCC: American Joint Committee on Cancer; PSA: prostate-specific antigen.



Data Gathering and Preparation

The data used in this study were obtained from the UCSC Xena Browser, specifically from the GDC TCGA-PRAD cohort [34,35]. The data included Illumina HumanMethylation450 BeadChip data and the corresponding phenotype information, both downloaded in February 2025. However, the latest phenotype presented missing fields essential to the labeling process. To supplement missing fields in the latest phenotype release, particularly those essential for the labeling process, an earlier version of the phenotype dataset retrieved in early 2024 was also incorporated. The complete version of the phenotype dataset is available in Multimedia Appendix 1.

The Illumina 450k DNA methylation dataset consists of approximately 450,000 CpG sites, with β values ranging from

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0 to 1 (indicating the methylation status: hypermethylated or hypomethylated). However, in the dataset, there are several CpG sites for which all values are null in all samples and partially null in some samples, indicating that no methylation data are available at all for those sites. In this case, not only are the null cells ignored, but also all columns of completely empty CpG sites are excluded from the feature selection process, and partially empty CpG sites are replaced with 0 to indicate that the sites are not methylated, ensuring that only features with valid information are included in the subsequent analysis.

The DNA methylation dataset consists of 4 types of CpG sites, namely, cg, ct, ch, and rs, each representing a specific location on the DNA where methylation occurs. Among the 4 types, cg-type CpG sites are the most dominant, accounting for more than 90% of the data. In contrast, ct, ch, and rs types have high levels of missing values, with ch containing more than 60% null values and rs being entirely null. Owing to the high proportion of missing values in these 3 types and in order to maintain data quality and consistency, this study only used features derived from cg-type CpG sites, while features of ct-, ch-, and rs-type CpG sites were excluded from the analysis. After obtaining the cg dataset, the samples were separated based on each race in the phenotype data. The data of the race with the highest number were used for training and testing. Each race dataset presented partially missing values in the cg data. To handle this, the mean imputation method was used to compensate for the missing values [36,37]. The remaining racial samples were used for external validation of the possibly racially based characteristics of the methylation data.

Sample Labeling

This study began by labeling each sample in the dataset based on cancer stage. Labeling was performed using the prostate cancer labeling manual from the American Joint Committee on Cancer (AJCC) Cancer Staging Manual (Table 1). There are 5 stages of prostate cancer staging. However, in the labeling process, stages IIA and IIB were combined into a single class, namely stage II, reducing the total number of stages to 4. Labeling was carried out based on these 4 stages, which were further shortened. Stages I and II were classified as “early” (the tumor has not spread to areas other than the prostate), and stages III and IV were classified as “late” (the tumor has spread to the lymph nodes or has metastasized) [38]. Several criteria that distinguish cancer stages were referred to in the AJCC Cancer Staging Manual, including T (presence of tumor), N (spread to the lymph nodes), M (metastasis), prostate-specific antigen (PSA), and Gleason score. However, since the PSA and Gleason score criteria were missing from the Xena Browser phenotype dataset in 2025, this study compensated for the missing criteria from the Xena Browser phenotype dataset in 2024.

The distinction between “early” stages (stages I and II) and “late” stages (stages III and IV) is critically important. Early stages, including stage I (very early, often microscopic, and localized within the prostate) and stage II (cancer confined within the prostate capsule), are characterized by localized disease that has not spread to the lymph nodes or distant organs. This localization makes these stages highly manageable with treatments focused on the prostate, such as surgery or radiation, typically leading to a favorable prognosis [39]. In contrast, late stages, including stage III (cancer extending just beyond the prostate capsule) and stage IV (cancer spreading to regional lymph nodes or distant organs), represent more advanced, often systemic disease. At these stages, the spread of the cancer makes complete eradication through local treatments less likely, and systemic therapies are generally required to manage the widespread disease, resulting in a less favorable prognosis.

Table . American Joint Committee on Cancer (AJCC) instructions regarding prostate cancer stage groups [38]. AJCC guidelines stratify patients into distinct groups (I, IIA, IIB, III, and IV) based on key diagnostic parameters: T (tumor size and extent), N (regional lymph node involvement), M (distant metastasis), PSA (prostate-specific antigen) levels, and Gleason score. These parameters collectively inform the cancer’s aggressiveness and spread. However, this research follows a common rationale for consolidating stages IIA and IIB into a singular group “stage II,” which is based on the following shared characteristic: the tumor remains primarily confined within the prostate (T1 or T2) without any evidence of spread to regional lymph nodes (N0) or distant sites (M0). Despite minimal differences in tumor volume or specific T2 subclassifications between IIA and IIB, their localized nature justifies a combined classification for simplified communication and initial treatment planning.

Stage group	Characteristics
I	Localized, PSA <10, Gleason ≤6
II	Localized, higher PSA (10–20) or Gleason 7
III	Locally advanced (T3)
IV	T4, nodal involvement, or metastasis

Feature Selection

Feature selection began with a DMP analysis of all genes against the label to find methylation values that were outliers. DMP analysis serves as an initial feature-screening step rather than as a stand-alone inferential endpoint. We therefore applied a nominal probe-wise threshold of $P<.05$ as a broad initial filter to reduce CpG sites to a reduced subset before applying RFE and downstream model-based selection. Similar 2-stage strategies, where relatively lenient P-value filters are combined with additional feature selection, have been proposed in high-dimensional methylation workflows to balance sensitivity and computational feasibility [40]. Methylsuite uses regression models to compare β values between early and late stages at each CpG site [41] with the methylsuite Python package using the function *methylize.diff_meth_pos.diff_meth_pos*, which accepts sample ID, β value, and label. The function returns the DMP analysis results consisting of the columns “cg pos” and “P-val.” Then, from the analysis results, a cutoff limit is given at $P<.05$. Because these DMPs were further reduced via RFE and we did not claim individual CpG sites as statistically confirmed differential methylation biomarkers in the classical

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sense, we opted for a more permissive threshold to avoid discarding potentially informative sites. The cg number obtained from the analysis was used as a feature for the MLP model. To minimize the number of features, the RFE algorithm was further implemented by using the support vector classifier algorithm as a classifier. The RFE process produces several subsets of data that are used to evaluate the minimum number of features, where too few features cause the model to have difficulty in distinguishing between classes. To validate the biological significance of selected CpG sites, genes related to the CpG sites were tracked using Infinium HumanMethylation450 v1.2 BeadChip product files [42].

To validate the results of feature selection, gene mutation checks were performed on all selected CpG sites. Gene mutation checking starts by taking the Illumina ID of the CpG site (example: cg00000029) and matching the Illumina ID with the gene symbols available from the Infinium HumanMethylation450 v1.2 BeadChip product files. After obtaining a list of gene symbols, gene mutations can be checked by querying an external dataset of cancer genes known to have mutations in prostate cancer cases through COSMIC, matching gene symbols in the dataset, and calculating the percentage of individual gene mutations from the number of samples that have been tested and the number of samples that have recorded mutations [43]. Further validation can be performed on cBioPortal by querying gene symbols in the Prostate Adenocarcinoma dataset (TCGA, PanCancer Atlas) to obtain more detailed information about gene mutations per prostate cancer stage in the sample dataset used in this study (TCGA) [44,45].

MLP Development

Construction of the MLP model started with determining the scheme of the MLP to be used. We used an MLP with 2 hidden layers to balance capacity and generalization. While a single layer is a universal approximator, 2-layered networks can represent important functions much more compactly, and deeper stacks (≥3 layers) add parameters and overfitting risk on small tabular datasets without consistent gains [46]. The number of neurons in each layer is usually determined heuristically, for example, by taking the average of the number of input and output neurons or using a decreasing pattern such as 32-16-8. Activation functions, such as rectified linear unit (ReLU), are commonly used in the hidden layer to improve the ability to represent nonlinear data, while sigmoid or softmax activation functions are used in the output layer according to the type of classification. As this case involved binary classification, sigmoid activation functions were used for all output layers. The final architecture selection is generally determined through experimentation and validation to avoid overfitting and ensure optimal model performance.

After determining the MLP model scheme, model training began by separating the dataset into training and testing data. The training and testing data were obtained by separating the initial dataset. The cross-validation method was implemented in the training process to prevent potential overfitting or bias in the training data, thus expanding the generalizability of the model. Model training was performed incrementally in epochs until the process was automatically stopped by an early stopping mechanism. This mechanism stops training if there is no improvement in the model's performance on the validation data after a certain number of epochs, thus preventing overfitting. During the training process, the model was evaluated using the Adam optimizer. All training scenarios used a consistent loss function, binary cross-entropy, in accordance with the nature of the binary classification problem.

Performance Evaluation

Model evaluation was performed using the *classification_report* function, focusing on harmonization among the F_1-score, accuracy, precision, and recall metrics. Model performance was evaluated based on the results of training and testing data to ensure reliability without overfitting or underfitting. In addition, the AUC value was also used as an additional metric to assess the model's ability to distinguish between classes.

To enhance model interpretability in classifying prostate cancer stages into "early" and "late" stages, we used post-hoc explainable AI (XAI) methods: Shapley Additive Explanations (SHAP; version 0.48.0; Scott Lundberg) and Local Interpretable Model-Agnostic Explanations (LIME; version 0.2.0.1; Marco Tulio Ribeiro). These methods provide insights into how individual features contribute to model predictions, offering both global and local interpretability [47-49].

For SHAP, 100 random training data points were used as the background distribution for SHAP calculations. DeepExplainer was chosen based on model compatibility, and SHAP values were computed on combined data between the test and validation sets. To visualize the SHAP computation results, summarization plots were used.

LIME focused on local fidelity. To obtain a global scene of feature importance in LIME, each feature's weight applied by the model was aggregated and compiled into a data frame, which revealed patterns of feature trends and a feature ranking based on the absolute mean of each feature weight. LimeTabularExplainer was built using the test data, feature names, and class names. LIME helped confirm the consistency of important features across individual predictions and detect any variability in the model's decision-making at the sample level.

Results

Prepared Data

The data for this study consisted of 2 correlated secondary datasets. The datasets were obtained through the public databases Xena Browser GDC TCGA-PRAD DNA methylation-Illumina Human Methylation 450 and Xena Browser GDC TCGA-PRAD phenotype 2024 and 2025. The DNA methylation-Illumina Human Methylation 450 dataset contains 553 samples with TCGA barcodes and 486,428 identifiers or CpG sites with beta values (0-1), as shown in Multimedia Appendix 2.

The GDC TCGA-PRAD phenotype 2024 and 2025 datasets have 572 samples in the form of TCGA barcodes and 88

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identifiers in the form of categorical clinical data, as shown in Multimedia Appendix 1.

The initial DNA methylation dataset consists of a total of 486,428 CpG site features and a total of 893 samples, and the phenotype data only involve 572 samples. This study only took samples that were in both datasets for model construction. From the methylation dataset with 553 samples, only 415 samples were taken, as this research only used White population data from both phenotype datasets by equalizing the TCGA barcodes of both datasets. After identifying null values, it was found that 64,728 CpG sites had null values in all samples (no methylation values at the sites). Such features were considered to have no analytical value and were excluded entirely from the dataset.

After the removal of completely empty CpG sites, the number of features was reduced to 421,699 or about 87% of the original data, and then, the samples were separated by race. The White race was the dominant race in the dataset, covering up to 415 out of 572 total samples, and was therefore used as the basis for the MLP model construction process. The remaining samples with other races were used for validation of the hypothesized race-based characteristics of the dataset. The races used for validation included Asian (12 samples) and Black or African American (60 samples). There were races in the phenotype datasets that were not covered by this study owing to "not reported" race values and an insufficient number of labels for prediction. This process ensured that only features with valid and analyzable methylation information were used in the DMP and RFE analysis stages.

Labeling

Based on the labeling performed using the AJCC Cancer Staging Manual guidelines, each sample in the dataset was successfully classified into the appropriate prostate cancer stage. Some samples had missing values in one or two of the main criteria (T, N, or M), but no samples had missing values in all 5 criteria at once. To handle this, missing values in the T, N, and M categories were treated as T0, N0, and M0, respectively, which were assumed to be conditions without significant spread or growth. Meanwhile, the PSA and Gleason columns had no missing values and could be fully used for labeling. From a total of 415 White race samples, the label distribution was obtained as represented in Multimedia Appendix 3.

This distribution showed a predominance of samples at advanced stages (stage II), reflecting possible population bias or the availability of more data for advanced cases. The labeling process was performed manually and adjusted to the AJCC classification scheme to ensure accuracy and consistency between samples. All label data were then used for further analysis, including classification or clustering of prostate cancer stages.

Feature Selection

Feature selection was performed in 2 stages, namely DMP analysis using methylsuite and advanced feature reduction using the RFE algorithm. The goal of this process was to obtain a minimum subset of CpG site features that are most relevant to prostate cancer staging.

The implementation of DMPs using methylsuite started by excluding CpG sites that had been recorded as insignificant or had no correlation to oncology from journals or public databases, which resulted in the elimination of 137,111 CpG sites [41,50-55]. The remaining 281,723 features were then subjected to DMP analysis using a *P*-value cutoff of <.05 to evaluate their influence on the label. DMP analysis with a cutoff of $P<.05$ resulted in 6501 CpG sites that were significant to the label. The cutoff of $P<.05$ was chosen as the default value because it is considered to provide a balance between selectivity and the number of features that can still be processed efficiently.

Then, the RFE algorithm was used to evaluate and select the most informative features from the 6501 CpG sites. RFE was applied by gradually generating several feature subsets, namely by reducing the number of features to 100, 90, 80, 70, and 60. Each of these feature subsets was used to form a different dataset for each race that would be used for training and testing classification models. Each dataset had its own characteristics depending on the number of features and estimators used in the RFE process. The final feature selection considered the balance between model complexity and classification performance, with the aim of avoiding the risk of overfitting or underfitting.

The biological relevance of features to labels was validated by checking several online datasets. Reference genes were searched from 100 selected CpG sites. The reference genes were obtained from the Infinium HumanMethylation450 v1.2 BeadChip manifest file by matching CpG sites to gene symbols. A total of 58 symbols were obtained from sites that had reference genes. The 58 gene symbols were matched with the COSMIC Cancer Browser tool by selecting prostate cancer tissue, exporting all data about genes that are often found in prostate cancer, and recording the number of samples and the number of mutations that occur. Genes with a mutation rate above 5% are shown in Table 2.

Based on the COSMIC database, the selected genes showed low mutation frequencies in prostate cancer samples. *MACROD2* led with a mutation rate of 28.6%, followed by *MAGI2* (24.37%), *FAM155A* (22.84%), and *DLGAP2* (22.14%). These 4 genes alone were mutated in more than one out of five cases, suggesting a potential role in the pathogenesis of prostate cancer.

While classical tumor suppressor genes, such as *TP53* and *PTEN*, are not included in this list, the mutation rates observed here may reflect less well-known but recurrent alterations in prostate cancer stages. Notably, genes, such as *FMN2*, *NTM*, and *L3MBTL4*, also showed relatively comparable mutation rates, raising questions about their functional significance. However, COSMIC does not provide context regarding cancer stage (early vs late disease), leading to a lack of information on whether these mutations occur exclusively in early- or late-stage tumors and how external factors, such as age and race, may influence these mutations. However, further validation using cBioPortal, which provides mutation data linked to cancer stages and clinical outcomes, will be crucial to determine whether these frequently mutated genes are enriched in early-stage or late-stage prostate cancer.

The same gene symbols were evaluated using TCGA data via cBioPortal, and those genes with an alteration frequency of 5%

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or higher were selected, resulting in the OncoPrint shown in Multimedia Appendix 4. Visual inspection of selected genes, including *DLGAP2*, *PCDH17*, *CALB1*, and *VGLL2*, revealed distinct patterns of genetic alterations across prostate cancer stages, ranging from T2A and T2C (early) to T3A and T4 (late). Notably, *DLGAP2* and *VGLL2* exhibited prominent deep deletions (represented in blue) found across various stages but predominantly in early-stage prostate cancer, suggesting a potential tumor suppressor role. In contrast, *CALB1* and *PENK* displayed consistent amplifications (represented in red), especially in late-stage samples, indicating a possible association with disease progression or aggressive traits. According to the OncoPrint results, race and age at diagnosis did not show a strong correlation with gene alterations, as their distributions appeared random and inconsistent across cancer stages. These stage-associated alteration patterns reinforce the likelihood that these genes may contribute differentially to prostate cancer. This visual stratification, when aligned with earlier COSMIC mutation rates, supports prioritizing these genes for further analysis based on mutation type, frequency, and stage-specific behavior in clinical samples.

Table . Genes with a mutation rate above 5% in prostate cancer.

Gene	Mutated samples, n	Samples tested, n	Mutation rate (%)
MACROD2	616	2154	28.60
MAGI2	539	2212	24.37
FAM155A	492	2154	22.84
DLGAP2	477	2154	22.14
FMN2	321	2154	14.90
NTM	305	2154	14.16
L3MBTL4	291	2154	13.51
SHISA9	276	2154	12.81
PCDHGA4	218	2154	10.12
FBXL7	189	2154	8.77
GABRB3	165	2154	7.66
PCDH17	127	2154	5.90

MLP Performance

Based on conventional methods of consideration and preliminary experiments, several MLP architectures were selected to be tested on numerical data. The structures used consisted of 2 main categories, namely MLPs with 1 hidden layer and those with 2 hidden layers. For the architecture involving 1 hidden layer, the number of neurons used varied among 8, 16, and 32, with ReLU or sigmoid activation functions and dropouts between 0.2 and 0.4 to prevent overfitting. Meanwhile, the architecture involving 2 hidden layers was designed with a combination of neuron counts, such as 16 - 8 and 32 - 16, using consistent activation functions between layers (ReLU or sigmoid), as well as customized dropouts in each layer. The selection of these combinations aims to evaluate the effect of network depth, neuron number, activation function, and dropout on the classification performance of the model.

To identify weaknesses in model performance, we used stratified 3-fold cross-validation to maintain class balance in every split, keep approximately 110 samples per validation fold for stable estimates while reserving sufficient training data, and limit the computational burden of the nested feature-selection pipeline, which is an accepted trade-off in small, high-dimensional biomedical datasets. Prior to stratification, all features were scaled using scikit-learn's *StandardScaler()* function to equalize the scale of values between features and speed up convergence during training.

Experiments in this study totaled 150 scenarios trained in a maximum of 100 epochs, and the number of scenarios came from a combination of 5 feature selection datasets, 3 data splitting schemes, and 10 model architectures. All scenarios were trained using an early stopping mechanism with a patience value of 10, taken from 10% of the number of epochs. Training was stopped automatically when there was no performance improvement on the validation data for a specified number of epochs. In addition, all optimizers used had a learning rate of 0.001 consistently across all training scenarios to maintain the stability of the reweighting process.

Table 3 presents the top 5 best-performing models among the 150 experiment scenarios, and Table 4 presents the top 5 best-performing models utilizing each individual feature count (ranging from 60 to 100).

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Table . Top 5 best-performing models among the 150 experiment scenarios.

Features	Data split (training/testing data)	CV[a] Acc[b] (%)	CV AUC[c] (%)	CV F_1[d] (%)	Test Acc (%)	Test loss (%)	Test AUC (%)	Test F_1 (%)	Asian Acc (%)	Asian F_1 (%)	Black Acc (%)	Black F_1 (%)
90	80/20	95	99	95	98	15	100	98	25	29	43	49
60	80/20	95	98	95	93	20	98	92	33	33	42	47
100	90/10	95	98	95	95	16	99	95	8	13	47	52
70	80/20	95	99	95	95	15	100	95	8	13	48	54
100	80/20	95	99	94	99	14	100	99	8	13	47	52

[a]CV: cross-validation.

[b]Acc: accuracy.

[c]AUC: area under the curve.

[d]F_1: F_1-score.

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Table . Top 5 best-performing models utilizing each feature count.

Features	Data split (training/testing data)	CV[a] Acc[b] (%)	CV AUC[c] (%)	CV F_1[d] (%)	Test Acc (%)	Test loss (%)	Test AUC (%)	Test F_1 (%)	Asian Acc (%)	Asian F_1 (%)	Black Acc (%)	Black F_1 (%)
60	80/20	95	98	95	93	20	98	92	33	33	42	47
60	90/10	93	98	93	95	12	100	95	17	17	43	49
60	80/20	92	96	92	94	21	99	94	17	24	43	50
60	70/30	91	95	91	93	24	98	93	25	29	32	35
60	70/30	89	95	88	94	18	99	94	25	29	40	45
70	80/20	95	99	95	95	15	100	95	8	13	48	54
70	90/10	94	98	94	98	18	100	98	8	3	38	42
70	80/20	91	94	91	86	49	83	84	25	29	52	58
70	90/10	90	96	90	95	22	100	95	0	0	33	36
70	90/10	90	95	89	100	28	100	100	8	13	42	48
80	80/20	95	99	94	92	24	98	91	25	33	42	48
80	90/10	93	98	93	95	12	99	95	8	3	33	37
80	90/10	91	96	91	98	19	100	98	0	0	38	42
80	90/10	91	97	90	86	33	95	83	33	42	58	63
80	90/10	91	96	90	76	38	99	66	83	76	83	76
90	80/20	95	99	95	98	15	100	98	25	29	43	49
90	90/10	94	98	94	100	11	100	100	8	3	35	39
90	90/10	92	97	92	98	16	100	98	0	0	35	39
90	70/30	90	94	90	98	16	100	98	8	13	38	45
90	80/20	89	96	89	93	29	97	92	25	33	43	50
100	90/10	95	98	95	95	16	99	95	8	13	47	52
100	80/20	95	99	94	99	14	100	99	8	13	47	52
100	90/10	93	96	93	98	13	99	98	0	0	37	41
100	90/10	92	98	92	100	12	100	100	8	3	37	40
100	90/10	92	98	91	76	37	95	66	83	76	83	76

[a]CV: cross-validation.

[b]Acc: accuracy.

[c]AUC: area under the curve.

[d]F_1: F_1-score.

Post hoc interpretability analyses using SHAP and LIME were conducted only on the best-performing MLP model, which was selected based on its superior generalization performance in the validation and test sets. This model consisted of 90 input neurons (equal to the selected feature count), 1 hidden layer with 32 neurons having a sigmoid activation function, a final sigmoid output layer, and the Adam optimizer. Regularization was applied using a dropout rate of 0.4 to mitigate overfitting.

A total of 184 samples were used for SHAP analysis, including 100 randomly selected training samples as background distribution and 84 combined samples from the validation and test sets for explanation. LIME was applied to the same set of 84 samples to generate local explanations. Figure 2 shows the SHAP summary plot, which highlights the most influential features across the model's predictions. Figure 3 presents a comparison of SHAP and LIME feature importance rankings.

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Figure 2. Shapley Additive Explanations (SHAP) summary plot of the top 20 most influential features. Each point represents a sample, with the x-axis showing the SHAP value (impact on model output) and the y-axis listing the top CpG sites ranked by importance. Colors represent the feature values (red=high, blue=low). Features with wider spreads and denser point distributions have a greater influence on the model's predictions.

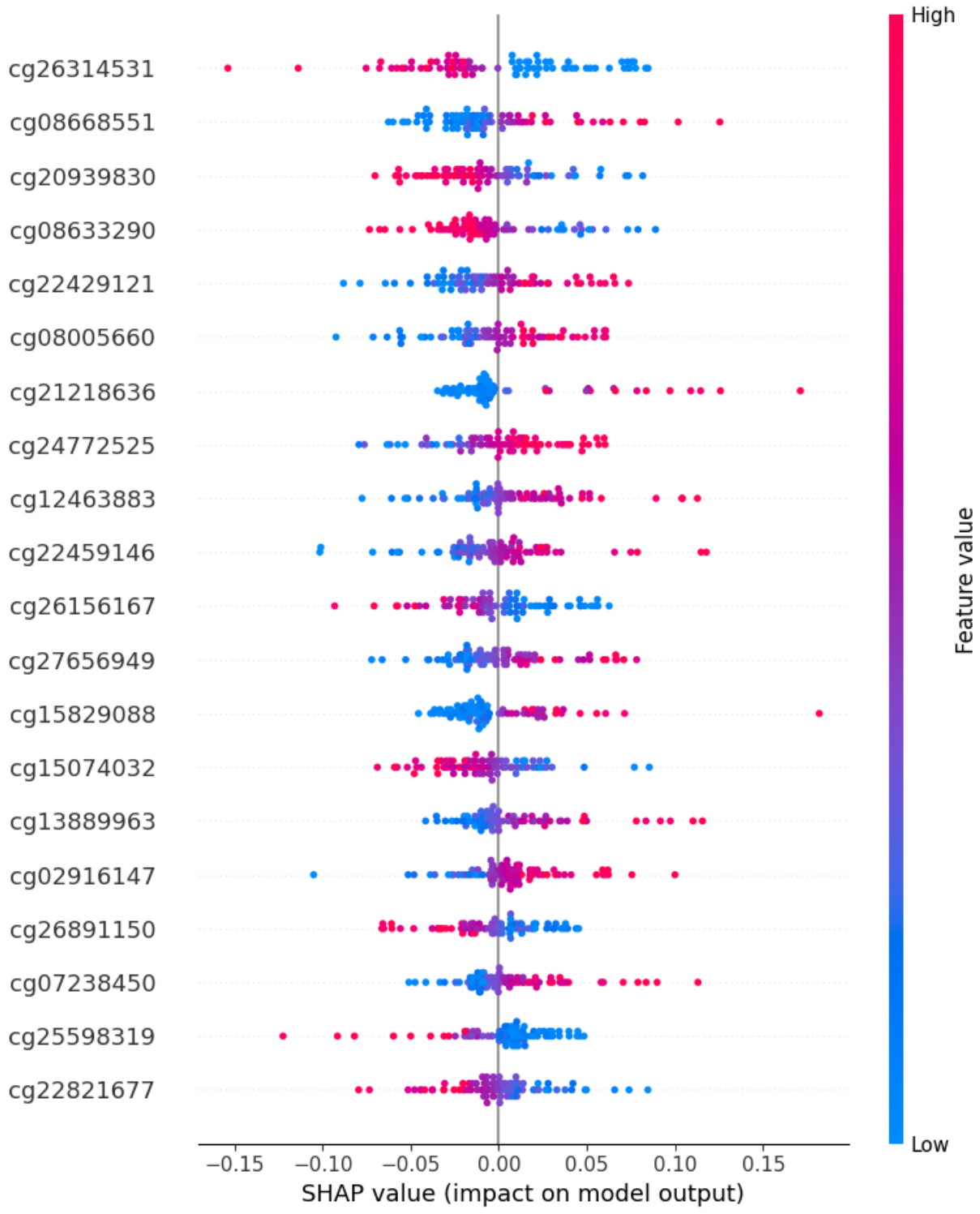

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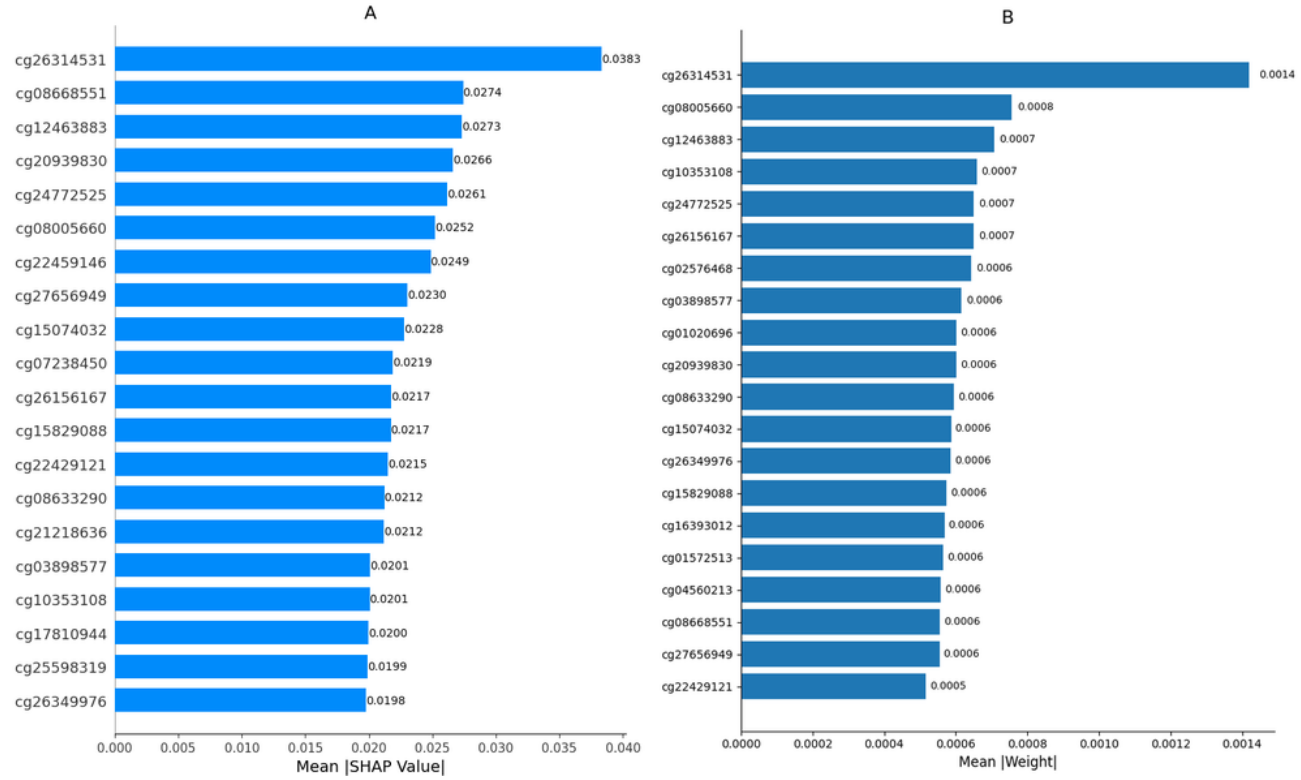
Figure 3. Comparison of the top 20 most influential features identified by Shapley Additive Explanations (SHAP) (A) and Local Interpretable Model-Agnostic Explanations (LIME) (B). The SHAP bar plot displays the average absolute SHAP values for each feature, indicating their overall contribution to the model's predictions across all samples. The LIME bar plot shows the average absolute weight assigned to each feature when locally approximating the model's output.



cg26314531 was identified as the most important feature by both SHAP and LIME. Annotation analysis involving the Infinium HumanMethylation450K v1.2 product files showed that the CpG lies in a regulatory region of the genome where methylation changes are likely to influence gene activity, and this provides a biological explanation for its importance in the predictive model [56]. These findings suggest that cg26314531 may represent an epigenetic marker associated with regulatory changes relevant to cancer progression.

Discussion

Principal Findings

This paper proposes a race-based prostate cancer stage detection framework, which distinguishes between early and late stages, by utilizing bioinformatics feature selection (DMP) and statistical (RFE) approaches on patient DNA methylation data. This framework is designed to minimize the number of features (CpG sites) used to build a robust and accurate MLP model for classifying prostate cancer stages. By minimizing the number of features required, this approach provides several advantages for both patients and hospitals. These include reduced implementation costs due to the absence of large computational resources, as well as allowing patients to target specific CpG sites in the NGS process, so that the NGS process for irrelevant CpG sites can be eliminated. The generalization of the model is race-based owing to the fact that DNA methylation data are highly influenced by disparities in lifestyle, genetic inheritance, and habits that vary by race [57-59].

In the labeling process, the distribution of prostate cancer stages in the sample data showed that most patients were diagnosed at stage 2 (362 out of a total of 415 samples). Stage I accounted for only 21 samples, while stages III and IV accounted for 39 and 82 samples, respectively. This imbalance in distribution, particularly the high number of samples of stages II and IV compared with stage I, may indicate a delay in the early detection of prostate cancer among White individuals, with most prostate cancer cases being found at intermediate to advanced stages. Therefore, there is a need for accurate prostate cancer staging detection methods to reduce the mortality rate resulting from a delayed diagnosis or misdiagnosis among patients with prostate cancer.

To test the performance of the MLP-based classification framework, a series of experiments was conducted using data with varying feature count configurations but with variations in the proportion of training and testing data (data split) and racial distribution. The results showed that the performance of the MLP model was generally quite high, as indicated by the good accuracy, F_1-score, and AUC values in the test dataset, which approached or reached the maximum value (1.00) in some configurations. However, a more in-depth analysis of the model performance by racial group revealed significant inequalities. To further validate the quality of the selected CpG sites, SHAP and LIME explainability methods were applied to analyze the contribution of each feature toward the model's prediction. SHAP summary plots highlighted CpG sites, such as cg26314531, cg08668551, and cg20939830, as having the most substantial impact across all samples. LIME analysis confirmed the importance of many of these same features at the

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individual prediction level, suggesting that the selected features are not only statistically relevant but also biologically meaningful in driving classification decisions. The overlap of SHAP and LIME top features strengthens confidence in their interpretability and consistency, especially in terms of functional relevance to cancer progression. Further analysis revealed that, although the experiment focused on configuring the number of features, the same trend was observed when testing the model on a smaller number of features in a separate dataset. The cross-validation accuracy values tended to stabilize in the range of 89% to 95%, with a reduction in the number of features, indicating that an increase in the available information improves the model's ability to recognize relevant predictive patterns. However, some configurations with a limited number of features still showed high accuracy. This phenomenon suggests that the quality and biological relatedness of the selected features are as important as the quantity of features.

In the context of DNA methylation data, there may be biological connections between CpG sites that function in specific biological processes, such as the regulation of gene expression in certain tissues or races [60-62]. The selected features may represent functionally interconnected biological networks that, despite their limited number, are still informative enough to maintain model performance [63-65]. SHAP's feature distribution plots also revealed that some CpG sites consistently contributed to increasing or decreasing model prediction depending on their methylation status, indicating that the biological signal captured is not arbitrary but directionally consistent with known methylation patterns associated with cancer stages.

Based on the model performance results, the disparity in performance between racial groups was apparent when evaluation metrics, such as accuracy and F_1-score, were compared on a per-race basis. While the model achieved a high accuracy and F_1-score overall, the performance for minority races, such as Asian and Black races, was much lower. For example, in one of the configurations where the overall test accuracy reached 99%, the accuracy for the Asian race was only recorded at 8%, with an F_1-score of 0.13, while the Black race only achieved an accuracy of about 47% and an F_1-score of 0.52. This disparity indicates that MLP models tend to only recognize patterns originating from certain racial groups, most likely the majority group, and fail to generalize the prediction results to other groups. One of the main causes of this bias is thought to be related to the imbalance in the number of samples between races. In the data used, the White race had a relatively high number of samples (63 samples), followed by the Black race (60 samples), while the Asian race had only 12 samples. This imbalance caused the model to receive more information during the training process from the majority group (White race), and thus, it was able to recognize their patterns better. In addition, the feature selection process conducted earlier was most likely based on the majority group, causing the selected features to be less relevant for minority races, and thus, the biological characteristics captured in the DNA methylation profiles of each race may produce different patterns. In the context of this study, the CpG site features selected as the basis for prostate cancer stage classification appeared to be more representative of the White group used for feature selection data and MLP model training, causing information on specific biomarkers in other races to be underrepresented. These biological differences may reflect interconnected genetic, epigenetic, environmental, and social factors that influence the methylation patterns of each race. The impact of this imbalance is not only limited to the performance of MLP models but also reaches wider areas of medical practice and public health. If predictive models are built based on data that are not racially inclusive, the risk of bias in diagnosis, prognosis, and clinical decision-making is higher, especially for racial minority groups. Therefore, the results of this study emphasize the importance of population representation aspects in DNA methylation data, as well as the need for methods that consider biological and demographic diversity in every stage of building artificial intelligence models for biomedical applications. Moreover, model interpretation tools, such as SHAP and LIME, offer valuable insights into whether feature contributions remain consistent across racial groups. In this study, these tools helped identify whether certain CpG sites unequally influenced predictions for specific races, potentially revealing biases in the model or guiding future fairness-aware feature selection strategies.

Relation to Prior Work

Numerous studies have explored cancer classification using either DNA methylation data or deep learning techniques. However, to our knowledge, no studies have combined race-aware modeling, malignant stage classification, and biologically driven minimal feature selection in prostate cancer. Most existing work has focused on pan-cancer classification or benign versus malignant categorization without considering disease progression stages or racial variation in methylation patterns [66-69]. Several studies have utilized DNA methylation profiles for cancer detection and classification. For example, Zheng et al [70] developed a DNN-based classifier for cancer origin prediction using TCGA's DNA methylation data from 7339 patients having 18 different cancer origins. The model used 1-way ANOVA followed by the Tukey honestly significant difference test to select significant features, resulting in 10,360 CpG sites used in the DNN. The model was then evaluated by using 10-fold cross-validation. The model achieved an almost perfect specificity score of 99.7% and a sensitivity of 92.6%. Another proposed 2-part system by Eissa et al [32] involved metaheuristic feature selection followed by a DNN for pan-cancer and malignancy status classification, which resulted in better classification in terms of recall, and similar and higher results in precision and accuracy, with excellent AUC values ranging from 0.85 to 0.89. While both studies demonstrated the potential of methylation-based classification, they did not address malignant stage classification within a single cancer type and did not consider racial disparities in methylation signatures. Moreover, their feature selection approaches focused largely on statistical or optimization-based techniques, without combining biological relevance. In contrast, our study provides a starting point for understanding racial gaps in model performance under standard training methods. Models trained mostly on data from White participants performed very well on

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similar White samples, but their performance dropped sharply for Asian and Black or African American samples. This shows the risk of using models that ignore racial differences in settings where DNA methylation patterns vary across populations. It also highlights the need for future research to carefully test training methods that aim to improve fairness when using methylation-based biomarkers. We adopted a bioinformatics-driven feature selection pipeline that combined DMP analysis and RFE to identify a minimal yet informative set of CpG sites. This approach enables more interpretable and race-aware modeling, addressing both the technical and biological limitations in prior work.

Limitations

This study has several limitations that should be addressed in future research. Most notably, the model was trained on a racially homogeneous dataset, which limits its generalizability to other populations. Our findings suggest that DNA methylation patterns vary significantly across racial groups, indicating that feature selection and model training must be performed on race-specific datasets to achieve accurate and fair classification outcomes. Without this, diagnostic models risk underperforming or misclassifying in underrepresented populations. Additionally, publicly available data were used, which introduces challenges, such as missing values and potentially outdated annotations, potentially influencing model robustness. Finally, the study was limited to single-omics data. Integrating multi-omics approaches could offer a more comprehensive view of prostate cancer progression across racial subgroups. Future work should prioritize race-aware feature selection approaches, stratified training pipelines, and advanced techniques, such as domain adaptation, to enhance both performance and equity in biomarker discovery.

Conclusions

This study presented a race-aware MLP model for prostate cancer stage classification using DNA methylation data, with enhanced feature selection through DMP analysis and RFE. Validation with external sources (COSMIC and cBioPortal) reinforced the credibility of our feature selection process, revealing important gene alteration patterns within the dataset. The results showed that the models built and tested within the White cohort achieved high performance (average testing accuracy >95%) but performed poorly when applied to Asian and African American samples (testing accuracy <50%). SHAP and LIME interpretations further confirmed the relevance of selected CpG sites and revealed how they influenced model predictions. These findings reveal clear racial disparities in DNA methylation profiles and emphasize the critical need for race-specific feature selection and modeling strategies while demonstrating the effectiveness of using a minimal feature set to capture significant biomarkers and avoid noise introduced by population heterogeneity.

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Data Availability

This study used publicly available data from the University of California, Santa-Cruz Xena Browser. However, recent updates to the repository have resulted in missing components within the phenotype dataset. The complete phenotype dataset used in this research is provided in Multimedia Appendix 1.

Authors' Contributions

DA, MW, MO, MIA, SYS, and NK contributed to the study’s concept and design, and critical revision of the manuscript. AM drafted the manuscript and, together with VK and JS, performed statistical analysis. DA handled funding acquisition, as well as administrative, technical, and material support. DA, MW, and MO supervised the study. All authors contributed to data acquisition, analysis, or interpretation.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Complete version of the phenotype dataset.
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Multimedia Appendix 2
DNA methylation dataset matrix example.
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Multimedia Appendix 3
Distribution of sample stage groups.
[DOCX File, 40 KB - formative_v10i1e82587_app3.docx]

Multimedia Appendix 4
OncoPrint.
[PDF File, 7565 KB - formative_v10i1e82587_app4.pdf]

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Abbreviations

ADC: apparent diffusion coefficient
AJCC: American Joint Committee on Cancer
AUC: area under the curve
CNN: convolutional neural network
COSMIC: Catalog Of Somatic Mutations In Cancer
DMP: differentially methylated position
DNN: deep neural network
GDC: Genomic Data Commons
IRB: institutional review board
LIME: Local Interpretable Model-Agnostic Explanations
MLP: multilayer perceptron
MRI: magnetic resonance imaging
NGS: next-generation sequencing
PSA: prostate-specific antigen
ReLU: rectified linear unit
RFE: recursive feature elimination
SHAP: Shapley Additive Explanations
T2W: T2-weighted
TCGA: The Cancer Genome Atlas
TCGA-PRAD: The Cancer Genome Atlas Prostate Adenocarcinoma
UCSC: University of California, Santa-Cruz

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Factors Influencing the Use of Mobile Apps and Wearables: Pre- and Post-Surgery Quality of Life Assessment Study

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Abstract

Background: Quality of life (QoL) is an important surgical outcome, commonly assessed through self-reports, and has the potential to be enhanced by objective information from personal technologies such as smartphone apps and wearables. Understanding patients' perspectives on this application of personal technologies is scarce.

Objective: This study aimed to identify operational aspects of smartphone- and wearable-based assessments, as well as human and operational factors that may influence the acceptability of already owned (mostly smartphone) or new (mostly wearable) technologies by patients for pre- and post-surgery QoL assessments.

Methods: Through purposive sampling, 41 patients from 3 health care centers in Switzerland, the United States, and the United Kingdom, who were undergoing or scheduled for surgery for degenerative cervical myelopathy (DCM), liver transplantation, or total hip replacement, were interviewed about their perceptions of QoL, current use of smartphones, health apps, and wearables for self-management and their views on using these technologies to assess QoL before and after surgery.

Results: Across the 3 studies (n=41), most (n=36) patients reported improved QoL after surgery, mainly due to reduced pain and fatigue and regained autonomy, while a few patients with DCM reported no change (n=2) or worsening (n=1). Patients were generally comfortable using smartphones and tablets, but few (n=4) used them for health management. Wearables were perceived differently across groups: they were well accepted in transplant@US, moderately in hip@UK, and least in myelopathy@CH. Many patients with DCM found wearables "useless," believing they added little to their self-awareness or recovery and could not replace human clinical judgment. Others expressed concerns about privacy, complexity, notifications, and battery life, while some acknowledged their motivational value when the data were clearly interpreted. Despite varying acceptance levels, most participants said they would consider using such devices if they contributed to research or improved care.

Conclusions: Given a mostly negative attitude of patients toward wearables, we discuss the use of smartphone-based automated logging of physical functioning (sleep and physical activity) instead. Such logging may be less accurate than a dedicated wearable, but it may be accurate enough to measure their pre- and post-surgery physical functioning changes. Additionally, a smartphone has the advantage of being already well integrated into the daily life of patients from the perspective of its functionality and the patients' routines, contrary to wearable devices, which would have been provided to the patients in the context of pre- and post-surgery clinical care and require additional attention for their continuous wear, charging, and data synchronization, among others.

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KEYWORDS

quality of life; degenerative cervical myelopathy; liver transplant; total hip replacement; technology-reported outcomes; surgery; wearables; mobile applications; mHealth; smartphone; telehealth; self-management

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Introduction

Quality of life (QoL) is an important component of surgical outcomes [1-6]. Historically, for example, the American College of Surgeons, among other organizations, called for focusing on "*the end result idea*," which postulates that it is important to follow up with patients after each operation to determine if it was successful, to learn from negative outcomes, and to develop a method to guarantee future success [7]. This approach was especially appropriate when postoperative morbidity and mortality were very high. The common practice was to observe and use postoperative complications to determine whether the surgery was successful. Nevertheless, given the decline in surgical mortality, a more pronounced focus is put on the morbidity and especially on changes in QoL among patients before and after surgery [8]. The QoL is a complex construct that includes all physical, psychological, social, and environmental domains and encompasses the patient's general health perception [8].

Currently, patients' QoL outcomes over a given period (eg, a month) are typically assessed via self-reports leveraging validated patient-reported outcomes (PROs), which are reports on the patient's health status that come directly from the patient without any interpretation of these responses by a physician or anyone else [9]. PROs are important because the clinical outcomes, which are the primary concern for surgeons, do not always reflect the health aspects that are most important to the patient. The PRO assessments can help the surgeon evaluate whether the patient needs surgery, follow the effect of surgery in the short and long term, and establish priorities for discussions during medical appointments. PROs also allow surgeons to understand and measure the benefits of different procedures from the patient's point of view. Thus, PROs complement the traditionally measured clinical outcomes by adding the patient's perspective [10]. However, these assessments are subject to biases affecting self-reporting, including memory and social desirability biases. It is increasingly important, as also emphasized by the regulators, to evaluate the patient's progress after the surgery with more granularity than self-reports and in ways that are more meaningful for patients than clinical outcomes [2,11]. Such evaluations can inform the assessment of the quality of care and ensure the patient's safety, for example, influencing the prescription of painkillers [12].

In parallel, personal technologies such as smartphone apps and wearables are becoming increasingly accurate in measuring long-term physical functioning (such as sleep and physical activity), psychological functioning (such as stress), and other outcomes contributing to the patient's QoL [12]. A recent scoping review has shown that the use of wearable devices can considerably improve clinical outcomes by enabling continuous monitoring. Positive correlations have been observed between PROs and wearable-derived metrics, often referred to as digital biomarkers, suggesting that these objective measures can provide complementary insights into patients' QoL [13]. Existing evidence supports an association between PROs and digital biomarkers, with moderate correlations reported between observed and predicted PRO values, particularly for domains such as social limitation, frequency and severity of symptoms, and overall QoL. Furthermore, biomarkers linked to activity intensity and volume have been consistently associated with PROs, reinforcing the potential of digital biomarkers to capture meaningful health-related changes beyond self-report [14]. However, the extent to which these technologies can provide complementary, meaningful QoL-related information for patients with surgical conditions, as well as the extent to which these patients would accept these technologies for the QoL outcome assessment, is unknown. It is known that the availability of the technologies does not directly translate into their usage by chronically ill patients [15].

To better understand the core of the patient's meaningful aspects of QoL, and especially the potential role of personal technologies for assessing these aspects before and after surgery, we selected groups of patients undergoing 3 different surgical procedures performed in 3 different countries (ie, Switzerland, the United States, and the United Kingdom). The diversity of procedures and locations was chosen to provide a broad understanding of the meaningfulness for patients' QoL-related outcomes that would be possible to be assessed via personal technologies and the patients' technology acceptance factors regardless of country or a surgery type. The 3 pathologies investigated were degenerative cervical myelopathy (DCM; Switzerland), liver transplant (LT; the United States), and total hip replacement (THR; the United Kingdom). In total, we recruited and interviewed patients who belonged to 1 of the 3 population groups through purposive sampling. The next section reports on the detailed methods leveraged in this study, followed by the results and their discussion.

Methods

Overview

This study was reported in accordance with the STROBE (Strengthening the Reporting of Observational Studies in Epidemiology) guidelines [16], and the completed STROBE checklist is provided as Checklist 1.

This overarching study included reanalysis of the datasets collected in 2 qualitative components (Switzerland and the United States) and a patient and public involvement (PPI) workshop (the United Kingdom) [17,18]. The qualitative interviews were primarily guided conversations in which patients provide knowledge, views, and experiences in response to the questions from the researcher [17,19], and all the collected answers were formally analyzed afterward.

The PPI is not designed or conducted as a formal data collection activity. The purpose of the PPI session was to gather broad input from patient representatives on priorities for future research and potential implications for the implementation of digital health tools. No audio or video recordings were made, and participants were not asked to provide personal health information or detailed accounts of their lived experience. Instead, field notes were taken during and after the session to capture general insights and reflections. The PPI allows for more dialogue and 2-way sharing of knowledge, experiences, and perspectives within the research team, developing the research agendas centered around patient experience. Therefore,

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the PPI notes acquired within this research were used only to contextualize and inform the interpretation of findings and were not included in the formal qualitative analysis or coded as part of the dataset.

This distinction is important in understanding the respective contributions of each method: while interviews generated in-depth, analyzable data on individual experiences and perspectives, the PPI workshop served a consultative and reflective function, aligned with best practices in co-producing future research directions [20].

The differences in methodology for each country are presented in Table 1: referred to as *myelopathy@CH* for DCM in Switzerland, *transplant@US* for LT in the United States, and *hip@UK* for THR in the United Kingdom. The 2 qualitative studies were approved by ethics committees, whereas this was not necessary for the PPI activity. The interview guides are available in the Multimedia Appendix 1.

Table . Comparison of research methods between the 3 studies.

Study	myelopathy@CH	transplant@US	hip@UK
Year	2021 - 2022	2019 - 2020	2021
Pathology	Degenerative cervical myelopathy	Liver transplant	Hip replacement
Overall approach	Individual patient–based	Individual patient–based	Group of patients: PPI[a]
Data types	Quantitative (PRO[b]) and qualitative (interview)	Quantitative (PRO) and qualitative (interview)	Qualitative (workshop and survey)
Research methods	PRO: QoL[c] PROMIS-GH[d]; semistructured interview	PRO: QoL SF-20[e]; semistructured interview: patients and their informal caregivers ('support persons')	PPI workshop; semistructured interview; online survey
Devices worn	None	Activity tracker: Fitbit Charge	None
Ethical approval	CCER PB_2018 - 00122	Stanford IRB-47833	Not required

[a]PPI: patient and public involvement.

[b]PRO: patient-reported outcome.

[c]QoL: quality of life.

[d]PROMIS: Patient-Reported Outcomes Measurement Information System-Global Health.

[e]SF-20: Short Form-20.

Rather than conducting exactly the same study with different cohorts, we have joined forces to meticulously code and analyze what we have already collected across these different studies because it all relates to the same research question. Combining the results from the myelopathy@CH, transplant@US, and hip@UK studies offers a valuable opportunity to compare hypothetical and real-world experiences with digital tools, enriching the overall understanding of patients' perspectives across different health care, cultural, social, and other important contexts and helping to distill the basic principles that influence human acceptance. Such an approach has been discussed in the literature as promoting the results' generalization [21,22].

Before combining the study results, the research team acknowledged contextual variability in technology adoption related to cultural and systemic differences across health care settings. In the United States, structural factors such as insurance-based models and an emphasis on individual responsibility may influence digital health adoption [23], whereas European countries with publicly funded systems often promote integration through coordinated policies and national strategies [24], fostering greater trust and engagement [25]. These contextual factors likely shape patients' willingness to use smartphones and wearables for self-management and QoL assessment before and after surgery [26]. By combining data across these settings, we aimed to identify common factors influencing patients' engagement with digital tools and their acceptance of such technologies for QoL assessment in diverse health care contexts.

Toward this end, we have combined the results from 3 studies to specifically identify patients' attitudes toward using passive data collection technologies to assess their QoL. We assumed that such measures can potentially support the existing PROs (especially for the physical functioning and activity) [27,28], and, with a more established and validated passive sensing of wearables functionalities in the future, even replace some PRO-based QoL assessments [29]. The details of each substudy are as follows.

myelopathy@CH: DCM at the University Hospitals of Geneva (CH)

DCM represents the most common cause of spinal dysfunction in adults [30]. DCM is caused by age-related changes in the spine, including degeneration of the facet joints, discs, and/or vertebral bodies; progressive spinal kyphosis; and ossification, calcification, or thickening of the spinal ligaments. These anatomic changes can lead to progressive spinal cord compression and, consequently, neurological deterioration and a significant decline in QoL [31]. It has been shown that the QoL of patients with DCM is more severely affected than most other chronic diseases in terms of physical functioning, especially physical activity, and is surpassed only by congestive heart failure. This is likewise the case for psychological functioning, behind only back pain and sciatica [32]. Surgical

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treatment remains the only definitive treatment for DCM and has been shown to improve QoL regardless of the severity of neurological impairment [33].

QoL in patients with DCM has typically been assessed by patient-reported measures similar to those used for other pathologies, including Short-Form Health Survey 36 (SF-36) [34], the Patient-Reported Outcomes Measurement Information System (PROMIS) [35], and the Neck Disability Index [36]. Patients are also assessed by health care practitioner–reported outcomes, such as the modified Japanese Orthopedic Association form [37] or the Nurick Scale [38].

The myelopathy@CH study presented here began with an individual semistructured interview regarding patients' health status, health self-management strategies, and general use of personal technologies and on their use with regard to personal health management, that is, what they thought of these new technologies, such as smartphone apps and wearables and whether they used them. We would then ask them about their subjective assessment of the QoL (via a semistructured interview) at the time of the interview and retrospectively before surgery (if they were after surgery). Finally, patients completed an online questionnaire for their demographic data and PROMIS Global Health (PRO, PROMIS-GH).

transplant@US: LT at the Stanford Medical Center (the United States)

LT is the second most frequent transplant after kidney transplant and concerns approximately 9000 individuals yearly in the United States alone. For reference, over 10,000 individuals were on a waiting list for LT as of March 2026 [39]. The quality of these patients' lives is severely impaired in all areas, especially physical (ie, autonomy in daily living) and psychological functioning, which then influences their overall QoL. According to recent research, the preoperative QoL of these patients improved in all areas of life, especially in physical health, daily activities, sexual functioning, and social functioning, including returning to the workforce [40-42].

There exist several self-report–based QoL assessment methods for patients undergoing LT: the SF-36 [34], Chronic Liver Disease Questionnaire [42], or Karnofsky Performance Status [43]. Owing to the likely cognitive impairment experienced by the patients undergoing transplantation [44,45], especially in the pre-surgery phase, each transplant patient is usually accompanied by an informal caregiver (family member or other acquaintance) for medical appointments. This person is called a "*support person*" by the care team.

The transplant@US study presented here focused on individual semistructured interviews with the same questions as in the myelopathy@CH case described earlier. The interview was conducted with a patient accompanied by a support person. Additionally, it is important to note that the results summarized here originate from a larger study. The overarching transplant@US study implied the involvement of patients and their support persons for 6 consecutive months, with a much larger battery of repeated QoL assessments (including, eg, sleep quality, hope, anxiety, and depression), in addition to weekly short self-assessments (eg, hope, anxiety, and sleep quality). The weekly self-assessments were launched on the patients' smartphones via the ecological momentary assessment method [46]. The support person's assessments of the patient's perceived state (eg, perceived hope, anxiety, and sleep quality) were launched on the support person's smartphones via a PeerMA method [47]. Additionally, in the overarching transplant@US study, selected patients agreed to wear an activity tracker, the Fitbit Charge, to understand their objective physical functioning patterns, including physical activity and sleep. The results of this study are being reported elsewhere [47].

hip@UK: THR at Exeter Hospital (the United Kingdom)

THR is one of the most common surgical procedures, with more than 1 million surgeries performed each year worldwide. Due to an aging population, these surgeries are expected to double in the next decade [48,49]. It has been estimated that 93% of surgeries are performed for severe cases of osteoarthritis with pain and physical functioning limitations [49]. Moreover, according to a 2013 meta-analysis, THR brings a real benefit to QoL, especially to physical functioning, within 2 years after surgery [4].

The hip@UK study presented here focused on results from a series of the THR patient involvement workshops. We conducted 3 workshops and online surveys about overall research priorities. The 3 workshops involved 5 patients who would require future hip replacement, 7 patients who had recently had a hip replacement, and 10 patients—a mix of pre- and post-surgery and follow-up meetings with those who had attended either of the previous ones. At the first 2 meetings, the patients discussed important QoL outcomes of their hip surgery, how they imagine these can be assessed beyond self-reports, and their views on using personal smartphones and wearables to measure these outcomes. The final meeting provided feedback and a summary from the initial meeting and discussed the potential burden of QoL outcome assessment and the potential clinical implications of the assessment. Additionally, the patients discussed how they imagine the overall results to affect future research design and planning in the THR. After all the meetings, an online follow-up survey was sent out to gain additional feedback, ask the patients to rank potential QoL outcome measures in order of importance, and gain insight into future research priorities.

Ethical Considerations

Ethical approval for the myelopathy@CH and transplant@US studies was obtained from the respective institutional ethics committees (CCER PB_2018 - 00122 and Stanford IRB-47833). In contrast, the hip@UK study was classified as a PPI project and therefore did not require formal ethics committee approval, as no intervention or collection of identifiable personal data was involved.

For the studies reviewed by ethics committees, participants provided written informed consent using committee-approved consent forms. For the PPI study, consent was implied through voluntary participation, and no additional consent procedures were required. All collected data were deidentified before analysis to protect participants' privacy and confidentiality. Participants did not receive any compensation for their

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participation in any of the studies. We confirm that no identifiable images or materials are included in the manuscript or supplementary files.

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Data Analysis Approach

In this study, qualitative data were drawn from interviews conducted with participants across the 2 substudies (myelopathy@CH and transplant@US). These interviews constituted the core dataset for the findings presented in this manuscript. These interviews were analyzed first using thematic analysis and, secondly, mapped onto own previous research in this domain.

We conducted a thematic analysis following the Braun and Clarke 6-phase framework [50,51], which provides a systematic yet flexible approach to qualitative data analysis. Researchers first familiarized themselves with the transcripts, then generated and organized initial codes into potential themes based on conceptual patterns. Themes were reviewed, refined, and clearly defined, with illustrative participant quotes used to contextualize findings. Two independent coders reached consensus on the codes and grouped them into thematic clusters.

Second, patients' negative and positive comments about the personal technologies were coded according to our 2 previous studies [15]: one focusing on factors influencing the quality of experience of mobile apps in the general public [52] and the second discussing these factors in the context of technology use for health self-management by patients with chronic conditions [15].

Study Participants Details

Patients were recruited at the respective hospitals by the care teams. All patients were informed about the goals of the study, the procedure, the data collected, stored, and processed for the purpose of research, the risks and benefits of participation, and that they could withdraw from the studies and request deletion of their data at any point in time without any negative consequences. Each patient signed the consent form providing the abovementioned information in detail. At the time of recruitment, all patients were assigned an anonymous identification code used throughout the study. The collection of personal information (eg, name and email addresses) was kept to a minimum. Patients' characteristics are presented in Tables 2 and 3. The details of the 3 studies are further detailed in Table 2.

Table . Study participants' details: recruitment channels and participant count.

Study	myelopathy@CH	transplant@US	hip@UK
Recruitment site	Division of Neurosurgery, University Hospitals of Geneva (Geneva, Switzerland)	Clinical Transplantation Unit, Stanford Medical Center (Stanford, CA, USA)	Patient advisory groups (United Kingdom)
Recruitment procedure	Recruited during clinical visits at the neurosurgery department	Identified and contacted through the clinical transplantation service	Recruited via email distribution of flyers through patient advisory networks
Periods of recruitment	May 2021 to February 2022	October 2019 to April 2020	May to July 2021
Inclusion criteria	Diagnosed with DCM[a]; either scheduled for surgery or operated <1 y before assessment	Scheduled for a liver transplant within the next year or had received a transplant <1 y before participation	On a pathway for hip replacement or had recently undergone hip replacement surgery
Exclusion criteria	Operated >1 y before assessment (to minimize recall bias in pre-surgery QoL[b] assessment)	Transplant performed >1 y before the study	Not applicable (PPI[c] study)
Number of participants	21	8 (7 support persons) and 6 patients wearing FitBit	12

[a]DCM: degenerative cervical myelopathy.

[b]QoL: quality of life.

[c]PPI: patient and public involvement.

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Table . Study participants details: detailed characteristics of the patients for the 2 qualitative studies.

	myelopathy@CH[a] (n=21), n	transplant@US[b] (n=8), n
Age range (y)		
40 - 49	3	—[c]
50 - 59	7	1
60 - 69	5	5
70 - 80	4	—
Undefined	2	2
Gender		
Man	12	7
Woman	9	1
Marital status		
Married or in a relationship	14	8
Single	2	—
Other	5	—
Time since surgery		
Before	5	3 (2 transplanted within the study duration)
1 - 3 mo	5	3
4 - 6 mo	1	2
7 mo to 1 y	10	—

[a]Quality of life outcomes (at the recruitment): Patient-Reported Outcomes Measurement Information System (score: 0-100, 50 is the population average, higher is better); Global Physical Health Raw Score: mean 61.43 (SD 15.90); Global Mental Health Raw Score: mean 66.90 (SD 17.14; interpretation: above-average physical and mental health in the study population, with a low variability).

[b]Quality of life outcomes (at the recruitment):Short Form-20 (score: 0-100, higher is better; n=6); physical functioning: mean 52.25 (SD 26.17; moderate, high variability); role functioning: mean 45.83 (SD 51.03; moderate, high variability); social functioning: mean 50 (SD 45.58; average, high variability); mental health: mean 76.67 (SD 11.71; good, low variability); health perception: mean 42.88 (SD 21.50; somewhat negative, high variability); pain: mean 50 (SD 24.49; moderate level, high variability).

[c]Not applicable.

The QoL instruments used in each cohort target distinct but complementary aspects of health-related QoL. The PROMIS Global Health measure [35], used in the myelopathy cohort, assesses general physical and mental health through 2 subscales: Global Physical Health and Global Mental Health. Higher scores indicate better health status. In the transplant cohort, the Short Form-20 (SF-20) [53] was used. It includes domains such as physical functioning, pain, general health perceptions, and emotional well-being. Like PROMIS, higher scores reflect better functioning.

Results

Overview

In the following sections, we present cumulative results from all 3 studies (N=41). We first describe patients' perceptions of QoL before and after surgery and relationships between outcomes (eg, pain affecting sleep). We then report on patients' current use of smartphones, apps, and wearables for health self-management, followed by their attitudes toward using these technologies for pre- and post-surgery QoL assessment. Figure 1 presents the summary of the research findings.

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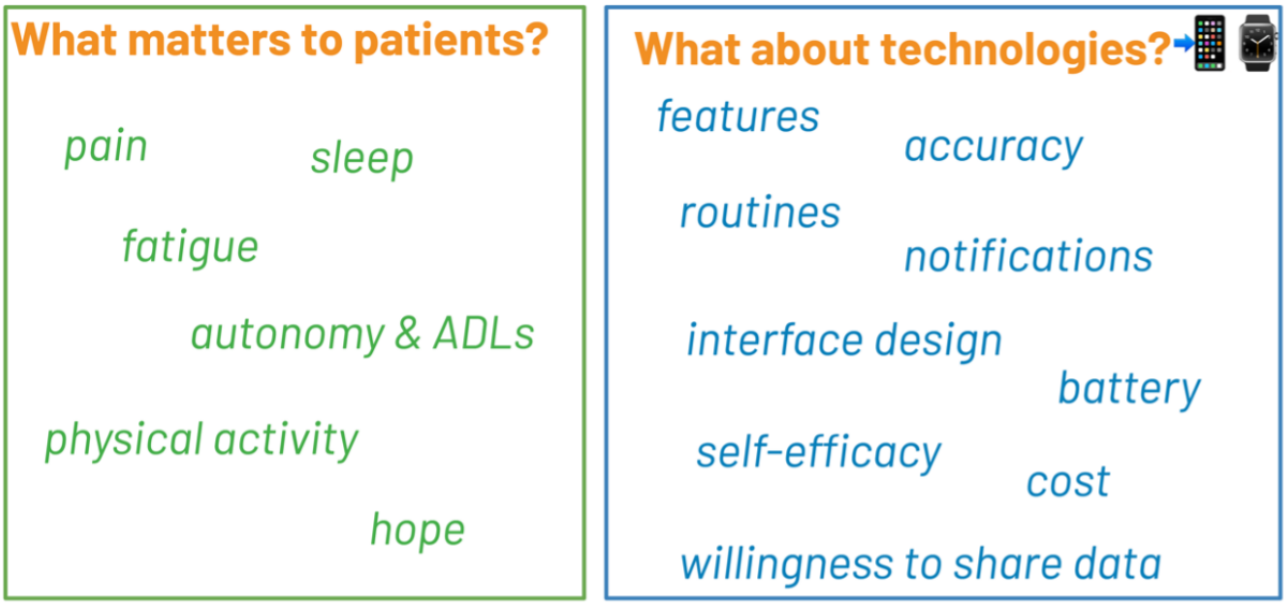
Figure 1. Summary of research findings. ADL: activity of daily living.



Patients' Pre-Post QoL Outcomes

Although there were 3 different pathologies requiring surgery, we observed similarities in the factors impacting the patients' QoL (n=41) and outcomes that have improved or deteriorated following the surgery (n=36). Most patients reported seeing their QoL improve greatly following surgery. A few patients with DCM (n=2) reported seeing no improvement after surgery, although they reported no worsening symptoms either. One patient with DCM did see their condition worsen after surgery.

Pain

Patients in the DCM and hip replacement groups both reported having pain before surgery (n=8). Specifically, patients with DCM had neck pain (n=3) and back pain (n=2), while patients undergoing transplantation (n=8) reported abdominal pain. Patients (n=5) have reported that having chronic pain impacts their sleep, which was especially present in the transplant group. One patient with DCM mentioned waking up several times a night because, depending on their position, they had pain or numbness, so they had to wake up to change position ("I wake up at night, stretch my arm and go back to bed."). In the hip replacement group, both pre- and post-operative patients reported less pain as a key positive impact of surgery. Pain can also impact morale and mental health; as one patient said, "I have pain all the time; it gets on my nerves. I become easily aggressive."

The surgery clearly relieved pain for the patients with DCM (n=3); following the surgery, they no longer reported the same pain levels they had before the surgery, which improved their mental health as well. A few patients with DCM (n=3, %) still reported some pain, but much less than before the surgery, which did not impact their QoL. A few patients (n=5) reported still having pain despite the surgery. Notably, patients who had a hip replacement mentioned having pain right after the surgery. Patients with DCM (n=9) who had been operated on between 6 months and 1 year before this study also reported sustained pain, especially back and neck pain, as well as hand pain in one case. Such chronic pain can lower morale because it is always present, and patients do not know how to manage it.

Sleep

Some patients (n=4) reported having difficulty sleeping after the surgery. For hip replacements, patients had to sleep only on their backs, which was uncomfortable. Overall, the improvement in pain after surgery allowed patients to sleep better. Patients (n=7) reported sleeping well or having no problems concerning sleep, and patients who underwent transplantation (n=5) reported better sleep overall. As the latter ones were long-term homebound and not working, they confirmed that they were able to sleep for extended periods in the postoperative period, having naps throughout the day.

Fatigue

Another symptom frequently mentioned by all the patients before the surgery was fatigue (n=18). Patients reported being always tired or very quickly tired, which impacted their activities of daily life and their daily functioning. Patients undergoing transplantation lacked the strength to manage daily activities requiring some force and coordination (eg, shopping). After the surgery, some patients (n=4) reported persistent fatigue. The fatigue experienced by patients who underwent transplantation improved within the first 3 months as their new liver started functioning well.

Autonomy and Activities of Daily Living

The loss of autonomy is characterized by the inability to accomplish certain activities of daily life without the help of a third person. This loss of autonomy can concern activities of daily living (ADLs), such as feeding, dressing, and toileting, or instrumental ADLs, such as cooking, cleaning, and shopping. Almost all the patients expressed a loss of autonomy during the preoperative phase, as they could no longer be as autonomous as before for several activities. For example, 2 patients from DCM expressed difficulties toileting before the surgery, and they had to ask their caregiver for help with washing. All

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patients undergoing transplantation (n=8) were additionally confused and unable to function cognitively.

Before surgery, several patients with DCM and patients undergoing transplantation (n=7) reported being unable to stand for long periods, with patients with DCM frequently needing to change position and patients undergoing transplantation fearing falls due to confusion or weakness. Patients with DCM described additional symptoms affecting autonomy, including partial paralysis, loss of strength, tremors, and tingling sensations in the arms or hands, which limited daily activities, such as writing, cooking, or carrying objects weighing more than 5 kg, which requires them to be accompanied to do their food shopping or have them delivered (n=5). Both patients with DCM (n=4) and patients undergoing THR experienced reduced walking ability, often relying on public transport or assistance due to imbalance or fatigue (n=3). Some reported near-falls and a need for accompaniment, describing their walking ability as resembling that of "little old men."

Some of the patients with DCM reported using a walker to get around. Walking among patients undergoing transplantation was influenced mostly by their fatigue or state of confusion, which prohibited them from even leaving home. In the United States, the walkability of many areas is relatively low, and many patients expressed being practically homebound for most of the preoperative period (n=5).

Patients (n=16) also reported being unable to drive before the surgery. A patient with DCM expressed that what handicapped them were his legs, which were "no longer able to press the brake pedal." Patients undergoing transplantation did not have the cognitive capability and physical force to drive.

After the surgery, a few patients (n=3) still reported having difficulty walking. They tire quickly when walking and can no longer walk long distances: "I have to make a considerable effort to walk 1 km." One patient also reported having difficulty cleaning themselves. While some need to get assistance, others said they always manage to do it, "but at my own pace." Following the surgery, patients with DCM (n=3) could also do their household chores worry-free or at their own pace ("It takes me longer to do [the cleaning], but I am autonomous."). They went back to doing their shopping but always had to be careful not to carry more than 5 kg (n=2). Most patients with DCM were also able to resume their professional activity following their surgery; 3 patients still practice their profession. After surgery, only a few patients with DCM (n=3) mentioned that they still had problems with their arm, such as persistent loss of strength to carry ("things that slip out of your hands"), tremors, numbness in their hand, or difficulties writing. "I have a permanently disabled hand; the feeling will never be the same."

Most patients could drive their car as they did before the surgery, especially for patients who underwent LTs (n=11). However, some patients who underwent transplantation were not able and willing to drive in the postsurgery period, as some expressed that they were afraid of being alone and confused in the car (n=3). As they were not working, they expressed that they did not need to start driving rapidly again, and it all started slowly. Despite the surgery, some patients still cannot drive (n=2). For 1 patient with DCM, they could no longer turn their neck to see behind them, so they no longer drove in the city. Another patient could no longer do their job as a taxi driver for the same reason, as the pain while driving handicapped him too much.

Physical Activity

The major QoL outcome for all the patients discussed for pre- and post-surgery period was physical activity beyond walking. Most patients expressed that they felt impacted by their pathologies because they were not able to do as much physical activity as they did before their diagnosis. Patients (n=3) were happy to be able to resume some physical activities, even if they could not do as much as before. Being able to resume their physical activity was very satisfying for them.

Hope

Patients awaiting liver transplantation (n=8) expressed that their overall health status depended on their hope of receiving transplants. After transplantation, the improvement in hope was significant—they said they were grateful for the transplant, had high hopes for their own life, and would like to contribute to others' health and QoL. Some patients expressed that participation in this study was also a way of giving back to the health care system. The hopes for the future were high, although the youngest patients (aged <60 y) were unsure if they could find a job after years out of their profession.

Personal Technologies Current Use and Attitudes Toward the Future Use

This section discusses results of factors influencing the use of personal technologies such as smartphone apps and wearables by patients in their daily lives, as well as their attitudes for use of these technologies for health self-management and pre- and post-surgery QoL assessments.

Current Use of Personal Technologies by Patients and ADLs

Most patients with DCM felt comfortable using personal technologies, especially smartphone apps. Eleven patients felt comfortable using smartphones, tablets, and computers. They use their smartphones daily without difficulty; they use them mainly for basic features such as calling, instant messaging systems, internet searches, and photos. The computer, on the other hand, for most patients, was considered a tool for work or administrative tasks (eg, paying bills and accessing bank accounts) and was, therefore, less often used: "impossible to do without (computer) today but as I am still working, I am still confronted with its use."; "the computer is just for work and at home." However, they still felt comfortable with this tool. One patient was a computer scientist and expressed feeling particularly comfortable with their computer.

On the other hand, 4 patients with DCM felt moderately comfortable with the smartphone and tablet and were not comfortable with the computer. Here too, patients use their smartphones daily but only for basic features such as calls and instant messaging services but said that they do not dare to do more on their smartphones and prefer asking a relative when they have a problem. "I use my phone a lot. Not very comfortable with it (smartphone), I don't really know how to

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install everything."; "I'm not very comfortable with it, but I know how to use it (new technologies) if I have to. But sometimes I feel like kicking the can down the road."

Patients who underwent transplantation all own and use a smartphone, and some of them use a tablet and feel comfortable with achieving the needed tasks. Again, it must be noted that their support persons admitted to taking over more complex tasks such as paying bills or scheduling medical appointments due to the patient's cognitive impairment due to the disease. Hence, the phone and tablet were mostly used for their communication, entertainment, and other personal hedonic needs. A computer was not mentioned at all; just one patient said that they used it to watch movies on a larger screen.

Patients undergoing total hip replacement were comfortable with new technologies, and they mentioned that it was interesting to be able to link in with devices already being used, such as smartphones or smartwatches.

Only one patient with DCM was not comfortable at all with all digital tools. He said they used the smartphone only to call and that their wife used these devices. In addition, 3 patients with DCM who were comfortable with the technologies reported that they could no longer use them because of their condition. One patient used other tools such as a voice-activated system to replace the mouse and send more voice messages. Another patient could no longer use their smartphone or computer because they no longer had sensitivity in their fingers. The third patient mentioned that they could no longer stay more than 30 minutes in front of their computer without having pain in the neck.

Current Use of Personal Technologies by Patients and Health Self-Management

Although patients with DCM, patients undergoing transplantation, and patients undergoing total hip replacement say they are comfortable with new technologies, very few of them use these for their health management. Only 2 patients with DCM and 2 patients undergoing transplantation had a smartwatch that could measure physical functioning, physical activity, and sleep. Three other patients with DCM had used a connected watch but no longer used it; for 2 patients, the reason was that it had proved "useless," and for 1 patient, the bracelet had broken, and it was impossible to repair it. Overall, very few patients also used mobile apps for health self-management. Patients undergoing transplantation mostly mentioned accessing apps for their medical appointments and electronic patient records ("myHealth" app). Some patients with DCM (n=4) mentioned looking at their personal statistics taken by the smartphone, such as the number of steps taken during the day. A single patient with DCM who used a smartwatch also used an app for stretching exercises and a meditation app.

As described earlier, we discussed with the patients the factors influencing their use of personal technologies for self-management, which were coded according to our previous studies [15,52]. No new factors were considered beyond those identified by the previous works. The results are as follows.

Personal Technologies: Features

The majority of patients with DCM evaluated wearable devices as "useless." For most of them, it was not useful to know the daily number of steps, the quality of sleep, or their heart rate because they knew if they had walked enough or slept well ("I know if I slept well or not. I don't see the point of the watch."; "I walk a lot; I don't need to calculate the number of steps"). Most patients with DCM are aware of their day-to-day behaviors and health status and do not find the device appealing. Another point mentioned by patients in all 3 studies was data privacy. They were worried about who could have access to their data and about paying attention to what was being done with their data. Especially, the patients with DCM in Switzerland have expressed that concern.

On a positive note, the patients with DCM and patients who underwent transplantation who had Fitbits (provided to them in the study) have reported looking at the data collected by their smartphone or smartwatch daily. They mainly looked at (from the most to the least mentioned) the number of steps, sleep quality, heart rate, and calories expended. They also thought it was important to have one device that does it all. Patients who underwent transplantation were more open to the device's features and potential use for self-care. However, patients awaiting surgery were too confused to understand what the numbers meant and how they related to their liver condition. Support persons of patients who underwent transplantation expressed that it would be good for them to know when the patient is sleeping (data from a wearable) and to be able to plan their visit, especially for those not living with the patient but occasionally visiting them.

Personal Technologies: Accuracy

Patients also questioned the accuracy of these devices. A patient in the hip replacement group said that when they knitted, the device had recorded steps but not when they walked on a treadmill. Another patient reported being perplexed about the accuracy of the data taken for the electrocardiogram. Patients with DCM mentioned that these devices could not replace the actual observations made by physicians. They could not replace humans but rather supplement or notify the presence of red flags but not replace them. On the other hand, patients who underwent transplantation seemed not to question the accuracy as much, likely assuming that it must be accurate enough if the device is provided to them in clinical settings.

Personal Technologies: User Routine

Patients from the hip replacement group found it positive that the devices were not intrusive in their daily lives, and they could adjust the device to their personal life. Yet, some patients found these devices to be stressful. Having access to all these data daily could make them anxious and hypochondriac. Without medical training, it can be difficult to know what is normal: "I don't want any of this; measuring his blood pressure, etc is getting paranoid!"; "I'm not interested; maybe one day I'll get into it. It's not useful right now. It's anxiety-provoking to watch your heart rate every day. I trust nature. I don't need it to know if I'm okay."; "I leave that (connected watch) to hypochondriacs."

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Personal Technologies: Notifications

All patients also mentioned that they did not want to be permanently disturbed by devices with notifications. Some patients found that they are already quite dependent on new technologies and already received enough notifications not to have to add more. They would be happy to use these devices if they did not disrupt their day-to-day activities.

Personal Technologies: Interface Design

Patients with DCM and patients who underwent transplantation were also concerned about the complexity of these wearables. Some patients with DCM and patients who underwent transplantation felt their devices were too complicated for them and feared that they would not know how to configure them. Patients with DCM also found these devices not user-friendly or inviting. Patients who underwent liver transplantation, in particular, as mentioned earlier, overall, may have been too confused to manage the device and its settings.

Personal Technologies: Battery

One last problem mentioned about these devices was having to remember to charge them regularly. Patients undergoing liver transplantation, in particular, were worried about this.

Personal Technologies: Self-Efficacy

Patients in the hip replacement group mentioned that device feedback could lower their sense of self-efficacy, that is, the belief that they are able to change, that they are capable. This can upset them, knowing they are in fact walking less than they thought they were. It can also stress them out, fearing that they may perform worse than they imagined. In addition, the pressure could be put on people who will take longer to recover after surgery because of other conditions or the context of their lives. They mentioned that it was very important to be able to customize these devices to each user with goals that will be achievable by the user according to their abilities (eg, adjusting the desired target for the daily number of steps). Conversely, patients across the DCM, transplant, and hip replacement groups reported that postsurgery activity data could enhance motivation, provide reassurance about progress, and support recovery when appropriately interpreted.

Personal Technologies: Cost

Patients in all 3 studies mentioned the price of these devices as a potential barrier to their acquisition. They may be interested in using them, but they may be too expensive for them, which can create inequalities. On the other hand, patients who underwent transplantation refused to use a “cheap plastic” wearable because they did not want to put it next to their expensive Rolex watch.

Personal Technologies: Willingness to Share Data

Patients with DCM, patients who underwent liver transplantation, and patients undergoing total hip replacement mentioned that being able to share their data with relatives or physicians was positive. Patients who underwent transplantation especially were hoping that the statistics from a wearable could be shared with a care team, who would then reach out to the patient if abnormalities were seen in the data due to, for example, extended pain periods (especially before surgery).

Patients’ Attitude Toward Technologies for Measuring the QoL Outcomes

Differences emerged between countries in patients’ perceptions of wearables for QoL assessment before and after surgery. In the transplant@US group, devices were generally well accepted, although some patients required assistance managing them before surgery due to confusion or fatigue. Participants in the hip@UK group were positive overall but expressed some concerns about data sharing and privacy. In contrast, acceptance was lowest in the myelopathy@CH group, where several patients found wearables intrusive or questioned their ethical relevance and ability to meaningfully reflect QoL (eg, distinguishing emotional from physical causes of reduced activity). Nonetheless, most patients indicated they would consider wearing such devices long term if this contributed to research or improved care.

Comorbidity Challenge

One of the most important results of this study that was especially significant for the patients with DCM, and to some extent for patients undergoing transplantation, was the fact that it is important to measure the patient’s overall QoL due to the presence of symptoms related to comorbidities, which also largely influence their daily life functioning, health status, and QoL. Namely, for myelopathy@CH and transplant@US patients, it is difficult to know what part of the symptoms is due to the pathology of interest or to other related diseases. For example, patients with DCM reported leg problems, but according to neurosurgeons, these problems are often due to a lumbar problem rather than DCM. That specific comorbidity is referred to informally as ‘double hit,’ that is, impacting the neck and the back. Additionally, one patient with DCM and one patient who underwent transplantation mentioned that most of their current poor QoL concerns were not due to myelopathy but due to their cancer-related treatments, including aggressive chemotherapy.

Moreover, for the myelopathy@CH patients, the DCM diagnosis is sometimes delayed, while the QoL is influenced negatively. Patients have reported seeing several specialists over a period of at least a year before seeing the neurosurgeon who diagnosed the DCM and scheduled surgery. Most of the time, they saw specialists who did evoke potential treatments, which, however, improved neither their functioning nor their QoL. Any further implementation of these approaches shall consider these aspects and assess the patients’ QoL holistically.

Discussion

Principal Findings

We observed a few similarities between the results of this study with different patients’ subgroups, despite the difference in pathologies, course of diagnosis and treatments, as well as the cultural and economic settings in which the interventions took place. Overall, initially, patients expressed having had a poor QoL before the surgery. What impacted the patients the most in the pre-surgery phase was pain, which, in the long term, affected their morale and their overall mental health. Patients

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also reported being either constantly tired or becoming tired very quickly. Finally, the other factor that influenced their QoL was the loss of autonomy, with difficulties in walking, standing, driving, shopping, or washing. Another factor mentioned specifically by patients with DCM is the time it takes to diagnose the pathology. Symptoms initially manifest by problems in the hands (eg, tingling, numbness, loss of sensation), and patients are often referred to other specialists. Often, they mentioned wasting up to a year consulting different specialists before finally seeing a neurosurgeon who diagnoses DCM and performs surgery. Indeed, the symptoms of DCM resemble those of other pathologies, such as carpal tunnel syndrome, and additionally, some physicians may hesitate to make more complex neurological diagnoses [54]. This explains why some patients reported having treatments with evoked potential and were diagnosed with DCM later, once their QoL had already deteriorated significantly.

After the surgery, most patients improve their QoL, especially within the first 6 months after surgery. Patients reported having great pain relief, better sleep, gaining autonomy (eg, self-care, driving, or even working), or enjoying physical activities again. But some patients, despite the surgery, still have pain, feel tired, have difficulty sleeping, or cannot drive or walk as much as before. However, for some patients, these persistent negative effects after surgery can be explained by comorbidities, such as a patient undergoing cancer treatment who was weakened by chemotherapy or patients with other spinal conditions that may explain the difficulties encountered in walking and pain.

Most patients with DCM and patients who underwent transplantation were comfortable with the daily use of new technologies, especially with their smartphones that could measure their physical activity and sleep. However, they generally had a poor appreciation of smartwatches, especially the patients with DCM. Most patients thought these devices were considered useless; they did not need them to know if they had slept well or walked enough. The patients also did not want to be bothered by notifications. Patients also feared that the watch would be too complicated. Indeed, the fact that these devices must be easy to use was also noted by patients in 2 other studies [55,56]. Patients have also mentioned that wearables can have a negative effect on self-efficacy if they observed lower results than what they expected (having taken fewer steps than they imagined). Finally, the cost of these devices was also one of the negative points discussed. This contrasts with the results of another study in which patients admitted that cost was not the most important factor in their decision to adopt wearables [55].

However, positive points were also discussed, especially for the transplant@US study. They particularly appreciated that they could view the data collected by the wearables on a daily basis. This also made it possible to see the progress made after surgery, which motivated them to put in more effort. Sharing personal sleep and activity data with relatives or health care practitioners was also positive because it was not considered too intrusive. Patients in a study also found it very useful to be able to share data collected by wearables with health care professionals, with 24.8% of participants using wearables having already shared their data [56]. In our previous studies, we have already observed a significant difference in attitudes between patients in Europe and the United States concerning the sharing of personal data with different stakeholders (either anonymously or not) for various services being provided based on that data [57]. Patients in Europe were generally more cautious when it came to sharing their data. Another possible explanation for the difference in perspectives and evaluations between the patients with DCM and patients undergoing transplantation is the level of their exposure to and familiarity with the wearable devices. Transplant patients had the opportunity to use a wearable device continuously over a 6-month period, allowing them to better understand its functionalities and to develop a more informed, and often more positive, opinion. In contrast, patients with DCM were asked to give their opinion hypothetically, based on the idea of wearing and using such a device, in many cases, without having had any direct or sustained experience with it. This lack of practical engagement may have limited their ability to assess the device's potential benefits and drawbacks in real-life contexts and could partially explain their more reserved or critical attitudes [27].

From these results, we derive the implications for future research. As we conclude that the factor that most affects the patient's QoL is pain, it is legitimate to think that wearables should measure pain. This could make it possible to better assess the prioritization of surgery and manage the course of convalescence. However, as such a device does not exist yet, despite huge research efforts [58,59], the only way to measure changes in pain is by measuring changes in functioning and assessing changes in sleep and activity. Specifically, the measurement of the number of steps taken in a day as well as their distribution is interesting because most patients mention difficulty walking before the surgery and an improvement after the surgery. Being able to observe their progress is motivating for them. The change in the number of steps is correlated with physical activity, although this function is not linear and depends on many personal and social factors [58].

Wearable technologies have thus emerged as valuable tools to support such monitoring, especially when linked to mobility and sleep metrics. They provide continuous and passive data that can complement traditional QoL instruments. However, as Wac and Wulfovich [60] point out, these data primarily capture physical function and activity and fall short of encompassing the full range of experiences that matter to patients in their daily lives [60]. Social, emotional, and cognitive dimensions of QoL remain largely inaccessible through wearable sensors alone. For QoL assessment to be truly patient-centered, digital tools must integrate both objective and nonmeasurable, subjective data sources. This may include combining wearable data with ecological momentary assessments, app-based questionnaires, or contextual signals derived from smartphone use and environmental factors. Such multimodal approaches can better reflect the lived experience of patients and yield richer, more meaningful insights into their health trajectories.

Alongside the abovementioned developments, as the field advances toward more patient-centered and real-world assessments of health, it is increasingly important to ensure that emerging metrics, particularly those derived from digital health technologies, are developed in alignment with regulatory

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expectations. The US Food and Drug Administration has emphasized the need for clinical outcome assessments to be supported by robust evidence demonstrating their validity, reliability, and relevance [61]. In this context, our exploration of wearable-derived data as a complement, or potential alternative, to traditional self-report–based QoL instruments represents a preliminary step toward regulatory and methodological alignment. While traditional self-report–based QoL measures remain valuable, they often lack the sensitivity to capture subtle or short-term changes in a patient's condition [62,63]. Wearable devices, in contrast, can passively and continuously collect data on key aspects of daily functioning, such as mobility and physical activity, offering a more responsive and granular view of patient health status [64]. Future research should focus on the development and validation of such digital end points within a clear regulatory framework, ensuring that they are both meaningful to patients and appropriate for use in clinical research and practice.

However, in contrast to previous research showing high levels of acceptance for wearables, particularly when they are integrated into clinical care and provide tangible value to patients, our study revealed more cautious attitudes, especially in the United Kingdom and Swiss cohorts. Smuck et al [65] highlight 7 key factors that influence the successful implementation of wearable technologies in health care, including care pathway integration, clinician endorsement, patient-centered design, and clear benefit communication. These structural enablers were largely absent from our European cohorts, where participants discussed wearables hypothetically and outside a care context. In contrast, the US transplant cohort, where patients had direct experience using wearable devices in their clinical care, expressed more positive attitudes. This difference underscores a key aim of our study: to explore how contextual and experiential factors shape patients' attitudes toward digital health tools. Our findings suggest that acceptability is not only linked to the technology itself but also to its perceived integration, clinical relevance, and user familiarity, reinforcing the need for context-aware implementation strategies.

On the other hand, most patients were reluctant to use wearables, and even if, as patients with DCM indicate, they would be willing to wear them for the QoL outcomes measurement, we would not be able to ensure the quality of the data collected; the patients may forget to charge the device, lose it, or otherwise unintentionally incur data loss [66]. We hypothesize that when designing the technologies for QoL outcome measurement, it is better to favor smartphones and sleep and activity sensors [67]. Indeed, the patients did not want to have to wear a designated smartwatch or other devices on them, but, on the other hand, they all have a smartphone with which they feel comfortable, and which is always with them. Therefore, collecting health data automatically captured by smartphones seems like a good alternative. Indeed, although these data are less accurate than those taken by a wearable, patients will accept the smartphone more.

Limitations

A key limitation of this study is the use of different study designs and data collection methods across patient groups, which limits comparability across studies due to differences in study design, participant demographics, and contextual factors, which may affect the generalizability of the synthesized findings. However, this methodological diversity also serves as a strength, allowing for the integration of both hypothetical and real-world perspectives on digital tool use. This broader view provides valuable insights into context-specific human factors influencing patients' acceptance and can guide the development of more flexible, patient-centered digital health solutions.

An important limitation is also that we have great disparity in our samples with low representativeness. That is a result of an overall strategy relying on convenience sampling and linked to difficulty recruiting patients in a short time in a clinical setting during the COVID-19 pandemic; for the patients with DCM and patients undergoing transplantation, the clinical appointments happen only once a week. Additionally, not all patients could express their opinion during the pre-surgery phase. Particularly for myelopathy@CH, for which we have patients who have not yet been operated on (n=5), others who have been operated on for less than 6 months (n=6), and others 1 year after their surgery (n=10).

It would also have been interesting to interview patients before and after their surgery and at several time intervals after the surgery. We could have asked them to complete the same QoL assessment as the SF-36. In this way, we could have observed whether the surgery increased the QoL of the patients and how long after the surgery a better QoL was observed.

There are the following limitations related to the use of the existing PRO-based QoL measures in the patient cohorts. In the myelopathy cohort, the PROMIS Global Health measure, while widely used, lacks condition-specific sensitivity and may not fully capture key symptoms, such as fine motor deficits, subtle functional decline, or pain and fatigue unique to spinal cord impairment. In the LT group, the SF-20, being a shorter and older measure, shows ceiling effects and provides limited insight into emotional well-being, medication burden, or transplant-specific QoL challenges. Both tools, although valuable, fall short in addressing the nuanced and evolving health experiences relevant to each patient population.

Additionally, some results can be explained by recruitment bias, such as the age of the patients undergoing transplantation and related digital literacy, and the cost of wearables, which is perceived as more problematic by people with a low socioeconomic status.

Another limitation occurs in our results related to comorbidity. As some of our data can be explained by comorbidities, it would have been wise to use a questionnaire such as the Charlson Comorbidity Index [68]. This would allow us to consider comorbidities and better control whether the symptoms are better explained by a comorbidity or by the pathology of interest in the study.

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Conclusions and Areas of Future Work

Although the different studies concern different pathologies (eg, myelopathy, hip replacement, and LT), we can observe the same problems that impact the patient's QoL: pain, loss of autonomy, and difficulties walking. For most patients, their QoL improved after surgery. The patients were pain-free, or their pain was greatly reduced; they regained their autonomy and could do the sports activities they used to do and walk more. Patients were reluctant to using wearables, some finding them unnecessary or not wanting to wear them daily. At the same time, they are very comfortable and use their smartphones daily. Therefore, for a measurement of the change in pre-and post-operative QoL in patients undergoing surgery, we recommend using smartphones instead of wearables to assess mostly the ADLs (including mobility) and sleep, as these are influenced by the level of experienced pain, correlate to a patient's autonomy, and will reflect the daily level of walking.

For future studies, we should have the same method to allow for better comparison. To have either interviews or focus groups for all the studies and to have the same questionnaires for the patient's QoL. It is interesting to assess the QoL before and after surgery to observe objectively if there has been an improvement. The use of the EQ-5D or other relevant instruments seems quite appropriate for this purpose but also to get the economic value of improvement in terms of QALYs [69].

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Data Availability

No data were available because ethics approvals did not include the option of sharing the data.

Authors' Contributions

The protocol development, gaining ethical approval, and patient recruitment were performed by LG, KW, EC, AB, AN, and ET. The data analysis was performed by EC, KW, AB, and LG. The first draft was written by LG. All authors reviewed and edited the manuscript and approved the final version of the manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Semistructured interview grid for the studies.
[PDF File, 933 KB - formative_v10i1e68293_app1.pdf]

Checklist 1
STROBE checklist.
[PDF File, 277 KB - formative_v10i1e68293_app2.pdf]

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Abbreviations

ADL: activity of daily living
DCM: degenerative cervical myelopathy
LT: liver transplant
PPI: patient and public involvement
PRO: patient-reported outcome
PROMIS: Patient-Reported Outcomes Measurement Information System
QoL: quality of life
SF-36: Short-Form Health Survey 36
STROBE: Strengthening the Reporting of Observational Studies in Epidemiology
THR: total hip replacement

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Multimodal Sentiment and Emotion Analysis Framework for Personalized Health Coaching Messages: Proof-of-Concept Study

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Abstract

Background: Text generation approaches in health care communication have evolved along 2 major paths. The first path involves generative adversarial networks, progressing from basic architectures to specialized variants like Text-to-Text Generative Adversarial Network (TT-GAN) and Time and Frequency Domain-Based Generative Adversarial Network (TF-GAN), which address challenges in discrete text generation through techniques such as Gumbel-Softmax and reinforcement learning. The second path emerges from transformer-based architectures, particularly Generative Pretrained Transformer-2 (GPT-2), which uses extensive pretraining and self-attention mechanisms to generate contextually appropriate text. GPT-2's transformer architecture enhances persuasive health communication by generating personalized messages using various strategies like task support, dialogue support, and social support for effective health interventions.

Objective: This study aimed to use GPT-2 as a generative method to construct persuasive text in a dataset and compare the performance of sentiment analysis and emotion detection analysis.

Methods: We combined sentiment analysis tools (VADER [Valence Aware Dictionary and Sentiment Reasoner] and TextBlob) with emotion detection methods (Text2Emotion and NRCLex [National Research Council Lexicon]) to analyze health coaching messages across different persuasive types: reminder, reward, suggestion, and praise.

Results: TextBlob and VADER achieved accuracies of 57% and 69%, respectively, while RoBERTa (robustly optimized BERT approach)-sentiment outperformed them with an accuracy of 88%. Emotion detection showed a high prevalence of "joy" and "happy" labels (93.69% positive skew). While transformers excel in accuracy, lexicon-based models like VADER offer a better performance-efficiency balance for real-time health communication systems. For emotion detection, all categories showed perfect accuracy (1.0), while trust showed mixed results, with precision, recall, and F_1-score values ranging from 0.81 to 0.96. The emotion detection analysis revealed varying success rates across different emotions, with some categories, such as anger and neutral, showing reasonable performance and others, such as trust, showing mixed performance.

Conclusions: This research contributes to understanding the emotional dynamics of persuasive health communication and highlights both the capabilities and limitations of current natural language processing tools in analyzing health-related persuasive messaging. This proof-of-concept study using synthetically generated data establishes a methodological framework for multimodal sentiment and emotion analysis. The findings require validation with real-world health coaching messages before clinical deployment.

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KEYWORDS

sentiment analysis; emotion detection; persuasive communication; health coaching; natural language processing

Introduction

Background

Health coaching has been actively researched, and the results are expected to increase human life expectancy. However, with the advancement of technology and social media, the pattern of life is also changing. It appears that health care professionals are not directly involved, and the content does not always align with the user's behavior or situation [1]. The necessity for advanced data preprocessing and analysis frameworks to improve system efficacy has been brought to light by the explosive growth of persuasive technology. The optimization of these components mostly depends on precise data processing and user behavior interpretation, even if contemporary persuasive systems use a variety of tactics (eg, reminders, rewards, suggestions, and praise). This study tackles the difficulties in converting raw data into useful insights by offering

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a thorough paradigm for preprocessing and customizing data in persuasive system design (PSD). Adherence to digital behavior change interventions is problematic, and some reasons for this include the absence of a social incentive from a health care practitioner and the presence of content that may not always be relevant to the user's circumstances [2].

Advanced data preprocessing and analysis frameworks are vital for improving system effectiveness, as evidenced by the quick development of persuasive technology. As pointed out in a previous study [1], the absence of social incentives and personalization makes it difficult to adhere to digital behavior modification treatments. Although computerized interventions offer practical ways to provide behavioral assistance at a reasonable cost [3], their efficacy mostly depends on precise data processing and user behavior interpretation.

Changing habits and lifestyle choices can significantly improve health outcomes and help prevent early mortality; thus, it is important to design compelling messaging strategies for a digital health assistant that can help individuals stay committed to their prescribed health programs and behavioral changes [4]. However, persuasive communication, which utilizes reinforcement learning (RL), has been implemented only in the reminder portion of PSD, and thus, it does not fully utilize the PSD capabilities proposed previously [5]. Moreover, this could lead to the dataset being used only for the reminder portion. On the other hand, there is no segment for implementing praise, reward, etc. This limitation motivated us to conduct our experiments with data preprocessing using Text-to-Text Generative Adversarial Network (TT-GAN) [6] and text generation with knowledge transfer from Generative Pretrained Transformer-2 (GPT-2) [7]. Generative adversarial networks (GANs), which represent a class of artificial intelligence (AI) models capable of producing incredibly realistic synthetic data, have emerged as a significant innovation and demonstrated impressive progress in machine learning studies.

Our framework encompasses multiple data processing layers, beginning with fundamental preprocessing techniques for cleaning and standardizing raw user interaction data. This includes handling missing values, normalizing temporal data, and standardizing input formats across various data sources. The behavior analysis component uses pattern recognition algorithms to identify user engagement trends, activity cycles, and response patterns to different persuasive elements. These patterns are crucial for developing effective personalization strategies.

The classification system utilizes machine learning algorithms to categorize user behaviors and preferences, enabling dynamic adaptation of persuasive strategies. Natural language processing (NLP) techniques are integrated to analyze user feedback and responses, extracting sentiment and context to refine the system's understanding of user needs. This multifaceted approach ensures that the persuasive elements are personalized, contextually appropriate, and timely.

Our research combines these components into a cohesive framework to address the gap between raw data collection and effective persuasive strategy implementation. Compared with traditional static approaches, the proposed system significantly improves user engagement and behavior change outcomes while maintaining scalability and real-time processing capabilities.

To close the gap between health care professionals' involvement and the GPT-2 architecture, we conducted an experiment combining the GPT-2 method and data preprocessing to obtain a better result for the PSD element. In this experiment, we advanced text generation using GPT-2. Then, we compared the result with the sentiment analysis finding and performed validation with health care practitioners to increase its relevance.

The contributions of this experiment are as follows:

- Introduce the framework of RL and persuasive technology (PT) as the combination of human-computer interaction elements and machine learning
- Demonstrate the effectiveness of using GPT-2 as a generative method to construct persuasive texts in datasets for health coaching messages
- Compare the performance of multiple sentiment analysis tools (VADER [Valence Aware Dictionary and Sentiment Reasoner] and TextBlob) when applied to health coaching messages across different persuasive types (reminder, reward, suggestion, and praise)
- Evaluate and compare the effectiveness of different emotion detection methods (Text2Emotion and NRCLex [National Research Council Lexicon]) for analyzing emotional content in health-related persuasive communication.

This study serves as a proof-of-concept for integrating generative AI with sentiment and emotion analysis in health-coaching contexts. We acknowledge that our use of GPT-2–generated synthetic data provides controlled conditions for methodological development but has inherent limitations in ecological validity. The findings represent baseline performance under ideal conditions and should not be extrapolated directly to real-world deployment without further validation using authentic patient-provider communication. This study provides a foundational computational framework for analyzing the sentiment and emotional characteristics of persuasive health coaching messages. We focused on establishing the baseline performance of NLP tools and identifying emotional patterns across persuasive types. However, we did not evaluate whether these sentiment/emotion labels translate to improved message quality, safety, or user outcomes. Such validation requires clinical trials with patient participants, which represents future work beyond the scope of this computational methodology study. Our contribution is the establishment of the analytical infrastructure necessary for future outcome-based validation.

In the next section, we discuss related work. Later, we provide some background on the knowledge used in the experiment and analyze the results. Lastly, we summarize the findings, provide conclusions, and indicate future directions.

Related Work

Overview

GANs are AI models in which 2 neural networks compete against each other—one generates fake data while the other tries to detect the fake data. Over several years of study and experimentation, many variations of GANs have been improved

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in terms of flexibility (f-GAN [8]), stable training behavior compared with a traditional GAN (w-GAN [9]), and learning of disentangled and interpretable representations (Information-Theoretic Generative Adversarial Network [InfoGAN] [10]). However, TT-GAN appears more appropriate than the stated GANs, as it is more reliable for language and transformer-based models when using teacher forcing. With regard to dialogue generation, document summarization, and machine translation, language models play crucial roles in optimizing linguistic structure. Based on a previous report [7], existing neural networks can be broadly categorized into 2 types: recurrent models (eg, recurrent neural network [RNN] and long short-term memory [LSTM]) and self-attention models (eg, GPT-2 and Transformer-XL).

Text Generation Using GANs

A previous study [6] demonstrated that TT-GAN could successfully provide 2 types of text outputs: semantic summarization and paraphrasing of movie reviews in both English and Chinese. However, an examination of the experiments reveals a lack of a precise comparative analysis between the proposed approach and existing methods in terms of limitations.

A previous survey [11] identified 3 main approaches to GAN-based text generation: Gumbel-Softmax differentiation, RL, and modified training objectives. The adaptation of GANs for text generation presents several challenges, including the initial design of GANs for continuous data (eg, images) and not discrete text data; the need to preserve grammar, syntax, and semantic properties; and the pretraining burden for many approaches. In terms of language structure requirements, it is important to preserve grammatical accuracy and maintain syntactic coherence. This can lead to the challenge of connecting sequences logically. Finally, technical limitations regarding memory consumption and context understanding remain persistent obstacles when adapting GANs for generating text.

Time and Frequency Domain-Based Generative Adversarial Network (TF-GAN), which has been proposed previously [7], transforms the active learning process from operating on discrete text elements to working within a continuous space of text features by utilizing maximum likelihood estimation (MLE) to convert features back into tokens. Because the MLE model is not an issue, TF-GAN can produce diverse, high-quality text outputs while maintaining variety in its generations.

InfoGAN is considered superior to other GAN methods for several key reasons. First, it uniquely achieves high-quality disentangled representations in a completely unsupervised manner, while previous approaches require supervision. Second, it successfully disentangles meaningful features like writing styles, pose, lighting, and facial attributes across various datasets (MNIST, 3D faces, SVHN, and CelebA) with quality that matches or exceeds supervised methods. Third, its information-theoretic approach of maximizing mutual information between latent codes and observations naturally discovers important data variations without supervision.

GPT-2 for Implementation

Using sophisticated computational methods, text generation systems can produce novel content in response to prompts, creating outputs that frequently appear similar to human writing. Language models that perform the best on linguistic tasks combine 2 key steps: initial pretraining and supervised fine-tuning [12]. Recent research indicates that specialized architectural designs for individual tasks may be unnecessary, and the use of multiple self-attention layers and their transfer are adequate [13,14].

In the context of health, when doctors are not available, health care workers can struggle to provide patients with complete information about their medications, including the benefits and side effects. The ability of GPT-2 to generate summaries could help address this information gap [15]. The study examined whether GPT-2 could accurately understand and explain medication instructions when provided with specific medication names as input [15]. A dataset from the PubMed National Library of Medicine was used for the assessment.

On comparing the proposed Generative Pretrained Transformer (GPT) model implementation for text generation in the health care domain with other methods (eg, InfoGAN and TT-GAN), the proposed approach appears to have some distinct advantages and tradeoffs. While InfoGAN focuses on learning disentangled representations in an unsupervised manner through mutual information maximization and TT-GAN is aimed at paraphrase generation using adversarial networks, the GPT-based method, specifically in [15], targets health care text generation with a more straightforward architecture.

The evolution from simple GANs to more sophisticated models like GPT demonstrates significant progress but also highlights the need to evaluate the generated content carefully. There are various GAN architectures for text generation, but their comparative performance metrics must be critically examined. While TT-GAN's capabilities in semantic summarization and paraphrasing have been mentioned [15], the challenges in text generation reveal significant gaps between theoretical models and practical implementation. The transition from traditional GANs to TF-GAN shows the evolution in handling discrete text data, yet questions remain about the tradeoffs between model complexity and output quality. While relevant, the inclusion of GPT-2 applications in health care appears disconnected from the main discussion of GAN-based text generation, suggesting a need for a more cohesive analysis of different generative approaches. Despite being outdated, GPT-2 still has value for certain applications, such as data augmentation and exploration of text generation concepts. GPT-2 is capable of producing excellent, grammatically sound, and semantically cohesive text. It can produce long-form content that is frequently indistinguishable from human-written text, such as essays, articles, and stories. GPT-2 has shown competence across diverse tasks like summarization, question answering, and text completion [16]. In the experiments, we used GPT-2 as the model for working with persuasive elements, serving as a baseline for future improvements. This establishes a benchmark for comparison with newer models in terms of performance, constraints, and other aspects in health care settings.

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Table 1 compares TF-GAN, InfoGAN, and GPT-2. Based on the findings, GPT-2 was chosen as the generating agent for the dataset. As noted by Karak et al [15], GPT models demonstrate superior performance in generating health care–appropriate content, particularly for patient communication tasks, which are similar to our health coaching scenario. While newer models exist, GPT-2 provides an established baseline for comparison and demonstrates the viability of transformer-based approaches over adversarial networks in this domain.

Table . Comparative analysis of GPT-2[a] and GAN[b]-based models for health text generation.

Criterion	TF-GAN[c]	InfoGAN[d]	GPT-2
Architecture	Adversarial (generator-discriminator)	Adversarial with mutual information maximization	Transformer with self-attention
Training stability	Prone to mode collapse and instability	Requires careful balancing of objectives	Stable autoregressive training
Text coherence	Struggles with long-form semantic coherence	Limited to feature disentanglement	Maintains grammatical and semantic consistency
Controllability	Requires complex conditional architecture	Unsupervised learning of latent codes	Direct prompt-based control for persuasive types
Domain adaptation	High pretraining burden for health care	Not designed for text generation tasks	Fine-tuning on health communication
Output diversity	Achieved through continuous space transformation	Good for representation learning	Natural diversity through temperature sampling
Health care suitability	Complex discrete-to-continuous conversion	Better for image/feature analysis	Proven effectiveness in medical text generation
Implementation complexity	High (adversarial training dynamics)	High (information-theoretic optimization)	Low (straightforward fine-tuning)
Baseline value	Limited health care text applications	Not applicable to text generation	Established baseline for transformer comparisons

[a]GPT-2: Generative Pretrained Transformer-2.

[b]GAN: generative adversarial network.

[c]TF-GAN: Time and Frequency Domain-Based Generative Adversarial Network.

[d]InfoGAN: Information-Theoretic Generative Adversarial Network.

Emotion Detection Analysis

In previous years, researchers explored 2 main approaches for detecting emotions in text: one approach used machine learning algorithms to train emotion detection models, and the other approach relied on lexicons (collections of words that typically express specific emotions) [17]. The discrete emotion model organizes emotions by sorting them into separate and distinct categories or classes. Like the Ekman theory, the Plutchik model proposes that a limited number of basic emotions exist in pairs of opposites, and these primary emotions can combine to create more complex emotional states [18].

The approach involves comprehensive emotion analysis of a given text message using 2 different emotion analysis libraries. The experiment implemented NRCLex emotion detection, which is the same as Plutchik emotion dyads (anticipation, joy, trust, fear, surprise, sadness, disgust, and anger; Figure 1) [19], but with the addition of positive and negative.

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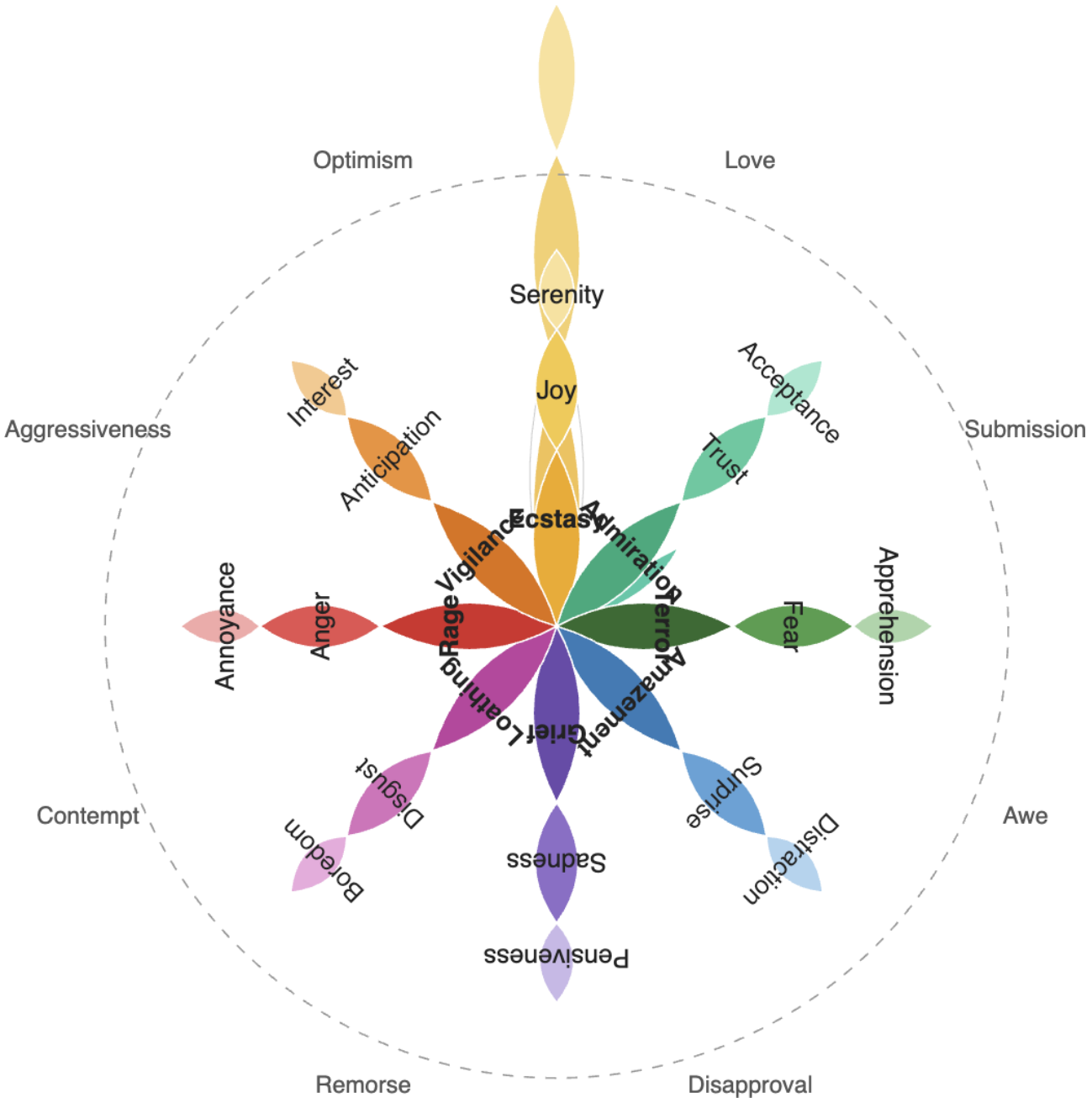
Figure 1. Plutchik emotion wheel [19].



PSD Framework

PSD provides the theoretical foundation for developing systems that influence user attitudes and behaviors through persuasion rather than coercion. Oinas-Kukkonen and Harjumaa [5] established the seminal PSD framework, identifying 28 design principles organized into 4 categories: primary task support, dialogue support, system credibility support, and social support. Among these, dialogue support principles are particularly relevant to health coaching applications, encompassing praise, reward, reminder, suggestion, similarity, liking, and social role elements.

The application of PSD to health behavior change has evolved significantly, yet critical gaps remain in existing implementations. Early health coaching systems focused primarily on single persuasive strategies. Beinema et al [1] implemented embodied conversational agents with automatic topic selection but primarily utilized reminder-based approaches. op den Akker et al [2] proposed the Council of Coaches framework for holistic behavior change, incorporating multiple PSD elements but facing implementation complexity challenges. Most significantly, Albers et al [4] developed an RL approach for persuasive conversational agents but implemented only the reminder component of dialogue support, leaving other PSD elements (praise, reward, and suggestion) unexplored in their dataset and system.

This limited implementation represents a significant gap in PSD research. The dialogue support category encompasses multiple complementary strategies, with each serving distinct psychological functions: reminders prompt action, praise provides positive reinforcement, rewards acknowledge achievements, and suggestions offer guidance. By focusing

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exclusively on reminders, previous research has not fully utilized the capabilities proposed by the PSD framework or examined how different dialogue support elements may carry varying emotional and sentiment characteristics. This research contributes to PSD literature by providing empirical evidence for how different dialogue support elements function emotionally and sentimentally. The finding that praise naturally carries higher emotional intensity than reminders or suggestions validates intuitive assumptions in PSD theory while providing quantifiable metrics for these differences. Understanding these emotional signatures enables more sophisticated PSD, where different PSD elements can be strategically deployed based on desired emotional impact and user state.

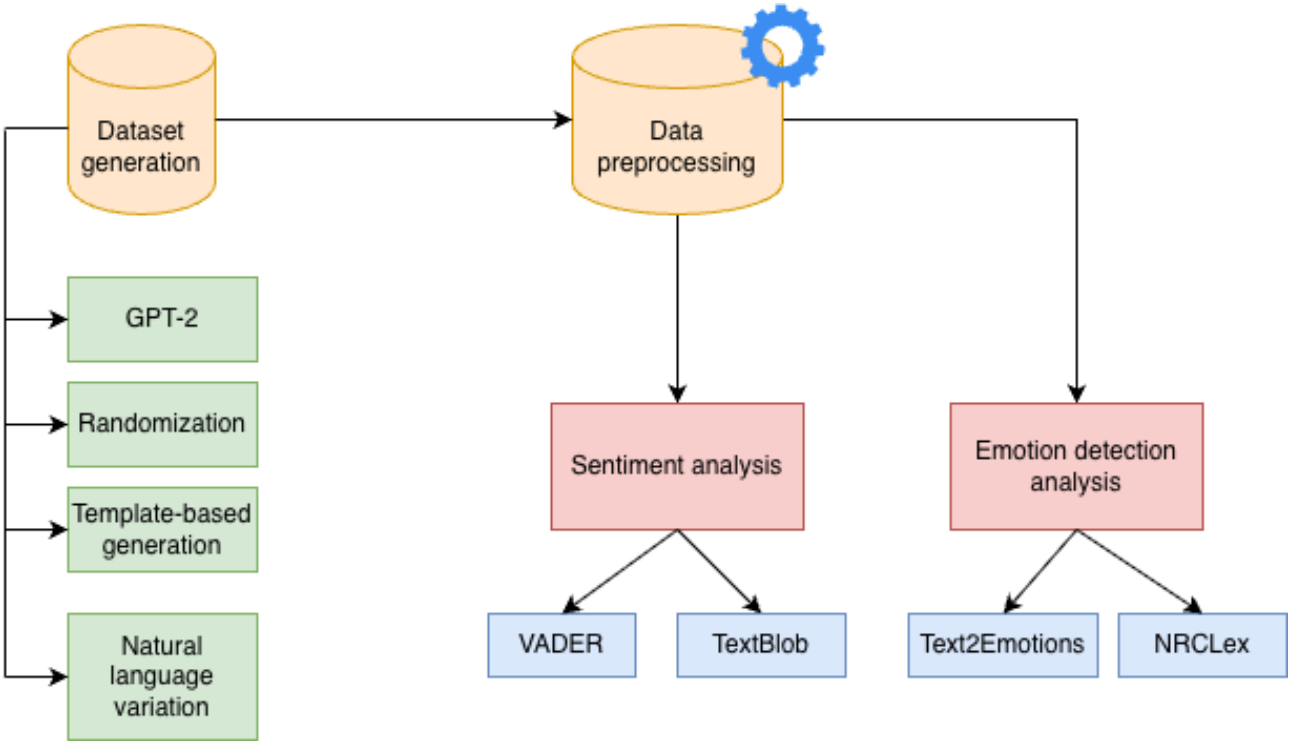
Methods

Study Design and Overview

This is a computational methodology development study (not a clinical trial) using synthetically generated health coaching messages (n=1300). No human participants or real patient data were involved. The primary objective was to validate sentiment and emotion analysis tools for health-specific persuasive communication.

We constructed the dataset using GPT-2, randomization, natural language variation, and template-based generation (Figure 2). This section will explain the step-by-step process of this experiment. In the first stage, the dataset was constructed using GPT-2 and Python. The second stage involved data preprocessing, including tokenization, stemming, lemmatization, etc. Subsequently, we performed sentiment analysis using VADER and TextBlob. When compared to complex machine learning methods, VADER's straightforward approach offers notable benefits. It provides fast and efficient processing while maintaining high accuracy levels. Additionally, unlike machine learning models, where the decision-making process is obscured in a black box, VADER's dictionary and governing rules are transparent and can be directly examined [20]. As a result, VADER can be readily reviewed, comprehended, expanded, or customized according to specific needs. TextBlob, implemented as a Python library, provides an uncomplicated interface to execute fundamental NLP operations. One of its key advantages is that it handles text much like Python strings, making it particularly user-friendly and straightforward to implement [21].

Figure 2. Process of the experiment. GPT-2: Generative Pretrained Transformer-2; NRCLex: National Research Council Lexicon; VADER: Valence Aware Dictionary and Sentiment Reasoner.



Data Generation

In the first phase of creating the dataset, we used GPT-2 for the pretrained dataset. We loaded the GPT-2 tokenizer and model using "tokenizer=GPT2Tokenizer.from_pretrained('gpt2')" and "model=GPT2LMHeadModel.from_pretrained('gpt2')," respectively. Activities for weight loss, such as water intake [22], portion control, meal planning, and healthy eating [23], were set to predefined activities. Then, we prompted text generation by categorizing it as reminder, reward, suggestion, and praise.

We used randomization, template-based generation, and natural language generation techniques to make it more interesting and natural. This dataset was artificially generated using GPT-2. However, the dataset is based on previous research [4]. It has been indicated that the dataset only used reminder as its PT element. Thus, we created a new dataset containing more PT elements (reminder, reward, suggestion, and praise). Based on a previous report [24], the use of at least 1000 samples in the dataset generally produces acceptable and reliable performance results when testing NLP models.

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Table 2 provides examples demonstrating that GPT-2 successfully generated diverse messages across persuasive types while maintaining semantic coherence and health-appropriate content, validating our choice of generative approach.

Table . Examples demonstrating GPT-2[a] diversity and generalization.

Persuasive type and activity	Example message	Diversity feature
Reminder		
Water intake	Don't forget to drink your water today! Staying hydrated helps your body function at its best.	Standard instructional tone
Meal planning	Time to plan your meals for the week. A little preparation goes a long way!	Task-focused approach
Reward		
Portion control	You've been great with portion control this week! Treating yourself to something special is well-deserved.	Achievement recognition
Healthy eating	By maintaining healthy eating, you'll feel better. Your dedication is paying off!	Health benefit emphasis
Suggestion		
Water intake	Try adding a slice of lemon to your water for extra flavor and vitamin C.	Practical tip with rationale
Praise		
Portion control	Excellent work on controlling your portions! You're making real progress.	Direct encouragement

[a]GPT-2: Generative Pretrained Transformer-2.

Our synthetic dataset generation was grounded in the real-world health coaching dataset from previous research [4]. This dataset contains authentic health coaching messages from a conversational agent study focused on physical activity and medication adherence.

Data Preprocessing

The analysis of persuasive messages was conducted through a comprehensive computational approach incorporating multiple NLP techniques (Textbox 1). The methodology consisted of several sequential phases designed to process and analyze the textual data systematically. The methodology began with systematic data preprocessing, which included text normalization through lowercase conversion, contraction expansion, and special character removal. Linguistic processing was performed using NLTK's word_tokenize function, with selective stopword removal that preserved critical semantic markers (eg, "not," "no," and "nor") and lemmatization via WordNetLemmatizer. Feature engineering encompassed both quantitative metrics (word frequency, character count, and sentence structure) and categorical data processing through label encoding for persuasive types and activities.

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Textbox 1. Pseudocode of text preprocessing.

```
FUNCTION preprocess_text(text)
INPUT: text - a string of text to be preprocessed
OUTPUT: preprocessed text as a string
// Convert text to lowercase
texttext = CONVERT_TO_LOWERCASE(text)
// Expand contractions (eg, “don''t” to “do not”)
texttext = EXPAND_CONTRACTIONS(text)
// Remove all characters except letters and spaces
texttext = REMOVE_SPECIAL_CHARACTERS_AND_NUMBERS(text)
// Normalize whitespace
texttext = REMOVE_EXTRA_WHITESPACE(text)
// Split text into individual words
tokenstokens = TOKENIZE(text)
// Initialize stopwords to remove
stop_wordswords = GET_ENGLISH_STOPWORDS() important_words = {‘'not,’‘not,’ 'no',‘no,’ ‘nor,’‘nor,’ 'but',‘but,’ 'and',‘and,’ 'or',‘or,’ ’should',‘should,’ ‘must’} stop_wordswords = stop_words - important_words
// Remove stopwords
filtered_tokenstokens = EMPTY_LIST
FOR EACH token IN tokens:
IF token NOT IN stop_words:
ADD token TO filtered_tokens
// Lemmatize words to their base form
lemmatized_tokenstokens = EMPTY_LIST
lemmatizerlemmatizer = INITIALIZE_LEMMATIZER()
FOR EACH token IN filtered_tokens:
lemmatized_tokentoken = LEMMATIZE(token)
ADD lemmatized_token TO lemmatized_tokens
// Join tokens back into text
RETURN JOIN_WITH_SPACES(lemmatized_tokens)
END FUNCTION
```

We used a methodical ground-truth labeling approach to create trustworthy standards for assessing sentiment and emotion analysis technologies. This procedure guaranteed that the emotional content and message sentiment of all persuasion types were consistently and reliably assessed. Three independent raters with backgrounds in psychology and linguistics annotated each message after the data were preprocessed.

A multistage protocol was used in the annotation process to reduce bias and increase dependability. Initially, a calibration set of 50 sample messages with preestablished labels was used to train raters. They then independently assigned labels to the entire dataset based on predetermined standards. Disputes over communications with different annotations were resolved through a consensus meeting. Using Fleiss κ to calculate interannotator agreement, we identified a moderate degree of agreement (κ=0.65) for emotion detection and a large degree of agreement (κ=0.78) for sentiment classification.

The mood and emotion ground-truth classification criteria are described in Table 3. Based on preliminary validation tests, we set specific thresholds for sentiment classification as follows: polarity between −0.05 and 0.05, neutral; polarity ≤−0.05, negative; and polarity ≥0.05, positive. This approach takes into account the subtleties of persuasive health communication while adhering to accepted standards in sentiment analysis research.

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Table . Classification type for sentiment analysis.

Classification type and category	Assignment criteria
Sentiment	
Positive	Messages expressing encouragement, optimism, approval, or positive reinforcement with polarity ≥0.05
Negative	Messages expressing caution, warning, criticism, or concern with polarity ≤−0.05
Neutral	Messages conveying information without strong emotional connotations with polarity between −0.05 and 0.05
Emotion	
Joy	Expressions of happiness, pleasure, or satisfaction (eg, “great job” and “excellent progress”)
Trust	Expressions of confidence, reliability, or dependability (eg, “you can count on” and “reliable method”)
Fear	Expressions of concern, caution, or warning (eg, “be careful” and “watch out for”)
Surprise	Expressions of astonishment or unexpectedness (eg, “amazing results” and “unexpected benefit”)
Sadness	Expressions of disappointment or regret (eg, “unfortunately” and “disappointing outcome”)
Disgust	Expressions of aversion or distaste (eg, “avoid unhealthy options” and “eliminate junk food”)
Anger	Expressions of frustration or irritation (eg, “challenging obstacles” and “frustrating setbacks”)
Anticipation	Expressions of expectation or looking forward (eg, “prepare for,” “plan ahead,” and “look forward to”)

We used the Plutchik wheel of emotions as our theoretical framework for classifying emotions, and we found that each message had 8 main emotions. Raters used clear textual clues to assign binary labels (present/absent) to each emotion category. When appropriate, a message may be assigned more than one emotion label. Lexical features (certain phrases that convey a particular emotion) and contextual clues in the message were both used in the emotion recognition procedure.

The resulting ground-truth labels provided a robust foundation for evaluating the performance of sentiment analysis tools (VADER and TextBlob) and emotion detection methods (Text2Emotion and NRCLex). By establishing these reliable benchmarks, we could accurately assess the strengths and limitations of each approach in analyzing persuasive health communication. Table 4 presents the composition and distribution of the dataset generated.

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Table . Dataset composition and distribution.

Dimension and category	Value (N=1300), n (%)
Persuasive_type	
Reminder	343 (26.4)
Reward	331 (25.5)
Suggestion	316 (24.3)
Praise	310 (23.9)
Activity	
Water intake	357 (27.5)
Healthy eating	331 (25.5)
Portion control	313 (24.1)
Meal planning	299 (23.0)

Sentiment Analysis

Sentiment analysis was conducted using a dual-method approach: VADER provided compound sentiment scores and classification with ±0.05 thresholds, while TextBlob analysis supplied complementary polarity and subjectivity metrics. VADER and TextBlob are sentiment analysis tools that help categorize text reviews into 3 emotional categories: positive, neutral, and negative [25]. Example pseudocodes for VADER and TextBlob are provided in Textboxes 2 and 3, respectively.

Textbox 2. Example pseudocode for VADER (Valence Aware Dictionary and Sentiment Reasoner).

```
FUNCTION apply_vader_sentiment(dataframe, vader_scores)
INPUT:
dataframe - table of text data
vader_scores - sentiment analysis scores from VADER
OUTPUT:
dataframe with added sentiment columns
// Add negative sentiment scores
FOR EACH row IN vader_scores:
dataframe['vader_negative''][row] = vader_scores[row]['neg'']
// Add neutral sentiment scores
FOR EACH row IN vader_scores:
dataframe['vader_neutral''][row] = vader_scores[row]['neu'']
// Add positive sentiment scores
FOR EACH row IN vader_scores:
dataframe['vader_positive''][row] = =vader_scores[row]['pos'']
// Add compound sentiment scores
FOR EACH row IN vader_scores:
dataframe['vader_compound''][row] = vader_scores[row]['compound'']
RETURN dataframe
END FUNCTION
```


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Textbox 3. Example pseudocode for TextBlob.

```
FUNCTION apply_textblob_sentiment(dataframe, message_column)
INPUT:
dataframe - table of text data message_column - column containing text messages
OUTPUT:
dataframe with added TextBlob sentiment columns
// Add polarity scores
FOR EACH row IN dataframe:
texttext = CONVERT_TO_STRING(dataframe[message_column][row])
blobblob = CREATE_TEXTBLOB(text)
dataframe['textblob_polarity''][row] = blob.sentiment.polarity
// Add subjectivity scores
FOR EACH row IN dataframe:
texttext = CONVERT_TO_STRING(dataframe[message_column][row])
blobblob = CREATE_TEXTBLOB(text)
dataframe['textblob_subjectivity''][row] = =blob.sentiment.subjectivity
RETURN dataframe
END FUNCTION
```

The statistical framework included a distribution analysis of sentiment across message categories and a correlation analysis between VADER and TextBlob scores. The implementation utilized Python 3.x with established NLP libraries (NLTK, VADER, and TextBlob) and used a modular design to ensure reproducibility and facilitate independent verification of each analysis component.

TextBlob is a Python library that helps developers work with text data in both Python 2 and 3 environments [26]. It offers straightforward tools for performing essential NLP tasks. With TextBlob, text can be analyzed to identify parts of speech, extract noun phrases, determine sentiment, categorize content, and convert text between languages. The library is designed to make these complex NLP operations accessible through a simple interface. All processed features were integrated into a unified dataset that preserved original messages alongside their processed versions, maintaining data integrity throughout the analysis pipeline. TextBlob provided the following 2 primary sentiment metrics: polarity and subjectivity. While polarity measures the positive-negative orientation of text, subjectivity quantifies the degree to which the text expresses personal opinions, emotions, or judgments versus objective information.

VADER's compound score calculation involves several steps to evaluate the emotional content of text. First, it scans the text to identify words and patterns that have known emotional meanings. Then, it adjusts how strong or weak these emotions are based on specific rules (eg, intensifiers, negations, etc). Next, it combines all these individual emotional scores found in the text. Finally, it converts the total score into a standardized number between −1 and 1, where −1 represents extremely negative sentiment and 1 represents extremely positive sentiment. The function of VADER is as follows:

$$\text{(1)compound score=normalize (raw score)=}\frac{x}{\sqrt{x^2+\alpha}}$$

In VADER's sentiment analysis equation, the compound score formula normalizes raw sentiment scores (x) to a range between −1 and 1. The α parameter, typically set to 15, acts as a stabilizing factor that prevents extreme scores when the raw sentiment value is small. The denominator's square root term helps create a smooth normalization curve while preserving the sentiment's direction.

The first function, get_vader_sentiment, takes a text input and calculates sentiment scores using VADER. It converts missing values into empty strings and returns a dictionary of scores, including negative, neutral, positive, and compound values. The second function, get_textblob_sentiment, performs a similar analysis using TextBlob, returning both polarity (how positive or negative) and subjectivity (how objective or subjective) scores.

The code then applies these sentiment analyses to a data frame's "message" column. It creates new columns by extracting individual components of the sentiment scores. For VADER, it separates the negative, neutral, positive, and compound scores into separate columns. Similarly, TextBlob extracts the polarity and subjectivity scores into separate columns. This separation makes it easier to analyze and compare different aspects of sentiment.

Finally, the code categorizes the overall sentiment of each message based on VADER's compound score using a standard threshold approach. Messages with compound scores greater than or equal to 0.05 are labeled "positive," those with scores less than or equal to −0.05 are labeled "negative," and those with scores between these values are labeled "neutral." This categorization provides a simple way to classify the emotional tone of each message into 3 distinct categories.

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We used precision, recall, F_1-score, and accuracy in this experiment to assess performance. We determined the true positive (TP), true negative (TN), false positive (FP), and false negative (FN) values. Precision was calculated by dividing truly positive classifications by all positive classifications as follows: TP/(TP+FP). Recall was calculated by dividing truly positive classifications by all positive examples as follows: TP/(TP+FN). F_1-score was calculated by dividing (precision×recall) by (precision+recall) as follows: (2×TP)/([2×TP]+FP+FN). Accuracy was calculated by dividing true classifications by all classifications as follows: (TP+TN)/(TP+TN+FP+FN).

Emotion Detection Analysis

Emotion detection is a branch of sentiment analysis that deals with the extraction and analysis of emotions. In this experiment, we conducted emotion detection analysis in the dataset. Text2Emotion and NRCLex were chosen as the techniques or methods in this experiment. NRCLex was selected as it does not require training data or model training and identifies multiple emotional categories beyond just positive/negative sentiment, including joy, anger, sadness, fear, trust, surprise, and others. NRCLex offers tools for plotting sentiment analysis outcomes [27]. While TextBlob was used for sentiment analysis (positive/negative/neutral), Text2Emotion was used for more granular emotional analysis that is needed for a deeper understanding [28].

In Text2Emotion, the following 5 emotions are involved: happy, angry, surprise, sad, and fear. On the other hand, NRCLex involves the following 10 emotions: fear, anger, trust, surprise, sadness, disgust, joy, anticipation, positive, and negative.

Text2Emotion follows a basic model for emotions. It starts by preprocessing the input text using a separate method. If the cleaning process results in empty text, it returns an empty analysis result. For the actual analysis, it processes the text through both the Text2Emotion and NRCLex libraries to get emotion scores. The method then calculates an overall emotion intensity based on these scores. To identify the dominant emotions, it converts the emotion scores from both libraries into lists of tuples and finds the emotion with the highest score for each library, defaulting to “neutral” if no emotions are detected. Additionally, it determines an overall sentiment score by subtracting the NRCLex negative score from the positive score. The final output is a dictionary containing the original message, emotion scores from both libraries, dominant emotions from each library, calculated sentiment score, and overall emotion intensity.

Experimental Setup

The experiments were conducted using Python programming within the Anaconda 3.0 environment and Jupyter Notebook interface. This section outlines the experimental setup, including details about the system specifications and parameter configurations used. Table 5 presents sentiment thresholds for the VADER and TextBlob analyzers, defining positive, negative, and neutral classifications and data preprocessing parameters for emotional analysis. The experiments were performed on a VICTUS gaming laptop (15-fa1231TX; HP Inc) with an Intel Core i5-12450H processor (2.00 GHz), 16 GB of RAM, and an NVIDIA GeForce RTX 4050 graphics card. The operating system was Windows 11 (Microsoft Corp).

Table 6 outlines emotion detection parameters using Text2Emotion and NRCLex libraries, with keyword categories and scoring methods for emotional analysis.

Table . Hyperparameter settings for sentiment lexicons.

Parameter name	Parameter value
VADER[a] positive	Sentiment score ≥0.05
VADER negative	Sentiment score ≤−0.05
VADER neutral	Sentiment score <0.05 or >−0.05
TextBlob positive	Sentiment score >0
TextBlob negative	Sentiment score <0
TextBlob neutral	Sentiment score 0
Emotion detection	High intensity > mean
Score normalization	Value/total when total >0

[a]VADER: Valence Aware Dictionary and Sentiment Reasoner.

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Table . Hyperparameter settings for emotion analysis.

Parameter name	Parameter value
Text2Emotion	Happy, angry, surprise, sad, fear (default classes)
NRCLex[a]	Fear, anger, trust, surprise, sadness, disgust, joy, anticipation, positive, negative (default classes)
Emotion keywords (joy)	Happy, great, excellent, good, wonderful, fantastic, excited
Emotion keywords (encouragement)	Can, will, try, achieve, possible, potential, progress
Emotion keywords (concern)	Careful, warning, attention, caution, important
Emotion keywords (neutral)	Maintain, continue, regular, routine, standard
Emotion keywords (directive)	Must, should, need, remember, don't forget
Emotion intensity	Calculated as max (Text2Emotion score, NRCLex score)
Emotion classification	Dominant emotion is the highest scoring category
Score normalization	Score/total (when total >0)

[a]NRCLex: National Research Council Lexicon.

Ethical Considerations

This research is exempt from institutional ethics review as it is a computational methodology development study exclusively using synthetically generated data. No human participants, human research participants, real patient data, or personally identifiable information were involved at any stage of this research. All health coaching data and messages (1300 messages) were generated using GPT-2 based on hypothetical and generic health coaching scenarios [4]. These messages were never derived from real patient communications, real medical records, or prior research data involving human participants. Therefore, no data sharing restrictions apply, and no privacy protections specific to human participants are required. The code and synthetic dataset are publicly available on GitHub [29]. This study represents a methodological proof-of-concept, and future clinical validation and deployment will require formal ethics review, informed consent, and adherence to applicable data protection regulations.

Results

Sentiment Analysis

Sentiment analysis revealed a highly positively skewed distribution across all health coaching messages (Table 7). The vast majority of messages (1218/1300, 93.7%) were classified as positive, with negative messages representing only 5.4% (70/1300) and neutral messages representing less than 1% (12/1300, 0.9%) of the total dataset. This overwhelmingly positive distribution suggests a deliberate messaging strategy designed to maintain an uplifting and constructive tone, typical of persuasive communication aimed at encouraging and motivating users toward health behavior change. The minimal presence of negative and neutral content indicates a conscious design choice to avoid discouraging or ambivalent messaging in favor of positive reinforcement. This pronounced positive skew aligns with established principles in health coaching, where supportive, optimistic communication has been shown to enhance user engagement and adherence to behavior change interventions.

Table . Overall sentiment distribution.

Sentiment category	Distribution value
Positive	0.936923
Negative	0.053846
Neutral	0.009231

The visualization in Figure 3 reveals a remarkable variation in sentiment compound scores among the reminder, reward, suggestion, and praise categories, with the latter demonstrating the highest median sentiment score and the most compact IQR. Praise messages exhibited a notably high concentration of positive sentiments (approximately 0.75 - 0.95), suggesting a consistent positive emotional valence in praise-based communication strategies. However, the presence of outliers in all categories, especially negative ones (ranging from −0.75 to −1.0), raises compelling questions about the contextual factors that generate these anomalous cases.

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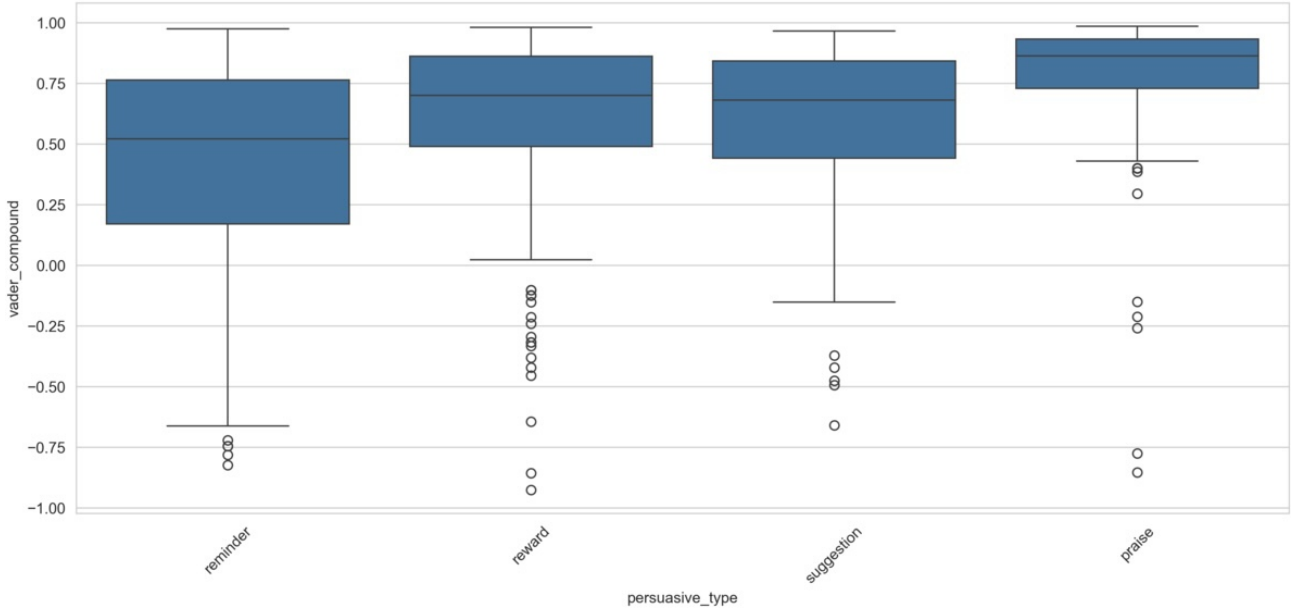
Figure 3. VADER (Valence Aware Dictionary and Sentiment Reasoner) sentiment distribution by persuasive type.



The reminder category showed the widest IQR, indicating greater variability in emotional content, which could be attributed to the diverse nature of reminder messages, which ranged from urgent warnings to gentle nudges. This heterogeneity in sentiment distribution might reflect the complex linguistic strategies used in reminder-based persuasion. The reward and suggestion categories demonstrated intermediate patterns, with reward messages showing slightly higher median sentiment scores than suggestions. This nuanced difference might be explained by the inherently positive nature of reward-related communication versus the more neutral or instructional tone often present in suggestions.

Theoretically, these patterns align with existing literature on persuasive communication, but they also challenge some conventional assumptions about the emotional loading of different persuasive strategies. The consistently high positive sentiment in praise messages supports established theories about positive reinforcement. However, the substantial variance in reminder sentiments suggests a more complex relationship between message type and emotional content than previously theorized. This analysis opens several avenues for future research, particularly in understanding how sentiment variation within each persuasive type correlates with message effectiveness and recipient engagement.

Figure 4 shows how 2 different sentiment analysis tools (VADER and TextBlob) compare when analyzing the same messages across different persuasive types (reminder, reward, suggestion, and praise). The pattern reveals an interesting relationship as follows: as VADER scores increase (moving right), TextBlob scores tend to also increase (moving up), creating a diagonal trend from bottom-left to top-right. This means both tools generally agree on whether messages are positive or negative. Most points cluster in the positive range (right side of the graph), especially for praise messages (shown in red), which matches what we would expect since praise is usually positive. However, there is quite a bit of scatter in the data, indicating that these tools do not always agree perfectly. We can see points spread out vertically for any given VADER score, meaning that while VADER might give one score, TextBlob could give quite a different rating for the same text. Reminders, rewards, and suggestions had similar proportions of positive and neutral components, though reminders appeared to have a slightly smaller positive component than the others. It is important to distinguish between VADER's component scores (the proportion of positive/neutral/negative words) and the final sentiment classification (based on the compound score). Figure 5 shows that neutral words dominated the composition of health coaching messages (70% - 80% of words). However, the strategic use of positive words, encouraging punctuation, and a supportive tone resulted in 93.7% (1218/1300) of messages being classified as overall positive. This pattern reflects effective health coaching communication design: using primarily informative (neutral) language enhanced with selective positive reinforcement.

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Figure 4. Correlation between VADER (Valence Aware Dictionary and Sentiment Reasoner) and TextBlob sentiment scores.

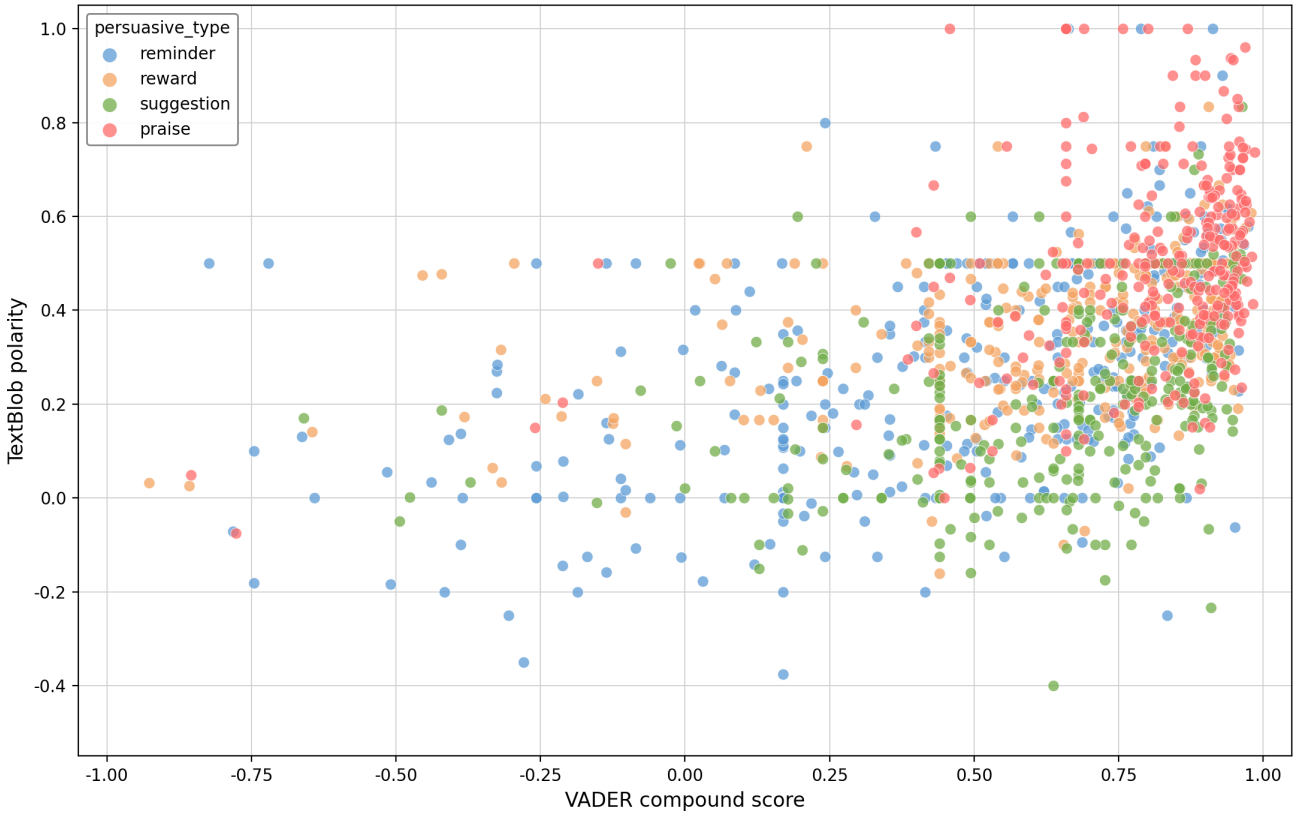

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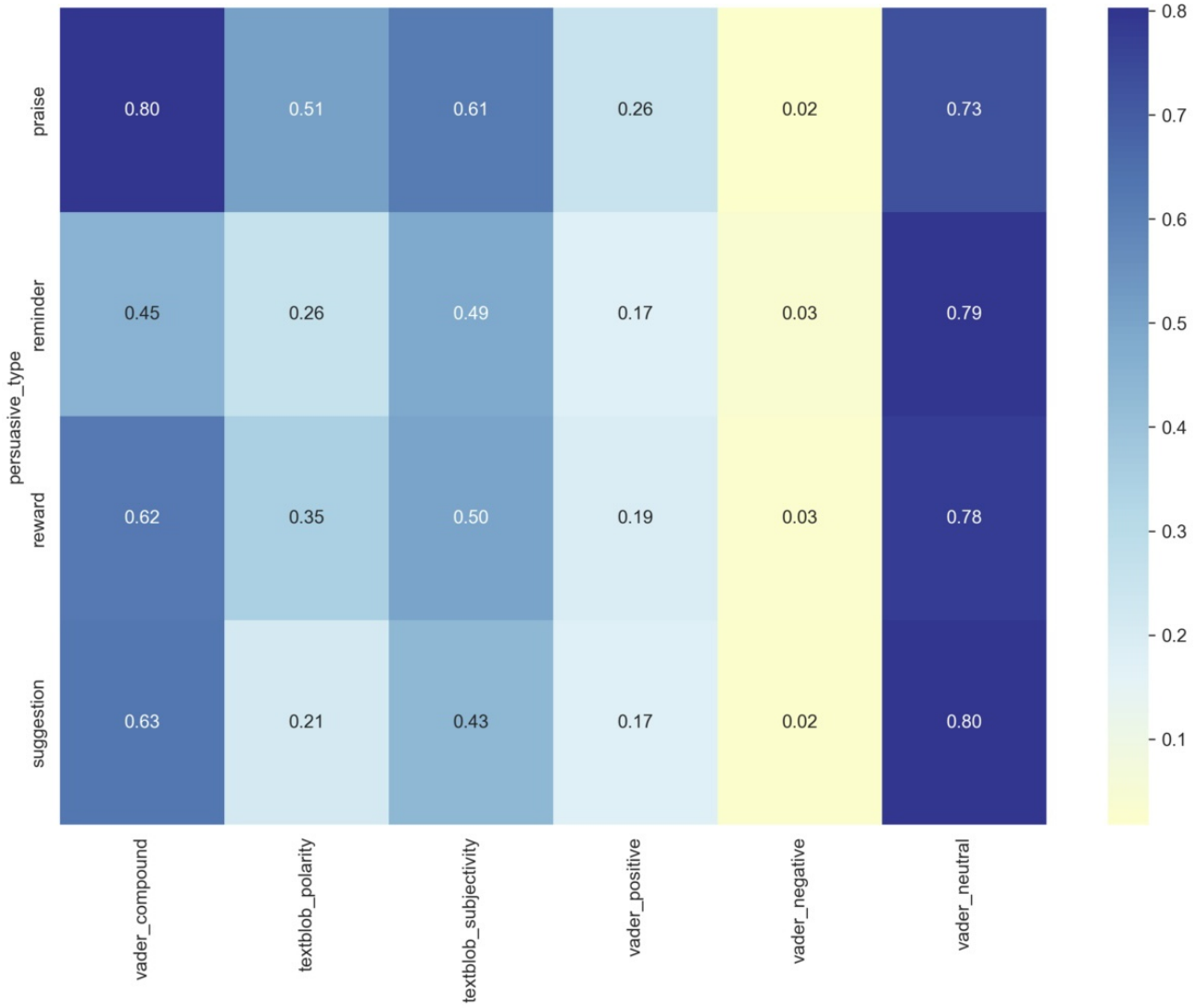
Figure 5. Sentiment metric heatmap by persuasive type. Darker blue indicates higher values, and lighter colors represent lower values.



The sentiment analysis heatmap in Figure 5 provides a comprehensive visualization of how different persuasive message types perform across various sentiment metrics. The data reveal fascinating patterns in how praise, reminder, reward, and suggestion messages carry emotional content. In the heatmap, we can see that praise messages consistently demonstrate the strongest positive sentiment, with the highest VADER compound score (0.80) and TextBlob polarity (0.51). The uniformly low negative sentiment scores (0.02 - 0.03) across all message types are particularly noteworthy, suggesting a deliberate approach to maintain constructive communication regardless of the message's purpose.

The neutral component (vader_neutral) consistently showed high values (0.73 - 0.80) across all message types, indicating that the messages maintained a balanced tone even while conveying different persuasive intentions. Reminder messages generally exhibited lower intensity scores compared to other types, which might reflect their more practical, straightforward nature. Meanwhile, suggestions and rewards showed similar patterns, with moderately high compound scores (0.63 and 0.62, respectively), suggesting that they carry comparable emotional weight in their delivery. This similarity in sentiment patterns across different metrics, visible in the vertical striping of the heatmap (Figure 5), indicates a consistent approach to emotional content within each message type, while the variations between types reflect their distinct communicative purposes.

Reward and suggestion messages showed remarkably similar overall sentiment scores (vader_compound: 0.625 and 0.626, respectively) yet diverged in their stylistic characteristics. Reward messages maintained moderate polarity (0.350) and subjectivity (0.498), balancing positive reinforcement with personal engagement. In contrast, suggestion messages displayed lower polarity (0.209) and the lowest subjectivity (0.434), indicating a more objective, advisory delivery style that prioritizes practical guidance over emotional appeal. This pattern reveals that while all message types maintain positive orientation, they use different degrees of emotional directness and personal perspective tailored to their specific persuasive functions—praise for celebration, reminders for neutral prompting, rewards for positive reinforcement, and suggestions for objective guidance.

The sentiment analysis across different persuasive types revealed distinct emotional profiles that aligned with their communicative functions (Tables 8 and 9). Praise messages demonstrated the highest sentiment intensity (vader_compound: 0.799;

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textblob_polarity: 0.513) and subjectivity (0.615), reflecting their emotionally expressive nature designed to acknowledge and celebrate user achievements. Reminder messages exhibited the lowest sentiment scores (vader_compound: 0.451; textblob_polarity: 0.257) with moderate subjectivity (0.489), indicating a more neutral, task-focused tone appropriate for prompting action without excessive emotional loading.

Table . Detailed sentiment analysis by persuasive type.

Persuasive_type	Vader_compound	Textblob_polarity	Textblob_subjectivity
Praise	0.799	0.513	0.615
Reminder	0.451	0.257	0.489
Reward	0.625	0.350	0.498
Suggestion	0.626	0.209	0.434

Table . Average sentiment by persuasive type.

Persuasive_type	Sentiment value
Praise	0.798766
Reminder	0.451110
Reward	0.624842
Suggestion	0.626238

The correlation matrix (Table 10) for sentiment analysis revealed distinct patterns in how different measures relate. VADER's compound score and TextBlob's polarity showed a moderate positive correlation (r=0.445), indicating that they generally agreed on sentiment direction, but each captured unique aspects of the text's emotional content. TextBlob's polarity demonstrated a stronger relationship with its subjectivity measure (r=0.508), suggesting that text with higher subjectivity tends to express more pronounced sentiments, according to TextBlob's analysis. In contrast, VADER's compound score had only a weak correlation with TextBlob's subjectivity (r=0.214), which indicates that VADER's sentiment detection operates more independently of how subjective the text is. The perfect correlations (r=1.000) along the diagonal represent each measure's correlation with itself, which is expected in a correlation matrix. The relationships suggest that while VADER and TextBlob share some common ground in sentiment detection, they each bring unique perspectives to the analysis. VADER is less influenced by text subjectivity, while TextBlob shows a stronger connection between subjective content and sentiment strength.

Table . Correlation matrix for sentiment analysis.

Variable	Vader_compound	Textblob_polarity	Textblob_subjectivity
Vader_compound			
r	1.000	0.445	0.214
P value	—[a]	<.001	<.001
Textblob_polarity			
r	0.445	1.000	0.508
P value	<.001	—	<.001
Textblob_subjectivity			
r	0.214	0.508	1.000
P value	<.001	<.001	—

[a]Not applicable.

The performance metric analysis (Table 11) revealed intriguing patterns when comparing the VADER and TextBlob sentiment analysis tools. VADER demonstrated moderate but realistic performance with an accuracy of 60%, indicating its ability to classify most messages correctly. Its high precision of 80% suggests strong reliability in its positive predictions, though its lower recall of 60% indicates that it might miss some positive cases. The F_1-score of 0.57, representing the harmonic mean of precision and recall, suggests a balanced but moderate overall performance. This pattern aligns with typical real-world sentiment analysis challenges where perfect classification is rare.

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Table . Performance metric results.

Metric	VADER[a]	TextBlob
Accuracy	0.69	0.57
Precision	0.76	0.61
Recall	0.69	0.57
F_1-score	0.68	0.58

[a]VADER: Valence Aware Dictionary and Sentiment Reasoner.

The stark contrast between VADER's realistic performance metrics and TextBlob's perfect scores warrants further investigation, potentially through expanded testing with a larger, more diverse dataset and the implementation of cross-validation techniques to ensure a more representative performance assessment. This finding underscores the importance of rigorous evaluation methodologies in sentiment analysis and suggests the need for careful consideration of tool selection based on specific use cases and requirements. The dataset had 1300 rows, which is moderate but may not be sufficient to evaluate sentiment analysis performance fully. Considering the analysis of a dataset of 1300 rows, several potential red flags emerge that warrant careful consideration. The dataset size is moderate but may not be comprehensive enough to fully evaluate sentiment analysis performance, particularly when considering the complexity and nuance of sentiment expression. A key concern is the need to verify whether there is a balanced representation across different sentiment categories, as imbalanced data could skew the evaluation results. The data showed some positive characteristics. Each message was unique and covered various health and wellness topics, including meal planning, portion control, and water intake. The messages also demonstrated varying lengths and complexity levels, which is generally good for testing robustness. However, TextBlob's perfect scores (1.0) across all metrics (accuracy, precision, recall, and F_1-score) raise significant concerns about the evaluation process. These perfect scores could indicate that the ground-truth labels are too closely aligned with TextBlob's built-in classification approach or that the dataset may lack sufficiently complex or ambiguous examples that would typically challenge a sentiment analysis model.

Emotion Detection Analysis

Emotion models serve as the essential building blocks for emotion detection systems by establishing how different emotions are represented and classified. These models are built on the premise that emotions can exist in different states, making it necessary to identify and differentiate between these distinct emotional states.

The chart in Figure 6 compares accuracy, precision, recall, and F_1-scores across different emotions (anger, anticipation, joy, neutral, sadness, and trust). The model used a hybrid or modified version of the Plutchik wheel of emotions with some adaptations. The data revealed varying levels of performance across different emotional categories. Anger demonstrated reasonable performance, with perfect accuracy (1.0) but moderate findings for other metrics (precision: 0.75, recall: 0.72, and F_1-score: 0.73). Joy showed consistent moderate performance, with all metrics, except accuracy, showing values ranging from 0.84 to 0.85. The neutral emotion category had an accuracy score of 1.0. Sadness exhibited a precision score of 0.86 and a recall score of 0.85. For entertainment, all metrics were above 0.80. Trust showed mixed results, with high accuracy, precision, and F_1-score (0.88-1.00) but lower recall (0.81), suggesting some reliability issues in its detection. These variations in performance across different emotions point to potential areas for model improvement, particularly in balancing detection capabilities across all emotion categories.

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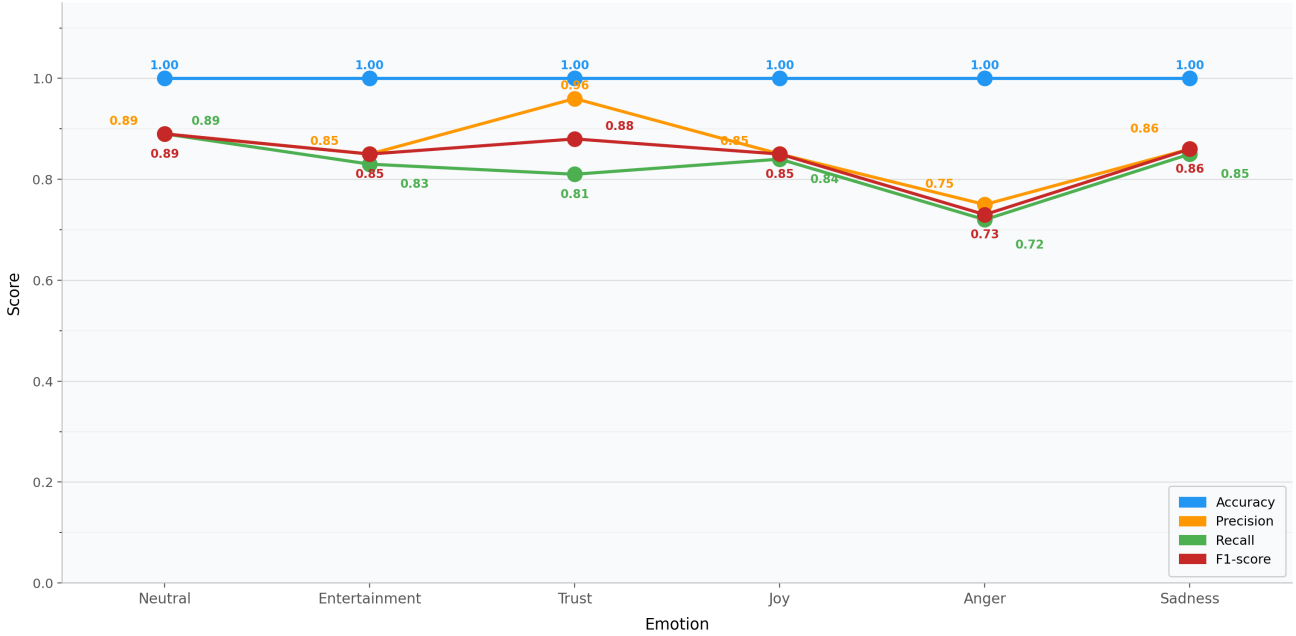
Figure 6. Performance metrics by emotion.



Comparative Evaluation With Existing Frameworks

Our comprehensive benchmarking analysis demonstrated significant performance variations across different sentiment analysis frameworks when applied to health coaching messages.

As shown in Table 12, RoBERTa (robustly optimized BERT approach)-sentiment achieved the highest overall performance, with 88% accuracy and an F_1-score of 0.8264, substantially outperforming other models. Interestingly, VADER delivered reasonable accuracy (69%) with a remarkably fast inference time (0.03 ms). It was over 1000 times faster than transformer-based approaches and maintained competitive precision (0.7476).

Table . Model performance.

Model	Accuracy	Precision	Recall	F_1-score	κ	Avg_inference_time (ms)
VADER[a]	0.6900	0.7476	0.6900	0.6771	0.4582	0.03
TextBlob	0.5700	0.7133	0.5700	0.6167	0.3067	0.23
BERT[b]-base-sentiment	0.5500	0.5938	0.5500	0.5707	0.2645	39.87
RoBERTa[c]-sentiment	0.8800	0.7832	0.8800	0.8264	0.7801	29.93

[a]VADER: Valence Aware Dictionary and Sentiment Reasoner.

[b]BERT: Bidirectional Encoder Representations from Transformers.

[c]RoBERTa: robustly optimized BERT approach.

This performance-efficiency tradeoff reveals important insights for health communication systems. While transformer models like RoBERTa offer superior accuracy, traditional lexicon-based approaches like VADER provide an excellent balance between performance and computational efficiency for real-time applications. Notably, BERT-base-sentiment underperformed with only 55% accuracy despite its significant computational cost (39.87 ms), suggesting that general-purpose sentiment models may require domain adaptation for health coaching contexts. TextBlob showed moderate performance (57% accuracy) but fell considerably short of its previously reported perfect scores, highlighting the importance of rigorous benchmarking against multiple competing frameworks for realistic performance assessment.

These findings align with our overall methodology while addressing any concern about the lack of benchmarking. By providing empirical comparisons across diverse model architectures, we have established clear performance baselines and identified the strengths and limitations of different approaches for health coaching sentiment analysis.

Feasibility and Validation of the Analytical Framework

Regarding tool feasibility, VADER (69% accuracy; <1 ms/message; real-time capable, transparent, and domain-adaptable) is considered suitable for deployment, while RoBERTa (88% accuracy; approximately 10 ms/message; black-box) is considered suitable for high-accuracy applications. Regarding the ground truth, interrater agreement (κ) was 0.78 for sentiment and 0.65 for emotion, with both exceeding the

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≥0.60 threshold. As synthetic data were used, future clinical validation is needed before real-world deployment.

Discussion

Principal Findings

The sentiment analysis findings revealed several significant patterns and methodological considerations when examining persuasive messaging through computational linguistics. Text sentiment analysis evaluated and classified the emotional content of writing, assigning it as positive, negative, or neutral based on its overall tone [30]. A notable strength lies in the dual-tool approach utilizing both VADER and GPT-2–based TextBlob, which provided complementary perspectives on sentiment analysis. The combination of VADER and TextBlob, along with GPT-2–generated content, provided rich insights into how different types of persuasive messages carry and convey emotional content, demonstrating both the capabilities and limitations of current NLP tools in understanding the nuances of communication strategies [31]. The moderate correlation (0.445) between VADER and TextBlob suggests that while they generally agree on sentiment direction, they capture different aspects of emotional content, with TextBlob showing stronger ties to subjectivity (0.508) compared to VADER (0.214). However, this raises the following critical weakness in current sentiment analysis approaches: the potential limitations of pretrained language models like GPT-2 in accurately capturing nuanced emotional contexts, particularly given the dataset's overwhelming positive skew (93.7%).

The study identified significant gaps in semantic understanding, particularly in how different persuasive types (reminder, reward, suggestion, and praise) maintain varying levels of emotional intensity while sharing similar neutral components (0.73 - 0.80). This paradox suggests potential limitations in the ability of current sentiment analysis tools to differentiate between genuine positive sentiment and formulaic positive language common in persuasive communication. Furthermore, outliers, especially in negative sentiments (−0.75 to −1.0), indicated potential edge cases where current sentiment analysis tools might fail to capture the full complexity of persuasive communication strategies. Sentiment analysis in health coaching faces challenges in matching text meaning with emotional labels, as tools typically analyze word patterns rather than grasping deeper semantic nuances.

While the findings align with established persuasive communication theories, they suggest limitations in NLP approaches. Future research could benefit from incorporating more advanced language models beyond GPT-2, such as transformer-based architectures that better capture the subtle interplay between sentiment and persuasive intent. Additionally, the study highlights the need for more sophisticated sentiment analysis tools that can better account for context-dependent sentiment variations and the relationship between linguistic features and persuasive effectiveness. By combining different types of data inputs, comprehensive sentiment analysis can provide deeper insights into how people think and feel about various topics [32].

In the performance comparison, VADER (69% accuracy) outperformed TextBlob (57% accuracy) for health coaching message classification. This finding challenges the assumption that more sophisticated polarity calculation methods necessarily yield better results. VADER's rule-based approach, specifically designed for social media text, appears better suited to the conversational tone of health coaching messages than TextBlob's pattern-based sentiment extraction.

Our comparative benchmarking revealed significant performance differences across sentiment analysis frameworks, with RoBERTa-sentiment achieving the highest accuracy (88%) and F_1-score (0.8264), and VADER offering a compelling balance between reasonable accuracy (69%) and exceptional efficiency (0.03 ms inference time). This performance-efficiency tradeoff has important implications for health coaching applications, where real-time interaction may prioritize VADER's speed, while more resource-intensive offline analysis might benefit from RoBERTa's superior accuracy. Notably, BERT-base-sentiment's underperformance (55% accuracy), despite high computational cost, suggests that general-purpose sentiment models may require domain adaptation for health contexts. These findings challenge our initial TextBlob results (moderate 57% accuracy vs perfect scores reported in Table 12) and underscore the critical importance of comprehensive benchmarking against multiple frameworks to establish realistic performance expectations and guide model selection based on specific application requirements in health communication systems.

To address the concerns, several improvements could be implemented. The dataset should be expanded with more diverse examples, including edge cases and ambiguous sentiments that better reflect real-world complexity. Proper cross-validation techniques should be implemented to ensure robust evaluation. The labeling process should be reviewed for potential biases, and results should be compared with additional sentiment analysis tools beyond just VADER. Finally, all preprocessing steps should be carefully examined to prevent any data leakage that might artificially inflate performance metrics. These adjustments would help ensure a more reliable and realistic evaluation of sentiment analysis performance.

Conclusion

This study demonstrated the effectiveness of combining multiple sentiment analysis approaches (VADER and TextBlob) with emotion detection tools (Text2Emotion and NRCLex) for analyzing persuasive health-related messages. The findings revealed a strong positive bias in the dataset, with 93.7% of messages classified as positive, suggesting a deliberate strategy in health coaching communication. The analysis showed distinct patterns across different persuasive types: praise messages consistently demonstrated the highest sentiment scores (vader_compound: 0.799), while reminder messages demonstrated the lowest scores (vader_compound: 0.451). Reward and suggestion messages maintained moderate positive sentiments (approximately 0.625). The moderate correlation (0.445) between VADER and TextBlob sentiment scores indicates that while these tools generally agree on sentiment direction, they capture different aspects of emotional content.

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Performance metrics revealed interesting contrasts between the tools, with TextBlob showing perfect scores across all metrics and VADER demonstrating more realistic performance (60% accuracy), suggesting potential evaluation biases that warrant further investigation. The emotion detection analysis showed varying performance across different emotions, with the anger and neutral categories achieving reasonable results and the trust category demonstrating mixed results.

The research highlights the potential and limitations of NLP tools in understanding persuasive health communication. Balancing detection capabilities across different emotional categories remains problematic, with performance metrics varying significantly between emotions. While the combined approach provides rich insights, the overwhelming positive skew in the dataset and the varying performance across different emotion categories suggest areas for improvement in future research, particularly in capturing nuanced emotional contexts and the relationship between linguistic features and persuasive effectiveness. Reconciliation of the significant differences in performance metrics between TextBlob (perfect scores) and VADER (more moderate scores) suggests potential evaluation methodology issues.

In terms of limitations, TextBlob's perfect performance metrics (1.0 across all metrics) suggest potential evaluation biases or limitations in the test dataset. The dataset size (1300 rows) may not have been comprehensive enough to evaluate sentiment analysis performance across all contexts fully, and future work should implement deeper interpretative analysis. The current approach may not effectively differentiate between genuine positive sentiment and formulaic positive language common in persuasive communication. In future research, we plan to apply this framework of RL and PT to real-world situations by implementing it into the development of cloud-based applications. We also suggest further exploration of the dataset in terms of comparing multiple sentiment and emotion analysis methods in this context. To address synthetic data limitations in future research, we plan to collaborate with health care institutions to access anonymized real messages and recruit 3 - 5 health coaching professionals for validation studies. These experts would review the dataset and assess appropriateness for patient communication. This approach would provide crucial validation of synthetic datasets against real-world standards, ensuring that our findings can be applied to actual health care settings.

This proof-of-concept study demonstrates the feasibility of multimodal sentiment and emotion analysis for synthetically generated persuasive health coaching messages. The findings provide a methodological foundation and baseline performance metrics under controlled conditions. However, significant limitations in ecological validity must be addressed before clinical translation. The synthetic nature of our dataset likely inflated tool performance compared with noisy, real-world patient communication. Future research must validate the findings with authentic health coaching messages, assess robustness to informal language and diverse populations, and establish links between sentiment/emotion metrics and clinical outcomes. We recommend this framework as a foundation for research and development rather than a deployment-ready solution for clinical settings.

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Data Availability

The code used for data generation, preprocessing, sentiment analysis, emotion detection, and performance evaluation is publicly available on GitHub [29]. All data in this study have been synthetically generated using GPT-2 and contain no human participant information, personal health data, or identifiable information. Therefore, there are no privacy concerns, ethical restrictions, or regulatory barriers preventing full public sharing.

Authors' Contributions

MAMZ conceptualized and designed the study, generated and curated the dataset using GPT-2, developed all software and code, conducted all formal analyses (including sentiment and emotion detection), created all visualizations, and wrote the original manuscript draft. NMA secured funding (grant GUP-2023-036), supervised the project, provided methodological guidance, administered the research project, and led the manuscript review and editing process. JKC contributed to methodology development, assisted with formal analysis and software optimization, and participated in manuscript review. All authors validated the research findings, contributed to manuscript revision, and approved the final version for publication.

Conflicts of Interest

None declared.

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Abbreviations

AI: artificial intelligence
FN: false negative
FP: false positive
GAN: generative adversarial network
GPT: Generative Pretrained Transformer
GPT-2: Generative Pretrained Transformer-2
InfoGAN: Information-Theoretic Generative Adversarial Network
MLE: maximum likelihood estimation
NLP: natural language processing
NRCLex: National Research Council Lexicon
PSD: persuasive system design
PT: persuasive technology
RL: reinforcement learning
RoBERTa: robustly optimized BERT approach
TF-GAN: Time and Frequency Domain-Based Generative Adversarial Network
TN: true negative
TP: true positive
TT-GAN: Text-to-Text Generative Adversarial Network
VADER: Valence Aware Dictionary and Sentiment Reasoner

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Promoting Family Communication for Cascade Cancer Genetic Testing With Relational Agent Role-Play: Quasi-Experimental Study

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Abstract

Background: If a patient with cancer is identified as having a pathogenic variant, at-risk relatives are eligible for genetic testing, known as cascade testing. However, in the United States, the patient is responsible for informing their family members, and only about 30% of these family members are ultimately informed and complete testing. There is a need to train patients with cancer to communicate risk information and motivate their family members to obtain genetic testing.

Objective: This study evaluates "GRACE," an online relational agent that trains patients with cancer to talk to their family about cancer risk, including role-play simulations that enable patients to practice communication skills.

Methods: A quasi-experimental study was conducted with 30 crowd workers with cancer. Primary measures included 5-point pre-post self-reported intent, importance, comfort, and confidence to share genetic test information with family members, as well as knowledge of cancer genetics (KnowGene), satisfaction with (10-item satisfaction measure), and usability of (SUS) the relational agent system.

Results: Likelihood of sharing genetic test information increased significantly pre-post from 4.43 (SD 1.04) to 4.67 (SD .66), Wilcoxon (Z=2.07, *P*=.04). Importance of sharing genetic test information increased significantly pre-post from 4.47 (SD .82) to 4.77 (SD .50), Wilcoxon (Z=2.46, *P*=.01). Comfort sharing genetic test information increased pre-post from 4.33 (SD 0.99) to 4.57 (SD 0.90), Wilcoxon (Z=1.811, *P*=.07). Confidence to share genetic test information increased significantly pre-post from 4.33 (SD 0.994) to 4.63 (SD 0.765), Wilcoxon (Z=2.23, *P*=.03). Knowledge of cancer genetics did not increase significantly (mean 13.27, range 1.911 to 13.7, SD 1.932, paired t_{29}=1.245, *P*=.22). Participants gave high scores for usability (SUS score=71%) and satisfaction (6.09 SD 0.96 out of 7.0), significantly greater than neutral, t_{29}=13.445, *P*<.001) with the relational agent system.

Conclusions: GRACE provides communication skills training and information better enabling patients with cancer to reach out to their families, and our preliminary study indicates a potential for future impact. While results were generally positive, these findings should be interpreted with caution due to limitations in the population included in the pilot, the quasi-experimental design and small sample size. Future development should focus on larger-scale evaluation and in-depth follow-up of family communication dynamics following the use of GRACE.

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KEYWORDS

virtual agents; cascade genetic testing; cancer genetics; cancer risk; communication skills training; embodied conversational agents

Introduction

In the United States, approximately 2 million people are diagnosed annually with cancer, and 5% - 10% of those cancers are due to a pathogenic variant (100,000 to 2,00,000 individuals) in a gene associated with cancer [1]. Once identified, their at-risk relatives are then recommended for testing. In the United States, the average family size includes 4 - 6 first degree relatives. Consequently, on average, 600,000 to 1,200,000 individuals are eligible for cancer genetic testing annually, and this number does not include the extended family and therefore is likely much larger [2]. However, due to multiple barriers [3], only 30% of these individuals are informed of their potential cancer risk [4], depriving them of potentially life-saving measures that could prevent cancer or detect it at an early, curable, stage [5]. Additionally, further relatives become eligible for testing once identified, creating a "cascade" effect that enhances

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family-centered health [5]. In the United States, the responsibility of this cascade cancer risk communication falls on the individual with cancer (the proband), who is often struggling with their diagnosis and treatment, and lacks the knowledge and communication skills to effectively inform their family.

In a recent meta-analysis aiming to understand interventions to facilitate family communication of genetic testing results, 14 interventions were identified that had been evaluated in a randomized controlled trial [6]. Within those results, 3 studies were web-based. Of these, outcomes were mixed, interventions were found acceptable and demonstrated an effect on improving knowledge, while one trial reported no impact. Additional protocol papers and early-stage reports have been identified that are evaluating digital tools for family communication [7-10]. The majority of completed and tested interventions identified in the meta-analysis required human counselor interactions [11]. Current approaches to promoting cascade genetic testing primarily involves the provision of standardized education materials to family members, along with tools to facilitate the transmission of this information from the patient with cancer. While these approaches reduce some barriers, they fail to address the most important ones regarding training and motivating the patient with cancer to reach out to their family members [11]. This research aimed to address these shortcomings by designing and evaluating an online intervention grounded in motivational interviewing theory [12,13] focused on the patient with cancer, and to leverage a user interface medium that is accessible to patients from all levels of health, reading, and computer literacy.

The purpose of this pilot project was to assess whether a relational agent intervention affects patients' knowledge, intent, and confidence in discussing cancer genetics test results with their family, motivates family members to test. We hypothesize that individuals who engage in the intervention will have increased knowledge of cancer genetic testing and have an intention to discuss results with family members to motivate family cascade testing and confidence in their ability to do so. Satisfaction and usability of the agent was also assessed.

Methods

Study Design

Our study report is guided by the Transparent Reporting of Evaluations with Nonrandomized Designs (TREND) reporting structure for nonrandomized studies [14]. The study was a nonrandomized single arm pre-post study. Study participants conducted a single online study session, involving pretest questionnaires, an interaction with the study intervention, GRACE, and post-test questionnaires.

Participants and Recruitment

All participants were recruited online through the Prolific web-based research platform [15]. The inclusion criteria were the following: (1) age 18 years or older; (2) reside in the United States; (3) speak and read English; and (4) have a current or prior diagnosis of cancer. Prolific's system prescreens participants and handles all aspects of recruitment automatically, offering enrollment to eligible participants until the recruitment target is met. A total of 30 participants who met the inclusion criteria completed the study. We used four "attention check" questions in the surveys, as is common practice in web-based studies [16-18] but no participants failed more than one; so all participants who completed the study tasks were retained. Participants engaged with the intervention remotely. The intervention and measure collection was completely automated.

Ethical Considerations

Ethics approval was received from the Institutional Review Board at Northeastern University (reference 25-04-01). All participants completed an informed consent process, which allowed them to opt out of any survey questions or withdraw from the study at any time. The participants were compensated US $15 after completing the survey. All collected data were deidentified.

Intervention

We developed an online system called "GRACE" (Genetic Relational Agent for Cascade) that features a relational agent (RA) that interacts with patients with cancer using simulated face-to-face conversation (Figure 1). GRACE was deployed as a web-based application developed using the Unity 3D game engine. The RA uses synthetic speech and animation to simulate a face-to-face conversation, and the patient responds with a touch screen or mouse. All dialogue is scripted so that accuracy and safety can be reviewed. This interface has been successfully used in several health interventions with thousands of patients across the health literacy spectrum [19-24], including a pilot study of a RA that provided pretest genetic testing to patients with cancer [25]. The content of GRACE was developed based on previous work within cancer genetics and cancer genetic testing, whose input was provided by health providers, patients, and families as the content was developed. All clinical content was created and approved by experts in cancer genetic counseling and testing. Previous work has verified that the structure, approach, and style of the Relational Agent is acceptable to patients. It is intended that this content take as much or as little time for the patient to review as necessary; however, it is designed to be brief, less than 20 minutes, and can be administered remotely.

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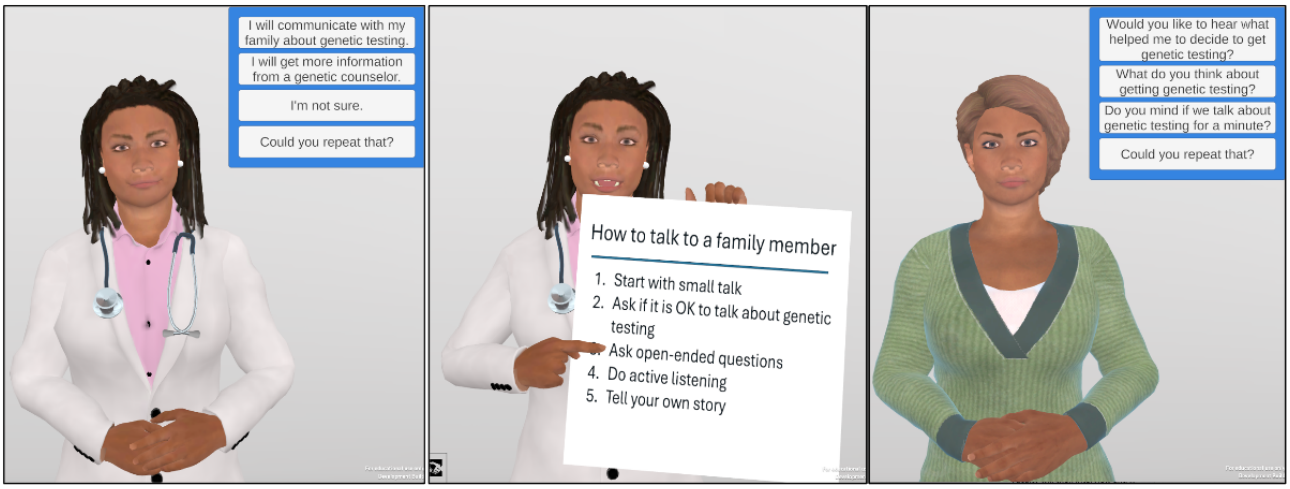
Figure 1. Screen shots of GRACE (Genetic Relational Agent for Cascade), showing: (**L**) the instructional Relational Agent and multiple-choice user input menus; (**M**) giving an overview of family communication; (**R**) the role-play agent.



The RA first spends several minutes reviewing the basics of cancer genetics, including the concepts of genes, pathogenic variants, inherited risk, what individuals can do to reduce their cancer risk if they know they have a pathogenic variant, and what the genetic testing process involves. It then elicits from the proband the most likely family member they would talk to first about genetic testing. It then covers a series of modules on communication skills, following Buckman's six-step strategy [16] augmented with techniques from Motivational Interviewing [17], starting with setting the context, building rapport, and asking permission to discuss cancer genetic testing, before progressing to asking open-ended questions, active listening, and relaying their own story about reasons for getting tested and what the process was like for them. For each module, GRACE first provides didactic instruction on the skill, including examples, before allowing the user to practice each skill in a role-play with a different conversational agent that takes on the persona of the family member the proband indicated they would talk to first. At each turn of the role-play, the proband is given the option of choosing from among one correct response and several alternatives representing common communication mistakes. If the user chooses the correct options throughout the role-play, the instructional RA gives positive reinforcement. However, if they make a mistake, the role-play agent provides immediate in situ feedback (eg, acting offended and leaving), the role-play is ended, and the user is given the option of repeating.

Outcome Measures

Web-based questionnaires were distributed in English to the participants using a Qualtrics web survey.

Primary Outcome

Cancer Genetics Knowledge

Cancer genetics knowledge was assessed before and after the intervention using KnowGene [18], a 19-item instrument designed to assess understanding of general concepts learned within a multigene panel genetic counseling session. A total score is calculated with higher scores indicating higher knowledge.

Secondary Outcomes

Family Communication

Participant attitudes towards sharing genetic test information with their family were assessed before and after the intervention using five five-point scale response items (Table 1). These measures were investigator-initiated based on CSER consortium recommendations [26] and previous trials. Immediately prior to answering each of these questions, participants were prompted with "Assuming you had just been informed that a mutation (pathogenic variant) in one of your genes likely contributed to your cancer."

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Table . Single-item measures of family communication.

Item	Anchor 1	Anchor 5	Pre mean (SD)	Post mean (SD)	*P* value[a]
How likely are you to share your genetic test results with your immediate family?	Very unlikely	Very likely	4.43 (1.04)	4.67 (0.66)	.04
How important do you believe it is to share your genetic test results with your family members?	Not important	Extremely important	4.47 (0.82)	4.77 (0.50)	.01
How comfortable do you feel about discussing your genetic test results with your family?	Very uncomfortable	Very comfortable	4.33 (0.99)	4.57 (0.90)	.07
How confident do you feel about discussing your genetic test results with your family?	Not confident	Very confident	4.27 (1.02)	4.63 (0.77)	.03

[a]All *P* values are 2-tailed, Wilcoxon Signed Ranks Tests of pre-post change.

Usability and Satisfaction

Usability was assessed after the intervention using the System Usability Scale (SUS) [27]. SUS scores range from 0 to 100, with higher scores indicating greater usability, and scores above 70 indicating good usability [28].

Satisfaction with GRACE was assessed after the intervention using a composite (averaged) score of 13 seven-point scale items (Table 2). In addition, perceptions of the interaction length were assessed with a single seven-point item "How do you feel about the length of the interaction you just had?," with responses ranging from "Too short" to "Too long."

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Table . Satisfaction measure items.

Item	Anchor 1	Anchor 7	Mean (SD)
How satisfied are you with the agent?	Not at all	Very satisfied	6.28 (1.18)
How satisfied are you with the instructional experience?	Not at all	Very satisfied	6.50 (0.86)
How much would you like to continue working with the agent?	Not at all	Very much	5.67 (1.67)
How much do you trust the agent?	Not at all	Very much	6.03 (1.25)
How much do you like the agent?	Not at all	Very much	5.80 (1.42)
How easy was interacting with the agent?	Very difficult	Very easy	6.60 (0.62)
How knowledgeable was the agent?	Not at all	Very knowledgeable	6.53 (0.97)
How clear and understandable was the information presented by the agent?	Very unclear	Very clear	6.63 (0.89)
How relevant was the information to your needs and concerns?	Not relevant at all	Extremely relevant	6.03 (1.22)
How likely would you be to recommend this system to other cancer patients?	Very unlikely	Very likely	6.03 (1.35)
How satisfied are you with the role-play interactions?	Not at all	Very satisfied	6.13 (1.38)
How effective were the role-playing interactions?	Not at all	Very effective	5.87 (1.46)
How realistic were the role-playing interactions?	Not at all	Very realistic	5.23 (1.65)
Composite	—[a]	—[a]	6.20 (0.90)

[a]Not applicable.

Statistical Analysis

Given the exploratory nature of the study, no formal sample size calculation was conducted. The research data were analyzed using IBM SPSS Statistics (version 28, IBM Corp). The distribution of pre-post differences in KnowGene scores was normal, indicating parametric paired sample t-test use for pre-post tests. All pre-post tests on single scale item Family Communication Measures were tested using non-parametric Wilcoxon Signed Ranks Tests. The distribution of scores for the composite measure of satisfaction as well as intervention duration were non-normal, thus non-parametric tests were used. Descriptive statistics were used to summarize the data. The threshold for statistical significance was set at $P<.05$.

Results

The 30 participants took an average of 40.87 (SD 19.25, range 18 to 104) minutes to complete the GRACE intervention session. Those who reported having had a genetic test completed spent significantly more time on the intervention (48.1 mins vs 31.4 mins, Mann-Whitney $U=58.5$, $P=.03$).

Sociodemographic Characteristics of Participants

Table 3 shows the sociodemographic characteristics of the 30 study participants. The age of the participants ranged from 19 - 79 years (mean 44.9, SD 16.4 y). A majority of participants identified as male (16/30, 53.3%), were White (24/30, 80.0%), and had at least some college education (25/30, 83.3%). The majority had received prior cancer-related genetic testing (17/30, 56.7%).

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Table . Sociodemographic characteristics of survey participants (N=30).

Characteristics	Values
Age (years), mean (SD)	44.9 (16.4)
Gender, n (%)	
Female	13 (43.3)
Male	16 (53.3)
Transgender	1 (3.3)
Race, n (%)	
White	24 (80.0)
Black	5 (16.7)
American Indian	1 (3.3)
Ethnicity, n (%)	
Hispanic	1 (3.3)
Non-Hispanic	29 (96.7)
Education, n (%)	
High school	5 (16.7)
Some college	8 (26.7)
College graduate	8 (26.7)
Advanced degree	9 (30.0)
Ever had a cancer-related genetic test	
Yes	17 (56.7)
No	13 (43.3)

Family Communication

Following the interaction with GRACE, participants indicated they were significantly more likely to share genetic test results with their family (Table 1). Participants also indicated that the importance of sharing genetic test results was significantly greater following the intervention, and that they felt significantly more confident in discussing genetic test results with their family. There was only a trending increase in the degree of comfort participants felt in discussing genetic test results with their family, P=.07.

Cancer Genetics Knowledge

KnowGene scores increased from pre-intervention, 13.27 (SD 1.91), to post-intervention, 13.70 (SD .35) but this difference was not significant, paired t_{29}=1.25, P=.22.

Usability and Satisfaction

Participants scored GRACE an average of 42.7/60 (71.2%) on the SUS.

Participants rated their satisfaction with GRACE an average of 6.20 (SD 0.90) on the composite measure of satisfaction (Table 2). A single sample Wilcoxon signed ranks test indicated this score (mean 6.2) was significantly greater than a neutral score of 4.0, P<.001. There was a significant positive correlation between time to complete the intervention and satisfaction, Spearman ρ=.537, P=.002.

Discussion

Principal Findings

We aimed to understand usability and the preliminary impact of a digital health intervention to support patients with cancer in communicating genetic testing information to at-risk relatives. Overall, we found that comfort, confidence, and intent to communicate increased, and that participants had high levels of satisfaction with the intervention. Cancer genetics knowledge remained constant. Preliminary results demonstrate that the intervention GRACE should be evaluated further to understand the impact on rates of cascade testing.

Limitations

Our study had some limitations. First, our sample was a convenience sample of individuals recruited from a research database. We did not select people who had completed cancer genetic testing and who had actual testing information to communicate. We therefore could not measure actual communication or uptake within a family. Additionally, the sample is small and relatively homogeneous, recruited from one online crowdsourcing site; therefore, results may vary as the sample diversifies. Specifically, KnowGene scores were relatively high at baseline, and therefore no change was found. If we targeted patients with varied educational levels and knowledge, we may have noticed an impact. This may have contributed to our lack in change in knowledge scores.

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Our study is the first to use a conversational agent to provide a fully virtual and automated intervention to promote family communication between a patient with cancer and at-risk relatives. Other forms of digital health interventions have been tested to improve these outcomes. In a recent meta-analysis focused on interventions to improve cascade genetic testing, only two technology-based interventions were identified [11]. One was the Family Gene Toolkit, a webinar-based intervention to promote communication in families with hereditary breast and ovarian cancer syndrome that also included face-to-face and telephone interactions over 5-weeks [7]. The published data for this study demonstrate acceptability [9], however, outcomes have not yet been published. The other was the Mobile Application for Genetic Information on Cancer (mAGIC) trial which focused on ovarian cancer risk communication using a mobile app over 3-months [6]. Outcomes of this pilot randomized trial demonstrated significant increases in hereditary cancer knowledge and family communication rates for the intervention group compared to control, but no significant differences in use of cancer genetic counseling services.

Three additional trials were identified since the publication of the meta-analysis that use technology to promote cascade testing, mainly through the use of video education, which was found to be non-inferior compared to usual care to provide genetics education [29] and also to not cause distress [30]. The Genetic Education, Risk Assessment, and Testing (GENERATE) Study used telemedicine and online genetics education through videos to reach family members of patients with pancreatic cancer and a known pathogenic variant, finding that it was successful at improving uptake of testing [31]. Two protocol papers were available related to video education trials: the Genetic Education for Men (GEM) trial (focused on men with prostate cancer [32]), and the Facilitated Cascade Testing (FaCT) trial [33].

While providing genetics education information through a video can be useful and effective at providing information, there are limitations that can be addressed through more interactive computer programs such as relational agents. Video education is static and often challenging to keep up to date and current, a need for those seeking genetics information. Additionally, providing information passively without interaction diminishes learning outcomes. Video education is also difficult to tailor for the nuances required within a genetics education setting.

Researchers and companies are now developing chatbots to facilitate testing or family communication both focused on cancer and within other inherited domains, such as familial hypercholesterolemia [34-36] . However, chatbots rely entirely on text-based interaction, limiting their use in low-literacy populations. Accessibility by family members across the literacy spectrum is essential to ensure that all at-risk individuals receive the genetic risk and mitigation information they need, including the 46% of US adults with low or marginal health literacy [37]. Additionally, chatbots driven by large language models, can hallucinate and provide false information [38], even when driven by retrieval augmented generation [39], making them potentially unsafe if their output is not entirely screened by clinicians. Therefore, solutions that provide trustworthy, controlled, and precise information are needed to ensure accurate and appropriate information without intensive provider oversight, and in a manner accessible to all.

Conclusions

In order to achieve the full public-health impact of cancer genetic testing, it is critical that information about hereditary cancer risk is communicated within families, often originating from the patient with cancer. The GRACE intervention demonstrates an opportunity to motivate patients with cancer to communicate genetic information and promote cancer genetic testing to at-risk relatives. Further large-scale randomized studies are needed to understand the impact of GRACE on genetic testing outcomes.

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Data Availability

The datasets generated or analyzed during this study are available from the corresponding author on reasonable request.

Authors' Contributions

Conceptualization: MB, MU, TWB
Data analysis: TWB
Methodology: MU, TWB
Project administration: MB
Software: TWB
Writing – original draft: MU, TWB
Writing – review & editing: MB

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Conflicts of Interest

None declared.

Checklist 1
TREND trial checklist.
[PDF File, 1199 KB - formative_v10i1e87623_app1.pdf]

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Abbreviations

FaCT: Facilitated Cascade Testing
GEM: Genetic Education for Men
GRACE: Genetic Relational Agent for CascadE
mAGIC: Mobile Application for Genetic Information on Cancer

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RA: relational agent
SUS: System Usability Scale
TREND: Transparent Reporting of Evaluations with Nonrandomized Designs

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Development of a Child Articulation Screening Test Within Digital Therapeutics: Delphi Study

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Abstract

Background: Speech sound disorders are common in children and are associated with an increased risk of academic reading difficulties. The COVID-19 pandemic further highlighted the need for remote and digitalized assessment tools. In South Korea, standardized instruments such as the Urimal Test of Articulation and Phonation and Assessment of Phonology and Articulation for children are widely used but have limitations, including reliance on face-to-face evaluation, and the absence of automated scoring.

Objective: This study aimed to develop and establish the content validity of an articulation assessment tool that can overcome these limitations and be integrated into digital therapeutics (DTx).

Methods: A 3-round modified Delphi survey was conducted between July and September 2025 with 92% (23/25) of the invited experts, including 52.2% (12/23) physiatrists and 47.8% (11/23) speech-language pathologists, with a mean professional experience of 10.69 (SD 5.09) years. All participants (23/23, 100%) completed all rounds. Panelists evaluated the appropriateness of word lists, phonological environments, and scoring criteria. Quantitative analyses, including calculations of content validity ratio (CVR), content validity index (CVI), and median and IQR, were performed. Consensus thresholds were set at a CVR of ≥0.39, a CVI of ≥0.78, a median of ≥3.5, and an IQR of ≤1.0. Items were retained only when all 4 criteria were satisfied. While formal qualitative analysis was not performed, the research team internally reviewed and synthesized core keywords and themes from the experts' open-ended responses to guide the refinement of items.

Results: These findings were summarized into four key areas: (1) modernization of word stimuli, (2) expansion of phonological coverage, (3) refinement of scoring criteria to reduce ambiguity, and (4) enhancement of result interpretability through visualization. In round 2, a revised 35-word list was evaluated across 25 items, of which 20 (80%) met all consensus criteria. In total, 20% (5/25) of the items failed to meet at least one threshold, including phonological environment adequacy (CVR=0.48; CVI=0.74), scoring redundancy (CVR=0.13; CVI=0.57), usefulness of proportion of whole-word correctness or percentage of word proximity (CVR=0.39; CVI=0.70), contribution of mean phonological length (CVR=0.22; CVI=0.61), and usefulness of feature-based indexes (CVR=0.30; CVI=0.65; IQR 2). Items that reached consensus showed CVR values of 0.57 to 0.91, CVI values of 0.78 to 0.96, a median score of 4, and IQR values of 0 to 1. In round 3, all remaining items achieved consensus.

Conclusions: This Delphi study developed a novel articulation assessment tool with robust content validity. This tool includes updated word stimuli, diverse analysis indexes, and visualization features, thereby enhancing its clinical utility and suitability for integration into artificial intelligence–based DTx. By standardizing and digitalizing articulation assessments, this tool has the potential to support personalized and accessible interventions for children with speech sound disorders.

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KEYWORDS

speech sound disorder; Delphi method; assessment tool; digital therapeutics; digital diagnostics; digital screening; pediatric screening; artificial intelligence; AI

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Introduction

Speech sound disorders (SSDs) represent one of the most prevalent communication disorders in childhood, typically manifesting as difficulty in accurate production or inappropriate use of speech sounds relative to developmental expectations for age [1]. Recent statistics suggest that approximately 24% of students with disabilities in US public schools are provided with services for speech or language disorders [2]. In South Korea, approximately 44.1% of children receiving speech therapy are diagnosed with SSDs, and approximately 9% of children aged 6 years present with articulation difficulties [3]. Children with SSDs are at increased risk of developing reading disabilities and other learning difficulties, resulting in significant implications for school readiness and overall academic achievement [4,5]. Therefore, early identification and intervention for SSDs are vital for reducing the risk of reading disabilities and promoting school readiness.

The COVID-19 pandemic had a profound global impact in 2020. Environmental factors, including potential effects of mask wearing, have been reported to negatively affect children's cognitive, social, and language development [6,7]. However, effects related to the COVID-19 pandemic persist, continuing to negatively affect language development in children [7]. Telerehabilitation and digital therapeutics (DTx) reduce health care costs, save patients time, and improve accessibility [8]. Furthermore, following the COVID-19 pandemic, the use of telerehabilitation increased substantially, with reported rates increasing from 3.4% to 19.3% [9]. There is a growing shift toward remote and digital approaches for both assessment and intervention. In this context, appropriate tools for evaluating SSDs are needed to ensure standardized quality, allow for home-based administration, and minimize the need for in-person visits.

In South Korea, the Urimal Test of Articulation and Phonation (U-TAP) and Assessment of Phonology and Articulation for Children (APAC) are among the most frequently used standardized instruments for the evaluation of SSDs [3]. However, despite their widespread use, both tools present certain limitations. They rely heavily on face-to-face administration and perceptual assessment, lack automated or digitalized scoring systems, and have limited applicability in remote or home-based assessment settings. Moreover, normative data are constrained to specific age groups and linguistic contexts, posing challenges for their broader clinical use.

Beyond these logistical and systemic constraints, these conventional assessments also have technical shortcomings in their analytical frameworks. For instance, both the U-TAP and APAC are time-consuming [3], and the U-TAP does not distinguish between medial and final positions when evaluating codas, making it difficult to accurately identify coda errors [10]. In contrast, the APAC defines the omission of a medial coda or regressive assimilation of a following medial onset into the coda as typical medial simplification and the omission of a medial onset or progressive assimilation of a medial coda into the following onset as atypical medial simplification [10]. On the basis of this framework, the APAC analyzes coda errors separately for medial and final positions. However, it does not differentiate between omission and substitution errors of medial codas as they are all categorized under medial simplification, limiting the detailed analysis of medial coda errors [10].

While recent advances in artificial intelligence (AI), particularly large language models, have expanded the potential for DTx applications in speech-language pathology [11], existing research has predominantly focused on intervention efficacy rather than the development of linguistically valid and digitally adaptable assessment frameworks [11-13]. In particular, recent studies have attempted to apply AI technologies to the detection and assessment of SSDs. In the context of recent advances in digital health, several studies have explored AI-assisted or digital approaches in speech-language pathology. For example, previous work has developed automated SSD detection systems using deep learning models based on automatic speech recognition and audio classification, achieving moderate classification performance (eg, unweighted average recall of approximately 70%) [14]. However, these approaches primarily focus on classification tasks (eg, distinguishing children with typical development from those with SSD) and rely on metrics such as proportion of whole-word correctness (PWC) without providing detailed linguistic analysis of articulation error patterns. In addition, their performance is influenced by the accuracy of speech recognition models and predefined thresholds, which may limit interpretability and clinical applicability. Although such studies demonstrate the technical feasibility of AI-based SSD detection, clinically standardized and linguistically grounded assessment tools suitable for widespread diagnostic use remain under development. Therefore, there remains a lack of clinically grounded and digitally adaptable diagnostic frameworks that can accurately capture articulation error patterns while being suitable for digital implementation. In this regard, unlike previous AI-based SSD detection studies focused on classification accuracy, this study aimed to establish a linguistically structured and clinically interpretable assessment framework that can support detailed error pattern analysis and future integration into DTx systems.

Rapid AI-powered large language models have drawn significant attention for their potential use in DTx [11]. To fully realize this potential, it is essential to clarify how such interventions function, what factors affect their effectiveness, and how AI can be systematically integrated into DTx [11-13]. To develop AI-based DTx for children with SSDs effectively, it is essential to accurately identify each child's specific error patterns and design algorithms to determine appropriate intervention strategies. The most fundamental step in this process is the precise evaluation of a child's articulation error patterns.

A previous study reported that, while speech-language pathologists demonstrated high intrarater reliability in the evaluation of speech intelligibility, interrater reliability was only moderate to excellent, indicating variability across clinicians [15]. Thus, conventional speech-language pathologist–based language assessments are limited by variability in scoring and interpretation across clinicians. This limitation may contribute to inequitable and potentially discriminatory access to assessments and treatments across rural and urban regions.

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Taken together, these limitations highlight the need for a novel articulation assessment tool that is not only clinically and linguistically robust but also specifically designed for digital and AI-based applications.

This study aimed to develop a new articulation development evaluation tool to overcome the technical and clinical limitations of the U-TAP and APAC, facilitate its transition to DTx, and verify its content validity and applicability through a Delphi study.

Methods

Study Design

The Delphi survey was conducted in 3 iterative rounds between July 2025 and September 2025. The number of rounds was predefined to a maximum of 3 to ensure a structured consensus-building process. We used a Delphi methodology to systematically gather expert consensus on digital assessment items for articulation and phonological disorders [16]. The Delphi technique collects expert consensus anonymously through structured questionnaires and iterative feedback [17]. It provides a systematic and objective approach for evaluating content that requires professional judgment and is widely recognized as a standard method for establishing the content validity of clinical assessment tools.

The initial questionnaire was developed by a multidisciplinary committee consisting of 3 physiatrists and 1 professor of speech-language pathology. The committee drafted the word list based on clinical experience, existing instruments (eg, U-TAP and APAC), and literature on word familiarity. Specifically, candidate words were selected to reflect age-appropriate vocabulary, phonetic balance across consonant positions, and clinical relevance for identifying common articulation error patterns. Relevant literature and existing standardized assessment tools were reviewed to ensure linguistic validity and familiarity for Korean-speaking children.

To minimize potential psychological biases, such as the bandwagon effect and interference effects; ensure anonymity; and enhance validity, we implemented a web-based modified Delphi process conducted via an online survey platform (Google Forms). All responses were collected anonymously, and participants were blinded to the identities of other panel members. Open- and closed-ended questions were used to facilitate consensus. In round 1, open- and closed-ended questions were used to evaluate the appropriateness of a word list and stimulus composition, diversity and usefulness of phonological environments, and validity of both scoring criteria. Round 2 served as an internal validation stage in which the results of round 1 were analyzed and restructured into closed-ended questions. Summarized feedback from round 1 was provided to participants in round 2 to support iterative consensus building. In round 3, additional feedback was incorporated to refine the items, and a final set was established. In rounds 2 and 3, a 5-point Likert scale was used supplemented with open-ended sections to allow participants to revise, add, or withdraw their opinions.

Between rounds, both quantitative and qualitative syntheses were performed. The feedback, including statistical summaries and qualitative syntheses, was provided uniformly to all participants to support consensus building. Although a formal qualitative analysis of open-ended responses was not performed, the research team internally reviewed and synthesized core keywords and themes to guide item refinement and establish priorities based on importance and appropriateness. Furthermore, even for items that reached statistical consensus, additional exploratory questions were included in subsequent rounds if the research team identified clinically significant issues requiring further expert deliberation. In addition, panelists were encouraged to consider the scalability and applicability of the assessment framework for future digital and AI-based implementation, including the use of structured, quantifiable scoring systems and standardized output formats that could support automated analysis.

Participants

An expert panel was convened, with specialists identified through the official membership lists of the Korean Academy of Rehabilitation Medicine and the Korean Association of Speech-Language Pathologists. Initially, the research team considered including DTx developers; however, the scope was purposefully narrowed to specialists in rehabilitation medicine and speech-language pathology to focus on establishing the foundational clinical validity of the assessment tool. The panelists were chosen based on their expertise in articulation and phonological disorders and their experience in digital assessment or related fields.

According to previous studies, homogeneous panels typically require 15 to 30 participants, whereas heterogeneous panels may be sufficiently represented with 5 to 10 participants [18]. Given that our Delphi panel included 2 distinct professional groups—speech-language pathologists and physiatrists—the panel could be considered heterogeneous. Therefore, the inclusion of 23 experts in this study exceeded the recommended size for heterogeneous panels, ensuring both adequacy and diversity of perspectives.

The criteria for panel selection were as follows: (1) possession of a degree in the relevant specialty, (2) a minimum of 5 years of clinical or research experience, and (3) understanding of study objectives and methodology with consent to participate. Exclusion criteria were as follows: (1) less than 5 years of clinical or research experience, (2) willingness to participate without sufficient understanding of the study objectives or Delphi method, and (3) inability to continue participation due to withdrawal or incomplete responses during the survey rounds. These inclusion and exclusion criteria were established a priori. A total of 25 potential experts were initially invited via email. Of these 25 experts, 23 (92%) agreed to participate, whereas 2 (8%) declined due to scheduling conflicts. No participants were excluded after enrollment, and all 23 experts completed all Delphi rounds and were included in the final analysis.

Ethical Considerations

This study was approved by the Institutional Review Board of Seoul National University Bundang Hospital (B-2507-987-301).

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All the participating experts were provided with information regarding the purpose of the study, expected time commitment, eligibility criteria, and importance of completing all rounds of the survey. Participation in the Delphi process was voluntary, and informed consent was obtained prior to involvement. Participants received monetary compensation of US $100 for their time and participation in the study. The compensation was determined to be appropriate and not coercive. To ensure anonymity, the survey was conducted online, and each expert was assigned a unique identification code. This procedure allowed responses to remain confidential while maintaining the integrity of the iterative Delphi process. All the responses were collected anonymously to protect participants' confidentiality.

Data Analysis

All responses were analyzed using equal weights. Predefined criteria for consensus were established prior to data collection to guide interpretation and agreement thresholds. To ensure content validity, basic descriptive statistics (mean, SD, and median), content validity ratio (CVR), and consensus indexes were examined and analyzed. CVR was calculated to assess the essentiality of each word item based on the number of panelists rating an item as "essential." Following the Lawshe formula, the minimum acceptable CVR value for 23 panelists was set at 0.37 [19]. Additionally, the content validity index (CVI) was calculated from a percentage of panelists giving each item a rating of 3 or 4 on a 5-point Likert scale, with a CVI of 0.78 or higher indicating high content validity [20].

Consensus levels were evaluated using the median and IQR. A median score of 3.5 or higher was regarded as positive consensus, whereas an IQR of 1.0 or lower indicated a high level of agreement among panelists [21].

Items were retained if they met all 4 criteria: CVR of 0.39 or higher, CVI of 0.78 or higher, median of 3.5 or higher, and IQR of 1.0 or lower. Items that met CVR and CVI thresholds but failed to reach consensus (median or IQR) were revised and re-evaluated in a subsequent round, whereas items that did not meet the CVR or CVI thresholds were either modified or eliminated.

Although a formal qualitative analysis was not conducted, open-ended responses were reviewed using a structured descriptive approach. Two investigators independently examined the responses to identify recurring themes and clinically relevant insights. Discrepancies were resolved through discussion, and the synthesized findings were used to refine questionnaire items and inform subsequent Delphi rounds.

Results

Overview

This study aimed to develop a diagnostic tool for children with SSD to support the creation of an AI-based DTx instrument. The three main objectives were to (1) construct a word list and diagnostic tool for children with SSD, (2) evaluate the content validity of the developed tool, and (3) establish diagnostic parameters for differentiating SSD using a Delphi survey process. The findings of the 3 study rounds (Figure 1 shows a flowchart of participation) are described in the following sections.

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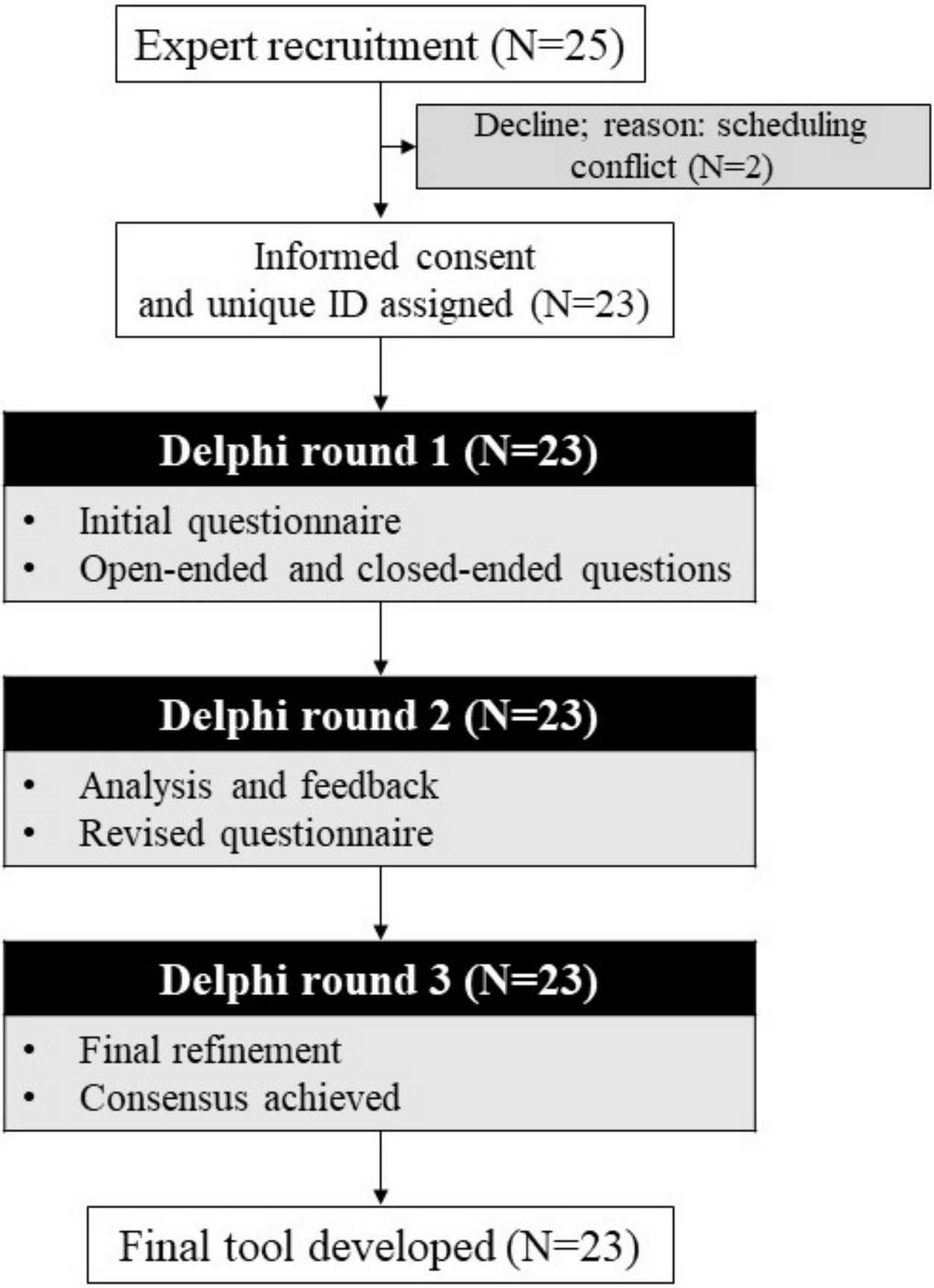
Figure 1. Flowchart of the 3-round Delphi process used to develop the articulation assessment tool. Of the 25 recruited experts, 23 (92%) participated in all rounds. The process included an initial assessment (round 1), feedback and revision (round 2), and final consensus (round 3), resulting in the final tool.



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Round 1

The first round of the Delphi survey was completed by all 23 experts who initially agreed to participate, achieving a 100% (23/23) response rate for this stage. The panel was asked open-ended and multiple-choice (5-point scale) questions regarding the appropriateness of the 26 initial words, diversity of phonological environments, and validity of the scoring criteria. On the basis of the comprehensive feedback from the 23 experts, the panel emphasized the need to include diphthong words, exclude words with potential dialectal variations (eg, *jajangmyeon* [black bean noodles]), and remove words unfamiliar to modern urban children (eg, *gulttuk* [chimney] and *radio*). They also highlighted the necessity of expanding and supplementing words containing fricative and affricate codes as well as increasing the overall number of test words.

Furthermore, the experts recommended incorporating listeners' subjective ratings of speech clarity, clarifying the scoring criteria for ambiguous productions, improving the scoring system, and presenting the results using graphical visualization. These qualitative insights, synthesized from the open-ended responses, provided the foundational rationale for the modifications implemented in the subsequent round. Notably, several of these refinements, such as the development of clearer scoring criteria and graphical visualization of results, were aligned with the need to generate structured and interpretable data that may be suitable for future AI-based analysis.

Round 2

Following the synthesis of results from the 23 panel members who responded to the round 1 Delphi survey, words from an initial 26-item list that were deemed inappropriate for modern urban children or had the potential to be dialectal were excluded (Table 1).

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Table . Word list for articulation assessment developed through a 3-round Delphi survey among experts in pediatric rehabilitation and speech-language pathology (n=35 words).

Target word in Korean	Meaning	IPA[a] transcription
타조	Ostrich	[t a .d o]
냄비	Pot	[n m.bi]
눈썹	Eyebrow	[nun.s p]
딸기	Strawberry	[t a l.gi]
국자	Ladle	[kuk .t a]
다리	Leg and bridge	[ta . i]
자동차	Car	[t a .do ŋ.t a]
씨앗	Seed	[i.a t]
바나나	Banana	[pa .na .na]
레몬	Lemon	[e .mo n]
코끼리	Elephant	[k o .k i. i]
곰	Bear	[ko m]
사탕	Candy	[sa .t a ŋ]
버섯	Mushroom	[p .s t]
펭귄	Penguin	[p e ŋ.g in]
마이크	Microphone	[ma .i.k]
연필	Pencil	[j n.p il]
까치	Magpie	[k a .t i]
빵	Bread	[p a ŋ]
아빠	Dad	[a p a]
책상	Desk	[t k .s a ŋ]
찌개	Stew	[t i.g]
오뚝이	Roly-poly toy	[o .t u.gi]
하마	Hippopotamus	[ha .ma]
구급차	Ambulance	[ku.g p .t a]
수박	Watermelon	[su.ba k]
과자	Snack	[kwa .d a]
돼지	Pig	[twe .d i]
요거트	Yogurt	[jo .g .t]
귀	Ear	[k i]
여우	Fox	[j .u]
우유	Milk	[u.ju]
야구	Baseball	[ja .gu]
원숭이	Monkey	[w n.su.ŋi]
의자	Chair	[i.d a]

[a]IPA: International Phonetic Alphabet.

These were replaced with alternative items, along with additional words representing diverse articulatory environments (eg, *remon* [레몬], meaning "lemon," *ottugi* [오뚝이], meaning "roly-poly toy," and *jjigae* [찌개], meaning "stew"). Furthermore, words containing diphthongs (eg, *yagu* [야구], meaning "baseball," *uija* [의자], meaning "chair," *wonsungi* [원숭이], meaning "monkey," *yogeoteu* [요거트], meaning "yogurt," *dwaeji* [돼지], meaning "pig," and *gwaja* [과자], meaning "snack" or "cracker") were incorporated, resulting in a final test list of 35 words. To facilitate a clearer interpretation of speech outcomes by both caregivers and clinicians, visual graphs were integrated

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into the scoring results to display consonant and vowel accuracies (Table 2).

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Table . Consensus articulation assessment measures and scoring system established through a 3-round Delphi survey.

Articulation outcome category and subcategory	Denominator	Unit used for scoring
Accuracy		
Consonant accuracy (PCC[a])	48	Percentage
Revised consonant accuracy (PCC-revised)	48	Percentage
Total consonant accuracy (total PCC)	48	Percentage
Total revised consonant accuracy (total PCC-revised)	48	Percentage
Vowel accuracy (PVC[b])	14	Percentage
Diphthong accuracy	0	Percentage
Word accuracy (PWC[c])	26	Percentage
PMLU[d]	26	Percentage
Articulation manner		
Plosive	23	Percentage
Fricative	5	Percentage
Affricate	6	Percentage
Nasal	10	Percentage
Liquid	4	Percentage
Articulation place		
Bilabial	12	Percentage
Alveolar	19	Percentage
Palatal	6	Percentage
Velar	10	Percentage
Glottal	1	Percentage
Phonological features		
Continuancy	6	Percentage
Delayed release	6	Percentage
Laterality	3	Percentage
Coronal	23	Percentage
Anterior	27	Percentage
Tenseness	18	Percentage
Aspiration	8	Percentage
High tongue	14	Percentage
Back tongue	10	Percentage
Roundedness	3	Percentage
High	6	Percentage
Low	1	Percentage
Back	7	Percentage
Error patterns—substitution		
Plosivization	21	Percentage
Fricativization	37	Percentage
Affricativization	37	Percentage
Nasalization	36	Percentage

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Articulation outcome category and subcategory	Denominator	Unit used for scoring
Liquidization	40	Percentage
Bilabialization	33	Percentage
Alveolarization	26	Percentage
Palatalization	37	Percentage
Velarization	35	Percentage
Glottalization	41	Percentage
Tense consonantization	34	Percentage
Aspirated consonantization	33	Percentage
Error patterns—assimilation		
Plosive assimilation	16	Percentage
Fricative assimilation	5	Percentage
Affricate assimilation	8	Percentage
Nasal assimilation	12	Percentage
Liquid assimilation	9	Percentage
Bilabial assimilation	11	Percentage
Alveolar assimilation	13	Percentage
Palatal assimilation	8	Percentage
Velar assimilation	14	Percentage
Glottal assimilation	2	Percentage
Tense assimilation	9	Percentage
Aspirated assimilation	9	Percentage

[a]PCC: percentage of consonants correct.

[b]PVC: percentage of vowels correct.

[c]PWC: proportion of whole-word correctness.

[d]PMLU: phonological mean length of utterance.

Subsequently, the round 2 Delphi survey used a 5-point Likert scale. This survey was conducted with the same 23 experts who completed the previous round, maintaining a 100% (23/23) retention rate for this round. The survey comprised 7 items that evaluated the appropriateness of the word list and stimulus composition, 5 items assessing the diversity and adequacy of phonological environments within the word list, and 13 items examining the validity of the scoring criteria (Table S2 in Multimedia Appendix 1).

In the second-round Delphi survey, most items demonstrated strong expert agreement, meeting the predetermined consensus thresholds of CVR of 0.39 or higher, CVI of 0.78 or higher, median of 3.5 or higher, and IQR of 1.0 or lower. These results indicate that most items of the word list, phonological environments, and scoring criteria were assessed to be appropriate and valid for clinical applications.

However, no consensus was reached regarding 5 items. Specifically, experts did not agree on whether (1) the phonological environments adequately reflected common child speech errors, (2) the scoring rubric was excessively detailed or redundant, (3) analyses using PWC or percentage of word proximity were useful for setting treatment goals, (4) the mean phonological length contributed effectively to the evaluation of phonological complexity, and (5) feature-based indexes provided practical benefits for error pattern analysis (Table 3). The specific results for each round, including items that achieved consensus and those that did not, are presented in Table 3 to provide a transparent overview of the refinement process.

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Table . Outcomes of the second-round Delphi survey evaluating the appropriateness of the word list, phonological environments, and scoring criteria for articulation assessment.

Category and survey question	CVR[a]	CVI[b]	Median (IQR)	Agreement (proportion, %)
Word list and stimulus appropriateness				
Word list matches assessment purpose	0.83	0.91	4 (0)	1
Word list appropriate for the ages of 2 - 18 y; familiar vocabulary	0.65	0.83	4 (0)	1
Words difficult to visualize or confusing	0.83	0.91	4 (0)	1
Presentation order appropriate for flow and difficulty	0.83	0.91	4 (0)	1
Word list appropriate for frequency and exposure by age	0.91	0.96	4 (1)	0.75
Word length appropriate	0.83	0.91	4 (1)	0.75
Factors to prioritize for engaging stimulus words	0.83	0.91	4 (0.5)	0.88
Phonological environments				
Adequate coverage of consonant positions, places, manners, and features	0.83	0.91	4 (0)	1
Selection of target vowels valid	0.74	0.87	4 (1)	0.75
Environments reflect common child speech errors	0.48	0.74[c]	4 (0.5)	0.88
Exclude dialectal or regional words	0.74	0.87	4 (0)	1
Option for diphthongs due to increased task difficulty or vocabulary load	0.74	0.87	4 (1)	0.8
Scoring criteria				
Understanding of indexes (PCC[d], PMLU[e], PWP[f], and PVC[g])	0.65	0.83	4 (0)	1
Usefulness of indexes in clinical practice	0.65	0.83	4 (1)	0.75
Validity of consonant error classification	0.91	0.96	4 (0)	1
Clarity of scoring criteria (place, manner, phonation, and features)	0.91	0.96	4 (1)	0.75
Appropriateness of scoring method	0.57	0.78	4 (0)	1
Sufficiency of indexes for clinical interpretation	0.57	0.78	4 (0.5)	0.88
Scoring rubric excessively detailed or redundant	0.13[c]	0.57[c]	4 (1)	0.75
Appropriateness for caregiver explanation	0.65	0.83	4 (1)	0.75
Usefulness of PWC[h] and PWP for goal setting	0.39	0.70[c]	4 (1)	0.75

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Category and survey question	CVR[a]	CVI[b]	Median (IQR)	Agreement (proportion, %)
Contribution of mean phonological length to complexity	0.22[c]	0.61[c]	4 (1)	0.75
Usefulness of accuracy by place and manner	0.91	0.96	4 (1)	0.75
Contribution of feature-based indexes to error analysis	0.30[c]	0.65[c]	4 (2)[c]	0.5[c]
Need for comprehensive report format	0.57	0.78	4 (1)	0.75

[a]CVR: content validity ratio.

[b]CVI: content validity index.

[c]Did not meet the predefined validity criteria.

[d]PCC: percentage of consonants correct.

[e]PMLU: phonological mean length of utterance.

[f]PWP: percentage of word proximity.

[g]PVC: percentage of vowels correct.

[h]PWC: proportion of whole-word correctness.

Round 3

The third-round Delphi survey was conducted with the same 23 experts, maintaining a 100% (23/23) retention rate across all 3 rounds of the study. This final round was developed based on the results of the second round, incorporating modifications that were refined through the internal synthesis of expert keywords and thematic feedback from previous open-ended responses. Following this process, percentage of word proximity was removed, and the measurement of mean phonological length was modified to a supplementary index.

The five items addressed in the third-round Delphi survey were as follows: (1) word-level phonological environments adequately reflect contexts in which children's speech errors commonly occur, (2) the scoring rubric is excessively detailed or redundant, (3) analyses using PWC are useful for establishing treatment goals, (4) the measurement of mean phonological length can serve as a supplementary indicator, and (5) consonant feature analysis contributes to the identification of error patterns. As a result, all 5 items reached consensus, meeting the thresholds of CVR of 0.39 or higher, CVI of 0.78 or higher, median of 3.5 or higher, and IQR of 1.0 or lower. This achieved the final expert consensus required for the development of the assessment tool.

Discussion

Principal Findings

In this study, we developed and validated stimulus words and an interpretation framework for articulation assessment in children with SSD using a 3-round Delphi process [22]. The resulting tool comprises 35 words that achieved expert consensus for developmental appropriateness and comprehensibility and incorporates updated stimuli, diverse analytical indexes, and visualization features to enhance clinical applicability and potential integration into AI-based DTx.

Compared with conventional standardized assessments such as the U-TAP and APAC, this tool introduces several important methodological and practical differences. First, while existing tools primarily rely on face-to-face administration and perceptual evaluation, our tool was designed with a structured and digitally adaptable framework, facilitating future integration into AI-based systems. Second, unlike the U-TAP, which does not distinguish between medial and final coda positions, this framework allows for more detailed positional analysis of phonological errors [10]. Third, although the APAC distinguishes positional coda errors, it does not differentiate between omission and substitution errors in medial codas; in contrast, our framework enables more granular classification of error patterns through structured indexes and feature-based analysis [10]. Furthermore, it enables the generation of diverse articulation analysis outcomes that can serve as a foundation for AI-based DTx. By standardizing and digitalizing articulation assessments, this tool has the potential to support personalized and accessible interventions for children with SSDs. Importantly, the structured and multidimensional output generated by this framework may facilitate its use as input data for future AI-based diagnostic or decision support systems. These findings extend prior AI-based SSD research by moving beyond classification-focused approaches toward a clinically interpretable and linguistically structured assessment framework. While previous studies have demonstrated the feasibility of automated detection, they have been limited in capturing detailed articulation error patterns and supporting clinical decision-making [14]. In contrast, this study emphasizes structured error analysis and interpretability, which are essential for clinical applicability and future integration into DTx systems.

These findings should be interpreted in relation to the gaps identified in the Introduction section. Specifically, this study addresses the lack of standardized and digitally adaptable assessment frameworks by establishing a structured scoring system and expanding phonological coverage. In addition, the

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incorporation of visualization features and multiple analytical indexes may contribute to improved interpretability and potential reduction in ambiguity in clinical assessment. However, some previously identified limitations remain unresolved [15]. In particular, interrater variability in perceptual judgment was not directly addressed, and automated or AI-based scoring systems were not implemented or validated in this study. Therefore, this work should be considered a foundational step toward digital assessment rather than a fully operational digital diagnostic system. In particular, while this study establishes a structured and AI-compatible assessment framework, further work is required to implement and validate automated or AI-driven diagnostic models based on this framework.

Compared with conventional assessment tools, which are often limited to static and paper-based formats, this tool provides a flexible and extensible digital framework. This aligns with recent trends in digital health and AI-assisted diagnostics, where standardized input and scalable data structures are essential for model training and clinical deployment.

This study holds significant value in establishing clinical content validity and a systematic derivation methodology, addressing the limitations of existing analog tools and the challenges of digital transition. To ensure that this tool functions as a reliable diagnostic system within a DTx environment, several directions for future research are proposed. First, the clinical reliability and validity of the word list and assessment system should be empirically verified through correlation analyses using existing standardized instruments (eg, U-TAP and APAC). In addition, large-scale normative data across different ages and genders should be collected to establish percentile-based reference values and objective diagnostic criteria for distinguishing typical from delayed development. Second, optimization studies addressing technical variables in real-world digital environments are required. These include evaluating the effects of environmental factors, such as background noise and device-related variability (eg, microphone performance), on the accuracy of AI-based automated scoring. Furthermore, systematic investigations are needed to establish technical guidelines that ensure consistent and reliable performance in home-based settings. The relationship between the linguistic properties of the target words and speech recognition performance should also be examined to support robust implementation. Finally, future studies should incorporate user interface and user experience design considerations. In particular, the cognitive load imposed on children in screen-based assessment environments should be carefully evaluated. Factors such as visual layout, stimulus presentation timing, and interaction design may influence attention, comprehension, and response accuracy. Accordingly, interdisciplinary collaboration with user interface and user experience specialists and educational technology developers will be essential to optimize usability and real-world applicability in DTx systems.

In addition, the interpretation of visualized assessment results should be approached with caution. Graphical outputs are intended to support understanding rather than serve as stand-alone diagnostic indicators, and clinical interpretation by qualified professionals remains essential to avoid potential misinterpretation. Furthermore, given that children's voice data constitute sensitive personal information, future implementation of this tool within DTx environments must incorporate robust data security measures and ethical management frameworks. This includes ensuring data privacy, secure storage, and compliance with relevant regulatory standards.

Limitations

This study has several limitations. First, although the Delphi method ensures content validity through expert consensus, it does not provide empirical validation of clinical reliability or diagnostic accuracy. Second, the panel consisted of experts from 2 professional groups, which, while appropriate for the study aims, may limit the generalizability of the findings to other disciplines or international contexts. Third, formal qualitative analysis of open-ended responses was not conducted, which may have limited the depth of thematic interpretation.

Conclusions

Overall, this study provides a foundational framework for the development of digitally enabled articulation assessment tools and highlights the potential for integrating clinically validated instruments into AI-based therapeutic systems.

Future studies should verify the noninferiority of the newly developed articulation assessment tool by comparing its outcomes, such as consonant and vowel accuracy, with those of standardized instruments (eg, U-TAP). Additionally, the results of evaluations by speech-language pathologists should be compared with those generated by an AI-based assessment tool within the application to further establish its clinical validity. Furthermore, integration of this tool into DTx should be followed by clinical trials to evaluate its real-world effectiveness.

Acknowledgments

The authors confirm that no generative artificial intelligence tools or large language models were used at any stage of the research or manuscript preparation.

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Data Availability

The datasets generated or analyzed during this study are available from the corresponding author on reasonable request.

Authors' Contributions

Conceptualization: JYK, YP, Jinju Lee, JSR, SYY, JHS
Data curation: SK, JYK, YP, Jinju Lee, JSR, SYY
Formal analysis: SK
Methodology: JYK, YP, Jinju Lee, JSR, SYY, JHS
Writing—original draft: Jaewon Lee, JHS
Writing—review and editing: JHS

Conflicts of Interest

None declared.

Multimedia Appendix 1
Round 1-3 Delphi questionnaire.
[DOCX File, 48 KB - formative_v10i1e90110_app1.docx]

Checklist 1
DELPHISTAR checklist.
[PDF File, 798 KB - formative_v10i1e90110_app2.pdf]

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Abbreviations

AI: artificial intelligence
APAC: Assessment of Phonology and Articulation for Children
CVI: content validity index
CVR: content validity ratio
DELPHISTAR: Delphi Studies in Social and Health Sciences–Recommendations for a Standardized Reporting
DTx: digital therapeutics
PWC: proportion of whole-word correctness
SSD: speech sound disorder
U-TAP: Urimal Test of Articulation and Phonation

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RoBuster—Corpus Annotated With Risk of Bias Text Spans in Randomized Controlled Trials in Physiotherapy and Rehabilitation: Corpus Development and Annotation Study

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Abstract

Background: Risk of bias (RoB) assessment of randomized clinical trials (RCTs) is vital to answering systematic review questions accurately. Manual RoB assessment for hundreds of RCTs is a cognitively demanding and lengthy process. Automation has the potential to assist reviewers in rapidly identifying text descriptions in RCTs that indicate potential risks of bias. However, no RoB text span annotated corpus could be used to fine-tune or evaluate large language models (LLMs), and there are no established guidelines for annotating the RoB spans in RCTs.

Objective: The revised Cochrane RoB 2 test (RoB 2) tool provides comprehensive guidelines for RoB assessment; however, due to the inherent subjectivity of this tool, it cannot be directly used as RoB annotation guidelines. The study aimed to develop precise RoB text span annotation instructions that could address this subjectivity and thus aid the corpus annotation.

Methods: We leveraged RoB 2 guidelines to develop visual instructional placards that serve as annotation guidelines for RoB spans and risk judgments. Expert annotators used these visual placards to annotate a dataset named RoBuster, consisting of 41 full-text RCTs from the domains of physiotherapy and rehabilitation. We report interannotator agreement (IAA) between 2 annotators for text span annotations before and after applying visual instructions on a subset (n=9) of RoBuster. We also provide IAA on bias risk judgments using Cohen κ. Moreover, we used a portion of RoBuster (n=10) to evaluate an LLM using a straightforward evaluation framework. This evaluation aimed to gauge the performance of an LLM (here GPT 3.5) in the challenging task of RoB span extraction and demonstrate the utility of this corpus using a straightforward framework.

Results: We present a corpus of 41 RCTs with fine-grained text span annotations comprising more than 28,427 tokens belonging to 22 RoB classes. The IAA at the text span level calculated using the F1 measure varies from 0% to 90%, while Cohen κ for risk judgments ranges between –0.235 and 1.0. Using visual instructions for annotation increases the IAA by more than 17 percentage points. LLM (GPT-3.5) shows promising but varied observed agreements with the expert annotation across the different bias questions.

Conclusions: Despite having comprehensive bias assessment guidelines and visual instructional placards, RoB annotation remains a complex task. Using visual placards for bias assessment and annotation enhances IAA compared to cases where visual placards are absent; however, text annotation remains challenging for the subjective questions and the questions for which annotation data are unavailable in RCTs. Similarly, while GPT-3.5 demonstrates effectiveness, its accuracy diminishes with more subjective RoB questions and low information availability.

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KEYWORDS

risk of bias; corpus annotation; natural language processing; large language models; LLM; information extraction; RoBuster; corpus; randomized controlled trials; RCT; reviewer; tools; physiotherapy; rehabilitation; effectiveness

Introduction

Systematic reviews (SRs) synthesized using randomized controlled trials (RCTs) are the highest quality of evidence in the evidence pyramid. SRs help medical professionals make informed health decisions and guide health policies [1,2]. An RCT tests an intervention's effectiveness by randomly assigning patients to intervention groups; for example, the impact of the intervention under investigation is compared to other interventions in a controlled setting [3]. Theoretically, RCTs are low on biases given the randomized design, but biases can still infiltrate the design, execution, or reporting phases. Such biases may cause medical professionals to misjudge intervention effects, impacting health outcomes [4,5]. Therefore, bias assessment, known as risk-of-bias (RoB) assessment, is vital for RCTs used for writing SRs.

There are several tools to assess RoB, including the Cochrane Collaboration's RoB Tool, PEDro RoB scale, revised Cochrane RoB 2 tool, AMSTAR (A Measurement Tool to Assess Systematic Reviews) or AMSTAR 2, EPOC (Effective Practice and Organization of Care) RoB Tool, and other checklists [6-11]. These tools provide structured questions to elicit bias-relevant information from RCTs. Manual RoB assessment, a time-consuming task requiring substantial expertise, can take hours per RCT and months for a full SR, emphasizing the need for automation [12,13]. Moreover, writing SRs is highly resource-heavy, taking about 6 months to several years to complete [6,14,15]. Machine learning (ML) could expedite this process by pinpointing bias-relevant RCT text, aiding quicker quality assessments [16]. Marshall et al [17] attempted automation of RoB assessment using a distant supervision approach supported by proprietary data from CDSR. The study was supported by the manually entered data from CDSR, which is behind a paywall and automates based on Cochrane RoB 1 guidelines and not the latest RoB 2 [7]. Although RoB 1 is most frequently used for assessment, the recently revised Cochrane RoB 2 offers significant differences [18]. Compared to RoB 1, RoB 2 provides a reliable and concrete structure to the RoB evaluation by developing comprehensive guidelines that aim to increase consistency [7,11]. The use of RoB 2 increased from 0% in 2019 to 24.1% in 2022, indicating the need to switch to this updated tool for bias assessment [19].

Millard et al [20] also explored ML-based RoB assessment using proprietary data. Their work using these pay-walled data was used to develop RobotReviewer, which has been evaluated by several studies for its human-level performance [17,21-24]. A lack of public RoB-annotated data still limits community advancements. Wang et al [25] recently released RoB datasets for animal studies, but human clinical trials still lack a comprehensive RoB corpus. Manual RoB assessment is a complex, expert-led task laden with subjective judgments [26,27]. Systematically translating this manual process for developing a RoB annotated corpus requires a carefully designed annotation scheme and annotation guidelines. We previously worked on a pilot study to test whether RoB 2 guidelines could be effectively used as annotation guidelines to annotate a corpus of RCTs with RoB. We concluded that RoB 2 cannot be used as text annotation guidelines but did not provide any annotation guidelines [28]. Here, we aim to establish clear annotation guidelines to annotate RCTs with RoB spans corresponding to the RoB 2 tool [11].

In addition, recent large language models (LLMs) have shown potential in handling complex tasks with minimal instructions [29]. However, their capability to identify RoB spans in RCTs has yet to be assessed. Our contributions with this paper are 5-fold as follows:

1. Development of detailed annotation guidelines for RCT RoB spans.
2. Development of visual placards to simplify annotation and assist trainee RoB assessors.
3. Compilation of "RoBuster," a corpus of 41 annotated RCTs with 22 RoB span types, for ML and LLM training or benchmarking.
4. Evaluation of an LLM in identifying answers to signaling questions using prompts.
5. Open sharing of annotation guidelines, dataset, and LLM prompts with the community.

Methods

Overview

This section details the annotation scheme, software, and visual placard development. With no existing RoB span annotation guidelines, we created them from scratch based on the revised Cochrane RoB 2 tool [6]. We created a draft of the visual guidelines, doubly annotating a fraction of RCTs using it, and refined the guidelines using identified conflicts. Figure 1 illustrates our methodology starting from data collection.

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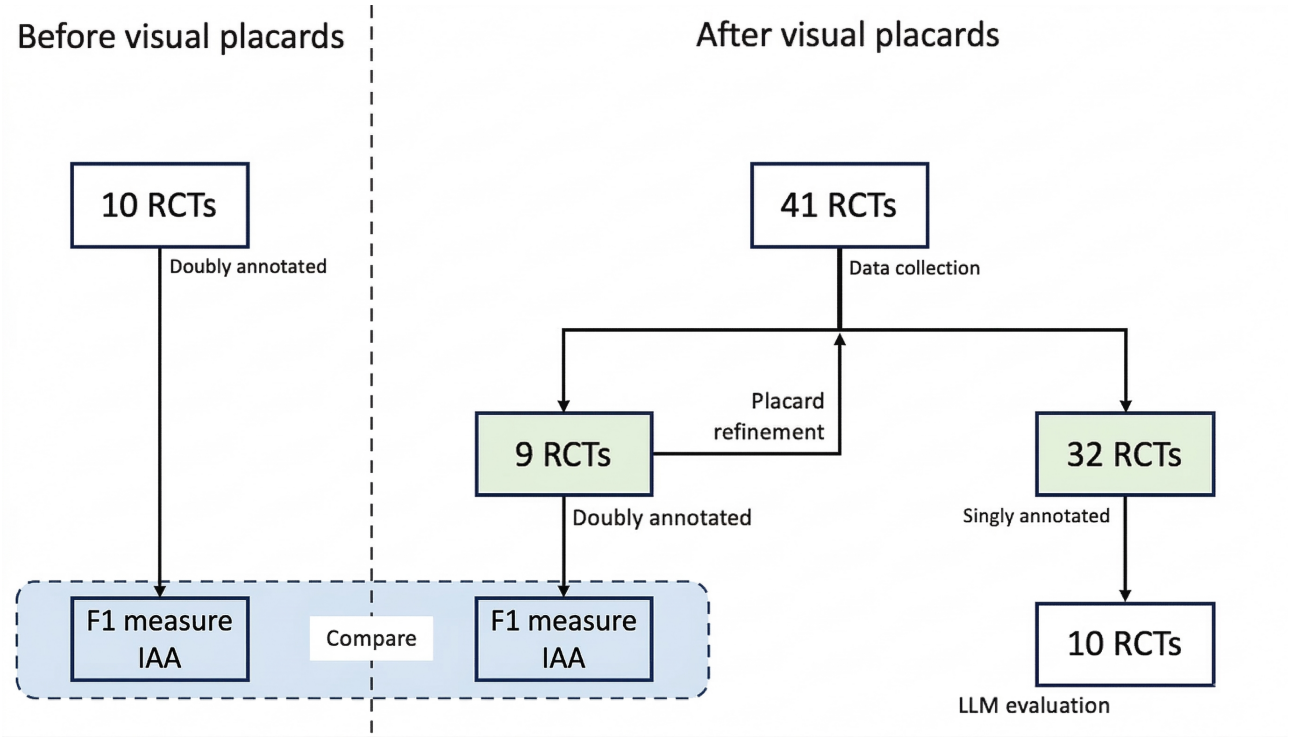
Figure 1. The flowchart (right) illustrates our methodology starting from data collection until interannotator agreement (IAA) calculation. The agreement is calculated between 10 RCTs annotated (left) in Dhrangadhariya et al [28] and 9 RCTs from the current work. LLM: large language model; RCT: randomized controlled trial



Expert Team

RoB annotation requires specialized expertise due to the need to thoroughly review the entire RCT text to identify 22 different bias categories. Our annotation team comprised 2 experts in RoB assessment in the physiotherapy and rehabilitation domains: an epidemiology researcher (RH) and an associate professor in physiotherapy (KMS), both with extensive experience in physiotherapy, statistical methods, and SRs. Two senior PhD students (KG and RC) contributed to the development of the visual annotation guidelines. Two researchers in natural language processing, an associate professor in computational linguistics (NN) and a PhD student in computer science (AKD), assisted in creating the visual guidelines, which serve as a benchmark for RoB text span extraction. Finally, JPTH provided feedback to shape the visual annotation guidelines (Multimedia Appendix 1).

Ethical Considerations

In accordance with the Swiss Federal Act on Research involving Human Beings (Human Research Act) of September 30, 2011 (SR 810.30), formal ethical approval by a Cantonal Ethics Committee was not required as the research did not concern human diseases or the structure and function of the human body. The experts who undertook the visual placards development and the annotation process for this corpus were informed about the purpose of the annotation project and agreed to voluntarily participate in the study. Even though they agreed to participate in the study, they can withdraw their participation at any time without consequences of any kind. They were informed of the purpose and nature of the study via a presentation and had an opportunity to ask questions. They were also fully informed about the eventual publication of the findings. Each expert provided consent for the publication of the annotated corpus, along with the understanding that any identifying information would be appropriately anonymized to protect their privacy. The expert annotators volunteered their time and received no financial compensation.

Annotation Scheme

Creating a new annotated corpus requires defining or adopting an annotation scheme. To our knowledge, the only existing RoB span annotation scheme is from our previous work [28]. Rather than developing a new one, we adapted and enhanced this scheme, addressing prior limitations. The scheme aligns with the RoB 2 assessment, which organizes bias into 5 domains reflecting different trial design aspects. Each risk domain decomposes into several signaling questions totaling 22 (Table 1). Each question prompts the assessor to look for relevant text evidence in the trial and judge risk response for that signaling question (SQ; Table 2). For detailed explanations of the SQs, see Cochrane RoB 2.0 guidelines as the original document and Multimedia Appendix 1 [6].

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Table . The table lists signaling questions from each bias domain from the revised Cochrane Risk of Bias (RoB) tool.

Question number	Signaling question
RoB 1	
RoB 1.1	Was the allocation sequence random?
RoB 1.2	Was the allocation sequence concealed until participants were enrolled and assigned to interventions?
RoB 1.3	Did baseline differences between intervention groups suggest a problem with the randomization process?
RoB 2	
RoB 2.1	Were participants aware of their assigned intervention during the trial?
RoB 2.2	Were carers and people delivering the interventions aware of participants' assigned intervention during the trial?
RoB 2.3	Were there deviations from the intended intervention that arose because of the trial context?
RoB 2.4	Were these deviations likely to have affected the outcome?
RoB 2.5	Were these deviations from the intended intervention balanced between groups?
RoB 2.6	Was an appropriate analysis used to estimate the effect of assignment to intervention?
RoB 2.7	Was there potential for a substantial impact (on the result) of the failure to analyze participants in the group to which they were randomized?
RoB 3	
RoB 3.1	Were data for this outcome available for all, or nearly all, participants randomized?
RoB 3.2	Is there evidence that the result was not biased by missing outcome data?
RoB 3.3	Could missingness in the outcome depend on its true value?
RoB 3.4	Is it likely that missingness in the outcome depended on its true value?
RoB 4	
RoB 4.1	Was the method of measurement of the outcome inappropriate?
RoB 4.2	Could measurement or ascertainment of the outcome have differed between intervention groups?
RoB 4.3	Were outcome assessors aware of the intervention received by study participants?
RoB 4.4	Could the assessment of the outcome have been influenced by knowledge of the intervention received?
RoB 4.5	Is it likely that the assessment of the outcome was influenced by knowledge of the intervention received?
RoB 5	
RoB 5.1	Were the data that produced this result analyzed in accordance with a prespecified analysis plan that was finalized before unblinded outcome data were available for analysis?
RoB 5.2	Is the numerical result being assessed likely to have been selected, on the basis of the results, from multiple eligible outcome measurements (eg, scales, definitions, time points) within the outcome domain?
RoB 5.3	Is the numerical result being assessed likely to have been selected, on the basis of the results, from multiple eligible analyses of the data?

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Table . The table lists bias domains from the revised Cochrane Risk of Bias (RoB) tool and the number of signaling questions (SQs) per domain.

Class	Domain	SQ
RoB 1	Biases arising from the *randomization process*	3
RoB 2	Biases due to *deviations from intended interventions*	7
RoB 3	Bias due to *missing outcome data*	4
RoB 4	Bias in the *measurement of the outcome*	5
RoB 5	Bias in the *selection of the reported result*	3

The response options for the RoB judgment include "Yes," "Probably yes," "No," "Probably no," or "No information." Reviewers assess each SQ by examining the factual evidence in the RCT. For example, the SQ "Was the allocation sequence random?" is assessed by checking the randomization method. A well-executed method results in a "Yes" response (low risk), while a poorly executed method leads to a "No" (high risk) [11].

For RoB span annotation, we mimic the assessment process by considering evidence text spans in the RCT as the main units of annotation. Each span corresponds to an answer for a specific SQ and is annotated with a label. Multiple spans (sentence and paragraph) across the RCT can be annotated to answer a single SQ if needed. The annotation label incorporates information about the SQ number and its domain (for the above example, "1.1" for the first domain and first SQ of the domain). The response option for risk judgment is incorporated in the label, such as "1.1 Yes Good" for a well-executed randomization procedure and "1.1 No Bad" otherwise (Figure 2). To improve interannotator agreement (IAA), we collapse "Yes" and "Probably Yes" to a single "Yes," and similarly for "No" and "Probably No" [28]. As shown in Figure 3, these collapsed responses do not affect the final risk judgment for a domain (low, high, or some concerns). Therefore, except for some special case SQs, we collapse these response options in this work. Our scheme includes 22 entities for the 22 SQs, each with 2 response options ("Yes" or "No") and 2 risk judgments ("Good" or "Bad"); "Good" implies low risk and "Bad" implies high risk. The "No Information" option is removed unless there's truly no text evidence, though it remains for specific SQs like SQ 2.1. For instance, if a trial describes a "random number generator and sealed envelopes" but lacks details on envelope opacity, "No Information" is considered an appropriate label.

Figure 2. Algorithm for suggested judgment of risk of bias (RoB) arising from the randomization process. The figure is recreated from the revised Cochrane RoB 2 tool (RoB 2) [6].

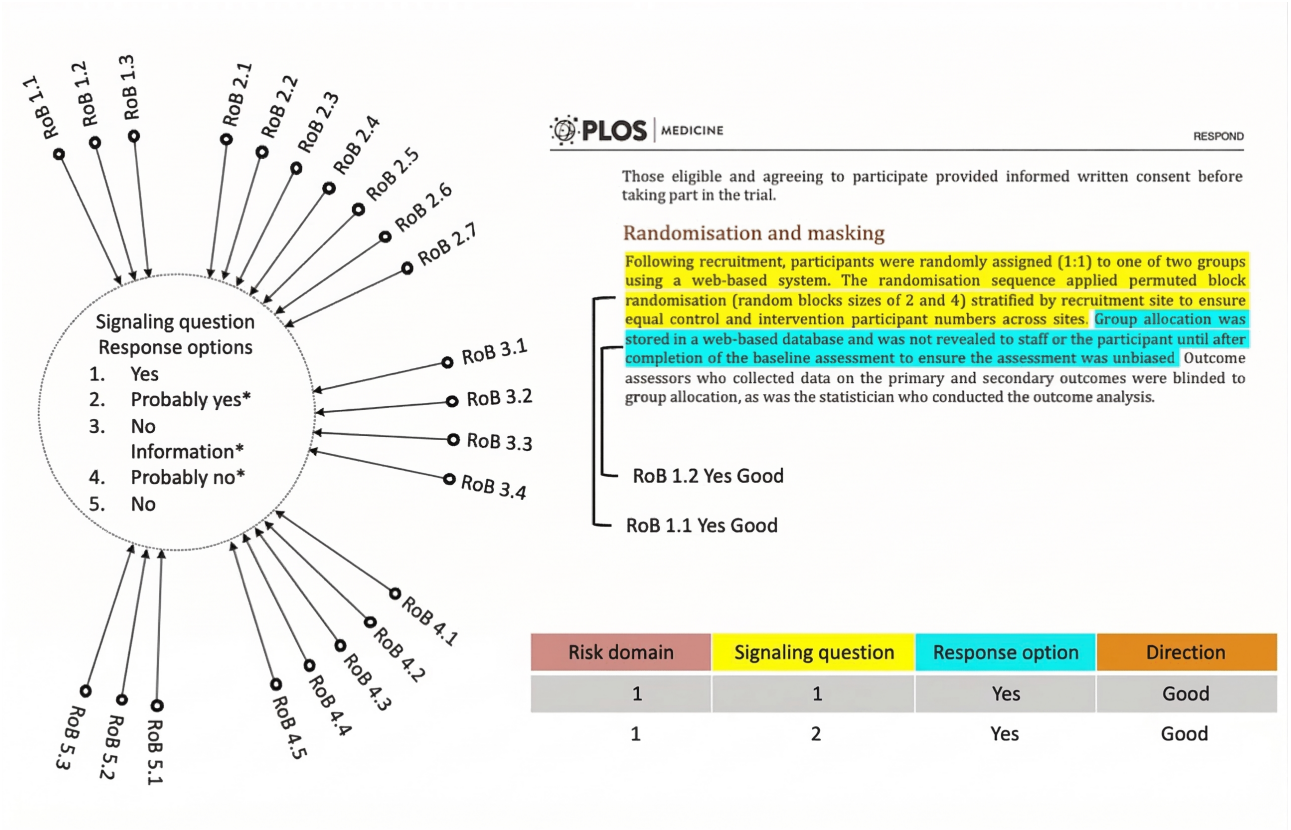

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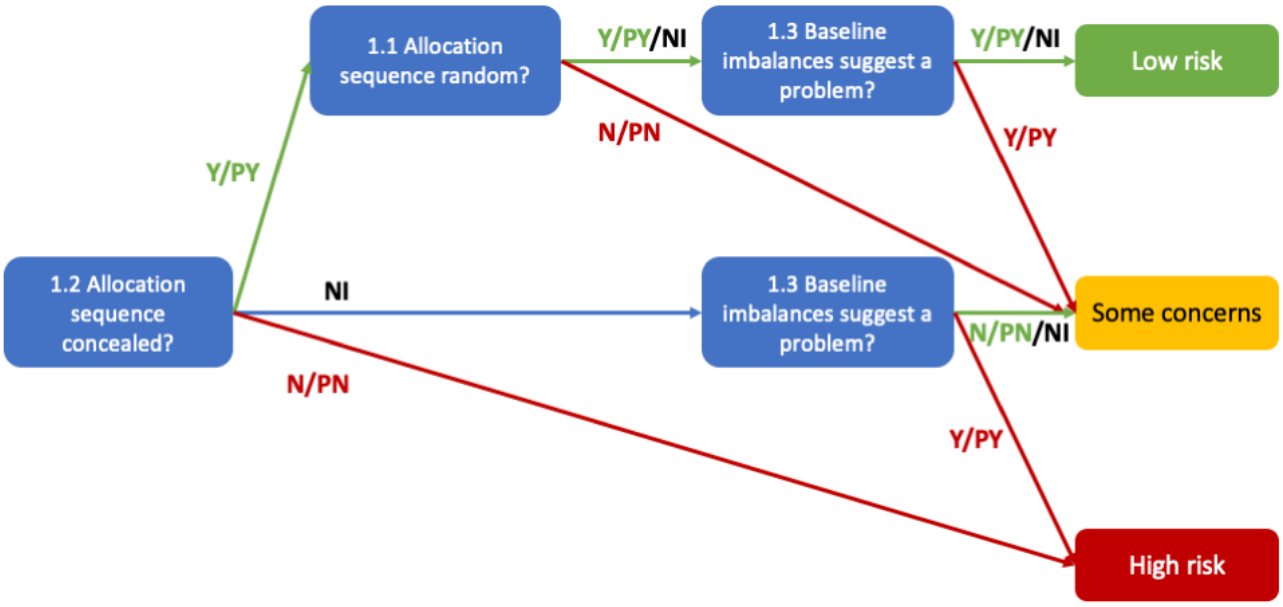
Figure 3. Algorithm for suggested judgment of risk of bias arising from the randomization process. The figure is recreated from the revised Cochrane Risk of Bias 2 tool. N: no; NI: no information; PN: probably no; PY: probably yes; Y: yes [6].



Data Collection

A dataset of 41 RCTs from the physiotherapy and rehabilitation domains was compiled by RH. The RCTs included in the corpus were carefully curated from a selection of high-quality journals in physiotherapy and rehabilitation, as recommended by our institute's librarian (eg, PLoS). To ensure consistency with modern reporting practices, we included only RCTs published after 2010. To facilitate open sharing and publication of the annotated corpus, we included only articles available under the CC-BY-0 license. Additional details are provided in Multimedia Appendix 1.

To create this corpus, PDFs of full-text RCTs were extracted, and each article was paired with its trial registry whenever available. Each PDF was renamed with the primary outcome to be assessed using the RoB 2 tool before being uploaded to the annotation software. To ensure that various primary outcome types were represented in the corpus, we included 17, 17, and 7 RCTs addressing objective, subjective, and mortality primary outcomes, respectively, following the rationale that RoB assessment results are related to the outcomes [30-33]. The rationale behind this is described in Multimedia Appendix 1.

Visual Placards Development

Although RoB 2 guidelines are widely used for bias assessment, there has been some research on their reliability. Minozzi et al [26,34] addressed this issue by creating an ID that reduces subjectivity in the RoB 2 guidelines, providing clearer instructions for assessment. Before implementing the ID, the agreement among 4 expert RoB assessors in the Minozzi et al's [26,34] study was zero, but it improved after adopting the ID. Several other papers explored the subjectivity and reliability of Cochrane RoB 1 and 2 tools [35,36]. To enhance consistency and reliability, we developed precise annotation instructions using the RoB 2 tool and collaborated with experts to format these into visual placards. Each placard, structured as a flowchart, guides annotators in answering SQs and labeling text with risk judgments. While RoB 2 SQs are mainly factual, they allow for subjective judgments, which the placards help standardize.

Annotation

The annotation process for the 41 RCTs (see "Data Collection" section) began after developing visual placards. Annotators used the complete RoB 2 guidance alongside these placards, following instructions closely for each SQ. For each SQ, the placards guided annotators to relevant sections within the RCTs, to identify and highlight pertinent text to answer each question, selecting labels as defined in the annotation scheme. Domain 2 of RoB 2 was assessed with respect to the effect of assignment to the intervention (intention-to-treat estimand). Signaling questions related to the "effect of adhering to the intervention" were not annotated.

The annotation was done in Tagtog (tagtog Sp. z o.o.), a commercial PDF annotation tool [37]. Of the 41 RCTs, 9 were doubly annotated by RH and KMS to calculate IAA, with the remaining (n=32) singly annotated by RH. Conflict resolution on the doubly annotated RCTs helped refine the visual placards before annotating the rest. After annotating the 9 RCTs, we transitioned to the PAWLS (PDF Annotation With Labels and Structure) annotation tool (Allen Institute for Artificial Intelligence; Figure 4), a free PDF annotation platform [38]. Annotating PDFs preserves the structure of sections, tables, and figures, improving annotation speed and quality and ease of annotation for our experts who volunteered for annotation. Feedback from them is detailed in Multimedia Appendix 2.

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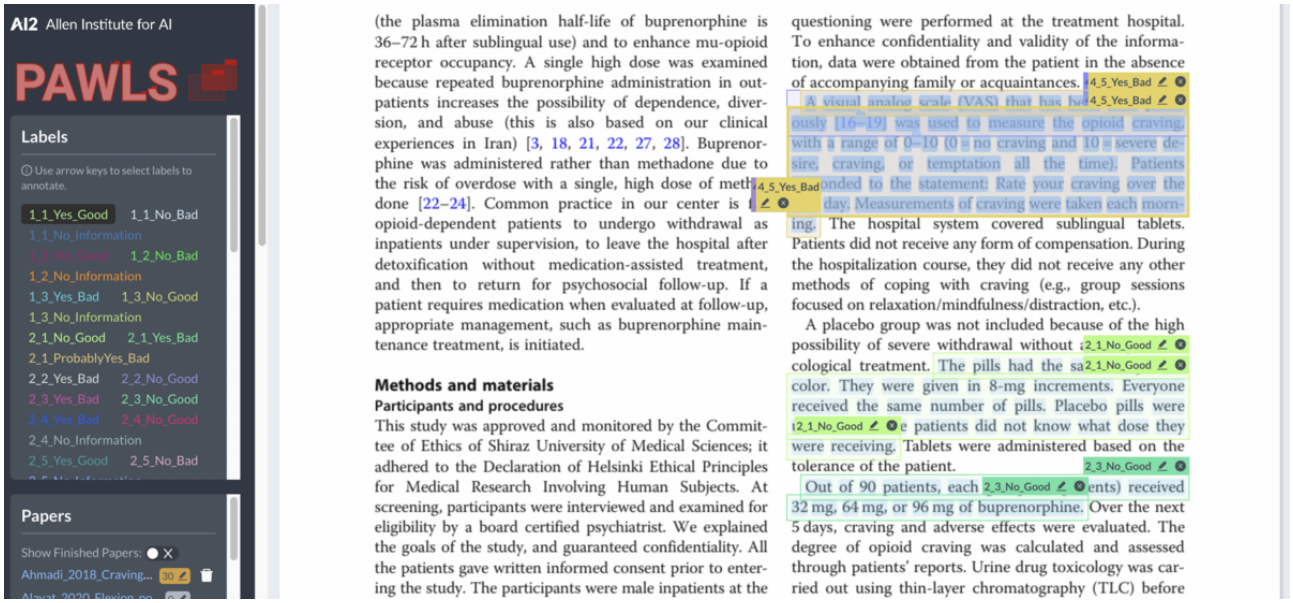
Figure 4. A screenshot of PAWLS (PDF Annotation With Labels and Structure; Allen Institute for Artificial Intelligence) interface with an example PDF and risk of bias (RoB) annotations.



IAA Measure

We report IAA on the doubly annotated RCTs. The IAA was calculated at 2 levels, assessing annotator agreement on text spans for SQs using pairwise F1, which excludes unannotated tokens and is well-suited for token-level annotation tasks. Pairwise F1 is measured as shown below for each pair of annotators by treating one annotator's labels as "true" and the other's as "predicted" [39,40]. In this study, IAA was measured after incorporating visual placards into the annotation process. To evaluate the impact of these placards on annotation quality, we also compare the F1 IAA with results from our previous work, where n=10 RCTs were annotated without the use of placards (Figure 1).

$$F1\text{-}measure = \frac{2 \times True\ Positive}{2 \times True\ Positive + False\ Positive + False\ Negative}$$

We also check annotator agreement on risk judgments for each SQ using prevalence and bias-adjusted κ (PABAK) and observed percent agreement. PABAK (κ_{PABAK}), an extension of Cohen κ that accounts for prevalence and bias, is commonly used for classification tasks and is ideal for evaluating reliability at the risk judgment level. Interpretation guidelines for both IAA measures are shown in Table 3 [41-44].

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Table . Interpretation of pairwise F1-measure, κ_{PABAK}, and observed agreement.

Metric	Value
Pairwise F1	
Poor	0 - 0.99
Slight	1 - 20.99
Fair	21 - 40.99
Good	41 - 60.99
Substantial	61 - 80.99
Almost perfect	81 - 99.99
Perfect	100
κ_{PABAK}	
No agreement	≤0
None to slight	0.0-0.20
Minimal	0.21 - 0.39
Weak	0.40 - 0.59
Moderate	0.60 - 0.79
Strong	0.80 - 0.90
Almost perfect	≥0.90
Perfect	100
Observed agreement	
None	0%
Very low	1% - 10%
Low	11% - 30%
Moderate	31% - 50%
High	51% - 70%
Very high	71% - 90%
Perfect	>90%

LLM Evaluation

Our annotation guidelines were initially adapted for benchmarking traditional ML approaches rather than LLMs. This meant we restricted certain annotations, assuming the PDFs would be converted into text via optical character recognition, thus losing table and figure structures that classical ML models cannot interpret without significant adjustments [45,46]. Recent advancements with LLMs have offered a better alternative and have made us rethink the evaluation. The bar for clinical applications is high, and it is necessary to evaluate LLMs for the challenging clinical tasks like RoB span extraction [47]. ChatPDF allows direct interaction between LLMs and PDFs, negating the clumsy PDF-to-text conversion [48]. Therefore, we consider it essential to evaluate LLMs instead of forcefully adapting the evaluation to a classical ML problem.

We formulated the task as a zero-shot RoB text span extraction task with an aim to gauge whether an LLM encodes knowledge related to assessing trial biases. We used simple prompt constructs of the structure “Answer the {*SQ*} + Action item to extract sentence supporting the answer” (Textbox 1). ChatPDF used these prompts to identify relevant paragraphs and generate answers to the SQs using GPT-3.5, mirroring the annotators’ task.

Textbox 1. Example prompt used for large language model evaluation.

Question 4.3: Were outcome assessors aware of the intervention received by study participants? Provide an answer and extract the supporting sentences that you write your answer based on. Extract the sentences in JSON format.

LLM performance was measured by agreement on response options and extracted text span or evidence. If the LLM’s response matched the expert annotator’s selection, it was considered correct. If the text extracted by LLMs as evidence for answering the SQ fuzzy matches the text selected by the expert annotator, it is considered a correct answer. Both skills were evaluated using observed agreement metrics, POExtraction for measuring agreement over extraction and POResponsefor

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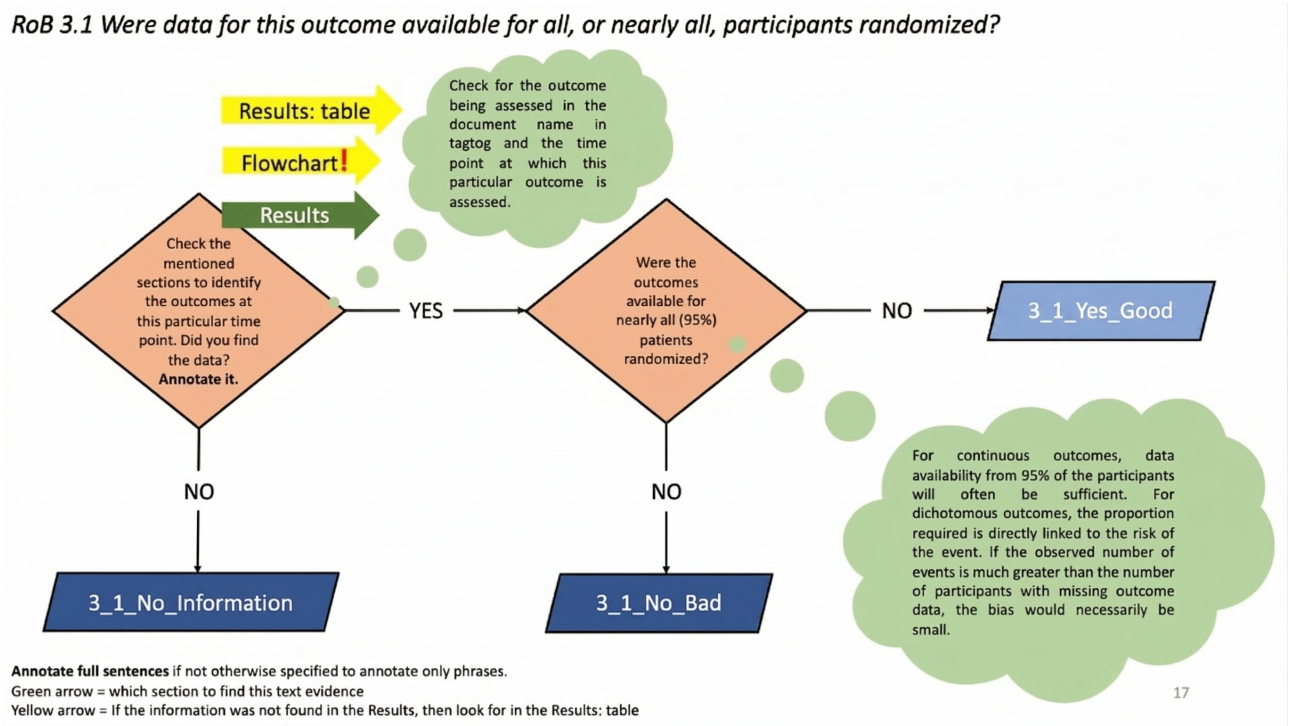
measuring agreement over response judgments and interpreted as per Table 3. Observed agreement is essentially the number of documents for an RoB SQ where LLM responses align with those of the human expert, divided by the total number of documents assessed [49]. For cases where annotators found no information in RCT, ChatPDF's ability to recognize this absence was also evaluated. We set the temperature to 0 to ensure a deterministic setting for span extraction and response generation. This ensures exact text spans are extracted from the input RCT. This evaluation was done manually for 10 out of the 41 annotated RCTs. Details of the RCTs used for LLM evaluation are in Multimedia Appendix 1.

Results

Visual Placards

A total of 27 placards were developed to address the 22 SQs. Details of the annotation guidelines and visual placards are available in Multimedia Appendices 1 and 3. Figure 5 shows an example placard for annotating SQ 3.1 ("Were data for this outcome available for all, or nearly all participants randomized?"), which assesses the completeness of outcome data in an RCT. Missing outcomes data can compromise statistical power and treatment effect estimates. The first diamond on the placard instructs annotators to check the "Results" section (priority indicated by green arrow) and the flowchart and table within the "Results" section (second priority) to identify outcome data at the specified time point. If outcomes data were available for at least 95% of participants, annotators mark relevant text descriptions as "3.1 Yes Good," indicating a low bias. If data were available for fewer than 95%, they mark it as "3.1 No Bad," indicating a high bias. The placard includes visual cues to guide the annotation process efficiently.

Figure 5. Sample annotation instruction placard for the signaling question (SQ) 3.1 designed and adapted using the Cochrane Risk of Bias (RoB) 2 tool [6].



The Corpus: RoBuster

Figure 6 shows that SQ 1.3 had a much higher number of annotated tokens (n=16,446), compared to fewer than 2600 tokens for other SQs. This is because SQ 1.3 required annotating the entire baseline patient characteristics table, as instructed by the visual placards. For other questions, the number of annotated tokens depended on the amount of detail provided on study design, methods, and results, which affected both annotation count and assessment subjectivity. Most other SQs had fewer than 2000 annotated tokens, with SQ 3.1 slightly exceeding this threshold. SQ 2.4 had the fewest tokens, with only 25 tokens.

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Figure 6. Total number of token annotations in RoBuster for each risk of bias (RoB) signaling question (SQ).

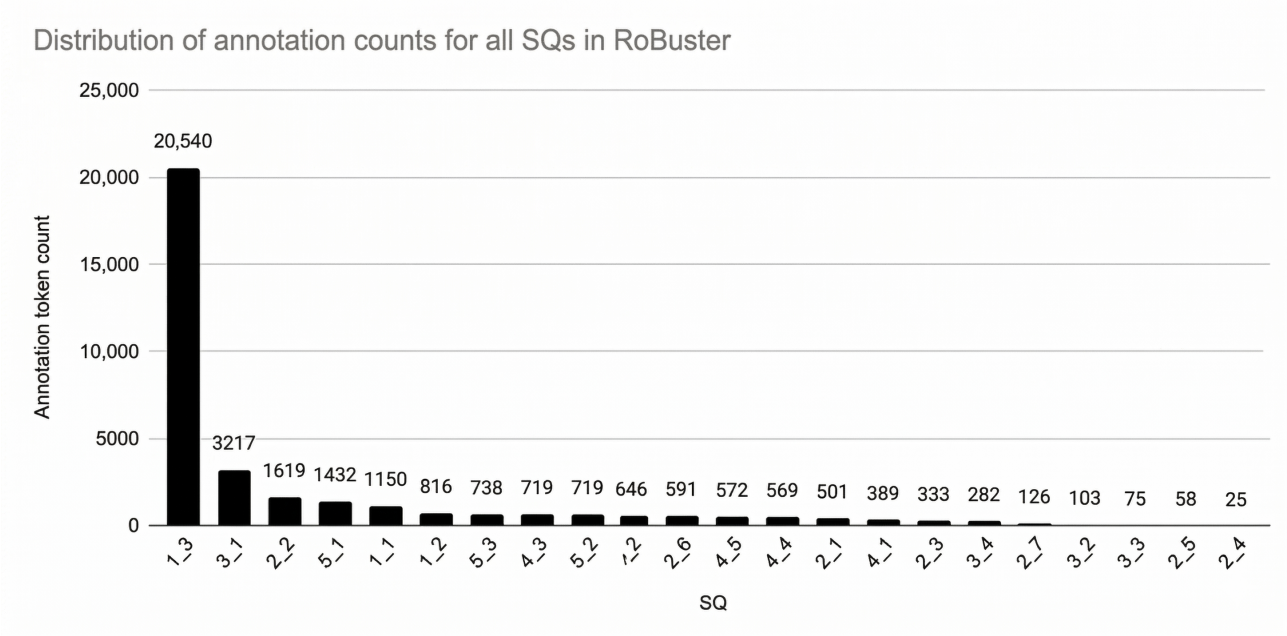
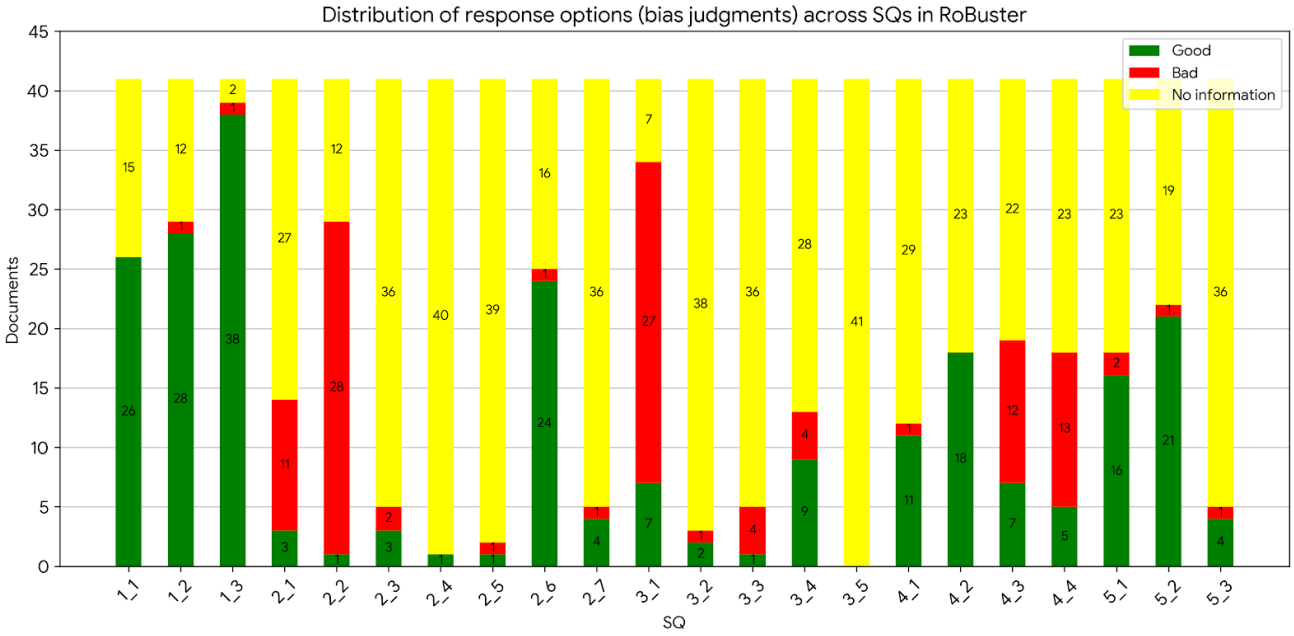


Figure 7, which shows the distribution of risk judgments across RoBuster, highlights that, for most SQs, no information was available (yellow bars) for answering the SQs. Exceptions included SQs 1.1, 1.2, 1.3, 2.2, 2.6, 3.1, 4.3, 4.4, and 5.2, where over 50% of documents had relevant information. In cases where even some information was available, bias tended to be low (green bar) with an exception for the SQs 2.1, 2.2, 3.1, 4.3, and 4.4, where bias was high (red bar). Studies with comprehensive information made evaluation easier, whereas those lacking key details made it challenging. Annotator feedback indicated that questions with fewer than 100 annotated tokens were consistently rated as "(very) low" information availability, whereas the top 5 SQs shown in Figure 6 were rated as "high" or "normal" availability. All study references are listed in Multimedia Appendix 1.

Figure 7. Distribution of bias judgment across risk of bias (RoB) signaling questions (SQs) in RoBuster.



IAA Measure

Table 4 presents the F1-measure (IAA) between 2 annotators, both before and after the development of the visual placards. The F1-measures before and after the guideline improvement were calculated on a different set of documents. To reiterate, the F1 IAA results before the visual placard development were drawn from our previous work, where 10 RCTs were annotated in the absence of the placards [28]. Initially, the average agreement across the corpus was 10.87%, which rose by 17.14% points to reach 28.01% with placard use. For the "randomization" domain, agreement improved from a low 31.72% to 63.30%. In the "deviations from intended interventions" domain, it increased from 12.76% to 27.02%. Agreement in the "missing outcomes" domain rose from 5.89% to 9.92%, while "missing outcome measurement" increased

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from 4.07% to 17.29%. For "selection of reported results," agreement increased from 0% to 16.49%.

Table . The table displays the F1-measure at the text span annotation level before and after visual placard development, with changes in absolute interannotator agreement (IAA) points.

Domain and SQ[a]	F1-measure IAA		Change
	Before guideline improvement	After guidelines improvement	
Domain 1			
RoB[b] 1.1	24.44	55.02	+30.58
RoB 1.2	50.28	44	–6.28
RoB 1.3	20.44	90.9	+70.46
Domain 2			
RoB 2.1	1.34	67.26	+65.92
RoB 2.2	7.23	38.66	+31.43
RoB 2.3	5.42	0	–5.42
RoB 2.4	—[c]	0	0
RoB 2.5	0	0	0
RoB 2.6	68.85	83.25	+14.4
RoB 2.7	6.52	0	–6.52
Domain 3			
RoB 3.1	23.57	39.68	+16.11
RoB 3.2	0	0	0
RoB 3.3	0	0	0
RoB 3.4	0	0	0
Domain 4			
RoB 4.1	6.51	61.71	+55.2
RoB 4.2	0	0	0
RoB 4.3	13.85	30.21	+16.36
RoB 4.4	0	56.25	+56.25
RoB 4.5	0	0	0
Domain 5			
RoB 5.1	0	0	0
RoB 5.2	0	49.49	+49.49
RoB 5.3	0	0	0

[a]SQ: signaling question.

[b]RoB: risk of bias.

[c]Dash (—) indicates that one of the annotators did not annotate any text for a particular SQ.

Substantial gains of over 50% points were seen in SQs 1.3, 2.1, 4.1, and 4.4. However, for 11 out of 22 questions, agreement remained at zero, and for nine of these, the lack of agreement persisted postguideline update. In contrast, agreement improved for SQs 4.4 and 5.2 from 0% to 56.25% and 49.49%, respectively, while SQs 2.3, 2.7, and 1.2 saw slight agreement declines. Across the 22 SQs, 11 had poor agreement, 3 fair, 4 good, 2 substantial, and 2 near-perfect (>81%); none of the SQs achieved a perfect F1-measure.

Table 5 presents the κ_{PABAK} agreement, observed agreement, and the percentage of κ_{PABAK} agreements stemming from "No Information" judgments. κ_{PABAK} measures agreement at the SQ risk judgment level. Overall κ_{PABAK} between annotators shows weak IAA at 0.412. Agreement for "randomization" (domain 1) averaged a moderate 0.629, "deviations due to intended interventions" (domain 2) was 0.64, and "missing outcome data" (domain 3) was minimal at 0.388. Domains 4 ("outcome measurement") and 5 ("selection of reported result") had slight or no agreement at 0.166 and 0.092, respectively.

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Table . κ_{PABAK} and observed agreement between annotator pairs at the risk judgment level for each signaling question (SQ).

Domain and SQ	κ_{PABAK} agreement	Observed agreement (%)	Contribution from "No information" (%)
Domain 1			
RoB[a] 1.1	0.8333	88.90	22.22
RoB 1.2	0.5	66.70	33.33
RoB 1.3	0.5556	77.80	11.11
Domain 2			
RoB 2.1	0.7037	77.80	5.56
RoB 2.2	0.5	66.70	38.89
RoB 2.3	0.5	66.70	77.78
RoB 2.4	0.5556	77.80	88.89
RoB 2.5	0.6667	77.80	83.33
RoB 2.6	1	100	55.56
RoB 2.7	0.5556	77.80	77.78
Domain 3			
RoB 3.1	0.8333	88.90	11.11
RoB 3.2	—[b]	100	100
RoB 3.3	0	33.3	55.56
RoB 3.4	0.3333	55.60	33.33
Domain 4			
RoB 4.1	0.5556	77.80	11.11
RoB 4.2	–0.5556	22.20	38.89
RoB 4.3	0.6667	77.80	27.78
RoB 4.4	0.1667	44.40	22.22
RoB 4.5	0	33.30	66.67
Domain 5			
RoB 5.1	–0.5556	22.20	61.11
RoB 5.2	0.5	66.70	22.22
RoB 5.3	0.3333	55.60	72.22

[a]RoB: risk of bias.

[b]Dash (—) indicates that one of the annotators did not annotate any text for a particular SQ.

The highest agreement, 1.0, occurred for SQ 2.6, largely due to "No Information" judgments. No SQs showed almost perfect or strong agreement; moderate agreements (0.60 - 0.80) were observed for SQs 1.1, 2.1, 2.5, 3.1, and 4.3, with "No Information" judgments impacting only SQs 1.1, 2.1, 3.1, and 4.3. Two SQs (4.2 and 5.1) had agreements worse than chance, with one annotator marking no text in SQ 5.1, resulting in negative IAA, and both annotators marking different parts of the text in SQ 4.2. SQs 3.3 and 4.5 had zero κ_{PABAK} due to mutually exclusive document annotations, causing no consensus.

LLM Evaluation

Table 6 shows the observed agreement between the LLM and expert assessments for extracting and responding to SQs on a subset (n=10) of RoBuster. In domain 1, GPT-3.5 had high agreement with experts (66.6% for extraction and 55.3% for response judgment), with no reliance on "No Information" responses, indicating good information availability. For domain 2, observed agreements were 64.3% (extraction) and 60.0% (response), but 40% of these were "No Information" responses, showing lower reporting quality. Domain 3 had moderate agreement at 47.5% for both extraction and response, while domain 4 had lower agreement (28% for response and 26% for extraction). To enhance transparency, we have included both the LLM-generated responses (via ChatPDF) and the corresponding annotator responses as Multimedia Appendix 4.

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Table . Large language models (LLMs) evaluation—observed agreements between LLM and experts over a subset of RoBuster.

Domain and SQ[a]	P_O(extraction; %)	P_O (response; %)	Contribution from "No information" (%)
Domain 1			
RoB[b] 1.1	90	70	0
RoB 1.2	70	60	0
RoB 1.3	40	30	0
Domain 2			
RoB 2.1	50	40	0
RoB 2.2	30	30	10
RoB 2.3	60	60	50
RoB 2.4	90	90	100
RoB 2.5	90	90	100
RoB 2.6	80	50	10
RoB 2.7	50	60	40
Domain 3			
RoB 3.1	30	40	0
RoB 3.2	60	40	40
RoB 3.3	30	30	30
RoB 3.4	70	80	70
Domain 4			
RoB 4.1	40	30	10
RoB 4.2	40	30	20
RoB 4.3	10	10	10
RoB 4.4	10	20	10
RoB 4.5	40	40	40
Domain 5[c]			
RoB 5.1	22.22	77.77	0
RoB 5.2	33.33	44.44	33.33
RoB 5.3	55.55	55.55	44.44

[a]SQ: signaling question.

[b]RoB: risk of bias.

[c]The LLM evaluation for domain 5 was conducted on 9 randomized controlled trials (RCTs), as one lacked a trial registry.

Discussion

Visual Placards

According to a study by Dhrangadhariyaet et al [28], 2 factors contributed to low F1 IAA in annotating text spans for SQs: a lack of guidance on annotation granularity and inconsistent annotation locations. Some annotators marked entire paragraphs, while others selected only the most informative text. Our placards address this by specifying whether to annotate a phrase, sentence, or sentences. Additionally, annotators often drew evidence from different parts of the text for the same SQ, lowering agreement. Our placards now restrict annotations for certain SQs to specific sections, such as "Methods," "Results," or "Flowcharts." Flowcharts and tables are designated as the lowest priority for all SQs except 1.3 due to ML models' difficulty in interpreting them. For example, although SQ 3.1 information appears in the flowchart, annotators are directed to the "Results" section, which better supports ML training.

The visual placards aimed to reduce RoB 2 subjectivity, particularly for SQs with insufficient information for risk judgment annotation. For example, in one trial, both annotators selected "71 allocated routine services, 67 allocated intervention service, 69 assessed at 8 weeks, 64 assessed at 8 weeks" from the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) flowchart to answer SQ 3.1 [50], but one responded "Yes" while the other chose "No." This question asks if outcome data were available for nearly all randomized participants but lacks a clear threshold. To standardize

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responses, we introduced a 95% threshold in the placard (Figure 5).

IAA Measure

Text-Span Agreement

F1 agreement at the text span level improved for 10 of the 22 SQs after implementing visual placards. The agreement increased as placards clarified whether to annotate a phrase, sentence, paragraph, or entire table. SQ 1.3 saw the largest increase (70.46 percentage points) due to instructions to mark the entire patient characteristics table. Previously, annotators only marked portions, leading to variability based on what they noticed first. For SQ 1.1, F1 improved by 30 points with instructions to prioritize marking comprehensive information on the randomization method in the Methods section, which offers a detailed description. Previously, annotators marked evidence variably, only including "randomized controlled trial" phrases without checking the randomization method. Placards clarified that "Yes Good" required detailed evidence of randomization. Similarly, SQs 2.1 and 2.2 saw increased IAA due to clear guidance on marking both intervention and placebo descriptions, resolving prior inconsistencies where only one of the two was marked.

While the agreement drastically increased for certain SQs, it remained at 0 for some SQs (2.3, 2.4, 2.5, 2.7, 3.2, 3.3, 3.4, 4.2, 4.5, 5.1, and 5.3), aligning with feedback on these SQs, which indicated high subjectivity, difficulty, and limited information. This suggests that subjectivity and data scarcity in RCTs challenge consistent annotation.

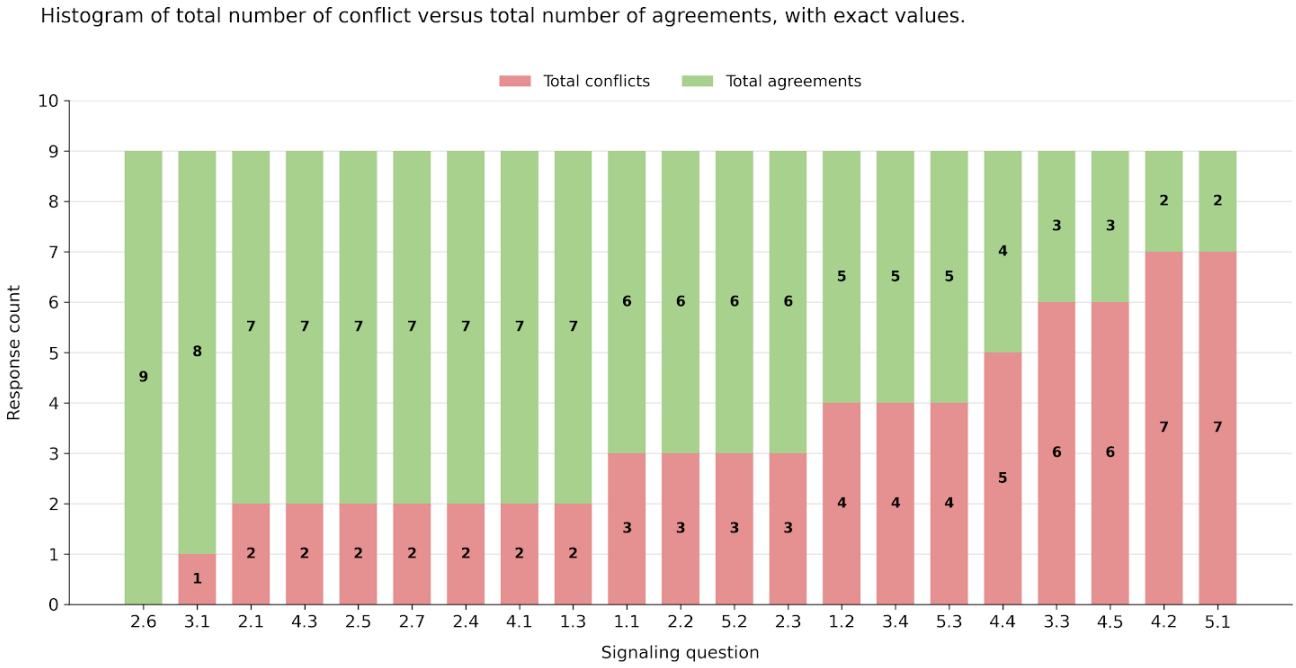
Response Option Agreement

Disagreements in response judgments stemmed from 2 main issues. Most disagreements (82.85%) occurred when one annotator provided a response while the other marked "No Information" due to no annotation. Agreements were also split between cases where both annotators labeled a text span similarly and cases where neither annotated, defaulting to "No Information." Therefore, a considerable chunk of both agreements and disagreements came from "No Information." This highlights the impact of "No Information" judgments, emphasizing the potential benefit of using high-quality journals to reduce these instances and improve annotation comprehensiveness.

SQs (1.1, 2.1, 2.5, 2.6, 3.1, and 4.3) with adequate agreement (>0.60 κ_{PABAK}) showed fewer "No Information" judgments, aligning with feedback that these questions had "normal" or "very high" information availability and low subjectivity. In contrast, SQs with low or negative agreement had more disagreements, leading to lower κ_{PABAK} scores.

Negative κ are unlikely to occur in practice, but two SQs (4.2 and 5.1) had negative κ_{PABAK} values due to frequent disagreements (in 7 of 9 documents), indicating strong disagreement among raters. The reason for the lower κ_{PABAK} for these questions was disagreements over 7 of the 9 annotated documents, which were the highest number of disagreements in the subset RCTs used for κ calculation (Figure 8). To note that these agreements came from "No Information" judgments. Though the κ_{PABAK} values for these SQs are considerably smaller than –0.10. Such values (<–0.10) suggest that the collected data may not be meaningful for these questions [41].

Figure 8. The histogram of total number of conflicts and total number of agreements in the subset of randomized controlled trials (RCTs) used to calculate prevalence and bias adjusted κ.



Domain 5 had nearly zero agreement, likely due to the complexity of assessing it, which requires annotators to reference both the RCT and its trial registry and then summarize the information. Zero IAA also stems from theoretical questions like SQ 3.4, which evaluates whether missing outcome data is linked to true outcome values, and SQ 4.5, which assesses

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whether outcome assessment was influenced by knowledge of assigned intervention. These questions require hypothetical judgments rather than direct evidence, increasing subjectivity. Since these aspects are often not explicitly covered in trial documentation, annotators were instructed to mark outcome and outcome measurement descriptions to provide a foundation for judgments and ensure relevant annotations for evaluating LLM.

There were certain aspects where question subjectivity led to low agreement. For SQ 2.4, which asks if deviations from intended intervention might affect outcomes, responses are inherently subjective, as assessors may differ on what they consider impactful. Limited information on deviations further complicates accurate judgment. Only 2 of the 9 RCTs had SQ 2.4 annotations, and only 1 annotator marked them, resulting in no text span agreement. SQ 3.3 requires assessors to judge whether missing data are related to the true outcome, which can be challenging to determine objectively. Annotating evidence is further complicated by the need to link missing data reasons to outcome values, such as "fatigue" in physiotherapy studies. If, for example, patients missed follow-up due to fatigue, this connection should be annotated. However, RCTs rarely include this level of detail. Placards instead advised annotators to mark outcome descriptions to support judgment, but 1 annotator did not follow this guidance, leading to zero text span agreement. Such cases indicate a need for extended training, conflict resolution rounds, and placard improvement.

LLM Evaluation

Direct Versus Indirect Responses

LLM gave direct responses ("Yes," "No," or "No Information") for some questions and responded indirectly for others. For instance, in an RCT by Gleason et al [51], it directly answered SQ 1.1, stating, "Yes, the allocation sequence was random," and extracted relevant supporting text. However, for SQ 5.2, instead of stating "No information was present to make a judgment," the LLM extracted a candidate paragraph along with the following text: "However, the study authors did not provide information on whether the numerical result being assessed was selected based on the results from multiple eligible outcome measurements within the outcome domain." This response implied that it found "No Information" for SQ 5.2.

Domain-Specific Findings

The LLM performed well in extracting information on participant randomization and allocation concealment for SQs 1.1 and 1.2, resulting in good POExtraction agreement. However, it sometimes reached the correct response judgment, leading to a higher POResponse, without fully extracting the required evidence. In an RCT by Stuck et al [52], the LLM extracted an irrelevant passage to answer SQ 1.1 with "Yes Good" (low risk of randomization bias) even though the extracted sentence did not contain information about the randomization method. For SQ 1.3, lower agreement was observed between the expert and LLM, as the LLM often relied on text rather than tables, where critical data were found. Text in tables is read by ChatPDF, but it might have problems correlating the correct rows and columns, leading to a distorted understanding of the tables. For Stuck et al's [52] RCT, both the expert and LLM answered SQ 1.3 with "No Good," but the expert used a table as the evidence to answer the question, while the LLM used the text evidence not found in the table.

In domain 2, approximately 40% of POResponse agreement was due to "No Information," indicating a lack of information in RCTs for SQs 2.4 and 2.5. In an instance, LLM evaluation led to the identification of an incorrect label from the expert. To elaborate, for SQ 2.6 in Hassett et al's [53] study, the expert had annotated an incorrect part of the text to answer the question with "Yes Good." LLM correctly extracted information about the intention-to-treat analysis, which led to correcting the final annotation in RoBuster.

In domain 3, bias assessment subjectivity emerged. A lenient assessor will judge a risk of bias as low in comparison to a stringent assessor judging a bias risk as high for any SQ, but it is more pronounced in subjective SQs. In Thorndike et al's [54] RCT, both the LLM and the expert used the same evidence, "...104 (82%) were randomized in January 2011. Five residents withdrew during Phase 1, and 99 continued participation in Phase 2...," to answer SQ 3.1. However, the LLM rated it as "Yes Good," whereas the expert rated it as "No Bad," following a strict rule that any outcome data missing for over 5% of participants indicates high bias risk, regardless of other study details. For SQ 3.2 in RCTs [55,56], the LLM was more lenient than the experts, extracting information about the sensitivity analysis carried out by the study authors to account for missing outcome data. However, the RCT authors were not explicit that there was no bias due to missing outcomes data. For SQ 3.3, LLM judged "No Information" 9 out of 10 times. It questions whether the missingness in outcomes depended on its true value and is quite subjective because the assessor needs to contemplate the reasons for missingness for a particular outcome and whether the true value could have affected the missingness. For example, they need to assess whether the fact that data on falls is missing can be attributed to the actual occurrence of falls in the study.

The agreement was lower in domain 4, despite outcome measurement data being present, as it often extracted nontargeted outcomes due to simple prompts. The annotators assess bias pertaining to the predecided target outcome and not all the outcomes reported in the trial. However, the information about the target outcome being assessed was not available in the simple prompts used to test LLMs. Consequently, the LLMs extracted information that did not necessarily pertain to the target outcome but rather to other outcomes reported in the trial. Enhancing prompt specificity, potentially with chain-of-thought or tree-of-thought styles, could improve the LLM's performance in RoB assessment [57].

In sum, while the LLM shows potential for automating RoB span extraction, further optimization is needed for handling subjective SQs, lack of information, and tailoring prompts to specific bias contexts.

Limitations

The scale of our annotations is limited to 41 RCTs due to financial constraints, which restricted our ability to hire expert annotators. Furthermore, we acknowledge that performing

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double-coding on a subset of 9 out of 41 RCTs (about 22% of the corpus) restricts the statistical precision of our reliability estimation. While this subset was key in identifying and resolving discrepancies during the annotation process, the resulting IAA metrics should be interpreted as indicative rather than exhaustive.

Our focus is limited to physiotherapy and rehabilitation as we relied on voluntary experts only from these domains. This limitation was necessary to have annotators proficient in the domain, as expanding to other domains could compromise the validity of expert judgments [6]. Though our approach restricts the broader applicability of the corpus, the annotations provided are robust, reflecting thorough assessment by experts within available resources. The sampling was restricted to articles published after 2010 to ensure consistency with modern CONSORT (Consolidated Standards of Reporting Trials) reporting practices. To facilitate open sharing and publication of the annotated corpus, we included only articles available under the CC0 license. While these criteria were necessary for methodological consistency and licensing requirements, they may limit generalizability to RCTs published prior to 2010, to other clinical domains, or to studies published in non–open-access venues.

The low IAA observed stems from the subjective nature of RoB 2, which requires evaluators to interpret nuanced details across various domains. While we have implemented visual placards to aid standardization, these improvements cannot fully resolve the underlying subjectivity in the tool's design. RoB 2, despite offering more structured guidance than its predecessor, still relies on subjective judgment in answering SQs, particularly in complex domains like deviations from intended interventions. This subjectivity is not unique to our study, but is a fundamental challenge in RoB assessments and is recognized in previous research. Given the interpretative nature of RoB assessments, it is not feasible to entirely eliminate these differences. While we continue to explore methods for improving standardization, it is crucial to recognize that the inherent subjectivity in RoB 2 will always impact IAA to some degree.

Our LLM evaluation at that time was restricted to using PDFs, limiting platform compatibility and model selection. Specifically, Google Bard is a freely available tool that interacts with PDFs, but we observed that the Bard results were less deterministic than ChatPDF. Another drawback was associated with the prompts used. Our prompts were also relatively simple and lacked specificity regarding target outcomes, resulting in general responses rather than targeted bias assessments. In retrospect, we should have attached the detailed trial protocol and the statistical analysis plan to each clinical trial before annotation and LLM evaluation. This limitation will be addressed in future expansions of the corpus by adding both the protocol and analysis plan to the RCTs for annotation.

While we have provided a detailed account of our LLM evaluation methodology, we acknowledge the importance of adopting structured reporting frameworks, such as the recently published STAGER (Standards for Transparent And Generative Evaluation and Reporting) checklist, for studies involving generative artificial intelligence. Future studies could benefit from adhering to such guidelines to ensure greater methodological rigor and transparency in reporting [58].

Conclusions

We present RoBuster, a new publicly available corpus of 41 full-text annotated RCTs with detailed RoB spans across 22 bias questions. This corpus and our rigorously developed annotation guidelines address a gap in resources for evaluating RoB text span extraction using ML. RoBuster includes fine-grained bias spans and annotator decisions, providing a benchmark for assessing LLM performance against human bias assessment. Created through collaboration between bias assessors and natural language processing experts, RoBuster can enhance automated bias assessment and support systematic literature review systems.

Our work reaffirms the complexity of bias assessment and the need for robust guidelines to improve IAA in both assessment and annotation. Challenges stemmed from variation in RCT reporting standards, leading to low information availability and the subjectivity inherent in RoB 2. Future work will focus on refining our visual placards, expanding RoBuster with more annotated texts, and using the placards to train new bias assessors.

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Data Availability

The 22 signaling question prompts used for large language model evaluation and the RoBuster dataset are provided in Multimedia Appendix 1 and Multimedia Appendix 5, respectively, with this manuscript. Upon publication, the dataset will be permanently hosted in a public repository (eg, GitHub or Zenodo) to ensure persistent access and version control.

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Conflicts of Interest

None declared.

Multimedia Appendix 1
Documentation of signaling questions and corresponding annotation instructions used in this study.
[DOCX File, 117 KB - formative_v10i1e55127_app1.docx]

Multimedia Appendix 2
Annotators' feedback on the risk of bias assessment and annotation for the randomized controlled trials in RoBuster corpus.
[PDF File, 238 KB - formative_v10i1e55127_app2.pdf]

Multimedia Appendix 3
The visual instruction guidelines in PPTX format. These placards are accompanied by Multimedia Appendix 1.
[PPTX File, 188 KB - formative_v10i1e55127_app3.pptx]

Multimedia Appendix 4
An .xlsx file containing the large language model (LLM) evaluation, detailing the text extraction and response of the LLM and the corresponding text span and response judgment labeled by the expert annotator for all the signaling questions.
[XLSX File, 814 KB - formative_v10i1e55127_app4.xlsx]

Multimedia Appendix 5
The RoBuster dataset in .tsv format.
[ZIP File, 11757 KB - formative_v10i1e55127_app5.zip]

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Abbreviations

AMSTAR: A Measurement Tool to Assess Systematic Reviews
CONSORT: Consolidated Standards of Reporting Trials
EPOC: Effective Practice and Organization of Care
IAA: interannotator agreement
LLM: large language model
ML: machine learning
PABAK: prevalence and bias adjusted κ
PAWLS: PDF Annotation With Labels and Structure
PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-Analyses
RCT: randomized controlled trial
RoB: risk of bias
SQ: signaling question
SR: systematic review
STAGER: Standards for Transparent And Generative Evaluation and Reporting

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Benefit of the N-of-1 Approach Versus Aggregate Analysis in Tracking Individual Trajectories During Pregnancy: Comparison of Longitudinal Wearable Observational Studies

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Abstract

Background: Personal digital health technologies (DHTs) enable real-time monitoring of physiological metrics and behavioral data, including heart rate variability (HRV), supporting analysis of pregnancy-related conditions and personalized care throughout the perinatal period. While recent studies demonstrate the utility of personal DHTs in tracking pregnancy-related symptoms, they often rely on aggregate statistical methods that overlook individual variability.

Objective: This study aims to compare aggregate and individual-level analyses of DHT data for pregnancy-related conditions, using the comprehensive BUMP (Better Understanding the Metamorphosis of Pregnancy) dataset to highlight the importance of individual variability and data heterogeneity.

Methods: We analyzed wearable and self-reported data from 256 participants enrolled in the BUMP study (January 2021 to May 2022), including HRV, sleep, and fatigue measured via Oura Rings and smartphone surveys. Individual-level (N-of-1) trajectories were evaluated and compared with aggregate results to uncover personal and collective trends. A statistical method was developed to assess the influence of adverse events and severe symptoms, while case studies explored confounding and modifying factors underlying heterogeneity. Comprehensive statistical analysis included the coefficient of determination, Kolmogorov-Smirnov tests, likelihood ratio tests, and Welch *t* tests, with interindividual variability flagged based on high-variability thresholds.

Results: Substantial interindividual variability was observed across all features. Only 4.76% (12/256) of participants exhibited an HRV inflection at the aggregate week-33 inflection point, with a coefficient of variation of 14.24%. The median value of the gestational week in individual fatigue troughs was 23 (IQR 8; range 8-38) weeks, differing from aggregate estimates. Distributional comparisons showed no statistically significant differences in individual-level model fit (R^2) by pregnancy complications or age (*P* values ranging from .06 to .99 across all model fit comparisons). Case studies further highlighted both intraindividual and interindividual differences, emphasizing the importance of considering external factors, such as adverse events and severe symptoms.

Conclusions: Our findings show that aggregate wearable data often fail to generalize across populations, oversimplifying pregnancy-related physiological and subjective changes. This simplification can obscure individual trajectories, leading to generalized insights that may not reflect many pregnant women's experiences. Our results highlight the impact of heterogeneity on pregnancy outcomes, emphasizing the need to move beyond one-size-fits-all models and leverage DHT for personalized care.

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KEYWORDS

digital health technologies and wearables; N-of-1 analysis and personalized insights; pregnancy; maternal health; advanced statistical modeling in health care

Introduction

Pregnancy is a critical period marked by significant physiological and psychological changes, influencing maternal and fetal health [1]. Conditions such as gestational hypertension, preeclampsia, preterm birth, and postpartum depression impose significant global health burdens [2]. Despite their prevalence, there is still a limited understanding of the underlying factors driving pregnancy outcomes and an essential need for improved support systems to address women's health during this critical transition [3].

Wearable devices, digital health apps, and other remote smart devices (personal digital health technologies [DHTs] [4]) are increasingly recognized for their potential to transform health care [5,6]. DHTs enable the semicontinuous, real-time monitoring of physiological measures and behavior information, including cardiovascular metrics, activity levels, sleep patterns, and high-frequency subjective symptoms [7-9], particularly relevant to pregnancy. These approaches offer an advantage over traditional aperiodic, symptom-monitoring methods in capturing subtle individual differences in a remote setting, filling in the gaps between clinic visits, and providing tools that could track key symptoms in populations who lack access to prenatal care [10,11]. Harnessing data from diverse DHTs could enhance early detection of pregnancy-related conditions [4,12,13] and enable personalized care throughout the perinatal period [14].

While recent studies have demonstrated the value of personal DHTs in tracking pregnancy-related symptoms and outcomes [15], they often rely on aggregate statistical methods [14,16-18] that can overlook individual variability, as a one-size-fits-all approach may not apply effectively to every individual [19]. A recent large-scale longitudinal study [20] demonstrates systematic deviations of sleep metrics from individual prepregnancy baselines across pregnancy and postpartum, providing population-level context in the field. However, variability in individual behaviors and physiological responses, along with limitations such as small sample sizes in some studies, continues to challenge the generalizability of population-based models. Personal DHTs in pregnancy offer individualized risk monitoring, but recent studies rely on aggregated data instead of N-of-1 analyses. Closing this gap is key to making N-of-1 a standard and maximizing wearable data in future research.

This paper aims to compare the generalizability of personal DHT study results derived from aggregate data with those based on N-of-1 analyses in pregnant individuals using data from a US-based digital health pregnancy study (the BUMP [Better Understanding the Metamorphosis of Pregnancy] study [21]). Three recently published pregnancy digital health studies [16-18] were selected that focused on 3 key measures: heart rate variability (HRV) [16], sleep [18], and fatigue [17]. Aggregated results from these studies were replicated using the BUMP study dataset and were extended by exploring N-of-1 analyses of these key measures. By applying N-of-1 methods, including spline fitting, pregnancy condition analysis, and analyzing certain women in case studies, we aimed to dissect individual differences often overlooked in aggregated approaches.

Methods

Study Design

The BUMP study was a participant-centric digital health study that tracked maternal symptoms using wearable devices and smartphone apps from preconception, through pregnancy, and up to 3 months postpartum [21]. The study was conducted fully remotely and designed to capture high-frequency physiological and self-reported data across the perinatal period. The present analysis focused on 3 key features, including HRV, sleep (deep sleep and awake time), and fatigue, drawn from multimodal data collected through devices like the Oura Ring (Oura Health Inc) [22]. These features were chosen to capture both objective and subjective measures of health and align with recently published maternal health wearable studies. Nighttime HRV was calculated using the root mean square of successive differences between normal heartbeats method from 5-minute interval data collected by the Oura Ring. Awake time and deep sleep were derived from the Oura Ring's 3D accelerometer measurements and 5-minute sleep rankings, respectively. Fatigue was a self-reported feature tracked daily via the BUMP study smartphone app.

Recruitment

Participants were recruited through systematic, multichannel digital outreach strategies as described in the published BUMP study protocol [21]. Recruitment occurred primarily via a secure patient-provider platform operated by Sema4, through which potentially eligible individuals received study invitations. Additional recruitment efforts included targeted outreach through digital advertisements and social media platforms to broaden reach and ensure diverse participation.

Ethical Considerations

The BUMP study was approved by the Advarra Institutional Review Board (Pro00047893). Electronic informed consent was obtained from all participants through the study application prior to any data collection. Participant privacy and confidentiality were protected through data deidentification and secure data storage practices. Access to coded study data is restricted and governed through controlled-access platforms in accordance with institutional and regulatory requirements. Participant compensation, where applicable, was provided as outlined in the approved study protocol.

Participants

Out of 431 participants, 275 were included after excluding those with more than 60% missing data, missing delivery information, or fewer than 30 data points. The number of participants in each complication group was as follows: 37 with preterm birth, 42

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with gestational diabetes mellitus, 38 with preeclampsia, 66 with gestational hypertension, 39 with postpartum hemorrhage, 189 with major depression, and 17 were categorized as healthy individuals (as defined as normal weight [BMI<25], age<35 years, and no complications during pregnancy and postpartum). Further demographic information is provided in Table S4 in Multimedia Appendix 1.

Data Preprocessing

Details on data collection and study measures are in Multimedia Appendix 1. We used aggregated daily summaries from 5-minute interval sleep data, calculating total duration for each sleep stage (deep sleep, awake, and rapid eye movement) across the sleep period. Moreover, HRV was averaged over the entire sleep period. Duplicated time points for objective features were removed. Outliers were identified using the 0.05 and 0.95 quantiles estimated from a randomly selected subset of 100 participants from the study population; these quantile thresholds were then applied uniformly across all participants and time points, with values outside the range set to not a number. For quadratic analysis, data were smoothed by gestational week, and averages were computed. Data preprocessing involved calculating the number of days relative to each participant's delivery date (days since delivery) at every sample point and determining the corresponding gestational age. Gestational age was calculated based on the estimated due date provided during the initial enrollment and adjusted according to the actual birth date when necessary. This information was crucial in aligning wearable device data and survey responses with the appropriate stage of pregnancy for accurate longitudinal analysis. Fatigue was kept in its continuous form between 1 and 7 values where 1 is "none" and 7 is "severe."

A case study analysis examined factors contributing to heterogeneity and varying signal behavior among participants, including self-reported severe daily events, severe symptom events, and adverse event (AE) reports. Severe symptoms, outlined in Table S2 in Multimedia Appendix 1, were reported biweekly. To enhance the evaluation of their impact on distribution change analysis, we applied the SentenceTransformer [23] model to generate embeddings for daily and biweekly features, enabling a more precise estimation of severe symptom timestamps.

Expanding this analysis, we examined the impact of AEs on feature trajectories using a dataset subset with free-text descriptions recorded by engagement experts after biweekly check-ins. To ensure consistency and extract insights, we used GPT-4-turbo to parse and label the free-text data, identifying explicit dates (MM/DD/YYYY or YYYY/MM/DD) and inferring incident dates from relative time references (eg, "one week ago"). GPT-4-turbo was prompted to generate concise labels for AEs by recognizing key occurrences, such as medical procedures or symptoms, and condensing them into meaningful terms. For example, "She started to get a cold 2 days ago, sinus and ear pressure, nasal congestion, and cough" was labeled as "Infection," while "Participant went to the emergency room with body aches and a fever" was labeled "Fever and body aches." This approach enabled efficient and consistent categorization of AEs, ensuring high-quality labeled data for analysis. Further details, including the complete list of event labels and their corresponding report counts, are provided in Table S5 in Multimedia Appendix 1. Additional information on the GPT model and its use is described in Multimedia Appendix 1.

Statistical Analysis

To assess the model's performance, we calculated the coefficient of determination (R^2), which quantifies how well the fitted quadratic model explains the variance in the observed data. An R^2 value closer to 1 indicates a better fit and was estimated as follows:

$$R2 = 1 - \Sigma yobserved - yfitted2\Sigma yobserved - \mu observed2$$

where $y_{observed}$, $\mu_{observed}$, and y_{fitted} represent the initial feature pattern, mean of observed data, and quadratic model output, respectively.

Kernel density estimation is a nonparametric method for estimating the probability density function of a continuous variable, providing a smooth data distribution representation. Kernel density estimation places a Gaussian kernel on each data point and sums them up to generate a continuous density estimate, avoiding parametric assumptions. To compare probability density function distributions between subgroups, we applied the Kolmogorov-Smirnov test [24]. A P value <.05 indicates a statistically significant difference, rejecting the null hypothesis.

To evaluate the impact of including age as a predictor, we performed a likelihood ratio (LR) test comparing the full model with age to a reduced model without it. The log-likelihoods of both models were computed, denoted as ll_{full} for the full model and $ll_{reduced}$ for the reduced model. The LR statistic was calculated as follows:

$$LR=-2\times(llreduced-llfull)$$

The degrees of freedom (df) for the χ^2 distribution were determined by the difference in the number of parameters between the full and reduced models. Using the χ^2 distribution, we computed the P value [25] based on the LR statistic and df, providing statistical evidence for comparing the 2 models.

For the case study analysis, we first conducted an intraindividual assessment. For each event, we compared signal behavior during a peri-event window (7 d before and after the event, defined relative to gestational age) to a baseline period (1 mo-7 d prior). Comparisons were included only if both the baseline and peri-event periods contained at least 7 data points, ensuring sufficient data for statistical analysis. We applied an unpaired Welch t test [26], which does not assume equal variance, to evaluate the null hypothesis of equal means between the 2 periods. The resulting t statistic and P value quantified the magnitude and statistical significance of differences in signal behavior associated with the event window relative to baseline.

We then performed an interindividual analysis to assess whether similar patterns were observed across individuals. Using consecutive 14-day windows spanning gestational ages from −270 days to delivery (0), we identified the occurrence of each

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event within each window and calculated the average *t* statistic for each individual. When multiple events occurred in close temporal proximity, events were analyzed only if their peri-event windows did not overlap; otherwise, they were treated as a single composite event. For Figure 1B, the sampling frame consisted of all participants with at least 1 adverse or severe event for which the intraindividual Welch *t* test indicated a statistically significant difference ($P<.05$) between baseline and peri-event windows. From this subset, 1 qualifying event per participant was randomly selected using uniform random sampling without replacement.

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Figure 1. Impact of adverse events and severe symptoms on fatigue, HRV, and sleep features over pregnancy. (A) Effects of adverse or severe events on deep sleep and HRV in example BUMP participants, with adverse events shown in red next to dashed lines. (B) Examples of adverse or severe events associated with significant shifts in the distribution of features throughout pregnancy. (C) Two women experiencing the same severe symptom at the same gestational week exhibiting different sleep and HRV patterns. BUMP: Better Understanding the Metamorphosis of Pregnancy; HRV: heart rate variability.

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To quantify heterogeneity in responses, we defined a high-variability threshold as twice the SD of the average *t* statistic across individuals. If the absolute difference in *t* statistics between any two individuals exceeded this threshold, the event was classified as demonstrating substantial interindividual variability in associated feature changes. For Figure 1C, the sampling frame included participants who experienced the same severe symptom within the same 14-day gestational window and demonstrated statistically significant physiological changes associated with that symptom. From this eligible pool, 2 participants were randomly selected using uniform random sampling to illustrate examples of interindividual variability in physiological response patterns.

Results

Overview of Analysis Strategy

We performed the analysis in 4 stages. First, we replicated previously reported aggregate-level maternal wearable findings in the independent BUMP cohort, focusing on HRV, fatigue, and sleep features. Second, we quantified the extent to which these aggregate patterns reflected individual-level behavior by examining participant-specific inflection points, extrema, slopes, and longitudinal trajectories. Third, we tested whether interpersonal heterogeneity could be explained by demographic or pregnancy-complication subgroups using distributions of individual model fit. Fourth, we conducted event-centered case studies to assess whether severe symptoms and AEs could account for deviations in individual trajectories.

Aggregated Analysis

To assess the generalizability of previously reported aggregate wearable-derived patterns in maternal health [16-18], we replicated analyses of HRV, fatigue, and sleep physiology using a larger, independent wearable dataset from the BUMP study (n=256) [21]. Aggregate trajectories over gestation were compared with those reported in prior studies, including the timing of inflection points and overall directional trends. In the following, we describe the degree to which these previously observed patterns were reproduced in the BUMP cohort and highlight areas of concordance and divergence across outcomes.

In the BUMP study, the aggregated results suggest that nighttime daily HRV shows a similar inflection point around week 7 before birth in both term and preterm pregnancies and at gestational week 33 in term pregnancies, though this trend is absent in preterm pregnancies (Figure 2A). However, the weekly mean HRV values differ significantly, with the BUMP data showing a smaller weekly variance compared to Jasinski et al [16]. For fatigue, the general trends in the BUMP study reproduce those reported in Nissen et al [17], with both showing an early peak around gestational weeks 7 to 8 and a trough around week 21, although substantial deviations from this pattern are observed at the individual level, particularly in the third trimester (Figure 2B).

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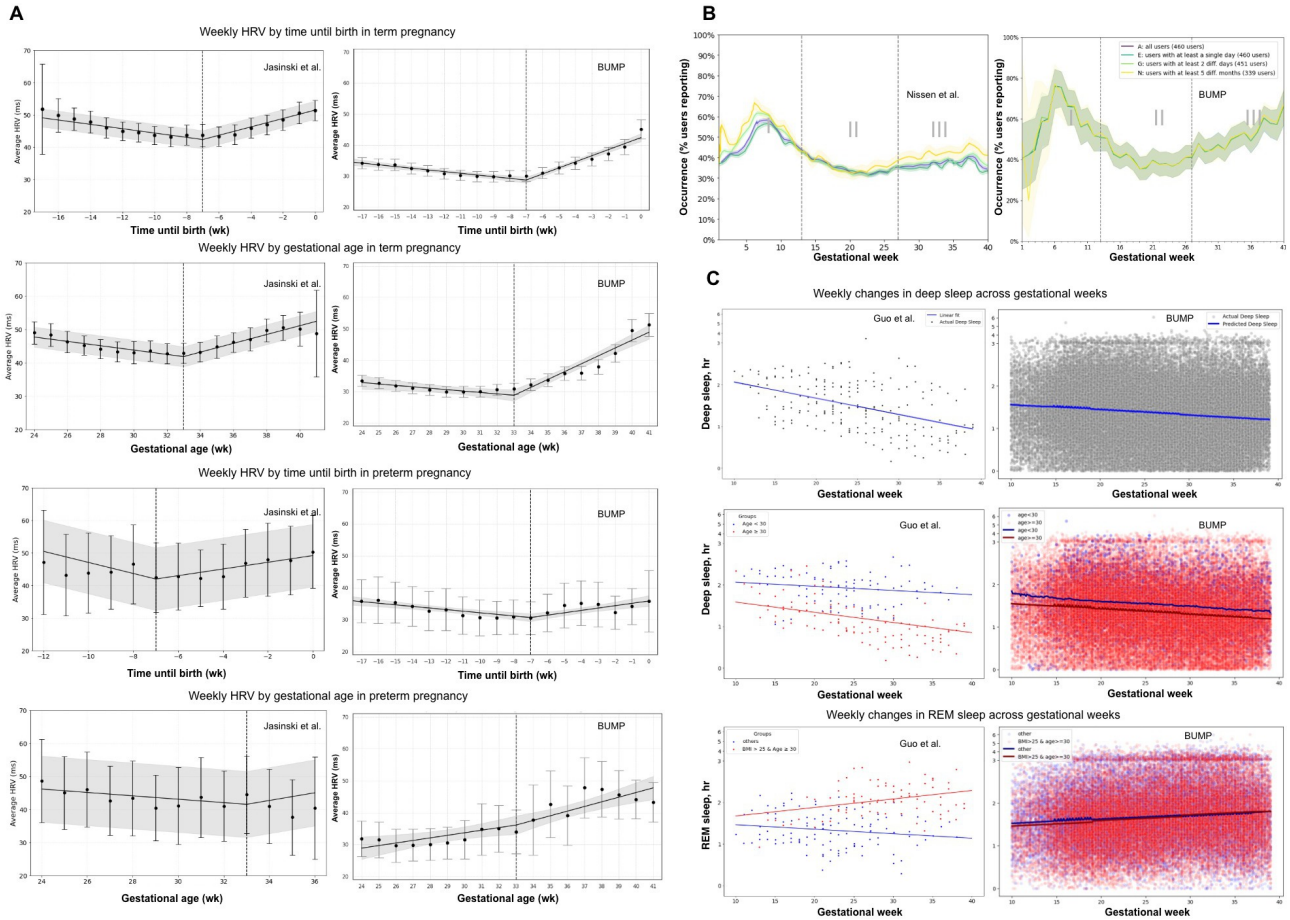
Figure 2. Aggregated results comparison of HRV, fatigue, and sleep patterns between BUMP [21] and prior pregnancy studies. (A) HRV trends show similar prebirth inflections, with less variance in the BUMP study. Error bars represent the 95% CI; the vertical dashed line marks the inflection point [16]. (B) Fatigue aggregate peaks and the troughs pattern in the BUMP study reproduce previously reported population-level trends, despite substantial variability in individual trajectories. Dashed vertical lines mark the pregnancy trimesters [17]. (C) Deep sleep trends differ in slope with less variation across BMI and age subgroups in the BUMP study [18]. BUMP: Better Understanding the Metamorphosis of Pregnancy; HRV: heart rate variability; REM: rapid eye movement.



Regarding deep sleep (Figure 2C), both the BUMP data and Guo et al.'s findings show a negative slope for aggregate deep sleep, with Guo et al [18] reporting a slightly steeper decline across 10 to 40 gestational weeks. Our analysis further reveals substantial variability and heterogeneity in sleep data, reflected in intraclass correlation coefficients of 0.618 for deep sleep and 0.502 for rapid eye movement sleep, both exceeding the 0.5 threshold for significance. In the BUMP data, BMI and age were not clearly separable predictors, unlike Guo et al.'s findings. Segmenting age into ≥30 years versus <30 years did not significantly improve model fit (P=.17), suggesting that Guo et al.'s proposed associations may not be generalizable to all populations. Similarly, stratifying the data by prepregnancy BMI and age (age ≥30 and BMI>25 vs others) yielded a P value of 1, further questioning the generalizability of these demographic factors as predictive indicators. These findings highlight that results from wearable maternal health studies are not easily generalizable across populations due to significant heterogeneity in wearable feature patterns and individual subjective symptom experiences.

The analysis of HRV, fatigue, and sleep metrics derived from personal DHT data during pregnancy underscores the limitations of aggregated models in capturing individual variability in maternal health. Figure 3 shows violin plots, using density curves to illustrate data distribution. Wider sections indicate higher data density, enabling intuitive comparisons of individual variability against aggregate trends. Gray lines mark key findings from each study, contrasted with BUMP dataset analyses to assess density across individual-level data.

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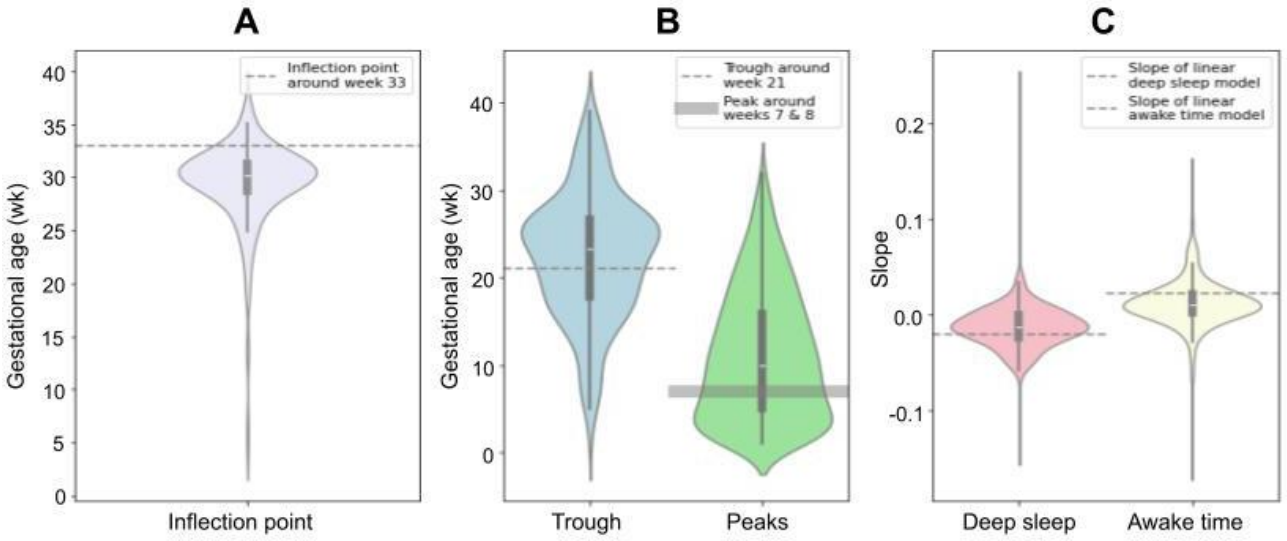
Figure 3. Key features extracted from wearable data during pregnancy in the BUMP study: (A) HRV, (B) fatigue, and (C) sleep. Horizontal dashed or highlighted lines represent the findings from Jasinski et al [16], Nissen et al [17], and Guo et al [18] based on aggregate results. The violin plots compare these aggregate findings with individual-level BUMP analysis, highlighting variability across participants. BUMP: Better Understanding the Metamorphosis of Pregnancy; HRV: heart rate variability.



Key comparisons include the following: For HRV, Jasinski et al [16] identified an inflection point around gestational week 33. To compare with individual-level inflection points, the BUMP data were analyzed using a quadratic model (weeks 10 - 40), identifying the minimum point as the individual inflection. Similarly, aggregate fatigue trends in BUMP are consistent with Nissen et al [17], showing early peaks at weeks 7 to 8 and a trough near week 21. Individual fatigue peaks and troughs were calculated to capture variability. For sleep, Guo et al [18] used a linear mixture model to estimate slopes for aggregated deep sleep and awake time, which were compared with individual-level slopes determined by fitting linear regression models.

Figure 3 and Table S7 in Multimedia Appendix 1 show that individual-level results from BUMP, visualized through density curves, did not fully align with the published findings and revealed substantial variation. Figure 3B highlights that the median value of the gestational week in individual fatigue troughs was 23 (IQR 8) weeks, which was 2 weeks earlier than the aggregate result. Similarly, individual fatigue peaks occurred 2 weeks later than the aggregate finding, with notable variability indicated by the IQR and density spread. These discrepancies underscore the need to account for individual variability, as aggregate findings do not universally apply, even to the majority of individuals.

N-of-1 Level Analysis

Individual patterns in HRV, fatigue, deep sleep, and awake time were examined and compared to aggregate trends using the BUMP study data (Figure 4).

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Figure 4. Spaghetti plots of four features from the BUMP study contrast aggregate trends with individual trajectories. Each colored line represents an individual's (A) HRV, (B) fatigue, (C) deep sleep time, and (D) awake time, highlighting variability across gestational weeks. BUMP: Better Understanding the Metamorphosis of Pregnancy; HRV: heart rate variability.

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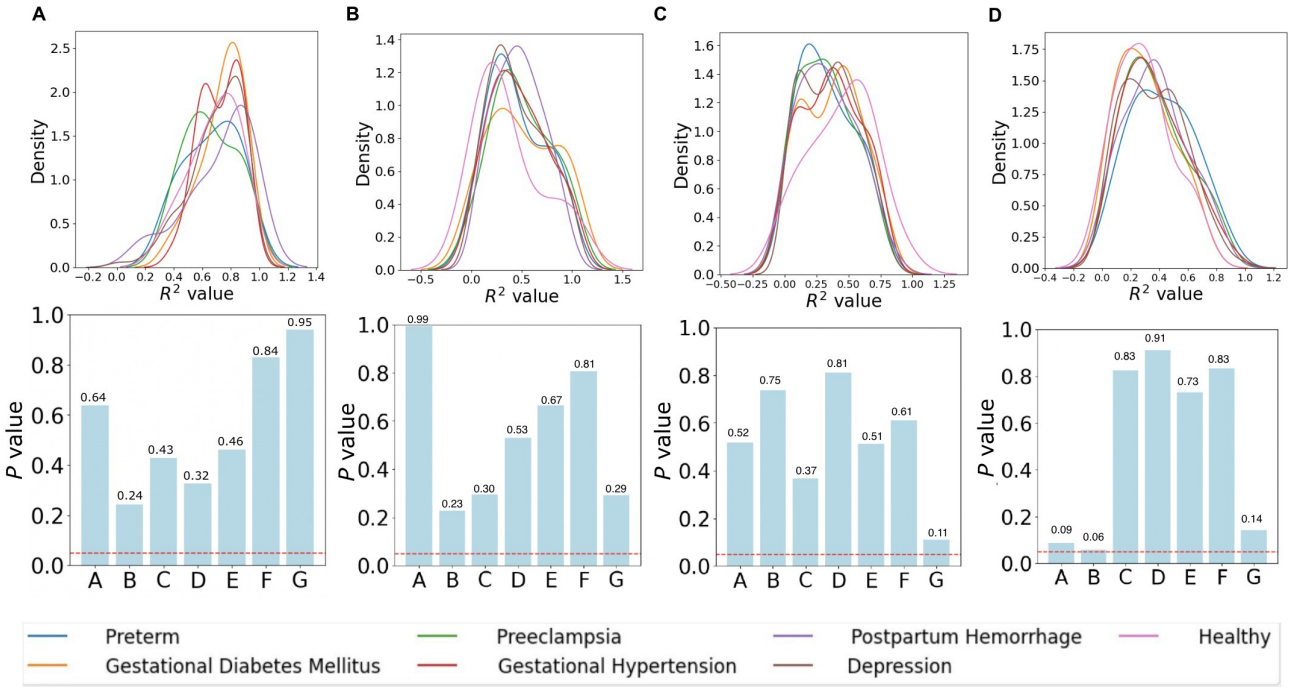
Figure 4 highlights the high variability in objective and subjective feature patterns during pregnancy, often lost in aggregate views. Individual HRV, fatigue, deep sleep, and awake time patterns vary significantly across gestational weeks. While the aggregate line (black) suggests a smooth trend, it overlooks individual complexities and key variations. Relying solely on aggregate data risks misinterpretation, especially when individual patterns deviate from the average.

In Figure 5, heterogeneity is formally quantified using distributions of individual-level model fit (R^2) and tested across subgroups using kernel density comparisons with associated *P* values. Modifying factors or confounders, such as pregnancy-related complications and demographic factors, may in part explain the observed heterogeneity in the model's performance. However, the kernel density plots and *P* values revealed no significant differences in R^2 distributions, indicating that the model's fit is relatively consistent across groups. Specifically, there were no significant differences in HRV, fatigue, deep sleep, or awake time trends among participants with different pregnancy-related conditions. All subgroup comparisons yielded *P* values >.05 (eg, *P*=.09, .06, .82 for awake time; *P*=.52, .75, .37 for deep sleep; *P*=.99, .23, .30 for fatigue; and *P*=.64, .24, .43 for heart rate variability) (see the lower section of Figure 5). The symmetric, overlapping kernel density plots suggest minimal variation in R^2 distributions, with no skewness or distinct clustering. These findings suggest that pregnancy-related complications and demographic factors (Figure S1 in Multimedia Appendix 1) were not associated with detectable differences in the model's ability to fit the observed outcomes.

Figure 5. Comparison of R^2 values assessing model fit across pregnancy-related complications in the BUMP study: (A) HRV, (B) fatigue, (C) deep sleep, and (D) awake time. Top plots illustrate kernel density distributions for each group, while bottom plots display *P* values, comparing each group's feature distribution to that of other women. The red-dashed line marks the significance threshold (*P*=.05). Kernel density plots and *P* values indicate no statistically significant differences detected in R^2 distributions across complication subgroups. BUMP: Better Understanding the Metamorphosis of Pregnancy; HRV: heart rate variability.



Case Studies

To explore sources of heterogeneity, we analyzed survey data on severe symptoms reported by users and AEs documented in research staff notes. Key events and their precise timing were identified from unstructured AE notes using GPT-based automatic prompting, with subsequent expert review to verify the accuracy and consistency of the extracted information. We also incorporated daily severe symptoms: very low energy, impaired cognition, very low mood, and extreme stress, referred to as severe daily features. Biweekly severe symptom surveys, aligned with daily reports, covered severe fever or cough, intense headaches, severe infections, vision changes, and urinary issues. Further details are available in the *Methods* section and Multimedia Appendix 1.

Figure 1A presents examples of high-frequency AEs and severe symptoms reported during pregnancy. Among 256 individuals, 4674 events were recorded, with a median of 9 (IQR 8) and an average of 21 (SD 25.337; range 1-153) events per person. Figure 1B highlights 2 participants randomly selected from those with statistically significant shifts in feature distributions before and after severe events, as determined by an intraindividual Welch *t* test comparing baseline and peri-event periods (*P*<.05). In participant C, a low-energy event 155 days before delivery was followed by increased fatigue and awake time, along with decreased HRV and deep sleep. In participant D, a severe infection 92 days before delivery was followed by similar effects.

Figure 1C illustrates variability in physiological patterns among pregnant women experiencing the same severe symptom at the same gestational week. Participants were randomly selected

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from those with significant physiological responses to the same symptoms, highlighting individual variability in adaptation. For example, both participants E and F experienced severe fever, sore throat, and/or cough in the same week; yet one had a sharp decline in deep sleep, whereas the other showed a gradual increase. A linear mixed model analysis indicated substantial between-individual variability in responses across all event types. These findings underscore the need to consider both inter- and intraindividual differences when evaluating responses to similar events. Additional examples are shown in Figure S4 in Multimedia Appendix 1.

Discussion

Principal Findings

This study aimed to evaluate whether aggregate trends in DHT measures of HRV, sleep, and self-reported fatigue during pregnancy accurately represent individual experiences and to explore whether demographic or clinical factors explain variability among individuals. Using the BUMP dataset and N-of-1 spline modeling, we report 3 principal findings. First, aggregate trends in HRV, sleep, and fatigue were broadly consistent with those reported in prior studies but masked substantial interindividual variability. Second, N-of-1 analyses revealed that many participants deviated markedly from population averages in the timing, direction, and magnitude of changes across pregnancy. Third, neither demographic factors, pregnancy complications, nor acute health events adequately explained the observed heterogeneity, suggesting that personalized analytical approaches are necessary to accurately interpret maternal health data.

Comparison to Prior Work

The aggregate results from these studies and the BUMP dataset demonstrate unique contours in these 3 measures of health. Notably, HRV appears to steadily decrease with gestational age, but then shows an inflection at approximately 33 weeks leading up to delivery. This inflection has been highlighted in the literature by others, suggesting a phenomenon that could reflect an individual's physiological readiness for delivery [16,27,28]. While this could be true for some, our N-of-1 analyses demonstrate that many individuals do not experience this HRV inflection, or an inflection is experienced, but in a significantly different pattern from the average. Fatigue aggregate trends show an early peak around gestational weeks 7 to 8, followed by a gradual decline to a trough near week 21 [17]. However, individual analyses reveal considerable variations in these patterns, as shown in Figure 3. Similarly, while average sleep trends show a steady decline in deep sleep and increased awake time, especially in the third trimester [18,29], N-of-1 analyses highlight substantial interindividual differences. Some individuals experience a progressive decline in deep sleep, whereas others show minimal or even opposite changes, underscoring the complexity of sleep adaptations during pregnancy.

Physiological and subjective changes during pregnancy often differ from group averages due to external factors. While previous studies [5,18] have often relied on standard demographic exclusions or subgrouping and stratified analyses by age or pregnancy complications, these approaches miss the substantial heterogeneity in individual patterns. Using N-of-1 analyses with spline models, we captured each participant's unique response to pregnancy-related changes, offering detailed insights into individual trajectories. Our N-of-1 analyses found no significant differences in HRV, sleep, and fatigue levels between participants with pregnancy complications and those without, suggesting that these conditions do not fully explain the observed heterogeneity. Some differences emerged across demographic factors, such as age and BMI; for instance, individuals with a BMI of 25 to 30 showed significant differences in HRV and deep sleep goodness-of-fit compared to other subgroups. However, this pattern was not observed for fatigue or awake time, indicating BMI alone is not a reliable indicator for subgrouping but warrants further exploration alongside other factors.

We further explored case studies in an attempt to isolate potential modifying factors of the examined maternal health metrics. The case studies further compounded the finding suggesting high heterogeneity of maternal health experiences. For example, in some participants, while there were associations between events, such as fever, cough, and very low energy levels, and significant increases in fatigue and awake time, there was high intraindividual and interindividual variability in responses to these events, emphasizing that pregnant individuals can exhibit diverse physiological responses to the same event at the same gestational week.

After extensive exploration into potential modifiers of HRV, sleep, and fatigue over pregnancy, we identify no clear factors explaining the observed high heterogeneity of these maternal health metrics, suggesting the necessity of personalized analytical approaches to accurately interpret maternal health data at the N-of-1 level. The significant variability among individuals highlights the complexity of deriving broadly applicable clinical insights. The absence of significant associations with the examined demographic or clinical factors should be interpreted cautiously, as limited power in smaller subgroups and unmeasured factors may contribute to the observed variability.

Limitations

Several limitations should be considered when interpreting these findings. First, the sample size limited statistical power for subgroup analyses; small subgroup sizes may have prevented detection of meaningful associations between demographic or clinical factors and the observed variability. Second, multiple unmeasured confounders may contribute to the heterogeneity observed and were not captured in this study. Third, we note that those prior studies and BUMP differed slightly in cohort selection criteria and protocol, but such differences are unlikely to affect our conclusion, as the studies used the same device types, measurement protocols, and aggregate feature definitions for comparison.

Conclusions

This study underscores the need for personalized and diverse assessments to capture the individuality of maternal health metrics. Moving beyond one-size-fits-all models is essential

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for embracing heterogeneity and tailoring insights to pregnant individuals' unique needs. By explicitly examining N-of-1 longitudinal patterns, this study contributes to early evidence highlighting the methodological considerations necessary for safe, interpretable, and personalized maternal health monitoring. Future work should prioritize developing personalized methods that account for variability and assess the causal effects of modifying factors. Effectively interpreting personal DHT maternal health data may require human-in-the-loop approaches, where users are prompted for additional context when deviations in feature patterns are detected.

Looking forward, the findings of this study motivate the development of analytical frameworks that explicitly accommodate individual variability while leveraging population-level information. A clinically actionable N-of-1 framework would require models that explicitly borrow statistical strength from population-level data while producing calibrated, individualized inferences. One promising direction is hierarchical Bayesian time-series modeling, in which population-level dynamics inform individual trajectories without enforcing a shared average response. For example, hierarchical Dirichlet process flow-style approaches [30,31] allow each person to follow a personalized latent dynamic while sharing structure across the cohort, improving individual-level prediction under sparse or noisy observations. In pregnancy monitoring, such models could learn typical gestational regimes while estimating patient-specific deviations, enabling individualized forecasting (eg, expected HRV trajectory) and anomaly detection relative to one's own baseline rather than a cohort mean.

Acknowledgments

The authors thank Phoebe Chuang for her assistance with data analysis. They would also like to thank all the women who participated in the BUMP (Better Understanding the Metamorphosis of Pregnancy) and BUMP-C studies for their ongoing commitment and valuable contributions to enhancing future pregnancy care. The authors declare the use of generative AI (GAI) in the research and writing process. According to the GAIDeT taxonomy (2025), the following tasks were delegated to GAI tools under full human supervision: proofreading and editing. The GAI tool used was ChatGPT-4o (OpenAI). Responsibility for the final manuscript lies entirely with the authors. GAI tools are not listed by the authors and do not bear responsibility for the final outcomes.

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Data Availability

Among participants who opt-in, the coded study data from the BUMP study participants are available on the Synapse platform at Sage Bionetworks [32] and can be freely accessed by any researcher who becomes "qualified" by becoming a registered and certified Synapse user [33], and by meeting the specific conditions of use that require submitting an intended data use statement alongside an Institutional Review Board (IRB)-approved protocol. The BUMP specific Synapse Project page [34] is listed as references and is accessible to registered Synapse users. The details of Reproducibility GitHub link [35] and the website page [36] are listed as references.

Authors' Contributions

JY and TB designed the methodology, conducted formal analysis, developed the software, interpreted and validated the results, and drafted the original manuscript. RY contributed to methodology design, analysis, software development, result interpretation, validation, data curation, and manuscript review and editing. AB assisted with data curation, software development, analysis, and manuscript review and editing. AG and SMG contributed to conceptualization, supervised the analysis, interpreted results, and reviewed and edited the manuscript. SHF led the overall study design and conceptualization, secured funding, supervised the analysis, interpreted results, and reviewed and edited the manuscript. All authors have read and approved the final manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Detailed methodology, data collection procedures, and extended analyses.
[DOCX File, 6300 KB - formative_v10i1e86203_app1.docx]

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Checklist 1
STROBE checklist.
[PDF File, 129 KB - formative_v10i1e86203_app2.pdf]

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Abbreviations

AEs: adverse events
BUMP: Better Understanding the Metamorphosis of Pregnancy
DHT: digital health technology
HRV: heart rate variability
LR: likelihood ratio
STROBE: Strengthening the Reporting of Observational Studies in Epidemiology

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A Conversational Platform (Okaya) for Multimodal Digital Biomarkers of Fatigue, Cognition, and Mental Health: Feasibility Observational Study

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Abstract

Background: Collection of multimodal data (video, audio, and text) can yield digital biomarkers relevant to mental health, fatigue, and cognition. However, the feasibility and signal characteristics in operational populations remain underexplored.

Objective: The objectives of this study were to (1) extract an evidence-based library of vision, speech, and language features; (2) assess the feasibility of a fully remote conversational platform (Okaya) for collecting analyzable multimodal data; and (3) conduct preliminary signal checks for depression, fatigue, and cognition.

Methods: Participants were recruited from the US Air Force and US Space Force. All participants completed the Okaya check-in, which included a voice conversation with a large language model. A total of 66 visual, acoustic, and text features were extracted from each interaction between the participant and the large language model. For validation purposes, the study also collected measures of depression (Patient Health Questionnaire–9), fatigue (Cancer Fatigue Scale), and cognition (trail making test). We evaluated the feasibility of the platform and correlation between the extracted features and the validated assessments.

Results: A total of 8 unique participants contributed with 62 sessions over a period from March 6, 2025, to August 6, 2025. The platform was deemed feasible as 6 of the 8 participants opted to complete more than one session, and the 3 participants who provided feedback reported high overall experience and usability. From the data perspective, preliminary correlations produced significant results for multiple potential digital biomarkers, including (1) pitch (P=.047), volume SD (P=.04), volume slope (P=.04), automated readability index complexity (P=.047), Flesch-Kincaid complexity (P=.04), and Gunning Fog complexity (P=.04) for depression; (2) pitch (P=.009), volume SD (P=.007), volume slope (P=.02), average F2 formant frequency (P=.03), Gunning Fog complexity (P=.049), and eyelid droop (P=.047) for fatigue; and (3) shimmer (P=.03) for cognition. We also observed how features varied over time among participants with multiple sessions.

Conclusions: The conversational and artificial intelligence–enabled platform was feasible among an operational sample as a method to collect multimodal data correlated with depression, fatigue, and cognition. These results align with those for previously discovered digital biomarkers of mental health, fatigue, and cognition and inform the development of personalized models for each user while detecting anomalies in a remote monitoring setting.

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KEYWORDS

digital biomarkers; multimodal sensing; computer vision; speech acoustics; natural language processing; artificial intelligence; AI

Introduction

Mental health, fatigue, and cognitive functioning are critical to overall well-being and operational performance, yet their assessment often relies on intermittent self-report or clinician-administered instruments. Such methods, while clinically validated, can be burdensome, subjective, and limited in their ability to capture dynamic changes over time [1-9]. Mobile health technology provides an alternative solution due to the ability of apps and sensors to collect high-fidelity and high-frequency data pertaining to activity, behavior, symptoms, and cognition [10-12]. With increasing demands for continuous and remote monitoring—especially in occupational and high-performance settings—digital biomarkers have emerged as a promising avenue for objective and scalable assessment of psychological and cognitive states [13-16].

Recent advances in computer vision, speech acoustics, and natural language processing have enabled the extraction of behavioral and physiological signals from everyday digital

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interactions. Multimodal sensing that integrates video, audio, and language data provides an opportunity to quantify indicators of affect, fatigue, and cognitive load with greater ecological validity than traditional laboratory tests [11,17]. Prior research has demonstrated associations between acoustic features (eg, pitch variation [18-23], jitter [18,19,24-26], and spectral harmonicity [25-28]), facial expression dynamics (eg, eye gaze [29-32] and microexpressions [33]), and linguistic markers (eg, sentiment [28,34,35], complexity [28,36], and emotional valence [28,35,37-41]) with symptoms of depression, stress, and cognitive decline. However, most existing work has been conducted in tightly controlled environments, and less is known about the feasibility of collecting such data in naturalistic or operational contexts [42].

Conversational platforms, especially those powered by large language models, introduce new opportunities for naturalistic data capture [43-46]. By engaging users through dialogue, these systems can simultaneously elicit and record multimodal signals—speech, facial behavior, and language—while maintaining a familiar and low-burden interaction format [47-52]. Such interfaces align with the increasing integration of conversational artificial intelligence (AI) into health, wellness, and performance domains, offering a pathway toward longitudinal, user-centered monitoring of mental and cognitive health. Nevertheless, empirical evaluation of these systems' feasibility and usability remains limited, particularly in real-world populations such as operational and occupational groups [53,54]. These groups can also be more susceptible to experiencing mental and cognitive health challenges due to their job functions [55,56].

The objective of this study was to evaluate the feasibility of a fully remote conversational platform, Okaya, for collecting analyzable multimodal data (video, audio, and text) in an operational population from the US Air Force (USAF) and Space Force. Specifically, we sought to determine whether participants would engage with the platform across multiple sessions and whether the system could reliably extract a comprehensive set of visual, acoustic, and linguistic features suitable for future digital biomarker modeling of depression, fatigue, and cognition. Finally, we present a case study for the design of a risk score based on a model of extracted digital biomarkers to illustrate the future potential of the platform.

Methods

Study Population

This study was part of an existing Small Business Innovation Research Direct to Phase II contract with the USAF, and a pool of potential participants from the 71st Special Operations Squadron, provided by the USAF, was introduced to the Okaya platform as part of a pilot program. Participation was entirely optional. A total of 8 unique users participated in the study, contributing 62 sessions (median 2.5, range 1-38, IQR 1.5-7.5). Participants provided data during the period from March 6, 2025, to August 6, 2025.

Ethical Considerations

Ethics approval for this study was obtained from Sterling Institutional Review Board (approval 12300-GMenvielle), and all participants signed an informed consent statement that specified anonymized access to research records, potential risks, and voluntary participation. No data were collected except for email addresses, which were required to access the Okaya platform. No demographic or sample composition information was collected due to requirements from the USAF. Participants received no compensation for taking part.

Procedure and Data Collection

Overview

Completion of Okaya check-ins [57] was entirely voluntary. Data collection took place on the Okaya website, and users were allowed to select the device they preferred to access the website with, such as smartphones, tablets, or laptops. The browser used to access the website was also free to select by the user. Once users had successfully acknowledged the consent statement and registered for an Okaya account, they could complete a workflow as described in Figure 1. Participants were asked to complete 3 assessments: the Patient Health Questionnaire–9 (PHQ-9) [58], Cancer Fatigue Scale (CFS) [59], and trail making test (TMT) [60].

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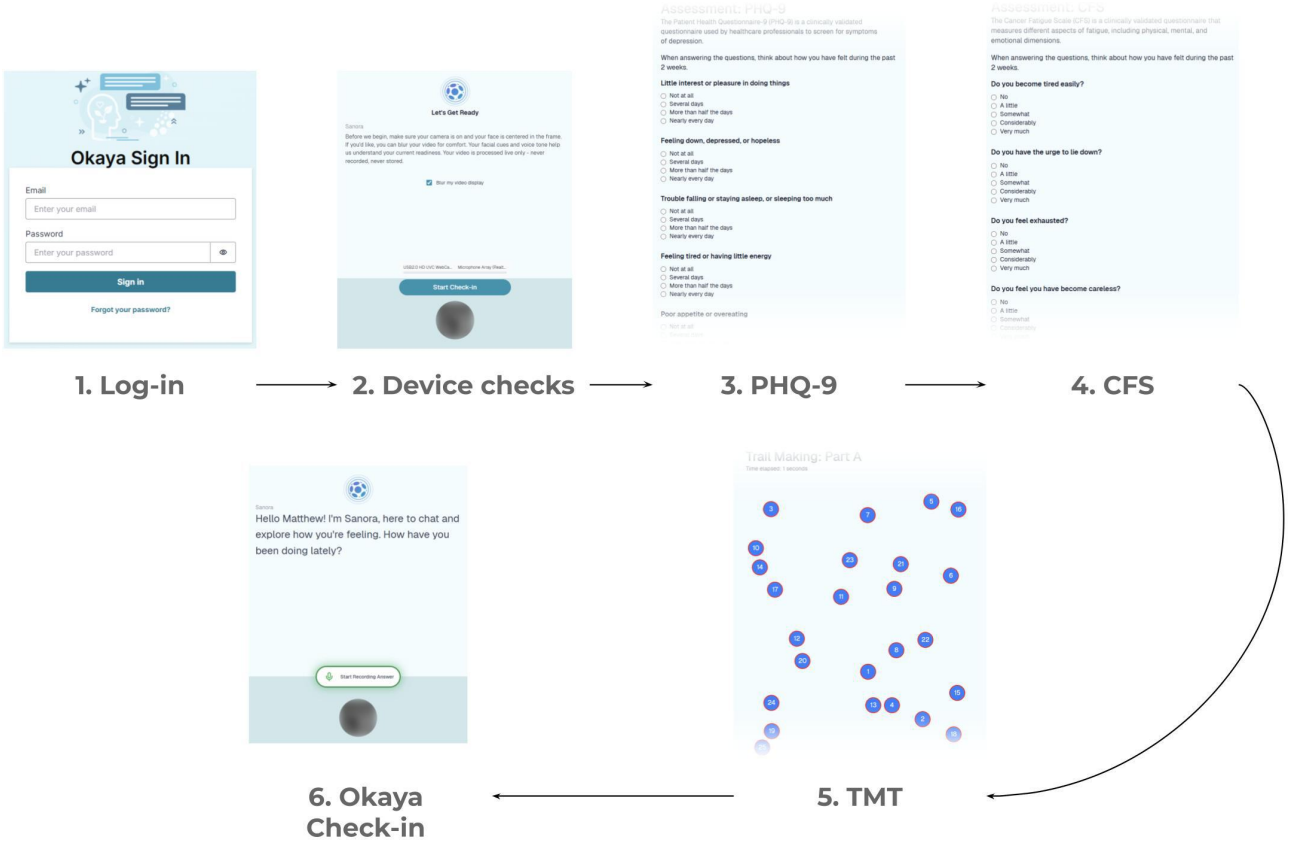
Figure 1. Illustration of the Okaya platform and data collection. The 6 steps for a successful sample collection include log-in, device checks, Patient Health Questionnaire–9 (PHQ-9), Cancer Fatigue Scale (CFS), trail making test (TMT), and Okaya check-in.



Upon successful completion of all 3 assessments, users were presented with a text and voice prompt from a large language model (using OpenAI's GPT-4o-mini model with a custom system prompt, referred to as "Sanora"), shown in Figure 2. Users were first required to meet the device and browser requirements, grant permission to access the microphone and camera, and meet an upload speed requirement of 2 Mb/s. Video was recorded continuously, and users could choose between webcam video, blurred video, a landmark representation of their face, an outline of their face, or a set of axes denoting the location of their face, designed to accommodate users with differing levels of comfort with being recorded. Although video was shown on the interface, raw video was not sent to our servers; instead, a set of facial landmarks was extracted via Google MediaPipe. These landmarks were automatically extracted using a proprietary machine learning model, and 478 landmarks were output, each with an x, y, and z coordinate, as well as 52 "blendshapes," each representing various facial expressions. The check-in interface, as shown in Figure 2, included the text of Sanora's prompt at the top; the representation of the user's webcam video at the center; and a control button, either "Record," "Stop," or "Continue," at the bottom of the screen.

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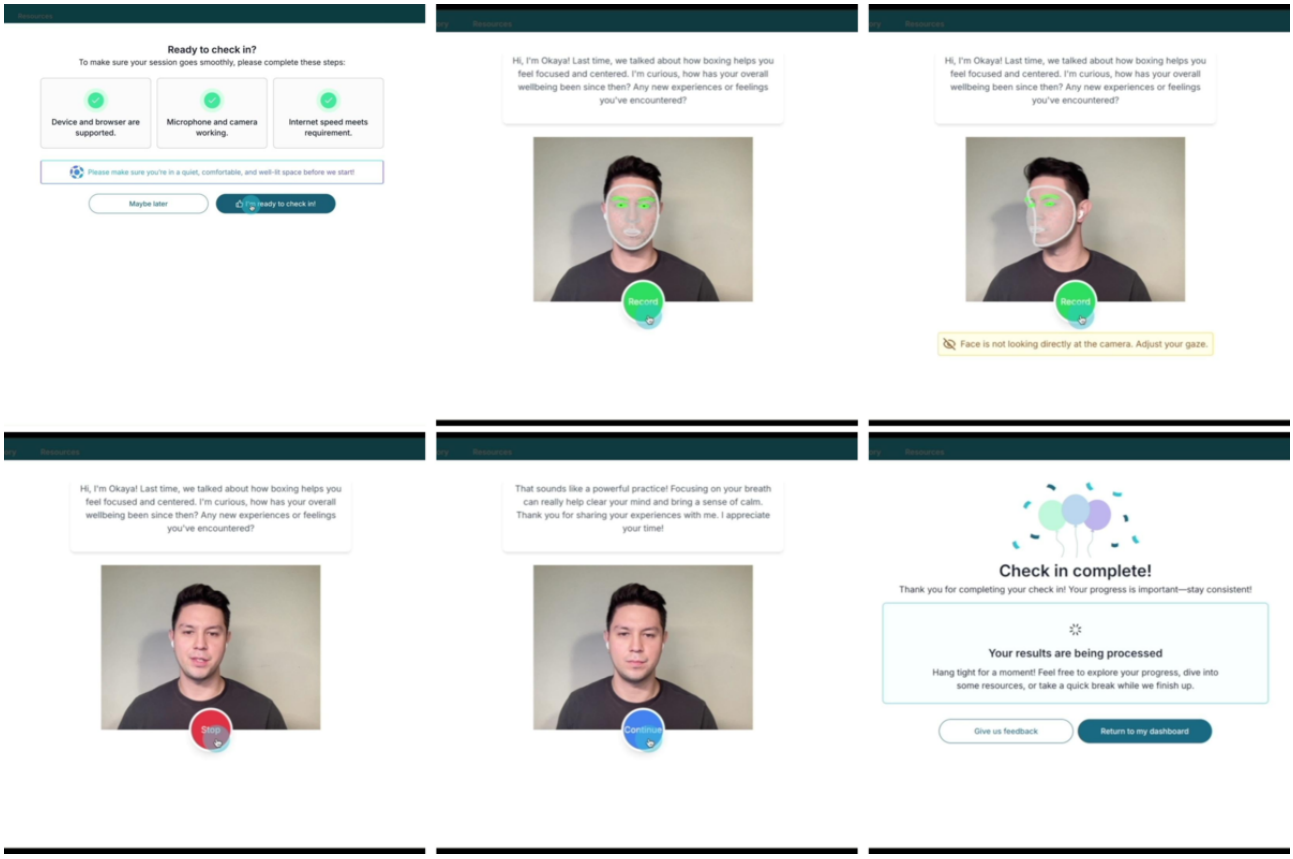
Figure 2. Screenshots of the Okaya check-in. Permission was obtained from the user depicted.



After passing device checks and clicking “I’m ready to check-in,” Sanora would generate a prompt for the user to respond to asking about their general mental well-being, emotions, or experiences they had had recently. Upon clicking “Record” to record a response to Sanora, the user’s microphone started recording, and an automatic transcription service from Amazon Transcribe started transcribing their speech until the user clicked “Stop” and stopped recording. Both the audio recording and transcribed text were sent back to the Okaya servers. Sanora then used the transcribed text to generate a response. This process continued for 4 turns (5 messages from Sanora and 4 responses from the participant). Upon conversation completion, the user clicked “Continue” to submit the session for analysis, after which a completion screen would indicate that the results were being processed. They would then be redirected to the research dashboard.

All back-end processing took place on Amazon Web Services infrastructure, with communication between the website (front end) and back end occurring via Representational State Transfer application programming interface calls. Data were also stored on Amazon Web Services infrastructure.

Feature Extraction

From the landmarks, audio, and transcribed text, we extracted 66 features based on the literature. A full list and descriptions of each implemented feature can be found in Multimedia Appendix 1, whereas summaries are shown in Tables 1-3.

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Table . Mapping features for depression.

Feature	Theoretical reasoning	References	Implemented features
Visual features			
Flat affect	A predominant lack of facial expressiveness can be observed in some individuals with depression. This might manifest as a “blank” or “emotionless” appearance even in situations that would typically provoke an emotional response.	[33]	Affect_measure
Facial expression	“Sad” facial expressions, such as less frequent smiling, have been associated with the severity of depression.	[31,40,61-63]	Mouth_curvature and eyebrow_droop
Reduced eye contact	People with depression might avoid making eye contact, which can be a sign of feelings of worthlessness or guilt.	[29-32]	Gaze_down_dist, gaze_x_dist, and gaze_y_dist
Slow movements	Psychomotor retardation can manifest as slowed facial movements or reactions in those with depression.	[61]	Movement_speech_measure
Audio features			
Monotone speech	Individuals with depression might exhibit a lack of variability in pitch, leading to speech that sounds monotonous.	[18-22,27]	Pitch and pitch_std
Reduced speech volume	Speaking more softly or with less projection than usual can be indicative of depression.	[18,22,64-67]	Vol, vol_std, and ealvi
Reduced vocal prosody	A decrease in the rhythmic and melodic aspect of speech can be indicative of depression.	[18-20,24,25,28,64,68]	Jitter, shimmer, timbre, and formant
Long pauses	Depression might result in more increased pauses between words or sentences, reflecting hesitancy, slowed thinking, or difficulty in organizing thoughts.	[18,21,68,69]	Audio_pauses
Transcript features			
Long pauses	Depression might result in more increased pauses between words or sentences, reflecting hesitancy, slowed thinking, or difficulty in organizing thoughts.	[18,21,68,69]	Transcript_pauses
Slow speech rate	People with depression might speak more slowly, potentially reflecting slowed cognitive processing.	[22,23,68-71]	Words_per_s
Reduced responsiveness	A person with depression might be less verbally responsive in conversations, potentially taking longer to reply or offering shorter answers.	[21,22,69,70]	Response_latency and transcript_len
Decreased complexity and length of speech	Speech in individuals with depression might be less complex in terms of vocabulary and sentence structure, and individuals might be less talkative overall.	[28,34-37,39,40,67]	Complexity, emotion_keyword_prop, and sentiment_score

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Table . Mapping features for fatigue.

Feature	Theoretical reasoning	References	Implemented features
Visual features			
Droopy eyelids	The muscles around the eyes may begin to sag due to tiredness, causing the eyelids to droop.	[72]	Eyelid_droop
Decreased blink rate	Fatigue can lead to a reduced rate of blinking.	[73-77]	Blinks_per_s and blink_len
Yawning	While yawning is a natural behavior, frequent yawning can be an overt sign of fatigue or drowsiness.	[76,78]	Yawns_per_s and yawn_len
Reduced expressiveness	Fatigue might cause an individual to have fewer facial movements or expressions.	[72]	Mouth_curvature
Audio features			
Decreased volume	A tired individual might speak more softly or with less energy than when they are well rested.	[8,79]	Vol and vol_std
Decreased pitch variability	A fatigued voice might sound more monotonous, with less variation in pitch.	[23,25]	Pitch and pitch_std
Flatter voice profile	Decreased variation and width of the voice's spectral profile can be indicative of fatigue.	[25,79]	Timbre and formant
Increased pauses	There might be more frequent and longer pauses between words or sentences, reflecting slowed cognitive processing or the need to gather thoughts.	[23,79,80]	Audio_pauses
Transcript features			
Increased pauses	There might be more frequent and longer pauses between words or sentences, reflecting slowed cognitive processing or the need to gather thoughts.	[23,79,80]	Transcript_pauses
Slow speech rate	The overall rate of speech might decrease when a person is tired.	[23,80]	Words_per_s
Shortened responses	Fatigued individuals might offer shorter answers or engage less in conversation.	[23]	Transcript_len
Impaired memory recall	Fatigued individuals might struggle to remember certain words, names, or details, leading to more frequent use of filler words such as "um" or "uh."	[80]	Hesitations_per_s

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Table . Mapping features for attention and cognition.

Feature	Theoretical reasoning	References	Implemented features
Visual features			
Decreased blink rate	Blinking might increase when in periods of high attention demand during cognitive tasks.	[81]	Blinks_per_s
Eye movements	Eye movements outside the line of focus might be reduced when in a period of visual attention.	[82]	Eye_movements_per_s
Audio features			
Volume	Speech volume can indicate differences in arousal and fatigue.	[26]	Vol, vol_std, vol_range, and volume_slope
Pitch and pitch variability	Pitch might be less varied during periods of low engagement or emotional expressivity.	[26,83]	Pitch and pitch_std
Voice timbre	Voice might be breathier or more strained when lacking attention.	[26]	Jitter, shimmer, and timbre
Transcript features			
Reduced responsiveness	Response latency has been shown to enable the detection of the Stroop effect (delay in reaction time).	[84]	Response_latency

The webcam capture rate varied depending on a number of factors, including the user's device and browser. As this capture rate was not controllable by the Okaya platform, the analysis had to handle landmark frames captured at nonregular times. Generally, the capture rate was 30 to 60 frames per second, but they were usually not captured at a consistent rate. All sessions were interpolated to a capture rate of 30 frames per second, where each time step was a linear interpolation between the 2 neighboring frames. Features were extracted in Python (Python Software Foundation) using the libraries *SciPy* and *NumPy*.

Similarly, audio capture rate varied per user, so all audio recordings were resampled to a sampling frequency of 22,050 Hz. Features were extracted in Python using the libraries *Librosa*, *NumPy*, *SciPy*, *Parselmouth*, and *Statsmodels*.

Text features were extracted in Python using the libraries *NumPy*, *Textacy*, and *Natural Language Toolkit* (Team NLTK). The exact implementation of each feature extractor is omitted as the details of the Okaya platform are proprietary.

Several temporal aggregations were used to calculate feature values: averaged per second, per frame, per response, or per detected event. The exact aggregation and unit used for each feature are listed in Multimedia Appendix 1.

Results

Engagement and Usability Results

Three participants provided qualitative and survey feedback following completion of their Okaya sessions. Full survey responses can be found in Multimedia Appendix 2. Overall, preliminary user satisfaction with the conversational platform was given a rating of between 4 and 5 out of 5 on overall experience and usability among all participants who provided feedback (3/3). These participants described the platform as intuitive and easy to navigate and reported feeling adequately supported during setup and use. One participant highlighted the responsiveness of the support team and appreciated having direct access to human assistance when needed.

Motivations for engagement included curiosity about the technology and the opportunity for structured self-reflection during check-ins. One participant noted that the conversations prompted personal insight and self-awareness, describing the process as a valuable moment to "intentionally reflect" on life aspects discussed during the session. Common barriers to more frequent engagement included time constraints, insufficient or poorly timed reminders, and occasional concerns about privacy when speaking in shared environments. Notably, all participants who completed the survey expressed overall confidence in data privacy and platform security, each giving this aspect a rating of 5 out of 5.

Suggestions for improvement focused on enhancing convenience and personalization, including text-based reminders with direct log-in links, greater mobile accessibility, and shorter baseline tasks prior to the conversational check-in. Survey participants also expressed interest in receiving personalized summaries or progress visualizations of their responses. All the participants who provided feedback indicated interest in participating in future sessions using the Okaya platform, reinforcing the platform's acceptability and potential for longitudinal engagement within operational populations.

Correlation Analysis

Overview

Pearson correlations and their associated significance are listed below. Although every participant was included in the dataset and most completed multiple sessions, we only took into account the earliest sample for each participant for the correlation

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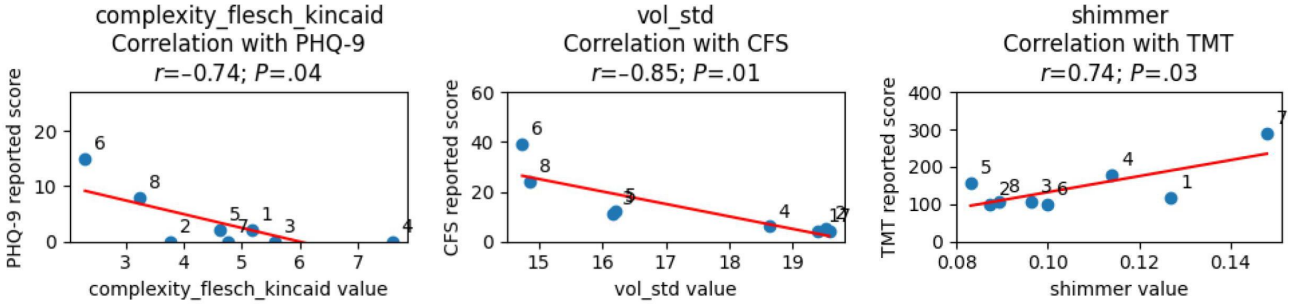
analysis. The earliest sample was used to illustrate the use of an initial sample as a baseline, upon which personalized models can be built, illustrated in the case study below. We also observed low intraparticipant variability for each clinical measure, which hindered the application of more sophisticated statistical models at this stage. For each feature, outliers (defined as any measurement more than 2 SDs from the mean) were removed. The most significant features are plotted against the associated measures in Figure 3.

Figure 3. Most significant features for each measure and their associated correlation. CFS: Cancer Fatigue Scale; PHQ-9: Patient Health Questionnaire–9; TMT: trail making test.



Correlations for Depression

Exploratory correlation analyses revealed several significant associations between multimodal features and depressive symptom severity as measured using the PHQ-9. Acoustic and linguistic indicators showed the strongest relationships. In this small sample specifically, pitch (r=0.71; P=.047) and volume slope (r=0.78; P=.04) were positively correlated with PHQ-9 scores. This suggests preliminary patterns and warrants further exploration into predictive modeling to validate that greater variability and upward trajectories in vocal intensity may correspond to higher self-reported depression levels. In contrast, volume SD was negatively correlated (r=−0.73; P=.04), encouraging a possible exploration into how participants with greater depressive symptoms may exhibit reduced dynamic range in speech.

Textual complexity metrics—including the automated readability index (r=−0.71; P=.047), Flesch-Kincaid complexity (r=−0.74; P=.04), and Gunning Fog index (r=−0.72; P=.04)—also demonstrated negative correlations with PHQ-9 scores; thus, the individuals in our preliminary dataset reporting higher depressive symptoms tended to produce shorter or linguistically simpler utterances during conversational interactions. Due to the low sample size, it is impossible to say whether there are any actual meaningful correlations; however, it does warrant further exploration with larger sample sizes and more resilient analyses. Due to our limited sample size, individual correlations are also not expected to be reliable or generalizable at this stage. Together, these relationships support the feasibility of deriving speech- and language-based digital biomarkers of depression from naturalistic conversational data.

Correlations for Fatigue

Analysis of correlations between multimodal features and fatigue as measured using the CFS identified several significant acoustic, visual, and linguistic markers. Among acoustic features, pitch (r=0.84; P=.009), volume slope (r=0.84; P=.02), and average F2 formant frequency (r=0.76; P=.03) were positively correlated with fatigue severity, whereas volume SD (r=−0.85; P=.007) showed a strong negative association. This warrants further investigation into how individuals reporting higher fatigue might exhibit flatter, less dynamically modulated vocal patterns, consistent with decreased speech energy and prosodic variation observed in fatigue-related speech studies.

Additionally, the linguistic Gunning Fog index was inversely correlated with CFS scores (r=−0.71; P=.049), indicating that higher fatigue levels were associated with simpler or less complex speech production. One visual feature, eyelid droop (r=0.71; P=.047), also demonstrated a significant positive association with fatigue, consistent with prior literature linking ocular and facial muscle changes to tiredness. Together, these findings highlight the sensitivity of both speech acoustics and facial metrics to self-reported fatigue, supporting their potential use as digital biomarkers for real-time fatigue monitoring. However, due to the limited sample size and analysis, individual associations should not be interpreted as predictive or applicable to general populations at this stage.

Correlations for Attention and Cognition

Exploratory analyses examining associations between multimodal features and cognitive performance as measured using the TMT identified a single significant relationship. The acoustic feature shimmer, which captures cycle-to-cycle variability in vocal amplitude, was positively correlated with TMT scores (r=0.74; P=.03). This association points to greater irregularity in voice amplitude when participants had longer task completion times. Further research into how lower cognitive efficiency might potentially relate to fatigue-related motor or attentional variability in speech production may be worthwhile. Although preliminary, this finding aligns with those of prior literature linking changes in vocal stability to fluctuations in attention and executive functioning. These results indicate that fine-grained acoustic features derived from conversational speech may offer a feasible, low-burden proxy for cognitive performance monitoring in remote or operational settings. Once again, although the exact associations found should not be treated as reliable or generalizable at this stage, this does suggest a potential future study with larger samples and analyses.

Descriptive Summary of Significant Associations

To complement the quantitative analyses, we conducted a descriptive review of the distribution of significant multimodal

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features across clinical domains. As shown in Table 4, depression-related features were primarily linguistic and acoustic in nature, with no significant visual markers identified. Fatigue exhibited the broadest feature coverage, encompassing 1 visual variable, 4 acoustic variables, and 1 linguistic variable. When examining fatigue subscales, distinct modality patterns emerged: the physical and affective fatigue components were each associated with multiple acoustic features, whereas the cognitive subscale was linked to both visual and acoustic indicators. In contrast, cognitive performance as measured using the TMT was primarily associated with a single acoustic feature, reflecting a narrower signal profile. It is important to note that feature set size also had an effect; for example, fatigue measures displayed a clear feature representation across audio features, but audio features also made up a larger proportion of the total features compared to visual and text features. There is no clear evidence of any specific feature modality showing broader significance or sensitivity.

Table . Count of significant features for each subscale of the clinical measures and feature type out of the total number of features tested.

Clinical measure and subscale	Feature categories, n (%)		
	Visual features (n=13)	Audio features (n=28)	Text features (n=25)
PHQ-9[a]	0 (0.0)	3 (10.7)	3 (12.0)
CFS[b]	1 (7.7)	4 (14.3)	1 (4.0)
Physical	1 (7.7)	4 (14.3)	3 (12.0)
Affective	0 (0.0)	5 (17.9)	0 (0.0)
Cognitive	1 (7.7)	5 (17.9)	0 (0.0)
TMT[c]	0 (0.0)	1 (3.6)	0 (0.0)
Part A	0 (0.0)	0 (0.0)	1 (4.0)
Part B	0 (0.0)	1 (3.6)	0 (0.0)

[a]PHQ-9: Patient Health Questionnaire–9.

[b]CFS: Cancer Fatigue Scale.

[c]TMT: trail making test.

Risk Score Case Study

To explore the feasibility of individualized monitoring, we conducted case studies on participants who completed multiple Okaya sessions. For each individual, a composite “risk score” was calculated by standardizing the significant multimodal features (z-scoring within participants) and summing the deviations from the mean, with directionality determined by the feature’s correlation with the clinical measure. This approach provided a demonstration of an interpretable, participant-specific index of deviation from baseline functioning across time; however, due to the low sample size and unstable correlations, it is purely used as a demonstration in this case, not a proof of actual meaningful capability.

An example use case can use a longitudinal visualization of these risk scores to reveal dynamic fluctuations in both depression- and fatigue-related indexes across sessions. For example, in participants with higher variability, increases in risk score can correspond to periods of increased self-reported symptom severity, whereas lower or stable values can align with more consistent well-being reports. Although exploratory, these case studies illustrate how multimodal conversational data can support within-person anomaly detection and temporal tracking of psychological and physiological states. This example provides a demonstration of how individualized, feature-based composite scores may offer a viable framework for early identification of changes in mood, fatigue, or cognitive function in remote monitoring contexts.

Data on depression and fatigue for the 2 participants with the most sessions are shown in Figures 4 and 5, respectively (TMT only exhibited 1 significant feature and, as such, a composite score was not meaningful).

Figure 4. Risk score case study for depression.

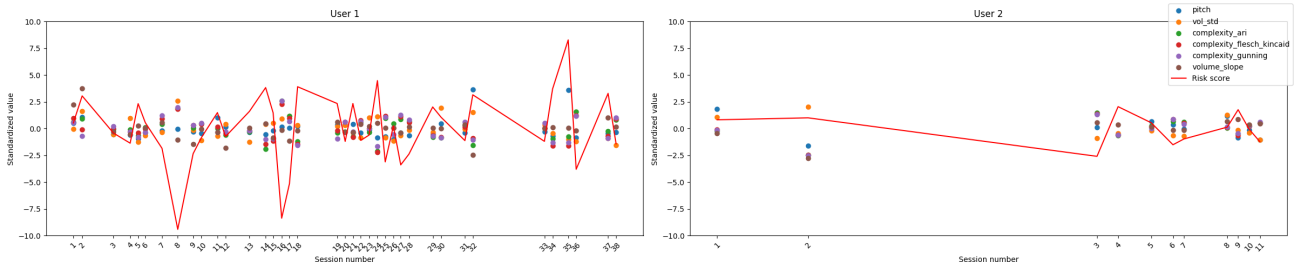

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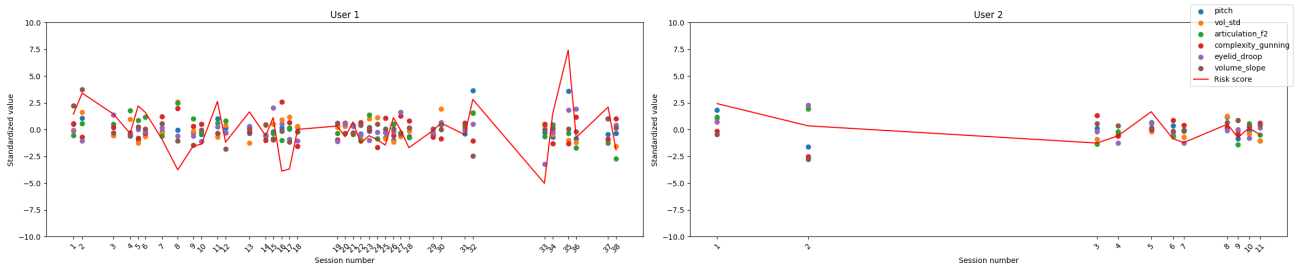
Figure 5. Risk score case study for fatigue.



Discussion

Principal Findings

We found several multimodal features that correlated with depression, fatigue, and cognition, some of which extended beyond patterns reported in prior literature. As expected, depression was characterized by reduced variability in vocal intensity and lower linguistic complexity, consistent with psychomotor slowing and affective flattening. Fatigue demonstrated a broader multimodal signature involving both acoustic and visual domains, including reduced volume variability, higher pitch, and greater eyelid droop, reflecting decreased energy and arousal. Notably, volume slope, a feature we did not find in the literature, was significant for both depression and fatigue, suggesting that individuals with depression or fatigue might have noticeable patterns in how speech volume progresses over time, especially during utterances provided on the Okaya platform. Additionally, complexity, a feature previously linked to depressive speech, was found to correlate with fatigue, indicating that depression and fatigue may share some similar effects on word choice and diversity [28,36]. Together, these findings highlight the potential for future study of established digital biomarkers in the Okaya platform and the emergence of cross-domain signals that may bridge affective, cognitive, and fatigue-related processes.

The findings of this feasibility study indicate that the Okaya conversational platform is both usable and acceptable for collecting multimodal data in an operational setting. Participants demonstrated relatively sustained engagement, with most completing multiple sessions, suggesting that the platform's conversational format and remote accessibility supported ongoing participation. Usability feedback further underscored this positive experience—participants rated the system highly in terms of ease of use, clarity of instructions, and overall satisfaction. Qualitative feedback revealed that users found the interaction intuitive and meaningful, often describing the check-in as an opportunity for reflection rather than a burdensome task. Importantly, participants expressed high confidence in data privacy and security, which is critical for user trust in AI-enabled health technologies [85-87]. At the same time, feedback highlighted opportunities for improvement, including more flexible scheduling options, reminders, and greater mobile accessibility. Together, these findings suggest that Okaya's design successfully balanced data collection rigor with user comfort and autonomy, supporting its feasibility for repeated deployment in diverse and high-performance populations. These results provide an encouraging foundation for the platform's next phase of validation and refinement, emphasizing scalability, personalization, and long-term adherence.

The findings from the case study align closely with the long-term vision for the Okaya platform. The observed fluctuations in individualized risk scores and their correspondence with self-reported symptom changes demonstrate the platform's potential for longitudinal, within-person monitoring—a central principle behind the Okaya Index and the simplified risk score we presented. Rather than relying on evidence from population-based studies, the Okaya platform emphasizes personalized baselines and interprets deviations relative to each individual's unique behavioral and physiological profile. This individualized approach reflects the platform's goal of enabling early identification of shifts in emotional, cognitive, or fatigue states. As the platform evolves, integration of these multimodal risk scores into the Okaya Index will enable continuous refinement of trajectories across time and populations, ultimately supporting adaptive, AI-driven insights that can inform both clinical decision-making and support for operational populations ranging from pilots to firefighters. This trajectory aligns with the goal of advancing proactive mental health and performance optimization in real-world settings.

From a clinical and research perspective, these findings illustrate the promise of conversational, multimodal sensing as a foundation for precision mental health and digital phenotyping. By capturing subtle changes in voice, facial behavior, and language over time, systems such as Okaya can complement traditional self-report and clinician-administered tools, providing a richer, continuous view of mental and cognitive functioning. Such individualized, data-driven assessments have potential applications across health care, occupational performance, and behavioral health monitoring, particularly in cases in which real-time insight and early intervention are critical. Importantly, the Okaya platform's emphasis on *nondiagnostic* and *privacy-preserving* analytics aligns with emerging standards for responsible AI in health technology [13,88,89]. As digital biomarkers move closer to clinical integration, continued validation across diverse populations and conditions will be essential to ensure generalizability, interpretability, and equity [85,86,90]. Ultimately, this study of the Okaya platform represents a step toward an ethically grounded, adaptive ecosystem for mental health monitoring—one that transforms multimodal data into actionable insights while safeguarding user trust and autonomy.

This study has several limitations that should be considered when interpreting the findings. First, the sample size was small and limited due to our focus on operational populations, which

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are harder to recruit, constraining generalizability and the ability to model interindividual variability. Thus, the correlations we report are not meant to be statistically resilient or generalizable at this stage. Therefore, these findings preclude reliable statistical inference of robust estimates of the correlations in these data and, rather, suggest future avenues for discovery. Second, although validated instruments such as the PHQ-9, CFS, and TMT were used for comparison, these measures may not fully capture the temporal dynamics or subtle within-person fluctuations that multimodal digital biomarkers are designed to detect. Traditional self-report and performance-based assessments tend to be episodic and relatively stable, which may underestimate moment-to-moment variability in affect, fatigue, and cognition. Future studies should incorporate higher-resolution clinical measures—such as ecological momentary assessment or brief daily self-reports—that provide richer temporal data and enable stronger coupling between behavioral features and self-reported states [1-3,87,91]. Integrating these temporally aligned measures would allow for more precise modeling of intraindividual change and enhance the ecological validity of the derived digital biomarkers. Finally, while the Okaya platform demonstrated feasibility and acceptability in this study, further validation with larger, more diverse samples and extended longitudinal follow-up is necessary for predictive modeling and design of personalized remote monitoring systems.

Conclusions

The conversational and AI-enabled platform (Okaya) was feasible among an operational sample from the US Air and Space Force as a method for collecting multimodal data correlated with depression, fatigue, and cognition. Future work will examine larger samples with repeated measures to assess the test-retest reliability and predictive validity of multimodal digital biomarkers. Ultimately, the goal of the platform is the development of personalized models for each user while detecting anomalies in a remote monitoring setting.

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Data Availability

The datasets generated and analyzed during this study are not publicly available due to their use in the development of a proprietary platform as well as confidentiality requirements from the US Department of Defense. Public release of the data could enable reverse engineering of the platform or unauthorized commercial use. However, unidentified data may be available from the corresponding author on reasonable request.

Authors' Contributions

Conceptualization: M So (lead), GM (equal), M Sobolev (equal)
Data curation: M So (lead), GM (equal)
Formal analysis: M So (lead), M Sobolev (equal)
Funding acquisition: GM
Investigation: M So (lead), M Sobolev (equal)
Methodology: M Sobolev (lead), M So (equal), GM (supporting)
Resources: M So (lead), GM (supporting)
Software: M So
Validation: M So (lead), M Sobolev (supporting)
Visualization: M So
Writing—original draft: M Sobolev (lead), M So (supporting)
Writing—review and editing: M So (lead), M Sobolev (equal), GM (supporting)

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Conflicts of Interest

M So and GM are employed by and hold financial interest in SmartTec Inc, who develops the Okaya platform, and could benefit from research outcomes. M Sobolev receives consulting fees from SmartTec Inc.

Multimedia Appendix 1
Feature list.
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Multimedia Appendix 2
Survey responses.
[DOCX File, 16 KB - formative_v10i1e87054_app2.docx]

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Abbreviations

AI: artificial intelligence
CFS: Cancer Fatigue Scale
PHQ-9: Patient Health Questionnaire–9
TMT: trail making test
USAF: US Air Force

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Development and Evaluation of a German Suicide Prevention Website for Men: Exploratory Study

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Abstract

Background: Men face a substantially higher risk of suicide. Effective suicide prevention strategies for men should specifically target gender-related risk factors, such as their lower likelihood of seeking professional help.

Objective: This study investigates the use and impact of a suicide prevention website for men between March 1, 2023, and December 31, 2024. The Männer Stärken website is the first suicide prevention platform for men in Germany, with the primary aim of facilitating help-seeking behavior. The development of the platform was informed by interviews with men who had attempted suicide, as well as by existing evidence on effective communication strategies for engaging men at risk.

Methods: This exploratory study combines quantitative web analytics and survey data with a qualitative analysis of open-ended responses from a feedback form. Using the web analytics tool Matomo, data were collected on the number of visits to the website and the subpages they accessed. In addition, 291 anonymous feedback forms were analyzed regarding visitors' perceptions of the website's helpfulness and its potential to support help-seeking behavior. A further component involved an online survey (n=40) examining whether a short suicide prevention film featured on the website could increase the intention to seek help.

Results: During the study period, the website recorded 29,279 visits. A majority (n=291) of the respondents reported via the feedback form that they found the website helpful (n=201, 69.1%) and believed it could encourage help-seeking behavior (59.8%). In the evaluation of the short film, a significant increase in participants' intentions to seek help was observed in situations involving suicidal ideation and personal difficulties and when considering professional support services. This effect was not observed with regard to informal sources of support, such as friends or family.

Conclusions: The data suggest that the website is being used. Among those who completed the anonymous survey form (N=291), a majority reported that the website fulfills its primary aim of providing helpful pathways to support services. The evaluation of the short film further supports this conclusion. However, certain limitations must be acknowledged: since the data were collected in a field setting, the ability to draw firm conclusions about the characteristics or representativeness of the visitor sample is limited. In addition, the sample size for the short film evaluation was small. Nevertheless, the findings point to a clear need for gender-specific suicide prevention initiatives. They indicate promising directions for the development of effective, low-threshold measures, which merit further investigation in future research.

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KEYWORDS

suicide; men; prevention; e-mental health; evaluation

Introduction

Worldwide, men are at significantly greater risk of dying by suicide. In Germany, men are approximately 3 times more likely to die by suicide than women [1]. Various risk factors for suicide in men are discussed in connection with this markedly increased risk. In a review of gender-specific risk factors for suicidal behavior, Richardson et al [2] found the strongest evidence for diagnosed depression, alcohol and/or drug use or dependence, and being single or widowed. Men also tend to use more lethal methods when attempting suicide [3-5]. Another important risk factor is that men are less likely to seek psychosocial help during suicidal crises and are less inclined to disclose suicidal thoughts within the support system [6-8]. Studies indicate that stigma and masculinity norms that discourage help-seeking (eg, self-reliance) may constitute barriers to seeking and accessing support [9-11].

The significantly higher suicide risk among men indicates that they are an important target group for suicide prevention. However, men are less likely than women to be reached by general, nongender-specific suicide prevention efforts [12]. To date, only a few suicide prevention programs worldwide specifically address men and their gender-specific risk factors. Promising examples from Australia include the MOVEMBER men's health promotion initiative [13] and the 2016 suicide

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prevention campaign MAN-UP [14-16]. The MAN-UP program consists of a 3-part documentary and a related website [17], both of which focus on masculinity, mental health or suicidality, and help-seeking. King et al [15,18] demonstrated that the website is used as a gateway to access support organizations and helps men to engage with the MAN UP team on topics such as suicidality and mental health. In addition, there is a Belgian suicide prevention campaign, "Get Out of Your Head," which also specifically targets men and includes information and testimonials from men with lived experience. A Dutch-language (Flemish) website [19] was developed and evaluated in 2022. Stas et al [20] demonstrated that the website led to an increase in help-seeking intentions and greater openness to communicating emotions among men.

In March 2023, the first German-language website dedicated to suicide prevention among men was launched [17]. The website was developed as part of the MEN-ACCESS project. In addition to the website for men at risk of suicide, an online program for gatekeepers was developed as part of the MEN-ACCESS project [21], and both measures were initially evaluated through qualitative interviews [22]. In Germany, the German Society for Suicide Prevention (Deutsche Gesellschaft für Suizidprävention) provides an online overview of resources for individuals with lived experiences and professionals [23]. The website is briefly presented and linked to as a dedicated resource for men in suicidal crises.

The website incorporates aspects and techniques that have been shown to improve help-seeking behavior among men [24]. These include the use of role models to deliver information, psychoeducation to enhance knowledge about mental health as well as problem-solving strategies, support in identifying symptoms, motivation for behavioral change, the introduction of and information about available support services, and the positive reframing of masculine traits in the context of help-seeking (eg, responsibility and strength). To inform the content development of the website, 14 qualitative problem-centered interviews [25] were conducted with men who had personal experiences of suicidal thoughts and behaviors and who had each attempted suicide at least once. The participants were between 19 and 61 years old. The interviews focused on various topics, including the development or signs of suicidal behavior, problem-solving behavior, communication of suicidal intent, support systems, protective factors, stigmatization of suicidal behavior, and possibilities for suicide prevention. The data were analyzed using structured qualitative content analysis [26]. The findings of Spahn et al [27] on facilitating and hindering aspects of help-seeking among men with suicidal behavior were directly incorporated into the development of the website's content. In line with a participatory approach, the website content was also reviewed not only by experts (including therapists) but also by 3 men with lived experiences of suicidality. Their feedback was incorporated, and the content was further refined in a joint iterative process.

The primary goal of the website [17] is to encourage men at risk of suicide to seek help, but it also aims to inform and reduce stigma. The website addresses and supports various steps of the help-seeking process [28]: recognizing the problem, assessing one's own situation (eg, subpages "Warning Signs" or "Assessing Your Own Situation"), deciding to seek help and overcoming barriers to help-seeking (eg, subpages or films on fear of stigma, fear of [involuntary] hospitalization, lack of trust in help services), and finding and accessing help (eg, the subpage "Navigating the Support System," communicating suicidal intentions).

Figure 1 illustrates the website's structure and provides an overview of the content presented on its subpages. Figure 2 shows the landing page of the website. The website provides content in the form of texts, graphics, and short films. The homepage features 3 main short films portraying 3 male protagonists: 1 younger, 1 middle-aged, and 1 older. The subpages include additional short films in which the 3 protagonists talk about specific topics, such as masculinity norms and seeking help. In the short films on the homepage, men talk about their own experiences with mental health crises, suicidal ideation, seeking help, and recovery. Studies have shown that positive narratives about coping with suicidal ideation can reduce suicidal thoughts ("Papageno effect") [29]. Films can also have a destigmatizing effect. However, the findings regarding changes in attitudes toward help-seeking remain inconclusive [15,30-32].

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Figure 1. Site map of the website [17]. LGBTQ+: lesbian, gay, bisexual, transgender/transsexual, queer, and other minority sexual orientations and gender identities.

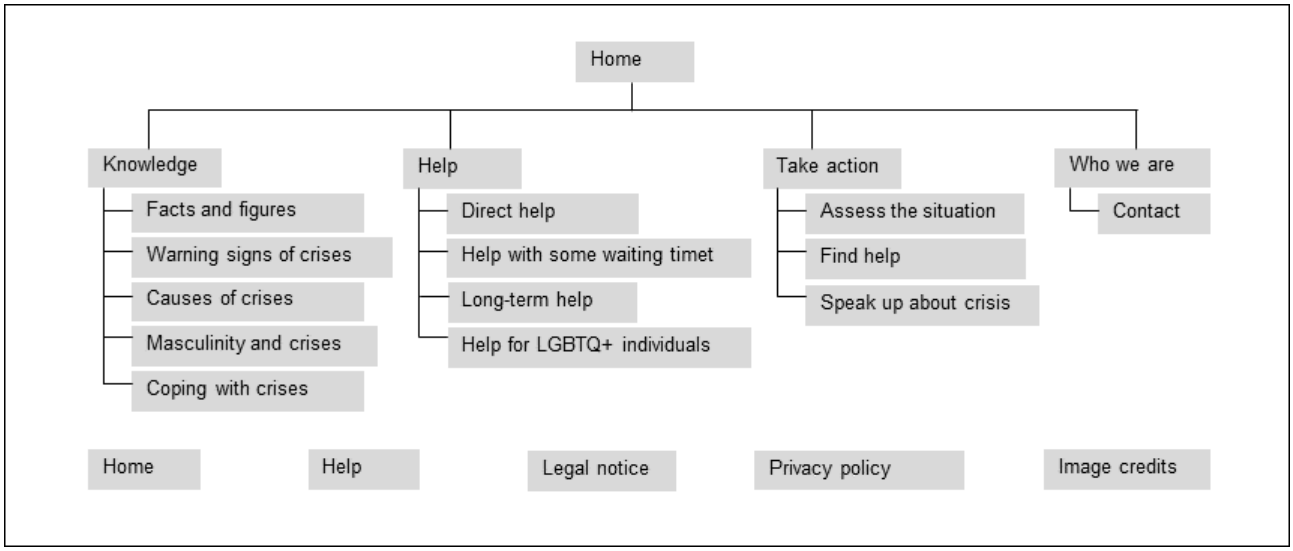
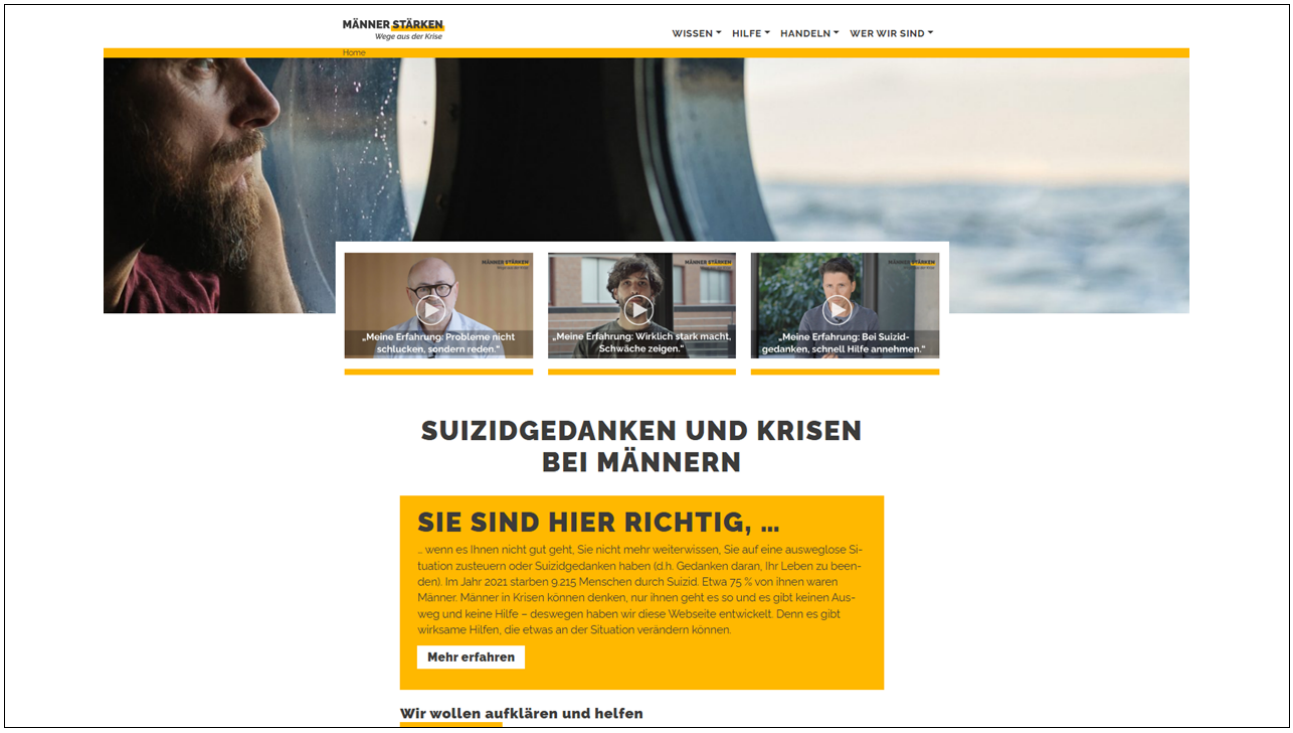


Figure 2. Homepage of the website [17].



This study examines the extent to which the website and its content achieved its goals based on three research questions:

1. How is the website accessed (number of visits and page views)?
2. Is the site perceived as helpful, and can it encourage men to seek help?
3. Does a short film on suicide prevention increase the intention to seek help?

Methods

The study combines quantitative web analytics and survey data with a qualitative analysis of open-ended responses from a feedback form to address the above questions.

Ethical Considerations

Ethical approval was granted by the ethics committee of the Medical Faculty of Leipzig University (365/21-ek). Participants in the short film study were informed at the outset about the study content, procedures, voluntariness, and data protection, and provided informed consent. Participants received compensation of €8.00 for their participation. The individuals appearing in the videos on the website have given their consent for the videos to be published.

Website Access

Matomo [33], a web behavior analysis tool, was installed to study the website usage by collecting data on user behavior. Specifically, it records, among other things, when a visitor accesses the site, which subpages are visited, how much time

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is spent on each subpage, and from which subpage the visitor exits the website. For both practical use and data protection reasons, it was important to ensure the anonymity of website visitors. Therefore, Matomo was used as the data collection method, as it prevents the unique identification of individuals and removes the requirement for a cookie banner. This study examines the number of visits and how visitors used individual subpages from March 1, 2023, to December 31, 2024.

Feedback on Helpfulness and Encouragement of Help-Seeking

The website includes a feedback form on 13 out of 21 subpages. The form contains the following introductory text: “Please answer the following questions. Your response will help us further develop this website. Your responses will be stored anonymously. Thank you!”. This is followed by 3 questions (“Is this website helpful to you?”, “Can this website motivate you to use support services?”, and “Do you need further information? If yes, what kind?”), each of which can be answered with “Yes,” “No,” or “Maybe.” After the last question, there is a free-text field with the note “Add ideas.”

This study analyzes feedback received via the form from March 1, 2023, to December 31, 2024. The responses to the 3 questions were analyzed quantitatively, and the responses from the free-text field were evaluated using thematic analysis [34]. Thematic analysis is a method for identifying, analyzing, and reporting patterns (themes) within qualitative data. As a first step, text segments containing substantive feedback on the website were coded. MAXQDA [35] was used for the coding process, and initial coding was conducted by CS. Subsequently, the coded texts and codes were discussed and refined through peer debriefing with HG and LS, as well as with other colleagues experienced in qualitative research. Then, they were clustered into higher-order themes. These were elaborated and substantiated based on the underlying text segments.

Change in the Intention to Seek Help

The 3 short films are documentary-style interviews without a visible or audible interviewer (“talking head”). They are testimonies. Some men describe their experiences, while other experiential accounts are fictionalized narratives drawing on experiences reported by men in interviews [27]. The protagonists are either actors or men with lived experience. They included elements recommended by Sagar-Ouriaghli et al [24] for interventions in men’s suicide prevention. One of these 3 short films, featuring a young male protagonist (approximately 25 - 30 years old), was tested in an online survey to determine its effect on the male participants’ intention to seek help.

The short film, lasting 6 minutes and 47 seconds, features an actor portraying a man who recounts how high-performance pressure and overwhelming work demands led to social withdrawal and depressive symptoms. After a breakup with his partner, he attempted suicide. He then describes seeking professional help and engaging in a recovery process marked by experiences of empathy, the rediscovery of personal strengths, and the development of new coping strategies. His narrative is accompanied by brief informational inserts on male suicidality and help-seeking behavior. The film concludes with contact details for professional support services.

G*Power software (version 3.1 [36]) was used to calculate the required sample size for the online survey seeking feedback on the film. Based on previous findings, we expected a moderate effect of the film on help-seeking intentions [37,38]. The calculation was conducted for a repeated-measures ANOVA using an effect size *d*. A correlation of 0.5 between the pre-, post-, and follow-up measurements was assumed. Statistical power was set at 0.95, and the significance level at .05. To detect the hypothesized effect, an initial sample of 43 participants was required. Considering an expected dropout rate of 25%, we aimed to recruit at least 54 participants.

Male-identified participants were recruited among students and academic networks at the University of Magdeburg between June and August 2023. A total of 64 people started the online survey on their intention to seek help. Of these, 57 completed the first phase. In the follow-up survey, 47 participants took part and were therefore included in the data analysis. Another 7 individuals were excluded from the analysis because the recorded time spent watching the short film indicated that they had not watched it, or because they did not identify as male.

The study was conducted using the online tool Social Science Survey [39]. Sociodemographic data were collected from the participants who also answered the General Help-Seeking Questionnaire (GHSQ [40,41]) before watching the short film, immediately afterward, and again 14 days later.

The 20-item GHSQ assesses self-reported intentions to seek help. It includes two 10-item scales addressing personal or emotional problems and suicidal ideation. Eight of the 20 items refer to private sources of help and 6 to professional sources. Thus, across problem types (personal or emotional problems, suicidal ideation), two subscales can be constructed for private and professional sources of help. The remaining items cannot be clearly assigned to either category (eg, “spiritual support”). Participants rated the likelihood of seeking help (eg, from a friend, doctor, or psychologist) on a 7-point Likert scale (1=extremely unlikely to 7=extremely likely). Item 10 (free-text) was excluded. Mean scores were calculated for each scale, with higher scores indicating stronger help-seeking intentions. The GHSQ demonstrates good psychometric properties. Internal consistency and test-retest reliability for the 2 problem scales were acceptable (α=.83/.70; r=0.88/0.86 [41]). Convergent validity has been shown with actual help-seeking and perceived quality of prior care. In our sample, internal consistency was α=.73 (suicidal ideation), α=.76 (private), and α=.79 (professional). The GHSQ was originally developed in English and was therefore translated for the German-speaking participants using a forward-backward translation procedure.

Before watching the film, the participants completed the Suicidal Ideation and Behavior Scale (SIBS [42]) and the 9-item Patient Health Questionnaire (PHQ-9 [43]). The SIBS comprises 6 items assessing the frequency of suicidal thoughts, intentions, reparation, and planning, rated from 1 (never) to 6 (many times every day). Two additional dichotomous (yes or no) items assess suicide attempts in the past 4 weeks and lifetime. One item on the frequency of past attempts was excluded. A sum score was

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calculated from items 1 - 6; suicide attempt items were reported separately. The SIBS shows excellent internal consistency (α=.92) and strong test-retest reliability (*r*=0.83) [42]. In our sample, internal consistency was good (α=.77). The PHQ-9 is a 9-item self-report instrument for screening and assessing depressive symptoms over the past 2 weeks. The validated German version was used [44]. Items (eg, "little interest or pleasure in doing things") are rated on a 4-point scale from 1 (not at all) to 4 (nearly every day). Total scores above 9 indicate minor and above 14 moderate-to-severe depression. The PHQ-9 is a reliable and valid instrument [43,44], with good internal consistency (α=.88). In our sample, internal consistency was α=.83.

Data analyses were conducted with the software R (version 4.3.0; R Core Team) [45] in the RStudio environment using the R package "rstatix" (version 0.7.2 [46]). To test for significant differences between measurement time points, a 1-way repeated-measures ANOVA was performed for each target variable. As a total of 4 tests were carried out, a Bonferroni correction was made by multiplying the *P* values by the number of comparisons. The reported *P* values reflect this adjustment. Prior to the analysis, the model assumptions for each ANOVA were checked. Post hoc analyses were performed using 2-tailed paired *t* tests comparing the 3 time points pairwise; here, too, *P* values were adjusted with the Bonferroni correction.

Results

Website Access

A total of 29,279 unique visits (single user session) were registered on the website via the Matomo analysis tool. Due to the degree of anonymization of visitors in the analysis tool (shortening of the IP address by the last 3 digits), it is not possible to determine how many visitors accessed the website repeatedly. For this reason, the number of visits is provided here. A visit may also involve viewing multiple subpages. The visits lasted an average of 1 minute and 35 seconds. On average, 2.1 actions were performed per visit on the website (page views, downloads, outbound links, and internal searches). Table 1 shows the most frequently visited subpages; the average time spent on the respective subpages; the bounce rate, which describes the proportion of visits that included only that subpage (without visiting any other subpages before or after); and the exit rate. This describes how often the subpage was the last subpage visited on the website.

Table . Key metrics on website visit behavior.

Page title	Page views	Bounce rate (%)	Average time on page (h:min:s)	Exit rate (%)
Home	31.019	73	00:00:35	88
Help	3.077	68	00:00:46	29
Help—direct help	1.993	80	00:01:08	49
Knowledge—warning signs of crisis	1.375	77	00:01:10	42
Knowledge—masculinity and crisis	1.233	76	00:00:47	47
Help—help with some waiting time	1.047	79	00:01:11	45

Feedback on Helpfulness and Encouragement of Help-Seeking

During the study period, a total of 291 completed feedback forms were analyzed. There were no indications that any of these forms were completed for advertising purposes or any similar purpose. As the feedback form was completed anonymously, it is not possible to provide any information about the individuals who completed it. However, the thematic feedback in the free-text field allows cautious conclusions to be drawn about the respondents. The feedback was analyzed using quantitative descriptive statistics and qualitative thematic analysis. The number of yes-no-maybe responses to the 3 questions is shown in Table 2.

Table . Results of the feedback form on the website (N=291).

Response	1. "Is this website helpful to you?" n (%)	2. "Can this website motivate you to use support services?" n (%)	3. "Do you need further information?" n (%)
Yes	201 (69.1)	174 (59.8)	85 (29.2)
No	42 (14.4)	42 (14.4)	109 (37.5)
Maybe	48 (16.5)	75 (25.8)	97 (33.3)

A total of 69.1% (n=201) report that the website was helpful to them, and 59.8% (n=174) confirm that the website could motivate them to seek help. In total, 14.4% (n=42) answered "no" to both questions. The free-text field after the last question was used by 75 (25.8%) of the respondents to provide thematic feedback. Of these 75 thematic responses, 57 (76%) referred to a positive assessment of the website (answering either "yes" or "maybe" to questions 1 and 2) and 18 (24%) referred to a

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negative assessment of the website (answering "no" to questions 1 and/or 2). This means that 42.9% of the negative responses to questions 1 and/or 2 also provided thematic feedback. The thematic analysis of the feedback indicates that it was primarily provided by men affected by suicidality, relatives, and professionals working in psychosocial care. To maintain clarity, only an overview of the themes identified through the thematic analysis is presented below. The positive feedback (at least one of the first two questions was answered affirmatively; n=38, 50.7%) relates in particular to the importance and need for suicide prevention services specifically aimed at men. This feedback was provided by affected individuals, as well as by relatives and professionals.

One example reads:

> *I think the site is great and highly relevant. From my own experience, I know how long it can take to admit that you need help. It is incredibly important that men, too, dare to talk more about depression and suicidal thoughts...Thank you for the website and your work!...*

In addition, the following themes were identified in the data: description of personal experiences, offer to collaborate, provision of information on support services, expressions of gratitude, needs of relatives and professionals, lack of specialized support services, technical issues, and the expressed desire for more experiential reports. Example texts include: "I am experiencing a professional crisis. I have now sought help and hope to overcome this crisis soon" (description of personal experience) or "As an occupational therapist, I would need informational materials to display in the waiting room" (needs of professionals).

The focus of the negative feedback (at least one of the first 2 questions was answered negatively; n=18, 24%) was on anger and frustration or despair that individuals experience in connection with the psychosocial support system recommended on the website. In their feedback, respondents reported having negative experiences with the support system or described situations in which they did not receive support from the system despite being in need.

This is illustrated by the following example:

> *I've already tried all the support services you mentioned, but unfortunately none of them provided any relief. Sometimes I even felt stigmatized or retraumatized by therapists....The support services you mentioned are just the same old system, a revolving door that people keep ending up in...*

Some negative responses reflected differing expectations and needs among users regarding the website. While some found the amount of information overwhelming, others expressed a desire for more detailed content. The following themes were identified in the free-text responses: frustration regarding gender-inclusive language, no new information provided, unclear purpose, technical issues or requests for changes, lack of specialized support services or difficulty locating support services, and the desire for more experiential reports. Examples of text passages include the following: "Your support services do not provide any new information" (no new information) or "Please stop with the gender-inclusive language!" (frustration regarding gender-inclusive language).

Change in the Intention to Seek Help

Table 3 presents the sociodemographic characteristics of the sample (n=40). The sample is relatively young (mean age 24.53, SD 5.03 y) and shows elevated depression scores (PHQ-9), and more than one third report prior experiences with suicidal thoughts and behaviors.

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Table . Descriptive statistics of sample characteristics (n=40).

Variable	Respondents
Age (y), mean (SD; range)	24.53 (5.03; 18-44)
Gender (free-text gender identity or assigned gender at birth), n (%)	
Cis male (male, men, cis male/male)	35 (87.5)
Trans-masculine (male, trans-masculine or female)	3 (7.5)
Other (not provided, “Doesn’t Matter”/male)	2 (5)
Education, n (%)	
Still in school	1 (2.5)
Finished secondary school	3 (7.5)
Qualification for university entrance	28 (70.0)
University degree	8 (20.0)
Occupation, n (%)	
Secondary school student	1 (2.5)
Apprentice	2 (5)
University student	34 (85)
Employee	3 (7.5)
Participants with elevated PHQ-9[a] scores, n (%)	
Moderate depression (PHQ-9=10 - 14)	9 (22.5)
Moderate severe depression (PHQ-9=15 - 19)	3 (7.5)
PHQ-9 score, mean (SD)	7.36 (4.43)
Participants who attempted suicide, n (%)	
In the last 4 weeks	0 (0)
Lifetime	5 (12.5)
Participants with SIBS[b] score >0, n (%)	14 (35)

[a]PHQ-9: 9-item Patient Health Questionnaire.

[b]SIBS: Suicidal Ideation and Behavior Scale.

The intention to seek help, in the case of suicidal ideation ($F_{1.49,58.16}$=10.51; P_adjusted=.002) as well as in the case of a personal problem ($F_{2,78}$=9.50; P_adjusted=.001), increased significantly. This significant increase in the intention to seek help was also evident at follow-up. The same applies to the intention to seek professional help ($F_{2,78}$=11.20; P_adjusted<.001). There was no significant increase in the intention to seek help from private sources directly after watching the film or at follow-up ($F_{1.74,67.93}$=4.56; P_adjusted=.72). The exact data of the analyses can be found in Figure 3 and Table 4.

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Figure 3. Boxplots of the intention to seek help (General Help-Seeking Questionnaire [GHSQ] scores) by measurement time points. ns: nonsignificant. ***P*<.01, ****P*<.001.

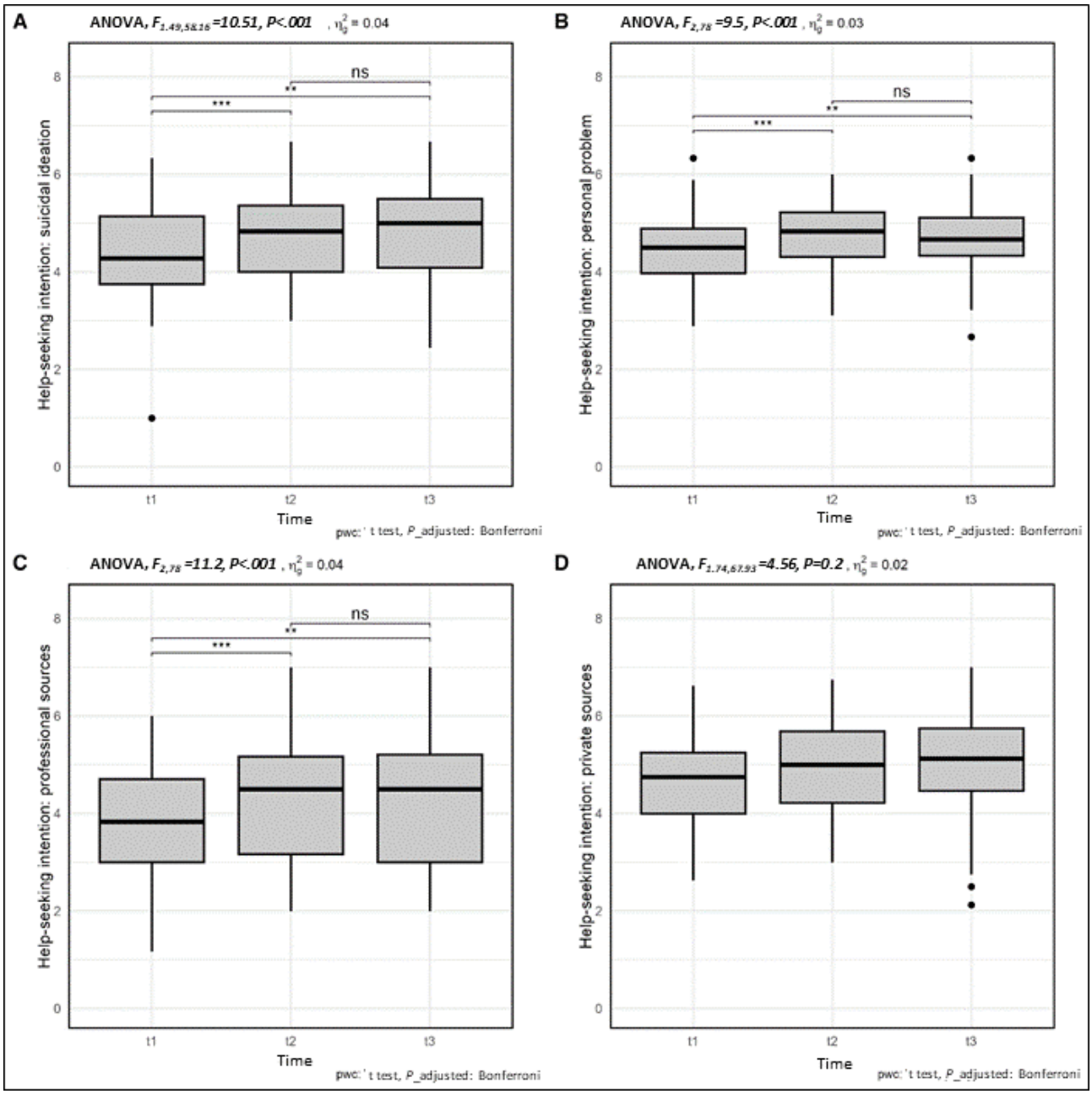

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Table . Post hoc tests for intention to seek help before and immediately after watching the film as well as 2 weeks later.

Outcome	Paired *2*-tailed *t* test (t_1-t_2)					Paired 2-tailed *t* test (t_1-t_3)			
	$Mean_{t1}$ (SD)	$Mean_{t2}$ (SD)	$Mean_{diff}$	*P*_adjusted	*d*	$Mean_{t3}$ (SD)	$Mean_{diff}$	*P*_adjusted	*d*
GHSQ[a]									
Suicidal ideation	4.34 (1.03)	4.75 (0.93)	0.41	<.001	0.67	4.80 (1.03)	0.46	.006	0.52
Personal problem	4.42 (0.70)	4.70 (0.76)	0.28	<.001	0.71	4.72 (0.84)	0.30	.005	0.54
Professional subscale	3.82 (1.12)	4.30 (1.28)	0.48	<.001	0.72	4.36 (1.34)	0.54	.002	0.59
Private subscale	4.66 (0.89)	4.95 (1.01)	0.29	.72	—[b]	4.95 (1.21)	0.29	—	—

[a]GHSQ: General Help-Seeking Questionnaire.

[b]Not applicable.

Discussion

Principal Findings

Online services are extremely important in suicide prevention, especially for target groups that are hard to reach, like men [47-49]. Websites can be accessed anonymously, from any location and at any time. The website [17] is the first suicide prevention website for men in Germany. It was developed with consideration of the limited research on how to effectively address men in online settings to prevent suicide. In line with a participatory approach, men with lived experience were actively involved in the development process. This exploratory study combines quantitative web analytics and survey data with a qualitative analysis of free-text responses to examine the extent to which the website achieves its primary objectives: encouraging men at risk of suicide to seek help, providing information, and reducing stigma. This study builds upon the investigation by Reifegerste et al [22], who demonstrated through qualitative interviews that the videos on the website [17] were perceived by men as engaging, clear, and empathetic. However, they were also considered too lengthy for a brief introduction. The balance between emotional and informational content was regarded as appropriate and supportive. Furthermore, the health information provided was viewed as credible and trustworthy.

In the period under review, the website received almost 30,000 visits. The information from the feedback form indicates that the website's target groups (affected men, relatives, and professionals working in psychosocial care) were reached. The number of visits is difficult to interpret, as very few studies report usage figures for prevention websites [50], and therefore, no comparative data are available. Moreover, no conclusions can be drawn about the number of unique visitors based on the number of visits. Due to data protection requirements and the protection of anonymity, individual visitors cannot be identified using the web analytics data. If it is assumed that some visitors accessed the website multiple times, the number of unique visitors is likely to be lower than 30,000. An analysis of the thematic subpages accessed shows that the help pages (short-term and medium-term support) were visited most frequently, as well as pages addressing gender-specific topics (warning signs in men and masculinity in the context of crises).

The 291 responses submitted via the form on the website show that the majority of those who completed the form rated the service as helpful, encouraging them to seek help. The thematic feedback clearly emphasizes the high demand for suicide prevention services specifically tailored to men, while also highlighting the lack of such services to date. In addition to the positive feedback, 15% (n=42) of the respondents indicated that they did not find the website helpful and did not feel motivated to seek help. This substantial proportion may reflect several factors. Certainly, a website that primarily serves as a first point of contact and provides only information, insights into others' experiences, and links to support services may not be the right resource for some men in (suicidal) crises. These individuals may require other forms of support, counseling, or therapy, which can be tailored to their individual needs. It should also be considered that the website targets a highly heterogeneous group—"men"—without differentiating between specific subgroups, such as age groups, minority groups, or other demographic characteristics. Consequently, many diverse perspectives and needs may not be directly addressed on the website and are instead generalized for the "majority." This could also contribute to some visitors feeling that the website does not adequately speak to them. In addition, the negative feedback provided through the feedback form points to issues of trust and frustration in dealing with the support system and its professionals, a concern also reflected in the literature [51]. Approximately 1 quarter (n=75, 25.8%) of the completed feedback forms contained entries in the free-text field. This high proportion of substantive contributions suggests that the website encouraged visitors to actively engage with the topic and share their perspectives. At the same time, it must be noted that, as described above, it is not possible to determine who completed the form or whether individuals may have submitted feedback more than once.

The investigation of the use of the website and the feedback via the form on the website are primarily descriptive in nature. On the one hand, they offer a high degree of realism (external validity), as they capture actual use and authentic feedback from

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real visitors. On the other hand, they do not take place under controlled conditions (low internal validity) and therefore do not permit reliable conclusions about the target group, impact, related factors, and so forth.

The study also examined the effect of a short suicide prevention film—also available on the website—on men's intentions to seek help. The short film portrays a young man describing the positive outcomes of seeking help after a suicidal crisis. The results showed that immediately after watching the short film, the intention to seek help increased significantly, both for suicidal thoughts and for personal problems. The intention to seek help from professionals also increased. The short film on suicide prevention thus has the desired effect. It was also shown that this significant increase in the intention to seek help remained even 14 days later (follow-up). However, the study also shows that there was no increase in the intention to seek help from friends and family. Since the film explicitly focuses on professional support rather than help from friends and family, this effect appears consistent with the content of the film.

The results are in line with previous studies showing that media narratives about overcoming crises can positively influence help-seeking behavior [15,29,32,37,52]. In addition, our study contributes to the still limited but growing body of research indicating that gender-specific approaches—particularly those incorporating male role models and addressing gender-specific aspects of suicide—have the potential to increase men's willingness to seek professional help [15]. Finally, it should be emphasized that this study measured only the intention to seek help, not actual help-seeking behavior. Although such intentions are regarded as reliable indicators of later behavior [41], the direct measurement of future help-seeking behavior was not part of the study design.

Limitations

There are limitations to this study that need to be acknowledged. In particular, a potential selection bias may limit the generalizability of the findings and may also lead to an underestimation or overestimation of the effects. The sample for the film study was predominantly young, consisting mainly of university students (see Table 3). Studies indicate that age and education influence help-seeking intentions in the context of mental health crises in different ways. Zhao et al [53] demonstrated in their review that help-seeking intentions are relatively high among university students. Mackenzie et al [54] further found that older populations with higher levels of education exhibited stronger help-seeking intentions than younger individuals. In addition, the sample studied had a rather high load in terms of depression and suicidality, indicating that the topic of suicide prevention may be relevant to them. However, not all study participants exhibited such levels of burden, which may also have influenced the results. Stas et al [20] demonstrated that among men reporting mental health problems, a suicide prevention website led to increased openness to communication and emotional expression. Further studies should investigate whether the increase in help-seeking intentions can be observed independently of levels of psychological distress.

While even small increases (d=0.52-0.72; Table 4) in help-seeking intentions could be clinically and preventively significant, as they may lead to earlier engagement with professional support, the results must be interpreted with caution regarding their clinical and preventive relevance. On the one hand, no reliable cut-off exists to determine whether the intention to seek help is present or absent. On the other hand, the limitations described regarding the generalizability of the findings must also be taken into account. To confirm the effects found on the intention-enhancing effect of the film or to extend them to other films with a similar content structure, further large-scale studies with more diverse populations are required. In both the examination of the film and the analysis of the content-related feedback, the small sample sizes limit the generalizability of the findings. Another important limitation is the absence of a control group. Without a control group, causal conclusions cannot be drawn; the findings should be replicated in future randomized controlled trials.

Conclusion

In summary, the findings of this study suggest that the website has been well received by the target group and is effective with respect to its stated objectives. These findings complement existing evidence by Till et al [55], which demonstrates knowledge gains through suicide prevention websites and suggests a reduction in suicidal ideation among vulnerable groups. The short film, in particular, may serve as an easily disseminated and cost-effective approach to suicide prevention in men. Potential applications extend beyond the website, for example, through high-reach social media channels. As the qualitative interview results by Reifegerste et al [22] have shown, shortened versions of the film could also be used in this context. However, to examine the effectiveness of these gender-specific, suicide-preventive media and website content more closely, considerably more research—particularly randomized controlled trials studies—is needed. The website and this study provide starting points for further research and campaigns that specifically address the high suicide risk among men. The high number of men who die by suicide each year worldwide underscores the urgent need for such approaches to gender-specific suicide prevention.

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responsibility for the content of the publication. GAI tools are not listed as authors and do not bear responsibility for the final outcomes.

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Data Availability

The data generated and/or analyzed during this study are not publicly available because this is not specified in the study participants' consent forms. The data are available from the corresponding author upon reasonable request.

Authors' Contributions

CS and HG wrote the main manuscript and conducted the analyses related to the website. GD designed and conducted the evaluation study of the short film, analyzed the data, and drafted the corresponding sections of the manuscript. LS supervised and critically reviewed the study. All authors reviewed and approved the final manuscript.

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Abbreviations

GHSQ: General Help-Seeking Questionnaire
PHQ-9: 9-item Patient Health Questionnaire
SIBS: Suicidal Ideation and Behavior Scale

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Evaluation of GPT-5 in Periodontitis Staging and Grading: Retrospective Observational Study

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Abstract

Background: Periodontitis is a chronic gum disease affecting approximately 42% of adults aged 30 years and older in the United States. Training dental students to accurately diagnose and manage periodontitis is a critical component of dental education and clinical care. Recent advances in large language models offer new opportunities to support both domains, yet their performance in periodontal diagnosis remains largely unexplored, particularly for newer models such as GPT-5.

Objective: This study conducted an exploratory evaluation of GPT-5's ability to stage and grade periodontitis.

Methods: A total of 25 publicly available clinical cases explicitly reporting periodontitis stage and grade were identified through Google and PubMed searches. Each case description was entered into GPT-5 using a zero-shot prompting approach to assess guideline-based reasoning without exemplar conditioning. The model's predictions were compared with the published reference diagnoses. Performance was measured using accuracy, 95% CI, unweighted Cohen κ, and weighted Cohen κ.

Results: Across these cases, GPT-5 showed marked class-dependent performance and a tendency to overestimate disease severity. Grading performance was notably imbalanced, with high recall for grade C but substantially lower discrimination for grade B. GPT-5 achieved a staging accuracy of 68% (95% CI 48.4%-82.8%) and a grading accuracy of 77.3% (95% CI 56.6%-89.9%), with corresponding Cohen κ values of 0.454 (95% CI 11.0%-75.6%) and 0.179 (95% CI −15.8% to 63.8%), respectively. While staging performance showed fair agreement beyond chance, the low κ for grading indicates poor agreement and limited reliability in distinguishing periodontal disease severity.

Conclusions: These findings suggest that although GPT-5 demonstrates potential for guideline-based periodontitis staging and grading, its current diagnostic performance, particularly for periodontitis grading, limits its use in clinical assessment and educational training. Meaningful application in periodontal diagnosis and training will require substantial improvements in reliability and rigorous validation in larger, more diverse, and prospectively collected datasets.

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KEYWORDS

large language model; ChatGPT; GPT-5; dental care; dental education; periodontitis; periodontitis staging and grading

Introduction

As the demand for accessible, accurate, and cost-effective resources to support dental care and education continues to grow, large language model (LLM)–based chatbots, such as ChatGPT [1], have emerged as potentially useful tools. Although not originally developed for dental and health care applications, these systems can generate humanlike responses with remarkable accuracy on many health-related topics [2-8], offering new opportunities for disease surveillance, biomedical research, and education.

Compared with traditional resources, LLMs offer distinct advantages for education and diagnostic support, including lower cost, continuous availability without the need for appointments, good accuracy for many diseases and conditions, customizable interactions, and user-friendly interfaces. As a result, people increasingly turn to them for medication information, self-diagnosis, and disease prevention guidance [9-12]. Clinicians, dental students, and medical students also

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use them to acquire knowledge and support clinical decision-making [13,14].

A growing body of research has examined LLMs' use in dental care and education [5,15-18]. Several benchmark studies have demonstrated LLMs' competitive performance on the American Academy of Periodontology in-service examination [6], the United States Medical Licensing Examination [2,7], and other major assessments [1,3,8]. In an educational study involving 77 second-year dental students, those who used LLMs for learning assignments were found to perform better on knowledge examinations than peers relying on traditional methods [19]. Furthermore, Rahad et al [5] showed that ChatGPT excelled in recognizing and correcting specialized dental terminology and achieved 66.7% accuracy in extracting and synthesizing information from documents. In the clinical context, Tastan Eroglu et al [4] evaluated ChatGPT-3.5 on 200 untreated periodontitis cases and reported moderate performance for staging and grading.

Despite these advances, critical gaps remain. Most prior studies used nonpublic datasets, limiting the reproducibility of their findings. Moreover, given the continual iteration and rapid improvement of LLMs, earlier assessments may not accurately reflect the capabilities of newer models such as GPT-5, released in August 2025, whose performance in dentistry has not yet been systematically evaluated. Evaluation of LLMs in high-stakes dental clinical contexts is essential to establish quality control mechanisms, mitigate risks of inaccurate or biased outputs, and guide their safe adoption into dental education and care.

An important component of dental education and care is training students to diagnose and manage periodontitis, a chronic gum disease affecting approximately 42% of adults aged 30 years and older in the United States [20]. Periodontitis staging (I-IV) reflects disease severity and extent based on levels of destroyed tissues, including gingival attachment and alveolar bone, while grading (A-C) estimates the rate of progression and future risk [21-23]. Even with explicit and standardized criteria for staging and grading [21-23], clinical diagnosis of periodontitis remains challenging and context dependent, requiring careful integration of radiographic evidence, periodontal charting, and patient-specific risk factors. An LLM capable of accurately analyzing, staging, and grading clinical periodontitis cases could serve as both a valuable diagnostic aid for clinicians and a useful educational resource for students. To address this need, we conducted an exploratory evaluation of the performance of the newly released GPT-5 in staging and grading periodontitis cases.

Methods

Case Identification and Data Collection

This study was conducted as an exploratory, case-based evaluation of GPT-5's diagnostic performance in periodontitis staging and grading. The unit of analysis was publicly available published clinical case descriptions rather than individual patients; thus, no clinical intervention or participant recruitment was involved. Standardized textual prompts were submitted to GPT-5, and the resulting categorical outputs were compared against the reference diagnoses reported in the source publications. The scope was strictly limited to assessing model-level diagnostic agreement and did not include evaluation of uncertainty calibration, triage behavior, clinical implementation, feasibility, or user acceptability.

We identified dental clinical cases by searching Google and PubMed in August and September 2025 using the keywords "periodontitis," "staging," and "grading." PubMed processes such queries through its automatic term mapping system, which searches across Medical Subject Headings (MeSH) terms and text fields. In contrast, Google search results are dynamic, not field restricted, and were accordingly used to supplement PubMed retrieval. These searches targeted peer-reviewed articles, case reports, and publicly available teaching materials that explicitly described periodontitis staging and grading according to established clinical criteria.

All records retrieved from the searches were screened manually. Review articles; duplicate records; and reports lacking complete staging or grading diagnoses, sufficient periodontal clinical descriptions, or adequate medical and dental histories were excluded. Records that did not provide sufficient quantitative or descriptive information to independently determine stage and grade under the 2017 World Workshop criteria were also excluded. After screening, 25 (48%) cases were retained from a total of 52 identified records. The workflow for data collection and case selection is illustrated in Figure 1.

Most of the public cases collected included panoramic and periapical radiographs, which, together with patients' dental histories and periodontal charting, play a central role in diagnosis. In these cases, the radiographs had already been systematically evaluated by the original authors, and numerical measures of the bone loss were extracted and reported in their publications. We manually extracted these clinically meaningful data from the publications and used them directly in our assessments. Radiographic images themselves were not used in our analyses.

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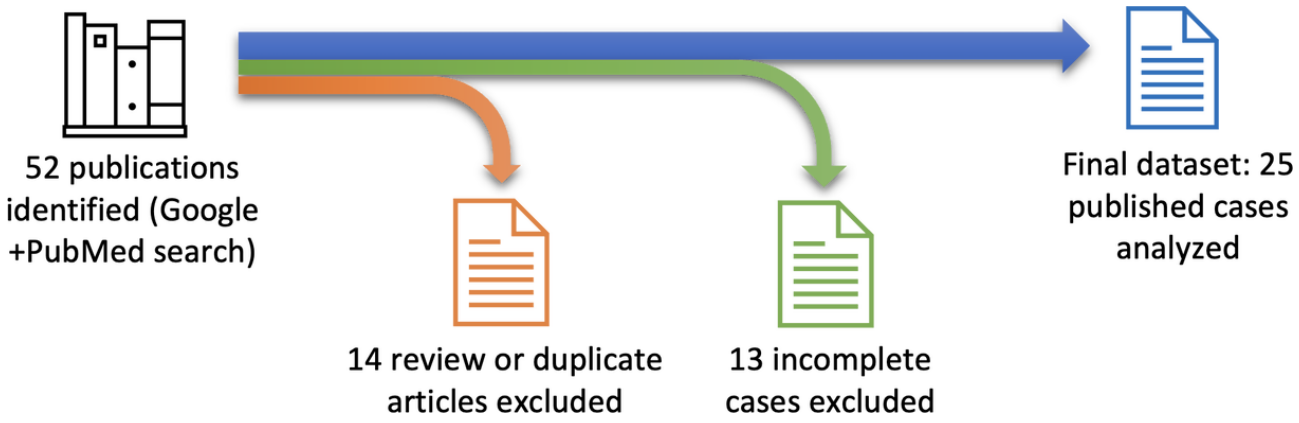
Figure 1. Data collection and case selection workflow.



It is important to note that publicly available and teaching-oriented cases, which are often unusually well documented and may not fully reflect the spectrum of routine clinical presentations, may introduce selection bias and limit generalizability. As a result, the GPT-5 performance observed in this exploratory study should be interpreted cautiously and may not reflect real-world diagnostic performance. These limitations are discussed in greater detail in the Discussion section.

GPT-5 Prompting and Evaluation

While GPT-5 can process multimodal data, we used only its interactive textual interface. All analyses were conducted between September 1 and 12, 2025, using the free GPT-5 version, without any paid enhancements. GPT-5 was accessed through its publicly available interactive interface, which does not permit user control over system-level parameters such as temperature and system prompts. Therefore, all interactions were conducted using the default system configuration (temperature=1.0).

Given GPT-5's demonstrated accuracy and reasoning improvements over earlier models [24], and because the criteria for periodontitis staging and grading outlined in the 2017 World Workshop are strictly guideline based [21-23], we adopted a zero-shot prompting strategy. This approach evaluates GPT-5's ability to apply explicit clinical thresholds and decision logic without exemplar conditioning. In contrast to few-shot prompting or fine-tuning [25-27], which may introduce anchoring effects or label leakage, zero-shot prompting provides a more conservative and transparent assessment of model reasoning. This design was intentionally selected to evaluate GPT-5's intrinsic application of guideline-based criteria without exemplar-based calibration.

Using zero-shot prompting, case descriptions were submitted directly to the model without examples or prior instructions, and GPT-5 was asked to return predictions of periodontitis stage and grade. Categorical outputs were recorded exactly as generated, and diagnostic reasoning text was not scored. Each case was processed independently, with no feedback incorporated across cases. Before submission, case descriptions were lightly reformatted to correct line breaks and formatting artifacts introduced during PDF extraction to improve readability. No clinical content was added, removed, reworded, or reorganized. An example prompt and model response are provided in Multimedia Appendix 1.

To assess response stability, each case was tested in multiple sessions using slight variations in prompt phrasing (eg, "Can you help determine the periodontitis stage and grade of this patient?" or "Please stage and grade the periodontitis of this patient"). The model consistently generated identical predictions, regardless of prompt phrasing or session timing, indicating stable behavior at the decision level under these conditions. For the final analyses reported in this study, we used a standardized prompt, "Please stage and grade the periodontitis of this patient," followed by the corresponding clinical case description.

Data collection and analysis were conducted by 7 domain experts, all of whom are coauthors of this study. The team included a dental student, a medical student, a mathematician, 2 professors from the School of Dentistry, and 2 professors from the School of Medicine at Meharry Medical College. Their responsibilities included extracting clinical cases from publications, developing prompts for GPT-5, and verifying the model's responses.

Performance Metrics

GPT-5 predictions were compared against published ground-truth diagnoses reported in the original case sources. The primary outcomes were staging accuracy, grading accuracy, and agreement beyond chance, quantified using unweighted Cohen κ. Because staging (I-IV) and grading (A-C) represent ordinal categories, weighted Cohen κ was additionally calculated using the R package irr (version 0.84.1) to account for partial agreement across adjacent categories.

We calculated 95% CIs for accuracy (Wilson method) and κ statistics (bootstrap resampling, 2000 iterations). To address potential class imbalance, macro-averaged F_1-scores and balanced accuracy were computed. In addition, confusion matrices were analyzed to characterize error patterns, including adjacent-category misclassification and directional bias (overestimation vs underestimation). All data analyses were conducted in R (version 4.3.3), and visualizations were generated using the R package ggplot2 (version 3.5.1).

Ethical Considerations

This study used publicly available, published clinical cases and did not involve human or access to protected health information.

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Only deidentified textual case descriptions were submitted to GPT-5; no patient images, radiographs, protected health information, or identifiable data were entered into or transmitted through the external LLM platform. Case materials were reviewed before submission to confirm the absence of identifiable information. Because this study involved only publicly available, deidentified materials and did not involve human participants, it does not constitute human subjects research and, therefore, does not require institutional review board approval. Accordingly, informed consent was not required and participant compensation is not applicable. Prompts and outputs were stored on secure, password-protected institutional computers accessible only to the research team. This study was designed and reported according to the Standards for Reporting Diagnostic Accuracy (STARD) and STARD-AI principles [28,29], and a completed checklist is provided in Checklist 1.

Results

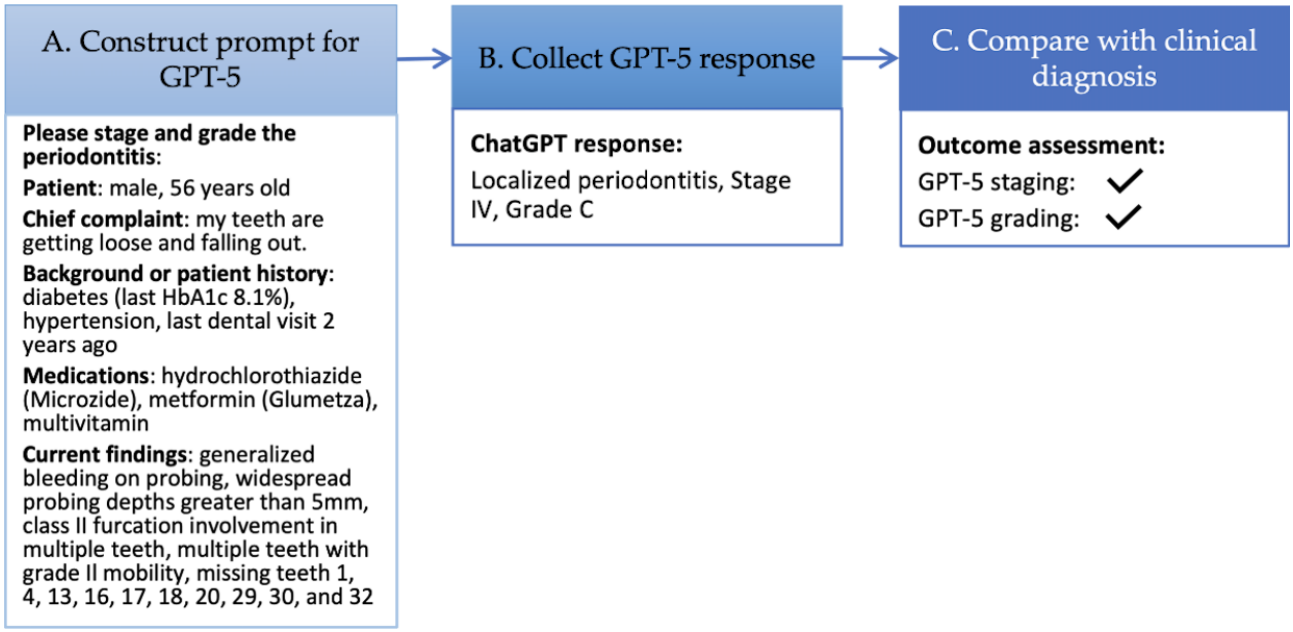
Description of Periodontitis Cases

Of the 25 periodontitis cases collected for evaluating GPT-5, 2 (8%) were borderline cases with staging ambiguities between stage III and stage IV, and 3 (12%) provided only staging information in the original publications. Full case descriptions and corresponding sources are provided in Table S1 in Multimedia Appendix 1. The median age of these patients was 45 (IQR 35-56) years, with most cases (17/25, 68%) occurring between 35 and 64 years. There were 3 participants aged 5-19 years, 4 aged 20-34 years, 9 aged 35-49 years, 8 aged 50-64 years, and 1 aged 65-80 years. Female participants comprised the majority (n=18, 72%), while male participants accounted for 28% (n=7) of the cohort. In terms of disease severity, stage III periodontitis was most common (n=14, 56%), followed by stage IV (n=9, 36%), stage II (n=1, 4%), and stage I (n=1, 4%). For grading, most cases were classified as grade C (n=17, 77%), with smaller proportions in grade B (n=5, 23%).

Workflow for Evaluating GPT-5

Figure 2 illustrates the workflow used to assess GPT-5. For each dental clinical case, we applied a zero-shot prompting approach (Figure 2A [30]), in which patient information and clinical details were extracted from publications and lightly reformatted to correct formatting artifacts introduced during PDF extraction for GPT-5 input. An example prompt for a male patient aged 56 years is provided in Figure 2A.

Figure 2. Framework for evaluating GPT-5 performance in periodontitis staging and grading. (A) A prompt was constructed from a publicly available case [30], with minor formatting adjustments (eg, line breaks and spacing) to improve readability for the model while preserving the original content. (B) GPT-5 generated categorical outputs for periodontitis stage (I-IV) and grade (A-C). (C) Model predictions were compared with the clinical reference diagnoses reported in the original publication to assess accuracy.



The prompt was then submitted to GPT-5, which was asked to determine the stage and grade of periodontitis. The model's response was collected (Figure 2B), recording only the predicted stage and grade while disregarding the diagnostic reasoning. The output was compared against the clinical diagnosis to evaluate accuracy (Figure 2C).

After all cases were processed, GPT-5's predictions were aggregated, and performance metrics were calculated to summarize its diagnostic accuracy and Cohen κ and assess its potential use in real-world clinical settings.

GPT-5 Performance in Periodontitis Staging and Grading

Across the 25 periodontitis cases (including the 2 borderline cases), GPT-5 achieved a staging accuracy of 68% (17/25; 95% CI 48.4%-82.8%) and a grading accuracy of 77.3% (17/22; 95% CI 56.6%-89.9%), excluding 3 (12%) cases without specified grades. The corresponding Cohen κ values were 0.454 for staging (95% CI 11.0%-75.6%) and 0.179 for grading (95% CI −15.8% to 63.8%). These findings indicate fair agreement beyond chance for staging and poor agreement for grading. The relatively wide CIs for both outcomes reflect substantial

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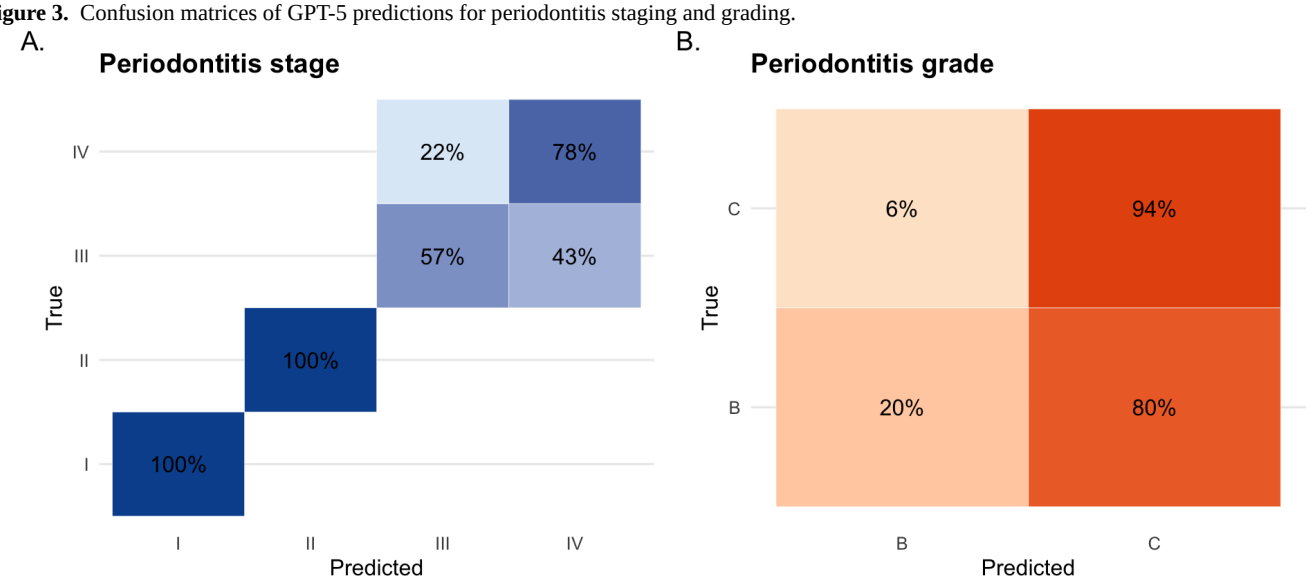
uncertainty attributable to the small sample size and class imbalance. Additional performance metrics for GPT-5, including weighted Cohen κ, balanced and stratified accuracy, and macro F_1-score, are provided in Tables S2 and S3 in Multimedia Appendix 1.

The confusion matrix in Figure 3A shows that all stage I and II cases were classified correctly (recall=100%), whereas recall was substantially lower for stage III (57%) and stage IV (78%). For grading, performance was markedly imbalanced, with high recall for grade C (94%) but very low recall for grade B (20%; Figure 3B). This class-dependent performance indicates that GPT-5 performs well for early-stage periodontitis and advanced disease detection but struggles to reliably distinguish intermediate disease categories.

Figure 3. Confusion matrices of GPT-5 predictions for periodontitis staging and grading.



Importantly, misclassifications exhibited nonrandom patterns: errors were confined to adjacent categories, with no stage I or II cases misclassified as stage III or IV, no stage IV cases misclassified as stage I or II (Figure 3A), and no "skipping" across nonadjacent categories for grading (Figure 3B). Because all errors were limited to adjacent stages and grades and no catastrophic misclassifications were observed, these patterns are clinically and educationally relevant.

Among the misclassified cases, 43% (6/14) of stage III cases were predicted as stage IV, while 22% (2/9) of stage IV cases were predicted as stage III (Figure 3A). For grading (Figure 3B), GPT-5 correctly classified 94% (16/17) of grade C cases, with most (4/5) grade B cases misclassified as grade C. These results suggest that GPT-5 tends to assign higher severity for both periodontitis stage and grade. GPT-5's predictions for the 25 cases are provided in Multimedia Appendix 1.

Table 1 and Figure 4 present contextual comparisons with 2 previous assessments. Tastan Eroglu et al [4] evaluated GPT-3.5 on 200 untreated patients and reported 59.5% accuracy in staging and 50.5% accuracy in grading—both notably lower than the performance achieved by GPT-5 on our dataset. However, this comparison should be interpreted cautiously because the datasets and evaluation protocols differ across studies. A direct head-to-head comparison was not feasible due to the unavailability of the datasets used in the previous study. The low κ values observed for both models (0.284 for GPT-3.5 and 0.179 for GPT-5) in Table 1 indicate that current LLMs have limited discriminatory ability in grading periodontitis beyond chance agreement.

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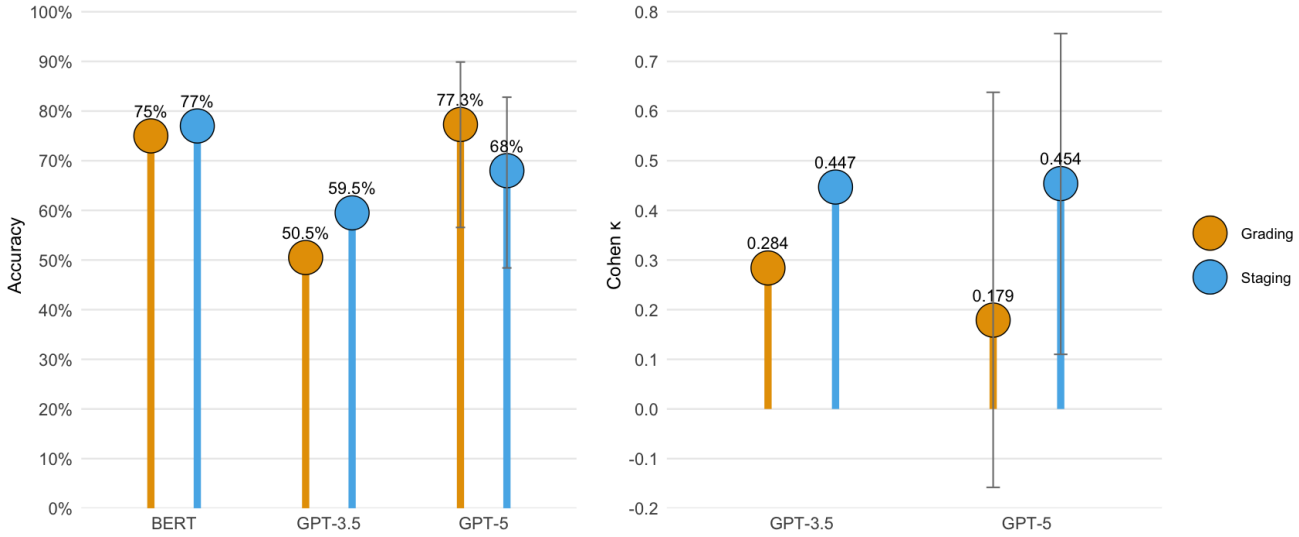
Table . Recent studies of periodontitis staging and grading using textual input.

Study	Dataset[a]	Model	Accuracy (%)		Cohen κ	
			Stage	Grade	Stage	Grade
Ameli et al [31]	309 periodontal charts and clinical notes	Bidirectional Encoder Representations from Transformers (BERT)	77	75	N/A[b]	N/A
Tastan Eroglu et al [4]	200 patients with untreated periodontitis	GPT-3.5	59.5	50.5	0.447	0.284
Our result	25 dental clinical cases from public sources	GPT-5	68	77.3	0.454	0.179

[a]The findings from the first 2 studies were extracted from published papers, while the details of our own assessment results are provided in Multimedia Appendix 1.

[b]N/A: not available.

Figure 4. Comparison of Bidirectional Encoder Representations from Transformers (BERT), GPT-3.5, and GPT-5 performance in periodontitis staging and grading. Data are derived from Table 1. Error bars indicate 95% CIs for GPT-5, calculated from case-level data from Table S1 in Multimedia Appendix 1; CIs were not reported for BERT and GPT-3.5 in the original studies.



Another study, summarized in Table 1 and Figure 4, conducted by Ameli et al [31] fine-tuned a Bidirectional Encoder Representations from Transformers (BERT) model using 309 anonymized periodontal charts and corresponding clinician notes. The model was trained on 70% of the data and tested on 32 holdout cases. The fine-tuned BERT model achieved 77% accuracy in staging and 75% in grading [31]. Although these results fall within a similar range and are presented alongside GPT-5 for contextual reference, they should not be interpreted as evidence of relative model superiority, as BERT was trained and evaluated on periodontal charts and clinician notes, whereas GPT-5 and GPT-3.5 were assessed using standardized textual case descriptions without task-specific optimization.

Discussion

Principal Findings

This exploratory study evaluated GPT-5's ability to perform periodontitis staging and grading using publicly available clinical case descriptions based on the 2017 World Workshop classification framework. Overall, GPT-5 demonstrated moderate diagnostic performance and fair agreement beyond chance for staging (accuracy 68%; κ=0.454), but substantially lower reliability for grading (κ=0.179). In addition, the model exhibited a tendency to overestimate disease severity. These findings suggest that while GPT-5 is capable of applying guideline-based diagnostic criteria, important limitations remain in its ability to reliably distinguish disease grades.

Interpretation and Implications of Findings

Although this study focused narrowly on GPT-5's performance in periodontitis staging and grading, the potential applications of LLMs extend more broadly to both clinical diagnostics and dental education. In clinical practice, LLMs could assist practitioners by consistently applying standardized staging and grading criteria, integrating charting and radiographic data, and generating preliminary assessments under appropriate clinician oversight. In education, LLMs can function as personalized learning assistants, offering structured feedback on case analyses and helping students navigate diagnostic complexity. Beyond these applications, LLM-based chatbots hold potential for reducing gaps in dental educational resources, particularly in

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underresourced institutions, thereby strengthening their capacity to deliver high-quality dental education and care.

However, the observed diagnostic agreement, particularly for periodontitis grading, highlights an important limitation. The low Cohen κ (κ=0.179) for grading indicates poor agreement beyond chance, suggesting that GPT-5 currently lacks sufficient reliability to accurately distinguish between periodontitis grades. Consequently, GPT-5 is not yet suitable for independent clinical grading or treatment decision-making, and its outputs should be interpreted with caution. In addition, in the absence of established minimum clinically important difference thresholds for artificial intelligence (AI)–assisted periodontitis staging and grading, κ=0.454 for staging should be interpreted cautiously and not as evidence of clinical readiness.

Looking forward, GPT-5 and other LLMs are likely to continue to improve diagnostic performance. Nevertheless, its meaningful clinical translation will hinge on overcoming current deficiencies in reliability and consistency. Beyond advancements in model development, a potential pathway toward high-stakes clinical and educational applications likely lies in the integration of LLMs with validated AI tools optimized specifically for clinical use. Such hybrid systems, which combine the precision of specialized diagnostic models with the reasoning, interpretability, and interactivity of LLMs, may provide more robust support for complex, multimodal clinical decision-making in dental care and education.

Limitations

Our exploratory evaluation of GPT-5 relied solely on published cases, which represent a relatively limited sample. Moreover, both the small sample size and the gender imbalance within the data may disproportionately reflect more severe or well-documented presentations, potentially inflating GPT-5's performance. In addition, publicly available case reports are often curated to highlight clear diagnostic features and may not accurately reflect the full clinical heterogeneity or noise encountered in real-world practice. As a result, such cases may underrepresent diverse patient populations and disease presentations commonly seen in routine clinical settings. Furthermore, the dataset was not constructed through a systematic review process and may, therefore, be subject to selection bias. Therefore, expanding the dataset in future studies to include larger, more diverse, and nonpublished clinical data will be essential to broaden the scope of evaluation, strengthen generalizability, and support meaningful clinical translation.

Additional methodological constraints include our use of GPT-5's interactive interface, which does not allow modification of underlying system parameters such as temperature and may therefore restrict reproducibility at the system level. In addition, we did not evaluate model stability across alternative prompting strategies, which are known to influence LLM behavior. We restricted model inputs to textual case descriptions and did not evaluate GPT-5's multimodal capabilities for direct radiographic interpretation. While this design was intended to isolate guideline-based reasoning, it does not reflect the full multimodal nature of periodontal diagnosis and, therefore, may not represent real-world diagnostic performance using raw clinical data. Furthermore, GPT-5 was required to provide categorical staging and grading outputs, and we did not assess its ability to recognize diagnostic uncertainty or defer ambiguous cases. Only 2 borderline or equivocal cases were included, which are insufficient to evaluate GPT-5's performance in diagnostically challenging scenarios where clinician disagreement is common and clinical judgment plays a critical role. Finally, performance was not tested on incomplete charts or unstructured clinical notes, which may better reflect real-world variability. Therefore, future studies should incorporate more diagnostically ambiguous cases, multimodal inputs, and heterogeneous clinical documentation and systematically compare prompting strategies to better evaluate model reliability and clinical relevance.

Finally, this exploratory study was conducted with consideration of established AI reporting guidelines, including STARD or STARD-AI [28,29], DECIDE-AI [32,33], and STROBE-AI [34]. While the exploratory design and reliance on publicly available clinical cases, rather than real-time clinical data, precluded full adherence to all framework components, key principles such as transparency in data sources, model use, limitations, and reproducibility were followed. Future prospective studies using large-scale, real-world clinical data will be better positioned to fully implement these reporting standards.

Conclusions

With the growing use of LLMs by dental and medical students, clinicians, and the general public, it is important to evaluate their performance in high-stakes diagnostic and educational settings to inform safety protocols and guide responsible applications. In this study, we assessed GPT-5's ability to stage and grade periodontitis—tasks central to periodontal diagnosis and student training. Contextual comparisons with prior models suggested comparable or improved performance, achieving 68% staging accuracy and 77.3% grading accuracy, with a staging κ of 0.454, indicating fair agreement beyond chance. However, these findings should be interpreted cautiously, as differences in datasets, case formats, and evaluation conditions preclude direct head-to-head comparisons with prior studies.

Despite these observed performances, the low κ for grading (0.179) underscores the very limited discriminatory capacity in distinguishing periodontitis grades, indicating that GPT-5 is not yet suitable for independent clinical applications. Additionally, our results demonstrated a consistent tendency for GPT-5 to overestimate disease severity. Therefore, inappropriate reliance on model outputs could increase the risk of overtreatment or unnecessary escalation of care. This highlights the importance of human oversight and the need for future evaluations of uncertainty reporting, refusal behavior, and decision-level safeguards before any clinical integration is considered.

In conclusion, while GPT-5 demonstrated potential as a supportive tool for education and clinical exploration, it is not yet ready for autonomous use. Meaningful application in periodontal diagnosis and training will depend on substantial improvements in reliability and rigorous validation in larger, more diverse, and prospectively collected clinical datasets.

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Data Availability

Data are supplied in Multimedia Appendix 1 available for download along with the published manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1
GPT-5's performance in periodontitis staging and grading on the textual input of 25 clinical cases.
[DOCX File, 60 KB - formative_v10i1e88407_app1.docx]

Checklist 1
STARD and STARD-AI checklist for reporting GPT-5 diagnostic accuracy.
[PDF File, 324 KB - formative_v10i1e88407_app2.pdf]

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Abbreviations

AI: artificial intelligence
BERT: Bidirectional Encoder Representations from Transformers

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LLM: large language model
MeSH: Medical Subject Headings
STARD: Standards for Reporting Diagnostic Accuracy

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Integrating GPT-4o Into Data Mining in Neurosurgery: Feasibility and Proof-of-Concept Study

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Abstract

Background: Large language models offer new possibilities for transforming unstructured clinical text into structured datasets. However, their performance in specialized and complex documentation environments, such as neurosurgery, remains insufficiently characterized. GPT-4o is a large language model with enhanced natural language capabilities, but its accuracy in extracting structured data from neurosurgical reports has not been systematically assessed.

Objective: This proof-of-concept study evaluated the feasibility and accuracy of GPT-4o for extracting predefined structured variables from unstructured neurosurgical reports of patients with vestibular schwannoma. Specific aims were to measure accuracy across variable types, assess the impact of prompt refinement, and explore the model's potential utility for research-oriented data mining.

Methods: In this retrospective single-center study, 10 consecutive patients with histologically confirmed vestibular schwannoma who underwent surgery between August and December 2023 were included. Four anonymized German-language documents per patient (discharge, surgical, histopathology, and 3-month follow-up reports) were processed using GPT-4o. Seventeen variables were extracted using a standardized zero-shot prompt. Targeted prompt refinements were subsequently applied for variables with low baseline accuracy. Two board-certified neurosurgeons independently validated all outputs, with discrepancies resolved by a senior neurosurgeon. Accuracy metrics, 95% CIs (Wilson method), and descriptive comparisons between variable types were calculated.

Results: GPT-4o achieved 100% accuracy for structured variables requiring minimal interpretation, including patient ID, date of birth, date of surgery, histopathological diagnosis, and World Health Organization grade. Several interpretative variables, such as symptoms at presentation, symptom type, symptom duration, extent of resection, and permanence of postoperative deficits, were also extracted with 100% accuracy. In contrast, intraoperative complications and new postoperative deficits were correctly identified in only 50% (5/10) of cases using the zero-shot prompt. After targeted prompt refinement, accuracy for these variables improved substantially, reaching 90% to 100% in most cases. The mean accuracy was highest for structured categorical variables (97.5%, SD 4.6%), intermediate for binary variables (80%, SD 27.4%), and lowest for conditional text variables (66.7%, SD 28.9%), without statistically significant differences (P=.25).

Conclusions: GPT-4o demonstrated strong feasibility for structured data extraction from standardized neurosurgical reports, particularly for variables with limited semantic complexity. However, the high accuracy observed reflects a narrow and highly controlled context and should not be interpreted as evidence of general reliability across diverse clinical settings. Larger, multi-institutional, and multilingual studies are needed to determine broader applicability and potential clinical integration.

(JMIR Form Res 2026;10:e77114) doi:10.2196/77114

KEYWORDS

artificial intelligence; AI; data mining; GPT-4o; patient privacy; automated coding; health care analytics

Introduction

The advent of artificial intelligence (AI) in health care has revolutionized data processing, decision-making, and research methodologies. Among these innovations, natural language processing (NLP) models, such as GPT-4o (released in May 2024; OpenAI), represent a significant leap in handling unstructured data. With their capacity to synthesize, analyze, and structure information, large language models (LLMs) provide a promising avenue for transforming how clinicians and researchers interact with medical records and literature.

In neurosurgery, the challenge of efficiently extracting insights from diverse and voluminous data, including imaging reports, clinical notes, and surgical documentation, is particularly pronounced. Studies have demonstrated that NLP models can bridge these gaps, optimizing both clinical workflows and research efforts [1,2]. Furthermore, by automating

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labor-intensive processes, these tools may enhance patient care, reduce costs, and streamline health care operations [3].

Despite the promise, challenges remain. Privacy concerns, data security, and the need for precise tuning of AI tools pose significant barriers to their widespread adoption [4-6]. While LLMs present remarkable opportunities, their limitations must also be recognized. Common challenges include hallucination, biases inherited from training data, and overfitting in specialized domains. These issues have historically limited their practical use in health care, highlighting the need for thorough validation and responsible implementation.

This proof-of-concept study aimed to explore the application of GPT-4o as a data mining tool in neurosurgery. Patients with vestibular schwannoma were selected because their management involves standardized documentation, including surgical, pathological, and follow-up reports. This provides a consistent and well-defined framework for assessing the capability of GPT-4o to structure complex clinical data. The approach presented here may serve as a template for future applications across other neurosurgical conditions. Specifically, we seek to evaluate the model's ability to extract and provide structured data from unstructured datasets and assess its feasibility as an aid in research environments.

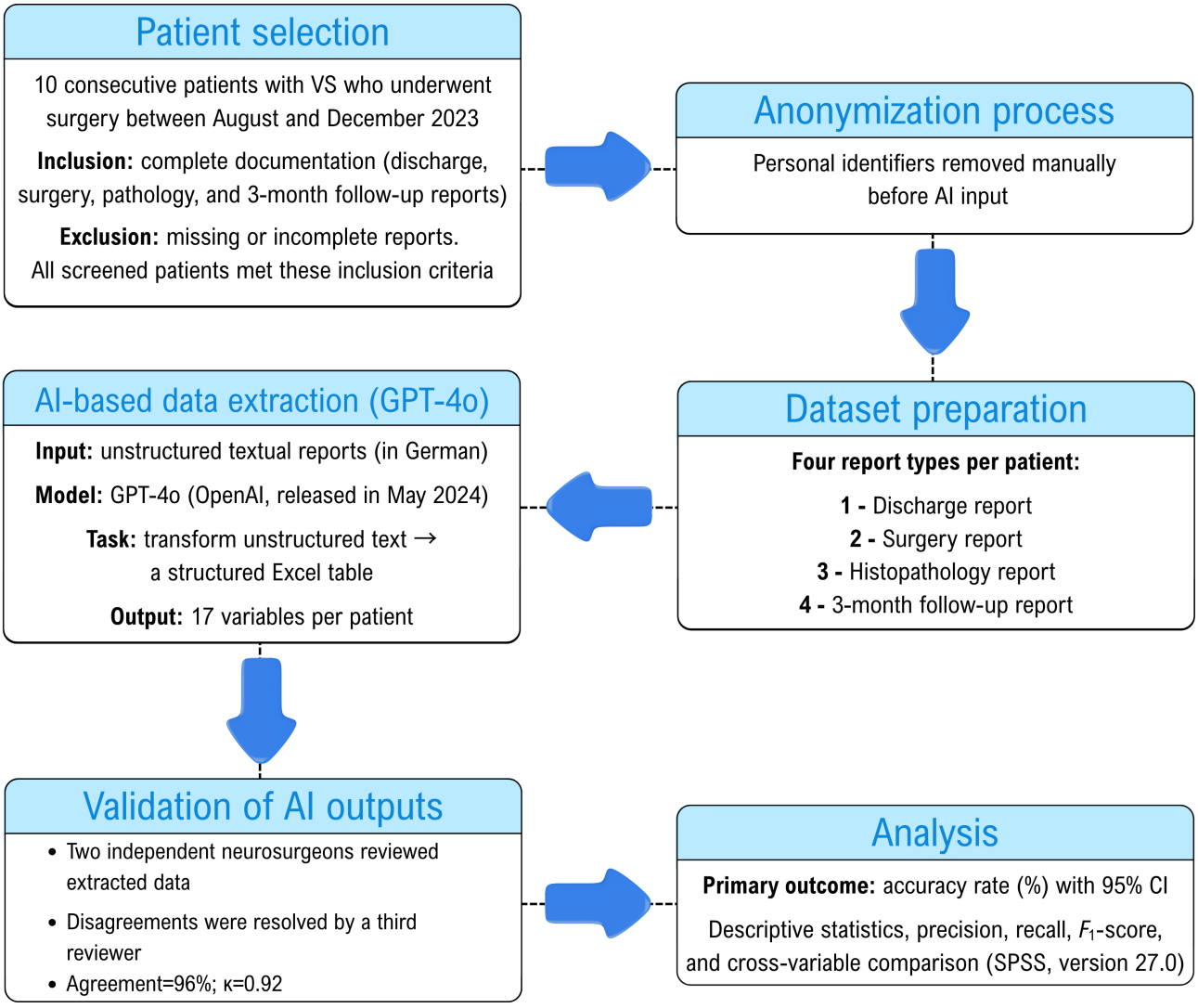
By leveraging GPT-4's NLP capabilities, we hypothesize that neurosurgical data can be extracted and structured reliably, facilitating accurate data aggregation and analysis across heterogeneous clinical reports.

Methods

Overview

This was a retrospective feasibility study conducted at a single tertiary neurosurgical center (Department of Neurosurgery at the University Hospital of Freiburg). The inclusion criteria comprised consecutive patients with histologically confirmed vestibular schwannoma who underwent surgical treatment between August and December 2023 and had complete documentation (discharge, surgical, pathology, and follow-up reports). Patients who lacked any of these reports were excluded from the analysis. Figure 1 illustrates the data flow and extraction process.

Figure 1. Workflow of data extraction and validation process. AI: artificial intelligence; VS: vestibular schwannoma.



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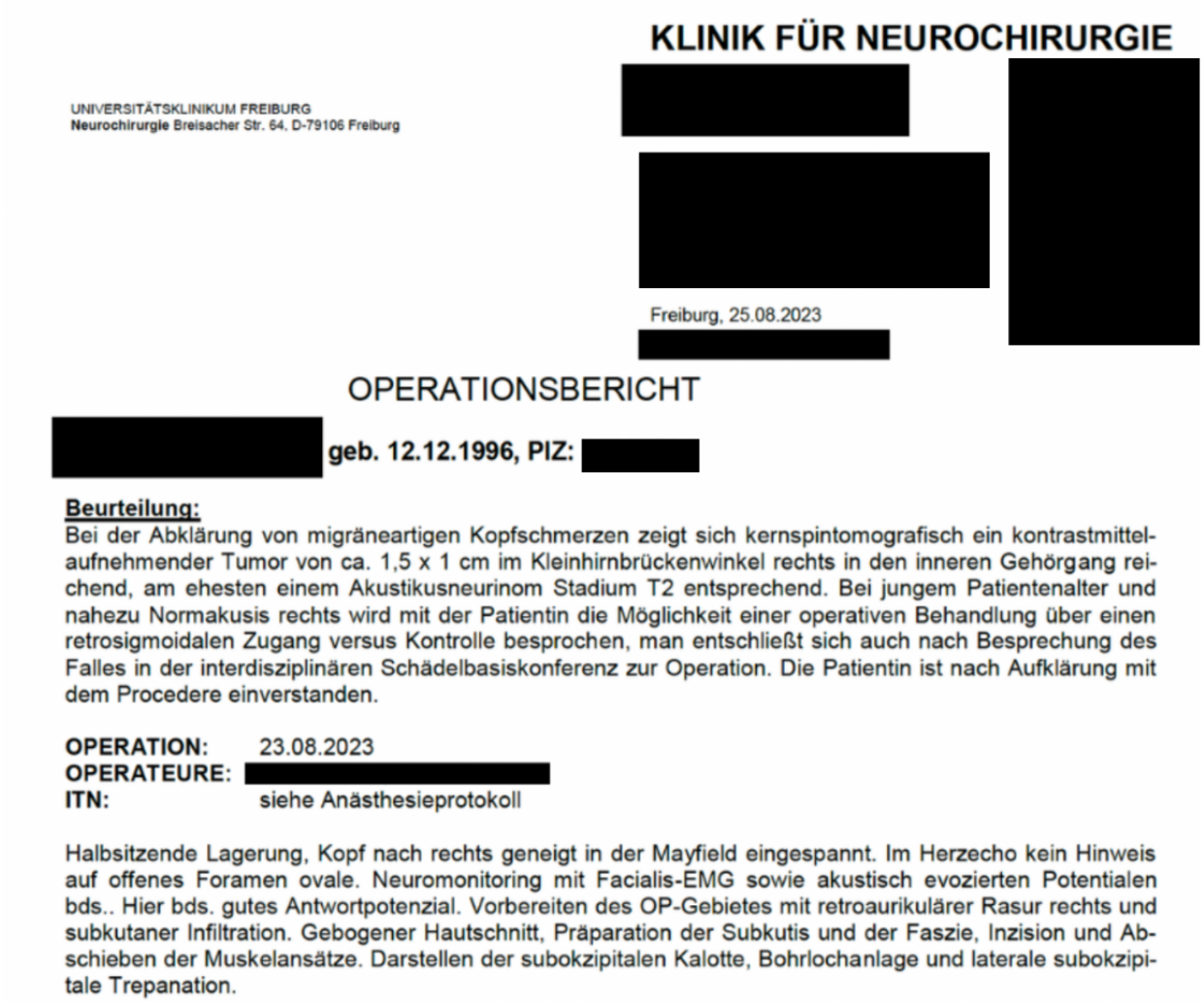
The primary outcome of the study was the accuracy rate in extracting structured information from the provided unstructured data. The ground truth for this evaluation was established by a medical team, which manually reviewed and assessed each response provided by the AI model. This ensured that the AI's performance was rigorously compared to expert human judgment.

All personal data of both patients and health care professionals that were visible in the original documents were anonymized before being processed by the AI model (Figures 2 and 3). Consequently, it was not possible to identify any individual patients from the data provided to the AI model for analysis. It is also important to note that the original language of all medical reports was German, and these unstructured data were presented to the AI model in its native form for analysis and extraction.

Figure 2. Surgical report. This surgery report was used as a raw dataset for extracting and processing unstructured data into structured data. Personal data were omitted from the artificial intelligence tool to ensure compliance with ethical standards and protect patient privacy.



KLINIK FÜR NEUROCHIRURGIE

UNIVERSITÄTSKLINIKUM FREIBURG
Neurochirurgie Breisacher Str. 64, D-79106 Freiburg

[redacted]

Freiburg, 25.08.2023

[redacted]

OPERATIONSBERICHT

[redacted] geb. 12.12.1996, PIZ: [redacted]

Beurteilung:
Bei der Abklärung von migräneartigen Kopfschmerzen zeigt sich kernspintomografisch ein kontrastmittelaufnehmender Tumor von ca. 1,5 x 1 cm im Kleinhirnbrückenwinkel rechts in den inneren Gehörgang reichend, am ehesten einem Akustikusneurinom Stadium T2 entsprechend. Bei jungem Patientenalter und nahezu Normakusis rechts wird mit der Patientin die Möglichkeit einer operativen Behandlung über einen retrosigmoidalen Zugang versus Kontrolle besprochen, man entschließt sich auch nach Besprechung des Falles in der interdisziplinären Schädelbasiskonferenz zur Operation. Die Patientin ist nach Aufklärung mit dem Procedere einverstanden.

OPERATION: 23.08.2023
OPERATEURE: [redacted]
ITN: siehe Anästhesieprotokoll

Halbsitzende Lagerung, Kopf nach rechts geneigt in der Mayfield eingespannt. Im Herzecho kein Hinweis auf offenes Foramen ovale. Neuromonitoring mit Facialis-EMG sowie akustisch evozierten Potentialen bds.. Hier bds. gutes Antwortpotenzial. Vorbereiten des OP-Gebietes mit retroaurikulärer Rasur rechts und subkutaner Infiltration. Gebogener Hautschnitt, Präparation der Subkutis und der Faszie, Inzision und Abschieben der Muskelansätze. Darstellen der subokzipitalen Kalotte, Bohrlochanlage und laterale subokzipitale Trepanation.

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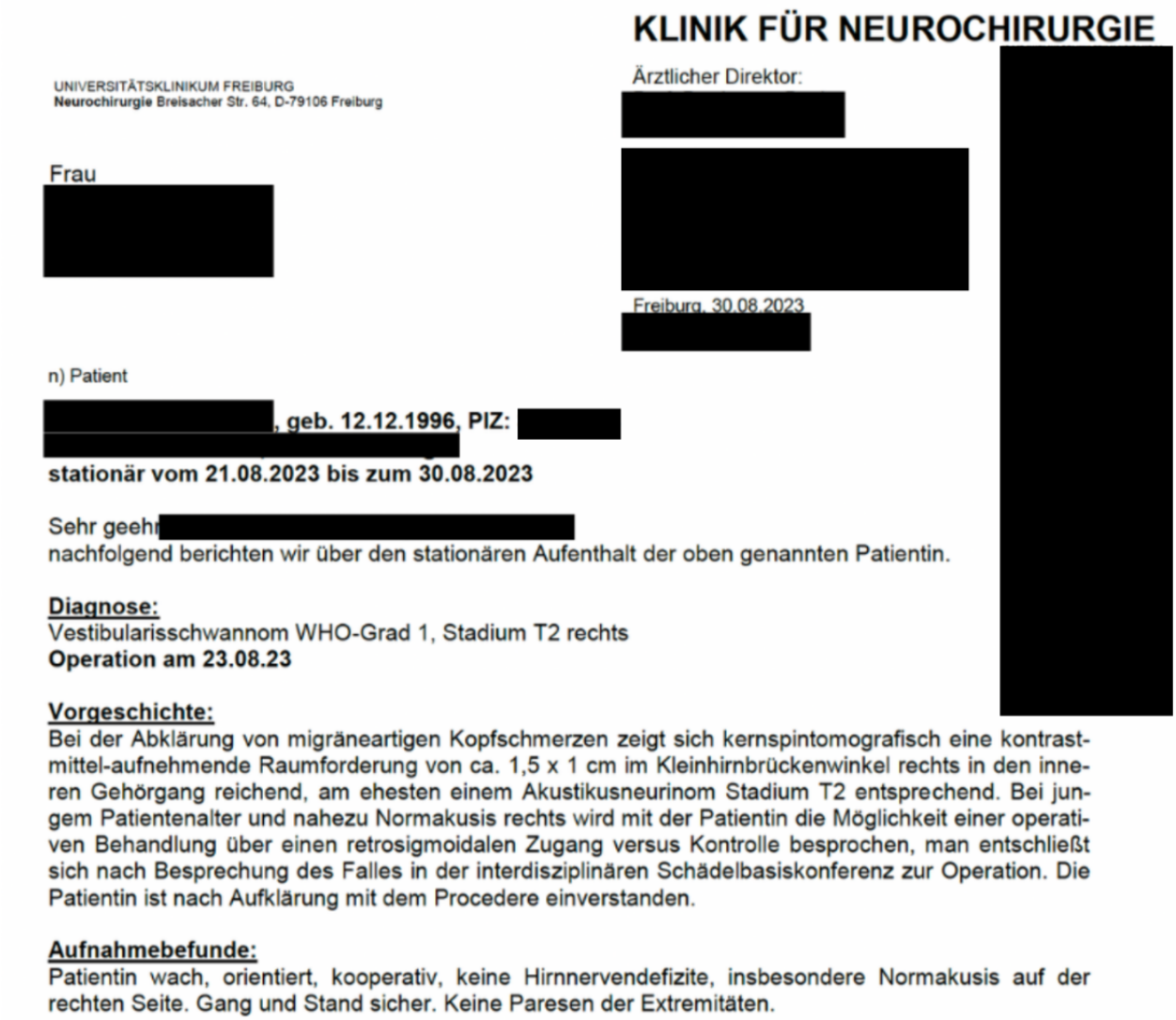
Figure 3. Discharge report. The discharge report was used as a raw dataset for extracting and processing unstructured data into structured data. Personal data were omitted from the artificial intelligence tool to ensure compliance with ethical standards and protect patient privacy.



KLINIK FÜR NEUROCHIRURGIE

UNIVERSITÄTSKLINIKUM FREIBURG
Neurochirurgie Breisacher Str. 64, D-79106 Freiburg

Ärztlicher Direktor:

Frau

Freiburg, 30.08.2023

n) Patient

, geb. 12.12.1996, PIZ:

stationär vom 21.08.2023 bis zum 30.08.2023

Sehr geehr
nachfolgend berichten wir über den stationären Aufenthalt der oben genannten Patientin.

Diagnose:
Vestibularisschwannom WHO-Grad 1, Stadium T2 rechts
Operation am 23.08.23

Vorgeschichte:
Bei der Abklärung von migräneartigen Kopfschmerzen zeigt sich kernspintomografisch eine kontrastmittel-aufnehmende Raumforderung von ca. 1,5 x 1 cm im Kleinhirnbrückenwinkel rechts in den inneren Gehörgang reichend, am ehesten einem Akustikusneurinom Stadium T2 entsprechend. Bei jungem Patientenalter und nahezu Normakusis rechts wird mit der Patientin die Möglichkeit einer operativen Behandlung über einen retrosigmoidalen Zugang versus Kontrolle besprochen, man entschließt sich nach Besprechung des Falles in der interdisziplinären Schädelbasiskonferenz zur Operation. Die Patientin ist nach Aufklärung mit dem Procedere einverstanden.

Aufnahmebefunde:
Patientin wach, orientiert, kooperativ, keine Hirnnervendefizite, insbesondere Normakusis auf der rechten Seite. Gang und Stand sicher. Keine Paresen der Extremitäten.

Prompt Design

Prompts were designed iteratively, meaning they were developed, tested, and refined to improve clarity and extraction precision. The initial zero-shot prompt served as a baseline framework for structured data extraction. On the basis of qualitative assessment of model responses, targeted refinements were introduced to better define certain variables that were prone to misinterpretation.

For example, the variable “intraoperative complications” was explicitly redefined in the prompt as “intraoperative damage to major vascular or neural structures,” and “new postoperative deficits” were clarified as “deficits developed after surgery, excluding preexisting ones.” These refinements were introduced to standardize semantic interpretation and reduce ambiguity during data extraction.

Refinement rounds continued until no further gains in extraction accuracy were observed, while ensuring that definitions of other variables remained unaffected. All prompts were executed in GPT-4o.

This prompt shown in Textbox 1 was used to generate a Microsoft Excel table with structured data extracted from medical reports written in natural language.

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Textbox 1. Prompt used to generate structured data table.

I am going to upload medical reports from a few patients, and I want you to transform the textual data (unstructured) into structured data in an Excel table. The documents are: discharge report, surgery report, histopathology report, and outpatient follow-up report from 3 months post-surgery. I want you to extract data from these documents to create a structured table where each row represents a patient and each column a variable, according to the following scheme: If the information is not present in any of the provided documents, respond non applicable (n/a). The column structure is as follows:

- Column 1: PIZ (patient identification number)
- Column 2: Date of birth
- Column 3: Date of surgery
- Column 4: Symptom present at disease presentation (yes or no)
- Column 5: If yes in column 4, specify the symptom; if no, respond “n/a”
- Column 6: Time from symptom onset to surgery (in months)
- Column 7: Intraoperative complication (yes or no)
- Column 8: If yes in column 7, specify the complication; if no, respond “n/a”
- Column 9: Postoperative deficits (yes or no)
- Column 10: If yes in column 9, specify the deficit; if no, respond “n/a”
- Column 11: Was the deficit permanent? (based on the 3-month outpatient follow-up report; yes or no)
- Column 12: Histopathological diagnosis
- Column 13: WHO tumor grade
- Column 14: Tumor resection grade according to the 3-month follow-up report (1 for total resection, 2 for subtotal, 3 for recurrence)
- Column 15: Preoperative Karnofsky score (based on the admission findings in the discharge report)
- Column 16: Postoperative Karnofsky score (based on the findings upon discharge in the discharge report)
- Column 17: Any new symptoms at the 3-month follow-up visit (based on the 3-month outpatient follow-up report)

This standardized prompt was used across all patient records to ensure consistency in data extraction, with the AI tasked with transforming unstructured medical data into a format suitable for subsequent analysis.

Data Anonymization

All original medical reports were manually anonymized by the research team before being entered into the GPT-4o interface. Identifiers such as names and addresses were removed. The anonymized reports were then processed through the official ChatGPT web platform for data extraction. No identifiable or sensitive information was transmitted, stored, or shared, ensuring compliance with General Data Protection Regulation (GDPR) and the standards of the local ethics committee.

Data Extraction

All analyses were performed using GPT-4o accessed through the official ChatGPT interface. At the time of data collection, research API (application programming interface) access was not available. The full dataset of 10 anonymized surgical cases was uploaded as a single compressed file for structured data extraction. Generated tables were manually reviewed and archived to ensure methodological traceability and reproducibility within the proof-of-concept framework.

Validation Process

Two board-certified neurosurgeons independently performed manual data extraction from the anonymized medical reports before the GPT-4o analysis, ensuring blinding to the AI-generated results. After completion of both manual and AI-based extractions, the datasets were compared to establish the ground truth. In cases where the 2 reviewers disagreed, a third senior neurosurgeon adjudicated the final classification. Interrater agreement between the 2 primary reviewers was calculated using Cohen κ.

Sample Size

The sample size of 10 patients was chosen based on feasibility for this proof-of-concept design, as the objective was not to achieve statistical power but to test the model’s capacity for accurate structured data extraction in a controlled, pilot environment.

Statistical Analysis

For each binary variable, model outputs were compared to the ground truth to derive the counts of true positives, false positives, false negatives, and true negatives. On the basis of these, accuracy, precision, recall (sensitivity), and *F*1-score were calculated primarily for binary variables, where such metrics are meaningful.

For conditional text and categorical or numerical variables, performance was mainly summarized using accuracy and corresponding 95% CIs computed via the Wilson method for binomial proportions. Additionally, Δ accuracy (postrefinement and prerefinement) was calculated to quantify improvement following prompt refinement.

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To explore potential differences in accuracy across variable types—binary, conditional text, and categorical or numerical—a Kruskal-Wallis test was applied. Given the small sample size and exploratory nature of this proof-of-concept analysis, no post hoc pairwise testing or correction for multiple comparisons was performed.

All analyses were performed using SPSS Statistics (version 27.0; IBM Corp) and R software (version 4.3.2; R Foundation for Statistical Computing).

Ethical Considerations

This research was conducted in compliance with the Code of Ethics of the World Medical Association (Declaration of Helsinki) for experiments involving human subjects. The local ethics committee of the University of Freiburg (23 - 1393-S1-retro; approval date: October 31, 2023) approved the waiver of informed consent due to the retrospective design, full anonymization of patient identifiers, and minimal-risk nature of the study, consistent with institutional and national regulations. As this was a retrospective analysis of fully anonymized clinical data, no participants were contacted and no compensation was provided.

Results

Overview

Ten consecutive patients diagnosed with intracranial acoustic neuromas who underwent surgical treatment at the Department of Neurosurgery at the University Hospital of Freiburg between August and December 2023 were included in this study. All screened patients met the inclusion criteria and were analyzed. GPT-4o generated an Excel table with structured data based on the zero-shot prompt described in the Methods section (Figure 4).

Figure 4. Part of the GPT-4o–generated table with structured data extracted from patient reports. These data were processed from unstructured medical records, while personal information was omitted to ensure compliance with ethical standards and protect patient privacy.

B		C	D	E
Date of Birth	Surgery Date	Surgery Date	Symptoms at Presentation (Yes/No)	Which Symptom?
12.12.1996	23.08.2023	23.08.2023	Yes	Headache
26.02.1993	13.12.2023	13.12.2023	Yes	Hearing loss
07.08.1967	11.10.2023	11.10.2023	Yes	Left-sided hearing loss, dizziness episodes
30.10.2000	10.11.2023	10.11.2023	Yes	Right-sided hearing loss, headache
23.02.1967	27.09.2023	27.09.2023	Yes	Right facial paresis, right-sided deafness
08.09.1963	19.10.2023	19.10.2023	Yes	Left hearing loss, tinnitus, imbalance
30.07.1997	05.10.2023	05.10.2023	Yes	Left-sided hearing loss, headache, nausea
23.07.1965	20.09.2023	20.09.2023	Yes	Facial pain
03.05.1970	18.10.2023	18.10.2023	Yes	Right-sided hearing loss, tinnitus, dizziness
04.01.1952	13.09.2023	13.09.2023	Yes	Right-sided deafness, dizziness
04.01.1952	13.09.2023	13.09.2023	Yes	Right-sided deafness, dizziness

Extraction of Structured Data

Regarding the collection of structured data that does not require text interpretation, such as date of birth, patient ID, date of surgery, histopathological diagnosis, and World Health Organization grade, and considering the physicians' opinion as the ground truth, the accuracy rate was 100% (Table 1).

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Table . Accuracy and 95% CIs (Wilson) for structured categorical variables.

Variable	Correct, n	Incorrect, n	Accuracy[a] (%; 95% CI[b])
Patient ID	10	0	100.0 (72.2 - 100.0)
Date of birth	10	0	100.0 (72.2 - 100.0)
Date of surgery	10	0	100.0 (72.2 - 100.0)
Histopathological diagnosis	10	0	100.0 (72.2 - 100.0)
WHO[c] grade	10	0	100.0 (72.2 - 100.0)

[a]All fields were extracted with perfect accuracy (100%) across 10 cases.

[b]CIs reflect the limited sample size rather than model variability.

[c]WHO: World Health Organization.

Extraction and Processing of Unstructured Data

In the zero-shot prompt, the collection and processing of unstructured data into structured data provided heterogeneous results. The following variables presented a 100% accuracy rate when compared to the physicians' evaluation: symptoms at presentation (yes or no), which symptoms, symptoms onset to surgery (in months), permanent deficits (yes or no), extent of resection (total, subtotal, and biopsy), and new symptoms at 3-month follow-up (Table 2).

In contrast, variables such as "intraoperative complications (yes or no)," "if yes, which complications," "new postoperative deficits," and "if yes, which deficits" achieved an accuracy rate as low as 50% in the zero-shot prompt. However, when the model was refined through additional prompt adjustments, as described in the Methods section, the accuracy rate improved to 90% to 100%, as presented in Tables 3 and 4.

Table . Accuracy and 95% CIs (Wilson) for binary, categorical, and conditional text variables requiring interpretative capabilities.

Variable[a]	Correct/total, n	Accuracy (%; 95% CI)
Symptoms at presentation (yes or no)	10/10	100 (72.2-100.0)
Which symptom?	10/10	100 (72.2-100.0)
Intraoperative complication (yes or no)	5/10	50 (23.7-76.3)
Which complication?	5/10	50 (23.7-76.3)
New postoperative deficits (yes or no)	5/10	50 (23.7-76.3)
Which deficit?	5/10	50 (23.7-76.3)
Was the deficit permanent (yes or no)	10/10	100 (72.2-100.0)
Extent of resection (3-month follow-up)	10/10	100 (72.2-100.0)
New symptoms at 3-month follow-up (yes or no)	10/10	100 (72.2-100.0)

[a]Variables are grouped with their corresponding descriptive fields ("Which…").

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Table . Case-level model outputs for intraoperative complication before and after prompt refinement[a].

Patient	Model performance before prompt refinement				Model performance after prompt refinement			
	Intraoperative complication	Assessment	Which complication	Assessment	Intraoperative complication	Assessment	Which complication	Assessment
1	No	Correct	None	Correct	No	Correct	None	Correct
2	Yes	Incorrect	Facial palsy (HB[b] II)	Incorrect	No	Correct	None	Correct
3	Yes	Incorrect	Facial palsy (HB II)	Incorrect	No	Correct	None	Correct
4	No	Correct	None	Correct	No	Correct	None	Correct
5	Yes	Incorrect	Facial palsy (HB V)	Incorrect	No	Correct	None	Correct
6	Yes	Incorrect	Facial palsy (HB IV)	Incorrect	No	Correct	None	Correct
7	Yes	Incorrect	Facial palsy (HB IV)	Incorrect	No	Correct	None	Correct
8	No	Correct	None	Correct	No	Correct	None	Correct
9	No	Correct	None	Correct	No	Correct	None	Correct
10	No	Correct	None	Correct	No	Correct	None	Correct

[a]Each variable (“intraoperative complication” and “which complication”) was independently assessed as correct or incorrect against the ground truth. The table highlights corrections achieved through prompt refinement.

[b]HB: House-Brackmann.

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Table . Case-level model outputs for intraoperative complication before and after prompt refinement[a].

	Model performance before prompt refinement				Model performance after prompt refinement			
	New postoperative deficit	Assessment	Which deficit	Assessment	New postoperative deficit	Assessment	Which deficit	Assessment
1	Yes	Incorrect	Mild dizziness and mild hearing loss (right)	Incorrect	No	Correct	None	Correct
2	Yes	Correct	Mild facial paresis and left-sided hearing loss	Correct	Yes	Correct	Mild facial paresis and left-sided hearing loss	Correct
3	Yes	Correct	Left deafness, dizziness, and mild facial paresis (temporary)	Correct	Yes	Correct	Facial paresis (temporary) and left deafness	Correct
4	Yes	Incorrect	Mild right facial hypoesthesia and tinnitus	Incorrect	No	Correct	None	Correct
5	Yes	Incorrect	Facial paresis (grade V), right facial hypoesthesia, and right deafness	Incorrect	No	Correct	None	Correct
6	Yes	Incorrect	Facial paresis (grade IV), chin hypoesthesia, and left deafness	Incorrect	No	Correct	None	Correct
7	Yes	Correct	Facial paresis (grade IV) and left deafness	Correct	Yes	Correct	Facial paresis (grade IV) and left deafness	Correct
8	Yes	Correct	Facial paresis (grade V) and left deafness	Correct	Yes	Correct	Facial paresis (grade V) and left deafness	Correct
9	Yes	Correct	Mild facial paresis (right)	Correct	Yes	Correct	Mild facial paresis (right)	Correct
10	Yes	Incorrect	Mild facial paresis (HB[b] II)	Incorrect	Yes	Incorrect	Mild facial paresis (HB II)	Incorrect

[a]Each variable ("New Postoperative Deficits" and "Which Deficit") was independently assessed as correct or incorrect against the ground truth. The table highlights corrections achieved through prompt refinement.

[b]HB: House-Brackmann.

Model performance across interpretative binary variables is summarized in Table 5. Accuracy ranged from 50% to 100%, reflecting variable complexity in contextual interpretation. While fields such as *was the deficit permanent?* and *new symptoms at 3-month follow-up* achieved perfect accuracy, others—particularly *intraoperative complication* and *new postoperative deficits*—showed lower precision due to false-positive predictions.

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Table . Model performance across interpretative binary variables.

Variable	TP[a]	FP[b]	FN[c]	TN[d]	Accuracy[e] (%)	Precision	Recall	*F*1-score
Symptoms at presentation (yes or no)	10	0	0	0	100	1	1	1
Intraoperative complication (yes or no)	0	5	0	5	50	0	—[f]	—
New postoperative deficits? (yes or no)	5	5	0	0	50	0.5	1	0.67
Was the deficit permanent? (yes or no)	1	0	0	9	100	1	1	1
New symptoms at 3-month follow-up?	1	0	0	9	100	1	1	1

[a]TP: true positive.

[b]FP: false positive.

[c]FN: false negative.

[d]TN: true negative.

[e]Accuracy ranged from 50% to 100%, with lower precision observed in fields requiring finer contextual understanding, such as intraoperative and postoperative deficits.

[f]Not applicable.

When comparing mean accuracies across variable types using the Kruskal-Wallis test, no statistically significant difference was observed (H=2.79; *P*=.25). Nevertheless, a consistent trend toward higher accuracy for structured categorical and numerical variables (eg, *patient ID*, *date of birth*, *World Health Organization grade*, *extent of resection*, and *Karnofsky scores*; mean 97.5%, SD 4.6%) and lower accuracy for conditional text variables (eg, *which symptom? which complication?* and *which deficit?*; mean 66.7%, SD 28.9% supports the descriptive results. Binary variables (eg, *symptoms at presentation*, *intraoperative complication*, *new postoperative deficits*, *was the deficit permanent*, and *new symptoms at 3-month follow-up*) showed intermediate performance, with a mean accuracy of 80.0% (SD 27.4%).

Discussion

Principal Findings

The findings of this study underscore the potential of GPT-4o and similar LLMs to revolutionize health care data mining. By achieving high accuracy rates for the extraction of structured information from unstructured medical records, GPT-4o demonstrated its utility in reducing the time and effort required for data analysis. Parameters such as symptom onset, tumor grade, and extent of resection were extracted with impressive accuracy, aligning with the work of Lee et al [7], who highlighted the power of NLP tools in parsing clinical trial data efficiently. However, these findings should be interpreted within the limitations of a small, single-institution feasibility study. While they demonstrate the technical viability of GPT-4o for structured data extraction, generalization to other clinical domains requires larger, multicenter validation.

However, not all data categories achieved uniform success. Variables such as intraoperative complications and new postoperative deficits presented challenges in zero-shot scenarios, emphasizing the need for prompt refinement and iterative learning to improve model performance. Similar observations have been reported by Adamson et al [8], who noted that model tuning significantly enhances the precision of clinical data extraction from electronic health records.

Beyond these technical aspects, the integration of LLMs into clinical workflows presents transformative opportunities. For instance, these models can support operational planning by predicting the allocation of resources such as surgical supplies and human labor based on historical data trends. This capability, as highlighted by Obermeyer and Emanuel [9], could reduce inefficiencies and improve overall patient outcomes. Moreover, automated coding of diagnoses and procedures, as discussed by Dong et al [10], could streamline billing processes, thereby alleviating administrative burdens for health care institutions. It should be emphasized that this study did not assess workflow integration, time efficiency, usability, or real-time clinical applicability. Any references to potential operational or efficiency benefits are therefore speculative and reflect broader opportunities described in the literature rather than outcomes directly evaluated in this analysis.

Despite these promising applications, ethical and practical challenges must be addressed. Ensuring data privacy and security is paramount, especially when handling sensitive patient information. Adherence to privacy regulations such as the Health

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Insurance Portability and Accountability Act and the GDPR is critical [11,12]. Furthermore, the "black box" nature of LLMs raises concerns about their interpretability and trustworthiness in clinical settings. Transparent AI frameworks, as advocated by Arrieta et al [13], could mitigate these issues by making model predictions more explainable. In this study, model interpretability was ensured by manually auditing GPT-4o outputs and verifying their correspondence with the original clinical context. Regarding privacy, all medical reports were manually anonymized prior to being uploaded to the GPT-4o interface. The analyses were conducted using the official ChatGPT web platform, with no identifiable patient information included at any stage. No data were stored, transmitted, or processed through third-party servers outside the OpenAI environment, ensuring full compliance with institutional and GDPR standards.

Recent scholarship has underscored the ethical and operational risks of deploying LLMs in health care. Ong et al [14] highlighted how bias propagation, lack of transparency, and accountability gaps remain major barriers to safe clinical implementation. Similarly, Elbattah et al [15] emphasized the need for transparent auditing mechanisms and robust validation pipelines to mitigate privacy and safety risks in medical AI applications. In line with these perspectives, this study reinforces the necessity of rigorous data governance, responsible model deployment, and continuous ethical evaluation when integrating LLMs into clinical research workflows.

The role of NLP in augmenting documentation accuracy and quality has been demonstrated in neurosurgical contexts. For example, Sastry et al [16] revealed that NLP models improved comorbidity documentation in inpatient admissions, illustrating their potential to enhance clinical record keeping. Similarly, Biswas et al [17] explored the application of NLP in automating the detection of intraoperative elements during lumbar spine surgery, further emphasizing the model's utility in surgical workflows. In addition, prior work has shown that LLMs can outperform manual abstraction in specific domains and significantly reduce time and labor requirements [18,19]. Compared with manual chart abstraction, which is labor intensive and time consuming, GPT-4o enabled near-instantaneous data extraction. Rule-based NLP systems, although established, require extensive customization and perform inconsistently across heterogeneous text. GPT-4o offers greater flexibility but introduces new challenges related to prompt sensitivity, hallucination risk, and limited explainability.

Another pressing concern is the potential for bias in AI models. As noted by Obermeyer et al [20], algorithms trained on biased datasets can perpetuate health care disparities, underscoring the importance of curating diverse and representative training data. Additionally, regulatory hurdles must be navigated carefully to ensure that these tools are deployed responsibly and ethically, as discussed by Char et al [21].

Looking ahead, the potential applications of LLMs in medicine are vast. Real-time decision support during surgeries, enabled by the synthesis of evidence from medical literature and intraoperative data, could significantly enhance surgical outcomes. Hashimoto et al [22] have already explored the promises and challenges of AI in surgical contexts, laying the groundwork for future innovations. Combining LLMs with complementary AI technologies, such as computer vision for imaging analysis, further expands their utility, as emphasized by Topol [23].

While GPT-4o and similar models represent a significant advancement in health care data mining, their practical implementation requires careful consideration of ethical, technical, and regulatory challenges. LLMs have the potential to not only transform data-driven research but also enhance the quality and efficiency of patient care.

This study highlights the transformative potential of LLMs such as GPT-4o in health care, particularly for mining and structuring complex medical data. The demonstrated accuracy in data extraction underscores their utility in reducing manual workloads and optimizing research and clinical processes. However, challenges such as data security, bias, and regulatory compliance remain significant hurdles. By navigating these obstacles thoughtfully, LLMs could redefine how health care systems manage and use data, ultimately improving patient outcomes and operational efficiencies. As these technologies continue to evolve, their integration must be guided by ethical frameworks and multidisciplinary collaboration to ensure their full potential is realized responsibly.

Limitations

The small sample size represents a central limitation of this study and results in wide CIs around several accuracy estimates. Consequently, the findings should be viewed as preliminary and interpreted with caution. Although some variables reached perfect accuracy, these were predominantly straightforward structured fields requiring minimal interpretative processing. As such, these results reflect a narrow and highly controlled context and should not be extrapolated as evidence that GPT-4o performs reliably across more complex or heterogeneous clinical data extraction tasks.

Furthermore, the analysis was conducted at a single institution, and all medical reports originated from one neurosurgical service and were written in German. This linguistic and institutional homogeneity may have influenced model performance and limits the generalizability of the results to other clinical environments, documentation styles, and languages. Given the known variability in LLM performance across languages and reporting conventions, external validation is essential.

Conclusions

Future studies involving larger, multi-institutional, and multilingual datasets, as well as more diverse clinical variables, will be necessary to assess reproducibility and determine whether these findings extend to broader clinical or operational contexts.

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Acknowledgments

No external data scientists, software engineers, or third-party experts were involved in this study. All prompt design, data processing, and analysis were performed by the authors, who have prior experience with clinical data workflows and research in neurosurgery. The authors declare the use of generative artificial intelligence (GAI) in the writing process. According to the GAI Delegation Taxonomy (2025), the following tasks were delegated to GAI tools under full human supervision: proofreading and editing. The GAI tool used was ChatGPT-4o and ChatGPT-5. Responsibility for the final manuscript lies entirely with the authors. GAI tools are not listed as authors and do not bear responsibility for the final outcomes.

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Conflicts of Interest

None declared.

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Abbreviations

AI: artificial intelligence
API: application programming interface
GDPR: General Data Protection Regulation
LLM: large language model
NLP: natural language processing

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Impacts of a Knowledge Mobilization Campaign for Carer-Inclusive Workplace Tools in Canada: Knowledge-to-Action Design Study

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Abstract

Background: Coupled with an aging population and lower fertility rates, there is a growing number of carer-employees (CEs), those balancing unpaid care with paid employment. Over 5.2 million Canadians are CEs juggling this dual role, often incurring negative impacts to their mental and physical health as a result. Given that unpaid care makes up 75% of care provided in Canada, the economic importance of supporting CEs extends to sustaining health care systems. Supporting and accommodating CEs in the workplace has not only been proved to be beneficial to the well-being of CEs but also to the organization through increased productivity and lower turnover rates. Despite the clear advantages of implementing carer-inclusive workplace practices (CIWPs) in the workplace, many organizations across Canada remain largely unsupportive of CE accommodations. The present study evaluated the impact of a knowledge mobilization (KMb) campaign.

Objective: The primary objective of the 2-phased campaign was to raise awareness of CIWPs in Canada and increase the uptake of various tools designed to support the implementation of CIWPs. Phase 1 published 4 articles in leading national industry magazines geared toward the target audiences; Phase 2 entailed a webinar series based around Phase 1.

Methods: This study uses a quantitative methodology using data collected primarily through the various magazine article publishing companies, as well as project partner McMaster Continuing Education. Engagement metrics and analytics associated with each KMb activity were collected through social media platforms and website analytics. Tracking engagement metrics, such as views, unique views, social media impressions, social media clicks, registrations, and attendees, was used to evaluate the impact of the campaign.

Results: The collected engagement metrics and analytics were analyzed to evaluate the campaign activities' impact on increasing the engagement with and uptake of specific tools. Phase 1 activities brought in a total of 36,308 views (mean 9077, SD 17,336), 2469 unique views (mean 617, SD 548), 55,445 social media impressions (mean 13,861, SD 19,424), and 432 social media clicks (mean 108, SD 101) across all 4 articles. The most successful activity was Article 3, pitched toward the small- to medium-sized business audience. Phase 2 was successful in engaging the target audiences with the campaign materials to further promote and disseminate the tools. Webinar attendance rates varied across sessions (22.1% - 30.6%) with overlapping 95% CIs. Noticeable increases in engagement with the CIWP tools are observed during the months when Articles 3 and 4 were published.

Conclusions: Results of the campaign suggest that published magazine articles targeted to the respective audiences are the most effective method of knowledge mobilization for this work, recognizing that paid activities had greater reach and better resources for dissemination. Future research in this area should focus on engaging with employers and professional stakeholders more directly.

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KEYWORDS

carer-inclusive; caregiving; employment; workplace; knowledge mobilization; knowledge translation; awareness campaign; quantitative; creating caregiver-friendly workplaces

Introduction

Background

The use of knowledge mobilization strategies for the dissemination of empirical research is becoming increasingly more prominent and crucial to many aspects of policy reform and development. While awareness of caregivers of adult dependents in Canada and their impact on society continues to emerge as a topic of concern economically, with a lens on the sustainability of health care systems in Canada, knowledge of how to support and accommodate these individuals for better

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health and well-being of both caregivers and care recipients remains to be seen more broadly.

Carer-Employee Demographic

Many caregivers in Canada are balancing their unpaid care for an adult dependent with paid employment obligations; these folks are known as carer-employees (CEs). According to the 2018 Statistics Canada General Social Survey (GSS), approximately 5.2 million Canadians are CEs [1]. Coupled with increasing life expectancy rates and lower fertility rates, Canada's population is aging rapidly, with the older adult (≥65 years) population in Canada expected to represent approximately 23% of the total population by 2030 [2-4]. With an increase in the numbers of those requiring care comes an increase in those needing to provide care; at the time of writing this, unpaid care makes up 75% of the care provided in Canada [5]. In addition to the majority of CEs working full-time employment positions [1], many provide around 5 hours of active care per day [6]. With this dual role come consequences to the overall health and well-being of both the CE and the care recipient. In particular, the intensity of balancing unpaid care responsibilities with paid employment can result in significant burnout, stress, fatigue, depression, and anxiety [7-12], which can lead to cardiovascular issues for the CE [13]. Analyzing the 2020 Carer Well-being Index, a study published in 2023 found that workplaces offering support and accommodation to their CEs during the COVID-19 pandemic resulted in better reported health and well-being by the CE. Specifically, from a 12-country comparison including the G7, Canada reported the least amount of support or accommodation from employers, and consequently, 71% of Canadian CEs reported worsening mental health and 52% reported negative impacts to their physical health [12]. Countries reporting higher levels of employer support for CEs also reported lower levels of negative impacts to mental and physical health [12]. As a result of juggling the dual role with little employer support, many CEs report feeling tired (80%), anxious (79%), and overwhelmed (73%) [12].

Business Case

Despite the clear connections between supporting CEs in the workplace and reported positive impacts to overall well-being, many workplaces in Canada remain largely unsupportive of CEs in the workplace. This, in part, can be attributed to a lack of awareness of the benefits to the employer, or the "Business Case" for supporting these employees. Benefits to the employer surround return on investment (ROI) related to productivity, retention, reduced turnover, reduced leaves, and reduced absenteeism [9,14,15]. A report by the American Association of Retired Persons (AARP) found that for every dollar invested in flextime, organizations can expect an ROI ranging from US $1.70 to US $4.34, while investments in telecommuting yield returns between US $2.46 and US $4.45 [16]. According to the 2018 GSS, CEs are feeling the strain in balancing their paid employment and unpaid care role, with 46% reporting presenteeism at work, which refers to being physically present in the workplace but unable to concentrate or focus on the task at hand [1]. As well, 51% missed part of full days of work due to caregiving responsibilities, with 1 in 7 CEs reducing their paid work hours to accommodate the unpaid care role; consequently, 6% (approximately 214,000 Canadians) left or intended to leave the workforce due to caregiving responsibilities [1]. Carer-inclusive workplace practices (CIWPs) are highly variable and include the many different types of supports and accommodations that organizations can offer to better respond to the needs of CEs in the workplace [8,17,18]. CIWPs are carer-inclusive policies, programs, and/or practices that an organization implements to better support CEs in the workplace in the interest of improving their overall health and well-being, in addition to improving their productivity and engagement within the workplace [9,12,14,19]. Intervention studies have shown the effectiveness of CIWPs in not only improving the well-being and satisfaction of CEs in the workplace but also providing a tangible ROI to the organization in terms of reduced absenteeism and turnover rates with improved retention of highly skilled and experienced employees [15,16,20]. Despite these tangible benefits of CIWPs to both the employer and the employee, many organizations across different sectors are resistant to such implementation due to existing workplace culture [9,11,17,19,21,22]. Workplace culture is often cited as the most important factor in effectively realizing the positive change in a workplace environment for CEs [10,17-19,21,23-25].

Gender Inequity

Globally, caregiving is often regarded as a women's role and responsibility [26]. Women's labor force participation is disproportionately impacted by unpaid care roles shaped by sociocultural norms [26,27]. While women have increasingly become a larger part of the workforce as many women enter the workforce in recent decades, the expectations around maintaining unpaid caring roles have remained the same [26,27]. This places significant strain on women's ability to remain active participants in the workforce, often having to resort to reducing their paid work hours, declining promotions, and leaving the workforce altogether, resulting in women making up 60% of those who leave the workforce in Canada due to caregiving [1]. Although the proportion of CEs in Canada is approaching parity between men (48%) and women (52%), women still make up the bulk of unpaid care work, providing up to 3 additional hours per week on caregiving compared with men [1]. We know that the majority of CIWPs are offered in sectors dominated by women, primarily health care and education [18], while sectors dominated by men are often faced with more stigma and negative workplace culture around identifying as a caregiver and requesting support [22]. While the prevalence of CEs in Canada continues to grow, awareness of the negative impacts on their mental and physical health resulting from inadequate workplace supports remains largely invisible at the broader economic level [12]. Recognizing that unpaid care makes up 75% of care provided in Canada, with an estimated value of $24-$31 million (US $ exchange rate at time of study for all CAD amounts listed throughout this paper was US $ 1=1.3978 CAD) [5], supporting those balancing their unpaid care with their paid employment is economically critical not only for the sustainability of health care systems in Canada but also for continued labor force participation for women [28].

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Objective

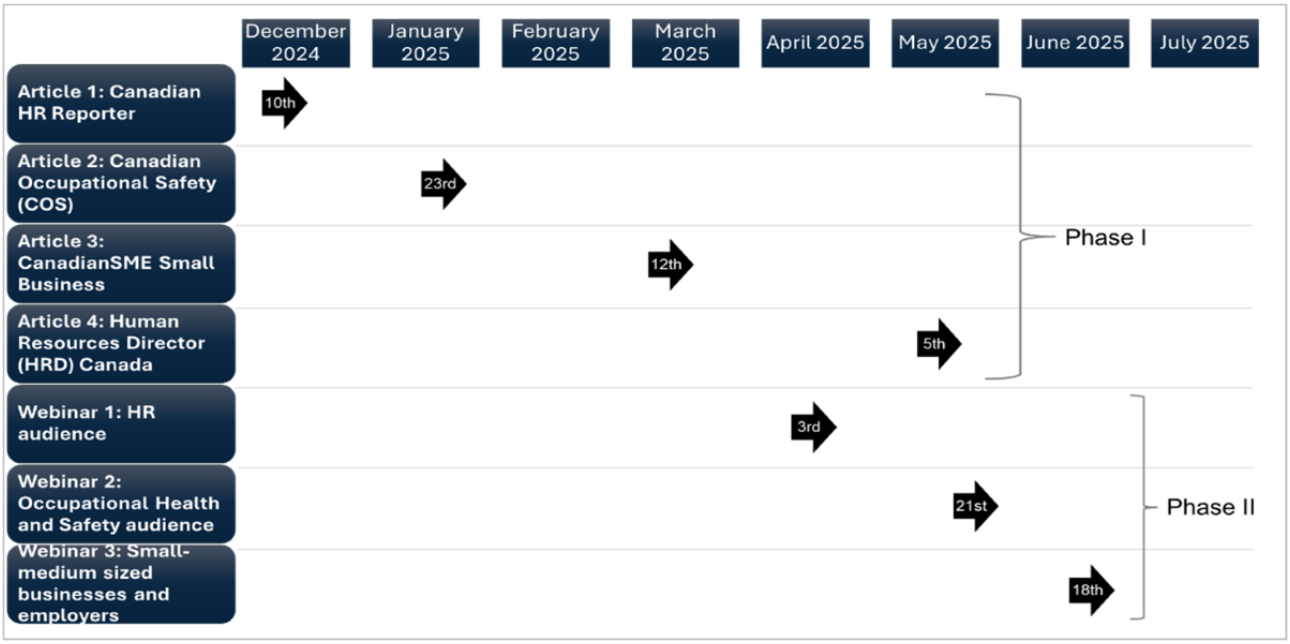
Given the ongoing need to raise awareness about CEs in Canada and the tools and resources available to support them, this study evaluated a knowledge mobilization campaign geared toward increasing employer uptake of CIWP tools. The objective of this paper was to determine the most effective knowledge mobilization strategy for increasing uptake of the Creating Caregiver-Friendly Workplaces (CCFWP) online course, offered through McMaster Continuing Education (MCE) [29] and provides the opportunity to earn a microcredential, as well as the CSA (Canadian Standards Association) B701 Carer-Inclusive and Accommodating Organizations Standard (Standard) across workplace sectors in Canada and the associated B701HB-18 Helping Worker-Carers in Your Organization Handbook (Handbook) [30]. This study was also concerned with increasing visitors to the Gender, Health, and Work (GHW) program website, which houses a range of evidence-based tools and resources that were used to build the CSA B701 Standard and Handbook, as well as the CCFWP course [31]. Specifically, this paper aims to evaluate and compare engagement metrics across the various phases and activities of the knowledge mobilization campaign, addressing the research question, "What is the most effective knowledge mobilization strategy toward increasing the uptake of carer-inclusive initiatives across Canada?" Previous work in this area has emphasized the use of social media channels for the focus of knowledge mobilization work in this area [32]. Accordingly, this study explores both social media and other media channels to determine their impact on increasing engagement with and uptake of the noted tools.

Methods

Overview

Through a Social Sciences and Humanities Research Council of Canada (SSHRC) Connection grant titled, "Disseminating tools for the creation of caregiver-friendly workplaces in Canada" (611-2024-0233), a knowledge mobilization campaign was conducted from December 10, 2024, to June 30, 2025. The campaign spanned 2 phases, Phase 1 being a series of 4 articles through various leading national professional magazines, and Phase 2 being a series of 3 webinars hosted by the project partner, MCE, virtually through Zoom (Zoom Communications). See Figure 1 below for a timeline of both campaign phases. Throughout both phases of the campaign, social media metrics were collected across each article and webinar through dissemination of the articles and webinars. A series of 4 infographics was created to boost the content of the first 3 articles, as well as the campaign products more broadly (ie, the CSA B701 Carer inclusive and accommodating organizations standard and the "Creating Caregiver-Friendly Workplaces" course).

Figure 1. Timeline for Phases 1 and 2 of the campaign.



Analytical Framework and Campaign Evaluation Methods

Following a process model developed by Graham et al [33], the Knowledge to Action (KTA) approach is used to frame this knowledge mobilization (KMb) evaluation. To facilitate the uptake and use of knowledge, the KTA model provides a cyclical process for translating knowledge into action through mobilization of the knowledge [34,35]. The application of this cycle follows the process of identification of a problem (knowledge-practice gap) and the reciprocal knowledge to disseminate in order to implement a knowledge mobilization campaign (action) and finally assess knowledge use [33,34]. The action element of the cycle is the primary focus of this evaluation, bridging empirically supported knowledge about supporting CEs in the workplace into practice across target or key audiences (ie, Human Resources, Occupational Health and Safety leaders, and C-suite executives, and employers). This model shaped the selection of the target audiences for the campaign through the identification of a knowledge-practice

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gap in supporting CEs in workplaces across Canada and the stakeholders with the authority to implement the knowledge into practice within employment settings. This was also directly informed by results of a previous mixed methods evaluation surrounding the uptake of the CSA B701 Standard, with implications for future engagement with the identified audiences [24]. The 2-phased campaign design follows a multimodel KTA process that attempts to engage the audiences in various ways, persistently mobilizing the selected knowledge to the target audiences.

To effectively evaluate the outcomes of the KMb campaign with respect to increasing engagement with the selected knowledge, various statistical analysis methods are used to measure campaign results. The engagement metrics collected for the Phase 1 magazine publications, Phase 2 webinar series, and associated social media posts are analyzed using descriptive statistics (means and SDs) to summarize engagement. Attendance rates and 95% CIs for the webinar series were calculated using a normal approximation to the binomial distribution (ie, attendance was treated as a yes or no outcome). Excel (Microsoft Corp) formulas are used to calculate the descriptive statistics. The engagement metrics for the published magazine articles are provided by the media company "KeyMedia," which manages 3 of the 4 selected industry magazines for the campaign (HR Reporter, HRD Canada, and Canadian Occupational Safety). The remaining metrics for the article directed at the employer audience were provided by said magazine, the CanadianSME. Details of the magazines with regard to reach and audience are outlined in the sections below.

Recruitment

Recruitment for the webinars was primarily conducted through the Customer Relationship Management (CRM) marketing software used by MCE (Microsoft); the 3 different audiences were strategically targeted through emails sent out by the MCE CRM database, which targeted those who had previously engaged in content or courses related to either human resources (HR) professional development or occupational health and safety, as well as small business owners and employers. The reach to the target audiences varied, shaped by MCE's scope of access to the audience through previous content, courses, and webinar offerings. For the articles, total counts of views, unique views, social media impressions, and clicks were collected and were not disaggregated by channels. Each article was promoted through a month-long campaign across the magazines' networks and social media channels.

Content Dissemination

Through KeyMedia, the first article was published in the Canadian HR Reporter magazine, a leading national magazine for HR professionals and managers to keep up to date on the latest trends in HR leadership and management, as well as how HR must respond to these societal changes. The HR Reporter magazine reaches approximately 30,000 HR professionals daily across the country; their website receives a monthly average of 200,000 page views and 124,000 users, as well as 15,000 email subscribers and 17,600 social media subscribers. Their audience is comprised primarily of female readers (79%), with 61% involved in product and/or service recommendation and 39% being end decision-makers for purchasing. A key focus of this magazine's audience is employment law and workplace legislation, with 28% of their readership being managers of HR.

The second article was published in the Canadian Occupational Safety magazine, managed by the same media company, which reaches around 25,000 health and safety professionals daily. Their website receives a monthly average of 80,000 page views and 50,000 users, with 13,000 email subscribers and 30,000 social media subscribers. A large portion of their audience consists of health and safety managers and directors (41%), with 25% being health and safety coordinators or specialists. Most of their readership is based in Ontario, Canada (52%).

The third article was published in the CanadianSME Magazine, a member of Magazines Canada. The CanadianSME reaches around 30,000 readers per month across the country with 80,000 monthly impressions, 100,000 website visitors per month, and over 60,000 subscribers and followers on social media. The CanadianSME magazine connects 30 different business chambers across the country to provide the most up-to-date information to small business owners and employers. Most of their readership is also based in Ontario, Canada (52%), with 62% of readers being small business owners, founders, chief executive officers, and directors, and 27% being presidents and vice presidents. With regard to business type, around 40% of their readership is in retail business or manufacturing, both typically physically demanding occupations.

The fourth and final article was published in the Human Resources Director Canada (HRD Canada) magazine, a leading national magazine for stakeholders in HR and recruitment. According to their readership, the primary industries are education (16%), software (14%), manufacturing (13%), and health care (13%), with most readers (48%) representing HR directors, vice presidents, executive vice presidents, and senior vice presidents, while 28% of readers are heads of talent and recruitment. The fourth article was also managed by KeyMedia and collected the same metrics as Articles 1 and 2. Article 3 collected slightly different metrics than the KeyMedia articles, although highlighting similar engagement metrics of total reach, post engagement, and link clicks to either the article itself through social media or clicks within the article to the CCFWP course.

Registrations, attendees, and polling results were collected for the webinars. Webinars 1 - 3 were framed around the content from articles 1 - 3 and directed at these 3 audiences (HR professionals, occupational health and safety professionals, and small business owners and employers), respectively. Social media engagement across the articles and webinars was collected for both GHW and MCE social media accounts. To measure the success of these campaign strategies in increasing uptake of carer-inclusive initiatives across Canada, the downloaded data for the Standard and Handbook were collected from the CSA, as well as the student enrollments and microcredential earnings from the MCE course. The total number of students, microcredentials, and Standard and Handbook downloads were evaluated across the various campaign activities in terms of determining which method was most successful for boosting engagement with carer-inclusive initiatives.

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Ethics Considerations

For purposes of this study, the researchers were not required to obtain research ethics approval through the McMaster Ethics Research Board (MERB) as this study did not collect any personal or sensitive information from human participants. Metrics collected from the campaign reflect publicly accessible activities available to any individual across Canada. As these study activities, such as reading a magazine publication online or attending a webinar (both anonymously), were open to the public, the study did not directly engage with recruited human participants. Metrics that were provided by KeyMedia and CanadianSME resulted from the published magazine articles and present information on the total number of views and clicks for the article itself on the public web page, with no identifying information collected. As well, the webinars were publicly accessible events for any individual across Canada to register and attend, with only information on total attendees and click rates recorded (ie, no identifying information was asked for or collected).

Results

Results of the knowledge mobilization campaign evaluation are outlined below, across the 2 phases.

Phase 1

Table 1 below outlines the Phase 1 article metrics across the various magazines (managed and collected by KeyMedia and CanadianSME). Article 1 was published on December 10, 2024, and collected campaign metrics through to April 3, 2025. As part of the native article publishing package, KeyMedia runs a month-long paid campaign to boost the efforts of article dissemination to the key audience, although metrics collection continues following this date. Throughout this time, the article collected 524 views, 431 unique views, 3863 social media impressions, and 62 social media clicks. With regard to views, of the 431 unique users who viewed the article, 93 individuals revisited the article a second or more times. Of the 3863 social media users who viewed the post about the article in the HR Reporter magazine, 62 individuals clicked on the links associated with the article from the social media post, bringing the user to the article. Through project partner MCE, the article was also posted to MCE news on the MCE website. The article mirrored the version published on HR Reporter, with a link to that article provided at the end of the MCE post. The results were measured from December 13, 2024, to July 11, 2025, for a total of 204 views (includes those who may have revisited the article more than once).

Table . Article details and engagement metrics from Phase 1 of the knowledge mobilization campaign.

Source	Title	Link	Dates (data collection)	Views	Unique views	Social media impressions	Social media clicks
HR Reporter	Caring for carer-employees: an ethical imperative	[36]	December 10, 2025-April 3, 2025	524	431	3863	62
Canadian Occupational Safety	Championing caregiver-friendly workplaces as an occupational health and safety issue	[37]	January 24, 2025-March 10, 2025	271	236	5819	43
CanadianSME	How small businesses can use carer-inclusive initiatives to help their business thrive	[38]	March 12, 2025-April 3, 2025	35,080	1430	42,937	258
HRD Canada	“People will punch out one way or another”: the risk of ignoring carer-employees	[39]	May 5, 2025-July 4, 2025	433	372	2826	69

Article 2, directed to the occupational health and safety audience, was published on January 24, 2025, and measured metrics up until March 10, 2025. The KeyMedia campaign for the article collected 271 total views (including those who chose to revisit the article), 236 unique views, 5819 social media impressions (including unique users and those who chose to revisit the social media post), and 43 social media clicks. Of the 236 unique views of the article, 35 users chose to revisit the article, potentially sharing it with their networks. As noted in the methodology section, Article 3 collected slightly different metrics than Articles 1, 2, and 4. However, it paints a similar picture across Facebook (Meta Platforms, Inc), Instagram (Meta Platforms, Inc), X, formerly known as Twitter (X Corp), and LinkedIn (LinkedIn Corporation), where the article had a reach of 42,937, with a total of 258 social media clicks to the article web page. With regard to the article itself, across the e-magazine editorial published in March 2025 and the article web page on the CanadianSME Small Business magazine website, a reach

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of 35,080 was achieved, with a total of 1430 unique users viewing the article, 170 of whom clicked links within the article, driving readers to the CCFWP course web page for more information and registration for the course.

LinkedIn

Overview

The article had a reach of 42,937, with a total of 258 social media clicks to the article web page. With regard to the article itself, across the e-magazine editorial published in March 2025 and the article web page on the CanadianSME Small Business magazine website, a reach of 35,080 was achieved, with a total of 1430 unique users viewing the article, 170 of whom clicked links within the article, driving readers to the CCFWP course web page for more information and registration for the course.

Finally, Article 4, published in HRD Canada magazine, targeted the HR audience and was published on May 5, 2025, and collected engagement metrics from the date of publishing through to July 4, 2025. The article's campaign resulted in a total of 433 views, 372 unique views, 2826 social media impressions, and 69 social media clicks. Of the 372 unique views, 61 users chose to revisit the article.

In Table 2, the means and SDs were calculated across the totals of views, unique views, social media impressions, and social media clicks for all 4 articles. The average number of views for Phase 1 was 9077, although this is significantly skewed by the total views for article 3. The average number of views across all articles (with Article 3 [35,080 views] removed) is 409, compared with 9077 if Article 3 is included in the average. The mean unique views across all articles is 617, with an average of 13,861 social media impressions and 108 average social media clicks. The SD emphasizes the significant differences between views (SD 17,336), unique views (SD 548), social media impressions (SD 19,424), and social media clicks (SD 101) between articles 1, 2, and 4, and article 3.

Table . Descriptive statistics for total views, unique views, social media impressions, and social media clicks across the 4 articles.

Article number	Title	Dates (data collection)	Views	Unique views	Social media impressions	Social media clicks
1	Caring for carer-employees: an ethical imperative	December 10, 2025-April 3, 2025	524	431	3863	62
2	Championing caregiver-friendly workplaces as an occupational health and safety issue	January 24, 2025-March 10, 2025	271	236	5819	43
3	How small businesses can use carer-inclusive initiatives to help their business thrive	March 12, 2025-April 3, 2025	35,080	1430	42,937	258
4	'People will punch out one way or another': The risk of ignoring carer-employees	May 5, 2025-July 4, 2025	433	372	2826	69
Total	—[a]	—	36,308	2469	55,445	432
Average, mean (SD)	—	—	9077 (17,336)	617 (548)	13,861 (19,424)	108 (101)

[a]Not applicable.

Figure 2 below provides a striking visualization of the overwhelming success of Article 3 for total views and social media impressions in comparison to the other articles.

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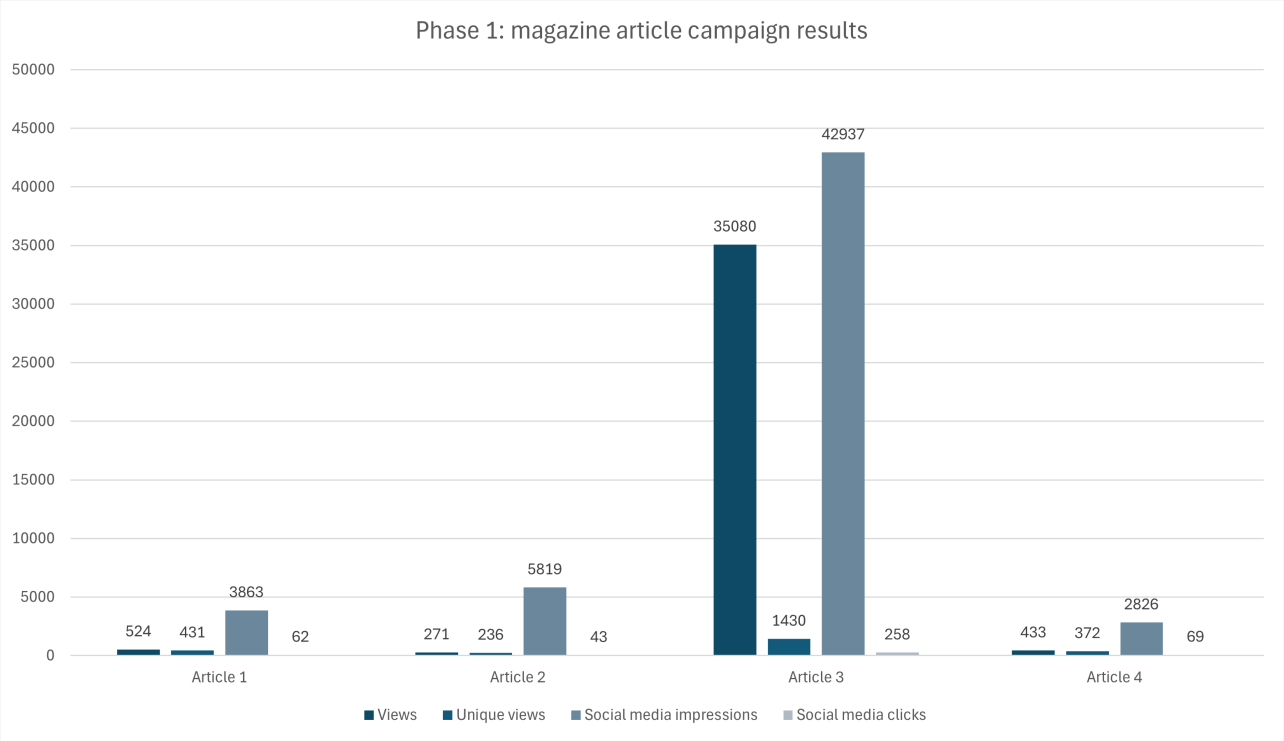
Figure 2. Engagement metrics across Articles 1 - 4.



In addition to collecting engagement metrics via the magazines directly, campaign partner MCE also collected engagement metrics for the articles through the posts to their website. The first article was published to the MCE website on December 10, 2025 collecting engagement metrics from December 13, 2024, to July 11, 2025, for a total view count of 204 (including unique views and overall views). Article 2 was published to the MCE website on January 31, 2025, collecting engagement metrics from January 31, 2025, to July 11, 2025, for a total of 114 views, while Article 3 measured results from May 7, 2025, to July 11, 2025, for a total of 136 views, and Article 4 a total of 81 views. Article 4 only measured views for the period of May 15, 2025-July 11, 2025 having been published to the website on May 15, 2025. Organic social metrics were collected for Articles 2 - 4 (timing and capacity for MCE resulted in no organic social metrics collected for Article 1), as outlined in Table 3, which reports the total impressions and views, reach, and engagements across articles 2 - 4. The averages and SDs for social media engagement across each article (2-4) are also included in Table 3 below. Overall, the most impressions and views collected across each platform for all articles were 495 Instagram impressions for Article 4. Article 3 had the greatest reach recorded across each of the articles and all social platforms, with 2935 being the total reach for X (formerly Twitter). Article 4, published in HRD Canada magazine, resulted in the greatest number of engagements recorded, recording a total of 13 engagements on Instagram. Across all social media platforms, X and Threads (Meta Platforms, Inc) had the highest percentage of engagement at 7% and 9%, respectively. Across all articles that recorded organic socials through the MCE website (Articles 2 - 4), Instagram resulted in the highest number of impressions (n=1134) and engagements (n=35), while X resulted in the highest reach (n=7563). It should be noted that the platforms LinkedIn and Threads do not record the total reach, and therefore this number is excluded from Table 3 below.

Table . McMaster Continuing Education (MCE) social media engagement metrics, means, and SDs for Articles 2 - 4.

Social platform	Article 2			Article 3			Article 4		
	Views	Reach	Engagements	Views	Reach	Engagements	Views	Reach	Engagements
Facebook, n	334	328	9	369	359	5	193	189	3
Instagram, n	228	188	12	411	296	10	495	343	13
LinkedIn, n	127	—	9	164	—	3	198	—	12
X, n	25	2314	1	64	2935	6	71	2314	4
Threads, n	9	—	1	5	—	1	8	—	0
Total, n	723	2830	32	1013	3590	25	965	2846	32
Mean (SD)	145 (138)	943 (1189)	6 (5)	203 (181)	1197 (1506)	5 (3)	193 (187)	949 (1185)	6 (6)

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Table 4 provides the means and SDs for the social platforms used in terms of views and impressions, reach, and engagement across all of the articles (2-4), clearly indicating Instagram had on average the greatest number of views or impressions (average views: mean 378, SD 137), while X had the highest reach (average reach: mean 2521, SD 359). Across the board, engagement was fairly low (as noted above) in comparison to views and impressions and reach. Instagram had the highest average engagement (average engagements: mean 2, SD 2).

Table . McMaster Continuing Education (MCE) social media engagement means and SDs across the social media platforms.

Social platform	Average views, mean (SD)	Average reach, mean (SD)	Average engagements, mean (SD)
Facebook	299 (93)	292 (91)	6 (3)
Instagram	378 (137)	276 (79)	12 (2)
LinkedIn	163 (36)	—[a]	8 (5)
X	53 (25)	2521 (359)	4 (3)
Threads	7 (2)	—	1 (1)

[a]Not available.

Phase 2

Phase 2 of the campaign collected data related to the webinar series' impact on increasing engagement with the CSA Standard, Handbook, and CCFWP course in a variety of ways. Data collection for this phase of the study was led by SSHRC Connection partner MCE. Each webinar was hosted through MCE's Zoom platform, recorded, and uploaded to MCE's YouTube (Google LLC) channel, as well as the GHW website. Through paid promotions and targeted webinar recruitment, MCE used various methods to bring in webinar registrants, corresponding with the target audience for each webinar. Table 5 below outlines the webinar series, including the title, link to the webinar recording, date of the event, total registrations, and total attendees.

Table . Phase 2 details of the webinar series.

Source	Title	Recording link	Dates	Registrations	Attendees
McMaster Continuing Education	Caring for carer-employees: an ethical imperative	[40]	April 3, 2025	272	60
McMaster Continuing Education	Championing caregiver-friendly workplaces as an occupational health and safety issue	[41]	May 21, 2025	170	52
McMaster Continuing Education	Carer inclusive employment policies: a strategy for small and medium-sized business success	[42]	June 18, 2025	120	32
Average, mean (SD)	—[a]	—	—	187 (77)	48 (14)

[a]Not applicable.

Table 6 provides the attendance rates and 95% CIs calculated separately for each webinar using a normal approximation to the binomial distribution (ie, "yes" or "no" for webinar attendance). Attendance rates ranged from 22.1% to 30.6%, with overlapping 95% CIs, indicating similar proportions of registrants attended each webinar despite the audience differences.

Table . Phase 2 webinar attendance rates and 95% CIs.

Webinar	Registrations, n	Attendees, n	Attendance rate, n	95% CI
Webinar 1	272	60	0.2206	0.1713-0.2699
Webinar 2	170	52	0.3059	0.2366-0.3751
Webinar 3	120	32	0.2667	0.1875-0.3458

Webinar 1 was held on April 3, 2025, and was built around Article 1 from Phase 1, directed toward the HR audience both at the managerial and C-suite levels. There were a total of 272 registrants on the day of the webinar, of which 60 attended the webinar. Primarily, email targets were used to connect with those who had previously engaged in one of the other HR-related programs offered through MCE, whether that be a course, program, or webinar. A total of 6427 individuals were targeted

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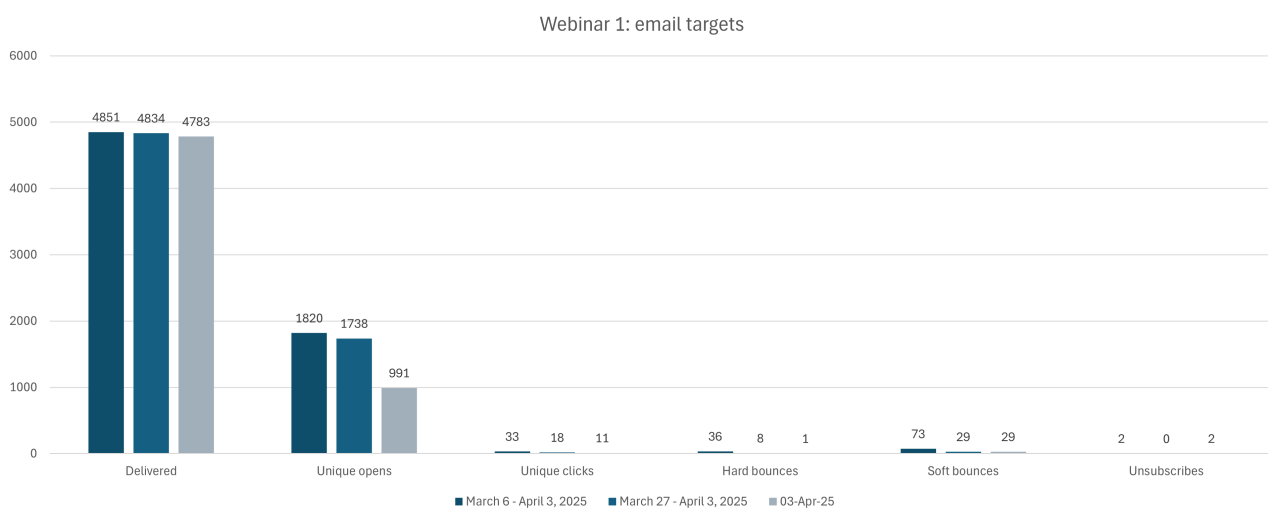
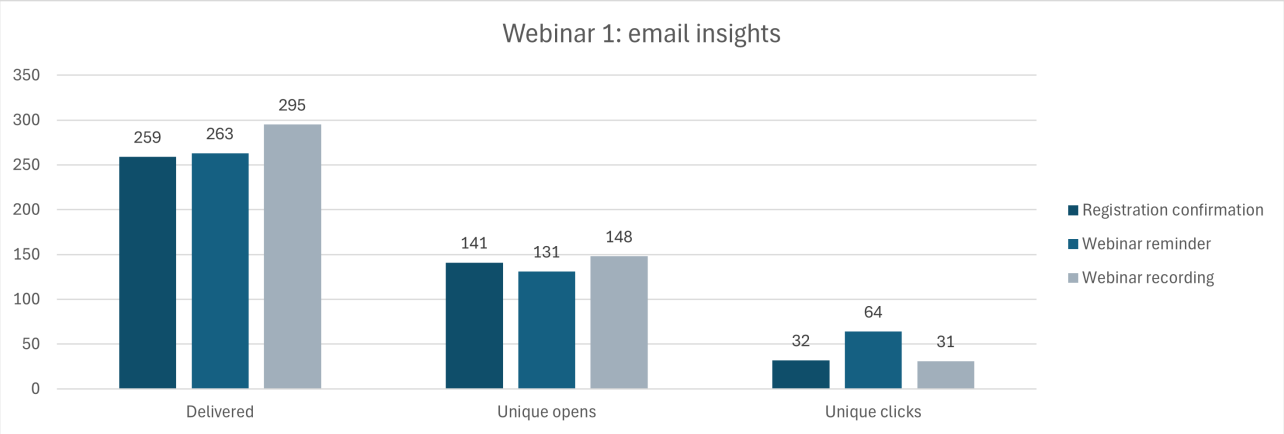
through the email CRM system, 59 of whom were MCE staff for a testing segment. MCE students actively enrolled and/or graduates of the Human Resources Management and Business Administration programs were targeted. Of the 6427 emails sent out, 4851 were delivered for Invite 1, with 1820 unique opens of the email (meaning 3031 people did not open the email) and 33 unique clicks (meaning 1787 people did not click any links within the opened email). For Invite 2, a total of 4834 were delivered, with 1738 unique opens and 18 clicks to register for the webinar. The third invite was sent out the morning of the webinar as a last call and reminder, with 4783 emails delivered, 991 unique opens, and 11 clicks. Figure 3 below provides a visual of the significant difference between the total amounts of those invitations delivered and the resulting clicks to register for the webinar.

Figure 3. Email targeting metrics from Webinar 1, collected through McMaster Continuing Education (MCE).



With regard to those who registered for the webinar, Figure 4 below visually outlines the total of emails delivered regarding the registration confirmation, a webinar reminder, and the webinar recording following the live webinar. About half of those who received each email opened the message, and a smaller portion of unique clicks within the opened email (the highest of which being those who clicked on the link to the webinar for the reminder email).

Figure 4. Metric insights from the email targets sent out by McMaster Continuing Education (MCE) to recruit for Webinar 1.



Paid social media advertisements were also deployed as part of the MCE marketing campaign for the webinar series through Meta Platforms, including Facebook and Instagram. The campaign featured a Facebook boosted event and a lead generation ad targeting users on both platforms. The paid social media advertisements for Webinar 1 measured impact from March 6, 2025, to April 3, 2025 (ie, “in market” timeline), with a budget of $150 CAD for the Facebook boosted event and $900 CAD for the lead generation ad. The Facebook boosted event resulted in 97 event responses, with a reach (unique users) of 9576 and 27,720 impressions (total times the ad was viewed, ie, unique users revisiting the ad more than once). The lead generation promotion resulted in 162 leads (ie, driving users to register for the webinar), with a reach of 27,008 and 74,488 impressions (see Table 7 below).

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Table . Paid social media advertisements through McMaster Continuing Education (MCE) platforms (Facebook and Instagram).

Type	In-market timeline	Budget	Results	Reach	Impressions	Cost per result
Boosted Facebook event	March 6, 2025-April 3, 2025	CAD $150	97 Event Responses	9576	27,720	$1.55 Per event response
Lead generation Ad	March 6, 2025-April 3, 2025	CAD $900	162 Leads	27,008	74,488	$5.55 Per lead

Webinar 2, held on May 21, 2025, brought in a total of 170 registrations and 52 attendees. MCE contacted a total of 6159 individuals through the CRM email marketing, 59 of those being MCE staff members for a testing segment. Geared toward the Occupational Health and Safety (OHS) audience, those active in or graduates of the Human Resources Management and Business Administration were again targeted, as there are no existing OHS programs through MCE. Three invites were sent as part of the targeted recruitment, the first capturing data from April 30, 2025, to May 21, 2025, for a total of 4549 emails delivered, 1640 unique opens of the email, and 29 unique clicks of the registration link to the webinar. Invite 2 collected data from May 15 to 21, 2025, with a total of 4576 emails delivered, 1573 unique opens, and 18 clicks of the registration link within the email. The third invite, sent out the day of the webinar, resulted in 4555 emails delivered, 988 unique opens, and 20 unique clicks (see Figure 5 below). The registration confirmation email measured delivery, unique opens, and unique clicks from April 23, 2025, to May 21, 2025, resulting in 170 delivered, 105 unique opens, and 19 unique clicks. The webinar reminder collected data on May 21, 2025 alone and resulted in 167 delivered, 141 unique opens, and 39 unique clicks. The email following the webinar regarding access to the webinar recording measured reach from May 23, 2025, to June 16, 2025 and resulted in 168 emails delivered, 106 unique opens, and 10 unique clicks. Figure 6 provides a visual of the decline in terms of ratio across delivered, opened, and clicked, with less than half of those who opened the email clicking on an embedded registration link.

Figure 5. Marketing email insights of those contacted by McMaster Continuing Education (MCE) for Webinar 2 recruitment.

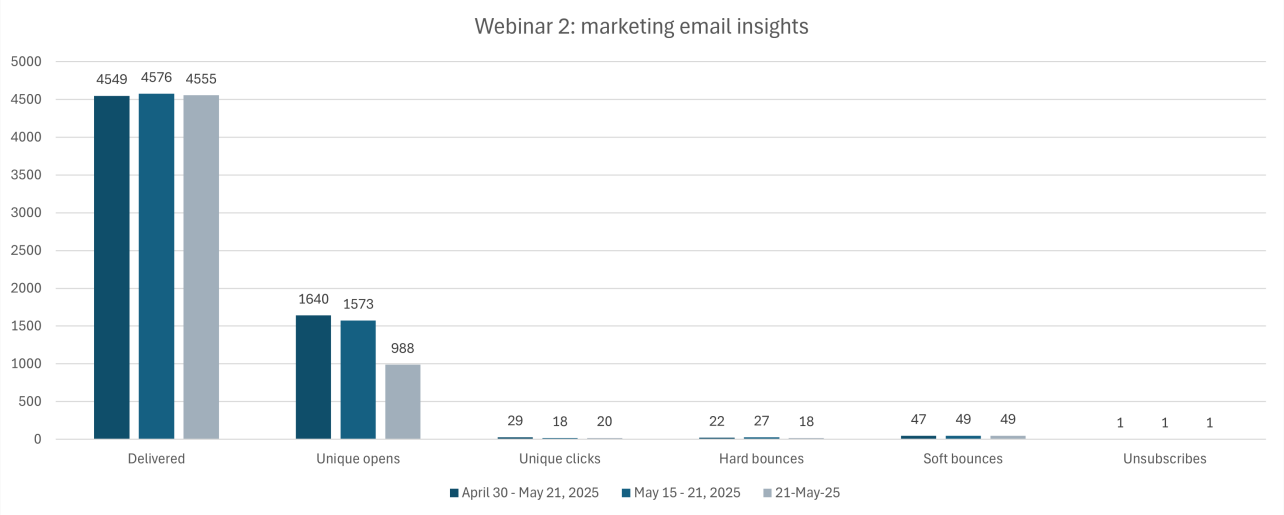

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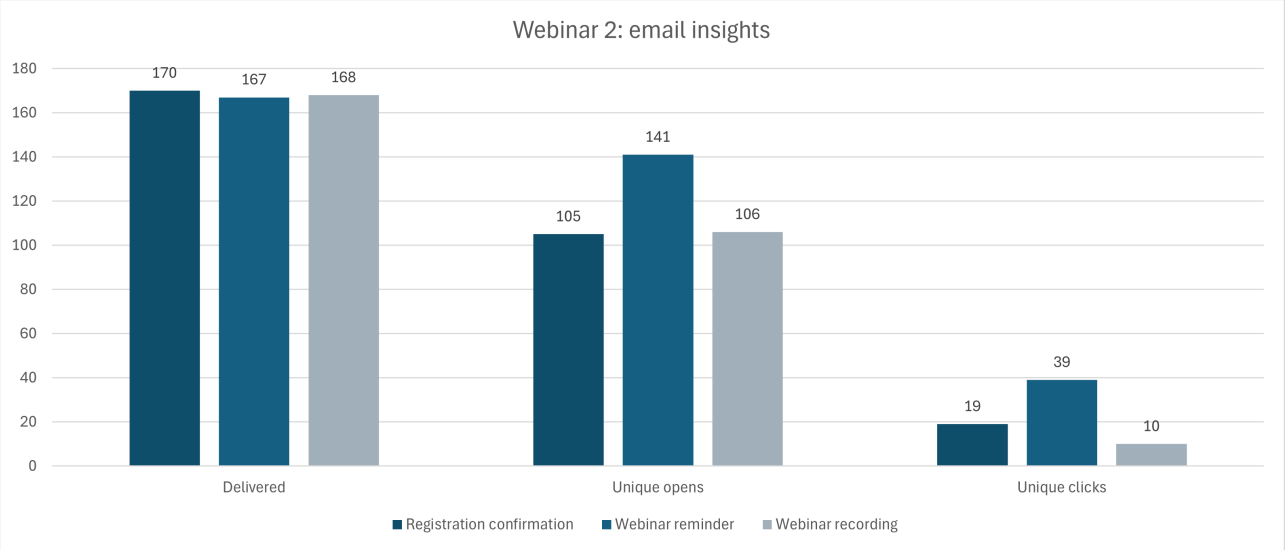
Figure 6. Metric insights from the email targets sent out by McMaster Continuing Education (MCE) to recruit for Webinar 2.



A boosted Facebook event and a lead generation ad were deployed as a recruitment strategy, collecting data from April 24, 2025, to May 20, 2025. The Facebook boosted event was budgeted at CAD $100, resulting in 65 event responses, reaching 6846 and 16,852 impressions. The lead generation ad was budgeted at CAD $900 and resulted in 110 leads (people who gave their contact information to register), with a reach of 32,969 and 93,172 impressions. The cost per result (CPR), which refers to the average cost per specific action throughout the paid advertisement campaign, for the Facebook Boosted Event was valued at $1.54, and the Meta Lead Generation Ad had a CPR of $8.18 (see Table 8 below).

Table . Paid social media advertisements through McMaster Continuing Education (MCE) platforms (Facebook and Instagram).

Type	In-market timeline	Budget	Results	Reach	Impressions	Cost per result
Boosted Facebook event	April 24, 2025-May 20, 2025	CAD $100	65 Event responses	6846	16,852	$1.54 Per event response
Lead generation Ad	April 24, 2025-May 20, 2025	CAD $900	110 Leads	32,969	93,172	$8.18 Per lead

Webinar 3 was pitched toward the small- to medium-sized business audience and was correlated to Article 3 Phase 1. Planning logistics impacting the timeline of the webinar led to a shorter period between recruitment for the webinar and the actual date of the webinar, specifically around speaker confirmation and session organization. As such, the third webinar, hosted on June 18, 2025, only collected data on one email invite to those within MCE's CRM for the period of May 23, 2025, to June 18, 2025. The webinar had a total of 120 registrations and 32 attendees. The invite was sent out to 22,174 individuals, targeted at those active at the time of this writing or a previous graduate in any of MCE's business programs, with 16,047 delivered, 5562 unique opens, and 75 unique clicks. For those who had registered, a registration confirmation email was sent, and responses were measured during the period of May 9, 2025, to June 18, 2025, for a total of 118 emails delivered, 78 unique opens, and 12 unique clicks to the webinar link. The webinar reminder email was sent out the day of the webinar for a total of 118 delivered, 59 unique opens, and 19 unique clicks to the webinar link (see Figure 7 below). The paid social media advertisements for webinar 3 mirrored that of webinars 1 and 2, measuring impact on Meta's social media platforms from May 22, 2025, to June 17, 2025. With a budget of CAD $100, the boosted Facebook event resulted in 70 event responses, with a reach of 6045 and 14,524 impressions at a rate of $1.43 cost per event response (or CPR). The lead generation ad, with a budget of CAD $900, generated 64 leads, reaching 13,886 individuals with a total of 49,445 impressions. For the lead generation ad, the CPR is significantly higher at $14.06 per lead (or CPR; see Table 9 below).

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Figure 7. Metric insights from the recruitment emails sent out by McMaster Continuing Education (MCE) for Webinar 3.

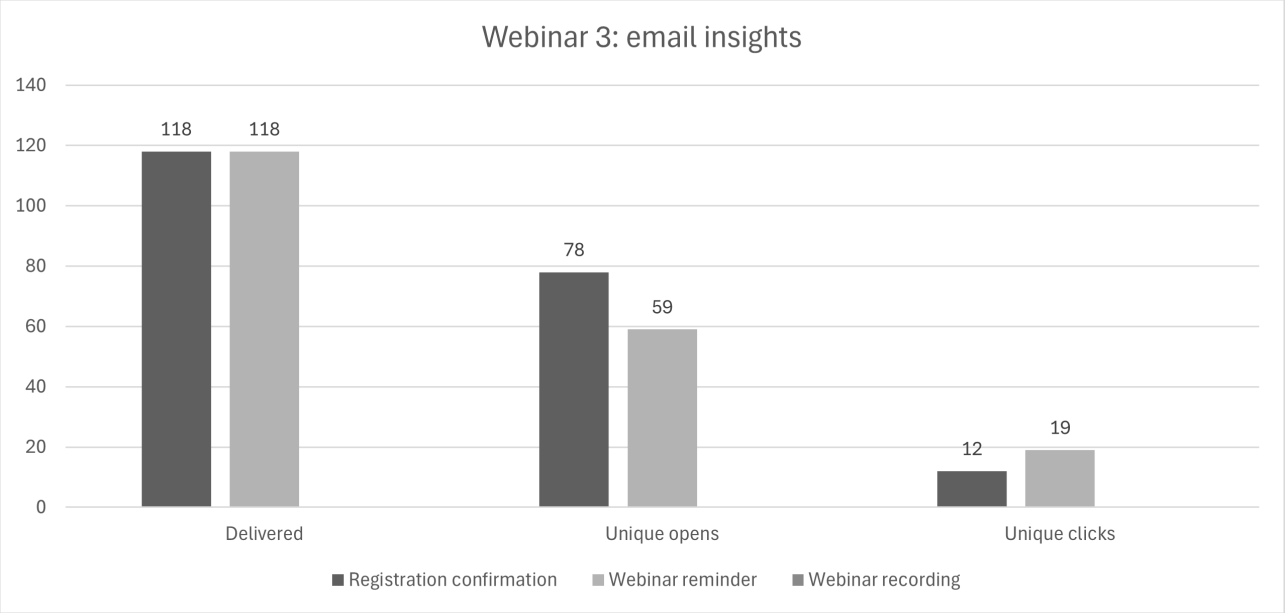

Table . Paid social media advertisements through McMaster Continuing Education (MCE) platforms (Facebook and Instagram).

Type	In-market timeline	Budget	Results	Reach	Impressions	Cost per result
Boosted Facebook event	May 23, 2025-June 17, 2025	CAD $100	70 Event Responses	6045	14,524	$1.43 Per event response
Lead generation Ad	May 22, 2025-June 17, 2025	CAD $900	64 Leads	13,886	49,445	$14.06 Per lead

Webinars 2 and 3 collected polling data during the live session from the audience members in order to gauge the impact of the webinar toward increasing uptake of the various CIWP tools and resources (primarily the CCFWP course and CSA B701 Standard and Handbook). Webinar 1 missed the opportunity to collect polling data, as the polls were launched too late into the session, following the question-and-answer period, when audience members had already logged off. This informed the structure of the remaining 2 webinars, where the polls were launched prior to the start of the question-and-answer period to ensure responses for the polls were collected before attendees began signing off from the session. Table 10 below provides an overview of the questions launched throughout Webinars 2 and 3, with polling question 2 from Webinar 2 belonging to the guest speaker for that session and not related to data collection of the knowledge mobilization campaign.

Table . Polling report summary for Webinars 2 and 3.

Poll name	Questions, n	Responses, n
Webinar 2 (registrations: 170; attendees: 52)		
Poll 1 - What is your position/role	1	18
Poll 2 - If you have been awake for 21 hours	1	29
Poll 3 - How likely are you to enroll in CCFW[a]	1	28
Poll 4 - How likely are you to pursue policies	1	27
Webinar 3 (registrations: 120; attendees: 32)		
CCFW[a] Web 3 - Poll 1 - workplace sector	1	11
CCFW Web 3 - Poll 2 - workplace size	1	11
CCFW Web 3 - Poll 3 - Likely to enroll	1	9
CCFW Web 3 - Poll 4 - Pursue policies at work	1	11

[a]CCFWP: Creating Caregiver-Friendly Workplaces.

From the table, we can see that Webinar 2 generated the most responses to the polling questions, likely related to the number of registrations and attendees, as Webinar 2 had 20 more attendees than Webinar 3. For Webinar 2, each attendee was asked what their position, role, and title at their organization are at the time of this writing, with responses ranging from

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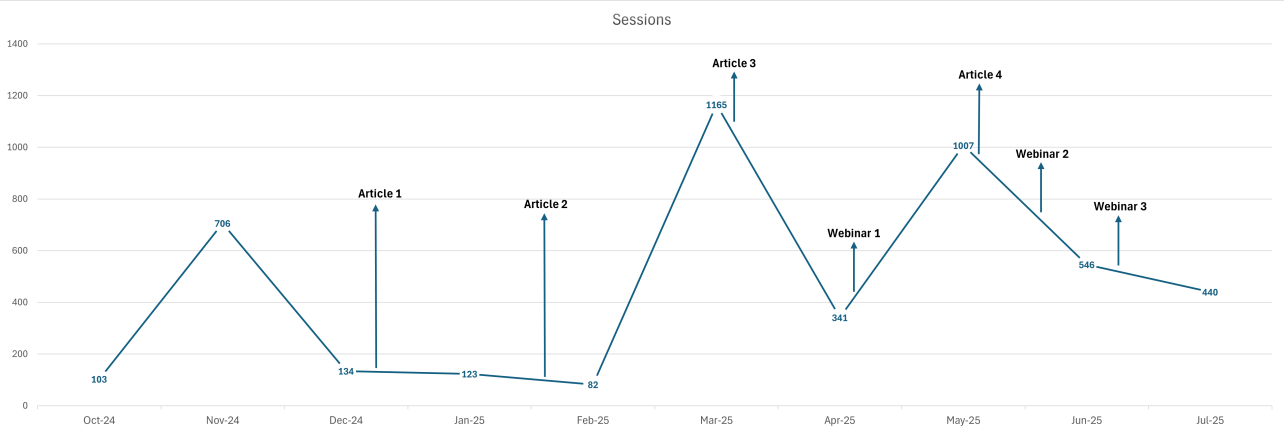
Health and Safety Manager, Officer, and Specialist to Consultant. A total of 28 responses were recorded for polling question 3, "How likely are you to enroll in the Creating Caregiver-Friendly Workplaces course?" as part of Webinar 2, with a Likert scale ranging from 1 to ‐10 (1 being the least likely and 10 being most likely), with 71% of respondents reporting 7 or higher and an average of 7 (SD 3) across the 28 responses. When asked, "How likely are you to pursue carer-inclusive initiatives or policy at your place of work?" a total of 27 attendees completed the poll, with 88% reporting 7 or higher and an average of 8 (SD 2), indicating Webinar 2 was successful in increasing potential engagement not only with the CCFWP course but with CIWPs more broadly. Webinar 3 asked a similar set of polling questions, starting with the workplace sector of the attendee. Given that Webinar 3 was geared toward the small (1 ‐ 99 employees) to medium (100 ‐ 499 employees) business audience, the polling question was more concerned with workplace sector as opposed to role, collecting a total of 11 responses ranging from finance and insurance to health and social services. The second question asked attendees about workplace size, with 100% of respondents (11 total) reporting from a small business. When asked how likely they were to enroll in the CCFWP course, 67% of the 9 respondents reported 7 or higher, with an average of 6 (SD 3). When asked how likely they were to implement CIWPs into their workplace, 91% of the 11 respondents reported 7 or higher, with an average of 8 (SD 3), indicating strong likelihood. This suggests Webinar 3 was also successful in increasing engagement with the tools and resources being disseminated as part of the KMb campaign.

Each webinar was recorded and posted to MCE's YouTube channel as part of the "Program Webinars" series. Within the week following the live sessions, each webinar recording was uploaded to the YouTube channel, collecting views from the period of posting to the date of checking the total views, July 24, 2025. The first webinar, geared toward the HR audience, was posted to the channel on April 7, 2025, and has a total of 67 views. The second webinar, geared toward the OHS audience, was posted May 23, 2025, and has a total of 39 views. The third webinar has a total of 33 views and was posted on June 25, 2025. Despite having been posted to the channel for the shortest period of time, Webinar 3 has fared similarly well to Webinar 2, which could suggest the small- to medium-sized business audience may be more receptive to the issues of CIWPs than the OHS audience. It should be noted that the first webinar has been uploaded to the channel for a longer period of time than the most recent webinars, potentially contributing to a difference in total views.

Impact on Uptake

In relation to driving traffic to the CCFWP course web page for increasing registrations to the course with the end goal of increasing uptake of CIWPs, the articles published in Phase 1 had the most success in increasing engagement with the CCFWP course web page. The number of monthly "Sessions" to the CCFWP course web page refers to visitors to the site, where we specifically see spikes and increases in visits to the website around the time of article publishing. Although it is important to note that increases in visitors to the CCFWP course web page do not indicate direct engagement with the course itself but do, nonetheless, increase awareness of the course through an increase in traffic. As shown in Figure 8 below, the highest spike in visitors (n=1165) to the website throughout the month of March 2025 coincides with the publishing of Article 3 in the CanadianSME magazine on March 12, 2025. The second highest spike in visitors to the website throughout the month of May 2025 (1007) is observed around the same time Article 4 is published in the HRD Canada magazine, geared toward senior and executive HR representatives in C-Suite with stakeholder influence. This observation does not necessarily indicate the spike in visitors to the web page is a result of the article publications, although it is possible the articles influenced this increased spike in traffic to the web page. Interestingly, there is an observed spike in visitors to the website in the month of November 2024 (n=706), the month predating the first article being published in HR Reporter magazine. There are no campaign activities that occurred around this time to explain the spike in visitors to the CCFWP web page. Notably, there is a limited increase of traffic to the web page around the time of the second article being published in the Canadian Occupation Safety magazine.

Figure 8. Sessions (visits) to the Creating Caregiver-Friendly Workplaces (CCFWP) web page throughout the months of the knowledge mobilization (KMb) campaign with Phases 1 and 2 activity indicators.



With regard to the CCFWP course and the impacts of the campaign on course enrollment and engagement, there are subtle yet noticeable spikes in activity following the publishing of Article 3 and the live session of Webinar 1. From that point

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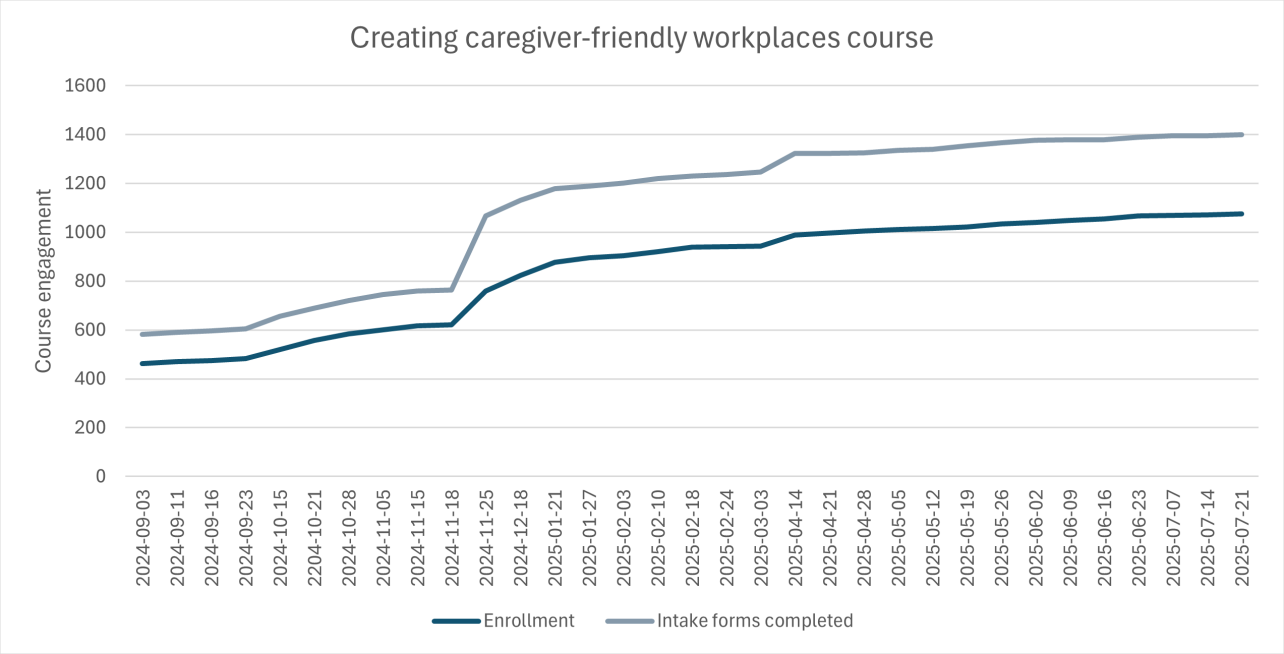
onward, traffic to the CCFWP web page appears to sit above the norm prior to February, excluding the spike in visitors in November 2024. This could potentially be influenced by the campaign activities, although more in-depth data collection and analysis would be needed to determine the association. Article 3 published in the CanadianSME magazine appears to be the most successful KMb activity, with an increase in traffic to the CCFWP course web page occurring around the same time as article publication, as well as an observed increase in registrations and enrollment in the course. Second to Article 3, Article 4, published in HRD Canada, appears to potentially have contributed to the second-highest spike in sessions to the web page, with an observed gradual increase in registrations and enrollments in the CCFWP course throughout the month of May 2025. Recognizing the limited evidence, we cannot conclude that the KMb campaign directly impacted the noted increases in traffic to the CCFWPs and enrollments in the course. As shown in Figure 9 below, there is a significant spike in enrollment and intake forms completed throughout the month of November 2024, coinciding with the spike in visitors to the CCFWP web page as noted in Figure 8 above, with a lack of explanation for the activities as part of the KMb campaign.

Figure 9. Registrations (intake forms completed) and student enrollments for the Creating Caregiver-Friendly Workplaces (CCFWP) course throughout the timeline of the knowledge mobilization (KMb) campaign with indicators of Phases 1 and 2 activities below the x-axis.



Following the publishing of Articles 1 and 2, there is an observed spike in downloads to the Handbook specifically, while the Standard did not appear to increase in downloads following the start of Phase 1. One download of the Standard occurred in December 2024, the same month Article 1 was published, in comparison to zero downloads in the months predating Article 1. Although this does not suggest Article 1 influenced the Standard download. Following the publication date of Article 1, the Handbook received a total of 11 downloads throughout the month of December 2024, in comparison to just one download for both the months of October 2024 and November 2024. Article 2 was published January 23, 2025, coinciding with a total of 9 downloads of the Handbook throughout the month of January 2025. No articles were published in February 2025. There is a drop in downloads observed, with just 2 downloads for the month of February 2025. There was an increase in downloads of the Handbook throughout the month of March 2025, for a total of 5 downloads.

There is a spike in visitors to the GHW program website throughout March 2025. It should be noted that due to restrictions in access to website analytics for the GHW website, only the previous 6 months were available for metrics (February-July 2025). The total number of visitors to the website (n=1903) and collective views across the various sections of the website (n=31,099) are substantially higher than is normal for traffic to this website. The primary campaign activity that occurred during this time was the publishing of Article 3, although no direct association or correlation has been made.

Discussion

Principal Findings

This study evaluated the impact of a 2-phased knowledge mobilization campaign pitched toward increasing awareness of and engagement with selected tools and resources for curating carer-inclusive workplaces. Overall, the findings indicate that the activities of Phase 1, particularly targeted industry magazine publications, generated more engagement with the campaign tools than the webinar series of Phase 2. Engagement varied across the target audiences, with higher HR professional and employer audience engagement. These findings address the study objectives by identifying industry magazine publications as the most effective within this campaign. Increased visits to the CCFWP course web page, registrations and enrollments to the course, increased visits to the GHW course web page, and Standard and Handbook downloads were observed around key campaign activities directed at the HR and employer audiences. The use of multiple channels for KMb dissemination is a

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growing common practice in KMb initiatives across researchers and research groups [35,43-47]. Specifically, the use of targeted strategies that directly engage with select audiences.

Phase 1 consisted of the 4 paid magazine articles in leading Canadian industry magazines, pitched toward the target audiences (HR professionals, OHS professionals, and small- to medium-sized businesses). The most noticeable increase in both visitors to the course web page and increase in registrations and course enrollments, as well as increased visitors and traffic to the GWH website, is observed around the activities of Phase 1. This phase resulted in a total of 36,308 views, 2469 unique views, 55,445 social media impressions, and 432 social media clicks across all 4 articles between the period of December 10, 2024, and May 5, 2025. Of the 4 articles, Article 3 (small- to medium-sized business audience) had the highest ratio of views to unique views (35,080:1,430) and had the lowest proportion of unique views to views (4%). Article 2 (OHS audience) had the lowest ratio of views and unique views (271:236). However, 87% of the total views for Article 2 were unique views, in comparison to 86% and 82% for Articles 4 and 1, respectively. Article 3 was also superior to social media engagement across the 4 articles, again with the highest ratio of social media impressions to social media clicks (42,937:258). Surprisingly, the success of Article 3 surpassed that of Article 1, given that the HR Reporter has 100,000 more monthly visitors to their website than the CanadianSME magazine. This could potentially reflect that 98.1% of businesses in Canada are classified as small businesses, equating to over 1.07 million small businesses in Canada [48]. The significantly greater reach of Article 3 skews the results of Phase 1, with large SDs around the mean (average views: 9077, SD 17,336; average social media impressions: 13,861, SD 19,424).

Given the results of the overall KMb campaign analysis, the HR and small- to medium-sized business audiences are observed to have the most engagement with the campaign materials and activities. Activities directed toward these audiences resulted in the highest levels of engagement through the magazine Articles 3 (March 2025) and 4 (May 2025). Corresponding spikes in visits to the CCFWP course web page were observed, with 1165 and 1007 sessions recorded, respectively, as well as registrations and enrollments to the course. While there are visible spikes in website traffic around the publication dates of Articles 3 and 4, it is uncertain whether this is a direct result of the KMb campaign. However, it is possible the articles contributed to increased awareness of the CCFWP course given the increased traffic around these times. More sophisticated quantitative analysis is needed to determine more direct impacts of campaign activities on increased engagement with the selected tools and resources.

Despite Phase 2's lower performance when compared to the impact of Phase 1, both in terms of views and engagement and observed traffic increases to the CCFWP website and GHW website, activities directed toward the HR and employer audiences received the highest engagement. Although Webinar 2 had greater registration and attendance than Webinar 3, the recording has garnered more engagement through the YouTube channel. With regard to the various social media channels, while X had the highest reach (7563 [82% of all reach across each article]) across all articles that collected organic socials (Articles 2 - 4), Instagram was the most effective platform for collecting the most impressions (42%) and engagements (39%) across all social media channels and metrics for Articles 2 - 4. This corroborates the findings of previous research in this area that found X to have the greatest reach for disseminating CE tools, while Instagram had the greatest depth of engagement (ie, longer engagement or interaction) [32]. While this study cannot establish the direct impact of the KMb campaign activities on the increase in activity to the CCFWP course web page and enrollments, GHW website, and Standard and Handbook downloads, future knowledge mobilization research in this area may benefit from an increased focus on the occupational health and safety audience as it appears to be more challenging to engage. It may be that alternative channels of outreach could be more successful in garnering engagement with campaign materials and activities with the OHS audience. Tools and resources may benefit from being better framed around psychological health and safety, and the implications of ignoring the challenges experienced by CEs in the workplace may be best disseminated through associated channels. Engaging with OHS stakeholders in future research can add value to existing research in the areas of KMb science specific to professional or technical audiences. Results of the campaign analysis show that the Handbook received more downloads when compared to the Standard throughout the duration of the campaign. This highlights results of a previous study that evaluated the uptake of the CSA B701 Standard and Handbook. The study found that the Handbook is often perceived as the preferred tool over the Standard given its greater usability and ability to engage with instruction [24].

Part of the intention of the 2-phased KMb campaign was to ensure the activities of Phase 2 complemented those of Phase 1, further disseminating and promoting the tools and resources to the target audiences. This follows the KTA framework of engaging with the target demographics or audiences in various and consistent ways, as well as existing KMb literature around best practices for engaging multiple audiences, which emphasizes the importance of using multiple channels of dissemination to lay and policy audiences [43-46,49]. While Phase 1 was evidently more successful around engagement and reach than the webinar series of Phase 2, the webinars may potentially have contributed to an increase in traffic to the CCFWP course web page, with 341 sessions observed throughout the month of April 2025 (the month of Webinar 1) and 546 sessions through the month of June 2025 (the month of Webinar 3), as well as a slight increase in traffic to the GHW website, which houses many free downloadable tools. Much of the KMb work within the care economy has been geared toward engaging the community and end users (ie, CEs and their care recipients) [50-54], rather than decision-makers and stakeholders. The findings of this study provide insight into potential best practices for engaging HR, OHS, and employer audiences in CIWPs.

Limitations

A major limitation of this paper is specific to the nature of the data collected for analysis of the KMb campaign. There was no data collected as to whether increased traffic to the CCFWP

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course web page, the GHW website, and the Standard and Handbook were a direct result of the campaign activities. While it is possible and likely that the KMb campaign activities increased engagement with the tools and resources of concern, given the results presented above, we cannot conclude this definitively. Further research in this area would benefit from additional data collection that can directly link KMb campaign activities to increased engagement with the selected knowledge. It is challenging to realize this for publicly available tools and resources that do not require the visitor to enter in any information. Another limitation of this paper is missing data around the engagement metrics for Article 1. This article was excluded from the organic social media posts through MCE campaigning for Phase 1, as well as the missing polling report data from Webinar 1 that is based on Article 1. The webinar polls for Webinar 1 were launched at the very end of the webinar when many attendees began to leave the webinar, resulting in zero responses to the polls as part of Webinar 1. This further informed the polls for Webinars 2 and 3, where polls were launched prior to the question-and-answer period toward the end of the webinars. Regarding the absence of organic socials for Article 1, project partner MCE was unable to collect this data for Article 1, although it was able to be collected for Articles 2 - 4. This presents implications for the results of this study, as inclusion of the missing data may have provided more accurate insight into the most successful method of knowledge dissemination as part of Phases 1 and 2.

Another limitation of this study surrounds the campaign timelines; given the first 2 articles of Phase 1 were between the months of December 2024 and January 2025, they were both likely impacted by holiday periods and the start of the new year. Recognizing many working professionals are less engaged and on holiday throughout these calendar year periods, future knowledge mobilization campaigns may look toward more active periods of professional engagement. Webinar 2 had less success in recruitment than Webinar 1, which was geared toward the HR audience, as the recruitment strategy for Webinar 2 was limited to those active in or graduates of the HR programs offered through MCE, with the absence of a channel for accessing the OHS audience. Given the students from the HR programs offered through MCE likely have limited focus on or expertise in the areas of psychological OHS, this may have hindered effective recruitment for Webinar 2. As well, Webinar 3 recruitment for the small- to medium-sized business audience was focused on all business administration programs offered through MCE, which may not effectively speak to the small- to medium-sized business audience. Finally, given the limitations of access to analytics through the GHW program website (powered by MacSites), only the previous 6 months of website traffic were able to be analyzed as part of this study (February-July), rather than the entire campaign time period (December-July). Finally, while the KMb campaign was directly informed by previous work in this area [24] with regard to key stakeholder audiences to engage, the audiences were not directly involved in the development of the campaign. Future work in this area should engage stakeholders of the target audiences directly for more curated campaigning.

Conclusion

The 2-phased KMb campaign ran from December 10, 2024, to June 30, 2025. Phase 1 of the campaign, surrounding the 4 published magazine articles, resulted in significantly higher engagement with the KMb campaign materials than Phase 2 of the campaign, which entailed a webinar series built around the articles published in Phase 1. Access to the audiences and networks of the leading national magazines for HR, OHS, and small- to medium-sized businesses in Canada potentially contributed to the observed increase in traffic to the CCFWP course web page, increased registrations to the course and student enrollments, as well as increased traffic to the GHW website, specifically around the publication date of Article 3. Across all 4 articles, Article 3 had the greatest reach to the target audience, coinciding with an increase in visitors to the CCFWP course web page and registration and enrollment throughout the entire campaign. While the Phase 1 articles performed well for the HR and small- to medium-sized business audience, Phase 2 was comparatively less successful with respect to engagement with the campaign tools amongst the target audiences. Formally publishing articles in nationally leading industry magazines that target audiences directly was observed to be the most effective method for this type of KMb focused on increasing awareness, engagement, and uptake (ie, CCFWP course enrollments and registrations and Standard and Handbook downloads). Overall, the campaign potentially contributed to increases in engagement with the tools and resources that were part of this campaign, which were designed to help organizations create more carer-inclusive workplaces across Canada. Nonacademic, industry magazine publications are an effective approach to engaging stakeholder audiences in CIWPs.

At the time of this writing, the landscape of literature surrounding KMb strategies and best practices for KMb research pitched toward stakeholders within the carer-inclusive policy space is limited. This research adds to the growing literature of KMb science with regard to best practices for engaging stakeholders and decision-makers within the carer-inclusive policy space. Specifically, more work is needed to establish causal and correlative associations, as well as engage more directly with workplaces and employers to realize a national shift toward more equitable and sustainable work for the growing number of CEs in Canada. With a rapidly aging population and increased strain on Canadian health care systems, building awareness and uptake of carer-inclusive workplace tools is imperative to support the growing number of CEs. Equipping workplaces in Canada with the CIWPs needed to sustain CE productivity and well-being through KMb science strategies presents a viable approach to mitigating these growing challenges. Further research in this area is needed to continue refining the KMb strategies that are most effective for raising awareness of CIWPs.

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Data Availability

All data generated or analyzed during this study are included in this published article.

Authors' Contributions

Conceptualization: BC, AW
Data curation: BC, HP
Formal analysis: BC
Funding acquisition: AW
Investigation: BC, HP
Methodology: BC, AW
Project administration: BC, AW
Supervision: AW
Validation: HP
Visualization: BC
Writing – original draft: BC
Writing – review & editing: AW, HP, BC

Conflicts of Interest

None declared.

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Abbreviations

AARP: American Association of Retired Persons
CCFWP: Creating Caregiver-Friendly Workplaces
CE: carer-employee
CIWP: carer-inclusive workplace practices
CPR: cost per result
CRM: Customer Relationship Management
CSA: Canadian Standards Association
GHW: Gender, Health and Work

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GSS: General Social Survey
HR: human resources
KMb: knowledge mobilization
KTA: Knowledge to Action
MCE: McMaster Continuing Education
MERB: McMaster Ethics Research Board
OHS: Occupational Health and Safety
ROI: return on investment
SSHRC: Social Sciences and Humanities Research Council of Canada

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A Comparison of Participant Demographics Across Co-Designed Recruitment Methods to Two Student Mental Health Trials: Cross-Sectional Observational Study

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Abstract

Background: Using social media platforms has been demonstrated to be a successful recruitment method, especially for young people. Two cited benefits of using social media for recruitment are its ability to quickly increase sample size and engage hard-to-reach participants.

Objective: This study aimed to (1) provide a pragmatic depiction of co-designing and implementing a social media strategy with our advisory group and (2) compare demographic information of participants recruited via social media and other methods. Our objective was to provide evidence for future trials to implement social media recruitment with maximum efficiency.

Methods: Participants were 2369 UK university students who consented to take part during the recruitment timeframe of 2 mental health trials. Our student advisory group advised on content, platform, and timing of engagement. We trialed 10 different adverts over a 12-month recruitment period. Descriptive analysis evaluated advert reach and link clicks using Meta/TikTok business data, website traffic using Google Analytics, screening consent, and enrollment using REDCap (Research Electronic Data Capture; Vanderbilt University) software. A cross-sectional observational analysis used chi-square and *t* tests to compare ethnicity, gender, sexual orientation, disability status, and university attended among 842 participants recruited via social media and 1527 participants recruited by other methods.

Results: Through extensive student advisor input, an Instagram carousel advert led to a boost in participant recruitment. However, this fluctuated over the academic year, with numbers dropping completely over the summer months. All tests used α=.05. There was a difference in gender among those recruited through social media versus other recruitment methods on campus (χ^2_2=8.34, *P*=.02), with social media resulting in a higher proportion of gender-diverse students (27/370, 7% vs 30/711, 4%; 95% CI 3.4% - 13.7%), but fewer male students (35/370, 4%, 95% CI [3.4% - 13.7%] vs 99/711, 7%, 95% CI [1.6% - 9.8%]). Those recruited from social media were younger than those recruited through other methods, with a mean difference of −3.49 years (SE=0.31, 95% CI [–3.94 to –3.04]; $t_{1927.5}$=15.146, *P*<.001). A significantly higher proportion of students in the social media sample were from the LGBTQIA+ community (180/351, 51%, 95% CI [41.3% - 60.6%] vs 350/711, 37%, 95% CI [28.2% - 46.8%]; χ^2_1=17.87, *P*<.001). There was also a significant difference in the reported disability (103/375, 27.5%, 95% CI [19.7%-37.0%] vs 154/723, 21.3%, 95% CI [14.4% - 30.3%]; χ^2_1=4.90, *P*=.03). There was no difference in ethnicity between the 2 groups (χ^2_1=2.4609, *P*=.12).

Conclusions: Our study describes how different recruitment approaches influence participant characteristics in clinical trials and highlights challenges in implementing a co-designed recruitment strategy in a university setting. This contributes to the field by providing research evidence on the efficacy of different recruitment strategies for planning future trials. Our key real-world recommendation is to allow time and resources for planning multiple recruitment strategies to ensure a diverse range of participants take part in research.

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KEYWORDS

social media; trial recruitment; mental health; intervention; diversity

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Introduction

The modern age presents equally modern issues for researchers in participant recruitment [1]. Social media has proven to be an effective recruitment method, often contributing to higher numbers of study enrollment than traditional, face-to-face methods [2-4]. It enables researchers to quickly reach target populations [5,6], increasing access to hard-to-reach groups, especially regarding socially sensitive research topics [7]. However, there are some concerns that social media recruitment leads to biased samples due to certain demographic groups being more active online [6,8].

There are a variety of metrics that can be used to consider the "success" of a post or advertisement on social media, such as view count (reach), user interaction (likes, shares, and comments), and link clicks. However, when considering using social media for research, there is a differentiation to be made between general outreach as indexed by the view count or interaction, versus targeted outreach to a specific population and the link clicks to a research webpage, which recruitment requires [9]. In terms of general outreach, there is increasing literature outlining how young people access mental health information on social media. Personal, authentic videos have been reported to be most successful [10,11], with evidence of the efficacy of a so-called "influencer" personality in promotion of mental health content [12]. However, increasing research is demonstrating that, if health professionals and academics can implement social media campaigns effectively, following formats demonstrated as successful by other content creators, they can both influence perspectives on health care and increase engagement with evidence-based health care information [13-15].

However, research into what constitutes a successful social media advert specifically for trial recruitment is in its infancy. A recent review of recruitment of young people to digital mental health interventions found that half the studies reviewed did not use social media, while 14% used exclusively social media [16]. However, research shows that online and offline recruitment methods have different levels of success and can impact the diversity of participants, with female participants and those of White ethnicity accounting for higher proportions of samples recruited online [17-19]. This suggests that studies should implement mixed methods in recruitment to lead to diverse samples, but there is a need for more research in this area in different trial populations. Additionally, those who use social media in recruitment report a significant impact of the format and content of advertisements, some reporting success with videos over images, others reporting Instagram over Facebook [20-22]. Given the complexities of social media marketing, there are queries about whether it is worth the need to train researchers in social media processes or recruit social media professionals [23].

It is clear that, given this is a relatively new and ever-changing methodology, more research needs to be done to maximize its effectiveness. Reuter [24] argues that for clinical trials to harness social media recruitment, we need more data on whether social media is better suited for the recruitment of study participants from certain demographic groups and the characteristics of effective messaging approaches. Additionally, she argues that we need to explore the effect of social media compared with other approaches on consent. Hence, we have two aims for this paper: (1) to provide a pragmatic depiction of co-designing and implementing a social media strategy with our advisory group, including the link between social media content and consent rate, and (2) to compare the demographic information of participants who were recruited via social media and other methods. We hope that our findings will support learning for future trials and researchers to implement social media recruitment with maximum efficiency.

Methods

Overview

In this paper, we conducted an observational analysis of social media as a recruitment method in a nested study within 2 mental health research trials aimed at university students. These trials are part of the Nurture-U research project [25] and test 2 separate interventions (see trial protocols for details):

1. "Reducing Worry": an app to reduce worry and boost confidence. This trial is preventative, aimed at people with worry, but no clinical symptoms of anxiety or depression. Participants are randomized to test the app or continue receiving treatment as usual (ISRCTN86795807) [26].
2. "Online CBT": a comparison of therapist-guided versus self-guided online cognitive-behavioral therapy, aimed at students with clinical levels of anxiety or depression. Participants are randomized to one of the 2 types of therapy (ISRCTN56784470).

The links from the social media adverts led to the Nurture-U trials webpage, which linked to the REDCap (Research Electronic Data Capture; Vanderbilt University) trials software [27]. The recruitment process was designed so that all potential participants were directed to one screening questionnaire on REDCap. Participants were screened using the Patient Health Questionnaire-9 [28], Generalized Anxiety Disorder-7 questionnaires [29], the Penn State Worry Questionnaire-short form [30], and the Ruminative Response Scale-Brooding [31]. If their scores indicated clinical anxiety or depression, they were directed to the information sheets and consent form for the online CBT trial. If not, but they indicated high levels of worry and rumination, they were directed to the Reducing Worry trial. There was one more trial in Nurture-U (ISRCTN18276230), but this recruited only from the University of Exeter and did not use social media for recruitment. Reducing Worry and Online CBT were recruited nationally, and hence, for consistency, we report only on the Reducing Worry and online CBT trials for this paper.

The Nurture-U project began in December 2021, with an 18-month intervention-development stage before trials began in July 2023. This paper includes an analysis of the social media recruitment from when we started using paid adverts in November 2023 to the end of the Reducing Worry recruitment in December 2024.

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Developing a Social Media Strategy With the Nurture-U Student Advisory Group

The Nurture-U student advisory group (SAG) has been engaged in every stage of the project from its inception. More details on the role of the SAG in the first year of the project have been published elsewhere [32].

The SAG developed Nurture-U's social media strategy. This involved initial meetings in Summer 2022, where Instagram was decided as the platform to focus on, and a plan to provide educational content alongside promotional material was made to encourage engagement. While accounts were created on X and Facebook, these accounts were not active beyond occasional promotional posts.

Instagram followers increased organically through promotion at Freshers Fairs in the participating universities. Engagement increased more actively through the summer and autumn of 2023 as student advisors led on creating and posting more student-generated content. At the time of writing, the project has 1087 followers on Instagram. Since Autumn 2023, on advice from the SAG, Nurture-U also launched TikTok and LinkedIn accounts. Video content generated by students and the research team is posted on both Instagram and TikTok, and LinkedIn is focused on making connections with both students and academics in the field.

The strategy for trial recruitment was developed with the SAG as a rolling point of discussion across termly SAG meetings in 2023 and 2024. The ad co-designing process with student advisors used tools like Mural and Canva to gain student advisory feedback; student advisors could both vote on our initial concepts (that included critical wording specific to the research) as well as rework the designs or create their own. We also explored market research options, taking note of what other research trials were promoting. The research team then developed and tested different adverts.

Data Collection and Analysis

We kept a record of the content of each advert we trialed, price per day, and duration on a Microsoft Excel spreadsheet. We collected data from Meta and TikTok business platforms, Google Analytics, and the REDCap platform we were using for Trials recruitment.

The recruitment journey and corresponding data collection points were as follows:

1. Potential participant clicking on the advert (Meta and TikTok "link clicks" data from business pages).
2. Potential participant landing on our "Take Part Now" Trials page of the Nurture-U website (Google Analytics).
3. Potential participant consenting to screening questionnaire to ascertain eligibility for trial participation (REDCap software).
4. Enrolled participant consenting to the Reducing Worry or online CBT trial (REDCap software).

The REDCap screening questionnaire included the question "Where did you find out about the Nurture-U project and this intervention study?." Students could tick "Instagram," "Facebook," "TikTok," "Twitter," or "other social media," as well as the other recruitment methods such as "University email," "Lecture shout out," or "Poster." We extracted the numbers who came into the screening database through the social media platforms we were advertising on each week to ascertain the success of the adverts. The REDCap consenting data also recorded participant location based on their university email, which enabled us to ascertain whether particular location-based advertising was effective.

All the data was input into an Excel spreadsheet. A descriptive analysis of the performance of the advertising over time was conducted using line graphs.

The REDCap data for all participants who consented to take part in the study were imported into R for analysis. Of the participants who consented to the trials, 46% (2081/4387) did not complete the baseline demographic questionnaires required for randomization and were therefore excluded from this analysis. As the aim of the study was to compare the demographics of participants who ultimately took part in the trials, and given that the missing data were due to dropout, we conducted a complete case analysis of those who had answered the demographic questionnaires. Multiple imputation was not considered appropriate, as the missingness was not at random and related to nonparticipation.

The answers to the REDCap question "Where did you find out about the Nurture-U project and this intervention study?" allowed us to create 2 groups of participants: those who had been recruited through social media and those who had not. Independent sample *t* tests were used to see if there were significant differences between the participants based on age. Chi-square was used to explore whether there was a significant difference between the sample recruited through social media and those recruited through other methods, according to ethnicity, gender, sexual orientation, disability, and university attended. Participants reported their ethnicity as one of 18 options; these were combined into "Asian," "Black," "Mixed or Other," and "White" to allow comparison between larger groups. Those who reported "Prefer Not to Say" or "Not Known" were excluded from the analysis (n=8). Participants reported on their gender as "Female," "Male," and "Gender diverse." "Prefer Not to Say" and "Prefer to Self Describe" were excluded from the analysis due to small numbers (n=17). Also, due to small numbers in some of the categories, the 7 possible responses for sexual orientation were collapsed into "LGBTQIA+" and "Heterosexual." Students reported their disability status as binary "yes" or "no response." The university students attended were elicited from their email, and these were combined into 2 groups according to whether they were from a Nurture-U partner university (Cardiff University; King's College London; Newcastle University; and the Universities of Exeter, Oxford, and Southampton) or another university. The significance level for all analyses was set at α=.05. This study was reported in accordance with the STROBE (Strengthening the Reporting of Observational Studies in Epidemiology) guidelines for cohort, case-control, and cross-sectional studies (combined).

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Ethical Considerations

Ethics approval for all Nurture-U trials was obtained from the University of Exeter Psychology Research Ethics Committee (institutional review board numbers: 523095; 523085). All participants in the REDCap dataset gave informed consent, and no personal data were visible to the researchers. Data collected from social media platforms contains no personally identifiable information; the data is only in the form of the number of clicks and views. Participants were remunerated for completing follow-up questionnaires as part of the Nurture-U trials (up to a total of £30 [US $40.53]), but did not receive payment at trial entry, which is the data used in this study.

Results

Development of Social Media Strategy

Ten different adverts were trialed over the 12-month period; a screenshot of the first page of each advert can be found in Table 1.

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Table . Social media advert content, duration, costs, and corresponding recruitment figures for university student mental health trials.

	Description	First page design	Months live	Cost per day (US $)	Numbers consented to screening	Numbers recruited to trial participation
A	Canva reel with music: Design from student cocreated poster mirroring successful campaign in previous trial.		• Nov-Dec 2023	• 6	• 0	• 0
B	Location-specific student callout reel (trialed in Glasgow, Leeds, Bristol, Dundee, Nottingham, and Sheffield).		• Dec 23 • Feb 24 (alongside D)	• 12.50 • 6	• 22 • See D below	• 8 • See D below
C	Cocreated advert with student advisors—students talking to camera.		• Feb 24 • Mar 24	• 6 • 10	• 0 • 6	• 0 • 2
D	Student talking to camera without script.		• Feb 24 (alongside B)	• 6	• 8	• 4
E	“Build your confidence” carousel post—different university logos according to location. Location details are provided in Table 2.		• Mar – Jun 24 • Jul – Aug 24 (alongside F) • Aug 24 (alongside G) • Sep 24 • Oct 24 (alongside H) • Nov 24 (alongside I) • Dec 24 (alongside J)	• 70 • 70 • 70 • 140 • 70 • 70 • 40-80	• 578 • See F below • See G below • 70 • See H below • See I below • See J below	• 282 • See F below • See G below • 31 • See H below • See I below • See J below
F	Summer carousel post.		• Jul – Aug 24 (alongside E)	• 70	• 31	• 8
G	Worry carousel post.		• Aug 24 (alongside E)	• 70	• 2	• 1
H	Rainbow carousel post.		• Oct 24 (alongside E and Instagram Story ad with same design)	• 70	• 57	• 24
I	Overthinking carousel post.		• Nov 24 (alongside E)	• 70	• 19	• 4
J	3 weeks left carousel post.		• Dec 24 (alongside E)	• 70	• 15	• 6

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Table . Total link clicks on social media adverts for recruitment to the university student mental health trial by advert location.

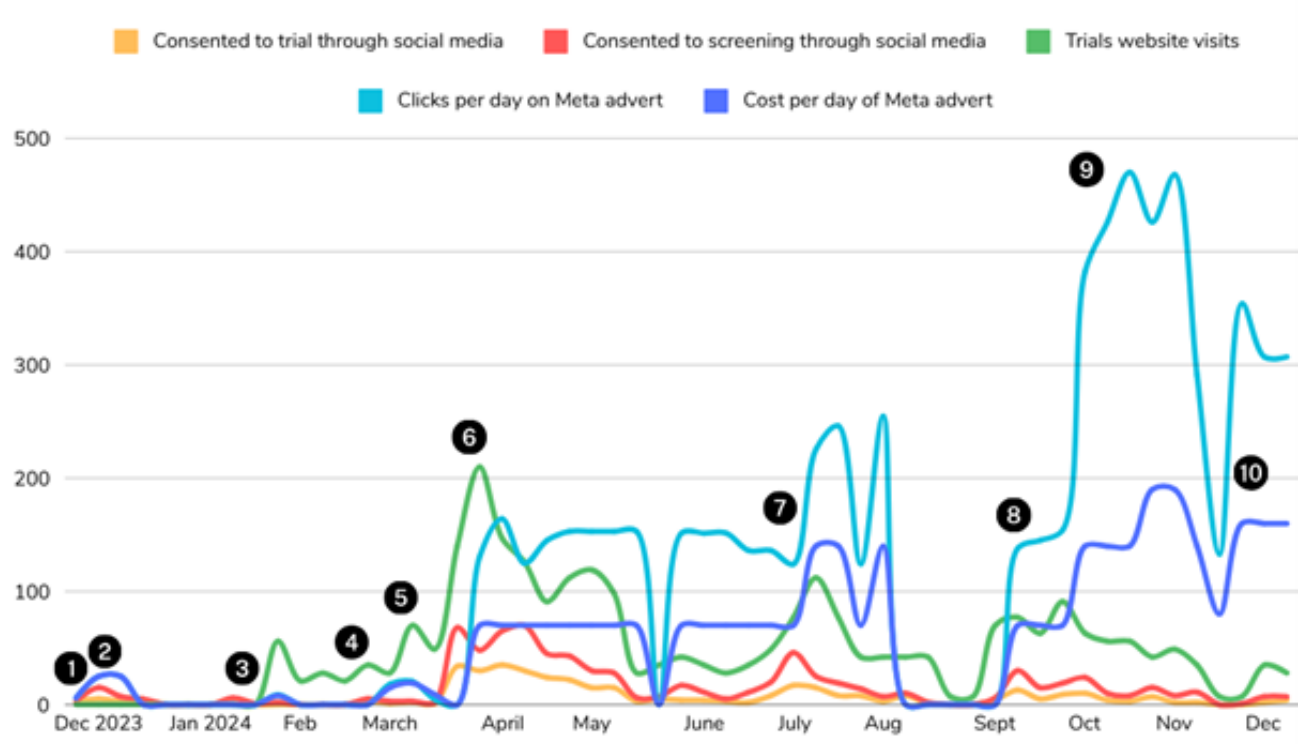
Location	Number of link clicks	Numbers consented to participation
London, Cambridge, Colchester (South East)	9718	186
Oxford, Birmingham, Reading, Staffordshire (South/Midlands)	8578	102
Leeds, Manchester, Newcastle, Nottingham, Sheffield, York (North)	6878	277
Scotland	5881	107
Wales	5728	134
Southampton, Bournemouth, Brighton (South)	5387	93
Exeter, Bristol, Plymouth, Falmouth (South West)	5342	172

Advertising Platform

The Meta advert did not specify which Meta platform, but 95% (n=748) of the 842 students who consented to participation from social media reported seeing an advert on Instagram. It was not possible to tell from the Meta business suite where our advert was primarily placed, so it is not clear whether Instagram was more successful than Facebook or whether Meta chose to place more adverts on Instagram.

The SAG advised us not to advertise on TikTok, citing minimal engagement with adverts on that platform. We trialed 2 reels (Figure 1 C,D) on TikTok across February. However, this resulted in 2 students consenting to screening, and neither of these consented to take part in the studies. Hence, we did not continue.

Figure 1. Shows the impact over time of advert content, broken down by link clicks, numbers consenting to screening, and numbers consenting to trial participation. As demonstrated by the spike in activity at point 6 on the graph, Advert E was initially extremely successful: an average of 63 students per week consented to screening, and 31 per week consented to trial participation and began the randomization process over the first 4 weeks. However, the number of participants consenting started steadily decreasing as the summer approached, despite the cost of the adverts and Meta's reports of clicks remaining consistent. We surmised that this might be due to students having exams and then finishing their university studies for the summer. Despite SAG-designed changes to content to reflect this (Table 1**F,G**), recruitment declined, and we paused adverts in August. As the new academic year began, recruitment rose again with a decline towards the end of term, despite new content and increased spend (Table 1**H-J**).



We did not pay for advertising on X, as undergraduate SAG members indicated that they did not use this platform. However, we did promote Nurture-U more generally across the year on X, and one participant indicated they had entered REDCap through a link on an X post.

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Advertising Content

Table 1 shows the content, dates run, costs, and numbers recruited in those dates. Figure 1 allows for more in-depth comparison over time, displaying (1) average of link clicks per day, (2) costs of each advert per day, (3) average numbers who landed on the Trials page of our website per day, (4) the numbers who consented to screening of the trials and (5) numbers randomized over the course of the recruitment period. The numbers in black circles indicate what changes were made at each stage in recruitment in this timeline, corresponding to Figure 1.

An initial reel (Table 1A) mirrored advertisements from a previous trial in 2019 [26]: a slideshow with text that played as a video with music. These initially were not successful, but location-specific designs (B) with higher budgets had more success. Advertisement was paused over the Christmas period and January to focus on local recruitment and plan a social media strategy with our SAG. This resulted in 2 reels using selfie mode with students talking to the camera, cocreated with student advisors (C+D). These were not successful in boosting recruitment.

A new design (E) was developed based on the following SAG input:

- Simple designs are important: People will just keep scrolling if they have to work out what they are looking at.
- Credibility is key: We need to be clear that we are from universities and not a potential sham company.
- Transparency: A clear example of the "product" or software in use will encourage people to click.
- Colorful or aesthetically pleasing images to support the text will also stop people from scrolling.

Carousel posts were implemented instead of reels, based on market research of other mental health apps and well-being advertising. We decided to focus the content of the adverts on the Reducing Worry app, hypothesizing that this was harder to recruit for than therapy. These core design decisions remained central to subsequent designs (Table 1 F-J), with slight changes in content and color according to time of year.

Implementation and Success of Social Media Strategy

Engagement and Recruitment Over Time

While there was attrition between consenting for eligibility screening and consenting to participation throughout the year, Figure 1 shows the same pattern in which numbers rise and fall, indicating that both metrics are responding proportionally to the external influences. These are most likely the time of year and advert content, given the money spent on the adverts remained the same or increased. In July and October, Meta reports of link clicks continued rising with the increase in cost-per-day of the advert, but the consent to screening and participation continued falling (points 7 and 9 on Figure 1). Hence, there was some discrepancy between Meta reports of successful advert engagement and resulting recruitment success.

Engagement and Recruitment by Location

Table 2 shows the total link clicks and numbers consented to participation of each location over the whole recruitment period. London was the most successful area for link clicks but had comparable recruitment success to the South West, which had 55% of the total link clicks of London and the South East. There were higher numbers of link clicks in Oxford and the Midlands compared with the larger university cities in the North of England, but the Northern location had the most recruited participants. The more sparsely populated south-central and west areas were the least successful on link clicks and recruitment numbers.

Comparison of the Sample

Table 3 details the comparisons between the sample collected through social media and the sample collected through other methods. There were 2369 students who consented to be trial participants in the observed timeframe. A total of 842 participants (35.6%) indicated they had been recruited through a social media advert, 1527 (64.4%) participants had been recruited through other methods. There was a 46% drop out after consent, meaning a total of 1329 participants completed demographic questionnaires and were randomized to trials. Of these, 554 (42%) were recruited through social media, and 775 (58%) were recruited through other methods.

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Table . Comparison of the sample recruited through social media and other methods.

Variables	Social media (n=554)	Other methods (n=775)	Comparison
Age (years)			
Mean (SD)	21.25 (2.63)	26.45 (7.93)	—[a]
Mean difference (SE)	—	—	−3.49 (0.31)[b]
t test (*df*)	—	—	15.146 (1927.5)
95% CI	21.06392 to 21.43937	24.33245 to 25.15566	−3.040178 to −3.944640
Ethnicity			
White, n (%)	280 (80.4)	504 (75.9)	—
Other, n (%)	68 (19.6)	160 (24.1)	—
Chi-square (*df*)	—	—	2.4609 (1)
Gender			
Female, n (%)	308 (83.3)	582 (81.9)	—
Male, n (%)	35 (9.4)	99 (13.9)	—
Gender diverse, n (%)	27 (7.3)	30 (4.2)	—
Chi-square (*df*)	—	—	8.3422 (2)[c]
Sexual orientation			
Heterosexual, n (%)	171 (48.7)	420 (62.7)	—
LGBTQIA+, n (%)	180 (51.3)	250 (37.3)	—
Chi-square (*df*)	—	—	17.867 (1)[b]
Disability			
Disabled, n (%)	103 (27.5)	154 (21.3)	—
Nondisabled, n (%)	272 (72.5)	569 (78.7)	—
Chi-square (*df*)	—	—	4.8992 (1)[c]
University			
Partner university, n (%)	235 (31.0)	999 (69.8)	—
Nonpartner university, n (%)	524 (69.0)	433 (30.2)	—
Chi-square (*df*)	—	—	432.33 (1)[b]

[a]Not applicable.

[b]*P*<.001.

[c]*P*<.05.

Those recruited through social media were significantly younger than those recruited through other methods ($t_{1927.5}$=15.15, *P*<.001). Participants recruited through social media had a mean age of 21.25 (SD 2.63, 95% CI 21.06 - 21.44) years compared with 26.45 (SD 7.93, 95% CI 24.33 - 25.156) years. There was a mean difference of −3.49 years (SE=0.31, 95% CI –3.041 to –3.945).

Due to small numbers of Black (n=31) and Mixed or Other students (n=77), these categories were combined into “White” and “Other Ethnic Group.” Of those who answered the ethnicity questions, the majority were White (728/1011, 72%). There was no significant difference between the social media and other methods group according to this variable (χ^2_1=2.4609, *P*=.12).

There was a significant difference in the samples according to gender (χ^2_2=8.34, *P*=.02). In the sample recruited through social media, 83.3% (n=308) were female, 9.4% (n=35) were male, and 7.3% (n=27) were gender diverse. The split in the sample recruited through other methods was 81.9% (n=582), 13.9% (n=99), and 4.2% (n=30), respectively. Hence, the differences appear to lie in there being more gender-diverse students recruited through social media compared with other methods (27/370, 7%, vs 30/711, 4%, CI 3.4% - 13.7%), but fewer male students (35/370, 4%, 95% CI [3.4% - 13.7%] vs 99/711, 7%, 95% CI [1.6% - 9.8%]). A significantly higher proportion of students in the social media sample were from the LGBTQIA+ community (180/351, 51%, 95% CI [41.3% - 60.6%] vs 350/711, 37%, 95% CI [28.2% - 46.8%]; χ^2_1=17.87, *P*<.001). There was also a significant difference in the sample reporting

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a disability (103/375, 27.5%, 95% CI [19.7% - 37.0%] vs 154/723, 21.3%, 95% CI [14.4% - 30.3%]; χ^2_1=4.90, *P*=.03).

Of participants recruited through social media, 69% (n=524) were from universities that were not the 6 Nurture-U partner universities, compared with 30.2% (n=433) of those from other methods (χ^2_1=302.01, *P*<.001).

Discussion

Principal Findings

Our observational study of the effect of trial recruitment methods on participant characteristics had important implications for planning future trials, highlighting the necessity to build in multiple recruitment approaches in order to ensure a diverse sample. The social media sample was younger and had a higher proportion of LGBTQIA+, disabled, and gender-diverse students, while male participants represented a larger proportion of the sample in those recruited through other methods. Co-designing a social media recruitment strategy allowed us to create advertising content that was appealing to students but still necessitated trial and error in establishing what formats enabled successful engagement and recruitment on different platforms. Alongside content, time of year was the key factor in successful campaigns, with recruitment numbers fluctuating alongside student engagement with the university in the academic year.

Our pragmatic description of how our recruitment fluctuated according to time of year and advert content shows the importance of co-designing recruitment strategies for each project, not relying on the research team's experience on previous projects. The simple, bright colors and large lettering of the successful adverts for the previous mental health trial, EcoWeb [26], were not successful for Nurture-U. There were 4 years between recruitment periods for the 2 trials, and in this time, there had been a marked shift in social media trends. The rise of TikTok and the increase in online interactions over the COVID-19 pandemic have led to societal awareness of the differences in social media platforms and the roles each one plays in our online lives [33]. Our student advisors were clear that Instagram would be the most effective platform for our advertising, and they were right. The fact that a simple carousel post was the most successful over more interactive videos and reels may reflect what people want from Instagram, and hence what people want from an Instagram advert. A research study's Instagram profile has been shown to affect participation [34], showing how important the social media presence of a study or research group can be on people's attitudes towards participation. Our SAG led our successful Instagram output, through which we have organically gained over a thousand followers through "day in the life" reels and student-focused wellbeing advice, and have built up a respectable level of TikTok engagement with similar content. However, similar approaches to our advertising content, ie, students speaking to the camera, were not successful. This demonstrates the difference between what works as content and what works as an advert and emphasizes the importance of effective market research.

Previous literature experimenting with different content for trial recruitment adverts has shown that using doctors to talk about clinical trials boosts recruitment as compared with using trial participants [14] and that information shared by a doctor may be more effective in disseminating formal and medical information and tackling logistical barriers to health [35]. We did not attempt to use an expert clinical voice as a method, and this may have been an omission. Our student advisors suggested applying to student influencers as prominent voices in the online space. We approached several suggested accounts, but we were not successful, and those who did respond charged very high fees. We believe there are 2 reasons for this. One is that people's profiles are carefully curated so that they are very specific in what they promote [36]. Second, and related, there remain negative conversations around these, which individuals may want to avoid. A recent study of reactions to influencers' posts about mental health found 25% of the comments were negative in content and 20% contained mental health stigma [37].

On reflection, a limitation of our co-design process with students is that we focused on content rather than on how we compete for student attention with external factors such as exams and university holidays. Our lack of planning for this meant we were left with only small windows for higher recruitment, specifically the beginning of academic terms. There is little research that has examined the influence of seasonality on recruitment. Langlois and Kriglstein [38] attributed not reaching participant targets in an online survey of Esport players partly to the recruitment period falling over the summer months, and there's acknowledgment of a reduction in clinical trial recruitment in the summer due to staff holidays in hospital settings [39]. While the student calendar is particularly variable and marked by different stages of activity, the wider population will also be affected by the time of year and corresponding variations in engagement in social media [40]. This is particularly challenging for research trials where recruitment windows are short, and further research is needed into the best methods to combat these fluctuations.

There were resource issues throughout the recruitment period that impacted our success, which have also been described by other research teams [23,40,41]. It was incredibly time-intensive for a research team inexperienced in creating paid advertising campaigns to both design and implement our recruitment strategy. There are a wide variety of ways to advertise on Meta alone. Our lack of expertise is also related to experimenting with different platforms. Our attempt at advertising on TikTok partly failed due to needing a TikTok Business account to enable links in videos and the challenges of navigating this with limited time and financial resources. As mentioned above, social media adverts will be more successful if they are linked to active and engaged accounts that post content regularly, which requires additional resources to maintain. There is no doubt that our costs were higher than they could have been if the team had known how to be more strategic in social media recruitment. There are published guides for social media recruitment to research, although many prioritize privacy and ethical concerns over marketing strategies [42]. Hence, studies that need to maximize the effectiveness of social media as a key recruitment strategy (for example, due to short recruitment windows or lack

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of other options for recruitment) may wish to use the services of a specialist company [42].

Social media strategy can only impact recruitment to a limited extent: once people have clicked the links, it is the study website and online data collection methods that are key for retention. Complexity and length of the screening process for clinical trials have previously been identified as a key barrier to recruitment [43]. The Nurture-U trials were set up to target widely and then siphon people into the appropriate trial based on the level of symptoms in the screening questionnaire. However, it takes a minimum of 10 minutes from the start of the screening process to consenting and being randomized for a trial. While this may not be considered a lengthy screening process for a clinical trial where participants are recruited in a hospital or university, marketing analytics indicate that the conversion rate from social media advert to website engagement can be as low as 1% - 9% [44]. Hence, 10 minutes is a big ask for people who have clicked through from a social media advert, considering they may be scrolling through Instagram while traveling, before a lecture, or in social situations. This is reflected in the reduction between the numbers in our REDCap database and those who consented to screening and then randomization.

Additionally, there was a challenge of advertising 2 trials in one. One trial contained an opportunity for therapy, and the other an app, and it was difficult to portray both options in a simple way in a social media advert. This led us to focus our content on the Reducing Worry app, our rationale being that it was under-recruiting. However, the unknown nature of the content of this app and its efficacy is likely to have affected the success of our advertising strategy [45]. Most trials of health-based apps recruit largely through clinical populations, targeting specific groups of people with specific symptoms or health goals, often through hospital settings [46]. We were aiming to recruit from a general university population and to prevent rather than treat symptoms. Trials of preventative interventions, recruiting people at risk of conditions but who do not have them yet, are far harder to recruit to than those testing different treatment options of an established condition [47].

There are many papers that cite the value of social media for widening the reach of adverts for research, but little research that directly compares the sample that was recruited through social media to those who were recruited through other methods [4,8]. Social media can increase representativeness through targeting campaigns to specific demographics, but by its nature, it will only reach those who use chosen platforms [23]. There are concerns that the more research recruitment takes place on social media, the more certain groups will be excluded, such as older participants or participants from specific ethnic groups [6]. Despite this, many studies report the benefits of recruiting hard-to-reach populations through social media [42]. This was also a key success of our strategy, in that there was a higher proportion of students from universities that were not part of Nurture-U in the sample recruited from social media. These students were harder to reach through other methods due to limited abilities to share study details in universities where the team was not based. Additionally, as the Nurture-U universities are all Russell Group universities, a group of universities with high research focuses requiring high grades to attend, increasing the breadth of universities involved in the project was a key priority to diversify our trial participants. When looking at link clicks by location, there were more link clicks in higher population areas such as London, but on examining the numbers consistently by location, it was evident that the more successful locations were those with large university student populations, for example, in the North of England. This is an important factor to keep in mind when planning social media strategies, that it is better to target locations according to your specific population, rather than larger general population numbers.

Many studies reported comparatively more females and younger participants recruited through social media [48]. We also had younger participants, likely explained by the 18 - 25 year age restriction on our adverts. Women are 3 times more likely to have a mental health diagnosis than men in the 16 - 24 year age group [49], which may explain our high female sample. While women are more likely to spend more time on social media, which leads to proportionally more impact on mental health [50], the use of social media compared with other methods did not appear to impact the proportion of females in our project. Interestingly, there was a larger contingent of males in the other recruitment methods, and a higher proportion of gender-diverse or self-defining students recruited from social media. This highlights the importance of using a mix of methods to enable a diverse sample.

There was no significant impact of social media on the ethnic diversity of our sample, which differs from other studies showing differences in ethnicity according to method [51]. There were, however, more students from the LGBTQIA+ and disabled communities recruited through social media compared with other methods. This finding builds on previous research that demonstrates social media as making it easier to recruit from this population, especially those who are less able to connect face-to-face, for example, due to living in a rural location or having impaired mobility [52,53]. The digital world can be a safe and supportive space for LGBTQIA+ and disabled youth, allowing exploration of identity [53,54]. It may be both that LGBTQIA+ and disabled students are more active on social media, but also that they interact with accounts that are similar to Nurture-U, with emphasis on well-being and community, meaning the algorithm pushed out advert more towards this sample. It is worth noting that social media can be a “double edged sword” for this community, with many experiencing discrimination and rejection [55], and these risks can extend to those researching in this space [56].

There are aspects of recruiting through social media that we did not explore in this study. There are ethical issues in social media advertising, including the lack of control over how posts are shared, what people comment, and privacy and data protection for those who interact with the adverts [57]. For example, we chose to focus on the Reducing Worry trial in advertising, which may have impacted people’s understanding if they were directed to the Online CBT study. In future research, it would be useful to include a measure to capture these issues, such as recording engagement or people’s understanding of the study messaging. Additionally, our study used post hoc comparisons; it was not

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designed specifically for a rigorous analysis and comparison of the success of different recruitment methods. A more robust study design, for example, an ABA design with direct comparison of different adverts, would provide stronger evidence of the efficacy of different approaches. Additionally, the ability to control for the impact of time of year, especially in the university population, would allow a more definitive exploration of the impact of advert content. Last, we are aware that, in recruiting university students, we are directly targeting a younger population who are more likely to be both engaged in social media and, as a result of growing up with it, more critical in their use. Both these factors will have implications for interpretation and generalizability for other settings and populations.

Conclusions

Our study is innovative in that it is one of the first studies that provides a description of how different recruitment approaches allow for differences in participant characteristics in clinical trials, alongside a pragmatic depiction of the challenges in implementing a co-designed recruitment strategy in a university setting. Our study demonstrates the positive effect of social media in accounting for a large proportion of our recruitment numbers and providing a higher proportion of gender-diverse and LGBTQIA+ students than other methods. However, the fact that other methods enabled more success in recruiting males, who are underrepresented in mental health research, demonstrates the importance of using diverse recruitment strategies. Our study also provided a pragmatic description of the co-design of a social media strategy, contributing to the literature by providing evidence of the importance of building time for adaptation of content and timing of social media adverts depending on your population within your research process. However, there are many challenges to the successful implementation of a social media recruitment campaign, including content design, recruitment timelines, resources available, and the ever-evolving internet landscape. Coproduction with those whom the research project is targeting, in our case, students, is key to a successful recruitment strategy. Our study contributes to the field by providing research evidence on the efficacy of different recruitment strategies for planning future trials. Our key real-world recommendation is to allow time and resources for planning multiple recruitment strategies in order to ensure a diverse range of participants take part in research.

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Data Availability

The datasets generated or analyzed during this study are available from the corresponding author on reasonable request.

Conflicts of Interest

None declared.

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Abbreviations

REDCap: Research Electronic Data Capture
SAG: student advisory group
STROBE: Strengthening the Reporting of Observational Studies in Epidemiology

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Assessing Night-to-Night Sleep Variability as a Hallmark of Chronic Insomnia Using Longitudinal, Contactless, Mobile Sleep Monitoring: Prospective Cohort Study

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Abstract

Background: Chronic insomnia affects more than 30% of US adults, is more prevalent in women and older adults, and is strongly associated with poor mental and physical health outcomes. Poor sleep quality and intraindividual variability of sleep are recognized to be key characteristics of chronic insomnia, but longitudinal assessment of sleep is largely subjective, with no objective characterization of sleep patterns and intraindividual variability over extended periods. Objective, ecologically valid longitudinal sleep measurements are needed to help identify and manage insomnia in both clinical and population settings. Consumer sleep technologies offer a possible solution, but their clinical utility remains relatively unexplored.

Objective: We aimed to evaluate the utility of a contactless, radio frequency–based device by demonstrating its ability to objectively characterize sleep in individuals with insomnia over an extended observation period in a naturalistic home environment.

Methods: Eighty-three participants meeting criteria for chronic insomnia and 29 healthy good-sleeper controls underwent 8 consecutive weeks of home-based sleep monitoring using an objective, contactless, radio frequency–based sleep monitoring device. Sleep efficiency, sleep latency, intermittent wakefulness, time in bed, and total sleep time were objectively quantified as daily means and SDs.

Results: Compared to healthy controls, individuals with chronic insomnia exhibited reduced sleep efficiency, increased sleep latency, and increased intermittent wakefulness. They also demonstrated significantly higher night-to-night variability (SDs) in sleep efficiency, sleep latency, and intermittent wakefulness than good-sleeper controls (all $P<.001$).

Conclusions: In the longest known objective characterization of sleep among individuals with chronic insomnia, we show that a radio frequency–based, contactless sleep monitoring device deployed in the participants' typical sleep environments accurately distinguished healthy good sleepers from those with insomnia. Importantly, we show that persistent night-to-night variability in objective sleep measures is a hallmark of chronic insomnia.

Trial Registration: ClinicalTrials.gov NCT04013321; https://clinicaltrials.gov/study/NCT04013321

(JMIR Form Res 2026;10:e73969) doi:10.2196/73969

KEYWORDS

insomnia; consumer sleep technology; noncontact sleep monitoring; insomnia phenotype; night-to-night sleep variability; sleep efficiency; sleep latency; intermittent wakefulness

Introduction

Chronic insomnia is a significant public health concern, affecting more than 30% of US adults [1], with similarly high rates of persistence at 1 year [2]. Insomnia is more prevalent in women and middle-aged to older adults and is strongly associated with poor mental and physical health outcomes [2]. Insomnia involves difficulty initiating or maintaining sleep or early morning

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awakenings occurring at least 3 nights per week for at least 3 months. According to the *International Classification of Sleep Disorders*, impairment in daytime functioning must also be present [3]. Poor sleep quality and intraindividual variability of sleep over time are considered key characteristics of chronic insomnia [4-7]. Specific sleep concerns and comorbidities vary among individuals with chronic insomnia, making evaluation and management challenging [8]. Presently, longitudinal assessment of sleep in people with insomnia is largely subjective, with no objective characterization of sleep patterns and intraindividual variability over extended periods. Objective, ecologically valid longitudinal sleep measurements are needed to help identify and manage insomnia at clinical and population levels.

Assessment of sleep using polysomnography (PSG) is not indicated for insomnia due to reverse first-night effects, in which sleep paradoxically improves in the laboratory setting [9]. Wrist actigraphy has been used to assess sleep in naturalistic settings [10-16]. These data, typically averaged within individuals over time, generally conclude limited differences between patients with insomnia and healthy controls, which leads researchers and practitioners to conclude that objective sleep differences between individuals with insomnia and healthy, good-sleeper controls are generally limited and minor [6,7,17,18]. However, this approach overlooks the marked intraindividual variability observed in some individuals with chronic insomnia [8,19]. Intraindividual variability in sleep parameters correlates with self-reported ratings of sleep quality, suggesting that the most challenging aspect of insomnia may not be continual exposure to poor sleep but rather night-to-night inconsistency of sleep [17].

For the benefit of both research and clinical practice, more extensive, objective, longitudinal, ecologically valid research is needed regarding the naturalistic sleep of individuals with chronic insomnia. This is modestly achievable with wrist actigraphy [20-22]; however, the measurement duration is substantially limited by battery life to approximately 2 weeks of monitoring. Furthermore, users must remember to wear the actigraph during sleep periods, and depending on the actigraph model, user, researcher, or practitioner, interaction may be required to download the data. Wearing the actigraph during sleep can be intrusive and thus negatively influence the very sleep it is measuring. Actigraphic data also require further processing [23] and scoring to reliably assess sleep parameters day by day. Finally, recent performance evaluations of traditional actigraphy highlight its poor specificity (ie, wake detection) relative to more novel and emerging consumer sleep technology (CST) devices [22]. The underestimation of wake after sleep onset—commonly observed with actigraphy measurement—is particularly problematic in populations with sleep disorders such as insomnia, in which sleep fragmentation is a typical sequela.

New CSTs involving contactless sleep measurement from the bedside may provide a solution to overcome these limitations. One such bedside sleep monitoring device is the SleepScore Max (SSM; SleepScore Labs). This noncontact device uses ultra–low energy radar to track bodily movements and respiration patterns through measurement of chest cavity motion to determine sleep stages. The SSM also measures light levels and ambient room temperature. The device is wall-powered by an AC adapter and communicates with a compatible smartphone through Bluetooth technology. If the Bluetooth connection is lost or interrupted, the SSM continues to track sleep as long as power is maintained [24]. Recorded data are transferred from the SSM to the smartphone for processing to identify the presence of a sleeper and to determine sleep periods and stages. The user is required to start and stop a recording in an associated app, after which the processed results are uploaded from the smartphone to the cloud. The contactless nature of the SSM may also lessen the chance of the measurement itself impacting sleep. Researchers affiliated with academic or clinical institutions can access the data stored in the cloud through a download portal provided by SleepScore Labs.

The SSM has been validated against polysomnography and wrist actigraphy in healthy sleepers [22], while previous generations of the device (eg, S+ and SleepMinder) have been validated in both healthy sleepers [25,26] and in patients with obstructive sleep apnea (OSA) [27,28]. Relative to polysomnography in healthy sleepers, the SSM's sensitivity to detect sleep was 94%, with a specificity of 50% [22]. For comparison, the sensitivity of wrist actigraphy is as high as 97%, but its specificity is lower at 39% [22]. In OSA, the SleepMinder's sensitivity to detect sleep is 86%, with a specificity of 52%. In a head-to-head comparison using the SleepMinder in patients with OSA, actigraphy showed slightly better sensitivity at 94% but substantially lower specificity at 34% [28]. Thus, the SSM's ability to monitor sleep naturalistically is comparable to wrist actigraphy, with the addition of long-term sleep monitoring, a contactless design, and higher specificity. This makes CSTs such as the SSM more suitable for long-duration studies of the naturalistic sleep of individuals with chronic insomnia.

Here, we present the results from the longest known objective assessment of sleep in people with chronic insomnia. Both groups underwent 8 consecutive weeks of contactless, naturalistic sleep monitoring using the SSM. On the basis of this study design, we compared daily means and daily variabilities of sleep between individuals with chronic insomnia and good-sleeper controls. Our objective was to determine the utility of a contactless, radio frequency–based device and to demonstrate its ability to characterize sleep in individuals with insomnia over an extended period of observation in a naturalistic environment.

Methods

Overview

Data presented here are part of a larger clinical trial to examine the efficacy of the SSM to (1) accurately measure naturalistic sleep at home in people with chronic insomnia as compared to healthy-sleeper controls and wrist-worn actigraphy and (2) test the ability of the SSM's integrated sleep coaching program to improve sleep in people with chronic insomnia compared to an active control group using the current standard of care, online cognitive behavioral therapy for insomnia, and passive control groups of individuals with chronic insomnia and healthy-sleeper

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controls. All participants collected 8 weeks of continuous nightly recordings using the SSM, with 1 week of wrist actigraphy recordings preceding and 1 week following the 8-week monitoring phase. We planned to enroll 90 carefully screened adults with chronic insomnia and 30 carefully screened healthy adult controls. The chronic insomnia group was randomized to 1 of 3 groups: SSM alone (passive control), SSM with online cognitive behavioral therapy for insomnia (active control), and SSM with a coaching program (test intervention), relative to healthy controls using the SSM alone. Here, we present results from aim 1, which was to evaluate the ability of the SSM to accurately measure sleep at home in people with chronic insomnia as compared to healthy-sleeper controls.

Power Analysis

Our preliminary data from a prior study with 17 chronic sleep-onset insomniacs and 29 healthy controls show a large effect size (Cohen d=1.99) for between-group differences. Using this effect size in our power calculations, we determined that 30 participants must be enrolled per group (90 total) in the proposed study to achieve 80% statistical power to address each of our aims at a type I error threshold of .05.

Participants

We enrolled adults with chronic insomnia as well as healthy-sleeper controls. Participants were recruited via print and online advertisements. Recruitment took place between November 2019 and November 2021. Six participants were screened in the laboratory and completed data collection before the COVID-19 pandemic. All other participants were screened remotely—through videoconference meetings and secure administration of online questionnaires—to adhere to COVID-19 social distancing requirements.

Prior to the start of the at-home sleep monitoring study, participants were screened via an interview with trained staff to determine whether they met the eligibility criteria. All participants were aged 18 to 65 years. Participants in the chronic insomnia group met criteria for chronic insomnia as defined by the *International Classification of Sleep Disorders*, 3rd edition, with no other clinically relevant condition contributing to their reported sleep disturbance [3]. Specifically, individuals with insomnia had difficulty sleeping at least 3 times per week for a period of at least 3 months. In addition, those with insomnia reported having at least 1 of the following next-day consequences: fatigue or malaise; attention, concentration, or memory impairment; impaired social, family, occupational, or academic performance; mood disturbances or irritability; daytime sleepiness; behavioral problems (eg, hyperactivity, impulsivity, and aggression); reduced motivation, energy, or initiative; proneness to errors or accidents; or concerns about or dissatisfaction with sleep. They had no other diagnosed sleep disorder other than chronic insomnia, as assessed by questionnaire. The reported sleep or wake concerns could not be explained by inadequate opportunity (ie, enough time allotted for sleep) or inadequate circumstances (ie, an environment that was safe, dark, quiet, and comfortable) for sleep.

Individuals in the healthy good-sleeper control group reported no current clinically relevant history of medical disorders or other illnesses and were free of suspected sleep disorders, as determined by the STOP-BANG (snoring, tiredness, observed apnea, pressure [high blood pressure], BMI, age, neck circumference, and gender) questionnaire [29] (score no greater than low risk for OSA) and the Pittsburgh Sleep Quality Index (score<5) [30]. Participants were required to have daily access to an iPhone (Apple Inc) to run the smartphone app associated with the SSM. All participants reported that they were not currently engaged in shift work.

Ethical Considerations

All participants provided written informed consent, and the study was approved by the institutional review board of Washington State University (protocol 17379). All sleep recording data were collected via participant IDs rather than direct identifiers. Upon completion of the study, participants were compensated with a US $20 gift card and were allowed to keep their SSM device.

Procedure

For data collection, participants were instructed to place the SSM within arm's length on their bedside table or nightstand and to collect 8 consecutive weeks of nightly sleep recordings. Participants manually initiated and ended each nightly recording through the smartphone app associated with the SSM.

Instrument

The SSM recorded sleep data in 30-second epochs classified as "wake," "light," "deep," "rapid eye movement," and "absence." "Absence" denotes that the subject was not present in the bed. The analysis window begins at the first epoch following the last absence preceding sleep onset and ends at the first absence after the final sleep epoch or at the end of the recording, whichever occurs first. Data were measured by the SSM and processed by the associated smartphone app. Time in bed and sleep parameters were estimated based on ultra-low energy radar measurements and were automatically uploaded to the cloud and later downloaded by the researchers. These data were linked to and coded for each participant using a unique study ID.

The following SSM sleep parameters were assessed for each of the recorded nights:

- Adjusted sleep latency (SL_{adj})—if absence occurs before the first sleep epoch, $SL_{adj} = t_{\text{first sleep}} - t_{\text{last Absence before sleep}}$; otherwise SL_{adj} = sleep latency
- Total sleep time (TST)—sum of light, deep, and rapid eye movement epochs within the analysis window
- Wake after sleep onset (WASO)—wake time *after* sleep onset and *before* final awakening; absence epochs were excluded
- Final awakening—time from the last sleep epoch to the end boundary (first absence after sleep or recording end)
- Time in bed—presence-based time in bed
- Sleep efficiency—ratio of TST to time in bed
- Rounding—analyses use epoch totals (0.5-minute granularity). The app displays TST and WASO rounded to whole minutes; mixing rounded and epoch values can yield differences of more or less than 0.5 minutes.

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Statistical Analyses

Data from the SSM were tabulated day by day, from which weekly means and SDs were calculated. Sleep variables were analyzed using maximum likelihood estimation in a nonlinear mixed-effects model called PROC NL Mixed (SAS, version 9.4; SAS Institute Inc) [31] to establish group means and within-subject SDs (as an index of night-to-night variability), while also controlling for age and sex. A random effect on the intercept for subjects was included to account for idiosyncratic, systematic interindividual differences. Results compared the chronic insomnia group to the good-sleeper controls by means of planned contrasts determined prior to data analysis. No imputation of missing data was performed for any of the analyses, as they were not contingent upon having complete datasets. In addition, 95% CIs for fixed effects and derived contrasts were computed from the model-estimated SEs. Data are plotted for female participants (who predominated in the sample) and the grand average age (36.1, SD 12.14 years).

Results

Study Participants

As shown in the CONSORT (Consolidated Standards of Reporting Trials) diagram (Figure 1), 127 participants were enrolled in the study: (n=96, 76%) adults with chronic insomnia and (n=31, 24%) healthy-sleeper controls; 112 completed the study. Table 1 shows that the final sample included 83 (74%) adults with chronic insomnia, aged 38.3 (SD 12.0) years, of which 58 (69.9%) were female. The average duration of insomnia was 8.5 years, and insomnia was of moderate severity as measured by the Insomnia Severity Index [31]. The controls were 29 (26%) healthy adults with self-reported good sleep, aged 29.7 (SD 8.8) years, of which 21 (72.4%) were female. The composition of our sample is consistent with higher prevalence rates of insomnia observed in women [32,33]. Baseline characteristics of the sample show that the insomnia group had significantly higher levels of subjective daytime sleepiness, as measured by the Epworth Sleepiness Scale [34], and sleep disruption, as measured by the Pittsburgh Sleep Quality Index [30]. They also endorsed significantly higher levels of anxiety and depression symptoms, as measured by the Generalized Anxiety Disorder 7-item scale [35] and the Patient Health Questionnaire–9 [36]. SSM data capture was generally high throughout, with an initial 97.3% (n=123) participation rate, a 91.7% (n=116) average weekly participation rate, with 83.0% (n=105) of participants using their device at least 2 nights per week across each of the 8 weeks of data collection. Across the entire 8-week period, overall use was higher in the insomnia group (75.9%) than in the healthy controls (71.8%). Overall weekly use in the insomnia group was more than 80% in weeks 1 to 2 before peaking in week 3 (83.8%), and then lowest at week 8 (63.2%). For the control group, overall use was highest in week 1 (80.8%) and lowest 69.5% in week 8 (69.5%).

Figure 1. CONSORT (Consolidated Standards of Reporting Trials)–style flow diagram showing recruitment, eligibility, enrollment, group allocation, and study completion.

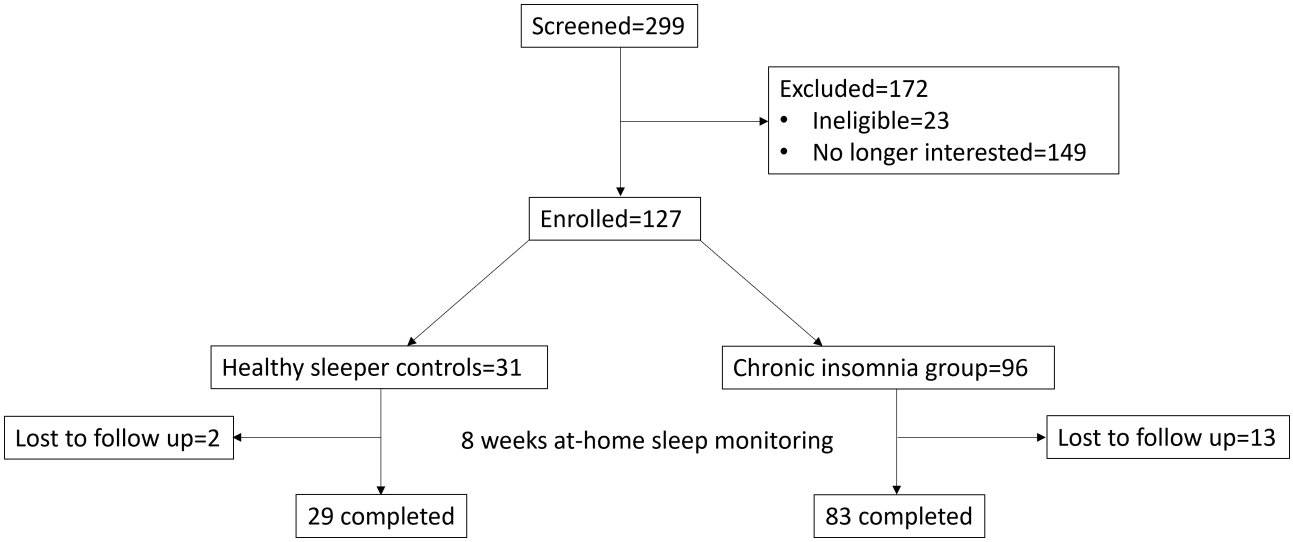

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Table . Baseline participant characteristics by group (N=112)[a].

Characteristics	Insomnia group	Good-sleeper control group
Participants, n (%)	83 (74)	29 (26)
Age (years), mean (SD)	38.3 (12.0)	29.7 (8.8)
Sex, n (%)		
Female	58 (69.9)	21 (72.4)
Bedtime (hours:minutes), mean (SD)		
Workdays	23:43 (1:46)[b]	22:30 (1:17)
Days off	00:03 (1:46)[b]	22:40 (3:28)
Insomnia duration (years), mean (SD)	8.5 (9.7)	[c]—
Wake time (hours:minutes), mean (SD)		
Workdays	08:08 (2:50)	07:08 (1:11)
Days off	08:20 (2:14)	07:37 (1:28)
Assessment, mean (SD)		
Epworth Sleepiness Scale	6.3 (4.3)[d]	3.7 (3.2)
General Anxiety Disorder 7	7.1 (5.1)[e]	2.9 (3.1)
Patient Health Questionnaire–9	7.8 (4.9)[e]	1.8 (2.5)
Pittsburg Sleep Quality Index	10.7 (3.2)[e]	3.3 (2.4)
Insomnia Severity Index	17.4 (5.8)	N/A

[a]Group differences were assessed by independent-sample *t* test.

[b]*P*<.05.

[c]Not applicable.

[d]*P*<.01.

[e]*P*<.001.

Characteristics of Chronic Insomnia

Figure 2 shows the daily measurements made with the SSM, averaged over the duration of the study (weeks 1-8) for participants with chronic insomnia as compared to the good sleepers. Table 2 shows the comparisons between study conditions for means and SDs. Compared to the good-sleeper controls, the insomnia group had lower mean sleep efficiency (*P*=.001) with higher night-to-night variability (*P*<.001) in SDs. For sleep latency, participants with insomnia had a higher mean sleep latency (*P*=.001) and greater night-to-night variability in SDs (*P*<.001) compared to good-sleeper controls. Additionally, participants with insomnia exhibited more intermittent wakefulness both in terms of daily means (*P*=.001) and SDs (*P*<.001) as compared to the good-sleeper controls. Across groups, no significant differences were observed in mean time in bed, which averaged 7.65 (SD 0.30) hours per night (*P*=.11), or in night-to-night variability for SDs (*P*=.34). The groups also did not differ in mean sleep duration, which averaged 6.59 (SD 0.16) hours per night (*P*=.91), or in night-to-night variability for SDs (*P*=.12).

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Figure 2. Head-to-head comparisons of sleep variables in individuals with chronic insomnia (red) vs healthy-sleeper controls (gray) for daily means (left side) and daily SDs (right side), as measured with the contactless sleep monitoring device, collapsed across days. Error bars denote SEs. ***P*<.01, ****P*<.001.

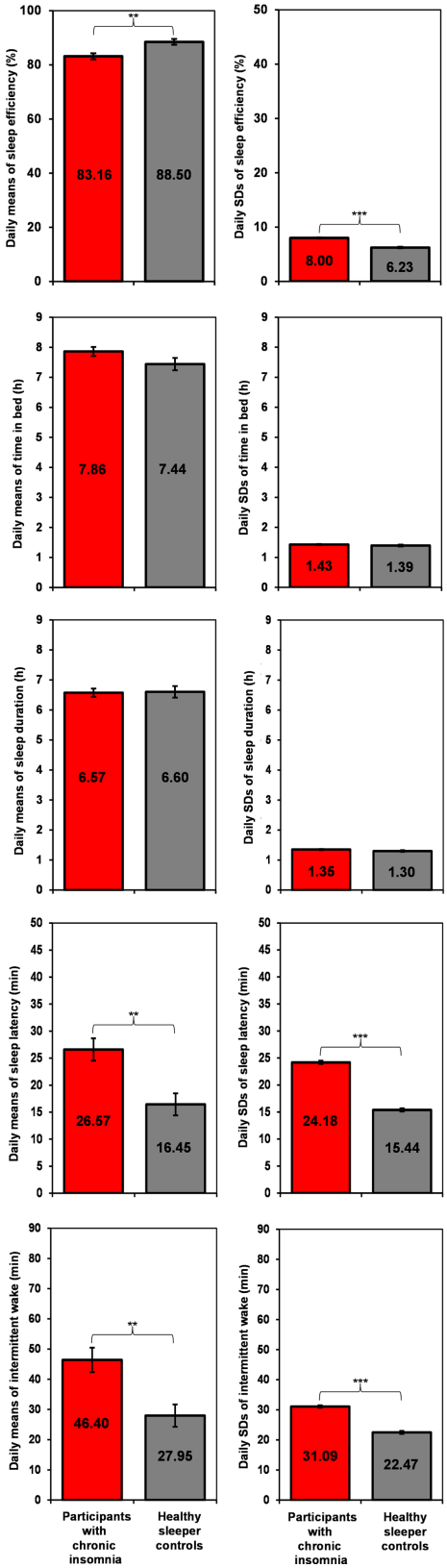

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Table . Group comparison of daily means and SDs between individuals with insomnia vs healthy sleeper controls.

Participants with insomnia vs healthy sleeper controls	Sleep efficiency		Time in bed		Sleep duration		Sleep latency		Intermittent wakefulness	
	F (*df*)	*P* value	*F* (*df*)	*P* value	*F* (*df*)	*P* value	*F* (*df*)	*P* value	*F* (*df*)	*P* value
Means	11.45 (1, 107)	.001	2.68 (1, 107)	.11	0.01 (1, 107)	.91	12.27 (1, 107)	.001	11.54 (1, 107)	.001
SD	117.91 (1, 107)	<.001	0.91 (1, 107)	.34	2.52 (1, 107)	.12	398.08 (1, 107)	<.001	204.46 (1, 107)	<.001

To provide further context, on average, sleep efficiency was 5.34% lower, sleep latency was 10.15 minutes longer, and intermittent wakefulness was 18.45 minutes higher in the individuals with chronic insomnia than in the good-sleeper controls. Night-to-night variability was greater for sleep efficiency by 1.77%, for sleep latency by 8.80 minutes, and for intermittent wakefulness by 8.60 minutes among individuals with insomnia compared to good-sleeper controls.

Discussion

Principal Results

In this longitudinal naturalistic study, we observed that the SSM detected objective differences in the sleep of individuals with primary chronic insomnia compared to healthy, good-sleeper controls. Even though average time in bed and sleep duration were similar, individuals with chronic insomnia demonstrated significantly less sleep efficiency, longer sleep latency, and more intermittent wakefulness than the good-sleeper controls. Importantly, we report a novel longitudinal, objective finding of significantly greater night-to-night variability in sleep efficiency, sleep latency, and intermittent wakefulness in participants with chronic insomnia compared with good-sleeper controls.

An increased focus on night-to-night variability in studies of insomnia has become prevalent in recent literature [5,13,17-19,37,38], but technological and methodological challenges—such as smaller sample sizes [5,13,17], lack of objective measures [37], shorter observation periods [5,13,17,19,37], and a focus on older adult populations [5,17,18]—have hampered efforts to consistently demonstrate night-to-night variability. While work by Buysse et al [5] has shown greater variability in intermittent wakefulness and sleep efficiency using 2 weeks of actigraphy, this was observed in a group of older adults (mean age 71.4 years) with insomnia, and they did not find significant differences in variability in sleep latency or in mean values of any sleep measure, as found in this study.

Previous work by Wohlgemuth et al [39] argued that 1 week of recordings with polysomnography or sleep logs was sufficient to assess temporal stability in sleep parameters in elderly adults with insomnia but noted that up to 3 weeks of recordings were needed to demonstrate stability in metrics such as WASO and sleep latency. This may explain why previous research has been unable to detect the differences observed in this study and provides support for longer observational periods across wider age ranges.

We show that a validated, contactless, longitudinal CST can detect differences in sleep patterns between individuals with insomnia and healthy good-sleeper controls. Thus, the SSM can be considered a valid method to accurately assess the sleep of those with insomnia and, as such, has the potential for clinical utility in the screening of this condition and may be considered for use in insomnia medication clinical trials.

Using a noncontact, CST-enabled, automated, relatively unobtrusive recording of sleep over extended periods (8 consecutive weeks). We found evidence of substantially increased night-to-night variability in measures of sleep onset and sleep continuity that has not previously been observed. The heightened variability from day to day in these sleep characteristics and the resulting uncertainty in the sleep experience of people with chronic insomnia may contribute to the characteristic concerns and burden of this disorder. We posit that night-to-night variability is a hallmark of the chronic insomnia phenotype and that objectively and longitudinally capturing this variability in an ecologically valid manner is key to investigating and understanding the disorder.

Limitations

This study focuses on the characterization of night-to-night variability through the examination of overall means and SDs in those with insomnia vs good-sleeper controls. The SSM also has the capability to perform sleep staging; however, as this was not the focus of this study, we are unable to comment on its accuracy.

Six of the 112 study participants completed data collection prior to the COVID-19 pandemic, and 106 were studied during the pandemic. We do not know to what degree the pandemic may have contributed to symptomology in our sample of individuals with chronic insomnia, and whether and how the pandemic may have shaped the observations in this study. Although the differences we found between individuals with chronic insomnia and good-sleeper controls are likely to be robust qualitatively, they may not generalize quantitatively to postpandemic circumstances. It is worth noting that sleep duration for our study participants averaged about 30 minutes less than the consensus recommendation of 7 or more hours per night on a regular basis [40], regardless of group or condition. However,

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the average sleep duration of our predominantly female sample was consistent with wearable-based findings for average sleep duration in US adults before the COVID-19 pandemic [41]. Our statistical analysis controlled for 2 specific factors (ie, age and sex) and combined all participants with insomnia into a single group. Future studies should consider including additional factors that may influence sleep patterns, as well as examining the potential effects of group assignment.

Our sample included 83 individuals with chronic insomnia and 29 healthy good-sleeper controls. While our included age range was broad (18 to 65 years), participants in our sample were relatively young overall (mean age 36.1, SD 12.1 years), which may indicate selection bias related to online recruitment efforts as well as the study requirement to have a smartphone (iPhone). Combined, these factors may have hindered access to a more representative age sample as well as those that were less economically affluent. Although the disparity in group size and age might have biased our results, it is more likely that this would have tempered, as opposed to enhanced, the observed differences between individuals with chronic insomnia and good-sleeper controls.

Conclusions

Capturing objective, longitudinal, contactless, within-person variability of sleep and mean differences in common measures of insomnia in the home setting adds an important dimension to our understanding of poor sleep and provides a more comprehensive, ecologically valid characterization of sleep problems as experienced in daily life. This study demonstrates the potential clinical and research utility of CSTs in the characterization and potential management of insomnia and our understanding of the disease.

In this 2-month, naturalistic sleep monitoring study, we documented the novel finding of persistently elevated night-to-night variability in measures of sleep onset and sleep continuity in individuals with chronic insomnia compared to healthy good-sleeper controls. This important finding was made possible by the use of a CST device, which enabled long-term, objective, naturalistic sleep recordings in a large sample at a relatively low financial and logistical cost. Night-to-night variability may be a critical aspect of the chronic insomnia phenotype, and long-term naturalistic sleep monitoring, as demonstrated in this study, is essential to reliably document this phenomenon.

It remains to be determined whether recognition of night-to-night sleep variability as a hallmark of chronic insomnia can shed new light on some enigmatic features of the disorder, such as the discrepancy between subjective and objective daytime impairments [11,42], the heightened sensitivity to performance impairment during sleep deprivation [43], or the dampened responsiveness to stressors [44,45]. In this context, the use of contactless CST for long-term naturalistic sleep monitoring in insomnia may constitute an important methodological advancement in both research and clinical settings.

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Data Availability

The datasets generated or analyzed during this study are available from the corresponding author on reasonable request.

Authors' Contributions

DAH designed the study, collected the data, assisted with the analysis, and drafted the manuscript. MEP collected the data and prepared the data for analysis. MGF collected the data. EG, SD-B, and RJEMR provided the sleep monitoring devices and edited the manuscript. DB contributed to the study design and edited the manuscript. NFW designed the study and drafted the manuscript. All authors reviewed and approved the final manuscript.

Conflicts of Interest

EG and SD-B are employed by Sleep.ai. RJEM is a scientific consultant and both RJEM and NFW serve on the scientific advisory board for Sleep.ai. Noncontact sleep monitoring devices were provided by Sleep.ai. Sleep.ai was not involved in the experimental design, study implementation, or data analysis.

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Abbreviations

CONSORT: Consolidated Standards of Reporting Trials
CST: consumer sleep technology
OSA: obstructive sleep apnea
SSM: SleepScore Max
STOP-BANG: snoring, tiredness, observed apnea, pressure, BMI, age, neck circumference, and gender
TST: total sleep time
WASO: wake after sleep onset

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Financial Burden in Adults With Chronic Illness in Switzerland: A Secondary Analysis of Qualitative Interviews Using Natural Language Processing and Topic Modeling

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Abstract

Background: Chronic illness may cause a financial burden that affects patients, their caregivers, and families. While international research, mostly from the United States, has largely focused on cancer-related financial hardship, less is known about whether financial distress due to other chronic illnesses exists, specifically in countries that have universal health insurance coverage, such as Switzerland.

Objective: This study aims to provide insights into how financial burden is discussed by individuals living with chronic illness in Switzerland.

Methods: Based on a natural language processing (NLP) approach, alongside topic modeling, a secondary analysis of 180 qualitative interviews of individuals living with chronic illness (dementia, chronic pain, multiple sclerosis, Parkinson disease, and rare diseases) from the Swiss Database of Individual Patient Experiences was conducted.

Results: Key categories identified were money issues, disability insurance, general insurance concerns, and work and loss of income. Individuals living with dementia and Parkinson disease appear to be more concerned with money issues, whereas people living with chronic pain, multiple sclerosis, and rare diseases are more burdened by insurance-related concerns, specifically disability insurance-related challenges. Bureaucratic hurdles and employment instability appear to contribute to the financial burden of people living with chronic illness in Switzerland.

Conclusions: Financial burden is a complex issue among individuals living with chronic illness in Switzerland. Our findings indicate that effectively addressing this burden requires a comprehensive and context-sensitive strategy. Targeted interventions should consider factors such as insurance eligibility, employment flexibility, and the mitigation of out-of-pocket costs to improve financial stability and quality of life for affected individuals.

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KEYWORDS

financial burden; chronic illness; natural language processing; topic modeling; qualitative data

Introduction

Due to an aging population and improvements in the early detection and treatment of certain diseases, the number of people with chronic illnesses is expected to increase further in Switzerland [1], where chronic illnesses currently account for approximately 80% of direct health care costs [2,3]. These demographic trends are expected to be further amplified by ongoing technological advances, leading to a steady rise in health care costs for chronic illnesses.

Over the past decade, research on the financial aspects of chronic illness has gained momentum, particularly in the United States, where the lack of universal health insurance has led to health care debts becoming a serious challenge to families' health and

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economic stability [4]. For example, 45% - 49% of people living with cancer in the United States report financial difficulties [5-7]. In other countries, cancer-related prevalence of financial burden ranges from 16% to 73% [7,8], probably depending on the type of health care system, as in countries with a publicly funded health care system, only 22% - 27% of study participants reported being affected by financial difficulties [8].

Much less is known about the financial burden among people living with other chronic illnesses. However, existing evidence indicates that approximately 70% of participants living with multiple sclerosis reported experiencing financial difficulties [9], compared to 45% of participants living with heart failure [10]. Overall, emerging evidence on financial burden appears largely to focus on specific chronic illnesses. This makes it difficult to understand whether and to what extent people with certain chronic illnesses experience financial burden differently from others, and how this relates to the welfare system. Such insights are crucial for improving our understanding of issues related to health equity, social cohesion, and the protection of groups in vulnerable situations.

Although the financial burden of chronic diseases has received considerable international attention over the past decade, to our knowledge, Switzerland has not yet fully attempted to understand or quantify it. Some studies have emerged that address financial toxicity in Swiss patients with cancer, for instance, identifying heightened financial burden among those with low incomes who live far from health care centers [11]. However, these studies have been limited in scope so far and continue to focus predominantly on cancer, which warrants a broader and more in-depth understanding of financial burden across chronic illnesses. This is even more the case given that, although Switzerland is a rich country on a global scale, wealth is unevenly distributed, and financial matters are considered taboo in Swiss society [12]. Establishing parallels for the Swiss context on the basis of international data is particularly challenging, given that the Swiss system is distinctive [13]: it is universal in coverage yet administered by private insurers, within a decentralized regulatory framework shaped by the influences of direct democracy [14]. This complex system carries the risk that individuals may not receive the financial support they need.

Therefore, the objective of this study is to obtain an initial understanding of whether financial burden exists across chronic illnesses in Switzerland and to identify patterns within and comparisons between chronic illnesses. The insights will contribute, in addition to other findings, to the development of a conceptual framework specific to Switzerland for assessing the extent of financial burden across different chronic illnesses thereafter. Further details on this framework's development have been published previously [15].

Methods

Overview

Natural language processing (NLP) was applied to a large existing textual corpus of qualitative interviews with people living with various chronic illnesses in Switzerland. This provided a valuable opportunity to rapidly explore the relevance of financial burden on a large scale and in a novel way. The approach allows for the identification of patterns of financial burden while also providing illustrative narrative examples [16-18]. The NLP analysis was complemented by topic modeling, which uses the co-occurrence of words to discover latent topics [19]. The Python programming language (developed by Guido van Rossum) was applied to prepare, process, and analyze the textual data. A Zenodo repository (developed and hosted by the European Organization for Nuclear Research) is openly accessible and contains both the computational procedures (ie, the code base) and the anonymized passages to ensure full transparency and reproducibility [20]. The NLP pipeline of this study, which details the steps from text processing to analysis, is summarized in Figure 1. Reporting herein is guided by the SRQR (Standards for Reporting Qualitative Research) checklist [21].

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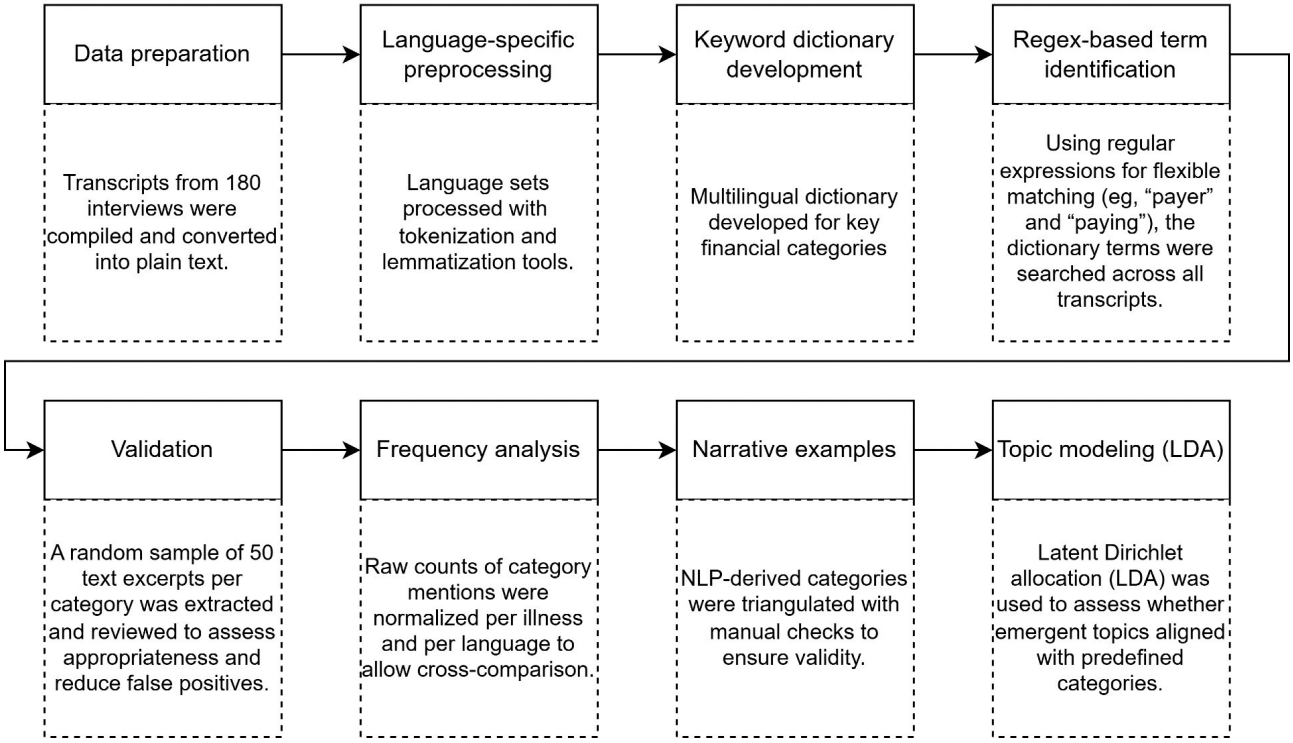
Figure 1. Natural language processing (NLP) pipeline for detecting themes of financial burden. This figure outlines the NLP workflow used to extract and analyze expressions of financial burden across the corpus. LDA: latent Dirichlet allocation; Regex: regular expressions.



Dataset

The textual dataset used herein is based on qualitative interviews drawn from the Swiss Database of Individual Patient Experiences (DIPEx) Switzerland [22]. DIPEx Switzerland is committed to the systematic standards of DIPEx International to ensure the reliability and validity of country- and health condition–specific qualitative data [23].

We only included interviews with people who had experienced chronic illnesses in the dataset, while other conditions represented in the broader DIPEx dataset, such as experiences of pregnancy, were not considered. The included textual dataset consisted of 180 qualitative interviews with people living with dementia (n=32), chronic pain (n=34), multiple sclerosis (n=37), Parkinson disease (n=43), and rare diseases (n=34). Interviews were conducted either in 1 of the three main Swiss languages (German, French, Italian) or in English. They were gathered between 2018 and 2023 by researchers of different genders and professional backgrounds, who were either trained according to the international DIPEx standards or were senior health social scientists.

Data Preparation

The textual dataset consists of the pseudoanonymized transcripts (.docx files), which were extracted using the textract library (PyPI, 2025b). Metadata (chronic illness, date of interview, language, and interview number) were retrieved from the file names. The extracted textual data were structured into a Pandas DataFrame [24], a spreadsheet-like data structure used in Python.

Language-Specific Preprocessing

NLP was used with pretrained models from the open-source spaCy library for NLP in Python [25,26]. Models for German, French, Italian, and English were carried out separately to process the textual data according to the interview language. The de_core_news_md model was used for German, it_core_news_md and fr_core_news_md were used for Italian and French, and en_core_web_md was used for English. To reduce the number of word variations in the textual data, a lemmatization process was used. This process converts words into their most fundamental form, known as lemmas, to standardize the text and to support accurate data preparation for analysis [25]. Afterwards, text segmentation was used to divide the large texts into passages.

Keyword Dictionary Development

In the next step, a comprehensive category and expression dictionary was developed to identify specific text passages related to financial burden. This dictionary was established through the generation of an initial list of German and English keywords selected by the research team. This list was subjected to a process of iterative translation (into French and Italian) and expansion through the review of interview transcripts. The process entailed the incorporation of linguistic variations, using regular expressions for flexible matching (eg, "payer" and "paying"), while allowing for the exclusion of keywords that identified text passages with no relevance to financial burden.

Categories and Expressions

This list of categories and expressions with extracted text passages was converted into a DataFrame together with the respective metadata. The category and expression dictionary is as follows (refer to the codebase: [20]):

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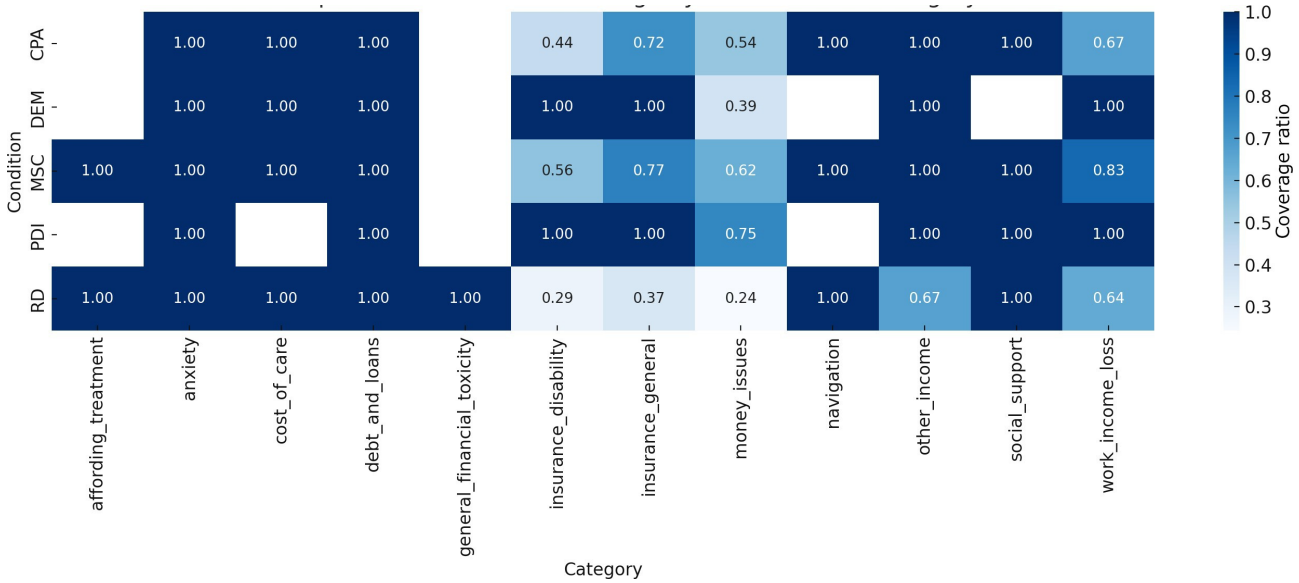
- General financial burden: captures expressions related to general financial difficulties and distress.
- Cost of care: includes expressions referring to the direct costs of medical care, treatments, and medications.
- Affording treatment: focuses on expressions related to the ability or inability to afford medical treatments.
- Insurance (general): addresses expressions related to health insurance coverage, premiums, deductibles, cost-sharing, and legal aspects.
- Insurance (disability): contains expressions related to disability insurance and pensions, including disability claims, compensation, and bureaucracy.
- Work and income loss: captures expressions reflecting loss of income due to illness, part-time and flexible work, job loss, and the ability or inability to continue work.
- Navigation: focuses on expressions associated with navigating the health care and social system, including case management and dealing with paperwork.
- Debt and loans: includes expressions related to financial debt and loans taken to cover medical or living expenses.
- Money issues: encompass expressions related to general financial concerns, such as having enough money, financial worries, and support.
- Other income: relates to alternative sources of income (pensions, savings, and salary).
- Social support: captures expressions related to social safety nets, including social security and social services.
- Anxiety: contains expressions that reflect financial anxiety, existential concerns, and fears about the future.

Sampling and Validation

To address the risk of selecting irrelevant text passages (false positives), we manually reviewed the extracted list of identified text passages and refined the dictionary, excluding terms that generated semantically inconsistent matches. All passages in categories with fewer than 50 extracted passages were reviewed in full. In categories with more than 50 extracted passages, 50 passages were selected at random and reviewed for relevance. Random selection of samples was conducted using Python's random function, which chooses a specified number of unique elements from a sequence or set, without replacement. The relative coverage of the false positives check is reported in Figure 2; the data are available in this study's repository [20].

Figure 2. Heatmap of manual review coverage by condition and financial category. This heatmap illustrates the proportion of text passages manually reviewed for each combination of illness group (condition) and financial burden category. Darker shades indicate higher review coverage. Full review (100%) was applied to all low-frequency categories (≤50 passages), and a capped sample of 50 passages was used for higher-frequency categories. CPA: chronic pain; DEM: dementia; MSC: multiple sclerosis; PDI: Parkinson disease; RD: rare diseases.



Recognizing the risk of false negatives, we also conducted a manual review of 2 full transcripts per condition and language (33 interview transcripts in total), searching for semantically relevant expressions that had not been captured by the dictionary. These additional expressions were then integrated to improve sensitivity while maintaining thematic coherence.

To further strengthen contextual accuracy, for each identified match, the 3 preceding and 3 following text passages were extracted, providing a broader interpretive window during both manual validation and downstream analysis.

Frequency Analysis

To quantify and compare the most frequently used categories and expressions within the extracted DataFrame, raw counts and normalized frequency (NF) analysis were used. NF analysis is widely used in text mining to detect the most frequently occurring expressions or categories [25] and to examine how these are distributed across text corpora, while accounting for text or document length.

Categories

First, the raw count of each category was calculated based on the extracted category and expression dictionary. To obtain normalized frequencies, the total raw count of each category

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was divided by the number of respective categories per chronic illness. This approach provides an overview of how the financial burden categories are distributed across the 5 chronic illnesses included in the study.

Expressions

First, the raw count of expressions was calculated based on the extracted category and expression dictionary. To produce normalized frequencies, the raw count of each expression was divided by the total number of expressions per category (considering language). This approach provides an overview of how the financial burden expressions are distributed across the different categories.

Narrative Examples

To provide narrative examples, an NLP-based auto-coding approach was applied to the created category and expression dictionary [27]. For each category, we computed a thematic density score based on the number of matched expressions within each text passage contained therein. This score served as a proxy for thematic salience: passages containing multiple relevant expressions were considered denser. Within each category, passages were ranked by score, and illustrative examples were drawn from the top-scoring passages. Selection prioritized both semantic clarity and variation in chronic illness and experience. While this approach is not exhaustive, it aimed to balance narrative richness with analytic focus. A broader range of examples is provided in the Multimedia Appendix 1.

To protect participants' anonymity, full interview transcripts are not publicly available but may be accessed in pseudo-anonymized form upon request.

Topic Modeling

To examine whether the fine-grained terms align with broader topics across the full textual corpus, without the predefined categories, latent Dirichlet allocation (LDA) was applied. Topic modeling through LDA is commonly used for the analysis of health-related unstructured textual data [28,29]. It is an unsupervised machine learning technique that identifies clusters of words that occur together, referred to as "topics," within a textual corpus [19]. It assigns each word to one or more latent topics based on the probability of this word's co-occurrence with other words. This reveals their distribution patterns. Through iterative word-topic assignments, the algorithm optimizes the model to identify a stable distribution that best represents the latent structure of a textual corpus. The output includes a set of topics, each defined by a list of words. To use LDA for topic modeling, it is necessary to define the number of target topics in advance [19]. The number of topics was determined by following an exploratory phase in which models with fewer (3-4) and more (6-8) topics were tested and found either to collapse distinct themes or to produce semantically fragmented topics. Model quality was assessed qualitatively through topic interpretability and alignment with thematic structures in the interviews, and quantitatively through inspection of topic stability across multiple random initializations. Thereby, 5 topics per language were considered feasible to strike a balance between capturing a broad range of topics and ensuring the interpretability of the results. To preserve contextual richness and enable a full topic modeling process, the Gensim library's LDA model was applied to the full corpus of interview transcripts included. While formal coherence scores were explored during model development, they were not used as a sole optimization criterion, as coherence metrics are known to correlate imperfectly with human interpretability in health-related qualitative corpora [30]. LDA was implemented using the Gensim library with standard priors (α and η set to "auto"), 1000 iterations, and multiple random seeds to assess robustness. Full details on hyperparameters, sensitivity analyses, and alternative model specifications, as well as interactive LDA visualizations, are provided in the accompanying Zenodo repository to ensure transparency and reproducibility [20]. The topics generated by the LDA model provided a computationally derived, yet thematically coherent, representation of how the financial issues were discussed in the interviews. Although abstracted, these topic clusters reflect tacit associations and co-occurrences that shape how chronically ill persons describe financial burden.

Ethical Considerations

The Ethics Committee of the Canton of Zurich reviewed DIPEx Switzerland and determined that it did not fall under the Swiss law on research involving human participants (BASEC no 2018 - 0050). Therefore, it was reviewed and approved by the internal review board of the Institute for Biomedical Ethics and History of Medicine at the University of Zurich (Switzerland, CEBES-2017 - 09).

Results

Overview

A total of 1509 text passages were extracted across all chronic illnesses and languages: chronic pain (n=347), dementia (n=225), multiple sclerosis (n=304), Parkinson disease (n=138), and rare diseases (n=565). Most text passages were in German (n=1053), followed by French (n=288), Italian (n=127), and English (n=111), reflecting the number of DIPEx interviews per language, with about two-thirds coming from the German-speaking part of Switzerland. Table 1 provides a detailed breakdown of extracted passages by chronic illness and language. The results presented in the following focus on German-language data, because results across the Swiss language regions were similar. Details showing this similarity are provided in the Multimedia Appendix 1. We adopted this approach to make the results section more comprehensible and readable, while ensuring that no content was lost.

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Table . Number of text passages extracted across languages and chronic illnesses.

Language	Chronic pain	Dementia	Multiple sclerosis	Parkinson disease	Rare diseases
German	242	171	190	90	360
French	72	46	74	15	81
Italian	33	8	40	11	35
English	—[a]	—[a]	—[a]	22	89

[a]Not applicable.

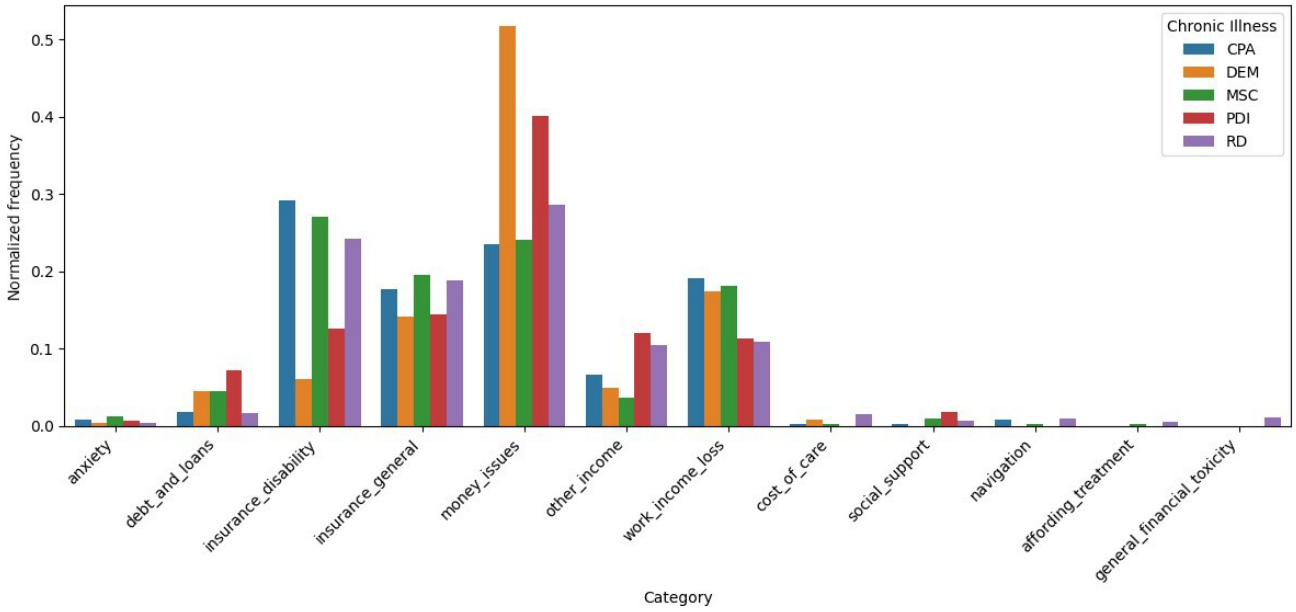
Frequency Analysis

Categories

The most frequently mentioned category is “money issues” with an NF of 33.63%, followed by “insurance (disability)” (NF=19.81%). “General insurance concerns” (NF=16.92%) are followed by “work and income loss” (NF=15.38%). Less common categories are “other sources of income” (NF=7.51%) and “debts and loans” (NF=3.92%).

The normalized frequencies of categories demonstrate distinct patterns across the different chronic illnesses, pointing toward variations in the experience of financial burden within the context of the Swiss health and social system (refer to Figure 3): “money issues” are more frequently encountered by individuals living with dementia and Parkinson disease, while “insurance (disability)” and “loss of work and income” appear more frequently voiced by individuals living with chronic pain, multiple sclerosis, and rare diseases. In comparison, the categories of “cost of care” and “social support” appear to be mentioned less frequently. For the normalized frequencies of categories across chronic illnesses, refer to Table S1 in Multimedia Appendix 1. Deviations of category frequencies per chronic illness from the overall mean are provided in Figure S1 in Multimedia Appendix 1.

Figure 3. Histogram of normalized frequencies of categories per condition. This histogram visualizes the normalized frequency distribution (range 0 - 1) of financial burden categories across 5 conditions: chronic pain (CPA), dementia (DEM), multiple sclerosis (MSC), Parkinson disease (PDI), and rare diseases (RD). Each bar represents the proportion of a category’s occurrence within the respective condition.



Expressions

Examining the most frequent expressions in each category provides an understanding of the vocabulary used to describe financial burden (Table 2). Expressions related to “insurance (disability),” “insurance (general),” and “money issues” were most frequently identified. The most prevalent German expression is invalidity insurance (IV; NF=18.61%), which is associated with the “insurance (disability)” category. This is followed by “Krankenkasse” (health insurance; NF=12.77%), which is associated with the “insurance (general)” category. Expressions such as “bezahlen” (to pay; NF=10.18%) and “kosten” (to cost; NF=8.01%) in the “money issues” category are most frequent, followed by the expression “Franken” (Swiss francs; NF=7.93%). Respective results for the other languages are provided in Table S2 and Figures S2-S5 in Multimedia Appendix 1. Taken together, the expressions suggest financial burden in chronic illness despite existing health and social insurance schemes.

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Table . Overview of raw counts and the highest normalized frequencies of expression per category (German).

Category	Expressions	Raw count	Normalized frequency
Insurance (disability)	Invalidity insurance (IV)	223	0.1861
Insurance (general)	Krankenkasse (health insurance)	153	0.1277
Money issues	Bezahlen (pay)	122	0.1018
Money issues	Kosten (costs)	96	0.0801
Money issues	Franken (Swiss francs)	95	0.0793

Narrative Examples

The top-scoring passages related to financial burden were predominantly found within the categories "money issues," "insurance (disability)," and "work and income loss." The following narrative example is intended to illustrate "money issues":

> *Ich sage die Materialien, die ich habe, sind natürlich nicht einfach wie ein einfaches Pflaster, wo man in der Migros kaufen kann. Es sind speziellere Sachen, die dementsprechend auch preislich höher. Und ja, ich sage, wenn ich jetzt viel hätte, wäre es für mich ein recht großer Kostenpunkt, wo ich nicht wüsste, wieviel kann ich von dem tragen. (I'd say the materials I use are, of course, not like a simple plaster you can buy at Migros (Swiss supermarket chain); they're more specialized and, accordingly, more expensive. If I needed a lot of them, it would be a significant financial burden for me, and I wouldn't know how much of it I could afford).* [Row 1016, rare diseases 01]

This passage emphasizes that the practical challenges and costs of medical necessities go beyond shopping for groceries; it sometimes requires special supplies and health care items, the procurement of which is described as burdensome. From the analysis, it appeared that experiences of financial burden related to "insurance (disability)" may also be connected to administrative delays and complex bureaucracies:

> *Ja, das war natürlich ziemlich schwierig, bis dann alles kam, auch von der SUVA [Schweizerische Unfallversicherungsanstalt]. Vor allem dieser ganze Papierkrieg… Also, es gibt einen Ordner voll mit SUVA und IV [Invalidenversicherung] und … ja. Das zog mich eben auch runter, mit diesen Finanzen. Denn die Rechnungen kamen ja trotzdem, man musste sie ja trotzdem irgendwie bezahlen. Und ich musste das alles von meinem Ersparten nehmen, bis heute. (Yes, it was quite difficult, especially waiting for everything to come through, even from SUVA [Swiss National Accident Insurance Fund]. Above all, the whole paper trail… I mean, there's a whole binder full of stuff from SUVA and disability insurance. And yeah, that really dragged me down, financially. Because the bills kept coming; you still had to find a way to pay them. And I had to use all of my savings for that, and still do, to this day.).* [Row 80, chronic pain 08]

This account reveals how delays in financial support due to administrative bureaucracy exacerbate the experienced distress, strain individual savings, and possibly contribute to experiences of poverty. This, in turn, can lead to feelings of devaluation, as exemplified below:

> *Und das hört er, und dann schreibt er ins Protokoll hinein: "Sie freut sich," also quasi, so schlecht kann es ihr nicht gehen. Das ist unglaublich. Ich habe das dann alles entsorgt nachher, ich wollte es nicht mehr lesen. Es war so, als ob er dachte: "Die macht jetzt wieder auf krank, die will einfach eine IV [Invalidenversicherung], weil sie das Gefühl hat ..." das fand ich schlimm. Und beim zweiten Vertrauensarzt, vom Taggeld aus, war es auch nicht besser. Der Neurologe hat zu mir gesagt: "In dieser Funktion können Sie sicher nicht mehr arbeiten. Wenn Sie so viel reden müssen, triggert das ja Ihre Beschwerden. Und anders kann man Ihnen auch nicht viel anbieten." Und er sieht das schon, hat er gesagt. Im Protokoll stand dann das Gegenteil: "Sie kann im jetzigen Job sofort wieder anfangen." (And he hears that, and then he writes in the report: "She's happy," meaning, basically, she can't be doing that badly. It's unbelievable. I threw it all away afterwards; I didn't want to read it anymore. It was like, as if he thought: "She's just pretending to be sick again, she just wants disability insurance because she thinks she deserves it…" That really upset me. And with the second insurance doctor, from the daily sickness benefit side, it wasn't any better. The neurologist told me: "In this role, you definitely can't work anymore. If you have to talk that much, it triggers your symptoms. And we can't really offer you much else." He clearly saw it. But in the report, it said the opposite: "She can return to her current job immediately.").* [Row 282, chronic pain 26]

This illustrated situation highlights how clinical recognition does not necessarily translate into recognition by the disability insurance system. Such contradictions may yet risk undermining trust, compounding burden, and perpetuating structural skepticism.

From the analysis, it appeared that work experiences and thus income loss ("work and income loss") are also influenced by the Swiss insurance system:

> *Ich hätte ja dann eine berufliche Eingliederung eigentlich, äh, zugute gehabt. Aber eben, man hat ja schon entschieden: Ich gehe in die Handelsschule,*

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> *und die haben sie übernommen. Ich wurde nicht gefragt, ob ich das wirklich möchte oder ob das das Richtige ist — wie man das heute abklären würde. (I was actually entitled to vocational reintegration, but it had already been decided that I would go to business school, and they covered that. I wasn't even asked whether I really wanted that or whether it was the right thing, like one would clarify today.).* [Row 1357, rare diseases 18]

This example underscores how decisions regarding work and training are, at times, made unilaterally by insurance providers, without considering the affected individual's agency or aspirations. Anticipating such negative experiences, others reported avoiding insurance support altogether:

> *Nein, selber habe ich mir, ehrlich gesagt, die Erfahrung erspart, weil ich von anderen Personen weiß, wie schwierig das ist. Äh, es ist ein Kampf. […] Man bekommt halt einfach — je nachdem — wirklich fast nichts oder gar nichts an Unterstützung. […] Ich habe einfach Angst gehabt, dass ich nachher wie abgestempelt werde. (No, to be honest, I spared myself the experience, because I know from others how difficult it is. It's a struggle. You end up getting almost nothing or nothing at all. […] I was just afraid that I'd be labeled—that they'd say I'm fully able to work, and then my employer would assume I have to work full-time because I'm now labeled as 100% able to work.).* [Row 183, chronic pain 15]

This narrative example shows the fear of stigmatization and discrimination, as well as the fear of impairment and psychological suffering. Applying for a reduced earning capacity pension may not lead to a positive outcome; instead, a devaluation of one's own experiences is expected, followed by increasing work pressure. The reduction in work and the associated loss of income are therefore borne by the individuals themselves and by the flexibility provided by their employers:

> *[…] Ähm, ja, da bin ich eigentlich sehr dankbar. Da habe ich einen sehr flexiblen Arbeitgeber. Und ähm, ja, ich bin jetzt mittlerweile Ausbilder für Physiotherapeuten oder begleite Physiotherapeuten. Da habe ich natürlich auch Verständnis von den Kollegen. Das ist alles im medizinischen Bereich — die wissen, was mit mir los ist. (Um, yes, I'm actually very grateful, I have a very flexible employer. And um, yes, I'm now a trainer for physiotherapists, or accompany physiotherapists. Of course, I still have understanding from my colleagues. It's all in the medical field, they know what's going on with me.).* [Row 5, chronic pain 01]

This case illustrates the importance of workplace flexibility and support in mitigating the financial impact of illness. Together, these narrative examples illuminate a landscape where formal support for work reintegration is often insufficient, inaccessible, or accompanied by fear of stigma and discrimination and invalidation of experiences.

Topic Modeling

The LDA-based analysis identified 5 key topics, highlighting distinct concerns across chronic illnesses that substantially align with the reported frequencies of categories. These topics include references to cost, work, health care providers, and bureaucratic navigation—components already identified as prominent, while also revealing subtle nuances beyond the dictionary approach. More specifically, the five identified LDA topics comprise (1) financial concerns, (2) work and mobility, (3) role of health care providers, (4) health care expenses, and (5) interplay between insurance entitlement and work. Topic tables across the different language corpora and interactive LDA visualizations are available in the study repository [20], and a detailed analysis is available in Multimedia Appendix 1; here, we focus on the German subcorpus.

Topic 1, "financial concerns," combines words such as "bezahlen" (to pay), "Krankenkasse" (health insurance), and "Geld" (money) with "irgendwie" (somehow) and "lachen" (laugh), indicating possible uncertainty and insecurity in expressing financial burden due to chronic illness in Switzerland. Topic 2, "work and mobility," encompasses the terms "Auto" (car), "Arbeit" (work), and "Leute" (people). This thematic connection potentially underscores the significance of transportation in facilitating social and professional interactions. Topic 2 also comprises words such as "selber" (oneself) and "denken" (to think), which may indicate an emphasis on autonomy and self-sufficiency. Topic 3, "role of health care providers," includes words such as "Arzt" (doctor), "brauchen" (to need), and "bekommen" (to receive). These words likely highlight the important role of health care providers and the needs and expectations of patients with chronic illnesses toward them. The term "bezahlen" (to pay) presumably emphasizes the financial aspects associated with this medical care. Topic 4 focuses on "health care expenses" and includes words such as "zahlen" (to pay), "Franken" (Swiss francs), "Krankenkasse" (health insurance), "IV," and "bekommen" (to receive). These words suggest both financial burden and support through insurance. The topic also contains words such as "arbeiten" (to work), which may show the connection between these benefits and employment. Words such as "irgendwie" (somehow) and "Sache" (thing) appear to hint at uncertainties, and "lachen" (to laugh) may express irony, frustration, or sarcasm. Topic 5, "interplay between insurance entitlement and work," includes words such as "arbeiten" (to work), "selber" (oneself), "IV," "bezahlen" (to pay), and "Krankenkasse" (health insurance), which, in combination with "denken" (to think) and "irgendwie" (somehow), may indicate the independence required to find ways to manage work and financial aspects on one's own despite chronic illness.

Discussion

Principal Findings

This study provides an initial insight into perceptions of financial burden across chronic illnesses in Switzerland, warranting further discussion. The NLP analysis of an existing large corpus of qualitative interviews revealed that the 4 most frequently mentioned categories were "money issues," "insurance

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(disability)," "insurance (general)," and "work and income loss." These are confirmed by the topic modeling and the top-scoring passages and the respective narrative examples, which are centered around the same categories, in particular, disability insurance.

Money Issues

The category "money issues" stood out across all chronic illnesses. This finding aligns with previous studies that have emphasized the financial burden placed on people with chronic illnesses and their families internationally [31-33] and in Switzerland [14,34]. The participants' narratives equally highlight the struggle with finances, a finding that should be taken seriously given the negative effects of financial strain on mental health as well as on physical and emotional well-being [10,35-39].

"Money issues" were frequently mentioned by people with dementia, Parkinson disease, and rare diseases. Regarding the former 2, 1 explanation might be that both illnesses primarily affect older adults [40,41] and are associated with a higher need for care. In Switzerland, previous studies found that 57% of people with dementia require daily or even around-the-clock care [42]. Concordantly, costs related to institutional care as well as indirect informal care costs, such as opportunity costs and health expenses, have been identified as the main cost drivers in dementia-related expenses in Switzerland and abroad [42-45]. While, to the best of our knowledge, detailed information on the informal care of people with Parkinson disease in Switzerland and related costs is lacking, findings from international studies suggest a similar pattern. In the United Kingdom, for example, formal domestic and personal care were accessed by only 25% each, while 80% relied on informal carers [46], resulting in substantial direct and indirect costs for both people with Parkinson disease and their caregivers [47,48]. Overall, the need for costly formal and informal care in people with dementia and Parkinson disease may explain the prominence of "money issues" in both illnesses.

People with rare diseases face distinct and multifaceted problems related to "money issues." Obtaining a correct diagnosis is typically a long and costly process, involving numerous medical appointments. In Switzerland, 41% of patients initially receive a false diagnosis, and 25% are correctly diagnosed only after 5 years, with diagnostic delays of up to 30 years reported in some cases [49,50]. Earlier diagnosis would not only reduce patient suffering but also lower resource usage and health care costs [51]. Even after diagnosis, treatment options remain limited. Only about 10% of people with rare diseases can be treated. Approximately 90% of these patients rely on off-label therapies [50], which are only partially reimbursed by health insurers. The same applies to many orphan drugs, that is, expensive drugs developed specifically for certain rare diseases, for which legal uncertainties persist in Switzerland regarding reimbursement and the criteria used to determine coverage [49-52].

Disability Insurance

"Disability insurance" is another frequently mentioned category, which is strongly emphasized in the modeled topics and narrative examples, most of which deal with disability insurance. In Switzerland, the guiding principle of the disability insurance system is "rehabilitation before pension" [53], meaning that disability pensions are only granted if rehabilitation and work integration options aiming to restore working capacity have been exhausted [53,54]. Previous research found that people applying for disability insurance in Switzerland perceived an unequal distribution of power, as disability insurance agents are authorized to end financial support if rehabilitation measures or insurance requirements are not met. Meanwhile, applicants saw only limited opportunities to negotiate their own rehabilitation and occupational path [55]. Other major criticisms included the opacity of placements on the disability scale and the inappropriateness of training courses or rehabilitation measures [55]. These issues are reflected in the narrative examples and topic 4 of our analysis, in which frustrations with disability insurance processes were expressed, together with the resulting emotional toll. However, it must also be considered that returning to employment through disability insurance measures allows for individuals' social reintegration, improving their quality of life [55,56].

Disability insurance was mentioned particularly often in relation to chronic pain, multiple sclerosis, and rare diseases. All 3 conditions often have an early onset [50,57-59]. Consequently, those affected frequently have not contributed sufficiently to the social security system to qualify for an old-age pension (state pension) and may also not have worked for a long enough period to build up substantial occupational pension or private benefits. These factors make them highly dependent on disability insurance.

The assumption that age is an important factor related to financial burden is supported by the fact that disability insurance was mentioned less often in the context of dementia and Parkinson disease. These conditions typically occur in older adults who have spent more years in the labor market and are therefore better covered by the 3 types of pension. However, once individuals reach retirement age, they are no longer eligible for disability insurance. This might be disadvantageous, as older adults in need of long-term care must finance most of these costs by themselves, with health insurance and the state pension covering only about 35% of the long-term care expenditures. In contrast, disability insurance and the government cover about 79% [14] for people with disabilities who have not yet reached retirement age and are therefore eligible for disability insurance. Therefore, for older people with dementia or Parkinson disease, the transition from disability insurance to an old-age pension can indeed result in a financial disadvantage.

In the case of multiple sclerosis, the progressive nature of the illness is another important factor, requiring expensive treatments and resulting in high rates of disability [9,60]. Findings from Switzerland indicate that the costs of multiple sclerosis are closely related to the severity of the disease and increase steadily with it [61,62], mainly driven by drug expenditures in early disease stages [61-63]. Furthermore, multiple sclerosis ranks among the diseases with the greatest increase in health care spending in Switzerland over the past decade [2]. Similarly, in the United States, multiple sclerosis is associated with the highest total out-of-pocket expenditures compared to other chronic illnesses and can even lead to medical

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bankruptcy [64]. Taken together, these findings underscore the importance of support from disability insurance and other social welfare systems.

Regarding rare diseases, many manifest early in life and are classified in Switzerland as "Geburtsgebrechen" (congenital disorders). In such cases, financial responsibility initially lies with the disability insurance (IV), which covers the costs of medical measures related to recognized birth defects up to the age of 20 years. However, reimbursement by the IV is dependent on a specific list of recognized congenital disorders ("Liste der Geburtsgebrechen") and a corresponding list of medicines. After the age of 20 years, responsibility typically shifts to mandatory health insurance. Navigating the administrative processes of this transition can be difficult and may lead to even more insecurity regarding reimbursement [50].

General Insurance

The third frequently mentioned category, "insurance (general)," includes an array of issues and seems to be similarly important across all chronic illnesses. According to narrative examples, major systemic barriers related to insurance are eligibility issues, insurance denials for people with pre-existing chronic conditions, and health insurance coverage. Although health insurance companies (37.7%) and the government (21.2%) together cover more than half of total health expenditures in Switzerland, a significant proportion of health care is financed by households' out-of-pocket payments (21.3%) [34], which are notably higher than in many other European countries [65]. For chronically ill people, it is particularly important that the total costs of copayments for outpatient treatment in Switzerland are capped [14], which is not the case for inpatient copayments. On the other hand, as Desborough et al [66] point out, people may also struggle to reach the copayment threshold. The narrative examples and topics 1 and 4 illustrate that these insurance-related barriers can lead to psychological distress—an issue confirmed in international literature [66-69].

Work and Income Loss

The category of "work and income loss" reflects the impact of chronic illness on the ability to maintain employment and income. It highlights the indirect financial consequences of chronic illnesses, which are often as critical as direct medical costs [47,70]. Loss of employment can further exacerbate existing financial burden [66], forcing chronically ill people and families into precarious living situations [71,72]. Another work-related issue that was underscored in the narrative examples relates to work flexibility. Concerns were expressed about unrealistic workplace expectations. This is equally emphasized in the literature [73], stressing how understanding in the workplace can alleviate some of the burdens associated with chronic illness.

The normalized relative frequency of this category was highest in people with chronic pain, dementia, and multiple sclerosis. Regarding chronic pain and multiple sclerosis, a possible explanation is again that many young or middle-aged adults are affected, who are still working, making "work and income loss" a relevant concern for them. Indeed, multiple studies from Switzerland and other countries have reported a decline in income in people with chronic pain [74-78] and multiple sclerosis [61] due to factors such as reduced working hours, job changes, absenteeism including sick leaves, resulting job loss, or early retirement. Particularly in more advanced stages of multiple sclerosis, absence from work, reduced productivity, and loss of employment have been identified as major drivers of illness-related costs [61,62]. These findings again underscore the importance of disability insurance to cover these costs or support work reintegration.

The relatively high frequency of words related to "work and income loss" in dementia may be explained by the role of informal caregivers in dementia care. Caregivers are also affected by work and income loss and face high costs, such as opportunity costs and health expenses [42,45]. In Switzerland, it has been shown that indirect costs, or opportunity costs through informal caregiving, respectively, account for approximately 44% of the total cost of dementia [42].

Topic Modeling

Overall, the topic modeling confirmed findings from the normalized frequencies analyses and narrative examples, demonstrating recurring concerns about health care costs, insurance coverage, and IV across multiple topics. The LDA results added value by surfacing cross-cutting patterns not captured by the predefined categories alone, for example, the entanglement of employment, autonomy, and insurance navigation that emerges as a latent theme across topics 2 and 5.

The frequent co-occurrence of work-related terms with bureaucratic and financial concerns reinforces the idea that these are interlinked experiences. Furthermore, the presence of emotionally charged and ambiguous terms (eg, somehow and laugh) in multiple topics suggests not only the material but also the affective complexity of financial burden and chronic illness. These findings align with prior research indicating that financial burden includes both economic hardship and its psychological correlates [36], while also validating and extending our frequency-based analysis through a different analytic lens.

Limitations

The study is subject to certain limitations. A major limitation is that it relies on a corpus of semistructured interviews from the Swiss DIPEx database that were collected before the study. The interviews covered a variety of topics, some of which were more comparable to each other than others. However, all interviewees had one thing in common: they had all experienced illness within the Swiss health care system. On the other hand, although certain topics addressed in the interviews varied, they related specifically to the participants' experiences of illness, which might have improved the validity [79]. The maximum diversity method was used for all DIPEx interviews included. This approach guarantees maximum variability in perspectives, but not representativeness [80]. Thus, the results provide valuable in-depth insights into the diversity of experiences but may not be generalizable. However, the findings are intended to inform the development of a conceptual framework that is based primarily on international literature and qualitative data from Switzerland, enabling broader generalization in subsequent

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research phases. Finally, no demographic variables from the participants were reported. Therefore, we could not examine potential differences between demographic groups. Prior research suggests that financial burden may vary between genders and across age groups [81], which is why the interpretability of our findings is limited. However, this information was not possible to retrieve from the DIPEx database. Nevertheless, this analysis was key to us in order to gain an initial impression of the different experiences in Switzerland, as the financial burden in relation to certain illnesses is still unknown [2].

Conclusions

In conclusion, our findings show that the financial burden in chronically ill people is not a singular issue but rather a multifaceted challenge that intersects with bureaucratic barriers, high out-of-pocket expenses, employment insecurity, insurance-related challenges, and health care access. Given the exploratory nature of this study, these results should not be interpreted as calls for systemic reform. Instead, they highlight specific areas that may warrant closer attention in future research and stakeholder discussions. For instance, simplifying and clarifying disability insurance procedures may be particularly relevant for individuals with fluctuating or less visible conditions, such as chronic pain, multiple sclerosis, or rare diseases, whereas people living with dementia or Parkinson disease may benefit from clearer guidance on available financial supports. Employment instability also emerged as a contributor to financial strain, suggesting that improved communication between employers, insurers, and affected individuals could be a promising area for further exploration.

Overall, addressing issues related to financial burden in chronically ill people requires a comprehensive and context-sensitive approach. This study provides a first step toward such an approach and informs the next phases of our larger research project [15]. As described above, the results will be integrated with international evidence from a scoping review and new qualitative interview data to develop a conceptual framework on financial burden and chronic illness specific to Switzerland, refined through stakeholder discussions. This framework will then guide the creation of a survey to measure financial burden in chronically ill individuals in Switzerland. Ultimately, survey results will be discussed with stakeholders to identify actionable solutions and potential changes to current policies and practices.

Through this stepwise process, our work lays the foundation for evidence-based discussions on how the Swiss health and insurance systems might better support individuals with chronic illnesses without overstating the conclusions that can be drawn from this exploratory study.

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Data Availability

The datasets analyzed in this study are available in the study's Zenodo repository [1,20]. The full primary datasets are not publicly available because they contain personal and sensitive information but are available from the corresponding author on reasonable request.

Authors' Contributions

GS developed the automated textual data analysis and visualizations and contributed to the initial methods and results sections. RV supported the analysis, validated the results, and led the initial manuscript draft, particularly the introduction. JS supported the analysis and wrote the discussion and summary sections. ASL and JJ contributed to the analysis, with JJ also formatting the manuscript. EA supported the analysis and coordinated study administration and analysis meetings. FG contributed to dictionary development, code implementation, and results analysis. KR and BS secured overall project funding. NBA designed the DIPEx part of the FINK project in the application and is responsible for the DIPEx work package as project partner. KR and BSsupported the analysis, and reviewed the manuscript. BS led the final review. All authors critically reviewed and approved the manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1

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Results across German, French, Italian, and English text corpora.
[DOCX File, 307 KB - formative_v10i1e79290_app1.docx]

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Abbreviations

DIPEx: Database of Individual Patient Experiences
IV: invalidity insurance
LDA: latent Dirichlet allocation
NF: normalized frequency
NLP: natural language processing
SRQR: Standards for Reporting Qualitative Research

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Validity of Galaxy Watch for Estimating Energy Expenditure During Intermittent Running: Cross-Sectional Study

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Abstract

Background: Smartwatches have gained popularity for their potential to provide accurate measurements of various physiological parameters. However, the validity of energy expenditure (EE) across different smartwatch models remains a topic of ongoing investigation. Discrepancies between results obtained from different models and gold standard methods are particularly critical across varying exercise intensities and types, as validation studies have demonstrated overestimation when wearable activity monitors are compared with indirect calorimetry.

Objective: This study investigated the accuracy of 2 versions of the Samsung smartwatch (Galaxy Watch [GW] 6 and 7) in measuring EE during intermittent moderate-intensity running exercises, using indirect calorimetry as the gold standard method.

Methods: This study included 148 healthy adults, comprising 80 men and 68 women. Participants performed intermittent treadmill running, consisting of walking at 5 km·h ¹ for 1 minute and running between 8 and 16 km·h ¹ for 2 minutes, based on participant preference, for a total duration of 27 minutes. The GW6 and GW7 models were used and EE was measured by indirect calorimetry using a wearable portable metabolic gas analysis system (K5; Cosmed), which is considered a gold standard method.

Results: No statistically significant differences were found between the GW models and the K5. The K5 showed a mean EE of 213.60 (SD 43.04) kilocalories, compared with 219.53 (SD 35.70) kilocalories for the GW6 and 202.67 (SD 47.42) kilocalories for the GW7 (all $P>.05$). Good Spearman correlations (0.63 - 0.70) and moderate intraclass correlation coefficients (0.65 - 0.74) were found. Mean absolute percentage error values ranged from 10.10% to 12.55%. Bland-Altman analysis revealed limits of agreement for all comparisons (K5 vs GW6 and GW7, −61.93 to 65.80 kcal).

Conclusions: The GW6 and GW7 devices showed moderate validity for estimating EE during intermittent running exercises, demonstrating the suitability of the GW as a low-cost and practical wearable option for daily physical activities.

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KEYWORDS

energy expenditure; calories; exercise; smartwatch; wearables

Introduction

The accurate measurement of energy expenditure (EE) during physical activity is essential for both research and practical applications in sports science, fitness, and health monitoring. Wearable technology, such as smartwatches, has become increasingly popular due to its convenience, ease of use, and ability to provide real-time data. Among these devices, smartwatches have gained popularity for their potential to offer accurate measurements of various physiological parameters, including heart rate, step count, and EE [1,2]. However, the validity and reliability of EE across different smartwatch models remain a topic of ongoing investigation.

Recent advances in sensor technology and algorithm development have enabled smartwatches to estimate EE by combining data from accelerometers, heart rate monitors, and other sensors. Despite these advancements, questions persist regarding the accuracy of these devices compared with established gold standard methods, such as indirect calorimetry and doubly labeled water techniques [1,3,4]. This discrepancy is particularly critical across varying exercise intensities and types, where the accuracy of EE estimation may fluctuate. Validation studies have demonstrated that wearable activity monitors tend to overestimate EE when compared with indirect calorimetry [5-7], highlighting the need for accurate EE estimation to ensure effective fitness monitoring and possible research applicability.

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Interdevice reliability differences in EE estimation were observed between Fitbit (Google LLC) smartwatch models depending on the type of exercise performed, with intraclass correlation coefficients (ICCs) ranging from 0.48 for jogging to 0.97 for walking. These values were compared with indirect calorimetry, which had ICCs ranging from 0.58 to 0.89 [6]. Le et al [1] evaluated the validity of the Apple Watch Series 6, Garmin FENIX 6, and Huawei Watch GT 2e for estimating EE during outdoor walking and running among young, lean Chinese adults. For walking and running activities, compared with indirect calorimetry, the Huawei Watch GT 2e demonstrated lower mean absolute percentage error (MAPE) values for EE estimation (9.9% and 11.9%, respectively), whereas Apple (19.8% and 24.4%, respectively) and Garmin (32% and 21.8%, respectively) showed higher MAPE values. For ICCs, higher values were observed for the Apple Watch during walking and running (0.821 and 0.74, respectively), followed by Huawei (0.760 and 0.698, respectively) and Garmin (0.216 and 0.594, respectively).

The Polar Grit X Pro smartwatch was considered valid for EE estimation across military training exercises (ICC, 0.8) when compared with indirect calorimetry assessment [3]. Similarly, Roos et al [8] analyzed the validity of 3 different smartwatches compared with indirect calorimetry at 2 different running intensities. The results showed that the accuracy of the smartwatches was intensity-dependent when compared at 30%, 50%, 70%, 90%, and 110% of the velocity associated with peak oxygen consumption ($VO_{2\ peak}$), with MAPE values ranging from 10.9% to 49.3% and the greatest variation observed at 110% of $VO_{2\ peak}$ between smartwatch estimates and criterion measurements.

Limitations in smartwatch validation research include the absence of regulatory standards [4], small sample sizes [1,3], heterogeneity of methods [3-5], and “black box” variables, such as algorithms and sensor updates. As demonstrated in previous studies, the accuracy of EE estimation and the heterogeneity of results across devices underscore the need for comprehensive validation methodologies, appropriate statistical approaches [3,5,8], and larger sample sizes [1,3].

The validity and accuracy of EE metrics provided by smartwatches are critical, as they are frequently used as decision-making data for physical activity and control of caloric intake [4,5]. In addition, the literature lacks three critical elements of smartwatch EE validity: (1) validity of EE measures in intermittent running activities, (2) accuracy across different models of the same smartwatch, and (3) more representative and larger sample sizes. Moreover, the validity of smartwatches is company- and model-dependent, as different companies tend to use distinct algorithms by patent issues, and the software may be upgraded in subsequent versions. In this context, it is important to conduct validity studies among growing companies in the health technology segment, such as Samsung, which has released at least 7 generations of smartwatches aimed at the health market.

This study aimed to evaluate the accuracy of 2 models of Samsung Galaxy Watch (GW; GW6 and GW7) in measuring EE during exercise, using gold standard methods as a reference (indirect calorimetry), during intermittent moderate-intensity running exercises. By assessing the performance of these devices, this study aimed to provide insights into their utility for both scientific research and everyday use among individuals seeking to monitor their health and fitness levels.

Methods

Study Design

This was a cross-sectional, within - subject study designed to compare estimated EE from 2 models of the Samsung GW (the GW6 and the GW7) with criterion measures of EE obtained using a wearable metabolic gas analyzer (K5; Cosmed) during intermittent running. Reporting followed the Guidelines for Reporting Reliability and Agreement Studies [9]. Three K5 gas analyzers were used to perform the measurements. Before any treadmill activity began, all participants were screened by a physician and a treadmill stress test was performed with a 12-lead electrocardiogram. After screening on a separate day, participants attended the laboratory to perform the tests. Skin color was measured using a Mexameter MX18 spectrophotometer (Courage+Khazaka electronic GmbH) and categorized between 1 and 6 following the Fitzpatrick Classification scale [10]. The exercise protocol consisted of intermittent walking and running.

Participants

This study recruited 148 healthy adults, comprising 80 men and 68 women. The participants were physically active and engaged in at least 150 minutes of moderate-intensity activity and/or 75 minutes of vigorous activity per week. Inclusion criteria were (1) being physically active, defined as engaging in at least 150 minutes of light- to moderate-intensity exercise, and (2) being aged 18 to 59 years. Exclusion criteria were (1) musculoskeletal injuries of the lower limbs, (2) cardiovascular or lung diseases, and (3) use of medications that impact heart rate response, such as beta blockers.

Ethical Considerations

All participants were informed about the study procedures and provided written informed consent. This study was conducted in accordance with the ethical principles contained in the Declaration of Helsinki and complied with national regulations governing research involving human participants (466/12 of the National Health Council). The experimental procedures followed established ethical standards and were approved by the Investiga - Institutos de Pesquisa ethics committee (CAE 62031722.4.0000.5599). The privacy and confidentiality of all research participants and their data and identities were maintained throughout the study. All personal identifiers were removed from the dataset, and data were anonymized to ensure compliance with ethical standards. Access to the data was restricted to the research team, and all data were stored securely in accordance with institutional guidelines. In accordance with the legal regulations of our country, participants in this study did not receive monetary compensation. However, they were provided with reimbursement for transportation and meal expenses as a token of appreciation for their time and contributions.

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Exercise Protocol

To test the validity of the GW6 and the GW7 under standardized laboratory conditions, participants performed an activity of intermittent walking and running for a total duration of 27 minutes, consisting of walking at 5 km·h ¹ and running between 8 and 16 km·h ¹, based on the participant's preference, on a commercial treadmill (Star Trac, E-TRxe). The protocol consisted of a 2-minute walking warm-up, followed by 7 repetitions of 2 minutes of running and 1 minute of walking, and concluded with an additional 4 minutes of walking recovery (27 min total).

Criterion Measure

The K5 portable metabolic cart was used as the criterion method for estimating EE. This device is considered a valid and reliable system for measuring metabolic variables [1,11]. Device set up, calibration, and data extraction were conducted via OMNIA Metabolic software (version 1.6.10) (Cosmed). For the calculation of EE, oxygen uptake (VO_2) was measured continuously, breath by breath, throughout the entire 27-minute protocol. Two pieces of K5 equipment were used for the data collection. Before each session, all K5 equipment was calibrated according to the manufacturer's instructions.

Wearable Activity Monitors

Two GW models (GW6 and GW7) were used and connected to a smartphone (A22; Samsung Electronics), and all EE data was exported using the Samsung Health app. In cases in which activity data required trimming, full health data were exported via the Samsung Health app, and the raw CSV file was imported into Microsoft Excel (version 2310) for further analysis and cleaning. Participants' weight, height, date of birth, and wrist orientation were entered into each watch before the activity protocol. The watches were positioned on the left arm, just above the wrist (2 cm above the ulnar styloid process), as per manufacturer instructions. The GWs were set to record the activity protocol as a workout, with watches being started and stopped at the beginning and at the end of the activity. The GWs were set to the "treadmill" mode.

Statistical Analysis

The sample size was estimated a posteriori using a custom Python script, with an α level of .05 and statistical power of 0.90, identifying a minimum sample size of 29 participants for the GW6, 18 participants for the GW7, and 21 participants for both GW models. The power calculated using the actual sample size was 1.0 for all comparisons. Additionally, the sample size was considered adequate based on the recommendations of Chevance et al [12], who consider sample sizes of more than 50 participants to be reasonably large. Moreover, the sample size in this study was larger than that of previous comparable studies of wrist-worn health-tracking devices, in which participant numbers ranged from 11 to 60 [1,3,8,13,14]. Data distribution was inspected, and outliers were identified using boxplot analysis and removed if they exceeded the standard error limits. The lower limit was defined as the first quartile minus 1.5 × the interquartile range (IQR), and the upper limit was defined as the third quartile plus 1.5 × the IQR. Data normality was verified by the Shapiro-Wilk test.

Two - sided paired *t* tests were used to compare the K5 with the GW6, the K5 with the GW7, and the K5 with the GW6 and GW7. Significant differences (P<.05) were interpreted using Cohen *d* effect sizes, with the threshold defined as trivial (<0.20), small (0.20 - 0.59), moderate (0.60 - 1.19), large (1.20 - 1.99), and very large (2.00 - 4.00) [15]. To evaluate systematic differences, correlation, precision, and agreement between the wearables and the criterion measure, MAPE (calculated as [actual – predicted]/actual × 100), ICC (2-way random-effects model, absolute agreement, single measurement), Spearman correlation, and Bland-Altman analysis were performed.

The MAPE value was interpreted as poor (≥20%), moderate (10.1%-19.9%), good (3.1%-10.0%), and excellent (0%-3%) [1,14,16]. Spearman correlation coefficients were interpreted as negligible (0.00-0.09), weak (0.10-0.39), moderate (0.40-0.69), strong (0.7-0.89), and very strong (0.90-1.00) [17]. Finally, ICC values were interpreted as poor (<0.50), moderate (0.50-0.74), good (0.75-0.89), and excellent (≥0.90) [18].

Statistical analyses were performed using JASP software (version 0.18.3; JASP Team) and a custom Microsoft Excel (version 2506) spreadsheet [19]. Statistical significance was set at P≤.05 (2-tailed). Based on the current literature, results were considered valid when values were at least moderate for ICCs, Spearman correlation, and MAPE.

Results

Participants had a mean age of 29.98 (SD 9.01) years, a mean height of 1.65 (SD 0.09) meters, a mean body mass of 65.53 (SD 11.18) kilograms, and a mean skin pigmentation score of 3.60 (SD 1.11) according to the Fitzpatrick classification scale. Energy expenditure during intermittent running is shown in Table 1.

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Table . Energy expenditure during intermittent running with the Galaxy Watch (GW), measured with the Cosmed K5 metabolic gas analyzer.

Devices (N=148)	Energy expenditure (kcal), mean (SD)	95% CI
K5_GW6 (n=79)	218.63 (39.70)	227.52-209.74
K5_GW7 (n=69)	207.84 (46.20)	218.94-196.74
K5_All (n=148)	213.60[a] (43.04)	220.59-206.61
GW6 (n=79)	219.53 (35.70)	227.53-211.54
GW7 (n=69)	202.67[a] (47.42)	214.06-191.28
GW_All (n=148)	211.67 (42.28)	218.54-204.80

[a]Statistical significance for the Shapiro-Wilk test ($P \leq .05$).

Table 2 shows systematic differences, correlations, and measure of precision. For systematic differences, a paired *t* test was conducted to compare EE values between the K5 and the GW6. No statistically significant differences were found between the K5 versus the GW6, the K5 and GW7, or the K5 and the combined GW6 and GW7 (GW6+GW7). Spearman correlation indicated moderate associations between the K5 and GW6 and between the K5 and the combined GW6 and GW7, and a strong association between the K5 and GW7. Moreover, moderate ICC and MAPE values were found for all comparisons.

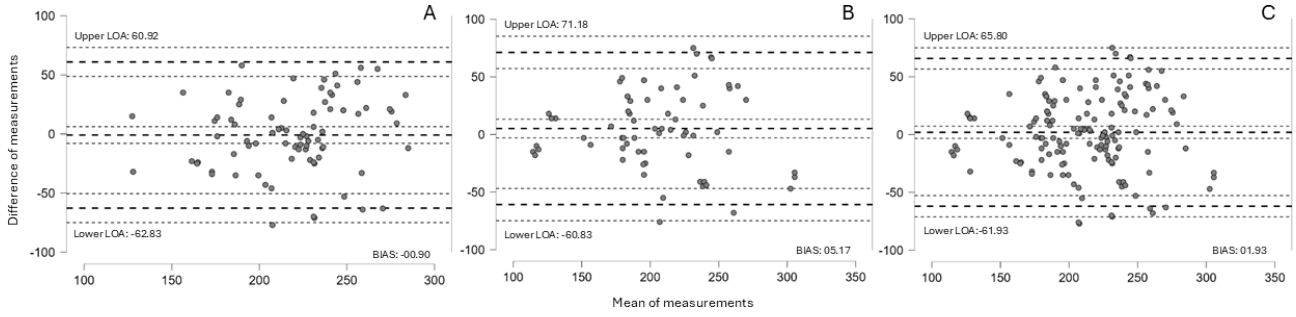
Table . Spearman correlation (SC), intraclass correlation (ICC), and mean absolute percentage error (MAPE) of energy expenditure during intermittent running with the Galaxy Watch (GW) and Cosmed K5 metabolic gas analyzer.

Devices (criterion, practical)	SC (95% CI)	ICC (95% CI)	MAPE, mean (SD)
K5, GW6	0.63[a] (0.47-0.75)	0.65 (0.55-0.74)	10.10 (9.34)
K5, GW7	0.70[a] (0.55-0.80)	0.74 (0.66-0.81)	12.55 (8.78)
K5_GW6+GW7	0.67[a] (0.57-0.75)	0.71 (0.62-0.78)	10.86 (9.06)

[a]Statistical significance for the Spearman correlation at $P \leq .05$.

Figure 1 shows Bland-Altman plots with bias and limits of agreement between criterion and practical measurements, presented as mean, upper, and lower calorie values.

Figure 1. Bland-Altman LOA between the (A) Cosmed K5 metabolic gas analyzer and GW6, (B) Cosmed K5 metabolic gas analyzer and GW7, and (C) Cosmed K5 metabolic gas analyzer and GW6 and GW7. GW: Galaxy Watch; LOA: limits of agreement.



Discussion

Principal Findings

The Samsung GW6 and GW7 models were evaluated for validity in estimating EE during intermittent, moderate-intensity exercise. The results showed a moderate to strong correlation and no statistically significant difference in paired *t* tests when compared with the gold standard of indirect calorimetry. Additionally, both the GW6 and GW7 models achieved a MAPE value of less than 15%, which indicates a moderate absolute error.

Existing literature reveals variability in smartwatch validation results due to differing algorithms, hardware generations, and study designs. For instance, LaMunion et al [20] found significant differences between 5 consumer devices, including 4 smartwatches, when compared with the Cosmed K4b^2 portable metabolic gas analysis system during semistructured daily activities. In contrast, the GW6 and GW7 models in our study showed moderate validity under intermittent running conditions compared with the K5 gas analyzer, likely due to advancements in technology and the structured exercise protocol used in this study.

Previous studies have reported EE estimation with mean ICC values ranging from −0.30 to 0.97 [3,5,6,21], 95% CIs ranging from −0.89 to 0.98 [5,6,21,22], and MAPE values ranging from 1.3% to 114.7% [21-23]. Among the studies, Wahl et al [21] analyzed 11 different wearable watches in walking and running

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protocols at speeds of 4.3, 7.2, 10.1, and 13.0 km·h^{-1}. Mean ICC values greater than 0.70 were observed for only 4 smartwatches, whereas ICC values greater than 0.50 were observed for 6 smartwatches. Mean absolute percentage error values ranged from 1.3% to 56.0%. For ICCs, 17 of 66 measurements were greater than 0.5, and only 3 of these were obtained under intermittent conditions (mean ICC range 0.54-0.74). For MAPE, 24 of 66 measurements were less than 10%, and only 5 of these were obtained under intermittent conditions, ranging from −9.2% to 5.6%.

The moderate ICC and MAPE values for the GW6 and the GW7 compared with the K5 were considered acceptable indicators of validity, as previously reported [1,5,12,13]. Associations between variables were also assessed using Spearman correlation, demonstrating moderate values for the GW6 group and the combined GW6 and GW7 group, and strong values for the GW7 group. Moreover, the database comprised both men and women, resulting in a heterogeneous sample. As expected, heterogeneous samples may influence accuracy metrics, as smartwatch EE estimates have been shown to differ across different demographic groups [24].

It is important to highlight that different types of exercises can affect the variability of smartwatch accuracy [1,21]. The assessment of EE in this study differs from previous investigations primarily in terms of device performance and testing conditions. Earlier research has demonstrated generally low validity for consumer wearable activity monitors in estimating EE (particularly under both constant and intermittent running protocols) [21]. Wahl et al [21] highlighted consistent overestimation of EE at lower speeds and underestimation at higher speeds. While not perfectly valid, the Garmin, Fitbit, and Withings (Withings SA) wearable watches generally showed better validity with small to moderate MAPE values (1.3% - 21.2%), particularly at faster velocities (10.1 km·h^{-1} and 13.0 km·h^{-1}) and in outdoor conditions. Devices such as the Garmin Vivofit, Garmin Vivosmart, Garmin Vivoactive, Fitbit Charge, and Fitbit Charge HR exhibited moderate to good ICCs, suggesting a relatively better correlation with the criterion measure compared with other brands. However, even for these devices, the limits of agreement were still insufficiently narrow, indicating considerable variability and imprecision.

For the intermittent protocol, which simulates conditions in sports such as soccer, the Fitbit Charge, Garmin Vivoactive, Garmin Vivosmart, and Polar Loop showed a relatively small MAPE (<5.6%). However, most other devices, including the Withings Pulse Ox (wrist or hip), Garmin Forerunner 920XT, Garmin Vivofit, Beurer AS80, and Bodymedia Sensewear, primarily underestimated EE during this dynamic activity. This reinforces the concern that most commercially available wearable activity monitors lack the accuracy required to reliably estimate EE in real-world exercise scenarios, especially among athletes.

The magnitude of the limits of agreement for these wearable activity monitors indicates that, although average error during intermittent running can be small to moderate in relative terms, individual-level EE estimates can still deviate by several hundred kilocalories in a typical session, which is likely too large for precise real-world monitoring, especially in athletes [21]. During intermittent exercise, rapid changes in speed, direction, and intensity violate the steady state assumptions many EE algorithms rely on, leading to larger MAPE values and wider limits of agreement than during constant-velocity running [21,25].

When compared with criterion measures, several studies have demonstrated that wearable activity monitors underestimate EE in both laboratory and outdoor tests [2,8,13,23,26], demonstrating a mean value of approximately 3 kilocalories and percentage errors ranging from −21.27% to 14.76% [23]. Importantly, few studies have analyzed the EE validity of Samsung smartwatches, with the Samsung Gear models being the most tested smartwatches [26]. Likewise, Sun et al [13] identified EE overestimation in the Apple Watch Series 6 when compared with a breath-by-breath gas analyzer (MetaMax 3B; CORTEX Biophysik GmbH) across different running velocities (6.4-11.2 km·h ¹), despite high MAPE values (–6.61 to 53.24).

One limitation of this study is that only 1 brand of smartwatch was tested. While this could be seen as a constraint, it also presents an advantage by allowing for a direct comparison of technological improvements for a specific model within the same brand. By examining the evolution of technology in this specific area, we gain valuable insights into how advancements have positively impacted the accuracy of these devices over time. Another limitation is that the study tested EE measurement during 1 type of exercise and only in healthy, lean people. This restricts the scope of our findings, as the accuracy of smartwatch EE estimates can vary across different forms of physical activity and physical characteristics. Future research should address this limitation by evaluating the performance of these devices across a wider range of populations and exercise modalities, such as resistance training, high-intensity interval training, and low-intensity steady-state exercise. This would provide a more comprehensive understanding of the accuracy of devices and limitations in various exercise contexts. Another limitation of this study is that 2 different K5 devices were used in data collection. Although manufacturer calibration was performed immediately after the data collection sessions, no between-device validation was conducted. Future research should use a single device throughout the data collection period or perform between-device validation.

Practical Implications

The following points summarize the practical implications of the present findings.

- Both the GW6 and the GW7 can be used for EE estimation in intermittent running exercises, providing valid data for athletes and fitness enthusiasts.
- Advancements in the GW7 highlight the importance of algorithm and hardware updates and underscore the need for continuous development in the wearable activity monitor industry.
- This study helps consumers make more informed decisions regarding which smartwatch model is best suited for accurate fitness tracking.

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- The results of this study set a benchmark for future validation studies, promoting a more standardized approach in wearable technology research.

Conclusions

Both the GW6 and GW7 models showed moderate validity for estimating EE during intermittent running exercises. These findings support the growing reliability of newer smartwatches for EE estimation in structured exercise settings. Given their relatively low cost and practicality, GWs emerge as a suitable wearable option for daily physical activity where EE is of interest.

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Conflicts of Interest

All authors are employees of the Sidia Institute of Science and Technology. The company was not involved in data or sample collection, analysis, or interpretation of the results. No restrictions were placed on the reporting of findings.

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Abbreviations

EE: energy expenditure
GW: Galaxy Watch
ICC: intraclass correlation coefficient
MAPE: mean absolute percentage error

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Long Short-Term Memory–GPT-4 Integration for Interpretable Biomedical Signal Classification: Proof-of-Concept Study

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Abstract

Background: Approximately 3.8 billion people lack access to essential health services, and diagnostic interpretation remains a major bottleneck in remote and resource-constrained settings. Limited access to specialists and the complexity of biomedical signal interpretation (eg, electrocardiogram [ECG] and electroencephalogram) contribute to delays in recognizing cardiovascular and neurological conditions.

Objective: The study aimed to develop and evaluate a technical framework integrating long short-term memory (LSTM) networks with GPT-4 to provide automated biomedical signal classification and human-readable interpretations, suitable as a foundation for future deployment in resource-constrained environments.

Methods: The 2-layer LSTM architecture (128→64 units) was selected based on preliminary experiments comparing configurations ranging from single-layer networks (64, 128 units) to deeper architectures (128→64→32 units). The chosen configuration balanced model capacity against overfitting risk and computational efficiency. The framework was evaluated using public PhysioNet datasets: Massachusetts Institute of Technology–Beth Israel Hospital (MIT-BIH) Arrhythmia, Physikalisch-Technische Bundesanstalt (PTB) Diagnostic ECG, Physikalisch-Technischen Bundesanstalt-extra large, Chapman-Shaoxing, Medical Information Mart for Intensive Care-III Waveforms, and Sleep-European data format. A patient-level split protocol (70/15/15) was used to reduce leakage risk. The LSTM architecture (128→64 units) performed temporal feature extraction with softmax-based classification for mutually exclusive classes. GPT-4 was integrated via an application programming interface with structured prompts to generate clinical interpretations from model outputs.

Results: For the expert evaluation, we randomly sampled 50 test cases per dataset (150 total: 30 from each class for MIT-BIH, 25 per class for PTB, and 20 per class for Children's Hospital Boston-Massachusetts Institute of Technology), ensuring balanced class representation. Three board-certified physicians (2 cardiologists for ECG datasets and 1 neurologist for the electroencephalogram dataset) independently reviewed GPT-4–generated interpretations. Reviewers were blinded to whether signals were correctly or incorrectly classified by the LSTM model. Each interpretation was rated on a 5-point Likert scale (1=clinically inappropriate and 5=highly accurate and clinically useful). Interrater reliability was assessed using Fleiss κ (0.78, substantial agreement). On held-out test sets, classification performance was as follows: MIT-BIH 92.3% accuracy (F_1=0.91, AUC=0.95), PTB Diagnostic 94.7% (F_1=0.94, AUC=0.97), Physikalisch-Technischen Bundesanstalt-extra large 88.9% (F_1=0.88, AUC=0.93), Chapman-Shaoxing 91.2% (F_1=0.90, AUC=0.94), Medical Information Mart for Intensive Care-III 89.5% (F_1=0.89, AUC=0.92), and Sleep-European data format 87.3% (F_1=0.86, AUC=0.91). Expert evaluation of generated interpretations (3 board-certified cardiologists) rated clinical accuracy 4.3 out of 5, clarity 4.6 out of 5, and actionability 4.2 out of 5, with strong interrater agreement (κ>0.85).

Conclusions: This proof-of-concept demonstrates an explicit methodological integration of deep learning–based biomedical signal classification with GPT-4–based interpretation, provides a technical foundation for future prospective clinical validation, field studies, and regulatory review prior to clinical deployment in underserved settings.

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KEYWORDS

artificial intelligence; cloud-based diagnostics; biomedical signal analysis; LSTM networks; long short-term memory; GPT-2; explainable artificial intelligence; health care accessibility; remote health monitoring; physiological data interpretation

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Introduction

Background

Universal health coverage remains limited by uneven access to diagnostic expertise, particularly in remote and resource-constrained environments [1]. In many regions, diagnostic devices may be available, but the trained personnel required to interpret complex biomedical signals are scarce [2]. For cardiovascular and neurological conditions, delays in interpreting diagnostics often lead to deferred treatment and poorer patient outcomes [3].

Recent advances in artificial intelligence (AI) offer an opportunity to assist frontline providers by automating pattern recognition in biomedical signals [4]. Traditional signal processing pipelines depend on hand-crafted features and careful parameter tuning; while foundational, these approaches are often brittle in the presence of noise, artifacts, and inter-patient variability [4]. Deep learning models, including convolutional and recurrent neural networks, have demonstrated improved performance across electrocardiogram (ECG) and electroencephalogram (EEG) classification tasks [4]. However, these systems typically generate technical outputs that are difficult for nonspecialist health care workers to interpret, creating a barrier to adoption in settings where clinical clarity and interpretability are essential [5].

Large language models (LLMs) have recently shown promise in generating readable summaries and decision-support messages for complex technical outputs [5]. However, applying generative models in diagnostic contexts introduces additional risks, including variable outputs, potential hallucination, and the need for careful framing to ensure that generated explanations function as decision support rather than autonomous diagnosis.

This work presents a technical proof-of-concept integrating a long short-term memory (LSTM)-based classifier with GPT-4 to generate structured, clinically oriented interpretations of biomedical signal classifications. The objective is to provide methodological transparency and a reproducible baseline that may support future clinical translation and deployment studies.

- Primary objective: Can an LSTM–GPT-4 pipeline provide accurate biomedical signal classification together with interpretable clinical reasoning suitable for nonspecialist diagnostic support?
- Research questions: Can modality-adaptive preprocessing enable consistent modeling across ECG and EEG signals? Does single-lead selection preserve diagnostic performance while aligning with point-of-care device constraints? Can GPT-4 generate clinically accurate, clear, and actionable interpretations from model outputs?
- Important clarification: This system has not been deployed clinically and is presented strictly as a proof-of-concept. Any clinical deployment would require prospective validation, workflow integration studies, and regulatory review [3,6].

Contributions

This work contributes to AI-assisted diagnostics research in the following ways:

1. *Modality-specific preprocessing*: Adaptive bandpass filtering (ECG: 0.5 - 50 Hz and EEG: 0.5 - 30 Hz) for preserving diagnostically relevant features while removing modality-specific artifacts
2. *Single-lead selection strategy*: Explicit methodology ensuring consistent input dimensionality (batch, 3000, 1) and alignment with point-of-care devices
3. *Single-label formulation*: Clear focus on mutually exclusive classification tasks with softmax activation, making it appropriate for primary diagnosis in resource-limited settings
4. *Patient-level data splitting*: Rigorous prevention of data leakage with formal verification (Algorithm 1), ensuring true generalization performance
5. *GPT-4 integration*: Natural language interpretation achieving high clinical accuracy (4.3/5.0) and clarity (4.6/5.0) from expert reviewers
6. *Open-source implementation*: Publicly available codebase with Representational State Transfer application programming interface (API) for community validation and extension
7. *Methodological transparency*: Comprehensive documentation of preprocessing parameters, architecture specifications, training procedures, and evaluation protocols enabling reproducibility

Related Work

Traditional Signal Processing Approaches

Early automated biomedical signal analysis relied on deterministic signal processing techniques, including Fourier transforms, wavelet decomposition, and rule-based feature extraction. In ECG analysis, classical pipelines typically involve beat segmentation followed by handcrafted features such as RR intervals, QRS width, and frequency-domain descriptors [7,8]. While effective in controlled settings, these approaches are sensitive to noise, motion artifacts, and interpatient variability, limiting robustness in real-world deployments [8].

In EEG analysis, spectral methods and rule-based heuristics have been used for sleep stage classification and neurological monitoring. Although clinically established, such approaches require careful parameter tuning and struggle with ambiguous transitions between physiological states, contributing to variability and reduced reliability in automated settings [9].

Deep Learning for Biomedical Signal Classification

Deep learning models have demonstrated significant improvements over traditional methods for biomedical time-series classification. Convolutional and recurrent neural networks have been successfully applied to ECG arrhythmia detection, achieving strong performance across multiple benchmark datasets [7,10-12]. LSTM architectures are particularly effective at modeling temporal dependencies in physiological signals, making them well suited for ECG and EEG classification tasks [10-12].

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Recent studies have explored attention mechanisms and interpretable deep learning architectures, particularly for multilead ECG analysis [13]. While these models improve feature attribution and performance, they typically require multilead inputs and substantial computational resources, limiting compatibility with portable point-of-care devices commonly used in resource-limited settings [14]. Performance metrics represent mean (SD) across 5-fold cross-validation. The 95% CIs for accuracy were as follows: Massachusetts Institute of Technology-Beth Israel Hospital (MIT-BIH) (91.1%-93.5%), Physikalisch-Technische Bundesanstalt (PTB) (88.9%-92.1%), Children's Hospital Boston-Massachusetts Institute of Technology (CHB-MIT) (85.2%-88.8%).

Despite strong predictive performance, most deep learning classifiers output numerical labels or probabilities without providing clinically meaningful explanations, which hinders adoption by nonspecialist health care workers [15].

Large Language Models and Clinical Interpretability

LLMs have recently shown promise in health care apps, including clinical summarization, medical question answering, and decision support [16,17]. Studies demonstrate that modern LLMs encode substantial clinical knowledge and can generate coherent, human-readable explanations when appropriately constrained [17].

However, deploying generative models in diagnostic contexts introduces additional challenges, including output variability, uncertainty communication, and the risk of overreliance on automated reasoning [18]. Prior work emphasizes that LLMs should function as decision support tools rather than autonomous diagnostic agents, with careful framing and human oversight [15,18].

While LLMs have been integrated with imaging pipelines, particularly in radiology, their application to time-series biomedical signals remains limited. Bridging this gap requires structured integration between signal classifiers and language models, along with methodological transparency and clear limitations [14,16].

Synthesis of Prior Work and Research Gaps

Table 1 summarizes representative approaches across biomedical signal processing, deep learning, and health care AI systems.

Table . Comparison of representative biomedical signal analysis approaches.

Approach	Signal processing	Cross-modal support	Interpretability	Deployment feasibility
Traditional ML[a] (SVM[b], RF[c]) [7,8]	Handcrafted	Limited	Moderate	High
LSTM[d]-based ECG[e] models [10-12]	Learned	Single modal	Low	Moderate
Interpretable DL[f] (12-lead ECG) [13]	Learned	Single modal	Moderate	Low
LLM[g]-only clinical models [17]	N/A[h]	Text-only	High	High
IoT[i] fog-enabled systems	N/A	Yes	Low	High
IoMT[j] security frameworks []	N/A	Yes	Low	Moderate
ML health care reviews	Survey-based	Yes	Moderate	Survey
Telemedicine systems [19,20]	N/A	Yes	Low	High
Proposed framework	Modality-adaptive	ECG + EEG[k]	High	Moderate[l]

[a]ML: machine learning.

[b]SVM: support vector machine.

[c]RF: random forest.

[d]LSTM: long short-term memory.

[e]ECG: electrocardiogram.

[f]DL: deep learning.

[g]LLM: large language model.

[h]N/A: not applicable.

[i]IoT: Internet of Things.

[j]IoMT: Internet of Medical Things.

[k]EEG: electroencephalogram.

[l]Pending prospective clinical validation.

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Identified Research Gaps

The research gaps are as follows:

- Generic preprocessing limits cross-modal robustness: Most deep learning pipelines apply uniform preprocessing across modalities, despite fundamental differences between ECG and EEG signal characteristics [7,9].
- Lack of interpretable outputs for nonspecialists: Existing classifiers provide technical output without contextual explanation, limiting usability for frontline health care workers [15,18].
- Mismatch with point-of-care constraints: Many state-of-the-art models depend on multilead recordings or high-end infrastructure, reducing feasibility in resource-constrained environments [14,19].

Methods

Study Design Overview

This is a retrospective technical proof-of-concept study using publicly available biomedical signal datasets. The analytical workflow consisted of (1) dataset acquisition and preprocessing, (2) patient-level data splitting to prevent leakage, (3) LSTM model training and validation using 5-fold cross-validation, (4) classification performance evaluation on held-out test sets, and (5) qualitative expert assessment of GPT-4 generated interpretations. Primary outcomes were classification performance metrics (accuracy, F_1-score, AUC-ROC) on 3 public datasets (MIT-BIH Arrhythmia, PTB Diagnostic ECG, CHB-MIT Scalp EEG). Secondary outcomes included feasibility (computational requirements and processing time) and acceptability (expert clinician ratings of interpretation quality on a 5-point Likert scale, with scores≥4 indicating acceptable quality). All preprocessing, model training, and evaluation code are available in the public GitHub repository to ensure full reproducibility.

Study Design, Data Flow, and Outcome Measures

This study presents a technical proof-of-concept for automated biomedical signal classification combined with natural language generation for clinician-facing interpretation. The pipeline consists of (1) modality-specific preprocessing and segmentation, (2) deep learning-based classification using recurrent neural networks, and (3) large language model-assisted generation of structured interpretations from model outputs. The evaluation was conducted offline using publicly available datasets.

Data Sources and Dataset Selection

Public biomedical signal datasets were used to evaluate performance across multiple cardiac and neurological tasks. The included datasets represented common ECG diagnostic benchmarks and EEG sleep staging benchmarks, supporting reproducibility and comparability with prior work in biomedical signal modeling.

Data Preprocessing

Modality-Specific Bandpass Filtering

To preserve diagnostically relevant signal content while reducing baseline drift and noise, the following modality-specific bandpass filtering was applied.

- *ECG filtering:* 0.5 - 50 Hz bandpass filtering was used to preserve QRS morphology and reduce baseline wander and high-frequency artifacts commonly present in ambulatory and intensive care unit (ICU) monitoring ECG data.
- *EEG filtering:* 0.5 - 30 Hz bandpass filtering was applied to retain physiologically relevant sleep frequency bands while attenuating high-frequency muscle noise.

Filtering was performed using a 5th-order Butterworth filter. Detailed modality-specific filter parameters are summarized in Table 2.

Table . Modality-specific bandpass filter parameters.

Dataset type	Low cutoff (Hz)	High cutoff (Hz)	Rationale
ECG[a] datasets	0.5	50	Preserve QRS morphology; reduce baseline drift and noise
EEG[b] datasets	0.5	30	Preserve sleep-related frequency bands; reduce EMG[c] artifacts

[a]ECG: electrocardiogram.

[b]EEG: electroencephalogram.

[c]EMG: electromyography.

Signal Normalization

To reduce amplitude variability across recordings and improve training stability, *z* score normalization was performed at the segment level:

$$(1) x_{norm} = \frac{x - \mu}{\sigma}$$

where, μ and σ are the mean and SD computed per segment.

Sampling Rate Handling and Segmentation

Signals were segmented using fixed-sample windows to standardize input dimensionality while avoiding interpolation artifacts that may distort diagnostic morphology. Each signal was divided into 3000-sample windows with 50% (1500/3000) overlap, improving coverage near transitions and reducing boundary effects. For ECG datasets, this window size was chosen to capture multiple cardiac cycles for rhythm characterization. For EEG datasets, 3000-sample windows supported epoch-based sleep staging while maintaining a

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uniform input shape for the neural network. The dataset-specific segmentation strategy is summarized in Table 3.

Table . Dataset-specific segmentation strategy.

Dataset type	Sampling rate (Hz)	Window size (samples)	Duration (s)	Rationale
ECG[a] datasets	Dataset-dependent	3000	Rate-dependent	Capture multiple cardiac cycles for rhythm characterization
EEG[b] datasets	Dataset-dependent	3000	Rate-dependent	Support epoch-based staging while maintaining uniform input shape

[a]ECG: electrocardiogram.

[b]EEG: electroencephalogram.

Multilead Handling and Lead Selection

To ensure consistent input dimensions and support feasibility for point-of-care devices, a single-lead approach was used when datasets provided multiple leads. The selected lead followed dataset conventions or common diagnostic practice used in prior arrhythmia or sleep modeling pipelines. For ECG datasets such as MIT-BIH, the MLII (lead II) channel was chosen when available, reflecting standard practice in arrhythmia modeling and benchmark comparisons. EEG sleep staging datasets used the primary EEG channel, typically Fpz-Cz, consistent with single-channel sleep staging studies. For ICU waveform datasets with variable lead configurations, the primary available monitoring lead was selected to align with outputs from clinical monitoring devices. The complete lead selection strategy is summarized in Table 4.

Table . Lead selection strategy.

Dataset	Total leads	Selected lead (example)	Rationale
ECG[a] datasets (eg, MIT-BIH)[b]	≥2	MLII[c] or Lead II (if available)	Commonly used in arrhythmia modeling and benchmark comparisons
EEG[d] Sleep Staging datasets	≥1	Primary EEG channel (eg, Fpz-Cz when available)	Frequently used in single-channel sleep staging studies
ICU[e] Waveform datasets	Variable	Primary available monitoring lead	Aligns with monitoring device outputs in clinical settings

[a]ECG: electrocardiogram.

[b]MIT-BIH: Massachusetts Institute of Technology-Beth Israel Hospital.

[c]MLII: modified lead II.

[d]EEG: electroencephalogram.

[e]ICU: intensive care unit.

Dataset Categorization and Label Formulation

The framework was evaluated on 6 PhysioNet datasets, which were categorized according to their label structure. *Single-label datasets*, where each sample belongs to exactly 1 class, included MIT-BIH arrhythmia (5 classes: normal, premature ventricular complex, fusion, atrial premature, and right bundle branch block), Sleep-European data format (EDF) (5 classes: Wake, N1, N2, N3, and rapid eye movement), and Medical Information Mart for Intensive Care (MIMIC)-III Waveforms (4 classes: normal sinus rhythm, atrial fibrillation, ventricular tachycardia, bradycardia). In contrast, *multilabel datasets*, where samples may exhibit co-occurring diagnoses, included PTB Diagnostic ECG (2 classes), Physikalisch-Technischen Bundesanstalt-extra large (PTB-XL) (71 diagnostic statements), and Chapman-Shaoxing (4 rhythm categories). For the single-label datasets, a softmax activation function was applied to the output layer to produce mutually exclusive class probabilities, whereas multilabel datasets used a sigmoid activation per class, allowing independent probability estimates for each diagnostic label.

Ethical Considerations

Ethics Approval and Informed Consent

This study exclusively used publicly available, deidentified biomedical signal datasets obtained from PhysioNet and did not involve direct human subjects research, prospective data collection, or clinical deployment. Institutional Review Board (IRB) approval was not required for this technical proof-of-concept study, as it constitutes a secondary analysis of publicly available, anonymized datasets that are exempt from human subjects review under 45 Code of Federal Regulation 46.104(d)(4). An *institutional case number* was not applicable (secondary analysis of publicly available deidentified data; exempt from IRB review per 45 Code of Federal Regulations 46.104[d][4]).

Dataset Ethics and Deidentification

All datasets used in this research were obtained from PhysioNet (physionet.org), a repository that provides ethically approved, deidentified physiological data for research purposes. The MIT-BIH Arrhythmia database was originally collected under

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protocols approved by the institutional committees of Beth Israel Hospital and the Massachusetts Institute of Technology, and all records are fully deidentified with no patient identifiers retained [21]. The Sleep-EDF Database was collected under ethics approval from the medical ethics committee of the hospital where recordings were performed, and all patient identifiers were removed prior to public release [22]. The MIMIC-III Waveform Database received approval from the IRBs of Beth Israel Deaconess Medical Center (Boston, MA) and the Massachusetts Institute of Technology (Cambridge, MA), and all protected health information was deidentified in accordance with Health Insurance Portability and Accountability Act (HIPAA) standards [23].

Algorithmic Fairness and Bias Mitigation

Potential biases inherent in the training datasets are acknowledged. The MIT-BIH Arrhythmia Database was collected during the 1970s-1980s from a predominantly nondiverse patient population at Beth Israel Hospital. The MIMIC-III database, although more recent, reflected the demographic distribution of intensive care unit patients from a single academic medical center in Boston. To address these limitations, dataset demographics and representation gaps were explicitly documented to promote transparency. A single-lead signal analysis approach was adopted to avoid compounding biases that may arise from multilead fusion algorithms performing inconsistently across demographic groups. Patient-level data splitting was used to prevent overfitting to individual subjects; however, population-level biases remain. A critical limitation is that the models have not been validated across diverse racial, ethnic, age, or geographic populations. Any clinical deployment would require extensive fairness audits and validation across underrepresented groups to ensure equitable diagnostic performance.

PhysioNet Data Use Agreement

Access to and use of PhysioNet datasets complied with the PhysioNet Credentialed Health Data Use Agreement, which mandates that data be used exclusively for research purposes, prohibits attempts at reidentification, requires proper citation of original data sources, and enforces responsible data handling practices.

AI Explainability and Clinical Accountability

The integration of GPT-4 for natural language interpretation introduces important considerations related to explainability and accountability. While LSTM model predictions were deterministic, GPT-4 outputs were probabilistic and may vary between runs. Structured prompt templates were used to promote consistency, although residual variability was acknowledged. The system was explicitly designed as a clinical decision support tool rather than an autonomous diagnostic system, and all outputs included disclaimers requiring review by a qualified health care professional. GPT-4 generated interpretations explicitly stated that AI-assisted outputs must be reviewed by a clinician. In cases where GPT-4 API calls failed, the system provided template-based responses derived from a curated medical knowledge base to ensure continuity of operation without compromising safety.

Responsible AI Deployment Framework

This work represented a technical proof-of-concept and has not been deployed in clinical settings or received regulatory clearance for diagnostic use. Translation to clinical practice would require regulatory approval, such as Food and Drug Administration 510(k) clearance or equivalent; prospective multisite clinical validation with IRB approval; fairness auditing across diverse demographic groups; integration into HIPAA-compliant clinical infrastructure with electronic health record support; structured health care worker training programs; and implementation of postdeployment monitoring systems to detect performance drift.

Equity and Access Considerations

Although the system was intended to support health care delivery in underserved communities, several equity-related challenges were recognized. Cloud-based deployment requires reliable internet connectivity, which may limit accessibility in remote settings. GPT-4 API costs may present financial barriers in resource-constrained environments, indicating the need for cost-optimized alternatives or subsidized access models. Current system outputs are limited to English, necessitating multilingual support for equitable deployment. Additionally, the system assumes a baseline level of clinical training among users, underscoring the importance of accompanying education and training initiatives.

Commitment to Responsible Research

To promote transparency and enable independent ethical review, all source code is publicly available under an open-source license [24], and model architectures, training procedures, dataset selection criteria, and known limitations are fully documented. Performance metrics reported both strengths and failure modes. Any future clinical implementation will require prospective IRB approval with informed consent protocols, algorithmic impact assessments aligned with emerging AI governance frameworks, engagement with underserved communities, and continuous monitoring for algorithmic bias and performance degradation.

Future Ethical Considerations for Clinical Translation

Should this system advance toward clinical implementation, several ethical requirements must be addressed, including full IRB review and approval for prospective validation studies, informed consent protocols for AI-assisted diagnostic interpretation, validation across diverse demographic groups to ensure algorithmic fairness, implementation of human-in-the-loop clinical oversight, deployment within HIPAA-compliant data infrastructure, and attainment of regulatory clearance in target deployment regions.

Deep Learning Model

Model Architecture

A recurrent neural network classifier was implemented using a 2-layer LSTM backbone to capture temporal dependencies in biomedical time-series signals, consistent with prior ECG classification work. The first LSTM layer contains 128 units with return sequences enabled, followed by a dropout layer of 0.2. The second LSTM layer has 64 units, followed by another

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dropout layer of 0.2. A dense layer with 32 units and rectified linear unit (ReLU) activation precedes the output layer, which uses a softmax or sigmoid activation depending on the classification task. The complete neural network architecture is summarized in Table 5.

Table . Neural network architecture.

Layer	Output shape	Activation
Input[a]	(None, 3000, 1)	—[b]
LSTM[c]-1 (128 units, return sequences)	(None, 3000, 128)	Tanh
Dropout (0.2)	(None, 3000, 128)	—
LSTM-2 (64 units)	(None, 64)	Tanh
Dropout (0.2)	(None, 64)	—
Dense (32 units)	(None, 32)	ReLU[d]
Output layer[e]	(None, C)	Softmax or sigmoid

[a]Input: (batch, 3000, 1).

[b]Not applicable.

[c]LSTM: long short-term memory.

[d]ReLU: rectified linear unit.

[e]Output: dataset-dependent class probabilities.

Output Formulation (Single-Label vs Multilabel)

Single-Label Classification (Mutually Exclusive Classes)

For tasks where each segment belongs to exactly 1 class, softmax activation was used:

(2)y^c=ezc∑j=1Cezj,∑c=1Cy^c=1

Multilabel Classification (Co-Occurring Diagnoses)

For tasks where segments may contain multiple labels (eg, ECG diagnostic statements), sigmoid activation was used per class:

(3)y^c=σ(zc)=11+e−zc

This enables independent per-class probabilities and supports multilabel evaluation protocols.

Training Configuration

The model was trained using the Adam optimizer with standard regularization and early adaptation to class imbalance via weighted loss. Architectural parameters included 2 LSTM layers with 128 and 64 units, respectively, followed by a dense layer with 32 units and dropout of 0.2. ReLU activation was applied in hidden layers, and softmax was used in the output layer. Optimization used a learning rate of 0.001 with β_1 =.9, β_2 =.999, and ε=1×10 . Training was performed over 50 epochs with a batch size of 32, using categorical cross-entropy as the loss function. Regularization strategies included class weighting (inversely proportional to class frequency) and a ReduceLROnPlateau scheduler with a reduction factor of 0.5 and patience of 10 epochs. Data augmentation was applied with a probability of 0.5, including Gaussian noise (factor 0.05), amplitude scaling (0.8-1.2), and temporal shifts (10%). Detailed training hyperparameters are summarized in Table 6.

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Table . Training hyperparameters.

Category and parameter	Value
Architecture	
LSTM[a] layer 1 units	128
LSTM layer 2 units	64
Dropout rate	0.2
Dense layer units	32
Activation (hidden)	ReLU[b]
Activation (output)	Softmax
Optimization	
Optimizer	Adam
Learning rate	0.001
β_1	0.9
β_2	0.999
ε	1×10^{-7}
Batch size	32
Epochs	50
Loss function	Categorical cross-entropy
Regularization	
Class weighting	Balanced (inversely proportional)
Learning rate scheduler	ReduceLROnPlateau
Learning rate reduction factor	0.5
Learning rate patience	10 epochs
Data augmentation	
Augmentation probability	0.5
Noise factor (Gaussian)	0.05
Amplitude scaling range	(0.8-1.2)
Temporal shift ratio	10%
Loss function	Categorical cross-entropy

[a]LSTM: long short-term memory.

[b]ReLU: rectified linear unit.

Data Splitting Strategy: Patient-Level Splitting to Prevent Leakage

To reduce the risk of inflated performance due to segment overlap across splits, patient-level splitting was applied when patient identifiers were available. All segments derived from a given patient were assigned exclusively to train, validation, or test partitions. This approach aligns with methodological guidance emphasizing the importance of proper separation between training and evaluation data in medical AI and broader concerns about reproducibility in AI systems (Textbox 1).

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Textbox 1. Patient-level data splitting.

Input: dataset D with patient IDs P, samples X, labels Y

Parameters: split ratios rtrain=0.70,rval=0.15,rtest=0.15,seed=42

Output:(Xtrain,Ytrain),(Xval,Yval),(Xtest,Ytest)

1. Extract unique patient IDs *P* from *D*
2. Shuffle *P* using fixed seed
3. Assign the first 70% of patients to train, next 15% to validation, remaining 15% to test
4. Extract all segments belonging to patients in each partition
5. Verify no patient overlap:

Ptrain∩Pval=∅,Ptrain∩Ptest=∅,Pval∩Ptest=∅

Data Augmentation

To reduce overfitting and improve robustness under physiologic variability and sensor noise, augmentation was applied only to training segments. Augmentations included additive Gaussian noise, amplitude scaling, and temporal shifting, consistent with common practices in ECG modeling. Augmentations were applied probabilistically.

Loss Functions

For single-label classification, categorical cross-entropy was used. For multilabel classification, binary cross-entropy was used. To address imbalance, class weights were applied.

(4)L=−∑cwcyclog (y^c)

where, w_c is inversely proportional to class prevalence.

Natural Language Generation for Interpretability

Prompt Engineering Framework

Integration of GPT-4 for clinical interpretation represents a key innovation in making diagnostic results accessible to nonspecialist health care workers. Unlike earlier approaches requiring fine-tuning on medical corpora, GPT-4 possesses extensive built-in medical knowledge, enabling zero-shot clinical interpretation through structured prompt engineering.

Prompting Strategy

A structured prompt template (Textbox 2) was used to generate clinician-oriented interpretations incorporating signal type, predicted label(s), confidence scores, and context. This follows prior evidence that interpretability and uncertainty communication are important for responsible clinical AI deployment.

- Signal type
- Predicted label(s)
- Confidence score(s)
- Requested format: explanation, clinical significance, recommended next steps
- Safety framing: decision support only

Textbox 2. Structured prompt template

You are a medical AI assistant helping primary care practitioners interpret biomedical signal analysis results.

Medical signal analysis report:

- Signal Type: {signal_type}
- Classification: {classification}
- Confidence: {confidence:.2%}
- Clinical Context: {context}

Provide a detailed clinical interpretation, including

- Explanation of the finding
- Clinical significance
- Recommended follow-up actions

Keep the response professional, clear, and actionable for health care workers in underserved regions.

LLM Integration

An LLM was called through an API to generate structured explanations for predicted outputs. Outputs were framed explicitly as decision support, not autonomous diagnosis, consistent with clinical AI impact guidance and risk considerations about uncertainty communication.

The system leveraged OpenAI's GPT-4 API for natural language generation, offering several advantages over locally fine-tuned

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models. These advantages included superior medical knowledge derived from extensive pretraining on medical literature, improved clinical accuracy (4.3/5.0) and clarity (4.6/5.0) based on expert review, elimination of local deployment requirements given GPT-4's scale (1.7 trillion parameters compared with 345 million for GPT-2-medium), regular model updates provided by OpenAI, and reduced system complexity due to the absence of fine-tuning infrastructure. Trade-offs associated with this approach included the requirement for network connectivity to support API calls, usage-based costs (approximately US $0.02-$0.05 per interpretation), an average generation latency of 1.3 seconds, and data privacy considerations, although API requests were not used for model training. For deployment scenarios with connectivity limitations or strict data locality requirements, future work could explore locally deployable alternatives, such as fine-tuned Llama-3-70B or Mistral-Large models, or an offline fallback using template-based interpretations.

Experimental Evaluation

Experimental Setup

All experiments were conducted on a distributed computing infrastructure comprising 16 nodes, each equipped with 8× NVIDIA A100 (80GB) GPUs. Training used mixed-precision computation (FP16) to optimize memory usage and computational efficiency. Hyperparameter optimization was performed using Bayesian optimization over 50 trials on the validation set.

Baseline Methods and Fair Comparison

To ensure rigorous evaluation, we compare the proposed LSTM architecture against 3 established baseline methods under identical experimental conditions.

The baseline methods include the following:

The fair comparison protocols include the following:

- Identical patient-level train/val/test partitions (70/15/15)
- Same modality-specific preprocessing and lead selection
- Same evaluation metrics computed on identical test sets
- Same hardware (NVIDIA Tesla V100 GPU, 32GB RAM)
- Hyperparameter tuning via 5-fold cross-validation on the training set for all methods

Evaluation Metrics and Justification

Model performance was evaluated using multiple complementary metrics, each chosen to capture specific aspects of medical diagnostic tasks, as summarized in Table 7. Accuracy was used as a baseline indicator of overall classification correctness. Precision was included to quantify the reliability of positive diagnoses, where false positives could lead to unnecessary interventions. Sensitivity (recall) was critical for identifying pathological conditions, as false negatives can have serious clinical consequences, while specificity was important for ruling out conditions and reducing false alarms in monitoring systems. The F_1-score provided a balance between precision and recall, particularly relevant given class imbalances in biomedical datasets. Finally, the area under the receiver operating characteristic curve (AUROC) assessed discriminative ability across all decision thresholds and is robust to class imbalance, providing a comprehensive measure of model performance.

Table . Evaluation metrics and rationale.

Metric	Rationale
Accuracy	Overall correctness summary
Sensitivity	Detecting true positives; important for avoiding missed pathology
Specificity	Avoiding false alarms; important for monitoring settings
Precision	Controls false positives; reduces unnecessary interventions
F_1-score	Balances precision and recall in imbalanced data
AUROC[a]	Measures discrimination across thresholds; robust summary statistic

[a]AUROC: area under the receiver operating characteristic curve.

For multiclass settings, macroaveraging was used to avoid dominance by majority classes.

Macroaveraging

All multiclass metrics use macroaveraging rather than microaveraging to ensure fair evaluation across imbalanced classes, preventing performance on common classes from dominating metrics.

Statistical Significance

Prior to statistical testing, we assessed normality of performance metric distributions using the Shapiro-Wilk test (α=.05). All metrics (accuracy, F_1-score, and AUC) were approximately normally distributed across the 5-fold cross-validation splits (P>.05 for all tests), justifying the use of parametric tests. Paired t-tests were conducted to compare model performance across datasets and conditions. Effect sizes were calculated using Cohen d, with $|d|\geq 0.5$ considered meaningful. All statistical analyses were performed using Python 3.9 with SciPy (v1.9.0) and statsmodels (v0.13.0).

Performance comparisons were evaluated using paired t-tests with a significance threshold of P<.05 across 5 random train or test splits to confirm the statistical significance of observed improvements.

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Results

Classification Performance

Classification performance was evaluated on held-out test sets, with patient-level splitting applied wherever patient identifiers were available to prevent data leakage and ensure true generalization, consistent with recommended practices for clinical AI evaluation. As summarized in Table 8, the framework demonstrated robust performance across both single-label and multilabel biomedical signal datasets.

Table . Classification performance metrics on test sets[a].

Dataset	Accuracy (%)	Sensitivity (%)	Specificity (%)	F_1-score	AUROC[b]
MIT-BIH[c] Arrhythmia	92.3	89.7	94.1	0.91	0.95
PTB[d] Diagnostic ECG[e]	94.7	93.2	95.8	0.94	0.97
PTB-XL[f]	88.9	86.4	91.2	0.88	0.93
Chapman-Shaoxing	91.2	88.9	93.1	0.90	0.94
MIMIC-III[g] Waveforms	89.5	87.1	91.8	0.89	0.92
Sleep-EDF[h]	87.3	84.6	89.7	0.86	0.91
Average	90.7	88.4	92.5	0.90	0.93

[a]Note: Metrics for multi-label datasets (PTB Diagnostic ECG, PTB-XL, Chapman-Shaoxing) represent macroaveraged performance across all labels. Single-label datasets (MIT-BIH, MIMIC-III, Sleep-EDF) use standard multiclass metrics with macroaveraging.

[b]AUROC: area under the receiver operating characteristic curve.

[c]MIT-BIH: Massachusetts Institute of Technology-Beth Israel Hospital.

[d]PTB: Physikalisch-Technische Bundesanstalt.

[e]ECG: electrocardiogram.

[f]XL: extra large.

[g]MIMIC: Medical Information Mart for Intensive Care.

[h]EDF: European data format.

Among single-label datasets, the MIT-BIH Arrhythmia dataset achieved 92.3% accuracy and 0.95 AUROC, reflecting well-defined arrhythmia patterns and high-quality expert annotations. The MIMIC-III Waveforms dataset showed 89.5% accuracy and 0.92 AUROC, indicating reliable generalization to diverse ICU waveforms and clinical monitoring scenarios. The Sleep-EDF dataset achieved 87.3% accuracy and 0.91 AUROC, with moderate performance influenced by subjective sleep stage boundaries, interindividual variability, and class imbalance. For multilabel datasets, the PTB Diagnostic ECG dataset achieved 94.7% accuracy and 0.97 AUROC, PTB-XL achieved 88.9% accuracy and 0.93 AUROC, and Chapman-Shaoxing achieved 91.2% accuracy and 0.94 AUROC, with macroaveraged metrics reflecting performance across all co-occurring diagnostic labels. Overall, the system achieved an average accuracy of 90.7% and an AUROC of 0.93 across all datasets, demonstrating consistent and generalizable classification performance while highlighting dataset-specific challenges.

Baseline Comparison

To validate the effectiveness of the LSTM architecture, performance was compared against 3 baseline methods using identical preprocessing and data splits. The results, summarized in Table 9, show that the proposed LSTM model outperforms traditional machine learning models (support vector machine and random forest) and a 1D CNN baseline in terms of accuracy and F_1-score. Although training time was longer for the LSTM, the gain in classification performance was seen particularly in the F_1-score, which justifies the additional computational cost for clinical applications where diagnostic accuracy was critical. Statistical significance of the improvements was confirmed using paired *t*-tests ($P<.05$).

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Table . Baseline method comparison on Massachusetts Institute of Technology-Beth Israel Hospital Arrhythmia dataset.

Method	Accuracy (%)	F_1-score	Training time (min)	Inference time (ms)
SVM[a] (RBF[b])	85.2	0.83	45	12
Random forest	87.6	0.85	32	18
1D CNN[c]	89.8	0.88	78	15
LSTM[d] (proposed)	92.3	0.91	95	87

[a]SVM: support vector machine.

[b]RBF: radial basis function kernel.

[c]CNN: convolutional neural network.

[d]LSTM: long short-term memory.

Computational Performance

System computational efficiency is critical for deployment in resource-constrained environments. As summarized in Table 10, signal preprocessing required 125 ms per sample with 256 MB of memory usage, while LSTM inference took 87 ms and 512 MB of memory. GPT-4-based natural language generation was the most time- and memory-intensive stage, requiring 1.3 seconds and 2.1 GB of memory per interpretation. Overall, the end-to-end pipeline completed in approximately 1.51 seconds, using 2.87 GB of memory, demonstrating the feasibility for real-time clinical decision support in typical computing environments.

Table . Computational performance benchmarks.

Pipeline stage	Processing time	Memory usage
Signal preprocessing	125 ms	256 MB
LSTM[a] inference	87 ms	512 MB
GPT-4 generation	1.3 s	2.1 GB
Total end-to-end	1.51 s	2.87 GB

[a]LSTM: long short-term memory.

Processing time and memory usage were measured across major pipeline components to quantify feasibility for time-sensitive workflows and resource-constrained deployments.

Quality of Generated Clinical Interpretations

Quality of GPT-4-generated interpretations was evaluated through expert review by 3 board-certified cardiologists using four criteria: clinical accuracy, relevance, clarity, and actionability.

Expert evaluation of GPT-4-generated interpretations demonstrated high quality across multiple criteria, as summarized in Table 11. Clinical accuracy received a score of 4.3 with 92% of criteria met and strong interrater agreement (κ=0.87). Relevance and clarity were similarly high, scoring 4.5 and 4.6 with κ values of 0.91 and 0.89, respectively, while actionability scored 4.2 with 89% of criteria met (κ=0.85). These results indicated that the generated explanations were clinically coherent, contextually relevant, and actionable. The consistently strong interrater agreement across all metrics confirmed the reliability of the generative natural language processing model for clinical decision support.

Table . Expert assessment of generated interpretations.

Metric	Mean score (1-5)	Interrater agreement (κ)	Criteria met (%)
Clinical accuracy	4.3	0.87	92
Relevance	4.5	0.91	94
Clarity	4.6	0.89	96
Actionability	4.2	0.85	89

Discussion

Performance Analysis and Cross-Dataset Interpretation

The experimental results demonstrate that the proposed pipeline achieves robust performance across multiple biomedical signal modalities using a consistent single-lead, single-label approach. The 2-layer LSTM architecture effectively captures temporal dependencies in physiological signals, while integration with GPT-4 provides interpretable outputs suitable for clinical decision-making. Performance variation across datasets reflects differences in signal characteristics, annotation quality, and clinical complexity. For single-label tasks, the model achieved

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the highest performance on MIT-BIH Arrhythmia (92.3% accuracy, 0.95 AUROC), benefiting from a high signal-to-noise ratio, gold-standard expert annotations, and sufficient sample representation for majority classes, with class weighting compensating for rare arrhythmias. Misclassifications primarily occurred between normal and right bundle branch block beats or fusion and premature ventricular complex beats, consistent with known interrater disagreement. Sleep-EDF showed moderate performance (87.3% accuracy, 0.91 AUROC), influenced by subjective sleep stage boundaries, low EEG amplitude, inter-individual variability, and class imbalance, with most errors occurring between adjacent stages (N1↔N2, N2↔N3, and wake↔N1). MIMIC-III performance (89.5% accuracy, 0.92 AUROC) reflects clinical diversity, prevalence of artifacts, variable sampling rates, and label noise, with misclassifications observed between normal sinus rhythm and sinus tachycardia, and between atrial fibrillation and atrial flutter.

We adopted a single-label (mutually exclusive) classification formulation rather than multilabel prediction for several reasons aligned with the resource-constrained deployment context. First, single-label classification simplifies clinical decision-making by providing a definitive primary diagnosis, which is more actionable for nonspecialist providers in low-resource settings. Second, the selected datasets (MIT-BIH, PTB, and CHB-MIT) were originally curated with mutually exclusive diagnostic categories, making single-label formulation more appropriate. Third, multi-label approaches substantially increase computational and interpretative complexity, requiring more sophisticated threshold selection and potentially generating conflicting diagnoses. For future work in contexts where co-occurring conditions are common (eg, concurrent arrhythmias), multilabel formulations with hierarchical class structures would be valuable extensions.

In comparison, multilabel datasets require independent probability estimation for each diagnosis via sigmoid activation. PTB Diagnostic ECG achieved high performance (94.7%) due to its binary classification structure, whereas PTB-XL (88.9%) reflects the challenge of predicting 71 simultaneous diagnostic categories with class imbalance. Chapman-Shaoxing performed moderately well (91.2%), demonstrating the model's ability to handle co-occurring rhythm categories. Overall, single-label tasks benefit from softmax normalization and are suitable for point-of-care scenarios where a primary diagnosis is needed, while multilabel tasks enable comprehensive diagnostic assessments in better-resourced clinical settings.

Cross-Dataset Generalization and Preprocessing Impact

Modality-specific preprocessing was essential for consistent performance. ECG signals were filtered at 0.5 - 50 Hz to preserve QRS morphology, while EEG signals were filtered at 0.5 - 30 Hz to retain physiologically relevant sleep frequency bands (Table 2). Ablation studies indicate that uniform filtering across modalities reduces average accuracy by 4.1%, confirming the importance of adaptive preprocessing. Single-lead selection (Table 4) and fixed-sample segmentation (Table 3) ensured reproducible input dimensions, supported point-of-care feasibility, and prevented data leakage via patient-level splitting.

Clinical Implications

GPT-4-generated natural language interpretations bridge the gap between raw signal classification and actionable clinical insights, enabling non-specialist health care workers to understand diagnostic reasoning. Cloud-based deployment considerations include connectivity, API costs, and regulatory compliance. The system's interpretability and alignment with portable ECG devices (eg, AliveCor) support deployment in resource-limited environments.

Comparison With State-of-the-Art

Compared with previous works, our system achieves competitive arrhythmia detection (92.3% accuracy vs 94.2%) [25] and AUROC (0.95 vs 0.96) [26], with the added advantage of single-lead compatibility and natural language output. Unlike text-only models such as BioBERT or ClinicalBERT, this pipeline integrates physiological signals with generative AI for end-to-end interpretability.

Limitations and Future Work

The study represents a technical proof-of-concept validated on retrospective public datasets only. The system has not been deployed in clinical settings, validated prospectively, or tested for patient outcome improvements. Limitations include single-label focus, single-lead restriction, potential dataset bias, cloud-based computational requirements, and limited dataset diversity. Future work includes prospective IRB-approved clinical pilots, multilead and multilabel extensions, multimodal integration, federated learning for privacy preservation, uncertainty quantification, edge deployment optimization, and cost reduction through alternative LLMs. Regulatory approval and usability testing will be essential before clinical deployment.

Several important limitations warrant discussion. First, this proof-of-concept was evaluated exclusively on curated public datasets that may not reflect the noise characteristics, artifact levels, and signal quality typical of real-world field deployments in resource-limited settings. Robustness to motion artifacts, electrode contact issues, and electrical interference remains untested. Second, our framework relies on cloud-based GPT-4 API calls, raising concerns about (1) data privacy and HIPAA compliance when transmitting patient signals, (2) dependence on stable internet connectivity, and (3) potential API cost barriers for sustained deployment. Alternative approaches using locally deployed open-source LLMs (eg, Llama-2 and Mistral) should be explored, though preliminary tests suggest current open models produce less clinically coherent interpretations. Third, we have not evaluated real-time performance constraints or edge-device deployment feasibility. The LSTM inference time (approximately 50 ms per signal on GPU) is acceptable, but resource requirements on low-power devices (eg, Raspberry Pi or mobile platforms) are unknown. Fourth, the PhysioNet datasets used may not adequately represent demographic diversity (age, sex, race, and comorbidities) or rare conditions, potentially limiting generalizability and introducing bias. Finally, while expert evaluation was promising (mean rating 4.2/5, SD 0.57), it was limited to 150 interpretations and did

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not assess long-term clinical impact or actual provider acceptance in practice settings.

This work presents a technical proof-of-concept and has not been deployed in clinical settings or evaluated using prospective patient data. The system remains a research prototype and would require extensive prospective validation across diverse patient populations, formal clinical trials with IRB approval prior to any clinical use, regulatory clearance (eg, Food and Drug Administration 510(k) or equivalent) for diagnostic applications, and ethics review for telemedicine deployment in underserved regions.

Generalization of model performance beyond PhysioNet benchmarks remains uncertain, particularly in real-world environments with differing patient populations and signal acquisition equipment. There is a risk of automation bias, whereby health care workers may overrely on AI-generated outputs, underscoring the need for interface designs that encourage critical evaluation. Future deployments must incorporate end-to-end encryption and secure data handling mechanisms to protect patient privacy. Liability considerations related to AI-assisted misdiagnosis remain unresolved and will require clearly defined legal and regulatory frameworks before clinical use.

Conclusion

Important caveats should be noted regarding near-term clinical deployment. This proof of concept demonstrates technical feasibility on retrospective public datasets but has not been validated in prospective real-world settings. Critical next steps include (1) prospective pilot studies in low-resource primary care clinics to assess real-world performance and provider acceptance; (2) testing on portable, low-power edge devices to confirm computational feasibility without cloud infrastructure; (3) evaluation with locally deployed open-source LLMs to eliminate API dependencies and privacy concerns; and (4) assessment of performance on signals with realistic noise and artifact levels. Only after these validations can clinical deployment be responsibly considered.

This work presents a comprehensive technical framework integrating LSTM-based biomedical signal classification with GPT-4-generated natural language interpretation, designed for deployment in resource-limited and remote settings. The framework's key contributions include a single-lead selection strategy (Table 4) for consistent input dimensionality and alignment with point-of-care devices, modality-specific preprocessing (Table 2) that preserves diagnostically relevant features while removing artifacts, and a unified architecture supporting both single-label (softmax) and multilabel (sigmoid) formulations, enabling applicability across diverse diagnostic scenarios. Patient-level data splitting ensures true generalization without leakage, while robust classification performance was demonstrated across 6 datasets, including MIT-BIH (92.3%), PTB Diagnostic (94.7%), PTB-XL (88.9%), Chapman-Shaoxing (91.2%), MIMIC-III (89.5%), and Sleep-EDF (87.3%). GPT-4-generated explanations achieved high clinical accuracy (4.3/5.0) and clarity (4.6/5.0) as assessed by expert reviewers (Table 11), highlighting the framework's practical clinical utility for interpretable AI-assisted decision support. The open-source implementation with Representational State Transfer API ensures transparency, reproducibility, and community validation. While prospective clinical deployment and real-world validation remain future steps, this framework provides a robust, methodologically transparent baseline for AI-driven diagnostics and supports equitable access to remote diagnostic tools across diverse health care settings.

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Generative artificial intelligence tools were used in a limited capacity during manuscript preparation. GitHub Copilot assisted with inline code comments and docstring generation for the open-source implementation. All code functionality was independently verified and tested by the authors. Generative artificial intelligence was not used for experimental design, data analysis, statistical computations, results interpretation, or generation of conclusions. The core intellectual contributions and scientific findings are entirely the work of the human authors. The authors take full responsibility for the accuracy and integrity of all content in this manuscript, regardless of the tools used in its preparation.

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Conflicts of Interest

None declared.

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Abbreviations

AI: artificial intelligence
API: application programming interface
AUROC: area under the receiver operating characteristic curve
CHB-MIT: Children's Hospital Boston-Massachusetts Institute of Technology
CNN: convolutional neural network
ECG: electrocardiogram
EDF: European data format
EEG: electroencephalogram
HIPAA: Health Insurance Portability and Accountability Act
ICU: intensive care unit
IRB: Institutional Review Board
LLM: large language model
LSTM: long short-term memory
MIH-BIH: Massachusetts Institute of Technology-Beth Israel Hospital
MIMIC: Medical Information Mart for Intensive Care
PTB: Physikalisch-Technische Bundesanstalt
PTB-XL: Physikalisch-Technischen Bundesanstalt-extra large
ReLU: rectified linear unit

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Development and Evaluation of a Human-in-the-Loop Data Curation Training Program to Support a Digital Clinical Trial Platform: Descriptive Feasibility Study

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Abstract

Background: LookUpTrials is a clinician-facing digital platform designed to support point-of-care navigation of institution-specific oncology clinical trials, incorporating artificial intelligence–assisted summarization and search functionalities. While embedding curated trial knowledge tools in community oncology workflows is feasible, the human infrastructure required to sustain high-quality, up-to-date trial data over time remains underexplored.

Objective: This study aimed to evaluate the feasibility of a structured training program embedding trainees within a supervised human-in-the-loop workflow for oncology clinical trial data curation in support of the LookUpTrials digital platform.

Methods: We conducted a descriptive feasibility evaluation of a cohort-based training and workflow model. A total of 10 undergraduate trainees curated publicly available trial information from institutional portals and ClinicalTrials.gov across 5 academic medical centers. Trial throughput and participant experiences were summarized descriptively.

Results: Over 10 months, trainees curated 2503 oncology clinical trial entries across 5 institutions, with processing rates increasing over time. Participants reported that structured onboarding and peer support facilitated engagement with data curation workflows.

Conclusions: Standardized human-in-the-loop workflows for clinical trial data stewardship can be implemented with individuals without prior clinical trials or informatics experience when supported by structured training and quality assurance. This study complements prior feasibility work on embedding trial knowledge tools in community oncology settings by focusing on the sustainability of the underlying content pipeline. Further evaluation is needed to assess scalability across institutions and durability over longer periods of platform maturation.

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KEYWORDS

clinical trials; undergraduate students; cancer; LookUpTrials; mobile app

Introduction

Access to timely, accurate, and institution-specific information about available oncology clinical trials remains a persistent operational challenge in routine cancer care [1-5]. Trial information is often fragmented across registries, institutional portals, and protocol documents, limiting clinicians' ability to efficiently surface relevant studies during time-constrained visits [2,3,5,6]. Digital clinical trial platforms have emerged to aggregate and present structured trial information at the point of care, but their real-world effectiveness depends not only on technical design and usability but also on the availability of high-quality, up-to-date trial data [7-12].

LookUpTrials is a clinician-facing digital platform designed to surface institution-specific oncology clinical trial information at the point of care. The platform integrates artificial intelligence (AI)–assisted protocol summarization and search functionalities to facilitate trial navigation in routine clinical workflows. Prior

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work has demonstrated the feasibility of embedding LookUpTrials within community oncology workflows [13,14]. However, sustaining such platforms requires ongoing data stewardship to ensure accuracy, completeness, and local operational relevance, including site-specific trial availability, investigator contacts, and recruitment status [2,15,16]. Scalable workforce models to support this data stewardship layer remain underexplored [2,16].

Human-in-the-loop approaches are increasingly recognized as essential complements to automated pipelines and registry-based feeds, which often lack the granularity and local context required for operational trial navigation [17-19]. In this study, undergraduate trainees were selected as a pragmatic test case to evaluate whether individuals without formal clinical or informatics training can be onboarded into standardized data curation workflows with appropriate supervision and quality assurance. This cohort provides a controlled environment to prototype training materials, workflow design, and quality control processes that could be adapted to more durable staffing models, such as research coordinators, centralized trial operations teams, or hybrid human-AI review pipelines.

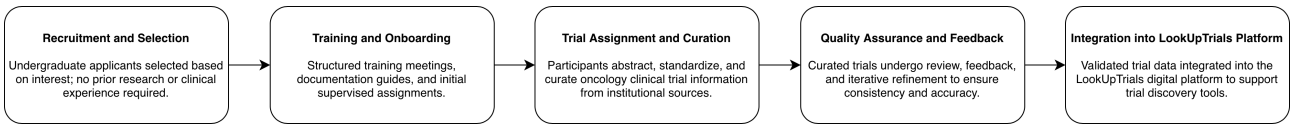
We therefore evaluated the feasibility of a structured undergraduate training program embedding trainees within a supervised human-in-the-loop workflow for oncology clinical trial data curation supporting LookUpTrials. This work complements prior feasibility studies of embedding trial knowledge tools in community oncology by focusing on the sustainability of the underlying content pipeline rather than downstream clinical adoption or enrollment outcomes [20,21].

Methods

Study Design and Setting

We conducted a feasibility evaluation of a structured training program embedding trainees within a supervised human-in-the-loop workflow for oncology clinical trial data curation in support of the LookUpTrials digital platform (Figure 1). The primary objective was to assess whether individuals without prior clinical trials or informatics experience could be onboarded into standardized data stewardship workflows with appropriate supervision and quality assurance. The evaluation focused on workflow feasibility and participant experience rather than clinical adoption or patient-level outcomes.

Figure 1. Overview of the undergraduate training and data curation workflow supporting the LookUpTrials platform. The figure illustrates the sequential processes through which undergraduate participants are recruited, trained, and engaged in oncology clinical trial data curation, including data abstraction, peer-led quality assurance, faculty review, and integration into the LookUpTrials platform.



Participants

A total of 10 undergraduate trainees from a university-based student organization were recruited through a competitive application process based on interest in clinical research, availability for longitudinal participation, and commitment to a defined weekly time allocation. Participants had heterogeneous academic backgrounds and varying levels of prior research experience, reflecting the study's intent to assess the trainability of standardized workflows among individuals without formal clinical or informatics training.

Training and Workflow Design

Trainees underwent structured onboarding that included orientation to oncology clinical trial concepts, navigation of public trial registries and institutional trial portals, and use of standardized data abstraction templates. Training materials included written documentation, example entries, and step-by-step workflow guides. Trainees were embedded within a supervised, multitiered human-in-the-loop workflow that incorporated peer review and faculty oversight to ensure data accuracy, consistency, and completeness. Iterative updates to training materials and workflow documentation were made based on trainee feedback and observed sources of error.

Data Sources and Curation Process

Trainees curated publicly available oncology clinical trial information from institutional clinical trial portals and ClinicalTrials.gov across 5 academic medical centers. The sampling frame included all oncology clinical trials listed as active or recruiting on participating institutions' public trial portals during the study period. Trials were selected systematically based on portal availability and recruitment status rather than through random sampling. Data collection was limited to 5 academic medical centers selected based on the availability of public institutional trial listings and existing program partnerships. The number of trials curated per institution was not intentionally balanced and varied according to institutional trial volume and portal structure.

Institutional clinical trial portals were used to capture site-specific information, such as local recruiting status and institution-level trial availability, which is not consistently available or timely in ClinicalTrials.gov. These data are necessary to support the institution-specific trial discovery functionality of the LookUpTrials platform. Extracted data elements included trial identifiers, disease site, eligibility descriptors, phase, recruiting status, and site-specific information. Data were entered into standardized templates designed to support downstream integration into the LookUpTrials platform. Quality assurance included peer review of entries and secondary verification by program leads to resolve discrepancies and clarify ambiguous protocol information.

Outcomes and Measures

The primary feasibility outcomes included trial throughput (number of trials curated over time) and descriptive changes in individual processing rates across the study period. The secondary outcomes included participant-reported experiences with onboarding, workflow clarity, peer support, and perceived

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learning, assessed via postprogram surveys with Likert-scale and open-ended items. Given the exploratory nature of the study and small sample size, analyses were descriptive and focused on characterizing workflow performance and participant engagement rather than formal hypothesis testing.

Ethical Considerations

This study was conducted as an educational program evaluation and did not meet the definition of human subjects research. The project evaluated a training workflow and analyzed program-level feasibility outcomes using aggregated data and deidentified participant feedback. No identifiable private information was collected, and no patient-level data or protected health information were accessed. All clinical trial information was obtained from publicly available registries and institutional trial portals.

In accordance with US Department of Health and Human Services regulations for the protection of human subjects (45 Code of Federal Regulations 46), this work did not require institutional review board review or approval [22]. As the study did not involve human subjects research as defined by these regulations, informed consent was not required. Participant responses were collected voluntarily and analyzed in aggregate, and no financial compensation was provided.

Results

Participant Characteristics

Participant demographic characteristics are summarized in Table 1. In total, 10 undergraduate trainees participated in the program across the study period. Participants represented diverse academic majors within the life sciences and had heterogeneous prior research experience. Several participants reported no prior exposure to oncology or clinical trials at baseline. This heterogeneity aligned with the study objective of evaluating the feasibility of onboarding individuals without formal clinical or informatics training into standardized data curation workflows.

Table . Demographic characteristics of undergraduate trainees participating in the clinical trial data curation workflow (n=10).

Characteristics	Values, n (%)
Sex	
Male	4 (40)
Female	6 (60)
Academic standing	
Sophomore	4 (40)
Junior	6 (60)
Academic major	
Biology	3 (30)
Biochemistry	2 (20)
Human Biology and Society	1 (10)
Microbiology, Immunology, and Molecular Genetics	3 (30)
Neuroscience	1 (10)
Cohort	
Cohort 1	6 (60)
Cohort 2	4 (40)
Prior research experience (years)	
None	5 (50)
<1	2 (20)
1 - 2	2 (20)
>2	1 (10)

Trial Curation Output and Coverage

The number of curated oncology trials by institution is summarized in Table 2. Over a 10-month period, trainees curated a total of 2503 oncology clinical trial entries sourced from publicly available institutional trial portals and ClinicalTrials.gov across 5 academic medical centers. The volume of curated trials varied by institution, reflecting differences in the size and scope of publicly listed oncology trial portfolios. Curated trials spanned multiple disease sites and trial phases, providing broad coverage of oncology clinical research activity represented within the source portals (Table 3).

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Table . Processed oncology clinical trials by institution across 5 academic medical centers (n=2503).

Institutions	Processed trials, n (%)
UCLA[a]	311 (12.4)
Cedars-Sinai Medical Center	92 (3.7)
University of California, Irvine	584 (23.3)
University of California, San Francisco	1004 (40.1)
University of California, San Diego	512 (20.5)

[a]UCLA: University of California, Los Angeles.

Table . Processed oncology clinical trial entries by cancer type across all participating institutions (n=1790).[a]

Cancer types	Processed trials, n (%)
Head and neck	85 (4.7)
Gastrointestinal	211 (11.8)
Gynecologic	85 (4.7)
Breast	113 (6.3)
Sarcoma	73 (4.1)
Lung	156 (8.7)
Central nervous system	155 (8.7)
Skin	175 (9.8)
Genitourinary	178 (9.9)
Hematologic	267 (14.9)
Miscellaneous	292 (16.3)

[a]Trials classified under nonspecific disease categories (eg, “solid tumors”) were not assigned to a single cancer type and therefore were not included in this distribution.

Workflow Performance Over Time

A descriptive analysis of individual trial processing rates indicated increases in throughput over time for most trainees (Figure 2). These changes were consistent with increasing familiarity with trial structures, data abstraction conventions, and workflow expectations rather than formal performance benchmarking. Variability in processing rates across trainees was observed, reflecting differences in baseline experience, availability, and learning trajectories.

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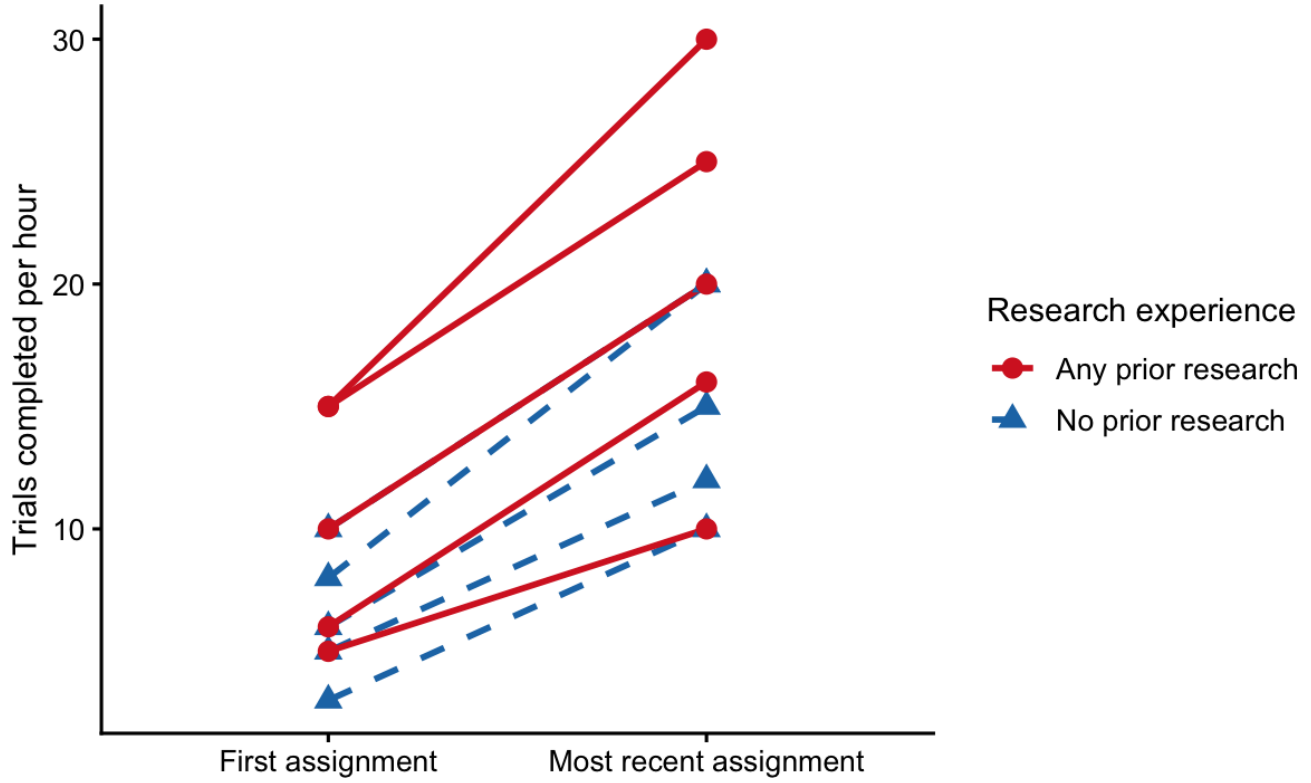
Figure 2. Individual changes in trial processing rates over time (n=10). Each line represents a single participant, illustrating trial processing rates measured during their first assigned trial abstraction and their most recent completed trial abstraction within the study period. Line style and symbol indicate prior research experience (dashed lines with triangles=no prior research experience; solid lines with circles=any prior research experience). The trial processing rate was defined as the number of oncology clinical trials fully abstracted and standardized per hour. Data are presented descriptively to illustrate within-participant variation.



Quality Assurance and Workflow Iteration

Throughout the study period, peer review and secondary verification by program leads identified common sources of ambiguity in trial protocols, including inconsistent terminology across institutional portals and variability in how eligibility criteria and recruitment status were reported. Iterative refinements to training materials and workflow documentation were made in response to these challenges. Over time, fewer clarifications were required per curated trial, suggesting increasing alignment with standardized abstraction conventions and quality assurance processes.

Participant-Reported Experience

Postprogram surveys indicated that participants perceived structured onboarding, shared documentation, and peer support as helpful components of the workflow. Participant ratings of select program components are shown in Figure 3. Trainees reported increased familiarity with clinical trial structure, eligibility terminology, and the role of structured trial information in supporting digital clinical research tools. Participants also noted challenges related to interpreting heterogeneous trial descriptions across institutions and managing time commitments alongside academic responsibilities (Textbox 1). Qualitative feedback suggested that the supervised, iterative workflow design supported learning and engagement despite these challenges.

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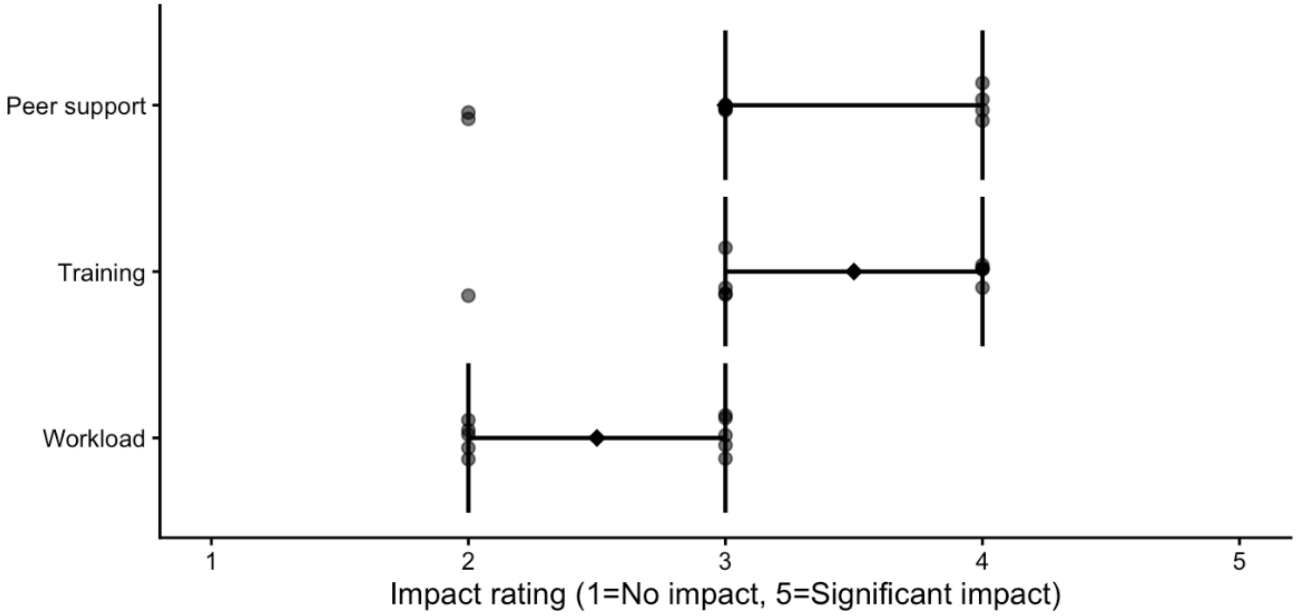
Figure 3. Participant ratings of selected program components (n=10). Points represent individual participant ratings on a 5-point Likert scale. Diamonds indicate median values, and horizontal bars represent the IQR. Components correspond to modifiable elements of the undergraduate training and data curation workflow (eg, training resources, peer support, and workload) and are presented descriptively to illustrate variability in participant perceptions.



Textbox 1. Principal challenges and solutions encountered by participants.

Challenges

- Lack of uniformity between clinical trial sites and dynamic statuses of clinical trial progress
- Difficulty in the production of accurate and cohesive data compilations among multiple program members
- Lack of research experience among program members and background knowledge on oncology broadly
- Ensuring consistent satisfaction and adequate use of time among program members

Solutions

- Emphasis on quality control and consistent collaborations to discuss arising issues and uncertainties among program members
- Use of standardized training materials, shared data abstraction templates, and hands-on onboarding to promote consistency
- Use of a shared communication platform and open access to members' previous work for review
- Open dialogue among program members and communicating feasible deadlines to support sustained participation

Discussion

In this feasibility evaluation, we found that a standardized, supervised human-in-the-loop workflow for oncology clinical trial data curation can be implemented with individuals without prior clinical trials or informatics training. Over a 10-month period, trainees curated more than 2500 trial entries across 5 academic medical centers, with descriptive increases in processing rates over time and favorable participant-reported experiences with structured onboarding and peer support. These findings suggest that with appropriate workflow design, training materials, and quality assurance processes, nonclinician trainees can contribute meaningfully to the data stewardship layer required to support real-world digital clinical trial platforms.

Digital clinical trial platforms increasingly integrate automated data pipelines and AI-assisted features to support point-of-care trial navigation. However, our findings reinforce that human-in-the-loop data stewardship remains a critical complement to automation, particularly for maintaining institution-specific trial information that is operationally relevant but inconsistently represented in registries. The observed learning curves and workflow stabilization over time highlight the importance of standardized abstraction conventions, shared documentation, and multitiered quality assurance in sustaining high-quality trial data. From an informatics perspective, this work underscores that the success of AI-enabled clinical research tools depends not only on algorithmic performance but also on the design of scalable sociotechnical workflows that maintain the underlying data infrastructure.

This study complements prior feasibility evaluations of embedding LookUpTrials within community oncology workflows by focusing on the sustainability of the content pipeline rather than downstream clinical adoption or enrollment outcomes [13,14]. Together, these findings support a layered model of digital clinical trial platforms in which clinician-facing tools can be embedded within routine workflows, and the underlying data stewardship processes required to maintain those tools can be supported through structured

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human-in-the-loop workflows. Framing digital trial platforms as sociotechnical systems with interdependent technical and human components may inform more durable implementation strategies as such tools scale across institutions.

Several limitations warrant consideration. First, the sample size was small and drawn from a single undergraduate program, which may limit generalizability to other trainee populations or institutional contexts. Second, while peer review and secondary verification were incorporated into the workflow, formal benchmarking of data accuracy, interrater reliability, or error rates against gold-standard sources was not performed in this feasibility evaluation. Third, the evaluation focused on workflow feasibility and participant experience rather than clinical outcomes, platform usability, or downstream effects on trial referral or enrollment. Finally, this study reflects an early-stage implementation context, and workflow performance may differ in more mature operational settings or under sustained production demands.

Future work should evaluate the scalability and durability of standardized human-in-the-loop workflows across diverse workforce models, including funded research coordinators, centralized trial operations teams, and hybrid human-AI review pipelines. Incorporating formal data quality metrics, automation-assisted abstraction, and continuous quality monitoring may further strengthen the sustainability of trial data stewardship processes. As digital clinical trial platforms mature, integrating these workflow designs into enterprise research operations could help ensure that AI-enabled tools remain supported by reliable, up-to-date, and operationally relevant trial data over time.

Acknowledgments

Generative artificial intelligence (ChatGPT-4, OpenAI) was used in a limited capacity to assist with grammar, clarity, and phrasing during manuscript preparation. The tool was not used to generate scientific content, analyze data, create figures, or develop references. All scientific interpretations and conclusions are the authors' own, and all content was reviewed and verified by the authors, who take full responsibility for the accuracy and integrity of the work.

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Data Availability

The clinical trial data extracted and processed by undergraduate participants were sourced from publicly available institutional clinical trial portals and ClinicalTrials.gov. The final curated dataset is publicly available through the LookUpTrials mobile app. Additional information about data processing methods is available upon request from the corresponding author.

Authors' Contributions

MI, OY, JD, S Arcot, AC, S Amara, SHB, IB, KS, and QD contributed to data interpretation and manuscript drafting. TKWH supervised the project and provided final revisions. All authors reviewed and approved the final version.

Conflicts of Interest

TKWH serves as an advisor to the TeamX Health chapter at University of California, Los Angeles, and is a developer of the LookUpTrials app. TKWH also helped design and implement the undergraduate training and onboarding workflows described in this study. MI, OY, JD, SA, AC, SHB, IB, KS, and QD participated as undergraduate trainees involved in the data curation workflows described. The authors declare no other personal financial conflicts of interest.

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Abbreviations

AI: artificial intelligence

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An Empirical Approach to Curriculum Mapping in Traditional Kampo Medicine Education in Japan: Practical Methodological Study

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Abstract

Background: The integration of traditional and complementary medicine (T&CM) into modern medical education remains a global challenge. Kampo medicine, a Japanese traditional pharmacotherapy, is recognized in the *International Classification of Diseases, 11th Revision*, and is widely used; however, no structured methodology exists for efficiently designing curricula within limited time and resources. To address this gap, this study proposes a methodological framework—illustrated through Kampo medicine but generalizable to other forms of T&CM—for organizing and visualizing curricular content to guide educational needs assessment and curriculum design.

Objective: The objective of this study was to develop and illustrate a reproducible mapping framework that integrates (1) real-world clinical utilization frequency and (2) the accumulation of biomedical evidence to inform educational prioritization and stepwise curriculum design for T&CM, using Kampo medicine as an exemplar.

Methods: A mapping approach was developed based on two perspectives: frequency of use in clinical training and level of biomedical evidence. Twelve years of outpatient prescription data from Kyoto University Hospital were analyzed to identify the most frequently prescribed Kampo formulas. For the 10 most common formulas, PubMed searches were conducted to determine the number of randomized controlled trials. Data were integrated using hierarchical clustering and plotted along frequency–evidence axes to produce an educational priority map, which informed a stepwise curriculum design grounded in adult learning theory.

Results: Prescription heat maps revealed substantial interdepartmental variation, and clustering identified distinct groups of formulas based on usage patterns. No statistically significant correlation was observed between prescription frequency and level of evidence (Pearson r=0.228, 95% CI −0.469 to 0.750; P=.53; Spearman ρ=0.498, 95% CI −0.308 to 0.926; P=.14). Integrating these two perspectives enabled interpretation of real-world prescription patterns and supported a transparent educational prioritization framework.

Conclusions: This study presents a feasible and adaptable framework that links real-world clinical data with biomedical evidence to inform curriculum design in T&CM. Rather than prescribing specific content, the framework offers visual decision-making tools that align educational priorities with institutional practice patterns and can be readily adapted to complementary, alternative, and integrative medicine programs internationally.

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KEYWORDS

traditional medicine; complementary and alternative medicine; CAM; curriculum mapping; evidence-based education; educational needs assessment

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Introduction

In recent years, increasing international attention has been directed toward the challenge of integrating traditional and complementary medicine (T&CM) into modern medical education. The World Health Organization (WHO) has published a global strategy for traditional, complementary, and integrative medicine for 2025 to 2034, which aims to position traditional, complementary, and integrative medicine as an integral component of people-centered health systems [1]. A recent systematic review on integrating T&CM into health systems highlighted the need for reforms in medical education to support safe and effective integration, reinforcing the importance of strengthening undergraduate training in this area [2].

In East Asia, established systems such as Traditional Chinese Medicine, Korean Medicine (Hanbang), and Kampo medicine in Japan have developed not merely as complementary modalities but also as regionally rooted medical traditions institutionalized through education and practice [3].

Recent work in traditional East Asian medicine education has demonstrated a shift away from purely traditional apprenticeship models toward reconstruction using contemporary educational frameworks, such as competency-based education and structured curriculum design, highlighting parallel challenges and solutions in traditional medicine education [4]. A recent scoping review reported that complementary and alternative medicine teaching in undergraduate medical curricula is widely inconsistent in both content and assessment approaches, underscoring the need for more structured and evidence-based curricular design [5]. Curriculum alignment and mapping are widely used to ensure coherence and transparency in medical curricula and to identify gaps and redundancies; however, practical guidance on how to implement these processes remains limited [6]. Recent implementations of integrative medicine education for medical students have reported improvements in learners' self-reported knowledge, attitudes, and course satisfaction; however, scalable approaches to prioritizing and sequencing curricular content remain an ongoing challenge [7].

Kampo medicine, Japan's traditional system of pharmacotherapy, originated from classical Chinese medicine and was introduced via the Korean Peninsula in the 5th to 6th centuries. In 742, the Tang dynasty monk Jianzhen (Ganjin) brought Chinese medical texts and crude drugs to Japan, laying the foundations of Kampo practice [8-10]. Thereafter, Kampo evolved uniquely in response to Japan's climate, culture, and constitution, while systematizing diagnostic and therapeutic principles with continued reference to Chinese classics [11,12]. Internationally, the WHO formally recognized Kampo as a traditional medical system in chapter 26 of the *International Classification of Diseases, 11th Revision* [13].

In Japan, Kampo medicines were officially integrated into the national health insurance system in 1976, thereby becoming broadly accessible to patients at relatively low cost [14,15]. Today, Kampo formulas are regulated by the Ministry of Health, Labor, and Welfare and are widely prescribed in routine clinical practice [16-19]. We previously reported on the extensive use of Kampo medicines at a university hospital, focusing in particular on their use in the Department of Anesthesiology and Pain Clinic [20]. More than 80% of Japanese physicians incorporate Kampo medicines into their practice, most often alongside Western medicine, highlighting their complementary role [21,22]. Importantly, the Model Core Curriculum for Medical Education in Japan, which provides the foundation for undergraduate training across all medical schools, explicitly includes the study of the fundamentals of Kampo medicine as one of its requirements [23]. Previous reports have suggested that the Japanese model of Kampo education could serve as a reference for traditional medicine curricula internationally, including in US medical schools [24]. Despite its historical background and widespread clinical use, undergraduate Kampo education in Japan remains constrained by limited curricular time, and the quantity and content of instruction vary across universities [25,26]. Although the scientific evidence base for Kampo has expanded with the accumulation of randomized controlled trials (RCTs) [10], an empirical and structured methodology for designing curricula that enables medical students to efficiently learn traditional medicine within limited time and resources has yet to be established.

In modern medical education, curricular priorities are often determined on the basis of disease prevalence and severity. For example, Machado et al [27] reported a curriculum design approach in Brazil that drew on mortality statistics and WHO burden of disease data (disability-adjusted life years) to align medical education with epidemiological impact. However, in traditional medicine education, the epidemiological frequency of diseases or conditions does not necessarily translate directly into curriculum design. Educational frameworks must instead focus on the distinctive modalities of intervention unique to traditional medicine [10]. In Kampo medicine, prescriptions are guided by *Sho*, a traditional diagnostic framework that classifies patients according to characteristic patterns of signs and symptoms rather than Western diagnostic categories, making the formula itself more closely aligned with the theoretical system. Consequently, the analysis of prescription frequencies lends itself to linking educational content with theoretical principles and offers a practical entry point for empirical approaches to curriculum design in traditional medicine education. In medical education, conducting a needs assessment is widely regarded as a foundational step in curriculum development, as it helps identify curricular goals and content priorities and align educational strategies with local context and available evidence [28]. Recent integrative work on theoretical models for undergraduate medical curriculum development has emphasized the importance of a situational analysis phase to align curricular objectives and content with the local context and stakeholders' needs [29].

Although this case analysis is based on actual prescription data from Kyoto University Hospital, the objective is not to generalize or prescribe a specific set of formulas or teaching content across institutions. Rather, the emphasis is on the types of data, methods of integration, and visualization techniques that can serve as a methodological framework for educational needs assessment and curriculum design—one that is more broadly applicable to traditional medicine. In the context of

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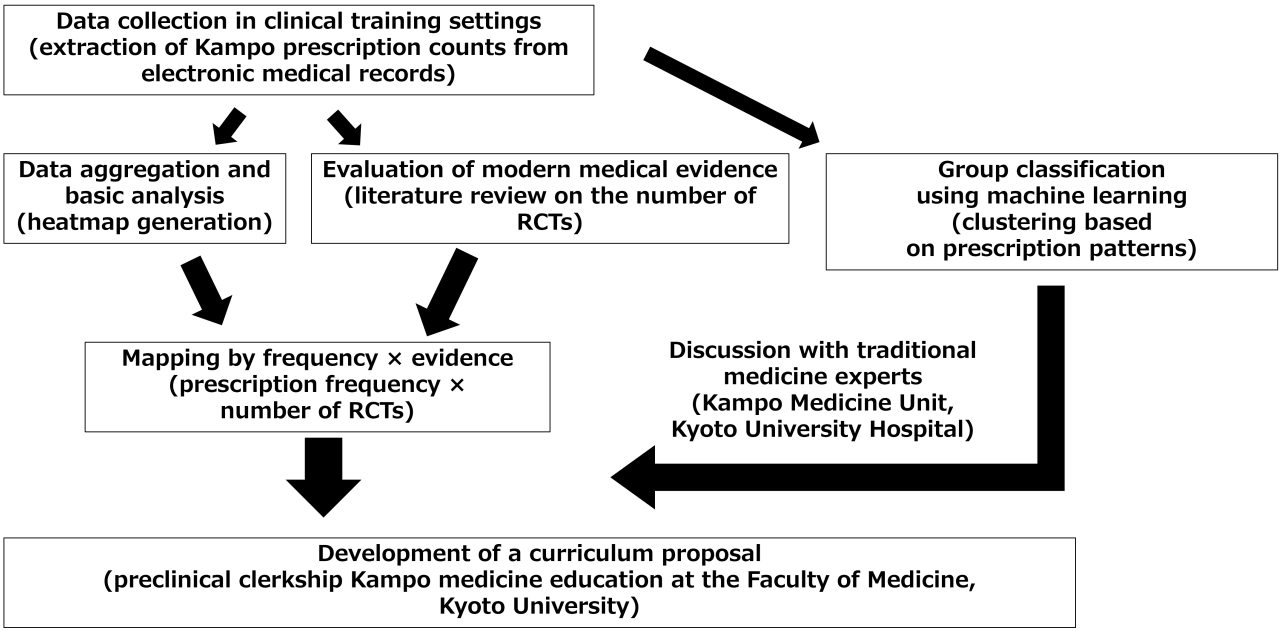
constrained health care resources and compressed instructional time, the prioritization and visualization of curricular content may help safeguard the quality of traditional medicine education. Curriculum mapping has also been used to evaluate coherence and progression in competency-based curricula by visualizing how learning objectives form a coordinated learning spiral across courses and institutions [30]. Therefore, the aim of this study is to develop and illustrate a methodological framework for needs assessment and curriculum design in undergraduate traditional medicine education through the mapping and visualization of prescription data.

Methods

Study Overview

This study presents a methodological framework for mapping and visualizing curricular content in traditional medicine education, focusing on two primary perspectives: frequency of use in clinical training settings and accumulation of biomedical evidence (measured by the number of RCTs). Clustering analyses were incorporated to extract structural insights, and the entire process was extended to the proposal of curriculum design. An overview of the analytic steps for traditional medicine curriculum development proposed in this study is shown in Figure 1.

Figure 1. Overview of analytic steps for curriculum design in traditional medicine. This figure illustrates the process from collecting real-world data on traditional medicine use in clinical practice to integrating frequency, biomedical evidence, and machine learning–based clustering and finally applying these results to curriculum design. Items in parentheses represent the elements specifically analyzed in this study. RCT: randomized controlled trial.



Data Sources

Prescription data on Kampo medicines under the national health insurance system were extracted from the electronic medical record system of Kyoto University Hospital for a 12-year period (April 2011 to March 2023). All clinical departments were included, and the number of prescriptions was recorded for each formula. Only Kampo products supplied by the same pharmaceutical company and continuously listed in the Kyoto University Hospital formulary throughout the 12-year study period were included; products newly introduced or discontinued during this period were excluded. In this study, "prescription count" refers to the number of times a Kampo formula was prescribed, regardless of dose or duration. Departments were aggregated according to electronic record system categories. Newly established or abolished divisions during the period were excluded, as were prescriptions recorded by the pharmacy for patient-brought medications. Subdivisions were consolidated under the higher-level department when applicable. Prescription frequency was operationalized as the number of prescription events recorded in the electronic medical record, irrespective of patient volume, dose, treatment duration, or repeated prescriptions for the same patient. This metric primarily reflects institutional prescribing activity and clinical workflow and should not be interpreted as a direct measure of unique patient exposure or the amount of hands-on clinical experience for individual medical students.

For the 10 most frequently prescribed formulas identified from the frequency data, an evidence evaluation was conducted through a literature review. PubMed searches were performed using each formula's accepted English name (eg, Yokukansan, Yi-Gan San) combined with the keyword "randomized controlled trial." Evidence strength was assessed based on the number of published RCTs. Inclusion criteria were original English-language articles published within the past 20 years that reported on the efficacy of the target formula. Exclusion criteria were articles without accessible full text (ie, unavailable through Kyoto University student accounts and institutional access) and studies not based on RCTs. Initial screening of titles and abstracts was conducted by one coauthor, followed by a full-text review and validation by another coauthor. In this study, the evidence indicator was operationally defined as the number of RCTs indexed in PubMed and published in English. This

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definition was adopted to ensure international comparability and accessibility for readers trained in biomedicine and does not represent the total accumulated evidence base for each Kampo formula.

Data Analysis

Heat maps were generated to visualize the distribution of prescriptions by department. A pivot table of "Kampo formula × department" was created, and each cell contained the sum of prescriptions. The resulting prescription matrix was visualized using the *heatmap* function of Python Seaborn library. To improve readability, additional heat maps restricted to the top 10 departments and top 10 formulas were generated. All figures were produced using the Matplotlib and Seaborn libraries.

Hierarchical clustering was performed to analyze similarities in prescription patterns across departments. The "department × formula" matrix was standardized using *z* scores, followed by agglomerative clustering with Ward method and Euclidean distance. Departments were clustered based on their relative prescription profiles and visualized as dendrograms. Similar clustering was conducted on the formula dimension to highlight groups of prescriptions with shared patterns of departmental use. This approach enabled classification of departments based on the similarity of prescription patterns and provided descriptive structural context to inform educational discussions and curriculum design. Hierarchical clustering was implemented using the scipy.cluster.hierarchy module (Ward method, Euclidean distance).

Educational content was mapped by integrating two primary dimensions: frequency of clinical use (total prescriptions aggregated by department) and biomedical evidence (number of RCT reports identified through PubMed review). Hierarchical clustering of formulas based on prescription patterns was added to provide a structural context. Prescription counts, RCT counts, and clustering data were combined in a scatter plot.

Statistical Analysis

Correlation analyses were performed between prescription counts and number of RCT reports to examine the relationship between clinical use and scientific evidence. Prescription counts were aggregated across departments for each formula. The Pearson correlation coefficient (r) was used to assess linear associations, and the Spearman rank correlation coefficient (ρ) was used to assess monotonic relationships. Analyses were performed using the *scipy.stats* module in Python, with P values of <.05 considered to indicate statistical significance. Effect sizes with 95% CIs were reported for correlation coefficients. Pearson CIs were calculated using Fisher *z* transformation, and Spearman CIs were estimated using percentile bootstrap resampling.

To provide a data-informed reference boundary (a pragmatic heuristic) for evidence, k-means clustering (k=2) was applied to RCT counts. A vertical reference line was drawn at the midpoint between the two centroids identified by clustering. Based on these integrated results, formulas were categorized from an educational perspective. The choice of k=2 dichotomized formulas into relatively evidence-rich and evidence-poor groups. This pragmatic classification reflects the educational purpose of determining a threshold in RCT availability rather than identifying multiple fine-grained clusters. Finally, as a case study, we constructed a curriculum design flow illustrating how such mapping could be integrated into traditional medicine education at Kyoto University.

Given the small number of formulas included in the correlation analysis (n=10), robustness checks were performed using (1) permutation-based tests for correlation (10,000 permutations) and (2) leave-one-out analyses to assess sensitivity to influential formulas. For the evidence reference boundary shown in Figure 2, stability of 1-dimensional k-means thresholding (k=2) was evaluated by repeating the procedure across multiple random seeds (0 - 199) and examining both centroid midpoint thresholds and resulting high/low group assignments. The k-means–derived reference boundary was compared with alternative cut points (median and 75th percentile of the RCT counts). The Kendall τ was calculated additionally as a rank-based correlation measure.

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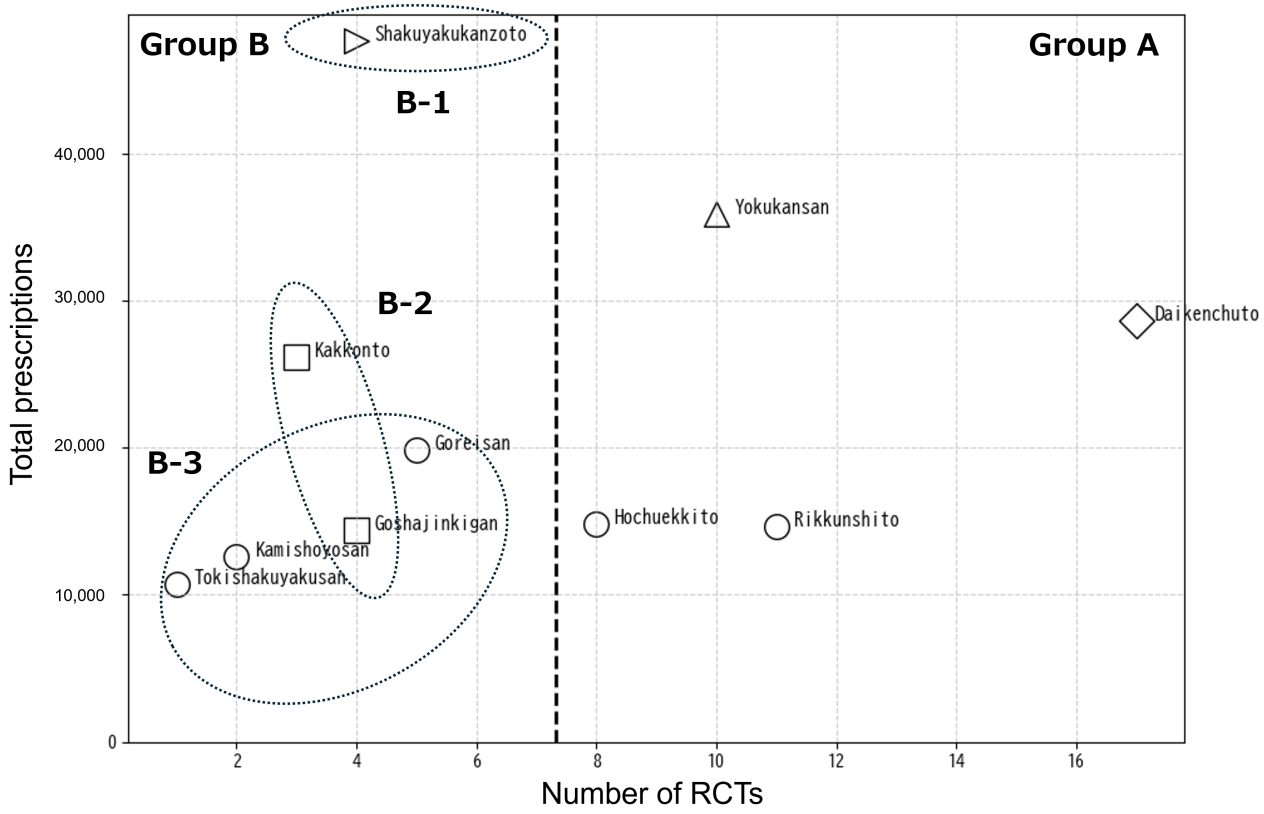
Figure 2. Mapping of Kampo formulas based on prescription frequency, evidence, and clustering information. Scatter plot showing total prescription counts (vertical axis) and number of randomized controlled trial (RCT) reports (horizontal axis). Marker shapes reflect cluster-based categorization. Group B formulas were subdivided into B-1 to B-3. A vertical dashed line indicates a data-informed reference boundary, defined as the midpoint between k-means centroids (k=2).



For hierarchical clustering, stability was assessed by repeating clustering under alternative preprocessing methods (eg, log1p transformation and row normalization), distance metrics (Euclidean, cosine, correlation), and linkage methods (Ward, average). Agreement with baseline clustering was quantified using the adjusted Rand index (ARI).

All analyses were performed in Python (version 3.12.2) using Pandas (version 2.2.2), NumPy (version 1.26.4), Matplotlib (version 3.9.0), Seaborn (version 0.13.2), SciPy (version 1.13.0), and Scikit-learn (version 1.5.0). The authors used ChatGPT (OpenAI, GPT-5, 2025) to assist with generation and refinement of Python scripts for data analysis and visualization. All code was reviewed, tested, and validated by the authors, who take full responsibility for the analyses and results presented in this study.

Ethical Considerations

This study used routinely collected clinical prescription data from Kyoto University Hospital and involved secondary retrospective analysis without direct patient contact. The study protocol was reviewed and approved by the Kyoto University Graduate School and Faculty of Medicine Ethics Committee (approval number R3806). The requirement for informed consent was waived by the ethics committee because the study analyzed existing clinical data retrospectively, the study posed minimal risk, and all data were deidentified and analyzed in aggregate form. In accordance with institutional policy for secondary use of clinical data, an opt-out opportunity was provided through a publicly available disclosure notice. Patients could request exclusion of their data by contacting the responsible office listed in the notice. Data were stored and analyzed on secure institutional servers and were accessible only to the study team. No compensation was provided to participants because this study involved secondary analysis of existing data and imposed no additional burden on patients. All data were anonymized prior to analysis, and no personally identifiable information was accessible to the researchers. Data extraction and analysis were conducted in accordance with institutional data protection policies to ensure participant privacy and confidentiality.

Results

Prescription Frequency and Departmental Prescription Patterns

A total of 169,406 prescriptions were analyzed. To visualize the number of prescriptions by department and Kampo formula, heat maps were generated from pivot tables of “formula × department.” A subset focusing on the top 10 departments and top 10 formulas was extracted to highlight major prescription patterns (Multimedia Appendix 1). During the study period, the 10 most frequently prescribed Kampo formulas were shakuyakukanzoto, yokukansan, daikenchuto, kakkonto, goreisan, hochuekkito, rikkunshito, goshajinkigan,

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kamishoyosan, and tokishakuyakusan. The heat maps revealed not only the overall frequency distribution of each formula but also distinct interdepartmental differences in prescription patterns.

Clustering of Departments Based on Prescription Patterns

To analyze similarities among departments, prescription matrices were standardized using *z* scores and subjected to hierarchical clustering (Ward method, Euclidean distance). Dendrograms demonstrated that the Pain Clinic, Neuropsychiatry, and Obstetrics & Gynecology departments exhibited distinctive prescription patterns and were classified as independent clusters, whereas most other internal medicine and surgical departments were grouped into a large shared cluster (Multimedia Appendix 2).

Clustering of Kampo Formulas Based on Prescription Patterns

To evaluate similarities among formulas, hierarchical clustering of "formula × department" matrices (standardized by *z* scores, Ward method) was performed. Some frequently used formulas, including shakuyakukanzoto, yokukansan, and daikenchuto, demonstrated unique prescription patterns and formed independent clusters. The remaining formulas were grouped into 2 major clusters (Multimedia Appendix 3). Cluster 1 included 37 formulas with a total of 89,488 prescriptions, and Cluster 2 included 3 formulas with 23,870 prescriptions. Cluster 1 prescriptions were concentrated in pain clinics, neuropsychiatry, and obstetrics and gynecology, suggesting that they represented formulas familiar to these specialties. By contrast, the 3 formulas in Cluster 2 were used more broadly across multiple departments (Multimedia Appendix 4).

Relationship Between Prescription Frequency and Evidence From Literature Review

For the 10 most frequently prescribed formulas, the number of RCTs identified in PubMed was compared with prescription counts (Multimedia Appendix 5). Correlation analysis using the Pearson correlation coefficient (linear association) and Spearman rank correlation coefficient (monotonic association) revealed no statistically significant correlations (Pearson r=0.228, 95% CI −0.469 to 0.750; P=.53; Spearman ρ=0.498, 95% CI −0.308 to 0.926; P=.14). Thus, among the most frequently prescribed formulas, no significant relationship was observed between frequency of clinical use and the number of RCT reports.

Mapping by Frequency and Evidence Level

The top 10 formulas were mapped using 2 axes: prescription frequency and number of RCT reports. Complementary insights into group-level trends were obtained by overlaying formula clusters derived from prescription patterns (Figure 2). Formulas with both high prescription frequency and high evidence (daikenchuto, yokukansan, rikkunshito, hochuekkito) were classified as Group A. Formulas with high prescription frequency but relatively low RCT counts (shakuyakukanzoto, goreisan, kakkonto, goshajinkigan, kamishoyosan, tokishakuyakusan) were classified as Group B. For curriculum design purposes, Group B was further subdivided into 3 educational subgroups (B-1 to B-3), informed by the baseline clustering marker patterns. Shakuyakukanzoto was assigned to B-1; kakkonto and goshajinkigan to B-2; and goreisan, kamishoyosan, and tokishakuyakusan to B-3. This complementary classification allowed educational prioritization, even for formulas that were difficult to categorize by frequency or evidence alone. Marker shapes indicate clusters derived from hierarchical clustering based on prescription patterns (Multimedia Appendix 3). The subgroups B-1 to B-3 do not correspond directly to individual clusters in the dendrogram; rather, they represent educational subclassifications derived by integrating cluster membership (marker shape) with relative evidence levels along the RCT axis.

Application of Mapping to Curriculum Design: Stepwise Learning Flow

Based on the integrated mapping of prescription frequency, evidence scores, and clustering, formulas were categorized from an educational perspective. As a practical application, a curriculum structure for preclinical Kampo medicine education was designed (Figure 3). This flow was developed in accordance with adult learning theory (Knowles), which emphasizes learners' receptiveness and connection with prior knowledge [31].

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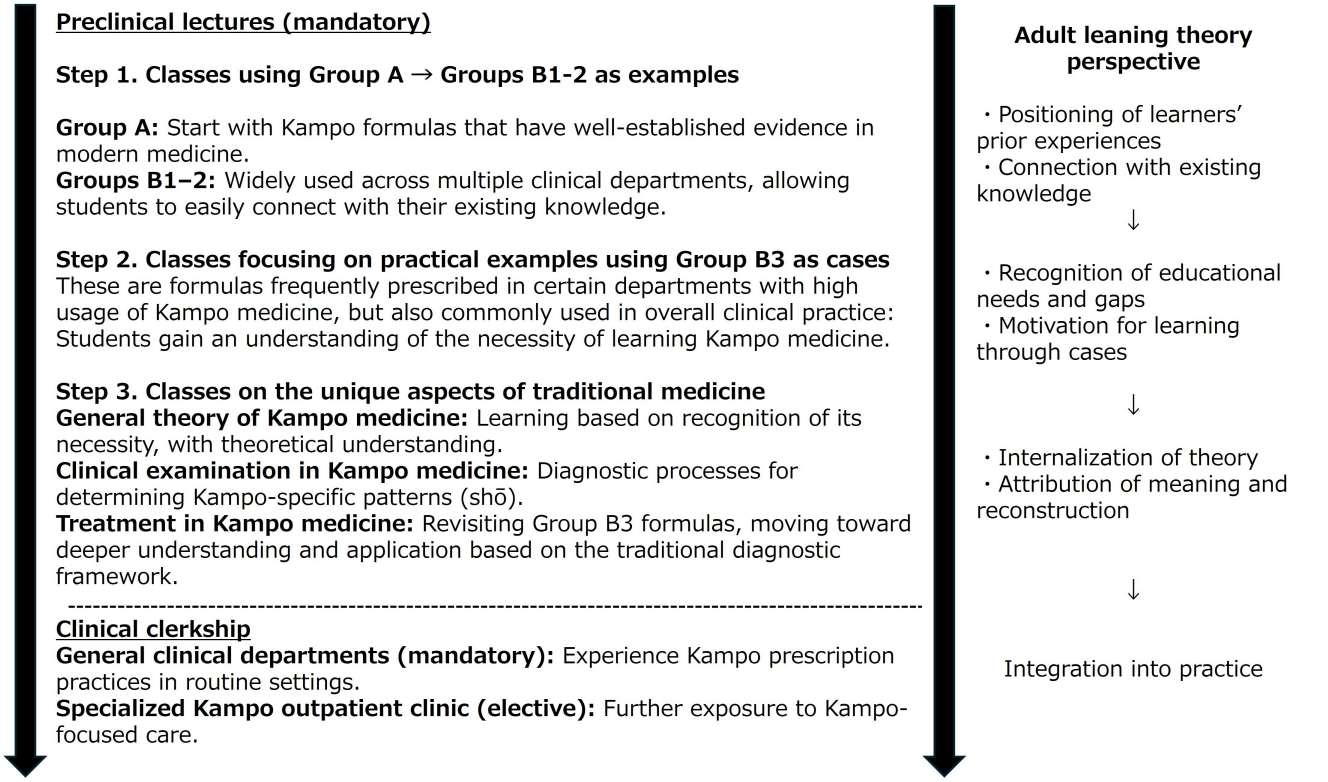
Figure 3. Stepwise Kampo education before clinical training and its alignment with adult learning theory. This figure illustrates the 3-step structure of preclinical Kampo lectures and its correspondence with adult learning processes: positioning learners' experiences, recognizing knowledge gaps, fostering motivation through case examples, internalizing theoretical frameworks, and integrating learning into clinical practice.



Step 1 begins with Group A formulas, which have both high prescription frequency and relatively higher biomedical evidence (as indexed by PubMed RCT counts), making them well suited as introductory examples. Then, Groups B-1 and B-2 formulas are introduced. These are widely prescribed across multiple departments and easily connected to students' prior biomedical knowledge, thereby facilitating smooth entry into Kampo learning.

In step 2, Group B-3 formulas are addressed. These are particularly prevalent in high-frequency prescription departments, such as pain clinics, neuropsychiatry, and obstetrics and gynecology. Case-based examples from these specialties emphasize their clinical relevance and highlight the need for further learning.

In step 3, the theoretical foundations of Kampo are presented, including diagnostic and therapeutic principles, while revisiting Group B-3 formulas. This reinforces understanding of the traditional diagnostic framework and facilitates the integration of knowledge into clinical applications.

Sensitivity Analyses and Stability Checks

Given the small sample size for the correlation analysis (n=10 formulas), correlation estimates were imprecise and not statistically reliable across robustness checks. The Pearson correlation between RCT counts and total prescriptions was r=0.228 (P=.53; permutation P=.52), the Spearman correlation was ρ=0.498 (P=.14; permutation P=.14), and the Kendall τ was τ=0.360 (P=.15; permutation P=.18). Leave-one-out analyses showed that effect estimates varied (Pearson r range 0.108 - 0.538; Spearman ρ range 0.310 - 0.667; Kendall τ range 0.197 - 0.500), consistent with limited power. Across 200 random initializations (seeds 0 - 199), the 1-dimensional k-means (k=2) evidence boundary was identical (threshold=7.33; centroids=3.17 and 11.50) and yielded identical high/low assignments for all 10 formulas: Hochuekkito (8 RCTs), Yokukansan (10), Rikkunshito (11), and Daikenchuto (17) were classified as higher-evidence formulas in 100% of runs, whereas the remaining formulas (1 - 5 RCTs) were classified as lower-evidence formulas in 100% of runs. Using alternative cut points changed the number of formulas classified as higher evidence (median cut point 4.5: 5/10; 75th percentile cut point 9.5: 3/10), indicating that borderline classifications depend on the chosen rule. The stability of hierarchical clustering varied by analytic settings. For departmental clustering, the top-level (k=2) partition was relatively consistent under log transformation and row normalization when using Ward linkage with Euclidean distance (ARI=0.81 and 0.76, respectively), whereas finer partitions and alternative metric/linkage choices showed lower agreement. For Kampo formula clustering, agreement across alternative preprocessing, metric, and linkage choices was generally low (ARI −0.05 to 0.37 across tested settings), indicating that specific formula-level cluster memberships should be interpreted as exploratory rather than definitive.

Discussion

Overview

In this study, we propose a methodological framework for organizing and visualizing educational content in traditional medicine curricula by integrating two perspectives—clinical use frequency and biomedical evidence—derived from

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real-world prescription data at a university hospital. This approach was then extended to curriculum design.

Prescription Frequency and Departmental Prescription Patterns

Formulas prescribed with high frequency are those that medical students are most likely to encounter during clinical training. Advanced learning about these formulas allows students to apply knowledge directly in practice. Such experiences may enhance students' perception of relevance ("what I learned was useful"), which in turn may stimulate self-directed learning. In this study, we did not explore departmental prescription biases in depth because our primary focus was the prioritization of limited preclinical instructional time and resources. Nevertheless, departmental prescription patterns likely reflect the specific patient populations and therapeutic cultures of each specialty. If curricular time for traditional medicine education can be secured during clerkships, educational interventions tailored to the prescription characteristics of each department may be meaningful. The prescription frequency and departmental data generated through the analytic flow presented here can also be applied to elective learning by offering individualized education aligned with students' clinical placements.

Several limitations should be considered when interpreting prescription frequency. Because our analysis was based on aggregated prescription events, the results may overrepresent formulas used on an as-needed basis and underrepresent formulas prescribed for chronic or constitution-based management. In addition, prescription counts are influenced by documentation practices, departmental workflows, and institutional prescribing cultures [21], rather than reflecting standardized student exposure across clinical training. Accordingly, in this study, we use prescription frequency as a pragmatic indicator of institutional practice patterns relevant to educational needs assessment, not as a direct proxy for educational importance or learner exposure.

Several institution-specific factors should also be considered when interpreting the prescription data. Because this study was conducted at a university hospital, the case mix may differ from that of community-based settings, and common, uncomplicated diseases may be underrepresented [32]. In addition, the range of Kampo formulas available for prescription was constrained by the hospital formulary, which may limit the diversity of prescriptions observed. Furthermore, affinity for Kampo prescribing varies across clinical departments, reflecting differences in patient populations, clinical focus, and local prescribing cultures. These factors may influence prescription patterns and should be taken into account when interpreting the results. In particular, the prominent influence of the Pain Clinic in the clustering analysis likely reflects the clinical characteristics of this specialty, where Kampo medicines are frequently used for chronic pain management, symptom modulation, and adjunctive therapy alongside Western medicine. As a result, prescription volumes and formula diversity in the Pain Clinic tend to be higher than in many other departments, which may disproportionately affect clustering patterns.

Taken together, prescription frequency should be interpreted as a pragmatic indicator of institutional practice patterns for educational needs assessment. From an educational perspective, frequently encountered formulas can serve as an accessible entry point for learning. More complex Sho-based reasoning, constitutional diagnosis, and long-term management concepts can be progressively layered through guided instruction and expert facilitation.

Clustering of Departments and Kampo Formulas

Hierarchical clustering based on prescription patterns was conducted for both departments and the Kampo formulas. The results revealed that certain specialties and formulas formed independent clusters, whereas many others were grouped together based on shared prescription patterns. This provides a visual and structural overview of the relationships between departments and formulas. However, this study had several limitations. First, clustering was based solely on prescription counts and did not capture prescribing intentions or department-specific treatment algorithms. For example, frequent use of a formula may reflect adherence to protocol or individual physician preference, distinctions not accounted for in this study. Second, prescription counts represent the total number of prescriptions and may include repeated prescriptions for the same patient or concurrent use of multiple formulas. In addition, decisions regarding the number of clusters and choice of distance metrics involve a degree of arbitrariness, which limits reproducibility and generalizability to other institutions. Prescription patterns may be influenced by patient demographics and case mix (eg, age, sex, and presenting symptoms), which were not statistically controlled in this study. Accordingly, cluster interpretation requires alignment with clinical and educational contexts rather than relying solely on numerical proximity. The value of clustering in this study lies not in identifying definitive prescription rules, but in providing a structural lens for reorganizing formulas and departments, thereby informing curriculum design.

Evidence Evaluation Through Literature Review

For evidence evaluation, we used the number of RCTs published in English and indexed in PubMed, a widely used international database. This approach has limitations because Japanese-language publications and studies published in domestic journals were not captured. However, the intent was to present indicators that are comprehensible and relatable to medical students trained in biomedicine while simultaneously offering perspectives that could inform curriculum design in diverse educational settings worldwide. For this reason, the evidence evaluation was restricted to English-language PubMed-indexed RCTs.

Accordingly, the evidence level of some widely used Kampo formulas may be underestimated in this mapping, which could influence their classification into lower-evidence categories. Therefore, the evidence axis should be interpreted as reflecting the availability of international, English-language biomedical evidence rather than overall scientific validity. In addition, characteristics of RCTs for Kampo medicines warrant consideration. In Japan, many commonly prescribed Kampo formulas have long been covered by the national health

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insurance system and widely incorporated into routine clinical practice [14,15]. As a result, there may be limited commercial or regulatory incentive to conduct large-scale RCTs for these established formulas, whereas newer or less widely used formulas may be more likely to be investigated in formal clinical trials [33]. This structural feature of the evidence base should be taken into account when interpreting the distribution of RCT counts across formulas.

In terms of student comprehensibility, not only proof of efficacy by RCTs but also mechanistic understanding is relevant. However, establishing objective criteria for mechanistic elucidation is challenging. Given our aim to develop a feasible methodology applicable to a wide range of traditional medicine curricula, we restricted our evaluation to RCTs. In practice, expert consultation remains necessary when interpreting data and determining the specific educational content for curriculum development.

Mapping by Frequency and Evidence

Our analysis revealed that several formulas were frequently prescribed despite limited RCT-based evidence, highlighting a clear gap between clinical practice and biomedical evidence. While bridging this "evidence gap" through further research is undoubtedly valuable, our findings suggest an additional perspective: these gaps may represent educational opportunities in which traditional medicine frameworks can be explicitly addressed. Rather than excluding formulas with limited biomedical support, traditional medicine education can help students appreciate the theoretical and cultural contexts underlying such practices. This provides unique learning that complements biomedical training rather than duplicates. Thus, the mapping methodology presented here offers a framework for reexamining the selection and sequencing of curricular content.

The evidence threshold used to distinguish higher- and lower-evidence categories was derived from k-means clustering (k=2) and represents a relative, data-dependent boundary within this dataset. Formulas located near the threshold may shift categories if analytic settings or datasets change. Accordingly, these groupings should be interpreted as pragmatic tools for relative educational prioritization rather than as absolute classifications of therapeutic validity or efficacy.

Several statistical limitations should be acknowledged. First, the correlation analysis was based on a small number of formulas, which limits statistical power and precision. Consistently, the 95% CIs around the correlation coefficients were wide, underscoring the limited precision of the correlation analysis. Second, clustering results and the evidence threshold depended on methodological choices such as distance metrics, linkage methods, and threshold settings. Consequently, group labels should be interpreted as relative and pragmatic categorizations within this dataset rather than fixed or universally applicable classifications.

Curriculum Design Informed by Mapping

The proposed curriculum design incorporated both the use frequency and evidence level, supplemented by clustering-derived group characteristics, to structure a stepwise learning flow. Beginning with formulas that are strongly evidence-based or easily connected to students' biomedical knowledge, and then progressing to formulas less easily explained within biomedical frameworks, aligns with adult learning theory, including processes of recognizing learning needs, internalizing theoretical perspectives, and transferring knowledge to clinical practice [31]. In medical education, self-directed learning has been reported to be an effective learning strategy compared with traditional didactic approaches, supporting our emphasis on designing learning sequences that foster learner autonomy and engagement [34].

In Figure 4, the horizontal axis represents learners' relative ease or difficulty in understanding Kampo concepts within a biomedical framework. Importantly, this "difficulty" should be understood as arising from at least 2 distinct factors. One factor is the limited availability of clearly articulated biomedical mechanisms, which may be partially reflected by the volume of RCT-based evidence. The other factor is the conceptual and terminological gap between Kampo medicine and modern biomedicine, as Kampo relies on its own diagnostic and therapeutic framework, including Sho-based reasoning [35], that is unfamiliar to many biomedical learners.

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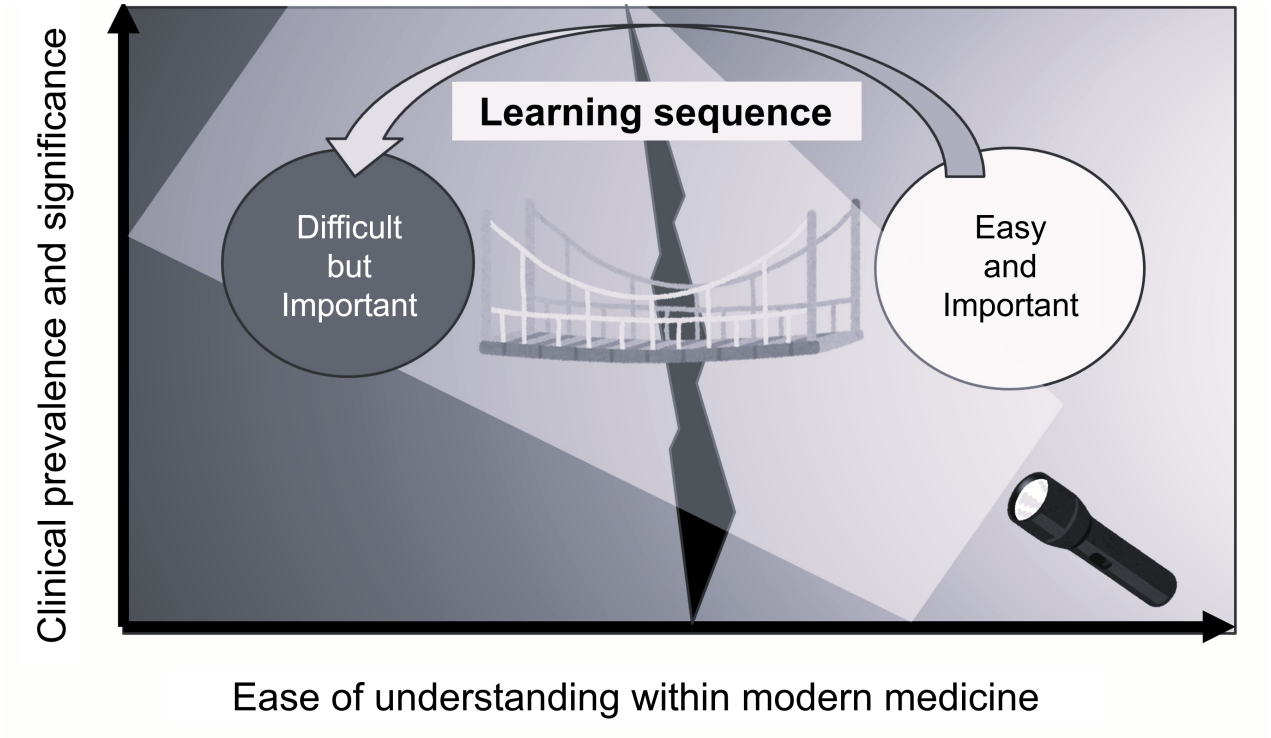
Figure 4. Conceptual diagram of strategic mapping in traditional medicine education. This figure presents a conceptual diagram that visualizes priority areas in traditional medicine education based on a 2-axis framework: affinity with biomedical knowledge (horizontal axis) and clinical importance or frequency (vertical axis). The intent is to begin instruction with the "Easy and Important" domain (content that is both accessible to learners and clinically significant) and then gradually progress to the "Difficult but Important" domain, thereby bridging existing educational gaps. By highlighting the suggested learning sequence and positioning of educational content, this framework supports strategic curriculum design that makes efficient use of limited educational efforts.



Accordingly, Figure 4 is intended as a conceptual guide for curriculum design rather than a direct mapping of RCT volume to learning difficulty. From an educational perspective, introducing frequently encountered formulas with relatively higher biomedical interpretability may lower the initial learning barrier. Learners can be progressively supported in engaging with Kampo-specific terminology, diagnostic concepts, and theoretical frameworks through structured instruction and expert facilitation.

This study was based on data from a single institution, and the specific flow proposed here should not be directly applied to other settings. However, given that Kyoto University Hospital is a multispecialty teaching hospital and a leading educational institution in Japan, the analytic process demonstrated here may serve as a feasible and flexible methodological framework for needs assessment and curriculum design at other institutions.

Our sensitivity analyses highlight that correlation, thresholding, and clustering results depend on analytic choices and are limited by sample size. With only 10 formulas, correlation results remained statistically non-significant across permutation and leave-one-out analyses, and effect estimates were imprecise. Although the k-means–derived reference boundary was stable across random initializations in this dataset, alternative reasonable cut points (eg, median or upper-quartile thresholds) lead to different classifications for borderline formulas, underscoring that the boundary should be treated as a heuristic rather than an objective standard. In addition, hierarchical clustering—particularly at the formula level—showed limited stability across preprocessing, distance metrics, and linkage methods. We therefore use clustering primarily as a descriptive visualization tool to highlight heterogeneity in prescribing patterns rather than as a definitive taxonomy.

In summary, the purpose of this study was not to prescribe a fixed set of educational content but to present a process for creating and utilizing visual decision-making tools that can be flexibly adapted to institutional educational philosophies and clinical contexts. This approach may provide a practical and generalizable framework for bridging educational practices with clinical reality in traditional medicine education.

Conclusion

In this study, we organized and visualized educational content in traditional medicine by integrating three components: prescription frequency, level of biomedical evidence, and clustering information based on prescription patterns derived from real-world data at a university hospital. Through this mapping methodology, existing educational gaps can be structurally identified, and the approach can be applied to the stepwise arrangement of learning content. To effectively promote traditional medicine learning within limited educational resources, curriculum design should introduce students to "Easy and Important" content (material that is readily accessible and easily connected to biomedical knowledge) while gradually bridging toward the "Difficult but Important" areas that may be less intuitive for learners but highly significant in clinical practice.

The conceptual diagram presented in this study (Figure 4) focuses on areas insufficiently addressed by biomedical-based

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curricula, and by visualizing the positioning of "content easily accessible to learners" versus "content requiring specialized education," it proposes a direction for educational construction that strategically and efficiently bridges these domains. We believe that this methodology serves as a practical framework for supporting the structural design of education and holds potential for application in other institutions and disciplines.

Acknowledgments

The authors used ChatGPT (OpenAI) to assist with code generation for data analysis and to support language refinement during manuscript preparation. The AI tool was not used to generate the study design, conduct/run the analysis, or interpret the results. All final decisions regarding analysis, interpretation, and manuscript content were made by the authors, who take full responsibility for the work.

Funding

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Data Availability

The datasets and analysis scripts used in this study are available from the corresponding author on reasonable request.

Authors' Contributions

YM and MI conceived the study idea and drafted the manuscript. YM, MI, and K Tsuyuki conducted the literature review for evidence evaluation. K Tsuyuki and AU extracted and organized prescription data. MI performed data processing and statistical analyses, including clustering. TO, MO, MU, K Kato, NO, ME, K Kaneda, and K Tanikawa provided expert advice on Kampo medicine. AT, TM, and HK provided expert advice on medical education. All authors reviewed and approved the final manuscript.

Conflicts of Interest

Karin Kato received a research grant from Tsumura & Co. Kiyoaki Tanikawa received lecture fees from Tsumura & Co. The authors declare no other commercial or financial conflicts of interest related to this study. None of the authors have served on the hospital's drug selection committee or any equivalent review body.

Multimedia Appendix 1
Heat maps of Kampo prescription counts by department and formula. (A) Heat map showing the overall distribution of prescriptions across departments (vertical axis) and formulas (horizontal axis). (B) Heat map restricted to the top 10 departments and top 10 formulas. Color intensity reflects prescription frequency, clearly illustrating formula-specific trends across departments.
[PNG File, 205 KB - formative_v10i1e88430_app1.png]

Multimedia Appendix 2
Hierarchical clustering of departments based on Kampo prescription patterns. Departments with similar prescription profiles were clustered together. The Pain Clinic, Neuropsychiatry, and Obstetrics & Gynecology formed distinct independent clusters, while most other departments clustered together due to similar prescription patterns.
[PNG File, 127 KB - formative_v10i1e88430_app2.png]

Multimedia Appendix 3
Hierarchical clustering of Kampo formulas. Some formulas (eg, yokukansan, shakuyakukanzoto, daikenchuto) formed distinct independent clusters, while the majority were grouped into three clusters based on departmental prescription distributions.
[PNG File, 103 KB - formative_v10i1e88430_app3.png]

Multimedia Appendix 4
Distribution of prescriptions in Clusters 1 and 2 across departments. Cluster 1 formulas were prescribed predominantly in three departments (Pain Clinic, Neuropsychiatry, Obstetrics & Gynecology), while Cluster 2 formulas showed broader cross-departmental use.
[PNG File, 264 KB - formative_v10i1e88430_app4.png]

Multimedia Appendix 5

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Relationship between prescription frequency and randomized controlled trial (RCT) counts. The number of RCT reports (evidence scores) for the top 10 formulas identified by PubMed review is shown against prescription frequency.
[PNG File, 100 KB - formative_v10i1e88430_app5.png]

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Abbreviations

ARI: adjusted Rand index
RCT: randomized controlled trial
T&CM: traditional and complementary medicine
WHO: World Health Organization

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Retrieval-Augmented Generation for Medical Question Answering on a Heart Failure Dataset: Performance Analysis

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Abstract

Background: The integration of retrieval-augmented generation (RAG) systems into the domain of medical question-answering (QA) presents a significant opportunity to enhance the effectiveness and accuracy of clinical support systems.

Objective: This study aimed to explore the design choices within the RAG framework and the use of large language model (LLM) classifiers to optimize medical QA systems, enhancing response quality for patient and caregiver queries of varying risk levels.

Methods: In total, we curated a dataset of 109 patient and caregiver questions related to heart failure (HF)—categorized into answerable (direct, fact-based queries), helpful deferral (general guidance or lifestyle advisory queries), and nonanswerable (out-of-scope or high-risk and medical intervention queries) types—along with relevant documents and a target answer for each question from the website *The Heart Hub*. Applying a system architecture leveraging RAG with a structured query taxonomy and robust classification mechanisms, this paper provided an empirical assessment for medical QA on a HF dataset and introduced a QA system pipeline design, providing a foundation for extended application across various medical fields. Specifically, we evaluated design choices in the initial retrieval stage of RAG and their impact on performance. We assessed final answer quality from the generation stage using popular passage scoring methods for QA, such as Recall-Oriented Understudy for Gisting Evaluation (ROUGE), BERTScore, and Intersection over Union score.

Results: The pipeline first uses an LLM-based classifier, achieving 65% accuracy for answerable and helpful deferral queries and 100% accuracy for identifying nonanswerable queries. In information retrieval, the BioMedical Contrastive Pre-trained Transformers (MedCPT) cross encoder performed best as a dense retrieval method, delivering an average of 93% recall @ 7 through ranked relevance scores to obtain the top documents with recall @ k denoting recall computed over the top-k retrieved items. For further retrieving snippets from such documents, its average performance was 72.5% for sentence-level snippets and 83% for paragraph-level snippets. A second LLM-based classifier, used to refine the generated responses, resulted in an overall reduction in ROUGE-1 recall by 13% and Bidirectional Encoder Representations from Transformers (BERT) precision by 11%. However, Intersection over Union scores, or the overlap between “gold answers” and system answers, increased by 24%, demonstrating enhanced alignment with ground truth responses. This also indicates the system’s improved ability to generate concise and accurate medical responses.

Conclusions: The implementation of a structured RAG framework paired with LLM classifiers for medical QA introduces a promising avenue for enhancing clinical decision support systems. By systematically analyzing the impact of query taxonomy, retrieval configurations, and response strategies, this approach clarifies the relative importance of each component within the medical RAG system using a HF dataset. Our findings provide actionable guidance on optimal design choices for maximizing retrieval and response accuracy; thus, informing the development of robust, scalable medical QA systems.

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(JMIR Form Res 2026;10:e84932) doi:10.2196/84932

KEYWORDS

medical question-answering; retrieval-augmented generation; information retrieval; heart failure; healthcare technology; machine learning

Introduction

Background

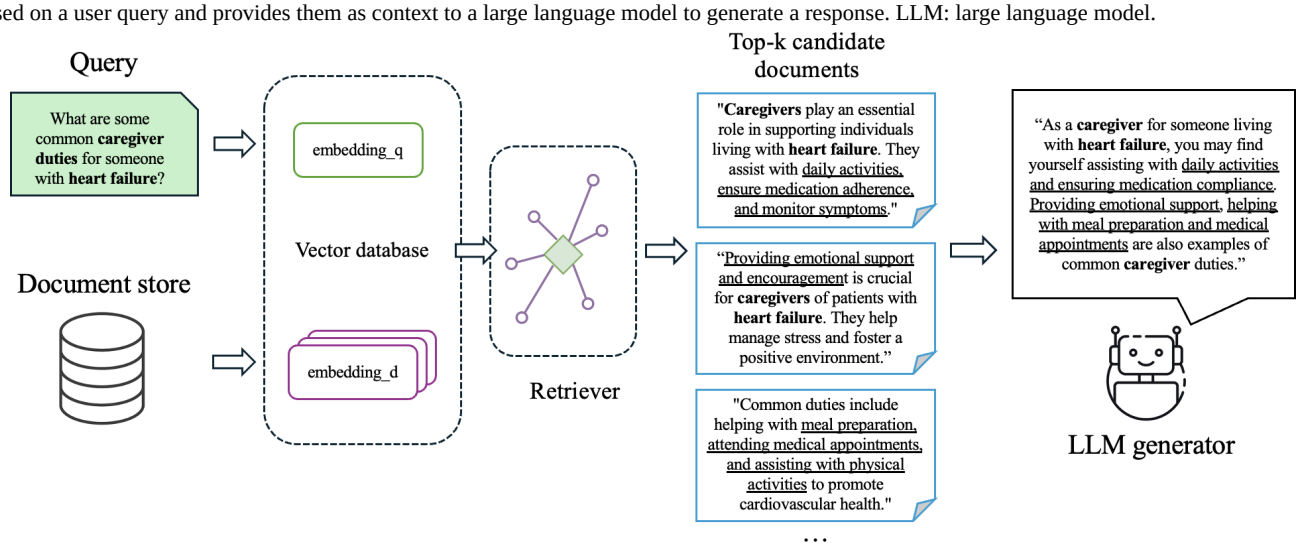
Medical question-answering (QA) systems, which can efficiently retrieve evidence-based medical information and deliver it to individuals during a dialogue appropriate to their knowledge level, have the potential to improve patient outcomes and enable better health self-management [1-4]. Such interactions have become more accessible with the recent introduction of generative artificial intelligence (GenAI) large language models (LLMs) as it integrates conversational dialogues that are not restricted by limited vocabulary and controlled inputs. LLMs possess advanced natural language understanding and conversational capabilities, enabling natural and engaging interactions while providing useful and relevant information. This is made possible through the transformer architecture, which is foundational for maintaining dialogue context and handling complex texts, such as the ones in the medical field [5].

However, LLMs also have limitations that might limit their use in real-world, high-risk scenarios, such as the potential of generating inaccurate responses (“hallucinations”). These hallucinations could, at best, spread misinformation and, at worst, lead to patient harm [1-3]. LLMs often lack domain-specific knowledge not included in their training data, which could result in hallucinations or outdated answers. Models like Google’s Med-PaLM [6], fine-tuned for health care, have been reported to include incorrect or inappropriate content, exhibit faulty reasoning processes, and occasionally contain biases in answers [7]. These inaccuracies, coupled with consumer feedback indicating lower helpfulness, highlight challenges in adaptability and specificity when addressing medical queries, especially in handling domain-specific questions. Other advanced open-source LLMs tailored for the biomedical domain, such as BioMistral [8] and Meditron [9], have sophisticated training on specialized corpora and adaptations for specific medical contexts but are still subject to issues including hallucinations, dynamic adaptation to new medical guidelines, and maintaining relevance across diverse medical specialties. This is primarily due to their initial designs that focus on large corpora and databases comprising a wide range of topics in the biomedical domain, such as PubMed Central, MEDLINE, and the Metathesaurus [10].

This knowledge gap can be addressed by retrieval-augmented generation (RAG), which improves performance by incorporating external knowledge (eg, evidence-based or peer-reviewed documents) and enhancing the system’s accuracy and relevance in medical contexts [7].

RAG is a highly popular method for performing QA tasks by using an information retrieval (IR) system to retrieve a small set of candidate documents that are then provided as context for an LLM that is prompted to produce an answer to the question (if it can be answered from the candidate documents). In Figure 1, for the example user query “What are some common caregiver duties for someone with heart failure?” and “What are some common caregiver duties for someone with heart failure?” the system first retrieves the most relevant documents from a document store. These top candidate documents contain key information, which is then passed as context to an LLM generator, which uses the provided text to construct a single, coherent answer. IR models, such as BioBERT [11], MiniLM [12], and TAS-B [13] are commonly used in these stages, leveraging dense retrieval methods to improve the semantic understanding of complex medical queries.

Figure 1. Overview of the retrieval-augmented generation (answer retrieval) pipeline. The system retrieves relevant documents from a vector database based on a user query and provides them as context to a large language model to generate a response. LLM: large language model.



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In addition to reducing hallucinations, RAG enhances the verifiability of LLM outputs by grounding answers in retrieved references and minimizes the presence of outdated information [14]. The sensitive nature of evidence-based health information in medical QA applications requires robust systems that are safeguarded against hallucinations and maintain tight dialogue control while enabling natural, dynamic user interactions and the delivery of accurate information.

Earlier medical QA methods relied on structured formats, like translating medical questions into SPARQL queries to retrieve information from structured medical databases [10]. This approach enabled handling multiple query types, including questions with more than one focus or expected answer type. However, their system faced challenges in scalability and required additional mechanisms to address more complex queries, such as "why" or "when" questions. Other approaches implemented natural language processing techniques, such as syntactic chunkers, to extract noun phrases in query generation and answer extraction [15]. However, such methods are highly dependent on the quality of the chunker's training data. This reliance was found to limit their ability to capture medical terminology, which hinders the retrieval of critical information in a medical context.

Building on earlier retrieval-based techniques, subsequent research integrated deep learning models to improve both the answer extraction and response generation stages. Early hybrid systems combined traditional sparse retrieval with advanced neural networks. For example, Yang et al [16] used a Bidirectional Encoder Representations from Transformers (BERT)–based "reader" to extract answers from documents initially retrieved by BM25 more accurately. A more foundational breakthrough, however, occurred in the retrieval stage with the shift to dense methods. The introduction of dense passage retrieval by Karpukhin et al [17] substantially improved the relevance of retrieved documents by embedding questions and passages in a shared vector space. This architecture of a dense retriever paired with a generative model became the foundation for modern RAG systems, later validated by benchmarks from Xiong et al [18] on a vanilla RAG system that highlighted improvements in both retrieval accuracy and final response quality.

In contrast to previous approaches, this paper introduces an enhanced RAG system featuring LLM-based classifiers designed to answer a variety of query types and optimize each stage in the pipeline. While it can be used in and scaled to other domains, the system was designed with a focus on health care, namely for the high-risk context of answering heart failure (HF) queries as part of an integrated chat feature in a digital HF management module. Our system categorizes and answers queries based on their nature and topic sensitivity levels. This enables broad query coverage and results in a comprehensive system of QA for the clinical domain of HF, and our methods can easily be extended through other similar domains in health care. Through systematic testing and evaluation, we identify the optimal system configuration and design choices for each stage, leading to a more effective RAG framework.

Goal of Study and Paper Structure

Our research leverages LLMs within an RAG framework to design and evaluate an LLM-based medical QA system with a specific focus on HF. This condition was chosen as it is one of the "fastest growing cardiovascular conditions in the world" [19], with over 750,000 Canadians living with HF and 100,000 new cases being diagnosed annually [20]. Digital interventions have been shown to improve outcomes in patients with HF and lead to better self-care. Medly (Centre for Digital Therapeutics) is an evidence-based digital therapeutic that enables University Health Network (UHN) patients in Canada to monitor weight, heart rate, blood pressure, and symptoms, as well as output alerts and actionable self-care feedback [21]. Patients can also talk to nurses during working hours through a Messenger feature, asking questions about HF and their course of treatment. However, they are not able to promptly communicate with their care team after work hours. In this manner, an LLM-enabled medical QA system for HF can be included as part of Medly Messenger to improve patient engagement and self-management of their conditions, allowing patients to receive guidance and resourcing anytime. The medical QA system described in this work serves as a first step toward having an after-hours chatbot for Medly, although its principles and architecture can be reused in domains other than HF.

To create our medical QA system, we first introduce a structured taxonomy of question types in this domain. Questions were devised by the study authors after consultation with nurses from UHN and medical students from the University of Toronto, ensuring the system is tuned to practical, real-world medical scenarios. Ground-truth answers were obtained from the HF-centric website *The Heart Hub* by the Ted Rogers Center for Heart Research [22], an evidence-based resource typically used by nurses to educate patients. With these resources, we developed a system architecture that leverages LLMs with specific instructions for each task—from question classification to IR and answer generation—which is adaptable and applicable to a wide range of complex medical QA scenarios.

The rest of the paper is structured as follows. First, the methods are presented, including a description of the query taxonomy, the dataset used, and the system architecture with the individual LLM classifiers. The results of the evaluation on a set of predefined questions are also presented. Finally, we discuss these results and the optimal design choices found during the evaluation and conclude the paper.

Methods

Dataset and Query Classification

The scope of the queries in the dataset was defined by the content of The Heart Hub, an educational resource developed by the Ted Rogers Center for Heart Research to support patients living with HF and their caregivers [22]. Having consulted clinicians and medical researchers from UHN, *The Heart Hub* was identified as an appropriate resource reflecting the range of topics relevant in HF education and built in partnership with people with lived experience in HF. As a result, the dataset includes queries addressing HF directly, as well as related cardiovascular topics, related conditions, treatments, and

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symptom management guidance covered within the source material and frequently discussed in the context of HF.

Based on the frequency of topic appearance, the medical relevance and urgency of the information, and common misconceptions about heart health, we generated a dataset of 109 potential patient and caregiver queries. To compile such queries, all webpages on *The Heart Hub* were first extracted using a web crawler and stored as individual documents, which served as contextual input to GPT-3.5-Turbo (OpenAI) [23]. A few sample raw documents can be found in Multimedia Appendix 1. The model was prompted to generate factual query-response pairs reflecting common informational needs and concerns of patients and caregivers regarding HF and related topics covered in the corpus. This ensures a comprehensive representation of patient and caregiver concerns.

In this study, we selected GPT-3.5-Turbo, an advanced state-of-the-art language model developed by OpenAI [23], among various LLMs for its unique advantages in processing complex medical data. While there are newer and larger models like GPT-4 (OpenAI), GPT-3.5-Turbo not only excels in accurately understanding and generating contextually relevant text, but it is also more cost-effective due to its open-source nature and requires less computing power [23,24].

Given the critical importance of accuracy and reliability in automated QA systems within the medical domain, we implemented measures to mitigate associated risks, such as misdiagnosis and misinformation. To achieve this, ground truth answers were instructed to be strictly extractive from the source text and limited to a maximum of 5 sentences to ensure concision while fully addressing each query. These sentences either directly answer the query or provide helpful information to enhance user understanding. The ground truths served as a standard for evaluating the system's performance, enabling the measurement of its adherence to the source material. To verify the quality of the dataset, members of the research team manually reviewed the generated query-response pairs to ensure relevance and alignment with the source material. Ground truth answers were considered sufficient if they directly addressed the query or provided contextually relevant information without introducing content beyond the source material.

To further address potential inaccuracies and the critical need for reliable information, we developed a taxonomy to categorize queries based on their associated risk. The development of this taxonomy was guided by discussions with medical researchers at UHN, who provided sample patient and caregiver queries that helped inform the identification of varying levels of urgency. Based on these considerations, queries were organized into 3 distinct categories—answerable, nonanswerable, and helpful deferral questions. More information on these 3 categories of query types is provided in Table 1.

Table . Taxonomy of medical queries categorized by risk level. Definitions and examples illustrate how the system distinguishes between direct factual answers, helpful deferrals, and out-of-scope or high-risk queries.

Query type	Query type definition	Example query	Ground truth for example query
Answerable	Fact-based queries that require direct information responses such as medical conditions, patient and caregiver experiences, or available resources.	What tests are used to diagnose heart failure?	Detecting heart failure can be difficult because symptoms may be confused with other conditions. Blood tests, electrocardiogram (ECG), echocardiogram (ECHO), and other imaging tests like chest X-rays are commonly used to diagnose heart failure.
Helpful deferral	Queries that are related to personal health management, lifestyle choices, and safety and precautions.	What lifestyle changes can I make to manage heart failure?	Personalized professional help from healthcare providers like dietitians, pharmacists, or your primary care physician will be more helpful for your individual needs. However, in general, a healthy lifestyle is essential. For someone with heart failure, this means paying extra attention to diet, getting regular exercise, avoiding alcohol, and taking care of your mental well-being.
Nonanswerable	Queries that either fall outside of the corpus's scope or pertain to situations requiring immediate medical intervention, accurate diagnosis, or specific treatment recommendations.	What specific medications can I take that are currently recommended for heart failure?	Sorry, I don't have enough information to answer your question. Please feel free to try another question. If you have any concerns or need detailed advice, please consult a professional such as a healthcare provider, dietitian, pharmacist, or your primary care physician.

Query type labels were assigned using a multistage process. First, few-shot prompting was applied using GPT-3.5-Turbo to generate initial labels for all queries based on the predefined taxonomy. These labels were then reviewed by members of the research team (EP and SZ). Queries identified as ambiguous or potentially misclassified were reviewed by both research team

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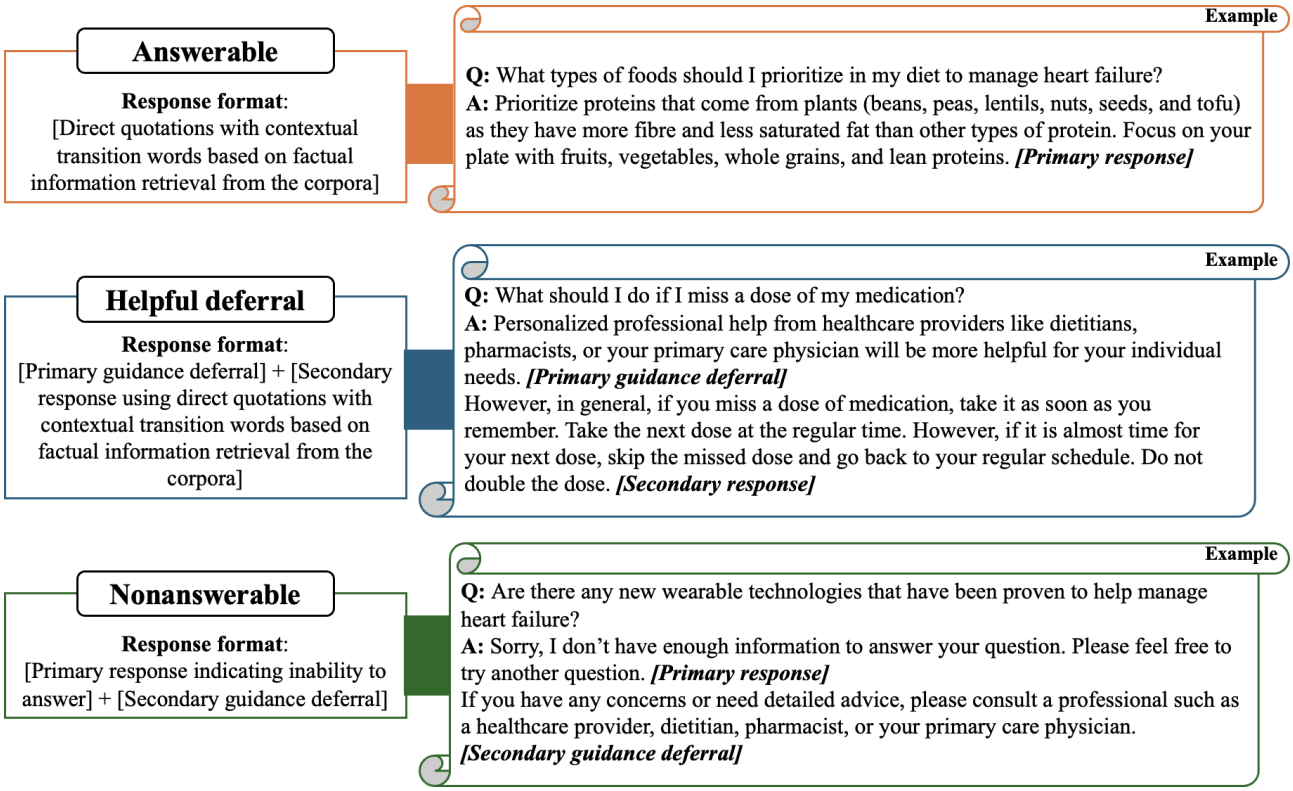
members, who agreed on the final label. While a third reviewer would have been consulted if disagreements remained, all queries were resolved by consensus.

This taxonomy establishes a foundational framework for determining the appropriate approach when answering queries, prioritizing patient well-being and promoting safe and effective interaction between automated systems and users. Each query in the dataset was systematically categorized according to the taxonomy. Of the 109 queries, 66 were classified as answerable, 17 as helpful-deferral, and 26 as nonanswerable. The full list of the 3 types of queries is listed in Multimedia Appendix 2.

In alignment with the established taxonomy, we designed a corresponding response format to address the varying risk levels associated with the queries, as detailed in Figure 2. For answerable queries, which present minimal risk, the response consists solely of direct extractive quotes from the corpus. For nonanswerable queries that fall outside of the corpus' scope or involve high-risk situations, a predefined response is used. This response first indicates the system's inability to provide an answer, then advises the user to seek professional medical assistance to address any remaining concerns. For helpful deferral queries, the response format includes direct quotes from the corpus, preceded by a cautionary statement recommending that users consult a health care professional for personalized advice. This precautionary statement is placed at the beginning of the response to ensure it is prominently read and understood, thereby prioritizing user safety and reducing potential liability for the system. This structured approach, informed by the query taxonomy, enhances the robustness of the system and supports safe and effective user interaction.

Figure 2. Response templates for the medical query taxonomy. These formats integrate the placement of professional guidance and cautionary statements to ensure user safety when providing information for sensitive or complex health queries.



System Architecture

The proposed medical RAG QA system uses a pipelined approach, as illustrated in Figure 3. Initially, incoming queries undergo categorization to determine the appropriate response format. For queries categorized as answerable and helpful deferral, the system implements the RAG process. This involves retrieving relevant information from the corpus through the IR and snippet retrieval stages. The generated response then undergoes verification and refinement before being presented to the user. Further details regarding each stage of the pipeline are outlined in the subsequent sections. The full implementation of the proposed system pipeline, including source code and experimental configurations, is available in Multimedia Appendix 3, where a link to the GitHub repository is included.

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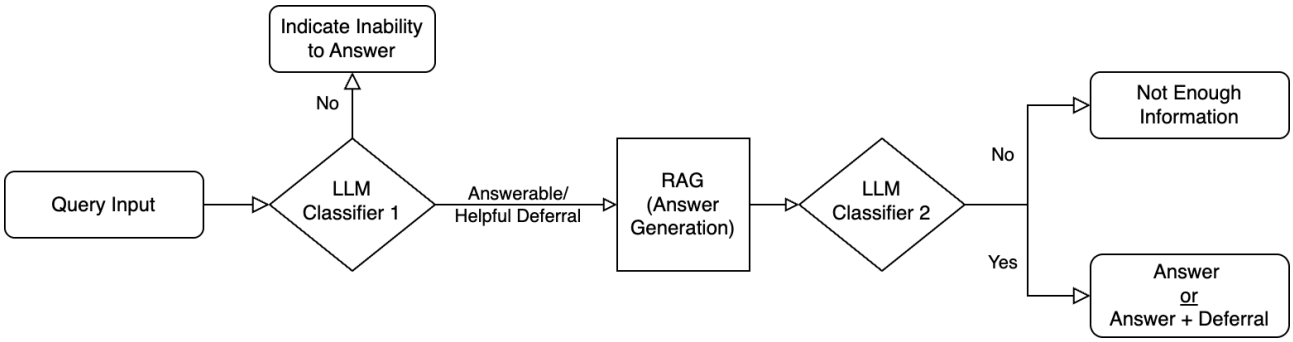
Figure 3. Proposed medical retrieval-augmented generation system pipeline. An initial large language model classifier categorizes input queries to determine answer feasibility. A secondary classifier then evaluates the answer generated through retrieval-augmented generation before delivering the final response. LLM: large language model; RAG: retrieval-augmented generation.



LLM Classifier 1

The initial stage of the pipeline uses GPT-3.5-Turbo to categorize queries into 1 of the 3 predefined taxonomy categories. In this phase, our objective is to mitigate the risk of providing inappropriate or harmful responses by preventing the system from answering high-risk, nonanswerable queries, thereby safeguarding user interactions. We evaluated both zero-shot and few-shot [25] prompting techniques with chain-of-thought prompting [26]. Zero-shot prompting autonomously generates responses without examples, while few-shot prompting enhances the model's output by supplying it with specific examples, thus illustrating the desired response format and reasoning process to improve categorization accuracy. Our iterative refinements revealed that using 5 examples per category at this stage significantly enhances the effectiveness of the few-shot, chain-of-thought approach, optimizing the system's ability to accurately categorize and respond to queries. The finalized prompt is presented in Multimedia Appendix 4. Additionally, the chain-of-thought technique facilitated the verification of the model's reasoning process and ensured consistency in the output. To address the inherent inconsistency of LLMs, the prompt was designed to encourage conservative and cautious classifications, prioritizing patient safety and minimizing the risk of misinformation.

RAG

IR

Following the initial categorization, the system proceeds to the retrieval stage, an essential component of the RAG pipeline, as showcased in Figure 1. This phase aims to identify and retrieve the most relevant documents by comparing the similarity between the embedded query and corpus documents [27]. Dense retrieval methods are designed to capture semantic and contextual relationships between queries and documents, leveraging vector representations that allow for more accurate matching compared with traditional keyword-based approaches [28]. This makes dense retrieval particularly effective in complex domains, such as medical information, where precise semantic understanding is critical. In contrast, sparse methods (like BM25 [29,30]) rely on exact keyword matching and are less capable of understanding deeper contextual relations. The design choices of the IR stage explored in this study include a range of dense retrieval models, namely paraphrase-MiniLM-L6-v2 [31], GPT-3 [25], BioMedical Contrastive Pre-trained Transformers (MedCPT) [32], BioBERT [11], BioMedBERT [33], and TAS-B [13].

Subsequent to document retrieval, the system refines the extracted information through snippet extraction. This process involves segmenting the relevant documents into smaller units, such as sentences, paragraphs, or sections as defined by text segments between header tags of the original web page, and using a retriever model to select segments that are the best match for answering the query [17]. By collecting high-quality snippets, the language model in the subsequent stage of the RAG system is better equipped to generate more precise and accurate responses. Similar to document retrieval, dense retrieval methods were used to capture semantic nuances within the snippets [28]. As such, the models tested in this stage include paraphrase-MiniLM-L6-v2 [31], GPT-3 [25], MedCPT cross encoder [32], BioBERT [11], BioMedBERT [33], and TAS-B [13]. Adjusting the length of snippets is crucial to gage the granularity at which these retrieval models can accurately identify and match sentences from the ground truths, thus enhancing response alignment accuracy. It is important to note that due to inconsistent HTML formatting on the *The Heart Hub* website, snippet lengths were restricted to sentences or paragraphs.

LLM Answer Generation

The final stage of RAG involves generating responses to user queries based on the relevant snippets retrieved in the preceding stage. To enhance response quality, we evaluated both zero-shot and few-shot chain-of-thought prompting techniques on the GPT-3.5-Turbo language model. The model was tasked with leveraging the information from the retrieved snippets to produce responses that are accurate, concise, and directly address the user's query. This process requires selecting the most relevant sentences from the snippets and delivering answers that are purely extractive, all while adhering to the predefined answer formats. The finalized few-shot prompt used in the experiments is included in Multimedia Appendix 5.

LLM Classifier 2

To mitigate the potential inconsistencies and inaccuracies inherent in LLMs [34], a second layer of verification was implemented using another LLM-based classifier. This classifier was designed to assess whether the generated response adequately addressed the user's query. If the response is deemed relevant and suitable, it is refined using the prompt in

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Multimedia Appendix 6, and the most pertinent information that answers the question is extracted. This condenses the responses to align with the ideal length for clarity and precision, as GPT-3.5-Turbo sometimes generates overly lengthy responses. For most queries tested, this resulted in responses being condensed to only a few sentences. Conversely, if the response is deemed irrelevant or inaccurate, the system discards the generated answer and produces a nonanswerable query output, thus preventing the system from providing misleading or incorrect information. This multistage approach was developed to minimize misinformation and maximize the accuracy and quality of the responses.

Evaluation

Recall-Oriented Understudy for Gisting Evaluation

To evaluate the performance of the generated responses, we implemented the Recall-Oriented Understudy for Gisting Evaluation (ROUGE) metrics, which are established tools for assessing the quality of automated text summarization and machine translation systems [35]. Specifically, the ROUGE-1 recall metric was used, which measures the proportion of unigrams (individual words) in the generated response that are also present in the ground truth [35]. It is calculated by dividing the number of exact unigram matches without stemming by the total number of unigrams in the ground truth. A higher ROUGE-1 recall score indicates a greater degree of overlap between the generated response and the ground truth, reflecting the system's effectiveness in adhering to the source material.

BERTScore

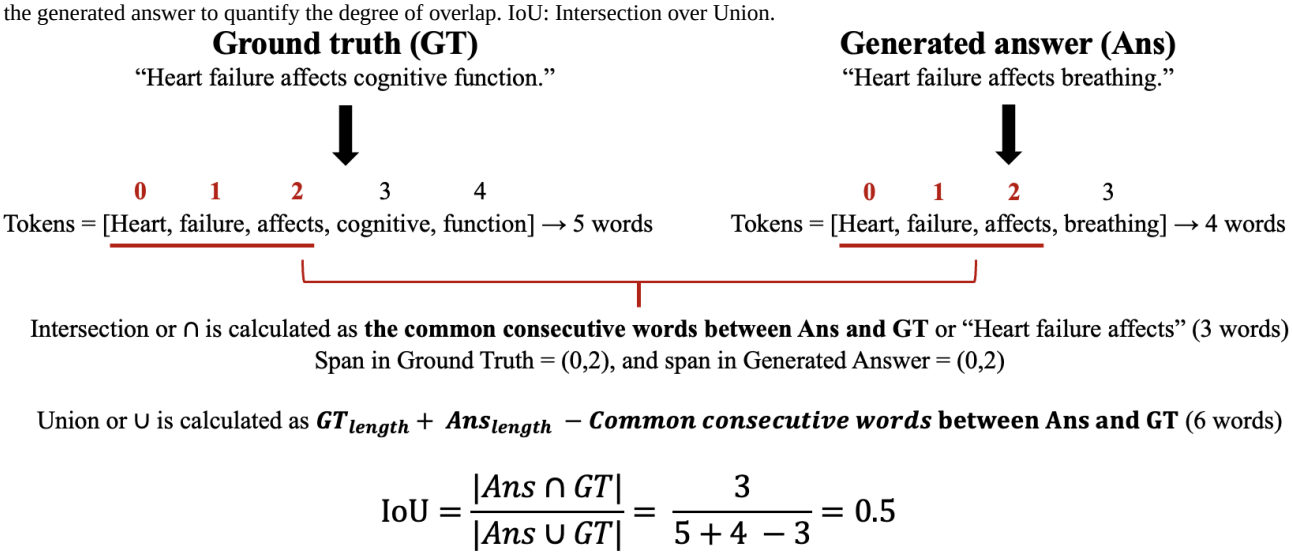
BERT is a deep learning model developed by Google for natural language processing [36]. Unlike ROUGE, which focuses on surface-level exact word matching, BERT captures more sophisticated semantic meaning through contextual word embeddings. BERTScore is a metric designed to leverage the pretrained contextual embeddings from BERT to evaluate text quality [37]. It measures the semantic similarity between the generated text and a reference text by comparing the vector representations of words or phrases, known as word embeddings, in both texts. In particular, we used the BERT precision metric, which calculates the average similarity of the word embeddings in the generated text to the most similar embeddings in the reference text. Unlike ROUGE-1 that only captures surface-level unigram matches, BERT precision provides a deeper understanding of how closely the generated responses semantically align with the ground truth.

Intersection over Union

Intersection over Union (IoU) is a metric originally developed for evaluating object detection performance in computer vision, where it measures the extent of overlap between predicted and ground truth boxes in an image [38]. As demonstrated in the following equation, "*Ans*" refers to the predicted answer span, and "*GT*" is the ground truth span.

When adapted for text evaluation, IoU quantifies the degree of overlap between generated responses and ground truth answers [37,39]. The numerator represents the number of elements common between the predicted answer and the ground truth, and the denominator is the total number of unique elements in both the predicted answer and the ground truth. In this case, IoU is computed by summing the length of all common substrings between the generated text and the ground truth, then dividing this value by the union of the generated answer and the ground truth, as illustrated by an example in Figure 4.

Figure 4. Example of Intersection over Union score calculation. The score identifies the ratio of shared consecutive words between the ground truth and the generated answer to quantify the degree of overlap. IoU: Intersection over Union.



This approach allows IoU to determine how closely the generated response matches the ground truth while penalizing answers that are longer than necessary, which ROUGE and BERTScore do not address. As shown in previous works like NLQuADind, IoU score can serve as an evaluation metric for the purpose of assessing sequence similarities [39]. It effectively shows that while all scores, such as F_1, ROUGE-1, ROUGE-2, and ROUGE-L, behave similarly in the higher values, the limitation of these metrics is that they overestimate the performance in the lower IoU values due to a higher chance of overlap between the bag of words, n-grams, or longer longest common subsequences in the prediction and target spans [39].

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Using IoU, we can ensure generated answers are both extractive and concise, minimizing the risk of misinformation.

Recall for Retrieval

To evaluate the performance of the retrieval stage, we used standard recall to assess the effectiveness of each design choice. First, recall was measured by determining whether the correct document containing the ground truth sentences was retrieved, with experiments conducted using different retriever models to select the top 3, 5, and 7 documents. In the snippet retrieval stage, recall was used to quantify the proportion of ground truth sentences among the extracted snippets, with tests conducted on snippet sizes of 15, 20, and 30 sentences, as well as 3, 5, and 10 paragraphs. This analysis aimed to determine the most effective snippet length for maximizing relevant information while minimizing irrelevant content. These evaluations provided insights into the performance of each retrieval stage, allowing for the optimization of design choices and enhancing the system's ability to deliver precise and relevant information in response to user queries.

Classifier Prompt-Based Evaluation

The performance of the classifiers was evaluated by using a prompt-based method to compare the outputs of the language models to the taxonomy labels for classifier 1 and the relevance of responses for classifier 2. Classifier 1 was evaluated by assessing whether the model's categorization of each query matched the predefined dataset categories. This involved calculating the proportion of correctly classified queries within each category to gage the model's effectiveness. Classifier 2 was evaluated on whether the model's assessment of the generated response's relevance aligned with the intended ground truth answer. A classification was considered accurate if the model correctly identified the presence or absence of relevant information, supported by a valid reasoning process. Through such evaluations, we were able to assess the effectiveness of each classifier in ensuring relevant responses and appropriate query handling.

Ethical Considerations

The study did not involve any human participants, human participant interaction, or expert or professional involvement. No personally identifiable information was used, and all data were derived from the publicly accessible *The Heart Hub* website. All annotations, labeling, and analyses were performed by the coauthors and related team members. As such, no ethics board approval was required.

Results

Overview

Based on the pipeline flowchart as illustrated in Figure 1, a testing methodology was designed to validate the efficacy of our system across its various components, with each evaluated separately to ensure comprehensive assessment. For each of the 3 query types, we developed a testing strategy which ensures that responses are tailored to the nature of the query, thereby optimizing safety and relevance in patient interactions. As mentioned in previous sections, testing measures such as ROUGE, BERTScore, Recall @ K, and IoU scores were used.

Evaluation Outcomes

Classifier 1 efficiently categorizes incoming queries into 3 types, setting the stage for a tailored response generation for user queries. As illustrated in the following contingency matrix (Table 2), the accuracy rate is 65% for answerable, 65% for helpful deferral, and 100% for nonanswerable queries, indicating robust classification for nonanswerable queries in particular.

Table . Classifier 1 accuracy contingency matrix. Accuracy rates demonstrate the system's ability to correctly categorize incoming queries, with the highest success rate observed in identifying nonanswerable queries.

Actual class	Predicted answerable	Predicted helpful deferral	Predicted nonanswerable	Accuracy rate
Actual answerable	43	15	8	0.65
Actual helpful deferral	2	11	4	0.65
Actual nonanswerable	0	0	26	1.00

In the IR stage of the RAG components, the best dense retrieval models suitable for this task were the MedCPT cross-encoder and TAS-B. Using these models, the system scored a high score of up to 94% recall @ 7 for answerable questions and 92% for helpful deferral questions, as seen in Table 3, confirming the relevance of retrieved documents. Additionally, our experiments on snippet testing with an IR stage on MedCPT cross encoder further highlighted the effectiveness of paragraph-length answers over sentence-length, with paragraph recall @ 3 achieving up to 77% for directly answerable questions (Table 4).

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Table . Results of information retrieval testing on sparse and dense retrieval models. High recall scores for the MedCPT cross-encoder and TAS-B highlight the effectiveness of dense retrieval in identifying relevant context.

Retrieval metric	BM25	Paraphrase-MiniLM-L6-v2	GPT3	MedCPT cross encoder	BioBERT	BioMedBERT	TAS-B
Answerable							
Recall @ 7	0.69	0.68	0.8	0.94	0.37	0.38	0.78
Recall @ 5	0.63	0.68	0.8	0.89	0.23	0.26	0.78
Recall @ 3	0.55	0.57	0.78	0.8	0.09	0.15	0.74
Helpful deferral							
Recall @ 7	0.56	0.8	0.84	0.92	0.44	0.48	0.92
Recall @ 5	0.52	0.8	0.84	0.92	0.16	0.36	0.92
Recall @ 3	0.52	0.68	0.8	0.92	0	0.32	0.76

Table . Results of snippet testing with information retrieval model of MedCPT cross encoder, k=5, and both sentence and paragraph-based snippet length, as indicated by their respective headers. These results demonstrate the impact of context size in IR, as paragraph-length snippets consistently achieve higher recall for both query types.

Retrieval metric	Whoosh TF-IDF	Paraphrase-MiniLM-L6-v2	GPT3	MedCPT cross encoder	BioBERT	BioMedBERT	TAS-B
Answerable (sentence-based)							
Recall @ 30	0.20	0.55	0.70	0.72	0.59	0.40	0.62
Recall @ 20	0.19	0.53	0.68	0.66	0.41	0.29	0.56
Recall @ 15	0.17	0.45	0.56	0.59	0.38	0.23	0.46
Helpful deferral (sentence-based)							
Recall @ 30	0.19	0.65	0.76	0.73	0.63	0.44	0.65
Recall @ 20	0.19	0.64	0.70	0.68	0.57	0.43	0.62
Recall @ 15	0.19	0.49	0.65	0.68	0.51	0.41	0.53
Answerable (paragraph-based)							
Recall @ 10	0.48	0.47	0.85	0.87	0.39	0.26	0.77
Recall @ 5	0.43	0.39	0.81	0.77	0.27	0.21	0.72
Recall @ 3	0.37	0.35	0.77	0.70	0.21	0.17	0.65
Helpful deferral (paragraph-based)							
Recall @ 10	0.47	0.65	0.82	0.79	0.35	0.47	0.82
Recall @ 5	0.41	0.59	0.65	0.65	0.29	0.29	0.68
Recall @ 3	0.29	0.53	0.59	0.53	0.24	0.29	0.68

In the final answer generation within the RAG system, we experimented with both zero- and few-shot prompting strategies to obtain a comprehensive evaluation of the system's capability to handle complex medical queries with high accuracy and reliability. Moreover, as Table 5 illustrates, results gathered using zero-shot prompting highlighted a nuanced performance with and without the snippet extraction step. Notably, queries generally performed better without snippet extraction, with answerable questions achieving a ROUGE-1 recall of 75% compared with 63% with snippets. Few-shot prompting, on the other hand, was more conservative and context-specific, showing improved results across all categories. In particular, for helpful deferral questions, few-shot testing without snippets showed an average ROUGE-1 recall of 61%, whereas the zero-shot approach resulted in an average of 57% only.

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Table . Zero-shot comparison testing of with or without snippet retrieval stage. The results demonstrate the system's ability to obtain higher evaluation scores when processing full document context over isolated sections.

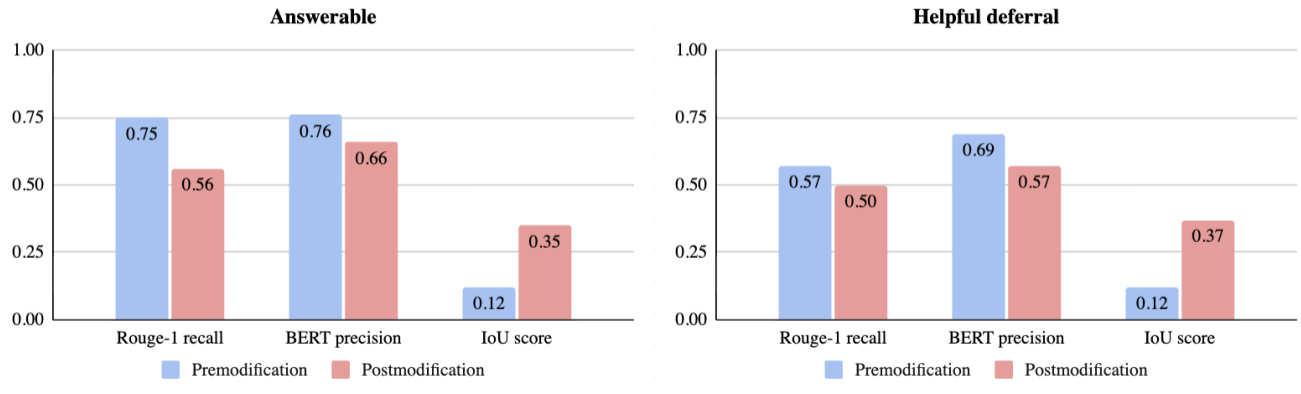
Evaluation condition	Rouge-1 recall	Bert precision	IoU score
Answerable			
With Snippets	0.63	0.71	0.23
Without Snippets	0.75	0.76	0.28
Helpful deferral			
With Snippets	0.45	0.61	0.21
Without Snippets	0.57	0.69	0.25

To further examine the effectiveness of the system, we have conducted comparison testing to evaluate specific performances of quantifiable improvements achieved by classifier 2 modifications. By examining the detailed comparisons, we were able to assess the system's adaptability and precision in managing diverse query complexities.

Following response generation, classifier 2 plays a critical role in ensuring relevance and accuracy by assessing if the answers generated meet the stringent criteria required for medical information. On average, classifier 2 showed strong accuracy in verifying against the dataset derived from the *The Heart Hub* website, achieving scores of 91% for answerable, 71% for helpful deferral, and 96% for nonanswerable questions. It is important to note here that, based on previous testing procedures which determined that performance without snippets surpassed that with snippets, we exclusively used the method of testing without snippets in the before-and-after assessments of classifier 2. Moreover, the impact of classifier 2 is evident in the before-and-after comparison, where improvements in the precision and interpretability of responses were noted.

As Figure 5 illustrates, the postmodification results demonstrated improved IoU scores, underscoring the classifier's efficiency in refining responses. For instance, the IoU score for helpful deferral questions increased from 0.12 to 0.37, illustrating the classifier's effectiveness in refining and validating system outputs. Admittedly, there is a slight drop in the other 2 metrics—shorter outputs tend to include fewer reference unigrams (lower ROUGE-1 recall) and may align less at the token level even when conveying the same information (lower BERT precision). However, the higher IoU score still suggests the revised responses are more targeted to the relevant context, despite being more concise. This is because classifier 2, whose prompt is included in Multimedia Appendix 6, assesses whether each generated output effectively answers the query with binary decisions (yes or no) after the refinement. Having the final judgment supported with logical reasoning as required by the output template, we can be sure that none of the important clinical details was deleted. As such, despite the dip in ROUGE-1 recall and BERT precision, the result of a higher IoU score shows improvement as it produces responses that prioritize accuracy and relevance while being shorter and easy for users to read and understand.

Figure 5. Premodification and postmodification results by classifier 2. The charts show a significant increase in Intersection over Union scores postmodification, indicating that responses become more concise and focused even as ROUGE-1 and BERT Precision scores decrease due to shorter output length. IoU: Intersection over Union.



Discussion

Principal Results

This section evaluates the performance of the system's components, including query classification, IR, and answer generation. This analysis provides valuable insights into optimizing both retrieval and classification stages to enhance the system's ability to deliver precise, reliable, and safe information in response to HF medical queries. The feasibility of the system is reflected by the consistent end-to-end pipeline execution across all configurations and stable generation without any null or incomplete answers. Acceptability of successful outputs is assessed based on the performance at each stage of the pipeline, such as appropriate deferrals of queries, the alignment with ground truth evidence, and output conciseness.

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LLM Classifier 1 Failure Analysis

Despite the generally accurate query classifications, as indicated by the accuracy rates reflected in the main diagonal of the contingency matrix in Table 2, classifier 1 was designed to favor more conservative or safer classifications, represented by the upper right triangle of the matrix. Notably, for 93% of inaccurately categorized queries, the classifier exhibited this conservative tendency, highlighting its effectiveness in prioritizing safety. This focus on safety is particularly important in the medical domain, and considering the final goal is to implement a similar system as part of Medly Messenger. Prioritizing caution can help prevent the delivery of harmful advice or recommendations that could compromise patient health.

Several queries categorized under the helpful deferral category were inaccurately labeled as answerable. Queries that are advisory in nature and may not always require personalized advice based on patient history were placed in the helpful deferral category to be more conservative and ensure patients and their caregivers receive the best quality advice. However, because advisory and precautionary queries can occasionally be generalized, the LLM sometimes classified them as answerable. For example, the query "How can I manage my heart failure care effectively?" was classified in the helpful deferral category due to its potentially personalized nature but was misclassified as answerable, as general advice on HF could be provided. This misclassification highlights ambiguity in the classification system, potentially leading to responses that may not be adequately safe or appropriate for higher-risk topics.

In cases where the categorization was clearer and more straightforward, the LLM showed greater consistency in identifying the correct question category. This was particularly true for nonpersonal informational queries, such as those requesting general medical facts or treatment guidelines, where the distinction of an answerable query was clear. Similarly, the model performed reliably for most helpful deferral queries related to personal health management. These patterns suggest that the LLM excelled when the queries involved nonsensitive topics or when it was evident that personalized responses were required. However, several patterns of misclassification were observed:

- *Answerable queries misclassified as helpful deferral*: Queries involving potentially personal topics were occasionally classified as helpful deferral despite being general advisory queries. An example of one of these misclassified queries is, "What can I do if I notice an increase in my water weight?" This was the most common misclassification, accounting for 51.7% (15/29) of incorrectly classified queries.
- *Answerable queries misclassified as nonanswerable*: Some queries addressing topics requiring medical attention or risks of complications related to medications were categorized as nonanswerable. An example is, "What should I do if I experience dizziness or lightheadedness while taking ACE inhibitors or ARBs?" This type of misclassification constituted 27.6% (8/29) of the total misclassifications.
- *Helpful deferral queries misclassified as nonanswerable*: Queries related to medications were often misclassified as nonanswerable, likely due to the sensitivity of these topics. For instance, the query "Can I take ACE inhibitors or ARBs with or without food?" was misclassified in this manner. This issue had a prevalence similar to the last category, making up 13.8% (4/29) of incorrectly classified queries.

These misclassifications indicate the challenges the classifier faces, particularly in distinguishing between general advisory queries and those requiring more personalized or sensitive responses.

IR Design Choices and Strategies

In the IR stage, it is evident that the MedCPT cross encoder demonstrated superior performance compared with other retriever models. This outcome is expected in comparison to sparse methods that rely on keyword matching. Indeed, sparse methods frequently struggle with accurate document retrieval due to frequent occurrences of the same keywords across different contexts, a common challenge in medical IR. In contrast, dense methods are more adept at understanding the meaning and context of queries, resulting in the effective retrieval of relevant documents.

MedCPT's strong performance is potentially due to its specialized training for medical contexts, using 255 million query-article pairs from PubMed search logs [32]. This extensive training in medical literature enhances MedCPT's ability to understand and retrieve pertinent information within the medical domain more effectively than other models. Additionally, the MedCPT cross-encoder implements a unique reranker that uses cross-attention computation between query and article tokens, providing greater accuracy compared with the dot product similarity used for the other models [28]. While other domain-specific retrievers like BioBERT, fine-tuned specifically for biomedical text mining [11], and BioMedBERT, which focuses on biomedical terminologies and concepts [33], are also trained on biomedical data, their specialized training may not align perfectly with the diverse types of queries and documents encountered in this context. This misalignment could contribute to these models' relatively lower performance.

Similar to the document retrieval stage, the MedCPT cross-encoder demonstrated superior performance overall in snippet retrieval. The document retrieval task benefits from specialized, domain-specific models like MedCPT, which excels in understanding and retrieving contextually relevant documents. However, it is important to note that snippet retrieval can also benefit from general-purpose models, such as GPT-3 and TAS-B, for their broad text processing capabilities as presented in Table 4 [13,17].

As expected, recall for snippet retrieval improved with the number of sentences or paragraphs extracted. Some models exhibited reduced performance with paragraph snippets, likely due to fewer opportunities to select relevant snippets. Nevertheless, models that performed well with sentence snippets also demonstrated enhanced recall with paragraph snippets. This improvement is due to the fact that paragraphs often contain consecutive sentences, which provide additional context that

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may not be captured in individual sentence snippets. However, inconsistencies in the HTML structure of the website occasionally led to inaccuracies in paragraph snippet grouping, reducing their overall reliability. Therefore, for the remaining experiments, we opted for sentence snippet retrieval with 30 sentences, which was the most effective configuration for this task.

Answer Generation Performance

For the initial answer generation stage, GPT-3.5-Turbo with zero-shot prompting achieved satisfactory results, particularly for answerable and nonanswerable queries. However, its performance significantly declined with few-shot prompting, likely due to the board variability in possible answers that few-shot examples struggled to capture comprehensively. As a result, the model often defaulted to not answering queries, as it could not effectively generalize from the examples provided. In contrast, when the same prompt was applied to GPT-4-Turbo, the model began to produce answers for most questions, demonstrating superior performance compared with GPT-3.5-Turbo. Specifically, GPT-4-Turbo generated responses that were not only more faithful to the context but also more concise. Additionally, we evaluated different system configurations, including a 2-stage approach, which involved IR followed directly by answer generation, and a 3-stage approach incorporating the snippet retrieval stage. The results revealed that the 2-stage system outperformed the 3-stage system, with average improvements of 12%, 6.5%, and 4.5% for ROUGE-1 recall, BERT precision, and IoU score, respectively, for answerable and helpful deferral queries. This superior performance of the 2-stage system is likely due to the high accuracy achieved in the IR stage, which diminished after the snippet retrieval stage, thereby reducing the likelihood of producing an accurate answer.

LLM Classifier 2 Refinement

Finally, the system's outputs were reassessed following the application of classifier 2, which refined the initial responses. The accuracy metric indicated that the classifier performed with high precision in identifying relevant responses from the initial answer-generation phase. Re-evaluating the system's answers after refinement, as illustrated in Figure 3, reveals a notable increase in the IoU scores. This improvement suggests that classifier 2 effectively selected the most relevant sentences, thereby producing more concise and relevant responses. Despite a reduction in ROUGE-1 recall and BERT precision scores for answerable and helpful deferral queries, this reflects a strategic trade-off between minimizing misinformation and striving to match as many answers to the ground truth as possible. Prioritizing accuracy and safety, it is advantageous to use classifier 2 to verify the quality of responses, particularly given the inherent inconsistencies of LLMs and the critical need to prevent misinformation.

Key Insights and Findings

In summary, this study presents several key insights into the performance of our medical QA system. Classifier 1 demonstrated solid accuracy in categorizing diverse medical queries, particularly by adopting a conservative approach that prioritizes safety, ensuring that sensitive queries are handled appropriately. While MedCPT proved to be the most effective model in both the IR and snippet retrieval stages, the 2-stage system, comprising only IR and answer generation, outperformed the setup that included snippet retrieval. This simplified approach, combined with zero-shot prompting for answer generation, produced the most accurate results by avoiding the challenges of generalizing from few-shot examples. Finally, incorporating classifier 2 at the end of the pipeline further enhanced response precision and concision, ensuring safer and more reliable answers, even at the expense of a slight reduction in lexical matching metrics. Overall, this approach highlights the critical balance between safety, accuracy, and quality in medical QA systems.

Limitations and Future Work

Despite the promising performance of our system in the study, one noted limitation is the difficulty in handling medical terminology abbreviation and layman term recognition, such as "HF" for heart failure. Oftentimes, there is a disconnect between the medical language used by patients and medical practitioners, leading to confusing intent and mistakes [40]. Indeed, patients often use colloquial or more familiar medical terms, such as abbreviations and acronyms, rather than strict scientific or medical terminology, which also poses a challenge to our current system since the corpora used for responses primarily use formal medical language. This can lead to misunderstandings or incomplete information being relayed if the system fails to accurately interpret these commonly used variants. Since misinterpretation of medical abbreviations can lead to inaccuracies in information exchange, potentially affecting recommendations and patient understanding of their medical condition, we see a need in future work to integrate a comprehensive biomedical vocabulary dataset for abbreviation recognition and expansion to better understand and provide useful answers to user inquiries. Additional evaluation metrics, such as robustness [41], which measures the system's resilience to handle disruptions like layman terms and adversarial attacks [3], should be included in the system.

Another limitation is associated with the use of snippets for response generation. Specifically, crucial information may be omitted if snippets extracted from sources are not seamlessly integrated. This was evident in cases where consecutive sentences from different parts of a source resulted in missing contextual links, leading to incomplete or disjointed information being presented to the user. As Figure 6 illustrates, the challenge of maintaining coherence across separate information sources is highlighted. A potential solution is to refine the snippet selection and merging strategies to ensure that the extracted information fully captures the nuances and complete context of the query. This involves enhancing the LLM's ability to understand and synthesize the thematic continuity between snippets, thereby improving the coherence and completeness of the responses.

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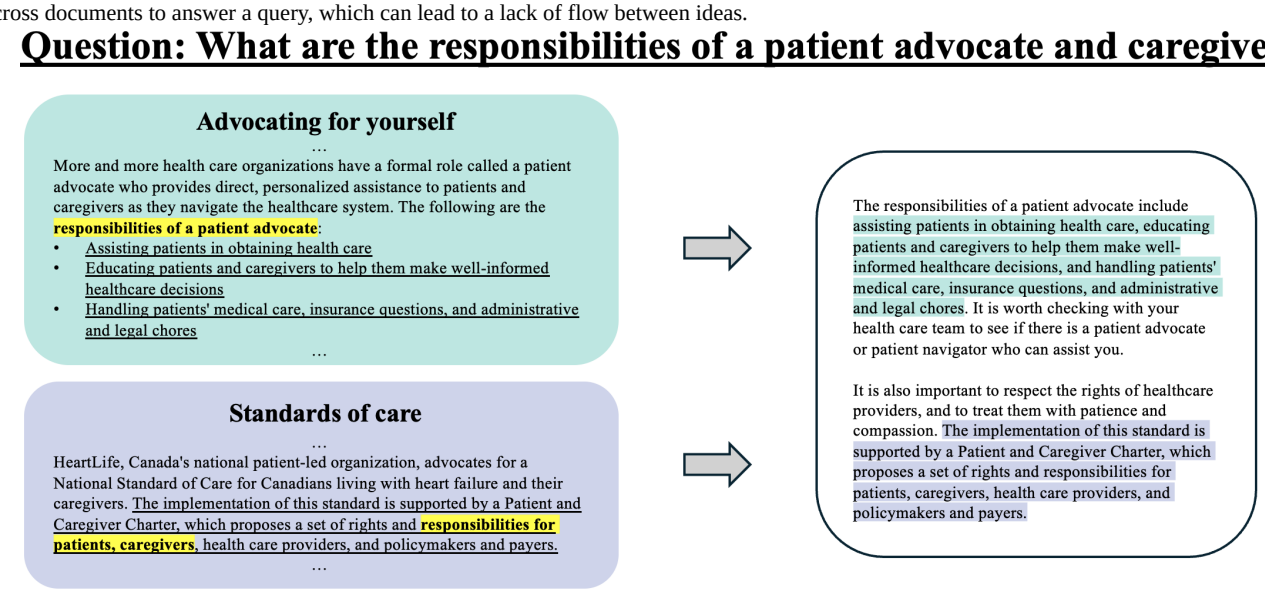
Figure 6. Example of a sample answer sourced from two distinct raw documents. This sample shows how the system can combine different sentences across documents to answer a query, which can lead to a lack of flow between ideas.



Additionally, our system was designed to handle single-topic queries to ensure depth in responses. While not the focus of our study, handling multitopic inquiries simultaneously might be helpful in medical management for better efficiency and patient care. For future improvements, we seek to explore a strategy that processes multiple query components separately and then synthesizes the responses into a cohesive answer, ensuring comprehensive and contextually appropriate information is delivered.

The results and insights presented here can be used in the future to inform an implementation of an instance of the system within Medly for further evaluation. This study is limited by the methodological text similarity and overlap performance evaluation without any clinical testing. However, the balancing act between safety and quality should be tested against real queries of patients with HF and their perceptions of interacting with the chatbot collected to inform additional testing and refinement. In other words, the proposed medical HF QA system showed promise in creating a relatively safe and accurate prototype for answering HF queries. Next steps include the validation and further refinement of this prototype through co-design with patients with HF using the proposed architecture.

However, it is important to note that using LLMs in the medical domain presents ethical, legal, and safety concerns, which are still very much open-ended questions within health care organizations [3,42,43]. Issues, such as data privacy and the potential consequences of LLM responses, demand rigorous scrutiny and the implementation of stringent controls to prevent misuse and ensure the safety and fairness of applications [44]. In particular, preventive measures should be taken for jailbreak LLM prompts to ensure the system is not used to elicit incorrect or unsafe answers [45,46]. To avoid such attacks and misuse, countermeasures such as restricting question frequency limits and preprocessing user questions before classifying should be implemented. The patient co-design process can aid in the definition of security and privacy as well through the understanding of the optimal safety parameters for the system according to the end users. These parameters will be the gold standard against which clinical implementations should be evaluated against.

Conclusions

This study investigated various design choices within the RAG framework to optimize medical QA systems. We examined the integration of classifiers into the RAG pipeline to address queries of varying risk levels and enhance the precision of answers generated by standard RAG. Our research encompassed a detailed evaluation of different retriever models and demonstrated that incorporating LLM-based classifiers significantly improves system performance. These classifiers contribute to generating more accurate and succinct responses by refining the system's approach to query handling. While our approach can be generalizable to several domains, we examined its implementation for HF as a proof-of-concept chatbot to improve the Medly digital therapeutic. The results are promising and indicate that such a medical QA system applied to HF could be used as part of Medly to allow patients to have support anytime and anywhere.

Enhancing the accuracy and relevance of responses not only improves the overall user experience but also mitigates the risk of misinformation. This improvement can lead to better patient outcomes by providing reliable and timely information and support. Such advancements are particularly valuable in alleviating patient anxiety, especially during after-hours when access to medical professionals may be limited. By ensuring that patients receive accurate and reassuring information when needed most, this approach promises to enhance the overall effectiveness and reliability of automated medical QA systems.

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Funding

The authors declared no financial support was received for this work.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Sample raw documents from The Heart Hub.
[DOCX File, 25 KB - formative_v10i1e84932_app1.docx]

Multimedia Appendix 2
Complete queries, labels, and ground truths.
[XLSX File, 47 KB - formative_v10i1e84932_app2.xlsx]

Multimedia Appendix 3
GitHub repository of source code.
[DOCX File, 13 KB - formative_v10i1e84932_app3.docx]

Multimedia Appendix 4
Prompt used for Classifier 1.
[DOCX File, 16 KB - formative_v10i1e84932_app4.docx]

Multimedia Appendix 5
Prompt used for answer generation.
[DOCX File, 16 KB - formative_v10i1e84932_app5.docx]

Multimedia Appendix 6
Prompt used for Classifier 2.
[DOCX File, 142 KB - formative_v10i1e84932_app6.docx]

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Abbreviations

BERT: Bidirectional Encoder Representations from Transformers
GenAI: generative artificial intelligence
HF: heart failure
IoU: Intersection over Union
IR: information retrieval
LLM: large language model
MedCPT: BioMedical Contrastive Pre-trained Transformers
QA: question-answering
RAG: retrieval-augmented generation
ROUGE: Recall-Oriented Understudy for Gisting Evaluation
UHN: University Health Network

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A Computerized Adaptive Test for the Knowledge of Effective Parenting Test–Internalizing Module: Instrument Validation Study

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Abstract

Background: The development of efficient, scalable, and precise tools to assess knowledge of evidence-based parenting strategies is critical, particularly as increased parenting knowledge is a core target of many intervention programs.

Objective: This study aimed to develop and evaluate a computerized adaptive testing version of the Knowledge of Effective Parenting Test–Internalizing module (KEPT-I CAT).

Methods: Using computerized adaptive testing simulations from a large (n=1000) national dataset, we compared the performance of the KEPT-I CAT to both the full-length Knowledge of Effective Parenting Test–Internalizing module and a 10-item static short form (KEPT-I Brief).

Results: Results indicated that the KEPT-I CAT achieved comparable efficiency to the KEPT-I Brief (10 items), while demonstrating superior psychometric properties and modestly reducing the potential for practice effects.

Conclusions: Given these advantages, the KEPT-I CAT is well-suited for post-intervention assessment and may facilitate research examining how increases in parenting knowledge relate to changes in behavior and reductions in child internalizing symptoms.

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KEYWORDS

parenting knowledge; assessment; computerized adaptive testing; internalizing symptoms; psychometrics

Introduction

The Role of Knowledge in Parent Training

Numerous parent training interventions have been developed to address problematic behaviors in children, offering substantial benefits to many families [1]. These interventions train parents in essential skills for behavior management that foster positive changes in their children [2,3]. In measuring baseline parenting and post-treatment outcomes, researchers typically rely on validated assessments of parenting behaviors and practices [4,5]. However, one crucial component that underlies successful behavioral change—parenting knowledge—is often overlooked in studies of program effectiveness [6-9]. Knowledge serves as a foundation upon which skills are built, yet few measures directly and rigorously assess the construct [10]. This limitation hampers accurate assessment of the full impact of interventions (ie, both the knowledge gained and the associations between that knowledge and skill use).

Knowledge of Effective Parenting Test

The Knowledge of Effective Parenting Test (KEPT) consists of 2 modules designed to assess knowledge of parent management skills [6]. The first module, the 21-item Knowledge of Effective Parenting Test–Externalizing (KEPT-E), assesses parent knowledge related to externalizing behaviors in children. The KEPT-E has demonstrated robust reliability and validity, including expected patterns of converging and diverging correlations between the KEPT and other measures of externalizing child behavior and child and parent psychopathology. The KEPT was recently expanded to include domains of parenting associated with the development of child internalizing symptoms, resulting in the addition of the 22-item KEPT-Internalizing (KEPT-I) module [11]. Item content for the KEPT-I includes parent knowledge of exposure principles, warmth, and behavioral activation, and the measure has demonstrated strong reliability and validity [11]. A 10-item short form of the KEPT-I (KEPT-I Brief) was developed by selecting items with strong psychometric properties and balanced content [11].

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Assessing parent knowledge related to internalizing issues is important as internalizing symptoms such as anxiety and depression are among the most common concerns endorsed by parents [12]. Many parent training programs include modules designed to enhance understanding of internalizing symptoms and related parenting strategies [13-15]. Furthermore, evidence-based therapies for child anxiety and depression that include parent education and skill development are among the most efficacious treatments to date [16,17]. However, few measures, other than the KEPT, explicitly assess parent knowledge of these constructs [10,18].

Computerized Adaptive Testing

Efficient, scalable, and precise assessment tools are necessary for feasible uptake of evidence-based measurement in both research and applied contexts. The full KEPT-I assessment may be less efficient than necessary in certain contexts, owing to the multimodal format that includes video vignettes and results in an average completion time of 25 minutes. Despite its utility, we propose computerized adaptive testing (CAT) as a promising approach to increase the efficiency of the KEPT-I for broader adoption [19,20]. CAT dynamically selects items to adjust question difficulty to the respondent's ability level using an Item Response Theory (IRT) framework to measure an underlying latent trait typically represented as a standardized score (theta) with a mean of 0.0 and SD of 1.0. In the context of the KEPT, a theta score of 0.0 indicates average parenting knowledge, whereas theta scores of 1.0 and −1.0 represent knowledge scores that are 1 SD above and below the mean, respectively [21,22]. This adaptive model can lead to greater efficiency and shorter test lengths compared with fixed-length counterparts [23,24]. Because CAT selects items from comprehensive item banks, it can administer different items at optimal times depending on a respondent's current level of a latent trait (or theta), and this feature has the potential to reduce practice effects for respondents. For researchers, use of CAT can lead to improved data quality, shorter administration time, and greater sensitivity to change. Several studies have demonstrated the validity of CAT by showing reductions in measurement error and strong correlations with traditional static measures [24-26].

Within the field of mental and behavioral health, research has consistently demonstrated the effectiveness of CAT in the study of depression [20,24,27]. CAT instruments have also been created for other mental health conditions, including anxiety [28,29], bipolar disorder [30], and psychotic disorders [31,32]. Recognizing the benefits of adaptive testing, a CAT version of the KEPT-E was developed in 2020 and was shown to increase efficiency while maintaining strong psychometric properties [33].

This Study

In this study, we developed a CAT prototype for the KEPT-I module (KEPT-I CAT) and evaluated its performance relative to the static 10-item short form (KEPT-I Brief) using simulations from the calibration sample of 1000 parents or guardians of children aged 5 to 12 years. The Firestar R package (version 1.9.2; R Foundation for Statistical Computing [34]) was used to conduct simulations. The goal was to find the stopping rules that best balanced the number of items administered and the accuracy of the measure. The development of such a tool holds the potential to enhance the accuracy and efficiency of assessments, thereby contributing to the advancement of research in the field of parenting interventions.

Methods

Overview

For the development and evaluation of the KEPT-I CAT prototype, simulations were conducted using the KEPT-I calibration data that were previously collected from a large national sample (n=1000) of parents or guardians (n=567, 56.7% female; mean age 40, SD 7.4 years) of children aged 5 to 12 years. The sample was demographically representative of the US population for key variables including race, ethnicity, income, education, and marital status (n=762, 76.2% White; n=179, 17.9% Hispanic, Spanish, or Latin origin; n=604, 60.4% earning less than US $100,000 annually; n=704, 70.4% with some college education or higher [11]). The KEPT-I demonstrated good internal consistency (α=.82 for the full 22-item version and α=.68 for the 10-item brief version) and showed significant correlations in the expected directions with parenting behaviors, child and parent psychopathology, and mental health service use, supporting its reliability and convergent validity.

A full description of the demographic characteristics of participants and the psychometric properties of the KEPT-I (ie, reliability and validity) is provided elsewhere [11]. The item bank for the KEPT-I CAT prototype included all 22 multiple-choice items from the IRT-calibrated version of the KEPT-I module [11] assessing knowledge of effective internalizing parenting skills across these content domains: exposure principles or encouraging bravery (3 items), relaxation (4 items), warmth (3 items), involvement (1 item), behavior activation (2 items), reducing criticism (5 items), and cognitive reframing (5 items). The multiple-choice items have 4 response options, with only 1 "correct or best" answer. All items are scored dichotomously as correct or incorrect. Figure 1 shows a sample item.

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Figure 1. Sample screenshot and item from the Knowledge of Effective Parenting Test–Internalizing module.

Ethical Considerations

The study was approved by the Institutional Review Board at the University of Pittsburgh (STUDY23100020), which waived the requirement for written informed consent due to the survey-based nature of the data used for this study. Participants were compensated with a US $25 gift card for completing the full survey. For participant privacy and confidentiality, data were deidentified before analysis as a protective measure to safeguard personal information.

IRT Calibration

IRT calibration of the items in the full bank KEPT-I was completed before this study, with results reported elsewhere [11]. The original item pool for the KEPT-I included 40 items. Of those, 18 (45%) items were removed due to poor factor loadings, low item discrimination parameter estimates, local dependency, or significant differential item functioning across racial or ethnic groups. The resulting 22-item bank for the KEPT-I CAT prototype includes only items with acceptable discrimination that functioned equivalently for racially or ethnically diverse respondents.

CAT Simulation Configuration

The Firestar R package, a CAT simulation program (version 1.9.2) [34], was used to conduct post hoc simulations. To perform the CAT simulations, item parameters from the full 22-item bank were entered into Firestar based on the 3-parameter logistic IRT calibration, along with the actual item responses from all 1000 participants in the calibration dataset. Firestar selects items from the full bank to administer one at a time based on one of several user-selected methods. Among the commonly used item selection approaches, maximum posterior weighted information was chosen based on prior evidence that it provides the greatest measurement precision [35]. The maximum posterior weighted information approach uses the information function weighted by the posterior distribution of trait (latent variable) values. The following additional specifications were selected to configure the CAT simulations: the maximum number of response categories across all items was set to 2, the theta range was set as −4.0 to 4.0, the posterior distribution was set as a normal distribution (mean 0.0, SD 1.0), interim theta and full-length theta values were estimated using an expected a priori method, the SE estimation method was set as the posterior SD, the first item location was set at theta 0.0, and the item selection method was set as the prior mean.

Manipulated Factors

On the basis of the CAT configuration specifications, we evaluated CAT performance by varying 2 CAT stopping rules. The primary stopping rule was termination after SE reached a minimum value. The secondary stopping rule was termination after a maximum number of items was administered. To identify the most efficient stopping paradigm, we crossed the 2 stopping

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rules in a 2×3 design, that is, the minimum SE was set as 0.50 (to be consistent with the minimum SE used for the KEPT-E CAT) or 0.45 (to examine the impact of requiring additional precision), and the maximum number of items to be administered was set to 15, 18, or 22 (full length).

Evaluation Criteria

To evaluate CAT performance in comparison with the 10-item static KEPT-I short form (KEPT-I Brief), simulated CAT theta scores were correlated with full-length theta scores. The correlations were then compared with the previously reported correlation between the full-length KEPT-I and KEPT-I Brief [11]. To evaluate the efficiency of each of the 6 CAT scenarios, the mean and median of CAT item length (the number of items administered) and the final values and distributions of theta scores and SEs were compared. To further evaluate the impact of the combined stopping rules, we investigated the cases that did not reach the target SE after the maximum number of items had been administered by identifying the proportion of cases that would have displayed SE reductions greater than 0.01 if additional items had been administered. The overall goal was to decide on the best CAT scenario based on a balance between efficiency and precision.

Results

Test Length and Theta Recovery

A median of 10 items (with a minimum of 6 items) was administered across the 15- (IQR 8-13), 18- (IQR 8-12), and 22- item (IQR 8-13) simulations with an SE of 0.50. The corresponding mean SEs were 0.50 (SD 0.03), 0.50 (SD 0.03), and 0.49 (SD 0.02), respectively. A median of 14 items (with a minimum of 7 items) was administered across the 15- (IQR 12-15), 18- (IQR 12-18), and 22-item (IQR 12-21) simulations with an SE of 0.45. The corresponding mean SEs were 0.47 (SD 0.04), 0.46 (SD 0.04), and 0.46 (SD 0.04), respectively. Table 1 shows the individual item length and final estimation for each of the simulation scenarios. Figures S1 and S2 in Multimedia Appendix 1 provide the frequency distributions of simulated CAT lengths across the 6 scenarios. For the 3 scenarios with the SE of 0.50 (Figure S1 in Multimedia Appendix 1), the percentages of cases with CAT terminated after 11 items or fewer (ie, one more item than the median item length) were 63.4% (634/1000), 62.8% (628/1000), and 62.1% (621/1000) for the 22-, 18-, and 15-item CAT, respectively. For the 3 scenarios with the SE of 0.45 (Figure S2 in Multimedia Appendix 1), the percentages of cases with CAT terminated after 15 items or fewer (ie, one more item than the median item length) were 62.7% (627/1000), 62.7% (627/1000), and 100% (1000/1000) for the 22-, 18-, and 15-item CAT, respectively.

Table . Item length, final estimation, and theta recovery comparisons across the 6 computerized adaptive testing (CAT) simulation scenarios.

	Item length		Final estimation		Theta recovery, RMSE[a]
	Mean (SD; range)	Median (IQR)	Theta, mean (SD; range)	SE, mean (SD; range)	
SE of 0.50					
22-item CAT	11.65 (4.58; 6 to 22)	10 (8-13)	0.03 (0.87; −2.49 to 1.71)	0.49 (0.02; 0.47 to 0.58)	0.262
18-item CAT	11.12 (3.59; 6 to 18)	10 (8-12)	0.02 (0.86; −2.47 to 1.69)	0.50 (0.03; 0.46 to 0.59)	0.249
15-item CAT	10.70 (2.76; 6 to 15)	10 (8-13)	−0.03 (0.86; −2.32 to 1.67)	0.50 (0.03; 0.46 to 0.67)	0.242
SE of 0.45					
22-item CAT	15.29 (4.57; 7 to 22)	14 (12-21)	0.01 (0.88; −2.34 to 1.71)	0.46 (0.04; 0.42 to 0.60)	0.164
18-item CAT	14.17 (3.15; 7 to 18)	14 (12-18)	−0.01 (0.88; −2.50 to 1.69)	0.46 (0.04; 0.42 to 0.59)	0.175
15-item CAT	13.26 (2.04; 7 to 15)	14 (12-15)	0.00 (0.88; −2.50 to 1.67)	0.47 (0.04; 0.43 to 0.72)	0.196

[a]RMSE: root mean squared error.

To evaluate the theta recovery of each simulation scenario, we further computed root mean squared error (RMSE) with the full-length theta. As shown in Table 1, for the SE of 0.50, the 15-item and 18-item CAT scenarios yielded similar RMSEs, with a slightly higher RMSE in the 22-item CAT. For the SE of 0.45, the 18-item and 22-item CAT scenarios yielded similar RMSEs, with a slightly higher RMSE in the 15-item CAT.

Secondary Stopping Rule

As shown in Figure S3 in Multimedia Appendix 1, for the 3 scenarios for the SE of 0.50, out of 1000 cases, there were 148 (14.8%), 123 (12.3%), and 109 (10.9%) cases with CAT terminated based on the secondary stopping rule of a maximum number of items for 22-, 18-, and 15-item CAT, respectively. These cases were in tails of the theta score distributions (eg, for the 123 cases from the 18-item CAT, n=26, 21.1% of the cases

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with theta below −1.0% and n=95, 77.2% of the cases with theta above 1.0, with a mean SE of 0.55 and a range of 0.50-0.59). For the 3 scenarios for the SE of 0.45 in Figure S4 in Multimedia Appendix 1, there were 247 (24.7%) cases, 282 (28.2%) cases, and 384 (38.4%) cases with CAT terminated based on the secondary stopping rule of a maximum number of items for the 22-, 18-, and 15-item CAT, respectively. Most of these cases were again in the tails of the theta score distributions (eg, for the 282 cases from the 18-item CAT, n=97, 34.4% of the cases with theta below −1.0% and n=130, 46.1% cases with theta above 1.0, with a mean SE of 0.51 and a range of 0.45-0.59). These results are consistent with the fact that IRT-calibrated tests typically display less precision in the tails of test information distributions, where there is less variability in responses, that is, when respondents are providing all correct (or incorrect) answers, each individual item becomes less discriminating.

Comparison With the Full-Length Test

The correlations between 9-item CAT theta and full-length theta reached 0.95 for both the SE of 0.50 and 0.45 scenarios, which exceeds the correlation between the KEPT-I Brief and the full form (r=0.90). Figure 2 summarizes the correlations between CAT theta scores varying by length and the full-length theta for the SE of 0.50 model. The correlation between CAT theta and full-length theta exceeds 0.90 with as few as 7 items. The figure also shows the correlation between the 10-item (short) static form and the full static form. On average, the 10-item static form offers the same precision as between 6 and 7 CAT-sequenced items, highlighting the benefit of CAT sequencing. Figure 3 shows the distribution of SEs of theta estimates as a function of test length for the 15-item CAT with the SE of 0.50.

Figure 2. Correlations between computerized adaptive testing (CAT) and static short-form thetas and full-length thetas for the SE of 0.50.

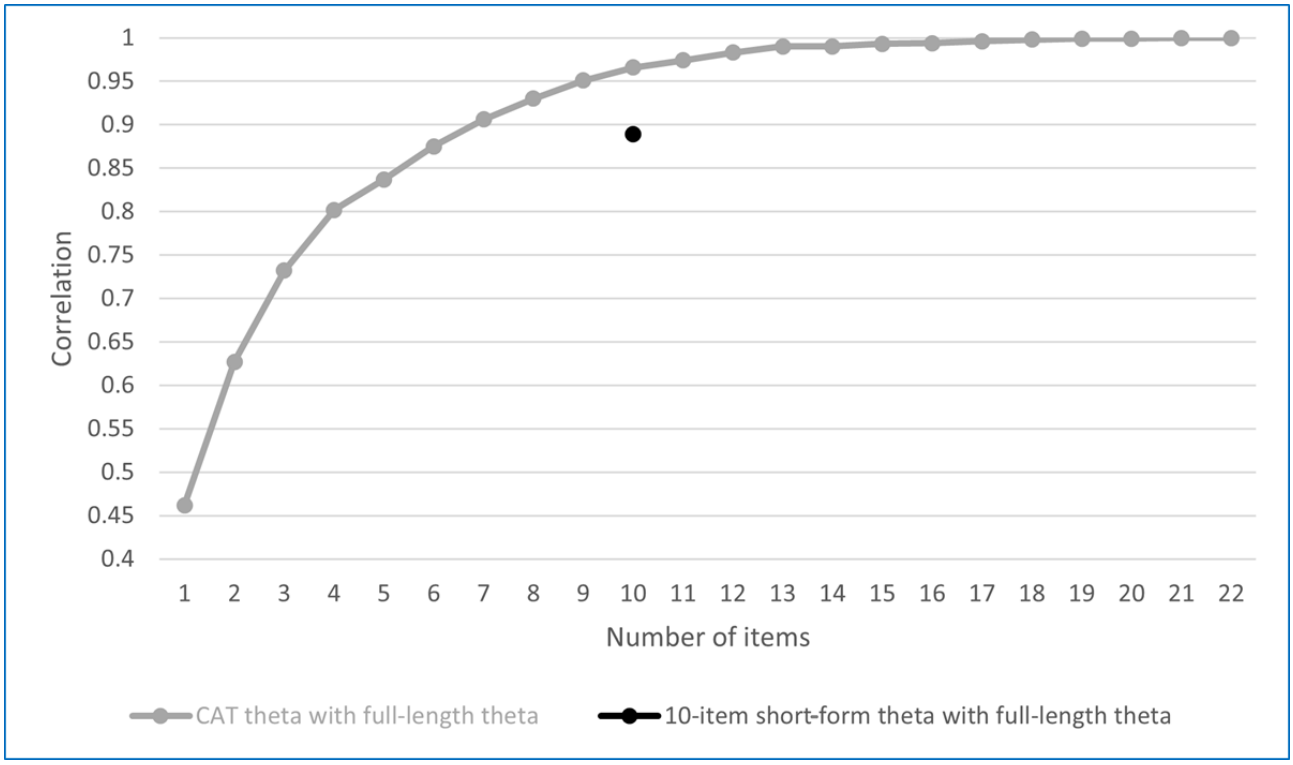

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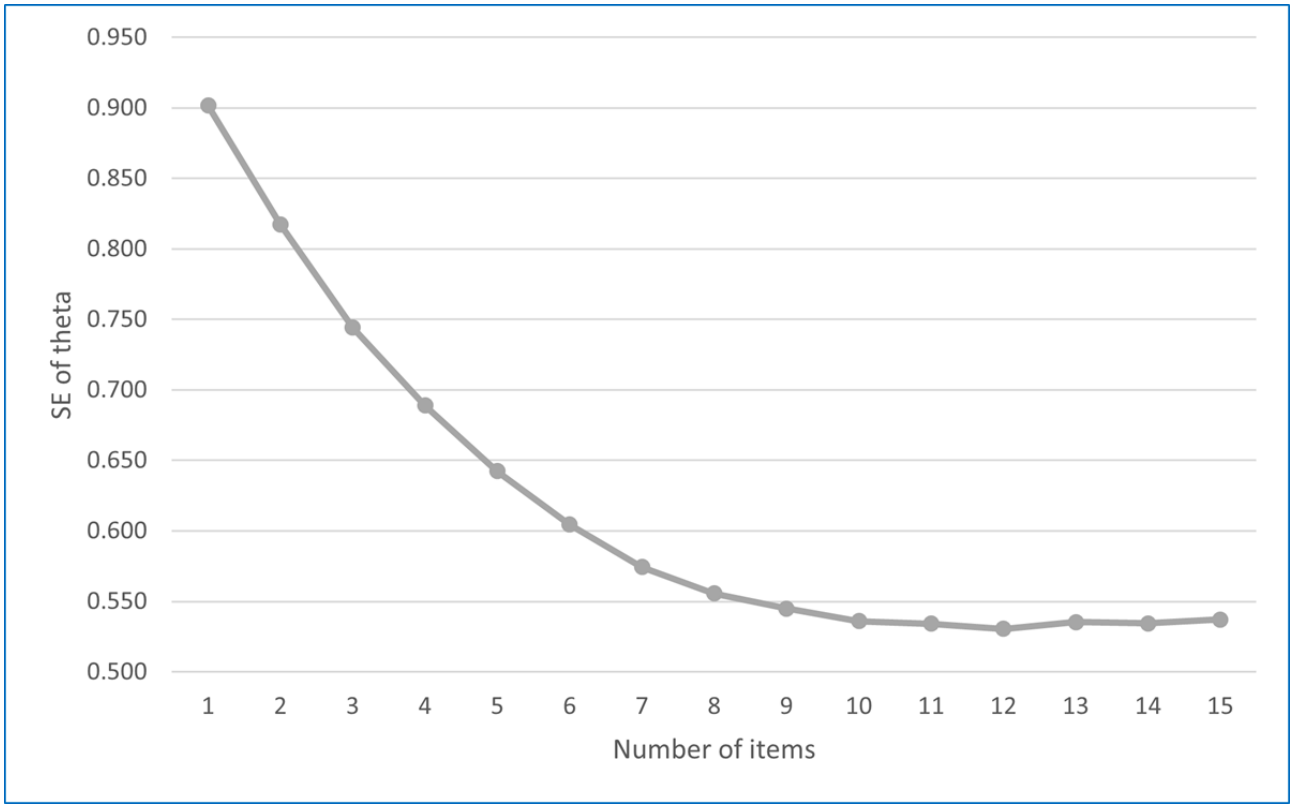
Figure 3. SE change over the 15-Item computerized adaptive testing with the SE of 0.50.



Impact of Additional Items on SE Reduction

Figure 4 summarizes the proportion of respondents with a SE reduction >0.01 for each next item between 10 and 21 items. Of the 471 cases that needed to take an additional item after completing 10 items, 308 (65.4%) had SE reductions larger than 0.01. The percentage of cases with an SE reduction greater than 0.01 decreased to 11.3% (20/177) among participants who required an additional item after completing 15 items. Additional items to the 16-item CAT only gained 6.6% (11/166) of cases with a SE reduction larger than 0.01. Again, because of these modest gains in SE reduction, when comparing stopping rules with the SE of 0.50 and SE of 0.45, the median number of items to be administered increased from 10 to 14. In summary, based on the preferred balance between efficiency and precision, the 15-item CAT with the SE of 0.50 was the best selection among the 6 CAT scenarios. Figures 4 and 5 provide the final theta distribution and item frequencies for the 15-item CAT with the SE of 0.50 (Multimedia Appendix 2).

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Figure 4. Proportion of SE >0.01 for participants taking the next item.

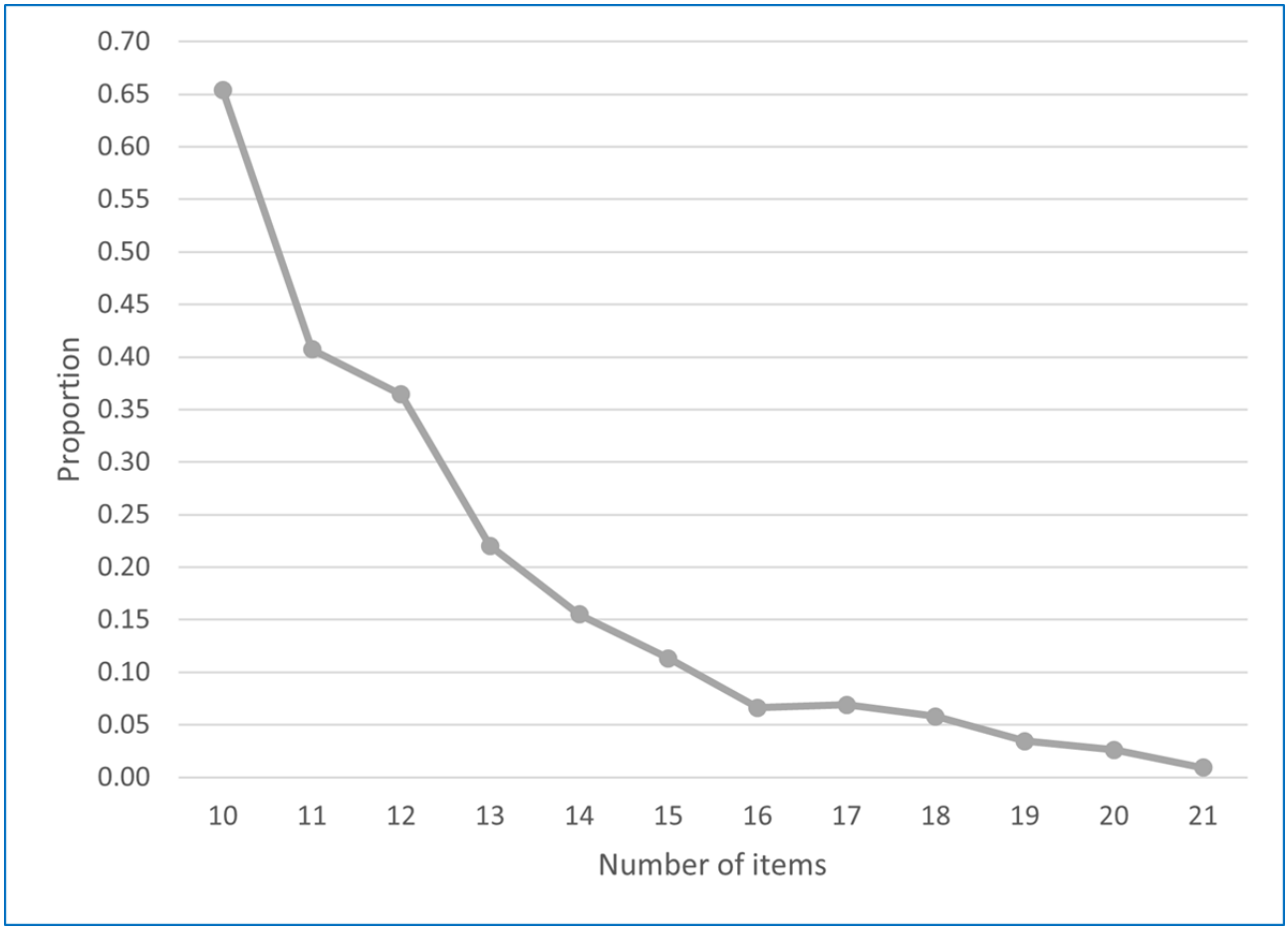

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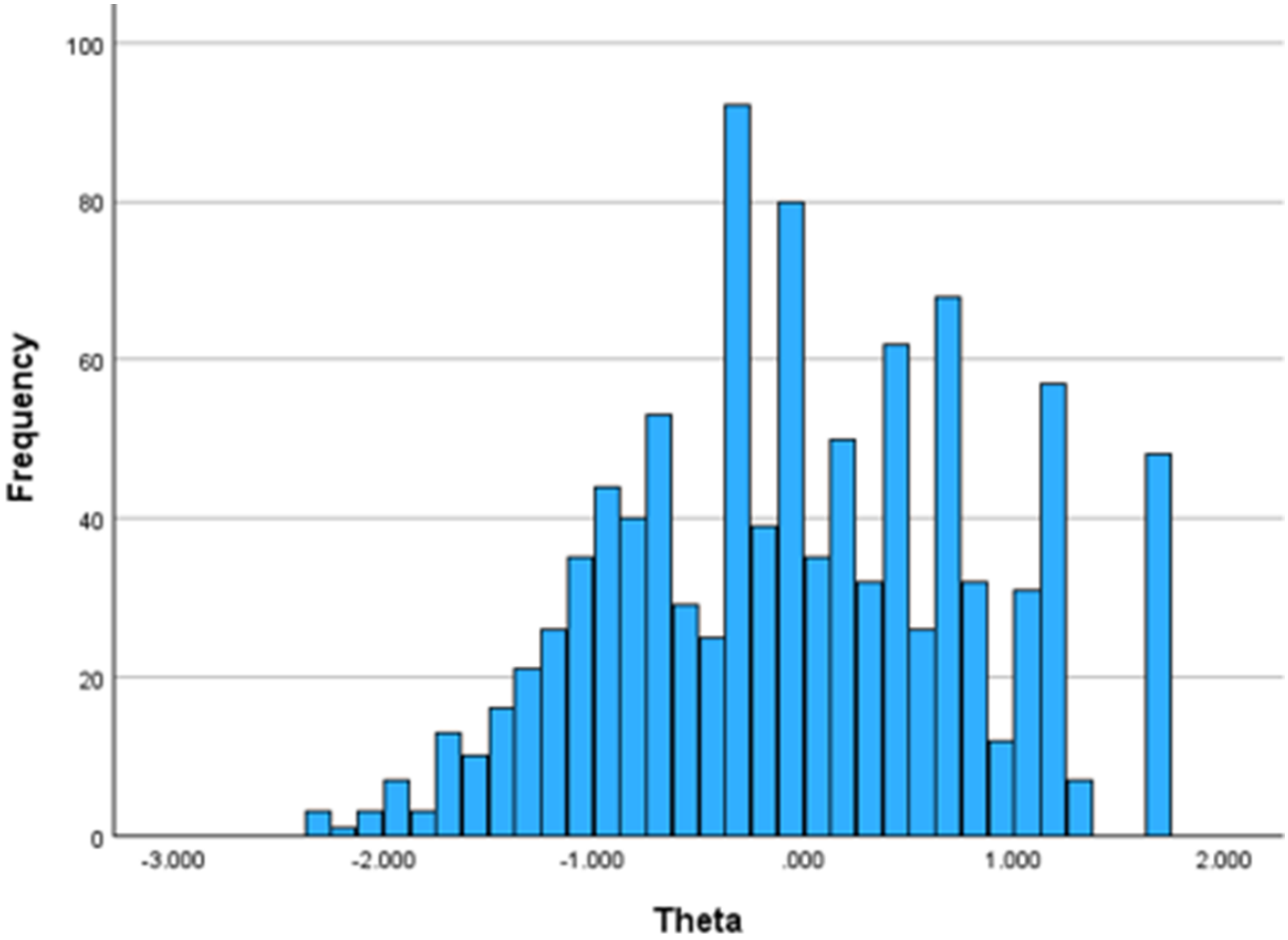
Figure 5. Final theta score distribution of the 15-item computerized adaptive testing with the SE of 0.50 (N=1000; mean –0.031, SD 0.862).



Discussion

Principal Findings

In this study, we developed a CAT version of the KEPT-I (KEPT-I CAT), which maintained the strong psychometric properties of the original measure while improving efficiency (albeit modestly). Although the KEPT-I CAT prototype is similar in length to the static 10-item KEPT-I Brief, the adaptive format tailors item selection to each respondent's latent level of parenting knowledge (ie, IRT ability), thereby maximizing information at each administration. Consequently, the KEPT-I CAT demonstrates incrementally stronger correlations with the full-length KEPT-I than the brief form, indicating greater fidelity to the original measure. These findings suggest that the KEPT-I CAT offers a marginal advantage over the static brief form by achieving comparable efficiency while providing more accurate and reliable estimates of overall parenting knowledge, particularly in research and clinical contexts where precision is prioritized. Another potential advantage of the KEPT-I CAT is its ability to modestly mitigate practice effects. Although the KEPT-I CAT is similar in length to the KEPT-I Brief, adaptive item selection may reduce repeated exposure to identical items across administrations. Given the limited item pool, any benefit in this regard is likely to be incremental.

The development of the KEPT-I CAT contributes to the emerging applications of adaptive testing in mental health research. While CAT has been used in studies of various mental health conditions [20,24,27], the CAT adaptation of the KEPT-I is the first to assess domains of parenting knowledge shown to be associated with the development and maintenance of child internalizing disorders [36-38]. While parenting involvement and knowledge are common targets of child internalizing disorder interventions [2,39], the KEPT-I is one of the few measures with strong psychometric properties designed to assess knowledge of parenting skills related to internalizing disorders [11]. The brevity and process of the KEPT-I CAT make it particularly useful for inclusion in lengthy test batteries, where participants may experience considerable assessment burden and where practice effects may occur if the static KEPT-I Brief is used.

Strengths and Limitations

The strengths of this project include a large national dataset used to evaluate the performance of the full-length, brief, and CAT versions of the KEPT-I module. The 22 items of the full KEPT-I module that were used as the item bank for the CAT version were rigorously selected from 40 original items using factor analysis and IRT analyses. High factor loadings, strong item parameters, and robust test information curves supported the reliability of all items. In addition, all items were free from significant differential item functioning by race or ethnicity [11].

In terms of limitations, because the item pool has a test information function with greater precision in the middle of the latent trait distribution than in the tails (as is typical of

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IRT-calibrated tests), measurement precision was more difficult to achieve for respondents in the tails of the distribution. Consequently, a secondary stopping rule was implemented to prevent the KEPT-I CAT from cycling through all the items in the item pool. In addition, because of the relatively small item pool, the CAT prototype does not include content balancing across all domains of parenting knowledge regarding internalizing problems, a feature sometimes used in longer adaptive tests to ensure equal coverage of items from all content areas.

Summary, Conclusions, and Future Directions

While CAT assessments are valuable tools for streamlining screening and assessment, it is imperative that these tools are scrutinized methodically for reliability and validity according to their intended use, as their utility may vary depending on the context [39]. With strong psychometric properties and improved efficiency, the KEPT-I CAT has the potential to serve as a valuable supplement to measures that directly assess parenting behaviors. The KEPT-I CAT's capacity to assess parenting knowledge will aid in further exploration to determine how parenting skills knowledge translates to skill use and how this could improve effective parenting strategies to reduce child internalizing symptoms. Further research is needed to validate the KEPT-I CAT in applied settings, including comparisons of its precision with the full 22-item KEPT-I in independent samples. Additional validation in clinical populations will also be important for examining real-world utility.

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Data Availability

The datasets generated or analyzed during this study are available from the corresponding author on reasonable request.

Authors' Contributions

All authors, with the exception of HDG and CST, are coprincipal investigators on the grant that funded this study. All authors contributed to the study conception and design. Material preparation and data collection were facilitated by all authors except HDG and CST. Data analysis was performed by LY in collaboration with OL. OL wrote and edited the Methods section, while LY wrote and edited the Results section. HDG and CST wrote and edited the Introduction and Discussion sections. All authors provided feedback on subsequent drafts and read and approved the final manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Test length and theta distributions for all models tested.
[DOCX File, 302 KB - formative_v10i1e81646_app1.docx]

Multimedia Appendix 2
Number of items used in 15-item computerized adaptive testing (SE 0.50).
[PNG File, 51 KB - formative_v10i1e81646_app2.png]

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Abbreviations

CAT: computerized adaptive testing
IRT: item response theory
KEPT: Knowledge of Effective Parenting Test
KEPT-E: Knowledge of Effective Parenting Test–Externalizing
KEPT-I: Knowledge of Effective Parenting Test–Internalizing
KEPT-I Brief: 10-item short form of Knowledge of Effective Parenting Test–Internalizing
KEPT-I CAT: Knowledge of Effective Parenting Test–Internalizing computerized adaptive testing
RMSE: root mean squared error

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Accuracy of Optical Heart Rate Measurements for 10 Commercial Wearables in Different Climate Conditions and Activities: Instrument Validation Study

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Abstract

Background: Commercial wearable devices allow for continuous heart rate (HR) monitoring in daily life. Their accuracy under ecologically valid conditions, however, remains insufficiently independently tested, especially during irregular activity, cognitive stress, and variable climates.

Objective: This study evaluated the HR accuracy of 10 commercially available wearables under controlled variations in physical activity, cognitive stress, and temperature. We hypothesized that physical activity irregularity, cognitive stress, and thermal climate conditions would affect measurement accuracy.

Methods: Forty-five healthy adults (21 - 68, mean 34, SD 12 y) completed a standardized protocol in climate-controlled chambers simulating neutral (23 °C), hot (36 °C), and cold (10 °C) conditions. Tasks included rest, cognitive stress (Montreal Imaging Stress Task), steady walking, and intermittent walking. Each of the 10 devices (Fitbit Charge 6, Fitbit Inspire 3, Garmin Vivosmart 5, Garmin Vivoactive 5, Apple Watch SE, Google Pixel Watch 2, Polar Ignite 3, Polar Pacer, Xiaomi Watch 2, and Oura Ring Gen 3) was compared against electrocardiogram-derived HR from a Zephyr BioHarness chest strap. Accuracy was assessed using mean absolute error (MAE), mean absolute percentage error (MAPE), repeated-measures concordance correlation coefficient (CCC), and Bland-Altman analysis.

Results: Significant variability across the devices was observed. Fitbit Charge 6 (MAE 4.5 bpm, MAPE 5.5%, CCC 0.93) and Google Pixel Watch 2 (MAE 4.9 bpm, MAPE 6.7%, CCC 0.87) showed strong agreement with the gold standard. In contrast, Fitbit Inspire 3, Polar Ignite 3, Polar Pacer, and Oura Ring displayed larger errors (MAE 9 - 14 bpm, MAPE 11% - 16%) and lower CCC values (0.45 - 0.66). The climate conditions did not significantly affect the measurement accuracy of the test devices. The activity type, however, did have a significant effect: intermittent walking increased errors for multiple devices.

Conclusions: Wearable HR measurement accuracy is device-specific and context-dependent. Moderate climates did not impair performance, but irregular movement reduced accuracy. Fitbit Charge 6 and Google Pixel Watch 2 demonstrated the highest reliability, supporting their use in health and sports monitoring. Careful device selection and context-aware interpretation remain critical for applied and clinical applications.

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KEYWORDS

heart rate; wearable electronic devices; fitness trackers; mobile health; monitoring; exercise; stress; climate

Introduction

Commercial wearable devices have become increasingly embedded in everyday life, enabling continuous physiological monitoring across a range of real-world contexts. Optical heart rate (HR) monitoring via photoplethysmography (PPG) is now a standard feature in many wearable devices. These wearables offer the potential for unobtrusive health tracking, behavior change interventions, and remote monitoring of chronic conditions [1,2]. However, their practical utility hinges on the accuracy of the measurements they provide, especially in dynamic and ecologically valid conditions.

Despite the rapid expansion of the wearable technology market, the pace of independent scientific validation lags significantly

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behind device release cycles. Most commercial wearables are launched without peer-reviewed evidence supporting their measurement accuracy or reliability under diverse conditions [3-5]. This creates a critical gap between consumer expectations and clinical or research-grade data quality, particularly in domains such as health promotion, personalized exercise prescription, and digital health interventions [6].

HR is a core variable in wearable monitoring, often used as a proxy for different physiological processes such as physical exertion, emotional stress, or recovery status [7,8]. PPG-based HR measurements can, however, be affected by several external and physiological factors. These include motion artifacts from limb movement, which have been shown to lead to mean absolute percentage errors (MAPE) of over 20% during vigorous intensity exercise [9]. Sensor placement and poor contact can similarly introduce errors [10]. Variations in skin tone affect the absorption and scattering of the light used in PPG, which can contribute to errors. This has been shown in the past for darker-skinned users of different smartwatch brands that HR was underestimated by 10 - 15 bpm at rest and by more than 20% during vigorous activity [11]. Finally, changes in blood flow due to vasoconstriction, vasodilation, or muscle tension also influence signal quality. For instance, significant changes in direct current and alternating current amplitudes of the PPG pulse have indicated that mild cold exposure has a substantial effect on finger blood circulation [12]. These authors suggested that mild cold exposure may have a delayed effect on the pulse transit time and, therefore, could be a potential source of error. Consequently, device performance may vary across activity types, from seated rest to vigorous or irregular movement, and may also be sensitive to environmental factors, such as temperature and humidity, which influence peripheral blood circulation [9].

To date, most validation studies of wearable HR monitoring have focused on standardized physical activities (eg, steady treadmill walking or cycling) under controlled laboratory conditions [13-15]. In these study designs, validation is performed across discrete, sustained activities, eg, walking at a certain intensity for 5 minutes. While such protocols provide valuable benchmarks, they often fail to capture the variability and unpredictability of everyday human movement. Moreover, few studies have systematically tested devices across a range of environmental conditions, despite growing interest in outdoor, occupational, or climate-sensitive applications of wearable monitoring [16]. Similarly, validation protocols rarely include cognitively demanding or stressful conditions, although wearables are increasingly applied for stress detection and mental health monitoring.

In this study, we evaluated the HR accuracy of 10 commercially available wearable devices across a standardized experimental protocol that varied in activity type, cognitive stress, and climate condition. The devices were selected based on their potential for use in research and commercial applications. The main selection criteria were cost, usability, and data availability.

Our goal was to assess how real-world influences, such as movement, cognitive stress, and ambient thermal environment, affect optical HR accuracy. We hypothesized that devices would show greater error during more vigorous and nonsteady-state activities due to increased motion artifacts. Additionally, acute cognitive stress was expected to reduce HR accuracy due to increased HR, cardiac contractility, systolic blood pressure, and peripheral vasoconstriction [17], all of which may affect PPG signal quality and accuracy [18]. Moreover, we hypothesized that exposure to extreme temperatures (hot or cold) would impair accuracy due to peripheral vasoconstriction or vasodilation affecting PPG signal quality.

Methods

Wearables

The following devices were included: Fitbit Charge 6, Fitbit Inspire 3, Garmin Vivosmart 5, Garmin Vivoactive 5, Apple Watch SE, Google Pixel Watch 2, Polar Ignite 3, Polar Pacer, Xiaomi Watch 2, and Oura (Gen 3). Thus, this selection contained 9 watches and 1 ring. The Zephyr BioHarness 3.0 chest strap was used as the gold standard reference measure. The Zephyr BioHarness 3.0 allows for collecting the raw electrocardiogram data and therefore to evaluate the data quality of the derived HR time series. It has demonstrated validity across many exercise modalities and contexts [19].

Study Design and Participants

A total of 45 healthy adult volunteers (23 male, 22 female) participated in this study. The participants ranged in age from 21 to 68 years, with a mean age of 34 (SD 12) years. All participants were free from known cardiovascular, metabolic, or musculoskeletal conditions that could interfere with data collection or affect physiological responses. The participants completed an hour-long experimental protocol. During each session, participants wore 2 watches and 1 chest strap. To ensure that there was no optical or electromagnetic cross-interference, only 2 watches were worn at any time, 1 on the left wrist and 1 on the right wrist. The independent operation and data storage of all devices also mitigated any potential data interference. They were instructed to wear the smartwatch snugly, just above the wrist bone, ensuring the optical sensor maintained direct skin contact. In addition, 10 individuals wore the Oura ring on their nondominant hand. The ring (size 10) was worn on the finger that ensured stable sensor contact. Each of the 10 wearable devices was tested 10 times across different participants, yielding a total of 100 unique testing sessions (10 per device). To control for potential placement effects, the location of the devices was counterbalanced across the left and right hands. This sample size balanced device coverage against the logistical constraints of the multisession environmental protocol.

Ethical Considerations

The study was approved by the Social and Societal Ethics Committee of KU Leuven (case G-2024-8195-R4(AMD)). Written informed consent was obtained from all study participants prior to participation after the nature and possible consequences of the studies were explained. To ensure privacy and confidentiality, all participant data were deidentified and stored on secure, password-protected institutional servers. No compensation was provided to participants.

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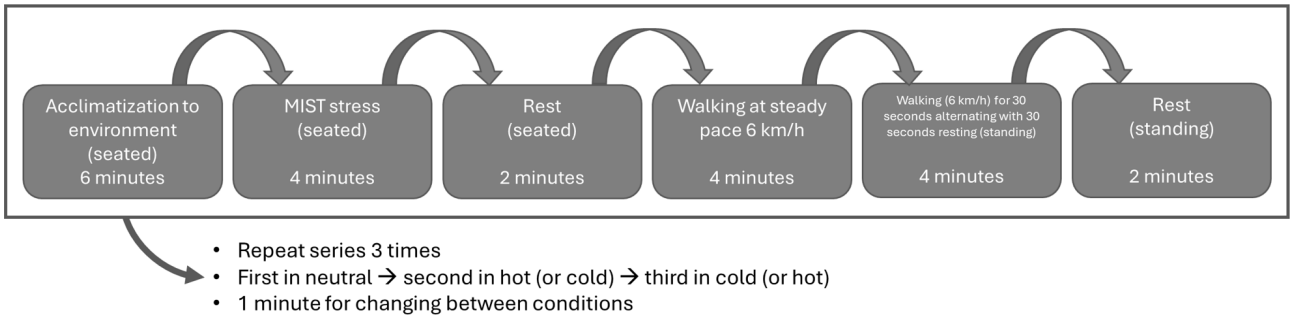
Experimental Protocol

All participants performed a standardized protocol in each of 3 environmental chambers: a neutral condition (23 °C, 50% relative humidity), a hot condition (36 °C, 70% relative humidity), and a cold condition (10 °C, 40% relative humidity). The 3 climate chambers were dimensionally identical (3.6 m by 2.4 m) and were located adjacent to one another, allowing for rapid participant transition. Half of the participants completed the protocol in the sequence neutral-hot-cold, while the other half followed the sequence neutral-cold-hot.

Within each environmental condition, participants completed six tasks lasting in total 22 minutes: (1) a 6-minute seated resting phase to acclimate to the chamber, (2) a 4-minute cognitive stress task (Montreal Imaging Stress Task [MIST] [20]) performed at a desk using a PC, (3) a 2-minute seated recovery phase, (4) a 4-minute steady walking task on a treadmill (Focus Fitness Jet 1) at 6 km/h, (5) a 4-minute intermittent walking task involving alternating 30-second walking and standing intervals, and (6) a final 2-minute standing rest phase. The sequence of these 6 tasks was fixed for all participants to maintain a standardized progression from rest to increasing cognitive and physical exertion, allowing for direct comparison of device performance across the controlled states. To mitigate systematic carry-over effects (eg, fatigue or learning) that might accumulate over the testing day, the order of the 3 main environmental conditions was systematically counterbalanced across participants. This experimental protocol was designed to simulate a range of ecologically valid use cases including cognitive and physical stressors, steady-state and intermittent movement, and environmental variation. The timeline of the research protocol is visualized in Figure 1.

Figure 1. Timeline of the research protocol. MIST: Montreal Imaging Stress Task.



Data Collection and Processing

HR data from the Zephyr BioHarness and each wearable device were recorded continuously throughout all tasks. The data were exported using manufacturer-provided software platforms or application programming interfaces. This yielded the HR data at the highest possible sampling frequency for each device. The Polar Ignite 3, Polar Pacer, and Oura collected data at 1 Hz. For the other devices, the sampling frequency was variable with the intervals varying from 1 to 7 seconds. To ensure alignment, HR time series from each wearable were synchronized with the reference series using timestamp-based matching. Any reference data points that could not be matched due to sparse wearable sampling were excluded from analysis. No additional data smoothing or outlier removal was performed.

Accuracy Metrics

Three key metrics were used to assess HR accuracy. First, mean absolute error (MAE) and MAPE were calculated between the wearable and reference HR signals for each condition and device. Second, we used the concordance correlation coefficient (CCC) [21]. Because the data consisted of repeated measurements over time for each participant, we extended the CCC using a repeated-measures framework [22]. The repeated-measures CCC accounts for the hierarchical structure of the data by estimating the variance components associated with between-subject and within-subject variability. This was done by fitting a linear mixed-effects model with a random intercept per participant, allowing variance components due to between-subject and within-subject variability to be separated. The repeated-measures CCC was then calculated using the model-based estimates of means, variances, and correlations, ensuring an unbiased agreement estimate under repeated measures. Third, we calculated the mean bias and limits of agreement for the Bland-Altman analysis [23] to assess the agreement between HR values recorded by the consumer wearable and the gold-standard chest strap. Similar to the calculation of the CCC, a mixed-effects adaptation of the original Bland-Altman analysis as described in Bland and Altman [24] was used to account for the repeated measurements.

The statistics outlined above were calculated both for the complete time series and for segments of the data corresponding to isolated activities and environmental conditions. This approach allowed for a statistical comparison to determine whether different conditions influenced the accuracy of the devices.

Statistical Analysis

Before formal analysis, the normality of the MAE and MAPE values for the different subsets was tested using Shapiro-Wilk testing. The significance level (α) was set to .05 for these tests. Given that the null hypothesis of the normally distributed data was rejected in most cases, it was decided to apply robust nonparametric testing. To determine whether certain devices yielded significantly differing MAE and MAPE values, Kruskal-Wallis testing was performed. When the test yielded a significant result, multiple Wilcoxon rank sum tests were performed to identify which pairs of devices differ significantly. Similarly, it was studied whether the experimental conditions (ie, the type of activity or thermal environment) yielded significantly differing MAE and MAPE values for each device. For this purpose, Friedman testing was performed. When the

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test yielded a significant result, multiple Wilcoxon signed-rank tests were performed to identify which pairs of experimental conditions differed significantly. To account for the family-wise error rate of repeated testing, Bonferroni-corrected α-values were considered. Specifically, the Bonferroni correction was applied to all multiple pairwise Wilcoxon rank sum tests and Wilcoxon signed-rank tests to maintain a family-wise error rate of α=.05 across the multiple device and condition comparisons performed. To enhance the interpretability of statistically significant findings, we calculated and reported effect sizes for the pairwise nonparametric tests. For all pairwise Wilcoxon signed-rank and rank sum tests, the rank-biserial correlation (*r*) was used to quantify the magnitude of the difference. These metrics are indicated in the main text of the paper when presenting the results.

All analyses were performed in MATLAB using the *fitlme* function to fit mixed-effects models and custom scripts to compute the extracted parameters.

Results

The statistics that describe the accuracy of the HR data for each wearable throughout the entire experimental protocol are summarized in Table 1. Furthermore, Figure 2 presents a visual comparison of the accuracy distributions (MAE values) across devices to allow for an immediate assessment of relative performance in addition to the tabulated values. The distribution of the MAE and MAPE values was used to test for significant differences between the various devices. The Kruskal-Wallis tests indicated that, for both the MAE and MAPE, at least 1 sample stochastically dominated one other sample (P<.05). In other words, there was a significant difference in the MAE and MAPE of at least 1 pair of wearables. Therefore, pairwise Wilcoxon rank sum tests were further performed to identify which pairs differ significantly. Given that the 10 wearables can form 45 unique pairs, the significance level was adjusted with the Bonferroni correction (α=.05/45=.0011). From these pairwise tests, it was observed that the MAE and MAPE values differed significantly between the Fitbit Charge 6 and the Fitbit Inspire 3, Polar Ignite 3, Polar Pacer, and Oura (Gen 3), with rank-biserial *r* values ranging between –0.76 and –0.84. In addition, significant differences for the MAE and MAPE were noted between the Fitbit Inspire 3 and the Garmin Vivoactive 5 and Google Pixel Watch 2 (rank-biserial *r* values between –0.75 and 0.84). Finally, the MAE values for the Google Pixel Watch 2 also differed significantly from the Polar Ignite 3 and Oura (Gen 3), with rank-biserial *r* values of –0.75 and –0.79, respectively.

Table . Measurement accuracy statistics for all tested wearables, over the full experimental protocol.

Wearable	MAE[a] (bpm), median (IQR)	MAPE[b] (%), median (IQR)	Repeated measures CCC[c]	Mixed-effects Bland-Altman		
				Mean bias (bpm)	Lower LoA[d] (bpm)	Upper LoA (bpm)
Fitbit Inspire 3	14.3 (10.3-27.9)[e]	16.5 (11.1-40.6)[e]	0.45	–14.4	–51.3	22.5
Fitbit Charge 6	4.5 (3.5-5.0)[f]	5.5 (4.6-6.5)[f]	0.93	0.7	–11.2	12.7
Garmin Vivosmart 5	7.0 (4.9-11.5)	8.1 (6.5-15.6)	0.78	4.8	–15.8	25.4
Garmin Vivoactive 5	5.1 (3.8-7.15)	6.3 (5.5-7.5)	0.83	–1.0	–18.6	16.7
Apple Watch SE	5.0 (4.9-5.8)	7.3 (5.7-8.4)	0.70	0.9	–21.4	23.0
Google Pixel Watch 2	4.9 (4.5-5.6)[g]	6.7 (5.7-7.6)	0.87	–0.4	–15.0	14.2
Polar Ignite 3	9.5 (8.4-12.6)	11.2 (9.7-19.2)	0.63	–4.3	–31.4	22.9
Polar Pacer	9.7 (8.0-11.6)	13.1 (9.7-16.2)	0.66	–3.9	–29.7	21.8
Xiaomi Watch 2	9.1 (5.5-11.4)	11.9 (7.3-15.8)	0.69	–3.0	–33.3	27.2
Oura (Gen 3)	11.0 (7.3-16.4)	15.0 (8.3-20.8)	0.61	–7.1	–35.5	21.3

[a]MAE: mean absolute error.

[b]MAPE: mean absolute percentage error.

[c]CCC: concordance correlation coefficient.

[d]LoA: limits of agreement.

[e]Significantly different from Garmin Vivoactive 5 and Google Pixel Watch 2.

[f]Significantly different from Fitbit Inspire 3, Polar Ignite 3, Polar Pacer, and Oura (Gen 3).

[g]Significantly different from Polar Ignite 3 and Oura (Gen 3).

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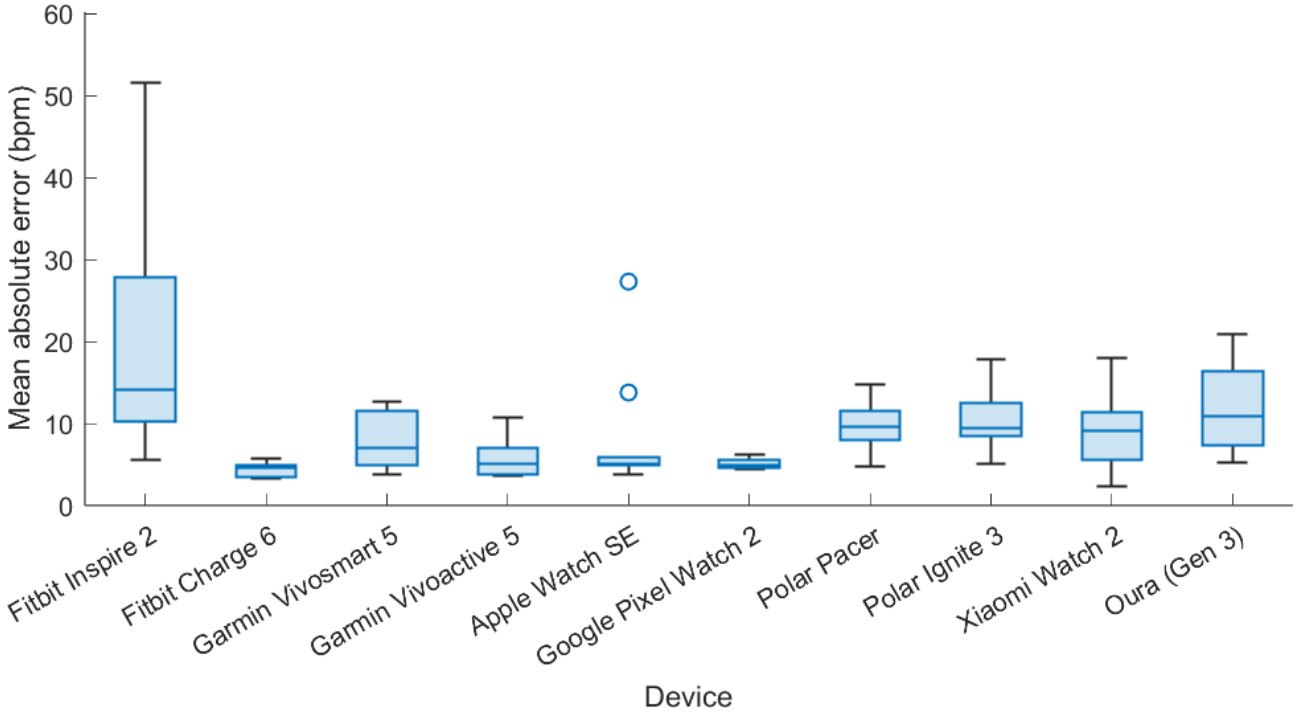
Figure 2. Visual representation of MAE values displayed in Table 1.



In addition to the comparison of the devices, we also evaluated the HR accuracy metrics for the different experimental conditions. Table 2 displays the accuracy of the HR data for each wearable in the 3 environmental conditions. Again, the distribution of the MAE and MAPE values was used to test for significant differences. In this case, it was checked for each wearable whether there were differences for the 3 climates. Given that 10 wearables were evaluated, the Friedman test was used 10 times. Therefore, the significance level was adjusted with the Bonferroni correction (α=.05/10=.005). The Friedman tests indicated that there were no significant differences in the device performance during the various climate conditions.

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Table . Measurement accuracy statistics for all tested wearables in the 3 environmental conditions.

Environment wearable	MAE[a], median (IQR)			MAPE[b], median (IQR)			Repeated measures CCC[c]			Mixed-effects Bland-Altman								
	Neutral	Hot	Cold	Neutral	Hot	Cold	Neutral	Hot	Cold	Mean difference			Lower LoA[d]			Upper LoA		
										Neutral	Hot	Cold	Neutral	Hot	Cold	Neutral	Hot	Cold
Fitbit Inspire 3	9.6 (7.8-30.1)	20.8 (16.7-24.5)	10.6 (4.9-15.1)	11.4 (8.6-43.4)	24.4 (21.0-31.5)	10.1 (6.0-18.7)	0.52	0.58	0.36	–15.4	–10.5	–13.7	–49.2	–40.5	–51.4	18.5	19.5	24.0
Fitbit Charge 6	4.1 (3.4-4.6)	4.7 (4.0-5.4)	3.8 (3.0-4.1)	5.1 (4.3-5.8)	5.8 (4.9-6.6)	4.1 (3.4-6.0)	0.94	0.94	0.91	0.8	0.9	0.8	–10.2	–10.0	–12.5	11.9	11.8	14.0
Garmin Vivosmart 5	6.8 (5.4-10.8)	7.6 (5.6-15.9)	6.0 (5.1-7.1)	7.8 (6.1-13.6)	8.5 (7.0-20.7)	7.4 (5.4-8.9)	0.79	0.88	0.70	5.0	5.9	3.5	–14.4	–9.5	–20.6	24.5	21.2	27.6
Garmin Vivoactive 5	5.2 (3.7-5.7)	5.4 (4.4-7.5)	4.6 (3.3-6.2)	5.9 (4.7-6.8)	7.3 (6.2-9.9)	5.3 (4.8-7.4)	0.81	0.90	0.77	–0.6	–0.7	–1.5	–18.6	–14.6	–21.6	17.4	13.1	18.7
Apple Watch SE	5.0 (4.8-5.5)	5.6 (4.7-6.3)	5.0 (4.3-6.4)	7.1 (6.6-7.9)	7.6 (6.4-9.9)	6.8 (5.2-8.4)	0.83	0.71	0.75	2.5	–2.4	–0.8	–13.1	–23.8	–19.0	18.0	19.0	17.4
Google Pixel Watch 2	4.7 (4.3-5.5)	5.4 (4.8-6.2)	4.4 (4.1-5.6)	6.6 (5.9-7.4)	6.7 (6.3-8.8)	6.1 (4.4-7.5)	0.84	0.87	0.81	–0.6	0.2	–0.9	–14.7	–14.0	–16.0	13.5	14.4	14.2
Polar Ignite 3	8.7 (6.6-15.1)	13.9 (6.7-15.3)	6.1 (4.6-9.9)	9.5 (8.2-22.4)	18.2 (8.2-22.9)	9.2 (5.7-15.2)	0.59	0.75	0.55	–2.7	–2.4	–7.7	–29.6	–23.2	–37.5	24.2	18.5	22.2
Polar Pacer	8.4 (5.4-10.6)	13.8 (5.9-17.1)	7.5 (5.4-7.8)	9.9 (7.9-17.6)	17.3 (7.4-26.8)	9.6 (6.3-11.4)	0.67	0.78	0.52	–3.6	–2.3	–7.2	–26.8	–21.2	–37.8	19.5	16.5	23.4
Xiaomi Watch 2	6.1 (3.5-10.4)	9.5 (7.0-22.5)	5.3 (4.1-9.4)	7.8 (4.6-12.7)	12.7 (8.0-20.7)	7.3 (4.2-10.1)	0.81	0.86	0.56	–2.1	–2.2	–4.9	–20.9	–20.5	–44.8	16.7	16.2	34.9
Oura (Gen 3)	9.4 (4.6-11.0)	16.2 (11.4-20.7)	9.1 (5.4-11.3)	9.9 (5.6-13.9)	18.3 (13.8-26.7)	10.5 (5.1-18.2)	0.78	0.80	0.32	–5.5	–7.2	–9.3	–25.3	–27.6	–40.5	14.2	13.5	21.9

[a]MAE: mean absolute error.

[b]MAPE: mean absolute percentage error.

[c]CCC: concordance correlation coefficient.

[d]LoA: limits of agreement.

Similar to testing for climate-related differences, the HR accuracy metrics were also checked for differences between the 3 types of activity: performing the MIST test, walking at a steady pace, and walking intermittently. Table 3 displays the statistics of the HR data for each wearable during the 3 activities. The Friedman test was again repeated for each wearable, and thus the Bonferroni was corrected to an α of .005. As a result, the tests indicated significant differences for the Apple Watch SE, Google Pixel Watch 2, Polar Ignite 3, and Xiaomi Watch 2. Therefore, multiple Wilcoxon signed rank tests were further performed to identify which pairs differed significantly, with rank-biserial *r* values ranging between 0.82 and 0.97. The Bonferroni-corrected significance level was set (α=.05/3=.0167)

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for the devices that are each tested for the 3 activities. The bilateral differences are indicated in Table 3.

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Table . Measurement accuracy statistics for all tested wearables for the 3 activities performed.

Activity wearable	MAE[a], median (IQR)			MAPE[b], median (IQR)			Repeated measures CCC[c]			Mixed-effects Bland-Altman								
	MIST[d]	Walking	Walking intermittent	MIST	Walking	Walking intermittent	MIST	Walking	Walking intermittent	Mean difference			Lower LoA[e]			Upper LoA		
										MIST	Walking	Walking intermittent	MIST	Walking	Walking intermittent	MIST	Walking	Walking intermittent
Fitbit Inspire 3	7.3 (4.2-18.3)	10.5 (6.8-21.4)	12.1 (7.1-17.4)	10.1 (6.3-27.2)	11.0 (6.6-23.0)	14.5 (6.4-18.5)	0.12	0.16	0.29	–11.1	–5.7	–13.8	–41.3	–33.3	–37.1	19.2	21.9	9.4
Fitbit Charge 6	3.6 (3.0-4.5)	3.8 (2.9-4.2)	3.4 (2.8-4.3)	5.2 (4.0-6.0)	3.7 (3.2-4.5)	3.6 (3.0-5.5)	0.67	0.78	0.80	0.8	3.3	0.5	–8.8	–8.3	–9.3	10.4	15.0	10.4
Garmin Vivosmart 5	5.3 (4.1-6.2)	7.9 (5.7-15.8)	6.5 (5.4-19.2)	7.4 (6.0-8.4)	6.5 (5.8-16.8)	6.8 (5.2-25.4)	0.42	0.41	0.34	6.9	7.1	0.7	–5.7	–17.6	–17.6	19.5	31.8	19.1
Garmin Vivoactive 5	4.3 (2.8-5.3)	5.9 (3.9-9.8)	5.6 (3.5-6.7)	5.4 (4.6-7.2)	6.4 (4.2-9.1)	5.9 (4.5-7.6)	0.49	0.55	0.52	0.6	0.6	–3.4	–11.7	–22.1	–20.1	12.8	23.2	13.4
Apple Watch SE	4.3[f] (3.6-6.4)	4.5[f] (4.0-6.9)	6.3 (5.4-7.6)	6.8 (4.8-9.0)	5.0[f] (3.8-7.6)	8.6 (6.3-9.3)	0.29	0.49	0.28	1.6	–0.8	–0.9	–10.0	–24.4	–28.5	13.3	22.7	26.6
Google Pixel Watch 2	4.0 (3.7-4.5)	6.1[g] (5.2-10.4)	5.5[g] (4.5-5.7)	6.2 (4.3-7.7)	6.2 (5.5-9.0)	6.8 (4.6-7.4)	0.63	0.45	0.72	0.1	–0.1	–1.0	–10.3	–22.2	–13.8	10.4	22.1	11.8
Polar Ignite 3	5.9 (3.3-6.8)	11.8 (7.2-16.8)	12.0[g] (10.3-16.8)	9.1 (4.6-9.6)	13.0 (7.2-14.3)	13.8[g] (10.7-23.4)	0.30	0.21	0.08	–1.0	2.9	–12.6	–15.6	–25.4	–37.6	13.7	31.1	12.3
Polar Pacer	7.0 (3.4-10.7)	8.2 (5.4-9.4)	10.5 (6.6-17.1)	10.4 (4.8-12.8)	7.9 (6.0-11.0)	11.4 (7.3-20.8)	0.21	0.23	0.18	–2.2	2.7	–8.5	–20.7	–21.0	–31.3	16.2	26.4	14.4
Xiaomi Watch 2	4.7 (2.9-7.3)	11.1[g] (6.4-14.1)	10.0[g] (8.0-19.2)	7.5 (4.3-10.2)	12.3[g] (6.0-15.7)	11.2[g] (8.2-21.1)	0.40	0.36	0.20	–1.1	1.2	–6.8	–15.7	–38.8	–42.2	13.4	41.2	28.5
Oura (Gen 3)	8.0 (4.2-20.4)	9.3 (4.7-13.9)	7.0 (5.1-13.5)	11.5 (5.1-29.0)	10.1 (4.7-14.0)	8.7 (4.3-16.4)	0.13	0.36	0.38	–7.8	1.3	–6.0	–33.7	–22.8	–25.9	18.2	25.4	13.9

[a]MAE: mean absolute error.

[b]MAPE: mean absolute percentage error.

[c]CCC: concordance correlation coefficient.

[d]MIST: Montreal Imaging Stress Task.

[e]LoA: limits of agreement.

[f]Significantly different from walking intermittently.

[g]Significantly different from performing the Montreal Imaging Stress Task test.

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Discussion

Principal Results

This study evaluated the HR accuracy of 10 commercially available wearable devices (9 watches and 1 ring) under varying environmental and activity conditions. Accuracy was assessed using multiple statistical approaches, including absolute and relative error metrics (MAE and MAPE), concordance with a reference chest strap (repeated-measures CCC), and agreement intervals (Bland-Altman analysis). To interpret these outcomes, established standards were applied. For example, the American National Standards Institute specifies a boundary of ±10% MAPE or ±5 bpm, whichever is greater, as acceptable error for cardiac monitors [25]. Correlation coefficients were interpreted as weak (≤0.5), moderate (0.5 - 0.7), or strong (≥0.7) [26,27], while a stricter criterion of CCC ≥0.80 has also been proposed in previous work [13,28]. Within this framework, our findings indicate differences in device performance: the Fitbit Inspire 3 and Oura Ring exhibited significantly higher errors and wider limits of agreement, whereas the Fitbit Charge 6 and Google Pixel Watch 2 met both the criterion of CCC ≥0.80 and the American National Standards Institute error boundaries. Interestingly, these results demonstrate that accuracy is not only brand-dependent but also device-specific, as even wearables from the same manufacturer, despite relying on similar PPG technology, can yield different outcomes.

Participants underwent repeated testing across 3 thermal environments, neutral (23 °C), hot (36 °C), and cold (10 °C), but we found no statistically significant effect of temperature condition on device accuracy after the Bonferroni correction. However, the type of physical activity did significantly affect HR measurement accuracy in several devices. Specifically, walking intermittently elicited larger errors in a subset of wearables. These results support our initial hypothesis that motion irregularity is a strong determinant of PPG-based HR accuracy.

Comparison With the State of the Art

The significant variability in accuracy across commercial wearables is consistent with earlier validation studies. Düking et al [29], for example, found marked differences in HR accuracy among 4 commercial wrist-worn devices (Apple Watch 4, Polar Vantage V, Garmin Fenix 5, and Fitbit Versa) during a structured treadmill protocol. They observed that vigorous or intermittent activities, particularly those involving sudden directional changes, were prone to introducing motion artifacts that degraded PPG signal quality. Our findings extend this line of work by demonstrating that even seemingly modest variations in movement patterns (eg, intermittent walking) can impact accuracy and that these effects differ between devices.

Interestingly, we did not find significant accuracy differences between climate conditions, which contradicts some theoretical expectations and anecdotal observations. Cold-induced vasoconstriction and heat-induced vasodilation are known to affect peripheral blood flow and optical signal amplitude [3,8,30]. However, it is possible that our selected temperature ranges (10-36 °C) were not extreme enough to meaningfully affect PPG signal quality, particularly in a short-term indoor protocol. Alternatively, modern signal-processing algorithms embedded in the wearables may have compensated for these physiological variations.

Prior studies have also highlighted the limitations of wrist-worn devices for certain populations and use cases. For example, variability in skin tone, arm hair, or wrist circumference can influence optical HR signal integrity [13,31], and these factors were not explicitly accounted for in our study. Nevertheless, the consistency of our findings across participants and the robustness of the repeated-measures statistical approach support the generalizability of our device comparisons.

Notably, the Fitbit Charge 6 consistently showed high accuracy across all conditions, with low MAE, low MAPE, and high repeated-measures CCC (>0.90). The Google Pixel Watch 2 and Garmin Vivosmart 5 also performed well, particularly during steady-state walking. In contrast, the Polar Ignite 3, Polar Pacer, and Oura Ring exhibited wider limits of agreement and lower CCC values, particularly during irregular activity. These differences may reflect varying PPG sensor designs, sampling rates, and proprietary signal-cleaning algorithms [32,33].

Physiological and Technical Considerations

PPG is inherently sensitive to movement artifacts, particularly when motion occurs along the axis of the light source or in tissues with variable compressibility (eg, wrists with varying musculature) [34]. Devices such as the Oura Ring, which is worn on the finger, may face additional challenges due to the vasomotor sensitivity of the digits and the smaller optical contact area. While rings offer the advantage of less wrist movement, they may be more susceptible to temperature-driven changes in blood flow [35], which could explain the relatively poorer performance of the Oura device in this study.

Furthermore, activity context plays a significant role. The MIST task, a standardized cognitive stressor with minimal physical exertion, was associated with lower HR variability and motion. This is consistent with evidence that cognitive demands and psychological stress typically reduce HR variability [36]. As a result, wearables generally performed well under these conditions. In contrast, intermittent walking introduced frequent postural and muscular transitions, posing a challenge for devices dependent on motion-compensated PPG. These findings align with previous observations that accuracy degrades in nonsteady-state conditions and that current algorithms may overfit to predictable, repetitive activity patterns [37,38].

Study Limitations

Several limitations should be acknowledged. First, the duration of each activity phase was relatively short (4 - 6 min). Longer monitoring periods might have revealed delayed effects of thermal stress or device drift. Second, while we designed the environmental conditions to simulate realistic hot and cold exposures, extreme climates or outdoor settings were not replicated. Third, we did not directly measure skin temperature or blood flow perfusion, which could have elucidated underlying physiological causes of error.

Moreover, our participant sample, although balanced across devices and arms, did not include diverse skin tones or body

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compositions, which may limit generalizability. We note from the literature that variations in skin tone are known to bias PPG accuracy [11], suggesting that device performance may differ in diverse populations. The skin tone of the participants in our study was not included in the data collection. In hindsight, we note a relatively homogenous population of lighter skin phototypes (Fitzpatrick type I-III). Additionally, while the sample had a broad age range (21 - 68 y) and a balanced sex distribution, the sample was predominantly younger adults, and only 5 older participants (ages 47 - 68) were involved. Hence, a formal analysis to quantify the isolated impact of skin tone, age, and sex on device accuracy was not performed, which may be a focus for future research. Finally, as with any study of commercial wearables, device firmware and algorithms may change over time, making it difficult to extrapolate our results to future updates of the same models.

Implications for Research and Practice

Our findings offer practical insights for researchers and health professionals selecting wearable devices for HR monitoring in mixed conditions. Devices such as the Fitbit Charge 6 and Google Pixel Watch 2 may offer sufficient accuracy for light-to-moderate physical activities in typical environmental conditions. However, researchers should exercise caution when using wearables for irregular activities or for applications that require high precision (eg, clinical monitoring or dose-response studies).

The study protocol can easily be replicated with other wearable devices, enabling comparisons between new devices and the 10 devices that have already been evaluated. For future validation studies, the inclusion of diverse populations, extended durations, and wearable signal-quality indices (eg, raw PPG, accelerometer-derived movement indices) would allow for a more granular understanding of error sources. Open-science practices, including the publication of raw validation data and code for statistical methods, will further support reproducibility and transparency in wearable health technology research.

Conclusions

In this comparative study of 10 commercial wearable devices, significant differences in optical HR accuracy were observed between brands and activity types. Climate conditions did not produce statistically significant effects on accuracy, suggesting robustness within the moderate temperature ranges tested. However, irregular movement patterns degraded performance in multiple wearables, highlighting the need for careful selection and context-aware interpretation of HR data in applied health and sports settings. Devices such as the Fitbit Charge 6 and Google Pixel Watch 2 demonstrated strong agreement with reference chest strap measurements, even across varied protocols. The device-specific findings should be interpreted with caution, as they pertain to the investigated models. Accuracy may vary considerably across other devices within the same brand, despite the use of similar PPG technology.

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Data Availability

The datasets generated and analyzed during this study are available from the corresponding author on reasonable request.

Authors' Contributions

Conceptualization: BB (supporting), CNVO (supporting), GD (supporting), JG (supporting), JMA (lead), NAJDW (supporting), RS (supporting), TC (supporting)
Data curation: CNVO (equal), JG (lead)
Formal analysis: CNVO (equal), JG (lead)
Funding acquisition: BB (lead), JMA (supporting), NAJDW (supporting)
Methodology: BB (supporting), CNVO (supporting), GD (supporting), JG (supporting), JMA (lead), NAJDW (supporting), RS (supporting), TC (supporting)
Project administration: BB
Supervision: JMA
Visualization: CNVO (equal), JG (lead)
Writing – original draft: CNVO (supporting), JG (lead)
Writing – review & editing: BB (supporting), CNVO (equal), GD (supporting), JG (lead), JMA (supporting), NAJDW (supporting), RS (supporting), TC (supporting)

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Conflicts of Interest

None declared.

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Abbreviations

CCC: concordance correlation coefficient
HR: heart rate
MAE: mean absolute error
MAPE: mean absolute percentage error
MIST: Montreal Imaging Stress Task
PPG: photoplethysmography

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Fine-Tuned Large Language Models for Generating Multiple-Choice Questions in Anesthesiology: Psychometric Comparison With Faculty-Written Items

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Abstract

Background: Multiple-choice examinations (MCQs) are widely used in medical education to ensure standardized and objective assessment. Developing high-quality items requires both subject expertise and methodological rigor. Large language models (LLMs) offer new opportunities for automated item generation. However, most evaluations rely on general-purpose prompting, and psychometric comparisons with faculty-written items remain scarce.

Objective: This study aimed to evaluate whether a fine-tuned LLM can generate MCQs (Type A) in anesthesiology with psychometric properties comparable to those written by expert faculty.

Methods: The study was embedded in the regular written anesthesiology examination of the eighth-semester medical curriculum with 157 students. The examination comprised 30 single best-answer MCQs, of which 15 were generated by senior faculty and 15 by a fine-tuned GPT-based model. A custom GPT-based (GPT-4) model was adapted with anesthesiology lecture slides, the National Competence-Based Learning Objectives Catalogue (NKLM 2.0), past examination questions, and faculty publications using supervised instruction-tuning with standardized prompt–response pairs. Item analysis followed established psychometric standards.

Results: In total, 29 items (14 expert, 15 LLM-generated) were analyzed. Expert-generated questions had a mean difficulty of 0.81 (SD 0.19), point-biserial correlation of 0.19 (SD 0.07), and discrimination index of 0.09 (SD 0.08). LLM-generated items had a mean difficulty of 0.79 (SD 0.18), point-biserial correlation of 0.17 (SD 0.04), and discrimination index of 0.08 (SD 0.11). Mann-Whitney *U* tests revealed no significant differences between expert- and LLM-generated items for difficulty (P=.38), point-biserial correlation coefficient (P=.96), or discrimination index (P=.59). Categorical analyses confirmed no significant group differences. Both sets, however, showed only modest psychometric quality.

Conclusions: Supervised fine-tuned LLMs are capable of generating MCQs with psychometric properties comparable to those written by experienced faculty. Given the limitations and cohort-dependency of psychometric indices, automated item generation should be considered a complement rather than a replacement for manual item writing. Further research with larger item sets and multi-institutional validation is needed to confirm generalizability and optimize integration of LLM-based tools into assessment development.

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KEYWORDS

medical education; multiple-choice questions; large language models; fine-tuning; psychometrics; assessment; anesthesiology; artificial intelligence

Introduction

Multiple-choice questions (MCQs) are fundamental to the objective assessment of medical students. They allow standardized testing across large cohorts and play a central role in evaluating foundational and applied knowledge [1]. However, the development of high-quality MCQs demands not only deep domain knowledge but also significant methodological and didactic expertise [2,3]. Effective items must balance appropriate difficulty, plausible distractors, minimal cueing, and strong discriminatory power to differentiate between varying levels of student performance [4].

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Recent advances in artificial intelligence (AI), particularly large language models (LLMs), offer novel tools for automated question generation. For instance, efforts comparing ChatGPT-3.5–generated MCQs with expert-written items in neurophysiology revealed similar difficulty levels but lower discriminatory power in LLM-generated questions [5]. A systematic review of LLM use in medical MCQ generation found that while LLMs can produce examination-relevant items, many require additional modification due to quality issues [6]. Other studies highlight linguistic and structural shortcomings in automatically generated MCQs, particularly regarding distractor plausibility and alignment with instructional content [7,8].

Recent domain-specific efforts such as Hypnos [9], CDGen [10], and the Chinese Anesthesiology Benchmark [11] have demonstrated that LLMs can be effectively fine-tuned or benchmarked within anesthesiology. However, these studies primarily focus on domain adaptation and benchmark performance rather than psychometric validation of automatically generated examination items. To address this gap, a GPT-based model was adapted using anesthesia-specific teaching materials, the National Competence-Based Learning Objectives Catalogue in Medicine (NKLM 2.0), past examination items, and faculty publications [12]. Item development for both expert- and AI-generated questions was systematically mapped to the NKLM 2.0, Bloom's taxonomy, and the local examination blueprint to ensure comprehensive curricular coverage and to allow a fair psychometric comparison.

This study aimed to evaluate whether a fine-tuned LLM can generate MCQs (Type A) in anesthesiology with psychometric properties comparable to those written by expert faculty.

Methods

Overview

This study analyzed the performance of MCQs used in the regular written examinations of anesthesiology in the eighth semester of medical training with 157 students. The examination consisted of 30 items. Half of the items (n=15) were written by senior faculty members, and half (n=15) were generated by a fine-tuned LLM. Nine faculty members from the Department of Anesthesiology, each with at least 10 years of experience, participated in item creation. All had prior training in assessment design through institutional workshops on multiple-choice item writing. In addition, all items were independently reviewed by an educational specialist with a Master of Medical Education degree to ensure adherence to established item-writing principles. Faculty were aware of the study but blinded to the psychometric comparison during data collection.

Data analysis was performed fully anonymously. The participating students were regular medical students in their eighth semester. They were not informed about the origin of the examination questions and therefore did not know whether an item was generated by faculty or the LLM.

A customized GPT-based model was developed specifically for this study. The model was built as a domain-adapted instance of GPT-3.5-Turbo, configured to generate single-best-answer MCQs. Adaptation followed a supervised instruction-tuning approach: several hundred standardized prompt-response pairs were created using anesthesiology lecture slides, NKLM 2.0, past examination questions, and faculty publications. Faculty publications were included to capture authentic domain phrasing and ensure that the model reflected institution-specific conceptualizations of anesthetic procedures. Previous research shows that faculty development and the use of high-quality source material improve item validity and discrimination [13].

These materials were curated to align with Bloom's taxonomy and national curricular requirements [14]. The fine-tuning pipeline can be found in Multimedia Appendix 1.

Item analysis followed established psychometric standards. Difficulty was defined as the mean proportion of correct responses (0 - 1). Values between 0.30 and 0.70 are generally considered optimal, those greater than 0.70 indicate easy items, and those less than 0.30 indicate difficult items [15,16]. The point-biserial correlation was classified as follows: negative correlation ($r<0$), very low correlation ($0\leq r<0.10$), low correlation ($0.10\leq r\leq 0.20$), and acceptable correlation ($r\geq 0.20$) [15]. The discrimination index (D) was calculated as the difference in difficulty between the upper and lower 27% performance groups, with values of 0.40 and above considered excellent; 0.30 - 0.39, good; 0.20 - 0.29, acceptable; and those less than 0.20, poor [15,16]. Statistical analysis was performed using SPSS Statistics version 27 (IBM Corp). Graphs were created with Prism 9 (GraphPad Software). Nominal variables were summarized as counts and percentages. The Shapiro-Wilk test was used to test for normal distribution. Group comparisons of categorical data were performed with the chi-square test or Fisher exact test if expected frequencies were less than 5. Continuous data were reported as mean and SD values and compared using the Mann-Whitney *U* test. A significance level of $P\leq .05$ was applied.

Figure 1 summarizes the item-generation workflow, including consolidated inputs, supervised instruction-tuning, the custom GPT MCQ generator, and parallel faculty-written items converging into the examination.

Ethical Considerations

The study was submitted to the Ethics Committee of the University of Würzburg, which confirmed (reference number 2024- - 258-ka on November 11, 2024) that no formal review was required and that no ethical objections were raised.

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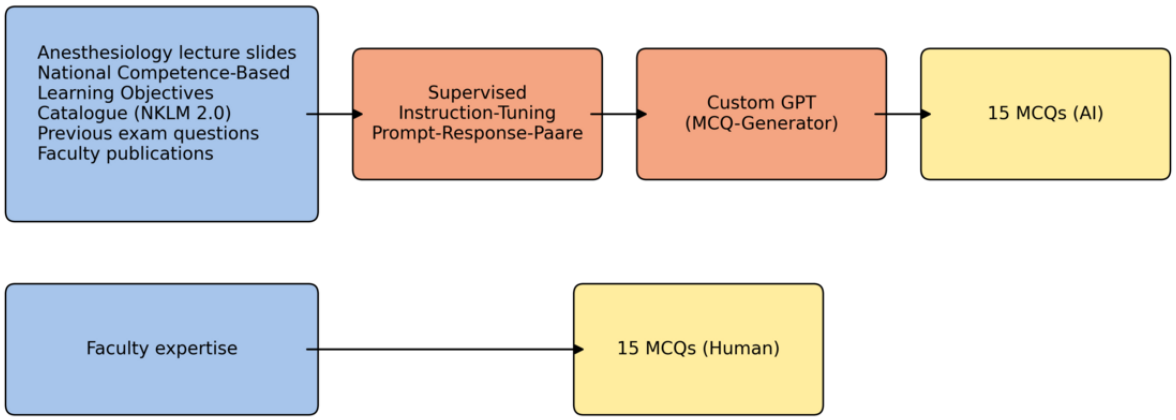
Figure 1. Item-generation workflow. Consolidated inputs (anesthesiology lecture slides, NKLM 2.0, prior examination items, faculty publications) inform supervised instruction-tuning of a custom GPT configured for single-best-answer MCQs to produce 15 AI-generated questions. In parallel, faculty authored 15 questions. AI: artificial intelligence; MCQ: multiple-choice question.



Results

A total of 30 MCQs were analyzed. One expert-generated item was excluded from analysis due to a strongly negative discrimination index (–0.22) and negative point-biserial correlation (–0.20). Its difficulty (*P*=.86) indicated a ceiling effect, suggesting that most students answered it correctly despite unclear key wording.

The final dataset therefore included 14 expert-generated and 15 AI-generated items. Table 1 displays the descriptive metrics for expert- and AI-generated items. Expert-generated items showed a mean difficulty of 0.81 (SD 0.19), a mean point-biserial correlation of 0.16 (SD 0.07), and a mean discrimination index of 0.09 (SD 0.08). AI-generated items had a mean difficulty of 0.79 (SD 0.18), a mean point-biserial correlation of 0.17 (SD 0.04), and a mean discrimination index of 0.08 (SD 0.11). Mann-Whitney *U* tests indicated no significant differences between expert- and AI-generated items with respect to difficulty (*P*=.38), point-biserial correlation (*P*=.96), or discrimination index (*P*=.59; Figure 2).

Table . Overview of question metrics by expert and artificial intelligence (AI).

Question created by	Questions, n	Metrics		
		Minimum	Maximum	Difficulty, mean (SD)
Expert				
Difficulty	14	0.48	0.99	0.81 (0.19)
Point-biserial correlation	14	−0.02	0.20	0.16 (0.07)
Discrimination index	14	0.01	0.24	0.09 (0.08)
AI				
Difficulty	15	0.44	0.98	0.79 (0.18)
Point-biserial correlation	15	0.08	0.25	0.17 (0.04)
Discrimination index	15	−0.07	0.33	0.08 (0.11)

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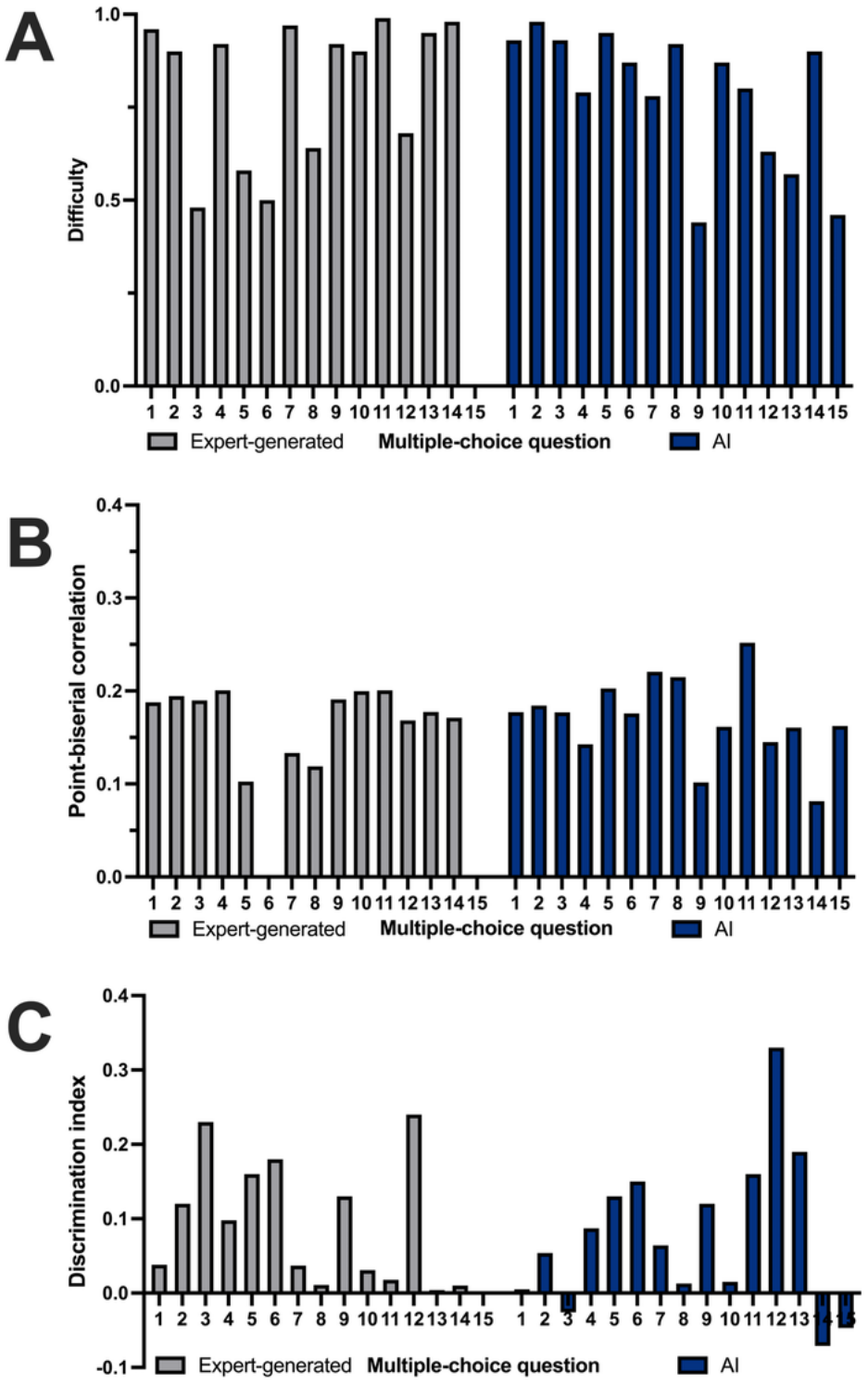
Figure 2. Psychometric characteristics of AI- and expert-generated multiple-choice items. (A) Item difficulty, (B) point-biserial correlation, and (C) discrimination index is displayed for each question. AI: artificial intelligence.



Reference ranges are as follows:

- Difficulty (P)=0.30-0.70 is considered desirable;
- Discrimination (r_{pb})≥0.20 is considered acceptable;
- r_{pb}<0 indicates flawed items [17].

The categorical distributions of item properties are summarized in Table 2.

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Table . Psychometric characteristics of expert- and LLM[a]-generated items displayed side by side for difficulty, point-biserial correlation, and discrimination index.

	Questions, n (%)	
	Expert-generated (n=14)	LLM-generated (n=15)
Difficulty categories		
Extremely difficult ($P \leq 0.25$)	0 (0)	0 (0)
Tends to heavy ($0.25 < P \leq 0.4$)	0 (0)	0 (0)
Optimal difficulty ($0.4 < P \leq 0.8$)	5 (35.7)	6 (40.0)
Very simple ($0.8 < P \leq 0.9$)	0 (0)	3 (20.0)
Extremely simple ($P > 0.9$)	9 (64.3)	6 (40.0)
Point-biserial correlation categories		
Negative correlation ($r < 0$)	1 (7.1)	0 (0)
Very low correlation ($0 \leq r < 0.10$)	0 (0)	1 (6.7)
Low correlation ($0.1 \leq r \leq 0.20$)	8 (57.1)	10 (66.7)
Acceptable correlation ($r \geq 0.20$)	5 (35.7)	4 (26.7)
Discrimination index categories		
Urgent need for revision (D'<0)	0 (0)	3 (20.0)
Need for revision (0≤D'<0.2)	12 (85.7)	11 (73.3)
Check required (0.2≤D'<0.3)	2 (14.3)	0 (0)
Potential for improvement (0.3≤D'<0.4)	0 (0)	1 (6.7)
Item effectively distinguishes (D'≥0.4)	0 (0)	0 (0)

[a]LLM: large language model.

Discussion

Principal Findings

In this study, we compared psychometric properties (difficulty, point-biserial correlation, and discrimination) of MCQs generated by a supervised fine-tuned LLM with those written by expert faculty in an undergraduate anesthesiology examination. Although no statistically significant differences were observed, the overall quality of both item sets remained moderate. The point-biserial correlations and discrimination indices suggest that neither set reliably distinguishes higher- from lower-performing students, a finding consistent with previous research indicating that even expert-authored items often underperform in psychometric analyses [18]. This pattern aligns with broader evidence in medical education, where cohort studies have demonstrated that AI-generated MCQs often achieve discrimination indices similar to expert-generated items but tend to be easier overall and still require expert review to ensure distractor plausibility and alignment with higher-order learning objectives [5,19-23].

Supervised adaptation with domain-specific materials likely contributed to the close alignment of psychometric indices between AI and faculty-written items. Other work shows that when AI-mediated question generation is guided by domain content, structured prompts, or instruction tuning, the output more closely resembles faculty items in both difficulty and discrimination [7,8,19,24]. Notably, neither item set in our study consistently achieved high point-biserial correlation or discrimination, confirming that generating functionally effective distractors remains a challenge for both experts and LLMs [25-30]. Prior studies have similarly identified that AI items often underperform in assessing higher cognitive levels or using plausible distractors without ambiguity [8].

The absence of psychometric superiority in either group suggests that AI-assisted question generation can produce items of comparable statistical quality to traditional item writing. However, psychometric analysis alone is insufficient for examination quality assurance; human oversight remains essential to safeguard content validity, blueprint alignment, and cognitive level coverage. Studies in high-stakes examination settings show that expert review reduces factual inaccuracies and improves alignment with assessment blueprints [31]. Importantly, in our study, the fine-tuned LLM generated all 15 candidate items within a few minutes. While we evaluated only a subset psychometrically, our study demonstrates that domain-adapted LLMs support rapid item drafting at scale. Automatic item generation methods have long promised efficiency gains by expanding item pools from templates rather than crafting each item manually [32]. Recent AI studies show that LLM-based MCQ generation can approach human performance while drastically reducing human effort [33]. In practice, educators may use LLM throughput to generate large candidate sets and then filter, refine, and align items to the blueprint and cognitive levels, shifting effort from generation toward qualitative review and validation.

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Limitations and Future Work

Study limitations include a small item sample size, single-institution administration, and fine-tuning with primarily local teaching resources, which may reduce external validity. Cognitive level of items (eg, recall vs application) was not measured, although comparative studies indicate this is an important differentiator between AI- vs expert-generated MCQs [31]. Future work should involve larger item pools, multi-institutional validation, and systematic qualitative review of items, including stem clarity, distractor plausibility, and distractor efficiency, as well as cognitive demand. It would also be valuable to compare different fine-tuning or prompt-engineering strategies and to assess students' perceptions of AI-generated items [34].

Conclusion

This study demonstrates that a supervised fine-tuned LLM can generate MCQs with psychometric properties comparable to those created by experienced faculty. While neither approach consistently produced items with high point-biserial correlation or discrimination, the results indicate that automated question generation can complement traditional item writing in medical education.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Technical workflow and dataset construction for fine-tuned large language model–mediated item generation.
[PDF File, 164 KB - formative_v10i1e84904_app1.pdf]

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Abbreviations

AI: artificial intelligence
LLM: large language model
MCQ: multiple-choice question
NKLM 2.0: National Competence-Based Learning Objectives Catalogue in Medicine

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Feasibility of a Noncontact Photoplethysmography–Based Mobile App for Noninvasive Hemoglobin Monitoring: Exploratory Observational Study

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Abstract

Background: Anemia is a widespread global health issue. Hemoglobin (Hb) concentration measurement remains the most common method for anemia screening and diagnosis. In recent years, there has been growing interest in the development of noninvasive point-of-care technologies that eliminate the need for blood sampling.

Objective: This pilot study explores the feasibility of using a noncontact photoplethysmography–based mobile app for Hb monitoring.

Methods: Adult volunteers aged 18 years and older, of both sexes, were consecutively recruited. Participants were seated and allowed a 2-minute rest before measurements. During testing, they faced a smartphone running comestai.app, which used the front-facing camera to capture facial videos. Simultaneous readings were collected for Hb over approximately 90 seconds using the app. Ambient lighting was standardized for all remote photoplethysmography recordings. No medical decisions were made based on the app-generated data. A complete blood count, including Hb levels, was used as a reference for comparison with the data collected using comestai.app.

Results: A total of 555 (female: n=313, 56.4%; male: n=242, 43.6%) individuals participated in the study. The app achieved a mean absolute error of 1.46, a mean absolute percentage error of 11.26, a mean error of −0.67, and a root mean square error of 1.88. The Bland-Altman plot evaluated the agreement between the app-based and laboratory-based Hb measurements, with the mean difference between the 2 methods being −0.70 g/dL. The method demonstrated an overall accuracy of 75%. The area under the curve was 0.701 (95% CI 0.655-0.745).

Conclusions: Comestai.app offers an innovative approach to wellness monitoring by providing noninvasive Hb estimation using the smartphone's front-facing camera. Continued development, including algorithmic refinement and larger-scale validation in diverse populations, will be key to enhancing accuracy and broadening its utility. By leveraging the ubiquity of smartphones, comestai.app contributes meaningfully to the democratization of health monitoring and the promotion of proactive self-care.

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Trial Registration: ClinicalTrials.gov NCT06427564; https://clinicaltrials.gov/study/NCT06427564

(JMIR Form Res 2026;10:e78820) doi:10.2196/78820

KEYWORDS

noncontact photoplethysmography; noncontact PPG; mobile app; hemoglobin; noninvasive monitoring

Introduction

Background

Anemia is a widespread global health issue and a major public health concern, particularly in resource-limited settings [1]. It affects individuals across all age groups and sexes, leading to adverse health outcomes and reduced national economic productivity [2]. According to the World Health Organization (WHO), anemia is estimated to affect approximately half a billion women aged 15 to 49 years and 269 million children aged 6 to 59 months worldwide. In 2019, an estimated 30% (539 million) of nonpregnant women and 37% (32 million) of pregnant women within this age group were affected by anemia [1,3].

Anemia can result from various underlying causes, including nutritional deficiencies (such as iron, vitamin B12, or folate), chronic blood loss, chronic or infectious diseases, genetic disorders, bone marrow and hematologic conditions, as well as exposure to toxins and certain medications [1]. Early and accurate detection of anemia is crucial for effective patient management and improved health outcomes [4].

Hemoglobin (Hb) concentration measurement remains the most common method for anemia screening and diagnosis [2-5,6]. Conventional techniques typically involve invasive procedures such as venipuncture or fingerstick blood tests, requiring trained personnel, laboratory infrastructure, and costly equipment [7-9]. These methods, while accurate, pose logistical challenges in remote settings, contribute to patient discomfort, introduce delays in reporting, and generate biomedical waste [7-9].

To address these limitations, point-of-care (POC) devices have been developed to facilitate rapid Hb estimation using capillary blood from a simple finger prick [3,10,11]. While such devices improve field usability, they still require reagent stability, periodic calibration, and controlled storage conditions [10,11].

In recent years, there has been a growing interest in the development of noninvasive POC technologies that eliminate the need for blood sampling [12-14]. These innovations aim to address the limitations of traditional and minimally invasive methods by enhancing usability, portability, and affordability, particularly in low-resource settings. Devices such as digital hemoglobinometers, pulse oximeters, and spectroscopy-based technologies have shown considerable promise in expanding access to anemia screening [15-17].

Among these, photoplethysmography (PPG)-based devices represent a particularly attractive approach [18,19]. By measuring variations in light absorption due to pulsatile blood flow, PPG enables indirect estimation of Hb concentration without requiring blood collection or chemical reagents, thereby increasing safety and convenience for both patients and health care workers.

In this context, smartphone-based technologies are also emerging as promising tools for noninvasive anemia detection using PPG signals [20-23]. By using the built-in camera and flash, several apps estimate Hb concentration through image analysis of anatomical regions such as the fingernail beds, palpebral conjunctiva, or lower eyelids. These systems often use machine learning (ML) algorithms to identify colorimetric or textural features correlated with Hb levels, offering a rapid, cost-effective alternative to traditional blood tests [21,24]. In addition, portable, smartphone-connected hemoglobinometers allow for more precise readings using small capillary blood samples, enabling longitudinal monitoring and integration with telehealth services [25]. While these solutions offer clear advantages in terms of accessibility and ease of use, further validation and regulatory approval are necessary to ensure clinical reliability and safety.

This Study

This pilot study explores the feasibility of using a noncontact, PPG-based mobile app, previously considered for the detection of vital signs [26,27], for Hb monitoring. The rise of noninvasive tools embodies the evolution of mobile health technologies aimed at promoting individual autonomy in health management through accessible, cost-effective, and scalable solutions, particularly suited for large-scale screening and use in resource-limited settings.

Methods

Study Design

This observational study evaluated the accuracy of a noncontact smartphone app, comestai.app (Come Stai S.p.A.), in measuring Hb, using a standard blood reference. All app data were collected by trained personnel, and smartphone connectivity was disabled during sessions to ensure offline data acquisition. Data were securely stored using anonymized identification numbers. The study's complete protocol has been registered on ClinicalTrials.gov (NCT06427564).

Recruitment

Adult volunteers (aged ≥18 years, both sexes) were enrolled from outpatient clinics at Azienda Socio-Sanitaria Territoriale-Fatebenefratelli Sacco-Buzzi Hospital (Milan, Italy), Istituto di Ricovero e Cura a Carattere Scientifico MultiMedica (Milan, Italy), and Istituto di Ricovero e Cura a Carattere Scientifico Istituto Auxologico Italiano (Milan, Italy) between September 2024 and April 2025. Participants were referred for management of obesity, diabetes, or hypertension. All patients attending the clinics during the study period were consecutively approached and invited to participate. Following verbal

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agreement, written informed consent was obtained in accordance with ethical standards. After consent was provided, demographic and biometric data, including sex, age, weight, height, and BMI (kg/m²), were collected through direct patient interview and verified against medical records. Subsequently, clinical measurements were performed in accordance with the study protocol.

Eligibility Criteria

To participate in the study, participants had to meet the inclusion criteria and not present any of the exclusion criteria listed in Textbox 1.

Textbox 1. Inclusion and exclusion criteria.

Inclusion criteria

- Ability to understand study information and provide written informed consent
- Participants aged between 18 and 65 years
- Capability and willingness to comply with all study-related procedures

Exclusion criteria

- Circulatory problems, injuries, or anatomical anomalies involving the fingers, hands, ears, forehead, skull, or any other body area essential to the study assessments
- Tattoos located in areas relevant to optical measurements that interfere with data collection
- Known hypersensitivity or allergic reactions to common medical-grade materials such as adhesives or latex used in sensor-based apps
- Any health condition that, based on the investigator's clinical judgment, could interfere with the performance or validity of study evaluations
- General unsuitability for participation as determined by the investigator

Measurement Procedure

Participants were seated and allowed a 2-minute rest before measurements. During testing, they faced a smartphone running comestai.app, which used the front-facing camera to capture facial videos. Simultaneous readings were collected for Hb over approximately 90 seconds using the app [26,27].

Ambient lighting was standardized for all remote photoplethysmography (rPPG) recordings. No medical decisions were made based on app-generated data.

A complete blood count, including Hb levels, was used as a reference for comparison with the data collected using comestai.app.

App Description

Comestai.app uses a proprietary signal processing pipeline for rPPG via the smartphone's front camera. The system captures facial video frames, focusing on the upper cheek, and processes red, green, and blue signals to extract subtle variations in skin coloration due to blood flow. As previously reported, the signal processing pipeline involves several sequential steps. First, raw signals are acquired using the app's software development kit. These signals are then analyzed through rPPG techniques, which detect subtle color fluctuations in the skin caused by pulsatile blood flow and convert them into raw pulse waveforms. The resulting signal undergoes processing to reduce noise and motion artifacts, using filtering, normalization, and quality control methods. Subsequently, advanced ML, deep learning, and computer vision techniques are applied to extract relevant features from the cleaned signal. Finally, the system validates the output in real time, ensuring that only measurements with high confidence levels are reported. The app functions offline and does not transmit user data. Version 5.6.3 was used on iOS devices during this study [27].

Statistical Analysis

Descriptive statistics for numerical variables (mean, SD, median, quartiles, and minimum-maximum) and frequencies for categorical variables were reported. Accuracy was assessed by comparing app readings with those from reference devices using mean error, mean absolute error (MAE), root mean square error, and mean absolute percentage error (MAPE).

Diagnostic performance was evaluated through sensitivity, specificity, positive predictive value, negative predictive value, accuracy, and likelihood ratios, each with 95% CIs.

Thresholds for normal physiological parameters were adopted from WHO references: Hb <12 g/dl for women and Hb <13 g/dl for men [1]. In our study, the reference to WHO diagnostic thresholds was used solely as a benchmark to contextualize the results within widely recognized clinical standards, not to suggest diagnostic use, and the app should be regarded as a proof-of-concept wellness app.

Correlations between app and reference data were calculated using Pearson *r*, with results visualized via regression plots including R^2 values. Agreement was further assessed with Bland-Altman analysis. All analyses were performed using Microsoft Excel (with Solver and Data Analysis ToolPak) and partially verified in R software (version 4.3.3; R Foundation for Statistical Computing) for cross-validation.

Ethical Considerations

To enhance the methodological quality, the protocol has been developed in accordance with the SPIRIT (Standard Protocol Items: Recommendations for Interventional Trials) guidelines for clinical trial protocols (Checklist 1).

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Results

A total of 555 participants (female: n=313, 56.4%; male: n=242, 43.6%) were enrolled. The sample was well balanced in terms of sex. Participants were distributed across 3 age groups: 8.3% (n=46) were aged between 18 and 35 years, 26.9% (n=149) were aged between 36 and 55 years, and 64.8% (n=360) were older than 55 years. The mean BMI was 30.69 (SD 7.34) kg/m², indicating that the study population predominantly comprised participants with overweight or obesity, as expected for the enrolled population. On the basis of blood Hb values, a prevalence of 10.27% (n=57) anemia was observed.

Table 1 summarizes the descriptive data and performance metrics of Hb values recorded using the mobile app compared to those obtained via standard laboratory methods. The app achieved an MAE of 1.46, MAPE of 11.26, a mean error of −0.67, and root mean square error of 1.88.

Table . Descriptive statistics and agreement metrics for hemoglobin values recorded via the mobile app and laboratory reference device.

Parameters	Mean (SD)	Median (IQR)	Mean absolute error	Root mean square error	Mean error	Mean absolute percentage error	Pearson correlation coefficient
App	13.37 (1.10)	13.30 (12.70-14.10)	1.46	1.88	−0.67	11.26	0.12
Laboratory	14.04 (1.51)	14.00 (13.10-15.00)	1.46	1.88	−0.67	11.26	0.12

In Table 2, the diagnostic accuracy of Hb detection using the app was assessed against conventional measurements. Sensitivity, specificity, positive predictive value, negative predictive value, positive likelihood ratio, negative likelihood ratio, and accuracy were calculated. The method showed good specificity (88.9%), but low sensitivity (6.4%), with an accuracy of 75%. As represented in Figure 1, the area under the curve was 0.701 (95% CI 0.655-0.745).

Table . Accuracy of vital parameters using the mobile app and the conventional method.

	Hemoglobin[a]
Specificity	0.889
Sensitivity	0.064
Positive predictive value	0.105
Negative predictive value	0.823
Accuracy	0.750
Positive likelihood ratio	0.577
Negative likelihood ratio	1.053

[a]Normal hemoglobin values are ≥12 g/dl for women and ≥13 g/dl for men.

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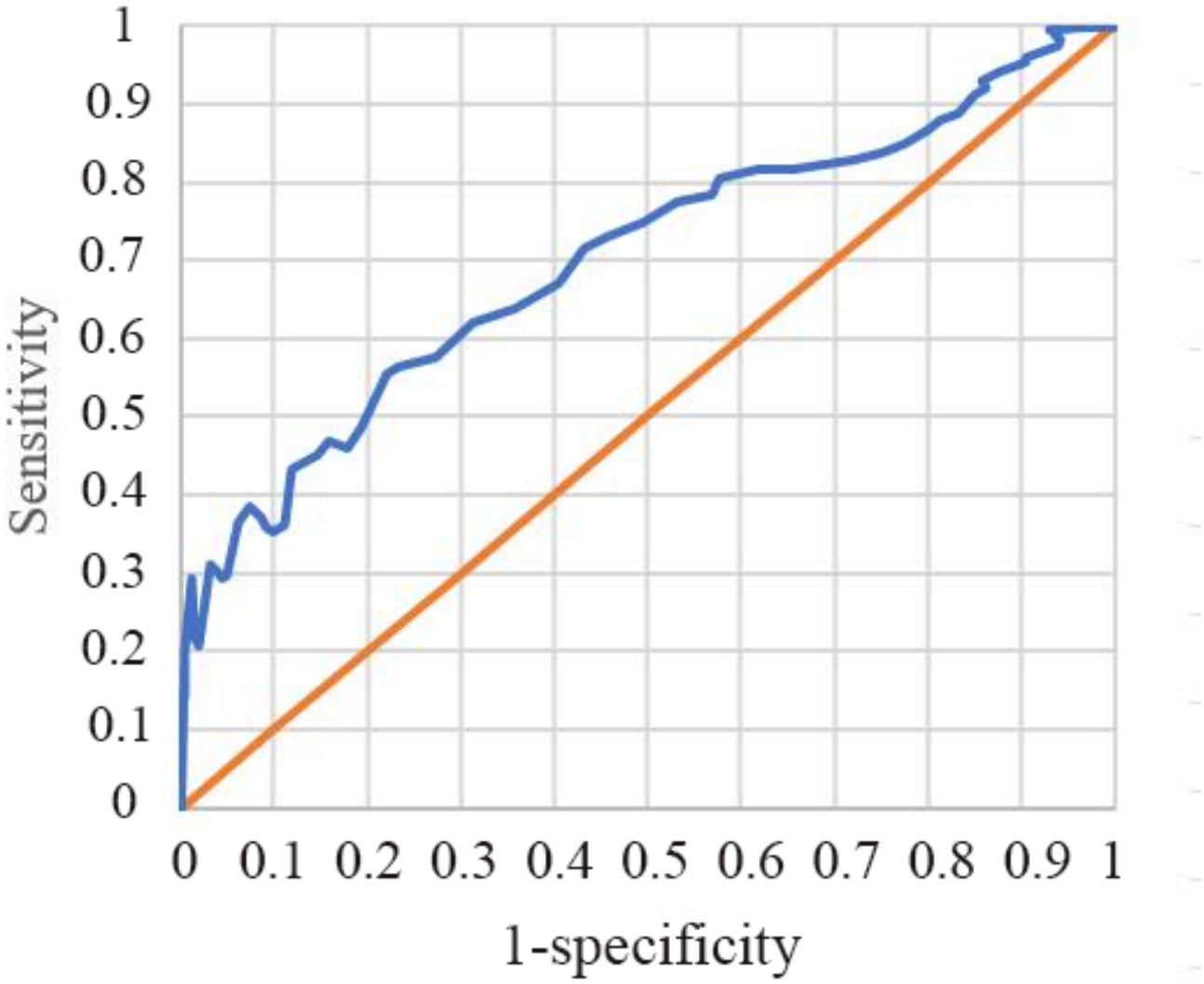
Figure 1. Receiver operating characteristic curve. The area under the curve was 0.701 (95% CI 0.655-0.745).



The Bland-Altman plot in Figure 2 evaluated the agreement between the app-based and laboratory-based Hb measurements. Most data points fell within the 95% CI, with the mean difference between the 2 methods being −0.70 g/dL. The clustering of points around the mean and a narrowing spread at higher Hb levels suggest a generally good agreement despite some systematic underestimation by the app.

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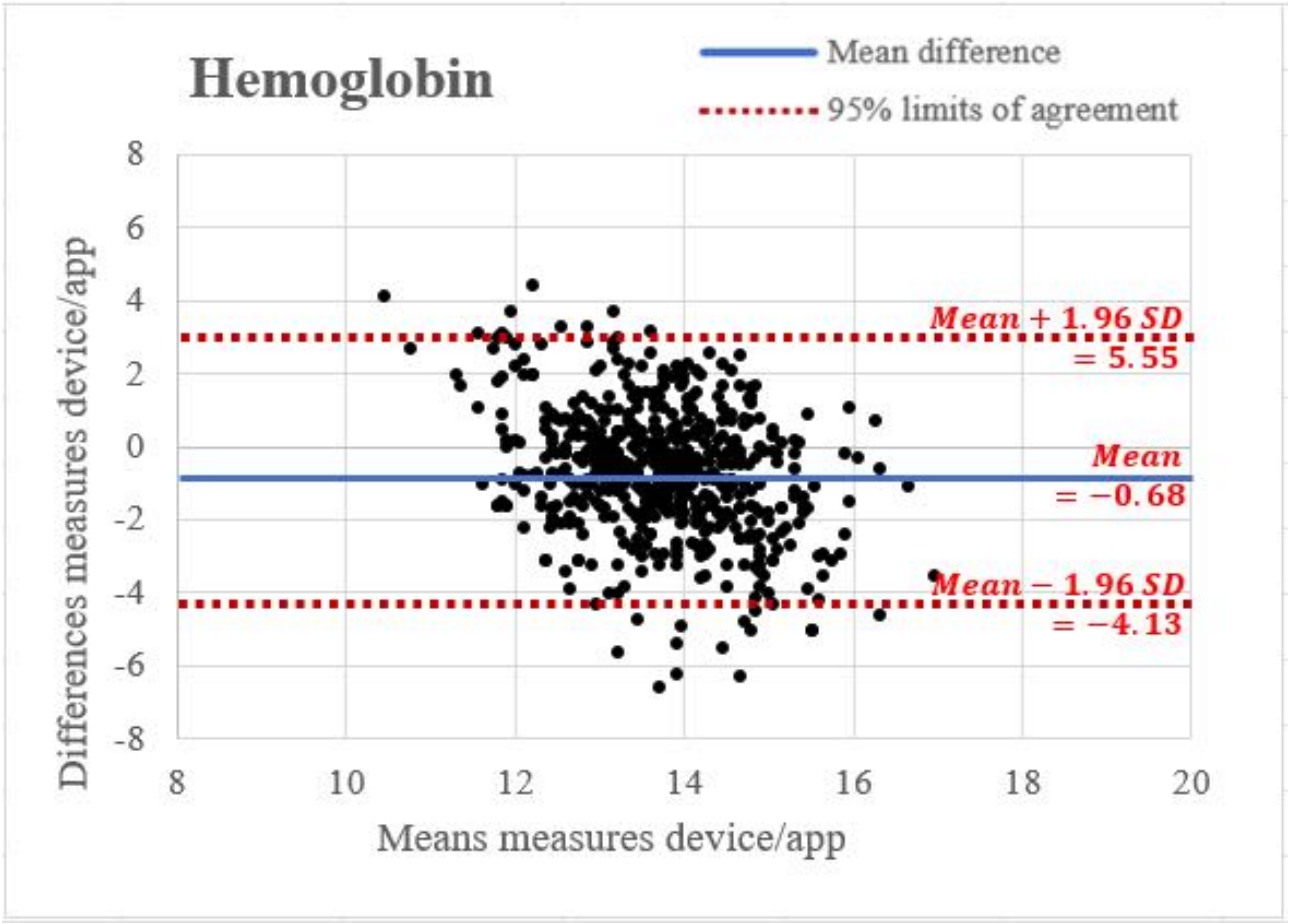
Figure 2. Bland-Altman plot for hemoglobin measurements comparing the mobile app with the standard method. The plot includes a central horizontal line indicating the average difference between the 2 measurement methods. Two additional horizontal lines are drawn to show the limits of agreement, defined as the mean difference (SD 1.96) times the SD of the differences. This range encompasses 95% of the differences between the methods, providing a visual representation of their agreement.



Discussion

Principal Findings

Comestai.app offers an innovative approach to wellness monitoring by providing noninvasive Hb estimation using the smartphone's front-facing camera. This study assessed the accuracy and diagnostic reliability of the app compared to standard laboratory methods. While the app slightly underestimated Hb values on average, overall agreement was observed, with most data falling within acceptable limits for nonmedical apps. These findings suggest that the app may serve as a useful tool for preliminary screening and self-monitoring, especially in wellness contexts where invasive methods are impractical or unavailable.

As indicated by the WHO [1], anemia is one of the most widespread health conditions globally, negatively affecting energy levels, productivity, and quality of life. Therefore, Hb monitoring is a fundamental tool in health promotion, especially in settings where access to conventional diagnostic tools is limited [28].

Conventional Hb measurement using venous blood is considered highly accurate and serves as the clinical gold standard. However, it involves discomfort due to needle pricks, requires trained personnel and expensive equipment, and causes delays in result reporting [5,7,8]. In contrast, noninvasive or minimally invasive POC devices offer quicker results, greater patient comfort, and ease of use, particularly in resource-limited settings. These devices enhance portability and patient satisfaction but may be less accurate and require regular calibration, while also being sensitive to environmental conditions such as light and temperature [10,11].

In this context, mobile health technologies have emerged as strategic tools for wellness-oriented self-assessment [29-31], including the monitoring of Hb levels [21,32]. Although not classified as medical devices, these solutions can facilitate individual health tracking and support the early identification of deviations from physiological norms, thereby contributing to improved self-management and preventive health care practices.

Mobile devices and digital apps, such as comestai.app, now allow users to track their blood levels directly from home, without the need for additional equipment or clinical infrastructure, thereby reducing the need for frequent medical visits [33-35]. This approach improves accessibility in remote or underserved areas, reduces costs compared to traditional laboratory testing, and fosters patient autonomy in managing anemia or chronic health conditions more proactively. It is particularly relevant for older individuals [36,37] who are more susceptible to anemia and often face mobility challenges, thus

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highlighting the importance of regular, noninvasive Hb monitoring.

Compared to other noncontact or smartphone-based technologies, comestai.app shows performance that is within the expected range. For example, HemaApp, a smartphone-based Hb monitoring tool proposed by Wang et al [38], achieved an accuracy of ±1.26 g/dL with a correlation coefficient of 0.82 when compared to standard blood tests. HemaApp required additional light sources for optimal performance, whereas comestai.app works using only ambient light and a smartphone camera, thus improving ease of use and accessibility, though possibly at the cost of slightly lower sensitivity.

A study published by Mannino et al [21] demonstrated a fingernail image–based system with 95% limits of agreement of ±2.4 g/dL and minimal bias, showing high sensitivity (up to 97%) in detecting anemia at a standard clinical threshold. In comparison, comestai.app showed excellent specificity but lower sensitivity, resulting in an overall good level of accuracy. This discrepancy is likely due to differences in the study population and the relatively small proportion of participants with low Hb levels in our sample. Such imbalance may have limited the model's exposure to pathological cases, reducing its diagnostic power for anemia detection.

Other promising rPPG-based models, such as one validated in a clinical setting in Singapore, reported a MAPE of 8.52% and a mean difference of 0.23 g/dL between predicted and laboratory Hb values. In our case, the MAPE was slightly higher, possibly reflecting differences in signal processing techniques, but still within the range reported for wellness-oriented apps [39,40]. The Bland-Altman analysis from our study revealed a narrow spread and clustering around the mean at higher Hb levels, suggesting greater measurement stability in individuals with normal or elevated values.

In our study, the Pearson correlation coefficient between Hb values estimated by the app and those obtained through standard clinical methods was low. However, a strong linear correlation is not necessarily required for the intended purpose of the app, which is not to reproduce exact laboratory values but rather to identify individuals at potential risk of anemia using threshold-based approaches. Even with limited absolute agreement, the app may still discriminate between individuals above or below clinically relevant cutoffs (eg, the WHO anemia threshold), highlighting potential utility despite weak linear correlation. Moreover, as previously reported for other vital parameters [41], improvements in the *P* value can be achieved by refining signal processing techniques and incorporating multiple facial regions of interest. These approaches could similarly contribute to improving the accuracy of Hb measurements. In addition, we acknowledge the presence of a systematic bias of −0.70 g/dL, which may be clinically significant and needs to be addressed in terms of both its implications and the possibility of algorithmic calibration in future versions. Therefore, future developments will prioritize optimizing the signal processing pipeline and enhancing robustness against confounding factors such as lighting variability and participant motion, with the aim of improving the accuracy and reliability of noninvasive Hb estimation.

One key advantage of comestai.app is its entirely contactless approach, making it suitable for frequent home use without additional equipment. This is especially valuable in wellness contexts and for populations with limited access to health care. In particular, it may offer a valuable alternative for specific populations, such as older individuals, who may require more frequent monitoring due to their increased susceptibility to anemia and reduced physiological reserves [42-44], as well as other at-risk groups including pregnant women [45-48], patients with chronic diseases (such as chronic kidney or inflammatory conditions) [49-54], and individuals with malabsorptive gastrointestinal disorders [55-57]. Looking ahead, such user-friendly, noninvasive technologies could contribute meaningfully to broader public health strategies by enabling early identification of at-risk individuals, promoting health awareness, and reducing reliance on clinical resources for routine screening. Future algorithm updates could substantially improve sensitivity and correlation, as previously demonstrated in research on digital monitoring of vital parameters [41]. With further improvements and appropriate adaptations, the tool may also become suitable for use in children, who often face logistical and emotional challenges with traditional blood sampling [58-60].

It is important to note that, unlike clinical-grade tools, comestai.app is not intended for diagnostic use. Its classification as a wellness device aligns with international standards that tolerate higher error margins for nonmedical apps, and the reported low sensitivity should be interpreted in light of the preliminary nature of this pilot study, the small sample size, and the limited number of patients with anemia. Nevertheless, given that anemia often presents without symptoms until reaching moderate to severe stages, tools capable of early detection, even with limited precision, can still offer significant public health value by promoting timely medical consultation.

In particular, as described by Saleh et al [61], the performance of these tools can be significantly enhanced by developing ML algorithms trained on clinical datasets and PPG signals. This strategy enables the differentiation between normal and anemic conditions via multistep processing pipelines involving data labeling, signal preprocessing, feature extraction, and model training. The referenced study showed that by combining red and infrared PPG data with a rich set of extracted features, anemia could be classified with up to 100% accuracy using a 5-fold cross-validation approach. Additionally, Mannino et al [32] showed that personalization of the app's artificial intelligence–augmented algorithm enhances self-monitoring of Hb levels, leading to an improvement in the app's MAE. These results highlight the potential of ML-augmented, PPG-based systems to serve as scalable, effective, and fully noninvasive solutions for anemia screening.

This study presents several limitations that should be acknowledged when interpreting the findings. First, although the sample included participants with different Hb levels, the prevalence of clinically significant anemia was relatively low (57/555, 10.27%), which likely reduced the statistical power and contributed to the limited sensitivity in detecting low Hb values. No formal power calculation was performed, further constraining the robustness of the diagnostic accuracy

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assessment. Moreover, recruitment from specialized outpatient clinics focusing on obesity, diabetes, and hypertension introduces selection bias, limiting the generalizability of the results to broader populations. Future studies should include a more balanced sample, particularly with a higher representation of individuals living with anemia. Second, the measurements were conducted in controlled settings, which may not fully capture the variability and challenges of real-world conditions. Factors such as ambient lighting, facial positioning, skin tone variation, and user movement can introduce noise and affect the reliability of Hb estimation in everyday use. Finally, no subgroup analyses were performed to evaluate performance across different health conditions; such stratified analyses would be necessary to assess the generalizability of the findings and to identify potential performance disparities in clinically relevant subpopulations.

Further research, including longitudinal studies, field-based validation trials, and large-scale deployment of ML-augmented PPG systems, is needed to enhance algorithm robustness, improve clinical utility, and confirm effectiveness across diverse populations and real-world settings. Such efforts will be essential to ensure generalizability, address potential sources of bias, and support the integration of these technologies into routine screening and preventive care frameworks.

Conclusions

This study explores the feasibility of a noncontact PPG-based mobile app for noninvasive Hb monitoring, demonstrating how comestai.app represents an innovative approach to wellness monitoring through Hb estimation using the smartphone's front-facing camera. While not yet suitable for clinical diagnosis due to limited sensitivity, its high specificity and ease of use support its role as a valuable tool for self-monitoring. It could also be useful in large-scale initial screening programs to identify individuals who may benefit from further clinical evaluation. Continued development, including algorithmic refinement and larger-scale validation in diverse populations, will be key to enhancing accuracy and broadening its utility. By leveraging the ubiquity of smartphones, comestai.app contributes meaningfully to the democratization of health monitoring and the promotion of proactive self-care.

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Data Availability

The datasets generated and analyzed during this study are available from the corresponding author upon reasonable request. All data have been anonymized to protect participant privacy and comply with applicable ethical standards.

Authors' Contributions

Conceptualization: GZ, PA, VC
Investigation: LL, EC, DB, MC, MEM, FL, AF, LB, SB, CCFB, MX
Methodology: GZ, PA, LL, EC, DB, PF, SB, MC, MEM, FL, AF, LB, SB, CCFB, AB, VC
Project administration: GZ, VC
Supervision: GZ, PA, SDP, VC
Writing – original draft: LL, VC, GZ
Writing – review and editing: GZ, PA, PF, SB, AB, SDP, VC

Conflicts of Interest

PA and SDP are cofounders of Come Stai S.p.A.

Checklist 1
SPIRIT checklist.
[DOC File, 111 KB - formative_v10i1e78820_app1.doc]

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Abbreviations

Hb: hemoglobin
MAE: mean absolute error
MAPE: mean absolute percentage error
ML: machine learning
POC: point-of-care
PPG: photoplethysmography
rPPG: remote photoplethysmography
SPIRIT: Standard Protocol Items: Recommendations for Interventional Trials
WHO: World Health Organization

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Stratified Causal Inference for Intensive Care Unit Risk Prediction: Informatics-Based Modeling of Anesthetic Drug Combinations

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Abstract

Background: Postoperative intensive care unit (ICU) admission affects 15% to 20% of surgical patients and represents a major source of morbidity and health care costs. Current anesthetic dosing relies on empirical guidelines rather than individualized risk assessment. We developed a counterfactual dose-response model to identify optimal fentanyl-propofol combinations.

Objective: This study aimed to develop and evaluate a stratified, causal machine learning framework using electronic health record data to identify optimal fentanyl-propofol dose combinations and predict postoperative ICU admission risk, enabling precision anesthesia and individualized clinical decision support.

Methods: We analyzed perioperative electronic health records of 67,134 surgical procedures from UC Irvine Medical Center (2017 - 2022). A hierarchical learning framework was used to estimate causal effects while controlling for confounding variables. A total of 6 dose-sensitive subgroups were identified through stratified analysis. The primary end point was postoperative ICU admission.

Results: High-risk combinations (fentanyl >5 mcg/kg with propofol <1 mg/kg) increased ICU admissions' absolute risk difference by 36% (absolute risk increase; 95% CI 0.351-0.509; P<.001). A total of 6 patient subgroups demonstrated distinct dose-response patterns, with populations considered vulnerable (high glucose, elevated creatinine) showing elevated risk even at standard doses. The optimal dose range for decision-making was determined to be 1.25 to 4.25 mg/kg for propofol and 3.5 to 4.0 mcg/kg for fentanyl.

Conclusions: Fentanyl-propofol combinations exhibit complex, nonlinear dose-response relationships with ICU admission risk. High-dose combinations markedly increase risk through synergistic effects, while specific patient subgroups require enhanced monitoring even at standard doses. These findings support the development of individualized dosing algorithms and risk assessment tools that could inform future decision support tools aimed at reducing postoperative ICU use, although their predictive performance and clinical impact would require external validation.

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KEYWORDS

fentanyl; propofol; intensive care; dose-response analysis; counterfactual modeling

Introduction

Postoperative intensive care unit (ICU) admission represents a serious complication of surgical care and, according to global data, contributes substantially to postoperative mortality, highlighting significant gaps in critical care access and delivery [1]. Despite advances in perioperative monitoring and anesthetic techniques, current approaches to drug dosing rely primarily on empirical guidelines and clinical experience rather than individualized risk assessment based on patient characteristics and drug interactions [2,3].

The combination of fentanyl and propofol, used in millions of surgical procedures worldwide, exemplifies this challenge. While both agents are essential components of modern anesthesia, their complex pharmacological interactions and dose-dependent effects on postoperative outcomes remain poorly characterized [4,5]. Current dosing guidelines provide broad ranges without specific guidance for individual patient risk

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factors or drug interaction effects, potentially exposing patients considered vulnerable to preventable complications requiring intensive care support [2].

Fentanyl is a potent synthetic opioid that can enhance the hypnotic effect of propofol, thereby effectively reducing the dosage of propofol and further improving the hemodynamic stability of patients [4,6]. Fentanyl and propofol demonstrate synergistic effects that can reduce individual drug requirements while maintaining effective anesthesia [4,5]. However, high-dose combinations may exacerbate cardiovascular and respiratory depression through additive mechanisms, potentially leading to hemodynamic instability and respiratory failure requiring ICU support [1,7].

Postoperative admission to the ICU represents one of the most resource-intensive outcomes. Treatment-resistant hypotension or respiratory failure is a common cause of ICU transfer [8-10]. An increasing number of studies emphasize the need for more precise intraoperative anesthesia management [2,3,10]. The implementation of an accurate medication strategy is anticipated to effectively decrease the risk of postoperative ICU admission [2,3]. Recent large-scale perioperative studies and safety reviews [1,10] have reinforced concerns regarding opioid-related respiratory depression, hemodynamic instability, and unplanned ICU admission following general anesthesia, particularly in heterogeneous surgical populations.

Causal machine learning, by estimating individualized treatment effects, is reshaping how medical evidence is generated and translated into patient-level decision-making [11,12]. Doubly robust orthogonal estimators integrate learning algorithms with principled confounding adjustment in high-dimensional observational data, thereby enhancing the validity of causal inference [13].

Recent clinical applications include causal forests combined with double machine learning estimation of average and heterogeneous effects of tuberculosis preventive therapy on antiretroviral therapy adherence [14] and meta-learning analyses of midwife-led continuity of care on low birth weight with individualized treatment effect recovery [15].

Building on this foundation, we developed a comprehensive counterfactual dose-response modeling framework to characterize both the joint dosing effects and treatment effect heterogeneity of fentanyl-propofol coadministration, enabling the identification of dose combinations associated with more favorable postoperative risk profiles and the delineation of high-risk patient subgroups to support individualized anesthesia management and reduce ICU-related risks.

Methods

Study Design

We performed a retrospective analysis of perioperative electronic health records for 67,134 surgical procedures at the University of California, Irvine Medical Center (2017 - 2022) [16]. This large, single-center cohort provides robust statistical power for detecting clinically meaningful dose-response relationships while maintaining consistent practice patterns and data quality standards. We excluded surgeries with an anesthesia duration of less than 60 minutes, patients younger than 18 years, patients aged 85 years or older, and cases lacking preoperative metabolic assessments. This study used fully deidentified electronic health records with no direct patient contact or intervention.

Data Preprocessing

We included preoperative patient data available within 7 days prior to surgery, reflecting real-world clinical decision-making factors, including demographic characteristics (eg, age and sex), comorbidities (eg, hypertension, diabetes mellitus, hyperlipidemia, and chronic kidney disease), surgical characteristics (eg, procedure category), physiological parameters (eg, blood pressure, oxygen saturation, American Society of Anesthesiologists physical status, and pain score), and laboratory values (eg, complete blood count and comprehensive metabolic panel).

Fentanyl and propofol were administered intravenously via a peripheral vein from anesthesia induction until the end of surgery. For each patient, the total cumulative intraoperative dose was derived by summing all bolus administrations and the total amount delivered via continuous infusion over the intraoperative period. Doses were subsequently weight standardized by dividing the cumulative dose by body weight (eg, fentanyl [mcg/kg] and propofol [mg/kg]). Postoperative ICU admission was defined as ICU admission occurring within 24 hours after the end of surgery.

Variables with a missing value ratio exceeding 20% in either dataset were excluded from the analysis. For the remaining variables with missing values, multiple imputation using chained equations [17] was performed independently within each cohort. This approach addresses a critical methodological concern: because multiple imputations using chained equations rely on the mean and SD of the observed data for each variable, performing imputation separately for the 2 cohorts is essential to minimize bias and preserve the internal validity of the imputed values within each group. A schematic representation of the temporal and causal structure of covariates, intraoperative dosing, and postoperative ICU outcome is provided in Figure S5 in Multimedia Appendix 1.

Covariate Classification

The treatment variable was defined as a 2D vector comprising intraoperative fentanyl dose and propofol dose. The outcome variable was postoperative ICU admission, coded as a binary variable. We categorized patient characteristics based on their likelihood of receiving certain drug combinations (propensity score) and their expected response to treatment (average treatment effect). All the selected confounding factors satisfy the backdoor criterion [18].

We evaluated 9 machine learning models for constructing the adjustment set and automatically tuned the hyperparameters for each model. Light gradient boosting machine was identified as the optimal model for constructing the adjustment set. After adjustment, the standardized mean difference (SMD) for most confounding factors was below the conventional threshold of 0.1, with a mean SMD of 0.0405. Multicollinearity was

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evaluated by calculating the variance inflation factor of the model design matrix. Variables with an SMD0.10 or a variance inflation factor greater than 5 were excluded.

Total Eligible Cohort Analysis

We used the CausalForestDML model to calculate conditional average treatment effects. This approach identifies which patients are most likely to benefit from or be harmed by specific dose combinations, supporting personalized anesthetic management. On the basis of the conditional average treatment effects estimates, we constructed a causal decision tree (CDT) to identify potential effect modifiers. Each CDT was constrained to a maximum depth of 6. This restriction reflects a fundamental principle of hierarchical learning and represents the upper bound of model complexity permitted within our framework. We selected 6 subgroups defined by the terminal nodes of the CDT for heterogeneity treatment effect analysis.

Dual-Exposure Cohort Analysis

We developed an extreme gradient boosting–based risk surface model to estimate group-level postoperative ICU admission risks associated with varying intraoperative fentanyl and propofol dose combinations in the dual-exposure cohort. We constructed a logistic regression model incorporating interaction terms to evaluate whether there was a statistically significant interaction between fentanyl and propofol doses.

To minimize the potential bias introduced by treatment effect heterogeneity, we identified 6 groups that were highly sensitive to combined medication dosages through heterogeneity treatment effect analysis. For each group, we independently trained XGBoost models with consistent hyperparameters.

Interpretation Framework

We used the explainable boosting machine [19] model to quantitatively evaluate the contribution of each predictor variable to the risk of ICU admission. We trained XGBoost models across 6 sensitive groups to elucidate the observed heterogeneity in treatment responses, computing the Shapley additive explanation (SHAP) values of the primary explanatory variables.

Ethical Considerations

This study was exempt from ethics review because it involved the analysis of publicly available, deidentified data. No human participants were directly involved, and no identifiable personal information was accessed.

This study was conducted using retrospective, fully deidentified patient data extracted from a single-center database. All datasets used were previously approved for research and made available through the Medical Informatics Operating Room Vitals and Events Repository (MOVER) data portal. The MOVER dataset was created under institutional review board approval at the University of California, Irvine, with a waiver of individual informed consent because all protected health information was removed or deidentified in a Health Insurance Portability and Accountability Act–compliant manner. Access to MOVER was obtained after application and execution of the University of California, Irvine, Operating Room Data Usage Agreement, which prohibits reidentification attempts and redistribution of the data and requires users to notify the dataset administrators if any potentially identifying information is detected. As all datasets were deidentified and released for secondary research use, the study was exempt from additional institutional review board approval, and informed consent was not required. All analyses complied with the ethical standards of the Declaration of Helsinki and relevant national regulations regarding secondary use of deidentified health data. Formal documentation of the institutional ethics exemption or waiver has been obtained and will be provided upon request.

Results

Cohort

As illustrated in Figure 1, a total of 23,658 surgical cases were included in the analysis cohort, with 16,949 (71.6%) cases receiving both fentanyl and propofol (dual-exposure cohort) used for primary dose-response modeling.

Binary variables are presented as n (%), and continuous variables are presented as median (IQR). The postoperative ICU outcome rate of the total eligible cohort was 66.64%. The postoperative ICU outcome rate of the dual-exposure cohort was 64.26%.

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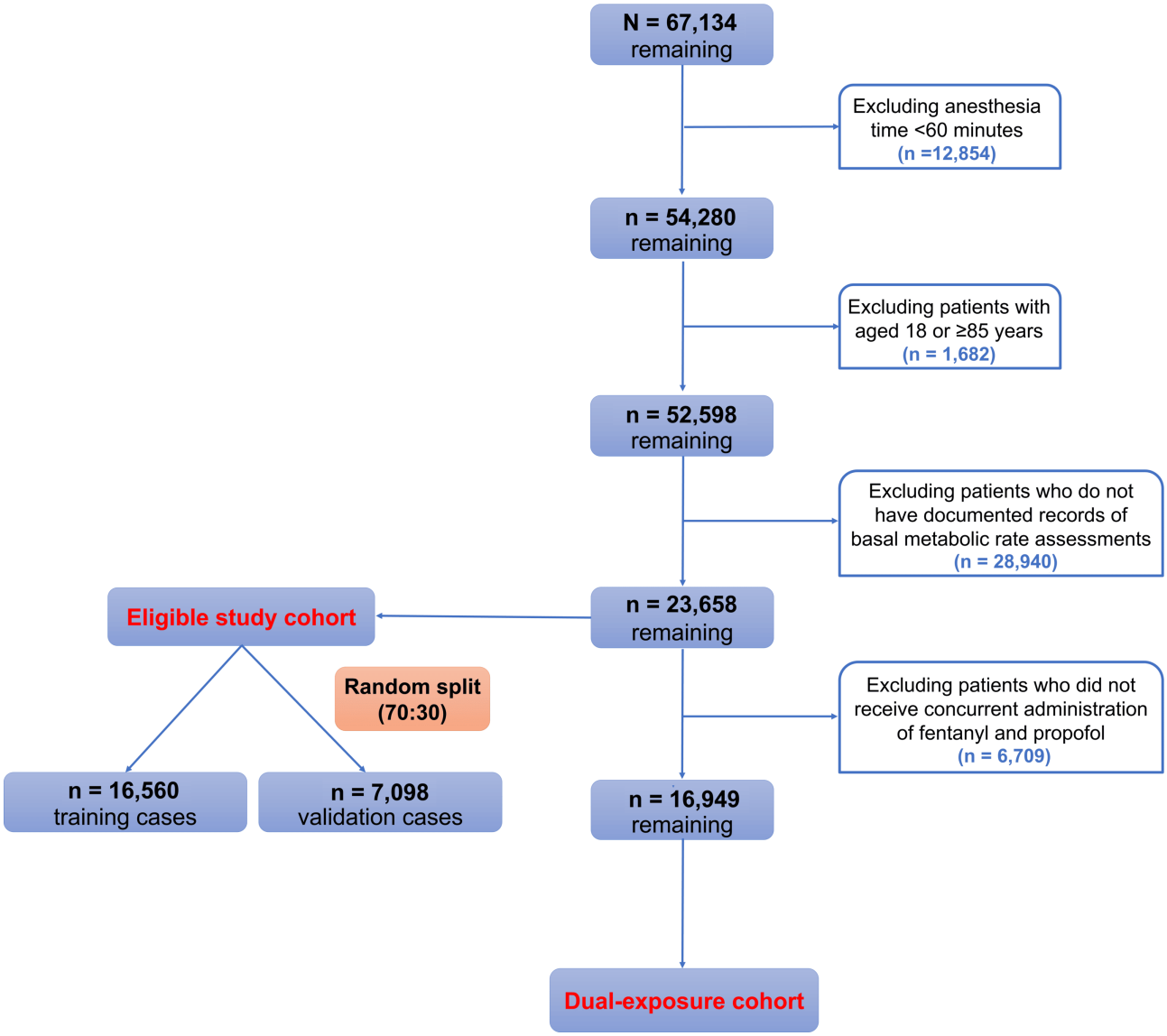
Figure 1. Study flowchart.



As presented in Table 1, baseline characteristics revealed clinically substantial patterns associated with ICU admission risk. Patients requiring ICU admission were more likely to be men (9979, 63.3% vs 4347, 55.1%), older (median 55, IQR 39-66 years vs median 50, IQR 35-64 years), and had higher ASA physical status than those not requiring ICU admission. Laboratory parameters showed concerning patterns in ICU patients with lower hemoglobin (g/dL) (median 11.09, IQR 9.14-12.80 vs median 12.10, IQR 11.30-13.70), higher glucose (mg/dL) (median 130, IQR 108.33-163 vs median 109, IQR 96-132), and elevated creatinine. Notably, patients admitted to the ICU postoperatively received higher fentanyl doses (median 1.60, IQR 1.10-2.52 mcg/kg vs median 1.47, IQR 1.08-2.14 mcg/kg) but similar propofol doses (median 2.00, IQR 1.47-2.56 mg/kg vs median 2.13, 1.72-2.59 mg/kg).

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Table . Baseline characteristics of the interpolated cohorts.

Variable	Total eligible cohort[a]			Dual-exposure cohort		
	ICU[b] admission (no)	ICU admission (yes)	*P* value	ICU admission (no)	ICU admission (yes)	*P* value
Demographics						
Age (years), median (IQR)	50 (35-64)	55 (39-66)	<.001	47 (33-61)	54 (38-65)	<.001
Sex, n (%)			<.001			<.001
Male	4347 (55.1)	9979 (63.3)		3321 (54.8)	6806 (62.5)	
Female	3543 (44.9)	5789 (36.7)		2737 (45.2)	4085 (37.5)	
Body weight (kg), median (IQR)	76.50 (64.70-90.67)	75.90 (63.79-89.90)	.08	77.11 (65.16-90.72)	76.25 (64.00-90.23)	.007
ASA[c] physical status, n (%)			<.001			<.001
1	705 (8.9)	328 (2.1)		649 (10.7)	304 (2.8)	
2	2892 (36.7)	2417 (15.3)		2607 (43.0)	2120 (19.5)	
3	3832 (48.6)	8524 (54.1)		2601 (42.9)	6340 (58.2)	
4	440 (5.6)	3996 (25.3)		200 (3.3)	2025 (18.6)	
5	21 (0.3)	503 (3.2)		1 (0.0)	102 (0.9)	
Pain score, n (%)			<.001			<.001
0	1981 (25.1)	3856 (24.5)		1115 (18.4)	2543 (23.3)	
1	609 (7.7)	1640 (10.4)		415 (6.9)	999 (9.2)	
2	690 (8.7)	1779 (11.3)		513 (8.5)	1142 (10.5)	
3	753 (9.5)	1928 (12.2)		621 (10.3)	1204 (11.1)	
4	867 (11.0)	1696 (10.8)		732 (12.1)	1176 (10.8)	
5	871 (11.0)	1517 (9.6)		765 (12.6)	1191 (10.9)	
6	834 (10.6)	1305 (8.3)		745 (12.3)	1061 (9.7)	
7	666 (8.4)	956 (6.1)		596 (9.8)	788 (7.2)	
8	408 (5.2)	618 (3.9)		367 (6.1)	469 (4.3)	
9	160 (2.0)	263 (1.7)		145 (2.4)	204 (1.9)	
10	51 (0.6)	210 (1.3)		44 (0.7)	114 (1.0)	
Medication exposure						
Fentanyl and propofol coadministration, n (%)			<.001			—[d]
No	1661 (21.1)	4772 (30.3)		—	—	
Yes	6229 (78.9)	10,996 (69.7)		—	—	
Fentanyl dose (μg/kg), median (IQR)	1.47 (1.08-2.14)	1.60 (1.10-2.52)	<.001	1.47 (1.08-2.14)	1.60 (1.10-2.52)	<.001
Propofol dose (mm/kg), median (IQR)	2.13 (1.72-2.59)	2.00 (1.47-2.56)	<.001	2.13 (1.72-2.59)	2.00 (1.47-2.56)	<.001
Surgical characteristics						
Surgery type, n (%)			<.001			<.001
Cardiothoracic	252 (3.2)	1113 (7.1)		100 (1.7)	721 (6.6)	
Neurovascular	983 (12.5)	1867 (11.8)		281 (4.6)	1221 (11.2)	
Abdominopelvic	2185 (27.7)	3614 (22.9)		1984 (32.8)	2638 (24.2)	

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Variable	Total eligible cohort[a]			Dual-exposure cohort		
	ICU[b] admission (no)	ICU admission (yes)	*P* value	ICU admission (no)	ICU admission (yes)	*P* value
Musculoskeletal	1765 (22.4)	2443 (15.5)		1606 (26.5)	2010 (18.5)	
Other	2705 (34.3)	6731 (42.7)		2087 (34.5)	4301 (39.5)	
Comorbidities, n (%)						
Hypertension			<.001			<.001
No	5890 (74.7)	11,378 (72.2)		4998 (82.5)	8044 (73.9)	
Yes	2000 (25.3)	4390 (27.8)		1060 (17.5)	2847 (26.1)	
Diabetes mellitus			.86			<.001
No	6866 (87.0)	13,709 (86.9)		5541 (91.5)	9635 (88.5)	
Yes	1024 (13.0)	2059 (13.1)		517 (8.5)	1256 (11.5)	
Hyperlipidemia			.48			<.001
No	6762 (85.7)	13,459 (85.4)		5452 (90.0)	9412 (86.4)	
Yes	1128 (14.3)	2309 (14.6)		606 (10.0)	1479 (13.6)	
Chronic kidney disease			<.001			<.001
No	6368 (80.7)	13-729 (87.1)		5447 (89.9)	9604 (88.2)	
Yes	1522 (19.3)	2039 (12.9)		611 (10.1)	1287 (11.8)	
Laboratory values, median (IQR)						
Hemoglobin	12.1 (11.30-13.70)	11.09 (9.14-12.80)	<.001	12.50 (11.53-13.90)	11.55 (9.46-13.08)	<.001
Neutrophil count	6.27 (4.80-7.85)	7.25 (5.16-10)	<.001	6.25 (4.75-8.16)	7.10 (5.10-9.76)	<.001
Serum chloride	103 (101-105)	104 (101-106.83)	<.001	103.50 (101.00-105.40)	103.72 (101-106)	<.001
Hematocrit	36.01 (33.98-40.42)	33.20 (27.28-38.10)	<.001	37.30 (34.50-41.19)	34.50 (28.15-38.90)	<.001
Platelet count	244 (206-292.50)	229 (174-296.50)	<.001	248 (207-299)	236.33 (184.13-303.44)	<.001
Serum potassium	3.93 (3.70-4.20)	3.93 (3.70-4.20)	.01	3.90 (3.70-4.14)	3.92 (3.70-4.19)	<.001
Blood glucose	109 (96-132)	130 (108.33-163)	<.001	109 (96.50-129.50)	125 (105-154.56)	<.001
Total carbon dioxide	25.07 (23.50-27)	24.50 (22.52-26.29)	<.001	25 (23.50-27)	24.75 (23-26.43)	<.001
Serum calcium	9.10 (8.77-9.40)	8.63 (8.10-9.10)	<.001	9.10 (8.75-9.40)	8.72 (8.20-9.17)	<.001
Serum creatinine	0.85 (0.70-1.29)	0.88 (0.68-1.30)	.65	0.80 (0.67-1)	0.84 (0.67-1.15)	<.001
Serum sodium	137 (135-138.33)	137 (134.93-139)	<.001	137 (135-138.33)	136.85 (134.80-138.65)	.04
Leukocyte count	8.84 (7.20-10.44)	9.71 (7.47-12.70)	<.001	8.84 (7.17-10.84)	9.60 (7.40-12.43)	<.001
Blood urea nitrogen	15 (11-23)	16.50 (11.89-26)	<.001	14 (10.50-19)	15.50 (11.24-23)	<.001
Erythrocyte count	4.24 (3.72-4.64)	3.79 (3.14-4.47)	<.001	4.31 (3.69-4.75)	3.88 (3.22-4.53)	<.001

[a]The doses of fentanyl and propofol in the total eligible cohort were not imputed.

[b]ICU: intensive care unit.

[c]ASA: American Society of Anesthesiologists

[d]Not applicable.

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Total Eligible Cohort Analysis

Primary dose-response analysis revealed clinically significant thresholds for ICU admission risk. The average treatment effect of 0.0102 indicated a 1.02% absolute increase in ICU admission risk associated with fentanyl-propofol combinations. The distribution of treatment effects showed significant right skewness, indicating that while most patients experience minimal increased risk, a subset faces substantially higher risk from drug combinations. The CDT identified serum creatinine as the primary splitting variable, with subsequent stratification by glucose, age, and calcium (along with erythrocyte count, ASA physical status, and electrolytes) defining patient subgroups with differential susceptibility.

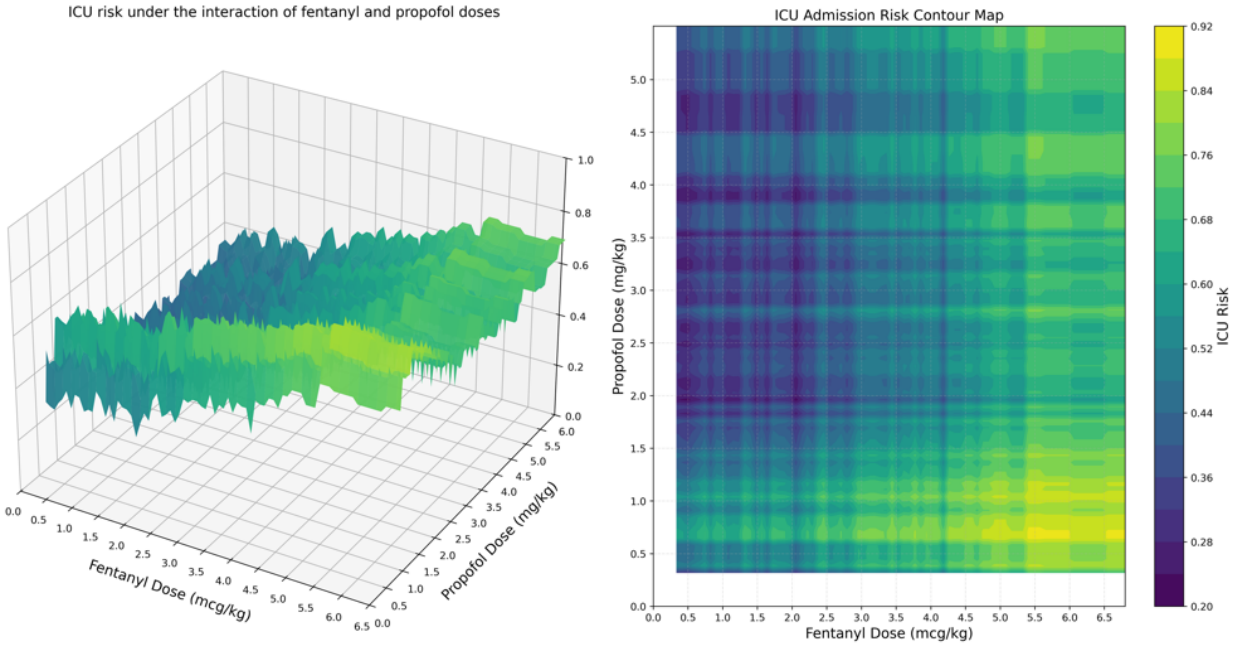
Dual-Exposure Cohort Analysis

Dose-response surface analysis identified distinct risk zones with immediate clinical applications (Figure 2). The average-dose region (fentanyl: 1.75 - 2.0 mcg/kg and propofol: 2.1 - 2.2 mg/kg) maintained ICU admission risk below 40%. The optimal dose range for decision-making was determined to be 3.5 to 4.0 mcg/kg for fentanyl and 1.25 to 4.25 mg/kg for propofol. In the moderate-dose region (fentanyl: 2.5 - 3.5 mcg/kg and propofol: 2 - 3 mg/kg), the ICU risk exhibited a nonlinear increase, gradually rising to 60%. Risk increased exponentially beyond these thresholds, reaching 92% for high-risk combinations (fentanyl >5 mcg/kg and propofol <1 mg/kg).

The 3D dose–response surface depicts the association between fentanyl dose (mcg/kg) on the x-axis, propofol dose (mg/kg) on the y-axis, and the model-predicted probability of ICU admission on the z-axis. The corresponding 2D contour plot presents the same dose ranges, with the color gradient indicating the predicted postoperative ICU admission risk.

Multivariate logistic regression analysis revealed a statistically significant positive interaction between fentanyl and propofol doses on the risk of ICU admission (interaction term β=.0243; *P*<.001). When the fentanyl dose exceeded 3 mcg/kg and the propofol dose exceeded 3.5 mg/kg, the synergistic effect between the 2 increased the predicted Δ risk of postoperative ICU admission by 36% (95% CI 0.351- 0.509; *P*<.001).

Figure 2. (Left) Intensive care unit (ICU) risk surface and (right) contour plot under fentanyl-propofol interaction.



Compared with the reference group, all 6 drug-sensitive groups (Figure 3) demonstrated a marked amplification and leftward shift of the risk gradient. In the 3D risk surface plot, this trend was marked by a steeper ascending slope in the low-dose region and an earlier onset of the high-risk plateau.

Figure 3A demonstrates that within the low-to-medium dose range, the early slope is steeper and the inflection point occurs at a lower combined dose. Figure 3B illustrates that the risk ridge along the fentanyl axis increases more abruptly, with the high-risk region compressed along the propofol axis and extended across a broader fentanyl range. In Figure 3C, the onset of risk occurs at lower doses and is accompanied by localized irregularities. Figure 3D shows that the risk surface flattens with increasing doses, with a gradual slope in the medium-dose range and an abrupt increase in the higher-dose region. Figure 3E exhibits a relatively flat surface, showing attenuated dose responsiveness and scattered high-risk plateaus. Figure 3F reveals a biphasic risk pattern, characterized by a rapid early increase followed by relative stabilization in the medium dose range.

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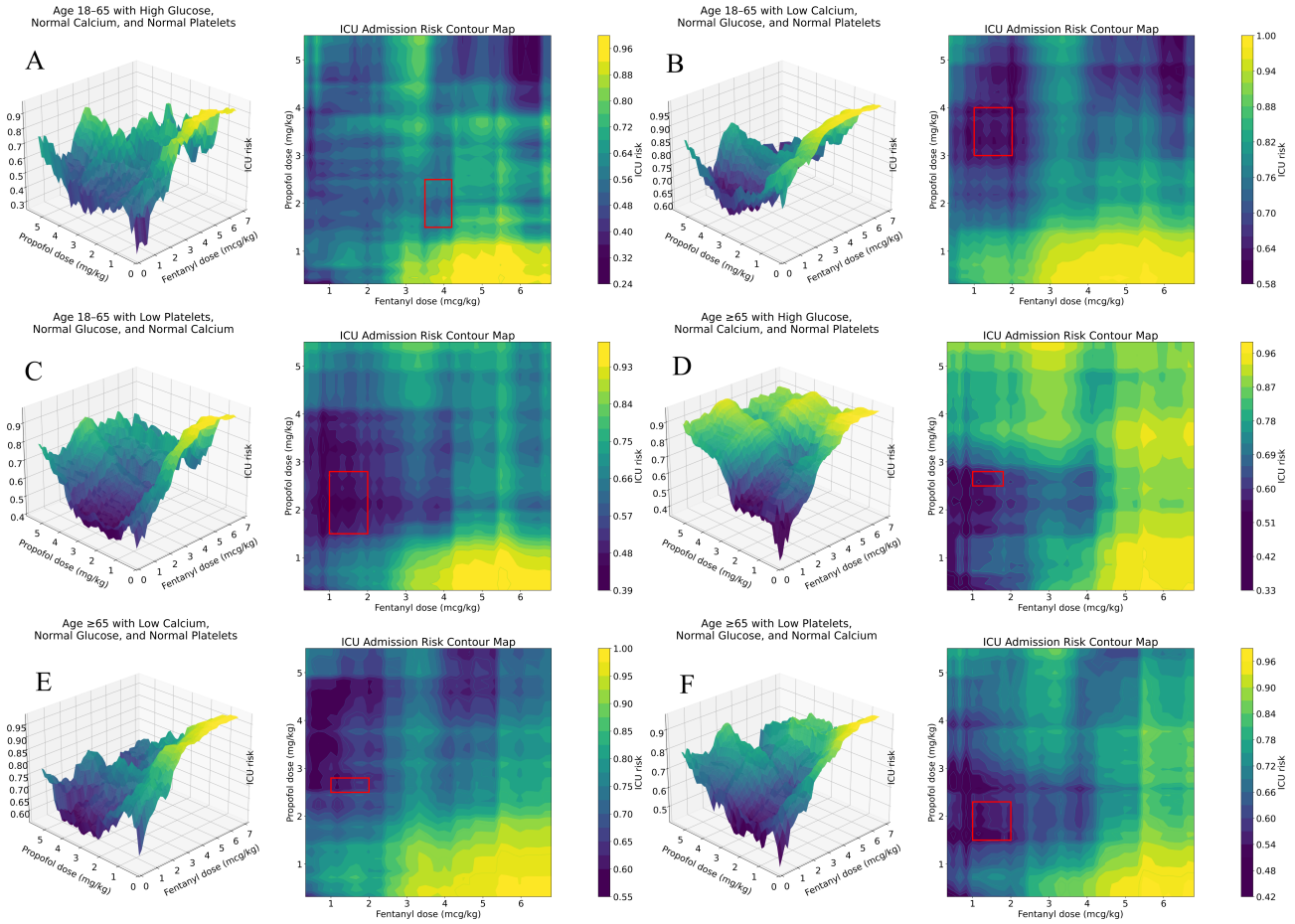
Figure 3. Dose-response surfaces and contour plots for sensitive groups.



Interpretability

Figure 4 demonstrates that among all predictors, ASA physical status exhibits the highest overall ranking, with serum calcium and blood glucose also showing relatively high importance. The 3D SHAP interaction plot reveals that the interactive contribution of creatinine changes nonlinearly with blood urea nitrogen and potassium levels, with more pronounced effects observed at higher creatinine-to–blood urea nitrogen ratios. This pattern aligns with the early and marked increase in ICU risk depicted in the dose-response relationship.

The bar chart displays the average absolute importance scores of clinical features calculated using the Explainable Boosting Machine model. In each 3D graph, the z-axis represents the SHAP value of a specific clinical variable, quantifying its contribution to ICU admission risk prediction. The x-axis and y-axis correspond to 2 interacting features that jointly determine the magnitude and direction of the variable's contribution.

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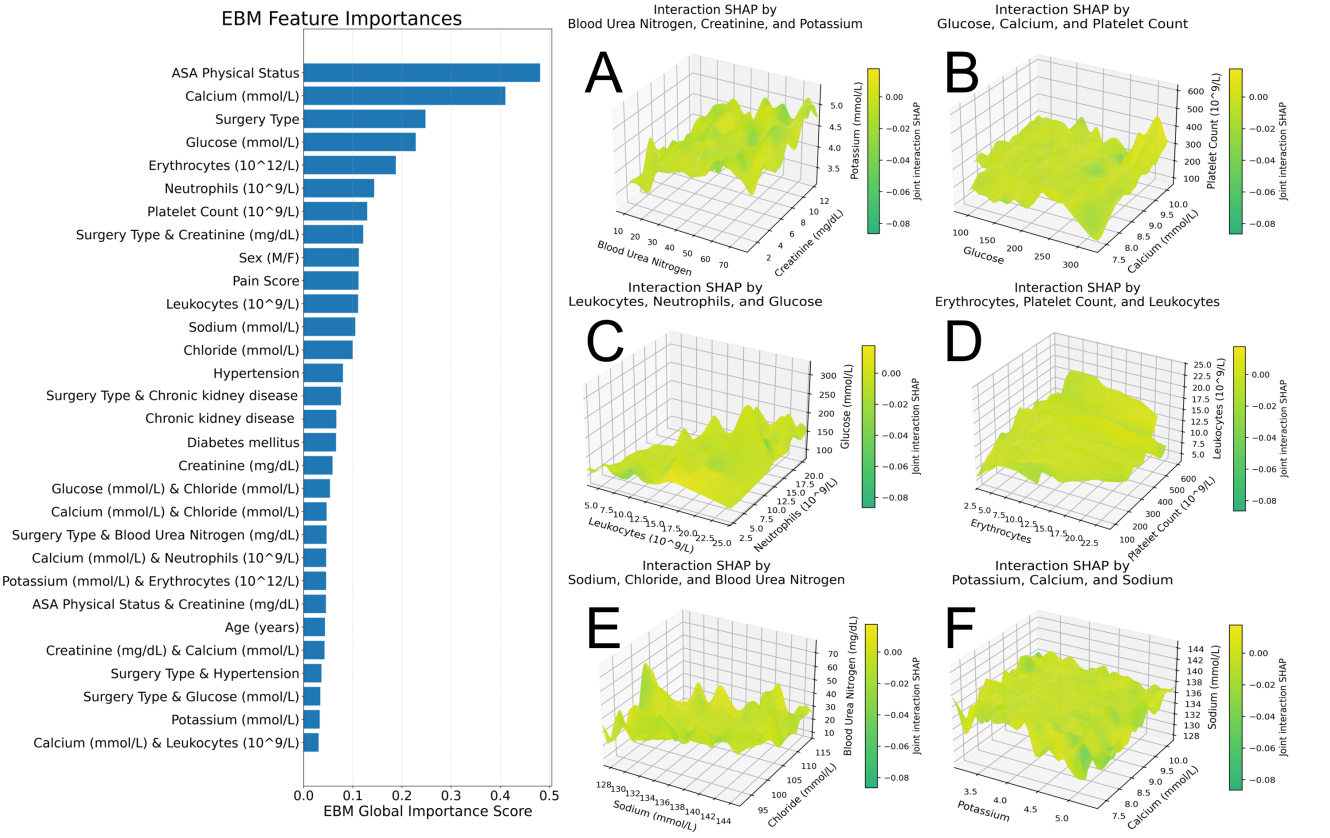
Figure 4. Global feature importance ranking from Explainable Boosting Machine (EBM) and group-specific Shapley additive explanation (SHAP) summary plots for intensive care unit (ICU) admission risk.



Discussion

Principal Findings

This study provides a counterfactual modeling approach to analyzing fentanyl-propofol dose-response relationships and ICU admission risk, with potential implications for clinical decision support and hypothesis generation. Our findings demonstrate that current empirical dosing approaches may expose patients to preventable complications, while individualized risk assessment could substantially reduce ICU admissions and associated costs.

The clinical significance of these findings is rooted in the respiratory depressant effects of both agents. Propofol can impair ventilation via upper-airway collapsibility and central respiratory depression [6,20,21], while fentanyl further suppresses brain stem ventilatory control and, at higher opioid exposure or with rapid administration, may cause chest wall rigidity that impairs ventilation [22]. These complementary effects plausibly contribute to the nonlinear risk escalation and ridge-like high-risk zones observed in our dose-response surfaces, particularly at higher fentanyl doses combined with lower propofol doses.

In all subgroups, the higher the fentanyl exposure, the more sharply the ICU predicted risk rose, which may reflect the combined effect of cardiopulmonary depression and propofol-induced vasodilation and systemic vascular resistance reduction [23,24]. Pharmacodynamic synergy can alter anesthetic requirements, such that minor changes in opioid exposure can alter the propofol dose needed to achieve adequate sedation and cause patients to cross the hemodynamic threshold, which is consistent with steeper spines and earlier inflection points observed on the curve [25,26].

Older patients are more susceptible because of their reduced cardiovascular reserve and higher sensitivity to anesthesia-related hypotension [24]. The pattern in the hyperglycemic subgroup is consistent with evidence that stress hyperglycemia is associated with postoperative complications and mortality [27,28]. Similarly, hypocalcemia may reduce patients' tolerance to intraoperative instability by affecting myocardial contractility, vascular tone, and coagulation function [29]. Finally, the elevated risk and irregular plateau in thrombocytopenia may reflect increased bleeding susceptibility and treatment escalation, as abnormal platelet counts and preoperative platelet transfusion are associated with higher ICU admission rates and longer hospital stays in noncardiac surgery [30,31].

In the dual-exposure cohort, as the doses of both drugs increase, the risk of ICU admission exhibits a nonlinear upward trend. When the fentanyl dose exceeds 3.5 mcg/kg, the predicted probability of ICU admission increases sharply, particularly when propofol doses are low to moderate rather than uniformly high, reaching 36% in the high-risk region and indicating a pronounced ridge-like dose-response gradient.

The asymmetric response pattern observed indicates that when propofol doses are below 3 mg/kg, incremental increases in propofol lead to a reduction in ICU admission risk. Conversely, across nearly all dose ranges, increasing fentanyl doses are associated with elevated ICU admission risks. This may be

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attributed to the relatively low frequency of the high-dose propofol+low-dose fentanyl combination in the sample, thereby constraining the model's generalization capacity in this region and necessitating cautious interpretation.

Our findings offer specific guidance for clinical practice: ICU risk is minimized within a narrow corridor of combined fentanyl and propofol dosing, delineated by the red box, and centered on fentanyl doses of 3.5 to 4.0 mcg/kg and propofol doses of 1.25 to 4.25 mg/kg. These results challenge the assumption that higher propofol doses uniformly increase risk [6,15]. Beyond this optimal range, risk escalates nonlinearly, with the highest-risk zone occurring when fentanyl exceeds 5 mcg/kg while propofol remains low (<1 mg/kg) [32]. Therefore, the optimal dosing window for clinical decision-making was defined as fentanyl 3.5 to 4.0 mcg/kg and propofol 1.25 to 4.25 mg/kg.

Clinical Practice Implications

These implications are exploratory and hypothesis-generating, as the findings arise from observational counterfactual modeling and require prospective validation before clinical implementation. The findings provide a foundation for transforming anesthetic dosing from empirical guidelines to evidence-based, individualized approaches. The identification of specific dose thresholds and patient populations considered vulnerable enables the development of real-time risk assessment tools incorporating patient characteristics that could be integrated into anesthesia information management systems [2,3]. This research establishes the foundation for transforming anesthetic dosing from empirical guidelines to precision medicine approaches; evidence-based dosing algorithms using patient-specific risk profiles could guide dosing decisions [3,10]. Enhanced monitoring protocols for high-risk patients could enable early intervention and help prevent progression to complications requiring ICU admission [2,3,10].

Limitations

Several limitations must be acknowledged. The single-center design may restrict the generalizability of findings across diverse health care systems, patient case mixes, and perioperative protocols, highlighting the necessity for external validation. As an observational study, causal inferences are inherently susceptible to residual confounding. Furthermore, the maximum depth constraint of the CDT algorithm may overlook extended confounding pathways. Before clinical implementation, these results must be validated in independent cohorts and varied health care settings.

Future Directions

This research establishes a foundation for several critical next steps: multicenter validation studies across diverse health care settings, interventional trials testing individualized dosing algorithms vs standard care, implementation research examining real-world application of risk assessment tools, technology integration with clinical decision support systems, and comprehensive cost-effectiveness studies.

Conclusions

This study demonstrates that fentanyl-propofol combinations exhibit complex, nonlinear dose-response relationships with ICU admission risk. These findings require external validation before they can inform clinical decision support or guide future research. The optimal dose range for decision-making was determined to be 3.5 to 4.0 mcg/kg for fentanyl and 1.25 to 4.25 mg/kg for propofol. High-dose combinations (fentanyl >5 mcg/kg and propofol <1 mg/kg) increase the risk of ICU admission by 36%, whereas 6 distinct patient subgroups show differential vulnerability, necessitating individualized management approaches.

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Conflicts of Interest

None declared.

Multimedia Appendix 1
Supplementary tables and figures.
[DOCX File, 11925 KB - formative_v10i1e80294_app1.docx]

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Abbreviations

CDT: causal decision tree
ICU: intensive care unit
MOVER: Medical Informatics Operating Room Vitals and Events Repository
SHAP: Shapley additive explanation

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Development and Validation of the Kazakhstan Version of the Questionnaire Based on the Telehealth Usability Questionnaire and Model for Assessment of Telemedicine Models for Evaluating the Usability and Effectiveness of Telemedicine Services Among Physicians: Multiphase Cross-Sectional Study

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Abstract

Background: Kazakhstan has lacked validated tools to comprehensively assess physicians' perceptions, usability, and perceived effectiveness of telemedicine services. International frameworks such as the Telehealth Usability Questionnaire (TUQ) and the Model for Assessment of Telemedicine (MAST) have not previously been adapted to the national clinical and organizational context.

Objective: This study aims to develop and validate TUQ-MAST-KZ, a Kazakhstan-adapted questionnaire integrating components of the TUQ and MAST models to assess physicians' perceptions, usability, and effectiveness of telemedicine services.

Methods: A multiphase study was conducted, including literature review, questionnaire development, linguistic and cultural adaptation, expert content validity assessment, and pilot testing. An online survey (Google Forms) was administered to 156 physicians representing different regions and levels of health care delivery in Kazakhstan. Internal consistency (Cronbach α) and content validity indices were calculated. Additional evaluations covered clarity, structure, and practical applicability.

Results: The final TUQ-MAST-KZ instrument contains 27 items capturing technological, clinical, organizational, and behavioral dimensions of telemedicine use. The scale demonstrated high content validity (scale-level content validity index=0.94). Internal consistency was excellent, with an overall Cronbach α of 0.924. Respondents reported that the questionnaire was clearly structured, easy to complete, and relevant to clinical practice. Organizational items identified key barriers to telemedicine adoption, including limited infrastructure, insufficient managerial support, and the need for additional training.

Conclusions: TUQ-MAST-KZ is a valid, reliable, and practice-oriented instrument for assessing physicians' perceptions of telemedicine services in Kazakhstan. It can support digital health monitoring, implementation analysis, educational planning, and policy development. Future studies should evaluate its applicability across broader samples and diverse clinical specialties.

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KEYWORDS

telemedicine; digital health; questionnaire validation; Telehealth Usability Questionnaire; TUQ; Model for Assessment of Telemedicine; MAST; Kazakhstan; physicians

Introduction

Telemedicine, which originated in the 1950s, has evolved into one of the most rapidly developing components of modern health care due to advances in technology and support from governmental and international organizations [1]. Its importance increased markedly during the COVID-19 pandemic, when remote technologies ensured continuity of medical care despite limited access to in-person consultations [2]. The effectiveness of telemedicine has been confirmed by systematic reviews

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demonstrating its positive impact on health care accessibility, clinical outcomes, and patient satisfaction [3].

According to the World Health Organization (WHO), telemedicine refers to providing health care services at a distance using information and communication technologies to transmit reliable information needed for diagnosis, prevention, treatment, and the education of health care professionals [4]. The WHO reports that the development of telemedicine in Kazakhstan began in the early 2000s. The country now operates a National Telemedicine Network that connects regional and district-level medical organizations. This system has significantly improved access to specialized medical care in rural and remote areas and has strengthened the capacity of health care personnel through remote consultations and training [5].

In line with Kazakhstan's national digital health policy, the development of telemedicine is viewed as one of the key priorities in the modernization of the health care system. According to the Healthcare Development Concept of the Republic of Kazakhstan until 2026, "telemedicine service delivery systems will be aligned with international standards, including an expanded range of diagnostic services and the use of modern digital solutions" [6]. Achieving this alignment requires not only technological modernization but also the introduction of systematic tools for assessing the quality and perception of telemedicine services. For the successful implementation of telemedicine, it is essential to systematically identify its limitations and strategies for overcoming them. This requires the use of structured instruments that enable a comprehensive assessment of the effectiveness, accessibility, safety, economic viability, and perception of telemedicine services from the perspectives of both patients and health care professionals. As noted by Hajesmaeel-Gohari and Bahaadinbeigy [7], the availability of such tools provides an evidence-based foundation for analyzing the strengths and weaknesses of telemedicine programs and supports the development of informed policies for their implementation.

A similar need for standardization was highlighted by Doraiswamy et al [8], who, in their scoping review of 543 publications, emphasized the importance of unified tools and terminology for evaluating the impact of telemedicine, particularly in resource-limited settings. The absence of standardized approaches restricts the ability to conduct cross-country comparisons and hinders the development of a robust evidence base for evaluating telemedicine effectiveness.

According to Gullslett et al [9], telemedicine has reached a stage of maturity in most European countries. Nevertheless, substantial barriers persist, including insufficient funding, infrastructural limitations, and the lack of systematic monitoring. Only 37% of countries conduct regular assessments of telemedicine service quality, reflecting global challenges in digital maturity and limiting the potential for cross-national data comparison [9]. These findings underscore the need to develop national tools for systematic telemedicine assessment, particularly in countries undergoing active digital health expansion, such as in Kazakhstan.

Despite the progress achieved, systematic research evaluating the perception, effectiveness, and barriers to the implementation of telemedicine remains limited. In this context, the development of nationally adapted instruments capable of providing a comprehensive assessment of telemedicine services and their acceptance within the medical community is particularly important. A systematic review by Kruse et al [10] identified key barriers to the adoption of telemedicine, including resistance to change, insufficient staff training, and the lack of standardized evaluation frameworks. These findings highlight the need for comprehensive and validated assessment tools.

This study analyzes the most commonly used questionnaires for evaluating telemedicine and remote health care technologies. Their selection was based on their frequency of use in systematic reviews and on their relevance to key dimensions of telemedicine evaluation, including perception, usability, and effectiveness.

In the context of large-scale digital health implementation, it is particularly important to use validated instruments capable of capturing the subjective experiences of users and the perspectives of health care professionals. Quantitative indicators—such as the number of consultations or measures of cost-effectiveness—do not fully capture how telemedicine is integrated into clinical practice or how it influences clinical decision-making, both of which are critical for systems with varying levels of digital maturity. Over the past decades, numerous instruments have been developed to assess satisfaction with and perceptions of telemedicine services, including the Client Satisfaction Questionnaire and the Patient Satisfaction Questionnaire, which assess overall patient satisfaction with medical care; the Questionnaire for User Interaction Satisfaction, the Post-Study System Usability Questionnaire, and the System Usability Scale, which evaluate usability and user interaction with digital systems; instruments based on the technology acceptance model, which focus on perceived usefulness and technology acceptance; as well as telemedicine-specific questionnaires such as the Telemedicine Perception Questionnaire, the Telemedicine Satisfaction Questionnaire (TSQ), the Telemedicine Satisfaction and Usefulness Questionnaire, the Patient Assessment of Communication during Telemedicine Questionnaire, and the Service User Technology Acceptability Questionnaire, all of which assess specific aspects of perception, satisfaction, and communication in telemedicine services [11-21]. However, most existing instruments are patient-oriented and assess only selected aspects of interaction—such as usability, communication, satisfaction, perceived usefulness, and technology acceptance—while the professional and organizational context, which is essential for physicians, is addressed to a limited extent. As a result, these scales lack a comprehensive assessment that encompasses both user-focused dimensions and the specific characteristics of clinical practice and conditions of telemedicine implementation, which is consistent with the findings of previously published review studies [7].

In this context, instruments specifically designed to assess health care professionals' perceptions of telemedicine remain scarce, even though physicians' perspectives play a crucial role in the successful implementation and overall effectiveness of telemedicine solutions. This gap underscores the need for validated assessment tools tailored to the professional

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community. Despite differences among existing instruments, their limitations are systemic and manifest in similar ways: a predominant focus on patients, the assessment of isolated components of interaction, and the absence of measures capturing professional and organizational aspects that are essential for physicians.

In recent scientific literature, several new instruments have been developed to assess the perception and organization of telemedicine services; however, their use remains limited. One such tool is the questionnaire by Cho et al [22], designed to characterize telemedicine programs in primary care. Despite its relevance and structured approach, it is not based on a theoretical model, has not undergone psychometric validation, and is used primarily for research purposes, which restricts its systematic application. Similar limitations are observed in the 2024 instruments: the Chinese tool developed by Du and Gu [23], which focuses exclusively on patients, and the German questionnaire by Traulsen et al [24], which was applied only in nursing homes. Both tools are highly specialized, lack multilevel validation, and are not intended for assessing telemedicine perceptions among health care professionals.

Thus, most contemporary instruments developed after 2020 have limited or one-time applicability, underscoring the need for a universal, validated, and practice-oriented tool for assessing physicians' perceptions, usability, and the effectiveness of telemedicine services. The Telehealth Usability Questionnaire (TUQ) questionnaire, developed by Parmanto et al [25] in 2016, is one of the most versatile and methodologically grounded instruments for evaluating telemedicine systems. Its structure incorporates elements from the technology acceptance model, TSQ, and Post-Study System Usability Questionnaire models, enabling a comprehensive assessment of user-related aspects such as usability, effectiveness, and satisfaction. Its high internal consistency (Cronbach α>0.93) and successful use in both video consultations and mobile apps confirm its reliability and broad applicability [7]. However, despite its psychometric robustness and broad coverage of user characteristics, the TUQ primarily reflects user and technological dimensions of interaction and does not address the organizational, economic, and ethical dimensions of telemedicine that determine its effectiveness at the health-system level.

At the same time, a systematic review by Gonçalves et al [26] demonstrated that evidence regarding the usability of telemedicine systems from the perspective of health care professionals remains limited, and standardized, validated instruments for such evaluation are lacking.

These limitations point to the need to expand telemedicine evaluation beyond the purely user-experience domain, incorporating clinical, organizational, economic, and legal dimensions. A multidimensional and robust assessment requires a methodology that captures both the micro-level perspective of users and the macro-level processes of telemedicine implementation within the health care system. However, due to the constraints described above, the TUQ cannot be used as a standalone tool for comprehensive telemedicine assessment, making it necessary to complement it with a framework that encompasses systemic and organizational aspects. Model for Assessment of Telemedicine (MAST) is one of the most widely recognized international models for the comprehensive evaluation of telemedicine programs and is used across health care systems in countries with varying degrees of digital maturity. Given the limitations of existing tools, which predominantly focus on user-related aspects and do not address the clinical and system-level components of telehealth implementation, an approach capable of analyzing telemedicine at a broader level is required.

To address this gap, the study integrated the MAST as proposed by Kidholm et al [27]. MAST provides a structured approach to evaluating telemedicine solutions across 7 domains—from clinical effectiveness and safety to organizational, socioethical, and legal aspects. The combination of the TUQ and MAST models enabled the development of an instrument that merges the psychometric precision of user-experience assessment with a system-level framework for analyzing the organizational maturity of telemedicine.

The TUQ provides an in-depth understanding of the perception and usability of telemedicine systems, whereas the MAST framework encompasses the clinical, organizational, economic, and socioethical aspects of their implementation. These models complement each other: the TUQ reflects the micro-level (user experience), while MAST captures the macro-level (effectiveness and implementation conditions). This methodological combination delivers a holistic, multi-level approach that cannot be achieved using either instrument independently.

This combination makes it possible to conduct a comprehensive evaluation of telemedicine that accounts for both the subjective experiences of physicians and the systemic parameters of telemedicine service functioning. Such an approach is particularly important for countries undergoing active digital health development, including Kazakhstan.

In Kazakhstan, digital health is developing at the intersection of international standards and national specificities, which necessitates the use of adapted evaluation tools that reflect the real clinical and organizational context. This makes it essential to use instruments capable of capturing both physicians' subjective perceptions and the operational characteristics of telemedicine services. Despite the expanding national telemedicine network and the active introduction of digital solutions, the country lacked validated instruments capable of systematically assessing physicians' perceptions and the effectiveness of telemedicine. This created a methodological gap and limited the ability to monitor the quality of telemedicine programs.

The TUQ-MAST-KZ developed in this study represents the first instrument adapted to the context of Kazakhstan and the first to integrate the psychometric structure of TUQ with the systemic MAST framework, making it a unique example of such model integration within Central Asia.

Although the need for comprehensive telemedicine assessment tools is not unique to Kazakhstan and is shared by many countries with comparable levels of digital health maturity, the

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present instrument was developed and validated within the health care system of Kazakhstan.

Kazakhstan is characterized by a centralized health care system, an actively developing national telemedicine network, a multilingual clinical environment (Kazakh and Russian), and ongoing digital health reforms aligned with international standards. These characteristics informed the development, linguistic adaptation, and initial psychometric validation of the instrument within this national context, thereby defining its designation as the Kazakhstan version.

At the same time, TUQ-MAST-KZ is not intended for exclusive use within a single country. Its conceptual structure allows for further cross-country adaptation and validation in health care systems with similar organizational characteristics and levels of digital health development.

Consequently, TUQ-MAST-KZ bridges a critical gap between user perception and the evaluation of telemedicine implementation effectiveness, providing a comprehensive approach essential for advancing digital health in Kazakhstan.

The aim of this study was to develop and validate TUQ-MAST-KZ, the Kazakhstan version of the questionnaire integrating elements of the TUQ and MAST models for a comprehensive assessment of physicians' perceptions and the effectiveness of telemedicine services.

Methods

Ethical Considerations

The study was conducted in accordance with the principles of the Declaration of Helsinki (1964 and subsequent revisions) and the national regulations of the Republic of Kazakhstan. The study protocol was reviewed and approved by the Local Bioethics Commission of the South Kazakhstan Medical Academy, Shymkent, Kazakhstan (protocol 3; approval date: April 25, 2025). All participants were informed about the purpose of the study and provided electronic informed consent prior to completing the questionnaire. No confidential or identifiable data were entered into any automated systems. The participants did not receive any financial or nonfinancial compensation.

Study Design

This study used a multiphase methodological and descriptive design (multiphase, nonexperimental, cross-sectional study) aimed at developing, culturally adapting, and psychometrically validating a new instrument—the TUQ-MAST-KZ questionnaire—intended to assess physicians' perceptions, usability, and perceived effectiveness of telemedicine services in Kazakhstan.

The study consisted of several sequential stages: (1) literature analysis and selection of the methodological framework (TUQ and MAST), (2) development and structuring of the questionnaire, (3) linguistic and cultural adaptation, (4) expert evaluation of content validity (CVI), and (5) pilot testing and analysis of internal reliability (Cronbach α).

Such a multiphase approach ensured the scientific rigor, transparency, and reproducibility of the instrument development process.

Instrument Development: Theoretical Framework (TUQ and MAST)

The methodological foundation of the TUQ-MAST-KZ questionnaire was based on the integration of two internationally recognized models for telemedicine evaluation:

1. TUQ [25]: an instrument designed to assess users' perceptions, usability, interface quality, and satisfaction with telemedicine technologies.
2. MAST [27]: a comprehensive assessment framework that includes seven domains: clinical, organizational, economic, ethical, legal, social, and technological.

The integration of these models made it possible to create a multilevel instrument that combines user-focused and system-level aspects of telemedicine evaluation. Based on TUQ and MAST, the TUQ-MAST-KZ questionnaire was developed, with its structure summarized in the "Questionnaire Construction" section.

Questionnaire Construction

The development of the TUQ-MAST-KZ questionnaire was based on an analysis of international telemedicine evaluation instruments, including the TUQ and MAST models. The initial set of items was formulated using the conceptual components of these models.

The draft version of the questionnaire was reviewed by an interdisciplinary expert panel to evaluate the logical structure, eliminate duplication, verify the accuracy of item wording, and ensure alignment with the domains of the MAST model. The experts' comments focused on refining terminology, removing overlapping items, and adapting statements to the clinical and organizational context of Kazakhstan.

The final version of the TUQ-MAST-KZ questionnaire included 27 items, including:

- 13 Likert scale statements (5-point scale ranging from 1="strongly disagree" to 5="strongly agree")
- 4 dichotomous questions ("yes/no" responses)
- 8 categorical questions reflecting demographic and professional characteristics of respondents
- 2 open-ended questions for additional comments and descriptions of individual experience

This structure made it possible to balance quantitative and qualitative data and to ensure a comprehensive assessment of physicians' perceptions, experiences, and conditions of telemedicine use in Kazakhstan.

The full version of the TUQ-MAST-KZ questionnaire, including all 27 items and their distribution across the adapted TUQ and MAST domains, is provided in Multimedia Appendix 1.

Linguistic and Cultural Adaptation

The linguistic adaptation was applied to the final version of the TUQ-MAST-KZ instrument. The adaptation process followed the international ISPOR (The Professional Society for Health

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Economics and Outcomes Research) guidelines for translation and cultural adaptation of assessment instruments [28]. The process consisted of four key stages:

1. Forward translation of the final set of TUQ-MAST-KZ items into Kazakh and Russian, performed by two independent professional translators with experience in medicine and digital health.
2. Reconciliation of translations during a meeting of an interdisciplinary expert panel, which included a physician, a public health specialist, a faculty member, and an IT specialist.
3. Back translation of both language versions into English by an independent linguist unfamiliar with the original instrument.
4. Comparative analysis of the original author-developed TUQ-MAST-KZ version and the back translations to ensure conceptual, semantic, and content equivalence.

The final Kazakh and Russian versions of the TUQ-MAST-KZ were deemed by experts to be fully consistent with the original author-developed version of the instrument, ensuring its correct application among physicians proficient in different languages.

Expert Validation

The content validity of the questionnaire was assessed using an expert evaluation approach with the participation of 6 independent experts. Each item was evaluated according to three criteria—relevance, clarity of wording, and necessity—using a 4-point scale, where 1 indicated “not relevant” and 4 indicated “highly relevant.”

The calculation of the individual content validity index (I-CVI) and the scale-level content validity index (S-CVI/Ave) was performed in accordance with the recommendations of Polit and Beck [29] and Lynn [30]. A number of experts met the international minimum requirements for content validation.

According to the results, all items had an I-CVI of ≥0.80, and the overall index was S-CVI/Ave=0.94, indicating high agreement among experts and excellent content validity of the questionnaire.

All calculations were performed manually and additionally verified in IBM SPSS (Statistical Package for the Social Sciences) Statistics (version 27.0) using the *Descriptive Statistics* function.

The experts confirmed that the content and phrasing of the items accurately reflect the intended construct areas and correspond to the structure of the MAST model.

Pilot Testing and Data Collection

The pilot online study was conducted in the Republic of Kazakhstan from May 30, 2025, to June 9, 2025, using a secure electronic survey form (Google Forms). A total of 156 physicians from various regions and levels of health care participated in the survey. The sample included general practitioners, internists, cardiologists, oncologists, surgeons, and other specialists representing both urban and rural health care facilities.

Participation was voluntary and anonymous. All respondents were informed about the purpose of the study and provided electronic informed consent.

Inclusion Criteria

The study included physicians working in public or private health care organizations in Kazakhstan, representing different levels of care (primary, secondary, and tertiary) and both urban and rural regions. Participants were required to be fluent in Kazakh or Russian and to agree to participate in the study.

The purpose of the pilot phase was to assess the applicability and clarity of the TUQ-MAST-KZ questionnaire, as well as to evaluate its usability in clinical practice. Based on the pilot results, several item wordings were refined to improve clarity and ensure better adaptation of the instrument to the health care context of Kazakhstan.

The pilot study was not intended to analyze factors influencing telemedicine perception. Its sole purpose was to test the functionality of the structure, content consistency, and internal reliability of the questionnaire. The final version of the TUQ-MAST-KZ includes 27 statements approved for the main phase of the study.

All collected data are stored in anonymized form and can be provided to the editorial office upon request.

Statistical Analysis

Data were analyzed using IBM SPSS Statistics (version 27.0) and Microsoft Excel (version 16.0). The analysis was performed using standard SPSS procedures—*Reliability Analysis* and *Descriptive Statistics*, which ensures the reproducibility of all computations.

To assess the internal consistency of the TUQ-MAST-KZ questionnaire, the Cronbach α was calculated. The interpretation of Cronbach α values followed the recommendations of Nunnally and Bernstein [31], where Cronbach α≥0.90 indicates excellent internal consistency. For the final version of the instrument, the Cronbach α coefficient was 0.93.

Frequencies, percentages, means, and SDs were used to describe the sample. During the pilot phase, SPSS was additionally used to evaluate the response distributions and basic domain-level indicators, allowing verification of item performance before the main stage of the study.

All statistical procedures followed international standards for reporting psychometric validation of questionnaires [29,32]. The significance level was set at $P<.05$.

A detailed quantitative analysis of physicians’ perceptions of telemedicine and comparisons across respondent groups will be presented in a separate publication focusing on the main phase of TUQ-MAST-KZ implementation.

Results

This section presents the quantitative findings from the pilot validation of the TUQ-MAST-KZ questionnaire, including sample characteristics, content validity indicators, and the instrument’s internal consistency metrics.

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Sample Characteristics

A total of 156 physicians were included in the analysis, representing different types of health care organizations and levels of urbanization. Among the participants, 62.2% (n=97) were women and 37.8% (n=59) were men. The age distribution was as follows: 23 to 30 years (n=50, 32.1%), 31 to 40 years (n=40, 25.6%), 41 to 50 years (n=24, 15.4%), 51 to 60 years (n=36, 23.1%), and over 60 years (n=6, 3.8%).

Professional experience was distributed as follows: 3 to 5 years (n=63, 40.4%), more than 20 years (n=52, 33.3%), 6 to 10 years (n=16, 10.3%), 11 to 15 years (n=12, 7.7%), and 16 to 20 years (n=13, 8.3%).

By type of medical organization, respondents represented polyclinics (n=70, 44.9%), hospitals (n=43, 27.6%), medical centers (n=25, 16%), medical universities (n=8, 5.1%), health administration bodies (n=4, 2.6%), dispensaries (n=1, 0.6%), and other institutions (n=5, 3.2%).

By level of urbanization of the workplace, participants were distributed as follows: metropolitan areas (n=87, 55.8%), large cities and urbanized zones (n=29, 18.6%), small towns (n=15, 9.6%), and rural areas (n=25, 16%).

Professional Profiles

Participants represented a wide range of clinical specialties. The largest groups included general practitioners (n=37, 23.7%), surgeons (n=17, 10.9%), otorhinolaryngologists (n=12, 7.7%), internists (n=11, 7.1%), and oncologists (n=10, 6.4%). Other specialties were represented in smaller proportions.

The linguistic and cultural adaptation of the questionnaire did not require substantial modifications.

I-CVIs ranged from 0.83 to 1.00, and the overall S-CVI/Ave was 0.94.

Pilot Testing

The pilot testing of the final version of TUQ-MAST-KZ was conducted among 156 physicians from various regions of Kazakhstan. The average completion time was approximately 10 minutes, indicating that the questionnaire is convenient to use and suitable for real-world clinical workloads.

During the analysis of the pilot data, several items were identified as requiring minor wording adjustments to improve clarity; these revisions were editorial in nature and did not affect the structure of the instrument. All items maintained logical coherence, and the sequence of domains was perceived by respondents as intuitive and easy to follow.

The questionnaire did not require substantial modifications—its structure, overall length, and item phrasing were found to be appropriate for clinical practice. The final version of TUQ-MAST-KZ includes 27 items and was used in the main stage of the study. The anonymized pilot data confirmed the technical correctness of the format and the absence of difficulties during completion.

Reliability (Cronbach α)

The internal consistency of the TUQ-MAST-KZ scale was evaluated using Cronbach α. The analysis included 10 Likert scale items (Q10, Q12-Q15, Q17-Q18, and Q19-Q21) corresponding to the key domains of the instrument. The overall Cronbach α coefficient was 0.924, indicating a high level of internal consistency.

The domain-level analysis confirmed the stability of the instrument's structural components:

1. Effectiveness and clinical applicability (Q12-Q15): α=0.879
2. Reliability and technical aspects (Q17-Q18): α=0.811
3. Quality of interaction (Q19-Q21): α=0.840

All values exceed the commonly accepted threshold of α≥0.70, indicating high reliability of the overall scale and its individual domains. The calculations were performed in IBM SPSS Statistics (version 27.0).

Only the Likert-type items, which form the multicomponent structure of the questionnaire, were used to assess internal consistency. Nonscale items (demographic, categorical, and open-ended questions) were excluded from the analysis, as they do not reflect latent constructs related to the perception of telemedicine (Table 1).

Table . Internal consistency (Cronbach α) of the TUQ-MAST-KZ[a] scale.

Domain	Items	Cronbach α	Interpretation
Effectiveness and clinical applicability	Q12-Q15	0.879	High consistency
Reliability and technical aspects	Q17-Q18	0.811	Good consistency
Quality of interaction	Q19-Q21	0.840	Good consistency
Overall scale	Q10, Q12-Q15, and Q17-Q21	0.924	Excellent consistency

[a]TUQ-MAST-KZ: Kazakhstan version of the questionnaire based on the Telehealth Usability Questionnaire and Model for Assessment of Telemedicine models

The final version of TUQ-MAST-KZ includes 27 items distributed across thematic areas that reflect key components of the MAST model and the clinical context of telemedicine use. The structure of the questionnaire was refined based on expert review and pilot testing, ensuring logical coherence, the absence of redundancy, and alignment with the national characteristics of Kazakhstan's health care system.

A separate section of the questionnaire includes 9 items designed to collect demographic and professional characteristics of respondents (Q1-Q9). This block is not part of the MAST model

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domains; however, it is essential for describing the sample and analyzing between-group differences.

The questionnaire contains 4 types of items: 13 Likert scale statements (1-5), 4 dichotomous items, 8 categorical questions, and 2 open-ended questions. The Likert scale statements form a multicomponent construct of physicians' perceptions of telemedicine services and serve as the basis for psychometric evaluation.

TUQ-MAST-KZ was designed to assess those domains of the MAST model that can be reliably and appropriately measured through physician-reported survey methods. The instrument covers technological characteristics, clinical applicability, reliability and safety, organizational aspects, and the subjective perception of telemedicine services—components that directly reflect the practical experience of health care professionals (Table 2).

Table . Final structure of the TUQ-MAST-KZ[a] questionnaire by domains.

Domain category	Basis	Construct content	TUQ-MAST-KZ items
Technological characteristics	MAST[b]: technological aspects	• Ease of use, efficiency, and perceived impact on quality of care	Q12-Q15
Clinical applicability	MAST: clinical aspects	• Clinical relevance and applicability of telemedicine • The feasibility of using telemonitoring in daily practice	Q16
Safety and technical reliability	MAST: safety or technical reliability	• Technical stability, errors, and perceived risks	Q17-Q18
Subjective perception and interaction	TUQ[c]: usability or interaction quality	• Comfort, ease of interaction, and quality of communication	Q10 and Q19-Q21
Organizational context	MAST: organizational aspects	• Organizational support, involvement, and availability of necessary conditions	Q11 and Q24-Q25
Organizational readiness and acceptance	MAST: sociotechnical or organizational readiness	• Perceived potential for further development of telemedicine and willingness to support its implementation	Q22-Q23
Qualitative feedback (author-defined domain)	Author modification	• Comments, barriers, and subjective suggestions	Q26-Q27

[a]TUQ-MAST-KZ: Kazakhstan-adapted questionnaire integrating components of the Telehealth Usability Questionnaire and Model for Assessment of Telemedicine models.

[b]MAST: Model for Assessment of Telemedicine.

[c]TUQ: Telehealth Usability Questionnaire.

The economic, legal, and socioethical elements of the MAST model were intentionally not included in the structure of the questionnaire, as their assessment requires specialized expert-based methodologies and lies beyond the scope of self-report survey instruments.

TUQ-MAST-KZ demonstrated a stable structure and good acceptability among physicians. The pilot testing confirmed the logical organization of domains, the absence of item redundancy, and the relevance of the questions to the clinical context of telemedicine practice in Kazakhstan. The instrument covers technological, clinical, and organizational aspects and provides a comprehensive description of physicians' experience with telemedicine services.

Discussion

Principal Findings

A questionnaire, TUQ-MAST-KZ, was developed and validated to provide a comprehensive assessment of telemedicine from the perspective of physicians. The integration of the TUQ and MAST models made it possible to combine measures of usability and perception with key organizational and clinical aspects of telemedicine implementation.

During development, a rigorous content-validation methodology was followed: the questionnaire items were mapped to the relevant domains of the MAST model, ensuring a coherent structure and construct alignment. The Cronbach α coefficient of 0.93 indicates high internal reliability, comparable to international adaptations of the TUQ conducted in Germany [33], Thailand [34], and Denmark [35].

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The linguistic and cultural adaptation was carried out in accordance with the recommendations of Wild et al [28], following established principles of content validation [29,30]. The forward and backward translations, expert reconciliation, and refinement of item wording ensured the instrument's appropriateness and accuracy for use in the Kazakhstani context.

The relevance of using the TUQ is supported by findings from recent systematic reviews. Özkeskin et al [36] demonstrated the importance of applying validated instruments to assess user experience in telemedicine. Nouri et al [37] highlighted the critical role of digital literacy; the high proportion of respondents in our study (70.5%) who reported a need for training reinforces this conclusion.

The development of TUQ-MAST-KZ addresses a significant gap in the tools available for assessing physicians' perceptions of telemedicine in Kazakhstan. The instrument can be used in studies of digital maturity within health care organizations, professional development programs, internal audits of telemedicine services, and during the implementation of new digital solutions. It also has the potential to be adapted for use in other Central Asian countries and further expanded—including the development of a patient-reported version.

Unlike previously developed instruments such as TSQ, Patient Assessment of Communication during Telemedicine Questionnaire, and Service User Technology Acceptability Questionnaire [18,20,21], which are primarily focused on assessing patient experience, the TUQ-MAST-KZ combines usability and perception metrics with components that reflect the organizational and clinical context of telemedicine practice. This makes the instrument more suitable for the systemic evaluation of telemedicine implementation. In the future, the development of a shortened version of the scale based on principal component analysis, as well as factor analysis on a larger sample, is planned. Thus, the TUQ-MAST-KZ can be recommended as a reliable, structurally valid, and practically applicable tool for assessing physicians' perceptions of telemedicine services, adapted to the national context and aligned with international methodological standards.

Conclusions

This study developed, culturally adapted, and conducted the initial validation of the TUQ-MAST-KZ questionnaire designed to assess physicians' perceptions, usability, and perceived effectiveness of telemedicine services within the health care context of Kazakhstan. The instrument is based on the integration of the TUQ [25] and MAST [27] models, which allowed for the combination of user-centered and organizational dimensions of telemedicine assessment and ensured its relevance to the national context. The TUQ-MAST-KZ represents the first validated tool developed specifically to evaluate physicians' perceptions of telemedicine services in Kazakhstan and is among the few instruments of this type available in Central Asia.

The pilot survey conducted among 156 physicians from various specialties confirmed the instrument's high internal reliability (Cronbach α=0.93) and strong content validity. The data demonstrated generally positive perceptions of telemedicine platforms across several dimensions, highlighted the need for additional training among health care professionals, and revealed specific organizational factors requiring further improvement. These findings underscore the importance of implementing structured assessment tools in clinical practice to support the sustainable development of telemedicine.

The TUQ-MAST-KZ can be applied in studies assessing the digital maturity of health care organizations, in the planning of professional education programs, in monitoring the implementation of telemedicine services, and in future research examining health care professionals' perceptions of digital technologies. The results obtained form a foundation for the broader application of the instrument and support the further development of the telemedicine digital maturity index (KazTeleHealthIndex), which will be presented in subsequent studies.

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Data Availability

The anonymized dataset used for questionnaire validation is available from the corresponding author upon reasonable request.

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Authors' Contributions

KK developed the study concept and design, conducted the literature review, coordinated the expert validation, and wrote the first draft of the manuscript. MR participated in data interpretation and manuscript revision. AS supported the validation process and linguistic review. AB and BA provided institutional support, supervised the project, and contributed to critical revisions. All authors reviewed and approved the final version of the manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1
TUQ-MAST-KZ, a Kazakhstan version of the questionnaire based on the Telehealth Usability Questionnaire (TUQ) and Model for Assessment of Telemedicine (MAST) models, for assessing physicians' perceptions and effectiveness of telemedicine services. [PDF File, 26 KB - formative_v10i1e80693_app1.pdf]

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Abbreviations

I-CVI: individual content validity index
ISPOR: The Professional Society for Health Economics and Outcomes Research
MAST: Model for Assessment of Telemedicine
S-CVI/Ave: scale-level content validity index
SPSS: Statistical Package for the Social Sciences
TSQ: Telemedicine Satisfaction Questionnaire
TUQ: Telehealth Usability Questionnaire
TUQ-MAST-KZ: Kazakhstan version of the questionnaire based on the Telehealth Usability Questionnaire and Model for Assessment of Telemedicine models
WHO: World Health Organization

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Original Paper

Demographic and Clinical Characteristics Influencing Ecological Momentary Assessment Compliance in Individuals With Bipolar Disorder: Observational Study

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Abstract

Background: Bipolar disorder requires immediate and frequent daily symptom monitoring due to its extreme mood fluctuations. Ecological momentary assessment (EMA) technology uses high-frequency data collection to achieve ecologically valid capture of patient symptoms. Investigating EMA compliance among Chinese patients with bipolar disorder and its influencing factors is essential for developing more feasible daily symptom monitoring protocols.

Objective: This study aimed to investigate the 14-day compliance rate of EMA among Chinese individuals with bipolar disorder and to examine the demographic and clinical characteristics associated with that compliance.

Methods: A total of 100 adults (63 female individuals) with bipolar disorder across mood states (depressive episode, n=29, 29%; hypomanic or manic episode, n=17, 17%; euthymic state, n=54, 54%) completed self-monitoring via the WeChat Mini Program "Xunkang Assessment System" 3 times daily for 14 days. The compliance rate was calculated as the percentage of completed questionnaires out of the total required over 2 weeks. Multivariate ordinal logistic regression was used to explore the factors associated with the compliance rate.

Results: The median compliance rate was 75% (IQR 35.7%-90.4%). Compliance did not differ significantly across mood states (*P*=.15). In multivariable models, higher Bech-Rafaelsen Mania Scale scores and lower Functioning Assessment Short Test scores were independently associated with better compliance (Bech-Rafaelsen Mania Scale: B=0.11; *P*=.03 and Functioning Assessment Short Test: B=−0.06; *P*=.01).

Conclusions: Two-week EMA monitoring via the WeChat Mini Program is feasible among Chinese individuals with bipolar disorder across mood states. Manic symptom severity and functional impairment were associated with EMA adherence and should be considered in study design and interpretation.

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KEYWORDS

ecological momentary assessment; bipolar disorder; patient compliance; self assessment; adherence

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Introduction

Bipolar disorder manifests as depressive, manic, or hypomanic mood swings, often accompanied by intraday fluctuations [1]. The unpredictable nature of bipolar episodes contributes to recurrent and chronic illness, impairing emotional regulation, cognitive functioning, and social role performance, while placing a significant burden on public health systems. According to the Global Burden of Disease 2019 study, the global disability-adjusted life years attributable to bipolar disorder increased by approximately 54% between 1990 and 2017—rising from 6.02 million to 9.29 million [2]. Moreover, these mood fluctuations present considerable challenges for early detection and timely intervention [3].

Traditional face-to-face assessments, conducted infrequently and reliant on patient recall, struggle to capture real-time symptom changes [4,5]. The ecological momentary assessment (EMA) [6] can address these limitations by collecting real-time data in naturalistic settings [7]. EMA has been used to characterize symptoms, identify relapse indicators and track their progression, and monitor treatment effects [8,9]. Furthermore, a recent meta-analysis of 14 randomized controlled trials (n=1776) reported that EMA-based interventions significantly reduced bipolar relapse and improved medication adherence [10]. Earlier EMA studies often relied on paper-and-pencil methods or study-specific devices, which increased participant burden [7]. With the widespread adoption of smartphones, participants can integrate assessment into daily routines, facilitating the collection of individual-level phenotypes and reducing burden compared with paper methods. Smartphones also enable automatic logging of response times, improving data reliability and precision [11].

However, the main challenge in using EMA is patient compliance [9,12]. Studies have shown that response rates to paper-and-pencil EMA surveys in psychosis, depression, and healthy participants ranged from 66% to 93% [13]. Two smartphone-based EMA studies in patients with bipolar disorder reported compliance rates of 80.4% in 21 days among adolescents and young adults aged 14 to 21 years [14] and 70% in 14 days among adults aged 18 to 65 years [15]. In contrast, few EMA studies have been conducted in China. One study conducted in Hong Kong found that only 70.8% of patients with bipolar disorder completed one-third of entries in 6 consecutive days [16], suggesting potentially lower compliance among Chinese participants than in Western contexts.

Cultural and systemic factors may further affect EMA engagement in China. Cultural emphasis on saving face and pronounced stigma surrounding mental illness can lead to concealment of mood fluctuations and delays in seeking care [17]. Limited recognition of treatment needs may also reduce motivation for sustained self-monitoring [18]. In addition, the expansion of digital mental health services has lagged behind that of many Western countries, with per-capita investment below the global average. This service gap may limit the adoption of digital health tools [19]. Digital EMA tools may overcome accessibility hurdles by enabling *mobile-as-a-service* through ecological momentary sampling, instantly scaling assessment nodes for the Chinese population [20].

However, few studies have examined EMA use in Chinese patients with bipolar disorder, and compliance rates and their correlates remain unclear. A previous study indicates that early adherence is a key precursor to long-term adherence [21]. Therefore, before deploying large-scale digital monitoring and intervention programs, it is important to evaluate EMA compliance and its predictors in this population. Previous research suggests that compliance rates may be affected by the form of study design, the demographic characteristics of samples, the participant population, and clinical features [6,14,22]. For example, greater current mood elevation symptom severity and a history of suicide attempts predicted considerably worse adherence in young individuals with bipolar disorder [14]. On the basis of these findings, it was hypothesized that greater symptom severity and lower functional status would be associated with lower EMA adherence. This study addressed two questions: (1) what is the level of EMA compliance among Chinese patients with bipolar disorder and (2) how is compliance associated with demographic and clinical characteristics, including symptom severity and functional status?

Methods

Participants

Participants were recruited from the outpatient clinic of Tianjin Anding Hospital from January 2023 to April 2024. The inclusion criteria were as follows: (1) age 18 years or older; (2) proficiency in using a smartphone; and (3) a diagnosis of bipolar I or bipolar II disorder according to the Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV) criteria. Participants with visual, hearing, intellectual, or physical disabilities; schizophrenia spectrum or other psychotic disorders; mixed episodes of bipolar disorder; substance use disorders; severe physical illnesses; and who were pregnant were excluded.

Participants were interviewed by trained psychiatrists using the Structured Clinical Interview for DSM-IV Disorders, Research Version (SCID-IV-RV) [23]. Eight psychiatrists with more than 2 years of clinical psychiatric experience underwent a rigorous 10-day Structured Clinical Interview for DSM-IV Disorders (SCID) training program and successfully passed the examination to ensure their proficiency with the diagnostic criteria. Standardized quantitative record forms and audio recordings were used to document the diagnostic information of each participant in detail. For each patient, 2 psychiatrists independently conducted diagnostic evaluations; if there were differences in the initial diagnoses, a senior supervisor conducted a joint discussion to reach a final diagnosis. The information about demographic and clinical characteristics was also collected. Meanwhile, the severity of symptoms and functional impairment were assessed using the 17-item Hamilton Depression Rating Scale (HAM-D17) [24], the Bech-Rafaelsen Mania Scale (BRMS) [25], and the Functioning Assessment Short Test Scale (FAST) [26].

After the baseline assessment, participants were divided into three groups based on the HAM-D17 and BRMS scores: (1)

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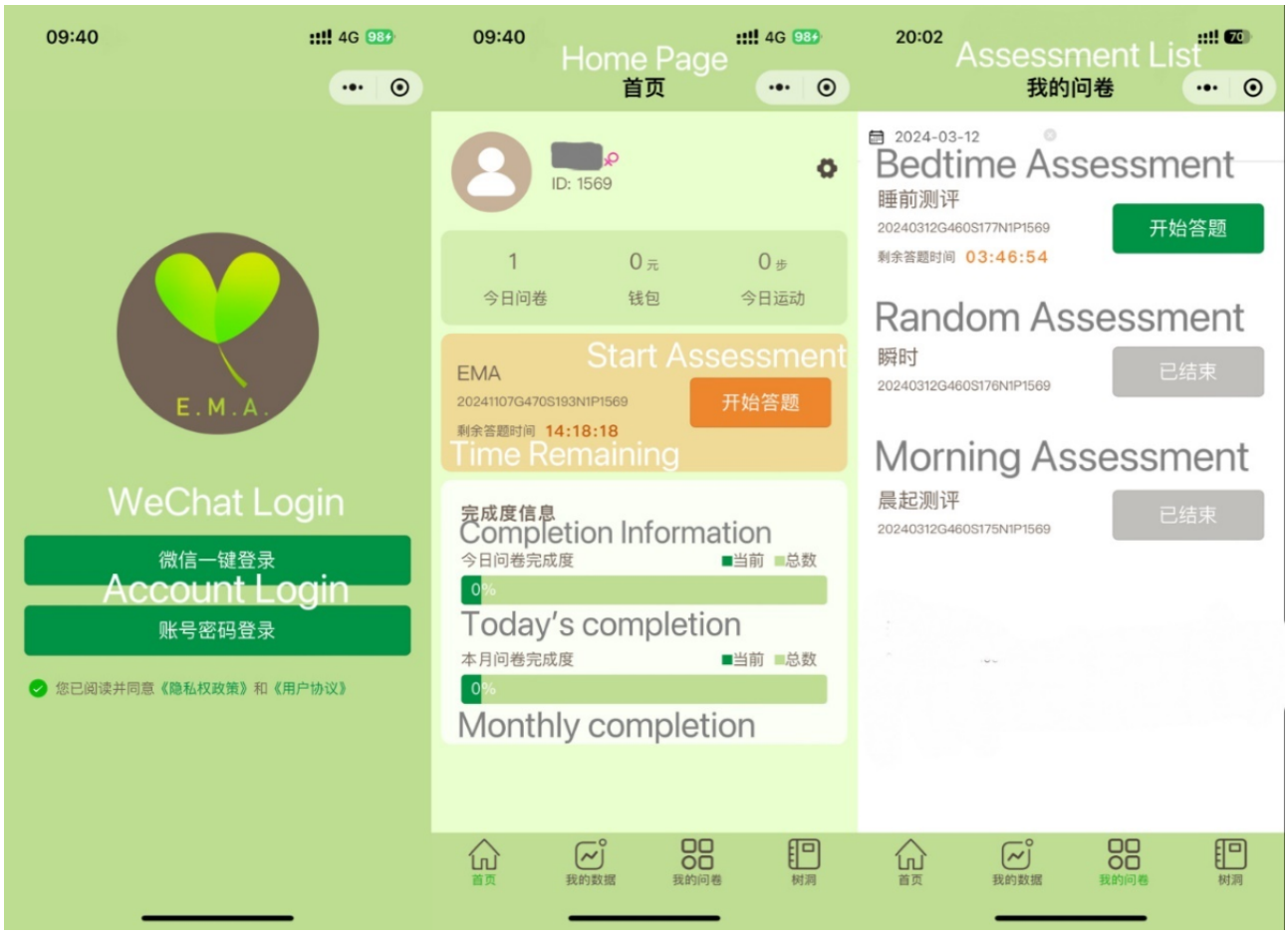
depressive episode group (total HAM-D17 score³17 points and total BRMS score£5 points), (2) current hypomanic or manic episode group (total BRMS score>5 points and total HAM-D17 score<17 points), and (3) euthymic state group (total HAM-D17 score<17 points and total BRMS score≤5 points). All participants were invited to complete a 2-week self-monitoring period.

EMA Procedure

All participants who completed the baseline survey were invited to register and conduct daily active self-monitoring via the WeChat Mini Program "Xunkang Assessment System" (Guangzhou Kangda Technology Co, Ltd), as shown in Figure 1. The WeChat Mini Program was designed to simplify responses through one-click access, a minimal interface (3 sliders and 1 submission button per page), and features to accommodate varying levels of digital literacy. The response data were encrypted and uploaded to the cloud in real time to ensure data security (for details regarding the user privacy policy, please refer to Multimedia Appendix 1). Typically, participants were prompted to complete questionnaires 3 times per day, including 2 scheduled questionnaires and a random questionnaire. The morning questionnaire was sent at 9 AM, the evening questionnaire at 8 PM, and the random questionnaire was dispatched at any time between 9 AM and 9 PM. Two participants required timing adjustments due to personal schedules: the evening questionnaire was shifted to 9 PM for 1 male participant (morning and random questionnaires unchanged), and the morning questionnaire was shifted to 08:30 AM for 1 female participant (random and evening questionnaires unchanged). For all participants, each questionnaire had a 90-minute response window. Participants who did not complete the questionnaire in time received a reminder every 30 minutes after the initial notification.

Literature indicates that monetary incentives are regarded as an "external reinforcement" mechanism in EMA research, aimed at enhancing participant completion rates. Systematic reviews and meta-analyses have demonstrated that EMA studies incorporating monetary incentives frequently report higher overall compliance rates [27]. However, multiple large-scale reviews have found no significant differences in the efficacy of monetary compensation for improving participant compliance across various emotional disorders, such as depression and anxiety [28]. This suggests that monetary incentives alone exert relatively balanced "enhancement" effects across different emotional states.

Figure 1. Screenshot of the interface of the Xunkang Assessment System.



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Instruments

Demographic and Clinical Characteristics

Baseline information was collected, including gender, age, living area, years of education, employment status, illness duration, marital status, family history of mental illness, general physical condition, health beliefs regarding medication, stigma related to mental illness, suicidal ideation, level of self-insight, and alcohol and tobacco use.

Diagnosis of Psychiatric Disorders

The SCID-IV-RV [23] is a semistructured interview for the assessment and diagnosis of psychiatric disorders. It was designed to assist clinicians and researchers in systematically assessing psychiatric disorders according to DSM-IV criteria. The SCID-IV-RV consists of multiple modules, each corresponding to a specific category of mental disorder. The diagnoses applicable to SCID-IV-RV include (1) mood disorders, (2) psychotic disorders, (3) substance use disorders, (4) anxiety disorders, (5) somatoform disorders, (6) eating disorders, and (7) adjustment disorders.

Severity of Depression

HAM-D17 [24] was used to assess the severity of a participant's depression over the past week. The scale includes 17 items that cover a variety of aspects, such as mood, somatic symptoms, cognitive symptoms, and daily activities. Each item was scored according to the severity of the symptoms, with scores ranging from 0 to 4 or 0 to 2. Higher total scores indicate more severe depressive symptoms, with conventional severity thresholds of mild (8-17), moderate (18-24), and severe (≥25). The Chinese version of the HAM-D17 has shown strong interrater reliability (κ=0.92) and acceptable internal consistency (Cronbach α= 0.714), with good structural validity [29].

Severity of Manic Symptoms

The BRMS [25] was used to assess the severity of manic symptoms in participants over the past week. The BRMS consists of 11 items covering elevated mood, speech activity, decreased sleep, difficulty concentrating, and impulsive behavior. Each item in the BRMS uses a 5-level scoring scale of 0 to 4. Each item has a standard scoring rule, and the total score is the primary outcome measure used for assessment. A total score of 0 to 5 indicates no significant manic symptoms, 6 to 10 indicates the presence of manic symptoms, and a score of 22 or more indicates that the patient has severe manic symptoms. The Chinese version of the BRMS has demonstrated excellent interrater reliability, with an intraclass correlation coefficient ranging from 0.97 to 0.99, and good construct validity, with a correlation coefficient of 0.92 when compared with the Global Assessment Scale [30].

Function Assessment

The FAST [26] was administered to assess the functioning of participants during the last 2 weeks. The FAST consists of 24 items divided into 6 functional domains: autonomy, occupational functioning, cognitive functioning, financial problems, interpersonal relationships, and leisure activities. Each item was scored according to the severity of functional impairment on a scale of 0 to 3, with a total score ranging from 0 to 72. Scores of ≤11 indicate no functional impairment, 12 to 20 indicate mild functional impairment, 21 to 40 indicate moderate functional impairment, and >40 indicate severe functional impairment. A higher total score indicates more severe functional impairment. The Chinese version of the FAST has demonstrated high internal consistency (Cronbach α=0.89 at baseline and 0.88 at week 1) and strong concurrent validity, as evidenced by significant correlations with the Global Assessment of Functioning scores and other established scales [31].

EMA Questionnaires

The daily self-assessment questionnaire included 3 self-assessments per day, including morning assessment, random assessment, and bedtime assessment. In the morning self-assessment, participants were required to report on several sleep metrics from the previous night, including sleep duration, time in bed, and subjective evaluation of sleep quality. Random self-assessment involved monitoring the participant's current mood, energy level, cognitive functioning, and activity level. For the bedtime self-assessment, the participants were asked to report their midday nap that day, tobacco or alcohol use, any life event that affects participant's emotions, and overall activity level throughout the day. For items in the daily self-assessment questionnaire, refer to Multimedia Appendix 2.

This study did not conduct a systematic statistical analysis of the collected EMA data because its primary objective was to predict adherence based on participants' clinical and demographic characteristics before the EMA project's commencement. The acceptability assessment in this study referenced findings from our prior in-depth interviews with participants, using a semistructured interview guide and conducting content analysis of the themes [32]. The data gathered through EMA served as core research material accumulated for subsequent studies exploring dynamic affective patterns and relapse prediction in patients with bipolar disorder.

Statistical Analysis

The differences in demographic and clinical parameters between groups were analyzed. Chi-square tests were used for categorical variables, and the Kruskal-Wallis *H* tests were used for continuous variables. The compliance rate was defined as the number of completed monitoring sessions divided by the total number of scheduled monitoring sessions over the 2-week period. Full adherence was defined as the completion of a total of 42 self-monitoring sessions (3 times per day), conducted by each participant over a period of 2 weeks [14]. To examine the trajectory of EMA adherence over time, a linear mixed-effects model was fitted to daily adherence rates. On the basis of prior research and the minimum data requirements for EMA analysis, participants were categorized into 3 groups according to their compliance rates: poor compliance (0%≤X<30%), insufficient compliance (30%≤X≤80%), and adequate compliance (80%<X≤100%). These thresholds were adopted from previous studies [14,16,33,34] to ensure consistency and interpretability [35]. Fisher exact test was used to compare the differences in adherence rates between different mood state groups. To investigate the demographic and clinical factors associated with the compliance rate, univariate ordered logistic regression analysis was conducted. In total, 11 candidate factors (5

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demographic variables and 6 clinical parameters) were evaluated in the univariable screen. Variables achieving $P<.20$ in univariate ordered logistic screening (5 clinical predictors) were entered into the final multivariate model [36]. The proportional odds assumption was upheld (score test $\chi^2_5=8.8$; $P=.12$), justifying the use of ordinal logistic regression (PLUM, SPSS software; version 26.0; IBM Corp). All statistical analyses were performed in SPSS software.

This observational study was conducted in accordance with the STROBE (Strengthening the Reporting of Observational Studies in Epidemiology) guidelines.

Ethical Considerations

This study adhered to the fundamental principles of the Declaration of Helsinki and was reviewed and approved by the Ethics Committee of Tianjin Anding Hospital (2022-56). Informed consent was obtained from all participants before their involvement in this study. All research data presented were also deidentified. In this study, all participants who completed the baseline assessment were informed that they would receive 100 RMB (US $14.13) upon completion of the 2-week dynamic active self-monitoring period.

Results

A total of 100 participants diagnosed with bipolar disorder were recruited for this study, including 17 (17%) patients with a current manic or hypomanic episode, 54 (54%) with a euthymic state, and 29 (29%) with a depressive episode. The demographic characteristics and between-group comparisons are presented in Table 1. During the 14-day dynamic monitoring period, no patients withdrew from the study.

The median compliance rate for all samples was 75% (IQR 35.7%-90.4%). The compliance rate was 69.1% (IQR 45.1%-94.0%) for the hypomanic or manic episode group, 66.7% (IQR 34.5%-82.1%) for the depressive episode group, and 78.6% (IQR 33.3%-91.1%) for the euthymic group. There was no statistically significant difference among the compliance rates of the 3 groups ($P=.15$). This nonsignificant finding reflects insufficient evidence to reject the null hypothesis of equal compliance, rather than confirming that no true difference exists. The Fisher exact test results are shown in Table 2. Although the hypomanic or manic episode group showed a numerically higher adherence rate, this difference did not reach statistical significance and therefore warrants cautious interpretation. During the 2-week period, the hypomanic or manic group completed more morning (10 times) and evening assessments (10 times) than random prompts (9 times), whereas the depressive episode group (9 times at each time point) and euthymic group (8 times at each time point) completed equal numbers across all 3 time points. Daily completion trajectories over 2 weeks are shown in Figure 2, indicating declines over time in all groups. Mixed-effects analysis revealed a significant group×time interaction ($P<.001$). Specifically, the hypomanic or manic episode group declined most rapidly (slope −0.03, 95% CI −0.07 to −0.03), followed by the euthymic group (slope −0.02) and the depressive episode group (slope −0.02; Table 3).

Table 4 presents the results of the univariate analysis and the demographic and clinical characteristics corresponding to different compliance categories. In the multivariate model, illness duration (years), medication adherence, total HAM-D17 score, total BRMS score, and total FAST score were included. The final model showed low-to-moderate explanatory power (Nagelkerke $R^2=0.16$; Akaike information criterion=208.4), implying that baseline demographics and clinical variables alone provided some insight into 14-day EMA compliance but were not highly predictive. Each 1-point increase in BRMS total score was associated with a 12% increase in the odds of higher adherence (odds ratio [OR] 1.12, 95% CI 1.01-1.24), whereas each 1-point increase in FAST score was associated with a 6% decrease in odds (OR 0.94, 95% CI 0.90-0.99). These results indicate that BRMS and FAST provide modest but meaningful predictive information for early identification of nonadherent individuals. Full results are presented in Table 5.

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Table 1. Sociodemographic and clinical characteristics of different groups (N=100).

Variables	Hypomanic or manic episode (n=17)	Euthymic state (n=54)	Depressive episode (n=29)	H/chi-square (*df*)	*P* value
Female, n (%)	10 (58.8)	32 (59.3)	21 (72.4)	1.6 (2)	.46
Age (y), median (IQR)	25.0 (19.5-32.5)	27.0 (22.0-37.0)	23.0 (20.5-25.5)	5.26 (2)	.07
Marital status, n (%)				2.9 (2)	.23
Married	5 (29.4)	21 (38.9)	6 (20.7)		
Unmarried	12 (70.6)	33 (61.1)	23 (79.3)		
Education (y), n (%)				0.9 (2)	.64
<9	5 (29.4)	12 (22.2)	9 (31)		
>9	12 (70.6)	42 (77.8)	20 (69)		
Employment, n (%)				3.4 (2)	.18
Full-time job	7 (41.2)	28 (51.9)	9 (31)		
Non–full-time job	10 (58.8)	26 (48.1)	20 (69)		
Illness duration (year), median (IQR)	4.0 (0.8-9.5)	3.0 (1.0-6.3)	4.0 (2.0-6.0)	0.41 (2)	.81
Medication adherence, median (IQR)	2.0 (1.0-3.0)	2.0 (1.0-3.0)	2.0 (0-3.0)	0.51 (2)	.78
Suicidal ideation, n (%)				0.8 (2)	.66
Yes	9 (52.9)	22 (40.7)	12 (41.4)		
No	8 (47.1)	32 (59.3)	17 (58.6)		
FAST[a] score, median (IQR)	22.0 (10.5-29.0)	11.5 (6.8-16.3)	20.0 (14.0-29.0)	24.55 (2)	*<.001* [b]
BRMS[c] score, median (IQR)	8.0 (6.0-13.0)	1.0 (0.0-2.0)	1.0 (0.0-2.5)	43.78 (2)	*<.001*
HAM-D17[d] score, median (IQR)	7.0 (3.5-14.5)	8.5 (3.0-13.0)	19.0 (18.0-23.0)	61.49 (2)	*<.001*
Compliance rates (%), median (IQR)	69.1 (45.1-94.0)	78.6 (33.3-91.1)	66.7 (34.5-82.1)	2.16 (2)	.34

[a]FAST: Functioning Assessment Short Test Scale.

[b]Italicization indicates significant *P* values.

[c]BRMS: Bech-Rafaelsen Mania Scale.

[d]HAM-D17: 17-item Hamilton Depression Rating Scale.

Table 2. Compliance rates in different mood state groups (N=100).

Variables	Poor compliance (n=19), n (%)	Insufficient compliance (n=39), n (%)	Adequate compliance (n=42), n (%)	*P* value
Hypomanic or manic episode	1 (5.9)	8 (47.1)	8 (47.1)	.15
Euthymic state	12 (22.2)	16 (29.6)	26 (48.1)	—[a]
Depressive episode	6 (20.7)	15 (51.7)	8 (27.6)	—

[a]Not available.

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Figure 2. The quantity of everyday compliances in different mood state groups.

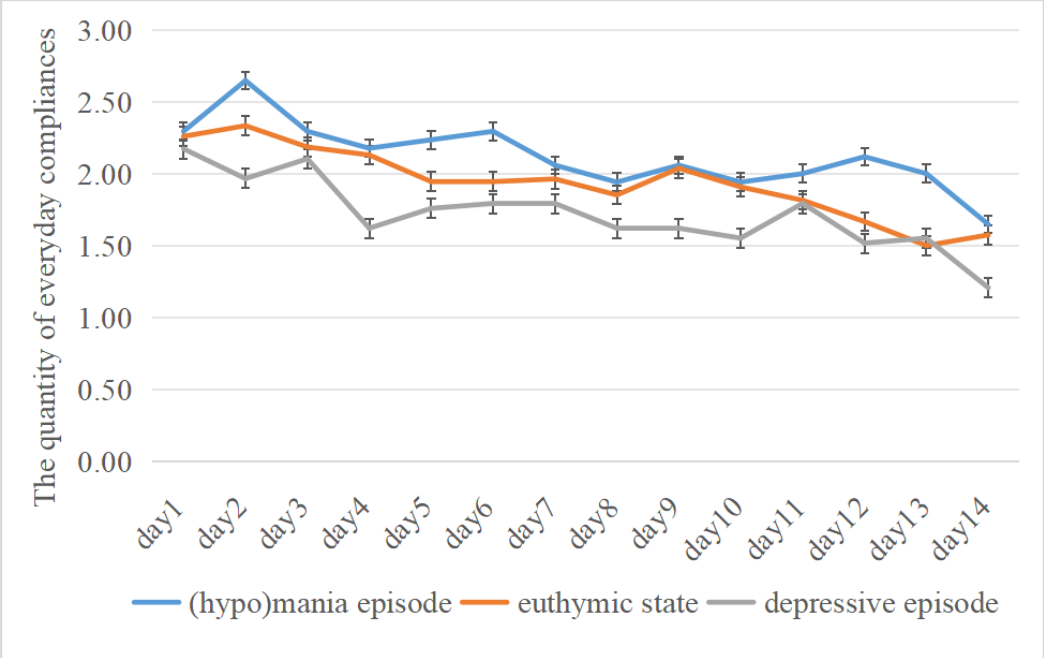

Table 3. Daily change in ecological momentary assessment adherence across 3 groups (N=42)[a].

Variables	Intercept a (95% CI)	Daily slope b (95% CI)	*t* (*df*)	*P* value
Hypomanic or manic episode	2.24 (2.12 to 2.35)	−0.03 (−0.07 to −0.03)	227.74 (36)	<.001
Euthymic state	2.31 (2.20 to 2.42)	−0.02 (−0.02 to −0.016)	131.28 (36)	<.001
Depressive episode	2.24 (2.12 to 2.35)	−0.02 (−0.02 to −0.012)	—[b]	—

[a]Mixed-effects model (depressive episode group as reference) with fixed effects group, day (centered), and group×day interaction; random effects include participant-specific random intercepts and random slopes for day (variance-components). Random-effect covariance is unstructured for the intercept-slope pair; residuals use a diagonal matrix.

[b]Not available.

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Table 4. Univariate ordered logistic regression analysis (N=100).

Variables[a]	Poor compliance (n=19)	Insufficient compliance (n=39)	Adequate compliance (n=42)	B	*P* value	OR[b] (95% CI)
Sex , n (%)						
Male	9 (47.4)	14 (35.9)	14 (33.3)	−0.36	.35	0.70 (0.33-1.49)
Female	10 (52.6)	25 (64.1)	28 (66.7)	—[c]	—	—
Age (y), median (IQR)	25.0 (21.0-34.0)	24.0 (21.0-34.0)	25.0 (21.8-35.3)	−0.01	.68	0.99 (0.96-1.03)
Illness duration (years), median (IQR)	4.0 (2.0-5.0)	3.0 (1.0-6.0)	4.0 (1.8-7.5)	0.06	*.19* [d]	1.06 (0.97-1.16)
Marital status, n (%)						
Unmarried	10 (52.6)	29 (74.4)	29 (69.0)	0.340	.40	1.41 (0.63-3.13)
Married	9 (47.4)	10 (25.6)	13 (31.0)	—	—	—
Employment status, n (%)						
Non–full-time job	11 (57.9)	24 (61.5)	21 (50.0)	−0.32	.40	0.73 (0.35-1.53)
Full-time job	8 (42.1)	15 (38.5)	21 (50.0)	—	—	—
Education (y), n (%)						
≤9	6 (31.6)	8 (20.5)	12 (28.6)	0.05	.91	1.05 (0.45-2.46)
>9	13 (68.4)	31 (79.5)	30 (71.4)	—	—	—
Suicidal ideation, n (%)						
No	13 (68.4)	22 (56.4)	22 (52.4)	−0.40	.29	0.67 (0.32-1.41)
Yes	6 (31.6)	17 (43.6)	20 (47.6)	—	—	—
Medication adherence[e], median (IQR)	1.0 (0-2.0)	2.0 (1.0-3.0)	2.0 (1.0-3.0)	0.28	*.05*	1.32 (0.99-1.74)
HAM-D17[f] score, median (IQR)	13.0 (6.0-18.0)	15.0 (5.0-18.0)	10.5 (4.0-16.0)	−0.04	*.16*	0.97 (0.92-1.01)
FAST[g] score, median (IQR)	22.0 (15.0-23.0)	14.0 (8.0-23.0)	12.5 (7.0-17.5)	−0.04	*.02*	0.96 (0.92-0.99)
BRMS[h] score, median (IQR)	0 (0-2.0)	2.0 (0-5.0)	2.0 (0.8-5.0)	0.06	*.21*	1.06 (0.97-1.16)

[a]The collinearity diagnosis of the independent variables showed that there was no collinearity. The reference values for the categorical independent variables were female, unmarried, non–full-time job, ≤9 years of education, and no suicidal ideation.

[b]OR: odds ratio.

[c]Not available.

[d]Italicization indicates significant *P* values.

[e]The medication adherence of patients is assessed using 4 questions, each with answers scored as "Yes=0 point" and "No=1 points." According to the scoring criteria of the Morisky Green Levine Medication Adherence Scale [37], higher scores indicate poorer adherence. A score of 0 denotes poor adherence, 1 to 2 denotes moderate adherence, and 3 to 4 denotes good adherence.

[f]HAM-D17: 17-item Hamilton Depression Rating Scale.

[g]FAST: Functioning Assessment Short Test Scale.

[h]BRMS: Bech-Rafaelsen Mania Scale.

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Table 5. Multivariate ordered logistic regression model.

Variables	B (SE)	*P* value	OR[a] (95% CI)
BRMS[b] score	0.11 (0.05)	.03	1.12 (1.01-1.24)
HAM-D17[c] score	0.25 (0.03)	.44	1.03 (0.96-1.09)
FAST[d] score	−0.06 (0.02)	.01	0.94 (0.90-0.99)
Illness duration (y)	0.05 (0.05)	.29	1.05 (0.96-1.16)
Medication adherence	0.29 (0.15)	.05	1.33 (1.00-1.78)

[a]OR: odds ratio.

[b]BRMS: Bech-Rafaelsen Mania Scale.

[c]HAM-D17: 17-item Hamilton Depression Rating Scale.

[d]FAST: Functioning Assessment Short Test Scale.

Discussion

Principal Findings

To the best of our knowledge, this is the first study to assess EMA compliance and its correlates in Chinese patients with bipolar disorder. More than half of the participants achieved a 2-week response rate exceeding 75%. At the current sample size, there was no statistically significant difference in 14-day EMA adherence across the 3 mood states. A decline in adherence was observed across all 3 mood state groups over the 2-week period. We used mixed-effects models to investigate the dynamic changes in EMA adherence over time and differences across clinical status groups. With the depressive episode group as the reference, the results revealed a significant interaction effect between group and time (P<.001), indicating statistically significant differences in the temporal decline of EMA adherence among the 3 clinical status groups. The hypomanic or manic episode group exhibited the steepest decline in adherence, with a slope of −0.03 (95% CI −0.07 to −0.03). This indicates that for every 10 days elapsed, the average adherence rate in this group is projected to decrease by approximately 0.3 units. Mild manic episodes represent a significant risk factor for accelerated decline in EMA adherence. This suggests that patients at this disease stage may require more proactive, individualized intervention strategies, such as simplified assessment processes, additional reminders, or motivational interviewing, to sustain engagement.

The overall compliance rate of 75% in this study is consistent with the 58% to 91.6% range reported in meta-analyses of EMA studies in bipolar disorder [38]. It was slightly lower than the adherence observed in adolescents and young adults with bipolar disorder (80.4%) [14] and comparable to the adherence reported in substance use populations using smartphone-based EMA (70.8%) [39]. In addition to differences in the samples, the methodology might also account for the compliance differences [40]. Previous studies have demonstrated that extending the response window can effectively improve EMA adherence rates [28]. The study used a 90-minute response window, compared with 120 minutes in the young-person cohort, which may have reduced participants' opportunities to respond [14]. In addition, because the platform was a WeChat Mini Program, participants could mute or disable prompts, which may have lowered completion rates [34].

Among patients with bipolar disorder, hypomanic or manic symptom severity predicted EMA compliance; each unit increase in the BRMS score corresponded to higher self-monitoring adherence. Although statistically significant, this association exhibited a small effect size and has limited clinical significance when considered alone. For clarification, in univariate analysis, BRMS was treated as a categorical variable, whereas in multivariate analysis, BRMS was treated as a continuous variable, which exhibited higher sensitivity for association detection. Moreover, in univariate analysis, BRMS was not significantly associated with EMA adherence (P=.21). However, in the multivariate ordered logistic regression model, BRMS became significant (P=.03; OR 1.12). This shift revealed the presence of a suppression effect, indicating that the "masking" effect of FAST on the relationship between BRMS and adherence became apparent after model control [41]. Despite similar overall participation, manic symptoms drove self-monitoring: elevated mood and heightened motivation led patients in manic states to engage more frequently [1]. It should be noted that our findings primarily apply to outpatient individuals with preserved insight and digital capabilities. People with hypomania often maintain good social functioning and high self-motivation in daily life [23], providing objective conditions for sustained EMA use. The presence of individuals experiencing hypomania within the hypomanic or manic group may have enhanced overall adherence within this cohort. Additionally, the presence of intense energy and vitality associated with manic symptoms facilitates greater activity and participation in self-monitoring tasks. While there is no direct literature indicating that patients with bipolar disorder exhibiting manic symptoms have better compliance with EMA tasks, the core clinical features of mania, such as increased activities in daily life, suggest that these patients may approach daily tasks with higher levels of engagement and responsiveness [42]. However, impulsivity and novelty seeking during manic episodes may initially enhance adherence but can lead to a rapid decline due to subsequent distractibility [43]. One possible reason for this study's outcome may be that the failure to differentiate between mild and severe manic symptoms obscured the internal negative effects, leaving only the positive contribution of mild mania.

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This study found no significant association between depression severity (HAM-D17 scores) and EMA compliance rates in patients with bipolar disorder. While this result differed from the hypothesis, it is not an isolated finding and can be reasonably explained through multidimensional analysis. A meta-analysis demonstrated no significant difference in EMA adherence between individuals with depressive disorders and healthy participants [33]. A study examining depression, anxiety, and suicidal ideation further confirmed that baseline depression severity and symptom fluctuations during follow-up did not affect EMA completion rates [44]. Although 1 study noted a slight negative impact of depressive history on compliance, no differences were observed in compliance between patients currently experiencing depression and those in remission [40]. These findings suggest that depression-related symptoms may not be direct predictors of EMA adherence.

Functional impairment was inversely associated with adherence. Higher FAST scores predicted lower odds of better adherence, consistent with a systematic review linking greater functional impairment to reduced retention and completion in digital monitoring [38]. Because higher FAST scores indicate more severe impairment in daily functioning, participants with greater functional deficits showed poorer compliance over the 2-week self-monitoring period. This may be attributed to the fact that, although depressive and manic symptoms may not directly determine EMA adherence, the overall functional impairments they cause may indirectly reduce patients' adherence to self-monitoring [45,46]. Future studies could use FAST subscales or targeted neuropsychological tests to isolate the independent impact of distinct functional domains on adherence. A second possibility is that, even in remission, residual depressive and manic symptoms continue to impair specific functional domains in patients with bipolar disorder [47]. Compared to healthy individuals, individuals with bipolar disorder experience greater cognitive, emotional, and technical burdens during the EMA task, as reflected by lower completion rates and higher subjective discomfort [15,48]. The FAST scale primarily assesses participants' long-term functional limitations in daily living, cognition, and social functioning, whereas EMA adherence reflects short-term, situational behavioral responses to mobile prompts at specific time points. These measures differ fundamentally in their dimensions and temporal scope; thus, FAST scores should not be directly interpreted as the sole cause of poor EMA adherence. Therefore, the association between functional impairment and EMA compliance should be regarded as correlational rather than causal. It is also noteworthy that after incorporating relevant covariates into the multilevel model, the negative effect of FAST scores on EMA completion rates remained significant after controlling for related factors. This indicates that the association should be considered and measured as an important factor.

Limitations

The study sample primarily consisted of patients with bipolar disorder treated at Tianjin Anding Hospital in Tianjin, China. Although the sample originated from multiple distinct regions, the findings remain limited in their generalizability to other psychiatric subgroups and geographic areas. Unfortunately, due to sample size limitations and imbalanced distribution within variables (such as living area, medication information, and family history), this study focused on exploring core clinical and demographic predictors of EMA adherence based on prior literature, while avoiding overfitting in multilevel analyses. The sample size for the hypomanic or manic group in this study was only 17, resulting in insufficient statistical power to detect differences in compliance across mood states. The findings of this study should not be generalized to individuals with bipolar mixed episodes and patients with bipolar disorder who are not proficient in using smartphones. Additionally, the findings reflect only short-term adherence patterns; long-term adherence requires further validation through extended observation periods in subsequent studies. Moreover, although we have provided full disclosure, due to potential tracking mechanisms on the WeChat platform, some participants may harbor concerns about data leakage, potentially leading to mild underreporting of self-reported emotional or behavioral data. The final model showed weak explanatory power, possibly due to unmeasured factors and potential nonlinear associations between predictors and adherence. The findings of this study can be cautiously extrapolated to a subset of patients with bipolar disorder undergoing EMA monitoring via WeChat Mini Programs. Additionally, to maintain consistency with previous research, this study used identical fixed adherence thresholds; this approach may introduce minor classification uncertainty for individuals at extremes of adherence. Furthermore, the 100 RMB incentive may have inflated adherence in some groups; its effect across mood states is unknown.

Future Research Directions

This study, as a predictive investigation, examined the adherence characteristics of a subset of Chinese patients with bipolar disorder using WeChat Mini Programs for EMA monitoring. The generalizability of the findings is limited by single-center recruitment, a sample size, the cross-sectional study design, lack of consideration for seasonal effects, and population restrictions. While medication adherence was assessed, this study did not further examine the impact of specific drug classes or dosages on EMA adherence. The sample included a large number of drug types (≥10) and frequent polypharmacy. Due to sample size limitations, reliable multivariate modeling was challenging. Future studies should examine whether specific mood stabilizers or antipsychotics modulate EMA adherence in larger or more homogeneous cohorts. Additionally, future research could use stratified randomization of incentives within mood state strata to assess differential effects on adherence and should replicate findings across multicenter settings, regional populations, and individuals with diverse mental health conditions to enhance generalizability, including examining differences in EMA adherence between the bipolar subtypes and conducting regular clinical assessments to determine the validity of the collected EMA data.

Conclusions

Two-week EMA monitoring via WeChat Mini Program is feasible among Chinese individuals with bipolar disorder across mood states. The observed decline in daily self-monitoring task completion over 2 weeks highlights the need for further investigation into the temporal dynamics of EMA compliance.

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Notably, greater manic symptom severity and greater functional impairment were associated with lower adherence, highlighting the importance of exploring diverse clinical features to better understand factors influencing EMA compliance.

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Authors' Contributions

GX and HY designed the study and should be considered as co-corresponding authors. L Yin, JL, and ML conducted the data analysis. L Yin drafted the initial manuscript. All authors critically reviewed the drafts and contributed to the revision of the manuscript. All authors read and approved the final version of the manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Xunkang assessment system privacy policy and supporting statistical analysis.
[DOCX File , 46 KB - formative_v10i1e74223_app1.docx]

Multimedia Appendix 2
Daily self-assessment questionnaire.
[DOCX File , 13 KB - formative_v10i1e74223_app2.docx]

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Abbreviations

BRMS: Bech-Rafaelsen Mania Scale
EMA: ecological momentary assessment
FAST: Functioning Assessment Short Test
HAM-D17: 17-item Hamilton Depression Rating Scale
OR: odds ratio
SCID-IV-RV: Structured Clinical Interview for DSM-IV Disorders, research version
STROBE: Strengthening the Reporting of Observational Studies in Epidemiology

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Original Paper

Development and Initial Validation of a Brief, Online Version of the Center for Epidemiological Studies Depression Scale (CES-D): Psychometric Study

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Abstract

Background: A growing volume of mental health research is conducted with participants recruited and responding online. However, to date, few psychometric scales have been specifically validated for online research.

Objective: We aimed to devise a brief, 12-item version of the Center for Epidemiological Studies Depression Scale (CES-D) in which first order factors are sufficiently measured.

Methods: We recruited 218 adults with depression and 226 comparison participants with no mental health history. Both groups completed the original 20-item CES-D and measures of social support, psychological distress, and sociodemographic information (eg, age, gender, and household income). Measurement of social support included online support, and psychological distress included symptoms of social media use disorder along with loneliness and life dissatisfaction.

Results: This brief, 12-item version of the CES-D was devised with persons with depression and replicated with comparison participants. For both, core sadness, somatic symptoms, interpersonal detachment, and absence of well-being each significantly contributed to measurement of a higher-order depression latent construct (P<.01). Structural equation modeling was performed to establish the construct validity of this 4-factor model in which depression is predicted by socioeconomic factors and depression predicts lower social support as well as greater psychological distress.

Conclusions: Responses to this 12-item, online version of the CES-D demonstrate factorial and construct validity. Clinical research is required in future to ascertain whether scores greater than 11 (of 36) are suggestive of elevated depressive symptomology.

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KEYWORDS

Center for Epidemiological Studies Depression Scale; CES-D; depression; social media use; social support; structural equation modeling

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Introduction

Background

As many facets of modern life are moving online, so too is mental health research [1]; this includes both participant recruitment and data collection [2]. According to King et al [3], this evolution of research methodology has had a democratizing effect, broadening recruitment beyond psychiatric hospitals and outpatient clinics and enabling contact with subpopulations who eschew biomedical interventions [4]. However, comparatively few psychometric scales have been validated specifically for online research. This paper describes the development of a brief online version of the Center for Epidemiological Studies Depression Scale (CES-D). The factor and construct validity of this online CES-D was tested relative to social support (including online social support) and psychosocial distress (including symptoms of social media use [SMU] disorder).

Our intent was to devise a brief version of the CES-D based on the original version that measures of each of the 4 factors identified across populations and over time [5]. This includes the interpersonal factor, which is currently measured using just 2 items; however, latent constructs should be measured by 3 or more items [6]. Due to the primary role of social relations and support in depression [7], this factor requires adequate measurement.

Clinical Depression

According to the *Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition, Text Revision* [8], depression is characterized by persistent low mood; loss of interest or pleasure in activities (ie, anhedonia); and various physical, cognitive, and behavioral symptoms. In addition, it has become increasingly clear in recent years that interpersonal factors are central to the experience of clinical depression [9]. A growing body of research underscores the importance of social networks, loneliness, and social support in relation to depression across populations [9-11].

Developed nearly 50 years ago [12], the CES-D remains a widely used screening tool and measure of depressive symptomology [13,14]. The original CES-D consists of 20 items [15] to which respondents indicate how each applies to how they have felt over the previous week. Different cutoff values have been suggested [5], yet few clinical or sociodemographic differences appear to affect the reliability of CES-D responses [16]. Over time, various brief versions of the CES-D have been proposed [17].

Factor analyses of CES-D responses have consistently identified 4 first-order factors mapping onto a higher-order latent construct [18]. That is, depression is not a singular phenomenon but a multidimensional construct composed of both physical and cognitive symptoms (cf insomnia vs sadness). The 4 first-order factors measured by the CES-D are core sadness (eg, “I had crying spells”), absence of well-being (eg, “I felt hopeful about the future”; reversed), somatic symptoms (eg, “My sleep was restless”), and interpersonal rejection (eg, “I felt that people dislike me”).

Emerging research supports the existence of SMU disorder as a bona fide psychiatric condition associated with clinical depression [19], though findings are inconsistent [20]. As a means for connection, online platforms such as Facebook and Instagram can shape perceptions and either foster or negate social connectedness. In its original form, the CES-D may not fully or efficiently measure the phenomenology of depression. Through the creation of a terse version of the scale but with interpersonal detachment more fully measured, the field will have an abridged CES-D specifically devised for online research.

For this study, we hypothesized that responses from persons with and without depression would be reliable (eg, internal consistency) and normally distributed. For both, we hypothesized that each CES-D factor would significantly contribute to measurement of a higher-order depression latent construct. Structural equation modeling (SEM) was used to demonstrate the construct validity of the responses to this brief CES-D relative to psychological distress, sociodemographic status, and traditional and online social support.

Methods

Recruitment

Adults with and without a diagnosis of clinical depression were recruited as part of a larger study on SMU and well-being. Participants had to be aged ≥18 years and able to read English. Both groups were recruited using the Positly platform. Positly has previously been used to recruit participants for both psychometric [21,22] and mental health research [3,21,22]. For this study, only those who had previously reported a depression diagnosis were asked to complete the depression questionnaire; similarly, participants in the comparison sample had to have reported no psychiatric history. We also excluded comparison participants who provided CES-D responses above the clinical threshold (ie, CES-D score >15) as possibly having depression but currently undiagnosed.

Most Positly participants are Amazon Mechanical Turk contractors who have established themselves as reliable over many piecework “gigs” in the crowdsourcing marketplace [23]. Over time and multiple projects, participants provide more descriptive information (ie, psychiatric diagnoses) to take part in better-paying gigs. Positly excludes participant responses (ie, not paid) if descriptive information contradicts that previously provided or if questionnaire responses are mostly missing or determined to be unreliable (ie, rapid responding without reading the questions). Positly is designed to work with the Qualtrics questionnaire platform (Qualtrics International Inc). Anonymized sociodemographic information is provided by Positly (eg, age and household income) along with questionnaire responses.

Instruments

The original CES-D [12] is composed of 20 items with responses reported on a Likert scale ranging from *rarely or none* (0) to *most or all the time* (3). The CES-D has been translated into more than a dozen languages [24].

As first noted more than 35 years ago [18], CES-D responses reflect a complex structure with correlated factors, each

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measuring a higher-order depression latent construct [16]. This has been demonstrated in cross-national research with representative samples [25].

Although other solutions have been proposed [26], the 4-factor structure first proposed by Hertzog et al [18] has been widely replicated across populations [25,27,28]. These first-order factors have been labeled as depressive affect (eg, "I thought my life had been a failure"), absence of well-being (eg, "I felt hopeful about the future"), somatic symptoms (eg, "I did not feel like eating; my appetite was poor"), and interpersonal rejection (eg, "I felt that people dislike me"). Scale scores greater than 15 out of 60 on the CES-D are suggestive of clinically significant depressive symptomatology [29].

The Brief University of California, Los Angeles (UCLA-8) Loneliness Scale [30] is an abbreviated measure developed to identify associations between loneliness and health-related behaviors [31]. Responses are reported on a Likert scale ranging from *I never feel this way* (0) to *I often feel this way* (3). Internal consistency of UCLA-8 responses is high (Cronbach α=0.84) [32].

The Satisfaction With Life Scale (SLS) [33] measures perceived quality of life based on person-specific criteria [34]. The SLS is composed of 5 questions (eg, "The conditions of my life are excellent") with response alternatives ranging from *strongly disagree* (1) to *strongly agree* (7). Test-retest reliability over 1 month has been reported as r=0.84 [34]. The concurrent validity of SLS responses has been demonstrated relative to the Fordyce global scale (r=0.82) [34].

The Brief Social Support Scale [35] measures perceived support, divided between emotional-informational and tangible support. Responses to each of the 6 items are reported on a Likert scale ranging from *very dissatisfied* (1) to *very satisfied* (6). The reliability of the responses to both subscales is high (Cronbach α=0.87 and 0.86, respectively) [35].

The Online Social Support Scale [36] is a 40-item measure of subjective online social support that divides support into 4 domains: instrumental, informational, esteem or emotional, and social companionship. Responses are reported on a Likert scale from *never* (0) to *a lot* (4). Responses have shown strong internal consistency (Cronbach α=0.97) [37], yet this high Cronbach α value may suggest item redundancy [6].

The Social Media Disorder Scale (SMD) [38] operationalizes excessive or pathological SMU as disordered or addicted behavior based on the proposed diagnostic criteria for internet gaming disorder (*Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition, Text Revision*) [8]. Responses to each of the 9 items are dichotomously reported (ie, "yes" or "no"). SMD total scores greater than 5 are suggestive of clinically problematic SMU [38]. SMD responses have good internal consistency (Cronbach α=0.81) [38].

A sociodemographic questionnaire was constructed for this study to obtain descriptive, psychosocial, and clinical information [39,40]. Participants reported date of birth, gender, country of residence, relationship status, level of education, occupation, and ethnicity. Both those with and without depression were also asked to list all diagnosed mental health conditions, approximate dates of diagnosis, comorbid psychiatric conditions, prescribed psychotropic medications, and alternate therapies. To verify the correct categorization of both persons with depression and comparison participants, we corroborated diagnostic information.

Statistical Analyses

We first performed multiple imputation to address missing scale responses using the *mice* package in R (R Foundation for Statistical Computing) [41]. Missing or skipped responses were less than 1% of scale responses and missing at random (ie, not specific to particular items). In part, this low percentage was due to the prompting function in Qualtrics requiring respondents to confirm that they intended to skip responses before proceeding to the next question. Descriptive statistics were first computed for both continuous dependent and independent variables to confirm that their distributions were relatively normal and had good internal consistency.

Confirmatory factor analysis (CFA) was conducted to examine responses to the original 4-factor CES-D. A revised 12-item model was proposed to enhance measurement of the interpersonal rejection latent factor. This model was independently replicated with participants with depression and those with no mental health history.

SEM was performed to confirm the construct validity of the responses to this revised CES-D. We hypothesized that each first-order CES-D factor would map onto a higher-order depression latent construct; in turn, depressive symptomatology was assumed to be predicted by social support and sociodemographic variables, and depressive symptomatology and social support were assumed to predict psychological well-being.

In accord with convention, we report 3 goodness-of-fit indexes to assess overall model fit for both CFA and SEM models: an incremental (comparative fit index; CFI), an absolute (standardized root mean square residual; SRMR), and a parsimonious (root mean square error of approximation; RMSEA) fit index. Ideal SRMR and RMSEA values are less than 0.055, and ideal CFI values are greater than 0.95 [6].

We also report the expected cross-validation index (ECVI) to compare distinct models. Unlike other goodness-of-fit statistics, there is no defined cutoff value for the ECVI; instead, lower values suggest greater likelihood of replication in the population than larger values [42]. Like with the RMSEA, 90% CIs are estimated for the ECVI.

Bootstrapping was also performed as a computationally intensive simulation approach to obtain parameter estimates in the population with this model. Bootstrapping treats the original sample as a pseudopopulation or stand-in for population data [43]. Multiple random samples are then drawn from the original sample along with replacement values; each is used to obtain a new set of parameter estimates. The distribution of these parameter estimates is used to compute bias-corrected CIs for path coefficients. CIs that do not cross 0 are statistically significant and likely to exist in the population [43].

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Descriptive and comparative analyses were performed using SPSS (version 29; IBM Corp); CFA, SEM, and invariance analyses were performed using SPSS AMOS (version 29; IBM Corp). SAS (SAS Institute) was used to estimate statistical power for CFA and SEM models.

Ethical Considerations

Ethics approval was obtained from the institutional review board at Ben-Gurion University of the Negev, Be'er Sheva, Israel (499-7; August 2023). Respondents provided informed consent to participate by clicking to proceed as stated on the study splash page. They were not required to provide identifying information aside from an email address if they wished to receive a summary of the findings or take part in the participant lottery (US $500). All aspects of this study were performed in accordance with the Declaration of Helsinki.

Results

Descriptive Statistics

From March 2024 to October 2024, we recruited 444 adults in the United States via the Positly platform; 218 (49.1%) were recruited from a pool of persons who previously indicated that they had been diagnosed with depression, and we also recruited a comparison sample of 226 (50.9%) adults with no mental health history. Participants in both groups confirmed this categorization at recruitment.

On average, participants took 15.47 (SD 10.09) minutes to complete the online questionnaires; this did not significantly differ between groups (t_{442}=0.26; P=.80). On average, participants were aged 45.88 (SD 13.13; range 22-79) years, yet the depression sample (mean age 44.56, SD 12.5 years) was somewhat younger than the comparison sample (mean age 47.25, SD 13.6 years; t_{444}=2.22; P=.03). Consistent with depression prevalence, there were significantly more women in the depression sample (147/218, 67.4% women vs 69/218, 31.7% men) than in the comparison sample (98/226, 43.4% women vs 110/226, 48.7% men; χ^2_3=50.0; P<.01). Among participants with depression, time since diagnosis varied widely, with a mean of 14.98 (SD 11.03) years, ranging from 2 months to 66.34 years (average age 14.98, SD 11.03 years).

Only 50% (109/218) of the participants with depression were currently prescribed psychotropic medication; almost one-quarter (52/210, 23.85%) reported various alternate therapies (eg, meditation or marijuana). Of those taking prescribed medication, many were taking multiple medications, including antidepressants, mood stabilizers, anxiolytics, and atypical antipsychotics (mean number of prescribed psychotropic medications 0.66, SD 0.78; range 0-4).

Scores on the 20-item CES-D by persons with depression were high (ie, mean 25.51, SD 13.1), with 77.52% (169/218) obtaining scores suggestive of clinically elevated symptoms (ie, CES-D score >15). In contrast, the scores of comparison participants were considerably lower (mean 5.56, SD 4.34; t_{444}=21.40; P<.01). Internal consistency was within ideal parameters for CES-D responses (Cronbach α=0.93 for both the depression and comparison groups) and all factors except interpersonal rejection (0.45<Cronbach α<0.71; Table 1).

Table 1. Descriptive statistics for study variables of participants with and without depression.

	Participants with depression (n=218)		Participants without depression (n=226)		*t* test (*df*)
	Mean (SD)	Cronbach α	Mean (SD)	Cronbach α	
Age (years)	44.56 (12.40)	—[a]	47.25 (15.35)	—	2.17 (444)[b]
Education (years)	15.34 (7.87)	—	15.40 (2.96)	—	0.75 (434)
Annual household income (US $)	71,985 (55,492)	—	77,724 (55,397)	—	1.09 (416)
Original 20-item CES-D[c]	25.51 (13.10)	0.97	5.56 (4.34)	0.93	21.40 (444)[c]
UCLA[d] Loneliness Scale	20.44 (5.49)	0.93	13.26 (3.78)	0.77	16.03 (444)[c]
Satisfaction With Life Scale	16.56 (7.89)	0.92	24.95 (7.16)	0.90	11.75 (444)[c]
Social Media Disorder Scale	1.81 (1.97)	0.79	0.61 (1.17)	0.69	7.78 (444)[c]
Tangible social support	8.35 (2.44)	0.90	9.88 (2.37)	0.92	6.73 (444)[c]
Emotional social support	8.33 (2.54)	0.92	10.03 (2.14)	0.89	7.58 (444)[c]
Online social support	30.39 (9.29)	0.92	32.60 (9.30)	0.94	2.50 (444)[c]

[a]Not applicable.

[b]P<.05.

[c]CES-D: Center for Epidemiological Studies Depression Scale.

[c]P<.01.

[d]UCLA: University of California, Los Angeles.

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Original 20-Item CES-D

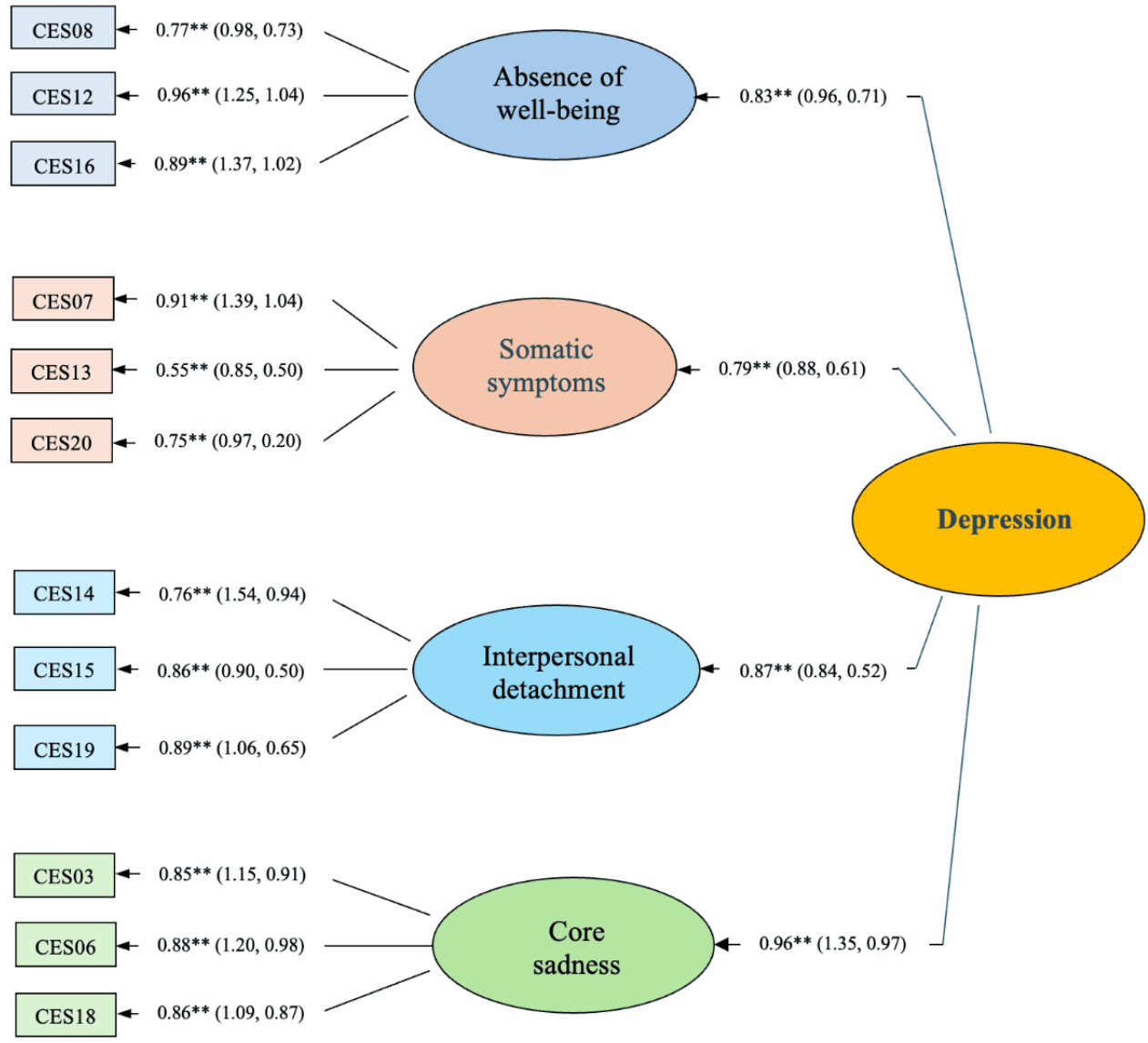
We first computed a CFA model examining responses by persons in the depression sample to the original 20-item version of the CES-D [12]. This CFA model was computed to generate comparative data for subsequent analyses. After correcting for correlated error between 9 of 210 possible item pairs, goodness of fit was within the ideal parameters for each statistic (χ^2_{158}=251.7; *P*<.01). More precisely, the CFI (0.96), SRMR (0.052), and RMSEA (0.052) were all within ideal parameters. The full 90% CI for the RMSEA was within adequate parameters (0.040<RMSEA CI 90% <0.064). The ECVI for this 20-item CES-D model was 1.64 (1.46<ECVI CI 90% <1.86).

Each CES-D item significantly loaded onto its respective first-order factor (ie, critical ratio values>|1.96|), though 3 of 20 items cross-loaded across 2 or more factors (ie, complex items). In addition, all first-order factors significantly contributed to measurement of a higher-order depression construct, including interpersonal rejection (β=0.73; *P*<.01). With 218 participants and 158 df, statistical power for this CFA model was sufficient to identify small effect sizes (ie, *d*>0.99) [6].

12-Item Online Version of the CES-D

We next set out to identify a brief version of the CES-D with all factors measured using a minimum of 3 items. We first excluded all complex items, then identified those that loaded most significantly upon their respective factors (ie, lowest error estimates). This allowed us to determine whether we could expand measurement of the interpersonal factor by removing the loneliness item (16) from the sadness factor. On this basis, we provisionally relabeled this factor as *interpersonal detachment* rather than *interpersonal rejection* (Figure 1).

Figure 1. Brief, online version of the Center for Epidemiological Studies Depression Scale (CES-D). The image shows standardized β values (maximum likelihood estimates), with the 95% CIs in parentheses. The * indicates *P*<.05 and the ** indicates *P*<.01.



Again, all 12 items loaded significantly onto their respective first-order factors (critical ratio>|1.96|), and all factors were found to significantly measure a higher-order depression latent construct. This includes the expanded interpersonal detachment

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factor with a standardized β value of 0.87 (P<.01) compared to 0.73 (P<.01) for the 20-item CES-D. However, the increase was not statistically greater than the baseline model ($\Delta\chi^2$=0.1; Δdf=1; P>.05), nor did measurement significantly differ for the other factors relative to the original 20-item model.

With the 12-item scale, correction for correlated error was required between items 15 and 19 (both on the interpersonal factor) to achieve ideal fit for all indexes (χ^2_{49}=72.0; P=.02). Thereafter, the CFI (0.99), SRMR (0.043), and RMSEA (0.046; 0.020<RMSEA 90% confidence level<0.068) were each within ideal parameters. With 218 participants and 49 df, this model had sufficient statistical power to detect small effect sizes (ie, d>0.99) [6].

As the 12-item model was nested in the 20-item CFA, we were able to compare relative fit ($\Delta\chi^2$ = 251.7 – 72.0 = 179.7). This difference significantly exceeded the threshold value of 134.37 (ie, Δdf = 158 − 49 = 109; P<.05), suggesting a better fit for the revised 12-item CES-D vis-à-vis the original. The ECVI was also lower for the 12-item model than for the original (0.60 vs 1.64). Moreover, the 90% CIs did not overlap (0.51-0.72 vs 1.46-1.86), suggesting that a superior fit for the 12-item CES-D is likely to be found more than 90% of the time if replicated with samples of equal size.

Replication of Findings for Persons Without Depression

We set out to replicate this 12-item, higher-order model with a comparison sample as the CES-D is administered as a screening measure to both persons with and without depression. Goodness of fit was again within the ideal parameters after correcting for correlated error between 2 item pairs (χ^2_{49}=69.6; P=.03; CFI=0.96; SRMR=0.052; RMSEA=0.043; 0.015<RMSEA 90% confidence level<0.065). With 226 participants and 49 df, this model also had sufficient statistical power to detect small effect sizes (ie, d>0.99 [6]; Table 2).

Table 2. Descriptive statistics for the revised 12-item Center for Epidemiological Studies Depression Scale (CES-D) for participants with and without depression.

	Participants with depression (n=218)		Participants without depression (n=226)		*t* test (*df*)
	Mean (SD)	Cronbach α	Mean (SD)	Cronbach α	
12-item online CES-D	16.60 (8.62)	0.92	3.53 (3.05)	0.69	21.14[a]
Range of scores	0-36	—[b]	0-12	—	—
1. Core sadness	4.27 (2.84)	—	0.44 (0.78)	—	19.19[a]
2. Absence of well-being	5.18 (2.65)	—	1.72 (1.81)	—	18.69[a]
3. Somatic symptoms	4.33 (2.43)	—	0.88 (1.24)	—	18.69[a]
4. Interpersonal detachment	2.82 (2.29)	—	0.48 (0.83)	—	14.17[a]

[a]P<.01.

[b]Not applicable.

As expected, responses to this 12-item CES-D were strongly correlated with loneliness and inversely associated with life satisfaction. Moreover, brief CES-D responses were moderately and inversely associated with all forms or social support, including online social support. These results emerged for both participants with and without depression (Tables 3 and 4).

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Table 3. Correlation coefficients between the 12-item Center for Epidemiological Studies Depression Scale (CES-D) and study variables for participants with depression.

	Tangible support	Emotional support	Online social support	Life satisfaction	Loneliness	Social media use disorder
12-item CES-D						
r	−0.36	−0.49	−0.21	−0.64	0.71	0.19
P value	.01	.01	.01	.01	.01	.01
Tangible support						
r	1	0.57	0.31	0.36	−0.47	−0.04
P value	—[a]	.01	.01	.01	.01	.52
Emotional support						
r	0.57	1	0.37	0.49	−0.59	0.04
P value	.01	—	.01	.01	.01	.52
Online social support						
r	0.31	0.37	1	0.19	−0.19	0.25
P value	.01	.01	—	.01	.01	.01
Life satisfaction						
r	0.36	0.49	0.19	1	−0.61	−0.04
P value	.01	.01	.01	—	.01	.60
Loneliness						
r	−0.47	−0.59	−0.19	−0.61	1	0.13
P value	.01	.01	.01	.01	—	.05

[a]Not applicable.

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Table 4. Correlation coefficients between the 12-item Center for Epidemiological Studies Depression Scale (CES-D) and study variables for participants without depression.

	Tangible support	Emotional support	Online social support	Life satisfaction	Loneliness	Social media use disorder
12-item CES-D						
r	−0.37	−0.38	−0.25	−0.39	0.53	0.20
P value	.01	.01	.01	.01	.01	.01
Tangible support						
r	1	0.72	0.23	0.34	−0.50	−0.06
P value	—[a]	.01	.01	.01	.01	.36
Emotional support						
r	0.72	1	0.32	0.33	−0.53	−0.09
P value	.01	—	.01	.01	.01	.52
Online social support						
r	0.23	0.32	1	0.14	−0.29	0.25
P value	.01	.01	—	.04	.01	.01
Life satisfaction						
r	0.34	0.33	0.14	1	−0.41	0.06
P value	.01	.01	.04	—	.01	.34
Loneliness						
R	−0.50	−0.53	−0.29	−0.41	1	0.13
P value	.01	.01	.01	.01	—	.05

[a]Not applicable.

Construct Validity of Responses to the 12-Item CES-D

Having devised a brief version of the CES-D with all factors sufficiently measured, we next set out to confirm its construct validity relative to sociodemographic factors, social support, and psychological well-being. Using SEM, we hypothesized that depression as measured using these 4 factors would significantly predict lower social support and psychological well-being (Figure 2).

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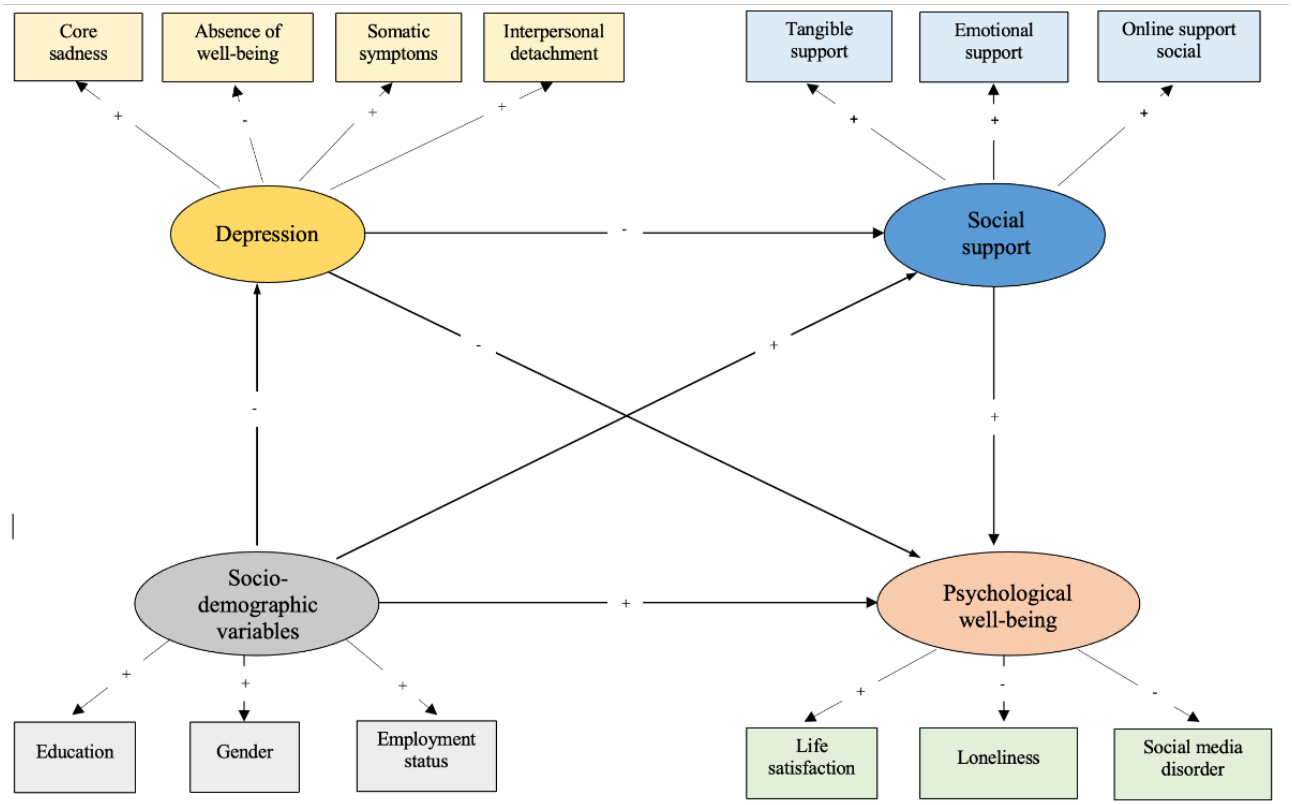
Figure 2. Hypothesized model; construct validity of 12-Item online Center for Epidemiological Studies Depression Scale (CES-D).



The resulting model emerged largely as hypothesized, yet neither gender nor employment status emerged as significant. Instead, we included household income and socioeconomic status based on work performed (now or before retirement). We relabeled this latent factor as socioeconomic status vs sociodemographic status. This suggests that depression is fostered by economic factors more than demographic factors (cf household income and gender).

Although lower socioeconomic status predicts depression, socioeconomic status did not predict social support or psychological well-being. It should also be noted that we relabeled psychological well-being as psychological distress to better reflect directions of association (ie, loneliness, life dissatisfaction, and SMU disorder; Figure 3).

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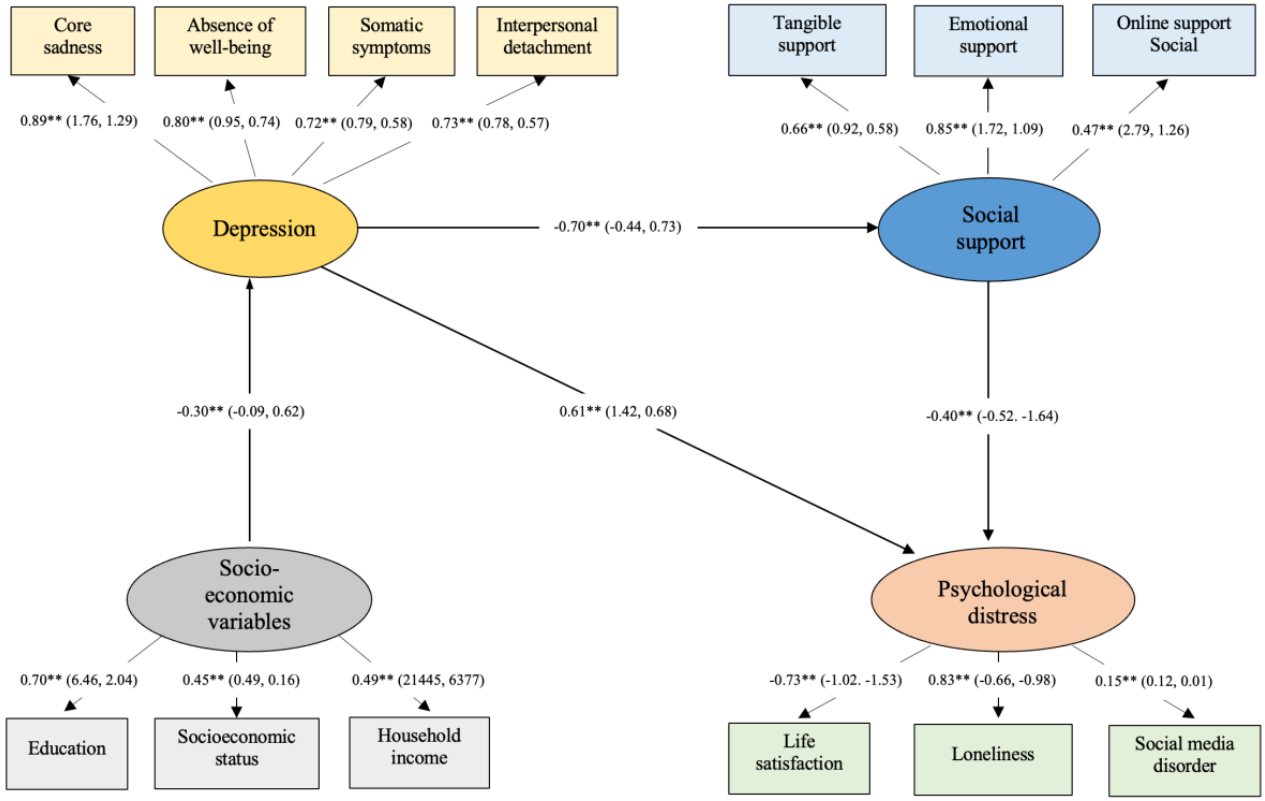
Figure 3. Construct validity of 12-Item Center for Epidemiological Studies Depression Scale (CES-D). The image shows standardized β values (maximum likelihood estimates), with the 95% CIs in parentheses. The * indicates *P*<.05 and the ** indicates *P*<.01.



Overall fit was ideal for this SEM model (χ^2_{56}=86.2; *P*<.01; CFI=0.97; SRMR=0.049; RMSEA=0.052; 0.028<RMSEA 90% confidence level<0.072). With 218 participants and 56 df, statistical power for this CFA model was sufficient to identify medium to large effect sizes (ie, *d*>0.80).

Depression as measured using this 4-factor CES-D significantly predicted lower social support and both directly and indirectly predicted psychological distress via lower social support. Both direct and indirect associations were statistically significant (Table 5). These findings support the construct validity of the responses to this revised 12-item CES-D.

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Table 5. Direct and indirect effects of depression and social support.[a]

	Socioeconomic status	Depression	Social support
Depression			
Direct effects	–0.30[c]	—[b]	—
Indirect effects	0.00[d]	—	—
Total effects	–0.30[c,d]	—	—
Social support			
Direct effects	0.00	–0.70[c]	—
Indirect effects	0.21[c,d]	0.00[d]	—
Total effects	0.2[c]	–0.70[c]	—
Psychological distress			
Direct effects	0.00	0.6[c]	–0.40[c]
Indirect effects	–0.27[c,d]	0.28[c,d]	0.00[d]
Total effects	–0.27[c]	0.89[c]	–0.40[c]

[a]Statistical significance estimated over 500 bootstrapped samples.

[b]Not applicable.

[c]$P<.01$.

[d]Direct effects are added to indirect effects, sum = total effects.

Discussion

Principal Findings

For this study, we set out to devise a brief, online version of the CES-D with an online sample for contemporary digital research. As mental health research continues to transition to online platforms, there is a growing need for psychometric tools validated for online research [2,44]. Reported findings demonstrate that this 12-item CES-D preserves the established 4-factor structure of the original scale while offering more robust measurement of the interpersonal dimension of depression, an area particularly relevant in context of online social interaction (Multimedia Appendix 1).

Across analyses, responses to this 12-item CES-D demonstrated strong internal consistency and consistent support for the 4 first-order factors (core sadness, absence of well-being, somatic symptoms, and interpersonal detachment), each significantly measuring a higher-order depression latent factor. The construct validity of this online version of the CES-D was supported relative to social support, psychological distress, and socioeconomic indicators. Our findings underscore the central role of interpersonal processes in depression, particularly in the context of SMU and contemporary patterns of social support. The revised 12-item CES-D offers a brief yet psychometrically robust measure of depressive symptomatology, including its interpersonal dimension, providing efficient and sufficient assessment suitable for online research [28].

A central goal of this study was to strengthen the assessment of the interpersonal factor, reconceptualized as interpersonal detachment. Prior research has shown that 2-item factors can be psychometrically unstable, particularly when used with diverse or nonclinical online samples. Our results confirm that expanding interpersonal measurement improves the reliability and factorial stability of the scale while maintaining the brevity essential for online administration. These findings are consistent with long-standing evidence that interpersonal difficulties, including loneliness, social withdrawal, and perceived rejection, are integral components of depressive symptomatology and not merely peripheral correlates.

Multivariate analyses suggest that social support serves as a buffer, mitigating the adverse effects of depression on psychological distress. Socioeconomic factors predicted depression and indirectly impacted psychological distress via depression. Educational level, socioeconomic status based on work performed, and household income collectively and uniquely contributed to measurement of socioeconomic status. In contrast, age, gender, and employment status did not significantly contribute to measurement, leading us to relabel this latent factor as socioeconomic status, not sociodemographic status. This suggests that economic factors such as income are more germane to depression than sociodemographic variables such as age. At least this appears true for relatively low-income participants. The average household income of the participants (both groups) at US $74,920 (SD US $55,478) is below the US median of US $83,730 for 2024 [45].

Consistent with our focus on digitally mediated social experience, we extended measurement of traditional social support (emotional and tangible assistance) to include online social support. Each contributed uniquely and significantly to the measurement of social support, underscoring the need to account for both offline and online relational resources in contemporary research. In addition, for this study, psychological distress was operationalized to include symptoms of SMU

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disorder in accordance with emerging evidence suggesting that problematic social media engagement may intersect with depressive processes [46]. Although loneliness and life dissatisfaction were the strongest indicators, findings underscore that social media functions both as a resource for connection and a source of strain for adults with depression [47].

This is not the first depression scale devised for online research. For instance, the 12-item Mental Health Screening Tool for Depressive Disorders proposed by Park et al [48] was developed to screen for depression in South Korea. (The CES-D was used in their study to demonstrate the concurrent validity of Mental Health Screening Tool for Depressive Disorders responses.) Similarly, Loe et al [14] described the development of a 17-item version of the CES-D [14]. However, 1 of the 3 items they suggested be deleted was an interpersonal detachment item, reducing measurement to a single item. In addition, a reduction of 3 items is not sufficient to consider this a brief version of the CES-D.

Limitations and Future Research

While this study reports notable findings, several limitations must also be acknowledged. First, as previously noted, the CES-D is widely used as both a screening tool and measure of the phenomenology of depression [12,13,17,25,49,50]; we do not address the former. Future research is needed to ascertain the scores suggestive of clinical symptomology for this 12-item online version of the CES-D [51,52].

Although establishing a clinical cutoff was not the focus of this study, research with existing versions of the scale provide a basis for estimation. Specifically, if we interpolate between the established cutoff for the 10-item CES-D (>10/30 [53]) and the original 20-item CES-D (>15/30 [29]), scores greater than 11/36 on the 12-item CES-D may suggest elevated depressive symptom levels. Clinical research is required in the future to ascertain the sensitivity and specificity of this and other cutoff points.

A second limitation is the cross-sectional design of this study, which prevents us from drawing causal associations among depressive symptoms, social support, and psychological distress. Associations are likely bidirectional over time [54]. Longitudinal research is needed to better understand how these variables interact. This will enable estimation of test-retest reliability, measurement invariance across time across factors, and differential change in depressive symptoms (eg, depressive subtypes). For instance, researchers could examine how various trajectories of depressive symptoms as measured using this 12-item CES-D impact mental health and well-being. Do different CES-D factors differentially impact psychological distress over time?

It is also important to stress that depression diagnoses were self-reported by participants and not clinically corroborated (eg, structured clinical interviews), nor did we collect information about treatment history, including psychiatric hospitalizations. However, CES-D scores were high in this sample, suggestive of clinical symptomology [55]. In addition, as previously noted with participants with depression and those with bipolar disorder [56], participants recruited online and via social media also appear more symptomatic than traditional samples composed of psychiatric outpatients. Future research is needed to determine how healthy and problematic SMU differ across mental health conditions (eg, social anxiety vs agoraphobia).

Conclusions

This study introduces a concise, psychometrically robust 12-item online CES-D that more fully measures interpersonal aspects of depression, an increasingly salient component of mood disturbance in digitally networked societies. Scale responses demonstrated strong factorial integrity, reliability, and construct validity with participants with both depression and euthymia recruited online. As online mental health research continues to expand, this online version of the CES-D provides an efficient measure suitable for use across diverse digital research settings. Continued validation across clinical, community, and cross-cultural samples will further clarify the scale's utility and ensure its relevance in the evolving landscape of mental health assessment.

Funding

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Data Availability

Anonymized datasets analyzed during this study are available in the Harvard Dataverse repository [57].

Authors' Contributions

MS and NO'R conceived the study; all authors acquired the data and contributed to the study design. APS and NO'R obtained grant funding. MS and NO'R analyzed the data and interpreted the study findings. All authors drafted, revised, and approved the final version of the manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1

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Brief, online version of the Center for Epidemiological Studies Depression Scale (CES-D).
[DOCX File , 3196 KB - formative_v10i1e81595_app1.docx]

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Abbreviations

CES-D: Center for Epidemiological Studies Depression Scale
CFA: confirmatory factor analysis
CFI: comparative fit index
ECVI: expected cross-validation index
RMSEA: root mean square error of approximation
SEM: structural equation modeling
SLS: Satisfaction With Life Scale
SMD: Social Media Disorder Scale
SMU: social media use
SRMR: standardized root mean square residual

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Original Paper

Translation and Validation of the User Version of the Mobile Application Rating Scale Into the Polish Language: Cross-Sectional Methodological Study

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Abstract

Background: Mobile health (mHealth) apps can innovatively diagnose, prevent, and treat many diseases. The increasing use of mHealth apps necessitates an appropriate assessment standard.

Objective: This study aimed to translate the User Version of the Mobile Application Rating Scale (uMARS) into Polish, followed by validation, cultural adaptation, and examination of its reliability and validity.

Methods: The Polish version of uMARS was adapted, translated, and validated based on the free STOP COVID ProteGO Safe app available for Android and iOS platforms. A total of 117 participants rated the app using the translated scale and rerated it 1 week later

Results: The conceptual equivalence of all items and subscales of the original uMARS and its Polish version was confirmed. The translated uMARS scale exhibited high reliability (Cronbach α=0.95). The perceived test-retest reliability and total influence score were acceptable, with intraclass correlation coefficient values of 0.59 and 0.65, respectively

Conclusions: The translated scale matched the reliability of the original scale. It can help users choose the best mHealth apps available in Poland and report their quality. The Polish version of uMARS was cross-culturally validated and was found to be as reliable as the original uMARS. The translated and validated uMARS tool can be used to evaluate mHealth apps in various aspects. App developers can reliably assess app components and determine areas that require further improvement and development to deliver higher-quality apps. The Polish version of the uMARS can become a standard tool for evaluating the quality of mHealth apps in Poland.

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KEYWORDS

translation; validation; Polish language; mobile health; mHealth; User Version of the Mobile Application Rating Scale; uMARS

Introduction

Mobile health (mHealth) apps provide innovative approaches [1] to health promotion [2-4], education [5-7], disease diagnosis [8-10], prevention [11], and management [12-15]. In 2017, the number of mHealth apps surpassed 325,000 [16], with an expected annual growth of approximately 41% from 2015 to 2020. The COVID-19 outbreak further accelerated the adoption of digital technologies [17,18], such as telemedicine [10,19-21], eHealth [22,23], and mHealth [9,18,21,24], resulting in an exponential increase in mHealth users [16,25,26].

According to the report by the IQVIA Institute for Human Data Science [27], app stores had approximately 350,000 health-related apps globally in 2020, with more than 90,000 being mHealth apps. The global mHealth app market size is expected to expand at a compound annual growth rate of 11.6% from 2023 to 2030 [27].

In Poland, the number of smartphone users reached 50.6 million in 2021 (132.1 subscriptions per 100 inhabitants), comprising 13.8 and 36.8 million prepaid and postpaid users, respectively [28]. According to a survey by Deloitte Digital [29], in 2022, 75% of the respondents in Poland used mHealth apps, primarily dedicated to fitness, lifestyle, and diet.

Developers, researchers, health care professionals, and web application library managers require appropriate, consistent, and objective tools to assess the quality and safety of mHealth apps. Users frequently choose mHealth apps based on star ratings and short comments in mobile app stores and repositories. Such star ratings may not adequately reflect the quality of the app [30,31]. Generally, user reviews posted on the app download sites provide biased and unreliable descriptions of the apps. These reviews often fail to specify the nature of the app and the circumstances under which it is used and may not cover all helpful features for an accurate evaluation. The traditional star-rating system lacks clarity and is ambiguous in its interpretation. A reliable rating system can help clinicians and patients identify valuable mHealth apps [32-35], streamlining the overwhelming range of available apps to a select few that merit consideration in clinical settings [8,9,14,33,34,36-41]. Many studies have examined the mainstream market status of mHealth apps [16,37,42] by evaluating functional distribution, without refined classifications of mHealth apps and information integrity [1]. In addition, the COVID-19 pandemic complicated the development of many mHealth apps, requiring close attention [18]. The User Version of the Mobile Application Rating Scale (uMARS) targeted this gap by providing an empirical basis for objectively assessing the critical quality criteria and offering users, practitioners, and researchers a rigorous measure of app quality [32]. It helps select and recommend apps [43], owing to growing interest in using objective and sustainable user ratings for mHealth apps, and clinicians and patients can use a measurable, repeatable, clustered evaluation system to ensure that a particular mHealth app can meet their specific needs effectively.

The uMARS provides an empirical basis for the objective evaluation of critical quality criteria. It offers a rigorous metric for evaluating app quality [32] and increasing user confidence [17,32]. With the increasing interest in objective and sustainable user ratings, using tools such as uMARS is well justified. [43].

The considerable international interest garnered by the original uMARS (English) [32] is evident from its translated and validated versions in Italian [44], Japanese [45], Greek [46], Portuguese (Brazil) [47], Spanish [17], and Turkish [48]. Many researchers have highlighted the significance of uMARS as an essential instrument in the evaluation of mHealth apps, with its international use growing continuously [17,35,44-46,49-51]. Although alternative scales [52,53] have been developed in response to the limitations of uMARS [53,54], the uMARS unquestionably fulfills its task and remains the most widespread tool for evaluating mobile apps worldwide [32,33,35,49-51,55-60].

Users' interest and demand for tools, such as uMARS, are also growing in Poland owing to the increasing number of mHealth apps in the country [61,62]. Consequently, the need for prioritizing individual apps when multiple apps may serve the same purpose has arisen [63].

A translated and validated version of the uMARS was unavailable in Polish despite the increasing number of Polish mHealth apps. Therefore, this study aimed to translate and culturally adapt the uMARS into Polish and test its reliability and validity. The strengths of this study lie in the standardized methods used in all procedures and the rigorous and reliable translation process.

Methods

Study Design and Participants

Validation Procedure, Participants, and Protocol

We followed the original methodology outlined by Stoyanov et al [32] to validate the final Polish version of uMARS. We assessed the internal consistency and test-retest reliability of the scale.

This cross-sectional methodological study followed STROBE (Strengthening the Reporting of Observational studies in Epidemiology) and COSMIN (Consensus-Based Standards for the Selection of Health Measurement Instruments) guidelines for the validation of patient-reported outcome measures.

The recruitment process focused on the general adult population, and participants who provided written informed consent were considered. The authors recruited volunteers from Polish universities. The inclusion criteria for participants were as follows: individuals aged 18 years or older, individuals who owned and confidently used a smartphone, individuals who were motivated to participate in the study and were fluent in Polish. Participants unable to comprehend or respond to the questionnaires, unable to understand Polish, or unavailable during the study period were excluded.

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Procedure and Data Collection

Questionnaire

The uMARS is a widely recognized tool designed to assess the quality and usability of mobile health apps from the perspective of end users. This study used uMARS to evaluate user perceptions and experiences with a mobile app. The original uMARS comprises 4 objective domains—engagement, functionality, aesthetics, and information—and 1 subjective quality subscale [32]. This structured questionnaire provides valuable insights into an app's strengths and areas for improvement, ensuring that it meets user expectations and effectively supports the intended health outcomes. By offering a nuanced understanding of user interaction and perception, uMARS contributes significantly to the app's effectiveness and adoption. Notably, uMARS is used worldwide and does not require special training, making it accessible and practical for diverse research settings.

The uMARS ratings of participants who responded twice per the study protocol were included in the analysis. Singular ratings were excluded from further analysis. The participants evaluated the selected apps. The decision to include only uMARS ratings from participants who responded twice while excluding single ratings was driven by the need to ensure reliability and validity in assessing mobile health apps. The methodology was crucial for ensuring reliability and reducing variability. By requiring participants to rate the app twice, we aimed to increase the consistency and trustworthiness of the collected data. Consistent ratings across the 2 time points helped confirm that user ratings were stable and not influenced by transient factors, such as mood or immediate environment. Excluding single ratings helped reduce the variability resulting from 1-time impressions and ensured that the data reflected a more stable and accurate user experience with the app. The STOP COVID ProteGO Safe app was rated most frequently. Finally, the research team agreed to validate the STOP COVID ProteGO Safe app [64]. The selected app parameters were timeliness, necessity, cost-effectiveness, practicality, and compatibility with Android and iOS platforms.

Considering the assumptions described by the authors of the original method [32], participants received task instructions in the Polish language. They familiarized themselves with the app for at least 10 minutes before providing the ratings using uMARS. This procedure was repeated twice to assess intrarater reproducibility. The sensitive data of the participants were well protected.

Adaptation and Translation

The process involved several stages: preparation, double translations from the original version, reconciliation, back translation, review and harmonization, and final proofreading [54,65-69]. Internationally accepted guidelines and checklists [49-51] were used to ensure thorough translation and validation processes [32,52,69]. A bilingual translator professionally translated the English version of uMARS into Polish. The translated output was compared with a validated expert scale. After discussions, minor adjustments were made. Back translation was performed to ensure compatibility and accuracy of meaning between the source and target languages and was reviewed for consistency with the original [49,50]. Finally, the Polish uMARS questionnaire was approved.

Validation of the Polish Version of the uMARS

The Polish version of the uMARS questionnaire was validated following the recommendations described by Stoyanov et al [32]. Cronbach α coefficient, which estimates questionnaire homogeneity, was used to measure internal consistency [53,70]. A high internal consistency coefficient was indicated by a value greater than 0.70. Participants completed the translated uMARS questionnaire online and then completed it again after 1 week. The intraclass correlation coefficient (ICC) was calculated to assess the reliability of the translated scale.

App Selection

This study was conducted from February 2022 to March 2022, and the STOP COVID ProteGO Safe app was used in this study [64]. The app was freely accessible to Android and iOS users aged 17 years or older.

Similar COVID-19 mHealth apps were available globally [9,18]. The STOP COVID ProteGO Safe app's Polish version was considered due to its universality and timeliness. The STOP COVID ProteGO Safe app became available in March 2020 [64] and remained active until March 31, 2022. The app received a rating of 4.6 stars for the iOS version (7600 user ratings) and 4.2 stars for the Android version (22,000 ratings from more than 1 million downloads). The official Polish app was developed in collaboration with the Chief Sanitary Inspectorate, which aided the fight against COVID-19. The developer certified the app's safety, anonymity, data security, and privacy. The app did not collect or share user data with third parties, track the user's location, or access any files or information on the user's phone. After the test, the app assessed the user's most likely COVID-19 risk group based on the guidelines of the World Health Organization and the Chief Sanitary Inspectorate.

Statistical Analysis

Statistical tests were conducted considering the satisfaction of the assumptions of these tests, including examining whether the distributions of the studied variables conformed to normality. The Shapiro-Wilk *W* test was used to assess the normality of variable distributions. Normal distribution of quantitative variables entailed calculations of mean differences (95% CIs with 1–α=.95 confidence level). External agreement between the 2 measurements was tested for each parameter at $P<.05$. The correlation between each domain and the uMARS total score was assessed using the Pearson correlation coefficient, where a value greater than 0.7 (significance level below 0.05) was considered sufficient to evaluate test-retest reliability. Finally, the ICC between the test and retest was calculated to determine weighted rater agreement values and evaluate the closeness rather than equality of scores.

The reliability of the uMARS questionnaire was assessed via the Student 2-tailed *t* test for dependent variables. The analysis used the final test results and individual categories (results of individual scale parts). Reliability was calculated using Pearson linear correlation and ICC of each variable. Cronbach α (0.95% CI) was calculated to assess internal consistency and reliability.

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The Cronbach α values were interpreted as excellent (≥0.90), good (0.80-0.89), acceptable (0.70-0.79), doubtful (0.60-0.69), weak (0.50-0.59), and unacceptable (<0.50). Furthermore, the results were supplemented with descriptive statistics (means and SDs).

All analyses were performed using TIBCO Software Inc (version 2017) and Statistica (version 13; Data Analysis Software System) [71]. The results were considered statistically significant at the significance level (α) of .05 if the critical level *P* value was less than .05.

Ethical Considerations

This study was approved by the Bioethical Commission (AKBE/60/2022). The study was conducted in accordance with the principles of scientific ethics and the Declaration of Helsinki. The Bioethical Commission approved the study protocol on February 21, 2022, and confirmed that the study complies with ethical standards for scientific research. All participants were adults and took part in the study voluntarily. Before participating in the study, participants received information about the purpose and procedures of the study and gave their informed consent in electronic form. Participants were informed that participation in the study was voluntary and that they could withdraw at any time without any consequences. No personally identifiable data were collected. All data were collected and analyzed anonymously. Data storage and processing complied with applicable data protection regulations, and access to the data was restricted to the research team. Participants did not receive any financial or other compensation for their participation in the study.

Results

Overview

This study enrolled 117 participants who fulfilled the inclusion criteria (women: n=81, 69.2%; men: n=36, 30.8%; mean age 20, SD 1.66 years). Among them, 90 (76.9%) participants were associated (academically or professionally) in the medical field; 19 (16.2%) were in biomedical engineering, 4 (3.4%) were in nursing, and 4 (3.4%) were in dentistry. Most respondents were undergraduate and postgraduate students enrolled at Cardinal Stefan Wyszyński University in Warsaw (n=39, 33.3%), the Medical University of Warsaw (n=60, 51.3%), and the Silesian University of Technology (n=18, 15.4%). A total of 71 (60.7%) respondents reported daily use of mobile apps, and 59 (50.4%) respondents used Apple, iOS, or other Android devices.

All respondents performed the initial app assessment twice with a 1-week gap using uMARS. The questionnaire was administered twice with a 1-week break to assess the repeatability of the Polish uMARS questionnaire. First, a paired *t* test was conducted to observe the differences between the 2 measurements for each subscore and total score. Test-retest reliability was assessed for each variable using the Pearson 2D correlation coefficient.

The participants rated the STOP COVID ProteGO Safe app twice. Every participant received clear and concise information regarding the study objectives, rules of participation, and procedures.

Translation Process

The translation process involved several stages: preparation, double translations from the original version, reconciliation, back translation, review and harmonization, and final proofreading [65,72]. Internationally accepted guidelines and checklists [66-68] were used to ensure thorough translation and validation processes [72,73]. Two native Polish-speaking translators independently translated the original English survey into Polish. A consensus meeting agreed upon a standard version as a unified translation. Similarly, 2 independent back translations into English were conducted anonymously using the Polish version of the uMARS. The interdisciplinary group reviewed and completed the questionnaires. No significant difficulties were encountered during the translation process, and a consensus was reached regarding minor discrepancies that reflected the cultural context of the Polish language or semantic issues. The final consensus on the Polish version of the uMARS was achieved after a group of pretesters tested the questionnaire. They confirmed its comprehensibility and transcultural adaptation. A translation history review and examination of the original questionnaire confirmed that all items in the original uMARS were flawlessly translated without major substantive problems. Consequently, the final version was presented to respondents unfamiliar with uMARS, seeking their input on the translated words, understandability, interpretability, and cultural relevance. A ready-to-use version of the Polish uMARS was made available after a final review.

Test-Retest Reliability

Participants completed the questionnaire twice, providing responses for an initial assessment (test) and a reassessment after a week (retest), considering the values obtained by pairs of the same respondents ($P>.05$; Table 1).

A paired *t* test was performed to compare the results of the test and retest to assess the reliability of the test and retest of the Polish version of uMARS.

The external consistency of the 2 measurements was statistically significant for each measured parameter ($P<.05$). The highest agreement was in category F (perceived impact; $r=0.73$; $P<.001$). The concordance for the total scale score was moderate ($r=0.40$; $P<.001$); however, concordance was not observed for category C12 (visual appeal; $P=.18$; Table 2).

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Table 1. Sociodemographic and educational characteristics of study participants (N=117).

Domain and subdomain	Paired *t* test		
	Test, mean (SD)	Retest, mean (SD)	*P* value
A (engagement)			
A1 (entertainment)	3.10 (1.16)	3.19 (1.16)	.20
A2 (interest)	3.61 (0.94)	3.68 (1.01)	.49
A3 (customization)	3.37 (0.87)	3.48 (1.08)	.37
A4 (interactivity)	3.45 (0.92)	3.53 (0.93)	.53
A5 (target group)	4.09 (0.80)	4.15 (0.88)	.52
A (engagement total)	17.02 (3.86)	17.29 (4.51)	.58
B (functionality)			
B6 (performance)	4.11 (0.80)	3.99 (0.81)	.11
B7 (ease of use)	3.95 (0.85)	3.98 (0.84)	.92
B8 (navigation)	3.87 (0.81)	3.90 (0.93)	.91
B9 (gestural design)	3.88 (0.78)	3.97 (0.88)	.55
B (functionality total)	14.90 (3.95)	15.09 (3.87)	.81
C (aesthetics)			
C10 (layout)	4.04 (0.80)	3.92 (0.97)	.17
C11 (graphics)	3.96 (0.88)	4.02 (0.84)	.70
C12 (visual appeal)	3.83 (0.82)	3.78 (0.79)	.54
C (aesthetics total)	11.63 (2.67)	11.65 (2.24)	.97
D (information)			
D13 (quality of information)	3.92 (0.80)	4.02 (0.77)	.39
D14 (quantity of information)	3.76 (0.76)	3.78 (0.88)	.91
D15 (visual information)	3.95 (0.82)	3.92 (0.84)	.48
D16 (credibility of source)	4.11 (0.79)	4.21 (0.71)	.45
D (information total)	14.51 (3.92)	15.02 (3.76)	.12
Quality			
(A+B+C+D)/4	14.47 (2.90)	14.75 (2.98)	.43
E (subjective quality)			
E17 (recommendation to others)	3.48 (1.14)	3.49 (1.01)	.75
E18 (use and relevance)	3.30 (1.30)	3.41 (1.18)	.48
E19 (payment)	2.46 (1.23)	2.54 (1.22)	.54
E20 (overall rating)	3.62 (0.79)	3.64 (0.87)	.99
E (subjective quality total)	12.56 (3.88)	12.91 (3.59)	.49
F (perceived impact)			
F1 (awareness)	2.72 (1.35)	2.87 (1.23)	.21
F2 (knowledge)	2.82 (1.34)	2.81 (1.13)	.85
F3 (attitudes)	2.80 (1.36)	2.61 (1.20)	.07
F4 (intention to change)	2.88 (1.32)	2.87 (1.27)	.85
F5 (help seeking)	2.92 (1.38)	3.02 (1.26)	.40
F6 (behavior change)	2.93 (1.32)	2.94 (1.30)	.60
F (perceived impact total)	16.71 (7.22)	16.51 (5.91)	.39
Total score	85.66 (21.87)	88.05 (18.58)	.29

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Table 2. Descriptive statistics of total scores and subscale scores of the User Version of the Mobile Application Rating Scale, Polish version (uMARS-PL).

Domain and subdomain	Reliability	
	Pearson correlation	*P* value
A (engagement)		
A1 (entertainment)	0.52	<.001
A2 (interest)	0.41	<.001
A3 (customization)	0.33	<.001
A4 (interactivity)	0.20	.041
A5 (target group)	0.27	.004
A (engagement total)	0.37	<.001
B (functionality)		
B6 (performance)	0.31	.001
B7 (ease of use)	0.41	<.001
B8 (navigation)	0.49	<.001
B9 (gestural design)	0.33	<.001
B (functionality total)	0.39	<.001
C (aesthetics)		
C10 (layout)	0.44	<.001
C11 (graphics)	0.35	<.001
C12 (visual appeal)	0.13[a]	.166[a]
C (aesthetics total)	0.29	.001
D (information)		
D13 (quality of information)	0.35	<.001
D14 (quantity of information)	0.45	<.001
D15 (visual information)	0.27	.009
D16 (credibility of source)	0.24	.02
D (information total)	0.52	<.001
Quality		
(A+B+C+D)/4	0.39	<.001
E (subjective quality)		
E17 (recommendation to others)	0.35	<.001
E18 (use and relevance)	0.53	<.001
E19 (payment)	0.49	<.001
E20 (overall rating)	0.30	.001
E (subjective quality total)	0.37	<.001
F (perceived impact)		
F1 (awareness)	0.61	<.001
F2 (knowledge)	0.64	<.001
F3 (attitudes)	0.76	<.001
F4 (intention to change)	0.67	<.001
F5 (help seeking)	0.67	<.001
F6 (behavior change)	0.63	<.001
F (perceived impact total)	0.73	<.001
Total score	0.40	<.001

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[a]Statistically significant difference between test and retest scores (P<.001).

The reliability analysis of Cronbach α confirmed the very high reliability of the scale at 0.95. No relevant factor lowered or increased the reliability of the entire tool (Table 3).

The ICC values were overall moderate. The highest ICC values were for the category *perceived impact* (ICC=0.59 for 0.29-0.53). The intraclass correlation coefficient for the total uMARS score was moderate (ICC=0.65), indicating moderate temporal stability. This level of agreement is consistent with comparable validation studies of user-rated app evaluation tools, where subjective perceptions of design and engagement may vary naturally between assessments.

Figure 1 presents a scatterplot depicting final test values (total test vs complete retest). The scatterplot shows the relationship between the overall scale scores on the test and retest. The results were positively correlated, as evidenced by the upward slope of the solid red regression line. Participants who gave higher ratings on the test tended to give higher ratings on the retest, whereas those who gave lower ratings on the test tended to give lower ratings on the retest. The dots running in an even pattern along the regression line illustrate this observation. The dashed lines indicate CIs of the mean scores.

Figure 2 shows the percentage distribution of individual ratings (1-5 points) provided by the respondents in each category. The left and right sides represent the test and retest results, respectively. Different colors denote each rating. Matching colors indicate specific assessments in both measurements with similar frequencies. The test results mirrored the retest results, thereby forming a mirror image pattern.

The overall ICC values and those for the entire scale were moderate (ICC=0.65). The highest ICC values were for the category *perceived impact* (ICC=0.59 for 0.29-0.53).

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Table 3. Internal consistency and test-retest reliability of the User Version of the Mobile Application Rating Scale, Polish version (uMARS-PL).

Domain and subdomain	Cronbach α
A (engagement)	
A1 (entertainment)	0.95
A2 (interest)	0.95
A3 (customization)	0.95
A4 (interactivity)	0.95
A5 (target group)	0.95
A (engagement total)	—[a]
B (functionality)	
B6 (performance)	0.95
B7 (ease of use)	0.95
B8 (navigation)	0.95
B9 (gestural design)	0.95
B (functionality total)	—
C (aesthetics)	
C10 (layout)	0.95
C11 (graphics)	0.95
C12 (visual appeal)	0.95
C (aesthetics total)	—
D (information)	
D13 (quality of information)	0.95
D14 (quantity of information)	0.95
D15 (visual information)	0.95
D16 (credibility of source)	0.95
D (information total)	—
Quality	
(A+B+C+D)/4	—
E (subjective quality)	
E17 (recommendation to others)	0.95
E18 (use and relevance)	0.95
E19 (payment)	0.95
E20 (overall rating)	0.95
E (subjective quality total)	—
F (perceived impact)	
F1 (awareness)	0.95
F2 (knowledge)	0.95
F3 (attitudes)	0.95
F4 (intention to change)	0.95
F5 (help seeking)	0.95
F6 (behavior change)	0.95
F (perceived impact total)	—
Total score	0.95

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[a]Not available.

Figure 1. Scatterplot of final test values: total test vs complete retest.

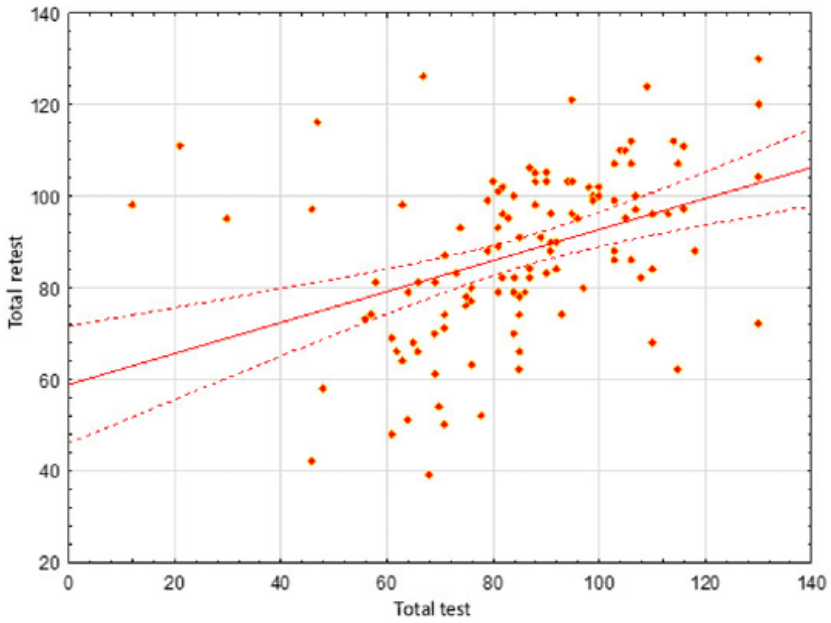
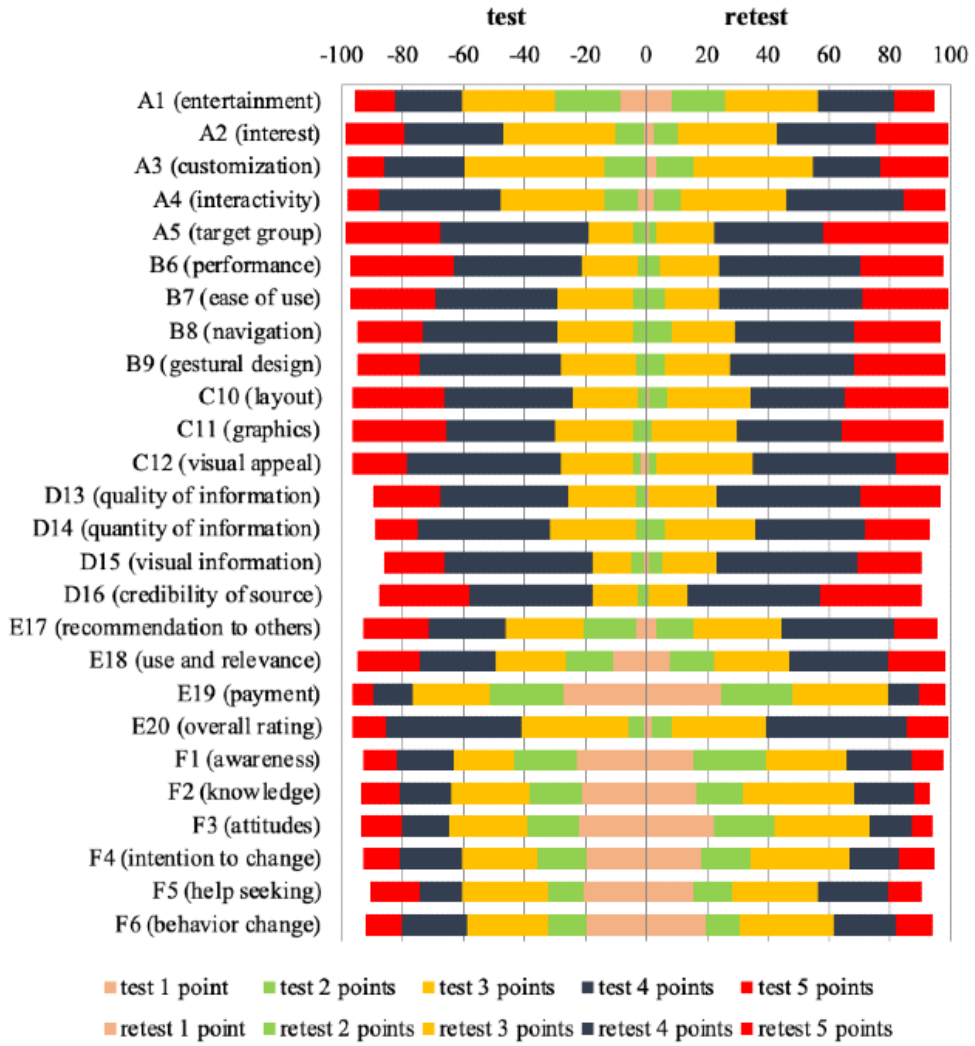


Figure 2. Detailed measurement results of the test and retest.



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Discussion

Principal Findings

The Polish version of uMARS exhibited excellent internal consistency and good short-term (weekly) test-retest reliability throughout the validation process. The subscales demonstrated either excellent or good reliability in all domains. This version enabled Polish users to obtain reliable measurements of mHealth app quality. The app evaluation system integrated evidence, user experience, and content values into a comprehensive evaluation system. The partial and total results of the assessed domains were reliable and correctly evaluated using the questionnaire.

This study used a single mobile app (STOP COVID ProteGO Safe) as a standardized reference for validation, ensuring linguistic consistency and minimizing contextual bias in participant responses. However, the use of a single app did not permit the assessment of factorial or convergent validity. This limitation aligns with early-phase validation studies of the original uMARS and its adaptations in other languages. Future research should incorporate multiple app categories to confirm construct validity and investigate potential subgroup differences.

The overall internal consistency of the Polish uMARS was high (Cronbach α=0.95). While this supports strong item homogeneity, uniformly high α values across subscales should be interpreted with caution, as they may reflect item redundancy within conceptually overlapping domains. Similar Cronbach α magnitudes have been observed in other uMARS validations and in multi-item satisfaction scales, suggesting that high interitem correlations are typical for this type of measure. Nevertheless, this potential redundancy represents a limitation inherent to user perception instruments. The Polish uMARS questionnaire responds to the growing need for standardization in the evaluation of health-related mobile apps, informed by user feedback. It offers a structured approach to assessing key quality aspects of apps in Polish, benefiting both users and developers.

The app in question is no longer available, as it was designed specifically for use during the COVID-19 pandemic and was withdrawn after it ended. This circumstance makes it impossible to repeat the study using this app, as the app was used only during the COVID-19 pandemic. However, this study aimed to verify the Polish language version of the app. Despite the limited duration of the app's operation, our goals were successfully achieved, as the aim of this study was to validate the Polish version of the scale.

This validation was conducted on a sample of young university students pursuing health-related education. Although this group was appropriate for the initial phase of linguistic and psychometric validation, it may not fully represent older or less experienced users of digital technology. However, the study group reflects the demographic most engaged in the use of health-related mobile apps. Therefore, focusing on this group was appropriate for initial linguistic and psychometric validation, ensuring that all participants were experienced smartphone users capable of providing reliable app ratings. Future research should evaluate the performance of the Polish version of uMARS among broader and more diverse populations. Validation efforts need to include participants from a wider range of age groups and varying levels of digital literacy to ensure the Polish uMARS's broader applicability.

Conclusions

Cross-cultural validation studies of the Polish version of uMARS were conducted, showing its reliability comparable to that of the original version. The Polish version of uMARS can be a valuable tool for assessing the quality of mHealth apps in Poland. From a user perspective, the Polish version of uMARS demonstrates appropriate metric properties for evaluating the quality of mHealth apps, providing comprehensive access to mHealth app ratings from different user perspectives.

Polish researchers can use the translated and verified Polish tool to collect end-user feedback and ratings, helping to identify highly rated apps. In addition, app developers can benefit from reliable app component ratings and gain valuable insights for further improvement and development, increasing the overall quality and impact of mHealth apps. Developers and app stores can present more comprehensive and documented evaluation results along with a star rating to provide users with better insight into the app's quality.

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Data Availability

The datasets generated and analyzed during this study are not publicly available due to ethical and privacy considerations but are available from the corresponding author on reasonable request.

Authors' Contributions

Conceptualization: WMG, TC, BG, SS

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Data curation: WMG, TC, JN
Formal analysis: WMG, TC, JN, SS
Investigation: WMG, TC, JN, RD, BM, BG
Methodology: WMG, JN, BG, SS
Project administration: WMG, TC, BG
Resources: WMG, TC, BG
Supervision: WMG, SS
Validation: WMG, TC, JN, RD, BM, BG, SS
Writing—original draft: WMG, JN, BG
Writing—review and editing: WMG, TC, JN, RD, BM, BG, SS

Conflicts of Interest

None declared.

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Abbreviations

COSMIN: Consensus-Based Standards for the Selection of Health Measurement Instruments
ICC: intraclass correlation coefficient
mHealth: mobile health
STROBE: Strengthening the Reporting of Observational Studies in Epidemiology
uMARS: User Version of the Mobile Application Rating Scale

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Original Paper

Preferences for an Experience Sampling Method–Based Tool as an Adjunct to Usual Treatment in Patients With Problem Substance Use: Qualitative Study

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Abstract

Background: Mobile health tools that use the Experience Sampling Method (ESM) appear to be a promising tool to streamline and improve the treatment of substance use disorders. However, patient involvement in the development of these tools is uncommon, and research on the preferences of people being treated for substance use disorders has been scarce. In the scope of the European Union IMMERSE (Implementing Mobile Mental health Recording Strategy for Europe) consortium, an ESM-based tool for Digital Mobile Mental Health (DMMH) was first codeveloped and later tested in 4 European countries.

Objective: This study aimed to achieve an understanding of preferences for features of DMMH among mental health service users with problem substance use.

Methods: In 4 European countries, service users were recruited for a semistructured qualitative interview, which started with the presentation of a prototype of the DMMH. Data analysis was performed through directed qualitative content analysis.

Results: The analytical sample consisted of 12 (5 female, 6 male, and 1 nonbinary person) participants with problem substance use aged 18-50 years. There were 4 participants from Slovakia, 3 from Belgium, 4 from Germany, and 1 from Scotland. Patient preferences were classified into 7 categories: notifications, questions, user interface, functionality changes, visualizations, sharing data with clinicians, and sharing data with others. The proposed intensive notification schedule was deemed acceptable by service users as long as the questionnaire is short. Participants expressed a preference for open-text response options, Ecological Momentary Interventions, and options for individual customization of several elements of the tool. Data visualization was considered an

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important aid for communication with clinicians, with whom all participants wanted to share data obtained with DMMH. The possibility of sharing data with other people depended on the quality of the relationship with them.

Conclusions: In the development of ESM-based mobile health tools for people with problem substance use, their preferences for content, functionality, and appearance of the tools should be considered so they match patients' treatment needs.

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KEYWORDS

mHealth; Experience Sampling Method; Ecological Momentary Assessment; digital mental health; user preferences; substance use; qualitative research

Introduction

Mobile health (mHealth) tools based on Experience Sampling Method (ESM) appear to be a promising element in delivering more person-centered mental health care [1-3]. mHealth is a public health practice supported by mobile devices such as mobile phones, tablets, portable patient monitoring devices, personal digital assistants, and other wireless devices [4]. ESM is a data acquisition process characterized by repeatedly sampling participants' actual behaviors and experiences in real time in their natural environment [5]. The goal of ESM is to minimize the memory biases that arise from retrospective assessment of experience and mental states, to maximize ecological validity, and to enable capturing microprocesses that influence behavior in real-world contexts [6]. The use of ESM as part of a treatment appears to be a promising avenue toward personalized, person-centered mental health care [7]. It can help patients better understand their adaptive and maladaptive behavior patterns and the reasons behind them. Providing patients with these tools allows them to become more active partners in the treatment process [8].

In the treatment of substance use disorders (SUDs), in addition to the aforementioned benefits, ESM can make a significant contribution to the early detection of impending relapse [9] and provide a reliable basis for individually tailored interventions based on the dynamic changes during the treatment [10]. Treatments provided in mental health settings are often ineffective for patients with SUDs [11], which may be related to the fact that treatment of SUDs and comorbid disorders requires high intensity and emphasis on psychosocial interventions [12]. Relapse is preceded by craving, the intensity of which fluctuates dynamically and is often triggered by external and internal factors. ESM is a good tool to catch it early [9,13,14]. Although we have limited evidence on the efficacy of mHealth tools in the treatment of SUDs [15], some methodologically rigorous studies have produced results on their effectiveness and usefulness in increasing the number of abstinence days both during treatment and in follow-up [16-18]. A challenge to the effective application of mHealth tools in the treatment of individuals with SUDs is to explore how to successfully implement them into clinical practice. Successful and sustainable implementation of new digital health technologies is challenging and depends on a variety of factors, including patient acceptance and expectations regarding the adoption and use of these tools [19]. The feasibility and acceptability of using digital instruments with embedded ESM in the treatment of SUDs appear to be high [20-22], and this is also true for tools with intensive data collection schedules [23,24]. However, low uptake and limited user engagement are common challenges observed in digital interventions within real-world care settings [25].

A systematic review conducted by Szinay et al [26] identified 3 categories of factors that influence the uptake and effective engagement in the use of mHealth tools: capability-enhancing factors, opportunity-enhancing factors, and motivation-enhancing factors. The first category relates to app literacy skills, app awareness, available user guidance, health information, statistical information on progress, well-designed reminders, features to reduce cognitive load, and self-monitoring features. The second category includes factors such as availability at low cost, positive tone, personalization factors, recommendations for health and well-being, embedded health professional support, and social networking opportunities. Finally, the third category entails factors such as positive feedback, available rewards, goal setting, and the perceived utility of the tool. Another important factor influencing the uptake and effective engagement with digital tools is their appropriateness for the intended users and the context in which they are to be implemented. Tools are more likely to be adopted when they are personally relevant and can be seamlessly integrated into users' daily routines [27]. A common reason for poor fit is the insufficient involvement of patients, stakeholders, and other end users in the development process. Stakeholders are typically engaged only in the final stages of development, such as during usability testing, when the opportunity to make substantive changes is limited [28,29]. Early and continuous involvement of stakeholders is essential to ensure that digital tools are aligned with real-world needs, thereby facilitating more effective implementation [30]. Qualitative research methods are central to understanding how to improve user uptake and engagement with mHealth tools [31].

Previous research on potential users of mHealth tools with SUDs has shown that positivity, personalization, monitoring of use, gaining insight into use, daily tips, and interactive features are considered facilitators of the use of mHealth tools. On the other hand, repetitiveness, receipt of nontailored content, and inability to self-navigate to desired content are considered barriers to the use of mHealth tools by individuals with SUDs [21,32,33]. Daily notifications can substantially impact the engagement of individuals in both positive and negative ways. Optimizing the notification policy to target both effectiveness and engagement is needed [34]. Although the general facilitators and barriers of mHealth tools for persons with SUDs are known, it is unclear whether and how these patterns manifest in a population with

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more complex needs, such as people with comorbid mental disorders.

Therefore, this study aimed to achieve a better and more detailed understanding of the preferences of mental health service users with problem substance use regarding the features of an ESM-based digital tool. More specifically, we aimed to explore what patients with problem substance use consider to be a satisfactory design (content, appearance, and functionality) of an ESM-based mHealth tool that they would use as part of their treatment.

Methods

Study Design and Research Paradigm

This study used a qualitative design using semistructured interviews, guided by an interpretivist-pragmatic paradigm [35], combining the interpretive understanding of participants' experiences with a pragmatic focus on the applicability of findings to clinical practice. Semistructured interviews were designed to collect information about relevant contextual factors within the Non-Adoption, Abandonment, Scale-Up, Spread, and Sustainability (NASSS) framework [19] related to the potential use of the Digital Mobile Mental Health tool (DMMH) as a part of the IMMERSE (Implementing Mobile Mental health Recording Strategy for Europe) project [36].

Setting and Context

The study was carried out in the context of the ongoing IMMERSE project. The IMMERSE project is dedicated to advancing person-centered mental health care through the development and implementation of the DMMH [2,36].

The DMMH consists of two components: (1) MoMent app (movisens GmbH) for patients, an ESM-based digital mobile app for systematic monitoring of patients' current mental state, mood, symptoms, activities, context, therapy goals, key problem areas, and momentary quality of life; and (2) a dashboard that allows clinicians to (a) customize individual treatment goals and questionnaires presented by the MoMent app and (b) produce automated reports that provide meaningful information from self-assessment data using the integrated dashboard, which is an interface to visualize and elaborate the collected data into customized feedback for patients and their clinician.

This paper reports on findings from Phase I of IMMERSE, where qualitative, semistructured interviews were conducted prior to the development of the DMMH tool and its implementation (Phase II). The aim of Phase I of the project was to develop, optimize, and examine in detail the contextual factors, processes, and strategies for the implementation of the DMMH intervention in routine mental health care in 4 European countries (Belgium, Germany, Scotland, and Slovakia). It involved conducting semistructured interviews with 4 groups of stakeholders, namely service users, clinicians, people from the service user support network, and health care administrators.

In this study, we focus on service users with problem substance use. In other groups of stakeholders, relatives of service users with problem substance use, clinicians specializing in this group of patients, and health care administrators for people with SUDs were underrepresented, so we do not focus on these groups of stakeholders.

Participants for the study were recruited from multiple clinical sites across participating countries. The target sample sizes for the interview component were 40 service users (10 per country). These were users of psychiatric services in outpatient and inpatient care. Clinical sites were located in Belgium (KU Leuven University Hospital and Psychiatric Center Sint-Kamillus, Bierbeek), Germany (Central Institute of Mental Health Mannheim and Psychiatric Centre Nordbaden Wiesloch), Slovakia (Psychiatric Clinic at University Hospital Bratislava plus outpatient clinics in Vranov nad Topľou/Hanušovce/Košice), and Scotland (NHS Lothian, including Lothian CAMHS).

Participants and Sampling

Participants were recruited using purposive sampling to ensure diversity of perspectives across treatment settings. Inclusion was based on predefined eligibility criteria relevant to the study's aims.

Inclusion criteria for service users were (1) aged 18-64 years, (2) seeking help for mental health issues and needing specialist assessment, (3) in contact with or awaiting local mental health services, and (4) able to give informed consent. Exclusion criteria were (1) psychiatric symptoms due to an organic cause (ICD-10 [*International Classification of Diseases, Tenth Revision*] F00-F09), (2) intellectual disability or severe psychiatric disorder (*ICD-10* F71-F89) impairing consent ability, (3) medical or psychological contraindications, inability to use a smartphone, insufficient language, or terminal illness. Given the aims of this study, we focused on service users who were problem users of psychoactive substances, that is, those who had a SUD or whose substance use caused them significant problems in their lives. Participants meeting the narrower criteria for inclusion in this paper were retrieved from the interview transcripts using the following search terms: "drugs," "alcohol," and "addiction." The identified transcripts were reviewed to determine whether the participants met the stated criteria.

Recruitment Procedure

Recruitment was conducted through a combination of strategies tailored to each site. At the Belgian sites, recruitment lasted approximately 4 months (late January 2022-late May 2022), using flyers, posters, email invitations, and contacting previous participants from related studies and patient organizations. At the German sites, recruitment spanned 6 months (late January 2022-late June 2022) and used clinical site contact, patient organizations, email invites, and on-site presentations. For the Slovak sites, recruitment lasted from December 2021 to May 2022. Initial clinical-site recruitment was supplemented by private clinics, psychiatric practices, civic associations, and personal contact with patients and their supporters. The Scottish site used posters, flyers, and email invitations beginning January 2022, and later made use of third-party registers (eg, Scottish Health Research Register [SHARE] and Scottish Mental Health Research Network [SMHRN]) when initial recruitment channels proved insufficient. Recruitment ceased when minimum targets were achieved or no further participants were required.

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Data Collection

Semistructured interviews were conducted by several trained researchers across participating clinical sites. All interviewers had previous training in psychology. Not all interviewers were coauthors of this manuscript; however, all received standardized training and followed a common interview protocol to ensure methodological consistency. The interviewers were supervised by (MW and TI), who also monitored adherence to the study guide and provided regular feedback during data collection.

Participants were interviewed either in person at the clinical site or via video call, depending on their preference. Interviews were recorded using an encrypted audio recorder with the written and verbal consent of the participants. The interviews were transcribed and coded in the local language at the sites where they were conducted.

Service users' views on notifications, questions, user interface, functionality changes, data visualizations, sharing data with clinicians, and sharing data with others and any other topics related to the design of the DMMH prototype and its use that emerged from the interviews were analyzed. We developed interview scripts that were used for data collection across all 4 participating countries (Multimedia Appendix 1). After informed consent, participants were informed about the purpose and how the DMMH is supposed to work; participants were shown prototypes of the MoMent app items and different visualizations of longitudinal patient data (Multimedia Appendices 2 and 3). Then participants were asked to share their feedback on the prototypes and how these could be implemented in their treatment. The interview guide comprised 23 questions, focusing on participants' experiences with digital health tools, feedback on the DMMH prototype, perspectives on DMMH usability and its potential impact on the treatment, and potential barriers and facilitators of the use of such a tool. Additionally, vignettes with service user case examples were presented and discussed.

Data Processing

Preliminary processing of interview data to derive structured data items was performed using software designed for qualitative data analysis, namely MAXQDA (VERBI Software GmbH) and NVivo (Lumivero LLC).

Quotes used in this study were translated from the original language into English using DeepL software (DeepL SE) and checked by a native speaker for accuracy.

Data Analysis

The analysis followed a directed (top-down) qualitative content analysis approach [37,38], which starts with codes that are derived from a predefined theory (NASSS framework) [19]. The initial coding using anchor samples was done by local researchers speaking the native languages and throughout multiple sessions across countries, comparing understanding of individual codes, assurance has been achieved that all codes were interpreted in the same way. During this process, some codes were merged, omitted, or added, and the final codebook was created. This was followed by the main analysis. This first level of coding (using the NASSS framework) conducted by 2 coders per country represented the primary analysis reported elsewhere [39], while we carried out a secondary, bottom-up analysis conducted by AK and NČ focusing on notifications, questions, user interface, functionality changes, data visualizations, sharing data with clinicians, sharing data with others, and any other topics related to the design of the tool and its use in general, and ESM data in particular. This was done by enriching the existing codes with new, more detailed subcodes that emerged from the analysis.

Techniques to Enhance Trustworthiness

To enhance the trustworthiness of the analysis, peer debriefing was carried out between 2 researchers (AK and NČ) to ensure consistency and credibility of interpretation. Emerging codes and themes were reviewed and discussed to challenge assumptions, refine interpretations, and ensure that findings accurately reflected participants' perspectives. Consensus among team members was reached before finalizing the structure of categories.

Researcher Reflexivity

Some of the interviews were conducted by researchers who had previous clinical contact with the participants in the context of their routine treatment. This familiarity facilitated rapport and openness during the interviews but was also acknowledged as a potential source of bias. To minimize its influence, interviewers followed a standardized interview guide and adhered to reflexive practices throughout data collection.

Ethical Considerations

Applications to each country's Ethics Review Board were coordinated using a joint protocol. Ethical approval was granted for all sites, in Belgium by Ethics Committee KU Leuven (S65990; January 11, 2022), in Germany by Ethics Committee II of Heidelberg University at the Mannheim Medical Faculty (633-21; September 24, 2021), in Scotland by South Central—Hampshire A Research Ethics Committee (REC reference: 21/SC/0397, IRAS project ID: 307153; December 23, 2021), and in Slovakia by Ethics Committee of the Faculty of Medicine, Comenius University and University Hospital Bratislava, Staré Mesto Hospital (115/2021; October 25, 2021) and Ethics Committee of the Faculty of Medicine, Pavol Jozef Safarik University in Kosice (1N/2022; January 27, 2022).

Participants received detailed written and oral information about the project as well as a comprehensive informed consent document.

The data collected during the interviews were pseudonymized and stored locally at the locations where the interviews took place. All subsequent data processing, including transfer to the IMMERSE project research database, was carried out using this pseudonymous identifier. The data are stored on a General Data Protection Regulation (GDPR)–compliant server at the University of Heidelberg's computing center. The data elements derived after qualitative analysis do not contain any directly identifying data.

Participants were compensated for their time spent participating in the interview with €10 (US $11.60) in European Union countries and £10 (US $13.40) in Scotland.

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Results

Participants

Of the 51 interviews, 12 participants met the narrower inclusion criteria for this study. The basic characteristics of the study sample are in Table 1.

Table 1. Overview of participants (N=12) included in a qualitative study exploring preferences for an Experience Sampling Method–based tool as an adjunct to usual treatment among patients with problem substance use.

Participant ID	Sex	Age group (years)	Country	Employment status	Education	Diagnosis
P1	Male	31-40	Slovakia	Employed	Secondary education	Substance use disorder
P2	Male	41-50	Slovakia	Employed	Secondary education	Substance use disorder
P3	Male	31-40	Slovakia	Employed	Graduate degree	Substance use disorder
P4	Male	31-40	Slovakia	Not working	Vocational qualification	Substance use disorder
P5	Female	41-50	Scotland	Not working	Primary	Schizophrenia
P6	Nonbinary	41-50	Belgium	Employed	Graduate degree	Substance use disorder
P7	Female	41-50	Belgium	Not working	Primary	Depression
P8	Female	41-50	Belgium	Employed	Graduate degree	Substance use disorder and borderline personality disorder
P9	Male	18-30	Germany	Not working	Vocational qualification	Schizophrenia
P10	Female	18-30	Germany	Employed	Secondary education	Substance use disorder, ADHD[a], and borderline personality disorder
P11	Female	18-30	Germany	Employed	Secondary education	Substance use disorder, depression
P12	Male	31-40	Germany	Not working	Primary	Substance use disorder, ADHD

[a]ADHD: attention-deficit hyperactivity disorder.

Main Findings

Seven categories were used from the original codebook and 8 subcategories were identified (Table 2).

Table 2. Main categories and subcategories were identified through directed content analysis of semistructured interviews.

Categories	Subcategories
Notifications	• Number of notifications per day • Questionnaire availability time
Questions	• Adding questions or answer options • Questionnaire length
User interface	—[a]
Functionality changes	• Interventions • Reminders • Gamification • Customization
Visualizations	—
Sharing data with clinicians	—
Sharing data with others	—

[a]Not applicable.

Notifications: Number of Reminders Per Day

Participants who were employed considered 8-10 notifications per day to be excessive and suggested 3-5 notifications per day.

> *That does make sense, but it's also a lot. I mean, if I think about it, my typical day runs from around 7:30 a.m. to 10 p.m. Getting 10 notifications in that time*

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> *is just a lot. ... I think realistically, something like 3 to 5 would make more sense.* [P10]

Those unemployed or hospitalized at the time considered 8-10 notifications per day feasible, even something that could help them structure the day. Also, even those who found 10 notifications too many at first would find this number acceptable if the questionnaire took a short time to complete.

> *I actually think it's good, so for me it's not too much. For others, it might be too much because- well, I'm currently unemployed, I have time, I can answer the questions. But there are people who work, and they can't really do that.* [P9]

> *Between 7 and 10 times a day? Ah yes, that seems like a lot, yes. And when then for example? Is that then, I'm just saying, every hour or what does that mean? Every two hours? ... [Interviewer: So that's actually, we usually count 2 minutes for a questionnaire.] Ah oh yes, then that's not a problem.* [P8]

It was also suggested to adapt the number of notifications to the patient's condition and stage of treatment.

> *The app would have to be taught somehow, in some way, to be adaptable to a given rhythm, or I don't know, because the patient would then have to essentially subordinate to the app in their life. Maybe two levels, a level for someone who has to adapt because the information is needed at these intervals, and it occurs to me that someone who has less of a problem, so that's where it could be adapted to them [number of notifications].* [P2]

Questionnaire Availability Time

Participants indicated that postponing a questionnaire, so that it could be filled out at a later time point, would be desirable and facilitate completion. The time window is preferred to be from 15 minutes to 1 hour.

> *Well, postponing it would be acceptable, I would like that. For example, I cannot do it now because I have a lot of work to do, and I postpone it for an hour that I know I have to complete something, and within an hour one finds those 5 minutes to complete it.* [P4]

Questions

Participants appreciated the brevity and clarity of the questions used in the DMMH. They commented that it would be helpful if the situation they were in could be described more specifically, to capture the thoughts they had in the situation, and possibly what they did to cope with it.

> *The questions are actually clear in what they're about, and that's already a good thing.* [P12]

> *Yeah, if I'm tense because it can catch me in the moment, if I'm arguing with somebody, so if I'm feeling tense or how I'm actually reacting when I'm tense or something more specific. Something else I would add in there would be questions like how I handled that tension or how did I handle that situation where I felt bad and why did I feel good...something came up, something along those lines. Such lighter questions, whether I'm succeeding or failing to meet the daily plan and such questions. ... Watch my thoughts, but I don't know how to do that, because those feelings are probably one of the most important, but those thoughts are important too, I find it important to watch my thoughts too. So was I thinking of drugs now, or was I thinking of alcohol, an accomplice from the past. For us addicts, I think it's a recurring thing, that it's about the same thoughts, that I've walked down the street where I used to do drugs and it automatically comes back to me, so that's where you go back to that past - how many times a day I remembered it, or something like that.* [P4]

Adding Questions or Answer Options

Participants were informed that there were planned questions about substance use and craving. They suggested adding questions about different additional issues that were relevant to them, such as eating frequency and physical activity. Suggestions for better specification of context and activities were repeated.

> *But the eating, for example, I have a problem with that now. With gaining weight, and I would very much like to have a regular diet. To have maybe even a reminder, like my therapist said, like for 10 or brunch, because I'm totally skipping that and I'm doing it wrong, so that would be a great thing to have a reminder, but also to follow up on. For example, some sort of note to register that I've eaten lunch at that time, I'd welcome that.* [P2]

> *Maybe those options [answers about context], it seemed to me, what I only saw cursorily, that maybe there weren't enough of them, that maybe even more detail could have been broken down, that there was only the exterior, maybe even more precise, that where I was could have been there, at least a theme or something, but that's just kind of my idea. Yeah, it seems to me exactly that I would specify it more as to whether it's some kind of nature or I'm thinking...the city centre, the built-up area where there are more people or a nature, that what is the element that's affecting that person. Also outdoors, I also seek out different environments depending on my mood and what I need.* [P2]

Questionnaire Length

Some participants were willing to dedicate 5-10 minutes to one questionnaire but preferred shorter durations, for example, 2-3 minutes.

> *So, 5 to 10 minutes. Anything in between is perfectly okay. [Interviewer: Okay. Yeah wow, so the idea was that it's even just 3 to 5.] Which is probably even better for the majority of people who would use that, because if it takes too much time, then you're more willing not to do it and just answer "larifari" [sloppy], sort of, as long as it's quick.* [P11]

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> *Two to three minutes, certainly no longer. But two minutes that goes at work. Ten minutes you shouldn't come off with.* [P6]

User Interface

There were repeated requests for a more colorful environment and clearer color differentiation of items from the background. Some participants preferred to see multiple questions, ideally all at once, rather than one at a time. Using an avatar was an acceptable option.

> *In theory, maybe you could make the background a bit more colorful, or at least the bubbles - just to make them stand out a bit more. You know, it's a bit monotone, I'd say.* [P12]

> *Yeah, the avatar's nice, I think it's nicer because it's taken in a playful way a little bit, so it's closer to people I think, it's closer to me personally, the avatar.* [P1]

Functionality Changes

In addition to a randomized schedule of questionnaires, participants also suggested a questionnaire that they could recall on demand, supplemented by the possibility of recording a note in the form of text. Two participants also suggested fixed morning, lunchtime, and evening questionnaires to fit in with their day's schedule.

> *Or, if I have some kind of little ache or something, then I can click somewhere in the app on "Menu" and then kind of save "Notes" somewhere on the side or something like that. … You do have those note things normally on your phone, but you usually don't use them, but, if you're already in the app, then maybe yeah. … Or you enter it in the calendar, and then you write a side note: "Had something happen today." Or I don't know. "Today this and that happened." … you click on "Menu" and then you can still write a note, kind of in the background where the scale was - where it was bad, let's say - if you had a bad day, then you could write something right there. Because, otherwise, you only kind of know what happened, and like this, you write on that day "Ah that really annoyed me" or "I managed it", or whatever. Or something especially positive too. … you can just tell yourself: "Hey, I'm not doing so well right now, so I'll just write something down." Because, for example, if the rhythm is every two hours, but now it's already after an hour or half an hour after something happened - something went wrong, and you're just really like [feeling] "baaah" - then you're not gonna wait one and a half hours until some kind of "bing" [notification prompt] comes again.* [P12]

> *You have a lot of other duties, I wouldn't mind for example during shopping, but I do manual work, I'm used to doing manual work and if I'm on the line and I run out two times on the app to fill it, the manager probably wouldn't praise me that what I'm doing all the time with that phone. Before work or before breakfast if I filled it out that how did I sleep let's say or how was my morning, at lunch it would ask me how my morning was, how am I feeling at the moment, in the afternoon or in the evening to do an inventory of the day, 3-4 times I would rate it that's just right.* [P4]

Interventions

The most commonly suggested addition to the app was the delivery of simple interventions informed by ESM data. Motivational quotes, grounding techniques, coping recommendations, crisis plans, or helpline contact were suggested.

> *Like there were just questions though, you might just be asking about that, but that maybe there would have been some solution to that as well. Or maybe something I would have suggested that something works for me, like I don't know... I'll give you an example, take five breaths, or be present, or I don't know.* [P3]

> *And maybe somewhere too, and this may be far fetched, but if things are really not going so well and they ask in the evening "What have you been up to?", this and that, and you're still like "Yes, I'm really not feeling well" and that's certainly going to be the case with some people, yes, that you still have a number somewhere or something you can call. Even if it's just including the Suicide Hotline. That's maybe not ideal, but it can be somewhere [in the app]. Suppose it doesn't go well, what can I do? "You don't feel well. Here are some people you can reach" and then the basic instances and their number.* [P8]

Reminders

Participants also indicated that they would use the app as a tool to remind them of other issues related to treatment and healthy lifestyle, such as taking medication, proper nutrition, and fluid intake.

> *Yes, I think sleep and maybe food and drink as well, because yes, I have moments when I have very little structure, and I know that's kind of common here often with people that they don't eat 3 times a day.* [P8]

Customization

There was a request for the ability to customize the color and number of notifications.

> *It could be that way, everyone could customize it with their own colour, we all like different colours, we all like different things, so if everyone could customize it to their own liking, that would probably be the best in my opinion.* [P4]

Gamification

One participant also suggested gamification elements, such as earning points or some kind of praise, or awards in case of good compliance and goal achievement.

> *I downloaded this app called 'I'm Sober' - it shows you how long you've been sober, and after a few days*

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> *this little rocket appears. You get kind of excited. And then you see, like, 'Okay, you've hit 100 days or 100 hours,' and this little character pops up and gives you a round of applause. It's completely silly [laughs]. But somehow it really motivates me to keep using the app [laughs]. Just to see that little creature again.* [P10]

Visualizations

The visualizations presented met with positive reactions. Participants appreciated their potential to contribute to understanding the relationships between their experience and the context in which it takes place.

> *I would personally find that amazing because effectively that can make you think again of hey, uh that's where I feel unhappy, so that's where I'm wasting my time. But if I want to be happier, then I need to pay more attention. That's super in my mind.* [P7]

Sharing Data With Clinician

All participants found sharing data from the app with their clinician useful. Participants reported that, based on these data, the clinician can better understand their problems and help them more effectively.

> *I think it's most interesting with a therapist. Someone who has effective insight into and who knows the app very well, as well as the thinking behind it. I also think an app for the individual is important because, as I said, not everyone has [a therapist], but I think that yes, I now have more of the idea that it's actually better with a therapist who really knows the app inside out.* [P7]

Sharing Data With Others

Participants differed in their willingness to share data from the app with their loved ones. Those who state that they have close relationships with others and feel understood by those around them find sharing data useful. Conversely, those who feel misunderstood in relationships are also less willing to share this information.

> *I personally wouldn't have a problem with that, because I really learned in treatment that honesty is absolutely the number one priority, so also in communication with parents, which I'm trying to improve in my diagnosis, so it would actually be another argument, really indisputable information, it also just sets out how I feel subjectively, but I would take it that it would be some quality output that the parents could see, that I would show them, and they would perhaps then be able to better understand certain situations and conditions if they had that information.* [P2]

> *I can imagine that that is useful for some people, but I keep my family and friends very much out of this. My parents didn't know for two years that I was coming to therapy. So... the relationship that I have with the person... but I don't immediately have many people with whom I would share it [my app data]. But I hear from other patients that they do involve more people in their story [therapy process], so that can certainly be useful.* [P6]

Discussion

Principal Findings

This study examined the preferences of patients with problem substance use regarding the content, functionality, and appearance of the DMMH prototype, the use of which is planned as an adjunct to the usual treatment. The findings suggest that patients generally perceive the DMMH prototype positively. They provided several specific suggestions for content, functional and visual changes which are summarized in Textbox 1.

Textbox 1. Recommendations for the design of an Experience Sampling Method–based mobile health tool as an adjunct to usual substance use disorders treatment.

Patient-reported design and functionality preferences

- Up to 10 notifications per day are acceptable, depending on the daily routine and the patient's condition.
- The questionnaire should be as short as possible.
- The questionnaire should also include open-text response options. These are mainly about circumstances, thoughts, and coping strategies.
- The time window to return to complete the questionnaire should be within 1 hour.
- Incorporate EMI in addition to monitoring.
- Use positive coloring and gamification.
- Visualize data in a simple and clear way.
- Enable data sharing with the clinician.
- Provide a voluntary option to share data with relatives.
- To allow individual customization in all the areas mentioned.

In general, multiple daily notifications were considered acceptable. Participants preferred a number and schedule of notifications that was tailored to their daily routine as well as their current treatment needs. A time window in which to return

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to the questionnaire was suggested, with 2 participants preferring a time of 1 hour. The acceptability of daily notifications is consistent with the findings of other authors where participants perceived it positively and as a feature that keeps them engaged with the app [33,40]. This could be specific to the group of patients with SUDs, as in studies with patients with other psychiatric diagnoses, 10 notifications per day was considered a rather burdensome amount [41,42]. In a research context, a higher frequency and number of notifications is tolerated if the questionnaire is short [43]. Also, being able to enter the questionnaire when the user unlocks the screen improves compliance [44], which means that it may be advantageous to allow the patient to return to the questionnaire at a later time, but this comes at the cost of not capturing the moment when the notification arrived.

Participants suggested adding to the questions the possibility of recording circumstances, thoughts, or even coping strategies they used. Such a requirement was also a pressing concern in work that surveyed psychiatric patients' attitudes toward a very similar tool informing the development of the DMMH [42]. Quantifying experience and context alone do not seem to capture all that patients consider important, and noting the specifics of a given situation could increase the potential to understand their patterns of behavior. Self-reflection and resulting insight in people recovering from SUDs are associated with higher treatment engagement, adherence, and abstinence maintenance [45,46]. Recurring suggestions for tracking and promoting healthy lifestyles are consistent with the general popularity of using mobile apps for these purposes [47] and it is an important part of recovery from SUDs [48]. Therefore, it is important to consider this area when designing mHealth tools for individuals with SUDs.

Simple interventions, also called Ecological Momentary Interventions (EMIs), which should be proactively offered to patients based on ESM data, represent a shift from monitoring to intervention and may be useful in relapse prevention [16,49], although the effectiveness of specific kinds of EMIs requires further investigation [50]. If the tool offers such interventions, this contributes to its interactivity, which is a facilitator of user engagement [32,33].

Often, a more colorful design was requested, corresponding to a general preference for a more positive appearance and content for this type of tool [32,33]. Paradoxically, gamification was only suggested by 1 participant. The fact that this option was not mentioned by several participants may be because they were not asked specifically. However, when developing tools of this type, gamification elements should be offered to users as they increase engagement in their use [51]. Of course, whether to use them and, if so, what the gamification features should look like should be discussed with users.

Patients find data visualization useful, especially as a tool to better understand their patterns of behavior and experiences and the contexts in which they take place. Such perceptions of self-monitoring data visualizations are consistent with other studies [52,53]. Well-designed data visualizations can promote patient engagement and compliance, as well as increase the ability of both clinicians and patients to explore, interpret, and discuss data [54,55]. Patients usually best understand number lines and bar graphs, and clear color differentiation is effective in communicating risks, improving understanding and increasing confidence in interpretation [56]. Participants clearly preferred sharing data with their clinicians. They perceived this as an appropriate and valuable addition of information that could help to make treatment more effective. This agrees with the findings of Lyzwinski et al [21], who found that patients in several studies perceived such sharing in a similar way. Willingness to share ESM data with loved ones varied. It depended mainly on the perceived quality of these relationships and a sense of being understood, which is also common when sharing information in other forms in mental health care settings [57].

In terms of content, functionality, and appearance, there were often requests for customization and individualization options for the DMMH. This is consistent with other studies [32,33] and recommendations for increasing user engagement with such tools [31]. Nevertheless, clinicians do not make much use of personalization options, which may be due to time and organizational constraints. Therefore, when developing mHealth tools, it is important to strike a balance between the possibilities of individual personalization and the resulting demands on both the clinician and the patient [42]. Participatory inquiry followed by collaboration of important stakeholders, especially patients, clinicians, researchers, IT and user experience experts, increases the likelihood that the tool will be satisfactory and patients will be more willing to use it [58]. This willingness is enhanced by their early involvement in development [59].

Implications for Future Research

The results of our study suggest several avenues for further research directions in the development and implementation of ESM-based mHealth tools for people with substance use problems. First, in collaboration with patients and clinicians, look for ways and opportunities to tailor the intensity of monitoring to the patient's current needs as well as treatment goals. Specifically, consider the patient's work-family balance and ability to respond to notifications. Also, consider the phase of treatment, where more intensive monitoring with a random schedule may be desirable in the initial phases, after relapse or when changing medication, but may not be necessary and may be burdensome for the patient at the time of remission and stabilization. In such a case, fixed schedule monitoring can be applied. Second, look for technical ways to effectively capture qualitative data to complement quantitative data in ESM protocols and to use it in a meaningful way for the benefit of patients, so that it is not too burdensome for them or for clinicians. Third, explore opportunities for effective linkage between ESM and EMI. This should include proactively offering an intervention based on ESM data, for example, when craving intensifies or intrapsychic tension increases.

The findings highlight the importance of tailoring ESM-based tools to patients' preferences and treatment contexts. Within the broader IMMERSE project [36], additional qualitative work was conducted to capture the perspectives of other stakeholders, including clinicians, people from the service user support network, and health care administrators involved in implementing such tools for use in general psychiatry setting.

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However, relatives of service users with problem substance use, clinicians specializing in this group of patients, and health care administrators for people with SUDs were represented only to a limited extent in the project. Future research should therefore ensure their adequate inclusion to better understand how ESM-based interventions can be integrated into clinical settings in a way that meets the needs of all stakeholders in the field of SUD treatment.

Limitations

Several limitations should be considered when interpreting the results of this study. First, the sample size is relatively small, which may reduce the generalizability of the results. Also, the relatively homogeneous sample in terms of age, with younger and older age groups missing, may have constrained the variability of perspectives. Moreover, the lack of data on race and ethnicity represents an important limitation. Cultural background may shape attitudes toward digital mental health tools, data sharing, and clinician-patient interaction, and these factors could not be examined in this study. Second, there is a risk of selection bias as it can be assumed that participants who are interested in digital technologies will agree to participate in such research and those who are sceptical will also be less willing to participate. Third, there is a risk of bias in terms of social desirability. Although the semistructured format and use of supplementary questions aimed to minimize this bias, participants knew that the interviewers were members of the wider team involved in the development of the DMMH and could therefore provide more positive feedback than they would otherwise have given. In addition, some interviews were conducted by researchers who had previous clinical contact with the participants.

Conclusions

Participants generally perceived this DMMH positively and expressed a willingness to undergo daily repeated monitoring, especially if one questionnaire takes as little time as possible to complete. This was the sole finding that distinguished individuals with problematic substance use from those with other mental health issues, as all other preferences were similar. Participants considered the possibility of noting down the specifics of situations in the form of open text to be important. Supplementing the monitoring with simple momentary interventions was welcome. Participants considered sharing the collected data with the clinician as beneficial for their collaboration and the success of the treatment. The possibility to adapt the content, the schedule of notifications, and the appearance of the tool to individual needs and preferences was considered important. The study concludes by highlighting the involvement of patients in the development of ESM-based mHealth tools for exploring the alignment of patients' identified preferences with the realities of clinical practice.

Acknowledgments

The authors declare that generative artificial intelligence (GenAI) tools were used during the research and manuscript preparation process. Specifically, GenAI was used exclusively for translation purposes. The tool used was DeepL. All outputs generated by the GenAI tool were reviewed, verified, and edited by the authors, who take full responsibility for the content of the final manuscript. No GenAI tool was listed as an author or contributed to study design, data analysis, interpretation, or conclusions. All quotations included in this manuscript were translated from the original language into English using DeepL software and subsequently checked for accuracy by a native speaker of the respective language.

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Data Availability

The datasets generated or analyzed during this study are available from the corresponding author on reasonable request.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Supplementary Materials 1. IMMERSE Service User Interview Guide.
[PDF File (Adobe PDF File), 42 KB - formative_v10i1e79510_app1.pdf]

Multimedia Appendix 2
Supplementary Materials 2. IMMERSE MoMent app prototype.
[MP4 File (MP4 Video), 3566 KB - formative_v10i1e79510_app2.mp4]

Multimedia Appendix 3

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Supplementary Materials 3. IMMERSE Visualisation Examples.
[PDF File (Adobe PDF File), 656 KB - formative_v10i1e79510_app3.pdf]

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Abbreviations

DMMH: Digital Mobile Mental Health

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EMI: Ecological Momentary Intervention
ESM: Experience Sampling Method
GDPR: General Data Protection Regulation
ICD-10: International Classification of Diseases, Tenth Revision
IMMERSE: Implementing Mobile Mental health Recording Strategy for Europe
mHealth: mobile health
NASSS: Non-Adoption, Abandonment, Scale-Up, Spread, and Sustainability
SHARE: Scottish Health Research Register
SMHRN: Scottish Mental Health Research Network
SUD: substance use disorder

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Original Paper

Digital Health Tools Embedded in a Cancer Genetics Clinic: Observational Study

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Abstract

Background: Digital Health Tools (DHTs), including wearables and mobile apps, offer promising avenues for personalized care and real-time monitoring, but user engagement and clinical utility—especially in pediatric populations—remain unclear. Li-Fraumeni syndrome (LFS) is a genetic mutation in the *TP53* tumor suppressor gene, predisposing individuals to cancer, requiring lifelong surveillance and associated psychological stress.

Objective: We evaluated engagement with DHTs in a cancer genetics clinic for families affected by LFS and explored their utility for patients and clinicians. Our goal was to identify insights that could inform future integration of DHTs in chronic disease populations and contribute to research.

Methods: We conducted an observational study (January-December 2022) involving patients with LFS and family members aged 5 years and older. Participants received an Empatica EmbracePlus smartwatch and a suite of self-report surveys assessing psychosocial well-being at varying frequencies (ie, daily, weekly, etc). We used survival analysis to characterize engagement over time across age, *TP53* status, and previous cancer history. Generalized additive models were used to explore physiological patterns relative to cancer surveillance events. Semistructured interviews provided qualitative insight into user experiences and preferences.

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Results: We enrolled 9 children and 36 adults. Adults wore their smartwatches more often than children (mean 81%, SD 19% vs mean 56%, SD 26%; $t_{10.1}$=2.72; *P*=.02) and were engaged in the study for a longer duration (median retention 153, IQR 119-179; 95% CI 133-177 vs median 77, IQR 36-151; 95% CI 17-171 days; log-rank χ^2_1=4.4; *P*=.04). Daily wear time was similar between the 2 groups (mean 17.6, SD 3.1 hours vs mean 15.7, SD 2.9 hours; $t_{13.2}$=1.70; *P*=.11). There were no differences in survey engagement between adults and children, nor were there differences in engagement across *TP53* status or previous cancer history. Children reported greater psychosocial burden, with more depressive symptoms (PHQ-9 [Patient Health Questionnaire-9] score mean 10.0, SD 5.2 vs mean 4.2, SD 4.4; $t_{7.8}$=2.8; *P*=.03), worse sleep (PROMIS SRI [patient-reported outcomes measurement information system sleep-related impairment] score mean 22.7, SD 5.9 vs mean 16.5, SD 5.5; $t_{8.1}$=−2.58; *P*=.03), and increased frequency of stress (mean 36.3%, SD 19.9% vs mean 14.3%, SD 19.2%; $t_{8.3}$=−2.7; *P*=.03) than adults. A suicide alert system was triggered in 5 participants (11%) and prompted timely clinical intervention. Generalized additive model analysis showed individualized yet consistent physiological patterns of stress associated with cancer surveillance. Qualitative feedback from participants identified perceived value in stress awareness, but highlighted challenges with device comfort, functionality, and personalization.

Conclusions: DHTs are feasible and can capture clinically meaningful psychological and physiological data in high-risk pediatric and family populations with LFS. They enable timely detection of distress and facilitate targeted interventions. Our findings can inform best practices for patient-centered DHT integration into clinical care, with relevance to pediatric oncology and broader digital health contexts.

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KEYWORDS

digital health; cancer; wearables; pediatrics; engagement

Introduction

Digital Health Tools (DHTs)—wearable devices, smartphone apps, and remote monitoring systems—are being integrated into clinical care [1,2]. DHTs promise enhanced physiological monitoring in settings outside traditional health care touchpoints (eg, home and work) [3,4], improved treatment and study engagement through digital notifications, and longitudinal collection of patient-reported outcomes [5,6]. DHTs are often paired with study apps for activity annotation and event flagging, enabling feedback and longitudinal outcome measures [7,8]. One specific use case that offers promise is the use of DHTs to monitor chronic disease progression [9-12]. Wearable sensors can capture physiological states outside clinical settings, encompassing not only disease biology but also the lived experiences (eg, psychosocial consequences) and the iatrogenic impacts of interventions, through serial patient-reported outcomes via app-based measures.

In our study, we focus on the application of DHTs for individuals and families affected by Li-Fraumeni Syndrome (LFS; MIM 151623) at a major Canadian hospital network. LFS is a genetic disorder caused by mutations in the *TP53* tumor suppressor gene, significantly increasing the risk of developing cancer from an early age [13,14]. Individuals with LFS face a lifetime cancer risk of approximately 40% by 20 years of age and over 90% by 70 years of age, requiring ongoing cancer surveillance using modalities such as magnetic resonance imaging (MRI) [15]. Survivors of a primary cancer have an 83-fold risk of developing subsequent malignancies. Clinical surveillance protocols [16] have significantly reduced mortality and treatment-related morbidity. However, the continuous cancer threat and intensive surveillance impose considerable psychological and emotional burdens on affected individuals and their families. Notably, ‘scanxiety’ is a period of emotional distress around cancer surveillance [17]. This impacts entire families—not only through the genetic nature of LFS but also the threat of future cancer diagnoses in loved ones and the shared experience of repeat surveillance.

DHTs show significant potential in providing clinicians with deeper insights into the lived experiences of patients with LFS and the iatrogenic impacts of cancer surveillance protocols. However, the extent to which this potential can be realized remains a blind spot in research. Recently, the World Health Organization outlined a classification of digital health interventions [18]—we propose addressing our study objectives on 3 fronts in accordance with the taxonomy described in their report: engagement with DHTs, benefits for health care providers, and benefits for patients. These domains are described below:

1. Engagement. Do patients want to use DHTs, and will they? This section addresses engagement with DHTs among families with LFS. We study the willingness of patients to use DHTs and the factors influencing their engagement.
2. Clinician benefits. How can DHTs benefit clinicians? This section explores the potential advantages DHTs offer to health care providers.
3. Patient benefits. How can DHTs benefit patients and families? This section explores the positive impacts of DHTs identified by patients and their families.

Our study builds on existing work studying the integration of DHTs into health care [8,10,19,20]. We study the role of DHTs in a unique patient population (children and adults with cancer predisposition), with an emphasis on benefits to multiple stakeholders (ie, clinicians and patients), and we identify unforeseen consequences from such interventions. We intend for this work to inform how DHTs can be integrated into cancer clinics and health care in general.

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Methods

Study Design

This observational study collected longitudinal data via repeat survey measures and wearable technologies from individuals and families affected by LFS. Participants aged 5 years and older were recruited from the cancer genetics program clinics at The Hospital for Sick Children (SickKids) and the Princess Margaret Cancer Center, with Research Ethics Board (REB) approval from both institutions (REB 1000072240). As outlined in Textbox 1, families of at least one affected member with LFS, including affected and unaffected relatives, were recruited during routine follow-up visits. A clinical fellow (RR) conducted biweekly check-in calls with families to support participation and gather insights on their study experience, disease, and familial burden. These calls provided rich qualitative data to inform future digital health studies for high-risk families. Recruitment for the study was done on a rolling basis from January to June 2022, as families presented to the clinic for their usual appointments. The target follow-up period was 6 months (180 days) for each participant, with a study end date of December 2022.

Textbox 1. Inclusion and exclusion criteria for study recruitment.

Inclusion criteria

- Families in whom either a parent or a child is affected with Li-Fraumeni syndrome (confirmed pathogenic germline variant in TP53).
- A noncarrier family member from a family where either a parent or a sibling is a confirmed carrier of a pathogenic germline variant in TP53.
- Able to comfortably wear the Empatica EmbracePlus band on the wrist or ankle.
- Able to speak, write, and read English (not applicable for younger children where assent was sought).
- Able to provide informed consent or assent (in children).
- Adult participants must have a personal smartphone and be willing to use their phone for the study, including downloading study apps and syncing devices (locked phones provided for participants aged 11 years or older without phones).

Exclusion criteria

- An active cancer diagnosis, undergoing active cancer therapy at enrollment, less than 6 months post systemic cancer therapy (except hormonal therapy for breast cancer), or less than 3 months post cancer surgery if no other therapy is recommended.
- Women who are pregnant or planning to become pregnant within 6 months.

Study Measures and Preprocessing

Overview

Study participants were given an EmbracePlus smartwatch built by Empatica Inc. Participants were also instructed to download the MyCap study app developed by REDCap (Research Electronic Data Capture; Vanderbilt University) on their phone for repeat survey administration. The study was designed to capture both passive (smartwatch) and active (survey) information longitudinally. We intentionally chose devices and platforms that are already approved for clinical use and can therefore be scaled easily for future work.

Smartwatch

The EmbracePlus smartwatch uses the Empatica Health Monitoring Platform and is certified with 510k clearance (US Food and Drug Administration) and as a class IIa medical device (European Union). It features several sensors:

1. Ventral electrodermal activity (EDA): detects subtle changes in electrical conductance at the surface of the skin.
2. Optical photoplethysmogram: measures heart rate and heart rate variability (HRV).
3. Digital skin temperature: reads peripheral skin temperature.
4. Accelerometer and gyroscope: collect raw acceleration and angular velocity data.

These physiological parameters are sampled at 64 Hz and sent via Bluetooth to a dedicated mobile app. This app automatically syncs all data to the Empatica Cloud and is compatible with iOS and Android smartphones. The smartwatch has previously been validated in clinical and research settings to monitor patient health via detection of physiological changes [21,22].

Study App

The MyCap study app administered daily, weekly, biweekly, and monthly surveys. Responses were stored on a secure REDCap instance at SickKids Hospital. Specific, age-appropriate surveys were administered to different age groups. For children aged 5-10 years, parents completed the surveys on behalf of their children. The MyCap app facilitated continuous engagement and data collection, allowing us to gather comprehensive information on participants' health and well-being. For a full list of measures, descriptions, rationale for selection, and the frequency of administration, please see Tables S1-S3 in Multimedia Appendix 1. Each survey was selected based on several factors: previous validation in the specific age group administered, as well as previous utility in similar study designs. They also contain a set of both subjective and objective measures of stress and well-being.

Data Management and Deployment

Our dataset comprised 3 sources: the Epic electronic health record, the Empatica Smartwatch, and the study app. Epic provided baseline clinical information, including patient demographics. The smartwatch collected various physiological data streams stored on Amazon S3, with participants able to

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access their own data via Empatica. Participants did not have access to their completed survey responses.

Upon study completion, data from these sources were transferred to a secure SickKids server with high-performance computing (HPC) capabilities. The HPC environment facilitated the integration, merging, and preprocessing of records, enabling analysis from all 3 data sources. This data management system marked the first use of such a pipeline for DHTs at SickKids hospital, establishing a framework for future clinical applications of DHTs (Figure S1 in Multimedia Appendix 1).

Analysis

Statistical Analyses

We compared overall survey completion and smartwatch use rates between subgroups (ie, adults vs children, *TP53* wild-type [wt] vs mutant [mut], and cancer history vs none) using 2-sample *t* tests with Welch correction. Unlike a 2-tailed t test, the Welch t test does not assume equal variances or balanced group sizes, making it more robust to heteroscedasticity in real-world engagement data. All *P* values are 2-tailed and were rounded to 3 decimal places.

Engagement Survival Analysis

Participant engagement was assessed quantitatively via adherence to daily surveys and smartwatch usage, and qualitatively through biweekly check-ins and clinical visits exploring barriers and benefits to participation.

Engagement metrics across digital health studies vary widely [23], so we explicitly outline our metrics here. Overall, survey engagement was quantified as the percentage of daily surveys completed per participant over the follow-up period (specifically, the Daily Stress Measure described in Table S1 in Multimedia Appendix 1). We also calculated rolling weekly averages of survey completion rates to examine how engagement fluctuates over time. Overall, smartwatch engagement was defined as the proportion of days participants wore the smartwatch for at least 6 hours, excluding improper wear artifacts identified by the manufacturer's algorithm. We also computed rolling weekly averages to represent dynamic engagement trends. This analysis does not differentiate between awake and sleep wear, though we separately analyzed awake versus sleep wear distribution by age group (Table 1).

Table 1. Participant characteristics and smartwatch wear metrics by age category.

Measure	Child (<18 years; n=9)	Adult (≥18 years; n=36)
LFS[a] (*TP53* mutation), n (%)	9 (100)	26 (72)
Cancer history, n (%)	4 (44)	10 (29)
Age (years), mean (range)	15.1 (7.9-18)	43.1 (22.8-68.1)
Daily survey completion rate (%), mean (SD)	51 (24)[b]	65 (22)
Smartwatch wear (≥6 hours/day)		
Smartwatch wear (days), mean (SD)	58 (56)	86 (50)
Days worn (%), mean (SD)	56 (26)	81 (19)
Total wear time (hours), mean (SD)	15.7 (2.9)	17.6 (3.1)
Sleep time (hours), mean (SD)	3.7 (2.2)	4.4 (2.1)
Awake time (hours), mean (SD)	6.8 (4.2)	9.1 (4.4)
Smartwatch wear (≥1 hour/day)		
Smartwatch wear (days), mean (SD)	65 (58)	93 (50)
Days worn (%), mean (SD)	62 (25)	86 (16)
Total wear time (hours), mean (SD)	14.0 (3.5)	16.5 (3.5)
Sleep time (hours), mean (SD)	3.3 (2.1)	4.2 (2.0)
Awake time (hours), mean (SD)	6.1 (4.0)	8.6 (4.3)

[a]LFS: Li-Fraumeni syndrome.

[b]Daily survey completion rate calculated for children aged 11-17 years only (n=7).

To compare engagement patterns across subgroups (eg, age), we used survival analysis. Measuring smartwatch engagement is challenging due to intermittent usage patterns. Therefore, we adopted the methodology described by Cho et al [20] to define participation end points for survival analyses clearly (see original paper for a detailed description). Briefly, each observed day was classified into 1 of 2 states: active if smartwatch wear exceeded a defined threshold (≥6 hours), or nonactive otherwise. Similarly, survey days were classified as active upon completing the Daily Stress Measure and nonactive if incomplete. Initially, all nonactive days were labeled exit; these were reclassified as inactive if followed by subsequent active days, reflecting temporary disengagement. Survival analysis used the first observation as time 0 days and 6 months (time 180 days) as the end date. Participants with events after this interval were considered censored. We modeled smartwatch and survey engagement where the event is defined as the first sustained exit within 180 days. Individuals who did not have an exit event

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were deemed as censored. Kaplan-Meier curves were created to model the survival functions generated by this analysis, and log-rank tests were used to compare median engagement across demographic subgroups.

Temporal Analysis

We conducted temporal (time series) analysis to characterize time-dependent patterns in survey and smartwatch adherence. Both survey and smartwatch adherence data for each engagement were smoothed using a centered 7-day rolling average. For each participant, we then computed the Pearson correlation coefficient between the 2 smoothed time series (ie, smartwatch and survey adherence). To characterize seasonal patterns in individual engagement, we applied a real-valued Fast Fourier Transform (FFT) to each detrended daily series. Specifically, for each participant's smoothed time series of engagement metrics, we subtracted the sample mean to detrend each time series then computed the FFT to transform data to the frequency domain. We then converted positive frequencies to periods in days (ie, inverse of frequency is period). Dominant periods were identified as the 3 largest spectral magnitudes. This FFT-based periodogram method has been used previously to reveal weekly, monthly, and other cyclic patterns in wearable sensor data [8].

Generalized Additive Model

To investigate the phenomenon of "scanxiety"—heightened anxiety and stress before clinical surveillance scans (eg, MRI to detect tumor recurrence or remission)—we used generalized additive models (GAMs) [24]. GAMs were used to model the relationship between the time-varying physiological measures from the smartwatch and proximity to each scan (ie, time-to-event regression). Their flexibility in capturing nonlinear relationships with cubic splines and interpretability made them ideal for this task.

Using the *pygam* library [25], separate GAMs were fit for each surveillance event (eg, participant A's MRI) with default hyperparameters. High-frequency smartwatch data (minute-level) up to 3 days before each scan provided thousands of data points per event.

Data preprocessing (Figure S2 in Multimedia Appendix 1) included imputation of missing values via multivariate imputation via chained equations (MICE) and feature normalization (log EDA, heart rate, log HRV, respiratory rate, and temperature) to zero mean and unit variance. We note that HRV and EDA were log-transformed to reduce positive skew and stabilize variance, ensuring approximate normality and improving model interpretability. A feature capturing missingness at each time step was included as a proxy for imputed data. This was done to study any possible relationship between missingness and the scan event, as we assume that data are not missing at random. Nonlinearities were modeled using cubic splines, and restricted maximum likelihood estimation was used to fit each GAM. Model performance was assessed using mean squared error from 5-fold cross-validation, and partial dependency plots visualized feature relationships with scan proximity (Table S4 in Multimedia Appendix 1).

Participants included in this analysis were those with at least 2 scans and at least 300 hours of smartwatch wear-time leading up to each scan. The final cohort consisted of 2 children and 7 adults. This was done to study inter- and intraindividual differences in the physiological sensor data within proximity to scan events.

Qualitative Experiences

Upon study completion, we interviewed each family to gather feedback on successes and challenges in the study design. We did not conduct a formal qualitative study or thematic analysis. Instead, qualitative insights were collected as part of routine operational monitoring. Telephone conversations were not recorded or transcribed; the study coordinator (author RR) documented them in semistructured free-text fields in REDCap, guided by a priori domains (eg, device usability, barriers to engagement, and emotional response to alerts) while allowing open-ended notes.

These entries were reviewed during biweekly team meetings, where common themes were identified through discussion and used to adapt the monitoring protocol. Some qualitative findings were supported by quantitative data (eg, frequency of PHQ-9 [Patient Health Questionnaire-9] alerts). We acknowledge that the absence of formal qualitative methods, coding, or interrater checks limits reproducibility, but we aimed to offset this with consistent documentation, reflexive team discussion, and integration of participant-reported experiences with engagement metrics.

Ethical Considerations

This study was reviewed and approved by the REB at SickKids Hospital, Toronto, Ontario, Canada (REB 1000072240), in accordance with the ethical standards outlined in the 1964 Declaration of Helsinki and its later amendments. All participants provided written informed consent before enrollment in the study. The consent process included agreement to the collection of both quantitative and qualitative data, as well as the use of anonymized responses for research publication purposes. No additional consent was required for the analysis presented in this manuscript, as it fell within the scope of the original ethics approval and participant consent. All data used in this study were deidentified before analysis to protect participant privacy and confidentiality. No identifying information was linked to the analysis datasets, and access to the raw data was restricted to authorized members of the research team in compliance with institutional data governance policies. No compensation was provided to participants for their involvement in the study.

Results

Recruitment

A total of 82 individuals were approached for enrollment, including 22 families (67 individuals) and 15 solo individuals. Of these, 59 (72%) individuals provided informed consent. Reasons for refusal included stress concerns related to their disease (n=7), recent cancer diagnosis (n=3), incompatible mobile phone (n=3), nonresponsiveness (n=3), recent cancer diagnosis in a child (n=1), owning a second smartwatch (n=1),

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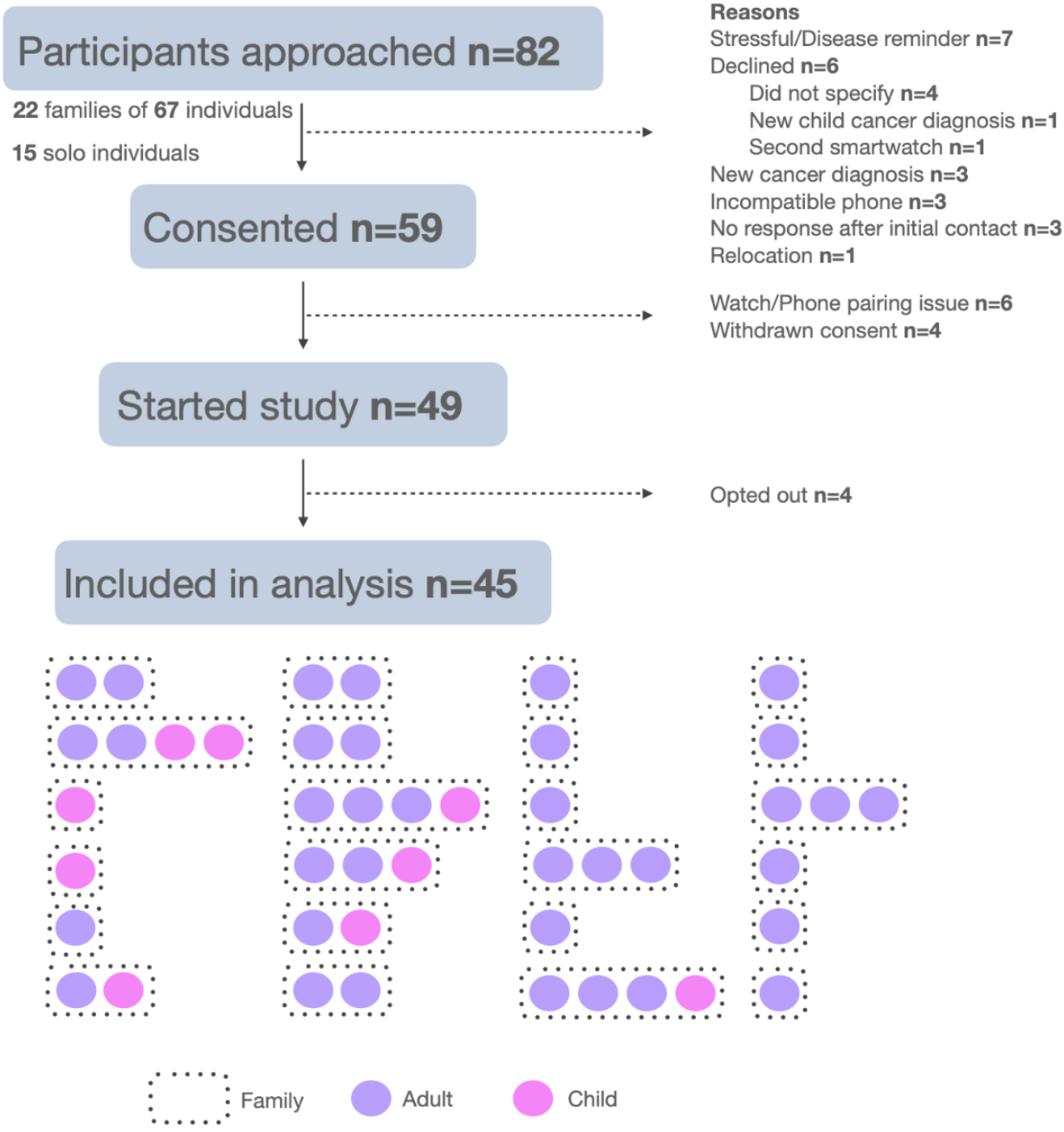
relocation (n=1), and unspecified reasons (n=4). Among consenting participants, 49 initiated the study, 6 experienced technical issues pairing the smartwatch, and 4 withdrew consent. Ultimately, 45 participants were included in the final analysis, as 4 did not wear the watch for unspecified reasons. The cohort comprised 12 families (each with at least 2 related participants) and 12 solo participants. Study recruitment and final cohort demographics are detailed in Figure 1.

Figure 1. Flowchart detailing participant recruitment and retention in the study. Out of 82 participants approached, 59 consented, 49 started the study, and 45 were included in the final analysis.



The cohort was diverse in age, *TP53* status (*TP53* wt: unaffected, *TP53* mut: affected), and other demographics (Table 1). Unfortunately, we were unable to recruit child noncarriers (ie, *TP53* wt). We flag this limitation for readers as differences between carriers and noncarriers may be confounded by adult and child differences.

Engagement

Long-term engagement in DHT-based studies is not only challenging to ensure, but it is also difficult to measure [20,23]. The difficulty in measurement can be attributed to the multitude of definitions for "engagement" when using repeated measures (ie, how to properly define disengagement). To circumvent these limitations and provide a holistic description of our study's engagement statistics, we considered both cohort-level and individual-level engagement rates.

Cohort engagement refers to the overall completion rates of survey engagement and the total wear time of the smartwatch during the follow-up period. As described in the "Methods" section, we define smartwatch engagement as 6 hours or more

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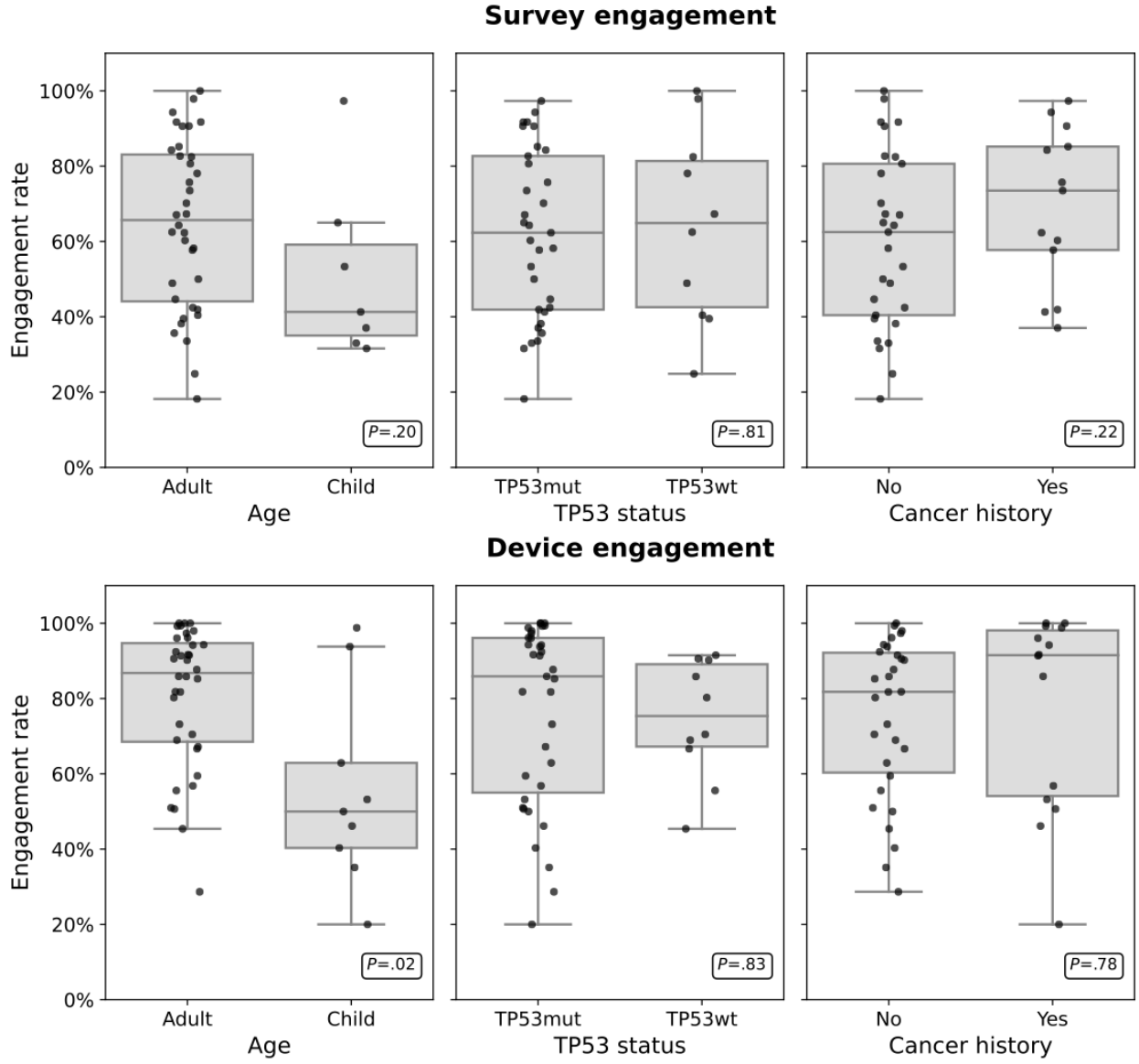
of proper wear time per day and survey engagement as % of daily survey instances completed during the follow-up period. We can see from Table 1 and Figure 2, all participants demonstrated high engagement for survey completion with no significant differences between adults and children (mean 65%, SD 22% vs mean 51%, SD 24%; $t_{8.3}$=1.39; *P*=.20). When comparing across different subgroups, survey engagement did not significantly differ between *TP53* wt and *TP53* mut participants mut (mean 64%, SD 26% vs mean 62%, SD 22%; $t_{13.5}$=−0.25; *P*=.81) or between those with previous cancer history and those without (mean 69%, SD 21% vs mean 60%, SD 23%; $t_{25.8}$=−1.25; *P*=.22). Interestingly, adults had better smartwatch engagement than children (mean 81%, SD 19% vs mean 56%, SD 26%; $t_{10.1}$=2.72; *P*=.02). Though on days where devices were worn at least 6 hours, wear time was similar between the 2 groups (mean 17.6, SD 3.1 hours vs mean 15.7, SD 2.9 hours; $t_{13.2}$=1.70; *P*=.11). Both adults and children wore their devices while sleeping for at least 3 hours per night (mean 4.4, SD 2.1 hours vs mean 3.7, SD 2.2 hours; $t_{11.7}$=0.83; *P*=.42). Daytime wear was also at least 6 hours per day on average between the 2 groups (mean 9.1, SD 4.4 hours vs mean 6.8, SD 4.2 hours; $t_{12.8}$=1.44; *P*=.17). There were no differences in smartwatch engagement rates across *TP53* wt and *TP53* mut (mean 75%, SD 16% vs mean 76%, SD 24%; $t_{22.2}$=0.22; *P*=.83) or between those with previous cancer history and those without (mean 77%, SD 26% vs mean 75%, SD 21%; $t_{21.1}$=−0.29; *P*=.78). There was also a strong coupling of engagement rates when studying the correlation between smartwatch and survey engagement rates across the study population (Figure S3 in Multimedia Appendix 1).

Figure 2. Overall survey and device engagement rates across the study duration, stratified by age group (left), TP53 status (middle), and cancer history (right).



To study individual-level engagement patterns across time, we plotted engagement over time. Qualitatively, there was substantial inter- and intraindividual variability in engagement alignment, with survey and smartwatch rates fluctuating both between and within individuals (Figure 3). Notably, strong seasonal trends with peaks, troughs, and declining engagement

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were observed. FFT analyses identified pronounced biweekly and monthly engagement cycles aligning with our biweekly clinical check-ins with participants (Figure 4). This was consistent across all strata (age, *TP53* wt status, and cancer history). The dashed line in Figure 4 annotates 2 to 4 weeks.

Figure 3. Engagement rates to smartwatch usage (blue) and survey completion (yellow) over time for randomly selected participants, separated by age group (left column: children, right column: adults).

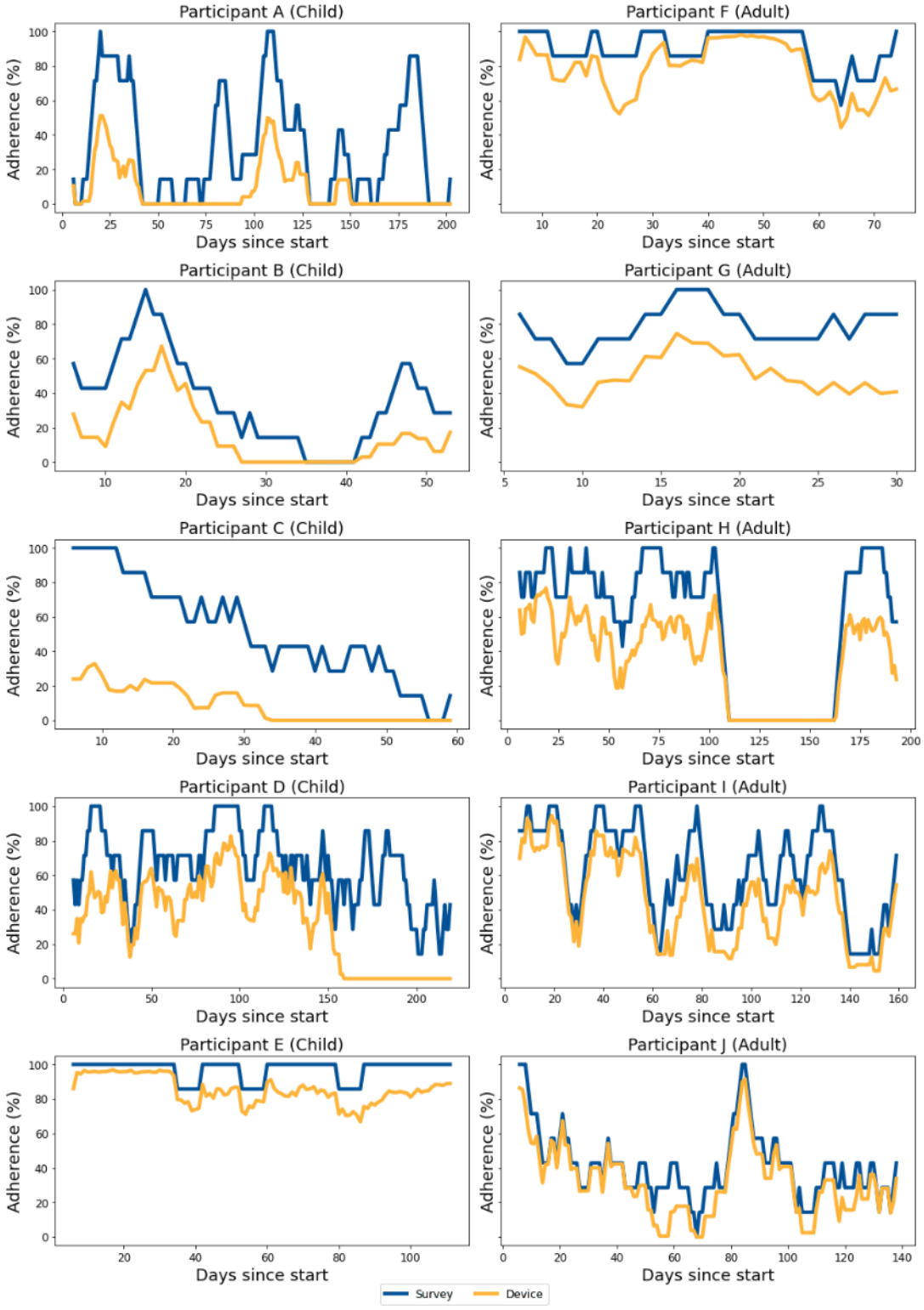

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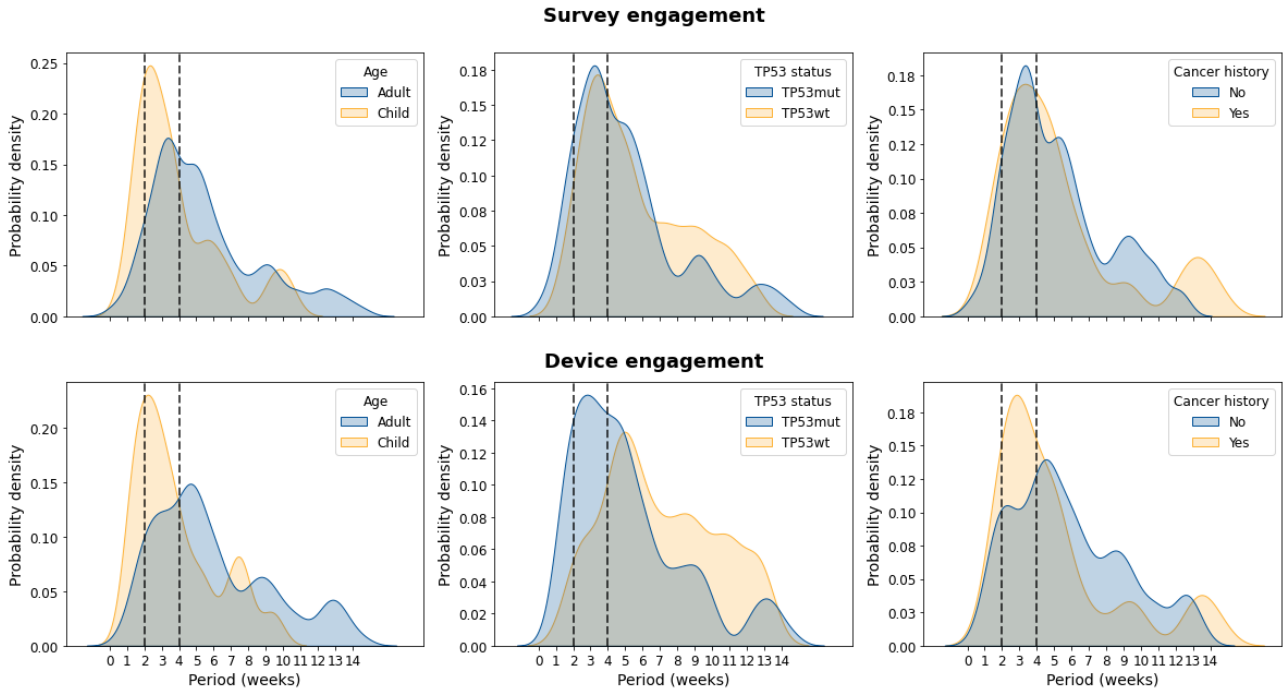
Figure 4. Top 3 peak period distribution (weeks) after Fast Fourier Transform decomposition of survey and smartwatch engagement rates stratified by TP53 status, age, and cancer history.



Finally, survival analysis uncovered interesting differences in study retention across age groups. Median survey retention was 146 (IQR 121-178; 95% CI 128-174) days for adults versus 60 (IQR 54-NA; 95% CI 46-NA) days for children, with no significant difference between groups (log-rank χ^2_1=0.2; *P*=.70). By *TP53* status, median retention was 131 (IQR 84-179 days; 95% CI 107-158) for *TP53* mut participants versus 160 (IQR 141-178 days; 95% CI 1-178) for *TP53* wt participants (log-rank χ^2_1=0.1; *P*=.71). Participants with a cancer history had a median retention of 146 (IQR 107-179; 95% CI 7-179) days compared to 141 (IQR 103-178; 95% CI 121-174) days for those without, with no significant difference observed (log-rank χ^2_1=0.2; *P*=.64). In Figure 5, the bottom row represents smartwatch engagement, and the top row represents survey engagement as defined in the “Methods” section. Number of participants at t=0: TP53 mut - 32, TP53 wt - 9, adult - 34, child - 7 (9 for smartwatch), cancer History - 27, no cancer history - 13. In this figure, we see that median smartwatch retention was 153 (IQR 119-179; 95% CI 133-177) days for adults versus 77 (IQR 36-151; 95% CI 17-171) days for children. Adults demonstrated significantly greater smartwatch retention compared to children (log-rank χ^2_1=4.4; *P*=.04). By *TP53* status, retention was 149 (IQR 77-179; 95% CI 119-171) days for *TP53* mut participants versus 158 (IQR 98-176; 95% CI 2-176) days for wt participants, with no significant difference (log-rank χ^2_1=0.06; *P*=.81). Participants with a cancer history had a median retention of 148 days (IQR 77-179; 95% CI 75-179) days compared to 153 (IQR 98-179; 95% CI 129-176) days for those without, with no significant difference (log-rank χ^2_1=0.4; *P*=.53).

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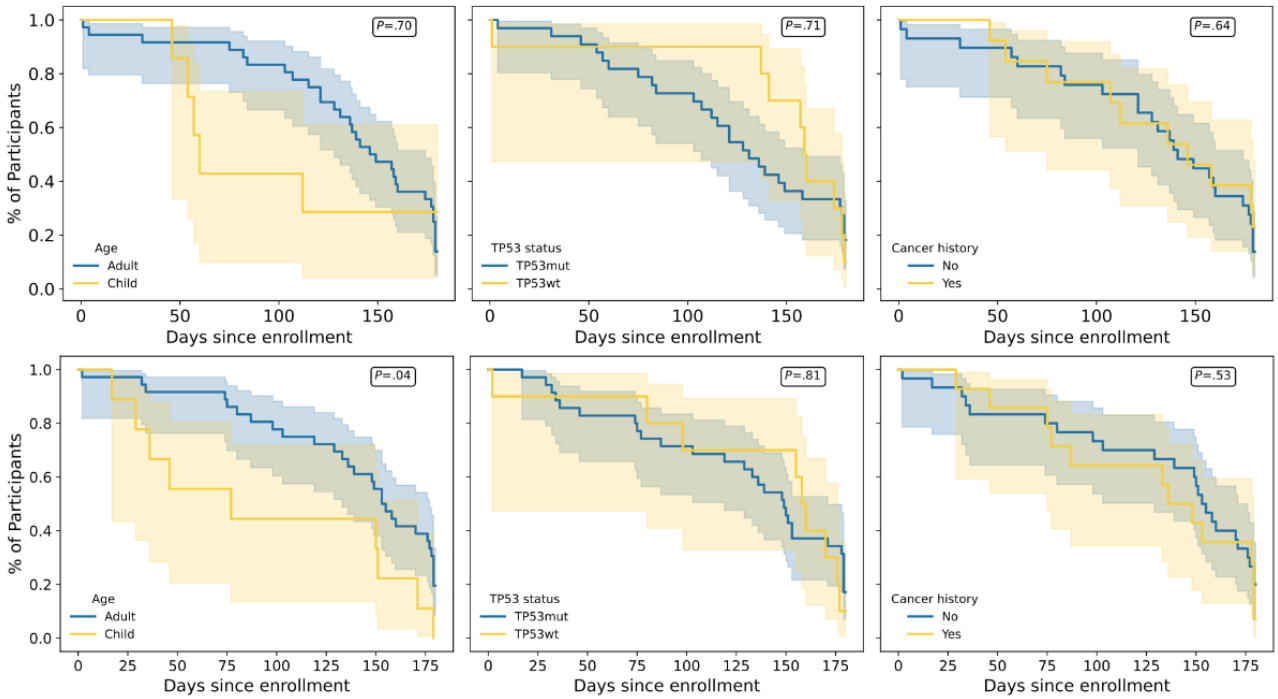
Figure 5. Plots showing the survey retention (top row) and smartwatch retention (bottom row) over time since enrollment, stratified by TP53 status (left column), age group (middle column), and previous cancer history (right column).



Revealing Insights Into Patient Psychosocial State

Patient-reported Outcomes Measurement Information System Sleep-related Impairment (PROMIS SRI), PHQ-9, Perceived Stress Scale-4 (PSS-4), and Generalized Anxiety Disorder-7 (GAD-7) among participants reveal important insights into the psychological and emotional distress experienced by different participants.

Figure 6 presents the distribution of these scores across all subgroups in our study. Children exhibited significantly higher mean PHQ-9 (mean 10.0, SD 5.2 vs mean 4.2, SD 4.4; $t_{7.8}$=−2.8; P=.03) and PROMIS SRI (mean 22.7, SD 5.9 vs mean 16.5, SD 5.5; $t_{8.1}$=−2.58; P=.03) scores compared to adults, indicating greater levels of depressive symptoms and sleep-related impairment, respectively (Figure 6). Children also reported being “very stressed” significantly more often than adults (mean 36.3%, SD 19.9% vs mean 14.3%, SD 19.2; $t_{8.3}$=−2.7; P=.03); Figure 6). Interestingly, we found no differences in overall stress reporting, anxiety (GAD-7), or depression (PHQ-9) when stratifying by previous cancer history or *TP53* mutation status.

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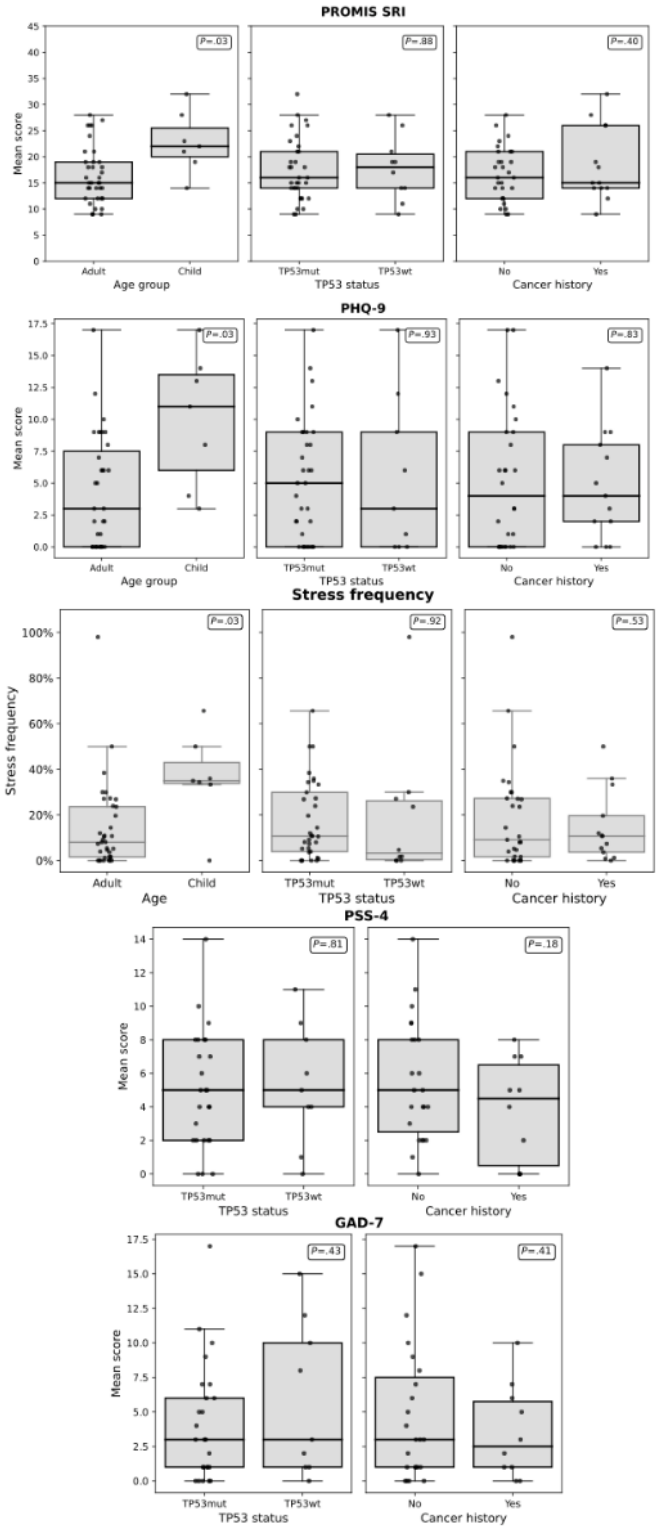
Figure 6. Distributions of baseline survey scores by group, plotted one survey per row. From top row to bottom row: PROMIS SRI, PHQ-9, stress frequency, PSS-4, and GAD-7 scores are each shown across the 3 groupings (age group, TP53 status, and cancer history). GAD-7: Generalized Anxiety Disorder-7; PHQ-9: Patient Health Questionnaire-9; PROMIS SRI: Patient-reported Outcomes Measurement Information System Sleep-related Impairment; PSS-4: Perceived Stress Scale-4.



We use the heat map in Figure S4 in Multimedia Appendix 1 to provide a dynamic visualization of the rolling mean scores for GAD-7, PHQ-9, PROMIS SRI, PSS-4, and daily stress indicators across different participants over the study period. This visualization allows us to observe how patients transition in and out of periods of high stress, depression, and anxiety. Notably, the heat map reveals fluctuations in psychological and emotional states between clinical visits that may otherwise go unnoticed if these are not recorded. The markers indicating scan events may help to correlate these transitions with specific clinical activities, providing insights into how such events may impact patient well-being.

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Flagging Critical Mental Health Events

The PHQ-9 survey asks the respondent about self-harm and suicide-related thoughts. If a participant responded positively to this question via the app, a built-in alert mechanism was activated, immediately notifying the principal investigators of the study who were the treating clinicians for some participants. This alert system was used to assess risk for and prevent future suicide-related behaviors.

In the course of our study, this alert system was triggered by 5 (11%) participants. Notably, 3 participants belonged to the same family, comprising 2 adolescent siblings and their mother. This unique cluster of participants, all encountering similar psychological distress, presented a compelling focal point for further investigation into the triggers of such emotional distress, which, in this context, were predominantly linked to their experiences with LFS.

All participants who triggered the alert were swiftly and comprehensively assessed by a dedicated clinician, ensuring that their emotional well-being was attended to with urgency and care. This response underscores the importance of monitoring the well-being of individuals and families grappling with the complexities of LFS and the emotional challenges it presents.

Sensor-Based Measures to Examine “Scanxiety”

During the study, 17 unique participants underwent clinical surveillance visits, which included medical imaging (eg, ultrasound or MRI) to screen for malignancy. These visits are typically preceded by stress and anxiety due to potential diagnoses. While the survey and app provided psychosocial insights, we investigated physiological signatures from the smartwatch coinciding with these surveillance events, observing notable inter- and intrapatient variability.

As described in the “Methods” section, 9 participants with at least 2 surveillance visits were included in this analysis. No interaction terms were included in the GAMs to balance interpretability with variance explained. Partial dependence plots (Figure 7) demonstrated significant interindividual heterogeneity, with unique patterns of dependence for each physiological measure and proximity to scans. This underscores the individualized nature of physiological responses to clinical surveillance. Of note is the similarity in dependence pattern within the same individual across different scans—indicating that some relationship between physiological feature and time-to-scan is conserved within individuals.

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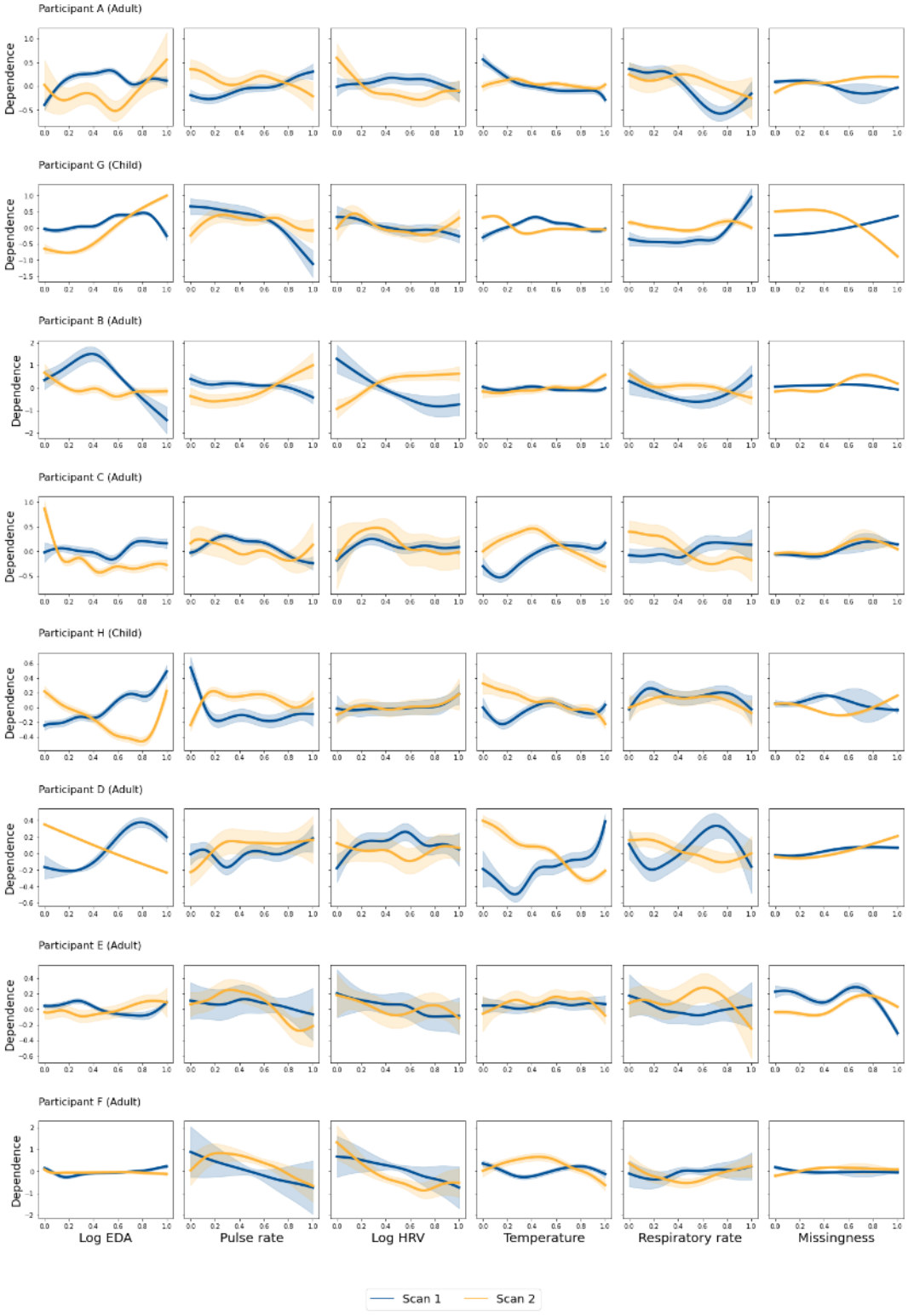
Figure 7. Partial dependence plots for various physiological features from a generalized additive model show individual participants (each row) with more than one scan. Overlaid plots for each scan are displayed in blue (scan 1) and yellow (scan 2). EDA: electrodermal activity; HRV: heart rate variability.



Patient Perspectives and Unforeseen Consequences

Qualitative feedback was elicited from study participants through an end-of-study questionnaire and interview (Figure 8). Participants described their experiences during the research and offered insights into the advantages and drawbacks of using smartwatches for stress assessment in the context of LFS.

In sum, the detailed feedback from the study underscores the complex emotional state of individuals with LFS and the role of integrated psychosocial support systems. The findings highlight the value of DHTs in monitoring stress and the pivotal role of safety protocols like the survey alert system in providing immediate care to those in acute distress.

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Summarized feedback (ie, key quotations) highlighted various observations about study strengths and weaknesses which can inform insights and recommendations for future work using DHTs.

Figure 8. Qualitative feedback was elicited from study participants through an end-of-study questionnaire and interview. DHT: Digital Health Tool; LFS: Li-Fraumeni syndrome.

Discussion

Principal Findings

Our findings underscore the implications of integrating DHTs into clinical care for children and families with LFS. While DHTs offered valuable insights into patients' psychological and emotional states, maintaining engagement was particularly challenging for children and adolescents. Physiological data from DHTs identified changes linked to surveillance visits, demonstrating the potential to model iatrogenic effects like "scanxiety"—stress and anxiety triggered by clinical monitoring. Qualitative feedback showed general enthusiasm for the study but pointed out areas for enhancing engagement and smartwatch usability in future DHT research. This study serves as a benchmark for larger investigations and informs the design of DHT-based interventions in chronic disease. Although our findings may extend to other chronic conditions, further work is needed for external validation.

With respect to our first objective, engagement with DHTs varied by *TP53* status, cancer history, and age, with overall survey completion exceeding 50% and higher smartwatch engagement among adults. Using multiple DHTs (eg, surveys and smartwatches) appeared to support engagement, as indicated by the strong correlation in intermodality usage among the population [26,27]. Engagement also showed cyclical patterns, likely influenced by biweekly check-ins from study organizers, consistent with trends reported in other studies [8,28]. Despite a median (IQR) smartwatch retention time of 153 (119-179) days in adults and 77 (36-151) days in children, overall engagement declined over time. Participant feedback highlighted challenges related to device practicality, comfort, and aesthetics, emphasizing the need for seamless integration of DHTs into daily life to sustain engagement. Future studies should address these barriers to facilitate longer-term observation.

Our second objective was to assess patient perspectives, as LFS imposes significant psychological and emotional burdens [29,30]. In this population, we found increased stress, higher PHQ-9 scores (depression), and sleep impairment among children compared to adults. These findings align with prior research [17,31], reinforcing the need for mental health interventions in those with chronic illness requiring surveillance. Notably, self-harm alerts were triggered through app-based PHQ-9 surveys, highlighting the utility of DHTs in facilitating timely interventions that might otherwise go unnoticed. Our qualitative analysis revealed that DHT integration encouraged patients to reflect on their existing stressors, and some conveyed optimism about the potential for future tools to better identify or reduce stress.

Our final objective was to explore the benefits for clinicians. Traditional care models provide limited snapshots of patient well-being during visits [32]. DHTs offer continuous psychosocial and physiological data between appointments, revealing insights into patient experiences that would otherwise remain latent. GAM analysis demonstrated inter- and intraindividual heterogeneity in physiological responses to clinical visits, highlighting the potential of wearable sensors to

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detect iatrogenic effects like "scanxiety." Future research should explore the physiological signatures of clinical surveillance to develop early warning systems and proactive interventions. Integrating DHT data from surveys and smartwatches into clinician dashboards could enable real-time monitoring of patient well-being during treatment and follow-up.

Study limitations include a small sample size and a niche patient population, which may affect generalizability. In particular, this is a patient population with extensive clinical follow-up built into their existing care model—engagement may be reduced in populations where touchpoints to care are sparse. Our diverse population of children and adults identified unique age-specific differences: specifically, that the burden of stress is higher in children, but engagement is worse. Future studies should aim to better understand this gap, as the subgroup that may benefit the most from DHTs is also the most difficult to engage. Unlike many prior studies focused exclusively on individuals with active disease, our cohort included unaffected family members who also participate in lifelong disease surveillance, highlighting both the potential for monitoring caregivers and the broader burden of "scanxiety" experienced across entire families rather than individual patients. That being said, families with LFS are not unique to the phenomenon of "scanxiety"—surveillance is common practice in oncological [33,34] as well as nononcological disease [35]. Our insights about DHT integration may generalize to other populations monitored for chronic disease as well. Other limitations may have affected our findings as well; participants reported issues with smartwatch comfort and functionality, as the research-grade Empatica smartwatch lacked consumer features such as messaging or apps. Some felt the smartwatch was a constant reminder of their disease, potentially reducing engagement. This highlights the importance of selecting DHTs that seamlessly integrate into patients' daily lives. Technical challenges, such as missing data and imputation, may have introduced bias into our GAM analysis, though we mitigated these effects by explicitly modeling missingness and analyzing only individuals with sufficient data.

Conclusion

In conclusion, this study demonstrated the use of wearable technology and smartphone app surveys to engage children and families affected by LFS. The diverse dataset, spanning various ages, families, and *TP53* mutation statuses, has been made publicly available to facilitate further research and advancements in understanding and managing LFS. Participant feedback provided valuable insights for improving future digital health studies, particularly at larger scales. While DHTs hold significant promise in chronic disease management and psychosocial monitoring, larger studies are needed to optimize their application and address potential challenges.

Acknowledgments

We would like to thank all the patients and their families who participated in the study. 4YouandMe is a non-profit organization that studies the feasibility of digital health interventions from a patient-centric perspective. DM holds the Canadian Imperial Bank of Commerce (CIBC) Children's Foundation Chair in Child Health Research. Generative artificial intelligence (ie, ChatGPT) was only used for spelling and grammar suggestions, as well as software generation for figure aesthetics and beautification.

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Data Availability

The datasets generated or analyzed during this study will be available open access on Sage Bionetworks.

Authors' Contributions

Conceptualization: SF (lead), DM (equal), RR (equal), SG (equal), AG (equal), SN(equal)
Data curation: SN (lead), RR (supporting), RG (supporting), HB (supporting)
Formal analysis: SN (lead), RR (supporting)
Methodology: SN (lead), SG (supporting), SF (supporting), AG (supporting)
Software: SN (lead), RG (supporting), HB (supporting)
Funding acquisition: AG (lead), DM (equal), SG (equal), AV (equal), RK (equal), SF (equal)
Supervision: SF (lead), SG (equal), AG (equal), DM(equal)
Project administration: LB (lead), CK (equal), EK (equal)
Writing – original draft: SN (lead), RR (equal)
Writing – review & editing: SN (lead), RR (supporting), SG (supporting), LB (supporting), CK (supporting), AV (supporting), RK (supporting), EK (supporting), RG (supporting), HB (supporting), MO (supporting), AG (supporting), DM (supporting), SF (supporting)

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Conflicts of Interest

None declared.

Multimedia Appendix 1
Additional materials including further descriptions of methods and additional figures.
[DOCX File , 479 KB - formative_v10i1e74375_app1.docx]

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Abbreviations

DHT: digital health tool
EDA: electrodermal activity
FFT: fast fourier transform
GAD-7: generalized anxiety disorder-7
GAM: generalized additive model
HPC: high-performance computing
HRV: heart rate variability
LFS: Li-Fraumeni syndrome
MICE: multivariate imputation via chained equations
MRI: magnetic resonance imaging
mut: mutant

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PHQ-9: patient health questionnaire-9
PROMIS SRI: patient-reported outcomes measurement information system sleep-related impairment
PSS-4: perceived stress scale-4
REB: research ethics board
REDCap: research electronic data capture
wt: wild-type

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Original Paper

Factors Influencing Physicians' Perceived Compensation Satisfaction in China: Cross-Sectional Study

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Abstract

Background: Physicians' perceived compensation satisfaction enhances work enthusiasm, ensures health care system stability, and inspires health care quality. However, few studies have investigated the combined effect of multiple influencing factors on this perception.

Objective: This study investigates the factors influencing Chinese physicians' perceived compensation satisfaction.

Methods: A cross-sectional survey was conducted between April and May 2024 to examine physicians' perceived compensation satisfaction, alongside their sociodemographic characteristics and perceived transparency of compensation schemes. A total of 325 valid responses were obtained, with 163 male and 162 female participants. Qualitative comparative analysis was then employed to identify the factors associated with physicians' perceived compensation satisfaction.

Results: The analysis yielded two models: junior physicians' perceptions and senior physicians' perceptions. For junior physicians, compensation scheme transparency contributed to higher perceived compensation satisfaction, regardless of salary or work hours. For senior physicians, two paths contributed to perceived compensation satisfaction: (1) higher salary and compensation scheme transparency and (2) lower salary and compensation scheme transparency combined with a higher technical rank and fewer work hours.

Conclusions: The determinants of perceived compensation satisfaction showed heterogeneity between junior and senior physicians, which underscores the necessity of formulating tiered, targeted compensation packages to improve their perceived compensation satisfaction.

(JMIR Form Res 2026;10:e85936) doi:10.2196/85936

KEYWORDS

compensation perceptions; compensation satisfaction; qualitative comparative analysis; compensation scheme transparency; junior physician; senior physicians; Chinese physicians; health care quality

Introduction

Perceived compensation satisfaction constitutes a critical component of health care human resources management. Within the health care sector, physician compensation satisfaction is instrumental in safeguarding the stability of the health care system and enhancing interprofessional care coordination [1-3]. Notably, physicians' satisfaction with their compensation exerts

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a significant impact on their work motivation: higher levels of compensation satisfaction facilitate the retention of elite medical talent and incentivize the delivery of high-quality clinical services. Conversely, low compensation satisfaction may erode work motivation, which in turn could compromise the efficiency and quality of health care provision.

Studies have explored the factors associated with physician perceived compensation satisfaction from 3 perspectives. The first considers physicians' demographic characteristics, including educational background, years of work experience, and technical rank [4,5]. The second considers work hours, which are typically taken as representing physicians' input [6]. The third considers physicians' output, represented by financial compensation; this perspective most frequently focuses on the past [7,8]. These studies assume that the factors associated with physicians' perceived compensation satisfaction are independent. However, these perceptions are complex and shaped by multifaceted comparative assessments captured in the Equity Theory. The Equity Theory was proposed by American psychologist J Stacy Adams in 1965, whose core purpose was to explain how individuals' perceptions of the fairness of reward distribution affect their work attitudes and behaviors [9]. The Equity Theory suggests that individuals think about their compensation by comparing their inputs with their outputs, as well as by comparing those inputs and outputs against others' outputs [10,11]. Inputs include experience, skill, education, and effort, and outputs include basic salary, bonus, and benefits. When the input is perceived as exceeding the output, the perception of a need for greater compensation arises, and vice versa. Thus, the factors influencing this perception are not independent but interact to impact perception, and the compensation scheme is the basis for evaluating the relationship between input and output. To the best of our knowledge, few studies have investigated the combined effects of multiple influencing factors on physicians' perceived compensation satisfaction. Furthermore, although it has been shown to deliver a competitive advantage in achieving employee satisfaction in the business field [12], little research has examined the influence of compensation scheme transparency in a physician context, considering physicians' awareness of the compensation scheme, their level of understanding, and how promptly they are informed.

Our study attempts to address these gaps in the literature by examining the interaction of the factors influencing perceived compensation satisfaction along with compensation scheme transparency. Following previous studies, we include demographic characteristics, work hours, and compensation scheme transparency to represent alternative explanations for our research outcomes.

Methods

Study Design

We conducted a cross-sectional survey in China from April to May 2024 to collect the necessary data. To understand which factors or combinations thereof are most important for perceived compensation satisfaction, we used qualitative comparative analysis (QCA). Although QCA is traditionally associated with qualitative research, its application in this study aligns with a mixed methods approach.

Procedure

We designed the questionnaire according to the aim of our study. First, we conducted a pilot survey on a small sample (n=10) in Beijing, Shandong, Hainan, Jiangsu, and Ningxia that included representatives of different cultures across North, South, East, and West China, respectively. The participants in the pilot surveys were colleagues or acquaintances of the researchers. We then revised the questionnaire according to the pilot test feedback. Pilot participants suggested clarifying terms such as compensation scheme fairness, leading to revised wording in the final questionnaire (eg, I think the department's compensation scheme is fair). Second, our sample size meets the robustness requirements for QCA [13,14]; so, the research members tried their best to recruit more physicians to complete the questionnaire before data collection was scheduled to terminate. All questions were mandatory. The survey was anonymous, and the answers were sent directly to the database to ensure confidentiality.

Ethical Considerations

This study was approved by the ethics committee of China-Japan Friendship Hospital (approval 2022-KY-218) and conducted in accordance with the World Medical Association Declaration of Helsinki. Informed consent was obtained from all participants via an online consent form on the questionnaire's opening page (participants could only proceed after clicking "agree"), and all retained the right to opt out at any stage without adverse consequences. The survey was anonymous, with all participant data fully anonymized and deidentified. Participants who completed the survey received ¥1 in electronic compensation via WeChat, equivalent to US $0.14 at the time of data collection (April-May 2024).

Measurements

The questionnaire consisted of three parts: sociodemographic characteristics (eg, sex, age, place of residence, education level, technical rank, specialty, and monthly salary), compensation scheme transparency, and perceived compensation satisfaction. The physicians rated compensation transparency and perceived compensation satisfaction on a 5-point Likert scale, with strongly disagree (score 1), disagree (score 2), neither agree nor disagree (score 3), agree (score 4), and strongly agree (score 5). Lower perceived compensation satisfaction was defined as an average score of less than 3 on the compensation perception questions. Higher perceived compensation satisfaction was defined as an average score equal to or greater than 3 on the compensation perception questions [15,16]. Cronbach α and the Kaiser-Mayer-Olkin value for the questionnaire were 0.955 and 0.924, respectively, indicating high total reliability and validity. All items loaded significantly on a single factor with loadings greater than 0.6, and the cumulative variance explained was 65.3%. These results collectively support the use of these constructs as unidimensional scales.

Sociodemographic Characteristics

The questionnaire collected various sociodemographic characteristics of the physician participants to provide a

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comprehensive background for understanding their perceived compensation satisfaction. These characteristics included sex, categorized as male and female; age, recorded in years and further classified into several ranges (≤30, 31-40, 41-50, ≥51); education level, classified as bachelor and below, masters, and doctoral degree; technical rank, grouped into resident, attending physician, and (associate) professor; department, with specialties such as surgery, internal medicine, obstetrics and gynecology, pediatrics, traditional Chinese medicine, general practice, and emergency department; monthly salary, categorized into different ranges (≤¥3000; ¥3001-¥6000; ¥6001-¥10,000; ¥10,001-¥20,000; >¥20,000); and weekly work hours, classified as the average number of hours worked per week. All variables were collected via the online questionnaire.

Compensation Scheme Transparency

Compensation scheme transparency was assessed through four questions: (1) in my opinion, I am very familiar with the compensation scheme; (2) when I want to learn about the compensation scheme, I can easily find out; (3) I am able to learn about the compensation scheme in a timely manner; and (4) senior leaders proactively share the compensation distribution details with me. The Cronbach α for this dimension was 0.947, indicating relatively high reliability.

Perceived Compensation Satisfaction

On the basis of the comparative theory, perceived compensation satisfaction was assessed from multiple perspectives: external comparison, internal comparison, input–output comparison, expectation–reality gap, and compensation scheme perception. These were measured using 7 questions: (1) compared with other professions in the hospital, my compensation level is reasonable; (2) compared with physicians in other departments, my compensation level is reasonable; (3) compared with senior physicians in my department, my compensation level is reasonable; (4) compared with physicians of the same level in my department, my compensation level is reasonable; (5) my compensation is consistent with my efforts and contributions; (6) the actual compensation is in line with my expectation; and (7) I think the department's compensation scheme is fair. The Cronbach α for this dimension was 0.944, indicating relatively high reliability.

Sample Selection

We used the survey platform Questionnaire Star to host our questionnaire and distributed a generated link through WeChat. Each WeChat account could respond to the questionnaire only once (to avoid repeated responses) unless modified. Our trained research members were assigned to different geographical regions, including Beijing, Hainan, Shandong, Jiangsu, and Ningxia. Each sample hospital is a tertiary public hospital and has approximately 500 to 1000 physicians. The research members visited the sample hospitals to recruit physicians face-to-face through convenience sampling until the sample size was reached. Meanwhile, they explained the purpose of the study, informed the physicians of the anonymity of the survey, and stated that it would take about 10 minutes of their time if they were available. If the physicians agreed to participate in the survey, the research members would immediately present a QR code and help the physicians scanning it. The informed consent form was also on the opening page. Only after reading and clicking the "Agree" button could participants proceed to the questionnaire. Researchers were also available to respond to questions that prospective participants had regarding unclear terms or the questionnaire items. Compensation of ¥1 (US $0.14) was offered to participants who completed the survey. We also ensured a balance of sex, age, technical rank, and specialty to ensure the representativeness. The only participation exclusion was work experience of less than 6 months.

The response rate was approximately 80.2% (401/500). In total, 401 physicians responded to the survey. Among the questionnaires received, 76 were excluded owing to unreasonable response durations or logistic errors. Ultimately, 325 questionnaires were included in our analysis. Based on QCA recommendations, 10-80 cases are required for robust analysis. Our sample size of 325 far exceeds this threshold, ensuring sufficient statistical power.

Statistical Analysis

SPSS software (version 24.0; IBM Corp) was employed to assess the reliability and validity of the questionnaire, conduct factor loading analysis, and compare the differences among groups.

As perceived compensation satisfaction has several complex influences rather than a single impact, we used fuzzy-set qualitative comparative analysis (fsQCA) to explore different combinations of factors. QCA was selected to analyze how combinations of factors jointly influence satisfaction. Traditional regression models assume linear relationships, whereas QCA identifies nonlinear interactions and multiple pathways to outcomes. This approach bridges qualitative and quantitative methods [17]. We used the fsQCA 3.0 software with a package developed by Charles Ragin and Sean Davey for this analysis.

We calibrated the raw data of the selected variables following previous research [14]. First, we determined the three calibration points that represented (1) fully belong, (2) the cross-point, and (3) fully do not belong. For this, we encoded the Likert scale data of strongly agree as fully belong, neither agree nor disagree as the cross-point, and strongly disagree as fully do not belong. Following the method of preset scale anchor points as thresholds [18,19], education level was set as 3, 2, and 1, and technical rank as 4, 2.5, and 1. Continuous variables were designated for 3 qualitative breakpoints (0.95, 0.5, and 0.05), the data were converted into values between 0 and 1 [20-22]. By setting these 3 thresholds, the original data were transformed into fuzzy scores ranging from 0 to 1 by using the Calibrate (x, n1, n2, n3) function in the fsQCA software.

The initial phase of QCA involves assessing the necessity of a singular condition as well as its absence for the full adoption of the phenomenon. A condition was considered sufficient when the consistency level exceeded 0.8. Furthermore, when the consistency level exceeded 0.9, this condition was deemed essential [20-24].

The next phase of QCA is configuration analysis, which was applied to our truth table to reveal the sufficiency of the perceptions associated with different configurations of multiple

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conditions. To calculate the complex, parsimonious, and intermediate solutions, the consistency threshold was set to 0.8 and the case frequency threshold to 1.

Statistical significance was assessed using *P* values, with a threshold of $P<.05$. Group differences (eg, technical rank, department, monthly salary) were analyzed via 2-sided chi-square tests for categorical variables and 2-sided *t* tests for continuous variables.

Results

Participant Characteristics

Of the 325 participants, 163 (50.2%) were males and 162 (49.8%) were females. The majority were aged either 31-40 years (131/325, 40.31%) or 41-50 years (133/325, 40.92%). The ratio of residents to attending physicians to (associate) professors was approximately 1:2:2.3. Among the physicians, 49.8% (162/325) earned more than ¥10,000 (US $1378) per month. The average weekly work hours were 52.30 (SD 12.26) hours. Table 1 presents the sociodemographic characteristics of the participants.

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Table 1. Participant characteristics.

	Physicians with lower compensation satisfaction[a] (n=133)	Physicians with higher compensation satisfaction[b] (n=195)
Sex, n (%)		
Male	59 (36.3)	104 (63.8)
Female	74 (45.7)	88 (54.3)
Age (y), n (%)		
≤30	19 (46.3)	22 (57.3)
31-40	56 (42.7)	75 (57.3)
41-50	52 (39.1)	81 (60.9)
≥51	6 (30)	14 (70)
Education level, n (%)		
Bachelor and below	46 (49.5)	47 (50.5)
Master	61 (38.6)	97 (61.4)
Doctorate	26 (35.1)	48 (64.9)
Technical rank		
Resident	26 (41.9)	36 (58.1)
Attending	59 (48.8)	62 (51.2)
(Associate) Professor	48 (33.8)	94 (66.2)
Department, n (%)		
Surgery	38 (46.9)	43 (53.1)
Internal medicine	26 (34.7)	49 (65.3)
Obstetrics and gynecology	3 (30)	7 (70)
Pediatrics	9 (37.5)	15 (62.5)
Traditional Chinese medicine	9 (29)	22 (71)
General practitioner	16 (84.2)	3 (15.8)
Emergency department	10 (55.6)	8 (44.4)
Others	22 (32.8)	45 (67.2)
Monthly salary, n (%)		
≤¥3000 (US $≤412)	10 (71.4)	4 (28.6)
¥3001-¥6000 (US $413-$826)	19 (48.7)	20 (51.3)
¥6001-¥10,000 (US $827-$1378)	52 (47.3)	58 (52.7)
¥10,001-¥20,000 (US $1379-$2756)	42 (35)	78 (65)
>¥20,000 (>US $2756)	10 (23.8)	32 (76.2)
Weekly work hours, mean (SD)	54.65 (13.35)	50.67 (11.19)
Perceived compensation scheme transparency, mean (SD)	2.43 (0.99)	3.71 (0.83)

[a]Lower compensation satisfaction was defined as an average score of less than 3 on the compensation perception questions.

[b]Higher compensation satisfaction was defined as an average score of equal to or greater than 3 on the compensation perception questions.

Perceived Compensation Scheme Transparency

Overall, most physicians felt that their compensation schemes were transparent (see Table 2). The average score for perceived compensation transparency was 3.19 (SD 1.09). Their responses indicated that they had the means to learn more about the schemes and could do so promptly. They indicated that they were familiar with their compensation schemes and that their leaders were available to provide compensation details.

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Table 2. Perceived compensation scheme transparency.

Item	Values, mean (SD)
In my opinion, I am very familiar with the compensation scheme.	3.18 (1.17)
When I want to learn about the compensation scheme, I can easily find out.	3.29 (1.18)
I am able to learn about the compensation scheme in a timely manner.	3.27 (1.16)
Senior leaders proactively share the compensation distribution details with me.	3.01 (1.20)

Participants' Perceived Compensation Satisfaction

As shown in Table 3, significant differences emerged in expectation–reality gap scores (2.70) compared with input–output comparisons (2.85; $P<.05$), suggesting that unmet compensation expectations drive dissatisfaction; the compensation gap within a department was perceived as being more reasonable than that among departments. The perceived compensation satisfaction was the lowest when compared with expectation, followed by the comparison of input and output.

Table 3. Physicians' perceived compensation satisfaction.

Item	Values, mean (SD)
External comparison	
Compared with other professions in the hospital, my compensation level is reasonable.	2.98 (1.04)
Compared with physicians in other departments, my compensation level is reasonable.	2.96 (1.04)
Internal comparison	
Compared with senior physicians in my department, my compensation level is reasonable.	3.18 (1.05)
Compared with the same-rank physicians in my department, my compensation level is reasonable.	3.47 (0.90)
Input-output comparison	
My compensation level is commensurate with my effort and contribution.	2.85 (1.13)
Expectation-reality gap	
The actual compensation I receive matches expected compensation.	2.70 (1.15)
Compensation scheme	
I think the compensation scheme is fair.	3.31 (1.04)

Factors Associated With Physicians' Perceived Compensation Satisfaction

Necessity Analysis of Individual Conditions

Table 4 shows the test results of the necessary conditions for physicians' perceived compensation satisfaction. Compensation scheme transparency was identified as a necessary condition for higher perceived compensation satisfaction, as indicated by its high consistency score of 0.901, which exceeds the conventional threshold of 0.9 [17].~Monthly salary and ~Weekly work hours were found to be sufficient conditions, with consistency scores of 0.805 and 0.803, respectively [25,26].

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Table 4. Necessity test of the factors associated with physicians' perceived compensation satisfaction.

Condition variable	Higher perceived compensation satisfaction		Lower perceived compensation satisfaction	
	Consistency	Coverage	Consistency	Coverage
Education level	0.704	0.620	0.579	0.711
~[a]Education level	0.672	0.533	0.691	0.765
Technical rank	0.681	0.642	0.574	0.756
~Technical rank	0.741	0.555	0.728	0.761
Working experience years	0.673	0.558	0.631	0.730
~ Working experience years	0.675	0.567	0.618	0.725
Weekly work hours	0.631	0.573	0.648	0.821
~Weekly work hours	0.803	0.621	0.663	0.715
Monthly salary	0.625	0.714	0.487	0.777
~Monthly salary	0.805	0.529	0.821	0.753
Perceived compensation transparency	0.901	0.799	0.525	0.650
~Perceived compensation transparency	0.606	0.477	0.838	0.922

[a]~ denotes the absence of a condition in fuzzy-set qualitative comparative analysis.

Adequacy Analysis of Conditional Configuration

As indicated in Table 5, three paths lead to higher perceived compensation satisfaction. The unique coverage for S1, S2, and S3 was 0.155, 0.019, and 0.109, respectively. Overall, these three paths show strong explanatory power owing to their good consistency (0.866) and relatively high coverage (0.709).

Table 5. Configuration analysis of the factors associated with perceived compensation satisfaction.

Conditions	Higher perceived compensation satisfaction[a]		
	Junior physicians (model 1)	Senior physicians (model 2)	
	S1 (one pathway)	S2 (pathway 1)	S3 (pathway 2)
Years of work experience	AC[b]	CC[c]	CC
Education level	CC	CC	IS[d]
Technical title	AC	IS	CC
Weekly work hours	IS	IS	AC
Monthly salary	IS	PC	AC
Compensation scheme transparency	PC[e]	PC	PC
Consistency	0.928	0.916	0.914
Raw coverage	0.434	0.399	0.435
Unique coverage	0.155	0.019	0.109

[a]Solution consistency=0.886; solution coverage=0.709.

[b]AC indicates absence of condition.

[c]CC indicates core condition.

[d]IS indicates insignificant.

[e]PC indicates the presence of a condition.

We merged the three paths into two to build models with greater explanatory power.

1. The first model is the junior physician model, which includes S1. Its basic expression is M1 = ~years of work experience × education level × ~technical title × compensation scheme transparency, that is, junior physicians care less about weekly work hours and salary when the compensation scheme is perceived as transparent. In this situation, they are satisfied with their compensation.
2. The second model is the senior physician model, which includes S2 and S3. The basic expression is M2 = years of work experience × compensation scheme transparency (education level × monthly salary × technical title × ~weekly work hours × ~monthly salary), that is, for senior physicians, a higher monthly salary and perceived

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compensation scheme transparency lead to higher perceived compensation satisfaction. If the salary is lower, a higher technical title and fewer weekly work hours combined with a transparent compensation scheme will drive perceived compensation satisfaction.

Robustness Test

We set the consistency level from 0.8 to 0.85 and 0.73 to examine the robustness of the results. Compared with those before adjustment, the configuration paths, coverage, and consistency did not change substantially after adjustment. Thus, the results are robust.

Discussion

Principal Findings

QCA enables the analysis of complex causal configurations in quantitative data, making it suitable for exploring interactions between multiple factors influencing compensation satisfaction [17].

Through the application of QCA, we analyzed how combined factors influence physicians' perceived compensation satisfaction. We found that compensation scheme transparency was a necessary condition for higher compensation satisfaction. Physicians who were more familiar with their compensation schemes, whether actively or passively, found it easier to learn about the scheme promptly and were more satisfied with their compensation. This finding aligns with a prior study by Chinese scholars investigating rural physicians' compensation satisfaction, which found that township hospital health care workers were not satisfied with their salary unless they were aware of the salary scheme design [27]. Research conducted in the United States has found that the gender salary gap among surgeons led to burnout among female surgeons, and while compensation transparency reforms narrowed this gap, disparities persisted. Consequently, the researcher promoted a transparent, performance-based, and objective compensation plan [28,29]. In China, physician compensation comprises fixed and variable components. The fixed part, which is primarily determined by years of work experience and one's professional title, constitutes a minor proportion of the total compensation with narrow disparities among physicians. The variable part, typically based on performance, including clinical workload, medical quality, patient satisfaction, and academic research outputs, ranges from 50% to 70% of total compensation [30,31]. Therefore, regarding compensation scheme transparency, the most important aspect is the variable part design and associated feedback. To improve physicians' perceived compensation satisfaction and work behavior, hospital managers should maintain transparent performance assessment criteria and provide clear performance feedback.

The determinants of compensation perception were heterogeneous between junior and senior physicians. For junior physicians, if the compensation scheme is transparent, they would be satisfied even with lower pay or longer working hours. In contrast, they prioritized the transparency of the compensation scheme. For senior physicians, transparent compensation combined with a relatively high salary contributed to high compensation satisfaction. In the case of a lower salary, senior physicians' satisfaction was promoted by a transparent compensation scheme, a higher technical title, and fewer work hours. For junior physicians, neither salary nor work hours seemed to be significantly associated with their compensation satisfaction. Therefore, junior physicians differ from other young adults at a similar career stage, who are particularly interested in higher salaries and work-life balance and unwilling to pay more than a minor amount for training to enhance their skills and knowledge [32,33]. The difference may originate from the fact that the salary of physicians increases over time with training [34]. Furthermore, the unique nature of the medical profession and the complexity of medical knowledge could explain why junior physicians do not feel the need to pursue higher salaries at this stage of their career. Moreover, junior physicians are eager to acquire more professional skills to enhance their competence in the field [35], and they understand that this initially requires long work hours and a lower salary. A survey of junior physicians in Sudan has found that their training program served as a nonmonetary incentive to trade off portions of their salaries [36]. Given the priority on professional skills, training plans offered to junior physicians should be carefully designed, and measures to address supervision-related issues are recommended in the short term from a cost perspective. For senior physicians, in addition to compensation scheme transparency, monthly salary, technical rank, and work hours all combined to affect compensation satisfaction. High entry-level requirements for physicians regarding education, training, and certification are common worldwide. Thus, we may hypothesize that high entry barriers would lead to higher salaries [37-39]. Logically, physicians should earn a relatively high compensation, as their salary is an essential component of their occupation that enables them to fulfil family responsibilities. Our findings are in line with previous research reporting that higher salaries can lead to higher satisfaction and stimulate employee enthusiasm for work [40,41]. Chinese scholars have found that low salaries relative to high training costs and low compensation for medical staff strongly incentivize overtreatment, contributing to increased medical service expenditures [42]. Given the entry-level requirements and low compensation among Chinese physicians, increasing their salaries is a significant incentive to ensure their satisfaction and avoid opportunistic behavior.

Additionally, we found that physicians with a higher technical rank and fewer work hours had higher compensation satisfaction, even when their salaries were low. This higher satisfaction with compensation may stem from Maslow's Needs Theory, which suggests that the highest level of need is the realization of self-worth, and once the needs of a higher level are fulfilled, the more basic needs such as salary become less important [43,44]. Regarding technical rank, a survey conducted in 161 US universities also reported that associate professors were less satisfied in their jobs than full professors [45]. Thus, the title of professor serves as an approval of worth and could be the goal for many physicians. Therefore, to ensure higher compensation satisfaction, hospital managers should pay attention to the technical promotion pathway for physicians. Notably, due to the cross-sectional design, the next step will require a cohort study to validate the findings of this research.

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Limitations

This study has limitations. As the physicians were selected through convenience sampling, the nonrandomness of this technique could have introduced limiting factors. Although we strictly controlled sex, age, technical rank, and specialty distribution to ensure sample balance across these four key aspects, the inherent nature of convenience sampling still limits sample representativeness, and the generalizability of the conclusions requires further validation. For example, the samples were mainly from physicians willing to participate in the survey at sampled hospitals, which may lead to self-selection bias. Meanwhile, the results may be overestimated or underestimated because of the self-reporting design of our questionnaire. There are some potential influencing factors such as occupational risk that should be considered. Future research is required that employs more rigorous sampling methods, incorporates larger and more diverse samples across multiple institutions, and accounts for more potential influencing factors—all of which would enhance the generalizability of our findings and the stability of our results.

Conclusions

Our study considered the dynamic effects of multiple factors on physician compensation satisfaction and provided management advice to hospitals and other institutions looking to retain personnel. We found that the factors associated with compensation satisfaction differed between junior and senior physicians. For junior physicians, compensation scheme transparency, not salary level, influenced their perceived compensation satisfaction. For senior physicians, salary level was an important factor but not consistently the only decisive factor influencing satisfaction. A higher technical rank could offset the adverse effects of lower salaries. Therefore, hospital managers should focus on improving the transparency of compensation schemes and customizing benefit packages for specific employees.

Acknowledgments

We thank the interviewees who participated in the study.

Data Availability

Study data are available from the corresponding author upon reasonable request.

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Authors' Contributions

CZ had a significant role in conceptualization, methodology, data curation, and writing the original draft. WW participated in the investigation and wrote the original draft. NH was responsible for the methodology, data curation, and writing the original draft. JM, XJ and AZ performed the investigation. All authors were involved in the design of the questionnaire; they contributed to writing, reviewing, and editing and approved the final manuscript.

Conflicts of Interest

None declared.

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Abbreviations

fsQCA: fuzzy-set qualitative comparative analysis
QCA: qualitative comparative analysis

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Original Paper

Using AI in Forward-Backward Translation of Questionnaires for Men Invited to Prostate Cancer Screening: Methodological Study

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Abstract

Background: Translation is important in research to ensure cultural relevance, accuracy, and generalizability, particularly in cross-cultural studies. The forward-backward translation method of the World Health Organization (WHO) is commonly used to improve linguistic and conceptual accuracy but is often time-consuming and resource intensive. The development of advanced artificial intelligence (AI) offers new opportunities to make the translation process more efficient, potentially reducing time and costs. However, concerns remain regarding the ability of AI to capture cultural nuances and complex linguistic structures, which may affect translation quality. Therefore, evidence on how AI can be effectively integrated into established translation frameworks remains limited.

Objective: This study aimed to explore the use of AI in the forward-backward translation process for questionnaires.

Methods: We used an adapted version of the WHO 4-step forward-backward translation method to translate the questionnaires from English into Polish. The questionnaires included the Prostate Cancer Screening Education (PROCASE) Knowledge Index, the Attitude Scale, Risk Perception items, and the Brief Health Literacy Scale for Adults. First, 2 AI tools (ChatGPT [GPT-3.5] and Microsoft Bing Copilot) were used for translating from English to Polish. Second, 2 native Polish speakers focused on content understanding independently reviewed and corrected the AI-generated Polish version and agreed on a new version. Third, the AI-generated Polish translation was back-translated from Polish into English using the same AI tools. Any discrepancies were discussed by an expert panel consisting of native speakers of English and Polish. This procedure ensured linguistic accuracy and conceptual similarity. Finally, 3 individual cognitive interviews were conducted with native Polish-speaking men to identify whether the questionnaires measured the intended constructs and to find any issues that the respondents might encounter during the response process.

Results: Minor discrepancies between the two AI-generated Polish phrases “umiera z innej przyczyny” and “umiera z powodu innych przyczyn” were merged by native Polish speakers in the PROCASE Knowledge Index. The original questionnaires and the AI-generated questionnaires had minor differences, but they did not affect the meaning of the questions or what was being asked. We conducted individual cognitive interviews (n=3) with participants aged 47 to 74 years. After the interviews, the questionnaires were adjusted with a few changes to make them easier to understand. In the Attitude Scale, the AI-generated Polish translation was changed from “nieco” to “trochę” to align with everyday language and improve understanding.

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Conclusions: AI can be an effective tool in the translation process, offering time and resource savings while maintaining accuracy. However, human involvement is still needed to optimize translation.

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KEYWORDS

artificial intelligence; AI; forward-backward translation; questionnaire adaptation; prostate cancer screening; cross-cultural research; cognitive interviews; health survey translation

Introduction

Translation of questionnaires in research is essential to ensure cultural relevance by making questions understandable and clear for respondents from diverse backgrounds, leading to more accurate data [1]. Translation also increases the reach of the research, allowing for the inclusion of participants who speak different languages, thereby improving the generalizability of the findings. Furthermore, accurate translation maintains the validity and reliability of the questionnaire, ensuring that the translated version measures the same constructs as the original [2]. In international or cross-cultural studies, translated questionnaires allow for comparisons between different groups, facilitating a better understanding of global differences. As international research relies on standardized questionnaires across multiple countries and languages, the need for translation methods that are both methodologically strong and practically feasible has become more apparent. Therefore, the World Health Organization (WHO) introduced the forward-backward translation method in 2007 to ensure this need [3]. This method involves translating the questionnaire from the original source language to the target language (forward translation) and then translating it back to the source language again (backward translation) by a different translator. The original and back-translated versions are then compared with identify differences and ensure linguistic accuracy and conceptual similarity, and the process concludes with cognitive interviews with the target population. This is quite time-consuming, costly, and requires many researchers and experts in the two languages to translate the questionnaires [3]. These practical challenges may limit the feasibility of applying the full translation framework in large, multicountry studies with restricted time and resources.

With the development of artificial intelligence (AI), the use of AI in research has led to a significant change in how scientific research is conducted and data are analyzed [4]. AI offers models that can process large amounts of data with speed and precision [5]. This capability is particularly valued in fields such as medicine, where AI can enhance diagnostic speed and accuracy, optimize treatment plans, and simplify clinical trials [6]. More recently, AI has also been increasingly explored as a tool to support linguistic tasks, including translation, in health and social science research [7]. However, AI may also introduce new errors and hamper transparency due to a lack of clarity regarding the data on which AI is trained. AI translation may struggle with cultural nuances or specific terminology, potentially leading to misinterpretation or lack of clarity in responses [8]. Additionally, some AI systems might not handle complex linguistic structures well, potentially leading to errors in interpreting nuanced survey questions. For questionnaire translations, where accuracy of phrasing can influence survey responses, these issues can be critical [9]. Despite these concerns, AI translation tools are widely used in practice, often without systematic evaluation of how they perform within established translation frameworks. By acknowledging these potential limitations, there may be opportunities to optimize the forward-backward translation process. AI can assist in the translation of the questionnaires and potentially reduce human error and save resources such as time and staffing [10]. Optimizing the translation process through AI may help maintain the high standards of translation accuracy required in cross-country research while improving efficiency. However, evidence remains limited on how AI can be responsibly integrated into standardized translation procedures while preserving linguistic and conceptual accuracy. We aimed to translate questionnaires from English to Polish by incorporating AI into the WHO's translation process, accounting for potential AI errors by continuing to involve human expertise.

Methods

Setting

Prostate cancer (PCa) is the most frequent cancer among men in Europe, with around 450,000 European men diagnosed with PCa each year at an average age of 69 years at the time of diagnosis [11]. Furthermore, approximately 107,000 European men die from PCa per year. Organized screening, including prostate-specific antigen (PSA) testing, can lead to early detection and reduce morbidity and mortality from PCa [12,13]. Today, PCa screening often occurs in an opportunistic setting, which has proven to be ineffective, with no mortality reduction but considerable overdiagnosis, psychological harms, and associated costs [14,15].

This study is part of a 3-year European Union project, PRAISE-U (grant 101101217), in which a systematic multistep PCa screening strategy will be developed, implemented, and evaluated in 4 countries—Poland, Lithuania, Ireland, and Spain (Manresa and Galicia)—including men aged 50 to 69 years. Beyond the clinical measures, the focus is on the evaluation of men's knowledge about and attitudes toward PCa screening, individual risk perceptions, and health literacy. These variables are measured through questionnaires distributed to the men who are invited to PCa screening, applying the Prostate Cancer Screening Education (PROCASE) Knowledge Index [16], Attitude Scale [17], Risk Perception [18], and the Brief Health Literacy Scale for Adults (B-HLA) [19]. Given that this is an international pilot study, it is important to ensure the accuracy and consistency of these questionnaire translations between countries [20].

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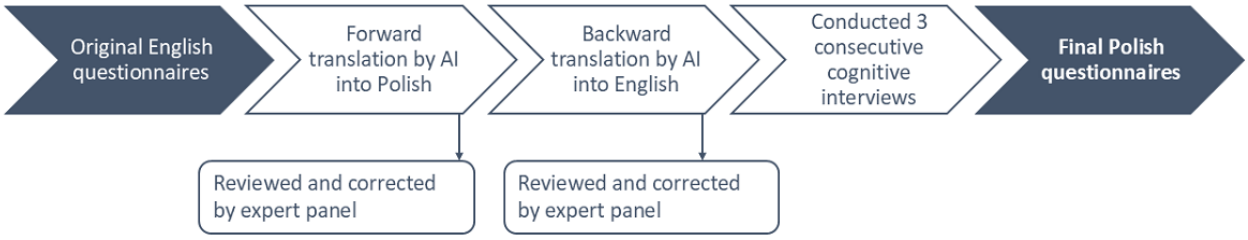
Translation Procedure

In this study, we followed the WHO forward-backward translation method, which is widely used to ensure linguistic and conceptual accuracy across languages. The WHO's forward-backward method involves the following steps:

1. Translating the questionnaire from the original source language to the target language (forward translation) by 2 independent people whose native language is the target language and who are fluent in the original source language.
2. Translating it back to the source language by a different translator (backward translation) by 2 independent people whose native language is the source language and who are fluent in the target language.
3. Comparing the original and back-translated versions.
4. Conducting cognitive interviews with the target population.

The translation process in this study followed an adapted version of the WHO forward-backward method, integrating AI tools to ensure linguistic accuracy and conceptual similarity. The translation process is shown in Figure 1.

Figure 1. Flowchart of the translation process. AI: artificial intelligence.



Step 1 involved translating the original English versions of the questionnaires into Polish using 2 AI tools: ChatGPT (GPT-3.5; OpenAI) and Microsoft Bing Copilot. These tools were used because they are widely accessible and because of their expertise in language processing and translation tasks. While both models are based on large language models, ChatGPT works as a standalone language model that generates translations based on its internal training data, whereas Microsoft Bing Copilot may draw on web-based information when producing outputs. A simple prompt ("translate to Polish") was used for both AI tools to evaluate baseline translation performance under realistic conditions, reflecting typical use in which people may not use advanced or detailed prompts. This helped us understand how well their basic translations are and identify areas where more specific instructions could improve the results.

The focus was on assessing whether AI-generated translations are a feasible and useful approach within an established translation framework. Following the AI-generated translations, an expert panel consisting of 2 native Polish speakers was recruited to review and refine the translated Polish versions, with a focus on ensuring linguistic accuracy and conceptual similarity. In this step, the two AI-generated translations were reviewed individually, after which each reviewer independently merged the AI-generated versions into a single document. This process was guided by personal linguistic preferences in Polish and informed by an understanding of the target population for whom the questionnaires were intended. After individual reviews, the two native Polish speakers met to discuss any differences found in the AI-generated translations and agreed on a revised Polish version. This step aimed to address any disparities that might arise during the AI translation process, ensuring the final version was understandable.

To evaluate the performance of the two AI models used for translation (ChatGPT and Microsoft Bing Copilot), we used a structured evaluation framework focusing on translation quality. The evaluation was integrated into the existing WHO forward-backward translation workflow.

Each AI-generated translation was reviewed according to three factors often used in translation research: (1) linguistic accuracy, defined as change of grammar, vocabulary, and syntax; (2) conceptual alignment, defined as maintenance of the original meaning; and (3) clarity and readability, defined as clarity for the target population.

For each questionnaire item, the AI-generated translations were independently reviewed by 2 native Polish language experts during the expert review phase. Revisions were classified using a scoring system:

- No issue—no revision needed.
- Minor issue—wording revision without a change in meaning.
- Major issue—conceptual revision needed.

Scores were noted for translations generated by ChatGPT and Microsoft Bing Copilot. The number and type of issues identified for each AI model were summarized descriptively to allow for a comparison of translation performance. Discrepancies were resolved through expert consensus, resulting in a final revised Polish version.

For step 2, the revised Polish version underwent back-translation into English using the same AI tools used in the initial translation phase (ChatGPT and Microsoft Bing Copilot). This step aimed to assess the consistency and quality of the translated content by comparing it with the original English questionnaire. The 2 AI back-translated versions were merged into a single translated version. This was done by a project manager familiar with the original English questionnaires, and this process was also guided by linguistic preferences in English and an understanding of the target population.

Step 3 consisted of validating the accuracy and conceptual similarity of the translated questionnaire; therefore, an expert panel was convened, consisting of 2 Polish researchers proficient in English and experts in PCa screening, as well as 2 researchers who were either native English speakers or proficient in English

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and experts in the subject addressed by the questionnaires. The expert panel systematically reviewed the AI back-translated English version against the original English version and provided comments, discussing any discrepancies observed and additionally resolving any linguistic or conceptual challenges. The same project manager involved in Step 2 then merged and revised the AI back-translated English version based on the expert panel's feedback and consensus.

On the basis of the feedback and comments from the expert panel, a final version of the AI-generated translated questionnaires was refined, ensuring linguistic accuracy and alignment with the original English questionnaires. The finalized Polish version of the questionnaires represented the final step of the forward-backward translation process, validated through collaborative efforts between AI tools and different researchers' expertise.

Cognitive Interviews

The fourth and final step involved cognitive interviews. Cognitive interviewing is a qualitative method, and the purpose of this study was to evaluate the quality of the AI-generated Polish-translated questionnaires. This method aims to identify whether the questionnaires measured the intended constructs and to find any issues that the respondents may encounter during the response process [21].

The cognitive interviews were conducted using a structured interview guide to ensure consistency in data collection. Each participant was informed of the purpose of the interview before the start and signed a consent form. Participants were asked to complete the questionnaires one by one. After completing each questionnaire, participants were asked specific questions related to their understanding of the items. Additionally, the interviewer also asked follow-up questions to probe the participant's initial thoughts and to identify any uncertainties or confusion. Examples of these questions included the following:

> *What was your initial thought when answering the questionnaire?*
>
> *Were there any questions you found ambiguous or confusing?*
>
> *What do you think about when answering these questions?*
>
> *What considerations do you make before selecting your answer from the options?*

In addition to the specific follow-up questions, participants were asked general questions after they had answered all the questionnaires. Examples of these questions included the following:

> *Is there anything else you would like to add or comment on regarding the questionnaires?*
>
> *Is there anything else we should know about your thoughts on these questionnaires?*

The interviews were recorded to ensure accurate capture of the participants' responses. Additionally, the interviewer took notes during and after each interview to document any nonverbal signals and to capture initial impressions and observations.

Ethical Considerations

According to the Consolidation Act on Research Ethics Review of Health Research Projects, Consolidation Act number 1083 of September 15, 2017, section 14(2), health science survey studies and interview-based investigations that do not involve human biological material are exempt from notification to the research ethics committee system. The project was listed in the record of processing activities for research projects in the Central Denmark Region (1-16-02-286-24) according to the European Union's General Data Protection Regulation. All participants were anonymized, and no identifying information was reported in accordance with standard ethical and reporting practices. Participants did not receive any financial compensation or incentives for participation.

Results

AI Translation

Forward Translation

For the translation process, we used the same prompt for both AI models and prompted them with "Translate to Polish."

Similar words and synonyms are terms with identical or closely related meanings. Across the 4 questionnaires (26 items), both AI tools generated translations that were largely comparable to the original English versions. For ChatGPT, 18 of 26 (69.2%) items showed no identified issues, while 6 (23.1%) items were classified as having minor issues and 2 (7.7%) items as having major issues. Similarly, Microsoft Bing Copilot generated 19 (73.1%) translations with no identified issues, 4 (15.4%) with minor issues, and 3 (11.5%) with major issues.

Overall, most identified issues were minor and primarily related to wording, stylistic preferences, or readability rather than changes in meaning.

ChatGPT needed fewer major conceptual revisions compared with Microsoft Bing Copilot, whereas Microsoft Bing Copilot showed fewer minor issues overall. The main problems were cases where words such as "not" were added or left out, which changed the meaning of factual statements, especially in the PROCASE Knowledge Index. All major issues were resolved during the expert review phase, resulting in a final translation that preserved conceptual alignment across all items. Detailed item-level comparisons are available in Multimedia Appendix 1.

To outline some of the minor issues identified, examples from the PROCASE Knowledge Index and Attitude Scale are explained below. For instance, in the PROCASE Knowledge Index, the similarity in meaning between the phrases "...z innej przyczyny" ("...from other causes") and "z powodu innych przyczyn" ("...due to other causes") was discussed during the expert review. As both phrasings have the same meaning, the ChatGPT version was selected to keep the sentence shorter without losing its meaning (Textbox 1).

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Textbox 1. Example of minor wording differences identified during forward translation of the Prostate Cancer Screening Education Knowledge Index (differences shown in italics).

- ChatGPT (question 1): Większość mężczyzn zdiagnozowanych z rakiem prostaty umiera z *innej przyczyny.*
- Microsoft Bing Copilot (question 1): Większość mężczyzn zdiagnozowanych z rakiem prostaty umiera z *powodu innych przyczyn.*
- Revision after expert review (merged version): Większość mężczyzn zdiagnozowanych z rakiem prostaty umiera z *innej przyczyny.*

Similarly, in the Attitude Scale, differences were identified in the wording of the response options that were closely related in meaning. For example, the terms "złe rzeczy" ("bad things") and "niekorzystne" ("unfavorable"), as well as "niezbyt przyjemne" ("not very pleasant") and "nieprzyjemne" ("unpleasant") are all similar or closely related words with the same meaning rather than differences in conceptual meaning. The differences between "niezbyt przyjemne" and "nieprzyjemne" are mainly related to the degrees of unpleasantness (Textbox 2).

Textbox 2. Example of minor wording differences identified during forward translation (Attitude Scale).

ChatGPT (answer options)

- (c) 1: Złe rzeczy, 7: Dobra rzecz
- (d) 1: Przyjemne, 7: Niezbyt przyjemne

Microsoft Bing Copilot (answer options)

- (c) 1: Niekorzystne, 7: Korzystne
- (d) 1: Przyjemne, 7: Nieprzyjemne

Revision and correction by native Polish speaker

- (c) 1: Niekorzystne, 7: Korzystne
- (d) 1: Przyjemne, 7: Nieprzyjemne

Backward Translation

After the 2 AI-translated questionnaires were merged into one by the native Polish experts, this version was translated back into English using the prompt "translate to English" for both AI models. The original questionnaire and the AI-generated translated questionnaire were compared by an expert panel consisting of native English and Polish-speaking researchers. The differences between them are presented in Textbox 3.

Textbox 3. Example of minor wording differences identified during backward translation.

Prostate Cancer Screening Education (PROCASE) Knowledge Index

- Artificial intelligence (AI) generated (question 1): Most men diagnosed with prostate cancer die *from other causes.*
- Original questionnaire (question 1): Most men diagnosed as having prostate cancer die *of something else.*

Attitude Scale: AI-generated answer option

- (c) 1: Unfavorable, 7: Beneficial

Attitude Scale: original questionnaire answer option

- (c) 1: Bad thing, 7: Good thing

Overall, only minor differences were observed between the translations generated by ChatGPT and Microsoft Bing Copilot, primarily related to wording and sentence structure rather than conceptual meaning. These differences were resolved during the expert review process and did not affect the final translated versions.

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Cognitive Interviews

The cognitive interviews included men aged 47 to 74 years with no history of PCa. The men were from Poland and had Polish as their native language but resided in Denmark. They were recruited through postings on the hospital's website or through networks. The men's professions included a handyman, a researcher, and a retired businessman. The age range was chosen based on the age range selected in the PRAISE-U PCa screening program. However, due to difficulties in finding men aged 50 to 69 years, this range was extended by a few years. One interview was conducted with a Polish translator by profession, one was conducted in English, and one was conducted in Danish.

The cognitive interviews led to some changes in the Polish questionnaire. These changes were made to improve clarity and accuracy based on the feedback from the interviewees. Below are the specific changes described, and Table 1 gives an overview of the changes.

Table 1. Overview of the changes after cognitive interviews (change shown in italics).

Interviewee	Questionnaire	Item	AI[a]-generated Polish-translated questionnaire	Change after cognitive interview
2	PROCASE[b] Knowledge Index	Questions 6-8	PSA[c]	PSA *badaniekrwi*
3	Attitude Scale	Introduction text	Jeśli Pan uważa, że jest to *nieco* korzystne, proszę zaznaczyć 3	Jeśli Pan uważa, że jest to *trochę* korzystne, proszę zaznaczyć 3
2	B-HLA[d]	Question 1	Mam *adekwatne* informacje na temat zdrowia	Mam *dobre* informacje na temat zdrowia
3	B-HLA	Question 5	Potrafię łatwo podać przykłady *promowania* zdrowia	Potrafię łatwo podać przykłady *poprawy* zdrowia
3	B-HLA	Answer option	Całkowicie *prawda*	Całkowicie *prawdziwe*

[a]AI: artificial intelligence.

[b]PROCASE: Prostate Cancer Screening Education.

[c]PSA: prostate-specific antigen.

[d]B-HLA: Brief Health Literacy Scale for Adults.

In the PROCASE Knowledge Index, the Polish AI-generated translation of "(PSA)" was revised to "(PSA badanie krwi)." The term "PSA" alone was found insufficiently clear for respondents. Adding "badanie krwi" (blood test) provided necessary context, ensuring that participants understand the question refers to the PSA blood test and helps those men who do not know what PSA is.

In the Attitude Scale, the Polish AI-generated translation was "Jeśli Pan uważa, że jest to *nieco* korzystne, proszę zaznaczyć 3" This was revised to "Jeśli Pan uważa, że jest to *trochę* korzystne, proszę zaznaczyć 3." The term "nieco" ("somewhat") was changed to "trochę" ("a little") to better reflect the intended meaning and because this word is more of an everyday term, making the sentence more understandable.

For the B-HLA questionnaire, several changes were made. For question 1, the original translation, "Mam *adekwatne* informacje na temat zdrowia," was revised to "Mam *dobre* informacje na temat zdrowia." The word "adekwatne" ("adequate") was changed to "dobre" ("good") because it is a more commonly used term and makes the sentence easier to understand.

For question 5, the original translation, "Potrafię łatwo podać przykłady *promowania* zdrowia" was revised to "Potrafię łatwo podać przykłady *poprawy* zdrowia." The term "promowania zdrowia" ("promoting health") was revised to "poprawy zdrowia" ("improving health") to better align with the intended context of providing examples of health improvement.

Last changes in the B-HLA questionnaire were made to the answer options. The original translation, "Całkowicie prawda," was changed to "Całkowicie prawdziwe." The term "prawda" ("true") was changed to "prawdziwe" ("truthful") to enhance grammar and clarity in the context of a response option and to ensure consistency across response options. Additionally, the word is a more commonly used term.

The cognitive interviews highlighted specific areas where the AI-generated Polish translations could be improved for better understanding. The changes made were essential to ensure that the questionnaire correctly reflects the intended meanings and is easily understood by the respondents.

Discussion

Principal Findings

This study explored how AI could help translate questionnaires for a PCa screening study, with the purpose of making the process faster and more efficient. By using AI models for translation, the study found that AI could create Polish translations that were very similar in meaning to the original English versions. While the AI-generated translations were accurate, some minor adjustments were still needed to ensure that the meaning was clear and culturally appropriate. Rather than simply showing that AI can be used to translate questionnaires, this study also evaluated how well AI performs when integrated into an established WHO translation process. By reviewing and comparing AI-generated translations, we provided insight into the strengths and limitations of using AI as part of questionnaire translation in cross-cultural health research.

The original forward-backward translation method is a widely used approach for adapting questionnaires across languages and

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cultures. The quality of the translation depends heavily on the skills and expertise of the translators involved [22]. Ideally, translators should be fluent in both the source and target languages and have knowledge of the subject matter of the questionnaire. However, even with skilled translators, bias in understanding can influence the translation process. Differences in translators' understanding, level of education, or perspectives may introduce variations between the original and translated versions. Therefore, validation of the translated questionnaire is an important step to ensure its reliability. Validation involves measuring the psychometric properties of the instrument, such as reliability (internal consistency) and construct validity [23,24]. This process helps confirm that the translated questionnaire measures the same constructs as the original version and is consistent across different populations. Psychometric validation was not done as part of this methodological study, as the primary aim was to assess the feasibility of integrating AI-assisted translation within the WHO workflow. Future research will include reliability testing, construct validity assessment, and cross-cultural equivalence analyses to ensure that the translated instruments measure the same constructs as the original versions.

A strength of this study was the process used to ensure the translations were accurate. When translating questionnaires, it is crucial to have collaboration among stakeholders and involve skilled translators, particularly those with expertise in the subject area [25]. In this study, we used AI as the translator and involved skilled translators and researchers who were native Polish or English speakers to review and correct the AI-generated translations, and expert panels were involved to confirm that the translated questions retained their original meaning. Additionally, it is essential to address cultural sensitivity when translating questionnaires. This involves adapting questions to align with cultural norms and expectations while preserving their original intent [25]. ChatGPT can perform multilingual translations, but it struggles with low-resource languages or dialects not represented in the training data [26]. These challenges include terminology inconsistencies across languages and translation of context-specific phrases, potentially resulting in misinterpretations or unclear responses. However, despite these challenges, AI can improve cross-linguistic communication. Therefore, translation remains dependent on human expertise, because while AI models assist in translation, they cannot replace certified translators in contexts requiring precision and cultural sensitivity [27]. We tried to avoid this by incorporating an expert panel and cognitive interviews with native Polish speakers. The Polish men helped identify any areas where the wording could be confusing, allowing the researchers to make final adjustments. However, this study also showed that AI is not perfect. While the translations were accurate, there were some differences between the AI version and the original English version. While AI models like ChatGPT can efficiently process and generate translations, particularly for preliminary drafts or repetitive tasks that save time [26], they still require human involvement to ensure the translations have the correct meaning, especially when dealing with more complex or sensitive topics. Additionally, AI-assisted translation is often described as a time-saving approach, but this study did not formally measure or compare the time needed for AI-generated translation and expert review with that of a traditional forward-backward translation process. Therefore, any statements regarding efficiency should be interpreted as contextual rather than empirical.

AI continues to develop and improve constantly. A study found that a comprehensive evaluation of ChatGPT's performance demonstrated remarkable accuracy, consistency, and the ability to improve over time [28]. Therefore, the translation of questionnaires using AI will improve in the future and become better at adapting the language to the target audience as AI continues to improve. In this study, the prompt was intentionally limited to "translate to Polish or English" to evaluate AI performance. Future research could explore whether domain-specific prompts, including information about the questionnaire's purpose, key terminology, and intended respondents, improve translation quality and conceptual accuracy. Additionally, future work should incorporate comparisons between AI-generated translations and professional human translations. This kind of comparison could give a clearer understanding of the strengths and weaknesses of different translation approaches, help identify where AI may need additional human help, and contribute to the development of evidence-based guidelines for the effective use of AI in questionnaire translation.

The cognitive interview sample was small (n=3), which reflects that this was a study focusing mainly on feasibility. Additionally, after the third cognitive interview, only a few minor changes to the questionnaires were made, and it was therefore assessed that data saturation had been reached and that additional interviews were not necessary. Furthermore, the 3 men participating in the cognitive interviews were residing in Denmark, which may have influenced their language use and may not fully reflect Polish as spoken in Poland. Nevertheless, we considered it preferable to include these participants rather than skip cognitive interviewing altogether, given the practical challenges of recruiting male participants within the project timeframe. In addition, the translation process relied on 2 AI models, selected based on availability, accessibility, and relevance at the time of the study. While the inclusion of additional AI systems could potentially give different results, it remains unclear whether this would alter the overall findings. Further research comparing multiple AI models is therefore relevant.

Finally, the findings from this methodological study are intended to be interpreted in combination with the broader PRAISE-U project outcomes. The translated questionnaires were used within an ongoing multistep screening program, and results from these instruments will be reported alongside PRAISE-U results, allowing further assessment of their performance in real-world research settings.

Translating questionnaires, particularly for health research, requires careful attention to linguistic, cultural, and methodological factors to ensure accuracy and relevance, and it is important to consider multiple aspects, with or without the use of AI. By addressing these considerations, researchers can ensure that translated questionnaires are both linguistically

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accurate and culturally relevant, improving the reliability and validity of data collected across diverse populations.

Conclusions

This study shows that AI can play an important role in translating questionnaires without losing their original meaning. While AI models offer efficiency in generating translations, several factors influenced the translation process. These included the role of the expert panel, input from native Polish speakers, and the need to adapt the questionnaires to the target population, which consisted of Polish men. AI helped make the translation process quicker, as it generated translations that were close to the original meaning. Overall, the findings suggest that AI can be a useful support tool in questionnaire translation when combined with human review and a structured evaluation process.

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Generative artificial intelligence (AI; ChatGPT) was used to assist with proofreading and improving the clarity of the language. All content was generated based on the authors' original work. In addition, AI was used to translate the questionnaires.

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Data Availability

The datasets generated or analyzed during this study are available from the corresponding author on reasonable request.

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Authors' Contributions

SMA led the project and formulated the research aim, designed the adapted translation process using artificial intelligence (AI), conducted the cognitive interviews, managed and coordinated the research process, and wrote the initial manuscript. KT and KH-S combined and merged the AI-generated translations and reviewed the translated questionnaire. All authors read, reviewed, and approved the final manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Overview of item-level translation issues identified using ChatGPT and Microsoft Bing Copilot, highlighting conceptual issues and their resolution following expert review.
[DOCX File , 22 KB - formative_v10i1e81900_app1.docx]

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Abbreviations

AI: artificial intelligence
B-HLA: Brief Health Literacy Scale for Adults
PCa: prostate cancer
PROCASE: Prostate Cancer Screening Education
PSA: prostate-specific antigen
WHO: World Health Organization

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Original Paper

Online Social Support - an Adjunct or Substitute for Traditional Social Support: Cross-Sectional Study

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Abstract

Background: In contrast to all previous generations, life today is lived both in-person and online. This creates both opportunities and risks to mental health and well-being. Social interaction is no longer geographically constrained, yet the anonymity and impersonality of social media create new problems. To quote Mike Tyson (July 2020), “Social media have made y’all way too comfortable with disrespecting people and not getting punched in the face for it.”

Objective: This study set out to propose and test a hypothesized model to identify both direct and indirect predictors of life satisfaction. Independent or predictor variables included social media use, loneliness, and online and traditional social support.

Methods: From March 2024 to October 2024, a total of 112 adults in the United States were recruited online and proceeded to complete study questionnaires. Participants were aged 42.62 (SD 12.74) years on average, had completed an average of 15.46 (SD 3.25) years of education, and reported an average household income of US $67,005 (SD US $41,560) per year.

Results: Using path analysis, we found that social media use and online social support emerged as significant, indirect predictors of life satisfaction via loneliness and traditional in-person social support (P<.01). In total, 39% of variance in life satisfaction was explained by this path model (R^2=0.39; P<.01).

Conclusions: Contrary to hypothesis, these findings support the *rich get richer* hypothesis regarding online social support, not the *social compensation theory*, that is, online social support appears to function as an adjunct to in-person support, not as a substitute. The results of this study need to be replicated with more diverse, larger samples, with responses collected over multiple time points.

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KEYWORDS

life satisfaction; loneliness; online social support; social media use; social support

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Introduction

Background

As of 2025, there were 5.42 billion social media users worldwide, underscoring both the omnipresence and ever-growing impact of social media [1]. What were initially static, text-based pages have evolved to include photos, videos, and interactive live streams. Platforms such as Facebook, Instagram, and TikTok are most popular today [2]. These provide diverse opportunities for interaction, support, and social connection unconstrained by proximity or borders [3].

However, as social media have evolved and expanded, so too have concerns regarding the impact of social media on mental health [4]. Some studies have found that social media have a positive effect on mental health [5], whereas others report no or negative effects [6]. Social media use (SMU) has become such a public health concern that the US Surgeon General suggested that warning labels appear on platforms stating that social media are harmful to mental health [7]. However, Hall [8] contends that the adverse effects of social media are overstated and specific to certain populations with existing mental health conditions [9].

To date, most research examining SMU and well-being has centered on teenagers and young adults, who tend to be heavy users of social media. However, this leaves a gap as findings from research with teenagers cannot necessarily be generalized to young and older adults [10]. For this study, we identified both direct and indirect effects of social media on mental health. Our hypothesized model also examined the mediating role of online social support on life satisfaction.

Social Media and Life Satisfaction

Associations between SMU and life satisfaction are complex and multifaceted as social media affect well-being in various ways [11]. Moreover, the effects of social media vary by platform [12] and the personal characteristics of users [9,13].

SMU has commonly been operationalized as 3 correlated facets reflecting different online behaviors and motivation: active social SMU, active nonsocial SMU, and passive SMU [14]. Active social use entails direct engagement (eg, chatting or commenting on posts). Active nonsocial use is similar but does not entail interaction with others (eg, tagging photos and posting videos). Finally, passive SMU refers to browsing and scrolling without interaction or visible footprint. These various types of SMU have both direct and indirect effects on psychological well-being [15], and their impact is both positive and negative [11].

For instance, research reports that active SMU predicts well-being, whereas passive use is associated with anxiety and psychological distress [16]. However, results regarding the effects of passive SMU on life satisfaction are inconsistent and contradictory. As reported by Godard and Holtzman [6], the impact of passive SMU may depend on how social media are used (eg, general use vs Facebook groups).

Some suggest that the effects of social media on life satisfaction are too small to warrant concern [8]. Time spent on social media does not inevitably make users sad, lonely, and depressed, nor is there clear evidence that more time spent on social media is inherently problematic [8]. However, even if weak, these effects are nonetheless statistically significant [6]. It may be that positive and negative effects of SMU cancel each other out, suggesting no impact where, instead, effects are bidirectional [10]. Multivariate analyses are needed to identify both direct and indirect effects of SMU on life satisfaction.

Social Support and Life Satisfaction

Social support is integral to life satisfaction [17] and today may entail both online and traditional in-person support. However, online and in-person support likely affect life satisfaction in different ways. Trepte et al [18] reported that online resources provide informational support, yet traditional support is needed for emotional and instrumental assistance. As a result, only traditional social support appears to directly predict life satisfaction [18]. However, in longitudinal research, positive online interactions predict positive affect, perceived support, and life satisfaction [19].

Two theories have been proposed to describe the role and function of online social support. The *rich get richer* hypothesis contends that those with wide, in-person social networks benefit most from online social support [20]. That is, those with trusted confidants and supportive networks simply extend that support online. Online and in-person social support are assumed to be positively correlated, although only in-person support predicts psychological well-being; that is, online support is assumed to be an adjunct to in-person support.

In contrast, online social support may, instead, provide a corrective or compensatory opportunity for those with few in-person contacts and limited social networks to redress these absences. Known as *social compensation theory*, those with weak social networks benefit most from social support garnered online [20]. Those with strong, traditional social networks are less motivated to garner support online. As a result, online and in-person social support are assumed to be inversely associated, yet both are assumed to predict psychological well-being. Existing research supports the social compensation theory for those with low levels of social interaction or support [21-25]. Our hypothesized model tested this social compensation theory with an online sample of adults in the United States.

Loneliness, SMU, and Life Satisfaction

Loneliness significantly undermines life satisfaction [26]. This entails both social isolation and emotional detachment. That is, people can still be lonely even when surrounded by others [27]. Findings regarding associations between SMU and life satisfaction are ambiguous, whereas links between SMU and loneliness are more consistent [6]. That is, SMU enables users to feel less lonely; however, this varies across platforms and users [26].

For instance, the effect of loneliness on life satisfaction is significant but indirect, mediated by SMU [28]. Similarly, the negative effects of problematic SMU on life satisfaction can be explained by loneliness [29]. Again, the type of SMU, passive vs active, determines how SMU affects loneliness [30]. In contrast, the amount of time spent on social media is largely

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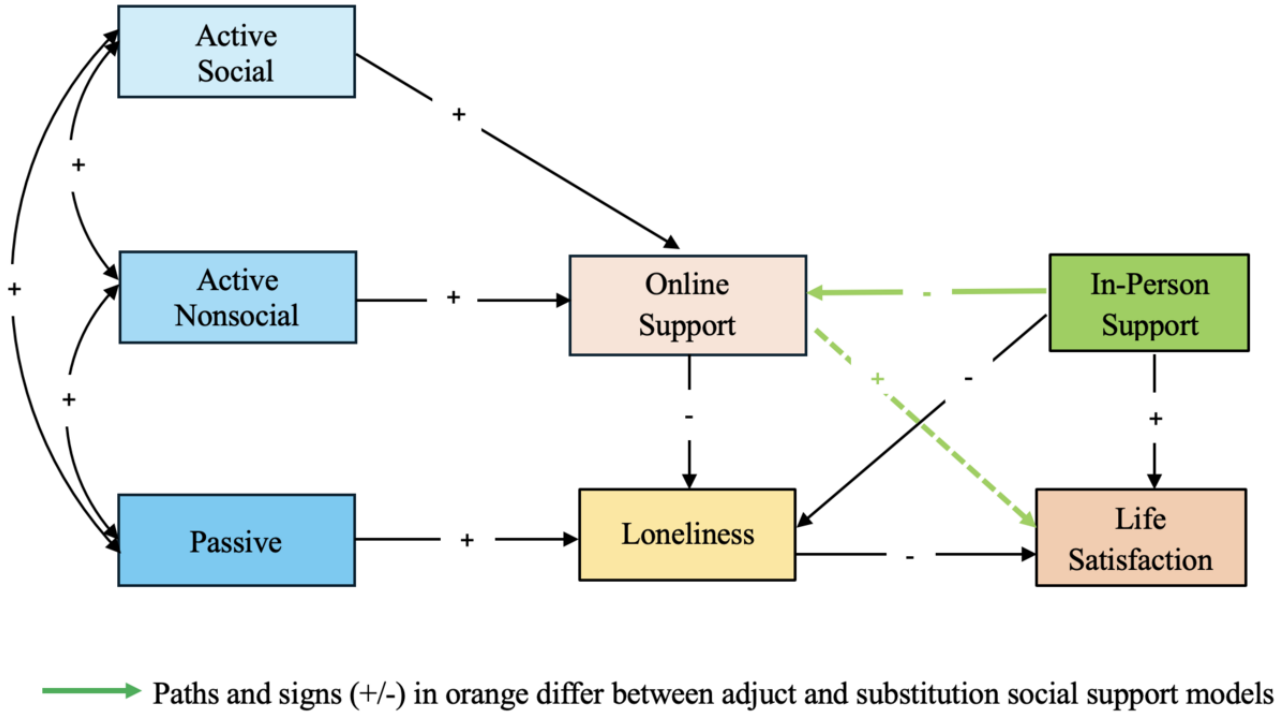
unrelated to loneliness or life satisfaction [8]. However, differences may exist across different groups of users [31].

For this study, we applied the theory of social compensation to describe the effect of online social support on life satisfaction with an adult sample of social media users. We assumed that online and in-person support are negatively associated; that is, those with limited traditional support will foster and sustain compensatory online support networks. In addition, both online and in-person social support were assumed to directly predict life satisfaction. These effects were assumed to be both direct and indirect via lower loneliness (Figure 1).

Figure 1. Compensatory model of online social support: a substitute for in-person support. SMU: social media use.



Methods

Participant Recruitment

Adults aged ≥18 years were recruited as part of a larger study of SMU and well-being [32]. Prospective participants were recruited via Facebook and Instagram (Meta Inc) and the Positly platform. These platforms have previously been used to recruit participants for mental health research with general adult samples and those with psychiatric conditions [33]. For this study, we examined responses from participants with no psychiatric history but who scored within clinical range on the depression screening measure. These were participants who did not meet inclusion criteria for the central study.

Most Positly participants are Amazon Mechanical Turk contractors who have established themselves as reliable over many piecework "gigs" in the crowdsourcing marketplace [33]. Over time and multiple projects, participants provide more descriptive information (ie, psychiatric diagnoses) to gain the opportunity to take part in better-paying gigs. Positly excludes participant responses if descriptive information contradicts that previously provided or if questionnaire responses are mostly missing or determined to be unreliable (ie, rapid responding without reading the questions). Positly is designed to work with questionnaires hosted on the Qualtrics (Qualtrics International Inc) platform. Anonymized sociodemographic information is provided by Positly (eg, age and household income) along with questionnaire responses.

Study Design

For this cross-sectional study, participants completed a series of questionnaires assessing SMU, social support, and life satisfaction. Prospective participants were first directed to an information page outlining the study and inclusion criteria. A dedicated website was created using the Qualtrics platform for secure online data collection [15,34]. Following enrollment, participants completed the instruments outlined in the following sections, along with several open-ended items regarding their use of social media.

Ethical Considerations

Ethics approval was received from the Institutional Review Board at Ben-Gurion University of the Negev, Be'er Sheva, Israel (499-7; August 2023). Respondents provided informed consent to participate by clicking to proceed as stated on the study splash page. Participants were anonymous; they were not required to provide identifying information aside from an email address if they wished to receive a summary of findings or take part in the participant lottery (US $500). All aspects of this study were performed in accordance with the Declaration of Helsinki.

Study Instruments

The Passive and Active Facebook Use Measure [14] was developed to study the differential effects of Facebook use. Exploratory factor analyses suggest 3 distinct patterns: active social use, active nonsocial use, and passive use. Active social

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use pertains to direct engagement (eg, chatting or commenting on posts), whereas active nonsocial use does not entail direct interaction with others (eg, posting videos or tagging photos), and passive use is limited to viewing photos and checking the statuses of others (ie, no engagement). Internal consistency across subscales ranges from adequate to good (0.70<Cronbach α<0.81). Construct validity for these different SMU constructs has been provided in a recent meta-analysis [6] and pilot research conducted with adults with bipolar disorder [15]. For this study, measurement was extended to general SMU by replacing the word "Facebook" with "social media" where necessary.

The brief University of California, Los Angeles Loneliness Scale (ULS-8) [35] is an abbreviated measure developed to identify associations between loneliness and health-related behaviors [36]. Responses are reported along a Likert scale ranging from "I never feel this way" (0) to "I often feel this way" (3). The internal consistency of ULS-8 responses is high (Cronbach α=0.84) [37].

The Satisfaction With Life Scale (SWLS) [38] measures perceived quality of life based on person-specific criteria [39]. The SWLS is composed of 5 questions (eg, "The conditions of my life are excellent") with response alternatives ranging from "strongly disagree" (1) to "strongly agree" (7). Higher totals are suggestive of greater life satisfaction [40]. Test-retest reliability over 1 month has been reported as r=0.84 [41]. Concurrent validity of SWLS responses has been demonstrated relative to the Fordyce Global Scale (r=0.82) [40]. Internal consistency (Cronbach α=0.89) is strong [42].

The Brief Social Support Scale [43] measures perceived support, divided between emotional-informational support and tangible support. The reliability of the responses to both subscales is high (Cronbach α=0.87 and 0.86, respectively) [43].

The 40-item Online Social Support Scale [44] is a measure of social support received online, divided into 4 factors: instrumental (eg, financial aid, resources, and help with tasks), informational (eg, advice, help with coping, and sharing information), esteem and emotional (eg, caring, validation, and sympathy), and social companionship (eg, belonging and sharing interests and activities). Responses are reported on a Likert scale ranging from "never" (0) to "a lot" (4). Online Social Support Scale responses have shown strong internal consistency (Cronbach α=0.97) [45].

A sociodemographic questionnaire was developed for this study to obtain descriptive and psychosocial information. Participants reported their date of birth, sex, country of residence, relationship status, level of education, ethnicity, and occupation.

Path Analysis

Path analysis was performed for this study as a 3-step process [46]. A hypothesized model was first tested (Figure 1), nonsignificant paths were deleted, and statistically significant paths not initially hypothesized were added if supported by existing research or theory.

Path analysis is an extension of linear regression, with 3 significant advantages. Path analysis allows us to simultaneously predict one or more dependent variables (indicated by the arrowhead in path models). Arrows pointing from independent to dependent variables represent significant prediction (ie, critical ratio values>|1.96|; P<.05). Path analysis is a multivariate statistical procedure, meaning that all significant paths emerge concurrently (ie, over and above other statistically significant results).

Path analysis allows us to identify both direct and indirect predictors of life satisfaction. Indirect prediction occurs via other variables (ie, ≥2 pathways between variables). In more complex models, variables can have direct and indirect effects on dependent variables, and indirect effects may be equal to or greater in magnitude than direct effects (total effects=direct+indirect effects).

Computing path analyses using structural equation modeling software allows us to obtain goodness-of-fit information for the overall model. Good model fit is required to interpret models [44]. In accordance with convention, we report 3 goodness-of-fit-indexes to assess overall fitness for path models: an incremental (comparative fit index; CFI), an absolute (standardized root mean square residual; SRMR), and a parsimonious (root mean square error of approximation; RMSEA) fit index. Ideal SRMR and RMSEA values are less than 0.055 [46], and ideal CFI values are greater than 0.95 [47]. Descriptive and comparative analyses were performed using SPSS (version 29; IBM Corp), and path analyses were performed using AMOS (version 29; IBM Corp).

Bootstrapping was also performed as a computationally intensive simulation approach to estimate parameters in the population [48]. Bootstrapping treats the original sample as a pseudopopulation or stand-in for population data. Multiple random samples are then drawn from the original sample along with replacement values; each is used to obtain a new set of parameter estimates. The distribution of these parameter estimates is used to compute bias-corrected CIs for path coefficients. CIs that do not cross 0 are statistically significant and likely to exist in the population [48]. Bootstrapping also allowed us to estimate statistical significance for both direct and indirect effects and compute the Bollen-Stine (BS) statistic as a further, simulation-based goodness-of-fit index.

Results

Descriptive Features

For this study, 112 participants were recruited between March 2024 and October 2024. The sample was almost evenly divided between men and women (n=45, 40.2% male; n=44, 39.3% female; n=13, 11.6% of the participants did not report sex). On average, participants had completed 15.46 (SD 3.25) years of education; however, household income was comparatively low given this level of education (mean US $67,005, SD US $41,560). As also reported in Table 1, the psychometric properties of responses to study instruments were largely normal and within accepted parameters.

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Table 1. Descriptive statistics for study variables (N=112).

	Values, mean (SD)	Values, range	Skewness	Kurtosis	Cronbach α
Age (y)	42.62 (12.74)	21-84	0.75	0.17	—[a]
Education (y)	15.46 (3.25)	6-27	0.14	1.30	—
Household income (US $ per year)	67,005 (41,560)	4500-225,000	1.85	5.27	—
SMU[b]—active social use	13.60 (3.87)	5-25	0.06	0.45	0.78
SMU—active nonsocial use	7.46 (3.50)	4-20	1.43	1.95	0.87
SMU—passive use	13.71 (3.18)	4-20	–0.32	0.06	0.70
Online social support	30.58 (9.44)	12-60	0.41	0.46	0.93
In-person social support	15.31 (4.54)	6-24	0.11	–0.73	0.90
Loneliness	21.54 (5.42)	9-32	–0.34	–0.43	0.88
Life satisfaction	15.34 (7.40)	3-32	0.40	–0.82	0.90

[a]Not applicable.

[b]SMU: social media use.

Path Analyses

We first tested the hypothesized model. Several hypothesized paths were not significant; others were added to achieve ideal fit for 2 of 3 indexes examined (χ^2_{11}=9.2; *P*=.30). That is, the CFI (0.99; cutoff of ≥0.95) and RMSEA (0.001; cutoff of ≤0.055) were both within ideal parameters; the SRMR was within adequate limits (0.057; cutoff of ≤0.080). With 112 participants and 6 independent variables, this model had sufficient statistical power to identify medium to large effect sizes [46].

In Table 2, we compare male and female participants. Of note, they appeared demographically similar. That is, men and women were of similar age, educational level, and average household income. Moreover, responses to the study scales were similar; only for online social support did men report significantly greater support than women.

Bootstrapping was performed to estimate bias-corrected CIs for parameter estimates, statistical significance for indirect effects, and the BS statistic. For the latter, the BS chi-square value was estimated and averaged across 500 bootstrap samples (BS χ^2=10.9; *P*=.58), similar to the original sample (χ^2_{11}=9.2; *P*=.60). Nonsignificant chi-square values suggest generalizability of findings to the population [48].

As hypothesized, each of the 3 forms of SMU was positively correlated with online social support; however, their effects differed. For instance, both active social use and active nonsocial use predicted online social support; in contrast, passive SMU predicted neither loneliness nor online social support (Figure 2).

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Table 2. Descriptive statistics for study variables: men vs women[a].

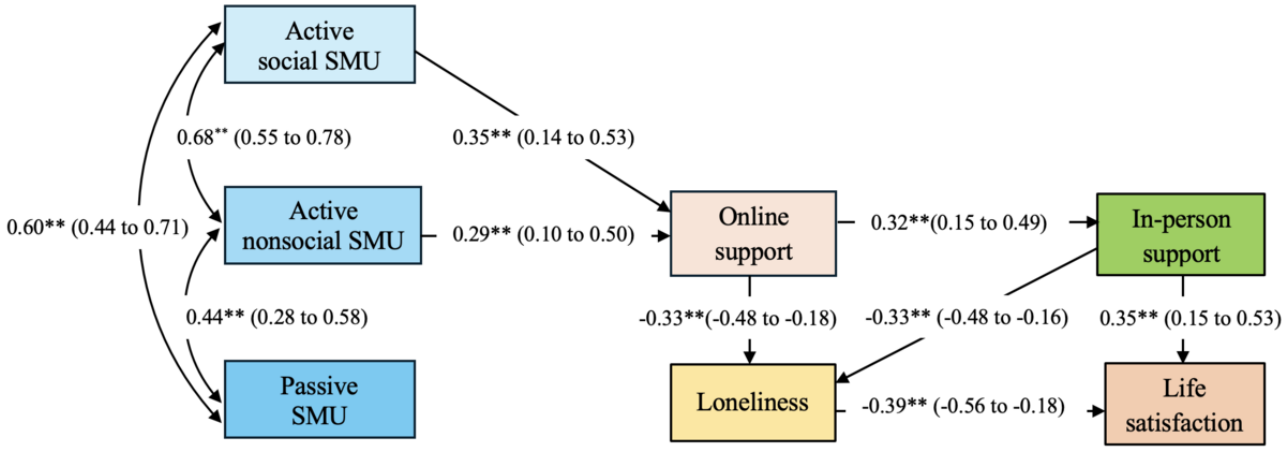
	Male participants (n=45), mean (SD)	Female participants (n=44), mean (SD)	*t* test (*df*)
Sociodemographic variables			
Age (y)	40.33 (9.52)	44.66 (13.32)	1.76 (87)
Education (y)	15.55 (2.14)	15.47 (3.49)	0.13 (83)
Household income (US $ per year)	65,444 (38,307)	68,602 (45,035)	0.36 (87)
SMU[b]			
Active social use	13.44 (3.45)	12.93 (3.76)	0.67 (87)
Active nonsocial use	7.76 (3.27)	6.82 (2.79)	1.45 (87)
Passive use	13.80 (2.88)	13.20 (3.05)	0.95 (87)
Social support			
Online	32.36 (7.99)	27.39 (8.04)	2.92 (87)[c]
In-person	15.24 (4.23)	15.11 (4.42)	0.14 (87)
Psychological well-being			
Loneliness	21.09 (4.99)	22.11 (5.93)	0.88 (87)
Life satisfaction	15.64 (7.67)	13.95 (6.99)	1.09 (87)

[a]Sex not reported by 11.6% (13/112) of the participants.

[b]SMU: social media use.

[c]*P*<.01.

Figure 2. Social media use (SMU), social support, and psychological well-being. Parameter estimates are expressed as maximum likelihood estimates (standardized solution). Parenthetical numbers indicate CIs (500 bootstrapped samples). Zero is not traversed in any of the above CIs (outside of range), indicating both statistical significance and generalizability to the population. **P<.01.



However, the resulting path model did not support social compensation theory as we had hypothesized. For instance, online social support and in-person social support were not inversely associated; the path coefficient between the 2 forms of social support was positive (β=0.32; *P*<.01). Nor did online social support directly predict life satisfaction; instead, the effect was indirect via both lower loneliness and greater in-person social support. Nonetheless, this indirect effect of online social support on life satisfaction was positive and statistically significant (Table 3). These findings instead support the rich get richer hypothesis. In total, 39% of variance in life satisfaction was explained by this model (R^2=0.39; *P*<.01).

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Table 3. Direct and indirect effects of social media use (SMU), social support, and well-being (N=112)[a].

	Online social support	In-person social support	Loneliness	Life satisfaction
Active nonsocial SMU				
Direct effects	0.29[b]	0.00	0.00	0.00
Indirect effects	0.00	0.10[b]	–0.13[b]	0.08[b]
Total effects	0.29[b]	0.10[b]	–0.13[b]	0.08[b]
Active social SMU				
Direct effects	0.36[b]	0.00	0.00	0.00
Indirect effects	0.00	0.12[b]	–0.16[b]	0.10[b]
Total effects	0.36[b]	0.12[b]	–0.16[b]	0.10[b]
Online social support				
Direct effects	—[c]	0.32[b]	–0.33[b]	0.00
Indirect effects	—	0.00	–0.11[b]	0.28[b]
Total effects	—	0.32[b]	–0.44[b]	0.28 [b]
In-person social support				
Direct effects	—	—	–0.33[b]	0.35[b]
Indirect effects	—	—	0.00	0.13[b]
Total effects	—	—	–0.33[b]	0.48[b]
Loneliness				
Direct effects	—	—	—	–0.39 [b]
Indirect effects	—	—	—	0.00
Total effects	—	—	—	–0.39 [b]

[a]Statistical significance estimated over 500 bootstrapped samples.

[b]$P<.01$.

[c]Not applicable.

Discussion

Principal Findings

Contrary to our hypothesized model, passive SMU did not predict online social support. In addition, online social support and in-person social support appeared to be positively associated. Moreover, online social support did not directly predict life satisfaction; effects were significant but indirect. These results support the rich get richer hypothesis, as online social support appears to be an adjunct to, rather than a substitute for, traditional in-person social support. The resulting model largely emerged as hypothesized; no unhypothesized paths were added.

These findings support the assertion that online social support is distinct from traditional in-person social support [32]. Both predicted lower loneliness, but only traditional social support directly predicted life satisfaction, consistent with the rich get richer hypothesis. In addition, online social support mediated associations among SMU, loneliness, and life satisfaction. This result is consistent with previously published research reporting that associations between online social support and psychological well-being are mediated via traditional support [49].

Although a greater proportion of life is lived online today, there is no virtual substitute for traditional in-person social support [18]. Online friends cannot provide certain forms of tangible support, such as driving someone to the airport, pet sitting, or watering plants. However, this will invariably change; new programs and applications will enable online friends to provide tangible support even at a distance, a type of support that is available today only from those who are physically around us. These results are largely consistent with findings from previously published research and meta-analyses. For example, active SMU has an indirect but positive effect on life satisfaction [6]. As previously reported, associations between SMU and life satisfaction are complex; the effects of SMU on life satisfaction are similarly complex. That is, the effects of both SMU and online social support on life satisfaction appear to be mediated by loneliness and in-person social support.

Our findings do not suggest that passive SMU affects life satisfaction either directly or indirectly. Passive SMU was significantly correlated with active social and nonsocial SMU,

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yet passive SMU did not predict online social support, loneliness, or life satisfaction. This finding stands in contrast to those of previous research suggesting an association between passive SMU and loneliness. Moreover, we found no association between passive SMU and online social support [6]. One explanation for these conflicting findings may be the evolution of social media over time. TikTok, for instance, was only introduced in the United States in late 2018. As a result, research published before 2018 was conducted primarily or exclusively with Facebook. More photo- and video-based platforms have transformed SMU in recent years. Passive consumption of TikTok videos, for instance, may have different effects than passive use of Facebook. Accordingly, Masciantonio et al [12] contend that various social media platforms have differential effects on mental health and well-being. Instagram, for instance, appears to have an especially negative impact on teenagers and young adults [50].

Limitations

The path model that emerged from this study allowed us to identify both direct and indirect predictors of life satisfaction. However, various limitations should be acknowledged. We did not measure personality traits, which are known to moderate social support and psychological well-being. For instance, introverted persons tend to have comparatively few acquaintances and friendships, but the latter tend to be important. Extroverts, in contrast, tend to have many acquaintances and friends. Similar personality and interpersonal differences have been found in relation to online social capital and support [51].

Differences in online support may also exist between those high and low in the trait of neuroticism [52,53]. Given their propensity for negative emotional responsivity, persons high in neuroticism seeking online social support may, instead, experience social overload, jealousy, and envy [54]. This might be due to differences in emotional regulation [55]. Research is needed to examine each of the Big Five personality traits in relation to online social support.

Future research should also be conducted with larger, more diverse samples via multiple means of recruitment. Our sample of 112 participants was sufficient for path analysis with 6 predictors; however, a larger sample size would allow us to generalize findings with greater confidence. For instance, depressive symptoms reported by study participants were high and may have confounded their responses. Our model needs to be replicated with euthymic persons (ie, those with mood within normal parameters). The findings should also be replicated using more traditional recruitment methods.

Additionally, longitudinal research is needed to identify moderating and mediating associations between SMU and well-being, and determinants of change over time. It should be stressed that the term “prediction” in path analysis is used as in multiple regression; prediction should not be conflated with causation. Replication of findings with data collected over multiple time points with diverse populations is needed to suggest causal associations. This should include cross-cultural replication and comparison to account for cultural differences in support-seeking norms and acceptance of online support.

Conclusions

As new media technologies continue to shape social relationships, understanding their effects on mental health is essential. This study suggests that SMU influences life satisfaction largely through indirect pathways involving social support and loneliness. Online social support appears to augment rather than replace traditional in-person support. These findings support the *rich get richer* hypothesis: individuals with stronger offline networks derive greater benefit from online support. Quality of online interaction, rather than quantity of SMU, may be the critical factor in psychological well-being.

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Data Availability

The dataset analyzed for this study is available in the Harvard Dataverse [56].

Authors' Contributions

RL and NOR conceived the study. NT, APS, MS, and NOR acquired data and contributed to the study design. APS and NOR obtained grant funding. RL, APS, and NOR analyzed the data and interpreted the study findings. All authors drafted, revised, and approved the final version of the manuscript.

Conflicts of Interest

None declared.

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Abbreviations

BS: Bollen-Stine
CFI: comparative fit index
RMSEA: root mean square error of approximation
SMU: social media use
SRMR: standardized root mean square residual
SWLS: Satisfaction With Life Scale
ULS-8: University of California, Los Angeles Loneliness Scale

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Original Paper

Clinical Summaries of Social Media Timelines for Mental Health Monitoring: Human Versus Large Language Model Comparative Evaluation Study

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Abstract

Background: Social media timelines contain rich signals of users' mental states but are too voluminous for direct clinical review. Although large language models (LLMs) demonstrate robust linguistic and summarization capabilities in general-purpose tasks, distilling clinically relevant insights demands deeper psychological analysis and sensitivity to each individual's unique personality and context. Accurately capturing subtle, personalized affective and behavioral patterns remains a significant challenge for current models. A thorough, systematic evaluation of LLM-generated clinical summaries is therefore essential to understand their readiness for real-world mental health monitoring.

Objective: This study evaluates the ability of an LLM-based pipeline to generate clinically meaningful summaries of social media timelines, compared to summaries written by human clinicians. The summaries are structured along 3 key clinical aspects, including an overall mental health assessment, intrapersonal and interpersonal patterns, and mental state changes over time.

Methods: We use a recent state-of-the-art approach that combines a hierarchical variational autoencoder (VAE) with an LLM (Large Language Model-Meta AI 2 13-billion-parameter version; LLaMA2 13B). This method first summarizes the patient's history using the VAE and then transforms this summary into a clinical narrative using the LLM. We also test both single-step and multistep LLM-prompting techniques and devise comprehensive clinical prompts. For 30 social media timelines, model outputs were evaluated against human-written summaries through human ratings and expert qualitative analysis. Linguistic diversity was automatically measured as a proxy for personalization.

Results: Human summaries scored highest for factual consistency (3.75) and general usefulness (3.63). The timeline-hierarchical variational autoencoder (TH-VAE) model outperformed LLaMA for factual consistency (3.35 vs 3.08) and general usefulness (3.28 vs 3.38). Both 2-step models were comparable to humans in describing interpersonal and intrapersonal patterns (3.45-3.48 vs 3.33) and changes over time (3.42 vs 3.35-3.30). The naive LLaMA baseline scored lower on all criteria except factual consistency. Furthermore, a qualitative analysis observed that human summaries provided more accurate, deep, and personalized insights, while LLMs offered more exhaustive but generic descriptions. Quantitatively, linguistic diversity was higher in human summaries both at the semantic level (mean Cohen d=1.19) and at the surface level (mean Cohen d=1.31).

Conclusions: At this time medium-size LLMs can generate largely accurate and informative clinical summaries of social media timelines, and advanced prompting boosts performance modestly. However, at the time of this writing, they underperform human

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clinicians in capturing subtle psychological nuances and individual idiosyncrasies. Future work should integrate domain-specific fine-tuning and enhanced context modeling to improve LLM clinical fidelity.

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KEYWORDS

social media; monitoring mental health; clinical summaries; natural language processing; large language models

Introduction

Social media platforms have emerged as a window into individuals' inner lives, providing a rich source of information about their thoughts, emotions, and experiences. These vast, unstructured data hold immense promise for enhancing mental health monitoring and support, but their sheer volume and complexity pose challenges for clinicians seeking to extract meaningful insights. This study investigated how advanced artificial intelligence (AI), specifically large language models (LLMs)—powerful AI algorithms trained on large amounts of textual data—can be leveraged to distill this wealth of data into concise, clinically relevant summaries.

Current methods for assessing mental health primarily depend on self-reports completed by patients or structured interviews conducted by clinicians. While these methods are essential in mental health research and practice, they have notable limitations. Self-report measures can be influenced by limited self-awareness, reluctance to complete questionnaires, and the constraints of predefined response options [1]. Clinician assessments, though valuable for their expertise, tend to be time-intensive, expensive, and reliant on patients proactively seeking help, factors that can hinder early detection and intervention. In addition, these methods often provide a static snapshot of an individual's mental state and fail to capture its dynamic and fluctuating nature [2]. Leading researchers have highlighted the urgent need for innovative assessment methods that can better track these dynamic shifts to enhance monitoring and prevention efforts [3].

In recent years, social media has emerged as a particularly promising resource. With appropriate safeguards and informed consent, it provides a continuous stream of self-reported data and interactions that could complement traditional mental health assessments [4]. Posts often reflect emotional states, relationships, and life events, potentially yielding valuable insights into an individual's well-being. However, the sheer volume and unstructured nature of social media data present challenges for clinical application. The noise of irrelevant content and the complexities of online self-expression make it difficult to discern meaningful patterns and track changes in mental state over time.

Clinically focused summaries of social media timelines could address these challenges by synthesizing the most pertinent information into a coherent narrative. Such summaries, capable of capturing fluctuations in mental states and highlighting key clinical concepts, have the potential to enhance clinical understanding, support ongoing monitoring, and aid in the early detection and prevention of mental health issues. By efficiently presenting relevant information, these summaries could augment clinicians' capacity to provide timely and effective care.

The emergence of powerful language technologies, particularly LLMs, offers new avenues for summarizing clinically relevant information from social media timelines. Trained on massive datasets, LLMs can capture complex linguistic patterns and generate fluent, context-sensitive outputs [5-7]. Their generative abilities build on decades of progress in text summarization, which has advanced from classic extractive approaches [8,9] to neural extractive models [10] and modern pretrained sequence-to-sequence abstractive methods [11]. These developments have paved the way for applications in specialized domains, where summarization is required to handle diverse and noisy inputs.

Recent research has applied LLM-based summarization to a range of clinical contexts, including electronic health records [12], clinical trial reports [13], therapy sessions [14], and mental health forum posts [15]. Beyond summarization, LLMs have also been used to generate structured medical notes from physician-patient encounters [16], condense electronic health records [17], and extract key information from medical texts while addressing hallucination risks [18]. They have further been explored for tasks such as triage, diagnostic support, and even simulated therapy dialogue, highlighting both their promise and the need for rigorous evaluation in mental health settings.

In parallel, computational mental health studies confirm the effectiveness of AI in analyzing social media data with user consent for support purposes [19-22]. However, most of these approaches have centered on classification, detecting signals of depression, anxiety, or suicidal ideation using supervised learning and engineered features such as n-grams, linguistic inquiry and word count categories [23], and posting behavior. While valuable for large-scale risk detection, classification methods often overlook the contextual richness of individuals' timelines and do not produce coherent, human-readable accounts of lived experience. By contrast, generative tasks such as timeline summarization may capture evolving trajectories of thoughts, emotions, and behaviors, promoting a more comprehensive and bottom-up understanding of mental health [24-27].

Despite their promise, LLMs face key challenges when applied to mental health summarization. Ensuring factual accuracy is crucial in clinical contexts, as models may generate inaccurate or misleading information [28]. Modeling temporal dynamics is also difficult; LLMs are typically optimized for short-range coherence and may miss subtle emotional changes across time [29-31]. Moreover, current models often struggle with personalization, defaulting to generic phrasing and failing to reflect an individual's unique expressive style, interpersonal

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context, or situational nuance [32]. Finally, the clinical integration of LLMs must proceed cautiously, with attention to safety, fairness, and reliability, including robust anonymization and safeguards against bias to avoid perpetuating disparities [24-26]. Successful implementation requires close collaboration between clinicians and AI researchers to ensure that models are shaped by clinical reasoning, grounded in psychological theory, and responsive to patient welfare [33].

Thus, creating social media timeline summaries that accurately capture individuals' mental states and dynamics remains a challenging yet crucial goal. To advance this effort, this study investigates the potential of advanced LLM-based methods in generating clinically insightful summaries from social media timelines and evaluates their quality as compared to clinicians' summaries. We implement both straightforward prompting techniques as well as a recent approach that incorporates unsupervised abstractive summarization through a hierarchical variational autoencoder (VAE) [34]. To analyze the quality of the generated summaries—ensuring they are factually accurate, include all significant information from the timeline, and capture the unique characteristics of the patient—we conduct a comprehensive evaluation involving quantitative comparison of human ratings, qualitative expert analysis, and computational metrics.

The aim of this study is thus to evaluate whether LLM-generated social media summaries can approximate the clinical quality of human-written ones, thereby assessing their feasibility as tools for augmenting mental health monitoring.

Methods

Dataset

We use the TalkLife dataset [35], which comprises 500 user timelines from the TalkLife platform (TalkLife Ltd). The timelines, which vary in length (12-124 posts, average 35) and time span, have been manually pseudonymized to remove personal names and places.

This dataset is preannotated with moments of change [35], denoting sudden mood shifts (switches) and gradual mood progression (escalations). Each timeline is segmented into subtimelines based on moments of change labels that group consecutive posts with the same label ("In Escalation," "In Switch," or "0" for no change). This segmentation, assuming similar mood characteristics within subtimelines, helps identify distinctive features and relationships and was leveraged for structured timeline encoding during modeling.

Task Formulation

The purpose of these summaries is to extract clinically relevant information from a sequence of potentially lengthy and unfocused social media posts. The goal was to generate a concise summary that can be used by clinicians for a variety of diagnostic and therapeutic purposes. Summaries of this type can contribute to the early detection of mental health risks or illnesses, thus enabling timely intervention and support. They can also help clinicians track and assess patients' ever-changing mental states, particularly during follow-up periods or between therapy sessions.

Specifically, the summaries aim to address three core aspects of mental health:

1. Overall mental state assessment: identification and evaluation of the individual's general mood, level of functioning, and any indications of potential mental health issues.
2. Intrapersonal and interpersonal patterns: identifying patterns in self-perception, social interactions, and interpersonal relationships.
3. Mental state fluctuations over time: tracking changes in mood, level of functioning, and symptoms across the timeframe covered by the posts.

Multimedia Appendix 1 presents a comprehensive list of clinical topics for each of these core aspects.

Computational Modeling Approach

Transforming raw social media timelines into clinically relevant summaries is a complex task that requires intricate reasoning over extended contexts. To address this, we adopt a three-step modeling approach (Figure 1): (1) key phrase identification, (2) first-person timeline summarization (evidence summary), and (3) high-level clinical narrative generation. First, we automatically identify key phrases of potential clinical significance within each segment of the timeline, where a segment is denoted by a moment of change. Next, a first-person abstractive "evidence summary" is generated, guided by the key phrases to distill clinically relevant information. Finally, we generate an abstractive clinical narrative that integrates this evidence summary to offer insights into the user's mental state.

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Figure 1. Modeling pipeline for clinical summary generation. LLaMA: large language model Meta AI; LLM: large language model; TH-VAE: timeline-hierarchical variational autoencoder;.

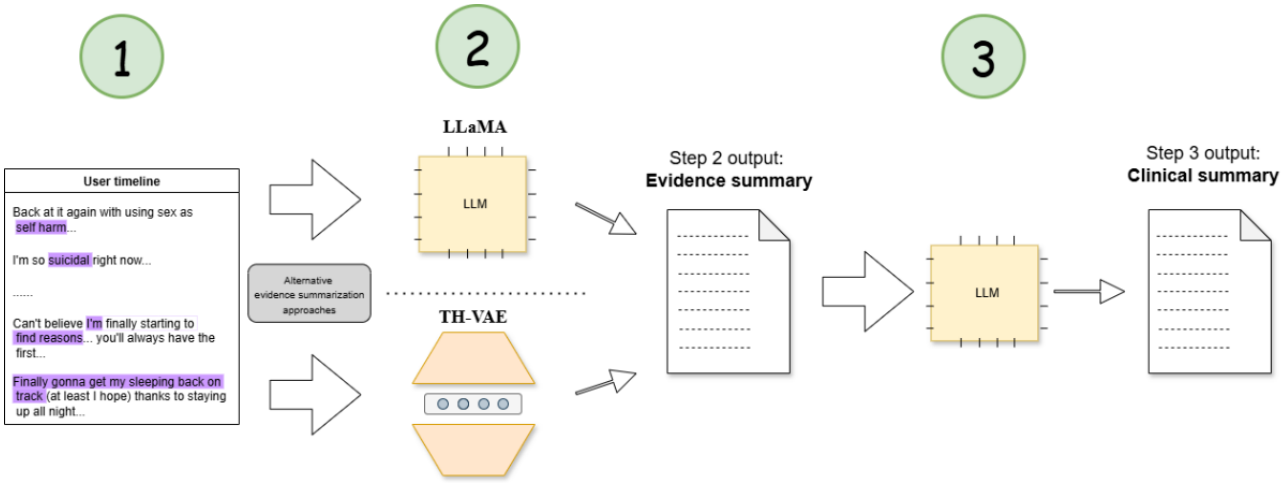

Figure 1 shows the 3-step modeling pipeline for generating clinical summaries from social media timelines on the TalkLife mental health support platform (2018-2021). Step 1 uses the large language model Meta AI (LLaMA 2; 13B) to highlight clinically relevant phrases. Step 2 generates evidence summaries via either zero-shot LLaMA 2 or the previously published timeline-hierarchical variational autoencoder (TH-VAE) model. Step 3 uses instruction-tuned LLaMA 2 to produce structured, clinically meaningful summaries.

In several places throughout this work, we leverage the in-context learning capability of LLMs. This refers to LLMs' ability to adapt to new tasks based on examples provided within a prompt by harnessing their language understanding and pattern recognition abilities to generate custom outputs [5,36]. Specifically, we use the in-context learning capability of LLaMA 2 (13B) [37], a popular open-weight LLM, in annotating key phrases, translating the evidence summary into clinical insights, and for one of our baseline methods, in generating the evidence summary. The open-weight nature of LLaMA 2 is crucial for our use case, because it allowed us to use the model without compromising the privacy of sensitive user data.

Clinical Key Phrase Identification

To set the stage for automatic key phrase identification, 3 graduate students in clinical psychology were trained to highlight clinically relevant key phrases in a subset of three timelines. We then used LLaMA 2 in a few-shot prompt format, primed with these examples, to automatically annotate the remaining timelines.

Evidence Summary Generation

We explored 2 approaches for generating evidence summaries based on the highlighted clinical key phrases:

LLaMA

Leveraging LLaMA 2's zero-shot capabilities with a prompt instructing it to "write a TLDR of the timeline focusing on the key phrases," where the key phrases were obtained at the previous step using LLaMA 2. The instruction "TLDR" (ie, Too Long; Didn't Read), which is a common internet abbreviation, acts as a natural cue for the language model to produce a concise summary.

TH-VAE

We use the TH-VAE model [34], a method for generating abstractive summaries of social media timelines, to create evidence summaries that focus on clinically relevant content. This approach is particularly well-suited for addressing the challenges of lengthy and complex timelines, as it incorporates a hierarchical structure that captures both fine-grained details and overarching themes.

The TH-VAE model begins by dividing the timeline into smaller, more manageable coherent segments based on the Moments of Change annotations. Each segment is then encoded into a numerical representation that captures its essential information, with particular emphasis on the clinically relevant key phrases. These segment representations are then combined to create a holistic representation of the entire timeline.

TH-VAE uses a variational autoencoder to compress and reconstruct timeline segments into concise evidence summaries. Its unique architecture specializes in capturing both local details and overarching themes. For full architectural and training details, see Atkins et al [34].

Clinical Summary Generation

Following Song et al [34], we leverage an instruction-tuned LLM (LLaMA-2-13B-CHAT) to transform the timeline summaries into high-level clinical narratives. This process implements a 2-stage prompting approach. First, in the "map" stage, the LLM is prompted to extract clinically relevant observations from the evidence summary, focusing on specific topics (Multimedia Appendix 1). Then, in the "reduce" stage, the LLM integrates these observations into a cohesive and concise summary, structured along the three core clinical aspects. The full prompts are provided in Multimedia Appendix 2.

Human Summaries

To establish a gold-standard benchmark for evaluation, we collected human-expert clinical summaries for 33 timelines (randomly sampled from our 500-timeline dataset). Three

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clinical psychology graduate students, who are fluent in English, annotated the dataset after 2 training sessions, followed by discussion and guideline refinement with an expert clinical supervisor (DA-S).

The annotators first highlighted textual spans conveying information related to the 3 core mental health aspects mentioned above. Next, the annotators wrote comprehensive summaries, dedicating a paragraph to each core aspect. They were instructed to focus on providing the most essential and clinically relevant information that would be useful for a hypothetical clinician reading the summary. Of these 33 expert summaries, 30 were reserved for summary evaluation, and 3 were used for model development and key phrase extraction examples.

Evaluation Procedure

We compared the performance of the AI models (described below) against the human expert summarizers across three prime dimensions:

- Salient meaning preservation: retaining essential clinical information while discarding less important details.
- Factual consistency: ensuring the summary accurately reflects the timeline's content without introducing errors or hallucinations.
- Personalization, or diversity: capturing the individual's unique voice and experiences, avoiding generic language.

While Song et al [34] used automated metrics to evaluate model performance, this paper focuses on assessing and comparing the strengths and weaknesses of both human- and model-generated summaries via human evaluation. Specifically, salient meaning preservation and factual consistency were directly judged by human clinicians. Personalization (diversity) was evaluated through a combination of qualitative inspection and confirming automatic analysis.

We selected three models for evaluation and comparison to the human summaries:

1. TH-VAE: the 3-step model in which the evidence summary is generated by the hierarchical VAE described above.
2. LLaMA: the 3-step model in which the evidence summary is generated directly by the zero-shot LLaMA.
3. Naive LLaMA: a baseline approach, in which the high-level clinical summary is generated by LLaMA in one pass (omitting the Clinical Key Phrase Highlighting and Evidence Summary Generation stages) given the full timeline (see prompt instructions in Multimedia Appendix 2).

Human Evaluation of the Summaries

The 3 clinical psychology graduate students who generated the human summaries also served as summary raters for their peers. In a blind rating process, the experts each read a full timeline and then evaluated four summaries: 3 model-generated and one written by one of their peers. The summary was rated for five metrics: factual consistency, meaning preservation/general usefulness, and aspect-specific usefulness for the three core clinical aspects on a 1-5 Likert scale.

The annotators were trained to use the evaluation guidelines and had detailed definitions of the assessment criteria (Multimedia Appendix 3). After a preliminary agreement exercise and further clarification, they rated the summaries of the remaining test timelines.

Qualitative Analysis of the Summaries

To gain deeper insights into the differences between human- and model-generated timeline summaries, we conducted a qualitative evaluation. Two clinicians (a clinical expert and a graduate student in clinical psychology), who were not involved in the model development or human summary creation, independently read 4 timelines and extracted their essential clinical aspects. They then comparatively assessed the human- and model-generated summaries for each timeline, focusing on meaning preservation, factual consistency, and personalization/psychological depth. This aimed to uncover the specific strengths and limitations of each summary type in capturing clinically meaningful insights from the nuances of self-expression patterns in social media posts.

Quantitative Assessment of Personalization via Diversity

While the qualitative analyses yielded several valuable insights, a particularly salient observation pertained to the potential lack of personalization in the model-generated summaries. This prompted us to further investigate this issue using computational means.

To quantitatively assess the elusive property of personalization in generated summaries, we devised and computed automatic measures capturing the linguistic diversity within the summaries generated by each system. Although linguistic diversity can be attributed to various factors, such as disfluent language or hallucinated irrelevant content, we hypothesize that in high-quality, factually consistent summaries, higher linguistic diversity would correlate with greater personalization. In contrast, a system that yields summaries that are more similar to each other (though characterizing different individuals) would be weaker at using the potential of rich, diverse language to reflect the unique personality and experience of each individual. In short, we conjecture that low diversity remotely signals a generic, nonpersonalized style. We explored 2 complementary dimensions of linguistic diversity, including semantic diversity and surface diversity.

Semantic Diversity

To measure the extent of diversity in conveyed meaning, we used Sentence Transformers (aka SBERT; Reimers & Gurevych, 2019), pretrained language models that encode text meaning into latent embedding vectors. In natural language processing, the semantic similarity between texts is typically computed using the cosine similarity between their corresponding vectors. To assess the variance within each system's summaries, we computed the centroid vector (the center of the embedding distribution) and calculated the mean cosine similarity between all summary embeddings and this centroid. Lower mean cosine similarity indicates greater semantic diversity. We used various pretrained SBERT models for a robust assessment.

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Surface Diversity

Surface diversity pertains to the variation in words and phrases used across summaries, reflecting differences in style and vocabulary. To quantify this, we used ROUGE scores [38], which are commonly used in summarization evaluation. ROUGE measures n-gram overlap between 2 texts; that is, the percentage of consecutive expressions (composed of 1 word for 1-gram, 2 words for 2-gram, etc) that co-occur in both texts relative to the total number of these expressions.

We defined self-ROUGE as a surface linguistic diversity metric based on pairwise ROUGE scores. Specifically, we calculated the mean pairwise ROUGE scores over all pairs of summaries within a system. Lower self-ROUGE scores signify higher surface diversity, indicating less lexical overlap between summaries. We used a variety of ROUGE metrics to capture different aspects of lexical diversity:

- ROUGE-1: unigram (individual word) overlap, providing insights into the diversity of word choices across summaries.
- ROUGE-2, ROUGE-3: bigram or trigram overlap, providing a measure of phrasal diversity and the variety of local word combinations.
- ROUGE-L: overlap of the longest common subsequence between summaries, capturing similarity in the overall structure and information ordering.
- ROUGE-S2 (Skip-Bigram): overlap of skip-bigrams (pairs of words with a gap of up to k=2 words), offering a broader perspective on phrasal diversity.
- ROUGE-SU2 (Skip-Bigram and Unigram): combining unigram and skip-bigram information for a more comprehensive assessment.

Both semantic and surface diversity can serve as proxies for personalization in summaries. Higher semantic diversity suggests a broader range of interpretations and experiences conveyed, while higher surface diversity indicates greater variation in linguistic expression, potentially reflecting more unique and individually tailored clinical descriptions.

To see if the differences in diversity between human and AI summaries were statistically significant, we use permutation testing. This robust method is particularly helpful when we cannot make distributional assumptions about the data.

Specifically, we conduct permutation tests with paired samples. For each iteration, we randomly shuffle system labels (eg, “Human” or “LLaMA”) within each summary pair, keeping summaries from the same source text together. We calculate the difference in mean self-ROUGE between permuted groups and compare it to the observed difference of the original, real groups. By repeating this 1000 times, we obtain a *P* value corresponding to the proportion of permutations where the absolute observed difference is smaller than the absolute permuted difference. Intuitively, this *P* value indicates the likelihood of observing the actual difference by chance. We also calculate Cohen *d* as a standardized measure of effect size.

Ethical Considerations

This study analyzed user-generated mental health content from TalkLife, a peer support platform. Ethical oversight was provided by two institutional bodies to cover the distinct phases of data collection and subsequent processing:

- Primary data collection: Initial ethical approval for the collection and analysis of the timeline data was obtained from the Institutional Review Board (IRB) of Queen Mary University of London (QMUL; Ref: BSREC 40/19-20, titled "Creating time sensitive sensors from user-generated language & heterogeneous content"). This framework focused on analyzing social media and peer-support content to address the temporal aspects of user-generated data.
- Annotation and processing: Further ethical approval for the specific annotation of timelines and the generation of human and model-based clinical summaries—the core focus of the current work—was granted by the IRB of Bar-Ilan University (BIU).

A formal data-sharing agreement and project proposal were approved by TalkLife, granting the research team data access under strict privacy guidelines. TalkLife users provide consent for research use of their anonymized data through the platform’s terms of service. The dataset shared with researchers was deidentified by TalkLife before release. Additional measures were taken by the research team to ensure user anonymity, including the removal of user handles, timestamps, and other potentially identifying metadata.

Human annotation was carried out by trained in-house research assistants, who produced summaries of user timelines and rated generated summaries. Annotators signed confidentiality agreements and were informed about the potentially distressing nature of the content. They were encouraged to take breaks as needed and were compensated at a rate of NIS 50 (US $14.3) per hour, exceeding the legal minimum wage in Israel and in accordance with institutional guidelines.

No real user timelines or verbatim user-generated text are presented in this manuscript. The paper does not include any images, excerpts, or figures that could potentially reveal the identity of individual users.

Finally, as this study evaluates the use of LLMs to generate clinical summaries of mental health timelines, we acknowledge the ethical risks posed by these technologies. While LLMs demonstrate potential for capturing behavioral and emotional patterns from user-generated content, they are susceptible to factual inaccuracies, hallucinations, and oversimplified interpretations. Such errors could lead to serious consequences if these models were used in clinical decision-making without oversight. We strongly emphasize that automatically generated summaries are not substitutes for professional mental health evaluations. Any future clinical application of such tools must involve trained practitioners who critically assess model outputs within a broader therapeutic framework. Rigorous validation, ethical safeguards, and continued oversight are essential before these systems can be responsibly integrated into mental health care.

This manuscript was edited with the assistance of Gemini Advanced (Google DeepMind), a LLM from Google AI, powered by the Gemini Pro 1.5 model [39]. Details regarding

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the terms of service and use are provided in Multimedia Appendix 4.

Results

Human Evaluation of Summaries

The results of the quantitative human judgments are summarized in Figure 2.

In terms of general usefulness and salient meaning preservation, the human summaries were rated as significantly more useful than those generated by the naive LLaMA model (P<.001; Cohen d=1.78). The differences between the human summaries and those generated by TH-VAE (P=.07) and LLaMA (P=.11) did not reach statistical significance. Both the TH-VAE and the LLaMA summaries, which used a three-step approach and leveraged clinical prompts, were rated significantly higher than the naive LLaMA summaries (P<.001; Cohen d=1.15 and 1.43, respectively), whereas no significant difference was observed between the former (P=.57).

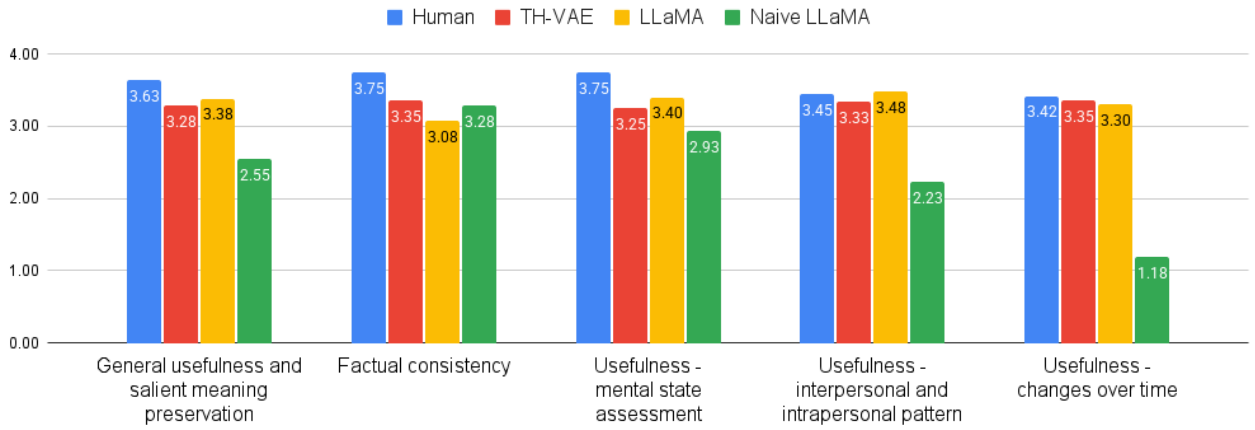
In terms of factual consistency, human-written summaries were rated significantly higher than those generated by TH-VAE (P=.003; Cohen d=0.92), LLaMA (P<.001; Cohen d=1.26), or Naive LLaMA (P=.003; Cohen d=0.82). The comparisons between the modeling approaches, while not statistically significant on this small sample, show that TH-VAE (P=.09; Cohen d=0.51) and Naive LLaMA (P=.23; Cohen d=0.31) score higher than LLaMA. LLaMA and TH-VAE performed on par (P=.73).

Regarding the specific aspect of usefulness for assessing mental states, the human summaries were rated significantly higher than all the model-generated summaries: LLaMA (P=.02; Cohen d=0.57), TH-VAE (P=.005; Cohen d=0.91), and Naive LLaMA (P<.001; Cohen d=1.34). Naive LLaMA was rated lower than LLaMA (P=.001; Cohen d=0.69) and TH-VAE (P=.06; Cohen d=0.51). No significant difference was found between LLaMA and TH-VAE summaries on this dimension (P=.40).

In terms of the usefulness of the interpersonal and intrapersonal patterns aspect, the human-written summaries were scored similarly to LLaMA (P=.90) and TH-VAE (P=.52). No significant difference was found between the LLaMA and the TH-VAE summaries for this dimension (P=.33). However, the Naive LLaMA summaries were rated as significantly less useful than all the other systems, including human summaries (P<.001; Cohen d ranging from 1.65 to 1.95).

Finally, for the aspect of changes in mental state over time, the Naive LLaMA summaries were rated as significantly less useful than all the other systems, including human summaries (P<.001; all Cohen d measures were greater than 3.4). Aside from this, the permutation tests did not indicate any other statistically significant differences (all P values greater than .60).

Figure 2. Mean human ratings of timeline summaries. Each metric was rated by a trained clinical psychology graduate student, rating 30 timeline summaries on a 1-5 Likert scale (high is better). LLaMA: large language model Meta AI; TH-VAE: timeline-hierarchical variational autoencoder;.



Qualitative Analysis of the Summaries

Our qualitative evaluation aimed to provide a deeper characterization of human- vs model-generated summaries. The clinical expertise of the evaluators, coupled with the open-ended nature of this analysis, allowed for insights beyond quantitative metrics.

The evaluators observed a trade-off between comprehensiveness and precision. Model-generated summaries were generally more comprehensive, capturing a wider range of details, while the human summaries were found to be better at focusing on the most clinically salient themes. This suggests that models, though adept at information extraction, may struggle with prioritizing information in line with clinical needs.

Importantly, the human summaries excelled in capturing the nuances of psychological dynamics, thus demonstrating a more personalized and accurate understanding of underlying patterns compared to the models. For example, in one case, the model's description of a central interpersonal relationship was somewhat generic, whereas the human summary accurately portrayed the related interpersonal pattern, including the causal links between the individual's desires (wish for closeness), perception of the other (hurtful; due to a prior experience of hurt), reaction toward the other (anger and aggression), and self-reaction (self-harm and despair). This highlights the challenge for models to understand the deeper psychological motivations and interconnectedness of mental elements, even when identifying key details.

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On the other hand, the models tended to identify clinically relevant features that the human summaries missed, pointing to their potential to surface subtle patterns or trends at scale. For example, the model noted an individual's use of aggressive communication and instances of adaptive self-states, both of which could be crucial when tailoring therapeutic interventions. The evaluators noted that the human summarizers were more selective in their choice of content, potentially reflecting a prioritization of the most salient aspects, but possibly also due to inherent human limitations such as fatigue or time constraints.

In terms of the model comparisons, LLaMA and TH-VAE performed comparably, in that both effectively summarized interpersonal/intrapersonal patterns and changes over time but occasionally missed important nuances or made unsupported diagnostic inferences (Mental State Assessment). The basic-prompt model (Naive LLaMA) provided a less comprehensive overview, omitting crucial clinical concepts and failing to reflect significant clinical insights.

Overall, the qualitative evaluation suggests that both human and model-generated summaries have their own unique strengths and limitations. Models offer comprehensiveness and a potential to uncover hidden patterns but may lack the in-depth understanding of human relationships and internal psychological processes that clinicians bring to their work. Human summaries, while more focused, individualized, and clinically insightful, may be limited in their scope and susceptible to human biases.

Quantitative Assessment of Personalization via Diversity

The results of the semantic diversity analysis, as measured by the mean cosine similarity of sentence embeddings to the centroid, are presented in Table 1. The Naive LLaMA model exhibited the highest variance (ie, lowest intersimilarity) in summary content. Human-generated summaries followed, with the two more performant, three-step models, TH-VAE and LLaMA, demonstrating the least diversity.

Table 1. Semantic linguistic diversity.

Sentence embedding model	Naïve LLaMA[a]	TH-VAE[b]	LLaMA	Human
All-mpnet-base-v2	0.79	0.88	0.89	0.85
All-MiniLM-L6-v2	0.77	0.87	0.87	0.82
Paraphrase-albert-small-v2	0.80	0.83	0.84	0.80
Average-word-embeddings-glove.6B.300d	0.95	0.98	0.98	0.95
Average	0.83	0.89	0.89	0.86

[a]LLaMA: large language model Meta AI.

[b]TH-VAE: timeline-hierarchical variational autoencoder.

The difference in diversity between Naive LLaMA and the human summaries was statistically significant for the first 2 sentence embedding models (P<.001; Cohen d average of 0.84), but not for the other embedding models. In addition, the differences between the human summaries and those generated by the other models (TH-VAE and LLaMA) were all statistically significant (average of P=.01 for the 8 comparisons). The Cohen d values for these comparisons ranged from 0.60 to 2.40, with an average of 1.19, indicating medium to very large effect sizes depending on the specific embedding model used.

In Table 1 semantic diversity is measured by the mean cosine similarity of sentence embeddings to the centroid embedding. Lower figures indicate lower semantic similarity between summaries of the system, that is, greater diversity.

In terms of surface diversity, Table 2 shows the computed self-ROUGE measures for all systems. The human summaries demonstrated the highest surface diversity across all ROUGE measures. Naive LLaMA came second, whereas the TH-VAE and LLaMA models exhibit the lowest diversity.

The differences between Human and Naive LLaMA were all statistically significant (P<.001) except for the ROUGE-L measure. The Cohen d values for these significant effects ranged from 1.24 to 1.39, with an average of 1.31, indicating an overall high effect size.

In Table 2 surface diversity is measured by Self-ROUGE scores for each summarization system, calculated using various n-gram overlap metrics. Lower scores indicate lower word overlap between summaries of the system; that is, greater diversity. ROUGE-1 measures unigram (single word) overlap. ROUGE-2 measures bigram (2-word sequence) overlap, ROUGE-3 measures trigram (3-word sequence) overlap, ROUGE-L measures the longest common subsequence overlap, ROUGE-S2 measures skip-bigram overlap (allowing for gaps between the 2 words in the sequence), and ROUGE-SU2 measures skip-bigram plus unigram overlap.

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Table 2. Surface linguistic diversity.

N-gram overlap measure	Naïve LLaMA[a]	TH-VAE[b]	LLaMA	Human
ROUGE-1	0.36	0.47	0.48	0.28
ROUGE-2	0.10	0.17	0.17	0.05
ROUGE-3	0.04	0.08	0.07	0.01
ROUGE-L	0.23	0.38	0.38	0.22
ROUGE-S2	0.09	0.15	0.15	0.04
ROUGE-SU2	0.16	0.23	0.23	0.11
Average	0.17	0.25	0.25	0.12

[a]LLaMA: large language model Meta AI.

[b]TH-VAE: timeline-hierarchical variational autoencoder.

Discussion

Overview

In this study, we explored the potential of LLMs to generate clinically meaningful summaries from social media timelines. We followed both straightforward prompting techniques and state-of-the-art, hybrid architecture to use the power of LLMs for generating such summaries. We then conducted a comprehensive evaluation to assess their performance compared to human summarizers across 3 critical dimensions, including salient meaning preservation, factual consistency, and personalization.

Salient Meaning Preservation

Capturing clinically relevant information from noisy social media timelines is challenging, demanding both linguistic and clinical understanding. Our evaluation showed that while LLMs can identify key themes, they may struggle to prioritize clinical relevance and discern subtle nuances. The 3-step models, which used key phrase highlighting and clinical prompts, significantly improved performance, closing most of the gap between the naive prompting baseline and human summaries.

The qualitative analysis indicated that even advanced models may favor comprehensiveness over focused clinical insights, which echoes findings in general natural language processing summarization [40]. The inherent complexity of extracting and synthesizing a psychologically coherent narrative from the multifaceted nature of social media posts further amplifies this prioritization hurdle. The human summaries, though less comprehensive, effectively captured the most essential topics from a clinical perspective.

Encouragingly, the gap in scores between the human and the stronger model summaries was small (~0.3 on a 1-5 Likert scale). Future computational research could explore controllable summarization, trading off comprehensiveness and focus based on user needs. From a practical clinical perspective, integrating human and model strengths through collaborative approaches may yield optimal summarization and monitoring outcomes.

Factual Consistency

Accurate reflection of timeline information is essential for clinical applications. While prior research has examined factual consistency (or faithfulness) in other domains such as news and science [41,42], its evaluation in clinical summaries is less often explored. Our findings reveal that although LLMs can produce largely consistent summaries (average scores exceeding 3 on a 5-point Likert scale), the human summaries were rated significantly higher, particularly when it came to psychological formulations rather than factual details. This suggests that applying abstract clinical concepts, which necessitate a profound understanding of human psychology, to lengthy and intricate first-person narratives poses a significant challenge to current LLM capabilities. Of all the models, TH-VAE was substantially more faithful than LLaMA, highlighting the importance of robust evidence summary generation.

The substantial gap between human and model performance (0.40-0.67 Likert points, large effect sizes) raises questions as to whether future LLMs can overcome these limitations or whether this task reveals the inherent limits of unsupervised language modeling. These results underscore the need for careful scrutiny of LLM-generated summaries in high-stakes clinical settings. Future research should prioritize enhancing clinical accuracy, potentially by incorporating external knowledge bases or grounding inferences on explicit definitions.

Personalization and Diversity

Personalization, the ability to tailor outputs to an individual's unique characteristics and needs, is crucial for effective human-computer interaction [43], especially in mental health, where empathy and understanding are paramount [44,45]. Research has explored methods for incorporating personalization into natural language generation [46-48], but achieving true personalization in clinically relevant summaries from social media remains complex.

Our qualitative evaluation highlighted the disparity in personalization between human- and model-generated summaries, where the latter often exhibited a more generic style. This is consistent with the observation that human summarizers demonstrate superior accuracy in capturing psychological insights. The ability to delve deeply into underlying mental mechanisms with high levels of detail facilitates idiosyncratic descriptions, whereas the lack of this type of incisive understanding leads to more generic and obscure narratives. In other words, when it comes to clinically meaningful summaries, accuracy and personalization are densely intertwined.

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Quantitatively, we used diversity metrics as a proxy for personalization. Our findings confirmed that the human summaries exhibited significantly greater linguistic diversity, suggesting higher personalization. We explored two complementary linguistic dimensions: content diversity and surface diversity. Content diversity, as assessed through cosine similarity of sentence embeddings, relies on opaque embedding models, thus making it a less interpretable evaluation measure. As shown, while some trends emerged, the comparative picture varied depending on the specific embedding model, leading to inconsistent results.

By contrast, surface diversity, as measured by n-gram overlap, consistently showed that the human summaries were significantly more diverse across all metrics. This suggests that despite their capacity to produce factually accurate and clinically relevant summaries, current models struggle to capture individuals' unique clinical portraits. We attribute this deficiency to 2 primary factors.

The first is the models' limited psychological depth, as evidenced by their lower accuracy in capturing more fine-grained psychological formulations as measured in Factual Consistency, which hinders their ability to generate truly personalized summaries. This lack of sharp and clear understanding, required for producing genuinely idiosyncratic, faithful summaries reflecting an individual's unique experiences, compels them to resort to more generic, repetitive descriptions. Second, the inherent nature of LLMs, shaped by their training data and objectives, may contribute to this tendency toward generic language. Language modeling prioritizes the identification of the most probable text sequence in a given context, which inevitably steers models toward commonplace, frequent linguistic patterns while avoiding idiosyncrasies. This phenomenon is akin to a "regression to the mean" effect, where the model's predicted text, aiming for maximum probability, defaults to a generic style and repeats "safe" phrases to remain within the realm of high-probability language.

Overall, our findings underscore the difficulties associated with achieving true personalization in LLM-generated clinical summaries of social media timelines. While models demonstrate proficiency in capturing factual information and conveying general clinical impressions, they at the time of this writing fall short of reflecting individuals' unique voices and experiences. Addressing this limitation requires further research into both the technical aspects of language modeling, such as developing methods for incorporating individual-level information and encouraging more diverse or user-specific language generation, and the incorporation of theoretical psychological understanding into the reasoning processes of computational models. Nevertheless, our conclusions must be tempered due to the lack of robust evaluation criteria for personalization in summarization. While our evaluation represents a first step toward devising such metrics, further work is needed to verify their appropriateness.

Limitations, Future Directions, and Clinical Implications

While this study provides valuable insights into the potential of LLMs for clinical mental health monitoring on social media, it is important to acknowledge its limitations. First, our dataset was extracted from a forum that primarily caters to teenage girls struggling with self-harm and hence represents a limited range of mental health issues and demographics. It is therefore not fully representative of the variety of online behaviors and mental health presentations. Future work should prioritize dataset expansion to ensure generalizability across diverse clinical populations.

Second, while our evaluation encompassed key dimensions, the quality of a clinical summary is multifaceted and should ideally be assessed from various perspectives. Future work could explore additional, complementary evaluation metrics on the usefulness and clinical applicability of timeline summaries.

Third, our evaluation was limited to English-language content, for which current LLMs perform more strongly compared to low-resourced languages. Future research should investigate the effectiveness of LLMs in summarizing social media content in other languages, especially those with distinct cultural norms and expressions of mental health, to ensure equitable access to these tools across diverse populations.

Despite these limitations and future challenges, our findings have major clinical implications. The ability to generate clinically relevant summaries from social media timelines could revolutionize mental health monitoring and support, empowering clinicians with a more comprehensive and continuous understanding of their patients' experiences. These summaries have the potential to serve as valuable tools for early detection, intervention, and treatment planning, particularly for individuals who may not actively seek help or have limited access to mental health services. Furthermore, high-quality summaries of large public social media channels could provide a rich resource for psychological and societal research by offering both in-depth individual insights and timely population-level trends.

Conclusion

This study advances the understanding of how LLMs can support mental health monitoring by systematically evaluating their ability to generate clinically relevant summaries from social media timelines. We evaluated the summarization capabilities of LLaMA 2 (13B) across three modeling approaches, including multistep pipelines designed to enhance clinical relevance. Through a detailed evaluation comparing model-generated summaries to those written by trained clinicians, we provide insight into the current strengths and limitations of generative models in this sensitive domain.

While the tested LLM demonstrated some ability to generate factually coherent and clinically relevant summaries, it fell short in capturing the nuanced psychological depth that human experts provide. These limitations are particularly salient in contexts requiring the recognition of subtle emotional shifts, personal meaning, and interpersonal dynamics. Importantly, the performance we observe may not generalize to other model families or sizes, and further testing with more advanced or fine-tuned models is warranted.

Rather than positioning LLMs as replacements for clinical judgment, our results support a more cautious and integrative view: human-in-the-loop approaches—where clinicians interpret,

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curate, or augment model outputs—may offer the most promising path forward. Such collaborative frameworks could potentially combine the exhaustiveness and scalability of automated summarization with the psychological accuracy and ethical sensitivity of human professionals.

Continued development, evaluation, and interdisciplinary dialogue will be essential to responsibly integrate LLM-based tools into clinical mental health workflows.

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The authors used generative AI tools, including ChatGPT (OpenAI) and Gemini (Google), to support language refinement, clarity improvements, and structural editing during multiple stages of manuscript preparation. All content was reviewed and revised by the authors to ensure accuracy, coherence, and alignment with the study's scientific intent. No AI tools were used for data analysis, result generation, or content creation beyond linguistic and editorial assistance.

Data Availability

The datasets generated or analyzed during this study are not publicly available due to privacy and ethical considerations. Specifically, the TalkLife dataset used in this study contains user-generated mental health data collected from the TalkLife peer support platform. To protect user confidentiality and comply with data protection policies, the dataset cannot be shared publicly. Researchers interested in accessing the data must apply directly to TalkLife and obtain approval through their data access request process. Researchers who have obtained approval from TalkLife may contact the authors to request access to the annotated data produced in this study, including the human-written summaries and human evaluation ratings.

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Conflicts of Interest

None declared.

Multimedia Appendix 1
Clinical Topics for the Summary.
[DOC File , 43 KB - formative_v10i1e71230_app1.doc]

Multimedia Appendix 2
Model Prompts.
[DOC File , 36 KB - formative_v10i1e71230_app2.doc]

Multimedia Appendix 3
Summary Evaluation Guidelines.
[DOC File , 50 KB - formative_v10i1e71230_app3.doc]

Multimedia Appendix 4
TalkLife Data Sharing Agreement.
[PDF File (Adobe PDF File), 484 KB - formative_v10i1e71230_app4.pdf]

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Abbreviations

AI: artificial intelligence
LLaMA: large language model Meta AI
LLM: large language model
TH-VAE: timeline-hierarchical variational autoencoder
VAE: variational autoencoder

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Original Paper

Participatory Approach to Program Sustainment: Example From a Multisite National Geriatrics Telemedicine Program

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Abstract

Background: Sustainment of evidence-based programs within dynamic health care environments requires ongoing adaptation to internal and external changes. Yet, strategies to support the sustainment of large-scale programs in heterogeneous settings are understudied. We developed and implemented a 3-phase participatory approach to support the sustainment of GRECC Connect, a 19-site Veterans Health Administration program that uses a hub-and-spoke model to expand rural access to geriatric specialty care.

Objective: Our goal is to describe a novel participatory approach for identifying sustainment strategies for large-scale health care programs in complex environments, using our experience with GRECC Connect as an example to illustrate the application of this approach.

Methods: We implemented the following 3-phase participatory approach with GRECC Connect team members from 19 hub sites. Phase 1: hub site clinicians and staff completed the Program Sustainment Assessment Tool, a publicly available online self-assessment of sustainability capacity. Phase 2: all sites then participated in a virtual retreat to exchange information, knowledge, and experiences related to sustainment strategies. Phase 3: each site submitted a locally-developed sustainment plan created with input from hub site team members. The sustainment plan worksheet included 3 questions asking respondents to reflect on the value of the participatory approach to sustainment. The process and experience of implementing this approach were also documented in structured meeting notes. Responses to Likert scale questions were analyzed with descriptive statistics, and qualitative data were analyzed using conventional content analysis.

Results: Overall, there was a high level of participation across all 19 hub sites. In phase 1, a total of 25 individuals from 14 sites responded to the Program Sustainment Assessment Tool survey; in phase 2, a total of 58 individuals from 19 sites attended

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the retreat; and in phase 3, a total of 17 site sustainment plans were completed. Three primary sustainment paths were proposed and discussed during the retreat. Sites varied in their confidence to sustain program activities, but were able to articulate several barriers and facilitators specific to their site. The level of specificity in the sustainment plans varied considerably across sites. Most sites reported that this participatory approach was "very useful" (ie, ≥7 on a 10-point Likert scale) for planning their program sustainment.

Conclusions: This approach offered a framework for sites to learn from one another, anticipate local barriers and facilitators, and move from reflection to identifying next steps for maintaining core program activities. Here, we describe the process used to guide 19 site teams through sustainment activities. We found the process is well-received, with sites reporting that their participation was useful for planning their sustainment journey. In elucidating our process, we provide a blueprint for other programs seeking to support sustainment across heterogeneous health care networks.

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KEYWORDS

telehealth; adaptation; maintenance; sustainment planning; aging; implementation science

Introduction

Sustainability has been defined as "the continued use of program components at sufficient intensity for the sustained achievement of desirable program goals and population outcomes" [1]. Many health care programs and services, even after being shown to be successful, are not sustained after their initial implementation period [2,3]. A wide array of program characteristics and organizational factors influence health care programs' sustainability, including leadership support, consistent funding, adequate staffing, accountability, and role clarity [3,4]. Adding to the challenge, many have noted the need for programs to continually adapt to enhance their long-term sustainability amid ongoing internal and external contextual changes [5,6]. However, adaptation is complicated for large-scale, national health care programs that exist in heterogeneous settings. For programs operating across a system that includes varied settings, distinct contexts shape the program's processes and details of service provision in unique ways that likely preclude the use of a singular sustainment strategy across sites.

Considering the myriad challenges facing health care (eg, COVID-19 pandemic, staff turnover, and decrease in budgets) in the United States [7], it is important to support the sustainment of evidence-based programs (EBPs) where appropriate to avoid the costs and burdens of implementing new, similar, or ineffective programs. Despite being recognized as a gap in the literature [8], strategies to support effective program sustainment remain understudied [1,3]. Work is needed to identify approaches that support the development of strategies to sustain effective health care services across networks [3,9]. Specifically, implementation science literature has recently called for research looking at EBPs in liminal periods of sustainment, meaning the time when a program has not yet been sustained or discontinued [9].

The Veterans Health Administration's national GRECC Connect program is an example of an EBP that is in a liminal stage of sustainment. The GRECC Connect program, a multisite rural geriatric consultative network with nationwide reach, was developed as an innovation project to enhance access to geriatric care for rural veterans. As part of the planning for sustained program impact beyond the innovation phase, the national GRECC Connect leadership team initiated activities across multiple sites to identify potential sustainment paths. Prior descriptions of the GRECC Connect program reported differences across sites in their clinical setup, mainly reflective of the different context and needs of each site [10]. Given these differences, it seemed unlikely that a uniform, top-down prescriptive approach to sustaining GRECC Connect services would be successful [11]. To address this, we designed a participatory approach to support sustainment so each hub site could plan the most feasible and successful sustainment strategy for its own site.

We describe a 3-phase participatory approach used to support the sustainment of GRECC Connect that can serve as a template for planning the sustainment of other large-scale clinical innovations. Guided by the typology of sustainment approaches by Wolfenden et al [12], we label our approach "dynamic sustainment support," which is defined as "a deliberate approach whereby external agencies provide resources or strategies to support [EBP] sustainment that continue to change over time…." due to program complexity or evolution. This contrasts with "self-sustainment" and "static sustainment" approaches included in typologies by Wolfenden et al [12]. As Wolfenden et al [12] noted, there is a need to characterize these approaches "to support sustainment and reflect on circumstances where they are most appropriate" to begin to address this gap of understanding in the literature [12]. To add to the limited literature on approaches to sustaining large-scale programs, we use our experience with the GRECC Connect program as an example to provide a robust description of a participatory approach to support program sustainment.

Methods

Case Example: Description of GRECC Connect

The GRECC Connect program, started in 2014 and funded by the Department of Veterans Affairs (VA) Office of Rural Health (ORH), connects geriatric interdisciplinary teams from 19 urban hub sites with older veteran patients in rural areas through secure VA-approved videoconferencing platforms [10]. Geriatric specialty clinicians at the hubs connect to patients who are either located in a rural community-based outpatient clinic (clinical video telehealth) or are in their home (VA Video Connect). This hub-and-spoke model delivers geriatric care based on the needs

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of primary care teams in rural areas and on the expertise available at the hub sites. The types of geriatric consultation services delivered by hub sites include the assessment or management of cognitive impairment, bone health and fall prevention, comprehensive geriatric assessments, and management of complex comorbidities (see Pimentel et al [10] for a full description of the GRECC Connect program).

GRECC Connect has demonstrated success at identifying unmet care needs, avoiding potentially inappropriate medications, and linking patients with needed care [10,13]. Patients and caregivers who have experienced GRECC Connect clinical encounters report numerous benefits (eg, high satisfaction and reduced caregiver burden) [14] aligned with standards for comprehensive geriatrics care [15]. While GRECC Connect providers were pioneers in providing telemedicine to older adults, since the COVID-19 pandemic, this practice has become more widespread [16,17]. However, the interdisciplinary nature of the service, focus on rural older adults, and the expertise built over almost a decade providing high-quality geriatric care online, make the GRECC Connect program unique.

GRECC Connect has been designated as a "promising practice" by ORH [18] and received "innovation" funding support, that is, special funding for the initial project development and the subsequent spread of the practice to multiple hospitals. Initially, GRECC Connect was developed and implemented by clinicians affiliated with several Geriatric Research, Education, and Clinical Centers (GRECCs) [19]. GRECCs are VA geriatric centers of excellence focused on aging that are located at medical centers across the country. They often act as incubators for new models of care. To be sustained long-term beyond the initial "innovation phase," however, these GRECC Connect activities need to be integrated into established VA health care system services as part of routine care for veterans. This means the innovative processes that were developed and implemented specifically to increase access to geriatric specialty care telemedicine visits for rural patients would need to be intentionally incorporated into and supported by the existing system. Given the size and complexity of the US Veterans Health Administration network, there may not be a one-size-fits-all integration solution across all health care facilities. Integrating into the existing system could involve shifting how resources are allocated, hiring new staff, or requiring existing staff to expand their scopes of practice. In the absence of this effort, any gains achieved by this innovative program could be lost. For example, while telemedicine in general is likely to continue, the capacity to engage in geriatric telemedicine may decline, or the target audience (ie, rural veterans) may not be reached. In fall 2022, in anticipation of the innovation funding shifting, national GRECC Connect leadership initiated a process to identify strategies for sustaining GRECC Connect clinical services (ie, specialty geriatric telemedicine care) at the 19 hub sites.

We leveraged the program's already developed infrastructure and expertise in designing and carrying out the participatory process planning. GRECC Connect's robust administrative structure consists of a national director and 4 "core" groups (Figure 1). These core groups help coordinate the activities of the 19 GRECC Connect site directors and their associated team members. Core group team members are a subgroup of staff from the 19 hub sites, many having volunteered to participate in more than one core group. These groups include (1) an evaluation core that has qualitative and quantitative subgroups and is charged with evaluating the program's process and outcomes, (2) an education and workforce development core that focuses on developing and implementing a case conference series on geriatric care for rural providers, (3) a sustainment core that works within and across sites to guide on implementing GRECC Connect best practices and overcoming barriers to implementation, and (4) an administrative core charged with guiding and developing budgets and reports. The administrative work of GRECC Connect is moved forward through a series of online meetings: each core group meets monthly or quarterly, the leads of the 4 core groups meet monthly with the national director, and members of all 19 hub site teams join a monthly national GRECC Connect "all site" meeting.

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Figure 1. GRECC Connect example: participation in a 3-phase participatory approach to program sustainment. PSAT: Program Sustainment Assessment Tool; VA: Department of Veterans Affairs.

Participants		Contribution to the 3-phase participatory approach to program sustainment			
		Preimplementation	Phase 1	Phase 2	Phase 3
VA Office of Rural Health resource center leadership	Regional leadership team of 3 rural health clinicians and program experts	Strategic mentoring; collaboration and support			
GRECC Connect national leadership team (some members are on multiple core teams, and all core team members are also part of hub site teams)	National director and 4 core teams (N=14) -Administrative -Education -Evaluation -Sustainment	Design participatory approach	Facilitate and summarize data	Facilitate and summarize data	Facilitate and summarize data
Hub sites	Across 19 hub sites there are 66 hub site team members (eg, geriatricians, nurse practitioners, geropsychologists, neurologists, social workers, occupational therapists, program coordinators, and data analysts)		25 individuals from 14 hub sites responded to the PSAT survey	58 individuals from 19 hub sites attended the retreat	17 hub site teams completed sustainment plan worksheets

The GRECC Connect Qualitative Evaluation Core team (QualEC) evaluates the program via interviews, surveys, and other qualitative methods. Members include 6 VA researchers with expertise in program evaluation, qualitative methods, implementation science, geriatric medicine, and primary care. Using the GRECC Connect administrative infrastructure described above, this QualEC team supported the development of a 3-phase participatory approach in collaboration with sustainment core leadership. The process and experience of implementing this approach were documented in structured meeting notes.

Implementation of 3-Phase Participatory Approach to Program Sustainment: GRECC Connect Example

In phase 1, we established a baseline understanding of each hub site's perception of the likelihood of sustainment of their GRECC Connect-related activities beyond the current period of funding support. In phase 2, we shared information about potential sustainment strategies and supported discussion among the sites to exchange experiences and knowledge and to help each site determine next steps in their planning process. Phase 3 involved encouraging site-level participatory processes by asking sites to complete a sustainment plan worksheet with input from all members of their local GRECC Connect team (Figure 2).

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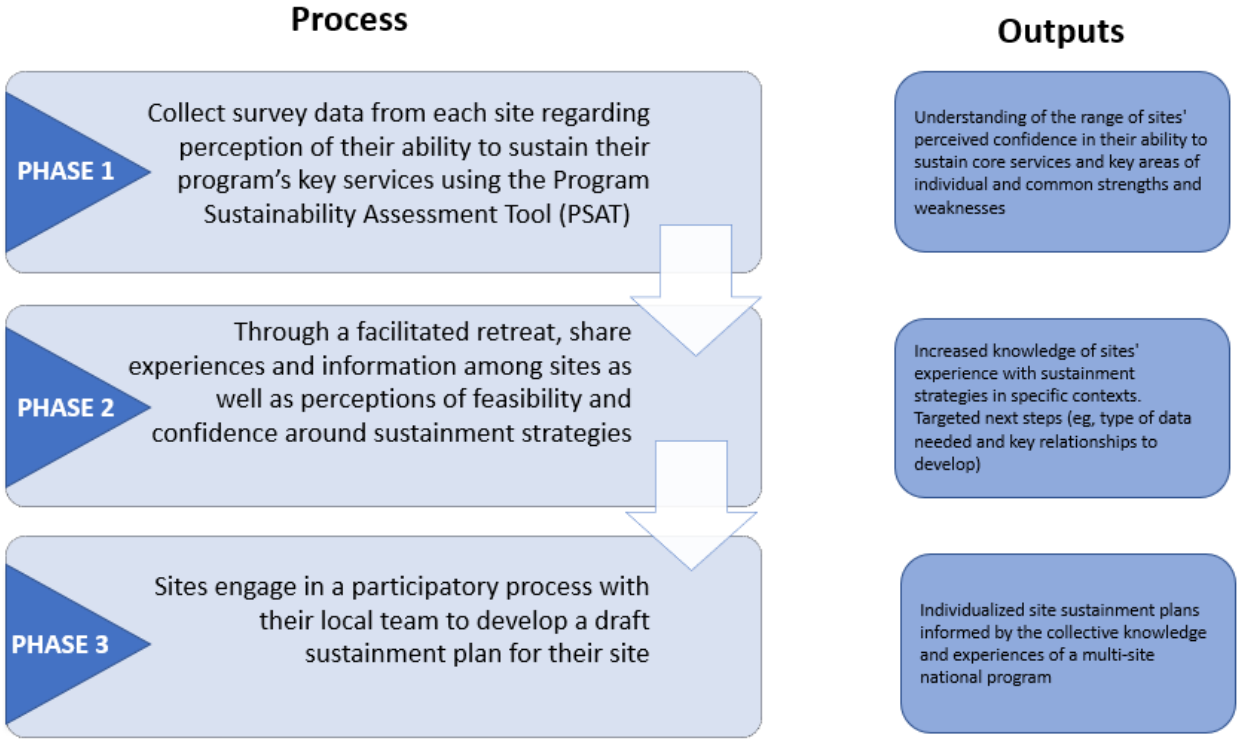
Figure 2. Process and outputs of the 3-phase participatory approach to program sustainment. PSAT: Program Sustainment Assessment Tool.



Phase 1: Establishing a Baseline Understanding of Sites' Perceptions of Sustainability

In spring 2023, we used the Program Sustainability Assessment Tool (PSAT [20]) to gauge sites' perceived ability to sustain core GRECC Connect activities beyond the initial period of funding. The PSAT is a publicly available, online self-assessment tool that measures a program's perception of its sustainability capacity. The 8 components measured in the PSAT include environmental support, funding stability, partnerships, organizational capacity, program evaluation, program adaptation, communications, and strategic planning. The scale for each domain ranges from 1 (no extent) to 7 (full extent). We emailed a link to the PSAT to team members at each of the 19 hub sites and requested that site clinicians and staff complete PSAT assessments within 1 week. Our goal was to begin a reflective and participatory process to help sites understand factors influencing future sustainability and to gauge areas of strength and weakness within their site. This also provided a baseline sustainability score for each site and insight into promising components to focus on to enhance their likelihood of sustainment, as well as what areas in which they may need support.

The PSAT data were exported into Excel (Microsoft Corp) for analysis. QualEC team members calculated the average and range for each of the 8 PSAT components and for the overall score across all sites. Where more than one PSAT was completed for a given hub site, we first averaged the responses within the site and then used the average in the cross-site analysis.

Phase 2: Sharing Experiences and Information Among the National Group

Overview

We followed the PSAT administration with an opportunity for sites to share experiences and information about sustainment strategies. We believed a national discussion that included perspectives from multiple sites would be necessary to design sustainment strategies relevant to each site's unique context. Some sites had more sustainment experience and expertise that would be valuable to share with the other sites. We extended a regularly scheduled monthly GRECC Connect all-site national meeting from 1 to 2 hours and used that time to host the online retreat using the Teams (Microsoft Corp) platform, organizing multiple breakout rooms to promote sharing by different roles and professions of staff participants.

Identification of Potential Sustainment Strategies

In collaboration with the GRECC Connect sustainment core, the QualEC developed the retreat agenda focusing on three potential sustainment strategies: (1) integrating services into a regional telemedicine hub that provides gap care coverage due to staffing shortages (the Clinical Resource Hub [CRH] [21] integration strategy); (2) integrating services into the teams or departments that currently serve older adults (the Geriatric Patient Aligned Care Team [GeriPACT] [22]/Geriatrics and Extended Care [GEC] integration strategy); and (3) exporting the model to other interested teams throughout the health care system through a mentoring hub (the telegeriatric mentorship strategy, see Figure 3 for details and further explanation). These strategies were previously identified and developed by the GRECC Connect core team leadership in consultation with our funders at ORH and with input from the field (ie, GRECC Connect team members from hub sites across the country) during

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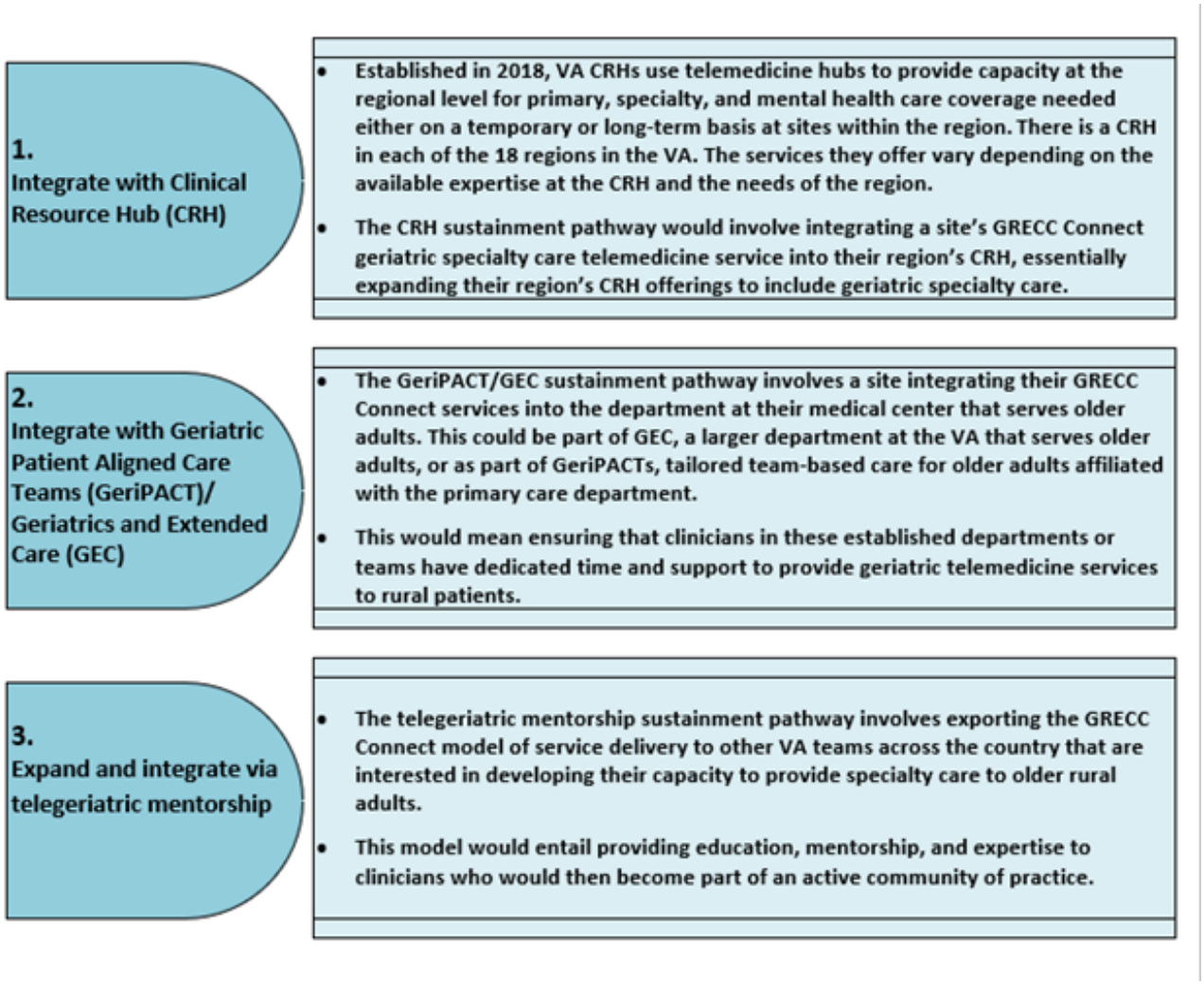
one of the regularly scheduled national all-site meetings. Each potential model had previously been established within individual VA facilities or as a mechanism for supporting a national VA initiative. These proposed sustainment strategies were frameworks for sites to use to begin their sustainment process planning and helped identify ways in which sites may need to be supported.

Figure 3. GRECC Connect example: sustainment strategy details. CRH: Clinical Resource Hub; GEC: Geriatrics and Extended Care; GeriPACT: Geriatric Patient Aligned Care Team; VA: Department of Veterans Affairs.



Retreat Agenda

All GRECC Connect sites participated in the online retreat held in March 2023. The GRECC Connect national director shared the purpose of the retreat—to discuss how to continue bringing geriatrics interdisciplinary team care to older, rural patients—and the history of GRECC Connect and its status as an ORH Promising Practice. We shared sites' anonymized PSAT scores to promote a common understanding of the range of perceptions of sustainability capacity. We then launched an electronic poll to assess each participant's confidence that their site's service to older, rural patients would be sustained beyond current ORH funding (on a scale of 0-10, 0=not at all). Before separating into predetermined "breakout" rooms, GRECC Connect site leads with knowledge on the 3 potential sustainment strategies gave a brief overview of each. After each overview, we launched 2 polls to assess, on a scale of 1-7 (1=not at all), participants' perspectives on the feasibility and importance of the potential sustainment pathways for their site.

Breakout Rooms

We assigned the GRECC Connect hub site staff to 1 of 3 discussion groups focused on each strategy. Preassigning groups for each sustainment strategy allowed us to control group composition to encourage staff of varying backgrounds and site locations to join the discussion. For example, we purposefully distributed higher-level leadership and participants from sites with more expertise and experience among the breakout rooms. Preassigned groups also meant that GRECC Connect staff from various geographic sites, which have different operating contexts, would be able to share their knowledge and insights. The goal was to provide an environment that would enable sites to learn from one another.

Discussion within each of the 3 breakout rooms was guided by and adapted from the suggested exploration of the maintenance dimension of the RE-AIM (Reach, Effectiveness, Adoption, Implementation, and Maintenance) framework [23] by Shelton et al [6]: (1) How important is this strategy? Why or why not? (2) What could dissemination to the field look like? (list

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scenarios) and (3) What are barriers? What are the factors that may facilitate this?

Participants were given the same template to use in each breakout room, regardless of the strategy they were discussing. The template also guided how to facilitate the discussion and included space for notes. Participants discussed the strategy for 20 minutes. After the allotted time, attendees returned to the larger online platform, where each group's assigned lead reported their small group discussion to the larger group.

The final component of the retreat was a second round of 20-minute breakout rooms. Participants selected their desired breakout room based on the preceding large group discussion and perceived usefulness for their own site. Participants used a template to guide discussion and identified interested parties relevant to their sustainment strategy, data that would be needed to support "buy-in" to the sustainment strategy, and 3-4 concrete next steps to move the strategy forward (see Multimedia Appendix 1 for a full list of questions used in the breakout rooms). As in the first breakout session, groups were assigned a lead who reported back to the larger group.

We collected the notes from each breakout group's assigned lead and summarized them. We also exported and calculated descriptive statistics on the data from the 6 poll questions.

Phase 3: Using National Collective Knowledge and Local Participation to Develop Tailored Site-Specific Sustainment Plans

Overview

The retreat output (ie, summarized qualitative discussion notes and quantitative poll results) guided our understanding of the type of support that was needed and the most useful next steps. After the retreat, the national program director met with each site to discuss ongoing administrative topics as well as their immediate postretreat thoughts on sustainment. He invited sites to join a weekly QualEC meeting to brainstorm ways of collecting data they needed to either inform the decision of what path to choose or to help them navigate their sustainment pathway of choice.

We created a "sustainment planning worksheet" for each site to complete and return within 2 months of receipt. Its purpose was to encourage sites to begin to think through their need for the GRECC Connect program and how they envisioned their individual program being sustained. The sustainment planning worksheet mimicked a brief grant proposal and included sections on background and rural significance, purpose and objectives, design and planned activities, key partners, measurement plan, products and deliverables, long-term planning, and potential barriers to their proposed sustainment plan (Multimedia Appendix 2). This process ensured that team discussions and thought exercises would occur with enough time to address any barriers that surfaced and to facilitate a planful transition. We emphasized the importance of including all GRECC Connect site team members when completing the worksheet. During this period, GRECC Connect continued to hold a regular monthly call, where leadership dedicated time on the agenda to answer questions staff had while completing the sustainment worksheet.

Soon after we distributed the sustainment planning worksheet, the team members at the GRECC Connect site that leads the QualEC group piloted the sustainment worksheet with all team members, documenting additional clarifying guidance that would be helpful to know as it was being completed. We shared the guidance with the national team and, once again, offered to meet individually with sites to help guide them as they worked through their site's sustainment planning worksheet. We also distributed supportive documents to help sites pursue information about which sustainment pathways might best align with their sites' needs and context, such as contact information for each region's CRH director. Completed sustainment worksheets were reviewed in detail by members of the sustainment and evaluation core teams. Then, to facilitate comparison, responses to the worksheets were entered into an Excel template where each column was a question on the template and each row was a hub site. Qualitative data were analyzed using the conventional content analysis approach [24].

Evaluation of the 3-Phase Participatory Approach to Program Sustainment

The second part of the sustainment planning worksheet included a series of reflection questions about the participatory process itself. The reflection portion of the worksheet included 3 Likert scale questions followed by a space to add a comment. The reflection questions were as follows: (1) To what extent was your participation in the March 2023 Online GRECC Connect Retreat, as well as other site planning activities (discussions with other sites regarding sustainment strategies, self-assessment tools [PSAT]), useful for your sites' planning? (Scale 0 to 10, 0=not useful at all); (2) To what extent was the process of completing this proposal useful for your sites' planning? (Scale 0 to 10, 0=not useful at all); (3) How confident are you that your service to rural patients can be sustained using your proposed site sustainment strategy? (Scale 0 to 10, 0=not confident at all). An additional open-ended question asked, "Are there additional things that GRECC Connect leadership could do to support your sites' sustainment planning?" Likert scale responses were aggregated into 3 categories (0-3=minimally useful, 4-6=useful, 7-10=very useful; 0-3=minimally confident, 4-6=confident, and 7-10=very confident, Multimedia Appendix 2). Responses to Likert scale questions were analyzed with descriptive statistics, and qualitative data were analyzed using conventional content analysis [24].

Ethical Considerations

The VA Bedford Healthcare System Institutional Review Board determined this work was undertaken to inform VA operations as part of program evaluation and quality improvement activities and was not human participants research. The need for ethics approval was waived by the VA Bedford Healthcare System Institutional Review Board, which determined this program evaluation activity to be nonresearch. As a nonresearch activity, formal informed consent was not required; however, participants were informed about the project plans, including that participation was voluntary, they could opt out of being recorded, and all data collected would be deidentified for publication purposes. Under VA policy, no compensation is provided to VA staff for their participation in these activities.

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Results

Implementation of Approach: GRECC Connect Example

Phase 1: Establishing a Baseline Understanding of Sites' Perceptions of Sustainability

We received 25 individual PSAT responses across 14 (of 19) GRECC Connect sites; 6 sites had more than 1 respondent. Respondents included geriatricians, nurse practitioners, geropsychologists, neurologists, social workers, and occupational therapists (Figure 1).

Sites varied in their perceived confidence to sustain their GRECC Connect program. Overall sustainability scores across the 14 sites were wide ranging (mean 4.8, SD 0.9; range: 1-7). The "program adaptation" domain had the highest average rating across sites (mean 5.8, SD 0.7), while "partnerships" had the lowest average score (mean 3.4, SD 1.3). Respondent rated the other domains as follows: "environmental support" mean of 5.4 (SD 0.7), "funding stability" mean of 4.3 (SD 1.3), "organizational capacity" mean of 4.5 (SD 1.1), "program evaluation" mean of 5.4 (SD 0.9), "communications" mean of 4.5 (SD 1.4), and "strategic planning" mean of 4.6 (SD 1.2).

Phase 2: Sharing Experience and Information Among the National Group

A total of 58 (of 66) GRECC Connect hub site team members (eg, geriatricians, other clinicians, project coordinators, and administrative staff) from all 19 sites participated in the retreat (Figure 1).

When publicly polled, sites reported varying confidence in their ability to continue serving rural patients beyond current funding (mean of 5.12, SD 2.54; range of 0-10). Sites had mid-range perceptions of the importance and feasibility of the 3 sustainment strategies. Out of a maximum score of 7, the GeriPACT/GEC strategy was rated the most important (mean 4.9, SD 1.18) and most feasible strategy (mean 3.9, SD 1.43). The average importance of the CRH strategy was rated a 3.8 (SD 1.87) and the feasibility a 3.5 (SD 1.58) while the average importance and feasibility of the telegeriatric mentorship strategy was rated a 4.3 (SD 1.49) and 3.6 (SD 1.06), respectively.

Sites talked openly about anticipated barriers to sustainment and also potential facilitators. Guided by prompts, this led to strategy development that purposefully considered their local context, intentionally leveraging and addressing the facilitators and barriers. Some potential next steps identified by the GeriPACT/GEC small group included, for example, starting conversations between GeriPACT directors and local GRECC Connect directors about interest, feasibility, and logistics (eg, data collection or gap analysis that would start to support a business case for GeriPACT/GEC to support GRECC services).

Phase 3: Using National Collective Knowledge and Local Participation to Develop Tailored Site-Specific Sustainment Plans

After the retreat, 17 of the 19 sites completed and returned the sustainment proposal worksheet (Figure 1). Of those, 14 identified a primary sustainment path for their site; 11 chose at least 1 of the 3 paths presented, while 3 identified new, different sustainment paths for their site. One site indicated they required significant additional support to identify a sustainment strategy and plan for future implementation. The level of specificity included in the completed worksheets varied considerably. At one end of the spectrum, 7 sites submitted sustainment plans that were rigorous and thorough enough to guide their sustainment journey. On the other end of the spectrum, 4 sites submitted vague plans, lacking sufficient detail to act as a blueprint for implementation. The remaining plans demonstrated certain details, but with some steps needing further consideration.

Evaluation of Approach

Sites reported that participation in the online retreat was useful for planning their program sustainment (mean of 5.75, SD 2.33; range: 0-9), with 9 sites finding it "very useful" (ie, 7 or greater on a 10-point Likert scale). Those with favorable views of the usefulness of the retreat reported that the retreat and other planning activities gave them actionable information to identify and adapt a sustainment strategy. Some sites, however, reported that participation in the retreat and other activities was minimally useful because they already had high confidence in their ability to sustain GRECC Connect program activities. A small number of sites did not rely as heavily on external innovation funding, so they felt the absence of that funding would have minimal impact.

Similarly, sites reported that the sustainment proposal worksheet was useful to plan for their program sustainment (mean of 6.56, SD 2.34; range: 0-10), with 10 sites reporting it was "very useful" (ie, 7 or greater on a 10-point Likert scale). The process of completing the proposal was minimally useful for some sites; however, those sites felt they could already sustain program activities and would not be impacted by a potential shift in funding. Sites that found the proposal activity "very useful" shared that they dedicated time as a team to "sit down" and talk about a sustainment strategy. Although not all sites may have found a concrete solution, staff reported that having time allocated to discussing future sustainment was useful for identifying potential barriers or facilitators to sustaining future program activities. Site-level discussions enabled team members to consider a variety of local options for future sustainment strategies.

Sites were confident that services to rural patients would be sustained using their proposed strategy (mean of 7.38, SD 2.18; range: 3-10), with 12 sites being "highly confident" (ie, 7 or greater on a 10-point Likert scale). One site had low confidence owing to "higher competing demands for resources at their facility." Another site expressed uncertainty about the proposed shift in funding and was unclear about what the next steps would be, needing more guided support. Many sites that felt "highly confident" shared that they were already well integrated into

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another hospital service line that could support future program services.

Discussion

Principal Findings

Our 3-phase participatory approach—in and of itself a sustainment strategy, and a process for identifying strategies that will sustain the program across 19 sites—serves as an example of how to support maintenance of a large-scale health care program that exists within diverse settings. Given the lack of examples of how to sustain such programs, this is an important contribution to the implementation science literature.

Strengths of the Approach

In this case example of sustainment support, we found the approach supported broad participation. It intentionally allowed for staff in various roles and professions to engage in the process, learn about the "bigger picture" of the local and national trajectory of the program, share experiences, and voice their ideas and opinions about sustaining GRECC Connect activities. Additionally, this approach enabled sites to distill their thoughts over the course of 3-phases, moving them from a reflection-based response to identifying concrete next steps for program sustainment. Sites had an opportunity to learn from others' experiences, and a preexisting, strongly supported administrative structure helped facilitate cross-site learning. Many of the activities described above occurred during previously established meeting times, mitigating scheduling barriers and enabling many hub sites and their team members to meaningfully engage with the participatory process.

Considerations for Future Use of the Approach

Challenges with this approach included balancing direction from the program funder (ie, ORH staff) and leadership (ie, GRECC Connect national director and Core Team members) with the generation of ideas from the group level. While the hub site teams were included in the initial discussions about potential sustainment strategies during monthly all-site meetings before the retreat, the core team leads chose what they felt to be the 3 most promising strategies to discuss in depth at the retreat. This made the retreat discussion more manageable, but may also have unintentionally, prematurely limited the scope of possible sustainment paths discussed and considered by each site. Providing more opportunities for the sites to generate ideas at the local level before hosting the retreat may have mitigated this issue.

Another challenge was that, in trying to adapt to local contexts among the sites, the sustainment worksheet was purposefully not overly specific in the type of responses requested. As the sites interpreted the site sustainment worksheet in their own way, the responses received were wide-ranging in their specificity. This made it difficult to compare across sites and determine next steps for supporting them. More clarity or instructions for how to interpret the worksheets would have been helpful. Additionally, the sustainment planning worksheet was designed to mirror a grant proposal, a format that many clinicians were not familiar with. A more useful format may have been one that encouraged them to develop a business case for their program because the next steps often included convincing leadership of the need to sustain their services.

Finally, throughout the participatory process, the QualEC team offered support to sites at a consistent time and day of the week as an "office hours" format. No sites used that time for support. We found more success inviting participants to ask questions or express concerns during national monthly calls in the months following the online retreat.

Implications

By describing our approach in detail and highlighting the benefits and challenges, we are responding to a call in implementation science literature [3,9] to provide models for supporting program sustainment. This 3-phase participatory approach is not only an example of dynamic sustainment support but also functions to identify the type of dynamic sustainment support that would be successful in each site's given context. Wolfenden et al [12] recently highlighted a public health example of dynamic sustainment support called "physically active children in education." This model of support was used to improve primary schools' implementation of a mandatory physical activity policy. The pilot study of this approach found that it was effective at increasing teachers' implementation of the physical activity policy and led to a significant increase in students' physical activity levels. Like our example, the physically active children in education model was used to sustain a large-scale program that exists in heterogeneous settings and occurred in phases, each successive phase informed by the last, to develop sustainment strategies.

We used our participatory approach during what Nevedal et al [9] consider a "liminal stage" of program sustainment: GRECC Connect is at a crossroads and, given anticipated shifts in funding, can neither be considered sustained nor discontinued. Similar to our findings, Nevedal et al [9] found that among facility representatives, a wide range of perceived optimism about their site's ability to sustain the evidence-informed practices in question. This underscores the fact that the "liminal stage" of a program's sustainment is a critical moment in a program's lifecycle, a moment in which providing additional sustainment support can be particularly beneficial.

Finally, our model makes an important contribution to the literature in that it uses a participatory approach to address the reality that successful sustainment strategies will likely look different for each of the 19 sites where GRECC Connect is implemented. To best support them, we must learn about each site's local barriers and facilitators. At the same time, a large-scale program has cumulative knowledge and a broad perspective that enhances local staff's capacity to plan for sustainment. This participatory approach may be of value to other large-scale health care programs with established administrative and organizational structures to support cross-site information exchange and significant site-level participation.

Limitations

This description of our 3-phase participatory approach to program sustainment has limitations. First, we have not had the opportunity to assess the impact of this approach and therefore cannot yet speak to its efficacy in sustaining clinical services.

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As the dynamic sustainment support continues to be adapted to support GRECC Connect programming, future research will reveal if sites were able to maintain access to geriatric services for older patients in rural areas over the long term. Additionally, the generalizability of our approach may be limited insofar as other clinical programs may not have the robust administrative structure needed to help guide this 3-phase participatory approach.

Conclusions

The sustainment of EBPs, such as GRECC Connect, is an important goal to help avoid the costs and burdens of implementing new, similar programs. Without established methods to support the sustainment of these programs, implementation science continues to lack concrete models of how to place frameworks into practice. In this participatory case example, we identify processes and tools to identify appropriate sustainment strategies for a large-scale, national health care program that exists in heterogeneous settings. While more work is needed to understand its efficacy, our approach serves as an innovative example of a dynamic sustainment support strategy conducted in the liminal stage of program sustainment.

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Data Availability

The datasets generated or analyzed during this study are available from the corresponding author on reasonable request.

Authors' Contributions

All authors have been personally and actively involved in substantive work leading to this paper and will hold themselves jointly and individually responsible for its content.

Conflicts of Interest

None declared.

Multimedia Appendix 1
GRECC Connect retreat breakout room discussion questions.
[PDF File (Adobe PDF File), 135 KB - formative_v10i1e82409_app1.pdf]

Multimedia Appendix 2
GRECC Connect site sustainment planning worksheet.
[PDF File (Adobe PDF File), 229 KB - formative_v10i1e82409_app2.pdf]

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Abbreviations

CRH: Clinical Resource Hub
EBP: evidence-based program
GEC: Geriatrics and Extended Care

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GeriPACT: Geriatric Patient Aligned Care Team
GRECC: Geriatric Research, Education, and Clinical Centers
ORH: Office of Rural Health
PSAT: Program Sustainability Assessment Tool
QualEC: GRECC Connect Qualitative Evaluation Core team
RE-AIM: Reach, Effectiveness, Adoption, Implementation, and Maintenance
VA: Department of Veterans Affairs

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Original Paper

Engaging LGBTQ+ Youth in Human-Centered Design of a Digital Health Intervention via Discord: Implementation Case Study

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Abstract

Background: Lesbian, gay, bisexual, transgender, and queer/questioning, plus (LGBTQ+) youth experience significant health challenges relative to their peers, including higher rates of HIV, sexually transmitted infections, and mental health symptoms, partly due to minority stressors. Digital health interventions hold promise for addressing these issues, but their effectiveness hinges on human-centered co-design that ensures relevance and engagement.

Objective: This study aimed to examine the use of Discord as a platform for conducting human-centered design (HCD) activities to adapt a digital text-based intervention designed to improve HIV testing rates among LGBTQ+ youth.

Methods: We recruited 21 LGBTQ+ youth (aged 13-18 years) in the United States via social media and participant registries, oversampling minoritized gender, racial, and ethnic identities to ensure diverse representation. Over 9 months, participants engaged in structured HCD activities on a private Discord server, including polls, open-ended discussions, and interactive feedback tasks. Design insights were collected iteratively and used to refine the intervention in real time. We also surveyed participants to examine the acceptability of Discord as a tool for hosting the HCD process.

Results: We identified best practices for integrating HCD methods within Discord, including cocreating the server environment with participants and enabling real-time iteration of intervention components based on youth input. The privacy of the Discord server supported psychological safety; facilitated open and effective communication between participants and the research team; and fostered an informal, familiar atmosphere.

Conclusions: Discord provides an effective and acceptable environment for conducting HCD processes in the design of digital health interventions. Its structural features, including anonymity, accessibility, and community-driven interaction, facilitated meaningful youth engagement in co-design activities. These insights offer a model for leveraging social media platforms to support participatory intervention development for LGBTQ+ populations.

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KEYWORDS

sexual and gender minority groups; LGBTQ+; human-centered design; Discord; social media

Introduction

Lesbian, gay, bisexual, transgender, and queer/questioning, plus (LGBTQ+) youth in the United States face many health challenges, including disproportionately high rates of HIV and poor mental health compared to their cisgender heterosexual peers [1-4]. LGBTQ+ youth's risks are further heightened if they hold multiple minoritized identities, including sexual

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orientation, gender, race, and ethnicity, and these risks often stem from minoritized stress experiences (ie, stigma and harassment) [5-7]. However, existing interventions are often designed without considering the unique needs or experiences of LGBTQ+ youth, which may undermine intervention effectiveness.

Digital interventions can provide LGBTQ+ youth with accessible and equitable interventions and information to tackle low rates of HIV testing and uptake of HIV or sexually transmitted infection prevention tools, minority stressors, and poor mental health outcomes [8-10]. Indeed, most adolescents from various racial and economic backgrounds access the internet daily [11]. Furthermore, texting remains the dominant mode of communication for adolescents [12]. Although digital interventions hold promise for improving youth health outcomes, this technology alone does not guarantee success. It is essential that digital interventions are engaging, evidence based, and acceptable for diverse LGBTQ+ end users [9]. One method to ensure these qualities in digital interventions is by using a human-centered design (HCD) approach with LGBTQ+ youth for the development and implementation of interventions [13,14].

HCD incorporates user feedback throughout the intervention design and implementation process, contributing to a more acceptable and usable final digital health intervention. Co-design is one strategy that can be used within HCD that purposefully includes end users in the development process [15-17]. Together, the HCD approach has been shown to be feasible with LGBTQ+ youth in both online and in-person environments for the cocreation of digital interventions that target health disparities among LGBTQ+ youth. These include interventions that improve outcomes such as loneliness, depressive symptoms, and relationship abuse [13,18,19].

Discord (Discord Inc) is a social media platform that has great potential to accommodate the HCD process with LGBTQ+ youth. Discord is a communication platform that allows users to create servers dedicated to specific interests or communities in which people can communicate. Discord's ability to foster communities and facilitate interaction has contributed to its widespread use among LGBTQ+ users, who can access social support and resources through the platform [20]. LGBTQ+ youth may use Discord partly due to its privacy features, which allow these groups to develop in relative comfort and safety, for example, by enabling users to remain anonymous or to create private servers that help keep out bad actors [21].

Previous research has used Discord for research purposes, such as eliciting experiences of digital interventions, recruitment, hosting design workshops, and forming advisory committees, all of which have shown promise for engaging LGBTQ+ youth [22-25]. However, the use of Discord as a holistic setting that can support all of these research purposes has not been explored to our knowledge. This study describes the use of Discord as an online setting to engage LGBTQ+ youth in the HCD process for the development and adaptation of an existing digital intervention and examines its acceptability from the user perspective. As social media platforms often fall out of favor with adolescents, this paper presents best practices for engaging youth in HCD methods that can be used on Discord and across different social media platforms.

Methods

Background

The following activities occurred in the context of a hybrid effectiveness-implementation study, which first sought to adapt and modernize a previous sexual health intervention called Guy2Guy, originally developed from 2012 to 2013 [26]. Guy2Guy was intended to increase condom use and other HIV prevention and testing behaviors among gay and bisexual teenage boys. The intervention consisted of 8 to 10 daily texts sent to participants over 6 weeks and included various interactive features, including a chatbot and one-on-one anonymous texting buddies. This intervention was associated with a 3-fold increase in HIV testing in the active treatment arm vs an information-only control arm [27,28].

In the new study, which began a decade after Guy2Guy's original development, we sought to expand the intervention to be inclusive of LGBTQ+ adolescents who could benefit from HIV prevention and testing behaviors, adapt Guy2Guy to include updated HIV and sexually transmitted infection prevention information, modernize the texting delivery (eg, multimedia messaging service rather than SMS), and update other technological components such as the chatbot and texting buddies. This adaptation and modernization process was informed by feedback from a diverse sample of LGBTQ+ youth (aged 13-18 years; n=21) hosted on Discord over a 9-month period.

Recruitment

We recruited participants through paid social media advertisements and an existing institute-wide participant registry. Social media advertisements were developed following the CAN-DO-IT (conceptualize scope, acquire expertise, navigate platform and strategy, develop ad content, optimize recruitment workflow, implement campaign, track, and respond) model [28] and were posted on Meta platforms (Instagram and Facebook). Eligibility criteria were as follows: (1) sexual and/or gender minority identity; (2) age 13 to 18 years; (3) ability to read English at an eighth-grade level; (4) for minors, ability to provide informed assent and pass a capacity to consent assessment; and (5) residence in the United States or US territories.

Interested individuals were directed to complete the eligibility screening, consent, and capacity to consent surveys in Research Electronic Data Capture (REDCap; Vanderbilt University). We purposely oversampled transgender, gender-diverse, and minoritized racial and ethnic participants to ensure diverse feedback. A total of 24 participants were enrolled in the study. Only 12.5% (3/24) of participants formally requested to withdraw before the Discord server officially started its research activities, most commonly citing competing time commitments. Over the active course of the 9-month period of Discord activities (March 2023 to November 2023), no additional participants withdrew. The remaining 87.5% (n=21) of active participants comprised the analytic sample for this paper and

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participated in the survey reported here, as well as the primary study activities described later.

Ethical Considerations

This study was approved by the Northwestern University Institutional Review Board (IRB; STU00217358 and STU00222652). Informed consent was obtained from all participants prior to participation in the advisory council. A waiver of parental permission was approved by the IRB on the basis of minimal risk and the potential for increased harm if parental consent were required. Previous IRB-approved studies conducted by the investigative team with sexual and gender minority (SGM) adolescents younger than 18 years have demonstrated that parental permission does not consistently function as a protective mechanism for this population [29]. Many SGM adolescents are not out to their parents and do not disclose sexual orientation, gender identity, or sexual behavior due to fear of rejection, victimization, or family conflict [29]. Therefore, requiring parental consent could increase risk by inadvertently "outing" participants or exposing them to harm and would likely result in systematic exclusion of youth most in need of sexual health research. Consistent with previous studies of adolescent SGM sexual health, the IRB determined that requiring parental permission would introduce significant sampling bias and may compromise participant welfare, while the study procedures themselves posed no greater than minimal risk [30-33]. Assent procedures, confidentiality protections, and access to supportive resources were implemented to ensure ethical participation. Through the consent process and subsequent orientation, participants were given information about the activities associated with the advisory council, details concerning privacy and confidentiality, possible risks and benefits, and reminders that participation was voluntary and could be stopped at any time.

We paid participants US $30 per month for active participation, defined as answering 75% or more of the questions asked in each month, delivered via virtual gift cards. Participants also had the opportunity to get paid an additional US $60 every 3 months for completing optional extra activities, such as creating a social media post or providing more in-depth feedback about the intervention. All data were stored on private servers accessible only to study staff, in compliance with the Health Insurance Portability and Accountability Act. Participants were assigned unique identifiers for analysis and reporting requirements. All data were deidentified, and all personally identifying information was removed before data were shared beyond the research team to ensure privacy and confidentiality.

Measurement

High-level feedback about the acceptability of Discord for these activities was assessed by an online survey completed by all participants (21/21, 100%) hosted through Qualtrics (Qualtrics Inc) 6 months after the start of Discord activities. Questions were developed for the purpose of understanding perceived acceptability in the context of the features of Discord (eg, "I felt comfortable sharing my thoughts and ideas on Discord") and were aligned with the core principles of HCD, such as reporting iterative changes based on participant feedback (eg, "I felt like the research team echoed or reported our SHER [Sharing Health Educational Resources] feedback back to us after making changes").

Additionally, we allowed participants to provide open-ended answers to the following question: "Would you use Discord again for future research projects like this? Please tell us why." Results of this survey and the open-ended answers are presented together in thematic groupings and include the themes of psychological safety and ease of communication. We used a rapid, inductive qualitative approach to analyze open-ended Discord feedback [34,35]. Two team members independently reviewed and grouped responses, refining categories through discussion in weekly meetings. Because the purpose was exploratory and aligned with HCD processes, we resolved differences by consensus rather than by computing interrater reliability. Coding and data management were conducted in Microsoft Excel.

Discord Configuration and Process Overview

The study's Discord server consisted of multiple channels organized into 3 categories: "Information," "Activities," and "Creative and Fun." "Information" channels included server guidelines, resources, a channel to directly contact staff, and a copy of the consent form. "Activities" channels consisted of weekly questions that engaged participants in the HCD process. Feedback from the HCD activities was collected through poll responses and open-ended threads on Discord. When responding to poll questions, participants were prompted to react to staff messages by selecting the emoji corresponding to their chosen vote, and open-ended questions used the "thread" feature to organize responses in one location within the channel.

All weekly questions, extra activities, and retention activities on Discord were developed during weekly collaborative staff meetings with the full study team. Staff identified "themes" for weekly questions and key areas for participant feedback based on the needs of the project (eg, new intervention content, adaptation of existing intervention content, and software design and development). The questions and relevant materials were organized in an Excel document. Discord moderation team members then reviewed the questions proposed by the research team to ensure consistency with the language and tone of the Discord server. After internal approval, questions were posted to Discord by research staff. Participant feedback was copied and pasted into a separate Excel document to facilitate easier visualization and data analysis. Key findings from participants were presented during weekly research team meetings and content development meetings, where the research team decided which feedback to implement. This process included qualitatively interpreting Discord posts through these team discussions to contextualize participant comments and clarify emerging insights. Any clarifying questions were also proposed back to the participants.

Study Design and Theoretical Framework

Overview

This study used an HCD approach to engage LGBTQ+ youth as cocreators in adapting a digital health intervention. HCD emphasizes an iterative approach to design that can be applied under the EDIPT (emphasize, define, iterate, prototype, and

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test) model with end users to ensure solutions are grounded in lived experience and are usable [36]. Our approach was also informed by participatory and co-design methods, which center on user agency and position participants as active contributors to the design process [37]. We drew on design justice principles (eg, equitable and inclusive solutions), emphasized community-led design, and adopted an intentional approach to intersectional differences by diversifying recruitment.

Discord was selected as the design space for its cultural relevance, familiarity, and flexibility for LGBTQ+ youth and based on recommendations from the research team's youth advisors in a previous study [38]. Its hybrid structure, which included supporting both asynchronous and synchronous interaction, allowed for accessible, sustained engagement in a setting aligned with youth preferences and safety needs. We describe the HCD process by presenting a polling feature that was co-designed with participants in this study.

Empathize: Building Trust and Understanding Youth Needs

We began by creating a welcoming, private Discord server designed with input from LGBTQ+ youth advisors to ensure safety and cultural relevance. The approximate weeks and months associated with each phase, along with an estimate of moderation activities, are presented in Table 1.

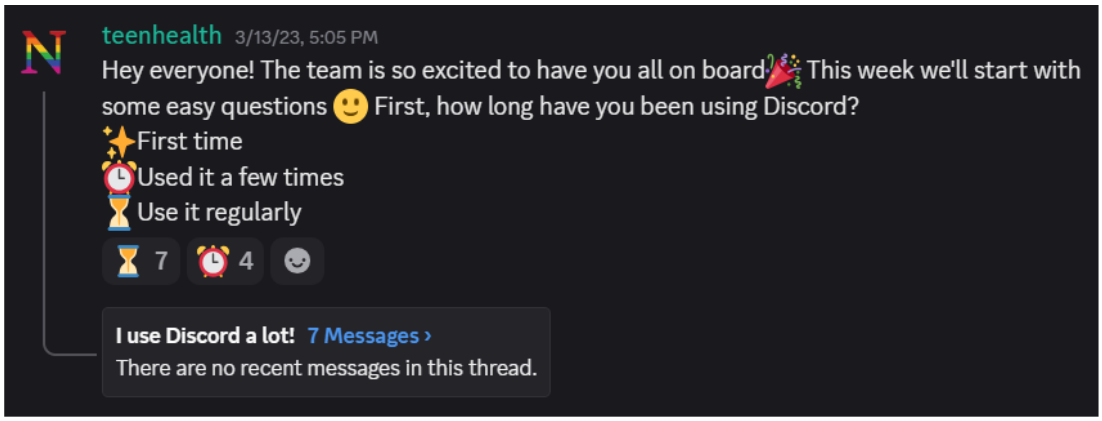
In the first month, moderators heavily focused on orientation and empathizing with participants through low-effort onboarding prompts (eg, introductions, pronoun sharing, community agreements, and icebreaker questions). However, we continued this stage throughout the entirety of the design process. These activities generated active open-ended threads monthly and served as early relationship-building activities (Figure 1). When appropriate, moderators responded to each post to model engagement and build trust throughout the length of participation. Participants also began sharing early experiences with digital interventions, which helped us understand their baseline needs and expectations.

Table 1. EDIPT (emphasize, define, iterate, prototype, and test) design activities timeline.

EDIPT phase	Months engaged	Weeks engaged	Polls	Open-ended prompts
Empathize	1-9	All weeks	1-2 per week[a]	1-2 per week[a]
Define	1-9	2, 3, 5-7, 9, 15, 21, and 34	4-6 per week	2-4 per week
Ideate	1-9	3-5, 8, 9, 19, 21, 22, and 35	4-5 per week	2-4 per week
Prototype	2-9	7, 8, 12, 23, and 35	3-5 per week	2-3 per week
Test	1-6 and 9	4, 11, 13, 14, and 23-25	4-6 per week	2 per week

[a]Empathize phase had a higher frequency of Discord engagement closer to orientation.

Figure 1. Screenshot of the moderation team using an icebreaker activity on Discord to engage participants.



Define: Cocreating Problem Statements

Using guided prompts in dedicated threads and polls, participants identified challenges they faced with text-based interventions. Participants offered examples of what felt disengaging or ineffective. Figure 2 shows one of these open-ended discussion threads. The research team synthesized these contributions into draft problem statements and posted them back to the group for refinement. In this example, this iterative exchange clarified that one major challenge was that text-based interventions felt "boring" or insufficiently interactive. This insight directly informed the next design phase.

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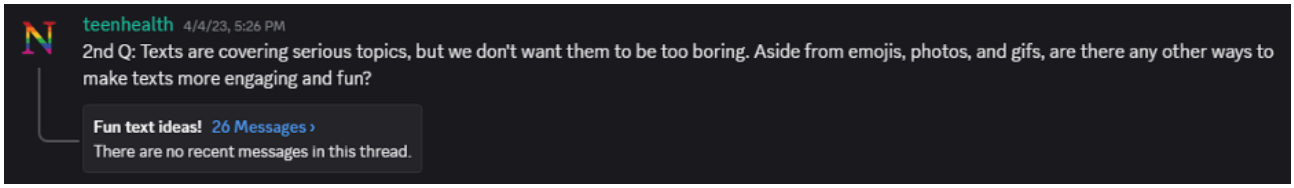
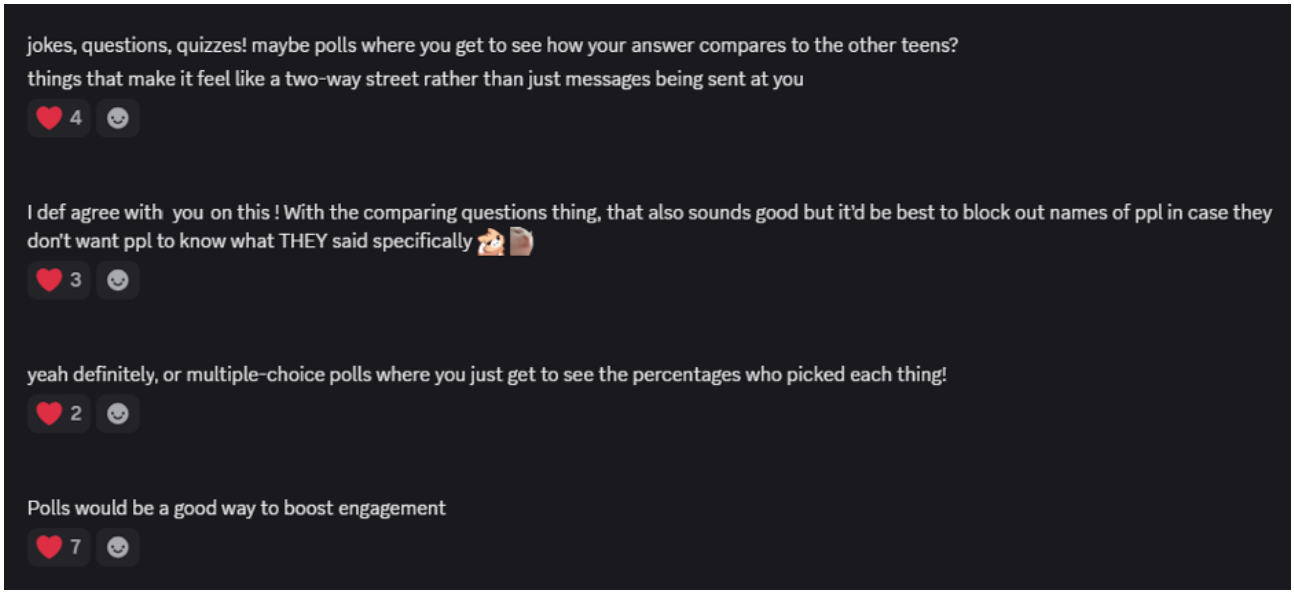
Figure 2. Screenshot of the moderation team asking participants to answer a prompt about making the digital intervention more engaging.



Ideate: Brainstorming Youth-Led Solutions

We facilitated a series of ideation threads in which participants proposed features that they believed would improve engagement to the problem they specified. Youth generated solution ideas across multiple threads, using reactions and emoji-voting features to identify those with the highest level of interest, as shown in Figure 3. For example, participants prioritized adding quizzes and polls as a way to increase interactivity. These ideation artifacts (eg, thread transcripts, prioritized lists, and voted-on features) formed the basis of the initial mock-ups that the research team crafted.

Figure 3. Screenshot of participant-generated solutions for improving engagement in the digital intervention.



Prototype: Exploring Early Concepts Together

The research team translated youth-generated ideas into low-fidelity prototypes using Canva, which we introduced in Discord as static screenshots. Participants evaluated these prototypes in dedicated threads and polls, responding weekly to specific prompts to further iterate on the prototype (eg, preferred visual formats, clarity of instructions, and color preferences), as shown in Figure 4. Their feedback informed 3 rounds of prototype refinement. Updated mock-ups were posted back to the server after each cycle, creating a clear, traceable artifact trail documenting iterative changes.

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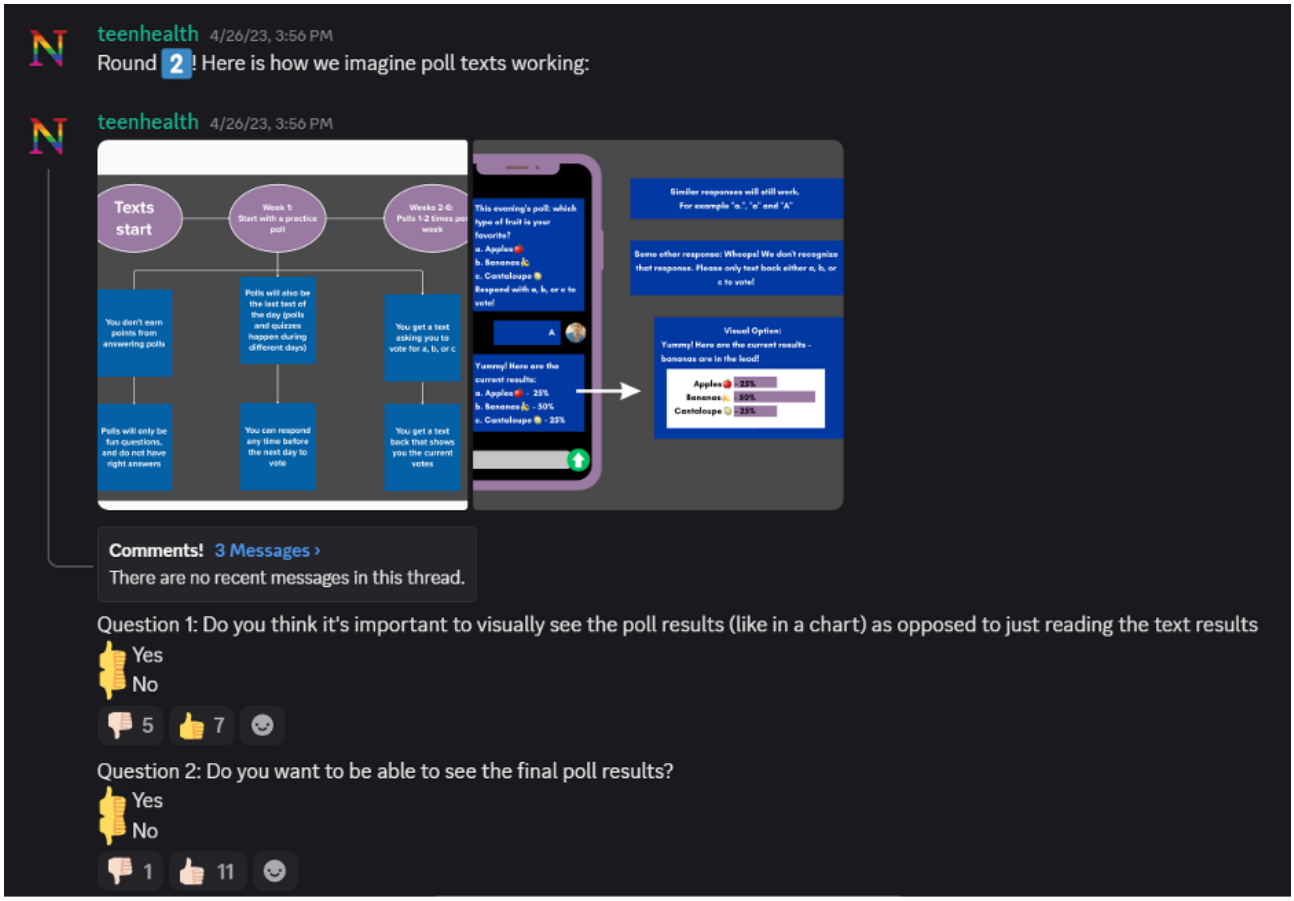
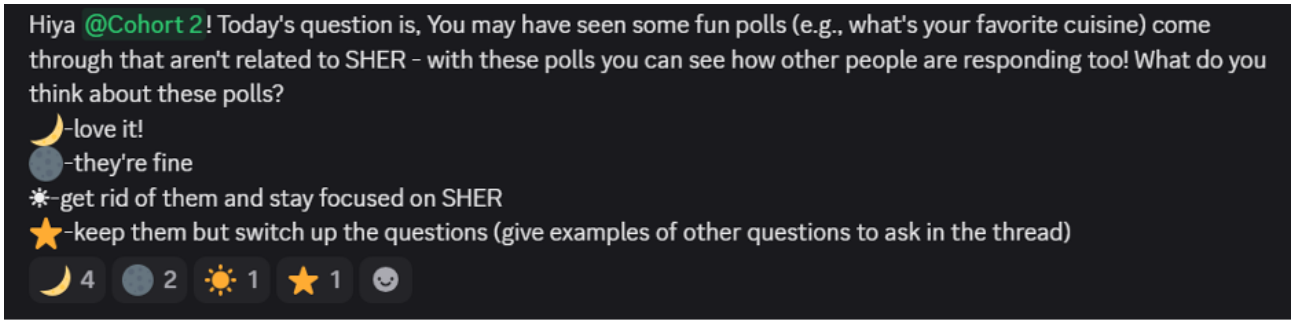
Figure 4. Screenshot of the moderation team showing participants prototype mock-ups of their ideas on Discord.



Test: Gathering Feedback and Refining Ideas

Testing was done throughout the design process, starting with simple 1-day testing sessions during which we manually sent texts to select participants early in the process. Participants also engaged in informal alpha testing when the early poll features were built into the intervention during the last weeks of the Discord process. Using Discord polls and open discussion prompts, youth shared their experiences with the prototype poll feature after participating in the test. These discussions generated additional refinements to the poll prototype, as shown in Figure 5. Finalized prototype features (Multimedia Appendix 1) directly reflect this testing feedback. Across the 9-month engagement period, moderators posted design prompts approximately weekly, resulting in more than 40 active threads spanning the EDIPT phases. These artifacts, including threads, refined problem statements, ideation lists, prototype screenshots, and feedback discussions, demonstrate iterative, youth-driven engagement throughout the process.

Figure 5. Screenshot of the moderation team gathering participant feedback on the prototype engagement strategies that were used in alpha testing on Discord. SHER: Sharing Health Educational Resources.



Results

Overview

Full sociodemographic information of the participants is presented in Table 2. Participants had a mean age of 17.4 (SD 0.98) years. The sample was diverse across multiple identities, including sexual orientation, gender, and location, with participants representing 16 different states. Results of the survey informed our best practices when engaging in HCD on Discord for digital intervention design and adaptations. For the full results of the survey, refer to Multimedia Appendix 2.

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Table 2. Sociodemographic variables (N=21).

Sociodemographic variables	Participants, n (%)
Age (years)	
15	1 (4.8)
16	2 (9.5)
17	7 (33.3)
18	9 (42.9)
19	2 (9.5)
Gender	
Man or boy	16 (76.2)
Woman or girl	4 (19.0)
Gender nonconforming	1 (4.8)
Race	
American Indian or Alaska Native	4 (19.0)
Black or African American	3 (14.3)
Native Hawaiian or other Pacific Islander	1 (4.8)
Other	3 (14.3)
White	10 (47.6)
Transgender identity	
Yes	9 (42.9)
No	11 (52.4)
Unsure	1 (4.8)
Sexual orientation	
Gay	6 (28.6)
Bisexual or pansexual	8 (38.1)
Queer	4 (19.0)
Questioning	2 (9.5)
Other	1 (4.8)

Discord Facilitated Psychological Safety and Familiarity

One benefit of using Discord for HCD activities was the ease of participation and the ability to ensure safety and anonymity. Participants consistently described feeling at ease participating in design activities within Discord compared to more formal research settings, which likely contributed to high engagement. One reason for this was that participants largely reported no concerns about their privacy on Discord; about 90% (19/21) responded that they had no privacy concerns on the platform. The flexibility to engage asynchronously, use chosen names or pronouns, and opt into different modes of participation contributed to high engagement across our HCD activities. In total, 80% (n=17) of participants responded that they were comfortable visiting Discord to engage in the HCD activities and posting their opinions in threads and activities online. Additionally, participants reported that their familiarity with Discord in their personal lives made them likely to use the platform again for a similar project. Two participants mentioned this factor:

> *It's convenient because I am active on Discord for other purposes, and I am able to stay updated with the server due to my frequent use of the platform.*
>
> *I primarily use Discord anyway and it's very helpful for this.*

Discord Maintained Effective Communication Between the Research Team and Participants

A critical component of the HCD process is maintaining effective, ongoing communication between design teams and participants across the EDIPT phases. We found that Discord facilitated highly efficient communication among participants, moderators, and the research team. Most participants (18/21, 85%) reported feeling that the research team listened to their suggestions for improving the intervention, and 90% (n=19) noted that the team communicated how their feedback directly influenced design changes. This feedback loop was essential; participants overwhelmingly indicated that seeing their ideas reflected in the evolving intervention strengthened their sense

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of contribution and improved their overall experience with the HCD process. Participants reiterated this qualitatively:

> *I think it's pretty easy to use and works well for communicating with others and the research team.*
>
> *It is easier to speak with other participants and researchers than email and text.*

Improved communication between the research team and participants may have also supported conflict resolution. Although this was not assessed in the survey, a participant reported a conflict directly to the research team, suggesting a level of trust in the moderation process.

HCD Was Most Effective in Casual, Low-Stakes Formats

Lightweight tools such as emoji reactions and informal polls proved to be more engaging and generative than structured surveys or longer text-based threads. Participants (19/21, 90%) agreed that it was easy to share feedback on Discord using our methods, which included using preselected emojis to respond to questions (Figure 1). Additionally, a majority of participants (n=16, 76%) mentioned that they felt they were able to share all their suggestions for the prototypes and interventions, which suggests that our lightweight approach to data collection was acceptable and capable of capturing their feedback. For instance, one participant mentioned the following:

> *It was easy to use [which] makes participation simple.*

Another participant commented about the tone and the use of emojis in the activities:

> *I think it simplifies data gathering by putting it into a familiar text format.*

To establish best practices for using Discord for HCD design purposes, the moderation team described effective, casual study procedures that improved engagement and psychological safety. Refer to Textbox 1 for a brief report on the best practices reported by the moderation team.

Textbox 1. Best moderation practices for improving engagement and psychological safety on Discord.

Procedures that improved engagement and psychological safety

- Conduct a group orientation for Discord to ensure participants understand how Discord works and to set up first connections between moderators and participants.
- Include strict rules of conduct in the orientation that participants must agree to abide by to encourage respectful behavior.
- Build trust between moderators and participants by purposefully finding opportunities to bond, such as through shared interests and introductions, within the same day in nonresearch channels.
- Ensure that the moderation team responds daily to what participants are posting by responding with comments and/or emojis.
- Avoid extended pauses in content.
- Use emojis to collect data and limit the number of open-ended questions so participants can respond quickly. If more detailed responses are needed, communicate this clearly.
- Communicate how participant feedback has impacted the intervention content and design. If feedback is not used, explain why.
- Allow flexibility for participants to take breaks or choose between different activities.
- Conduct ongoing assessments of participation burden in relation to the compensation offered.

Discussion

Principal Findings

Our team developed a novel research participation hub on Discord to engage LGBTQ+ youth in HCD for the adaptation of a digital health intervention. Our methods encouraged high engagement and, most importantly, were considered acceptable by participants. Hosting this process on Discord allowed direct and instantaneous access to LGBTQ+ youth for supporting the successful adaptation of a digital health intervention component. Our findings support the acceptability of Discord as a tool for engaging in HCD activities in a community-based participatory research in a digital setting. We demonstrated how this digital environment can facilitate the co-design of digital health interventions.

The moderation team also assessed satisfaction, Discord acceptability, and Discord server recommendations with participants quarterly. For instance, when we assessed participant suggestions for improving data collection on Discord, participants mentioned that it was difficult to respond to specific prompts (Multimedia Appendix 3). We changed our Discord structure so that all posts contained all possible response emojis. This way, participants could click on the emoji reaction to "vote" without manually searching for the specific emoji. By asking for feedback surrounding the design of data collection itself, participants can cocreate and democratize the server environment to meet their own needs. This approach also ensures that researchers can improve participant retention, satisfaction, and participation.

There are many benefits to using Discord in the HCD process for digital interventions. Discord allowed for substantial anonymity (eg, not requiring real names or profile pictures), does not require transit, and does not require parental or guardian approval for participation among users older than 13 years. In addition, the platform is familiar and easy to navigate for many young people in the United States, particularly LGBTQ+ youth, who are often highly connected in digital communities. Our participants reported that the HCD activities conducted on Discord were widely acceptable. Additionally, Discord allowed affordances that followed the principles of community-based

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participatory research, specifically shared decision-making, mutual ownership of the research process and its outcomes, colearning, and recognition of the community as a unit of identity [37,39].

We also found that the digital affordances and structure of Discord were useful for this research. We were able to sort different conversations into specific channels for specific topics. For example, we had separate channels for more HCD-focused discussions, and others focused on building a sense of community. This fostered a more holistic and inclusive research environment for participants, where they could be present on Discord not only as study participants helping to design a health intervention but as individuals with diverse interests who were invested in being part of a community [39-41]. The use of Discord for engaging in HCD activities is effective at lowering barriers between academic professionals and LGBTQ+ youth [42] and offers avenues for direct and clear communication between the groups [21]. By centering the design of interactions around meeting youth on platforms they already use, such as Discord, researchers are able to develop bonds with and learn more efficiently from community youth, leading to improved intervention design. Liem et al [43] also demonstrated the process of how the feedback from this Discord youth advisory board informed the adaptation of a separate digital health intervention.

Limitations and Strengths

Social media platforms may fall in and out of favor over time, so adapting digital HCD methods as existing platforms evolve and new platforms arise will be necessary. However, the best practices we shared are generalizable to many current social media platforms that researchers may use for the HCD of digital interventions with youth, LGBTQ+ youth, and others. While an HCD approach to digital interventions is valuable, there are clear limitations. Our own study relied on a small number of end users, which, while common in HCD work, does hamper our ability to generalize to other end users [44]. Sample adequacy in HCD is instead evaluated based on the diversity of perspectives, sufficiency of idea generation, and whether additional participants yield novel design insights. Across sessions, we observed recurring themes and did not observe substantively new insights emerging, indicating that the sample size was appropriate for the aims of this study.

Our purposeful sampling approach also helped to ensure a diversity of perspectives by intentional recruitment efforts focused on racial and ethnic minority persons who are LGBTQ+. Consequently, nearly half of the sample identified as belonging to racial or ethnic groups other than White. In addition to sample size, participation required access to Discord and a baseline level of digital literacy, which may have deterred some youth and introduced platform-specific selection bias. These factors limit the generalizability of our accessibility model. However, participants in this study demonstrated high familiarity with Discord, consistent with previous research showing higher Discord use among LGBTQ+ youth than among heterosexual peers and broader patterns of youth social media engagement [20,45]. Future work should assess variation in digital literacy and examine whether these methods translate to other platforms.

In addition to sample size, participation required access to Discord and a basic level of digital literacy, which may have excluded or deterred some youth and introduced platform-specific bias. These barriers limit the generalizability of our “accessible” model. Understanding the extent of youth digital literacy and whether the reported methods are usable on other platforms should be addressed in future work.

Furthermore, as HCD is an iterative process, it can be infeasible for some intervention developers due to the cost and time required for maintaining an ongoing Discord server for the purpose of intervention design and adaptation. Our 9-month Discord engagement period was moderately resource intensive and may not be easily scalable. However, while certain routine tasks could be automated (eg, onboarding or reminder bots), maintaining participant trust required active human facilitation. Moderation from research staff would have to be responsive to a higher number of participants in any one server. Future research should identify which components can be automated and explore the most effective amount of moderation. Despite this potential limitation, this online methodology was cost-effective and potentially more feasible for youth participation than intensive in-person alternatives, such as iterative focus groups, which require travel expenses and logistics. While other studies have used Discord for similar research purposes, they often used already existing Discord servers or communities [25]. Our approach allowed for the bottom-up and community-forward creation of a Discord server that fostered participatory benefits and improved engagement throughout the HCD process.

Conclusions

This study highlights the innovative use of Discord as a dynamic, youth-friendly platform for engaging LGBTQ+ youth in HCD activities. By leveraging a space where participants already feel comfortable and connected, we demonstrate how this digital environment can facilitate more authentic, accessible, and sustained involvement in the co-design of digital health interventions. Our findings underscore the potential of integrating familiar social media technologies into participatory research practices, ultimately advancing inclusive and acceptable digital intervention design. This work contributes valuable insights for researchers and designers who engage in HCD to create more equitable and responsive interventions for marginalized youth communities.

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principal investigator: Michael Newcomb). The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institute of Health.

Data Availability

The datasets generated or analyzed during this study are not publicly available due to the ongoing intervention but are available from the corresponding author on reasonable request.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Screenshots of polling feature prototypes in alpha testing.
[DOCX File , 457 KB - formative_v10i1e80852_app1.docx]

Multimedia Appendix 2
Table showing full acceptability survey.
[PDF File (Adobe PDF File), 48 KB - formative_v10i1e80852_app2.pdf]

Multimedia Appendix 3
Screenshot of participant feedback on improving data collection on Discord.
[PNG File , 89 KB - formative_v10i1e80852_app3.png]

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Abbreviations

CAN-DO-IT: conceptualize scope, acquire expertise, navigate platform and strategy, develop ad content, optimize recruitment workflow, implement campaign, track, and respond
EDIPT: emphasize, define, iterate, prototype, and test
HCD: human-centered design
IRB: Institutional Review Board
LGBTQ+: lesbian, gay, bisexual, transgender, and queer/questioning
REDCap: Research Electronic Data Capture
SGM: sexual and gender minority
SHER: Sharing Health Educational Resources

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Original Paper

Video-Based Gait Assessment Using Machine Learning to Classify Age and Sex in Low-Resource Settings: Cross-Sectional Study

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Abstract

Background: Gait assessment is an important tool for evaluating health risks in older adults but remains underused in low-resource settings. We explored the feasibility of using a low-cost, simple walking protocol with smartphone video capture to extract health-related gait signals by classifying sex and age. Sex and age are fundamental biological factors linked to most health- and aging-related outcomes. Establishing baseline classification performance provides justification for future exploration of more complex health-related conditions using this protocol.

Objective: This study aimed to assess whether pose parameters derived from smartphone-based gait videos can be used by machine learning models to classify age and sex.

Methods: A cross-sectional study was conducted with 155 participants (Thailand: n=59, 38.1%; India: n=96, 61.9%). Participants performed a simple walking protocol while being recorded using smartphones. Pose estimation was conducted using the MediaPipe algorithm to extract 109 features related to joint distances, angles, and walking speed. For feasibility assessment, we calculated the proportion of recordings for which pose estimation could be extracted. Elastic-net logistic regression and histogram-based gradient boosting classifiers were used for analysis. Model performance was evaluated using 5-fold cross-validation. Outcomes were sex (male vs female) and age group (aged<65 vs ≥65 y).

Results: Pose parameters were successfully extracted from 145 (93.5%) of the 155 video recordings. Among the 145 participants, 94 (64.8%) were female, and 55 (37.9%) were aged 65 years or older. The 2 analytic models demonstrated comparable performance. Sex classification achieved a maximum mean area under the receiver operating characteristic curve of approximately 0.90 (SD 0.06), whereas age classification achieved a maximum mean area under the receiver operating characteristic curve of approximately

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0.70 (SD 0.09). Classification performance was primarily influenced by the number of features used, clothing characteristics, and the quality of pose estimation.

Conclusions: This simple smartphone-based gait assessment protocol was able to extract meaningful pose parameters and classify biological features (age and sex). Further studies are warranted to evaluate its potential utility for disease screening, risk stratification, and longitudinal health monitoring.

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KEYWORDS

gait assessment; smartphone video recording; machine learning; age and sex classification; low-resource setting

Introduction

Older people face substantial unmet health care needs globally [1]. Health problems specific to older people include geriatric syndromes, such as frailty, sarcopenia (muscle loss), and falls, as well as neurodegeneration and multimorbidity [2,3]. These conditions account for substantial loss of quality-adjusted life years as well as economic costs, and their burden is increasing rapidly in the context of population aging [4]. Solutions for scalable geriatric screening and treatment services are urgently needed [5].

The biological processes of aging involve functional decline of various physiological systems, including the musculoskeletal, cardiopulmonary, and neurological systems, impeding the performance of usual functions, such as walking [6]. In geriatric medicine, gait assessment (assessment of how a person walks) is a gold-standard approach for risk-stratifying older patients and screening for a range of health conditions, including risk of falling [7]; frailty; malnutrition [8]; and early symptoms of neurodegenerative disorders, such as dementia [9] or Parkinson disease [10].

Typically, in clinical practice, gait is assessed by clinicians using a battery of simple tests and measurements, which can include walking speed, the Timed Up and Go test, the dynamic gait index, functional ambulation classification, and gait abnormality rating scale [11]. However, gait assessment is generally underused in primary care for assessing aging-related conditions [12]. Barriers to using gait assessment tools include patients' personal factors (level of education, priority, and physical function), environmental factors (eg, lack of training and facilities, time taken to complete, and cost), and measure-specific factors (eg, subjectivity in gait scoring and lack of recognized population-appropriate tools) [12,13]. In many low-resource settings, this is compounded by a lack of geriatricians and training of primary care physicians in geriatric health issues.

Although technology-driven gait analysis has been widely explored, most studies rely on laboratory settings that require green screens, reflective markers, multiple camera angles, high-resolution recording, and specialized analysis software [14-16]. These requirements make such methods impractical for addressing the diagnostic gap in low-resource or rural health care settings.

A low-cost, automated gait assessment tool could provide a scalable solution to support or replace conventional gait assessments typically performed in clinical practices, particularly in low-resource or rural health care settings [12]. Smartphones are a low-cost and near-ubiquitous technology capable of gathering movement-related information via video recording and sharing this remotely via mobile internet [17]. In health care, machine learning (ML) models applied to high-dimensional data are increasingly capable of assisting or automating clinical diagnoses [18]. Several studies have applied ML to videos acquired in specialized gait laboratories to automatically classify certain diseases and gait abnormalities [19,20]. Smartphones have been used to enhance observational gait analysis among children with cerebral palsy [21]. However, to our knowledge, the potential of using smartphone videos of people walking in free-living environments to automatically characterize aging-related phenotypes, such as healthy aging, frailty, and fall risk, has not been explored.

In this study, we presented a simple walking protocol and an analytic pipeline for extracting gait features from a smartphone video to train ML models to classify aging-related characteristics. We demonstrated proof of concept by using our pipeline to classify the age and sex of participants from 2 distinct geographic settings in India and Thailand. Age and sex are important biological factors linked to most health- and aging-related outcomes. Establishing this baseline performance justified the exploration of more complex health-related conditions using our protocol.

The specific objectives of this study were to (1) establish the feasibility of deriving pose parameters from simple gait assessment protocols based on smartphone videos and (2) assess the ability to differentiate participant age and sex using ML techniques applied to these derived pose estimates.

Methods

Study Design, Setting, and Population

A cross-sectional study was conducted in community and primary care sites in India and Thailand, respectively. In India, data were collected in chronic disease screening clinics conducted in 29 villages near Hyderabad. These clinics were part of the fourth follow-up wave (2022-2023) of the Andhra Pradesh Children and Parents' Study (APCAPS) cohort study and included participants aged 45 years or older, details of which have been described elsewhere [22]. We excluded participants who were unable to walk independently, such as individuals requiring a wheelchair, walking aid, or assistance from another person for locomotion.

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In Thailand, participants were recruited from a geriatric clinic at the Faculty of Medicine, Chiang Mai University Hospital, from May 13, 2022, to November 30, 2022. Participants visiting the clinic usually had at least 1 chronic noncommunicable disease (eg, essential hypertension, type 2 diabetes, and dyslipidemia). We invited all patients attending the clinics, with the same exclusion criteria as mentioned in India. Basic demographic data consisting of age, sex, body weight, and height were collected.

Ethical Considerations

The study protocol was approved by the ethics committees of Indian Council of Medical Research–National Institute of Nutrition (CR/1/V/2023), India; the London School of Hygiene and Tropical Medicine (21771/RR/19113), United Kingdom; and the Research Ethics Committee Panel 5, Faculty of Medicine, Chiang Mai University (study code: FAM-2565-08949), Thailand. All procedures were conducted in accordance with the ethical standards of the respective institutional review boards and the World Medical Association Declaration of Helsinki.

Written informed consent was obtained from all participants before study participation. Participants were informed of their right to withdraw from the study at any time without consequence. All identifying information was removed before analysis, and no personally identifiable information is presented in this publication. Participants received monetary compensation for their participation. In Thailand, participants received 250 Baht (US $6.5).

Simple Walking Protocols

The simple walking protocol was designed to mirror commonly used clinical gait tests, such as the 10 Meter Walk Test, where patients are timed while walking a distance of 10 m [23], or the Timed Up and Go test, where participants are asked to stand and walk 3 m then turn around and walk back (6 m in total) [24]. For our protocol, patients were asked to walk for 5 to 6 m in a straight line, with a 1- to 2-m walk-in period before recording the videos. The camera was placed 3 to 5 m perpendicular to the midpoint of the walking path. The camera was set between 105 and 130 cm above the ground, such that the whole height of the participant could be captured during the entire 5 to 6 m walking distance (Figure 1). We allowed slight flexibility in the protocol to accommodate different settings where space to conduct this assessment was limited. The detailed protocol and devices used for each site are summarized in Table 1. Participants were allowed to wear any type of clothing without restrictions. Participants were positioned behind the starting line. Video recording was manually initiated immediately before signaling the participant to walk and was maintained for the duration of the walking protocol.

Figure 1. Simple walking protocol.

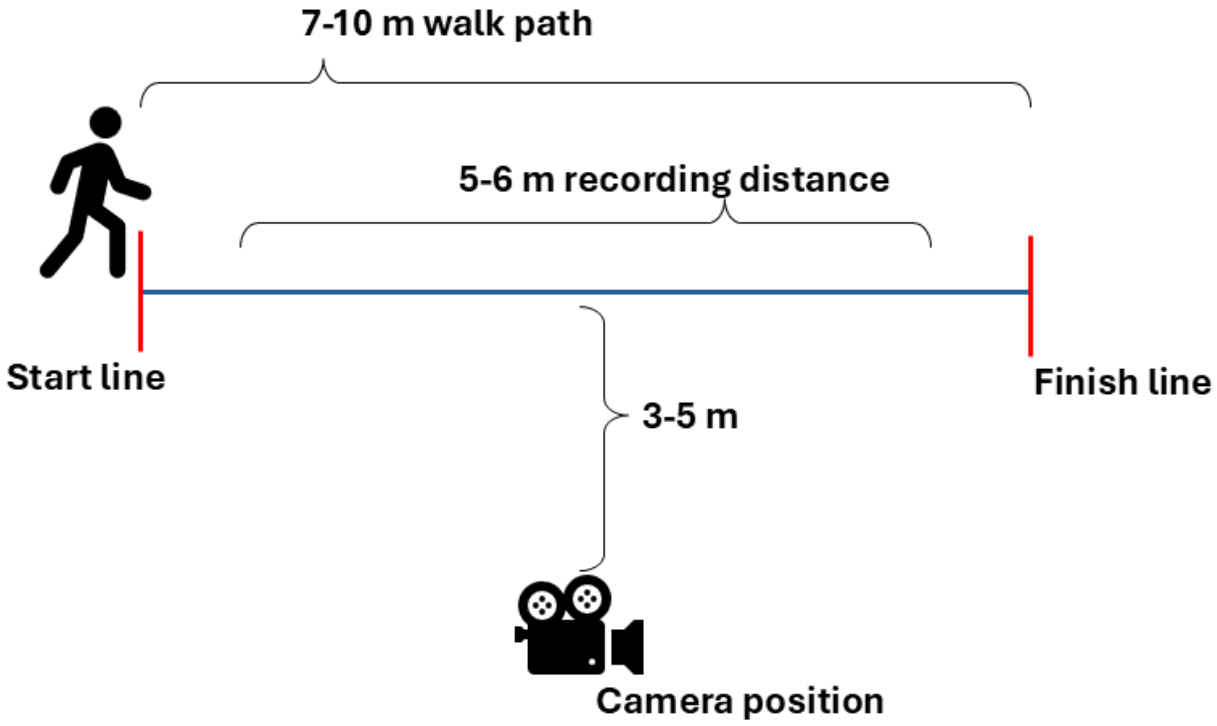

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Table 1. The protocol and devices used for each site.

	Thailand	India
Walking in distance (m)	7	10
Video recording distance (m)	5	6
Camera height (from the ground; cm)	105	130
Recording devices used	Samsung Galaxy Tab S6 Lite	Samsung Galaxy Tab A7
Resolution	720p	1080p
Frame rate (Hz)	30	30

Pose Estimation and Gait Cycle Extraction

We applied an open-source pose estimation algorithm, MediaPipe (Google LLC) [25,26], in 2D mode to all video recordings. MediaPipe is an artificial deep neural network algorithm that allows estimates for 33 joints (Figure 2). To identify the gait cycle, we calculated the absolute distance between the left and right ankles. We identified a gait cycle as a time interval of 3 consecutive time points at which the distance between the left and right ankles was 0. In practice, time points at which the distance is exactly 0 are rare due to noise in pose estimations. Therefore, we used time points when the distance was at the extreme local minimum instead of 0. We extracted pose positions only in the second gait cycle, so the pose estimations were not affected by being on the edge (beginning) of the video.

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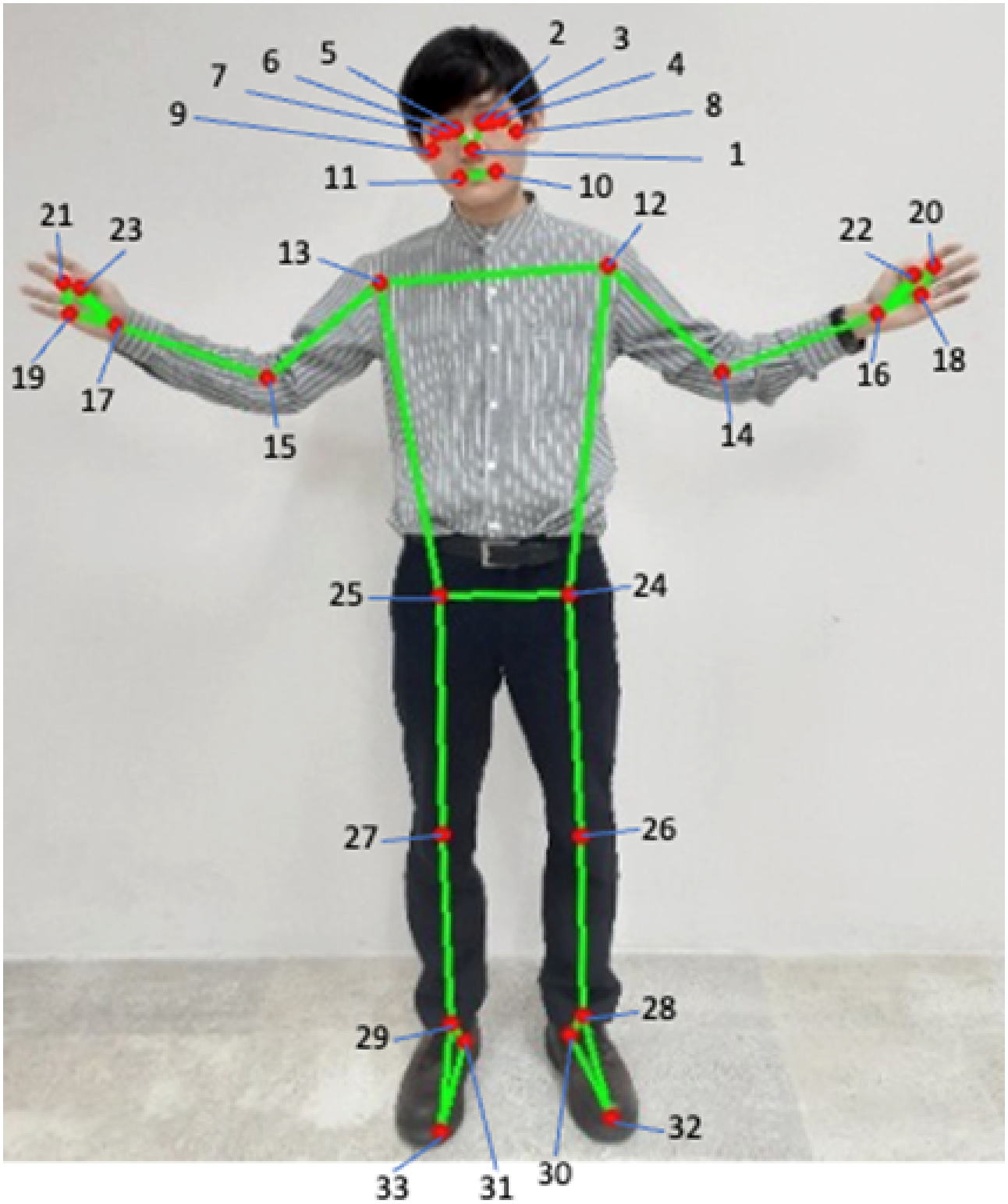
Figure 2. Pose estimates using the MediaPipe algorithm. 1: nose; 2: left eye inner; 3: left eye; 4: left eye outer; 5: right eye inner; 6: right eye; 7: right eye outer; 8: left ear; 9: right ear; 10: mouth left; 11: mouth right; 12: left shoulder; 13: right shoulder; 14: left elbow; 15: right elbow; 16: left wrist; 17: right wrist; 18: left pinky; 19: right pinky; 20: left index; 21: right index; 22: left thumb; 23: right thumb; 24: left hip; 25: right hip; 26: left knee; 27: right knee; 28: left ankle; 29: right ankle; 30: left heel; 31: right heel; 32: left foot index; 33: right foot index.



Feature Extraction

We used the number of frames extracted from the second cycle as a surrogate feature for walking speed. Our method for feature extraction was adopted from a study by Ahmed and Sabir [27]. First, we calculated distances between 15 pairs of joints (Table S1 in Multimedia Appendix 1) in every frame in the second cycle of each participant. For the 15 distance features, we converted all distances in pixels to meters using an in-video reference object placed near the walking path. For participants from Thailand, reference object was a standard measuring tape of 1 m. For participants from India, it was the height of the orange traffic cone used to mark the walking path. Additionally, we extracted 12 different joint angle features (Table S2 in

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Multimedia Appendix 1) in every frame in the second cycle, as joint angles also provide information regarding health conditions [28-30]. In each participant and for each feature, we calculated the mean, SD, skewness, and kurtosis during the second cycle. This resulted in the extraction of 109 features: 108 joint-derived features and 1 walking speed surrogate feature.

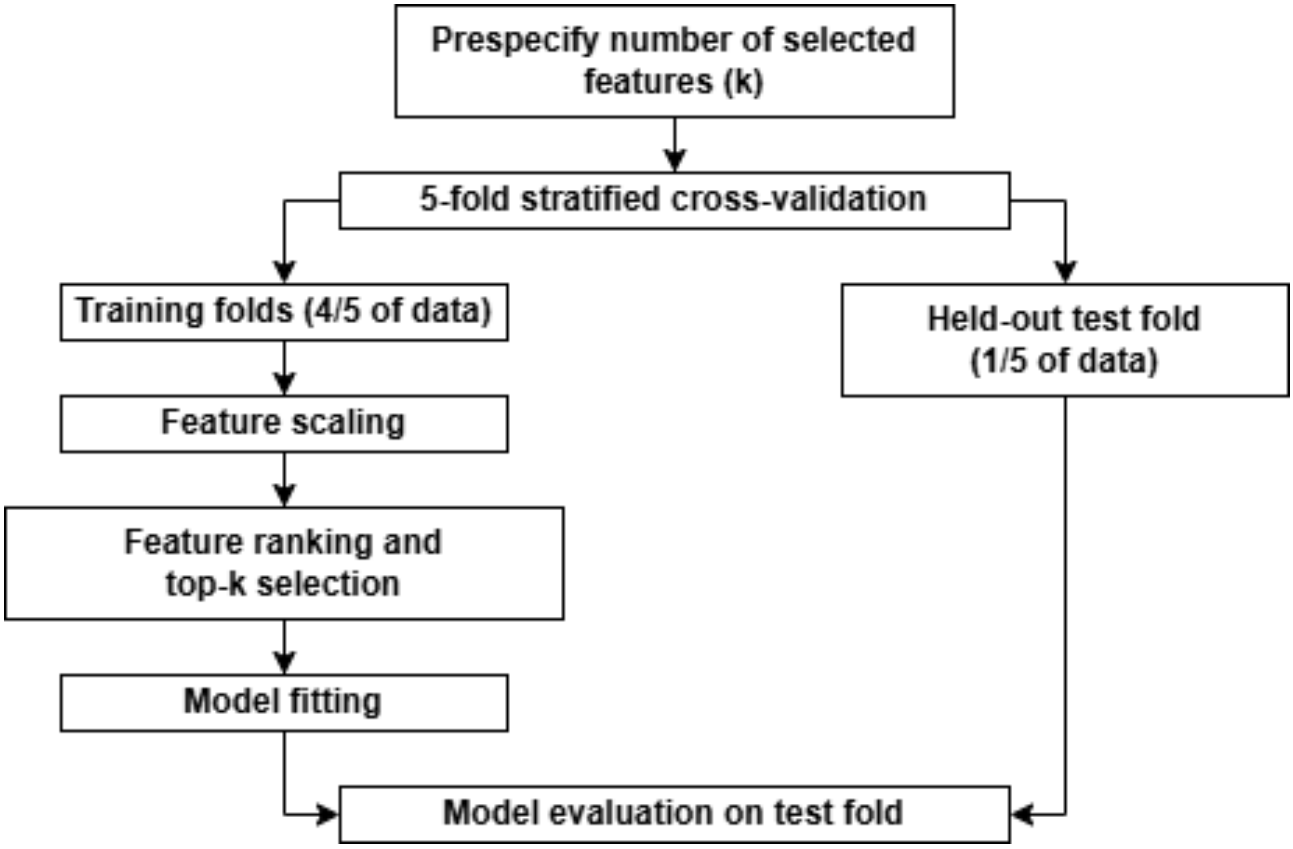
Data Analysis

Two binary outcomes were examined: (1) sex (male vs female) and (2) age group (<65 vs ≥65 y). Given the high number of features, model feasibility was explored by systematically varying the number of input features rather than fixing a single feature set. Before model training, the number of features to be used was prespecified and iteratively varied from 1 to 50. For each predefined feature subset size, the complete model training and evaluation pipeline was repeated independently.

Evaluation Strategies

As part of the feasibility assessment, we calculated the proportion of recordings for which pose estimation could be extracted. Model performance was evaluated using a repeated stratified cross-validation framework. Specifically, 5-fold cross-validation was used, with folds stratified by the outcome to preserve class proportions. This procedure was repeated 20 times using different random splits, yielding 100 resampled train-test evaluations for each feature subset size (Figure 3).

Figure 3. Evaluation strategies.



Feature Scaling, Ranking, and Selection

All data preprocessing and modeling steps—including feature scaling, feature ranking and selection, model fitting, and probability estimation—were performed entirely within each training fold and then applied to the corresponding held-out test fold. This strict separation was enforced to prevent information leakage between training and evaluation phases.

Within each training fold, continuous features were standardized using z score normalization based on the training data only. Feature ranking was then performed using an elastic net–regularized logistic regression (LR) model fitted to the scaled training data. The elastic net penalty combined L1 and L2 regularization (hyperparameter details are provided in Table S3 in Multimedia Appendix 1). To account for class imbalance during feature ranking, balanced class weights were applied. Features were ranked according to the absolute magnitude of their fitted regression coefficients. For each cross-validation fold and repetition, the top-ranked features corresponding to the predefined feature subset size were selected. Feature ranking and selection were recomputed independently for every fold and repetition.

Statistical Analysis and Evaluation Metrics

Two classification models were evaluated: (1) elastic-net LR, a linear classifier, was used as the baseline model for feasibility assessment and (2) a histogram-based gradient boosting (HistGB) classifier, a tree-based ensemble method, was used to probe potential nonlinear relationships in the data.

Both models were trained using only the selected features within each training fold. Balanced class weights (or sample weights, where applicable) were used to mitigate class imbalance.

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Hyperparameter specifications for both models are reported in Table S3 in Multimedia Appendix 1.

As an assessment of the acceptability of the simple gait protocol to derive biological features (age and sex), model discrimination performance was assessed using the area under the receiver operating characteristic curve (AUC-ROC), overall accuracy, per-class sensitivity, per-class F_1-score, and Matthews correlation coefficient (MCC).

Explore Factors Affecting Classification

To explore factors associated with classification, we conducted 5 sensitivity analyses.

First, classification performance estimates were aggregated across folds and repetitions to generate performance curves versus the number of features, allowing assessment of classification feasibility as a function of feature dimensionality.

Second, to explore how body shape may influence the classification performance, we stratified the performance metrics by BMI 25 kg/m^2 or greater and less than 25 kg/m^2, which served as a rough surrogate for body shape.

Third, we repeated the analysis by site subgroups (India and Thailand) to explore whether the pooling of the dataset from the 2 sites diluted the meaningful signals within, exploring the generalizability of the data collection protocol.

Fourth, we identified the 10 individuals for whom the models demonstrated good and poor performance. We qualitatively reviewed the walking videos and documented any factors that may contribute to poor pose estimation, such as clothing, environment, the alignment of the camera, and the quality of pose estimation.

Fifth, we plotted the distribution of the commonly selected features by outcomes to investigate whether the distribution of features differed by outcomes.

Results

Overview

A total of 155 videos were recorded (Thailand: n=59, 38.1%; India: n=96, 61.9%). Upon quality assessment and applying the pose estimation algorithm, we were able to extract pose parameters from 145 (93.5%) videos. In the remaining 10 (6.5%) videos, pose estimation failed due to incorrect joint estimations, often capturing nonhuman elements instead. In 1 case, there was an object that obstructed the participant's image. Of the 145 participants, 51 (35.2%) were from Thailand, and 94 (64.8%) were from India. In total, 94 (64.7%) participants were female, and 55 (37.9%) participants were aged 65 years or older (Table 2).

Table 2. Participant demographics.

	Total (N=145)	Thailand (n=51)	India (n=94)
Female, n (%)	94 (64.8)	33 (64.7)	61 (64.9)
Age, median (IQR)	50 (48-69)	64 (29-67)	50 (49-70)
Aged ≥65 y, n (%)	55 (37.9)	22 (43.1)	33 (35.1)
BMI, median (IQR)	22.96 (19.84-26.40)	23.26 (20.13-27.58)	22.70 (19.73-25.13)
BMI ≥25, n (%)	51 (35.2)	21 (41.2)	30 (31.9)

Performance for Sex Classification

Using 5 features, both models demonstrated good discriminative ability, achieving area under the curve (AUC) values above 0.8. Increasing the number of selected features to 15 further improved discrimination, with AUC values approaching 0.9 for both models (Figure 4).

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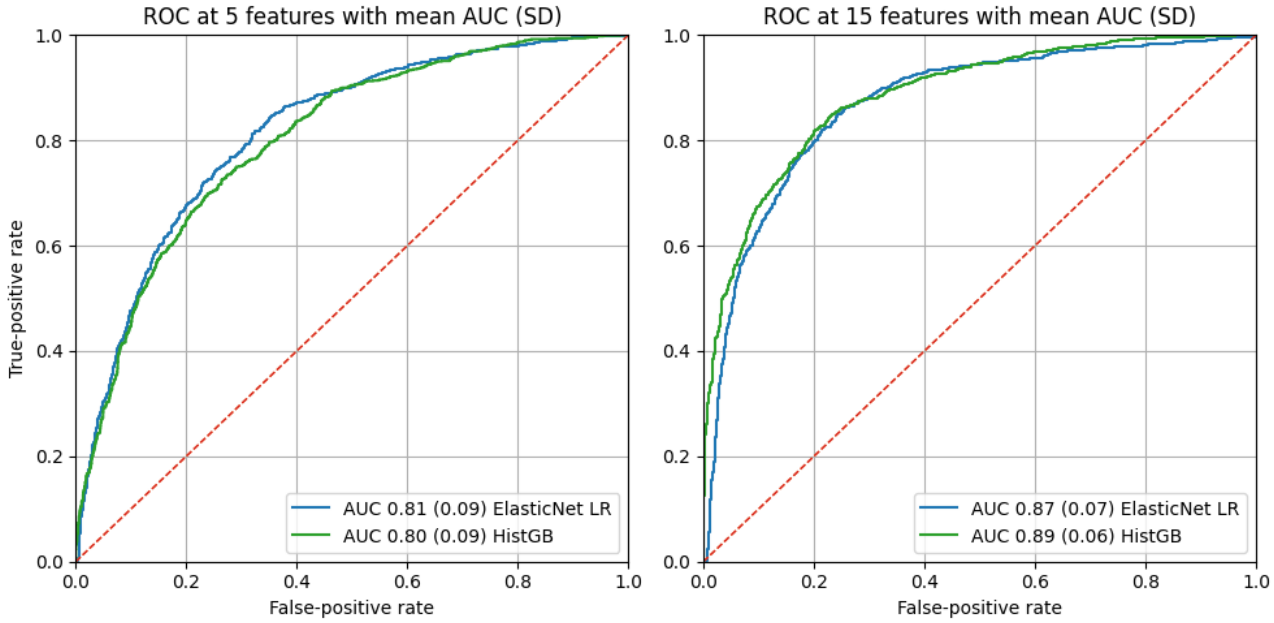
Figure 4. Performance for sex classification. AUC: area under the curve; HistGB: histogram-based gradient boosting; LR: logistic regression; ROC: receiver operating characteristic.

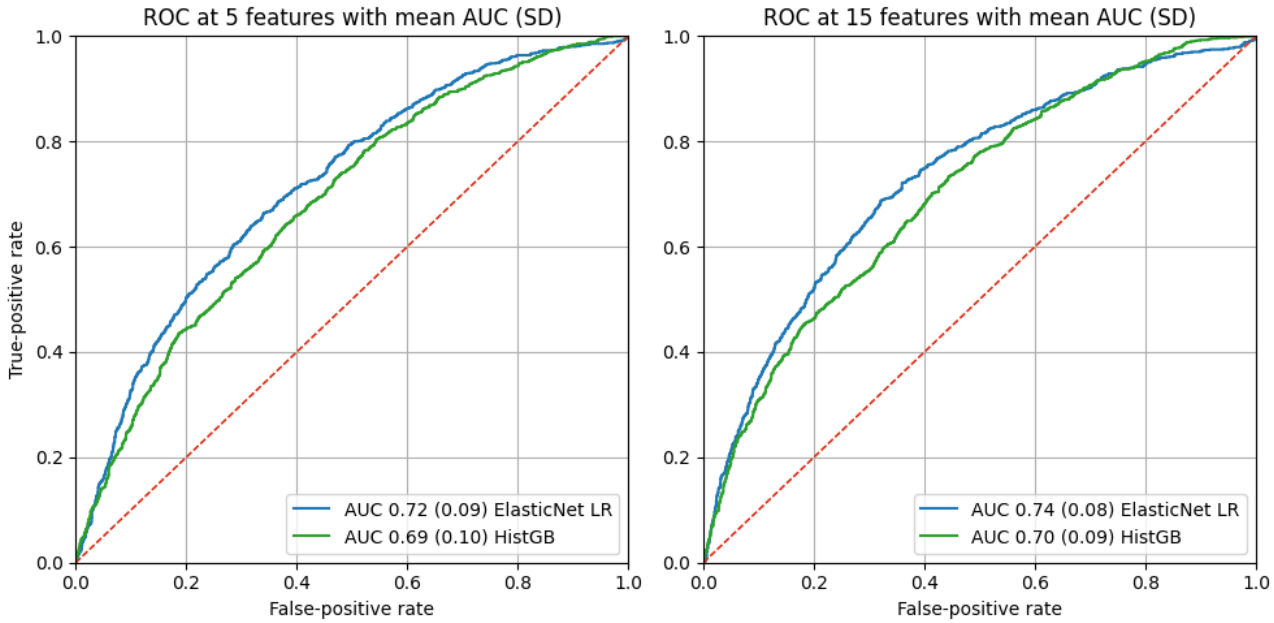


Detailed results for additional evaluation metrics of sex classification across all feature subset sizes are presented in Figure S1 in Multimedia Appendix 1.

Performance for Age Classification

Using 5 selected features, both models demonstrated modest discriminative performance. ElasticNet LR achieved a mean AUC of 0.72 (SD 0.09), while HistGB achieved a mean AUC of 0.69 (SD 0.10). Increasing the number of selected features to 15 resulted in a small but consistent improvement in discrimination, with mean AUC values increasing to 0.74 (SD 0.08) for ElasticNet LR and 0.70 (SD 0.09) for HistGB (Figure 5).

Figure 5. Performance for age classification. AUC: area under the curve; HistGB: histogram-based gradient boosting; LR: logistic regression; ROC: receiver operating characteristic.



Detailed results for all evaluation metrics across feature subset sizes are presented in Figure S1 in Multimedia Appendix 1.

Exploration of Factors Affecting Classification

Number of Features

Performance metrics stratified by the number of features used suggested a strong influence of the number of features in sex classification when fewer than 10 features were used but only had a weak influence on age group classification (Figure S1 in

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Multimedia Appendix 1). Across the full range of feature subset sizes (top-k=1-50), AUC-ROC increased rapidly from approximately 0.6 with a single feature to nearly 0.9 at approximately 10 features, after which performance plateaued. HistGB consistently achieved slightly higher AUC-ROC values than ElasticNet LR, although the variability across resampling iterations overlapped. Other evaluation metrics—including accuracy, sensitivity, F_1-score, and MCC—exhibited similar patterns, with steep improvements at low feature counts and minimal gains beyond approximately 8 to 10 features. Sensitivity and F_1-scores were consistently higher for female classification than for male classification across both models. Overall, these metrics demonstrated convincing discriminative performance for feasibility evaluation (Figure S1 in Multimedia Appendix 1).

In contrast, for age classification, across the full range of feature subset sizes (top-k=1-50), AUC-ROC increased gradually from approximately 0.65 to 0.70 at low feature counts and plateaued after approximately 10 to 15 features at an AUC-ROC of 0.70 to 0.75, with only minimal gains thereafter (Figure S1 in Multimedia Appendix 1). ElasticNet LR consistently achieved slightly higher AUC-ROC values than HistGB across most feature levels, although the performance variability across resampling iterations overlapped. Other evaluation metrics exhibited similar patterns. Accuracy improved modestly with increasing feature counts and stabilized beyond approximately 10 features. Sensitivity and F_1-scores were consistently higher for younger adults than for older adults across both models, while performance for older adults remained lower and more variable. MCC values increased slightly at low feature counts but remained relatively low overall. The metrics reflected the limited discriminative separation between age groups (Figure S1 in Multimedia Appendix 1).

BMI Measurements

In both sex and age classification, the graphs generally showed slight separation of performance metrics between the 2 groups (Figures S2 and S3 in Multimedia Appendix 1). The models tended to perform slightly better for individuals with higher BMI (>25 kg/m^2) for age-sex classification but lower in age classification. Revealing that there is the possibility that the shape of a person may have an effect on modifying, although to a small degree.

Variability in Data Collection Between Sites

Rerunning the model training and evaluation separately by site (Thailand and India; Figures S4-S7 in Multimedia Appendix 1), the performance metrics in the Thailand dataset showed a similar pattern when compared to the pooled dataset in both classes. AUC-ROC for sex classification increased in the first 5 features, then plateaued at about 10 features at a value just under 0.90 in both analysis models. While in age classification, the AUC-ROC slightly increased in the first 5 features, then plateaued at about 10 features as AUC-ROC of just under 0.70. These patterns were observed in other performance metrics as well (Figures S4 and S6 in Multimedia Appendix 1).

For the India dataset, for sex classification, similar patterns compared to the pooled dataset were found; however, at the plateau, the performance reached slightly higher compared to the pooled dataset at approximately AUC-ROC of 0.90 in ElasticNet LR and 0.95 in the HistGB model. For age classification, the prediction performance started low at an AUC-ROC of approximately 0.60 to 0.65, then gradually increased to more than 0.75 at 50 features. These patterns were observed in other performance metrics from the India dataset as well (Figures S5 and S7 in Multimedia Appendix 1).

Qualitative Exploration

For sex prediction, the 5 individuals with the worst prediction for sex were all male, while the top 5 were all female. For age prediction, a similar trend emerged in that the 10 best predictions occurred in individuals younger than 65 years (and they were all female). In comparison, 9 of the 10 worst predictions occurred in individuals aged 65 years and older (5 male and 5 female). A qualitative review of videos revealed that among those for whom the model performed poorly, there were some jitters in the pose estimations among those with male skirts or trousers (Tables S4 and S5 in Multimedia Appendix 1).

Distribution of Commonly Selected Features

Exploring the distribution of the commonly selected features demonstrated that for sex discrimination, the distribution of many of the selected features varied by sex (Figure S8 in Multimedia Appendix 1). However, for age discrimination, there was a more substantial overlap in the distribution of the features commonly selected (Figure S9 in Multimedia Appendix 1).

Discussion

Principal Findings

In this proof-of-concept paper, we demonstrated the feasibility of a simple standardized walking protocol. Our method enabled us to estimate poses and extract features from more than 93.5% (145/155) of the videos analyzed. Moreover, we demonstrated that there are signals that allow simple ML models to discriminate sex and age, important biological factors linked to most health- and aging-related outcomes, making a case for the exploration of more complex health-related phenotypes, building on the walk protocol and analytic pipeline in the future.

All classifiers produced by the proposed framework achieved a mean AUC-ROC of approximately 0.80 to 0.90 for sex prediction. Our model performance was similar to that of another study, which used inertial sensors (accelerometers and gyro sensors) to classify sex [31,32]. However, our method did not perform as well when compared to those using ultrawide band radar [33] or Kinect sensors [34], which reported accuracies exceeding 90%. It is likely that Kinect sensors and radar can more effectively capture gait parameters. Kinect sensors use at least 2 sensors (red, green, blue image and depth sensors) to provide information on joint positions [34], and radar sensors provide information on surface geometry and orientation of an individual [33], while inertial sensors only capture the body's acceleration and rotation data [31,32]. Any improvements in data collection or pose estimation—such as higher resolution cameras or enhanced pose estimation algorithms—could potentially improve the accuracy and stability of gait parameter

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measurements, thereby enhancing sex classification. This assumption is further supported by our observation that among individuals in whom the model performed poorly, significant joint position jitters were observed.

For age prediction, our method achieved a mean AUC-ROC of approximately 0.65 to 0.70. Another similar study that was conducted in 48 female individuals who were classified as young (aged 21-30 y) and older (aged 55-70 y) adults using a support vector machine–based model achieved an accuracy of more than 95% [35]. While our population differs from their dataset, which may limit direct comparability, their pose estimation data were captured using reflective markers and 8 synchronized digital infrared high-speed cameras. This setup likely produced higher-quality pose estimation compared to our method. This highlights that improving pose estimation quality could significantly enhance age prediction accuracy. Another possible explanation is that the relatively similar ages within our study population made it more challenging to discriminate between age groups.

Stratification of evaluation metrics by BMI demonstrated slight separation between individuals with high and low BMI. This suggests that BMI, or to an extent, body size and shape, should be accounted for to assess the true gait pattern. Qualitative assessment of walking videos suggests that, among the individuals in whom the ML model performed poorly, it was observed that all were wearing loose-fitting clothes. Thus, to improve the accuracy of pose estimates, we suggest that individuals should not wear very loose-fitting clothes for accurate pose estimation [36,37]. The distribution of the extracted features also overlapped, particularly for our age prediction model. This suggests that the other transformations could be applied to some features. They may improve the ability to discriminate biological factors (ie, age and sex) of the features. Additionally, ML models of time-series analysis, such as recurrent neural networks and long short-term memory networks, could be applied instead of the traditional model used in this study. However, those ML models would require large datasets and should be the objective of future studies.

Strengths and Limitations

There are strengths and limitations to our study. The main strength of this work is the ability to demonstrate the feasibility of using a simple and low-cost walking protocol using smartphone cameras to extract meaningful features in 2 diverse real-world settings with participants wearing typical clothes in primary care from India and Thailand. This very simple protocol could be implemented in a range of community settings or without specialist input. This study explored variations in performance between the 2 different settings, Thailand and India, which represented different ethnicities, general body shape, and clothing and were slightly different in the walking protocol. When stratified by site, both sites achieved similar or only slightly better discrimination metrics, which represents the robustness of our methods across diverse settings.

There were some limitations due to the small sample size. As demonstrated in the model performance analysis, it seems that the class imbalance problem occurred. Individuals from the majority class in the data are predicted more accurately than individuals from the minority class. Despite this, the models demonstrated reasonable discriminatory capability and did not merely default to predicting the more prevalent classes. The problem could be resolved with a more balanced and larger dataset in future work, which could also allow for different resampling methods to address this issue [38]. With a larger sample size, it is possible that the discriminatory performance could be improved, and other time-series analyses can be explored for better extraction of health-related signals [39].

Our feature extraction approach may be subject to measurement noise. Gait speed was estimated from the number of frames within a single gait cycle, which may not fully capture true walking speed. In addition, all features were derived from only 1 gait cycle. Given the inherent jitter and variability in pose estimation, reliance on a single cycle may introduce noise and reduce the stability of the extracted features, thereby affecting model performance.

Several aspects of the proposed video-based gait assessment protocol require further refinement to enhance signal quality and analytic performance. First, improvements can be made at the level of raw data acquisition by optimizing the walking protocol. This includes providing clearer guidance on clothing to avoid occlusion of key anatomical landmarks as well as exploring the use of alternative or multiview recording configurations, either in addition to or instead of a perpendicular view, to improve the robustness and accuracy of pose estimation.

Implications for Future Developments to Improve Performance in Clinical Applications

Signal detection and analytic methods warrant further development. Future work should examine the use of multiple gait cycles rather than restricting analysis to a single cycle to better capture within-person variability and temporal dynamics. In addition, comparative evaluation of different pose-estimation algorithms and feature-extraction strategies may help identify representations that are more sensitive to clinically relevant gait characteristics. Finally, while this study focused on relatively simple classification models to assess feasibility, more complex modeling approaches—such as deep neural networks, graph convolutional networks, or convolutional neural network–based architectures—may further improve performance as larger and more diverse datasets become available.

Conclusions

This simple smartphone-based gait assessment protocol was able to extract meaningful pose parameters and classify biological features (age and sex) and showed promising robustness for deployment in diverse real-world outpatient settings. Although these findings support its feasibility, several aspects of the walking protocol and analytic methods warrant further refinement, including optimization of data capture and feature extraction. Future research should evaluate the utility of this approach for disease screening, risk stratification, and longitudinal monitoring across broader clinical populations.

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Data Availability

The data supporting the findings of this study are not publicly available due to privacy concerns, as they include identifiable walking videos of study participants, but deidentified data from Thailand are available from the corresponding author on reasonable request, subject to ethical approval and data-sharing agreements. Deidentified data from the APCAPS cohort are made available for sharing with bona fide collaborating researchers (subject to the APCAPS terms and conditions for collaboration, which are designed to ensure compatibility with original study ethics and participant consents). Applications can be made by submission of a completed APCAPS Collaborator Request Form [40] to apcaps.crf@gmail.com.

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Conflicts of Interest

None declared.

Multimedia Appendix 1
Analyses of sex and age classification performance, feature characteristics, model hyperparameter specifications, and qualitative assessments across Thailand and India datasets.
[DOCX File , 8083 KB - formative_v10i1e76755_app1.docx]

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Abbreviations

APCAPS: Andhra Pradesh Children and Parents' Study
AUC: area under the curve
AUC-ROC: area under the receiver operating characteristic curve
HistGB: histogram-based gradient boosting
MCC: Matthews correlation coefficient
ML: machine learning

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Original Paper

Development of a Contextualized, Research-Based Flemish Assessment Framework for Digital Care, Assistance, and Support: Delphi Study

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Abstract

Background: The rapid evolution of digital technologies has transformed health, mental health, and social care, offering new modalities of digital care, assistance, and support through web-based platforms, mobile apps, extended reality, wearables, and artificial intelligence systems. Despite this proliferation, there is little consensus on what constitutes “high-quality” digital care. Challenges persist regarding data security, interoperability, accessibility, sustainability, and professional competence, whereas existing standards and regulations provide fragmented guidance.

Objective: This study aimed to develop a contextualized, consensus-based quality assessment framework for digital care, assistance, and support in Flanders, Belgium. For this purpose, perspectives across technology, organizational processes, and professional competencies were integrated.

Methods: The study used a multiphase design comprising (1) 10 expert interviews with Flemish government officials; (2) a narrative literature review of 303 peer-reviewed and gray literature sources; (3) a 3-round Delphi study with 50 experts across 5 domains (end users, facilitators, technology developers, deontology and ethics experts, and digital inclusion and media literacy experts); and (4) 4 complementary focus groups and 3 interviews with specialists in artificial intelligence, regulation, social work, mental health, and IT. The Delphi rounds gathered iterative feedback through open-ended elicitation, structured rating, and classification of quality criteria. Quantitative data were analyzed using descriptive statistics, whereas qualitative feedback was subjected to thematic analysis.

Results: A total of 50 experts participated in round 1, a total of 40 (80%) participated in round 2, and 27 (54%) participated in round 3. Round 1 generated 577 unique quality criteria, consolidated into 26 clusters organized under 3 pillars: technology, organization, and professional competencies. The relative importance across pillars was balanced (mean score 37.29, SD 12.38 for technology; 33.33, SD 10.39 for professional competencies; and 29.80, SD 10.45 for organizations). Accessibility, reliability, and safety ranked highest for the technology; vision, quality monitoring, and infrastructure ranked highest for organization; and support, digital competencies, and ethics ranked highest for professional competencies. The finalized framework included 112 criteria, of which 35 (31.3%) were designated as optional and 77 (68.8%) were designated as minimum requirements. Focus groups and interviews validated the framework’s comprehensiveness and usability, emphasizing proportional implementation, user centrality, and alignment with European Union regulations. Stakeholders highlighted the need for tools, training, and governance mechanisms to ensure adoption and sustainability.

Conclusions: This study produced a codeveloped, context-sensitive quality assessment framework that balances technological robustness, organizational readiness, and professional competence in digital care, assistance, and support. The framework can serve both as a quality safeguard and a developmental road map. Accompanying self-assessment and governance tools enhance

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practical applicability. Implementation success will depend on governmental support, resource allocation, and structured feedback loops. Future research should pilot the framework in real-world settings, assess its impact, and establish mechanisms for continuous updates to maintain relevance in a rapidly evolving digital landscape.

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KEYWORDS

quality assessment framework; digital; mental health; health; social work; care; professionals; organizations; Delphi study; technology; artificial intelligence; AI

Introduction

Background

The proliferation of digital technologies has had a profound impact on the health, mental health, and social care sectors in recent years [1-3]. Digital technologies are used in services ranging from stand-alone online interventions to blended models that combine digital and face-to-face encounters, and they leverage a diverse toolset (eg, web-based platforms, mobile apps, extended reality, wearables, and artificial intelligence [AI]–enabled systems) for individuals; families; and specific groups such as children, youth, older adults, and persons with disabilities [4,5]. Therefore, the scope of their application is very broad, encompassing different topics, diseases, populations, and technologies. We use the umbrella term "digital care, assistance, and support" to refer to this integration of digital technologies into the provision, facilitation, or enhancement of health, mental health, social, and family-related services.

Because of their omnipresence in our current society, digital technologies are often also promoted as possible solutions to systemic issues in the health, mental health, and social care sectors, such as unmet needs, resource shortages, and personalized care [6,7]. However, their adoption does not come without barriers and challenges [8]. A major concern is safeguarding the quality and reliability of these technologies, which is often complicated by the rapid pace of technological innovation [9]. Key considerations include data security, system interoperability, accessibility for diverse user groups, and the sustainability of digital platforms [10]. Moreover, professionals must be specialized to effectively use these technologies as digital modalities often require additional competencies compared to in-person care [11]. For example, delivering online mental health therapy demands skills in digital communication, privacy management, and remote engagement. Furthermore, organizations and their managers also experience challenges implementing digital care, assistance, and support [12], for instance, organizing technical support for their professionals and end users.

Although European countries can fall back on a plethora of guidelines, regulations, certifications, and assessments, such as the International Organization for Standardization (ISO) guidelines, European Medical Device Regulation (MDR), European Union (EU) AI Act, and General Data Protection Regulation (GDPR) [13-15], there is no consensus on what really constitutes high-quality digital care, assistance, and support.

In addition, it often remains unclear how such quality requirements can be translated into everyday practice by the different actors involved in digital care, assistance, and support. Therefore, the framework developed in this study was intended not only as an assessment instrument but also as a practical guide for multiple user groups within the field. It can support professionals in reflecting on and improving digitally mediated practices; developers in designing and refining technologies in line with sector-specific quality expectations; and policymakers and organizations in shaping implementation, decision-making, and quality governance. In this way, the framework was conceived as a shared point of reference for the development, implementation, and evaluation of digital care, assistance, and support.

The need for such contextualization is particularly relevant in Belgium, where the organization of care, welfare, and support spans multiple policy and practice levels. In this study, we focused on Flanders because the framework was commissioned by the Flemish government and intended for use within the Flemish policy and practice context. This choice reflected the governance, organizational, and implementation setting in which the framework was meant to operate. The framework should also be distinguished from the Belgian validation pyramid for mobile health, which primarily supports the validation of and reimbursement for mHealth apps [16]. In contrast, this study aimed to develop a broader quality assessment framework for digital care, assistance, and support across a wider range of technologies, settings, and target groups. At this stage, the framework is intended primarily to support self-assessment, quality improvement, implementation, and governance in practice; any future reimbursement or formal policy applications fall outside the scope of this study.

Objectives

Therefore, the primary objective of this study was to codevelop a consensus-based quality assessment framework for digital care, assistance, and support contextualized to practice in Flanders, Belgium. This focus reflected both the Flemish policy context in which the study was commissioned and the Flemish practical setting in which the framework was intended to be implemented. We pursued this objective through a literature review, a 3-round Delphi process, and stakeholder engagement via interviews and focus groups.

Methods

Study Design

The study consisted of 4 phases (Figure 1). First, 10 expert interviews were conducted with officials from the Flemish

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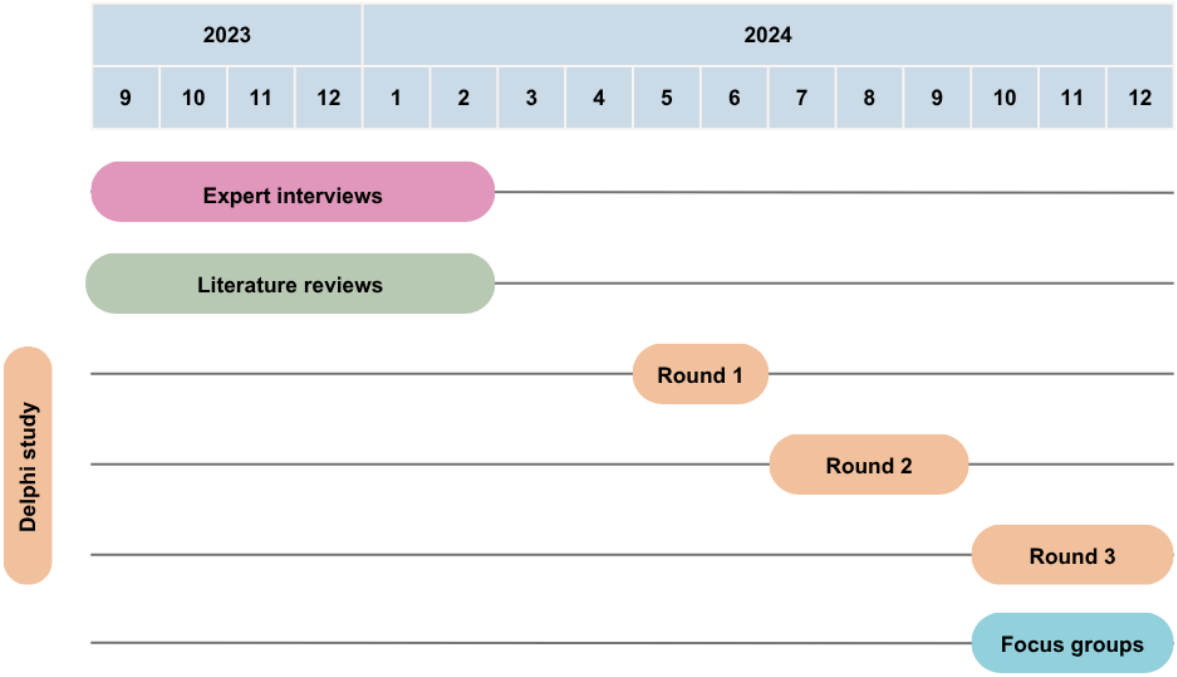
government, complemented by a narrative review of peer-reviewed and gray literature sources at the regional, national, and international level. Using this as a starting point, we subsequently conducted a 3-round online Delphi study that aimed to develop a consensus across a diverse panel of experts via an iterative, anonymous, and structured process with controlled feedback [17]. A full draft of the quality assessment framework was also presented and critically appraised in in-depth focus groups and follow-up interviews with specialists in AI, regulation, social work, mental health care, and IT.

Figure 1. Timeline of the framework development phases.



Expert Interviews

The preparatory phase commenced with semistructured online interviews with 10 experts from the Flemish government's policy domain welfare, public health, and family. Participants were recruited within the steering committee of the project. The interviews focused on ongoing initiatives and anticipated needs within digital care, assistance, and support.

Literature Review

In parallel with the interviews, we conducted an exploratory literature search between September 2024 and October 2025 to identify relevant peer-reviewed studies, regulatory documents, and other contextual sources. We searched bibliographic databases, including PubMed, Web of Science, and Scopus, using broad keyword combinations related to digital health, digital mental health, implementation evaluation, and digital competencies. The search strings included the following: ("digital health" OR eHealth OR mHealth OR "health app*" OR "mental health app*") AND (evaluation OR assessment OR quality OR framework OR usability); ("digital mental health" OR "e-mental health" OR telepsychotherapy OR "online psychotherapy" OR "video consulting") AND (implementation OR ethics OR accessibility OR regulation OR review OR sustainability OR adoption); and ("digital competenc*" OR "digital skill*" OR "digital literacy") AND ("social worker*" OR "health care professional*" OR clinician* OR therapist*).

This search was complemented with gray literature, including institutional websites, policy documents, and selected practice-oriented materials, to help contextualize the academic literature and address differences in the availability of quality assessment publications across subfields of digital care, assistance, and support. The aim was two-fold: (1) to determine a limited number of frameworks that could offer a starting point for the all-encompassing quality assessment framework and (2) to find additional relevant sources that have the potential to contextualize and tailor these frameworks to end up with an all-encompassing quality assessment framework.

Delphi Study

Participant Recruitment

A 3-round online Delphi study was set up to which 87 Flemish experts were personally invited. These experts were selected following an exploratory search and included to ensure stakeholder diversity across the following domains: (1) end users, (2) facilitators, (3) digital technology developers, (4) deontology and ethics experts, and (5) digital inclusion and media literacy experts. One reminder followed the initial invitation. Of the 87 invitees, 54 (62.1%) accepted, with each domain represented. They were subsequently asked to partake in each of the 3 rounds scheduled between May 2024 and January 2025. Each participant who completed round 1 was invited to every subsequent round.

Round 1

Participants were asked to respond to an open-ended prompt on what constitutes high-quality digital care, assistance, and support, deliberately without predefined criteria to capture the widest possible range of perspectives. Participants then organized their own proposed criteria by mapping them onto

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the study's 3 conceptual pillars: technology, organization, and professional competencies. Subsequently, they provided meta-feedback on the 3-pillar structure (including suggestions for alternative subdivisions) and completed a 100-point allocation exercise across the pillars to indicate their perceived relative importance.

Additionally, various possible typologies of digital care, assistance, and support were discussed to structure the different quality criteria. As an example, participants were presented with the risk assessment of the EU AI Act and with the extent of professional human of involvement as defined in the ethical guidelines for technology-based suicide prevention programs to structure the quality criteria [14,18]. This led to a broader question: "Are there other typologies that can help differentiate between varying levels of quality criteria?"

Round 2

Round 2 invited participants to provide feedback on the introductory vision statement, which articulates the 3 pillars and foregrounds the user's role in the quality assessment framework for digital care, assistance, and support. Participants identified strengths, weaknesses, and missing elements to refine the statement. Next, we presented the full set of criteria with definitions. Experts assigned each criterion to 1 of the 3 pillars: technology, organization, or professional competencies. Moreover, they were asked to allocate points to indicate each criterion's perceived importance.

Finally, we examined a proposed typology for the criteria structured along 2 axes: degree of interactivity and level of risk assessment as this resulted from the previous round (see the Results section). The resulting matrix comprised 9 categories, each representing a distinct combination of these dimensions. Experts evaluated the usefulness and validity of this categorization for differentiating between levels of quality criteria.

Round 3

In round 3, the experts received the complete draft of the quality assessment framework, comprising (1) an introductory text articulating the vision (rationale, context, and explanatory notes), (2) an itemized list of 119 criteria mapped to the 3 pillars, (3) a section on cross-pillar interdependencies, and (4) user guidance on applying the framework.

Participants engaged with the draft in 2 ways. First, they provided annotated textual feedback on content, structure, and wording. Second, they reflected on the relevance of each criterion. For this reflection, they categorized each criterion as either minimum, meaning essential to ensure quality; optional, meaning desirable but not strictly necessary; or unnecessary, meaning that it could be omitted without compromising quality. In addition, open-ended questions probed the framework's purpose and structure, clarity and completeness, implementation feasibility, and contextualization.

Finally, we circulated the finalized framework (Multimedia Appendix 1) to all experts. Via an online form, participants were asked to indicate whether they agreed with the current version of the framework.

In-Depth Focus Groups and Interviews

In parallel with round 3 of the Delphi process, online focus groups and individual interviews were conducted to test topic-specific coverage and implementation issues alongside the Delphi study. Participants were selected for their relevant expertise and involvement in digital care, assistance, and support across policy, practice, technology, and ethics or legal domains.

Before their session, participants received the draft framework and provided annotated comments; completed the "minimum," "optional," or "unnecessary" classification used in the Delphi study; and answered brief open-ended questions. Sessions opened with informed consent and a short overview of the framework, followed by a structured discussion on (1) comprehensibility (goals, structure, and wording), (2) completeness and consistency of the criteria (including ethical and legal aspects), and (3) implementation feasibility (roles, support needs, and tools). Recordings, annotations, and researcher notes were collated into session summaries; where changes to the framework were warranted, they were implemented and explicitly flagged when diverging from the original source frameworks.

Analyses

For the expert interviews, a thematic analysis was conducted. Additionally, the results of the literature review were derived using an exploratory thematic analysis in Citavi (Swiss Academic Software GmbH) [19], complemented by a categorization based on source type, thematic focus, geographical scope, and data characteristics. The various rounds of the Delphi study were assessed through a combination of thematic analysis, clustering techniques, and descriptive statistical methods.

Ethical Considerations

Ethics approval from a medical ethics committee was not required under Belgian national law as operationalized by the Ethics Committee Research University Hospitals Leuven/KU Leuven [20]. All participants provided informed consent for each data collection wave of the Delphi study and before each focus group. All participants who wished to receive a voucher of EUR €30 (US $34.76) for Bol, a Dutch-Belgian online retail platform, were provided with one after completing their participation. Data were processed in accordance with the GDPR [15] and in line with the privacy policy of Thomas More University of Applied Sciences [21].

Results

Expert Interviews

The semistructured online interviews with 10 government experts found respondents calling for clearer regulation, guidance, and a coherent framework. They also stressed the need to preserve room for locally tailored digital services. Experts widely judged the current approach to be insufficient, citing gaps in knowledge and expertise, limited support, and the absence of an overarching framework. Key concerns concentrated on legal compliance (eg, GDPR) and secure communication. They furthermore stressed accessibility and

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inclusiveness as nonnegotiable quality criteria, noting barriers related to language, culture, age, disability, and digital literacy. Collectively, the findings pointed to the need for a practical, inclusive, and codeveloped framework with service providers that accounts for sector-specific contexts and diverse target groups.

Literature Search

In the subsequent literature search, 303 sources were identified and coded by source type, thematic focus, geographic scope (regional, national, and international), and data characteristics (Multimedia Appendix 2). From this, 3 overarching pillars emerged to structure the draft framework: technology, organization, and professional competencies. As became clear from the literature and the interviews, the quality of digital care, assistance, and support depends not only on the quality of the technology but also on its contextualization and on the training of professionals. To substantiate each pillar, we anchored the draft in three established source frameworks: (1) ISO/TS 82304-2:2021, "Health software—Part 2: Health and wellness apps," an internationally recognized ISO framework for assessing the quality and reliability of health apps; (2) the organization domain of the Health Technology Assessment Core Model, a European framework developed within the European Network for Health Technology Assessment to address organizational conditions, workflows, and implementation factors relevant to health technologies; and (3) the framework for digital competences of professional social workers, a practice-oriented framework developed in the Flemish and Belgian social work context that specifies the digital competencies required for blended and digitally supported professional practice [12,22,23].

These 3 source frameworks were selected because they are established and authoritative within their respective domains; are recognized at the international, European, or local professional field level; and provide a sufficiently strong conceptual and empirical basis for developing a framework tailored to the broader Flemish context of care, assistance, and support.

Delphi Study

Participant Characteristics

The first Delphi round resulted in 57.5% (50/87) of responses. Table 1 provides an overview of the distribution of expertise among the respondents. As previously mentioned, all experts who participated in the first round were invited to subsequent rounds. The response rate in the second round was 80% (40/50), which declined to 54% (27/50) in the third round.

Table 1. Number of participants taking part in each round and the responses per round, with an additional breakdown within each round of the different areas of expertise and their percentages.

Expertise	Invited experts (n=87), n (%)	Delphi round 1 (n=50), n (%)	Delphi round 2 (n=40), n (%)	Delphi round 3 (n=27), n (%)
End users	22 (25.3)	10 (20)	5 (12.5)	4 (14.8)
Facilitators	20 (23)	10 (20)	11 (27.5)	7 (25.9)
Technology developers	19 (21.8)	13 (26)	10 (25)	8 (29.6)
Deontology experts	18 (20.7)	12 (24)	9 (22.5)	7 (25.9)
Digital inclusion and media literacy experts	8 (9.2)	5 (10)	5 (12.5)	1 (3.7)

In addition to the Delphi study, 4 focus groups and 3 individual interviews were conducted. The focus group with members of the steering committee included 11 participants, the ethics and legal focus group had 5 participants, the information and communications technology developer focus group consisted of 4 participants, and the well-being professional focus group included 5 participants.

Round 1

The open-ended elicitation yielded 577 distinct criteria from 50 participants. After thematic analysis, these were consolidated into 26 clusters and cross-checked against insights from the literature study.

In the 100-point score allocation exercise to indicate the relative importance of the 3 pillars, the distribution was broadly balanced: the technology pillar was considered the most important (mean 37.29, SD 12.38), followed by professional competencies (mean 33.33, SD 10.39) and organizations (mean 29.80, SD 10.45). Participants also proposed additional pillars, most frequently user, which was mentioned by 18 participants and governance, which was mentioned by 10 participants; other suggestions appeared only once. In response, the importance of the user and the need for attention to governance of a quality assessment framework were explicitly addressed in the framework's introduction to clarify their overarching relevance.

Finally, respondents brainstormed typologies to differentiate criteria. The most frequently suggested was interactivity (n=20), followed by risk taxonomy (n=6). Nonobligation (voluntariness of use) and anonymity were each mentioned 3 times, with all other typologies mentioned once. As no single typology received a clear majority, this question was carried forward to the next round for further exploration.

Round 2

Experts first reviewed the introductory section. Of the 40 respondents, 37 (92.5%) expressed full agreement, whereas 3 (7.5%) disagreed. Highlighted strengths included user centrality, autonomy, flexibility to accommodate evolving insights, interdependencies among pillars, and a graduated (proportional) approach. Proposed areas for improvement included ambiguity regarding end user responsibility, sharper wording for the 3 pillars, absence of broader societal context, and overall clarity

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and structure. Where feasible, these suggestions were incorporated into a revised introduction.

Participants then categorized all criteria under the 3 pillars and allocated importance points at the criterion level. Table 2 reports, for each pillar, the top 3 criteria, including the number of respondents endorsing each and the mean points assigned. When comparing these results with the source frameworks from the preparatory research, a considerable overlap was observed between the criteria grouped under the 3 pillars.

Table 2. Top 3 criteria for each pillar, including the number of participants who mentioned each criterion and the average points allocated (n=40).

Pillar and criterion	Participants, n (%)	Score (0-100), mean (SD)
Technology		
Accessibility	29 (72.5)	20.48 (8.79)
Reliability	26 (65)	23.23 (8.04)
Safety	24 (60)	20.38 (6.28)
Organizations		
Vision	32 (80)	26.19 (8.07)
Quality monitoring	24 (60)	19.92 (6.31)
Infrastructure	18 (45)	19.28 (3.54)
Professional competencies		
Support	27 (67.5)	21.74 (8.19)
Digital competencies	26 (65)	24.00 (8.26)
Ethics	21 (52.5)	22.57 (9.02)

The final aspect of this round focused on the typology. A total of 85.3% (29/34) of the participants agreed with the proposed typology, which was structured around interactivity and risk taxonomy. Despite this strong support and positive feedback, several concerns were raised. These included the abstract nature of the terminology; the difficulty of making objective classifications; the complexity of having 9 distinct categories; and the challenge of applying this typology across the entire field of digital care, assistance, and support. As a result, the typology was incorporated into the quality assessment framework as a suggested vision for evaluating specific interventions within specific contexts. It was not implemented as a universal classification system for all criteria across the framework or the broader field.

Round 3

Experts reviewed the full draft and provided annotated comments on content, structure, and wording. The feedback clustered primarily around organizational implementation and professional roles and competencies, with recurrent requests to simplify language and strengthen user participation. We implemented changes where feasible to improve clarity, remove minor redundancies, and standardize phrasing across the 3 pillars and cross-pillar sections.

Participants then classified each of the 119 criteria as minimum, optional, or unnecessary; applying the prespecified rule (flagging as optional if more than two-thirds of the participants selected “optional,” removing if more than two-thirds selected “unnecessary,” and otherwise retaining as a minimum criterion) yielded 46 (38.7%) optional items and no deletions (Multimedia Appendix 3).

Finally, responses to brief open-ended questions on purpose and structure, clarity and completeness, implementation feasibility, and contextualization led to 2 targeted additions: a self-assessment instrument that supports a growth pathway and selective completion (pillars need not be completed at once) and the explicit embedding of a proportionality typology in the introduction using risk stratification and degree of interactivity as practical lenses to tailor criterion selection to organizational context.

After the Delphi round 3, the framework contained 119 criteria across 3 pillars (n=53, 44.5% in the technology pillar; n=28, 23.5% in the organizations pillar; and n=38, 31.9% in the professional competencies pillar), of which 73 (61.3%) were classified as minimum and 46 (38.7%) were classified as optional criteria.

In-Depth Focus Groups and Interviews

Concurrent with round 3, we engaged experts across policy, well-being practice, technology, and ethics and legal domains in 4 online focus groups and interviews to assess topic coverage and implementation, focusing on comprehensibility, completeness, consistency, and implementation feasibility.

The focus groups largely confirmed the structure and content of the framework while highlighting clarifications needed for usability and proportional adoption. Participants called for a sharper articulation of target users and use cases, a strong separation between binding minimum requirements and guiding optional criteria, and practical guidance tailored to organizational and developer contexts. They also emphasized that the framework should not be understood solely as a formal assessment tool but also as a practical guide to support reflection, implementation, and quality improvement in practice. Input from experts with backgrounds in law and ethics emphasized the need for (1) direct legal signposting rather than paraphrasing; (2) technology-neutral and use case–specific

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wording to avoid rapid obsolescence; and (3) a proportional, comply-or-explain orientation that permits reasoned trade-offs across principles while preserving legal certainty. Input from technological experts underscored the need for (1) clear accountability and maintenance expectations across the life cycle, (2) feasible baselines for small or medium-sized enterprise and start-ups, and (3) signposting to recognized norms (eg, interoperability and accessibility) alongside lighter risk management baselines as stepping stones. Finally, well-being professionals stressed (1) the translation gap between technical language and day-to-day practice, (2) the central role of service users, and (3) the value of supporting roles to embed the framework. Common implementation needs converged across groups: training professionals, governmental support and resources, simple implementation tools (eg, checklists, templates, and audits), and a feedback loop after launch.

The interviews brought forth similar themes and added emphasis on alignment with EU-level initiatives (eg, the MDR, EU AI Act, GDPR, and European Health Data Space regulation [13-15,24]) and the expectation that technology providers and developers justify state-of-the-art technical and organizational measures without hard-coding specific technologies.

Building on the combined input from Delphi round 3 and these focus groups and interviews, the framework was adapted. This adaptation reflected a qualitative streamlining: 9 new criteria were added (eg, on avoiding dark patterns, affordability for clients, and explicit alignment with EU legislation such as the European Health Data Space), whereas conceptually overlapping criteria were merged (several clusters of 2 to 3 similar items combined into 1 broader criterion) and 9 redundant items were removed because they were fully covered elsewhere. As a result, the final framework is slightly shorter but more precise and up-to-date in legal terms.

Resulting Quality Assessment Framework

All consolidated efforts resulted in a contextualized quality assessment framework for digital care, assistance, and support in Flanders, Belgium (Multimedia Appendix 1) with a final set of 112 criteria (n=53, 47.3% in the technology pillar; n=23, 20.5% in the organizations pillar; and n=36, 32.1% in the professional competencies pillar), with 77 (68.8%) minimum and 35 (31.3%) optional items. Three established source frameworks were taken as a starting point and modified using input from key stakeholders. All these modifications were made to be traceable: each departure from or addition to a source framework is explicitly referenced (either to existing literature or to insights, requests, or recommendations from stakeholders during the course of this study) to ensure provenance, auditability, and transparency regarding the rationale for adaptation. Beyond its assessment function, the resulting framework is intended to support reflection, quality improvement, implementation, and decision-making across different contexts of digital care, assistance, and support.

Discussion

Principal Findings

This study aimed to develop a contextualized quality assessment framework for digital care, assistance, and support in Flanders, Belgium. Drawing on initial interviews with policymakers and a literature review, a 3-round Delphi study with key experts was conducted and complemented by focus groups and interviews. Together, these methods yielded a framework that synthesizes perspectives across 3 pillars: technology, organizations, and professional competencies.

The results of the Delphi study demonstrated a relatively balanced distribution of importance across the pillars, with technology receiving slightly higher priority. This balance underscores the interdependence of technological robustness, organizational aspects, and professional competencies in ensuring the quality of digital care, assistance, and support. Furthermore, the classification of criteria into minimum and optional highlights a dual function of the framework: on the one hand, it provides essential requirements to safeguard quality, and on the other hand, it creates a growth path for continuous improvement. This graded approach enhances the usability of the framework for diverse stakeholders, ranging from small organizations to larger institutions.

Throughout the focus groups and interviews, participants emphasized the importance of the introductory section of the framework, particularly the central role assigned to the user. This focus on user needs, autonomy, and accessibility aligns with broader European and international discourses on digital inclusion and human-centered design [25]. Moreover, the typology based on risk and interactivity offered a pragmatic lens for contextualizing the application of criteria even though participants expressed concerns about its complexity and operationalization for the entire framework. Experts also highlighted the necessity of clarifying terminology, ensuring a clear distinction between binding and guiding criteria, and aligning the framework with existing regulations (eg, GDPR, EU AI Act, and MDR). Importantly, the inclusion of frontline practitioners stressed the need for translation into practice-oriented tools and language. This reinforces that the framework not only provides conceptual clarity but also that derivative instruments were developed.

When compared with existing European assessment and reimbursement frameworks for digital health, this framework shows both substantial overlap and a distinct contribution. At the level of technology assessment, the core domains identified in this study are largely consistent with those found in other frameworks already in use. For example, the German digital health application fast track assesses product qualities such as data protection, information security, interoperability, quality, and user-friendliness in addition to evidence of a positive health care effect [26]. The Belgian validation pyramid similarly focuses on CE marking, GDPR compliance, interoperability, connectivity, usability, and reimbursement requirements for mobile health apps [27]. In Finland, Digi-HTA combines traditional health technology assessment domains such as safety, effectiveness, and cost with digital-specific domains, including

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usability and accessibility, data security and protection, interoperability, and technical stability [28]. Similarly, the French Prise en Charge Anticipée Numérique (PECAN) pathway is primarily oriented toward reimbursement of sufficiently mature digital medical devices, with emphasis on clinical and/or organizational benefit, as well as compliance with data protection, interoperability, and security requirements [29].

The added value of this framework lies not only in broadening the scope of assessment but also in confirming the relevance of these established technology-related domains within the wider field of digital care, assistance, and support. The expert input gathered in this study indicates that criteria such as usability, interoperability, data protection, and security remain highly relevant in this broader context. At the same time, the framework extends beyond a narrow product assessment or reimbursement logic by integrating 2 domains that are much less explicitly elaborated on in most existing frameworks, namely, organizational conditions and professional competencies. In that sense, it conceptualizes quality as a contextual, practice-based, and sociotechnical issue. This is particularly relevant for digital care, assistance, and support, where quality depends not only on the technical properties of a tool but also on how it is embedded in organizational workflows, governance arrangements, and the capabilities of the professionals who use it. A further contribution of the framework is its contextualization to the Flemish care, welfare, and support landscape while remaining aligned with broader European legal and regulatory requirements. Within the scope of this study, the framework was developed primarily to support quality assessment, self-reflection, implementation, and quality improvement in practice rather than as a reimbursement model. At the same time, its possible future policy applications fall beyond the scope of this study.

Strengths, Limitations, and Considerations

A key strength of this study and the resulting quality assessment framework is its interdisciplinary and participatory approach. The diversity of expertise in the Delphi panel, focus groups, and interviews facilitated the development of a shared language and common understanding across different domains of digital care, assistance, and support, whereas the iterative, participatory feedback fostered high engagement and ownership among participants.

Nevertheless, limitations must be acknowledged as well. First, the starting point of the quality assessment framework was based on an exploratory literature review rather than a formal systematic review. Although this approach allowed us to include a broad range of peer-reviewed, regulatory, and gray literature sources, the search and, more specifically, the selection of the source frameworks could have been more structured and standardized. A second limitation is that the time-intensive nature of the process may have deterred broader involvement of stakeholders. This was also reflected in the Delphi method, which does ensure consensus but saw participation rates decline across rounds, potentially limiting representativeness. A third limitation is that the framework is contextually grounded in Flanders. Although it remains sensitive to international developments, this may limit its applicability to other regions as adaptation to local context remains key for technologies and frameworks alike [30]. Nonetheless, for the technology pillar, another recent adaptation of the European Committee for Standardization ISO/TS 82304-2 standard in Catalonia has demonstrated that this can be done in a relatively straightforward process [31].

Furthermore, it remains to be seen how the quality assessment framework will be implemented in practice. Real and lasting impact will only be achieved through proper governance strategies. Finally, digital care, assistance, and support is a rapidly evolving field that necessitates periodic updates to maintain the relevance and validity of the framework. This underscores the need for a structured governance approach that provides clear roles, oversight, and periodic review cycles to keep the framework current and trustworthy.

Conclusions

The framework provides a valuable foundation for assessing and guiding the quality of digital care, assistance, and support in Flanders. To support its implementation, accompanying tools have already been developed, including a practical self-assessment instrument and governance guidelines. These resources aim to facilitate translation into daily practice by offering organizations concrete means to apply the framework in a structured and proportional way. Nevertheless, successful adoption will also depend on adequate governmental support, allocation of resources, and the establishment of sustainable feedback mechanisms. Future research should focus on piloting these tools and the framework in diverse real-world contexts, evaluating their feasibility and impact, and identifying strategies for keeping them up-to-date in light of rapid technological and societal developments. In addition, future studies could explore how the framework may be updated or adapted to the specific contexts and needs of other regions.

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Data Availability

The qualitative data generated and analyzed during this study are not publicly available due to confidentiality and anonymization considerations. The quantitative datasets are available from the corresponding author on reasonable request.

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Authors' Contributions

Conceptualization: TVD (lead), FB (equal), TS (equal), JV (equal)
Data curation: FB (lead), TS (supporting), TVD (supporting)
Formal analysis: FB (lead), TS (supporting)
Funding acquisition: TVD (lead), JV (equal)
Investigation: FB (lead), TS (equal), TVD (supporting)
Methodology: TVD (lead), FB (equal), TS (equal), JV (equal)
Project administration: TVD (lead), FB (supporting)
Supervision: TVD
Validation: TVD (lead), FB (equal), TS (equal), JV (equal)
Visualization: FB (lead), TS (supporting)
Writing—original draft: FB (lead), TS (supporting)
Writing—review and editing: FB (lead), TS (supporting), TVD (supporting), JV (supporting)

Conflicts of Interest

None declared.

Multimedia Appendix 1
Quality assessment framework.
[PDF File (Adobe PDF File), 490 KB - formative_v10i1e88512_app1.pdf]

Multimedia Appendix 2
Overview of the literature.
[PDF File (Adobe PDF File), 529 KB - formative_v10i1e88512_app2.pdf]

Multimedia Appendix 3
Classification criteria.
[PDF File (Adobe PDF File), 286 KB - formative_v10i1e88512_app3.pdf]

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Abbreviations

AI: artificial intelligence
EU: European Union
GDPR: General Data Protection Regulation
ISO: International Organization for Standardization
MDR: Medical Device Regulation
PECAN: Prise en Charge Anticipée Numérique

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Original Paper

An Internet of Things–Based Audio and Radio Connected System Supporting Older Adults With Physical and Cognitive Health Challenges: Qualitative Stakeholder-Informed Design Study

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Abstract

Background: Older adults managing chronic illnesses, such as cancer and Alzheimer disease and related dementias (ADRD), often experience significant physical or cognitive impairments that hinder daily activities and increase caregiver burden. Smart Internet of Things (IoT) technologies offer promising solutions by enabling passive monitoring, timely reminders, and personalized support at home. However, these technologies must be carefully tailored to accommodate users' individualized needs and preferences.

Objective: This formative qualitative study aimed to explore stakeholder perspectives, including patients, caregivers, health care providers, and technical experts, on the use of smart home–based IoT systems to support chronic illness management. The goal was to inform the early development of the audio and radio connected (AURA) system, an IoT prototype integrating Wi-Fi sensing, wearable trackers, and voice-assistive features.

Methods: Semistructured interviews were conducted with 6 patients who underwent postostomy creation for colorectal or bladder cancer treatment and 5 patients with ADRD and their caregivers. Input from additional stakeholders, including 2 health care providers, 2 community health workers, and 2 computer scientists, was also included in the report. Stakeholders reviewed a demonstration video depicting the conceptual features of the AURA system. Interviews explored stakeholders' needs and preferences for using such systems. Thematic analysis was guided by the extended Unified Theory of Acceptance and Use of Technology 2 (UTAUT2) framework, with 5 adapted constructs: performance expectancy, effort expectancy, social influence, facilitating conditions, and hedonic motivation and habit.

Results: Stakeholders identified distinct yet complementary needs across populations. Patients with cancer emphasized physical health monitoring, integration with health care systems, and customization; ADRD stakeholders prioritized routine support, emotional engagement, and simplicity; caregivers and clinicians emerged as key influencers of adoption. Barriers included privacy concerns, technology literacy, and fatigue, while facilitators included perceived caregiving support, streamlined interfaces, and electronic health record integration. Patients with cancer focused on motivational cues for physical activity, while emotional engagement and habit were more prominent for ADRD users.

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Conclusions: Stakeholder insights underscore the importance of designing adaptable, user-centered IoT systems that reflect the varied capabilities and care needs of older adults with chronic illnesses. These findings informed the design of the AURA prototype and highlighted theoretical considerations for technology acceptance in health care. Future work will test AURA in real-world settings to evaluate usability, acceptability, and clinical relevance.

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KEYWORDS

Alzheimer disease; assistive technology; cancer; Internet of Things; older adult; self-management; stakeholder engagement

Introduction

Physical and Cognitive Health Challenges in Older Adults With Chronic Illnesses

Physical and cognitive health challenges associated with chronic illnesses can significantly impact the daily lives of older adults and their caregivers. The challenges can impair patients' ability to maintain independence, manage health effectively, and ensure safety at home [1]. Physical impairments, such as limited mobility or fatigue, can hinder basic functions, including walking, eating, and using medical equipment [2]. Cognitive impairments, including memory loss and difficulties in decision-making, disrupt essential routines and increase the reliance on caregivers for activities of daily living (ADLs) [3]. The limitations contribute to heightened caregiver burden and reduce patients' ability to manage their health at home safely.

Physical and Cognitive Challenges in Patients With Cancer and Alzheimer Disease and Related Dementias

Among older adults with chronic illnesses, 2 representative groups particularly affected by the aforementioned challenges are patients with cancer recovering from ostomy surgeries and patients living with Alzheimer disease and related dementias (ADRD). Patients undergoing bladder or colorectal cancer treatment with ostomy placement often experience physical limitations that impede recovery and elevate the risks of dehydration [4], infection [5], or complications related to stoma care and ostomy bag management [6]. In contrast, patients with ADRD primarily struggle with cognitive impairments that interfere with daily routines such as eating, medication adherence, and hygiene, which often require constant supervision and prompting [7]. In both populations, unmet care needs in the home environment can threaten quality of life (QoL) and increase strain on caregivers.

Applications of Internet of Things in Supporting Physical and Cognitive Challenges

As more older adults continue to age in place despite declines in physical and cognitive health, there is a growing need for home-based solutions that promote safety, autonomy, and the continuity of care [8]. Smart Internet of Things (IoT) technologies offer a promising pathway to meet these needs by embedding real-time monitoring and assistive functions into the living environment. These technologies comprise networks of connected devices and sensors that communicate and share data to enable automated, real-time responses tailored to individual needs [9].

IoT technologies have been applied to support various health needs for older adults. For those with physical impairment, IoT-enabled monitoring systems can track movement [10], detect falls [9], and manage medical devices such as ostomy bags or health sensors [11,12]. For individuals with cognitive impairment, IoT-connected voice assistants can deliver personalized reminders for tasks such as taking medications, eating meals, or attending appointments [13]. Meanwhile, health monitoring systems empowered by IoT, such as Wi-Fi sensing or motion detectors, can noninvasively detect deviations in daily routines, potential safety issues, or the need for caregiver support [14]. Additionally, IoT systems can foster social interaction and reduce isolation and loneliness by providing reminders for social activities or virtual interactions through web-based chat, videoconferencing, group chat, and email [15]. These functionalities can enhance daily functioning, reduce risks, and promote emotional well-being in the home setting.

Designing IoT for Individualized Care Needs

Despite the potential of smart IoT technologies to support patients and their caregivers, designing individualized systems to address complex care needs remains difficult [16]. Many existing technologies are not adequately tailored to the diverse functional and cognitive profiles of older adults. Solutions must balance complexity and simplicity [17] while maintaining privacy [18], supporting caregiver roles [19], and ensuring ease of use [20]. For example, patients with cancer may benefit from activity tracking and hydration prompts, while patients with ADRD may need intuitive, voice-activated routines that are accessible with their impaired cognitive ability.

To support the development of a smart IoT-based system prototype that addresses complex needs, this study aims to explore stakeholder needs and preferences for using smart home monitoring and assistive technologies. By gathering input from stakeholders, including patients, caregivers, health care providers, and technologists, we provide early formative evidence to inform the design of inclusive and user-centered systems. Specifically, this study contributes to the literature by (1) applying an extended and adapted framework to examine the perceived value, usability, and adoption barriers of smart IoT technologies among older adults with physical and cognitive impairments, (2) highlighting cross-population differences that should inform design tailoring, and (3) offering actionable recommendations to bridge the gap between user needs and technological design. These insights lay the groundwork for future development, refinement, and deployment of personalized IoT solutions that support aging in place and reduce caregiver burden.

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Methods

Study Design

This study used a qualitative, exploratory design to collect stakeholder input, that is, the needs and preferences that would inform the early development of a smart home–based IoT system to support physical and cognitive health challenges. Data were collected through semistructured interviews with older adult patients and caregivers from 2 distinct populations representing physical and cognitive impairments, namely (1) patients with cancer who had ostomies and (2) patients with ADRD and their caregivers.

Involving both patients and caregivers in the early design process was critical to capturing a comprehensive understanding of home care needs, preferences for system use, and usability considerations [21]. Patients provide insight into their lived experiences and functional limitations, while caregivers contribute perspectives on feasibility, usability, and continuity of care, particularly relevant for people with ADRD, who may have limited decision-making capacity.

In addition to patients and caregivers, health care providers, community health workers, and computer scientists were also interviewed to offer broader perspectives on the clinical, community, and technical implications of developing a supportive IoT-based system.

Stakeholders and Recruitment

Stakeholders enrolled in this study included the following:

1. Patients with cancer who had ostomies: eligible patients had a history of bladder or colorectal cancer treated with curative intent ostomy, were 18 years of age or older, and were able to read and speak English.
2. Patients with ADRD and their caregivers: eligible patients were diagnosed with mild cognitive impairment or early-stage ADRD, lived with a caregiver present at least 4 hours/day for at least 6 months, were 18 years of age or older, and had sufficient vision and speech to use a voice-assistive system.
3. Health care professionals and technical experts: a neuropsychologist, a geriatrician, 2 community health workers who provide direct care and service to patients with ADRD, and 2 computer scientists were recruited to offer broader perspectives on care needs and system development.

Patients with cancer were referred from the Oncology Clinic at the Mays Cancer Center, while patients with ADRD were referred by clinicians from the Geriatrics and Palliative Care Clinic, all of which are affiliated with the University of Texas Health Science Center at San Antonio. After confirming eligibility through a medical record review, the research team contacted potential patients and caregivers to schedule interviews.

Setting and Procedures

Eligible patients and their caregivers participated in in-person interviews at the School of Nursing Community Simulation Lab. Interviews with nonpatient stakeholders, including health care providers, community health workers, and computer scientists, were conducted remotely via Zoom (Zoom Communications, Inc). Semistructured interviews were conducted by trained research assistants, lasting 30-45 minutes each. A researcher-developed interview guide was used to explore patients' and caregivers' needs and preferences for smart IoT technologies. To facilitate discussion, stakeholders were shown a brief demonstration video presenting a conceptual example of how a smart IoT-based system might function in the home environment. The video illustrated how simulated scenarios of daily activities and care challenges, such as monitoring mobility and prompting medication adherence, could be supported by passive activity detection and monitoring, as well as voice-assisted reminders (Figure 1). The purpose was to help stakeholders visualize potential applications in everyday care.

Interview questions were open-ended and neutrally phrased to reduce confirmation and social desirability bias [22]. The interviewer emphasized that the system was still under development and encouraged stakeholders to reflect on its relevance, including potential benefits and limitations, to their daily routines and caregiving needs. Interviewers avoided leading prompts to ensure that responses reflected authentic perspectives rather than agreement with the demonstrated concept. Sample interview questions included the following: "What are the benefits of using such a system?" and "What are the issues in relation to the use of such a system?" Moreover, questions such as "How do you feel this will replace what you are using now?" were included to prompt stakeholders to consider the potential role in their real-life setting, beyond what was shown in the video. All interviews were audio-recorded and transcribed verbatim for analysis.

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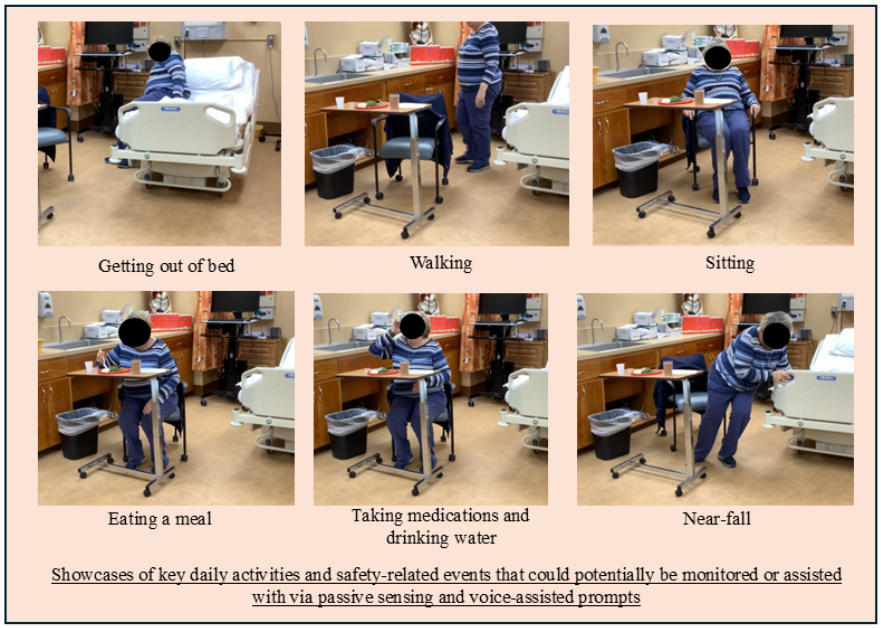
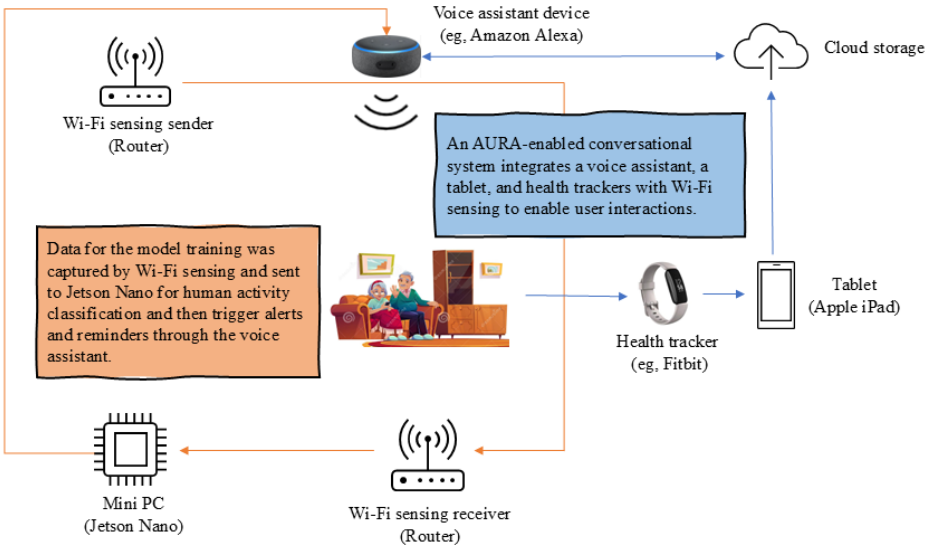
Figure 1. Simulated scenarios in the demonstration video.



Initial Smart IoT System Concept: Audio and Radio Connected

To address the complex challenges associated with managing chronic illnesses at home, the research team conceptualized the audio and radio connected (AURA) system, an integrated smart IoT solution designed to support older adults with physical and cognitive impairments. Inspired by the needs of stakeholders identified during our previous Patient Reported Outcomes-Informed Symptom Management System (PRISMS) study [23], AURA aimed to provide individualized, real-time support, with a minimally intrusive design (Figure 2).

Figure 2. Initial audio and radio connected system concept.



The envisioned system integrated 3 core components: Wi-Fi sensing, wearable health trackers, and voice-assistive technologies. At the heart of the system was a deep neural network [24] trained on Channel State Information (CSI) data collected from Wi-Fi sensing [25]. Using this radio frequency sensing approach, standard Wi-Fi routers and a deep learning model running on a Jetson Nano edge device could unobtrusively record and classify user activities, such as walking, sitting, or lying down, without requiring wearable devices [26]. This passive monitoring framework was particularly well-suited to individuals with limited mobility or cognitive impairments who may not consistently engage with wearable technology [27].

While the Wi-Fi sensing system supported user comfort and privacy, we enhanced this approach by incorporating wearable health trackers (eg, Fitbit, smart scales, and smart bottles). These devices collected continuous data on sleep quality, hydration, physical activity, and weight, which were critical for maintaining health during treatment recovery or cognitive decline. For example, patients with cancer who had ostomies were at increased risk for dehydration or delayed recovery due to inactivity. AURA could detect prolonged sedentary periods and

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issue reminders to drink water or engage in light movement. Similarly, patients with ADRD, who frequently forgot routine tasks, could benefit from scheduled voice prompts for meals, hydration, and medications.

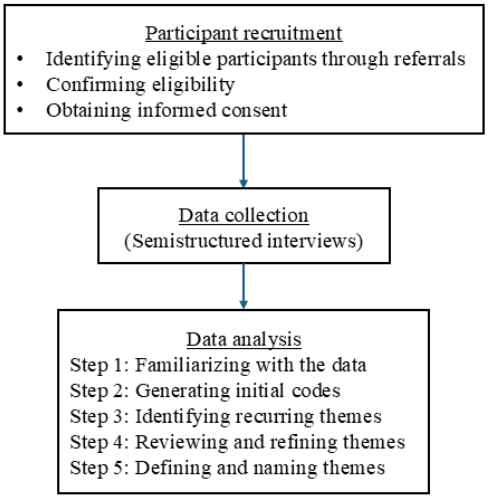
Voice-assistive technologies, such as Alexa (Amazon), were envisioned as a central interface for patient engagement. These tools would deliver context-aware alerts and initiate personalized daily check-ins to assess users' well-being. For example, voice prompts might ask whether a patient had eaten, how they were feeling, or if they were experiencing any discomfort (eg, changes in urine color or surgical site pain). By combining passive Wi-Fi sensing, health tracking, and engaged interaction, AURA supported both physical safety and cognitive functioning without requiring complex manual operation, making it especially valuable for older adults aging in place.

Overall, the AURA system concept was designed to enhance independence, promote safety, and reduce caregiver burden through an adaptable, user-centered approach to smart home care.

Data Analysis

We followed Braun and Clarke's thematic analysis framework [28] for data analysis, with additional guidance from the extended Unified Theory of Acceptance and Use of Technology 2 (UTAUT2) framework [29] (Figure 3). NVivo 14 (Lumivero) [30] was used to assist in organizing and coding the data. The thematic data analysis process consisted of the following 5 iterative steps.

Figure 3. Study procedure.



Step 1. Familiarizing With the Data

The research team reviewed the verbatim transcribed data to ensure accuracy and a comprehensive understanding of the content. Repeated readings of the transcripts were conducted to immerse in the data and identify preliminary patterns relevant to stakeholders' experiences and preferences for AURA.

Step 2. Generating Initial Codes

Several researchers, including JL and DG, independently performed open coding to identify meaningful data segments related to stakeholder needs and preferences for AURA, which may shape AURA's essential features and functionalities. Coding discrepancies were resolved through discussions among researchers (JL, DG, LS, and XW) to maintain consistency.

Step 3. Identifying Recurring Themes

The UTAUT2 framework was used to guide thematic analysis. The UTAUT2 framework is an extension of the original UTAUT model, which was developed to examine technology acceptance in consumer contexts [31]. In UTAUT, there are 4 foundational constructs: performance expectancy, effort expectancy, social influence, and facilitating conditions, which collectively explain the drivers of technology adoption [29]. UTAUT2 builds on UTAUT and introduces 3 additional constructs (hedonic motivation, price value, and habit) to capture the nuanced factors influencing behavioral intention and technology use in voluntary, consumer-driven settings. For this study, we combined "hedonic motivation" and "habit" due to their conceptual overlap in this early-stage design context. Specifically, stakeholders' expressions of emotional engagement and perceived enjoyment (eg, social interaction and mental stimulation) were closely tied to anticipated routine use. Since stakeholders interacted with a conceptual video rather than a functioning prototype, their responses reflected hypothetical experiences, and the distinction between intrinsic enjoyment and habit was not clearly articulated. We excluded "price value" because AURA has not yet been commercialized, and stakeholders were not evaluating its affordability.

Therefore, we focused on 5 constructs: performance expectancy, effort expectancy, social influence, facilitating conditions, and hedonic motivation and habit, to explore anticipated benefits, ease of use, external support, and emotional engagement (Table 1). This adapted framework was particularly relevant to examine stakeholder feedback on a home-based IoT system intended to support chronic illness management. This step was conducted primarily by researchers JL, DG, and others.

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Table 1. Overview of UTAUT2[a] constructs used for thematic analysis.

Constructs	Definition
Performance expectancy	Stakeholders' perceptions of the benefits AURA[b] could provide in supporting health outcomes and caregiving tasks
Effort expectancy	The system's ease of use and perceived simplicity, particularly for patients with physical or cognitive challenges
Social influence	The impact of caregivers, clinicians, and social networks on the potential adoption of AURA
Facilitating conditions	The resources and infrastructure required to support the adoption and integration of AURA into daily care routines
Hedonic motivation and habit	The nuanced user preferences and potential adoption barriers

[a]UTAUT2: Unified Theory of Acceptance and Use of Technology 2.

[b]AURA: audio and radio connected.

4. Reviewing and Refining Themes

Identified themes were refined by researchers (JL, DG, and XW) to ensure consistency and alignment with stakeholder feedback. This iterative process involved reviewing themes for overlap, redundancy, and relevance to the study's aim of informing the development of AURA. Any inconsistencies were resolved collaboratively among the research team members.

5. Defining and Naming Themes

Each theme was clearly defined in relation to the research aims and the UTAUT2 constructs by researchers (JL and DG), along with ongoing group discussion. Detailed descriptions and illustrative quotes were used to support and contextualize each theme, ensuring their interpretive robustness and relevance to AURA development.

Ethical Considerations

The study was approved by the Institutional Review Board at the University of Texas Health Science Center at San Antonio (20210261HU and 20220750HU). All stakeholders signed consent forms before data collection. Every participating patient with cancer who had an ostomy received US $20 in compensation; every patient with ADRD and their caregiver received US $50.

Results

Patient Characteristics

The study included 11 patients, 6 of whom had cancer. The mean age was 78.7 (SD 6.6) years. The 6 patients with cancer who had an ostomy included 3 females and 3 males. Most patients (n=4) identified themselves as non-Hispanic White, while the remaining patients identified themselves as Hispanic. Marital status varied with 3 married, 1 widowed, and 2 divorced. Five patients had at least a bachelor's degree, and 1 reported having completed high school. The types of ostomies among patients with cancer included urostomies (n=5) and colostomies (n=1).

Among the 5 patients with ADRD, 3 were female; all were non-Hispanic White, except for 1 male Hispanic patient; and 4 were married. Regarding education levels, all patients held at least a bachelor's degree, and 3 had postgraduate degrees. Primary caregivers included spouses (n=4) and adult children (n=1). Detailed demographic information for patients is provided in Table 2.

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Table 2. Patient characteristics.

Characteristic	Patients with cancer who had ostomy (n=6)	Patients with ADRD[a] (n=5)
Age (years), mean (SD)	75.7 (4.7)	82.4 (7.1)
Sex, n (%)		
Female	3 (50)	3 (60)
Male	3 (50)	2 (40)
Race, n (%)		
White	6 (100)	5 (100)
Ethnicity, n (%)		
Hispanic	2 (33)	1 (20)
Non-Hispanic	4 (67)	4 (80)
Marital status, n (%)		
Married	3 (50)	4 (80)
Widowed	1 (17)	1 (20)
Divorced	2 (33)	0 (0)
Education level, n (%)		
High school	1 (17)	0 (0)
Bachelor's degree	3 (50)	2 (40)
Postgraduate degree	2 (33)	3 (60)
Type of ostomy, n (%)		
Urostomy	5 (83)	—[b]
Colostomy	1 (17)	—
Primary caregiver, n (%)		
Spouse	—	4 (80)
Adult child	—	1 (20)

[a]ADRD: Alzheimer disease and related dementias.

[b]Not applicable.

Major Themes of Stakeholders' Needs and Preferences

This study investigated the needs and preferences of stakeholders regarding the envisioned AURA envisioned system, which was intended to support patients with physical and cognitive health challenges. Guided by the UTAUT2 framework, thematic analysis of stakeholder interviews identified 5 main themes. Table 3 presents a summary of stakeholders' needs and preferences, with more detailed results for each theme provided below.

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Table 3. Summary of stakeholders' needs and preferences.

Major themes	Stakeholders' needs and preferences	
	Patients with cancer	ADRD[a] stakeholders
1. Performance expectancy	• Prioritize physical health management (eg, activity tracking and bag change reminders) • Emphasize EHR[b] integration	• Need support for routines (eg, medications, meals, and hydration) • Emphasize emotional and social engagement
1. Effort expectancy	• Feel comfortable with moderate complexity if usability is maintained • Prefer practical, streamlined interfaces without unnecessary features	• Require a simple, intuitive design • Prefer 1- or 2-step voice commands to avoid cognitive overload
1. Social influence	• Clinician endorsement builds trust	• Caregivers are primary decision-makers • Want features that ease caregiving, especially when caregivers are not present
1. Facilitating conditions	• Barriers include physical fatigue and device maintenance • Facilitators include customization and health care synchronization	• Barriers include low-tech literacy and privacy concerns • Facilitators include perceived caregiving support
1. Hedonic motivation and habit	• Interested in motivation for physical activity and habit formation	• Emphasize social connection, emotional engagement, and cognitive stimulation through interactive features

[a]ADRD: Alzheimer disease and related dementias.

[b]EHR: electronic health record.

Theme 1: Performance Expectancy

Stakeholders across both groups highlighted the potential benefits of the AURA system, including improved daily life and reduced caregiving burdens.

Needs and Priorities of Patients With Cancer

Physical Health Management

Patients with cancer who had ostomies focused on physical health management as their primary need. For these patients, practical features, such as activity tracking and ostomy bag change reminders, were seen as transformative. As 1 patient explained, "Tracking my activity levels and reminding me to change my bag before it's too late would be life-changing." Another similarly noted that "reminders for bag changes or tracking how long I've been active – those would make things so much easier." Beyond task management, patients also described the emotional reassurance provided by passive monitoring, with 1 individual stating, "It's reassuring to know something is monitoring me, especially when I'm on my own. It gives peace of mind."

Electronic Health Record Integration

The ability to integrate with health care systems further enhanced the system's perceived value. Patients expressed a desire for seamless communication with clinicians, with one noting, "Sharing my health data with my doctor could prevent unnecessary visits and give me more confidence in managing my care." These comments also underscored how AURA could address physical and emotional needs.

ADRD Stakeholders' Needs

Support for Routines

For ADRD stakeholders, the focus was on the system's ability to support cognitive tasks and routines (eg, taking medications, eating meals, and keeping patients hydrated), which are essential for maintaining daily functioning and reducing caregiver burden. A caregiver explained, "It's all about routine. If the system can help maintain that, it would take a load off me." This highlights the pressing need for tools that not only assist in task management but also provide consistency in care. The importance of reminders for medications and meals was frequently mentioned, with caregivers appreciating how such features could help reduce their own stress. One caregiver shared, "If the system can remind them about medications and meals without waiting for them to ask, it would be a huge help."

Emotional and Social Engagement

Beyond routine management, stakeholders saw potential in the system to foster emotional and social engagement. A community health worker noted, "If AURA could prompt him to talk to a family member or remind him to join an activity, it would really reduce his isolation." This reflects the dual benefit of supporting caregiving tasks while also addressing patients' emotional well-being, which stakeholders linked to improved QoL, noting that "something that keeps them engaged socially and emotionally would make a big difference." Some even described the system as having the potential to become meaningfully integrated into daily life, with 1 stakeholder reflecting that "just having a system to be part of their day-to-day routine, like a family member almost, could be transformative."

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Theme 2: Effort Expectancy

Ease of use emerged as a critical consideration for stakeholders, though expectations differed between the 2 groups.

Patients With Cancer

Feeling Comfortable With Moderate Complexity as Long as Usability Is Maintained

Patients with cancer demonstrated more comfort with moderate complexity if the system delivered meaningful benefits, compared to ADRD stakeholders. A patient explained, "I'm okay learning how to use something if it really helps me keep track of my care."

Preferring Practical, Streamlined Interfaces Without Unnecessary Features

While this group was open to learning, they still valued streamlined interfaces without unnecessary features. One patient stated, " I don't need all the bells and whistles. Just make it practical," while another similarly remarked, "I don't need a bunch of extras. Just give me a simple system that does the basics well." These inputs reflect patients' preference for a system that is simple, functional, and free of unnecessary features.

ADRD Stakeholders

Requiring a Simple, Intuitive Design

For patients with ADRD and their caregivers, simplicity was paramount. Stakeholders highlighted the importance of clear and intuitive design, as exemplified by the neuropsychologist's remark, "If it's too complicated, they won't use it. It needs to be as simple as turning on a light switch." A caregiver echoed, "I don't want to spend hours teaching them how to use it. It should just work." This reflects the necessity for a system that minimizes cognitive strain for users with impairments.

Preferring 1- or 2-Step Voice Commands to Avoid Cognitive Overload

Voice interfaces were frequently mentioned as a solution, with stakeholders emphasizing the need for 1- or 2-step commands. One geriatrician explained, "If you overload them with commands or steps, it just won't work. They'll shut down." This further explains that AURA can better serve individuals with limited technological experience by reducing complex commands.

Theme 3: Social Influence

Social influence refers to the impact of opinions and behaviors of nonpatient stakeholders on the decision to adopt and use AURA. In this study, stakeholders indicated that caregivers and clinicians significantly influenced patients' decisions regarding AURA system adoption, particularly in guiding or endorsing its use.

Patients With Cancer: Clinician Endorsement Builds Trust

For patients with cancer, clinician endorsement was a significant factor in building trust and encouraging adoption. One patient remarked, "If my doctor tells me it's useful, I'm more likely to trust it." Another echoed this sentiment, noting, "Knowing my healthcare team can access the data makes me feel more confident." Patients indicated that integration with their health care team increased their confidence in the system's relevance and reliability.

ADRD Stakeholders

Caregivers Are Primary Decision-Makers

As the primary decision-makers, caregivers' evaluations focused on how the system could significantly assist patients while alleviating their caregiving burden. One caregiver stated, "If it helps me manage their medications and appointments, I'll absolutely support using it." Stakeholders described caregivers as both end users and primary influencers in decisions about system use.

Wanting Features That Ease Caregiving, Especially When Caregivers Are Not Present

Caregivers also emphasized the importance of a system that could support patients when they were not physically present. As 1 caregiver explained, "Caregivers need something that can fill in the gaps when we're not around." Another similarly highlighted the shared benefit, noting that "a system that reminds them and keeps track of things when I'm not there—it would make a huge difference for both of us." Stakeholders identified a need for features that support patient monitoring and task reminders when the caregiver is absent.

Theme 4: Facilitating Conditions

Barriers and facilitators to adoption varied across the 2 groups.

Patients With Cancer

Barriers Included Physical Fatigue and Device Maintenance

Patients with cancer focused more on physical barriers, such as fatigue and device maintenance. One patient explained, "Some days, I don't have the energy to keep up with everything. The system needs to be low maintenance."

Facilitators Included Customization and Health Care Synchronization

Facilitators for this group included customization and integration with health care platforms. A patient noted, "If it syncs with my doctor's system and reminds me to do things like hydrate or exercise, that would be a game-changer."

ADRD Stakeholders

Barriers Included Low-Tech Literacy and Privacy Concerns

ADRD stakeholders identified technological literacy and privacy concerns as significant barriers. Caregivers and health care providers frequently noted that older adults often struggled with technology. One health care provider remarked, "They're not tech-savvy, so anything overly complicated won't work." Another added, "Technology is hard for older adults. If something goes wrong with the internet, they might not know how to fix it." These challenges highlight the need for robust support systems and fail-safe mechanisms to address user concerns.

Privacy was another prominent concern, with stakeholders emphasizing the importance of data security. One caregiver

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stated, “I worry about who else might have access to the data. We want to feel safe, not monitored.”

Facilitators Included Perceived Caregiving Support

Despite these challenges, many stakeholders recognized the system’s potential. As 1 caregiver put it, “If it can help me manage daily routines, that’s worth overcoming the tech challenges.”

Theme 5: Hedonic Motivation and Habit

Patients With Cancer: Interested in Motivation for Physical Activity and Habit Formation

While both groups valued practical applications of the system, patients with cancer expressed an interest in features that encouraged physical activity. One patient shared, “Having a system reminds me to move, even if just a little, keeps me motivated to stay active.” Another added, “Something that motivates me to get up and move, even a little bit, would be great.” These responses reflect the potential for the system to support healthier habits and improve overall QoL.

ADRD Stakeholders: Emphasizing Social Connection, Emotional Engagement, and Cognitive Simulation Through Interactive Features

Emotional and social benefits were emphasized primarily by ADRD stakeholders. For this group, social engagement features were seen as essential. One health care provider explained that “sometimes they just need a reminder to call a family member or take a break—it helps them feel less isolated.” A caregiver similarly noted that “engagement features that give them something to look forward to would be wonderful.”

Stakeholders also highlighted the value of mental stimulation. One caregiver noted, “Features that promote mental stimulation, like games or conversation prompts, could really improve their mood and quality of life.” Stakeholders expressed interest in features that support emotional well-being by providing cognitively engaging and uplifting experiences.

Discussion

Principal Findings

This study explored stakeholders’ needs and preferences, primarily older adult patients aged 70 years and older with either physical or cognitive impairments, to inform the development of a preliminary smart IoT system, AURA, a user-centered solution designed to support care at home. Guided by the UTAUT2 framework, the thematic analysis revealed distinct yet complementary needs and preferences across 2 target populations—patients with physical and cognitive challenges. Additionally, valuable insights from health care providers, community health workers, and computer scientists enriched the understanding of user expectations and system design considerations.

The findings highlight distinct differences in stakeholder priorities between the 2 populations. Patients with cancer who had ostomies focused on features that assisted with physical self-care tasks, such as activity monitoring, hydration reminders, and managing their ostomy bags. In contrast, ADRD stakeholders primarily emphasized support for memory, routine management, and emotional well-being, reflecting the cognitive challenges of this group. These differences underscore the need for a flexible, adaptable system design that accommodates both physical and cognitive impairment care needs, while offering valuable guidance for optimizing AURA’s design and functionality to ensure its acceptability and effectiveness.

Unlike many existing IoT studies focused solely on older adults or specific technologies (eg, wearable sensors [32] and fall detection [33]), our study explores a broader range of user needs across 2 populations and highlights their preferences that cut across physical and cognitive domains. While some studies focus on technical feasibility, few engage patients and caregivers at this formative stage to inform the development process [34]. This stakeholder-informed approach adds value to the design of inclusive, usable technologies.

Performance Expectancy

Stakeholders across both groups recognized the potential of AURA to support ADLs and reduce caregiving burdens, but their needs and preferences differed significantly. Patients with cancer who had ostomies prioritized physical health management, particularly features such as activity tracking, fall detection, and reminders for ostomy bag maintenance. Integration with health care systems was also a key expectation, reflecting the importance of seamless communication with clinicians to improve care coordination. Interestingly, this group placed less emphasis on emotional support, diverging from the literature that underscores the psychosocial needs of cancer survivors [35]. These findings suggest that patients with cancer who have undergone surgery may prioritize practical, health-focused functionalities over emotional engagement tools.

Conversely, for ADRD stakeholders, the system’s ability to provide cognitive support through reminders for medications, meals, and activities was critical. These findings are consistent with the systematic review, which suggests that the ability of passive monitoring and assistive technologies to provide immediate and tangible benefits, such as enhanced safety and support for daily routines, facilitates acceptance and adherence [36]. Emotional well-being and social engagement also emerged as important findings, with stakeholders emphasizing the need for features that combat isolation and foster interaction.

Effort Expectancy

Ease of use was universally important, yet stakeholders’ expectations differed. Patients with cancer demonstrated a higher tolerance for a complex system as long as it effectively met their health management needs. Although they also favored practicality and intuitive interfaces, this group prioritized a balance between essential functions and ease of use. In contrast, ADRD stakeholders emphasized the need for simplicity, with a preference for intuitive design and minimal steps to minimize cognitive strain. They also preferred voice commands and intuitive interfaces as key facilitators and worried that complex systems would likely result in disengagement. These findings not only align with studies showing that simplicity and ease of use are critical to technology adoption among older adults [37]

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but also highlight the need for a flexible system design that adapts to varying user capabilities and expectations.

Social Influence

The stakeholders emphasized the crucial role of caregivers and clinicians in influencing the acceptance and adoption of the AURA system. For patients with cancer, clinician endorsement and integration with health care platforms emerged as critical facilitators in building trust and encouraging system adoption. Integrating AURA with health care systems was viewed as critical to enhancing its perceived value and credibility, underscoring the importance of clinician-patient collaboration in chronic disease management [38].

For ADRD stakeholders, caregivers often act as gatekeepers and decision-makers, underscoring the importance of designing a system that alleviates caregiving burdens and enhances patient care and well-being. They emphasized the importance of features that could provide continuity of care when they are unavailable. This aligns with existing research emphasizing the central role of caregivers in technology adoption for patients with dementia [39].

Facilitating Conditions

Barriers to adopting the AURA system varied across the 2 groups. Patients with cancer highlighted barriers, including physical fatigue and the complexity of device maintenance. Customization options and integration with health care platforms were identified as key facilitators of system adoption, consistent with research emphasizing the value of interoperability in health care technologies [40]. ADRD stakeholders identified technological literacy and privacy concerns as significant challenges. Older adults often struggle to manage complex technology, and privacy concerns related to voice-assistive devices, such as Alexa, were particularly common [41].

Despite these barriers, stakeholders acknowledged the system's potential to support caregiving when caregivers are unavailable and to improve routine care management. These findings highlight the importance of designing AURA to be minimally demanding, both physically and cognitively, by incorporating intuitive interfaces, a simple setup, and reliable passive-sensing features. Privacy safeguards must be clearly communicated and customizable to address user concerns. Facilitators such as integration with existing health care systems, perceived caregiving support, and the ability to tailor the system to individual routines suggest that AURA should be flexible, interoperable, and responsive to user needs. Addressing these factors early in the design process will be essential to enhancing adoption, especially among older adults and individuals with limited digital literacy.

Hedonic Motivation and Habit

Hedonic motivation and habit, defined as the degree of pleasure or enjoyment derived from using technology, emerged as a meaningful factor in the adoption of AURA, particularly among stakeholders caring for patients with ADRD. Patients with cancer tended to focus less on hedonic motivation and habits. Still, they appreciated features that encouraged physical activity and health tracking, which demonstrates the system's potential to support physical health and healthy behaviors. While both groups valued practical applications, ADRD stakeholders particularly preferred features that support emotional well-being and social engagement to reduce isolation, highlighting the system's potential to enhance QoL beyond basic caregiving tasks. The findings reveal that emotionally engaging features, such as social prompts, games, or personalized voice interactions, can foster positive user experiences and sustained use. These elements may enhance mood, reduce isolation, and improve adherence to care routines. Designing AURA with enjoyable and engaging components is therefore instrumental in ensuring long-term user engagement, especially in populations at risk of cognitive or emotional decline.

Research Implications

The findings underscore the need for AURA to be adaptable and customizable to meet the distinct needs of older adults who manage physical and cognitive health challenges in home settings. For patients with cancer, advanced health tracking, customization, and seamless integration of health care are critical. For patients with ADRD and caregivers, simplified interfaces, proactive reminders, and privacy safeguards are essential. By integrating these features, the system can provide personalized, context-aware support that enhances independence, safety, and QoL.

The divergent preferences between these 2 patient populations suggest a fundamental trade-off in IoT system design: how to balance system simplicity (critical for cognitively impaired users and their caregivers) with the richer functionality desired by users with physical limitations but preserved cognitive capacity. Designing AURA to meet both needs requires modular interfaces or adaptive personalization features that adjust complexity based on user type or profile.

The contrast in effort expectancy between cancer patients and ADRD caregivers aligns with the UTAUT2 model but also reveals its limitation in capturing how cognitive capacity moderates perceived usability. Our findings suggest that cognitive impairment, rather than age or experience alone, is a key moderator that should be considered in future adaptations of UTAUT2 for health care settings.

The difference in hedonic motivation suggests that emotional engagement may not be a universal adoption driver across all chronic illness groups. While social stimulation is crucial for ADRD users, patients with cancer viewed motivation more behaviorally (eg, reminders to move). AURA's design should therefore allow customization of motivational features based on user context, rather than assuming a one-size-fits-all engagement strategy.

Limitations and Future Directions

The following limitations warrant consideration when interpreting the findings: (1) this study included only older adult populations managing ostomies for cancer treatment or ADRD in home settings; they were selected to capture physical versus cognitive health challenges that pose common challenges in chronic illness management. However, we recognize that these groups do not represent the broader spectrum of chronic conditions. As such, future research is needed to validate and

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expand these findings in other chronic illness populations to inform the scalability and broader applicability of smart IoT-based home care systems such as AURA.

Next, while the study provided rich, in-depth insights from stakeholders representing 2 older adult populations with distinct care needs related to self-management in home settings, the sample size was relatively small and lacked demographic diversity. Most stakeholders identified as non-Hispanic White and had high levels of education. However, as this was a formative, exploratory phase focused on understanding stakeholder needs and preferences for using IoT and voice-assistive technologies, the primary aim was to obtain detailed, user-centered input rather than achieve population-level representativeness. To address this limitation, the subsequent phase of the AURA project expanded recruitment to include stakeholders from diverse racial, ethnic, and socioeconomic backgrounds, thereby ensuring broader applicability and inclusivity in future development and testing.

Furthermore, this study used a preconstructed demonstration video to introduce the initial AURA concept during the semistructured interviews, as a fully developed prototype was not yet available. While this approach allowed stakeholders to visualize the proposed functionalities, it may have introduced social desirability or confirmation bias, as stakeholders might have shaped their responses in line with perceived expectations. However, the video presented generalized daily scenarios rather than idealized outcomes. Interview questions were neutrally worded and designed to elicit both positive and critical feedback, and interviewers avoided leading prompts. Future studies, including the pilot in the next phase, will involve deploying the actual AURA prototype at home to gather real-world usability and acceptability data.

Finally, this formative study did not include real-world testing of the AURA system and thus does not capture how user perceptions may evolve over time with actual system use. While stakeholders expressed enthusiasm for features such as reminders and activity tracking, this study did not assess measurable outcomes such as improvements in ADLs or reductions in caregiver burden. Therefore, although stakeholders perceived these features as beneficial, their actual impact remains to be evaluated. The next phase of the AURA project focuses on refining the prototype and conducting field usability testing. The research team has completed a home-based deployment study (phase 2) evaluating the usability, acceptability, and preliminary performance of AURA in real-world environments. Data analysis and the manuscript are currently under development. Future development will also emphasize cultural inclusivity, adaptive personalization based on user needs, and further integration with health care systems to support broader implementation.

Conclusion

This study examined stakeholders' perspectives on the initial concept of the smart IoT system AURA, designed to support older adults with chronic illnesses, specifically, patients with cancer who had an ostomy and patients with ADRD. Perspectives were also gathered from health care providers, community health workers, and computer scientists. By applying the UTAUT2 framework, this study revealed key differences and commonalities in stakeholder needs and preferences for using smart IoT and voice-assistive technologies in home-based care.

While the findings provide valuable insight to guide the early design of user-centered technology, several limitations should be acknowledged. The study sample was relatively small and lacked demographic diversity, which may limit the generalizability of results. Additionally, stakeholder feedback was based on conceptual demonstrations rather than real-world use, and outcomes such as feasibility, acceptability, or health impact were not directly measured.

Despite these limitations, this formative research lays the groundwork for developing scalable IoT solutions that can support ADLs, facilitate self-management, promote healthy behaviors, and reduce caregiver burden. Future work should focus on refining and prototyping the AURA system and evaluating its usability, acceptability, and effectiveness in real-world home settings.

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Data Availability

The datasets generated or analyzed during this study are available from the corresponding author on reasonable request.

Authors' Contributions

Conceptualization: LS, SN
Methodology: LS, SN
Software: JX, YZ, MM, WW, SN

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Formal analysis: JL, DDG, LS, XW, AV
Data curation: JL, DDG
Writing – original draft: JL, LS
Writing – review & editing: JL, LS, XW, BS, DDG, AV, JX, YZ, RS, MG, NP

Conflicts of Interest

None declared.

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Abbreviations

ADL: activity of daily living
ADRD: Alzheimer disease and related dementias
AURA: audio and radio connected
CSI: Channel State Information
IoT: Internet of Things
PRISMS: Patient Reported Outcomes-Informed Symptom Management System
QoL: quality of life
UTAUT2: Unified Theory of Acceptance and Use of Technology

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Restoring Engagement in Digital Self-Control Tools Using Nudge Reconfiguration Prompts: Quasi-Experimental Study

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Abstract

Background: Digital self-control tools (DSCTs) have emerged as technological interventions to address excessive smartphone usage and promote digital well-being. However, these tools face persistent challenges with user attrition and sustained engagement, compromising their long-term effectiveness. Current literature lacks an understanding of how observable behavioral indicators, as opposed to self-reported measures, are associated with user engagement and readiness to change in DSCTs.

Objective: This study addresses three research questions (RQs): (RQ1) whether prompting passive DSCT users to reconfigure nudges increases subsequent user-nudge interaction, (RQ2) how engagement evolves over time and what behavioral divergence emerges between accepting and rejecting users, and (RQ3) whether observable in-app behavioral indicators are more strongly associated with intervention acceptance than traditional self-reported measures.

Methods: We conducted a quasi-experimental study (N=252) targeting users who had disabled nudges. Participants were randomly assigned to receive a prompt to reconfigure their nudge settings during daily check-ins (n=138, experimental group) or to a control condition (n=114, no intervention). The experimental group was further classified into acceptance and rejection subgroups based on their response to the intervention. Data collection included DSCT configuration logs, usage-triggered nudge logs, and self-reported questionnaire responses. We analyzed user-nudge interaction ratios using difference-in-differences with permutation tests (RQ1) and nudge configuration parameters and manual app blocking using independent-samples *t* tests with Cohen *d* (RQ2) and compared behavioral indicators against self-reported measures using *t* tests and chi-square tests (RQ3).

Results: Of the experimental participants, 46% (63/138) accepted the nudge reconfiguration prompt. Post intervention, the acceptance subgroup's 7-day average user-nudge interaction ratio increased from 29.7% to 58.5% (peak of 65% on day 1), a significant increase even after controlling for the temporal decline observed in the control group (difference-in-differences=+36.3 percentage points, $P<.001$). The rejection subgroup's decline was not significantly different from the control group's decline ($P=.82$). The acceptance subgroup showed preexisting behavioral indicators of higher readiness to change, including 21.53% shorter consecutive usage thresholds ($P=.03$) compared to the rejection subgroup, with a directionally consistent but nonsignificant difference in cooldown length (+20.56%). Behavioral divergence in consecutive usage thresholds widened post intervention, with Cohen *d* increasing from −0.47 to −0.67 ($P=.002$). Acceptance subgroup participants demonstrated a significantly lower tendency to select leisure-oriented daily goals (15.6% vs 26.2%; chi-square $P=.001$, Cramer $V=0.13$). Self-reported measures of screen time goals and scrolling regret were not significantly associated with intervention acceptance ($P>.10$).

Conclusions: Observable in-app behavioral indicators, rather than self-reported measures, effectively differentiate intervention receptiveness. Study results suggest that effective DSCT design should incorporate adaptive strategies that recognize and respond to users' readiness to change, as evidenced by their in-app behaviors, while preserving autonomy. Such systems are likely to outperform static interventions or designs that rely solely on self-reported preferences.

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KEYWORDS

digital self-control tools; digital well-being; smartphone addiction; nudge; self-determination theory; behavior change; user engagement; mobile apps; self-report; screen time

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Introduction

Background

Concerns about digital well-being, the equilibrium individuals maintain in their relationship with mobile devices [1,2], have become a prominent public health issue as smartphones increasingly mediate daily activities [3,4]. Social media platforms, driven by engagement-maximizing recommendation algorithms [5,6], create environments in which users' conscious intentions to moderate their digital consumption compete against scientifically designed engagement mechanisms [7], contributing to excessive screen time and associated mental health concerns [8]. As awareness of these dynamics has grown, so has interest in interventions that support users in self-regulating their digital behaviors without removing the underlying technologies from their lives.

In response to these emerging public health challenges, researchers and developers have explored technological solutions to promote digital well-being and self-regulation. These attempts led to the emergence of digital self-control tools (DSCTs) designed to help users monitor and regulate their digital activities [9,10]. These tools embody a paradoxical approach: using technology to regulate technology by using digital interventions that modify users' decision-making environments [11]. DSCTs operate across various platforms and contexts, from browser extensions that modify YouTube's user interface by removing recommendation feeds [12] to mobile apps designed to address excessive smartphone usage [10].

Central to DSCTs is the concept of the nudge: an element of choice architecture that predictably alters behavior without restricting options [13]. Increasingly applied to digital environments as "digital nudging" [14], DSCTs employ various nudge strategies, from friction-based approaches that intercept every app launch [15] to threshold-based nudges that activate only when usage exceeds a self-configured limit [9,10]. The latter approach preserves user autonomy by operating passively until triggered by actual behavior, but its effectiveness depends critically on configuration: thresholds set too high may never trigger, rendering the tool inert, whereas settings perceived as too restrictive may provoke abandonment [16]. This makes the user's willingness to configure and maintain meaningful nudge parameters, rather than the tool's technical capabilities, a central determinant of DSCT effectiveness.

One Sec, a mobile DSCT, exemplifies the friction-based approach: it intercepts every attempt to open a target application with a deliberative interface combining messaging, temporal friction, and the option to cancel [15]. While effective over a 6-week period [15], the high-friction nature of such interventions generates user resistance [16], highlighting a broader tension in DSCT design between intervention intensity and long-term retention.

Empirical evidence underscores this tension: studies on DSCTs have yielded mixed results, with one study finding that such interventions lacked perceived effectiveness [17]. While a meta-analysis found that control tools may be linked to reduced smartphone use, it did not address whether disconnection alone fosters digital well-being [11]. Current implementations of these tools face substantial limitations, particularly in maintaining sustained user interaction [18], which is a common issue for digital and smartphone-based interventions [19-21]. The prevalent approach of implementing prescheduled interventions often results in a misalignment between users' initial motivations and their subsequent behavioral patterns, sparking a feeling of helplessness or annoyance in users and ultimately compromising the long-term effectiveness of these tools [16]. The primary challenge lies in developing interventions that not only initiate but also maintain behavioral change while preserving user autonomy throughout the process.

User retention is a well-documented problem across mobile health apps [22], with motivational decline identified as a primary abandonment factor [23]. Within DSCTs, specifically, excessive or unreliable interventions might precipitate tool abandonment. Current literature identifies 2 critical research priorities: implementing effective blocking strategies and encouraging users to maintain properly configured nudge settings that generate meaningful interventions over time. Our study focuses on the latter: users who have disabled their nudge configurations are of particular interest because they represent a subgroup that initially engaged with the DSCT but subsequently became passive, potentially signaling declining readiness to self-regulate.

Understanding what drives users to actively configure and engage with DSCTs requires a theoretical framework for motivation and behavior change. Self-determination theory (SDT) posits that sustained behavior change depends on the satisfaction of 3 basic psychological needs: autonomy, competence, and relatedness [24]. When applied to technology design, SDT suggests that autonomy-supportive interfaces, those that allow users to set their own parameters rather than imposing restrictions, foster more lasting engagement [25,26]. Complementary to SDT, the transtheoretical model frames behavior change as progressing through stages of readiness, from precontemplation to maintenance [27]. In the DSCT context, users who actively configure nudge parameters may be at a different readiness stage than those who have disengaged, and observable in-app behaviors could serve as proxies for these otherwise latent motivational states [28].

Despite growing research on DSCT effectiveness, a critical gap remains: current literature relies primarily on self-reported measures to assess user engagement and motivation, yet the behavioral factors, observable through configuration logs and usage data, that determine whether users continue to engage with nudges over time remain underexplored. There is limited work investigating whether in-app behavioral indicators can predict intervention receptiveness more effectively than traditional self-reported measures. Identifying such indicators is essential for developing adaptive interventions that not only initiate behavioral change but sustain it through continued user engagement.

Research Questions

This study investigates whether prompting passive DSCT users to reconfigure their nudge settings can restore engagement and whether observable behavioral indicators are more strongly

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associated with intervention receptiveness than self-reported measures. Through a quasi-experimental protocol, we target users who have disabled nudges (or have set their usage threshold excessively high so that nudges are never triggered) and invite them to reconfigure their nudge settings. We address the following 3 research questions (RQs):

- RQ1: To what extent does prompting users to reconfigure nudges after deactivation increase subsequent user-nudge interaction and engagement?
- RQ2: How does user engagement with nudges evolve over time after a reconfiguration prompt, and what behavioral divergence emerges between accepting and rejecting users?
- RQ3: To what extent do users' in-app behavioral indicators, including nudge configurations, usage-triggered interaction logs, and daily goal selections, serving as proxies for intent and readiness to change, reveal meaningful differences between users who accept and those who reject DSCT intervention prompts, in comparison with self-reported measures?

The findings aim to inform the design of more effective digital well-being interventions by identifying observable indicators of user engagement and readiness to change.

Methods

Digital Self-Control Tool

Tool Development

Detox [29] is an iOS app launched in November 2023 designed to foster sustainable digital well-being by implementing targeted app-blocking mechanisms. The app specifically targets excessive smartphone use over short durations, a behavior commonly associated with *doomscrolling*—the excessive consumption of short-form content on smartphone apps [30]. While the term originally emerged during the COVID-19 pandemic to describe the excessive consumption of negative news, it has since evolved in colloquial usage to refer more broadly to the inability to disengage from endless or infinite scrolling interfaces displaying short-form videos on social media [31].

The development of Detox followed an iterative methodology inspired by the lean startup model [32]. An initial prototype was created prior to conducting user interviews or engaging early adopters. Once the first version was released, usage patterns of early adopters were monitored, and approximately 50 in-depth user interviews were conducted to refine the product. Feedback from these interviews highlighted that Detox effectively mitigated excessive social media engagement, particularly patterns linked to doomscrolling, thereby guiding the app's evolution to better meet user needs.

Over a 12-month period, Detox evaluated various behavioral modification strategies by adjusting the "friction coefficient" of smartphone app access, including social media access. This involved experimenting with restrictive interventions, such as blocking access to apps until the following day after excessive use, and more lenient approaches, such as only sending reminders in the form of notifications to stop scrolling. By November 2024, insights from more than 8000 users supported the creation of a theory-informed and empirically anchored framework of digital interventions, drawing on behavioral data, interviews, and SDT. These interventions were meticulously calibrated to address maladaptive social media interaction patterns to promote healthier digital habits.

Underlying Conceptual Framework

The theoretical underpinning of Detox's intervention framework prioritizes user autonomy in self-regulation over the imposition of restrictive measures [24,33]. Grounded in SDT, Detox emphasizes 3 core psychological needs—autonomy, competence, and relatedness—which are widely recognized as critical components of apps designed to facilitate behavior change [24,26,34]. These constructs are conceptualized as follows:

- Autonomy: The need to perceive oneself as the originator of one's actions, with behaviors aligned to personal values and interests.
- Competence: The need to feel proficient and effective in one's endeavors. When competence is satisfied, individuals gain confidence in their ability to master tasks and attain desired outcomes, thereby bolstering motivation and engagement.
- Relatedness: The need to experience meaningful connections and a sense of belonging within interpersonal relationships. Fulfillment of this need fosters psychological well-being and sustains motivational processes.

According to SDT, the satisfaction of these 3 needs supports intrinsic motivation, promotes personal growth, enables sustained behavior change, and contributes to psychological well-being. This framework aligns closely with contemporary theories of behavioral modification that advocate for sustainable change [28]. By embedding these principles, Detox's approach offers a theoretically robust foundation for addressing phone addiction while respecting individual agency.

Intervention Design

For each intervention, users maintain the agency to decide which apps they want to monitor. Detox implements 3 distinct categories of interventions, as illustrated in Figure 1.

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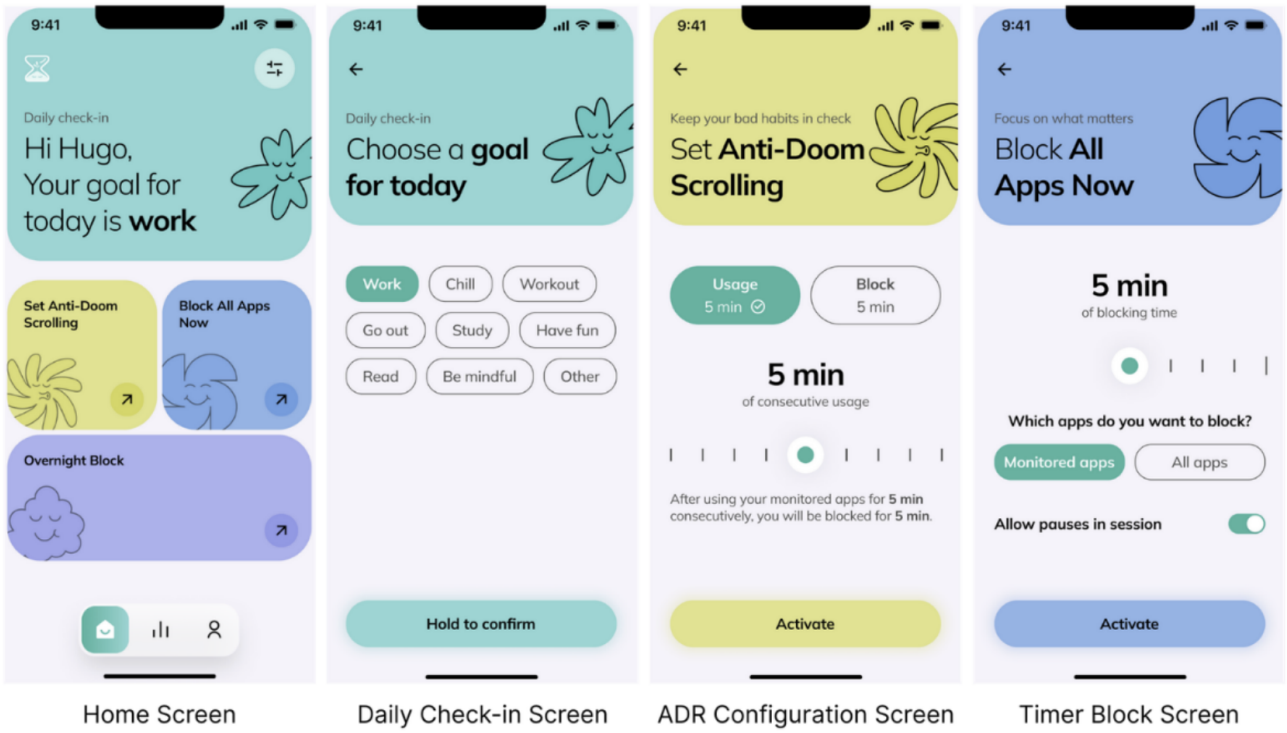
Figure 1. Main screens of the Detox app demonstrating the user interface design grounded in self-determination theory, featuring customizable intervention parameters that preserve user autonomy while facilitating digital self-regulation.



The Daily Check-In

This serves as the primary forced intervention mechanism. Beginning at 4 AM daily, the system automatically restricts access to monitored apps until users complete their daily check-in within the Detox interface. During this process, users establish a daily objective (eg, "Chill," "Work," or "Study"), which informs subsequent intervention protocols throughout the day (Figure 1, second panel).

The Anti-Doomscrolling Reminder

This represents a user-configured nudging mechanism that is activated based on continuous usage patterns. The intervention is triggered when usage duration exceeds a user-defined threshold (eg, 5 min of continuous engagement), resulting in a temporary restriction period (eg, 1 min). Both the continuous usage threshold and restriction duration are customizable parameters determined by the user (Figure 1, third panel).

The Timer Block/Overnight Block

These functionalities enable temporal restriction of monitored apps for user-specified durations (Figure 1, fourth panel).

For clarity and consistency throughout the remainder of this paper, we will employ the following terminology: "Daily Check-In" will continue to be referred to as such; "The Anti-Doomscrolling Reminder" will be referred to as the "nudge feature"; and "The Timer Block/Overnight Block" will be referred to as "manual app blocking." These designations will facilitate precise discussion of each intervention type and its respective effects on user behavior.

Study Design

Participant Recruitment

The study population consisted of users from the DSCT user base who engage with the app through mandatory daily check-ins. Within this population, we distinguish between active users—those who demonstrate regular user-nudge interaction on a weekly basis by receiving nudges—and passive users—those who complete daily check-ins but do not receive any nudges. Our recruitment specifically targeted users who had disabled nudges prior to enrollment; that is, users who had previously configured nudge settings but subsequently deactivated them or set their consecutive usage threshold too high for nudges to be triggered.

The total DSCT user base comprised 472 daily check-in users: 252 (53.4%) were passive users meeting our eligibility criteria, whereas 220 (46.6%) were active users with regular nudge interactions and thus ineligible for this experiment. We successfully recruited all 252 eligible passive users through a rolling enrollment protocol over 3 days (November 22 - 24, 2024). Participants in the experimental group (n=138) each received exactly 1 prompt to reconfigure settings during this period. This sample represents the maximum possible recruitment from the target population.

Participants were randomly allocated to 1 of 2 conditions: the experimental group (n=138, 54.8%), which received a prompt to reconfigure their nudge settings during their daily check-in, or the control group (n=114, 45.2%), which consisted of passive users who met the same eligibility criteria but received no intervention, serving as a baseline for comparison. Within the experimental group, those who accepted the prompt were subsequently classified as the acceptance subgroup, whereas those who declined formed the rejection subgroup.

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Randomization between experimental and control groups was performed automatically at the device level, with allocation decisions executed independently for each participant. Although the study protocol targeted an equal distribution (50%) between groups, the observed imbalance resulted from the decentralized randomization process, which operated without global coordination and allowed for independent assignment variations across devices. No incentives were provided for participation or intervention acceptance; participants' decisions to accept or decline the prompt were entirely voluntary and self-motivated.

Procedure

The experimental group (n=138) was presented with the intervention before completing their daily goal selection during the rolling enrollment window (November 22 - 24, 2024). Based on their response, participants were classified into acceptance or rejection subgroups. Group assignment remained fixed throughout the study period.

The control group (n=114) completed their daily check-in without receiving any intervention, maintaining access to all application features.

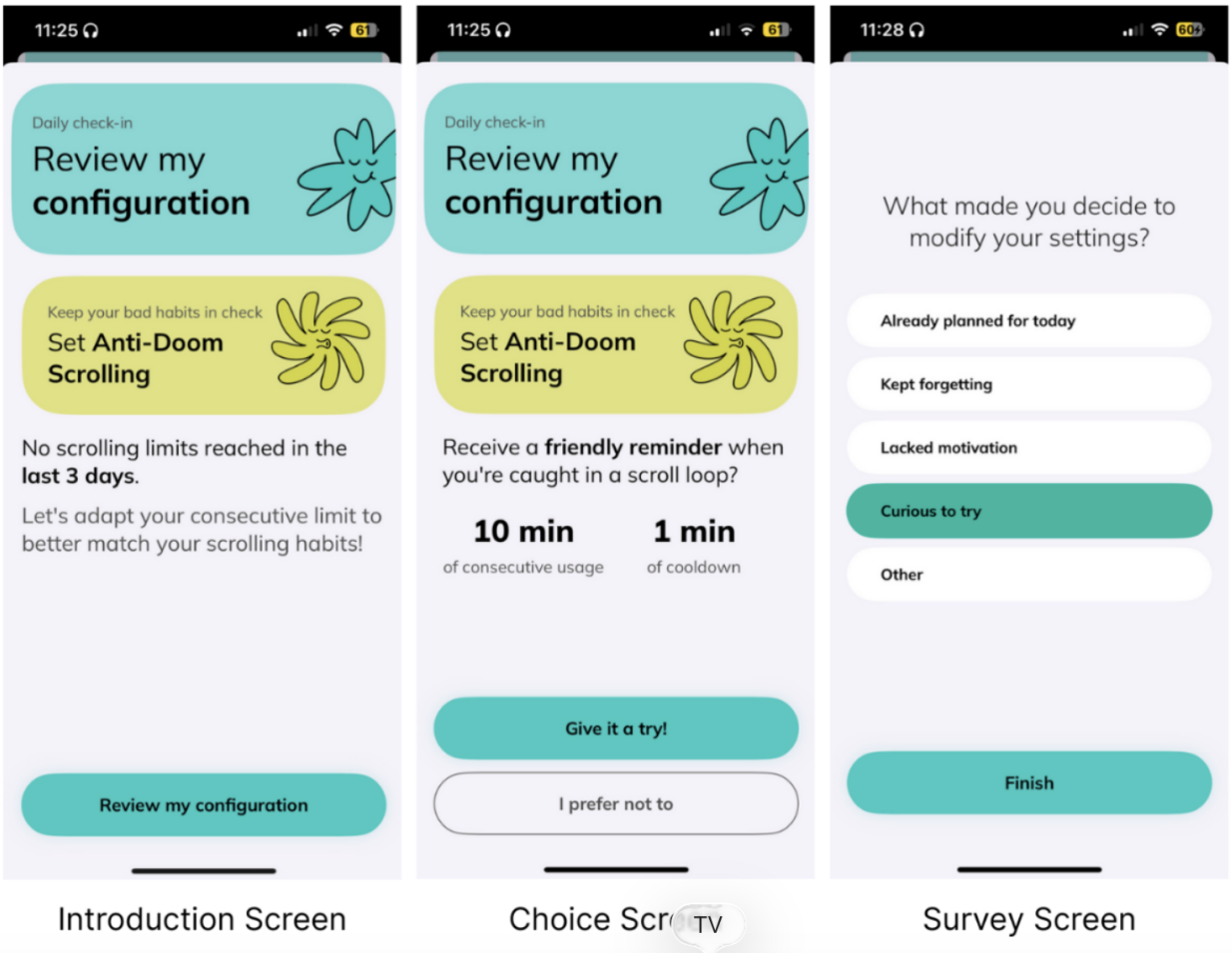
Usage data were collected continuously for 5 weeks: 1 week before intervention and 4 weeks post intervention.

Intervention

The intervention consisted of 3 screens integrated into the daily check-in flow, as depicted in Figure 2. The detailed user journey of the experiment design can be found in Figure S1 in Multimedia Appendix 1. The intervention screens are as follows:

- Introduction screen: Presented before daily goal selection, this screen highlighted the user's inactive nudge configuration with the message "Review my configuration" and prompted them to "Set Anti-Doom Scrolling."
- Choice screen: Displayed a suggested nudge configuration of 10-minute consecutive usage followed by a 1-minute cooldown period. Users could accept ("Give it a try!") or decline ("I prefer not to") this configuration.
- Survey screen: A mandatory single-choice questionnaire captured the user's rationale for their decision, with response options including "Kept forgetting," "Looked motivating," and "Other."

Figure 2. Experiment screens illustrating the quasi-experimental protocol for the nudge reconfiguration prompt, highlighting the preservation of user autonomy through voluntary participation and the systematic data collection framework.



Experimental participants maintained complete autonomy regarding intervention acceptance and subsequent settings adjustments. For those who accepted the prompt, the system suggested a 10-minute consecutive usage limit as a default reconfiguration option. This recommendation was designed to provide a reasonable, nonextreme starting point that would minimize potential user frustration [16] while encouraging engagement with the nudge system. Participants remained free to adjust their settings to higher or lower thresholds at any time

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following their initial reconfiguration, ensuring continued autonomy over their digital well-being preferences.

Data Collection and Instruments

Data collection was conducted through the Mixpanel analytics platform, which implemented event-based logging protocols to systematically record user interactions. We collected 2 categories of data: (1) DSCT configuration logs and usage-triggered nudge logs, which serve as observable behavioral indicators (used for RQ1, RQ2, and RQ3) and (2) self-reported questionnaire data from onboarding surveys and postintervention surveys (used for RQ3). Key metrics are defined below.

- User-nudge interaction ratio: The user-nudge interaction ratio represents the daily proportion of users in a given group for whom the nudge mechanism was effectively triggered (ie, the user reached the configured consecutive usage threshold and a "nudge reached" event was logged), relative to the total number of users in that group. This metric reflects actual behavioral intervention based on real usage, not merely whether the nudge feature was enabled in the app configuration.
- Consecutive usage threshold: A user-configured nudge parameter (in min) representing the continuous screen time threshold on monitored apps before a nudge is triggered.
- Cooldown length: A user-configured nudge parameter (in minutes) representing the duration of app blocking once the consecutive usage threshold is reached.
- Daily goal selection: An optional, self-selected daily intention chosen during the check-in (Chill, Work, Study, or Skipped). Purely indicative and does not alter nudge parameters. Treated as an in-app behavioral indicator of goal selection patterns, distinct from traditional self-report, because it is a repeated contextual choice reflecting immediate priorities rather than retrospective attitudes.

Usage-triggered nudge logs captured "nudge reached" events—the date and time at which users' consecutive usage exceeded their configured threshold, triggering app blocking. DSCT configuration logs recorded updates to nudge parameters (consecutive usage threshold and cooldown length), monitored app selections, and monitored interactions with manual app blocking features. Daily check-in completions, including the user's daily goal selection, were recorded with associated timestamps. Together, these data sources provided the behavioral indicators used for RQ1 (user-nudge interaction ratio over time), RQ2 (configuration divergence and spillover effects), and RQ3 (preintervention behavioral differences between subgroups).

Self-reported data were gathered through multiple modalities:

1. Onboarding surveys: Participants completed assessments of their device usage patterns, including daily screen time, intended screen time goals, frequency of regretted scrolling sessions, and contexts in which such regret occurred. These measures, collected at app installation, serve as traditional self-reported baseline indicators (used for RQ3).
2. Postintervention survey: A single-choice questionnaire capturing participants' rationale for accepting or rejecting the reconfiguration prompt (used for RQ3).

Demographic data were collected through multiple methodological approaches: age and gender data were obtained via DSCT onboarding surveys, and geographical location was determined through Mixpanel analytics tools.

Related to the nudge reconfiguration prompt, experimental response data documented the temporal sequence of intervention-related events with precise timestamps. The platform recorded intervention acceptance or rejection, subsequent nudge settings adjustments, and postintervention interaction patterns.

The daily engagement framework, facilitated by the mandatory daily check-in feature, ensured consistent participation and enabled measurement of daily user interaction and attrition rates. Together, these mechanisms established a robust environment for examining variations in user interaction and self-regulation outcomes.

Data Analysis

We structured our analyses around the 3 research questions.

For RQ1, we computed the daily user-nudge interaction ratio for each group and compared 7-day preintervention (November 16 - 22, 2024) and postintervention (November 24 - 30, 2024) averages across the acceptance subgroup, rejection subgroup, and control group. The preintervention and postintervention windows were selected to maximize temporal separation from the rolling enrollment period (November 22 - 24, 2024) while maintaining 7-day averaging; minor overlap on boundary days was mitigated by aggregation. To assess whether the acceptance subgroup change was attributable to the intervention rather than temporal trends, we applied a difference-in-differences (DiD) analysis at the daily aggregate level, using permutation tests (10,000 iterations) to derive *P* values. This approach compares each subgroup's pre-to-post change against the control group's change.

For RQ2, we analyzed the time-series of the user-nudge interaction ratio across a 5-week window (1 week preintervention and 4 weeks postintervention) to assess the sustainability of re-engagement. We compared DSCT configuration parameters (consecutive usage threshold and cooldown length distributions) and manual app blocking interactions between the acceptance and rejection subgroups at 2 time points (preintervention: November 20, 2024; postintervention: November 29, 2024) using independent-samples *t* tests with Cohen *d* as a measure of effect size.

For RQ3, we compared 2 categories of indicators between the acceptance and rejection subgroups: (1) observable behavioral indicators—consecutive usage threshold and cooldown length (independent-samples *t* tests) and daily goal selection coded as binary leisure versus nonleisure (chi-square test with Cramer *V*)—and (2) traditional self-reported measures—onboarding survey responses on screen time goals, scrolling regret frequency, and emotional responses (independent-samples *t* tests) and postintervention survey responses. By comparing the statistical significance of behavioral indicators against self-reported measures, we assessed which category better

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differentiates users who accept from those who reject the reconfiguration prompt.

All statistical analyses were conducted by exporting Mixpanel data into a Jupyter Notebook environment. The study applied a statistical significance threshold of $P<.05$. All *t* tests were 2-tailed. Effect sizes were calculated using Cohen *d* for continuous variables and Cramer *V* for categorical comparisons.

Ethical Considerations

This study was considered a service evaluation of a commercially available app, analyzing anonymized and nonidentifiable in-app usage data. As such, it was not subject to the requirements for formal ethics committee approval, consistent with institutional guidelines for nonclinical research involving deidentified data. No personally identifiable information was collected, and participants could not be reidentified by researchers due to the app's tokenization system, which is compliant with Apple's privacy guidelines for app monitoring. Participants, or their legal representatives in the case of minors, consented to the use of their anonymized data for research purposes through the app's terms of service and onboarding process. All data were stored and processed in compliance with applicable privacy regulations, and no compensation was provided to participants.

Results

Participant Characteristics

Analysis of participant demographics (Table 1) confirmed alignment with the broader DSCT user base. The sample was predominantly young, with 51.4% (71/138) of experimental participants and 57% (65/114) of control participants aged 18 to 24 years. Among the 137 (54.4%) participants who reported gender, 86 (62.8%) identified as male. Participants were geographically distributed across 55 countries, with the largest concentrations in North America and Europe. No significant demographic differences were found between the experimental and control groups (all $P>.05$; Table 1), validating the initial randomization. Demographic distributions were also consistent between the acceptance and rejection subgroups within the experimental condition (age: $P=.68$; gender: $P=.33$; geography: $P=.19$), demonstrating that demographic characteristics did not influence participants' decisions to accept or reject the prompt.

Table . Demographic characteristics of study participants by group assignment.[a]

Characteristic	Experimental (n=138), n (%)	Control (n=114), n (%)	*P* value[b]
Age (y)			.24
<18	38 (27.5)	25 (21.9)	
18 - 24	71 (51.4)	65 (57)	
25 - 34	16 (11.6)	13 (11.4)	
≥35	13 (9.4)	4 (3.5)	
Gender[c]			.16
Male	42 (30.4)	44 (38.6)	
Female	21 (15.2)	26 (22.8)	
Other or prefer not to say	0 (0)	4 (3.5)	
Not reported	75 (54.3)	40 (35.1)	
Geographic region[d]			.30
North America	38 (27.5)	37 (32.5)	
Europe	48 (34.8)	42 (36.8)	
Asia-Pacific	25 (18.1)	22 (19.3)	
Middle East and Africa	22 (15.9)	8 (7)	
Latin America	5 (3.6)	5 (4.4)	

[a]The experimental (n=138) and control (n=114) groups showed no significant differences in age, gender, or geographic distribution (all $P>.05$), confirming successful randomization.

[b]*P* values from chi-square tests comparing the experimental and control groups. The gender test excludes participants who did not report gender. Age data were unavailable for 7 control participants due to nonnumeric entries in the analytics platform.

[c]Gender data were collected via an optional onboarding survey item. Among the 137 out of 252 (54.4%) participants who reported gender, 86 (62.8%) identified as male, 47 (34.3%) as female, and 4 (2.9%) as other or preferred not to say.

[d]Geographic region determined via app analytics geolocation.

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RQ1: Intervention Effect on User-Nudge Interaction

Overview

To assess the intervention's effect on user-nudge interaction, we compared 7-day preintervention and postintervention averages and applied a DiD analysis to control for temporal trends (see the Methods section). Of the 138 experimental participants, 46% (n=63) accepted the nudge reconfiguration prompt, yielding 3 cohorts: the acceptance subgroup (n=63), rejection subgroup (n=75), and control group (n=114). Figure 3 illustrates the temporal evolution of the daily user-nudge interaction ratio, and Table 2 summarizes the DiD results.

Figure 3. Temporal evolution of the daily user-nudge interaction ratio (%) across the acceptance subgroup (n=63), rejection subgroup (n=75), and control group (n=114). Shaded bands represent 95% Wilson score CIs. The orange band marks the rolling enrollment window (November 22 - 24, 2024). Postintervention, the acceptance subgroup's 7-day average rose from 29.7% to 58.5%, whereas both the rejection subgroup and control group showed declines.

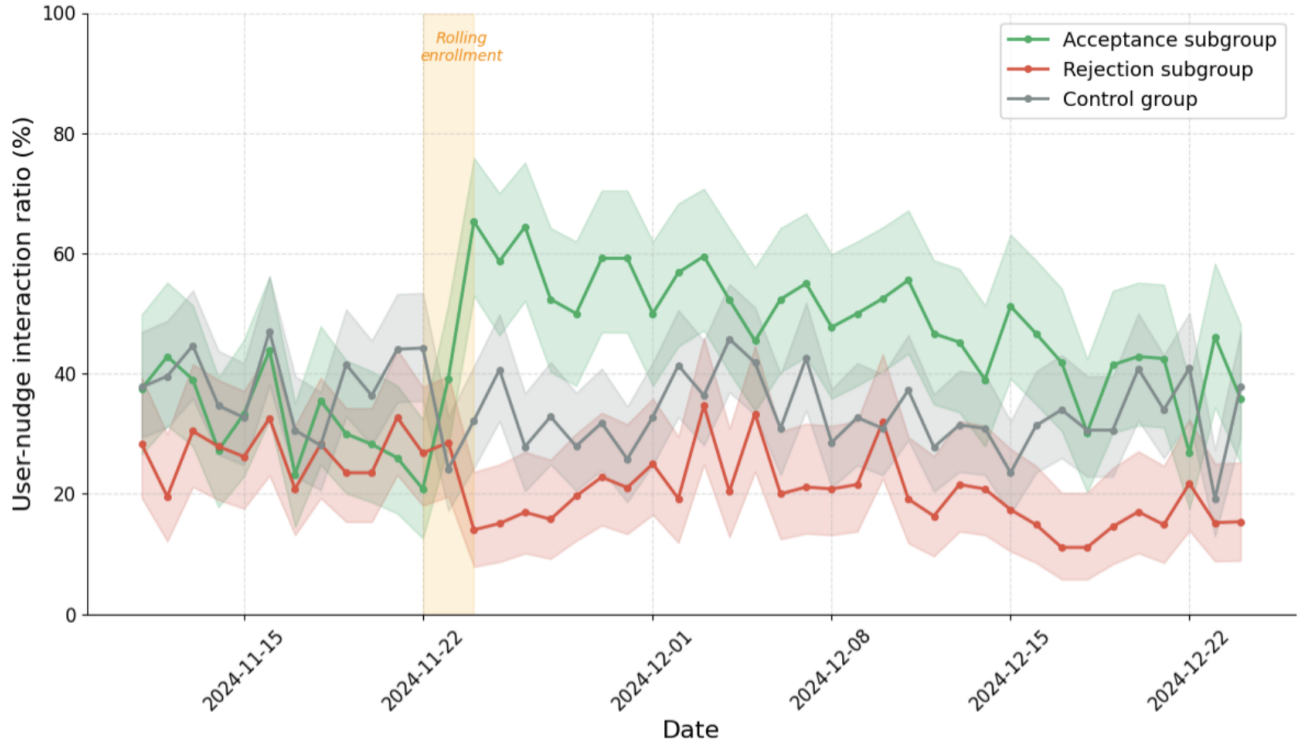

Table . Difference-in-differences analysis of user-nudge interaction ratio (7-day preintervention and postintervention averages).[a]

Comparison	Subgroup change (pp[b])	Control change (pp)	Difference-in-differences (pp)	*P* value
Acceptance vs control	+28.8	−7.5	+36.3	<.001
Rejection vs control	−9	−7.5	−1.4	.82

[a]The acceptance subgroup's increase was significant after controlling for the temporal decline observed in the control group (difference-in-differences=+36.3 pp, *P*<.001), whereas the rejection subgroup's decline was not significantly different from that of the control group (difference-in-differences=−1.4 pp, *P*=.82), confirming the intervention was not counterproductive.

[b]pp: percentage points.

Acceptance Subgroup Outcomes

The acceptance subgroup's 7-day average user-nudge interaction ratio increased from 29.7% preintervention to 58.5% postintervention (peak of 65% on day 1). This increase remained significant after controlling for the general temporal decline observed in the control group (Table 2).

Rejection Subgroup Outcomes

The rejection subgroup's 7-day average declined from 26.9% to 17.9%. This decline was not significantly different from that of the control group's decline (Table 2), confirming that the intervention was not counterproductive for users who declined the prompt. Throughout the observation period, this subgroup consistently demonstrated the lowest engagement rates across all cohorts.

Control Group Performance

The control group's 7-day average declined from 38.8% to 31.3%, consistent with a general temporal trend unrelated to the intervention. The acceptance subgroup's interaction ratio converged with the control group's, approximately 1 month post intervention.

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RQ2: Temporal Evolution and Behavioral Divergence

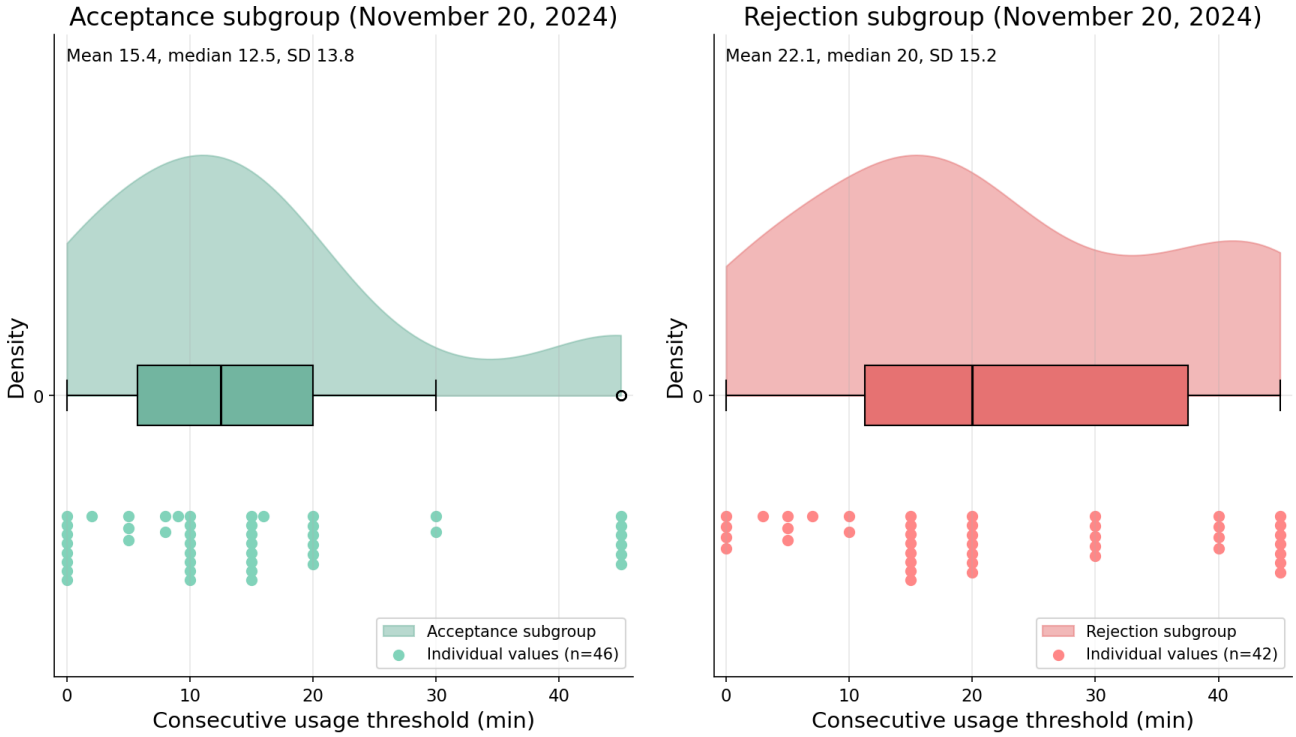
Overview

Having established the significance of the intervention effect (RQ1), we examined the sustainability of re-engagement over time. Figure 3 illustrates the temporal evolution of the user-nudge interaction ratio across the 5-week observation window. The acceptance subgroup elevated engagement persisted above baseline for approximately 2 weeks before gradually declining, converging with control group levels by the 1-month mark. The rejection subgroup sustained the lowest engagement across all cohorts throughout the observation period.

Nudge Settings Configuration

Three days prior to the reconfiguration prompt, the acceptance subgroup configured shorter consecutive usage thresholds (−21.53%) and longer cooldown periods (+20.56%) compared with the rejection subgroup. The consecutive usage threshold disparity widened significantly 1 week post prompt, from t_{86}=−2.19, P=.03, Cohen d=−0.47 to t_{98}=−3.28, P=.002, Cohen d=−0.67, as depicted in Figures 4 and 5 (data from November 20 and 29, 2024). The cooldown length difference was not statistically significant at either time point (pre-intervention: t =0.62, P=.54, Cohen d=0.13; post-intervention: t =−0.08, P=.93, Cohen d=−0.02). Acceptance subgroup participants largely maintained their reconfigured nudge settings (median=10 min) post intervention.

Figure 4. Distribution of consecutive usage threshold (min) between the acceptance subgroup (n=63) and rejection subgroup (n=75) on November 20, 2024 (preintervention). Acceptance subgroup participants configured 21.53% shorter consecutive usage thresholds (t_{86}=−2.19, P=.03, Cohen d=−0.47). Individual values reflect participants with active nudge configurations on the indicated date.



t_{86}=−2.19, P=.03, Cohen d=−0.47.

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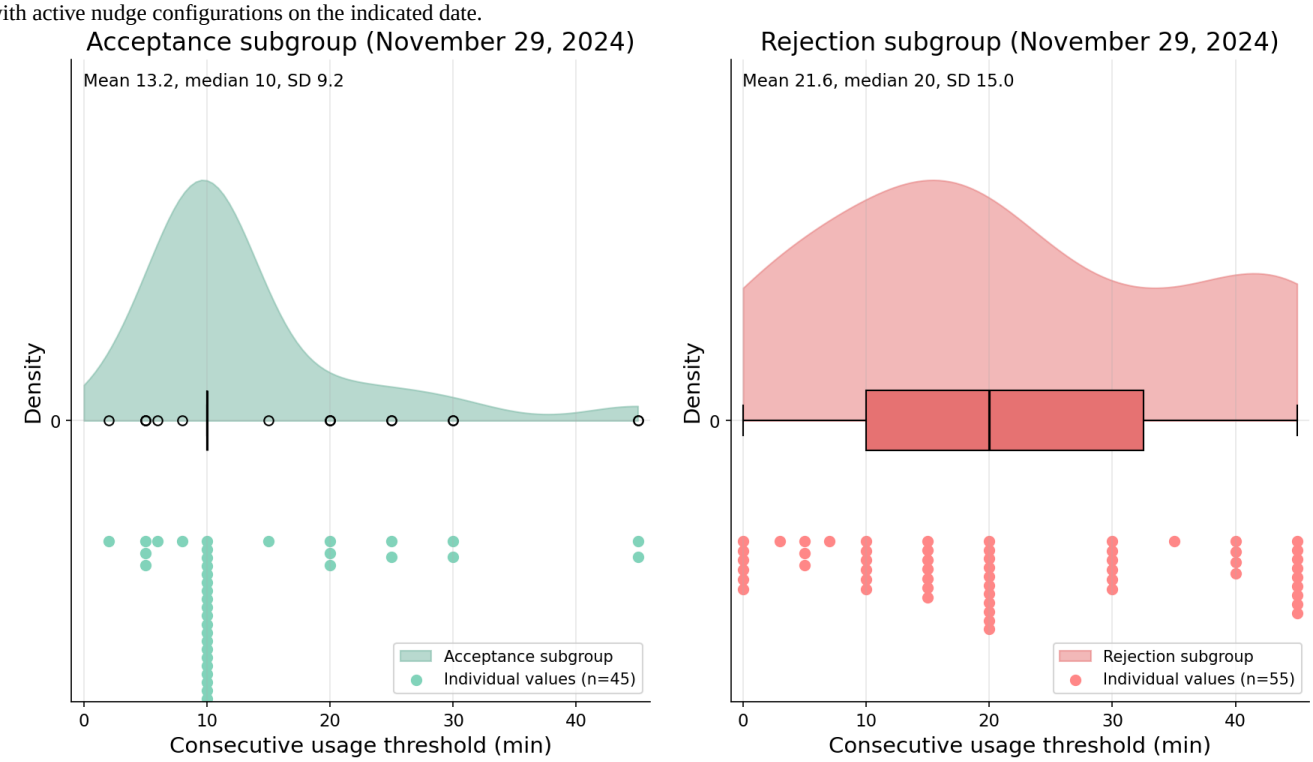
Figure 5. Distribution of consecutive usage threshold (min) between the acceptance subgroup (n=63) and rejection subgroup (n=75) on November 29, 2024 (postintervention). The effect size widened from Cohen d=−0.47 to Cohen d=−0.67 (t_{98}=−3.28, P=.002). Individual values reflect participants with active nudge configurations on the indicated date.



t_{98}=−3.28, P=.002, Cohen d=−0.67.

Manual App Blocking Interaction

Although the reconfiguration prompt targeted nudge settings rather than manual app blocking, the distribution of manual app blocking interactions between the acceptance and rejection subgroups diverged during the postintervention observation period. This divergence increased from November 20 (t_{86}=1.82, P=.07, Cohen d=0.39) to November 29 (t_{98}=2.58, P=.01, Cohen d=0.49), as shown in Figure S2 in Multimedia Appendix 1.

RQ3: Behavioral Indicators Versus Self-Reported Measures

Overview

The behavioral divergence reported under RQ2, particularly in consecutive usage threshold (P=.03) and, to a lesser extent, cooldown length (P>.05), suggested that observable DSCT configuration differences predate the intervention. To determine whether such in-app behavioral indicators are more strongly associated with intervention acceptance than traditional self-reported measures, we compared both categories of indicators between the acceptance and rejection subgroups, as described in the Data Analysis section.

Daily Check-in Goals

Compared with the rejection subgroup, acceptance subgroup participants demonstrated a significantly lower tendency to select “Chill” (leisure) as a daily goal (15.6% vs 26.2%; chi-square P=.001, Cramer V=0.13), as illustrated in Figure S3 in Multimedia Appendix 1. This pattern was stable across the observation period, showing no preintervention or postintervention change.

Onboarding Survey Analysis

Analysis of onboarding survey responses regarding current screen time, and screen time reduction goals revealed no significant differences (P>.1) between acceptance and rejection subgroups, as depicted in Figures S4 and S5 in Multimedia Appendix 1.

Further analysis of responses regarding scrolling regret frequency and associated emotional responses also yielded no significant differences (P>.1) between groups, as shown in Figures S6 and S7 in Multimedia Appendix 1. While response patterns were similar, both distributions exhibited comparable trends, evidenced by the similar distribution of the “Disappointed” response for scrolling-associated emotions.

Postintervention Survey

Postintervention survey data showed no statistically significant differences between the acceptance and rejection subgroups (P>.05), consistent with the pattern observed for other self-reported measures in this study.

Discussion

RQ1: Effectiveness of the Reconfiguration Prompt

The 46% (63/138) acceptance rate for nudge reconfiguration among passive users indicates that nearly half possess latent readiness to re-engage with DSCTs when prompted. The DiD analysis confirms that the acceptance subgroup’s increase in user-nudge interaction (DiD=+36.3 percentage points, P<.001) is attributable to the intervention rather than temporal trends, as the rejection subgroup’s decline was not significantly

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different from the control group's decline (DiD=−1.4 percentage points, *P*=.82). The comparable preintervention baselines between subgroups further support the conclusion that the observed change is driven by the intervention itself.

RQ2: Temporal Dynamics and Behavioral Divergence

The preintervention behavioral differences between subgroups are particularly noteworthy. Acceptance subgroup participants configured 21.53% shorter consecutive usage thresholds and descriptively longer cooldown periods (+20.56%, though not statistically significant) compared with the rejection subgroup, even before receiving the intervention. The widening of the consecutive usage threshold gap postintervention (Cohen *d* increasing from −0.47 to −0.67) indicates that the prompt amplified existing behavioral differences rather than creating new ones. The spillover effect observed in manual app blocking behaviors (Cohen *d* increasing from 0.39 to 0.49) further suggests that successful re-engagement with one DSCT feature may catalyze broader self-regulatory behaviors. However, the gradual decline in user-nudge interaction after approximately 2 weeks, converging with control group levels by 1 month, demonstrates the limitations of single-prompt interventions and aligns with SDT: extrinsic prompts alone cannot sustain behavioral change without corresponding intrinsic motivation [24].

RQ3: The Intention-Behavior Gap

The most striking finding is the disconnect between self-reported measures and behavioral indicators. Despite no significant differences in stated screen time goals, scrolling regret frequency, or emotional responses between the acceptance and rejection subgroups (all *P*>.1), observable behavioral indicators—shorter consecutive usage thresholds (*P*=.03) and lower selection of leisure-oriented daily goals (*P*=.001)—clearly differentiated those who would accept the reconfiguration prompt. Even the postintervention survey, which directly captured participants' rationales, showed no significant differences (*P*>.05). This intention-behavior gap [35] underscores the limitations of relying on self-reported data to characterize DSCT engagement and highlights the value of DSCT configuration logs and in-app behavioral choices as proxies for readiness to change.

Implications for DSCT Design and Implementation

Our findings challenge conventional approaches to DSCT user engagement. The 46% (63/138) acceptance rate among passive users and subsequent boost in user-nudge interaction challenge the binary classification of users as either engaged or disengaged, suggesting instead that engagement exists on a continuum with opportunities for reactivation even among seemingly passive users. This perspective encourages DSCT developers to implement proactive re-engagement strategies rather than simply accepting attrition as inevitable.

These proactive re-engagement strategies have proven more effective for users with higher readiness to change. Our preintervention data revealed that acceptance subgroup participants configured significantly shorter consecutive usage thresholds (−21.53%, *P*=.03), with a directionally consistent but nonsignificant difference in cooldown length (+20.56%), indicating that observable DSCT configuration behaviors are significantly associated with intervention receptiveness. DSCTs aiming to offer personalized experiences should leverage such behavioral markers to identify users most likely to benefit from re-engagement prompts, thereby optimizing intervention effectiveness.

However, the temporary nature of increased engagement reveals a critical limitation. While our intervention successfully boosted the acceptance subgroup's 7-day average user-nudge interaction ratio from 29.7% to 58.5% (peak of 65% on day 1), convergence with the control group after approximately 1 month demonstrates that single-prompt interventions alone cannot sustain behavioral change. Sustainable engagement requires progressive feature designs that transition users from external prompts to self-directed regulation, perhaps through adaptive goal setting, competence-building feedback, and autonomy-supportive interfaces.

Throughout these design considerations, the preservation of user autonomy emerges as a fundamental principle. DSCTs must navigate the inherent tension between providing behavioral support and avoiding paternalistic control. This delicate balance requires thoughtful intervention framing, opt-in mechanisms, customizable parameters, and transparent communication about the rationale behind nudges and restrictions. Only by respecting user agency can DSCTs foster the intrinsic motivation necessary for lasting behavior change, as our divergent group outcomes clearly demonstrate.

Limitations

This study has several limitations that inform the interpretation of our findings. Although the DiD analysis strengthens causal inference by controlling for temporal trends shared across groups, our quasi-experimental design cannot fully rule out self-selection effects, as preexisting behavioral differences between acceptance and rejection subgroups—particularly in nudge configurations—suggest self-selection dynamics [36] that complicate attribution of outcomes solely to the intervention. While these baseline differences provide valuable insights about readiness indicators, they prevent definitive conclusions about intervention causality.

Beyond design constraints, our reliance on behavioral proxies for psychological constructs introduces measurement limitations. Although usage patterns and configuration choices offer objective indicators, they cannot fully capture the complexity of readiness to change. Moreover, onboarding survey data used to assess baseline attitudes may not reflect participants' psychological states at the time of the experiment, as these surveys were collected at app installation, which for some participants occurred months before study enrollment.

Additionally, generalizability constraints arise from our sample characteristics. Participants were drawn exclusively from a single DSCT (Detox) with a specific design philosophy, predominantly young users (with over half aged 18 - 24 y and approximately one-quarter aged <18 y), and geographic concentration in North America and Europe. These factors may limit the applicability of our findings to other DSCTs, age groups, or cultural contexts in which digital self-regulation

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practices differ. An important point to note is that our sample consisted exclusively of users who voluntarily installed a DSCT to reduce screen time, suggesting higher baseline motivation than the general population. This limits generalizability to individuals who have not actively sought digital self-regulation tools.

Furthermore, we cannot determine whether the decline in user-nudge interaction observed in Figure 3 represents a successful change in behavior that reduces reliance on the tool or disengagement from self-regulation efforts, as we lack direct measures of participants' real-world digital well-being behaviors outside the DSCT environment.

Future Research Directions

Our findings illuminate critical avenues for advancing DSCT effectiveness research. The convergence of acceptance and control groups after 1 month raises fundamental questions about intervention durability. This pattern suggests that single-prompt interventions have limited sustainability, pointing toward the need for longitudinal studies investigating optimal intervention cadences. Research should test whether periodic re-engagement at empirically determined intervals can maintain elevated user engagement without inducing prompt fatigue.

Building on our identification of behavioral readiness indicators, predictive modeling represents a promising research direction. While our study identified several behavioral indicators associated with acceptance, comprehensive models incorporating temporal patterns, contextual factors, and usage trajectories could enable dynamic, personalized intervention timing. Machine learning approaches could identify complex behavioral signatures that signal optimal intervention moments, moving beyond static threshold rules to recognize when users are most receptive to change. Future research may integrate comprehensive psychological assessments, ecological momentary assessments of human-device interaction, objective and longitudinal measures of smartphone and app use (eg, usage logs), as well as contextual data on physical and social environments to better understand how these factors jointly influence digital well-being.

Furthermore, comparative effectiveness research across theoretical frameworks is essential for establishing evidence-based DSCT design principles. Our study examined 1 SDT-based approach, but the field would benefit from systematic comparisons of different intervention philosophies. Understanding which approaches work best for different user segments, cultural contexts, and problematic usage patterns could guide the development of more personalized and effective interventions.

These research directions collectively aim to transform DSCTs from static tools to adaptive systems that recognize and respond to users' evolving motivational states while preserving the autonomy essential for lasting behavioral change.

Conclusion

This study demonstrates that prompting passive DSCT users to reconfigure their nudge settings can effectively restore engagement (RQ1), with effects persisting for approximately 1 month before converging with baseline levels (RQ2). Observable behavioral indicators—including shorter consecutive usage thresholds (P=.03) and lower selection of leisure-oriented daily goals (P=.001)—differed significantly between participants who accepted versus rejected the intervention, whereas self-reported measures showed no such differences (RQ3). This intention-behavior gap underscores the value of in-app behavioral data over self-report measures for understanding user engagement with digital well-being interventions.

Our findings suggest that the future of effective DSCT design lies not in creating more restrictive or feature-rich tools but in developing adaptive systems tailored to the needs of specific population clusters and based on SDT principles that recognize and respond to users' motivational states while preserving their autonomy, increasing their competence and reinforcing relatedness. As digital well-being becomes an increasingly critical public health concern, understanding the psychological mechanisms underlying successful self-regulation in digital contexts becomes essential for developing interventions that create lasting positive change.

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Data Availability

Data are not publicly available due to the sensitive nature of the content and the risk of participant reidentification. However, distributions of usage logs and survey responses, along with representative deidentified participant quotes, are included in the manuscript to support key findings. Additional data may be made available from the corresponding author upon reasonable request and with appropriate institutional approvals.

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Authors' Contributions

AKPA and LL contributed to software development and investigation, including participant recruitment, screening, and data collection. AKPA was responsible for formal analysis, data curation, visualization, and writing the original draft. SI, YK, JCF, and DG contributed to conceptualization, methodology, supervision, and reviewing and editing the manuscript. LL contributed to reviewing and editing the manuscript. All authors approved the final version of the manuscript.

Conflicts of Interest

AKPA and LL developed the mobile app used in this study. Participants were recruited from the broader user base and were not personally known to the researchers. AKPA and LL maintained complete separation from user decision-making processes to ensure study integrity and prevent any potential bias that could compromise the validity of the results. All other authors report no conflicts of interest.

Multimedia Appendix 1
Detailed nudge reconfiguration settings, participant inclusion criteria, and supplementary statistical analyses.
[PDF File, 556 KB - formative_v10i1e85349_app1.pdf]

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Abbreviations

DiD: difference-in-differences
DSCT: digital self-control tool
RQ: research question
SDT: self-determination theory

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Experiences From an Internet-Delivered Treatment Program for Individuals With Obesity: Pilot Study

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Abstract

Background: The prevalence of obesity is a global health challenge, as obesity is associated with various comorbidities, reduced quality of life, and increased mortality. Providing effective treatment to improve health and quality of life for people with obesity is a major health care concern. Internet-delivered treatment (IDT) is an alternative treatment that increases patient accessibility and reachability; however, pilot testing is required before such interventions are evaluated in full-scale studies or implemented.

Objective: This study aims to investigate the feasibility and user-friendliness of an IDT program for obesity (IDT-O); to evaluate body weight, dietary habits, physical activity, psychosocial functioning, and experiences of treatment in those who completed the 6-month treatment; and to investigate the dropouts' experiences of the treatment.

Methods: A prospective 1-year observational approach, evaluated through a multimethod research design, was adopted. Inclusion criteria were age 18 years and older, BMI of ≥30 kg/m^2, or BMI of 28 - 29.9 kg/m^2 with obesity-related comorbidity. Participants were offered a 6-month therapist-assisted IDT-O program providing evidence-based obesity treatment, behavioral and lifestyle support, and strategies to address weight stigma. BMI, participants' dietary habits, self-reported physical activity, psychosocial functioning, experiences of treatment effects, and treatment satisfaction were measured before treatment and after 6 and 12 months. Dropouts were followed up through qualitative interviews.

Results: A total of 20 participants (17 females and 3 male; mean age 44.2, SD 16.4 years) started the IDT-O program, and 35% (7/20) completed all 12 modules. Ten (8 females) out of 13 dropouts were interviewed. Both quantitative and qualitative findings showed that participants were generally satisfied with the content and design of the intervention. Those who completed the IDT-O lost some weight (mean 2.0%, 95% CI −1.09 to 5.13), reported improved dietary habits (effect size [ES] 0.25, 95% CI −0.51 to 1.00), increased physical activity (ES 0.93, 95% CI −0.08 to 1.87), and improved psychosocial functioning (distress: ES 0.43, 95% CI 0. - 0.37 to 1.19; avoidance: ES 0.67, 95% CI −0.18 to 1.48), 6 months after completing the treatment. The qualitative analysis of the interviews revealed "The programme was OK, but it does not suit everyone" as the main theme. The main themes were based on the 3 subthemes: "It wasn't for me," "There were good things," and "There are things to improve."

Conclusions: The findings indicate that the IDT-O holds potential as a treatment for people with obesity, although one limitation is that only 35% (7/20) of the participants completed the pilot program. Improvements in lifestyle habits and psychosocial functioning were observed in those who completed the IDT-O, but these findings are preliminary and need to be confirmed in a more comprehensive study. The issue of nonadherence underscores the importance of both thoroughly assessing patients before treatment and further development of IDT-O programs.

Trial Registration: ClinicalTrials.gov NCT04150445; https://clinicaltrials.gov/study/NCT04150445

(JMIR Form Res 2026;10:e79853) doi:10.2196/79853

KEYWORDS

cognitive behavioral therapy; internet-based intervention; multimethods; obesity; pilot projects; social stigma

Introduction

The prevalence of obesity has increased over the past 30 years and represents a global health challenge [1]. Obesity is a chronic disease associated with various comorbidities, reduced quality of life (QoL), and increased mortality risk [2]. Providing effective treatment to improve health and QoL for the large proportion of the population with obesity is a major health care concern.

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Lifestyle interventions focusing on dietary habits and physical activity are central components of weight loss treatment [3], but in-person treatment is staff-intensive and entails high costs, limiting the number of people who can receive optimal care. Internet-delivered treatment (IDT) is an alternative that increases accessibility and reachability for the patient [4] and is cost-efficient [5,6]. Through the use of cognitive-behavioral therapy (CBT) techniques, treatment via the internet provides therapists with good opportunities to guide patients and provide support for behavioral and lifestyle changes [7], although they face several professional challenges when moving from treatment in person to IDT [8,9]. A review of studies comparing therapist-assisted CBT via the internet (iCBT) versus face-to-face interventions for the treatment of psychiatric and somatic disorders found similar outcome effects [10].

Several reviews have demonstrated that IDT programs for the treatment of obesity can have beneficial effects in terms of behavioral and lifestyle changes, as well as weight reduction and health improvements [11-13]. However, the designs of different program packages vary greatly in terms of mode of delivery, the behavioral techniques and components included, unguided or therapist-assisted support, and the intensity and duration of treatment, making it difficult to determine which elements of the programs actually produce behavioral change. The outcomes in terms of weight loss and health improvements vary, and each IDT program should therefore be evaluated separately to ensure its effectiveness. Studying the experiences of both completers and dropouts is essential when evaluating IDTs. By incorporating feedback from noncompleters, valuable insights can be gained to improve program design and treatment strategies.

A CBT-inspired, 6-month IDT program for individuals with obesity (IDT-O) was developed at the obesity unit at Örebro University Hospital in Central Sweden. The IDT-O program was based on an in-person group treatment program that has been routinely used to treat people with obesity since 2010 [14]. The goals of the IDT-O intervention were primarily to offer evidence-based knowledge about obesity, to provide support for behavioral and lifestyle changes that can contribute to reduced body weight and improved health status, and to mitigate the negative effects of weight stigma. Evaluation of the program is necessary before implementing the program in clinical practice.

The aims of this pilot study were to investigate the feasibility and user-friendliness of the IDT-O program; to evaluate treatment outcomes regarding body weight, dietary habits, physical activity, and psychosocial functioning in those who completed the 6-month treatment; and to investigate dropouts' experiences of the treatment.

Methods

Study Design

The pilot study was a prospective 1-year observational study, evaluated via a multimethod research design [15]. The participants answered questionnaires, height and weight were measured, and interviews with dropouts were conducted.

Participants and Setting

Patients referred for assessment and treatment at the obesity unit at the Örebro University Hospital, which is located in an urban area of Central Sweden, were invited to participate. Those who wanted to participate in the program were consecutively included. Referrals to the obesity unit of patients with obesity can be made by health care professionals, such as general practitioners or public health nurses. At the obesity unit, psychologists, dietitians, physiotherapists, and physicians are employed. In this study, the intervention was delivered by all staff, except the physician, and the providers are referred to as therapists throughout the paper. The study ran from November 2019 to January 2021.

The inclusion criteria were patients aged 18 years or older and either a BMI of ≥30 kg/m^2 or a BMI of 28 - 29.9 kg/m^2 along with concomitant hypertension, prediabetes, type 2 diabetes, coronary artery disease, hyperlipidemia, hepatic steatosis, sleep apnea, or polycystic ovary syndrome. The exclusion criteria were severe mental illness, an ongoing eating disorder, pregnancy, breastfeeding, cancer in active treatment, weight loss treatment in the last 6 months, active abuse of alcohol or drugs, and being unable to express oneself in Swedish in speech and writing.

As part of the study, 3 individual visits to the obesity unit were included, before participation in the IDT-O, after completion of treatment at 6 months, and at the 12-month follow-up. The IDT-O started within 2 weeks of the first visit. Dropouts were interviewed after they had terminated their participation.

IDT for Obesity

Participants were provided with access to the IDT-O program via a secure login to the Swedish national health e-services called 1177.se. This platform is used for digital treatment and for digitally based contact with the official health care system in Sweden. The program lasted for 6 months and comprised 12 treatment modules with participants working for 2 weeks per module. The main content of the modules is shown in Table 1. The modules primarily consisted of text, but videos and images were also included. Each module ended with 1 or more practice tasks to be completed before the next module was started. Each participant had regular written contact with 1 of 4 therapists at the obesity unit via the treatment platform; the same therapist provided written feedback on completed practice tasks and answered questions from the participant.

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Table . Main content of the modules of the IDT-O[a].

Module	Main content	Task
1. Introduction	Overview of the program structure, what to expect, and goal-setting introduction to the logbook	Completion of the "My Goal, My Plan" questionnaire
2. Cornerstones of healthy lifestyle habits and the disease obesity	Healthy lifestyle behaviors; causes and consequences of obesity	Recording a 4-day food diary
3. Goal setting	Introduction to functional goal setting using the SMART model[b]; weight versus health	Formulation of personal goals within the 'My Goal, My Plan' framework
4. Dietary choices	Information on nutrition, including meal rhythm and portion sizes	Recording of meal rhythm and daily vegetable intake
5. The change process	Emphasis on self-monitoring as the initial step in behavior change, overview of stages in the change process, and identification of potential risk situations	Identification and management of risk situations
6. Physical activity	Reduction of sedentary behavior, general recommendations for physical activity and the physiological benefits of regular exercise, and common barriers to physical activity	Daily step count recording and completion of an activity log
7. Life balance	Exploration of life balance, including stress physiology, the impact of stress on health and the role of sleep; stop and reflect	Engagement in a mindfulness exercise ("Breathe") for a duration of 1 week
8. Eating behavior	Examination of unconscious eating patterns, emotional eating, and the physiological mechanisms of hunger and satiety; strategies for managing food cravings	Completion of a food diary (based on hunger-satiety patterns); situational analysis related to emotional eating triggers
9. Problem-solving	Introduction to problem-solving in 6 steps	Application of the 6-step problem-solving model to real-life scenarios
10. Societal body ideals and norms	Exploration of societal body image ideals, the internalization of negative body thoughts, and the role of body activism; emphasis on self-compassion	Identifying characteristics of admired individuals and recognizing positive aspects of one's own body
11. Success factors	Success factors in weight loss; introduction to strategies for weight maintenance	Completion of a personalized maintenance plan utilizing the "Traffic Light"[c] model
12. This is my life	Review of the program and reinforcement of personal autonomy in the treatment process	Self-monitoring of healthy lifestyle behaviors (eg, food diary, meal timing, vegetable intake, and physical activity); comparison of current progress with earlier records

[a]Treatment lasts for 6 months. Participants work with each module for 2 weeks, completing tasks after each module on which they receive written feedback from the therapist.

[b]The SMART (Specific, Measurable, Achievable, Relevant, and Time-bound) model: A method for setting goals.

[c]"The traffic light": strategies to maintain healthy lifestyle habits and a stable weight. Green light: I am on the right track. Yellow light: I am moving away from my goals. Red light: I have lost focus.

Outcome Measures

Overview

Measurements were taken during visits to the obesity unit before treatment and after 6 and 12 months, unless otherwise noted. Body weight— with participants wearing light clothing but no shoes—was measured to the nearest 0.1 kg using an electronic scale. Height was measured to the nearest 0.01 m at baseline, with participants in a standing position and without shoes. BMI was calculated. The questionnaires were answered in paper by the participants on site and thereafter handed over to the therapist.

Dietary Habits

Dietary habits were assessed using the Swedish National Board of Health and Welfare's 4 validated dietary index questions [16]. These questions measure the frequency of consumption of (1) vegetables and root vegetables, (2) fruits and berries, (3) fish and shellfish, and (4) rolls, sweets and chocolates, and sugar-sweetened drinks. More frequent consumption gives higher scores on the first 3 questions, while the opposite scoring is used for the fourth question. The responses are summed to a total score ranging from 0 to 12, where a higher score signifies more favorable dietary habits.

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Self-Reported Physical Activity

Self-reported physical activity was assessed using the Swedish National Board of Health and Welfare's 2 validated questions about the frequency of vigorous and moderate physical activity [17]. The 2 questions are answered on a 6-point response scale (0, <30, 30 - 60, >60 - 90, >90 - 120, or >120 minutes per week), where 0 minute per week is coded as 1 and >120 minutes per week as 6. The response for moderate activity is scored from 1 to 6, whereas the response for vigorous activity is multiplied by 2 to account for a higher intensity. A summary score is then calculated, ranging from 3 (lowest level) to 18 (highest level).

Obesity - Related Problems Scale

The Obesity - related Problems (OP) Scale is an obesity - specific QoL instrument developed for measuring the impact of obesity on psychosocial functioning in 2 domains: distress and avoidance [18-20]. Participants are asked to rate how bothered they are by their body size in different social situations and to what extent they avoid such situations. Scale scores range from 0 to 100, and higher scores indicate more dysfunction. A distress score of <40 is interpreted as mild, 40 - 59 as moderate, and ≥60 as severe dysfunction.

Experiences of Treatment Effects

Study-specific questions about the participants' experiences of the treatment effects were used at the 12-month follow-up. We asked whether the treatment had helped them in changing their lifestyle habits and whether the treatment had had positive effects on their health and well-being. A 5-point response scale was used for perceived changes in lifestyle habits (Not at all, A little, Pretty much, A lot, and Very much) and for perceived treatment effects (No positive effects, Small positive effects, Fairly large positive effects, Great positive effects, and Very large positive effects).

Treatment Satisfaction

After the participants had completed each treatment module, they were asked to rate how satisfied they were with the content and how relevant or meaningful the practice task was. The questions were answered on a 5-point response scale with the anchors 1 (Poor) to 5 (Very good) for treatment satisfaction and the anchors 1 (Not relevant) to 5 (Very relevant) for satisfaction with the practice tasks.

Interview Procedure for Dropouts

Participants who dropped out of the treatment were invited to participate in a telephone interview about their experiences with the treatment and their reason for dropping out. Prior to the interviews, the participants received oral information about the aim of the interviews. A semistructured interview guide was used, covering areas such as previous experience of digital working methods; experience of the modules of the IDT-O; amount of time needed to complete the modules, including the practice tasks; experiences of their digital contact with the therapist; and whether they had experienced any effects of their participation in the IDT-O. All interviews started with a question about their reason for dropping out. The questions were based on both clinical and scientific interest in the further development of the IDT-O.

The semistructured interviews were conducted by a researcher with nursing background experienced in qualitative methods (first author [AAC]), who had no previous relationship with the participants or the staff at the obesity unit. The duration of the interviews varied within 18 - 69 minutes (mean 31, median 24.5 minutes). Interviews were digitally recorded, after consent from the informants, and were transcribed verbatim by a professional transcriptionist. There was a variation in time span from patients dropping out from the intervention and being interviewed. This was partly because it was not always explicit when a participant had decided to discontinue the intervention. Sometimes they just stopped fulfilling their tasks and did not reply to the therapists' messages. The longest interval between dropping out and being interviewed was therefore just less than 4 months.

Statistical Analysis

The mean and SD are presented for continuous variables, and relative frequencies are provided for categorical variables. The effect size (ES) of a change between baseline and 6- and 12-month follow-up was estimated by calculating the standardized response mean (SRM)—that is, the mean change divided by the SD of change. ES or SRM was evaluated according to standard criteria: <0.20=trivial, 0.20 - 0.49=small, 0.50 - 0.79=moderate, and ≥0.80=large [21]. The sample size was too small for significance testing of the treatment outcomes. Analysis was performed using SAS (version 9.4; SAS Institute Inc).

Qualitative Inductive Content Analysis

The analysis was inspired by the steps described by Graneheim and Lundman [22]. First, the first author (AAC), who both conducted the interviews and is experienced in qualitative methods, listened to all the interviews, corrected any errors from the transcriptions, and attempted to get a sense of the whole. Next, the interviews were imported into NVivo software (QSR International) for further analysis. Meaning units were identified and labeled with a code illustrating the content. Thereafter, the codes were scrutinized for similarities and differences and were clustered into categories describing the manifest content of the interview data. Finally, the categories were reflected on, and their latent content was identified in the form of subthemes and a main theme. The analysis was performed by the first author (AAC) and, in order to ensure rigor and trustworthiness, was later discussed with the other authors. The other authors all had experience of working with patients living with obesity, working as a licensed psychologist (JK), a general practitioner (SJ and MG), or a public health nurse (AI). During the process of analysis, the authors practiced reflexivity by discussions comparing their preunderstanding with what was revealed in the dataset [23].

Ethical Considerations

This study was approved by the Swedish Ethical Review Authority (registration number 2019 - 04695). At the first visit to the obesity unit, participants were informed orally and in writing about the study, and written consent was obtained. No compensation was offered to the participants, but the intervention and the health care visits included in the study were

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offered free of charge. The quantitative and qualitative data were deidentified before analysis. When presenting quotes in the "Results" section, this was done cautiously, ensuring that the information could not be traced back to a certain participant. All quotations have been marked with the participation number, instead of names.

Results

Overview

A total of 20 participants started the IDT-O program and 35% (7/20) completed all 12 modules. Of the participants, 17 were females, the mean age was 44.2 (SD 16.4) years, and about half (11/20, 55%) had a university education (Table 2). Mean body weight was 117.1 (SD 19.8) kg, and mean BMI was 42.8 (SD 6.4) kg/m^2. Ten (8 females) out of 13 dropouts agreed to participate in an interview. Two participants could not be reached, and 1 declined participation. The majority of the participants had previous experience with weight-reducing interventions. There was variation in the number of modules participants completed before dropping out.

Table . Baseline characteristics of the 20 participants who started treatment, the 7 participants who completed the 6-month treatment, and those who dropped out and participated in the interview study.

Characteristics	Started treatment	Completed treatment	Dropouts interviewed
Participants, n (%)	20 (100)	7 (35)	10 (50)
Sex, n (%)			
Males	3 (15)	0 (0)	2 (20)
Females	17 (85)	7 (100)	8 (80)
Age (years)			
Age, mean (SD)	44.2 (16.4)	49.4 (18.3)	42.9 (15.8)
Age range	20 - 77	27 - 77	26 - 73
Age groups, n (%)			
20 - 34	6 (30)	2 (28.6)	3 (30)
35 - 49	8 (40)	2 (28.6)	4 (40)
50+	6 (30)	3 (42.9)	3 (30)
Education, n (%)			
Mandatory	1 (5)	0	0
High school	6 (30)	2 (28.6)	3 (30)
University	11 (55)	5 (71.4)	6 (60)
Other	2 (10)	0	1 (10)
Body weight (kg)			
Body weight, mean (SD)	117.1 (19.8)	111.2 (18.0)	123.0 (20.0)
Body weight range	84.6 - 159.0	84.6 - 137.5	89.7 - 159.0
BMI (kg/m^2)			
BMI, mean (SD)	42.8 (6.4)	43.1 (7.1)	43.6 (6.6)
BMI range	33.5 - 57.7	33.5 - 51.4	35.9 - 57.7
BMI interval, n (%)			
28 - 29	0	0	0
30 - 34.9	1 (5)	1 (14.3)	0
35 - 39.9	7 (35)	2 (28.6)	3 (30)
40 - 44.9	5 (25)	1 (14.3)	3 (30)
45 - 49.9	4 (20)	1 (14.3)	3 (30)
50+	3 (15)	2 (28.6)	1 (10)

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Outcome Measures

Of those who completed the 6-month treatment, the mean percent weight reduction was 2.1% (95% CI 0.1 - 4.0) after 6 months and 2.0% (95% CI −1.1 to 5.1) after 12 months (Table 3). Two participants achieved a weight reduction of at least 5% after 12 months.

Table . Treatment outcomes at 6- and 12-month follow-up for the 7 participants who completed the 6-month treatment program.

Outcome measures	Baseline	6-month follow-up	12-month follow-up
Body weight (kg)			
Mean (SD)	111.2 (18.0)	109.0 (18.5)	109.0 (18.5)
Change, mean (95% CI)	—[a]	−2.2 (−4.2 to 0.1)	−2.2 (−5.8 to 1.4)
Change (%), mean (95% CI)	—	−2.1 (0.1 to 4.0)	−2.0 (−1.1 to 5.1)
BMI (kg/m^2)			
Mean (SD)	43.1 (7.1)	42.3 (7.3)	42.2 (6.9)
Change, mean (95% CI)	—	−0.8 (−1.7 to 0.1)	−0.9 (−2.3 to 0.6)
Eating habits[b]			
Mean (SD)	6.1 (3.3)	7.3 (2.2)	6.9 (1.7)
Change, mean (SD)	—	1.1 (2.3)	0.7 (2.8)
SRM[c] (95% CI)	—	0.50 (−0.31 to 1.28)	0.25 (−0.51 to 1.00)
Physical activity[d]			
Mean (SD)	8.1 (2.9)	11.4 (4.6)	12.7 (3.9)
Change, mean (SD)	—	3.3 (5.9)	5.0 (5.4)
SRM (95% CI)	—	0.56 (−0.26 to 1.35)	0.93 (−0.08 to 1.87)
OP[e]			
Distress, mean (SD)	52.4 (25.5)	55.0 (29.2)	41.8 (21.7)
Change, mean (SD)	—	2.6 (14.7)	−10.6 (24.8)
SRM (95% CI)	—	−0.17 (−0.92 to 0.58)	0.43 (−0.37 to 1.19)
Avoidance, mean (SD)	34.1 (20.1)	24.9 (16.6)	22.7 (14.7)
Change, mean (SD)	—	−9.2 (10.4)	−11.4 (16.9)
SRM (95% CI)	—	0.89 (−0.03 to 1.75)	0.67 (−0.18 to 1.48)

[a]Not available.

[b]The score ranges from 0 to 12, with a higher score indicating more favorable dietary habits.

[c]SRM: standardized response mean (effect size of change). SRM criteria: <0.20 = trivial; 0.20 - 0.49 = small; 0.50 - 0.79 = moderate; and ≥0.80 = large.

[d]Self-reported physical activity on a scale from 3 to 18, where a higher value indicates more minutes per week spent on physical activity.

[e]OP: Obesity - related Problems scale (score range 0 - 100). Higher distress scores indicate more obesity-related psychosocial distress in social situations, and higher avoidance scores indicate more avoidance of social situations.

In the completers, dietary habits scores indicated a moderate improvement (SRM 0.50, 95% CI −0.31 to 1.28) after 6 months and a small improvement (SRM 0.25, 95% CI −0.51 to 1.00) after 12 months (Table 3). The change in self-reported physical activity showed a moderate improvement (SRM 0.56, 95% CI −0.26 to 1.35) after 6 months and a large improvement (SRM 0.93, 95% CI −0.08 to 1.87) after 12 months.

No change in OP distress scores was noted after 6 months (SRM 0.17, 95% CI −0.92 to 0.58), while a small improvement (SRM 0.43, 95% CI −0.37 to 1.19) was observed after 12 months. The change in OP avoidance scores indicated a large improvement (SRM 0.89, 95% CI −0.03 to 1.75) after 6 months and a moderate improvement (SRM 0.67, 95% CI −0.18 to 1.48) after 12 months.

The responses at the 12-month follow-up to the question of whether the treatment had helped in changing participants' lifestyle habits were as follows: 42.9% (3/7) "a little," 28.6% (2/7) "pretty much," 14.3% (1/7) "a lot," and 14.3% (1/7) "very much" (Table S1 in Multimedia Appendix 1). The answers to whether the treatment had positive effects on participants' health were as follows: 28.6% (2/7) "small effects," 42.9% (3/7) "fairly large effects," and 28.6% (2/7) "great effects." The same response pattern was obtained for the question about positive effects on well-being.

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In completers, the mean treatment satisfaction rating for the 12 modules was 4.5 (range 3.7 - 4.9, where 1 = Poor and 5 = Very good), while the mean rating for the relevance or meaningfulness of the practice tasks was 4.6 (range 4.0 - 5.0, where 1 = Not relevant and 5 = Very relevant) (Table 4). The dropouts' mean satisfaction ratings for the completed modules and the practice tasks were about the same as those of the completers. Dropouts completed on average 4.4 modules with a range of 1-9 modules.

Table . Satisfaction ratings with the 12 treatment modules and the practice tasks for those who completed the 6-month treatment program and for dropouts.

Treatment module	Satisfaction with treatment[a]		Satisfaction with practice task[b]	
	Completers (n=7), mean	Dropouts (n=13), mean	Completers (n=7), mean	Dropouts (n=13), mean
1	3.7	4.4 (n=12)	4.0	4.5 (n=12)
2	4.0	4.6 (n=13)	4.6	4.5 (n=13)
3	4.9	4.5 (n=11)	5.0	4.5 (n=11)
4	4.2	4.0 (n=5)	4.5	4.6 (n=5)
5	4.7	5.0 (n=3)	4.6	5.0 (n=3)
6	4.9	4.0 (n=1)	4.7	5 (n=1)
7	4.6	4.0 (n=1)	5.0	4.0 (n=1)
8	4.7	5.0 (n=2)	4.9	5.0 (n=2)
9	4.6	4.0 (n=1)	4.6	5.0 (n=1)
10	4.6	__[c]	4.7	—
11	4.3	—	4.4	—
12	4.2	—	4.3	—
Mean 1 - 12	4.5	—	4.6	—

[a]The content of the treatment module has generally been ___ (answered using a 5-point response scale with anchors from 1 [Poor] to 5 [Very good]).

[b]Was the practice task for the module relevant/meaningful? (answered using a 5-point response scale with anchors from 1 [Not relevant] to 5 [Very relevant]).

[c]Not available.

Qualitative Findings

The analysis resulted in 1 main theme—namely, *The programme was OK, but it does not suit everyone*—which was the latent content of all the data running through the categories and subthemes. Despite having dropped out from the IDT-O, the participants mainly believed that the content was relevant and of good quality; nevertheless, it did not suit them—at least not at this specific time in life. The 3 subthemes focus on 3 main messages. The first of these, *It wasn't for me*, highlights issues explaining why the IDT-O did not suit some participants at this stage of life. The second subtheme, *There were good things*, points to aspects that were found to be valuable. The third subtheme, *There are things to improve*, comprises ideas that are worth considering in order to further improve the IDT-O. Table 5 provides an overview of the results.

Table . Overview of the qualitative findings: main theme, subthemes, and categories.

Main theme	"The programme was OK, but it does not suit everyone"		
Subthemes	It wasn't for me	There were good things	There are things to improve
Categories	• The treatment wasn't in line with my expectations and needs. • It wasn't the right timing for me to participate. • There were some aggravating factors in my everyday life complicating participation.	• The content is relevant for people like me. • Internet treatment offers freedom. • The therapist was supportive.	• Parts of the programme and the digital platform were not user-friendly. • The supportive aspect should be further developed.

It Wasn't for Me

The subtheme *It wasn't for me* is built on the categories *The treatment wasn't in line with my expectations and needs*, *It wasn't the right timing for me to participate* and *There were some aggravating factors in my everyday life complicating participation*.

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The Treatment Wasn't in Line With My Expectations and Needs

There were various reasons why participants believed that the IDT-O was not the right treatment option for them, having to do with the content or mode of delivery. As many participants had been living withobesity for a long time and had tried to lose weight before, they experienced the content as being too basic and adding nothing new. Furthermore, it did not match their expectations. They claimed that treatment needed to be individually adapted, and some said that they had expected to be offered more specific advice regarding what to eat, instead of treatment influenced by CBT. Some were uncertain about the explicit goals of the treatment, while they themselves had joined the IDT-O to lose weight. One participant said, "Well, the introduction, or whatever you call it, was very informative. They had put together information about overweight in a good way, but what I miss is the help to deal with overweight, that's what it lacks" (Participant ID 1).

There were also accounts of dropping out of treatment because of self-blame during modules focusing on recording the participants' own behaviors. The participants already knew that their behaviors were not ideal and did not want to repeatedly consider that. Instead, they wanted support focusing on how to change these behaviors, as well as getting tips and exercises tailored to their needs.

With regard to the mode of delivery, some felt alone in the digital treatment and wished for at least 1 in-person visit with the therapist. Half of the participants also reported difficulties finishing the treatment modules in time, especially when the practice task involved reflecting on a specific topic. Therefore, the participants suggested that they themselves should be able to decide their pace of working through the modules, as it was difficult to catch up when they fell behind. For example, a participant commented, "... So, I ended up behind, and then I found it overwhelming to catch up" (Participant ID 5).

It Wasn't the Right Timing for Me to Participate

A common explanation for dropping out from the IDT-O was that the timing was not right for participation. Many of the dropouts revealed that their life situation was turbulent. For example, some had started a new job, were just about to separate, or were moving. Another reason was illness, either their own or a family member's: 'Well, I believe I could have managed to fulfil my engagement with the programme if it hadn't been for Covid and if things had been more settled around me. However, this simply wasn't the case" (Participant ID 10). There were also accounts of realizing that they needed to deal with their own existing psychological health issues before starting treatment to lose weight. Another participant specifically mentioned that her poor walking ability influenced her decision to drop out of the IDT-O, as she found it impossible to complete the modules that focused on physical activities.

There Were Some Aggravating Factors in My Everyday Life Complicating Participation

Some participants reported that, despite the freedom to attend the IDT-O from a place of their choice, they had experienced unexpected difficulty regarding finding a time and place to sit and concentrate on reading the modules and doing the practice tasks. One participant noted, "Being a parent of young children, you simply don't have the time" (Participant ID 3). Thus, some of the participants postponed their tasks and did not finalize their assignments until they received a reminder from the treatment platform or therapist.

There Were Good Things

The subtheme *There were good things* focuses on the participants' positive comments about the IDT-O, comprising the categories *The content is relevant for people like me*, *Internet treatment offers freedom*, and *The therapist was supportive*.

The Content Is Relevant for People Like Me

The participants regarded the content of the IDT-O as relevant for people with obesity, and they could theoretically see themselves participating in the IDT-O on another occasion. Although some of the content was not new to them, they still found it worth repeating. Participants specifically identified the module focusing on recording their food intake as beneficial, as it created a base for reflecting on their behavior in relation to eating. Although it was not always easy to adopt the theory in practice, participants reported that they had changed some behaviors in their daily life, despite dropping out from the IDT-O:

> *Actually, I've changed. I am better at having breakfast after this programme. Because, before, I hardly ever had breakfast...And, after this programme, I've started to have some breakfast—well, perhaps not every day, but on four mornings out of seven. Previously, I had breakfast 1 out of 7 days at the most (laughs). Yes, so that's something I've changed; yes, I more frequently have breakfast (laughs).* [(Participant ID 4)]

Other examples of changed behavior included reflecting more on what to eat and how to think about food intake and physical activity, and making more conscious choices, such as adjusting portion sizes. The content about obesity being defined as a chronic illness made one person feel less guilty about the condition, while another participant questioned the relevance of such knowledge.

Internet Treatment Offers Freedom

One major benefit of participating in the IDT-O was the participants' freedom to read or watch the content in the modules or to work with practice tasks at a time most convenient to them. Some worked at odd hours, and some had small children who needed attendance. In such cases, IDT was feasible: "It worked really well for me, having access to it [the programme] whenever convenient, but, as I said, when having children and working full-time, you have to squeeze it into your life whenever possible" (Participant ID 9). Some explained that, for them, it would not have been possible to attend on-site meetings at scheduled times. The IDT made it possible for them to work at a pace that suited them; moreover, if they were ill, they did not necessarily miss a treatment visit. In addition, the participants found it practical to work from home.

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The Therapist Was Supportive

The therapists acted in a way that made the participants feel understood and respected; they were perceived as encouraging, although some participants described a need for more constructive criticism: "Well,...ehm...but they have been encouraging as well, but they haven't.... you need to hear bad things as well; well, it has to be both for it to work" (Participant ID 7). The therapists offered advice and took time to comment on the practice tasks, although some participants perceived these comments to be too general. When the participants were late completing their practice tasks, the therapists repeatedly sent reminders and tried to motivate the participants to stay with the IDT-O. These reminders were regarded as helpful.

There Are Things to Improve

Although the participants were positive to a certain degree, they also had insights about possible drawbacks. The categories in this subtheme are *Parts of the programme and the digital platform were not user-friendly* and *The supportive aspect should be further developed*.

Parts of the Programme and the Digital Platform Were Not User-Friendly

One major issue with regard to non–user-friendliness was the amount of text participants had to go through. The bulky text could be experienced as overwhelming, making it difficult to get an overview and comprehend the content. For some, just the sight of the amount of text had made them close the program and postpone their reading to another day.

The amount of text also caused problems for some working via a mobile phone; it was difficult to read the text in small font and in a nonpage format, where the text just continued. Furthermore, it was inconvenient to report extensive practice tasks using a mobile phone. However, it was acceptable to use a phone for shorter communication with the therapist.

As some of the participants had problems working on a computer due to concentration issues, they would have preferred to print out the modules and practice tasks. However, it was difficult to figure out how to print the text, and the platform did not permit printing more than 1 page at the time (ie, instead of a whole chapter).

Participants with dyslexia said that they would have benefitted from an audio function to be able to listen to the content of the IDT-O instead of reading it. When they worked on their own, the practice task took them a considerable amount of time, making it necessary for a family member or a friend to assist with some of the reading. Although these participants informed the health care professionals about their reading problems when they were first included in the IDT-O program, they were advised to try it anyway: "...Yes, they said I could give it a try, despite my problems, so... [I did]" (Participant ID 2).

The digital platform for the IDT-O was regarded as not very user-friendly. There were multiple pages, and many clicks were needed to reach the IDT-O and the content of a module, to submit practice tasks and to read comments from the therapist. This hindered some participants, who would have liked to make notes and comments while on the move. One participant had problems with saving the answers to assignments, which was frustrating and time-consuming, as the information needed to be entered again.

The Supportive Aspect Should Be Further Developed

As feedback was an important aspect of the treatment, participants claimed that they would have liked to meet with the therapist at least once during the treatment period, or for follow-up to have been offered by phone. They believed that a meeting would have offered a more personal dimension to their treatment. Another major drawback was the insufficient individualized support and advice; also, no one actually followed up on whether the participants adhered to their own plan or what the results of certain activities were:

> *What works best for me, that's when showing up at the therapist and being asked, "How have things worked out for you?" I sort of need to have someone to report to, someone somewhat keeping an eye on me, keeping control.* [(Participant ID 8)]

General encouragement was not regarded as facilitating enough in relation to the needs of the participants. Some also mentioned that they would have benefited more from a group intervention.

Discussion

Principal Findings

This pilot study was a first step in evaluating the feasibility and effectiveness of an IDT program for individuals with obesity. Both qualitative and quantitative methods were used to assess the intervention. The findings indicate that the IDT-O holds potential as a treatment option for people with obesity, although only 35% (7/20) of the participants completed the program. The quantitative and qualitative findings show that the participants were generally satisfied with the content and design of the intervention. Those who completed the IDT-O lost some weight, reported improved dietary habits, increased physical activity, and improved psychosocial functioning, and maintained these behaviors for 6 months after completing the treatment. However, the quantitative findings were based on only 7 participants who completed the IDT-O and should be considered preliminary. The qualitative findings, defined in the 3 subthemes: "It wasn't for me," "There were good things," and "There are things to improve," also revealed that the intervention was not deemed useful by everyone, and various reasons for dropping out were provided. The interviewees also offered suggestions that may be useful for program improvements.

The efficacy of a digital intervention is linked to user motivation and engagement, with nonadherence being a common problem [24]. Studies show that almost half of those who start iCBT treatment do not complete the program [25,26]. In this study, 65% (13/20) of the participants dropped out of treatment, typically early in the program, indicating that the IDT-O program did not suit all participants. Some participants had unmet expectations for the treatment; for example, they wanted more detailed advice, more contact with the therapist, or had difficulty concentrating and reading. Some dropouts were due to factors external to the treatment, such as unforeseen circumstances in life that affected participation. This study was

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conducted during the Covid-19 pandemic, which may have contributed to the high dropout rate due to participants' own or family members' illness. Aside from this factor, the reasons for dropout identified in this study are broadly consistent with the findings of a qualitative study on nonadherence to iCBT for generalized anxiety disorder [24], as well as with patients' and therapists' experiences of challenges related to other internet-delivered interventions [9,27,28]. Given the issue of nonadherence, this finding underscores the importance of thoroughly assessing patients' expectations and clarifying the goal of the program before offering such treatment [4], although doing so can be challenging [9]. Such assessments are crucial, both from a professional standpoint and for the patients, as both parties invest resources in the treatment. Additionally, patients who do not complete the treatment may experience feelings of guilt and shame, as the treatment is largely based on their own initiative [29,30].

Both the dropouts and the completers reported high satisfaction ratings regarding the completed modules and practice tasks, although this comparison was limited to the initial 5 out of 12 program modules. This positive view of the program content was supported by the findings based on interviews with the dropouts. The completers demonstrated improvements in self-reported dietary habits, physical activity, and psychosocial functioning at follow-up, in line with previous research [13]. The completers also stated that the IDT-O program had helped them change lifestyle habits and had positive effects on health and well-being. However, due to the limited number of participants who completed the program, the observed changes are uncertain and must be confirmed in a more comprehensive study. Interestingly, the dropouts also reported that they had benefitted from the content of the modules they had completed and had made some changes to their dietary habits.

The weight loss among completers 12 months after starting treatment was modest (–2.2 kg) and slightly lower than that observed in previous studies. In a comprehensive review including 44 studies on web-based obesity interventions, the average weight loss was –3.5 kg (range –0.1 to –7.8 kg) after treatments lasting between 2 and 24 months [12]. The modest weight loss might be explained by the fact that the content of the IDT-O program is not exclusively focusing on weight loss, but on change of behaviors, which is not a quick fix. From both a public health and individual perspective, even moderate weight loss is considered relevant [31,32], and improvements in dietary habits and increased physical activity after treatment can have further long-term positive effects on weight and health [33]. To increase the effectiveness of weight management, integrating the IDT-O program with pharmacological treatment for weight loss may facilitate the achievement of more substantial long-term weight reduction and weight maintenance thereafter. In a recent publication, the American Diabetes Association recommended that pharmacological obesity treatment should be used in combination with other therapies, focusing on nutrition, physical activity, and behavioral changes, to achieve health goals. They base their recommendations on research showing that addition of pharmacological treatment to lifestyle interventions improves weight reduction and weight loss maintenance [34].

Obesity is a stigmatized condition [33], and reducing weight stigma was one of the goals of the IDT-O program. In the study, the OP scale was used to measure stigma-related impacts of obesity on psychosocial functioning, a key domain in the assessment of QoL in people with obesity. Among the completers, improvements in psychosocial functioning (distress and avoidance) were noted at follow-up, likely due to a combined effect of weight loss and behavioral treatment. Reducing body weight and weight stigma can be complementary goals in obesity treatment. By focusing on reducing internalized stigma, beneficial effects on general health and QoL may be achieved, independent of weight reduction [33,35].

In this intervention, only written online communication between the therapist and the participant was used. The interviewed participants expressed a need for increased contact with the therapist and suggested that face-to-face or telephone contact should be included during the treatment—a finding consistent with other qualitative studies of iCBT [24,28,36]. Blended treatment, which combines online communication with face-to-face meetings, has been proposed as a means of enhancing iCBT interventions [7]. The use of video or phone consultations as supplements to written online communication is another option. However, the potential benefits of blended treatment are largely unknown, and further research is needed to determine the most effective mix of online and face-to-face consultations and whether or not the therapeutic alliance is increased by such modifications. Moreover, the potential benefits must be weighed against the increased costs of a blended intervention.

Some participants found it difficult to adhere to the standardized 2-week schedule for each module and suggested that the treatment should be more flexible and tailored to individual needs. This is a common reaction to internet-delivered therapy [24,28,37]. There were many reasons given for not managing the time limit of the scheduled modules. One that might need extra consideration was that the amount of text could be overwhelming for those with reading difficulties or having problems concentrating. The notion of extensive text to read [27] and the requirement for reading and writing skills [24] call for future innovative and assessable solutions, including text-to-speech features.

Due to the incomplete adaptation to mobile devices, participants encountered difficulties accessing the program via their phones. Given that mobile phones are the most common gateway to the internet today [38], it is critical for IDT programs to be fully optimized for mobile devices. As in the current findings, technical issues are a recurring topic when investigating patients' experiences with IDTs [4,9,29]. These issues should be addressed when offering these treatments to patients or when developing IDTs, as technical issues have been given as a reason for dropping out of treatment [27].

Strengths and Limitations

The IDT-O program was evaluated in a real-life clinical setting without extra resources, which is a strength with regard to its further development and future implementation. However, the therapists were inexperienced with IDT, which may have affected the results of this study.

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The use of qualitative and quantitative methods, along with the inclusion of data from both completers and dropouts, resulted in comprehensive data, which allowed us to evaluate different perspectives. The findings of this pilot study are valuable for designing a full-scale study and for further refining the IDT-O program. The trustworthiness of this study was enhanced by the fact that the interviewer was a neutral party, uninvolved in the design of the IDT-O program and with no prior or ongoing therapeutic relationship with the interviewees. In addition, the mix of the researcher's professional backgrounds and preunderstanding contributed to the credibility.

Despite the strengths of the study, there are also some limitations to consider. First, the sample size was too small for significance testing; instead, we calculated effect sizes (ESs) to describe changes over time for those who completed the IDT-O. However, the ES estimates are uncertain because they are based on a small number of participants. Second, the dropout rate was higher than expected, but most of the dropouts participated in the qualitative interviews and shared their experiences, adding valuable insights to the evaluation of the IDT-O program. Third, the Covid-19 restrictions may have affected participants' daily life habits regarding physical activity and eating habits [39], which in turn may have influenced the outcomes of this study.

Conclusions

In many respects, the IDT-O can be deemed feasible as a treatment option for people with obesity. Among those who completed the IDT-O, body weight decreased and dietary habits, self-rated physical activity, and psychosocial functioning improved. Despite these positive findings, the dropout rate was high, with participants indicating different reasons for discontinuing the treatment. Therefore, more research is needed before concluding the positive results. The results can, together with existing literature on the topic, form a base for future development and further evaluation of the IDT-O. Suggestions for further development of the IDT-O include adding a text-to-speech feature, improving the platform's compatibility with mobile phones, and enhancing its overall accessibility and usability. In the future, we recommend a more tailored assessment of potential patients before offering the IDT-O, further development of the technical aspects of the platform, an evaluation of the benefits of adding individual visits with the therapist, and testing of the program when combined with other treatment regimens (eg, pharmacotherapy) for obesity. These modifications could potentially lead to greater effects on various aspects of patients' health.

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Data Availability

The datasets generated during and/or analyzed during this study are not publicly available due to them being of sensitive nature and because there is no ethical approval for sharing the data, but they are available from the corresponding author on reasonable request.

Authors' Contributions

Conceptualization: AAC, SJ, MG, JK
Data curation: AAC, JK
Formal analysis: AAC, AI, MG, SJ, JK
Investigation: AAC, JK
Methodology: AAC, JK
Project administration: JK
Visualization: AAC, AI, JK
Writing – original draft: AAC, AI, MG, SJ, JK
Writing – review & editing: AAC, AI, MG, SJ, JK

Conflicts of Interest

MG has been a lecturer for the Eli Lilly and Novo Nordisk companies, as well as a local principal investigator in medical trials for Novo Nordisk and Boehringer Ingelheim.

Multimedia Appendix 1
Experiences of treatment effects after 12 months in the 7 participants who completed the treatment program.

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Checklist 1
COREQ (Criteria for Reporting Qualitative research) checklist.
[PDF File, 433 KB - formative_v10i1e79853_app2.pdf]

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Abbreviations

CBT: cognitive behavioral therapy
ES: effect size
iCBT: cognitive behavioral therapy via the internet
IDT: internet-delivered treatment

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IDT-O: internet-delivered program for obesity
OP: Obesity-related Problems Scale
QoL: quality of life
SMART: Specific, Measurable, Achievable, Relevant, and Time-bound
SRM: standardized response mean

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A Digital Inclusion Intervention to Improve Access to a Digital Health Intervention Among Digitally Excluded Adults: Mixed Methods Pilot Randomized Controlled Trial

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Abstract

Background: The National Health Service 10-year health plan emphasizes an increasing shift toward digital health care delivery. However, there is limited research on how best to support, engage, and include individuals who are digitally excluded. As health care services become more digitally driven, evidence-based interventions are needed to address digital exclusion and ensure equitable access to care, particularly for people living with long-term conditions.

Objective: This study aimed to evaluate the feasibility and acceptability of providing digital literacy training alongside a digital health intervention (DHI; Ex-Tab intervention), compared with providing a DHI alone. Kidney Beam, a DHI designed to promote physical activity and improve quality of life in people with chronic kidney disease (CKD), was used as an exemplar DHI.

Methods: This mixed methods, single-site pilot randomized controlled trial recruited 40 adults with CKD who were digitally excluded. Digital exclusion was defined as lacking access to a Wi-Fi–enabled digital device or having a Digital Health Care Literacy Scale (DHLS) score of <7 (range 0‐21). Participants were randomized 1:1 to receive either the Kidney Beam Ex-Tab intervention or Kidney Beam alone (control). The intervention group received a Wi-Fi–enabled iPad on loan with Kidney Beam preinstalled, digital literacy training, and ongoing support to access the 12-week Kidney Beam program (twice weekly live exercise and education sessions). The control group received sign-up instructions for Kidney Beam only. Feasibility outcomes were assessed against a priori progression criteria and included screening, recruitment, retention, adherence, safety, and acceptability. Secondary outcomes included the Kidney Disease Quality of Life Questionnaire, Chalder Fatigue Questionnaire, and Patient Health Questionnaire-4. Outcomes were measured at baseline and 12 weeks. Acceptability and user experience were explored through semistructured interviews with participants from both groups at 12 weeks (n=25).

Results: Between September 2023 and September 2024, a total of 169 individuals were screened and 40 were enrolled (median age 66.5 years; 20 male individuals; median DHLS score: 4). Twenty-one participants were randomized to the Kidney Beam Ex-Tab group and 19 to the Kidney Beam alone group. Of the 40 participants, 35 (88%) completed the 12-week follow-up (intervention: n=18; control: n=17). All prespecified feasibility criteria for recruitment, retention, adherence, and safety were met. Qualitative findings indicated that the tablet loan and digital literacy training were acceptable and highly valued, enhancing confidence, motivation, and DHI engagement. Providing loaned devices was particularly important for overcoming access barriers, especially for participants unable to afford their own device.

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Conclusions: Providing Wi-Fi–enabled devices and digital literacy training alongside a DHI was feasible and acceptable for people with lower digital literacy levels. The findings support progression to a future definitive multicenter trial or implementation study and offer transferable insights for the design of digital inclusion strategies for other long-term health conditions.

Trial Registration: ClinicalTrials.gov NCT04872933; https://clinicaltrials.gov/study/NCT04872933

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KEYWORDS

renal rehabilitation; digital inclusion; digital health intervention; Kidney Beam; exercise

Introduction

Digital health technology is the field of knowledge and practice associated with the development and use of digital technologies to improve health [1] and includes the utilization of smartphone apps, wearable devices, and platforms that provide remote health care [2]. A growing body of evidence indicates that digital health technologies provide significant benefits, including enhanced convenience, patient empowerment, improved self-management of chronic conditions, and notable environmental and economic efficiencies [3]. Furthermore, the UK Government's 10-year health plan highlights the benefits of harnessing the digital revolution to create the world's most digitally accessible health system [4], with the success of this vision relying on a shift toward digital delivery. Studies evaluating the use of digital health interventions (DHIs) have demonstrated feasibility, acceptability, clinical effectiveness, and cost-effectiveness across a wide range of long-term conditions, including type 2 diabetes [5], hypertension [6], chronic respiratory conditions [7], chronic kidney disease (CKD) [8], and cancer [9].

Kidney Beam [10] delivers online physical activity and self-management support and was co-designed with people living with CKD. A multicenter randomized controlled trial (RCT) showed that Kidney Beam is a clinically effective and cost-effective solution to improve health-related quality of life [8,11], confirming that DHIs can offer a scalable solution to deliver health care across people living with chronic conditions and can make interventions available for more people at a lower cost [12].

Despite the growing number of benefits, there are known barriers to accessing DHIs. These include a lack of physical resources; a lack of multilingual applications; low health and digital literacy; and socioeconomic limitations, including low household income, unstable employment, and housing insecurity [13]. If these limitations are not adequately addressed, they risk perpetuating the digital divide and further exacerbating existing health inequalities. The National Health Service (NHS) England has identified an urgent need to develop digitally enabled care pathways to increase inclusion [14]. This includes addressing the barriers to opportunity, access, knowledge, and skills for using technology [15]. The current evidence base is significantly underdeveloped in this area [16], and existing research has been primarily driven by the needs of health care providers, rather than the perspectives and priorities of underserved and digitally excluded service users.

Current evidence from the medical literature indicates that interventions to address digital health exclusion in health care are most effective when they are multifactorial and tailored to the needs of disadvantaged groups [17]. Interventions that combine efforts at the interpersonal, organizational, and policy levels, such as programs linking health care providers with other organizations and peer or family support, improve digital health literacy [18]. There is currently very limited RCT evidence specifically investigating interventions to improve digital inclusion among populations who are digitally excluded in health care. The existing body of literature is largely composed of scoping reviews, qualitative studies, and mixed-methods research, and notably, digital health literacy is absent from the development of all studies [19]. While these studies emphasize the importance of tailored, multiactor interventions, they provide limited evidence from robust RCTs targeting digitally excluded groups.

To address potential implementation barriers, this study aimed to evaluate the feasibility and acceptability of providing an iPad, digital literacy training, and support alongside a DHI (Ex-Tab intervention), compared with providing a DHI alone. The study used Kidney Beam as an exemplar DHI.

Methods

Ethical Considerations

The substudy was approved by the Bromley NHS Research Ethics Committee (reference number: 21/LO/0243) and Health Research Authority, and was preregistered on ClinicalTrials.gov (NCT04872933). Study information and consent materials were provided in accessible, nondigital formats, and researchers ensured that adequate time and opportunity were given to ask questions before consent was obtained. Participation was voluntary, and nonparticipation did not affect access to clinical care. Written informed consent was obtained from all participants before their involvement in the study (Multimedia Appendix 1). All collected data were deidentified to protect participant privacy and confidentiality. No compensation was provided to the participants.

Study Design, Setting, and Participants

A feasibility RCT was conducted at a single site as a substudy of the Kidney Beam trial. The study protocol is presented in Multimedia Appendix 2. Adults aged ≥18 years with established CKD were recruited from King's College Hospital in the United Kingdom, which serves a diverse urban population in South London. The inclusion and exclusion criteria for this study differed from those of the main study. The study included individuals lacking access to a Wi-Fi–enabled digital device or scoring <7 on the Vanderbilt University Medical Center Digital

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Health Care Literacy Scale (DHLS) [20,21]. The DHLS score ranges from 0 to 21, with higher scores indicating greater digital health literacy. In this study, a score of <7 was used to indicate reduced digital health literacy. Participants from the main study were not included in this substudy. The complete inclusion and exclusion criteria are provided in Table S1 in Multimedia Appendix 3. This manuscript is informed by relevant CONSORT (Consolidated Standards of Reporting Trials) extensions (Checklist 1) [22-24], the TiDieR (Template for Intervention Description and Replication) for intervention description [25], and the COREQ (Consolidated Criteria for Reporting Qualitative Research) for qualitative research (Checklist 2) [26].

Recruitment

Potential participants were screened by the clinical team, and recent clinical records were reviewed to confirm eligibility at the time of enrollment. Suitable adults were approached in person during routine clinic visits, at outpatient physiotherapy appointments, or via telephone, by trained research staff. All participants provided written informed consent, which was obtained by the lead researcher (CW). Participants attended in-person assessments at baseline and 12 weeks at an NHS Health Centre. Some participants chose to complete their 12-week assessment via telephone. Outcome measures were completed online using SurveyMonkey, and support was offered by the researcher. Demographic and clinical characteristics were gathered from patient records (see Table S2 in Multimedia Appendix 3).

Randomization

Participants were randomly assigned 1:1 to the Kidney Beam Ex-Tab group or the Kidney Beam alone group. Randomization was performed using a web-based system (Sealed Envelope [27]). Owing to the nature of the intervention, it was not possible to blind either the health care professionals delivering the intervention or the participants to group allocation.

Kidney Beam Alone (Nonintervention) Group

Participants who were allocated to the Kidney Beam alone group were signed up on the Kidney Beam website and given a user guide on how to access the relevant exercise classes (Multimedia Appendix 4). They were instructed to exercise twice per week for 12 weeks.

Kidney Beam Ex-Tab (Intervention) Group

The Kidney Beam Ex-Tab intervention was guided by patient and public involvement (PPI). Participants allocated to the Kidney Beam Ex-Tab group were provided with an iPad for 12 weeks, which had Kidney Beam preloaded. Moreover, they were provided with a Kidney Beam account and trained on using the iPad (Multimedia Appendix 5) and navigating the Kidney Beam website. This approach enabled a comparison of Kidney Beam usage between the 2 study groups.

The teaching session was delivered in person individually at an NHS Health Center by the research physiotherapist (CW) leading the study. It involved a demonstration, joint use of the iPad with feedback from the researcher, and autonomous participant use of the iPad. The teaching session was no longer than 60 minutes and was completed immediately after randomization at the baseline research visit. The teaching could not be individualized, and the instructional process remained consistent throughout the study period. Adherence to the intervention was monitored by recording the number of exercise classes completed, although fidelity of delivery was not formally assessed.

Participants were able to contact the research team and ask for assistance if they had any difficulties using the iPad from home, and in-person support was offered on request. Participants were instructed to use the iPad to exercise on the Kidney Beam website twice per week for 12 weeks. The iPads were configured with restricted access using device management settings, allowing participants to access only the Kidney Beam website via the preinstalled browser. No additional apps or websites were available. Participants were informed of this prior to providing consent. At the 12-week assessment, the iPad was returned to the research team. Features of the study intervention are presented in Textbox 1.

Textbox 1. Kidney Beam Ex-Tab intervention summary.

The intervention involves the following steps:

1. Account creation for the Kidney Beam (digital health intervention) website
2. Demonstration of how to use the basic functions of an iPad (turning on and off, and how to swipe, click, and charge the device)
3. Demonstration of how to navigate the Kidney Beam website to access relevant exercises (eg, seated or standing) and educational content
4. Participant trialing on how to use the iPad and navigate the Kidney Beam website with verbal support from the researcher
5. Independent iPad practice and use of the Kidney Beam website, without any verbal support from the researcher
6. Loaning of the device for 12 weeks to access Kidney Beam only (once the participant is fully independent, is satisfied with iPad use, and knows how to navigate Kidney Beam; Multimedia Appendix 6)

Sample Size

Formal power calculations were not completed as recommended by the CONSORT guidelines for feasibility studies [22]. The target sample was 40 participants to allow assessment of recruitment, acceptability, and procedural issues, rather than statistical outcomes.

Primary Outcomes for the Pilot Study

Primary feasibility outcomes included screening, recruitment, retention, randomization, outcome acceptability, intervention

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acceptability, and safety. Adverse events were monitored throughout the study and assessed by the research team for potential relatedness to the intervention or study procedures. For key feasibility outcomes, a priori criteria (Table 1) were used to establish progression to a definitive trial [28]. For each criterion, "stop" (indicating there were fundamental challenges that may impede a definitive trial) and "go" (indicating there were no challenges) thresholds were established. Results falling between these thresholds ("amber") indicated that adaptations may render the definitive trial viable [28]. For secondary outcomes included within the pilot, refer to Table S3 in Multimedia Appendix 3.

Table . Progression criteria.

Outcome and status	Threshold
Recruitment (number of people recruited per month)	
Stop	<2 people recruited per month
Amber	2 - 3 people recruited per month
Go	>3 people recruited per month
Intervention acceptability	
Stop	Engagement with less than 6 sessions
Amber	Engagement with 6 - 11 sessions
Go	Engagement with at least 12 sessions
Outcome acceptability	
Stop	Less than 60% completion rate
Amber	61% - 79% completion rate
Go	At least 80% completion rate
Loss to follow-up	
Stop	More than 50% dropout rate during the pilot phase
Amber	21% - 49% dropout rate
Go	Less than 20% dropout rate

Interviews

One-to-one, semistructured interviews were conducted with participants from the Kidney Beam Ex-Tab and Kidney Beam alone groups to explore their experiences of taking part in the trial and the experiences of the Kidney Beam Ex-Tab intervention. A purposive sample of participants from both groups was invited to complete individual semistructured interviews, either in person or via telephone. Interview participants were purposively sampled for maximum variation to ensure diversity across the sample. The sampling framework included ethnicity, age, sex, stage of CKD, history of renal replacement therapy (eg, dialysis), and intervention adherence level.

Topic guides (Table S5 in Multimedia Appendix 3) were developed in advance, and the PPI group reviewed and provided feedback prior to the first interview. The topic guides were broadly comparable for both groups, although questions relating to the intervention were excluded for the Kidney Beam alone group.

Consistent with the information power model [29], the sample size was not predetermined. Rather than aiming for theoretical saturation, which is associated with grounded theory, this study was guided by a framework analysis approach. We therefore sought to recruit a purposive sample of knowledgeable participants across both treatment groups, capturing a range of CKD stages and experiences of renal replacement therapy. Recruitment proceeded iteratively alongside analysis and ceased when the research team judged that the dataset provided sufficient information to address the study aim. This judgment was based on the focused research question, the specificity and relevance of the sample, and the depth and quality of the interview data. In later interviews, no substantially new insights were identified, and instead, these interviews elaborated and refined concepts already developed from earlier transcripts and did not add data that extended the existing analytical framework. Accordingly, data collection was concluded when additional interviews were assessed as unlikely to contribute meaningfully to the development of the analysis.

Interviews were conducted by experienced qualitative researchers who are renal physiotherapists working with people living with CKD (CW [male] and JB [female]). Participants were informed of the roles of the research team, with the lead researcher (CW) being responsible for assessments, randomization, and teaching, and the other researcher (JB) leading the Kidney Beam exercise classes. The researchers had no prior relationship with the participants before recruitment. All qualitative researchers kept a diary to enhance reflexivity and rigor [30]. Multiple researchers (CW, HMLY, and SF) coded the transcripts and ensured that the analysis and interpretation remained grounded in the data. Interviews were

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conducted as part of the 12-week reassessment either face-to-face or via telephone and were audio recorded.

The lead researcher (CW) held multiple roles in the study, being involved in randomization, delivering the teaching intervention, and conducting some of the qualitative interviews. This relationship may have influenced participants' responses, for example, through social desirability or a perceived power dynamic. To mitigate this, participants were reminded that interviews were confidential, their responses would not affect their course participation or assessment, and honest feedback (both positive and negative) was valued. Interview questions were semistructured and neutrally phrased to minimize leading responses. The research team maintained reflexive diaries throughout the study to reflect on potential researcher influence during data collection and analysis, and interpretations were discussed among the wider research team to support reflexive awareness and analytical rigor.

Data Analysis

Quantitative analysis was conducted by an independent statistician (JC) using SPSS (Version 29; IBM Corp). Descriptive statistics were used to estimate feasibility outcomes. Continuous variables that were not normally distributed are presented as median (IQR). Normally distributed continuous variables are presented as mean (SD). Categorical variables are presented as n (%). Secondary outcomes were considered exploratory; therefore, no *P* values are reported.

Qualitative interviews were independently transcribed verbatim. Data were managed using NVivo v15 (Lumivero) and Excel software (Microsoft Corp). Qualitative analysis was undertaken according to the framework approach [31] informed by the digital inclusion framework [32]. The framework identifies 5 domains where action is needed for digital inclusion: access to devices and data, accessibility and ease of use of technology, skills and capability, beliefs and trust, and leadership and partnerships. Transcripts were reviewed and coded line by line. Initial codes were discussed and refined, culminating in an analytical framework that was then systematically applied to the remaining transcripts. A matrix, which summarized the data from each participant by theme, was created.

Results

Feasibility Outcomes

Eligibility and Recruitment

Screening and recruitment occurred from September 2023 to September 2024, with data collection completed by November 2024. Of the 169 adults screened, 129 were not enrolled. Figure 1 outlines the progression of participants through the pilot study.

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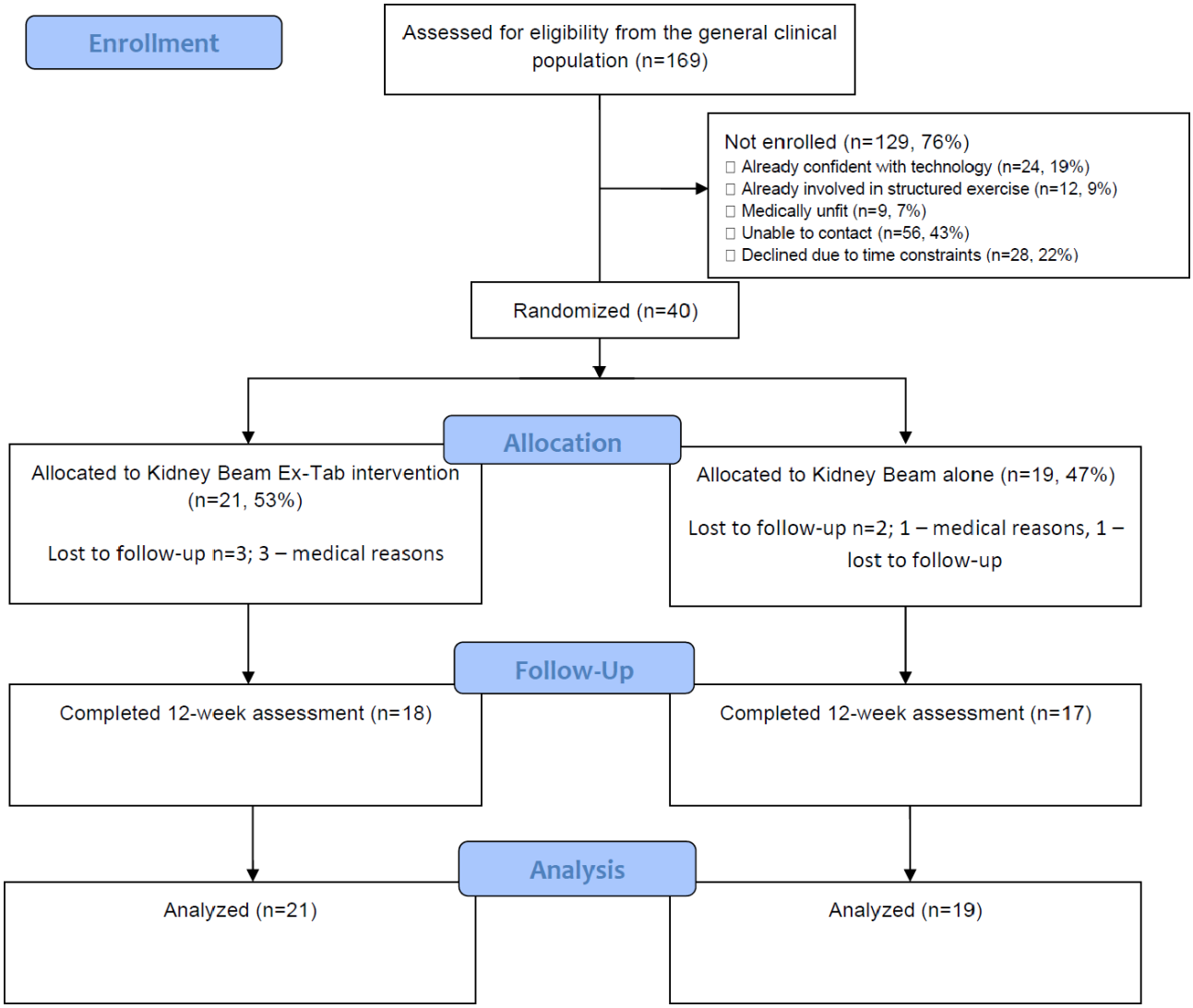
Figure 1. CONSORT (Consolidated Standards of Reporting Trials) flow diagram.



Cumulative monthly recruitment rates are shown in Figure 2. The single site recruited a mean of 3 participants per month. Of those who consented, 40 progressed to randomization. Of the 40 participants randomized, 21 were allocated to the Kidney Beam Ex-Tab group and 19 were allocated to the Kidney Beam alone group. Recruitment stopped once the target of 40 participants was achieved.

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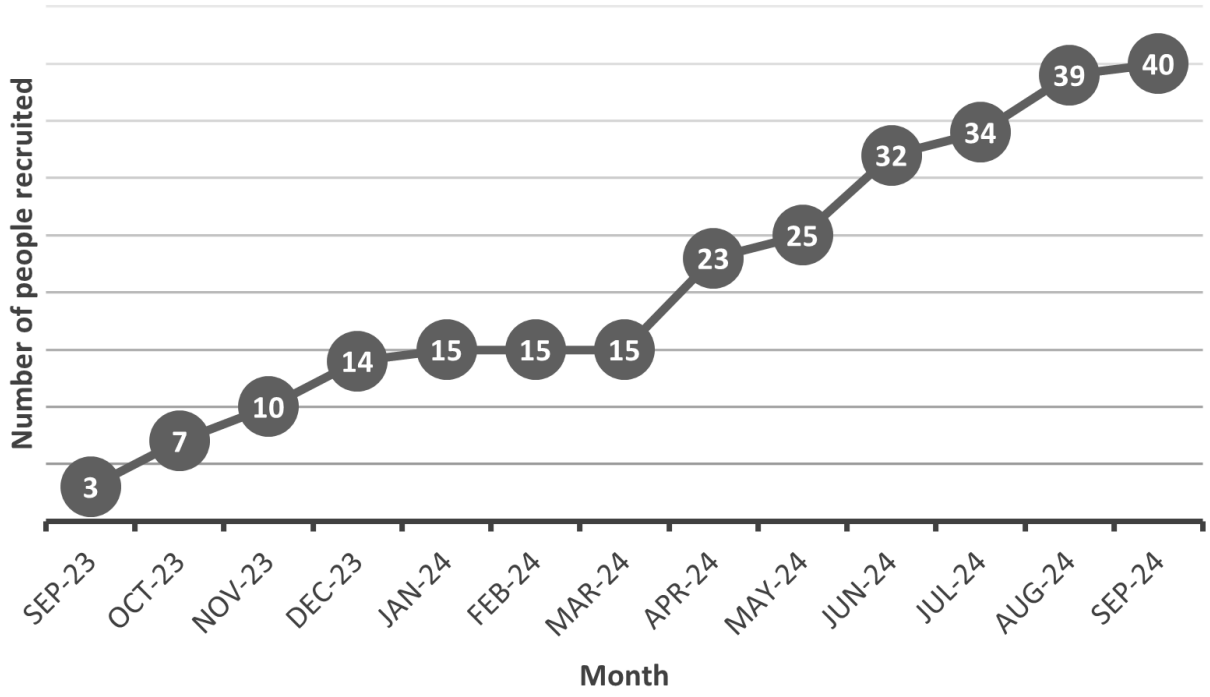
Figure 2. Actual rate of recruitment during the pilot trial (cumulative monthly recruitment).



Participant Characteristics

Overall, there were 20 (50%) male and 20 (50%) female participants, and the majority of participants were Black adults (19/40, 48%). At baseline, the Kidney Beam Ex-Tab group had older participants and more female participants compared with the Kidney Beam alone group. Other factors were well matched between the groups (Table S2 in Multimedia Appendix 3). Digital health literacy scores were similar in both groups.

Retention

Of the 40 participants, 5 (13%) were lost to follow-up, including 3 (8%) from the Kidney Beam Ex-Tab group and 2 (5%) from the Kidney Beam alone group. The reasons for withdrawal included becoming medically unfit (n=4) and being lost to follow-up (n=1).

Exercise Adherence

Participants in the Kidney Beam Ex-Tab group completed more exercise sessions and spent more time on the platform compared with the Kidney Beam alone group (Table 2). In the Kidney Beam Ex-Tab group, participants performed a median of 9 (IQR 2 - 18) exercise sessions, with 12 participants performing at least two sessions (2 - 43 completed classes). In the Kidney Beam alone group, only 2 participants completed any classes (one participant completed 2 classes, and the other completed 1 class), and the remaining participants did not complete any classes. The time spent on exercise classes in the 2 groups is presented in Figure 3.

Table . Exercise adherence levels by the number of exercise sessions in the Kidney Beam Ex-Tab and Kidney Beam alone groups.

Variable	Kidney Beam Ex-Tab group (n=21), n (%)	Kidney Beam alone group (n=19), n (%)
Engagement with less than 6 sessions	9 (43)	19 (100)
Engagement with 6 - 11 sessions	4 (19)	0 (0)
Engagement with at least 12 sessions	8 (38)	0 (0)

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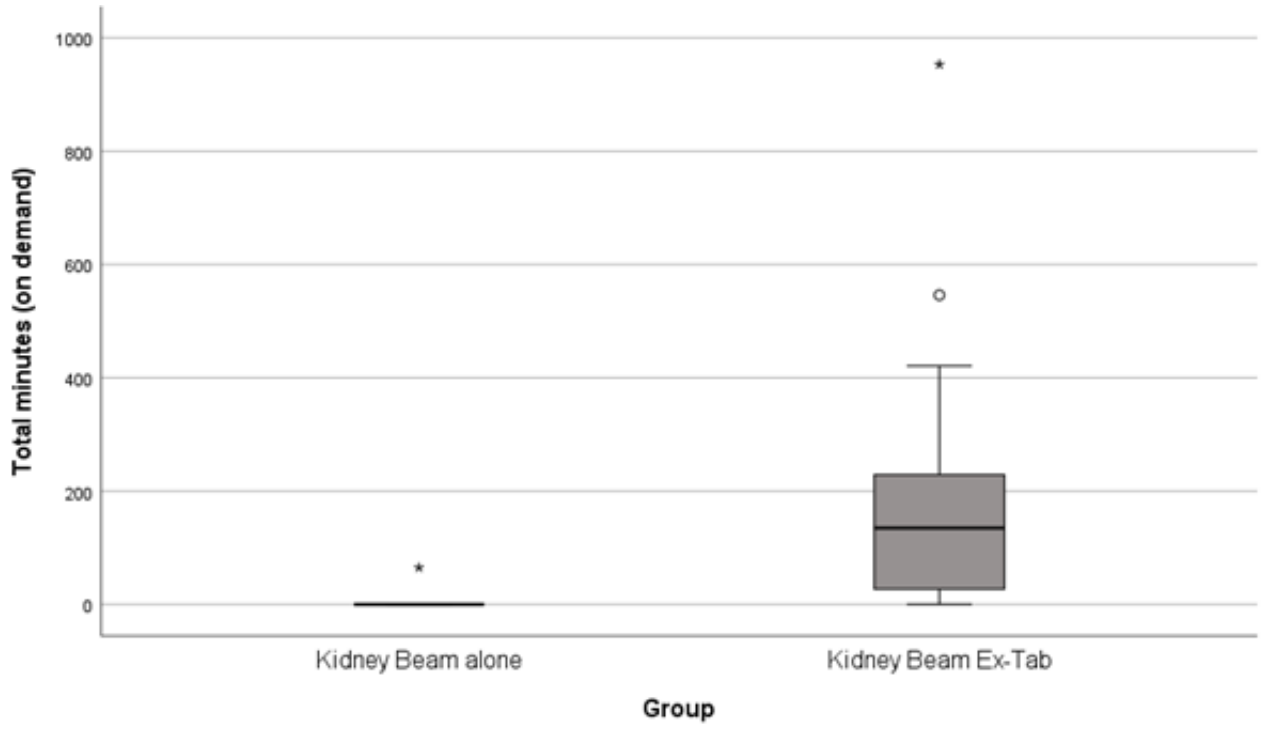
Figure 3. Time spent (minutes) on completing classes on Kidney Beam in the Kidney Beam alone and Kidney Beam Ex-Tab groups. The asterisk denotes an 'extreme outlier' in a box and whisker plot. Extreme outliers: Values that are more than 3.0 x IQR below Q1 or above Q3 are represented by asterisks.



Outcome Acceptability

Overall, 88% - 100% of outcome data were completed at baseline, and 80% - 85% were completed at 12 weeks (Table 3). A total of 5 participants completed the assessment by telephone rather than attending in-person evaluations (2 in the Kidney Beam Ex-Tab group and 3 in the Kidney Beam alone group).

Table . Secondary outcome measure completion rates at baseline and 12 weeks.

Measure	Completed at baseline, n (%)	Completed at 12 weeks, n (%)
Sit-to-stand test (60 s)	40 (100)	32 (80)
PHQ-4[a]	38 (95)	34 (85)
Chandler Fatigue Scale	35 (88)	34 (85)
KDQoL-SF1.3[b]	39 (98)	34 (85)

[a]PHQ-4: Patient Health Questionnaire-4.

[b]KDQoL-SF1.3: Kidney Disease Quality of Life-Short Form version 1.3.

Safety

Three serious adverse events occurred during the study period, including 1 cardiac arrest in the Kidney Beam alone group and 2 deaths in the Kidney Beam Ex-Tab group (1 following emergency surgery and 1 of unknown cause). The 2 participants in the Kidney Beam Ex-Tab group had not undertaken any Kidney Beam exercise classes. Based on the clinical information available to the research team, none of these events were considered to be related to participation in the study or the intervention.

Secondary Quantitative Outcome Measures

Secondary quantitative outcome data are summarized in Table 4.

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Table . Secondary outcome measure results.

Measure	Kidney Beam Ex-Tab group			Kidney Beam alone group		
	Baseline	12 weeks	Difference	Baseline	12 weeks	Difference
Kidney Beam exercise time (min), median (range)	—[a]	135.0 (13.5 - 244.5)	—	—	0 (0-0)	—
KDQoL-SF1.3[b] MCS[c], mean (SD)	49.20 (11.9)	51.25 (8.03)	+2.05	50.46 (11.24)	50.51 (12.38)	+0.05
KDQoL-SF1.3 PCS[d], mean (SD)	32.43 (10.07)	37.99 (11.49)	+5.56	37.28 (10.75)	33.18 (11.93)	−4.10
Sit-to-stand test (60 s) repetitions, mean (SD)	13.67 (5.38)	16.87 (5.38)	+3.20	17.53 (7.78)	13.06 (11.38)	−4.47
PHQ-4[e] score, median (range)	3.00 (0.00 - 7.00)	0.00 (0.00 - 3.00)	−3.00	3.00 (0.00 - 6.00)	1.00 (0.00 - 7.00)	−2.00
Chandler Fatigue Scale score, median (range)	14.00 (11.75 - 15.25)	11.00 (11.00 - 20.50)	−3.00	13.00 (12.00 - 20.00)	15.00 (12.00 - 22.00)	+2.00

[a]Not applicable.

[b]KDQoL-SF1.3: Kidney Disease Quality of Life-Short Form version 1.3.

[c]MCS: mental component summary.

[d]PCS: physical component summary.

[e]PHQ-4: Patient Health Questionnaire-4.

Qualitative Findings

Overview

From both groups, 27 participants were approached, and of these, 25 agreed to complete qualitative interviews. Two declined owing to not wanting to have their voice recorded. Baseline characteristics of the 25 participants are summarized in Table 5. Interviews were conducted between March 19, 2024, and November 27, 2024. Participants were interviewed either by telephone at their homes or in person at an NHS medical center, without the presence of nonparticipants.

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Table . Demographic and clinical characteristics of the qualitative participants.

Variable	Value (N=25)
Age (years), median (range)	67.92 (59-74)
Sex, n (%)	
Female	11 (44)
Male	14 (56)
Ethnicity, n (%)	
White	8 (32)
Black	14 (56)
Asian	3 (12)
Treatment group, n (%)	
Kidney Beam Ex-Tab (intervention)	13 (52)
Kidney Beam alone (control)	12 (48)
Treatment modality, n (%)	
Non–dialysis-dependent kidney disease	9 (36)
Kidney transplant recipient	4 (16)
Dialysis therapy	12 (48)
Exercise sessions completed, n (%)	
Less than 6 sessions	15 (60)
6 - 11 sessions	3 (12)
At least 12 sessions	7 (28)
Length of interviews (min), median (range)	23 (11-43)

The results are outlined in 5 themes based on the NHS digital inclusion framework: access to devices and data, accessibility and ease of use of technology, skills and capability, beliefs and trust, and leadership and partnerships.

Access to Devices and Data

Digital Inequities

Participants described limited digital literacy, low motivation to engage with technology, and barriers to device maintenance and connectivity. Participants encountered difficulties with basic mobile phone functions like answering the phone and sending SMS text messages. Limited understanding of key digital concepts, such as Wi-Fi and mobile data, further compounded these challenges. Although some participants had access to Wi-Fi at home, many lacked the knowledge to effectively use it or connect their devices. Minimal use of digital communication beyond essential functions was common, restricting patients' interactions with digital health platforms, and some participants showed little interest in enhancing their digital skills, which constrained their use of health-related technologies. Participants also faced issues with internet connectivity, and unreliable signals and buffering frequently disrupted their online activities, causing frustration.

> *I don't know which button to push to answer the damn thing… I don't know how to answer the phone.* [Male, 75 years old, kidney transplant recipient, White British]

> *When the internet keeps buffering and things like that. I think it's more losing the signal and you get frustrated because you're in the middle of doing something.* [Female, 68 years old, kidney transplant recipient, White British]

Financial Strain

Financial strain was a significant barrier to accessing and maintaining digital devices essential for health engagement. Affordability influenced the initial acquisition of technology and decisions around repair and replacement. Other financial priorities often took precedence over purchasing or repairing a digital device, while reliance on others or government benefits limited the ability to invest in better devices. Frequent technology issues and costly or failed repairs added to the challenge, sometimes requiring new purchases. Limited knowledge of maintenance worsened the problem, creating major barriers to using digital devices effectively. Community support and donations were seen as potential solutions to ease these financial burdens.

> *To buy it, you've got to know what you want to use it for. At the moment, that's one of the reasons. The other… is finance. At the moment I'm going through decorating my place. And also I've got other things to deal with, like I've got to sort a headstone for my mother. And they're taking priority in that sense.* [Male, non–dialysis-dependent kidney disease, 67 years old, Black Caribbean]

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Role of Social Support

Many participants emphasized the importance of social support and cohabitation in facilitating their access to and use of digital technologies. Those living with family or partners often relied on others' devices.

> *I think I don't really need it because when she [participants daughter] comes, I always use her [participants daughters] phone.* [Male, dialysis-dependent kidney disease, 60 years old, Black African]

> *I haven't really got much help from anybody and I live on my own… Because I'm in one of those situations where I'm on my own. Everything I have to do on my own.* [Male, dialysis-dependent kidney disease, 73 years old, White British]

> *That kind of put me back a bit when I haven't got no-one in the house… so that means I don't learn as fast.* [Female, dialysis-dependent kidney disease, 74 years old, Black Caribbean]

Access to Devices and Data (Intervention Acceptability)

Participants in the Kidney Beam Ex-Tab group generally regarded the loaning of tablets and associated training as a valuable and acceptable aspect of the intervention, which facilitated engagement and motivation in completing exercises. The loaning of devices was widely welcomed as a means to overcome the challenges of having access to a device, especially for those unable to afford their own device.

Other positives from having access to an iPad included participants valuing the opportunity to develop digital skills and increase their confidence and willingness to use digital technology following the completion of the study. Many participants frequently expressed concerns about responsibility for the loaned devices. Some participants feared potential damage or loss and worried about the financial repercussions of this, and thus, they adopted protective behaviors to avoid damage. Overall, participants recognized that borrowing devices demanded responsibility but considered this an acceptable tradeoff for increased access to digital devices like iPads.

> *Not everybody can afford to buy one… And it gets you active again. Helps you get active again to get on that program.* [Female, kidney transplant recipient, 68 years old, White British]

> *It's a good idea to those that need it and does not have it and would like it and that would help them, of course it's a good idea… Because it will help them isn't it, whatever the need is, because sometimes you have a need and you haven't got the equipment, whatever, for that need, but when you have the equipment it will help.* [Female, dialysis-dependent kidney disease, 74 years old, Black Caribbean]

> *It's OK to borrow things on the NHS but I'd be terrified of losing things! Or breaking things!… Nobody likes to break something that's not theirs and one would feel a bit guilty! Because everything costs money… So yes, I think it's a good idea to be that people are able to reach out and get things, it's just for me when it breaks I don't like it!* [Female, non–dialysis-dependent kidney disease, 69 years old, Black Caribbean]

Accessibility and Ease of Use of Technology

Participants struggled to navigate the iPad, the internet, and Kidney Beam due to low digital confidence and unfamiliarity. They found it difficult to move between pages, locate exercises, and manage passwords. Using Kidney Beam on mobile devices was especially challenging because of unclear website navigation, small screens, and limited awareness of options like casting to a television screen. Password management added further barriers, with participants frequently forgetting details and having concerns about storing the details securely. These issues often led to inconsistent use and reliance on family support.

> *Sometimes I get into it and then something will happen and it sort of disappears and I don't know how to get back to it and it's a lot of fiddling and faddling and I'm calling my son saying 'help me get back on this', or whatever…* [Male, dialysis-dependent kidney disease, 59 years old, Black Caribbean]

> *The negative is the screen is so small – I know it's a big iPad, but then you're trying to exercise. You're like not in front of it as such.* [Female, dialysis-dependent kidney disease, 58 years old, Black Caribbean]

> *Everybody seems to want passwords and codes and all the rest of it. The more I get, the more confused I get and I don't necessarily remember them all.* [Male, dialysis-dependent kidney disease, 77 years old, White British]

Participants also reported a range of physical challenges that impeded their ability to use digital devices. Visual impairments, including severe sight loss and deteriorating eyesight, made it difficult for some to see and interact with screens effectively. In addition to vision problems, physical health conditions, such as arthritis and back pain, affected participants' ability to handle devices. Pain, stiffness, and limited dexterity in the hands often resulted in difficulties tapping screens accurately or sustaining interaction with the technology. These physical limitations not only reduced usability but also contributed to feelings of frustration and decreased motivation to engage.

> *I didn't really use technology at all, because I'm registered severely sight-impaired. So I can't see screens. My phone, I ask it to get me a telephone number and I ask it to read me a text message. But other than that, I wish I could see it.* [Female, non–dialysis-dependent kidney disease, 78 years old, White British]

> *But at the moment, honestly, to tell you the truth, I don't feel good at all. My health, my arthritis is affecting me.* [Female, non–dialysis-dependent kidney disease, 80 years old, Asian]

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Skills and Capability

Many participants described having limited or basic digital skills and abilities. Several participants reported struggling with fundamental digital functions, such as typing, or using software and mobile devices. A minority of participants reported moderate or advanced digital skills, often linked to previous work experience; however, this did not always translate into regular or confident use.

> *I don't know much about the clouds and all that… nobody has taught me about it.* [Female, dialysis-dependent kidney disease, 57 years old, Black African]

> *I can search for some things but… I'm not always confident of when you get into these sites.* [Male, dialysis-dependent kidney disease, 59 years old, Black Caribbean]

> *Well I'm reasonably confident with the things I know how to do. But anything more complicated I struggle with.* [Male, dialysis-dependent kidney disease, 77 years old, White British]

Many participants reported difficulties with memory, attention, and cognitive processing. These challenges were described as both persistent and frustrating and were linked to aging, neurological conditions, or general cognitive decline.

> *After the stroke, I tell you, everything left my head. Everything is like… a blank space.* [Male, dialysis-dependent kidney disease, 55 years old, Black African]

> *I suppose actually remembering the different steps to take to get the computer working…* [Male, kidney transplant recipient, 72 years old, Asian]

> *It can come now today in my head and tomorrow I can forget it.* [Male, dialysis-dependent kidney disease, 57 years old, Asian]

Skills and Capability (Intervention Acceptability)

Participants emphasized the importance of guided support. Instructions and practice were included in the intervention, and participants were able to develop the skills and confidence to use the iPad effectively. Several participants highlighted the need for clear, hands-on teaching or being shown step-by-step instructions. Learning to use the iPad by repetition was helpful. Participants found the initial teaching as part of this study helpful, noting that it boosted their confidence. Many participants described improvements and the practical benefits of using the iPad over time.

> *You explained it properly to me, you know, I still didn't quite get it straightaway but eventually I got it as spoke to each other then I got used to it, you explained it properly to me and showed me how to use it, so I was fine with that.. you explained it properly to me, I didn't have no problem with understanding you or you telling me what to do.* [Female, non–dialysis-dependent kidney disease, 65 years old, Black Caribbean]

> *My confidence is more, should I say, I have more confidence than before…Because you know when you just start something, you say oh I don't think I can do this for, what, for three months and something, yeah, I've got confident now, yeah.* [Female, dialysis-dependent kidney disease, 64 years old, Black African]

Beliefs and Trust

Participants described ambivalence toward technology, which was strongly influenced by generational factors and shaped by individual beliefs and trust concerns. Many older adults expressed resistance to adopting digital technologies, describing themselves as "not of the computer age" (male, hemodialysis, 77 years old, White British) or being "a bit of a dinosaur" (male, posttransplant, 75 years old, White British), highlighting a generational divide in familiarity and comfort with technology. The perception that technology is "too much" (female, stage 2, 69 years old, Black Caribbean) or "too complicated" (male, hemodialysis, 77 years old, White British) led some participants to disengage entirely from digital services. This resistance was frequently attributed to perceived complexity and lack of personal relevance, with participants emphasizing a preference for traditional, interpersonal modes of communication and transactions over digital interfaces.

> *I'm just not really of the computer age… it's just not something I grew up with.* [Male, dialysis-dependent kidney disease, 77 years old, White British]

> *It's not personal, you know? I like talking to someone face-to-face, not just buttons and screens.* [Male, dialysis-dependent kidney disease, 59 years old, Black Caribbean]

There was widespread apprehension regarding security and privacy, with participants voicing fears of fraud, scams, and hacking. Several participants had been targeted by scammers, which significantly undermined their trust in digital platforms.

> *I'm afraid I press the button and give away the little money that I've got or something! Or let somebody else in my account or whatever. I'm just afraid of it.* [Female, non–dialysis-dependent kidney disease, 69 years old, Black Caribbean]

> *I'm very, very aware of scammers and that. So I don't have a mainline telephone any more. I used to get odd calls on that. But I'm very, very aware of what scammers do. So maybe that's an advantage in a way that I don't use it, because I can't be scammed.* [Female, kidney transplant recipient, 57 years old, Black African]

Despite concerns, some participants acknowledged the inevitability of adapting to technology, often framed as a reluctant acceptance driven by practical necessity rather than enthusiasm. Some participants demonstrated cautious trust, stating that they would use digital health apps "if they trusted it" (male, stage 3a, 67 years old, Black Caribbean).

> *I mean you've got digital banking coming on now right, you know? They move away all the banks, so they turn round telling you "Oh, do it online." So you*

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slowly move towards that direction… If I didn't trust it, I wouldn't use it, you know. I think you've just got to be, keep an open mind about it. Stuff that is too dodgy your bank will stop it, or if it does go through, you can get back on it. [Male, non–dialysis-dependent kidney disease, 67 years old, Black Caribbean]

If I didn't trust it, I wouldn't use it, you know. I think you've just got to be, keep an open mind about it [about using Kidney Beam in the future] [Male, dialysis-dependent kidney disease, 59 years old, Black Caribbean]

Beliefs and Trust (Intervention Acceptability)

Participants continued to have mixed beliefs about technology and digital interventions even after completing the study, which were influenced by personal confidence, perceived usefulness, and trust in their ability to engage. Some participants recognized the growing relevance of digital tools in business and other areas and would consider using them in the future. Participants appeared to hold the view that borrowing resources from the NHS was permissible, given its status as a trusted and authoritative organization. Many participants who used Kidney Beam would continue to use it if support remained and it was convenient. Overall, attitudes reflect a balance of hesitation and openness, with familiarity, necessity, and perceived benefit playing key roles in shaping future iPad and Kidney Beam engagement.

The way it's going, it's the way things are going to be going anyway. So it's already going to that way. But for me personally, yeah, I mean it's going to impact on everybody, but again, I don't see me delving into the heights of technology to be honest. [Male, dialysis-dependent kidney disease, 59 years old, Black Caribbean]

I don't think I have the mind to use the, to follow the technology that's coming into the system. With my set of mind and my mind, and my level of education I've had and gone through, and I'm really, really scared to use these new, these technologies, these computers, these laptops. [Male, non–dialysis-dependent kidney disease, 83 years old, Black African]

If, like I say, if it could go on my little tablet and I was shown how to do, like I was shown how to do that one, then I could most probably carry on doing it. [talking about continuing with Kidney Beam in the future] [Male, kidney transplant recipient, 75 years old, White British]

Leadership and Partnerships

Participants emphasized the need for stronger leadership and clearer support structures with digital technologies. Many participants expressed a desire for more frequent check-ins, reminders, and personalized guidance to stay engaged and overcome challenges. Where formal support was lacking, some turned to family members or peers, but this was not an option for everyone. Participants also highlighted the value of one-to-one interactions and suggested that accessible digital devices or remote support could improve autonomy and confidence. Participants suggested strengthening partnerships with in-center dialysis units and libraries to offer support and leadership with engagement for digital technologies.

Well, my daughter and that sort of thing that can help me you know. But she's not here all the time. That's the problem… They are too busy in their own things. So you know nowadays children don't have time for you… That's what I feel. I don't bother them. I can't rely on them. [Female, non–dialysis-dependent kidney disease, 80 years old, Asian]

Well probably, just probably more contact, right? More reminders or one to one ongoing talk. [Male, non–dialysis-dependent kidney disease, 67 years old, Black Caribbean]

In sense of people come to dialysis centres, communicate with them, talk to them, educate them about this and what we are trying to do, this is how to achieve the aim [getting more people exercising online]. [Female, dialysis-dependent kidney disease, 57 years old, Black African]

Leadership and Partnerships (Intervention Acceptability)

Participants highlighted the importance of the intervention package (encouragement, support, and access) used in this study in shaping its acceptability and potential effectiveness. Many participants suggested that other digitally excluded people would also benefit from this intervention and that it should be supported by leaders and organizations to achieve wider reach. Several individuals stressed the value of flexibility and autonomy enabled by borrowing an iPad and having access to Kidney Beam, reinforcing the need for supportive systems that allow users to engage on their own terms. Participants also acknowledged the role of guidance and reminders from the research team, suggesting that effective leadership in the form of clear instructions or check-ins can enhance engagement. Some participants advocated for peer encouragement and shared responsibility. Overall, these reflections underline the importance of partnerships among patients, health providers, and digital health leaders, where encouragement, accessible resources, and sustained support foster engagement.

It could help a lot of people in lots of different ways…well it helped me I think… but I think on the whole it is a good idea. [Male, kidney transplant recipient, 75 years old, White British]

I got a lot of encouragement from the young guy and especially that young lady. She was marvellous.. I'm never going to be the 'Green Goddess' or nothing like that but yeah, it suited me, because I was able to do it in my own time. But you still need somebody there at least once in the week to encourage you. And then you think about that, and that gives you an incentive to do it yourself. So you're not reliant on that person all the time, but it gives you an incentive to carry on doing it. [Female, non–dialysis-dependent kidney disease, 78 years old, White British]

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> *Well I would say to other patients go for it. It's worthwhile, yeah…I feel fitter. Happier. Able to do more… Well when I get my new computer I'll do it on my computer or I might even invest in getting myself an iPad.* [Female, kidney transplant recipient, 68 years old, White British]

Mixed Methods Synthesis

A convergent mixed methods analysis was used, in which quantitative and qualitative data were collected and analyzed separately but concurrently before being integrated within a joint display (Table 6). This joint display brings together the quantitative feasibility outcomes and qualitative interview findings to identify adaptations for a future definitive trial, highlighting how qualitative insights help explain the quantitative engagement patterns and inform refinements to the intervention and study design.

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Table . Joint display of quantitative and qualitative findings with integrated interpretation and implications for a future definitive trial.

Feasibility domain	Progression criteria	Quantitative findings	Qualitative findings	Mixed methods interpretation	Adaptations required for a definitive trial
Recruitment	Amber: 2 - 3 people recruited per month	An average of 3 participants consented per month	Not explored in qualitative interviews	Recruitment targets were met but were modest, suggesting that recruitment was feasible but may have been limited by the single-site design, rather than participant acceptability of the intervention.	Quantitative: Open recruitment to other sites in the United Kingdom.
Intervention acceptability	Amber: Engagement with 6 - 11 sessions	Mean of 11 exercise classes completed	Participants reported increased access to Kidney Beam, development of new digital skills, and improved confidence using digital technology. The one-to-one teaching and support were perceived as helpful and acceptable.	Qualitative findings help explain the relatively high engagement observed in the quantitative data. Participants indicated that provision of a device, training, and support enabled them to use the platform confidently, suggesting that these elements facilitated sustained engagement with the intervention.	Quantitative: Monitor session completion and engagement to optimize intervention intensity. A digital inclusion exercise program should be created; Qualitative: Reduce password and login burden, create individual shortcuts on the iPad, provide remote support, and refine the teaching process to improve usability.
Outcome acceptability (for all outcome measures)	Go: At least 80% outcome completion rate	80% - 85% outcome completion rate	Not explored in qualitative interviews	High completion rates suggest that the outcome measures were acceptable and feasible to administer in this population.	Quantitative: Validate outcome measures for assessing digital literacy and for use at baseline and 12-week assessments.
Loss to follow-up	Go: Less than 20% dropout rate	12.5% dropout rate	Not explored in qualitative interviews	The low dropout rate indicates good participant retention and overall acceptability of the study procedures.	Quantitative: Maintain follow-up procedures; Qualitative: Clear identification of liability and responsibility for the iPad.
Study design	—[a]	—	—	Considerations arising from feasibility findings suggest that a more robust design may be required to strengthen internal validity in a future trial.	Consider an attention-matched control or stepped-wedge design to improve internal validity.
Fidelity of intervention delivery	—	—	—	Ensuring consistent delivery of the intervention will be important in a larger trial.	Include fidelity monitoring using checklists or session recordings to ensure the intervention is delivered as intended.

[a]Not applicable.

Discussion

Principal Findings

This mixed methods pilot study evaluated the feasibility, acceptability, and design of a future RCT for a novel digital inclusion intervention designed for individuals who are digitally excluded from DHIs. The study achieved its predefined progression criteria for outcome acceptability and loss to follow-up, and adverse events were unrelated to the intervention.

There is a limited body of published literature examining interventions specifically designed to address digital exclusion within health care settings. Consequently, limited prior evidence regarding expected recruitment rates for digital inclusion studies further complicated planning, as this remains an emerging area of research [33]. The recruitment target of 40 participants was

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achieved over 12 months, with an average of 3 participants consenting each month. Although recruitment was slower than initially anticipated, this aligns with well-documented challenges in engaging people living with CKD in research [34], including limited understanding of research participation, competing health and personal priorities, and lower literacy levels, particularly within dialysis populations [35,36]. Additionally, more people than expected did not meet the inclusion criteria, with screened participants being of higher digital literacy levels and/or having access to Wi-Fi–enabled technology.

In the main Kidney Beam trial [11], 19 participants (1.7%) assessed for eligibility reported having no access to a suitable device or Wi-Fi connection. This figure is likely underestimated, as digital access was self-reported by participants and is more difficult to verify than medical exclusion criteria, which can be confirmed through clinical records. Furthermore, neither the main study nor previous studies routinely screened for digital literacy; therefore, the digital screening process implemented in this pilot was newly developed.

Baseline demographic characteristics were broadly comparable between groups in this study. However, there were some clinical differences, with a greater proportion of non–dialysis-dependent participants in the Kidney Beam alone group and more kidney transplant recipients in the Kidney Beam Ex-Tab group. In a small sample, baseline imbalances may occur by chance but could influence engagement or retention, as age, sex, and modality can affect health behaviors and participation in digital or exercise interventions. As a pilot study, these differences should be interpreted cautiously and addressed in future larger trials.

Outcome data completion rates were high at baseline (88% - 100%) and at 12 weeks (80% - 85%). The Kidney Beam pilot study [37] by comparison had 90% - 100% data completeness at baseline and 62% - 83% at 12 weeks, where assessments were delivered virtually. The high retention rate (88%) could be attributable to face-to-face study visits and the requirement to return loaned iPads in person, which helped maintain contact and engagement. The Kidney Beam pilot study [37] by comparison reported a retention rate of 83.4% and subsequently progressed to a successful, fully powered RCT.

No safety events or deaths were related to study participation, and all iPads were returned undamaged, suggesting that the device loan system was manageable and acceptable to participants and families. Implementation required the provision of iPad devices and mobile data connectivity. Ten iPads were purchased at £525 (US $696) each (£5250 [US $6964] total), and SIM cards were provided at £5 (US $6.6) per month. Twenty-one participants used the devices during the study. When distributed across participants, the estimated hardware cost was approximately £250 (US $331) per participant, with an additional £5 (US $6.6) per participant per month for data. Future costs may be reduced through device reuse, participant-owned devices, or institutional Wi-Fi access.

The lower time spent on the platform by intervention participants in this pilot study compared with the main study [11] may reflect differences in both program allocation and participant characteristics. In the main study [11], participants were signposted to a specific exercise program, whereas in this pilot study, some participants completed seated-only exercise sessions due to reduced mobility and balance. These sessions are shorter in duration, which likely contributed to the lower overall engagement time observed. Additionally, participants in the pilot study were older than those in the main trial (mean age 66.5 vs 53.8 years) [38], and the sample included a substantially higher proportion of participants from Black ethnic backgrounds (47.5% vs 11.5%). Comorbid conditions were also more prevalent among participants from the pilot study than among participants from the main study (diabetes: 60.0% vs 22.4%; hypertension: 92.5% vs 69.1%) [11]. The lower cumulative engagement observed in this study may still represent an appropriate intervention “dose” for individuals with greater functional limitations, particularly where shorter and more accessible sessions support participation that might otherwise not occur. These differences suggest that a digital inclusion exercise program tailored to the needs of this population group may be required, as their needs appear to differ from those of participants in the main study [11,38].

Further work is needed to increase time spent on the platform to optimize potential health benefits, as demonstrated in the main study [11]. The benefits of exercise can still be achieved through sporadic, accumulated activity [39]; therefore, this older, more comorbid population may benefit from interventions lasting longer than 12 weeks to increase overall time spent exercising. Greater collaboration with communities is also required to better understand and address participant preferences and needs across organizations, thereby improving practice and supporting wider implementation across services [15,40]. The difference in the time spent on the platform between the main study [11] and this study may be explained by variations in program allocation. Participants in the main study [11] were signposted to a specific exercise program, whereas some participants in this pilot study completed seated-only exercise programs due to reduced mobility and balance. These seated sessions were shorter in duration than the exercise program used in the main study [11], which likely contributed to the lower total engagement time observed. The qualitative findings identified consistent barriers, including password and login burden, low digital confidence, physical and memory limitations, and fear of damaging the device. These issues indicate that the intervention requires further refinement to simplify access and improve support before a larger trial.

The teaching component of the intervention was highly valued. Participants emphasized the importance of step-by-step instructions, opportunities for repeated practice, and ongoing support. The intervention appeared to enhance participants’ confidence in navigating digital devices, including basic functions such as logging in, scrolling, and online navigation. Digital literacy was assessed only at baseline as part of the inclusion criteria; however, future studies should consider measuring changes in digital literacy over time to quantitatively capture improvements resulting from the intervention.

This study contributes to the growing literature suggesting that addressing digital health exclusion requires multifactorial and tailored approaches. Consistent with previous studies highlighting the importance of interventions spanning

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interpersonal and organizational levels [17,18], the provision of devices alongside digital literacy training and ongoing support was found to be feasible and acceptable among participants. The existing evidence base for digital inclusion interventions in health care has been limited by a lack of RCTs and a predominance of qualitative and mixed methods research [19]. While the study was not designed to assess effectiveness, it addresses an important gap by demonstrating the feasibility of embedding digital access and literacy support within a DHI.

This digital inclusion intervention was overall deemed acceptable from the qualitative findings, as access to an iPad and tailored digital training were key enablers of engagement. Participants described the intervention as both a practical solution to digital exclusion and a gateway to developing new digital skills. However, some participants expressed anxiety regarding the responsibility for loaned devices and the potential for device damage. This is an important lesson for future digital health inclusion studies, including those involving other long-term health conditions. Future trials should therefore include clear communication protocols and reassurances about device liability to reduce participant concern.

Limitations

This study was conducted at a single site in London, United Kingdom, where the study sample included a relatively high proportion of Black participants (48%), which differs from national CKD demographics in the United Kingdom. As a result, the findings may not be fully generalizable to other regions of the United Kingdom with different demographic profiles. Digital exclusion may present differently in rural or less ethnically diverse settings, where barriers may relate more to infrastructure limitations, internet connectivity, or geographic isolation, rather than language, socioeconomic inequalities, or varying levels of digital literacy. Future studies should therefore consider multisite recruitment across diverse geographic and demographic contexts to enhance generalizability.

Qualitative interviews focused on exploring barriers to digital health engagement and the perceived impact of the intervention. Broader study procedures, such as recruitment, data collection, and randomization processes, were not explored qualitatively, and feedback on the study procedures would have helped inform future studies.

Participants in the Kidney Beam alone group were not offered the opportunity to borrow an iPad with Kidney Beam access. The control condition reflected current usual care, where individuals without access to a suitable device or the necessary digital skills may be unable to engage with DHIs. Future definitive trials may benefit from alternative comparator designs, such as attention-matched controls or stepped-wedge designs, to provide a more balanced comparison.

The fidelity of delivering the teaching component was not formally evaluated in this study. As these onboarding sessions were conducted over a 12-month recruitment period, some variation in delivery may have occurred. Future definitive trials should incorporate fidelity monitoring strategies, such as structured training protocols, checklists, and session recording, to ensure standardized delivery and to support scalability across multiple instructors and sites.

Digital literacy was assessed at baseline using the DHLS to screen for participants with lower levels of digital literacy (score <7). As this pilot study primarily aimed to examine recruitment, acceptability, and engagement with the intervention, follow-up assessment of digital literacy was not included. However, it is recognized that changes in digital literacy represent an important outcome for digital inclusion interventions. Future definitive trials should therefore incorporate follow-up DHLS assessments to evaluate changes in digital literacy over time.

This study delivered a complex intervention that included providing a loaned device, preloaded access, setup support, training, and ongoing assistance. Because these elements were delivered together, it is not possible to determine the relative contribution of each component to the observed effects. Qualitative interviews provided insights into potential mechanisms underlying the observed changes; however, future studies could examine the individual contribution of these components to better understand how the intervention influences engagement.

Conclusion

The findings of this pilot study support progression to a definitive trial to robustly assess the intervention's effectiveness in addressing digital exclusion. The intervention was considered to be acceptable, although qualitative feedback identified areas for refinement, particularly in improving usability and providing clearer guidance around responsibility for the loaned iPads. Future research should focus on refining and personalizing the intervention to better meet individual needs, as the causes of digital exclusion are diverse. Moreover, this approach holds promise for adaptation and evaluation in other long-term conditions, offering a potential pathway to reduce digital exclusion and improve equitable access to digital health resources.

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Data Availability

The data related to this article will be shared upon reasonable request to the corresponding author.

Authors' Contributions

CW, SAG, and HMLY were responsible for the conception and design of the project and prepared the manuscript. CW, JB, SF, EM, CD, SB, KB, JOB, JC, PAK, JM, MWT, DCW, SAG, and HMLY contributed to the design of the study, provided methodological input, wrote the manuscript, and prepared the tables. All authors reviewed the manuscript. All authors had full access to all the data in the study and had the final responsibility for the decision to submit for publication. CW, SAG, HMLY, and JC verified the data.

Conflicts of Interest

King's College Hospital NHS Trust and SAG were involved in the conception and development of Kidney Beam. SB is a trustee of Kidney Research UK. DCW has an ongoing consultancy contract with AstraZeneca and has received honoraria or consultancy fees from Astellas, Boehringer Ingelheim, Bayer, Eledon, Galderma, GlaxoSmithKline, Gilead, Janssen, Mundipharma, ProKidney, Tricida, Vifor, and Zydus for activities related to education and clinical trials. PAK has received honoraria or consultancy fees from AstraZeneca, Novartis, CSL Vifor Pharma, Pharmacosmos, Medice, and Boehringer Ingelheim. All other authors declare no competing interests.

Multimedia Appendix 1
Informed consent form.
[DOCX File, 50 KB - formative_v10i1e91438_app1.docx]

Multimedia Appendix 2
Study protocol.
[DOCX File, 196 KB - formative_v10i1e91438_app2.docx]

Multimedia Appendix 3
Data to support the study.
[DOCX File, 35 KB - formative_v10i1e91438_app3.docx]

Multimedia Appendix 4
Kidney Beam website screenshots.
[DOCX File, 1155 KB - formative_v10i1e91438_app4.docx]

Multimedia Appendix 5
iPad user guide.
[DOCX File, 8342 KB - formative_v10i1e91438_app5.docx]

Multimedia Appendix 6
iPad loan agreement document.
[DOC File, 72 KB - formative_v10i1e91438_app6.doc]

Checklist 1
CONSORT checklist.
[PDF File, 221 KB - formative_v10i1e91438_app7.pdf]

Checklist 2
COREQ checklist.
[PDF File, 450 KB - formative_v10i1e91438_app8.pdf]

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Abbreviations

CKD: chronic kidney disease
CONSORT: Consolidated Standards of Reporting Trials
COREQ: Consolidated Criteria for Reporting Qualitative Research
DHI: digital health intervention
DHLS: Digital Health Care Literacy Scale
NHS: National Health Service
PPI: patient and public involvement

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RCT: randomized controlled trial
TiDieR: Template for Intervention Description and Replication

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Evaluating a Telemedical Follow-Up Program for Continuity of Care After Hospital Discharge: Prospective Clinical Intervention Study

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Abstract

Background: The transition from hospital to primary care is a vulnerable period for patients. Telemedicine may enhance continuity of care; however, evidence on its role in supporting hospital-to-primary-care transitions remains limited.

Objective: We implemented and evaluated a telephone-based follow-up program to support the transition from hospital to home and primary care, focusing on patient health as well as patient and health care provider satisfaction.

Methods: In this prospective, single-center intervention study (University Hospital Basel, September 2022-December 2024), 234 patients discharged from the emergency unit or internal medicine wards received structured telemedical follow-up for up to 10 days until their first primary care appointment. Primary outcomes were patient health and satisfaction; secondary outcomes were health care provider satisfaction. Data were collected using patient-reported outcome measures, patient-reported experience measures, and provider assessments and analyzed descriptively and analytically (P=.05).

Results: Patient-reported outcome measure and patient-reported experience measure scores changed during follow-up, while no deterioration was observed. Health care provider satisfaction varied, with telemedical physicians reporting the highest ratings, hospital physicians intermediate ratings, and general practitioners the lowest, citing challenges in information transfer and perceived added value.

Conclusions: This study outlines both the potential benefits and the practical challenges of implementing a telephone follow-up program after hospital discharge. Variations in physician satisfaction highlight the need for more user-friendly technical infrastructure and clearer role definitions. Future multicenter studies with broader patient samples, usual care controls, and simplified recruitment processes are required to strengthen the feasibility and generalizability of this approach.

Trial Registration: ClinicalTrials.gov NCT05617560; https://clinicaltrials.gov/study/NCT05617560

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KEYWORDS

hospital at home; transition of care; telemedicine; patient safety; discharge process; telecare; health care environment

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Introduction

Background

Transition of care from hospital to home represents a critical phase in the continuum of health care, particularly for older patients who are highly vulnerable to medical and nonmedical complications following discharge. Patients frequently face challenges such as limited understanding of their diagnosis, symptoms, and treatment plans. They also experience uncertainty in adapting to their new situation and often lack adequate support for daily activities and mental health [1-4]. Adverse events following hospital discharge remain challenging in primary care management [5-7]. Most of them have been identified as preventable or reducible through appropriate discharge strategies, which are also associated with a reduced need for subsequent acute care services [3,4,8].

Transitions of care between health care institutions have become a central focus of efforts to enhance patient safety and continuity in care [9,10]. Although definitions vary, patient care transition is generally understood as a multidimensional process involving the handover of care between hospitals, home settings, and primary care providers. It addresses both medical and nonmedical needs of patients and their families through appropriate transitional interventions [10]. Recent research has reported positive impacts of transitional interventions, including timely telephone follow-ups [11,12]. Telephone follow-up is considered an effective modality for reinforcing health information, providing education and guidance, managing symptoms, and identifying complications early. It also offers reassurance, improves adherence, and supports both the physical and emotional well-being of patients [13,14]. However, the type and intensity of required transitional interventions depend on patient disabilities, therapeutic requirements, and specific social and geographical contexts [10].

Telemedicine, encompassing a range of electronic information and communication technologies such as voice calls, videoconferencing, messaging platforms, and other digital tools, enables the remote delivery of health care services [15-17]. It offers substantial advantages by facilitating access to care, supporting remote diagnostic and therapeutic interventions, and potentially reducing time and financial burdens for all parties involved [17,18]. In the context of growing resource constraints in health care systems, demand for telemedicine has increased [18], a trend further accelerated globally by the COVID-19 pandemic [19]. Telemedicine has since remained widely used and is increasingly recognized as a safe and effective alternative to traditional in-person care [20-22]. Patient acceptance has generally been positive [21,22], with documented benefits for emotional well-being, physical activity, and quality of life [23]. Nevertheless, research emphasizes that the effectiveness of telemedicine varies according to medical, social, and geographical determinants. A comprehensive understanding of these factors is essential to ensure equitable access to telemedical services, high user satisfaction, and safe, individualized interventions [24].

Objectives

Telemedicine has shown benefits across various settings, including transitions between health care institutions, and is generally associated with high patient satisfaction. However, research on telemedicine-based interventions that specifically support the transition from hospital to primary care, considering patient and provider acceptance, remains limited. To address this gap, we implemented and evaluated a telephone follow-up program, focusing on patient health as well as patient and health care provider satisfaction during the transition from hospital to home and primary care. The study was conducted within the framework of the Innosuisse Flagship Project SHIFT (Smart Hospital: Integrated Framework, Tools, and Solutions).

Methods

Study Design

This investigator-initiated, prospective, single-center clinical intervention study was conducted at the University Hospital Basel (USB), Switzerland, between September 2022 and December 2024.

Participants and Recruitment Procedure

Patients were screened for eligibility using predefined inclusion and exclusion criteria applied to electronic medical records in the hospital information system. Patients were eligible if they met all of the inclusion criteria and were excluded if they met any of the exclusion criteria (Textbox 1).

If all eligibility criteria were met, the responsible hospital physician assessed suitability for telemedical follow-up. Subsequently, the patient's general practitioner (GP) was contacted to ensure collaboration in primary care. Written informed consent was obtained from all participants prior to enrollment.

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Textbox 1. Inclusion and exclusion criteria.

Inclusion criteria

- Adults (18 years and older)
- Hospitalization in the emergency unit or internal medicine ward with a planned discharge within 2 days
- Ability to communicate via telephone and email
- Absence of significant cognitive, psychiatric, or language-related barriers
- Coverage by Swiss Health insurance
- Clinical need for short-term follow-up care suitable for telemedical management

Exclusion criteria

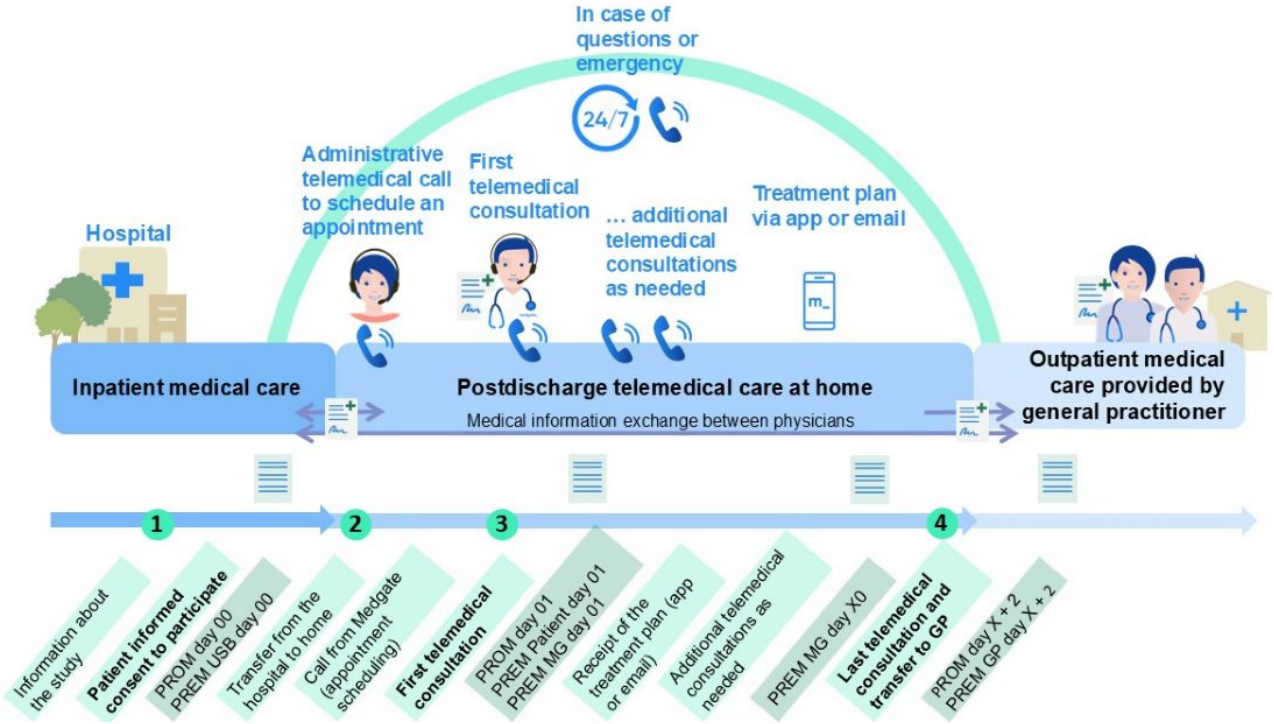
- Requirement for in-person follow-up (eg, diagnostic or therapeutic procedures necessitating direct contact)
- Planned transfer to another hospital for further diagnostic or therapeutic interventions
- Indication for inpatient rehabilitation

Intervention: Telemedical Follow-Up Program

The telemedical follow-up program was delivered by Medgate, a telemedical care provider offering 24/7 physician consultations via telephone and video [25]. On the day of hospital discharge, the telemedical team received a standardized, Health Insurance Network–secured email that included (1) patient identifiers, (2) discharge information (date and location), (3) procedures defined by discharging physician, (4) insurance data, (5) patients contact details (telephone number and email address), (6) GP information (address, telephone number, and email address), (7) most recent laboratory results, and (8) provisional discharge letter.

Patients were contacted by telephone the same day by administrative staff to schedule the first teleconsultation with a telemedical physician (TP) within 24 hours of discharge. Subsequent follow-up telephone calls were scheduled according to the patient's individual health status and needs. Per protocol, the program was limited to a maximum of 10 days. At that point, care was formally handed over to the patient's GP or another primary care provider if no GP was available (Figure 1). In the event of adverse outcomes during follow-up (eg, health deterioration and failed contact attempts), the TP assessed the need for rehospitalization. If repeated contact attempts were unsuccessful, the sponsor-investigator was notified and assumed responsibility for further safety measures, including contacting the patient directly and informing the GP if required.

Figure 1. Overview of the telemedical follow-up program, illustrating key contact points and corresponding time points for questionnaire-based data collection. GP: general practitioner; MG: medication guidance; guidance; PREM: patient-reported experience measure; PROM: patient-reported outcome measure.



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Data Collection Procedure and Baseline

Patient characteristics, including demographics and medical history, were extracted from electronic medical records of the hospital information system and supplemented by personal interviews, with final documentation in a case report form. Collected data included year of birth, age, sex, height, weight, contact details, GP information, medical history, living and family situation, and the outcome-based nursing assessment for acute care (ePA-AC). The ePA-AC is a daily assessment tool used at the USB that supports the nursing process and classifies activities of daily living. Its numeric outcome, the Self-Care Performance Index (SPI), is derived from 10 ePA-AC questions and reflects the patient's level of independence in domains such as mobility, dressing, and information processing. Each item is rated on a 4-point scale, producing an SPI score ranging from 0 to 40, with lower values indicating greater care needs [26]. Patients were screened daily by internal ward nurses. Diagnosis clusters were defined by the principal diagnosis most accurately describing the reason for hospitalization.

Patient Health, Patient Satisfaction, and Health Care Provider Satisfaction

Patient health, patient satisfaction, and health care provider satisfaction were assessed using structured questionnaires, including patient-reported outcome measures (PROMs) and patient-reported experience measures (PREMs). These questionnaires were emailed to patients and health care providers at predefined time points during the transition process (Table S1 in Multimedia Appendix 1; Table S2 in Multimedia Appendix 2; Multimedia Appendix 3).

PROM surveys were used to assess health-related quality of life. Patient health was assessed with the EQ-5D-5L (EuroQol Group), a generic tool for evaluating health-related quality of life [27]. It consists of 5 items: mobility, self-care, daily activities, pain or discomfort, and anxiety or depression, each rated on a 5-point Likert scale (1=no problems, 5=extreme problems). In addition, overall health was assessed on a scale ranging from 0 (worst health) to 100 (best health), which was normalized to the 5-point scale for consistent analysis. Lower composite scores indicated better patient-reported health.

Patient and health care provider satisfaction was assessed as composite scores based on 5 items: safety, convenience, trust, empowerment, and overall satisfaction. Each item was evaluated through one or more questions, with responses rated on a 7-point Likert scale (1=lowest, 7=highest acceptance). Higher scores reflected greater acceptance of the intervention. As there was no control group, PREMs also included relative questions to capture hypothetical comparative perspectives. Full details of items, response scales, and corresponding questions are provided in Table S1 in Multimedia Appendix 1 and Table S2 in Multimedia Appendix 2.

Additional Metrics

Discharge rates, readmission rates, and reasons for readmission were obtained from hospital records and the telemedicine provider's information system.

Study Outcomes

The primary outcome was patient health and satisfaction during the transition from hospital discharge to home and the first primary care appointment under the structured telephone-based follow-up program. The secondary outcome was health care provider satisfaction, including hospital physicians, TP, and GP. The primary end points were based on the hypothesis that patient health and satisfaction would be considered favorable if they remained stable or improved during the transition process. The secondary end point was based on the hypothesis that health care provider satisfaction would be considered favorable if it remains stable or improves during the transition process, and on whether satisfaction levels differed across health care provider groups.

Statistical Analysis

Descriptive statistics were used to summarize patient characteristics, reported as frequencies for categorical variables and mean (SD) for continuous variables. Normality of continuous variables was assessed using Q-Q plots. For PROM and PREM scores, descriptive statistics included the mean (SD). If multiple questions formed a single item, the mean item score was calculated and used in the analysis.

Analytical statistics were applied as follows:

- Within-patient changes over time: the paired *t* test were used to assess changes in PROM and PREM scores across time points.
- Between-group comparisons: unpaired *t* tests were used to compare PREM scores across hospital physicians, TPs, and GPs.

The threshold for statistical significance was set at P=.05. Effect sizes were reported with 95% CIs. All statistical analyses were performed in RStudio (version 2024.12.1; Posit Software, PBC).

Ethical Considerations

This study is registered at ClinicalTrials.gov (NCT05617560), which is also listed in the World Health Organization (WHO) International Clinical Trials Registry Platform and the Swiss National Clinical Trial Portal. Ethical approval was obtained by the Ethics Committee Northwest and Central Switzerland (BASEC 2022 - 01440). The study was conducted in accordance with the Declaration of Helsinki, the European Medical Device Regulation (EU 2017/745), ISO (International Organization for Standardization) 14155, ISO 14971, ICH-GCP, as well as the Swiss Human Research Act. Prior to enrollment, all participants received information about the study procedures and provided written informed consent. Participants could withdraw at any time without consequence. All personal identifiers were removed prior to data analysis, and all data were handled in accordance with applicable privacy and confidentiality regulations. There was no financial reward or compensation given to the participants.

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Results

Baseline Characteristics

Between September 2022 and December 2024, we screened a total of 9162 patients at the USB. Of these, 4225 (46.1%) were female and 4918 (53.7%) were male; sex data were missing for 19 (0.2%). Most screenings occurred on internal medicine wards (7290/9162, 79.6%), followed by the emergency unit (1714/9162, 18.7%); 158 cases (1.7%) lacked ward assignment. The mean age was 68.3 (SD 17.4) years; age data were missing in 26 (0.3%) cases. Of all screened patients, 8907 out of 9162 (97.2%) were deemed ineligible, most frequently due to planned physical follow-up (1405/8907, 15.8%), planned rehabilitation (1381/8907, 15.5%), language barriers (1105/8907, 12.4%), or mental disorders (941/8907, 10.6%).

We enrolled a total of 255 out of 9162 (2.8%) patients, of whom 111 out of 255 (43.5%) were female and 144 out of 255 (56.5%) were male. Most were recruited from internal medicine wards (201/255, 78.8%) and the remainder from the emergency unit (54/255, 21.2%). The mean age was 65 (SD 17.6) years. After enrollment, 21 out of 255 (8.2%) patients were excluded prior to first telemedical contact at all due to newly identified exclusion criteria and classified as screening failures.

Consequently, we included 234 patients in the final analysis (101/234, 43.2% female; 133/234, 56.8% male); mean age was 64.8 (SD 17.5) years. Among these patients, 25 out of 234 (10.7%) reported not having a GP, 70 out of 234 (29.9%) lived alone, and 162 out of 234 (69.2%) either with a partner, family, or friends; data were missing for 2 out of 234 (0.9%) patients. Per-protocol completion was achieved by 146 out of 234 (62.4%) patients. A total of 88 out of 234 (37.6%) patients discontinued early due to withdrawal of consent (51/234, 21.8%), telephone unavailability for >24 (27/234, 11.5%) hours, or rehospitalization (10/234, 4.3%; Figure 2; Table 1).

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Figure 2. CONSORT (Consolidated Standards of Reporting Trials) flow diagram illustrating the screening and recruitment procedure, including the absolute number of participants at each stage (n) and reasons for exclusion expressed in absolute numbers (n). GP: general practitioner.

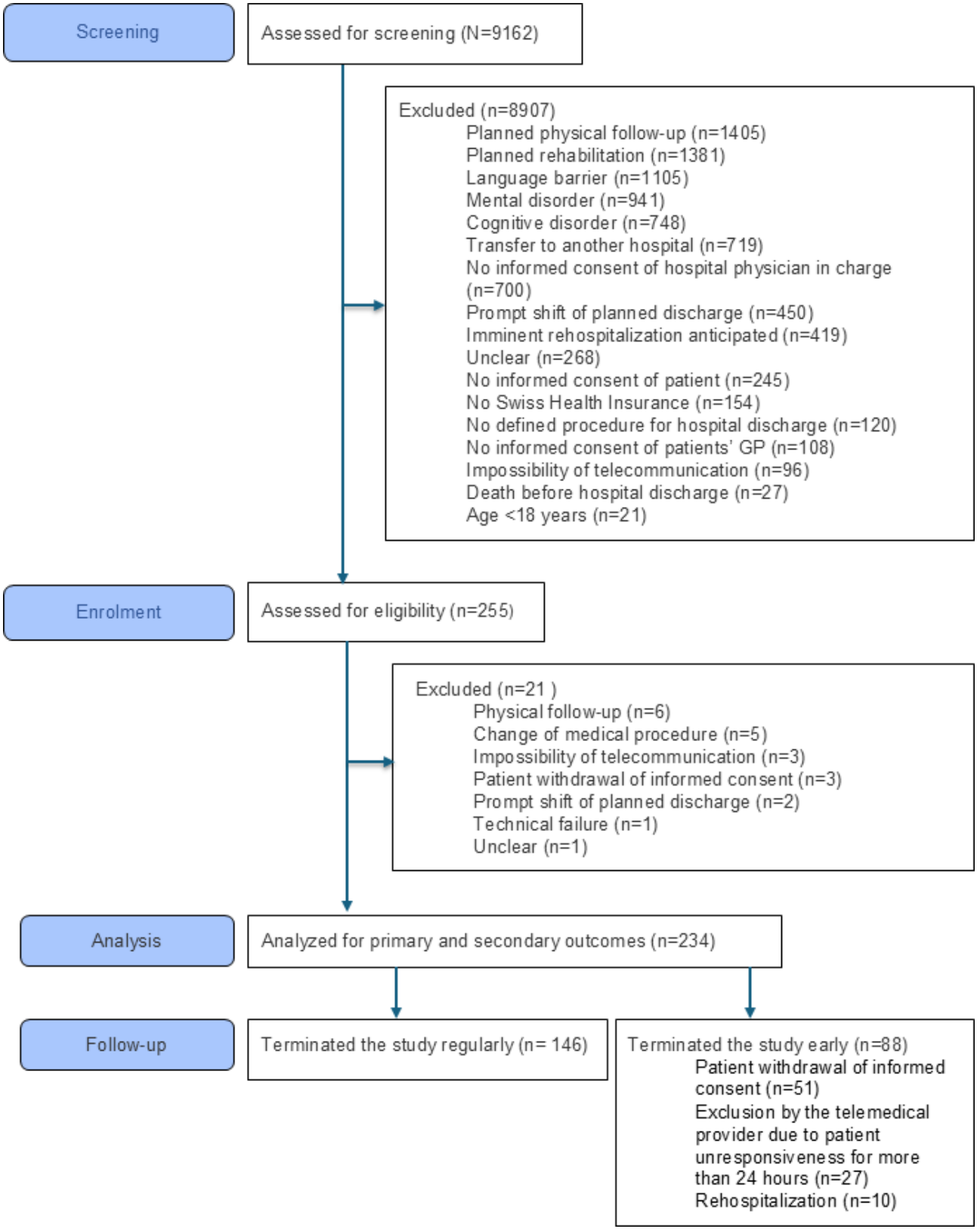

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Table . Baseline characteristics of all participants (N=234), including completers and early dropouts.

Characteristics	Regular termination	Early termination			Total
		Patient incompliance	Patient withdrawal	Rehospitalization	
Participants, N	146	27	51	10	234
Age (years), mean (SD)	63.9 (17)	61.6 (18.9)	70.5 (16.2)	56.5 (22)	64.8 (17.5)
Sex, n (%)					
Female	69 (47.3)	11 (40.7)	16 (31.4)	5 (50)	101 (43.2)
Male	77 (52.7)	16 (59.3)	35 (68.6)	5 (50)	133 (56.8)
Hospital stay, n (%)					
Emergency unit	27 (18.5)	8 (29.6)	11 (21.6)	3 (30.0)	49 (20.9)
Internal medicine ward	119 (81.5)	19 (70.4)	40 (78.4)	7 (70.0)	185 (79.1)
General practitioner, n (%)					
Yes	132 (90.4)	21 (77.8)	46 (90.2)	9 (90.0)	208 (88.9)
No	13 (8.9)	6 (22.2)	5 (9.8)	1 (10.0)	25 (10.7)
Missing data	1 (0.7)	—[a]	—	—	1 (0.4)
Primary diagnosis, n (%)					
Allergological	1 (0.7)	0 (0)	0 (0)	0 (0)	1 (0.4)
Angiological	1 (0.7)	0 (0)	0 (0)	0 (0)	1 (0.4)
Dermatological	1 (0.7)	0 (0)	0 (0)	0 (0)	1 (0.4)
Endocrinological	2 (1.4)	1 (3.7)	1 (2.0)	1 (10.0)	5 (2.1)
Gastroenterological	12 (8.2)	1 (3.7)	2 (4.0)	0 (0)	15 (6.4)
Hematological	0 (0)	0 (0)	2 (4.0)	0 (0)	2 (0.9)
ENT[b]	3 (2.1)	0 (0)	1 (2.0)	0 (0)	4 (1.7)
Infectious	14 (9.6)	3 (11.1)	9 (17.6)	1 (10.0)	27 (11.5)
Cardiological	36 (24.7)	8 (29.6)	10 (19.6)	2 (20.0)	56 (23.9)
Nephrological	1 (0.7)	0 (0)	0 (0)	1 (10.0)	2 (0.9)
Neurological	11 (7.5)	1 (3.7)	5 (9.8)	0 (0)	17 (7.3)
Pulmonary	29 (19.9)	3 (11.1)	6 (11.8)	3 (30.0)	41 (17.5)
Rheumatological	4 (2.7)	0 (0)	0 (0)	0 (0)	4 (1.7)
Accident	10 (6.8)	1 (3.7)	5 (9.8)	0 (0)	16 (6.8)
Urological	2 (1.4)	0 (0)	3 (5.9)	1 (10.0)	6 (2.6)
No confirmed primary diagnosis	19 (13.0)	9 (33.3)	7 (13.7)	1 (10.0)	36 (15.4)
Living situation, n (%)					
Alone	42 (28.8)	8 (29.6)	19 (37.3)	1 (10.0)	70 (29.9)
Family members or friends	102 (69.9)	19 (70.4)	32 (62.7)	9 (90.0)	162 (69.2)
Missing data	2 (1.4)	—	—	—	2 (1.0)
Family situation, n (%)					
Divorced	11 (7.5)	3 (11.1)	3 (5.9)	1 (10.0)	18 (7.7)
Married	84 (57.5)	15 (55.6)	30 (58.8)	7 (70.0)	136 (58.1)
Separated	6 (4.1)	0 (0)	1 (2.0)	0 (0)	7 (3.0)
Single	30 (20.5)	6 (22.2)	14 (27.5)	2 (20.0)	52 (22.2)

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Characteristics	Regular termination	Early termination			Total
		Patient incompliance	Patient withdrawal	Rehospitalization	
Widowed	14 (9.6)	2 (7.4)	3 (5.9)	0 (0)	19 (8.1)
Missing data	1 (0.7)	1 (3.7)	—	—	2 (0.9)
SPI[c] and ePA-AC[d,e]					
Count, n (%)	117/146 (80.1)	19/27 (70.4)	40/51 (78.4)	7/10 (70.0)	183/234 (78.2)
SPI score, mean (SD)	38.6 (3.1)	39.1 (1.8)	38.7 (2.4)	38.6 (2.1)	38.7 (2.8)
ePA-AC, mean (SD)					
Upper body undressing and dressing	3.9 (0.4)	3.9 (0.2)	3.9 (0.3)	3.7 (0.5)	3.9 (0.4)
Lower body undressing/and dressing	3.8 (0.5)	3.9 (0.2)	3.8 (0.5)	3.7 (0.5)	3.8 (0.5)
Locomotion	3.8 (0.5)	3.8 (0.4)	3.7 (0.6)	3.9 (0.4)	3.8 (0.5)
Upper body care	3.9 (0.4)	3.9 (0.2)	3.8 (0.4)	3.7 (0.5)	3.9 (0.4)
Lower body care	3.7 (0.6)	3.8 (0.4)	3.7 (0.6)	3.7 (0.5)	3.7 (0.6)
Eating	4 (0.2)	3.9 (0.2)	4 (0.2)	3.9 (0.4)	4 (0.2)
Drinking	4 (0.3)	4 (0)	4 (0.2)	4 (0)	4 (0.3)
Stool excretion	3.9 (0.3)	3.8 (0.7)	4 (0.2)	4 (0)	3.9 (0.4)
Urine excretion	3.9 (0.4)	3.8 (0.7)	4 (0.2)	4 (0)	3.9 (0.4)
Change in body position	3.9 (0.4)	3.9 (0.2)	4 (0.2)	4 (0)	3.9 (0.3)

[a]Not available.

[b]ENT: ear, nose, and throat.

[c]SPI: Self-Care Performance Index.

[d]ePA-AC: the outcome-based nursing assessment for acute care.

[e]SPI score (0-40) from the ePA-AC (10 questions, 0-4) assesses care needs, with lower scores indicating greater dependency.

Patient-Reported Health Outcomes

Response rates for PROMs were 137 out of 234 (58.5%) at baseline (day 00), 120 out of 234 (51.3%) after the first teleconsultation (day 01), and 105 out of 234 (44.9%) after the last teleconsultation (day X+2; Figure 3).

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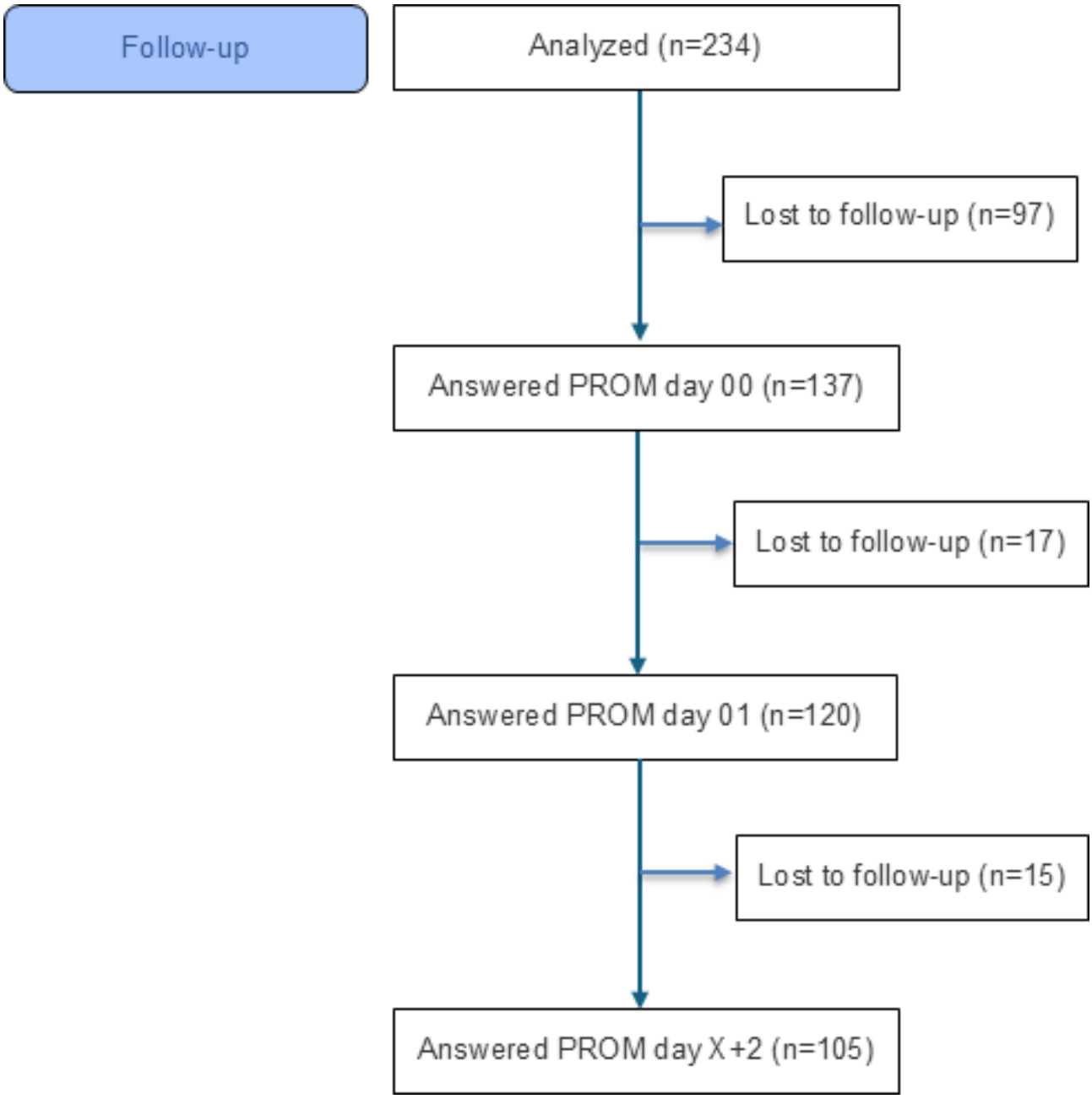
Figure 3. CONSORT (Consolidated Standards of Reporting Trials) flow diagram illustrating the patient-reported outcome measure follow-up, including the absolute number of participants at each stage who completed the questionnaires and those who were lost to follow-up (n). PROM: patient-reported outcome measure.



Changes in Composite Scores

Composite health scores (mobility, self-care, daily activities, pain or discomfort, anxiety or depression, and overall health; Likert 1 - 5) improved significantly from baseline to final follow-up (mean difference –0.227, SD 0.334; t_{93}=−6.60; P<.001; 95% CI −0.296 to −0.159), from day 00 to day 01 (mean difference −0.137, SD 0.375; t_{104}=–3.75; P<.001; 95% CI −0.210 to -0.064) and from day 01 to day X+2 (mean difference −0.101, SD 0.357; t_{94}=–2.77; P=.007; 95% CI −0.174 to -0.029). Patient-reported health did not deteriorate at any time (Table 2; Figure 4).

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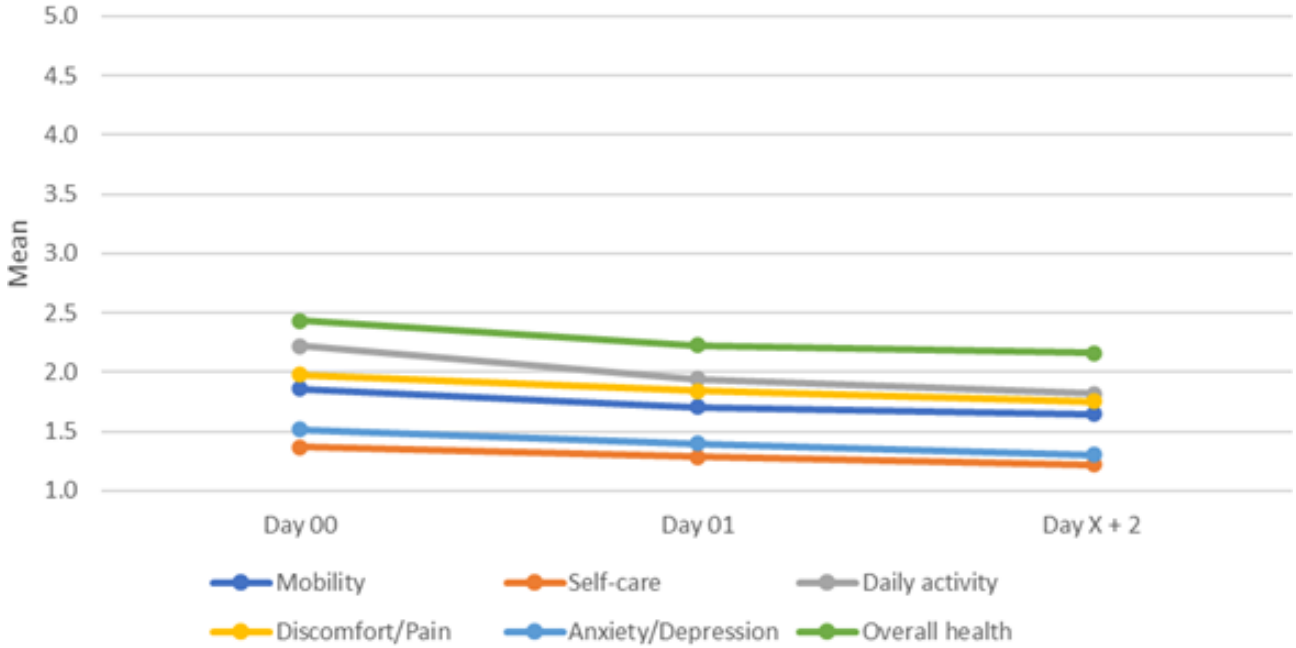
Table . Patient-reported health outcomes[a], including 6 items and the composite, are presented as mean (SD).

Items	Day 00, mean (SD)	Day 01, mean (SD)	Day X + 2, mean (SD)
Mobility	1.9 (0.9)	1.7 (0.8)	1.6 (0.8)
Self-care	1.4 (0.8)	1.3 (0.7)	1.2 (0.6)
Daily activity	2.2 (1.1)	1.9 (1)	1.8 (0.9)
Discomfort or pain	2.0 (1)	1.8 (0.9)	1.8 (0.8)
Anxiety or depression	1.5 (0.8)	1.4 (0.7)	1.3 (0.7)
Overall health[b]	2.4 (0.8)	2.2 (0.8)	2.2 (0.8)
Total	1.9 (0.7)	1.7 (0.6)	1.6 (0.6)

[a]Patient health outcomes were assessed using patient-reported outcome measure questionnaires with a 5-point Likert scale (1=best, 5=worst) at day 00, day 01, and day X + 2.

[b]Overall health scores, originally normed on a 0-100 scale, were rescaled to a 5-point scale for comparability.

Figure 4. Line chart showing mean patient-reported health scores over time across 6 items.



Patient-Reported Satisfaction Outcomes

PREM response rates were 128 out of 234 (54.7%) at day 00, 116 out of 234 (49.6%) at day 01, and 101 out of 234 (43.2%) at day X+2 (Figure 5).

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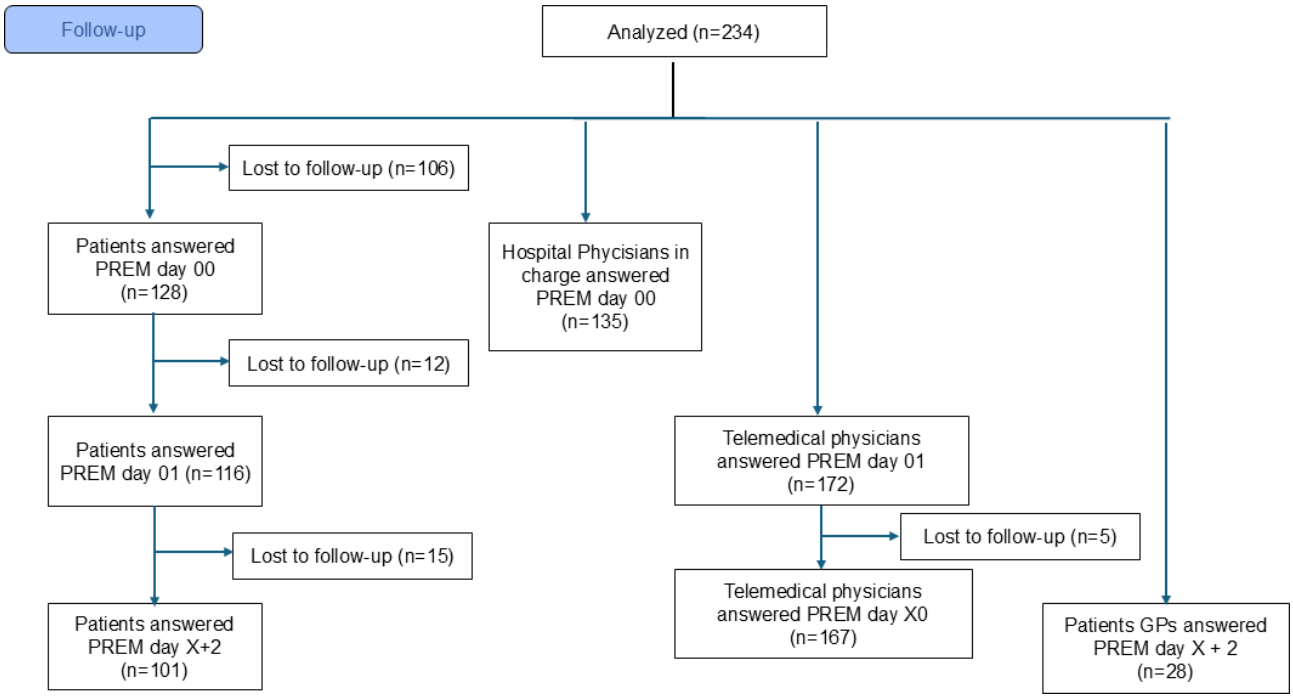
Figure 5. CONSORT (Consolidated Standards of Reporting Trials) flow diagram illustrating the patient-reported experience measure follow-up, including the absolute number of participants at each stage who completed the questionnaires and those who were lost to follow-up (n). GP: general practitioner; PREM: patient-reported experience measure.



Changes in Composite Scores

Composite satisfaction scores (safety, convenience, trust, empowerment, and overall satisfaction; Likert 1 - 7) improved significantly between day 00 and day 01 (mean difference 0.443. SD 1.058; t_{95}=4.10; P<.001; 95% CI 0.228 - 0.657), from day 00 to day X+2 (mean difference 0.714. SD 1.031; t_{87}=6.50; P<.001; 95% CI 0.496 - 0.933) and between day 01 and day X+2 (mean difference 0.176, SD 0.606; t_{92}=2.80; P=.006; 95% CI 0.051-0.300). Patient-reported satisfaction did not deteriorate at any time (Table 3; Figure 6).

Table . Patient- and stakeholder-reported satisfaction[a] outcomes, including 5 items and the composite, are presented as mean (SD).

Items	Day 00. mean (SD)		Day 01, mean (SD)		Day X0, mean (SD)	Day X + 2, mean (SD)	
	Patient	Hospital	Patient	TP[b]	TP	Patient	GP[c]
Safety	5.2 (1.6)	5.7 (1.1)	5.7 (1.2)	5.8 (1.6)	5.7 (1.7)	6 (1.2)	4.6 (2.1)
Convenience	4.7 (1.3)	5.5 (1)	5.7 (1)	5.8 (1.2)	5.8 (1.3)	5.9 (0.9)	3.8 (1.6)
Trust	4.5 (2.1)	3.9 (1.8)	5.8 (1.1)	5.9 (1.5)	5.7 (1.7)	6.1 (1.1)	3.5 (1.8)
Empowerment	4.8 (1.8)	4.8 (1.4)	5.3 (1.8)	6.1 (1.2)	6 (1.4)	5.4 (1.8)	3.8 (1.8)
Overall satisfaction	5.6 (1.5)	5.5 (1.1)	6 (1.3)	6.3 (1)	6.2 (1)	6.1 (1.3)	3.8 (1.7)
Total	5 (1.4)	5.1 (1)	5.7 (1.1)	6 (1)	5.9 (1.1)	5.9 (1.1)	3.9 (1.6)

[a]Patient and health care provider satisfaction outcomes were assessed using patient-reported experience measure questionnaires with 7-point Likert scale (1=lowest, 7=highest).

[b]TP: telemedical physician.

[c]GP: general practitioner.

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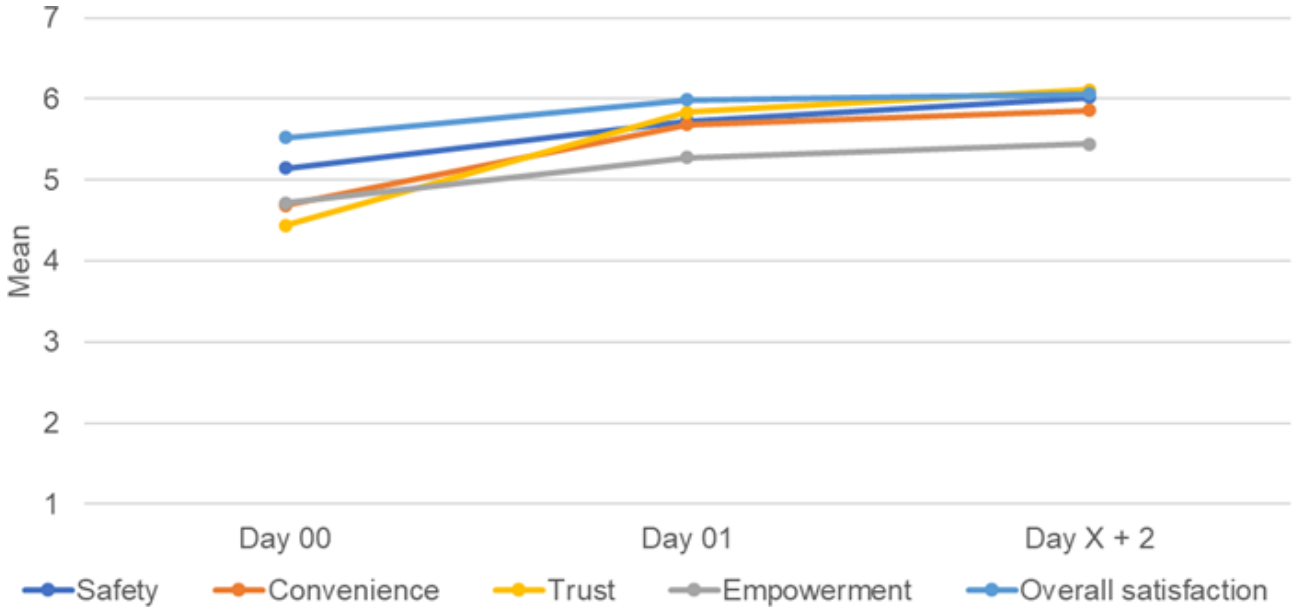
Figure 6. Line chart showing mean patient-reported satisfaction scores over time across 5 items.



Detailed Insights

We classified patient-rated satisfaction as positive if scored ≥5. At baseline, 69.5% (89/128) reported feeling medically safe, increasing to 85.3% (99/116) after the first consultation and 90.1% (91/101) at follow-up. Similarly, the transfer process was rated as easy by 71.9% (92/128) at baseline, 86.2% (100/116) at day 01, and 87.1% (88/101) at follow-up. Telemedical monitoring was perceived as facilitating the transition by 86.2% (100/116) at day 01 and 85.1% (86/101) at follow-up, while feeling well looked after was reported by 85.3% (99/116) and 90.1% (91/101), respectively. Perceived independence in daily life improved from 59.4% (76/128) at baseline to 75.9% (88/116) at day 01 and 78.2% (79/101) at follow-up. Overall satisfaction followed a similar pattern, increasing from 76.6% (98/128) at baseline to 88.8% (103/116) at day 01 and 91.1% (92/101) at follow-up (Table S1 in Multimedia Appendix 1).

Health Care Provider–Reported Satisfaction Outcomes

Response Rates

Health care providers (hospital physicians, TPs, and GPs) returned 135 out of 234 (57.7%), 172 out of 234 (73.5%), 167 out of 234 (71.4%), and 28 out of 234 (13.5%) questionnaires at predefined time points (Figure 5).

Between-Group Changes in Composite Scores

Composite satisfaction scores differed significantly between groups: higher for hospital physicians (mean 5.081, SD 0.978) than GPs (mean 3.886, SD 1.613; $t_{31.24}$=3.78; P<.001; 95% CI 0.551 - 1.841), higher for TP (mean 5.919, SD 0.831) than hospital physicians (mean 5.081, SD 0.978; $t_{262.8}$=7.95; P<.001; 95% CI 0.630 - 1.045), and higher for TPs (mean 5.919, SD 0.831) than GPs (mean 3.886, SD 1.613; $t_{29.38}$=6.53; P<.001; 95% CI 1.397 - 2.667; Table 3; Figure 7).

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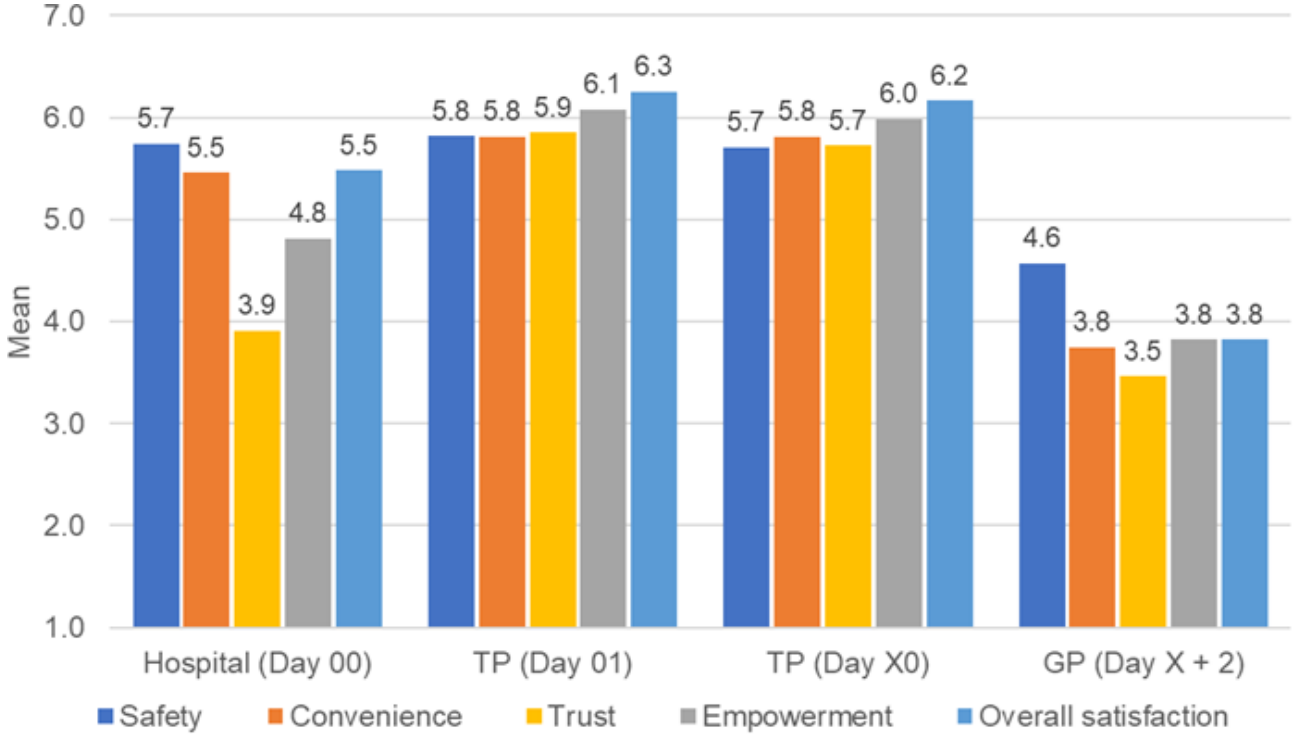
Figure 7. Column chart showing mean health care provider–reported satisfaction scores across 5 items.



GP Satisfaction: Detailed Insights

We classified ratings as negative if scored ≤3. Among 28 GPs, 7 (25%) rated the transfer process as difficult, and 9 (32.1%) reported incomplete patient information at the required time. More than half (15/28, 53.6%) perceived less to no added value for themselves or their patients compared with usual discharge. Nearly half (13/28, 46.4%) reported insufficient communication and were unlikely to recommend telemedical support. Perceived patient independence and overall satisfaction were low (10/28, 35.7%; Table S2 in Multimedia Appendix 2).

Discussion

Principal Findings

We implemented and evaluated a telephone-based follow-up program to support patient health and satisfaction as well as health care provider satisfaction during the transition from hospital discharge to home and the first primary care appointment.

Of 9162 screened patients, 255 (2.8%) were enrolled, and 234 (2.6%) were included in the final analysis. Per-protocol completion was achieved by 146 out of 234 (62.4%) patients, whereas 88 out of 234 (37.6%) patients discontinued early due to withdrawal of consent, telephone unavailability for >24 hours, or rehospitalization (Table 1; Figure 2). Patient-reported health and satisfaction changed during follow-up, while no deterioration was observed (Tables 2 and 3; Figures 4 and 6). Health care provider satisfaction differed across groups, with TPs reporting the highest and GPs the lowest levels, citing challenges in information transfer and perceived added value (Table 3; Figure 7).

Comparison With Previous Work: Differences From Standard Follow-Up Care

In standard care, patients typically attend an in-person primary care follow-up after discharge, with waiting times depending on GP workload but ideally within 10 days, as reported by Riverin et al [28]. In contrast, participants in our study were proactively contacted by telephone to schedule their first teleconsultation within 24 hours of discharge. This approach standardized the transition, eliminating the need for patients to arrange care or travel. Additionally, patients had 24/7 access to the telemedical provider for immediate medical support.

The telemedical follow-up program was not designed to accelerate hospital discharge but to bridge the vulnerable postdischarge period until the first GP visit [1-4,8]. It aimed to reduce the workload of GPs and their covering physicians by remotely managing suitable patients and helping to prevent unplanned primary care visits, as follow-up needs after discharge are often urgent. Hospital physicians largely supported this intention, although their PREM ratings also reflected some indecision about the value of telemedicine for discharge planning. Conversely, GPs reported lower perceived benefit for practice management (Table S2 in Multimedia Appendix 2), consistent with the lower composite satisfaction scores among GPs (Table 3; Figure 7). However, given the small GP sample (28 participants), these differences may be unstable and should be interpreted with caution. Although cost analysis was not the primary objective of this study, the program incurred higher expenditures due to the complex recruitment procedures inherent to clinical trial settings. Nevertheless, it is anticipated to be cost-neutral—or potentially cost-saving—under routine care conditions by alleviating GPs' workload without increasing consultation frequency. Given the limited evidence on telemedicine facilitating transitions from hospital to primary

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care, further research is warranted to comprehensively evaluate its economic implications.

Feasibility of the Intervention

Feasibility was constrained by a low inclusion rate of 2.8%, largely due to the study design. All patients hospitalized in the emergency unit and internal medicine wards were screened, with many excluded because of strict eligibility criteria. Among these, nearly half (4374/8907, 49.2%) required some form of physical treatment, including planned physical follow-up, planned rehabilitation, transfer to another hospital, prompt changes in discharge plans, or anticipated imminent rehospitalization (Figure 1). The acute care profile of the USB, which treats a disproportionately high number of patients with complex medical conditions, contributed indirectly to the low inclusion rate, as many of these patients could not be discharged directly home.

Recruitment was further hindered by procedural barriers. The responsible hospital physician first had to confirm eligibility, followed by obtaining consent from the patient's GP. Delays in these steps occasionally rendered patients ineligible due to changes in their medical plans. Finally, informed consent had to be obtained from the patient.

Despite these challenges, 62.4% of included patients adhered to the program per protocol, demonstrating feasibility for selected patient groups. Based on our findings, the intervention appears most suitable for patients who (1) are aged 18 years or older; (2) have cardiological, pulmonary, or infectious diseases; (3) are able to communicate via telephone and email; (4) possess adequate language proficiency and cognitive or mental capacity; and (5) have a discharge plan appropriate for remote follow-up, including no planned physician follow-up appointments, no planned rehabilitation stays, no transfers to another hospital, no imminent rehospitalization is anticipated, and no need for tests that must be conducted in a health care institution (laboratory testing, ECG, etc).

Early Discontinuation: Nonresponsiveness

Failure to establish contact within 24 hours after discharge led to exclusion per protocol. During follow-up, 27/234 (11.5%) patients could not be reached (Figure 2). This represented an uncomfortable situation for TPs who were unable to determine the underlying cause. Technical or personal factors were most implicated, as identified through proactive outreach by the study team; however, medical emergencies cannot be ruled out.

This finding highlights the potential added value of integrating wearable sensors (eg, vital signs) in the early postdischarge period. They provide complementary information beyond the importance of physiological data to patients and health care providers. Future research should investigate the determinants of patient unreachability and, more broadly, the reasons for withdrawal. This could help improve telemedical follow-up program design and enhance patient acceptance, as also emphasized by Bjarnadóttir et al [24].

Early Discontinuation: Rehospitalization

Rehospitalization occurred in 10 out of 234 (4.3%) patients in this study, higher than the rate observed among contemporaneously discharged patients from the USB without telemedical follow-up (2.8%). While this finding may suggest potential limitations of the intervention, it may also reflect improved early detection of clinical worsening due to 24/7 accessibility to telemedicine. Rehospitalizations in this study were often initiated to rule out acute medical emergencies following the onset or worsening of symptoms, ensuring patient safety. This aligns with previous research demonstrating a higher demand for acute health care services among patients with acute conditions receiving telemedical follow-up. In contrast, readmission rates tend to be lower among patients with chronic diseases [29-31]. Notably, 17.5% (41/234) of patients in this study were diagnosed with pulmonary diseases (Table 1), and respiratory symptoms were the main cause of rehospitalization in 40% of cases, mirroring trends observed in prior studies [31].

In contrast, inherent limitations of remote care, such as reduced diagnostic capability as well as communication and technical challenges, may also have led to diagnostic uncertainty and influenced rehospitalization decisions. These factors are consistent with findings from Shah et al [32], who reported similar challenges in their evaluation of telehealth interventions.

Furthermore, unlike the rehospitalization rate reported by the USB, which includes only readmissions to its own facility within 18 days after hospital discharge, our study also captured rehospitalizations to external hospitals. This broader inclusion criterion may have contributed to the higher observed rate.

Impact on Patient Health and Satisfaction

Changes were observed in patient-reported health and satisfaction during the follow-up period, with no deterioration noted (Tables 2 and 3; Figures 4 and 6). These findings are consistent with previous reports of high patient satisfaction with telehealth [33,34].

However, the observed changes may also have been influenced by contextual factors beyond the telemedicine-based intervention itself (Table 1). Natural recovery after discharge, coupled with the fact that most participants were married or lived with family members who could support their self-care, potentially contributed to higher patient-reported health scores. Additionally, the mean SPI score was 38.7 (SD 2.8), indicating relatively high baseline functional status (Table 1). Nevertheless, evidence from recent studies suggests that patients with lower functional capacity may also benefit from telemedical follow-up [35].

Impact on Health Care Provider Satisfaction

Health care provider satisfaction differed across groups (Table 3; Figure 7). Although GP consent was obtained to support collaboration, they reported lower satisfaction levels, which may reflect limited familiarity with telemedicine or concerns regarding coordination and responsibility. In contrast, TPs who were more experienced with telemedicine workflows reported higher satisfaction levels. It should be noted that the GP sample was small (28 participants), and the observed differences may be unstable. These results should therefore be interpreted with caution. Overall, the findings indicate variability in provider experiences and highlight the need for further research to better understand factors influencing satisfaction across professional

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groups. Strengthening engagement, improving interoperability between hospital, telemedical, and primary care services, and addressing provider-specific concerns may help improve the acceptability and sustainability of telemedical follow-up programs.

Clinical and Digital Implications

This study on a telephone-based follow-up program demonstrates how structured postdischarge support can inform digital health policy and hospital discharge workflows. The program may serve as a model for a unified hospital follow-up system and standardized post discharge care management. It enables targeted resource use in hospitals and primary care by reducing unplanned visits and saving clinician time through structured, standardized processes. The intervention has the potential to reduce costs and improve patient safety during the vulnerable postdischarge period, while continuous support facilitates the transition to home and enhances patient recovery. Moreover, feasibility results provide a foundation for more complex digital interventions (eg, continuous vital sign monitoring) by identifying both benefits and challenges. Finally, findings on patient and health care provider satisfaction provide important insights for digital health policy, supporting the development of follow-up programs that meet the needs of all stakeholders. As noted by Chen et al [36], it is important to continually revise such models, as technology evolves rapidly, shaping individuals' expectations of the possibilities offered by telemedicine.

Limitations

This study has several limitations. First, the study was conducted at a single center without a comparison to usual care, which may limit the generalizability of the findings to other clinical settings and constrain conclusions about the intervention's effectiveness. Second, participants were recruited exclusively from the internal medicine wards and the emergency unit, which may restrict the applicability of the results to other patient populations. Third, despite a per-protocol completion rate of more than half, the low inclusion rate—driven by multiple exclusion criteria—and the very high functional status of enrolled patients resulted in a highly selective sample. Consequently, the intervention's generalizability and feasibility are limited, as it could not be delivered to the majority of discharged patients. Fourth, the technical infrastructure required for routine care is not yet fully established, which may affect the feasibility of integrating this telemedicine-based intervention into everyday clinical practice at present. Fifth, although the categories for early discontinuation were documented, a detailed exploration of the underlying causes was beyond the scope of this study. Sixth, given natural recovery after discharge and other concurrent care, improvements in PROMs and PREMs cannot be solely attributed to the telemedical program. Finally, the frequency distribution of scores in PROMs and PREMs should be interpreted with caution, as the loss to follow-up may have introduced response bias that could lead to an overestimation of favorable outcomes. Patients who were more favorable toward the study were likely to remain enrolled and complete the questionnaires, whereas those less engaged were more likely to discontinue participation and not complete them.

Conclusion

This study outlines both the potential benefits and the practical challenges of implementing a telephone follow-up program to support the transition from hospital to home and primary care. Variations in physician satisfaction underscore the need for a more user-friendly technical infrastructure and clearer role definitions across providers. Future research should be conducted in multicenter settings, involving a broader patient population and a control group receiving usual care. Moreover, efforts should be directed toward streamlining the recruitment process to enable the inclusion of a larger study population, thereby improving the feasibility and generalizability of the findings.

Acknowledgments

We would like to thank MSc Manfred Gram for his technical support and advice. The authors declare the use of generative artificial intelligence (AI) in the research and writing process. According to the GAIDeT taxonomy (2025), the following tasks were delegated to general AI tools under full human supervision: proofreading and editing. The generative AI tool used was ChatGPT-5. Responsibility for the final manuscript lies entirely with the authors. Generative AI tools are not listed as authors and do not bear responsibility for the final outcomes (declaration submitted by JSG).

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Data Availability

The datasets generated or analyzed during this study are available from the corresponding author on reasonable request.

Authors' Contributions

JG was contributing to data collection, cleaned, analyzed, and interpreted the data and finally wrote the manuscript. All authors read and approved the final manuscript.

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Conflicts of Interest

None declared.

Multimedia Appendix 1
Patient-reported satisfaction ratings (n, %) across 5 items (day 00: n=128, day 01: n=116, day X + 2: n=101).
[DOCX File, 21 KB - formative_v10i1e85467_app1.docx]

Multimedia Appendix 2
Health care provider-reported satisfaction ratings (n, %) for each question across 5 items (hospital physician: n=135, TP day 01: n=172, TP day X0: n=167, GP: n=28).
[DOCX File, 23 KB - formative_v10i1e85467_app2.docx]

Multimedia Appendix 3
Questionnaires.
[DOCX File, 30 KB - formative_v10i1e85467_app3.docx]

Checklist 1
CONSORT checklist.
[DOCX File, 33 KB - formative_v10i1e85467_app4.docx]

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Abbreviations

ePA-AC: outcome-based nursing assessment for acute care
GP: general practitioner
ISO: International Organization for Standardization
PREM: patient-reported experience measure
PROM: patient-reported outcome measure
SHIFT: Smart Hospital: Integrated Framework, Tools, and Solutions

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SPI: Self-Care Performance Index
TP: telemedical physician
USB: University Hospital of Basel
WHO: World Health Organization

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Implementation, Acceptability, and Actions After Using an AI Workplace Health Kiosk in a Low-Resource Public School Workplace Setting: Cross-Sectional Pilot Study

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Abstract

Background: Artificial intelligence (AI)–enabled digital health kiosks are increasingly used in workplaces and communities to promote health awareness, especially in low- and middle-income countries. However, evidence on their real-world use, user acceptability, and immediate behavioral responses remains limited, especially outside formal clinical care.

Objective: This study evaluated the implementation experience, user acceptability, and immediate self-reported actions associated with the use of an AI-enabled workplace health kiosk among public school teachers in an urban, low-resource setting in the Philippines.

Methods: We conducted a study involving 384 teachers who used an AI health kiosk during wellness activities. The kiosk provided informational health indicators. Postuse surveys assessed usability; trust; privacy concerns; and self-reported actions, such as health consultations and sharing results. Analyses were descriptive and exploratory. The study did not evaluate diagnostic accuracy, clinical validity, disease prevalence, or health outcomes.

Results: Most participants (162/189, 85.7%) rated the kiosk experience as good or excellent, and 93.1% (176/189) found it easy to use. Overall, trust in kiosk results was high, although 31.7% (60/189) of the participants expressed privacy concerns. After using the kiosk, 70.9% (134/189) of the participants consulted a health care professional, and 66.7% (126/189) made lifestyle changes. A small percentage (32/189, 16.9%) reported no follow-up actions, mainly due to uncertainty about the next steps. User feedback highlighted convenience and accessibility but also noted operational issues such as queuing and connectivity problems.

Conclusions: In this workplace setting, an AI health kiosk was feasible, acceptable, and linked to immediate self-reported health actions. Findings are preliminary and context specific. Formal validation, follow-up studies, and further evaluation are needed before use in diagnostic, population health, or policy contexts.

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KEYWORDS

AI enabled; artificial intelligence enabled; Philippines; workplace; teachers; pilot

Introduction

Noncommunicable diseases (NCDs) continue to be the leading cause of illness and death worldwide, with a disproportionate impact in low- and middle-income countries (LMICs), where access to routine preventive screening is often limited. Workplace health promotion has been suggested as a practical approach to raise health awareness among employed adults, especially in the public sector where structured wellness programs are inconsistently implemented. Public school teachers in the Philippines constitute a large and stable workforce that is exposed to known occupational stressors and has limited access to employer-supported preventive health services. Previous studies have shown increased psychosocial strain and NCD risk factors among educators, highlighting the need for scalable, low-burden health awareness interventions within this group. Digital health kiosks have been increasingly used in nonclinical settings, such as workplaces and community spaces, to promote self-directed health engagement. Evidence from mostly high-income countries suggests that these kiosks can improve convenience, short-term awareness, and user participation; however, existing research has primarily focused on technical feasibility and measurement validation rather than real-world implementation and user acceptability, especially in LMICs. Recently, artificial intelligence (AI) has been integrated into health kiosk platforms to enable rule-based risk stratification, personalized feedback, and automated health

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messaging. These AI-enabled kiosks are designed as supportive, nondiagnostic tools that enhance health awareness without substituting clinical judgment. Across digital health initiatives, early deployment typically emphasizes implementation feasibility, usability, and trust before moving on to formal clinical validation and outcome assessment.

Concerns about data privacy, trust, and perceived surveillance have consistently been reported in workplace digital health initiatives, especially where boundaries between personal health information and employer oversight are unclear. These concerns are particularly prominent in public sector and institutional employment settings. In this context, this study examined the deployment of an AI-enabled health kiosk used during routine workplace wellness activities among public school teachers in an urban Philippine setting. This study did not assess diagnostic accuracy, disease prevalence, or clinical effectiveness. Instead, it addresses a gap in the literature by documenting real-world implementation, user acceptability, and immediate self-reported responses to an AI-enabled health kiosk in a nonclinical workplace setting within an LMIC context.

Methods

Design

This was a cross-sectional implementation and acceptability study conducted during scheduled workplace wellness activities in selected urban public schools in the Southern Philippines between July and October 2025. The study was designed to describe implementation, user acceptability, and immediate self-reported responses following interaction with an AI-enabled health kiosk in a real-world, nonclinical setting.

Participants and Recruitment

A total of 384 public school teachers volunteered to participate, with recruitment coordinated by the Department of Education. Inclusion criteria included being an active public school teacher, aged 21 years or older, and willing to undergo screening and complete the postscreening survey. Teachers who were pregnant or acutely ill were excluded. Recruitment took place 6 months before the study began through school communications and announcements shared by school administrators during faculty meetings. These communications briefly explained the study's goals, procedures, and the voluntary nature of participation. Participation was entirely voluntary, with no financial incentives, and all participants provided informed consent.

AI-Enabled Health Kiosk

The DigiHealth system is a self-contained, AI-enabled health kiosk designed to support health awareness and engagement through automated health information delivery. The kiosk integrates basic physiological sensors commonly used in health kiosks, such as automated blood pressure measurement and, when available, anthropometric inputs for BMI calculation. Structured user inputs include brief demographic characteristics and selected NCD risk factor questions. The AI component applies rule-based stratification or decision logic to generate individualized, nondiagnostic outputs, including color-coded health indicators (eg, within-range vs elevated values), brief lifestyle guidance, and prompts encouraging users to seek formal screening or consultation when values fall outside recommended thresholds. Where enabled by the platform, a summary report could be generated and shared electronically with participants. The system is not intended for diagnosis or clinical decision-making. As the DigiHealth kiosk has not yet undergone independent clinical validation, all device-generated values in this study were treated strictly as informational prompts to elicit user perceptions and responses. Outputs were not interpreted as accurate clinical measurements, and no clinical decisions were made based on kiosk results. Participants were explicitly informed, both on-screen and verbally, that all outputs were informational only and required confirmation by licensed health care providers before any action.

Implementation Phases

The kiosk deployment occurred in 2 operational phases as part of routine implementation logistics. During phase 1, two kiosks were deployed simultaneously and functioned as intended throughout the scheduled wellness activities. During phase 2, only 1 kiosk was used operationally. The second unit was temporarily withdrawn from use after an isolated instance of atypical output prompted recalibration procedures. As a precautionary measure, data collection continued using a single kiosk to ensure consistency and uninterrupted implementation activities. Operational differences between phases primarily affected workflow logistics, including queuing time and throughput, particularly during peak participation periods. These differences were managed on-site through scheduling adjustments and staff assistance to maintain an orderly participant flow.

Data Collection

Two sources of data were collected:

1. Postuse survey data, assessing usability, perceived reliability, trust, privacy concerns, and immediate self-reported actions following kiosk use
2. Optional open-ended responses, allowing participants to provide brief comments on their experience

No clinical diagnoses, treatment decisions, or medical interventions occurred during the study. Participants who received kiosk outputs categorized as "outside recommended thresholds" were advised, through standardized on-screen messages and verbal guidance from trained staff, to seek a confirmatory evaluation from a licensed health care provider. Referrals followed existing institutional pathways and were presented as routine components of standard care.

Analysis

The analyses were mainly descriptive and exploratory. Categorical variables were summarized using frequencies and percentages. Open-ended responses were reviewed to provide examples of user feedback. No inferential analyses were conducted to evaluate diagnostic accuracy, clinical outcomes, or causal relationships. The study was neither designed nor powered to compare acceptability outcomes between different implementation phases. Acceptability data were analyzed descriptively across the entire sample to reflect the overall user experience with the kiosk system. Although operational

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differences between phase 1 and phase 2 affected workflow efficiency, no formal comparison of acceptability metrics, such as satisfaction, perceived reliability, or privacy concerns, was conducted for each phase. This is a limitation of this study and points to an area for future research, especially regarding scalability and resource efficiency.

Ethical Considerations

The Zamboanga City Medical Center Ethics Review Board approved this study under the assigned case protocol codes ZCMC-ERB-2025-34 and SPN-2025-06. The ethics review board approved the study solely as an implementation and acceptability assessment of an informational, nondiagnostic device. Participants were informed that the results required confirmation and were provided with standard referral guidance. Participants provided informed consent, with clear notices that kiosk outputs were informational, not diagnostic. Abnormal results were flagged on-screen, and medically trained staff provided verbal guidance and referral recommendations. Participants with abnormal results were advised to seek follow-up evaluation at a hospital. Trained staff explained the kiosk's purpose and limitations and addressed questions to reduce anxiety and misinterpretation. Follow-up actions were voluntary. Participation was voluntary, and no financial compensation or incentives were provided. All collected data were anonymized, securely stored, and managed in accordance with the Philippine Data Privacy Act of 2012 (Republic Act 10173) [1].

Results

Participant Characteristics

A total of 384 public school teachers participated in the study. Most participants were female (n=312, 81.3%), whereas 18.8% (n=72) were male. The median age was 44 (IQR 37 - 52) years, and the median length of service was 17 (IQR 10 - 24) years. Table 1 summarizes the participants' demographic characteristics.

Table . Sociodemographic profile of participants (N=384).

Variable	Participants, n (%)
Sex	
Female	312 (81.2)
Male	72 (18.8)
Age group (y)	
25 - 34	48 (12.5)
35 - 44	102 (26.6)
45 - 54	95 (24.7)
55 - 64	83 (21.6)
≥65	56 (14.6)
Length of service (y)	
<10	84 (21.9)
10 - 19	124 (32.3)
20 - 29	92 (24)
≥30	84 (21.9)

Implementation of the AI-Enabled Health Kiosk

The AI-enabled health kiosk was implemented in 2 phases during workplace wellness activities at public schools from July to October. Phase 1 (July to August) involved deploying 2 kiosks, enabling parallel use, and reducing wait times during peak periods. Phase 2 (September to October) used a single kiosk, which increased queues and wait times during periods of high demand. Deployment was coordinated with school administrators and integrated into routines to minimize disruption. Kiosks were installed in accessible areas, and participants used them individually according to on-screen instructions. Throughout both phases, physicians and trained staff were present to explain the nondiagnostic nature of outputs, answer questions, and reinforce advisories about confirmatory evaluations for flagged outputs. Operational challenges included internet issues; variable wait times, especially during phase 2, when only 1 machine was functioning; and crowd management in a limited space. Assistance was required for some users, and privacy was addressed by minimizing screen visibility and providing verbal reminders, although some concerns persisted. The deployment demonstrated that the kiosk could be integrated into wellness activities under resource constraints, highlighting logistical challenges related to device availability and support in nonclinical settings.

User Acceptability and Experience

User acceptability was high, with 85.7% (162/189) of the participants rating it as "good" or "excellent." Only 9.5% (18/189) rated it as "fair," and 4.8% (9/189) rated it as "poor" or "very poor." Usability was rated very highly, with 93.1% (176/189) of the participants finding it "simple and easy to use" and the instructions clear, with a median score of 5 (IQR 4-5). Perceived reliability was also high, with a median score of 5;

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86.8% (164/189) of the participants trusted the results, although 13.2% (25/189) were neutral or doubtful due to discrepancies. Privacy concerns were significant, with 31.7% (60/189) of the participants seeking stronger safeguards, such as partitioned spaces and clearer protocols.

Illustrative Feedback on User Experience

Optional open-ended responses highlighted perceived convenience, accessibility, and time efficiency of the kiosk. Some participants noted operational challenges, including queuing, intermittent connectivity, and the need for on-site assistance. These comments are presented illustratively and were not subjected to formal qualitative analysis.

Immediate Self-Reported Actions

After 1 to 2 weeks of kiosk use, 70.9% (134/189) of the participants reported consulting a health care professional, and 66.7% (126/189) reported making lifestyle changes, such as dietary adjustments or increased physical activity. Additionally, 82.5% (156 /189) of the participants shared their results with family members or coworkers. A small portion of the participants (33/189, 17.5%) reported no follow-up action, mainly due to uncertainty about the next steps or a perceived lack of urgency.

Discussion

Principal Findings

This cross-sectional implementation study showed that an AI-enabled health kiosk can be introduced in a workplace setting within a low-resource urban environment and is generally well received by users. High usability scores and positive user perceptions align with previous evidence indicating that integrated health kiosks can promote health engagement when incorporated into routine, nonclinical environments such as workplaces and community settings [2-4]. The presence of immediate self-reported actions after kiosk use, such as consulting health care providers and making lifestyle changes, suggests short-term behavioral activation. Similar trends have been observed in other workplace and community-based digital health and kiosk deployments, where exposure to personalized health information prompts reflection and initial action rather than sustained change [5-8]. Importantly, in line with methodological guidance on cross-sectional studies, these findings should not be interpreted as evidence of causal or long-term behavioral effects [9-12].

Interpretation

The findings should be interpreted in the context of a nonclinical, informational intervention. The kiosk outputs used in this study were not clinically validated and were not intended to serve as diagnostic tools. As a result, the user responses observed are best seen as reactions to increased health awareness rather than responses to verified clinical risk. This distinction is well recognized in the literature on digital screening tools, self-testing technologies, and early-stage AI health systems, where informational outputs may encourage engagement without serving as diagnostic evidence [13-15].

Privacy and Trust in Workplace-Based Digital Health

Privacy concerns raised by approximately one-third of the participants (63/189, 33.3%) align with earlier research on multiuser health kiosks and digital health systems, especially in work or semipublic environments, where perceived surveillance, employer oversight, and potential data misuse can undermine trust [4,16-18]. In workplace settings, worries are not only about data security but also about how health information might be accessed, interpreted, or used to influence employment-related decisions. These findings underscore the importance of clearly distinguishing health awareness tools from formal occupational health surveillance systems. In addition to transparency, several practical, workplace-specific measures can help reduce these concerns. These include explicit preuse statements clarifying that individual-level data are not accessible to school administrators or employers; visible on-site signage explaining data handling, storage duration, and deletion policies in plain language; and the use of anonymized or aggregated reporting formats when institutional summaries are created. Allowing participants to directly control whether a summary report is generated or shared, such as through an opt-in format rather than default sharing, may further enhance perceptions of autonomy and trust. Overall, these measures address not only technical privacy but also perceived boundaries between personal health information and employer oversight that are essential in employment-based digital health initiatives [19,20].

Contextualization Within AI-Enabled Health Technologies

The DigiHealth kiosk falls into a broader category of task-focused, assistive AI tools created to aid human decision-making instead of replacing clinical judgment. Similar design principles are seen across various AI-powered health technologies, including computer vision and deep learning systems used in digital imaging and orthodontics, such as Dynasmile and Smile.AI. These systems focus on usability, engagement, and workflow integration during early deployment phases, often before formal clinical validation [13,21,22]. Across AI health domains, early-stage tools usually follow a phased development process, starting with assessments of implementation feasibility and acceptability before moving on to validation, effectiveness, and outcome evaluation [23-25]. Importantly, this study is within this early implementation phase and does not suggest that all AI systems are clinically ready, high-performing, or legally approved at this stage. Instead, it provides evidence on how users perceive and interact with assistive AI technologies when they are introduced into everyday workplace settings.

Implementation Implications

From an implementation perspective, this study highlights several practical considerations for deploying AI-enabled health kiosks in workplace settings. First, usability and interface simplicity remain essential for adoption, particularly in environments with varying levels of digital literacy. Previous kiosk research consistently demonstrates that clear visual cues, minimal text, and intuitive navigation enhance engagement and reduce user uncertainty [4,16,26].

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Second, having physicians or medically trained staff on-site likely increased trust and helped ensure proper understanding of kiosk outputs. Human assistance acts as an important safeguard in digital health implementations by providing context to automated information, answering questions in real time, and emphasizing that the outputs are not diagnostic [13,24,27,28].

Third, privacy governance in workplace deployments needs more than just technical safeguards. Clearly separating health awareness initiatives from employment evaluation processes through explicit institutional policies should be both communicated and enforced visibly. Practical steps might include written assurances supported by both implementers and host organizations, clear role definitions that prevent supervisors from accessing individual data, and standardized communication scripts used by staff to consistently explain these boundaries. These measures are especially important in public sector workplaces, where hierarchical structures can heighten concerns about surveillance or coercion.

Finally, the findings of this study are specific to a single occupational group in an urban Philippine setting and involved phased deployment with varying device availability. Therefore, the results cannot be generalized to other populations, rural areas, or health systems without further research. Success in implementation largely depends on institutional culture, workforce dynamics, and access to follow-up care. Future studies should investigate how privacy perceptions and acceptability differ across various employment settings and explore governance models that balance scalability with trust and ethical deployment [29,30].

Limitations

This study has several important limitations that should be considered when interpreting the results. First, the AI-enabled health kiosk used in this study has not been independently validated against gold standard laboratory or clinical reference methods. Therefore, device-generated outputs should not be regarded as accurate biomedical measurements or used to estimate disease prevalence, metabolic risk, or diagnostic accuracy. The study was mainly designed to assess implementation and acceptability, rather than clinical performance, so the conclusions are limited [13,15,24]. Second, the cross-sectional design restricts findings to a single point in time and does not allow evaluation of sustained behavior change, adherence, or long-term clinical outcomes. Actions taken after kiosk use were self-reported and immediate; thus, causal relationships cannot be established [9-13,31]. Self-reported data are also prone to recall bias and social desirability bias, which may influence estimates of postuse actions [12]. Third, the study was conducted among a single occupational group, public school teachers, in an urban area of the Philippines, using a phased rollout with limited device availability. These contextual factors limit the extent to which the findings can be generalized to other populations, rural areas, informal workers, or health systems with different organizational or cultural features [32]. Fourth, although helpful user feedback was collected through optional open-ended survey responses, the study did not use a formal qualitative methodology. Therefore, the qualitative findings serve to provide context for the quantitative data rather than detailed thematic analysis. Finally, although physicians and medically trained staff were present during implementation and abnormal outputs were referred through standard hospital care pathways, the study did not track clinical follow-up outcomes.

Implications for Practice and Future Directions

Despite these limitations, the study provides important insights for designing and evaluating AI-powered health kiosks in workplaces and nonclinical settings. From an implementation perspective, the results emphasize the importance of usability, on-site support, and clear communication about data privacy and limitations. Having medically trained staff appears to assist in accurately interpreting informational outputs and may be vital in early deployments [14,24,27]. Privacy concerns voiced by many participants highlight the need for trust-building strategies that go beyond compliance with data regulations. Specific data encryption, storage, and anonymization protocols should be strictly enforced to ensure adherence to Republic Act 10173. Clear explanations of data flows, visible safeguards, and a distinct separation between health data and employer oversight are crucial for successful adoption in workplaces [17-20]. Future research should focus on formal clinical validation of these kiosks, including assessments of accuracy, precision, sensitivity, and specificity, as well as comparisons with gold standard laboratory and clinical methods. Such validation is essential before evaluating diagnostic usefulness, public health impact, or the integration of these kiosks into clinical or screening programs [15,23]. Long-term and mixed methods studies are also vital for understanding ongoing engagement, behavioral maintenance, and health outcomes after use. Using validated behavioral models, standardized acceptability measures, and follow-up evaluations can enhance causal and theoretical understanding [7,31,33]. Finally, comparative implementation research across occupational groups, regions, and resource levels can help identify factors that influence the successful deployment and scaling of AI-based health kiosks across various settings [4,16].

Conclusions

This cross-sectional implementation study shows that an AI-enabled health kiosk can be feasibly deployed and is generally well accepted in a workplace setting within an urban, low-resource public school context. High usability scores and positive user perceptions suggest that such kiosks may support health awareness and short-term engagement when incorporated into routine workplace wellness activities. However, these results are preliminary and specific to this context. The study did not evaluate diagnostic accuracy, disease prevalence, or clinical effectiveness, so it cannot draw conclusions about causal or long-term behavioral or health outcomes. The immediate self-reported actions following kiosk use probably reflect increased awareness rather than responses to validated clinical risk. Notably, the presence of privacy concerns among many participants highlights the importance of careful design and governance when deploying digital health tools in employment settings. Future implementations might benefit from concrete safeguards that directly address employer oversight concerns, such as anonymizing data at collection, avoiding storage of identifiable individual data, and providing clear on-screen

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assurances that results are not accessible to school administrators or employers. Additional steps, including optional user-controlled report generation (eg, personal printouts or direct delivery to individuals without institutional access), may further build trust and reinforce perceived autonomy. Overall, AI-enabled health kiosks can serve as informational and engagement tools in nonclinical workplace settings. However, their responsible use depends on thorough clinical validation, long-term assessment, and clear privacy protections that are openly communicated to users. Addressing ethical, trust, and governance issues, especially those related to separating health information from employment oversight, will be crucial before these technologies are widely deployed, used for population health, or integrated into official health systems.

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Data Availability

The datasets generated or analyzed during this study are available from the corresponding author on reasonable request.

Authors' Contributions

Conceptualization: NJ (equal), JB (equal), JKP (equal)
Data curation: NJ
Formal analysis: NJ
Investigation: NJ
Methodology: NJ (lead), JB (supporting)
Project administration: JB (lead), JKP (supporting)
Supervision: JB (lead), JKP (supporting)
Writing – original draft: NJ (lead), JP (supporting)
Writing – review & editing: NJ (equal), JB (equal), JKP (equal)
All authors meet the International Committee of Medical Journal Editors criteria for authorship and agree to be accountable for all aspects of the work.

Conflicts of Interest

None declared.

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Abbreviations

AI: artificial intelligence
LMIC: low- and middle-income country
NCD: noncommunicable disease

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A Text Messaging–Based Program to Transition From Basal Insulin to Glucagon-Like Peptide-1 Receptor Agonists in Safety-Net Diabetes Care: Pilot Quality Improvement Intervention Study

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Abstract

Background: Glucagon-like peptide-1 receptor agonists (GLP-1 RAs) and basal insulin both lower blood sugar, but while insulin puts people at risk of hypoglycemia and weight gain, GLP-1 RAs do not. In addition, GLP-1 RAs have added cardiometabolic and renal benefits. For these reasons, when possible, many primary care providers prefer their patients with *well-controlled* type 2 diabetes to be *transitioned* from basal insulin to a GLP-1 RA. This transition process can be labor intensive, requiring multiple dosing adjustments and a watchful eye for hypoglycemia and hyperglycemia. The Mobile Insulin Titration Intervention (MITI)–GLP1 program uses SMS text messaging–based technology to support a streamlined and supervised transition process from basal insulin to a GLP-1 RA. This program takes place at a multilingual safety-net clinic.

Objective: Our objectives were to assess program feasibility and acceptability to determine whether the intervention was doable, practical, and worthy of further investigation via a larger controlled trial. Preliminary clinical outcomes are also discussed in this paper.

Methods: Patients were enrolled on a secure web platform that sent them a daily SMS text message asking the following: “What was your fasting blood sugar this morning?” Each weekday, texted responses containing patients’ fasting blood sugar levels were checked for alarm values, and once weekly, patients were called and advised on whether and how to lower their basal insulin and increase their GLP-1 RA dose. The program was co-run by general internal medicine physicians and nurses and continued until the patient had their insulin stopped completely and/or their GLP-1 RA dose reached the maximum, or 16 weeks elapsed. All enrolled patients were included in the analyses.

Results: A total of 72 patients completed the pilot program. Feasibility and acceptability were high. Of 3671 SMS text messages sent by the program, 3520 (95.89%) received a response from patients. Of 719 cumulative weeks in which Thursday titration phone calls were attempted, successful connections with patients were made in 649 (90.26%) instances. Preliminary clinical outcomes were promising. Insulin doses were meaningfully reduced (55/72, 76.39% had their basal insulin reduced by at least 50%; 45/72, 62.5% had their insulin stopped completely). GLP-1 RA doses were meaningfully increased (64/72, 88.89% had their GLP-1 RA dose increased by ≥1 level; 45/72, 62.5% were discharged on the maximum dose of their GLP-1 RA). There was minimal hypoglycemia (5/3520, 0.14% of the SMS text messages reported a value of <80 mg/dL) and hyperglycemia (1/3520, 0.03% of the SMS text messages reported a value of >400 mg/dL).

Conclusions: A general internal medicine–run MITI-GLP1 pilot program using SMS text messaging and interdisciplinary teamwork between internists and nurses is a feasible and acceptable intervention for safely and effectively transitioning people with well-controlled type 2 diabetes away from basal insulin and toward a GLP-1 RA.

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KEYWORDS

type 2 diabetes; basal insulin; basal insulin dosing; glucagon-like peptide-1 receptor agonists; GLP-1 receptor agonists; glucagon-like peptide-1 receptor agonist dosing; GLP-1 receptor agonist dosing; primary health care; safety net; delivery of health care; SMS text messaging; telemedicine; mobile health; mHealth; eHealth; health care disparities; social drivers of health

Introduction

Insulin lowers blood sugar but introduces the risk of hypoglycemia and weight gain [1-5]. Glucagon-like peptide-1 receptor agonists (GLP-1 RAs) also lower blood sugar. However, unlike insulin, GLP-1 RAs are associated with a low risk of hypoglycemia and support weight loss [6,7]. In addition, studies have shown that GLP-1 RAs improve meaningful clinical outcomes for many people with type 2 diabetes (T2D), including reducing cardiovascular events in adults with T2D and established or high risk of atherosclerotic cardiovascular disease, reducing heart failure–related symptoms and physical limitations in adults with T2D and symptomatic heart failure with preserved ejection fraction and obesity, and slowing down the progression of chronic kidney disease in adults with T2D and chronic kidney disease [8-17]. Thus, many general internal medicine physicians would prefer their patients to be maximized on GLP-1 RAs with their insulin minimized.

Adding a GLP-1 RA to the regimen of a patient who is already on basal insulin *and* who has *well-controlled* blood sugar requires careful adjustment and monitoring [18,19]. If the basal insulin dose is lowered too quickly, blood sugar can rise, and the patient is at risk of "losing faith" in the new GLP-1 RA medication. (They may request to return to the basal insulin that previously kept their blood sugar well controlled.) On the other hand, if the basal insulin is not lowered quickly enough in a patient who has a robust blood sugar–lowering response to the GLP-1 RA (eg, because of increased pancreatic production of insulin or due to side effects that lead to decreased oral intake), hypoglycemia can occur. Frequent check-ins with successive small titrations allow the transition to proceed without leading to blood glucose values that are too low or too high. They also ensure that any large deviations from what had been the baseline, well-controlled blood sugar level are noticed immediately.

The Mobile Insulin Titration Intervention (MITI)–GLP1 is a program that supports the transition from basal insulin to GLP-1 RAs in people with well-controlled T2D. It was designed and carried out in a primary care internal medicine safety-net clinic in New York City, New York, where many patients face barriers related to social drivers of health. To the best of our knowledge, it is the only study in the literature to examine the use of an SMS text messaging–based program to adjust 2 different classes of diabetes medication simultaneously: basal insulin and GLP-1 RAs. Our objectives in this study were to assess program feasibility and acceptability to determine whether the intervention was doable, practical, and worthy of further investigation via a larger controlled trial. Preliminary clinical outcomes such as the decrease in insulin, increase in GLP-1 RAs, and avoidance of hypoglycemia and hyperglycemia during the transition are also discussed in this paper.

Methods

Overview

Bellevue Hospital is a safety-net hospital and part of NYC Health + Hospitals, the largest public health care system in the United States. Patients at the Bellevue Hospital Adult Primary Care Center with T2D who have *well-controlled* fasting blood sugar levels using basal insulin but who are either not on a GLP-1 RA at all or on a submaximum dose of a GLP-1 RA were enrolled on a secure web platform called Lumeon (Lumeon, Inc). Lumeon sent them an SMS text message every weekday morning at a time they had chosen and that best aligned with their typical morning routine of waking up and checking their blood sugar prior to eating. The SMS text message asked the following: "What was your fasting blood sugar this morning?" Texted responses containing patients' fasting blood sugar levels were recorded on the Lumeon web platform in a dedicated individual log. On weekdays, the nursing team quickly logged onto Lumeon to check the logs for alarm values. Then, once weekly on Thursdays, the nursing team called patients to review their fasting blood sugar levels, check in regarding any side effects from the GLP-1 RA, consult with the preceptor, and advise patients on whether and how to lower their basal insulin dose and raise their GLP-1 RA dose accordingly. The goals of the program were to decrease insulin, increase GLP-1 RA, and avoid hypoglycemia and hyperglycemia during the transition. The program lasted until the patient had their insulin stopped completely and/or their GLP-1 RA dose reached its maximum, or until 16 weeks elapsed (at which point the patient was discharged from this remote MITI-GLP1 program and returned to usual in-person care with our primary care diabetes team).

Several outcomes were measured. To assess program feasibility and acceptability, patient engagement was evaluated using 2 metrics: the SMS text message response rate and the once weekly call connection rate. The SMS text message response rate was defined as the percentage of SMS text messages sent to patients that received a response. The once weekly call connection rate was defined as the percentage of weeks in which patients were reachable by the MITI-GLP1 nurses for the Thursday titration call. These metrics were chosen because, at a safety-net clinic such as ours, resources are limited, and it is important that new programs are shown to be feasible and acceptable to both patients and the clinic. Preliminary clinical outcomes were also reviewed. In terms of insulin, the percentage of patients who had their insulin dose lowered by at least 50%, as well as the percentage of patients who had their insulin stopped completely, was evaluated. In terms of GLP-1 RAs, the percentage of patients who had their GLP-1 RA dose increased by at least one dosing level, as well as the percentage of patients discharged on the maximum GLP-1 RA dose, was evaluated. The hypoglycemia rate was calculated as the percentage of SMS text message responses with a value of less

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than 80 mg/dL. Although hypoglycemia is generally defined as any value of less than 70 mg/dL, the MITI-GLP1 program defined hypoglycemia as any value of less than 80 mg/dL out of an abundance of caution [20,21]. Hyperglycemia was defined as any value above 400 mg/dL. As is appropriate for feasibility pilots with small sample sizes, we summarized aggregated metrics rather than using time-series statistical process control, which would examine factors beyond the scope of our pilot.

Key contextual factors were as follows. Throughout the study period, the workload, availability, and competing clinical priorities of MITI nurses were monitored regularly at a weekly team meeting. MITI nurses consulted with preceptors each week in real time before giving titration advice and support to patients over the phone. The overall progress of active patients was reviewed (among MITI nurses, the MITI coordinator, and the program's medical director) at weekly team meetings.

Statistical Analysis

Because this quality improvement (QI) review was designed to assess feasibility and acceptability, all analyses were descriptive. Continuous variables are presented as means with SDs, and categorical variables are presented as counts and percentages with 95% CIs. CIs for proportions were calculated using the Wald (normal approximation) method. We did not perform hypothesis testing or make inferential comparisons as the study was not powered for that level of analysis. This approach is consistent with standard reporting practices for pilot and QI work.

Ethical Considerations

This was a QI review of the MITI-GLP1 pilot program, which was implemented as part of routine clinical care at Bellevue Hospital's Adult Primary Care Center. Patients were referred by their primary care providers (PCPs) and enrolled through a secure web-based platform called Lumeon, which is supported by NYC Health + Hospitals. Data containing protected health information such as the daily SMS text messages were sent and stored securely by Lumeon. Analyses for the QI review were conducted using deidentified data.

The project was formally classified using the New York University Langone Health Institutional Review Board (IRB) QI self-certification process and met all institutional criteria for QI activities not requiring IRB review. Consistent with definitions in Title 45 of the Code of Federal Regulations §46.102 cited in the institutional policy, the primary objective was to improve local clinical care processes rather than conduct a systematic investigation designed to contribute to generalizable knowledge [22]. The intervention involved no greater-than-routine clinical risk, did not follow a fixed research protocol, was not externally funded as research, and was not part of a multicenter study. In accordance with New York University Langone Health IRB policy, projects meeting these criteria are not considered human subject research and do not require IRB review or oversight.

Given that MITI-GLP1 was a part of routine clinical care, no informed consent was required. There was no compensation for participation.

Results

The observed contextual factors were as follows. No major policy or staff changes occurred during the pilot period. The American Diabetes Association guidance that a GLP-1 RA–based medication is generally preferred as the first injectable medication in patients with T2D remained the same over the course of the program. No modifications to the process of the intervention were made during the pilot period. The Lumeon texting platform worked reliably for all 72 patients. No technical difficulties interfered with program outcomes.

Data are complete, with all 72 patients represented for each metric.

Table 1 shows MITI-GLP1 patient demographics. A total of 72 patients enrolled in the pilot program. Their average age at baseline was 54 (SD 11) years, with 70.83% (n=51) self-identifying as Hispanic or Latinx, 61.11% (n=44) opting for SMS text messages in Spanish, and 61.11% (n=44) having no health insurance. Of the 72 patients enrolled, 64 (88.89%) completed the program. The remaining 11.11% (n=8) responded to SMS text messages but were unreachable for the titration calls. These 8 patients were discharged from the program and returned to in-person care. All 72 enrolled patients were included in the analyses.

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Table . MITI-GLP1 program patient demographics (N=72).

Demographics	Values
Age (y), mean (SD)	54 (11)
Female sex, n (%)	30 (41.67)
Race, n (%)	
Native American or Alaska Native	0 (0.00)
Asian	0 (0.00)
Black or African American	11 (15.28)
Native Hawaiian or Pacific Islander	1 (1.39)
White	5 (6.94)
Other—Hispanic or Latinx ethnicity	51 (70.83)
Other—Non–Hispanic or Latinx ethnicity	3 (4.17)
No health insurance, n (%)	44 (61.11)
Language used for SMS text messages, n (%)	
Spanish	44 (61.11)
English	25 (34.72)
French	1 (1.39)
Urdu	1 (1.39)
Hungarian	1 (1.39)

Table 2 shows MITI-GLP1 patient engagement outcomes. Patient engagement was meaningfully high; of 3671 SMS text messages sent to patients by the program, 3520 (95.89%; 95% CI 95% - 71%) received a response. Of 719 cumulative weeks during which MITI-GLP1 nurses attempted to reach patients by phone, they were able to connect in 649 (90.26%; 95% CI 88% - 92%).

Table . MITI-GLP1 patient engagement outcomes (N=72).

Patient engagement outcome	Values
SMS text message response rate	
SMS text messages sent by the MITI-GLP1 program, n	3671
Patient SMS text message responses received, n/N (%; 95% CI)	3520/3671 (95.89; 95 - 71)
Once weekly call connection rate	
Weeks with Thursday titration phone calls attempted, n	719
Weeks with Thursday titration phone calls successfully reaching patients, n/N (%; 95% CI)	649/719 (90.26; 88 - 92)

Table 3 shows MITI-GLP1 patient baseline clinical information. The average starting basal insulin dose was 20 (SD 11) units once daily, the average starting BMI was 30 (SD 6) kg/m^2, and the average starting fasting blood glucose level was 126 (SD 19) mg/dL. Among these 72 patients, the GLP-1 RA used was semaglutide in 83.33% (n=60) of patients, dulaglutide in 13.89% (n=10) of patients, and liraglutide in 2.78% (n=2) of patients. Of note, semaglutide was the weekly GLP-1 RA on Bellevue Hospital's formulary during the pilot period.

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Table . MITI-GLP1 patient baseline clinical information (N=72).

Baseline clinical information	Values
Starting basal insulin dose (units), mean (SD)	20 (11)
Starting BMI (kg/m^2), mean (SD)	30 (6)
Starting fasting blood glucose (mg/dL), mean (SD)	126 (19)
GLP-1 RA[a] used, n (%)	
Semaglutide	60 (83.33)
Dulaglutide	10 (13.89)
Liraglutide	2 (2.78)

[a]GLP-1 RA: glucagon-like peptide-1 receptor agonist.

Table 4 shows MITI-GLP1 preliminary clinical outcomes. Insulin doses were decreased substantially. A total of 76.39% (55/72) of the patients (95% CI 66% - 86%) had their basal insulin dose reduced by 50% or more. In total, 62.5% (45/72) of the patients (95% CI 51% - 74%) had their insulin stopped completely. GLP-1 RA doses increased markedly. A total of 88.89% (64/72) of the patients (95% CI 82% - 96%) had their GLP-1 RA dose increased by 1 level or more, and 62.5% (45/72) of the patients (95% CI 51% - 74%) were discharged on the maximum dose of their GLP-1 RA medication. The average ending fasting blood glucose level was 122 (SD 34) mg/dL.

Table . MITI-GLP1 preliminary clinical outcomes (N=72).

Outcome	Values
Insulin dose changes, n/N (%; 95% CI)	
Insulin lowered by ≥50%	55/72 (76.39; 66 - 86)
Insulin stopped completely	45/72 (62.50; 51 - 74)
GLP-1 RA[a] dose changes	
GLP-1 RA dose increased by at least one level, n/N (%; 95% CI)	64/72 (88.89; 82 - 96)
GLP-1 RA dose at discharge was the maximum dose, n/N (%; 95% CI)	45/72 (62.50; 51 - 74)
Ending fasting blood glucose (mg/dL), mean (SD)	122 (34)
Hypoglycemia	
SMS text message responses reporting <80 mg/dL, n/N (%; 95% CI)	5/3520 (0.14; 0.02 - 0.27)
SMS text message responses reporting <70 mg/dL, n/N (%)	1/3520 (0.03)
Symptomatic hypoglycemia, n/N (%)	0 (0.00)
Hyperglycemia, n/N (%; 95% CI)	
SMS text message responses reporting >400 mg/dL	1/3520 (0.03; 0.00 - 0.08)
Symptomatic hyperglycemia	0 (0.00)

[a]GLP-1 RA: glucagon-like peptide-1 receptor agonist.

Hypoglycemia was minimal. A total of 0.14% (5/3520) of the SMS text message responses (95% CI 0.02% - 0.27%) reported a value of less than 80 mg/dL; 4 of these 5 values were in the range of 70 to 79 mg/dL (79, 79, 74, and 73 mg/dL), and only 1 was below 70 mg/dL (63 mg/dL). None were symptomatic.

Hyperglycemia was also minimal. In total, 0.03% (1/3520) of the SMS text message responses (95% CI 0.00% - 0.08%) reported a value above 400 mg/dL. The value was 494 mg/dL. The patient was asymptomatic.

Discussion

Principal Findings

The MITI-GLP1 program is a promising, feasible, and acceptable intervention. Patient engagement was high, as evidenced by both high SMS text message response rates and high weekly call connection rates. Our pilot program sent 3671 SMS text messages to patients asking the following: “What was your fasting blood sugar this morning?” We received a reply 95.89% (3520/3671) of the time. This is notable, especially at a safety-net clinic where social drivers of health often create obstacles to engagement in care. High patient engagement was also reflected in our once weekly call connection rate. MITI-GLP1 nurses attempting to reach patients each week of

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the program were able to connect with them in 90.26% (649/719) of the weeks. We interpret these metrics to indicate that not only is MITI-GLP1 a convenient and accessible program for *patients* to engage with, it is also a highly feasible program for our *nursing staff*, who were able to successfully reach the patients in their care.

Following American Diabetes Association guidelines, our Adult Primary Care Center generally uses a GLP-1 RA as the first-line injectable agent for most patients with T2D [20,21]. However, the following question arose: what should we do for our patients with T2D who already have *well-controlled* blood sugar levels on basal insulin but who are currently either not on a GLP-1 RA at all or on a submaximum dose of a GLP-1 RA? One option is to simply inform these patients that their blood glucose control is sufficient, refill their medications, and see them back in several months for their next routine visit. Another option is to attempt to transition them to a GLP-1 RA. In our safety-net, primary care internal medicine clinic in New York City, New York, where many of our patients have cardiometabolic and renal disease, we generally prefer the option of attempting to decrease insulin and increase GLP-1 RA dose.

Safely transitioning a person with T2D who has *well-controlled* fasting blood sugar from basal insulin to a GLP-1 RA requires careful monitoring [18,19]. If the basal insulin is not lowered enough by the time the GLP-1 RA starts working, the person may be at risk of hypoglycemia. If the basal insulin is lowered too much before the GLP-1 RA has a meaningful effect, the blood sugar can rise above the goal level of 80-130 mg/dL. In either scenario, the person—who, up until this transition began, had well-controlled fasting blood sugar levels—may lose faith in the new GLP-1 RA medication and may wish to return to their basal insulin, which worked well for them. Our primary care diabetes team began using the MITI-GLP1 program to support this transition, with the overall goals of reducing basal insulin, increasing GLP-1 RA doses, and avoiding both hypoglycemia and hyperglycemia.

Primary care providers do not *need* a MITI-GLP1 program to transition their patients with well-controlled T2D from basal insulin to a GLP-1 RA. Instead, they can advise on dose changes during normal visits and arrange for frequent check-ins (conducted either by themselves or a team member) outside of a formal MITI-GLP1 program. Of note, our primary care diabetes team was doing just that prior to the creation of the MITI-GLP1 program. At any given time, our team knew which patients with *well-controlled* fasting blood sugar were switching from basal insulin to a GLP-1 RA, and these patients remained heavily on our radar during their transition period. We highlighted them at our weekly team meetings and assigned a team member to call them at least once a week to check in about their fasting blood sugar levels and any GLP-1 RA side effects.

For these reasons, including the need to provide multiple titration check-ins and monitor for hypoglycemia and hyperglycemia, we anticipated that a MITI-GLP1 program would successfully support patients and our clinic in the transition from basal insulin to GLP-1 RAs. Indeed, this is what we found.

There are just a handful of publications in the literature describing programs that use SMS text messages to adjust injectable diabetes medications [23-26]. One of those publications reflected the prior work of this team on the original MITI program (which was designed for patients with poorly controlled T2D who needed uptitration of their basal insulin). Beyond the program discussed in our original MITI paper, none of the other studies in the literature were carried out in a safety-net population, none focused on a population who predominantly did not speak the native language, and none involved titration of a GLP-1 RA. What makes MITI-GLP1 most unique is that it is the only study in the literature describing an SMS text messaging–based program whose purpose is to adjust 2 different classes of diabetes medications simultaneously: basal insulin and GLP-1 RAs.

The implications of our work are several-fold. First, receiving daily SMS text messages allows a team to keep a close watch for hypoglycemia and hyperglycemia. There were only 5 cases of hypoglycemia; there was only 1 case of hyperglycemia. However, our team knew about these abnormal glucose values right away and could contact patients and make medication adjustments in real time.

Second, having the fasting blood glucose data gathered in advance changes the quality of the weekly telephone interaction by allowing the team to focus on education and titration rather than on data gathering. Health care providers tasked with calling patients to check in about self-monitored blood glucose values and advise on medication adjustments know that check-in calls often require a significant amount of time to elicit the recent blood glucose values. Patients may not be home when called and, thus, may have to recreate a log of recent blood sugar levels from memory. Alternatively, patients may be home, but it still takes ample time to scroll back through the values on their glucometer or continuous glucose monitor. In contrast, having accurate fasting blood glucose values in front of the health care provider at the start of the phone call makes the call more efficient and allows the health care provider to devote more time to check in about any GLP-1 RA side effects, give medication titration advice, and offer general support.

Finally, having a program such as MITI-GLP1 can be a factor that encourages PCPs to recommend the labor-intensive transition in the first place, especially given time constraints in a safety-net clinic. Without a MITI-GLP1 program, a PCP may evaluate their patient with well-controlled T2D who is on basal insulin *but not on a GLP-1 RA* and may recognize, given their patient's high cardiometabolic and renal risk, that it would be *better* for their long-term health to attempt the transition to a GLP-1 RA. However, in the context of a 20-minute visit, it can be challenging for the PCP to find the time to put that plan into motion. Thus, the decision to do so may be deferred. With the existence of the MITI-GLP1 program, PCPs can devote *more of their time* to obtaining patient buy-in by educating them about the reasons why a GLP-1 RA may be superior to basal insulin and *less of their time* on titration logistics. Specifically, the presence of the MITI-GLP1 program can eliminate the need for the PCP to arrange a series of follow-up appointments to check in about potential GLP-1 RA–related gastrointestinal symptoms and provide ongoing titration advice. If the patient agrees to

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switch over from insulin to a GLP-1 RA, the PCP can simply refer the patient to our program. Conveniently, we take it from there.

The MITI-GLP1 program systematically operationalizes the transition process, taking it off the shoulders of the *individual* PCP and assigning it instead to a multidisciplinary *team* that is not only well versed in transitioning patients from basal insulin to a GLP-1 RA but also able to use convenient, patient-centered SMS text messaging and a once weekly phone call to provide much more continuous guidance, support, and supervision during the process.

This work is the first description in the literature of an SMS text messaging–based program that aims to titrate both basal insulin and GLP-1 RAs. The MITI-GLP1 program was feasible and acceptable, demonstrated strong preliminary outcomes, and warrants further investigation in a larger clinical trial.

Program costs include the cost of the secure SMS text messaging platform (Lumeon) and the cost of the program coordinator. While there is a "cost" to the nursing time as well as the time of the preceptor involved in titration discussions, the authors argue that these are not opportunity costs because they would be incurred whether a patient was having these medications adjusted via the MITI-GLP1 program or outside a formal MITI-GLP1 program.

Limitations

The MITI-GLP1 pilot program has several limitations. First, the program's small sample size limits generalizability and power. Second, the lack of a control group prevents attribution of the stability of blood glucose values to the intervention. Third, the short follow-up period provided in the MITI-GLP1 program is insufficient to assess long-term durability of glycemic control. Additionally, the scalability of the intervention may be impacted by staff differences across clinics. This program was carried out by diabetes-focused primary care nurses who are considerably experienced and comfortable in managing injectable medications for people with complex T2D. Not all primary care nurses will share this comfort level. Finally, a MITI-GLP1 program requires access to a secure SMS text messaging platform. We are lucky to have access to Lumeon in our health care system and realize that not everyone will. Of note, it was important that SMS text messages sent by our program through Lumeon were standard SMS text messages only requiring the patient to have a cell phone, a regular SMS text messaging plan, and a basic understanding of how to receive and send SMS text messages. We strongly preferred this to a platform requiring patients to own a smartphone, download an app, or have access to Wi-Fi as these would have been additional barriers for our safety-net patients.

Conclusions

"Well-controlled T2D" in 2026 does not merely refer to healthy blood glucose values, but rather, it refers to effective glycemic control in the broader context of medications that reduce cardiometabolic and renal complications. A primary care internal medicine–run MITI-GLP1 program using SMS text messaging and teamwork between internists and nurses is a feasible and acceptable intervention for safely and effectively transitioning people with well-controlled T2D away from basal insulin and toward a GLP-1 RA. Further confirmatory studies, such as those involving a larger controlled trial, are needed.

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Data Availability

The datasets generated and analyzed during this study are not publicly available due to the presence of protected health information and institutional restrictions. Data may be available from the corresponding author on reasonable request and with appropriate institutional approval.

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Authors' Contributions

Conceptualization: NL, OS, SB, AD, CU, YJL
Data curation: NL, KN
Formal analysis: NL, KN
Investigation: NL, OS, SB, AD, CU, YJL
Methodology: NL
Project administration: NL, KN, OS
Supervision: NL
Validation: NL, KN
Visualization: NL, KN
Writing—original draft: NL, KN, OS, SB, AD, CU, YJL
Writing—review and editing: NL, KN, OS, SB, AD, CU, YJL

Conflicts of Interest

None declared.

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Abbreviations

GLP-1 RA: glucagon-like peptide-1 receptor agonist
IRB: institutional review board
MITI: Mobile Insulin Titration Intervention
PCP: primary care provider
QI: quality improvement
T2D: type 2 diabetes

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Comparing Large Language Models and Traditional Machine Translation Tools for Translating Medical Consultation Summaries: Quantitative Pilot Feasibility Study

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Abstract

Background: Translation of medical consultation summaries is essential for equitable health care communication in culturally and linguistically diverse populations. While machine translation (MT) tools and large language models (LLMs) are widely accessible, their feasibility and safety for health care contexts remain underexplored.

Objective: This pilot study investigates the feasibility and limitations of using LLMs and traditional MT tools to translate medical consultation summaries from English into the most common languages other than English spoken in Australia—Arabic, Chinese (simplified written form), and Vietnamese.

Methods: Two simulated summaries—a simple patient-facing summary and a complex clinician-oriented interprofessional letter—were translated using 3 LLMs (GPT-4o, Llama-3.1, and Gemma-2) and 3 MT tools (Google Translate, Microsoft Bing Translator, and DeepL). Translations were benchmarked against professional third-party interpreter translations using Bilingual Evaluation Understudy, Character-level F-score, and Metric for Evaluation of Translation with Explicit Ordering metrics.

Results: The translation performance varied across languages, tools, and summary complexity when assessed using automatic evaluation metrics. Traditional MT tools outperformed LLMs on surface-level metrics, while LLMs showed relative strengths in semantic similarity for Vietnamese and Chinese. Arabic translations improved with complex input, suggesting morphological advantages. The metric-based evaluation highlighted feasibility but also risks, particularly in Chinese clinical contexts.

Conclusions: This pilot study provides formative evidence of opportunities and limitations in applying artificial intelligence translation for health care communication. Findings underscore the importance of human oversight; domain-specific evaluation metrics; and further formative and clinical research to guide the safe, equitable use of artificial intelligence translation tools.

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KEYWORDS

feasibility study; pilot evaluation; translation; large language models; machine translation; consultation summary; responsible artificial intelligence; responsible AI; artificial intelligence; AI

Introduction

Machine translation (MT) has seen rapid evolution in recent years, particularly with the advent of large language models (LLMs). Traditional neural MT tools, such as Google Translate [1], Microsoft Bing Translator [2], and DeepL [3], have been widely used in general and domain-specific applications. These tools rely heavily on sequence-to-sequence architectures and large-scale parallel corpora, showing strong performance for high-resource language pairs with abundant linguistic data. However, the effectiveness of MT is often constrained in domains that demand specialized vocabulary and contextual precision, such as medical communication [4]. While studies on digital translation in clinical care have reported improvements in communication quality and efficiency, they also highlighted limitations of MT in accuracy and further noted that direct, word-for-word translation, without accounting for cultural and contextual nuances, may lead to patient misunderstanding or even emotional distress [5,6].

In contrast, LLMs such as GPT [7], Gemma [8], and Llama [9] have emerged as versatile alternatives capable of performing a wide range of natural language tasks [10-16], including language translations [17,18]. These models leverage extensive pretraining on diverse corpora, enabling them to capture broader contextual

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relationships and discourse-level semantics across languages. Previous studies have shown that LLMs can outperform traditional MT tools in document-level linguistic translation by better preserving coherence and semantic intent [17]. Moreover, recent work has shown that LLMs can act as effective quality estimators for translation output, even without explicit references [18].

Despite these advances, the application of LLMs in medical translation remains underexplored and presents unique challenges [19,20]. Medical texts require not only accurate translation of terminology and clinical concepts but also contextual sensitivity, as even small errors can lead to harm [4]. Terminological consistency, expansion of abbreviations, and the handling of multilingual clinical guidelines add layers of complexity [21]. These challenges are heightened in multilingual health care settings such as Australia, where languages such as Arabic, Chinese, and Vietnamese are widely spoken but often underrepresented in medical translation tools [22]. The accuracy and safety of using general-purpose LLMs in such contexts remain largely untested.

This pilot feasibility study builds on existing research by providing an early-stage, empirical comparison of LLMs and traditional MT tools in translating palliative care consultation summaries—a use case that is both medically sensitive and linguistically nuanced [23]. Our study focuses on 3 of the most spoken languages other than English in Australia—Arabic, Chinese, and Vietnamese—each posing different linguistic and morphological challenges [22]. While Vietnamese, like many other languages, is relatively undersupported in traditional MT tools (eg, not supported by DeepL), LLMs have the potential to fill these gaps through flexible, prompt-based translation.

We designed 2 types of simulated summaries in English to reflect real-world use cases: a simple summary for patients, written in lay language and a complex, clinician-targeted version featuring domain-specific jargon, abbreviations, and nuanced medical reasoning. Translations were generated using default prompt settings for each LLM and default web versions of each MT tool and evaluated against professional third-party medical interpreter translations. Automatic evaluation metrics—Bilingual Evaluation Understudy (BLEU) [24], Character-level F-score (CHR-F) [25], and Metric for Evaluation of Translation with Explicit Ordering (METEOR) [26]—were used to capture surface-level overlap, morphological robustness, and semantic similarity, respectively [27]. This multifaceted analysis allowed us to assess the models not only in terms of fidelity to reference but also their ability to generalize across languages and document complexity.

By comparing performance across tool types, summary complexity, and languages, this formative study provides insights into the current feasibility and limitations of LLM-based translation for medical applications. Our findings highlight language-specific challenges, the shortcomings of current evaluation metrics for clinical accuracy, and the implications of deploying AI translation tools in health care communication. Importantly, translation errors in clinical contexts can compromise patient safety, reduce provider efficiency, and hinder equitable access to care [28].

This study is intentionally designed as a *pilot feasibility investigation*. Its goal is not to benchmark optimal system performance or establish clinical readiness but to explore practical risks, limitations, and methodological challenges of using LLMs and MT tools for medical translation and to inform the design of future, clinically grounded evaluation studies.

Methods

Overview

This pilot feasibility study presents an early-stage comparison between popular LLMs and traditional MT tools in translating medical documents. We selected the latest and most capable variants of 3 state-of-the-art LLMs: GPT-4o (OpenAI), Gemma-2-27B (Google), and Llama-3.1-405B (Meta). For traditional MT tools, we selected 3 widely used services: Google Translate, Microsoft Bing Translator, and DeepL. LLMs have demonstrated strong capabilities in general-purpose translation, and commercial translation products based on LLMs have already been introduced into the market. However, the extent to which LLMs can be reliably and safely used for translating medical texts, especially in safety-critical areas such as digital health, remains largely unexplored. This study aims to investigate this gap by evaluating translation quality across both LLMs and traditional MT tools. Our design was intentionally small scale and exploratory, with the goal of generating formative evidence to inform larger clinical studies.

Ethical Considerations

This study used entirely fictitious medical consultation summaries that were constructed by an experienced palliative care clinician and did not contain any real patient information, personally identifiable data, or clinical records. As a result, formal human research ethics approval was not required.

Original Summaries in English

To simulate realistic clinical use cases, we created 2 types of fictitious consultation summaries in English. The first is a short and relatively simple summary with minimal medical terminology intended for patient-facing medical documents. It summarizes a simulated palliative care consultation of a patient with progressive dementia who recently recovered from a urinary tract infection. It captures the necessary components of a patient-facing summary, including medical history, recent care updates, and future recommendations. The second summary is longer and more complex, featuring extensive medical jargon, including abbreviations and acronyms, typically used for communication purposes between clinicians (eg, correspondence letter between the specialist and family physicians) or toward health care provider documents such as discharge summaries. These summaries were designed to reflect common clinical communication scenarios while ensuring no real patient data were used. The complex summary described a patient with advanced acute myeloid leukemia and treatment complications, requiring specialized care.

It is important to emphasize that the summaries were entirely fictitious and meticulously constructed by a qualified palliative care expert with over 25 years of clinical experience. No personally identifiable information or sensitive patient data were

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included. This ensured compliance with ethical standards and minimized risks to participants, in line with formative study expectations.

Selected Languages

The target languages for translation were Arabic, Chinese (simplified), and Vietnamese, which were chosen because they are the 3 most commonly spoken languages other than English in Australia, as reported by the Australian Bureau of Statistics [22]. Due to DeepL not supporting Vietnamese at the time of the study, its outputs for that language were not included in our analysis. The language set was chosen to reflect the culturally and linguistically diverse populations most relevant to the Australian health care system.

Reference Translations

The reference translations for both summaries were generated by a professional third-party translation service with extensive experience in translating medical documents. The service is certified under ISO 17100, an international standard that establishes requirements to ensure the quality of translation services. All translators involved were accredited by the National Accreditation Authority for Translators and Interpreters. Each translation underwent a rigorous quality assurance process, which included a review by an independent translator (ie, a linguist not involved in the original translation task or providing verification) to identify typographical errors, formatting inconsistencies, untranslated or mistranslated content, and placeholder artifacts that may arise during document handling or after editing.

To ensure that reference translations were reflective of industry practice and standards, we engaged accredited translation services. However, it is important to note that the contemporary professional translation workflow commonly incorporates machine-generated drafts as a starting point for human postediting. There are no regulations that prohibit the use of machine-generated translations, and ISO 17100 also incorporates guidelines for using machine-generated translations as preliminary drafts. Consequently, while every effort was made to ensure the quality and accuracy of the translations, obtaining translations that are purely human generated from first principles is increasingly difficult in modern professional settings. While the translation provider indicated that the Chinese and Vietnamese translations were produced entirely by human translators, the first draft of the Arabic translation was generated with the assistance of artificial intelligence (AI)–based translation tools and later reviewed by the human translator. This further underscores the increasingly widespread adoption and normalization of generative AI technologies to assist professional translation services.

Generated Translations

For each summary, 2 sets of translations were generated as shown in the translation task matrix (Table 1). The first set consisted of 3 LLM-generated translations. This experiment aimed to mimic laypeople using LLMs as a translation service; therefore, the basic web platform was used instead of the developer's application programming interface, which means alll parameters (including system prompt) were set as the model's default values. All LLM-generated translations also used the same basic prompt: "Can you translate this document into Arabic/Chinese/Vietnamese, make sure no information is lost. '*DOCUMENT*'," where *DOCUMENT* is the original summary. All LLM experiments in this study were conducted using a *zero-shot setting*, without any examples, prompt tuning, or system-level customization. The single, minimal prompt was intentionally chosen to reflect typical lay-user (eg, patients) behavior, rather than to evaluate the maximum achievable capability of each model. No terminology constraints, abbreviation handling rules, unit normalization, or do-not-translate rules were provided. Therefore, the results should be interpreted as reflecting realistic, nonexpert use, not optimized or clinician-engineered performance.

Table . Translation task matrix (summary type×language×system).[a]

Summary type and language	GPT	Gemma	Llama	Google Translate	Microsoft Bing	DeepL
Simple						
Arabic	✓	✓	✓	✓	✓	✓
Chinese	✓	✓	✓	✓	✓	✓
Vietnamese	✓	✓	✓	✓	✓	
Complex						
Arabic	✓	✓	✓	✓	✓	✓
Chinese	✓	✓	✓	✓	✓	✓
Vietnamese	✓	✓	✓	✓	✓	

[a]DeepL did not support Vietnamese translation at the time of this study. A total of 34 translations were produced across 36 combinations.

The second set of translations was produced using traditional MT tools—Google Translate, Microsoft Bing Translator, and DeepL—by inputting the same English summaries into their publicly accessible web interfaces. As with the LLMs, no customization or advanced application programming interface use was applied, ensuring that the outputs reflect a typical user experience. This approach reflects feasibility testing rather than optimized performance.

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Statistical Analysis

We used 3 widely used automatic metrics from the MT domain to obtain a comprehensive assessment for each generated summary. These were BLEU, CHR-F, and METEOR. Although originally developed for MT, these metrics remain widely applied to LLM outputs and were used here to provide indicative, rather than definitive, measures of quality [19,29]. Currently, there are no standardized evaluation metrics specifically designed for LLM-generated translations, although recent studies suggest LLMs themselves may serve as quality estimators [18]. A brief description of each metric used and its limitations are listed in Table 2. The values of each metric range from 0 to 1, where 1 indicates an identical match between the reference translation and generated translation, while 0 indicates no overlap at all.

Table . Description and limitations of each statistical metric used in the evaluation.

Metric	Description	Limitation
BLEU (Bilingual Evaluation Understudy)	Measures the word level of overlapping between candidate and reference translations. It is the most common metric in machine translation.	Lacks acceptance of synonyms, paraphrasing, and overall semantic meaning.
CHR-F (Character-level F-score)	Measures the character level of overlapping between candidate and reference translations, making it particularly effective for languages with complex morphology or segmentation issues.	Lacks acceptance of synonyms, paraphrasing, and overall semantic meaning.
METEOR (Metric for Evaluation of Translation with Explicit Ordering)	Aligns words between candidate and reference translations, incorporating synonyms, stemming, and paraphrasing, offering a balance between surface and semantic matching, and is also sensitive to syntax.	Struggles with complex semantics or meanings that require deep understanding.

Specifically, BLEU measures the *surface similarity at the word level compared to the reference translation*. A high score in BLEU in the health setting means the medical terminology and linguistics for symptoms or diagnosis are captured accurately. CHR-F measures the *surface similarity at the character level compared to the reference translation*, which handles morphological variation better than BLEU. A high CHR-F score means that the generated translation is capturing medical jargon, especially abbreviations, better. METEOR measures *similarity at the semantic level*. A high METEOR score indicates that even when a medical condition or advice is expressed differently, the core semantic content is still preserved.

Results

Overview

Table 3 presents a comparative evaluation of translation quality for 2 English medical consultation summaries—simple (layperson-friendly) and complex (clinician-oriented)—translated into Arabic, Chinese, and Vietnamese using 3 LLMs (GPT-4o, Llama-3.1, and Gemma-2) and 3 traditional MT tools (Google Translate, Microsoft Bing Translator, and DeepL). Translation outputs were scored using 3 established automatic evaluation metrics: BLEU (for surface-level n-gram overlap), CHR-F (for character-level fidelity), and METEOR (for semantic similarity and paraphrasing tolerance).

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Table . Translation performance comparison across 3 automatic evaluation metrics—Bilingual Evaluation Understudy (BLEU), Character-level F-score (CHR-F), and Metric for Evaluation of Translation with Explicit Ordering (METEOR) —for 3 LLMs (GPT-4o, Llama-3.1, and Gemma-2) and 3 traditional MT tools (Google Translate, Microsoft Bing Translator, and DeepL).

	GPT	Llama	Gemma	Microsoft Bing Translator	Google Translate	DeepL
Arabic						
Simple						
BLEU	0.6536	0.5947	0.6051	0.6405	0.6528	0.6523
CHR-F	0.5064	0.4562	0.4693	0.5078	0.5151	0.5156
METEOR	0.3166	0.2568	0.2810	0.3289	0.3399	0.3048
Complex						
BLEU	0.6300	0.6029	0.6006	0.6149	0.6787	0.6692
CHR-F	0.4957	0.4726	0.4768	0.5005	0.5907	0.5423
METEOR	0.3343	0.3575	0.3682	0.4012	0.4988	0.4171
Chinese						
Simple						
BLEU	0.4266	0.4164	0.5227	0.5018	0.4358	0.4322
CHR-F	0.4165	0.3910	0.4392	0.4193	0.3709	0.3844
METEOR	0.4698	0.5033	0.5678	0.5169	0.4564	0.5097
Complex						
BLEU	0.2662	0.2422	0.2466	0.2393	0.2596	0.2603
CHR-F	0.2871	0.2387	0.2576	0.2427	0.2729	0.2526
METEOR	0.3055	0.3347	0.3394	0.3294	0.3349	0.3331
Vietnamese						
Simple						
BLEU	0.7188	0.7517	0.7458	0.7464	0.7719	—[a]
CHR-F	0.5956	0.5979	0.5957	0.5864	0.6184	—
METEOR	0.5566	0.5894	0.5489	0.5373	0.5908	—
Complex						
BLEU	0.6857	0.7441	0.7118	0.7059	0.7325	—
CHR-F	0.5494	0.6055	0.6130	0.5862	0.6252	—
METEOR	0.4652	0.4787	0.5399	0.5222	0.5744	—

[a]Not available.

Simple vs Complex Summary Translation Performance

We observed a consistent pattern across the Chinese and Vietnamese languages, where simple summaries—written in layperson language with minimal technical jargon—achieved higher scores across most metrics compared with complex summaries. This trend was less pronounced or even reversed in Arabic. For example, in Vietnamese, BLEU scores for the simple summary were high across all models, with Google Translate achieving the highest score of 0.7719, followed closely by Llama (0.7517) and MS (0.7464). CHR-F and METEOR scores also reflected strong alignment, with Google Translate again leading in METEOR score (0.5908).

However, for the complex summary, BLEU scores dipped across all models (eg, GPT declined from 0.7188 to 0.6857), although the degradation for Vietnamese was relatively minor, suggesting good resilience for Vietnamese translation. A dramatic drop was observed in Chinese performance. For instance, Gemma's BLEU score fell from 0.5227 (simple) to 0.2466 (complex). CHR-F and METEOR scores showed a similar drop, with CHR-F scores dropping from 0.4392 to 0.2576 and METEOR scores dropping from 0.5678 to 0.3394. This suggests a struggle in translating complex, technical content due to syntactic and terminological challenges.

In Arabic, an interesting reverse trend emerged. For instance, Google Translate's BLEU score increased from 0.6528 (simple) to 0.6787 (complex). The METEOR score also jumped significantly, from 0.3399 to 0.4988. This may be due to Arabic's rich morphology, where longer, more context-rich

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sentences provide better clues for disambiguation and grammatical accuracy.

LLMs vs Traditional MT Tools

Across all languages, traditional MT tools (Google Translate and Microsoft Bing Translator) generally outperformed LLMs such as GPT-4o, Llama, and Gemma on standard metrics, particularly for complex summaries.

For example, in Arabic complex summaries, Google Translate achieved a BLEU score of 0.6787 and a METEOR score of 0.4988, outperforming GPT (BLEU: 0.6300; METEOR: 0.3343), Llama, and Gemma. Similar trends were seen in CHR-F, where Google Translate scored 0.5907, the highest among all systems.

This reflects the focus of traditional MT tools on token-level alignment and training objectives that favor metrics such as BLEU and CHR-F, rewarding close n-gram matches. On the other hand, LLMs often prioritize fluency and coherence, producing paraphrased outputs that, while semantically accurate, may score lower due to structural differences.

However, Llama outperformed GPT-4o in Vietnamese and Chinese METEOR scores, and Gemma did the same except for Vietnamese simple summaries. For example, in Vietnamese simple summaries, Llama outperformed GPT with a METEOR score of 0.5894 vs 0.5566, suggesting that specific LLMs may better capture semantic nuances in certain linguistic contexts.

Language-Specific Performance Trends

The 3 target languages demonstrated distinct translation characteristics in response to summary complexity and model type:

- Arabic: translation quality improved with complex summaries across most models. For instance, GPT's CHR-F score went from 0.5064 (simple) to 0.4957 (complex)—a small drop, but METEOR scores rose from 0.3166 to 0.3343 and other models (such as Llama and Gemma) saw larger METEOR score gains. This supports the hypothesis that longer, more redundant input helps Arabic models resolve morphological ambiguities.
- Chinese: performance dropped sharply from simple to complex summaries. BLEU scores for Gemma fell from 0.5227 to 0.2466 and METEOR fell from 0.5678 to 0.3394. This suggests transliteration issues, syntactic mismatches, and rare term handling present challenges in Chinese clinical text translation. Similar challenges in Chinese medical translation have been reported in previous studies, where syntactic ambiguity, segmentation issues, and limited domain-specific parallel corpora reduce translation accuracy [21].
- Vietnamese: scores declined modestly from simple to complex, showing the least performance degradation. For example, Llama's BLEU score only dropped from 0.7517 to 0.7441 and CHR-F score actually increased from 0.5979 to 0.6055. This suggests that Vietnamese translation is robust, possibly due to better multilingual representation in modern models.

Discussion

Principal Findings

This pilot feasibility study compared LLMs and traditional MT tools for translating medical consultation summaries into Arabic, Chinese, and Vietnamese. Translation performance varied substantially by language, document complexity, and system type.

Overall, traditional MT tools achieved higher scores on surface-level metrics such as BLEU and CHR-F, particularly for complex, clinician-oriented summaries, reflecting optimization for lexical fidelity. In contrast, LLMs demonstrated relative strengths in semantic similarity in selected language-summary combinations, as reflected by METEOR scores, particularly for Vietnamese and Chinese simple summaries. These patterns suggest that while traditional MT tools may better preserve surface form, LLMs may capture broader semantic intent in some contexts.

Language-specific trends further illustrate the complexity of multilingual medical translation. Chinese translations showed a marked decline in performance for complex summaries, highlighting challenges related to segmentation and specialized terminology. Vietnamese translations were comparatively robust across summary complexity, while Arabic translations improved for more complex input, potentially due to increased contextual redundancy supporting disambiguation in morphologically rich language structures. Importantly, metric-based performance alone does not indicate clinical safety or appropriateness for health care use.

Implications

These findings should be interpreted in light of how translation quality is evaluated and how AI translation tools are used in real-world health care settings. Differences observed between systems reflect not only model capability but also the interaction between evaluation metrics, linguistic structure, and user behavior.

Automatic translation metrics such as BLEU and CHR-F prioritize surface-level similarity and therefore favor systems optimized for n-gram alignment. METEOR partially accounts for paraphrasing but remains unable to capture clinical salience, pragmatic intent, or contextual appropriateness. As a result, metric differences should not be interpreted as indicators of clinical safety. In health care communication, mistranslating a medication name or dosage carries far greater risk than stylistic variation, yet current metrics penalize both equally [30,31]. This reflects a broader challenge in evaluating AI-generated medical translations.

Differences between LLMs and traditional MT tools further illustrate this issue. Traditional MT systems generally achieved higher surface-level scores, while LLMs often produced more fluent and paraphrased outputs that diverged structurally from professional reference translations. Reliance on automatic metrics alone may therefore underestimate communicative strengths while simultaneously obscuring clinically meaningful errors that require expert judgment to identify.

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The observed language-specific patterns underscore the need for language-aware evaluation approaches. Performance differences across Arabic, Chinese, and Vietnamese suggest that linguistic structure, morphology, and contextual density influence how effectively models disambiguate clinical meaning. These findings caution against assuming uniform translation performance across languages in health care contexts.

Finally, the results must be interpreted in the context of real-world use. The workflows evaluated in this study intentionally reflect nonexpert use, where patients or carers rely on publicly accessible tools without structured prompts, terminology constraints, or professional oversight. Translation quality in LLMs is known to be prompt sensitive [32,33], and professional translation workflows increasingly involve human postediting of machine-generated drafts. Accordingly, the findings represent feasibility and risk under typical lay-user conditions rather than upper-bound system capability.

Limitations and Future Directions

This study has several limitations that define its methodological scope and directly inform future research priorities.

First, the experimental design reflects lay-user translation behavior rather than professional or clinical workflows. We used a single minimal prompt for LLMs and default web interfaces for MT tools, without terminology constraints, glossary enforcement, abbreviation expansion, or structured output formats. While such safeguards are standard in clinical translation services, they are rarely applied by nonexpert users. Future work should systematically compare lay-user workflows with clinically realistic translation pipelines to distinguish model capability from misuse-related risk.

Second, no human expert adjudication was conducted. Without clinician or professional translator review, it is not possible to classify error types, assess severity, or determine potential impacts on patient understanding or clinical decision-making [28,30,31,34]. Future studies should incorporate structured human-in-the-loop evaluation to identify safety-critical errors.

Third, the study is deliberately small in scale, using 2 simulated consultation summaries representing limited clinical contexts. This precludes generalization across specialties, documentation styles, or real-world variability. Larger multidomain datasets are required to assess generalizability.

Fourth, statistical reporting is limited to point estimates of automatic metrics. CIs, uncertainty estimation, and robustness analyses were not performed due to the small sample size. Future evaluations should adopt statistically robust analysis frameworks while avoiding overinterpretation of metric differences. While some studies indicate that LLMs themselves can be used as evaluators to grade the quality of translation, the research is still at a very early stage and lacks a comprehensive understanding of the limitations [35].

Finally, existing automatic metrics are poorly aligned with clinical risk and cannot distinguish stylistic variation from safety-critical errors. There is a clear need for translation-specific clinical evaluation frameworks that integrate human judgment and explicitly assess dimensions such as accuracy of critical entities, hallucination rate, trustworthiness, and interpretability in multilingual health care contexts [35-37].

Together, these limitations and future directions underscore that the primary contribution of this study is not to establish clinical readiness but to clarify key risks, evaluation gaps, and methodological challenges that must be addressed before AI-assisted medical translation can be responsibly used in health care communication.

Conclusion

This pilot feasibility study provides an early, structured comparison of LLMs and traditional MT tools for translating medical consultation summaries into Arabic, Chinese, and Vietnamese within a palliative care context. The findings highlight that while both system types can produce translations that appear usable under automatic evaluation metrics, performance varies substantially by language, document complexity, and evaluation method. Importantly, metric-based similarity does not equate to clinical safety, and unstructured use of AI translation tools—particularly by nonexpert users—poses tangible risks in health care communication.

This pilot feasibility study does not assess clinical safety or readiness for deployment. Instead, it clarifies key methodological challenges and evaluation gaps that must be addressed before AI-assisted medical translation can be responsibly integrated into health care practice. Human oversight and clinically grounded evaluation remain essential.

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Conflicts of Interest

None declared.

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Abbreviations

AI: artificial intelligence
BLEU: Bilingual Evaluation Understudy
CHR-F: Character-level F-score
LLM: large language model
METEOR: Metric for Evaluation of Translation with Explicit Ordering
MT: machine translation

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Patient Perceptions of Artificial Intelligence in Diabetes Self-Management: Cross-Sectional Survey Study

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Abstract

Background: Artificial intelligence (AI) is increasingly applied in chronic disease management, including diabetes, where it has the potential to support real-time data interpretation, improve clinical decision-making, and enhance patient engagement. Although AI tools are often developed to increase efficiency and personalization, there is limited evidence on how patients perceive the role of AI in managing their condition, particularly in relation to shared decision-making (SDM) and the patient–provider relationship.

Objective: This study explored how people with diabetes perceive the usefulness of AI across key self-management tasks and examined their preferences for AI versus health care provider (HCP) involvement. It also assessed predictors of AI preference and proposed a conceptual foundation for integrating AI into a triadic SDM model involving patients, HCPs, and AI.

Methods: We conducted a cross-sectional online survey of adults with diabetes in New Zealand. Participants were asked to rate 7 diabetes self-management tasks in terms of (1) current HCP involvement, (2) perceived usefulness of AI, (3) comfort with HCPs using AI, and (4) preference for AI, HCP, or both in completing each task. Tasks included data collection, data interpretation, medication adherence, treatment decision-making, lifestyle management, personal reflection, and evaluation of treatment options. Both ordinary least squares regression and ordinal logistic regression (proportional odds models) were used to identify predictors of AI preference.

Results: A total of 48 participants completed the survey. Of these participants, 38 (79%) were female, 27 (56%) were aged 26 to 45 years, and 26 (54%) had higher education. Mean HCP involvement across tasks was 2.82 (SD 1.23; range 1-5). AI was viewed as moderately useful overall (mean 3.67, SD 1.20), with highest usefulness for tracking (mean 4.23, SD 1.06) and interpreting information (mean 4.40, SD 0.87). Actual AI use was reported by 15/48 (31%) participants. Participants preferred HCP involvement for tasks involving treatment decision-making (17/48, 35% vs 9/48, 19%) and personal reflection (23/48, 48% vs 9/48, 19%). Across regression models, perceived usefulness of AI was a significant predictor of preference for AI in 4 tasks: data collection (P=.02), data interpretation (P=.005), treatment decision-making (P=.04), and lifestyle management (P=.046). The patient-HCP relationship significantly predicted lower preference for AI in treatment decision-making (P=.03) and medication adherence (ordinary least squares P=.005). Comfort with HCPs using AI was generally nonsignificant. Effects were modest (adjusted R^2=0.08-0.21).

Conclusions: Patients demonstrated task-specific openness to AI involvement in diabetes management, particularly for structured, data-intensive activities. These findings provide a foundation for future development and evaluation of AI-integrated SDM models. Broader exploration of technology types, relationship dynamics, and collaborative decision-making will be essential as AI becomes increasingly embedded in chronic care management.

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KEYWORDS

artificial intelligence; diabetes self-management; shared decision-making; patient preferences; digital health; chronic disease management

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Introduction

Background

Diabetes is one of the most significant global health challenges, with the number of affected adults projected to reach 783 million by 2045 [1]. In 2021, diabetes ranked among the top 10 causes of mortality worldwide, contributing to 6.7 million deaths and health care costs nearing US $1 trillion [1]. As the prevalence of diabetes continues to rise, effective care and management strategies are urgently needed. Despite advances in diabetes care, many individuals struggle with poor glycemic control, increasing their risk of complications. In New Zealand, a review of more than 3500 individuals with type 2 diabetes found that more than half had uncontrolled diabetes [2]. Contributing factors include late diagnosis, inequitable distribution of medical resources, inadequate support for lifestyle changes, and weak therapeutic relationships between patients and health care providers (HCPs) [2,3]. These factors compromise both clinical outcomes and patient engagement in care.

Shared decision-making (SDM) is a cornerstone of patient-centered care and is particularly important in chronic conditions such as diabetes, where daily self-management depends on aligning clinical guidance with the patient's goals, values, and lived experience [4,5]. SDM fosters collaboration between patients and HCPs to select treatments and self-management strategies that reflect personal preferences and real-time health needs [6,7]. When effectively implemented, SDM builds trust, enhances confidence, and supports long-term self-efficacy [8]. However, SDM in practice is often constrained by time pressures, limited health literacy, and role confusion between patients and HCPs [9-11]. These barriers can result in mismatched expectations and leave patients to self-manage without meaningful collaboration, thereby undermining the very goals of SDM [7,12]. Furthermore, while patients value active participation in decision-making [13,14], evidence on how patients perceive SDM in their care remains scarce [15].

Artificial intelligence (AI) has emerged as a potential enabler of more responsive, patient-centered diabetes care [16]. AI-enabled technologies, including continuous glucose monitors (CGMs), mobile health apps, and smart insulin pumps, provide real-time tracking, data interpretation [3,17-21], and personalized feedback for dietary choices, exercise planning, and medication decisions [22-26]. These tools help patients manage their condition outside clinical settings, which is essential for sustained engagement and the prevention of long-term diabetes complications [23]. Recent studies also suggest AI has the potential to support aspects of SDM by simplifying complex medical information [23,26,27], helping patients to evaluate treatment options [3,28], and generating personalized insights to inform conversations with HCPs. While these capabilities align with the goals of SDM—supporting informed, values-aligned decisions—they are rarely discussed in relation to the relational dynamics that SDM entails. Existing research tends to focus on AI's functionality in isolation, rather than its role in collaborative decision-making frameworks. Recent literature shows that patient acceptance of AI depends not only on functionality but also on trust, safety, and transparency [29,30]. Although patients may find AI tools helpful, they remain cautious about potential risks, data privacy, and the possibility of misinterpretation, and many still depend on HCP guidance to interpret AI outputs. Acceptance is further shaped by digital literacy, comorbidities, or socioeconomic factors [29].

These evolving insights highlight the need to understand not only how patients use AI tools but how they perceive AI's role relative to HCPs in the complex, relational process of decision-making. In chronic disease contexts like diabetes, decisions such as interpreting glucose data, adjusting behaviors, or understanding treatment options are made outside clinical consultations and increasingly involve digital tools. Yet current research rarely examines how patients distribute trust, responsibility, and decision-making authority among themselves, their HCP, and AI.

This study contributes to the SDM literature in 3 ways. First, it disaggregates diabetes care into 7 distinct self-management tasks, mapping patient preferences for AI versus HCP involvement in each. Second, it empirically tests how patient-HCP, patient-AI, and HCP-AI relationships influence these preferences. Third, it proposes a novel triadic SDM framework that reimagines decision-making as a distributed process involving human and digital actors, thereby expanding current conceptualizations of SDM beyond the consultation room. The novelty of this framework lies in its examining of patients' views on 3 dyadic interactions in SDM and in assessing their relative importance in shaping preferences for either HCPs or AI at each step of the diabetes management process.

Conceptual Framework

Our proposed triadic model expands traditional SDM by incorporating AI as an additional decision partner (Figure 1). This model is a theoretical extension of existing SDM models, incorporating AI as a third actor based on prior literature and clinical reasoning. It is not presented as an empirically validated model but as a conceptual lens that focuses on patient perceptions of 3 key relationships—patient-HCP, patient-AI, and HCP-AI—and how these shape preferences for decision support across specific diabetes self-management tasks.

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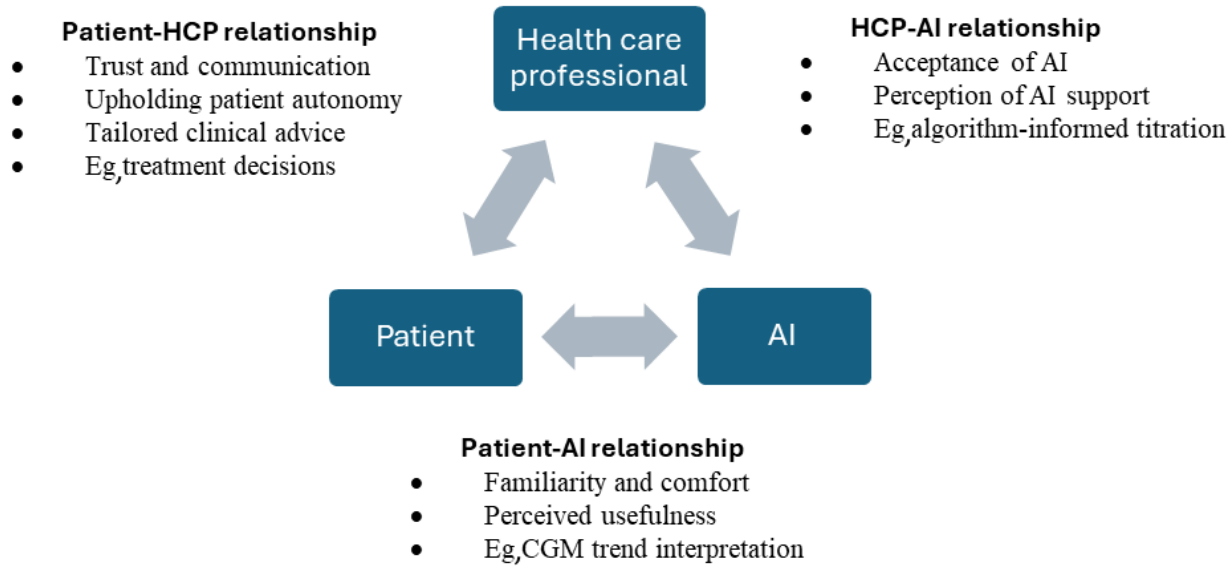
Figure 1. The triadic shared decision-making framework integrating artificial intelligence (AI) in diabetes care. CGM: continuous glucose monitoring; HCP: health care professional.



Patient-HCP relationship refers to the patient's perception of their HCPs' involvement in their care and reflects trust, communication, and confidence in the HCP to make clinical decisions. As patients take on more responsibility for daily self-management, they rely on continuous support from HCPs to ensure that their decisions are aligned with long-term health goals [5,28]. Our research explores whether AI is likely to require HCPs to continue to support patients or, alternatively, whether it would allow patients to feel more autonomous and less reliant on their HCPs.

Patient-AI relationship refers to the patient's familiarity and perceived usefulness of AI for self-management tasks. AI provides personalized recommendations based on real-time data, enabling patients to make informed decisions about their care [16,24,31]. Our research examines whether a higher perceived usefulness of AI can, in fact, enhance patients' preferences for AI. We note that perceived usefulness may reflect the anticipated value of AI, which is not always based on direct experience. This differs from the patient-HCP relationship, which often reflects accumulated lived interactions.

HCP-AI relationship refers to the patients' acceptance of HCPs using AI to inform care. Current research suggests that HCPs remain the primary decision-makers for tasks requiring clinical judgment and empathy, particularly for complex cases where patients rely on their expertise [21,31]. Our research explores whether patients accept HCPs using AI in their treatment and for which tasks.

AI is not treated as a monolithic tool but conceptualized along a spectrum from passive (eg, data collection) to active (eg, predictive suggestions) to actively assistive (eg, closed-loop insulin pumps). Each actor contributes to different phases of diabetes self-management, ranging from data tracking to contextualized decisions, depending on the nature of the task and the capabilities of the support system.

Bidirectional arrows between AI and patients/HCPs are used to represent perceived interactions**,** not literal reciprocity. While AI does not reciprocate relationships, it can offer feedback loops (eg, data interpretation, tailored prompts) that patients experience as responsive or personalized. Similarly, HCPs may rely on AI insights to inform care decisions. In the model, these constructs are treated as parallel relational perceptions rather than equivalent forms of experience.

Self-Management Tasks

This study focuses on specific self-management tasks to address 2 overarching types of processes: data-driven tasks and contextualized decision-making tasks (Textbox 1).

Data-driven tasks include activities such as collecting health data, interpreting trends, and evaluating general treatment information. These tasks are supported by current AI technologies (eg, CGMs, mobile health applications with predictive capabilities). Patients often perform these tasks independently, with AI enabling tracking, interpretation, and visualization of data. In this sense, AI acts as an enabler of self-efficacy, often facilitating early insights or triage that may later be shared with HCPs. Contextualized decision-making tasks include clinical judgment (eg, selecting treatment plans, medication adherence) and personal reflection (eg, weighing personal pros and cons, aligning care with goals and values). We group them together to highlight a shared demand for understanding beyond data. These tasks rely on contextualized reasoning, relational trust, and emotional nuance. AI may support aspects of this domain through decision aids, reminders, or empathetic conversational agents, but cannot yet fully replicate the relational aspects of human care.

The 7 tasks selected for this study were informed by established patient-centered categories of daily diabetes management, particularly those outlined by Moser et al [32]. These tasks represent broad, recurring decision-making processes that patients commonly navigate in routine care, rather than an exhaustive list of all diabetes-related behaviors. This classification also reflects the fundamental functions of AI, which range from collecting and processing information (often

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referred to as big data approaches) to learning from this data through machine learning, and ultimately adapting and personalizing outputs to individual contexts [33]. Previous research highlights the value of AI-driven tools to enhance patient knowledge and tailor support to their real-time needs [3]. In this sense, the selected tasks reflect high-level domains where decision-making could plausibly be distributed between patients, HCPs, and AI systems.

Textbox 1. Patients' diabetes self-management strategies and tasks associated with them.

Data-driven tasks

- Collecting and tracking health data (eg, blood glucose levels and medical history): routine data capture and monitoring supported by wearables and sensors.
- Interpreting diabetes data (eg, analyzing blood sugar levels and recognizing potential problems or complications that may arise): AI tools can detect patterns and provide alerts and/or predictions.
- Evaluating medical information, including pros and cons of different treatments: focuses on information retrieval and comparative decision support by identifying or summarizing research evidence (eg, guidelines) to present evidence-based options.

Contextualized decision-making tasks

- Personal reflection (ie, sharing thoughts and feelings about personal circumstances, goals, beliefs, and values): reflecting on personal health beliefs to weigh up personal pros and cons of treatment and lifestyle options.
- Lifestyle management (ie, managing diet, exercise, and lifestyle): integrating healthy eating, physical activity, and social and emotional support.
- Medication adherence (ie, taking medications correctly): following prescribed medication schedules and ensuring consistent use of medications. Requires a mixture of habit-forming and behavioral support.
- Seeking medical advice on how to manage diabetes/deciding on the best treatment plan: involves seeking guidance and making informed decisions when encountering unexpected health issues or irregularities.

Methods

Study Design

The study used a cross-sectional quantitative survey design. We followed the STROBE (Strengthening the Reporting of Observational Studies in Epidemiology) guideline for observational studies (Checklist 1) and the online survey component is reported according to the CHERRIES (Checklist for Reporting Results of Internet E-Surveys) checklist (Checklist 2).

Ethical Considerations

Ethical approval was granted by the University of Auckland Human Participant Ethics Committee (Reference number 26326). Consent was obtained via participants clicking a button to show they had read and accepted participation in the study. No identifying information (including IP addresses) was collected. Data were stored on a secure, password-protected server at the University of Auckland. As compensation, participants could enter a draw to win 1 of 2 US $90 supermarket vouchers to acknowledge their participation.

Recruitment

Participants were recruited via convenience sampling from New Zealand (NZ) diabetes organizations, including Diabetes NZ, Manawatu Horowhenua Tararua Diabetes Trust, North Shore Diabetes Support Group, Diabetes Wellington, and Diabetes Trust Palmerston North, as well as diabetes-focused Facebook groups and online communities. These organizations were contacted through email, telephone, or private messaging to request their assistance and consent to advertise the questionnaire to their members through their channels. Inclusion criteria were NZ residents aged 18 and older who had been diagnosed with type 1 or type 2 diabetes. To participate, individuals were not required to have prior experience with AI. Because the survey link was openly distributed through diabetes organizations and social media, the number of individuals who viewed the invitation could not be determined, and participation and completion rates could not be precisely calculated.

Survey Design

As no existing validated instrument captured the task-specific distribution of AI versus HCP involvement in diabetes self-management, bespoke items were developed for this study. The quantitative survey was informed by existing literature and expert consultation and was designed to explore participants' perceptions of AI and their preferences for AI versus HCP involvement across a range of self-management tasks. Because each task reflects a distinct and conceptually independent aspect of diabetes self-management, these items were treated as independent ratings rather than components of a unified scale. For this reason, no internal consistency or reliability testing was conducted. The questionnaire used a fixed item order; no randomization or adaptive questioning was applied. Participants were able to review and change their responses using a back button throughout the survey.

The survey consisted of 5 sections comprising 26 mandatory questions. The first section assessed the impact of diabetes on participants' daily life, including physical, emotional, social, financial, as well as what strategies they currently used to manage their condition (eg, blood glucose monitoring, medication use, dietary changes, and stress management). The second section examined motivation, knowledge, and perceived control of their diabetes. Participants were asked how motivated they felt to manage their diabetes, how this motivation had changed over time, how knowledgeable they felt about their

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condition, and how much control they believed they had over their diabetes.

The third section assessed the importance of specific tasks and the current role of HCPs in managing these tasks. Participants rated the importance of 7 diabetes self-management tasks and the degree to which their HCP was currently involved in each. These tasks were presented with high-level descriptors. For example, "sharing your thoughts and feelings about your personal circumstances, goals, beliefs, and values" was used to represent the task we categorized as *personal reflection*.

The fourth section focused on use and perception of AI. Participants were provided with a definition of AI in the context of diabetes care:

> *Artificial Intelligence (AI) is increasingly being used in healthcare to help people manage their diabetes. For instance, an app could use AI to analyze a person's diet, medication, exercise, and blood sugar levels, and then give personalized advice to help them control their blood sugar. Additionally, AI can be used in other ways, including wearable devices (eg, smart watches), continuous glucose monitoring devices (eg, Dexcom™, Freestyle Libre™), computerized insulin pumps, or diagnostic tools used by clinicians.*

Participants were asked whether they currently used AI for each of the diabetes tasks (Yes/No), how useful they would find AI for those tasks, and how comfortable they were with their HCP using AI to assist in their care. The survey did not focus on specific AI technologies used.

The final section collected demographic information, including age, gender, ethnicity, education level, and region of residence.

Data Collection

The questionnaire was piloted with 6 people (3 with type 2 diabetes) for clarity, comprehension, and wording, but did not include psychometric validation. Based on feedback, jargon and ambiguous terminology were reworded, repetitive or obscure questions were removed, and further examples of AI were given to aid comprehension. Pilot survey results were excluded from the final dataset. Qualtrics (Qualtrics) was used to create, distribute, and manage the questionnaire and data collection. The software afforded participants anonymity and allowed for convenient distribution. Data were collected from September 1 to 30, 2023.

Statistical Analysis

While the survey included broader items on motivation and disease impact, this study reports only responses relevant to AI-supported care and SDM. Additional analyses will be reported in future publications.

Descriptive statistics (means, SDs, percentages) were used to summarize participant demographics and survey responses. For each self-management task, 4 key variables were derived:

1. Perceived HCP involvement (patient-HCP relationship)—rated on a 5-point Likert scale (1=not at all, 5=a great deal).
2. Perceived usefulness of AI (patient-AI relationship)—rated on a 5-point Likert scale (1=not at all, 5=a great deal).
3. Comfort with HCP using AI (HCP-AI relationship)—rated on a 7-point Likert scale (1=strongly disagree, 7=strongly agree).
4. Preferences for a human HCP provider—rated on a 5-point scale (1=HCP only, 3=AI and HCP equally, 5=AI only).

Task-specific preferences for AI were analyzed using both ordinal logistic regression and ordinary least squares (OLS) regression on the 5-point outcome. This dual approach is consistent with recommendations in behavioral and health research, where 5-point Likert-type variables are frequently treated as either ordered categories or approximately interval. Extensive simulation work shows that parametric analyses remain robust to violations of interval-level assumptions when scales contain 5 or more response categories [34,35]. For tasks 2 - 5, where the proportional-odds assumption was satisfied, ordinal logistic regression served as the primary analysis; for tasks 1 and 6, where this assumption was violated, interpretation relied on the corresponding OLS estimates.

The patient-HCP, patient-AI, and HCP-AI relationships were entered simultaneously (enter method) rather than using stepwise selection to minimize the risk of overfitting and enhance interpretability.

Data analysis was performed using SPSS (version 29; IBM Corp), and statistical significance was set at $P<.05$. Adjusted R^2 values are reported to indicate model fit. Due to the modest sample size (N=48), findings are interpreted as exploratory and hypothesis-generating. Post hoc power calculations indicate that with 5 predictors in the regression models, this study had approximately 80% power to detect an overall model effect of about $R^2\approx0.23$ (Cohen $f^2\approx0.30$) at $\alpha=.05$. Power to detect smaller effects (eg, $R^2=0.10$) was low (~0.34). Accordingly, nonsignificant findings should not be interpreted as evidence of no association.

Results

Participant Demographics

A total of 48 participants (N=48) completed the survey. Of the 48 participants, 27 (56.3%) had been living with diabetes for more than 10 years, 38 (79.2%) were female, 27 (56.3%) were aged 26 to 45 years, and 36 (75%) identified as European. A majority had higher education qualifications (26/48, 54.2%). Participants were distributed throughout New Zealand, with the highest concentration of participants located in Auckland and Coromandel (15/48, 31.3%) (Table 1).

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Table . Participant demographics (N=48).

Characteristic	Participants, n (%)
Age, y	
18-25	9 (18.8)
26-35	14 (29.2)
36-45	13 (27.1)
46-55	7 (14.6)
56-65	2 (4.2)
>65	3 (6.3)
Gender	
Female	38 (79.2)
Male	8 (16.7)
Ethnicity	
Asian	3 (6.3)
Māori	4 (8.3)
MELAA[a]	1 (2.1)
European	36 (75)
Pacific People	1 (2.1)
Other	3 (6.3)
Education	
Some secondary school	3 (6.3)
Completed secondary school	8 (16.7)
Technical certificate	10 (20.8)
Bachelors degree	19 (39.6)
Postgraduate degree	7 (14.6)
Other	1 (2.1)
Diabetes diagnosis duration	
<1 y	4 (8.3)
1 - 5 y	10 (20.8)
5 - 10 y	8 (16.7)
>10 y	26 (54.2)
Region	
Northland	2 (4.2)
Auckland and Coromandel	15 (31.3)
Waikato	6 (12.5)
Manawatu	4 (8.3)
Bay of Plenty	1 (2.1)
Hawkes Bay and Gisborne	1 (2.1)
Wellington	9 (18.8)
Canterbury	8 (16.7)
Otago	1 (2.1)
Southland	1 (2.1)

[a]Middle Eastern, Latin American, African.

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AI Use and Perception in Diabetes Management

Participants rated HCP involvement in diabetes management tasks as modest overall (mean 2.82, SD 1.23; 5-point scale; Table 2). Involvement was particularly low in tasks related to lifestyle management (mean 2.28, SD 1.19) and personal reflection (mean 2.44, SD 1.35). In contrast, participants rated AI as moderately useful (mean 3.67, SD 1.20; 5-point scale). AI was seen as particularly useful for collecting and tracking data (mean 4.23, SD 1.06) and for interpreting diabetes data (mean 4.40, SD 0.87). However, the actual use of AI across all tasks remained relatively low (mean usage rate of 31%), suggesting a gap between perceived usefulness and real-world adoption. AI use was most common for tasks involving health data tracking and interpretation, and least common for personal reflection.

Participants' comfort with HCPs using AI was high across all tasks (mean 5.27; 7-point scale), indicating general openness to AI-assisted care, especially when used by an HCP in their care. There was a noteworthy preference for AI where the utility was already recognized (tasks 1 and 2).

Table . Mean (SD) scores of survey data related to diabetes management tasks and the use and perception of artificial intelligence (AI) in these tasks (N=48).

	Patient-HCP[a] relationship	Patient-AI relationship		HCP-AI relationship	Patient's relationship with HCP and AI
Tasks	HCP's current involvement (1=Not at all; 3=Moderate; 5=A great deal)	AI usefulness (1=Not at all; 3=Moderate; 5=Extremely)	Current use of AI (0=No; 1=Yes)	Agree with HCP using AI (1=Strongly disagree; 5=Somewhat agree; 7=Strongly Agree)	Preference for 1=HCP only; 3=HCP & AI; 5=AI only[b]
Task 1: Collecting and tracking health data	3.10 (1.15)	4.23 (1.06)	0.58	5.81 (1.23)	3.48 (0.85)
Task 2: Interpreting diabetes data	3.02 (1.19)	4.40 (0.87)	0.50	5.71 (1.27)	3.25 (0.81)
Task 3: Seeking medical advice and making treatment decisions	3.06 (1.21)	3.60 (1.17)	0.25	5.30 (1.69)	2.77 (1.04)
Task 4: Lifestyle management	2.28 (1.19)	3.52 (1.37)	0.21	4.98 (1.82)	3.26 (0.85)
Task 5: Medication adherence	3.00 (1.34)	3.83 (1.2)	0.32	5.42 (1.67)	2.90 (1.04)
Task 6: Personal reflection	2.44 (1.35)	2.61 (1.44)	0.09	4.33 (1.94)	2.54 (1.17)
Task 7: Evaluating medical information	2.83 (1.19)	3.52 (1.27)	0.23	5.35 (1.54)	2.88 (0.94)
Overall mean	2.82 (1.23)	3.67 (1.20)	0.31	5.27 (1.59)	3.01 (0.96)

[a]HCP: health care professional.

[b]Preference ratings indicate participants who preferred to perform each task.

Participant Preferences for AI Versus HCPs

When asked to choose between AI, HCPs, or both for completing specific tasks, participants demonstrated a clear task-specific preference pattern (Figure 2). They favored AI for data-driven tasks, such as collecting and tracking data (mean 3.48, 50%) and interpreting data (mean 3.25, 33%), while HCPs were preferred for contextualized tasks involving clinical judgment (eg, treatment decisions, mean 2.77, 35%) and personal reflection (mean 2.54, 48%).

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Figure 2. Bar graph showing the percentage of patients who preferred artificial intelligence (AI) or health care providers (HCPs) for each diabetes task.

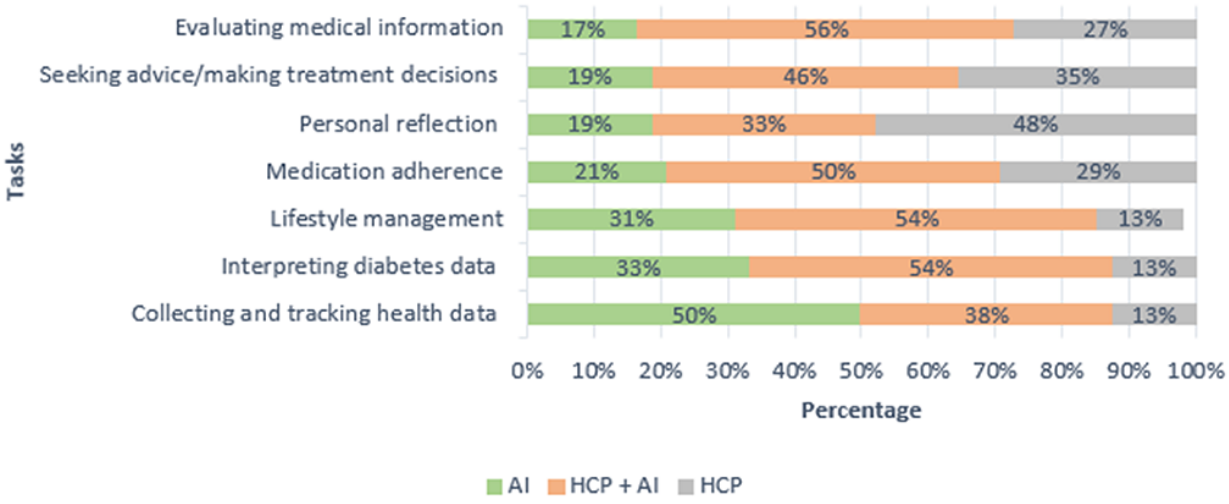

Table 3 summarizes the results of the OLS and ordinal logistic regression models. Across both modeling approaches, with the exception of 2 effects in task 5, consistent patterns emerged. The participants' perceived usefulness of AI (the patient-AI relationship) was a positive predictor of AI preference for four tasks: collecting/tracking health data, interpreting data, seeking medical advice/treatment decisions, and lifestyle management, with no significant effects observed for the remaining tasks. These associations suggest that individuals who perceive AI as valuable may be more inclined to accept its use across a range of diabetes self-management functions. Conversely, the patient-HCP relationship negatively predicted AI preference for treatment decision-making (both models) and medication adherence (OLS model only). These findings suggest that stronger engagement with HCPs reduces preference for AI in tasks requiring clinical judgment or behavioral support. Perceptions of the HCP-AI relationship (ie, their comfort with clinicians using AI) showed minimal influence, reaching significance only for medication adherence in the ordinal model. Gender and age did not reliably predict AI preferences. The convergence across analytical approaches strengthens confidence in the robustness of these findings despite the modest sample size.

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Table . Regression results (enter method) predicting participants' preferences for artificial intelligence (AI) versus health care professional (HCP).[a]

Predictor/ summary	Task 1: collecting and tracking	Task 2: interpreting data	Task 3: medical advice/treatment decisions	Task 4: lifestyle management	Task 5: medication adherence	Task 6: personal reflection
OLS[b] model summary	• $F(5,42)=2.05$ • $P=.09$ • Adj $R^2=0.10$	• $F(5,42)=2.39$ • $P=.05$ • Adj $R^2=0.13$	• $F(5,41)=3.22$ • $P=.015$ • Adj $R^2=0.19$	• $F(5,39)=1.72$ • $P=.15$ • Adj $R^2=0.08$	• $F(5,41)=3.52$ • $P=.01$ • Adj $R^2=0.21$	• $F(5,40)=2.22$ • $P=.07$ • Adj $R^2=0.12$
Ordinal model summary	• $\chi^2(5)=9.19$ • $P=.10$ • $R^2=0.19$ • PO[c] violated	• $\chi^2(5)=11.71$ • $P=.04$ • $R^2=0.24$ • PO met	• $\chi^2(5)=17.16$ • $P=.004$ • $R^2=0.33$ • PO met	• $\chi^2(5)=8.54$ • $P=.13$ • $R^2=0.19$ • PO met	• $\chi^2(5)=17.14$ • $P=.004$ • $R^2=0.33$ • PO met	• $\chi^2(5)=11.30$ • $P=.046$ • $R^2=0.23$ • PO violated
Patient-HCP	• OLS: ns[d] • Ordinal: ns	• OLS: ns • Ordinal: ns	• OLS: –.27 (.12) • $P=.03$ • Ordinal: –.67 (.26) • $P=.01$	• OLS: ns • Ordinal: ns	• OLS: –.32 (.11) • $P=.005$ • Ordinal: ns	• OLS: ns • Ordinal: ns
Patient-AI	• OLS: .32 (.13) • $P=.02$ • Ordinal: .76 (.34) • $P=.02$	• OLS: .39 (.13) • $P=.005$ • Ordinal: 1.02 (.38) • $P=.007$	• OLS: .31 (.15) • $P=.04$ • Ordinal: .63 (.32) • $P=.049$	• OLS: .25 (.12) • $P=.046$ • Ordinal: .63 (.32) • $P=.049$	• OLS: ns • Ordinal: ns	• OLS: ns • Ordinal: ns
HCP-AI	• OLS: ns • Ordinal: ns	• OLS: ns • Ordinal: ns	• OLS: ns • Ordinal: ns	• OLS: ns • Ordinal: ns	• OLS: ns • Ordinal: .48 (.24) • $P=.04$	• OLS: ns • Ordinal: ns
Gender (female)	• OLS: ns • Ordinal: ns	• OLS: ns • Ordinal: ns	• OLS: ns • Ordinal: ns	• OLS: ns • Ordinal: ns	• OLS: ns • Ordinal: ns	• OLS: ns • Ordinal: ns
Age (≥36)	• OLS: ns • Ordinal: ns	• OLS: ns • Ordinal: ns	• OLS: ns • Ordinal: ns	• OLS: ns • Ordinal: ns	• OLS: ns • Ordinal: ns	• OLS: ns • Ordinal: ns

[a]OLS: B (SE); ordinal: B (SE); OLS significance based on *t* tests; ordinal significance based on Wald tests.

[b]OLS: ordinary least squares.

[c]PO: proportional odds assumption.

[d]ns: not significant.

Discussion

Principal Results

This study explored how patients with diabetes perceive the role of AI in their self-management, focusing on task-specific preferences and perceived relationships with HCPs and AI systems. Participants generally rated their HCPs' involvement as moderate to low across most self-management tasks, especially for lifestyle support and personal reflection. In contrast, AI was rated as moderately useful, particularly for data-focused tasks like tracking and interpreting health data, although actual use of AI technologies remained limited. These results suggest a potential disconnect between perceived utility and real-world uptake, which may reflect accessibility, familiarity, or trust in existing AI tools.

Comparison With Prior Work

Clear patterns emerged in how participants allocated tasks between AI and HCPs. Consistent with prior research on technology acceptance theory [36], participants who viewed AI as useful were more likely to prefer AI involvement in data-driven tasks such as data collection and tracking and interpreting health information. These domains align with established strengths of digital tools, such as CGM devices, smartwatches, and smartphone applications in managing health data. These tools are valued for their efficiency, accuracy [31,37], and the ability to provide real-time insights, excelling in areas requiring routine monitoring and pattern recognition—areas where human oversight may be more prone to errors or delays [3,17,19,21,22]. Our findings also showed that many participants perceived AI as useful, despite having limited personal experience with AI-enabled tools, highlighting a conceptual rather than experiential form of acceptance. This distinction is important, as users may associate step tracking or glucose monitoring with AI, even when the device itself lacks predictive or adaptive features. Although the study employed a broad and accessible definition of AI in the survey, AI capabilities vary widely, and the line between "monitoring" and

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"intelligent assistance" is often blurred. The gap between perceived usefulness and actual use may also reflect broad awareness of AI's potential coupled with limited access to more advanced tools, leading participants to endorse AI aspirationally rather than from direct experience.

In contrast, participants preferred HCPs for tasks involving clinical judgment (particularly medication and treatment decisions) and personal reflection (eg, goal alignment). The regression analyses indicated that stronger patient-HCP relationships were associated with lower preference for AI in clinically sensitive tasks, tentatively highlighting the importance of human involvement in tasks requiring contextual judgment and personalized clinical guidance [38]. While some studies suggest a strong, ongoing preference for HCPs over AI [24,39], others highlight emerging support for a blended approach that combines the efficiency and analytical strengths of AI with the relational strengths of HCPs [17,21,40]. These mixed preferences are likely due to the still-evolving nature of AI applications and their ability to deliver contextually relevant recommendations. For instance, AI shows promise in improving the accuracy of dietary monitoring and enhancing patients' understanding of complex medical information tailoring [3,41], but limited adoption may stem from challenges in addressing cultural and individual preferences [39]. In New Zealand, Māori and Pacific Peoples have shown a strong preference for human involvement in health care, reflecting cultural values that prioritize personal connections and face-to-face interactions in medical decision-making [21]. Importantly, our findings suggest that patients with weaker HCP relationships may view AI as a potential source of support where relational or clinical continuity is lacking. While this interpretation remains exploratory, it aligns with the broader aim of digital tools to enhance patient empowerment and self-engagement in care [38]. In cases where patients feel unsupported, AI may offer a sense of responsiveness or access. However, the diversity of AI tools in the marketplace is likely to contribute to varied levels of acceptance, reinforcing the need to assess AI preferences at a task and technology-specific level rather than assuming uniform acceptance or rejection.

An important finding in this study was the low perceived usefulness of AI for personal reflection, where participants overwhelmingly favored HCPs. Interestingly, participants also rated their HCP's current involvement in personal reflection as below average, highlighting a broader gap in support for these more relational aspects of care. This contrasts with evidence showing that patients value opportunities to reflect on how diabetes affects their symptoms, daily lives, and treatment plans [9,42]. One possible explanation for this discrepancy is uncertainty about the relevance of personal reflection to SDM or limited prior experience with these conversations in routine care. Patients may also hesitate to express vulnerability to a non-human entity, given their reliance on HCPs for empathy, compassion, and trust to aid decision-making [43]. Given AI's current inability to replicate these human attributes fully, there are understandable doubts about its effectiveness in offering personal support or facilitating deeper patient-HCP relationships. However, recent developments in generative AI suggest this may be changing. Studies show that AI systems can exhibit empathetic tone and rapport that, in some cases, outperform physicians in perceived bedside manner [44,45]. Chatbots have also shown promise in supporting mental health, particularly where users value guidance or nonjudgmental listening [46]. Low perceived usefulness in our study may therefore reflect a lack of access or experience with these tools rather than inherent limitations.

Although the HCP-AI variable was not a significant predictor in our regression models, this measure reflects only participants' comfort with clinicians using AI and does not fully capture the broader concept of HCP-AI collaboration within decision-making. Taken together, these findings suggest that while AI may have the potential to support SDM, its integration into clinical workflows may not yet be perceived as necessary for effective collaboration. Previous studies support the notion that patients are generally comfortable with AI technologies being used by HCPs for screening and diagnosis, particularly when clear physician oversight is maintained [21,47]. Such supervision provides reassurance, increasing patient confidence in AI outputs when mediated by their clinicians. For HCPs, delegating routine tasks to AI could theoretically free up time for higher-value interactions with patients, enhancing personalized diabetes care [3], improving diagnostic accuracy, and reducing bias in treatment-related decisions [21]. However, the potential of AI in data collection and tracking remains underrecognized despite its demonstrated efficiency and utility in these tasks [48,49].

Limitations

Several limitations should be considered when interpreting the findings of this study. While we propose a triadic AI-SDM model involving patients, HCPs, and AI tools, the regression analyses conducted in this study treated each relationship (patient-HCP, patient-AI, HCP-AI) as an independent predictor of AI preference. This statistical approach allowed exploration of relational perceptions individually, but did not fully capture the collaborative and interactive dynamics central to SDM. Furthermore, although the task preference measure was adapted from the Control Preferences Scale, it assessed which actor (AI, HCP, or both) participants preferred to perform each task, rather than the extent of collaboration or shared agency. As such, our findings reflect task assignment preferences rather than preferences for co-deliberation or SDM processes. Additionally, the perceptions of AI usefulness may not align with future real-world experiences, particularly since participants varied in their direct exposure to AI tools. This perception–experience gap is typical in early adoption cycles and should be evaluated longitudinally in future work.

We also did not measure or adjust for several clinical and experiential factors that could plausibly influence both perceived usefulness and preferences for AI, such as diabetes type, duration of diabetes, comorbidity burden, prior use of digital health tools (eg, CGMs, apps), or digital health literacy. Unmeasured confounding may therefore contribute to the observed associations. Future research with larger samples should incorporate these covariates and test more fully adjusted models.

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Because this was a self-report survey, responses may also be subject to recall bias, social desirability bias, and variations in participants' interpretations of key terms. Although we provided a standardized definition of "AI," individual mental models of AI likely differed, given the rapid evolution of AI technologies and varying levels of familiarity among participants. The 5-point preference scale included a midpoint ("both equally"), but we cannot determine how consistently respondents interpreted this option. Several constructs were measured using single-item indicators, which can introduce measurement noise even though this approach reduced respondent burden. Responses may also have been influenced by the online survey format, including differences in device type or environmental distractions.

The modest sample size further limits statistical power and increases the risk of type II error, meaning that small to moderate associations may have been missed. In addition, estimates from multivariable models in small samples can be unstable (ie, sensitive to small changes in the data), so coefficients and standard errors should be interpreted cautiously. In line with the post-hoc calculations reported above, the study was best powered to detect moderate to large overall effects.

Over half of our population had higher qualifications, and 75% were between 18 and 45 years old, with 66.7% living in larger cities in New Zealand, which can be attributed to the location of diabetes organizations that promoted the survey. This recruitment approach may have disproportionately attracted individuals who are more digitally engaged or open to technology, potentially inflating the perceived usefulness of AI relative to the broader diabetes population. Māori were underrepresented compared to national averages [50] as were older adults, who often have different cultural expectations and relational preferences in health care. Thus, our findings should be interpreted as exploratory and reflective of a digitally engaged subset rather than the general New Zealand diabetes population. Additionally, the absence of qualitative data limits our ability to fully understand the potential fears, mistrust, or contextual factors influencing participants' preferences and attitudes toward AI and HCP collaboration. Data-wise, the study's adjusted R^2 values ranged from 0.08 to 0.21, indicating that our model explains only a small proportion of the variance in AI-related preferences. This suggests that other unexplored factors, such as familiarity with technology or past experiences with AI, likely play a role in shaping preferences. These modest values suggest that AI preferences are influenced by numerous additional factors not accounted for in the current models, and the observed associations should therefore be interpreted as limited and exploratory.

Implications for Health Care

Integrating AI into diabetes care offers a promising opportunity to address the challenges in primary care settings, including time constraints, limited staffing, and the growing complexity of chronic disease management [24,51]. Our findings suggest that participants in this sample appeared more receptive to AI for data-driven, routine tasks, such as collecting, tracking, and interpreting information, where automation could relieve HCP workload and increase system efficiency. This aligns with our regression results, which showed strong associations between perceived usefulness of AI and preferences for AI involvement in these tasks. In contrast, participants preferred HCP involvement in treatment decision-making, medication adherence, and personal reflection, emphasizing the importance of human relationships and relational trust in these domains.

For HCPs considering the integration of AI into practice, several actionable recommendations emerge:

- Prioritize AI for backend data analysis, pattern recognition, and patient self-monitoring tools, where patient preference for automation is stronger. Use AI outputs to inform, but not replace, clinical conversations.
- HCPs should clearly explain to patients when and how AI tools are being used, especially in emotionally sensitive or decision-making contexts, to avoid undermining trust.
- Recognize that some patients place a high value on personal, face-to-face care. AI integration strategies should respect and adapt to these cultural expectations, ensuring that relational care is never sacrificed for technological efficiency [52].

It is also important to recognize that AI tools are not without risk. Black-box AI systems lacking transparency erode patient trust and complicate informed decision-making [28,53,54]. While human-in-the-loop models offer oversight, they are not infallible and may still perpetuate bias or introduce complacency. Additionally, the deployment of AI raises broader ethical considerations related to patient safety (eg, erroneous recommendations or automation bias), data privacy (eg, extensive data collection or unclear data-sharing pathways), and accountability for AI-supported decisions, all of which must be addressed to ensure safe integration into clinical practice. Framing AI purely as a supportive tool without critical evaluation overlooks these challenges. Instead, AI should be incorporated through task-specific validation, transparent design, ethical oversight, and continuous evaluation of patient experience.

Given the modest sample size and exploratory nature of this study, further research is needed to gain a deeper understanding of how different patient populations perceive and experience AI in care. Qualitative studies are especially necessary to explore patients' emotional safety, cultural expectations, and boundaries around AI use in relational care. Future work should also assess how specific AI tools impact trust, decision-making, and patient-HCP dynamics across diverse populations.

Conclusions

This study examined how people with diabetes perceive the role of AI in key self-management tasks and how their preferences compare with the role of HCPs. Across the sample, AI was viewed as most useful for data-driven tasks such as collecting, tracking, and interpreting health data, where its accuracy and efficiency excel. However, tasks requiring contextual judgment, emotional support, or personal reflection remain firmly within the domain of human providers.

While these findings offer early insight into how patients may distribute roles between AI and clinicians, they should not be interpreted as empirical validation of the proposed triadic AI–SDM framework. Instead, they highlight how patient

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preferences are shaped by the interplay of perceived usefulness of AI and the strength of existing patient-HCP relationships. Participants with stronger relational trust in their clinicians were less willing to allocate clinically sensitive tasks to AI, highlighting the enduring importance of human judgment and contextual understanding in SDM. Although the HCP-AI variable was not a significant predictor, this reflects the narrow focus of the survey item rather than the broader relevance of HCP-AI collaboration. Taken together, these results suggest that AI may play a complementary role in SDM, but its integration must reinforce, rather than displace, the relational foundations of person-centered care.

Future work should assess how preferences evolve over time as AI tools become more capable, regulated, and socially familiar. Longitudinal designs (eg, repeated surveys or cohort follow-up) could determine whether increasing exposure to AI-enabled diabetes technologies, improvements in explainability and safety, and shifting norms about AI-mediated care change the balance patients prefer between AI and HCP involvement, particularly for higher-stakes or more relational tasks.

Given the exploratory design, modest sample, and digitally engaged participant group, these findings should be interpreted cautiously. Nonetheless, they provide foundational insights to guide task-specific AI integration into diabetes care. Future research should examine how AI preferences vary among older adults, Indigenous communities, and rural populations and should prioritize qualitative inquiry to explore emotional safety, trust boundaries, and culturally appropriate models of AI in chronic disease management. A broader exploration of technology types, relationship dynamics, and collaborative decision-making will be essential as AI becomes increasingly embedded in chronic care.

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Conflicts of Interest

None declared.

Checklist 1
STROBE checklist.
[PDF File, 178 KB - formative_v10i1e83030_app1.pdf]

Checklist 2
CHERRIES checklist.
[PDF File, 140 KB - formative_v10i1e83030_app2.pdf]

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Abbreviations

AI: artificial intelligence
CGM: continuous glucose monitor
CHERRIES: Checklist for Reporting Results of Internet E-Surveys
HCP: health care professional

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SDM: shared decision-making
STROBE: Strengthening the Reporting of Observational Studies in Epidemiology

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Comparing 3 Goal-Setting Techniques to Promote Adherence to National Physical Activity Guidelines in Midlife Adults: Feasibility Trial of a Mechanistic Study Design

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Abstract

Background: Engaging in regular aerobic physical activity (PA) during midlife is associated with reduced risk for Alzheimer disease and related dementias. Yet, most midlife adults fail to meet national PA guidelines. Goal setting is a commonly used behavior change technique to increase PA, but limited empirical evidence exists regarding whether certain types of goal setting are more effective than others. This study served as an initial step toward understanding how different goal-setting strategies may enhance PA and promote adherence to national PA guidelines among insufficiently active midlife adults with obesity.

Objective: This study aimed to establish the feasibility and acceptability of a 4-arm mechanistic trial design comparing 3 different PA goal-setting techniques with a non–goal-setting comparison condition.

Methods: This study was a 6-month stage IA mechanistic trial (based on National Institute on Aging's Stage Model) that randomized insufficiently active midlife adults with obesity to 1 of 4 study groups: (1) Static Goal-Setting Group (weekly moderate to vigorous physical activity [MVPA] goal of 150 minutes), (2) Self-Selected Goal-Setting Group (participants self-selected a weekly MVPA goal), (3) Incremental Goal-Setting Group (weekly MVPA goal 20% greater than the previous week), and (4) Non–Goal-Setting Comparison Group (encouraged to increase MVPA without specific reference to a weekly goal). All participants (n=24) received a standardized, Social Cognitive Theory–based PA promotion intervention, which consisted of structured action planning sessions and a Fitbit activity monitor for self-monitoring of MVPA. The only difference across study groups was the goal-setting technique implemented. Primary outcomes included feasibility of study implementation, as assessed by recruitment, retention, and engagement rates; the ability to deliver the intervention as planned and collect outcomes necessary for evaluating the effects of different goal-setting techniques in a subsequent larger-scale trial; and participant acceptability of the intervention, as assessed by participant perceptions of and satisfaction with the intervention.

Results: The sample (n=24; mean age 54.1, SD 5.8 years; mean BMI 36.3, SD 5.0 kg/m^2) was recruited in approximately 4 months, equating to an enrollment rate of 6 participants per month. Retention at 6 months was 87.5% (21/24). Participants completing the intervention attended 85.9% of action planning sessions and wore the Fitbit for >10 hours per day on 87.1% of intervention days. Data collection rates for outcome measures ranged from 96% to 100%. Most participants expressed satisfaction with the intervention, with 86% (18/21) reporting gaining knowledge about PA and 90% (19/21) reporting that they would recommend the study to a friend.

Conclusions: The next step in this research is to build on these findings by conducting a larger-scale phase 1B proof-of-concept trial to examine the preliminary effects of the goal-setting techniques for increasing MVPA and promoting adherence to national aerobic PA guidelines.

Trial Registration: ClinicalTrials.gov NCT05980052; https://clinicaltrials.gov/study/NCT05980052

(JMIR Form Res 2026;10:e82494) doi:10.2196/82494

KEYWORDS

physical activity; exercise; goal setting; midlife adults; Alzheimer disease; dementia; prevention

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Introduction

Alzheimer disease and related dementias (ADRD) are progressive neurodegenerative conditions that gradually erode memory and cognitive function. As ADRD progresses, individuals slowly lose the ability to independently perform routine activities of daily living (eg, bathing, dressing, preparing meals, and managing medications) and will require increased levels of care and support. Currently, more than 7 million Americans live with diagnoses of ADRD, an estimate that is projected to increase to approximately 14 million by 2060 [1]. Despite advancements in pharmacological treatments for ADRD in recent years, there are still no cures, underscoring the need for prioritizing risk reduction, particularly through targeting modifiable risk factors, which are estimated to contribute to approximately 45% of ADRD cases [2].

Regular aerobic physical activity (PA) is an established behavior associated with reduced risk for ADRD [2-5]. Aerobic PA is believed to lower risk for ADRD by modifying a number of ADRD pathogenic processes, including reducing AD β-amyloid load, tauopathy, neurodegeneration, and oxidative stress, and increasing neurogenesis and synaptogenesis, brain-derived neurotrophic factors, and antineuroinflammation [6,7]. In addition to these neuroprotective effects, PA is a behavioral cornerstone for the prevention and management of cardiometabolic diseases (obesity, hypertension, and diabetes) [8], which are also independently associated with increased risk for ADRD [2,6,9].

Although the cognitive health benefits of regular PA are evident across the lifespan, it is especially important during midlife [2,4,10]. Maintaining high PA levels during this stage of life has consistently shown to lower ADRD risk, even among individuals who were previously sedentary [3,10]. Despite this, only half of US adults aged 45 - 65 years meet national PA guidelines for aerobic activity (ie, 150 minutes per week of moderate-intensity PA, 75 minutes per week of vigorous PA, or an equivalent combination of both moderate- and vigorous-intensity PA) [11]. Given the strong link between midlife PA and the risk of ADRD later in life, intervening to increase PA among insufficiently active individuals during midlife has potential to attenuate and reduce ADRD risk.

Previous interventions promoting PA during midlife have generally yielded modest and short-lived increases in PA [12,13]. Even among interventions that have successfully increased PA, most participants do not achieve or maintain PA levels consistent with national aerobic PA guidelines [12]. The continued inability of PA interventions to promote sustained increases in PA and adherence to national PA guidelines underscores the need for researchers to critically examine the behavior change techniques used in their intervention efforts, including those that appear to be effective, at least in the short term. Such analyses should pay particular attention to examining the psychosocial processes targeted by the behavior change techniques used, as failure to effectively engage or modify these underlying processes likely contributes to the modest impact and poor long-term adherence observed in many PA interventions. Understanding and addressing these mechanisms are essential to developing more effective interventions for promoting PA during midlife.

Goal setting is one of the most widely used behavior change techniques to increase PA. It is endorsed by leading authorities, including the National Physical Activity Guidelines for Americans [14] and the American College of Sports Medicine [15], and is a common feature incorporated into commercial PA trackers (ie, Fitbit, Garmin, and Apple Watch devices). Meta-analyses support the effectiveness of goal setting for increasing PA among participants of all ages [16,17], although long-term adherence to change is not well documented. Although goal setting appears to be an effective short-term strategy to increase PA, there is no clear consensus about how goal setting should be implemented to increase PA to support long-term engagement. This is evidenced by substantial heterogeneity in goal-setting techniques used by researchers [16] and ongoing debate in the peer-reviewed literature [18,19]. The variability and inconsistency in goal-setting techniques implemented by researchers may explain, in part, why most PA interventions fail to consistently result in participants achieving and maintaining high PA levels. Moreover, few studies have examined why different types of goal-setting techniques may be more effective for increasing PA and maintaining high PA levels than others [17].

The National Institutes of Health (NIH) Science of Behavior Change Program [20] has recommended the use of an experimental medicine approach to gain a better understanding of how and why behavior change occurs. This approach focuses on the identification and explicit testing of the underlying psychosocial processes (referred to as mechanisms) believed to underpin the use of specific behavior change techniques. In the context of PA, goal setting is thought to influence key psychosocial mechanisms of self-regulation (ie, ability to manage social, cognitive, and motivational processes to increase PA) and self-efficacy (ie, confidence or perceived ability to overcome barriers and increase PA) [15,21-24]. However, the literature lacks robust evidence on how specific goal-setting techniques influence these mechanisms, underscoring the need for mechanistic trials to empirically examine how PA goal setting can be best implemented to enhance these psychosocial processes for successful promotion of PA.

This study represented an initial step toward better understanding how different types of goal-setting techniques influence psychosocial mediators of self-regulation and self-efficacy, as well as PA and adherence to national PA guidelines. Specifically, we examined the feasibility and acceptability of a mechanistic study designed to compare 3 distinct goal-setting techniques and a non–goal setting comparison group for enhancing psychosocial constructs of self-regulation and self-efficacy and for promoting adherence to national aerobic PA guidelines. Focal areas of evaluation included the following: (1) Feasibility of study implementation, as assessed by the research team's ability to recruit, retain, and engage participants in the intervention; deliver the intervention as planned; and collect outcome data necessary for evaluating the effect of different goal-setting techniques on self-regulation, self-efficacy, and PA in a subsequent larger-scale trial. (2) Participant acceptability of the intervention, as assessed by

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participants' perceptions of and satisfaction with the intervention.

Methods

Overview

This study was conducted as part of an NIH/National Institute on Aging–funded R61/R33 phased award. The R61 phase of the award focused on intervention development and feasibility testing through conducting a stage IA feasibility trial to inform intervention refinement in preparation for larger-scale testing in a stage IB proof-of-concept trial in the R33 phase, which will evaluate the effects of goal-setting techniques to increase PA, promote adherence to national PA guidelines, and enhance psychosocial constructs of self-regulation and self-efficacy. This paper reports the design and outcomes of a stage IA trial conducted as part of the R61 phase of the award. Milestones for progression from the R61 to R33 phase of the award included (1) development of all intervention materials, (2) conducting the stage IA trial (24 participants), and (3) obtaining participant feedback for refinement of the experimental approach for subsequent testing in a stage IB trial. Accordingly, the study design and feasibility outcomes of the current trial were aligned with these progression milestones, rather than selection and achievement of predefined quantitative metrics of feasibility and acceptability to justify advancement to the next stage of research.

Study Design

Guided by the NIH Stage Model [25] and the feasibility framework of Bowen et al [26], a 6-month stage IA feasibility trial was conducted using a randomized, 4-arm mechanistic study design. All participants (n=24) received a standardized, Social Cognitive Theory (SCT)–based PA promotion intervention and were randomly assigned to 1 of the 3 goal-setting conditions or a non–goal setting comparison group (Table 1). This 4-arm study design was selected because when implemented in a fully powered trial, it will enable attribution of any observed difference in self-regulation, self-efficacy, and PA across study arms to the specific goal-setting technique tested in each group. Figure 1 illustrates the conceptual model underpinning the design of the study.

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Table . Description of the 3 goal-setting experimental conditions and the non–goal-setting comparison condition tested in the 4-arm feasibility trial.

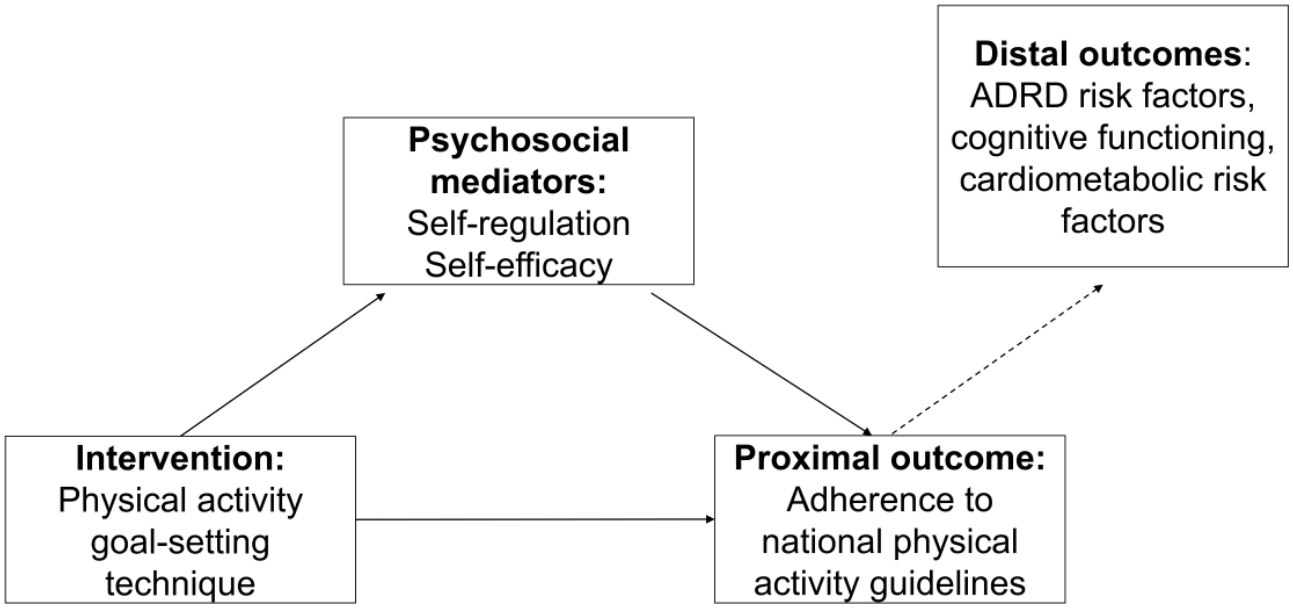
Goal-setting technique	Description	Rationale of inclusion in the proposed trial
Static weekly MVPA[a] goal of 150 minutes	Participants were assigned a fixed weekly MVPA goal of 150 minutes per week throughout the intervention. Each action planning session focused on the participant achieving this weekly goal.	This approach represents the straightforward recommendation of public health campaigns and health care providers and is a common PA[b] goal recommended in many PA promotion interventions.
Self-selected weekly MVPA goal	Participants self-selected their own minute-per-week MVPA goal each week. The goal could be any number of minutes, regardless of whether it was above, equal to, or below the national PA guidelines. Action planning sessions focused on helping participants achieve their self-selected goal.	This approach relies on the level of self-motivation to achieve the goal and incorporates participant autonomy. Self-selected goals have proven effective in both PA [16] and non–PA-related goal achievement [27]. This approach has also been suggested as ideal, particularly among individuals with low PA levels, because goals will be personally relevant, allow for flexibility, and account for priorities and time factors [16,18].
Incremental weekly MVPA goal increase	Participants were assigned a unique minute per week MVPA goal each week that was 20% greater than the minutes of MVPA performed the previous week, regardless of whether they achieved the incremental weekly goal assigned the prior week. Action planning sessions focused on the participant achieving this personalized goal.	This approach aligns with Locke and Latham's [28] goal-setting theory and tenets of SCT[c], using a gradual increase in steps to achieve national standards and allowing for steady adjustment to change in activity. Designed to make goals more achievable, this approach is predicted to lead to greater levels of self-efficacy, self-regulation, and adherence over time.
No stated MVPA goals (comparison condition)	Action planning sessions did not include explicitly stated MVPA goals. Sessions focused on increasing PA, in general, without mention of achieving a weekly PA goal.	This condition served as the comparison (or control) condition. Participants may have generated their own goals, but they were not addressed by the interventionist during PA action planning sessions. Inclusion of this study group allows for differences in PA outcomes across study groups to be attributed to the goal-setting techniques tested. This comparison group was selected instead of a wellness control or delayed intervention group because it allows for experimental testing of the effects of not using goal setting within the context of the broader SCT-based intervention provided to all participants.

[a]MVPA: moderate to vigorous physical activity.

[b]PA: physical activity.

[c]SCT: Social Cognitive Theory.

Figure 1. Illustration of the conceptual mediation model underpinning the design of the study. ADRD: Alzheimer disease and related dementias.



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Ethical Considerations

This study was reviewed and approved by the institutional review board of Arizona State University (STUDY00016394) and was registered with ClinicalTrials.gov (NCT05980052) within 30 days of enrolling the first participant. All participants provided written informed consent and were informed of their right to withdraw from the study at any time. Study data were deidentified prior to data analysis. Participants received up to US $120 in compensation (US $20 for completing the study orientation, US $50 for completing the baseline assessment, and US $50 for completing the 6-month follow-up assessment) and were allowed to keep their Fitbit Versa 2. Study methods and outcomes are reported in accordance with the CONSORT (Consolidated Standards of Reporting Trials) guidelines for randomized pilot and feasibility trials [29].

Sample Size Considerations

An a priori sample size of 24 participants was informed by recommended best practices for the design of pilot studies [30,31] and based on the research team's determination that it would provide sufficient data for evaluation of the primary aims for this phase of the research study, which were to establish the feasibility and acceptability of the scientific approach. Given that the study was not designed to assess within or between-group intervention effects, no formal power calculations were conducted.

Study Setting and Timeline

All study activities were conducted on the Downtown Campus of Arizona State University, located in Phoenix, Arizona. Recruitment occurred between June 2023 and October 2023. The first participant enrolled in the study on July 17, 2023, and the last participant completed all study-related activities on May 13, 2024, which concluded data collection for the pilot trial.

Recruitment

Community-based strategies were used to recruit participants. These strategies included email distribution lists, paid social media advertisements (ie, Facebook and Twitter), flyers posted at community locations, and word-of-mouth referrals.

Participants

Study participants (n=24) were insufficiently active midlife adults with obesity (Textbox 1).

Textbox 1. Inclusion and exclusion criteria.

Inclusion criteria

- Age 45-65 years.
- BMI between 30 kg/m^2 and 50 kg/m^2.
- Engaging in 60 minutes per week or less of self-reported moderate to vigorous physical activity at screening (based on Exercise Vital Sign Questionnaire [32]).
- Self-reported ownership of a smartphone with an iOS or Android operating system.

Exclusion criteria

- Endorsing an item on the Physical Activity Readiness Questionnaire [33] indicating contraindication to moderate to vigorous physical activities, unless written clearance from their health care provider for participation in the study was provided.
- Resting blood pressure greater than 200/110 mm Hg, as assessed at the baseline study assessment.
- Pregnant or plans to become pregnant in the next 8 months.
- Plans to relocate out of the metropolitan Phoenix, Arizona, area in the next 8 months.
- Participation in another physical activity, nutrition, or weight loss program at the time of screening or at any time during the intervention.
- Previous diagnosis of mild cognitive impairment (MCI) or a score indicative of MCI on the Montreal Cognitive Assessment [34], defined as a score of <26 for US-born participants or <23 for those who completed school in a country where English is not the primary language, as assessed during the study orientation.
- Being previously prescribed 1 of the 5 approved Alzheimer disease medications, including donepezil (Aricept), rivastigmine (Exelon), galantamine (Razadyne), memantine (Namenda), and memantine + donepezil (Namzaric).
- Scoring ≥16 on the Center for Epidemiological Studies Depression Scale.
- Current diagnosis of major depression.
- Currently taking 2 or more antidepressant drugs.
- Self-reported history of stroke.

Intervention Description

Overview

All participants received a standardized, SCT-based [22] PA promotion intervention that consisted of regular action planning sessions with a trained interventionist and a Fitbit Versa 2 activity monitor to wear daily to self-monitor their moderate to vigorous PA (MVPA). The only difference among the study groups was the specific type of PA goal participants were encouraged to achieve throughout the intervention, or the absence of goal setting in the comparison group. Additionally,

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all participants received a study handbook outlining the importance of PA for physical, mental, and cognitive health, along with tips for safely increasing activity and overcoming common barriers.

Theoretical Framework

SCT was selected as the theoretical basis for the standardized intervention delivered to study participants because it explains behavior using a dynamic and reciprocal model in which individual factors (beliefs and attitudes), the social and physical environments, and behavioral factors interact [22]. Given PA is largely influenced by an individual's thoughts, beliefs, attitudes, perceived control over their behaviors, and their social environment, SCT provided a meaningful framework to guide the PA action planning component of the intervention. Table 2 provides an overview of the SCT constructs leveraged by the intervention, as well as the specific behavior change techniques implemented in the action planning intervention based on each study group.

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Table . Overview of how the standardized intervention delivered to all study participants leveraged constructs of Social Cognitive Theory and established behavior change techniques to promote physical activity.

SCT[a] construct	Description of how the intervention targets each theoretical construct	Behavior change techniques employed based on Michie's Taxonomy (v1)[b]		Study group in which the behavior change technique was employed[c]			
		No.	Label	Static	Self-Selected	Incremental	Non-Goal
Behavioral Capability - knowledge and skill to perform a PA[d]	PA action planning materials and sessions provided information on the definitions of PA and exercise, different types of PA (aerobic vs. muscle strengthening), national PA guidelines, modes/types of PA that can be performed to achieve PA guidelines, how to determine PA intensity.	4.1	Instruction on how to perform a behavior	✓	✓	✓	✓
Outcome Expectations - Anticipated outcomes of PA	Action planning sessions provided participants with health and social outcomes associated with being physically activity, including reduced risk for ADRD[e], cognitive decline, heart disease and type 2 diabetes, weight maintenance, more energy to perform daily activities, improved quality and quantity (i.e., years) of life, being a good role model to family/friends.	5.1	Information about health consequences	✓	✓	✓	✓
		5.3	Information about social and environmental consequences				
		5.6	Information about emotional consequences				
	Action planning sessions had participants identify the personally relevant anticipated outcomes for increasing MVPA[f].	9.2	Pros and cons	✓	✓	✓	✓
		13.4	Valued self-identity				
		13.5	Identity associated with behavior change				

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SCT[a] construct	Description of how the intervention targets each theoretical construct	Behavior change techniques employed based on Michie's Taxonomy (v1)[b]		Study group in which the behavior change technique was employed[c]			
		No.	Label	Static	Self-Selected	Incremental	Non-Goal
Self-regulation-Ability to manage social, cognitive, and motivational processes to achieve a desired PA goal	Goal setting: Participants were encouraged to achieve their study-group specific weekly MVPA goal to ultimately achieve 150 min/week of moderate-intensity PA by end of the active 6-month intervention. During action planning sessions, the PA coach and participant jointly reviewed progress toward goal achievement and strategies to achieve the study-specific goal for the next week.	1.1	Goal setting (behavior)	✓	✓	✓	×
		1.5	Review of behavioral goal(s)				
		1.6	Discrepancy between current behavior and goal				
		2.2	Feedback on behavior				
	Self-monitoring: Participants used Fitbit to self-monitor MVPA.	2.1	Self-monitoring of behavior	✓	✓	✓	✓
	Self-reward: Interventionists encouraged participants in the static, self-selected, and incremental goal setting groups to create self-rewards for achieving MVPA goals. Participants in the non-goal setting group were encouraged to select self-rewards for PA behaviors in general, without reference to minutes/week of MVPA.	10.7	Self-incentive	✓	✓	✓	✓
		10.9	Self-reward				
		1.2	Problem solving	✓	✓	✓	✓
		1.4	Action planning				
		15.3	Focus on past successes				

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SCT[a] construct	Description of how the intervention targets each theoretical construct	Behavior change techniques employed based on Michie's Taxonomy (v1)[b]		Study group in which the behavior change technique was employed[c]			
		No.	Label	Static	Self-Selected	Incremental	Non-Goal
	Barrier problem solving: Participants were encouraged to identify personal barriers to MVPA and engage in problem solving discussions with action planning interventionist to overcome barriers.						
	Lapse/Relapse Prevention: Interventionists monitored Fitbit data to identify MVPA lapses and work with participants to identify reasons for lapses and to help overcome them in the future.	1.2	Problem solving	✓	✓	✓	✓

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SCT[a] construct	Description of how the intervention targets each theoretical construct	Behavior change techniques employed based on Michie's Taxonomy (v1)[b]		Study group in which the behavior change technique was employed[c]			
		No.	Label	Static	Self-Selected	Incremental	Non-Goal
Self-efficacy - Confidence in oneself to take action and overcome barriers	Mastery Experiences: Participants enact strategies identified during action planning sessions to increase MVPA and track their increases/decreases using the Fitbit and app activity tracking feature.	8.1	Behavioral practice/ rehearsal	✓	✓	✓	✓
		8.6	Generalization of a target behavior				
	Social Modeling: Action planning interventionists provided participant with strategies they utilize to be physically active and encourage participants to identify individuals in their own life they can look-up to as PA role models.	6.1	Demonstration of the behavior	✓	✓	✓	✓
		6.2	Social comparison				
	Verbal Persuasion: Action planning interventionists provided words of encouragement and empowerment for PA and provided individualized feedback/encouragement during action planning sessions.	15.1	Verbal persuasion about capability	✓	✓	✓	✓
		3.2	Social support (practical)				
		3.2	Social support (emotional)				
	Emotional arousal: Action planning sessions reinforced the notion that PA doesn't have to be structured or difficult by encouraging walking and by providing tips on how participants can incorporate more PA into the day.	15.1	Verbal persuasion about capability	✓	✓	✓	✓

[a]SCT: Social Cognitive Theory.

[b]Behavior change techniques are coded based on Taxonomy of Behavior Change (version 1) by Michie et al [35].

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[c]Check marks (✓) indicate that the behavior change technique(s) used to target the SCT construct were included in the study group's action planning sessions. Cross mark "X" mark indicates that the behavior change technique(s) were not included in the study group's action planning sessions.

[d]PA: physical activity.

[e]ADRD: Alzheimer disease and related dementias

[f]MVPA: moderate to vigorous physical activities.

In addition to SCT, Locke and Latham's Goal Setting Theory [28] guided the selection of the incremental goal-setting study group (Table 1). This theory posits that setting specific, challenging, yet achievable goals, combined with constructive feedback, enhances motivation and self-efficacy for achieving a goal, ultimately leading to behavior change to support goal attainment.

Goal Setting Experimental Conditions

Table 1 provides a detailed description and the underlying rationale for inclusion of each experimental condition. The three goal-setting experimental conditions included (1) static weekly goal, where participants were encouraged to meet a fixed weekly MVPA goal of 150 minutes; (2) self-selected weekly goal, where participants were encouraged to create their own weekly MVPA goals; and (3) incremental weekly goal, where participants were assigned a weekly MVPA goal 20% greater than the previous week's goal. In addition to these 3 goal-setting conditions, a non–goal-setting comparison group was included, in which participants were encouraged to increase MVPA without setting specific weekly goals.

Selection of the goal-setting techniques was informed by a comprehensive review of the literature on the types of PA goals commonly incorporated into PA promotion interventions [16], as well as a review of the theoretical assumptions underpinning the use of goal setting [18,19]. Minutes per week of MVPA was chosen as the behavioral target for all goal-setting study groups to align with the metric used in the national PA guidelines [14]. By directly comparing multiple commonly used goal-setting techniques and a non–goal-setting comparison condition within a single experimental framework, this study addresses an important gap in the literature, as few studies have systematically evaluated multiple goal-setting approaches to support midlife adults in meeting national PA guidelines.

Standardized SCT-Based Intervention

Over the duration of the 6-month intervention, participants engaged in 17 structured action planning sessions, which were referred to as "coaching sessions" by the research team for all participant-facing communications. These sessions were conducted via telephone or Zoom (Zoom Communications, Inc) videoconferencing platform, based on participant preference. Session frequency occurred weekly during months 1 - 3, every other week during months 4 and 5, and once during month 6. The gradual withdrawal of participant contact with study interventionists was designed to promote autonomy and encourage participants to rely on their own self-regulatory and self-efficacy processes promoted through their study arm–specific goal-setting technique to achieve weekly PA goals and ultimately national PA guidelines.

Table 3 illustrates the structured content of the action planning sessions. The first 2 sessions were designed to be approximately 1 hour in duration and focused on the interventionist working with the participant to develop an individualized action plan for increasing their PA. Sessions 3 - 17 were designed to be approximately 15 minutes in duration and consisted of reviewing the participant's PA progress since the last session, discussing PA successes and areas for improvement, engaging in PA barrier problem solving, discussing their next weekly PA goal (based on study arm allocation; participants in the non–goal-setting comparison group did not discuss PA goals), and identifying psychosocial and behavioral strategies for the participant to achieve their next PA goal. The action planning sessions were conducted by trained research staff, all of whom completed study-specific training led by the study investigators (RPJ and MM) before engaging with participants. Interventionists followed a manualized protocol when delivering coaching sessions and documented session activities and other relevant details about the session (eg, participant responses and reactions to prompts) in real time via the study's REDCap (Research Electronic Data Capture; Vanderbilt University) database.

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Table . Overview of the action planning session activities completed by participants across the 4 study groups as part of the standardized Social Cognitive Theory–based intervention.

Activity	Social Cognitive Theory and goal-setting[a] constructs targeted	Approximate duration
Session 1: Action planning activities		
I. Greetings and initial introductions.	N/A[b]	5 minutes
II. Review the purpose of the study.	N/A	5 minutes
III. Presentation of the national aerobic PA[c] guidelines and the different types and modes of PA that can be performed to achieve national aerobic PA guidelines.	Behavioral capability	10 minutes
IV. Overview of the health and social benefits of being physically active and achieving the national PA guidelines.	Outcome expectations and goal setting	5 minutes
V. Participant identifies reasons they want to be physically active and the types of aerobic PA they are interested in performing (ie, walking, group exercise classes, and cycling).	Outcome expectations	5 minutes
VI. Assignment of first weekly moderate-intensity PA goal (based on study arm); non–goal setting study arm did not engage in this activity.	Self-regulation and goal setting	1 - 2 minutes
VII. Participant identifies non–PA-related previous life experiences where they worked hard to achieve a goal they set out for themselves; the interventionist helps the participant identify effective strategies used to achieve the goal.	Self-regulation, self-efficacy, and goal setting	5 - 10 minutes
VIII. Review of common PA barriers; participant identifies PA barriers they anticipate facing and engages in problem-solving strategies with the interventionist to overcome anticipated barriers.	Self-regulation and self-efficacy	10 minutes
IX. Participant and interventionist brainstorm and identify behavioral strategies to incorporate PA into their day to achieve their study group–specific weekly PA goal, including specifying the types of PA participants would engage in to achieve their PA goal; non–goal-setting group focused on general strategies to increase their PA without reference to achieving a specific goal.	Self-regulation	5 - 10 minutes
X. Interventionist and participant schedule a time for next action planning meeting.	N/A	1 minute
Approximate duration of initial action planning session		1 hour
Session 2: Action planning activities		
I. Greetings and pleasantries.	N/A	1 - 2 minutes
II. Review of the purpose of the study, minutes per week of MVPA[d] performed since the previous action planning session, and progress toward achievement of previous week's PA goal; non–goal-setting group reviews minutes per week of MVPA without reference to any goal.	N/A	5 minutes
III. Participant and interventionist discuss the psychosocial and behavioral strategies the participant performed since the last action planning sessions to achieve their study group–specific PA goal; non–goal-setting group focuses on strategies used to increase their activity, without mention of a specific goal. Interventionists provide positive reinforcement for successfully implemented strategies.	Self-efficacy	5 minutes
IV. Interventionist provides an overview of self-rewards for achieving PA goals and the importance of social support when trying to achieve physical activity goals; non–goal-setting group focuses on self-rewards for being physically active, in general, and the importance of social support for increasing PA.	Self-regulation	10 minutes
V. Participant and interventionist collaboratively develop self-rewards for the participants achieving their short- and long-term PA goals; non–goal-setting group focuses on self-rewards for being physical activity in general, without mention of any specific goals. Discussion of the importance of social support.	Goal setting and self-regulation	10 minutes
VI. Participant and interventionist collaboratively identify people in the participant's life who can serve as sources of social support for PA.	Social support	10 minutes
VII. Participant identifies 3 PA barriers faced since last session, and strategies to overcome them during the next week, including specification of the types of PA they intend to engage in during the upcoming weeks.	Self-regulation and Self-efficacy	10 minutes

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Activity	Social Cognitive Theory and goal-setting[a] constructs targeted	Approximate duration
VIII. Assignment of PA goal for the next week.	Self-regulation and goal setting	5 minutes
IX. Interventionist and participant schedule a time for next action planning meeting.	N/A	1 minute
Aproximate duration of action planning session 2		1 hour
Sessions 3 - 17: Action planning activities		
I. Greetings and pleasantries.	N/A	1 minute
II. Review of PA goal(s) since last action planning session and progress toward goal achievement.	Goal setting	1 minute
III. Participant and interventionist discuss the psychosocial and behavioral strategies the participant performed since the last action planning sessions to achieve their study arm specific PA goal; interventionist provides positive reinforcement for successfully implemented strategies.	Self-efficacy	2 - 3 minutes
IV. Discussion of PA obstacles or barriers the participant faced since last action planning session.	Self-regulation and self-efficacy	2 - 3 minutes
V. Assignment or discussion of new weekly or biweekly moderate-intensity PA goal (based on study arm).	Goal setting	1 - 2 minutes
VI. Participant and interventionist discuss and identify strategies to overcome previously identified or anticipated PA barriers for the upcoming week(s), including encouraging the participant to specify the types of PA they intend to engage in to achieve their PA goal during the upcoming week; non–goal-setting group includes this activity but focuses on increasing overall PA, rather than achieving a specific goal.	Self-regulation and self-efficacy	2 - 3 minutes
VII. Reinforcement of the participant's value-based reasons they want to increase their PA (assessed during the initial action planning session).	Self-efficacy	2 - 3 minutes
VIII. Interventionist and participant schedule a time for next action planning meeting.	N/A	1 minute
Estimated duration of action planning sessions		12 - 17 minutes

[a]Participants in the non–goal-setting comparison condition did not engage in any goal-setting activities in sessions; coaching sessions focused on increasing PA in a general sense without reference to any specific goal.

[b]N/A: not applicable.

[c]PA: physical activity.

[d]MVPA: moderate to vigorous physical activities.

To facilitate self-monitoring of MVPA and to track progress for weekly MVPA goal achievement, participants were given a Fitbit Versa 2 activity monitor and asked to wear it 24 hours per day, except when charging. Fitbit's metric of "Active Minutes" was originally intended to serve as the self-monitoring measure of MVPA. However, during the early stage of study implementation, Fitbit modified the terminology and propriety algorithms used to assess MVPA and transitioned to use of "Active Zone Minutes," which subsequently served as the self-monitoring measure of MVPA following this change. All Fitbit accounts were preregistered to the research team to allow the team to troubleshoot participant-related Fitbit issues during the intervention and were connected to the Fitabase data collection management platform (Small Steps Lab LLC). This allowed the research team to remotely monitor and track participants' PA levels throughout the intervention.

Several steps were taken to ensure participant comprehension of what constitutes MVPA and how it feels to perform MVPA. First, during the baseline study assessment procedures, participants walked at a moderate intensity on a treadmill at 0% grade during the warm-up phase (based on age-estimated heart rate) of the cardiopulmonary exercise test (Table 4). Study staff explicitly referenced this walking pace and the associated physiological sensations (eg, heart rate and breathing) as the reference point for participants to gauge moderate-intensity PA throughout the study. In addition, coaching session 1 provided an overview of the types of activities that constitute MVPA and reviewed various methods for gauging exercise intensity, including heart rate–based monitoring using their Fitbit device, the "talk test" (eg, during moderate-intensity exercise, individuals should be able to talk but not sing; during vigorous-intensity activity, they should not be able to say more than a few words without taking a breath), and using a 1 - 10 perceived exertion scale, where moderate intensity corresponds to a rating of 5 - 6 and vigorous intensity corresponds to a rating of 7 or higher.

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Table . Key measures identified for inclusion in a subsequent larger-scale trial designed to evaluate the effects of different goal-setting techniques to enhance self-regulation and self-efficacy and adherence to national aerobic physical activity guidelines.

Measures	Timepoint collected	
	Baseline	6 months
Psychosocial mediators: self-efficacy and self-regulation		
Physical Activity Self-Regulation Scale (PASR-12) [21]: This 12-item scale assesses 6 PA[a]-related self-regulatory domains: self-monitoring, goal setting, eliciting social support, reinforcements, time management, and relapse prevention. The PASR-12 has established structural and construct validity, as well as interrater reliability [21].	Monthly	
Self-Regulation Scale from the Health Belief Survey [36]: This 10-item questionnaire assesses behavior strategies to incorporate PA into daily activities (ie, take stairs instead of elevator and walking instead of driving when running errands). This questionnaire has been validated and has acceptable reliability estimates in previous research (Cronbach α range: 0.64-0.74) [36,37].	Monthly	
Short Self-Regulation Questionnaire [38,39]: The 33-item Short Self-Regulation Questionnaire measures ability to regulate behaviors for goal pursuit. Publicly available in the NIH Science of Behavior Change repository, the measure has established validity and reliability (Cronbach α=0.92) [38,39].	Monthly	
Exercise Self-Efficacy Scale [40]: This 12-item questionnaire assesses confidence in one's ability to perform PA despite barriers or obstacles. This measure has established validity and adequate reliability (Cronbach α=0.78) [40].	Monthly	
Self-Efficacy Scale [41]: The 10-item questionnaire assesses beliefs in one's capacity to manage daily stressors and exert control in daily life. Publicly available in the NIH Science of Behavior Change repository, the NIH Toolbox [42] has established validity and reliability (Cronbach α=0.94) [41].	Monthly	
Proximal study outcomes: physical activity		
Objective Assessment of Physical Activity: Assessed using ActiGraph GT9X Link activity monitors worn on the nondominant wrist during waking hours for 7 consecutive days. Valid wear is defined as wearing the ActiGraph for >10 waking hours per day during the 7-day wear period based on the Choi algorithm [43] to determine nonwear time.	✓	✓
Subjective Assessment of Physical Activity: Assessed by the 7-Day Physical Activity Recall (7-Day PAR) [44]. This interviewer-administered instrument assesses self-reported minutes per week of MVPA[b]. The 7-Day PAR has established reliability among older adults [45] and has been validated against accelerometers for accurate assessment of PA [46].	✓	✓
Distal study outcomes: measures of cognitive functioning, ADRD[c], and cardiometabolic disease risk		

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Measures	Timepoint collected	
	Baseline	6 months
Episodic Memory: Picture Memory Test [47] from the Cognitive Assessment section of the NIH Toolbox for the Assessment of Neurological and Behavioral Function.	✓	✓
Executive Functioning: Dimensional Change Card Sort Test [48] from the Cognitive Assessment section of the NIH Toolbox.	✓	✓
Processing Speed: Pattern Comparison Processing Speed Test [49] from the Cognitive Assessment section of the NIH Toolbox for the Assessment of Neurological and Behavioral Function.	✓	✓
Serum and plasma measures of ADRD and Cardiometabolic Disease Risk: Assessed by standardized phlebotomy and blood-processing procedures collected after 8 hours of fasting. Measures of ADRD risk included plasma amyloid 42/40 ratio and plasma phosphorylated tau 231. Measures of cardiometabolic disease risk included fasting plasma glucose, serum insulin, and serum lipids (TG[d], total cholesterol, LDL[e]—cholesterol, and HDL[f]—cholesterol).	✓	✓
Cardiorespiratory Fitness: Assessed using a modified Blake treadmill protocol. Testing and termination criteria followed ACSM[g] guidelines.	✓	✓
BMI: Measured using an electric scale and calculated using the formula: weight (in kilograms) divided by height (in meters) squared.	✓	✓
Waist circumference: Measured at midpoint between rib and top of iliac crest.	✓	✓
Blood pressure: Assessed in triplicate following a 5-minute rest using an electronic sphygmomanometer.	✓	✓

[a]PA: physical activity.

[b]MVPA: moderate to vigorous physical activities.

[c]ADRD: Alzheimer disease and related dementias.

[d]TG: triglycerides.

[e]LDL: low-density lipoprotein.

[f]HDL: high-density lipoprotein.

[g]ACSM: American College of Sports Medicine.

Protocol

Individuals interested in participating in the study completed an online eligibility screening survey administered via REDcap. Those meeting initial eligibility criteria were contacted by the research team and completed a telephone screening interview to verify initial eligibility. Those who met the eligibility criteria and remained interested were invited to attend an in-person orientation session. During this session, a research team member reviewed the informed consent form, addressed any questions, and obtained written informed consent from participants who chose to proceed. Following consent, the research team measured participants' height and weight to confirm eligibility based on BMI and administered the Montreal Cognitive Assessment (MoCA) [34] and the Center for Epidemiologic Studies Depression Scale [50] to screen for cognitive impairment and depression, respectively. Participants who remained eligible after these assessments were scheduled for their baseline study visit, provided an ActiGraph GT9X Link accelerometer to wear for 7 days for objective assessment of their PA levels, and emailed the baseline survey measures (Table 4).

Following the 7-day accelerometer wear period, participants attended their baseline assessment visit. During this visit, preintervention data were collected, including anthropometric measures, phlebotomy, cognitive testing, self-reported PA levels via the 7-Day Physical Activity Recall [44], and a cardiopulmonary exercise test (Table 4). Once all baseline data were collected, the participant was randomized by a member of the research team using REDCap's randomization module. Stratified block randomization, using blocks of size 4, with strata biological sex (male and female) and obesity disease status

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(BMI 30 to <40 kg/m^2 [ie, class 1 and 2 obesity]; BMI >40 kg/m^2 [ie, class 3 obesity]), was performed. This approach ensured that treatment groups were balanced by sex and obesity class while also maintaining relatively equal group sizes throughout the rolling recruitment period. The randomization sequence was generated using PASS statistical software (NCSS, LLC) by the study statistician (KAP). All other members of the research team, including staff, were blinded to the predetermined allocation sequence. The participant was then informed of their study group assignment and provided a Fitbit Versa 2, along with wear instructions for the 6-month intervention. Next, the research staff assisted the participant with downloading and installing the commercial Fitbit app onto their mobile phone, creating a study-specific email account to register with Fitbit for use during the study, and connecting their Fitbit account to the Fitabase data management platform to enable the research team to continuously collect PA data throughout the intervention. At the end of the baseline study session, participants were provided the study handbook and scheduled for their initial action planning session, which occurred at least 1 week after the baseline appointment, allowing time for the participant to become familiar with the Fitbit and the research team to collect the initial PA data necessary to inform the week 1 MVPA goal for participants assessed to the incremental study group. Participants then progressed through the 6-month intervention.

To assess longitudinal changes in self-regulation and self-efficacy over the duration of the intervention, participants were emailed a REDCap survey link to complete these psychosocial surveys each month during the intervention. After the 6-month intervention period, participants returned to the research center for their follow-up study assessment. These assessment procedures were similar to baseline, with the exception that participants were invited to complete a postintervention satisfaction survey to provide feedback on their overall experiences with the intervention, including what they liked and did not like about the intervention, specific challenges faced, and how we can refine our intervention efforts for a subsequent larger-scale trial. Participants were again given an ActiGraph GT9X Link accelerometer to wear for 7 days to objectively measure their PA levels, provided mailing materials to return the device after the 7-day wear period, and subsequently scheduled for a final Zoom session, in which the 7-Day Physical Activity Recall [44] was administered. Participants were also guided through the steps of connecting their Fitbit to their personal email address. Due to the nature of the behavioral intervention, study investigators, staff delivering the intervention, and participants were not blinded to study group assignment. However, all non–self-reported outcome data were collected by assessors blinded to the participants' study group allocation.

Measures

Sociodemographic Characteristics

Participant sociodemographic characteristics were assessed using a self-report questionnaire. These characteristics included age, sex, race/ethnicity, relationship status, income, education, and employment status.

Feasibility of Implementation

Feasibility was assessed by evaluating the research team's ability to recruit, retain, and engage participants in the intervention; deliver the intervention as planned; and collect outcome data for the key measures identified for inclusion in a future larger-scale trial. Given the early stage of the research and following the recommendations of others [51], we did not set specific criteria or strict thresholds for establishing feasibility based on the individual metrics assessed. Instead, we adopted a holistic approach that focused on evaluating each feasibility metric within the context of the other metrics, with the goal of guiding protocol refinement for progression to larger-scale proof of concept trial (ie, stage 1B trial).

Participant Recruitment and Retention

Feasibility of recruitment was examined by tracking participant interest in the study via completion of the online eligibility screening, number of individuals eligible for participation based on completion of eligibility screening procedures, and the enrollment rate among those eligible. These data were collected to inform recruitment strategies and timelines for the subsequent larger-scale trial. Retention was calculated as the proportion of participants who completed the 6-month study assessment out of the total number of participants randomized.

Participant Engagement and Feasibility of Intervention Delivery

Participant engagement and feasibility of intervention delivery were assessed by examining the average number of coaching sessions each participant completed and the average number of days during the 6-month intervention period participants achieved valid Fitbit wear time, which was defined as wearing the Fitbit for at least 10 hours per day as determined by minute-level heart rate data. Periods without heart rate data were classified as nonwear during data processing.

Collection of Outcome Data

This outcome evaluated the ability and consistency of the research team to collect valid data from study participants for the key measures proposed for inclusion in a subsequent larger-scale trial of the intervention. Table 4 provides a brief description of each of these measures.

Acceptability

Participants' perceptions of and satisfaction with the intervention were assessed with a postintervention treatment acceptance survey administered at the end of the 6-month intervention. This 24-item measure, adapted from our previous work [52], included both multiple-choice and open-ended questions to capture participants' overall perceptions of the intervention, as well as their thoughts on the specific components, including the action planning sessions and use of the Fitbit to track and self-monitor their MVPA. Example items assessing overall perceptions of the intervention included: "Overall, how helpful did you find the study for promoting physical activity?" and "How motivated were you to increase your physical activity as a result of the study?" Items targeting specific intervention components included: "How helpful did you find the physical activity coaching sessions for promoting physical activity?" "Do you think you gained knowledge about exercise and physical activity

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from your coaching session?" and "How helpful did you find using the Fitbit to help increase your activity?"

Statistical Analysis

Quantitative data, including participant sociodemographic characteristics, intervention delivery and adherence rates, data collection rates, and Likert-like responses on the satisfaction survey, were summarized using descriptive statistics (eg, frequencies, means, and SDs). Fitbit wear time was determined using minute-level heart rate data; days or periods without recorded heart rate data were classified as nonwear time for analysis. Consistent with best practices for the design and evaluation of pilot studies [26,30,31], no formal hypothesis testing or inferential statistical analyses were performed, as the study was not sufficiently powered or intended to detect statistically significant effects. Qualitative data collected through the postintervention satisfaction survey were analyzed using direct content analysis [53]. For this analysis, participants' responses to the open-ended questions were coded using a deductive approach, with the specific intervention components (eg, action planning sessions and Fitbit activity monitor) and a general category labeled "overall perceptions of the intervention" serving as predefined codes. Within each of these primary codes, participant narratives were further examined to identify recurring patterns and themes by 2 members of the research team (RPJ and MM) using a collaborative, iterative process. Final interpretation and reporting of key qualitative findings were achieved through consensus between the 2 analysts.

Results

Participant Characteristics

Participants (n=24) had a mean age of 54.1 (SD 5.8) years and a mean BMI of 36.3 (SD 5.0) kg/m^2. The majority were female (21/24, 87.5%), identified as White (22/24, 91.6%) and non-Hispanic (21/24, 87.5%), and had a bachelor's degree or higher (18/24, 75%). Table 5 provides participant sociodemographic characteristics.

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Table . Sociodemographic characteristics of study participants (N=24).

Variable	Mean (SD)	Frequency, n (%)
Age (years)	54.1 (5.8)	N/A[a]
BMI	36.3 (5.0)	N/A
Sex		
Female	N/A	21 (87.5)
Male	N/A	3 (12.5)
Race		
White	N/A	22 (91.6)
American Indian or Alaskan	N/A	1 (4.2)
More than 1 race	N/A	1 (4.2)
Ethnicity		
Hispanic, Latino, or Spanish origin	N/A	3 (12.5)
Non-Hispanic, Latino, or Spanish origin	N/A	21 (87.5)
Relationship status		
Married	N/A	13 (54.2)
Not married but living with someone in a marriage-like relationship	N/A	2 (8.3)
Divorced	N/A	2 (8.3)
Never married	N/A	6 (25)
Declined to respond or missing	N/A	1 (4.2)
Annual household income		
<$25,000	N/A	1 (4.2)
Between $25,000 and $50,000	N/A	1 (4.2)
Between $50,001 and $75,000	N/A	5 (20.8)
Between $75,001 and $100,000	N/A	3 (12.5)
>$100,000	N/A	10 (50.0)
Declined to respond or missing	N/A	2 (8.3)
Education		
Two years of college or associate’s degree	N/A	4 (16.7)
Three years of college	N/A	2 (8.3)
Bachelor’s degree	N/A	10 (41.7)
Master’s degree	N/A	8 (33.3)
Employment status		
Employed full-time	N/A	17 (70.8)
Employed part-time	N/A	3 (12.5)
Unemployed	N/A	1 (4.2)
Homemaker	N/A	1 (4.2)
Declined to respond or missing	N/A	2 (8.3)

[a]N/A: not applicable.

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Feasibility of Implementation

Recruitment and Retention

Figure 2 illustrates participant flow through the intervention. The sample of 24 study participants was enrolled in approximately 4 months (July 2024 through mid-October 2024), equating to enrolling 6 participants per month into the intervention. Recruitment efforts yielded 336 individuals completing the online eligibility screener, with 73 classified as potentially eligible based on online screening responses. Among these, 33 attended an in-person study orientation session where informed consent was obtained, BMI was verified, and the MoCA and the Center for Epidemiologic Studies Depression Scale were administered. This screening process resulted in 1 individual being excluded for study participation based on BMI status (ie, >50 kg/m^2) and 6 individuals being excluded based on their MoCA scores. In addition, 2 participants declined study participation following the orientation, indicating that they were no longer interested in the study.

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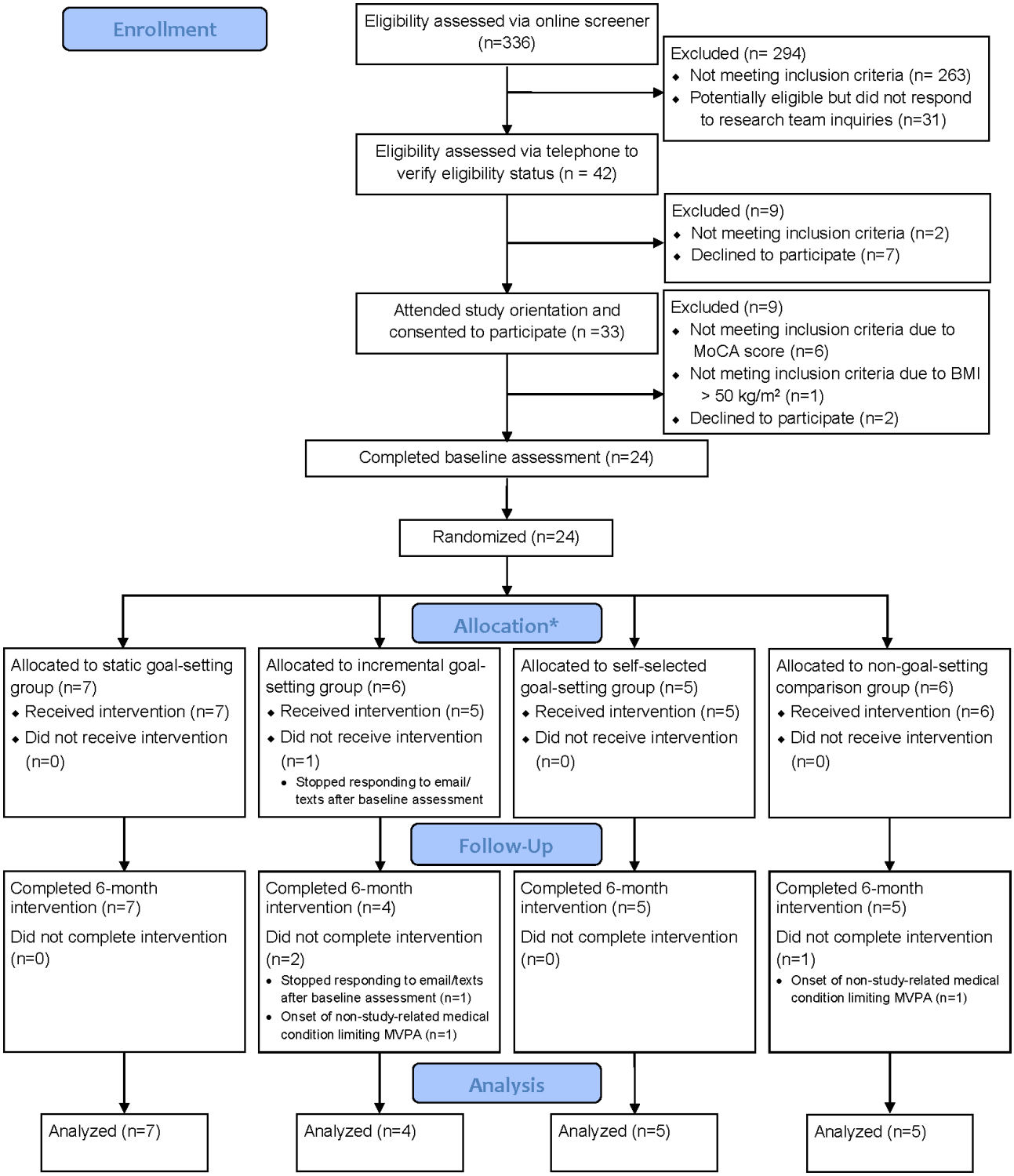
Figure 2. CONSORT (Consolidated Standards of Reporting Trials) diagram illustrating participant flow through recruitment, enrollment, randomization, and 6-month follow-up. MoCA: Montreal Cognitive Assessment; MVPA: moderate to vigorous physical activities. *Randomization error by research staff resulted in 7 participants being allocated to receive the static intervention group and 5 participants allocated to the self-selected group, instead of 6 in both of these study groups.



Among the 24 participants randomized to an intervention arm, 87.5% (n=21) were retained at 6 months. Reasons participants were lost to follow-up included the onset of a medical condition unrelated to study participation that limited participants' ability to safely engage in MVPA (n=2) and loss of contact (n=1; ie, participant's phone disconnected during coaching session 1 and subsequent attempts to reach the participant were successful).

Intervention Delivery

Virtual Action Planning Sessions

Participants (24/24, 100%), on average, attended 14.6 out of 17 (85.9%) virtual action planning sessions. Eight participants (8/24, 33.0%) attended all 17 sessions. Among the 21 individuals completing the intervention, the average number of sessions attended was 15.9 out of the 17 (93.5%). Multimedia Appendix

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1 illustrates action planning session attendance by study group over the duration of the 6-month intervention. Although the small sample size precluded formal testing of between-group differences in coaching session attendance, descriptive and visual analyses show similar patterns of session attendance across study groups and over time.

The duration of coaching sessions 1 and 2 (ie, more in-depth introduction, review of goals, and barriers) was mean 45.8 (SD 14.3) minutes and mean 39.9 (SD 11.6) minutes, respectively. Coaching sessions 3 - 17 (ie, the brief follow-up coaching sessions) were mean 13.5 (SD 6.2) minutes in length. The majority of coaching sessions were conducted via telephone (175/351, 49.9%), followed by Zoom video call (172/351, 49.0%) and Zoom audio-only call (4/351, 1.1%).

Fitbit Versa 2 to Self-Monitor MVPA

Participants completing the study (n=21) received the coaching intervention over a mean of 180 (SD 11.3) days (exact duration of intervention delivery varied slightly based on participant availability for their 6-month outcome assessment) and provided valid Fitbit wear time (defined as wearing the device for >10 hours per day) on 87.1% (SD 15.8%) of these days (equating to approximately 156.7 days or 6.1 days per week). Average wear time for days meeting the 10 hours per day threshold for valid wear was a mean of 20.1 (SD 4.7) hours per day.

Collection of Outcome Data

Data collection rates for key outcomes identified for inclusion in a future larger-scale mechanistic trial were high, ranging from 95% to 100% at both the baseline and 6-month assessment periods (Table 6). Completion rates of monthly surveys assessing self-efficacy and self-regulation ranged from 91% to 100% among the 21 participants completing the study. Specific completion rates for surveys were 100% for months 1 and 2, 95% (20/21 participants) completion for month 3, 91% (19/21 participants) completion for month 4, and 95% (20/21 participants) completion for month 5. As illustrated in Multimedia Appendix 2, no clear pattern of differential survey completion emerged across study groups.

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Table . Collection rates of valid assessment data at baseline and 6 months by study outcome and timepoint.

Measures	Baseline, n (%)	6 months, n (%)[a]
Self-regulation		
PA[b] Self-Regulation Scale (PASR-12) [21]	24 (100)	21 (100)
PA Self-Regulation Scale from the Health Belief Survey [36]	24 (100)	21 (100)
Short Self-Regulation Questionnaire [38]	24 (100)	21 (100)
Self-efficacy		
Exercise Self-Efficacy Scale [40]	24 (100)	21 (100)
Self-Efficacy Scale [42]	24 (100)	21 (100)
Physical activity		
Accelerometer-Measured PA[c]	24 (100)	20 (95)[d]
7-Day PA Recall [44]	24 (100)	21 (100)
Cognitive functioning		
Memory	24 (100)	21 (100)
Executive Functioning	24 (100)	21 (100)
Processing Speed	24 (100)	21 (100)
ADRD[e] and cardiometabolic disease risk		
Phlebotomy procedures for serum and plasma measures of ADRD and cardiometabolic disease risk	23 (96)[f]	20 (95)[f]
Cardiorespiratory Fitness assessed using a modified Balke treadmill test	23 (96)[g]	21 (100)
Body weight and anthropometrics	24 (100)	21 (100)
Blood pressure	24 (100)	21 (100)

[a]Percentages at the 6 months were calculated based on the number of participants completing the intervention (n=21).

[b]PA: physical activity.

[c]Participants, on average, wore the ActiGraph GT9X+ for approximately 16.3 (1.97) waking hours per day on 6.6 (0.82) valid days per week at baseline and 16.1 (1.88) waking hours per day on 6.8 (0.53) valid days per week at 6 months.

[d]One participant reported having a wrist injury that limited the use of wrist-worn device on their nondominant wrist and thus was not asked to wear the ActiGraph device.

[e]ADRD: Alzheimer disease and related dementias.

[f]Phlebotomists were unable to draw blood from the same participant at both baseline and 6-month assessment periods due to the inability of locating a vein suitable for the blood draw procedure.

[g]One participant's test was terminated before reaching peak oxygen consumption (VO_{2peak}) due to the participant feeling lightheaded.

Acceptability

Action Planning Sessions

Participants reported high satisfaction with the action planning sessions. Among the 21 participants completing the intervention, most participants rated the sessions as "very helpful" (n=9/21, 43%) or "helpful" (n=7/21, 33%) for increasing their PA (Figure 3A in Figure 3A,). Four participants (4/21; 19%) reported that the action planning sessions were "somewhat helpful," and 1 participant reported that they were "not helpful at all." Likewise, most participants found the action planning sessions to be motivating for increasing PA (n=6/21, 29% "very motivated"; n=7/21, 33% "motivated"; and n=7/21, 33% "somewhat motivated"; Figure 3A). Only 1 participant indicated that they were "not motivated" by the sessions. Additionally, 81% (n=17/21) of the participants reported gaining knowledge about PA and exercise from the coaching sessions.

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Figure 3. Participant-reported acceptability of the action planning sessions, Fitbit activity monitor, and overall intervention. (A) Acceptability ratings for the action planning sessions. (B) Acceptability ratings for the Fitbit activity monitor. (C) Acceptability ratings for the overall intervention. PA: physical activity.

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Regarding the frequency and duration of the action planning sessions, participants generally reported favorable responses. Seventy-six percent (16/21) of the participants completing the study reported that the frequency of sessions was "just right," while 19% (4/21) reported the desire for more frequent sessions and 1 participant reported that the coaching sessions were too frequent. Similarly, most participants were satisfied with the length of the coaching sessions, with 86% (18/21) reporting that the duration of the coaching sessions was the "right amount of time," whereas 14% (3/21) reported that the sessions were "too short"; no participants reported that the sessions were too long.

Participant narratives describing their experiences with the action planning sessions largely aligned with the positive responses from the closed-ended satisfaction survey. Many participants shared that they enjoyed the sessions, as well as the interventionists delivering them, and found the sessions to be encouraging for increasing their PA. Qualitative narratives highlighting this included, "[Coach's name] was a joy...the length and frequency [of the sessions] were pretty good. She met me where I was at.," "Coach was very personable and positive," "She [coach] was encouraging when I was discouraged," "It kept me accountable.," "Helped me think more about being active and ways to do it," and "Early in the study week, goal setting really helped me to be mindful and achieve my goals."

When asked how we can improve the coaching sessions, approximately half of the narratives provided by participants (n=8 out of 18) indicated that either no change was needed (n=4) or expressed satisfaction without offering specific suggestions for improvement (n=4). Quotes illustrating this included, "I don't sense improvement is needed.," "No changes.," "I felt the sessions were conducted very well," and "I was happy with the coaching." However, among participants offering constructive feedback, a common theme was the desire for more variety and flexibility in the coaching sessions. Some participants felt that the sessions were somewhat repetitive and suggested revisiting key topics from the initial action planning sessions (eg, sources of social support and short- and long-term goals) in the later sessions. Others emphasized the need for greater adaptability based on individual needs. Quotes illustrating these sentiments included, "[coaching sessions] never followed up on the [long or short-term] goals so there was not accountability.," "Sessions felt very stagnant, not personalized...the goals/rewards that were set in the beginning were never visited again," "I did not find revisiting my [weekly] goals every session was helpful," and "The sessions were too scripted. More flexibility to meet the needs of the participants would be nice."

Fitbit Activity Monitor

Most participants rated the Fitbit as "very helpful" (13/21, 62.0%) or "helpful" (5/21, 24.0%) for increasing their PA. Three participants (3/21, 14%) rated the device as being "somewhat helpful"; no participants rated it as being "not helpful" (Figure 3B). When asked how motivated they were to increase their PA as a result of wearing the Fitbit, the majority shared that they were either "very motivated" (9/21, 43%) or "motivated" (8/21, 38%). Three participants out of 21 (14%) reported that they were "somewhat motivated"; 1 participant out of 21 (5%) reported that they were "not motivated." Additionally, most participants found the Fitbit to be comfortable to wear (n=12/21 "very comfortable"; n=4/21 "somewhat comfortable"; and n=5/21 "a little bit uncomfortable) and the overwhelming majority reported not experiencing any difficulties remembering to wear the Fitbit daily (20/21, 95%).

Although most feedback regarding the Fitbit was favorable, some participants expressed discontent with the device during the intervention, as well as on the postintervention satisfaction survey. These concerns were both general in nature and specific in regard to the perceived accuracy of the Fitbit for assessing MVPA. Quotes illustrating general concerns included, "Wish the Fitbit would integrate better with iPhone.," "The Fitbit kinda sucks now (used to be better)," and "Maybe an alternative to the Fitbit." Accuracy-related concerns centered on the perception that the device overreported MVPA, with 1 participant noting during a coaching session that she was accumulating Active Zone Minutes while sitting in traffic. Although much of these discussions regarding the accuracy of the Fitbit occurred during structured coaching sessions, 1 participant mentioned this on the postintervention focus group with the following, "Fitbit was very inaccurate in regard to activity minutes." Notably, this concern was also shared by the research team during intervention delivery, as Fitbit data collected for some participants continually reported elevated levels of MVPA.

Overall Feedback About the Intervention

Overall feedback regarding the acceptability of the intervention generally reflected findings of the individual components. For example, most participants found the intervention to be "very helpful" (14/21, 67%) or "helpful" (3/21, 14%) for promoting PA and indicated that they were either "very motivated" (10/21, 48%) or "motivated" (5/21, 24%) to increase their PA as a result of the study (Figure 3C). In addition, 86% (18/21) reported gaining knowledge about PA and exercise from the study, and 90% (19/21) reported that they would recommend the study to a friend.

When asked how we can improve the intervention for larger-scale testing, almost half of the responses to this open-ended question (6/15 responses, 40%) either reflected that no changes were needed or offered only positive feedback. Illustrative comments included, "No improvements needed," "Nothing," and "The program was great. Sorry for not being able to suggest any improvements." In addition, 3 participants shared that they would like an in-person component incorporated into the study to allow for group exercise and/or instruction of how to perform certain activities. These quotes included, "I would not mind an in-person exercise class or 2 or more specific guidance on skills" and "Offer workshops like beginners pickleball or basketball shooting." The remaining responses to this item were varied and did not reveal insights not previously reported.

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Discussion

Principal Results

This study examined the feasibility and acceptability of a newly developed intervention designed to compare 3 different goal-setting approaches for enhancement of PA-related self-regulation and self-efficacy and adherence to national PA guidelines. The results demonstrated promising outcomes for advancing this line of research in a larger-scale trial, as evidenced by high participant retention and engagement, fidelity of intervention delivery, successful collection of primary outcome measures, and high participant satisfaction. Findings also identified several areas for refinement prior to broader implementation.

Interpretation of Findings and Comparisons With Prior Work

The research team was able to successfully recruit the study sample size in approximately 4 months, yielding a recruitment rate of approximately 6 participants per month. Given this study served as the research team's first attempt to recruit midlife adults with obesity using the specific inclusion criteria and eligibility screening procedures of this study, this outcome provides valuable insight for developing recruitment timelines for future studies for our intended study population. The observed retention rate of 88% was comparable with, or slightly higher than average rates reported in reviews and meta-analyses of health behavior change trials of similar durations [54], including PA interventions [12,55], lending support for feasibility of the intervention approach. Similarly, adherence to the action planning sessions was high, with participants attending 85.9% of sessions, as was Fitbit compliance, with valid wear (>10 hours per day) achieved on 87.1% of days. Successful collection of outcome data for measures intended for inclusion in a future larger-scale trial was also high, with valid data obtained for 91%-100% of participants across measures.

Participant acceptability of the intervention was favorable, as most participants found the overall intervention, as well as the individual components (ie, action planning sessions and Fitbit activity monitor) to be useful and motivating for increasing PA. However, qualitative narratives provided by participants highlighted several areas in which the intervention could be refined in future research. For example, several participants noted repetitiveness of some of the action planning session content, as well as the desire for follow-up on key topics discussed during the initial sessions. This feedback suggested the need to revise certain sessions to reduce redundancy and to enhance the brief action planning components by incorporating more structured follow-up on the comprehensive action plans developed in sessions 1 and 2. Participant concerns regarding the accuracy of the Fitbit for assessment of MVPA were also shared by the research team, as the research staff observed some participants consistently receiving high levels of weekly Active Zone Minutes. In an effort to explore concerns regarding Fitbit's accuracy, the research team informally compared minute-level heart rate data against minute-level Active Zone Minute data. Findings suggested that participants were accumulating Active Zone Minutes at a heart rate threshold of approximately 50% - 60% of their age-estimated maximum. Although this range aligns with recommendations for moderate-intensity PA from the American Heart Association [56], it is substantially below the 64% threshold recommended by the American College of Sports Medicine [57]. Given Fitbit's algorithm for determining MVPA and awarding Active Zone Minutes is proprietary, the exact methods used to assess MVPA are not publicly available.

Strengths and Limitations

This study has several strengths. The overarching 4-arm study design represents an experimental medicine approach to generate understanding of how goal setting influences the psychosocial processes of self-regulation and self-efficacy in promoting PA. The NIH Science of Behavior Change Program has encouraged such approaches to promote better understanding of *how* and *why* specific behavior change techniques lead to (or fail to produce) behavior change [20]. This study represents a necessary first step in pursuing this type of approach for understanding how different approaches to goal setting can increase PA and ultimately promote adherence to national PA guidelines. Second, selection of the primary outcome measures used to assess feasibility and acceptability, as well as the determination of the sample size, was guided by established frameworks [26] and guidelines [51] for conducting pilot and feasibility trials. Previous reviews and critiques of pilot and feasibility studies [30,31] have noted that many authors have inappropriately focused on outcomes related to efficacy or effectiveness, which are not suitable for feasibility studies. This study was carefully designed to avoid this common pitfall. Similarly, reporting of the study protocol and outcomes followed CONSORT guidelines [29] for randomized pilot and feasibility trials.

Several limitations should also be acknowledged. Although the goal-setting techniques included in this study are common approaches used in the PA promotion literature, they represent only a subset of ways in which goal setting can be operationalized. Numerous other approaches to conceptualizing and implementing PA goal setting exist, including variations in the underlying theoretical approach (eg, implementation intentions [58] and achievement goal theories [59,60]), PA metric used (eg, MVPA, steps, and frequency of PA sessions), and frequency of goal setting and evaluation of achievement. Exploring alternative approaches to PA goal setting is important for future research. In addition, despite a primary focus of the study being on the feasibility of intervention delivery, the action planning sessions were not audio recorded, limiting the ability to assess fidelity of the delivery of the session curriculum. Given that this is an important aspect to include for process evaluation, it will be included in future studies. Another potential limitation is that our study sample consisted of mostly non-Hispanic White women with higher income and education levels, which may limit generalizability of study outcomes. We anticipate that these sample characteristics are related to the use of convenience sample methods that primarily included social media and online advertising for recruitment. In future studies, we will prioritize more inclusive recruitment strategies to enhance the diversity of the study sample. Additionally, the validity of Fitbit's proprietary measures of MVPA (ie, Active Zone and Active

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Zone Minutes) is not publicly known, limiting definitive understanding regarding whether the metric is a scientifically valid method for assessment of MVPA. Finally, collection of acceptability data was limited to completers of the 6-month intervention, which may have introduced selection and social desirability bias, potentially positively skewing these results. However, given the high retention rate, we anticipate such bias to be minimal.

Conclusions and Implications for Future Research

Building on the findings from this pilot study, the research team implemented several modifications and refinements to the study protocol in preparation for a larger-scale testing. These refinements included (1) revising the action planning session curriculum to reduce repetitiveness and to include follow-up conversations regarding key topics discussed in the initial 2 action planning sessions (ie, social support, rewards, and short-term and long-term goals) in the latter, brief action planning sessions; (2) audio-recording of all action planning sessions to enable assessment of fidelity of session delivery; and (3) replacing the Fitbit Versa 2 with the Garmin Vivoactive 5 as the consumer wearable used by the participants to self-monitor their MVPA. The Garmin device allows for the research team to apply specific thresholds for classification of moderate- and vigorous-intensity activity (eg, 40% and 60% of participants' heart rate reserve [57]), rather than relying on Fitbit's proprietary algorithm.

The next step for this line of work is for our research team to expand upon these promising findings and to conduct a larger-scale (n=120) phase 1B proof-of-concept trial (based on National Institute on Aging's Stage Model). This trial will examine the preliminary effects of the 3 goal-setting techniques, compared with the non–goal-setting comparison group, on enhancing self-regulation, self-efficacy, and adherence to national aerobic PA guidelines over a 9-month intervention period. This intervention will consist of a 6-month active intervention delivery phase followed by a 3-month minimal contact period, allowing for additional insight into whether enhancements in self-regulation, self-efficacy, and MVPA are maintained after the active intervention delivery ends. These preliminary findings will provide valuable data regarding the effectiveness of various goal-setting techniques to maintain behavior change over time that will support overall physical health as well as reduce risk for ADRD.

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Data Availability

The datasets generated or analyzed during this study are available from the corresponding author on reasonable request.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Frequency of action planning session attendance by study group. (A) Static weekly MVPA goal of 150 minutes (n=7) study group. (B) Self-selected weekly MVPA goal (n=5) study group. (C) Incremental weekly MVPA goal (n=4) study group. (D) Non–goal-setting comparison (n=5) study group. MVPA: moderate to vigorous physical activity.

[PNG File, 142 KB - formative_v10i1e82494_app1.png]

Multimedia Appendix 2

Frequency of participant completion of monthly surveys assessing self-regulation and self-efficacy by study group. (A) Static weekly MVPA goal of 150 minutes (n=7) study group. (B) Self-selected weekly MVPA goal (n=5) study group. (C) Incremental weekly MVPA goal (n=4) study group. (D) Non–goal-setting comparison (n=5) study group. MVPA: moderate to vigorous physical activities.

[PNG File, 135 KB - formative_v10i1e82494_app2.png]

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Abbreviations

ADRD: Alzheimer disease and related dementias
CONSORT: Consolidated Standards of Reporting Trials
MoCA: Montreal Cognitive Assessment
MVPA: moderate to vigorous physical activity
NIH: National Institutes of Health
PA: physical activity
REDCap: Research Electronic Data Capture
SCT: Social Cognitive Theory

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Assessment of Emerging Technologies to Support Individuals With At-Risk Alcohol Consumption: Pilot Controlled Investigation Study

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Abstract

Background: The Swedish National Board of Health and Welfare recently updated the national guidelines for at-risk consumption of alcohol. Nearly 30% of the Swedish population now falls under the at-risk category and should be provided with support.

Objective: This project aims to identify and evaluate efficient, scalable tools to support individuals with risk-prone alcohol consumption. The project seeks to explore innovative, accessible technologies that could be implemented in large-scale public health interventions.

Methods: A pilot-scale clinical study was conducted to assess the feasibility of using emerging technologies for this purpose. Eight healthy volunteers participated in controlled alcohol consumption while being monitored through 2 methods: an eye-scanning tool integrated into a standard mobile phone and saliva sampling for biomarkers such as serotonin and orexin.

Results: Eye-scanning parameters began to shift in some participants at approximately 0.4 to 0.5 per mille blood alcohol concentration, particularly in the form of impaired eye convergence. Furthermore, at around 0.5 per mille, participants encountered practical difficulties in managing the eye-scanning app. Salivary biomarkers did not show any clear correlation with alcohol intake, presumably due to the low number of participants. Beyond biological findings, the study also generated important procedural insights for designing a large-scale clinical study.

Conclusions: Eye scanning showed potential as a noninvasive and accessible method for detecting and monitoring moderate alcohol consumption effects, while serotonin and orexin biomarkers were not informative in this context. On the basis of these findings and procedural learnings, eye-scanning tools warrant further investigation in larger clinical studies aimed at developing scalable support for risk-prone alcohol consumption.

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KEYWORDS

mobile health; alcohol; biomarkers; digital health; eye scanning

Introduction

The Swedish National Board of Health and Welfare has changed the limit for risk-prone alcohol consumption and proposes that all individuals at risk shall be offered support [1]. This is a daunting task, as according to a report from the Swedish Council for Information on Alcohol and Other Drugs published in February 2024, risky alcohol consumption was estimated at 31% across all age groups, except for those aged 50 to 64 years, where the proportion was 35%. Furthermore, the prevalence of risky use was higher (36%) in urban-adjacent areas compared to smaller towns and rural areas (30%) [2]. Hazardous alcohol consumption among Swedes aged 16 to 84 years is around 15%, even before the updated definitions of harmful drinking. According to the Public Health Agency of Sweden, hazardous alcohol consumption is more prevalent in young people and men [3]. Taken together, these figures highlight the magnitude and heterogeneity of the target population, underscoring the substantial demand on health services. To adequately respond to the needs of this sizable and diverse population, all support systems must be structured with a clear focus on both efficiency and scalability. In addition, the population needs to be informed of the hazards of moderate drinking to motivate acceptance of support.

Continuous monitoring of risk factors to maintain public health is common. Most programs screen the population at risk; for

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example, mammography screening for breast cancer typically begins for individuals aged 40 to 50 years. An increasing number of biomarker-driven screening tests are discussed, including those targeting specific diseases [4], those targeting generic longevity through multipanel approaches [5], and practical elements such as patient-participation considerations [6]. With alcohol being a significant contributor to illness [7], it is logical that monitoring programs for alcohol consumption should be implemented. Several possible interventions have been evaluated [8]. However, the social role of alcohol in everyday life probably makes policymakers hesitant.

Smartphone-based support tools for alcohol addiction therapy have been available for many years. One of the more advanced support tools allows frequent testing of breath alcohol using a breathalyzer in combination with tools for motivational interviewing (MI) and cognitive behavioral therapy (CBT), where the system is capable of even predicting relapses ahead of time [9]. Breathalyzers that assess breath alcohol concentration are particularly useful for delivering real-time information to both individuals receiving care and health care providers. This intervention represents an effective and proactive method for monitoring treatment [10]. MI is a collaborative, person-centered counseling approach that addresses ambivalence and enhances motivation for change [11]. It is widely used in health care and behavioral interventions to support adoption and maintenance of healthier behaviors. CBT has progressed through 3 waves: the first focused on behavioral principles; the second on cognitive processes; and the third on acceptance, mindfulness, and values. MI and CBT are 2 well-established, evidence-based psychotherapies that have been shown, particularly in combination, to be effective for conditions including anxiety, depression, and substance abuse [12].

We hypothesize that the support scenario concept for at-risk consumers could include 1 branch of support and 1 branch of testing. The support branch aims to reduce the alcohol consumption, and the test branch aims to monitor whether an individual is still within, or has left, the risk-consumption category. Using the already deployed support system for the management of alcohol use disorder as a template, a support system based on MI and CBT is feasible. However, self-reported consumption is not considered an option, due to underreporting [13], and testing a large population for alcohol consumption using a breathalyzer is very costly, indicating that other feasible and cost-effective approaches are necessary. Wearable sensors allowing direct measurements of alcohol are emerging [12] but are still not ready for large-scale deployment. In this context, measurements of secondary markers, that is, metabolites or bodily reactions, can provide the scale necessary for the intended population.

Individuals with elevated alcohol consumption also face increased risk of mental health issues such as anxiety, altered stress sensitivity, depression, and aggressive behavior. These conditions are often linked to changes in neurotransmitter and neurohormonal systems, including serotonin, oxytocin, orexin, and dopamine [14,15]. Women of childbearing age are also at risk for unknowingly affecting the offspring, where the prevalence of fetal alcohol spectrum disorders has been reported to be 1% to 5% [16]. Recently, a large cohort study from the United Kingdom reported that any alcohol consumption is associated with risk [17].

Assuming that the Swedish National Board of Health and Welfare is successful in establishing a public acceptance for the new lower limit for risk-prone alcohol consumption and also enforces the provision of, as is discussed in their announcement [1], support to individuals at risk, the currently generally ignorant individual consuming risk-prone levels of alcohol will, to some extent, rethink and maybe accept the support provided. As the provision of simple, SMS text messaging–based support to people with risk-prone alcohol consumption has been shown to be moderately efficient [18], the support would probably be composed of different components. In addition to supporting behavioral change, an acute-phase test capable of indicating that alcohol has been recently consumed may be combined with a slower-phase test that indicates physiological status seen over the course of weeks or months. By regularly collecting data of different types with different temporal patterns, it is foreseeable that prediction algorithms can be developed to further support the individual at risk, similar to what is already available for alcohol use disorder [9].

One option for large-scale monitoring is to evaluate eye characteristics using mobile phones, similar to eye scanners developed for the management of substance use disorder [19]. These have been shown to detect benzodiazepine drugs, which act on the same receptor family as alcohol [20]. Under the assumption that the majority of the population owns a mobile phone, this test device is readily available in the target population.

Another option is saliva sampling to test for relevant molecular biomarkers. Saliva sampling is a noninvasive and user-friendly technique for the collection of biological samples that is also cost-efficient, particularly if provided as a home kit. A well-known example is the rapid diagnostic kits developed during the COVID-19 pandemic, which enabled home testing and infection monitoring using noninvasive sampling methods such as saliva [21]. Human saliva contains proteins and other components that are present in serum, and in certain instances, the concentration levels in both matrices are comparable [22,23]. From an alcohol monitoring perspective, the detection of biomarkers in saliva, for example, through rapid home tests, represents an advantageous approach for the early identification of drinking. Importantly, at-home testing offers an additional benefit of discretion, making it particularly suitable for individuals who prefer to keep their alcohol consumption private. However, there remains a need for saliva-based biomarkers that can reliably capture average alcohol consumption over 1 to 4 weeks, similar to the blood test phosphatidylethanol [24,25], and that can be implemented in rapid, user-friendly home tests.

In this project, we hypothesized that the physiological effects of moderate alcohol consumption can be measured by a simple analysis of relevant digital and molecular biomarkers. Such biomarkers are already well-established tools for diagnosis, prognosis, and monitoring of health conditions. We report a small pilot clinical study where the ability to detect alcohol consumption through secondary markers is evaluated in an

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exploratory manner. Only noninvasive tests that could be converted for large-scale home use were included in this small pilot clinical study to comply with the efficiency requirement. One acute-type test and 1 test with a slower timeline were studied. The evaluation of eye scanning was conducted using a platform that can readily be deployed at scale. In lieu of a suitable rapid home-use saliva test, levels of serotonin and orexin in saliva were quantified in a regular laboratory. The main goal of the study was to confirm the feasibility of the methods and collect preparatory information for a larger study.

Methods

Ethical Considerations

The study was approved by the ethics board (Etikprövningsmyndigheten; 2024-00815-01-521250) on February 5, 2024. All participants signed an informed consent form before enrolling in the study. Collected data were deidentified and linked only to a numeric participant identifier. The key for connecting numeric participant identifiers to actual personal identifiers was archived separately, only accessible by the primary investigator. No compensation was provided for participation. The study protocol has been deposited on Research Gate [26]. The first participant enrolled and signed the informed consent on September 9, 2024.

Study Description

The study had the following inclusion criteria: individuals who were fully informed about the nature, scope, and relevance of the proposed exploratory study; individuals who voluntarily agreed to participate in the study and provided written informed consent; individuals who were aged between 18 and 67 years; women of childbearing age (18 - 50 years) with a negative pregnancy test (via a urine test); and healthy individuals, without anamnestic data of relevant chronic disorders or regular use of medication for medical conditions.

Exclusion criteria [26] included blindness; individuals who had undergone eye surgery that could influence pupillary reflexes based on the research physician's judgment; deafness; use of central depressants, sleeping pills, or medications contraindicating alcohol consumption; history or hereditary disposition for risk-prone use or dependency on alcohol; and regular alcohol consumption at or above the current recommendations for at-risk drinking.

The cohort consisted of 10 healthy volunteers recruited at a university campus in Sweden. The cohort comprised 4 (40%) male and 6 (60%) female participants aged 23 to 56 (median 45.4) years and weighing 60 to 125 (median 78.8) kg. In accordance with the study protocol [26], upon inclusion at visit 1, the participants received a brief training on how to use the eye-scanning app (version 4.3; Previct Drugs, Kontigo Care), and a saliva sample was donated (Salimetrics LLC). Visit 1 was held on several occasions to simplify recruitment. Between visit 1 and visit 2, the participants were asked to perform 12 eye-scanning tests in a sober condition because it is known that it may take some time before one learns how to conduct accurate eye-scanning events [20]. Visit 2 was the intervention when alcohol was consumed, taking place on 1 occasion when all participants were present. A total of 2 (20%) participants could not participate in visit 2 due to scheduling conflicts and were excluded from analysis. Among the 8 participants who were physically present during visit 2, a total of 5 (62.5%) completed all 12 eye-scanning tasks in the sober condition, whereas 3 (37.5%) completed between 5 and 11 tasks while sober. At visit 2, the participants first donated a saliva sample and performed an eye-scanning test and a breathalyzer test (Previct Alcohol, Kontigo Care) in a sober condition. Participants then repeated the procedure, consuming 1 glass of wine (white or red, 10% - 12% alcohol content, approximately 150 ml), waiting 15 minutes, completing an eye-scanning test, and subsequently performing a breathalyzer test, until either their blood alcohol concentration exceeded 0.6 per mille or they chose to discontinue. At the moment drinking stopped, a saliva sample was donated, and a usability questionnaire was completed. Subsequently, eye-scanning and breathalyzer measurements were recorded every 30 to 40 minutes for 1.5 to 3 hours. Before closing visit 2, a final saliva sample was donated.

Data Collection and Analysis

The Previct Drugs system conducts eye scanning in a smartphone app with rigorous embedded quality control. This means that data of poor quality are prevented from being reported by the app in the smartphone. Consequently, the app may entirely disqualify an eye-scanning test. The collected data used for analysis are identical to the data that passed embedded quality control. Eye-scanning results were available as 13 key features, each representing a magnitude related to the pupillary light reflex, nystagmus, and the ability to converge the eyes, as previously described [19] and summarized in Table 1.

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Table . Description of key features for the 3 test procedures—nonconvergence, nystagmus, and pupillary light reflex.

Key feature name	Description
Nonconvergence	
NCDiff	Ability to cross eyes
Nystagmus	
PeakCount	Number of nystagmus-like events
MotionMass	Magnitude of nystagmus-like events
Pupillary light reflex	
Dbase	Pupil size at ambient light
Dcon	Contracted pupil size after illumination
Dend	Pupil size at the end of measurement
Ctime	Time to maximum pupil contraction
MCA (Dbase-Dcon)	Maximum contraction amplitude
RMCA (Dbase-Dcon)/Dbase	Relative maximum contraction amplitude
MCV	Maximum contraction velocity
Latency	Time to first pupil reaction of illumination
PESC	Pupil escape (Dend-Dcon)
LeftEyeRedness	Color of sclera, left eye, expressed as CIELAB A

Saliva samples were examined for concentrations of serotonin and orexin using enzyme-linked immunosorbent assay (Invitrogen; catalog numbers EEL006 and EEL039). The change in measured concentration following alcohol consumption was evaluated by comparing the average value in a sober condition with results obtained at the highest blood alcohol concentration (using a 2-tailed *t* test) across all participants.

Statistical Analysis

The sample size for this study was determined based on a recent study on eye scanning of people under the influence of drugs [19]. The impairment of eye characteristics due to alcohol consumption was evaluated by comparing the average key feature value of all data collected in a sober condition with the 3 measurement results obtained at highest blood alcohol level (using a paired *t* test) for each participant, relying on a significance level of $P<.05$. The effect size was estimated using Cohen *d*. The saliva sample results were evaluated by comparing average values of results obtained in a sober condition with average values of results obtained under the influence of alcohol (using a paired *t* test).

Results

Eye-scanning results are presented in Table 2. Participant 9 was unable to complete any tests after having consumed alcohol. Effect sizes for significant ($P<.05$) observations were in the range of 0.50 to 2.5 (median 1.66, IQR 1.19-1.88). The ability to cross eyes, reported as the key feature NCdiff, often required some training. Time-series data are shown in Figure 1 for 2 participants. Participant 1 had difficulty crossing eyes in the beginning, but after 5 attempts, the NCdiff value was in the range of 0.4 to 0.5, which corresponds to clear ability to cross eyes. Upon consuming alcohol (measurement 9 onward), a gradual decline of convergence ability is seen. Participant 3 could cross eyes from start and lost some of the ability after having consumed alcohol (measurement 13 onward).

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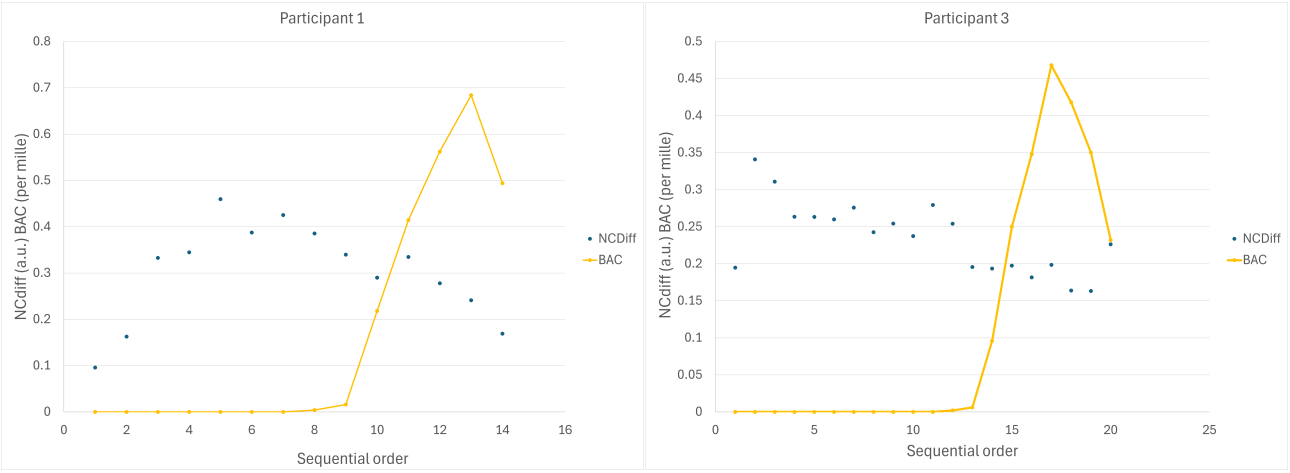
Table . *t* test results (*P* values) from the comparison of eye-scanning key feature values obtained in a sober condition with those obtained under the influence of alcohol.

Key feature values	Participant 1, *P* value	Participant 3, *P* value	Participant 4, *P* value	Participant 5, *P* value	Participant 6, *P* value	Participant 7, *P* value	Participant 8, *P* value
NCDiff	.33	.002	.051	.003	.86	.66	.78
PeakCount	.38	.10	.12	.97	.04	.91	.72
MotionMass	.94	.04	.19	.92	.06	.72	.84
Dbase	.19	.45	.32	.99	.65	.11	.62
Dcon	.03	.99	.63	.98	.93	.007	.72
Dend	.02	.48	.59	.03	.46	.07	.90
Ctime	.07	.03	.01	.51	.23	.49	.06
MCA	.33	.40	.24	.99	.49	.32	.58
RMCA	.44	.46	.23	.91	.38	.49	.66
MCV	.40	.82	.87	.60	.24	.08	.87
Latency	.76	.04	.72	.80	.39	.94	.59
PESC	.60	.52	.86	.02	.10	.09	.63
LeftEyeRedness	.47	.77	.98	.52	.15	.38	.21
Smallest *P* value per participant	.02	.002	.01	.003	.04	.007	.06

Figure 1. Time series of NCdiff (ability to cross eyes, expressed in arbitrary units [a.u.]) and blood alcohol concentration (BAC, expressed as per mille blood alcohol) for 2 participants. Participant 1 recorded 8 sober measurements, and participant 3 recorded 12 sober measurements before alcohol intake.



The usability of the eye-scanning app was generally good. In a sober condition, all participants managed to produce data of sufficient quality. When under the influence of alcohol at a blood alcohol concentration of approximately 0.5 per mille, the usability aspect changed. One participant was unable to produce any measurement with acceptable quality. Several participants failed 1 of the 6 eye-scanning tests conducted under the influence of alcohol. Overall, most participants exhibited reduced focus and diminished coordination at a blood alcohol concentration of 0.5 permille, consistent with expectations.

Participants 1, 3, and 9 deviated from the protocol and made too few sober tests at home before visit 2. No other protocol deviations were recorded.

One participant (participant 8) appeared to present an outlier pattern for breathalyzer measurements. According to the instructions for use of the breathalyzer, residual alcohol in the oral cavity can yield artificially elevated breathalyzer values. Hence, the protocol required a 15-minute waiting time between finishing a glass of wine and breathalyzer measurement. For participant 8, the following sequence was recorded: 1 glass of wine, blood alcohol concentration 0.06 per mille; second glass of wine, 0.2 per mille; third glass of wine, 0.66 per mille; and after a 30-minute wait, 0.22 per mille. No other participant in the study exhibited such a steep increase in blood alcohol concentration after a glass of wine, nor experienced such a rapid decrease over the following 30 minutes. Participant 8 was excluded from saliva biomarker analysis. Eye-scanning results are presented per participant, meaning that data from participant 8 should be evaluated with caution.

The 2 individuals weighing more than 100 kg both consumed 6 glasses of wine. Remaining participants consumed 3 to 4 glasses of wine, except for participant 8, who only had 1 glass

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of wine. One participant decided to stop drinking at 0.47 per mille. All other participants continued drinking until their blood alcohol concentration exceeded 0.6 per mille, with the highest recorded blood alcohol concentration being 0.72 per mille. Participants were, as anticipated, affected by alcohol consumption but only in a mild and transient manner. No serious adverse events were recorded.

When comparing averages across 7 participants, no significant differences were detected between saliva serotonin and orexin levels between the sober condition and after alcohol consumption (P=.50 and P=.40, respectively).

Discussion

We report a small pilot clinical study of methods suitable for managing a large population with risk-level alcohol consumption. The small pilot study was also designed to produce procedural insights for a larger future study.

To ensure population-wide accessibility, we evaluated an eye-scanning tool integrated into a standard mobile phone, assuming that widespread mobile phone ownership makes the device readily available to a larger population. Eye-scanning results after alcohol consumption are in line with benzodiazepine impairment, which is logical because both benzodiazepines and alcohol interact with the gamma-aminobutyric acid receptor family [20]. In this study, we examined whether eye characteristics are affected after moderate alcohol intake. One identified visible impairment in eye movements, the loss of the ability to converge their eyes, appeared as an acquired skill, meaning that participants initially had to learn how to converge their eyes. Our tests indicated that while participants could converge their eyes well in the sober condition, they lost some ability to converge their eyes when under the influence of alcohol, and for some individuals, signs of eye impairment were already observable at blood alcohol concentrations of approximately 0.4 to 0.5 per mille. While the effects of alcohol on eye characteristics have been described for high levels of alcohol consumption (blood alcohol concentration around 0.8 per mille) [27], this study indicates that eye-related effects may also be observed at lower blood alcohol concentrations.

The importance of compliance is evident in this study. Of the 3 participants who did not complete all 12 sober baseline measurements, 1 was unable to produce any data under the influence of alcohol due to clumsiness. For the 2 participants with incomplete baseline data (participants 1 and 3), there is a risk that they had not fully learned how to converge their eyes before eye scanning under the influence of alcohol. This would result in a false negative result because both an inability to converge eyes and the loss of convergence due to intoxication will result in low NCdiff scores. We note that the operational procedures of Previct Drugs require 10 to 12 sober initial measurements for substance use disorder therapy. As Previct Drugs is deployed and used in the clinic, it is possible to conduct such sober baseline measurements for patients with a substance use disorder. Lack of compliance in this study was probably due to a lack of motivation.

The measurement of a bodily reaction to a drug for the purpose of indicating ingestion has many advantages and disadvantages. The test specificity will be vague because similar drugs will cause similar bodily reactions. The loss of convergence induced by both alcohol and benzodiazepines is one such example. Tests relying on altered bodily reactions will hence serve as screening tools in cases where confirmed use of a particular substance is desired. In other instances, such as estimating if a person is fit to operate a dangerous machine, the measurement of bodily reactions as such may be sufficient to allow access because the cause of the altered bodily reaction is irrelevant. The same reasoning can be used for designer drugs, where the development of specific chemical tests is slow. A broad test for the designer drug family, potentially relying on analysis of bodily reactions, could be sufficient to indicate the use of a designer drug, although it may not identify the specific substance. Finally, bodily reactions may be altered by conditions such as fatigue or arousal. All these aspects need to be taken into consideration when implementing a test based on measurements of bodily reactions.

Saliva sampling is a noninvasive method well suited for home use. However, it typically requires samples to be sent to a laboratory, which introduces logistical challenges and increases costs. Lateral flow rapid tests offer a cost-effective alternative by reducing the need for laboratory analysis, as was successfully demonstrated during the COVID-19 pandemic. Currently, no rapid tests are available for biomarkers such as serotonin or orexin, but they can be developed if required. Although the biomarkers evaluated in this pilot study did not yield reliable results, likely due to the small sample size, saliva sampling and analysis should not be dismissed. The primary advantage of saliva sampling is likely its ability to monitor the longer-term effects of alcohol consumption, which may not be captured in an acute-phase study such as the one reported here. With a larger study population and longer follow-up times, the identification of more suitable biomarkers, and continued development of rapid testing methods, this approach may still hold significant potential for future use.

Conducting a small pilot clinical study as a preparatory step for a larger study warranted several vital learnings. The acquired skill of converging eyes means that strict compliance with home measurements is important, and more than 12, preferably around 20, measurements at home are advisable to ensure that all individuals learn how to cross their eyes before the intervention. This would further allow statistical comparisons between “sober data after having acquired the skill of converging the eyes” and “convergence ability under the influence.” Saliva sampling was tested only on site in the pilot study, but it should also be tested at home if included in the next phase. Having 8 participants consume alcohol simultaneously during visit 2 proved to be challenging; therefore, reducing the number of participants to a maximum of 6 is advisable. Serving a stronger alcoholic beverage at least once or twice, and adjusting the amount consumed according to the participant’s body weight, are recommended to rapidly reach a blood alcohol concentration of approximately 0.4 per mille, thereby reducing the duration of alcohol exposure. To understand the eye-scanning performance at blood alcohol concentration of 0.4 per mille,

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we estimate that the population size should be around 72, but not less than 36. This would also allow a fair estimate of the proportion of individuals who are unable to converge their eyes. Increasing the target blood alcohol concentration from 0.6 to 0.7 or 0.8 per mille will allow better analysis of the relationship between alcohol concentration and the onset of convergence loss. Finally, to avoid potential false breathalyzer readings, it is recommended to rinse the oral cavity with water before conducting a breathalyzer measurement.

Managing risk-level alcohol use across a population of millions presents a public health challenge. The burden extends beyond the health care system where traditional intervention strategies such as in-person screening, counseling, and laboratory testing are resource intensive and logistically impractical to scale. Moreover, because many risk-level users lack self-awareness, they often do not seek help proactively; therefore, early signs of harmful use may go unnoticed by professionals until consequences become severe. This underscores the need for proactive, knowledge-based prevention strategies, particularly targeting women of childbearing age to reduce the risk of fetal alcohol spectrum disorders, in line with Sweden's national public health objectives concerning alcohol and substance-related harm. Developing scalable, cost-effective, noninvasive, and nonintrusive tools for continuous assessment and engagement holds great potential to strengthen preventive measures at the population level and meet the growing societal demand for effective and discreet alcohol risk management.

In conclusion, this study demonstrated that alcohol consumption clearly affected eye characteristics in many participants, whereas the selected saliva biomarkers showed no measurable difference, at least with the measurement technique used. Therefore, the evaluated eye-scanning method may serve as a promising component for large-scale monitoring and support of at-risk individuals. Further studies, building on this pilot work, are warranted to confirm and extend these findings.

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Conflicts of Interest

KA is a subcontractor to Kontigo Care AB and was part of the development team for the Previct Drugs platform. Kontigo Care did not have any involvement in study design, data analysis, or manuscript preparation. The other authors declare no conflicts of interest.

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Abbreviations

CBT: cognitive behavioral therapy
MI: motivational interviewing

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A Peer-Led, Narrative-Based, and Mobile-Supported Intervention in Opioid Use Disorder: Multiphase Qualitative and Longitudinal Observational Study

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Abstract

Background: The ongoing opioid epidemic has been associated with increases in emergency department visits and hospitalizations for drug overdose and injection-related infections. These encounters with the health care system provide an opportunity to offer drug treatment linkage and support for people with opioid use disorder (OUD). There is a need for interventions that enhance linkage to and engagement in treatment with medication for opioid use disorder (MOUD) for people with OUD identified in hospital settings as they transition back to community settings.

Objective: The mTools4life (Johns Hopkins University) study aimed to develop and evaluate a peer-led intervention integrating narrative-based health communication into a mobile health (mHealth) app to increase posthospitalization engagement in MOUD and reduce substance use.

Methods: The formative phase of the study consisted of semistructured interviews with people with OUD and clinicians who provide care to people with OUD. Interviews sought to identify salient content to include in visual narratives within the mHealth app and information that may increase motivations for behavior change related to MOUD engagement. The intervention was developed in accordance with the information-motivation-behavioral skills model, transportation theory, and the transtheoretical model. The pilot phase of mTools4Life (Johns Hopkins University) aimed to evaluate the acceptability and usability of the intervention. People with OUD were recruited from the Johns Hopkins Hospital Emergency Department and consented to receive the intervention for a 3-month period. Participants completed a study survey at baseline and a 3-month follow-up. Data on demographics, past 30-day substance use, MOUD, and intervention appropriateness and acceptability were obtained at both time points. Additional data on intervention uptake and frequency of use were collected at follow-up. Dependent samples 2-tailed *t* tests were conducted on continuous data, and Fisher exact tests were conducted on count data.

Results: Twenty people with OUD piloted the intervention. The sample was mostly male (13/20, 65%) and non-Hispanic White (13/20, 65%) with a mean age of 41.1 (SD 8.7) years. Most participants (16/20, 80%) completed the 3-month follow-up. Fewer participants reported opioid use at follow-up (9/16, 56.3%) compared to baseline (20/20, 100%; *P*=.001, and mean days of opioid use out of the past 30 days declined from baseline (19.9, SD 11.7) to follow-up (8.3, SD 11.4; *P*=.002). MOUD treatment in the prior 3 months was reported by 65% (13/20) of participants at baseline and 81.3% (13/16) at follow-up (*P*=.46). Most participants used the app (11/16, 68.8%) or engaged with their peer navigator (10/16, 62.5%) during the intervention period. At follow-up, mean acceptability and appropriateness scores (scale 0 - 5; higher score indicating greater acceptability or appropriateness) were 4.5 (SD 0.5) and 4.3 (SD 0.8), respectively.

Conclusions: This study demonstrates the feasibility of the development and deployment of a narrative-based mHealth intervention to support OUD care engagement and preliminary data in support of the intervention's acceptability, appropriateness, and effectiveness

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KEYWORDS

opioid epidemic; opioid use disorder; substance use; mobile health intervention; mHealth; mobile app; graphic narrative; graphic novel; comics; animation; mobile health

Introduction

Over the past 2 decades, the opioid epidemic has been accompanied by dramatic increases in drug overdose deaths, peaking at over 100,000 overdose deaths in 2023 [1]. Similarly, injection-related infections such as HIV, hepatitis B virus, hepatitis C virus, and life-threatening bacterial and fungal infections have increased, leading to skin and soft tissue infections, osteomyelitis, endocarditis, and sepsis [2-8]. The rise in infections related to opioid use is associated with increases in hospitalizations, as demonstrated by an estimated increase in admissions for injection-related endocarditis in the United States from 2900 admissions in 2013 to greater than 20,000 admissions in 2017 [2] and increases of 12% - 35% for injection-related infections from 2016 to 2018 in Michigan [8]. Nationally, infective endocarditis-related mortality increased an average of 5% (95% CI 3-8) per year for people aged 25- 34 years and 2% (95% CI 1-3) per year for people aged 35-44 years from 1999 to 2020 and was associated with an increase in substance use disorder (SUD) as an underlying cause of death in both age groups [9]. These infections, in addition to nonfatal overdose injuries, have resulted in people who use drugs interfacing more frequently with the hospital system [7,10].

Prior studies show that people who use drugs are less likely to engage in outpatient health care, with stigma and previous negative encounters with health care providers and systems, cost, unstable housing, and unreliable transportation frequently cited as barriers to seeking care [11-14]. Fear of withdrawal symptoms and treatment side effects may also reduce willingness to seek medication treatment [11,15]. Consequently, people who use drugs are more likely to seek emergency care than the general population [16-18]. Emergency department (ED) encounters with or without subsequent hospitalization provide an opportunity to offer opioid use disorder (OUD) care and encourage ongoing engagement in OUD care after ED or hospital discharge [19].

Treatment of OUD with buprenorphine or methadone reduces opioid use, improves quality of life, and reduces opioid-related morbidity and mortality [20-24]. Several studies have demonstrated high patient acceptability and effectiveness of medication for opioid use disorder (MOUD) prescription in the ED [25-28]. MOUD uptake and retention in community settings, however, remain low [29-31]. Interventions linking people to MOUD that also support retention in community-based treatment are needed. The use of peer recovery support services (PRSS) is an approach to retention that provides support to challenge stigmatizing beliefs about long-term use of MOUD and offers relatable modeling for self-efficacy and behavior change. Peer navigators support patients by helping them interface with the medical system in productive and affirming ways while sharing their own stories of recovery. Peer navigation by individuals with lived experience has been associated with success in linking people with OUD in acute care settings to community MOUD, reducing substance use, increasing retention in OUD care, and reducing ED and inpatient hospital readmission [32-34].

Since peer navigators leverage their own narratives of recovery while supporting clients, they are a natural extension of and counterpart to mobile health (mHealth)–delivered narrative health communication. Integration of narratives for health communication into mHealth tools may further expand the reach of narratives as a health information tool and provide additional resources for the intended behavior change of SUD care engagement [35-40]. Therefore, the mTools4life study sought to develop and evaluate a peer-based intervention integrating narrative-based health communication into a mHealth app to increase posthospitalization engagement in MOUD through (1) formative work with people with OUD and service providers and (2) development, pilot, and evaluation of the intervention. Specifically, the pilot phase sought to examine the acceptability and appropriateness of the intervention and reveal any changes in patterns of MOUD engagement or substance use.

Methods

Study Design and Setting

The mTools4Life study was a multiphase formative and exploratory research study that aimed to develop and evaluate an intervention to enhance linkage to care for people with OUD through a peer support-based and narrative-centered intervention with mobile phone support. The core intervention consists of a peer navigator trained in PRSS and a guided introduction to the mTools4Life mobile app.

The formative phase of the study included semistructured interviews with 4 people with OUD and 4 care providers to people with OUD, which aimed to identify (1) key moments in substance use and recovery to include in the narratives, (2) salient information that may increase motivations for long-term use of MOUD, and (3) perspectives on barriers and facilitators of OUD treatment engagement to address in the mobile app. Interviews were thematically analyzed by reviewing transcripts for recurring ideas and grouping the ideas into broad themes that reflected shared experiences and perspectives. The qualitative interview results were used to develop the intervention, including the creation of narratives and content embedded in the mobile app. After deployment, mTools4Life underwent pilot usability and acceptability testing. People with OUD were recruited from the Johns Hopkins Hospital (JHH) ED and consented to receive the intervention for a 3-month period. Participants provided informed consent and completed a study survey at baseline and at a 3-month follow-up.

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mTools4Life App

Based on the identification of food insecurity, homelessness, transportation, and employment challenges as barriers to substance use recovery during the formative phase, tools aimed at addressing these issues were embedded in the mobile app. The app is downloadable for Apple and Android smartphones and includes five main sections: (1) My Health, which consists of peer navigator contact information, medication reminders, appointment reminders, and a withdrawal symptom tracker; (2) Resources; (3) Chat, to easily connect with a peer navigator by text or phone call; (4) Stories, which depicts two individuals' recovery journeys; and (5) the Crisis Hotline. The Resources section includes access to a list of geolocated community resources in Baltimore City, broken down into 5 categories, such as food assistance, housing assistance, employment assistance, transportation assistance, and syringe exchange. Syringe exchange was included as a resource for substance use harm reduction. Short motivational messages developed in collaboration with peer navigators and clinical providers of substance use care intended to promote self-efficacy and motivation for seeking treatment for OUD were embedded in the app and automatically deployed every other day.

Design of Narratives

The mTools4Life intervention development is guided by the information-motivation-behavioral skills model (IMB) for health behavior change and transportation theory. The IMB model asserts that provision of information can drive motivation and increase self-efficacy in behavioral skills, and the interactions of these constructs can evoke behavior change [41]. Various interventions, including mHealth apps, based on the IMB model have produced lasting behavior change [42,43]. The IMB model is often used as a foundation for mHealth interventions [44]. Providing information in narrative format has been shown to be an effective approach to enhancing health communication to promote behavior change [45]. Health communication through storytelling of health seeking, care access, and the recovery journey from individuals with a lived experience of substance use and recovery (ie, peer navigators) may be particularly effective as a communication tool for sustained health behavior change [46,47]. Transportation theory describes the sensation of being mentally immersed in the imagery of a narrative. Transportation has the potential to significantly impact behavior change through the reduction of cognitive counterarguments, new connections with characters who are successful at obtaining OUD care, vivid mental imagery, and emotional engagement with the story [48-50].

Roozenburg empirical design cycle [51,52] was used to guide the iterative process of developing the mTools4Life narratives (Figure 1). The narratives were created based on the data collected from semistructured interviews conducted in the Formative Phase and discussions with 2 peer navigators and a nurse practitioner involved in treating patients with OUD. The transtheoretical model (TTM) provided a foundation for organizing narrative elements around stages of change [53] (Multimedia Appendix 1). Decisional balance, a construct of TTM, represents an individual's assessment of the pros and cons of change as they transition through the precontemplation, contemplation, action, and maintenance stages [53]. Interviews were analyzed qualitatively for factors that were identified by participants as crucial to the decision to seek treatment for OUD or remain in recovery, including attitudes and beliefs, barriers to change, and information needed to pursue treatment. These factors, along with additional events and experiences documented in the interviews, were organized into pros and cons (Multimedia Appendix 2) and then reframed as exemplar events and experiences (Multimedia Appendix 1). The exemplars were grouped according to the TTM stage to which they best corresponded. For example, an exemplar experience of learning that taking buprenorphine is not "just trading one drug for another" could promote a character's transition from a state of ambivalence to having a desire for change as they contemplate the pros and cons of treatment. This exemplar was, therefore, placed under the contemplation stage in TTM.

The exemplars were then combined and arranged into 4 narratives that represented different races and genders. Each narrative followed the structure of TTM, which creates an opportunity for a narrative arc as the main character takes action and faces challenges during each stage, experiencing rises and declines in positive emotions typical of popular narratives [54]. In accordance with the IMB model, the stories provided health information relevant to OUD treatment and were intended to promote self-efficacy related to a personal recovery journey, thereby increasing motivation for behavior change. The narrative characters model self-efficacy as they move through stages of TTM. For example, one character believed that modifying her normal path home could help her avoid her drug dealer and avoid drug use (Figure 2).

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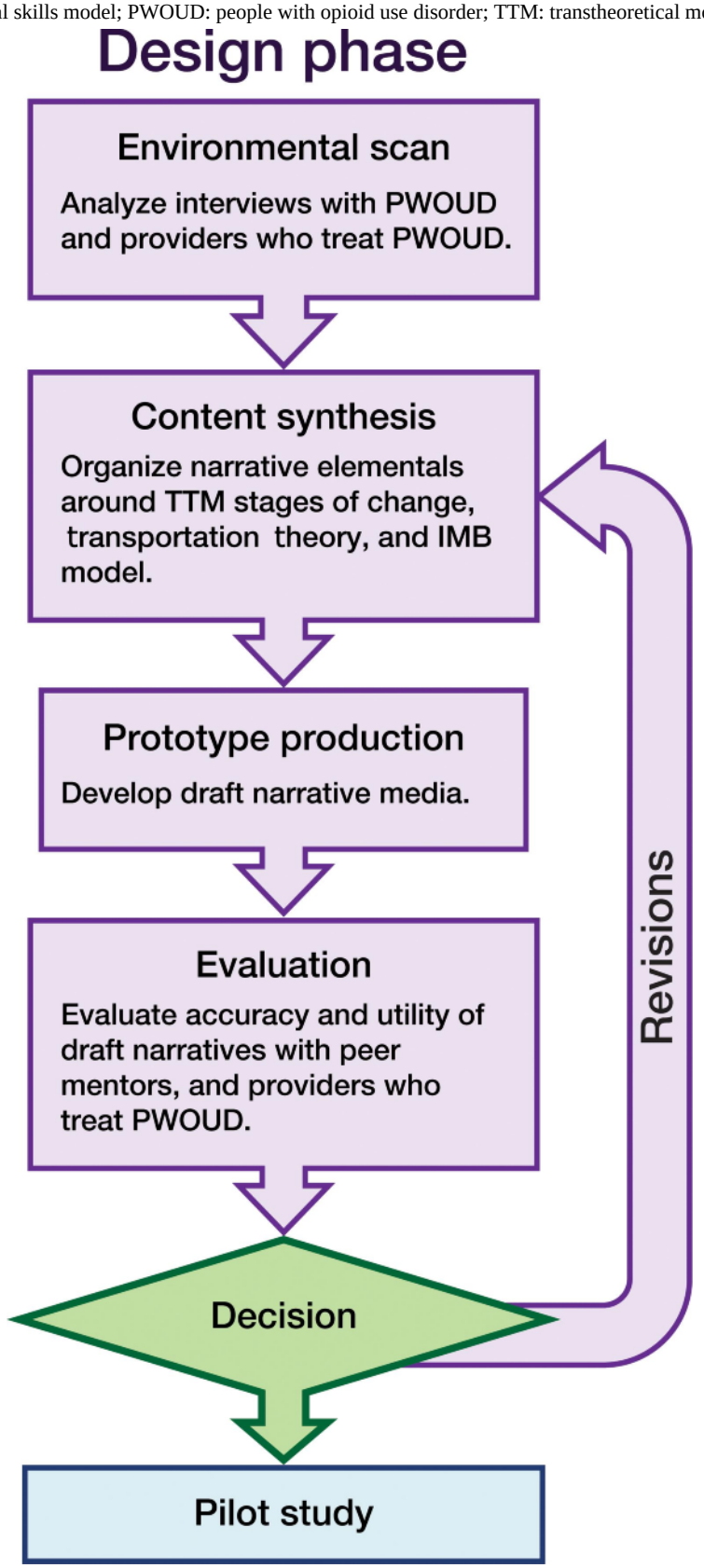
Figure 1. The modified version of Roozenburg empirical design cycle that was used in the process of developing the mTools4Life narratives. IMB: information-motivation-behavioral skills model; PWOUD: people with opioid use disorder; TTM: transtheoretical model.



In accordance with transportation theory, the narratives were designed with consideration for features of stories that can positively affect transportation levels, including identifiable, relatable characters; an imaginable, vivid plot; and verisimilitude of the narrative events [55]. For the recipient, the level of attention paid, familiarity with the subject, their demographics, and situational factors surrounding the expectations of the narrative can affect the level of transportation into a story [55]. To address these recipient-related factors, peer navigators helped

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familiarize participants with the app's purpose and features during study enrollment.

Of the 4 written narratives, 2 were chosen for full development into the graphic narrative format (ie, graphic novels, and comics; Figures 2 and 3, Multimedia Appendices 3 and 4). The narratives were illustrated using Adobe Photoshop (Adobe Systems) by a medical illustrator with graduate-level training and experience working in this format. Simple animations (Multimedia Appendices 5 and 6) consisting of fades between images and character voiceovers were created with Adobe After Effects. The graphic narratives and animations were incorporated into the "Stories" section of the app.

Figure 2. Representative images from Eva's Story, one of two visual narratives included in the story.

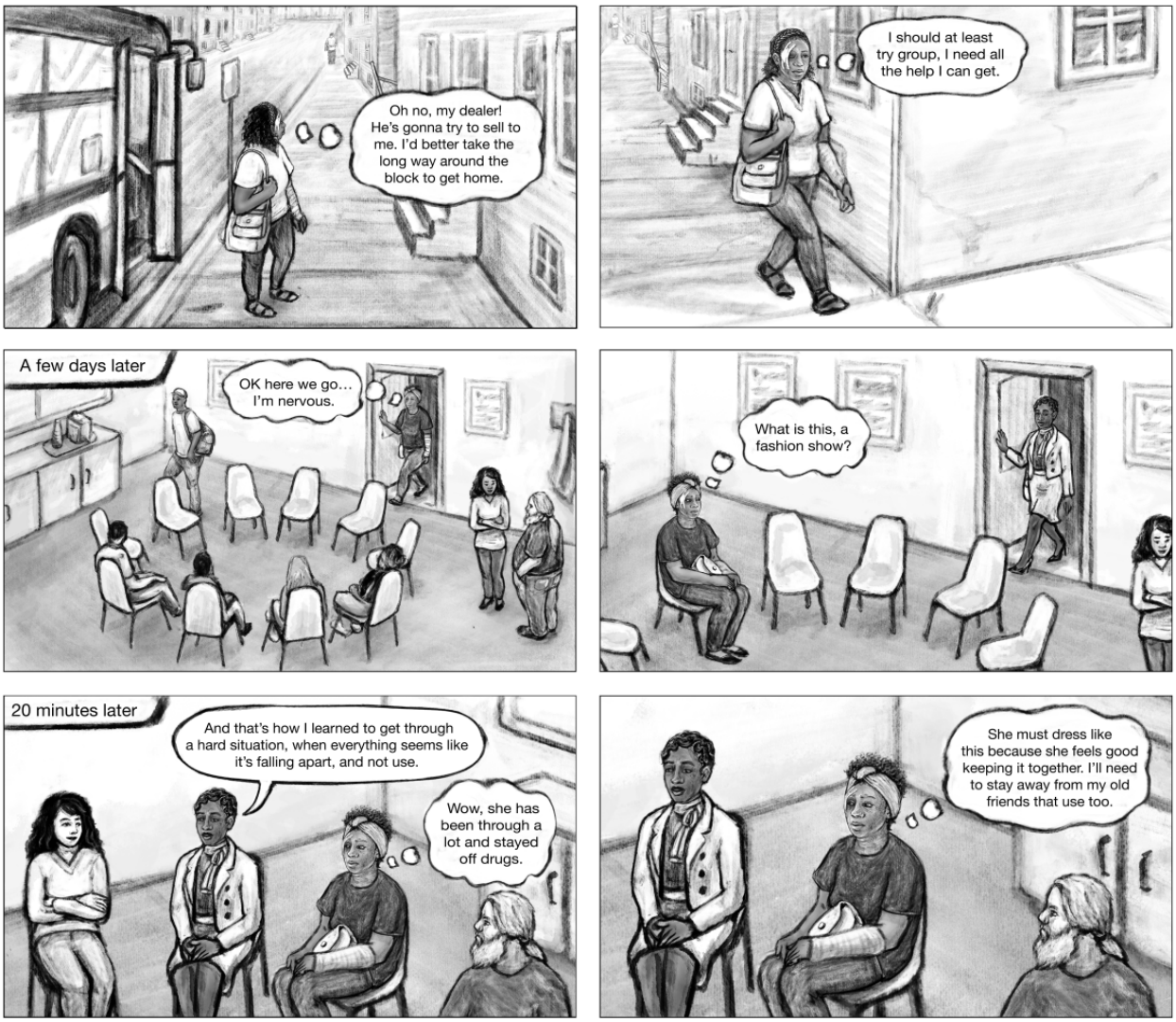

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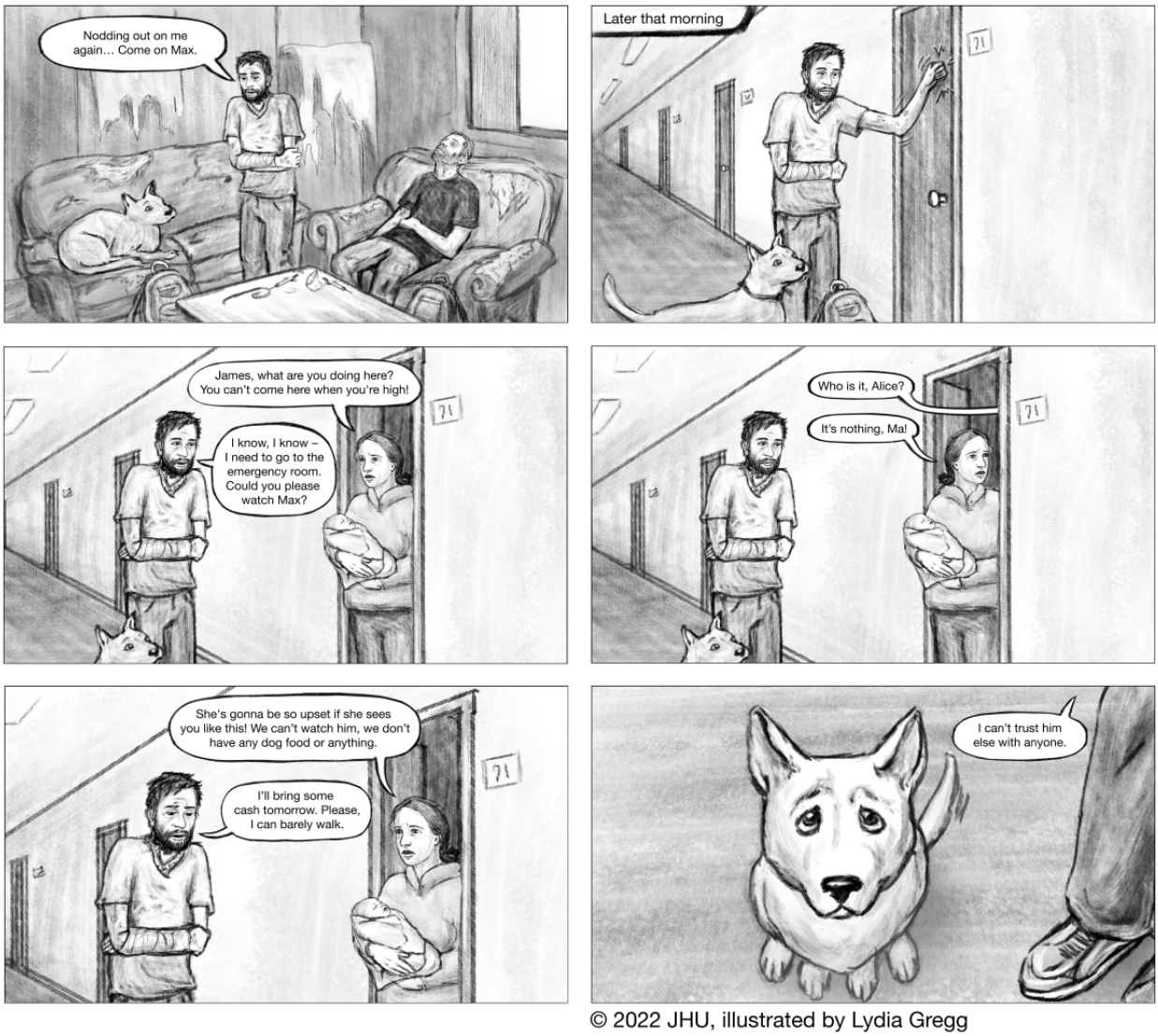
Figure 3. Representative images from James's Story, one of two visual narratives included in the story.



Peer Navigators

Three peer navigators with previous experience with OUD peer recovery support within outpatient and inpatient care settings provided support to participants, including through sharing their own personal narratives of recovery. Peer navigators provided support based on the principles of Recovery Support Services, including harm reduction, nonjudgment, person-centered support, and self-advocacy [56]. Peer navigators were trained to support study participants in downloading the mTools4Life app and demonstrated use of the app. Peer navigators used a participant engagement protocol with an expectation for at least weekly outreach either by phone or in person. Contacts were recorded in a spreadsheet and were considered successful if contact was achieved (ie, contact was reciprocal) or unsuccessful if contact attempts were not returned (eg, text was unanswered, phone call was unanswered, and voicemail did not receive a response).

Pilot Phase Procedures

Patients accessing care at the JHH ED between April and August 2022 were recruited for participation in the pilot phase. Inclusion criteria were (1) presentation to the ED with a substance use-related condition (eg, cellulitis, overdose, or wound care), (2) any use of illegal opioids or opioids not as prescribed in the previous 30 days, (3) English-speaking, and (4) possession of a smartphone capable of downloading the mTools4Life app. Patients were excluded if they were unable or unwilling to engage in study procedures.

Patients were referred for study participation either by ED staff (eg, clinicians, nurses, and social workers) or through assessment of potential eligibility based on chart review conducted by research staff. A research coordinator met with eligible patients, obtained informed consent, administered baseline assessments, and connected enrolled participants to an assigned peer navigator. Baseline assessments consisted of questions about demographics, employment, substance use, readiness for and confidence in their ability to reduce or cease substance use, physical and mental health, stigma, social support, and acceptability and appropriateness of the mTools4Life intervention.

Upon completion of the baseline assessments, participants were assigned to one of three peer navigators who met with

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participants either prior to ED discharge or in the community after discharge. Peer navigators were available by phone or in person from 8:30 AM to 5:00 PM, Monday through Friday. The number and purpose of engagements with participants were recorded.

Participants were contacted by research staff 3 months post enrollment and scheduled to complete a follow-up assessment. The follow-up assessment included the baseline questions about substance use and MOUD, as well as questions asking about participants' uptake of and satisfaction with the intervention, described more in the following section.

Pilot Phase Measures and Analyses

The primary outcomes of interest were engagement in MOUD treatment in the past 3 months (yes or no) and past 30-day substance use (yes or no). Secondary outcomes included the number of days of substance use in the past 30 days, the importance of, confidence in, and readiness for cutting down or quitting substance use, and the acceptability of, appropriateness of, and satisfaction with the intervention. All outcomes were assessed by self-report on a questionnaire.

Participants were asked 3 questions at each time point to assess the importance of, confidence in, and readiness for making a change (cutting down or quitting) in their substance use. Responses were measured on a scale of 1-10, where 1 means not at all (important, confident, and ready) and 10 means extremely (important, confident, and ready). These tools have generally been found to predict behavior change in studies of people who use drugs and other substances [57-59].

Two four-item scales, the Acceptability of Intervention Measure (AIM) and the Intervention Appropriateness Measure (IAM), were used to evaluate acceptability and appropriateness of the intervention [60]. Participants rated a series of statements about the intervention's acceptability and appropriateness for connecting people to treatment for OUD from 1 ("Completely disagree") to 5 ("Completely agree"). We calculated participants' average score for each measure out of 5. A participant was determined to have rated the intervention as acceptable or appropriate if their average score was greater than 3.

Participant evaluation of peer navigators was measured using the Texas Christian University (TCU) Treatment Engagement form questions on Counseling Rapport [61]. This 11-item tool was modified to replace the word "counselor" with "peer navigator." The total score for this scale ranges from 11 to 55, with higher scores indicating greater rapport.

Data on mobile app usage were self-reported by participants. Satisfaction with the app was measured using questions from the mHealth App Usability Questionnaire (MAUQ) [62], the Usefulness, Satisfaction, and Ease of Use (USE) questionnaire [63], and the Telehealth Usability Questionnaire (TUQ) [64]. Participants were asked 5 questions on usability, 9 on usefulness, and 8 on satisfaction and rated their agreement with each statement on a scale of 1 ("Disagree") to 7 ("Agree"). Total scores range from 5 to 35 for the usability subscale, from 9 to 63 for the usefulness subscale, and from 8 to 56 for the satisfaction subscale. Four statements rated on the 1 ("Disagree") to 7 ("Agree") scale were used to measure transportation into the narratives, 3 of which came from the Transportation Scale–Short Form (TS–SF) [65]. Relatability to the characters was measured with the statement, "I could relate to the characters in the stories in the app," modified from the original wording, "While reading the narrative I had a vivid image of [character name]." [65] Higher scores indicated greater usability, usefulness, and satisfaction with the app and transportation into the narratives.

Frequencies and means were obtained to describe sociodemographic characteristics and the outcomes. Fisher exact tests were conducted to assess the differences in the number of participants who reported using substances and who reported receiving MOUD at follow-up compared to baseline. Dependent samples 2-tailed *t* tests were conducted on paired data to examine the difference in the number of days of substance use in the past 30 days at baseline and follow-up (n=16). All analyses were conducted using R version 4.3.1 (R Foundation for Statistical Computing).

Ethical Considerations

The study was approved by the Johns Hopkins University School of Medicine Institutional Review Board (IRB 00220706). All participants provided informed consent. Data were deidentified. Participants received US $25 for completing the follow-up assessment.

Results

Formative Phase

Multimedia Appendices 1 and 2 summarize interview data analyzed during the formative phase, which were used to design the narratives. Both provider and patient opinions on the format of the narratives varied. Patient participants expressed that a mixture of different formats would be useful, given that individual preferences vary. Some pointed to animation as the best option, citing potentially low attention spans and low literacy levels among participants. Concerning the narrative content, the majority of patients expressed that narratives should not include any directives or patronizing content about the consequences of continued drug use. They generally expressed that there should be an emphasis on the benefits that treatment can bring to someone's life and that withdrawal is not as painful with MOUDs. Both provider and patient participants identified smartphone delivery of the content as a potential problem, noting that many people with OUD don't have cell phones and that many inpatient treatment facilities don't allow patients to bring their cell phones.

Pilot Phase: Study Sample

Overall, 219 people seen in the JHH ED for a substance use–related condition were referred for study participation during the recruitment period. Of 219, 14 declined to participate, 180 were screened and excluded for not meeting eligibility criteria, and 5 were enrolled but did not complete the baseline assessment. The most common reasons for noneligibility included not having a smartphone (n=85/180; 47.2%) and no opioid use in the past 30 days (n=62/180; 34.4%). The final sample of 20 participants was predominantly male (13/20, 65%)

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and Non-Hispanic White (13/20, 65%) (Table 1). The sample had a mean (SD) age of 41.1 (8.7) years. Half (n=10) of the participants reported being homeless in the preceding 3 months. Most participants (n=16/20, 80%) completed the 3-month follow-up interview.

Table . Demographics of study sample (N=20).

Characteristic	Value
Age, mean (SD)	41.1 (8.7)
Male, n (%)	13 (65)
Race and ethnicity, n (%)	
Non-Hispanic White	13 (65)
Non-Hispanic Black	5 (25)
Hispanic or Latino	1 (5)
Other	1 (5)
Phone operating system, n (%)	
Android	16 (80)
Apple	4 (20)
Homeless, past 3 months, n (%)	10 (50)
Health insurance, n (%)	
Medicaid	19 (95)
Medicare	2 (10)
Other (military or private)	2 (10)
Highest education attainment, n (%)	
Less than high school	2 (10)
High school diploma	8 (40)
Beyond high school	10 (50)
Relationship status, n (%)	
In a committed relationship	6 (30)
Separated, divorced, widowed, single	14 (70)
Infectious diseases, n (%)	
HIV infection	2 (10)
Ever diagnosed with HCV[a]	8 (40)
Opioid overdose, n (%)	
Any history of opioid overdose	12 (60)
Opioid overdose in past 90 days	3 (15)
Injection drug use in past 90 days, n (%)	14 (70)
Opioid use in the past 30 days, n (%)	20 (100)
Cocaine use in the past 30 days, n (%)	14 (70)

[a]HCV: hepatitis C virus.

Substance Use and Readiness to Change

All participants reported opioid use in the past 30 days at baseline (20/20, 100%). At follow-up, opioid use declined to 56.3% (9/16; *P*=.001; Table 2). Mean days of opioid use in the past 30 days declined from 19.9 (SD 11.7) to 8.3 (SD 11.4; *P*=.002; Table 3). Cocaine was used by 70% (14/20) of participants at baseline and 37.5% (6/16) of participants at follow-up (*P*=.09). Mean days of cocaine use declined from 13.3 (SD 12.2) to 4.8 (SD 9.4) in the past 30 days (*P*=.005).

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Table . Substance use in the past 30 days at baseline and 3-month follow-up (N=20).

Substance	Frequency at baseline, n (%)	Frequency at follow-up (n=16), n (%)	OR[a] (95% CI)	*P* value
Any opioid	20 (100)	9 (56.3)	∞(2.5-∞)	.001
Heroin	17 (85)	9 (56.3)	4.2 (0.7-31.6)	.07
Cocaine	14 (70)	6 (37.5)	3.7 (0.8-19.7)	.09
Cannabis	9 (45)	6 (37.5)	1.4 (0.3-6.5)	.74
Alcohol	4 (20)	3 (18.8)	1.1 (0.2-8.7)	≥.99

[a]OR: odds ratio.

Table . Days of substance use during past 30 days (n=16).

Substance	Baseline, mean (SD)	Follow-up, mean (SD)	*t* value (*df*)	*P* value
Any opioid	19.9 (11.7)	8.3 (11.4)	−3.7 (15)	.002
Cocaine	13.3 (12.2)	4.8 (9.4)	−3.3 (15)	.005
Cannabis	3.3 (5.2)	2.8 (7.5)	−0.3 (15)	.77
Alcohol	2.4 (7.5)	2.2 (7.5)	−0.5 (15)	.59

The mean score for perceived importance of making a change (quitting or cutting down) in substance use increased from 9.1 (SD 1.1) at baseline to 9.8 (SD 0.5) at 3-month follow-up on a 10-point scale (*P*=.009). Participant confidence in perceived ability to make a change in substance use had a mean score of 7.6 (SD 2.5) at baseline and a mean score of 8.4 (SD 2.2) at follow-up (*P*=.13). At baseline, readiness to make a change in substance use had a mean score of 8.6 (SD 2.6) and a mean score at follow-up of 8.8 (SD 2.1; *P*=.73).

Substance Use Treatment

At baseline, 13/20 (65%) participants had received MOUD treatment in the previous 3 months, including 55% (11/20) who received methadone, 15% (3/20) buprenorphine, and 5% (1/20) long-acting naltrexone. At follow-up, 13/16 (81.3%) participants who completed the 3-month follow-up assessment reported receipt of MOUD in the previous 3 months, with 62.5% (10/16) who received methadone and 37.5% (6/16) who received buprenorphine. Of the 13 participants who reported recent MOUD treatment at follow-up, 11/16 (84.6%) also reported MOUD use in the 3 months preceding baseline. There was no significant difference in the number of participants who received MOUD in the 3 months preceding baseline and follow-up (*P*=.46).

Acceptability and Appropriateness of Intervention

At baseline, the mean AIM scale score was 4.1 (SD 0.4; 5-point scale), and 94.7% (18/19) rated the intervention as acceptable (score of >3; Table 4). At follow-up, the mean AIM score was 4.5 (SD 0.5), and 100% (16/16) of participants rated the intervention as acceptable.

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Table . Acceptability and appropriateness of intervention ratings.

Measure	Baseline		Follow-up	
	Mean score (SD)	Participants who answered agreed or completely agreed (n=19), n (%)	Mean score (SD)	Participants who answered agreed or completely agreed (n=16), n (%)
Acceptability of Intervention Measure total score	4.1 (0.4)	—[a]	4.5 (0.5)	—
The intervention meets my approval.	4.2 (0.7)	18 (94.7)	4.3 (0.5)	16 (100)
The intervention is appealing to me.	4.0 (0.8)	17 (89.5)	4.6 (0.5)	16 (100)
I like the intervention.	4.3 (0.5)	19 (100)	4.6 (0.5)	16 (100)
I welcome the intervention.	4.1 (0.5)	18 (94.7)	4.4 (1.0)	14 (87.5)
Intervention Appropriateness Measure total score	4.0 (0.4)	—	4.3 (0.8)	—
The intervention would fit my needs.	3.9 (0.7)	16 (84.2)	4.3 (0.9)	14 (87.5)
The intervention feels suitable to me.	4.1 (0.3)	19 (100)	4.2 (0.8)	14 (87.5)
The intervention seems like a good match.	4.1 (0.3)	19 (100)	4.3 (0.8)	15 (93.8)

[a]Not applicable.

Regarding the appropriateness of the intervention, the mean of IAM scale score at baseline was 4.0 (SD 0.4), and 100% (19/19) of participants rated the intervention as appropriate. At follow-up, the mean of the IAM score was 4.3 (SD 0.8), and 93.8% (15/16) of participants rated the intervention as appropriate.

Intervention Uptake

At follow-up, 11/16 (68.8%) participants reported using the app at least once since baseline. Reasons for not using the app included (1) forgetting about the app (n=3), (2) losing phone (n=2), (3) losing access to or not being able to access the app (n=1), and (4) forgetting how to use the app (n=1).

Overall, 10/16 (62.5%) participants reported engaging with the peer navigator at least once following the baseline assessment. Reasons for not engaging with the peer navigator included: (1) lost cell phone or cell service (n=2), (2) forgot about the peer navigator (n=2), and (3) not interested in peer support (n=1). More than half of participants (9/16, 56.3%) reported engagement with both the app and peer navigator, while 4/16 (25%) participants engaged with neither; 2/16 (12.5%) participants used the app but did not engage with the peer navigator, and 1 (6.3%) participant engaged with the peer navigator but did not use the app. All participants who engaged with their peer navigator rated their satisfaction with their assigned peer navigator at follow-up. The mean satisfaction score was 51.7 (SD 3.5) out of a total score of 55. Multimedia Appendix 7 describes the association of intervention engagement with selected behavioral outcomes.

Participants who reported engaging with the intervention were asked about the frequency of using each component. The most frequently used aspect of the intervention was communication with the peer navigators, with a mean score of 2.6 (SD 0.7; scale 0-5, higher scores indicating closer to daily use). App use had a mean score of 1.9 (SD 0.7).

Of the app components, the stories (mean 1.7, SD 0.8) and the resource list (mean 1.4, SD 0.9) were used most frequently, followed by medication reminders (mean 1.0, SD 1.4) and appointment reminders (mean 0.9, SD 1.2). No participants reported using the app to record symptoms of withdrawal.

Throughout the 3-month follow-up phase, peer navigators recorded a total of 234 contacts or contact attempts, of which 141 (60.3%) were successful and 93 (39.7%) were unsuccessful. Peer navigators recorded a mean of 11.7 (SD 5.0) contacts per participant. Each participant had a mean of 7.1 (SD 4.7) successful or reciprocal contacts and 4.7 (SD 3.4) unsuccessful or unanswered contact attempts from their peer navigator. Most contacts (n=125, 53.4%) were via phone call, 65 (27.8%) contacts were in-person, with the rest of the contacts (n=25, 10.7%) through text message, the mTools4Life app (n=5, 2.1%), Zoom (Zoom Communications, Inc; n=1, 0.4%), letter (n=1, 0.4%), or other (n=12, 5.1%). The primary purpose of most of the contacts was outreach (n=164, 70.1%), followed by coaching and mentoring (n=34, 14.6%). The remaining contacts had the primary purpose of appointment schedule or reminder (n=4, 1.7%), engagement with mTools4Life app (n=6, 2.6%), housing support (n=1, 0.4%), link to health care (n=2, 0.9%) or SUD treatment (n=7, 3.0%), or other (n=16, 6.8%).

Usability and Usefulness of App

Responses on the usability and usefulness of the app were available for the 11/16 (68.7%) study participants who reported using the app at follow-up. The mean rating of the usability of the app was 33.9 (SD 1.7) out of a total score of 35. The mean

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usefulness rating was 59.7 (SD 5.2) out of a total score of 63, and the mean satisfaction rating was 54.8 (SD 2.1) out of a total score of 56. Participants who engaged with the stories (n=10) generally reported favorable responses related to transportation into the narratives (Table 5). The mean rating for all transportation-related statements was 5.9 (SD 1.8) out of 7 total points.

Table . Agreement with statements about stories (n=10).[a]

Statement	Value, mean (SD)
I could relate to the characters in the stories in the app.[b,c]	6.4 (1.1)
I was mentally involved in the stories while watching them.[d]	5.9 (2.1)
I wanted to learn how the stories ended.	5.8 (2.1)
The stories affected me emotionally.	5.5 (2.0)

[a]Four statements were used to measure transportation into the narratives on a scale from 1 (“Disagree”) to 7 (“Agree”).

[b]Relatability of the characters was measured with a modified statement.

[c]n=9 due to missing data.

[d]n=8 due to missing data.

Discussion

Principal Findings

In this study, we demonstrated successful development and deployment of a peer-supported, narrative-based, and mobile-supported intervention with preliminary evidence of effectiveness as demonstrated by reduction in substance use at 3-month follow-up compared to baseline. To the authors’ knowledge, this is the first study to evaluate narratives embedded into a mobile app to address SUD treatment engagement.

While a higher proportion of participants reported MOUD at 3-month follow-up compared to baseline (13/16, 81.3% vs 13/20, 65%), these differences are difficult to interpret due to the small sample size and the loss to follow-up. In addition, most of those who engaged in MOUD at follow-up also reported MOUD engagement at baseline (11/13, 84.6%), indicating that they may have already been open to MOUD treatment. The reduction in overall substance use and in paired analysis among participants with both baseline and follow-up data is reassuring and provides some preliminary evidence of intervention effectiveness.

The intervention was judged by study participants to be highly acceptable and appropriate. The component of the intervention that participants reported using most frequently was engaging with the peer navigators. In a recent study, Szpak et al [66] also found that their study sample of people with OUD engaged more with the peer navigator than the remote intensive outpatient program that the peer navigator was supporting. It is thus possible that this component of the intervention contributed significantly to the study findings of increased scores on perception of importance in change in substance use and the observed reduction in substance use. These study findings are supported by an extensive body of literature demonstrating the effectiveness of peer-based interventions in improving a range of outcomes related to SUD, including increased retention in SUD treatment and reduced rates of relapse [67]. The ability of peer navigators to engage with people who use drugs in culturally congruent ways, role model the substance use recovery journey, and provide a range of supports, including recovery and other social support (informational and emotional support), likely contributes to the effectiveness of peer recovery support interventions. The Chat feature and reminders within the mobile app could facilitate contact with peer navigators, potentially augmenting the positive effects of PRSS.

Overall, while nearly 3 quarters of participants who completed the 3-month follow-up reported the use of mobile app at least once, mobile app components of the intervention were used infrequently. The data on uptake of mobile app tools for substance use treatment or recovery support is mixed, with some studies reporting high uptake and effectiveness and others reporting low uptake [68,69]. Previously reported reasons for low uptake or effectiveness of mobile apps include low perceived usefulness, having limited access to or comfort with the technology, privacy concerns, and lack of personal motivation to engage in the intervention [68-71]. Similarly, we found that the reasons for not engaging with the app during the pilot period (ie, forgetting about the app, losing the phone, losing access to the app, and forgetting how to use the app) aligned with the ideas of low perceived usefulness or motivation and a lack of access to and comfort with the technology; though, interestingly, none of the participants in our study raised privacy concerns. The component of the mobile app that participants engaged with most frequently was the “Stories” section. The visual narratives may have thus contributed to the provision of information with the potential to change motivation and behavioral skills related to substance use recovery and engagement in care for OUD. Engagement with narratives may have been limited, with only 2 narratives embedded in the app.

The graphic narrative and animation formats were chosen with the aim of harnessing the ability of visuals to enhance learning [72-75] and the power of narrative transportation to affect behavior change [48-50] and appear to have been successful overall. Participants who engaged with the stories generally reported favorable responses related to transportation into the narratives (Table 5). Recipients with a lower self-reported ability to generate vivid mental imagery have been shown to experience lower levels of transportation into text-based narratives than narratives with accompanying visuals [76]. The graphic

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narratives and animations in this intervention may have assisted with overcoming this barrier by enabling such recipients to experience higher levels of transportation.

The development of narratives from remixes of reported lived experiences offered the opportunity to convey sensitive narratives about people with OUD visually. Sequential drawings, as opposed to fotonovelas [77] or video, allowed for depictions of characters in simplified, iconic visual form, which may differ from photographic representations in their ability to communicate information efficiently [78]. Visualizing topics, such as OUD-related injuries in an iconic style, also avoids photorealism of potentially disturbing content.

Video testimonials have been used as a means of persuading patients to taper off opioids for chronic pain [79]. A drawback of using video testimonials for OUD is the lack of storyteller anonymity required while discussing sensitive personal topics. Purely text-based testimonials, which would allow anonymity, may be less engaging for individuals with low literacy levels or low ability to generate vivid mental imagery [76]. The visual narratives allowed for anonymity of the storytellers, which enabled a vivid portrayal of content and behaviors that might not be discussed in testimonials. The format has potential as an effective approach to conveying health information related to SUD. Future studies could investigate the effectiveness and associated advantages and disadvantages of the visual narrative format and a peer-based format for narrative health communication.

Limitations

While this study has several strengths, including a behavior therapy-driven and systematic approach to intervention development, incorporating the perspectives and experiences of people with OUD and care providers to people with OUD in intervention development, and successful nonincentivized intervention deployment, the study also has several limitations. These limitations include the observational nature of this pilot study, with only 20 participants enrolled. We are unable to demonstrate which components of the intervention (peer navigation or mobile app support components) were most effective. Until we can investigate further, it is our belief that both parts of the intervention were integral to driving the observed outcomes. We were also unable to capture metrics for mobile app usage and thus unable to quantitatively describe the use of mobile app components. Finally, of the 219 patients referred for study participation, 85 (38.8%) failed to meet eligibility criteria due to not possessing a smartphone. This represents a lower rate of smartphone ownership than in a recent study of 494 people who inject drugs in Fresno, CA, where 13% did not own a smartphone [80]. This exclusion criterion in this study could have led to participants having less severe OUD, given that people with OUD who have cellphones have been shown to be less likely to be unhoused, share syringes, and reuse syringes [80]. More severe OUD could also be associated with a higher likelihood of ED visits, leading to lower smartphone ownership in this sample. Future evaluations of the intervention with a randomized controlled design could include a printed version of the intervention's content or include playing the animated versions of the narratives in the hospital to broaden participation to people with OUD without smartphones.

Conclusions

This study demonstrates the feasibility of the development and deployment of a peer-led, narrative-based intervention to support SUD care engagement and preliminary data in support of acceptability, appropriateness, and effectiveness. These data show a reduction in substance use at 3-month follow-up compared to baseline. The embedded visual narratives represent a promising approach for provisioning information and potentially evoking behavior change in accordance with the IMB model and transportation theory. Rigorous evaluation with a randomized controlled design in a larger population is needed to determine intervention effectiveness and which components of the intervention are critical for effectiveness.

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Data Availability

The datasets generated during this study are available from the corresponding author on reasonable request.

Authors' Contributions

Conceptualization: LG, MS, KET, CAL, OF-N. Data curation: MCL, SMK. Formal analysis: MCL. Visualization: LG. Validation: SMK. Supervision: TA. Software: RJS. Data collection: NF, TV. Funding acquisition: OF-N. Methodology: LG, CAL, OF-N. Project administration: OF-N. Writing – original draft: MCL, LG, OF-N. Writing – review & editing: MS, KET, SMK, TA, RJS, NF, TV, CAL

Conflicts of Interest

The authors declare the following financial interests/personal relationships which may be considered as potential competing interests: OF-N discloses institution research funding from AbbVie Inc and medical advisory funding from Gilead. All other authors report no conflict of interest.

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Multimedia Appendix 1
Messaging and experiences for narratives mapped to the transtheoretical model.
[PDF File, 200 KB - formative_v10i1e82485_app1.pdf]

Multimedia Appendix 2
Pros and cons of entering treatment for opioid use disorder and additional factors affecting treatment success.
[PDF File, 199 KB - formative_v10i1e82485_app2.pdf]

Multimedia Appendix 3
Graphic narrative of one of the stories: Eva's narrative.
[PDF File, 46789 KB - formative_v10i1e82485_app3.pdf]

Multimedia Appendix 4
Graphic narrative of one of the stories: James's narrative.
[PDF File, 39307 KB - formative_v10i1e82485_app4.pdf]

Multimedia Appendix 5
Full animation of one of the stories: Eva's narrative.
[MP4 File, 196869 KB - formative_v10i1e82485_app5.mp4]

Multimedia Appendix 6
Full animation of one of the stories: James's narrative.
[MP4 File, 198528 KB - formative_v10i1e82485_app6.mp4]

Multimedia Appendix 7
Fisher tests for app use and peer navigator engagement and the associations with opioid use and MOUD engagement. MOUD: medication for opioid use disorder.
[DOCX File, 27 KB - formative_v10i1e82485_app7.docx]

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Abbreviations

AIM: Acceptability of Intervention Measure
ED: emergency department
IAM: Intervention Appropriateness Measure
IMB: information-motivation-behavioral skills
MAUQ: mHealth App Usability Questionnaire
mHealth: mobile health
MOUD: medication for opioid use disorder
OUD: opioid use disorder
PRSS: peer recovery support services
SUD: substance use disorder
TCU: Texas Christian University
TS–SF: Transportation Scale–Short Form
TTM: transtheoretical model
TUQ: Telehealth Usability Questionnaire
USE: Usefulness, Satisfaction, and Ease of Use

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Development of a Social Media Campaign to Support HIV Prevention and Care Among Transgender Latina Women: Community-Engaged Mixed Methods Feasibility Pilot Study

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Abstract

Background: Transgender Latina women in the United States face disproportionate HIV risk due to intersecting social and structural vulnerabilities that limit access to care. While gender-affirming, culturally responsive, and eHealth strategies show promise for improving access, social media–based approaches remain underused despite their potential to reach marginalized groups at scale.

Objective: This study aimed to develop and pilot a culturally tailored social media campaign to increase awareness of HIV prevention and care services offered by a community-based organization (CBO) in King County, Washington, for transgender Latina women and to assess the campaign's feasibility and acceptability.

Methods: We conducted a community-engaged, mixed methods pilot study using a multiphase design. In phase 1, we conducted cross-sectional, in-depth interviews with transgender Latina women (n=20) recruited by a CBO in King County, Washington. Interviews were analyzed using thematic analysis, guided by the Unified Theory of Behavior, to inform campaign messaging priorities. A subsequent focus group (n=7) then reviewed and refined 6 draft campaign concepts according to the community preferences. In phase 2, the finalized campaign was piloted on Facebook and Instagram. A cross-sectional REDCap (Research Electronic Data Capture; Vanderbilt University) survey was conducted with a subset (n=100) of transgender Latina women exposed to the campaign who voluntarily consented to complete the survey after being directed from the campaign. Survey data were summarized using descriptive statistics to assess campaign reach and feasibility and acceptability outcomes.

Results: In-depth interview participants were a mean age of 37.6 (SD 9.5) years and reported an average of 10.2 (SD 10.8) years residing in the United States (n=20). Interviews revealed four key themes: (1) importance of HIV prevention and awareness, (2) accessibility of HIV services, (3) provision of culturally tailored care, and (4) need for confidentiality. Among survey respondents (mean age of 29.7, SD 5.2 years), 97% (97/100; 95% CI 91.5% - 99.0%) had ever tested for HIV and 44% (44/100; 95% CI 34.3% - 53.7%) reported testing within the past 6 months. A total of 3 respondents were living with HIV, all on antiretroviral therapy. Nearly all (91/100, 91%; 95% CI 84.3% - 95.2%) reported campaign-motivated action, including HIV testing or seeking information or services.

Conclusions: Findings demonstrate the feasibility and acceptability of a culturally tailored campaign, cocreated with community members, to promote HIV prevention and care among transgender Latina women. By integrating participatory methods with digital outreach, this study contributes an innovative model that centers community voices in campaign design while leveraging widely used platforms. The study has implications for providing CBOs with scalable, low-cost strategies to expand culturally responsive HIV services, reduce stigma, and motivate health-seeking behaviors in populations often overlooked by mainstream public health messaging. This work underscores how codesigned social media campaigns can complement traditional outreach and inform future HIV prevention strategies for underserved populations.

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KEYWORDS

community engagement; digital health; eHealth; health disparities; HIV prevention; latina; social media; transgender

Introduction

Transgender women, particularly transgender women of color, experience heightened risk of HIV transmission in the United States [1]. Most recent data from the National HIV Behavioral Surveillance Among Transgender Women, which monitors behavioral risk factors, HIV testing behaviors, and receipt of prevention services among transgender women in 7 US urban areas, reported that 42% of the 1608 transgender women interviewed between 2019 and 2020 were living with HIV [2]. Hispanic or Latina transgender women are disproportionately affected, accounting for over one-third of all new HIV diagnoses among transgender women [2,3].

Transgender Latina women experience multiple and intersecting forms of marginalization including stigma, discrimination, and violence related to both their gender and ethnicity [4]. Many are immigrants who may face additional challenges, including lack of insurance, unemployment, homelessness, and poor mental health [5,6]. These social and structural vulnerabilities increase their risk of HIV transmission and impede engagement in health services [7,8]. Moreover, transgender Latina women may have limited social support in the United States, which may further isolate them from community resources and exacerbate barriers to care [9]. Social isolation can undermine trust in health care systems and reduce awareness of available HIV prevention and treatment services, which can lead to delays in HIV testing and care [10,11]. These barriers contribute to low uptake of effective HIV prevention strategies such as pre-exposure prophylaxis (PrEP) in this population [12].

There is growing recognition that gender-affirming, person-centered services that address both social and cultural barriers are essential to improving engagement in HIV prevention and care for transgender populations [13,14]. However, there remains a dearth of HIV prevention intervention approaches that have been designed specifically for transgender Latina women and their specific needs [15]. While community-based service approaches have demonstrated effectiveness in improving service uptake [13], ensuring awareness and accessibility of these services within the transgender Latina community, again, remains a significant challenge. Specifically, approaches to reach this population must be culturally grounded and responsive, acknowledging and addressing the unique cultural, social, and structural contexts that shape the lives and identities of transgender Latina women [16].

Notably, mobile apps and eHealth offer opportunities to engage marginalized groups disconnected from traditional health care and deliver information that addresses structural barriers [17-19]. Social media platforms, which are widely used within Latino communities, remain an underused tool for expanding HIV prevention efforts to vulnerable populations [18,20]. In prior work, we developed and tested a social media campaign promoting HIV prevention among Latino gay, bisexual, and other men who have sex with men, which successfully reached the target population [21]. However, transgender Latina women face distinct social, cultural, and structural barriers that can differ from those of cisgender Latino men, including gender-based stigma. To reach transgender Latina women, therefore, required the development of a campaign to ensure that content reflected their lived experiences, preferences, and unique prevention needs. This called for qualitative inquiry to capture nuanced perspectives and community-driven insights to inform the design and framing of culturally relevant social media content [22].

We sought to develop a social media campaign for transgender Latina women to increase awareness of HIV prevention and care services offered at Entre Hermanos, a community-based organization (CBO) providing bilingual HIV testing and PrEP navigation support to Latino LGBTQ+ (lesbian, gay, bisexual, transgender/transsexual, queer, and other minority sexual orientations and gender identities) individuals in King County, Washington. The objectives of this paper are to describe the development process of the campaign and present pilot data on its preliminary feasibility and acceptability.

Methods

Research Design Overview

This study was conducted in the state of Washington from October 2023 to December 2024 and involved two phases: (1) the first phase involved qualitative interviews and a focus group with transgender Latina women to guide development of the social media content and campaign; and (2) the second phase involved piloting the campaign on social media platforms and assessing its feasibility via an online survey with transgender Latina women.

Phase 1: Development of Social Media Content and Campaign

Methods

For the first phase, we used a 2-step qualitative approach to conduct in-depth interviews and a focus group with transgender women who identified as Hispanic or Latina. A qualitative approach was particularly suited to explore preferences, perceived barriers, and culturally relevant communication strategies that may not be easily captured through quantitative methods.

Interviews were conducted between November 2023 and May 2024 with 20 participants, a sample size determined to be sufficient for achieving information saturation for our objectives [23]. Following the interviews, a focus group was conducted with participants in June 2024 to obtain feedback on the social media content developed from the interview findings. Approximately 5 to 7 participants were sought as an ideal size

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to promote open discussion and ensure that each participant had the opportunity to share detailed feedback.

Study Participants

Eligibility criteria for study participation included (1) identifying as Hispanic or Latina or Latinx individuals, (2) age greater than or equal to 18 years, (3) identifying as transgender, (4) assigned male at birth, and (5) living in Washington.

Participant Recruitment

Participants were recruited through Entre Hermanos, a Latino-serving CBO in King County, Washington. We purposively recruited participants via multiple community outreach methods designed to reach transgender Latina women engaged with Entre Hermanos' programs and broader community networks. Specifically, Entre Hermanos staff members who were part of the research team contacted potentially eligible participants to invite them to participate. In addition, recruitment materials were disseminated through the organization's email listserv, which advertised the study and provided contact information for enrollment. Participants were purposively recruited to ensure diversity in age and length of time living in the United States, which were factors considered important in shaping social media engagement.

In-depth interviews and focus groups were conducted in person at Entre Hermanos in a private, confidential space. The location was selected collaboratively by the research team and Entre Hermanos staff, given participants' trust and familiarity with the organization as a community-based setting.

Data Collection

In-Depth Interviews

All interested participants were screened for eligibility and consented to participate in the study. Prior to the interview, participants completed a brief demographic survey that asked about sociodemographic characteristics (eg, age, education, country of origin, current gender identity, assigned sex at birth, and time living in the United States).

In-depth interviews were semistructured and were guided by the Unified Theory of Behavior (UTB) [24] to explore factors related to normative pressures, beliefs and expectancies, self-concept or image, affect and emotions, and self-efficacy in relation to engaging in HIV services [25]. The UTB provided a comprehensive framework for understanding behavioral intentions and actions and incorporates multiple determinants, including individual and contextual level factors, that aligned closely with the goals of this formative phase. Interviews also asked about preferences and behaviors related to social media use to assess preferred platforms, content, and delivery strategies in relation to information about HIV and prevention for transgender Latina women. Interviews were conducted in person by 2 trained native Spanish speakers (KAP and JA) and lasted approximately 1 hour. Interviewers were bicultural and bilingual and had extensive experience working with Hispanic or Latino and transgender populations.

In-Depth Interview Analysis

Interviews were audio recorded and transcribed verbatim by 2 native Spanish speakers (PA and KAP). Data were analyzed in Spanish using thematic analysis, which led to the identification of main themes. Thematic analysis followed a primarily deductive approach guided by the UTB, which informed the interview guide and coding framework. However, inductive coding was also applied to capture emergent themes that extended beyond the predefined theoretical constructs. A total of 2 coders independently reviewed and open-coded the interview transcripts, repeatedly reading to become familiar with the data and produced detailed summaries with notes on key points and potential themes and subthemes. The coders then met to compare findings, resolve discrepancies, and refine the themes through iterative discussion [22,26]. The transcripts were coded using Microsoft Word. A final table of main themes was developed and reviewed with the study principal investigator to contextualize the findings within existing literature.

Focus Group

Following the analysis of the in-depth interviews, a communication agency was engaged to develop a creative concept proposal for the campaign. A focus group (n=7) was then conducted to obtain feedback and suggestions on the proposed social media content. Focus group questions were guided by five domains from the UTB influencing health behaviors [24]: (1) normative pressures and perceived norms, (2) beliefs about consequences of the behavior, (3) self-concept and perceived identity of individuals engaging in the behavior, (4) affective and emotional responses, and (5) self-efficacy and perceived ability to overcome barriers [27,28]. Additional feedback on design, messaging, graphics, and format preferences was also collected. The focus group was conducted in person by 2 trained native Spanish speakers with extensive experience working with the transgender Latina community and lasted approximately 2 hours.

Focus Group Analysis

Focus group data were analyzed using thematic analysis and a structured, collaborative approach. While sessions were recorded, detailed notes taken by 2 research team members served as the primary data source, with recordings used for verification. Each note taker independently summarized the discussions, identifying key points and emerging themes. The researchers then compared summaries to reconcile differences and reach consensus on key findings. This approach is consistent with a rapid qualitative analysis approach, which is an applied qualitative method designed to obtain actionable and targeted insights on a shorter timeline than traditional qualitative methods [29,30]. Given that the focus group was conducted to refine the social media content rather than to develop a new theory, this method was appropriate for the study's aims. A table was created to systematically organize themes across expression, general idea, visuals, and description for each campaign component [30]. This table was reviewed with the study team to finalize themes and ensure accuracy before sharing with the communication agency to revise campaign content.

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Positionalities and Potential Biases of the Research Team

The research team included individuals with diverse backgrounds and lived experiences, including members who identified as transgender, Latina, immigrant, and lesbian, gay, bisexual, or queer. Community members were integral parts of the research team and contributed to all stages of the study, including data collection procedures and interpretation to ensure that decisions were grounded in community priorities and perspectives. This collaborative structure fostered reflexivity and ongoing dialogue about potential biases and assumptions [31]. Throughout the process, the team remained attentive to positionality and power dynamics, intentionally centering community voices and lived experiences in the interpretation of findings.

Phase 2: Feasibility of Social Media Campaign Through Online Surveys

Methods

Based on findings from phase 1, a social media campaign was developed and piloted on Facebook and Instagram between November 2024 and December 2024. The campaign included 4 video posts promoting HIV prevention and care at Entre Hermanos among transgender Latina women. Each social media post included text inviting interested viewers to participate in an online survey. Clicking on the post directed individuals to a secure REDCap (Research Electronic Data Capture; Vanderbilt University) link, where they first reviewed and electronically signed an informed consent form [32]. Respondents were then screened for eligibility before completing the full survey.

Inclusion and Exclusion

Eligibility criteria for survey participation included: (1) self-identifying as Hispanic or Latina; (2) self-identifying as transgender; (3) reporting assigned male sex at birth; and (4) being at least the age of 18 years. Participants who did not meet these criteria were not eligible to participate.

Measures

The survey collected data on sociodemographic characteristics, HIV prevention behaviors, and reactions to the campaign content developed from previously validated instruments. Sociodemographic variables included age, country of birth, immigration status, education, employment, income, health insurance status, and religion. Behavioral variables included alcohol and drug use, sexual behaviors, and HIV prevention and care behaviors (HIV status, HIV testing history, HIV testing intentions, antiretroviral therapy [ART] use, and PrEP use). These behavioral variables were included as exploratory measures to provide information about participants' HIV-related risk and prevention behaviors. These behavioral patterns informed the interpretation of campaign feasibility and reach.

Participants were also asked to rate the relevance of the campaign content and indicate whether the campaign influenced them to take any HIV-related action. Surveys were offered in Spanish or English and capped at 100 completed responses. Eligible participants received a US $25 incentive for survey completion.

Data Analyses

Survey data were analyzed descriptively to assess the characteristics of transgender Latina women reached by the campaign and to assess whether the campaign could successfully engage this population. Descriptive analyses were used to summarize participant profiles and assess campaign feasibility and acceptability.

Ethical Considerations

The study was reviewed by the University of Washington Institutional Review Board and deemed exempt from federal human subjects regulations (study ID: STUDY00018207). In-depth interview and focus group participants provided verbal informed consent in accordance with approved study procedures, while survey participants completed electronic informed consent through the REDCap platform. In-depth interview and focus group participants received a US $50 incentive, and survey participants received a US $25 incentive for completion. Incentive amounts were determined in collaboration with our community partner to ensure appropriateness for participants' time and effort across study activities. All qualitative and quantitative data were deidentified for analysis. To ensure privacy and confidentiality, only study team members were present during data collection, and all participants provided informed consent emphasizing voluntary participation and data confidentiality. Participants were informed that they could decline to answer any question or withdraw from the study at any time. They were reminded that some questions might be sensitive or emotionally distressing. In such cases, the investigator was prepared to provide referrals to counseling services for additional support. No participants reported distress or required referral during data collection. Focus group participants contributed to the development of the social media campaign and are thus identifiable in Multimedia Appendices 1-4. Consent has been granted from all identifiable individuals for inclusion of their images and videos in this paper.

Results

Phase 1: In-Depth Interviews and Focus Group

Overview

Table 1 presents the sociodemographic characteristics and HIV-related behaviors of the in-depth interview and focus group participants (n=26). There was no missing data across all variables. The average age of participants was 37.6 (SD 9.5) years and 13 out of 26 (50%) were born in Mexico. No participants reported being married, and 15 out of 26 (58%) participants reported having health insurance. The majority (24/26, 92%) had previously tested for HIV, and 15 out of 26 (58%) participants were currently using PrEP.

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Table . Sociodemographic characteristics and HIV-related behaviors of transgender Latina women who participated in in-depth interviews and a focus group in the state of Washington (November 2023-June 2024; n=26).

Variables	Value[a]
Sociodemographic characteristics	
Age (y), mean (SD; range)	37.6 (9.5; 19.0 - 54.0)
Time in the United States (y), mean (SD; range)	10.2 (10.8; 0.1 - 32.0)
Country or region of origin, n (%)	
Mexico	13 (50)
Central America[b]	4 (14)
South America[c]	7 (27)
Other[d]	2 (8)
Preferred language[e], n (%)	
Only Spanish	8 (31)
More Spanish than English	11 (42)
Both Spanish and English	7 (27)
Monthly income (US $), n (%)	
0-1000	11 (42)
1000-4999	15 (58)
Education, n (%)	
High school or less	16 (62)
Technical degree	5 (19)
College or postgraduate	5 (19)
Marital status[f], n (%)	
Single	26 (100)
Has health insurance, n (%)	
Yes	15 (58)
HIV-related behaviors	
Ever tested for HIV, n (%)	
Yes	24 (92)
Tested for HIV in past 6 months, n (%)	
Yes	23 (89)
Current PrEP[g] use, n (%)	
Yes	15 (58)
Number of sex partners in past 6 months, n (%)	
0	2 (8)
1[a]	3 (12)
2 - 10	18 (69)
>10	3 (12)

[a]One participant from the in-depth interviews also participated in the focus group.

[b]Nicaragua, Honduras, El Salvador, and Guatemala.

[c]Colombia and Venezuela.

[d]Russia and the Philippines.

[e]No participants reported preferring only English or more English than Spanish.

[f]No participants reported being married.

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[g]PrEP: pre-exposure prophylaxis.

In-Depth Interview Themes

In-depth interviews revealed four key themes and messages to guide the campaign's development. The first theme focused on emphasizing prevention and awareness. Participants explained that it was important to promote PrEP availability, regular HIV testing, and diverse prevention strategies, including condom use. For example, one recommended that the content "include information about care and prevention, for example, advising them to use condoms if they have sexual relations, to take the PrEP pill, which is supposedly also used a lot here…" (34 years old, from El Salvador). Clear messaging around these measures was deemed essential for increasing awareness and encouraging proactive health behaviors.

The second theme was the need to highlight the accessibility of HIV services. Participants stressed that messages should convey that HIV services are accessible regardless of immigration status or insurance coverage. Specifically, participants proposed messages to encourage people to get tested such as, "I invite you to get tested for HIV and sexually transmitted diseases, the tests are free" (47 years old, from Mexico) and "We are all immigrants, we are all sisters" (44 years old, from Colombia). Emphasizing the availability of free services was viewed as critical to ensure that individuals do not feel excluded from care.

The third theme was the availability of culturally tailored services. Culturally tailored services, especially those provided by Latinos for Latinos, were identified as key to building trust and increasing engagement within the community. Among all, one participant explained why they sought services at a Latino-serving organization: "…first of all, they speak my language… Spanish, and they're Latinos, so I felt more comfortable there" (44 years old, from Colombia). Culturally sensitive approaches were seen as essential for improving health care uptake.

The fourth theme was focused on confidentiality and safety. Ensuring confidentiality and safety for individuals accessing services was a top priority. Participants underscored that addressing privacy concerns is necessary to reduce fear of stigma or discrimination and to encourage HIV testing and HIV prevention. For example, a participant highlighted that, "to announce the availability of tests through social media and also tell them that it's a test, one that isn't shared with anyone, that's confidential, so that they can also feel safe, knowing they won't be judged or criticized" (32 years old, from Mexico).

In addition to these core themes, participants highlighted the need to address misinformation by dispelling myths and providing accurate information. Participants explained that messaging should be empowering and encourage individuals to take control of their health through knowledge, self-love, and personal responsibility. Real-life testimonials were seen as particularly powerful in reducing fear associated with HIV diagnoses and demonstrating that living with HIV is manageable, especially because participants felt more identified with individuals who had lived similar experiences, unlike celebrities or spokespeople who had not personally navigated these challenges. Participants underscored that reducing stigma remains crucial, particularly in challenging misconceptions linking HIV testing or positive status to promiscuity.

Preferred Platforms and Formats

Participants identified Facebook as a widely used platform for connecting with family, engaging with community content, and sharing information via videos, images, and links. Instagram was also valued for its visual content and broad reach.

Regarding content format, participants favored short, engaging videos over static images or text posts. Testimonial videos featuring relatable individuals were noted as especially impactful. Participants highlighted that there should be a diversity of personal experiences with HIV prevention and treatment. Visually appealing content such as colorful graphics, infographics, and engaging images was considered effective in capturing attention and conveying information succinctly.

Participants also emphasized the importance of using a natural, conversational tone to maintain credibility and trust. Overly polished or commercialized content was viewed as less authentic. A respectful approach, free of explicit or offensive material, was strongly recommended. A varied mix of testimonial videos, images, and infographics was suggested to keep content dynamic and engaging for the target audience.

Focus Group Recommendations

The results from the in-depth interviews were shared with a creative consulting agency, which developed 6 preliminary concept proposals for the social media campaign (Table 2). Focus group participants (n=7) then provided detailed feedback to further refine and culturally tailor these concepts to ensure relevance and resonance with the target population.

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Table . Recommendations for the proposed social media concepts from the focus group with transgender Latina women conducted in June 2024 in the state of Washington.

Concept	Agency concept	Focus group recommendations
"For Your Family or Do it for Mom"	Framing HIV testing as an act of love for one's family, centered on mothers	• Broaden "family" to include friends, chosen family, and pets to reflect diverse support networks • Acknowledge that not all mothers are supportive; offer alternative sources of support • Incorporate emotional messaging emphasizing care and responsibility. Suggested messages: "Hazlo por tu familia (Do it for family)," "Creando historias (Creating stories)," "Hazte la prueba de VIH (Get tested for HIV)," and "Cuéntaselo a quien más confianza le tengas (Tell it to the person you trust most)" • Include real photos and stories of transgender women for authenticity
"Land of the Free"	Aspirational imagery celebrating freedom and self-expression	• Use ethereal, vaporous imagery reflecting exotic beauty and individuality • Reference 'Todos me miran' as cultural anchor of self-acceptance • Suggested messages: "No hay excusas para cuidarte (There are no excuses not to take care of yourself)," "No hay límites para estar bien (There are no limits to being well)," and "Una existe (She exists)" • Prioritize videos with some static images
"Living with HIV can be Fabulous"	Empowerment of individuals living with HIV	• Portray empowered individuals living with HIV, emphasizing resilience • Highlight theme: "Sin miedo a nada (Fearless)" • Include real-life testimonials demonstrating positive living • Use videos for dynamic storytelling
"Empowered and Protected"	Strength, protection, and unity within the community	• Feature group activities (eg, dancing and community events) that convey unity and joy • Avoid images reinforcing negative stereotypes • Emphasize community solidarity and mutual support
"Celebrating Sexy, Healthy You"	• Self-love is sexy and includes sexual health, enjoy your sexuality with confidence. • Protect yourself from HIV	• Depict a scene with someone getting ready for a romantic date, including condoms and PrEP[a]. • Use voice-over to narrate internal thoughts (eg, "Siempre lista, siempre protegida [Always ready, always protected]") • Normalize HIV prevention as part of self-care • Highlight relatable, everyday experiences • Use video with personal narrative
"She Can Do It, So Can I"	Inspiration through role models within the community	• Feature well-known community figures (eg, Wendy Guevara, Bambi Salcedo, and Alejandra Vogue) • Highlight success stories overcoming adversity • Reinforce empowerment and community leadership

[a]PrEP: pre-exposure prophylaxis.

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Key recommendations are described in Table 2 and include broadening definitions of family, incorporating real-life testimonials, leveraging well-known cultural references and role models, and emphasizing empowerment, preparedness, and community support. These insights directly informed the campaign design.

The enthusiasm expressed by focus group participants for the social media campaign led to direct community involvement in campaign development. A total of 6 focus group participants joined the project team to collaborate on content creation, contributing to message refinement, imagery, and narrative development. This collaborative process resulted in the development of 4 final videos used in the social media campaign (Multimedia Appendices 1-4).

Phase 2: Online Surveys

Table 3 presents the sociodemographic characteristics and HIV prevention and care behaviors of the transgender Latina women who completed the online survey (n=100). No missing data were identified across the sociodemographic or HIV-related behavioral measures. Among participants, 54 completed the survey in Spanish and 46 completed the survey in English. The average age of respondents was 29.7 (SD 5.2) years. The majority (97/100, 97%) reported being born in the United States and having health insurance (98/100, 98%). Most (86/100, 86%) had completed some college or higher.

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Table . Sociodemographic characteristics and HIV prevention behaviors of transgender Latina women survey respondents exposed to the social media campaign between November 2024 and December 2024 (n=100).

Variables	Value	95% CI
Sociodemographic characteristics		
Age (y), mean (SD)	29.7 (5.2)	—[a]
Race, n (%)		
Black	58 (58)	47.7 - 67.8
Native Hawaiian or other Pacific Islander	2 (2)	0.3 - 70
White	28 (28)	19.4 - 38.2
Other	12 (12)	6.6 - 20.3
Born in the United States, n (%)		
Yes	97 (97)	91.5 - 99.0
Highest level of education, n (%)		
High school	6 (6)	2.8 - 12.5
Technical or vocational training	8 (8)	4.1 - 15.0
Some college or bachelor's degree	69 (69)	59.2 - 77.4
Graduate degree	17 (17)	11.0 - 25.5
Annual household income (US $), n (%)		
10,000-19,000	2 (2)	0.3 - 7.0
20,000-29,000	1 (1)	0.0 - 5.4
30,000-39,000	6 (6)	2.8 - 12.5
40,000-49,000	10 (10)	5.6 - 17.2
50,000-74,000	51 (51)	40.9 - 61.0
75,000-99,000	29 (29)	20.6 - 39.1
>100,000	1 (1)	0.0 - 5.4
Has medical insurance, n (%)		
Yes	98 (98)	93.0 - 99.7
HIV-related behaviors		
Ever tested for HIV, n (%)		
Yes	97 (97)	91.5 - 99.0
Self-reported HIV status, n (%)		
Positive	3 (3)	1.0 - 8.5
Current PrEP[b] use, n (%)		
Yes	62 (62)	52.2 - 70.9
Alcohol use in past 12 months[c], n (%)		
Never	41 (41.4)	31.8 - 51.6
>once a month	2 (2.0)	0.3 - 7.0
2 - 4 times a month	21 (21.2)	14.4 - 30.1
2 - 3 times a week	30 (30.3)	22.0 - 40.3
>4 times a week	5 (5.1)	2.0 - 11.3
Used alcohol or drugs before last sexual encounter, n (%)		
None	51 (51)	40.9 - 61.0
Alcohol	33 (33)	24.4 - 43.0

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Variables	Value	95% CI
Drugs	2 (2)	0.3 - 7.0
Both	14 (14)	8.5 - 22.1
Sex without a condom in past 6 months, n (%)		
Yes	69 (69)	59.2 - 77.4
Number of sex partners in past 6 months, mean (SD; range)	2.5 (1.4; 0-8)	—
Group sex or orgies in past 12 months, n (%)		
Yes	33 (33)	24.4 - 43.0

[a]Not applicable.

[b]PrEP: pre-exposure prophylaxis.

[c]One participant reported "Don't Know"

Almost all respondents 97% (97/100; 95% CI 91.5 - 99.0) had previously tested for HIV, with 44% (44/100; 95% CI 34.3 - 53.7) indicating that they had tested within the last 6 months. Among all, 3 respondents reported being HIV positive, among which all reported currently taking ART. Approximately 58% (58, /100; 95% CI 48.3-67.7) reported alcohol use, with 35% (35/100; 95% CI 25.6 - 44.4) indicating drinking alcohol 2 or more times a week. About 49% (49/100; 95% CI 39.2 - 58.8) indicated using alcohol and/or drugs prior to their last sexual encounter, and 69% (69/100; 95% CI 59.2 - 77.4) reported having sex without a condom in the last 6 months. Respondents had an average of 2.5 (SD 1.4) sexual partners in the past 6 months and approximately 33% (33/100; 95% CI 24.4 - 43.0) reported engaging in group sex or orgies in the last year. Among respondents, 62% (62/100; 95% CI 52.2 - 70.9) reported currently using PrEP.

When asked about the relevance of the social media content to their community, 98% (98/100; 95% CI 95.3 - 100) indicated that the campaign was relevant. Qualitative responses to this question included, "I felt it was relevant as it is bringing out the happiness in trans women," "It depicted a happy trans woman and I loved it," "It reflects what I identify with," and "It is an eye-opening [advertisement] to the general public that trans women are living happy lives." Spanish responses (translated to English) included, "It gives hope to those infected and urges the community not to abandon them," "It reassures those infected that we are all in this together," and "This helps raise awareness in the community about HIV and its prevention measures, as well as not isolating those affected."

When asked whether the campaign motivated them to take action such as seeking more information, talking to others, or changing behaviors, 91% (91/100; 95% CI 85.4 - 96.6) indicated that it did. Qualitative responses explained that the campaign led some to engage in conversations with others about the topic, share the campaign with others, and seek more information about HIV prevention.

Beyond the survey data with the 100 respondents, performance data from Facebook and Instagram indicated that the 4 videos collectively had 211,355 views, a reach of 50,444 unique individuals, and 3267 link clicks over the course of the campaign period.

Discussion

Primary Findings

This study aimed to develop a social media campaign for transgender Latina women to increase awareness of HIV prevention and care services at a CBO. The use of a 2-phase, community-engaged approach allowed for the integration of participant perspectives throughout campaign development, ensuring that the content was both culturally relevant and responsive to the needs of the target population. The piloting of the campaign demonstrated its preliminary feasibility and acceptability of a culturally tailored social media content to reach transgender Latina women for HIV prevention services.

Findings from phase 1 revealed important themes related to prevention, accessibility, culturally tailored care, and confidentiality, which informed the development of the campaign content. Participants emphasized the importance of addressing stigma, misinformation, and the need for empowering messages delivered through accessible platforms such as Facebook and Instagram. Our findings align with prior research on HIV intervention development among transgender Latina populations, which emphasizes the importance of creating culturally responsive content that recognizes the diversity within the Latino community [33].

Notably, research focused on improving engagement in HIV prevention and care among transgender persons in the United States was limited to the last 2 decades but has expanded considerably in recent years [13]. In a recent systematic review of effective strategies to enhance engagement in HIV prevention among transgender populations, common features of successful interventions included community engagement in intervention design, testing with the target population to ensure acceptability, and addressing social determinants of health through empowerment-based and gender-affirming approaches [13]. Consistent with these findings, our study prioritized the unique needs of transgender Latina women and emphasized collaboration with community partners as well as pilot testing through survey assessments. The collaborative development process, which directly involved community members, strengthened the campaign's cultural relevance and resonance.

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Findings from phase 2 online surveys demonstrate the feasibility of our campaign in reaching transgender Latina women who may need HIV prevention and care services given high levels of reported engagement in HIV-related risk behaviors (eg, drug and alcohol use and sexual behaviors). Findings from phase 2 online surveys also suggest that the survey respondents reached through the online campaign may differ in important ways from those who participated in phase 1. Compared to the in-depth interview and focus group participants, phase 2 respondents were generally younger, predominantly US-born, had higher levels of education, and nearly all had health insurance. In addition, the use of ART and PrEP was relatively high.

These differences may reflect variation in social media platform use, online survey accessibility, or differing levels of engagement with HIV prevention services across subgroups of transgender Latina women. For instance, factors including digital access, health literacy, and language preferences play key roles in how social media messages reach communities and how they may be received [34]. A previous study that examined approaches to adapt mobile technology-based interventions for transgender Latina women found that the costs associated with smartphone ownership and internet use may limit engagement among socioeconomically disadvantaged groups [33]. Although the accessibility of mobile technology has improved over time, the diversity among phase 1 and phase 2 participants highlights the importance of considering heterogeneity within the broader population when designing and evaluating online versus other types of outreach efforts.

Transgender Latina women who are foreign-born may also face distinct barriers to HIV prevention and care compared to those who are US-born, as may those without health insurance [35]. These characteristics represent important social determinants of health that shape the contexts and experiences that influence HIV-related behaviors [36,37]. Although our study did not formally test for differences between phase 1 and phase 2 participants given the distinct purposes of each phase, the observed diversity between the 2 groups highlights the need to tailor outreach strategies to address varying levels of connectivity and access.

Despite these noted differences, most phase 2 participants rated the campaign as highly relevant to their community and reported being motivated to seek information, engage in conversations, and consider behavior change. Prior research identified strategies that successfully engaged transgender Latina women for an HIV prevention intervention trial, including leveraging existing social media platforms for outreach, ensuring the research team reflected the transgender Latina community, and relationship building with the community [38]. Similarly, our study reflects these effective approaches, while also highlighting a more organic, collaborative process in which ideas emerged during phase 1 in-depth interviews and informed the development of social media content. This iterative, community-engaged process proved critical for ensuring authenticity and resonance. Overall, our findings suggest that culturally grounded messaging has the potential to resonate across diverse segments of the population, while also underscoring the need for additional targeted efforts to reach subgroups who may be less connected to online platforms or who face more structural barriers to care.

Limitations

Several limitations should be noted. First, survey respondents may not be representative of the broader population of transgender Latina women, particularly those who are foreign-born, uninsured, or face greater barriers to care. Furthermore, the survey was capped at the first 100 responses due to funding limitations; hence, respondents may not represent the characteristics of all who were reached by the campaign. The online recruitment strategy may have preferentially reached individuals who are more digitally connected and engage with social media. Second, all data were self-reported and may be subject to recall or social desirability bias, particularly in reporting HIV prevention behaviors. Third, the small sample size of the focus group limits generalizability, though the community-engaged approach helped ensure cultural appropriateness of the campaign materials. Finally, this study focused on short-term feasibility and acceptability; future research is needed to assess the longer-term impact of such campaigns on HIV prevention and care outcomes.

Conclusion

This study demonstrates the potential of community-driven and culturally grounded social media strategies to enhance engagement in HIV prevention among transgender Latina women—a population often underrepresented in digital health initiatives. Our 2-phase, participatory study design centered on the voices, priorities, and lived experiences of transgender Latina women throughout campaign development. As participants who viewed the campaign and completed the survey rated the campaign as highly relevant to their community and reported being motivated to seek information, engage in conversations, and consider behavior change, our approach underscores the value of community partnership and cocreation in producing authentic and resonant health communication strategies.

Building on our promising results, future plans include expanding the campaign's reach through strategic partnerships with CBOs and evaluating its impact on engagement in HIV-related services over time. In doing so, this work extends beyond a single campaign to inform how community-centered digital health strategies can be scaled. More broadly, our findings highlight the broader need for inclusive and participatory models of digital public health that address both structural barriers and the importance of cultural relevance. As social media and digital technologies continue to shape access to health and HIV-related information, integrating culturally tailored content that is co-created with the communities most affected may promote sustained engagement and build trust across diverse populations.

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Data Availability

The qualitative data are not publicly archived or available for privacy and confidentiality reasons. The datasets generated and analyzed during this study are not publicly available but are available from the corresponding author upon reasonable request.

Conflicts of Interest

JA, MZ, and YC were employees at Entre Hermanos, a community-based organization that partnered in the development and implementation of the campaign described in this study.

Multimedia Appendix 1
Social media post 1.
[MP4 File, 174118 KB - formative_v10i1e79606_app1.mp4]

Multimedia Appendix 2
Social media post 2.
[MP4 File, 13637 KB - formative_v10i1e79606_app2.mp4]

Multimedia Appendix 3
Social media post 3.
[MP4 File, 10719 KB - formative_v10i1e79606_app3.mp4]

Multimedia Appendix 4
Social media post 4.
[MP4 File, 27265 KB - formative_v10i1e79606_app4.mp4]

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Abbreviations

ART: antiretroviral therapy
CBO: community-based organization
LGBTQ+: lesbian, gay, bisexual, transgender/transsexual, queer, and other minority sexual orientations and gender identities
PrEP: pre-exposure prophylaxis
REDcap: Research Electronic Data Capture
UTB: Unified Theory of Behavior

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An Ecological Momentary Assessment Protocol to Measure Stress, Socialization, and Other Contributors to Smoking Behaviors Among LGBTQ+ Adolescents: Multimethod Evaluation of Feasibility, Acceptability, and Appropriateness From the Puff Break Research Study

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Abstract

Background: Smartphone-based ecological momentary assessment (EMA) methods highlight the impact of minority stress and socialization (eg, discrimination and social support) on smoking behaviors in lesbian, gay, bisexual, transgender, queer, and other sexual and gender minority (LGBTQ+) adults; however, studies among LGBTQ+ adolescents are limited. The Puff Break EMA protocol was developed to address this gap.

Objective: This study aims to report on the acceptability, feasibility, and appropriateness of the Puff Break EMA protocol.

Methods: We utilized a multimethod design to evaluate the acceptability, feasibility, and appropriateness of the Puff Break EMA protocol. Participants who reported tobacco/nicotine or cannabis product use within the last 30 days engaged in a 2-week EMA trial, receiving 5 daily assessments measuring tobacco, nicotine, and cannabis use, stress and socialization, and product craving. Posttrial, participants completed a 15-minute exit survey and 60-minute semistructured exit interview. The exit survey used the 12-item Weiner acceptability, appropriateness, and feasibility measures and 6-item Mobile Application Rating Scale, app-specific subscale and also included 7 open-ended responses. The exit interview focused on a review of participants' data to help understand smoking patterns and experiences with the Puff Break EMA protocol along with questions guided by the Reach, Effectiveness, Adoption, Implementation, and Maintenance framework to understand how a future EMA mobile intervention aimed at monitoring and reducing tobacco, nicotine, and cannabis product use could effectively be disseminated to, accessed by, and implemented with LGBTQ+ adolescents. Lastly, lessons learned were obtained through feedback and data collected throughout the study.

Results: All 50 adolescents between the ages of 15 - 19 (mean 17.82, SD 1.19) were enrolled in the study August 2023 and July 2024. Participants predominantly reported using vaporized tobacco and nicotine products (47/50, 94%), followed by cannabis products (39/50, 78%). The study sample was diverse regarding sexual orientation and gender identities with 32% (16/50) identifying as gay or lesbian, 32% (16/50) bisexual or pansexual, and 14% (7/50) transgender (neither transmasculine nor transfeminine). The median EMA response rate was 75% (~53 of 70 EMA surveys). Results indicated high feasibility (mean 4.43, SD 0.77), acceptability (mean 4.15, SD 0.83), and appropriateness (mean 4.46, SD 0.67) of the Puff Break EMA protocol. The Mobile Application Rating Scale app-specific subscale also indicated high acceptability and feasibility for the EMA method to increase knowledge, awareness, and intentions to monitor tobacco/nicotine use (mean 4.14, SD 1.01). Triangulated results

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from closed and open-ended survey responses identified 5 key themes related to feasibility, acceptability, and appropriateness. Participants highlighted the ease of the Puff Break EMA protocol, prompt survey reminders, and increased product use awareness. Key feedback from exit interviews included increased flexibility for survey timing, better response-option alignment, and appropriate only for populations interested in monitoring or reducing their product use.

Conclusions: Findings indicate that using EMA methods to understand the impact of stress and socialization experiences on smoking behaviors in LGBTQ+ adolescents is feasible, appropriate, and acceptable.

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KEYWORDS

cigarette; feasibility studies; marijuana smoking; mobile apps; sexual and gender minorities; smoking; tobacco use cessation; vaping

Introduction

According to the 2024 National Youth Tobacco Survey, 8.1% of all middle and high school students surveyed reported current use of tobacco products, with 2.8% of youth reporting combustible cigarette use and 5.9% of middle and 7.8% of high school students reporting vaping [1] Although rates of e-cigarette use or vaping declined from the previous year, pointing to the continued success of public health policy and prevention efforts, the data also found that 38.4% of students who vaped reported frequent use (>20 out of 30 d) and 26.3% reported daily use [1]. Furthermore, recent US national data from the Monitoring the Future study indicate that past-year cannabis use remains substantial among adolescents despite declines in recent years, with 26% of 12th graders, 16% of 10th graders, and 7% of 8th graders reporting past year use [2]. Adolescents who use e-cigarettes are also more likely to co-use cannabis products. Findings from the Population Assessment of Tobacco and Health study found that 51% of adolescents aged 12 - 17 who ever used e-cigarettes also used cannabis in the last year [3]. Similar studies have found that adolescents who have ever used e-cigarettes had approximately 2.5 to 3.5 times higher odds of ever using cannabis products [3,4]. Taken together, early prevention of tobacco, nicotine, and cannabis use in all forms is critical. Such prevention efforts are particularly important among subpopulations who are at increased risk for tobacco, nicotine, and cannabis use.

Gender and sexual orientation disparities in tobacco and nicotine use emerge in adolescence and continue to persist into young adulthood, with lesbian, gay, bisexual, transgender, queer, and other sexual and gender minority (LGBTQ+) youth reporting earlier onset and elevated levels of tobacco and nicotine use relative to their cisgender- and heterosexual-identified peers [5-8]. LGBTQ+ youth are also more likely to engage in cannabis use than their cisgender and heterosexual peers [9]. Minority stress experiences (eg, bias-based victimization) and community socialization factors (eg, LGBTQ+ community norms regarding substance use) are unique, primary contributors to elevated risk for tobacco, nicotine, and cannabis use among LGBTQ+ youth [10-13]. Additionally, stress, interpersonal socialization factors, and tobacco, nicotine, and cannabis-related cravings are established influences on smoking and vaping behavior in the general adolescent population [14-19]. Research that delineates how such unique LGBTQ+ and general adolescent factors operate on a daily basis to shape tobacco, nicotine, and cannabis use can help inform prevention efforts. Despite the growth in research to examine the contributions of real-time psychological and contextual influences on substance use behaviors among LGBTQ+ adults [20-22], less research has advanced such assessment methods among LGBTQ+ adolescents. Ecological momentary assessment (EMA)—a technique for assessing the context, antecedents, and correlates of behavior in real-time—can be useful for understanding how daily factors affect tobacco, nicotine, and cannabis use among LGBTQ+ youth.

The Puff Break Research Study (Puff Break) used an EMA tool that includes validated and novel measures to capture the momentary associations between general stress, minority stress, socialization, craving, and other predictors of tobacco, nicotine, and cannabis product use among 50 LGBTQ+ adolescents, aged 14 to 19 years. The protocol was adapted from a prior EMA research protocol to examine smoking and vaping among LGBTQ+ adults. Puff Break was developed through an iterative design process including formative interviews from LGBTQ+ adolescents who engage in tobacco, nicotine, and cannabis use; key informant interviews with stakeholders, and subject matter experts in LGBTQ+ health, tobacco regulatory science, and EMA research. Feedback was obtained from a participatory planning group (PPG) consisting of public health professionals and representatives from nonprofit organizations focused on serving LGBTQ+ youth.

If successful at capturing antecedents and correlates of smoking behavior, the Puff Break EMA tool [23] has potential to inform real-time interventions among LGBTQ+ youth. The aim of this paper is to report on the feasibility, acceptability, and appropriateness of the Puff Break EMA protocol among LGBTQ+ adolescents via a multimethod evaluation along with key lessons learned.

Methods

Overview

Puff Break was a 2-week EMA trial where participants received 5 daily surveys evaluating tobacco/nicotine and cannabis use in addition to behavioral and contextual factors surrounding such use. Posttrial, participants completed an exit survey evaluating the feasibility, acceptability, and appropriateness of the Puff Break EMA protocol.

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Ethical Considerations

All study procedures were reviewed and approved by the San Diego State University Institutional Review Board (HS-2022 - 0101). Participants provided informed consent at the start of the study during their onboarding. Due to the potential risk of "outing" LGBTQ+ youth and disclosing unknown youth-smoking behaviors to their parents and guardians, a waiver of parental consent for participants under the age of 18 was authorized by the SDSU Institutional Review Board. All data collected were deidentified for analysis. Identifiable information was securely stored on a San Diego State University password-protected server with only access to study personnel. Participants were compensated up to US $255 for participation in the study. Details of our compensation structure can be found in the Puff Break protocol paper [23].

Study Design

This study used a multimethod design evaluating acceptability, feasibility, and appropriateness of the Puff Break EMA protocol through quantitative assessment (eg, completion rates, survey assessment with Likert scale ratings, and open-ended questions) and qualitative data (eg, semistructured interviews). The use of multimethods offers the opportunity for quantitative data to be further contextualized by qualitative open-ended responses, and the overall triangulation of results from different data sources provides a more comprehensive understanding of the results.

Participants and Recruitment

Participants for this study included LGBTQ+ adolescents who met the following inclusion criteria: (1) individuals who report current tobacco, nicotine, or cannabis product use (ie, any use in the past 30 d); (2) who are between the ages of 14 and 19 years; (3) who self-identify as LGBTQ+, and (4) who have daily access to a personal smartphone. A target sample size of 50 participants was selected to provide adequate power for future quantitative analysis as well as sufficient qualitative data to reach saturation of key ideas and themes. Participants were recruited from the greater San Diego County area between August 2023 and November 2024. We prioritized this region per the recommendations of our PPG and funding mechanism priorities. Multiple methods were used to recruit potential participants. Initial recruitment included distributing flyers, tabling at local youth and LGBTQ+ community events, and presenting to community and academic partners, and participant snowball sampling. All 7 flyers were developed by the Puff Break study team and were posted at a local school district, universities (eg, student union and LGBTQ+ resource center), and community settings (eg, library). A total of 8 presentations were conducted to community and academic partners along with 3 tabling events. Enrolled participants also provided referrals for individuals who may be eligible and interested in joining the study. As these efforts did not sufficiently engage youth younger than 18 years, we expanded recruitment through the use of social media. Using Meta (Facebook and Instagram), ad campaigns were iteratively created and configured to appeal to our target population. Advertisements were posted weekly and included 1 of our 7 flyers along with a short statement encouraging participation. The use of social media, along with adapting our protocol to include full remote procedures, increased our recruitment efforts. Further details of our recruitment procedures can be found in the Puff Break protocol paper [23].

Data Collection Procedures

Participants engaged in the 2-week Puff Break EMA protocol, receiving 5 daily surveys evaluating tobacco and nicotine use along with stress and socialization factors. Posttrial, participants engaged in an exit meeting which included a quantitative exit survey and qualitative exit interview further evaluating the acceptability and feasibility of the EMA protocol.

Quantitative Data Collection Procedures

Participants completed a 15-minute exit survey with open and closed-ended questions to assess acceptability, feasibility, and appropriateness, 3 key measurements of implementation outcomes, deemed indicative of an intervention's success [23]. Acceptability was operationalized as the perception among LGBTQ+ adolescents that the Puff Break EMA protocol was appealing, favorable, or satisfactory. Feasibility was operationalized as the extent to which the Puff Break EMA protocol could be successfully implemented among the target population (ie, number of participants who met the recommended threshold of completing 80% of scheduled EMA assessments). Appropriateness was operationalized as participant ratings of the Puff Break EMA protocol as fitting, suitable, applicable, or a good match to assess smoking behaviors. Close-ended questions were adapted from the 12-item acceptability of intervention measure, intervention appropriateness measure, and feasibility of intervention measure by Weiner et al [24] with expectations to reach a threshold of agree or strongly agree from the Likert scales . Pearson correlation coefficients for the original study scales were 0.83 for acceptability, 0.87 for appropriateness, and 0.88 for feasibility, indicating acceptable test-retest reliability[24]. As the scale is meant to be pragmatic and used across diverse settings and audiences, no adaptations were made. We also assessed the perceived impact of an app on the user's knowledge, attitudes, and intentions to change as well as the likelihood of actual change in the target health behavior via the validated 6-item Mobile Application Rating Scale (MARS) app-specific subscale [25,26]. The original MARS scale was found to have high internal consistency (α=.90) and interrater reliability, intraclass correlation coefficient (ICC=.79) [25]. Minor adaptations to questions included changing the word "improving" to "monitoring" and "increase/decrease" to "change." All items were measured via a 5-point Likert scale (1=strongly disagree, to 5=strongly agree). A total of 7 open-ended questions were adapted from the study team's adult EMA protocol which included, for example, the following questions: What did you like/dislike about the EMA method? What procedures were difficult to complete, confusing, or required additional support?

Qualitative Data Collection Procedures

A semistructured interview administered at the exit meeting further elucidated participants' experience with the Puff Break EMA protocol. The interview guide had 15 scripted questions, with additional probes. The first half of the interview focused

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on a review of participants' data to help understand smoking patterns and experiences with the EMA protocol. The second half of the interview was guided by the Reach, Effectiveness, Adoption, Implementation, and Maintenance framework [27] to understand how a future EMA mobile intervention aimed at monitoring and reducing tobacco, nicotine, and cannabis product use could effectively be disseminated to, accessed by, and implemented with LGBTQ+ adolescents. Interviews were recorded with participant consent and lasted approximately 60 minutes. Each participant received a US $25 gift card for completing the interview.

Lessons Learned

Lessons learned were obtained through iterative feedback from study staff, analysis of research participant qualitative data, and feedback from Puff Break PPG members consisting of 5 leaders within the local county health department and nonprofit organizations focused on serving LGBTQ+ youth to consult on their expertise related to the goals of the project.

Data Analysis

We first assessed demographic characteristics of the sample population, from the screening survey at baseline, and then calculated descriptive statistics as seen in Table 1. To determine feasibility, we conducted a descriptive analysis of sample characteristics and compliance data (ie, number of participants who met the recommended threshold of completing 80% of scheduled EMA assessments) along with mean survey scores according to the feasibility of intervention measure [24]. We also conducted a content analysis of the open-response feedback from the exit survey regarding protocol feasibility. To determine acceptability, we similarly conducted a descriptive analysis of the mean survey scores according to the acceptability of intervention measure [24] along with a content analysis of open-ended response feedback from the exit survey. For additional context, we also conducted a descriptive analysis of the protocol's appropriateness using the intervention appropriateness measure [24], content analysis of open-ended response feedback from the exit survey, along with analyzing mean survey scores from the MARS app-specific subscale [25,26] to understand the protocols perceived impact on users' knowledge, attitudes, and intentions to use an EMA protocol like Puff Break to monitor their tobacco, nicotine, and cannabis product use. Participants were retained in all analyses even if they had missing responses for individual items.

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Table . Demographic characteristics of the 50 enrolled participants in the Puff Break pilot study, August 2023 to November 2024.

Characteristic	Count, n (%)
Participants (enrolled)	50 (100)
Age[a] (years)	
14	0 (0)
15	4 (8)
16	3 (6)
17	7 (14)
18	20 (40)
19	16 (32)
Sex assigned at birth	
Female	42 (84)
Male	8 (16)
Gender identity	
Woman	20 (40)
Man	11 (22)
Nonbinary/genderfluid	9 (18)
Multiple gender identities	10 (20)
Transgender status	
Transmasculine	9 (18)
Transfeminine	0 (0)
Transgender, neither transmasculine nor transfeminine	7 (14)
No	31 (62)
Questioning	2 (4)
Not reported	1 (2)
Sexual orientation	
Lesbian/gay/queer	16 (32)
Bisexual/pansexual	16 (32)
Other written-in response	1 (2)
Multiple sexual orientation identities	17 (34)
Ethnicity	
Non-Hispanic or Latino/a/x	31 (62)
Hispanic or Latino/a/x	19 (38)
Race[b]	
White	27 (54)
Non-white	8 (16)
Multiracial or multiethnic	14 (28)
Not reported	1 (2)
Past 30 day tobacco/nicotine product use (any)[c]	
Combustible products	27 (54)
Smokeless products	8 (16)
Vaporized products	47 (94)
Cannabis products	39 (78)

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Characteristic	Count, n (%)
Other products	2 (4)
Combustible or vaporized product use: 5 times or more in a typical day[c]	
Combustible products	0 (0)
Vaporized products	33 (66)

[a]Age: mean (SD; range)=17.82 (1.19; 15-19) years.

[b]Race was a 9-category item that was collapsed to 3 levels due to small cell count: White (included White and Jewish); non-White (included Black/African American, Native American/Alaskan Native, Asian, Southeast Asian); Multiracial or multiethnic (included respondents who selected more than one category, eg, White and Black/African American).

[c]Responses are not mutually exclusive.

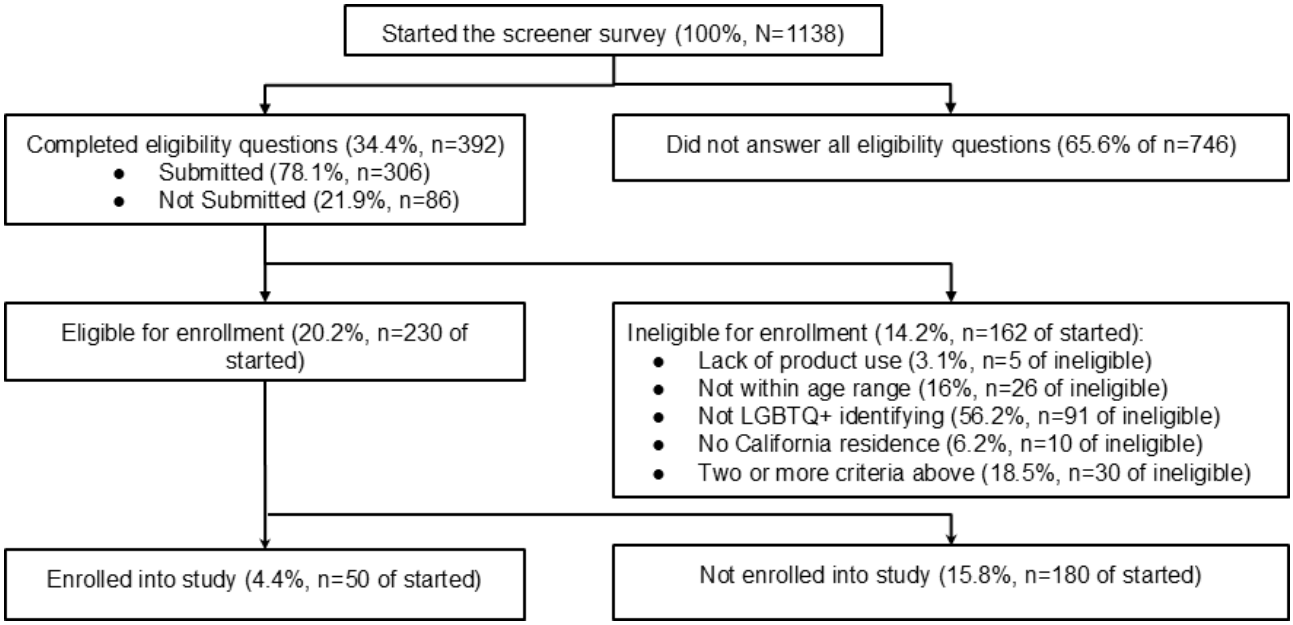
Data triangulation was used by comparing themes from open-ended survey responses with those derived from participant interviews. Interview transcriptions were obtained from Zoom's (Zoom Communications, Inc) cloud recording function. Transcripts were cleaned, memoed, and extracted into an Excel sheet to identify crosscutting trends in the data, leading to the generation of a preliminary codebook [28]. Subsequent analysis was conducted using Nvivo 14.23.4 (Lumivero, Inc) [29]. The analysis team simultaneously reviewed, discussed, and coded 20% of the transcripts, upon which the codebook was refined. Once the team was comfortable with the codebook, the lead author and research assistant independently coded another 20% of the transcripts to establish an interrater agreement of at least 80%. Discrepancies were discussed and resolved between the coders. Once interrater agreement was achieved, the remaining transcripts were independently coded. Once all transcripts were coded, the analysis team engaged in multiple rounds of dialogue to identify key themes and patterns across the data.

Results

Demographics

Recruitment efforts reached a total of 1138 potentially eligible participants, of which 306 completed the screener survey. Of these respondents, 230 were deemed eligible to participate based on our inclusion criteria. Ultimately, 50 participants were enrolled and completed the study between August 2023 and November 2024. The screener survey results are displayed in Figure 1.

Figure 1. CONSORT (Consolidated Standards of Reporting Trials) diagram displaying enrollment of participants in the Puff Break study based on youth who started the screener survey between August 2023 and November 2024. Those who completed eligibility questions but did not submit the screener were still contacted to join the study. Reasons for not enrolling included: not responsive to staff messages, did not attend onboarding meetings, and no longer interested. LGBTQ+: lesbian, gay, bisexual, transgender, queer, and other sexual and gender minorities.



As displayed in Table 1, participants' ages ranged from 15 to 19 years (mean 17.82, SD 1.19) with 8% (4/50) aged 15, 6% (3/50) aged 16, 14% (7/50) aged 17, and the majority (36/50, 72%) between 18 and 19 years. The majority of participants (42/50, 84%) identified as female sex at birth; 18% (9/50) of the study sample identified as transmasculine, and 14% (7/50) identified as transgender (neither transmasculine nor transfeminine). For sexual orientation, 32% (16/50) of participants identified as lesbian/gay/queer, 32% (16/50) identified as bisexual/pansexual, and 34% (17/50) identified as having multiple sexual orientation identities. Approximately 40% (19/50) of the participants identified as Hispanic/Latino/a/x, 54% (27/50) identified as White, and 28% (14/50) identified as multiracial. Participants reported using a range of tobacco and

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nicotine products in the last 30 days, including tobacco: combustible cigarettes (27/50, 54%), smokeless tobacco (8/50, 16%), vaporized nicotine (47/50, 94%), cannabis (39/50, 78%), and other types of products (2/50, 4%). While no participants reported using combustible products more than 5 times in a typical day, 66% (33/50) of participants reported using vaporized products at least 5 times in a typical day.

Feasibility, Acceptability, and Appropriateness of the Puff Break EMA Protocol

Feasibility

We were able to enroll 50 participants, with 100% of participants completing the study entirely (onboarding to exit). Participants were sent 5 surveys a day during the 2-week EMA trial (maximum of 70 surveys per participant). Participants' response rate varied, ranging from 12.9% (~9 of 70 EMA surveys) to 97.1% (~68 of 70 EMA surveys), with a median response rate of 75% (~53 of 70 EMA surveys). Additionally, 22 out of 50 participants (44%) met the 80% threshold for completing EMA surveys (56 of 70 EMA surveys). Participants were typically involved in the study for 16 days from onboarding to exit interview. Regarding subjective ratings, the Puff Break EMA protocol was given high scores on the feasibility of intervention measure (mean 4.43, SD 0.77).

Triangulated results from the open-ended responses and interview elucidated 1 overarching theme of *usability* with multiple subcomponents related to *timing and access*. Related to timing, participants highlighted how the structured timing of the EMA surveys made it challenging to complete their assessments. For instance, 1 participant said,

> *I mean I did take the 9 AM surveys a few times, but I also just never really woke up early enough to do so.* [19 y, Asian, nonbinary, and multiple sexual orientation identities]

while others also indicated:

> *The only thing that I did struggle with was just like the time cause you know how it has, like specific times. Yeah, sometimes I'm like at work, or I'm just sleeping, and I don't, I don't see them.* [18 y, multiracial, woman, and pansexual]

and

> *I think just like a more open time period, because I'd click on it like right at like 3 o'clock or like 6 o'clock, and sometimes I couldn't do it and like I would have work at like 3:30, or like 4, and then it wouldn't show up until, like a random time like 3:27, and I'd be like could have done this like 27 min ago. Now, I can't do it.* [17 y, White, woman, and bisexual]

Related to access, the analysis indicated that approximately 10% (5/50) of participants expressed challenges with app glitches and how that affected their ability to input their information, with participants stating,

> *The app can be very glitchy and unreliable, such as not allowing the users to open the survey when it's the required time to take it.* [17 y, White, woman, and bisexual]

and

> *It like would crash a lot, and just like in the middle of it, I'd be like great. I had to do this all over again.* [18 y, Hispanic, transmasculine, and gay]

Notably, 1 participant brought to light challenges with accessing their cell phone due to parental controls which contributed to their low response rates for evening surveys:

> *Either your parents give you free rein and don't care about what you do with your technology or your parents like mine, where they check your phone every week and like you're not allowed to have your phone with you overnight. And I have like very supervised technology usage.* [17 y, nonbinary/transmasculine, and gay]

Despite these challenges, 24% of participants expressed their overall satisfaction of being part of the study. For example, participants stated,

> *It was interesting, my first experience with documenting or keeping track of how I use substances and in regards to my emotions as well. It will be interesting to see what results might come out after this study is over.* [15 y, White, transmasculine, and multiple sexual orientation identities]

Similarly, another participant also expressed that they enjoyed the experience:

> *This was actually kind of fun, I liked that it was a scheduled thing and it put me into a cycle, a routine of sorts.* [18 y, White, woman, and gay/queer]

Lastly, 50% (25/50) of participants highlighted that the Puff Break EMA protocol was easy to use, with 1 participant stating,

> *I really like how like it didn't take that much time out of my day, and it was something that I could just easily get done throughout the day.* [17 y, Hispanic/White, woman, and multiple sexualities]

Acceptability

The Puff Break EMA protocol received high acceptability ratings via the acceptability of intervention measure (mean 4.15, SD 0.83). Triangulated results from the open-ended responses and interview elucidated 2 key themes of (1) *app features* and (2) *product use awareness*. Within *app features*, participants found the notifications to be beneficial, allowing them to stay on track with their EMA surveys. For example, 1 participant stated,

> *Yeah, I think like I was just thinking of the how the survey sent me notifications, and like that made it easier to remember.* [15 y, White, transmasculine, and multiple sexualities]

However, 1 participant indicated how the app felt very "assignments-y" coupled with the notification's wording of "it's time for your assessment" made them not want to complete surveys:

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> *It just kind of feels like very assignments-y.I think that the way the notifications are sent, like the words that are used, are kind of makes it harder, because, like they're like, "it's time for your assessment." And if they didn't say that, if they had like another wording, I think it- I'd be more inclined to at times.* [19 y, Hispanic/Black, nonbinary, and bisexual/queer]

Acceptability was also seen through the theme of *product use awareness* where 37% of participants indicated how tracking their product use within the app, and the data visualizations viewed at the start of the exit interview, opened their eyes to their product use and made them reflect on what they could do to reduce use. As shared by 2 participants,

> *I really liked like looking through like my stats right now [at the exit interview], like the graphs like my like, 2 week average like that was interesting. And I was like, Wow, like, especially for cannabis use like that's crazy.*
>
> *[19 y, Hispanic/White, non-binary, and queer]*

and

> *I do think like the whole like tracking. How many times I've like taking hits. did help a lot like recognize my usage.* [19 y, Asian, non-binary, and bisexual/queer]

This finding was further emphasized by another participant:

> *I feel like how you're showing you right now. It just kind of like puts it all into perspective, like what you're doing and learn like you can think by how I am like oh, like can I come up with like a different habit to do it at these times. And like for me, I'm looking at. I'm like, okay, it's at like 6 PM or [9 PM] at night, [going to gym] or something instead of just like smoking.* [19 y, White, woman, and bisexual]

Appropriateness

The intervention appropriateness measure indicated that the Puff Break EMA protocol was viewed as appropriate among LGBTQ+ youth (mean 4.46, SD 0.67). The MARS app-specific subscale, which aimed to specifically evaluate the quality of mobile health apps, also indicated high appropriateness (mean 4.14, SD 1.01). Results indicated that the Puff Break EMA protocol could increase participants' awareness, knowledge, attitudes, and intentions to monitor tobacco and nicotine as well as seeking help for or promoting a change in their tobacco and nicotine use behavior.

Triangulated results from the open-ended responses and interview elucidated three overarching themes of (1) *motivations to monitor or reduce tobacco use*, (2) *product use awareness*, and (3) *product-response option alignment*. Within *motivations to monitor or reduce tobacco use*, there was general consensus that the Puff Break EMA protocol and any future iterations of the study would only be appealing to individuals who were already interested in monitoring, reducing, or eliminating their tobacco and nicotine use as exemplified by feedback shared by the following participants:

> *If I had been shown the app like that at the beginning, like when I first hit a vape like in the school bathroom freshman year, I would have been like, I don't care. Like I don't need that, whatever, like who cares, like I'm just having fun.* [18 y, Hispanic/White, transmasculine, and bisexual]
>
> *This research study kind of helped me since the app allowed me to track it But if the person doesn't have the motivation to like Stop, there's no like, that's the only point of the app.* [18 y, Asian, woman, and bisexual]

Regarding *product use awareness*, results elucidated how participating in the study made participants more aware of their general product use and how it related to their stress, mood, or other aspects of their lives. One participant stated,

> *I was able to record my momentary moods, it was interesting to see how this corresponded with nicotine usage.* [17 y, White, woman, and gay/queer]

while another similarly indicated,

> *It made me consider a lot about my cravings and usage and how it correlated with my stress levels.* [19 y, Asian, non-binary, and bisexual/queer]

Notably, while some participants discussed how participating in the EMA trial led to a decrease in their product use, 2 participants indicated how being in the study had an unintentional effect of increasing their cravings, stating,

> *I think that's what really pushed me to use less was when I was inputting those numbers. Like, if I went a period where I used seven times at once, then the next period I'd be fine with not even using it at all, just because I had seen how much I used it in such a short period of time.* [18 y, Hispanic/White, transmasculine, and bisexual]

and

> *...the [survey], like hella increased like my cravings every time I opened it, even just seeing the word nicotine seeing vaporized like when you're trying to quit like seeing it is really rough.* [19 y, White, man, and gay]

Lastly, in regard to the theme of *response option wording*, participants mentioned their appreciation for the EMA questions not being too invasive or triggering. Additionally, they felt as if the questions being asked were appropriately worded. A participant claimed,

> *I feel EMA has a great system in keeping reasonable data without being invasive of noting common discomfort that may occur in LGBTQIA+ young adults.* [19 y, White, woman, and bisexual]

However, 12% of the participants provided feedback highlighting that questions were either too narrow, honing in on specific LGBTQ+ stressors, or too broad, limiting their ability to dive deeper into their reason for using tobacco or nicotine. For instance, participants stated,

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> *I didn't feel like it asked more nitty-gritty questions like "why did you start smoking?" or "what drives you to smoke?" in the first place.* [19 y, Hispanic/White, nonbinary, and pansexual]

as well as

> *I think that it would be helpful to identify the reasons for the stress score whether is was family, peers, occupation, or school.* [18 y, White/Black, nonbinary, and queer/pansexual]

and

> *I feel like there were not enough general "I am stressed" indicators because it was all about LGBT issues and not if I had a test earlier in the day or something.* [17 y, White, genderqueer, and bisexual/queer]

Lastly, the *product-response option alignment* theme also alluded to challenges with the way in which our EMA prompts were worded. When showing participants their own data, many reported not recalling using "other" or "smokeless products." Many participants confused smokeless products with other products. Some examples are mentioned below:

> *I'm almost completely certain I missed clicked on every time I put smokeless. I have not used a single smokeless product.* [17 y, Black/Asian, nonbinary/transmasculine, and demisexual]

> *so I didn't smoke any cannabis. So I don't think I put that on the survey. Maybe it was an accident a few times or something. When I took the surveys I was pretty careful about not putting wrong [or] anything, so I'm just confused.* [17 y, White, man, and bisexual]

> *Or for- is it smokeless or other I'm speaking about? I guess maybe I confused like Smokeless and Other, and I might have like Cause like there's like the like, not the patches, but like the gum ones, like the ones you put in your mouth. I might have like put those to confused them at one point, when I was doing the survey* [19 y, Hispanic/Black, woman/nonbinary, bisexual/queer]

Lessons Learned

The study team learned several lessons when administering the protocol amongst their sample. Lessons included the need to validate EMA survey responses about product use, the inclusion of more comprehensive measurement of cannabis product use, the establishment of regular data documentation and inventorying, prompt technical assistance and communication about survey technology and schedules, and the verification of screener survey responses and participant IDs. Table 2 summarizes the lessons learned throughout the duration of the Puff Break EMA protocol and recommendations from the research team for future studies that used EMA methodology.

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Table . Lessons learned and recommendations for future EMA research.

Study components and lessons learned	Recommendations for future EMA[a] research
Acceptability	
Participants had mixed feedback regarding the default, fixed features of the EMA survey platform that the research team chose for Puff Break.	• EMA researchers should thoroughly search and test the different EMA survey platforms that are available to ensure that the most appealing platform is chosen for their participants.
Feasibility	
EMA research participants can experience EMA tool issues at any point during the study and may need additional accommodations to their survey schedule to participate as much as possible.	• Encourage EMA research participants to contact research staff as soon as they experience technical issues and train staff to respond promptly within the hours of the survey delivery time windows. • Use a user-based survey schedule and allow the research participants to tailor their survey delivery time windows (such as an hour earlier or later) before their survey schedule is configured. • Schedule SMS text messaging or Zoom check-ins with participants two days after the participant begins their EMA trial participation to catch technological or scheduling challenges before they severely impact response rates. Schedule another SMS text messaging or Zoom check-in halfway through the trial as well.
Appropriateness	
Product use responses needed to be validated by the participants during the exit interview as participants claimed to not use certain products that were shown in their survey responses.	• Include data validations at the beginning of exit interviews, such as "we recorded responses for these types of products. Can you confirm whether or not you used each of these?" • When training participants on how to use the EMA tool, instruct them to answer survey questions carefully to avoid misclicks. If possible, enable a backspace button for participants to edit responses before submitting their survey. • Ensure that the definitions of product types are clear to the participants before they begin answering surveys, such as the differences between "smokeless" and "cannabis." • If the ability to customize the size of survey response text, or the distance between survey responses, do so to ensure responses are easy to read from an arm's length and reasonably spaced between each other.
More cannabis product-related measures could have been used as sole cannabis use and cannabis co-use with tobacco and nicotine products was much more prevalent in the sample than anticipated.	• Tobacco and nicotine product use measures should be adapted to include cannabis product use to reliably compare and contrast tobacco and nicotine, and cannabis product data.
Logistical (screening process)	
Online screener surveys are at risk for being flooded by bot-generated responses or ineligible persons who submitted disingenuous survey responses.	• Develop a brief data integrity protocol to flag bot-generated or disingenuous survey responses. The Puff Break protocol instructed staff to flag responses that used formulaic email addresses, rapid screener survey completion times, data discrepancies within survey responses, or IP addresses outside of the United States. • Implement ID verification before the participant enrolls in the study, using best judgment if the participant goes by a different name or gender identity. If on Zoom, require participants to use their camera and microphone. • Leverage in-person community networks for recruitment to reduce the risk of encountering bot or disingenuous screener survey responses via online recruitment methods.
Logistical (EMA trial)	
Multiple, robust codebooks and data cleaning protocols were needed to handle myriad formatting challenges that arose throughout the data download and merging process, especially with unanticipated updates to the EMA host platform.	• Regularly export and assess data formatting between survey participants to catch any changes made to the survey output and avoid challenges when merging participant datasets. • Document edits to EMA surveys, datasets, codebooks, and protocols as they are being made to avoid duplicating work at a later date.

[a]EMA: ecological momentory assessment.

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Discussion

Principal Results and Comparison With Prior Work

The purpose of this study is to use multimethod design to evaluate the acceptability, feasibility, and appropriateness of Puff Break, an EMA protocol measuring stress, socialization, and smoking behaviors among LGBTQ+ adolescents. Importantly, this study addresses a gap in the literature regarding the use of EMA methods and highlights the impact of minority stress and socialization (eg, discrimination and social support) on smoking behaviors in LGBTQ+ adolescents. Findings from 50 participants indicate that using EMA to understand the impact of stress and socialization experiences on smoking behaviors in LGBTQ+ adolescents is feasible, acceptable, and appropriate among LGBTQ+ adolescents aged 15-19 years. In particular, the study was able to recruit the intended sample size and had a 100% study completion rate among participants. Participants were prompted to complete 5 EMA assessments daily for 2 weeks, which resulted in a median response rate of 75%. The number of EMA assessments and duration of the protocol were determined by prior EMA research on substance use among adolescents and adults which ranged from 2 to 4 weeks [20,21,28]; (with 1 study highlighting the feasibility of using a 2-week EMA window among middle and high school students [30]), along our formative data collected in Phase 1 of the study which recommended this schedule as most feasible [23]. Our response rate was slightly lower than studies that had longer EMA trial periods of 4 to 12 weeks [31-33], which may be primarily attributed to design features (eg, survey timing) or technical challenges with the EMA tool (eg, app glitches) rather than the potential burden of completing 5 daily surveys. Some participants in our study repeatedly reported challenges with completing surveys due to work, school, and sleep schedules, with 1 participant indicating parental controls on cell phone usage as a barrier to survey completion. While some participants were generally less responsive, qualitative data suggested an overall positive experience and interest in the study, indicating that response rates could improve if these barriers are effectively mitigated. Additionally, in line with existing research on EMA and mobile interventions, the Puff Break study evaluated feasibility and acceptability in regards to enrollment completion rates [31-33]. However, this study extends beyond these measures by including appropriateness, including multimethod assessment to further elucidate the feasibility, acceptability, and appropriateness of the Puff Break EMA protocol.

Triangulated results from closed and open-ended survey responses as well as semistructured interviews indicated high scores for feasibility, acceptability, and appropriateness (range 4.15 to 4.46) and identified 5 key themes of (i) usability; (ii) product use awareness; (iii) app features; (iv) motivations to monitor or reduce tobacco use; and (v) product-response option alignment. These results highlight that the Puff Break EMA protocol is implementable among LGBTQ+ adolescents. Qualitative results highlight that the Puff Break EMA protocol was easy and simple to use with EMA surveys being straightforward and requiring minimal time for completion. The notifications and survey delivery, along with the simplicity and discretion of the EMA questions, were appealing to participants. Lastly, the inclusion of visualizations in the exit survey, along with tracking a wide variety of evidence-based predictors of tobacco, nicotine, and cannabis use, increased participants' awareness of their product use and offered opportunities for reflection. Notably, we found that while participants believed the Puff Break EMA protocol was appropriate for both LGBTQ+ and non-LGBTQ+ adolescents, it may be most appealing to individuals with an existing intention to monitor or quit tobacco, nicotine, or cannabis use. This is consistent with general public health theories and other tobacco cessation interventions where individual intention is a key motivator to behavior change [34,35]. Further research is needed to extrapolate on the additional measures that elucidated the feasibility and acceptability of the Puff Break EMA protocol, as well as the appropriateness of EMA research to address tobacco, nicotine, and cannabis use among adolescents, regardless of gender identity and sexual orientation.

Strengths and Limitations

The Puff Break EMA protocol has various strengths. First, the study recruited a diverse sample of LGBTQ+ adolescents across several racial and ethnic identities, gender identities, and sexual orientations. Though we were limited in participants who identified as transfeminine or assigned male sex at birth, the overall diversity allowed us to obtain varying lived experiences and unique perspectives in this pilot dataset. Second, we aimed to use a multitude of validated measures for tobacco and nicotine product use, stress, minority stress, socialization, craving, and mood. When curating measures for the EMA surveys and supporting assessments (eg, baseline and exit surveys), we used scales that were created, previously adapted for, or validated among adolescents such as the Sexual Minority Adolescent Stress Inventory [36] and Positive and Negative Affect Schedule [37]. When not available, we used validated instruments used extensively in prior research with adolescents, such as the Timeline Follow-Back instrument [38]. When needed, minor adaptations to validated measures were made to fit the context of our study. Measure adaptations were informed by community service providers, LGBTQ+ adolescents who smoke, and academic partners, which not only increased the quality of our measurement but also helped to develop an EMA protocol that is responsive to LGBTQ+ adolescents. Details of our measures and adaptations can be found in the Puff Break protocol [23]. Lastly, the use of multiple methods (eg, qualitative and quantitative) to gather robust feedback on the protocol led to iterative refinements that are likely contributing to the protocol's high acceptability, feasibility, and appropriateness scores and general excellence across qualitative feedback.

Nevertheless, the study is not without limitations. First, our study may not be generalizable to the larger LGBTQ+ populations outside of San Diego County. Second, although it was straightforward to recruit LGBTQ+ aged 18 to 19 years, recruiting adolescents younger than 18 was challenging. Engaging the PPG members in direct recruitment assistance increased the recruitment of younger participants, but none aged under 15 years were enrolled with this additional support. We believe that difficulties recruiting participants under the age of 18 in our study, specifically those 14 to 16 years, are attributable to the lower rates of overall tobacco and nicotine product use

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among younger adolescents, regardless of sexual orientation. For instance, while 7.8% of high school students reported using e-cigarettes within the last 30 days, the percentage is halved (3.5%) for middle school students [39]; LGBTQ+ youth would be a small subset of this population (ie, some subset of the total 3.5%), causing the potential recruitment pool to be small.

Despite formative work to identify an acceptable EMA platform, a third limitation of the study concerned the technical difficulties that occurred during the EMA trial, such as participants not receiving planned push notifications to take their surveys, not being able to open surveys when survey windows were open, and the inability to prepopulate survey responses prepopulated from previous surveys. All of these unanticipated factors could have affected our response rates. Such issues could have been addressed by selecting an EMA operating system that was more reliable or that offered such design features. Participants were given instructions on soft resets, as well as encouragement to contact research staff to troubleshoot difficulties. Lastly, we acknowledge the potential for selection and participation bias in our sample. It is possible that enrolled participants in this study were already interested in decreasing or quitting their tobacco, nicotine, and cannabis use via a mobile tool, resulting in potential selection bias and limiting our understanding of feasibility, acceptability, and appropriateness among LGBTQ+ adolescents in precontemplative stages of tobacco, nicotine, or cannabis cessation. Our primary recruitment strategies (flyers, social events, and social media) and requirement of smartphone access may have preferentially attracted adolescents who were already more engaged or resourced, which could introduce selection bias. However, data from the Pew Research Center highlights that among US adolescents aged 13 to 17 years, even those experiencing financial hardship (eg, annual household income less than $35,000), 89% have access to a smartphone and 51% use the internet *almost constantly* [40], thus suggesting that smartphone access may not pose a substantial barrier to youth participation. In addition, we bolstered our recruitment efforts with additional strategies, including recruitment from drop-in centers and referrals from enrolled participants, which may have increased the diversity of youth included in the research. Taken together, our recruitment approach strove to balance feasibility with inclusivity.

Conclusion

Despite the limitations identified, the Puff Break protocol demonstrated high feasibility, acceptability, and appropriateness. The Puff Break EMA protocol [23] has potential for further development to inform real-time tobacco, nicotine, and cannabis interventions among LGBTQ+ youth. Participants reported high acceptability, highlighted the app's simplicity, and noted a perceived increase in awareness of their own product use behavior. Additionally, participants reported that the Puff Break EMA protocol is appropriate for monitoring tobacco, nicotine, and cannabis use behaviors and has potential for adaptation as an interventive tool. These findings, plus the lessons learned, indicate the promise for EMA methodology to be used in tobacco, nicotine, and cannabis research, and real-time prevention efforts among LGBTQ+ adolescents.

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Data Availability

The datasets generated or analyzed during this study are not publicly available due to organizational policies but are available from the corresponding author on reasonable request.

Authors' Contributions

Conceptualization: JH, AJB, MM, HJJ, JPC
Formal analysis: LS, IE, ACL
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Investigation: LS, DK, JPC
Methodology: LS, JH, AJB, MM, HJJ, JPC
Project administration: DK, JPC
Software: DK
Supervision: JPC
Writing – original draft: LS, DK, IE, ACL, JH, AJB, MM, HJJ, JPC
Writing – review & editing: LS, DK, IE, ACL, JH, AJB, MM, HJJ, JPC

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Conflicts of Interest

None declared.

Checklist 1
STROBE checklist.
[PDF File, 185 KB - formative_v10i1e79957_app1.pdf]

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Abbreviations:

EMA: ecological momentary assessment
LGBTQ+: lesbian, gay, bisexual, transgender, queer, and other sexual and gender minorities
MARS: Mobile Application Rating Scale
PPG: Participatory Planning Group

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Evaluation of Hospice@Home for Home-Based Palliative Care: Development and Usability Pilot Study

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Abstract

Background: The demand for palliative care is rising due to population aging and increased chronic illness. However, access to timely palliative care remains limited, particularly for patients receiving home-based hospice care in rural areas. Digital health technologies present an opportunity to enhance care delivery and communication at home.

Objective: This pilot study aimed to (1) develop the Hospice@Home system, a digital in-home hospice care solution; (2) explore preliminary indications of usability and feasibility among patients with terminal cancer and their caregivers; and (3) identify challenges for future implementation.

Methods: Hospice@Home was developed following the human-centered, evidence-driven Adaptive Health Experience and Application Design approach. After the prototype was developed, alpha testing was conducted with 2 simulated patients to assess system functionality and identify technical issues. Usability was measured through structured observation and task completion success during these sessions. Feasibility was evaluated during a 3-week beta test involving 5 dyads of patients with terminal cancer and caregiver, recruited through a home-based palliative care agency. Challenges were identified through user feedback, field notes, and technical logs collected throughout the testing period.

Results: Hospice@Home is a web app optimized for Android devices. It integrates wearable biosignal data—blood pressure, pulse rate, sleep patterns, and oxygen saturation—measured via the Samsung Galaxy Watch 6. It also allows self-reporting of body temperature, pain levels, bowel movements, and the severity of symptoms tailored to individual patients. Medication compliance, including scheduled and pro re nata analgesics, was recorded in a smart medication box and automatically transmitted to Hospice@Home. Over 3 weeks, 5 patients (aged 53 - 93 y) with terminal cancer and their caregivers (aged 38 - 63 y) explored the system. Both patients and caregivers appreciated the consolidated symptom reporting and real-time data sharing, noting that the system helped them feel more reassured and connected to clinical support. Usability was assessed via satisfaction ratings, averaging 3.3 (SD 0.5) for patients and 4.0 (SD 0.7) for caregivers (5-point scale). Feasibility was evaluated through task compliance; dyads completed ≥13 of 18 tasks during stable periods. No major technical issues were reported. Challenges to consistent system use included data entry fatigue, psychological barriers to using technology, fluctuations in cognitive and physical functioning, and a general preference among patients and caregivers for phone calls rather than using the in-app communication.

Conclusions: Hospice@Home showed early signals of usability and feasibility among patients with terminal cancer and caregivers, but these preliminary observations require cautious interpretation given the pilot design. The findings highlight potential value in supporting home-based palliative care, while underscoring the need for ongoing refinement and iterative testing before making broader claims about effectiveness or clinical impact.

(JMIR Form Res 2026;10:e79334) doi:10.2196/79334

KEYWORDS

digital health; home care services; hospice care; usability; wearable devices

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Introduction

Palliative care is a specialized approach for people with serious, chronic, or life-threatening illnesses and has demonstrated positive outcomes, including improved quality of life, reduced health care costs, and high satisfaction among patients, families, and care providers [1]. The global demand for palliative care has been steadily increasing, driven by an aging population and rising prevalence of chronic diseases [2]. Having become a super-aged society in 2024 [3], South Korea is preparing for the implementation of the Act on Integrated Support for Local Medical and Long-Term Care Services in 2026, which is designed to strengthen community-based care that supports individuals through the end of life [4]. In South Korea, palliative care is provided through 3 main models: palliative care team, palliative care unit (PCU), and home-based palliative care (HPC) [5]. Palliative care team services are offered in general wards in hospitals or cancer centers, while PCU care is provided in dedicated palliative care wards within hospitals. HPC is delivered by dedicated home hospice nurses in the interdisciplinary PCU team, allowing for continued care in patients' homes. Within this system, national policy efforts have focused on expanding the availability and accessibility of home-based palliative care services.

For patients with cancer, HPC offers significant benefits over nonpalliative care, including higher patient satisfaction, fewer emergency room visits, and significantly lower medical costs [6]. Additionally, it has been reported to be more cost-effective than the care provided in PCUs [7]. Despite these advantages and growing demand, HPC remains underutilized in South Korea. While there are 92 PCUs, only 39 institutions offer HPC, serving just 3.5% of the hospice users nationwide [5]. Most palliative care in South Korea is delivered in acute care settings within general hospitals or higher-level facilities, primarily concentrated in urban areas [3]. Access to HPC in rural regions remains limited due to workforce shortages, including a lack of adequately trained personnel, resulting in disparities in care [8]. Paradoxically, rural areas with a higher proportion of older adults and greater need for palliative care often have fewer HPC services available, highlighting a mismatch between supply and demand. To mitigate this imbalance, strategic approaches are needed to strengthen service delivery capacity and ensure equitable access to HPC across regions.

In home settings, patients and caregivers often face challenges in managing symptoms and experience significant caregiving burdens, which may contribute to the low utilization of HPC [9]. Therefore, it is essential to improve the home care environment by developing efficient management systems that can maintain consistent quality of care even with limited human resources. Effective symptom management in HPC depends on precise monitoring, clear communication among patients and health care providers, and timely intervention. However, unlike inpatient settings, HPC lacks continuous 24-hour monitoring and often relies on patients' recall rather than real-time symptom reporting or objective data, such as vital signs. As a result, decision-making for symptom management, including medication adjustments, is frequently delayed until a nurse conducts an in-person visit. These delays often lead patients to prefer PCU admission. When PCU bed availability is limited or geographic access is difficult, patients and their families often opt for admission to nursing homes or geriatric hospitals as an alternative. In either case, patients are ultimately institutionalized, unable to remain at home during their final stage of life. The integration of digital technologies into home care can address these challenges by improving efficiency, accessibility, and the overall quality of care.

Digital health (DH) technologies—including wearables, telehealth, and mobile apps—offer promising opportunities to improve HPC by enabling remote symptom monitoring, tracking treatment adherence, and supporting decision-making. For example, Huang et al. [10] demonstrated that activity metrics collected through wearable devices could be used to assess patients' functional status and predict prognosis in hospice care settings, while Phongtankuel et al [11] reported the potential of mobile health apps to facilitate communication and symptom tracking in home hospice care. Beyond palliative care, remote patient monitoring has also shown measurable benefits in other clinical contexts, such as reduced hospital length of stay and improved care coordination among patients with COVID-19 [12]. These technologies may help overcome geographic barriers and improve continuity of care. However, several concerns have been raised regarding the feasibility and ethical implications of using digital technologies in end-of-life contexts, including patient fatigue, technology anxiety, data privacy issues, and the risk of depersonalizing care [11,13].

Evidence from recent reviews suggests that DH interventions in palliative care produce encouraging yet mixed results, showing promising effects, such as improved symptom management, communication, and caregiver support, but also notable methodological limitations, including small sample sizes and a lack of methodological rigor as clinical studies, with most research focusing on patients in earlier palliative stages rather than those receiving end-of-life care at home [14,15]. In addition, most systems applied fixed, one-size-fits-all symptom assessment tools that increased patient burden and did not account for individual variability in symptoms. Integration with real-time biosignal monitoring or existing electronic medical records was also largely absent, hindering clinical applicability. To address these gaps, the development of DH systems capable of timely symptom recognition, medication tracking, and effective communication tools within home settings has been recommended. Yet, despite growing global interest, the application of DH technologies in HPC remains largely unexplored in Southeast Asia, including South Korea [16]. Recent consensus efforts and policy discussions have emphasized the need to establish standardized evaluation frameworks, ensure interoperability with existing health systems, and expand reimbursement pathways to accelerate the adoption of DH in palliative care [17,18]. However, despite these global efforts, research specifically examining the usability and feasibility of DH in HPC in South Korea remains scarce. Most existing studies have primarily focused on DH interventions for relatively stable patients or those with chronic diseases, rather than for individuals at the end of life, and few have conducted empirical evaluations of tailored systems in HPC settings. Assessing the practical feasibility and user experience

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of such a system in this context is therefore essential to guide further development and large-scale implementation. This gap provides the rationale for this pilot study.

In response to these challenges, this study developed Hospice@Home, a digital home−based palliative care system designed to enhance the delivery of palliative care for patients in their homes. The system integrates remote biosignal monitoring, electronic medication tracking, and a patient-reported symptom management interface to support timely and personalized care. The aim of this pilot study was to develop Hospice@Home and evaluate its feasibility and usability. The research questions were as follows:

1. Is the Hospice@Home system usable and feasible in home-based palliative care?
2. What challenges and contextual factors affect its implementation?

Methods

Ethical Considerations

This study was approved by the Kyungpook National University Hospital Institutional Review Board (KNUH IRB 2023-12-045-002), and written informed consent was obtained from all patients and their family caregivers before participation in the study. Participant privacy was protected, and all collected data were anonymized and kept confidential. Participants received an in-kind compensation in the form of a thermometer valued at 100,000 KRW (approximately US $68) for their participation.

Study Design

This pilot study employed a mixed methods approach combining quantitative data collection and qualitative interviews with patients and caregivers. This study was guided by the Approach to Human-centered, Evidence-driven Adaptive Design (AHEAD), a systematic methodology that integrates empathy-driven problem-solving approach with the core stages of inspiration, ideation, and implementation [19]. The AHEAD framework involved five key steps: (1) defining the problem and assembling a team, (2) information gathering, (3) synthesis, (4) intervention design, and (5) evaluation. These steps were executed collaboratively by an interdisciplinary team comprising experts in palliative care, home care, engineering, and software development.

System Development

Step 1. Define the Problem and Assemble a Team

An interdisciplinary subject matter experts (SME) team was assembled, comprising a palliative care physician with 10 years of experience, a home hospice nurse from a regional hospice center, and 2 hospice advanced practice nurses. This team collaboratively identified key weaknesses in current HPC practices compared to PCU, including:

- Inconsistent monitoring of vital signs and symptoms
- Medication management challenges, such as missed fentanyl patch replacements and inaccurate pain logs, hindering pro re nata (PRN, as needed) medication tracking
- Limited provider-patient communication between visits due to connectivity constraints
- Delayed provider response to changes in patient condition due to insufficient real-time objective data

Based on these gaps, the SME team established core priorities for high-quality HPC. These included timely symptom and vital sign monitoring, accurate and proactive medication documentation and management, responsive provider-patient communication between home visits, and integration of real-time patient–reported outcomes to support clinical decisions.

Steps 2 and 3. Information Gathering and Synthesis

To address these challenges, the SME team conducted reviews of literature and online resources, consulted with DH companies, and piloted potential products. This process led to consensus on the essential features of the Hospice@Home system:

Real-Time Monitoring of Vital Signs and Symptoms and Data Integration

For the continuous, centralized tracking of vital signs and symptoms, the SME team evaluated wearable devices for their compatibility, reliability, and capacity to collect key biosignal data. The Galaxy Watch 6 was selected for its compatibility with Android platforms and ability to monitor key indicators, such as blood pressure (BP), pulse rate (PR), oxygen saturation (O_2 Sat), and sleep patterns. These biosignal parameters offer critical insights into patients' health status. For symptom assessment, the team reviewed validated instruments such as the Palliative Outcome Scale, Symptom Assessment Scale by Palliative Care Outcomes Collaboration, and the Edmonton Symptom Assessment Scale [20]. Most standardized symptom assessment tools for terminally ill patients evaluate 7‐9 common symptoms (eg, pain, fatigue, nausea, depression) using Likert scales. These tools also include open-ended items that allow patients to report and rate additional symptoms not listed. However, requiring patients to score every symptom—regardless of personal relevance—can increase reporting burden. To reduce reporting burden and improve compliance, the SME team recommended limiting assessments to 3 target symptoms—including pain—tailored to each patient's care needs. The Bristol stool chart was also adopted to standardize bowel diary entries. The system design incorporated functionality allowing patients and caregivers to transmit symptoms and biosignal data directly to providers, enabling remote, real-time monitoring and proactive intervention.

Smart and Flexible Medication Management

The SME team conducted a comparative analysis of commercially available smart medication boxes (SMBs), assessing features, such as reminder settings, support for various dosage forms and PRN medication, portability, ease of use at home, and affordability [21,22]. Most market-available SMBs, including pill organizers, vial caps, and alarm-enabled dispensers, were found to primarily accommodate solid-form medications, making them unsuitable for patients with palliative care who often require multiple medication forms (eg, oral solutions, transdermal patches, nasal sprays) and the complexity of palliative medication schedules (eg, opioid patch replacements every 48‐72 h or oral PRNs taken based on

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symptom intensity). Given these limitations, the team opted to develop a customized SMB prototype capable of supporting multiple formulations and flexible dosing intervals, along with built-in reminder functions and adherence alerts tailored to each patient's regimen.

Responsive Provider-Patient Communication

Limited communication between home visits was identified as a major gap in care continuity. To address this, the SME team emphasized the need for real-time communication pathways. Therefore, when patients press the emergency button, send a message, or when predefined thresholds are exceeded, automated alerts are immediately sent to health care providers. The system interface—customized for administrators, providers, and patients, respectively—displays structured visualizations of symptoms, vital signs, and medication adherence to support timely interventions and communication.

Personalized Alerts for Early Intervention

Delays in clinical decision-making were often attributed to the lack of timely and actionable data. To overcome this issue, the system was designed to incorporate automated alerts triggered when biosignal values or symptom severity deviate from predefined parameters. These real-time notifications enable providers to intervene earlier, preventing symptom escalation and unnecessary hospital visits.

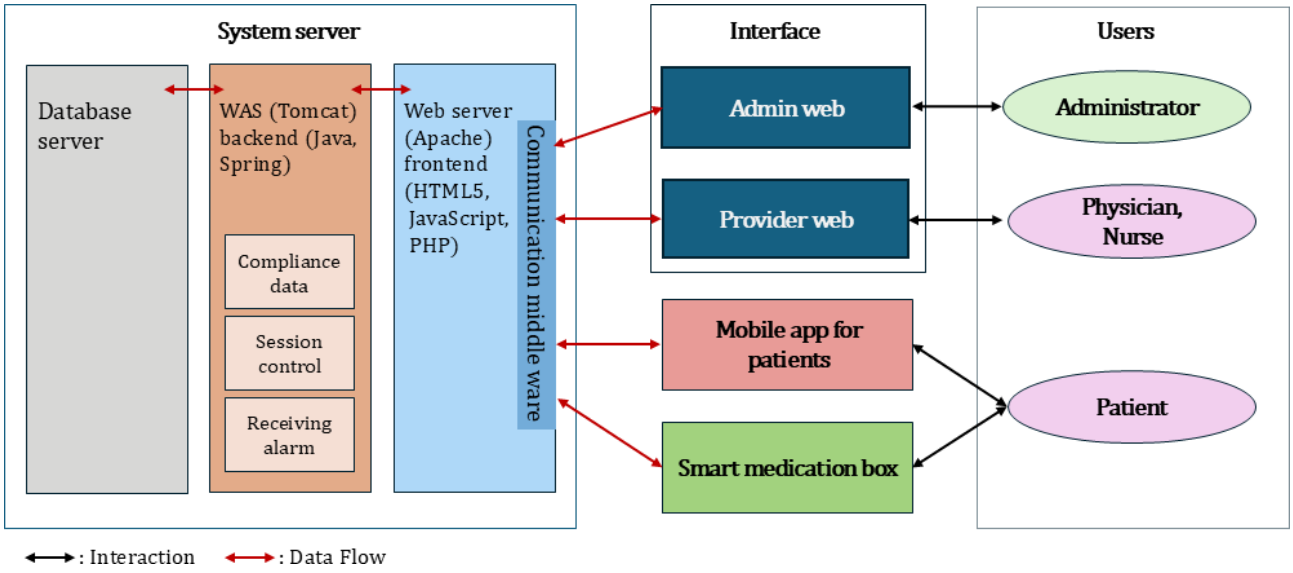
User-Friendly Design

The interface featured large, high-contrast fonts and simple icons, with 1‐2 step navigation to reduce cognitive load. Interactive elements, such as symptom sliders and medication checkboxes, allowed easy touch input. Text-to-speech system supported users with low literacy. These features aimed to accommodate older adults and cognitively or physically vulnerable users.

System Architecture and Security

The Hospice@Home System was built on Naver's Linux server infrastructure, incorporating a dedicated database server for secure data storage and a web app server for managing compliance data, session control, and alerts using Java Spring Legacy (Figure 1). Two web-based interfaces—one for administrators and another for health care providers—were developed using HTML5 and JavaScript to support role-specific functionality. The provider web interface also integrated a specialized alarm feature, developed in Flutter, that enabled nurses to receive and confirm alerts triggered by patient-reported symptoms and biosignal thresholds. This functionality allowed nurses to monitor patients in real time and respond promptly, even outside scheduled visits. The patient-facing Android mobile app, also built with Flutter, supported notifications and interactive features.

Figure 1. Hospice@Home system structure. WAS: web application server.



Secure and standardized data exchange was enabled through HL7 Fast Healthcare Interoperability Resources [23], while health care data and activity logs were managed by the Tibero 7 database management system [24], utilizing role-based access control to maintain data integrity and privacy. These components ensured reliable integration and secure transmission of medication usage data from the SMB, including compliance tracking, missed dose alerts, and timestamped medication logs. This supported real-time monitoring of medication adherence and facilitated clinical decision-making based on objective records. To safeguard personal information, the system implemented bidirectional encryption for personal data and unidirectional encryption for passwords, in full compliance with the Personal Information Protection Act [25]. A minimum viable product of the Hospice@Home system was developed and underwent multiple rounds of testing and refinement. The iterative process focused on optimizing system performance, enhancing user experience, and addressing potential issues to ensure reliable functionality.

Step 4. Intervention Design

In this step, the AHEAD framework emphasized establishing guiding principles and exploring ideation [19]. Accordingly, our study team developed the Hospice@Home service framework, outlining the workflow and information flow of this service (Figure 2). The Hospice@Home service framework facilitates coordinated palliative care for patients with terminal illnesses at home. The system integrates patient self-reporting,

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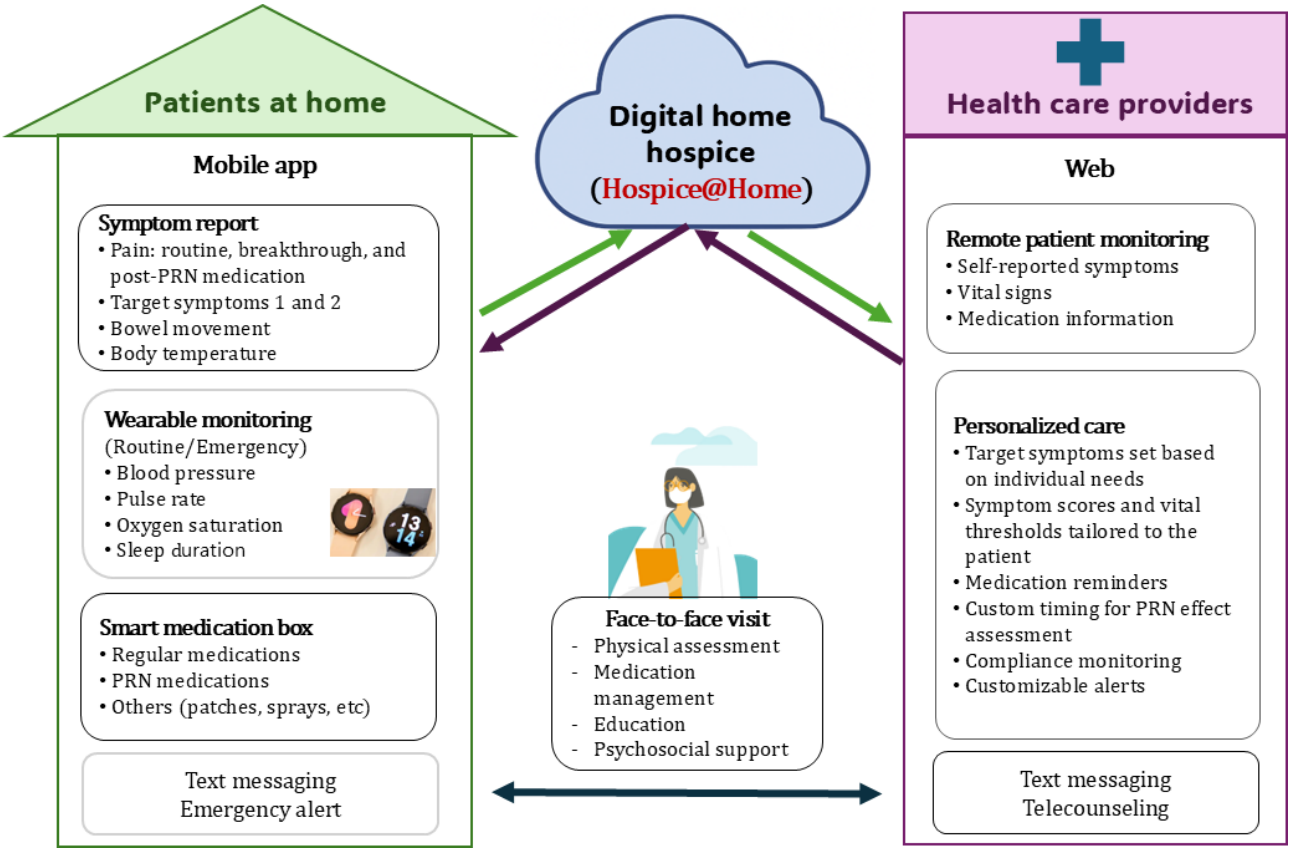
wearable biosignal monitoring, and smart medication tracking through a mobile app. Each day, patients or caregivers enter symptom data (eg, pain, bowel movement, body temperature) and confirm medication intake, while wearable devices automatically transmit vital signs, including BP, PR, O_2Sat, and sleep duration. All data are sent to the cloud-based platform in real time. Health care providers access this information through a web interface, which displays structured dashboards of patient-reported outcomes, vital signs, and medication adherence. The system is designed to track PRN medication use alongside pain scores, enabling clinicians to monitor the effectiveness of analgesics and detect patterns of breakthrough pain. Based on the patient's condition, providers set personalized symptom thresholds and medication schedules. When data exceed these thresholds—or when patients activate the emergency button or send a message—automated alerts are triggered, prompting timely clinical response. Providers may send instructions or reminders via in-app messaging or initiate teleconsultation as needed. Face-to-face visits supplement digital care by addressing complex needs such as physical assessment, medication titration, education, and psychosocial support. This hybrid approach ensures that communication and clinical decision-making remain responsive and patient-centered throughout the course of home-based hospice care.

Figure 2. Hospice@Home service framework. PRN: pro re nata.



To evaluate the functionality, the Hospice@Home prototype, which included the Galaxy Watch6, SMB, and Hospice@Home app, we conducted alpha testing using simulated scenarios with virtual patients and prescriptions. Two nurses alternated as simulated patients to identify potential usability issues and system malfunctions. During testing, the following issues were detected and addressed through system updates: (1) unstable Wi-Fi connectivity—addressed by implementing mobile hotspots to ensure consistent network access, (2) missed app alerts caused by delayed SMB synchronization—resolved by optimizing the communication interval between the app and SMB and reducing latency through firmware updates, (3) intermittent errors in biosignal display on the Galaxy Watch—corrected by updating to the latest wearable OS, and (4) incorrect fentanyl patch scheduling due to input errors in the initial dosing time—mitigated through a built-in reminder function for patch replacement. Additionally, a detailed user manual was created in both a printed booklet and a series of short video clips to guide users in navigating system functionalities and troubleshooting potential issues.

Usability and Feasibility Testing

Usability and feasibility testing were conducted as part of Step 5 (Evaluation) of the AHEAD framework.

Participant Recruitment

Participants were recruited consecutively from a single home–based palliative care center over a 6-month period (February-October 2024). Eligible participants were newly enrolled in HPC and met the following inclusion criteria: (1) ability to report symptoms using numeric rating scale, (2) access to wireless internet, and (3) willingness to provide informed consent. Recruitment leaflets and advertisements were posted in a PCU. Initial screening was conducted by the attending physician to confirm cognitive capacity for participation. Subsequently, a home hospice nurse conducted an in-home

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assessment to evaluate the internet environment and caregiver availability. Patients meeting these criteria were introduced to the study and, upon agreement, received a visit from the researcher, who provided system training and obtained written informed consent.

During the study period, 7 patients were recommended by the attending physician and subsequently screened by a home hospice nurse to verify eligibility based on home internet connectivity and caregiver support. Of these, 1 patient declined participation after the researcher's explanation due to discomfort with technology, and another withdrew during the study because of rapid clinical deterioration. Ultimately, 5 (71%) patient-caregiver dyads consented to participate and completed the beta testing. Although the final sample size was small, this is consistent with recommendations for pilot studies that aim to gain meaningful insights into the usability of a system rather than statistical generalizations [26].

Training

Each participant was provided with a Galaxy Watch 6, a Galaxy A13 smartphone preloaded with the Hospice@Home app, and an SMB. Patients and caregivers received hands-on training using a structured user manual. Additionally, a structured 2-hour training workshop was held for the attending physician and hospice nurses. The training covered key system functionalities, including user login, prescription entry, patient data review, and use of in-app chat feature. To enhance mobility and responsiveness, the app was also installed on nurses' personal smartphones, enabling real-time notifications and patient monitoring in the field.

Feasibility Measures

Feasibility testing was conducted over a period of 3 weeks. This duration was determined with reference to national hospice data in South Korea, where the average hospice enrollment lasts approximately 27 days [5]. Although the average survival of home hospice patients is around 2 months, a 3-week period was chosen to balance the need for sufficient observation with minimizing burden on patients with terminal illnesses and caregivers.

In this study, feasibility was defined as the extent to which the Hospice@Home system could be implemented and used as intended in HPC environment. Feasibility testing focused on two core domains: (1) technical feasibility, evaluated by examining the reliability of biosignal measurements obtained through the system, and (2) user feasibility, assessed through patients' and caregivers' engagement with symptom reporting and medication compliance. The reliability of biosignal measurements was assessed by comparing Galaxy Watch 6 data with readings from standard reference devices during the first 3 nurse home visits, each conducted on a separate day. At each visit, a single comparison was made for systolic and diastolic BP, PR, and O_2 Sat, using the Omron HEM-7121J and Dr. Healing HPO-010 as reference devices. A total of 60 paired measurements (systolic blood pressure, diastolic blood pressure, PR, and O_2 Sat), measured across 3 separate visits in 5 participants, were collected for intraclass correlation coefficient (ICC) analysis. Sleep duration was excluded from the ICC analysis due to difficulty in distinguishing sleep from rest periods and the lack of consistent verbal reports from patients, which limited comparison with reference data.

Symptom reporting and medication compliance were analyzed through system-generated compliance metrics extracted from the administrator dashboard. These metrics included vital sign measurement, symptom reporting, and medication use pattern. Compliance was scored as follows:

1. Vital sign compliance: Each of the 4 daily vital sign measurements (BP, PR, body temperature, O_2 Sat) was scored separately, with 2 points for full completion, 1 point for at least 1 measurement, and 0 points for none, for a total possible score ranging from 0 to 8 points.
2. Symptom reporting: 2 points were assigned for daily entries including pain and at least 2 additional symptoms (eg, dyspnea), and 0 points for no entry, yielding a daily score ranging from 0 to 6.
3. PRN pain score reporting: 2 points for both pre- and postmedication pain reports, 1 point for prereporting only, and 0 points for no report. If no PRN medication was administered during the evaluation period, the case was scored as 2 points, indicating full adherence.
4. Scheduled medication use pattern: 2 points for full completion of regularly scheduled medications (excluding PRN use) and 0 points for any omissions.

The total possible compliance score ranged from 0 to 18 points, reflecting overall engagement with the system and adherence to the clinical protocols.

Usability Measures

The 5-item usability questionnaire used in this study was developed by the research team to reflect core aspects of user experience, including overall satisfaction, ease of use, perceived helpfulness, likelihood of recommendation, and communication improvement. These domains represent the key constructs commonly assessed across validated usability instruments such as the System Usability Scale, the mHealth App Usability Questionnaire, and the Mobile Application Rating Scale [27]. Given the frailty of the target population, a brief 5-item format was adopted to reduce respondent burden. Although this simplified tool was not formally validated, it was deemed acceptable for this early-stage feasibility study, and the use of validated instruments is planned for future large-scale evaluations.

Qualitative feedback on system features was also gathered to supplement usability ratings and provide contextual insight into caregivers' experiences with system use. Although all 5 patient-caregiver dyads who completed the beta testing were eligible for qualitative interviews, the patients were unable to participate due to clinical deterioration. Consequently, qualitative interviews were conducted with all 5 caregivers. To collect these qualitative data, caregivers participated in in-home interviews conducted at least once per week over the 3-week evaluation period. Before each interview, written informed consent for audio recording was obtained. Interviews were held in the patient's home, incorporated brief field observations, lasted approximately 60 minutes, and were audio-recorded and

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transcribed verbatim. These interviews were conducted throughout the 3-week evaluation period and were used to supplement usability ratings by providing deeper insight into caregivers' experiences, including challenges encountered during use, features they found helpful, and suggestions for improvement.

Statistical Analysis

Statistical analysis was performed using Microsoft Excel and IBM SPSS Statistics (version 28). Descriptive statistics, including means, SDs, frequencies, and percentages, were used to summarize participants' demographics, compliance metrics, and user satisfaction scores. To evaluate the reliability of biosignal measurements obtained from the Galaxy Watch 6 in comparison to standard reference devices, ICCs and 95% CIs were calculated using a 2-way random-effects model for absolute agreement based on average measures. This model was selected because the wearable device and reference device represent random samples of potential measurement tools, and the aim was to assess absolute agreement rather than consistency. ICC values were interpreted using commonly applied thresholds (<0.50 = poor, 0.50 - 0.75=moderate, 0.75 - 0.90=good, and >0.90 = excellent agreement). Quantitative results were then integrated with qualitative findings to provide contextual explanations of usability scores and compliance patterns, following a complementary mixed methods framework. Specifically, qualitative themes related to usability barriers (eg, fatigue, cognitive fluctuations) and facilitators (eg, reassurance, data consolidation) were compared with individual-level compliance trends and satisfaction ratings. This comparison allowed us to identify converging and diverging patterns across qualitative experiences and quantitative engagement metrics. Together, these mixed methods findings provided contextual explanations for variability in engagement and supported interpretation of the system's preliminary performance.

Qualitative Analysis

Qualitative data from patient and caregiver interviews, along with researchers' field notes, were analyzed using conventional content analysis [28]. This approach was chosen to allow categories and themes to emerge inductively from the data without imposing preexisting theoretical frameworks. Two researchers independently coded interview transcripts and field notes, identified recurring meaning units, and discussed discrepancies until agreement was reached. Coding proceeded through 3 stages: initial open coding, grouping of codes into broader conceptual categories, and iterative development of themes. A shared codebook was developed and refined throughout the analysis, and discrepancies between coders were discussed until consensus was achieved. Themes were organized to capture shared and divergent experiences among patients, caregivers, and health care providers, and the codebook was refined iteratively through discussion. Although the small pilot sample did not allow for full data saturation, the thematic patterns provided preliminary insights into system usability, engagement barriers, and implementation considerations in home hospice care.

Results

Interfaces of the Hospice@Home App

The Hospice@Home mobile app allowed patients to record daily information including pain intensity (both routine and post-PRN), bowel movements, target symptoms, and medication intake times. The app also provided a view of vital sign trends collected via the Galaxy Watch6, a chat function for asynchronous communication with providers, and an emergency button to request immediate assistance (Figure 3A-F). The patient-entered data were transmitted in real time to the provider's system to support continuous monitoring.

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Figure 3. Patient-facing mobile app interface and smart medication box. (A) Main screen. (B) Symptom report. (C) Bristol constipation scale. (D) Pain score at the time of taking pro re nata (PRN) medication. (E) History of vital signs. (F) Chat with provider. (G) Front view of the smart medication box. (H) Inside of the smart medication box.

Integrated via Wi-Fi, the SMB supported scheduled and PRN medication adherence through a drawer-type radio frequency identification (RFID)–tagged system. Voice and light alerts reminded patients of scheduled doses, while RFID tagging verified actual medication removal—unlike conventional devices that only detect box opening. For PRN analgesics, tagging

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prompted the app to request a predose pain rating and later sent a reminder for postdose reassessment. Real-time intake data were automatically transmitted to the mobile app, provider interface, and server. The SMB accommodated over 7 days of medications, including oral drugs, opioid patches, and PRNs, and was designed with LED indicators and voice guidance tailored to older adult users (Figure 3G,H).

The provider-facing web interface received real-time data from patients, including symptoms, biosignal signals, and medication records. Providers could review trends and set personalized threshold–based alerts to facilitate timely interventions. This interface enabled the care team to assess medication adherence—particularly for PRN usage—and evaluate pain control through linked pre- and postdose data. Customizable alerts and a patient-specific dashboard allowed rapid clinical decision-making in home-based palliative care (Figure 4).

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Figure 4. Web and mobile app interfaces for providers. (A) Main dashboard in the desktop view. (B) Main dashboard on the smartphone. (C) Pain history screen on the smartphone. (D) Medication history screen on the smartphone.

Although not directly used for clinical care, the administrative interface supported system management functions, such as account creation, patient registration, and alert configuration. It also enabled access management for providers and remote troubleshooting for system components (eg, connectivity, syncing errors). The admin panel served as the backbone for operational coordination and data integration across devices and users.

User Demographics

Of the 7 patient-caregiver dyads, 5 successfully utilized the Hospice@Home system for 3 weeks. The patients ranged in age from 53 to 93 years (mean age 73.4, SD 15.7) and included two women and three men. Four had a high school and below education, and 1 held a college degree. All patients were married and living with their spouses, except 1 who was widowed. All patients had terminal cancer, with illness durations from 4

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months to 8 years; however, all had received hospice care for less than 2 weeks at the time of enrollment. Three patients had 1 or more comorbidities, including hypertension (n=3), diabetes (n=1), benign prostatic hypertrophy (n=1), and chronic obstructive pulmonary disease (n=1). Prevalent target symptoms were pain (n=4) and loss of appetite (n=3), followed by weakness, pruritus, constipation, dizziness, urinary disorder, edema, and sleep disturbance.

Caregivers (1 sister, 4 daughters) were aged 38-63 years old (mean age 47.6, SD 9.8). Four had college degrees. The average duration of daily caregiving was 9.1 hours (range: 2.5 - 21 h). The visiting nurse was a hospice advanced practice nurse in her early 40s with over 15 years of clinical experience.

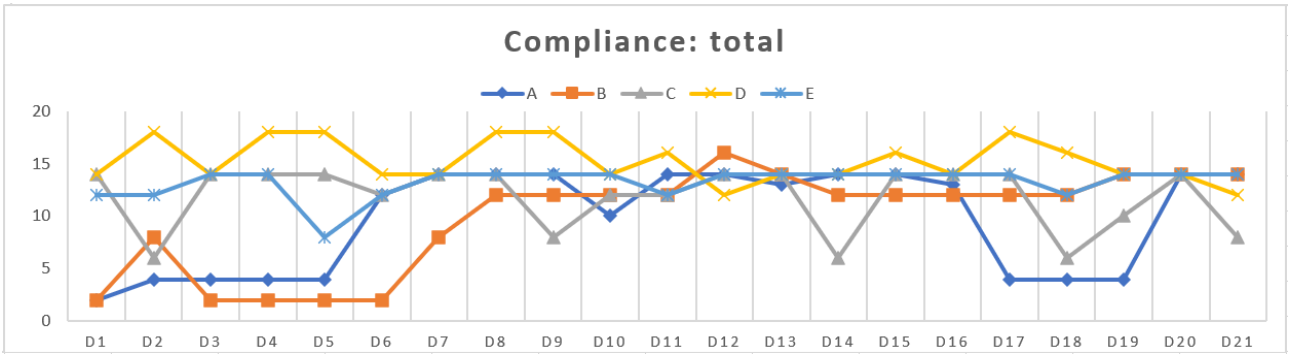
Reliability of Biosignal Measurements From the Galaxy Watch 6

The biosignal ICC values were as follows: systolic BP: ICC=0.679, 95% CI 0.103-0.782, *P*=.007; diastolic BP: ICC=0.495, 95% CI –0.812 to 1.949, *P*=.09; PR: ICC=0.985, 95% CI 0.956-0.994, *P*<.001; and O_2Sat: ICC=0.771, 95% CI 0.313-0.923, *P*=.005. Additionally, significant correlations were found across the 18 paired measurements (Pearson *r*=.921, *df*=16, *P*<.001). The minimum ICC of 0.75 is generally recommended for acceptable reliability in biosignal measurements [29]. Based on this criterion, PR and O_2Sat readings from the Galaxy Watch 6 demonstrated acceptable reliability, while BP measurements fell below the recommended threshold. Notably, in 1 case involving a patient with arrhythmia, a significant discrepancy was observed between the reference device (Omron HEM-7121J: BP: 129/50; PR: 43) and the Galaxy Watch 6 (BP: 89/54; PR: 65).

User Engagement and Compliance With the System

User compliance varied by participants' familiarity with the technology and their health status, without a consistent pattern across users (Figure 5). Daily compliance scores were calculated based on 4 monitoring categories—vital sign measurements, symptom reporting, PRN pain score reporting, and scheduled medication adherence—using a predefined scoring system, with a possible range of 0-18 points per day. In this study, observed daily scores ranged from 2 to 18 across participants.

Figure 5. Patient compliance with the Hospice@Home system.



Participant A initially showed low compliance with vital sign monitoring due to a poorly fitting Galaxy Watch 6 sensor strap. Replacing it with a metal strap improved sensor contact and biosignal data collection. However, during days 17 - 19, overall compliance, including vital sign measurements, symptom reporting, PRN medication logging, and scheduled medication adherence, temporarily declined due to an emergency room visit in response to worsening symptoms. Compliance levels recovered after this period. Participant B was unable to record biosignal data in the early phase of testing due to delirium and unstable vital signs. Following clinical stabilization, the participant achieved consistent and stable data entry across all monitoring categories, including vital signs, symptom reports, PRN medication use, and scheduled medication. Participant C maintained generally high engagement, with occasional lapses in scheduled medication adherence and vital sign reporting, particularly on days 9 and 19. Despite these fluctuations, this participant sustained near-daily use of core functions throughout the testing period. Participant E, the oldest participant, demonstrated stable and consistent compliance in all 4 areas throughout the testing period. Her daughter assisted with monitoring and reporting, contributing to steady performance in vital sign measurements, daily symptom logging, PRN medication, and scheduled medication intake.

User Experience and Satisfaction

Overall satisfaction scores averaged 3.3 (SD 0.5) among patients and 4.0 (SD 0.7) among caregivers. Ease of use received comparable scores from patients (mean 3.3, SD 1.0) and caregivers (mean 3.2, SD 1.3). Perceived helpfulness was rated, with means of 3.5 (SD 1.0) for patients and 3.6 (SD 0.5) for caregivers. Caregivers were more likely to recommend the system (mean 3.8, SD 0.4) compared to patients (mean 3.3, SD 0.5). Communication improvement was rated at 3.3 (SD 1.0) by patients and 3.6 (SD 0.9) by caregivers.

Qualitative data revealed both positive experiences and areas requiring refinement across patients, caregivers, and health care providers. Patients generally found the system useful for structured care and symptom monitoring. Some appreciated the ability to track biosignal data through the wearable device. However, others reported difficulties in using the device consistently. For example, 1 participant stated, "I feel so fatigued that the watch feels heavy, and it's difficult to measure four times daily" (participant A). Patients also expressed a preference for direct phone calls over the in-app chat feature, suggesting that synchronous communication was more reassuring in the home hospice context.

Caregivers reported several benefits, particularly valuing the system's role in enhancing patient safety and enabling timely

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decision-making at home. For instance, 1 caregiver shared, "My father had dizziness, so I measured his oxygen saturation with the watch and discovered his oxygen level was low. I was relieved when his dizziness improved after applying oxygen immediately" (participant D's daughter). Another caregiver emphasized the system's impact on medication management. "Previously, my father would take medication whenever he felt he needed it, which worried me. I appreciated that he didn't overuse his medicine since he didn't access the doses stored in the medicine box" (participant E's daughter). Nonetheless, some caregivers encountered challenges, particularly in supporting patients with cognitive or behavioral issues. One caregiver noted, "My mother has trouble sleeping and experiences delirium, so she doesn't cooperate and keeps moving, which prevents the watch from taking measurements" (participant B's daughter). Like patients, caregivers also favored phone calls over the system's chat function, highlighting the need to improve communication features.

Health care providers, 1 physician and 2 home hospice nurses, highlighted the system's clinical value. They noted that receiving objective information on patients' conditions prior to visits facilitated more efficient care planning. The ability to monitor real-time medication adherence was also viewed as a major advantage. However, providers expressed concerns about the system's lack of integration with the hospital's electronic medical record (EMR) system. As a result, nurses were required to manually reenter patient data into the system during registration, leading to increased administrative burden.

Discussion

Principal Results

The adoption of DH technologies in HPC has steadily increased, enhancing information sharing, communication, and caregiver education [30]. This study developed Hospice@Home, an integrated system that combines patient monitoring, symptom and medication management, and prompt clinical response. By providing real-time data, the system supports clinical decision-making, improves communication, and complements face-to-face visits rather than replace them.

Although digital interventions can improve care coordination, they often impose a substantial data-entry burden on users, particularly those with advanced illness or limited digital literacy [31]. Hospice@Home sought to mitigate this barrier through individualized symptom targeting and automated medication tracking using an SMB. This design likely reduced redundant data entry and simplified routine use, which may explain the relatively high compliance observed among participating dyads. However, some patients still experienced data entry fatigue or cognitive difficulty in interacting with the wearable device, highlighting the continuing challenge of balancing data accuracy with usability in this population. While many mobile cancer-symptom management apps rely on fixed sets of standardized symptom items [32], Hospice@Home incorporated user-selected symptoms and PRN opioid monitoring, allowing more tailored and clinically meaningful data capture. This individualized approach enabled providers to assess medication efficacy in real time and to adjust care plans promptly. Nonetheless, personalization may also complicate data comparability across patients, which should be addressed in future system iterations and larger-scale validation studies.

Participants in the pilot study varied in age, health condition, and technological familiarity, which influenced their patterns of system use. Some initially expressed reluctance to engage with unfamiliar devices or reported fears of making errors. Nevertheless, the touch-based interface was generally perceived as intuitive and easy to learn, even among older adults. Notably, the oldest participant, who received assistance from her daughter, demonstrated consistently high compliance across all system features. This underscores the pivotal role of family caregivers in the adoption and sustained use of DH technologies—particularly for patients with terminal illnesses with significantly reduced functional capacity. For patients to remain at home until the end of life, technological solutions must be designed to alleviate, rather than add to, caregiver burden [33]. For home-based hospice care to remain sustainable, systems such as Hospice@Home must evolve toward greater automation, simplified feedback loops, and integration with existing care routines. The observed variation in user engagement highlights the need for adaptive designs that account for differences in digital literacy, functional status, and the level of caregiver involvement.

Wearable devices provide valuable objective data to complement subjective symptom reporting [34]. In this study, the Galaxy Watch 6 showed high ICCs for PR and O_2 Sat, indicating acceptable reliability for physiological monitoring in home hospice care. However, blood pressure readings demonstrated lower reliability, falling below commonly applied thresholds for acceptable agreement. This was especially evident in a participant with arrhythmia, where discrepancies between wearable and manual measurements were substantial. Such inaccuracy may undermine clinical decision-making and pose safety risks if treatment adjustments rely on erroneous data, reflecting the variable measurement accuracy often reported for consumer-grade wearables in complex clinical conditions [35]. These findings suggest that wearable-derived blood pressure values should be interpreted cautiously in patients with terminal illnesses. Robust validation using diagnostic performance metrics—such as sensitivity, specificity, and predictive accuracy—will therefore be essential before clinical adoption. Although accuracy studies on wearable devices are accumulating, most have been conducted in healthy or mildly ill populations [34,35]. Empirical data remain limited for patients experiencing extreme physiological fluctuations, such as those in terminal illness, where unstable hemodynamics may further compromise measurement accuracy. In addition, although sleep duration was monitored using the Galaxy Watch 6, recorded sleep time often overestimated actual sleep reported by patients. This likely reflects the tendency of patients with terminal illnesses to spend extended periods lying down without truly sleeping. Frequent device removal during the night, especially among patients with advanced illness and reduced stamina, further limited continuous use, underscoring the need to adapt wearable technologies to the physical realities of terminal illness rather than assuming uninterrupted adherence. Such challenges, combined with the profound impact of sleep

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disturbance on quality of life in patients with terminal illnesses, highlight the need for alternative strategies to improve the accuracy of sleep monitoring.

User compliance varied depending on participants' health status, comfort with technology, and the presence of caregiver support. Daily compliance scores across the 4 monitoring domains—vital signs, symptom reporting, PRN pain reporting, and scheduled medication adherence—ranged from 2 to 18 points (maximum possible: 18). Participants who appeared more comfortable using the technology or had consistent caregiver assistance tended to show more stable engagement, while temporary declines in compliance were observed during periods of clinical deterioration or device-related discomfort. Although the small sample size limits generalizability, these observations may be considered in relation to the technology acceptance model, which proposes that perceived ease of use and perceived usefulness influence an individual's intention to adopt technology [36]. In particular, functional decline, older age, and limited technology literacy often necessitated caregiver mediation, suggesting that adoption in HPC settings is influenced not only by individual factors but also by relational and contextual variables. The variation in user engagement and feedback further highlights the importance of social support and user confidence in the successful adoption of DH systems in HPC settings. In this study, most data entry was performed by caregivers rather than patients, reflecting both the advanced illness of participants and the practical challenges of sustained self-reporting. This reliance underscores how caregiver involvement mitigates patient burden but may also introduce risks of data entry fatigue and intrusiveness, which should be considered in future system design.

Participants appreciated the system's ability to consolidate symptom tracking, medication adherence, and vital sign data in a single interface. This integrated design may reduce cognitive burden and improve perceived control, both of which are critical for patients experiencing high symptom burden and uncertainty. The RFID tagging system allows patients and caregivers to directly report medication administration, ensuring accurate medication records. However, attaching an RFID tag after each dose, especially during nighttime medication, was perceived as inconvenient. To address this issue, an alternative solution could involve automatically transmitting medication information when the medication is dispensed from the SMB without RFID tagging. However, this approach may not always accurately reflect actual medication intake, as discrepancies could arise between dispensed and consumed medication. For example, medication could be dispensed from the SMB without the patient actually taking it, leading to inaccurate records. Therefore, this study prioritized the RFID tagging method to ensure medication record accuracy. This calls for future development of solutions that can achieve both accurate medication tracking and greater ease of use by integrating direct device to app data transfer. Additionally, the drawer-type SMB addressed issues related to limited hand strength, making it more accessible for patients with advanced illness and was preferred by patients with terminal illnesses and their families.

Although the app included an in-app chat feature, both patients and caregivers preferred phone calls, suggesting a mismatch between system design and users' interpersonal expectations. While remote monitoring technologies have proven effective in chronic disease management, concerns remain about reducing interpersonal contact and increasing patient responsibility [37]. In the hospice context, the preference for phone calls likely reflects not only the need for real-time communication and timely clinical response but also the desire for human reassurance and emotional connection. For patients nearing the end of life, a compassionate and responsive human presence often provides greater comfort than remote monitoring data alone. This finding aligns with previous research indicating that after-hours telephone contact in hospice care primarily serves to provide reassurance in response to patients' and caregivers' anxiety and uncertainty [38]. To better reflect user preferences, communication features should be redesigned to facilitate more face-to-face-like interactions. Beyond improving communication, the successful implementation of DH technologies requires addressing broader systemic barriers, particularly those related to integration with existing health care infrastructure and minimizing disruption to clinical workflows [39]. This tension between automation and relational care highlights a key challenge in palliative care: maintaining interpersonal relationships while leveraging digital tools. Future system design and health care policy should encourage hybrid care models that combine automated monitoring with meaningful, human-centered interactions.

At the system level, clinician feedback identified the lack of integration with the hospital EMR system as a significant barrier to efficient workflow. The Hospice@Home system required manual re-entry of patient data into the EMR, resulting in duplicated tasks and increased administrative burden. While this was manageable during small-scale pilots, this could pose substantial challenges for routine clinical practice. Ensuring interoperability between home-based digital systems and institutional EMRs remains a global challenge due to stringent privacy regulations, firewalled hospital networks, and heterogeneous data standards [40]. Future development should therefore focus on establishing secure data exchange frameworks and standardized interoperability protocols that enable real-time integration while maintaining robust data protection and cybersecurity compliance. Integration with EMR systems will be essential to improve workflow efficiency, provide real-time access to monitoring data, and ensure continuity of care across home, emergency, and inpatient settings. To ensure smooth adoption, system development should involve clinicians and IT staff in codesign and proceed through stepwise pilot testing. For long-term success, system architectures must be designed with compatibility and interoperability in mind.

Recommendations for Future Research

Improvements should focus on simplifying the medication recording process by replacing RFID tagging with a more user-friendly method integrated into the dispenser. Enhancing the reliability of vital sign monitoring, especially for patients with arrhythmia, hypotension, or poor peripheral circulation, is essential for safe and informed clinical decision-making. Increasing accessibility by making the mobile app easier to download and use can further boost engagement. Future system

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development should also include EMR integration to support scalability and routine clinical use.

Limitations

This pilot study has several limitations. The small sample size, 5 patient-caregiver dyads, limits generalizability. Recruitment was difficult due to the frailty and fluctuating symptoms of home hospice patients. Moreover, the small number of screened dyads and reasons for nonparticipation may reflect potential selection bias, further limiting generalizability. The study was conducted in a single geographic and cultural context (South Korea), which may affect its applicability to more diverse populations or health care settings. System development relied on input from an SME team that consisted only of health care providers, without the inclusion of psychosocial team members, which may limit the breadth of perspectives incorporated. Usability was also assessed using a simplified, nonvalidated questionnaire developed for this pilot study. This approach facilitated feasibility in a vulnerable population but limits comparability with studies using standardized tools. While provider perspectives were incorporated during the system development phase through the SME team, the usability evaluation in this pilot study focused only on patients and caregivers and did not formally assess provider usability, which may limit the comprehensiveness of usability findings. In addition, the absence of validated outcome measures, including standardized usability scales and clinical endpoints, further restricts the interpretability and generalizability of the findings. Clinical outcomes such as long-term symptom control and caregiver burden were not assessed. Moreover, potential biases, such as volunteer bias, social desirability in satisfaction ratings, and short-term Hawthorne effects, may have influenced the findings. Finally, the system was not integrated with hospital EMRs, requiring the manual re-entry of patient information and increasing the administrative burden, which may have affected user satisfaction.

Conclusions

This pilot study explored the feasibility and usability of Hospice@Home, a DH system designed to support HPC in South Korea. The system integrated wearable biosignal monitoring, PRN medication management through an SMB, and electronic symptom reporting to enhance communication and HPC coordination. Preliminary findings indicate that the system appeared to be usable and acceptable within a small sample of patients with terminal illnesses and caregivers, but these results should be interpreted cautiously given the homogeneous cohort, the very limited sample size, and the use of nonvalidated usability measures. The short duration of the testing also precludes any definitive conclusions about clinical effectiveness. These findings, therefore, emphasize the preliminary potential of the system. Future research should involve larger and more diverse samples, validated outcome measures, and longer follow-up periods to evaluate the system's clinical impact, patient outcomes, and sustained engagement over time. Based on the key barriers identified in this pilot, immediate priorities for further development include streamlining data entry workflows, improving biosignal accuracy (particularly for blood pressure), and achieving EMR integration to reduce administrative burden and ensure continuity of care.

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Authors' Contributions

SHK contributed to the conceptualization, funding acquisition, methodology, project administration, and drafting and revising of the manuscript. MAL contributed to the project validation and critically reviewed and edited the manuscript. YJK was responsible for formal analysis, investigation, methodology, and visualization. SHP contributed to investigation, software development, and visualization. MJL was involved in the investigation. YH contributed to software development. ASK was involved in resources and supervision. All authors have read and approved the final version of the manuscript for publication.

Conflicts of Interest

None declared.

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Abbreviations

AHEAD: Approach to Human-centered, Evidence-driven Adaptive Design
BP: blood pressure
DH: digital health
EMR: electronic medical record
HPC: home-based palliative care
ICC: intraclass correlation coefficient
O_2Sat: oxygen saturation
PCU: palliative care unit
PR: pulse rate
PRN: pro re nata
RFID: radio frequency identification
SMB: smart medication box
SME: subject matter expert

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Adaptive Feeding Robot With Multisensor Feedback and Predictive Control Using Autoregressive Integrated Moving Average–Feed-Forward Neural Network: Simulation Study

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Abstract

Background: Eating is a primary daily activity crucial for maintaining independence and quality of life. Individuals with neuromuscular impairments often struggle with eating due to limitations in current assistive devices, which are predominantly passive and lack adaptive capabilities.

Objective: This study aims to introduce an adaptive feeding robot that integrates time series decomposition, autoregressive integrated moving average (ARIMA), and feed-forward neural networks (FFNN). The goal is to enhance feeding precision, efficiency, and personalization, thereby promoting autonomy for individuals with motor impairments.

Methods: The proposed feeding robot combines information from sensors and actuators to collect real-time data, that is, facial landmarks, mouth status (open or closed), fork-to-mouth and plate distances, as well as the force and angle required for food handling based on the food type. ARIMA and FFNN algorithms analyze data to predict user behavior and adjust feeding actions dynamically. A strain gauge sensor ensures precise force regulation, an ultrasonic sensor optimizes positioning, and facial recognition algorithms verify safety by monitoring mouth conditions and plate contents.

Results: The combined ARIMA+FFNN model achieved a mean squared error (MSE) of 0.008 and an R^2 of 94%, significantly outperforming the standalone ARIMA (MSE=0.015; R^2=85%) and FFNN (MSE=0.012; R^2=88%). Feeding success rate improved from 75% to 90% over 150 iterations (P<.001), and response time decreased by 28% (from 3.6 s to 2.2 s). ANOVA revealed significant differences in success rates across scenarios ($F_{3,146}$=12.34; P= .002), with scenario 1 outperforming scenario 3 (P=.030) and scenario 4 (P=.010). Object detection showed high accuracy (face detection precision=97%, recall=96%, 95% CI 94%-99%). Force application matched expected ranges with minimal deviation (24 [1] N for apples; 7 [0.5] N for strawberries).

Conclusions: Combining predictive algorithms and adaptive learning mechanisms enables the feeding robot to demonstrate substantial improvements in precision, responsiveness, and personalization. These advancements underline its potential to revolutionize assistive technology in rehabilitation, delivering safe and highly personalized feeding assistance to individuals with motor impairments, thereby enhancing their independence.

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KEYWORDS

assistive technology; ARIMA; autoregressive integrated moving average; FFNN; feed-forward neural network; feeding robotics; forecasting; motor impairment; time series analysis; personalized assistance

Introduction

Eating unaided remains impossible for millions of people with upper-limb impairments, turning every meal into a reminder of lost autonomy. Demographic change will magnify this challenge. By 2050, 1 in 6 individuals will be aged over 65 years, up from 1 in 11 in 2024 [1]. Aging correlates with disability, and about 1 billion people already live with an impairment, a figure set to rise as populations gray [2]. The result is a rapidly growing cohort that needs daily feeding assistance, further straining care networks that are already under pressure [1,3]. Assistive devices are critical, especially in low-resource settings where professional carers are limited. In the United Kingdom, for example, many adults aged over 75 years live alone and receive only brief daily visits, leading to malnutrition and declining health [4,5].

Robotic feeding assistants offer a promising solution, demonstrating consistent patience, adaptability, and precision.

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By tailoring actions to user preferences, they can provide a personalized and empowering dining experience [6,7].

Several commercial and noncommercial assistive feeding robots have already been developed to support individuals with upper limb impairments [8-11]. Examples include My Spoon (SECOM Co, Ltd) [12], SnackBot (Carnegie Mellon University Robotics Institute) [13], the Assistive Robotic Manipulator (Exact Dynamics Ltd) [14], Obi Robot (DESiN LLC) [15], iEat (Assistive Innovations) [16], and Bestic (Camanio Care AB) [17]. Table 1 outlines the key advantages, limitations, and available quantitative evidence for 7 commercial or research-based assistive feeding systems. While some platforms offer user-friendly features such as switch-based control or teach modes, most lack real-time adaptation, user-state sensing, and robust bite-delivery evaluation. The table highlights the current gaps in autonomy, sensor integration, and evidence-based validation across devices. These are predominantly passive, relying on fixed routines with limited adaptability [18]. Therefore, they struggle with delayed user responses, varied food types, and environmental challenges such as poor lighting or plate movement.

Table . Comparative analysis of existing assistive feeding robots.

Robot name and autonomy	Key advantages	Key disadvantages	Quantitative evidence
My Spoon [12]	• Offers automatic, semiautomatic, and manual modes (5-DOF[a] arm)	• Requires joystick input • Uses fixed mouth-position routines—no real-time adaptation	• None
SnackBot [13]	• Mobile platform delivers snacks in human spaces (human-robot interaction)	• Not designed for bite-by-bite feeding assistance • Lacks user-state feedback	• The platform was never evaluated for bite delivery or self-feeding
ARM[b] (iARM, Exact Dynamics; JACO arm, Kinova) [14]	• Versatile arm mounts on wheelchairs. Performs multiple ADLs[c] (eating, drinking, and manipulation)	• No autonomous feeding intelligence • Lacks specialized sensors and adaptive control	• 79% of 31 users completed all 16 movements • 93% completed a 6-task subset • Bite success not documented
Obi Robot [15]	• Lightweight, compact tabletop feeder • Simple switch interface, teach mode, 4-bowl food choice	• Must be manually taught spoon-mouth position • Cannot sense user readiness	• Speech-interface pilot (n=11) showed positive usability • No bite delivery data reported
Bestic [17]	• 4-DOF arm with rotating bowl (one-button semiautonomous control)	• Uses fixed preset motions • No real-time adjustment or user-state feedback	• Focuses on design philosophy and user perceptions.
Meal Buddy [19]	• Bowl-edge scraper removes excess food (3-DOF)	• Executes preset feeding sequences only • Lacks force and vision feedback	• Pilot (n=3 able-bodied): mouth detection accuracy of 73%, 67%, and 52%. • No bite delivery recorded
Mealtime Partner [20]	• Rotating plate and mechanical spoon lift (one-button bite delivery)	• Static delivery pattern • No sensing of user state or environment	• Historical evaluations found high abandonment • Slower than human assistance

[a]DOF: degree of freedom.

[b]ARM: Assistive Robotic Manipulator.

[c]ADL: activities of daily living.

Various researchers have aimed to improve adaptability and intelligence through sensing and control strategies. Predictive models such as hidden Markov models have been used to estimate bite timing based on social cues and food characteristics, achieving timing errors of 1.57 seconds [7]. However, these systems often operate in open-loop and cannot adjust if the user hesitates. Similarly, support vector machines and convolutional neural networks (CNNs) [21,22] have been employed to locate bites on a plate, but they also lack real-time feedback.

More advanced systems have integrated vision and control frameworks. For instance, Mashrur et al [23] used a Personal Robot 2 (PR2; Willow Garage) equipped with faster region-based CNN and red green blue–depth (RGB-D) cameras, achieving 93% precision and an 82.8% food delivery success rate. A study by Park et al [8] deployed PR2 with a GUI interface and model predictive controller, enhancing arm safety and anomaly detection, though food handling precision remained a challenge. Hybrid controllers, such as an adaptive neuro-fuzzy inference system–proportional integral derivative controller [24] and fuzzy logic-based inverse kinematics (IKs) [25], have improved control smoothness and efficiency, but they lack real-time mouth-state feedback.

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Artificial neural networks have also been applied to solve IKs [26], and low-cost platforms, such as 3D-printed arms with facial recognition [27], have broadened accessibility. However, these systems continue to rely on scripted motions. Studies conducted by Serrezuela et al [28], Mystkowski et al [29], and Gilca [30] demonstrate promise in trajectory tracking and facial landmark detection; however, sensor fusion and robustness under environmental variation remain limited. Simulation tools [31] and digital twins [32] have explored virtual training and control evaluation, but fall short of real-world responsiveness. Together, these limitations highlight the need for a fully adaptive, closed-loop feeding system that anticipates user intent, verifies safe delivery, and dynamically adjusts in real-time. To meet this need, we present a novel autonomous feeding robot that integrates time-series forecasting, machine learning, and multisensor feedback to deliver personalized, safe, and efficient feeding assistance. Our system combines autoregressive integrated moving average (ARIMA) models (to capture linear trends) with a feed-forward neural network (FFNN; to learn nonlinear behaviors), enabling real-time predictions of mouth readiness. Data from vision-based mouth detection, ultrasonic distance sensing, and strain-gauge force feedback closes the loop, allowing the robot to respond to delayed reactions, variable food textures, lighting changes, and plate movement. This study advances assistive feeding robotics through five key contributions:

1. Multimodal sensing for safe, precise delivery: integrating computer vision, ultrasonic, and force sensors ensures accurate and gentle food placement.
2. Hybrid predictive control: fusing ARIMA and neural networks enables real-time prediction of user behavior.
3. Closed-loop adaptation: a unified control loop compensates for user delays and environmental variability.
4. Demonstrated performance gains: our system improved feeding success by 15% and reduced response time by 28% over baseline models.
5. Toward truly adaptive feeding: this study lays the foundation for a learning-driven platform that supports independent eating for individuals with motor impairments.

Methods

Robotic Arm Hardware and Control System

The assistive feeding robot in this study is built around a 4-degree-of-freedom open manipulator, powered by 4 XM Series servo motors. It is equipped with a Raspberry Pi Camera Module 2 for vision, an HC-SR04 ultrasonic sensor for distance measurement, and a load cell to monitor force. The HX711 amplifier reads signals from the load cell and transmits them to an Arduino Nano, which then forwards the data to a Jetson Nano microcontroller (Figure 1).

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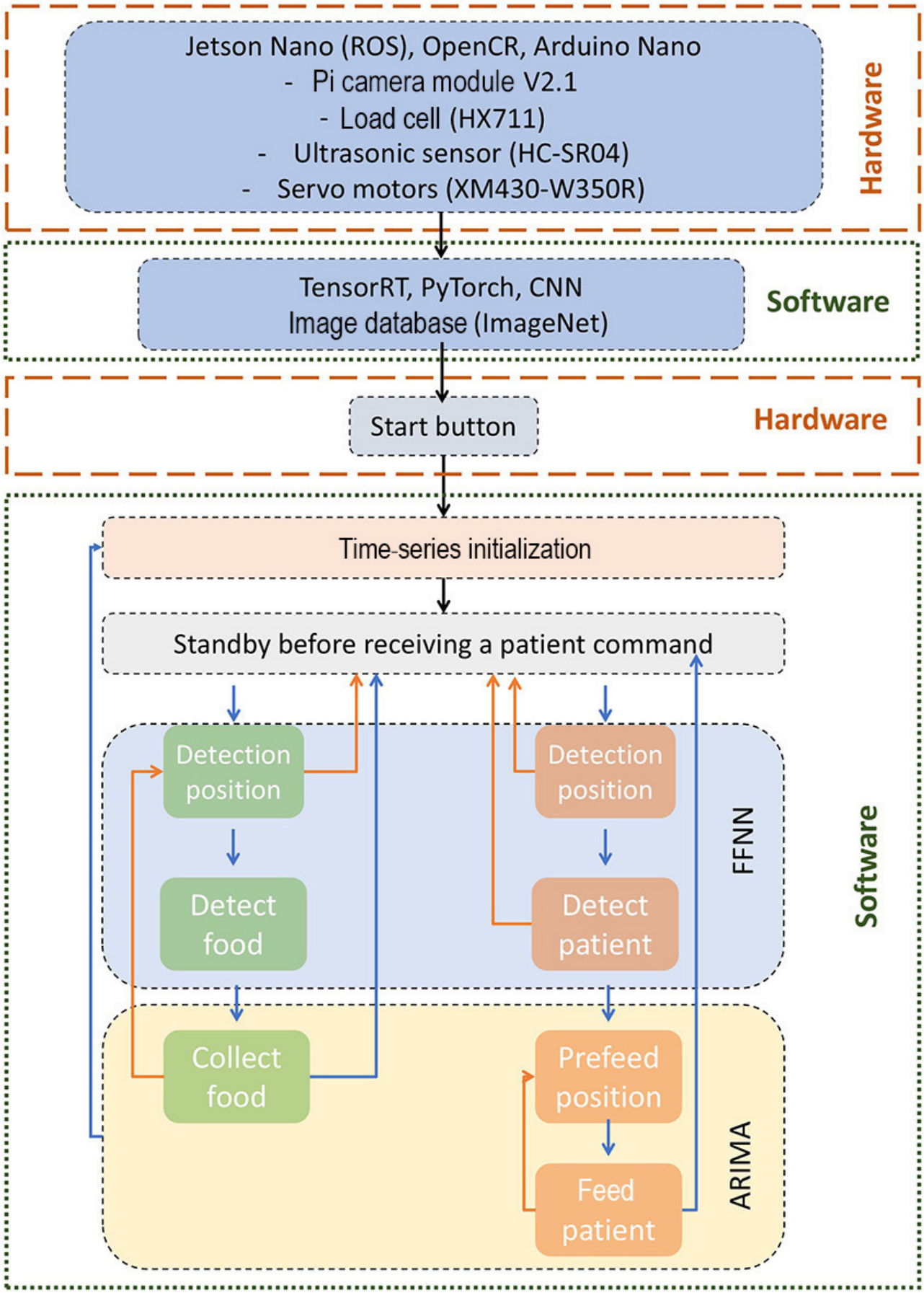
Figure 1. System architecture of the adaptive feeding robot. ARIMA: autoregressive integrated moving average; CNN: convolutional neural network; FFNN: feed-forward neural network; ROS: Robot Operating System.



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To enable efficient communication between sensors and the control logic, a lightweight WebSocket server is hosted on the Jetson Nano, a compact artificial intelligence (AI)-enabled edge computing device with a built-in GPU. The server allows continuous, 2-way data exchange between the camera, ultrasonic sensor, and load cell, and the decision-making module that directs the robotic arm. WebSockets ensure low-latency updates, allowing the system to adjust movements dynamically in response to user behavior. For simulation and real-time testing, a digital twin of the robot was developed in Unity using its networking application programming interfaces (APIs). The Jetson Nano uses the *WebSockets* library of Python (Python Software Foundation) to run the server, while Unity serves as the client via the Native WebSocket library, maintaining synchronized sensor and actuator states between the virtual and physical environments. The Jetson Nano also runs the Robot Operating System (ROS), which manages the robot's control architecture. NVIDIA TensorRT was used to accelerate the inference of neural networks, while the *PyTorch* library was used to train object detection and classification models.

Feeding Simulation Scenarios in Unity

Four scenarios are simulated in Unity to test the control algorithms for the assistive feeding robot.

Scenario 1: Standard Operation

The robot operates under normal conditions without external disturbances or unexpected user behavior to measure the success rate of food delivery, timing, and force accuracy. The parameters are (1) feeder distance to plate and the mouth (approximately 10 cm; near), (2) distance to mouth (medium), (3) lighting (standard indoor lighting), (4) user behavior (opens mouth as the feeder gets within 15 cm), and (5) environmental stability (no movement of the table or plate).

Textbox 1. Input and time-series decomposition.

Parameters

- Degree of freedom (DOF): for the robotic arm (default=4)
- $y_{t-k:t}$: past states of the robotic arm in time window t−k to t
- $strain_{t-k:t}$: strain gauge data for the same time window
- $sonar_{t-k:t}$: sonar sensor data for the same time window
- $camera_{t-k:t}$: camera data (.eg, user mouth open or closed)
- u_t: optional user input or manual adjustments

Step 1: initialization

- Set the DOFs for the robotic arm (DOF=4).
- Initialize the feed-forward neural network model with multiple layers to extract temporal features.
- Define static parameters (such as arm configuration or user preferences)

Step 2: input

- Collect past states of the arm: $y_{t-k:t} = \{y_{t-k}, \ldots, y_t\}$
- Collect strain gauge data: $strain_{t-k:t}$
- Collect sonar data: $sonar_{t-k:t}$
- Collect camera data: $camera_{t-k:t}$
- (Optional) receive user input u_t for manual adjustments or feedback

Step 3: time-series decomposition

- Decompose past arm states, strain gauge, and sonar data into trend, seasonality, and residuals: trend, seasonality, residual = decompose($y_{t-k:t}$,$strain_{t-k:t}$, $sonar_{t-k:t}$)

Step 4: autoregressive integrated moving average (ARIMA) model

- Fit an ARIMA model to the residuals of the decomposed data: ARIMA_model ← ARIMA(Residual)
- Use the ARIMA model to predict the next state for the residual component

Scenario 2: Delayed User Response

The user delays opening their mouth after the robot delivers the food, testing the system's ability to adapt to user behavior. The parameters are (1) distance to plate (near), (2) distance to mouth (near), (3) lighting (standard indoor lighting), (4) user behavior (opens mouth, approximately 1-2 s late), and (5) environmental stability (no movement of the table or plate).

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Scenario 3: Low-Light Conditions

The system operates in low-light conditions, testing the robustness of the object detection algorithm. Assess object detection accuracy, success rate, and timing under reduced visibility. The parameters are (1) distance to plate (medium), (2) distance to mouth (medium), (3) lighting (dim indoor lighting; approximately 50 lux), (4) user behavior (opens mouth as expected), and environmental stability (no movement of the table or plate).

Scenario 4: Dynamic Environment

The table or plate moves slightly during the robot's operation, simulating a dynamic environment, and testing the system's ability to adapt to real-time changes in plate position using the sensor's feedback and ensure successful food delivery. The parameters are (1) distance to plate (medium), (2) distance to mouth (far), (3) lighting (standard indoor lighting), (4) user behavior (opens mouth as expected), and (5) environmental stability (plate shifts, 2-3 cm randomly)

Object Detection and Classification

The robot's vision system relies on state-of-the-art object detection techniques, leveraging large datasets and advanced frameworks. ImageNet, a large-scale image database organized according to the WordNet hierarchy, was used for visual object recognition. The system is trained to detect key objects, such as tables, plates, faces, mouths, and various fruit types (including apples and strawberries). The ImageNet Large Scale Visual Recognition Challenge (ILSVRC) dataset was combined with CNNs for further training.

Since existing datasets were not sufficient for the purpose (specific tasks), transfer learning was applied. A pretrained model was fine-tuned using a custom dataset manually labeled by the research team. The custom dataset was trained on the Jetson Nano, with models preloaded with 1500 objects automatically downloaded during the build process. The system compares real-time captured images with a prebuilt database of reference images, taken under diverse lighting conditions and orientations. This ensures robust and accurate detection of objects and states, even in dynamic environments.

Predictive Modeling Using ARIMA and FFNN

Data from sensors generates time-series interactions, serving as inputs for ARIMA (autoregressive integrated moving average) and FFNN predictions. These predictions guide the robotic arm in achieving precise movements and actions. Time-series decomposition is applied to past states and sensor data to isolate trends and residuals, with the ARIMA model predicting the residual component that captures linear relationships. The FFNN extracts features from the time-series data, learning nonlinear relationships and temporal patterns.

Fusion of Time Series Decomposition With ARIMA and FFNN

To integrate ARIMA into the time-series decomposition framework, the residual component R_t was modeled with ARIMA. FFNN was used to capture nonlinear dependencies and refine predictions. The mean squared error (MSE) and R^2 metrics were calculated to evaluate the model's accuracy, yielding a combined model MSE of 0.008 and an R^2 of 94%.

We first decompose the time series into trend (T_t), seasonality (S_t), and residual (R_t), and then apply ARIMA to model the residuals. This is enhanced by introducing the FFNN to learn deeper, nonlinear relationships from the interaction data.

$$(1) Yt = Tt + St + Rt$$

where Y_t is the observed interaction data at time t (eg, feeding times and user preferences), T_t is the trend component (long-term changes in user interaction), S_t is the seasonal component (cyclical patterns in user behavior), and R_t is the residual component (remaining patterns or noise after removing trend and seasonality).

The residuals R_t are modeled using the ARIMA model:

$$(2) Rt = \phi 1Rt-1 + \phi 2Rt-2 + \cdots + \phi pRt-p + \vartheta 1\varepsilon t-1 + \vartheta 2\varepsilon t-2 + \cdots + \vartheta q\varepsilon t-q + \varepsilon t$$

where $\phi_1, \ldots, \phi_p$ are the parameters for the autoregressive part, which models the dependency of the residuals on their past values; $\theta_1, \ldots, \theta_q$ are the parameters for the moving average part, which models the dependency of the residuals on past forecast errors (shocks or noise); ε_t is the white noise (random error term at time t); p is the order of the autoregressive part; q is the order of the moving average part; and d is the degree of differencing to make the series stationary (integrated part of ARIMA).

The residuals R_t can also be processed using an FFNN to further refine the predictions by capturing non-linear and complex patterns:

$$(3) RtFFNN = FFNN(Rt-1, Rt-2, \ldots, Rt-k)$$

where FFNN($R_{t-1}, \ldots, R_{t-k}$) represents the application of the FFNN model on the sequence of past residuals, R_{t-k} to R_{t-1} for feature extraction and nonlinear modeling, R^{FFNN} is the refined residual prediction after applying the FFNN model, and k is the size of the window of past residuals used as input to the FFNN.

The final combined model is as follows:

$$(4) Yt = Tt + St + (\phi 1Rt-1 + \cdots + \phi pRt-p) + (\vartheta 1\varepsilon t-1 + \cdots + \vartheta q\varepsilon t-q + \varepsilon t) + RtFFNN$$

In this framework, the ARIMA model captures the remaining structure in the residuals R_t after removing trend and seasonality, and the FFNN further refines this by learning nonlinear dependencies.

Adaptive Learning and Performance Optimization

Simulation Setup and Evaluation Procedure

Unity simulations were executed over 150 iterations to assess the system's learning curve. At each iteration, the robot's internal model is updated based on the newly generated data. Approximately 1000 feeding simulations were conducted in Unity's game engine to fine-tune these movements. The Unity environment allowed precise control over variables, enabling reproducible testing of different scenarios. MSE and R^2 statistical metrics were computed to evaluate model

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performance. ANOVA was used to compare success rates and timing accuracy across scenarios.

Fuzzy Logic System

A fuzzy logic system was integrated to control the feeder fork's actions based on the distance (ultrasonic data), fruit type (camera), force (load cell), and angle (stepper motor). The following rules are: (1) rule 1: if the distance to the plate is near and the distance to the mouth is medium or far, then apply normal stabbing force based on the fruit type; (2) rule 2: if the distance to the plate is medium and the distance to the mouth is near, then reduce the force to avoid overshooting; and (3) rule 3: if the distance to the plate is far, then do not proceed with the stabbing action (safety rule). If the fruit type is apple and the distance to the plate is near, then high force (20 - 30*N*) is applied with a steep angle (approximately 60°) for better penetration. If the fruit type is strawberry and the distance to the plate is near, then a low force (5 - 10*N*) with a shallow angle (approximately 45°) is needed to prevent damage.

A fuzzy logic system regulated the force and angle adjustments based on food type and distance. First, if the distance to the plate is near, the distance to the mouth is medium or far, and the fruit type is apple, then high force (20 - 30*N*) is applied with a steep angle (60°). Second, if the distance to the plate is near, the distance to the mouth is near, and the fruit type is strawberry, then a low force (5 - 10*N*) is applied with a shallow angle (45°).

The operational block diagram of the feeding robot is shown in Figure 1. It illustrates the integration between the hardware components (represented by orange dashed boxes) and the software modules (represented by green dashed boxes). The top hardware block includes the Jetson Nano, OpenCR, and Arduino Nano, interfaced with the Pi Camera Module V2.1, HX711 load cell, HC-SR04 ultrasonic sensor, and XM430-W350R servo motors. These components collect real-time sensory data to inform feeding decisions. The software stack comprises TensorRT, *PyTorch*, and a CNN trained on ImageNet, which supports object detection and feature extraction. The control loop is triggered via a hardware start button, followed by time-series initialization and standby mode. Two predictive models, FFNN and ARIMA, work in tandem to drive the feeding logic. The FFNN handles real-time object and face detection tasks (left: food pipeline; right: user monitoring), while ARIMA governs motion planning for food collection and patient feeding. This closed-loop architecture allows the robot to adapt to user behavior dynamically, based on synchronized input from all sensory sources.

The robot operates in 2 primary sequences: scooping and forking, represented by the green blocks, and feeding, represented by the orange-colored blocks. Sequence planning is illustrated using blue arrows for "valid detection" and orange-colored arrows for "error detection" at each step in the process. The block diagram also highlights the implementation of the FFNN in the detection steps and the ARIMA model in the positioning steps. The robotic arm is equipped with joint encoders and a force sensor to generate torque commands that achieve the desired end-effector positions and orientations. Figure 2 illustrates the hardware setup and schematic architecture of the feeding robot, along with its dimensions. Figure 2A is the top view of the robotics arm, Figure 2B is the top view and Figure 2C is the 3D image with a corner view. A control system based on IK equations to execute movements was required for forking food. It includes the detailed mechanical drawings of the robot arm's structure and joint limits. The labeled schematic highlights each degree of freedom of the arm's mechanical range and physical configuration.

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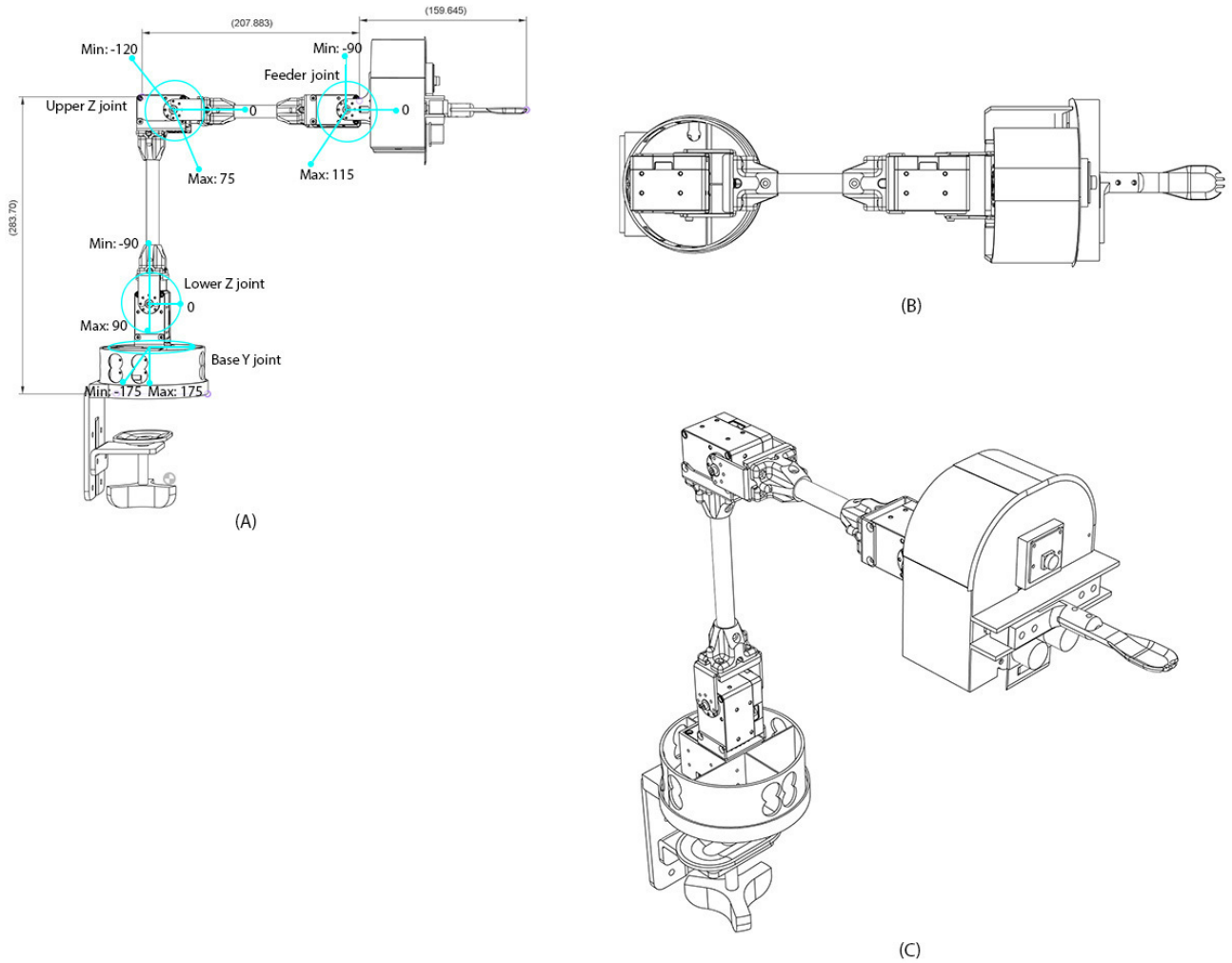
Figure 2. Design and configuration of the assistive robotic feeding arm. (A) 2D schematic of the robot arm showing joint labels, rotational limits, and key dimensions, including the base Y joint, lower and upper Z joints, and the feeder joint. (B) Top-down orthographic view of the robotic arm layout for spatial footprint analysis. (C) 3D perspective rendering of the full robotic assembly illustrating joint orientation and end-effector positioning for feeding tasks.



The controller system was implemented on the physical robot using an open-source ROS. The system's physical components were fabricated using 3D printing and computer numerical control machining. The camera provided a direct line of sight for monitoring the food on the plate and the user's mouth.

Ethical Considerations

This study was conducted in accordance with ethical guidelines and received approval from the Anglia Ruskin University Research Ethics Committee (approval: ETH2425-0342). Participant information and consent forms were obtained before their involvement in the study. This study exclusively used simulated environments and datasets. The decision to avoid live participants was made to prioritize safety and ensure reproducibility during the robot's development phase. Future work may incorporate user trials following ethical approval from the National Institute for Health and Care Research.

Results

After powering on the robot, an initialization subroutine begins, using stored positioning memory, ARIMA optimizations, and FFNN refinements. At each step during the robot's operation, sensory data were used as training data for the FFNN and ARIMA models to enhance the patient experience further. The trained neural network was then used to initialize subsequent robot startup sequences. Figure 3A shows the front view of the primary camera in Unity, and Figure 3B highlights the facial landmarks and distances between points on the face to identify whether the mouth is open or closed. Figure 3C presents 2 perspectives: one from the primary camera and the other from the feeder camera, illustrating the integration of the object detection algorithm.

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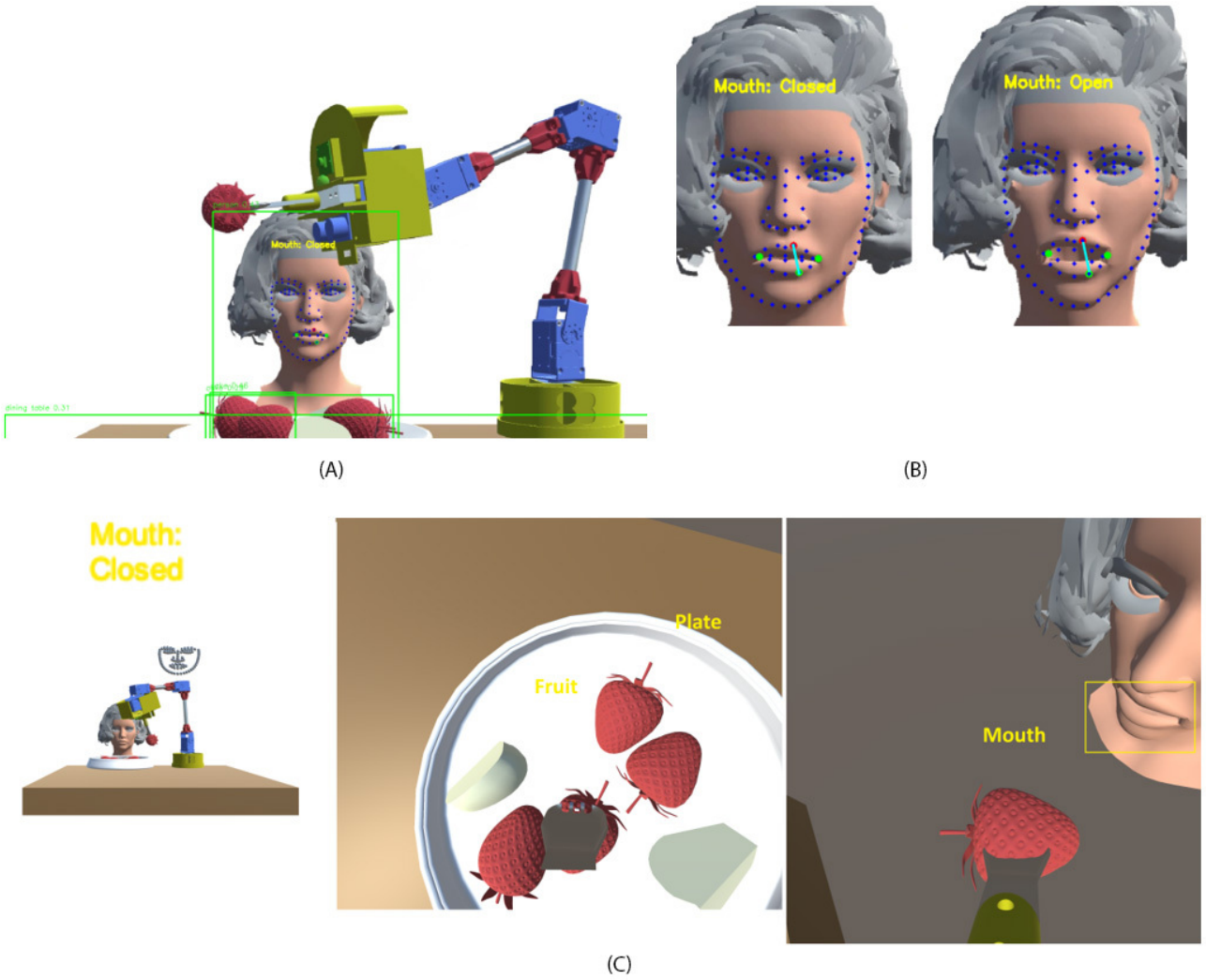
Figure 3. Simulated robotic feeding scenario in Unity. (A) The assistive robot detects the user's head, mouth, and food position in 3D space using bounding boxes and landmark features. (B) Real-time mouth state detection, achieved through facial landmarks, distinguishes between open and closed mouth states to determine feeding readiness. (C) Task environment visualization: left, a full scene of robot-user interaction showing "Mouth: Closed" status; center, top-down view of the plate with multiple food items; right, bite delivery scene with mouth proximity detection using bounding box alignment.



The combined ARIMA and FFNN models predict the next system state to optimize portion size and timing while also handling sensor-based adjustments. The strain gauge adjusts pressure for stabbing or scooping food, the sonar sensor adjusts position and timing based on user proximity, and the camera ensures the robotic arm only operates when the user's mouth is open. This real-time camera feedback enhances safety and efficiency by adjusting feeding dynamics based on sensor inputs, optimizing the overall feeding process. Recurring use of the robot by the same patient can improve response time, reduce delays in sequence execution, and smooth the robot's kinematics.

The performance of the feeding robot was evaluated across 4 simulated scenarios, with a focus on success rates, timing accuracy, and force application. The combined ARIMA and FFNN models demonstrated significant improvements in feeding accuracy and personalization. Object detection, adaptive learning, and statistical validations were conducted to illustrate system robustness.

Table 2 summarizes the robot's performance metrics. Scenario 1 achieved the highest success rate (95%) and the lowest response time (1.5 s), while scenario 4 demonstrated adaptability to dynamic environments with a success rate of 80%. ANOVA revealed significant differences in success rates across scenarios ($F_{3,146}$=12.34; P=.002), with scenario 1 (mean success rate of 95%, SD approximately 3.2%) outperforming scenario 3 (mean success rate of 85%, SD approximately 4.1%; P=.030) and scenario 4 (mean success rate of 80%, SD approximately 5.0%; P=.010).

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Table . Average performance metrics across scenarios

Metric	Scenario 1, mean (SD)	Scenario 2, mean (SD)	Scenario 3, mean (SD)	Scenario 4, mean (SD)
Success rate (%)	95 (approximately 3.2)	90 (approximately 3.8)	85 (approximately 4.1)	80 (approximately 5.0)
Timing accuracy (s)	1.5 (approximately 0.21)	2.0 (approximately 0.32)	2.5 (approximately 0.41)	2.8 (approximately 0.48)
Force application (N)	25 (2)	20 (4)	18 (4)	22 (5)

The four scenarios simulated in Unity to test the control algorithms for the assistive feeding robot are as follows:

1. Standard operation (scenario 1): the feeding robot demonstrated optimal performance, achieving the highest success rate of 95%. The average response time was 1.5 (SD 0.21) seconds, and the force applied during the feeding process was exact, remaining within 2 N of the desired value. This scenario establishes the robot's baseline capabilities under normal conditions.
2. Delayed user response (scenario 2): the robot showcased adaptability by adjusting its actions when the user delayed opening their mouth by 1 to 2 seconds. While the success rate decreased to 90% due to delayed feedback, the response time increased to 2 seconds compared to the standard operation. These results highlight the robot's ability to manage user-specific behavior variations effectively.
3. Low lighting conditions (scenario 3): the object detection system experienced a slight reduction in precision and recall under dim lighting conditions (approximately 50 lux). Consequently, the success rate dropped to 85%, and the response time increased to 2.5 seconds, reflecting the challenges posed by reduced visibility. Despite these limitations, the system maintained a reasonable level of performance, demonstrating robustness.
4. Dynamic environment (scenario 4): the robot successfully adapted to plate movements of 2 to 3 cm, showcasing its real-time recalibration capabilities. However, this scenario had the lowest success rate at 80% and the highest response time of 2.8 seconds due to increased task complexity. These results emphasize the robot's ability to handle dynamic and unpredictable conditions.

Table 3 presents the object detection metrics of the system, including precision, recall, and confidence, across key tasks. For example, the plate detection precision was 95%, while the face detection precision reached 97%. These metrics ensure accurate feeding operations, enhancing user safety and satisfaction.

Table . Object detection metrics

Object	Precision (%)	Recall (%)	Confidence (%)
Plate	95	93	90
Face	97	96	92
Open mouth	92	91	89

The combined ARIMA and FFNN model significantly outperformed standalone ARIMA and FFNN models. It achieved the lowest MSE (0.008) compared with 0.015 and 0.012, respectively, and the highest R^2 (94%), relative to 85% and 88%, respectively. These results indicate the superior capability of the hybrid model to capture user interaction dynamics.

A fuzzy logic system was used to regulate the force and angle for food forking. Inputs included plate distance (ultrasonic), fruit type (camera classification), and resistance (load cell). Rules were defined for different fruit types:

- Apple: high force (20-30 N), steep angle (approximately 60°). During operation, the system measured an average applied force of 24 N (SD 1 N) and an angle of 59° (SD 1°), aligning closely with expectations.
- Strawberry: low force (5–10 N), shallow angle (approximately 45°). The measured force was 7 N (SD 0.5 N), with an angle of 44° (SD 1°), ensuring minimal fruit damage and controlled delivery.

Force and angle adjustments were verified by comparing expected versus measured values recorded by sensors during the operation.

Figure 4 illustrates the robotic arm in a real-world setting while performing food targeting, picking, and delivery tasks. In Figure 4A-B, the apple is successfully forked and picked up, showcasing the effectiveness of the stabbing mechanism. Finally, Figure 4C shows the robotic arm delivering the food to a designated mouth position. This demonstrates the robot's operational workflow, covering critical steps of targeting, stabbing, and delivering food to a target. The experiment under scenario one yielded an average accuracy rate of 87% over 50 iterations, emphasizing the system's reliability and consistency.

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Figure 4. Operational sequence of the assistive feeding robot during a food delivery task. (A) The robotic arm localizes and targets a food item (apple slice) for acquisition. (B) The robot successfully pierces and lifts the apple slice using a fork-like end-effector. (C) The arm moves the food toward the user's mouth position, demonstrating autonomous bite delivery.

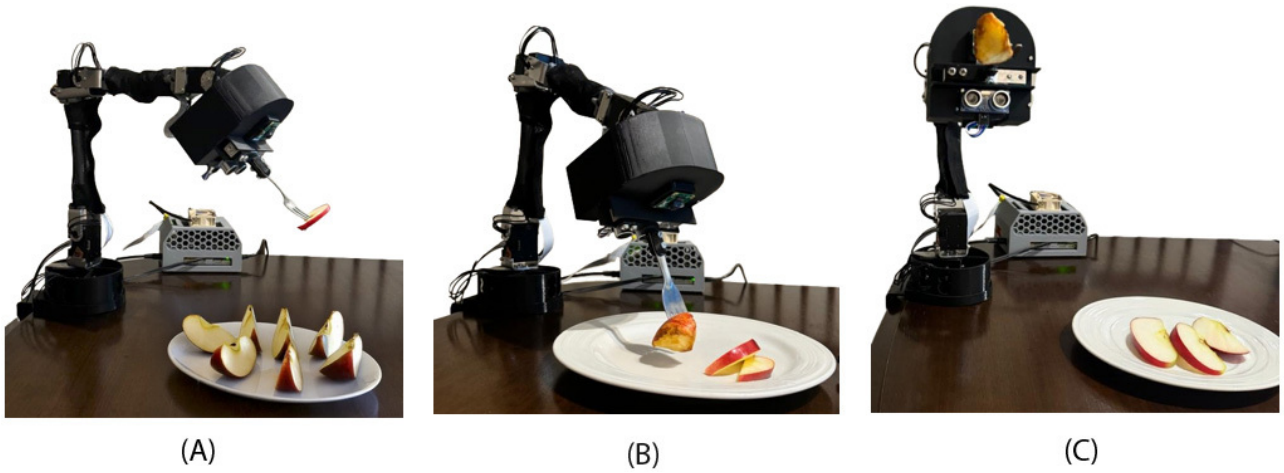
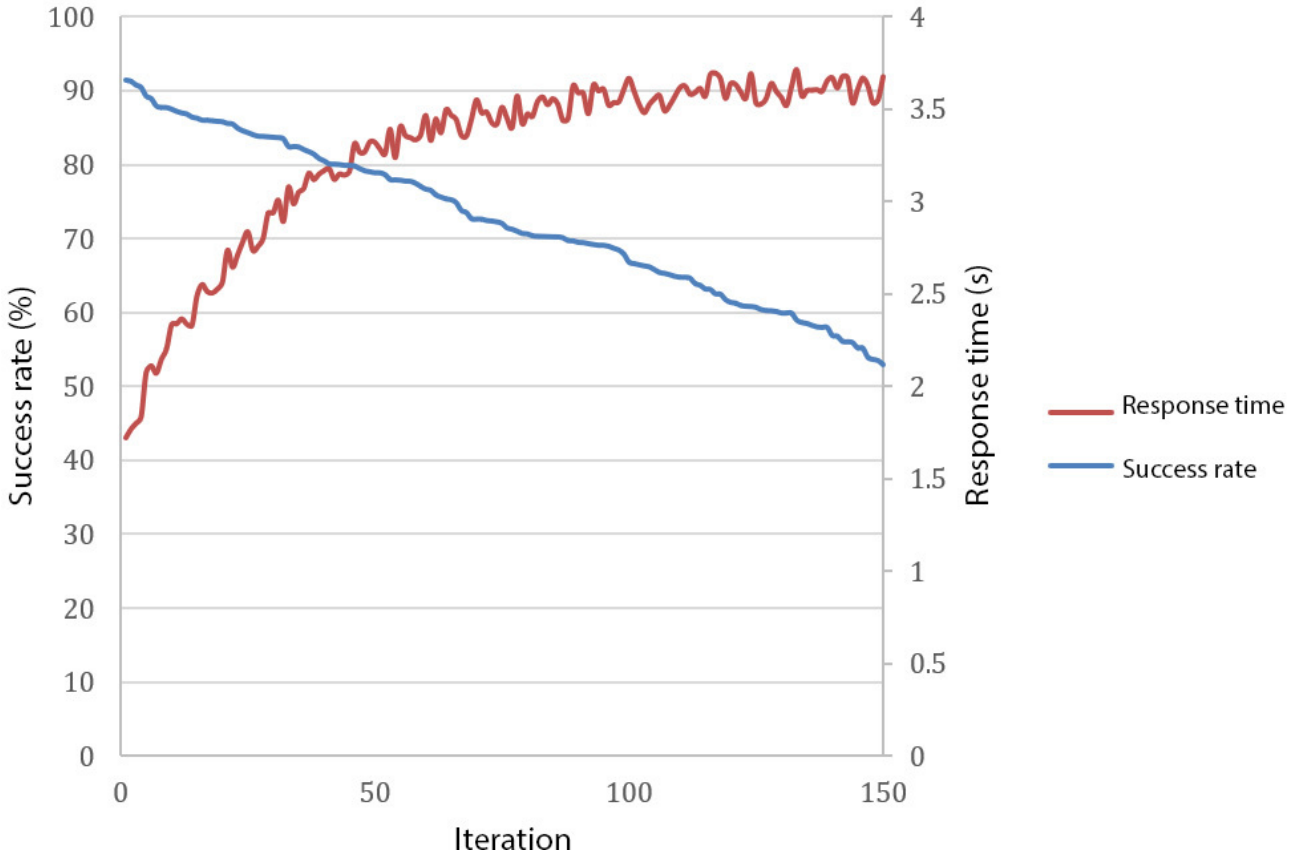


Figure 5 illustrates the iterative improvements in success rate and response time over 150 iterations in the fourth scenario of the simulated environment. Key parameters analyzed included stabbing angles, applied forces, and success rates for apples, demonstrating the robot's adaptability to varying conditions. It showed a steady improvement in success rate, starting at approximately 40% in initial iterations and stabilizing at 90% after 90 iterations. This progression underscores the effectiveness of the adaptive learning approach in optimizing performance. Figure 5 also illustrates the corresponding reduction in response time, which starts at 3.6 seconds and improves to 2.2 seconds (P<.001), highlighting enhanced efficiency.

Figure 5. Performance improvements across iterations. The red line represents the success rate over 150 iterations. The blue line represents the reduction in response time over iterations.



The kinematic response and stability of the robot have also been enhanced, as demonstrated in Figure 6. Figure 6A illustrates the angular movement of each joint during a specific motion sequence. In contrast, Figure 6 depicts the 3D spatial positioning of the actuator during the execution of the same movement set. Both graphs compare the optimized system's performance to the original untrained control system output. Notable improvements in the robot's pathfinding and control system

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output are evident in both graphs. In Figure 6A, there is an apparent reduction in the overshooting and undershooting of servo adjustments needed to achieve the desired joint angles, minimizing errors and enhancing precision. These refinements have significantly reduced the jerkiness in the robot's arm movements and diminished vibrations in the final actuator. Consequently, food delivery to the user is smoother and more controlled, which underscores the improved kinematic performance and stability of the robot.

Figure 6. (A) Joint angle trajectories during movement execution show reduced overshooting and undershooting compared to the untrained control system. (B) The actuator position is in 3D space during the same movement, with an optimized path and control system output. The red line represents the success rate over 150 iterations, while the blue line represents the reduction in response time over iterations.

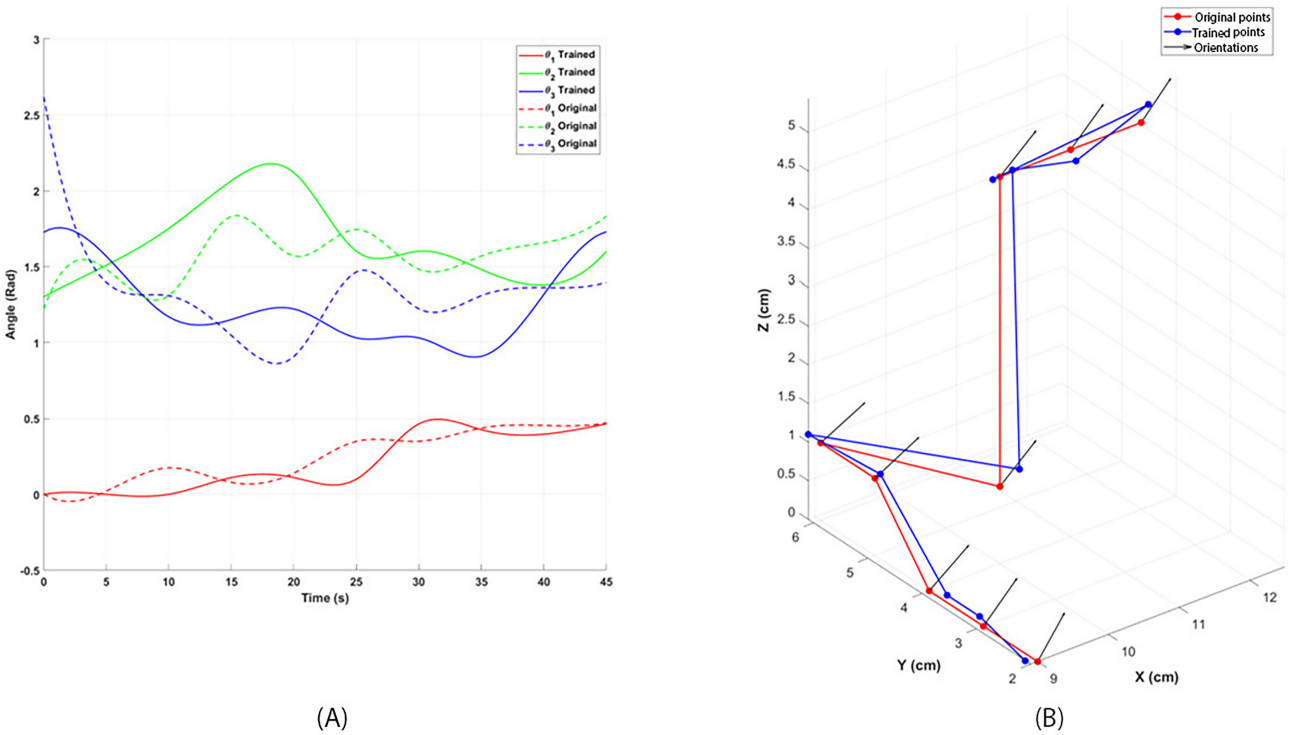

Figure 7 illustrates the facial recognition and mouth detection neural networks integrated into the robot. Using advanced image recognition techniques. Using a VGG 16 convolutional network (proposed by the Visual Geometry Group at the University of Oxford [33]), the robot detects and highlights the users' facial features. It determines if they have an open mouth or not before approaching the user. The neural network initially separates the user's face from the background and then identifies the control volume box where the user's mouth is located. Depending on the facial characteristics of a user, the neural network constantly updates the status of the user between mouth open and closed. This is a key feature of the robot that enables it to perform the feeding task reliably, providing a layer of system control within the feeding sequence. Whenever the user has a closed mouth, the feeding sequence is halted, waiting for either an override command or the mouth open status to continue the feeding sequence.

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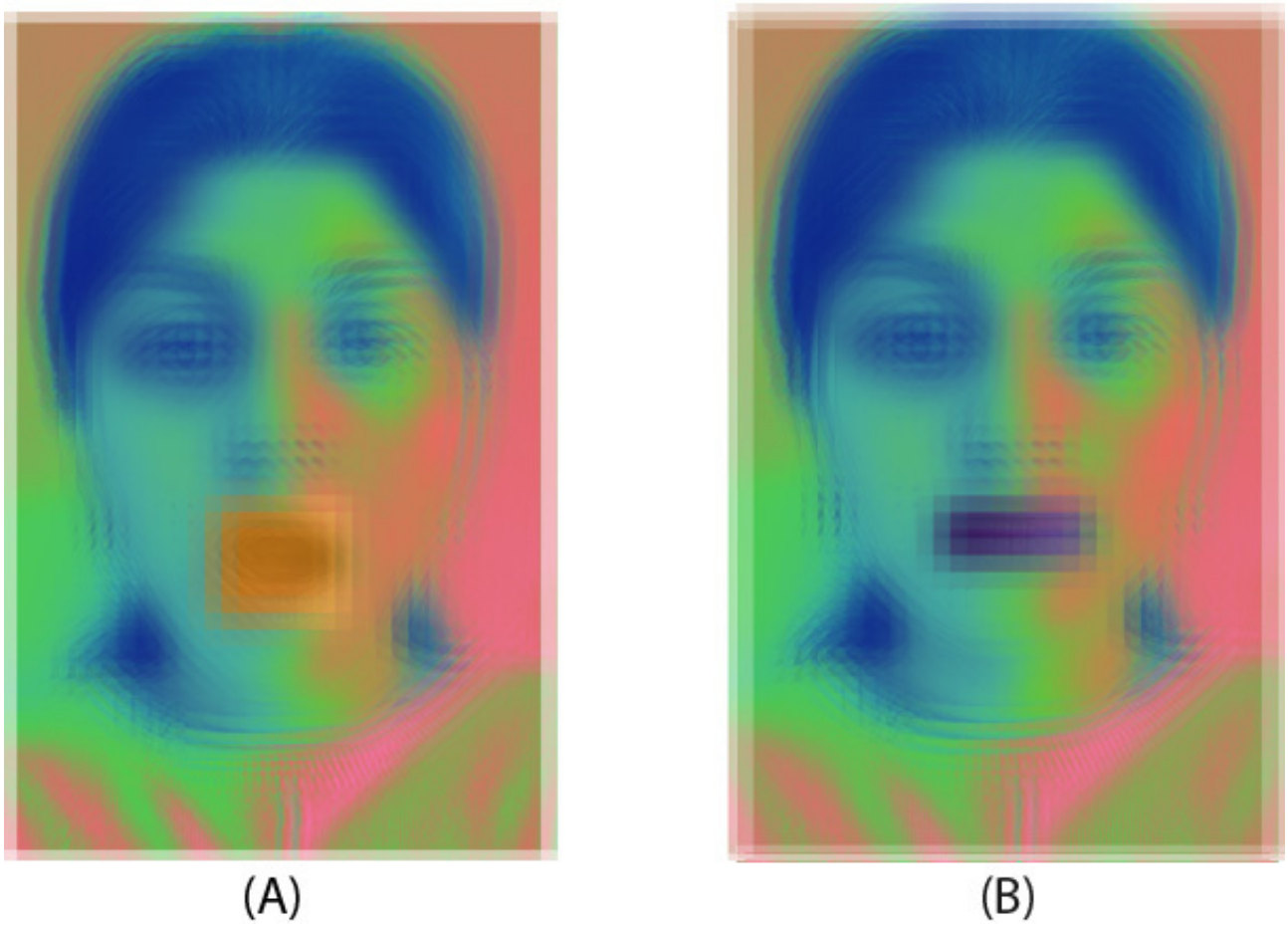
Figure 7. Mouth state detection using neural network image segmentation. (A) The system detects an open mouth using a region-of-interest (ROI) around the lips, highlighted in orange. (B) The system detects a closed mouth with a reduced feature response in the ROI, shown with a darker overlay. This classification supports the robot's decision-making process for safe and timely food delivery.



Discussion

Principal Findings

In this study, we demonstrated that a hybrid control architecture, combining time-series forecasting (ARIMA), nonlinear modeling (FFNN), and multisensor feedback, can significantly enhance the performance of an assistive feeding robot in both simulation and physical hardware. Our approach yielded a combined MSE of 0.008 and an R^2 of 94%, which improved feeding success rates from 75% to 90% and reduced response times by 28% (from 3.6 s to 2.2 s), outperforming both ARIMA-only and FFNN-only controllers. These results underscore the value of fusing statistical and machine-learning techniques. ARIMA captures linear trends in a user's eating rhythm, while the FFNN models nonlinear variations, together enabling proactive adjustment of timing and portion size. The closed-loop integration of vision-based mouth readiness detection, ultrasonic ranging, and strain-gauge force sensing further enables the system to adapt to delayed user responses, diverse food textures, low-lighting conditions, and plate movements, which are conditions under which prior passive or semiautonomous feeders struggle. Our fuzzy logic–driven force and angle controller also proved effective at tailoring grip strength to different foods (eg, apples vs strawberries), minimizing spills and enhancing safety. Compared to legacy systems like My Spoon and Obi Robot, which rely on fixed trajectories or manual "teach" modes, our robot autonomously adjusts its behavior in real-time, reducing caregiver intervention and improving user autonomy. Despite the promising results, several limitations remain and will guide future research. While the Unity simulation enabled rapid iteration and control benchmarking, it cannot fully replicate the unpredictability of real-world settings, including table height variability, user posture changes, and lighting variation.

This study focused on only 2 food types, which limits generalizability to more complex diets involving varied textures, consistencies, and utensil requirements (eg, soups or mixed meals). Although the system is designed to operate autonomously, setup and supervision may still be required. User-friendly interfaces, minimal daily calibration, and rapid onboarding for caregivers will be key to adoption. We are exploring guided setup workflows and voice-driven overrides to reduce learning curves. Furthermore, no real-user trials have been conducted, meaning aspects such as user comfort, adaptability, and long-term acceptance remain unexplored. To address these limitations, we are transitioning our control system to a physical robotic arm integrated with the proposed sensor suite. Initial bench-top experiments will assess trajectory accuracy, timing responsiveness, and force safety across a broader range of feeding conditions. Following this, a pilot study involving 3 to 5 individuals with upper-limb impairments is planned to evaluate comfort, performance, and real-world

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usability. By addressing deployment challenges, including safety, maintenance, training, and personalization, we aim to ensure that future iterations are not only technically robust but also clinically viable and user-friendly. These evaluations will inform iterative improvements and alignment with clinical standards. Ultimately, our goal is to deliver a safe, autonomous feeding solution that promotes independence, comfort, and dignity for individuals with motor impairments across diverse care environments.

Limitations and Conclusions

In this work, we used simulated environments and datasets to validate an adaptive feeding robot that significantly advances the state of assistive dining technology. By integrating time-series forecasting (ARIMA), nonlinear modeling (FFNN), and multisensor feedback (vision, ultrasonic ranging, and strain-gauge force sensing), our system anticipates each user's unique feeding pace. It dynamically adjusts both timing and force for safe, precise spoon-to-mouth delivery. In over 1000 Unity simulations and on physical hardware, the hybrid controller achieved an MSE of 0.008 (R^2=94%), increased feeding success from 75% to 90%, and reduced response times by 28% (3.6 s-2.2 s; P<.001), outperforming ARIMA-only and FFNN-only baselines. Despite these promising results, our study has several limitations. First, performance was primarily evaluated in simulation; real-world variability, such as unstructured environments, diverse plate geometries, and spontaneous user movements, remains to be tested in live trials. Second, we focused on 2 food types (apple and strawberry); future work should encompass a broader range of textures, shapes, and portion sizes. Finally, user acceptance, comfort, and long-term usability were not assessed; ethical considerations surrounding autonomy and trust in human-robot interaction warrant further investigation. Looking ahead, we plan to conduct clinical pilot studies to evaluate real-world efficacy and user satisfaction, extend our sensor suite to include depth cameras and tactile arrays, and explore advanced forecasting methods (eg, recurrent neural networks and transformers) for even finer-grained personalization. By addressing these challenges, we aim to transition from a laboratory prototype to a robust, user-centered assistive solution, empowering individuals with motor impairments to dine independently and with dignity.

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Conflicts of Interest

None declared.

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Abbreviations

ARIMA: auto regressive integrated moving average
CNN: convolutional neural network
FFNN: feed-forward neural network
IK: inverse kinematic
ILSVRC: ImageNet Large Scale Visual Recognition Challenge
MSE: mean squared error
PR2: Personal Robot 2
RGB-D: red green blue–depth

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Original Paper

Evaluation of a Tablet-Based Emotion Regulation Intervention for Surrogate Decision-Makers of Patients With Critical Illness: Pilot Nonrandomized Trial

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Abstract

Background: Psychological distress among surrogate decision-makers (surrogates) for patients with critical illness is well documented. Existing interventions for supporting surrogates in their role often target surrogates' informational needs without directly addressing surrogates' acute emotional burden. Therefore, we developed the Reappraisal-Enhanced Foundation for Regulating Affect and Managing Emotions (REFRAME) intervention, a tablet-based app that empowers surrogates to manage their psychological distress with cognitive reappraisal.

Objective: We sought to (1) determine the feasibility, acceptability, and appropriateness of implementing REFRAME and (2) examine its preliminary effects on surrogates' psychological distress.

Methods: We conducted a pilot nonrandomized trial at a tertiary medical center in northeast Ohio. We recruited adult surrogates for incapacitated intensive care unit (ICU) patients (≥48 hours). The first 20 participants received usual care (UC); the next 28 received UC and REFRAME, consisting of 3 sequential 10- to 15-minute modules administered every 24 to 48 hours (T1-T3) post enrollment (T0). We evaluated implementation outcomes both quantitatively and qualitatively by describing enrollment and completion rates, surrogates' scores on the Acceptability of Intervention Measure and the Intervention Appropriateness Measure, and thematically analyzing feedback from each interventional module. We measured psychological distress with the Patient-Reported Outcomes Measurement Information System Anxiety and Depression short forms at enrollment (T0) and approximately 1-week post enrollment (T3). We used linear mixed-effects models to assess changes in anxiety and depression severity between groups from T0 to T3, adjusting for the surrogate's gender, patient relationship, prior decision-making experience, and perceived stress.

Results: Our analytic sample included 48 surrogates (UC=20; REFRAME=28). Two-thirds (19/28, 67.9%) of those assigned to REFRAME completed all 3 modules, with over 70% finding it acceptable and appropriate. Qualitative feedback indicated that surrogates appreciated the intervention's normalization of their emotions and provision of practical reappraisal strategies. Both groups showed reductions in psychological distress severity, with greater reductions in depressive symptoms reported by surrogates in the REFRAME group (d=0.68).

Conclusions: REFRAME was feasible to implement, well-received by users, and considered relevant in the ICU setting. We observed preliminary improvement in depressive symptoms, though the effects on anxiety are less certain. Our findings indicate that incorporating brief cognitive reappraisal tools into routine ICU practice may support surrogates' psychological well-being.

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Larger, more diverse trials with longer follow-up are necessary to confirm these initial findings and assess their impact on shared decision-making.

(JMIR Form Res 2026;10:e73769) doi:10.2196/73769

KEYWORDS

coping; critical care; emotion regulation; intensive care unit; shared decision-making

Introduction

Psychological distress is a significant challenge for surrogate decision-makers (hereafter, surrogates) in the intensive care unit (ICU), with more than 50% reporting symptoms of anxiety and depression [1,2]. This distress is associated with impairments in sleep, cognition, and judgment that diminish their capacity to make value-concordant decisions for the patient [3-8]. Left unaddressed, psychological distress may contribute to nonbeneficial, value-discordant care and increase surrogates' risk of long-term psychiatric morbidity [2,9-11].

Over the last 4 decades, many supportive interventions have been developed to address surrogates' psychological needs. However, these interventions show limited and unreliable effectiveness in reducing both short- and long-term psychological distress [12-15]. Most prioritize surrogates' informational needs by implementing proactive multidisciplinary consultations and enhancing communication between surrogates and providers. While these strategies are crucial for ensuring informed decision-making and increasing surrogate satisfaction, they do not directly address surrogates' internal capacity to manage their psychological experiences, which is essential when making high-stakes decisions amidst profound uncertainty and maintaining long-term psychological well-being [5,16].

Consequently, ICU investigators have piloted emotionally oriented interventions grounded in principles of clinical psychology. These include 2 clinician-led interventions delivered in face-to-face or telehealth formats, and a third that involves implementing a commercially available mental health app (Sanvello) [17-20]. This small body of evidence supports the feasibility, acceptability, and preliminary efficacy of these interventions. However, only 1 intervention has undergone a fully powered clinical trial, which revealed no significant between-group effects on the primary psychological outcomes (eg, anxiety, depression, and posttraumatic stress symptoms) [19,21]. Furthermore, several limitations persist. Clinician-led interventions may be too resource-intensive to scale in less-equipped health care settings. Commercial applications like Sanvello offer scalability but lack customization for surrogates' specific psychological needs. Most importantly, these interventions primarily address long-term psychological symptoms post-ICU discharge, offering surrogates little guidance when managing acute distress during the early days of the patient's ICU stay, a critical period when decisions can significantly influence patients' clinical trajectories and necessitate even more complex decisions from surrogates [22].

Therefore, we developed the Reappraisal-Enhanced Foundation for Regulating Affect and Managing Emotions (REFRAME) intervention, a tablet-based app designed to help surrogates manage acute psychological distress during the critical early phase of a patient's ICU stay. Grounded in the Process Model of Emotion Regulation, REFRAME both educates surrogates and promotes the use of cognitive reappraisal (reappraisal) for managing psychological distress during the patient's ICU stay [23-27]. Reappraisal is widely regarded as a practical, adaptable, and highly effective strategy that surrogates can use to reframe negative stressors and reduce the intensity of ensuing psychological distress [28-30]. For instance, a surrogate can use reappraisal to alleviate the emotional burden of withdrawing life-sustaining care for the patient by reframing their role as an opportunity to honor the patient's preferences. We found that surrogates with stronger reappraisal tendencies experience less intense symptoms of psychological distress and use fewer cognitive resources when receiving both active and passive forms of decision support [31,32].

In summary, considering the urgent need for on-demand interventions that assist surrogates in managing acute psychological distress, their openness to emotionally focused interventions offered in digital formats, the compelling evidence showing the feasibility of such interventions in the ICU setting, and the extensive research highlighting the effectiveness of reappraisal across various cultures and contexts, we sought to evaluate the implementation and preliminary efficacy of REFRAME in a prospective sample of ICU surrogates. We hypothesized that REFRAME would be feasible to implement, perceived as acceptable and suitable by surrogates, and linked to a more significant reduction in psychological distress symptoms compared to standard ICU care. To test these hypotheses, we pursued the following aims: (1) evaluate the implementation (ie, feasibility, acceptability, and appropriateness) of REFRAME and (2) examine the preliminary effects of REFRAME on symptoms of psychological distress (ie, anxiety and depression).

Methods

Our reporting practices for this study were guided by the CONSORT (Consolidated Standards of Reporting Trials) statement for nonrandomized pilot and feasibility studies [33,34].

Ethical Considerations

Before conducting screening, recruitment, and data collection procedures, we obtained approval from the Institutional Review Board (IRB) at University Hospitals Cleveland Medical Center (IRB00001691), in accordance with the ethical standards of the Declaration of Helsinki. Participants provided written informed consent before data collection, understanding that all study data would be deidentified and stored securely in an encrypted REDCap (Research Electronic Data Capture; Vanderbilt

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University) database prior to analysis. We offered a US $25 gift card as compensation for participants who completed all study procedures.

Design

Initially, we planned to conduct this study as a parallel group randomized trial; however, we encountered usability issues with the REFRAME intervention that prevented us from implementing it at the start of our recruitment period. Therefore, we modified our design to a pilot before-and-after (nonrandomized) study with a 1:1 group allocation ratio. We enrolled the first 20 participants in our control condition (usual care [UC]), followed by participants in the intervention condition (REFRAME). We oversampled the intervention group, aiming to complete all 3 intervention modules with 20 participants.

Control Condition (UC)

We defined UC as the communication and decisional support routinely provided to surrogate decision-makers of ICU patients. UC practices varied among clinical teams, ranging from brief interactions to extensive discussions. We recognize that research procedures, such as obtaining informed consent, may have heightened participants' awareness of their emotional needs, but these processes were not considered a structured intervention.

Intervention Condition (REFRAME)

REFRAME is a tablet-based app designed to support emotion regulation in ICU surrogates. The intervention consisted of 3 sequential modules corresponding to stages in the Extended Process Model of Emotion Regulation, with the user interface design grounded in Cognitive Load Theory [24,35]. Apart from incorporated assessment components (eg, surveys), all educational and instructional components were audio guided with corresponding closed captioning. For minor disruptions (<15 minutes) or attentional lapses, participants were allowed to repeat previous content from their desired location within the module. We required participants to restart the intended module after major interruptions (>15 minutes). Each module required 10-15 minutes to complete. To minimize the risk of contamination and minimize staff burden, bedside clinicians were not involved in delivering or reinforcing REFRAME and received no training in intervention principles.

We designed module 1 to evaluate the users' beliefs about emotion regulation [36], establish a foundational knowledge base related to participants' awareness of physiological and psychological symptoms of anxiety and depression, introduce the concept of reappraisal, and provide an example of how to apply it within the context of the surrogate role (Figure S1 in Multimedia Appendix 1). Module 2 further expands upon this knowledge by introducing users to different reappraisal strategies (ie, reconstruing and repurposing) with context-relevant examples (Figures S2 and S3 in Multimedia Appendix 1), guiding participants through an evaluation of the various applied examples, and establishing an implementation intention to use their preferred strategies when they become aware of symptoms discussed in module 1 [27,37,38]. Finally, module 3 integrates the principles of reappraisal to evaluate a hypothetical tracheostomy and feeding tube decision-making scenario from multiple perspectives: self-interested, projected interests, best interest, and substituted interest (Figure S4 in Multimedia Appendix 1) [39].

Participants

We enrolled adults (aged ≥18 years) recognized by the ICU team as the legally authorized representative for a decisionally incapacitated adult who had been residing in the ICU for at least 48 hours and was not expected to be discharged in the following 24 hours. We excluded participants who could not read or speak English because the study instruments and the study intervention were available only in English. We recruited all participants from the cardiothoracic, medical, neurological, and surgical ICUs at a tertiary medical center in northeast Ohio.

Sample Size Justification

We determined the sample size for this pilot trial using recommendations for estimating variance and minimizing overall trial size in pilot and main trials. For small- to medium-effect sizes (δ=0.2-0.5), Whitehead et al [40] recommend a pilot trial sample size of 20 participants per arm to estimate variance with reasonable precision while avoiding unnecessary participant recruitment. Similarly, a large group of investigators recently reported small- to medium-effect sizes (Cohen *d*=0.24-0.39) of a cognitive reappraisal intervention on negative emotions across a multinational sample (N=21,644) [30]. Thus, we sought to recruit 20 participants per study arm to evaluate REFRAME's implementation.

Instruments

Implementation Outcomes (Aim 1)

Feasibility

We measured feasibility—the extent to which an intervention can be successfully implemented—by evaluating the completion percentages of participants assigned to the intervention condition. We also monitored participants' adherence to the intervention protocol during delivery and reasons for missed doses. This approach allowed us to gauge the intervention's practicality and identify potential implementation barriers for future iterations [41]. We defined completion as the user reaching the end of the module section containing postmodule feedback assessments. Using previous recommendations and findings, we sought an a priori benchmark of 70% completion across all 3 modules as supportive feasibility evidence for REFRAME's implementation [41-43].

Acceptability and Appropriateness

We measured acceptability—the evaluation of one's satisfaction with an intervention—with the Acceptability of Intervention Measure (AIM); we measured appropriateness—the assessment of an intervention's compatibility within a given context—with the Intervention Appropriateness Measure (IAM). Both scales contain 4 items scored on a 5-point Likert scale. A total score is calculated by averaging the item responses, with higher scores indicating greater acceptability or appropriateness. Before analyzing the study data, we defined mean item scores of 4 or higher on the 5-point scale as evidence of acceptability and appropriateness, consistent with the "agree" response option

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for these measures. The scales' creators provide extensive evidence of the AIM's and IAM's readability, structural validity, construct validity, reliability, and sensitivity to change [44]. Across multiple administrations of each measure, the internal consistencies (Cronbach α) for AIM and IAM ranged from 0.82-0.97 and 0.92-0.97, respectively. In addition, after each module, participants were asked to share what they liked and what could be improved about REFRAME, which they responded to directly in the app with a standard keyboard (ie, "QWERTY").

Psychological Distress (Aim 2)

We measured symptoms of psychological distress with the PROMIS (Patient Reported Outcomes Measurement System) Emotional Distress–Anxiety and Depression short forms. Both scales contain 4 items scored on a 5-point Likert scale. We calculated the sum of item responses for each scale to calculate raw scores, which we then converted to T scores using precalculated conversion tables [45]. Higher scores indicate greater severity of psychological distress. Previous investigators have provided robust evidence of the Anxiety and Depression short forms' structural and construct validity, as well as reliability [46,47]. At baseline in our sample, the internal consistency (Cronbach α) of the Anxiety and Depression short forms was 0.87 and 0.89, respectively.

Sociodemographic Characteristics

We used recommended items from the Phenotypes and eXposures Social Determinants of Health Toolkit to measure the surrogate's age (years), gender identity, racial identity, marital status, household income, education, and employment status; we also used previous team-generated items to measure the surrogate decision-maker's relationship to the patient, advance care planning experience, and decision-making experience [48].

Perceived Stress

We measured surrogates' baseline perceived stress levels with the 10-item Perceived Stress Scale (PSS) [49]. Participants rated each item on a 5-point Likert scale ranging from "never" (0) to "very often" (4). We calculated total scores by summing item responses, with higher scores reflecting greater perceived stress. To align the PSS timeframe with the surrogate's acute ICU experience and other study instruments, we modified its reflection period from "over the past month" to "in the last week." This modification is supported by evidence of the PSS's psychometric robustness over shorter timeframes [50], its strong correlations with baseline anxiety (r=0.68; P<.001) and depressive symptom severity (r=0.66; P<.001), and its excellent internal consistency (α=0.90) in our sample.

Participant Screening and Recruitment

We recruited participants from the adult cardiothoracic, medical, neuroscience, and surgical ICUs at University Hospitals Cleveland Medical Center in Cleveland, Ohio. We followed a standardized, IRB-approved protocol to ensure consistency. Each day, a research assistant (RA) would screen the electronic medical records of adult ICU patients to verify their age (≥18 years) and ICU length of stay (≥48 hours). For these patients, the RA would confer with the patient's bedside provider (ie, nurse, nurse practitioner, physician, or physician assistant) to confirm discharge status (≥24 hours) and evaluate the patient's decision-making capacity using an IRB-designated assessment: (1) Is the patient alert and able to communicate? (2) Is the patient comfortable enough to communicate? and (3) Is the patient medically stable enough for an informed consent discussion? The patient was deemed incapacitated if any of the assessment parameters were not met. In rare cases of uncertainty from the provider or RA, the RA would consult the principal investigator (GP) for a designation. Upon confirming the patient criteria, the RA would consult the provider to identify and introduce the patient's surrogate. Then, the RA would confirm the surrogate's age (≥18 years), verify their ability to read and understand English, introduce the study, and ascertain their interest in participating. For interested surrogates, the RA would initiate an informed consent discussion within the patient's room or a preferred location near the ICU.

Data Collection

The RA would confirm and notify the surrogate of their group allocation upon obtaining written informed consent. Next, they would administer the sociodemographic questionnaire, the psychological distress instruments, and other instruments not referenced in this study. This interview (T0) required about 20 minutes. The RA conducted 3 follow-up interviews (T1-T3) 24-48 hours after each preceding interview. For those in the UC group, the RA would administer the psychological distress instruments in person or by telephone; these interviews lasted 5-10 minutes. For those in the REFRAME condition, the psychological distress, acceptability, and appropriateness assessments were embedded within the interventional modules, with each module requiring 10-15 minutes for completion. The REFRAME modules were not scheduled relative to specific clinical milestones. Because this was a feasibility pilot, our priority was to evaluate implementation procedures and maintain comparable assessment timepoints between study arms, rather than synchronizing intervention delivery with specific clinical milestones.

Treatment Fidelity

We incorporated fidelity-enhancing strategies across 4 of the 5 domains outlined by the National Institutes of Health Behavior Change Consortium framework [51,52]. We did not measure the enactment of treatment-related skills because the primary focus of this study was on evaluating REFRAME's implementation in surrogates.

- Study Design: We operationalized REFRAME using the Standard and Extended Process Model of Emotion Regulation [20,21]. We developed detailed guides to designate module content, sequence, design, and user interface, ensuring alignment with the theoretical framework.
- Training: To ensure consistent intervention delivery, we provided standardized training for research staff, including role-plays, booster sessions, and random delivery audits.
- Delivery: The modular content was identical for all recipients, and we followed prespecified protocols for reviewing content following short interruptions (≤15

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minutes) and restarting the module following lengthy interruptions (>15 minutes).
- Receipt: All educational content was delivered via prerecorded audio with synchronized subtitles and accompanying visual displays to promote intervention receipt. Reviews of key modular content were embedded at the end of each module and the beginning of the next module.

Analysis

Before our primary analyses, we examined descriptive statistics to assess variable distributions, identify potential outliers and influential cases, and evaluate assumptions for our quantitative analyses. We assessed patterns of missing data with descriptive summaries, Pearson chi-square tests, independent-sample *t* tests (2-tailed), and logistic regression.

Implementation Outcomes (Aim 1)

We conducted all quantitative analyses using SPSS (version 29; IBM Corp). To evaluate the feasibility, acceptability, and appropriateness of REFRAME, we analyzed module completion percentages and raw scores on the AIM and IAM using descriptive statistics (ie, means, SDs, and frequencies). To contextualize our quantitative findings, we examined reasons for missed doses and conducted a thematic analysis of participants' typewritten feedback, collected after each module. These open-ended responses typically ranged from 1 to 3 sentences. A total of 2 independent coders used open coding to manually categorize responses, identifying different barriers and facilitators to REFRAME's implementation. They resolved discrepancies through discussion until reaching a consensus. We selected thematic analysis because it allowed us to group common patterns from participant feedback while remaining flexible to unanticipated insights related to REFRAME's implementation [53].

Psychological Distress (Aim 2)

Following methodological recommendations for early-phase behavioral intervention studies [34,54,55], we examined changes in psychological distress severity from baseline (T0) to 1 week postbaseline (T3) between the intervention (REFRAME) and UC groups by calculating individual change scores (Δ=T3–T0) for anxiety and depressive symptoms and comparing mean changes between groups with independent samples *t* tests. We quantified between-group effects by interpreting Cohen *d* and corresponding 95% CIs, using standard conventions for small (≥0.2), medium (≥0.5), and large (≥0.8) effects [56].

Given our sequential, nonrandomized design, we conducted post hoc sensitivity analyses using linear mixed-effects models to evaluate the robustness of our findings. In each model, we included fixed effects for group (UC=0; REFRAME=1), timepoint (T0, baseline=0; T3, 1 week postbaseline=1), and their interaction (group × timepoint). Although this analysis was underpowered for multivariable inference, we added gender (man=0; woman=1), patient relationship (spouse/domestic partner=0; nonspouse/nondomestic partner=1), previous health care decision-making experience (no=0; yes=1), and perceived stress as a priori covariates to reduce residual variance and ensure that between-group differences were not confounded by known correlates of psychological distress in surrogates [2]. We specified random intercepts for each participant to account for baseline differences in psychological distress severity and used a diagonal covariance structure to model the repeated measurements of outcomes. The model coefficients were estimated using restricted maximum likelihood with Satterthwaite-adjusted degrees of freedom.

Results

Participant Enrollment and Attrition

Between August 2022 and June 2023, we screened 2587 patients for eligibility, with the majority being ineligible due to a pending discharge status (989/2587, 38.2%), an ICU length of stay of less than 48 hours (583/2587, 22.5%), or possessing capacity for decision-making (387/2587, 15.0%). Of the 95 eligible surrogates (3.7%), a total of 46 (48.4%) declined participation. During the 10-month recruitment period, we enrolled 49 surrogates (4.8 per month). The first 20 participants were allocated to UC, and the following 29 to REFRAME. Notably, 1 participant assigned to the REFRAME condition withdrew from the study after providing informed consent but before baseline data collection, resulting in a final analytic sample of 48 surrogates.

As shown in Figure 1, we experienced greater attrition in the REFRAME group (n=9) than in the UC group (n=3), with withdrawal reasons including patient discharge or death and the participant either being nonresponsive, feeling overwhelmed, or physically ill. Despite this, study group (χ^2_1=1.8; *P*=.18) and all other proposed covariates were not associated with study attrition, suggesting our data were at least missing at random.

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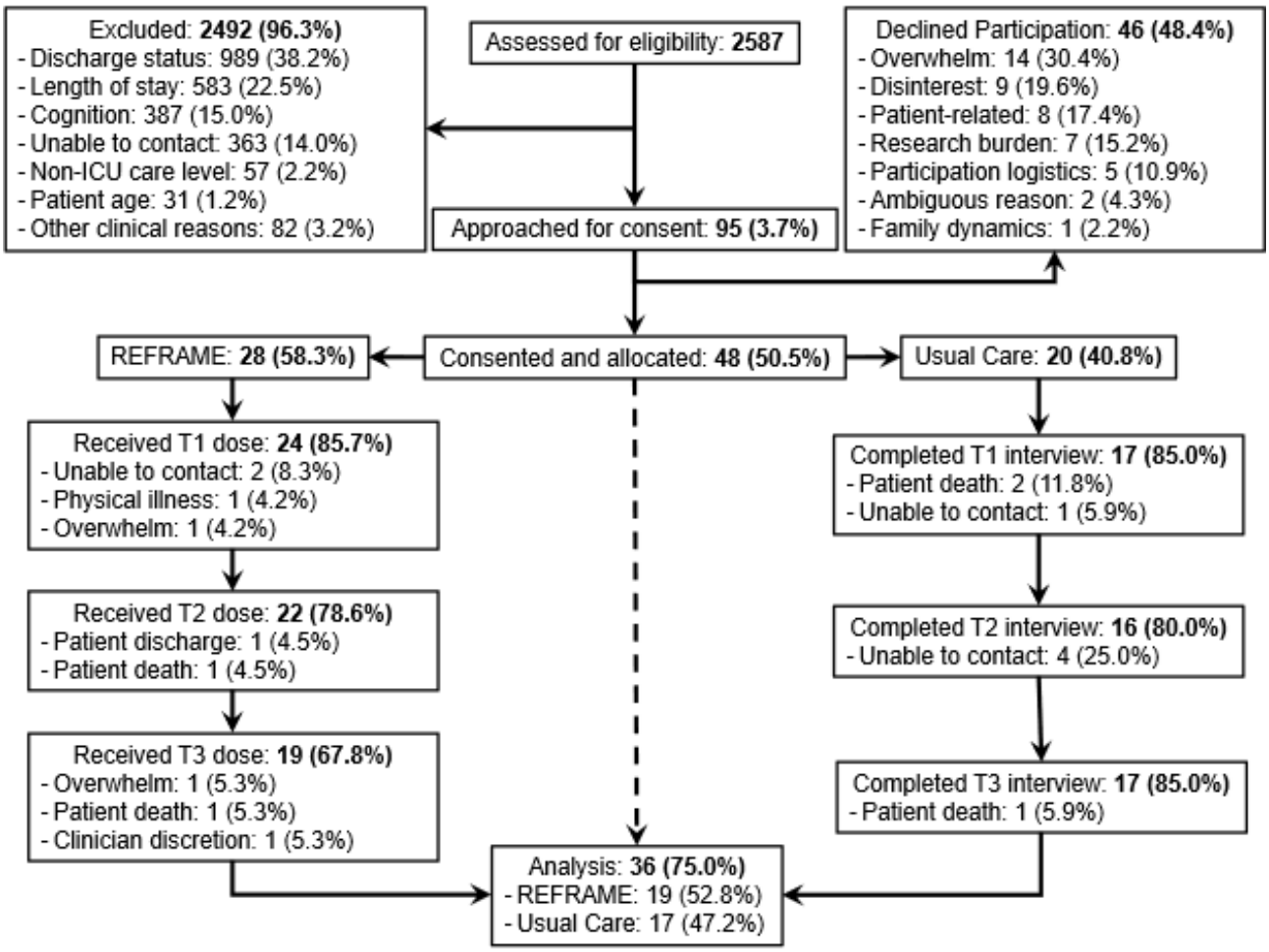
Figure 1. CONSORT (Consolidated Standards of Reporting Trials) flowchart of participant enrollment, allocation, and adherence. ICU: intensive care unit.



Participant Baseline Characteristics

Table 1 compares surrogate baseline characteristics by study group. Overall, our sample's average age was 58.6 (SD 13.2) years, and it was predominantly comprised of women (36/48, 75%) and White individuals (41/48, 85.4%). Most participants were married (33/48, 68.8%), employed full-time or part-time (27/48, 56.2%), nonbaccalaureate educated (26/48, 54.2%), and living in a household with an annual income of less than US $100,000 (25/48, 52.1%). Most surrogates had not discussed the patient's preferences regarding cardiopulmonary resuscitation (32/48, 66.7%), mechanical ventilation (30/48, 62.5%), artificial nutrition (40/48, 83.3%), or dialysis (33/48, 68.8%), despite more than half reporting that they had discussed end-of-life care (25/48, 52.1%). More than 62.5% (30/48) of surrogates reported moderate to severe anxiety symptoms, and one-third (16/48, 33.3%) endorsed moderate to severe depressive symptoms. While the baseline characteristics of participants were mostly balanced across groups, 75% (15/20) of surrogates in the UC group were the patient's spouse, compared with 39% (11/28) in the REFRAME group (Pearson $\chi^2_{1,48}$=6.0; *P*=.01). Furthermore, 95% (19/20) of surrogates in the UC group lacked experience in making health care decisions for the patient, a larger proportion than surrogates in the REFRAME group (19/28, 67.9%) (Fisher exact test, *P*=.03).

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Table 1. Baseline characteristics of enrolled surrogates by study group (N=48). Data available for 26 participants in the Reappraisal-Enhanced Foundation for Regulating Affect and Managing Emotions (REFRAME) group and 17 participants in the usual care (UC) group due to declined responses.

Variable	REFRAME (n=28)	UC (n=20)	*P* value[a]
Age (years), mean (SD)	58.1 (13.8)	59.2 (12.6)	.77
Gender, n (%)			.499
Woman	20 (71.4)	16 (80)	
Man	8 (28.6)	4 (20)	
Racial identity, n (%)			.37
White	25 (89.3)	16 (80)	
Non-White	3 (10.7)	4 (20)	
Marital status, n (%)			.43
Married	18 (54.5)	15 (75)	
Not married	10 (35.7)	5 (25)	
Relationship to patient, n (%)			.01
Spouse/domestic partner	11 (39.3)	15 (75)	
Nonspouse/nondomestic partner	17 (60.7)	5 (25)	
Employment status, n (%)			.66
Employed (full/part time)	15 (53.6)	12 (60)	
Not employed	13 (46.4)	8 (40)	
Highest education attained, n (%)			.96
≤High school	6 (21.4)	5 (25)	
Some college/associate degree	9 (32.1)	6 (30)	
≥Bachelor's degree	13 (46.4)	9 (45)	
Household income (US $), n (%)			.49
<60,000	9 (34.6)	5 (29.4)	
60,000-99,999	8 (30.8)	3 (72.7)	
≥100,000	9 (34.6)	9 (52.9)	
Prior ACP[b] conversations (Yes), n (%)			
CPR[c]	10 (35.7)	6 (37.5)	.68
Mechanical ventilation	10 (35.7)	8 (40)	.76
Artificial nutrition	5 (17.9)	3 (37.5)	.56
Dialysis	7 (25)	8 (40)	.27
End-of-life care	14 (50)	11 (55)	.73
Decision-making experience, n (%)			.03
No	19 (67.9)	19 (95)	
Yes	9 (32.1)	1 (5)	
Perceived stress raw score, mean (SD)	24.2 (4.4)	21.8 (4.2)	.06

[a]*P* values were calculated using Pearson chi-square or Fisher exact tests for categorical variables and independent-samples *t* tests (2-tailed) for continuous variables.

[b]ACP: advance care planning.

[c]CPR: cardiopulmonary resuscitation.

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Implementation Outcomes (Aim 1)

Feasibility

Of the 28 enrolled surrogates in the REFRAME group with baseline data, a total of 19 received all 3 intended intervention doses (19/28, 67.9%). Of those (n=9) who did not receive all intended doses, a total of 3 (33.3%) missed doses because of patient-related factors (eg, discharged from ICU or patient death), 3 (33.3.%) claimed they were too overwhelmed or busy to remain committed to the study protocol, 2 (22.2%) were not responsive to our follow-up efforts, and 1 (11.1%) participant developed an illness that prevented them from visiting the ICU.

Acceptability and Appropriateness

Quantitative Findings

Surrogate perceptions of REFRAME's acceptability and appropriateness were positive across all 3 modules (Table 1). Over 70% of surrogates' average scores were at least 4.00 across all 3 modules, indicating that the intervention was acceptable and appropriate. For acceptability, we observed favorable ratings (≥4.00) for 79.2% (19/24), 78.3% (18/23), and 73.7% (14/19) of participants for each module. Appropriateness followed a similar trend, with 70.8% (17/24), 73.9% (17/23), and 78.9% (15/19) of participants providing favorable ratings for the same modules (Table 2).

Table 2. Acceptability and appropriateness summary statistics by Reappraisal-Enhanced Foundation for Regulating Affect and Managing Emotions (REFRAME) module.

Module (timepoint)	Frequency, n	Acceptability		Appropriateness	
		Minimum-maximum	Mean (SD)	Minimum-maximum	Mean (SD)
1 (T1)[a]	24	2.75-5.00	4.36 (0.70)	3.00-5.00	4.34 (0.68)
2 (T2)[b]	23	3.00-5.00	4.37 (0.69)	3.25-5.00	4.35 (0.66)
3 (T3)[c]	19	1.00-5.00	4.28 (1.00)	1.25-5.00	4.26 (1.00)

[a]T1: 1-2 days post enrollment.

[b]T2: 3-4 days post enrollment.

[c]T3: 5-6 days post enrollment.

Qualitative Findings

To provide deeper insight into our quantitative findings, we identified themes related to strengths and areas for improvement among participants across the three intervention modules. Table S1 in Multimedia Appendix 2 summarizes the primary themes and subthemes we identified in our analysis with supporting participant quotes. Across the modules, participants appreciated the intervention's ability to validate their emotional experiences, introduce practical emotion regulation skills, and provide an example of how they can frame decisions they may encounter during the patient's ICU stay. Importantly, participants shared that we could further improve the intervention by tailoring its content to their unique experiences, enhancing its usability, and considering how to adeptly present emotionally charged content.

Module 1: Introducing Emotion Regulation

Surrogates highlighted several ways the first module validated their emotional experiences, demonstrated the importance of practical tools for managing those emotions, and emphasized the necessity for adjustable narration pacing. A common theme among participants was the appreciation for normalizing their feelings. For instance, one participant noted, "It is helpful to point out that stress and sadness are normal and that there are ways to deal with it," while another wrote, "It helps me focus on my feelings and self-care while also focusing on my loved one." Furthermore, participants recognized the value of providing a practical framework for managing emotions, such as refocusing strategies during distress. One participant remarked, "It gives family members a practical tool to manage emotions." In addition to these insights, participants provided feedback on enhancing usability by allowing control over narration pacing. One participant explained, "I would benefit from reading through the entire presentation at my own reading speed."

Module 2: Reappraisal Strategies

Surrogates provided positive feedback on the second module, highlighting the introduction of reappraisal techniques and the reinforcement of existing coping mechanisms that were immediately applicable. One participant shared, "This seems to be exactly what I need. I have tried several strategies, and they have helped me see a better way to cope." Users appreciated how the module reinforced existing coping mechanisms while introducing varied approaches. As another participant noted, "This is a great reminder for me to use a familiar process in times of stress." However, some participants expressed concerns about the content's simplicity and repetitiveness, especially for those who may be more adept at managing stress. One remarked, "It seems a bit too simplistic because you can guess what point is going to be made next." Thus, while the module was well received for its practical approaches, there remains room for greater depth and engagement.

Module 3: Decision-Making Application

Surrogates expressed strong appreciation for the third module, noting its importance in providing relevant tools for navigating real-life decisions in the ICU. Participants highlighted the module's practicality in real-life situations, with one stating, "The scenarios were appropriate for decisions I have had to make for my loved one." Another participant remarked on its support for making "clear and difficult decisions" during emotionally charged moments. However, one participant raised

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a crucial point regarding the need to consider a surrogate's emotional readiness when addressing challenges such as end-of-life decisions: "The death discussion is too scary for that time when the family member is in the ICU."

Effects on Psychological Distress (Aim 2)

Table 3 displays within- and between-group changes in psychological distress severity from baseline (T0) to approximately 1 week postbaseline (T3). At T0, anxiety and depressive symptoms were higher in the REFRAME group (t_{34}=−1.69; P=.10 and t_{34}=−1.33; P=.19), and at T3, psychological distress severity decreased in both groups. However, anxiety symptoms decreased by an average of 2.2 points more in the REFRAME group (95% CI −2.08 to 6.53), and depressive symptoms decreased by an average of 4.01 points more in the REFRAME group (95% CI −0.01 to 8.02). These differences favoring the REFRAME group correspond to a small effect for anxiety symptoms (d=0.35, 95% CI −0.31 to 1.01) and a medium effect for depressive symptoms (d=0.68, 95% CI −0.001 to 1.35).

Table 3. Within- and between-group changes in psychological distress severity from baseline (T0) to 1 week postbaseline (T3) in surrogate decision-makers.

Variable and group	T0[a], mean (SD)	T3[b], mean (SD)	Δ mean (SD)[c]	Between-group Δ (95% CI)[d]	Cohen d (95% CI)[e]
Anxiety				2.22 (−2.08 to 6.53)	0.35 (−0.31 to 1.01)
UC[f]	59.78 (10.61)	56.35 (10.04)	3.43 (6.37)		
REFRAME[g]	65.21 (8.67)	59.56 (9.81)	5.65 (6.33)		
Depression				4.01 (−0.01 to 4.08)	0.68 (−0.001 to 1.35)
UC	52.71 (8.04)	52.20 (8.17)	0.51 (3.95)		
REFRAME	56.97 (10.77)	52.45 (10.18)	4.52 (7.23)		

[a]T0: baseline.

[b]T3: 5-6 days postbaseline.

[c]Change from T0 to T3 ($\Delta=T_3 - T$).

[d]Between-group difference in mean change scores (REFRAME–UC).

[e]Standardized mean difference; small ≥0.2, medium ≥0.5, and large ≥0.8.

[f]REFRAME: Reappraisal-Enhanced Foundation for Regulating Affect and Managing Emotions.

[g]UC: usual care.

Sensitivity Analysis

The findings from our sensitivity analysis align with those from our primary analysis (Tables S2 and S3 in Multimedia Appendix 2). Anxiety symptoms decreased in both groups from T0 to T3, with the REFRAME group reporting a larger decrease (b=−2.14, 95% CI −6.20 to 1.92). Of our prespecified covariates, perceived stress (b=1.38, 95% CI 0.99-1.78), identifying as a woman (b=−4.82, 95% CI −8.74 to −0.89), and having prior decision-making experience (b=−6.26, 95% CI −11.17 to −1.35) were positively associated with anxiety severity. Similarly, depressive symptoms decreased in both groups from T0 to T3, with the REFRAME group reporting a larger decrease (b=−4.06, 95% CI −7.91 to −0.21). Unlike the anxiety model, perceived stress was the only covariate associated with depression severity at P<.05 (b=1.36, 95% CI 0.93-1.79). Figure 2 depicts the model-estimated marginal means for changes in anxiety and depressive symptoms from T0 to T3, adjusted for all prespecified covariates, providing convergent evidence for the robustness of the observed patterns in our primary analysis.

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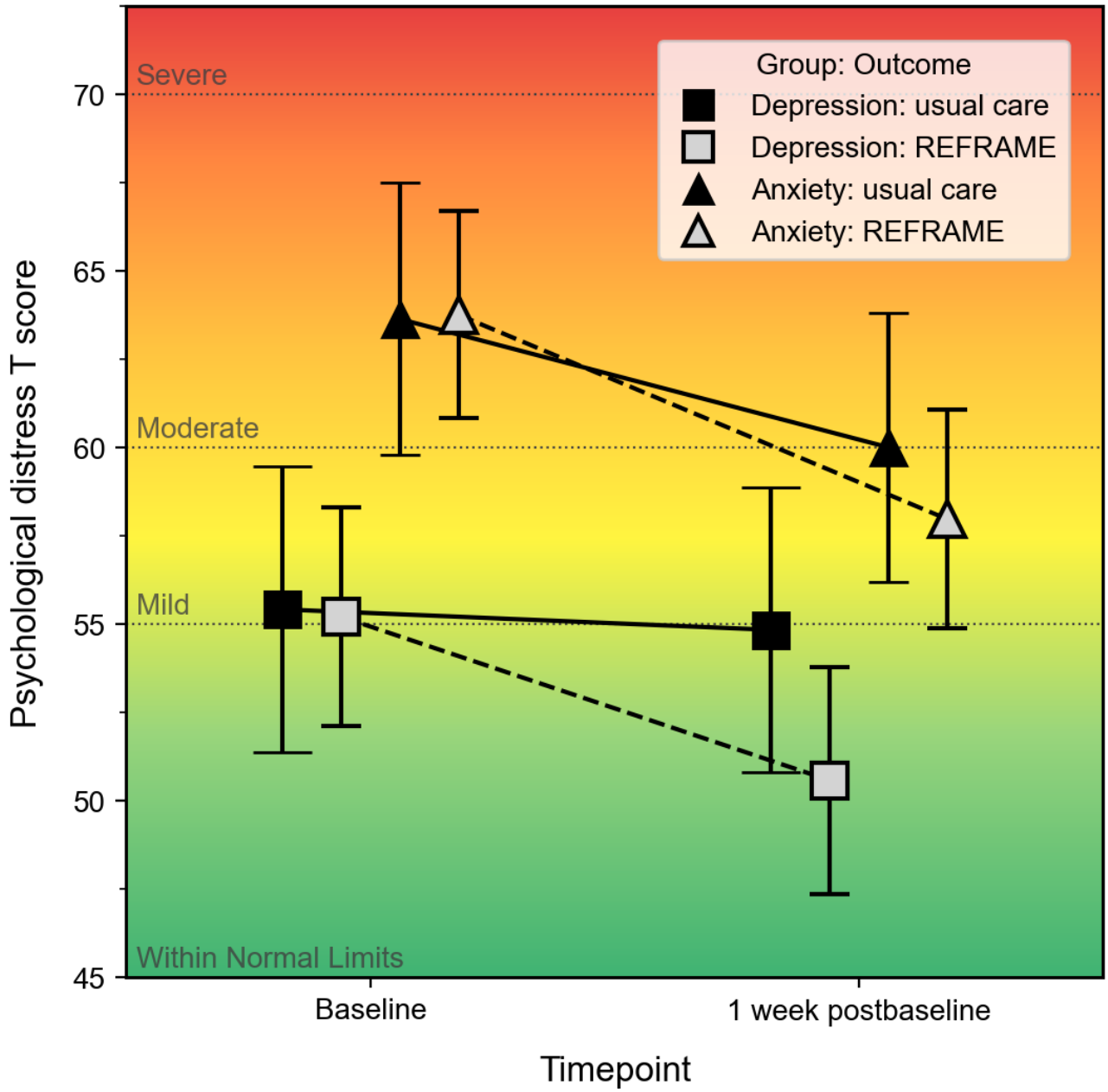
Figure 2. Estimated marginal means (EMMs) of anxiety and depressive symptom severity (PROMIS [Patient Reported Outcomes Measurement Information System] T scores) from baseline (T0) to approximately 1 week postbaseline (T3) by study group. Lines and points represent model-estimated EMMs from mixed-effects models that adjust for gender, patient relation, prior decision-making experience, and perceived stress; error bars indicate 95% CIs. Usual care is represented with black-filled symbols connected by solid lines, and Reappraisal-Enhanced Foundation for Regulating Affect and Managing Emotions (REFRAME) with gray-filled symbols connected by dashed lines. Anxiety severity is indicated by triangles, and depression severity is indicated by squares. The background color bands illustrate PROMIS severity categories for interpretation: green indicates within normal limits (<55), yellow represents mild (55-59.9), orange denotes moderate (60-69.9), and red indicates severe (≥70).



Discussion

Implementation Outcomes (Aim 1)

Principal Findings

We present evidence that REFRAME, our tablet-based emotion regulation intervention, can be feasibly implemented, is user-friendly, and is relevant to surrogate decision-makers of patients with critical illness. Over a 10-month recruitment period, we enrolled and allocated 48 out of 95 eligible surrogates (50.5%). Two-thirds of participants in the intervention group completed all 3 modules, with over 70% rating the intervention as acceptable and appropriate. Emerging themes from our qualitative findings indicate that surrogates valued the intervention's ability to normalize their emotional experiences, offer practical reappraisal techniques for managing distressing emotions, and incorporate reappraisal principles into their decision-making. However, participants also identified several areas for improvement, including adjusting the intervention's pacing, addressing emotionally charged content with greater sensitivity, and tailoring the content to individual needs. Compared with the existing literature, our findings highlight the potential of REFRAME to provide crucial support to this particularly vulnerable population.

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Comparison With Prior Work

The feasibility of enrolling and retaining ICU surrogates in clinical trials is often hindered by their concerns for the patient or limited emotional bandwidth. Many patient-oriented trials fail to reach their intended sample size, with refusal rates approaching 70% [57-60]. However, investigators conducting surrogate-oriented trials of similar psychological interventions have reported higher enrollment rates, even though, before REFRAME, these interventions had not been directly implemented during ICU stays. For example, investigators piloting a telephone-based coping skills training (CST) intervention for acute lung injury survivors and their informal caregivers recruited 10 dyads across 4 sites between 2009 and 2010 (~0.8 dyads/month), achieving 92% session completion and unanimous endorsement of the intervention's usefulness [19]. Similarly, investigators piloting Enhancing and Mobilizing the Potential for Wellness and Resilience (EMPOWER)—a clinician-led mental health intervention delivered in face-to-face and telehealth formats—enrolled approximately 2 participants/month, with low refusal rates (23%) and high adherence rates (89%), but moderate attrition after 3 months (37%) [18]. In comparison, we enrolled nearly 5 participants per month, exceeding the per-site pace reported in the CST and EMPOWER trials, while achieving a slightly lower retention rate (~68%) in the REFRAME condition, which approached our a priori goal of 70% retention. This is expected, as we sought to recruit surrogates during a distressing and unpredictable period of the patient's ICU stay, and differences in population acuity and timing (during vs after ICU) limit direct comparisons of enrollment and retention across studies.

While interventions like CST and EMPOWER are promising, they may require significant resources, which can limit their scalability across different ICU contexts. Thus, we deliberately chose a tablet-based platform for REFRAME to provide on-demand and scalable psychological support. For example, investigators trialing the web-based decision aid, Electronic Collaborative Decision Support (eCODES), reported high acceptability ratings, with enrollment, adherence, and attrition percentages comparable to the EMPOWER trial [61,62]. Likewise, in 2 pilot trials of the commercially available Sanvello mental health app, investigators reported moderate-to-high satisfaction and 20% attrition over 60 days, though engagement varied substantially [17,20]. Notably, EMPOWER, eCODES, and Sanvello targeted psychological outcomes weeks to months after ICU admission.

In contrast, we designed REFRAME to target psychological distress during the acute phase of critical illness—when well-intentioned routine procedures and urgent interventions can escalate into highly complex clinical scenarios—demanding surrogates to make life-altering decisions in the face of intense uncertainty [22]. In this period, surrogates are often overwhelmed at this early stage with balancing new and unfamiliar information, contemplating high-stakes decisions, and managing acute psychological distress. Considering this context may partly explain why we had lower enrollment and adherence percentages than interventions delivered later in the ICU stay or post discharge. Consistent with previous findings, many eligible surrogates felt too overwhelmed to enroll in this study [63,64]. Nonetheless, supporting surrogates during this critical period may ultimately enhance value-concordant care for patients while mitigating long-term psychological morbidity for surrogates.

Effects on Psychological Distress (Aim 2)

Principal Findings

Both anxiety and depressive symptoms decreased from moderate to mild severity across study groups from baseline (T0) to approximately 1 week postbaseline (T3). However, anxiety improvement was not linked to group assignment. In contrast, depressive symptoms in the REFRAME group declined from mild severity to near-normal limits, while those in the UC group maintained mild depressive severity throughout the study period. The magnitude of this change met the PROMIS Depression minimally important difference (≈3-4 T score points) threshold established from 3 separate randomized trials (N=651), potentially indicating a clinically significant effect [65]. However, because participants in the intervention group entered the study with slightly higher baseline distress and distress naturally subsides over the first few days of an ICU stay, the observed improvement may reflect circumstantial adaptation or regression to the mean [3,66].

Nonetheless, our primary analysis findings are further supported by our more analytically robust sensitivity analysis, in which perceived stress emerged as the strongest predictor across all variables in both models. Although women, patient spouses or partners, and individuals with prior health care decision-making experience reported higher levels of psychological distress, these associations' CIs were wide in both models and only excluded zero in our anxiety model. Notably, our limited sample size restricted our ability to detect smaller effects that may be clinically meaningful, especially for anxiety symptoms, emphasizing the need to examine REFRAME's effectiveness in a more adequately powered trial.

Comparison With Prior Work

Research on surrogate psychological distress during ICU stays is scarce, often limited to single-time assessments, with follow-ups occurring weeks to months after discharge [2,12,14]. Our previous descriptive study at the same institution found similar distress trajectories between ICU days 3 and 10 [3]. These studies further align with a Spanish study of 104 surrogates that observed decreased anxiety and depressive symptoms from ICU day 3 to post discharge [67]. However, Bolosi et al [68] found stable anxiety and increasing depressive symptoms among 108 Greek surrogates from ICU days 1 to 7, possibly due to cultural, contextual, or methodological differences. Surrogates' psychological well-being can fluctuate daily, influenced by structural, interpersonal, and intrapersonal factors [5,16,69]. Therefore, routinely monitoring their distress is crucial for implementing targeted interventions that optimize their psychological capacity for sound decision-making and improve long-term psychological outcomes.

Historically, ICU-based clinical trials have mainly focused on fulfilling the informational needs of surrogates, yet they have had limited impact on their long-term psychological well-being [62,70-72]. In contrast, fostering surrogates' emotion regulation

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and coping skills through clinician-led or self-directed interventions may improve their resilience against adverse psychological outcomes following the patient's ICU stay [17,18,21]. These interventions used cognitive-behavioral, acceptance, and commitment therapy techniques, targeting underlying psychological mechanisms that promote long-term psychological well-being. We build on these efforts with REFRAME, highlighting reappraisal as a practical skill for managing acute psychological distress by reframing immediate stressors in the ICU. Furthermore, although baseline depressive symptoms in our sample were mild on average, even subclinical depression can interfere with the cognitive control and motivational processes that support complex medical decision-making, reducing a surrogate's ability to override emotionally driven impulses in favor of value-based reasoning [73-75]. As a result, mild depressive symptoms during the ICU stay may impair a surrogate's capacity to integrate information, tolerate ambiguity, and stay engaged in value-based choices, helping to explain the well-documented connection between early depressive symptoms and long-term psychological morbidity after the ICU stay [76-79].

Acute depressive symptoms decreased more in surrogates exposed to REFRAME compared to those unexposed. This finding is consistent with evidence linking reappraisal training to strengthened prefrontal-amygdala connectivity that reduces negative thought patterns observed in depressive psychopathology (eg, rumination and catastrophizing) [80,81]. However, reappraisal may be less preferable or effective for surrogates during emotionally intense periods [82,83]. At baseline, surrogates assigned to REFRAME primarily reported mild (8/28, 28.6%) or moderate (9/28, 32.1%) depressive severity, a psychological context well suited to reappraisal-based strategies. In contrast, most REFRAME-exposed surrogates reported moderate (12/28, 42.9%) or severe (7/28, 25.0%) anxiety symptoms, which may hinder reappraisal efforts. Surrogates often manage intense anxiety and sleep deprivation, diminishing their capacity for emotion regulation and information processing [3,4,84,85]. In such contexts, alternative strategies such as acceptance or distraction may be less cognitively demanding and offer immediate relief, thereby enhancing future reappraisal efforts [86,87]. Future interventional research should promote context-dependent emotion regulation strategies flexibly, empowering surrogates to meet immediate emotional needs and foster long-term psychological resilience [29].

Limitations

Our findings should be considered with several limitations in mind. First, the small, homogeneous sample limits how well the results apply to more diverse populations, such as non-White men. Second, the nonexperimental design introduces selection bias because surrogates who declined participation due to distress may have benefited most from REFRAME, and observed improvements could partly result from regression to the mean, as baseline distress was higher in the REFRAME group. Additionally, participants' awareness of their group assignment might have influenced their decision to consent, potentially inflating acceptability ratings. Third, while REFRAME aimed to reduce acute psychological distress, the short follow-up restricts the ability to assess long-term or delayed effects on decision-making and outcomes. Fourth, higher attrition in the intervention group could indicate scalability challenges in larger REFRAME evaluations. Fifth, we did not set predefined feasibility benchmarks for enrollment or consent rates, which limits formal comparisons across trials; however, the enrollment rate suggests that a future, fully powered randomized trial of REFRAME is feasible. Lastly, reliance on self-report instruments introduces the possibility of social desirability or recall biases, and the PROMIS measures might reflect immediate ICU-related distress rather than chronic psychiatric symptoms, which should be considered when interpreting short-term changes in distress in this context.

Conclusions

We provide preliminary evidence that REFRAME can be successfully implemented and is acceptable to ICU surrogates during the acute phase of critical illness, with qualitative feedback supporting its value in normalizing their experiences and providing concrete strategies for managing distress. We also observed improvements in depressive symptoms that favored surrogates in the REFRAME group, although the nonrandomized design and small sample size prevent definitive conclusions about the intervention's effects. Nonetheless, our findings highlight the practicality of delivering brief, on-demand emotional support to surrogates by tablet-based tools during this high-stress period. A larger, randomized trial with longer follow-up is needed to replicate our findings, evaluate its impact on surrogate decision-making, and examine its downstream influences on long-term psychological well-being. With continued refinement and more rigorous testing, interventions like REFRAME have the potential to improve psychological well-being in surrogates during critical moments of a patient's ICU stay and to inform future strategies for supporting those making high-stakes medical decisions for a loved one with critical illness.

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The corresponding author (GP) used generative artificial intelligence (AI; ChatGPT-4; OpenAI) during the research and manuscript preparation process. In alignment with the Generative Artificial Intelligence Disclosure and Transparency (GAIDeT) taxonomy (2025), tasks delegated under full human supervision included literature search support, organization of references, and proofreading

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and language editing. No sections of the manuscript were automated without human oversight, and all conceptual framing, interpretation of results, and final text revisions were completed by the authors. Generative AI tools are not listed as authors and bear no responsibility for the content, analysis, or conclusions. Some early ChatGPT interactions from the literature search phase were not retained because they occurred before JMIR's policy requiring transcript archiving.

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Data Availability

The data sets generated and analyzed during this study are not publicly available due to ethical considerations; however, they are available from the corresponding author upon reasonable request.

Conflicts of Interest

GP conceptualized and directed the development of the REFRAME intervention but does not hold ownership, patent rights, or a financial interest in the software or its potential commercialization. All other authors declare no financial or nonfinancial competing interests.

Multimedia Appendix 1
REFRAME modules' screenshots.
[PDF File (Adobe PDF File), 406 KB - formative_v10i1e73769_app1.pdf]

Multimedia Appendix 2
Supplementary tables for quantitative and qualitative analyses.
[PDF File (Adobe PDF File), 138 KB - formative_v10i1e73769_app2.pdf]

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Abbreviations

AIM: Acceptability of Intervention Measure
CONSORT: Consolidated Standards of Reporting Trials
CST: coping skills training
eCODES: Electronic Collaborative Decision Support
EMPOWER: Enhancing and Mobilizing the Potential for Wellness and Resilience
IAM: Intervention Appropriateness Measure
ICU: intensive care unit
IRB: institutional review board
PROMIS: Patient-Reported Outcomes Measurement Information System
PSS: Perceived Stress Scale
RA: research assistant
REDCap: Research Electronic Data Capture
REFRAME: Reappraisal-Enhanced Foundation for Regulating Affect and Managing Emotions
UC: usual care

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Original Paper

Web-Based Group Photovoice Through the Lens of Survivors of Critical Illness Recovery: Photovoice Qualitative Pilot Study

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Abstract

Background: The broad spectrum of issues that survivors face after critical illness and the contextual factors that help or hinder remain underexplored, as do their perspectives on what is important during recovery. Photovoice methods offer a means to convey experiences through participant-generated photographs and related narratives that can extend existing notions of illness and wellness.

Objective: This pilot study aimed to (1) describe intensive care unit (ICU) survivor recovery after hospital discharge depicted through survivor-generated photographs and photograph discussions, (2) assess the feasibility of recruiting and retaining participants in a web-based group photovoice focused on ICU recovery, and (3) describe the impact of study participation.

Methods: The web-based group photovoice involved 5 weekly 2-hour group discussion sessions, after which individual interviews were conducted with each participant. Photographs and transcript data from the group discussions and individual interviews were analyzed using a qualitative interpretive description approach.

Results: A total of 5 ICU survivors (4 women and 1 man) participated. The aspects of critical illness recovery that featured prominently included (1) protracted physical recovery; (2) profound psychosocial challenges encompassing fear of the future, emotional turmoil, shifting self-perception, changes in family dynamics, and feelings of disconnection; (3) discrepancies in health needs and support offered; and (4) need for perseverance and resilience. The web-based group photovoice was feasible, with participation characterized as an opportunity to build social connections and draw strength from fellow survivors of critical illness unavailable elsewhere.

Conclusions: Given the compelling insights our pilot study provided into lesser-explored aspects of critical illness recovery, along with its potential therapeutic value and ability to foster social connectedness, future research is warranted to assess the impact of a scaled-up application.

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KEYWORDS

critical illness; recovery; post-intensive care; survivor; photovoice; qualitative; patient engagement; survivors; web-based; pilot study; illness; wellness; photograph discussions; survivor-generated photographs; feasibility; individual interviews; interviews; web-application; therapeutic

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Introduction

There has been a shift in critical care from a focus on survival alone to considerations of quality of life and longer-term recovery. The large majority of people with a life-threatening illness that is treated in an intensive care unit (ICU) will now survive. Among these survivors, more than half experience postintensive care syndrome (PICS)—a myriad of physical, emotional, and cognitive challenges which often co-occur [1,2]. Physical impairment can include muscle weakness, pain, and fatigue, while cognitive impairment can manifest as impaired memory, poor executive function, and inattention [1,3-5]. The most commonly reported psychological challenges include anxiety, depression, and symptoms of posttraumatic stress disorder [3,4]. PICS can endure long-term, although most research has focused on the first 2 years after hospital discharge [6,7]. As a consequence of PICS, survivors commonly experience difficulties with daily life and poor health-related quality of life [8]. Health care needs can also be substantial, with pooled data indicating that 38%-65% of survivors of critical care are readmitted to the hospital in the first year after critical care discharge [9].

Research over the past decade has yielded robust evidence regarding PICS. However, much of this evidence has been focused on a relatively narrow range of medical challenges deemed important by researchers, overlooking the priorities identified by survivors themselves. Current PICS research has described challenges to self-identity, existential worries, disrupted family and interpersonal relationships, financial difficulties, and employment challenges [1,3]. Yet, the broad spectrum of issues that each survivor faces after critical illness and the contextual factors that help or hinder their experiences remain underexplored. Further, only limited research has identified survivors' perspectives on what is important. Moreover, while the development and dissemination of information that describes PICS is necessary, it alone is likely insufficient to fully support survivors and their families. There is a pressing need to explore effective ways to communicate the broader impact of critical illness. This includes extending the focus beyond mere medical issues to address the myriad ways in which life is altered and the diverse experiences of those affected. Efforts to complement medically focused education with innovative communication and engagement strategies could greatly enhance support for survivors. Arts-based research, including web-based group photovoice, offers an innovative, participatory means of illuminating the diverse, underexplored experiences and perspectives of ICU survivors and communicating the broader personal and social impacts of critical illness beyond medical PICS outcomes, thereby informing more meaningful and supportive post-ICU care.

Photovoice methods, conceived by Wang and Burris [10], are arts-based and grounded in the tenets of participatory action research, where community members are empowered to capture and share their health and illness experiences using photographs and narratives. Photovoice provides a process through which participants create a visual, metaphoric representation of illness, facilitating the production of rich, nuanced narratives that convey their experiences, which can extend existing notions of illness and wellness [11]. Photovoice data goes beyond verbal interviews and text alone and is an excellent means for distilling nuanced, emotional, internal, and subjective experiences [12]. Additionally, photovoice empowers participants to not only document but also actively shape, interpret, and articulate what matters to them in their health and illness narratives. Moreover, Photovoice can generate portrayals of health challenges that complement medical information by conveying complex and diverse experiences from patients' perspectives [13]. Viewing authentic experiential portrayals may help people glean insight, hope, and validation, and feel they are not alone [14]. Photovoice, in particular, has the potential to raise awareness of issues that matter to communities as a step to advocacy leading to social change [15].

Using a longitudinal qualitative design, our team has been investigating critical illness recovery at home and drivers of hospital readmission through patient and family caregiver perspective evidence. Recruitment and data collection for the larger project began during the COVID-19 pandemic, forcing our team to pivot to virtual interviews. Thus, we were no longer able to interview people in person in their homes to understand their recovery in the context of their daily lives. As part of the pivot to online data collection, we wondered about the potential value of photovoice in facilitating pieces that were missing from the original home visit plan for data collection, including participant self-expression and self-reflection; articulation of aspects of critical illness recovery of priority to survivors; and the generation of engaging portrayals not available elsewhere. One of our patient partners (AD), who had extensive experience with photovoice, saw the potential of group photovoice with participant dialogue and discussion to garner additional insights into survivor perspectives of critical illness recovery. We also saw the innovative potential of web-based group photovoice to enhance accessibility for survivors across diverse locations and for those facing challenges with mobility and travel, which is common among ICU survivors. We did not know whether a web-based group photovoice would be feasible and what the impact of participation would be on study participants; therefore, the current pilot study was planned.

This pilot study aimed to (1) describe ICU survivor recovery after hospital discharge depicted through survivor-generated photographs and discussions about their photographs, (2) assess the feasibility of recruiting and retaining participants in a web-based group photovoice focused on ICU recovery, and (3) describe the impact of study participation.

Methods

Study Setting, Team, Design, and Methodology

This research was conducted in British Columbia, Canada, where publicly funded universal health care is provided to all residents. This patient-oriented research was co-led by a patient partner (AD) who had lived experience of surviving a critical illness and was involved, not as a research participant, but as a research team member from study conceptualization to knowledge dissemination. Our team collectively had clinical expertise in critical care, research expertise in survivorship,

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qualitative methodologies, and arts-based methods, including photovoice.

Methodologically, this pilot study emphasized group and individual reflections and discussions of participant-generated photographs, participant and researcher interpretations, and the cocreation of a virtual exhibit, although the details of the virtual exhibit are not described in detail here. We integrated the photovoice methodology with a qualitative interpretive description [16] approach when conceptualizing this study and collecting and analyzing data. Interpretive description is designed to meet the knowledge needs of applied health research and was selected for its ability to generate evidence that is relevant for clinical implications [16]. Photovoice and interpretive description share a commitment to understanding complex human experiences, particularly in health and social contexts, while remaining grounded in real-world applicability rather than generating abstract theory. Both allow for methodological flexibility and adaptation based on context, with an emphasis on respectful, meaningful representation of participants' experiences.

We combined photovoice and interpretive description methodologies to leverage photography as a means of gaining unique, survivor-led perspectives, and interpretive description with an eye to clinical application. In contrast to conventional photovoice alone, the use of interpretive description shifted analysis and interpretation beyond participants' experiences as revealed in their photographs, allowing for their interpretation of those experiences as well. Thus, rather than relying on formal analysis of visual data, a common analytic approach in applied health photovoice research, we centered participants' critical reflections as an interpretive mechanism [12]. While photovoice has commonly been anchored in social justice and empowerment research with the intention of promoting community action, this study's adaptation of the method aligned more closely with the desire to generate practice-relevant insights and participant-informed evidence to improve care. Thus, our approach became a means of engaging participants to produce evidence that privileged and affirmed their insights and fostered a meaningful and valuable research process for participants.

Participants and Recruitment

We included participants who had received care within the past 5 years in a Canadian ICU, were admitted to the ICU for a minimum of 48 hours, were aged 19 years or older, spoke English, and could provide informed consent. Exclusions included individuals with neurological diagnoses (brain trauma and intracerebral bleed), who had undergone cardiac surgery or organ transplantation, or who were receiving palliative care. We recruited participants from late fall of 2022 to early winter of 2023 by distributing electronic study posters via e-newsletters and shared on the websites of several organizations that distribute information to patient audiences. The posters were promoted on social media platforms, including X (formerly Twitter; X Corp), LinkedIn, and various Facebook (Meta Platforms, Inc) groups. We used snowball sampling, where participants were invited to share study details with other potentially interested individuals. We have experienced tremendous success recruiting study participants using these strategies for previous studies. Prospective participants who expressed interest by contacting this study's team by telephone or email were screened for eligibility, provided study information, and had the opportunity to seek clarifications or ask questions regarding their participation. All participants provided electronic informed consent.

Our target sample size was 4-6 participants, which was determined based on this study's feasibility aim of having a sufficient number of participants for a group photovoice that would enable robust participant interactions. This feasibility target was informed by the research team members' experiences of conducting photovoice research. A total of 5 individuals participated in this study, and although the sample size was relatively small, we were struck by the high information power in our dataset. Information power is an approach to determining sample size distinct from data saturation. Information power suggests that the more information the sample holds for this study, the fewer participants are needed [17]. We considered the sample to have high information power due to significant variation in participant characteristics (eg, age, medical characteristics, and time since critical illness) and the diverse experiences they described, as well as the richness of their individual interview accounts and the high quality of dialogue during group photovoice discussion sessions.

Group Photovoice Discussion Sessions

In preparation for the group sessions, the patient-partner co-lead (AD) conducted one-on-one virtual meetings with each participant to provide them with an opportunity to recount their experiences with critical illness and establish a shared understanding and connection with the facilitator. During these one-on-one virtual meetings, AD shared with each participant that she had lived experience as an ICU survivor. Subsequently, the group photovoice discussion sessions included five 2-hour weekly virtual sessions via Zoom (Zoom Communications, Inc), facilitated by the project co-leads (AFH and AD). The discussion sessions occurred from January to February 2023. AFH took field notes following each session, capturing overall impressions of common themes and noting unique aspects of each participant's experiences and perspectives.

The first session served as an introductory session, whereas the subsequent sessions involved participants each presenting their photos and discussing them. Each session included a brief icebreaker and overview of the session topic, as well as a wrap-up activity and review of instructions for the next session. Participants were invited to take digital photographs with a device of their choice and upload the images to the University of British Columbia's secure version of OneDrive (Microsoft OneDrive, 2007). A photo reflection form (Multimedia Appendix 1) was emailed to participants to assist in reflecting on their photos before each discussion session, though these were not submitted to the research team.

In group sessions 2 to 5, each participant shared and discussed 2 of their photos with the group, pertaining to distinct themes assigned for each week: going home from the hospital, organizing life and using technology, mental health, and reorienting life. These themes were informed by our in-progress complementary qualitative study investigating critical illness

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recovery at home and drivers of hospital readmission. See Textbox 1 for an overview of the group photovoice sessions. The group cofacilitators used a discussion guide for each week's session to ensure each participant had the opportunity to respond to the participant sharing their photo and to ensure all participants were able to share their photos in the 2 hours.

Textbox 1. Group photovoice content.

Presession

- Virtual meeting with patient partner cofacilitator

Session 1

- Introduction to photovoice and photography

Session 2

- Systems
  - What was it like to transition from hospital to home?
  - What were challenges and facilitators to this transition?

Session 3

- Organization/technology
  - What did you do to organize and adapt your life in your home, at first and/or ongoing?
  - What did you and your family need when you're at home, at first and/or ongoing?

Session 4

- Emotional/mental health
  - What was your emotional and mental health like after your critical illness and intensive care unit (ICU) experience?
  - What are the lingering emotional and mental health effects of your critical illness and ICU experience?

Session 5

- Reorienting life: what's important to understand?
  - Where are you at now with your life?
  - How has your life and ideas about the future changed?
  - What is important for others to understand about life after a critical illness?

Data Collection

The group photo discussion sessions were video recorded, transcribed verbatim using the machine transcription service Temi, accuracy checked, and digital photos were then embedded into the corresponding sections of the transcripts. After completing all 5 photo discussion sessions, 1 team member (KL) conducted one-on-one, semistructured interviews with each participant virtually via Zoom. We used a semistructured guide (Multimedia Appendix 1) that prompted participants to describe their experiences and perspectives of critical illness recovery and the impact of participating in the group photovoice sessions. Each individual interview lasted 45-60 minutes.

Analytic Approach

Guided by interpretive description, we took an inductive thematic approach to the analysis of transcripts, aiming for interpretation rather than pure description and with an eye to clinical relevance. We relied on participants' critical reflections of the photos generated and shared during the group photo sessions and individual interviews, rather than the research team explicitly analyzing the photographs. We used data management software NVivo (version 12; Lumivero, Inc) and conceptual diagramming software Miro throughout the analysis. Several study team members independently reviewed the transcripts to become familiar with the data. One team member (RH) read the transcripts multiple times and used an inductive coding approach to generate initial codes that represented initial patterns, ideas, and diversity related to the research objectives. Through research team dialogue and discussion, these initial inductive codes were grouped and regrouped to create a coding frame that was then applied to all transcript data. Coded data were then extracted and inductively analyzed to identify the main themes and ideas within each theme and to determine an organizing structure for presenting the findings. This involved diagramming to visualize the themes and the use of constant comparative methods to compare and contrast within and across participants, moving from descriptive to more interpretive analysis.

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Research team members discussed and iteratively refined the evolving analysis during biweekly meetings. These group meetings were also an opportunity for collective reflexivity, enabling our research team members, who brought varied experiential, disciplinary, and methodological backgrounds, including a patient partner with experience of ICU survivorship, to reflect on our positionalities, assumptions, and biases, and how we were influencing the data collection, analysis, and interpretation. Through these reflective dialogues, we considered various contextual influences and deepened and clarified emerging insights. These reflexive engagements informed our ongoing analysis and refinement of our interpretations. This study's findings are reported following the COREQ (Consolidated Criteria for Reporting Qualitative Research) guidelines and checklist [18].

We assessed the feasibility of recruiting and retaining participants in this pilot study by evaluating whether we could recruit 4-6 individuals and whether they would complete all group photovoice sessions and the postsession individual interviews.

Ethical Considerations

This study protocol was approved by the University of British Columbia Behavioural Research Ethics Board (H22-02507). After eligibility screening, a REDCap (Research Electronic Data Capture; Vanderbilt University) link containing an e-consent form was emailed to participants, and all participants provided electronic informed consent. Consent was also reaffirmed at the beginning of each one-on-one interview. Participants each received CAD $275 (a currency exchange rate of CAD $1=US $0.73 was applicable) in e-gift card honoraria (CAD $50 for each discussion session and CAD $25 for the one-on-one interview) and were compensated after each session or interview. We attest to maintaining the privacy and confidentiality of research participants' data and/or identity. The data were deidentified.

Results

Overview

A total of 4 women and 1 man participated, with a mean age of 48.6 (SD 16.8, range 22-64) years, with the majority identifying as self-reported European background (4/5), college or university-educated (5/5), married or common law (4/5), and living in a large city (4/5). Participants were admitted for sepsis (2/5), bradycardia (1/5), pulmonary embolus (1/5), or pneumonia (1/5), with the majority having been in the ICU <10 days (4/5). Before critical illness, the majority were employed (4/5); after the critical illness, a minority were employed (2/5), and the majority did not have difficulties living on their total household income either before or after their critical illness (4/5). Participants reported that at the time of this study, they had no problems with their physical activity (2/5), mild impairment in their level of physical activity (2/5), or some change in their level of physical activity such that they required bedrest less than 50% of waking hours (1/5).

The aspects of critical illness recovery that featured prominently in group photo discussions, survivor-generated photos, and individual interviews included (1) protracted physical recovery; (2) profound psychosocial challenges encompassing fear of the future, emotional turmoil, shifting self-perception, and changes in family dynamics and feelings of disconnection; (3) discrepancies in health needs and support offered; and (4) need for perseverance and resilience. The web-based group format was feasible and characterized by survivors as an opportunity to make sense of and share their experiences, feel heard, validated, and supported by others, and learn from their peers.

Protracted Physical Recovery

Through participant-generated photos and commentary, the survivors portrayed the harrowing and physically demanding journey of recovery from critical illness at home. Many recounted the shocking realization of their profound physical decline, particularly the severe loss of muscle strength, especially after extended ICU and hospital stays. The extent of their impairment was starkly highlighted by 1 survivor's recollection of their inability to perform even basic daily tasks, such as preparing and eating meals, drastically diminishing their quality of life. Others characterized their physical recovery as "long and arduous." Despite making significant progress in the months and even years following their critical illness, some continued to grapple with persistent aftereffects, such as impaired physical functioning, chronic pain, and breathlessness, with one expressing deep concern that these lingering health issues would "always be a part of [their] life," fearing she would "hurt like this forever."

Given the severity and persistent physical symptoms and impairments, survivors described their physical home environment as fraught with unexpected obstacles to their recovery. For example, 1 survivor's photo of the stairs leading to their entryway vividly illustrated a tangible physical barrier that also symbolized the profound and related psychological challenges they faced (Figure 1, left). They described the stairs as looking unsafe, and given their physical condition, they doubted their ability to fix them, feeling daunted and overwhelmed with tasks once easily performed. Obstacles such as these stairs not only served as physical barriers, but also as stark evidence of a frightening and arduous recovery. Other survivors captured images representing the significant and sometimes extensive adaptations required for their recovery, including modifications to couches, bathtubs, toilets, and living and sleeping arrangements. Yet, obstacles in the home could not always be overcome, as depicted by a photo titled "ground zero" (Figure 1, right) of a survivor's couch that was the central hub where they spent their days. For all survivors, the initial recovery at home appeared to be marked by seemingly insurmountable obstacles that demanded immense patience and time to overcome.

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Figure 1. Protracted physical recovery; (left) “inviting resilience inside” illustrated a tangible barrier that also symbolized 1 survivor’s psychological challenges. (Right) “ground zero” showed another participant’s couch, the central hub where they spent their days.

Profound Psychosocial Challenges

Overview

The survivors’ photos and commentaries highlighted the profound and intense emotions they endured while recovering at home, including fear of the future, emotional turmoil, shifting self-perception, and changes in family dynamics and feelings of disconnection.

Fear of the Future

Following their hospitalization, the survivors described the uncertainty and fear when initially coming home and then beyond. For some, leaving the safety of the hospital left them apprehensive and fearful about how they would cope at home, the support they would need, and what the future would entail. A photo of a moss-covered log (Figure 2, left) represented the potential dangers 1 survivor feared when “crossing over” from the hospital to home and not knowing what the future held.

Figure 2. Fear of the future; (left) “fear of the future” represented the potential dangers 1 participant feared when transitioning from the hospital to home. (Right) “facing uncertainty” depicted another survivor’s feelings of uncertainty and unpredictability in their recovery trajectory.

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Considering all they had endured, along with the extent and severity of ongoing health issues, the survivors questioned whether they would ever fully recover physically and emotionally and feared an unpredictable future. When discussing their photo (Figure 2, right) titled "facing uncertainty," 1 survivor reflected on not "know[ing] how you were going to come back from that." Survivors described their future physical health as uncertain and fragile, likened to an unclear "road ahead," marked by discouragement, fear, and dread of incomplete recovery or further health setbacks. Moreover, reflecting on their perceived fragile health, survivors worried about their heightened risk for a recurrence of their initial illness that would land them back in the hospital, if not the ICU, as 1 person shared:

> *That's one of the post long haul symptoms I've had, is living with that fear of getting, for my case, getting sick again and ending up back in hospital and experiencing that all over again.* [Participant 3]

Emotional Turmoil

The surge of profound feelings—having survived a life-threatening illness, transitioning from the hospital to home, experiencing uncertainty, fear, anxiety, depression, and profound loneliness—culminated in what 1 survivor characterized as "emotional turmoil." A survivor's photo of cracked eggs (Figure 3, left) symbolized their sense of feeling physically and emotionally "shattered and fragile," and overwhelmed by the extent of recovery they were facing. Another survivor described the emotional volatility and struggles they experienced after returning home as "feeling so vulnerable and just crushed," with their "emotions all over the place" (Participant 4). This emotional fragility was especially pronounced for another survivor who wished to avoid appearing vulnerable in front of others and sought invisibility during these moments. When overwhelmed by their illness or feeling like a burden to their family, they described wanting to escape their feelings and "hide in the shadows," like the hidden angel figurine depicted in their photo (Figure 3, right).

Figure 3. Emotional turmoil; (left) "fragile reflections: cracked resilience" illustrated 1 survivor's sense of feeling physically and emotionally fragile. (Right) "silent retreat within" represented another participant's desire to escape their feelings.

The profound emotional turmoil seemed to be exacerbated by the significant physical challenges the survivors faced. Accustomed to independence before their critical illness, being forced to rely on others for simple tasks at home contributed to them feeling like they were sick and incapable, heightening their sense of vulnerability even with their close family members. For example, 1 survivor shared the discomfort of needing their mother's assistance with showering, which left them feeling extremely embarrassed during and after those moments. While another survivor spoke of their gratitude for the deep love conveyed through their son's assistance around the home, the heavy reliance on others for daily tasks also instilled a sense of vulnerability and even shame and guilt. Transitioning from being independent and active before critical illness to relying on others, even close, trusted, and loving family members, was a disorienting change that resulted in emotional turmoil.

Shifting Self-Perception

Upon returning home, the survivors conveyed feeling as though everything had changed: their homes, themselves, and how others perceived them. One survivor indicated that hospitalization "created distance and disconnect from who I was before and from others, making the world feel out of reach." Several survivors linked their lowered self-worth to "dehumanizing" hospital experiences, such as overhearing ICU clinicians' condescending comments about themselves and other patients, which eroded dignity, lingering for months and even years. Shifts in self-perception also appeared to be closely tied to physical and functional impairments. One survivor's photograph of a broken pedestrian light (Figure 4, left) symbolized their sense of "lower value," and the struggle to "prove my competence," reflecting feelings of powerlessness and visible brokenness.

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Figure 4. Shifting self-perception: (left) "fallen light, rising resilience, and embracing self-worth" illustrated 1 survivor's sense of appearing broken on the outside but still functional and strong within. (Right) "transforming reflections: resilience in change" depicted another participant's shifts in self-perception through unhealthy coping mechanisms.

The survivors commonly described shifts in their self-perception "mentally and physically," and the need to rebuild their self-identity and navigate insecurities through environmental- and self-modifications. Seeing their much-altered reflections in the mirror, 1 survivor recalled removing all mirrors in the house, making drastic wardrobe changes, and cutting their own hair, in what they indicated were "reckless attempts to feel a sense of self." Environmental triggers, such as sounds, smells, and lighting, commonly continued to trigger painful memories and feelings about themselves. Some survivors described feeling lost while trying to navigate their shifts in self-perception and doing so through unhealthy coping mechanisms, as depicted by 1 survivor's photograph of staples on a telephone pole (Figure 4, right):

> *The remaining staples and tacks remind me of the surgeries I've had, leaving staples in my lungs and metal twist ties in my chest. At one point, I just thought, what is the use? I'm doomed anyway. So, I started smoking three years after I'd had heart surgery.* [Participant 2]

With time, some described cultivating awareness of what they needed to rebuild their self-worth and self-esteem. One survivor reflected on learning "to surrender and just see things differently…find happiness within [myself]…without keeping friendships or situations that don't serve [me] anymore" (Participant 5).

Changes in Family Dynamics and Feelings of Disconnection

After having relied so heavily on hospital staff, the survivors described longing for independence in their daily lives during their recovery. Yet, their impaired health and functioning meant they were reliant on their family caregivers in ways they had not been before, and unable to resume their roles in the household, such as cooking, shopping, and caring for others. This contributed to shifts in how they perceived their roles in the family and appeared to result in changes in family dynamics. While the survivors expressed gratitude for the love, care, and support of family members, they commonly indicated feeling overly reliant on others and guilt for burdening them.

The survivors' photos and narrations also conveyed a profound sense of emotional disconnect from their family members, who the survivors thought could not fully relate to their life-threatening ordeal and subsequent challenges. One survivor reflected, "I mean, unless you've really experienced that and you've been through that, I don't think people really do understand or can understand." They perceived that their families were ready to move on from the critical illness experience. Yet, the survivors continued to grapple with the physical and emotional repercussions. Many felt as if their lives had come to a standstill while everyone else's continued, making it difficult to feel connected with friends and family and exacerbating feelings of being misunderstood and lonely.

This sense of alienation left survivors perceiving themselves to be on a "different level, different frequency, different growth" than their family members. Despite yearning for validation and understanding, several survivors described being unable to confide in their family members and being compelled to protect them, even at the expense of their own emotional well-being. Consequently, 1 survivor created a photo of themself smiling but overlayed blue tears on their cheeks to depict their masking

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of emotions, leaving them feeling utterly alone with their physical and emotional pain. They explained,

> *Despite experiencing vulnerability and emotional turmoil, I felt compelled to protect those around me and prioritize their well-being. My family, unaware of the severity of my condition, struggled to cope, and I was preoccupied with their emotions rather than addressing my own. I faced anxiety, panic attacks, and physical pain alone, unable to openly express my struggles… I felt like for everybody else I had to put on that mask, or slap on that smile, or put on that happy face and just pretend that everything was fine… I was trying not to make everybody else worry.* [Participant 4]

Another survivor recounted negative interactions with their family members, who conveyed limited empathy and understanding of the suffering they continued to endure, indicating they had "no one really in [their] immediate environment that [they] could truly empathize with or that could support [them]." This survivor recalled their family's disappointment in their slow recovery, leaving them feeling rejected, invalidated, and ashamed, with no one to turn to for practical or emotional support, deepening their sadness and isolation in recovery.

Need for Perseverance and Resilience

Through their photos and narratives, the survivors depicted the immense difficulty of confronting numerous challenges while recovering at home. Still ongoing, this process was a bumpy road, a journey fraught with setbacks and obstacles. Survivors described making tremendous efforts to heal and resume their family, work, and social roles and responsibilities. However, with no advice on how to do so and uncertainty about what they could do, this was not always straightforward, and setbacks were commonly described. For example, 1 survivor's photo of their apron (Figure 5, left) represented their resumption of previous responsibilities that were ultimately too much to manage, leading to a pivotal moment in their recovery journey:

> *After a period of progress and resuming my daily responsibilities, exhaustion and emotions caught up with me, leading to a traumatic panic attack three months later. Recognizing the need for space and clarity, I took a trip…. This time away allowed me to reflect, reassess my priorities, and make important changes in my life…. Hitting rock bottom physically and mentally ultimately led me to emerge stronger.* [Participant 5]

Figure 5. The need for perseverance and resilience; (left) "hiatus" represented 1 survivor's resumption of previous responsibilities that were ultimately too much to manage. (Right) "stitches of resilience" depicted another participant's process of building resilience.

With time, all the survivors indicated that their mental health improved, though this took intentional effort. For 1 individual, their beloved cat provided a "sense of normalcy and unconditional love," providing constant companionship and "serving as a source of comfort during times when I felt misunderstood or alone." Mental health counseling was helpful for 2 survivors, while others found ways to help make sense of their experiences, express and manage their emotions, and set future goals. Useful tools included journaling, vision boards, and reading about others' experiences and sharing their own experiences online.

The survivors also shared their journey of recovery as encompassing a shift in their self-perception, personal growth, and a transformed outlook on life. Some described learning to embrace their current circumstances by reframing their fears and obstacles as opportunities for mental and physical

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self-growth, as highlighted by 1 survivor's comment that their "fears actually could be the best thing that [ever happened]." Others portrayed self-acceptance of the "new versions" of themselves as key to embracing their current circumstances, reflecting that "it's okay to accept that you may never be that former self again."

Some survivors appeared to draw strength from the knowledge that they survived a life-threatening illness and continued to persevere through recovery. Acceptance, positivity, and resilience were fostered by cultivating an attitude that they were a "work in progress" and that "this too shall pass." The survivors described embracing the imperfection in recovery, emphasizing the significance of trying to have a "humbling outlook and gratitude in life." One survivor symbolized their ongoing healing and building of resilience with a photo of a hat they were knitting (Figure 5, right), indicating that "just like this unfinished hat, I will continue to work on myself, knowing one day I will reach a point of completion and resolution."

Unmet Health Needs

Throughout group discussions and individual interviews, the survivors remarked on significant unmet health needs due to insufficient follow-up care after being discharged from the hospital. They emphasized the desire for a mentorship or support group or a point of contact for help when leaving the hospital to help address the "massive gaps in [the] healthcare system." They also suggested ICU diaries and journals to help survivors and their family members fill memory gaps. The survivors commonly indicated that the lack of mental health support severely and negatively impacted their recovery:

> *If there's anything the system really needs to improve on it's the treatment of patients and also to focus on the mental aspect of being hospitalized because we felt like once we were discharged, they kind of just forgot about us and they never really followed up.* [Participant 1]

The survivors highlighted the intrinsic link between mental and physical health in their commentaries and photos (Figure 6), noting that "if you're not well mentally, you can't do well physically." They expressed frustration with the prioritization of physical symptoms while neglecting emotional and mental health aspects.

Figure 6. Unmet health needs; "the art of noticing" illustrated the link between mental and physical health in recovery.

Feasibility of Web-Based Group Photovoice

Five participants were recruited, all of whom completed all group photovoice discussion sessions, submitting a total of 42 photographs, and completing a one-on-one interview, thus suggesting the feasibility of this study's protocol. However, given that there are no dedicated follow-up clinics, aftercare programs, or recovery initiatives in the province to recruit

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through, reaching eligible participants proved challenging, which prolonged the process of finding participants available and willing to commit to the project. A few months following the completion of the group sessions, all survivors became patient partners to pilot the development of a website [19] to disseminate their curated photos.

Impact of Web-Based Group Photovoice

Overview

Although the web-based group photovoice was not initially intended to have a therapeutic impact, survivors overwhelmingly reported immense benefits from participating.

Power of Images: Making Sense and Sharing

The group photovoice experience enabled survivors to revisit and reinterpret their ICU experiences and recovery at home. Participants reported that the structured photograph assignments prompted self-reflection, helping them make sense of all they had been through. This introspective journey was therapeutic and empowering, reinforcing their identities as resilient survivors. The group setting also offered a unique platform for sharing and interpreting their photographs, with survivors struck by the power of photography to convey emotion and understanding meaning. Centering the photographs during sharing sessions provided an opportunity for individual expression and communal connection, as participants found resonance and validation in the images and explanations of others:

> *Some [photos] were very powerful images and spoke very profoundly to my own journey…. We looked at [someone else's] picture and thought "[I can] hardly wait to hear the story behind the picture." Each one of them always seemed to hit the mark once you got the explanation.* [Participant 3]

The process of sharing and interpreting photographs within the group context required a high degree of openness, which participants also found to be "humbling" and a "privilege."

Feeling Heard, Validated, and Supported by Others

The survivors described discovering a powerful sense of community, exchanging advice and "words of wisdom" with others who had also endured critical illness. This newfound connection was characterized as providing strength and validation, helping them realize they were not alone in their struggles. Survivors expressed a sense of being profoundly heard and understood in a way they had not before, and "like nobody else could." One survivor's description conveyed the deep emotional connections, the impact of empathy, and the healing that was facilitated by the group discussions.

> *To be able to talk about it so freely and to know that people can understand and empathize was so comforting. And I think I really needed that. I don't think I really realized how validating it would be to talk about it with a group where they've also experienced the same treatment…. It makes me quite emotional to think that... people [I] have never met, really were able to make me feel so whole and so strong again.* [Participant 1]

Further, the survivors highlighted that the development of group cohesiveness was rapid and profound. They reported an immediate sense of belonging and genuine care, contributing to a supportive and safe environment. This nurturing atmosphere was conveyed as crucial in enabling the survivors to share sensitive personal experiences and receive empathetic feedback. Several remarked on the transformative power of group photovoice, describing it as a "genuine expression of experience," "part of a healing process that [I] didn't even know existed," "the missing link in [my] recovery," and a potential "form of therapy."

Learning From Their Peers

Survivors expressed that their fellow participants helped them learn coping skills and ways to adjust to their current situation. One survivor commented on reorienting their outlook to a more "positive approach" based on what another survivor had exuded. The survivors appreciated "all these different views, points of view, or at least expressions of experience." The exposure to the group's diversity in age demographics, life experience, and time duration from ICU discharge was seen as a major strength since it allowed participants to learn from the vast range of experiences. Being able "to provide that sense of hope and encouragement to those that aren't quite there yet" was described as healing in itself. Empowered by the empathy and compassion of fellow participants, survivors noted they felt that they could lower their protective guard, embrace hope for their ongoing recovery, and offer comfort and support to others on a similar journey.

Discussion

Principal Findings

Our findings highlight aspects considered by critical illness to be central to recovery, namely, immense physical and emotional health challenges along with shifting self-perception, changes in family dynamics, and feelings of disconnection. Despite the enormity of health needs, these were not accompanied by access to appropriate health care services or support. Recovery was further depicted as requiring substantial perseverance, but also contributing to resilience and strength. The group photovoice web-based format was feasible and perceived by survivors to be an opportunity to make sense of and share their experiences, feel supported by others, and learn from their peers.

Comparison to Prior Work

Our findings align with the robust literature describing the persisting physical sequelae and functional impairment common post-ICU [20,21] and extend knowledge of how the home environment can be fraught with obstacles to recovery. These obstacles were unexpected and required marked effort from survivors and, oftentimes, their family members to make the necessary adaptations. Our findings suggest that functional impairments are not solely inherent to individuals; rather, the home environment plays an under-recognized and modifiable role in influencing recovery. Our photovoice approach enabled participants to convey the contexts shaping their everyday realities experienced during recovery. Given that ours was a small pilot study, additional research is warranted to understand

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the extent and nature of obstacles to recovery commonly encountered in the home, adaptations to support survivors in their activities of daily living, and the role that occupational therapy and home assessments could play.

Emotional challenges of fear of the future, uncertainty, vulnerability, emotional turmoil, guilt, loneliness, and social disconnect figured prominently in our study. These appeared to encompass a much broader array of psychological sequelae than the anxiety, depression, and posttraumatic stress that are most often described in the literature [3,4]. Further, the emotions highlighted by participants through their photographs not only stemmed from physical and cognitive sequelae but were entwined with newfound dependence on others, which was couched in shame, and changes in family dynamics. These relational dimensions of recovery were uniquely conveyed through participants' photographs and commentary. Further exploration of the full scope of emotional challenges may reveal targets for innovative psychosocial interventions, such as those found in survivorship research for other illnesses. For example, in the last decade, fear of cancer recurrence has emerged as a problematic long-term issue for survivors of cancer, with promising treatment options being investigated [22]. Similarly, while a small but growing body of literature suggests that survivors of critical illness may experience changes in personal identity and outlook [3,23], the participants in our study conveyed the importance of their experiences of shifting self-perception. Pursuing this line of inquiry in future research might inform the development or adaptation of interventions or approaches targeting identity that show promise elsewhere, such as narrative therapy [24-26].

An important finding from this pilot study that warrants further inquiry was the participants' photographs and narratives of perseverance and building of strength and resilience, which may be akin to posttraumatic growth. By inviting participants to express what was most meaningful in their experiences, the photovoice approach shifted the findings from a focus solely on challenges commonly described in the literature to also include aspects of recovery where participants found meaning, ways of coping, and strength. Posttraumatic growth is the experience of positive psychological change that can result from the struggle with life crises and trauma, and can manifest in a variety of ways, including an increased appreciation for life, more meaningful interpersonal relationships, an increased sense of personal strength, changed priorities, and a richer existential and spiritual life [27]. Jones et al [28] made a solid argument for the relevance of the concept for survivors of critical illness, noting parallels to other populations who experience trauma. They also proposed strategies and mechanisms that could promote posttraumatic growth during and after ICU stays and suggested avenues for future research including, integrating assessments of posttraumatic growth into ICU aftercare and self-help resources, exploring which domains and trajectories of posttraumatic growth are unique to ICU survivors, determining which interventions could foster posttraumatic growth after critical illness, and identifying effective methods to disseminate and implement this knowledge among providers to encourage posttraumatic growth in patients [28].

Our findings resonate with scholarship on illness narratives, especially the ways that survivors of critical illness described disrupted embodiment and self-identity. Frank [29] proposed that illness narratives often reflect altered experiences of being in one's body, the search for meaning, self-identity reconstruction, and repositioning of relationships. Our participants also expressed uncertainty, shame, and vulnerability that appeared to reflect existential disruptions associated with illness and a disintegration of the taken-for-granted body and a reorientation in sense of self [30]. The shame associated with newfound dependence and altered family dynamics also aligns with dignity-focused scholarship, which emphasizes the psychosocial and relational dimensions of suffering and identity erosion during serious illnesses [31]. By surfacing these layered embodied, emotional, and relational dimensions through photographs and related narratives, our study uniquely situates post-ICU recovery as not only medical or functional but also as an embodied, existential, and socially mediated experience. As a medium of expression, photovoice helped convey the recovery experience from the vantage of survivors.

The participant-generated photographs and commentary in our study served as distinctive and authentic portrayals of aspects of critical illness recovery that were important to participants. Recognizing the value of these portrayals to provide insight and validation, our team piloted the codevelopment with all study participants of a virtual gallery as a knowledge translation strategy [19]. Among other populations, photovoice exhibits can be a powerful means of confronting gaps between what researchers and policymakers assume people experience and what people show that they experience and need [32]. By creating space for participants to convey their own ideas and experiences, photovoice can reinforce people's right to be seen and heard as they choose [33]. This is particularly relevant for people who have survived critical illness, during which vulnerability and loss of control can be marked. Photovoice exhibits can further serve as a means of moving findings outside traditional academic settings, perhaps to be more appealing and accessible to public audiences, and a bridge to action and change at individual, interpersonal, community, institutional, and policy levels [32,34]. Further research examining the impact of photo exhibits in the context of critical illness recovery could provide novel means of raising awareness and inspiring change.

Strengths and Limitations

Our piloting of web-based group photovoice suggested that this approach was not only feasible but was also impactful. The therapeutic benefits and enhancement of social ties apparent in our study seem akin to benefits found in arts-based research, including photovoice, reported in other populations [15,33,35]. The use of group photovoice and even other arts-based methods ought to be studied further as a complement to existing interventions, such as peer support groups. Emerging evidence suggests that peer support among survivors of critical illness can be beneficial, with many of the mechanisms similar to those we witnessed in our group photovoice study. By sharing experiences through peer support groups, survivors have reported diminished anxiety and concerns, enhanced motivation and hope, feeling validated, gaining a greater understanding of their ICU illness and care trajectory, and experiencing a sense

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of purpose in assisting others [36,37]. Our group photovoice was facilitated by a patient partner who was an ICU survivor themselves. This approach seemed to foster trust and rapport, with participants coming to the first workshop session appearing comfortable sharing sensitive experiences. This peer connection may have enhanced the relevance and depth of the data, as well as the participants' sense of mutual support. However, this peer facilitation may have also introduced potential biases, such as assumptions of shared understanding and a failure to fully explore aspects not aligning with those of the facilitator. Further, social desirability may have influenced participants such that they shaped their narratives and photographs to align with shared experiences or the facilitator's expectations.

While our findings are promising, it is important to note that this was a pilot study with a small, self-selecting sample. Future research is required to assess the scalability and potential integration of group photovoice into clinical programs or existing care structures. Further, a key consideration in photovoice, like other arts-based methods, is the potential for exclusion. Collective and creative formats might not appeal to all individuals, particularly those less comfortable with expressive modalities or group-based activities. As observed in our sample, participation skewed toward self-reported European background, more educated individuals, living with a family member, and in an urban area, suggesting a need to consider means of promoting accessibility, equity, and cultural appropriateness in recruitment efforts and future offerings of group photovoice. Otherwise, future research risks contributing to health inequities. Moreover, while virtual delivery enhanced accessibility and flexibility, it also may have introduced inequities related to digital literacy, technology access, and privacy that warrant future consideration. Future research ought to attend to these structural and digital barriers in study design, recruitment, and support for participation to promote photovoice that is inclusive and representative of diverse survivor experiences.

This pilot study, conducted in Canada during the COVID-19 pandemic, involved 4 women and 1 man, most of whom had some university or college education and were financially stable. Consequently, the insights into critical illness recovery presented may not reflect the experiences of individuals in different geographic or socioeconomic contexts. The mental and physical strains of the pandemic may also have influenced the results. Additionally, the benefits observed from participating in web-based group photovoice sessions may not extend to those who did not choose to participate, or to individuals who do not see value in sharing experiences or who are not emotionally prepared for such engagement. Photovoice demands significant time and emotional investment, which many ICU survivors may not be able to afford, especially at time points in their healing when they are at their most vulnerable. While increasing access geographically, the virtual format may also limit the participation of those with minimal access to a computer or phone, possibly excluding individuals facing significant social and structural challenges.

Future Directions

Given the insights our small pilot study has provided into lesser-explored aspects of critical illness recovery, the potential therapeutic value and ability of web-based group photovoice to foster social connectedness, and possibilities for innovative knowledge translation, future research is warranted to assess the impact of a scaled-up application.

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Authors' Contributions

AFH, who is an expert in research examining the health service needs of survivors of acute life-threatening illness, supervised all researchers. AD, LMC, AFH, and KL conceptualized this paper, designed the study, and handled the methodology. AD and AFH facilitated group discussion. KL conducted one-on-one interviews. KL, AFH, and RH carried out the data analysis. The RH wrote the initial manuscript draft, and KL and AFH executed additional writing, review, and editing. All authors have read and agreed to the published version of this paper.

Conflicts of Interest

None declared.

Multimedia Appendix 1
The photo reflection form and the one-on-one interview guide.
[DOCX File , 29 KB - formative_v10i1e66601_app1.docx]

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Abbreviations

COREQ: Consolidated Criteria for Reporting Qualitative Research
ICU: intensive care unit
PICS: postintensive care syndrome
REDCap: Research Electronic Data Capture

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Original Paper

Assessing the Feasibility, Usability, Acceptability, and Efficacy of an AI Chatbot for Sleep Promotion: Quasi-Experimental Study

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Abstract

Background: Poor sleep is a concerning public health problem in the United States. Previous sleep interventions often face barriers such as high costs, limited accessibility, and low user engagement. Recent advancements in artificial intelligence (AI) technologies offer a novel approach to overcoming these limitations. In response, our team developed a prototype AI sleep chatbot powered by a large language model to deliver personalized, accessible sleep support.

Objective: This study aimed to examine the feasibility, usability, acceptability, and preliminary efficacy of the AI chatbot for sleep promotion.

Methods: We conducted a quasi-experimental, single-group study with adults in the United States aged 18 to 75 years who self-reported poor sleep. The chatbot was integrated into a commercially available messaging app. Participants were asked to engage with a virtual sleep therapist via texting over 2 weeks. The chatbot provided ongoing, individualized sleep guidance and adapted recommendations based on participants' prior conversations. Feasibility, usability, and acceptability were descriptively summarized. Sleep was assessed using questionnaires before and after the intervention.

Results: Of the 107 adults who enrolled in the study, 88 (82.2%) completed chatbot registration. Among these 88 participants, 65 (73.9%) initiated interactions, and 44 (50%) completed the 2-week intervention. The final analysis included 42 adults (mean age 36, SD 11 years; n=12, 28.6% male). On average, participants engaged with the chatbot for 58 (SD 42) minutes, with each chat session lasting approximately 9 (SD 6) minutes. Most reported favorable experiences with the chatbot. The average usability score was 85.2 (SD 10.7) out of 100, which was well above the benchmark of 68. The chatbot was rated as highly acceptable, with a satisfaction score of 27.3 (SD 4.1) out of 32. All participants perceived the chatbot as effective, with ratings ranging from "slightly effective" to "extremely effective." The preliminary evidence showed improved sleep outcomes after chatbot use: total sleep time increased by 1.4 hours (P<.001); sleep onset latency decreased by 30.9 minutes (P<.001); sleep efficiency increased by 7.8% (P=.007); and scores improved for perceived sleep quality (mean difference [MD] −5.4; P<.001), insomnia severity (MD −7.9; P<.001), daytime sleepiness (MD −4.7; P<.001), and sleep hygiene skills (MD −13.2; P<.001). No significant change was observed in sleep environment (MD −1.1; P=.16).

Conclusions: Our AI chatbot demonstrated satisfactory feasibility, usability, and acceptability. Improvements were observed following chatbot use, although causality cannot be established. These findings highlight the potential of integrating state-of-the-art large language models into behavioral interventions for sleep promotion. Future research should include objective sleep measurements and conduct randomized controlled trials to validate the study findings. If confirmed, this AI chatbot could be scaled to support sleep health on a broader level.

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KEYWORDS

artificial intelligence; AI; large language models; chatbot; feasibility; usability; acceptability; sleep

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Introduction

Poor sleep is a major public health concern in the United States. Major guidelines recommend that adults sleep at least 7 hours per night [1,2]. Over 25% of adults in the United States do not meet this recommendation, and 14.5% had difficulty falling asleep on most days or every day over the previous month [3]. Deviations from optimal sleep duration and quality play a crucial role in the development and progression of various health conditions. For example, adults with chronic experience of poor sleep have a higher risk of developing depression later in life [4]. Similarly, extensive epidemiological evidence links insufficient sleep to an increased risk of cardiovascular disease [5-7]. Adults with poor sleep quality have a 1.38-fold higher mortality rate in comparison to those with good sleep quality [8]. The ramifications extend beyond individual health. Poor sleep directly links to reduced productivity, lower work performance, and increased health care use [9]. On average, poor sleep is associated with US $3400 to US $5200 in additional health care expenditures per person [10]. At the population level, insufficient sleep causes the United States to lose approximately 1.23 million workdays annually, with projected economic costs of up to US $456 billion by 2030 [11]. Despite these serious consequences, health care providers rarely target sleep as an approach to improve health outcomes [12]. Therefore, implementing an effective intervention to alleviate the public health burden resulting from poor sleep is a must.

Existing behavioral interventions such as cognitive behavioral therapy for insomnia (CBT-I) have proven effective in improving sleep outcomes. However, their widespread use is primarily constrained by high costs, limited accessibility, and a lack of personalization. These barriers hinder the broad adoption of sleep interventions. Consequently, digital tools have emerged as a solution for enhancing sleep health. There has been growing interest in incorporating artificial intelligence (AI) into treatments. AI-based technologies, particularly conversational tools, have shown growing evidence of health behavior change. A recent systematic review found that chatbots can promote healthy lifestyles, support smoking cessation, improve medication adherence, and reduce substance use [13]. By simulating humanlike conversations, chatbots deliver on-demand, tailored support that is typically not achievable with traditional in-person or telehealth care. Although limited, emerging research has suggested the potential benefit of using chatbots in improving sleep [14]. Nurses who used a chatbot that offered care support and coping assistance reported better sleep quality after 6 weeks in comparison to the control group [15]. Another study used a chatbot to gather conversations about sleep from parents of preterm and term infants to better understand their personal experiences [16]. Yet, most chatbot interventions still rely on decision tree algorithms, which often struggle to interpret conversational nuances and context. Recent breakthroughs in generative AI offer novel alternatives to conventional behavioral interventions. Generative AI systems learn patterns from large datasets to produce new, realistic, and coherent content that resembles human communication. A prominent example is large language models (LLMs), an advanced form of generative AI that uses deep learning to comprehend and generate natural-sounding responses. Currently, there is scarce or no evidence on integrating state-of-the-art LLMs in sleep interventions. In response, we developed a prototype AI chatbot using LLMs that provides responses specifically to promote sleep. This study sought to (1) evaluate the feasibility, usability, and acceptability of the AI chatbot; and (2) test the preliminary efficacy of the AI chatbot on improving sleep outcomes.

Methods

Study Design and Sample

We used a quasi-experimental 1-group design. Using a convenience sampling approach, participants who self-reported poor sleep in the previous month were recruited nationwide in the United States. Our inclusion criteria were (1) age of 18 to 75 years, (2) a raw score of 23 or higher on the Patient-Reported Outcomes Measurement Information System Sleep Disturbance [17], (3) ownership of a smartphone and ability to access the internet, (4) willingness and ability to participate through texting on a smartphone, and (5) ability to read and understand English. Individuals were excluded if they were pregnant, lactating, or concurrently participating in other research studies focused on lifestyle modifications.

Generative AI Technology

Figure 1 illustrates the automated workflow of the generative AI technology. The main body of the infrastructure comprises a central app designed by our study team, which communicates with a messaging app and LLMs via an application programming interface.

We created an AI chatbot on the messaging app platform that allowed participants to exchange texts as if they were interacting with a real sleep therapist. The chat operates on a commercially available messaging platform, which has a wide user base in the United States and is available to both iOS and Android smartphones. When a participant sends a message to the chatbot, the message is pushed to the central app. The central app is entirely controlled by our study team. It processes incoming messages based on the participant's chat history and then sends a query to the LLMs. We used Gemini-1.5-pro-001 (Google) and the CBT-I manual as the context for each prompt, with guidance focused on the following treatment components: stimulus control (strengthen the bed as a cue for sleep), sleep hygiene practices (promote healthy sleep habits), relaxation training (improve techniques that relax the mind and body), and cognitive restructuring (change negative thoughts and beliefs about sleep). For safety concerns, the prompts were designed to exclude sleep restriction therapy, a key CBT-I element that involves reducing time in bed. The responses from the LLMs then return to the central app, which subsequently forwards them to the participant through the chatbot on the messaging app.

To ensure participant safety, we implemented several safeguards and configured the LLMs with a reasonably high safety setting. Details of the model configuration and safety parameters are provided in Multimedia Appendix 1. All conversational inputs and outputs were screened for hate speech, harassment, sexual

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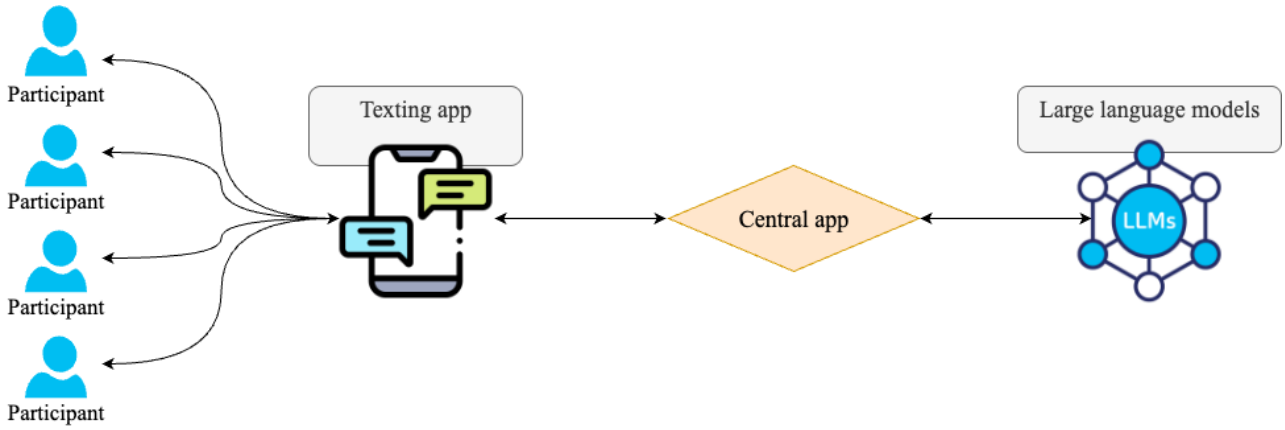
content, self-harm, or medical misinformation. Before deployment, we prompted the LLMs to avoid providing medical diagnoses or medication advice and stress tested them with adversarial prompts. Participants were instructed not to share personal identifiers when interacting with the chatbot. Any inadvertent disclosures were immediately removed from the chat history by the study team. Communications with the LLMs and with the third-party messaging app were encrypted in transit using HTTPS. Our team monitored the conversational dialogues daily throughout the intervention phase to ensure that the advice delivered to participants was appropriate and safe, and to promptly identify any conversations necessitating immediate action (eg, indication of self-harm).

Figure 1. Workflow of the generative artificial intelligence sleep chatbot. LLM: large language model.



Intervention Description

The intervention lasted 2 weeks and was delivered through the chatbot designed to function as a virtual sleep therapist. It created individualized treatment plans tailored to each participant's needs and feedback. By applying motivational interviewing techniques, the chatbot explored underlying causes of sleep disturbances and identified appropriate solutions aligned with key components of CBT-I. If certain issues were unresolved, the chatbot conducted further analysis using LLMs to examine additional strategies. The chatbot also retained memory of previous conversations, allowing it to follow up with participants, reinforce recommendations, and detect any challenges in adherence. An example of conversations between the AI chatbot and a participant is illustrated in Figure 2.

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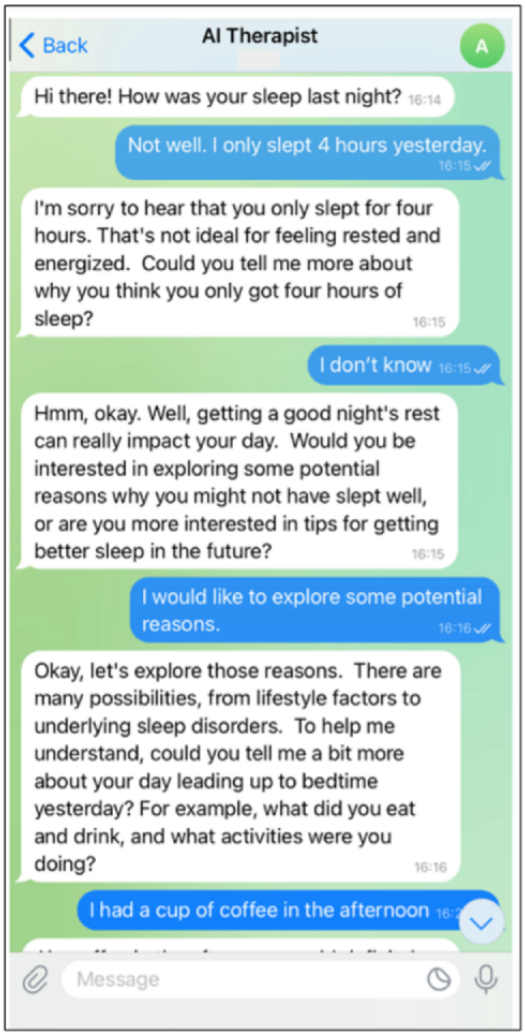
Figure 2. Example of conversations between the chatbot and participant.



Ethical Considerations

This study was approved by the New York University Institutional Review Board (FY2024-9037). Informed consent was obtained from all participants before any procedures. Participation was voluntary. Individuals could withdraw at any time or skip any question without penalty. Each participant was assigned a unique study ID. Data were securely stored on university-managed, access-controlled devices and systems with access limited to study personnel. The university devices and systems encrypt the data at rest. We did not have a data processing agreement with the third-party messaging app. However, participants were informed during the consent procedures that the study required the use of a third-party messaging platform. All personal identifiers were removed before analysis. Deidentified analytic files will be retained for 5 years after publication and then permanently deleted.

Procedures

After providing informed consent, participants registered for the chatbot on a third-party messaging app. They then completed a prestudy survey that inquired about their sociodemographic information, clinical background, and sleep characteristics. The intervention began when participants initiated conversations with the chatbot via texting. To protect confidentiality and privacy, the chatbot only responded to those who initiated contact. Participants were instructed to text with the chatbot at least every 3 days for 2 weeks, with each chat session lasting approximately 3 to 5 minutes. We classified individuals as dropouts if they interacted with the chatbot fewer than 4 days in total or had an average daily duration of engagement of less than 1 minute during the intervention period. In this study, participants could chat as frequently or as long as they preferred. After the initial conversations, the chatbot followed up with participants if no interactions were detected within 72 hours. In subsequent sessions, the chatbot checked in with participants about their sleep concerns, reinforced recommended sleep promotion strategies, and suggested new ones when necessary. Finally, participants completed a poststudy survey upon concluding the intervention.

Measurements

Participant Flow

Feasibility was assessed based on the following metrics: (1) the proportion of individuals who registered for the chatbot; (2) the proportion of registered participants who initiated engagement with the chatbot; (3) the proportion of active participants who completed the 2-week intervention; and (4) chatbot engagement, including the total number of days interacting with the chatbot, total duration of chat sessions, and average duration per session.

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Usability

Usability was measured via the Chatbot Usability Questionnaire (CUQ) [18]. This instrument consists of 16 items scored on a 5-point Likert-type scale ranging from 1 (“strongly disagree”) to 5 (“strongly agree”). It measures personality, onboarding, user experience, and error handling of a chatbot. Odd-numbered items assess positive aspects, whereas even-numbered items assess negative aspects. Responses to all items are summed and then converted to a 100-point scale to be comparable with the System Usability Scale [19]. A total score of 68 is typically used as the threshold for acceptable usability [20].

Acceptability

Acceptability was measured using the adapted Client Satisfaction Questionnaire (CSQ) [21] and 6 questions developed by the study team. The original CSQ is an instrument to assess a client’s overall level of satisfaction [21]. We revised the wording to make the questions fit with the study context. Each item is rated on a 4-point Likert scale from 1 (“poor”) to 4 (“excellent”). The total score ranges from 8 to 32, with a higher number indicating greater satisfaction. We also developed the following questions to evaluate the participants’ experiences: (1) “What changes have you noticed about your sleep after engaging with the chatbot?”; (2) “How effective were the chatbot’s tips for improving your sleep?” (rated from 1=“Not effective” to 5=“Extremely effective”); (3) “Did the chatbot offer personalized advice based on your input?” (rated from 1=“Never” to 5=“Always personalized”); (4) “How well did the chatbot adapt to your sleep concerns?” (rated from 1=“Not at all” to 5=“Very well”); (5) “How well did the chatbot remember your preferences in follow-up conversations?” (rated from 1=“Not at all” to 5=“Very well”); and (6) “Did you feel supported by the chatbot during your interactions?” (rated from 1=“Not at all” to 5=“Very well”). These self-developed items were validated scales, and they were intended only for formative evaluation.

Preliminary Efficacy

The preliminary efficacy of the chatbot was examined using several metrics.

Habitual sleep patterns and perceived sleep quality were measured using the Pittsburgh Sleep Quality Index [22]. This 19-item instrument evaluates sleep quality and disturbances over the previous month. The items cover 7 components: subjective sleep quality, sleep onset, sleep duration, habitual sleep efficiency, sleep disturbances, use of sleep medication, and daytime dysfunction. Each component score ranges from 0 to 3. These components are then summed to generate a global score ranging from 0 to 21, where a cutoff score of 5 or higher indicates poor sleep quality. Additionally, we used items from the Pittsburgh Sleep Quality Index to assess 3 habitual sleep patterns, which included sleep onset, sleep duration, and sleep efficiency. Sleep onset was measured using the question “How long has it usually taken you to fall asleep each night?” Sleep duration was measured using the question “How many hours of actual sleep did you get at night?” Sleep efficiency was calculated by dividing sleep duration by time spent in bed and multiplying the result by 100.

Insomnia severity was measured using the Insomnia Severity Index [23]. The Insomnia Severity Index assesses the severity and impact of insomnia over the previous 2 weeks. It comprises 7 items, with the score of each item evaluated on a 5-point Likert-type scale. The total score ranges from 0 to 28, and a higher score indicates more severe insomnia symptoms. A total score over 14 indicates clinical insomnia.

Daytime sleepiness was measured using the Epworth Sleepiness Scale. The Epworth Sleepiness Scale is an 8-item, 4-point Likert scale that measures the likelihood of dozing off or falling asleep in 8 common life situations [24]. Participants who had not experienced some of the situations were asked to estimate how each might affect them. A total score over 10 indicates excessive daytime sleepiness.

Sleep hygiene was measured using the Sleep Hygiene Index [25]. The Sleep Hygiene Index is a 13-item, 5-point Likert scale to evaluate the frequency of participants engaging in specific sleep behaviors. The sum of each item score yields a global score ranging from 0 to 52, with a higher score representing more maladaptive behaviors that compromise sleep hygiene.

Sleep environment was measured using the Assessment of Sleep Environment [26]. This instrument includes 13 items that quantify the impact of light and dark, noise, smell, humidity, comfort of the sleeping surface and pillows, and safety on an individual’s sleep. Each item is rated on a scale from 0 (“strongly disagree”) to 3 (“strongly agree”) and can be summed to obtain a total score. A higher total score suggests living in a poorer sleep environment.

Statistical Analysis

Sociodemographic and clinical characteristics were summarized as mean and SD for continuous variables or as count and percentage for categorical variables. Conversational dialogue data were analyzed descriptively to assess the level of engagement. Usability and acceptability measures were used to visualize bar plots. Changes in each sleep measure before and after the intervention were assessed for normality using the Shapiro-Wilk test and visualized using histograms and *Q-Q* plots. Outliers were identified and removed. Depending on whether normality assumptions were met, pretest-posttest differences in each sleep variable were evaluated using either 2-tailed paired *t* tests or Wilcoxon signed rank tests. We also computed the Cohen *d* to estimate the effect size associated with each pretest-posttest change. Additionally, we used scatterplots to visualize individual changes in sleep variables, with posttest values on the x-axis and pretest values on the y-axis. We also calculated the proportion of participants who showed improvements in each sleep measure after the intervention. All statistical analyses were performed using R (version 4.5.0; R Foundation for Statistical Computing) [27]. The significance threshold was set at α=.05.

Results

Feasibility

Figure 3 presents the participant flow diagram for this study. A total of 196 individuals were screened for eligibility. Of those 196 individuals, 107 (54.6%) adults met the study criteria and

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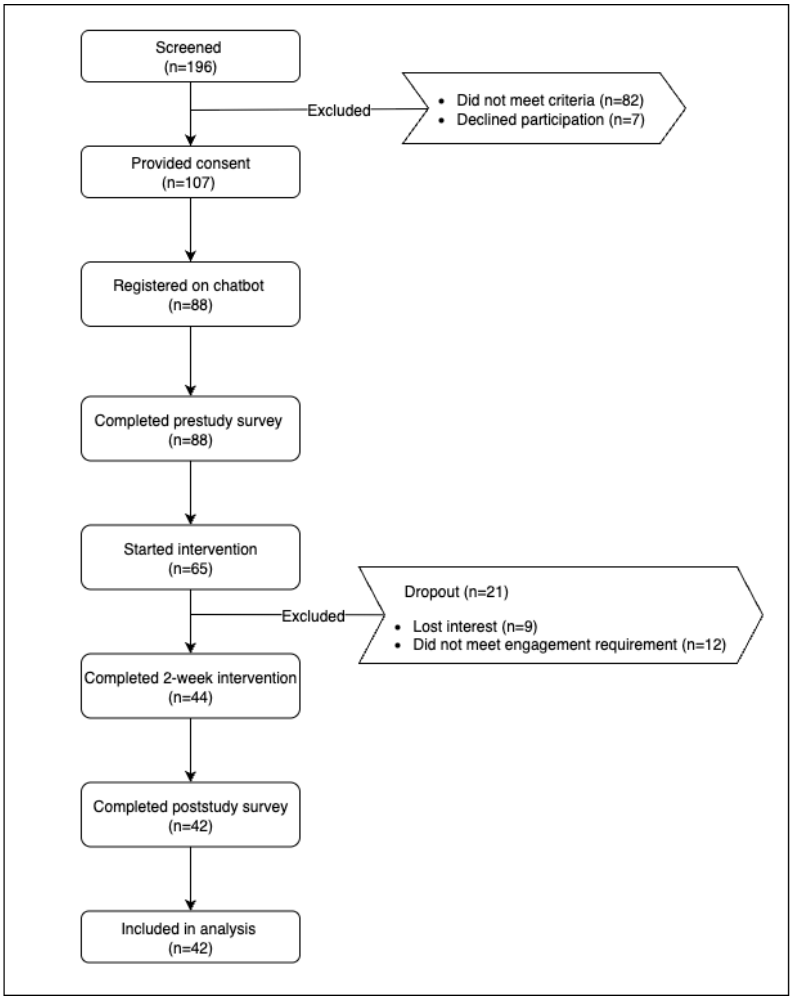
provided informed consent. Of these 107 adults, 88 (82.2%) completed chatbot registration and the prestudy survey. A total of 60.7% (65/107) of the participants initiated conversations with the chatbot. In total, 41.1% (44/107) of the participants completed the 2-week intervention. Of these 44 participants, 42 (95.5%) completed the poststudy survey and were included in the final analysis. The completion rates for all outcome variables were 100% without missing data. In Multimedia Appendix 2, we compare baseline characteristics between participants who completed the intervention and those who did not start it or did not complete it. No statistically significant differences were found between the 2 groups.

Figure 3. Participant flow diagram.



Sample Characteristics

Table 1 summarizes the key sociodemographic and clinical characteristics of the 42 study participants. Their mean age was 36 (SD 11) years, with a range from 22 to 59 years. A total of 28.6% (12/42) of the participants were male, and 61.9% (26/42) were White individuals. In total, 28.6% (12/42) reported taking sleep medications at night. A total of 81.0% (34/42) of the participants slept less than 7 hours per night. Nearly all (41/42, 97.6%) reported having poor sleep quality. In total, 73.8% (31/42) met the criteria for clinical insomnia, and 47.6% (20/42) experienced excessive daytime sleepiness.

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Table 1. Characteristics of the study sample (n=42).

Characteristic	Values
Sociodemographic and clinical characteristics	
Age (y), mean (SD)	36 (11)
Sex, n (%)	
Male	12 (28.6)
Female	30 (71.4)
Race, n (%)	
Non-White	16 (38.1)
White	26 (61.9)
Educational level, n (%)	
Lower than a bachelor's degree	15 (35.7)
Bachelor's degree or higher	27 (64.3)
Employed, n (%)	24 (57.1)
Insured, n (%)	39 (92.9)
Income (US $), n (%)	
≤50,000	18 (42.9)
50,001-99,999	14 (33.3)
≥100,000	10 (23.8)
BMI (kg/m^2), mean (SD)	29.7 (8.2)
Normal, n (%)	11 (26.2)
Overweight, n (%)	15 (35.7)
Obese, n (%)	15 (35.7)
Sleep characteristics, n (%)	
Short sleep (<7 hours per night)	34 (81.0)
Poor sleep quality (Pittsburgh Sleep Quality Index>5)	41 (97.6)
Clinical insomnia (Insomnia Severity Index>14)	31 (73.8)
Excessive daytime sleepiness (Epworth Sleepiness Scale>10)	20 (47.6)
History of taking sleep medications	12 (28.6)

Engagement With the Chatbot

Participants engaged with the chatbot for an average of 7 days over the 2-week intervention (median 7, IQR 5-8, range 4-13 days). On average, they spent 58 minutes interacting with the chatbot (median 49, IQR 27-69, range 9-201 minutes), with each chat session lasting approximately 9 minutes per day (median 7, IQR 4-11, range 1-36 minutes). Correlations between daily chatbot use and each outcome variable are presented in Multimedia Appendix 3. In brief, satisfaction with the chatbot was the only variable that showed a strong correlation with daily use time (r=0.39; P=.01).

Usability

The average CUQ score was 85.2 (SD 10.7), indicating a high level of usability compared to the benchmark score of 68. Usability was further assessed across 4 CUQ domains (Figure 4). The onboarding experience received positive feedback, with 98% (41/42) of participants agreeing that the chatbot clearly explained its scope and purpose, and no one felt that the chatbot failed to indicate its purpose. Regarding personality, 88% (37/42) to 98% (41/42) agreed that the chatbot was realistic, welcoming, able to understand them, and friendly, although 14% (6/42) felt that it was somewhat robotic. Participants also reported favorable overall experiences, with 81% (34/42) to 100% (42/42) indicating that the chatbot was easy to navigate and use and that it provided useful and appropriate responses. Only 2% (1/42) found the chatbot complex. In contrast, responses regarding error handling were mixed. There were 57% (24/42) of participants indicating that the chatbot handled mistakes well, 40% (17/42) remained neutral, and 2% (1/42) believed that it was unable to manage errors effectively.

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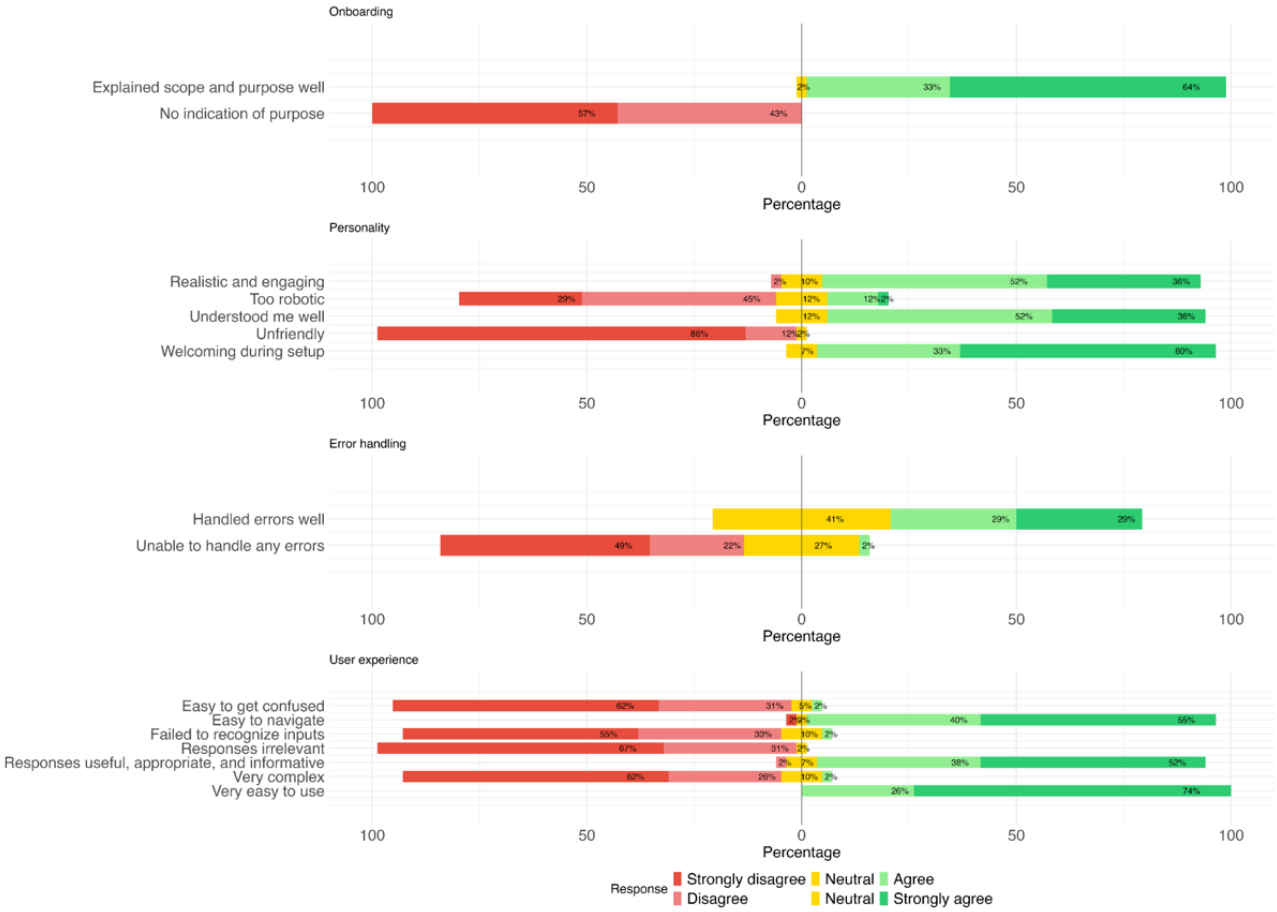
Figure 4. Survey responses to the Chatbot Usability Questionnaire.



Acceptability

The participants found the chatbot highly acceptable, providing an average adapted CSQ score of 27.3 (SD 4.1). Most (38/42, 90%) expressed overall satisfaction with the chatbot. The chatbot's educational content and advice were well received, with 95% (40/42) agreeing that it helped them manage sleep problems more effectively. Most participants (35/42, 83%) found that their needs were met: 50% (21/42) reported "most needs met," and 33% (14/42) reported "almost all needs met." In total, 88% (37/42) indicated that they would use the chatbot again, and 93% (39/42) would recommend it to others (Figure 5).

Participants expressed improvements in several sleep-related areas. The most frequently reported improvement was overall sleep quality (25/42, 60%), followed by mood enhancement (22/42, 52%) and feeling more refreshed in the morning (19/42, 45%). Over one-third reported falling asleep more quickly (16/42, 38%), experiencing more consistent energy throughout the day (15/42, 36%), sleeping longer (15/42, 36%), and waking less frequently during the night (14/42, 33%). All participants considered the chatbot effective, with ratings ranging from "slightly effective" to "extremely effective." A total of 71% (30/42) reported that the chatbot always personalized its advice, 14% (6/42) felt that personalization was inconsistent, and another 14% (6/42) perceived the responses as generic. Most participants (37/42, 88%) reported that the chatbot adapted its responses to their needs somewhat to very well; however, 5% (2/42) indicated that it did so not very well. A total of 93% (39/42) said that the chatbot was able to remember previous conversations, although 7% (3/42) reported poor or no recall. While most participants viewed the chatbot as a supportive companion, 24% (10/42) felt that its level of support could be better (Figure 6).

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Figure 5. Survey responses to the Client Satisfaction Questionnaire.

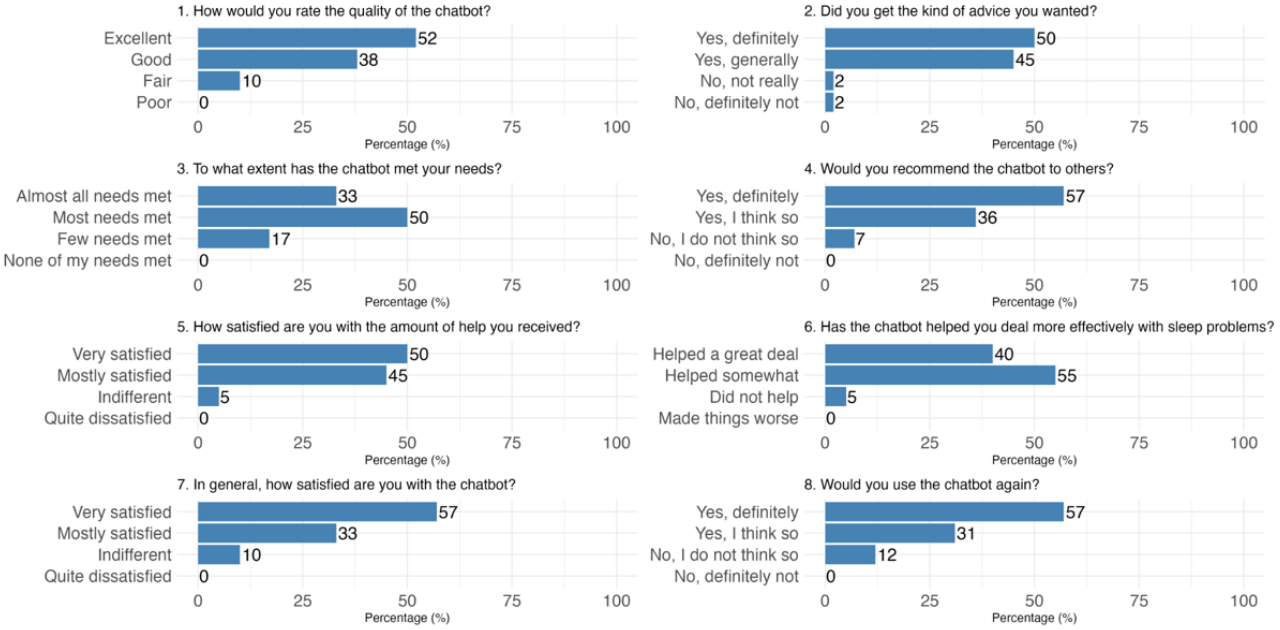
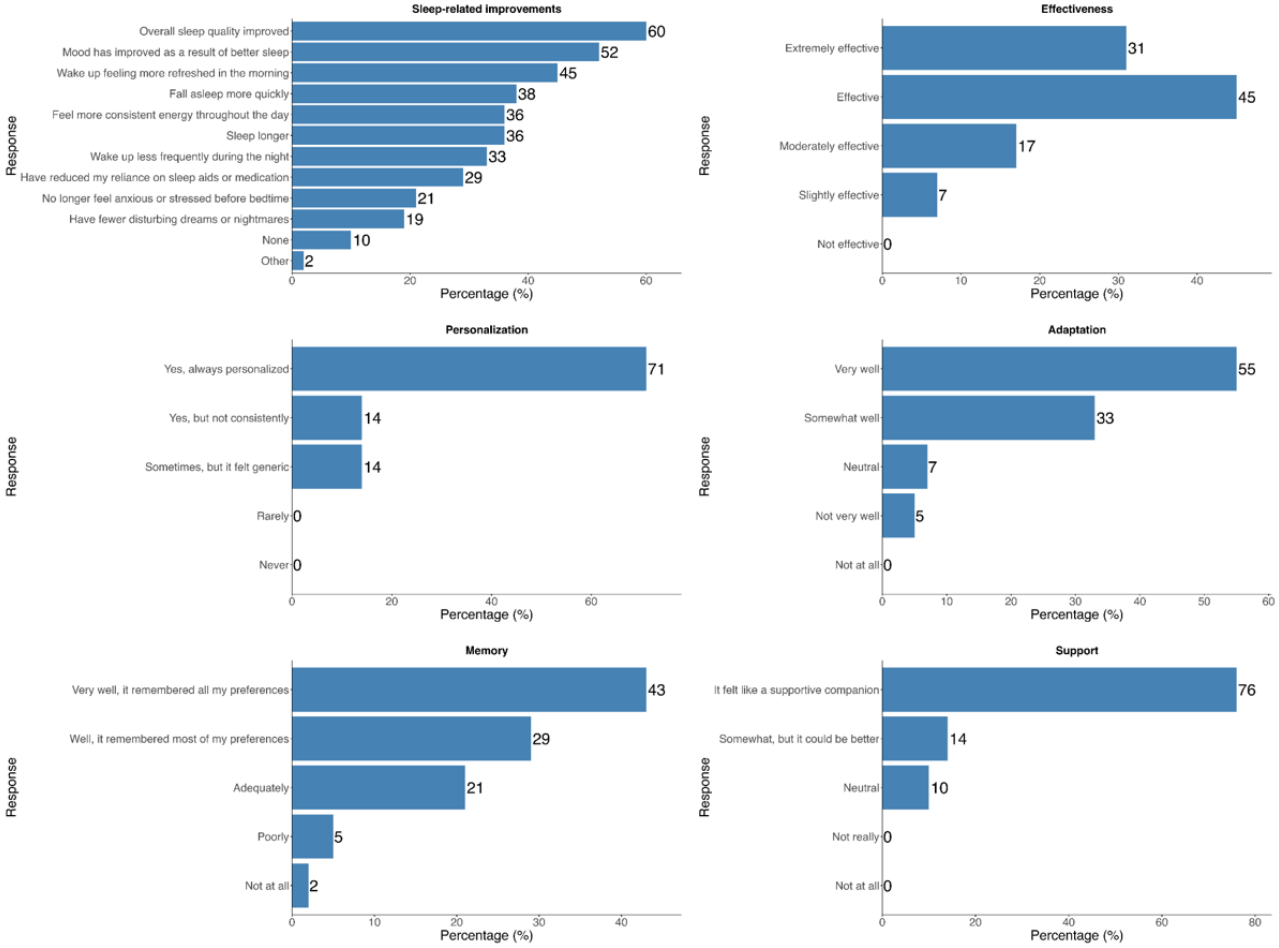


Figure 6. Acceptability of the chatbot.



Preliminary Efficacy

The sample reported an average total sleep time of 5.3 hours, a sleep onset of 59.5 minutes, and a sleep efficiency of 76.2% at baseline. Following the intervention, changes were observed in all 3 habitual sleep metrics: total sleep time increased by 1.4 hours (P<.001), sleep onset decreased by 30.9 minutes (P<.001), and sleep efficiency increased by 7.8% (P=.007). We also found reductions in the scores of sleep quality (mean difference [MD] 5.4; P<.001), insomnia severity (MD -7.9; P<.001), daytime

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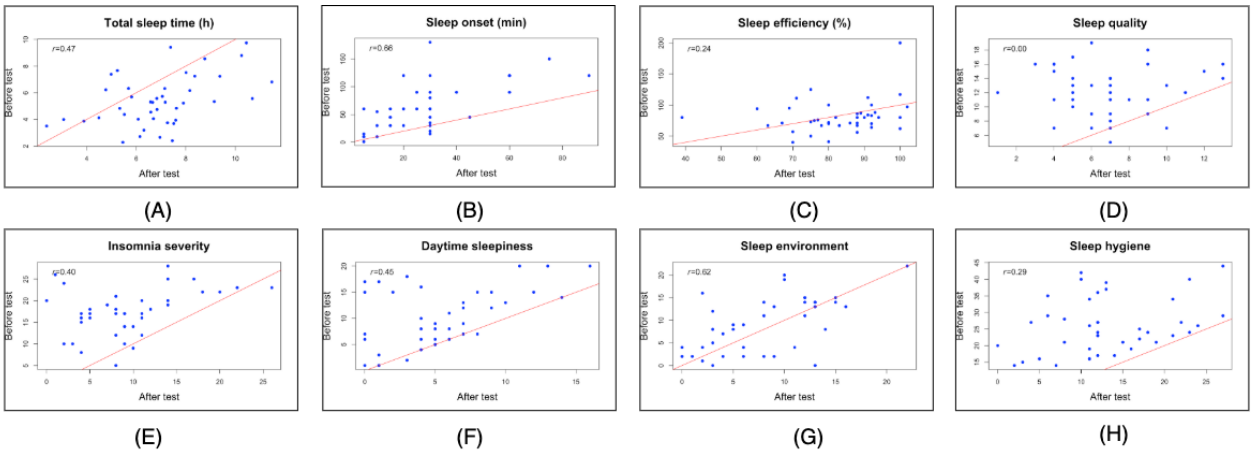
sleepiness (MD −4.7; *P*<.001), and sleep hygiene practices (MD −13.2; *P*<.001). There was no statistically significant difference in sleep environment scores (MD −1.1; *P*=.16) before and after the intervention. The proportion of participants who showed improvement in sleep measurements ranged from 60% (25/42; sleep environment) to 100% (42/42; sleep hygiene practices). The pre- and postintervention changes in sleep measurements are shown in Table 2 and Figure 7.

Table 2. Differences in sleep measurements before and after the intervention (n=42).

Sleep variables	Pretest time point, mean (SD)	Posttest time point, mean (SD)	Pretest-posttest differences			Participants improved, n (%)
			Mean difference (SD; 95% CI)	*P* value	Cohen *d*	
Nocturnal sleep metrics						
Total sleep time (h)	5.3 (1.5)	6.7 (1.3)	1.4 (1.4; 1.0 to 2.0)	<.001	0.99	30 (71.4)
Sleep onset[a] (min)	59.5 (38.3)	28.7 (20.0)	−30.9 (27.5; −39.6 to −22.2)	<.001	−0.83	34 (82.9)
Sleep efficiency[a] (%)	76.2 (17.0)	84.0 (10.5)	7.8 (16.8; 2.2 to 13.3)	.007	0.54	30 (78.9)
Sleep quality (0-21)	12.2 (3.4)	6.8 (2.6)	−5.4 (4.3; −6.7 to −4.0)	<.001	−1.77	38 (90.5)
Insomnia severity (0-28)	17.3 (5.1)	9.4 (5.7)	−7.9 (6.0; −9.8 to −6.0)	<.001	−1.45	39 (92.9)
Daytime sleepiness (0-24)	10.1 (5.6)	5.4 (4.1)	−4.7 (5.2; −8.5 to −4.0)	<.001	−0.95	30 (71.4)
Sleep environment (0-39)	9.2 (6.0)	8.1 (5.3)	−1.1 (4.9; −2.6 to 0.4)	.16	−0.19	25 (59.5)
Sleep hygiene (0-52)	26.2 (8.4)	13.0 (6.6)	−13.2 (9.1; −16.0 to −9.5)	<.001	−1.72	42 (100.0)

[a]One outlier was removed for sleep onset for analysis (n=41), and 4 outliers were removed for sleep efficiency for analysis (n=38). All variables were assessed for normality using the Shapiro-Wilk test. Because sleep onset, daytime sleepiness, and sleep hygiene violated normality assumptions, we used the rank-based Wilcoxon signed rank test to examine the pretest-posttest differences.

Figure 7. Pre- and postintervention differences in sleep measurements. The red line indicates the diagonal line of equality (y = x). Each blue dot represents an individual participant. Dots below the line indicate higher posttest values than pretest values, whereas dots above the line indicate lower posttest values than pretest values. r indicates the pre-posttest correlation for each sleep measure. Panels show (A) total sleep time, (B) sleep onset, (C) sleep efficiency, (D) sleep quality, (E) insomnia severity, (F) daytime sleepiness, (G) sleep environment, and (H) sleep hygiene.



Discussion

Principal Findings

To the best of our knowledge, this study was the first to assess a generative AI–based sleep chatbot intervention. Our findings support the feasibility, usability, and acceptability of this prototype AI chatbot. Improvements were found in habitual sleep patterns, subjective sleep quality, severity of insomnia, daytime sleepiness, and sleep hygiene practices after engaging with the chatbot for 2 weeks. Our study highlights the potential of leveraging AI technologies in behavioral interventions to enhance sleep behaviors and outcomes.

Our AI chatbot was feasible in terms of implementation and user engagement. An 82.2% (88/107) sign-up rate among consenting participants suggests that the setup process, including downloading the messaging app and registering for the chatbot, was clear and easy to follow. However, the overall uptake and adherence rates were 60.7% (65/107) and 41.1% (44/107), respectively, which were slightly below expectations. This was because participants had to initiate conversations to start the intervention, an important step that we did not emphasize clearly in this study. Many waited for the chatbot to reach out, leading to missed interactions and reducing the overall adherence. To improve future study retention, we plan to provide clearer instructions and introduce regular check-ins to increase the

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adherence rate. Encouragingly, participants who completed the 2-week intervention demonstrated high levels of engagement. On average, they interacted with the chatbot for 7 days, which was more frequent than the instructed minimum of once every 3 days. Throughout the study, our participants spent nearly an hour in total using the chatbot, with an average of 9 minutes per day. Although evidence on engagement with sleep chatbots is scarce, we found similar engagement rates with chatbots developed for other health behaviors. For example, one study reported an average chatbot use of 5.1 minutes per day for promoting physical activity [28]. Another study found that adolescents spent approximately 45 minutes using a health education chatbot, with sessions averaging 4 minutes [29]. Nevertheless, caution should be taken when comparing engagement rates across chatbot interventions due to variations in study focus, design, duration, and mode of delivery.

Participants reported positive experiences with the chatbot. They found the chatbot easy to use, appreciated its realistic and welcoming tone, and considered it helpful. Participants also expressed satisfaction with the chatbot's personalized and adaptive content. In general, the level of usability and acceptability of our chatbot was higher than that reported in previous research. A systematic review by Aggarwal et al [13] found that users rated chatbot interventions as having low to moderate ease of use. Additionally, fewer than 50% of users reported satisfaction with the chatbot [13]. The favorable outcomes in our study were primarily driven by the generative AI technology. LLMs are inherently adaptive, enhancing participant engagement by simulating realistic human conversations and allowing for personalized learning through reinforcement learning. As participants interact, the LLMs progressively refine responses to enhance their performance as individual data accumulate. This interactive process enables the models to update sleep recommendations in real time, which is a feature unachievable with traditional sleep interventions. Despite overall high satisfaction, several areas for improvement were identified. Some participants perceived the chatbot's responses as generic or robotic, highlighting the need for further training of LLMs to promote more natural and coherent interactions. In addition, enhancing the chatbot's memory capabilities is critical to maintain conversational continuity and deliver more personalized, contextually relevant responses.

Our findings provide preliminary evidence of sleep improvement after chatbot use. The study results echoed prior evidence on the use of conversational agents for monitoring and promoting sleep. Werner-Seidler et al [30] evaluated a 6-week app-based program that delivered CBT-I through text–based interactions with a virtual sleep therapist. Compared to the control group that received weekly sleep tips via texting, the intervention group experienced significantly greater reductions in insomnia severity and better sleep quality after the intervention and 2-month follow-up [30]. Similarly, another study developed 2 apps and randomly assigned adults with insomnia to either a control group (sleep diary only) or an intervention group (personalized recommendations from a virtual companion) [31]. After 17 days, the intervention group exhibited reduced insomnia severity, gained 48 additional minutes of sleep per night, increased sleep efficiency, and decreased wake after sleep onset (P<.05) compared to the control group [31]. Although our chatbot achieved comparable improvements within a shorter time frame, the study findings should be interpreted with caution because all sleep outcomes were assessed via questionnaires. Discrepancies between subjective and objective sleep measurements are well documented [32,33]. One study found that self-reporting overestimated sleep duration by 64 minutes compared with actigraphy- and polysomnography-measured sleep [32]. We acknowledge that the observed sleep improvements could be subject to reporting bias. In our next trial, we will include wrist actigraphy to obtain a more accurate, comprehensive evaluation of sleep outcomes.

Several additional features of the AI chatbot support its potential for broader implementation and scalability. First, it is cost-effective. Traditional individual sleep therapy sessions such as CBT-I cost between US $750 and US $2500 [34]. As some insurance plans do not cover CBT-I treatments, the out-of-pocket expenses often pose financial challenges for many individuals struggling with sleep problems. In contrast, our AI chatbot is fully automated, substantially reducing the need for human resources. Unlike previous digital sleep interventions that required considerable local storage and computing power for machine learning models and data processing, our chatbot operates via LLMs hosted on cloud servers, eliminating the need for high-performance hardware. Additionally, the use of LLMs allows for seamless integration into a variety of software systems, which minimizes costs associated with app development and maintenance. Furthermore, the AI chatbot is highly accessible. Access to sleep therapy has been a long-standing issue because it is often administered by clinical specialists in person or in group settings. This issue is more notable in regions (eg, rural areas) with a shortage of trained health care providers [35]. Deploying the chatbot through a widely used commercial texting app eliminates the need for participants to learn new technology or undergo technical use training. The texting app's simple, intuitive interface enables individuals with basic smartphone skills to seek sleep support anytime and anywhere. Using a private, text–based platform can also help reduce the stigma often associated with in-person therapy, an important factor to boost engagement.

Limitations

Despite the aforementioned advantages, our study has several limitations. First, as the quasi-experimental design cannot infer causality, a randomized controlled trial needs to be conducted to confirm the study findings. Second, we did not examine the long-term effects of the intervention. Future studies should include follow-up assessments to evaluate the sustainability of sleep improvements. Third, although participants were recruited nationwide, the study is underpowered due to its small sample size. Additionally, convenience sampling contributed to sociodemographic imbalances (eg, age, race, and educational attainment). These factors introduced selection bias and may limit the generalizability of the findings. In our next trial, we will use stratified sampling to achieve a more balanced and representative cohort. Fourth, the intervention delivery mode may exclude certain populations, such as individuals who have insufficient smartphone technological skills, who do not own a smartphone, or who are unwilling to engage with a chatbot

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through texting. Finally, sleep was assessed only using self-report. Prospective work should integrate objective sleep assessments to provide a more comprehensive examination of the intervention effects.

Conclusions

Our study demonstrates that an AI-powered, text–based chatbot is a feasible, usable, and highly acceptable intervention for adults with poor sleep. The findings provide preliminary evidence of the association between chatbot use and improved sleep outcomes. Building on the study results, future research will refine the chatbot's design and functionality based on the limitations identified in this study. Rigorous evaluation through randomized controlled trials is necessary to validate the study findings and establish causality. If confirmed, the chatbot's affordability, engaging interface, and personalized features position it as a potential tool for large-scale implementation.

Funding

This study was supported by New York University Rory Meyers College of Nursing and partially supported by the National Institute on Minority Health and Health Disparities (P50MD017356-4).

Data Availability

The datasets generated or analyzed during this study are not publicly available due to the protection of participants' privacy and confidentiality but are available from the corresponding author upon reasonable request.

Authors' Contributions

Conceptualization: XL, JL (equal)
Data curation: XL
Formal analysis: XL (lead), JL (supporting)
Funding acquisition: XL
Investigation: XL, JL (equal)
Methodology: XL, JL (equal)
Project administration: XL (lead), JL (supporting)
Resources: XL
Supervision: JL
Visualization: XL, JL (equal)
Writing—original draft: XL
Writing—review and editing: XL, JL

Conflicts of Interest

None declared.

Multimedia Appendix 1
Model configuration and safety settings of generative artificial intelligence.
[PDF File (Adobe PDF File), 52 KB - formative_v10i1e84023_app1.pdf]

Multimedia Appendix 2
Comparison of sociodemographic and clinical characteristics between completers and noncompleters.
[PDF File (Adobe PDF File), 85 KB - formative_v10i1e84023_app2.pdf]

Multimedia Appendix 3
Correlations between chatbot daily use time and study variables.
[PDF File (Adobe PDF File), 60 KB - formative_v10i1e84023_app3.pdf]

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Abbreviations

AI: artificial intelligence
CBT-I: cognitive behavioral therapy for insomnia
CSQ: Client Satisfaction Questionnaire
CUQ: Chatbot Usability Questionnaire
LLM: large language model
MD: mean difference

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Original Paper

Exploring Proof of Concept for a Novel Web-Based Self-Management Support Intervention for Polycystic Ovary Syndrome: Multimethod Study

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Abstract

Background: Polycystic ovary syndrome (PCOS) is a common chronic hormonal condition affecting 8%-13% of women and individuals assigned female at birth. Symptoms may include subfertility, menstrual, skin, and metabolic problems, with long-term health risks including diabetes and cardiovascular disease. PCOS has a significant negative impact on mental health, quality of life, and well-being. We explored proof of concept for a web-based self-management support intervention, "Hope PCOS," designed to reduce anxiety and depression and increase positive well-being for women living with PCOS.

Objective: We aim to pilot the intervention to test feasibility for web-based recruitment and delivery, acceptability, and potential to reduce anxiety and depression and increase positive well-being.

Methods: Women with PCOS were recruited via social media with support from a patient advocacy charity and offered places on a 6-session cohort of the intervention. In a pre-post design, participants reported depression (Patient Health Questionnaire 9-Items), anxiety (Generalized Anxiety Disorder 7-Items), well-being (Warwick-Edinburgh Mental Wellbeing Scale), hope (SHS [State Hope Scale]), and gratitude (GQ-6 [Gratitude Questionnaire]) at baseline and 6 weeks. All participants who accessed 3 or more sessions were invited to a follow-up qualitative interview to explore user experience. Data from 8 interviews were thematically analyzed, and pre-post data were explored with descriptive statistics.

Results: A total of 63 eligible women responded and were given access to the intervention. Three withdrew, leaving a baseline sample of 60, aged 20-58 (median 30, IQR 25-36) years. Further, 48 of the 60 started, of whom 46% (22/48) completed at least 3 sessions, and 29% (14/48) completed all 6. Additionally, 8 women (aged 25-38, median 29, IQR 26-35) years who completed between 3 and 6 sessions reported acceptability and experiences in exit interviews, including prioritizing self-care, developing a self-management mindset, setting motivating goals, improved mental health, self-compassion, reduced shame, openness about PCOS, preparedness for future health concerns, and continuing practice to consolidate behavior change. Furthermore, 11 women aged 25-43 (median 31, IQR 27-37) years, who completed 1-6 sessions (median 6, IQR 6-6), completed pre- and postintervention outcomes. Descriptive quantitative analysis indicated decreases in anxiety and depression and increases in hope agency, hope pathways, and gratitude. There was a meaningful (≥3 points) increase in well-being. Among patients with baseline and follow-up data, 73% (8/11) met clinical caseness for depression at baseline and 36% (4/11) post intervention.

Conclusions: We explored proof of concept. Web-based recruitment and delivery online were feasible. We detected early signs of acceptability and potential benefits for anxiety, depression, and positive well-being that warrant testing in a controlled trial. Future research should assess the feasibility of a randomized controlled trial to evaluate effectiveness, acceptability, and cost-effectiveness.

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KEYWORDS

polycystic ovary syndrome; PCOS; women's health; self-management; peer support; web-based health intervention; psychoeducation; anxiety; depression; positive wellbeing

Introduction

Background and Rationale

Polycystic ovary syndrome (PCOS) is a complex, lifelong endocrine disorder affecting women and other individuals assigned female at birth (AFAB), from menarche onward [1]. Although diagnostic criteria vary, PCOS is estimated to affect around 10% of adult women and AFAB individuals worldwide [2], and its incidence is rising in the United Kingdom [3]. Individuals with PCOS are at increased risk of several metabolic disorders, reproductive conditions, mental health issues, and sleep conditions [4-6]. PCOS has a significant adverse impact on mental health and quality of life [7,8], including higher rates of depression [9-12], anxiety, body image concerns [13], sexual dysfunction [14,15], relationship issues, and disordered eating [16-18]. While often considered a concern of the reproductive years, PCOS is lifelong, with enduring health consequences such as increased risks of type 2 diabetes, cardiovascular disease, and endometrial cancer [19-23]. The condition also has significant socioeconomic costs for affected individuals and wider society [24-27].

Recent international, evidence-based guidelines for PCOS management recommend an integrated health care approach that addresses the multifaceted nature of the condition [2]. These guidelines emphasize person-centered care, shared decision-making between patients and professionals, and advocate for patient education on cardiometabolic, dermatological, lifestyle, reproductive, and psychological aspects. Best practice also includes nonstigmatizing, weight-neutral self-management support, attentive to mental health and emotional well-being. Additionally, several countries have publicly recognized the health inequalities experienced by women in general and developed women's health strategies to address these [28,29]. Further, the UK women's health strategy for England [29] aims to prioritize care for gynecological conditions such as PCOS, educate and empower women and girls, and provide more support in or near patients' homes. This includes harnessing the power of digital technology and accelerating the implementation of evidence-based digital interventions into the UK National Health Service (NHS). Person-centered, digital, self-management support interventions such as Hope PCOS have a key role to play in educating, empowering, and supporting patients with PCOS in their own homes, while complementing clinical care provided by health care professionals.

Despite recommendations from clinical guidelines and announcements of health care policy change, many people with PCOS encounter barriers to managing their condition, including limited access to specialized care or multidisciplinary treatment, lack of social support, and unmet needs for trustworthy self-management advice. High prevalence of comorbid depression and anxiety means mental health needs are often unaddressed. Psychological and behavioral interventions, especially those based on cognitive behavioral therapy, can reduce depression symptoms in PCOS, and may benefit anxiety, body image, disordered eating, and health-related quality of life [30-32]. Self-management interventions—successful in other chronic conditions such as diabetes—hold promise for PCOS, especially digital formats that are accessible and scalable. These can provide knowledge, skills, and confidence for self-management, also addressing psychological impact.

Research by the ORCHA (Organisation for the Review of Care and Health Apps) [33] has found a strong appetite for the use of digital health apps and web-based interventions across the United Kingdom, but a relative dearth of digital health literacy in those choosing apps for personal use. App users typically report basing the decision to download and use an app on how many times it has been downloaded previously, or on customer reviews, rather than checking whether the app is evidence-based or had health care provider input into its development. ORCHA suggests that individuals seeking digital health support face a largely unregulated marketplace with thousands of apps, of which as few as 20% meet basic quality standards. To address the gap for an evidence-based, digital, self-management support app for psychological well-being in PCOS, we conducted the first proof-of-concept test of an evidence-based, modular, and online intervention, Hope PCOS [34]. This intervention incorporates evidence-based PCOS-related information with hope and gratitude activities designed to increase positive well-being and improve mental health. Cultivating hope may empower individuals to cope adaptively, set and achieve meaningful goals, and maintain a positive future outlook despite health challenges [35,36]. Gratitude practices, which shift one's focus toward positive experiences, may increase resilience and resources for chronic illness management and enhance well-being [37]. Incorporating hope and gratitude practices has the potential to reduce depression and anxiety in PCOS.

Objectives

This proof-of-concept trial was deliberately designed as a formative, discovery-oriented investigation focused on providing descriptive evidence and understanding whether a larger, definitive trial is warranted, rather than confirming or formally assessing the impact or benefit of an intervention through formal hypothesis testing [38]. The first aim of this study was to pilot the Hope PCOS intervention to assess the feasibility of web-based delivery and its acceptability to participants. The second aim was to assess the intervention's potential to improve anxiety, depression, and positive well-being.

Methods

Design

This study followed a multi-method design, primarily qualitative, with supportive, descriptive quantitative data. In a pre-post design, all participants were given access to the 6-week intervention at the same time. At baseline (T0), participants

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completed a web-based questionnaire confirming that they met the inclusion criteria. Please see the completed CONSORT (Consolidated Standards of Reporting Trials) Extension Pilot and Feasibility Trials Checklist [39] (Multimedia Appendix 1) for details.

Age, time since diagnosis, and secondary outcome measures were collected via web-based questionnaires at baseline, and secondary outcome measures were repeated 6 weeks after baseline, when the intervention delivery was complete (T1). At T1, all participants who completed 3 or more hope sessions were contacted and invited to take part in a follow-up semistructured telephone interview to report the acceptability of the intervention.

As this was an early proof-of-concept study, a pragmatic approach was taken to selecting the sample size. We aimed to recruit enough participants to allow for supportive but low-intensity peer interaction within the intervention cohort, which previous experience on other programs on the same digital platform suggests is likely to be at around 30-70 participants [40-42]. We initially aimed to recruit a minimum of 30 participants for this study.

Participant Recruitment

Participant recruitment was planned for September and early October 2019, to recruit 15-30 participants. Participants were recruited from a United Kingdom community setting online. Verity, a UK PCOS advocacy organization, shared a call for research participation on their social media channels. The call included a link to this study's website, hosted on the Qualtrics platform (Qualtrics), which is General Data Protection Regulation compliant and certified to the ISO (International Organization for Standardization) 270001 standard [43]. The website included consent and screening questions to allow adults to self-report their eligibility and complete this study's demographics and baseline measures.

Eligibility criteria were as follows: (1) adults aged 18 years or older, (2) self-reporting a diagnosis of PCOS made by a general practitioner or a hospital specialist, (3) being based in the United Kingdom, (4) having access to the internet and a device to allow engagement with the intervention, and (5) being sufficiently fluent in English to engage with this study and intervention materials.

Intervention

The Hope PCOS web-based self-management support intervention was delivered online via the secure internet platform provided by the social enterprise Hope for the Community (H4C) [44]. This theory-led, evidence-based self-management and peer support program was cocreated by adults living with PCOS, advocates for patients with PCOS, health care professionals, and an academic research team led by a psychologist with lived experience of PCOS. Designed for women with PCOS and other AFAB, the intervention addresses self-management needs, psychological well-being, and social support. It is underpinned by positive psychology principles, including the cultivation of hope and gratitude, and informed by the broaden-and-build theory of positive emotions to enhance emotional self-regulation, increase positive affect, and support coping with anxiety and depression. The development process is reported in detail elsewhere [34].

The online, asynchronous version evaluated in this proof-of-concept study was facilitated by trained peer supporters with lived experience of PCOS and delivered in a group format. The intervention followed a standard 6-week structure, with 1 themed educational module released on the same day each week (Multimedia Appendix 2) and designed to take about 2.5 hours to complete at the participants' own pace. Modules included topic-specific information, audiovisual materials, cognitive-behavioral activities, and practical exercises. Two recurring elements in every session were gratitude journal entries and goal setting, with each session ending in goal setting and the following session beginning with solution-focused facilitator feedback on previous goals. Secure forums and messaging functions enabled peer-to-peer encouragement, while facilitators moderated discussions, provided supportive feedback, and monitored participation. Tailoring was achieved through open goal setting, individualized support via the forum, and flexible pacing, allowing participants to access materials at their convenience. Fidelity was planned through controlled module release schedules, peer facilitator checklists, and engagement metric monitoring. The intervention was delivered as planned. Participant adherence is described below. Please refer to the TIDieR (Template for Intervention Description and Replication) [45] checklist in supplementary files (Multimedia Appendix 3).

Primary Outcomes

Overview

The primary outcome measures included adherence, engagement, and acceptability.

We calculated the proportion of participants who completed the baseline measures and subsequently logged in to the intervention platform.

Adherence

There is no agreement on what constitutes adherence in digital health interventions. Work on engagement in digital mental health interventions shows 7%-42% of participants typically engage in moderate use, defined as completing 40%-60% of modular, fixed-length programs or continuation of app usage after 4 weeks [46]. Participants were deemed adherent to Hope PCOS if they completed at least 3 of the 6 intervention sessions (50%).

Engagement

The intervention platform collects user engagement data, including the number of sessions completed per participant, and the number of gratitude entries, goals set, and comments posted.

Acceptability

We assessed the acceptability of the intervention by qualitative interviews at T1. All participants (n=22) who had completed at least 3 sessions were emailed and invited to take part in a private, individual audio-recorded, 30-60 minute, semistructured telephone interview 9-10 weeks post intervention. Follow-up telephone calls were made to arrange the time and date of the interview. All who accepted the email invitation (8/22) were

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interviewed by the H4C quality assurance manager about their perceptions and experience of the acceptability of the program. The female interviewer had a BSc and a PhD, previous experience in qualitative interviewing, and extensive experience in working with people living with long-term health conditions. To encourage open and honest disclosure from participants, the interviewer was not known to participants before the interview and was neither part of the intervention development team nor directly involved in the delivery of the intervention. She introduced herself at the beginning of the interviews, explained her role at H4C, and the purpose of the research: to explore participants' experiences of and views on how to improve the Hope PCOS course. Interview questions included expectations and experiences of the program and any changes in mental or physical health or self-management activities attributed to participation in the program. Questions were not pilot-tested as they had been used in previous evaluations. No repeat interviews were conducted. Interview data were transcribed manually, the verbatim transcripts were checked for accuracy against the original recordings, and the audio was destroyed.

The transcripts were analyzed following the steps recommended by Braun and Clarke [47,48], which allow flexibility to use a deductive or inductive approach, or a combination of these. Reflexive thematic analysis described Braun and Clarke [47,48] supports flexible, iterative coding and theme development, and does not rely on formal coding trees as used in some other qualitative analytic traditions.

Preliminary deductive analysis of the interview data was carried out directly from the audio by the interviewer, who identified "domain summaries" of participants' motivations for participating in the intervention, views on the appropriateness of content and delivery, any unmet expectations, and suggestions for future iterations of the intervention refinement. This preliminary analysis informed the intervention delivery team at H4C. The verbatim transcripts were then analyzed inductively by the first author, following the recommendations by Braun and Clarke [47,48] for reflexive thematic analysis. The first author, a university lecturer and experienced qualitative researcher with lived experience of PCOS, a BSc and PhD, transcribed the data manually to familiarize herself with it, reading, rereading, and noting initial impressions. She then coded the data line by line, generating initial codes that ranged from more semantic, descriptive codes, based on the manifest content of participants' descriptions, to more conceptual codes, based on reflexive interpretation. Codes were collated into an Excel (Microsoft Corp) spreadsheet and then sorted repeatedly to search for potential themes. Themes were then identified, reviewed, and checked against corresponding coded extracts, the preliminary deductive domain summaries, and the whole dataset. Themes were then discussed with the third author, a Chartered Health Psychologist, Professor of Digital Self-Management, and experienced qualitative researcher with a BSc and PhD, before being defined and named, and the analysis was written up. This study used a mixed inductive-deductive, realist, experiential framework. Theme development was iterative and reflexive, balancing researcher and participant subjectivity with the need to rapidly inform the intervention team of potential platform and material improvements.

For reflexive thematic analysis, data saturation is not viewed as a meaningful or appropriate standard, and claims to have "reached saturation" are discouraged in favor of transparency about the reasoning behind sample size and the depth of analysis [49]. As this was an unfunded study without compensation for participation, to avoid burdening participants, member checking of transcripts and analysis was not used. Please see the completed COREQ (Consolidated Criteria for Reporting Qualitative Studies) checklist [50] in supplementary files (Multimedia Appendix 4).

Secondary Outcomes

The secondary outcomes chosen for this study were informed by the core outcomes set for PCOS research [51,52], and by the researchers' aim to test whether the intervention produced changes in the underpinning constructs of hope and gratitude. This was to establish proof of concept only, not to test hypotheses or the magnitude of any changes. Participants completed questionnaires at T0 (baseline) and T1 (6 weeks later, when the intervention ended).

The Patient Health Questionnaire (PHQ-9) [53] is a 9-item scale, with items measuring symptoms of depression. Items ask participants to state how much in the last 2 weeks they have been bothered by problems, including, for example, "little interest or pleasure in doing things" and "feeling down, depressed, or hopeless." Each of the 9 items has responses ranging from 0 to 3 (0=not at all, 1=several days, 2=more than half the days, and 3=nearly every day), leading to a total score between 0 and 27. Higher scores indicate greater severity of depression. The PHQ-9 has good internal consistency (Cronbach α=0.89). Scores of 10 or more are regarded as indicating the clinical range for depression, so participants scoring 10 or more were categorized as depressed for this study. Item 9 of the PHQ-9, "thoughts that you would be better off dead, or of hurting yourself in some way," is used to screen for suicidal ideation and suicide risk.

The Generalized Anxiety Disorder Scale (GAD-7) [54] is a 7-item scale measuring symptoms of generalized anxiety disorder. Items ask participants to state how much in the last 2 weeks they have been bothered by problems, including, for example, "feeling nervous, anxious or on edge" and "not being able to stop or control worrying." Each of the 7 items has responses ranging from 0 to 3 (0=not at all, 1=several days, 2=more than half the days, and 3=nearly every day), leading to a total score of 0 to 21. Higher scores indicate greater anxiety. GAD-7 has good internal consistency (Cronbach α=0.92). Scores of 8 or more are regarded as indicating the clinical range for anxiety, so participants scoring 8 or more were categorized as having anxiety for this study.

The Warwick-Edinburgh Mental Wellbeing Scale (WEMWBS) [55] is a 14-item scale measuring positive mental well-being in adults. Items ask participants to state how much in the last 2 weeks they experienced certain (positive) feelings and thoughts, including, for example, "I've been feeling optimistic about the future" and "I've been dealing with problems well." Each of

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the 14 items has responses ranging from 1 to 5 (1=none of the time, 2=rarely, 3=some of the time, 4=often, and 5=all of the time), leading to a total positive mental well-being score ranging from 14 to 70. Higher scores represent greater positive mental well-being. The WEMWBS has good internal consistency (Cronbach α=0.91). A change of 3 or more is regarded as a meaningful change in positive well-being [56].

We administered the GAD-7, PHQ-9, and WEMWBS at 2 timepoints—immediately before and after the 6-week intervention—using the standard 2-week recall period each time, in line with best practice and the questionnaires' validated use. This approach was chosen to preserve the tools' established reliability and validity, as altering the recall period or increasing the frequency of assessment might compromise data quality or increase participant burden. By anchoring assessments to the periods immediately preceding and following the intervention, we were able to capture recent anxiety, depression, and well-being status, and any changes in these, without overburdening participants.

The GQ-6 (Gratitude Questionnaire) is a 6-item scale measuring the disposition to experience gratitude [57]. Each of the 6 items has responses ranging from 1 to 7 (1=strongly disagree and 7=strongly agree), leading to a total gratitude score ranging from 6-42, with higher scores representing higher levels of gratitude. Items ask participants to state how much they agree with 3 positively worded statements about gratitude, including, for example, "I have so much in life to be thankful for," and with 3 negatively worded (reverse coded) statements about gratitude including, for example, "when I look at the world I don't see much to be grateful for." The GQ-6 has good internal consistency (Cronbach α=0.76 to 0.84) [57,58].

The SHS (State Hope Scale) is a 6-item scale measuring goal-directed determination and the sense of having pathways to successfully meet one's goals [59]. The items ask participants to select a number that describes how they think about themselves in relation to 6 statements about goal-oriented hope. Three of the statements relate to "hope agency," a sense of oneself as being determined and motivated to achieve one's goals, for example, "at the present time, I am energetically pursuing my goals." Three of the statements relate to "hope pathways," the sense of having pathways to successfully meet one's goals, for example, "I can think of many ways to reach my current goals." Each of the 6 items has responses ranging from 1-8 (1=definitely false and 8=definitely true), leading to a total hope score ranging from 6-48, with higher scores representing higher levels of hope. Pathways subscale scores range from 3-24, with higher scores indicating higher levels of pathways thinking. Agency subscale scores range from 3-24, with higher scores indicating higher levels of agency thinking.The SHS has good internal consistency (Cronbach α=0.93).

All quantitative data were collected via web-based questionnaires administered using Qualtrics Survey Software.

Analysis

Descriptive analysis of quantitative data was conducted using IBM SPSS 26 (IBM Corp, released 2019). The analyses involved tabulated summaries of primary outcomes and, for secondary outcomes, pre- and post intervention, using medians and IQRs.

As a proof-of-concept study, this study was not powered to perform inferential statistical analyses. Pre- and postprogram medians and IQRs for scores on outcome measures are reported to indicate the potential to reduce depression and anxiety and increase positive well-being.

Safety Considerations

Individuals scoring 2 or above on PHQ-9 question 9 (used to screen for suicidal ideation) were contacted to clarify that this study did not offer psychotherapy and were advised to seek professional help. They were encouraged to consult their general practitioner and given contact details for mental health agencies. Those wishing to continue were granted access to the program and trial. The digital platform includes links to suicide prevention advice and information on accessing the UK's primary mental health care services.

Ethical Considerations

This study received clearance from the Coventry University Research and Ethics Governance Committee (approval P93500). Participants visited this study's website, read a participant information sheet, and ticked a digital informed consent statement before completing each web-based survey. They completed a written informed consent form before participating in the qualitative interview. Interview transcripts were anonymized for analysis, and participants are referred to by participant number, for example [P1]. No compensation was offered to any participants.

Results

Recruitment started October 1, 2019, and ran on to October 7, 2019, via Twitter (subsequently rebranded X; the first author's account) and Facebook (Verity PCOS's account). A total of 63 participants responded to the social media invitation, completing the web-based consent and baseline measures.

Descriptive Data

Overview

A total of 63 women completed the baseline questionnaires.

Participant characteristics are shown below (Table 1), and participant flow through this study is shown in Figure 1.

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Table 1. Participant demographic information at baseline for adults with PCOS[a] who accessed the online 6-week self-management intervention and completed follow-up measures or interviews in a multi-method proof of concept study.

Characteristics	Sample at enrollment (N=60)[b]	Accessed intervention and completed baseline and postprogram questionnaire (n=11)	Completed postprogram qualitative interview (n=8)
Age (years), median (IQR)	30 (25-36)	31 (27-37)	29 (26-32)
Years since diagnosis, median (IQR)	7 (3-17)	12 (4-23)	7 (3-14)
Baseline depression caseness[c] PHQ-9[d], n (%)	42 (70)	8 (73)	5 (63)
Baseline anxiety GAD-7[e], caseness[f], n (%)	33 (55)	5 (45)	6 (75)

[a]PCOS: polycystic ovary syndrome.

[b]Excludes n=3 who withdrew from this study and whose data were withdrawn.

[c]Defined by Patient Health Questionnaire 9-Items threshold for depression.

[d]PHQ-9: Patient Health Questionnaire 9-Items.

[e]GAD-7: Generalized Anxiety Disorder 7-Items.

[f]Defined by Generalized Anxiety Disorder 7-Items threshold for anxiety.

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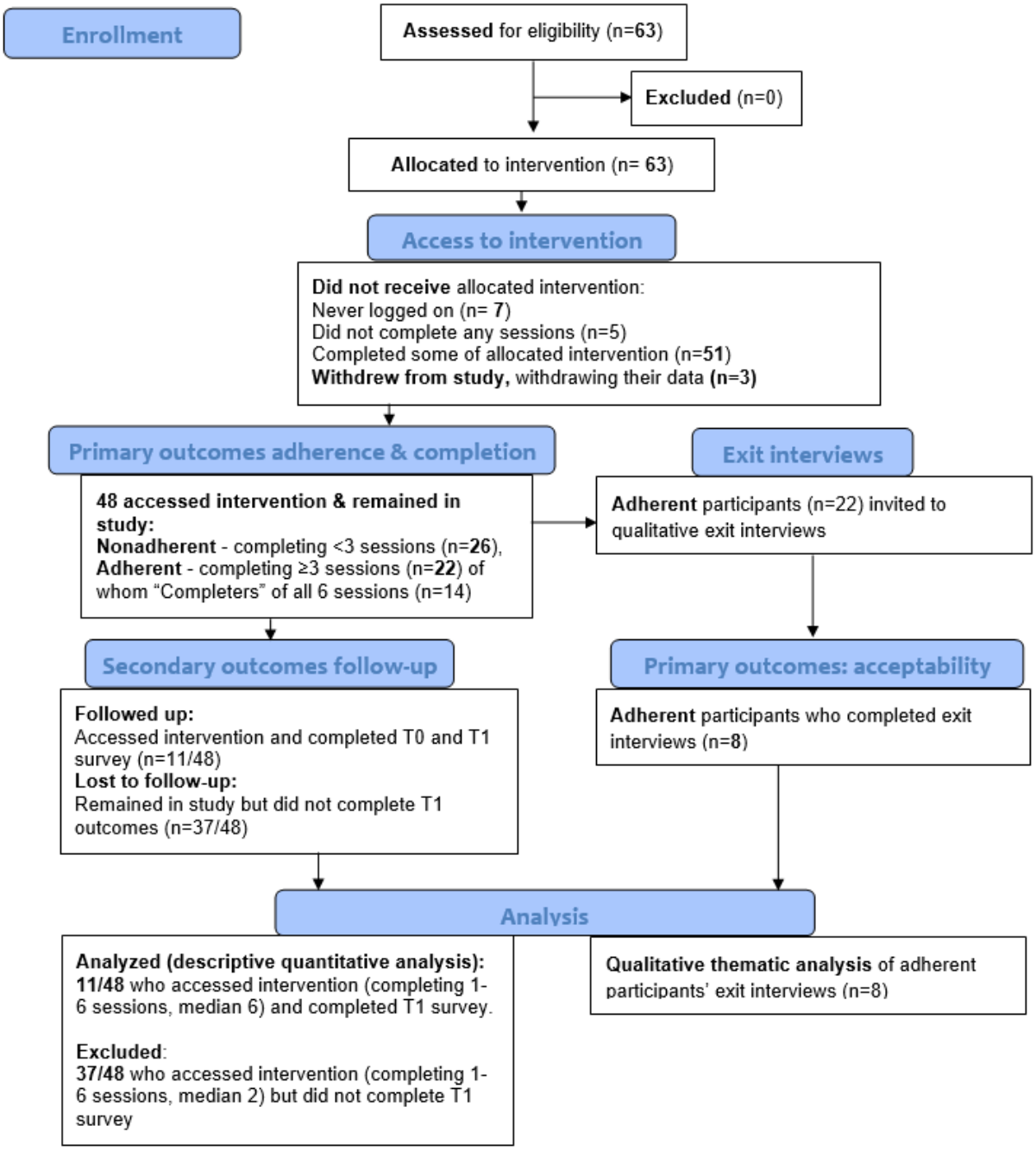
Figure 1. CONSORT flow diagram showing flow through proof-of-concept study for adults with PCOS in the online 6-week Hope PCOS self-management intervention. CONSORT: Consolidated Standards of Reporting Trials; PCOS: polycystic ovary syndrome.



Withdrawals

Three women withdrew from this study at weeks 3 (n=1) and 6 (n=2), respectively. As per the procedures in this study's ethical approval, their data were all withdrawn and destroyed, leaving a sample of 60. For those who withdrew, 2 reported experiencing life events that made them too busy to commit to study participation, and 1 reported disliking the positive mental health focus of the intervention, stating that it was "not her cup of tea at all." As per the data protection section in our approved participant information sheet, withdrawn participants' personally identifiable information, age, time since diagnosis, and secondary outcome data were removed from this study's records.

The 60 women who completed the baseline measures at enrollment and whose data remained in this study were aged 20-58 (median 30, IQR 25-36)) years. Time since diagnosis ranged from 0 to 38 (median 7, IQR 3-17)) years.

PHQ-9 scores indicated high baseline levels of depression symptoms, with 42/60 (70%) participants scoring at or above the level indicative of clinical depression. GAD-7 scores indicated high baseline levels of anxiety symptoms, with 33/60 (55%) scoring at or above the level indicative of clinical anxiety.

A total of 11 women aged 25-43 (median 31, IQR 27-37)) years, all of whom had completed 1-6 (median 6, IQR 6-6) intervention sessions, completed both pre- and postintervention outcomes.

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Their time since diagnosis ranged from 3 to 25 (median 12, IQR 4-23)) years.

Further, 22 "adherent" women who had completed at least 3 hope sessions were invited to an exit interview. Furthermore, 8 agreed and were interviewed. They were aged between 25 and 38 (median 29, IQR 26-32) years and had been diagnosed between 3 and 18 (median 7, IQR 3-14) years ago.

Harms

At baseline, 3 participants scored 2 or above on PHQ-9 item 9, indicating suicidal ideation, and were contacted as per the safety protocol. All chose to proceed with this study. No participants scored 2 or above in PHQ-9 item 9 at the T1 follow-up.

Primary Outcomes

Adherence and Engagement

Of the sample of 60 at baseline and remaining in this study, 7 (7/60, 12%) never logged on to the intervention, and 5 (5/60, 8%) completed no intervention sessions. Further, 48 women who completed the baseline measures went on to complete at least part of the intervention (48/60, 80%), of whom 22/48 (46%) met the adherence definition by completing at least 3 intervention sessions, and 14/48 (29%) completed all 6 sessions. Participants posted 256 comments and gave 157 likes of their peers' posts, recorded 93 gratitude entries, and set 71 self-management goals, though use of the platform's features varied widely. Adherent participants posted 0-11 comments per session (mean 1.7, SD 2.4), 0-8.3 likes of peers' posts per session (mean 1.1, SD 2.2), recording 0-3.3 gratitude entries per session (mean 0.7, SD 0.9), and setting 0-1 goals per session (mean 0.5, SD 0.3). Nonadherent participants posted 0-2.5 comments per session (mean 0.75, SD 0.8), 0-4 likes of peers' posts per session (mean 0.3, SD 0.8), recording 0-1 gratitude entries per session (mean 0.3, SD 0.4), and setting 0-1 goals per session (mean 0.3, SD 0.4). As a group, adherent participants posted more comments and likes of peers' posts for each session they completed, as well as more gratitude entries and goals per session.

Acceptability

The 8 adherent participants who were interviewed had completed between 3 and 6 intervention sessions each (median 6, IQR 6-6). They described the intervention as acceptable and having met or exceeded expectations, with some critical feedback. All who were interviewed reported experiencing some changes in self-management behavior as a result of taking part. Themes derived from the thematic analysis are presented below (Table 2).

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Table 2. Summary of qualitative interview themes for adults with PCOS[a] who were adherent to the online, 6-week, self-management intervention in the multimethod proof-of-concept study.

Theme	Summary
Prioritizing self-care	• Self-care is important and not selfish
Developing a self-management mindset	• PCOS is valid but not dominant; openness, pacing, and gradual activity
Setting more manageable, realistic, and motivating goals	• Small steps, facilitator support, and lasting change, even with low engagement
Improved mental health: being able to experience and cope with a wider range of emotions, both positive and negative	• More self-awareness, acceptance, and confidence; and peer support benefits
Increased self-compassion and reduced shame	• Compassion focus and peer support normalized distress
Greater openness about PCOS	• Selective or trusted disclosure, sharing to help others, and advocacy
Noticing physical changes	• Better sleep, more diet or exercise motivation, and return of periods
Being prepared for future health concerns	• Conception planning, proactive information-seeking, and ongoing self-care
Continuing practice to consolidate or extend what was learned from the program	• Ongoing skill use and lifestyle change, and long-term commitment
Experience of content, tools, and format	• Concise, accurate content; ongoing resource; and personal relevance varies • Gratitude aided positive focus, balance, accept bad days; and sustained use • Peer facilitation aided clear or realistic goals, accountability, and overcame sharing hesitation • Peer support aided motivation, connection; flexible engagement; and desire more interaction
Suggestions for future iterations of the program	• Privacy options for goal sharing • Extended facilitator availability • Integrate into NHS[b] care

[a]PCOS: polycystic ovary syndrome.

[b]NHS: National Health Service.

Prioritizing Self-Care

Taking part in the intervention allowed some participants to prioritize care for themselves and their own health. For example, P16 described participating as a process of learning and permitting herself to prioritize her own needs.

> *Learning to you know respect and love myself and put myself first is not a selfish thing* [P16, completed 6 sessions]

She emphasized that looking after her own health was not selfish. That she needed to state this reflects a difficulty in attending to her own health needs without being (or being seen as) selfish or self-centered. Another participant experienced the intervention as an opportunity to assess her own self-management needs.

> *It's been encouraging me a lot more to want to think about… me (laughs) me, some of my personal needs* [P27, completed 6 sessions]

She laughs as she repeats "me," again, emphasizing the difficulty in prioritizing self-care.

Developing a Self-Management Mindset

Several participants described changes to their way of thinking about their PCOS or responding to its challenges as a result of the intervention. These changes reflect a realization that PCOS is a valid, long-term health condition that needs to be monitored but does not necessarily have to dominate life. For example, P44 described how taking part in PCOS Hope had helped validate her health concerns and encouraged her to acknowledge these to her employer, without having to offer other explanations for illness.

> *I sort of feel a bit validated by my experience to the point where if I have to phone in sick because of reasons relating to my PCOS I say exactly why … instead of another reason* [P44, completed 5 sessions]

That P44 had previously felt her condition might not be regarded as valid seems to have discouraged her from disclosing it in her workplace, so feeling validated had enabled her to be more open about her need for sickness absence. Since taking part in the intervention, P21 had started actively monitoring her symptoms in order to recognize times when flare-ups might occur, using this to plan and pace her work accordingly.

> *I keep a symptoms diary which kinda helps me think to say well that potentially could be the worst day so*

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> *I can't do anything that day … don't overcrowd your diary … allow myself permission to do that which was huge.* [P21, completed 6 sessions]

Pacing, often recommended by health professionals for long-term health conditions, was something that P21 felt allowed to do, having taken part in the PCOS self-management intervention.

For some participants, the self-management support provided by the program enabled them to obtain a sense of keeping PCOS in its place. For example, P26 described moving away from having her life on hold toward taking steps to become more active, in a stepwise and manageable way:

> *It's actually made me think … about putting life on hold and things like that. I've actually started to do a little bit more so if it's a bit more yoga and I decide to do little bits and pieces that I know that my body can handle just to get myself a little bit more active again.* [P26, completed 6 sessions]

The self-management mindset developed by these participants was one in which PCOS was more recognized and accepted, while not necessarily preventing active steps to continue important activities such as work and physical activity.

Setting More Manageable, Realistic, and Motivating Goals

Weekly goal setting and solution-focused feedback were mentioned as valuable by all participants interviewed. For example, P14, who set and shared 5 goals during the program, valued the small stepwise approach to setting manageable goals, which motivated her to keep making changes:

> *Just kind of the motivation to keep doing small steps … and keep setting small goals in my week … to give me a bit of focus and to keep a little bit of momentum.* [P14, completed 6 sessions]

The repetition of the goal setting throughout the program seems to have helped P14 maintain focus on and actively engage with her self-management. The peer facilitators' support with goal setting was reported by P21 as particularly helpful:

> *At the beginning I was setting really unrealistic goals so it was really nice to have someone coming back … feedback to try to make them more manageable … it was just really helpful for me to see what I can do and that healthy expectations and when I need to draw back on unhealthy expectations.* [P21]

The peer facilitators' support (using motivational interviewing skills, adjusting goal difficulty, goal specificity, assessing goal commitment, and giving solution-focused feedback) had helped P21 stay engaged with goal setting throughout the program, not giving up or becoming discouraged by missing targets that may have been unrealistic at first.

The interviewed participants who engaged less with the program and set fewer goals, still reported having gained some benefit from the goal-setting process. For example, P45, who set 2 goals in total, felt the process had had a lasting impact, and had connected with other self-management learning she had done:

> *The goal setting thing was actually the most useful part of the whole project and something that I've carried on. I think it's sort of joined up with something else that I'd listened to about goal setting and rewarding yourself for things and so I've been working on that to help me improve my exercise basically.* [P45, completed 3 sessions]

Despite having limited engagement with goal setting during the period of the intervention, P45 continued using goal setting to increase physical activity 9-10 weeks after completing the program.

Improved Mental Health: Being Able to Experience and Cope With a Wider Range of Emotions, Both Positive and Negative

Several participants reported feeling their mental health had improved and that they felt this was related to attending the program. Some attributed this to being more self-aware, mindful, or accepting that they experienced distress, feeling more supported, or noticing positive aspects of life despite PCOS. For example, P16 reported feeling more in tune with her emotions and recognizing that, despite inevitable challenges, she was hopeful and more self-confident after taking part in the intervention:

> *I've got a long way to go but it doesn't feel like like a kind of treacherous path it feels like ok you're gonna hit stumbling blocks but you will get through it. … I'm a lot more positive and self-assured and self-confident than I was perhaps before I started the programme definitely … the programme made me tune in to more to myself …* [P16]

Acknowledging distress and tuning in to emotional experiences was described as part of the way through "stumbling blocks" and challenges. This was echoed by P26, who emphasized how the program has given her permission to recognize her own feelings of distress when faced by the challenges of PCOS:

> *Saying you know you are you are allowed to feel these things. And I think for me that was one of the biggest things.* [P26]

Clearly, for P26, having difficult emotions validated and validating her own experience was a major impact of the intervention. P44, who participated 12 times in group discussions, found the peer group format of delivery beneficial in providing social support and improving her mental well-being:

> *That definitely helped me feel like my mental health was being a bit more supported and yeah I'd say that I'm probably mentally in a better place.* [P44]

Not all participants found the peer group sharing helpful for their well-being. P45, who had scored as moderately severe for depression symptoms at baseline and experienced a traumatic life event during the intervention period, found the shared gratitude activities particularly difficult, especially after reading other participants' gratitude posts:

> *It's difficult when the doctor can't think of anything to suggest and the fertility clinic can't think of*

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> *anything to suggest and then you're sort of faced with this website and its saying all things for it to be hopeful for and you're like oh… I think reading other people's (gratitude posts) just made me even more down because it was like… we're really scraping the barrel if this is the kind of stuff … (laughs). I don't know it just made me feel even more hopeless. …* [P45]

This highlights a potential difficulty with positive psychology interventions and with peer group support, in that some participants may find positive psychology activities cloying or alienating, and not all participants will experience comparisons within the group as therapeutic. Despite this, P45 did conclude that there was some benefit to practicing gratitude activities herself:

> *The gratitude thing I think even though I found it really hard I think it, it did shift something in my brain.* [P45]

Increased Self-Compassion and Reduced Shame

Some participants reported feeling more compassionate toward themselves and the emotional distress they experienced. For some, this meant learning to practice self-compassion and reduce self-criticism. For example, P16 described the program as helping her recognize that negative thinking can be part of life, not something to judge or punish herself for:

> *I'm a bit of a perfectionist and I tend to also spiral into the negatives … having the programme that's helped … the compassion focused reminding yourself you are human … that actually that's ok its life.* [P16]

The peer group setting and group dynamics of the program had helped temper P18's tendency to be self-critical:

> *It was a bit more of a caring environment … rather than letting me self-criticise.* [P18, completed 6 sessions]

Both these participants had found a shift from self-criticism toward self-compassion helpful for their mental health.

The self-compassion therapy activities in the program encouraged participants to acknowledge and not to judge their own emotional distress, reducing embarrassment and shame. For example, P14 found the program helped her appreciate how common emotional distress is in PCOS, and to feel less ashamed about her own feelings:

> *I feel a little bit happier about the struggles between PCOS and mental health whereas I felt a bit ashamed and kind of confused about before.* [P14]

Likewise, P21 reported a reduction in shame when she realized that she was not to blame for her PCOS symptoms or her associated emotional distress:

> *It was taking away for me the embarrassment of it and the shame that came from it and just understanding that actually it wasn't my fault.* [P21]

Greater Openness About PCOS

Associated with a reduction in self-criticism and shame was a greater willingness for some participants to share their diagnosis with others. For some, this was a small-scale change, perhaps sharing with only a few trusted people. For others, there was an openness to sharing the diagnosis in the workplace or wider social networks. P44 reported being a little more willing to share information about her condition:

> *It probably has helped me to be slightly more open about my PCOS.* [P44]

Since taking part in the intervention, P26 had been disclosing her diagnosis at work:

> *I've probably been much more open with work colleagues.* [P26]

P27 was disclosing selectively and also making decisions about how disclosure to trusted social networks might get her the support she needed most:

> *I'm thinking probably a lot more about the networks I'm keeping and the ones that are the most supportive to me.* [P27]

Greater openness was associated with obtaining support for some participants, and for some, with being empowered to help others with PCOS. P16 felt empowered to share her diagnosis, and some information and tools from the program, with both a friend and her own partner:

> *I've got a friend who who's got PCOS … I'm able to maybe offer better advice than I was before. … so in that sense it helps other people --- my partner and I … it really helped to read it to him as I was doing it.* [P16]

P16's experience shows the potential for the intervention to help individuals beyond the participants themselves. This scope was broadened further by participants who decided to engage more with activism as a consequence of attending the intervention. For example, P18 described stepping up her involvement with a PCOS advocacy group and writing to a high-ranking health official to ask for change:

> *I've engaged more with Verity … I've also been a lot more outspoken about it … some of us are planning on sending emails to the women's minister demanding more research.* [P18]

Noticing Physical Health Changes

Although physical health outcomes were not recorded as outcome measures in this pilot study, some participants interviewed described noticing changes in their physical health that they attributed to taking part in the intervention. For example, P26 reported improvements in sleep:

> *I've started reading mindfulness sort of activities …coming out from the programme … it's helped with quality of sleep.* [P26]

P16 felt motivated to make changes to her diet and do more physical activity to manage her PCOS:

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> *I'd already started changing to a PCOS diet and exercise and things and I had lost quite a bit of weight … it helped keep me motivated …* [P16]

For P27, shifting her focus to prioritize her own self-care had seen her periods return:

> *It's encouraging me to think more about what's good for my body again. Thinking about my self-care, now I'm thinking about myself more my periods have actually, they've actually come back. Which is like hallelujah!* [P27]

For P27, this change was associated with taking care of her body and prioritizing what it needed.

Being Prepared for Future Health Concerns

Several participants reported feeling better prepared to deal with future health concerns associated with PCOS as they arose. These might be changes related to life stage, changing family circumstances, or changes to treatment options. For example, P16 felt information gained on the program would help prepare her and her partner for future conception:

> *We're getting married … the next step is children … some of the information that was in there … that's been really helpful for both of us …* [P16]

P18 felt she was "armed" and empowered to proactively seek out new information about medication and treatment options in the future.

> *I'm armed with a little bit more information so I'm hoping as medications and things change, I will bear it in mind going forward to be proactive in keeping it that way.* [P18]

P18's use of the metaphor "armed" suggests an anticipated battle for which she must continue to be prepared. P27 was also encouraged to stay informed and ready to cope with future health issues:

> *It's just been another way to encourage me more to ensure that I'm well informed in the areas for myself really and my future health …* [P27]

Continuing Practice: To Consolidate or Extend What Was Learned From the Program

At the time of the interview (9-10 weeks post intervention), several participants emphasized that their use of what they had learned in the program was ongoing, and they would continue to work on it for the foreseeable future. For example, P26 was still thinking about program materials and applying changes in her everyday life:

> *Even now however many weeks it is away from when we finished it's still something that I'm still processing and going through and making those changes and sort of noticing how its changing my life for me … there's still things that I can still work on.* [P26]

P44 also described the "work" of self-management as ongoing, and something that required a long-term commitment of effort:

> *A lot of the mental health support aspects of it … I can see that having a longer-term impact – it's something that you need to constantly work on and they'll always feature as sort of part of your self-care … things are always a work in progress really.* [P44]

P14 was also motivated to keep practicing skills learned in the program to maintain and enhance her well-being:

> *I'm still motivated to try and work on both kind of the physical and the mental health aspects. And that's not that's not something that I'm going to stop any time soon.* [P14]

Experience of Content, Tools, and Format

As part of the ongoing cocreation process, participants were asked what they liked and disliked about the program content, activities, tools, and delivery format, including any recommendations for modifications to future iterations of the intervention.

Most participants interviewed reported that the evidence-based informational content presented in an online multimedia format was easy to understand and intuitive to navigate, helping them to be better informed and understand PCOS more. P26 contrasted the condensed and accessible format of the program materials to a "bombardment of books" she had encountered elsewhere:

> *There was a lot of information in there that… some of it I knew a lot of it I already knew but it was nice to have it condensed and simplified rather than being in a bombardment of books that three or four hundred pages long and you've got loads of information to take in.* [P16]

P18 contrasted the accuracy of program materials with unfiltered material often found on the internet:

> *Accessing that information, which I know is accurate as well cos that's another downside of "Doctor Google" you don't know what you're gonna come across. I know that that (programme information) is backed and up to date and everything so that's a reassuring resource.* [P18]

Further, 2 participants described the information acquired in the program as a "bank" they could return to later as required, for example, P16 had saved recommended links to her internet history to consult in the future:

> *Having that knowledge bank in my mind and having some of the things saved on my internet history so I could go back to them helped me to seek the help and seek the different things that I needed in order to improve my life in other areas as well.* [P16]

Most participants interviewed reported finding the information component of the program helpful or personally relevant, but P45 did not find anything new of interest:

> *Quite a lot of the sort of PCOS related stuff was stuff I already knew so working through that wasn't helpful … I've had my diagnosis for quite a long time so I, if I'd been new to it it would have been helpful but at this point it wasn't.* [P45]

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Participants interviewed described positive experiences of using the self-management tools provided. The gratitude activities were described as important in maintaining emotional well-being. For example, P26 described focusing beyond the negative:

> *It probably helps with the mindset thing is thinking about the things that are that are good … that are good in life and not necessarily focusing on all the … you know the negative things that are going on.* [P26]

P27 had continued to use the gratitude journaling activity after the intervention period and found it a useful response to distress:

> *Actually doing them it was quite rewarding and it just gives them that positive that positivity again so even if things are a little bit shaky during the day you're always remembering the positives which I suppose is a balance.* [P27]

P16 also referred to using the gratitude activities to maintain emotional balance:

> *I really liked having that kind of try and find something positive in your day. As I say some days were awful and you just can't comment and that's fine and that's life. It was similar with one of the talks they had a video about positivity thing cos again I'd read (inaudible) book about face the fear and do it anyway and everything in that book sort of was like everything has to be positive in life and sometimes it isn't. Whereas the video and having the gratitude enabled you to kind of get the right balance that there are positives even on a bad day but some days are just bad and that's ok to accept when it is bad. And that really helped so yeah. It gave some balance.* [P16]

What P16 describes here is using gratitude to maintain perspective on both positive and negative emotions, rather than feeling pressure to maintain a relentlessly positive outlook—an important distinction that is embodied in gratitude interventions in chronic health conditions.

The solution-focused goal-setting support and feedback provided by the peer facilitators were valued, particularly for helping participants to set and adjust goals to make them both challenging and achievable, and in providing accountability that motivated participants to persist. For example, P27 found the goal setting helpful in establishing clarity, in keeping goals realistic, in finding ways to problem-solve goal barriers, and in motivating her to complete her goals:

> *That was the thing I found really useful so it was very good encouraging me to to set a very clear goal … set myself something very targeted. I tried my best not to do something too … too erratic cos I'd then never do it. But then having someone I was accountable to as well… and find ways made a ginormous difference.* [P27]

P44 found that the accountability from the peer facilitators helped her set goals that challenged her but were also achievable:

> *It was kind of like a nice way to stretch yourself a bit but also then get that that lovely reinforcement that the facilitators were giving kind of about how you were doing and so yeah the accountability was helpful.* [P44]

Being accountable to peers was something that some participants felt unsure about initially, but were more comfortable with as time went on:

> *I did set some goals … I found that a bit challenging from the sense of setting a goal and other people knowing what your goal is and that being kind of a public thing and I think my initial reaction was I don't want to share a goal with anyone. I found that everyone was really supportive the facilitators were really good at encouraging you and like supporting you on the goals and it was nice to it was nice to be able to reflect back on it when it had gone well and when I hadn't achieved the goal no-one was critical of it - they were quite encouraging.* [P14]

Participants reported finding the peer group delivery of the intervention helpful, with some caveats, most of which were related to the extent of information sharing and the level of participation and engagement across the group. For example, P14 was wary at first about sharing personal information in the group via her personal profile. As time passed and the group dynamics became clearer (and perhaps a sense of what data could be seen and by whom), she found interacting with other participants beneficial:

> *I think initially … I was quite daunted by doing something like on an open platform and where you were posting and other people could see what you were posting… but found it like easy to use and I think… as time went on I got less worried about posting on that like open forum and I found the interaction with other people helpful.* [P14]

P16 experienced the support of peers in the group as beneficial for managing negative emotions or discouragement, even when she was not logged in to the intervention:

> *Having that little group of cheer leaders and even though I only keep in contact with one of them in my mind sometimes if I'm having a negative moment or I'm having a bit of a waver I sometimes think of that group and I think come on you've got a little group of cheerleaders somewhere out there come on! (laughs) It's something simple like that but it really does make a big impact. Especially on a negative day.* [P16]

The mental imagery of a supportive group of cheering peers was a resource P16 was still drawing on to help her 9-10 weeks after the intervention had finished.

The fact that peers shared personal information, experiences, goals, and progress was valued by participants, as it gave a sense of belonging to a group of relatable, recognizable, empathic humans, rather than interacting with an impersonal or "robotic" digital entity. For example, P21 contrasted taking part in the PCOS Hope intervention with using health apps:

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> *Although I knew everything was very confidential it really … I felt it put a name to someone, so it wasn't like (reads out number). When you were reading like feedback on somebody, or you could see little comments they were putting up it was like "That's that girl" … and it became more personal for me anyway cos a lot of the time when you do things like this you feel like you're just talking to robots. But it meant for me I was like this is actually really people that potentially know exactly how I'm feeling.* [P21]

Despite deriving benefits from seeing others share their personal information, some participants preferred to observe without sharing quite so much information themselves. For example, P18 described herself as lurking and seeing others' goal progress:

> *There was no pressure to have to engage with that as well so sometimes I can be a bit of a lurker and see what other people were doing to complete goals etc.* [P18]

P18 described a sense that the platform exerted no pressure to engage or share personal information, although a (perhaps inevitable) consequence of this was that information sharing and group discussion varied across the group. For example, P18 found she did not have as much one-to-one interaction as she would have liked, and no geographically local connections were made:

> *I think the idea was that it was supposed to be a sort of quite a social thing as well. I didn't quite have that experience. I'd comment on things on people's posts, etc. but I thought there might be one to one messaging perhaps as someone, if I saw someone was more local had a similar experience. I understand probably quite a lot of us were quite shy so perhaps I could have been more out there with it. But there didn't seem to be a lot of that in particular and I was kind of hoping for a little bit more of that.* [P18]

The lack of any pressure to engage also meant that information sharing and group discussion diminished in the later weeks of the intervention, something that was regretted by P14:

> *Towards the end of the course there was only there was only a small number it seemed that were active on there on the portal so it kind of would have been nice if there'd been a few more.* [P14]

Suggestions for Future Iterations of the Program

Future modifications to the program that were suggested by participants included introducing refined information-sharing options within the group, for example, offering the choice to share goals and progress with facilitators only, an option to access support from the peer facilitators for longer than the 6-week intervention period, and making the intervention more widely available as part of routine care for PCOS.

One participant suggested refining privacy settings to allow group members to share only some details of their goals with the peer group, or to share goals and goal progress anonymously:

> *Perhaps if there was an option for certain aspects of your goal setting to perhaps be anonymous. So it could maybe state that you had set a goal … but if you wanted the goal itself to be anonymous might have encouraged me a little bit more … or if you could like on the news feed it might appear that you had set a goal or something like that or you had completed it- that would still be able to be posted on but if it you know if you didn't want to necessarily disclose the exact content.* [P18]

P14 would have liked access to the support of the peer facilitators after the 6-week intervention period, in order for participants who might have fallen behind the main group to catch up:

> *The facilitators were on the course for the six weeks and then once the six weeks were up they weren't on the platform any more. And I think it may have been helpful to have I don't know one more week when they were still available or a bit longer because if you weren't able to keep up with getting through each week's worth of stuff then by the time you got to the end not all of the support would be available.* [P14]

P44 suggested that the intervention should be made available for all newly diagnosed patients in the NHS:

> *To be honest its exactly the type of thing that the NHS should be rolling out for people who get a PCOS diagnosis because there's so little support and if you're if one of your goals isn't fertility based there's even less for you. Having something that people when they get that diagnosis can kind of go through and be like this is a serious condition it will have knock on effects on my life you know how can I best manage those? It is exactly the type of thing that I think should be rolling out.* [P44]

Pre- and Postprogram Secondary Outcomes

Those participants who completed both the baseline and postprogram questionnaires were included in the pre- and postprogram quantitative analysis (n=11).

Median and IQRs for outcomes pre- and postintervention for participants who completed at least 1 session of the intervention and completed questionnaires at both T0 and T1 are shown below (Table 3).

Between T0 (baseline) and T1 (post intervention, 6 weeks), there were decreases in depression and anxiety, and increases in hope agency, hope pathways, and gratitude. There was a meaningful (≥3 points) increase in mental well-being.

In participants completing both baseline and follow-up measures, 73% (8/11) met clinical caseness for depression at T0 and 36% (4/11) at T1. In participants completing both baseline and follow-up measures, 45% (5/11) met clinical caseness for anxiety at T0 and 45% (5/11) at T1.

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Table 3. Anxiety, depression, mental well-being, gratitude, hope agency, and hope pathways pre-and postintervention scores for adults with PCOS[a] who accessed the online, 6-week, self-management intervention and completed follow-up measures in the multimethod proof-of-concept study.

Outcome	Preintervention (n=11), median (IQR)	Postintervention (n=11), median (IQR)
Depression (PHQ-9[b])	11 (8-16)	7 (6-13)
Anxiety (GAD-7[c])	7 (4-11)	6 (4-14)
Mental well-being (WEMWBS[d])	40 (35-44)	48[e] (40-54)
Gratitude (GQ-6[f])	35 (27-37)	37 (32-39)
Hope agency (SHS[g])	13 (10-15)	17 (12-19)
Hope pathways (SHS)	15 (14-17)	17 (12-20)

[a]PCOS: polycystic ovary syndrome.

[b]PHQ-9: Patient Health Questionnaire 9-Items.

[c]GAD-7: Generalized Anxiety Disorder 7-Items.

[d]WEMWBS: The Warwick-Edinburgh Mental Wellbeing Scale.

[e]Indicates a clinically meaningful change.

[f]GQ-6: Gratitude Questionnaire 6-Items.

[g]SHS: State Hope Scale.

Discussion

Overview

To the best of our knowledge, this is the first study to explore the feasibility, acceptability, and potential benefits of a PCOS self-management intervention combining positive psychology and cognitive behavioral therapy theory and practice. We aimed to test the intervention for its feasibility for web-based recruitment and delivery, and its acceptability to patients. It was feasible to recruit via the internet and deliver the intervention online. We also aimed to explore the intervention's potential to improve anxiety, depression, and positive well-being.

Principal Findings

We have explored proof of concept in that it was feasible to recruit via the internet and deliver this first web-based intervention for self-management support in PCOS. We have identified preliminary evidence that the intervention is acceptable to a range of participants. Women who completed the program and reported their experiences described it as acceptable and beneficial, highlighting perceived gains in self-care, goal-setting, mental health, self-compassion, openness about PCOS, and preparedness for future health needs. They reported valuing concise content, practical tools, gratitude practices, and peer support, which enhanced motivation, confidence, and sustained behavioral change. Suggestions for improvement included more flexible goal-sharing options, extended facilitator support, and better integration into NHS care pathways.

This study produced encouraging data on the primary outcomes of adherence and engagement, with 46% of those using the intervention meeting the adherence definition and 29% completing the whole program. This level of adherence is similar to that typically seen in digital mental health interventions [46].

Descriptive quantitative analysis suggests the intervention has potential benefits for anxiety, depression, and positive well-being. Those who were followed up showed, on average, decreased scores on depression and anxiety, and significantly increased scores on hope agency, hope pathways, and gratitude between pre- and postintervention time points. There were meaningful increases in positive mental well-being between pre- and postintervention time points.

Limitations

While we were able to successfully recruit from social media with the support of the patient advocacy organization, there is potential for selection bias in our sample. For example, women with PCOS who are already following a patient advocacy organization on social media may have accessed the organization's educational materials and be better informed about their condition, or they may be more highly motivated to take part in research or seek self-management support. They may not be representative of the demographic characteristics of all adults living with PCOS, which we know may vary across age, ethnicity [60], and gender [61]. For future studies, attention should be given to recruiting from a wider range of sources and to monitoring key characteristics of participants recruited, including, for example, PCOS phenotypes or symptom clusters, ethnicity, gender, and socioeconomic status. As this was a proof-of-concept study, limited demographic data (age and time since diagnosis only) were collected, and no information was recorded on prior experience with therapy or digital self-management programs. More detailed demographic data and information on participants' experience will be collected at baseline in future trials.

Although informed by a systematic review of adherence in digital mental health interventions [46], the adherence definition we chose, of at least 3 sessions, was selected somewhat arbitrarily, as there is no agreed-upon definition of adherence. We cannot draw clear conclusions as to how many sessions of the intervention are required to achieve improvements in the secondary outcome measures, and it is possible that some intervention sessions are redundant, or that participants become

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fatigued after a certain number of sessions. A future, fully powered study may enable us to identify the number of intervention sessions required to achieve clinically and statistically significant improvements in the secondary outcome measures.

There may be some selection bias in the process by which participants volunteered for the qualitative interviews we used to assess acceptability. For example, participants who found the program particularly beneficial may have been more likely to volunteer for an interview. Critical feedback from 1 participant interviewed suggested she experienced peer interaction in the program as nonsupportive or, at times, counterproductive. The potential for a negative impact from peer interaction should be investigated further in future studies. Individuals who are less engaged with an intervention are less inclined to participate in qualitative research with volunteer samples. This might be addressed in future work by including exit surveys for participants who drop out, in order to identify barriers to engagement or purposively recruiting intervention noncompleters for interview and emphasizing to them that their perspectives are valuable to the researchers, particularly if they are critical.

We considered a range of outcomes, including those measuring the adverse impact of PCOS on health-related quality of life, for example, the Polycystic Ovary Syndrome Questionnaire [62] and the Modified Polycystic Ovary Syndrome Questionnaire [63]. As we were interested in the potential for enhancing positive well-being, we chose WEMWBS as a measure of positive well-being. Future projects will test the feasibility of using measures that address PCOS-specific concerns. We conducted the GAD-7, PHQ-9, and WEMWBS assessments at 2 points—directly before and after the 6-week intervention—using the standard 2-week recall timeframe to maintain the measures' recognized reliability and validity. This approach allowed us to capture participants' recent levels of anxiety, depression, and well-being, as well as any overall changes, while minimizing burden and safeguarding data quality. Nonetheless, future studies could explore a more detailed picture of session-by-session changes by incorporating more frequent assessments.

As this was an exploratory proof-of-concept study, we intentionally adopted a purely qualitative approach to explore the variety and complexity of perceived physical health changes, which may be assessed more robustly with quantitative or self-reported biomarker measures in future studies.

More work could be carried out to enhance adherence and engagement with the intervention by building on participant feedback on acceptability. For example, intervention content could be updated and expanded to include newly emerging scientific information on PCOS and information of interest to older and longer diagnosed participants, offering a range of privacy settings that allow participants to select which peers see particular posts, and including more prompts to encourage peer interaction. As this was a descriptive exploratory study, we did not attempt to mitigate or measure the influence of peer effects or peer dynamics. The course facilitators encouraged peer interaction, for example, by encouraging participants to post questions on discussion forums and respond to peers' posts, but this was not compulsory. Future research will explore preferences for and experience and effects of peer interaction.

The follow-up rate for participants completing T1 postintervention outcome measures was low, with 11/48 (23%) completing these. This means that the sample for whom follow-up data is available is not likely to be representative. For example, follow-up data is only available for women diagnosed between 3 and 25 years ago. In future studies, it may be advisable to offer compensation to study participants to increase the number completing follow-up measures. It would also be insightful to follow up with participants longer term to assess any prolonged impact on anxiety, depression, and well-being.

This proof-of-concept study had no control group and was not powered to detect statistically significant differences in pre- and postprogram scores on secondary outcomes. Future feasibility trials will be required to confirm the sample size required for a definitive trial. Therefore, while we have established proof of concept, we are unable to demonstrate definitively that the intervention is effective. Data from a fully powered trial with an adequate sample size and an appropriate control arm will allow us to report any statistically significant differences in pre- and postprogram scores for both an intervention group and a control group and demonstrate efficacy under trial conditions. A fully powered study would also help us identify the characteristics of participants more likely to fully engage with and benefit from the intervention.

Conclusions

We have established proof of concept for the Hope PCOS intervention. The next challenges for our team will be to conduct definitive trials of our intervention in a range of clinical settings, to test its clinical and cost-effectiveness, and to find ways to integrate it into existing clinical care pathways for PCOS. If successful, H4C's platform and the Hope PCOS intervention may support the development of prototype interventions for other women's health conditions.

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Data Availability

The quantitative datasets generated or analyzed during this study are available from the corresponding author on reasonable request.

Conflicts of Interest

AT is a nonexecutive director of Hope for the Community. BA is Quality Assurance Lead at Hope 4 The Community.

Multimedia Appendix 1
CONSORT 2010 checklist.
[PDF File (Adobe PDF File), 225 KB - formative_v10i1e69206_app1.pdf]

Multimedia Appendix 2
Intervention content.
[PDF File (Adobe PDF File), 96 KB - formative_v10i1e69206_app2.pdf]

Multimedia Appendix 3
TIDieR checklist.
[PDF File (Adobe PDF File), 255 KB - formative_v10i1e69206_app3.pdf]

Multimedia Appendix 4
COREQ checklist.
[PDF File (Adobe PDF File), 198 KB - formative_v10i1e69206_app4.pdf]

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Abbreviations

AFAB: assigned female at birth
CONSORT: Consolidated Standards of Reporting Trials
COREQ: Consolidated Criteria for Reporting Qualitative Studies
GAD-7: Generalized Anxiety Disorder 7-Items
GQ-6: Gratitude Questionnaire
H4C: Hope for the Community
ISO: International Organization for Standardization
NHS: National Health Service
ORCHA: Organisation for the Review of Care and Health Apps
PCOS: polycystic ovary syndrome
PHQ-9: Patient Health Questionnaire 9-Items
SHS: State Hope Scale
TIDieR: Template for Intervention Description and Replication
WEMWBS: The Warwick-Edinburgh Mental Wellbeing Scale

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Original Paper

Co-Designed Mental Health Screening App (Here for You) for University Students: Pilot Feasibility Mixed Methods Study

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Abstract

Background: Mental health disorders are a growing public health concern among university students globally and in India, exacerbated by stigma and limited access to care. Mobile health (mHealth) apps offer a potential solution, but user engagement and cultural relevance remain key challenges. This pilot study evaluated Here for You, a mental health screening app co-designed with Indian university students to provide accessible, nonstigmatizing support.

Objective: This mixed methods study aimed to (1) describe the user-centered codevelopment and pilot testing process of the Here for You app; (2) evaluate the app's feasibility, user acceptability, and engagement; and (3) assess the concurrent validity of the app's screening tool, the Depression, Anxiety, and Stress Scale-21 (DASS-21) against established clinical measures (Hamilton Depression Rating Scale [HAM-D], Hamilton Anxiety Rating Scale [HAM-A], and Perceived Stress Scale [PSS]).

Methods: This study used a 4-phase user-centered design involving students with lived mental health experience, clinicians, and developers. A purposive sample of 30 university students (mean age 21, SD 1.8 years; n=15, 50% female) diagnosed with depression, anxiety, or stress participated. Participants completed the DASS-21 via the app and underwent clinical assessments using the HAM-D, HAM-A, and PSS scales. User experience was evaluated using the User Mobile App Rating Scale and qualitative feedback. Data analysis included Pearson correlation coefficients and thematic analysis.

Results: App-based DASS-21 scores showed strong correlations with clinician-administered scales: HAM-D (r=0.819; P<.001), HAM-A (r=0.887; P<.001), and PSS (r=0.972; P<.001), indicating high concurrent validity. However, wide CIs reflected the small sample size typical of pilot studies. The app received high usability ratings on a 5-point scale (User Mobile App Rating Scale mean score 4.4), exceeding published benchmarks for mental health apps in low-resource settings, particularly for functionality (mean 4.7, SD 0.3) and aesthetics (mean 4.5, SD 0.4). Qualitative feedback highlighted usability and enhanced privacy due to features such as quick exit, cultural resonance, and the desire for integrated support features. The co-design process directly addressed student concerns, implementing features such as simplified language and crisis support links.

Conclusions: This pilot study provides preliminary evidence for the feasibility and user acceptability of the Here for You app, co-designed using a participatory approach with Indian university students. Strong correlations between app-based screening and clinical assessments (r=0.819, r=0.887, and r=0.972) suggest promising concurrent validity. These findings from a single-site pilot study require validation through multisite studies across diverse educational and cultural contexts before broader implementation recommendations. By integrating user experience, clinical rigor, and ethical safeguards, such as adherence to digital personal data protection guidelines, the app offers a culturally resonant and scalable model for digital mental health screening in low-resource settings. This approach underscores the value of the "nothing about us without us" principle in developing effective mHealth interventions.

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KEYWORDS

mobile health; mHealth; co-design; user engagement; mental health screening; university students; artificial intelligence; AI

Introduction

The mental health and well-being of university students have emerged as a critical public health concern in India. According to the National Mental Health Survey 2015 to 2016 conducted by the National Institute of Mental Health and Neurosciences, 10.6% of adults in India had mental disorders, with lifetime prevalence reaching 13.7% [1]. The crisis is particularly acute among university students, with a recent multistate study of 8542 students across 9 Indian states revealing that 33.6% reported moderate to severe symptoms of depression and 23.2% reported moderate to severe symptoms of anxiety. Most alarmingly, 18.8% had considered suicide during their lifetime, with 6.7% having attempted it [2].

The Indian digital mental health ecosystem faces unique challenges that distinguish it from global contexts. India's health care system faces unprecedented challenges in addressing this crisis. This severe shortage creates a treatment gap ranging between 70% and 92% for different mental disorders [1], meaning most of those needing mental health care receive no treatment, with digital solutions often failing due to a lack of user involvement and cultural relevance. The National Mental Health Survey 2019 update showed that while 70% of urban youth own smartphones, only 12% have accessed mental health apps, primarily due to privacy concerns and cultural inappropriateness of existing tools. Most concerning, a 2024 analysis of 25 leading Indian mental health apps found that 68% lacked meaningful user involvement in development, and 84% had no clinical oversight, which may pose safety risks for vulnerable populations [3].

The situation among medical students, who are often considered representative of the broader student population, illustrates the severity of the crisis. A national task force report found that 27.8% of undergraduate medical students had mental health conditions, while 31.3% of postgraduate students experienced suicidal thoughts [4]. These statistics underscore that even students in health care fields, who should theoretically have better access to mental health resources, are struggling significantly.

According to National Crime Records Bureau data for 2022, India recorded 170,924 suicide cases, marking a 4.2% increase from the previous year. Of these, 13,044 (7.6%) were student suicides. This represents a significant rise from 6654 student suicides reported in 2011, indicating that the incidence of student suicides has nearly doubled over the past decade [5].

Digital mental health initiatives have emerged as a promising solution to bridge these gaps. The government's Tele MANAS initiative, launched in October 2022, had received more than 1.81 million calls by February 2025, demonstrating massive unmet demand for accessible mental health support [6,7]. The program operates 24×7 through a toll-free helpline (14416) in more than 20 Indian languages, with 53 operational cells across various states [6]. However, the World Health Organization (WHO) estimates indicate that the burden of mental health problems in India is 2443 disability-adjusted life years per 100,000 population, with an age-adjusted suicide rate of 21.1 per 100,000 population [8], highlighting the massive scale of intervention needed.

Mobile health (mHealth) interventions offer particular promise in India's context, where traditional mental health care remains inaccessible due to geographic barriers, financial constraints, and persistent stigma. Recent meta-analyses have supported the efficacy of smartphone apps in alleviating symptoms of depression and anxiety, underscoring their potential as adjuncts to traditional care [9,10].

However, while mHealth tools offer many benefits, challenges remain regarding user engagement, acceptability, and integration into clinical practice. Evidence indicates that the success of digital mental health solutions depends not only on technological robustness but also on the meaningful involvement of end users throughout the development process. Interdisciplinary approaches that integrate clinical expertise with direct user input have been shown to enhance both usability and clinical relevance [10].

In response to these insights, this pilot study evaluated Here for You, a mental health screening app co-designed with Indian university students. The app's name encapsulates its mission to provide discreet, nonstigmatizing support within India's unique cultural and health care context. This study aimed to develop and pilot-test a mental health screening app, integrating clinical expertise and user feedback to evaluate the app's feasibility and acceptability, and assess its preliminary validity by comparing app-based screening scales with established clinical assessments. Beyond co-design, the app demonstrates technical innovation through Advanced Encryption Standard (AES)-256 encryption, Firebase architecture optimized for Digital Personal Data Protection (DPDP) act compliance, cross-platform Flutter development ensuring accessibility across diverse device ecosystems, and the integration of crisis intervention protocols with real-time clinical oversight. By integrating participatory design, clinical validation, and ethical safeguards aligned with India's DPDP Act, the app addresses systemic gaps in accessible mental health care, offering a scalable blueprint for addressing the documented treatment gap in India's mental health crisis [11].

Methods

Study Design

This pilot study adopted a 4-phase iterative structure grounded in user-centered design principles and community-based participatory research (Textbox 1 and Figure 1). Students with lived experiences of mental health challenges were actively involved as co-designers throughout the process from ideation

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to evaluation, ensuring that the app addressed their unique needs while maintaining clinical rigor.

This study followed reporting guidelines from the STROBE (Strengthening the Reporting of Observational Studies in Epidemiology) checklist for quantitative components, COREQ (Consolidated Criteria for Reporting Qualitative Research) checklist for participatory design phases, and the mHealth Evidence Reporting and Assessment for digital health intervention reporting.

By integrating participatory design, clinical validation, and ethical safeguards, the app addressed systemic gaps in accessible mental health care, offering a scalable blueprint for low-resource settings. The initiative was originally sparked by students with lived mental health experience who articulated a need for an accessible, stigma-free platform for self-assessment and support. This collaborative model aimed to enhance user engagement and trust, aligning with broader trends in technology-based interventions designed to improve help-seeking behaviors.

By integrating rigorous clinical assessment methods with a co-design approach that placed end users at the forefront, this study sought to contribute to the evolving literature on digital mental health interventions. The goal was to establish a model for developing mHealth solutions that are not only effective in symptom detection but also resonate with the unique needs of their target population.

Textbox 1. Phases of user-centered development.

Phase 1: needs assessment (focus group discussions)

- Participants: 15 students (subset of the final sample) participated in this phase.
- Activities: two 90-minute focus group discussions identified barriers (eg, stigma and privacy concerns) and solutions (eg, anonymized assessments). Affinity mapping was used by the students to prioritize features, with quick exit and crisis support ranking highest. Language simplification involved replacing clinical terms (eg, pathology) with student-suggested alternatives (eg, stressors).

Phase 2: co-design workshops

- Participants: students (n=15), clinicians (n=3), developers (n=2), user experience designers (n=2) participated in this phase.
- Activities: wireframing involved students designing low-fidelity prototypes using Figma (Figma, Inc), advocating for a calming color palette (soft blues and greens) and a minimalist layout. Feature voting was conducted using anonymous dot voting, through which features were prioritized (eg, quick exit received 80% of the votes). Content cocreation included students coauthoring psychoeducational modules on exam stress and family dynamics.

Phase 3: iterative prototyping

- Beta testing: weekly usability testing with 30 students over 8 weeks was conducted.
- Feedback loops: task-based testing involved participants performing tasks (eg, navigating to crisis support) while researchers recorded pain points. Real-time revisions were implemented by developers within 48 hours (eg, added progress bars and simplified menus).

Phase 4: evaluation

- Clinical validation: Depression, Anxiety, and Stress Scale-21 scores were compared with the Hamilton Depression Rating Scale, Hamilton Anxiety Rating Scale, and Perceived Stress Scale.
- User experience: user experience was assessed using the User Mobile App Rating Scale, a 26-item scale assessing functionality, aesthetics, and information quality. Qualitative feedback was collected through open-ended questions (eg, “What features enhanced your sense of safety?”). Student validation involved participants reviewing final app screens to ensure alignment with their input.

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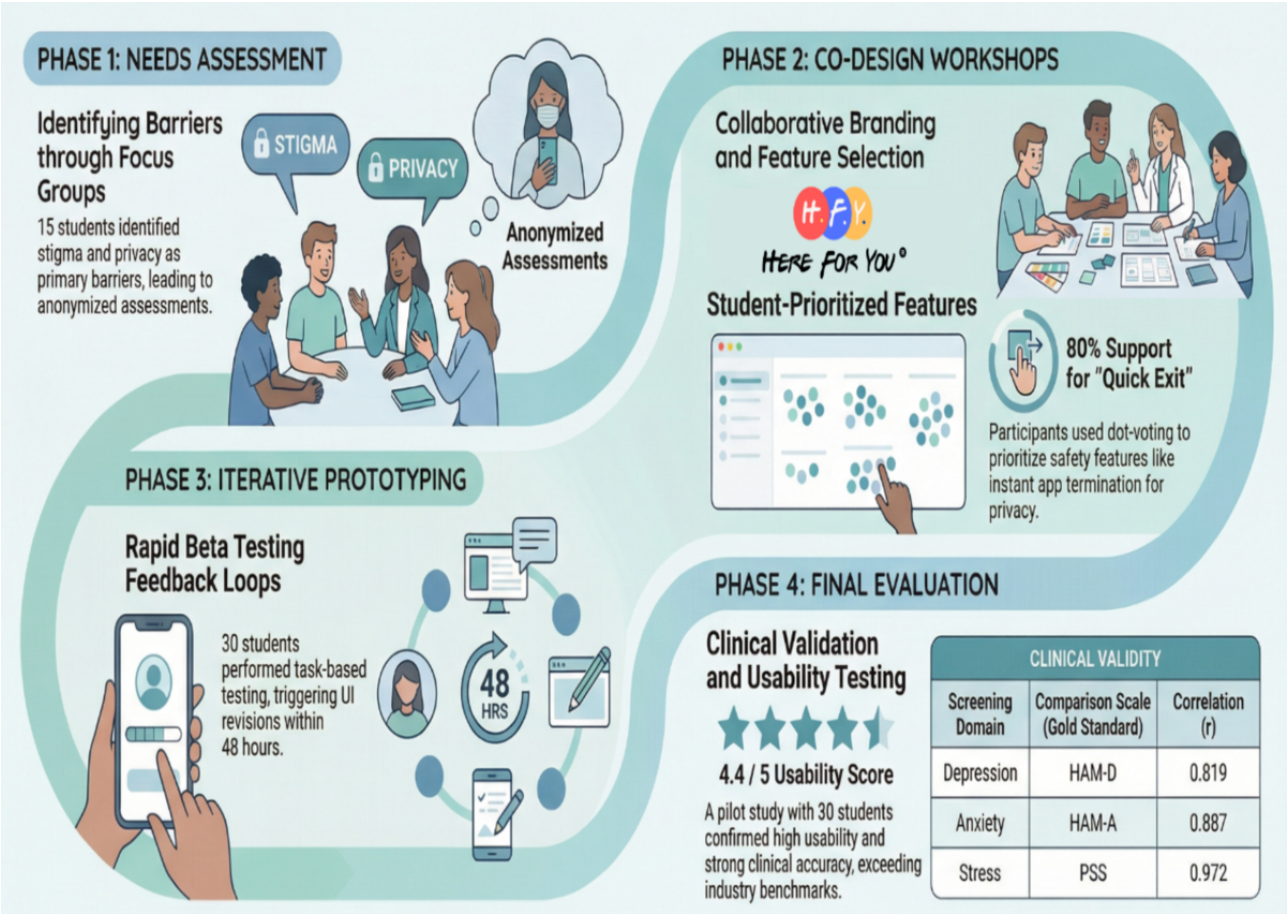
Figure 1. The 4-phase user-centered design process adopted for the Here for You app. The study used a participatory approach moving from needs assessment through co-design and iterative prototyping to final clinical and usability evaluation.



Ethical Considerations

This study received comprehensive ethics approval from the Institutional Ethics Committee of SRM Medical College Hospital and Research Centre, Kattankalathur, Tamil Nadu (1956/IEC/2020).

Given the vulnerable nature of the student population, additional safeguards were implemented: (1) all participants provided written informed consent with explicit withdrawal rights; (2) no monetary compensation was provided to avoid coercion; (3) crisis intervention protocols were established with direct links to university counseling services; (4) data minimization principles were strictly followed with 30-day automatic data deletion; and (5) end-to-end AES-256 encryption protected all data in transit and at rest.

To ensure user privacy and safety, the app used multiple layers of protection. All data, both in transit and at rest, were secured using AES-256 encryption, the industry standard for data security. User profiles were fully anonymized, collecting no personally identifiable information to protect user identity. Furthermore, in line with data minimization principles, all user data were automatically deleted after 30 days. For immediate, situational privacy, a quick exit feature allowed users to instantly terminate the app. These technical safeguards were complemented by robust crisis intervention protocols, which provided direct links to university counseling services, ensuring that users had immediate access to professional help when needed.

Participants and Recruitment

Setting

Recruitment occurred at a large urban university in Chennai, India, with approximately 50,000 students across engineering, humanities, and science programs. The university's psychiatry outpatient department serves approximately 150 students monthly, while the counseling center serves 80 to 100 students.

Recruitment Procedures

A systematic 3-pronged recruitment strategy was used over 8 weeks (June-August 2022).

First, primary recruitment occurred through the psychiatry outpatient department, accounting for 60% (18/30) of the participants. Treating psychiatrists identified eligible students during routine clinical visits. Students meeting the *Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition* (*DSM-5*) criteria for depression, anxiety, or stress-related disorders were provided with information sheets. Interested students were referred to the research team for formal consent procedures conducted 48 hours later to allow reflection time.

Second, secondary recruitment was conducted via the university counseling center, contributing to 27% (8/30) of the participants. Licensed counselors referred students with confirmed diagnoses (documented by previous psychiatric consultation) using

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identical procedures. This pathway captured students already engaged in support services but not in psychiatric care.

Third, peer referral networks accounted for 13% (4/30) of the participants. Students who completed participation could refer peers through a secure online form (no identifying information was shared without consent). Referred students underwent the same diagnostic confirmation and consent procedures.

Systematic Procedures

The recruitment and enrollment process followed a standardized sequence to ensure eligibility, diagnostic accuracy, and informed participation:

1. Eligibility screening was conducted, during which all referred students completed a structured telephone screening (10 min) assessing inclusion and exclusion criteria.
2. Diagnostic confirmation was performed, with eligible students attending an in-person psychiatric interview (30-45 min) using the *Structured Clinical Interview for DSM-5* modules for depression, anxiety, and trauma and stress-related disorders.
3. Informed consent was obtained by trained research assistants 48 hours after information provision, using the teach-back method to confirm understanding.
4. Baseline assessment was scheduled within 1 week of consent.

Selection Bias Mitigation

We maintained running stratification targets (sex 50:50, academic years first through fourth, and symptom severity mild to moderate) and paused recruitment from oversaturated strata. All eligible students were enrolled until targets were met.

Documentation

Recruitment logs tracked the source of referral, eligibility screening outcomes, reasons for nonparticipation, and time from referral to enrollment (median 12, IQR 9-16 days).

Of the 30 participants, the sample consisted of 15 (50%) female participants, with a mean age of 21 (SD 1.8) years. Participants were clinically diagnosed according to the *DSM-5* criteria, with depression disorders (n=12, 40%), anxiety disorders (n=10, 33%), and trauma- and stress-related disorders (including adjustment disorders, acute stress disorder; n=8, 27%) [12]. The recruitment process aimed to ensure diversity in academic year (first through fourth), symptom severity (mild to moderate), and gender representation. Exclusion criteria included comorbid substance use disorders, gaming addiction, or acute psychosis to minimize potential confounding factors. All individuals participated on a voluntary basis and did not receive monetary compensation for their involvement.

Recruitment involved 3 strategies to minimize selection bias: primary recruitment from the psychiatry outpatient department (18/30, 60%), supplemented by university counseling center referrals (8/30, 27%), and peer referral networks (4/30, 13%). While this clinical recruitment may overrepresent help-seeking students with higher mental health literacy, we maintained demographic balance (50:50 sex ratio) and representation across undergraduate years and symptom severity levels. We explicitly acknowledge that the findings' generalizability may be limited, as the sample likely has higher mental health literacy and technology acceptance than the wider student population.

Procedure

Following informed consent, eligible participants underwent a preliminary clinical interview conducted by a psychiatrist to confirm diagnoses of depression, anxiety, or stress. This was followed by a comprehensive clinical assessment using standardized instruments: the Hamilton Depression Rating Scale (HAM-D), Hamilton Anxiety Rating Scale (HAM-A), and Perceived Stress Scale (PSS). These established measures provided baseline assessments of symptom severity. Participants were then invited to download the beta version of the mobile app and independently complete the Depression, Anxiety, and Stress Scale-21 (DASS-21) questionnaire in English through the app interface. The app was developed for both Android and iOS platforms using the Flutter framework. Participants used their personal smartphones (screen sizes ranging from 13.97 to 17.018 cm) to test the beta version. Device compatibility was confirmed across major Android (version 8 or later versions) and iOS (version 12 or later versions) operating systems. To evaluate the app's usability and overall quality, participants subsequently completed the User Mobile App Rating Scale (UMARS), which assessed functionality, aesthetics, information quality, engagement, and subjective quality [13-17].

App Architecture and Features

The mobile app was developed using a Flutter (Dart) frontend to ensure cross-platform compatibility, with Firebase (Google LLC) used as the backend for real-time data storage. All data were encrypted following India's DPDP guidelines to ensure user privacy and data security.

Assessments

The app-based DASS-21 served as the primary tool for screening depression, anxiety, and stress symptoms. Clinical assessments administered by the psychiatrist using HAM-D, HAM-A, and PSS scales functioned as a gold-standard comparator for evaluating the app's validity. User experience was quantitatively assessed with the 26-item UMARS, which rated key aspects such as usability, functionality, aesthetics, informational content, and engagement on a 5-point Likert scale. Additionally, participants provided qualitative feedback through 2 open-ended questions aimed at identifying areas for improvement and enhancing cultural relevance and privacy features.

Data Analysis

Quantitative data analysis followed the guidelines proposed by Julious [18], with a sample size of 30 deemed adequate for pilot investigations and methodological refinement. Data analysis was conducted using SPSS software (version 28.0; IBM Corp) for quantitative analyses. Qualitative analysis was performed using ATLAS.ti (version 9.0; ATLAS.ti Scientific Software Development GmbH). Pearson correlation coefficients were computed to examine the relationship between app-based DASS-21 scores and clinician-administered HAM-D, HAM-A, and PSS scores. Descriptive statistics, including means and SDs, were calculated for UMARS subscales and total scores. For qualitative data, thematic analysis was performed using

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ATLAS.ti software to code participant responses, with emergent themes focusing on areas such as privacy, usability, and cultural relevance.

Results

Participant Demographics

A total of 30 university students participated in the pilot study, with an equal distribution of male and female participants (n=15, 50% each) and a mean age of 21 years (SD 1.8). Diagnoses included depressive disorders (n=12, 40%), anxiety disorders (n=10, 33%), and trauma and stress-related disorders (n=8, 27%), as confirmed through clinical interviews based on *DSM-5* criteria. Most participants (n=18, 60%) were in their second year of study, representing a range of academic disciplines, including engineering, humanities, and science. This cohort was purposefully stratified to capture diverse academic stressors while maintaining diagnostic consistency.

Clinical Validity

App-based screening scores, obtained via DASS-21, demonstrated strong correlations with clinician-administered gold-standard assessments, indicating high concurrent validity (Table 1). Specifically, DASS-21 depression scores correlated with HAM-D scores (r=0.819, 95% CI 0.712-0.926; P<.001), anxiety scores with HAM-A (r=0.887, 95% CI 0.804-0.970; P<.001), and stress scores with PSS (r=0.972, 95% CI 0.944-1.000; P<.001). While strong correlations were observed, the wide CIs (depression 95% CI 0.712-0.926) reflected the small sample size (N=30) typical of pilot studies and limited the precision of effect size estimates. This limitation necessitates larger validation studies before broader implementation. Although mean scores differed between the app and clinical assessments (eg, HAM-D: mean 9.63, SD 6.88 vs DASS-21 depression: mean 22.03, SD 10.55), these variations are consistent with previous studies validating the sensitivity of DASS-21 to a broader range of symptom severities, including subclinical presentations.

Table 1. Concurrent validity between app-based Depression, Anxiety, and Stress Scale-21 (DASS-21) scores and clinician-administered assessments in Indian university students with depression, anxiety, or stress disorders (N=30, single-site pilot study)[a].

Domain	Clinician-administered score, mean (SD)	App-based score, mean (SD)[b]	Pearson r (95% CI)	P value
Depression	9.63 (6.88)[c]	22.03 (10.55)	0.819 (0.712-0.926)	<.001
Anxiety	15.13 (11.02)[d]	15.73 (11.88)	0.887 (0.804-0.970)	<.001
Stress	25.17 (9.97)[e]	26.27 (11.42)	0.972 (0.944-1.000)	<.001

[a]Pearson correlation coefficients with 95% CIs comparing the mobile app screening tool against gold-standard clinical measures administered by psychiatrists. Participants were university students aged between 19 and 24 years with Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition–confirmed diagnoses, recruited from an urban Indian university.

[b]App-based screening using DASS-21.

[c]Clinician-administered assessment using the Hamilton Depression Rating Scale.

[d]Clinician-administered assessment using the Hamilton Anxiety Rating Scale.

[e]Clinician-administered assessment using the Perceived Stress Scale.

User Experience

Participants rated the app highly across all domains of the UMARS, with a mean overall score of 4.4 out of 5. The app's UMARS ratings (overall 4.4) exceeded published benchmarks for mental health apps in low-resource settings, where typical ratings range from 3.2 to 3.8 for functionality and 3.0 to 3.6 for aesthetics. Functionality received the highest rating (mean 4.7, SD 0.3), attributed to features such as the quick exit button and intuitive navigation. On average, aesthetics were rated at 4.5 (SD 0.4), reflecting the minimalist, student-informed design. Information quality scored an average of 4.6 (SD 0.3), highlighting the relevance of culturally tailored psychoeducational content, particularly addressing stressors such as exam pressures. Engagement was rated slightly lower at an average of 4.2 (SD 0.6), although participants appreciated features such as progress tracking and easy access to crisis support. Overall, the app's UMARS ratings exceeded benchmarks from comparable mental health apps evaluated in low-resource settings, underscoring its user-centered design and accessibility [19].

Qualitative Feedback

Table 2 summarizes how student feedback was systematically integrated into the app across development phases, with corresponding UMARS scores and use metrics. A systematic thematic analysis, following COREQ guidelines, identified 4 primary themes from participant feedback. Of the 30 participants, the most frequently endorsed theme was privacy and safety features, mentioned by 28 (93%). The quick exit functionality was frequently highlighted as enhancing user confidence, directly addressing privacy concerns raised during initial focus groups. As one participant noted, "The Quick Exit button was a lifesaver during hostel room checks" (female second-year engineering student aged 20 years). The second major theme was usability and navigation (n=27, 90%), which reflected the success of student-led wireframing sessions. Participants praised the app's logical flow, with one stating, "The layout felt intuitive, no endless scrolling or hidden menus" (male third-year humanities student aged 21 years).

A strong desire for future enhancement needs (n=25, 83%) also emerged, with participants expressing interest in clearer next steps beyond screening. Representative feedback included,

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"After seeing my scores, I wanted clearer next steps, like a chatbot or peer support" (female fourth-year science student aged 22 years), which informs future development priorities. Finally, cultural resonance (n=22, 73%) was a significant theme, validating the cocreation approach to content. A student remarked that "the module on 'Coping with Family Expectations' felt like it was written for us, not at us" (male first-year engineering student aged 19 years). All themes directly corresponded to elements from the participatory design process, demonstrating the successful integration of student perspectives into the app's final design and functionality.

Table 2. Co-design process illustrating student feedback integration and measurable outcomes in mental health app development among Indian university students (N=30; 4-phase participatory design study).

Student feedback	Phase implemented	Implemented feature	Outcome metric[a]	Evidence of impact
"I need to exit the app quickly if someone walks in."	Co-design	Quick exit button (top-right corner)	Functionality score: 4.7	In total, 90% (27/30) of the participants used this feature.
"The questions feel like a medical test."	Needs assessment	Simplified language (eg, "How often do you feel overwhelmed?" vs "Rate your symptom severity")	Information quality score: 4.6	Qualitative feedback was as follows: "Felt less judged."
"I want to track my progress in surveys."	Prototyping	Progress bar added to Depression, Anxiety, and Stress Scale-21	Engagement score: 4.2	In total, 85% (25/30) of the participants reported reduced survey anxiety.
"I don't know where to get help after the test."	Co-design	Floating crisis button linking to the university counseling	Subjective quality score: 4.4	In total, 70% (21/30) of the participants clicked the button during testing.
"The app looks too clinical."	Prototyping	Calming color palette (soft blues and greens) and minimalist design	Aesthetics score: 4.5	Participant quote was as follows: "Feels welcoming, not like a hospital app."

[a]Outcome metrics were assessed using the User Mobile App Rating Scale, with domain scores reported on a 5-point Likert scale.

Student Validation Process

All 30 participants reviewed the final app implementations to confirm their feedback integration and (n=30, 100%) approved the final feature set, with participants noting that their specific suggestions were visibly incorporated into the user interface and functionality.

Discussion

Summary of Main Findings

This pilot study provides preliminary evidence for the feasibility and user acceptability of a student-centered, clinician-supported mental health screening app developed specifically for the Indian university context. Strong correlations between app-based screening and clinical assessments suggest promising concurrent validity, while high UMARS ratings indicate successful user-centered design. These findings address critical gaps in India's digital mental health landscape, where a lack of user involvement and clinical oversight contributes to a documented 70% to 92% treatment gap [1].

Detailed Discussion and Literature Comparison

Unlike most mental health apps in India, which lack meaningful user involvement or clinical oversight, our approach achieved high user satisfaction (UMARS mean score 4.4) through systematic co-design with the target population [3,20]. The strong correlations between DASS-21 scores and gold-standard clinical assessments validate the app's utility as a screening tool, consistent with previous validations of DASS-21 in diverse populations [21-23]. Crucially, the app's design, informed by student feedback, prioritized brevity and nonclinical language, addressing stigma-related barriers to help seeking identified in focus group discussions. This participatory approach mirrors the findings by Torous et al [24], who advocated for user-driven design to enhance engagement in digital mental health tools.

The app's high UMARS ratings reflect the success of its co-design process. For instance, the quick exit button, a student-requested feature, was used by 90% (27/30) of the participants, underscoring its role in fostering trust. These results contrast starkly with critiques of existing Indian mental health apps, which often neglect user preferences and cultural context [25]. By integrating region-specific stressors and anonymized crisis support, this app bridges a critical gap in India's mHealth ecosystem, where generic tools frequently fail to resonate.

A recent UK *Daily Mail* investigation (2024) highlights the darker implications of unregulated artificial intelligence (AI)–driven mental health tools, revealing that more than a million individuals in the United Kingdom now rely on chatbots as perfect partners for emotional support, often prioritizing algorithmic interactions over human connections [26]. Tragically, this trend has been linked to severe consequences, including cases where users experiencing suicidal or homicidal ideation received harmful advice or were inadequately redirected to professional help, culminating in adverse consequences. These incidents underscore the dangers of deploying AI-driven mental health tools without robust safeguards, ethical oversight, or integration with human expertise. The *Daily Mail* investigation directly validates our physician-led approach. Unlike AI-driven tools that automate risk assessment, our app maintains human clinical oversight at every stage, ensuring that users receive evidence-based guidance while preserving access to mental health professionals. In stark contrast, our

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physician-led app design explicitly avoids replacing human judgment with automation. Instead, it leverages technology to augment clinical expertise, ensuring that users receive evidence-based guidance while maintaining direct access to mental health professionals. This approach aligns with the Indian Council of Medical Research guidelines for AI in health care, which mandate a human-in-the-loop framework to preserve accountability, accuracy, and ethical integrity [27]. By embedding clinician oversight at every stage from content curation to crisis response, our app mitigates the risks of unsupervised AI systems while retaining the scalability benefits of digital tools [28].

India's leadership in ethical digital innovation is further exemplified by its progressive DPDP rules, which prioritize user consent, data minimization, and stringent penalties for breaches [11,21]. Our app's architecture adheres rigorously to these standards, using anonymized user profiles, end-to-end encryption, and transparent data use policies. While our app demonstrated successful DPDP Act compliance, implementation revealed significant challenges. Data localization requirements necessitated restructuring the Firebase architecture, increasing development costs by approximately 40%. The act's ambiguous cross-border data transfer provisions created uncertainty regarding cloud service providers. Most critically, government exemption clauses raised concerns for mental health apps should agencies request user data during crisis interventions, the Act provides insufficient protection for users' privacy rights. These measures not only comply with regulatory mandates but also foster trust among users, a critical factor for vulnerable populations such as students grappling with mental health crises.

The app's development exemplified the transformative potential of "nothing about us without us" in digital health. Students rejected clinical jargon, coauthored psychoeducational content, and prioritized features such as progress bars to reduce assessment anxiety. This aligned with global evidence that user involvement improves retention and efficacy in mHealth tools [24]. For instance, the app's minimalist interface and calming color palette, which were direct outcomes of co-design workshops, were praised by 85% (25/30) of the participants for reducing perceived stigma. Such findings counter critiques of top-down mHealth approaches, which often alienate users through impersonal design [29].

Broader Implications

The quadripartite framework (Figure 2) offers a replicable model for digital health innovation in low-resource settings, demonstrating that meaningful stakeholder collaboration not technological novelty alone drives both clinical utility and user trust. This approach aligns with WHO's calls for participatory mental health innovation in low- and middle-income countries, where top-down interventions frequently fail due to cultural misalignment.

The success of this app lies not in its technological novelty but in its synergistic framework, a harmonized collaboration between developers, end users, clinicians, and regulators. This model, visualized in Figure 2, reimagined digital mental health innovation as a shared responsibility rather than a siloed endeavor. The subsequent section describes how this quadripartite framework addresses systemic gaps in mental health care delivery.

Developers often prioritize functionality, but in this study, they embraced ethical coding, embedding student feedback into the app's architecture. This shift from user-centered to user-embedded design mirrors the digital solidarity paradigm where technology adapts to human needs, not vice versa [30].

Students did not just inform the app; they rewrote its vocabulary. The app's name, chosen by students during focus group discussions, underscores its departure from stigmatizing terminology. For instance, while naming the app, participants rejected terms such as Screening Hub, Mood Meter, and Psych-pal in favor of Here for You, something that evokes peer support. Their contributions challenged the deficit model of mental health tools, reframing users as experts rather than patients.

Physicians bridged clinical rigor with digital pragmatism and dynamic validation. Unlike static validation studies, clinicians conducted live audits during prototyping, flagging mismatches between app scores and real-time symptom changes. Crisis triaging integrated a tiered alert system in which low-risk cases received self-help tips, while high-risk cases triggered immediate clinician outreach. This approach contrasts with AI-driven tools that automate risk assessment, often overlooking contextual nuances [8].

In the app's development, regulators played a vital but bounded role. While students, clinicians, and developers cocreated features, regulators ensured compliance with India's DPDP Act and Indian Council of Medical Research guidelines. For instance, anonymized user profiles and end-to-end encryption, critical to student trust, were implemented to meet the DPDP Act's stringent data protection mandates. This pragmatic approach balanced innovation with accountability, reflecting real-world regulatory dynamics in which compliance is non-negotiable but not synonymous with collaboration [11,27,31].

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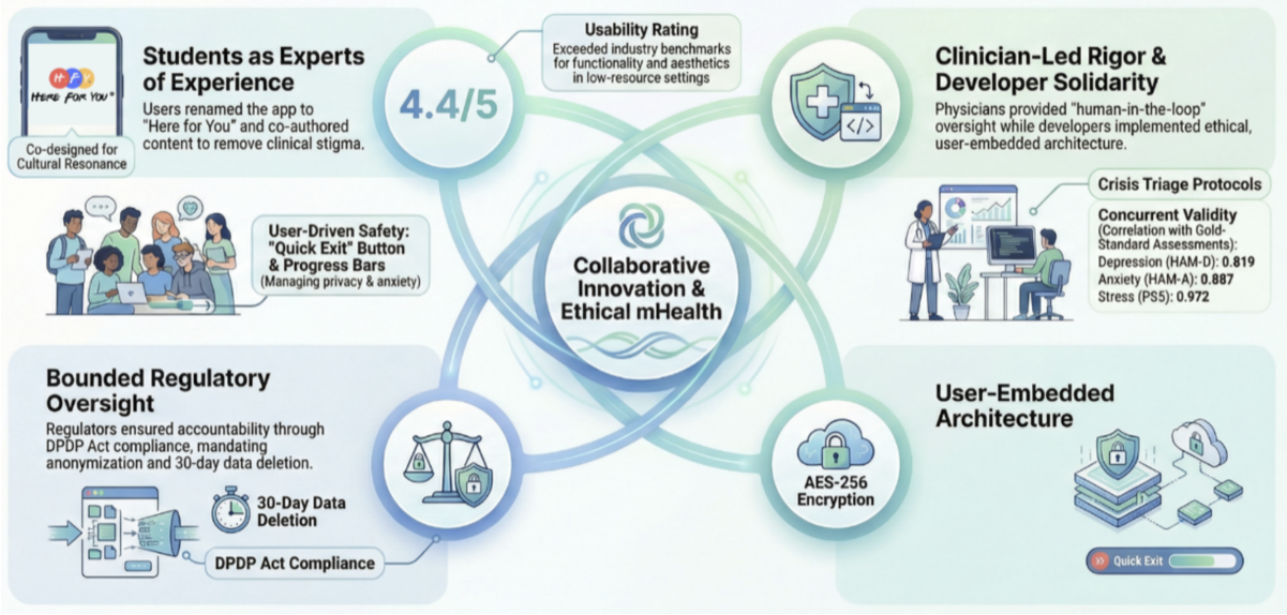
Figure 2. The quadripartite framework for collaborative digital mental health innovation. This model illustrates the synergistic roles of students, physicians, developers, and regulators in creating a clinically rigorous, culturally resonant, and compliant mental health intervention. DPDP Act: Digital Personal Data Protection Act.



Limitations

Although promising, this pilot study has several limitations that frame the scope of its findings. The modest sample size (N=30), though appropriate for a pilot, limits statistical power for subgroup analyses. Generalizability is constrained, as participants were recruited from a clinical setting, potentially overrepresenting help-seeking students with higher mental health literacy from an urban, English-speaking university. Methodologically, the single-institution design and short-term evaluation period prevent the assessment of broader applicability and long-term engagement. Finally, the app's current iteration focuses primarily on screening; future versions could expand this scope. These findings provide preliminary evidence from a single-site pilot study that requires validation through larger, multisite studies across diverse educational and cultural contexts before broader implementation recommendations can be made.

Future Directions

Future work will address these limitations on multiple fronts. The next iteration of the app could integrate therapeutic features, such as AI-driven personalization with adaptive cognitive behavioral therapy modules, while preserving essential clinician oversight. To validate this enhanced model, subsequent research must include a large-scale, multicenter randomized controlled trial with a diverse sample to assess effectiveness and scalability. A longitudinal study is also needed to evaluate long-term engagement and symptom outcomes. Beyond the research context, policy advocacy is essential to embed participatory design into national digital health strategies, helping to address the urgent global need for scalable and effective mental health interventions for students.

Conclusions

Beyond this pilot's immediate findings, this study validated participatory design as both an ethical imperative and a pragmatic necessity for digital mental health tools. As India's student suicide rates continue to rise, scalable screening solutions that balance clinical rigor with cultural resonance are urgently needed. Future research must test whether this co-design model maintains fidelity across diverse institutional contexts, ultimately informing national digital health policy that mandates user involvement as a regulatory standard.

This pilot study provides preliminary evidence for the feasibility and acceptability of a co-designed mental health screening app developed specifically for Indian university students. Strong correlations with clinical assessments (r=0.819, r=0.887, and r=0.972) suggested promising concurrent validity; however, confirmation through larger, multisite validation studies is essential before broader implementation. By centering student voices alongside clinical expertise, the app achieved high user satisfaction while addressing culturally specific barriers to mental health care access. The participatory design framework and clinical oversight model offered a methodologically rigorous approach that other institutions can adapt; however, successful replication will require attention to local cultural contexts and institutional resources. Future research should evaluate the app's long-term engagement, clinical outcomes, and scalability across diverse educational settings through controlled trials with representative samples. As India's digital mental health landscape evolves, integrating student-centered design with clinical rigor offers a promising pathway for addressing the documented treatment gap while maintaining safety and cultural relevance.

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Data Availability

The datasets generated during this study are not publicly available due to the sensitive nature of mental health data and privacy protections under India's Digital Personal Data Protection Act 2023, but anonymized aggregate data supporting the study conclusions are available from the corresponding author on reasonable request and institutional ethics approval.

Authors' Contributions

Conceptualization: MISS, TM, TC, SBM
Data curation: MISS
Formal analysis: MISS, TM, TC, SBM
Funding acquisition: MISS, TM
Investigation: MISS
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Validation: MISS, TM, SBM
Visualization: MISS
Writing—original draft: MISS, TM, TC, SBM
Writing—review and editing: MISS, TM, TC, SBM

Conflicts of Interest

None declared.

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Abbreviations

AES: Advanced Encryption Standard
AI: artificial intelligence
COREQ: Consolidated Criteria for Reporting Qualitative Research
DASS-21: Depression, Anxiety, and Stress Scale-21
DPDP: Digital Personal Data Protection
DSM-5: Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition
HAM-A: Hamilton Anxiety Rating Scale
HAM-D: Hamilton Depression Rating Scale
mHealth: mobile health
PSS: Perceived Stress Scale
STROBE: Strengthening the Reporting of Observational Studies in Epidemiology
UMARS: User Mobile App Rating Scale
WHO: World Health Organization

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Original Paper

Acceptability of a Culturally Tailored eHealth Video Intervention "Put Yourself First" to Promote Preexposure Prophylaxis Awareness and Knowledge Among Young Black Women: Mixed Methods Pilot Study

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Abstract

Background: Black women experience dual disparities with disproportionately high rates of HIV infection and low uptake of preexposure prophylaxis (PrEP). To address this issue, a culturally relevant eHealth video intervention was developed to increase awareness and uptake of PrEP.

Objective: This study aims to evaluate the usability, acceptability, and impact of a culturally tailored eHealth video intervention ("Put Yourself First") on PrEP-related knowledge and motivation among young Black women.

Methods: This study used a sequential, mixed methods design. Thirteen young, primarily heterosexual, Black women, aged 18-25 years, were recruited from community-based organizations and social networks in New York City to participate in 2 evaluation focus groups. Participants completed pre- and postvideo assessments, followed by facilitated focus group discussions to elicit qualitative feedback on the video's usability, acceptability, and impact on PrEP knowledge.

Results: After watching the eHealth video, knowledge scores increased significantly postviewing (P=.04). Most participants indicated willingness to consider PrEP (10/13, 77%), and all reported intentions to recommend it to others (13/13, 100%). Overall, 92% (12/13) of the participants rated the video as very good or excellent. Participants found the video to be very interesting (11/13, 85%) and useful (12/13, 92%). The qualitative findings suggest that representation, authenticity, and the normalization of PrEP use emerged as critical drivers of acceptability. It also highlighted the video's relatability, cultural relevance, and ability to dispel misconceptions, while also identifying areas for refinement for future studies.

Conclusions: Findings support the acceptability and usability of culturally tailored sex-positive eHealth interventions for improving PrEP awareness and motivation among young Black women. Culturally resonant multimedia centering the voices of young Black women to affirming pleasure, agency, and addressing structural barriers to engagement offers a promising strategy for HIV prevention.

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KEYWORDS

Black women; culturally tailored interventions; eHealth; health education; HIV prevention; PrEP; sex positive; stigma

Introduction

Despite Black women's vulnerability to HIV transmission and the availability of preexposure prophylaxis (PrEP) in the United States, many Black women continue to lack essential information about its benefits and accessibility [1,2]. According to the Centers for Disease Control and Prevention (CDC), only a small percentage of eligible Black women were aware of PrEP, and even fewer were using it [3-6]. Cultural and structural factors, such as inadequate representation in PrEP advertising and provider discomfort discussing HIV prevention options with Black women, further hinder PrEP adoption [7]. Addressing these challenges requires culturally relevant messaging and targeted outreach to reduce multilevel barriers, such as limited functional knowledge of PrEP, low perceived susceptibility to HIV transmission, medical mistrust, stigma, and constrained health care access [5,7-12]. These efforts must also be aligned with empowering Black women to make informed decisions about their sexual health practices, including HIV prevention [13].

Research suggests that animated educational videos can be practical tools for improving health knowledge and health literacy across diverse populations [14-16]. These videos are generally well-received by participants and can raise awareness, facilitate engagement, and reduce anxiety [17-19]. Video-based interventions have been shown to increase not only knowledge but also comprehension, which reduces uncertainty in decision-making and improves patient outcomes compared to written material [19-21]. Multimedia formats, such as animation [21], and delivery channels, including mobile video messaging, have enhanced PrEP knowledge and increased comfort discussing PrEP with providers [22].

In the context of HIV prevention, video interventions have shown promise in increasing knowledge, awareness, and intentions to use PrEP among various populations, including Black women [23,24]. However, most video-based HIV prevention tools have been developed for men who have sex with men or broad, mixed-gender audiences. Black women's prevention needs are shaped by gendered racism, relationship dynamics, and systemic health care inequities [4,25,26]; yet, few video-based HIV interventions have been explicitly designed for them related to PrEP [21,27]. Current eHealth interventions also tend to focus narrowly on nominal awareness, while neglecting relational and structural barriers, such as provider bias, partner mistrust, and burdensome medical monitoring that disproportionately shape Black women's PrEP decisions [26,28]. A recent longitudinal study with young Black women also highlights that barriers to PrEP initiation change over time, emphasizing the need for ongoing support and integrated, culturally tailored PrEP education for women's sexual health care [29]. Most HIV prevention messaging tends to focus on risk framing, while sex-positive narratives that affirm pleasure, intimacy, and autonomy are largely absent when directed toward women [30]. This common practice leaves a critical gap in approaches, perpetuates invisibility, and disengagement in HIV prevention efforts that could resonate more powerfully with the intersectional dynamics of Black women's lived experiences [25].

The literature suggests that eHealth interventions, particularly video-based educational tools, can effectively increase awareness and knowledge about PrEP among Black women [21]. By addressing the current gaps in understanding and using engaging multimedia formats, there is potential to overcome barriers to accessing PrEP and ultimately improve health outcomes in this underserved population. The purpose of this study is 2-fold: (1) to evaluate the usability, acceptability, and impact of a culturally tailored eHealth video intervention ("Put Yourself First") on PrEP-related knowledge and motivation among young Black women, and (2) to gather participant feedback to inform future refinements to its content and delivery. By directly addressing misconceptions, providing evidence-based information, and promoting open communication between providers and patients, this video aims to empower Black women to make informed decisions about their sexual health. Notably, the intervention uses culturally authentic narratives that are grounded in a sex-positive framework [31], positioning PrEP not only as an HIV prevention tool but also as a means of supporting autonomy, intimacy, and pleasure as integral aspects of women's sexual well-being. This study was grounded in multiple theoretical frameworks that informed both the development and evaluation of the intervention. Specifically, intersectionality [6,32], Black Feminist Thought (BFT) [33], and the Theory of Triadic Influence (TTI) [34] helped identify multilevel barriers to PrEP uptake among young Black women, while the Information-Motivation-Behavioral Skills (IMB) model [35] guided mapping behavioral determinants of PrEP use. In addition, the education-entertainment (edutainment) framework [36,37] guided the translation of these theoretical insights into culturally tailored, sex-positive, and engaging video content. Collectively, these frameworks informed the design of a culturally tailored, sex-positive, action-oriented video intervention aimed at improving PrEP awareness and uptake.

Methods

Study Design Overview

The LOVE (Learning Options through Video Education) study is a sequential, mixed methods pilot study designed to explore factors influencing Black women's interest in oral PrEP and to assess the feasibility of a brief, culturally tailored eHealth intervention aimed at increasing PrEP awareness and motivation. Figure 1 depicts the study's phased approach to developing and evaluating an innovative intervention. The four phases included (1) conducting exploratory focus groups to identify barriers and facilitators to PrEP uptake; (2) intervention mapping [38]; (3) development of the 5-minute, 3-part animated video, "Put Yourself First"; and (4) evaluation focus groups to assess the video's usability, acceptability, and impact on PrEP knowledge. Detailed procedures for Phases 1, 2, and 3, including the

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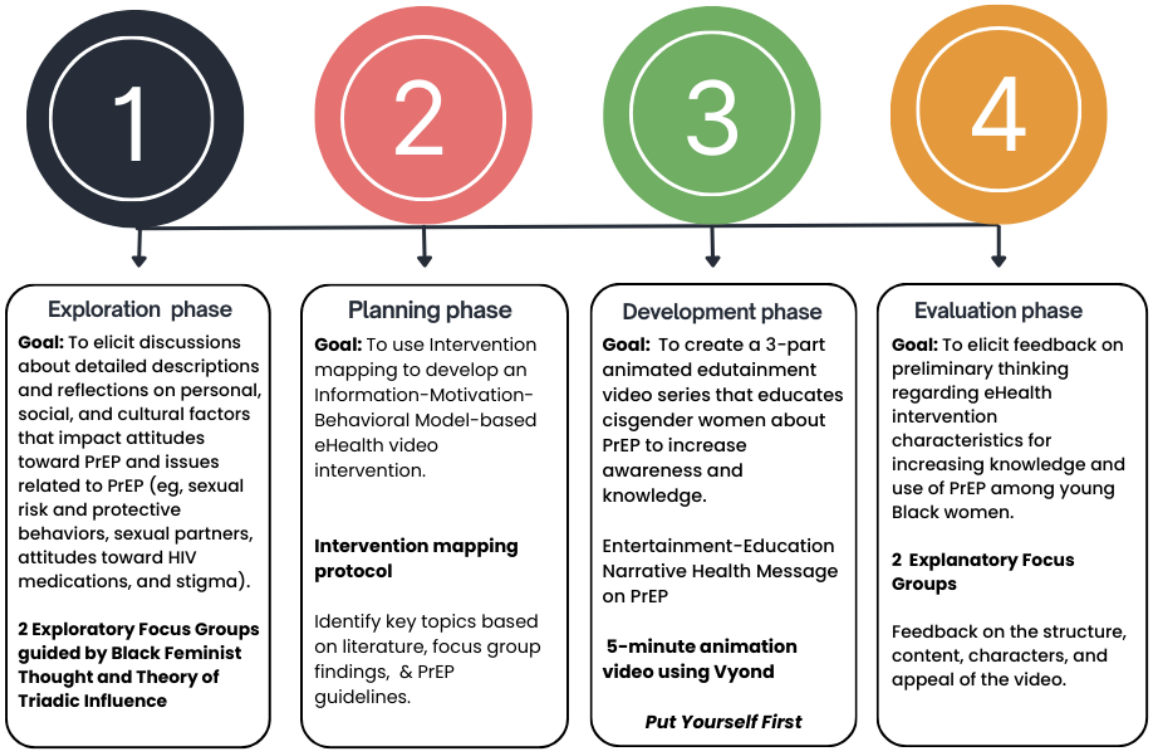
literature review process and leadership of the intervention mapping activities, will be reported in a separate manuscript. This paper focuses exclusively on Phase 4, which evaluated the "Put Yourself First" video intervention.

Figure 1. Project creation timeline for the "Put Yourself First" eHealth video intervention. PrEP: preexposure prophylaxis.



Study Sample

Women were recruited from community-based organizations and through social networking sites in New York City. The study recruited heterosexual Black women residing in New York City. The study prioritized this population due to the city's disproportionately high HIV prevalence among Black women and the persistent gaps in PrEP awareness and uptake documented in prior research [39]. A member of the research team screened the women based on the following criteria: (1) aged 18 to 25 years; (2) self-identified as heterosexual; (3) self-identified as African American, Black, Caribbean Black, or multiethnic Black; (4) self-reported HIV-negative or with unknown HIV status; (5) reported oral, vaginal, or anal sex with a man in the past 12 months; (6) current or past problematic substance use; and (7) residency in New York City. We screened 78 women, of whom 37 (47%) were eligible and 26 (33%) consented to participate in the study. Reasons for nonparticipation after screening were not systematically collected. No nonparticipants (eg, observers or organizational staff) were present during the focus groups aside from the cofacilitators. Thirteen women from the final sample participated in the explanatory focus group discussions.

Procedures

Study visits were conducted in English by trained research staff in a private space. The evaluation focus groups were co-led by the first author (a qualitative researcher with doctoral training in public health and extensive experience conducting focus groups with Black women) and a trained research assistant. Both facilitators were identified as Black women, which may have enhanced rapport and comfort among participants. Neither facilitator had prior personal relationships with participants. During recruitment and consent, participants were informed that the purpose of the groups was to gather honest feedback about the "Put Yourself First" video, and facilitators emphasized that there were no right or wrong answers. After rescreening for eligibility, participants underwent a detailed verbal informed consent process prior to data collection commencing. Eligible women were invited to participate in a Brief Assessment Battery (BAB) survey administered by tablet or paper and a focus group. The BAB validated measures to assess women's initial knowledge of PrEP [40], HIV knowledge [41], sexual behaviors, relationship dynamics [42], self-efficacy [43], and HIV stigma [44]. During Phase 4, participants were recruited to participate in explanatory focus groups to evaluate the video's effectiveness through 2 focus groups (Group 3: n=7; Group 4: n=6). The first part of the explanatory focus group examined the factors that impede and facilitate PrEP use [6]. Participants were shown the 5-minute educational video, "Put Yourself First" (Figure 2).

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Figure 2. "Put Yourself First" video screenshot–animated scene introducing PrEP. PrEP: preexposure prophylaxis.

A still image from the eHealth intervention's animated video shows 3 Black women characters engaging in a casual conversation at a café, introducing the topic of PrEP. The central character gestures while discussing PrEP, with the acronym prominently displayed in large white letters and the full term, Preexposure Prophylaxis, in pink text below. This visual design situates PrEP education within a relatable, everyday social setting, reflecting the intervention's culturally tailored, peer-to-peer communication approach to normalize PrEP discussions among Black women.

After viewing the video, participants completed a postvideo survey to assess the acceptability, perceived impact, and effects on knowledge and intentions. The second part of the explanatory focus groups was conducted to elicit feedback on the video's usability, structure, and appeal. The focus group guide included questions not only about the video's content (accuracy, clarity of PrEP information, cultural resonance, and stigma reduction) but also about its format, style, and representation (eg, use of animation, relatability of characters, and overall usability and appeal). The guide ensured that participant feedback addressed both informational and stylistic components of the video. This article is centered on the section of the focus group discussion that addressed the video's usability, structure, and appeal. The audio-recorded focus groups took approximately 2 hours to complete. Although field notes were not taken, audio recordings were transcribed verbatim to ensure accuracy. This paper was prepared in accordance with the COREQ (Consolidated Criteria for Reporting Qualitative Research) checklist to enhance transparency and rigor in reporting qualitative methods and findings [45].

Postvideo Survey

The postvideo survey was administered immediately after participants watched the animated PrEP video ("Put Yourself First"). The postvideo survey comprises five parts: (1) PrEP knowledge (10 items, "True," "False," and "Don't know") covering core facts such as HIV-negative eligibility, 3-month HIV testing while on PrEP, typical side effects, condom recommendations, distinction from postexposure prophylaxis, and hepatitis B virus considerations; (2) concerns about PrEP (13 items, "Yes," "No," and "Don't know") assessing safety (long-term and reproductive), side effects, resistance, perceived incomplete protection, daily pill burden, potential risk compensation (self and partners), stigma and privacy, comfort discussing sex with providers, and cost; (3) conditions for uptake (8 items, "Yes," "No," and "Don't know") eliciting enabling factors such as no-cost access, free HIV testing and monitoring, one-on-one or text-based counseling, group adherence support, and nonclinic access points; (4) acceptability, intentions, and global rating including willingness to recommend the video (Yes or No), a 1-6 overall quality rating, and intentions to consider or recommend PrEP; and (5) narrative engagement and perceived impact plus a brief global appraisal (5-point items) capturing story realism, message salience, character identification and liking, perceived social diffusion, and the likelihood of behaviors such as asking a provider about PrEP, requesting condom use, resisting unwanted sex, and obtaining HIV testing, alongside ratings of interest, usefulness, amount learned, comprehension, and liking.

Data Analysis

Descriptive statistics from the surveys were calculated for the participants using IBM SPSS Statistics for Windows, version 29.0.2.0 [46], to summarize the data, including

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sociodemographic characteristics, sexual behavior, PrEP knowledge, and video acceptability. Pre- and posttest scores for PrEP knowledge were compared using paired-sample *t* tests for the full sample and within each group. Statistical significance was defined as $P \leq .05$.

Audiotapes of the focus group discussions were transcribed. The transcripts were imported into Dedoose (SocioCultural Research Consultants, LLC) [47] software for coding and analysis. The research team analyzed the transcripts, but they were not returned to the participants for comment. Similarly, participants did not engage in formal member checking of findings, which we note as a methodological limitation. Two lead analysts and a research assistant, trained in qualitative methods, identified codes and used a multilayered strategy based on the topics addressed in the focus group guide. Analysis occurred in multiple stages, corresponding to the inductive approaches of open coding and axial coding used in grounded theory [48,49]. Codes were compared, refined, and reorganized through consensus discussions. To assess the breadth of issues raised, themes from the first focus group were compared to those from the second. While the small sample size precluded claims of definitive saturation, no substantially new themes emerged in the second group beyond those identified in the first. This consistency suggested adequate coverage of core issues for the scope of this exploratory evaluation [50,51]. Thus, we characterize our findings as reflecting preliminary thematic coverage rather than full saturation, consistent with grounded theory approaches in small-sample qualitative studies [52]. Here, we report evaluation findings from the 2 explanatory focus groups that assessed the eHealth video's effectiveness and acceptability for increasing knowledge and addressing barriers to PrEP uptake among young Black women. All analysts worked independently to identify codes, ensuring that themes were consistently represented in the data.

Ethical Considerations

This study was reviewed and approved by the New York University Institutional Review Board (approval number IRB-FY2017-408). All participants provided written informed consent prior to participation. Participants who completed the focus groups received US $45 in compensation and a 2-fare New York City Metrocard. To protect participant privacy and confidentiality, all data were deidentified, stored in a secure location, and securely transferred electronically to investigators involved in the analysis.

Results

Sample Description

Table 1 presents the sociodemographic characteristics of the participants in the explanatory focus group (N=13). Participants had a mean age of 22 (SD 2.4) years, and the majority were US-born (11/13, 85%). Over half (7/13, 54%) had completed high school or a General Education Diploma, while 38% (5/13) had some college or trade school education, and 8% 1/13) held a college degree; 38% (5/13) were current students. Most participants were unemployed (6/13, 46%) or worked part-time (5/39, 39%), with the majority (10/13, 77%) reporting an annual income of less than US $19,999. All participants had health insurance, and 62% (8/13) had a primary care provider.

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Table 1. Description of LOVE (Learning Options through Video Education) study explanatory focus group participants (N=13).

Characteristics	Participants
Age (years), mean (SD)	22 (2.4)
US-born, n (%)	
Yes	11 (85)
Education, n (%)	
High school or GED[a]	7 (54)
Some college or trade school	5 (38)
College degree	1 (8)
Current student, n (%)	
Yes	5 (38)
Employment, n (%)	
Full-time	2 (15)
Part-time	5 (39)
Unemployed	6 (46)
Annual income, n (%)	
Less than US $19,999	10 (77)
More than US $40,000	3 (23)
Health insurance, n (%)	
Yes	13 (100)
Primary care provider, n (%)	
Yes	8 (62)
Has children, n (%)	
Yes	3 (23)
Relationship status, n (%)	
Committed relationship	4 (31)
Dating	8 (62)
Single	1 (8)
Current HIV test (past year), n (%)	
Yes	9 (69)
Positive STI[b] results (lifetime), n (%)	
Yes	7 (54)
Have main or steady partner, n (%)	
Yes	13 (100)
Have sex with nonmain partners, n (%)	
Yes	5 (39)
Main or steady partner has sex with other, n (%)	
Yes	5 (39)
Did not use condom, 3 months, n (%)	
Main or steady partner	12 (92)
Other partner (n=5)	3 (60)
Knowledge of PrEP[c], n (%)	
Yes	10 (77)

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Characteristics	Participants
Used PrEP, n (%)	
Yes	2 (15)
Knowledge of PEP[d], n (%)	
Yes	8 (62)
Used PEP, n (%)	
No	13 (100)

[a]GED: General Education Diploma.

[b]STI: sexually transmitted infection.

[c]PrEP: preexposure prophylaxis.

[d]PEP: postexposure prophylaxis.

Regarding family and relationships, 23% of participants (3/13) had children, and most (8/13, 62%) reported being in a dating relationship, while 31% (4/13) were in a committed relationship. All participants reported having a primary or steady partner, and 39% (5/13) also engaged in sex with nonmain partners; notably, 39% (5/13) indicated their steady partner had other sexual partners. Condomless sex with steady partners was nearly universal (12/13, 92%) and occurred with 60% (3/5) of nonmain partners. Concerning HIV prevention, 69% (9/13) tested for HIV within the past year, and over half (7/13, 54%) reported having a sexually transmitted infection (STI) at some point in their life. While most participants knew about PrEP (10/13, 77%), only 2 (15%) had ever used it. Awareness of postexposure prophylaxis was lower (8/13, 62%), with no reported use.

Pre- and Posttest of PrEP Knowledge

Table 2 presents the pre- and posttest knowledge scores for the participants by group and collectively. Across all participants (N=13), mean scores increased significantly from 4.6 (SD 2.9) at pretest to 6.5 (SD 1.8) at posttest, for a mean difference of –1.9 points (95% CI –3.7 to –0.14; t_{12}=–2.3; *P*=.04). Group-level analyses indicated significant gains among Group 3 participants (n=7), whose mean scores improved from 4.2 (SD 2.9) to 6.3 (SD 2.1), a mean difference of –2.0 points (95% CI –3.3 to –0.69; t_6= –3.7; *P*=.01). Group 4 (n=6) demonstrated improvement as well, with mean scores rising from 5.0 (SD 3.1) to 6.8 (SD 1.5), though the change was not statistically significant (mean difference –1.8; 95% CI –6.4 to 2.7; t_5= –1.04; ns).

Table 2. Pre- and posttest PrEPa knowledge scores by group.

Group	N	Pretest, mean (SD)	Posttest, mean (SD)	Mean difference	95% CI	*t* test (*df*)	*P* value
Both	13	4.6 (2.9)	6.5 (1.8)	–1.9	(–3.7 to –0.14)	–2.3 (12)	.04
Group 3	7	4.2 (2.9)	6.3 (2.1)	–2.0	(–3.3 to –0.69)	–3.7 (6)	.01
Group 4	6	5.0 (3.1)	6.8 (1.5)	–1.8	(–6.4 to 2.7)	–1.04 (5)	ns[b]

[a]PrEP: preexposure prophylaxis.

[b]ns: not significant.

Barriers and Facilitators to PrEP Uptake

Table 3 presents the key barriers and facilitators to PrEP uptake. Barriers to PrEP included concerns about side effects and stigma related to others noticing medication use, each reported by 62% (8/13) of participants, as well as concerns about reproductive health (7/13, 54%). Participants reported cost, daily pill burden, and partner expectations less frequently. Notably, no participants expressed discomfort about discussing sexual health with a provider. In contrast, strong facilitators were identified, particularly access to text-based support (12/13, 92%), counseling about sex and relationships (11/13, 85%), and free HIV testing, monitoring, and one-on-one counseling (10/13, 77%). More than half also reported that free medication (8/13, 62%) and group-based adherence support (7/13, 54%) would enable uptake.

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Table 3. Barriers and facilitators to PrEPa uptake among young Black women postviewing (N=13).

Item	Participants
Barriers, n (%)	
I am worried about the long-term effects of PrEP on my overall health.	6 (46)
I am worried about the long-term effects of PrEP on my reproductive health.	7 (54)
I am worried about the side effects.	8 (62)
I am worried that if I do become HIV positive, certain medicines won't work because I was taking PrEP.	2 (15)
I am worried that PrEP does not provide complete protection against HIV.	5 (39)
I am worried about having to take a pill every day.	2 (15)
I am worried that taking PrEP might make me more likely to have sex without a condom.	4 (31)
I am worried that having to take PrEP means I am putting myself at risk for HIV.	3 (23)
I am worried that PrEP might make my partner(s) expect me to have sex without a condom.	1 (8)
I am worried that people will see me taking medication and think I have HIV.	2 (15)
I am worried that people will see me taking medication and will want to know why I am taking it.	8 (62)
I am worried about having to talk to my doctor about my sex life.	0
PrEP is too costly.	2 (15)
Facilitators (I would take PrEP, if...), n (%)	
I did not have to pay for PrEP.	8 (62)
I had access to free HIV testing.	10 (77)
I had access to free sexual health and monitoring while on PrEP.	10 (77)
I had one-on-one counseling and support around PrEP use.	10 (77)
I had access to text-based support for PrEP use.	12 (92)
I had access to support or counseling about my sex life.	11 (85)
I did not have to go to my regular doctor to get PrEP.	4 (31)
I had access to group-based adherence support for PrEP use.	7 (54)

[a]PrEP: preexposure prophylaxis.

Video Acceptability and Perceived Impact

Table 4 presents findings on postviewing acceptability and intentions related to the PrEP video intervention. Most participants (10/13, 77%) reported they would consider using PrEP, and all (13/13, 100%) stated they would recommend it to others. The majority rated the video's quality as very good (9/13, 69%) or excellent (3/13, 23%), and nearly all found it very or extremely interesting (11/13, 85%) and useful (12/13, 92%). Overall, 62% (8/13) reported learning a great deal of new information, while 92% (12/13) indicated they understood the content very well and liked the video very much.

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Table 4. Postviewing acceptability and intentions of participants (N=13).

Item	Participants
Intention to consider PrEP[a], n (%)	
Yes	10 (77)
Intention to recommend PrEP to others, n (%)	13 (100)
Overall video quality rating, n (%)	
Very good	9 (69)
Excellent	3 (23)
How interesting was the video, n (%)	
Very interesting	5 (39)
Extremely interesting	6 (46)
How useful was the video, n (%)	
Very useful	6 (46)
Extremely useful	6 (46)
Amount of new information learned from video, n (%)	
None	2 (15)
Little	1 (8)
Some	2 (15)
A great deal	8 (62)
How much did you understand in this video, n (%)	
Very much	12 (92)
How much did you like the video, n (%)	
Very much	12 (92)

[a]PrEP: preexposure prophylaxis.

Table 5 presents data on narrative engagement and the perceived impact of the PrEP video. Most participants found the storyline credible (9/13, 69%) and agreed that the message raised awareness (10/10, 77%) and supported action (8/13, 62%). Overall, 62% (8/13) reported relating to some characters and 31% (4/13) to most or all of them. The main character was universally well-received, with all participants describing her as likable, relatable, and compelling at emphasizing key messages. In terms of behavioral intentions, participants expressed a high likelihood of obtaining HIV testing (11/13, 85%) and asking a provider about PrEP (10/13, 77%), with a moderate likelihood of recommending PrEP (8/13, 62%), requesting condom use (7/13, 54%), and resisting condomless or unwanted sex (6/13, 46%).

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Table 5. Narrative engagement and perceived impact of the video (N=13).

Item	Participants
Story realism or credibility, n (%)	
Definitely Yes	9 (69)
Message raises awareness, n (%)	
Definitely Yes	10 (77)
Message supports action, n (%)	
Definitely Yes	8 (62)
Identification with characters, n (%)	
I could relate to some of the characters.	8 (62)
I could relate to many of the characters.	1 (8)
I definitely related to most or all the characters.	4 (31)
Main character, n (%)	
Likeability	13 (100)
Type of friend you like to talk to	13 (100)
Emphasize important messages	13 (100)
Add to experience of learning about PrEP[a]	11 (85)
Likelihood, n (%)	
Ask a provider about PrEP	10 (77)
Recommend PrEP to someone	8 (62)
Request condom use	7 (54)
Change attitude about having unwanted sex	6 (46)
Resist condomless sex	6 (46)
Obtain HIV testing	11(85)

[a]PrEP: preexposure prophylaxis.

Feedback From Explanatory Focus Groups

The qualitative findings identified 6 areas of focus: viewers' engagement and perceived impact, relatability through authentic representation, navigating relationships while prioritizing personal health, structural and practical barriers to PrEP adherence, empowerment through health autonomy, and domains requiring further development.

Viewers' Engagement and Perceived Impact

Participants found the video engaging and informative, describing it as "cute" and compelling in its provision of critical information about PrEP. The participant said, "It's a nice way to get information out." For some participants, the video served as a valuable educational tool by introducing new information about PrEP's availability for women. As 1 participant noted, "It gives you more of that knowledge and info, so you understand it a little bit more." The video successfully addressed the misconception that PrEP is only for gay men, reinforcing its relevance for women. They appreciated how it addressed and clarified misconceptions, such as the belief that PrEP is only for gay men. As 1 participant shared, "It helps with the message because the main person that was talking was a Black lady and she was just basically letting them know it's not only for gay people and you know, whatever the case may be. And it's good for women to take it because it helps as an addition to the condoms, you know." Many participants described the video's message as powerful and informative, providing a better understanding of PrEP's purpose and its role in preventing HIV. Participants valued the emphasis on PrEP being a personal choice, with one saying, "powerful message," and another adding, "It gives you more of that knowledge and info so you understand it a little bit more."

Relatability Through Authenticity

Participants found several scenarios in the video particularly relatable to their own experiences. Many appreciated the conversational style, noting the realistic portrayal of 3 friends casually discussing PrEP over coffee, mirroring how "home girls" would talk among themselves, which added credibility to the message. One participant stated, "It was just a conversation between 3 home girls. I say home girls having coffee or whatever. You know it wasn't. Well, of course, it's scripted, but it didn't feel scripted. It felt like you were just watching like three characters having a normal conversation." Another participant noted that the friends' reactions to PrEP in the video reflected how she expected her peers to respond, with some being receptive and others skeptical. "I feel like that's how my friends would react, the way her friends were reacting. You know you're trying to tell people things to help them, especially

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your friends, but everybody has their own opinion and everybody [does] things on their own time." Participants emphasize how the characters engaged in a mutual exchange of information about PrEP, making the learning process feel organic and authentic. As 1 participant highlighted the collaborative and peer-driven learning aspect of the video, "The good thing was that all three of them [were] sharing information about PrEP to each other. They were actually learning from each other."

Navigating Relationships While Prioritizing Personal Health

Many participants resonated with the challenge of balancing personal health decisions with concerns about how a partner might perceive PrEP use, including fears of mistrust or judgment. A discussion centered around how introducing PrEP might raise questions in a relationship: "It probably would raise questions, but at the same time, then it's like, you know, why are you taking this all of a sudden?" A recurring theme in the discussion was relationship dynamics and the tendency for Black women to put others' needs before their own, particularly in relationships, making it difficult to prioritize personal health. The scenario where a character contemplates her partner's response to her using PrEP resonated deeply, reflecting common experiences among participants. One participant highlighted this dynamic, stating, "One of the characters was like, 'What about what he thinks,' and she was like, 'That's the problem with Black women. They always put people first before themselves.' I closely identify with that, but I never really thought about it. I think that's one of our biggest traits." Another participant echoed this sentiment, emphasizing the tendency to prioritize a partner's feelings over personal health: "She's not thinking about herself first. She's thinking about what he's going to think." Concerns about a partner's perception of PrEP use also emerged, as one participant explained, "I would say letting her partner know. I mean, like, to be honest, for some women, they would feel some type of way because you're taking something to prevent them, so probably the man that she's with is going to feel like she's doing something."

Structural and Practical Barriers to PrEP Adherence

Participants found the video's depiction of a character's reluctance to adhere to the medical visits required for PrEP highly relatable and honest. Many agreed that frequent doctor visits pose a structural barrier to adherence, as women often juggle multiple responsibilities, making it difficult to schedule regular health care appointments. To improve accessibility, some participants suggested including alternative options, such as home testing, in the messaging. One participant emphasized this point, stating, "The biggest issue is the inconvenience of having to go to the doctor. A home test would make a big difference. Along with your prescription, you get a home test." The video also ignited a discussion on the varied perspectives surrounding adherence and health care engagement. While some participants expressed a strong sense of personal responsibility in maintaining their health, others highlighted the challenges of staying consistent with medical visits. One participant explained, "I say it could, but it depends on who you are. Some people like to keep up with themselves. Like me, I'm that type of person. Like, I don't want anything to happen to me. I'm overprotective. I try to protect myself from a lot of stuff, you know. You only get one life. So, some people are different." However, others acknowledged that even if someone is committed to taking PrEP, maintaining regular medical visits can be difficult. Another participant noted, "I think some people may just take the medication but just not go to the doctor, as they're supposed to. It's not to say it's going to stop them from taking the medicine, but they just might not go to the doctor every three months like they're supposed to." This suggests that the video could further emphasize solutions for making healthcare more accessible and convenient.

Additionally, the conversation explored the practicability of taking PrEP alongside birth control, a common concern among participants. Some felt confident in their ability to manage both medications, with one stating, "Fine, because if you can remember to take your birth control pill every day, you're going to remember to take the PrEP too." However, others pointed out the challenges of maintaining a daily medication routine. One participant shared, "I always miss my birth control pills because I have alarms. Sometimes I'm like, 'Oh my god. It's nine o'clock,' and I miss my pill. I'm not really good with pills, to be honest. I'm not really good with it, but I try my best or I'll ask somebody else to remind me. But if it's important like that, I feel like it should be a priority." This suggests that the video could acknowledge real-life struggles with adherence and offer practical strategies for staying on track. Beyond forgetfulness, concerns about misuse also emerged, with some participants expressing worry that individuals might treat PrEP similarly to birth control, believing they could compensate for missed doses or use it as a justification for engaging in riskier behaviors.

One participant explained, "I kind of just look at this stuff like, just like the birth control pill, women who use the birth control pill will use the PrEP. But I feel like people would be less responsible as far as, like, with the birth control pill. 'Oh, I just missed a day. I can just double up this day,' or 'I could have unprotected sex, but I know if I just take the pill...' or 'If I take the PrEP, if I double up this day, I can have unprotected sex this day.' People will abuse it like they abuse everything else."

This concern suggests that the video could benefit from reinforcing clear messaging about proper PrEP adherence and dispelling misconceptions about its use.

Empowerment Through Health Autonomy

The video's message about taking PrEP as an act of self-care resonated strongly, reinforcing the importance of prioritizing one's health over others' opinions. The main character in "Put Yourself First" emphasized taking PrEP for oneself rather than for others. Participants recognized the significance of making their own health decisions without feeling pressured to seek validation or approval from others, especially their partners. One participant said, "I just don't feel like he needs to know that. It's going to lead to another conversation. I don't think he needs to know everything. They don't need to know every detail because they don't tell us every detail." This quote underscores the belief that women should have autonomy over their health choices and should not feel pressured to disclose every aspect of their health care decisions. Another participant reinforced

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this perspective, asserting, “You don't have to tell your partner about it,” highlighting that PrEP use is a personal choice and women should feel empowered to take control of their sexual health on their own terms. Affirming this theme of self-determination, another participant stated, “You're doing it for yourself at the end of the day,” further emphasizing the message that prioritizing one's health is an act of self-care and autonomy. Overall, these scenarios and messages were praised for authentically representing the realities and concerns of young Black women considering PrEP. Participants particularly valued the framing of PrEP as an act of self-care and empowerment, resonating with sex-positive narratives that affirm women’s right to prioritize both protection and pleasure in their intimate lives.

Domains Requiring Further Development

Table 6 outlines the domains identified by the participants that require further development to enhance the educational video about PrEP for future research. While participants found the video informative, they identified areas for enhancement to increase its relatability and impact. Participants suggested making future videos more relatable by incorporating real-life characters and scenarios to enhance impact and engagement. Participants suggested incorporating more storylines that reflect women’s daily lives and strategies for addressing the challenges and barriers to PrEP use, as well as adding depth to character interactions to make the video more engaging. They recommended replacing animations with real women to create a stronger emotional connection and enhance trustworthiness. While participants appreciated the inclusion of details about PrEP, they expressed concerns that highlighting side effects, such as nausea, could discourage viewers. They suggested presenting sufficient information to educate without overly emphasizing negative aspects, ensuring the benefits of PrEP remain central. Overall, the recommendations aim to enhance the video’s realism, solution-oriented approach, and impact by equipping the target audience with the skills necessary to address challenges related to accessing and maintaining PrEP adherence.

Table 6. Suggestions for improvement from explanatory focus groups (N=13).

Area of focus	Critical feedback	Suggestions for improvement	Illustrative quotes
Scenario	Realism and relatability: While the video was informative, but it lacked the realism needed to resonate with the target audience fully.	More realistic storylines: Participants suggested adding a storyline that more authentically reflects women's daily lives and challenges to make the video feel more genuine and engaging. Adding more depth to the character dynamics and their interactions could make the video feel even more realistic.	• “Have people bring up past experiences. Have people have testimonies and that will get to people as people know that people have been through stuff and it's not just them and they could get through it or they can take this and be better or protect themselves better.”
Characters	Character relatability: While the characters conveyed the message well, some participants felt the group’s dynamic was a bit unusual.	Using real characters: Participants wanted to see real women (humans instead of animation) discussing PrEP[a], as they felt this would make the message more trustworthy and more straightforward to connect with.	• “I think maybe a...With actual, real characters. Maybe like a little scenario. You see how they were there but something a little more realistic. Like a little story line. That would reach more people and grasp their attention more, but this was nice. It was informative but it was a little silly. I think if you use a real scenario with real people, it might reach a greater population.”
Content	Side effects mentioned: Some participants felt that discussing potential side effects, like nausea, could be off-putting or scare potential users.	Balancing details: Participants wanted enough information to be well-informed but felt that too many details, especially about side effects, might discourage viewers from considering PrEP.	• “If you go into any more details, you're gonna start scaring people.” • “It was enough because then you talked about having to have kidneys checked and stuff like that. When you start talking about people got to get their kidneys checked, they are going to question,” what is this going to give to me?” Because your kidneys are very important.”

[a]PrEP: preexposure prophylaxis.

Discussion

Principal Findings

This study evaluated “Put Yourself First,” a culturally tailored, sex-positive, animated eHealth video intervention designed to increase PrEP awareness among young Black women. Participants found the video to be engaging, relatable, and informative, reporting increased knowledge of PrEP, a heightened willingness to consider it, and strong intentions to recommend it to their peers. Participants’ feedback suggested the importance of representation, authenticity, and the normalization of PrEP use for women, indicating the need for culturally resonant multimedia to enhance HIV prevention messaging. However, they also identified several aspects that could be refined to enhance its impact and resonance with the target audience.

Focus group findings demonstrate that the video was both engaging and educational, with participants praising its clarity,

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appeal, and ability to dispel misconceptions, such as the notion that PrEP is exclusively for gay men, while emphasizing its relevance and safety for women. These results align with prior research highlighting the importance of culturally tailored and gender-specific messaging in increasing PrEP awareness among women [8,53,54]. Importantly, these findings extend earlier exploratory studies [21] by demonstrating that an intervention explicitly grounded in sex-positive and empowerment frameworks can enhance knowledge while also resonating emotionally with the target audience. Previous research has shown that interventions can be enhanced by improving communication about sexual health within a young Black woman's social network, particularly with emotionally supportive friends and family [55]. The conversational format among friends was viewed as authentic and relatable because it included a peer-to-peer exchange that mirrored participants' real-life discussions. In edutainment, content is presented in ways that feel authentic and familiar, such as the script of the video, which conveys information on PrEP through a conversation among friends [37]. This educational method allowed the participants to see themselves or people like them. When people see peers (or peer characters) discussing, modeling, or demonstrating healthy behaviors, it helps participants believe that the behavior is possible, socially acceptable, and relevant [37]. The peer-to-peer exchange also models collectivism among Black women and communities [54].

At the same time, women identified relational challenges, particularly the tension between prioritizing their own health and concerns about partner perceptions, which reflects broader gendered and racialized dynamics that influence sexual health decision-making among Black women [6,55-57]. This reflects intersectional dynamics that Black women experience [6,55], where their overlapping identities, gendered expectations, and experience of racialized stigma impact structural inequities and constrain women's HIV prevention options. Finally, the video's framing of PrEP as an act of self-care and empowerment resonated strongly, affirming women's right to make autonomous decisions about their sexual health. This finding contributes to the literature on sex-positive and empowerment-based approaches to HIV prevention, emphasizing the importance of interventions that affirm pleasure, center health autonomy and agency rather than relying solely on risk framing [58,59]. Together, these insights suggest that narrative-based, culturally resonant, and empowerment-framed interventions may be particularly effective for increasing PrEP engagement among Black women.

Although the video has notable strengths, participants noted several challenges that could limit its acceptability. While the video was informative, some participants found the use of animation somewhat limiting in fostering deep emotional connection and trust. They suggested incorporating real-life testimonials from women who use PrEP, live-action scenarios, or documentary-style storytelling on topics such as conversations with partners, health care visits, or navigating daily life while on PrEP, to enhance authenticity and relatability in PrEP-focused edutainment content [60]. There was a strong desire to see more authentic scenarios depicting real challenges women face when discussing PrEP with partners and health care providers, such as fear of judgment, accusations of infidelity, or adverse partner reactions. This aligns with prior studies highlighting the central role of interpersonal stigma and relationship dynamics in shaping women's PrEP decision-making [6]. While women view PrEP as a tool for maintaining health and relationships, women's romantic feelings and expectations can affect their risk perceptions and interest in using PrEP [61]. Imbalanced relationship dynamics, including power struggles, infidelity concerns, and trust issues, significantly influenced women's PrEP decisions [62]. In addition, framing PrEP within a sex-positive, empowering context that aligns with women's reproductive values may increase uptake [31,63]. These strategies not only enhance authenticity but also align with principles of edutainment, where culturally resonant narratives and modeled behaviors transform health information into engaging, meaningful content that promotes learning and supports behavior change.

Along with increasing awareness, participants emphasized the importance of directly tackling the institutional constraints that influence women's PrEP decisions. They described persistent challenges, such as PrEP stigma, frequent medical visits, medical mistrust, and challenges with daily pill adherence, which often parallel their experiences with birth control [64-66]. Although the video demonstrated PrEP's effectiveness, it did not fully address structural concerns, such as navigating the health care system, financial accessibility, or alternative care models, including pharmacy-based PrEP access or telehealth services [67-69]. Taken together, these findings emphasize the importance of advancing practice innovations that reduce both structural and interpersonal barriers through accessible care models, stigma-free environments, and culturally responsive provider communication. To enhance the impact of future interventions, messaging should include practical strategies to overcome these barriers, such as highlighting mail-order PrEP services, home HIV or STI testing kits, and financial assistance programs [68]. At the same time, future research is needed to evaluate multilevel strategies that address these barriers and generate evidence on how best to sustain equitable PrEP uptake among Black women. Such efforts will be crucial to ensuring that PrEP implementation not only increases awareness but also translates into meaningful improvements in HIV prevention outcomes [69]. Finally, these findings suggest the importance of expanding insurance coverage, integrating PrEP into reproductive and primary care services, and funding community-based initiatives that directly address the structural inequities limiting Black women's access to HIV prevention [70].

In addition to addressing these structural barriers, it is crucial to consider how the "Put Yourself First" video can be disseminated most effectively. The findings emphasize the importance of designing HIV prevention interventions that not only raise awareness but also facilitate direct connections to services. Future dissemination strategies should leverage trusted community-based organizations, college health centers, sexual and reproductive health clinics, and digital platforms (both social networks and institutional services) to maximize reach and engagement among young Black women [9,10,13]. To

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ensure that the awareness generated by the video translates into tangible access to PrEP-related services and strengthens its real-world impact, direct referral pathways could be embedded within these dissemination channels, such as integrating links to PrEP locators, telehealth services, or peer navigation programs [54,67-69]. By pairing education with actionable referral tools, the intervention can more directly support women in moving from interest to uptake. These strategies can help bridge the persistent gap between PrEP awareness and actual uptake, ensuring that dissemination efforts are linked to concrete service access and continuity of care [26,28].

Limitations

Several limitations warrant consideration. The findings are based on a small sample of young Black women from a single urban location, which limits their generalizability. Future work should extend recruitment to multiple geographic regions, including the South and rural communities where HIV disparities are most pronounced. Black women's experiences are diverse and shaped by intersecting factors such as age, sexuality, and socioeconomic status. Future studies should purposively sample across these intersecting identities to capture heterogeneity within the population. While knowledge gains and acceptability outcomes were encouraging, the findings should be interpreted with caution, as they were not uniformly significant across all groups (eg, Group 4). Participants continued to express concerns about side effects, daily adherence, and structural barriers, such as frequent medical visits and medical mistrust. The evaluation was limited to immediate outcomes and did not assess downstream behaviors such as PrEP initiation or adherence. Participants also explicitly called for greater realism through live-action or testimonial-based storytelling and requested deeper engagement with structural barriers such as stigma, provider bias, and medical mistrust. These mixed findings temper the conclusions and highlight the need for future studies to address both behavioral and structural outcomes in addition to knowledge and acceptability. Longitudinal and controlled studies are needed to evaluate whether such interventions increase actual PrEP uptake and adherence. By incorporating these refinements, future studies can better bridge the gap between pilot findings and real-world application, ensuring that dissemination strategies not only raise awareness but also facilitate access and sustained use of PrEP.

Although no new themes emerged after the second focus group, the small qualitative sample limits the claim of saturation. Focus group methodologists typically recommend 3-5 groups per relatively homogeneous population to ensure adequate coverage of perspectives, suggesting that saturation should be monitored across, rather than within, groups [71,72]. While Guest and colleagues [73] demonstrated that most themes emerge within 6-12 participants, a benchmark often used to justify 2-3 focus groups for achieving saturation. This analysis of the explanatory focus groups aligns with this range, as it is a relatively homogeneous sample and the study consisted of targeted research questions. Additionally, focus group settings may have introduced social desirability bias, potentially leading participants to overemphasize favorable responses about the video. This study did not include specific methodological steps recommended by COREQ. For example, reasons for nonparticipation were not collected, field notes were not taken during focus groups, and transcripts were not returned to participants for validation. While focus groups were co-led by trained facilitators who shared social identities with participants, reflexivity was addressed through consensus-based coding discussions rather than participant checking of themes. These omissions may have limited opportunities to triangulate interpretations or further ensure the credibility of findings. Despite these limitations, the study provides critical insights into the acceptability and impact of a culturally tailored, sex-positive eHealth intervention video, offering a valuable foundation for refining and scaling PrEP promotion strategies for young Black women. This study reinforces existing research that demonstrates the effectiveness of culturally relevant, video-based educational interventions in improving engagement and increasing knowledge of PrEP among Black women [21,27,74].

Conclusion

This study highlights the critical need for culturally tailored interventions to enhance PrEP awareness and uptake among young Black women. This research emphasizes the importance of using sex-positive, engaging, and culturally affirming sexuality educational tools to address the ongoing barriers of stigma, misinformation, and health care inequities. By embedding PrEP within sex-positive and empowerment frameworks, this study contributes novel evidence that HIV prevention can be framed not only as risk reduction but also as a pathway to autonomy, intimacy, and pleasure. The findings show that eHealth interventions, especially edutainment animated videos, can effectively raise awareness, dispel misconceptions, and encourage informed decision-making regarding PrEP. These findings will guide future iterations, examining the long-term effects of eHealth video interventions on PrEP uptake and adherence and ensuring that dissemination strategies extend beyond awareness to support real-world access and sustained PrEP use. Ultimately, this study emphasizes the transformative potential of culturally competent and innovative health communication strategies in tackling disparities and empowering Black women to take control of their sexual health. Centering women's voices, addressing structural barriers, and affirming pleasure and agency must remain central as PrEP interventions continue to evolve.

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Authors' Contributions

KTB led the conceptualization, methodology, investigation, formal analysis, writing of the original draft, supervision, project administration, and funding acquisition. PW contributed to the investigation, data curation, and formal analysis, and participated equally in reviewing and editing the manuscript. PT contributed equally to the review and editing of the manuscript. DB supported visualization efforts and assisted with reviewing and editing. AG contributed to the conceptualization and led the formal analysis and participated equally in reviewing and editing the manuscript.

Conflicts of Interest

KB is an Associate Editor of *JMIR Formative Research* at the time of this publication. The other authors declare no conflicts of interest.

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Abbreviations

BAB: Brief Assessment Battery
BFT: Black Feminist Thought
CDC: Centers for Disease Control and Prevention
COREQ: Consolidated Criteria for Reporting Qualitative Research
IMB: Information-Motivation-Behavioral Skills
LOVE: Learning Options through Video Education
PrEP: preexposure prophylaxis
STI: sexually transmitted infection
TTI: Theory of Triadic Influence

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Original Paper

AI-Powered Ambient Scribe Technology Experiences Among Emergency Physicians: Cross-Sectional, Mixed Methods Pilot Survey Study

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Abstract

Background: Health care organizations have started to implement artificial intelligence–powered ambient scribe technology in clinical documentation workflows. Early outpatient studies have shown mixed results. Few studies have evaluated ambient scribes in the emergency department (ED). Due to differences in setting and patient acuity between the ED and ambulatory clinics, there remains a pressing need to research this technology in the ED.

Objective: This study aimed to evaluate emergency physicians' (EPs) satisfaction, perceived documentation efficiency, after-shift documentation time, and trust in ambient scribe–generated notes compared with in-person scribes or independent documentation, and to identify ED-specific challenges.

Methods: A cross-sectional survey was conducted among 16 board-certified adult and pediatric EPs who were granted access to the ambient scribe technology across 4 EDs. EPs used the ambient scribe for several months before completing a survey with multiple-choice and free-text responses. We performed a mixed methods analysis by summarizing quantitative data through descriptive statistics and performing a practical thematic analysis on free-text responses.

Results: Of the 16 EPs, 14 (87.5%) completed the survey. Among respondents, 9 (64.3%; 95% CI 38.7%-83.7%) reported being satisfied or very satisfied with the ambient scribe, while 3 (21.4%; 95% CI 7.6%-47.6%) expressed dissatisfaction. When given the option, 7 (50%; 95% CI 26.8%-73.2%) respondents preferred the ambient scribe, 4 (28.5%; 95% CI 11.7%-54.6%) preferred in-person scribes, and none (95% CI 0%-20.6%) preferred independent documentation. Among previous users of in-person scribes, 50% (4/8; 95% CI 21.5%-78.5%) favored the ambient scribe. The ambient scribe was reported to improve documentation efficiency (10/14, 71.4%; 95% CI 45.4%-88.3%) and reduce after-shift documentation time (9/14, 64.3%; 95% CI 38.7%-83.7%). However, only 42.9% (6/14; 95% CI 22.3%-69.2%) of respondents trusted the accuracy of ambient scribe–generated notes, compared with 75% (6/8; 95% CI 40.9%-92.9%) who trusted in-person scribes. Few respondents found the ambient scribe helpful for physical examinations (3/13, 23.1%; 95% CI 8.2%-50.3%) or medical decision-making documentation (5/14, 35.7%; 95% CI 16.3%-61.2%). A thematic analysis identified 5 themes: challenges due to the workplace environment, challenges due to the patient population, workflow improvement, workflow harm, and narrow usefulness.

Conclusions: This mixed methods pilot study is among the first to evaluate ambient scribe technology in the ED. Our results add ED-specific insights to literature focused on the outpatient setting. Our findings reveal the potential for enhancing documentation efficiency and reducing administrative burden while highlighting setting-specific challenges. While most EPs preferred artificial intelligence–assisted documentation over independent charting, confidence in documentation accuracy and functionality remains limited compared with human scribes and varies by note component. As the demand for efficiency in emergency medicine

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continues to grow, scalable solutions such as ambient scribes could play a pivotal role if functionality, reliability, and physician trust can be further optimized.

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KEYWORDS

artificial intelligence; AI; natural language processing; electronic health records; clinical documentation; medical scribes; emergency department operations; health care technology

Introduction

Emergency physicians (EPs) are tasked with providing timely, quality patient care in a fast-paced care environment. In addition to direct patient care responsibilities, it is considered best practice for EPs to complete documentation in real time on shift for reasons including improved patient safety, documentation accuracy, medical-legal protection, and physician wellness. Because of this, a significant portion of the EP workday, upward of 40% of every shift, is consumed by administrative tasks such as the documentation of patient encounters in the electronic health record [1]. This administrative burden contributes to reduced job satisfaction and clinician burnout [2,3], as well as compromised patient interaction time [4]. This is particularly relevant in the field of emergency medicine (EM), as EPs have long been known to experience higher rates of burnout than physicians of any other specialty [5].

Progress in artificial intelligence (AI), particularly the development of large language models (LLMs) via deep neural networks, has created new opportunities to use existing natural language processing technology to generate comprehensive clinical documentation. These systems, such as the Nuance Dragon Ambient Experience (DAX) Copilot, typically use a smartphone- or computer-based microphone to capture and process physician-patient dialogues before transforming the information into structured clinical documentation. Some early studies in the outpatient setting have shown that AI-powered ambient scribe technology reduces time spent on notes with improved clinic visit experiences for physicians and patients [6,7], saving users of ambient scribes in one large medical group over 15,000 hours of physician time compared with nonusers [8]. Early pilot studies of ambient scribe technology have revealed large, statistically significant reductions in physician task load, burnout, and favorable utility [9], as well as a greater sense of engagement with patients during outpatient appointments [10].

However, other studies from the primary care setting suggest that ambient scribes do not make clinicians, as a group, more efficient [11]. Additionally, the accuracy of LLMs and ambient scribes has been questioned, as the programs have been found to commit errors of "hallucination," where information not present in the input data is generated, and "omission," where relevant information is excluded in the output, at rates that may be clinically significant [12]. One study of ambient scribe technology found 70% of generated notes contained errors, with an average of nearly 3 errors per note [13]. These concerns are shared by patients, with one study showing that while patients are generally open to the use of ambient scribes in their physicians' offices, many have concerns about documentation accuracy and privacy [14]. As most studies of ambient scribe technology have been quantitative in nature, there is a relative lack of qualitative or mixed methods studies in the literature. Mixed methods approaches are particularly valuable in implementation-based quality improvement, where physician perspectives and usability directly influence successful adoption. Given that most of the available literature is quantitative, few existing studies examine the physician experience in their own words. Furthermore, most studies have taken place in the outpatient setting, with researchers calling for "further analyses...of AI scribes across various clinical scenarios and physician and patient demographic groups" [8].

The emergency department (ED) presents a significantly different environment from the outpatient setting due to patient acuity, clinical workflows, and environmental disruptions. Therefore, findings from the ambulatory setting may not generalize to the ED. Although there has been preliminary exploration of LLM utility in the ED for purposes other than note documentation [15,16], few studies have evaluated the use of ambient scribes in the ED setting. Due to the large and increasing volume of critical health care services delivered in the ED, there remains a pressing need to research the potential value of ambient scribe technology in this unique setting. Given the potential for significant improvement in workflow, documentation speed, and workplace satisfaction, we aimed to evaluate EPs' satisfaction, preferences, perceived documentation efficiency, time spent documenting outside of shift, and trust in ambient scribe–generated notes. We additionally compared ambient scribing to in-person scribes and independent documentation and used qualitative thematic analysis to identify ED-specific challenges.

Methods

Inclusion and Exclusion Criteria

Inclusion criteria were (1) board certification in EM or pediatric EM and (2) ownership of an Apple iPhone device compatible with the ambient scribe app. All adult and pediatric EPs in the group were emailed an invitation and could opt in to being randomized to receive one of the available licenses. There were no exclusion criteria.

Study Design and Objectives

This study used a cross-sectional, descriptive, nonexperimental mixed methods design. The objective of this pilot study was to evaluate the EPs' satisfaction, preferences, perceived documentation efficiency, time spent documenting outside of shift, and trust in ambient scribe–generated notes compared with in-person scribes and independent documentation and to identify ED-specific usability challenges through thematic

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analysis of free-text responses. The primary independent variable was the documentation method (ambient scribe, in-person scribe, or independent documentation), and the dependent variables were physician-reported satisfaction, preferences, perceived documentation efficiency, time spent documenting outside of shift, trust in documentation accuracy, and perceived usefulness by note component. We performed a mixed methods analysis of quantitative and qualitative free-text responses from a cross-sectional survey of a pilot group of EPs to characterize their experiences with ambient scribe technology in the ED [17].

Participant Characteristics, Sample Size, and Selection Procedures

Initially, 16 licenses for the software were obtained by the physician group. This is the maximum number of initial licenses that allocated funding allowed. All adult and pediatric EPs in the group were emailed an invitation to opt in to receive one of the available licenses. Among EPs who met the study's inclusion criteria, 16 were selected to receive an initial license using a random number generator. As the license number was limited to 16 physicians as part of a pilot quality improvement project, a power analysis was not performed, as it was not feasible to adjust the number of pilot licenses. The physicians were selected among those who expressed an interest using an equally weighted randomizer. All physicians were board-certified in either EM or pediatric EM and practiced in one or more of 4 EDs within a single, urban medical system. Of the 16 physicians, 14 (87.5%) responded to the survey and represented a range of 0 to ≥21 years of practice: 0 to 5 years (n=3, 21.4%), 6 to 10 years (n=3, 21.4%), 11 to 15 years (n=2, 14.3%), 16 to 20 years (n=3, 21.4%), and ≥21 years (n=3, 21.4%).

Setting and Study Dates

The individual sites included a large tertiary-care academic medical center, a midsize community hospital, a small community hospital, and a pediatric ED. All users attended an hour-long mandatory training session with a representative from the technology company, and all had the opportunity to participate in additional, optional training sessions. They were granted access to the ambient scribe on a rolling basis beginning September 1, 2024, and completed the survey between April 29, 2025, and May 27, 2025.

Survey Instrument and Data Collection Procedures

An electronic survey was created by the research team and administered via REDCap (Research Electronic Data Capture) [18,19] and distributed by email to the group of EPs. The survey instrument was not adapted from a previously validated scale, and as such, no psychometric testing was performed. The survey functioned as the only instrument and consisted of multiple-choice and open-ended items. There was no masking, as the study used a voluntary, anonymous survey without treatment arms. As no inferential hypothesis testing was conducted, there are no inferential analytic strategies or data diagnostics to report. Quantitative data were summarized descriptively, and all responses were included without imputation. Study data were collected and managed using REDCap electronic data capture tools hosted at Brown University Health.

The survey assessed physicians' baseline use of in-person medical scribes and their experience with the ambient scribe and compared their preferences between in-person scribes, the ambient scribe, and independent documentation. Survey responses for multiple-choice questions were aggregated and presented as descriptive quantitative statistics without inferential analysis. 95% CIs were calculated using the Wilson score interval, which is validated for small sample sizes. There were no missing or imputed data.

Thematic Analysis

A practical thematic analysis was performed by 2 members of the research team (TM and YB) on free-text responses in a 3-step process: reading the free-text responses, drafting effective codes or labels for concepts in the responses that were relevant to our study objective, and constructing meaningful themes in accordance with a framework as described by Saunders et al [20]. In step 1, we read the unedited free-text responses and independently wrote individual summary memos. In step 2, we performed data management and early data analysis by creating codes in the form of complete thoughts or sentences, rather than broad categories. We compared codes with other members of the team and developed a shared codebook. In step 3, we drafted themes independently before participating in a thematic analysis session in which we shared different perspectives and developed shared overarching, meaningful themes. The participating researchers were EPs with prior experience using the ambient scribe technology and employed by the same academic medical group as the participants. The themes were reported according to the frequency with which they arose in the free-text responses of survey participants. Saturation was not reached.

Mixed Methods Integration

We relied on the results of both our quantitative and qualitative analyses to draw conclusions that provide a richer, more nuanced understanding of EPs' experiences with ambient scribe technology than could be gathered from either analysis alone. We adhered to all SQUIRE 2.0 publication guidelines for quality improvement reporting [21].

The survey in its entirety is shown in Multimedia Appendix 1.

Ethical Considerations

This human subject research study was deemed exempt by the local institutional review board (IRB; protocol 002825). The IRB approved a waiver of written informed consent. Participants received an email invitation containing IRB-approved information on the study's purpose, procedures, risks, and benefits. The invitation text is available in Multimedia Appendix 1 with contact information redacted. All study data were deidentified. Participant data in the figures and appendix have been fully deidentified. A US $25 gift certificate was awarded to 2 study participants, selected at random among those who opted into the optional drawing.

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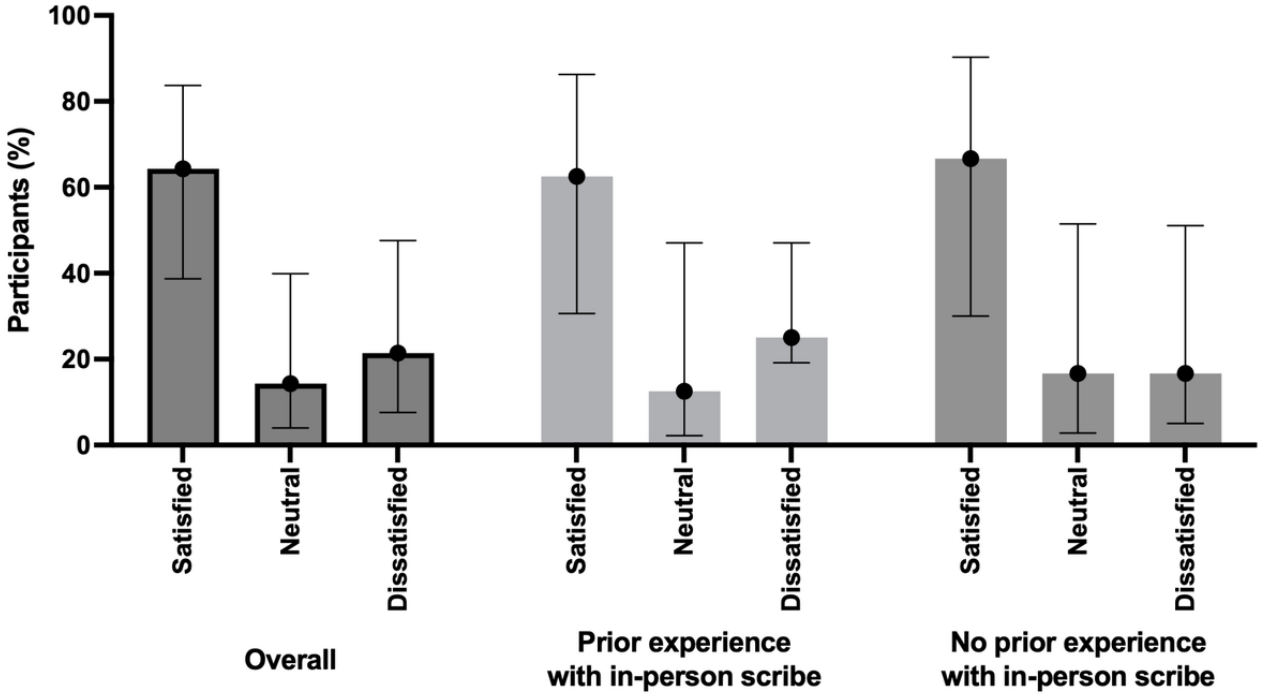
Results

Of the 16 EPs, 14 (87.5%) members of the cohort, consisting of 8 (57.1%) general EPs and 6 (42.9%) pediatric EPs, completed the survey during the study period. Among the cohort, 2 (12.5%) general EPs did not respond to the survey. Additionally, 8 (57.1%) respondents previously used in-person medical scribes in their routine practice and completed questions comparing their experience with the ambient scribe to in-person medical scribes, in addition to the standard questions about ambient scribe technology.

Among 14 respondents, 9 (64.3%; 95% CI 38.7%-83.7%) reported feeling either satisfied or very satisfied with the ambient scribe, 2 (14.3%; 95% CI 4%-40%) felt neutral, and 3 (21.4%; 95% CI 7.6%-47.6%) reported feeling either dissatisfied or very dissatisfied with the ambient scribe (Figure 1). When asked about preferences between an in-person scribe, ambient scribe, or neither, 4 (28.5%; 95% CI 11.7%-54.6%) respondents preferred an in-person scribe, 7 (50%; 95% CI 26.8%-73.2%) preferred the ambient scribe, 3 (21.4%; 95% CI 7.6%-47.6%) were indifferent between the two, and none (95% CI 0%-20.6%) preferred independent documentation. Of the 8 respondents who reported using a medical scribe regularly before the introduction of the ambient scribe, 4 (50%; 95% CI 21.5%-78.5%) reported a preference for the ambient scribe.

Figure 1. Overall satisfaction with artificial intelligence–powered ambient scribe technology among 14 board-certified emergency and pediatric emergency physicians who completed a cross-sectional survey across 4 emergency departments in a single urban health system. The satisfied category includes answers for very satisfied or satisfied. The dissatisfied category includes answers for very dissatisfied or dissatisfied.



In the series of questions specifically comparing the ambient scribe to independent documentation, 71.4% (10/14; 95% CI 45.4%-88.3%) of the respondents preferred the ambient scribe, 71.4% (10/14; 95% CI 45.4%-88.3%) reported improved efficiency with documentation, and 64.3% (9/14; 95% CI 38.7%-83.7%) reported decreased time spent outside of shift on documentation (Figure 2). When comparing an ambient scribe to an in-person scribe, 50% (4/8; 95% CI 21.5%-78.5%) of respondents reported improvement in efficiency with documentation, and 25% (2/8; 95% CI 19.2%-47.1%) reported decreased time spent outside of shift on documentation (Figure 2).

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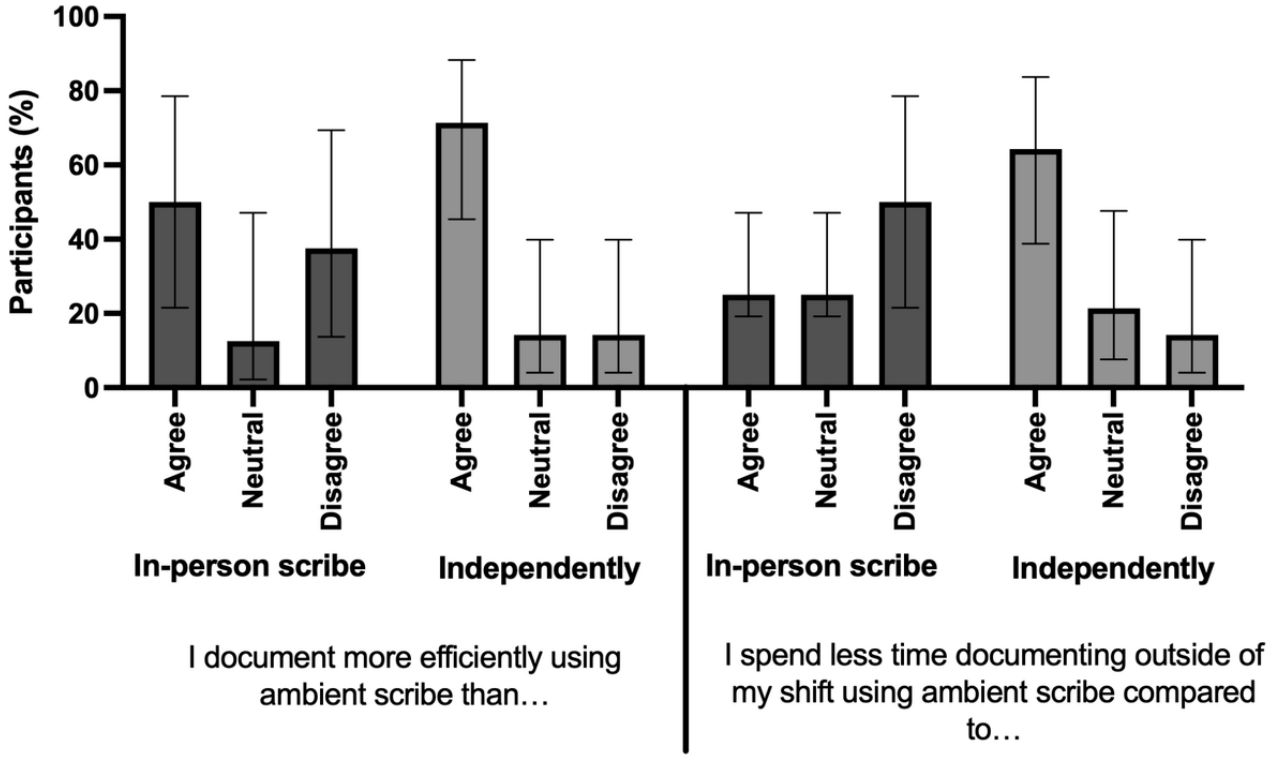
Figure 2. Physician-centered outcomes of documentation efficiency and time spent on documentation after shift using artificial intelligence–powered ambient scribe technology or an in-person scribe. Data were collected from 14 board-certified emergency and pediatric emergency physicians who completed a cross-sectional survey across 4 emergency departments in a single urban health system. The agree category includes answers for strongly agree or agree. The disagree category includes answers for strongly disagree or disagree.



We asked respondents which documentation elements they found in ambient scribe technology to be most helpful. We found that only 23.1% (3/13; 95% CI 8.2%-50.3%) of the respondents reported the ambient scribe to be helpful for the physical examination (PE), and 35.7% (5/14; 95% CI 16.3%-61.2%) of the respondents reported the ambient scribe to be helpful for medical decision-making (MDM; Figure 3). Of the respondents who regularly use an in-person scribe, 75% (6/8; 95% CI 40.9%-92.9%) reported that they find it helpful to have scribes record the PE, and none (95% CI 0%-32.4%) reported it helpful to have scribes record their MDM. Overall, 42.9% (6/14; 95% CI 22.3%-69.2%) of respondents believe they can trust the ambient scribe's documentation to be accurate, whereas 75% (6/8; 95% CI 40.9%-92.9%) of respondents with previous in-person scribe experience reported that they trust in-person scribes' documentation to be accurate.

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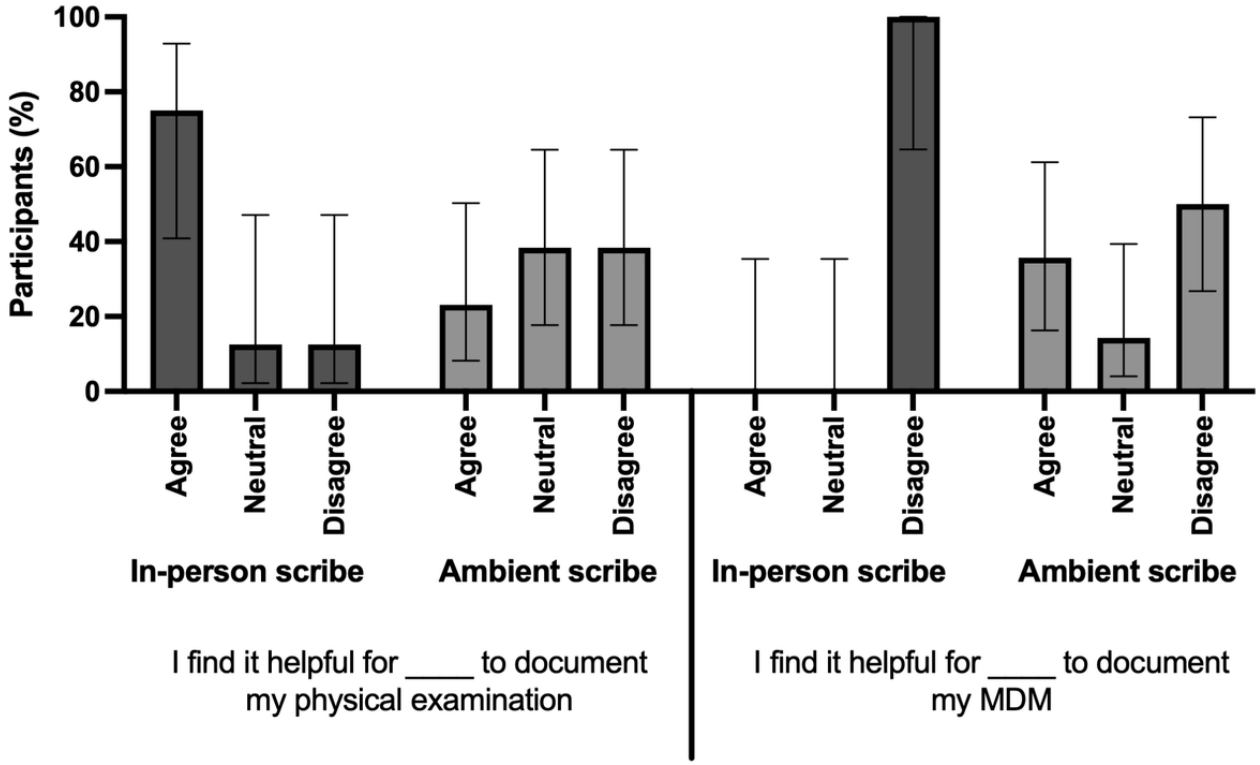
Figure 3. Preferences for the use of an ambient scribe or in-person scribes for elements of documentation are shown. Data were collected from 14 board-certified emergency and pediatric emergency physicians who completed a cross-sectional survey across 4 emergency departments in a single urban health system. The agree category includes answers for strongly agree or agree. The disagree category includes answers for strongly disagree or disagree. MDM: medical decision-making.



At the end of the multiple-choice questions, respondents were asked to "please leave any comments that may be helpful to understand your physician experience with DAX Copilot" in a free-text box. There were several qualitative comments shared by the survey respondents, as presented in Textbox 1. A thematic analysis of these open-ended responses found 5 broad, frequently cited themes, which included challenges due to the workplace environment, challenges due to patient population, workflow improvement, workflow harm, and narrow usefulness. These themes were pervasive in survey respondents' free-text responses. As shown in Multimedia Appendix 2, the most common theme was workflow harm (6 instances), followed by workflow improvement (4 instances). The remaining themes were each mentioned 3 times.

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Textbox 1. Free-text survey comments are presented verbatim without edits. These are the results of a cross-sectional survey that was conducted among 16 board-certified emergency and pediatric emergency physicians across 4 emergency departments within a single urban health system. Physicians were granted access to the ambient scribe and subsequently invited to complete an anonymous electronic survey.

- "DAX copilot has been difficult to use in a busy ER setting given the noise in the department, elderly patient population, and nonverbal communication such as nodding."
- "does a great job. there is a learning curve. you still need to review notes as they will need minor edits or corrections."
- "I don't have the option to use a scribe at work currently or recently (I think you asked about this at the beginning), so there is little point in asking me numerous questions about how DAX compares to a scribe. Unfortunately, only a minority of our ED patients can give a clear history, even when guided with straightforward 'Yes' or 'No' questions. Consequently, for the majority of ED patients, DAX generates a lousy history that then takes a lot of time to edit -- assuming you want a history that actually reflects the situation. Alternatively, if you don't care much about what's in the history (e.g. you are just interested in "filling in a blank" for billing and coding), then DAX is fine. DAX might work better just as a dictation tool -- instead of trying to listen in on a conversation and generate a history. For dictation, DAX seems to work better than Dragon which still -- after a decade -- still freezes up, drops words or parts of sentences. and at times makes egregious errors."
- "Dax has been inaccurate, has weird wording and often takes me more time because I have to explain my use of it to patients to consent them and then heavily edit my notes. I do not trust Dax and have been very disappointed with is so far."
- "DAX>Scribe when considering HPI gathering, though DAX is so verbose. The ideal state is to have Scribe tailor the HPI generated by DAX and Scribe tailor the physical. That is an expensive ideal state, so it is not practical. I find both to be very helpful. Scribes also grab patients' blankets and food. DAX cannot do that. Similarly, it is often nice on an overnight or other orphan shift to have a companion to shoot the breeze with. The morale boosting aspect of interacting with a young, eager (good) and appropriate scribe is another helpful aspect of scribe-physician interaction. Happy to answer any other questions."
- "Dax copilot has completely changed my workflow when I see patients independently. I get my charts done real time and it doesn't slow down flow (like when I'd pile up 3-4 and do them in a period when I was waiting for results/studies to be done). It doesn't get everything correct, but it's as good/better than most scribes. If it was less clinic and more ED focused on its AI components, that would make it top notch!"
- "It is tough for physical exam and MDM, and it is not that helpful when patient is non-verbal or critically ill. Scribes are better for those patients, can get info from EMS/NH."
- "I don't think that DAX does a good job with the HPI or MDM. The HPI is disorganized. When I write/dictate an HPI, I organize it. DAX simply writes stream of consciousness of what happened during the encounter. The parent may talk about the location of the patient's pain, then mention that they missed school, then state that their older daughter had an appointment to go to, then come back to associated symptoms... and DAX will write it all in that haphazard order. It's painful to read back! It's like an awful medical student presentation! I have tried to change modes (to the more concise note), but I have the same issues. Similarly, the MDM uses my language, which is often diluted for patients (ex. 'bellyache')."
- "Only use for HPI documentation, often will redictate based on notes captured during hx taking. Does enhance ability to see multiple patients rapidly. Do not like MDM sections generated by DAX and never use. Has been some years since I used scribes- good scribes are far superior to DAX, but most scribes are not, and while some can be delegated to do other human tasks, ultimately slowed me down because of (enjoyable) human interaction/feedback/discussion outside of patient care."
- "DAX copilot is efficient, accurate, and a huge job satisfier. The only concerns are it drains my personal cell phone battery and I don't like bringing my personal cell phone into patient rooms."

Discussion

Most EPs surveyed reported a positive or neutral experience with ambient scribe technology, preferring the ambient scribe to independent documentation, citing improved efficiency and less time spent on documentation outside of shift in their responses to multiple-choice questions. Our thematic analysis yielded similar results but helped provide more granularity to physician experiences. Through this mixed methods approach, several important trends emerged. While respondents generally preferred the ambient scribe to documenting independently, they found its usefulness varied depending on the component of their required documentation for which it was being used. Many physicians identified the ambient scribe as useful for completing the history of present illness, while fewer found it helpful for PE or MDM. Trust in documentation accuracy was also limited, and lower than the level of trust reported for in-person scribes. Notably, unique challenges presented by the ED setting and its patient population were common themes, as respondents cited factors such as noise level and critically ill or nonverbal patients contributing to decreased satisfaction with ambient scribe technology.

This study is one of the first to show promise for the use of ambient scribe technology in the ED setting, complementing literature that calls for research on ambient scribes across additional clinical settings and physician groups [8]. Given that approximately half of all hospital-based health care in the United States is delivered in the ED, the setting represents an important, yet relatively understudied area in ambient scribe technology [22]. Most EPs in our study were overall satisfied with the technology and believed its use resulted in increased efficiency and time savings, consistent with studies that support its benefits in the outpatient setting [5-7]. One of these studies found that the implementation of ambient scribes by a large California medical group produced an estimated time savings of more than 15,700 hours for users compared with nonusers over a 1-year period [8]. Although our study was not designed to quantitatively assess time savings per EP or across EPs as a group, this remains an area for future research. To our knowledge, no research currently exists that evaluates the cost savings of the deployment of ambient scribe technology across

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a medical group or health system. This research would likely be consequential to health care administrators evaluating the advantages and risks of financial investment in the technology.

Ambient scribe technology has also recently shown promise in significantly reducing physician burnout in the ambulatory setting [23]. This is particularly relevant to the ED setting, as EPs have long been known to experience higher rates of burnout than any other group of physicians [5]. While our study did not directly evaluate the effect of ambient scribe technology on EP burnout, we consider it likely that less time spent documenting outside of shift would have a positive impact on reducing rates of EP burnout. Furthermore, ambient scribe technology has been shown to lead to a greater sense of engagement with patients during outpatient appointments [10]. While this outcome likely has a positive impact on reducing physician burnout, its effect on patients is likely positive, as well. A survey of patients at a clinic using ambient scribes in its practices showed that patients are generally open to the use of ambient scribes in their physicians' offices and can see their potential benefits, although a significant number have concerns about documentation accuracy and privacy [14]. Interestingly, EPs surveyed in our study did not comment on experiencing a greater sense of patient engagement, but they shared patients' concerns over documentation accuracy.

While our findings underscore the promise of ambient scribe technologies in alleviating documentation workload of EPs, several caveats exist. Importantly, EPs found that the AI-generated output still required significant editing, negatively impacting their views on its reliability and ability to improve their documentation efficiency, consistent with other studies showing that AI scribes remain error prone [12,13]. Importantly, the ambient scribe's performance varied by note component, providing insight into an area that may be best suited for future improvement efforts. It is perhaps unsurprising that EPs in our study identified ambient scribes as most useful for documenting the history of present illness, as LLM-powered AI is widely considered useful for the summarization of information. Many electronic medical record systems have embedded capabilities to reduce the time spent on PE documentation through the use of templates. As such streamlining already exists, there may be less room for improved efficiency through the use of an ambient scribe or may require building on these already-existing solutions, such as integrating templated examinations with ambient scribing. Few other studies exist that examine physician experience and efficiency by note component, although this would be important to study in the future to identify potential gaps in current workflows where technology can improve efficiency.

Our pilot study has numerous limitations, the most significant of which is the small size of our population studied. Although most study participants responded to our survey, only 16 EPs across our hospital system were granted early access to the ambient scribe technology and were therefore eligible to participate in our study. While the 14 physicians who responded to our survey were well distributed in years of practice and EM vs pediatric EM training, their willingness to experiment with and adopt AI scribe technology may not be representative of all EM physicians, as they were self-selected and understood that they would be part of a group of early adopters of the technology at our institution. As there are multiple AI-powered ambient scribe technologies currently on the market, DAX Copilot may not be representative of the current state of ambient scribe technology due to product variation. Furthermore, we consider it likely that user experiences with ambient scribe technologies will change over time. There may be a "learning curve" while users adapt to the ambient scribe, and we expect aspects of the technology to evolve based on user preferences and feedback. Finally, our study did not evaluate patient experience or patient outcomes, which would be an important area of future research, as studies are currently limited.

This mixed methods pilot study is among the first to evaluate ambient scribe technology specifically in the ED, a unique environment that has been overlooked by the current body of literature focused on the outpatient setting. By combining quantitative survey outcomes with a qualitative thematic analysis of physician experiences, our study provides a more nuanced understanding of how this technology may function in a high-acuity and chaotic setting. Our findings highlight setting-specific challenges, such as noise and critical illness, variability in the trust of ambient scribe–generated output, and differences in the perceived utility of ambient scribing technology for different note components. By adding ED-specific evidence to the overall body of literature, our study offers guidance on how to tailor the technology for its use in the emergency setting. As the demand for efficiency in EM continues to grow in the face of persistent concerns over physician burnout and retention, scalable solutions such as AI scribes could play a pivotal role if their functionality, reliability, and physician trust can be further optimized. Areas of improvement may include improved functionality in noisy environments, decreasing errors and the need for manual editing, and development of enhanced or more tailored MDM sections. This technology may have particular value for institutions that do not have the resources to provide assistance with trained human scribes. The current value for sites with robust scribe programs is less clear. Future research should focus on longitudinal assessments of user experience and objective measures of documentation quality, time savings, and patient outcomes. With continued development and thoughtful integration, AI scribe technologies may ultimately help restore time for bedside patient care while improving physician well-being in the ED.

Data Availability

The dataset for this investigation was submitted to JMIR with the manuscript and is available upon request by contacting the corresponding author (YB).

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Authors' Contributions

Conceptualization: MK, YB
Formal analysis: TM, YB
Investigation: TM, MK, JSA, AMN, LLB, YB
Methodology: TM, MK, JSA, AMN, LLB, YB
Project administration: YB
Supervision: YB, AMN, LLB
Writing—original draft: TM, YB
Writing—review & editing: all authors

Conflicts of Interest

YB reports serving as an unpaid advisor to Esplanade Ventures.

Multimedia Appendix 1
Full survey.
[PDF File (Adobe PDF File), 22 KB - formative_v10i1e80401_app1.pdf]

Multimedia Appendix 2
Results from a thematic analysis of free-text survey responses are shown. Five major themes were identified throughout the comments. The y-axis represents the number of times each theme was mentioned. Data were collected from 14 board-certified emergency and pediatric emergency physicians who completed a cross-sectional survey across 4 emergency departments in a single urban health system.
[PNG File , 117 KB - formative_v10i1e80401_app2.png]

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Abbreviations

AI: artificial intelligence
ED: emergency department
EM: emergency medicine
EP: emergency physician
IRB: institutional review board
LLM: large language model
MDM: medical decision-making
PE: physical examination
REDCap: Research Electronic Data Capture

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Original Paper

Engaging Patient and Caregiver Partners in Codeveloping a Patient Educational Video for Improving Clostridioides difficile Infection Education: Participatory Co-Design Study

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Abstract

Background: Patients with recurrent *Clostridioides difficile* infection (rCDI) and their caregivers often face considerable uncertainty regarding medical management, including the use of fecal microbiota transplantation (FMT), largely due to the scarcity of accessible and credible educational resources. Codeveloping educational materials with patients and caregivers offers a structured way to address these gaps and ensure that resources reflect the informational, psychological, and emotional needs of patients.

Objective: The study team sought to cocreate an educational resource through an iterative process including patient and caregiver partners with lived experience of rCDI to improve *C difficile* infection education.

Methods: This study examined the cocreation process of a patient-centered educational resource between the study team and patient or caregiver participants through a series of focus group (FG) sessions. Five participants took part in 3 serial FG sessions (3-5 participants each) over 13 months. Each FG session was audio recorded, transcribed, and analyzed using the NVivo (version 14) quantitative analysis software. A semantic thematic analysis framework was applied to interpret the results. Key areas of concern and preferred formats were identified following the first FG session. The first version of the educational resource was developed by the study team to address areas of concern and was iteratively refined following feedback from subsequent FG sessions with the study participants.

Results: Participants expressed concerns about the lack of credible information on treatment options and their associated risks, especially with regard to FMT. They noted inadequate coverage of *C difficile* infection recurrence and its physical, psychological, and emotional impacts. Participants expressed a preference for educational resources in video format. On the basis of further feedback, refinements were made to improve pacing, consistency of animation, and narration, incorporating emotional and mental health considerations. The codeveloped video was well received and valued for its clear language, messaging, step-by-step guidance, and overall accessibility and clarity.

Conclusions: Our study demonstrated the feasibility and utility of patient and caregiver involvement in cocreating an educational resource on the management of rCDI, with FMT being a treatment option. Despite efforts to address knowledge gaps and preferences expressed for a video format, uncertainties remain regarding the most effective educational resource format. The integration of patient, caregiver, and study team perspectives contributed to a codeveloped video that addresses unmet needs and is patient centered. However, diverse patient experiences remain underrepresented. Future research should consider including

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more diverse participants as well as evaluating the effectiveness of knowledge improvement through various educational resource formats and patient health care experiences and levels of satisfaction.

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KEYWORDS

Clostridioides difficile infection; patient educational resources; digital health; fecal microbiota transplant; codevelopment; informational video

Introduction

Commonly triggered by the use of antibiotics, *Clostridioides difficile* infection (CDI) is a gram-positive bacterial infection that occurs due to intestinal dysbiosis. The first-line therapy for CDI is vancomycin, which further exacerbates dysbiosis. Consequently, the risk of CDI recurrence continues to rise, from 20% to 30% after the first episode up to >60% after the third episode [1,2].

Fecal microbiota transplantation (FMT), a procedure that transfers stool from a rigorously screened donor into the intestine of a recipient, is a highly effective, guideline-recommended therapy for managing recurrent CDI (rCDI). The efficacy is at least 80% after a single treatment [3]. However, awareness and understanding of FMT remain limited among patients and health care providers, particularly regarding what the procedure entails, what the potential risks are, when FMT is indicated, or how to access it.

Although the global burden of CDI has consistently increased over the last 20 years [4], there is still a lack of credible and evidence-based resources available to the public [5]. Many patients seek information from unreliable sources [6] or delay seeking medical attention [7]. Studies exploring patient experience with rCDI have identified confusion and uncertainty about symptoms as predominant concerns among patients and their families [8,9]. Additionally, surveyed patients emphasized the importance of understanding their condition and expressed a desire for greater access to educational resources. When asked about their preferred methods of learning, patients indicated a preference for verbal and written education supplemented with online resources [8]. The illness experience is impacted by various factors, including prior experiences and the quality of care received. Notably, patients cited their lack of knowledge and understanding as negative contributors to their overall experience with rCDI [8].

Patients and health care professionals often have differing priorities when it comes to research and resource development. While health care professionals prioritize communication and effectiveness, patients tend to focus on psychosocial consequences and human behavior [10]. Patient partnerships are grounded in experiential knowledge, defined as “the knowledge embedded in the patient’s experience of managing and living with an illness” [11]. Patient partners view themselves as equal members of the health care team and become more engaged in their own health due to their participation; they are further motivated by the opportunity to improve care quality for others. As such, patient partners play a crucial role in the resource development process by integrating patient perspectives to ensure that resources are tailored to the populations they are designed to serve [12]. Ultimately, the final product will be shaped by both the scientific and experiential knowledge of health care professionals and the lived experiences of patients [13].

Given the paucity of credible, patient-centered educational resources for the management of rCDI, this paper describes the iterative process of codeveloping an educational video by patient and caregiver partners with health care providers and how the final product was perceived and disseminated.

Methods

Design

The study team from the FMT program in Edmonton, Alberta, aimed to cocreate a patient-centered educational resource to guide patients and caregivers through rCDI treatment. A qualitative approach was taken, using serial focus group (FG) sessions to collect data to inform the format and content of the educational resource. Three 60-minute FG sessions with patient partners and caregivers were conducted, facilitated by the Alberta Health Services (AHS) Health Systems Knowledge and Evaluation (HSKE) team. The sessions followed a semistructured format framed by an interview guide in addition to open-ended questions. A separate interview guide was designed for each FG. The final product was the result of an iterative process of cocreating an educational video with important feedback from patient partners and caregivers on their experiences with rCDI and FMT.

Ethical Considerations

Ethics approval was obtained from the Health Research Ethics Board of the University of Alberta (Pro00130489), where the study was conducted. Informed consent was obtained after explaining the study protocol and the voluntary nature of involvement to all participants. Each participant signed a written consent form that explicitly covered both study participation and the audio recording of FGs. Financial compensation was provided to participants in the form of gift cards. All data were deidentified to protect the privacy of participants and maintain confidentiality.

Participant Recruitment

Participants were recruited through convenience sampling, as they were former patients of the single FMT clinic in Edmonton. Eligibility criteria included having previously received FMT or having cared for an FMT recipient. The FMT clinic nurse navigator contacted eligible individuals to provide an overview of the study and assess their interest and availability to participate in 3 FGs. Upon receiving written consent for

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participation and audio recording, virtual meeting invitations were distributed. While all participants contributed meaningfully to the study, attendance varied across the FGs.

Data Collection and Analysis

Zoom (Zoom Video Communications) was used for FG 1, which took place on October 15, 2023. Microsoft Teams was used for FG 2 on August 15, 2024, and FG 3 on November 5, 2024. Each FG lasted approximately 60 minutes. Sessions were transcribed using the auto-transcription features on both Zoom and Microsoft Teams. The first session served as an opportunity to explore patient experiences with rCDI, their emotional responses throughout the illness, access to educational resources, preferred formats for the resources, and the most effective methods of dissemination. The purpose of the initial FG was to establish a baseline understanding of the current landscape of educational resources and patients' perspectives of them. The second and third FGs were used to gather insights and opinions from participants to involve them in the cocreation of the educational resource.

In response to this feedback, the study team developed the initial draft of the educational video and shared it with participants 2 weeks before FG 2.

During the second FG, participants were asked to provide feedback on ways to improve the educational resource. Their responses, combined with input from the AHS Clinical Knowledge and Content Management team, were compiled and used to refine the educational resource further. A similar process was followed before FG 3, where the revised product was sent to the participants who had contributed to FG 2. They were asked to review the updated product and provide feedback on whether the modifications adequately addressed their concerns from FG 1. The study team revised the educational resource based on the feedback and provided a revised version to the participants 2 weeks before FG 3.

To prepare the data for analysis, all FG transcripts and interviews were reviewed and cleaned for accuracy by the HSKE team. Identifying patient information was replaced with study identifiers to maintain participant confidentiality. Thematic analysis was used to examine the qualitative data extracted from the FG transcripts. The NVivo software (version 14; Lumivero) was used to aid in coding the data by the HSKE team using a semantic approach, ensuring that participant perspectives were accurately captured. A semantic approach to thematic analysis was considered favorable for this study, as it involves coding data based on explicit content, resulting in a descriptive rather than interpretative analysis [14]. This approach was particularly useful in this context, as it facilitated the categorization of patient suggestions into various thematic groups, allowing for their seamless integration into the final version of the educational resource.

Results

Participants

Of 20 patients and caregivers approached, 7 (35%) participants were recruited (n=6, 86% patients and n=1, 14% caregivers). Ultimately, 2 (29%) participants withdrew before initiating the study due to other competing responsibilities, time constraints, or scheduling conflicts at the time of the FGs. Of the 5 participants from FG 1, a total of 3 continued with participation in the subsequent FGs. Attrition following the initial FG occurred because participants were unable to commit to additional time. Baseline participant characteristics are summarized in Table 1.

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Table 1. Summary of participant demographics by focus group.

Characteristic	Focus group 1 (n=5)		Focus groups 2 and 3 (n=3)—patients
	Patients	Caregivers	
Male, n (%)	2 (40)	0 (0)	2 (67)
Age (years), mean (SD)	49 (13.5)	53 (N/A[a])	43 (8.7)
Educational level, n (%)			
University	2 (40)	1 (20)	2 (67)
Nonuniversity postsecondary education	1 (20)	0 (0)	0 (0)
High school	1 (20)	0 (0)	1 (33)
Ethnicity, n (%)			
South Asian	1 (20)	0 (0)	1 (33)
Southeast Asian	1 (20)	1 (20)	1 (33)
White	2 (40)	0 (0)	1 (33)
Comorbidities, n (%)			
Multiple comorbidities[b]	1 (20)	0 (0)	1 (33)
Cognitive impairment	0 (0)	0 (0)	0 (0)
Living situation, n (%)			
Independent	4 (80)	1 (20)	3 (100)

[a]N/A: not applicable (as only 1 participant was present).

[b]Includes type 2 diabetes, dyslipidemia, kidney transplant for end-stage renal disease, hyperparathyroidism, hypophosphatemia, and coronary artery disease.

FG Discussions

Three FG sessions were conducted between October 2023 and November 2024. The findings highlighted key areas of concern for patients with rCDI, including previously unknown information, content that patients found valuable, and gaps in coverage and representation in existing resources. A summary of FG discussions can be found in Table S1 in Multimedia Appendix 1.

In FG 1, participants reported feeling frustrated and confused while searching online resources about FMT and rCDI. While some information was perceived as credible and trustworthy, other content was considered too generic, inaccurate, or outdated, leading to uncertainty about its reliability (Table S1 in Multimedia Appendix 1):

> *I found while there were very trustworthy sources online like the World Health Organization and the US Centers for Disease Control and some other Canadian health jurisdictions as well, in the United States, there were an equal number of sources that may not be considered as trustworthy. So, I found that doing research online was a little bit nerve wracking because you didn't know what treatment options were accurate, when the documents were last updated, so maybe there was an outdated treatment method as well, so I found that to be more concerning looking stuff up online than actually informative.* [Participant 2]

A common issue identified was the lack of awareness of FMT among physicians and associated delays in its implementation as a treatment option. Participants were alarmed that primary care providers appeared to be unfamiliar with FMT as a treatment option, despite thinking rCDI was a prevalent illness (Table S1 in Multimedia Appendix 1):

> *My doctor didn't have that information either, and I'm the one that brought it up. I'm the one that researched Dr. X and then when I took it to her, she says, "yeah, OK." So, the lack of information out there in regards to the fecal transplant is, I find very alarming.* [Participant 3]

Participants identified several important topics for educational resources for patients with rCDI, including causes of rCDI, signs and symptoms, available treatment options, potential risks, and when to seek treatment (Table S1 in Multimedia Appendix 1):

> *I think the signs and the symptoms of it, if people know what to look for because I didn't know, I thought I'd eaten something bad, and it wasn't that at all.* [Participant 1]

> *If it was known that [there] is a high possibility of it reoccurring. That's good information to have and, I know I had to be an advocate for my own health because, I knew it, I wasn't better.* [Participant 3]

Furthermore, participants emphasized the importance of raising awareness about the significant likelihood of the recurrence of

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CDI and its impact on mental health (Table S1 in Multimedia Appendix 1):

> *For me it was not only challenging physically to deal with so much of it, but mentally as well. And there were times, I was thinking, oh my goodness. When is this going to end?... I thought, every now and then, you know what, I need to give up on this, this is just too much. So, for me, I feel that having information about not giving up, surrounding yourself with people you love, and who love you back, is important as well.* [Participant 2]

Participants felt that a video format would offer the most comprehensive approach, as it allows for easy accessibility and can effectively capture and maintain viewer attention when hosted on trusted platforms such as the AHS website. At the same time, they expressed a desire for mixed-format patient educational resources in the future (Table S1 in Multimedia Appendix 1):

> *For digital resources, I feel that since a lot of people are using social media these days, like TikTok, Instagram, Facebook.... I think it was [Participant 4] who mentioned having little ads on TV, I feel that having little ads on social media as well that refer the user to go to the Alberta Health Services website or My Health. That can help as well.* [Participant 2]

> *I love those small pamphlets that you take from a plastic thing, and then you open it...information's there on FMT and then the marketing would be on the front page, something like "been pooping lately?" And then at the bottom something like "try FMT" and then as you open the page "what is FMT?" with some short information on it. Because I got lots of that before [my] kidney transplant. And boy, did I learn a lot from it.* [Participant 5]

On the basis of the feedback from FG 1, a video about CDI and FMT was considered the preferred format. Patient partners emphasized that representation was a key priority, noting a significant lack of diversity within existing educational resources. As a result, the development of new materials needed to intentionally incorporate principles of diversity, equity, and inclusion, ensuring that content reflected a broad spectrum of socioeconomic backgrounds, genders, and other underrepresented subgroups. To incorporate this feedback, the resource was drafted using inclusive language and written at an eighth-grade reading level to ensure accessibility for a broad audience. Additionally, both male and female narrators were included in the video to enhance representation and reflect greater diversity.

Before FG 2, the study team developed a script and storyboard for an animation-style video in a question-and-answer format (Table S2 in Multimedia Appendix 1). Key topics included a holistic perspective on managing CDI, benefits and limitations of FMT, patient expectations associated with FMT, and prevention of future CDI. This draft video was shared with participants 2 weeks before FG session 2.

Participants in FG 2 expressed that the video was clear and concise and effectively addressed questions that patients might have. They also found that the video was easy to follow, engaging, user-friendly, and free from complex medical jargon (Table S3 in Multimedia Appendix 1):

> *I found it to be very clear and to the point, effectively conveying the most important information. So, it basically answered most of the questions I would have if I were still a patient and I appreciated that it explained the screening process for donors since this can provide additional comfort to patients.* [Participant 2]

> *It's not jargon. It's not medical jargon. It's not too simple. It's not too complex.* [Participant 7]

The participants expressed a desire for consistency in both the visuals and audio. They noted that the male and female speakers had differing audio qualities and volumes, which made the overall balance feel off. Furthermore, all participants pointed out that there were moments in the video in which the audio seemed to move faster than the images and the slide transitions were too rapid (Table S3 in Multimedia Appendix 1):

> *Yeah, I noted that same thing as well, where the female narrator was louder than the male narrator. I was constantly having to fiddle with the volume controls on my laptop just to compensate for that.* [Participant 2]

Participants felt that the amount of information presented in the video about rCDI and FMT was appropriate for the length of the video. However, they thought that the video could be longer (Table S3 in Multimedia Appendix 1):

> *[F]or information with this much value, I don't think it would be much of an issue to extend the video by maybe another minute or so.* [Participant 2]

Participants did recommend adding more information and indicating specific timestamps (eg, 3:35) in the portion of the video that talked about recurrence of CDI to improve clarity (Table S3 in Multimedia Appendix 1):

> *For myself, I found the information to be quite clear. However, there was one specific question. "How do you know if the FMT was successful?" and the answer was if the diarrhea does not come back, then you can consider yourself cured.... But I found that to be quite vague, since there is no window of recurrence specified. So, if the diarrhea does not come back in three days are they cured? or three weeks? etcetera.* [Participant 2]

Participants also requested more details about the potential risks of FMT and sought clarification on the process used to handle the fecal matter after it is collected from the donor. The script was consequently updated to reflect these preferences (Tables S3 and S4 in Multimedia Appendix 1):

> *I'm not sure if I saw this in the video, but what are the risks of the FMT...? I don't think that was covered.* [Participant 2]

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> *[W]e could potentially think about adding a little bit...about...how it goes from donor to the capsule or to, whatever form you're using. So, it might be valuable to say that this is fecal filtrates, or that it's processed in a certain way...or whatever you want to say. We don't have to get scientific, but it would be nice so that they know there's a process to refining it so that it's not just stool to you, right?* [Participant 7]

Participants were shown examples of health education on the website of MyHealth Alberta and asked for feedback on the most and least helpful formats. They preferred question-and-answer and video formats but suggested offering information in multiple formats to accommodate various audiences and situations, such as providing video transcripts for those unable to watch videos in public (Table S3 in Multimedia Appendix 1):

> *I really like the Q&A style that's then augmented by having the video, which is further augmented by having that transcript, if that's how you prefer to learn, or hear it, or view it, or whatever.* [Participant 7]

In FG 3, participants felt that the audio and visual issues from the second FG were resolved and appreciated the additional information provided in the video. However, they agreed that the term "fecal slurry" was unpleasant. The visuals were deemed suitable for CDI-affected audiences, except for the image of the glass of fecal slurry. The animations accompanying this portion of the video were changed before submitting the video to the MyHealth Alberta website for publication (Table S5 in Multimedia Appendix 1):

> *Yeah. I didn't expect anything more than that. I felt it covered it very well in terms of specifically the composition of the FMT capsules, which was interesting to see.* [Participant 2]

> *And then that "fecal slurry," that was an interesting picture. Some people might find that too much information.* [Participant 7]

Thematic analysis of the FG sessions reflected informational needs, emotional and practical challenges associated with rCDI, and preferences regarding the delivery of educational content (Figures 1-3). Participants emphasized the importance of clarity, reassurance, and transparency surrounding treatment risks and benefits within the video content. In addition, preferences related to video pacing, diction style, and audiovisual elements were identified. The finalized video was published on MyHealth Alberta in February 2025.

Figure 1. Thematic map of focus group session 1 (FG 1). AHS: Alberta Health Services; FMT: fecal microbiota transplantation; rCDI: recurrent Clostridioides difficile infection.

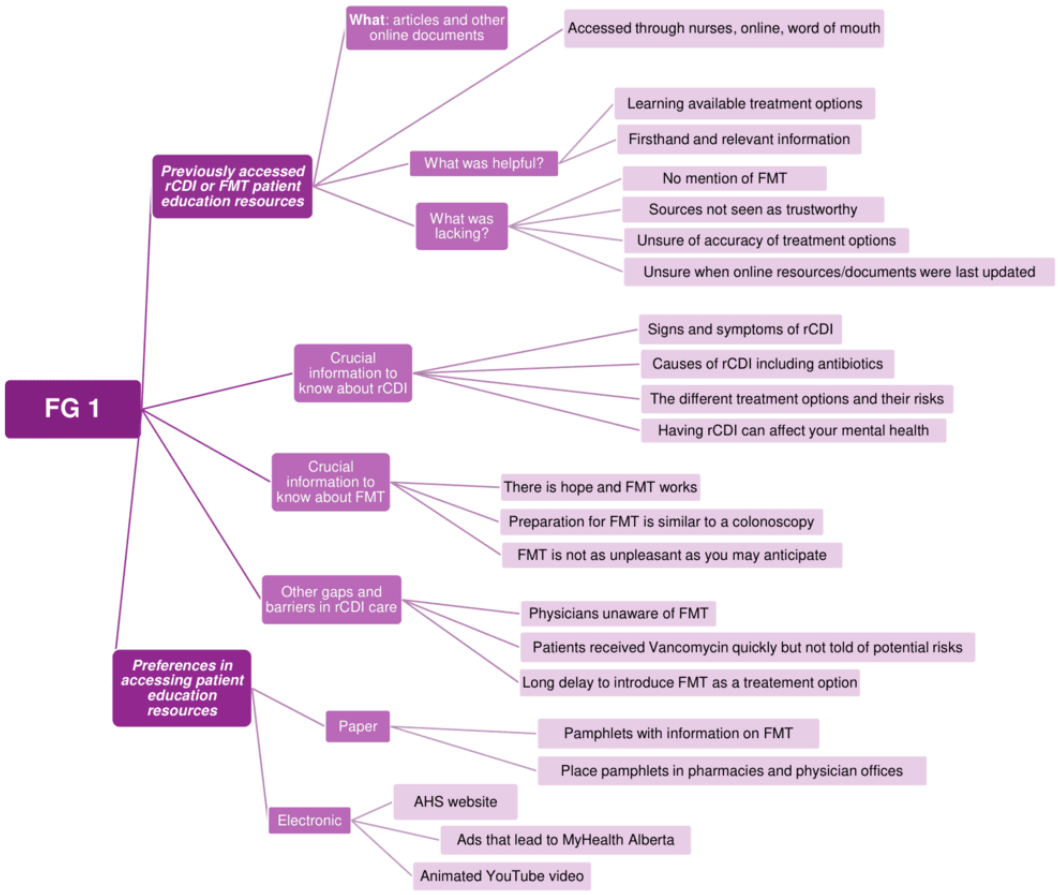

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Figure 2. Thematic map of focus group session 2 (FG 2). CDI: Clostridioides difficile infection; FMT: fecal microbiota transplantation.

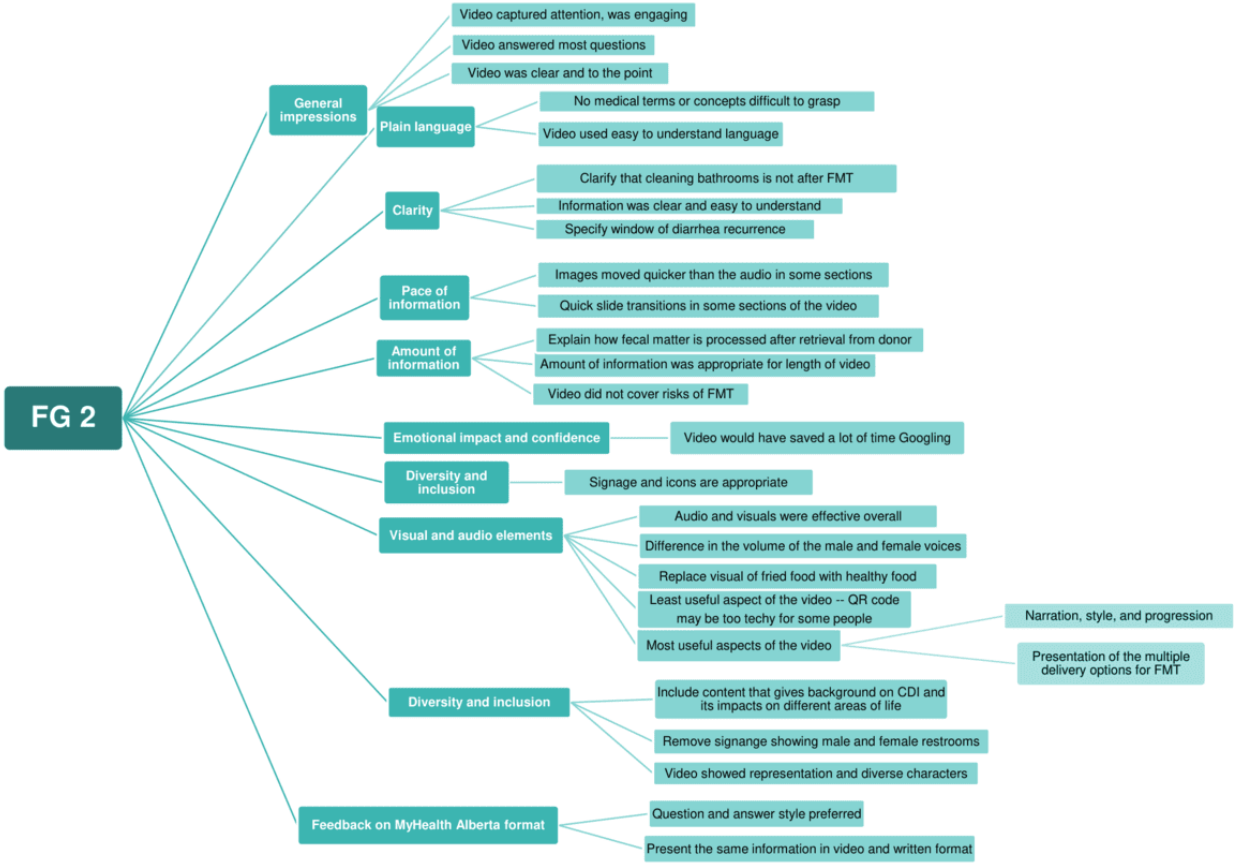

Figure 3. Thematic map of focus group session 3 (FG 3). CDI: Clostridioides difficile infection; FMT: fecal microbiota transplantation; rCDI: recurrent Clostridioides difficile infection.

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Discussion

Principal Findings

Patient and caregiver partners in our study identified the inadequacy of existing educational resources in addressing their concerns throughout their rCDI journey. Using an iterative cocreation process with our partners, we developed an animated patient-centered video focused on rCDI and FMT, the most effective therapeutic option. This video was regarded by our partners as medically informative, relevant, reassuring, and inclusive while authentically capturing patient perspectives, demonstrating the value and feasibility of patient-centered, cocreated educational resource development.

Current Landscape

Low health literacy is strongly associated with worse health outcomes and higher health care costs [15]. Patient educational materials are *actionable* when "consumers of diverse backgrounds and varying levels of health literacy can identify what they can do based on the information presented" [16]. Furthermore, pictograms have been shown to improve the acquisition and comprehension of complex medical information [17]. Multiple surveys of patients with CDI and health care providers have found that education provision is inconsistent [18,19]. While educational resources on rCDI exist, they often fail to reflect patient experiences, contributing to frustration and a lack of understanding [16]. A systematic appraisal of 19 educational materials for patients with CDI using the validated Patient Education Materials Assessment Tool found that the understandability averaged at 73.4 (range 62.7-82.9), whereas the overall actionability score was 50.5 (range 13-73.3), and none used visual aids [20]. While the American Gastroenterological Association [21] released an educational video in 2024 specifically on FMT, it has limited patient engagement and does not address many concerns raised by our study participants, including risks associated with FMT, what to expect after FMT, or how to prevent future recurrence.

Perspectives shared by participants reflect a broader pattern of underuse of FMT despite its endorsement in clinical practice guidelines. A survey including 31 hospital-based FMT centers across 17 European countries reported a total of 1874 FMT procedures in 2019, of which 1077 (57%) were performed for CDI. In contrast, an estimated 12,400 (range 6100-28,500) annual cases of multiply rCDI with an indication for FMT occur in Europe, suggesting that current FMT activity reaches only approximately 10% of eligible patients [22]. Several factors likely contribute to this discrepancy between guideline recommendations and real-world practice. Knowledge-related barriers [23,24] among health care professionals may include unfamiliarity with FMT as a treatment and its efficacy or uncertainty regarding the timing of referral or which specialists to refer to. In addition, a 2024 survey of infectious disease physicians and other health care professionals in the United States found that although 87% of respondents reported having previously recommended FMT for rCDI, only 48% [25] indicated having access to FMT using donor stool. Recent approval of Rebyota, a donor stool–based microbial therapy, by the Food and Drug Administration and Health Canada may potentially improve access to treatment.

Target Population

Participants in our study may appear younger and healthier than the traditional CDI population, once linked to hospitalized, older, frail, or comorbid adults. However, approximately 30% of patients with rCDI evaluated in the Edmonton FMT program were aged <50 years without significant comorbidities (D Kao, unpublished data, December 2025). Similarly, emerging evidence from the last 20 years has highlighted a drastic shift in CDI epidemiology worldwide, with more frequent occurrence causing severe disease in populations that were previously thought to be at low risk [26]. Additionally, those with community-acquired CDI tend to be younger [27].

Despite this CDI epidemiological shift, advanced age and frailty continue to be risk factors for CDI, and it is important to consider how to best structure and disseminate educational resources within these populations. As participants in our study were relatively young (mean age of 54, SD 9.3 years), this may have influenced the preference for digital formats, perspectives on self-advocacy, and familiarity with online search engines. As a result, findings from our study may have limited applicability to older adults, particularly those with comorbidities, cognitive impairment, or limited digital literacy. A study exploring digital health literacy among older adults found that respondents scored relatively low in the domains of technology familiarity, technology confidence, and technology incentive [28]. While 61% of the respondents in that study experienced no stress while using a computer, 9% of participants experienced high or very high stress levels. At the same time, there is evidence suggesting that technology and mobile device use among older adults is steadily increasing, with rising mobile phone ownership among individuals aged ≥65 years, supporting the feasibility of digital health education in this population [29]. As reliance on digital dissemination alone may be insufficient to reach all populations, particularly older adults and individuals with limited digital literacy, it is important to consider multimodal dissemination strategies to improve patient education.

Although concerns remain regarding older adults' ability to access digital educational resources, this mode of dissemination offers several advantages that align with findings from our FG sessions. Since the completion of our educational video, it has been uploaded to My Health Alberta, an online health information source built by the government of Alberta and AHS. The link to this video is also embedded in the provincial-based referral pathway for CDI, allowing other health care providers to directly share the resource with patients. In addition, all patients referred to the Edmonton FMT clinic receive a link to this video before their scheduled appointment, as well as support from members of the clinical care team, who assist those experiencing difficulties accessing the video resource.

Importance of the Cocreation Process

There is increasing recognition that cocreation is essential for developing patient educational resources that are relevant, accessible, and impactful. A study of brain cancer resources

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that combined content analysis with participant interviews highlighted 4 critical design imperatives: authenticity, visual engagement, concise key messages, and clear information. Participants favored resources that met contemporary visual standards and featured multiple narrators [30], similar to preferences expressed by our study participants. Valuable insights that might otherwise be overlooked can emerge using a cocreation approach. Evidence across the literature shows that cocreation is associated with improved treatment adherence and better health outcomes [31-33]. Moreover, it supports the delivery of patient-centered care by aligning health care services with individual needs and preferences, thereby enhancing overall satisfaction [32,33].

The recurrence and stability of themes across FGs indicate that thematic saturation was reached, supporting the robustness of the insights that informed the cocreation process.

Comparison of Various Formats

Print pamphlets have long been considered an effective means of disseminating patient education, largely due to their accessibility across socioeconomic groups [34]. However, their high production costs and low rates of patient recall significantly limit their impact [35]. In contrast, clinician-produced videos have demonstrated improvements in decision-making, knowledge acquisition, and anxiety reduction [36,37]. Multimedia formats incorporating slide and sound presentations have been shown to outperform both pamphlets and face-to-face dialogue in facilitating knowledge translation [38]. A cocreated child-narrated video on uveitis showed that self-rated understanding of uveitis, described as “good,” increased from 33% to 51% upon viewing the video. Those who self-rated their understanding as “none” dropped from 19% to 0% [38]. Objective knowledge scores, measured through asking various questions about video content, increased significantly for all 6 questions posed to participants. Notably, a study with patients with psoriasis comparing the effectiveness of pamphlets with that of videos through tests found that post–pamphlet plus video test scores (mean 86.25, SD 17.58) were significantly higher than the postpamphlet test score alone (mean 72.08, SD 26.33; $P<.001$) [24].

There were several reasons for prioritizing a video-based format. First, our participants preferred this format. Second, it can integrate multiple modes of information delivery, including visual text, imagery, and spoken content. Existing literature suggests that incorporating diverse learning modalities may enhance knowledge acquisition [39,40] and retention among patients. Third, there is a limited availability of clinically developed, patient-facing educational videos on CDI that patients can reliably access. Fourth, videos enable participants to pause, rewatch, or visually interpret information if spoken content is unclear, providing greater flexibility in comprehension [41]. While clinician dialogue is valuable, it does not offer unlimited access. Similarly, pamphlets often require distribution through medical visits, limiting accessibility. Outdated pamphlets also require physical replacement, unlike videos. Videos allow patients to review information before attending appointments, potentially enhancing preparedness for discussions with health care providers.

It is important to consider that, when investigating the effectiveness of knowledge transfer, some studies have found that adding an instructional video on bowel preparation before colonoscopy improved preparation quality, while other studies have not [42]. Additionally, digital engagement tends to decline among older adults and individuals with lower educational attainment [43]. These challenges can be mitigated through targeted coaching and clear guidance from health care providers. These strategies can help patients navigate and trust online resources, linking video-based education to improvements in health literacy and more equitable access to information [44-46]. The extent to which any educational tool optimally turns information into lasting understanding and action and subsequent impact remains uncertain [42]. Future studies should incorporate an evaluation process to assess patient comprehension in a systematic manner.

Limitations

This study has several limitations that should be considered when interpreting the results.

The small sample size of 5 participants limits the generalizability of the findings. A larger sample could have captured a broader range of perspectives, particularly regarding differences in patient experiences across various demographic groups. Given the limited number of participants, those who chose to take part may have had stronger opinions or a greater interest in the development of patient educational resources than the general population of patients and caregivers. This self-selection bias could have affected the topics and content included in our educational resource, which may not be of interest to a more diverse audience.

The use of FGs has inherent limitations, including susceptibility to bias, as dominant participants or the moderator may influence individual or group opinions [47,48]. As a result, distinguishing personal opinions from group consensus can be challenging. However, FGs remain a valuable method in health research, as their interactive nature encourages participants to voice their perspectives, ultimately enhancing data collection [49]. Additionally, FG sessions offer a convenient and effective approach, particularly in an evolving digital health space, to gather meaningful insights into patient experiences, perspectives, and needs [50].

Retention is a well-recognized challenge in qualitative research, which we also encountered, as participants may have had limited capacity to commit to multiple 1-hour sessions due to competing responsibilities, including employment and caregiving obligations. Additional barriers may include technological constraints such as limited access to the internet or devices. In future studies, retention may be enhanced through the provision of multimodal options for FG participation (eg, in-person, virtual, or asynchronous formats), as well as more proactive and individualized communication with participants regarding accommodations that could facilitate continued involvement. Gaining a clearer understanding of individual-level barriers to participation may allow research teams to implement targeted solutions, thereby improving retention and reinforcing participants’ sense of value in the research process [51].

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The study sample lacked representation from frail, institutionalized, and cognitively impaired populations. These groups are likely to have distinct educational needs and may rely more heavily on caregivers for health system navigation. To ensure a greater inclusion of diverse perspectives, future studies should implement appropriate recruitment and retention strategies. The literature suggests that multifaceted recruitment approaches, those that provide clear study information, offer incentives in multiple forms (eg, financial, health related, or educational), and are initiated by a trusted member of the health care team, are associated with improved engagement [52]. Furthermore, involving participants in project development has been shown to support retention by fostering a sense of ownership and relevance [51]. While participant involvement was incorporated in this study through a cocreation process, engaging patients more directly in the qualitative design, including feedback mechanisms and FG facilitation, may further reduce attrition [53].

In terms of data collection, a standardized qualitative research checklist, such as COREQ (Consolidated Criteria for Reporting Qualitative Research) or SRQR (Standards for Reporting Qualitative Research), was not used in this study. Incorporation of such frameworks in future research may strengthen methodological transparency and rigor [54,55]. Moreover, the FG guides were not pilot-tested, which may have limited the ability to assess and refine their content validity [56].

Conclusions

Cocreating educational resources with patient partners is a highly feasible approach that yields patient-centered, well-received tools for managing rCDI. Future work should evaluate the acceptability and effectiveness of additional formats to ensure that diverse patient populations have access to the most engaging and clinically relevant resources.

Given the diversity of patient and caregiver populations and the wide range of individual experiences with CDI, many perspectives remain underrepresented in the current collection of educational materials. To ensure inclusivity and relevance, it is essential to continue collaborating with health care providers, patient partners, and other stakeholders to allow for the continuous evolution of these resources. Further studies should explore the effectiveness of patient educational videos for CDI and FMT in improving patient knowledge, treatment adherence, and overall health care experiences. Additional evaluation studies, both quantitative and qualitative, are necessary to assess the impact of such resources on prevention and treatment outcomes. To determine the effectiveness of different formats of patient education, exploratory qualitative studies could be used to investigate the extent to which codevelopment processes can address existing gaps in CDI-related patient education.

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Conflicts of Interest

None declared.

Multimedia Appendix 1
Focus group and video script tables.
[DOCX File , 69 KB - formative_v10i1e81643_app1.docx]

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Abbreviations

AHS: Alberta Health Services
CDI: Clostridioides difficile infection
COREQ: Consolidated Criteria for Reporting Qualitative Research
FG: focus group
FMT: fecal microbiota transplantation
HSKE: Health Systems Knowledge and Evaluation
rCDI: recurrent Clostridioides difficile infection
SRQR: Standards for Reporting Qualitative Research

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Original Paper

GPT-Powered Chatbot-Based Positive Psychology Intervention for Well-Being Among Parents of Children With Autism Spectrum Disorder: Single-Arm Mixed Methods Study

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Abstract

Background: Parents of autistic children frequently experience elevated stress levels, depressive symptoms, and reduced well-being. Positive psychology interventions (PPIs) can strengthen resilience, and chatbots offer a scalable channel through which such skills can be delivered. However, evidence on the evaluation of large language model–guided PPI-based chatbots for this population is limited.

Objective: This study evaluated the feasibility and acceptability of a GPT-powered chatbot (“Allie”). This study was designed to deliver culturally adapted PPIs to parents of autistic children and to explore their preliminary effects on well-being, depression, stress, and health-related quality of life.

Methods: We conducted a single-arm mixed-methods pilot study with 19 parents with autistic children. These parents engaged with Allie for 2 weeks to complete 8 structured PPI exercises. The primary outcomes were feasibility (completion, ease of use, and practicality) and acceptability (multidimensional user ratings). Secondary outcomes were the World Health Organization–Five Well-Being Index (WHO-5), Patient Health Questionnaire-9, Perceived Stress Scale-10, and Short Form-12 Health Survey (version 2) Physical and Mental Component Summary scores. Outcomes were analyzed using paired *t* tests or Wilcoxon signed-rank tests. Optional postintervention interviews were analyzed using reflexive thematic analysis.

Results: A total of 17 (89.5%) participants completed all the exercises, which indicated a high degree of procedural feasibility. There were also high ratings for ease of use and practicality (means 4.47/5, SD 0.70, and 4.32/5, SD 0.67, respectively). Acceptability was favorable (overall satisfaction mean=5.68/7, SD 0.70; prompt response time=6.37/7, SD 0.68). The WHO-5 score improved significantly from 32.84 to 46.11 (t_{18}=2.48, P=.02; Cohen d=0.52). Changes in the Patient Health Questionnaire-9 (z=−0.49, P=.63; r=0.11), Perceived Stress Scale-10 (t_{18}=−0.82, P=.43; Cohen d=0.12), and Short Form-12 Health Survey (version 2) Physical Component Summary (t_{18}=−0.94, P=.36; Cohen d=0.18) and Mental Component Summary (t_{18}=−0.89, P=.39; Cohen d=0.17) scores were not significant. Qualitative feedback (14/19) described benefits aligned with PPI mechanisms such as greater self-reflection, a more positive orientation, perspective-taking, emotional support, and coping skills. However, participants also suggested refinements, such as more natural conversation (colloquial Cantonese), shorter or less repetitive outputs, user-chosen sequencing with reminders and progress tracking, multimodal features, and autism spectrum disorder–specific resources.

Conclusions: This pilot study revealed the feasibility, acceptability, and preliminary improvement in well-being (WHO-5) of a PPI-based GPT-powered chatbot, Allie, among parents of autistic children. Although there was no significant short-term change

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in other outcomes, the findings provide insights into design priorities, including personalization, conversational naturalness, multimodal content, and autism spectrum disorder–specific guidance. Larger, controlled trials with longer exposures and more diverse samples are needed to establish efficacy and durability.

Trial Registration: ClinicalTrials.gov NCT06438120; https://clinicaltrials.gov/study/NCT06438120

(JMIR Form Res 2026;10:e85060) doi:10.2196/85060

KEYWORDS

autistic children; autism; parental well-being; chatbot; positive psychology; digital intervention; ASD; ChatGPT; autism spectrum disorder

Introduction

Background

Autism spectrum disorder (ASD) is a neurodevelopmental condition that is often diagnosed in early childhood and has become a growing public health concern worldwide. The World Health Organization estimates that approximately 1 in 100 children worldwide has ASD [1]. On the basis of official data from the US Centers for Disease Control and Prevention, approximately 1 in 44 children were diagnosed with ASD in 2018 [2]. In Hong Kong, the Census and Statistics Department's General Household Survey for 2019 and 2020 revealed a prevalence rate of 1.4% for ASD among the local population younger than 15 years of age [3].

Poor Mental Health Among Parents of Autistic Children

ASD is characterized by different levels of disability and challenges in social communication, cognitive growth, and emotional expression. Moreover, ASD includes limited, repetitive behaviors and interests, along with sensory processing problems [4]. Raising autistic children can be stressful and difficult for parents. This stress can increase the risk of mental health issues and other negative effects. Previous research has indicated that approximately half of parents of ASD children, including Chinese parents, report depressive symptoms [5,6]. Parents of autistic children also report lower well-being and quality of life related to health compared with parents of children without ASD [7].

Multiple factors affect the mental health of these parents. These factors include a perceived lack of control over their child's behavior, worries about the child's developmental progress and daily living skills, and the ongoing demands of caregiving. Time limitations, strained relationships with their children, and uncertainty about the child's future add to parents' stress [8,9]. These stressors foster modifiable psychosocial processes—strengthening perceived control and self-efficacy to counter helplessness [10], identifying and intentionally using personal and family strengths to navigate daily caregiving [11], applying positive reappraisal and meaning-making to cope with developmental uncertainties [12], and fostering hope and future-oriented goal setting to organize demands into attainable steps; and nurturing supportive relationships [13]. Orienting intervention content to these processes directly serves the objective of helping parents recognize and mobilize their strengths and manage stress more positively.

Positive Psychology Interventions

To address these challenges, emerging evidence supports the use of positive psychology interventions (PPIs) [14,15]. While relatively few randomized controlled trials (RCTs) have tested PPI strategies among parents or caregivers of autistic children, different RCTs and systematic reviews have indicated that parent-focused interventions, including PPIs delivered digitally or in group formats, can enhance parental well-being and self-efficacy and reduce caregiver distress [16-19]. PPIs, proposed by Seligman et al [20], consist of evidence-based exercises aimed at fostering positive emotions, cognition, characteristics, and behaviors. PPIs focus on individuals' strengths and resources, which distinguish them from traditional psychotherapies. PPIs are brief and require only a few sessions. PPI instructions are straightforward to follow, which allows for self-administration.

Research has shown that PPIs not only reduce depressive symptoms and stress and anxiety levels but also place equal emphasis on enhancing well-being among individuals with major depression [21]. A meta-analysis of 20 studies suggested that cognitive behavioral therapy is not superior to PPIs in reducing depressive symptoms but that PPIs significantly improve well-being [22]. The effectiveness of PPIs in improving well-being has been demonstrated in individuals with chronic pain and physical disabilities [23] and in undergraduate students [24]. Our research group applied PPIs among Chinese parents who lost their only child and reported that PPIs significantly improved their well-being [14]. Overall, we hypothesize that PPIs can improve well-being, reduce stress levels and depressive symptoms, and enhance the quality of life of Chinese parents of autistic children.

Chatbot-Based Interventions to Promote Mental Health: Advantages

Digital health tools, especially chatbots, offer a scalable and accessible method for delivering the benefits of positive psychology skills programs to parents of autistic children. First, these tools are perceived as being accessible and offering a structured set of content that mimics real-life conversations with a supportive friend. This is especially important for these parents, who often face heightened isolation and reduced social support due to caregiving demands [5,7]. Second, access to effective psychological help can be limited by geographical barriers, a lack of resources, or social stigma [25]. Digital tools such as chatbots can help eliminate these barriers by providing easy access to proven psychological support. Chatbots are available 24/7 and can provide immediate feedback and support.

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Third, chatbots can technically collect data on users' interactions, which can guide the improvement and adaptation of the interventions and thus can be tailored to meet personal needs.

Recent advances in large language models (LLMs) have expanded how chatbots can be used in different domains. In the context of parenting and autism, recent studies have begun to validate the utility of these models. For instance, Entenberg et al [26] demonstrated the feasibility of a menu-based chatbot microintervention for parents, achieving high levels of engagement and learning outcomes. More recently, the focus has shifted to generative artificial intelligence (AI)'s ability to handle complex queries. Almulla and Khasawneh [27] evaluated several LLMs, including GPT-4 and Google Gemini, and found them highly accurate and readable when these LLMs answered common questions from parents of autistic children. Similarly, McFayden et al [28] reported that ChatGPT (OpenAI) can provide accurate information to parents of individuals with ASD. Seo et al [29] highlighted the role of AI-driven chatbots in facilitating pediatric communication, further supporting the potential of this technology to bridge the gaps in child, parent, and provider interactions.

However, while these studies confirm that LLMs can effectively provide information and support communication, there remains limited evidence on their ability to deliver structured therapeutic interventions. Liu et al [30] recently identified key success factors for GPT-based PPIs, which suggested that retrieval-augmented generation can effectively enhance user engagement in general mental health contexts. However, peer-reviewed reports of LLM-guided chatbots delivering a fully structured PPI for parents of autistic children are scarce. Instead, prior ASD-related chatbots typically focus on information, diagnostic support, or education for autistic individuals [31-33]. To fill this gap, we developed one of the first chatbots (named "Allie") to promote well-being in this population. The primary aim of this pilot study was to evaluate the feasibility and acceptability of Allie among parents. A secondary aim was to explore its potential impact on parents' well-being, stress, depressive symptoms, and quality of life.

Methods

Study Design

This was a single-arm mixed-methods design to develop and evaluate a GPT-powered chatbot named "Allie." The overall study period lasted from September 2023 to January 19, 2025. This study included an initial setup, participant recruitment, data collection, and qualitative interviews. We selected a single-arm design because this study was an early-stage feasibility and proof-of-concept evaluation that focused on acceptability and technical stability. This approach is consistent with the obesity-related behavioral intervention trials model for early-phase behavioral treatment development and suggests that user acceptability and technical stability be prioritized before we invest resources in an RCT [34]. This study was approved by the Research Ethics Committee of Hong Kong Metropolitan University (RD/2023/1.20).

Development of Chatbot Intervention

Allie is a customized chatbot powered by OpenAI's GPT-4o model, which was released in May 2024. This model was selected for its strong performance on Chinese and Cantonese tests [35]. This model has a 128k contextual window that supports multiturn therapeutic dialog without the loss of previous interactions. This linguistic capability allowed Allie to capture cultural nuances and idiomatic expressions from the parents of autistic children.

The intervention period was set at 2 weeks, during which time participants engaged in approximately 1 new exercise every 1 to 2 days. We used a 2-week schedule to minimize participant burden to test the feasibility and engagement with Allie. The objective of this pilot study was procedural feasibility rather than an estimation of maximal clinical effects.

To ensure therapeutic fidelity and reduce the risk of AI hallucination, we limited Allie's outputs to evidence-based PPI content [20,21,36]. This content included 8 core exercises that were adapted and validated among Chinese parents [14]. The 8 core exercises were based on the Positive Emotions, Engagement, Relationships, Meaning, Accomplishment (PERMA) framework [37]; details of the PERMA framework and exercises are summarized in Multimedia Appendix 1. The structure of the exercises was built on foundational concepts such as identifying strengths before diving into exercises that require deeper reflection, such as gratitude or savoring the moment.

To translate these 8 core exercises into interactive interventions that move beyond a simple prompt-based system, we implemented a retrieval-augmented generation architecture for Allie (Figure 1).

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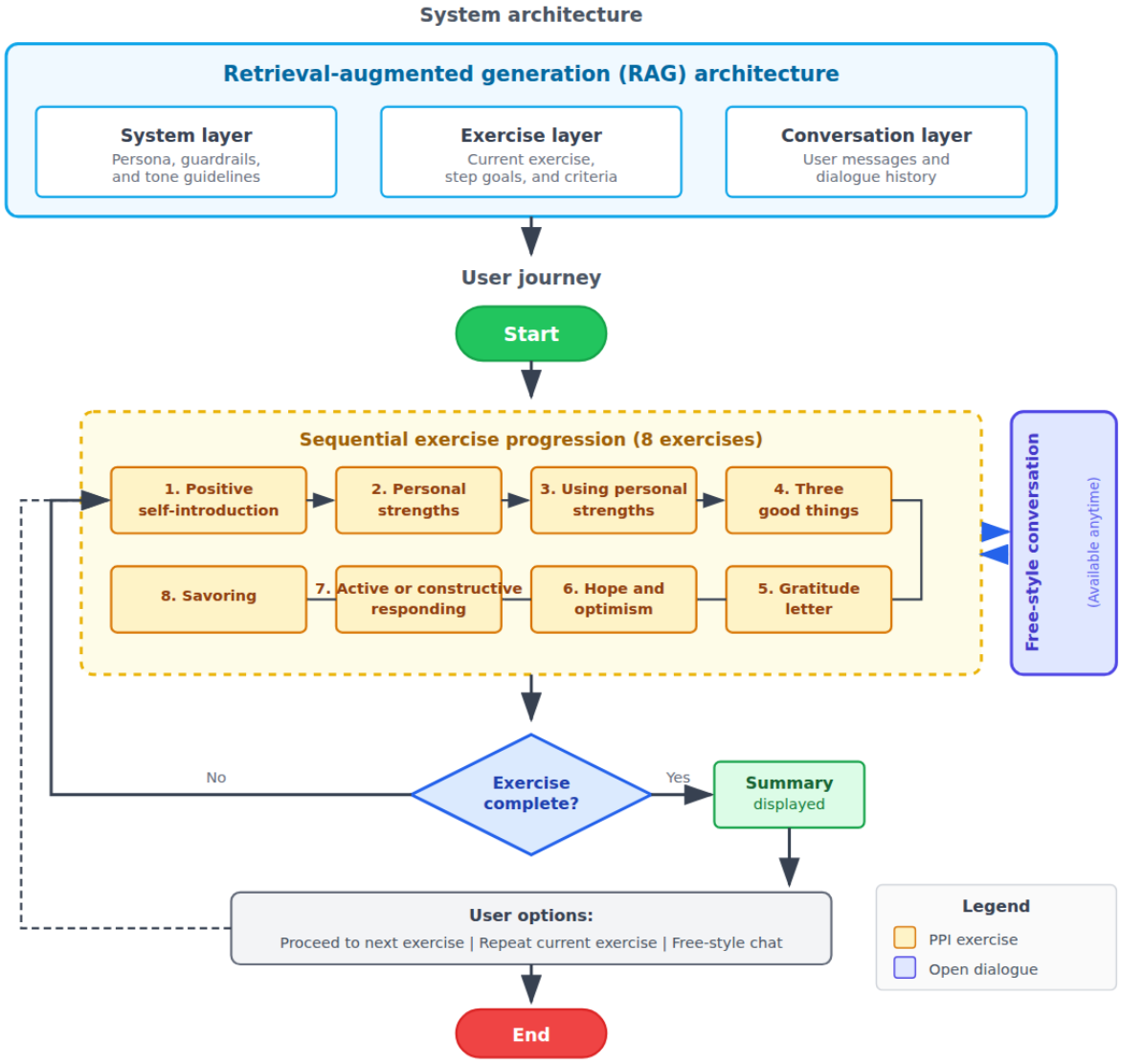
Figure 1. Allie system architecture and user flow. The system uses a 3-layer RAG architecture (system, exercise, and conversation layers) to deliver 8 sequential positive psychology exercises. After completing each exercise, participants received a summary and could proceed to the next exercise, repeat the current exercise, or engage in free-style conversation at any time. PPI: positive psychology intervention; RAG: retrieval-augmented generation.



First, domain-knowledge grounding. The 8 core exercises were segmented into approximately 500-token passages and embedded with the text-embedding-3-large model. Passages and associated meta-tags (exercise ID, intended learning objective, and cultural notes) were stored in a vector database (Supabase pgvector). At runtime, each user's turn triggered a semantic search (top-k=3); retrieved passages were prepended to the model's context, grounding generation to validated content while allowing for conversational flexibility.

Second, prompt engineering workflow. We implemented the prompt stack in a 3-layer structure as follows:

1. System layer (approximately 300 tokens): this layer defines Allie's persona (warm peer-mentor and uses written Chinese), guardrails (no diagnosis or medical advice, respect user autonomy, and refuse harmful requests), and tone guidelines drawn from the PERMA framework.
2. Exercise layer: this layer is a message block that encodes the current exercise, such as "using strengths," step goals, and success criteria. When an exercise is completed, a system flag allows Allie to move forward automatically or wait for the user's choice.
3. Conversation layer: in this layer, the full user message and the last 2 assistant responses are retained to maintain dialog coherence without exceeding the token limits.

Through these steps, Allie learned to use a tone, phrasing, and content structure that reflected positive psychology principles such as promoting positive emotions and resilience. This approach allowed Allie to include cultural adaptations such as humility, which are important in Chinese culture. For instance, in the "three good things" exercise (Figure 2), Allie was programmed to encourage users to share positive moments in their lives.

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Figure 2. Parent-Allie chatbot conversation during the "three good things" exercise. This figure shows a standard interface. On the left sidebar, participants could select exercises 1 to 8 according to their progress or the "free-style conversation." The corresponding content and dialog appear on the right. In this screenshot, the participant highlighted the following two positive experiences: (1) her son's strong examination performance and (2) feeling relaxed after watching a television drama. Allie acknowledged these moments and prompted deeper reflection, asking how the child's success and their interactions affected family dynamics and her mood. Allie encouraged the participant to value and cherish these proud and joyful moments. The full translation of the dialogue is documented in Multimedia Appendix 2. MU: Hong Kong Metropolitan University.

Allie was designed to guide participants sequentially through the exercises. Participants could repeat or skip content on the basis of their preferences. Allie also extended its role from delivering structured content to "free-style conversation." By using pretraining on a wide range of internet data, GPT-4o enabled Allie to generate coherent and empathetic responses to different user inputs. This ability allowed parent participants to discuss topics of their choice, such as real-life issues, emotional challenges, or their children's homework, thus making use of the flexibility of LLMs.

Data Security and Privacy

To safeguard data privacy, the research team ensured that no personal identifiers were sent to OpenAI. User IDs were created by partial digits of participants' phone numbers; the transcripts were encrypted in transit (TLS 1.3; Transport Layer Security; Internet Engineering Task Force) and at rest (AES-256; Advanced Encryption Standard; US National Institute of Standards and Technology). This study obtained explicit consent for this data flow, which is consistent with the JMIR and CONSORT-AI (Consolidated Standards of Reporting Trials–Artificial Intelligence) transparency recommendations.

The pilot platform was access-controlled (password-protected) for privacy and security; therefore, the original URL is not publicly accessible. Representative screenshots are provided in Multimedia Appendix 3.

Participants

Participants were parents who were providing long-term care for primary school-aged children (6-11 years of age) diagnosed with ASD. This age range was selected because the social and communication interactions of autistic children may be progressively more awkward during this period when social demands become more prominent [38]. Caregivers were eligible if they (1) self-identified as primary caregivers, (2) were aged 18 years or older, (3) were fluent in reading and communicating in Cantonese, and (4) had access to at least one mobile device with internet connectivity.

Caregivers were ineligible if their child did not meet the age range or ASD diagnostic criteria. Additionally, caregivers were excluded if they (1) had concurrent participation in a similar psychological intervention within one year, (2) were currently on regular psychotropic medications for mental health conditions, or (3) could not read or write in Chinese or Cantonese. No other exclusion criteria were applied.

As this was a feasibility study, no formal sample size calculation was needed. We estimated the sample size on the basis of the recommendation that a sample of 15 participants is appropriate for detecting a medium effect size. Assuming a 20% dropout rate, we planned to recruit 19 parents [39]. A sample size of 19 aligns with the recommendations for pilot trials [40,41]. These studies suggest that 12-20 participants are sufficient for estimating recruitment rates and variance for future power calculations.

Procedure

A recruitment poster was distributed to NGOs, shared in Facebook (Meta) groups, and sent to parents who participated in our previous study. Interested parents contacted the research team and were screened against the eligibility criteria. Those who met all the inclusion criteria and provided written informed consent were enrolled. We then made arrangements for the baseline assessment. Upon enrollment, participants accessed Allie through standard web browsers [42] on their mobile phones or computers. While the intervention was designed to be self-paced, participants were required to complete the 8 core exercises sequentially within 14 days. We chose this brief schedule for 3 reasons. First, the primary aim of this pilot trial

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was to examine the feasibility and acceptability of the Allie chatbot rather than to estimate its maximal clinical efficacy. Methodological guidance on pilot and feasibility studies recommends using minimally burdensome protocols that are sufficient for testing recruitment, engagement, and study procedures [43,44]. Second, parents of autistic children often juggle intensive caregiving and employment responsibilities; thus, a shorter program was expected to be more acceptable and reduce attrition. Third, prior research has shown that brief PPIs, which last approximately 1 to 2 weeks, can improve well-being in other populations. Such interventions include 2-week "best possible self" writing; 2-week nostalgia, gratitude, or optimism exercises; and a 2-week nature-based noticing intervention [45-47]. Consistent with these precedents, we treated this 2-week exposure as a conservative starting point to test whether parents would engage with Allie. This approach also aimed to obtain initial estimates of attrition and user experience before a longer intervention was implemented.

Measures

Overview

The following 2 categories of data were collected: demographic and outcome data. Demographic data were collected at baseline. Outcome data consisted of quantitative and qualitative measures. Assessments occurred at the following 3 time points: baseline (preintervention), immediately postintervention, and at an optional follow-up semistructured interview. Qualitative interviews were intended to gain deeper insights into intervention feasibility and acceptability, user experiences, and suggestions for future improvement.

Baseline Demographics

The demographic data included parent age, gender, education level, employment status, marital status, experience with AI, and household composition. Information about the age and gender of their autistic children was also included.

Primary Outcome Measures

Feasibility

We assessed feasibility by examining intervention completion rates, ease of use, practicality, and qualitative feedback. We used modified items from the Feasibility of Intervention Measure to measure ease of use and practicality [48]. These were 5-point Likert-type items with responses ranging from completely disagree (1) to completely agree (5). A high completion rate and user-reported ease of interaction with the chatbot were common indicators of feasibility in eHealth pilot studies [43,44]. Qualitative feedback on feasibility was obtained via semistructured interviews and is analyzed in the Results section.

Acceptability

Acceptability was measured with a custom questionnaire based on the work of Liu et al [49], 2023. Acceptability included several aspects of user satisfaction and perceived usefulness. These aspects included overall satisfaction, perceived appropriateness of session length and response time, adaptability and availability of the chatbot, relevance and trustworthiness of the information provided, interpersonal perceptions, privacy concerns, and intentions for future use. Items were rated on 5- or 7-point Likert scales depending on the dimension assessed.

Secondary Outcome Measures

Overview

Exploratory secondary outcomes were assessed using the following validated instruments.

Well-Being

The World Health Organization–Five Well-Being Index (WHO-5) measures subjective psychological well-being over the previous 2 weeks. This 5-item instrument uses a 6-point Likert scale (0 "at no time" to 5 "all of the time"), with raw scores converted to a 0-100 scale, where higher scores indicate better well-being. The WHO-5 is known for its brevity and strong psychometric validity [50]. Its Chinese version has also been validated [51].

Depression

The Patient Health Questionnaire-9 (PHQ-9) measures the severity of depressive symptoms. The PHQ-9 uses a 4-point Likert scale, where 0 indicates "not at all" and 3 denotes "nearly every day." Total scores of 5, 10, 15, and 20 indicate mild, moderate, moderately severe, and severe levels of depression, respectively [52]. The reliability and validity of the Chinese version of the PHQ-9 have been validated [53].

Stress

The Perceived Stress Scale-10 (PSS-10) is used to assess perceived stress levels. The scale has 10 items that measure how individuals view situations in their lives as stressful over the past month. Each item is rated on a 5-point Likert scale ranging from 0 ("never") to 4 ("very often"). Higher scores indicate greater levels of perceived stress. Its psychometric properties have been reviewed [54], and the Chinese version has been validated [55].

Quality of Life

The Short Form-12 Health Survey (version 2; SF-12v2) is used to assess health-related quality of life. This tool provides 2 summary scores—the Physical Component Summary score and the Mental Component Summary score. These scores reflect physical functioning, bodily pain, general health, emotional well-being, and role limitations due to physical or emotional challenges. The SF-12v2 includes 12 questions taken from the longer SF-36. The scores use norm-based T-scoring (mean 50, SD 10), with higher scores indicating better quality of life. The reliability and validity of the SF-12v2 have been proven in Chinese populations [56,57].

Qualitative Measures

Qualitative data were collected through optional semistructured interviews after participants completed the chatbot intervention. An interview guide was designed to explore users' experiences with the intervention in an open-ended, conversational manner. Topics included users' experiences and overall impressions, design and usability, perception of the exercises, emotional and behavioral impacts, and suggestions for future improvements.

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Data Analysis

Quantitative Analysis

Statistical analysis was performed using RStudio (versions 4.4.1 and 4.5.2; Posit Software, PBC). Descriptive statistics were used to summarize the demographics and baseline scores. Normality was checked using Q-Q plots and Shapiro-Wilk tests. Paired *t* tests were used for normally distributed outcomes; Wilcoxon signed-rank tests were applied for nonnormal distributions. We additionally reported change estimates with 95% CIs for each outcome—paired *t* test mean change for normal outcomes and Hodges-Lehmann estimate for the PHQ-9. To visualize individual-level change and heterogeneity, we also created paired dot plots for the WHO-5, which show each participant's pre-post scores. Effect sizes were reported using Cohen *d* (paired *t* tests) or *r* (Wilcoxon tests) as appropriate.

Qualitative Analysis

Although the interview guide provided a general structure, participants were not prompted to respond in predefined conceptual domains. This analysis followed the 6-phase procedure outlined by Braun and Clarke [58] (2006). We used a bottom-up inductive approach to identify emerging patterns from participant responses without preconceived theories. The primary researcher manually coded the transcripts, and a second coder reviewed the initial codes in weekly peer-debriefing sessions to ensure reliability. Throughout this process, reflective memos were kept to document the evolving interpretation of the data. This approach followed the thematic analysis framework by Braun and Clarke [58], which helped identify themes on the basis of participants' own expressions.

Ethical Considerations

This study was approved by the Research Ethics Committee of Hong Kong Metropolitan University (Ref: HE-RD/2023/1.20) and conducted in accordance with the principles outlined in the Declaration of Helsinki. To protect privacy, no personal information, such as participants' real names, addresses, or identification numbers, was collected. Each participant was assigned a pseudonymous code to replace identifiable data. However, participants' phone numbers were retained solely to facilitate communication and follow-up during the study period. These phone numbers were stored securely and were not included in the analytical dataset. All participants signed written informed consent forms before enrollment. Participants received monetary compensation of up to HK $200 (US $25.6) for their participation in the study. Those who participated in the additional interview received an extra HK $100 (US $12.8).

Results

Participants

A total of 35 parents were initially recruited for this study. Despite multiple outreach methods, recruitment for this population proved challenging due to practical barriers. A total of 3 were ineligible because their child did not meet the age or ASD diagnostic criteria. Among the remaining 32 eligible parents, 13 parents were excluded—11 did not respond to our follow-up contact, 1 reported being unavailable during the intervention period, and 1 declined to participate because the program was too complex and time-consuming for her. Nineteen eligible parents completed the baseline assessment and were enrolled in the 2-week intervention. No participants withdrew after enrollment (Figure 3).

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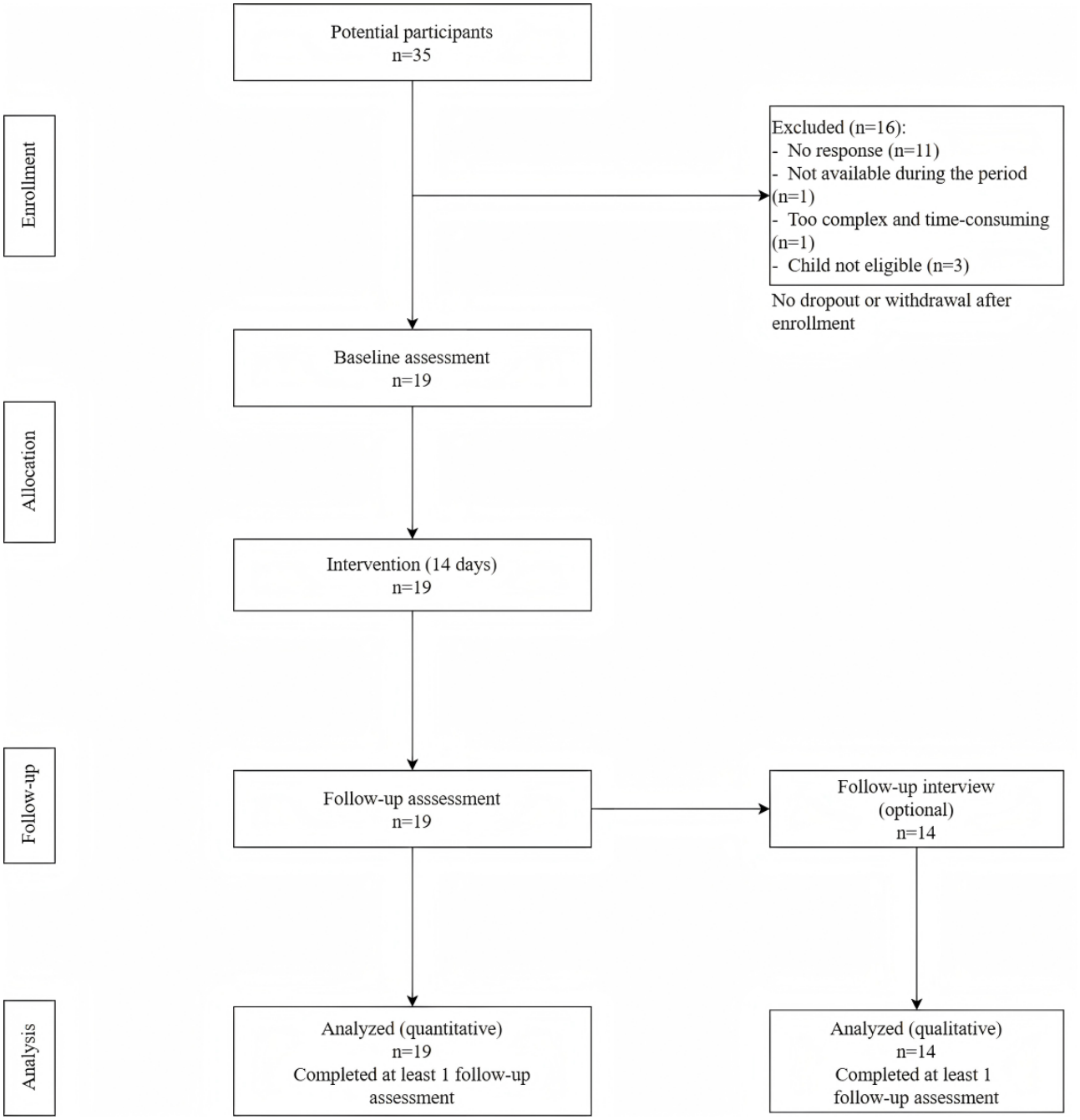
Figure 3. Participant flowchart.



The baseline characteristics of the participating parents are summarized in Table 1. All the participants were female (N=19, 100%). The parents' mean age was 41.7 (SD 4.3; range 32-51) years. The majority had attained a bachelor's degree (2/19, 36.8%), followed by high school education (5/19, 26.3%). With respect to experience with AI, 68.4% (13/19) of the participants had never tried AI before, while the remaining participants reported minimal to occasional AI use.

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Table 1. Baseline characteristics of parent participants (N=19).

Characteristics	Values
Parents	
Age (years), mean (SD)	41.7 (4.3)
Gender, n (%)	
Female	19 (100)
Education level, n (%)	
Middle school	1 (5.3)
High school	5 (26.3)
Diploma or associate's degree	4 (21.1)
Bachelor's degree	7 (36.8)
Master's degree or above	2 (10.5)
Employment status, n (%)	
Employee	5 (26.3)
Self-employed	2 (10.5)
Homemaker or unpaid family worker	12 (63.2)
Marital status, n (%)	
Single or unmarried	2 (10.5)
Married	16 (84.2)
Separated	1 (5.3)
Experience with AI, n (%)	
Never	13 (68.4)
Occasional use	3 (15.8)
Tried only a few times	3 (15.8)
Caregiver support available, n (%)	
Yes	15 (78.9)
No	4 (21.1)
Children	
Age (years), mean (SD)	8.5 (1.4)
Gender of children, n (%)	
Male children	17 (89.5)
Female children	2 (10.5)
Number of children in household, n (%)	
Only 1 child	10 (52.6)
More than 1 child	9 (47.4)
Number of autistic children in household, n (%)	
Only 1 child	17 (89.5)
More than 1 child	2 (10.5)

Most participants (17/19, 89.5%) had 1 child diagnosed with autism at home. The mean age of the children was 8.5 (SD 1.4; range 6-11) years, and 89.5% (17/19) were male. Nearly 80% (15/19) of parents reported having additional caregiver support. With respect to employment, most parents were homemakers or unpaid family workers (12/19, 63.2%), while 5 (26.3%) were employed. Most participants were married (16/19, 84.2%).

Quantitative Findings

Feasibility

We assessed feasibility along the following 3 dimensions: completion or attrition, practicality, and ease of use. The qualitative feedback related to feasibility is reported in the Qualitative Findings subsection.

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Completion and Attrition Rate

The completion rate for the chatbot intervention exercises was high among parent participants. A total of 17 of 19 (89.5%) parents completed all 8 exercises within 14 days. Further, 2 (10.5%) participants completed only half of the exercises. The main reason reported was "forgetting to complete" (Table 2).

Table 2. Completion rate and reasons for incomplete participation (N=19).

Completion status	Values
Rate of completion, n (%)	
Completed all exercises	17 (89.5)
Completed half of the exercises	2 (10.5)
Less than half of the exercises	0 (0)
Reasons for incompletion, n (%)	
Forgot to complete	2 (100)
No time	0 (0)

Practicality and Ease of Use

Parent participants found the chatbot easy to learn, as indicated by a mean ease-of-use score of 4.47 (SD 0.70) on a 5-point scale. They also highly rated its practicality, with a mean score of 4.32 (SD 0.67) for applicability to real-world settings.

Acceptability

Acceptability was evaluated by 7 dimensions that are composite scores. These scores are presented in Multimedia Appendix 4.

Overall, participants (N=19) reported that the chatbot intervention was acceptable. The mean level of satisfaction was 5.68 (SD 0.70) on a 7-point scale. A total of 18 (94.7%) participants reported that the duration of the exercise was appropriate. The mean perceived response promptness was 6.37 (SD 0.68). Participants rated the information provided as relevant (mean 5.82, SD 0.80) or trustworthy (assurance, mean 5.80, SD 0.70). They showed strong intentions to continue using the chatbot (usage intention, mean 5.68, SD 0.95). Adaptability (mean 5.53, SD 1.07) and empathy (mean 5.32, SD 1.15) received slightly lower ratings. Privacy concerns were also low (mean 4.43, SD 1.43), with lower scores indicating fewer concerns.

Exploratory Outcomes

Table 3 presents the pre-post outcomes and change estimates with 95% CIs. The mean increase in the WHO-5 score was 13.26 points (SD 23.31, 95% CI 2.04 to 24.49; t_{18}=2.48; *P*=.02; Cohen *d*=0.52). Individual changes were heterogeneous, as reflected in the paired dot plot (Multimedia Appendix 5), ranging from –24 to +72 points. Most participants experienced small changes, while a smaller subset showed larger improvements.

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Table 3. Pre- and postintervention scores for parent participants (N=19).

Measure	Pretest mean (SD)	Posttest mean (SD)	Pretest median (IQR)	Posttest median (IQR)	Test statistic	Change estimate (95% CI)[a,b]	*P* value	Effect size
PHQ-9[c]	N/A[d]	N/A	10 (14)	6 (7)	–0.49[e]	–0.50 (95% CI –2.50 to 1.50)	.63	0.11[f]
PSS-10[g]	20.53 (6.74)	19.74 (6.89)	N/A	N/A	–0.82 (18)[h]	–0.79 (95% CI –2.82 to 1.24)	.43	0.12[i]
WHO-5[j]	32.84 (24.86)	46.11 (26.00)	N/A	N/A	2.48 (18)[h]	13.26 (95% CI 2.04 to 24.49)	.02[k]	0.52[i]
SF-12[l] PCS[m]	45.04 (8.40)	43.36 (9.91)	N/A	N/A	–0.94 (18)[h]	–1.69 (95% CI –5.45 to 2.07)	.36	0.18[i]
SF-12 MCS[n]	42.68 (8.65)	40.81 (11.88)	N/A	N/A	–0.89 (18)[h]	–1.86 (95% CI –6.27 to 2.54)	.39	0.17[i]

[a]Change estimate (95% CI) refers to the paired *t* test mean change for normal outcomes; the Hodges-Lehmann estimate for the Patient Health Questionnaire-9.

[b]For the Patient Health Questionnaire-9 and Perceived Stress Scale-10, a negative change indicates symptom reduction (improvement); for the World Health Organization–Five Well-Being Index and Short Form-12 Health Survey, a positive change indicates improvement.

[c]A Wilcoxon test was used because of the nonnormal distribution posttest (Shapiro-Wilk *P*=.04; see Multimedia Appendix 6).

[d]N/A: not applicable.

[e]z: standardized test statistic.

[f]Effect size *r*.

[g]PSS-10: Perceived Stress Scale-10.

[h]*t* test (degrees of freedom).

[i]Effect size *d*.

[j]WHO-5: World Health Organization–Five Well-Being Index.

[k]*P*<.05.

[l]SF-12: Short Form-12 Health Survey (version 2).

[m]PCS: Physical Component Summary.

[n]MCS: Mental Component Summary.

Changes in depressive symptoms, perceived stress levels, and physical and mental health–related quality-of-life scores were not significant. Specifically, depressive symptoms measured by the PHQ-9 decreased slightly (Hodges-Lehmann estimate –0.50, 95% CI –2.50 to 1.50; Wilcoxon z=–0.49; *P*=.63; *r*=0.11). Similarly, perceived stress (PSS-10) changed minimally (mean –0.79, SD 4.20, 95% CI –2.82 to 1.24; t_{18}=–0.82, *P*=.43; Cohen *d*=0.12). With respect to health-related quality of life, the SF-12v2 physical and mental component scores decreased slightly after the intervention, but the changes were not significant (Physical Component Summary mean –1.69, SD 7.84, 95% CI –5.45 to 2.07; t_{18}=–0.94; *P*=.36; Cohen *d*=0.18; Mental Component Summary mean –1.86, SD 9.11, 95% CI –6.27 to 2.54; t_{18}=–0.89; *P*=.39; Cohen *d*=0.17). See Multimedia Appendix 6 for statistical assumption checks.

Qualitative Findings

Perceived Feasibility

Participants' responses echoed the quantitative feasibility results. Among the 19 participants, 14 joined the optional interview and completed the 8 core exercises. They commonly highlighted the chatbot's user-friendliness and practicality. For instance, as 1 mother noted, "I think it's quite good because it really feels like I'm chatting with a real person" (Participant 5, a homemaker aged 44 years who has no experience using AI). These verbatim excerpts illustrate high perceived usability and engagement. The key characteristics of the participants are listed in Multimedia Appendix 7.

Most Helpful Exercises

When asked to identify the most helpful components, participants prioritized exercises focused on strength-building. "Using personal strengths" and "personal strengths" were the most frequently cited favorites among the 8 exercises (Figure 4). The table showing the choices of participants is in Multimedia Appendix 8. These exercises helped them rediscover capabilities that had been overshadowed by their caregiving demands.

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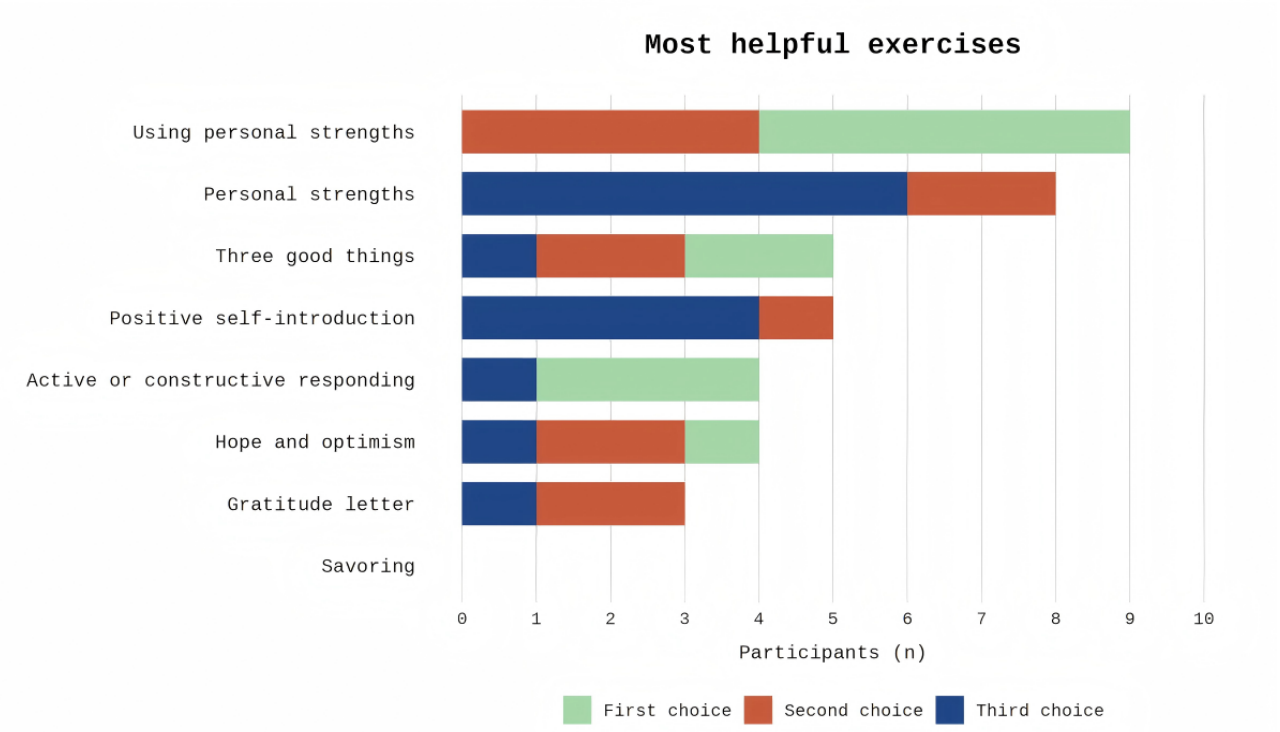
Figure 4. Most helpful exercises identified by participants.



Thematic Analysis of User Experience

Thematic analysis of the 14 semistructured interviews revealed participants' perspectives on the chatbot intervention, which were categorized into the following 6 major themes.

Theme 1: Fostering Self-Reflection and Insight

Many parents described how the exercises prompted them to pause and reflect more deeply on their daily lives. For instance, participant 13 (an employed mother aged 51 years) reflected on the "gratitude letter" exercise as follows:

> *It actually flips things around and makes you think about why you want to thank this person... It is a really good opportunity to reflect on this person or this event and why it matters so much to you.*

Similarly, participant 5 (a homemaker aged 44 years with no AI experience) explained that Allie's guided prompts encouraged her to notice aspects of her daily life she might otherwise overlook. She realized how her usual communication style might be perceived as "negative" or a "conversation stopper." This suggests that Allie functioned as an "interactive mirror," making implicit habits explicit, and that Allie supported reflective work by lowering the emotional barrier through stepwise questioning rather than requiring parents to generate insight unaided. Shorter excerpts are provided here, with more verbatim quotes in Multimedia Appendix 9.

Theme 2: Promoting Positive Psychology Orientation

Participants consistently noted a shift from deficits and stressors toward positive moments. After completing an exercise, participant 3 (an employed mother aged 40 years with no AI experience) said the following:

> *Oh yes, there are things I should be grateful for. It really changed some of my thinking.*

Beyond "thinking positive," some parents described a more compassionate reappraisal of negative experiences; an example is as follows:

> *Even when there were unhappy or negative thoughts, it helped reframe them with more understanding and empathy.* [Participant 6, a homemaker aged 35 years with minimal AI experience]

Taken together, these accounts suggest that the chatbot did not go beyond eliciting positive statements and helped caregivers reframe their thoughts and emotions when they were dealing with ongoing stress.

Theme 3: Offering New Perspectives

Several parents reported that Allie's questions and feedback helped them reframe challenges and that it broadened problem-solving options and reduced cognitive narrowing. Parent 1 (a self-employed mother aged 42 years) described moments of realization as follows:

> *It would say, 'Actually, you could try doing this,' and I realize, 'Yes, that's right. Why didn't I think of that myself?'*

Another participant echoed this view. She highlighted that new perspectives came from challenging blind spots rather than replacing the parents' own thinking, as follows:

> *Everyone has blind spots… it helps me move beyond my narrow thinking… it might give me a new direction.* [Participant 11, a homemaker aged 47 years who occasionally used AI]

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This theme shows that the chatbot offered more than emotional reassurance; it helped parents adopt new perspectives on which they could act.

Theme 4: Providing Emotional Support

A recurring experience involved feeling heard, comforted, and supported. Participant 2 (a homemaker aged 43 years with no AI experience) explained this as follows:

> *It felt like someone was comforting me... When I thought about its presence, I would chat with it a little, at least to help pull myself back up and not let myself sink too deeply. The more I thought about it, the heavier it felt, and then, I would start to feel like crying.*

Another participant described mood repair through validation and positive reframing as follows: "...realizing you're not as bad as you thought. Your mood got better. Then, it gave me lots of positive ideas, and that helped improve my mood" (Participant 8, a homemaker aged 32 years with no AI experience). She also noted Allie's role as an accessible outlet when human support was unavailable as follows:

> *At times when I was overwhelmed and unsure how to cope and when I had emotions I wanted to express but it isn't convenient to share them with others, I would turn to it.*

These accounts indicate that caregivers perceived emotional support through the chatbot's immediacy, responsiveness, and nonjudgmental tone, particularly when time and access to supportive conversations were limited.

Theme 5: Developing Coping Skills

Parents also reported acquiring or strengthening coping strategies through exercise. Participant 1 noted that the program helped her manage her temper with her child as follows:

> *I felt less angry... I tried to hold it in as much as possible. After getting through that moment, the situation would usually feel better.*

Similarly, participant 14 (a homemaker aged 42 years with no AI experience) agreed that stress-management techniques were practical for managing emotional challenges.

These coping approaches could be applied to both parents and their children. Participant 4 (a homemaker aged 46 years with no AI experience) emphasized that practical coping strategies mattered on 2 levels as follows:

> *How to help my child, how to… help myself too; these are personally very important.*

These accounts indicate that the chatbot supported skill generalization—parents were not only reassured at the time but also gained the language and steps they could reuse in future stressful situations. Other verbatim quotes are presented in Multimedia Appendix 9.

Theme 6: Recommendations for Future Improvements

Despite positive feedback, participants also recommended enhancements for future iterations of Allie. First, several participants wanted more human-like interactions. For example, participant 4 felt that colloquial Cantonese would be preferable, stating the following:

> *I think a more spoken Cantonese-style tone would be better.*

Conversational continuity was another key expectation. Participants wanted Allie to acknowledge what was just said rather than repeating or asking questions in a generic way, as follows:

> *If it were a real person, they would acknowledge what you had just said. (Participant 13)*

Smaller content segments instead of long messages were also suggested for human-like interactions. As participant 5 commented,

> *I mean, it shouldn't send a whole long block all at once. It could split the content into parts and send it out in two or three messages.*

All these human-like requests were intended to make Allie more natural, less burdensome, and more practically supportive in daily caregiving routines.

Another recommendation was greater flexibility and personalization in the program structure. Some parents proposed allowing parents to choose exercises on the basis of their needs rather than following a fixed sequence:

> *So, I think it would be better if it were more flexible, letting you choose what you want to do (Participant 6).*

One parent also suggested tailoring recommendations on the basis of their interaction with Allie. This implies that perceived usefulness can increase when the chatbot helps users select the "right" exercise at the "right" time.

Additionally, participants proposed engagement-enhancing features (eg, role-play practice, visuals, optional audio, and emojis) and practical reminders. As 1 participant noted, "I would be afraid of forgetting" (participant 3). These requests suggest that usability improvements were not only aesthetic but also related to adherence and practicality in the real world.

Several parents also requested more concrete external resources, such as parenting guides, suggestions for suitable family activities, and access to community support services. These resources were seen as a way to supplement psychological support and better meet parents' practical needs in real-world settings.

Discussion

Principal Findings

This pilot study evaluates one of the first generative LLM-based PPIs for parents of autistic children. The Allie chatbot demonstrated high degrees of feasibility and acceptability, which is evident in the 89.5% (17/19) completion rate across 8 exercises and favorable ratings for practicality and ease of use. Participants also reported significant improvements in their well-being, as measured by the WHO-5. Given the single-arm design and small sample size, this improvement should be

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interpreted as preliminary and hypothesis-generating. Additionally, there were no significant changes in depressive symptoms (PHQ-9), stress levels (PSS-10), or health-related quality of life (SF-12v2) during the 2-week intervention.

The qualitative findings provided deeper insight into the user experience. These findings indicated that Allie functioned as a supportive companion and facilitated core PPI processes. Parents described benefits that map closely to established PPI mechanisms, such as fostering greater self-reflection, promoting a more positive orientation, encouraging perspective-taking, providing perceived emotional support, and practicing new coping skills. Despite the positive feedback, participants also offered clear recommendations for refinement. They expressed a clear preference for a more personalized, interactive, and resource-rich virtual assistant rather than for a simple scripted chatbot.

Comparison With Prior Work

This study differs from previous related research in 2 areas. First, some digital interventions for parents of autistic children have incorporated rule-based menu-style conversational components (eg, a virtual counselor delivered via menu-list options) [59]. While these systems can be helpful, they are often limited to setting conversation paths and do not have the flexibility to manage various user inputs. Second, earlier studies using LLMs in the ASD field have concentrated on applications for professionals, such as creating care plans or diagnostic comparisons [33,60,61], instead of offering a parent-facing and interactive therapeutic intervention. By embedding culturally adapted Cantonese PPI scripts in GPT-4o, Allie offers a structured, dynamic, and novel experience. This approach highlights a scalable, culturally aware option for the mental health care of parents with autistic children.

Our findings align with and extend recent research on AI-driven interventions. Consistent with the findings of Entenberg et al [62], who reported high levels of engagement (66.3% completion) with a menu-based parenting chatbot, our study revealed an even higher completion rate (89.5%) with the use of a generative interface. This finding suggests that the conversational flexibility of LLMs may further lower barriers to engagement even for highly stressed groups such as caregivers. This is particularly important for busy parents to overcome common barriers such as time, location, childcare, and cost. Similarly, participants reported their preference for less repetitive responses, more conversational continuity, and shorter messages. These recommendations mirror prior conversational-agent findings in the user experience—users can experience bonding and gratitude toward chatbots but may also feel frustrated when responses are repetitive and generic or when the agent misunderstands their input [63].

Additionally, our results support the findings of Liu et al [30], showing that GPT-powered chatbot-based PPIs can achieve high satisfaction ratings among participants. This supports the potential effectiveness of this architecture for specific clinical populations, such as those of caregivers of children with autism. Evidence from a free-text cognitive behavioral therapy conversational agent further suggests that conversational AI can sidestep stigma-related barriers while remaining engaging [63]. Finally, while Almulla and Khasawneh [27] validated the accuracy of LLMs for answering informational questions about autism, our study takes the next step by demonstrating that these models can also effectively deliver structured therapeutic exercises, not just information. All these findings complement web-based parent programs for ASD and other digital PPIs that have demonstrated improvements in caregiver well-being and self-efficacy. These results suggest that a brief strength-focused LLM chatbot can achieve user experience outcomes in line with broader digital mental health tools.

We also observed gains in WHO-5 scores. This finding mirrors that of previous studies showing that PPI can promote emotional resilience in stressed individuals [22,23], supporting the utility of a strength-focused approach for caregivers of individuals with ASD.

The lack of significant changes in depressive symptoms, perceived stress levels, and quality of life is likely due to the following two study characteristics: (1) the brief two-week dosage and (2) the small sample size (N=19). These factors possibly limited the statistical power and increased the risk of type II error. Meta-analytic work suggests a dose-response pattern, with longer PPIs yielding larger effects. Bolier et al [64] recommend at least 4 weeks and preferably more than 8 weeks; Sin and Lyubomirsky [65] likewise report greater gains with relatively longer durations. A more intensive or extended program with a larger cohort may therefore be required to influence deeper-seated distress and overall quality of life.

Implications for Future Design

The interview findings translate into 4 refinement priorities. First, in terms of conversational naturalness and personalization, colloquial Cantonese should be used when appropriate, repetition and length should be reduced, and continuity should be improved by remembering prior inputs with consent. Second, in terms of flexible engagement and pacing, users should be allowed to choose sequences of exercises, break content into smaller chunks, and add reminders and a simple progress view to support adherence. Third, in terms of multimodal, interactive coaching, images and short videos (eg, illustrating savoring or strengths-in-action), and light, optional audio should be incorporated in practice. Fourth, in terms of ASD-specific guidance and navigation, brief, practical parenting techniques and links to community and professional resources should be provided. These directions are consistent with evidence that personalization and interactivity enhance engagement with digital health tools [66,67].

Accordingly, the next iteration (“Allie 2.0”) will transition to a multimodal LLM to handle text, images, and short video; expand the curated knowledge base with ASD-specific content; implement user-level memory and reminders with explicit consent; and strengthen guardrails.

Limitations

This study has several limitations. First, the single-arm, nonrandomized design limits the ability to draw causal conclusions about the effectiveness of the intervention. We therefore interpreted changes in clinical outcomes as exploratory signals only and focused our primary inferences on feasibility

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and acceptability. Second, recruitment and data collection were challenging in this population despite our efforts in outreach through multiple channels. We ultimately enrolled a small sample of 19 participants. The high number of nonresponses and scheduling issues among eligible parents may lead to self-selection, meaning those who were more available or more comfortable with digital tools participated. This may have inflated our estimates of feasibility or acceptability. Third, the sample was composed entirely of mothers. This restricts the generalizability of the findings to fathers or other caregivers. Fourth, the intervention period was set at 2 weeks. However, while this reduced participant burden, this duration may have limited our ability to detect significant changes in depressive symptoms and quality of life. Fifth, we did not collect or analyze adverse events; no harm or disturbances were reported by participants. Finally, there was no long-term follow-up assessment in this study. These factors constrain the understanding of the sustained impact of the intervention and user adherence over time.

Future research should adopt RCTs to closely assess efficacy and comparative effectiveness. It is essential to expand recruitment across multiple sites, such as clinics, schools, and ASD service providers. Longer recruitment periods, flexible onboarding start dates, and reminders should also be considered to improve enrollment and relieve caregiver burdens. Additionally, it would be beneficial to include different caregiver groups, such as fathers and those from different cultural backgrounds. Extended follow-up periods would also provide deeper insights into sustained psychological impacts and adherence.

Conclusions

In summary, this pilot study revealed that Allie is a novel, practical, and acceptable digital psychological tool for parents of autistic children. While these findings are preliminary, they point to the promise of chatbot-based interventions for improving caregiver well-being. They also highlight important areas for further technological improvement and thorough evaluation.

Acknowledgments

The authors thank the participating parents for their time and for generously sharing their experiences. We also thank Polyhedrontech Company Limited for their technical collaboration in customizing and deploying the positive psychology intervention content, which was developed by the Hong Kong Metropolitan University research team, within the Allie chatbot.

Data Availability

The datasets generated or analyzed during this study are not publicly available due to data sensitivity; however, they can be obtained from the corresponding author upon reasonable request.

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Conflicts of Interest

None declared.

Multimedia Appendix 1
Intervention content based on the PERMA model (positive emotions, engagement, relationships, meaning, and accomplishment).
[DOCX File , 28 KB - formative_v10i1e85060_app1.docx]

Multimedia Appendix 2
Example parent-Allie dialogue in figure 2.
[DOCX File , 14 KB - formative_v10i1e85060_app2.docx]

Multimedia Appendix 3
Screenshots of participant's flow of interaction with Allie.
[DOCX File , 615 KB - formative_v10i1e85060_app3.docx]

Multimedia Appendix 4
Seven acceptability scores among the participants.
[DOCX File , 13 KB - formative_v10i1e85060_app4.docx]

Multimedia Appendix 5

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Paired dot plot of WHO-5 (World Health Organization–Five Well-Being Index) scores.
[DOCX File , 124 KB - formative_v10i1e85060_app5.docx]

Multimedia Appendix 6
Data normality test results.
[DOCX File , 13 KB - formative_v10i1e85060_app6.docx]

Multimedia Appendix 7
Characteristics of the 14 participants in the qualitative interview.
[DOCX File , 14 KB - formative_v10i1e85060_app7.docx]

Multimedia Appendix 8
Most impactful exercises voted by participants.
[DOCX File , 12 KB - formative_v10i1e85060_app8.docx]

Multimedia Appendix 9
Verbatim quotes illustrating helpful aspects and recommendations.
[DOCX File , 18 KB - formative_v10i1e85060_app9.docx]

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Abbreviations

AES-256: Advanced Encryption Standard
AI: artificial intelligence
ASD: autism spectrum disorder
CONSORT-AI: Consolidated Standards of Reporting Trials–Artificial Intelligence
LLM: large language model
PERMA: Positive Emotions, Engagement, Relationships, Meaning, Accomplishment
PHQ-9: Patient Health Questionnaire-9
PPI: positive psychology intervention
PSS-10: Perceived Stress Scale-10
RCT: randomized controlled trial
SF-12v2: Short Form-12 Health Survey version 2
TLS 1.3: Transport Layer Security
WHO-5: World Health Organization–Five Well-Being Index

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Original Paper

Utility of a Smartphone-Based Clinical Decision Support System for Pressure Ulcer Management by Physicians: Randomized Crossover Pilot Study

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Abstract

Background: Clinical decision support systems (CDSSs) are widely used in various health care settings. In Japan, pressure ulcers are becoming a major concern in an aging society due to their increasing prevalence. However, management is often handled by nonspecialists in wound care due to regional disparities in specialist availability.

Objective: To provide support for nonspecialists in wound care, we developed a prototype smartphone-based CDSS for pressure ulcer management. The system prompts users to answer questions about the wound's condition and recommends appropriate ointments and wound dressings by using a safety-first approach. This study aims to evaluate the utility of this system.

Methods: We conducted a randomized crossover pilot study involving 28 general internal medicine (GIM) physicians. Participants were randomly assigned to group A (intervention-control) or group B (control-intervention). Participants evaluated 10 standardized pressure ulcer photographs and selected the most appropriate ointment and wound dressing for each. The unit of analysis was the individual response to each question (N=280 total observations). We used generalized estimating equations with an exchangeable correlation structure to account for within-subject clustering and adjust for potential period and sequence effects.

Results: The overall correct response rate during the intervention phase was significantly higher than that during the control phase (49.3% vs 4.3%, respectively). After adjusting for clustering and crossover biases, the use of CDSS was associated with a 29.1-fold increase in the odds of a correct response (95% CI 8.2-103; *P*<.001). Secondary analyses revealed significant improvements in ointment selection (adjusted odds ratio [aOR] 2.4, 95% CI 1.5-3.8; *P*<.001) and wound dressing selection (aOR 8.9, 95% CI 4.9-16.1; *P*<.001). However, no significant period (*P*=.11) or sequence (*P*=.25) effects were observed for the primary outcome.

Conclusions: The prototype CDSS improved the accuracy of treatment decisions made by GIM physicians in a pilot study that used photographs and fixed options. Within the parameters of this investigation, CDSS effectively guided participants toward standardized, safety-oriented choices as defined by our scoring criteria.

Trial Registration: UMIN Clinical Trials Registry UMIN000057294; https://tinyurl.com/36a6vvah

(JMIR Form Res 2026;10:e85452) doi:10.2196/85452

KEYWORDS

clinical decision support system; pressure ulcer; wound healing; ointment; wound dressing; general internal medicine

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Introduction

Background

Clinical decision support systems (CDSSs) are software programs that integrate individual patient characteristics with a computerized knowledge base to generate patient-specific assessments or recommendations. These assessments and recommendations are designed to support physicians or patients in making clinical decisions [1]. Some CDSSs are primarily used at the point of care, enabling physicians to combine their expertise with the information or recommendations provided by CDSS [2]. CDSSs can optimize patient care by issuing warnings, reminders, and suggestions during diagnosis, examination, and treatment [3]. Research has also demonstrated that CDSSs can improve adherence to clinical guidelines [4]. This finding is especially relevant considering the low compliance rates with clinical guidelines worldwide. CDSS development is currently underway across various medical settings [5-8].

Epidemiological Burden of Pressure Ulcers

Pressure ulcers are a health problem worldwide that are common among inpatients and older adults. According to a systematic review and meta-analysis, the incidence of pressure ulcers in inpatients is approximately 1 out of 10 [9]. Furthermore, population-based studies have highlighted that pressure ulcers occur outside health care settings. For example, a study conducted in a rural area of Japan reported a prevalence rate of 20.3 per 1000 individuals older than 65 years, rising to 44.6 per 1000 among those older than 80 years [10]. These data indicate a growing burden of pressure ulcers in aging populations.

Barriers to Clinical Guideline Adherence

Despite the recognized importance of pressure ulcer management, the implementation of current clinical practice guidelines is insufficient. Notably, some physicians report a lack of confidence in diagnosing and treating pressure ulcers [11]. Moreover, of the 107 family physicians in Canada who participated in the survey, only approximately 16% expressed confidence in managing leg ulcers. Of these 107 physicians, 90 answered the attitude questions; the concerns reported included a lack of evidence-based clinical practice guidelines for leg ulcer treatment (74/90, 82.2%), which could lead to a decline in care quality such as delayed wound healing [12].

Current State of CDSS for Pressure Ulcers

In Europe, a CDSS for wound care, treatment, and management has been developed [13]. CDSS is designed to facilitate wound assessment and guide the selection of appropriate wound products from the clinical product formulary. This CDSS is at the point of care and across various settings, encompassing acute and primary care. Further, in Japan, the following projects are progressing: preparations for the development of a CDSS for home-visiting nurses in pressure ulcer management [14] and the development of an AI-integrated DESIGN-R scale evaluation process to enhance diagnostic consistency and accuracy [15]. Therefore, CDSS for pressure ulcer management is an area with significant room for further development.

Local Context and Study Objectives

In Japan, pressure ulcer management faces the issue that, due to regional disparities in the distribution of plastic surgeons, pressure ulcers are not necessarily treated by wound care specialists [16]. To address this issue, we developed a prototype CDSS developed with reference to Japanese clinical guidelines, specifically optimized to guide nonspecialists in wound care toward standardized, risk-averse treatment pathways. The primary objective of this study was to evaluate whether general internal medicine (GIM) physicians using this CDSS could accurately select appropriate and specifically safe management options for pressure ulcers.

Methods

Study Setting

This study was a randomized crossover study. As the utility of the system has not yet been established, the study was designed as a pilot trial. This study was conducted by the Department of Diagnostic and Generalist Medicine (the Department of GIM) at Dokkyo Medical University Hospital, Tochigi, Japan, between March 2025 and May 2025. This study consisted of two major components: (1) the development of a CDSS for pressure ulcers and (2) the evaluation of the utility of CDSS. This study adhered to the CONSORT-EHEALTH (Consolidated Standards of Reporting Trials of Electronic and Mobile Health Applications and Online Telehealth) guidelines (Multimedia Appendix 1).

Ethical Considerations

The research adhered strictly to the Declaration of Helsinki guidelines to ensure ethical conduct in human participant research. Ethics approval was obtained from the institutional review board at Dokkyo Medical University Hospital (R-89-7J). After a detailed explanation of the study, written informed consent was obtained from all participants before participation. The data were processed anonymously so that individuals cannot be identified. Participation was entirely voluntary, and participants could withdraw from the study at any time without penalty. No compensation or incentives were provided to the participants.

Participant Recruitment

This study included older residents and faculty members from the Department of GIM at Dokkyo Medical University Hospital in 2025. Older residents and faculty members with clinical practice of more than 3 and 6 years after graduation, respectively, were included. The exclusion criteria were refusal to participate in this study or the presence of severe vision loss.

Development of CDSS for Pressure Ulcers

For this study, a prototype CDSS was created using the web-based no-code platform Canva [17]. CDSS is a prototype of a web application designed for use on mobile devices such as smartphones. The system has been developed to provide a framework for decision-making regarding the selection of ointments and wound dressings through a series of questions related to the patient's pressure ulcers, as illustrated in Figure 1. Figure 2 presents an example of option selection in CDSS.

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Figure 1. The clinical decision support system for pressure ulcers. (A) Selection screen for the phase when the pressure ulcer developed. (B) Selection screen for the depth evaluation in the chronic phase. (C) Selection screen for assessing the condition of deep pressure ulcers in the chronic phase. (D) Selection screen for the exudate level of deep pressure ulcers in the chronic phase. (E) Recommendation of ointments and wound dressings.

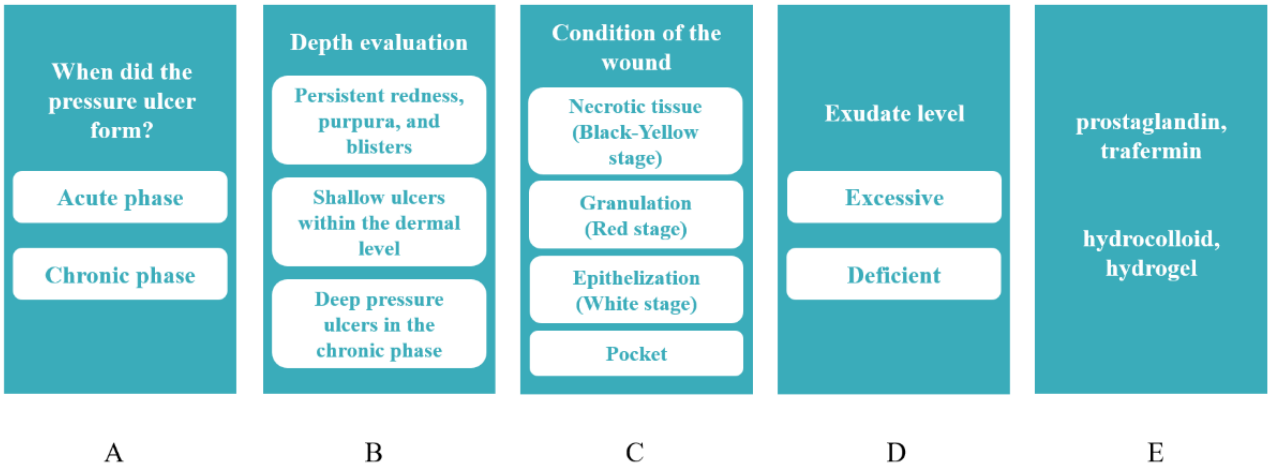
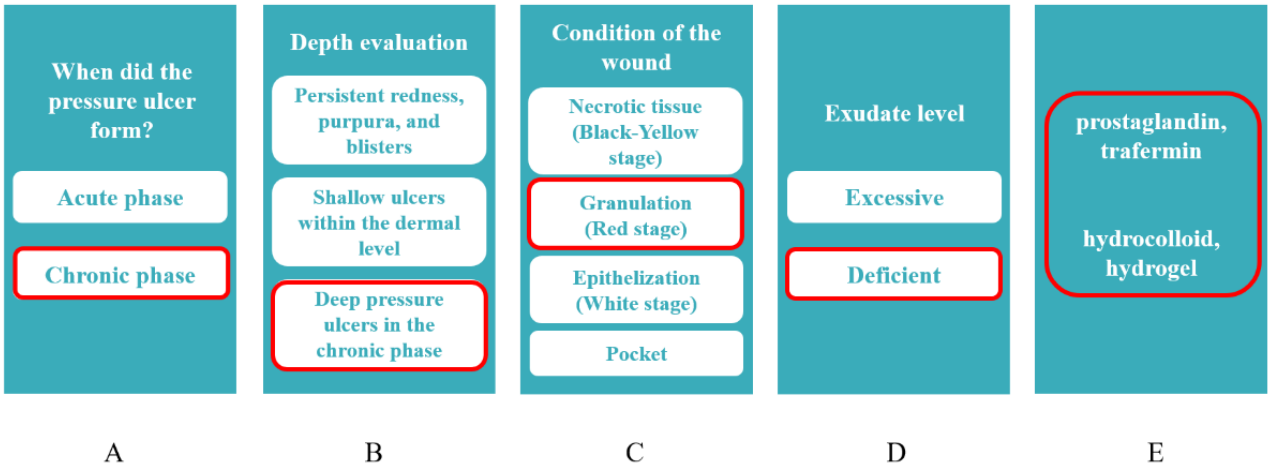


Figure 2. An example of how to use the clinical decision support system. Question 7: an ulcer with insufficient granulation tissue and minimal exudate. The selection buttons relevant to question 7 are highlighted in red. The screens transition sequentially from (A) to (E).



The decision logic of CDSS was constructed with a safety-first approach. Since the target users are nonspecialists in wound care who may not have access to surgical debridement, the algorithm was programmed to ensure safe management and strictly avoid high-risk options such as occluding infected sites, even when guidelines might offer conditional recommendations.

The system was developed based on two established clinical guidelines published by the *Japanese Dermatological Association* and the *Japanese Society of Pressure Ulcers* (JSPU) [18,19]. However, it was not designed to be an exact reproduction of these documents. Instead, we operationalized and simplified complex clinical algorithms, transforming them into structured decision trees tailored for GIM physicians who prioritize conservative, risk-averse decision-making.

According to the clinical algorithm in the Guidelines for the Diagnosis and Treatment of Pressure Ulcers, the first step is to diagnose the suspected lesion as a pressure ulcer [20]. The next step is to determine whether the pressure ulcer is in the acute or chronic phase. The subsequent management of pressure ulcers depends on their depth, and in particular, depth should be evaluated in chronic-phase ulcers. For severity classification and healing process quantification, the pressure ulcer staging scale DESIGN (depth, exudates, size, inflammation/infection, granulation, necrosis, and pocket) was developed by the JSPU Scientific Education Committee and published by the *Japanese Society for Pressure Ulcer Care* in 2002. The weighting of each of the 7 DESIGN criteria has been reviewed based on evidence, and the scale was published as DESIGN-R in 2008 [21].

According to the guidelines' clinical algorithm for the treatment of chronic-phase deep pressure ulcers, the aim in the early treatment stages (black and yellow stages) is wound bed preparation based on the TIME concept. The TIME concept is based on the idea of evaluating factors that prevent wound healing from the viewpoint of tissue (T), infection or inflammation (I), moisture (M), and the wound edge (E) [22]. In the latter stages of treatment (red and white stages), the aim is to achieve moist wound healing [20]. In the black and yellow stages, the treatment of pressure ulcers involves removing the necrotic tissue, reducing the bacterial load, preventing wound drying, controlling excessive exudates, and treating pockets and wound edges. Subsequently, during both the red and white stages, maintaining the wound surface in a moist environment

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is crucial. CDSS suggests appropriate ointments and dressing materials based on users' replies to prompts, which are generally structured per the process described above.

Study Flow and Randomization

The randomization process was conducted electronically using Microsoft Excel and a computer-generated randomization table. By block randomization with the sealed envelope method, participants were randomly assigned to group A or B in a 1:1 ratio. This study used a crossover design, where all participants participated in both the intervention and control phases.

Participants were presented with pressure ulcer photographs and asked to select the most appropriate ointments and wound dressings from a set of options. Participants in group A initially participated in the intervention phase during period 1. In this phase, participants used CDSS to respond to the first set of questions (questions 1-5), followed by a washout period of at least 1 week. Subsequently, group A participants transitioned to the control phase during period 2, in which they answered the second set of questions (questions 6-10) without using CDSS. Participants in group B first completed the control phase during period 1, responding to questions 1-5 without using CDSS, followed by a washout period of at least 1 week. Group B participants then proceeded to the intervention phase during period 2, where CDSS was used to answer questions 6-10.

Responses were collected using an online form created with Microsoft Forms. The form contained the clinical photographs of pressure ulcers accompanied by multiple-choice response options. Participants could access the form by scanning a 2D barcode provided by the study coordinator or via a uniform resource locator shared through a group chat application.

The duration of the washout period was determined based on established theories of memory decay [23]. Additionally, in a previous study, a 1-week interval was implemented between the two phases to mitigate recall bias [24]. Consequently, a washout period of at least 1 week was implemented to mitigate carryover effects from the initial evaluation.

Evaluation Materials

Participants evaluated the clinical photographs of pressure ulcers sourced from two publications by JSPU [25,26]. These publications are medically validated and authoritative sources that ensure the reliability and standardization of the referenced content. A total of 10 photographs were used, categorized into two sets (questions 1-5 and questions 6-10), with each set comprising 5 photographs. JSPU has formally provided permission for the use of these photographic materials in this investigation, contingent upon the requisite citation of the source. For all clinical scenarios, it was stipulated that surgical intervention was not available.

Regarding the selection of ointments, participants were instructed to select the most appropriate option from the following: (1) silver sulfadiazine; (2) povidone-iodine, cadexomer iodine, or iodoform; (3) povidone-iodine or bucladesine sodium; (4) povidone-iodine; (5) zinc oxide, dimethyl isopropyl azulene, or white petrolatum; and (6) prostaglandin or trafermin.

For the selection of wound dressings, participants were instructed to select the most appropriate option from the following: (1) silver-containing hydrofiber or silver-containing polyurethane foam, (2) silver-containing hydrofiber or silver-containing hydrocolloid, (3) silver-containing hydrocolloid or hydrogel, (4) polyurethane film or silver-containing hydrocolloid, (5) hydrogel, and (6) use of a dressing was considered inappropriate. Rather than standard non–silver-containing variants, silver-containing variants were used for several dressing categories to reflect contemporary clinical availability.

Question 7, for example, provides a second example of an ulcer with insufficient granulation tissue and minimal exudate (Figure 3). Topical treatments for such wounds include ointments such as prostaglandin or trafermin as well as wound dressings such as hydrocolloid or hydrogel. These treatments help to maintain adequate moisture on the wound surface. Therefore, the most appropriate choices are "prostaglandin or trafermin" ointment and "silver-containing hydrocolloid or hydrogel" wound dressing (Figure 2).

Definition of Correct Answers and Scoring

The correct answers for ointments and wound dressings were defined by referencing the treatment algorithms and specific descriptions outlined in *Japanese Dermatological Association* and JSPU guidelines [18,19]. The clinical characteristics of each photograph and their corresponding correct answers are summarized in Table 1. For each question, one "most appropriate" option was selected for both the ointment and the dressing to ensure consistency in the statistical analysis. Regarding ointment selection, specifically for question 4, the source material [25] suggests that "silver sulfadiazine" and "povidone-iodine" are applicable; however, the guideline's text explicitly recommends "povidone-iodine" [19]. To eliminate ambiguity and ensure statistical rigor, we established a strict scoring criterion that accepted only "povidone-iodine" as correct for this analysis (Figure 3).

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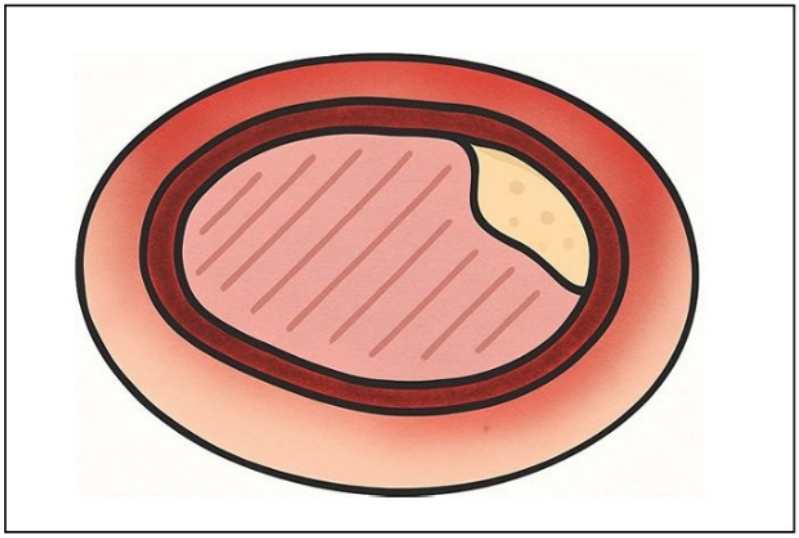
Figure 3. An illustrative image (used for question 7) of a sample version created to resemble the actual questionnaire used. This image was created with the assistance of ChatGPT (OpenAI), based on the authors' instructions.

Question 7



Please select the most appropriate ointments from options (1) to (6).

(1) silver sulfadiazine

(2) povidone-iodine, cadexomer iodine, or iodoform

(3) povidone-iodine or bucladesine sodium

(4) povidone-iodine

(5) zinc oxide, dimethyl isopropyl azulene, or white petrolatum

(6) prostaglandin or trafermin

Please select the most appropriate wound dressings from options (1) to (6).

(1) silver-containing hydrofiber or silver-containing polyurethane foam

(2) silver-containing hydrofiber or silver-containing hydrocolloid

(3) silver-containing hydrocolloid or hydrogel

(4) polyurethane film or silver-containing hydrocolloid

(5) hydrogel

(6) use of a dressing was considered inappropriate.

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Table 1. Details of the photographs used in each question and the correct answer.

	Details of the question	Ointments[a]	Wound dressings[b]
Question 1	Erosions or shallow ulcer involving damage limited to the dermis	(5) zinc oxide, dimethyl isopropyl azulene, or white petrolatum	(3) silver-containing hydrocolloid or hydrogel
Question 2	Ulcer with insufficient formation of healthy granulation tissue and a high amount of exudate	(3) povidone-iodine or bucladesine sodium	(1) silver-containing hydrofiber or silver-containing polyurethane foam
Question 3	Ulcer covered with dry black necrotic tissue, presenting minimal exudate and no signs of infection	(1) silver sulfadiazine	(5) hydrogel
Question 4	Ulcer with necrotic tissue in pockets but without signs of infection	(4) povidone-iodine	(6) use of a dressing was considered inappropriate
Question 5	Ulcer with well-developed healthy granulation tissue and abundant exudate	(3) povidone-iodine or bucladesine sodium	(1) silver-containing hydrofiber or silver-containing polyurethane foam
Question 6	Acute-stage pressure ulcer	(5) zinc oxide, dimethyl isopropyl azulene, or white petrolatum	(4) polyurethane film or silver-containing hydrocolloid
Question 7	Ulcer with insufficient granulation tissue and minimal exudate	(6) prostaglandin or trafermin	(3) silver-containing hydrocolloid or hydrogel
Question 8	Ulcer presenting with blisters	(5) zinc oxide, dimethyl isopropyl azulene, or white petrolatum	(4) polyurethane film or silver-containing hydrocolloid
Question 9	Ulcer covered with yellow necrotic tissue, abundant exudate, and clear signs of infection	(2) povidone-iodine, cadexomer iodine, or iodoform	(6) use of a dressing was considered inappropriate
Question 10	Ulcer with well-formed granulation tissue and minimal exudate	(6) prostaglandin or trafermin	(3) silver-containing hydrocolloid or hydrogel

[a]For ointment selection, participants were instructed to select the most appropriate option from the following: (1) silver sulfadiazine; (2) povidone-iodine, cadexomer iodine, or iodoform; (3) povidone-iodine or bucladesine sodium; (4) povidone-iodine; (5) zinc oxide, dimethyl isopropyl azulene, or white petrolatum; and (6) prostaglandin or trafermin.

[b]For the selection of wound dressings, participants were instructed to select the most appropriate option from the following: (1) silver-containing hydrofiber or silver-containing polyurethane foam, (2) silver-containing hydrofiber or silver-containing hydrocolloid, (3) silver-containing hydrocolloid or hydrogel, (4) polyurethane film or silver-containing hydrocolloid, (5) hydrogel, and (6) use of a dressing was considered inappropriate.

Furthermore, in clinical scenarios where the guidelines offered multiple options or weak recommendations, CDSS and the scoring criteria were designed to prioritize conservative, safety-oriented decision-making to minimize clinical risks for nonspecialists in wound care. Given the study's constraint that surgical intervention was unavailable, this safety-first approach distinguished between facilitating healing in stable wounds and avoiding high-risk occlusion in unstable wounds, especially in the dressing section.

Specifically, for an ulcer covered with dry, black, necrotic tissue, presenting minimal exudate and no signs of infection (question 3), “hydrogel” was the correct answer. Without surgical intervention, hydrogel is a conservative, low-risk method that facilitates autolytic debridement; the benefit of softening necrosis outweighs the minimal risk of complications.

Conversely, in scenarios where occlusion posed a significant clinical risk, such as an ulcer with necrotic tissue in pockets but without signs of infection (question 4) or an ulcer covered with yellow necrotic tissue, abundant exudate, and clear signs of infection (question 9), “use of a dressing was considered inappropriate” was the correct answer. Regarding question 4, sealing a cavity containing necrotic tissue carries a high risk of abscess formation or exacerbation of occult infection, especially given the constraints of this study, where surgical debridement was unavailable. Furthermore, regarding question 9, while the guideline offers “weak suggestion” (recommendation 2D) for silver-containing dressings in infected wounds, it also emphasizes that dressings are generally inappropriate in the presence of infection [19].

The “most appropriate” answers to the remaining questions were determined by ensuring they were supported by treatment algorithms or descriptive recommendations in at least one of the referenced guidelines [18,19].

Data Collection and Outcome

Data regarding age, sex, and years since obtaining a medical degree were collected from all participants as baseline demographic data. This study used a questionnaire that required respondents to select the most appropriate ointments and wound dressings for treating pressure ulcers (Figure 3). The primary outcome was the proportion of participants who selected the correct answers for both ointment and wound dressing options. The secondary outcomes were comparisons of the average correct response rates for ointment selections and those for wound dressing selections. In order to evaluate the potential influence of learning or carryover effects despite the washout period, a sensitivity analysis was performed, restricted to period

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1 data only. As an exploratory analysis, we investigated the utility of CDSS for identifying wound depth as deep or non-deep ulcers.

Statistical Analysis

Statistical analyses were performed using R software (version 4.5.0; The R Foundation for Statistical Computing) for Windows. The unit of analysis was each individual question response (N=280, 28 physicians × 10 questions). To account for the crossover design and clustering of responses within physicians, generalized estimating equations (GEE) with a binomial distribution and logit link function were used. An exchangeable correlation structure was used to account for within-subject correlation. The model included the following fixed effects to assess intervention effects while adjusting for potential learning and carryover biases: treatment (intervention phase vs control phase), period (period 1 vs period 2), and sequence (group A vs group B). The intervention effect was reported as an adjusted odds ratio (aOR) with a 95% CI. Statistical significance was set at $P<.05$. The Mann-Whitney *U* test was used to compare continuous variables for baseline participant characteristics, which are presented as medians (IQRs). Fisher exact test was used to compare categorical and binary baseline participant characteristics, which are presented as counts (percentages).

Results

Baseline Characteristics

A total of 28 GIM physicians participated in this study (Figure 4). The median age of all participants was 32.2 (IQR 7.0) years; 20 participants (71.4%) were male, and the median number of years since graduation was 7.3 (IQR 6.0). Participant age ($P=.39$), sex ($P=.21$), and years since graduation ($P=.25$) did not differ significantly between group A and group B (Table 2).

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Figure 4. Flowchart of the study participants and allocation into groups. CDSS: clinical decision support system.

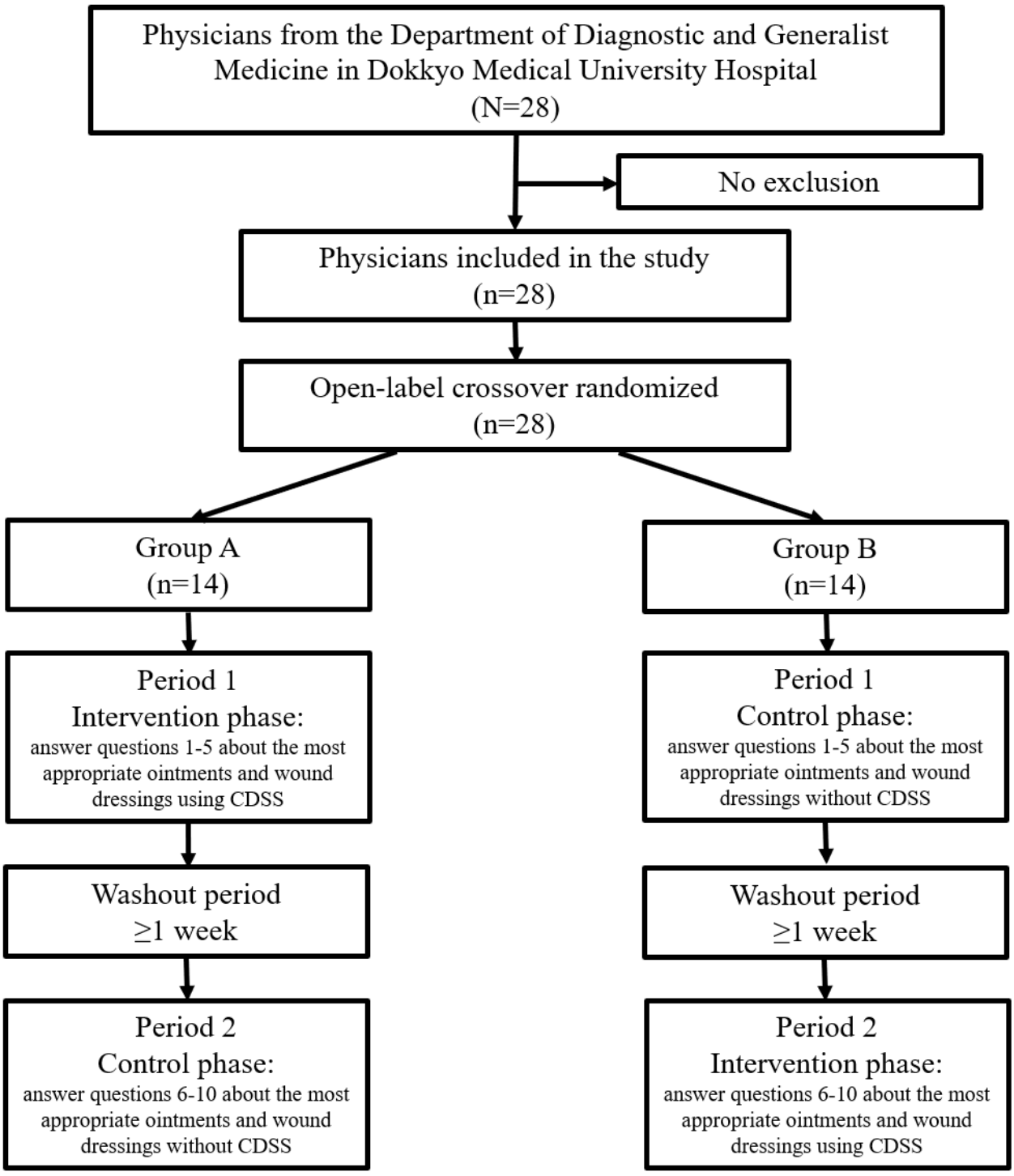

Table 2. Baseline characteristics of the participants.

Variable	Group A (n=14)	Group B (n=14)	*P* value
Age (y), median (IQR)	32.8 (6.8)	31.6 (5.0)	.39[a]
Men, n (%)	12 (85.7)	8 (57.1)	.21[b]
Years after graduation (y), median (IQR)	8.1 (5.8)	6.5 (3.8)	.25[a]

[a]Mann-Whitney *U* test.

[b]Fisher exact test.

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Primary Outcomes

The primary outcome was the proportion of participants who correctly selected both the most appropriate ointment and the most appropriate wound dressing (Table 3). The overall correct response rate during the intervention phase was significantly higher than that during the control phase (49.3% vs 4.3%). After adjusting for clustering within physicians and potential crossover effects using GEE, CDSS use was associated with a 29.1-fold increase in the odds of a correct response (95% CI 8.2-103; *P*<.001). Regarding potential biases in the crossover design, there was no significant period effect (*P*=.11) or sequence effect (*P*=.25) for the primary outcome. This confirms the adequacy of the 1-week washout period.

Secondary Outcomes

The secondary outcomes were comparisons of the average correct response rates for ointment and those for wound dressing (Table 3). Significant improvements were also observed in the secondary outcomes. The correct response rate for ointment selection increased from 42.9% in the control phase to 64.3% in the intervention phase (aOR 2.4, 95% CI 1.5-3.8; *P*<.001). Although a minor sequence effect was observed (*P*=.03), the intervention effect remained significant after adjustment. For wound dressing selection, the correct response rate increased from 15% in the control phase to 59.3% in the intervention phase (aOR 8.9, 95% CI 4.9-16.1; *P*<.001). A period effect was noted (*P*=.009), indicating a learning trend; however, the CDSS intervention remained the dominant predictor of success in the adjusted model.

Table 3. Effect of the clinical decision support system on pressure ulcer treatment selection (N=28).

	Intervention phase (%)[a]	Control phase (%)[a]	Adjusted odds ratio (95% CI)	*P* value
Total[b]	49.3	4.3	29.1 (8.2-103)	<.001
Ointments[c]	64.3	42.9	2.42 (1.5-3.8)	<.001
Wound dressings[c]	59.3	15	8.86 (4.9-16.1)	<.001

[a]Corresponding absolute values are not provided in the case of percentages that have been adjusted by the generalized estimating equations model.

[b]The primary outcome measure was the proportion of participants who correctly answered both the ointment and wound dressing selections. A total of 28 participants answered 5 questions during the intervention phase and another 5 during the control phase.

[c]The secondary outcome measures were comparisons of the average correct response rates for ointment selections and those for wound dressing selections. A total of 28 participants answered 5 questions during the intervention phase and another 5 during the control phase.

Discussion

Principal Results

This study yielded 3 main findings. First, the use of CDSS significantly increased the odds that GIM physicians would select the correct pressure ulcer treatment. The correct response rate increased from 4.3% to 49.3%, which is a 29.1-fold improvement (95% CI 8.2-103; *P*<.001). The extremely low correct response rate in the control phase underscores the inherent difficulty of appropriate treatment selection. This was likely influenced by our strict scoring criteria, which prioritized conservative, safety-oriented choices over multiple potential options. This result suggests that CDSS has the potential to assist physicians in cases of uncertainty about the appropriate treatment for pressure ulcers.

Second, CDSS demonstrated a particularly strong impact on wound dressing selection (aOR 8.9, 95% CI 4.9-16.1; *P*<.001) compared to ointment selection (aOR 2.4, 95% CI 1.5-3.8; *P*<.001). Notably, CDSS was particularly useful in identifying clinical scenarios in which dressings should be avoided. While some physicians lack knowledge about dressing properties [27], our system's design emphasizes the risks of occlusion in unstable wounds such as pockets or infection. This likely prevented hazardous treatment choices. Therefore, assistance in selecting wound dressings is likely to impact clinical practice in settings where consultation with specialists is not available immediately.

Third, we rigorously evaluated potential biases inherent in the crossover design by using GEE. For the primary outcome, neither the duration nor the sequence had a significant effect on the results, confirming the efficacy of the washout period. Although a significant period effect was observed in the dressing selection model (*P*=.009), indicating some spontaneous learning, the CDSS intervention effect remained significant after adjusting for this bias. This methodological approach ensures that the observed improvements are directly attributable to CDSS.

Strengths

This study has 2 major strengths. First, the evaluation uses standardized clinical photographs from JSPU, which ensures reliability. Second, CDSS was designed to operationalize and optimize clinical algorithms. Unlike verbatim reproductions of guidelines, CDSS incorporates original, safety-first logic designed to minimize clinical risks such as abscess formation for nonspecialists in wound care working under the constraint of no surgical intervention. By converting complex and sometimes ambiguous guideline text into a structured, risk-averse decision tree, CDSS can standardize clinical decision-making and ensure patient safety in primary care settings.

Limitations

This was a pilot study with 3 limitations. First, the study's methodology was confined to the analysis of clinical photographs of pressure ulcers, excluding clinical courses, other physical examinations, and investigation results from real-world

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settings. Consequently, to substantiate the efficacy and legitimacy of CDSS for pressure ulcer management in clinical practice, subsequent studies involving actual patients, with careful consideration for patient safety, are required.

Second, the sample size was relatively small. This study was conducted by a department of GIM at a single institution. In the future, studies should include a more diverse sample of the target population. For example, home-visit physicians and physicians from other specialties working in inpatient wards should be included.

Third, the study used a forced-choice format based on a safety-first scoring system. This method may not fully capture the flexibility required in clinical practice. Although guidelines typically offer multiple options or weak recommendations, this study intentionally defined a single "most appropriate" answer to ensure statistical rigor and prioritize conservative management. In real-world settings, specialists might choose more varied treatments based on complex risk-benefit assessments that were not fully represented in the simplified scenarios of this pilot study.

Comparison With Prior Work

There are some CDSSs for pressure ulcers that suggest treatment methods in addition to the one we have used that are currently available, for example, the WOUND COMPASS Clinical Support App [13]. However, to our knowledge, no study has compared the ability of physicians using CDSS to select appropriate treatments for pressure ulcers.

Future Direction

The CDSS in this study was developed mainly by GIM physicians. In the future, collaboration with other specialists, including wound care experts, is required. To further improve the accuracy of CDSS, functions that support appropriate pressure ulcer assessment, as well as continuous skill training, should be incorporated. Furthermore, this CDSS is currently not approved by medical authorities. Achieving official approval through trials administered by medical authorities is crucial to establishing its credibility, safety, and adherence to recognized standards [28].

Conclusions

This study was conducted as the first step in developing a CDSS for pressure ulcer management for GIM physicians who have limited opportunities to consult with wound care specialists. The prototype CDSS improved the accuracy of treatment decisions made by GIM physicians in a pilot study that used photographs and fixed options. Within the parameters of this investigation, CDSS effectively guided participants toward standardized, safety-oriented choices as defined by our scoring criteria.

Acknowledgments

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Conflicts of Interest

None declared.

Multimedia Appendix 1
CONSORT-EHEALTH checklist.
[PDF File (Adobe PDF File), 2637 KB - formative_v10i1e85452_app1.pdf]

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Abbreviations

aOR: adjusted odds ratio
CDSS: clinical decision support system
CONSORT-EHEALTH: Consolidated Standards of Reporting Trials of Electronic and Mobile Health Applications and Online Telehealth
DESIGN: depth, exudates, size, inflammation/infection, granulation, necrosis, and pocket
GEE: generalized estimating equations
GIM: general internal medicine
JSPU: Japanese Society of Pressure Ulcers
TIME: tissue, infection/inflammation, moisture, edge

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Original Paper

Feasibility and Acceptability of an eHealth-Based Physical Activity Coaching Intervention During Pulmonary Rehabilitation for People With Chronic Obstructive Pulmonary Disease: Mixed Methods Study

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Abstract

Background: Physical inactivity is a modifiable and significant trait in people with chronic obstructive pulmonary disease (COPD). While traditional exercise-based pulmonary rehabilitation (PR) improves symptoms and exercise tolerance, its impact on physical activity (PA) levels remains limited. Digital health (eHealth) interventions may help address this gap.

Objective: This study aimed to assess the feasibility and acceptability of integrating an eHealth PA coaching intervention into PR for people with COPD.

Methods: Patients enrolled in an outpatient PR program were recruited for a 3-week PA coaching intervention, which used a smart band connected to a mobile patient app and a web application for health care professionals (HCPs). The intervention included PA monitoring (steps per day); weekly goal setting; and app notifications for goal updates, achievement, and motivational messages. Weekly telephone calls supported goal adjustment and identification of PA barriers. The acceptability of the intervention was explored through a patient focus group.

Results: Five patients with COPD (mean 67, SD 9 years; n=4, 80% female; mean predicted forced expiratory volume at 1 second of 49%, SD 23%) participated with 100% retention and adherence to the intervention (daily synchronization). No adverse events or PA barriers were identified. One patient reported an app connection issue that was resolved by restarting the app. Patients found the app easy to use and helpful for their PA awareness and remote monitoring by HCPs. Weekly goal adjustments and contact with an HCP were valued. Limitations regarding the app use included a lack of personalization, goal setting restricted to steps, and occasional step miscounts.

Conclusions: The intervention was feasible and well accepted. Future studies with a larger sample are needed to assess the impact of the intervention on PA outcomes.

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KEYWORDS

chronic obstructive pulmonary disease; COPD; eHealth intervention; physical activity; pulmonary rehabilitation

Introduction

Chronic obstructive pulmonary disease (COPD) is a highly prevalent lung disease that imposes a significant burden on health care systems and is a major cause of long-term disability [1]. Physical inactivity is a crucial treatable trait in COPD, as it is related to increased risk of exacerbations, hospitalizations, and mortality [2,3]. Thus, improving physical activity (PA) levels in these patients is a global priority [1].

Pulmonary rehabilitation (PR) is a nonpharmacological and evidence-based intervention known to improve symptomatology and functional performance in patients with COPD [4,5]. Exercise training is considered a cornerstone of PR. Previous studies have found inconsistent results regarding the impact of exercise-based PR on patients' PA levels. This suggests that behavioral interventions such as PA coaching should be integrated into PR to optimize promotion of an active lifestyle [6-8]. This strategy allows clinicians to detect and intervene early in case of low PA adherence [9].

Therefore, it is crucial to develop strategies to optimize patients' PA during and after the PR. PA coaching can be supported by information and communication technologies such as eHealth, including mobile apps, as their use is increasingly common in everyday life [10] and technology is embedded into the health care systems [11]. Mobile apps can monitor PA in real time, enabling automated and continuous self-monitoring and feedback [12], facilitating low-burden measurement of activity with acceptable accuracy [13], and providing continuous access to recorded data both longitudinally and in real time [12].

Prior to conducting effectiveness trials, eHealth interventions such as PA coaching must be assessed for feasibility and acceptability to ensure their optimization [14]. Identifying specific barriers is a vital prerequisite for developing robust, personalized, and scalable interventions capable of fostering long-term active lifestyles in patients with COPD. Therefore, this study aimed to evaluate the feasibility and acceptability of an eHealth-supported PA coaching intervention for patients with COPD attending a PR program.

Methods

Ethical Considerations

This study was approved by the ethics committee of the institution involved, that is, the Local Health Unit of the Leiria Region (reference 10/2024, acta number 022024/01/16). Participant data were handled in accordance with applicable data protection regulations. Patients who agreed to participate in the study provided written informed consent before any data collection.

Design

This was a single-group feasibility and acceptability study that investigated a 3-week PA coaching intervention implemented during a PR program. This study is part of the Effectiveness of Physical Activity Coaching using eHealth in patients with COPD (Physical Activity in COPD Using eHealth) study, which aims to assess the effectiveness of a personalized eHealth coaching intervention integrated into PR to increase the PA levels in patients with COPD. This feasibility study was reported in accordance with guidelines for reporting pilot and feasibility studies (adjusted for a single-arm study) [14-16]. Participant data were handled in accordance with applicable data protection regulations. The focus of this study was on the feasibility and acceptability of the intervention, specifically to test the PA goal-setting algorithm and assess the receptivity and acceptance of the intervention, including the digital platform, to identify any necessary adjustments for its implementation in a larger study. For this purpose, 3 weeks were needed for patients to interact with the platform, test its acceptability, and refine the algorithm.

Participants

Potential participants were recruited from the Local Health Unit of the Leiria Region (Portugal). The participant eligibility criteria are shown in Textbox 1.

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Textbox 1. Participant eligibility criteria.

Inclusion criteria

- Aged ≥40 years
- Diagnosis of chronic obstructive pulmonary disease according to Global Initiative for Chronic Obstructive Lung Disease criteria [1]
- Clinically stable (ie, with no exacerbations in the previous month)
- Outpatients attending the pulmonary rehabilitation program at the hospital
- Able to understand and provide informed consent

Exclusion criteria

- Simultaneous participation in another physical activity (PA) behavioral modification program
- Not having a smartphone
- Having a clinical condition that could preclude participation in a PA intervention (eg, severe musculoskeletal or neurological disorders)
- Other primary respiratory disease
- Unstable cardiovascular disease and/or history of recent neoplasia (including last treatment) in the previous year

The physician responsible for the PR program identified the eligible participants and briefly explained the study to them. Those interested in participating were then contacted by the researcher via telephone to inform them about the study procedures (data collection, dates, and intervention delivery), confirm their eligibility, and ask about their willingness to participate. Reasons for not participating were recorded. Patients who agreed to participate provided written informed consent before any data collection.

Procedures

This study included 4 interaction time points with patients, as described in Figure 1. The assessments took place at baseline (T1) and 3 weeks after, corresponding to the end of the intervention (T4). In the baseline assessment (T1), participants completed a questionnaire with sociodemographic and health-related information (ie, age, sex, educational level, occupational status, smoking history, comorbidities using the Charlson Comorbidity Index [17], exacerbation history, medication, weight, and height), preferred physical activities (eg, walking, swimming, and dancing), and questions about the type and features or apps used on their smartphone. Lung function was assessed through spirometry [18] to further classify patients based on Global Initiative for Chronic Obstructive Lung Disease (GOLD) grades of airflow obstruction severity (GOLD 1: forced expiratory volume at 1 second [FEV_1]≥80% predicted, GOLD 2: 50%≤FEV_1<80% predicted, GOLD 3: 30%≤FEV_1<50% predicted, and GOLD 4: FEV_1<30% predicted) [1]. GOLD A, B, and E categories were determined according to the patients' exacerbation history and symptoms [1]. The impact of COPD on daily living, dyspnea, fatigue, exercise tolerance, quality of life, and self-efficacy for PA was also assessed, as described in detail in the Secondary Outcome Measures (Health-Related Outcomes) section.

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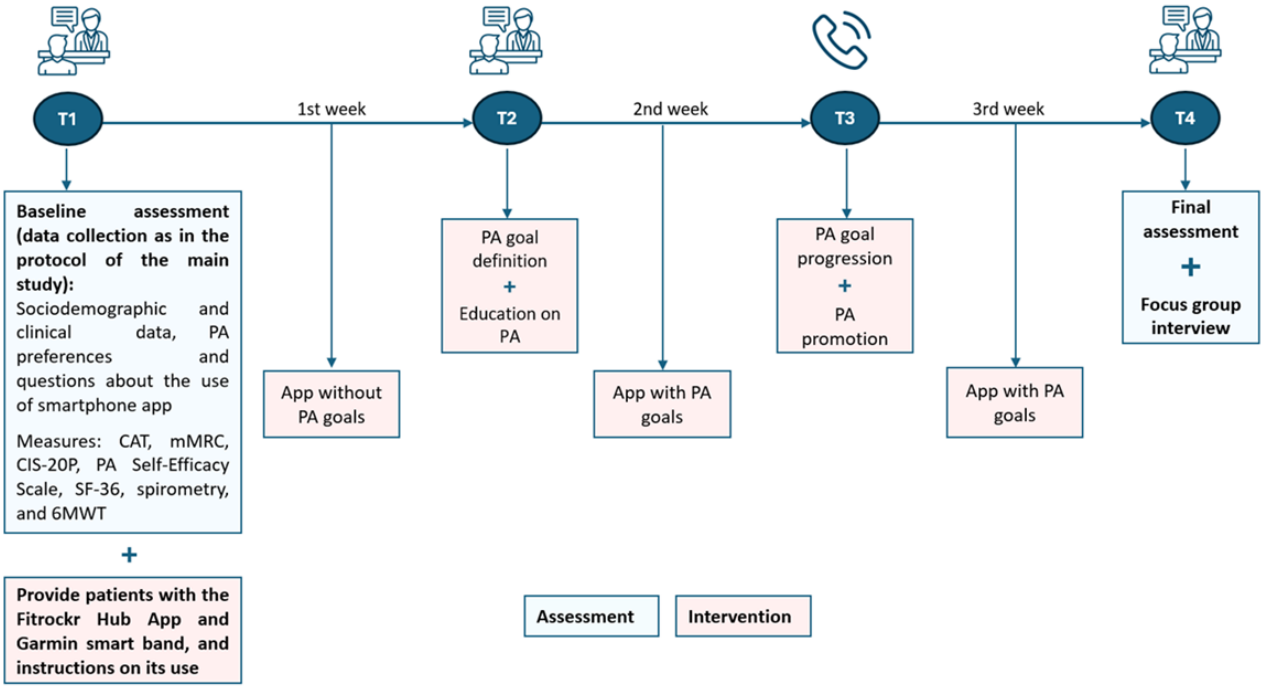
Figure 1. Design of the feasibility study. 6MWT: 6-Minute Walk Test; CAT: COPD Assessment Test; CIS-20P: Portuguese version of the Checklist of Individual Strength; mMRC: modified Medical Research Council; PA: physical activity; SF-36: 36-item Short Form Health Survey.



Then, patients received the PA mobile app paired with a smart band to use during the study period. In the first week, their baseline step count was established for goal setting in the following weeks. In the second time point (T2—end of the first week), patients received education on the importance of PA and recommendations and agreed on the first PA goal set. In the third time point (T3—end of the second week), the researcher reviewed the achievement of the previous PA goal, explored barriers to PA behavior and potential adverse events, and set the next goal with the patient through a telephone call. One week later (T4—end of the third week), patients returned the app and the smart band and were reassessed as in T1. A focus group with patients was also conducted to assess their feedback on the PA coaching intervention, including their experience with new technology; perspectives on the importance of PA promotion interventions; app functionality; and acceptability, barriers, and facilitators of its use. The intervention is described in detail below (refer to the PA Coaching Intervention section).

Intervention

eHealth Platform for PA Coaching

The eHealth platform used in this study was the *Fitrockr Hub App* (Fitrockr Health Solutions). This eHealth platform enables tailoring PA coaching to each patient by monitoring patients' adherence to predefined PA goals and enabling individualized notifications.

The Fitrockr Hub App platform comprises 2 applications: a web application for HCPs and a mobile app for patients. The mobile app synchronizes with a Garmin smart band (Garmin Vivosmart 4; Garmin), which allows for PA monitoring (ie, steps, distance, and calories), access to PA history (in days), daily PA goals (defined in the web application), and notifications on the patient's performance based on the fulfillment of their personal goals. The web application for the HCPs allows them to monitor patients' daily PA to define and/or change individualized goals, which will then appear on the home page of the mobile app. Through the web page, HCPs can also insert new patients, prescribe personalized PA goals for each patient (ie, steps), monitor their daily PA activity (eg, observe how many steps take on a given day), check whether patients met their prescribed goals, and send personalized notifications. The data can be exported to Excel files for further analysis.

PA Coaching Intervention

In this study, the principal researcher assumed the role of the HCP responsible for PA coaching, with exclusive access to the PA platform and responsibility for delivering the intervention. Hospital HCPs were responsible for the delivery of the PR program, which all participants attended as usual, with the PA coaching intervention provided as an additional component.

The PR program was delivered in accordance with the European Respiratory Society's and American Thoracic Society's recommendations [5] and had a duration of 8 weeks, as recommended. Participants were not all at the same stage of the PR program at the time of enrollment in the study, but the same protocol (Figure 1) was applied to all participants.

Patients were asked to wear the smart band connected to the Fitrockr Hub App every day for 1 week to set their baseline steps (T1). As the mobile app does not synchronize automatically with the smart band, patients were asked to manually synchronize them twice a day (ie, upon awakening and before retiring for the night), every day, by clicking a button in the app.

After the first week (T2), patients received information about the importance and recommendations of PA, and the first PA

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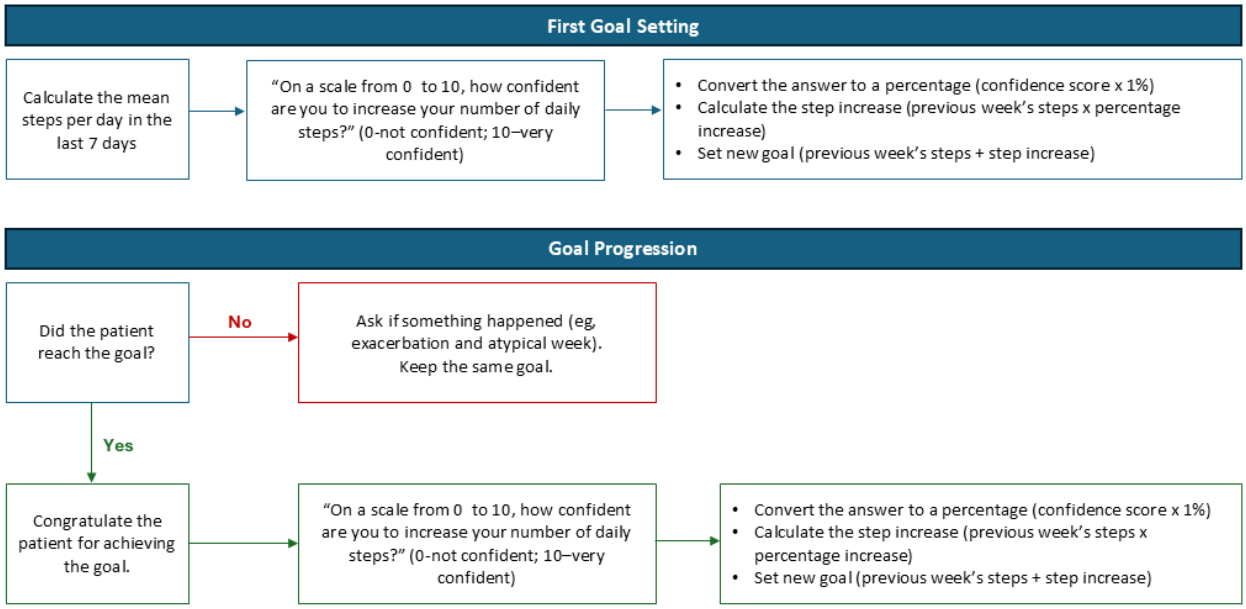
goal was set (in person). The personalization of the goal was based on an algorithm (Figure 2) that considered the amount of PA performed in the previous week (ie, the average number of daily steps in the last 7 days) and patients' confidence in changing the goal. The "confidence" level was then translated into a percentage increase from the previous goal, and the adjusted goal was then displayed in the Fitrockr Hub App. To avoid the risk of injuries and to ensure tolerability, the weekly increase in PA goals did not exceed 10% [19]. During the week, patients received an automatic notification every day at 6 PM about their goal achievements, providing them with the opportunity to increase their PA to reach their daily goal if needed. During the intervention, patients received sporadic personalized notifications sent manually by the researcher (eg, notifications about bad weather suggesting indoor activities and incentive messages). At the end of the second week (T3), patients received a telephone call to check their PA progression. If patients did not achieve their goals in the previous week, the researcher asked them to identify potential barriers to PA improvement and discussed possible strategies to overcome them (examples are provided in Multimedia Appendix 1). Then, the goal for the next week was set according to the algorithm presented in Figure 2. During the intervention, patients were allowed to contact the researcher by telephone to receive technical support, if needed.

Figure 2. Algorithm for goal setting and progression of physical activity coaching.



Reasons for not progressing the goals as well as possible adverse events and technical issues related to app functioning were recorded. The diary of telephone calls and goal progression was recorded and is provided in Multimedia Appendix 2.

As PA is a complex behavior [20], the intervention included several behavior change techniques (BCTs), according to the BCT Taxonomy v1 [21], including goals and planning, feedback and monitoring, natural consequences, repetition and substitution, comparison of outcomes, and self-belief. More information on how these BCTs were implemented is provided in Multimedia Appendix 3.

Outcomes

Primary Outcomes

Feasibility

Feasibility was defined as the extent to which the intervention can be successfully implemented within a given setting or larger study [22]. Feasibility was evaluated through the following parameters assessed during the intervention:

Feasibility of the study design:

- Recruitment rate (%)=(number of recruited patients÷number of eligible patients)×100
- Study retention (%)=percentage of patients who completed the intervention and data collection (The expected recruitment rate and study retention were 80%, at least [15])
- Dropout rate (and its reasons)=(number of dropouts÷number of patients recruited)×100

Feasibility of the intervention:

- Adherence to intervention (%) was assessed by the number of days patients had synchronized the app with the smart band throughout the intervention, regardless of whether they achieved the goal.
- Intervention safety=adverse events and/or unplanned health care use (self-reported)
- Technical issues about app functioning (self-reported)
- Duration and content of the telephone calls

Acceptability

Acceptability was defined as the extent to which patients receiving the intervention considered it appropriate to promote PA during PR [23]. Acceptability was assessed through a focus group with a semistructured guide and audio-recorded for

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posterior transcription and analysis. The focus group guide is provided in Multimedia Appendix 4. No field notes were made during the interview. The focus group covered the following topics: (1) feedback about the intervention—questions about patients' experience with the intervention, specifically the importance of this type of intervention to improve their PA levels, barriers and facilitators to the use of mobile apps to promote PA, goal setting and progression, notifications, and HCPs' contact; and (2) feedback about the functioning of the app—questions about barriers and facilitators of app use: the experience of interacting with the smartphone app and the smart band, as well as the degree of technological complexity.

Secondary Outcome Measures (Health-Related Outcomes)

Given the short duration of the intervention (3 weeks), no changes in health-related outcomes were expected. However, these measures were included in assessment moments to replicate the procedures of the subsequent randomized controlled trial data collection processes. Functional exercise capacity was measured using the 6-Minute Walk Test [24], and predicted values were computed using the equation developed for Portuguese adults [25]. The test was conducted in a 30-meter corridor according to guidelines from the European Respiratory Society and American Thoracic Society [26]. Vital signs were measured before and after the test [27], and symptom scores for dyspnea and fatigue were assessed using the modified Borg scale [28]. The impact of COPD on daily living was assessed using the COPD Assessment Test [1], dyspnea using the modified Medical Research Council Dyspnea Scale [29], quality of life using the Medical Outcomes Study 36-item Short Form Health Survey version 2 [30,31], and self-efficacy for PA using an adapted version of the Physical Exercise Self-Efficacy Scale (adapted with the authors' permission) [32]. Fatigue was measured with the Checklist of Individual Strength and categorized into 3 categories (normal fatigue: score ≤26, mild fatigue: score between 27 and 35, and severe fatigue: score ≥36) [33].

Data Analysis

Descriptive statistics were used to characterize the sample using SPSS Statistics (version 28.0; IBM Corp). Continuous variables were summarized as mean (SD) when normally distributed and as median (IQR) when normality assumptions were not met. Categorical variables were described using absolute frequencies (n) and percentages (%).

Data collected through the focus group were analyzed using a qualitative methodological approach, namely, thematic analysis [34]. Participants were anonymized using alphanumeric codes (P1, P2, etc) during data analysis. Themes and categories were developed in an Excel spreadsheet, enabling the identification of the main topics discussed by the participants. The analysis was primarily conducted independently by 2 researchers. Subsequently, both researchers met to systematically compare codes and themes and to reach consensus. Themes were generated and analyzed question by question, following the focus group guide. Once no new categories were identified, the information was organized into a descriptive framework [34].

Researchers' Reflexivity

The interviews were conducted by 2 female physiotherapists with a master's degree in the respiratory field and experience in PA assessment and promotion. Both researchers made efforts to ensure neutrality throughout the analysis process, complying with established qualitative research rigor guidelines. The research team also included a senior member with experience in COPD management, PA promotion, and qualitative research.

Results

All patients were recruited in March 2024, and the follow-up lasted until May 2024. A total of 6 patients participating in an outpatient PR program were eligible for recruitment; however, 1 patient refused to participate due to lack of interest; therefore, the final sample consisted of 5 patients.

Patients' Characteristics

Patients had a mean age of 67.0 (SD 8.9) years and a mean predicted FEV_1 of 49% (SD 22.8%), indicating a population with moderate to severe airflow limitation. The sample was predominantly female (n=4, 80%), with most patients classified as GOLD E (n=4, 80%), suggesting a high risk of exacerbations and symptom burden. Regarding educational level, 60% (n=3) completed 10 to 12 years of formal education, and all patients were retired (n=5, 100%). The mean COPD Assessment Test score was 13.0 (SD 9.0). Fatigue levels, assessed using the Portuguese version of the Checklist of Individual Strength, showed a mean score of 78.4(SD 28.9). Dyspnea severity, measured by the modified Medical Research Council Dyspnea Scale, had a median score of 3.0 (IQR 0.5-3.5). On average, each assessment session lasted approximately 40 minutes. Characteristics of participants are presented in Table 1.

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Table 1. Participants' sociodemographic and clinical characteristics (N=5).

Characteristics	Values
Age (years), mean (SD)	67.0 (8.9)
FEV_1[a] % predicted, mean (SD)	49.0 (22.8)
BMI (kg/m^2), mean (SD)	26.3 (8.7)
Sex, n (%)	
Female	4 (80)
Male	1 (20)
Education level, n (%)	
5-9 years	1 (20)
10-12 years	3 (60)
Higher education	1 (20)
GOLD ABE[b] classification, n (%)	
GOLD A	1 (20)
GOLD E	4 (80)
GOLD FEV_1 classification, n (%)	
GOLD 1	1 (20)
GOLD 2	1 (20)
GOLD 3	2 (40)
GOLD 4	1 (20)
CCI[c], n (%)	
Mild	1 (20)
Moderate	4 (80)
CAT[d] total score, mean (SD)	13.0 (9.0)
CIS20-P[e] total score, mean (SD)	78.4 (28.9)
CIS20-P subjective fatigue, n (%)	
Normal fatigue	1 (20)
Mild fatigue	2 (40)
Severe fatigue	2 (40)
mMRC[f], median (IQR)	3.0 (0.5-3.5)
6MWD[g] (meters), mean (SD)	419.0 (102.0)
6MWD (% predicted), mean (SD)	88 (23)

[a]FEV_1: forced expiratory volume at 1 second.

[b]GOLD: Global Initiative for Obstructive Lung Disease Groups A, B, E.

[c]CCI: Charlson Comorbidity Index.

[d]CAT: COPD Assessment Test.

[e]CIS20-P: Portuguese version of the Checklist of Individual Strength.

[f]mMRC: modified Medical Research Council.

[g]6MWD: 6-Minute Walk Distance.

Regarding the experience with new technologies, all patients used smartphones, performing various tasks on them, such as browsing the internet and listening to music (n=5, 100%); sending or receiving SMS text messages (n=4, 80%); taking photos, playing games, and using social media (n=3, 60%); and using GPS (n=2, 40%).

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Feasibility of the Study Design

The recruitment rate was 83% (5/6) with 100% retention and no dropouts.

Feasibility of the Intervention

During the intervention, no adverse events or unplanned health care use were reported. Only 1 technical issue with the app was reported, involving difficulties connecting to the app; the researcher restarted the app, and the problem was resolved. Adherence was 100% (5/5), with patients syncing the mobile app daily. The call for goal progression (T2) lasted an average of 10 (SD 3.13) minutes. The summary of goal progression and diary of telephone calls (to report technical issues from the app, goal setting, and PA promotion) was recorded, and it can be found in Multimedia Appendix 2.

Acceptability

1. The focus group lasted 1 hour and 6 minutes, and the several themes were identified.

Value of the PA coaching intervention using eHealth and its impact on PA levels—all patients considered this type of intervention an added value, both for themselves to increase their perception of PA and for health care professionals (HCPs) to help them monitor patients' PA levels:

> *I think this is important also for doctors to see our capabilities and solve our problems accordingly...it provides guidance [on PA] to the doctor.* [Patient #5]
>
> *I think this helps us to have a better idea of our effort and to know if we need to walk more….* [Patient #2]

2. Barriers and facilitators of the use of Fitrockr Hub App to promote PA—the focus only on step counts to define PA goals, the lack of personalization (excluding PA activities other than walking), occasionally step miscounts (through the smart band), and not having the app for free in the real context were considered barriers. Participants identified a user-friendly layout, acceptable time demands, and the prescription of PA goals as facilitators:

> *This app should have more options than just walking...it is reductive in this way.* [Patient #2]
>
> *In my personal opinion, I think it's extremely important [PA goals]; it encourages us to exercise more because we have that goal, and if we focus on a goal, we'll likely try to achieve it every day.* [Patient #1]

3. Goal setting, progression, PA monitoring, and promotion—patients considered goal setting to be a collaborative and personalized process, highlighting the importance of negotiated PA goals with their HCPs. Patients considered the adjustment of their PA goals (based on performance and willingness to increase) adequate and emphasized the identification of barriers to PA and strategies to overcome them every week as being beneficial for PA engagement. The main barriers to not reaching the PA goals by patients were bad weather, exacerbations or worsening of symptoms, and variability in response to PA. The importance of maintaining contact with HCPs during the intervention, either via video call or telephone, was also highlighted by all patients:

> *Each patient has their own PA goal, and this is important because people have different health conditions, not everyone has de same degree of severity so you cannot set the same goals for everyone.* [Patient #2]
>
> *(the revision of PA goals) should be weekly because if there is any correction or adjustment needed, it can be done (right away).* [Patient #4]
>
> *It was great to have a possibility to contact our healthcare professional.* [Patient #3]
>
> *In week 2, I have the goal of 8000 steps/day but this coincided with cold weather and I did not have achieve the goal because I was not going leave the house with bad weather...* [Patient #2]
>
> *I think is a good option to talk by telephone calls...[in that way,] the colleagues that live far away do not need to come on purpose if they can talk by telephone.* [Patient #4]
>
> *By videocall is better...the communication is done a lot through gestures, eyes, voice...and you can even get a better sense of whether the person is more or less engaged based on their facial expression.* [Patient #2]

Discussion

Main Findings

Overall, this PA coaching intervention using eHealth appears to be feasible and well accepted by patients. Patients' feedback about the intervention was positive, as they considered the app easy to use and valuable for PA self-management and remote monitoring by HCPs. Patients underlined the importance of weekly goal adjustments, frequent app notifications, and weekly contact with HCPs through telephone or video calls. However, patients identified some limitations regarding the use of the app, including a lack of personalization, the exclusive focus on step counts to define PA goals, and occasional step miscounts.

Despite a shorter intervention period compared with similar eHealth-based PA interventions in COPD [35,36], this study achieved high recruitment and retention rates (>80%) supporting the feasibility of this study design [15]. These rates are comparable to or higher than those reported in previous feasibility studies, suggesting that integrating PA coaching alongside PR is practicable within this clinical context. However, these findings should be interpreted with caution due to the small and relatively homogeneous sample, which was predominantly female, retired, and familiar with smartphone use. Therefore, the generalizability of these results is limited. Consistent with previous literature, future studies should recruit more diverse samples, including individuals with lower digital literacy [37], varying levels of motivation for PA [38], and higher multimorbidity burden [39], as these factors are known to influence engagement with eHealth interventions.

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Regarding intervention feasibility, no major technical or PA barriers were identified during implementation. This contrasts with previous reports highlighting poor digital literacy and technical challenges as key barriers to eHealth adoption in COPD [40] and may be partly explained by the short intervention duration and the provision of technical support. Over time, factors such as comorbidities, environmental challenges, and psychological barriers (eg, fear of breathlessness) can become more pronounced, potentially impairing adherence to the intervention [41].

Regarding the feasibility of PA goal-setting algorithm, although participants did not consistently achieve their weekly goals, they reported that the algorithm was appropriate, with a period of revision and incremental increases being acceptable. These findings align with previous literature recommending weekly goal adjustments, with step count increases ranging from 5% to 15%, tailored to individual tolerance and adherence levels [42-44].

The intervention was proven to be acceptable—patients demonstrated full adherence by synchronizing the smart band with the app daily, regardless of goal achievement. Most patients found the PA app easy to use and well integrated into daily life, supporting evidence that the simplicity and usability of technology can be more decisive than personalization for engagement, as technical issues often lead to participant's dropout [35]. Patients also highly valued the weekly contact with HCPs, which aligns with evidence highlighting patient-professional interaction as a key facilitator of PA promotion [45], particularly in eHealth interventions [40]. Consistent with the literature, personalized goal setting, tailored to individual needs, and feedback notifications were identified as essential components of these interventions [46,47]. However, important limitations were identified, including the exclusive use of step-based goals and limited app personalization, which may reduce patients' motivation, engagement with the intervention, and sustained behavior change. While the eHealth platform could not be modified, as it was already developed and PA coaching may not have been its primary focus, future studies should consider greater personalization to better meet patients' needs. Patients reported PA barriers consistent with the literature, particularly health-related issues (eg, symptom exacerbations), individual variability, and environmental factors such as weather [48]. Addressing these barriers is essential for developing effective and individualized PA interventions. In this study, several evidence-based behavioral strategies, such as goal setting, feedback and monitoring, repetition, substitution, and self-belief, were applied and have since been shown to improve PA in individuals with COPD by supporting barrier identification and problem-solving [49-51].

The findings of this feasibility study suggest that the goal-setting algorithm is appropriate for patients with COPD. Weekly contact between HCPs and patients to establish PA goals, identify potential barriers and corresponding strategies to overcome them, and provide feedback on performance emerged as essential components to retain in future larger-scale studies.

Limitations

Although PA coaching using eHealth may represent a promising approach for self-managing COPD, the findings of this study should be interpreted with caution due to the small sample size and the predominance of participants with prior digital literacy. This limits the generalizability of the results, as previous literature has indicated that individuals with greater interest and experience in technology are more likely to benefit from eHealth interventions [52]. Given the short duration of the intervention, significant changes in PA behavior were not expected. Instead, collecting health-related outcome measures at baseline and the end of the study primarily served to assess the feasibility of data collection procedures and inform refinements for future large-scale trials.

Conclusions

This feasibility and acceptability study showed that the PA coaching intervention using eHealth is feasible and well accepted by the patients. However, some barriers still need to be addressed in future studies to ensure adherence to the intervention. Regarding feasibility, while the remote monitoring procedures were successful, future research must prioritize the robustness of the digital infrastructure to eliminate technical errors and data discrepancies, which can undermine clinical reliability. To ensure acceptability and long-term adherence, it is critical that future interventions move toward a more comprehensive model of personalized coaching. This approach should be tailored to each patient's unique clinical characteristics and PA goals.

Acknowledgments

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(FCT; UID/05704/2025; [53]). This work was also supported by Centro Interdisciplinar de Estudo da Performance Humana (UIDB/00447/2020). ASG was financially supported by a PhD fellowship [54] funded by FCT and by iBiMED (UIDB/04501).

Conflicts of Interest

None declared.

Multimedia Appendix 1
Suggestions on how to overcome barriers to physical activity.
[DOCX File , 18 KB - formative_v10i1e83783_app1.docx]

Multimedia Appendix 2
Records of goal progression and diary of the weekly phone calls.
[DOCX File , 19 KB - formative_v10i1e83783_app2.docx]

Multimedia Appendix 3
Behavior change techniques included in the intervention.
[DOCX File , 19 KB - formative_v10i1e83783_app3.docx]

Multimedia Appendix 4
Focus group guide.
[DOCX File , 20 KB - formative_v10i1e83783_app4.docx]

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Abbreviations

BCT: behavior change technique
COPD: chronic obstructive pulmonary disease
FEV1: forced expiratory volume at 1 second
GOLD: Global Initiative for Chronic Obstructive Lung Disease
HCP: health care professional
PA: physical activity
PR: pulmonary rehabilitation

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Personalized Informational Support for Patients With Hypertension: Single-Arm Pretest-Posttest Study

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Abstract

Background: Informational support has been demonstrated to enhance patients' treatment adherence. However, which specific mode of informational support is more effective for patients with hypertension remains undetermined.

Objective: The primary objective of this study was to conduct a feasibility exploration of personalized informational support in patients with hypertension using a single-arm pretest-posttest design.

Methods: A prospective, single-center, pretest-posttest study was used to investigate the feasibility of providing an informational support intervention to patients with hypertension attending a community health facility in Chengdu, China. The intervention combined in-person follow-ups and telephone counseling. Adherence and clinical outcomes (blood pressure, ambulatory blood pressure, and laboratory tests) were measured at baseline and the postintervention time point. Patients' health behaviors were assessed at baseline and the postintervention time point using validated structured questionnaires. Descriptive statistics and effect sizes were calculated to determine clinically important changes relative to baseline.

Results: Significant improvements were observed: medication adherence scores increased by 0.65 points (95% CI 0.38-0.91; *P*<.001). Nutrition scores increased by 1.31 points (95% CI 0.53-2.09; *P*<.001), interpersonal relationship scores increased by 1.17 points (95% CI 1.03-2.02; *P*=.007), health responsibility scores increased by 2.42 points (95% CI 0.33-3.80; *P*=.001), and the total Health-Promoting Lifestyle Profile II–Revised score significantly increased by 6.81 points (95% CI 3.01-10.61; *P*=.001). Nighttime systolic blood pressure decreased significantly by 5.07 mm Hg (95% CI −8.12 to –2.01; *P*=.001), and nighttime diastolic blood pressure decreased significantly by 3.39 mm Hg (95% CI −5.12 to −1.67; *P*<.001).

Conclusions: This feasibility study found that a structured informational support intervention was well accepted (93/100, 93% retention) and was associated with preliminary improvements in medication adherence and nocturnal blood pressure. These findings suggest potential benefits and support the need for a definitive randomized controlled trial to establish efficacy.

Trial Registration: Chinese Clinical Trial Registry ChiCTR2000039621; https://www.chictr.org.cn/showprojEN.html?proj=63776

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KEYWORDS

hypertension; adherence; blood pressure; social support; informational support

Introduction

Background

Hypertension is a major risk factor for many diseases. World Health Organization data show that, worldwide, 33% of people aged 30 to 79 years have hypertension, constituting 1.3 billion people. In China, the prevalence is 27.9% with 245 million patients, but only 41% are aware, 34.9% are treated, and 11% have controlled blood pressure [1]. Poor treatment adherence is the main reason for uncontrolled blood pressure. The World Health Organization defines treatment adherence as following the physician's plan, including medication and lifestyle. Nonadherence makes it 2.15 times harder to control blood pressure, 2.08 times more likely to have complications, and 1.38 times more likely to die [2]. Thus, improving hypertension management is urgent and important.

Despite significant advances in medication accessibility, treatment adherence remains suboptimal. This nonadherence crisis necessitates a paradigm shift toward nonpharmacological determinants of treatment outcomes. Informational support is an important part of social support, defined as the strategic delivery of evidence-based guidance, therapeutic counseling, and health literacy interventions aimed at stress mitigation and illness coping skill development [3]. This knowledge translation

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process empowers patients to navigate complex treatment regimens while optimizing self-efficacy in chronic disease management, simultaneously alleviating patients' anxiety and perceived uncertainty to enhance therapeutic adherence.

There is emerging evidence suggesting that nontailored informational support modalities may engender maladaptive health beliefs, undermining medication adherence through distorted risk-benefit perceptions [4] and, ultimately, compromising blood pressure trajectory stabilization [5]. A recent study published in the *Journal of the American Medical Association* demonstrated that SMS text message reminders for patients who delayed initiating cardiovascular medication supplementation did not enhance medication adherence or decrease clinical events at the 12-month follow-up [6]. Notwithstanding these gaps in delivery optimization, systematic reviews highlight promising yet inconsistent efficacy signs for dyadic communication strategies, particularly protocol-driven face-to-face follow-up (mean difference 1.00, 95% CI 0.46-1.54) [7] vs structured telephone consultations (risk ratio=1.30, 95% CI 1.07-1.59) [8].

However, the implementation pathways of informational support in hypertension management remain underexplored. Current clinical practices face several challenges: (1) fragmented health education models that lack systematic integration and refinement; (2) the provision of standardized informational support failing to account for patient individuality, resulting in inadequate attention to critical needs; and (3) overreliance on clinic-based in-person sessions. To address these gaps, this study developed a hierarchical progressive informational support framework. The integrated intervention synergizes personalized in-person follow-up (for trust building and rapport establishment) with telephone-delivered counseling, forming a dual-modality framework that has demonstrated potential efficacy in prior feasibility studies [9]. Therefore, we conducted this prospective single-arm study to assess the acceptability of the personalized informational support intervention and preliminary changes in clinical indicators to inform a future randomized controlled trial (RCT).

Objectives

This study used a single-arm pretest-posttest design to explore the feasibility of personalized informational support for patients with hypertension. The primary objectives were to (1) assess the implementation feasibility of the intervention, (2) observe preliminary changes in therapeutic adherence and blood pressure control following the intervention, and (3) inform the design and sample size calculation for a future RCT.

Methods

Study Design and Participants

A prospective, single-center, pretest-posttest study was conducted at the Cuqiao Community Health Service Center in Wuhou District, Chengdu. This study adopted a consecutive enrollment method targeting patients with hypertension visiting community clinics, with enrollment stopped after 100 participants were included. Recruitment began on May 25, 2019, and ended on June 15, 2019. This study adhered to the reporting content of the Transparent Reporting of Evaluations With Nonrandomized Designs guidelines.

The diagnostic criteria for hypertension were established as follows: (1) office-measured systolic blood pressure (SBP) of ≥140 mm Hg and/or diastolic blood pressure (DBP) of ≥90 mm Hg obtained through 3 separate measurements on different days and (2) documented history of hypertension with current use of antihypertensive medications, with confirmed diagnosis maintained even when SBP <140 mm Hg and/or DBP <90 mm Hg.

The inclusion and exclusion criteria are shown in Textbox 1.

Textbox 1. Inclusion and exclusion criteria.

Inclusion criteria

- Essential hypertension
- Residence in the community for >1 year
- Age range of 40 to 80 years

Exclusion criteria

- Hypertensive emergency
- Acute-phase myocardial infarction
- Acute-phase cerebral infarction
- Pregnancy or lactation
- Inability to participate in study procedures due to significant cognitive impairment, hearing deficits, or physical disabilities

Sample Size Calculation

In previous studies, an educational intervention by health care professionals was shown to reduce SBP by 8 mm Hg with a paired-difference SD of 22.86 mm Hg [10]. Using an α value of .05 (2 sided) and 80% power, a minimum of 65 participants was required. Accounting for 20% attrition, we planned to recruit 92 participants. A total of 100 people were recruited in the end.

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Intervention

Overview

The current hypertension management model in communities primarily relies on clinic-based management, with a greater emphasis on medication adjustment. There is a significant lack of attention to informational support, and the health education provided is often sporadic and superficial, lacking systematic and personalized approaches. In this study, we designed a personalized informational support strategy that integrates the educational level and age of patients to formulate the support tactics. Moreover, the emphasis of the support is dynamically adjusted according to the patients' comprehension and mastery levels.

The informational support intervention comprised monthly 30-minute face-to-face sessions delivered by trained community physicians over 3 months. Content included knowledge about hypertension, lifestyle guidance, medication adherence strategies, and monitoring and follow-up protocols. All sessions were standardized using a structured manual, and physicians received uniform preimplementation training.

Additionally, uniformly trained community nurses provided monthly telephone counseling interventions (approximately 10 - 15 minutes per call). These calls focused on reviewing home blood pressure measurements from the previous month, assessing dietary habits and physical activity levels, and evaluating medication adherence. Nurses also encouraged patients to follow the lifestyle recommendations in the health handbook distributed to each patient before the start of the study, addressed patients' concerns, and reminded them of upcoming follow-up appointments.

In-Person Follow-Up

At the initial consultation, patients' age and highest educational attainment were recorded through a structured questionnaire, and health education materials were distributed covering hypertension risks; lifestyle recommendations (dietary guidelines and physical activity regimens); quantitative self-assessment methods; and management of hypertension-related conditions, including blood glucose and lipid control. During the 3-month intervention, patients received monthly 30-minute follow-up sessions. The content of these sessions was tailored to the patients' educational level, health literacy, and age to optimize the delivery and comprehension of informational support.

Tailoring by Educational Level and Health Literacy

For individuals with lower educational attainment or limited health literacy, information was delivered using low-literacy principles. This involved the following:

- Simplified language: avoiding complex medical terminology (eg, "hypertension" was consistently referred to as "high blood pressure"). Instructions were concrete and action-oriented (eg, "Take this pill every morning after breakfast" instead of "Administer the antihypertensive agent upon waking").
- Visual-centric modalities: heavy reliance on pictograms, color-coded charts, and illustrative diagrams. For instance, medication schedules were presented using images of the sun and moon to denote day and night doses, and dietary recommendations used visual portion size guides (eg, a clenched fist representing 1 serving of vegetables).
- Interactive demonstration: instead of passive receipt of information, patients were actively involved in demonstrations, such as practicing with a blood pressure monitor or using a salt restriction spoon with mock food.

Conversely, for individuals with higher educational attainment, the information included more comprehensive explanations of the underlying pathophysiology and the evidence base for recommendations. Patients were actively engaged in shared decision-making regarding their therapeutic regimens, discussing the pros and cons of different lifestyle choices.

Tailoring by Age Group

For middle-aged patients (41-60 years), a hybrid approach was used. They received access to a mobile health app alongside printed materials, allowing them to choose their preferred information channel.

For older patients (>60 years), who might be less comfortable with digital technology, information was delivered primarily through face-to-face interactions and enlarged-print materials. The content was paced more slowly, with key points repeated for emphasis. The health education materials are shown in Figure 1.

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Figure 1. Health education materials distributed to patients with hypertension in the Cuqiao community before the intervention.

Training for General Practitioners and Intervention Framework

General practitioners received structured competency training via the Community Cardiovascular Disease Prevention and Management Platform developed by the National Center for Cardiovascular Diseases. Key objectives included (1) establishing an evidence-based knowledge repository for hypertension and coronary heart disease management, (2) enabling real-time specialist teleconsultations, and (3) implementing an efficient clinical decision support question-and-answer system. These interventions targeted measurable improvements in primary care physicians' diagnostic accuracy and guideline-adherent therapeutic decision-making within the trial cohort.

During the first follow-up visit, all patients received an approximately 30-minute standardized informational support intervention, which included disease knowledge education, lifestyle guidance, treatment plan discussions, and follow-up monitoring instructions, among other components. A self-designed quiz was administered before each of the 2 subsequent follow-up visits to assess the patients' understanding of the informational support content from the previous session. The quiz consisted of a total of 9 questions, with 3 questions for each dimension. On the basis of the quiz results, targeted support was provided to address the patients' weak areas to consolidate the effectiveness of the informational support. The detailed intervention framework is shown in Table 1.

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Table . In-person follow-up protocol for hypertension management: a structured face-to-face intervention framework targeting blood pressure control and lifestyle modification.

Follow-up content and intervention module	Standardized intervention content
Disease knowledge	
Disease education	• Pathophysiology: hypertension staging and target organ damage warning signs (heart, brain, kidney, or retina) • Metabolic targets (BP[a]: <140/90 mm Hg at the clinic and <135/85 mm Hg at home; fasting glucose: ADA[b] standard of <5.6 mmol/L; LDL-C[c]: ACC[d] and AHA[e] guideline of <2.6 mmol/L)
Lifestyle recommendations	
Nutrition management	• Sodium restriction: salt restriction spoon (≤6 g per d) and identification of hidden sodium sources • Dietary modification: 300-500 g of vegetables (>50% dark colored), 200-350 g of fruits (low GI[f] preferred), and >50% of whole grains
Addiction cessation	• Stepwise smoking cessation: nicotine replacement therapy options and withdrawal symptom management • Alcohol control: alcohol abstinence
Exercise prescription	• Personalized exercise plan: target heart rate zone (Karvonen formula); 3-5 sessions of 40-60 min per wk of aerobic exercise and 2 sessions per wk of resistance training • Sedentary behavior intervention: 2-min activity breaks every 30 min
Weight management	• Caloric deficit protocol: 300-500 kcal per d deficit and 1.2-1.5 g per kilogram of protein intake (normal renal function) • Central obesity control: waist circumference monitoring (<90 cm for male individuals and <85 cm for female individuals)
Treatment plan	
Medication	• Conduct patient-centered therapeutic education: explain pharmacological mechanisms, potential adverse effects, and medication administration protocols; collaboratively identify adherence barriers; and codevelop personalized strategies to overcome these obstacles
Monitoring and follow-up	
Monitor and document BP readings and tailor subsequent follow-up care	• Instruct the patient on how to monitor and record BP in a standardized manner and provide guidance on the timing of the next follow-up visit

[a]BP: blood pressure.

[b]ADA: American Diabetes Association.

[c]LDL-C: low-density lipoprotein cholesterol.

[d]ACC: American College of Cardiology.

[e]AHA: American Heart Association.

[f]GI: glycemic index.

Telephone Follow-Up

Monthly telephone consultations were conducted by trained community nurses. If the initial call went unanswered, up to 3 additional attempts were made on separate days within the same month. Each consultation lasted approximately 10 to 15 minutes. During these calls, nurses (1) assessed patients' home blood pressure measurements, dietary habits, and physical activity levels over the preceding month; (2) evaluated medication adherence using the scale recommended by the 2018 Chinese hypertension guidelines; (3) provided tailored encouragement for adhering to recommended lifestyle modifications; (4) addressed patient concerns; and (5) reminded patients to attend their next scheduled in-person follow-up visit.

Outcome

This study explicitly took medication adherence as the primary outcome, with blood pressure, lifestyle adherence, and other blood test indicators as exploratory outcomes.

Primary Outcome

Patient medication adherence was measured via a scale recommended by the 2018 Chinese hypertension guidelines [10] at baseline and 3 months. This scale demonstrated good

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reliability and validity, with a Cronbach α coefficient of 0.736 and a content validity index of 0.970. On the basis of the total score, medication adherence was categorized into 3 levels: low (<6 points), moderate (≥6 and <8 points), and high (8 points; Table S1 in Multimedia Appendix 1).

Secondary Outcome

Lifestyle adherence was evaluated using the healthy lifestyle index (HLI), with total scores ranging from 0 to 9. Higher scores indicate superior adherence behaviors. The HLI comprises 9 risk factors, specifically including smoking (0 - 2 points), BMI (0 - 1.5 points), physical activity (0 - 1.5 points), high-sodium diet (0 - 1 point), alcohol consumption (0 - 1 point), low fruit intake (0 - 0.5 points), sleep (0 - 0.5 points), whole grain intake (0 - 0.5 points), and sugar-sweetened beverage intake (0 - 0.5 points). This proportion allocation is based on the ranking of disease burdens (measured using disability-adjusted life year percentages) of various risk factors in the 2017 Global Burden of Disease Study [11]. Following the principle of "higher risk, higher weight; lower risk, lower weight," scores are assigned to 9 key lifestyle dimensions, with a total of 9 points. This design aims to scientifically reflect the differential health impacts of each behavior and achieve quantitative assessment of lifestyle adherence. Specific items and determination criteria are shown in Table S2 in Multimedia Appendix 1. The reliability of the HLI was tested in 50 pilot participants: internal consistency was acceptable (Cronbach α=0.71), and test-retest reliability over 2 weeks was good (intraclass correlation coefficient=0.82).

Blood pressure metrics comprised clinic measurements and 24-hour ambulatory monitoring. For clinic blood pressure measurement, the Omron HBP-1300 was used, which has passed the British Hypertension Society A/A validation protocol and the European Society of Hypertension International Protocol 2010 revision. For ambulatory blood pressure monitoring, the Omron M2-180A was used; this model fulfills the Association for the Advancement of Medical Instrumentation and International Organization for Standardization 81060-2:2018 accuracy criteria. There should be no fewer than 20 active readings during the daytime and no fewer than 7 active readings during the nighttime. The total number of active readings within a 24-hour period must account for more than 70% of all measured instances. Health-promoting lifestyle was assessed using the Health-Promoting Lifestyle Profile II–Revised, scored on a scale from 1 ("never") to 4 ("always"), and was classified into 6 factors: interpersonal relationships, health responsibility, stress management, nutrition, physical activity, and spiritual growth. The higher the score, the better the health-promoting lifestyle. It was specifically tailored for the Chinese population by Cao et al [12]. Reliability analyses have indicated acceptable internal consistency (Cronbach α=0.63 - 0.81), moderate split-half reliability (0.64 - 0.78) for all subscales, and test-retest stability (r=0.69). Height and weight were assessed using a flexible measuring tape and a body composition analyzer (V-body HBF-371). BMI was calculated using the formula BMI = weight (kg)/height (m) squared. Waist circumference was also measured using flexible measuring tape. Fasting blood samples (3-5 mL) were collected from the median cubital vein during morning hours. Samples were processed within 30 minutes after collection through centrifugation at 3000 revolutions per minute for 10 minutes at 4 °C.

Covariates

This study included age, sex, marital status, educational level, living situation, and household size as covariates.

Data Analysis

Overview

Analyses were conducted on outcomes at baseline and the 3-month postintervention follow-up. Data entry was performed independently by 2 researchers using EpiData (version 3.1; EpiData Association), with subsequent statistical processing completed in SPSS (version 26.0; IBM Corp). For quantitative analysis, univariate descriptive statistics and frequency distribution calculations were performed on the complete sample. Differences in mean values before and after the intervention were evaluated using paired t tests (2 tailed). Effect size, a method quantifying therapeutic impact, was used to interpret intervention efficacy: 0.2 indicates a small effect, 0.5 indicates a medium effect, and 0.8 indicates a large effect. In addition to demonstrating clinical relevance through effect sizes, statistically significant differences were observed in primary outcome measures (P<.05).

Handling of Missing Data

Missing data were managed using a 2-pronged approach to ensure the robustness of our findings. The primary issue involved missing postintervention outcome measures, which occurred in 7% (7/100) of the participants, primarily due to loss to follow-up.

Complete Case Analysis

As an initial sensitivity analysis, we included only participants with complete data at both baseline and the 3-month follow-up (n=93). This approach served to assess whether the results were sensitive to the exclusion of participants with missing data.

Multiple Imputation

For the primary analysis, we used multiple imputation by chained equations using the *mice* package (version 3.14.0) in R (R Foundation for Statistical Computing) to handle missing data. This method was chosen as it is a gold standard for longitudinal data, preserves statistical power, and reduces bias under the missing at random assumption. The imputation model included all baseline variables (eg, age, gender, and baseline blood pressure measures), intervention exposure indicators, and all outcome measures. We generated 10 imputed datasets, and the results were pooled according to the Rubin rules to obtain final estimates and SEs that accounted for the uncertainty inherent in the imputation process.

The complete case analysis provided a benchmark for assessing potential bias introduced by complete case exclusion. The multiple imputation approach, being more robust, was used for the primary inference. The consistency of the intervention effects (statistically significant improvements in primary outcomes) across both analytical approaches enhanced our confidence in the stability and validity of the study conclusions.

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Ethical Considerations

This single-center, pretest-posttest study involving human participants was reviewed and approved by the institutional review board (IRB) of the West China Hospital, Sichuan University (registration 2019; review 573). The IRB specifically evaluated the study design (self–pretest-posttest comparison) to ensure minimal risk to participants, focusing on the safety of the health education intervention and the confidentiality of personal health data.

Written informed consent was obtained from all participants before the baseline assessment. The consent form clearly explained (1) the study purpose (to evaluate the impact of a health behavior intervention on clinical and behavioral outcomes via self-comparison), (2) the procedures (baseline data collection; 3-month intervention, including health education manuals and dietary counseling; and postintervention follow-up), (3) the potential risks (eg, no improvement in outcomes and temporary inconvenience from data collection), and (4) participants' rights (to withdraw at any time without affecting clinical care and access to their deidentified data summary). For participants with low literacy, verbal consent was obtained in the presence of a study nurse (witnessed and documented with the witness's signature), as approved by the IRB.

All personal identifiable information (eg, names and medical record numbers) was removed at the time of data entry. Deidentified datasets were used for all analyses, ensuring that participants' privacy was protected throughout the study.

All participants in this study volunteered to take part and received no financial compensation.

This study was registered with the Chinese Clinical Trial Registry under the identifier ChiCTR2000039621.

Results

Patient Characteristics

We enrolled 100 consecutive patients with hypertension from the general outpatient clinic of a community health care center between May 2019 and June 2019. All 100 patients completed the baseline assessment, 3 (3%) withdrew from the study, and 4 (4%) were lost to follow-up due to relocation. Hence, 93% (n=93) completed assessments at 3 months. Details are provided in Figure 2.

The mean age of the study participants was 60.88 (SD 10.43) years. Most were female (59/100, 59%) and married or cohabiting (96/100, 96%), had a high school education or lower (90/100, 90%), and were living with family (98/100, 98%). Details are provided in Table 2.

Figure 2. Participant flow diagram of a before-and-after study on an informational support intervention for patients with hypertension (postintervention time point and 3-month follow-up assessments; Cuqiao Community Health Service Center).

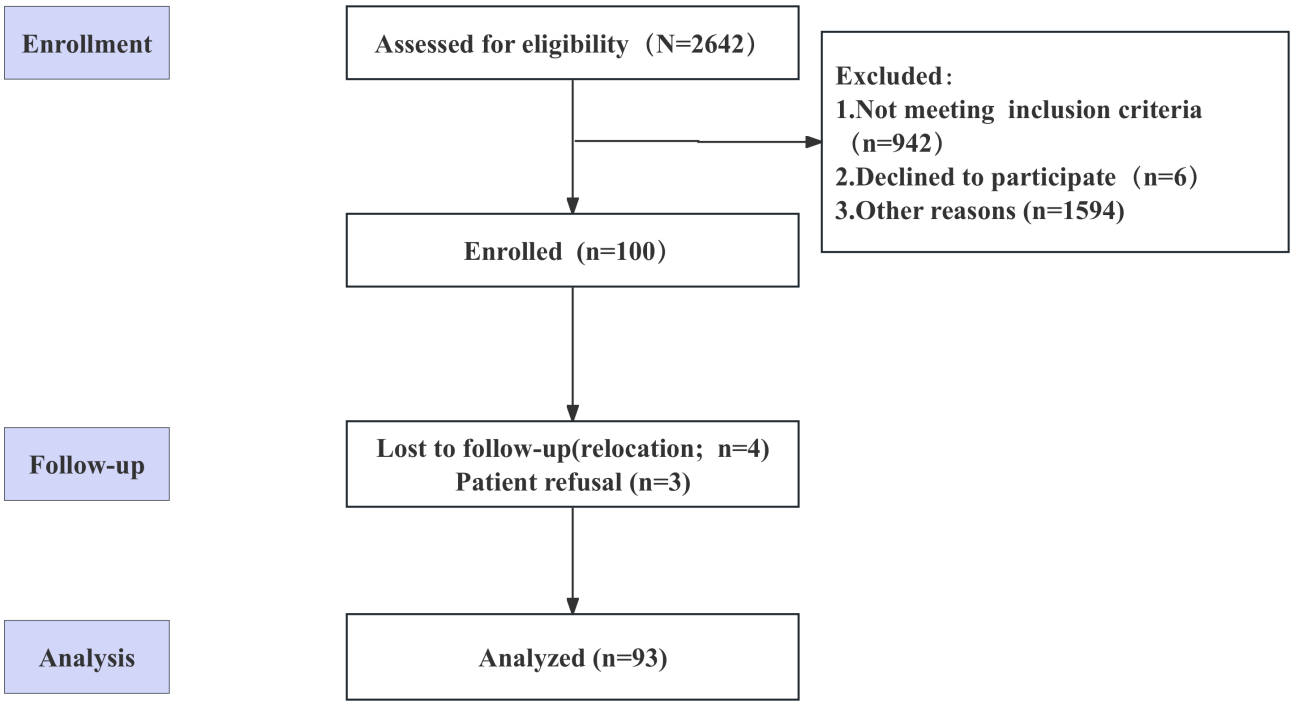

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Table . Baseline characteristics of patients with hypertension at the Cuqiao Community Health Service Center (N=100).

Characteristic	Values
Age (years), mean (SD)	60.88 (10.43)
Sex, n (%)	
Male	41 (41)
Female	59 (59)
Marital status, n (%)	
Married or cohabiting	96 (96)
Divorced	0 (0)
Widowed	4 (4)
Educational level, n (%)	
Primary school and lower	29 (29)
Middle school	28 (28)
High school	33 (33)
College	8 (8)
University	1 (1)
Postgraduate	1 (1)
Living alone, n (%)	
No	98 (98)
Yes	2 (2)
Number of family members participants lived with, n (%)	
1-2	27 (27)
3-4	25 (25)
≥5	48 (48)

Pre- and Postintervention Differences in Adherence

The medication adherence score exhibited a statistically significant improvement of 0.65 points (95% CI 0.38 to 0.91; *P*<.001) at 3 months after the intervention compared to baseline measurements. In contrast, the lifestyle adherence score exhibited a modest increase of 0.24 points (95% CI 0.17 to 0.64; *P*=.25) following the intervention.

Health Promotion Behaviors

Statistically significant differences were observed in the nutrition (*P*<.001), interpersonal relationships (*P*=.001), health responsibility (*P*=.001), and overall health-promoting behavior scores (*P*=.001) of patients with hypertension before vs after the intervention. However, no statistically significant differences were detected in the physical activity (*P*=.54), stress management (*P*=.14), and spiritual growth (*P*=.17) dimensions. Details are provided in Table 3.

Table . The difference in health behaviors before and after an informational support intervention in a before-and-after study of patients with hypertension at the Cuqiao Community Health Service Center.

Domain	Baseline, mean (SD)	3 months, mean (SD)	Mean difference (95% CI)	*P* value	Cohen *d*
Nutrition (0-24)	11.17 (2.90)	12.48 (1.99)	1.31 (0.53 to 2.09)	<.001	0.353
Physical activity (0-32)	15.86 (4.35)	16.24 (4.10)	0.38 (–0.84 to 1.61)	.54	0.065
Stress management (0-20)	8.54 (3.32)	9.17 (2.77)	0.63 (–0.22 to 1.48)	.14	0.154
Interpersonal relationships (0-20)	9.57 (3.16)	10.76 (2.39)	1.17 (0.33 to 2.02)	.007	0.287
Health responsibility (0-44)	16.62 (4.62)	19.03 (5.55)	2.42 (1.03 to 3.80)	.001	0.364
Spiritual growth (0-20)	8.56 (3.48)	9.22 (3.09)	0.67 (–0.30 to 1.64)	.17	0.154
Total scores (0-160)	70.29 (12.72)	77.10 (13.53)	6.81 (3.01 to 10.61)	.001	0.379

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Clinical Outcomes

The postintervention nocturnal blood pressure parameters exhibited statistically significant reductions, with SBP decreasing by 5.07 mm Hg (95% CI –8.12 to –2.01; *P*=.001) and DBP decreasing by 3.39 mm Hg (95% CI −5.12 to −1.67; *P*<.001). In contrast, no statistically significant alterations were observed in daytime SBP or DBP (*P*=.19 and *P*=.72, respectively), 24-hour ambulatory blood pressure metrics (SBP: *P*=.52; DBP: *P*=.76), waist circumference (Δ=–0.08 cm; *P*=.89), or BMI (Δ=0.27 kg/m^2; *P*=.17) following the intervention protocol. Office blood pressure measurements, BMI, waist circumference data, and laboratory indicators are presented in Table 4, whereas ambulatory blood pressure monitoring results are illustrated in Figure 3.

Table . The difference in clinical outcomes before and after an informational support intervention in a before-and-after study of patients with hypertension at the Cuqiao Community Health Service Center.

Variable	Baseline, mean (SD)	3 months, mean (SD)	Mean difference (95% CI)	*P* value	Cohen *d*
Systolic blood pressure (mm Hg)	131.80 (11.76)	131.82 (10.38)	0.07 (−2.37 to 2.51)	.96	0.006
Diastolic blood pressure (mm Hg)	78.17 (8.45)	77.87 (7.56)	−0.39 (−2.30 to 1.52)	.68	0.042
BMI (kg/m^2)	25.17 (2.79)	25.44 (3.22)	0.27 (0.12 to 0.66)	.17	0.293
Waist circumference (cm)	86.07 (7.43)	85.99 (6.18)	−0.08 (−1.18 to 1.03)	.89	0.014
Glucose (mmol/L)	5.56 (1.26)	5.40 (0.75)	−0.17 (−0.45 to 0.11)	.24	0.124
Triglycerides (mmol/L)	1.61 (0.89)	1.56 (0.66)	−0.06 (−0.24 to 0.13)	.54	0.064
Total cholesterol (mmol/L)	5.00 (1.04)	4.86 (0.87)	−0.14 (−0.39 to 0.11)	.27	0.116
Low-density lipoprotein cholesterol (mmol/L)	1.58 (0.23)	1.56 (0.35)	−0.02 (−0.08 to 0.05)	.64	0.114
High-density lipoprotein cholesterol (mmol/L)	2.76 (0.86)	2.64 (0.97)	−0.11 (−0.31 to 0.09)	.28	0.049

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Figure 3. Impact of informational support on ambulatory blood pressure in patients with hypertension: comparison of baseline vs 3 months after the intervention in a before-and-after controlled study (Cuqiao Community Health Service Center). DBP: diastolic blood pressure; SBP: systolic blood pressure.

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Discussion

This community-based implementation study addressed the aim stated in the Introduction section to evaluate whether a structured informational support intervention could improve adherence, lifestyle behaviors, and clinical outcomes in patients with hypertension. It provides novel evidence of feasibility (93/100, 93% retention, exceeding the National Institutes of Health's 80% benchmark) and preliminary efficacy, with findings aligned with the reach, effectiveness, adoption, implementation, and maintenance framework's reach and adoption dimensions, suggesting strong potential for scale-up in resource-limited settings.

Adherence Indicators

According to social support theory, informational support enhances adherence by boosting health literacy (eg, helping patients understand how medications control blood pressure) and self-efficacy (eg, building confidence to manage side effects) [13]. Consistent with this, we observed clinically meaningful improvements in medication adherence scores. Notably, 73.1% (68/93) of the patients showed improved adherence, a rate comparable to that of recent RCTs of health literacy interventions [14]. While HLI scores increased nominally, this aligns with prior work showing that lifestyle modification is more challenging than medication adherence [15]. This may be attributed to the fact that the short-term benefits of changes in lifestyle are less pronounced than those of medications, which has also led patients to place less emphasis on long-term lifestyle modifications. This suggests that future research should pay greater attention to lifestyle changes, enhance the intensity of related interventions, extend intervention durations, and prioritize the monitoring of adherence to lifestyle interventions so as to achieve better intervention outcomes.

Health Behavior

Traditional hypertension interventions often use one-off health education or target single groups, leading to low engagement [16]. The improvements in nutrition and interpersonal relationship scores in our study may be associated with the intervention. However, physical activity remained unchanged, likely because we did not include personalized tools such as activity trackers or weekly feedback—consistent with longitudinal studies highlighting exercise adherence as a persistent challenge. Future studies should integrate objective activity monitoring to bridge this gap.

Clinical Outcome

Our study data revealed that enrolled community-dwelling patients with hypertension exhibited well-controlled blood pressure and other cardiovascular risk factors. This observation suggests potential associations with the socioeconomic characteristics of the study population: all participants were recruited from Chengdu's first-tier economic zone, where robust primary care management systems and higher resident health literacy may be associated with optimized baseline risk factor control. Consequently, the intervention implemented in this study demonstrated limited potential for further improvement in clinical outcomes given that the population's preexisting optimal management status may have created a ceiling effect for measurable therapeutic efficacy. Previous longitudinal cohort studies have indicated that clinically significant improvements in anthropometric parameters (eg, waist circumference and BMI) typically require a minimum of 6 months of sustained intervention to achieve detectable changes [17]. Additionally, each 1-cm reduction in waist circumference corresponds to a cumulative energy deficit of approximately 7700 kcal based on adipose tissue energy density estimates. Achieving such energy imbalance through lifestyle interventions typically requires ≥180 days, consistent with adipose tissue turnover kinetics [18]. Existing studies have confirmed that the cardiovascular benefits of nocturnal blood pressure dipping significantly surpass those of daytime blood pressure reduction [19]. Our study found that informational support was associated with marked improvements in nocturnal blood pressure. Although few recent studies have explored the intervention effects of social support on ambulatory blood pressure, previous research has corroborated our findings [20,21]. This aligns with previous theoretical studies on social support, potentially mediated by improved sleep quality [22], enhanced treatment adherence, and buffering of psychological stress [13,23], with informational support identified as the most significant predictor [24]. Therefore, the implementation of comprehensive informational support for patients with hypertension in community settings holds promise for reducing nocturnal blood pressure and improving cardiovascular outcomes.

Additionally, no statistically significant differences were observed between pre- and postintervention levels of clinical indicators such as blood glucose and lipids. This null effect may be attributable to the relatively brief duration of our intervention. Future research should lengthen intervention periods and increase intervention intensity to optimize effectiveness.

Strengths and Limitations

This study investigated the effects of informational support on medication adherence, blood pressure control, adoption of healthy lifestyles, and clinical indicators among patients with hypertension. The findings demonstrate significant clinical implications: observed improvements in patient adherence, nocturnal blood pressure, and select health behaviors may collectively contribute to reduced cardiovascular risk and enhanced quality of life.

Several limitations warrant consideration. First, while the prospective design addressed temporal relationships, the absence of a control group represents a critical issue that not only complicates causal inference but also makes it impossible to avoid the influence of confounding factors such as seasons. However, it is crucial to note that this feasibility pilot study aimed to generate preliminary data essential for designing methodologically robust large-scale trials. Second, there is potential reporting bias as self-reported measures constituted portions of the dataset. Third, recruitment from resource-advantaged communities within Chengdu may limit generalizability. Participants' elevated health literacy and physicians' structured management protocols likely yielded response patterns not fully representative of broader populations.

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Future investigations should prioritize multiregional sampling to enhance external validity.

Conclusions

In conclusion, this feasibility study indicates that delivering a structured informational support intervention in a community setting is feasible and acceptable. We observed promising preliminary changes in key outcomes such as medication adherence and nocturnal blood pressure. These findings, while preliminary, justify and inform the design of a full-scale RCT to rigorously evaluate the efficacy of this approach.

Funding

No funding was received for this study.

Data Availability

The data are available upon request.

Authors' Contributions

CH contributed to study design and writing. RY and LL collected the clinical specimens and information. YJ and XL led the conceptualization and study design and oversaw the project administration and timeline. All authors read and approved the final manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Scales used in this study.
[DOCX File, 17 KB - formative_v10i1e82147_app1.docx]

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Abbreviations

DBP: diastolic blood pressure
HLI: healthy lifestyle index
IRB: institutional review board
RCT: randomized controlled trial
SBP: systolic blood pressure

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Association of Fall-Risk Factors and Margin of Stability While Tripping in Community-Dwelling Older Adults: Experimental Pilot Study

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Abstract

Background: Falls are a leading cause of injury among older adults, often resulting from dynamic balance disturbances. It is influenced by a complex interplay of intrinsic and extrinsic fall-risk factors. To identify individual fall risks, it is important to understand the underlying associations.

Objective: This study aimed to build an experimental setup modeling selected factors leading to a loss of balance, measured by the margin of stability (MoS) in an ecologically valid real-world example (tripping). Additionally, these analyses aimed to assess the feasibility and safety of the protocol and to explore the use of the MoS as part of a prototypical dynamic fall-risk model to differentiate between fall-risk groups.

Methods: Nineteen community-dwelling older adults (mean age of 71, SD 3.67 y; n=7, 37% women) completed the tripping protocol involving perturbations under various conditions. Clinical assessments were used to identify relevant fall-related intrinsic fall-risk factors. MoS was measured using an 8-camera motion capture system. Receiver operating characteristic analyses determined the ability of MoS to distinguish between low and high fall-risk groups.

Results: Approximately one-quarter of participants discontinued before or at the start of the tripping scenario because of discomfort or fear of perturbations, indicating that perceived safety is an important feasibility factor. Perturbations significantly disrupted MoS, with a median MoS of −106.05 (IQR –181.40 to –41.50) mm during the perturbed step compared to 114 (IQR 81.20-155.20) mm in the preperturbation step. Recovery steps showed progressive stabilization, with the second recovery step achieving a median MoS of 88.45 (IQR 47.50-137.80) mm. The second recovery step exhibited the highest predictive accuracy for fall-risk differentiation, with area under the curve values reaching 82.3% during slow walking with a series of right-sided perturbations. In contrast, fast walking with random perturbations yielded lower area under the curve values (64.9%). Slow walking conditions generally demonstrated the clearest separation between fall-risk groups.

Conclusions: This pilot and feasibility study demonstrates the applicability of a tripping paradigm to perturb MoS in older adults and provides preliminary insights into its association with fall-risk indices. While the protocol proved safe and feasible for fit older adults, perceived safety limited full participation. The findings are exploratory and intended to guide the design of larger prospective studies rather than to establish predictive conclusions. These data suggest that MoS during controlled tripping may help differentiate fall-risk strata, but confirmation will require adequately powered studies in more diverse and frailer older populations—and across multiple real-world scenarios—before any clinical implementation can be considered.

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KEYWORDS

dynamic balance; fall-related activity; fall risk; fall risk factor; laboratory setting; margin of stability

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Introduction

Falls are a major public health concern among older adults, with significant implications for morbidity, disability, and long-term care. According to the World Health Organization, falls are the second leading cause of unintentional injury deaths worldwide, with an estimated 684,000 fatal falls each year—most of them among individuals aged over 60 years [1]. Furthermore, approximately 28% to 35% of people aged 65 years and older fall each year, and recent systematic reviews confirm that physical risk factors such as gait and balance impairments, frailty, chronic disease, and psychological conditions (eg, fear of falling) are among the most consistently associated with fall risk [2,3]. Falls can result in serious consequences including fractures, reduced mobility, loss of independence, and institutionalization. Consequently, research on falls and fall-related aspects has intensified in recent years. This highlights the urgent need for effective prevention strategies.

Despite numerous prevention efforts, fall risk in older adults remains difficult to manage due to the complex interplay of physiological, behavioral, and environmental factors. Systematic reviews demonstrate that multifactorial and exercise-based interventions can reduce fall rates, but findings remain heterogeneous, and many programs show limited transferability to real-world contexts [4-7]. Many current approaches fail to adequately account for this dynamic and multifactorial nature, limiting their effectiveness in real-life contexts [2]. Traditional assessments, such as binary outcomes (fall or no fall), provide only limited insights into subtle changes in fall risk. To overcome these limitations, continuous biomechanical measures like the margin of stability (MoS) have emerged as promising tools for assessing instantaneous fall risk. The MoS, introduced by Hof et al [8], quantifies dynamic stability by considering both the position and velocity of the center of mass (CoM) relative to the base of support (BoS). While MoS has become a widely accepted measure of dynamic stability, most applications to date have been limited to controlled laboratory conditions, such as steady-state treadmill walking. Reviews emphasize that this restricts ecological validity, as real-world falls typically involve unexpected perturbations rather than regular gait cycles [9-11]. Biomechanically, a system is stable when the projected CoM is within the BoS boundaries. However, dynamic situations, such as walking or perturbations, require extending this static concept. The MoS calculates the distance between the extrapolated CoM and the BoS, incorporating movement dynamics. If the extrapolated CoM surpasses the BoS, the MoS becomes negative, indicating instability and the need for corrective actions to prevent a fall. Populations at risk, such as stroke survivors or amputees, often adopt compensatory strategies to increase their MoS. These include widening step width to enhance mediolateral stability, and in some cases, reducing step length to improve anteroposterior MoS [12-14]. These adaptations may help mitigate instability in the frontal plane during walking. While these adaptations enhance stability in the short term, they may limit the ability to respond effectively to unexpected perturbations [15]. Moreover, age-related compensatory strategies such as increased mediolateral MoS have also been observed in healthy older adults, suggesting an altered motor control mechanism to preserve balance [16]. However, these compensatory strategies may mask deficits under steady-state conditions. Studies have consistently shown that when older adults are exposed to perturbations such as slips or trips, they often demonstrate a reduced ability to restore a safe MoS, which is strongly linked to the increased fall risk [11,17,18]. Likewise, several investigations confirmed that reduced MoS during perturbations is associated with impaired balance recovery and elevated fall risk [19-23]. Additionally, Robinovitch et al [18] highlighted from real-world fall video analyses that overconfidence and incorrect weight shifts are major contributors to falls in older adults. These findings emphasize the need to examine both biomechanical and behavioral aspects of fall risk. Against this background, perturbation paradigms such as tripping provide ecologically valid insights into stability and recovery, complementing traditional steady-state gait assessments. To investigate the dynamic interplay of intrinsic and extrinsic factors contributing to falls, this study builds upon findings from the FARSEEING project. The FARSEEING consortium, funded by the EU's 7th Framework Program for Research, collected a dataset of over 200 validated real-world falls measured by body-worn sensors, providing insights into common fall scenarios and environmental factors [24]. The analysis of these real-world data highlighted tripping as one of the most frequent and ecologically valid fall scenarios, which forms the basis for the experimental setup in this study.

However, most sensor devices lack context, environmental conditions, and intrinsic fall risk factors. Reenactment of known fall events has proven to be an effective method for capturing the complexity of real-world falls in a safe, repeatable environment [25]. This method improves simulation protocols and produces realistic fall simulations [26] while enabling further analysis.

In addition, predictive models such as the web-based Fall Risk Assessment Tool for community-dwelling older people (FRAT-up) tool [27] can complement experimental approaches by integrating clinical and environmental factors that contribute to fall risk.

Together, these methodological advances highlight the importance of combining experimental, biomechanical, and predictive approaches to better understand the multifactorial nature of falls. To address this complexity, it is essential to investigate scenarios that are both ecologically valid and relevant to real-life situations. Tripping, being one of the most common and significant causes of falls, serves as an ideal experimental paradigm because of its practical relevance and the ability to replicate it under controlled conditions. This study is part of a broader protocol encompassing four fall-related scenarios aimed at capturing the multifactorial nature of falls in older adults [28]. Tripping was chosen as the initial focus due to its prevalence and ecological validity, providing a solid foundation for exploring dynamic stability in hazardous situations.

Accordingly, the present pilot and feasibility study had two objectives: first, to examine the feasibility and construct validity of a laboratory-based tripping paradigm designed to perturb the MoS in community-dwelling older adults; and second, to explore

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preliminary associations between MoS parameters during perturbation and recovery steps and an independently derived fall-risk index.

Methods

Ethical Considerations

This study was approved by the ethics committee of the University of Tübingen (protocol: 245/2018BO2) and forms part of a broader registered protocol on fall-related scenarios. All participants provided written informed consent for study participation and for the use of deidentified data for scientific purposes. Data were pseudonymized using numeric identifiers and stored on secure institutional servers with access restricted to the study team. No video recordings obtained during the study are published in this paper or supplementary material. No images included in this study permit participant identification. Participants were offered parking tickets to cover travel expenses if needed.

Study Design

This analysis, as a focused part of a broader experimental pilot study on perturbations, simulated a tripping scenario with task variations that increased complexity, such as carrying an object or performing a cognitive task. The broader study also included other perturbation scenarios, such as opening a door, walking on a slippery surface, and standing in a bus while it accelerates. All participants underwent extensive clinical and quantitative assessments and performed the full study protocol to evaluate the effect of different fall scenarios on individual fall risk at the Robert Bosch Hospital, Stuttgart.

Eligibility Criteria

German-speaking, community-dwelling, healthy, as well as prefrail individuals aged 60 years or older were recruited. People who needed more than 12 seconds for the Timed Up-and-Go (TUG) test [29] were classified as prefrail. Exclusion criteria included a current diagnosis of a serious neurological or sensory disease (eg, Parkinson disease and a history of stroke); uncorrected visual difficulties; dizziness; uncontrolled or serious cardiovascular or metabolic disorders (eg, diabetes with neuropathy); cognitive impairments beyond dementia that would preclude informed consent or following multistep instructions (eg, moderate to severe mild cognitive impairment and psychiatric conditions interfering with task compliance) as well as contraindications for perturbations, including osteoporosis, joint replacement, joint stiffening, severe spinal disease, or recent fracture. Participants had to be able to walk continuously for at least 5 minutes without walking aids. This threshold was chosen to ensure that participants could safely complete repeated treadmill trials, adapt to the treadmill, and tolerate perturbations without excessive fatigue. All participants provided their written informed consent and were insured.

Recruitment

Participants were community-dwelling older adults who had previously indicated willingness to be contacted for further research after taking part in earlier gerontological studies at the Robert Bosch Hospital, Stuttgart, Germany. Potential participants were first contacted either by telephone or—if initial information was provided by email or postal mail—were subsequently followed up by telephone. During this call, the study objectives and procedures were explained, allowing individuals to decide whether they were interested in attending an appointment at the hospital's gait laboratory. At the appointment, participants received detailed written study information and had the opportunity to discuss any questions before providing written informed consent.

The study sessions took place in the gait laboratory of the Department of Geriatric Rehabilitation, equipped with an instrumented treadmill and safety harness system. In total, 26 individuals were invited to participate. One individual was excluded on arrival because the inclusion criterion of being able to walk freely for at least 5 minutes was not met, and therefore, no measurements were initiated. Of the remaining 25 participants who started the protocol, 19 completed the full tripping scenario and were included in the analysis. The main reasons for noncompletion were withdrawal due to discomfort or fear of perturbations.

In line with the recommendations by Thabane et al [30], the sample size was set pragmatically based on feasibility considerations. As the primary goal was not hypothesis testing but to assess recruitment potential, study procedures, and the need for protocol adaptation, no formal sample size calculation was conducted.

Clinical Assessments

To identify relevant intrinsic fall risk factors and to describe the cohort, appropriate clinical assessments were selected. These clinical assessments were conducted for all participants prior to the experimental protocol, and all assessments were performed by trained assessors.

Clinical data included sex, age, body weight, physical activity, and medical history. Additionally, the general state of health and comorbidity were evaluated using the Functional Comorbidity Index (range 0 - 18, higher scores indicating more comorbidities) [31]. The occurrence of falls over the past 12 months was recorded. Fall-related self-efficacy was assessed using the short form of the Falls Efficacy Scale-International (FES-I; range 7 - 28, higher scores reflecting greater concern about falling), which is strongly correlated with both previous and subsequent falls [32].

Physical performance was evaluated using the Short Physical Performance Battery (SPPB; range 0 - 12, higher scores indicating better performance) [33] and the TUG test (time in s to stand up, walk 3 m, turn, return, and sit down again; longer times reflect lower mobility) [29].

Experimental Setup

All participants followed the same overarching study protocol, which included 4 ecologically valid scenarios: tripping, opening a door, walking on a slippery surface, and standing in a bus while it accelerates. These scenarios were selected based on data from the FARSEEING database [24], with the tripping scenario standing out due to its high frequency and relevance in real-life fall situations, as well as its significant public health

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impact. Consequently, this first analysis focuses specifically on the tripping scenario. For safety reasons and to prevent injuries, participants wore a safety harness that ensured no contact with the ground except for their feet. All study participants received instructions for safe performance (including guidance on shoes and safety harness) and were asked to perform all paradigms as long as they felt comfortable. The test protocol involved the primary activity of tripping while walking on a treadmill, combined with additional tasks to progressively increase the level of difficulty.

To induce tripping repeatedly, 2 attachment loops were fixed to the participants' heels with a custom-made strap fixation (see Multimedia Appendix 1 for a schematic illustration of the experimental setup). Initially, participants walked on the treadmill at a self-selected gait speed to acclimate to the treadmill. Self-selected speed was defined as a comfortable walking pace at which participants reported feeling at ease on the treadmill. They were informed that the speed would later be increased, so they were asked to choose a relaxed, "strolling" pace rather than a fast or strenuous one. After this habituation phase, the inelastic cords were hooked into the attachment loops. Two inelastic cords, attached behind the treadmill, were adjusted in length with low resistance via a coil spring while the participant walked. The length variation of the cords could be interrupted at the push of a button. When the button was pressed at the end of the stance phase, the subsequent swing phase was perturbed. At random intervals, participants' feet were briefly blocked until the button was released, perturbing the swing phase while allowing continuous walking without stopping or limping. The sequence of perturbations was pseudorandomized: one random sequence was generated at the beginning of the study and then applied identically to all participants. This sequence was unknown to the participants and consisted of 4 right-foot and 3 left-foot perturbations. A fall event was defined by registering more than 30% of body weight on a load cell attached to the safety harness [34].

Additional tasks included carrying a laundry basket, interacting with a memory buzzer game, and increasing the self-selected gait speed by 33%. The memory buzzer was a children's electronic memory game with 1 central button and 4 colored outer buttons that lit up and were accompanied by an acoustic signal. Participants were required to press the correct button as quickly as possible. If successful, the sequence was extended by 1 additional stimulus, while the previous sequence had to be repeated in the correct order. This created a progressively more demanding cognitive motor dual-task condition during treadmill walking.

Measurement Instruments

An 8-camera VICON T10 system (Vicon Motion Systems Ltd) was used to record absolute body motions and limits of stability at 100 Hz. The VICON motion tracking system is able to measure a person's movement and its duration with high precision. Reflective markers were placed at anatomical landmarks (eg, shoulders, pelvis, knees, and ankles) according to the standard plug-in gait model (Vicon, Oxford Metrics). This widely used biomechanical model estimates joint centers and whole-body CoM from segmental anthropometric data, allowing reproducible calculation of kinematic variables. This means that the software reconstructs a simplified skeleton from the marker positions and uses it to calculate gait parameters such as CoM position and velocity. Treadmill speed was continuously measured via the same system.

All laboratory experiments in this project were also recorded by a video camera (Basler pilot piA640-210gc).

Outcome Measure and Data Analysis

3D data were processed in Vicon Nexus 2.14.1 and analyzed in MATLAB (version r2023a; the MathWorks Inc). Small gaps in marker trajectories, up to 20 frames, were filled with a spline function, and marker trajectories were filtered with the Vicon plug-in gait standard Woltring filter [35]. Large gaps were filled using the Vicon Bodybuilder. The marker-based CoM position was extracted from the plug-in gait model. Using a custom-developed algorithm in MATLAB, toe-off and heel strike events were automatically detected. During perturbations, events were manually set if the automatic algorithm missed events due to transient marker occlusions. In such cases, synchronized video and marker trajectories were reviewed frame-by-frame. This ensured consistent event identification despite occasional signal artifacts.

Once the events were defined, the MoS was calculated for each heel strike in the anterior-posterior direction. The calculation was based on the approach described by Hof et al [8], but with modifications to account for treadmill conditions. Specifically, the extrapolated center of mass (x_{CoM}) was computed by incorporating treadmill belt speed into the CoM velocity (sign chosen according to the laboratory axis conventions):

$$xCoM = CoM + vCoM - vtreadmill\sqrt{g/l}$$

CoM is the anterior-posterior center of mass position, v_{CoM} its velocity, $v_{treadmill}$ the treadmill belt speed, g the gravitational acceleration, and l the effective leg length. In our implementation, leg length was approximated as the distance between the center of mass and the heel marker at heel strike. The MoS was then determined as the distance between the anterior boundary of the BoS at heel strike and the x_{CoM}. For all steps, the toe markers of the plug-in gait full-body model were used to define the anterior and posterior boundaries of the BoS. This consistent definition was chosen to simplify event detection across leading and trailing limbs and to ensure uniform processing of all gait phases.

$$MoS = BoSboundary - XCoM$$

Statistical significance was assessed using the nonparametric paired Wilcoxon test to analyze differences between steps, including the step immediately before the perturbation, the perturbed step, and the subsequent 3 recovery steps.

The initial study protocol aimed to use experimentally induced falls as the primary outcome. Falls were defined as harness loads of at least 30% of body weight. Post hoc inspection of the load-cell data (for methodological verification) showed that brief peaks above this threshold occurred 9 times across all perturbation trials. However, none of these events represented a visible loss of balance with full suspension in the harness, and participants were able to continue walking without interruption.

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Because these short, isolated peaks were not reproducible and did not meet the practical definition of an observable fall, no actual falls were analyzed. Consequently, fall-risk stratification was conducted using the FRAT-up tool as a proxy measure. To calculate the risk of falling, we used an updated version of the FRAT-up, a web-based application designed to assess fall risk in community-dwelling older adults. The original tool, referenced in [27], has been modified, and in this unpublished updated version, 2 changes were implemented: the short FES-I replaced the fear of falling assessment by Deshpande et al [36], and the 4-meter walking test was used instead of the TUG test. The updated version was chosen because it incorporated clinical and functional assessments collected in this study and thus allowed for better integration with our dataset. The FRAT-up tool was populated with the collected data, including gender, age, fall history, use of walking aids (yes or no), Parkinson disease (yes or no), stroke (yes or no), diabetes (yes or no), time for the 4-meter walking test, and the score from the short FES-I. Variables not directly assessed in our protocol—such as other comorbidities or medications—were left blank and subsequently populated according to FRAT-up guidance using literature-based prevalence estimates for community-dwelling older adults. These default or imputed values ensure completeness of the FRAT-up risk calculation even when certain data are missing. This approach is consistent with the methodology described by Palumbo et al [27]. To distinguish between high and low fall risk, the participants were divided into tertiles. Tertile classification was applied only as an exploratory approach to illustrate potential differences within the small sample. This division resulted in subgroups with lower, medium, and higher fall risk within the overall group.

To explore the ability of MoS measures to distinguish between these subgroups for the tripping scenario, receiver operating characteristic analyses were performed, providing descriptive estimates of discriminative ability. The receiver operating characteristic analyses focused on identifying the area under the curve (AUC) to determine the model's ability to discriminate between different fall risk categories. Three combinations were used to group the FRAT-up tertiles. Variant 1 considers only the upper and lower tertiles. In the other 2 variants, the middle tertile is combined once with the lower tertile and once with the upper tertile. For all 3 variants, the MoS values for the perturbed step, as well as the subsequent 2 recovery steps, were analyzed. The AUC was also calculated for unperturbed walking in all 3 variants.

All statistical analyses were performed using R (version 4.4.1; R Foundation for Statistical Computing).

Reporting Guideline

The reporting of this study followed the CONSORT (Consolidated Standards of Reporting Trials) extension for pilot and feasibility trials (Checklist 1) [37].

Results

Overview

Figure 1 shows the CONSORT flow of participants through the tripping protocol. Nineteen of the 25 recruited subjects completed the tripping protocol. Six participants who discontinued the protocol expressed fear of falling although they were secured by a safety harness. No adverse events or injuries were observed. Table 1 provides a detailed description of the participants involved in the tripping scenario, with a mean age of 71 (SD 3.67; range 63-76) years, including 7 (37%) women.

On average, participants had 2 (SD 1.65) comorbidities and a mean short FES-I score of 8 (SD 2.27), with scores ranging from 7 to 16. The average SPPB score was 11 (SD 0.96), and the mean time for the TUG test was 8.03 (SD 1.78) seconds, indicating a relatively fit study population. Due to the fact that only 1 (5%) participant had a TUG score of more than 12 seconds, the planned classification into fit and prefrail groups was not implemented. Additionally, only 2 (10%) participants had fallen in the last 12 months. Mean score of the FRAT-up tool was 23.6 (SD 4.17).

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Figure 1. CONSORT (Consolidated Standards of Reporting Trials) flow diagram showing participant inclusion, discontinuation, and analysis in the tripping scenario of the experimental pilot study.

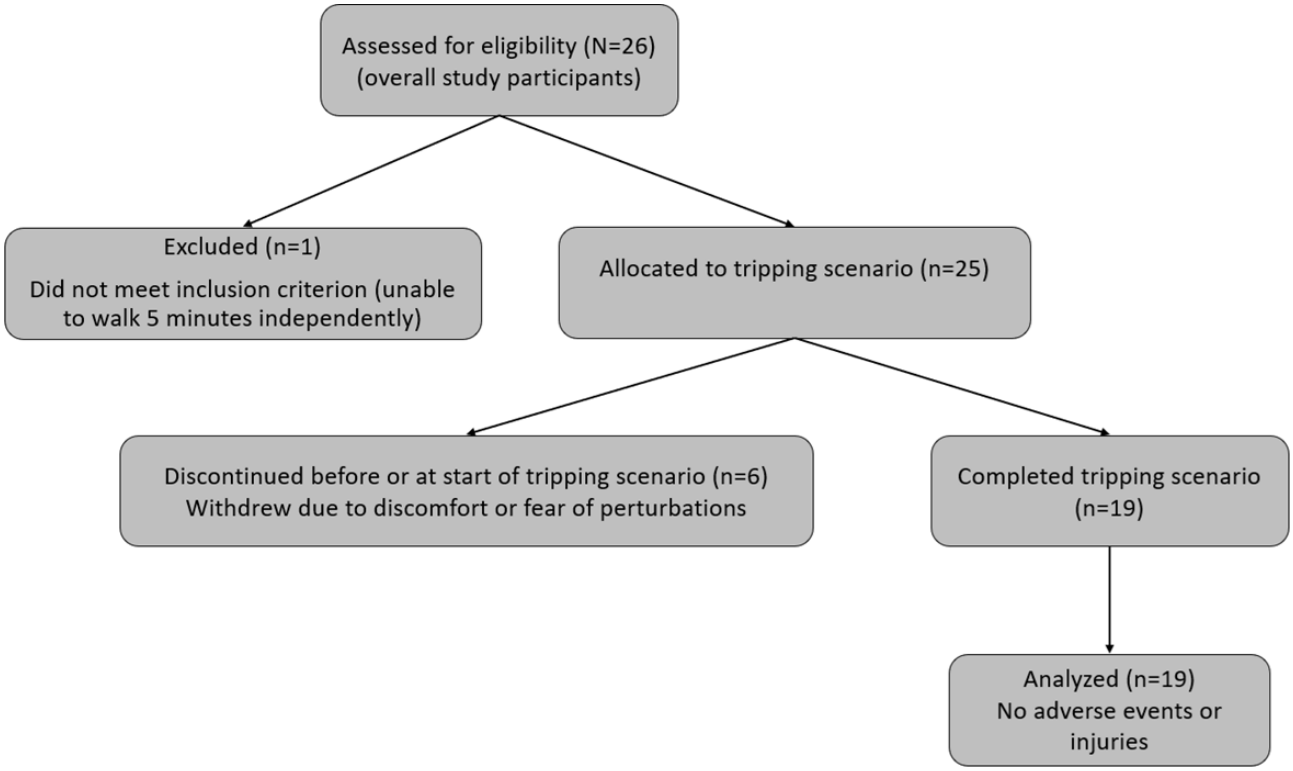

Table . Baseline characteristics of community-dwelling older adults included in the experimental pilot study of tripping perturbations in a gait laboratory (N=19).

Characteristics	Mean (SD)	Min-Max
Age (y)	71 (3.67)	63 - 76
Body height (cm)	173 (8.57)	153 - 185
Body weight (kg)	81 (18.6)	49 - 116
Comorbidities (0 - 18)	2 (1.65)	0 - 6
Short FES-I[a] (7-28)	8 (2.27)	7 - 16
SPPB[b] (0 - 12)	11 (0.96)	9 - 12
TUG[c] (s)	8.03 (1.78)	5.51 - 12.78
Faller (≥1 fall in the last 12 mo)	0 (0.32)	0 - 2
Score of FRAT-up[d]	23.6 (4.17)	20.4 - 33.3
Slow treadmill speed (m s^{-1})	0.57 (0.17)	0.3 - 0.9
Fast treadmill speed (m s^{-1})	0.76 (0.23)	0.4 - 1.2

[a]FES-I: Falls Efficacy Scale–International.

[b]SPPB: Short Physical Performance Battery.

[c]TUG: Timed Up-and-Go Test.

[d]FRAT-up: Fall Risk Assessment Tool for community-dwelling older people.

Evaluation MoS

Figure 2 shows the steps during normal walking at the baseline measurement after the participants have acclimated to the treadmill. Furthermore, as an additional reference, the last step before the perturbation was presented. It can be observed that the median values of the MoS for unperturbed walking at baseline (median 118.85, IQR 96.88-151.50 mm) and the steps immediately preceding the perturbation (median 114, IQR 81.20-155.20 mm) differed significantly (P=.018). Consequently, in the following analysis, the MoS values from the last steps before the perturbation were used for comparison with the values for the perturbed step and the subsequent recovery steps 1 to 3, which are also shown in Figure 2. All

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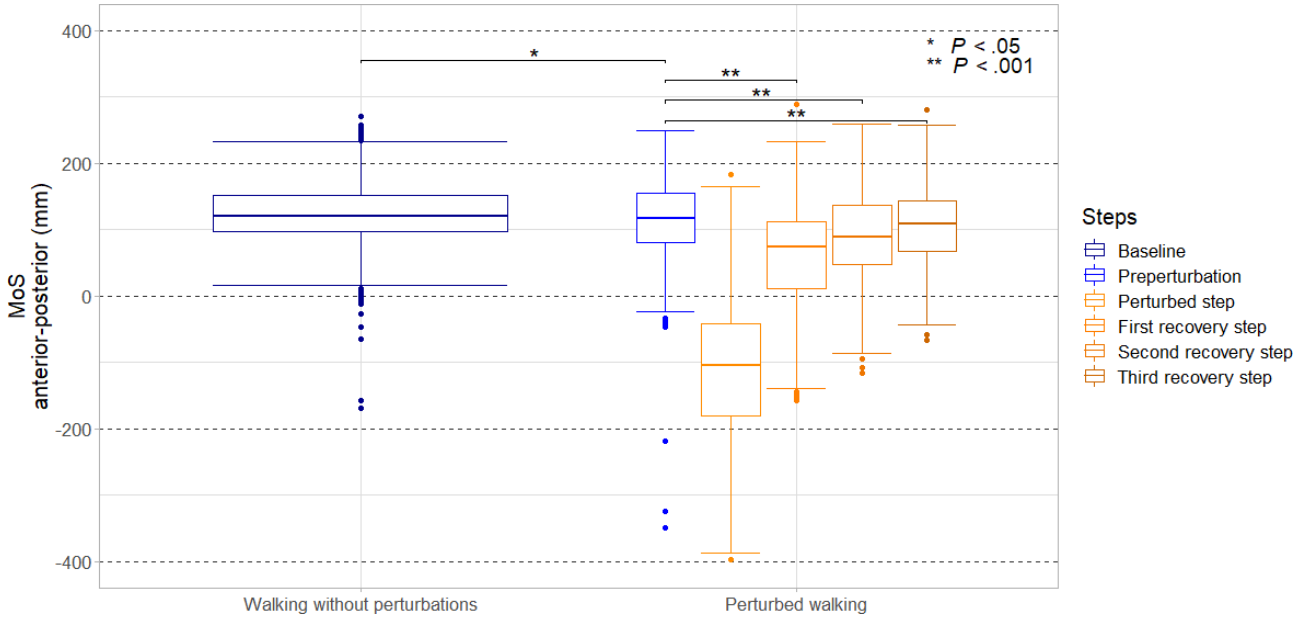
conditions are presented in the same figure to identify the most affected steps for further analyses. The disturbed step showed the greatest difference to the reference values, with a median MoS of −106.05 (IQR −181.40 to −41.50) mm, making it the only step with a median below zero. The difference between the preperturbation step and the perturbed step was highly significant (P<.001), underscoring the disruptive effect of the perturbation on dynamic stability. The first recovery step displayed a median MoS of 74.45 (IQR 11.90-112.80) mm, which is higher than the median value of the perturbed steps, but still significantly lower than the preperturbation step (P<.001). The second recovery step showed further stabilization, with a median MoS of 88.45 (IQR 47.50-137.80) mm, while the third recovery step exhibited a median MoS of 108.8 (IQR 67.10-144.18) mm. Both the second and third recovery steps demonstrated highly significant differences compared to the preperturbation step (both P<.001). Notably, the third recovery step approached the median MoS level of the median value of the preperturbation step. In the following analysis, the perturbed step as well as the recovery steps 1 to 3 were included, as they differed significantly from the reference (preperturbation step) and demonstrated the significant impact of the perturbation on the walking stability.

Figure 2. Distribution of margin of stability (MoS) values in the anterior–posterior direction during unperturbed walking as well as perturbed walking with subsequent recovery steps in community-dwelling older adults (N=19). Boxplots show preperturbation, perturbed step, and recovery steps 1 - 3. Asterisks indicate significant differences between conditions (**P<.001 and * P<.05). Experimental pilot study conducted at the Robert Bosch Hospital gait laboratory, Stuttgart, Germany.



Evaluation of Different Conditions and Step Selection

Figure 3 illustrates the MoS means and 95% CIs stratified for various conditions and fall risk categories. The lower tertile (representing lower fall risk) corresponds to a FRAT score of 21.1% or less, while the upper tertile (representing higher fall risk) corresponds to a FRAT score of 25.6% or more. Table S3 in Multimedia Appendix 2 provides an overview of linear regression coefficients and their variations across steps and conditions.

The analysis focused on the MoS values for the step directly before the perturbation, the perturbed step, and the subsequent 3 recovery steps, which were further divided according to the different conditions.

The preperturbation steps revealed the fluctuating MoS values across all 3 groups. The group with the lowest fall risk consistently exhibited the smallest MoS values, while the group with the highest fall risk usually showed the largest MoS values (eg, in the “slow walking, series of perturbations right” condition, MoS values were 91 mm [lower fall risk], 145 mm [medium fall risk], and 163 mm [higher fall risk]). This trend was also evident during the baseline measurement, before the participants had experienced any perturbation. However, the middle-risk group sometimes also demonstrated higher MoS values, leading to occasional overlaps between risk groups. In the second condition (slow walking, series of perturbations left), the difference between the lower (MoS=108 mm) and the higher fall risk group (MoS=148 mm) was only 40 mm and not significant.

For the perturbed step, the MoS values decreased significantly for all groups (eg, in “fast walking, random perturbation,” values dropped to −171 mm [lower fall risk], −129 mm [medium fall risk], and −117 mm [higher fall risk]). The group with high fall risk exhibited smaller decreases in MoS compared to the other groups. However, an exception to this trend was observed in the condition “slow walking, series of perturbations left” where this difference was not as pronounced (MoS: −97 mm [low], −91 mm [medium], and −64 mm [high]).

The subsequent 3 recovery steps highlighted how participants coped with balance disturbances and their ability to regain equilibrium. Within these steps, MoS values gradually increased across all groups, with the lower fall risk group still showing the lowest values. For example, in “fast walking, random perturbations + memory buzzer,” MoS values recovered to 14

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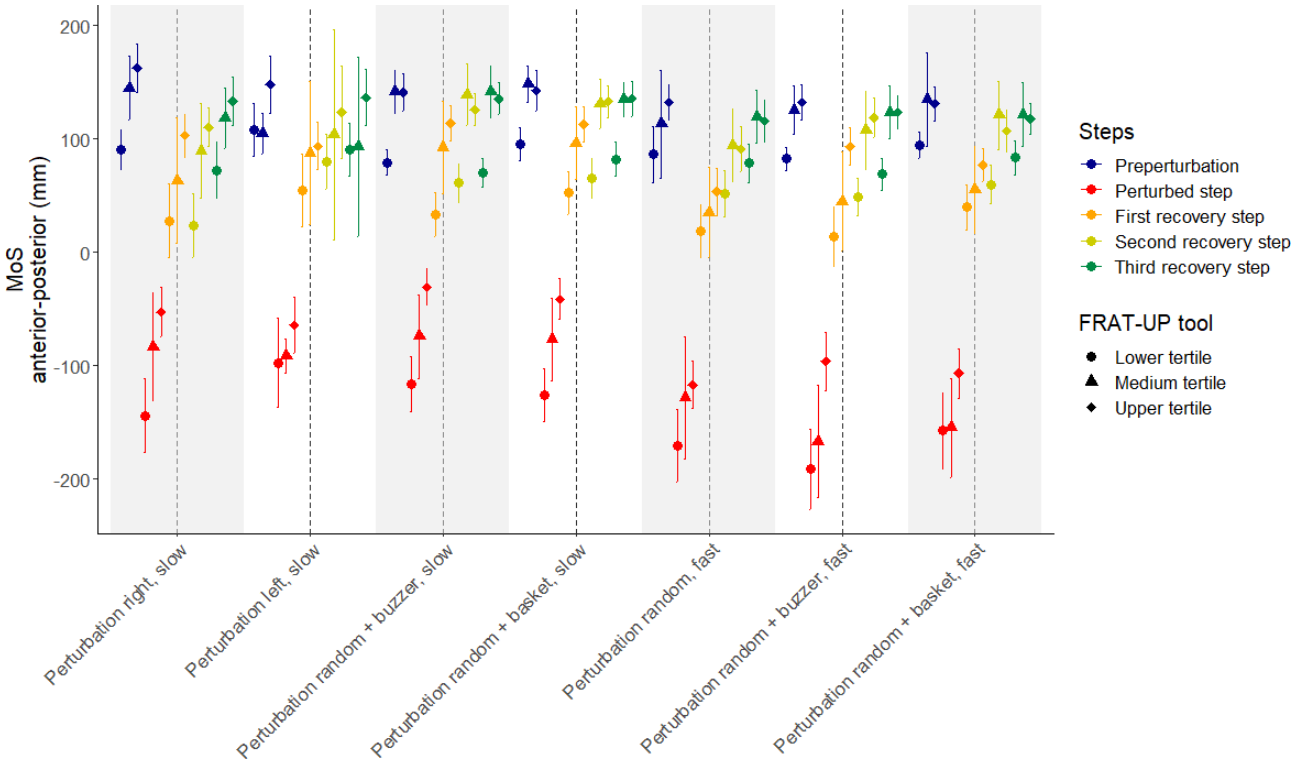
mm (lower fall risk), 45 mm (medium fall risk), and 93 mm (higher fall risk) in recovery step 1, and further increased to 49 mm (lower fall risk), 108 mm (medium fall risk), and 119 mm (higher fall risk) in recovery step 2.

Recovery steps 1 and 2 exhibited stable differences between the groups, with the lower fall risk group maintaining lower MoS values compared to the medium and higher fall risk groups. This trend was consistent across most conditions. In recovery step 3, the average rate of change in MoS decreased, and the separation between the groups became smaller.

The condition "slow walking, series of perturbations left" discriminated the least between the subgroups with lower and higher fall risk, with overlapping CIs. Similar results can be seen regarding the condition "fast walking, random perturbations." Significant differences between the lower and higher fall-risk subgroups could be observed in all other conditions. Furthermore, conditions involving fast walking with an additional task, particularly with the use of the memory buzzer, highlighted the largest differences in MoS values between the groups during the perturbed and recovery steps (eg, perturbed step: −191 mm [lower fall risk], −167 mm [medium fall risk], −96 mm [higher fall risk]; recovery step 2: 49 mm [lower fall risk], 108 mm [medium fall risk], 119 mm [higher fall risk]).

Figure 3. Mean values and 95% CIs of the margin of stability (MoS) in the anterior–posterior direction across different walking and perturbation conditions in community-dwelling older adults (N=19). The x-axis depicts the various perturbation conditions (slow or fast walking, series or random perturbations, and with or without additional tasks), and the y-axis shows MoS values (mm). Colors indicate the chronological steps (preperturbation, perturbed step, and recovery steps 1 - 3), while symbols denote Fall Risk Assessment Tool (FRAT)-up fall-risk tertiles (circle=lower tertile or low risk, triangle=medium tertile, and diamond=upper tertile or high risk). Data were collected in an experimental pilot study at the Robert Bosch Hospital gait laboratory, Stuttgart, Germany.



Evaluation Outcomes

Table 2 presents the results for the AUC values for different analysis variants. Overall, variant 1 (T_{low} vs T_{high}, where T_{low} represents the lower tertile=lower fall risk and T_{high} represents the upper tertile=higher fall risk) yields the best results for unperturbed walking and also for the perturbation scenarios compared to the other two, with AUCs of 76.7% and 86.2%, respectively. However, variant 1 did not include all subjects. Therefore, variants 2 (T_{low} versus T_{mid}+ T_{high}) and 3 (T_{low}+ T_{mid} vs T_{high}) were particularly compared.

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Table . Area under the curve (AUC) for margin of stability (MoS) in differentiating between fall-risk tertiles in community-dwelling older adults (N=19). Experimental pilot study conducted at the Robert Bosch Hospital gait laboratory, Stuttgart, Germany. Comparisons were made between the lower tertile (T_{low}, low fall risk) versus the higher tertile (T_{high}, high fall risk), T_{low} versus the combined middle and higher tertiles (T_{mid}+ T_{high}), and the combined lower and middle tertiles (T_{low}+ T_{mid}) versus T_{high}. Conditions include unperturbed walking, slow or fast walking with series or random perturbations, and perturbations combined with cognitive (buzzer) or motor (basket carrying) tasks. Values are for perturbed walking during the perturbed step, recovery step 1, and recovery step 2. Superscript letters indicate best and worst values within analyses and best discriminative performance across key comparisons.

	T_{low} versus T_{high} (AUC; %)	T_{low} versus T_{mid}+ T_{high} (AUC; %)	T_{low}+ T_{mid} vs T_{high} (AUC; %)
Walking without perturbation (all steps)	76.7	76.5[a]	69.3
Slow walking, series of perturbations right	82.2, 78.4[b], 86.2[c]	78.4, 73.3[b], 82.3[a,c]	75.1, 72.8[b], 77.7[c]
Slow walking, series of perturbations left	60.4, 59.2[b], 69.4[c]	58.8, 58.7[b], 68.9[c]	60.8, 58.7[b], 69.2[a,c]
Slow walking, random perturbations+ buzzer	78.8[b], 81.8, 80.2[c]	72.3[b], 77.5, 80.1[a,c]	75.6[c], 74.0, 69.5[b]
Slow walking, random perturbations+ basket	79.9, 76.4[b], 82.2[c]	74.7, 72.6[b], 81.2[a,c]	74.3[c], 69.6[b], 72.0
Fast walking, random perturbations	66.2[c], 64.0[b], 64.9	63.5, 60.6[b], 64.4[a,c]	63.1[c], 61.1, 59.1[b]
Fast walking, random perturbations+ buzzer	71.7[b], 76.9, 80.7[c]	66.0[b], 70.1, 78.4[a,c]	71.7[c], 74.0, 71.5[b]
Fast walking, random perturbations+ basket	63.4[b], 68.3, 72.7[c]	58.5[b], 63.1, 73.3[a,c]	64.7[c], 64.6, 62.8[b]

[a]Best discriminative performance for the two key comparisons (T_{low} vs T_{mid}+T_{high} and T_{low}+T_{mid} vs T_{high}).

[b]Worst value within that variant.

[c]Best value within a given analysis.

Variant 1 already showed that the second recovery step during perturbation scenarios predominantly demonstrated the best discriminative ability. The same trend was noticeable in variant 2, where the lower and middle tertiles were combined into 1 group. Across all scenarios, the discriminative ability was best during the second recovery step. Baseline walking exhibited an acceptable performance with an AUC of 76.5%. However, the best results were observed in the condition “slow walking, series of perturbations right” (82.3%), followed by “slow walking, random perturbations + buzzer” (80.1%) as well as slow walking with random perturbations and carrying a basket (81.2%). Generally, in all 3 variants, analyses with slow walking speed showed stronger discriminative ability than the others, except for the series of perturbations to the left condition.

In variant 3, the analysis showed the best results during the perturbed step. However, the second recovery step exhibited even better results compared to the first recovery step. When comparing variants 2 and 3, variant 2 outperformed the other one, except for the condition “slow walking, series of perturbations left.” In this case, the discriminative ability was best during the second recovery step. The AUC values for this variant are depicted in Figure 4.

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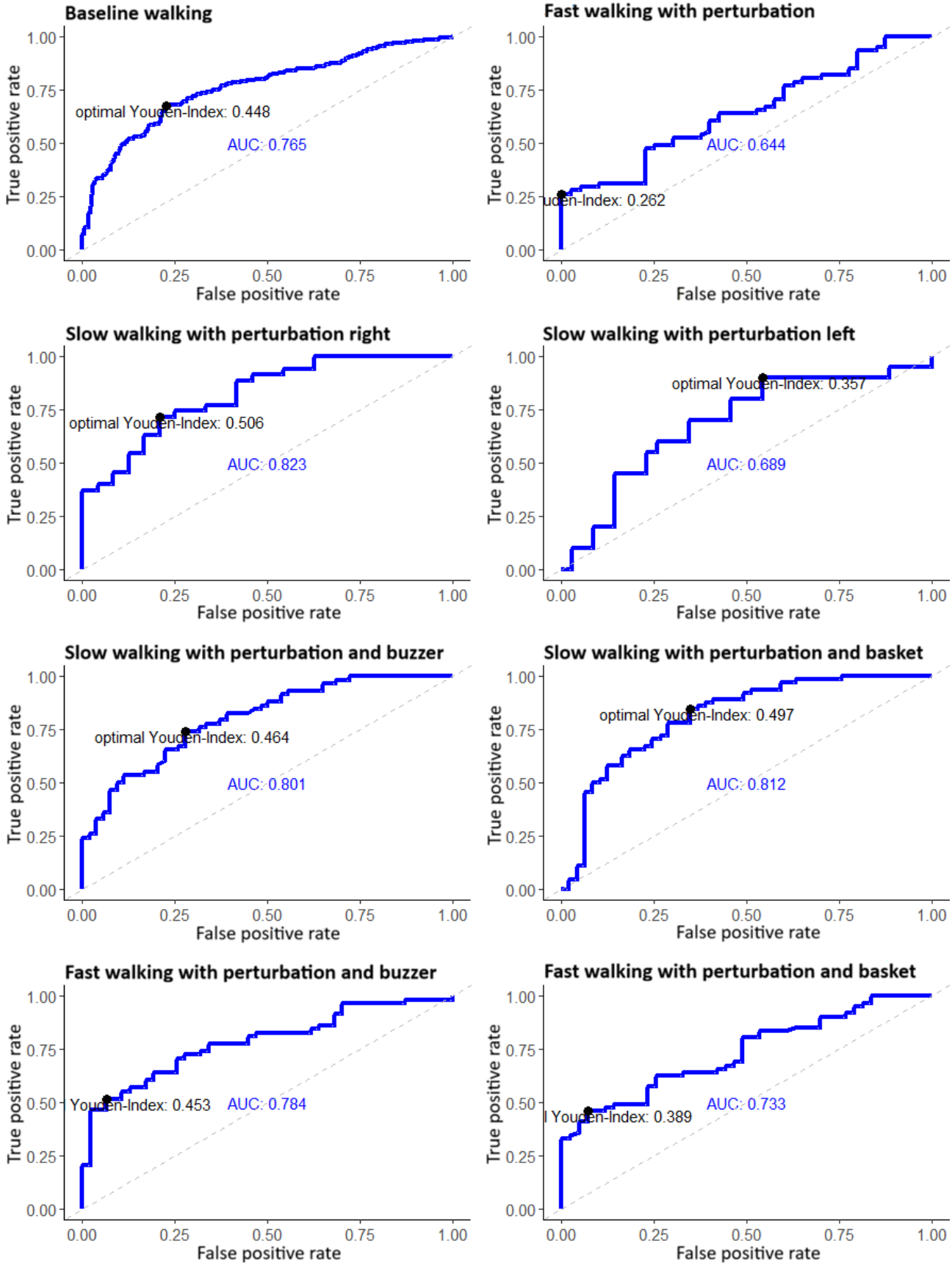
Figure 4. Receiver operating characteristic (ROC) curves showing the area under the curve (AUC) for margin of stability (MoS) values in the second recovery step across different walking and perturbation conditions in community-dwelling older adults (N=19). Analyses differentiate between the lower Fall Risk Assessment Tool (FRAT)-up tertile (representing lower fall risk) and the combined middle and upper tertiles (representing higher fall risk). Panels illustrate results for baseline walking as well as slow and fast walking with perturbations, with or without additional cognitive (buzzer) or motor (basket carrying) tasks. Experimental pilot study conducted at the Robert Bosch Hospital gait laboratory, Stuttgart, Germany.



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Discussion

Principal Findings

This pilot study examined the feasibility of a tripping paradigm and its exploratory association with fall-risk indices in community-dwelling older adults. In terms of feasibility, the study revealed important aspects. Approximately one quarter of participants discontinued before or at the start of the tripping scenario because of discomfort or fear of perturbations. While this confirmed the overall safety of the protocol, it also highlighted that the tripping paradigm may be challenging for older adults with lower confidence or higher frailty levels. These reactions underscore that procedural refinements, such as extended familiarization, gradual perturbation intensities, or shorter testing sessions, may be necessary to enhance tolerability and extend feasibility to frailer populations in future studies. Importantly, the fact that several participants discontinued before or during the tripping scenario highlights a critical feasibility limitation of the current setup. Even among relatively fit older adults, the protocol was perceived as challenging, suggesting that its direct application in frailer populations may not be feasible without substantial procedural adaptation. The study was originally designed to experimentally induce near-falls or loss-of-balance events to assess stability thresholds. However, no participants reached the predefined fall criterion during this scenario, likely because those most prone to losing balance discontinued participation due to discomfort or fear. This indicates that the paradigm may require modification to safely elicit critical balance losses in future, more heterogeneous samples. In this pilot, heterogeneity was not the primary aim; the focus was to first test procedural feasibility and ensure participant safety. Although objective safety was maintained at all times, perceived safety concerns led several participants to discontinue, highlighting that future adaptations should also aim to enhance participants' sense of security when applying the paradigm to frailer populations. Beyond feasibility, three key findings emerged. First, group differentiation was already apparent during baseline walking, suggesting that steady-state gait measures may capture relevant aspects of fall risk even without perturbations. Second, the second recovery step consistently provided the clearest separation between risk strata, highlighting its potential value as a marker of balance recovery capacity. Third, the tertile-based stratification yielded counterintuitive patterns, with higher fall-risk groups sometimes exhibiting larger MoS values, which we interpret in light of compensatory strategies and risk perception. These findings are discussed below in relation to previous research.

Overall, the results highlight the significant impact of perturbations on dynamic stability, as measured by the MoS. Perturbations caused marked disruptions, with the perturbed step showing the largest deviation, evidenced by a median MoS below zero. Recovery steps revealed a gradual stabilization process. While the second recovery step may play a role in recovery dynamics, its specific contribution to fall risk group differentiation remains underexplored in the existing literature. Taken together, this supports the view that recovery dynamics, rather than the perturbed step itself, may provide more nuanced insight into fall-risk differentiation. Additionally, broader research emphasizes the use of dynamic assessments, such as those highlighted by Herssens et al [15], in identifying stability deficits that may relate to fall risk.

Interestingly, differentiation between fall-risk groups was already apparent during baseline walking, even without perturbations. Gait variability in steady-state walking, as emphasized by Menant et al [38], underscores the potential of baseline gait measures for identifying fall risk in diverse populations. While Kazanski et al [12] primarily focused on perturbation-induced variability, their findings align with this perspective. Importantly, recent research has shown that MoS can be reliably estimated using wearable inertial sensors, enabling its use as a low-resource screening tool. Akiyama et al [39] demonstrated that MoS can be classified with over 90% accuracy in both forward and lateral directions using only inertial measurement unit acceleration data, even under gait asymmetry conditions. Similarly, Guaitolini et al [40] validated a mobile, magneto-inertial sensor-based approach to assess MoS with high accuracy in daily living conditions. Baseline walking MoS assessments could serve as a low-resource, accessible screening tool in the future, particularly in settings without advanced perturbation setups. Delbaere et al [41] highlighted that baseline measures are particularly effective in identifying intrinsic stability differences. Their findings also underscore that the disparity between perceived and physiological fall risk significantly influences fall likelihood, reinforcing the importance of considering psychological factors such as overconfidence and fear of falling in screening and prevention strategies.

The tertile classification provides valuable insights into fall risk stratification but also reveals challenges, particularly regarding the middle tertile, where overlaps with low- and high-risk groups complicate interpretation. This limitation likely reflects the high mobility and narrow functional range of the present cohort, reducing between-group differentiation. Accordingly, these results should be considered exploratory.

As outlined in the introduction, prior studies [19-23] generally found that lower MoS is associated with higher fall risk. In contrast, in our exploratory analysis, the low fall-risk group exhibited lower MoS values compared to the high fall-risk group across all conditions. While higher MoS values typically indicate greater stability, this counterintuitive result may be related to differences in risk perception, as suggested by Delbaere et al [41] and Young and Williams [42]. However, these interpretations remain speculative since the cited studies did not involve perturbation paradigms, which primarily elicit automatic postural responses. This unexpected direction of effects also raises questions about how well the present paradigm captures stability differences related to fall risk. Although MoS differences between risk strata were evident, their direction was contrary to theoretical expectations. Further validation in larger, more heterogeneous samples with prospective fall data is needed to challenge this finding. Robinovitch et al [18] analyzed real-life falls in long-term care settings and showed that overconfidence during routine activities, such as walking or standing quietly, often led to incorrect weight shifts, a primary cause of falls. Taken together, these findings suggest that both behavioral and biomechanical factors may contribute to fall

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risk. Future studies should assess confidence levels alongside biomechanical measures to better capture these dynamics.

The analysis of recovery steps confirmed the value of the second recovery step in differentiating fall risk. This step demonstrated consistent increases in MoS and clear differentiation between tertiles, highlighting its significance as a critical phase for assessing fall risk recovery dynamics. In contrast, the third recovery step demonstrated smaller MoS changes and reduced separation between groups, limiting its relevance. These findings align with Song et al [43], who emphasized the importance of early recovery phases in understanding and assessing stability dynamics. One possible explanation for its relevance is that the second recovery step marks the crucial transition where the CoM is brought back into the base of support. During this phase, the remaining destabilizing forces are compensated for, and the body is repositioned, enabling effective balance recovery and overall stabilization. Individuals at high risk of falling might have greater difficulty effectively returning the CoM to the base of support during this step, potentially resulting in poorer balance recovery. As such, analyzing the second recovery step could provide valuable exploratory insights for distinguishing between individuals with higher and lower fall risk, although validation in larger and frailer cohorts is required.

Perturbation response varied across experimental conditions. Slow walking conditions, especially those involving secondary tasks such as carrying a basket or using the memory buzzer, yielded the clearest tertile differentiation, with AUC values reaching 0.823. In contrast, fast walking with random perturbations showed lower AUC values. This is consistent with Song et al [44], who noted that higher walking speeds reduce MoS variability across subjects. There could also be a ceiling effect for stability at high walking speed. Together, these findings emphasize the need to test perturbation paradigms across a range of conditions to identify which are most sensitive for differentiating fall risk.

It was observed that right and left leg responses might differ, but asymmetries in perturbation response were not analyzed separately due to limited data. However, previous studies suggest this could provide valuable insights. Liu and Finley [45] and Kozlowska et al [46] found that dominant legs contribute more to controlling gait deviations, potentially affecting recovery strategies. Including assessment and analysis of effects by limb dominance might further improve the results.

Limitations

This study has several limitations. The small sample size, with only 19 participants completing the tripping protocol out of the initial 25 recruited, limited the generalizability of the findings and reduced statistical power for subgroup analyses. The study population, characterized by high mobility and good balance (as indicated by TUG and SPPB scores), further constrained variability and reduced differentiation between risk groups. No actual falls were observed during testing, partly due to participants' heightened awareness of upcoming perturbations and related discomfort, which also contributed to several dropouts. Because of the absence of fall events, the FRAT-up tool was used as an alternative, exploratory stratification measure. While the FRAT-up tool demonstrated moderate predictive accuracy (AUC=0.65), it lacked a clear cutoff for classification. Additionally, the updated version used in this study has not yet been independently validated, and its psychometric properties remain uncertain.

Another limitation is that interindividual differences in self-selected treadmill speeds may have influenced MoS values, as walking speed directly enters the x_{CoM} calculation. We chose self-selected speed to ensure ecological validity and participant safety, and both slow and fast conditions were defined relative to the baseline. Nevertheless, between-subject comparisons should be interpreted with caution.

Further sources of bias must also be considered. These include possible measurement errors due to transient marker occlusions, manual corrections of gait events, and assumptions in the Plug-in Gait model (eg, estimation of CoM position and effective leg length). Variability introduced by individualized treadmill speeds and the nonparametric statistical methods applied in a small sample further limits robustness. Moreover, certain clinical and environmental risk factors (eg, medication use and home hazards) were not captured in this protocol but may significantly influence fall risk in real-world settings.

The treadmill-based setup, while offering practical replication of real-world scenarios, introduced its own set of challenges. The use of a safety harness, essential for participant safety, may have reduced the perceived risk and potentially influenced behavior during testing.

Conclusions

This pilot and feasibility study provides preliminary evidence that MoS measures differ between fall risk categories in community-dwelling older adults. Baseline walking already showed some group separation, and perturbation trials yielded stronger exploratory associations, particularly in the second recovery step. Slow walking conditions appeared especially sensitive in this small sample. However, these findings must be interpreted cautiously given the small, relatively fit cohort, the exploratory tertile-based stratification, and potential methodological biases. The results should therefore be seen as hypothesis-generating rather than conclusive. Future research with larger and frailer populations, as well as additional fall scenarios, is needed to confirm these preliminary patterns and to determine whether MoS can ultimately serve as a clinically useful measure of fall risk. The fact that no participants reached the predefined fall threshold in this scenario further highlights the feasibility limitations of the current multitask-based setup. There is a need to refine the perturbation paradigms to elicit loss of balance in a safe yet ecologically valid manner, particularly when extending such protocols to more vulnerable populations.

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Acknowledgments

Generative artificial intelligence was only used to create the graphical abstract and the schematic illustration of the treadmill-based tripping experiment setup. No generative artificial intelligence tools were used in data analysis, interpretation, or the writing of the manuscript.

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Data Availability

Raw data are not publicly available to preserve individuals' privacy under the European General Data Protection Regulation.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Schematic illustration of the treadmill-based tripping experiment setup. Participants walked on a treadmill while wearing a safety harness attached to an overhead rail. Straps were fixed to both heels with cords extending backward to induce tripping perturbations.
[PNG File, 837 KB - formative_v10i1e74418_app1.png]

Multimedia Appendix 2
Regression coefficients of the margin of stability (in mm) across different perturbation conditions and steps in community-dwelling older adults (N=19). Values represent regression coefficients stratified by fall-risk tertiles according to the Fall Risk Assessment Tool for community-dwelling older people index (low risk, medium risk, and high risk). Conditions include slow and fast walking with series or random perturbations, as well as perturbations combined with a concurrent cognitive task (memory buzzer) or a motor task (basket carrying). Steps are presented separately for preperturbation, perturbed step, and recovery steps 1-3. Experimental pilot study conducted at the Robert Bosch Hospital gait laboratory, Stuttgart, Germany.
[DOCX File, 18 KB - formative_v10i1e74418_app2.docx]

Checklist 1
CONSORT checklist for pilot or feasibility trial.
[PDF File, 270 KB - formative_v10i1e74418_app3.pdf]

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Abbreviations

AUC: area under the curve
BoS: base of support
CoM: center of mass
CONSORT: Consolidated Standards of Reporting Trials
FES-I: Falls Efficacy Scale–International
FRAT-up: Fall Risk Assessment Tool for community-dwelling older people
MoS: margin of stability
ROC: receiver operating characteristic
SPPB: Short Physical Performance Battery
TUG test: Timed Up-and-Go test

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A Short Patient-Reported Outcome Measure for Oral Anticancer Agents: Multicenter Observational Study

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Abstract

Background: The Michigan Oncology Quality Consortium developed a rapid patient-reported outcome measure (RapidPRO) focused on oral anticancer agents (OAAs). We piloted this measure in 6 oncology practices to determine its usefulness in representing the symptom experience and medication adherence among individuals taking OAAs. It is common in oncology for cancer-specific approaches to be used. We sought to use 1 instrument for all OAAs as a means to simplify future implementation in practice.

Objective: This study aimed to describe the use of RapidPRO in practice and quantify clinical metrics in RapidPRO for symptom burden, confidence to manage symptoms, confidence to know when to seek care, and OAA medication adherence.

Methods: This observational study was conducted across 6 practices from July 2016 to December 2018. RapidPRO assesses symptoms, patient confidence, and medication adherence with respect to OAAs.

Results: There were 2252 RapidPROs completed by 695 patients. Among individuals completing at least 2 RapidPROs, the median number of days between them was 28 (IQR 14-42). Of the 2252 completed RapidPROs, 1213 (53.9%) reported at least one moderate or severe symptom, and 28% (485/1705) reported medication nonadherence. Most bothersome symptoms (MBSs; n=1045) were reported in 35.1% (790/2252) of the RapidPROs, and 46.5% (323/695) of all patients reported an MBS. In exploratory analyses, RapidPROs that reported a moderate or severe symptom or lower confidence to manage symptoms were more likely to be nonadherent to OAA therapy. The most common reason for medication nonadherence was “experienced side effects.”

Conclusions: These results show that most RapidPROs reported at least one moderate or severe symptom and 28% (485/1705) reported medication nonadherence. As well, RapidPRO was able to capture most patients’ MBSs. By implementing RapidPRO, practices can identify patients who experience symptoms, as well as those who report medication nonadherence.

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KEYWORDS

patient-reported outcomes; symptoms; adverse effects; medication adherence; oral anticancer agent

Introduction

The increasing use of oral anticancer agents (OAAs) has led to more convenient medication administration and improved patient survival rates [1-3]. OAAs are a heterogeneous group of oral therapies, including cytotoxic chemotherapies, hormonal therapies, targeted therapies, and immunomodulatory agents, that are administered at home under patient self-management, unlike parenteral chemotherapy administered under direct clinical supervision [3-5]. The benefits of OAAs are significant, including receipt of treatment at home, opportunities for patients to carry on with daily activities, and avoidance of complications from intravenous chemotherapy. As well, patients generally prefer oral medication compared to infusions [4-8]. Despite the ease of OAA administration, this shift in responsibility from oncologists and oncology professionals to patients introduces unique challenges that can negatively impact patients’ quality of life and disease course [9], including difficulties related to medication adherence, self-management of toxicities or adverse effects, and misconceptions that OAAs are less effective than intravenous chemotherapy [8,10-15]. A total of 30% of patients have reported that their symptoms are the primary reason for nonadherence to their OAAs [16].

While the use of OAAs has continued to grow, the ways in which practices assess and support medication adherence and self-management of toxicities are inconsistent. However, OAA

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self-management is crucial and necessitates patient education and confidence to take medication and identify, manage, and/or report treatment side effects [17-21]. Patient-reported outcome measures (PROMs) are reports provided by patients about their own quality of life or functional status as a result of their disease and health care [22]. PROMs provide direct insight into the patient's perspective on symptoms and treatment-related experiences, complementing clinician assessments [23]. In this study, a rapid PROM tool (RapidPRO) was used as a practical monitoring tool to identify symptom burden and medication adherence concerns in real time [24]. PROMs for symptom monitoring have been found to increase quality of life and overall survival when the information is acted upon by oncologists and oncology professionals [25,26]. Because OAAs require significant self-monitoring and patient adherence as compared to infusion therapies, patients' confidence to self-monitor and know when to report symptoms is particularly critical. Evidence from cancer populations indicates that greater self-efficacy or confidence in managing treatment and symptoms correlates with better symptom control and higher medication adherence [27-29]. Therefore, assessing patients' confidence alongside symptom burden may offer a powerful approach to identifying patients at risk of medication nonadherence. While remote symptom-monitoring systems have been increasingly adopted in oncology, assessing patients' confidence to self-manage proactively as part of a PROM is novel.

The Michigan Oncology Quality Consortium (MOQC) is a continuous quality improvement collaborative comprising 46 ambulatory oncology practices that collect and share data about the quality of cancer care. They also implement changes, seeking to improve oncology care and outcomes across the state of Michigan [26-28]. The MOQC developed a PROM (RapidPRO), and it was distributed at selected practice sites to monitor symptom burden and medication adherence. Having 1 PROM rather than drug- or condition-specific measures is likely to increase uptake of PROMs because of the simplicity of using 1 measure and understanding how to use and interpret it [26,29]. Additionally, prior evidence shows that using a single standardized PROM across diverse cancer populations enhances feasibility, supports consistent quality improvement efforts, and provides actionable patient-reported data in routine oncology practice [30]. Therefore, the objective of this study was to (1) describe the use of the RapidPRO in oncology practice and (2) quantify the clinical metrics captured in the RapidPRO for symptom burden, confidence to manage symptoms, confidence to know when to seek care, and medication adherence. In routine practice, it was unclear whether 1 short PROM could be used in daily oncology practice to assess the use of OAAs. What is challenging is working with oncology practices to incorporate such assessments routinely into their workflows, especially before visits so that oncologists and oncology professionals can then discuss the findings with patients during visits. These preliminary results can help us understand whether symptomatology is prevalent and complex across many OAAs and whether such assessments could increase the benefits of cancer care delivery.

Methods

Study Design

This archival, multicenter, observational quality improvement study was conducted across 6 practice sites in the state of Michigan from July 2016 to December 2018. A total of 2252 PROMs were completed by 695 patients from 6 practices during the study period. Patients were eligible to be included in the study if they were aged 18 years or older and taking a US Food and Drug Administration–approved OAA for the treatment of cancer (excluding endocrine therapy). A focus on OAAs excluding endocrine therapy was chosen to emphasize medications with more acute toxicities for which additional support from clinic staff for medication adherence and/or symptom management may be needed. Patients completing the RapidPRO while on OAA therapy were included, and patients could complete more than one RapidPRO during their treatment. Patients completing the assessments could receive concurrent intravenous chemotherapy in addition to an OAA. Six practices participated in this quality improvement study. The practices ranged in size from approximately 400 to 3000 new oncology patients per year and from 2 to 12 full-time medical hematology and oncology physicians. They were geographically located across Michigan and were not academic medical centers.

Ethical Considerations

This study was reviewed by the University of Michigan Institutional Review Board and was determined to be not regulated (nonregulated studies do not require informed consent) as human subject research because it met institutional criteria for quality improvement activities (HUM00099930). The MOQC reimbursed each site a stipend of US $2000 as compensation for their effort in deidentifying the PROM data and sending them to the MOQC. Payment occurred at the completion of 12 months of participation.

Data Collection Process

MOQC practices were able to volunteer to participate in this phase of the MOQC Oral Oncolytics program after they learned about it at the MOQC Biannual Meeting. Each participating practice took part in an introduction phone call where they discussed their current process for managing patients receiving OAAs. All practices also learned about the following five requirements for participation: (1) completion of a baseline survey to quantify the perception of OAA nationally recognized standards; (2) completion of a baseline chart audit (20 patients on OAAs) to quantify OAA nationally recognized standards in the practice; (3) implementation of the RapidPRO at the site for tracking patients' symptoms and medication adherence, where practices were instructed to have patients complete the RapidPRO once within the first month of therapy (ideally 7-10 days after initiation) and then routinely at each outpatient visit; (4) collection of at least 12 months of PROM data sent to the MOQC for evaluation; and (5) completion of a postimplementation survey related to OAA nationally recognized standards. Key team members from each practice also participated in an onboarding call with the MOQC coordinating team. During this call, the MOQC provided training on the use of PROMs for symptom follow-up in oncology, the

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importance of medication adherence during OAA therapy, and best practices from early pilot sites. Practices were also given a concise user guide with recommended follow-up actions based on symptom thresholds and instructions for integrating RapidPRO into workflows. A standardized onboarding process and a single MOQC user guide were provided to all sites to promote uniform administration. To further ensure consistency, all completed RapidPRO forms were centrally entered into REDCap (Research Electronic Data Capture; Vanderbilt University) by MOQC staff rather than by individual sites.

Practices were expected to participate in regular phone calls with frequency determined at the discretion of the MOQC team and the oncology practice. On-site meetings with the MOQC team and MOQC support in developing new workflows were offered and took place on an as-needed basis. Practices were offered a tablet computer if they wished to use it for patients to complete the RapidPRO at the office, and a RapidPRO paper version was also available.

RapidPRO Measure

The RapidPRO was developed to examine symptom burden, confidence in self-managing side effects, and adherence to OAAs [27,31,32]. RapidPRO is a 19-item, 2-page survey that takes approximately 3 minutes to complete. Each patient completed 1 RapidPRO per assessment period regardless of the number of OAAs prescribed. The measure was designed to capture overall treatment-related symptoms and medication adherence without attributing specific symptoms to individual medications. It incorporates a modified version of the Edmonton Symptom Assessment System (ESAS), a validated tool originally designed to assess general symptom burden among patients with cancer [33]. The ESAS has been modified in several contexts to address symptom monitoring in specific populations, such as outpatients with advanced cancer [34]. The modified ESAS in the RapidPRO collected patients' symptom severity on a scale from 0 to 10 (0=none; 10=worst possible). The literature indicates that the ESAS has validity and reliability for patients with cancer [34,35]. For the classification of symptom burden, a score of 1 to 3 was considered mild, a score of 4 to 6 was considered moderate, and a score of 7 to 10 was considered severe [27], and these severity thresholds are consistent with established scoring conventions used in the ESAS literature [33,36]. Symptoms assessed included pain, tiredness, drowsiness, nausea, lack of appetite, shortness of breath, depression, anxiety, best well-being, constipation, diarrhea, tingling or numbness, mouth sores, and rash.

Additionally, a question in the PROM asked patients in a free-text format to identify the most bothersome symptom (MBS) they were experiencing, and patients were allowed to list multiple MBSs. During analysis, 3 clinical reviewers (a medical oncologist, a nurse, and a pharmacist) independently reviewed the MBS responses to categorize them by symptom type based on the review of systems classification [37]. If the categorization for a symptom was inconsistent between reviewers, the symptom was re-evaluated to reach a consensus.

The PROM also included questions asking patients to rate their confidence in managing side effects and their confidence in seeking medical care for side effects on a scale from 0 to 10 (0="I'm not confident"; 10="I am confident") [27,31,32].

Next, patients were asked to rate their medication adherence over the previous month using a 5-point scale ("excellent," "very good," "good," "fair," or "poor"). This single-item measure, previously validated in studies of patients taking antiretroviral therapy, demonstrated good concordance with objective medication adherence data based on pill bottle openings. The 1-month recall period has been shown to reduce overreporting compared with 3- and 7-day recall windows. Similarly, using a 5-point rating scale rather than frequency-based measures further minimized overreporting of medication adherence [38,39], and less than "excellent" corresponds approximately to <80% adherence [38,39]. Because routine assessment of medication adherence in daily oncology practice is challenging, this single-item measure provides a practical approach to identifying patients at risk of medication nonadherence. Reasons for not taking one's OAAs, such as experiencing side effects, financial issues, and forgetfulness, were also assessed [27,31]. Conceptually, the purpose of RapidPRO is to provide an opportunity for patients to report their symptoms and medication experiences outside the office visit and for oncologists and oncology professionals and personnel to follow up proactively on those reports when needed.

Additional information and links to the complete RapidPRO intake form, assessment forms, and tool guide are available in Multimedia Appendix 1.

Data Analysis

Practices submitted completed, deidentified RapidPRO forms to the MOQC for entry into REDCap, which is a password-protected, user-authenticated, encrypted, and firewalled application used to collect and enter sensitive data in compliance with HIPAA (Health Insurance Portability and Accountability Act). Standard audits took place throughout data entry. Discrepancies were resolved by the project manager. Missing data were accounted for by presentation of the valid sample size, with noninclusion in the denominator. The regression had missing values that were removed listwise.

For objective 1, practice-level metrics were established, including the number of PROMs completed per week and the mode of administration. The average, median number, and range of PROMs per medication, as well as by days between PROMs, were determined and reported for medications with at least 100 PROMs. The number of PROMs, as well as the number of patients represented by those PROMs, was determined.

For objective 2, the patient-reported symptoms and medication adherence were quantified using frequency distributions. This analysis aimed to evaluate whether changes in symptom burden and confidence to manage or seek care were associated with medication adherence over time. Interaction terms (time × symptom burden and time × confidence) were included to test whether these associations changed across repeated assessments in individuals with 2 or more PROMs.

We used a predictive generalized linear mixed interaction model as well as smoothing splines for presentation of results. A

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random intercept for each patient ID allowed for handling of intrapatient correlation. All data were analyzed using R (version 3.5.2; R Foundation for Statistical Computing) [40,41], and the generalized linear mixed model was performed using the R package *lme4* [42].

Results

RapidPRO Data Collection

The number of PROMs completed per week varied by practice (Table 1), and all practices preferred paper forms for completion. Almost one-third of PROMs (710/2252, 31.5%) were completed by patients as part of a self-assessment during visits, and at least 2 practices had the PROM completed during a telephone follow-up by a pharmacist or nurse.

Across practices, substantial variation in clinic size and staffing was observed, including annual new oncology patient volume ranging from 421 to 3000 and the number of oncologists and oncology professionals ranging from 2 to 12 per site (Table 1). These differences were reflected in RapidPRO implementation metrics, with PROM completion per site ranging from 79 to 1411 assessments over the study period, corresponding to practice capacity and workflow differences.

Table . Practice characteristics and implementation of the rapid patient-reported outcome measure (RapidPRO).

Variable	Clinic 1	Clinic 2	Clinic 3	Clinic 4	Clinic 5	Clinic 6
Practice characteristics						
Number of new patients annually	—[a]	421	3000	992	1110	550
Patients with private insurance (%)	—	34	35	52	15	36
Patients with Medicare (%)	—	50	55	43	70	40
Total number of physicians	—	6	12	9	6	2
Total number of nurse practitioners	—	4	5	12	1	0
Total number of physician assistants	—	2	5	0	1	0
RapidPRO implementation characteristics						
PROMs[b] (n=2252), n (%)	84 (3.7)	119 (5.3)	1411 (62.7)	428 (19)	79 (3.5)	131 (5.8)
Patients (n=695), n (%)	49 (7.1)	65 (9.4)	301 (43.3)	178 (25.6)	52 (7.5)	50 (7.2)
Date range	July 5, 2016 to June 6, 2017	February 14, 2017 to November 27, 2018	May 2, 2017 to December 25, 2018	July 11, 2017 to December 11, 2018	September 19, 2017 to January 30, 2018	January 30, 2018 to December 25, 2018
Weeks with PROMs, n (%)	31 (64.5)	54 (58)	55 (63.9)	72 (97.3)	11 (57.9)	45 (95.7)
Weeks without PROMs, n (%)	17 (35.4)	39 (41.9)	31 (36)	2 (2.7)	8 (42.1)	2 (4.3)
PROMs during weeks with PROMs (n), mean (SD)	1.71 (1.87)	1.27 (1.58)	16.22 (15.58)	5.71 (3.27)	3.95 (5.92)	2.73 (1.69)

[a]Missing data.

[b]PROM: patient-reported outcome measure.

A total of 2252 PROMs were completed by 695 patients across the 6 participating practices (Table 2). Of these 695 patients, 448 (64.5%) completed at least 2 PROMs, accounting for 69.1% (1557/2252) of the total PROMs. OAAs were reported in 92.8% (2089/2252) of the PROMs, and over half (1313/2252, 58%) of the PROMs were completed for 7 drugs. Cancer diagnosis was reported in only 580 PROMs, most commonly prostate (n=137, 23.6%), breast (n=111, 19.1%), colorectal (n=56, 9.7%), lung (n=35, 6%), ovarian (n=30, 5.2%), and pancreatic (n=21, 3.6%) cancer.

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Table . Number of patient-reported outcome measures (PROMs) by medication.

Medication (patients, n)	PROMs, n	PROMS per patient, mean (SD)	PROMS per patient, median (IQR)	PROMS per patient (n), range
All (n=695)	2252	3.24 (3.18)	2 (1-4)	1 - 39
Capecitabine (n=150)	372	2.48 (2.18)	2 (1-3)	1 - 13
Palbociclib (n=52)	220	4.23 (3.62)	3 (1-6)	1 - 15
Lenalidomide (n=41)	173	4.22 (3.76)	3 (2-6)	1 - 15
Hydroxyurea (n=41)	168	4.10 (2.49)	4 (2-6)	1 - 11
Abiraterone (n=59)	152	2.58 (1.93)	2 (1-3)	1 - 10
Ibrutinib (n=43)	115	2.67 (1.61)	2 (1-4)	1 - 7
Temozolomide (n=41)	113	2.76 (2.69)	2 (1-3)	1 - 12

Among individuals completing at least 2 PROMs, the mean interval between assessments was 37 days (mean 37.54, SD 38.18 days, median 28 days) across all medications (Table 3). The mean and median were less than 30 days for capecitabine, palbociclib, lenalidomide, and temozolomide, consistent with their dosing cycles.

Table . Time between patient-reported outcome measures (PROMs) by medication.

Medication (patients, n)	PROMs, n	Time between PROMs (days), mean (SD)	Time between PROMs (days), median (IQR)	Time between PROMs (days), range
All (n=448)	1557	37.54 (38.18)	28 (14-42)	0 - 342
Capecitabine (n=85)	222	29.57 (33.13)	21 (14-32)	0 - 342
Palbociclib (n=37)	168	28.85 (19.23)	28 (15 - 31.25)	1 - 133
Lenalidomide (n=31)	132	27.28 (24.05)	24 (11-29)	0 - 119
Hydroxyurea (n=35)	127	58.14 (47.81)	42 (28 - 78.5)	3 - 275
Abiraterone (n=37)	93	38.59 (37.41)	29 (14-55)	3 - 247
Ibrutinib (n=29)	72	53.42 (52.14)	35 (14.75 - 78.75)	3 - 257
Temozolomide (n=23)	72	29.54 (26.91)	25.5 (8-35)	3 - 147

RapidPRO Clinical Metrics

Symptoms

Of the 2252 completed PROMs, 625 (27.8%) reported at least one severe symptom, and 1213 (53.9%) reported at least one moderate or severe symptom (Figure 1). A high symptom burden, defined as 4 or more total severe symptoms, was reported in 3.4% (n=76) of the PROMs. Additionally, 17.8% (n=400) of the PROMs reported at least 4 moderate or severe symptoms combined.

In addition to the symptoms reported in the ESAS, patients were asked to state their MBS, and patients could report more than one (Table 4). A total of 1045 MBSs were reported in 35.1% (790/2252) of the PROMs. Of the 695 patients, 323 (46.5%) reported an MBS. The most common MBS categories were constitutional including fatigue, gastrointestinal, musculoskeletal, and neurological (Table 4). MBSs reported were compared to the symptoms included in the RapidPRO, and ESAS symptoms accounted for 70% (731/1045) of the MBSs that were reported by patients. Fatigue was the most common severe and moderate ESAS symptom and the most commonly reported MBS. Among symptoms not covered by the ESAS, constitutional concerns were most common, and others occurred infrequently.

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Figure 1. Edmonton Symptom Assessment System (ESAS) symptom severity in rapid patient-reported outcome.

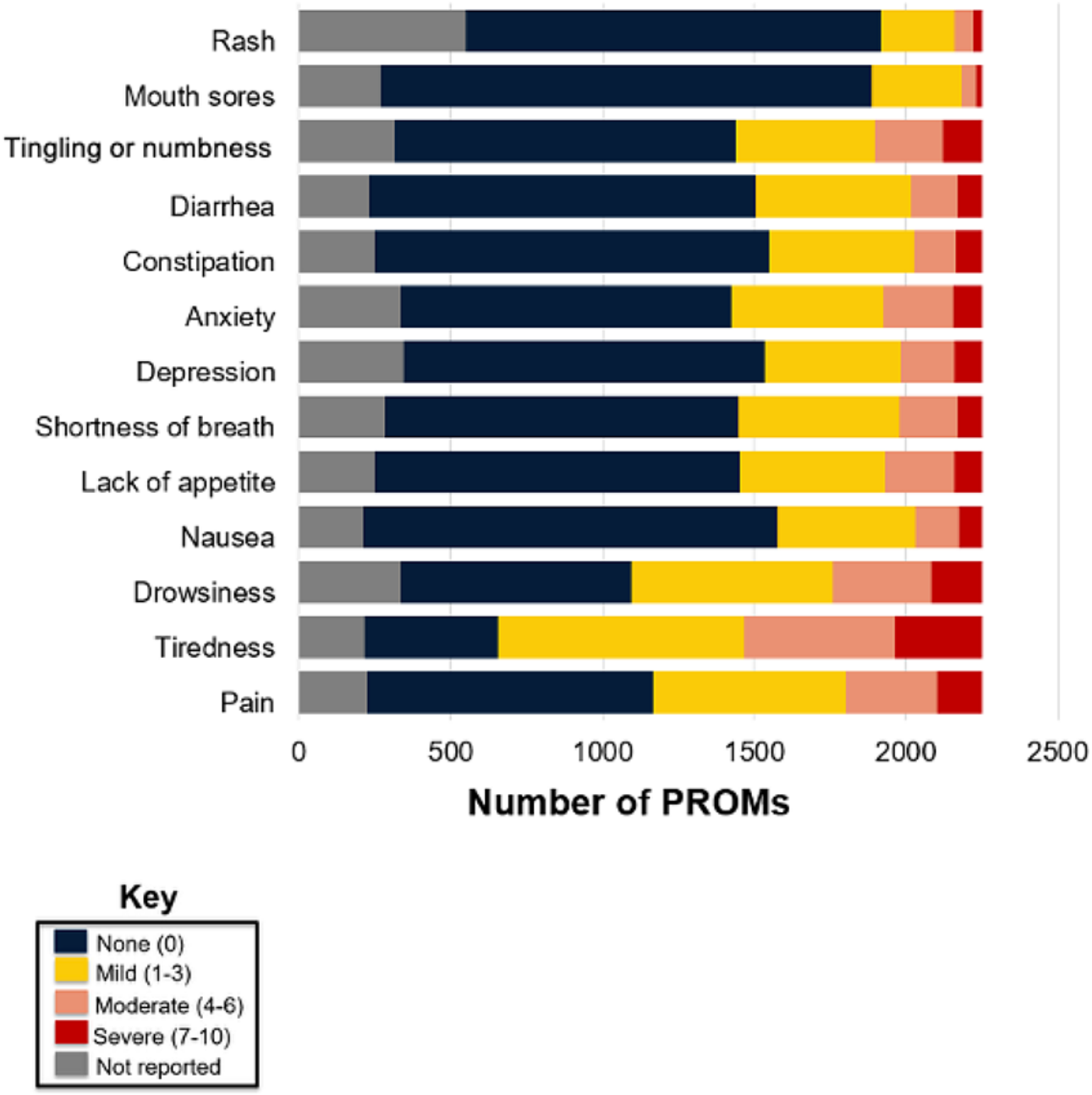

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Table . Most bothersome symptoms reported in 790 patient-reported outcome measures by patients taking oral anticancer agents (N=1045).

Symptom category	Symptoms, n (%)
Constitutional symptoms (fatigue, fever, weakness, or weight loss)	323 (30.9)
Gastrointestinal	225 (21.5)
Musculoskeletal	101 (9.7)
Neurological	93 (8.9)
Integumentary or skin	83 (7.9)
Ears, nose, mouth, or throat	59 (5.6)
Cardiovascular	52 (5)
Psychiatric	41 (3.9)
Respiratory	18 (1.7)
Eyes	12 (1.1)
Genitourinary	11 (1.1)
Hematologic or lymphatic	8 (0.8)
Allergic or immunologic	2 (0.2)
Endocrine	1 (0.1)
Financial	1 (0.1)
Other	15 (1.4)

Confidence

Overall, most patients expressed high confidence in both managing and seeking help for OAA-related symptoms. Patients reported their confidence to self-manage their symptoms related to OAAs in 72.9% (1642/2252) of the completed PROMs (Table 5). Of those 1642 PROMs, 1252 (76.2%) rated their confidence as high (7-10). Confidence to seek medical care for symptoms related to OAAs was reported in 74.8% (1685/2252) of the PROMs. Of those 1685 PROMs, 1475 (87.5%) reported confidence as high.

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Table . Confidence, adherence, and reasons for nonadherence reported in the rapid patient-reported outcome measure (PROM; N=2252).

Outcome	PROMs, n (%)
Confidence to seek medical care (n=1642)	
Low (0 - 3)	236 (14.4)
Moderate (4-6)	154 (9.4)
High (7-10)	1252 (76.2)
Confidence to self-manage symptoms (n=1685)	
Low (0 - 3)	119 (7.1)
Moderate (4-6)	91 (5.4)
High (7-10)	1475 (87.5)
Self-rated adherence to oral anticancer agents (n=1705)	
Excellent	1220 (71.6)
Nonadherent or less than excellent	485 (28.4)
Reasons for nonadherence (n=430)[a]	
"I did not have money to pay for this medicine."	24 (5.6)
"I did not have the medicine because the pharmacy was out of this medicine."	10 (2.3)
"I experienced side effects from this medicine."	156 (36.3)
"I have concerns about possible side effects."	83 (19.3)
"I have concerns about long term effects."	64 (14.9)
"I do not think I need this medication anymore."	9 (2.1)
"I do not think that this medication is working for me."	14 (3.3)
"I have trouble managing all the medicines I take."	13 (3)
"I would have taken it but simply missed it."	125 (29.1)
"I would have taken it but missed it because of a busy schedule."	42 (9.8)
"I would have taken it but have problems forgetting things in my daily life."	43 (10)
Other	109 (25.3)

[a]Patients could select more than one reason.

Adherence

The medication adherence assessment was completed in 75.7% (1705/2252) of the total PROMs, and 28% (485/1705) of PROMs had a rating defined as nonadherent (Table 5). Commonly reported reasons for medication nonadherence included side effects or concerns about side or long-term effects (303/2252, 13.5%) and forgetfulness or missed doses (223/2252, 9.9%).

Relationships Among Clinical Metrics

The relationships among symptom burden, confidence, and medication adherence were examined among individuals completing at least 2 PROMs (Figure 2). In the figures developed from the predictive mixed interaction models (left panels in Figure 2), more symptoms and less confidence were related to poorer medication adherence over time. In the raw data (right panels in Figure 2), these relationships were more variable, although higher total symptom scores and lower confidence levels showed similar trends.

In the mixed-effects models for patients with multiple PROMs, those with low confidence to self-manage symptoms or low confidence to seek medical attention were also more likely to report medication nonadherence (P<.001 and P=.001, respectively). Individuals with PROMs that reported a moderate or severe symptom on the ESAS were more likely to be nonadherent to OAA therapy (P=.02), as were patients who were receiving capecitabine (P=.005).

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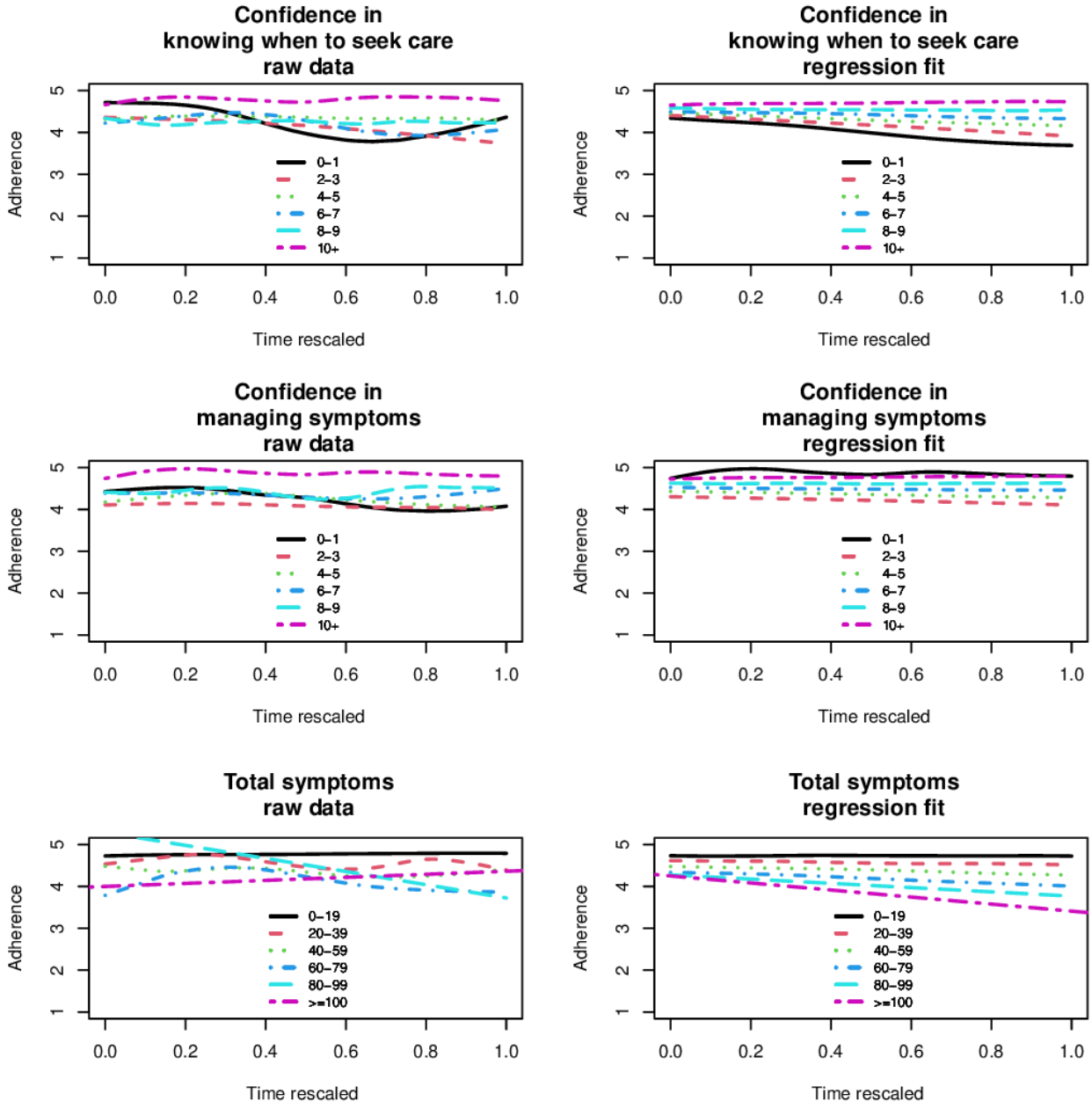
Figure 2. Variation in patient-reported outcome measures (PROM) of total symptoms (sum of symptoms 0 to >100 [worst]), confidence to manage symptoms, confidence to know when to seek care (0 to 10 [best]), and adherence (1 to 5 [best]) among patients with multiple PROMs using a predicted mixed interaction model (left) and a smoothing spline for each line showing raw data (right).



Discussion

Principal Findings

Using PROMs to evaluate symptom burden and medication adherence in patients receiving OAAs should be considered to enhance the quality of care as the responsibility for managing symptoms and medication adherence lies heavily on patients [32,43]. A short, easy-to-use PROM was used in 6 clinical practices, and it was completed by almost 700 patients. Importantly, it can be completed by patients in approximately 3 minutes. It comprises previously validated survey items that assess symptom burden, patient self-management confidence, and medication adherence concisely for all OAAs and allows oncologists and oncology professionals to respond in a timely way [27,32,34,35,38,39,44]. This PROM can be used broadly for all OAAs as an initial screening tool vs the need to customize for each drug or cancer type. This is helpful when establishing a consistent workflow within practices, especially given the large number of OAAs that are available. The practices did show variability in the number of completed PROMs each week during their participation, as well as variation in administration mode.

Data from the RapidPRO were used to explore factors associated with medication nonadherence, and individuals with more severe symptoms and lower confidence in self-management of symptoms were more likely to be nonadherent to therapy. These findings are consistent with those of previous studies. Patients have previously indicated experience or fear of side effects as a main reason for medication nonadherence [5,16,27,45-48]. In addition, patients with colorectal cancer who experienced more

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severe or episodic side effects have expressed more difficulty with self-management, which led to medication nonadherence [27,49,50]. Patients with lower confidence in self-managing symptoms may also be unsure of whether symptoms are expected or require clinical attention, which can lead to skipped doses and medication nonadherence. Prior studies of oral oncolytics show that lower self-efficacy is associated with difficulty performing self-management behaviors and poorer adherence [27]. Difficulty managing symptoms can also heighten distress and impair daily functioning, further disrupting medication-taking routines [28]. Inadequately managed symptoms can also signal early clinical deterioration and are associated with greater unplanned health care use [29]. These findings suggest that confidence ratings on the RapidPRO may function as an early indicator of patients who may benefit from proactive symptom management interventions and adherence support.

A question was added to the PROM related to the patients' MBS given the varying medication side effect profiles between OAAs in the event that patients were experiencing symptoms that were not included in the ESAS. We found that, even with this additional reporting option, the ESAS captured most symptoms that patients experienced, further justifying its use within RapidPRO [19,33,36].

RapidPRO provides a brief, clinically focused alternative suitable for routine use with patients receiving OAAs compared with other cancer patient-reported outcome tools such as the Functional Assessment of Cancer Therapy–General (27 items) and the European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire Core 30 (30 items), which assess broad physical, emotional, social, and functional domains and require more time to complete [51]. Patient-Reported Outcomes Measurement Information System measures offer flexible item banks for general health-related functioning and include a generic medication adherence scale, but they are not cancer specific and do not capture symptom burden or confidence in managing OAA-related side effects [52]. RapidPRO instead integrates validated ESAS symptom items with patient confidence and medication adherence—domains directly relevant to daily OAA self-management. Consistent with recent reviews showing that short, symptom-focused tools are more feasible in busy oncology workflows than comprehensive health-related quality of life instruments [53], RapidPRO fills a distinct niche by delivering rapid, actionable information to guide clinical care.

Given the extent of symptom experience and medication nonadherence, these results suggest the critical need to use a process that routinely assesses toxicities, medication adherence, and confidence, and RapidPRO is not overly burdensome or complex. By identifying patients who are at risk of medication nonadherence, practices have the ability to provide additional medication teaching, symptom management support, and other targeted interventions. Implementing a PROM into daily oncology workflows remains challenging. Despite standardized data collection procedures across all clinics, the number of completed RapidPRO assessments varied due to differences in staffing and workflow capacity. This represents typical variation in how PROMs are incorporated into routine care in community oncology settings. The oncology practices experienced common barriers, including staffing constraints, visit schedule variability, and differences in administration processes. These challenges reflect prior evidence showing that PROM implementation is often hindered by time burden, workflow disruption, and limited technical integration [54]. Cancer-specific implementation studies similarly highlight workflow variability as a key barrier to sustaining routine PROM collection [55].

In this project, the MOQC helped mitigate these barriers by providing onboarding training, a written user guide with follow-up thresholds, ongoing support, and flexible administration options (paper or telephone). These strategies facilitated the integration of RapidPRO into routine care, although further workflow standardization may improve consistent use. Moreover, recent evidence shows that PROMs improve mortality and health-related quality of life at 12 weeks with moderate certainty [30,56]. Collectively, these results provide strong external evidence that patients would benefit from PROM assessments such as RapidPRO. This single instrument could be used for all OAAs. The introduction of new OAAs also with toxicities or side effects provides additional impetus.

One of the limitations of this study is that, because it focused on testing the feasibility of using RapidPRO in clinical practice, only information included in the PROM itself was collected. Detailed clinical characteristics from electronic medical records such as cancer stage, time since diagnosis, or treatment intent were not captured, and cancer diagnoses were missing for many PROMs. While these data reflect real-world clinical use, they limit the ability to compare results across clinical subgroups. Future work linking RapidPRO data with electronic medical record information will be important for evaluating how RapidPRO performs across specific cancers and treatment pathways.

Conclusions

An easy-to-administer RapidPRO for monitoring patients taking OAAs was used across 6 sites, with variability in its daily use. Symptom burden was common for patients taking OAAs, with 17.8% (400/2252) of the PROMs reporting at least 4 moderate or severe symptoms combined, and 28% (485/1705) of the PROMs reported less than excellent medication adherence. The most prevalent patient-reported reason for medication nonadherence was side effects. By implementing the RapidPRO, practices can identify patients who experience symptoms, as well as those who report medication nonadherence.

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Data Availability

The datasets generated or analyzed during this study are available from the corresponding author on reasonable request.

Authors' Contributions

Conceptualization: EM, JJG, and KF
Data curation: EM, KR, and MA
Formal analysis: EM, TW, VDM, and KF
Methodology: EM, TW, KR, JJG, and KF
Supervision: EM, JJG, and KF
Visualization: VDM
Writing—original draft: EM, TW, and KF
Writing—review and editing: TW, KR, MA, JJG, and KF

Conflicts of Interest

KF and EM report a research grant from AstraZeneca effective up to June 2023. All other authors declare no other conflicts of interest.

Multimedia Appendix 1
Michigan Oncology Quality Consortium rapid patient-reported outcome measure resource links.
[DOCX File, 15 KB - formative_v10i1e85201_app1.docx]

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Abbreviations

ESAS: Edmonton Symptom Assessment System
HIPAA: Health Insurance Portability and Accountability Act
MBS: most bothersome symptom
MOQC: Michigan Oncology Quality Consortium
OAA: oral anticancer agent
PROM: patient-reported outcome measure
RapidPRO: rapid patient-reported outcome measure
REDCap: Research Electronic Data Capture

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Insights on Recruitment, Implementation, and Movement Pattern Detection by Exploring the Feasibility of Sensor-Based Insole Technology in Long-Term Care: Mixed Methods Feasibility Study

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Abstract

Background: Sensor-based footwear is increasingly discussed as a promising tool for mobility monitoring and fall-risk assessment, yet its applicability in long-term care remains largely unexamined. In particular, little is known about whether such systems and the study procedures needed to evaluate them can be feasibly integrated into dementia care settings. This feasibility study provides practice-based evidence of using a sensor-equipped insole system with cognitively impaired residents.

Objective: The study examines recruitment feasibility, integration of the device into daily care routines, and the operationalization of the study design under everyday institutional conditions. Furthermore, it explores whether movement patterns, including agitation-related behaviors, can be detected in situ, acknowledging the exploratory nature of this aim due to the rarity and unpredictability of natural agitation episodes.

Methods: An exploratory feasibility study was conducted in 2 long-term care facilities in Eastern Switzerland. Six residents with mild-to-moderate cognitive impairment and increased fall risk were recruited through a multistep, staff-supported process, offering rare documentation of real-world recruitment constraints. The insole system recorded continuous gait and movement data during daily activities and weekly walking tests. Controlled simulations of agitation-related patterns were conducted to generate reference data, as natural agitation events were infrequent and difficult to capture systematically. Feasibility outcomes were informed focusing on recruitment capability, acceptability and adherence, feasibility of continuous data acquisition, and the practicality of integrating the system into daily care routines.

Results: The study identified substantial feasibility constraints, including contextual limitations posed by sedation practices, fluctuating health status, and consent-related barriers. Practical challenges such as inconsistent battery charging, communication gaps across rotating staff, and difficulties achieving adequate shoe fit directly affected protocol adherence and data yield. Continuous sensor-based data collection was technically feasible when the shoes were worn, and machine-learning models consistently classified predefined agitation-related patterns under controlled conditions. Natural agitation episodes were rare, making simulated reference data essential for establishing fundamental detectability. Resident acceptance varied, with some individuals reporting increased perceived stability due to the shoe's firm construction rather than its vibration feature.

Conclusions: This feasibility study demonstrates that sensor-based footwear is technically feasible and shows situational acceptability in long-term care, while also highlighting key contextual constraints related to recruitment, workflow integration, device handling, and adherence. The findings provide early empirical evidence on what is practically achievable in this population and setting, clarifying the exploratory nature and methodological necessity of using simulated agitation patterns, and underscoring the need for context-sensitive, participatory strategies when introducing sensor-based technologies into dementia care.

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KEYWORDS

sensor-based monitoring; wearable technology; gait analysis; agitation detection; ambient-assisted living; feasibility study; technology implementation; long-term care; nursing home

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Introduction

Background

Mobility limitations, gait instability, and a high risk of falls are among the most pervasive challenges in long-term care. Older adults, particularly those living with cognitive impairment, experience fluctuating functional capacities, reduced hazard awareness, and difficulties communicating emerging physical changes [1]. Recent evidence highlights that falls are highly prevalent in long-term care facilities and result from a complex interplay of mobility limitations, cognitive impairment, environmental factors, and organizational conditions. Older adults in long-term care experience markedly higher fall rates than community-dwelling older adults, underscoring the need for reliable approaches to monitor mobility and fall risk in these settings [2]. This elevated fall risk is even more pronounced among residents with dementia, as cognitive impairment further reduces hazard awareness, affects judgment, and limits the ability to respond adequately to environmental challenges [3]. Furthermore, up to 86% of long-term care residents with dementia exhibit agitation, and about 40% experience clinically significant symptoms [4]. These symptoms are clinically relevant not only because of their association with caregiver burden and reduced well-being but also because they can serve as prognostic indicators of disease progression [5].

Despite the clinical relevance of mobility changes and fall risk, everyday monitoring in long-term care largely relies on brief, subjective staff observations conducted under considerable workload pressures [6]. This lack of continuous, objective monitoring restricts the ability of care teams to detect emerging restlessness, identify early indicators of fall risk, or differentiate transient fluctuations from clinically meaningful deterioration. Technological approaches such as multimodal wearables and artificial intelligence (AI)-based detection systems may help address this monitoring gap; however, these systems have rarely been evaluated under real-life long-term care conditions [7], and their usability and acceptance among people with dementia remain insufficiently understood. This gap underscores the need to first evaluate whether such systems can be feasibly implemented in everyday care routines before considering their clinical use.

Usability and acceptance are particularly critical in populations with cognitive impairment, where device comfort, unobtrusive design, intuitive handling, and minimal maintenance demands strongly influence adherence and sustainable use [8]. Trust, perceived usefulness, and low-threshold interaction design further shape acceptance, especially in settings where residents may be unfamiliar with or sensitive to digital technologies [9-11]. Many commercially available wearables, including smartwatches, are perceived as inaccurate in slow walkers, require frequent charging, or are easily misplaced, which limits their suitability for older adults with dementia [12]. These findings underscore the need for context-sensitive and user-centered design principles when deploying sensor-based monitoring approaches in long-term care environments [13].

Against this backdrop, sensor-equipped footwear represents a promising alternative. By embedding sensors directly into everyday shoes, mobility and gait-related parameters can be captured unobtrusively and with minimal behavioral change, reducing the risk of device loss and improving usability [14,15]. Advances in AI further enable the detection of clinically relevant movement patterns, including those associated with agitation or fall risk [16]. Nevertheless, such systems have not yet been systematically evaluated in real-world long-term care settings, and evidence on their feasibility, acceptance, and integration into routine dementia care remains sparse.

In response to these gaps, this study examines the feasibility of using a sensor-based insole system in the everyday context of long-term care. While the system also allows exploratory examination of specific movement characteristics, such as restlessness or agitation-related patterns, its primary purpose in this pilot study is to determine whether such a technology and its associated study procedures can be realistically implemented under the complex and variable conditions of long-term care. Recent research emphasizes the importance of patient-centeredness, outcome orientation, and the acceptability of technologies in vulnerable populations and complex care environments [17,18]. Despite promising technological advances, no established solutions currently use in-shoe sensors to monitor agitation-related motor activity in long-term care, underscoring the exploratory and innovative character of this feasibility study.

Study Objectives and Research Questions

The aim of this feasibility study is to examine the practicality of introducing a sensor-based insole system into everyday long-term care. Specifically, the study investigates (1) the wearability, usability, and user acceptance among residents with cognitive impairment; (2) the feasibility of integrating the system into routine care workflows, including adherence and compatibility with daily procedures; and (3) the technical feasibility of continuously recording movement patterns and obtaining initial indications of the detectability of health-relevant behaviors, including agitation-related motor activity, under real-world conditions.

Accordingly, the primary objective is to determine whether the system can be realistically used in daily care practice, whether continuous valid movement data can be acquired, and whether exploratory analyses can provide preliminary insights into the detection of abnormal movement patterns associated with increased health risks. Particular attention is given to movement patterns potentially indicative of agitated motor behavior. The vibration component is conceptualized as an adjunctive feature rather than a central intervention under investigation.

The study uses a sensor-equipped insole system that continuously records movement data and applies exploratory AI-based analyses to quantify mobility parameters and identify predefined movement signatures. Beyond monitoring, the system includes an optional vibration feature that delivers low-intensity tactile impulses to the plantar surface. Prior research suggests that such stimulation may enhance sensory feedback and support gait and balance in older adults [19,20], although evidence remains preliminary. Consistent with the feasibility focus, this feature is examined only in an exploratory manner.

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Building on these aims and system characteristics, the study was structured around three feasibility domains that align with established objectives for feasibility research. These domains guided the formulation of the research questions (RQs) as outlined as follows:

- Process feasibility (recruitment, study design, and implementation)
  - RQ1: To what extent is the study design including recruitment processes, organizational integration, and day-to-day implementation feasible in long-term care facilities?
- Acceptability and perceived value
  - RQ2: How do residents, particularly those with cognitive impairments, perceive and accept the sensor-based system in daily care?
- Technical feasibility (data capture and system functionality)
  - RQ3: Under real-world conditions, to what extent is it feasible to obtain analyzable movement data during naturally occurring agitation episodes, and which sensor signals show preliminary indicators of potential usefulness for subsequent model development?
  - RQ4: How practical, robust, and reliable is the insole-based sensor system in capturing movement patterns under real-world long-term care conditions?
  - RQ5: Under controlled conditions, to what extent can agitation-related movement patterns be exploratively characterized, and which sensor modalities and machine-learning approaches appear technically feasible for this purpose?

Methods

Study Design

This study was designed as an exploratory feasibility study, structured around 3 core feasibility dimensions: process feasibility, acceptability and perceived value, and technical feasibility.

Sample and Recruitment

Participants were recruited from 2 long-term care facilities in eastern Switzerland, comprising specialized dementia units, general nursing wards, and a unit for residents with comorbid substance use disorders. Eligible participants were residents with mild-to-moderate cognitive impairment, documented increased fall risk and/or notable movement behaviors (eg, agitation), and the capacity to provide informed consent.

Recruitment followed a multistage, staff-supported process. After institutional approval, nursing staff and the research team identified potentially eligible residents and provided individualized verbal and written information about the study's purpose and procedures. Interested residents were approached personally and invited to participate voluntarily. Sociodemographic data and cognitive status (Mini-Mental State Examination) were collected at baseline.

Intervention and Data Collection

The feasibility study was conducted over a 4-week period in both facilities. All participants received a pair of study shoes equipped with integrated acceleration and pressure sensors. The system recorded gait and movement data continuously during daily activities whenever the shoes were worn. A brief introductory training session was provided to each participant to familiarize them with donning and doffing the shoes.

Weekly standardized walking tests (6 - 12 min) were conducted under everyday conditions within the facilities. During these tests, the sensor system captured parameters such as step count, acceleration patterns, frequency and duration of movement, and ankle joint angle dynamics. Sensor data were wirelessly transferred to a secure analysis server during weekly on-site visits by the research team.

To complement real-world data collection, a series of controlled simulation procedures was conducted by the research team following predefined protocols (Multimedia Appendix 1). These simulations replicated characteristic agitation-related motor behaviors described in the *International Classification of Diseases, Tenth Revision* (ICD-10; eg, R45.1 "restlessness" and R46.3 "hyperactivity"), including restlessness in sitting and standing, repetitive nonlocomotor movements, and selected fall-like sequences. The simulated sequences served as reference data for exploratory model development and for examining the system's ability to differentiate predefined movement signatures under controlled conditions.

The 2 data sources, simulation sequences and weekly walking tests, served distinct purposes. Simulation-derived data provided controlled reference patterns for algorithmic comparison, while longitudinal walking-test data allowed examination of continuous sensor function and variability across measurement occasions. Both datasets were processed using statistical and exploratory machine-learning procedures to support feasibility assessments regarding data capture, stability, and the detectability of movement signatures.

Data Analysis

Data analysis was informed by the feasibility framework proposed by Orsmond and Cohn [21] and structured around three domains aligned with the guiding RQs: (1) process feasibility, (2) acceptability and perceived value, and (3) technical feasibility. Analyses examined how the system was used within everyday care routines, how residents and staff perceived its value, and under which practical conditions continuous movement-data acquisition was achievable in long-term care.

Process Feasibility (Recruitment, Study Procedures, and Organizational Integration)

This domain assessed the feasibility of conducting the study under routine institutional conditions. Three qualitative and descriptive data sources informed the analysis: nonparticipant behavioral observations (30-min sessions) during weekly walking tests, using a structured, time-stamped observation protocol. Informal staff feedback was collected continuously throughout the study period. Documentation of procedural

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deviations, including technical malfunctions, illness-related absences, and instances of nonuse of the shoe system. These data were analyzed descriptively to assess whether the study procedures were workable within daily routines, to identify facilitators and barriers to adherence, and to understand the organizational conditions influencing implementation feasibility.

Acceptability and Perceived Value (Residents and Staff)

To address RQ2, observational field notes and staff feedback were examined for indicators of residents' and professional caregivers' acceptance of the system. Content analysis focused on: observed user behaviors (eg, restlessness, engagement, and withdrawal), system-handling behaviors during everyday use, spontaneous verbal comments or reactions, perceptions of comfort, usefulness, and burden. The goal was to determine whether the system was tolerated or preferred by residents and how its perceived value shaped willingness to use it in daily care.

Technical Feasibility (Data Capture, System Functionality, and Exploratory Detection)

This domain (RQ3-RQ5) focused on the practicality and robustness of continuous sensor-based data acquisition under real-world conditions. Analyses included the following: completeness and quality of sensor data recorded during daily activities and weekly walking tests, type, frequency, and context of technical malfunctions; feasibility of capturing analyzable movement signals during naturally occurring restlessness or agitation; and exploratory examination of simulation sequences designed to elicit predefined agitation-related movement patterns. These analyses were descriptive and exploratory.

Ethical Considerations

Data collection, storage, and analysis were conducted in compliance with data protection regulations. All participants received written and oral information about the study objectives, procedures, potential risks, and their rights and provided written informed consent prior to participation. Participation was voluntary, and participants could withdraw from the study at any time without providing a reason and without any negative consequences. No financial or other compensation was provided for participation. Personal data were pseudonymized, and the transmission and storage of sensor data were secured via a password-protected system with restricted access. The study was approved by the ethics committee of Eastern Switzerland (Req-2024-01190; EKOS24/163).

Results

Process Feasibility (Recruitment, Study Design, and Implementation): Recruitment Processes, Organizational Integration, and Day-to-Day Study Conduct (RQ1)

Recruitment was carried out across 2 long-term care facilities over a 12-week period. Each facility comprised 5 residential units, resulting in a recruitment pool of 10 units. Despite this coverage, only 6 residents (age range: 60 - 81 y; 4 female and 2 male individuals) were ultimately enrolled as shown in Table 1. Screening was resource-intensive, as many residents did not meet the inclusion criteria due to advanced cognitive impairment, acute or fluctuating illness, limited mobility, or unavailability of legal consent. Recruitment required close and continuous coordination with nursing leadership to balance ethical considerations with practical feasibility.

Table . Participants within the study and intervention from weeks 1 to 4.

Characteristics				Week 1	Week 2	Week 3	Week 4	Notes
Participant	Sex	Age (y)	MMSE[a] score					
T1	Female	80	23/30	✔	✔	✔	✔	—[b]
T2	Female	81	17/30	✔	✔	✔	✔	—
T3	Male	71	19/30	✔	✔	✔	✔	—
T4	Female	60	18/30	✔	✔	✔	✔	Went to hospital
T5	Female	79	17/30	✔	✔	✔	—	—
T6	Male	63	18/30	✔	—	—	—	Drop out

[a]MMSE: Mini-Mental State Examination.

[b]not applicable.

Participation during the study period showed considerable variability. Several residents missed individual measurement days due to scheduled medical appointments, illness episodes, or sedation. Only a small number of natural agitation episodes occurred. Care staff reported that some residents who typically display frequent agitation were pharmacologically sedated during data collection, which limited opportunities to capture agitation-related behaviors.

On the technical side, difficulties with the inductive charging process were frequent. Shoes needed to be placed correctly on the charging pad, and this step was occasionally missed or performed incorrectly, resulting in insufficient battery levels on scheduled data collection days. Rotating staff schedules and incomplete internal communication contributed to inconsistent handling, requiring repeated clarification by the research team and additional reminders at charging stations.

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Organizationally, uneven information flow and shifting responsibilities within the multiprofessional team affected the regularity of system use. Acute health fluctuations, including fatigue, cognitive disorientation, hospital stays, or prescribed rest times, further limited opportunities for consistent measurement. Participant selection was also constrained by practical considerations such as shoe fit and cognitive ability to provide meaningful subjective feedback.

Participants also exhibited heterogeneous mobility levels, ranging from independent ambulation to short-distance walking with a rollator, often requiring nursing support, which influenced the practical organization of walking tests and sensor-based monitoring.

Acceptability and Perceived Value in Everyday Care: User Perception and Acceptance (RQ2)

Acceptance Among Residents and Staff Perceptions

Resident acceptance varied considerably. The transition from commonly used open slippers to closed, form-fitting shoes was initially unfamiliar for several participants. Over time, many residents described an increased sense of stability while walking. Reports of feeling safer occurred even when the vibration feature was inactive, suggesting that perceptions were shaped mainly by the physical characteristics of the footwear. The vibration function elicited mixed reactions. Some residents did not notice the impulses or accepted them without comment, whereas others expressed irritation due to the unfamiliar sensation or perceived strength of the vibration.

Nursing staff reported perceived improvements in certain residents, such as calmer motor activity or more stable standing and walking. These impressions were often attributed to the system as a whole. Staff frequently did not differentiate between the mechanical support of the shoe and its technological features, which may reflect limited familiarity with sensor-based footwear systems.

Usage and Adherence

Adherence was generally satisfactory under study conditions, with residents and staff managing to incorporate the shoes into daily routines. Tolerance was high, as participants rarely expressed discomfort or rejected the footwear. However, perceived usefulness varied substantially among residents with dementia. While some described the system as helpful or engaging, others found no added value. This diversity highlights that acceptance does not necessarily translate into perceived personal benefit and that subjective relevance may be a critical factor for long-term adoption.

The presence of research personnel appeared to influence participant engagement. Many residents responded positively to the additional social interaction, suggesting that the research context may have contributed independently to increased activity levels or willingness to participate.

Technical Feasibility (Data Capture and System Functionality)

RQ3 and RQ4: Real-World Data Capture Feasibility and Exploratory Assessment of Gait Characteristics Under Vibratory and Nonvibratory Conditions

Although naturally occurring agitation episodes were limited and heterogeneous, the study demonstrated that analyzable movement data could be obtained under real-world long-term care conditions. Preliminary inspection indicates that spatiotemporal gait parameters (eg, stride length and toe clearance) are technically extractable and may serve as candidate signals for subsequent agitation-related model development.

During daily use and weekly walking tests, the sensor system showed generally stable functionality whenever the shoes were worn and adequately charged. However, the frequent use of mobility aids (eg, rollators) altered walking patterns, introducing additional variability that future machine-learning models will need to account for, particularly in real-world care settings.

Vibration was not evaluated as an intervention but was examined exploratively to assess whether low-intensity tactile impulses produced measurable variations in gait characteristics. For each participant, several walking tests were conducted with vibration activated and deactivated in alternating order. During these tests, the following gait characteristics were calculated:

- Stride length: the stride length in meters
- Strike angle: the initial contact (strike) angle of the heel in degrees
- Heel clearance: the maximum heel clearance in meters
- Toe clearance: the minimum toe clearance in meters

Table 2 provides an overview of the observed ranges of variation and the proportion of comparisons showing statistically significant differences between vibration and nonvibration conditions.

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Table . Overview of impact on gait characteristics[a].

Participant	Stride length (m)	Strike angle (°)	Heel clearance (m)	Toe clearance (m)
T1	• Range of impact: −0.06 to 0.12 • Significant impact: 50%	• Range of impact: −3.15 to 4.62 • Significant impact: 25%	• Range of impact: −0.02 to 0.02 • Significant impact: 30%	• Range of impact: −0.005 to 0.001 • Significant impact: 10%
T2	• Range of impact: −0.13 to 0.02 • Significant impact: 29%	• Range of impact: −7.15 to 6.10 • Significant impact: 64%	• Range of impact: −0.03 to 0.12 • Significant impact: 43%	• Range of impact: −0.004 to 0.005 • Significant impact: 21%
T3	• Range of impact: −0.09 to 0.17 • Significant impact: 100%	• Range of impact: −3.29 to 5.83 • Significant impact: 66%	• Range of impact: −0.01 to 0.02 • Significant impact: 50%	• Range of impact: −0.006 to 0.007 • Significant impact: 33%
T4	• Range of impact: −0.09 to 0.57 • Significant impact: 75%	• Range of impact: −3.66 to 7.73 • Significant impact: 75%	• Range of impact: −0.06 to 0.008 • Significant impact: 25%	• Range of impact: −0.029 to 0.006 • Significant impact: 25%
T5	• Range of impact: 0.03 to 0.09 • Significant impact: 100%	• Range of impact: −0.80 to 1.57 • Significant impact: 50%	• Range of impact: 0.007 to 0.016 • Significant impact: 100%	• Range of impact: −0.002 to 0.004 • Significant impact: 75%

[a]Participant T6 was enrolled in the study but dropped out before data collection was completed. As no complete or analyzable data were available for this participant, T6 was not included in the table.

Across participants, no consistent or unidirectional effect of vibration was observed on the measured gait characteristics. Variability occurred in both directions (increases and decreases), and the proportion of statistically significant differences varied widely across parameters and individuals. Two exceptions were noted for participant T5, whose stride length and heel clearance showed consistently positive and statistically significant differences; however, these findings are based on only 1 measurement on each of 2 days and must therefore be interpreted with caution.

Overall, these exploratory results suggest that vibration-induced changes in gait, if present, are highly individualized and not robustly detectable with the current dataset.

RQ5: Detectability of Agitation Patterns in Controlled Settings

Controlled simulations were conducted to examine whether predefined agitation-related movement patterns could be captured and differentiated using the multisensor insole system. Four prototypical patterns based on ICD-10 agitation-related motor behaviors were repeatedly performed:

- Static sitting posture: feet firmly placed on the ground
- Seated toe-tapping: rapid, mainly vertical foot movements (tiptoeing)
- Seated foot-sliding: predominantly lateral foot movements (sliding)
- Standing toe-tapping: rapid, mainly vertical foot movements (tiptoeing) while standing

Each movement pattern was executed 40 times by 2 trained research staff members wearing the sensor-equipped shoes. All sessions were video-recorded for post hoc validation and cross-referencing with sensor data. Detailed descriptions of the testing procedures are provided in Multimedia Appendix 1.

Across these simulation trials, distinct acceleration signatures were observable for each movement type. The 3D accelerometer alone provided sufficient signal variation for preliminary classification, indicating that pressure sensors were not essential for differentiating the simulated patterns. Visual inspection of raw acceleration data confirmed that seated toe-tapping, seated foot-sliding, and standing toe-tapping produced characteristic oscillatory patterns in specific axes (Figures 1-3).

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Figure 1. Example of acceleration measurements of seated toe-tapping.

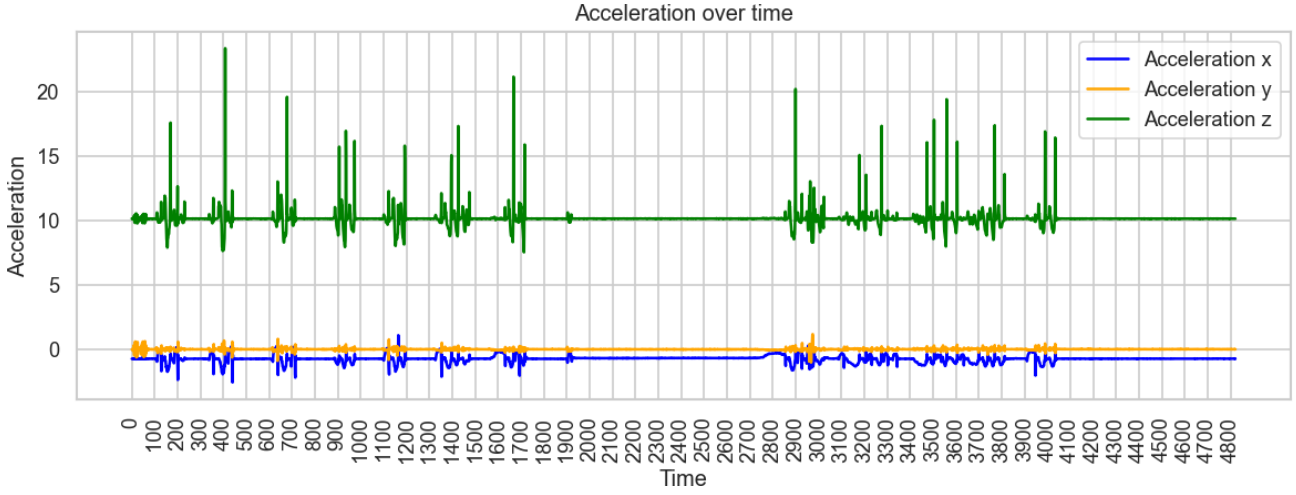


Figure 2. Example of acceleration measurements of seated foot-sliding.

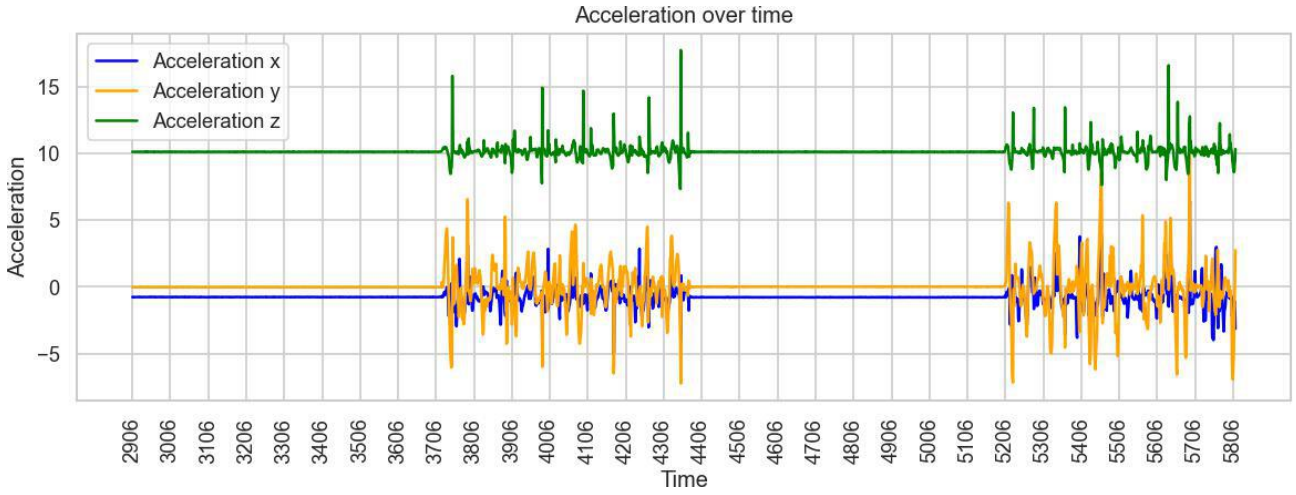
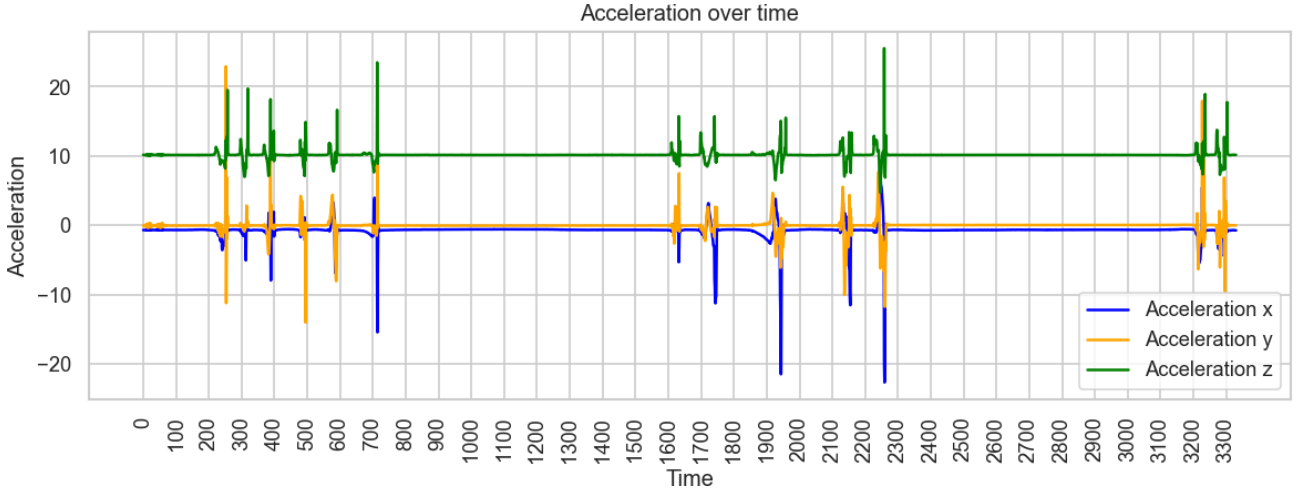


Figure 3. Example of acceleration measurements of standing toe-tapping.



Two exploratory machine-learning approaches were applied as follows:

1. Feature-based models (random forest, extreme gradient boosting, logistic regression, and simple neural network), using detrended and fast Fourier transform features.
2. A sequence-based hidden Markov model (HMM) using raw accelerometer data without preprocessing.

The feature-based models classified nearly all test observations correctly, with the random forest, as illustrated in the confusion matrix (Figure 4), performing slightly better than the other classifiers (Table 3).

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Figure 4. Confusion matrix of the random forest classifier.

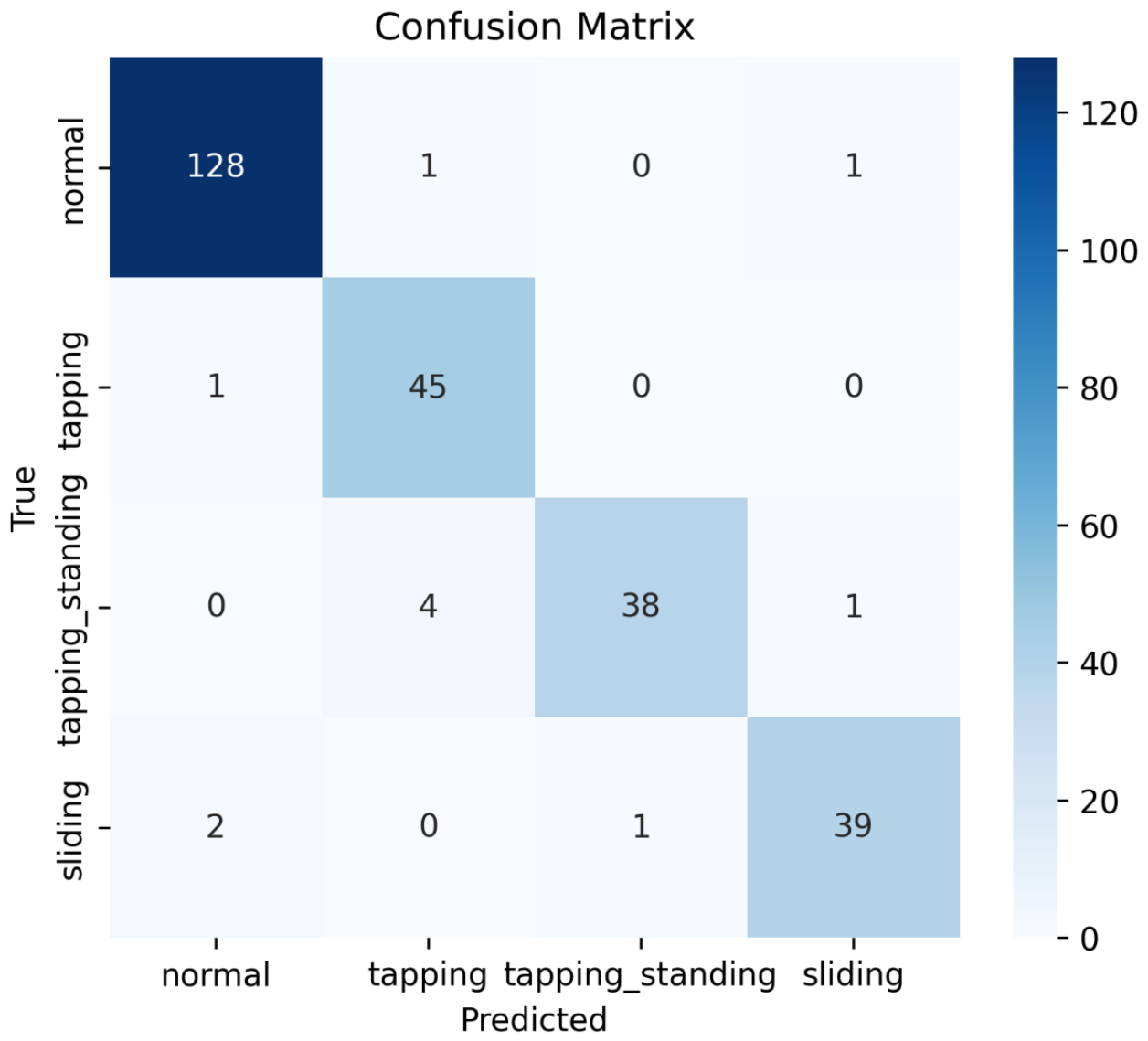

Table . Evaluation metrics of preprocessed classification models.

Pattern	Precision	Recall	F_1-score
Static sitting posture	1.0	0.98	0.99
Seated foot-sliding	0.93	1.0	0.97
Seated toe-tapping	0.98	0.96	0.97
Standing toe-tapping	0.97	0.88	0.93

In contrast, the HMM approach showed lower precision and recall for the more dynamic patterns (particularly sliding and tapping while standing), although seated patterns were identified with higher accuracy (Table 4; Figures 4 and 5). The learning curve (Figure 6) suggests that HMM performance is likely to improve with larger datasets.

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Table . Evaluation metrics for the hidden Markov model classification.

Pattern	Precision	Recall	F_1-score
Static sitting posture	1.0	0.82	0.90
Seated foot-sliding	0.74	1.0	0.85
Seated toe-tapping	0.98	0.98	0.98
Standing toe-tapping	0.76	0.93	0.84

Figure 5. Confusion matrix of the hidden Markov model (HMM).

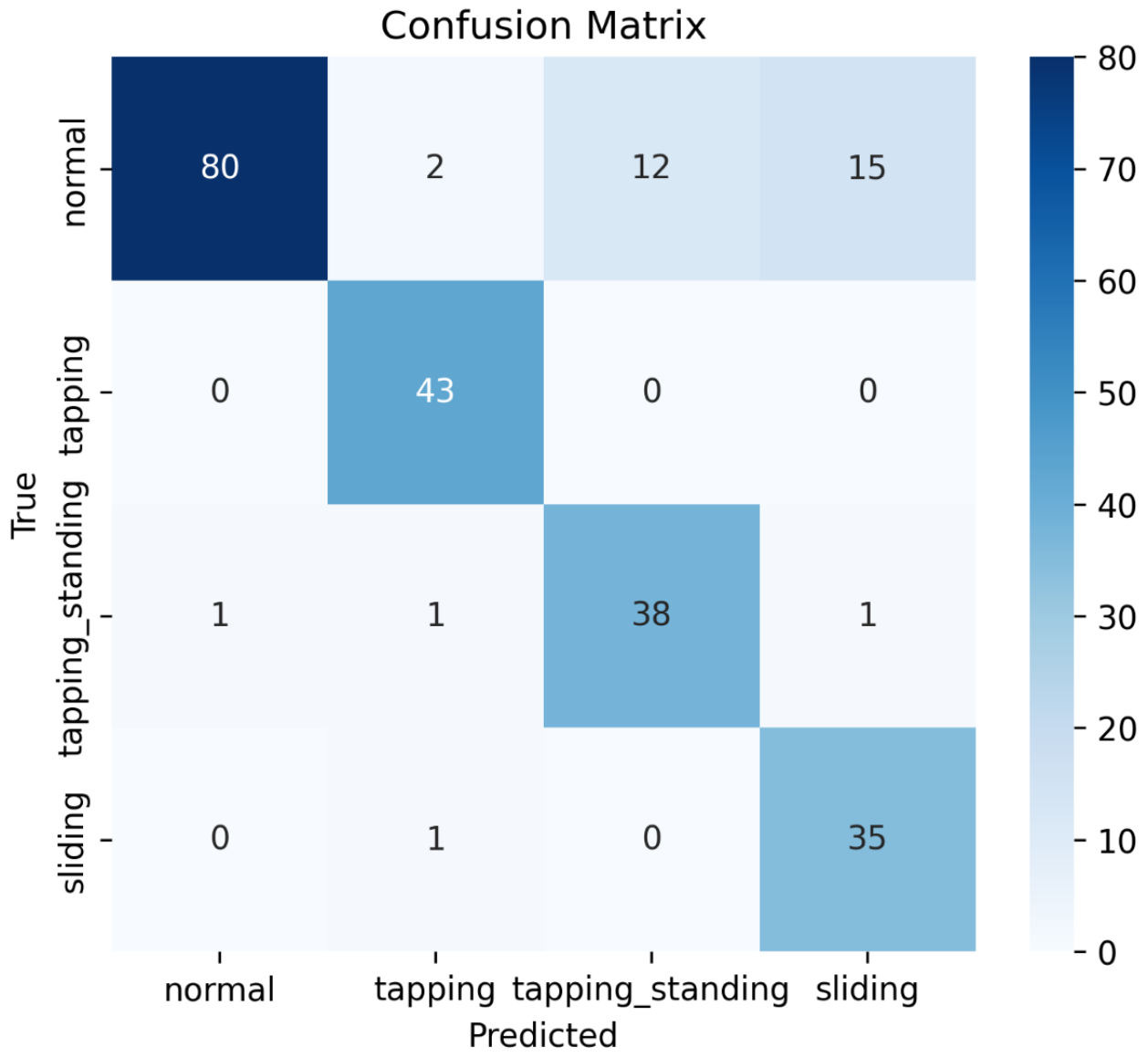

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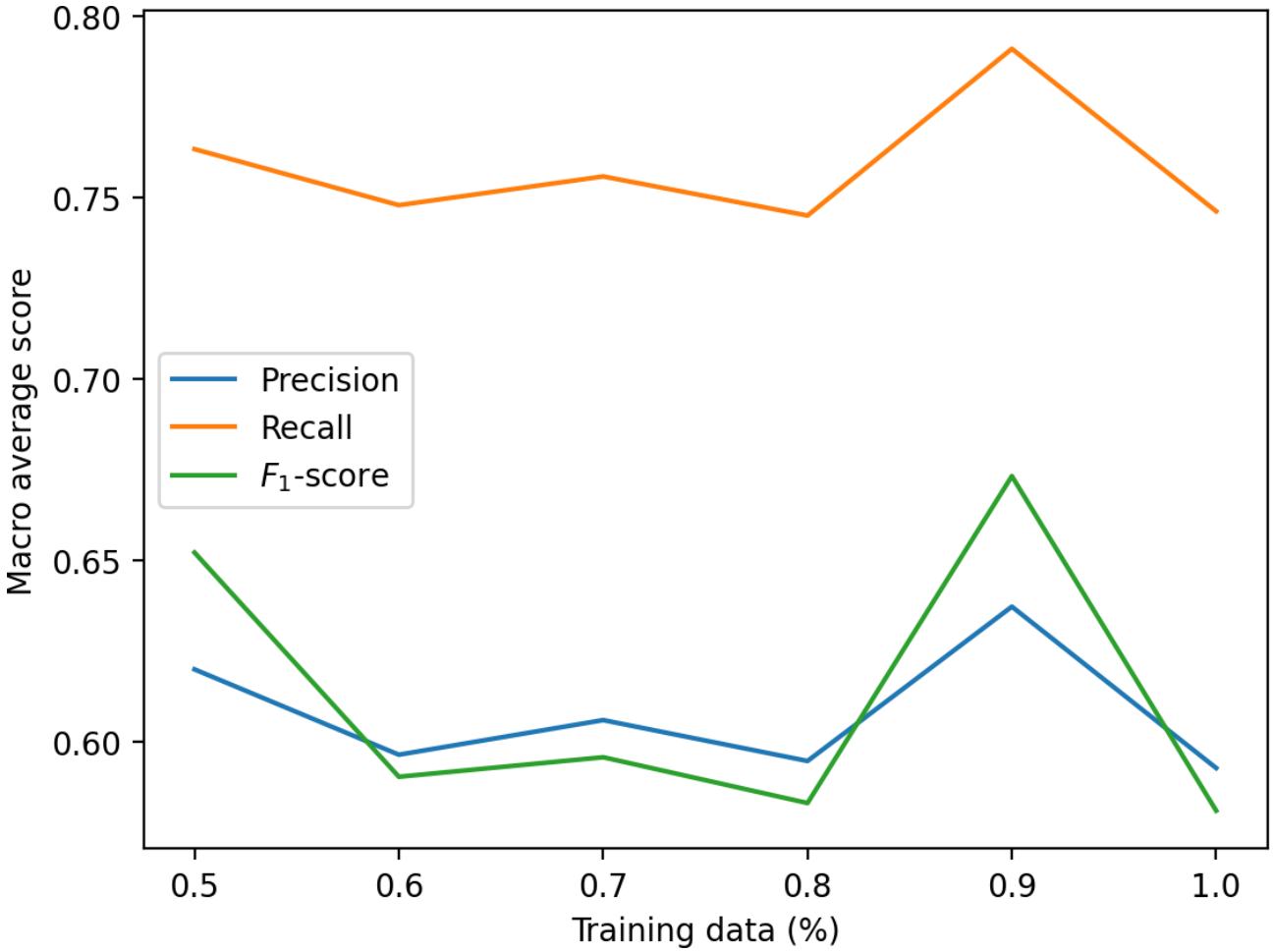
Figure 6. Learning curve for the hidden Markov model (HMM).



As a second, sequence-based approach, an HMM was used to identify the 4 states "normal," "tapping," "tapping_standing," and "sliding." The main advantage of HMM lies in the fact that there is no need for preprocessing and feature extraction; one can directly use the raw data from the 3D accelerometer. Accordingly, the need for processing power of a sensor system is lower than that for our first approach, which may enable a more resource-efficient implementation in future systems. As the confusion matrix in Figure 5 shows, the performance of the HMM algorithm is lower than that of the random forest.

The precision for "sliding" and "tapping_standing" is notably lower than that of random forest. Nevertheless, because HMMs are generative models that rely heavily on statistical estimates, they tend to benefit from larger datasets more than, for example, random forests, which increases the chances of improved performance with more training data. This idea is also supported by the calculated learning curve as shown in Figure 6.

These findings indicate that under controlled conditions, agitation-related motor patterns can be explored and differentiated using in-shoe accelerometer data, and that multimodal, feature-based models currently outperform raw-data sequence models for this dataset. These results should be considered preliminary, reflecting the limited sample and controlled environment.

Discussion

Integration of Findings Into Nursing Practice

This feasibility study provides initial insights into the acceptability and real-world practicality of sensor-based footwear for mobility and agitation-related movement analysis in institutional long-term care. Although the system demonstrated situational alignment with nursing needs, particularly regarding mobility support and movement-related data capture, its implementation was influenced far more by organizational and contextual conditions than by technical performance (eg, inconsistent charging routines). This is in line with implementation research showing that the integration of digital technologies in nursing care is strongly shaped by contextual and subjective factors such as nurse experience, structural conditions, and technical specifications which ultimately determine whether a technology can be embedded sustainably into everyday workflows [22-24]. The following operational constraints limited the extent to which feasibility could be interpreted in a broader implementation sense; communication gaps across rotating staff, limited availability of suitable shoe sizes, and resident-related fluctuations such as fatigue, illness, or episodic confusion repeatedly interfered with planned measurement sessions. These challenges affected protocol adherence and underscore the complexity of introducing new technological systems into routine care. Similar barriers, including inconsistent device handling, workflow disruptions,

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staffing variability, and fluctuating cognitive or health status, have been widely documented in implementation research on digital nursing technologies and wearables [10,12,13]. These studies collectively highlight that successful implementation depends not only on technological functionality but also on stable routines, device maintenance capacity, and the organizational readiness of care environments. Accordingly, feasibility should be interpreted with caution: although the system functioned under everyday conditions, achieving consistent and routine integration into care workflows would require additional organizational support, tailored training, and adaptations that account for the heterogeneity and unpredictability inherent in long-term care. Any future implementation would therefore require workflow-compatible procedures, clearly defined responsibilities, and organizational support structures capable of accommodating additional tasks such as charging devices, coordinating measurement schedules, and monitoring device use over time. Considerations related to resource allocation, including ongoing maintenance and staff training, further underscore the need to align technological solutions with the existing capacities and constraints of long-term care environments.

A clear discrepancy emerged between the intended target population and residents reachable under everyday institutional conditions. Sedation, health fluctuations, and inconsistent participation limited the capture of natural agitation. This underscores the tension between research design and long-term care realities, where dynamic health trajectories, risk management, and logistical constraints shape participation and data quality. These findings are consistent with prior work highlighting the need for pragmatic, context-sensitive approaches in complex care settings [25] and the inherent difficulty of attributing outcomes within multifaceted psychosocial and organizational nursing systems [26].

An additional aspect emerging from the study concerns the ethical tension between mobility promotion and safety-related practices. Sedation may reduce immediate risks associated with agitation but also restricts autonomy, mobility, and overall quality of life. While sensor-based monitoring could, in principle, contribute to earlier recognition of restlessness or instability, technologies must be implemented in a manner that supports person-centered care, respects residents' comfort, and remains sensitive to ethical considerations. Their use should therefore be carefully calibrated to avoid reinforcing restrictive practices or adding burdens to already strained care routines.

Although this study was conducted in institutional long-term care settings, some insights may inform future adaptation of sensor-based footwear in home-based care. Portability across environments, independence from fixed-location infrastructure, and the potential to capture meaningful movement patterns in daily living contexts could offer advantages over stationary monitoring technologies. At the same time, the adoption of such systems in home care will depend on affordability, intuitive handling, and clearly perceived benefits for older adults and caregivers, factors consistently identified as essential determinants of technology acceptance in aging populations [27].

Research at the Intersection of Standardization and Care Practice

This study illustrates the limitations of classical standardization in real-world long-term care. Methodologically rigorous and reproducible data collection often conflicts with the realities of everyday care [26,28]. These findings reinforce the broader insight that technological innovations cannot be meaningfully examined in isolation from the organizational environments in which they are situated.

Pragmatic exploratory studies such as this one play an important bridging role between technology development, nursing science, and day-to-day care delivery. They do not aim to produce classical randomized controlled trial evidence but instead generate practice-based insights that contribute to the growing body of "real-world evidence" [29]. In doing so, the study aligns with the goals of implementation science, which examines not only whether an intervention works but also how, for whom, and under what contextual conditions [30]. The findings highlight the central influence of nursing professionals and organizational culture on the meaningful use of sensor-based technologies in care environments [22]. By applying a context-sensitive and multiperspective approach, the study explores whether AI-supported sensor technology is not only technically functional but also ethically acceptable and organizationally compatible with the realities of nursing practice.

The study indicates that sensor-equipped footwear is generally acceptable for residents and feasible to use in principle. Although agitation detection appeared to have limited clinical relevance in this context, applications related to movement quality and fall-risk assessment seem more promising and may be achievable with simplified sensor configurations. Such configurations could support scalability and reduce resource requirements.

The findings also emphasize the importance of moving beyond sedation-centered behavioral management toward mobility-promoting and person-centered care models. Evidence from long-term care settings, particularly in the Netherlands and Belgium, suggests that nonpharmacological, activity-based approaches are associated with reduced agitation and lower reliance on psychotropic medication. In contrast, higher levels of staff distress have been associated with increased prescription of psychotropic drugs in residents with dementia [31-33]. Sustainable use of sensor-based systems would require workflow compatibility, adequate staff training, and supportive organizational structures. The project shows that a technology "drop-in" without structural embedding is unlikely to result in lasting adoption.

Residents generally accepted the device, and the technical functioning of the insole system could be demonstrated, yet several contextual barriers shaped feasibility. These included limited accessibility of the intended target group, frequent pharmacological sedation, acute health fluctuations, inconsistent charging, communication gaps across shifts, and practical issues such as shoe fit. Together, these observations offer an empirical foundation for refining implementation strategies and designing larger studies aimed at evaluating feasibility and early effectiveness under more controlled operational conditions.

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Beyond implications for study feasibility, these findings also raise questions about the practical value of sensor-based agitation detection in everyday long-term care. In settings where agitation is predominantly managed through pharmacological sedation or restrictive practices, residents who might benefit most from continuous monitoring are often those for whom detectable agitation-related behaviors are least observable. Under such conditions, sensor-based agitation detection may have limited immediate clinical use. However, the absence of detectable agitation should not be interpreted as the absence of underlying distress. From a longer-term perspective, sensor-based movement monitoring may still provide value by making care practices more visible, supporting reflection on sedation use, and enabling the evaluation of alternative, mobility-oriented approaches to managing behavioral symptoms. The findings, therefore, suggest that the added value of agitation detection technologies is strongly context-dependent and closely linked to institutional care cultures and management strategies.

Limitations

This feasibility study has several limitations that should be considered when interpreting the findings. The sample size was very small and shaped by substantial recruitment barriers, including prevalent sedation practices and fluctuating health status, which restricted the pool of eligible participants. These constraints limited the diversity and representativeness of the sample and affected the consistency of participation across measurement days.

Natural agitation episodes occurred only rarely during the study period, which restricted the opportunity to observe spontaneous agitation-related behavior under real-world conditions. Although controlled simulations served as a methodological proxy to characterize agitation-related movement patterns, they cannot fully substitute for naturalistic observations and should therefore be interpreted as exploratory.

The machine-learning analyses relied on a restricted and highly standardized dataset derived largely from controlled testing, which increases the risk of overfitting and limits generalizability. Larger datasets with more heterogeneous patterns will be necessary to develop robust detection models.

Furthermore, inconsistent charging routines, workflow interruptions, and variable communication across shifts affected protocol adherence and introduced procedural variability that may have influenced data completeness and system performance.

These limitations are typical for early-stage feasibility studies in complex care environments. They nonetheless highlight important methodological considerations for future research, including the need for expanded samples, improved charging and communication routines, and study designs that more effectively accommodate the unpredictability of long-term care.

Conclusions

This feasibility study demonstrates that sensor-based footwear is generally acceptable to residents and has the potential to be technically feasible under everyday conditions in long-term care. Real-world contextual factors, particularly pharmacological sedation, fluctuating health status, and organizational constraints (eg, inconsistent charging routines) significantly hinder the system's everyday usability. These constraints delineate the feasibility boundaries of sensor-based agitation monitoring and clarify why certain target outcomes could not be meaningfully assessed in this setting.

Our findings provide essential early insights into the contextual determinants that shape the use of sensor-based technologies in institutional care. They identify the technological refinements, procedural adjustments, and organizational prerequisites that must be addressed before larger-scale evaluations can be conducted. By revealing how feasibility is conditioned by institutional routines, staffing structures, and resident characteristics, the study lays important groundwork for subsequent research and supports the development of digital innovations that are aligned with everyday nursing practice. Ultimately, such technologies have the potential to promote mobility, autonomy, and well-being provided they are adapted to the realities of long-term care and embedded in supportive organizational frameworks.

Acknowledgments

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Data Availability

The data supporting the findings of this study are available from the corresponding author upon reasonable request.

Authors' Contributions

SH contributed to study conception, participated in data collection, and co-analyzed the observational and situational data. SH also contributed substantially to manuscript writing.

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AVB led data collection and performed analysis of observational and situational data related to the implementation process. Additionally, AVB prepared the initial manuscript draft.
MZ was responsible for the analysis of the sensor-based shoe data and manuscript writing of the results.
All authors actively contributed to drafting, revising, and approving the final version of the manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Simulation protocol for algorithm validation.
[DOCX File, 24 KB - formative_v10i1e83133_app1.docx]

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Abbreviations

AI: artificial intelligence
HMM: hidden Markov model
ICD-10: *International Classification of Diseases, Tenth Revision*
RQ: research question

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The Role of Fear, Hope, Message Fatigue, and Message Shocking Value in Promoting the Public's Understanding and Support Toward COVID-19 Wastewater Monitoring: Experimental Study

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Abstract

Background: Although wastewater monitoring is an effective, nonintrusive public health strategy for tracking community-level COVID-19 prevalence, there has been limited research on public perceptions of this novel surveillance method. A significant gap exists in understanding how to design effective communication campaigns to gain public support for wastewater monitoring and persuade individuals to take preventive actions based on the data.

Objectives: This study aimed to examine the impact of emotional appeals (fear vs hope) and pronoun use (we vs you) on public support for COVID-19 wastewater monitoring, intentions to discuss the intervention, and intentions to engage in preventive behaviors.

Methods: An online 2 (emotional appeal: fear vs hope) × 2 (pronoun use: you-language vs we-language) between-subjects experiment with a control condition was conducted. A total of 603 US residents were recruited via Prolific in July 2023. Participants were randomly assigned to view 1 of 5 message stimuli and then completed a survey measuring emotional responses, message judgments (fatigue and shocking value), and the primary outcome variables.

Results: Fear appeals led to greater support and stronger intentions to engage in preventive behaviors than hope appeals, while pronoun use had no significant effect. Additionally, message fatigue and shock value mediated the relationship between the message-evoked emotions and the outcome variables, whereby message fatigue was negatively associated with the outcome variables, and message shock value was positively correlated with policy support and communication intention.

Conclusions: The findings suggest that while fear-based messages are effective, communication strategies should also aim to mitigate message fatigue to sustain public engagement and support for long-term public health initiatives.

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KEYWORDS

emotional appeals; we-language vs you-language; COVID-19 preventive behaviors; message fatigue; message shocking value

Introduction

Background

Since the outbreak of COVID-19, various measures have been implemented to get up-to-date information on the prevalence of infection in order to take necessary steps for the patients and to prevent the spread of the disease among community members [1,2]. One effective, nonintrusive way to track the infection is through wastewater monitoring (ie, wastewater surveillance; [3,4]). Although interest in the use of wastewater for public health surveillance has grown exponentially during the COVID-19 pandemic [5], there has been limited research on the actual perceptions and understanding of the community members regarding the novel strategy [6], including how to gain the public's support toward this surveillance intervention and persuade them to take necessary actions based on the wastewater monitoring data.

To begin filling this gap for the campaign design, this study examines the effects of emotional appeals (fear vs hope appeal) and type of pronouns (we-language vs you-language) on support for COVID-19 wastewater monitoring, interpersonal communication about COVID-19 wastewater monitoring, and intentions for COVID-19 preventive behavior upon viewing the wastewater monitoring data. Wastewater monitoring is a relatively unfamiliar, population-level surveillance tool that relies on anonymous and indirect data, yet its success depends on public understanding and policy support [3,4]. This study uses a 2×2 experimental design to provide practical evidence for how strategic framing of emotional appeals and pronoun

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usage can enhance public engagement with this health surveillance technology.

We begin by reviewing the roles of fear and hope in the context of COVID-19, examining how the variations of the pronouns in fear and hope appeals may lead to different persuasive outcomes. Next, we investigate the 2 message judgments (ie, message fatigue and message shocking value) as mechanisms for how fear and hope appeals lead to persuasive outcomes. Finally, we report on and discuss a study that tests our predictions about the message effects on persuasive outcomes.

Communicating COVID-19 Wastewater Monitoring to the Public

Wastewater surveillance involves analyzing sewage water to detect and monitor the presence and concentration of pathogens, such as viruses, shed by a community [5]. The Centers for Disease Control and Prevention launched the National Wastewater Surveillance System in September 2020 in response to the COVID-19 pandemic [7]. The National Wastewater Surveillance System coordinates with communities in the United States to detect the presence of SARS-CoV-2, which is the virus that causes COVID-19. Wastewater monitoring is an effective tool that can inform timely public health responses to prevent further spread of COVID-19, providing quick and efficient community-level data for early detection and warning [8]. Unlike other types of COVID-19 surveillance, wastewater monitoring is independent of health care access or testing availability, with the potential to detect various infectious disease threats in the future [9,10]. That is, it retains clear relevance as a long-term public health strategy because the infrastructure and analytic capacity developed during the pandemic can be leveraged to monitor a range of emerging and reemerging infectious diseases, including influenza, respiratory syncytial virus (RSV), and potential future pathogens of concern [11].

Although wastewater monitoring proves to be a promising tool in tracking community-level viral spread, the public health communication challenge lies in engaging and educating the public about the relevance and necessity of this surveillance method. A nationwide survey indicated that survey respondents had limited knowledge of the basic functions of wastewater monitoring [12]. Findings from another survey revealed a similar gap in understanding, with 49% of respondents reporting that they did not know COVID-19 can be detected in municipal sewer systems [6]. Moreover, some participants expressed skepticism and mistrust toward the method due to a lack of familiarity in the same survey. Although more recent survey data suggest overall public support for wastewater monitoring, researchers continue to call for expanded public education, as concerns regarding privacy and anonymity persist [11]. Successfully addressing these challenges involves not only gaining public support and sustaining their interest in wastewater monitoring but also encouraging individuals to take preventive measures in response to wastewater data. To this end, we investigate the message features and underlying mechanisms that influence support toward COVID-19 wastewater monitoring, interpersonal communication about the COVID-19 wastewater monitoring, and intention to take preventive measures in response to wastewater monitoring data.

Emotional Appeals Using Different Types of Pronouns (We-Language vs You-Language)

The COVID-19 pandemic stirred widespread feelings of fear within the public, a negatively valenced emotion instigated by an emerging threat or perceived danger [13,14]. Fear has been recognized as a significant driving force behind preventive health behaviors against COVID-19, including social distancing, frequent hand washing, and mask-wearing [15,16]. Messages that evoke fear (ie, fear appeals) effectively induce high perceived severity and susceptibility, motivating individuals to adopt risk preventive measures [17]. During the pandemic, health messages often used fear appeals to promote public health behaviors [18]. Meanwhile, increasing attention has been drawn to the use of positively valenced emotions such as hope in persuasive communication (eg, [19]). Especially in the context of COVID-19, several researchers have called for a need to counterbalance prevalent negative emotions with positive emotional appeals to reduce undesired consequences, such as message avoidance and reactance [20,21]. For instance, hope plays a crucial role in aiding individuals to cope and persevere, particularly under stressful and challenging circumstances [22]. Hope appeals have been noted as a powerful motivator for behaviors that enable oneself to obtain future rewards and avoid punishment [23].

In addition to evoking emotional responses such as fear and hope, COVID-19 has triggered a sense of both individualistic and collectivistic perspectives to address the public health issue. Individually, people were confronted with risks of infection and pain from short- and long-term post symptoms even after recovery, such as a change in smell or taste, shortness of breath, chronic chest pain, depression, and changes in menstrual cycles [24]. COVID-19 was a life-threatening problem to some individuals in the most extreme cases, as more than 1 million Americans have lost their lives due to COVID-19 [25]. Simultaneously, the pandemic necessitated a communal approach, with fundamental prevention measures like masking and quarantine relying on individuals being socially aware that their actions impact not just themselves, but others in their community who might be more vulnerable [26].

Noting the dual nature of COVID-19, researchers examined the pronoun usage (ie, we vs you) to understand effective message design for combating COVID-19 [27,28]. Previous research generally showed that we-language is effective in inducing a collective self-concept, enhancing communal coping perceptions, attitudes, and social connectedness [29,30]. In the COVID-19 context, Jordan et al [27] conducted experimental studies with messages that emphasized personal, public, or their combined benefits of prevention behaviors, showing the importance of highlighting the public benefits of COVID-19 prevention behaviors.

Pronoun usage has often been investigated along with emotions as they yield some interactive influences on communicative, relational, and behavioral outcomes [31,32]. In this study, we examine the interactive effects of pronoun usage with 2 message-induced emotions, fear and hope, on attitudinal,

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communicative, and behavioral intentions related to COVID-19 wastewater surveillance. Given the lack of clear directional predictions in the existing literature regarding the interaction between pronoun usage and message-induced emotions, we explore these effects through research questions. Therefore, we pose the following research questions:

- RQ1: Will the type of pronouns (we-language vs you-language) used in the message moderate the influence of fear appeal on (1) support for wastewater surveillance, (2) interpersonal communication about wastewater surveillance, and (3) intention to perform COVID-19 preventive behavior?
- RQ2: Will the type of pronouns (we-language vs you-language) used in the message moderate the influence of hope appeal on (1) support for wastewater surveillance, (2) interpersonal communication about wastewater surveillance, and (3) intention to perform COVID-19 preventive behavior?

Message Fatigue and Message Shocking Value as Mediators

To understand the mechanisms of how fear and hope appeals influence the public's support for and understanding of wastewater monitoring against COVID-19, we considered 2 message judgments as mediators in the relationship: message fatigue and message shocking value. Message fatigue refers to an aversive motivational state caused by overexposure to campaign messages or information perceived to be similar and redundant over an extended period of time [33,34]. Message fatigue is associated with adverse cognitive, affective, and behavioral outcomes of persuasive messages, including message avoidance, annoyance, desensitization, counterargument, and less message elaboration [34].

Research suggests that emotional responses can shape the degree of message fatigue audiences experience. For instance, COVID-19 message fatigue was positively correlated with negative emotions including fear and sadness, while hope acted as a buffer against the aforementioned negative consequences [33]. We may infer that fear heightens perceived threat salience [35,36] and makes repeated exposure more taxing, thereby exacerbating message fatigue. In contrast, hope fosters a sense of efficacy and solution-oriented thinking [23], functioning as a buffer against the aversive effects of repeated exposure. Drawing on these insights, we hypothesize that COVID-19–related fear will be positively associated with message fatigue, whereas COVID-19–related hope will be negatively associated with message fatigue.

In various health contexts including COVID-19, message fatigue has been associated with reactance, yielding undesirable health outcomes such as less favorable attitudes and behavioral intentions toward positive health behaviors [37,38]. Feeling fatigued with messages has also reduced the likelihood that one will share the message content with others [39]. Despite the relatively novel aspects of wastewater monitoring, we expected to observe negative effects of message fatigue in the current study due to the general fatigue that the public is experiencing regarding COVID-19 [40]. Drawing from the previous empirical findings, we posit the following hypotheses regarding the antecedents and consequences of COVID-19 message fatigue:

- H1: Message fatigue is (1) positively associated with fear but (2) negatively associated with hope.
- H2: Message fatigue is negatively associated with (1) support for COVID-19 monitoring in wastewater, (2) intentions to talk about the monitoring with others, and (3) intentions to engage in COVID-19 safety behaviors.

We posed a message with shocking value as a mediator between the 2 discrete emotions and the proposed message outcomes. Defined as a combination of surprise and extremity regarding a message, message shocking value was positively associated with the specific emotional appraisals (eg, feeling dangerous) of threat messages [41,42]. Fear, as a primary appraisal of threat [43], may heighten sensitivity to novel or extreme elements in a message [44], thereby increasing its perceived shocking value. Hope is often considered a core element of secondary appraisals of fear that provides people with abilities and motives to take appropriate actions to escape from the current negative state [16]. In the context of wastewater monitoring, which is a relatively novel public health strategy, hope may lead individuals to interpret the message's innovative aspects as surprising and promising, thus elevating shocking value. From the above theoretical assumptions, we expect that both fear and hope would be positively correlated with message shock value. In addition, shocking health messages are more likely to attract attention, be talked about, and be shared among people [45,46]. In line with previous findings, we expect that message shocking value will be associated with greater intentions to talk about the message topic.

However, there is a lack of empirical investigation on how message shocking value relates to behavioral outcomes, such as support for wastewater surveillance policies and engagement in preventive health behaviors. We thus posed a research question to explore the relationship between message shocking value and behavioral outcomes:

- H3: Perceived message shocking value is positively associated with (1) fear and (2) hope.
- H4: Perceived message shocking value is positively associated with the intention to talk about COVID-19 monitoring in wastewater.
- RQ3: Does perceived message shocking value have a significant association with (1) support for COVID-19 monitoring in wastewater and (2) intentions to engage in COVID-19 safety behaviors?

Additionally, as we only focused on 2 mediators in this experimental study, we hoped to explore other factors that might influence individuals' support for waste monitoring for COVID-19 prevention. Given the exploratory nature of this inquiry and the absence of clear theoretical or empirical guidance regarding these additional factors, a research question was most appropriate. Therefore, we posed the following research question and examined the participants' open-ended responses to the question:

- RQ4: Why do people decide to support (or not support) COVID-19 monitoring in wastewater?

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Methods

Study Design and Message Stimuli

The study was a 2 (emotional appeal: fear appeal vs hope appeal) × 2 (types of pronouns: you-language vs we-language) between-subjects design with 1 control condition (ie, informational message only). All participants read an informative message about COVID-19 monitoring in wastewater, followed by 5 different message stimuli (see Multimedia Appendix 1 for the messages).

Participants

Upon receiving approval from the university's institutional review board, participants were recruited using Prolific (Prolific Academic Ltd), a widely used online crowdsourcing platform that allows researchers to post study advertisements that participants voluntarily complete in exchange for monetary compensation [47]. The present study was posted on the Prolific platform with predefined eligibility criteria, which restricted participation to US residents who are 18 years or older.

Ethical Considerations

This study received approval from the Institutional Review Board at the University of Denver (IRB approval 2061013 - 1). All participants provided informed consent for their participation and the publication of their anonymized data. The survey collected sociodemographic data (age, gender, education, race, employment, and income) but no personal identifiable information. Participants received monetary compensation (US $3.50) for completing the survey.

Procedures

The survey was conducted between July 18 and July 19, 2023. After giving consent, participants were asked to select the wastewater use service area that matches their residential area or the one that they think is the closest to where they live. All participants then read an informative message about COVID-19 monitoring in wastewater. Participants in all 5 conditions read additional message stimuli, which were followed by questions about their emotional responses, message judgments, and attitudinal, communicative, and behavioral outcomes regarding wastewater monitoring for COVID-19.

Measures

Overview

We used multi-item scales to assess fear, hope, perceived message shocking value, message fatigue, support for COVID-19 monitoring in wastewater, interpersonal communication about COVID-19 monitoring in wastewater, and preventive behaviors against COVID-19 (see Multimedia Appendix 1 for the full list of items). All variables were based on 5-point scales from 1 (*strongly disagree*) to 5 (*strongly agree*) and averaged, unless otherwise stated. Across items, there were a total of 17 missing observations. The missing data were replaced with mean scores for nonmissing observations for the given scale [48]. A confirmatory factor analysis was conducted in AMOS version 26 (Prolific Academic Ltd) to test the measurement properties of these scales. We used the following criteria to evaluate the overall model fit: $\chi^2/df<3.00$, comparative fit index (CFI) greater than 0.90, and root mean squared error of approximation (RMSEA) less than 0.08 [49,50]. The measurement model included all items for each latent construct, and latent constructs were allowed to covary. The fit for the initial measurement model showed room for improvement ($\chi^2/df=4.51$, CFI=0.91, and RMSEA=0.09, 90% CI 0.081-0.089). Based on the modification indices, we allowed the error terms of 3 pairs of items for message fatigue and 3 pairs of items for COVID-19 preventive behaviors to covary. The adjusted measurement model showed a good fit to the data ($\chi^2/df=2.55$, CFI=0.96, and RMSEA=0.06, 90% CI 0.053-0.061).

Message Informativeness

To ensure the experimental conditions do not differ in informational content, message informativeness was measured with 3 items, including "I learned something from reading the message" and "The message provided me with meaningful information" (mean 3.90, SD 0.88; α=.87).

Fear

Fear was measured by asking participants how much of the following 3 emotions—fear, scared, and afraid—they felt after reading the message. Responses, marked on the 5-point scales from 1 (*none of this emotion*) to 5 (a *great deal of this emotion*), were averaged into 1 score, with higher scores indicating greater fear (mean 1.52, SD 0.82; α=.96).

Hope

Hope was measured by asking participants how much of the following 3 emotions—hope, inspired, and encouraged—they felt after reading the message. Responses, marked on the 5-point scales from 1 (*none of this emotion*) to 5 (a *great deal of this emotion*), were averaged into 1 score, with higher scores suggesting stronger hope (mean 1.96, SD 1.14; α=.93).

Message Fatigue

Adapted from So et al [34], message fatigue was assessed with 8 items, including "Messages about COVID-19 are all beginning to sound the same to me," and "I'm tired of hearing about the importance of COVID-19 preventive behaviors" (mean 2.95, SD 1.23; α=.96).

Message Shocking Value

Adapted from Smith et al [41], message shocking value was assessed with 3 items that measured the degree to which participants judged the message to be surprising, shocking, and alarming (mean 1.72, SD 0.79; α=.87).

Support for COVID-19 Monitoring in Wastewater

Support for COVID-19 monitoring in wastewater was assessed with 4 items including "I'm supportive of COVID-19 monitoring in wastewater" and "I think COVID-19 monitoring in wastewater is helpful" (mean 4.04, SD 1.06, α=.98).

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Interpersonal Communication About COVID-19 Monitoring in Wastewater

Interpersonal communication about COVID-19 monitoring in wastewater was assessed with 5 items such as "I will tell others about COVID-19 monitoring in wastewater" and "I will talk about COVID-19 monitoring in wastewater with my family" (mean 2.81, SD 1.20; α=.96).

Intention for Preventive Behavior Against COVID-19

Intention for preventive behaviors against COVID-19 was assessed with 6 items including "I will wear a mask in indoor spaces," and "I will try to avoid crowded locations and mass gatherings" (mean 4.14, SD 0.93; α=.89).

COVID-19 Involvement

COVID-19 involvement was assessed with 3 items: "Preventing COVID-19 is important to me," "Preventing COVID-19 is relevant to me," and "Preventing COVID-19 is meaningful to me" (mean 4.32, SD 0.94; α=.95).

Political Ideology

Political ideology was measured by asking participants to indicate their political ideology on a 5-point scale from 1 (*extremely liberal*) to 5 (*extremely conservative*); mean 2.36, SD 1.15.

Attitude Toward the Policy

Respondents' open-ended responses were collected for an in-depth understanding of the reasons behind their support (or nonsupport) toward wastewater monitoring (RQ4). The codebook was developed after the initial review of the entire set of open-ended responses. Regarding the attitude toward the policy, the responses were categorized into support, conditional support, no support, and neutral. The reasoning category for policy support included informative value, effectiveness, novelty, nonintrusiveness, community protection, etc. The reasoning category for not supporting the policy included waste of money, government mistrust, not enough information, low perceived threat toward COVID-19, and privacy concerns. These categories were nonexclusive. The unit of analysis was a complete answer about participants' opinions with or without specific reasons. Based on the codebook, the authors coded 20% (120/576) of the open-ended responses and resolved a few disagreements through discussion. The 2 coders independently coded the rest of the data. Intercoder reliabilities ranged from 0.94 to 1.00.

Results

Participants

Of the total 609 participants, 5 participants who failed the attention check question and 1 participant who took less than 5 minutes to complete the survey were eliminated from the following analyses. The final sample included 603 (n=330, 54.7% female) participants who, on average, were 39.59 (SD 12.94; median 37, min 18, max 81) years old. The average completion time was approximately 20 minutes (mean 20.38, SD 9.90 minutes). Table 1 presents demographic information of the participants.

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Table . Respondent demographics.

	Frequency, n (%)
Gender	
Female	330 (54.7)
Male	261 (43.3)
Transgender	5 (0.8)
Prefer not to answer	7 (1.2)
Education	
Attended high school	10 (1.7)
Graduated from high school	209 (34.7)
Graduated from college with an associate's degree (AA, AS, etc)	70 (11.6)
Graduated from college with a bachelor's degree (BA, BS, etc)	233 (38.7)
Graduated with a graduate degree (MA, JD, MD, PhD, and etc)	80 (13.3)
Race[a]	
White	441 (73.1)
Black or African American	91 (15.1)
Hispanic, Latino, or Spanish origin	59 (9.8)
Asian	53 (8.8)
American Indian or Alaska Native	16 (2.7)
Native Hawaiian or other Pacific Islander	4 (0.7)
Some other race, ethnicity, or origin	5 (0.0)
Income (US $)	
<20,000	91 (15.1)
20,000-34,999	95 (15.8)
35,000-44,999	117 (19.5)
50,000-74,999	122 (20.3)
75,000 -99,999	74 (12.3)
≥100,000	101 (16.8)
Employment	
Employed by a company that you do not own	334 (55.4)
Self-employed	95 (15.8)
Full-time student	36 (6.0)
Unemployed	97 (16.1)
Retired	41 (6.8)

[a]Participants were allowed to respond to multiple options for race/ethnicity.

Manipulation Checks

We first assessed whether (1) the fear appeal was the most fear-inducing, (2) the hope appeal was the most hope-inducing, and (3) the 5 messages were comparable in levels of informativeness. The ANOVA results showed that participants reported greater fear in response to the fear appeal (mean 1.73, SD 0.91, 95% CI 1.62 - 1.85) than the hope appeal (mean 1.40, SD 0.72, 95% CI 1.31 - 1.49) or informational appeal (mean 1.36, SD 0.72, 95% CI 1.23 - 1.49; $F_{2,600}$=13.59; P<.001; η^2=0.04). The ANOVA results showed that participants reported greater hope in response to the hope appeal (mean 2.10, SD 1.24, 95% CI 1.95 - 2.26) than the fear appeal (mean 1.84, SD 1.08, 95% CI 1.70 - 1.98), but there was no statistically significant difference with the informational appeal (mean 1.93, SD 1.03, 95% CI 1.75 - 2.12; $F_{2,600}$=3.27; P=.04; η^2=0.01). The ANOVA results showed that perceived informativeness did not vary by message condition ($F_{4,598}$=1.98; P=.10; η^2=0.01). The CIs for the message conditions overlapped, indicating that the difference between the conditions was not statistically significant: informational appeal (mean 4.06, SD

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0.67, 95% CI 3.94 - 4.18), fear appeal in we-language (mean 4.03, SD 0.88, 95% CI 3.87 - 4.18), hope appeal in we-language (mean 3.95, SD 0.80, 95% CI 3.81 - 4.10), fear appeal in you-language (mean 3.85, SD 0.91, 95% CI 3.69 - 4.01), and hope appeal in you-language (mean 3.81, SD 0.93, 95% CI 3.65 - 3.98). In the subsequent analyses, we included a total of 482 participants in the fear appeal and hope appeal conditions.

Preliminary Analyses

To inspect overall patterns in the data, we examined the means and SDs of all variables and the correlations among them. Table 2 presents the correlation matrix.

Table . Correlation matrix for the study variables (n=603)[a].

	1	2	3	4	5	6	7	8	9
(1) Fear									
r	1								
P value	—[b]								
(2) Hope									
r	0.06	1							
P value	.17	—							
(3) Msgfatig									
r	–0.18	–0.32	1						
P value	<.001	<.001	—						
(4) Msgshock									
r	0.53	0.12	–0.12	1					
P value	<.001	.002	.003	—					
(5) Support									
r	0.10	0.35	–0.51	0.13	1				
P value	.01	<.001	<.001	<.001	—				
(6) Comm									
r	0.26	0.34	–0.42	0.29	0.45	1			
P value	<.001	<.001	<.001	<.001	<.001	—			
(7) Intention									
r	0.11	0.21	–0.49	0.10	0.63	0.37	1		
P value	.005	<.001	<.001	.01	<.001	<.001	—		
(8) Involve									
r	0.17	0.24	–0.51	0.14	0.59	0.38	0.67	1	
P value	<.001	<.001	<.001	<.001	<.001	<.001	<.001	—	
(9) Political									
r	–0.04	–0.05	0.37	0.04	–0.37	–0.16	–0.36	–0.30	1
P value	.36	.19	<.001	.33	<.001	<.001	<.001	<.001	—

[a]Msgfatig refers to message fatigue, msgshock refers to message shocking value, support refers to support for wastewater surveillance, comm refers to interpersonal communication about wastewater surveillance, intention refers to intention to perform COVID-19 preventive behavior, involve refers to involvement with COVID-19, and political refers to political ideology (ie, higher score refers to stronger conservative political ideology).

[b]Not applicable.

One notable feature of the data was relatively low mean values for fear and hope. We also noted the relatively high levels of support for COVID-19 monitoring in wastewater and intentions to engage in COVID-19 safety behaviors. Because COVID-19 involvement and political ideology showed significant associations with substantive variables, we conducted our main analyses with these variables as covariates, following the procedure by Tabachnick and Fidell [51].

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Hypotheses and RQs

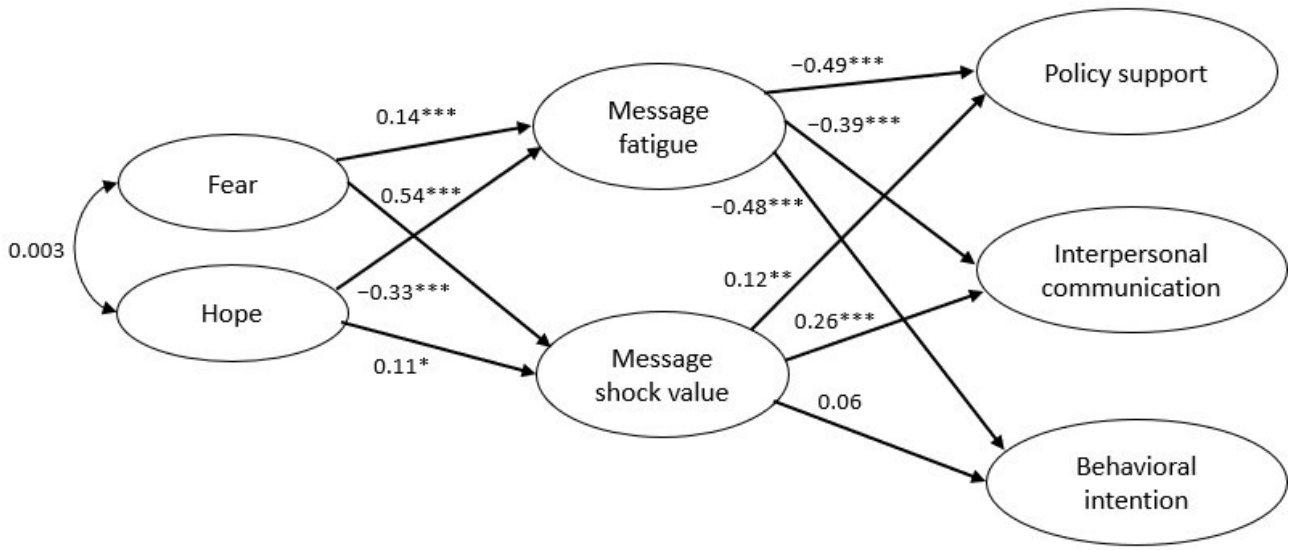
Emotional Appeals and Pronoun Use Across Message Outcomes

To explore RQ1 and RQ2, we ran a series of 2 (emotional appeal: hope vs fear appeals) × 2 (pronouns: we- vs you-language) analysis of covariance to examine message effects on support for COVID-19 wastewater monitoring, interpersonal communication about COVID-19 wastewater monitoring, and COVID-19 preventive behavior intention, controlling for involvement with COVID-19 and political ideology. Results of a 2-way analysis of covariance found that fear appeal (mean 4.11, SD 1.00) led to significantly higher support for COVID-19 wastewater monitoring than hope appeal (mean 3.91, SD 1.16; $F_{1,476}$=5.15; P=.02; partial η^2=0.011). Pronouns used in the message ($F_{1,476}$=1.57; P=.21; partial η^2=0.003) or interaction between emotional appeal and pronouns ($F_{1,476}$=1.83; P=.18; partial η^2=0.004) did not influence higher support for COVID-19 wastewater monitoring. Neither the main effects of emotional appeal ($F_{1,476}$=0.53; P=.47; partial η^2=0.001) and pronouns ($F_{1,476}$=0.03; P=.86; partial η^2=0.001) nor the interaction effects of the two ($F_{1,476}$=0.75; P=.39; partial η^2=0.002) were significant for interpersonal communication about COVID-19 wastewater monitoring. Fear appeal (mean 4.18, SD 0.87) led to significantly higher intentions for COVID-19 preventive behavior than hope appeal (mean 4.02, SD 1.03; $F_{1,476}$=4.67; P=.03; partial η^2=0.01). Pronouns used in the message ($F_{1,476}$=1.30; P=.26; partial η^2=0.003) or interaction between emotional appeal and pronouns ($F_{1,476}$=0.03; P=.86; partial η^2=0.000) did not influence higher intentions for COVID-19 preventive behavior.

Indirect Mechanisms of Message Fatigue and Shocking Value

Hypotheses H1-H4 and RQ3 were tested using structural equation modeling. The initial model included 2 exogenous variables (ie, fear and hope). Perceived message shocking value and message fatigue were treated as mediating variables, and support for COVID-19 monitoring in wastewater, interpersonal communication about COVID-19 monitoring in wastewater, and preventive behaviors against COVID-19 were the outcome variables. The initial model included all possible paths from the exogenous variables to the mediating variable, all possible paths from the mediating variable to the outcome variables, and no direct paths from the exogenous variables to the outcome variables. COVID-19 involvement and political ideology were added as covariates to the model. The estimated model indicated good fit to the data (χ^2/df=2.70, CFI=0.95, and RMSEA=0.06, 90% CI 0.056-0.063). Figure 1 presents the significant pathways between the exogenous and endogenous variables.

Figure 1. Structural equation modeling (SEM) diagram presenting the effects of discrete emotions on the 3 outcome variables mediated by message fatigue and perceived message shocking value. Note: The model presents standardized regression weights. Covariate and error terms were included in the analysis and are omitted from the figure for the sake of parsimony. *P<.05; **P<.01; ***P<.001.



H1 predicted (1) a positive relationship between fear and message fatigue while proposing (2) a negative relationship between hope and message fatigue. Both fear (β=–0.21; P<.001) and hope (β=–0.32; P<.001) were negatively associated with message fatigue, partially supporting H1.

H2 proposed a negative association between message fatigue and the 3 proposed outcomes. Supporting H2, message fatigue was negatively associated with (1) support for COVID-19 monitoring in wastewater (β=–0.53; P<.001), (2) intentions to talk about the monitoring with others (β=–0.41; P<.001), and (3) intentions to engage in COVID-19 safety behaviors (β=–0.37; P<.001).

H3 proposed a positive relationship (1) between the message shocking value and fear, and (2) between the message shocking value and hope. Supporting H3, both fear (β=0.61; P<.001) and hope (β=0.08; P<.01) were positively associated with perceived message shocking value (β=0.61; P<.001).

H4 and RQ3 were proposed to examine the relationship between the perceived message shocking value and the 3 proposed outcomes. Supporting H4, the message shocking value was

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positively associated with intentions to talk about COVID-19 wastewater monitoring with others (β=0.34; *P*<.001). Regarding RQ3, the results showed that the perceived message shocking value was positively associated with support for COVID-19 monitoring in wastewater (β=0.13; *P*<.01) but had a nonsignificant relationship with intentions to engage in COVID-19 safety behaviors (β=0.07; *P*=.15).

Themes From Open-Ended Responses on Reasons for Supporting Wastewater Monitoring

Participants' open-ended responses allowed for a more in-depth understanding of their attitude toward wastewater monitoring (RQ4). Most respondents (n=425, 74.2%) indicated they supported COVID-19 monitoring in wastewater, whereas 62 (10.8%) did not support the policy and 61 (10.6%) answered as neutral. For reasons to support wastewater monitoring, most of the respondents claimed that they support the intervention considering its effectiveness and informative value, followed by offering protection to the community. The leading reason for not supporting the intervention was due to financial concerns, followed by a low-risk perception of COVID-19 and government mistrust. A total of 19 respondents who were neutral about the intervention stated that they would need more information before forming an opinion, while others did not specify reasons for their neutral stance. The coding categories and examples for each category are presented in Table 3.

Table . Examples, frequency, and intercoder reliability of the reasons for supporting and not supporting the COVID-19 wastewater monitoring policy.

Coding category	Examples	Frequency, n	Intercoder reliability, k
Reasons for supporting COVID-19 wastewater monitoring			
Informative value	"I support any means to keep track of the outbreaks."	138	1.00
Effectiveness	"I do support it. It is another tool we can use to stop infections."	157	0.94
Novelty	"I would support it because it's an effective, new technique that can beneficially help communities know about outbreaks quickly."	2	1.00
Nonintrusiveness	"Sure, because it's a non-invasive way to track COVID spread."	37	1.00
Increase public awareness	"I think we should because it's a potential public health hazard regardless."	13	1.00
For vulnerable population	"I would support it because I think it's important to know if there is a spike of COVID in a community, especially for those who are at risk."	1	1.00
Protect community	"I support any effort done to monitor and minimize COVID-19 in the community."	96	0.96
Importance of COVID-19	"Yes I support it. If it helps eradicate COVID; I'm all for it."	36	0.96
No downside	"I don't see any reason to not support it."	29	1.00
Reasons for not supporting COVID-19 wastewater monitoring			
Waste of resources	"I wouldn't support it. It's a waste of money and resources."	19	1.00
Government mistrust	"Not a big deal. Gov makes big deal out of nothing to control and gain power."	10	1.00
Not enough information	"I would not support the COVID-19 monitoring in wastewater until I knew it was real."	5	0.96
Low perceived threat	"COVID has a low fatality rate and is no longer important."	12	0.96
Privacy concerns	"I do not support monitoring wastewater because I believe it is an invasion of citizen's privacy."	5	1.00

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Discussion

Principal Findings

This study investigated the impact of emotional appeals (ie, fear and hope appeals) and pronoun use on the attitudinal, communicative, and behavioral outcomes related to wastewater monitoring for COVID-19. Although the main effect of pronoun use was not significant, we observed that the fear appeal led to greater support for the policy and intentions to engage in COVID-19 preventive behaviors compared to the hope appeal. Additionally, significant mediating mechanisms, involving message fatigue and shock value, were observed between message-evoked emotions (ie, fear and hope) and the proposed outcomes.

While empirical data reveal the impact of pronoun use on people's emotions and judgments, we did not observe the main effect of pronoun use on our proposed outcomes. We speculate that testing the psycholinguistic features (specifically "we" vs "you") alongside emotional appeals may have confounded the effects. "You" language is often associated with negative feelings such as fear, especially when the source of a problem is being investigated. This attributive nature in "you" language facilitates denigrating or accusing a person of wrongdoing (eg, you should have behaved this way to prevent COVID-19; [52]). Conversely, "we" language obscures the singular source of the problem, making it less explicit. Thus, using "you" language in messages can effectively induce fear, whereas fear appeals in "we" language are more prone to trigger cognitive dissonance by conveying contradictory perceptions. Future research should delve into the distinct emotional valence associated with each pronoun.

We found intriguing mediating mechanisms between discrete emotions and COVID-19-related preventive measures using message fatigue and message shocking value as mediators. Both fear and hope were negatively correlated with message fatigue, with hope acting as a buffer, aligning with previous research [53]. The unexpected negative relationship between fear and message fatigue may be related to fear's novelty-inducing nature [54]. Given the prevalent message fatigue around COVID-19, experiencing any emotion might reduce fatigue. Participants with lower message fatigue were more likely to support COVID-19 wastewater monitoring, engage in discussions, and adopt preventive behaviors drawn from wastewater data. This suggests that emotional appeals may be particularly effective when addressing issues with high message fatigue.

As predicted, both fear and hope were positively associated with message shocking value, supporting the notion that messages that evoke discrete emotions are likely to be perceived as shocking [55]. The results highlight the importance of message shocking value as the mediating mechanism, as shocking messages promote support toward the novel health intervention and encourage intentions for discussions. Meanwhile, the message shocking value did not have a significant influence on preventive actions against COVID-19, as the message shocking value was mostly driven by the description of the novel health intervention in the message, rather than the information about COVID-19 preventive actions that were also presented in the message. Future research should explore ways to translate public interest in novel health interventions into adherence to recommended health behaviors.

Practically, we believe that the use of emotions and different pronouns in message design can be applied to other contexts and is worth investigating further, as they can generate unique psycholinguistic features in the messages. Although we did not find an interaction effect between the 2 message features, we believe that this is one of the crucial areas of message design that can be applicable to various contexts in need of more attention. More importantly, our results regarding the effectiveness of emotional appeals as a remedy for message fatigue demonstrate that well-designed messages can counteract fatigue in topics that typically suffer from audience disengagement, such as COVID-19 or climate change, thereby sustaining attention and support for diverse public health and environmental issues. This potential to alleviate message fatigue represents a central contribution of the present study.

Furthermore, this was one of the first studies to investigate effective message strategies to increase public support and understanding of COVID-19 wastewater monitoring. Analysis of the open-ended responses revealed that support for this intervention is highly affected by the perceived effectiveness and informative value. To garner public support, emphasizing the unique advantages and efficiency of COVID-19 wastewater monitoring compared to other interventions is crucial. Moreover, concerns about wasting resources and government mistrust drew people away from favoring the policy. While establishing trust in government requires long-term sustained efforts, public health campaigns can effectively focus on alleviating concerns related to resource wastage. Health messages to increase public support toward wastewater monitoring of COVID-19 could, for instance, highlight the cost-effective aspect of this intervention. Considering several participants who were neutral about the intervention due to their desire for more information before forming an opinion, it seems especially pertinent to underscore in the health messages not only the necessity of COVID-19 wastewater monitoring but also its functionality in enhancing public health.

Limitations

This study is not without limitations. First, this study used a cross-sectional design, which makes it difficult to draw causal inferences. Future research should use longitudinal designs or repeated-exposure experiments to determine if these emotional appeals can effectively mitigate "message fatigue" over the course of an extended period. Next, the generalizability of these findings may be limited by the specific context of the study. COVID-19 wastewater monitoring represented a novel health issue by the time of data collection, and it is possible that the message effects observed in the current study context may differ when applied to more routine health behaviors through different mechanisms. Future research should investigate whether message strategies in this study hold true for diverse health topics. In addition, our use of an online convenience sample may further limit the generalizability of the findings. Future research should examine these relationships using more diverse and representative samples. We also note that the context of our

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study can be referred to as being paradoxical, in which the situational setting of message topic was concerned with feelings of fatigue and boredom (ie, overwhelming messages about COVID-19 prevention) and feelings of novelty (ie, wastewater monitoring as a novel health intervention) simultaneously. While this setting provided us with an interesting context to test the predictions, we wondered if such a context had any influence on the message effects. This remains speculative due to the lack of empirical data in the current study, leaving room for future investigation. At last, although several effects were statistically significant, their magnitudes were small, which limits conclusions regarding the practical or real-world significance of findings. Future research should examine whether small effects accumulate over time or translate into meaningful behavioral change in real-world public health communication contexts.

Conclusions

In conclusion, this study investigated the effects of emotional appeals and pronoun use on the communicative, attitudinal, and behavioral consequences of messages regarding wastewater monitoring for COVID-19. The current study sheds light on understanding the influence of message-evoked emotions in the unique context of promoting the public's support and understanding of wastewater monitoring for COVID-19 and the underlying mediating mechanisms that add to its explanatory power. By showing that lower message fatigue was associated with greater policy support, discussion intentions, and preventive behavior intentions, our findings highlight the potential for well-designed emotional appeals to counteract fatigue on high-exposure issues. This capacity to mitigate message fatigue, which is relevant not only to COVID-19 but also to other sustained public health and environmental challenges such as climate change, represents a meaningful contribution to both theory and practice.

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Data Availability

The data that support the findings of this study are available on request from the corresponding author.

Authors' Contributions

YK conceptualized and acquired funding for the study. YK and MJ investigated the research and conducted formal analyses. MJ drafted the original manuscript. YK reviewed and edited the manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Message stimuli and measurement items.
[DOCX File, 2838 KB - formative_v10i1e83060_app1.docx]

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Abbreviations

CFI: comparative fit index
RMSEA: root mean square error of approximation

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Acute Physiological and Emotional Responses to a Brief 24-Minute Yoga Session: Randomized Exploratory Pilot Study With Waitlist Comparison

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Abstract

Background: Wellness tourism increasingly incorporates short yoga sessions for stress management, yet evidence on their immediate physiological and emotional responses remains limited.

Objective: This exploratory pilot study aimed to generate preliminary data on acute physiological and emotional responses to a single 24-minute yoga session (breathing, postures, and meditation) compared with quiet sitting in novice practitioners.

Methods: In this single-center, randomized waitlist-controlled exploratory pilot study (1:1 allocation), 19 university-affiliated adults with self-reported daily stress and no prior guided yoga experience were allocated to an immediate 24-minute yoga session (n=10) or quiet sitting (n=9). The primary outcome was change in salivary cortisol from baseline to postintervention. Secondary outcomes included salivary alpha-amylase, heart rate (Apple Watch [Apple Inc], subset n=12), and real-time emotional indices (stress, calmness, and concentration) measured by a commercial single-channel electroencephalogram (EEG) device (Kansei Analyzer [Dentsu ScienceJAM], subset n=8). Data were analyzed using change scores relative to the breathing phase, with between-group comparison performed by independent *t* tests or multivariable linear regression adjusted for age, sex, and baseline values as appropriate.

Results: No significant between-group differences were observed for salivary cortisol or alpha-amylase. In the yoga group, heart rate increased during postures and remained mildly elevated during meditation relative to the breathing phase, consistent with mild physical exertion. Exploratory individual EEG analyses suggested reduced stress and increased concentration during breathing and meditation phases in some participants.

Conclusions: In this small exploratory pilot study, a single 24-minute yoga session did not significantly alter salivary stress biomarkers at the group level. However, it induced measurable cardiovascular activation and heterogeneous EEG-derived emotional responses. These hypothesis-generating findings demonstrate marked interindividual variability, suggesting the need for larger validation studies with improved control conditions.

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KEYWORDS

yoga; salivary cortisol; heart rate; electroencephalography; wellness tourism; wearables; exploratory pilot study

Introduction

Health tourism is a form of travel that provides nonroutine experiences aimed at restoring, maintaining, and enhancing health, typically in nature-rich environments that promote well-being [1]. The global market for health tourism is expected to reach US $411 million by 2030 [2], positioning this sector as strategically important within the broader tourism industry. Within health tourism, wellness tourism has emerged as a major subcategory because of its focus on scientifically grounded activities and programs that support physical and mental well-being [3]. Wellness tourism integrates diverse elements, including health care services, treatment and recovery programs, relaxation techniques, dietary therapy, and physical exercise during travel experiences [1,4].

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As global awareness of mental and physical self-care rises, wellness tourism is increasingly sought by travelers desiring physical renewal, psychological balance, and personal transformation [5-7]. Yoga retreats, a key modality within wellness tourism, offer structured programs that blend movement, breathwork, and meditation in calming natural settings. These programs promise not only relaxation and stress relief but also opportunities for deep emotional engagement and transformation [8].

As a key component of wellness tourism, yoga is increasingly recognized for its ability to meet the needs of travelers seeking to improve physical and mental health and achieve spiritual fulfillment [9]. Frequently incorporated into wellness tourism programs, yoga offers a combination of physical and mental health benefits through practices such as *Pranayama* (breathing techniques), *Asanas* (physical postures), and *Dhyana* (meditation) [10]. Given that chronic stress is a major contributor to numerous physical and mental health issues, including cardiovascular diseases, anxiety disorders, and depression [11], these yoga practices are expected to reduce chronic stress, improve mental health, and promote overall well-being [10]. Thus, integrating yoga into wellness tourism programs could have the potential to enhance their effectiveness in promoting long-term health and wellness.

Despite the increasing popularity of yoga in wellness tourism, further scientific evidence is required to validate its stress-reduction effects, particularly its immediate short-term effects, in various contexts. Previous studies have compared the effects of yoga on stress reduction, mental health, and physiological responses, frequently comparing yoga practitioners with control groups using subjective assessments and objective biomarkers. Subjective assessments, such as the Perceived Stress Scale (PSS) and self-reported emotional state surveys, consistently emphasize the effectiveness of yoga in decreasing perceived stress and improving well-being [12]. However, participants' expectations or response biases can influence subjective evaluations, highlighting the need to complement these assessments with objective physiological indicators to increase the reliability of analysis. Objective studies provide evidence supporting the physiological effects of yoga. For example, yoga interventions have been associated with decreased cortisol levels, which are a primary stress biomarker [13]; improvements in heart rate variability, indicating improved balance of the autonomic nervous system [14]; and decreases in salivary alpha-amylase (sAA) levels, reflecting decreased activities in the sympathetic nervous system and attenuated stress responses [15]. However, many of these studies used a nonrandomized design and focused on the long-term effects of sustained yoga practice, leaving its short-term effects under controlled conditions largely unexplored.

To address this gap and strengthen the evidence base for yoga programming in wellness tourism, we conducted a randomized waitlist-controlled design to investigate the acute physiological and emotional effects of a brief yoga session. Additionally, we used a novel approach by integrating traditional biomarkers with real-time emotional analysis using the Kansei Analyzer (Dentsu ScienceJAM) [16,17], an ambulatory electroencephalogram (EEG) device designed to objectively measure emotional variability. By combining traditional biomarkers with this advanced emotional analysis device, this study aimed to provide new insights into the acute stress-reduction effects of yoga. This approach may reinforce the importance of incorporating yoga into wellness tourism programs and offer practical, evidence-based information for practitioners and policymakers in the field. The specific objectives were to test the hypothesis that a brief yoga session would reduce salivary cortisol (primary) and improve secondary outcomes (sAA, heart rate [HR], emotional states) compared to waitlist control, while exploring individual variability.

Methods

Study Design

This single-center, prospective, randomized, waitlist-controlled, exploratory pilot study assessed the acute physiological effects of a brief yoga intervention (eg, breathing exercises, poses, and meditation) on stress markers. This study was conducted on a single day. Participants were randomly assigned to a yoga group, which performed the yoga program, or a waitlist control group, which rested quietly in a seated position during the intervention period. Subsequently, the participants completed a baseline questionnaire providing demographic and lifestyle data, including age, sex, occupation, living situation (alone or with others), presence of comorbidities, alcohol consumption habits, and smoking habits. The participants also completed the Japanese version of the PSS (PSS-14) to assess their perceived stress levels before the intervention. The validity and reliability of the Japanese version of the PSS-14 have been previously established [18]. The study was conducted at Kakuma no Sato Kanazawa University, a 2-story building situated in a quiet, natural environment away from road traffic, surrounded by greenery and providing a calm, retreat-like atmosphere. The first floor was allocated to the waitlist control group to ensure a calm resting environment, whereas the second floor was designated for the yoga intervention group and provided adequate space for movement and focus (Figure 1).

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Figure 1. The study site. Left: Exterior view of the facility in a quiet, natural setting. Top right: Second-floor activity room used for yoga sessions. Bottom right: First-floor conference room used as a resting space.

Ethical Considerations

All procedures adhered to the Ethics Guidelines for Medical and Biological Research Involving Human Subjects in Japan [19]. The study was approved by the Medical Ethics Committee of Kanazawa University (2023 - 250, Receipt Number: 114441). Before randomization, an explanatory session was held to provide details on the procedures and obtain written informed consent. The trial design was parallel group with a 1:1 allocation ratio. No important changes to methods occurred after trial commencement. Participant privacy and confidentiality were strictly protected. No personally identifiable information was collected beyond what was necessary, and all data were anonymized during analysis and reporting. Participants received a 1000 Japanese yen (US $0.0063) shopping card as compensation for their time and participation.

Study Participants

We recruited the staff, students, and their families at Kanazawa University as participants via the internal communication system of the university. The inclusion criteria were as follows—participants (1) aged 18 years or older at the time of consent (no sex restriction), (2) who self-reported subjective daily mental and physical stress, (3) with interest in participating in stress-management yoga programs, and (4) with no previous experience in professionally instructed yoga or meditation programs. The exclusion criteria were as follows: participants (1) who could not complete salivary tests; (2) who were unable or unwilling to wear an Apple Watch (Apple Inc) (provided by researchers); (3) who could not undergo the Kansei Analyzer evaluation, as determined by the principal investigator or coinvestigators; and (4) who did not provide written informed consent. Participants received a 1000 Japanese yen (US $0.0063) shopping card as compensation for their time and participation. As this was a pilot study, no formal sample size calculation was performed; recruitment aimed for 20 participants to assess feasibility and generate preliminary data for future trials.

Yoga and Waitlist Control Groups

The 24-minute duration was deliberately chosen to mimic brief yoga sessions commonly offered in wellness tourism settings (eg, hotel morning classes, airport yoga rooms, or short retreat modules), where time constraints are typical, rather than to replicate full-length retreat sessions. The sequence (breathing → postures → meditation) and phase duration were designed to reflect a balanced, beginner-friendly practice while allowing examination of phase-specific responses.

Participants in the yoga group engaged in a 24-minute session led by a certified instructor (RK; Figure 2). This session commenced with approximately 5 minutes of *Pranayama* (breathing exercises), which is characterized by focused nasal breathing comprised of a controlled 4-count inhalation and 4-count exhalation. This exercise yields approximately 3 - 4 breaths per minute and emphasizes diaphragmatic movement (abdominal expansion during inhalation and contraction during exhalation). After the breathing exercises, the participants performed approximately 15 minutes of *Asanas* (yoga poses). This sequence included cow pose (Bitilasana), cat pose (Marjaryasana), downward-facing dog (Adho Mukha Svanasana), plank pose (Phalakasana), a knee-down variation of Chaturanga Dandasana, cobra pose (Bhujangasana), and a concluding hip joint relaxation exercise that involves gentle leg swaying (Figure 2). The asana sequence was designed to be light-to-moderate intensity, typical for beginner Hatha yoga. The yoga session concluded with approximately 4 minutes of *Dhyana* (meditation) in a seated Siddhasana (Accomplished Pose), guiding participants to focus on natural breathing while maintaining an upright spinal posture. After completing the yoga session, saliva tests were then conducted for the yoga group (as an initial evaluation period).

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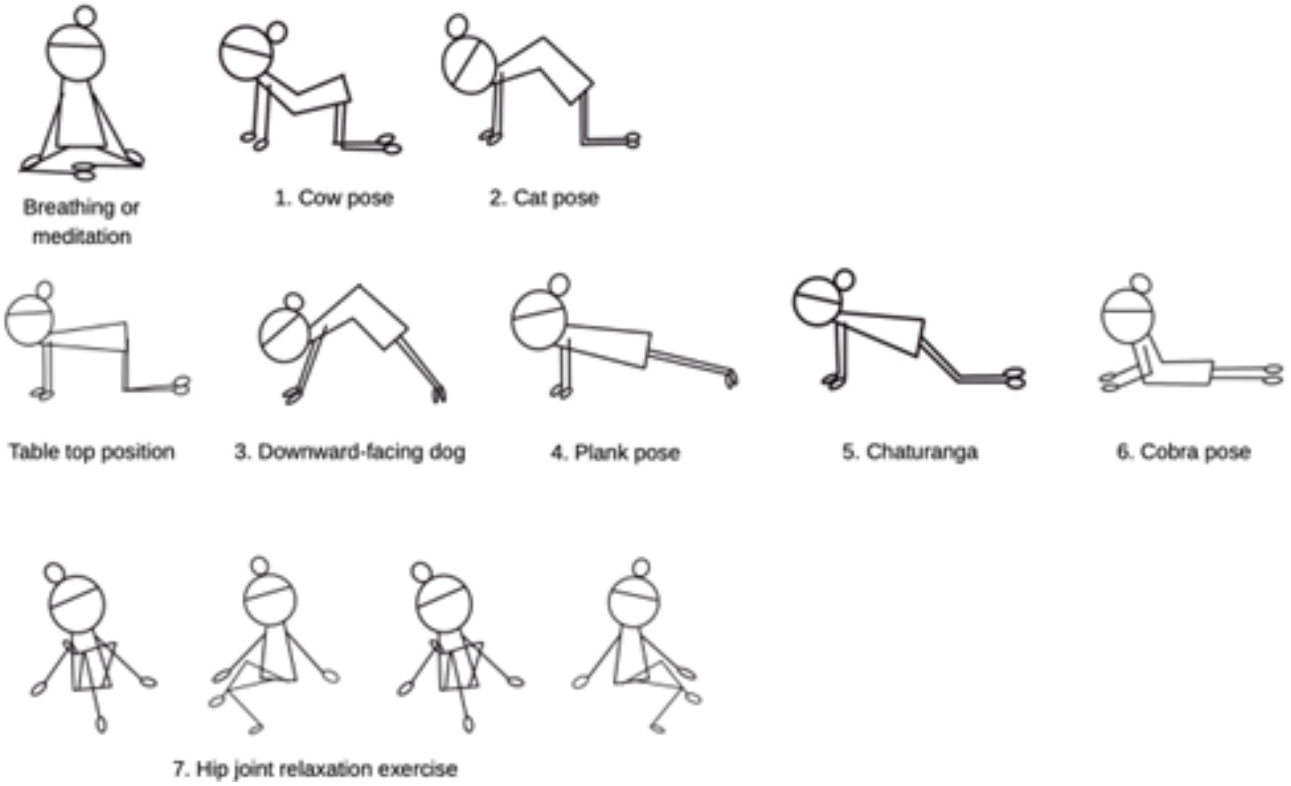
Figure 2. Illustration of the yoga pose flow.



Concurrently, participants in the waitlist control group engaged in a 24-minute period of quiet, seated rest. During this time, activities such as reading or using mobile phones were prohibited to maintain a restful state comparable to the nonphysical aspects of the start and end of the yoga intervention. After finishing this rest period and the subsequent data collection (as the initial evaluation period), the waitlist control group participated in an identical 24-minute yoga session (including breathing, poses, and meditation) led by the same certified instructor (LK) who guided the yoga group. After completing the session, saliva tests were also conducted (as the second evaluation period).

Outcomes

The study evaluated primary and secondary outcomes, which were measured at different time points relative to the intervention period (before, during, and after). The primary outcome was the change in salivary cortisol levels, a stress biomarker related to hypothalamic–pituitary–adrenal axis activity, during the initial evaluation period. The secondary outcomes included changes in salivary cortisol levels during the second evaluation period and sAA levels, a marker of sympathetic nervous system activity, during the initial and second evaluation periods for the waitlist control group. We also assessed within-group changes of these salivary biomarkers during the initial and second evaluation periods. Furthermore, the study monitored real-time physiological and emotional changes during the sessions as secondary outcomes: HR was tracked using Apple Watch devices, while emotional status (ie, stress, calmness, and concentration) was assessed using the Kansei Analyzer (Figure 3). While salivary measures (cortisol and sAA) were obtained from all participants, data collection using HR and the Kansei Analyzer was limited to subsets due to equipment availability. No changes to trial outcomes were made after commencement.

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Figure 3. Kansei Analyzer. Left: Kansei analyzer headset and tablet for monitoring emotional status. Top right: example of how the device is worn. The individual depicted provided informed consent for publication of the image.

Randomization and Blinding

Randomization was performed using a manual allocation method. Group assignments (yoga or waitlist control, 1:1 allocation) and device assignments (Apple Watch or Kansei Analyzer, due to limited availability) were designated using codes (eg, C1, C2, C3 for waitlist control; Y1, Y2, Y3 for yoga group; with additional codes indicating device allocation) written on cards and placed into opaque sealed envelopes by YZ (study coordinator). Participants were enrolled by AN (researcher responsible for enrollment), and each participant randomly drew an envelope to determine their group and device assignment. Assignments were revealed immediately upon drawing and recorded by YZ. Due to the behavioral nature of the intervention, participants and instructors were not blinded. However, laboratory technicians analyzing saliva samples and data analysts for saliva, HR, and Kansei Analyzer outcomes were blinded to group assignment. Blinding of objective outcomes (saliva, HR, and Kansei Analyzer) minimized bias. The trial was not prospectively registered because it was a pilot study, which is common for exploratory studies.

Saliva Analysis

We collected saliva samples from all participants before and after the initial intervention/rest period. An additional post-yoga saliva sample was then collected from the waitlist control group after the completion of the subsequent yoga session. Salivary cortisol and sAA concentration levels were measured using kits from Salimetrics (State College). Salimetrics via a Japanese intermediary performed the measurements, and samples were transported frozen. Final concentrations were based on duplicate measurements per sample. Saliva collection followed the procedures outlined in the *Saliva Collection Handbook* [20]. The participants were instructed to refrain from dental treatment within 24 hours; report consumption of alcohol, caffeine, nicotine, or medication within 12 hours; avoid eating or drinking for 60 minutes, avoid brushing their teeth for 45 minutes prior to collection; and disclose any oral blood contamination. These instructions were provided via e-mail and reiterated at briefing prior to the experiment. Samples were collected using the passive drool method with collection tubes from Salimetrics (State College). To minimize the influence of diurnal variation, all collections were conducted between 2:00 PM and 3:30 PM. We placed the collected samples in an ice-packed container (4 °C for up to 2 h) and transported them to a freezer with a temperature of −20 °C at Kanazawa University, which adheres to storage guidelines for delayed freezing [20].

Heart Rate Analysis

HR was continuously monitored using Apple Watch devices worn on the wrists of the participants. Falter et al [21] previously validated the accuracy of Apple Watches for HR monitoring. Data were exported for analysis of changes in HR during the rest and yoga phases. As 12 Apple Watches were available, the devices were randomly assigned to 6 participants each in the yoga and waitlist control groups during the initial intervention or rest period. In the second period, the waitlist control group practiced yoga using the same 6 devices they had previously used during the first period as controls. Thus, HR data during yoga practice were obtained from a total of 12 participants (n=6

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from the initial yoga group and n=6 from the waitlist control group during their yoga session), and HR data during quiet rest were obtained from 6 participants from the waitlist control group during the initial period.

Kansei Analyzer (EEG-Based Emotional State Analysis)

The study used the Kansei Analyzer to assess real-time emotional status [16]. This lightweight device uses a single electrode placed on the left forehead (Fp1, according to the International 10‐20 system) and a reference electrode attached to the left earlobe (Figure 3). Brainwave data are recorded at 128 Hz and analyzed in real-time to estimate levels of liking, interest, concentration, calmness, and stress on a calibrated scale of 0‐100 for each patient [16,17]. This study focused on stress, calmness, and concentration.

Four units of the Kansei Analyzer were used in the study. During the initial evaluation period, 1 device was assigned to a randomly selected participant from the yoga group and 3 devices were assigned to randomly selected participants from the waitlist control group. During the second evaluation period (when the waitlist control group performed yoga), the 3 participants in the waitlist control group who previously wore the device during the rest period continued to wear them. Additionally, the device previously used by the participant from the yoga group was reassigned to a fourth randomly selected participant from the waitlist control group. Consequently, data from the Kansei Analyzer during yoga were obtained from 5 participants (n=1 from the yoga group during the initial evaluation period and n=4 from the waitlist control group during their second evaluation period). Moreover, data during the rest period were obtained from 3 participants from the waitlist control group during the initial evaluation period. Explicit written informed consent for publication of the image in Figure 3 was obtained from the individual depicted.

Statistical Analysis

To address potential concerns about repeated measures being treated as independent observations, change scores relative to the breathing phase (Δ breathing-to-posture and Δ breathing-to-meditation) were calculated for heart rate and Kansei Analyzer outcomes. This ensured that each participant contributed only one value per phase interval in the primary between-group comparisons.

The collected data were checked for completeness and consistency before analysis. Descriptive statistics (means and SDs for continuous variables; frequencies and proportions for categorical variables) for baseline characteristics and outcomes were calculated for both groups. To assess the primary and secondary outcomes related to salivary biomarkers (cortisol and sAA), pre–post intervention changes from baseline to the initial evaluation period were compared between the yoga and waitlist control groups using independent *t* tests. Within-group analyses were also performed for each group in the initial (both groups) and second (waitlist control group) evaluation periods using paired *t* tests. Regarding the assessment of HR changes, we performed multivariable linear regression adjusted for age, sex, and baseline HR. Two change metrics were calculated: changes (a) in the breathing-to-posture (B–P) interval (HR during the posture phase minus HR during the breathing phase) and (b) in the breathing-to-meditation (B–M) interval (HR during the meditation phase minus HR during the breathing phase). The regression model predicted changes in HR (B–P and B–M intervals) using group assignment (combined yoga group vs the waitlist control group) as the primary predictor. Additionally, we performed within-group comparisons of HR across the breathing, posture, and meditation phases using paired *t* test for both groups. For emotional responses measured using the Kansei Analyzer, changes in scores for stress, calmness, and concentration were compared between the combined yoga group (n=5) and the waitlist control group (n=3) using the same B–P and B–M intervals used for HR. Within-group comparisons of stress, calmness, and concentration across the breathing, pose, and meditation phases were also performed using the paired *t* test. Exploratory individual case analyses were performed using paired *t* test to compare emotional indicators (stress, concentration, and calmness) counted per minute between the yoga and sitting conditions for each corresponding interval (grouped by breathing [1‐5 min], posture [6‐20 min], and meditation [21‐24 min]) for each individual who participated in both conditions. Statistical analyses were performed using R (version 4.4.2; R Foundation for Statistical Computing) and SPSS Statistics (IBM Corp). Additional analyses (eg, individual cases) were exploratory and distinguished as such. Given the exploratory nature of this pilot study and the small sample size, *P* values less than .05 were considered noteworthy rather than statistically significant. The study is reported in accordance with the CONSORT checklist (Checklist 1).

Results

Participant Flow and Recruitment

Recruitment occurred from March 1 to March 22, 2024. Of the 23 applicants, 4 were unable to participate due to scheduling conflicts, and 19 were eligible and randomized (n=10 to yoga and n=9 to waitlist control). All randomized participants received their allocated intervention and were analyzed for the primary outcome (no losses or exclusions after randomization; see Figure 4 for flow). The trial ended as planned after data collection.

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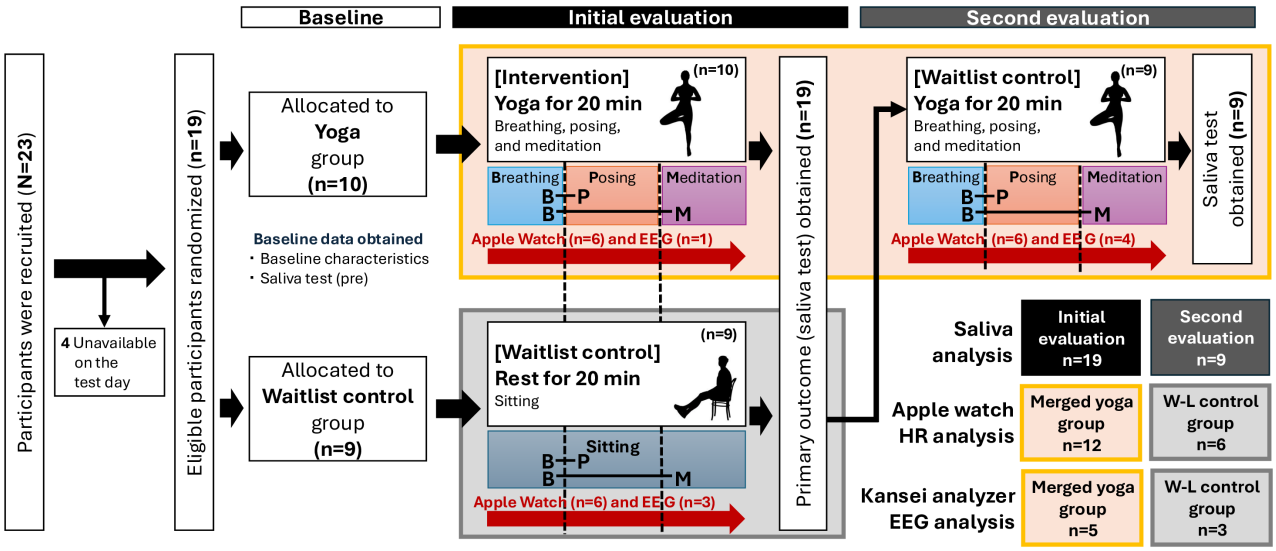
Figure 4. Flow diagram of the study. EEG: electroencephalogram; HR: heart rate.



Baseline Characteristics

The baseline characteristics of the participants are presented in Table 1. The mean ages of the participants in the yoga and waitlist control groups were 29.0 (SD 10.4) and 40.1 (SD 16.6) years, respectively. In the yoga group, 50% (5/10) of the participants were female compared with 67% (6/9) in the waitlist control group. No participants reported comorbidities, such as hypertension, diabetes, or dyslipidemia. Moreover, baseline PSS-14 scores, salivary cortisol levels, and sAA levels were well-balanced between the groups.

Table . Baseline characteristics of the participants.

Characteristics	Total (n=19)	Yoga group (n=10)	Waitlist control group (n=9)
Age (y), mean (SD)	34.3 (14.4)	29.0 (10.4)	40.1 (16.6)
Female, n (%)	11 (58)	5 (50)	6 (67)
Social factor, n (%)			
Living together	11 (58)	5 (50)	6 (67)
Living alone	8 (42)	5 (50)	3 (33)
Comorbidities, n (%)			
Hypertension	0 (0)	0 (0)	0 (0)
Diabetes mellitus	0 (0)	0 (0)	0 (0)
Dyslipidemia	0 (0)	0 (0)	0 (0)
Alcohol, n (%)			
None	8 (42)	4 (40)	4 (44)
Occasional	10 (53)	6 (60)	4 (44)
Daily	1 (5)	0 (0)	1 (11)
Smoking, n (%)			
Never	18 (95)	10 (100)	8 (89)
Former	1 (5)	0 (0)	1 (11)
Current	0 (0)	0 (0)	0 (0)
PSS[a], mean (SD)	23.6 (6.9)	22.9 (6.8)	24.4 (7.3)
High-PSS group (29-56), n (%)	6 (32)	3 (30)	3 (33)
Low-PSS group (0 - 28), n (%)	13 (68)	7 (70)	6 (67)

[a]PSS: Perceived Stress Scale.

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Saliva Analysis

For the primary outcome, changes in pre–post salivary cortisol levels from baseline to the initial evaluation period were not significantly different between both groups (mean difference: 0.033; 95% CI −0.057 to 0.12; *P*=.48). For the secondary outcome, changes in pre–post sAA levels also did not exhibit significant differences between the groups (mean difference: 2.9; 95% CI −63 to 69; *P*=.93; Table 2). Additionally, no significant within-group differences in salivary cortisol and sAA levels were observed from baseline to the initial or second evaluation period between the groups (Table 2). All 19 participants were included in these analyses (intention-to-treat).

Table . Changes in salivary cortisol and alpha-amylase levels from baseline to each evaluation period between and within groups.

	Baseline vs initial evaluation	Baseline vs second evaluation
Between-group difference		
Salivary cortisol, mean change (95% CI); *P* value	0.033 (−0.057 to 0.12); *P*=.48	—[a]
Salivary α-amylase, mean change (95% CI); *P* value	2.9 (−63 to 69); *P*=.93	—
Within-group change		
Yoga group (n=10)		
Salivary cortisol, mean change (SE); *P* value	0.029 (0.03); *P*=.37	—
Salivary α-amylase, mean change (SE); *P* value	−36 (24); *P*=.16	—
Waitlist control group (n=9)		
Salivary cortisol, mean change (SE); *P* value	−0.003 (0.025); *P*=.91	0.055 (0.061); *P*=.39
Salivary α-amylase, mean change (SE); *P* value	−32 (16); *P*=.09	−18 (39); *P*=.65

[a]Not available.

Heart Rate Responses

To evaluate the immediate physiological effects of the yoga intervention, we analyzed changes in HR. For between-group comparisons, the combined yoga group exhibited an increase in HR in the B–P interval (adjusted difference: 15.5; 95% CI 10.7-20.2; *P*<.001) and B–M interval (adjusted difference: 5.1; 95% CI 0.87-9.2; *P*=.02; Table 3) compared with that in the waitlist control group. Within-group comparisons revealed increased HR in the combined yoga group during the B–P (*P*<.001) and B–M (*P*=.007) intervals, whereas the waitlist control group showed no significant changes in either interval (Table 3).

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Table . Changes in heart rate and emotional state during yoga session or resting control between and within groups.

	Breathing vs Posture (B–P)	Breathing vs Meditation (B–M)
Between-group difference		
HR[a] responses (n=18)		
HR change estimate, β (95% CI); *P* value	15.5 (10.7 to 20.2; *P*<.001)	5.1 (0.87 to 9.2); *P*=.02
Emotional state analysis (n=8)		
Stress, mean change (95% CI); *P* value	6.5 (−11.3 to 24.4); *P*=.38	−6.8 (−24.0 to 10.4); *P*=.31
Concentration, mean change (95% CI); *P* value	−10.7 (−21.6 to 0.28); *P*=.054	−5.5 (−15.8 to 4.8); *P*=.22
Calmness, mean change (95% CI); *P* value	1.5 (−1.7 to 4.6); *P*=.28	2.0 (−2.4 to 6.4); *P*=.30
Within-group change		
Combined yoga group		
HR (n=12), mean change (SE); *P* value	13.9 (1.2); *P*<.001	3.5 (1.1); *P*=.007
Stress (n=5), mean change (SE); *P* value	5.2 (4.1); *P*=.28	−6.8 (2.7); *P*=.07
Concentration (n=5), mean change (SE); *P* value	−11 (4.0); *P*=.05	10.8 (2.7); *P*=.02
Calmness (n=5), mean change (SE); *P* value	−2.2 (1.2); *P*=.13	0.0 (1.6); *P*>.99
Waitlist control group		
Heart rate (n=6), mean change (SE); *P* value	−1.5 (1.7); *P*=.39	−1.4 (1.5); *P*=.39
Stress (n=3), mean change (SE); *P* value	−1.3 (5.2); *P*=.82	0.0 (4.9); *P*>.99
Concentration (n=3), mean change (SE); *P* value	−0.3 (1.8); *P*=.87	16.3 (3.0); *P*=.03
Calmness (n=3), mean change (SE); *P* value	−3.7 (0.3); *P*=.008	−2.0 (0.6); *P*=.07

[a]HR: heart rate.

Real-Time Emotional State Analysis (Kansei Analyzer)

For emotional state analysis, we observed no significant between-group differences for stress, concentration, or calmness during B–P or B–M intervals. For within-group analysis, changes in concentration increased during the B–M interval for the combined yoga (*P*=.02) and control (*P*=.03) groups. Moreover, stress and calmness exhibited no significant changes in either group, except for a decrease in calmness during the B–P interval in the waitlist control group (*P*=.008; Table 3).

We further performed exploratory analyses of continuous emotional variations in the 3 individuals from the waitlist control group who were equipped with the Kansei Analyzer and participated in the sitting and yoga sessions (Figure 5). For individual 1, participating in yoga was associated with lower stress levels during the breathing (*P*=.007) and meditation (*P*=.002) phases than in the rest session. This individual also exhibited high scores in concentration during the breathing phase compared with those in the rest session (*P*=.04). For individual 2, stress levels decreased during the breathing phase relative to the rest phase (*P*=.007); however, a decrease in calmness was also observed during the same phase (*P*=.007). Additionally, a decrease in concentration was observed during the posture phase (*P*=.02) compared with the corresponding phases during the sitting position. In contrast, no significant differences were observed between the yoga and sitting sessions for individual 3 across the 3 parameters of emotional status. Individual EEG analyses suggested stress reduction in some participants. These individual EEG analyses were exploratory in nature. No harms or unintended effects were reported in either group.

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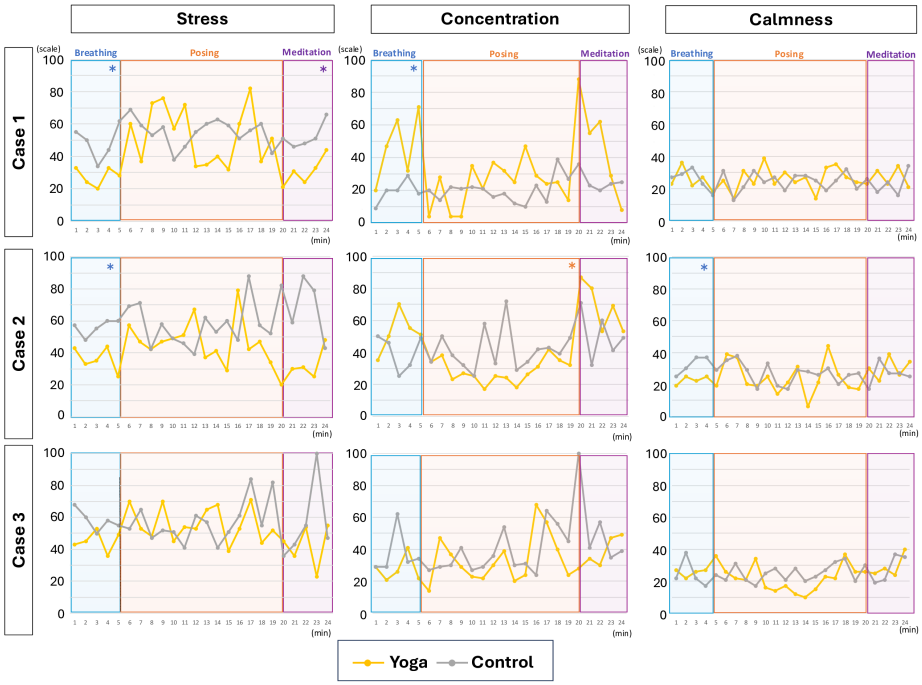
Figure 5. Changes in emotional status during yoga and sitting sessions in participants receiving interventions. *P<.05.



Discussion

Principal Findings

This exploratory pilot study investigated acute physiological and emotional responses to a single 24-minute yoga session in novice practitioners using a randomized waitlist-controlled design. No significant group-level reductions were observed in salivary cortisol or alpha-amylase. Heart rate increased during the posture phase and remained mildly elevated during meditation relative to the breathing phase in the yoga condition, consistent with the mild-to-moderate physical exertion expected in beginners. Exploratory individual EEG analyses using a commercial single-channel device suggested possible reductions in stress and increases in concentration during the breathing and meditation phases in some participants, although responses were highly heterogeneous and subsample sizes were very small. The absence of detectable changes in salivary stress biomarkers aligns with previous evidence that acute, brief interventions may not consistently alter hypothalamic-pituitary-adrenal or sympathetic-adrenal-medullary axis markers immediately post intervention, particularly when measured without delayed sampling [22,23]. The timing of saliva collection (immediately after the session) may have missed potential delayed cortisol peaks. Similarly, the physical components of yoga likely contributed to the observed heart-rate elevation, which does not necessarily indicate a stress response but rather normal cardiovascular adaptation to light exercise in novices.

Real-time emotional monitoring revealed considerable interindividual variability, highlighting that breathing and meditation phases may induce favorable emotional shifts in some individuals while others show neutral or mixed responses. However, the proprietary nature of the Kansei Analyzer algorithms and the limited peer-reviewed validation of its absolute scoring preclude strong conclusions about these emotional indices.

This small exploratory pilot generates hypotheses about phase-specific and individual responses to brief yoga but provides no confirmatory evidence of stress-reduction efficacy. The findings highlight the limitations of underpowered acute-intervention studies and emphasize the need for larger trials with appropriate control conditions, validated measurement tools or biosensors, and diverse populations to support the integration of yoga into wellness tourism programs.

Limitations and Future Directions

This exploratory pilot study has several important limitations that preclude definitive conclusions. First, the small sample size (n=19 overall; wearable subsets n=12 and n=8) and lack of formal sample-size calculation severely limited statistical power. Second, the waitlist-control design likely introduced expectancy and motivation bias, as control participants knew they would later receive yoga. Third, change scores and limited blinding of participants and the instructor may have contributed to residual bias. Fourth, salivary cortisol was measured immediately postintervention, potentially missing delayed peaks. Fifth, the Kansei Analyzer is a commercial single-channel EEG device with proprietary algorithms; its construct validity for absolute scoring of “stress,” “calmness,” and “concentration” has not been fully established in peer-reviewed literature. Sixth, the trial was not prospectively registered, and no correction for multiple comparisons was applied given the exploratory aims. This is consistent with the primary objective of pilot studies to assess feasibility and generate hypotheses. Finally, participants were university-affiliated novices and may not represent typical wellness tourists.

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Conclusions

This small exploratory pilot study found no significant group-level reductions in salivary cortisol or alpha-amylase following a single 24-minute yoga session compared with quiet sitting. Heart rate elevation during postures and meditation was consistent with mild-to-moderate physical exertion in novice practitioners. While EEG-derived emotional indices suggested potential stress reduction and increased concentration during breathing and meditation in some participants, marked interindividual variability was observed. Overall, these hypothesis-generating findings demonstrate the complexity of assessing acute interventions and emphasize the need for larger validation studies with improved control conditions.

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Data Availability

The full protocol is available in Multimedia Appendix 1. The data are not publicly available due to privacy restrictions.

Authors' Contributions

Conceptualization: AN, AT, NY, PC, RK, YM, YZ
Data curation: AN, PC, YZ
Formal analysis: AN, YZ
Funding acquisition: AN
Investigation: AN, AT, NY, PC, RK, YM, YZ
Methodology: AN, AT, NY, PC, RK, YM, YZ
Supervision: AN
Writing – original draft: AN, YZ
Writing – review & editing: AN, AT, NY, PC, RK, YM, YZ

Conflicts of Interest

None declared.

Multimedia Appendix 1
Research protocol for yoga.
[DOCX File, 708 KB - formative_v10i1e87077_app1.docx]

Checklist 1
CONSORT checklist.
[PDF File, 1267 KB - formative_v10i1e87077_app2.pdf]

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Abbreviations

B–M: breathing-to-meditation
B–P: breathing-to-posture
CONSORT: Consolidated Standards of Reporting Trials
EEG: electroencephalogram
HR: heart rate
PSS: Perceived Stress Scale
sAA: salivary alpha-amylase

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Original Paper

Adapting a Sexual Health Intervention for Adolescents Exposed to Adversity: Feasibility Study

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Abstract

Background: Although sexual exploration is normative during adolescence, sexual activities that are unprotected and occur under the influence of substances can pose significant risks to young people. Youth exposed to adversity are among the groups most vulnerable to sexual risk-taking in adolescence. Selective interventions that consider lived experiences and the local context may help reduce sexual risk-taking among this population.

Objective: This pilot study assessed the feasibility of participant recruitment and retention as well as participant engagement with an adapted version of Focus on Youth with Informed Parents and Children Together for Black youth exposed to household challenges.

Methods: Participants were recruited using school and community presentations, digital flyers, and referrals. A total of 121 youth from 3 sites in Baltimore, Maryland, were screened. Participants completed 3 assessments: baseline, posttest, and 3-month follow-up. Participant enrollment, session attendance, and assessment completion were used to determine feasibility and engagement. Sexual health knowledge, pregnancy intentions, partner communication, and sexual behaviors were explored as secondary outcomes.

Results: Funded by the National Institutes of Health, the data for this study were collected between January 2022 and April 2023. A total of 61 youth (aged 13-16 years) were recruited and randomized to either the intervention or the control condition (n=33 and n=28, respectively). In total, 87% (53/61) of the participants completed all 3 assessments. There was high engagement: 80% (48/61) of participants attended at least 3 sessions, and 75.2% (115/153) of after-session responses revealed they would recommend a session to a friend. Among the 18 participants who reported having any sex, all 18 (100%) abstained from alcohol use and 12 (67%) abstained from drug use before sex. The intervention group showed a significant increase in sexual health knowledge. No changes in sexual health behaviors or partner communication were observed.

Conclusions: Findings suggest that recruiting, retaining, and engaging participants in the adapted Focus on Youth with Informed Parents and Children Together intervention is feasible. Additional research is needed to determine the extent to which this intervention can mitigate sexual risk-taking among youth exposed to adversity. The findings will inform the redesign of our assessments to capture additional factors that may affect sexual health behaviors.

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Trial Registration: ClinicalTrials.gov NCT05033821; https://clinicaltrials.gov/study/NCT05033821

(JMIR Form Res 2026;10:e72782) doi:10.2196/72782

KEYWORDS

sexual health; adolescent; adverse childhood experiences; intervention; recruitment; feasibility; engagement

Introduction

Adverse childhood experiences (ACEs) are potentially traumatic events that occur before the age of 18 years and can have significant negative impacts on adolescents' health and well-being [1,2]. In a meta-analysis of more than 250,000 participants, Hughes et al [3] estimated that the global prevalence of an ACE ranged from 38.8% to 59.3%, with an average of 57%. Disparities exist among youth exposed to ACEs, with Black youth being twice as likely to report at least 1 ACE compared to White youth [4]. In Baltimore, Maryland, where 79% of the youth are Black, experiences of household challenges, a subset of ACEs, are common. According to the Centers for Disease Control and Prevention's Youth Risk Behavior Survey, among youth in Baltimore, 28% had a parent with a mental illness, 25% had a parent with a history of substance use, and 46% had a family member who had gone to prison or jail [5].

Adolescent sexual risk-taking and substance use contribute to some of the most prevalent yet preventable public health problems in the United States [6]. Adolescents have higher rates of unprotected sex and substance experimentation than adults [7-9]. Adolescent substance use is associated with increased rates of sexual intercourse, multiple sexual partners, and lower rates of condom use [10,11]. Adolescents who use substances are more likely to contract a sexually transmitted infection or become pregnant than their nonsubstance-using peers [12,13]. Findings from the 25 countries included in the Violence Against Children and Youth Surveys found that exposure to ACEs is associated with lifetime experiences of sexually transmitted diseases, unwanted pregnancies, and sexual risk-taking [14-16]. In Baltimore, 16.9% of youth reported being currently sexually active, of whom 50.4% did not use a condom during their last sexual encounter, and 20% reported using substances before sexual intercourse [5]. Baltimore youth who reported 1 household challenge were 80% more likely to report alcohol use, 78% more likely to report marijuana use, 137% more likely to report heroin use, and 231% more likely to report nonmedical use of prescription opioids [17]. The co-occurrence of these risk behaviors among adolescents warrants preventive interventions that target both [18-20].

Programs designed to reduce sexual risk-taking and related substance use may fail to reach youth today, given that most were developed and deemed effective before the year 2000 and before the integration of technology in learning, expanded vocabulary of gender identity, and comprehensive conversations about consent [21-25]. Thus, adapting evidence-based interventions to reflect current contexts may be an efficient and cost-effective strategy to address risk-taking among adolescents and build on previous effective interventions [26].

Focus on Youth with Informed Parents and Children Together (hereafter referred to as FOY+ImPACT) is a universal, group-level, Centers for Disease Control and Prevention-endorsed, evidence-based intervention that reduces sexual risk-taking and substance use behaviors among urban adolescents [27,28]. Developed in Baltimore, Maryland, it is a comprehensive community-based intervention that involves caregivers in a single session. Our research team adapted and updated the FOY+ImPACT to be delivered to youth exposed to household challenges. On the basis of formative work with families experiencing household challenges, we incorporated trauma-informed principles and gender-inclusive language, standardized the session length, and modernized the content. The process is detailed elsewhere [29]. FOY+ImPACT is a promising approach to address sexual risk-taking among Black youth exposed to household challenges. Thus, this study aimed to assess the feasibility of participant recruitment and retention, participant engagement, and the initial efficacy of the adapted program among this group.

Methods

Study Design

From January 2022 to April 2023, we partnered with 3 local organizations to assess the feasibility and initial efficacy of the adapted FOY+ImPACT intervention in a small, randomized trial. An online random number generator was used to randomize participants to either the control or the intervention group. Randomization occurred at the family level, allowing all eligible youth from a single family to be in the same condition and minimizing the potential for contamination of intervention effects. Participants completed electronic assessments at 3 time points: baseline, posttest, and 3-month follow-up.

Ethical Considerations

The study was approved by the Johns Hopkins Bloomberg School of Public Health Institutional Review Board in Baltimore, Maryland (approval 17282). Interested youth were required to complete a participant interest form that included their name, as well as their caregiver's name and contact information. A study team member contacted the caregivers to inform them of the study and assist with completing a screener to determine the youth's eligibility. A study team member reviewed the purpose and procedures of the study, as outlined in the parental permission form. The permission form was emailed and texted to caregivers via Qualtrics (Qualtrics LLC) to obtain signatures. Once permission was granted, all eligible youth in the family were assigned a participant ID. Oral assent was obtained from all youth prior to completion of the baseline survey. Caregivers and participants were informed that they could stop participating at any point without consequences. The trial was registered at ClinicalTrials.gov (NCT #05033821).

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Participants were compensated US $25 for each session they attended and each assessment they completed. All participants received a participant identification number and data were deidentified before analysis.

Recruitment and Enrollment

Youth enrollment occurred 1 month before the start of the intervention. To be eligible, participants had to be aged 13-16 years, identify as Black or African American, and have experienced 1 or more household challenges. Direct youth recruitment occurred when the study team members invited families to participate via presentations at each organization. Participants were also recruited indirectly through referrals from organizational staff and enrolled participants. Recruitment materials and presentations did not include household challenges as an eligibility criterion, thereby reducing the risk of stigma associated with participation.

Curriculum Delivery and Content

Both intervention and control group sessions occurred twice a week, in person, during nonschool hours (eg, summer or after school). No more than 10 youth were allowed to participate in each group. Sessions were co-facilitated by 2 study team members.

Adapted FOY+ImPACT

Consistent with the original version of FOY+ImPACT, the adapted version had 2 components: Focus on Youth (FOY) and ImPACT. The FOY component was an 8-session intervention emphasizing the core components of establishing a strong support network, decision-making, goal setting, communication, and negotiation. This adapted curriculum incorporated trauma-informed principles and gender-inclusive language, standardized session length to 100 minutes, and updated age-appropriate content for the priority population. The ImPACT component was a single-session intervention for youth and caregivers, in which families received information about sexual health topics and practiced communication skills. This single session was held via Zoom (Zoom Video Communications) before the third FOY session.

Youth in the Media

We used a time-matched control group to reduce temporal bias and control for potential unmeasured confounds; control group participants participated in a time-matched program called Youth in the Media (YM). Delivered in 8 in-person, 100-minute sessions concurrently with FOY sessions, the YM program was designed to (1) increase participants' awareness of and access to the different types of media and free resources available at their local libraries, (2) discuss different types of media that center on stories and experiences of Black youth, and (3) expose participants to careers in media. Sessions covered a range of media types, including sports broadcasting, spoken word, blogging, and comic books. Each session opened with a theme-related icebreaker and closed with a review of key points and a lesson-related practice activity. There was no caregiver component for the YM program.

Measures

Primary Outcomes: Feasibility and Engagement

Feasibility

Process measures were assessed through interest forms and screening logs. We defined recruitment success as the ability to recruit at least 10 youth per cycle. Retention was assessed by the proportion of youth who completed the posttest and the 3-month follow-up. We defined retention success as more than 80% of the sample being retained at the posttest and 3-month follow-up.

Engagement

Engagement was assessed in 2 ways. First, dosage (ie, the number of sessions the participant attended) was used to assess engagement. We defined high-dosage success as youth attending ≥5 sessions, moderate dosage as attending at least 3 sessions, and low dosage as participants attending ≤2 sessions. Second, we administered feedback surveys at the end of each session. These surveys asked if participants would invite a friend to a session (ie, yes, no, or maybe) and "What, if anything, could have made the session better?" The latter was an open-ended question.

Secondary Outcomes: Knowledge, Attitudes, Communication, and Behaviors

Sexual Health Knowledge

A total of 15 items assessed sexual health knowledge. The questions covered topics related to sexually transmitted infections, contraceptives, and contraceptive use behaviors. All questions were true or false statements. Each correct response was given 1 point, whereas an incorrect response was scored 0. Scores were summed up, and the maximum score was 15. Cronbach α was 0.54 at baseline, 0.86 at posttest, and 0.69 at the 3-month follow-up.

Pregnancy Attitudes

A total of 5 items assessed attitudes about pregnancy during adolescence. Participants were asked to indicate their level of agreement with general statements about pregnancy (eg, "I am okay with being pregnant now" and "I am ready to be a parent"). Two questions were reverse-coded (eg, "My family would be really upset if I got pregnant or got someone pregnant as a teen" and "I would be really upset if I got pregnant or got someone pregnant"). All questions were measured using a 4-point Likert scale. Scores were summed up and averaged. A higher score indicated fewer negative attitudes about pregnancy during adolescence. Cronbach α was 0.40 at baseline, 0.66 at posttest, and 0.63 at the 3-month follow-up.

Partner Communication

A total of 4 items were used to create a scale of perceptions about communicating with a partner about sexual health. Participants were asked to indicate their level of agreement with statements about communicating about condom use (eg, "How difficult would it be for you to ask a partner to use a condom, even if it might make them think you have a sexually transmitted disease?" and "How difficult would it be for you to start requiring a partner to use a condom, even though you haven't

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used one in the past?"). All questions were measured using a 4-point Likert scale (1=not difficult at all; 2=not very difficult; 3=somewhat difficult; and 4=very difficult). The average of the items was used to capture partner communication. A higher score indicated higher levels of difficulty in communicating with a partner about condom use. Cronbach α was 0.80 at baseline, 0.84 at posttest, and 0.83 at the 3-month follow-up.

Behaviors

Sexual health behaviors were assessed in 2 ways. First, participants responded to a question about whether they had ever had sex or had sex in the past 3 months. If they reported ever having sex, they were asked about alcohol, drugs, and contraceptive use during their last sex. Participants responded "yes" or "no."

Data Analysis

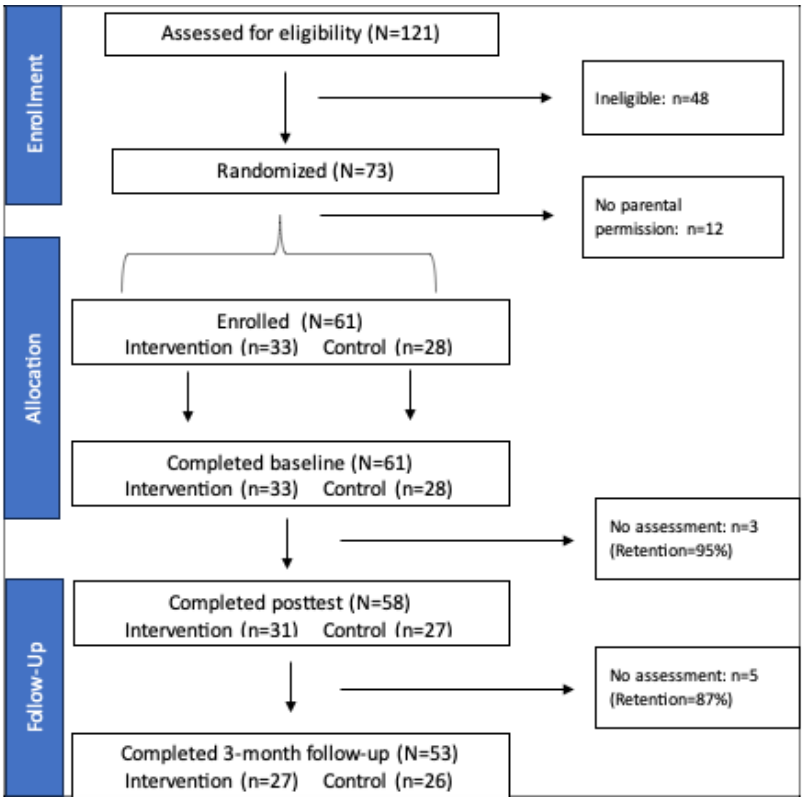
Descriptive statistics were calculated for demographics, feasibility of recruitment and retention, and sexual health knowledge, pregnancy attitudes, partner communication, and behaviors. Open-ended responses were analyzed deductively using a qualitative content analytic approach [30]. Using this approach, the study team reviewed and summed the responses to identify the major themes. Two-tailed paired *t* tests were used to compare the means of knowledge, pregnancy attitudes, and partner communication at each time point in the study. A mixed repeated measures ANOVA was used to test whether the intervention influenced changes in knowledge, pregnancy attitudes, and partner communication over time. Chi-square tests assessed changes in behavior over time and by group assignment. All statistical analyses were conducted using Stata (version 18.0; StataCorp).

Results

Feasibility and Engagement

Figure 1 displays the participant flowchart for this study. More than 150 youth or parents completed an interest form to be screened for eligibility (N=121). In total, 39.6% (48/121) of the interested youths were ineligible because they did not have a caregiver with a history of substance use, mental health issues, or incarceration. Among the 73 eligible participants, 12 (16%) did not return their parental permission forms after at least 5 attempts from the study team. Ultimately, 61 Black youth (aged 13-16 years) exposed to household challenges were enrolled in the study and randomized to a condition. A total of 87% (53/61) of the participants completed all 3 assessments, and 62% (38/61) attended at least 5 sessions (high dosage). We received 153 feedback survey responses across all sessions. Of the 153 responses, 115 (75.2%) said "yes" when asked if they would invite a friend to the session. When asked about what could be done to improve the sessions, 61 participants provided 111 responses across all sessions. The most frequent responses (75/111, 67.6%) were "nothing, none, or nope," coupled with comments such as "it was really good," "it was perfect," and "I was satisfied."

Figure 1. Participant flowchart for the pilot study.



Knowledge, Attitudes, Communication, and Behaviors

We used a moderate dosage to assess the initial efficacy. A total of 20% (12/61) of the participants were excluded from the analysis for initial efficacy due to low dosage (eg, attending ≤2 sessions). Thus, the analytic sample size was 80% (49/61) of Black youth of the initial sample who attended an average of 6 sessions. The average age of our sample was 15 years, with

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those in the intervention group being significantly younger than those in the control group (P=.015). There were more male participants (26/49, 53%) than female participants (20/49, 41%), or those who identified with other gender identities (3/49, 6%). Having an incarcerated parent was the most common household challenge (22/49, 46%), followed by having a parent with a mental illness (15/49, 31%), and a parent with a history of substance use (13/49, 27%). Table 1 presents the detailed demographic statistics for the sample.

Table 2 displays the results of the paired *t* test at each time point. The means of sexual health knowledge and pregnancy attitude scores were similar across the groups. At baseline, there were significant differences in partner communication beliefs, with the intervention group finding it more difficult to communicate with a partner about sexual health topics compared to the control group. Posttest and 3-month follow-up results showed no significant differences between the groups at each time point.

Table 3 displays the results from the repeated mixed ANOVA comparing time and group assignment across all domains. There was a significant interaction between time and study group assignment for knowledge scores ($F_{2,47}$=3.27; P=.04). The effect size for changes in knowledge over time by group assignment was moderate (η^2=0.08). Post hoc comparisons showed that trends in the mean knowledge scores in the intervention group increased over time but these results were not statistically significant (P=.07). However, there were significant changes in knowledge within the control group over time, where knowledge scores decreased from baseline to the posttest (P<.001) and increased from the posttest to the 3-month follow-up (P=.03). There were also significant differences in pregnancy attitudes over time but not by group assignment. Youth in both groups had fewer negative attitudes about pregnancy during adolescence from baseline to the 3-month follow-up ($F_{2,47}$=28.22; P<.001). The effect size was large for pregnancy attitudes (η^2=0.40), which indicated a large and meaningful effect. No significant findings were observed regarding partner communication.

At baseline, most participants (30/48, 63%) reported never having any type of sex. Among those who reported having any type of sex, 100% (18/18) abstained from alcohol use before sex, and 67% (12/18) abstained from drug use before sex. More than half (8/15, 53%) of the sexually active youth who responded to questions about contraception reported the use of birth control during their last sexual encounter. The intervention participants found it significantly more difficult to communicate with a partner about contraceptive use than the control group at baseline (P=.03). Trends suggest that the intervention group reported more contraceptive use in the last sex than the control group, but these results were not statistically significant (P=.07). However, the posttest and 3-month follow-up results showed no significant differences in behaviors between the groups.

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Table 1. Baseline demographic characteristics.

Variable	Overall (N=49)	Control (n=21)	Intervention (n=28)	*P* value (control vs intervention)
Age (years), mean (SD)	15.10 (0.82)	15.43 (0.60)	14.86 (0.89)	*.02* [a]
Attendance, mean (SD)	6.04 (1.68)	5.95 (1.77)	6.11 (1.64)	.75
Gender, n (%)				.44
Female	20 (41)	11 (52)	9 (32)	
Male	26 (53)	9 (43)	17 (61)	
Nonbinary	2 (4)	1 (5)	1 (4)	
Other (gender-fluid)	1 (2)	0 (0)	1 (4)	
Sexual health knowledge, mean (SD)	11.48 (1.71)	11.9 (1.80)	11.18 (1.61)	.15
Pregnancy attitudes, mean (SD)	1.73 (0.39)	1.69 (0.40)	1.75 (0.38)	.63
Partner communication, mean (SD)	2.02 (0.89)	1.70 (0.76)	2.26 (0.92)	*.03*
Have had any type of sex (vaginal, oral, or anal), n (%)				.60
Yes	18 (38)	7 (33)	11 (41)	
No	30 (63)	14 (67)	16 (59)	
Used alcohol before sex, n (%)				—[b]
Yes	0 (0)	0 (0)	0 (0)	
No	18 (100)	6 (100)	12 (100)	
Used drugs before sex, n (%)				>.99
Yes	6 (33)	2 (33)	4 (33)	
No	12 (67)	4 (67)	8 (67)	
Current sex (sex in the past 3 mo), n (%)				.67
Yes	9 (60)	4 (67)	5 (56)	
No	6 (40)	2 (33)	4 (44)	
Used contraception at last sex, n (%)				.07
Yes	8 (53)	1 (20)	7 (70)	
No	7 (47)	4 (80)	3 (30)	

[a]Italics indicate a statistically significant difference.

[b]Not applicable.

Table 2. Two-tailed paired *t* tests for knowledge, attitudes, and communication (N=49).

	Baseline, mean (SD)			Posttest, mean (SD)			3-mo follow-up, mean (SD)		
	Combined	Control	Intervention	Combined	Control	Intervention	Combined	Control	Intervention
Sexual health knowledge	11.48 (1.71)	11.9 (1.80)	11.18 (1.61)	10.74 (2.87)	10.06 (2.92)	11.24 (2.79)	11.44 (2.70)	11.22 (2.67)	11.6 (2.77)
Pregnancy attitudes	1.73 (0.39)	1.69 (0.40)	1.75 (0.38)	1.51 (0.53)	1.55 (0.54)	1.47 (0.53)	2.14 (0.46)	2.08 (0.50)	2.18 (0.44)
Partner communication	2.02 (0.89)	1.70 (0.76)	2.26 (0.92)	2.33 (0.96)	2.31 (1.02)	2.35 (0.92)	2.23 (1.0)	1.92 (1.02)	2.46 (0.93)

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Table 3. Repeated mixed ANOVA results (N=49).

	F test (*df*)	*P* value	Partial η^2 (effect size)
Sexual health knowledge			
Time	2.93 (2, 47)	.06	0.07
Assignment	0.31 (1, 48)	.58	0.01
Interaction (time x assignment)	3.27 (2, 47)	*.04* [a]	0.08
Pregnancy attitudes			
Time	28.22 (2, 47)	*<.001*	0.40
Assignment	0.00 (1, 48)	.96	0.00
Interaction (time x assignment)	0.54 (2, 47)	.59	0.01
Partner communication			
Time	2.33 (2, 47)	.10	0.05
Assignment	3.38 (1, 48)	.07	0.07
Interaction (time x assignment)	1.19 (2, 47)	.31	0.03

[a]Italics indicate a statistically significant difference.

Discussion

This study aimed to assess the feasibility of participant recruitment and retention, as well as participant engagement with an adapted program for youth exposed to household challenges. Exposure to household challenges can affect youth behaviors and their options for healthy decision-making. Although all youth were exposed to 1 or more household challenges, among those who were sexually active, many reported using protection and abstaining from substance use during sex. The adapted intervention improved the sexual health knowledge of the intervention participants. Both the intervention and control group participants also became less negative toward pregnancy during adolescence over time. However, the groups did not differ in partner communication or sexual health behaviors over time.

While many teen pregnancies are unplanned and unintended, some may be planned and intended [31,32]. One study found that nearly 30% of adolescent females desired to be pregnant within 5 years [33]. Furthermore, as young people age and have prolonged exposure to household challenges, negative views of pregnancy may dissipate, given the perceived rewards of filling emotional bonds [34]. Thus, the tendency of study participants to become less negative may be a function of their maturity and environment. Future studies should consider assessing and offering tailored resources to young people who desire pregnancy and those who do not. Using this approach, findings related to sexual behaviors can be understood in the context of the individual reproductive health plans of young people.

The lack of group differences in partner communication and sexual health behaviors may best be attributed to the low baseline rates of sexual risk-taking and low dosage. More than one-third of the participants received a low or moderate dose of the intervention. Dosage significantly affects intervention outcomes [35-37]. Thus, higher exposure may have a more positive impact on partner communication. In addition, although 38% (18/48) of the youth reported having sex at baseline, nearly all were doing so responsibly (with protection and without substances). Therefore, the opportunities to observe changes over time were minimal.

Methodological limitations of this pilot study include a small sample size, limited measures, low internal reliability of measures, and no long-term follow-ups. Although the sample size and follow-up window were dictated by funding, improvements in the measure can be more easily addressed in future research through the refinement of measures and the integration of motivational components into the intervention. The extent of missingness and bias across our measures may have contributed to the observed results. Other factors that we did not capture may have influenced participant attendance and outcomes. According to behavior change theories [38-41], increasing knowledge is an essential precursor to changing behaviors, but it is not sufficient. Motivation, self-efficacy, fear, the desire for status and respect, and external factors also play a significant role in behavior change [42,43]. Study groups did not differ by most demographic factors or initial scores on outcome measures. In future studies, we will extend the follow-up period and redesign our questionnaire to capture additional factors that may impact sexual health behaviors. Additionally, we will explore other strategies to ensure that students complete all parts of the survey, including reading the survey to students or offering the option to take it on multiple days to prevent survey fatigue.

Despite these limitations, the study findings suggest that the adapted FOY+ImPACT was feasible and engaging. However, additional research is needed to determine the extent to which it can mitigate sexual risk-taking among youth exposed to adversity. For youth exposed to household challenges, parents may not be readily available. The adapted FOY+ImPACT intervention offered information and strategies for youth to connect with their parents, peers, partners, and other trusted adults to promote healthy sexual health habits. A growing body of research has demonstrated the value of tailoring interventions

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for new groups as a strategy to support population health and extend the impact of evidence-based interventions [26,29,44,45]. Study findings also provide additional evidence of the complexity of adolescent sexual health decision-making, especially among youth exposed to household challenges. For example, although knowledge increased and pregnancy attitudes became less negative, no significant behavioral changes were observed. Thus, additional research is needed to understand what will work, for whom, and under what circumstances to reduce sexual health risk-taking.

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Data Availability

The datasets generated or analyzed during this study are not publicly available because participants did not consent for their data to be shared publicly.

Authors' Contributions

Conceptualization: TP
Data curation: BDS
Formal analysis: BDS
Funding acquisition: TP
Investigation: OK (lead), QLW (equal), AH (supporting), ED (supporting), NM (supporting)
Methodology: TP (lead), AO (supporting)
Project administration: AO (lead), QLW (equal)
Resources: TP
Supervision: TP (lead), AO (supporting), QLW (supporting)
Validation: TP
Visualization: BDS
Writing – original draft: TP (lead), BDS (supporting)
Writing – review & editing: AO (lead), OK (supporting), QLW (supporting), NM (supporting), AH (supporting), ED (supporting), AL (supporting)

Conflicts of Interest

None declared.

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Abbreviations

ACE: adverse childhood experience
FOY: Focus on Youth
FOY+ImPACT: Focus on Youth with Informed Parents and Children Together
YM: Youth in the Media

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Original Paper

Impact of Prescribed and Self-Selected Music Interventions on Stress, Sleep, Heart Rate Variability, and Brain Connectivity in Surgeons Using 7-Tesla Functional Magnetic Resonance Imaging and Wearable Actigraphy: Multimodal Feasibility Randomized Controlled Trial

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Abstract

Background: Stress, sleep deprivation, and burnout are significant safety risks for acute care surgeons, negatively impacting performance, well-being, and clinical outcomes.

Objective: This pilot randomized controlled trial aimed to measure neurophysiological effects of prescribed music (PM) and self-selected music (SSM) on surgeon stress, burnout, and neurophysiological responses using a multimodal protocol that integrated functional magnetic resonance imaging (fMRI), wearable biosensor monitoring, and psychological self-assessments.

Methods: Full-time attending surgeons at a quaternary care hospital were invited to participate in a 3-armed trial (1:1:1 block allocation). Intervention groups were instructed to listen to 30 minutes (minimum 15 minutes) of either PM or SSM daily at bedtime for 6 weeks, reflecting real-world conditions. PM comprised original compositions based on elements promoting perceived relaxation from a prior study. The control arm avoided music in the 30 minutes before bed. Allocation was concealed from the recruiting investigator; the fMRI technicians, the statistician, and lead investigators were blinded until analyses were completed. Functional connectivity patterns were measured using fMRI at baseline and 6 weeks while participants listened to simulated intensive care unit noise, PM, and SSM. Secondary outcomes included continuous actigraphy for sleep quality and self-reported anxiety, sleep quality, and burnout using validated scales (State-Trait Anxiety Inventory, Pittsburgh Sleep Quality Index, and Maslach Burnout Inventory).

Results: A total of 22 surgeons were assessed; demands of fMRI and data collection schedule led 3 to decline and 2 (allocated to PM) not to finish baseline measures; 6 PM, 5 SSM, and 6 controls received allocated intervention; 2 PM participants were withdrawn for nonadherence and missing follow-up data and 1 control missed follow-up collection due to scheduling (final analysis set after missing data: PM: n=4, SSM: n=5, control: n=5). One control participant experienced transient vertigo in fMRI. Trends in fMRI data indicated that both intervention groups experienced less negative emotional arousal and anxiety, with physical

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tension reduced in the PM group. The PM group exhibited reduced stress response in the frontal lobes when exposed to intensive care unit alarms, suggesting diminished attentional response to the high-stress auditory environment, compared to control. However, lack of statistical significance and baseline variability entail cautious interpretation. Observations of sleep quality were mixed, and no statistically significant differences in stress surveys were observed.

Conclusions: Both music interventions trended toward positive changes in neurophysiological responses, suggesting potential benefits in reducing surgeon stress. However, due to the small sample, mixed or nonsignificant results, and the exploratory nature of this study, findings should be considered preliminary. Further research with larger, diverse cohorts is required to confirm trends, refine both the intervention approach and recruitment strategies, and determine whether objective compositional elements or personally selected music drive the mechanisms of potential positive effects.

Trial Registration: ClinicalTrials.gov NCT05980429; https://clinicaltrials.gov/study/NCT05980429

(JMIR Form Res 2026;10:e84899) doi:10.2196/84899

KEYWORDS

actigraphy; burnout, psychological; heart rate; intensive care units; magnetic resonance imaging; music therapy; pilot projects; sleep quality; surgeons

Introduction

For health care providers working in high-stress, high-autonomy, high-immediacy, and high-risk work environments, stress and sleep deprivation are serious safety hazards. A reported 65% of acute care and subspecialty surgeons experience acute and chronic sleep deprivation [1], and 50%-70% of emergency room physicians report symptoms of burnout [2-4]. Sleep-deprived surgeons are rated to perform with less competence and speed than even their intoxicated peers [5,6]. Numerous studies have emphasized that health care professionals in the intensive care unit (ICU) are highly cognizant of the elevated noise levels, which impair their well-being, performance, and attention [7,8].

Sleep deprivation has also been associated with impaired emotional regulation. Functional magnetic resonance imaging (fMRI) studies have demonstrated that sleep deprivation hinders the ability to down-regulate negative emotions, as evidenced by decreased functional connectivity (FC) between brain regions such as the anterior cingulate cortex and the amygdala, as well as between the frontal lobe and emotional regulation areas [9-14]. Moreover, individuals experiencing high occupational stress have shown reduced brain volumes and diminished FC in areas linked to empathetic responses [15]. Collectively, these findings highlight the vulnerability of prefrontal-limbic regulatory networks in chronically stressed clinical populations [16,17].

Pharmaceutical treatments have traditionally been the main approach for addressing stress- and anxiety-related sleep deprivation. However, these interventions may lose effectiveness over time and carry the risk of addiction [18]. As a promising alternative, music has been suggested as a nonpharmacological, low-risk, and cost-effective intervention to mitigate stress and improve well-being [19].

Music is a well-known modulator of the human stress response [20,21] and has been shown to increase heart rate variability (HRV) [22-24]. HRV, which measures the variation between heartbeats, is an established marker of how the cardiovascular system responds to stress and has served as a biological indicator of overall well-being [25-27]. Higher HRV is generally associated with improved emotional regulation and cardiovascular health, reflecting a more adaptive balance between sympathetic and parasympathetic activity [28-31]. The neurovisceral integration is a functional network linking the prefrontal cortex and the autonomic nervous system, which governs emotional regulation, cognition, and health. Within this framework, higher HRV is associated with stronger prefrontal inhibitory control over subcortical regions such as the amygdala, enhancing cognitive flexibility and adaptive stress responses. Moreover, autonomic regulation manifested by fluctuations in HRV provides a mechanistic link between central neural activity and peripheral physiological responses [32,33].

Beyond its autonomic effects, music has demonstrated the ability to reduce the need for sedatives in clinical populations, alleviate stress, and enhance sleep quality [21]. Music processing engages distributed neural circuits involved in emotion, reward, and empathy, including limbic, paralimbic, and prefrontal regions [34,35], further suggesting its potential therapeutic effects. Neuroimaging studies have shown that pleasurable music listening can engage dopaminergic reward pathways, including the ventral striatum and nucleus accumbens, supporting its role in affective modulation [36]. Recent fMRI studies have further demonstrated that music can enhance FC by promoting integration across cognitive, auditory, motor, and visual systems [37-40]. However, despite this growing literature, there remains limited research directly examining how specific musical interventions differentially modulate FC through identifiable neurophysiological mechanisms, particularly in high-stress professional populations such as surgeons [41]. As Chen et al [41] observed, “If we are ever to harness music’s multitude of influences, we need a solid understanding of the neural circuitry involved and rigorous evidence about how it is engaged by music.”

In our prior research [42], we identified specific features in musical works, such as soft dynamics, minimal accentuation, smooth articulation, and flexible rather than highly pulsed rhythm, that were most effective in enhancing perceived relaxation. Familiar music was also consistently rated as more calming. This evidence-based framework defined compositional elements of relaxation (CERs) that align with resting heart rate (HR) to encourage relaxation. However, this prior work relied on subjective assessments and did not incorporate neuroimaging

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or objective autonomic measures to evaluate underlying mechanisms.

The purpose of this study was to explore the feasibility of assessing the neurobiological impacts of defined musical interventions on surgeons using multimodal outcome measures. Specifically, we examined whether prescribed music (PM), standardized according to relaxation-promoting compositional features, and self-selected music (SSM), which may engage greater personal relevance, familiarity, and perceived control, would differentially influence FC and physiological stress markers [43]. By integrating neuroimaging, wearable actigraphy, and psychological self-assessments, this pilot study aimed to generate preliminary data to inform future hypothesis-driven investigations.

To accomplish this, the study used a novel methodology incorporating both PM and SSM alongside advanced neuroimaging and wearable technologies. The substantial resource requirements (including access to 7-Tesla fMRI, as detailed in the Methods section) and the scheduling constraints inherent to a surgical population warranted an initial pilot design.

Methods

Trial Design, Participants, and Recruitment

This pilot study was conducted at a quaternary care hospital from July 2020 to June 2021 to evaluate the feasibility of assessing the impact of music interventions on surgeon stress, burnout, and neurophysiological responses. The parallel randomized controlled design (NCT05980429) involved a small sample of full-time attending surgeons in acute care or other surgical subspecialties. Inclusion criteria required participants to be actively practicing surgeons, while those diagnosed with sleep apnea, hearing and cognitive impairments, metal implants, or self-reported regular use of prescribed sleep medications were excluded.

Between June 2020 and November 2021, potential participants were identified by the principal investigator (PI) from the Department of Surgery at Houston Methodist Hospital based on inclusion criteria. Eligible participants received study invitations via email, which included an overview of the research objectives, procedures, and contact details of the research team for further inquiries. The PI subsequently approached interested individuals in person for a detailed discussion about the study and to obtain written informed consent. Cognizant of the gender imbalance in the department (few women), the PI reached out to eligible specialist surgeons in urology and vascular to obtain a more representative sample within the predefined inclusion criteria.

Randomization followed a computer-generated 1:1:1 block design using Stata (version 16; Stata Corp LLC) for number generation. Demographic characteristics, such as age, gender, race, and surgical specialty, were recorded for each participant. Baseline assessments were conducted in week 1, followed by the application of the music intervention or control from week 2 to week 6. End-of-study assessments were completed on the final day of week 6.

Intervention

The PM group was instructed to listen to PM (recommended 30 minutes, minimum 15 minutes) at bedtime. The SSM group was asked to listen to 30 minutes of music of their choosing at bedtime. The control group was instructed not to listen to music during the 30-minute period before bedtime preparation period. Blinding participants to their groups was not possible due to the nature of the intervention; however, allocation was concealed from the recruiting investigator, and the fMRI technicians, the statistician, and all lead investigators were blinded to participants' groups until all analyses were completed.

The musical works selected for the prescribed intervention contained CERs (Textbox 1), identified and evaluated for their impact on promoting perceived relaxation in a demographically diverse cohort [42,44]. The selected pieces were analyzed, prepared, and recorded by professional musicians (samples available [44]). Music used for the study was downloaded from a password-protected Google Drive accessible to the study participants assigned only to the PM group. The SSM consisted of participants’ own musical tracks without exclusions and did not overlap with the PM.

Participants were instructed to wear noise-canceling headphones to reduce distractions from external stimuli and were asked to note whether they fell asleep while listening to music. Each participant reported their adherence to the music assignment on a weekly basis using a 5-question survey (tabulated below in Results).

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Textbox 1. Compositional elements of relaxation used to select prescribed music.

Inclusion criteria

- Without strong accents
- Legato and portamento articulation
- Pianissimo to mezzo-forte range
- Unfamiliar
- Master performer
- Smooth melodic shape
- High recording quality
- None to minimal repetition
- Low to middle frequency 50-1000 Hz; (eg, cello, piano, viola, horn, and harp)
- Rubato with flexibility
- Tempo of 60-90 beats per minute
- Lower/middle strings, piano, lower/middle-range winds, and harp
- Time period from 1650 to modern
- Tonality characterized by major and minor keys, pentatonic, and consonances

Exclusion criteria

- With strong accents
- Staccato articulation
- Forte to fortissimo range
- Familiar
- Amateur/mediocre performer
- Jagged melodic shape with large leaps
- Low to medium recording quality
- Excessive repetition
- High frequency >1000 Hz (eg, piccolo and upper strings)
- Rigid rubato, without flexibility
- Tempo above 95 beats per minute
- Vocal music, upper strings, and high-frequency winds (eg, piccolo)
- Pre-1650 time period
- Atonal, unpredictable melodic and/or harmonic structures, and excessive dissonances

Outcome Measures

FC and fMRI

The primary mechanistic outcome tested in this pilot and to be proposed at scale was the change in brain FC. The 7-Tesla fMRI (Siemens MAGNETOM Terra [Siemens Healthineers]) was used to measure this outcome. To replicate the high-stress auditory environment routinely experienced by acute-care surgeons and intensivists, all participants were exposed to ICU noise during the fMRI sessions. We selected ICU noise as the control stimulus rather than a “neutral” baseline of ambient hospital noise to represent a more ecologically valid working environment. In critical care, periods of peak concentration and high-stakes decision-making occur at periods of substantial and meaningful background noise. In contrast to clinicians in, for instance, the operating room, who can regulate their background conditions (including the option to use music), the ICU soundscape is largely uncontrollable and can be persistently intrusive; therefore, ICU noise provides a realistic reference condition against which to evaluate potential effects of both PM and SSM.

All groups listened to the PM playlist, specifically curated to include CERs aimed at promoting relaxation, as well as SSM based on individual preferences. The ICU noise, PM, and SSM were played in the same sequence for all participants during the baseline and 6-week follow-up fMRI sessions.

To quantify the strength of FC, we used the Analysis of Functional NeuroImages (AFNI) software (National Institute of Mental Health, Scientific and Statistical Computing Core),

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which allowed for a more detailed quantitative calculation of FC. Following standard AFNI preprocessing, the acquired fMRI images were spatially normalized into Talairach space using the TT_icbm452 atlas as the reference. Each participant's brain was parcellated into anatomically defined regions based on this atlas. The analysis focused on detecting changes between brain regions associated with empathetic responses (anterior cingulate cortex, a region linked to empathy and compassionate behavior, and one where oxytocin receptors are expressed) [45,46] and pain perception and multisensory awareness (insula region) [47]. For more details, see Multimedia Appendix 1.

The fMRI scans were performed at baseline (week 1) and again at the end of the study (week 6). Harms, such as transient vertigo, were monitored during the fMRI sessions. This methodology was selected to test the feasibility of using advanced neuroimaging techniques to evaluate the neurophysiological impact of music interventions in this population of surgeons. The ICU noise, PM, and SSM were played in the same sequence for all participants during the baseline and 6-week follow-up fMRI sessions.

To quantify the strength of connectivity within defined brain networks, graph structures were constructed using the *igraph* package in the R software (version 4.3.1; R Foundation for Statistical Computing), where each node represented a brain region and the edge weights were defined by the Pearson correlation coefficients between Blood Oxygen Level Dependent time series. For each network, the average of the edge weights between all region pairs belonging to that network was used as a summary measure of network connectivity strength.

Secondary Outcomes

Wearable 3-Axis Actigraphy and Sleep Activity

The WHOOP (version 3.0; Whoop, Inc) wearable actigraphy wristband was used to assess the selected secondary outcomes: resting HR, HRV, and sleep activity. The WHOOP records 100 measurements per second, each of HR, HRV, ambient temperature, skin conductivity, and movement via a 3-axis accelerometer. It can detect rapid eye movement (REM) sleep, 2 stages of light and slow-wave sleep (SWS), and the time to sleep (latency). The device's accuracy (86%), sensitivity (90%), and positive predictive value (93%) are well established [48]. WHOOP data were accessed through the WHOOP application programming interface.

Participants were asked to wear the WHOOP device continuously over a 6-week period and download the WHOOP smartphone app to create a deidentified profile. Daily and average weekly WHOOP sleep scores were recorded. All participants were required to log into the WHOOP app on their phones daily to ensure uninterrupted data collection during on-call and noncall nights. The app also recorded data on daytime naps. The number of hours worked and days on call per week were also recorded to assess potential confounding factors related to sleep patterns. No standardized restrictions were imposed regarding hydration status, caffeine and alcohol intake, or physical activity during the 6-week monitoring period. Participants were instructed to follow their usual daily routines.

Measures of Stress

Secondary outcomes also included self-reported measures of anxiety, sleep quality, and burnout. Stress was assessed using the State-Trait Anxiety Inventory [49], a validated tool for measuring anxiety levels, with lower scores reflecting less anxiety. The Pittsburgh Sleep Quality Index [50] was used to assess sleep quality, with lower scores indicating better perceived sleep. To measure burnout, the Maslach Burnout Inventory [49] was administered, focusing on levels of occupational stress. All surveys were administered at baseline (week 1) and again at the end of the study (week 6) to assess potential changes over the course of the intervention.

Statistical Analysis

Participant characteristics and baseline sleep measurements were reported with summary statistics, stratified by intervention groups. Power calculations were not conducted at this pilot stage; rather, the number of participants assessed for eligibility (see the Results section) was based on initial interest in response to the email invitation.

To evaluate the impact of music intervention on sleep measurements, for each intervention group and each sleep measurement, a generalized estimating equations (GEE) model was applied to model the sleep outcomes of participants over time with music intervention as a predictor, adjusted on previous sleep debt, naps, and music-listening compliance. First-order autoregressive covariate structure and a Gaussian distribution were used in the GEE model to handle the multiple measurements of each participant over time.

To investigate the impact of music intervention, logistic regression was applied using music intervention as the predictor, adjusted for previous sleep debt and naps. The preintervention and postintervention surveys were summarized using mean ± standard deviation and compared using a paired t-test. Participants who had inconsistent music listening adherence were dropped from the GEE analysis and logistic regression analysis.

Specifically, for the fMRI data interpretation, changes in brain network connectivity strength were calculated by comparing postintervention connectivity values to those obtained at baseline. This comparison was conducted separately for each participant and each network. By aggregating across participants within experimental groups, it was possible to identify patterns of increased or decreased FC across the somatomotor, limbic, stress-related, and other canonical brain networks. These longitudinal changes provided insight into the neurofunctional effects of the intervention and were statistically evaluated using paired 2-tailed *t* tests.

Analyses were performed using Stata version 16 with significance set at $P<.05$. Given the exploratory nature of this study, these analyses are intended to provide preliminary insights and inform the design of future, larger-scale studies.

Ethical Considerations

The study protocol was approved by the Houston Methodist Research Institute Institutional Review Board (protocol number Pro00024163). All participants provided informed consent.

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Participants did not receive financial compensation or incentives for their involvement in the study. No identifiable data are presented in this report.

Results

Overview and Participant Demographics

A total of 22 surgeons expressed interest in the study, though scheduling difficulties led to 3 declinations and additional withdrawals with missing follow-up data (Figure 1). In the PM group, 2 participants had challenges with adherence and were unable to complete the study (reported inconsistent music listening and WHOOP data, with no follow-up fMRI data collected); only 4 participants were included in the analyses for this group. The SSM and control groups each included 5 participants, after excluding 1 control participant who did not complete follow-up data collection for analysis.

The average participant age was 45 (SD 9) years, with most participants identifying as non-Hispanic White (9/14, 64.3%) and male (13/14, 92.9%). Most participants (9/14, 64.3%) had a subspecialty other than acute care surgery (Table 1). No harms were reported from music listening or headphone use. One participant in the control group experienced vertigo in the fMRI, which was resolved by a brief period of rest. Adherence to the intervention, notwithstanding the withdrawals due to scheduling, was acceptable among the remaining 4 who filled the adherence survey (Table 2).

The SSM group chose a heterogeneous mixture of tracks: “Erik Satie’s Gymnopédie” for piano and “Beethoven’s Symphony No. 9,” both classical works; rock works “Bohemian Rhapsody” (Queen) and “Sur L’Ocean Couler de Fer” (Alcest); and the alternative trip hop track “Aqualung” (Morcheeba). To assist in interpreting the effect of variability within the self-selected tracks and points of convergence or divergence from attributes of CER, the authors classified these tracks (Multimedia Appendix 2).

Figure 1. Participant flow diagram.

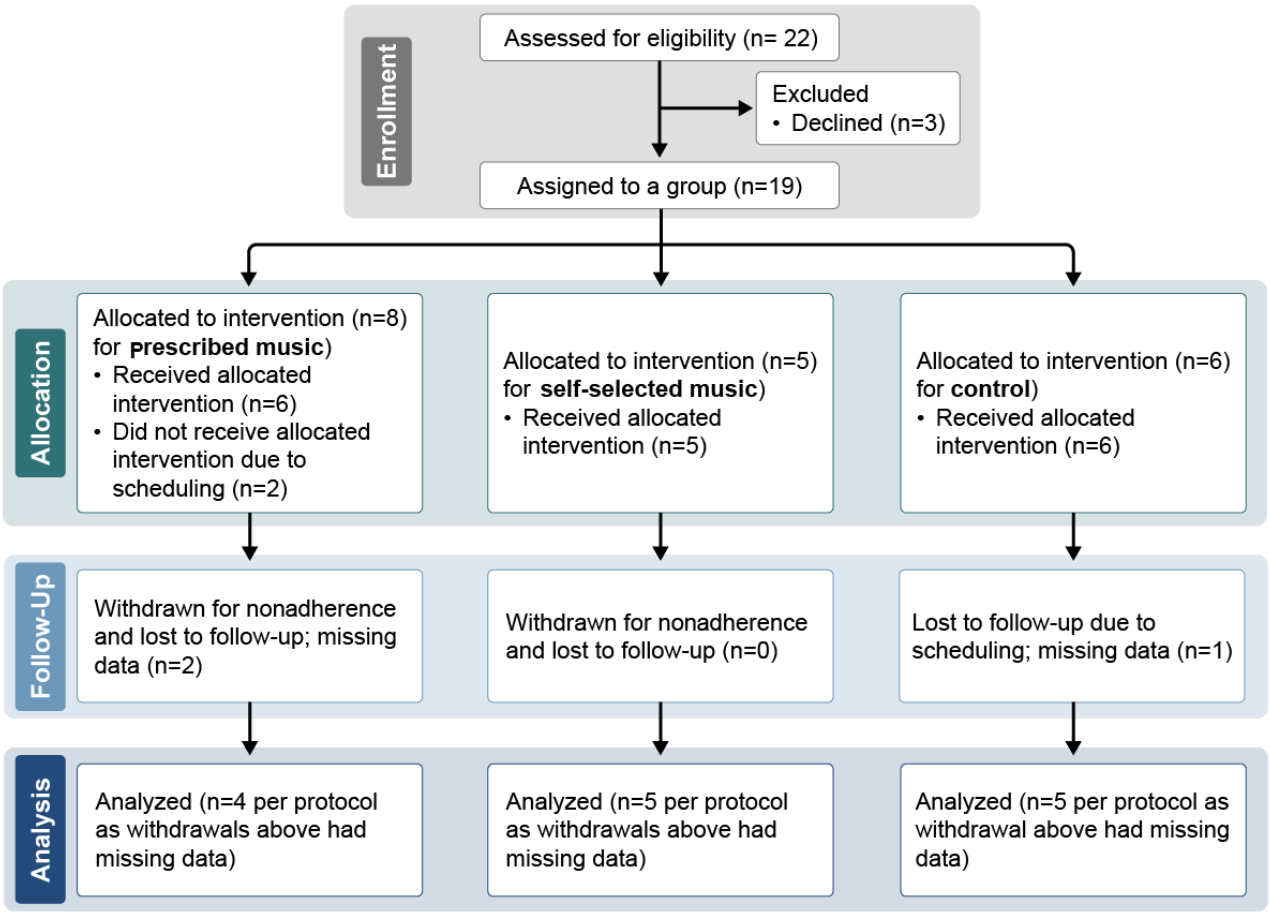

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Table 1. Baseline demographic characteristics of general and acute surgeons participating in the music intervention sleep study.

Characteristic	Overall (n=14)	Prescribed music group (n=4)	Self-selected music group (n=5)	Control group (n=5)	*P* value[a]
Age (years), mean (SD)	45.2 (9.0)	46.2 (12.1)	45.8 (11.1)	43.8 (5.4)	.92
Gender, n (%)					.38
Female	1 (7.1)	0 (0)	0 (0)	1 (20)	
Male	13 (92.9)	4 (100)	5 (100)	4 (80)	
Race and ethnicity, n (%)					.47
Asian	3 (21.4)	0 (0)	1 (20)	2 (40)	
Hispanic	2 (14.3)	1 (25)	0 (0)	1 (20)	
Non-Hispanic White	9 (64.3)	3 (75)	4 (80)	2 (40)	
Specialty, n (%)					.63
Surgical subspecialty	9 (64.3)	2 (50)[b]	4 (80)[c]	3 (60)[d]	
Acute care surgery	5 (35.7)	2 (50)	1 (20)	2 (40)	

[a]For numeric variables, the ANOVA test was used; for categorical variables, the chi-square test was used.

[b]General surgery (oncology) and transplant surgery.

[c]Colorectal surgery, general surgery (bariatric), general surgery (oncology), and thoracic surgery.

[d]General surgery (bariatric), thoracic surgery, and transplant surgery.

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Table 2. Participant self-reported adherence to study protocol for those not lost to follow-up[a].

Question/response	PM[b], n (%)	SSM[c], n (%)	*P* value[d]
Question 1[e]			.52
4-5	2 (50)	4 (80)	
6-7	2 (50)	1 (20)	
Question 2[f]			.49
10-20	1 (25)	2 (40)	
20-30	3 (75)	2 (40)	
30-45	0	1 (20)	
Question 3[g]			>.99
50-74	0	1 (20)	
75-100	4 (100)	4 (80)	
Question 4[h]			>.99
Yes	4 (100)	5 (100)	
No	0	0	
Question 5[i]			.36
2	0	1	
4	0	1	
5	1	0	
6	0	2	
7	1	0	
8	2	0	
9	0	1	

[a]Early withdrawals due to scheduling, inconsistent listening throughout the study, or wearing the WHOOP device <50% of the time while listening to music, precluded full analysis due to missing data (ad hoc determination by study statistician).

[b]PM: prescribed music.

[c]SSM: self-selected music.

[d]Paired *t* tests were conducted for *P* values.

[e]Question 1: How frequently were you able to follow the listening protocol, nights per week? (Count).

[f]Question 2: Approximately how long did you listen to music each time? (Minutes).

[g]Question 3: While listening to the music, what percentage of the time were you wearing the WHOOP device? (Percent).

[h]Question 4: During your on-call days/nights, did you wear the WHOOP device?

[i]Question 5: On a scale of 1-10, how would you characterize your work stress level during the study period? (1=minimal level of stress and 10= maximum level of stress; table shows only scores selected by at least 1 participant).

Findings From fMRI

At baseline (preintervention), after exposure to ICU noise, PM and SSM were played in a randomized sequence for each participant. Therefore, the observed differences in brain network activation across the 3 participant groups reflect inherent variability in individual functional brain connectivity related to these 3 audio stimuli (Figure 2 and Table 3). Some networks, such as the limbic and stress-related systems, show notably higher mean activation in the control and PM groups, suggesting natural differences in emotional and physiological regulation. The somatomotor and frontoparietal networks also exhibit variability that may relate to differences in intrinsic motor control and cognitive engagement among participants. These baseline values provide an important reference point for evaluating the effects of the intervention and help establish individual and group-level differences in neural network dynamics under noninterventional conditions.

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Figure 2. Baseline activation of measured brain regions across groups.

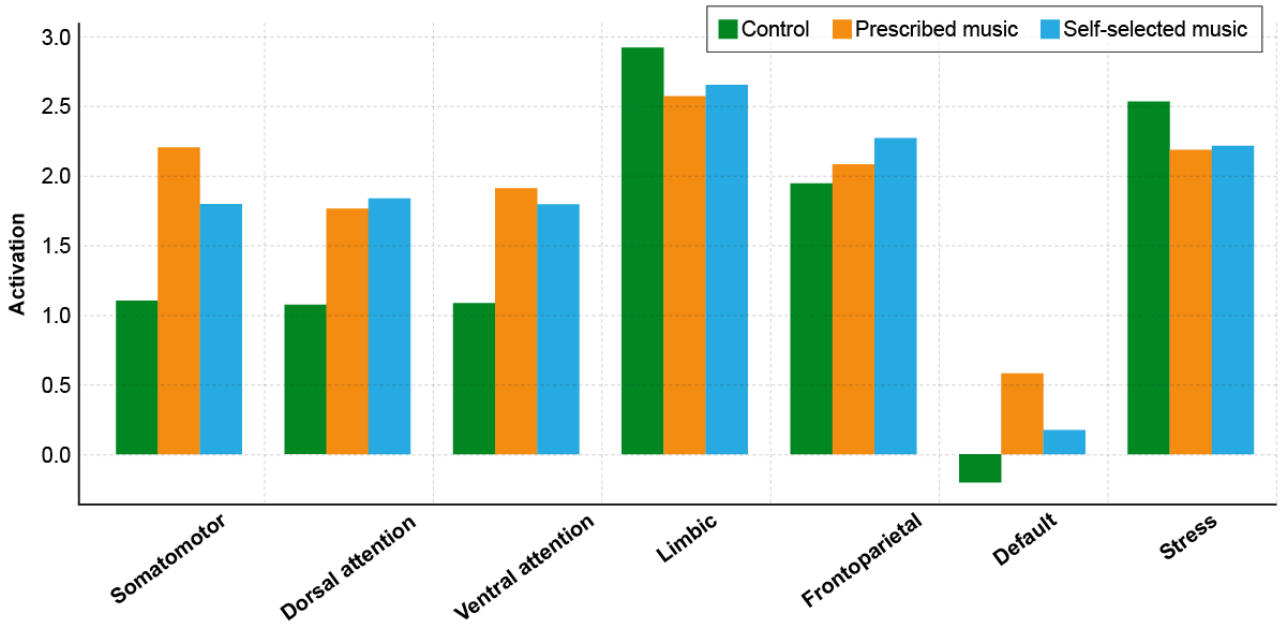

Table 3. Brain network connectivity strength at baseline.

Network	Control, mean (SD)	Prescribed music, mean (SD)	Self-selected music, mean (SD)
Somatomotor	1.11 (3.26)	2.21 (2.56)	1.81 (3.27)
Dorsal attention	1.08 (2.82)	1.78 (2.25)	1.85 (2.11)
Ventral attention	1.09 (2.17)	1.93 (1.26)	1.80 (1.69)
Limbic	2.94 (1.42)	2.59 (0.63)	2.67 (1.01)
Frontoparietal	1.95 (1.41)	2.10 (1.33)	2.29 (1.84)
Default	–0.20 (1.80)	0.59 (1.95)	0.18 (1.95)
Stress	2.54 (1.17)	2.20 (0.85)	2.23 (1.05)

At the 6-week follow-up fMRI (postintervention), ICU noise, PM, and SSM were played in the same sequence for all participants as during the preintervention scan. Following the music listening during the 6-week follow-up fMRI scan (postintervention), most brain networks showed a general reduction in activation across all groups (Figure 3 and Table 4). This was especially notable in networks such as the somatomotor and default mode networks. The consistent decline suggests a calming or regulatory effect of music exposure during the scan, potentially reducing motor readiness and default internal thought processes across the board.

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Figure 3. Postintervention activation of measured brain regions across treatment groups.

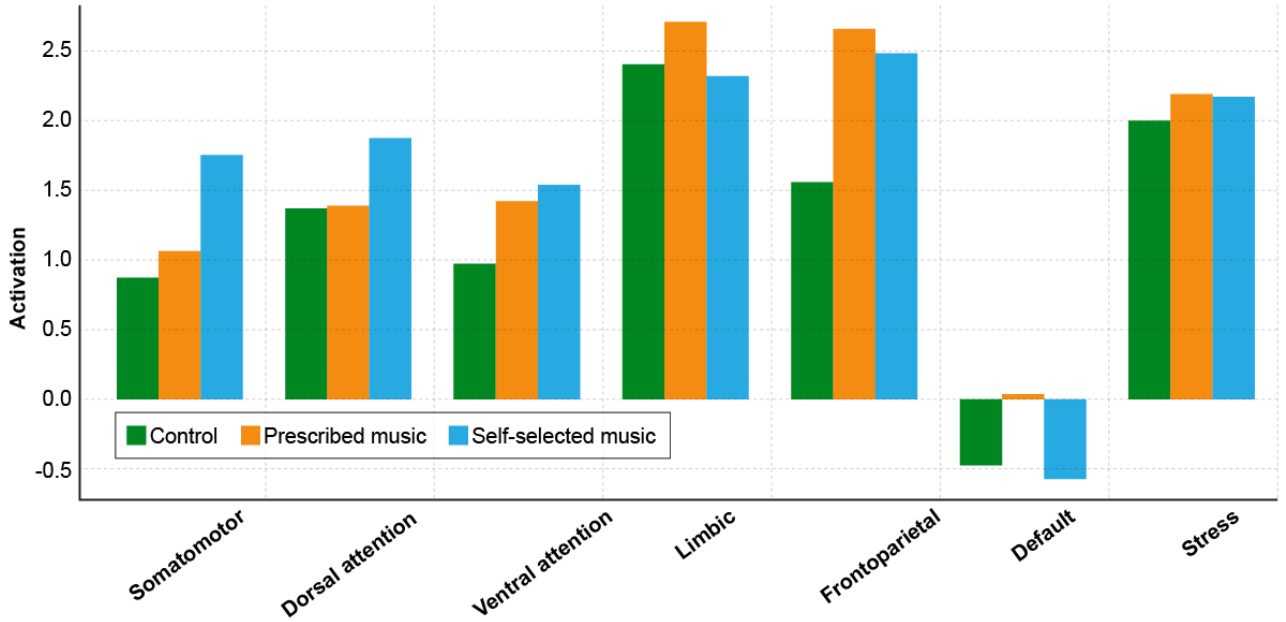

Table 4. Brain network connectivity strength measured postintervention.

Network	Control, mean (SD)	Prescribed music, mean (SD)	Self-selected music, mean (SD)
Somatomotor	0.88 (3.34)	1.08 (3.78)	1.76 (3.52)
Dorsal attention	1.38 (2.52)	1.39 (2.11)	1.88 (2.15)
Ventral attention	0.97 (1.95)	1.43 (1.68)	1.54 (1.78)
Limbic	2.40 (1.05)	2.70 (1.16)	2.32 (0.92)
Frontoparietal	1.56 (2.02)	2.66 (2.30)	2.49 (1.93)
Default	–0.47 (1.32)	0.04 (1.75)	–0.57 (2.01)
Stress	1.99 (1.24)	2.19 (1.22)	2.17 (1.08)

Differences between the follow-up and baseline conditions did not reach statistical significance within the context of this pilot-sized study, though trends are noted here to indicate how the intervention may influence each brain network (Figure 4 and Table 5). The somatomotor network, responsible for motor control and bodily movement, showed a marked reduction in the PM group, suggesting a potential decrease in areas associated with physical tension. The limbic system, central to emotion processing and memory, showed a reduction, albeit not statistically significant, in the SSM group, which could reflect emotional calming or reduced anxiety levels. Although the stress network exhibited a decline in the control group in terms of effect size, signifying reduced stress or arousal at follow-up, we could not establish statistical significance.

Nonsignificant differences were also observed in how each group responded to stress-triggering ambient ICU noise during the fMRI scan (Figure 5). Both the PM and SSM groups showed large changes in FC, including both strengthening and dissociation of FC in disparate brain regions. In particular, the PM and SSM groups exhibited overlapping results: both groups showed increased FC in the cerebellar areas and inferior parietal lobes—regions associated with empathy, movement planning and coordination, decision-making, spatial attention, and body-sensory awareness. Notably, when exposed to stress-triggering ICU alarms, the PM group exhibited lower FC in the frontal lobes and hippocampus—regions involved in attention and physiological regulation—compared to control and SSM. Additionally, the PM group showed strengthened FC in the occipital lobes, associated with visual, spatial, and melodic processing and memory encoding, and the parietal regions, associated with attention and sensory integration, suggesting that the intervention may have a shielding effect against negative, stress-inducing environmental acoustic stimuli.

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Figure 4. Difference in activation of measured brain regions (from baseline to postintervention) across treatment groups.

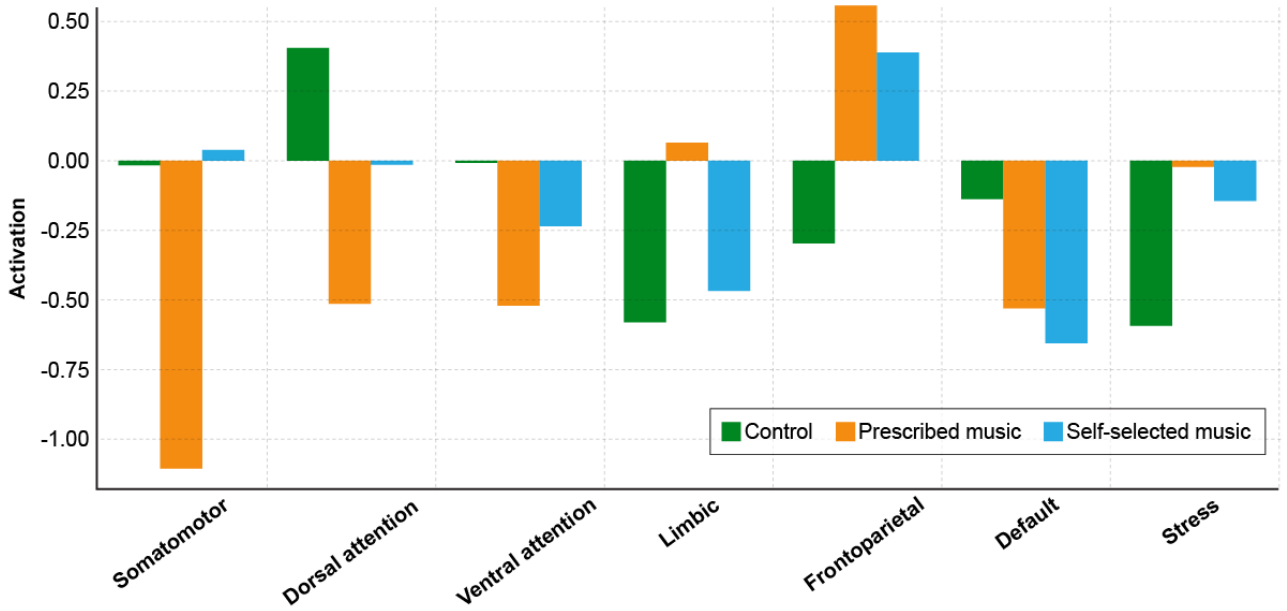

Table 5. Difference between brain network connectivity strength (from baseline to postintervention).

Network	Control		Prescribed music		Self to selected music	
	Mean difference (95% CI)	*P* value[a]	Mean difference (95% CI)	*P* value	Mean difference (95% CI)	*P* value
Somatomotor	–0.02 (–1.85 to 1.81)	.98	–1.11 (–3.35 to 1.13)	.18	0.04 (–1.84 to 1.92)	.95
Dorsal attention	0.40 (–1.08 to 1.88)	.64	–0.52 (–2.03 to 0.99)	.48	–0.02 (–1.20 to 1.16)	.98
Ventral attention	–0.01 (–1.15 to 1.13)	.99	–0.52 (–1.55 to 0.51)	.21	–0.24 (–1.20 to 0.72)	.52
Limbic	–0.58 (–1.27 to 0.11)	.21	0.07 (–0.58 to 0.72)	.84	–0.47 (–1.00 to 0.07)	.16
Frontoparietal	–0.30 (–1.27 to 0.67)	.53	0.56 (–0.74 to 1.86)	.42	0.39 (–0.66 to 1.44)	.50
Default	–0.14 (–1.01 to 0.73)	.81	–0.54 (–1.82 to 0.74)	.30	–0.66 (–1.76 to 0.44)	.30
Stress	–0.60 (–1.27 to 0.07)	.19	–0.03 (–0.76 to 0.70)	.94	–0.15 (–0.74 to 0.44)	.69

[a]Longitudinal changes were statistically evaluated using within-group paired *t* tests (α=.05) comparing pre-post intervention for each network; unit of analysis = mean network strength per participant.

The SSM group exhibited a decrease in FC in the default mode network, potentially reflecting a shift in focus toward processing personal memories related to the SSM music. Contrary to PM, the SSM group showed reduced FC in the occipital lobes, potentially due to the familiarity of the SSM music compared to the PM, and an increase in FC in the temporal gyrus, a region involved in memory processing, though these findings would need to be confirmed in larger studies, as trends were not statistically significant. Notably, neither the PM nor the SSM groups demonstrated any decreases in FC in the anterior cingulate or insula regions—key areas for emotional processing and bodily awareness—suggesting that the music interventions provided a shielding, protective effect against the environmental acoustic stressors (ICU alarms).

The control group showed small changes in FC post intervention compared to baseline. FC in the executive regions increased, suggesting heightened awareness of the ICU noise. Decreases in FC were observed in the anterior cingulate and insula regions, indicating that the ICU noise may have a suppressive effect on emotional regulation and bodily awareness. These changes may reflect a negative neural response to the stressful environment of the ICU (again, to be confirmed to ensure significant results).

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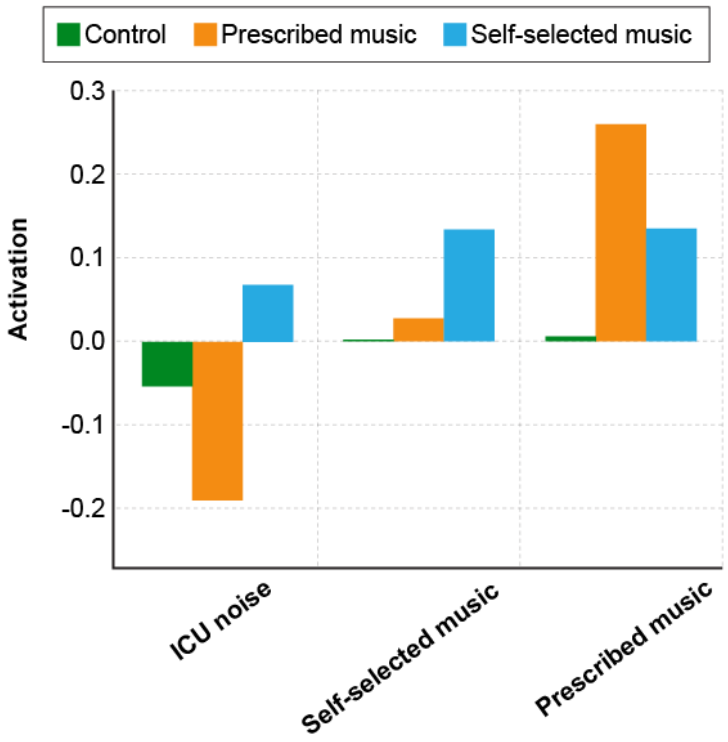
Figure 5. Changes in total brain connectivity after music listening intervention relative to baseline. ICU: intensive care unit.



Findings From WHOOP

Overall, the baseline sleep latency was 127.8 seconds, time in bed was 6.8 hours per sleep, with SWS duration of 1.4 hours, and REM sleep duration of 1.7 hours (Table 6). Participants had resting HR of 60.0 and HRV of 49.1 milliseconds (root-mean-square of successive differences between normal heartbeats). No significant differences in sleep and HR were observed between the groups at baseline.

Participants in the PM group experienced no change in sleep activity during the study (Table 7). After 6 weeks of SSM intervention, participants in this group were in bed longer (0.49 hours; *P*=.01), slept longer (0.39 hours; *P*=.01), and spent more time in light sleep (0.3 hours; *P*<.001). Overall, the SSM group experienced a 0.84% decrease in sleep efficiency (*P*=.001). The control group had no significant changes in sleep activity.

In the PM group, observations were mixed: 1 participant had increased HRV by 9.74 milliseconds while another participant decreased by 11.37 milliseconds, and in 2 participants, no change was noted (Table 8). In the SSM group, the individual logistic regression showed an increased HRV post intervention, ranging from 1.31 to 11.55 milliseconds. This result is consistent with the GEE model, which estimates an overall increase of 2.76 milliseconds (*P*=.03). The control group showed no change in HRV from baseline to the end of the study.

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Table 6. Baseline sleep characteristics of acute and subspecialty surgeons[a].

Metric	Overall	Prescribed music group	Self-selected music group	Control group	*P* value
Baseline sleep activity					
Latency (seconds), mean (SD)	127.8 (74.4)	142.4 (148.5)	132.2 (29.2)	111.7 (4.4)	.84
Time in bed (hours), mean (SD)	6.8 (1.0)	7.3 (0.3)	6.5 (1.0)	6.6 (1.4)	.60
Light sleep duration (hours), mean (SD)	3.0 (0.6)	3.1 (0.5)	3.0 (0.6)	2.9 (0.8)	.83
Slow-wave sleep duration (hours), mean (SD)	1.4 (0.2)	1.4 (0.2)	1.3 (0.1)	1.4 (0.2)	.53
REM[b] sleep duration (hours), mean (SD)	1.7 (0.4)	2.1 (0.2)	1.5 (0.4)	1.7 (0.2)	.07
Total sleep duration (hours), mean (SD)	6.1 (0.9)	6.6 (0.5)	5.9 (0.9)	6.0 (1.2)	.54
Wake duration (hours), mean (SD)	0.6 (0.3)	0.7 (0.3)	0.6 (0.2)	0.6 (0.3)	.85
Arousal time (hours), mean (SD)	0.2 (0.1)	0.2 (0.0)	0.3 (0.1)	0.3 (0.1)	.49
In-sleep efficiency (%), mean (SD)	91.6 (2.9)	91.6 (3.4)	91.5 (2.0)	91.8 (3.9)	.98
Respiratory rate (breaths/minute), mean (SD)	15.5 (1.1)	15.5 (1.0)	15.4 (0.6)	15.6 (1.6)	.98
Disturbances count, median (IQR)	5.9 (4.6-8.3)	5.6 (4.7-6.40)	7.0 (4.6-8.7)	5.6 (4.7-9.3)	.70
Baseline recovery, mean (SD)					
Resting heart rate (bpm)	60.3 (11.3)	64.4 (15.8)	62.5 (9.5)	54.9 (8.8)	.43
HRV[c] rMSSD[d] (ms)	49.1 (21.2)	59.5 (26.7)	37.5 (20.4)	52.3 (14.8)	.30

[a]For continuous variables summarized with mean (SD), the ANOVA test was used; for ordinal variables summarized with median (IQR), the Kruskal-Wallis test was used; for categorical variables, the chi-square test was used.

[b]REM: rapid eye movement.

[c]HRV: heart rate variability.

[d]rMSSD: root-mean-square of successive RR interval differences.

Table 7. Generalized estimating equation model comparing the change in sleep activity from pre- to postintervention for all groups.

Variables	Prescribed music group (n=4), coefficient (95% CI)	*P* value[a]	Self-selected music group (n=5), coefficient (95% CI)	*P* value	Control group (n=5), coefficient (95% CI)	*P* value
Δ in sleep latency (seconds)	9.21 (–5.00 to 23.42)	.20	15.62 (–21.71 to 52.95)	.41	49.67 (–7.93 to 107.28)	.09
Δ in sleep efficiency (%)	–2.78 (–5.58 to 0.02)	.05	–0.84 (–1.35 to 0.33)	.001	–1.1 (–4.05 to 1.85)	.47
Δ time in bed (hours)	0.27 (–0.18 to 0.72)	.24	0.49 (0.11 to 0.86)	.01	–0.18 (–0.69 to 0.33)	.49
Δ total sleep duration, (hours)	0.09 (–0.10 to 0.28)	.36	0.39 (0.08 to 0.69)	.01	–0.21 (–0.77 to 0.36)	.47
Δ light sleep duration (hours)	0.00 (–0.29 to 0.30)	.98	0.3 (0.15 to 0.45)	<.001	0.01 (–0.31 to 0.33)	.95
Δ REM[b] duration (hours)	0.07 (–0.17 to 0.30)	.58	0.07 (–0.11 to 0.26)	.45	–0.10 (–0.23 to 0.03)	.13
Δ slow-wave duration (hours)	0.05 (–0.02 to 0.12)	.19	0.04 (–0.06 to 0.14)	.42	–0.10 (–0.26 to 0.06)	.23

[a]Generalized estimating equation model and Wald test statistic were used to calculate *P* values.

[b]REM: rapid eye movement.

Table 8. Generalized estimating equation model comparing the change in heart rate and variability from pre- to postintervention for all groups.

Variables	Prescribed music group (n=4), coefficient (95% CI)	*P* value[a]	Self-selected music group (n=5), coefficient (95% CI)	*P* value	Control group (n=5), coefficient (95% CI)	*P* value
Δ resting heart rate (bpm)	–0.82 (–2.43 to 0.80)	.32	1.31 (–0.43 to 3.05)	.14	1.71 (–3.69 to 7.11)	.53
Δ HRV[b] rMSSD[c] (ms)	–2.04 (–8.71 to 4.63)	.55	2.76 (0.35 to 5.16)	.03	4.51 (–5.15 to 14.16)	.36

[a]Generalized estimating equation model and Wald test statistic were used to calculate *P* values.

[b]HRV: heart rate variability.

[c]rMSSD: root-mean-square of successive RR interval differences.

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Subjective Measures of Stress

No statistically significant differences were observed in the self-reporting surveys after music intervention (Table 9).

Table 9. Summary of subjective stress survey measures.

Survey component and study period	Prescribed music (n=4)	Self-selected music (n=5)	Control (n=5)
State anxiety[a]			
Pre, mean (SD)	31.25 (6.90)	29.20 (5.07)	30.30 (4.35)
Post, mean (SD)	27.25 (7.18)	26.20 (3.63)	29.00 (3.08)
P value[b]	.11	.27	.63
Trait anxiety[a]			
Pre, mean (SD)	37.75 (8.45)	35.70 (7.28)	32.30 (5.56)
Post, mean (SD)	37.00 (9.52)	32.00 (5.66)	34.60 (8.82)
P value	.80	.12	.70
Global PSQI[c]			
Pre, mean (SD)	7.50 (1.00)	4.50 (0.58)	6.00 (3.87)
Post, mean (SD)	6.50 (2.08)	4.75 (0.96)	6.20 (4.44)
P value	.25	.64	.90
Burnout [d]			
Pre, mean (SD)	15.75 (11.24)	11.00 (10.61)	8.80 (3.42)
Post, mean (SD)	8.25 (5.12)	8.20 (6.61)	8.60 (3.51)
P value	.13	.23	.80
Depersonalization[d]			
Pre, mean (SD)	11.00 (10.61)	7.20 (4.60)	8.20 (4.15)
Post, mean (SD)	8.20 (6.61)	6.60 (4.47)	4.00 (2.00)
P value	.23	.50	.06
Personal achievement[d]			
Pre, mean (SD)	8.80 (3.42)	43.80 (3.83)	40.80 (1.30)
Post, mean (SD)	8.60 (3.51)	45.00 (3.54)	42.40 (2.41)
P value	.80	.58	.10

[a]From State-Trait Anxiety Inventory; higher scores indicate greater anxiety. Missing answers were filled with 2.5 points.

[b]Paired 2-tailed *t* tests were conducted to compare the pre-post scores.

[c]PSQI: Pittsburgh Sleep Quality Index; higher global scores indicate worse sleep quality.

[d]Maslach Burnout Inventory; for Burnout and Depersonalization, higher scores indicate higher-level burnout; for Personal achievement, higher scores indicate lower-level burnout.

Discussion

Principal Findings and Comparisons to Literature

This pilot feasibility study suggested potential associations between music interventions and changes in the neurophysiology of surgeons. While results did not show significant changes across groups, the use of precision tools such as 7-Tesla fMRI for assessing brain FC and 3-axis actigraphy for evaluating sleep and HRV showed promise in detecting subtle differences between participants who received music interventions and those who did not. These precision tools provided valuable insights into the potential impact of music on stress reduction and merit use in larger, confirmatory studies, providing a foundation for future research efforts.

In 2019, Coleman et al [1] published a study using WHOOP actigraphy to examine the prevalence and pattern of sleep deprivation among acute care surgeons. While identifying consistent patterns of acute and chronic sleep deprivation among these surgeons, the study did not test any type of intervention regimen. To our knowledge, ours is the first study that has tested PM and SSM interventions and quantified their effects using fMRI and wearable actigraphy.

Participants in the PM group exhibited reduced FC in the frontal lobes while listening to ICU noise in the 7-Tesla fMRI scanner, suggesting that music may have diminished their negative

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attentional response to an induced high-stress auditory environment. In contrast, the control group showed an increase in FC in the frontal lobes when exposed to ICU noise, indicating heightened distraction and impaired focus. The control group also had reduced connectivity in brain areas tied to emotion and bodily awareness, suggesting a negative impact of ICU noise on emotional processing.

Compared to baseline, the PM group also showed reduced activity in the somatomotor network, possibly reflecting less physical tension. The SSM group showed a nonsignificant reduction in the limbic system, which could signal emotional calming.

These findings are particularly noteworthy given the well-documented adverse effects of noise pollution in high-stress occupational environments, which include increased cortisol release [51], oxygen consumption, and hypertensive risks, along with impaired sleep quality [52-55]. Our results suggested that regular musical exposure can reduce the negative neural impact on practicing surgeons caused by excessive alarms, beeping, and other ICU acoustic stimuli. While many studies have focused on ICU noise and how it distracts clinicians [7,8], our study went further to assess how music intervention impacts the surgeons' FC and their ability to concentrate on the critical tasks at hand while blocking out the ICU noise.

Both music interventions showed promising, though nonstatistically significant, fMRI trends, as reflected in the changes in FC found at the end of the study compared with baseline. Despite the small number of participants, our findings indicate that music may modulate the human stress response, but the exact neurophysiological mechanisms underlying these effects require further exploration. These preliminary insights into the impact of music on brain connectivity offer an important starting point for refining the intervention protocols and targeting larger populations in future studies.

Notably, while both the PM and SSM showed neurological changes not found in the control group, their outcomes differed. Choice of repertoire was likely a contributing factor; for instance, the prescribed playlist was controlled and homogenous to include CER-compatible tracks, such as avoiding music with a strong beat, but the SSM group's choices were not constrained in this way and reflected a mix of classical and rock genres. Personal preferences may also have played a limited role. Upon analyzing the qualities of the SSM group (Multimedia Appendix 2), 2 participants selected tracks that would qualify as having elements overlapping with CER, while the other 3 were characterized by complexity, dynamic tempos and textures, and/or heavy beats.

Participants in the SSM group showed a marked improvement in HRV, a result that was not observed in the PM or control groups. This finding suggests that familiar music, which aligns with individual preferences, may offer unique benefits. The intrinsic qualities of the music—how they interact with individual taste and exposure—remain an important area for further investigation.

While the SSM group exhibited modest improvements in sleep, including longer time in bed and increased sleep duration, no significant changes in sleep latency, REM or SWS sleep, or sleep efficiency were observed in either the PM or SSM groups. These findings may reflect the erratic sleep patterns of surgeons, with their on-call schedules and other work-related factors influencing sleep outcomes. Despite the promising results observed for FC and HRV, the lack of significant changes in sleep parameters highlights the complexity of the relationship between music intervention and sleep quality. It suggests that further refinement of intervention protocols may be necessary to achieve significant improvements in sleep, particularly in this high-stress, highly variable work environment. In particular, larger sample sizes and longer follow-up periods could prove more resilient to missing actigraphy data and confounding variables based on the inherent variability in surgeon sleep patterns and schedules, which may have influenced the sleep time and duration. Larger samples in the SSM group would also afford a broader range of SSM to explore the compositional elements of what participants select as their perceived (versus physiologically) relaxing music playlist.

Strengths and Limitations

This study design has several strengths. First, the study focused on surgeons, a profession known to be accompanied by erratic sleep patterns and exposure to occupational noise. Second, the study design incorporated high-precision tools for outcomes assessment. Third, the study randomized participants into music intervention groups, controlling both for no music within the nighttime routine and the use of music that may not possess all the desired CERs for maximum therapeutic benefit, thus addressing longstanding mechanistic questions via an appropriately comparative method.

However, these strengths also had their drawbacks. One of the inherent challenges of conducting a real-world study is attributing observed effects specifically to the intervention, rather than to unrelated life events or external factors—especially with a small sample size. Despite these limitations, the changes in FC observed in both music groups stood out as noteworthy and consistent. Whereas targeting surgeons allowed investigators to assess the music intervention on both FC and sleep quality outcomes, few participants completed this study with data sufficient for analysis. Furthermore, due to the circumstantial imbalance in gender among our surgeons at the time and 2 female participants dropping out of the study, the majority were male, which weakened the overall generalizability of the results. Participant withdrawals were primarily due to unpredictable schedules and personal life events, highlighting a key challenge in conducting studies with high-demand populations. None of the surgeons reported dissatisfaction with the study design. Full-scale study recruitment targets should account for attrition and further refine recruitment strategies to ensure more balanced gender representation.

HRV, while an important marker of autonomic nervous system function and well-being [26,27], has limitations due to significant individual variances influenced by age, gender, and hydration, necessitating personalized analysis for accuracy. Sleep's relationship with HRV is complex; both excessive and insufficient sleep may not directly reflect recovery levels, as

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underlying causes such as illness or stress impact HRV. WHOOP, acknowledging these nuances, minimally incorporates sleep into HRV calculations, focusing on measurements during SWS for consistency, as HRV data from other sleep stages, particularly REM, are more variable and less reliable.

The use of high-precision tools for measuring outcomes provides confidence in the changes observed despite the small sample size. However, the specialized nature of the 7-Tesla fMRI limits its availability for broader population studies, making wearable actigraphy a useful alternative when fMRI is not feasible.

The music selection for the PM group only included examples from Western classical music, because the majority of prior evidence-based music intervention studies used this repertoire [56,57]. Meanwhile, the self-selected playlist was completely at the discretion of each participant and largely featured other genres. Given participant preferences, it would be worthwhile to examine selections from these other genres that incorporate the CERs. In addition, studies have shown that participant agency in selecting their listening tracks can positively impact music therapy [58]. It remains an open question to what degree it was the music itself or the participants' self-reliance that produced the observed effects on HRV in the SSM group.

We selected ICU noise as the control stimulus during fMRI scanning. We acknowledge that ICU noise is itself a known stressor and therefore may elevate baseline arousal; however, we consider this a feature rather than a flaw in our design, because it frames PM and SSM as potential modulators of stress-related neural and physiologic responses under credible real-world auditory strain in our target population's working environment.

There were a few other limitations. Participants used their personal smartphones to capture actigraphy data. Reminding participants to update the app on their smartphone was a mild deterrent. Compliance was self-reported; an automated system might be more reliable. Finally, the study took place during the COVID-19 pandemic, which added significant challenges to participant recruitment, scheduling, and data collection. These factors likely influenced the overall completion rate and may have introduced additional confounding variables. Additionally, as no standardized restrictions were imposed regarding hydration status, caffeine and alcohol intake, or physical activity during the 6-week monitoring period, individual variabilities in these factors may potentially influence HRV measurements and therefore represent potential sources of variability in the physiological data.

Conclusion

This pilot study tested an innovative multimodal protocol for evaluating music as an intervention, incorporating neuroimaging, wearable actigraphy, and psychological questionnaires. Each of these research tools revealed distinct insights into the potential effects of music interventions. For example, fMRI findings suggest that music may reduce attentional reactivity to ICU noise and help preserve FC in regions linked to empathy, emotional regulation, and bodily awareness—effects not observed in the control group. These subtle neural shifts would likely have gone undetected using only traditional self-report or wearable data, highlighting the value of multimodal assessment in stress research. In contrast, SSM at bedtime was associated with increased HRV, an outcome not addressed by neuroimaging data.

Results regarding sleep were more equivocal, likely due to the small sample size and the unpredictable schedules of the surgeon participants. Taken together, this preliminary data suggests that music could serve as a nonpharmacological, cost-effective, and safe intervention for preserving empathic neural pathways and improving HRV—a key indicator of improved health.

As a pilot study, these findings provide valuable insights but must be interpreted with caution due to the study's small sample size and feasibility design. Larger and longer-term studies are warranted to further evaluate the potential of music interventions in reducing stress and burnout and improving well-being for those working in high-stress occupations, with this study providing a promising, multimodal methodology that could be adapted for future research on the effects of music in stress management and cognitive well-being.

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The authors declare that they have not used generative AI (GenAI) in any aspect of the research, writing, or visualizations presented in this article. Responsibility for the final manuscript lies entirely with the authors. GenAI tools are not listed as authors and do not bear responsibility for the final outcomes.

Data Availability

The datasets generated or analyzed during this study are not publicly available due to the small and potentially reidentifiable number of participants and the nature of the mental health and imaging data; data are available from the corresponding author on reasonable request and pending an institutional review board–approved collaborative study if deemed necessary.

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Authors' Contributions

Conceptualization: MR (lead), AB (equal), JTF (supporting), AD (supporting)
Data curation: EH (lead), MVA (supporting)
Formal analysis: EH (lead), CK (supporting)
Funding acquisition: JTF (lead)
Investigation: MVA (lead), MR (equal)
Methodology: AB (lead), MR (equal), AD (supporting), CK (supporting), LM (supporting), AV (supporting)
Project administration: MVA (lead), LM (equal)
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Supervision: AD (lead)
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Visualization: EH (lead), CK (equal), AV (supporting)
Writing — original draft: MR (lead), AB (equal), AD (equal), AV (supporting)
Writing — review and editing: All (equal)

Conflicts of Interest

None declared.

Multimedia Appendix 1
Brain network assignment of Talairach regions and coordinates.
[DOCX File , 39 KB - formative_v10i1e84899_app1.docx]

Multimedia Appendix 2
Self-selected music repertoire.
[DOCX File , 19 KB - formative_v10i1e84899_app2.docx]

Multimedia Appendix 3
CONSORT checklist for pilot feasibility studies.
[PDF File (Adobe PDF File), 6004 KB - formative_v10i1e84899_app3.pdf]

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Abbreviations

AFNI: Analysis of Functional NeuroImages
CER: compositional elements of relaxation
FC: functional connectivity
fMRI: functional magnetic resonance imaging
GEE: generalized estimating equations
HR: heart rate
HRV: heart rate variability
ICU: intensive care unit
PI: principal investigator
PM: prescribed music
REM: rapid eye movement
SSM: self-selected music
SWS: slow-wave sleep

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Original Paper

Knowledge, Attitudes, and Training Needs for AI in Primary Care: National Survey Study of Clinicians in the Veterans Health Administration

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Abstract

Background: Clinicians are the interface between artificial intelligence (AI) applications and patient care. To maximize benefits and minimize risks of AI, clinicians must be "AI-ready"—that is, willing and able to understand, evaluate, and appropriately use AI tools in practice. Prior literature suggests that clinicians lack fundamental competencies in the use of AI. These gaps could be especially problematic in primary care, given its broad reach into patient care. We surveyed primary care providers (PCPs) in the United States' largest integrated health care system, relatively early in its widespread implementation of clinical AI for frontline use, in order to identify readiness gaps that may warrant particular attention as part of a comprehensive AI implementation strategy.

Objective: The aim of this study was to characterize PCPs' use, knowledge, attitudes, and training priorities related to AI in order to inform health system AI implementation efforts.

Methods: We conducted a national cross-sectional survey of United States Veterans Health Administration (VA) PCPs in October 2025, assessing AI use, self-reported knowledge, attitudes, and training experience. Descriptive analyses summarized responses with exploratory bivariate comparisons across clinician subgroups. Conventional content analysis with inductive coding was used to characterize open-ended responses providing a definition of AI.

Results: Among 170 respondents (170/989, 17.2% response rate), 66.5% (113/170) reported current AI use, most commonly generative AI and decision support tools. Overall attitudes toward AI were positive, with 70.6% (120/170) mostly enthusiastic or more enthusiastic than apprehensive. Confidence in understanding sources of AI bias (62/170, 36.5%) and ethical issues (81/170, 47.6%) was limited. When asked to define AI, very few respondents provided an accurate technical definition. Key concerns about use of AI included accountability, accuracy, and transparency. Though 88.2% (150/170) identified AI training as a priority, only 26.5% (45/170) had any training. Training experiences ranged widely in source, focus, and structure.

Conclusions: PCPs are eager to harness AI's practical advantages but lack foundational competencies to do so in ways that maximize benefit and minimize risk. Our findings highlight a need for targeted education that prioritizes critical appraisal, workflow integration, and risk mitigation, supported by governance that addresses clinicians' concerns and validated measures to evaluate progress toward an AI-ready workforce. These steps can empower PCPs to leverage AI safely and effectively and strengthen the quality and safety of primary care delivery at scale.

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KEYWORDS

artificial intelligence; primary health care; surveys and questionnaires; health personnel; education; professional

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Introduction

Clinician readiness for artificial intelligence (AI) in health care is critical to realizing AI's potential in practice. Clinicians are the interface between AI applications and patient care. They are responsible for interpreting and integrating AI outputs within the complex realities of individual patients, incomplete information, and clinical uncertainty. Even when AI systems are "trustworthy," with rigorous risk assessment and mitigation built in, vulnerabilities remain at the point of clinical application where judgment, workflow integration, and accountability ultimately reside. To maximize benefits and minimize risks, clinicians must be "AI-ready"—that is, willing and able to understand, evaluate, and appropriately use AI tools in practice, as reflected by their knowledge and attitudes related to clinical AI.

AI introduces a unique set of concerns for clinicians, including accountability for errors, algorithmic bias, and potential erosion of the patient-clinician relationship [1,2]. Without sufficient knowledge or supportive attitudes, clinicians may fail to realize AI's benefits. But of greater concern are threats to clinical quality, safety, ethics, patient trust, and clinician well-being. Recognizing these risks, health systems and professional organizations have identified an AI-ready clinical workforce as a top strategic priority [3,4].

AI use in clinical care is expanding rapidly, including ambient documentation [5], image analysis, and point-of-care clinical guidance. However, existing literature suggests clinicians have limited understanding of AI fundamentals, data and algorithmic bias, and ethical and legal implications, alongside concerns about workflow integration and clinician-patient relationships [6-9]. These gaps may be particularly problematic in primary care. Primary care providers (PCPs) are the first point of contact for most patients and interact with a wide range of clinical, operational, and administrative technologies. Limited readiness among PCPs could therefore have broad implications for patient safety and quality of care.

We conducted a national survey of PCPs in the Veterans Health Administration (VA) to describe current AI use, characterize knowledge and attitudes regarding AI in clinical care, and identify priority areas for education and implementation support. We also explored variations in knowledge and attitudes across PCP subgroups. Findings on readiness components are intended to inform health system efforts to ready PCPs for safe, effective AI use.

Methods

Setting and Sample

The VA is the largest integrated health system in the United States, with over 9.1 million enrollees across 1380 facilities [10]. We conducted a cross-sectional survey of VA PCPs in October 2025. All VA PCPs were eligible. Using the VA Corporate Data Warehouse, we randomly selected 1000 PCPs and emailed invitations to complete an online survey using MS forms, with 2 reminders; 989 PCPs were successfully contacted. Participants were informed that identifying information would be used solely to link responses to demographic data and would be blinded for analysis.

Survey Development

Survey development was guided by Rogers' Diffusion of Innovation Theory, which positions user knowledge and attitudes as key determinants of technology adoption [11]. We aimed to understand PCP readiness rather than the implementation context as a whole (ie, the organizational context for use). To develop the survey, we first reviewed measures in the literature that have been used to measure knowledge and attitudes toward AI among various groups, including the general population, employees, medical students, and health professionals [12-20]. None were well-suited to our goal of using a brief survey to measure high-level knowledge about clinical AI or attitudes toward use of AI in clinical care specifically. For example, measures were too detailed in their assessments of AI literacy for a group that has not undergone a formal curriculum [12,13], focused on negative attitudes toward AI [14-17] or examined user experience [18-20] with a single tool. We therefore drafted knowledge items based on topics commonly measured in literacy surveys that might reasonably be assessed via self-report, common attitudes about use of AI widely reported in the literature, and potential outcomes from use of AI in primary care. The initial pool of 20 items was reviewed, refined, and reduced to 14 items in total with input from AI and clinical leadership at the national and regional level (n=4). The final survey included an item assessing current AI tool use, 2 closed-ended and one open-ended item on self-assessed AI knowledge, 4 items on attitudes toward AI, and 4 items on training experience and priorities. Knowledge questions were intended as indicators of foundational AI literacy, and attitude questions captured perceived benefits and risks relevant to AI in clinical care.

Data Analysis

We calculated descriptive statistics and compared survey respondents to nonrespondents on age, gender, rurality, and clinical credential (physician vs other credential), using VA Corporate Data Warehouse data. We summarized patterns in AI use, knowledge, attitudes, and training priorities. Open-ended responses to the question asking for a definition of AI were analyzed using conventional content analysis. An inductive coding approach was used, allowing categories to emerge directly from the data rather than a predetermined framework. This process involved repeated reading of responses to categories of responses with iterative refinement into broader categories to characterize the range and depth of respondents' understanding of AI concepts.

No inferential tests were performed given the exploratory nature of the study; however, we conducted planned bivariate comparisons across clinician subgroups to inform system-level targeting of training and implementation support. We examined whether responses on the 2 knowledge questions ("I feel confident describing potential sources of bias in AI applications" and "I have a good grasp of the ethical issues that may arise in my use of AI;" Strongly Agree/Agree vs Strongly Disagree/Disagree/Neither Agree nor Disagree) and on the overall attitude question ("What is your overall attitude toward

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using AI tools in your work as a PCP?"; Mostly Enthusiastic/More Enthusiastic than Apprehensive vs Mostly Apprehensive/More Apprehensive than Enthusiastic/Equally Enthusiastic and Apprehensive) differed by age (continuous variable), rural practice setting (yes/no), current use of any AI tools (yes/no), and prior AI training (yes/no).

Ethical Considerations

This project was determined to be quality improvement and not human subjects research by the VA Bedford Healthcare System Institutional Review Board.

Results

Participants' Characteristics

A total of 170 PCPs completed the survey (170/989, 17.2% response rate). Respondents and nonrespondents did not differ significantly on demographic characteristics. The majority of the respondents were aged 40 to 59 years (110/170, 64.7%), female (115/170, 67.6%), and physicians (105/170, 61.8%); about one-third practiced in rural locations (Table 1). One-third (52/170, 30.6%) considered themselves among the earliest adopters of new technology in general, with another 51.2% (87/170) considering themselves among early (but not the earliest) adopters. Nearly half (80/170, 47.1%) of the respondents used VA GPT (the VA's internal generative AI chat tool), 37.1% (63/170) used OpenEvidence (an AI-enabled clinical decision support platform), 11.2% (19/170) used Microsoft Copilot, and 33.5% (57/170) reported no current AI use.

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Table 1. Demographic characteristics of the respondents (N=170).

Characteristic, category	Values, n (%)
Age group (y)	
30-39	27 (15.9)
40-49	52 (30.6)
50-59	58 (34.1)
60-69	29 (17.1)
70-79	3 (1.8)
Missing	1 (0.6)
Rural practice location	
Rural	53 (31.2)
Nonrural	117 (68.8)
Gender	
Female	115 (67.6)
Male	55 (32.4)
Clinical credential	
Physician (MD/DO)	105 (61.8)
Non-physician clinician (Nurse Practitioner, Physician Assistant, etc)	65 (38.2)
Current use of artificial intelligence tools[a]	
No current use	57 (33.5)
VAGPT	80 (47.1)
OpenEvidence	63 (37.1)
Ambient scribing/dictation using VAGPT	14 (8.2)
Microsoft Copilot	19 (11.2)
Other artificial intelligence tools	12 (7.1)
General stance toward new technology	
First to try, willing to take risks	52 (30.6)
Embrace early after seeing potential impact	87 (51.2)
Wait until technology has proven value	24 (14.1)
Skeptical and cautious, adopt after most others	6 (3.5)
Last to adopt, prefer traditional approaches	1 (0.6)
Formal or informal artificial intelligence training	
No training	125 (73.5)
Yes training	45 (26.5)

[a]"Check all that apply" item; respondents could select multiple artificial intelligence tools.

Knowledge of AI

Confidence describing potential sources of bias in AI was mixed: 36.5% (62/170) agreed or strongly agreed that they were confident, 41.8% (71/170) were neutral, and 21.2% (36/170) disagreed. Confidence in grasping ethical issues arising from AI use was somewhat higher, with 47.6% (81/170) agreeing or strongly agreeing, 32.9% (56/170) neutral, and 18.8% (32/170) disagreeing or strongly disagreeing. Increasing age was positively associated with more confidence describing potential sources of bias.

Respondents were asked "Based on your current level of familiarity, how would you define AI technology in a few words?" The breadth of content across responses ranged widely, containing elements of definitions but also descriptions of how AI works, use cases, perceived impact, and attitudes toward AI. While very few responses were technical definitions that referenced AI's ability to simulate human intelligence, one participant defined AI as "A computer system designed to perform tasks that typically require human intelligence such as reasoning, learning, and decision making. It works through algorithms and analyzing databases." When definitions were

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provided, they were more often nontechnical: “a system that uses data and engineering to produce solutions.” Several responses defined AI via a use case: “A way to summarize the visit and create a template for review to save time on tedious documentation.” Others defined AI in terms of impact, both positive “a time saver” and negative “horrific as it is a HUGE concern for patient privacy.” Still others simply expressed a lack of knowledge: “Not sure of exactly what it is. My guess is like ChatGPT that it can help with writing, looking for clinical diagnosis, etc.”

Attitudes Toward AI

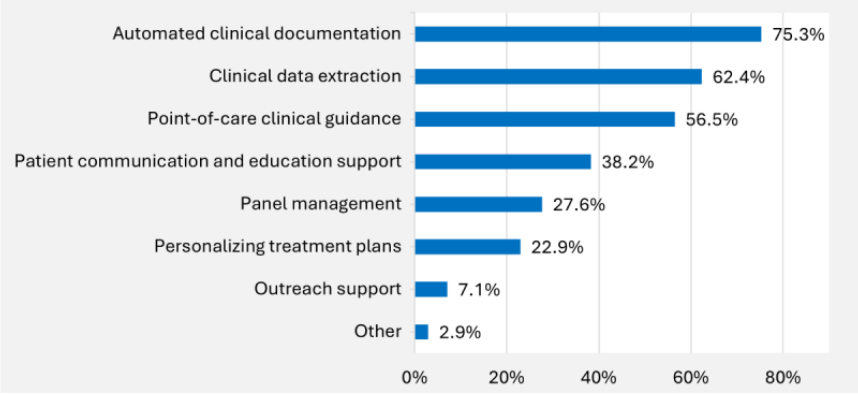
Most respondents expressed positive attitudes toward AI tools in clinical work: 38.8% (66/170) were mostly enthusiastic, 31.8% (54/170) more enthusiastic than apprehensive, and 18.8% (32/170) equally enthusiastic and apprehensive. Only 3.5% (6/170) were mostly apprehensive. A more positive overall attitude toward AI was associated with current use of AI, but not age, rurality, or AI training.

When asked to select the 3 positive outcomes about which they were most enthusiastic, respondents most frequently selected reduced time on administrative tasks (133/170, 78.2%), more informed clinical decision-making (96/170, 56.5%), and increased face-to-face time with patients (75/170, 44.1%) (Figure 1).

Figure 1. Positive outcomes of artificial intelligence in clinical care about which primary care providers are most enthusiastic (top 3 choices). Bars represent the percentage of respondents who selected each option among their top 3 choices; percentages do not sum to 100%.

Respondents were also asked to indicate the three use cases about which they were most enthusiastic (Figure 2). Most frequently selected were automated clinical documentation (128/170, 75.3%), clinical data extraction (106/170, 62.4%), and point-of-care clinical guidance (65/170, 38.2%).

Figure 2. Use cases for artificial intelligence in clinical care about which primary care providers are most enthusiastic (top 3 choices). Bars represent the percentage of respondents who selected each option among their top 3 choices; percentages do not sum to 100%.



Regarding potential concerns, respondents were “moderately apprehensive” or “very apprehensive” about accountability and liability (123/170, 72.4%), accuracy of outputs (117/170, 68.8%), and transparency in how AI reached a decision (113/170, 66.5%) (Figure 3). Of less concern were job security (66/170, 38.8%), workflow integration (64/170, 37.6%), and impact on patient-clinician relationships (55/170, 32.4%).

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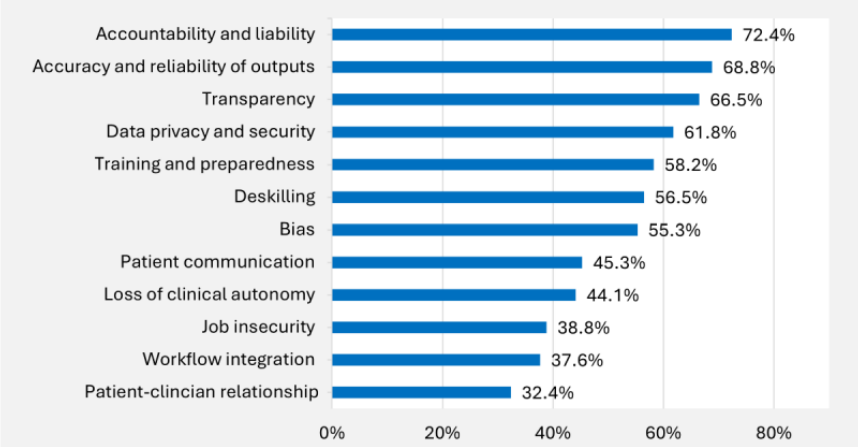
Figure 3. Potential issues raised by artificial intelligence in clinical care about which primary care providers are most apprehensive. Bars represent the percentage of respondents who selected "moderately apprehensive" or "very apprehensive" for the listed issues.



Training Experience and Priorities

Only 26.5% (45/170) reported having any formal or informal AI training, with sources ranging from YouTube and in-service sessions to Google AI and formal coursework. Training was a moderate or high priority for 88.2% (150/170). For their top 3 training priorities, 78.2% (133/170) selected workflow integration; 58.8% (100/170) selected how to evaluate output for accuracy, safety, and bias; and 49.4% (84/170) selected tool-specific training. Foundational AI knowledge (74/170, 43.5%) and ethical, legal, and regulatory issues (78/170, 45.9%) were also commonly prioritized. Communication about AI with patients was least frequently prioritized (17/170, 10%).

Taken together, these results show that PCPs are actively using and optimistic about AI tools, yet experience notable gaps in foundational knowledge, evaluative skills, and training exposure.

Discussion

This national survey of VA PCPs reveals a promising foundation for successful AI implementation in primary care. Respondents expressed strong enthusiasm for tools that could improve workflow efficiency and enhance decision-making, especially in high-value use cases such as automated documentation, data extraction, and point-of-care guidance. Many respondents had already adopted AI chat or decision support tools. These findings highlight meaningful openness to AI innovation in primary care and suggest that health systems could capitalize on existing clinician interest and experimentation with AI at the front lines.

At the same time, respondents reported uneven knowledge about AI fundamentals and limited confidence addressing bias and ethical issues, which are domains central to safe and responsible AI use. Qualitative responses underscore the limited technical understanding of AI among many clinicians. Apprehension regarding liability, accuracy, and transparency suggests that clinicians recognize key risks and feel ill-equipped to evaluate or mitigate them. Training experience was limited and heterogeneous despite nearly universal interest. Together, these findings illuminate a tension, which is that PCPs are eager to harness AI's practical advantages but lack foundational competencies to do so in ways that maximize benefit and minimize risk.

Our results align with prior studies showing clinicians' rapid AI uptake alongside uncertainty around the implications of use, including technical evaluation, risk mitigation, and professional responsibilities [6-9]. Our study extends existing research by focusing on primary care—a setting with broad clinical reach and substantial implications for quality and safety—and by examining a single, integrated health system actively pursuing AI readiness. By identifying specific gaps in knowledge, attitudes, and training, our findings point to levers that health system leaders directly influence through implementation support and governance.

The VA and other health systems have prioritized developing an "AI-ready" workforce [21]. Our findings suggest concrete steps toward this goal. Standardized, clinician-focused training on foundational AI concepts, paired with policies requiring baseline AI literacy and tool-specific training, could help establish consistent expectations and competency across a health system. Many states mandate continuing medical education in high-impact areas such as end-of-life care, risk management, and electronic health record usage. Given that AI carries comparable implications for patient safety, quality of care, and workflow, similar mandatory educational requirements may be warranted as AI's role in care delivery expands. Validated measures of AI readiness could further support needs assessment, targeted training and implementation efforts, and evaluation over time. Beyond education, governance structures can establish expectations for transparency, accountability, and workflow integration.

Concerns that were lower ranked on the survey remain important for comprehensive AI implementation, such as communicating about AI with patients, considering impact on patient-clinician relationships, and using AI for outreach support and population health management. Respondents may have prioritized these concerns lower because they are less immediate than daily workflow demands. Nonetheless, focused educational content can raise awareness of these important issues without overwhelming core training needs. A tiered approach to training could address immediate workflow and safety concerns first while introducing relational and population health considerations as AI use matures in practice.

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Although this study focuses on VA primary care, several findings likely generalize beyond this setting. VA PCPs practice within an integrated health system that offers relatively consistent access to new technologies, training resources, and technical support. These features may facilitate earlier exposure to AI tools compared with some non-VA settings where access to these resources may be more variable. At the same time, our findings suggest that even in a system with substantial organizational capacity, clinicians still report uneven foundational knowledge and limited preparedness to evaluate potential risks, suggesting that these challenges may be at least as notable in more resource-constrained environments. Similar findings have been reported outside of the United States, showing that clinicians across diverse health systems express enthusiasm for AI but face gaps in readiness [17,22,23]. The parallels within the VA context and outside of it emphasize a broader need for health systems to invest in developing AI readiness among their clinicians in the interest of supporting safe and effective AI use.

This study has limitations. While our response is consistent with other VA clinician surveys [24-26] and respondents resembled nonrespondents demographically, technologically enthusiastic respondents may be overrepresented. Knowledge gaps and apprehensions in the population of nonrespondents may be even more pronounced, which would only emphasize the importance of readiness efforts to optimize clinicians' AI use. Also, our subgroup analyses are intended to be hypothesis-generating rather than definitive; future studies should examine subgroup differences with finer grain.

VA PCPs demonstrate strong enthusiasm for AI tools promising workflow efficiencies and clinical support and report current use of generative AI and decision support technologies. However, they also report limited training and uneven knowledge in foundational and evaluative domains. These findings highlight a need for targeted education that prioritizes critical appraisal, workflow integration, and risk mitigation, supported by governance that addresses clinicians' concerns and validated measures of progress toward an AI-ready workforce. By providing one of the first system-wide assessments of PCP's AI readiness within an integrated health system that is itself relatively early in its AI implementation journey, this study offers novel insights into how frontline clinicians are engaging with AI, where critical gaps in readiness exist, and which levers health systems can use to enable safe and effective AI adoption that optimizes patient care while minimizing risks. Addressing these gaps will enable health systems to capitalize on clinician openness while strengthening the quality and safety of primary care delivery at scale.

Data Availability

The datasets generated or analyzed during this study are available from the corresponding author on reasonable request.

Disclaimer

The contents of this paper do not represent the views of Veterans Health Administration or the US Government.

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Authors' Contributions

Conceptualization: VGV
Data curation: AJL
Formal analysis: AJL, BK
Supervision: VGV
Visualization: AJL
Writing – original draft: VGV
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Conflicts of Interest

None declared.

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Abbreviations

AI: artificial intelligence
PCP: primary care provider
VA: Veterans Health Administration

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Enhancing the Predictive Value of Formative Evaluation in Extended Reality Adoption: Addressing the Experience Gap

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Abstract

Formative evaluation is widely used in implementation science to anticipate barriers and facilitators prior to the deployment of health technologies, typically relying on stakeholders' reported beliefs collected before real-world exposure. This approach has proven informative for many digital health tools; however, its application to immersive and embodied technologies such as extended reality (XR) warrants closer scrutiny. Most XR interventions in health care are delivered through head-mounted displays, which depend on spatial perception and sensorimotor engagement. Several implementation-relevant properties, including comfort, perceived intrusiveness, safety, and workflow disruption, often become apparent only through direct interaction. At the same time, large segments of the health care workforce remain XR-naive, such that preuse judgments are frequently shaped by anticipation rather than experience. Drawing on concepts from implementation science, grounded cognition, and human-computer interaction, this Viewpoint examines a plausible interpretive problem in XR adoption and argues that perception-based formative evaluation, when applied through frameworks developed for screen-based technologies, may misclassify barriers and facilitators. Rather than questioning formative evaluation as a methodological approach, we identify a boundary condition for its interpretability in experience-dependent technologies and propose a pragmatic refinement: incorporating brief experiential familiarization before eliciting stakeholder perceptions to strengthen early-stage assessment and improve alignment with real-world implementation decisions.

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KEYWORDS

extended reality; formative evaluation; implementation science; experience gap; perception-based evaluation; embodied interaction; digital health

Introduction

Formative evaluation is a core component of implementation science, intended to surface early barriers and facilitators that may influence the uptake of new health technologies [1]. This emphasis on early-stage evaluation aligns with international health policy priorities concerning system performance, resilience, and equitable access [2,3].

In most adoption and implementation models, preuse assessment relies on stakeholders' expectations and perceived attributes to judge feasibility, readiness, and priority [4-6]. As health systems increasingly consider immersive technologies within broader processes of digital transformation, the adequacy of existing formative evaluation approaches becomes a matter of practical and policy relevance [7].

Extended reality (XR), including virtual, augmented, and mixed reality, differs from many conventional digital tools in that interaction unfolds through perceptually immersive environments and embodied engagement rather than indirect, screen-based interaction [8,9]. In health care, these systems are typically delivered through head-mounted displays in real clinical environments, often under professional supervision [10,11]. Theoretical and experimental work suggests that experiential phenomena such as presence and embodiment can shape attention, emotional response, and bodily perception in ways that are directly implicated in therapeutic effect [8,12,13]. Therefore, these characteristics are not incidental features of user experience but are part of the mechanism through which many XR interventions exert their effects.

These immersive systems introduce perceptual, cognitive, and sensory demands that are difficult to infer from description alone. Physical comfort, perceptual effort, situational awareness, attentional load, interface complexity, and sensory mismatch may influence tolerability, task performance, and learning; however, these properties often become apparent only through

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direct interaction [10,11,14,15]. This creates a methodological challenge for formative evaluation. Established adoption and implementation frameworks provide validated constructs for assessing anticipated value and feasibility [1,4,5]; however, they say little about how such perceptions should be interpreted when a technology's defining features only emerge through embodied interaction. For experience-dependent systems such as XR, clarifying the scope and limits of early stakeholder judgments becomes important [1,10].

This paper does not report original comparative data on pre-exposure vs postexposure judgments. Rather, it offers a conceptual and methodological analysis that draws on literature from implementation science, grounded cognition, human-computer interaction, and XR adoption research. Its purpose is to clarify a plausible interpretive problem in formative evaluation, define the experience gap as a hypothesis-generating construct, and propose brief experiential familiarization as a pragmatic preparatory step before eliciting selected stakeholder judgments. The literature cited was selected to reflect complementary perspectives on how technologies are appraised before use, how experiential properties emerge through interaction, and how user experience may shape adoption and evaluation.

Limits of Perception-Based Evaluation in XR Adoption

Formative evaluation often assumes that stakeholders can anticipate barriers and facilitators before deployment. This is more plausible when the technology resembles tools already embedded in routine practice, as respondents can draw on prior experience to ground their judgments [4,5]. With immersive technologies such as XR, that experiential grounding is often absent.

At the point when formative assessments are typically conducted, direct clinical experience with XR remains absent or limited among health care professionals. Survey data support this pattern. In a public hospital study, only 5% of clinicians reported having used virtual reality (VR) in clinical care [16]. Similarly, a large survey of physical therapy clinicians in the United States found that just 7.1% were currently using VR in practice [17]. In this context, responses to preuse questionnaires are predominantly expectation driven. Judgments about ease of use, intrusiveness, safety, or workflow compatibility are formed without an experiential reference and may reflect imagined difficulty or general uncertainty rather than properties encountered during actual use.

Qualitative research echoes this pattern. Users with no prior XR experience may have limited ability to anticipate what interaction will involve, sometimes stating explicitly that, beforehand, they did not know what to expect prior to immersion [18]. In these circumstances, early perceptions may be recorded as barriers even when they reflect uncertainty rather than direct experience. This is particularly evident when unfamiliarity with immersive systems is combined with blurred distinctions between VR, augmented reality, and conventional screen-based technologies [10]. Therefore, apparent barriers may partly reflect concerns about the modality being judged rather than stable evidence of its usability.

Theoretical work in grounded cognition helps explain why these difficulties arise. When prior sensorimotor experience is absent, people rely on partial mental simulation to evaluate tools and actions, which limits the accuracy of anticipatory judgments [19]. Similar concerns have long been noted in human-computer interaction research, where usability and interaction-related properties are recognized as hard to assess without hands-on engagement, especially for systems that depend on embodied interaction [20].

These constraints are visible in implementation-oriented XR research. Consensus exercises and survey-based studies often ask stakeholders to judge feasibility, barriers, and facilitators despite heterogeneous or minimal direct exposure to XR systems [16,21,22]. The resulting assessments frequently combine expressed interest with uncertainty about practical implications. By contrast, qualitative studies suggest that even limited experiential exposure can shift evaluations away from abstract concerns toward more concrete appraisals of clinical value and implementation requirements [23], while implementation reviews indicate that many early assessments are based on expected rather than observed factors [10].

This body of evidence suggests that preuse perceptions in XR-naive samples are shaped less by experience-informed judgment than by incomplete understanding of the modality being assessed. In the context of immersive technologies, this makes formative findings harder to interpret and increases the risk that early barriers and facilitators reflect expectations and concerns more than observed use or hands-on experience.

The Experience Gap and the Misclassification of Adoption Barriers

The limited experiential grounding described previously leads to a specific problem for perception-based formative evaluation in XR adoption. When stakeholder judgments are collected before any direct interaction with the technology, commonly used indicators of feasibility and readiness may no longer behave as stable signals of likely future use. Rather, they may reflect judgments formed under a partial understanding of what the technology actually entails. We refer to this interpretive mismatch as the experience gap. Figure 1 presents a conceptual model illustrating the hypothesized relationship between experiential exposure and perception-based evaluation and is intended as a hypothesis-generating framework rather than an empirically validated representation.

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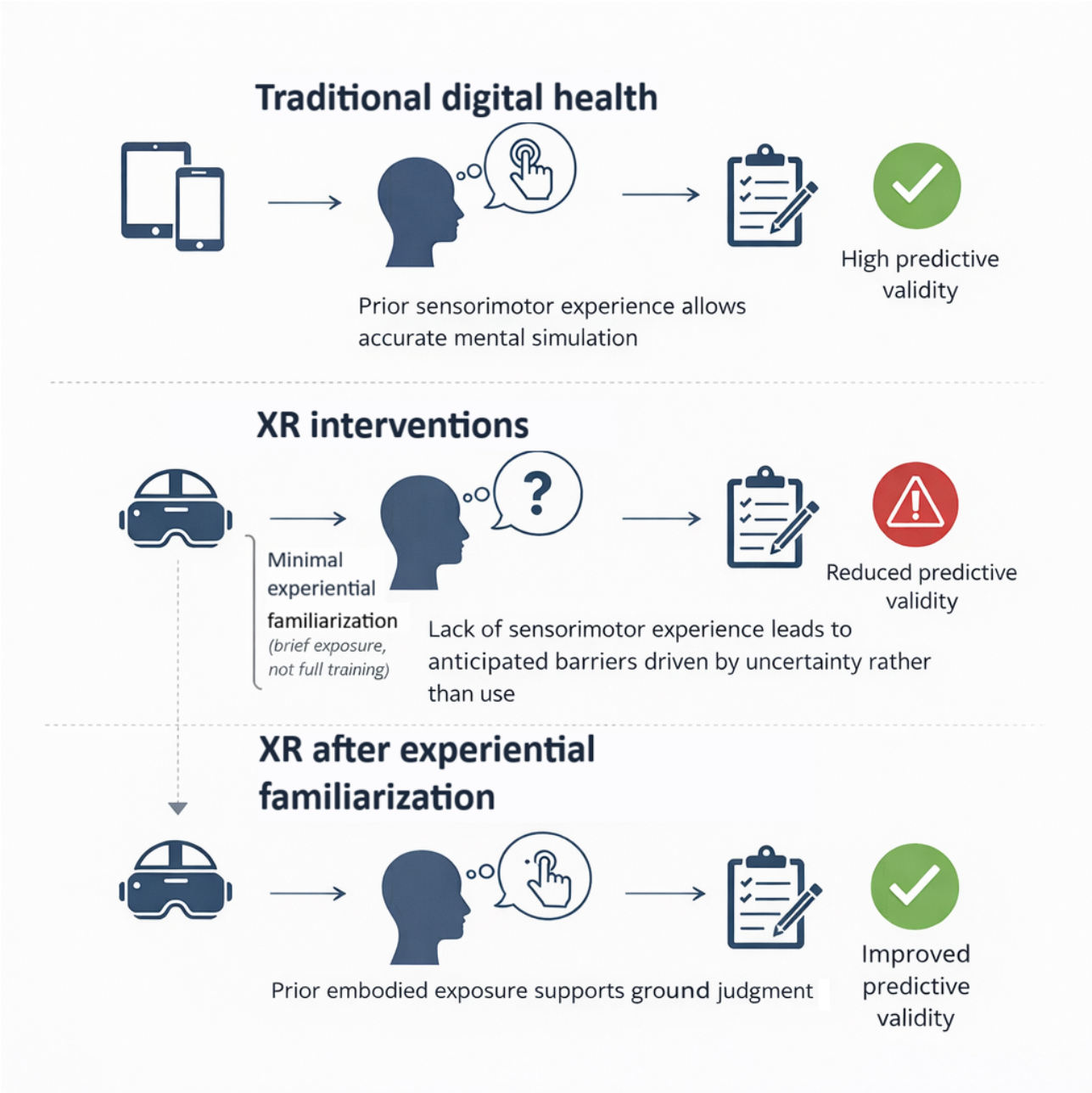
Figure 1. Conceptual model of the "experience gap" in perception-based formative evaluation, proposed here as a hypothesis-generating framework. For conventional digital health tools, stakeholders often have sufficient prior interaction experience to support plausible anticipatory judgments. In extended reality (XR), limited sensorimotor exposure reduces the interpretability of preuse assessments and raises the risk that uncertainty is recorded as an implementation barrier. Experiential familiarization is proposed as a pragmatic methodological condition to establish a minimal reference point before eliciting feasibility and acceptability judgments, rather than as a validated or sufficient intervention.



In this situation, familiar formative constructs used to characterize feasibility and readiness may no longer capture reflections grounded in prior practice. Rather, they express attempts to reason forward in the absence of concrete experience. While these constructs are well established for technologies that resemble existing systems [4,5], their interpretability may be more limited when applied to immersive interventions, whose defining features are difficult to anticipate prior to use.

Therefore, in XR-naive contexts, preuse ratings may be more likely to signal hesitation, risk sensitivity, limited experiential grounding, or initial impressions formed before meaningful use rather than fully informed judgments about likely barriers or facilitators [18,23]. Under these conditions, early assessments may reflect assumptions that have not yet been grounded in direct experience with the technology, whether expressed as concern or as early enthusiasm.

This does not suggest abandoning formative evaluation in XR research, nor does it imply that stakeholder perceptions are uninformative. Rather, it points to a boundary for interpretation and an opportunity for improvement. When assessments are conducted entirely before any immersive exposure, their outputs should not be treated as definitive classifications of implementation barriers. Ignoring the experiential constraints under which these judgments are produced risks treating uncertainty-driven concerns as intrinsic properties of the

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technology or the clinical context, rather than as artifacts of when and how the evaluation was conducted.

Epistemic and Structural Barriers

When formative evaluation takes place before any immersive exposure, certain concerns might be confounded with fixed obstacles to implementation. In XR research, this tendency may be less a sign of resistance than a consequence of how judgments are formed. At this point, it becomes useful to distinguish between epistemic uncertainty and structural barriers to implementation. Current formative frameworks do not always make this separation explicit, as they often assume that relevant perceptions can be elicited before sustained use [1,24,25].

Certain concerns seem to arise mainly because stakeholders have not yet had direct experience with XR and may therefore be assessing it under conditions of uncertainty [18,26]. These may relate to safety and comfort, including intrusiveness, discomfort, or cybersickness, as well as usability, acceptability, and the perceived value of immersive interaction [8,18]. Because such dimensions depend heavily on actual use, they are especially vulnerable to misclassification when judged before exposure [8,26]. In practice, this may give disproportionate weight to anticipated burden while leaving the experiential value of XR less clearly defined before first use.

By contrast, other barriers are likely to remain relevant regardless of prior immersive use. These include workflow integration, staffing, physical space, hardware logistics, infection control, technical support, and broader organizational conditions [10]. The methodological problem described here does not imply that all early concerns are misplaced. Rather, it suggests that this interpretive distortion may arise when epistemic uncertainty, together with the low confidence that often accompanies it, is interpreted and documented as though it reflected a stable structural barrier to implementation [1,10,18]. Current formative approaches do not always distinguish clearly between concerns that may diminish with exposure and barriers that remain structurally relevant [10,23].

These distinctions matter because formative evaluation findings rarely remain neutral observations. Early barrier profiles are often used to inform decisions about organizational readiness, resource allocation, and the continuation or discontinuation of pilot initiatives [1]. When judgments formed under conditions of uncertainty are documented as definitive barriers, they can influence strategic decisions about XR adoption independently of how the technology performs once introduced into practice [10]. The issue is not that formative evaluation lacks value, but that the timing and experiential context of data collection shape which barriers are identified and how firmly they are interpreted.

Toward Experience-Informed Formative Evaluation

These distinctions have practical implications for how formative evaluation is conducted in XR. The refinement proposed here is to introduce brief experiential familiarization before stakeholders are asked to assess selected dimensions of feasibility, acceptability, or fit with practice. For such judgments to remain interpretable, stakeholder perceptions need to be elicited under conditions that provide at least minimal experiential grounding. This proposal differs both conceptually and practically from staged pilot testing. Although pilot implementation evaluates feasibility, workflow integration, and clinical use over time during early deployment, experiential familiarization functions as a limited preparatory step at the formative stage. Its primary purpose is to establish a shared experiential baseline before more formal implementation or procurement decisions are made.

At a practical level, such encounters can be brief and structured. A familiarization session may include 3 simple elements: initial operational handling of the equipment, a short first-person immersive experience, and an immediate postexposure assessment. This may take the form of a guided interaction lasting approximately 10 to 20 minutes, during which stakeholders handle the equipment, wear the head-mounted display, and complete simple tasks relevant to the intended use context, ideally using the same content or application under consideration for routine practice. Depending on logistical constraints, these sessions may be conducted individually or in small groups.

This approach is already used by the authors as a routine practice when introducing XR into new clinical settings and among teams considering its adoption. In these sessions, the familiarization process is typically projected onto an external screen so that participants can follow each step of the setup, from defining the safe interaction area and floor level to launching the selected application and beginning first-person use. This makes the operational demands of XR visible from the outset while allowing participants to observe and discuss the process collectively before or during direct interaction.

This brief exposure serves several complementary functions. First, practical interaction with the hardware and interface can provide an initial understanding of setup demands, coordination needs, and operational complexity [11]. Second, first-person use allows stakeholders to experience immersion, physical comfort, and attentional demands directly, helping to anchor their judgments more firmly in observed interaction than in abstract expectation [26]. It may also help temper initial enthusiasm by grounding expectations in concrete clinical tasks and operational demands rather than idealized assumptions [27].

Several dimensions that are central to XR adoption are difficult to judge meaningfully without direct interaction. When sensorimotor experience is absent, anticipatory assessments rely on an incomplete mental simulation or expectations, constraining their accuracy [19,23]. Brief experiential familiarization does not eliminate uncertainty; however, it may allow it to be expressed in relation to experience rather than hypothetical assumptions [18,23]. This is particularly relevant for concerns that are experience dependent. By contrast, short-term encounters are not sufficient to assess broader implementation challenges or issues that emerge only through sustained use, such as technical and logistical problems or the organizational burden of integration across routine care pathways [10,11,28]. Figure 2 summarizes the proposed

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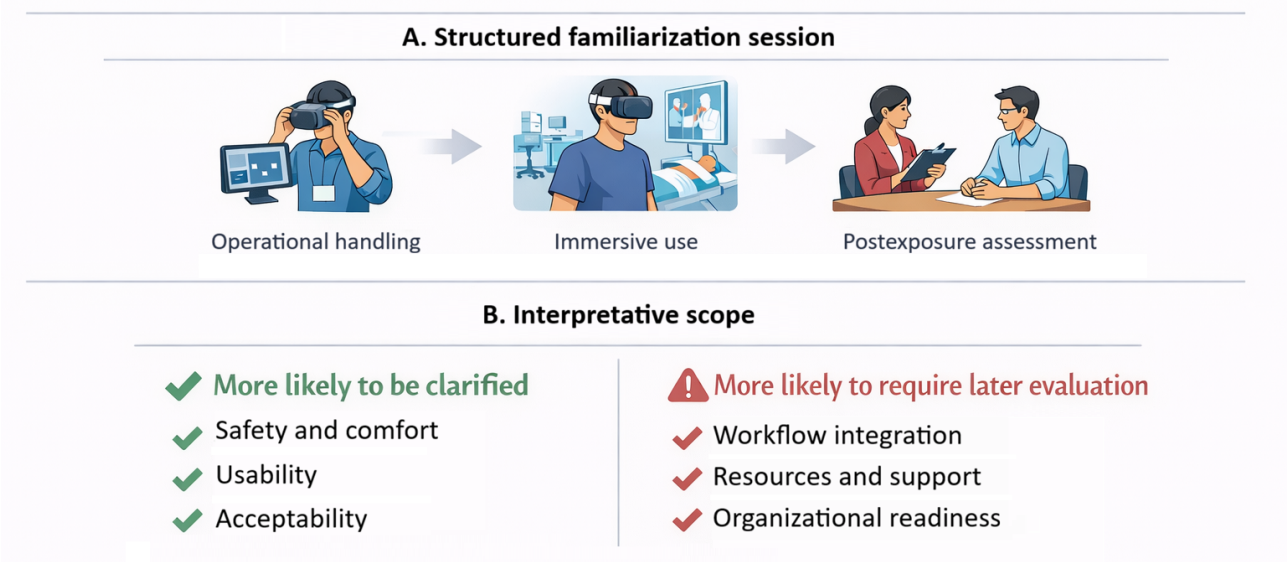
structure of this brief familiarization process and distinguishes the dimensions more likely to be clarified at this stage from those that typically require later implementation assessment.

Figure 2. Proposed structure and interpretive scope of brief experiential familiarization in extended reality (XR) formative evaluation. (A) A brief structured familiarization session comprising operational handling, first-person immersive use, and postexposure assessment; and (B) evaluation domains, classified into those more likely to be clarified through brief familiarization, such as safety, comfort, usability, and acceptability, from broader implementation dimensions more likely to require later-stage evaluation, such as workflow integration, resources, support, and organizational readiness.



At present, no single framework currently defines how a postdemo appraisal for XR should be structured, and the implementation literature points to a recurrent set of domains that are relevant to early decision-making. Reviews and consensus work have consistently identified usability, safety and comfort, workflow fit, training needs, resource demands, and organizational support as central determinants of XR adoption in health care, while broader implementation models remain useful for interpreting feasibility, readiness, and perceived value at the service level [10,11,21,24,25]. XR-specific guidance has also strengthened the reporting of safety and technical characteristics but has not yet established a practical structure for early appraisal across experiential, organizational, and strategic dimensions [29]. Therefore, in practice, an immediate postdemo assessment may reasonably address domains such as perceived clinical relevance, safety and comfort, usability, acceptability, workflow implications, training requirements, resource considerations, and perceived organizational fit, while recognizing that wider regulatory, ethical, and implementation issues usually require later-stage evaluation in real clinical settings.

A further implication concerns study design. Future research could make experiential conditions explicit within formative designs. For instance, pre-post approaches could compare stakeholders who receive brief, guided XR exposure with those who receive only informational or vicarious familiarization, such as written descriptions or nonimmersive materials. Examining within-person changes in perceived barriers and facilitators following hands-on interaction would allow researchers to assess whether preuse profiles among XR-naive stakeholders reflect imagined frictions more than judgments grounded in direct experience, as suggested by recent formative XR studies [23].

Importantly, this proposed approach remains compatible with existing implementation frameworks. It does not require new constructs or additional instruments. Established measures of acceptability, usability, and perceived usefulness continue to apply; however, their interpretive strength increases when responses are shaped by experience rather than anticipation alone. Framed in this way, brief experiential familiarization represents a modest refinement of current practice, improving the interpretability of early-stage findings while remaining aligned with the practical constraints of implementation research in immersive health technologies.

Beyond XR, similar interpretive limits may also affect other digital health technologies when their practical demands cannot be judged adequately without direct use, including applications such as artificial intelligence [30]. The issue may be particularly marked in XR, as perceptual immersion, sensorimotor interaction, and embodied experience are integral to usability, comfort, and perceived value [19,20].

Conclusions

The difficulties examined in this viewpoint do not arise from inherent limitations of XR as a clinical technology. They reflect a methodological misalignment between the embodied character of immersive systems and the conditions under which formative evaluation is often conducted. When XR interventions are assessed primarily through preuse perceptions, particularly among stakeholders with limited prior exposure, judgments about feasibility and acceptability may be shaped by anticipation rather than by experience. In these circumstances, early findings risk being treated as stable indicators, even though they are better understood as provisional assessments formed under uncertainty.

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This analysis does not diminish the role of formative evaluation in implementation science. Rather, it clarifies a boundary condition for its interpretation in experience-dependent technologies. For XR, the timing and experiential context of perception-based assessment are consequential. Introducing minimal embodied exposure before eliciting stakeholder judgments represents a pragmatic refinement that strengthens existing evaluative practice without requiring new frameworks, constructs, or measurement tools.

The contribution of this viewpoint is twofold. Conceptually, it frames the experience gap as a structural feature of XR adoption research, distinct from professional resistance, negative attitudes, or individual skill deficits. Methodologically, it proposes brief experiential familiarization as a low-burden preparatory step that may improve the interpretability of selected formative judgments before more formal implementation decisions are made.

For researchers, this perspective supports a more cautious reading of preuse perceptions in XR studies and closer alignment between formative designs and the embodied properties of immersive systems. For health systems and decision-makers, it underscores the value of experience-informed assessment when judging feasibility, acceptability, and readiness for implementation. More broadly, it suggests that some barriers reported in early XR research may reflect the timing and conditions of evaluation rather than obstacles that persist once technologies are encountered in practice. Brief experiential familiarization may help ensure that early judgments about XR reflect firsthand interaction more than unfamiliarity, making formative evaluation more useful for implementation decisions.

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Authors' Contributions

JFC conceptualized the manuscript, led the theoretical development, conducted the analytical work, and drafted the initial and final versions of the paper. MAR contributed to the conceptual framing, supervised the theoretical review, and provided critical revisions that strengthened the implementation science perspective and the overall coherence of the manuscript. Both authors reviewed and approved the final version.

Conflicts of Interest

None declared.

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Abbreviations

VR: virtual reality
XR: extended reality

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Building a Science-Driven Business: How National Institutes of Health Funding Enabled an Evidence-Based Approach to Maternal Mental Health Innovation

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Abstract

The digital mental health (DMH) industry has grown drastically over the last decade; yet, many DMH products have failed to demonstrate meaningful clinical outcomes, in large part due to lack of scientific evidence. This viewpoint paper highlights an example of how early-stage DMH companies can prioritize science as a strategic advantage. We discuss Moment for Parents, an artificial intelligence–driven maternal mental health app built entirely with support from the National Institutes of Health (NIH) Small Business Innovation Research (SBIR) program. We illustrate the advantages and challenges of building a science-backed product with federal funding. Benefits include credible evidence generation, independence in product development, and enhanced market differentiation. We also discuss the challenges of navigating the SBIR ecosystem, including grant writing and administrative demands, and aligning business objectives with federal research priorities. By showcasing both the promise and complexity of SBIR funding, this viewpoint paper offers actionable insights for founders and chief executive officers who aim to prioritize science in the DMH space.

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KEYWORDS

digital mental health; NIH SBIR grant; maternal mental health; chatbot; mHealth Apps

Introduction

The digital mental health (DMH) landscape has evolved significantly over the last decade, with periods of rapid expansion and then strategic adjustment. Prior to 2016, DMH was largely defined by delivering services via telehealth (eg, teletherapy) and organizing patient records electronically [1]. Since then, the widespread adoption of mobile smartphones and other mobile devices (eg, wearables) has led to a surge in mobile mental health and DMH interventions designed to support mental health with minimal or no human involvement [2]. While DMH technology emerged as a promising solution to the mental health treatment gap, most commercial DMH products have not been rigorously evaluated [3,4], and there is a concern that many DMH products may be ineffective or have iatrogenic effects, such as excessive self-monitoring, privacy breaches, and biased advice [5-9]. Given recent evidence that screen time may negatively impact mental health [10], DMH products, which necessarily increase users' screen exposure, have had to demonstrate that their benefits outweigh potential risks. In line with this, payers and users have begun to demand more rigorous validation of DMH tools, thus exerting pressure on DMH companies to develop scientific evidence for the effectiveness of their product [11,12]. This shift is reflected in evolving insurance coverage requirements, with some payers classifying apps as experimental due to a lack of clinical evidence [13].

One way in which DMH may differentiate itself from competitors and develop the scientific evidence to position itself in the competitive DMH market is to gain funding from the National Institutes of Health (NIH) Small Business Innovation Research (SBIR) program, a mechanism that supports research for commercial health products [14]. The NIH SBIR program was established by Congress in 1982 to increase federal investment in innovative health sciences research and has received broad bipartisan support since its inception [15]. This funding opportunity was designed for US for-profit businesses with fewer than 500 employees, which are majority-owned by a US citizen or permanent resident, or by multiple investment firms as long as no single firm has more than 50% of ownership. NIH SBIR funding supports the development and commercialization of innovative technologies and ultimately advances the research interests and goals of the NIH. Most importantly, NIH SBIR funding enables DMH companies to establish a proof of concept without requiring financial support from investors and giving up equity in their company in exchange for investment. For example, 10% - 20% equity is often given up during seed fundraising and 20% - 30% during series A fundraising [16,17]. This equity dilution can be

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accompanied by a loss of control over product direction, as investor priorities for rapid growth and profitability may conflict with the rigorous scientific validation that is important for effective DMH interventions. Additionally, because of its reputation, NIH SBIR funding may make companies more appealing to venture capital if and when they are ready to raise funding [18]. Despite the availability of NIH SBIR funding as a resource for small businesses, many DMH companies may struggle to successfully navigate the complex and competitive SBIR grant application process or to effectively align their business goals with the structure and requirements of federal grants. These difficulties can make it more difficult for companies to leverage SBIR funding as a pathway for research and development.

To illustrate how DMH companies can successfully leverage government funding, we examine Moment for Parents, a DMH company supported exclusively by SBIR grants. Moment for Parents was selected as an illustrative case because it represents an early-stage DMH company that relied on federal SBIR funding, rather than venture capital, to support research and development and to generate scientific evidence for its product. As such, it provides an example of how SBIR funding can function as a primary pathway for evidence generation and product development within the DMH space. Moment for Parents is an artificial intelligence–powered mobile app that engages women in personalized pregnancy, parenting, and psychosocial support from conception up to 3 years post partum. The chatbot draws upon evidence-based approaches to support perinatal mental health, such as strategies for emotional support and educational content on perinatal mental health [19]. These approaches were selected based on research showing their potential benefit for supporting women in perinatal periods [20,21]. The platform incorporates these approaches through daily mood check-ins, which in turn tailor content to support users' emotional states and preferences. Together, the platform enables personalized support that adapts to the dynamic needs of the perinatal period. Since its founding in 2019, Moment for Parents has been grounded in its science-driven approach and was first awarded NIH SBIR funding in 2023. To date, Moment for Parents has obtained US $1.27M in federal funding to evaluate the feasibility and acceptability of its chatbot-based platform and has not sought investors for funding.

Using Moment for Parents as a proof of concept, this viewpoint paper aims to (1) demonstrate how NIH SBIR funding supports DMH companies in achieving scientific validity and market credibility, (2) examine practical challenges DMH companies may face when pursuing NIH SBIR funding, and (3) outline the implications for the broader DMH field seeking to explore NIH SBIR funding. Through these aims, we hope to inform DMH companies that government funding remains a viable pathway to building robust, scalable, and clinically informed DMH interventions.

How Federal Funding Supports DMH Companies

There are several advantages to securing early-stage NIH SBIR funding.

Making Research Core to the Business

Government funding fundamentally changes the relationship between business development and scientific research. Rather than viewing research as a costly barrier to market entry, NIH SBIR funding positions research as core to a company's business plan. NIH SBIR submissions are centered around a "Specific Aims" page—the "roadmap" of the grant. For example, Moment for Parents focused their Specific Aims on generating preliminary evidence for their product. Their initial submission included a usability study as well as a small pilot efficacy study. Preliminary findings demonstrated that the chatbot-based Moment for Parents app was feasible and acceptable for perinatal mental health screening, with positive user experience and sustained engagement. These findings are currently being prepared for peer-reviewed publication. Aligning Moment for Parents' business goals around the structure of an SBIR grant allowed for a strategic, evidence-based approach to their product development and ensured that product innovation and iteration were driven by data and results.

As part of the standard SBIR peer review process, Moment for Parents received formal written feedback from subject matter experts, which informed refinements to its research approach and strengthened the company's scientific strategy for building credibility around the Moment for Parents app. The competitive nature of the SBIR funding, with phase I success rates reaching approximately 13% - 16% for NIH awards, ensures that only scientifically rigorous proposals receive funding [22]. This contrasts sharply with the broader industry landscape of largely unvalidated DMH tools [23], where market credibility is focused on business metrics rather than clinical evidence. We contend that the approach supported by NIH SBIR—embedding science into the business model—is a necessary next step for the field because products developed under these constraints are more likely to deliver meaningful outcomes.

Using Evidence to Stand Out

Beyond scientific innovation, NIH SBIR funding provides DMH companies with strategic business advantages around market differentiation. While the DMH market includes many products that cite unsubstantiated claims or limited evidence [3,24], SBIR-supported validation offers a signal of higher scientific rigor and credibility that stakeholders increasingly recognize [18,25]. Using the SBIR program, Moment for Parents collects data to generate scientific evidence, differentiating them from their industry competitors. As a result of SBIR funding, Moment for Parents has been able to market its product as supported by federally funded research and peer-reviewed through the SBIR process. Users increasingly value evidence-based tools, and they are more likely to select, stick with, and benefit from tools that are rooted in strong science, making this invaluable for any DMH product [26].

Making Product Choices Without Investor Pressure

NIH SBIR funding provides companies with capital that is not tied to immediate profitability, allowing chief executive officers to make product decisions based on user input and achieve important health outcomes rather than rapid scaling. DMH products may need several rounds of product iteration before

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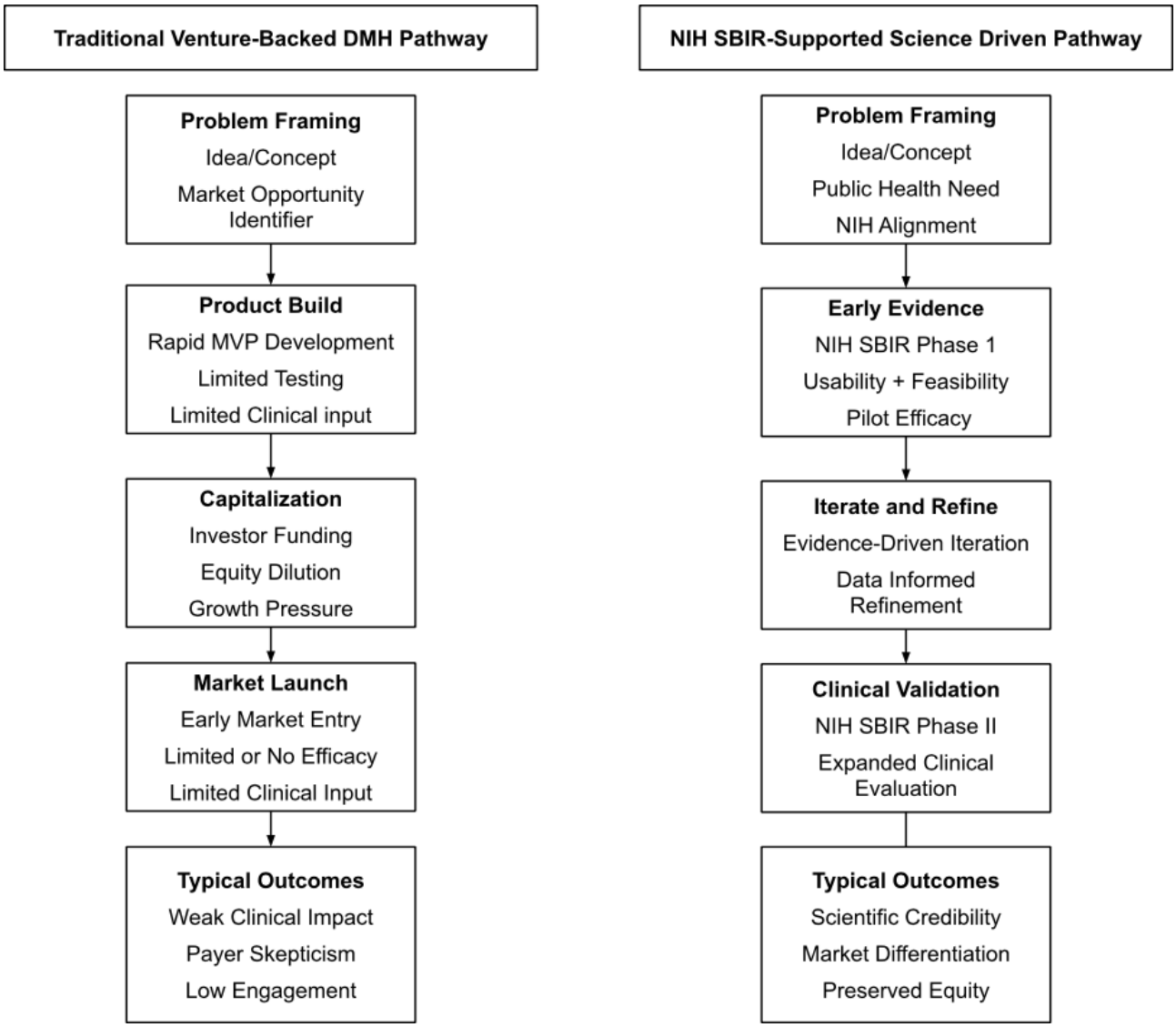
meaningful and reliable clinical outcomes are demonstrated. However, pressure to meet investor timelines can lead to premature market entry, increasing the risk that patients are exposed to underdeveloped, ineffective, or harmful interventions. NIH SBIR funding can help mitigate this risk by supporting the necessary time and flexibility for responsible product development. For example, in the first Moment for Parents usability study, results informed significant and unexpected shifts in the app experience. Mixed user preferences for the chatbot led to the addition of other coping mechanisms such as venting and meditations. Users also expressed a desire for more agency in their experience. In response to feedback from a first round of users that certain features were not helpful, recruitment slowed, and time was taken to make necessary changes in the app. Now, through three cycles of testing and redeployment, the app has been iteratively refined and is continuously reevaluated. Changes in outcomes between versions of the app will be tested. Together, this example highlights how government funding can support deliberate, user-informed iteration in DMH product development. Importantly, these revisions reflect an ongoing, evidence-informed evaluation and refinement process.

Illustrated in Figure 1, NIH SBIR–supported, science-first pathways embed evidence generation and validation into early-stage DMH development. In a field where systematic reviews continue to demonstrate limited published evidence of efficacy [27], Moment for Parents illustrates how making research core to the DMH business model can support both scientific validity and market credibility.

Figure 1. Comparing traditional venture-led and SBIR-supported, science-driven pathways in digital mental health. The conceptual figure contrasts traditional venture-backed development pathways with NIH SBIR–supported, evidence-first pathways. It visually summarizes the key concepts discussed in the paper and highlights a science-driven approach to digital mental health innovation. DMH: digital mental health; NIH: National Institutes of Health; SBIR: Small Business Innovation Research.



Challenges of SBIR Funding

While NIH SBIR funding provides numerous benefits, it is not without challenges. Successfully obtaining and implementing SBIR grants requires overcoming several hurdles, from navigating complex applications to aligning business and research priorities.

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Partnership Requirements

Writing an SBIR grant requires skills and experience. DMH founders may lack the expertise necessary to write a successful grant application and, therefore, need to cultivate external partnerships in the grant-writing process. In practice, the complexity of federal grants often drives early collaboration with consultants and academic partners, which can strengthen both the scientific design and the likelihood of success. In the case of Moment for Parents, the founder was supported to write the NIH SBIR by BBC Entrepreneurial Training & Consulting (BBCetc), a Federal and State partnership program, which supports start-ups in all aspects of NIH SBIR applications, from writing to administration [28]. This type of technical assistance has been proven effective, with states offering NIH SBIR support programs achieving higher success rates than the national average of funding awards [29]. Moment for Parents also leveraged academic partnerships to help develop a robust study design and analytic plan for their first NIH SBIR submission. Following the Moment for Parents model, DMH founders should seek technical assistance programs early in their planning through their state's Federal and State program. This would provide low-cost SBIR proposal development support. Applications may also be strengthened by partnering with academic institutions or researchers to develop collaborative study designs and enhance the study's rigor.

Administrative Hurdles

Writing a federal grant, and in particular an NIH grant, is a highly competitive and resource-intensive process [30]. Only around 15% - 20% of phase I NIH SBIR grant submissions are ultimately funded [22,30] (although of note, this is a high success rate compared to the 1% of companies that ultimately raise venture capital funds), and the process is notoriously lengthy. An additional challenge for DMH companies in a field where technology evolves rapidly is that by the time funding is secured and research is completed, the underlying technology may have become obsolete. For example, at Moment for Parents, 3 months were spent on the preparation and writing of the initial grant, and it took an additional 2 years of resubmissions and reviews until the funding was awarded.

After securing funding, navigating the administrative requirements of the NIH SBIR grant can be challenging and time-consuming. In the case of Moment for Parents, they partnered with a strategic applied science firm to help execute their NIH SBIR–funded research. The science firm wrote and submitted Moment for Parents' first Institutional Review (ethics) Board submission, assisted in dissemination of research results, including analyzing data and writing scientific publications. In an additional effort to reduce the administrative burden of SBIRs, Moment for Parents hired an accounting firm that specializes in recordkeeping for NIH SBIR grants. To manage these administrative demands, DMH founders should replicate Moment for Parents' approach by budgeting for specific support services across their grant applications, including NIH SBIR–specialized accounting firms for financial compliance or university partnerships for institutional review board submission. Moreover, DMH founders should leverage the NIH's postaward support resources [31], which provide free guidance on reporting requirements and common administrative challenges.

Aligning Business Goals With Science Goals

Aligning a company's business goals with (1) the NIH's priorities, and (2) the company's own science goals can be a challenge. The NIH comprises 27 Institutes and Centers (ICs) that each have unique funding priorities. In the case of Moment for Parents, each application was focused on research to align with what was valuable for their business and also aligned with the NIH IC (eg, National Institute of Mental Health, National Institute on Drug Abuse, and National Institute of Minority Health and Health Disparities) priorities. For example, for the first NIH SBIR submission, Moment for Parents identified a special funding opportunity that aligned well with their product development goals, which was focused on digital interventions for at-risk individuals. To best align business goals with science goals, DMH founders should thoroughly review the funding priorities and specific funding announcements of relevant NIH institutions to identify funding priorities and approaches that seamlessly align with the company's mission and product development.

Implications for the Field

Taken together, these insights point to how federal funding can shape the broader DMH industry. In particular, SBIR-supported approaches can:

- Raise the scientific bar for DMH by embedding rigorous evidence generation into product development, as SBIR-funded companies have demonstrated more robust scientific study designs than venture-backed companies [32].
- Signal credibility to investors and stakeholders through NIH peer-reviewed validation, which can increase the probability of attaining venture capital by 20% - 30% [33].
- Strengthen sustainability by reducing early equity dilution and short-term growth pressures.
- Establish a scalable model for integrating academic–industry collaboration in DMH to help translate research into evidence-based DMH products [34].

Conclusion

The evidence we present here supports a fundamental reimagining of how the DMH industry approaches innovation. Rather than the current paradigm, where clinical validation may follow commercial success, we suggest that evidence generation should precede and guide market entry. Government funding such as the NIH SBIR mechanism provides a viable pathway to this future, and our experience with Moment for Parents validates this alternative approach. Ultimately, however, the real opportunity lies in industry-wide adoption. By leveraging SBIR grant funding, DMH companies can enhance their market differentiation, accelerate growth, contribute to scientific advancement, and ultimately improve public health outcomes.

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Conflicts of Interest

MK is the chief executive officer (CEO)/founder of Moment for Parents, and Moment for Parents is the product discussed in this viewpoint paper. JH is the CEO of Fit Minded and a paid consultant for Moment for Parents. KM is employed by Fit Minded, and LB was previously employed by Fit Minded. However, the authors' employment status and/or salary are not dependent upon the results of their research.

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Abbreviations

DMH: digital mental health
IC: Institute and Center
NIH: National Institutes of Health
SBIR: Small Business Innovation Research

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The Coordination on Mobile Pandemic Apps Best Practice and Solution Sharing (COMPASS) Framework: Holistic Approach to Pandemic mHealth Apps

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Abstract

The COVID-19 pandemic has highlighted the crucial role of smartphone apps in public health, but it has also revealed challenges in terms of user acceptance and trust, as well as the secure integration of medical data. To overcome these, the COMPASS initiative (Coordination on Mobile Pandemic Apps Best Practice and Solution Sharing)—part of the German Network University Medicine (NUM) program—developed a structured framework for the coordinated development and delivery of pandemic apps, with a focus on usability, accessibility, security, and scalability. By incorporating expertise from 9 university hospitals and external partners, COMPASS provided a modular approach to pandemic app development that balances technology, regulation, and public acceptance. The framework includes governance, best practices, compliance, research compatibility, interoperability, and a scalable technology platform. In addition, standardized app components and templates were created to support an effective pandemic response. Real-world validation was provided by study-specific apps such as the Mainz Gutenberg Study COVID-19 app (University Medical Center Mainz) and the SentiSurv app (University Medical Center Mainz), which generated nearly 1 million data points from over 25,000 participants. COMPASS successfully developed study-specific apps, improved core functionalities, and contributed to larger digital health projects such as the InnovationHub CAEHR. Beyond its immediate applications, COMPASS serves as a scalable blueprint for future mobile health solutions, with a focus on data protection, user trust, and open-source collaboration. By integrating important technological, ethical, and user-oriented considerations, it sets a new standard for digital health innovation and ensures sustainable and widely accepted pandemic preparedness.

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KEYWORDS

patient-reported outcome; pandemic app; mobile health; Network University Medicine; Coordination on Mobile Pandemic Apps Best Practice and Solution Sharing; COMPASS; technical framework; medical device regulation; medical devices; smartphone app; application; development; user engagement; app effectiveness; questionnaire; use

Introduction

Overview

The COVID-19 pandemic underscored the crucial role of smartphones in disseminating health information, particularly during lockdowns and social distancing [1]. This period saw a surge in pandemic-specific mobile apps aimed at managing public health crises [2]. However, their success depended on widespread adoption and public trust, especially when handling sensitive medical data and personal risk assessments [3]. Developers faced the challenge of balancing usability, security, and rapid deployment, while also addressing critical concerns regarding data protection and user control.

To tackle these challenges, the COMPASS initiative (Coordination on Mobile Pandemic Apps Best Practice and Solution Sharing [4]) was established as part of Germany's Network University Medicine (NUM) program. From the outset, COMPASS aimed to create a structured framework for developing, evaluating, and deploying pandemic apps, leveraging expertise in science, technology, and legislation. Its

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core objective was to ensure that pandemic apps were effective, interoperable, and research-ready, facilitating their rapid and optimal use in future health emergencies.

A key challenge was the absence of clear legal, regulatory, and technical guidelines for integrating app-collected data into COVID-19 research while ensuring compliance with privacy standards [5]. This gap created uncertainties in assessing the effectiveness of these apps and limited their utility for stakeholders such as researchers, clinicians, and public health authorities.

Through interdisciplinary collaboration between scientists, industry, and academic partners, COMPASS developed an open-source, modular technology platform that allows for the rapid adaptation and reuse of pandemic apps. The initiative provided best practice guidelines, standardized app components, and frameworks to ensure compliance, usability, and security. Its approach bridges the gap between technological innovation and real-world health care application, demonstrating how mobile health (mHealth) solutions can be effectively integrated into pandemic management.

This paper highlights the interplay of key components within the COMPASS framework, emphasizing its strategic approach to coordinating mHealth solutions. By integrating best practices in app development, governance, interoperability, and data security, COMPASS establishes a sustainable model for future health crises. Beyond Germany's NUM program, its findings contribute to global efforts in advancing digital health strategies for pandemic preparedness.

Background Information on COMPASS

The COMPASS approach integrated the expertise and experience of 9 university hospitals and external partners in the development and use of pandemic apps. It established a collaboratively coordinated and standardized platform to ensure the legally compliant and interoperable deployment of such apps. Table 1 provides an overview of all 9 participating institutions, including their commonly used abbreviations and the affiliations of the authors contributing to this paper.

Table . Participating institutions in the COMPASS[a] initiative and their areas of expertise.

Institution name	Abbreviation	Expertise
Charité – Berlin University Medicine (Peter Gocke)	CHA	Mobile apps, telemedicine, medical informatics, and hospital information systems
University Medicine Göttingen (Dagmar Krefting)	UMG	Health information exchange, medical informatics, data management, ethics, and wearable electronic devices
University Medicine at the Johannes Gutenberg University in Mainz (Christian Elsner)	UMM	Health information systems, mobile apps, telemedicine, project management, and health planning
University Hospital Würzburg (Rüdiger Pryss and Michael Winter)	UKW	Mobile apps, psychology, ergonomics, telemedicine, and public health informatics
University Hospital Cologne	UKK	Health information exchange and questionnaires
University Hospital Muenster	UKM	Multilingualism and mobile apps
University Hospital Regensburg	UKR	Mobile apps, public health informatics, and data collection
University Hospital Ulm	UKU	Mobile apps, telemedicine, psychology, and ergonomics
University Hospital Erlangen	UKEr	Data collection and mobile apps

[a]COMPASS: Coordination on Mobile Pandemic Apps Best Practice and Solution Sharing.

Table 2 provides a summary of the COMPASS project, outlining its primary objectives, duration, key participants, development principles, focus areas, sustainability efforts, and accessibility. This overview highlights the core components of the initiative, offering a quick reference to its scope, structure, and strategic direction.

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Table . Key features and overview of the COMPASS[a] initiative.

Feature	Description
Project name	COMPASS (Coordination on Mobile Pandemic Apps Best Practice and Solution Sharing)
Objective	To develop sustainable app technology for managing pandemics through collaborative solutions and best practices.
Duration	September 2020 to December 2021
Participants	9 University Hospitals forming an interdisciplinary team, including scientists from various fields, alongside partners from science and industry
Development basis	Entire development based on open-source principles
Key focus	Ensuring research compatibility, interoperability, and adherence to relevant medical research and care standards internationally and in Germany
Sustainability efforts	Developing sustainability structure concepts alongside the main project goals
Accessibility	Publicly accessible through an online directory for widespread use
Contact information	NUM-COMPASS website: [4]; Email: compass@unimedizin-mainz.de

[a]COMPASS: Coordination on Mobile Pandemic Apps Best Practice and Solution Sharing.

Status Quo Before and After COMPASS

Despite being developed 4 years ago, smartphone-based medical apps remain in high demand, largely due to the growing emphasis on patient-reported outcomes (PROs) [6], which COMPASS actively supports. Studies highlight significant discrepancies between health care professionals' assessments and patients' actual symptom experiences [7], emphasizing the importance of PROs. Their impact is now widely recognized, with Newsweek recently including PROs as a criterion in its global hospital rankings [6]. Notably, research, particularly in oncology, demonstrates that PROs can improve patient survival rates [8].

However, 4 years after COMPASS, similar initiatives remain scarce. Our literature review [9,10] confirms this gap, and a technology search for freely available frameworks similar to COMPASS yielded minimal results [10]. Several factors contribute to this limited adoption [11], including stringent regulatory requirements, high development costs, and the rapid evolution of smartphone technology [12]. Additionally, many apps fail to prioritize user needs, lack comprehensive guidelines, and struggle to integrate into existing health care workflows. The broader digital health sector faces challenges in integrating health apps into clinical practice. While many apps exist, most lack clinical validation and remain underused. Key barriers include education and awareness gaps, missing digital formularies, limited workflow integration, and unclear reimbursement models. The digital divide also persists, preventing some populations from accessing or effectively using these technologies. Furthermore, the impact of health apps on clinician workload and burnout remains insufficiently studied.

Related Work

A substantial body of literature exists on COVID-19 health apps [13,14]. However, many studies overlook a significant number of available apps [15,16], and those that do include them often fail to address broader mHealth frameworks for pandemic management. There are several initiatives related to COMPASS [17,18], some closely aligned and others more general in scope. However, none provide the comprehensive, interdisciplinary approach that COMPASS offers. Research has consistently highlighted barriers to adoption [19,20], reinforcing the need for fundamental frameworks such as COMPASS in both mHealth apps and PRO integration.

International Initiatives, Frameworks, and Projects Related to COMPASS

In this document [21], COMPASS identified and compared national and international initiatives, frameworks, and projects related to pandemic apps. Our overall goal was to evaluate how such initiatives align with the goals of the COMPASS project and provide insights for future developments in mHealth apps.

Objectives

Our objectives were as follows:

1. Identify international activities related to pandemic apps beyond Germany.
2. Analyze useful insights from these initiatives for future pandemic preparedness.
3. Assess international frameworks that focus on mHealth apps.
4. Compare findings with COMPASS to determine gaps, best practices, and interoperability.

Instruments

The following instruments were used:

1. Contacting international organizations with expertise in mHealth apps.
2. Conducting an online search for pandemic-related projects and frameworks.
3. Surveying international partners in the COMPASS network.

The findings showed that no direct equivalent to COMPASS exists internationally at the time of development, highlighting

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the necessity of a structured, interoperable pandemic app framework. However, several international initiatives and frameworks provide valuable insights and technical solutions (Table 3).

Table . Relevant international initiatives.

International initiative	Description
GNSS (European Global Navigation Satellite Systems Agency)	Provides navigation and positioning data crucial for GPS-based pandemic apps, ensuring the accuracy, integrity, and availability of location-based services [22].
UN-DESA[a] Digital Government Initiatives (COVID-19 Response)	Compendium of global digital government responses to COVID-19, helping countries share best practices [23].
WHO[b] Academy and WHO Info Apps	Mobile tools providing COVID-19 guidance, virtual training, and educational resources for health care professionals [24].

[a]UN-DESA: United Nations Department of Economic and Social Affairs.

[b]WHO: World Health Organization.

In addition, we identified 14 pandemic-related frameworks, 13 of which focus on contact tracing (Table 4). The most notable ones are described below.

Table . Pandemic-related frameworks.

Framework	Description	Usage
ViraTrace [25]	Uses advanced proximity detection models to improve contact tracing. Integrated into India's Aarogya Setu app (National Health Authority, India).	Aarogya Setu (India)
PEPP-PT (Pan-European Privacy-Preserving Proximity Tracing) [26]	Aimed at standardizing contact tracing in Europe while ensuring GDPR[a] compliance.	ROBERT (France) and StopCovid (Georgia)
Coalition Network [27]	Bluetooth-based contact tracing.	Coalition App (Global)
Google-Apple Exposure Notifications System [28]	A global contact tracing protocol adopted by several national apps.	Corona-Warn-App (Germany), COVID Alert (Canada), Immuni (Italy), etc
DP-3T (Decentralized Privacy-Preserving Proximity Tracing) [29]	Open-source protocol ensuring privacy-preserving exposure notifications.	Coronalert (Belgium)
PACT (MIT's Private Automated Contact Tracing) [30]	Privacy-first contact tracing protocol developed with academic institutions and hospitals.	COVIDSafe (United States)
SORMAS (Surveillance Outbreak Response Management and Analysis System) [31]	Monitors and analyzes infection outbreaks in Germany.	Used in German health departments.

[a]GDPR: General Data Protection Regulation.

Survey Results

The international survey assessed pandemic app initiatives and COMPASS's relevance. Key insights:

1. Respondents confirmed that more international collaboration is needed.
2. The open-source approach of COMPASS was widely supported.
3. A few pandemic apps were identified, such as OstaniZdrav (Republic of Slovenia) [32] and Virusafe (Council of Ministers of the Republic of Bulgaria) [33].
4. There was no clear consensus on additional missing focal points in COMPASS.
5. Discussions with the European Health Futures Forum helped increase international visibility.

Strategic Aims and Objectives of the COMPASS Initiative

COMPASS was structured into 7 activity clusters (ACs), as illustrated in Figure 1. Table 5 provides a concise summary of the key tasks and outcomes across these clusters.

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Figure 1. Organizational structure and workflow of the Coordination on Mobile Pandemic Apps Best Practice and Solution Sharing initiative's activity clusters.

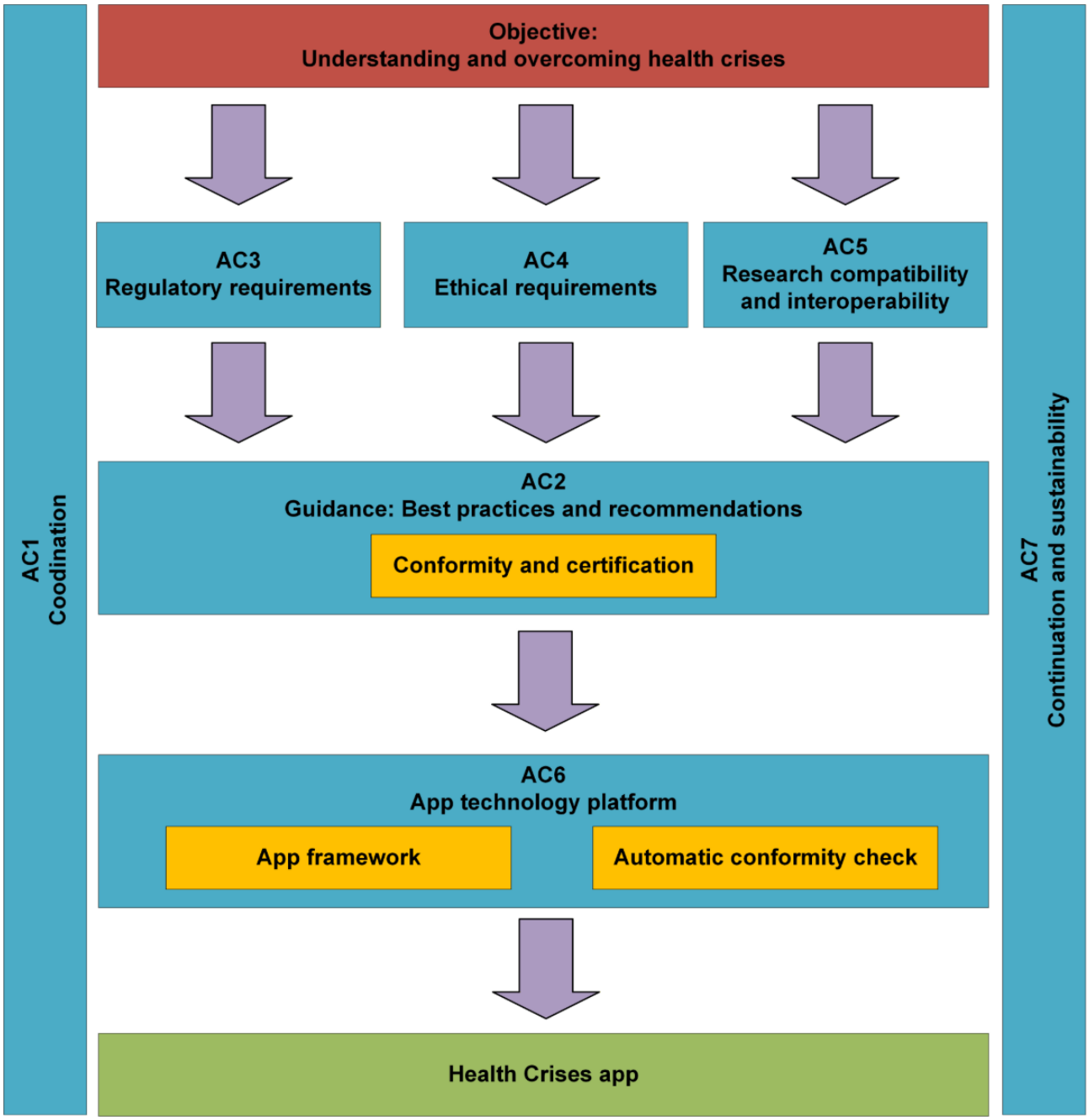

Table . Number of participants and data records for studies using COMPASS[a] apps.

Study	Number of participants (n) and data records (D)
Mainz Gutenberg Study COVID-19 app [34]	n=7500; D=227,000
SentiSurv [35]	n=19,700; D=654,000
SAM[b] [36]	n=110; D=568
FORTEe [37]	n=12; D=not available

[a]COMPASS: Coordination on Mobile Pandemic Apps Best Practice and Solution Sharing.

[b]SAM: Self-Monitoring App for Employee Health.

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AC1: Coordination

A governance structure was established to monitor project milestones, enable rapid response to deviations, and ensure alignment with AC2. Effective communication and coordination with international pandemic networks were prioritized to synchronize technical developments.

AC2: Guidance (Best Practices and Recommendations)

Best practices and guidelines were developed to enhance the effectiveness, efficiency, and research compatibility of pandemic apps. A digital knowledge database was created to support partners in meeting regulatory requirements. Advisory structures were also established to disseminate these guidelines.

AC3: Regulatory Requirements

Regulatory demands for pandemic apps proved more stringent than for standard medical apps, requiring a different development approach. Guidelines were formulated to address these challenges and ensure compliance with fast-evolving requirements.

AC4: Ethical Requirements

Ethical considerations were critical due to public concerns over mandatory app usage during pandemics. The cluster focused on trust-building measures to help citizens and researchers navigate the ethical implications of pandemic apps.

AC5: Research Compatibility and Interoperability

Key requirements for using app-collected data in pandemic research were identified. Concepts and recommendations were developed to guide app configuration, which were integrated into AC2. A generic HL7 FHIR (Fast Healthcare Interoperability Resources) interface was initially created and iteratively expanded to accommodate specific data models [38].

AC6: App Technology Platform

A modular technology platform was developed, featuring templates, technical components, and a semiautomated compliance check for regulatory adherence. Reference implementations for both native and cross-platform development were provided, all under open-source licenses, ensuring quick adaptability for future pandemics.

AC7: Continuation and Sustainability

Long-term strategies were designed to ensure the ongoing operation of the platform, including regular updates aligned with legal and scientific advancements. A certification framework was proposed, alongside a responsive advisory structure for future pandemics. Maintenance efforts focused on keeping apps compatible with evolving mobile operating systems.

Overview of Solutions Orchestrated Through COMPASS

Upon its successful completion, the COMPASS project achieved significant milestones in 3 key areas: the development and implementation of study-specific apps, the enhancement of technical components, and the application of nontechnical insights for future use.

Pillar 1: Development and Implementation of Study-Specific Apps

This pillar highlights the successful deployment of multiple study-related apps (Table 5):

1. Mainz Gutenberg Study COVID-19 app: used for monitoring COVID-19 within the scope of the Mainz Gutenberg Study.
2. DZHK App for Medication and Anamnesis (Universitätsmedizin Göttingen): employed at the German Center for Cardiovascular Research for recording medication and medical histories.
3. SentiSurv app: applied in Mainz for the continuous monitoring of the SARS-CoV-2 pandemic.
4. SAM (Self-Monitoring App for Employee Health; Universitätsmedizin Mainz): developed under the NUM project egePan Unimed, this app is currently under evaluation and further development in the NUM subproject “PREPARED” of the second funding phase.
5. Stress Radar (Universität Würzburg): designed to assess the psychological stress of employees.
6. FORTEe Study (Universitätsmedizin Mainz): conducted in the realm of pediatric oncology, in collaboration with IZKS, as part of the FORTEe project. This involved the use of both web and native apps.

Pillar 2: Advancement of Technical Components

This domain primarily focused on the extensive development of the questionnaire editor, with detailed technical specifications available at [39]. Simultaneously, ongoing maintenance and enhancement efforts have ensured the optimization of key components, as outlined in [40].

Pillar 3: Continuation and Use of Nontechnical Findings

For example, within the InnovationHub CAEHR project, findings on Medical Device Regulation and eHealth insights have been successfully integrated and reused. Regular high-frequency monthly inquiries about these results ensure their continued relevance and refinement.

Structured Summary of COMPASS Results

Table 6 below provides a structured summary of COMPASS results across the ACs.

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Table . Summary of tasks and work results across COMPASS[a] initiative activity clusters.

Activity cluster	Task	Work results
AC1	• Synchronize and document the work content of national and international groups	• Identified relevant projects (4), frameworks (12), and artifacts (9) that were developed internationally during COVID-19.
AC2	• Conformity check for pandemic health apps • Prototype advisory structures to attract further institutions • Job description for consulting and inquiry management • Prototype advisory structures to attract further university hospitals	• Developed modules for evaluating the conformity of health apps with established protocols, focusing on privacy and technical specifications. • Developed a scalable framework to facilitate collaboration and support among various stakeholders. • Defined a job role focused on consulting and managing inquiries, enhancing the use of COMPASS components in health care. • Created advisory structures for interacting with university hospitals, focusing on guidelines and services synchronization.
AC3	• Explanation of the technical development variants for pandemic apps • Interim results best practices and checklists regulatory requirements • Regulatory field report • Best practices and checklists	• Analyzed and compared different development approaches for pandemic apps, focusing on performance, costs, and regulatory compliance. • Outlined preliminary checklists for developing regulation-compliant pandemic apps. • Examined regulatory frameworks to ensure that pandemic app development processes comply with standards. • Provided guidance on regulatory compliance for mobile health apps, especially under pandemic conditions.
AC4	• Catalog of best practices and checklists usability, diversity, and licensing • Study design and recruitment strategy for the social acceptance study • Literature review on the evidence of pandemic apps • Literature review on ethical recommendations and normative governance guidelines • Best practices and guidelines of ethical-social requirements	• Analyzed usability, diversity, and licensing issues, producing best practices and checklists. • Designed and executed studies to understand public attitudes toward pandemic apps and their effectiveness. • Assessed the effectiveness of pandemic apps through scientific, user, and legal lenses, using bibliometric analyses. • Reviewed ethical and governance guidelines for pandemic app development, focusing on privacy, transparency, and participation. • Explored usability, diversity, and licensing in pandemic apps, providing recommendations for improvement based on user feedback.
C5	• Research compatibility and interoperability • FAIR[b] principles • Specification of data and metadata models • Concept for ensuring research compatibility for apps • Late mapping scheme	• Identified requirements and recommendations for the use of app-collected data in pandemic research. • Focused on implementing FAIR principles to improve the management and use of research data. • Developed specifications for data and metadata models to ensure compatibility and integration with the NUM[c] platform. • Provided concepts and recommendations for integrating app-collected data into pandemic research, ensuring interoperability and scientific reuse. • Addressed compatibility issues for data collected prior to coordination with the NUM COMPASS project.

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Activity cluster	Task	Work results
AC6	• App framework • Templates: privacy statements, terms of use, and further information	• Developed a platform containing frameworks for essential components of pandemic apps. • Compiled templates for legal and privacy aspects necessary for pandemic apps.
AC7	• Survey of existing guidance structures and economic analysis of guidance operation • Survey of technology platforms	• Developed strategies for sustainable management of the COMPASS platform, incorporating best practices and regular updates. • Explored strategies for sustainable operation and continuity of technology platforms used in pandemic management.

[a]COMPASS: Coordination on Mobile Pandemic Apps Best Practice and Solution Sharing.

[b]FAIR: Findable, Accessible, Interoperable, Reusable.

[c]NUM: Network University Medicine.

Scientific Output of COMPASS

The COMPASS project has shared its findings through numerous scientific publications (Table 7), with 13 papers covering the development, implementation, and evaluation of COVID-19 apps within the NUM-COMPASS framework. Key contributions include the integration of PROs into the centralized CODEX research platform (Network University Medicine), analyses of regulatory and usability aspects, and the promotion of interoperable standards using the GECCO (German Corona Consensus) dataset. Additionally, studies examined public perception and acceptance, fostered community-driven open-source solutions, and developed educational materials to support data standardization and interoperability. These efforts strengthen data sharing and research capabilities during and beyond the pandemic.

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Table . Overview of scientific publications resulting from the COMPASS[a] initiative.

Title	Description	Reference
Medical Device Regulation Efforts for mHealth Apps During the COVID-19 Pandemic—An Experience Report of Corona Check and Corona Health	This paper uses specific examples to analyze the costs associated with rapidly implementing COVID-19 apps in compliance with the Medical Devices Act.	[41]
Integration of Patient-Reported Outcome Data Collected Via Web Apps and Mobile Apps into a Nation-Wide COVID-19 Research Platform Using Fast Healthcare Interoperability Resources: Development Study	This paper describes the integration of data collected via the COMPASS reference app framework into the central German CODEX platform to facilitate secondary research. The paper demonstrates how patient-reported outcome data can be standardized, shared, and reused across various research studies to enhance COVID-19 research.	[38]
Motivating Developers to Use Interoperable Standards for Data in Pandemic Health Apps	This work discusses COMPASS in general.	[42]
Public Perception of the German COVID-19 Contact-Tracing App Corona-Warn-App	This article examines the public perception (based on the store reviews) of the official German Corona Warn app to derive lessons for future pandemics.	[43]
Relevant Aspects for Sustainable Open-Source Pandemic Apps and Platform Deployment with Focus on Community Building	Based on a literature review, a classification for the long-term success of open-source software was developed. This paper introduces a classification centered on five distinct categories: (1) structural decisions, (2) revenue generation, (3) user focus, (4) openness, and (5) community building. Developed within the NUM-COMPASS project, the classification focuses on pandemic apps and the open-source framework. We offer insights into the community-building dimension by discussing the factors essential for creating sustainable communities.	[44]
Pandemic Apps: Broad Acceptance	A representative telephone survey on pandemic apps for research in Germany reveals that many Germans are willing to share their health data with researchers. This paper presents the results of the survey.	[45]
Making COVID-19 data interoperable: the COMPASS GECCO recommendations	We analyzed data standardization in pandemic apps and developed training materials for researchers and developers with limited knowledge of semantic and syntactic interoperability. This includes a how-to guide and a conformity checkpoint for data models, using GECCO[b] as the reference. We identified weaknesses in interoperable data collection and interviewed developers from other COVID-19 projects to understand their needs. An executive summary was created to raise awareness among executives about NUM-COMPASS. Additionally, a First Contact Package was devised to inform researchers and developers. It simplifies the concept of interoperable data capturing and guides them through the FAIR[c] principles and the GECCO Implementation Guide.	[46]
Tutorial: Configure the NUM-Compass App for your interoperable NUM study (in German)	A full day course with hands-on configuration of the COMPASS backend and the web app on a specific use case in configured virtual machines for each participant.	[47]
Exploring the Usability of the German COVID-19 Contact Tracing App in a Combined Eye Tracking and Retrospective Think Aloud Study	This article examines the usability of the official German Corona Warn app to derive lessons for future pandemics.	[48]

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Title	Description	Reference
Corona Health— A Study- and Sensor-based Mobile App Platform Exploring Aspects of the COVID-19 Pandemic	A study was conducted within an existing COVID-19 app to assess users' knowledge of regulations, as part of the COMPASS project.	[49]
Towards FAIR Patient Reported Outcome: Application of the Interoperability Principle for Mobile Pandemic Apps	During the COVID-19 pandemic, numerous apps were developed to collect and track medical data. Despite addressing similar aspects, diverse data models and formats prevent joint analysis of the data. The NUM-COMPASS project, part of the German COVID-19 Research NUM[d], created a coordination and technology platform for researchers and app developers. This platform ensures data collection complies with the GECCO, focusing on interoperability as part of the FAIR principles. This paper details how NUM-COMPASS implements these principles to support joint analysis of data from various app-based studies.	[50]
Attitudes Towards Mobile Apps for Pandemic Research Among Smartphone Users: Results from a National Survey in Germany	The aim of this study was to explore the potential for the acceptance of research-oriented apps in the German population. To this end, we identified distinctive attitudes toward pandemic apps and data sharing for research purposes among smartphone users in general and with a focus on differences in attitudes between app users and nonusers in particular.	[51]
Toward an interoperable Ecosystem within the Network University Medicine – adopting the Compass App to the central CODEX platform	Within the NUM, different projects have been carried out to support the understanding and handling of the COVID-19 pandemic. The CODEX project has developed a platform to collect and provide clinical routine data of COVID-19 patients in the GECCO format, but also to provide a platform for app-based study data. On the other hand, the COMPASS project has focused on an open-source framework for research-compatible pandemic apps. In this work, we adopted the Compass app to connect directly to the central CODEX platform.	[52]

[a]COMPASS: Coordination on Mobile Pandemic Apps Best Practice and Solution Sharing.

[b]GECCO: German Corona Consensus Dataset.

[c]FAIR: Findable, Accessible, Interoperable, Reusable.

[d]NUM: Network of University Medicine.

Narrative Summary

The following section provides a narrative summary of key findings from COMPASS. These findings are currently accessible in various German-language reports on the COMPASS website. A complete list of these documents is referenced in Table 8, and they have also been archived for long-term access in the following GitHub repository. We recommend referring to the files in this repository, which can be easily translated using tools such as ChatGPT (OpenAI).

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Table . Documents produced by the COMPASS[a] project.[b]

Document no.	Description
Document 1	Documentation and comparison of work content from national and international groups (German)
Document 2	Conformity check for pandemic health apps
Document 3	Prototype of advisory structures for the acquisition of additional university hospitals
Document 4	Job description for consulting and request management
Document 5	Prototype of advisory structures for the acquisition of additional university hospitals
Document 6	Explanation of technical development options for pandemic apps
Document 7	Regulatory experience report
Document 8	Regulatory best practices and checklists
Document 9	Catalog of best practices and checklists on usability, diversity, and licenses
Document 10	Study design and recruitment strategy for the societal acceptance study
Document 11	Literature review on the evidence of pandemic apps
Document 12	Literature review on ethical recommendations and normative governance guidelines for the development, design, and application of pandemic apps
Document 13	Best practices and guidelines for ethical and societal requirements
Document 14	Research compatibility and interoperability
Document 15	FAIR[c] principles
Document 16	Specification of data and metadata models: Part 1
Document 17	Specification of data and metadata models: Part 2
Document 18	Concept for ensuring research compatibility in apps
Document 19	Late mapping scheme
Document 20	Technical app framework
Document 21	Templates: Privacy policies, terms of use, and additional information
Document 22	Survey of existing guidance structures and economic analysis of guidance operations
Document 23	Survey of technology platforms and analysis of technology operations

[a]COMPASS: Coordination on Mobile Pandemic Apps Best Practice and Solution Sharing.

[b]Documents can be accessed in the following repository: [53]. Document 20 can be accessed here: [40].

[c]FAIR: Findable, Accessible, Interoperable, Reusable.

During discussions with researchers throughout the pandemic and shortly thereafter, several critical insights emerged regarding COMPASS and its applications in pandemic-related apps specifically, as well as mHealth apps in general. A key takeaway is that a technical solution must be available both as a web app and as a native app in app stores to provide maximum flexibility for different user needs and scenarios. COMPASS successfully implemented this approach within a short timeframe, and the corresponding codebase can be found at [54].

Furthermore, it became evident that many mHealth apps require integrated questionnaire functionalities. The ability to configure questionnaires within a web-based tool—ideally with access to preexisting standardized questionnaires—is essential. Additionally, adherence to standards such as FHIR should be ensured, and all questionnaire elements should be fully annotated, not only at a technical level (eg, sliders and yes or no questions) but also semantically. To address this, a dedicated questionnaire editor was developed. Originally, the project aimed to integrate this tool with the Medical Data Models (MDM) portal of the University of Münster. However, due to time constraints, this integration could not be completed within the project's timeframe. The MDM portal [55] provides extensive access to standardized medical data models.

Another significant achievement of COMPASS was the development of a technical framework for the automated testing of mHealth apps (Table 8).

As shown in Table 8, additional findings were obtained on various other aspects. Future developments will determine the extent to which these findings will play a role in further research and application.

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Critical Discourse and Evaluation of COMPASS

The COMPASS project invites critical discourse on its approach and outcomes, particularly its innovative use of smartphone-based health apps—both a strength and a point of contention.

A key concern is the balance between technological advancement and user privacy. While COMPASS prioritizes ethical data collection and user consent, the extensive collection of health-related data raises questions about privacy safeguards and potential security risks. Given the sensitivity of medical data, ensuring robust protections against breaches remains a crucial challenge.

Another area of scrutiny is public trust and app adoption. While COMPASS aims to improve user confidence and uptake, its effectiveness in overcoming skepticism—especially amid misinformation and concerns surrounding health technologies—remains an open question. Addressing diverse public perceptions is essential for broader acceptance.

The project's open-source framework enhances accessibility and adaptability; yet, it also poses challenges for standardization and interoperability. Many health care infrastructures lack seamless integration capabilities, making it critical to ensure that pandemic apps remain both interoperable and functionally robust.

While COMPASS's interdisciplinary approach is a strength, it also introduces coordination challenges. Effective communication and integration across diverse expertise and disciplines are essential but logistically complex.

Finally, the sustainability and scalability of COMPASS require continued evaluation. Although the project established a foundation for long-term collaboration, its ability to adapt to evolving health care challenges remains to be tested.

Despite these challenges, COMPASS represents a significant step forward in health technology and pandemic management. Addressing privacy concerns, public trust, standardization, interdisciplinary collaboration, and long-term sustainability will be key to refining future health technology initiatives and ensuring their lasting impact.

Discussion: Implications and Future Considerations

Overview

The COMPASS initiative demonstrates that effective pandemic mHealth apps require systemic coordination beyond technological innovation. While designed for pandemic response, its framework addresses fundamental challenges in health care digitalization: balancing rapid innovation with regulatory compliance, integrating patient-generated data into research infrastructure, and ensuring interoperability across fragmented systems. The emphasis on PROs and standardized data collection has implications extending to chronic disease management, remote monitoring, and routine clinical care. However, COMPASS's experience raises critical questions about whether such frameworks can be sustained outside crisis contexts that create urgency and overcome traditional implementation barriers.

Despite COMPASS's open-source design and adherence to international standards (HL7 FHIR and FAIR [Findable, Accessible, Interoperable, Reusable] principles), its transferability across different contexts remains uncertain. The absence of similar international initiatives suggests deeper structural barriers: fragmented health care systems, varying regulatory environments, and insufficient incentives for collaborative development in health care. Moreover, the framework's applicability to resource-limited settings or endemic disease management requires further exploration.

User adoption challenges persist beyond technical solutions. Digital health apps inherently exclude populations without devices or digital literacy, potentially exacerbating health disparities during crises. While COMPASS surveys suggest German citizens' willingness to share health data, this may not generalize globally, and trust deficits reflect broader concerns about data capitalism and surveillance that technical measures like encryption cannot fully address. Future frameworks must explicitly engage with health equity and meaningful public participation in governance.

A notable gap in COMPASS evaluation is a detailed analysis of integration into clinical workflows and impact on health care provider workload. The paper acknowledges that clinician burden remains insufficiently studied, yet this represents a critical implementation challenge for already strained health care systems. While COMPASS's modular design addresses adaptability, questions remain about long-term maintenance responsibilities, evolution alongside changing technology, and the effectiveness of proposed sustainability structures beyond initial project funding.

Several critical research questions emerge: how do COMPASS apps perform against alternatives in terms of data quality and public health impact? What organizational factors enable successful adoption? How can apps serve diverse populations with varying digital access? What business models support ongoing maintenance beyond project funding? The nearly 1 million data points collected demonstrate feasibility but not effectiveness or translational impact.

COMPASS's navigation of Medical Device Regulation offers valuable lessons for regulatory frameworks during health emergencies, suggesting the need for expedited pathways that maintain safety standards. The international fragmentation in pandemic app approaches indicates potential value in World Health Organization (WHO)–convened coordination mechanisms, though questions of sovereignty and resource distribution complicate such efforts.

The evaluation focuses on process and outputs rather than health outcomes. Whether COMPASS apps improved pandemic management or public health decision-making remains unclear. The paper predominantly reflects developer and researcher perspectives rather than end users, health care providers, or

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public health officials—stakeholder voices that should be centered in future work.

The 4-year gap since completion offers an opportunity to assess actual sustainability: which components remain actively maintained? Did proposed advisory structures and certification frameworks materialize? What barriers emerged? These questions are critical for understanding whether COMPASS achieved its objectives and informing future initiatives.

In summary, COMPASS demonstrates that coordinated, interdisciplinary pandemic app development is feasible, but translating technical capabilities into sustained public health impact requires addressing deeper challenges of trust, equity, clinical integration, and institutional sustainability. The true test lies not in what COMPASS achieved during its funding period, but whether its components influence subsequent digital health initiatives and improve preparation for future pandemics. COMPASS should be understood as the beginning of a longer conversation about digital health infrastructure rather than its conclusion.

COMPASS: A Comprehensive Summary

COMPASS is a cohesive initiative in medical informatics, bringing together interdisciplinary expertise to develop a structured platform for coordinating pandemic apps and technology. It underscores the role of smartphones in health communication and the importance of public trust and adoption for effective pandemic response. By integrating technology into health care, COMPASS provides a practical framework for future medical research and public health strategies, particularly in health crises. Through its collaborative approach, it addresses current challenges while laying the groundwork for future advancements in health care technology and research.

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Conflicts of Interest

None declared.

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Abbreviations

AC: activity cluster
COMPASS: Coordination on Mobile Pandemic Apps Best Practice and Solution Sharing
FAIR: Findable, Accessible, Interoperable, Reusable
FHIR: Fast Healthcare Interoperability Resources
GECCO: German Corona Consensus Dataset
MDM: Medical Data Models
mHealth: mobile health
NUM: Network University Medicine
PRO: patient-reported outcome
SAM: Self-Monitoring App for Employee Health
WHO: World Health Organization

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Viewpoint

From “Black Box” to Learning System: Formative Viewpoint on Digital Health Governance for Childhood Cancer Information in Japan

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Abstract

Japan has universal coverage and designated pediatric oncology centers, yet the childhood cancer information ecosystem remains a “black box.” The incidence is measurable, but treatment exposure and long-term follow-up are not reliably linked across hospitals, registries, and survivorship services. The World Health Organization (WHO) CureAll framework highlights information governance as a lever for equity. This study aims to propose a formative design for national digital governance connecting registries, clinical systems, and survivorship in Japan. We synthesized international guidance and Japanese statutes, plans, and registry reports. Drawing on operational experience, we specified a minimal pediatric dataset, an HL7 Fast Healthcare Interoperability Resources (FHIR)–based interoperability architecture, and governance to align standards, consent, and data use. No new empirical data were collected. We outline a 4-layer architecture. Source systems (electronic health records, laboratory and radiology systems, pathology, and cooperative group databases) feed an HL7 FHIR gateway. A national Pediatric Data Steward governs standards and interoperability (FHIR profiles and application programming interfaces), terminology and coding (International Classification of Diseases for Oncology and International Classification of Childhood Cancer, with mappings to Systematized Nomenclature of Medicine–Clinical Terms and Logical Observation Identifiers Names and Codes), privacy and consent, data-use agreements, data quality, and audit. Outputs flow to the National and Hospital-based Cancer Registries and a patient-facing Digital Survivorship Passport, with bidirectional clinic updates and linkage to the resident registry and vital statistics. Security, audit, and public reporting span all layers. We define pediatric indicators and a staged road map. Transforming Japan’s pediatric oncology information into a learning system is chiefly a governance task. A Pediatric Data Steward, a harmonized pediatric data dictionary via FHIR, and a portable survivorship passport with layered consent can improve timeliness, completeness, follow-up, and transparency.

(JMIR Form Res 2026;10:e86775) doi:10.2196/86775

KEYWORDS

childhood cancer; cancer registries; long-term follow-up; Fast Healthcare Interoperability Resources; FHIR; health information governance

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Why Childhood Cancer Data Governance Matters in Japan

Marked improvements in childhood cancer survival are uneven across and within countries [1,2]. The World Health Organization's (WHO) Global Initiative for Childhood Cancer targets at least 60% survival globally by 2030 and frames information systems as core enablers of planning, quality improvement, and accountability [3]. Cancer registries, clinical networks, and patient-facing documentation together build the measurement and feedback loops required for learning health systems [4-6].

Japan has a unified National Cancer Registry (NCR) mandated by law and coordinated national cancer information services [7-10]. Designated childhood cancer core hospitals have concentrated expertise and clarified referral pathways [11]. Nevertheless, the pediatric oncology ecosystem can feel like a black box to international collaborators. Population-level incidence and survival can be monitored, but detailed treatment exposure, risk-based survivorship, and real-world coordination are not consistently visible at the national scale. These blind spots relate less to technology than to governance—custodianship, consent, standards, and aligned incentives [12].

This paper offers a formative viewpoint aimed at stakeholders who can operationalize change—national cancer control and registry leaders, designated childhood cancer core hospitals and survivorship clinics, cooperative groups, and health IT and standards implementers.

This study aims to propose a governance-first, implementable design that connects registries, clinical systems, and survivorship services for childhood cancer in Japan, using open standards and proportionate privacy and consent.

The key messages of this viewpoint are as follows: (1) the main bottleneck is governance rather than software; (2) a clearly mandated Pediatric Data Steward function can align purposes, consent, agreements, and audit; (3) a harmonized pediatric data dictionary implemented through HL7 Fast Healthcare Interoperability Resources (FHIR) profiles and application programming interfaces (APIs) can reduce burden and improve data quality; and (4) a patient-facing Digital Survivorship Passport (DSP), with explicit provenance and layered consent, can return value to families while strengthening the learning loop.

Formative Approach and Scope

We synthesized international guidance on registry quality and survivorship documentation and health data interoperability [4-6,13-16]. We also reviewed Japanese policy instruments and technical reports relevant to national cancer control, registration, and data governance [7-9,11,17,18]. Our practical experience with registry operations and pediatric oncology networks informed feasibility considerations.

We identified a minimal pediatric dataset spanning diagnosis, treatment summary, long-term follow-up (LTFU), and outcomes; mapped it to FHIR resources; and bound it to International Classification of Diseases for Oncology (ICD-O) and the International Classification of Childhood Cancer (ICCC) with pragmatic pathways to Systematized Nomenclature of Medicine–Clinical Terms (SNOMED CT) and Logical Observation Identifiers Names and Codes (LOINC) for clinical decision support and international comparability [15,16]. For FHIR implementation, we propose a reuse-first profiling strategy: starting from widely used international oncology and survivorship artifacts where applicable, and defining Japan-specific FHIR profiles only where required by Japanese registry items, consent models, and linkage workflows—while maintaining mappings to support international comparability. We delineated a governance role—the Pediatric Data Steward—to harmonize purposes and agreements under the Act on the Protection of Personal Information (APPI) and the Next Generation Medical Infrastructure Act (NGMIA) [17,18]. We did not conduct new empirical analyses or a formal consensus process; rather, we framed a design for pilot testing and iterative refinement.

Current Strengths and Blind Spots in Japan

Japan contributes to the global evidence base on cancer epidemiology and survival [2]. The NCR aggregates incident cases nationally and, with linkage to the resident registry and death certificates, enables survival analyses; the hospital-based cancer registry (HBCR) provides richer clinical granularity [8,19,20]. Incidence patterns for childhood, adolescent, and young adult cancers broadly align with other high-income settings [21]. Access to timely diagnosis and protocol-based therapy is generally strong in designated centers [11]. Nevertheless, barriers persist. Pediatric-specific variables in the NCR have not routinely captured treatment exposure at levels sufficient for risk-based survivorship planning. HBCR data are richer but variably connected to survivorship clinics and patient-reported outcomes. To make these blind spots concrete for international readers, examples of survivorship-critical data elements that are often missing or unevenly captured across systems include:

- Cumulative chemotherapy exposure (eg, cumulative anthracycline dose)
- Radiotherapy details (eg, field or site and dose)
- Key treatment events and outcomes relevant to late effects planning (eg, hematopoietic stem cell transplantation, relapse and progression dates)

Regional variation in pediatric oncology workforce density and referral timeliness remains, as seen in other specialized services [12,22]. These gaps underscore the need for pediatric indicators in national dashboards and a governance mechanism that aligns registries, clinical networks, and patient-facing documentation.

Legal and Regulatory Context

The Act on Promotion of Cancer Registries mandates standardized reporting for national planning and research [7]. The APPI and associated guidance define duties for controllers

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and processors handling "special care-required" personal information [17]. The NGMIA provides a framework for certified operators to generate and manage anonymized medical data for research [18]. In practice, pediatric oncology data governance must navigate these statutes when linking cooperative group databases to registries and when enabling secondary use. Institutional variation in deidentification thresholds, consent renewal at transition to adult care, and cross-institutional sharing can delay projects. International experience suggests that clear, proportionate rules and privacy-by-design consent processes help sustain the social license for data reuse [23,24]. Within this envelope, a national Pediatric Data Steward could standardize templates for data-sharing agreements, consent language, and role-based access and coordinate audits and public reporting.

LTFU and Survivorship

Children cured of cancer face heterogeneous risks of late effects across cardiac, endocrine, neurocognitive, fertility, and second-malignancy domains. International guidelines and tools convert cumulative treatment exposure into risk-based surveillance plans, enabling shared care between specialists and primary care [13,14,25]. In Japan, LTFU practices have advanced in several childhood cancer core hospitals and cooperative groups, but national visibility remains limited because survivorship documentation often sits in hospital silos and is not consistently linked to registries [11]. Transitions to adult services risk information loss. Interoperable, patient-facing summaries built with HL7 FHIR can travel across systems and embed granular consent preferences [15,16,26,27]. A minimal survivorship dataset embedded in the NCR and HBCR, paired with a bilingual DSP aligned to international terminologies, would support continuity for families and create a feedback loop for service planning.

Education, Research, and Incentives

Japan's pediatric oncology workforce is experienced and organized in mature cooperative groups such as the Japan Children's Cancer Group (JCCG) [11]. As in other high-income settings, competing demands on clinician time, limited registrar capacity, and scarce clinical informatics support can hinder routine, high-quality data entry and use. Adoption depends on perceived value and ease of use at the front line as much as on policy mandates [28-30]. National instruments already support clinical research and quality improvement, but the next step is to close the loop between registries, cooperative group data, and LTFU clinics so that a single pediatric data dictionary serves care, research, and patient-facing summaries. Financing models that recognize data completeness and LTFU adherence as quality indicators would help [9,11,19].

An FHIR-Enabled Governance and Data Architecture

We propose a 4-layer architecture with explicit governance responsibilities and standardized data flows (Figure 1). We propose a 4-layer architecture with explicit governance responsibilities and standardized data flows. Source systems include electronic health records, laboratory and radiology information systems, pathology, and cooperative group databases. These feed an HL7 FHIR gateway that exposes validated, profile-conformant resources. Terminology and coding are handled in a distinct service that binds ICD-O and ICCC codes to relevant FHIR elements and maintains pragmatic mappings to SNOMED CT and LOINC to support clinical decision support and international comparability [16,27]. A national Pediatric Data Steward oversees standards and interoperability (FHIR profiles and APIs), terminology and coding, consent and privacy aligned to APPI and NGMIA, data-use agreements, data quality, and audit. Outputs are routed to the NCR and HBCR and to a patient-facing DSP. Bidirectional exchange should be governed by explicit provenance and validation rules. Clinician-verified treatment summaries and key exposures (eg, chemotherapy and radiotherapy details) should originate from clinical systems and cooperative group databases and remain the source of truth for registry-grade data. By contrast, patient or caregiver inputs—such as patient-reported outcomes and selected self-entered updates (eg, vaccination history and follow-up attendance and adherence information)—should be stored and exchanged as patient-reported data, clearly labeled as such, with audit trails. Patient-reported information should not overwrite clinician-verified registry elements and should be incorporated into analytics or learning workflows only under defined governance, including clinician review or attestation where clinically relevant. In particular, patient-reported inputs should not be written back into the NCR or HBCR as registry-grade fields unless and until they are reviewed and attested by an authorized clinician. Linkage to the resident registry and vital statistics supports survival analysis; linkage to claims databases (eg, the National Database) can be staged as a future extension. Security, audit logs, and public reporting span all layers and are core features rather than add-ons [8,19].

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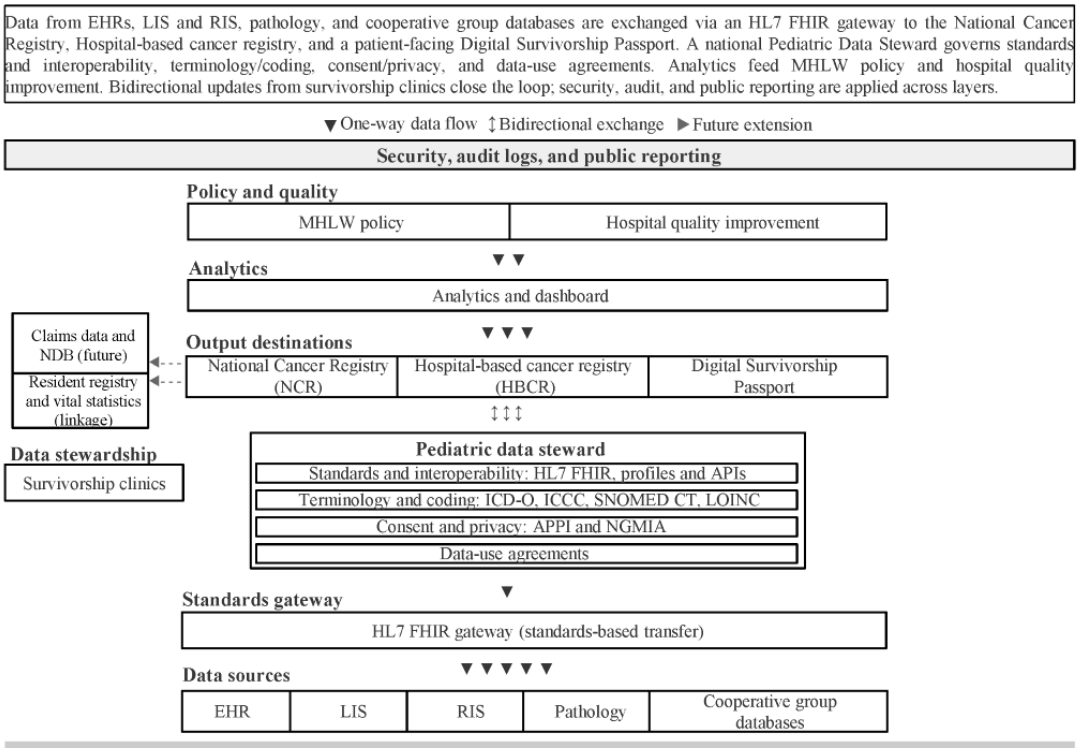
Figure 1. Governance and data flow for childhood cancer in Japan. Source systems (electronic health records [EHRs], laboratory and radiology information systems, pathology, and cooperative group databases) exchange data via an HL7 Fast Healthcare Interoperability Resources (FHIR) gateway. A national Pediatric Data Steward governs 2 separated domains—Standards and Interoperability (FHIR profiles or application programming interfaces [APIs]) and Terminology and Coding (International Classification of Diseases for Oncology [ICD-O], International Classification of Childhood Cancer [ICCC], with mappings to Systematized Nomenclature of Medicine–Clinical Terms [SNOMED CT] and Logical Observation Identifiers Names and Codes [LOINC])—together with consent and privacy and data-use agreements. Outputs flow to the National Cancer Registry and the hospital-based cancer registry and to a patient-facing Digital Survivorship Passport. Bidirectional updates from survivorship clinics close the loop, with provenance labeling and clinician review or attestation for patient-reported inputs; security, audit, and public reporting apply across layers. Claims linkage is shown as a future extension. APPI: Act on the Protection of Personal Information; LIS: laboratory information system; MHLW: Ministry of Health, Labour and Welfare; NDB: National Database of Health Insurance Claims; NGMIA: Next Generation Medical Infrastructure Act; RIS: radiology information system.



Priority Governance Actions and Evaluation

We outline five practical steps:

1. Designate a Pediatric Data Steward within national cancer control to harmonize purposes, agreements, and consent across registries, cooperative group datasets, and survivorship services [7,9,17,18].
2. Adopt and publish a harmonized pediatric data dictionary that embeds minimal registry and survivorship elements mapped to ICD-O and ICCC and implemented through FHIR APIs with built-in validation [4-6,15,16].
3. Operationalize a DSP generated at the end of treatment and updated at milestones with layered, revisitable consent, clear patient-facing language, and offline-capable access where needed [13-16,26,27].
4. Link governance to financing by incorporating pediatric data completeness and LTFU adherence into quality indicators for designated hospitals, with modest performance-linked support [9,11,19].
5. Commit to routine public reporting of pediatric-specific dashboards—case ascertainment, timeliness from diagnosis to registry entry, survival trends, treatment abandonment, LTFU coverage, and regional equity—together with commentary on actions taken [8,19,20].

A staged road map over 3 years can move from pilot to national scale while maintaining attention to workload, security, and acceptability. Table 1 summarizes these priority governance actions by domain and aligns them with international exemplars.

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Table 1. Priority governance actions for Japan aligned with international exemplars. For each domain—custodianship and policy; standards and interoperability; privacy and consent; and financing and accountability—the table summarizes the current state and tools in Japan, actionable next steps, and international exemplars.

Domain	Current state and tools in Japan	Actionable next steps	International exemplars and key references
Custodianship and policy	NCR[a] and HBCR[b] established under the Cancer Registry Act; JCCG[c] and 15 designated childhood cancer core hospitals exist; yet custodianship remains fragmented with no explicit Pediatric Data Steward.	• Designate a Pediatric Data Steward within national cancer control; publish a pediatric data strategy with standard templates for purposes, data-use agreements, and consent.	IARC[d] registry governance and quality framework [5,6]; WHO[e] GICC[f] implementation guidance [3]; CONCORD transparency practices [2].
Standards and interoperability	Registry items standardized in NCR and HBCR; pediatric treatment exposure and LTFU[g] variables unevenly captured; JCCG databases use custom formats; FHIR[h] adoption limited.	• Adopt a pediatric core data dictionary mapped to ICD-O[i] and ICCC[j]. • Implement HL7 FHIR APIs[k] and terminology services. • Establish low-burden data transfer between EHRs[l] and cooperative groups.	European Survivorship Passport standard and tools [13,14]; SMART[m] on FHIR [15]; FHIR in oncology registries [27]; international registry harmonization (Cancer Incidence in Five Continents and CONCORD) [2,6].
Privacy and consent	APPI[n] and NGMIA[o] frameworks established; institutional interpretations of consent requirements, pseudonymization thresholds, and cross-institutional sharing vary widely.	• Standardize layered, revisitable consent model aligned with the APPI and NGMIA. • Enforce role-based access controls and comprehensive audit logs. Maintain transparent public communication.	ESP[p] consent model [13,14]; APPI and Personal Information Protection Commission guidance [17]; international data-sharing ethics frameworks [23,24].
Financing and accountability	Public pediatric-specific indicators are limited; financial incentives for data completeness and LTFU documentation are minimal; performance metrics for childhood cancer core hospitals focus on service capacity.	• Embed data completeness and LTFU attendance in quality indicators. Introduce modest performance-linked support. • Publish annual pediatric dashboards (eg, case ascertainment, timeliness, and LTFU coverage).	CONCORD public reporting [2]; IARC quality evaluation standards [5,6]; ESP diffusion indicators [13,14]; WHO GICC dashboards [3,10]

[a]NCR: National Cancer Registry.

[b]HBCR: hospital-based cancer registry.

[c]JCCG: Japan Children's Cancer Group.

[d]IARC: International Agency for Research on Cancer.

[e]WHO: World Health Organization.

[f]GICC: Global Initiative for Childhood Cancer.

[g]LTFU: long-term follow-up.

[h]FHIR: Fast Healthcare Interoperability Resources.

[i]ICD-O: International Classification of Diseases for Oncology.

[j]ICCC: International Classification of Childhood Cancer.

[k]API: application programming interface.

[l]EHR: electronic health record.

[m]SMART: Substitutable Medical Applications and Reusable Technologies.

[n]APPI: Act on the Protection of Personal Information.

[o]NGMIA: Next Generation Medical Infrastructure Act.

[p]ESP: European Survivorship Passport.

Implications for Policy and Implementation

This viewpoint reframes Japan's childhood cancer information landscape as a digital health governance problem. The NCR and HBCR are strong foundations, but richer pediatric variables and LTFU data need to flow with less friction [8,19]. The proposed architecture intentionally separates standards and interoperability from terminology and coding, acknowledging that FHIR is a transport and representation standard, whereas ICD-O and ICCC are classification systems [16]. Embedding survivorship as a first-class output through a DSP changes the value proposition: data are not only for registries and research but must return to children and families in an immediately usable form [13,14].

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Institutional Home and Authority of the Pediatric Data Steward

We use "Pediatric Data Steward" to denote a mandated function (not necessarily a new standalone organization) that can be operationalized through an existing national body with clear accountability. Because the steward function includes standard-setting, data-use agreements, quality audits, and public reporting, its institutional anchoring determines whether the model can be enforced and sustained. In Japan, locating the steward solely within the Ministry of Health, Labour and Welfare could provide policy authority and convening power but may be less suited to day-to-day technical operations. Locating it solely within the National Cancer Center could ensure operational proximity to registry infrastructure and technical capacity but would require an explicit national mandate to convene hospitals and cooperative groups.

We therefore propose a hybrid model: a nationally mandated Pediatric Data Steward function under the cancer control framework, with policy leadership aligned with the Ministry of Health, Labour and Welfare and an operational and technical secretariat aligned with National Cancer Center registry and cancer information functions, governed through a formal multistakeholder structure (designated childhood cancer core hospitals, cooperative groups, such as JCCG, survivorship services, and patient and family representation). This arrangement aims to combine authority, implementation capacity, and legitimacy while avoiding fragmentation of responsibility.

International experience is consistent, but it also shows that technical interoperability alone rarely dissolves institutional silos. Registries work when purposes are clear, financing is stable, and quality is audited [5,6]—and when contributing sites receive visible value back for sustained participation. Survivorship passports diffuse when they are co-designed with survivors and families and embedded in routine workflows [13,14].

From Governance Design to Implementation and Incentives

In Japan, a governance-first approach should therefore pair standards with reciprocity and credible support. Our proposed "performance-linked support" is best understood as targeted operational support—such as funded registry staffing time, shared technical services, or implementation assistance—linked to measurable indicators (eg, timeliness and completeness of pediatric core items and LTFU coverage), and implemented alongside workload-reducing measures (eg, FHIR-enabled reuse of existing clinical data rather than duplicate manual entry). Equally important is returning timely, usable outputs to hospitals (benchmarked dashboards, case-finding feedback, and survivorship care tools) so data sharing is experienced as an enabler of local quality improvement and legitimate research, not as a loss of institutional assets. Our proposal adapts these lessons to Japanese law and infrastructure, with a light but accountable governance layer and an implementation path that can be evaluated and adjusted.

Evaluation should be formative. Early pilots ought to track process metrics—case ascertainment, timeliness from diagnosis to registry entry, completeness of pediatric core items, LTFU attendance—and outcome metrics—stage distribution, relapse detection intervals, guideline-concordant surveillance, and early detection of late effects—alongside equity gradients by region and socioeconomic markers [4,19,28-30]. Workload, usability, and cybersecurity also require attention, especially for FHIR-based integration and patient-facing tools [26]. Where terminology licenses or system heterogeneity create hurdles, national support and shared services can mitigate site-level costs [16].

Limitations

This is a viewpoint and does not report new empirical analyses. The arguments synthesize peer-reviewed literature, Japanese policy documents, and national statistics and may not fully capture heterogeneity across institutions and prefectures. Important operational differences likely exist in how the NCR and HBCR capture pediatric variables, how consistently LTFU clinics operate across designated childhood cancer core hospitals, and how readily cooperative group databases can be linked to registries under current governance and technical constraints [8,11,19]. Arrangements are dynamic and may change with policy revisions, software updates, and evolving guidance under APPI and NGMIA [7,17,18]. International exemplars cited here operate in different insurance and digital environments; direct transferability to Japan has limits despite conceptual alignment [13,14]. Because we did not conduct a structured consensus process or formal stakeholder analysis, prioritization reflects the authors' synthesis and may embed bias.

Conclusions

Japan's pediatric oncology system has strong assets but limited national visibility into treatment exposure, LTFU, and real-world coordination. The decisive levers are governance and stewardship. A Pediatric Data Steward, a harmonized pediatric data dictionary exposed through FHIR, and a portable DSP with layered consent, tied to financing and public dashboards, can turn a black box into a learning system. Implemented iteratively, these interventions would support earlier diagnosis, reduce loss to follow-up, and enable prevention and timely detection of late effects, while strengthening Japan's contribution to regional and global learning in line with the WHO Global Initiative for Childhood Cancer [3,9,19].

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Authors' Contributions

Conceptualization was led by RU. KK and RU reviewed the Japanese policy and registry landscape. KK drafted the manuscript. RU critically revised it for intellectual content. Both authors approved the final version and share first authorship.

Conflicts of Interest

None declared.

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Abbreviations

API: application programming interface
APPI: Act on the Protection of Personal Information
DSP: Digital Survivorship Passport
FHIR: Fast Healthcare Interoperability Resources
HBCR: hospital-based cancer registry
ICCC: International Classification of Childhood Cancer
ICD-O: International Classification of Diseases for Oncology
JCCG: Japan Children's Cancer Group
LOINC: Logical Observation Identifiers Names and Codes
LTFU: long-term follow-up
NCR: National Cancer Registry
NGMIA: Next Generation Medical Infrastructure Act
SNOMED CT: Systematized Nomenclature of Medicine–Clinical Terms
WHO: World Health Organization

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Viewpoint

Designing an Indicator-Driven, Value-Based Architecture for Pneumonia Prevention in Japan: A Formative Policy Viewpoint on Adult Vaccination and Oral Care

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Abstract

Japan's aging society concentrates pneumonia burden across communities, long-term care, perioperative pathways, and hospitals. Adult pneumococcal and influenza vaccination are supported by trials and meta-analyses and are often cost-effective; yet, realized value depends on targeting, measurement, financing, and pairing with bedside prevention such as oral care and hospital-acquired pneumonia bundles. This viewpoint proposes a formative, indicator-driven architecture linking cost-effectiveness to operations by aligning vaccination with complementary oral-care prevention and value-based payment under the existing policy infrastructure. Working within the Ministry of Health, Labour and Welfare/Central Social Insurance Medical Council health technology assessment framework, Center for Outcomes Research and Economic Evaluation for Health methods, and claims–electronic health record linkage via My Number insurance card, we specify a compact national indicator set: vaccination coverage and timeliness, nonventilator hospital-acquired pneumonia, ventilator-associated pneumonia, postoperative and stroke-associated pneumonia, antibiotic days of therapy, and length of stay, with pragmatic risk adjustment and present-on-admission flags. Value levers first reward reliable reporting and adherence to evidence-based bundles and then share verified, risk-adjusted savings. Long-term care facilities receive add-ons for professional oral care in high-risk residents; hospitals receive quality add-ons and shared savings; perioperative pathways may incorporate oral health management; and stroke units standardize oral hygiene with dysphagia screening. A phased roadmap details the pilot co-design, governance, risk-adjusted reporting with equity safeguards, and iterative recalibration by using real-world evidence. The learning loop—measure, report, improve, generate evidence, adapt cost-effectiveness, recalibrate payment—converts modeled value into lived experience: fewer pneumonias, reduced antibiotic exposure, shorter stays, improved function, and dignity at favorable or potentially lower costs, context-depending on baseline pneumonia rates, implementation fidelity, and local unit costs.

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KEYWORDS

adult vaccination; pneumococcal; influenza; oral care; hospital-acquired pneumonia; cost-effectiveness; value-based payment; Japan

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Introduction

Japan's rapidly aging society concentrates the burden of pneumonia across community settings, long-term care, perioperative pathways, and hospitals. Pneumonia remains among the leading causes of death and hospitalization, with aspiration-related events common in nursing homes and poststroke care and with hospital-acquired pneumonia worsening outcomes in wards and in intensive care units (ICUs) [1-4]. Adult vaccination against pneumococcal disease and influenza (flu) reduces disease and complications according to randomized trials and meta-analyses and is frequently cost-effective across risk groups [5-8]. Alongside this evidence, Japan has assembled policy infrastructure capable of translating value into practice through a national health technology assessment (HTA) program under Japan's Ministry of Health, Labour and Welfare (MHLW) and the Central Social Insurance Medical Council (Chuikyo), guided by the Center for Outcomes Research and Economic Evaluation for Health (C2H) methods [9,10]. The rollout of the My Number health insurance card and the progress in health information standardization enable claims–electronic health record (EHR) linkages for routine measurement and learning [11].

Economic models persuade at the time of decision; however, value is diluted when uptake is uneven, outcomes are inconsistently measured, or payment recalibration occurs in opaque ways. Realized value from adult vaccination depends on reaching high-risk cohorts, ensuring timely influenza vaccination, and embedding vaccination within high-quality bedside prevention. Professional and mechanical oral care lowers pneumonia in nursing homes [12]; perioperative oral health management is associated with reduced postoperative pneumonia and mortality in cancer surgery [13]; and prevention bundles for nonventilator hospital-acquired pneumonia (NV-HAP) and ventilator-associated pneumonia (VAP) improve outcomes when implemented with fidelity [14-16]. Vaccines complement rather than substitute for these elements. In practical terms, the proposed architecture aims to close the implementation gap by making prevention performance visible and comparable (through computable and auditable indicators with present-on-admission [POA] safeguards and pragmatic risk adjustment) and by linking these measures to staged incentives that fit Japan's existing fee schedule and HTA review cycles. For example, in long-term care, an add-on for professional oral care can be tied to verified delivery in high-risk residents and tracked alongside risk-adjusted aspiration pneumonia and vaccination coverage indicators. In acute and perioperative care, facilities can first be rewarded for reliable reporting and documented adherence to prevention bundles, and only subsequently participate in shared savings once improvements in risk-adjusted outcomes and length of stay are independently validated. This staged "measure → report → improve → verify → recalibrate" loop is intended to translate modeled value into consistent bedside practice while maintaining transparency and equity safeguards. This viewpoint proposes an indicator-driven, value-based architecture that connects cost-effectiveness to operations for pneumonia prevention in Japan. The design is formative and non-eHealth by intent: it focuses on policy rules, workforce and supplies, computable indicators, and payment incentives that can be implemented with existing digital rails and institutional processes. We draw on Japanese and international evidence, HTA methods, and stakeholder insights, including a recent policy recommendation issued through the Health and Global Policy Institute Expert Policy Advocacy Platform [17]. The goal is to make the link between modeled value and lived experience credible, visible, and improvable.

Policy Context and Rationale for a Formative Approach

Under Japan's HTA program, cost-effectiveness informs pricing and reimbursement while recognizing uncertainty and the need for periodic review [9,10]. Interoperability efforts using the My Number insurance card create the technical and governance conditions to link administrative and clinical data at scale with appropriate safeguards [11,18]. These conditions favor a formative approach that begins with low-burden, transparent measurement; publishes versioned specifications; and evaluates new payment levers in pilots before national rollout. The approach emphasizes deliverables that de-risk implementation: indicator logic and change logs, minimum datasets and data flows, a data-protection impact assessment and standardized data-use agreements, POA education and audits, and validation protocols that compare algorithm-flagged cases with clinical reviews in a sample.

A Value-Based Logic Model

Figure 1 summarizes the logic model. Governance and digital enablers include MHLW/Chuikyo rules, C2H methodological guidance, transparency and public engagement, privacy- and trust-by-design, and interoperability between claims and EHRs [9-11,17,18]. Value levers comprise a national indicator set, value-based payment, and workforce and supplies. Interventions are setting-specific. In long-term care, professional and mechanical oral care complements caregiver-delivered daily care. In perioperative care, preoperative and perioperative oral health management is incorporated into enhanced recovery pathways and coordinated with surgeons, anesthesiologists, nurses, and dentists [13]. In general wards, nurse-driven NV-HAP bundles include oral care, mobility, head-of-bed elevation, positioning, and suction as clinically indicated, guided by national toolkits [15,19]. In ICUs, VAP bundles integrate ventilator care, sedation minimization, early mobility, and oral care, with context-dependent use of oral chlorhexidine aligned to guidelines [14,16]. In stroke units, standardized oral hygiene is coordinated with dysphagia screening and management [20]. Mechanisms operate through higher vaccination coverage and timeliness, better adherence to oral care and bundles, antibiotic stewardship, and safer transitions, leading to reductions in NV-HAP and VAP, postoperative and stroke-associated pneumonia, antibiotic days of therapy (DOT), length of stay, and readmissions.

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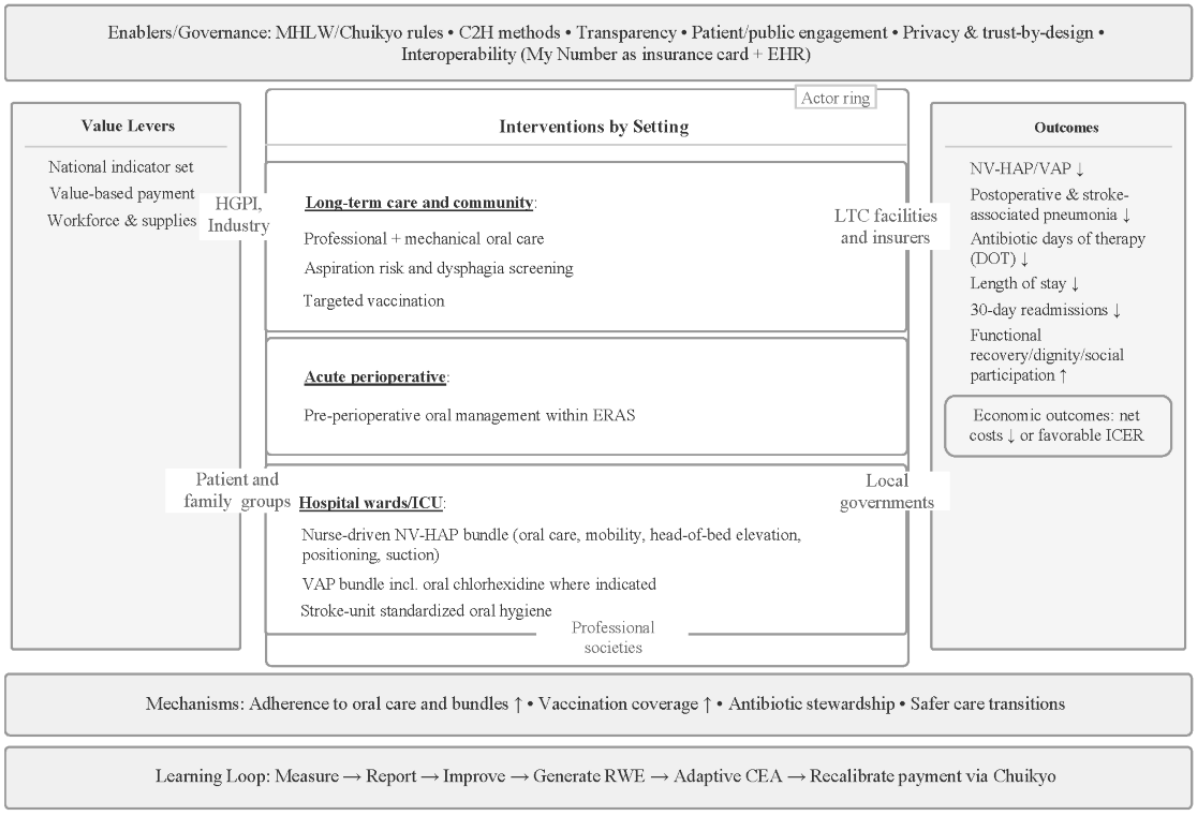
Figure 1. Logic model for value-based pneumonia prevention in Japan. This logic model shows how governance and digital enablers (MHLW/Chuikyo rules, C2H methods, transparency, patient/public engagement, privacy-by-design, and My Number–EHR interoperability) connect value levers (a national indicator set, value-based payment, and workforce/supplies) to setting-specific interventions across long-term care, perioperative care, and hospital wards/ICU. Through improved adherence to oral care and bundles, higher vaccination coverage, antibiotic stewardship, and safer care transitions, the learning loop of measure–report–improve–generate RWE–adaptive CEA–payment recalibration yields measurable gains, including lower NV-HAP/VAP, postoperative and stroke-associated pneumonia, reduced DOT, shorter length of stay, and fewer 30-day readmissions, alongside better function and dignity and favorable costs/ICERs. C2H: Center for Outcomes Research and Economic Evaluation for Health; CEA: cost-effectiveness analysis; Chuikyo: Central Social Insurance Medical Council; DOT: days of therapy; EHR: electronic health record; ICER: incremental cost-effectiveness ratio; ICU: intensive care unit; MHLW: Ministry of Health, Labour and Welfare; NV-HAP: nonventilator hospital-acquired pneumonia; RWE: real-world evidence; VAP: ventilator-associated pneumonia.



Ethical Considerations

This viewpoint uses only publicly available sources and proposes a formative policy design without human participant data.

Indicator Set and Computable Definitions

Because EHR capabilities vary across facilities, specifications are designed to be computable using claims as a baseline, with clearly flagged EHR-based enhancements where available (eg, medication administration records for DOT). Versioned specifications, minimum datasets, and validation (eg, sampled chart review) are used to support comparability while making data limitations explicit. Indicators tie model assumptions to reality and must be computable, comparable, and auditable. We propose a compact suite that can be extracted from routine data with versioned specifications and public change logs. Coverage indicators assess pneumococcal and seasonal influenza vaccination among older adults and prespecified high-risk cohorts, with timeliness for influenza measured as vaccination before a seasonal cutoff [5-8]. Outcome indicators include pneumonia hospitalizations per 1000 older adults, NV-HAP per 1000 patient-days with clear surveillance definitions that exclude POA cases, ventilator-associated events and pneumonia per 1000 ventilator-days, 30-day postoperative pneumonia for specified procedures, and stroke-associated pneumonia within 7 days of admission or stroke onset [4,13-16,19-21]. Antibiotic consumption is captured as DOT per 1000 patient-days using the National Healthcare Safety Network antimicrobial use specification, with transparent claims-based proxies when electronic medication administration records are unavailable [22]. In long-term care, aspiration pneumonia per 100 resident-years and, where feasible, antibiotic DOT per 100 resident-days are adjusted for care-need level and comorbidities [3,12]. Multimedia Appendix 1 and Multimedia Appendix 2 provide the minimum indicator specifications and the illustrative budget impact scenario (including assumptions and an unfavorable-case scenario) in full.

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Operationally, we envision a staged data-flow model. In the pilot phase, indicator computation is performed primarily by facilities or municipalities using standardized, version-controlled specifications, with My Number–enabled linkage used to reconcile claims-based denominators and utilization with EHR time-stamps (eg, antibiotic starts, imaging) under agreed governance; aggregated, deidentified outputs are then submitted for benchmarking. As interoperability and governance mature, the same linkage can support more centralized, automated indicator calculation and auditing.

Fair comparisons require pragmatic risk adjustment. Minimum adjustment includes age, sex, comorbidities, emergency vs elective admission, diagnosis and procedure classes, ward or ICU type, and severity proxies, drawing on established guidance [23]. POA flags protect facilities from penalties for community-onset disease and interfacility transfers. For stroke-related outcomes, models incorporate stroke severity and dysphagia screening when recorded [20]. To address misclassification concerns, NV-HAP algorithms combine coded diagnoses with treatment and imaging signals and are validated against structured chart review in a sample per facility. Public reporting should include uncertainty intervals and peer grouping by case mix to reduce spurious league tables. The minimum specifications are summarized in Multimedia Appendix 1.

Payment Levers Aligned With Evidence

Payment design can determine whether evidence-based prevention is implemented with fidelity, particularly when reporting burden and front-line workload are high. We therefore adopt a conservative sequence that pays first for verified reporting and adherence and then shares a fraction of risk-adjusted, independently verified savings. In long-term care, facilities receive an add-on for professional and mechanical oral care in high-risk residents. Evidence from randomized and quasi-experimental studies indicates that oral care reduces pneumonia incidence and mortality risk in frail older populations [12], and cost structures in Japan make this strategy plausible from a payer perspective. Facilities that improve vaccination coverage and reduce risk-adjusted aspiration pneumonia rates receive public recognition and, after validation, modest shared savings.

In acute care, hospitals receive add-ons tied to adherence with NV-HAP and VAP prevention bundles supported by infection prevention and critical care guidelines [14-16]. Adherence focuses on documented oral care frequency and technique, head-of-bed elevation, early mobility, ventilator care, sedation minimization, and suction when indicated. A conservative shared-savings mechanism returns a fraction of verified risk-adjusted reductions in pneumonia-related costs and length of stay relative to a rolling baseline. For perioperative pathways, enhanced-recovery payments require preoperative and perioperative oral health management for selected procedures, with postoperative pneumonia as a quality gate informed by national database studies linking oral health management with lower postoperative pneumonia and improved survival [13]. For vaccination, modest pay-for-performance elements reward providers and municipalities that reach age- and risk-adjusted coverage targets, with additional weight for people with multimorbidity, frailty, or a recent pneumonia. Parameter values are initialized using published effect sizes and Japanese prices and are recalibrated using observed outcomes and net costs after pilots [9,24].

A simple budget impact scenario illustrates fiscal feasibility. This scenario is intended as an illustrative, order-of-magnitude calculation (not a hospital-specific economic evaluation); all parameters and calculation steps are shown in Multimedia Appendix 2. We assume baseline NV-HAP of 1.2 per 1000 patient-days and VAP of 5 per 1000 ventilator-days, with illustrative conservative relative reductions (25% for NV-HAP and 30% for VAP) and excess lengths of stay of 4 and 6 days, respectively. Published implementation studies of oral care–centered NV-HAP prevention bundles have reported larger reductions in NV-HAP incidence than those assumed here, supporting the plausibility of using conservative illustrative effect sizes for an order-of-magnitude example [25]. Under these assumptions, gross savings are approximately ¥8.16 million (US $53,310) with incremental program costs of ¥4.39 (US $28,670) million in year 1; sharing 30% of verified savings still leaves payer-side net savings. Multimedia Appendix 2 also includes an unfavorable-case scenario (lower baseline incidence, smaller effect size, and lower unit costs) showing that the budget impact can approach break-even. This scenario deliberately excludes additional gains from perioperative oral health management and dysphagia screening, which would further improve the budget profile [13,20].

Phased Implementation Roadmap and Formative Deliverables

A feasible path begins with a 12-month pilot that co-designs indicator specifications with public posting and version control; defines a minimum dataset and data flows leveraging claims–EHR linkage; automates antibiotic DOT extraction where possible; selects pilot regions that include an urban–rural mix; funds staff training and low-cost oral-care kits; and launches adherence-focused add-ons under a prespecified evaluation design such as a stepped-wedge or controlled before–after design [15,17,22]. To address confounding and site heterogeneity, pilot sites will be stratified by key characteristics (eg, urban/rural context and facility type), and roll-out timing may be randomized where feasible (stepped-wedge). Analyses will incorporate prespecified risk adjustment and time effects (including seasonality) to support fair within-site and between-site comparisons. Deliverables include a data-protection impact assessment and standardized data-use agreements consistent with international recommendations [18], POA education materials and audits, a validation protocol for NV-HAP definitions, and a brief staff workload/acceptability assessment (eg, short staff surveys and time-burden checks) to ensure feasibility alongside fidelity monitoring. Chuikyo endorsement and publication of methods serve as the first decision gate [9,10]. Over the subsequent 24 months, national scale-up introduces dashboards and risk-adjusted public reporting with equity safeguards, standardizes perioperative and stroke oral-care pathways, and recalibrates thresholds, risk adjustment, and payment levels by using pilot real-world evidence, with technical assistance for facilities serving complex populations [13,20,21]. Thereafter,

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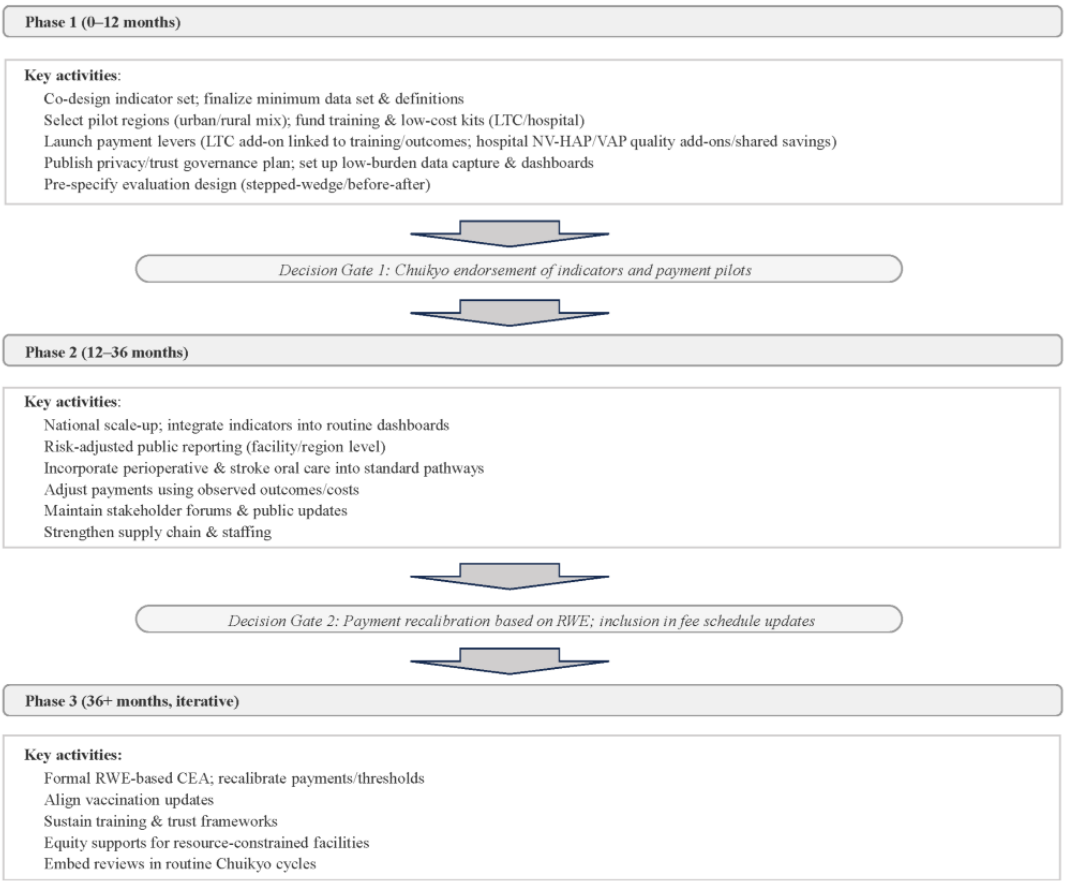
real-world evidence-based cost-effectiveness, periodic recalibration, and alignment of vaccination policy with the broader prevention package are institutionalized (Figure 2).

Figure 2. Phased implementation roadmap (12 to 24+ ongoing months). The roadmap outlines a staged implementation plan for an indicator-driven, value-based pneumonia prevention architecture. Phase 1 (0-12 months) focuses on co-designing indicators and minimum datasets, selecting pilot regions, funding training and low-cost oral-care resources, launching initial payment levers, and establishing privacy/trust governance and low-burden data capture. Decision gate 1 marks Chuikyo endorsement of the indicator set and payment pilots. Phase 2 (12-36 months) scales up routine dashboards and risk-adjusted reporting, standardizes perioperative and stroke oral-care pathways, and refines payment parameters using observed outcomes and costs. Decision gate 2 reflects payment recalibration based on real-world evidence and potential inclusion in fee schedule updates. Phase 3 (36+ months) institutionalizes iterative evaluation, real-world-evidence–based cost-effectiveness analysis, periodic recalibration, and equity supports. CEA: cost-effectiveness analysis; Chuikyo: Central Social Insurance Medical Council; LTC: long-term care; NV-HAP: nonventilator hospital-acquired pneumonia; RWE: real-world evidence; VAP: ventilator-associated pneumonia.



Governance, Privacy, Trust, and Equity

Data linkage and payment experimentation require trust. Governance should treat transparency, patient and public engagement, and privacy-by-design as first-class requirements. Reporting burden is contained by automating data extraction from EHRs and administrative systems; using POA fields and device-day denominators to attribute outcomes fairly; and explaining public reports in plain language [14,15,18,22]. Equity safeguards include outreach to rural and disadvantaged areas, flexible delivery in long-term care, and supplemental support for providers caring for complex patients. Public communication should emphasize that comparisons are risk-adjusted and that thresholds are periodically recalibrated under published rules rather than ad hoc pressure [17].

Anticipated Impact and Economic Value

When implemented together, vaccination and complementary prevention can produce measurable gains with favorable economics. NV-HAP and VAP fall when oral care, mobility, and ventilator bundles are implemented with fidelity [4,14-16]; postoperative and stroke-associated pneumonia decline with perioperative oral health management and standardized oral hygiene plus dysphagia coordination [13,20]; and antibiotic DOT decreases as infections are prevented rather than merely managed, reinforcing stewardship goals [22,26]. Length of stay and readmissions should fall accordingly. Under plausible baseline rates and Japanese unit costs, these changes are likely to be cost-effective and may be cost-saving, particularly when reductions in pneumonia events translate into fewer excess bed-days. The illustrative budget impact scenario (Multimedia Appendix 2) makes assumptions explicit and includes an

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unfavorable-case scenario, in which results approach break-even, highlighting dependence on baseline incidence, excess length of stay, unit costs, and implementation costs. As programs mature, incremental cost-effectiveness ratios improve because fixed training costs are amortized, adherence rises, and feedback loops accelerate learning.

Limitations

This viewpoint synthesizes published evidence and policy documents rather than new empirical analyses. Effect sizes for vaccines and complementary interventions vary by population, setting, baseline risk, and implementation fidelity, and some bundle components such as oral chlorhexidine in ICU settings remain context-dependent and may have heterogeneous effects across institutions [14,16,19]. As a result, the magnitude of benefits described here should be interpreted as plausible ranges rather than fixed expectations for every site.

Second, our indicator proposals rely primarily on routinely collected administrative and electronic health record data. While this approach lowers burden and enables scale, claims-based risk adjustment cannot fully substitute for clinical granularity. Misclassification of NV-HAP is a recognized challenge; algorithms based on diagnosis codes, antibiotic starts, and imaging orders may be sensitive to ordering practices and documentation culture. The availability and consistency of present-on-admission fields, stroke severity measures (eg, National Institutes of Health Stroke Scale/Score), dysphagia screens, and medication administration records will influence precision [20,22,23]. We propose chart-review validation in a sample at each pilot site and public version control of indicator logic to mitigate these risks, but residual bias is possible.

Third, data linkage and public reporting entail governance and privacy risks. Although we outline a data-protection impact assessment, standardized data use agreements, and transparency measures aligned with international recommendations [18], stakeholder trust depends on consistent practice, clear communication, and visible redress mechanisms. Differences in local EHR architectures and data quality may also create inequities in reporting capability; technical assistance will be required to avoid penalizing resource-constrained facilities.

Fourth, payment levers may generate unintended consequences if poorly calibrated. Paying for adherence may shift attention toward measured processes at the expense of unmeasured but important elements of care (“gaming” or checklist fatigue). Shared-savings models can create selection incentives if risk adjustment is inadequate, and savings attribution is complicated by concurrent initiatives. To limit these risks, the design emphasizes verification, conservative sharing percentages, risk-adjusted peer comparisons, and periodic recalibration using real-world evidence, but some behavioral responses are difficult to anticipate. These sampled chart-review validations also function as an active safeguard against misclassification and gaming by flagging discrepancies between algorithm-reported indicators (and documented bundle adherence) and clinical documentation, triggering feedback, specification updates, and—where applicable—payment recalibration.

Fifth, the budget impact scenario is illustrative. We selected conservative but still uncertain assumptions for baseline NV-HAP/VAP rates, excess length of stay, and unit costs. Local unit prices, staffing costs, and baseline performance will shift the crossover point between budget neutrality and savings. Additional benefits from perioperative oral health management and dysphagia screening were intentionally excluded from the base case and would likely improve the fiscal picture, but we do not claim precise net effects absent in site-specific modeling [13,20,24].

Sixth, generalizability has boundaries. Several enablers are specific to Japan—Chuikyo fee schedule cycles, the C2H methodological framework, the Diagnosis Procedure Combination database, and the evolving use of the My Number insurance card for health data linkages [9-11,21]. We argue that the core logic is portable (computable indicators with POA rules, staged incentives, low-burden data flows, and adaptive recalibration); yet, transfer to other systems will require tailoring to local legal, technical, and workforce contexts.

Finally, implementation capacity is a real constraint. Reliable oral care and mobility require protected time, training, and supplies; ICU bundles depend on interprofessional coordination; and long-term care facilities vary widely in staffing and access to dental professionals. Up-front investment and change management may be difficult during workforce shortages. The phased plan explicitly funds training and low-cost kits and provides technical assistance, but timelines may need adjustment in settings with severe resource limitations.

These limitations motivate the formative design itself: public, version-controlled indicator specifications; validation against clinical review; equity safeguards in reporting; conservative payment parameters; and iterative recalibration based on real-world evidence.

Conclusions

A vaccination-centered prevention strategy can deliver its promised value only when surrounded by reliable measurement, transparent governance, practical payment incentives, and bedside prevention that addresses aspiration risk and hospital-acquired pneumonia. Japan has the ingredients to make this link credible and visible: an established HTA framework; improving interoperability through the My Number insurance card; and professional capacity in nursing, dentistry, infection prevention, geriatrics, and informatics. A formative, indicator-driven architecture that ties vaccination to oral-care–based prevention and value-based payment can reduce avoidable harm and spending, preserve function and dignity, and strengthen public confidence. The approach is testable now and generalizes to other vaccine-preventable syndromes where bedside practice, program design, and financing interact.

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Data Availability

No new datasets were generated or analyzed. All sources cited are publicly available.

Authors' Contributions

KI and KK conceived the manuscript. KK and AI developed the methodology. KK and SF conducted investigation and curation. KK developed the economic framing with input from AI. KK and SF drafted the manuscript. All authors reviewed and approved the final manuscript. KI and KK are the guarantors.

Conflicts of Interest

KK and AI serve as a fellow of the Health and Global Policy Institute (HGPI). HGPI had no role in the conception, analysis, interpretation, writing, or the decision to submit this manuscript, and the views expressed are solely those of the authors. The other authors declare no conflicts of interest.

Multimedia Appendix 1
Summary of the clinical effectiveness, economic value, implementation keys, and candidate indicators by intervention and setting.
[DOCX File , 22 KB - formative_v10i1e86912_app1.docx]

Multimedia Appendix 2
Simple budget impact scenario.
[DOCX File , 20 KB - formative_v10i1e86912_app2.docx]

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Abbreviations

C2H: Center for Outcomes Research and Economic Evaluation for Health
Chuikyo: Central Social Insurance Medical Council
DOT: days of therapy
EHR: electronic health record
HTA: health technology assessment
ICU: intensive care unit
NV-HAP: nonventilator hospital-acquired pneumonia
POA: present-on-admission
VAP: ventilator-associated pneumonia

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Viewpoint

Trustworthy AI-Augmented Objective Structured Clinical Examinations in Nursing Education: Taiwan-Japan Viewpoint on 5 AI Roles, Governance, and Cross-Border Implementation

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Abstract

Generative artificial intelligence (AI) is arriving in high-stakes assessment; however, governance, validity evidence, and faculty readiness remain uneven. From a Taiwan-Japan perspective, we outline a pragmatic, transferable approach to integrating AI into nursing objective structured clinical examinations (OSCEs) using a 5-AI-role model—learning assistant, AI-augmented standardized patient, assessment assistant, case generator, and learning analyst—mapped across pre-OSCE, peri-OSCE, and post-OSCE workflows with human-in-the-loop final judgment. Taiwan contributes agile interdisciplinary development, staged pilots (practice, mock OSCE, and limited high-stakes stations), A/B comparisons, and explainability-by-design logging that links scores to time-stamped evidence. Japan contributes robust policy scaffolding (national AI use guidance in K-12, a revised nursing model core curriculum with outcomes and assessment blueprints, and institutional research cultures that support auditability and quality assurance). We distill 4 cross-cutting governance pillars—human oversight, learning process transparency, ethics and safety, and traceability—into implementable techniques (machine-readable rubrics, standardized patient persona cards, bias monitoring, and targeted faculty development). Aligning with international principles (International Advisory Committee for AI; Organisation for Economic Co-operation and Development; United Nations Educational, Scientific and Cultural Organization; World Health Organization; European Commission's High Level Expert Group; and National Institute of Standards and Technology), we propose a joint road map and shared registry to benchmark reliability, validity, equity, and workload impact. This viewpoint targets OSCE directors, nursing educators, and institutional leaders and provides a phase-gated governance blueprint rather than reporting original trial outcomes. Taiwan-led agility, complemented by Japan's standards-driven assurance, can form an Asia-Pacific reference model for trustworthy AI-augmented OSCE in nursing education.

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KEYWORDS

objective structured clinical examination; OSCE; nursing education; generative artificial intelligence; generative AI; standardized patient; assessment governance; transparency and traceability; Taiwan-Japan collaboration; artificial intelligence; AI

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Introduction

Generative artificial intelligence (AI) is steadily making its way into health professions education, but its use in high-stakes assessment remains measured—and rightly so. Benefits will be realized only if reliability, validity, fairness, and accountability are protected and can be shown in the day-to-day reality of teaching and examining [1-6]. Objective structured clinical examinations (OSCEs) have long provided a structured approach to eliciting clinical performance, and the method has matured through improvements in station design, rater training, and standard setting [7,8]. Contemporary assessment programs also push beyond single-event decisions toward programmatic assessment, in which evidence accumulates over time and feedback is central to learning [9]. Therefore, validity arguments must connect the blueprint and rubric to what we actually observe and to the decisions we ultimately make [10,11]. Against this backdrop, the question for many nursing programs is not whether AI will touch OSCEs but how to make it help rather than harm.

This viewpoint takes a pragmatic stance from a Taiwan-Japan collaboration. Taiwan brings agile interdisciplinary development, with short iteration cycles and pilots instrumented for explainability by design. Japan brings standards-driven governance, including national guidance on generative AI in education and a revised nursing model core curriculum that supports outcomes-aligned blueprints and auditability [12-14]. We argue that combining Taiwan's agility with Japan's assurance can yield a credible regional reference model aligned with international guidance on trustworthy AI [1-6]. Although we write with nursing OSCEs in mind, the approach generalizes to other health professions.

Aim, Key Messages, and Intended Audience

Aim

This viewpoint proposes a practical governance and implementation blueprint for integrating generative AI into nursing OSCEs in ways that remain auditable, fair, and safe in high-stakes contexts.

Key Messages

We argue that (1) AI functions in OSCEs should be decomposed into distinct roles ("5 AI roles") to reduce uncontrolled automation; (2) each role must be paired with concrete governance artifacts (eg, machine-readable rubrics, persona cards, and versioned prompts and logs) and explicit human decision rights; (3) adoption should be phased (practice, mock OSCEs, and limited high-stakes stations) with predefined gates for reliability, validity, equity, and workload; and (4) cross-border learning is feasible if registry design defaults to the minimum necessary, deidentified data and ensures auditability.

Intended Audience

The primary audience includes OSCE directors, nursing educators, simulation or standardized patient (SP) program leads, assessment committees, and institutional leaders responsible for educational quality and risk management. Secondary audiences include informatics teams, procurement, and legal and privacy offices.

Why AI in OSCE Now—Promise and Pitfalls

OSCEs generate a wealth of multimodal evidence—verbal exchanges, checklists, global ratings, and timing data. Capturing that evidence consistently is labor intensive, and synthesizing it into timely feedback is even harder. Large language models (LLMs) and related tools can help standardize prompts and portrayals, extract evidence, and assemble individualized feedback. When done well, this can improve interrater agreement on observable behaviors, reduce rater workload, and shorten the feedback loop. Standardized, bounded, AI-augmented SP (AI-SP) behaviors may also support equity by reducing unwanted variation in case portrayal.

However, the hazards are obvious. Unconstrained models can hallucinate, apply rubrics unevenly, and may amplify biases inherent in the data. Automated scoring can underrepresent constructs by overvaluing what is easy to detect and undervaluing tacit elements of professional judgment [11]. Overautomation can dull rater calibration and erode student trust. Model updates can drift silently, undermining comparability across cohorts. These risks argue for human-in-the-loop oversight, transparent logging, and governance grounded in accepted frameworks for trustworthy AI and risk management [1-6]. Nursing education must also track shifts in licensure and competency assessment—such as the Next Generation National Council Licensure Examination emphasis on clinical judgment [12]—and adhere to national guidance on responsible AI use [13,14].

Evidence Snapshot: What Published Studies Suggest (and What Remains Uncertain)

Empirical studies on AI-supported assessment and OSCE-adjacent tasks suggest both promise and nontrivial limitations that matter in high-stakes contexts. First, for structured written outputs scored against explicit rubrics, a peer-reviewed JMIR Medical Education study compared ChatGPT (with GPT-3.5; OpenAI) scoring with SP scoring across 85 rubric elements in 168 first-year medical students' SP-based history and physical notes (14,280 scoring opportunities) and reported a markedly lower incorrect scoring rate for ChatGPT (1%) than for SPs (7.2%) [15]. This supports the feasibility of LLM-assisted scoring for checklist-appropriate elements under constrained prompts and clear rubrics while leaving open questions about generalizability across institutions, cases, and languages.

Second, a pilot randomized trial comparing an AI chatbot–based simulation with peer role-play for OSCE preparation reported complementary strengths (eg, autonomy and repeatable practice with structured feedback vs authenticity and an exam-like

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environment), suggesting scenario-dependent effects rather than uniform superiority [16]. Third, emerging transcript-based OSCE grading work applying LLMs to video-derived transcripts reports high alignment with human graders for selected rubric items (and includes failure analyses describing when reliability degrades) but also highlights sensitivity to prompting and risks of confident but incorrect rationales—reinforcing the need for evidence linking, uncertainty signaling, and human verification rather than autonomous scoring for high-stakes decisions [17].

Finally, the broader measurement literature on automated scoring emphasizes that fairness cannot be assumed; subgroup performance differences, construct underrepresentation, and drift require continuous monitoring with predefined indicators and remediation or rollback pathways [18]. Collectively, this evidence supports a phased adoption model in which AI remains advisory, each AI function is constrained by governance artifacts (machine-readable rubrics, persona cards, and versioned prompts), and scaling decisions are gated by reliability, validity, equity, and workload metrics. Related work has also proposed LLM-based approaches to evaluate SP simulations and has discussed whether LLMs can supplement (rather than replace) SP programs, reinforcing the need for bounded roles and governance in assessment contexts [19,20].

A 5-AI-Role Model Across the OSCE Life Cycle

We propose a 5-AI-role model—learning assistant, AI-SP, assessment assistant, case generator, and learning analyst—mapped to pre-OSCE, peri-OSCE, and post-OSCE workflows. The intention is to augment, not replace, human expertise and make the assessment enterprise more transparent and improvable. Figure 1 sketches the overall architecture and its relationship to governance pillars and the Taiwan-Japan pathway, and Table 1 summarizes the 5 AI roles, governance artifacts, and human control points.

Figure 1. Conceptual framework for trustworthy artificial intelligence (AI)–augmented objective structured clinical examinations (OSCEs) in nursing education. The 5 AI roles—learning assistant, AI-augmented standardized patient (AI-SP), assessment assistant, case generator, and learning analyst—map to pre-OSCE, peri-OSCE, and post-OSCE workflows. Four governance pillars—human oversight, learning process transparency, ethics and safety, and traceability—surround the workflow. The Taiwan-Japan pathway layers agile pilots and explainability-by-design logging (Taiwan) with standards-driven blueprinting and policy scaffolding (Japan), feeding a shared, deidentified registry for benchmarking reliability, validity, equity, and workload. RAG: retrieval-augmented generation.

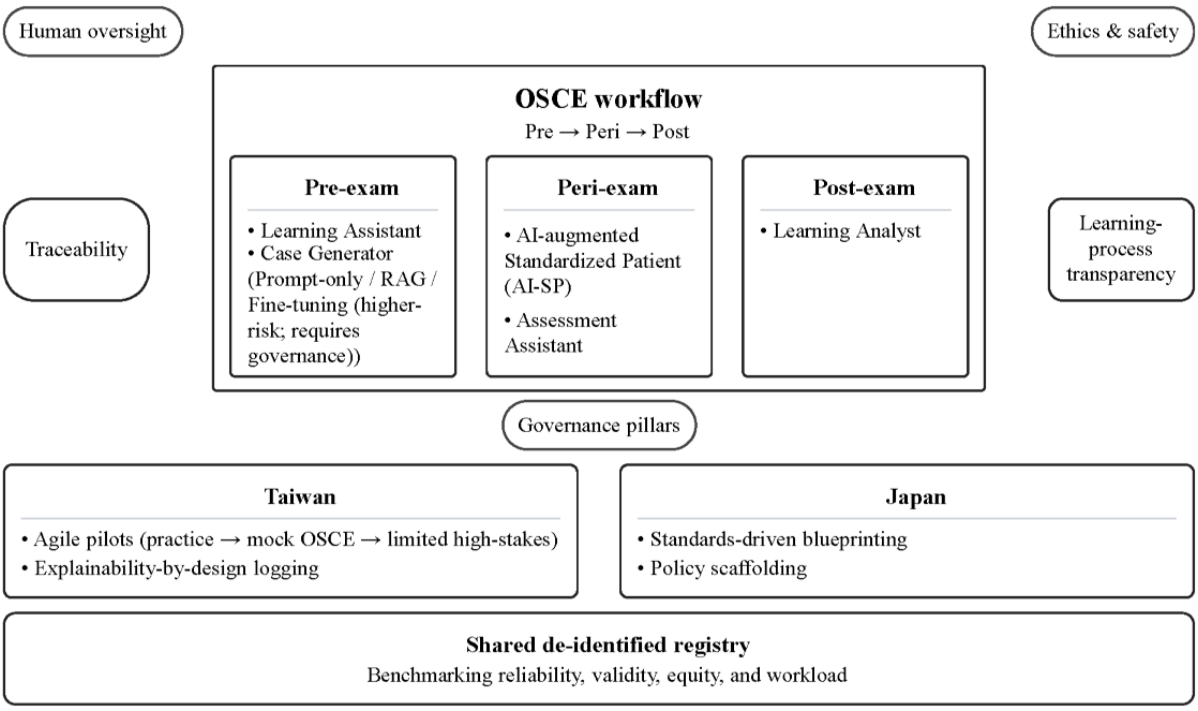

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Table 1. Five artificial intelligence (AI) roles, governance artifacts, and human control points.

AI role	Primary function in OSCE[a]	Typical inputs	Typical outputs	Governance artifacts examples	Human control points	Key risks to monitor
Learning assistant	Practice support and formative feedback	Approved rubric, station objectives, and approved prompt set	Practice prompts and rubric-anchored feedback drafts	Prompt library, rubric versioning, and disclosure text	Allowed scope set by faculty and learner-contested outputs	Overscaffolding, misinformation, and privacy leakage
Case generator	Generate station or case variants within difficulty bands	Blueprint metadata, difficulty bands, and approved case library	Draft stations and localized variants	Difficulty bands, prohibited content rules, provenance notes, and faculty sign-off	Faculty review and approval before use	Unsafe or inaccurate content, cultural mismatch, and leakage of sensitive information
AI-augmented standardized patient	Standardized yet bounded interaction during stations	Persona card, response boundaries, and safety filters	Student-facing responses and interaction logs	Persona cards, safety or red-team checklist, model and version logs, and kill switch	Standardized patient trainer or faculty approval, with escalation route	Inconsistent portrayal, unsafe content, and bias in interaction
Assessment assistant	Evidence extraction and prescoring suggestions	Audio, video, or text and rubric items	Time-stamped evidence links and suggested checklist marks	Evidence-linking rules, uncertainty flags, and audit logs	Verified, edited, or rejected by a rater; final scoring done by a human	Construct underrepresentation, rater deskilling, and subgroup errors
Learning analyst	Post-OSCE feedback and monitoring dashboards	Scores, evidence logs, and rater actions	Individual feedback and reliability, equity, or workload metrics	Indicator definitions, access controls, and retention policy	Committee reviews trends and approves changes	Model drift, fairness gaps, and privacy risks from rich logs

[a]OSCE: objective structured clinical examination.

We refer back to Figure 1 as we outline the roles and the accompanying safeguards.

Before the exam, AI serves as a learning assistant and case generator. Institution-approved prompt sets and machine-readable rubrics seeded with blueprint metadata guide rehearsal of communication, reasoning, and procedural steps. Case generation produces variants that respect difficulty bands and cultural and linguistic localization; faculty always reviews outputs before use. Encoding rubrics and blueprints in structured formats enables consistent prompts and downstream alignment between station objectives, observable behaviors, and scoring criteria. This preparation supports explicit construct definitions and strengthens the validity argument that links observations to decisions [10,11].

For case generation, institutions can choose among three increasingly complex options: (1) constrained prompting using institution-approved templates, machine-readable rubrics, and difficulty bands (no model-weight updates); (2) retrieval-augmented generation grounded in an institution-approved local case library to improve factual consistency while preserving governance; and (3) fine-tuning, which should be considered only where there is a clear legal basis and robust controls (dataset provenance documentation; data minimization; deidentification where feasible; and predeployment evaluation against safety, bias, and leakage test suites). Regardless of approach, faculty review and sign-off remain mandatory before any generated case enters mock or high-stakes OSCE use.

During the exam, AI-SPs aim to improve standardization while allowing bounded adaptivity. Persona cards specify history, affect, cultural considerations, difficulty, and response boundaries, with model responses constrained to approved domains. Assessment assistants prescore specific behaviors or extract time-stamped evidence mapped to rubric items so that raters can verify, edit, or reject suggestions. Human assessors have final authority, and every AI suggestion comes with a rationale linked to auditable evidence, consistent with explainability by design [21].

After the exam, a learning analyst synthesizes performance into individualized, rubric-anchored feedback and cohort-level dashboards. Feedback emphasizes actionable suggestions and makes the evidentiary link to scores explicit. Cohort dashboards track blueprint coverage, rater effects, and subgroup performance differences to support continuous improvement and equity monitoring. Transparency artifacts—model cards and data sheets—document intended use, data sources, and limitations so that faculty can supervise with eyes open [22,23].

Governance Pillars: Human Oversight, Transparency, Ethics and Safety, and Traceability

Trustworthy AI-augmented OSCEs require governance that is rigorous yet workable. We summarize the 4 pillars that translate international guidance [1-6] into daily assessment practice.

First, human oversight ensures that AI remains advisory. Trained assessors make final judgments, using AI-extracted evidence to inform rather than dictate scores. Calibration sessions can leverage AI-curated exemplars to align interpretations of rubric items. Human-in-the-loop routines minimize construct underrepresentation and preserve accountability central to programmatic assessment [9,11].

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Second, learning process transparency is about showing how results were produced. For students, this means preserving prompts, drafts, and reflections. For assessments, it means keeping machine-readable blueprints, station rubrics, persona cards, and logs that capture who did what, when, and on which evidence. Explainability is judged by auditability rather than by opaque post hoc rationales [21-23].

Third, ethics and safety demand deidentification, data minimization, and guardrails against clinical misinformation, scope-of-practice drift, and inappropriate content. Safety checklists and red teaming apply to AI-SP prompts and assessment assistant outputs before deployment and after significant model updates. Procurement criteria and transparency artifacts create a baseline for safe integration, drawing on established digital technology assessment frameworks [24].

Fourth, traceability links choices to evidence across time. Standardized logs connect scores to time-stamped utterances or actions, raters, and model versions. This enables audits, drift detection, and equity monitoring. Where subgroup gaps arise, leaders adjust prompts, persona cards, or rubric anchors and repeat evaluation—treating fairness as an ongoing obligation in line with evidence of algorithmic disparities in health settings [25].

Closed-Loop Monitoring and Improvement

During scoring, raters label each AI suggestion as accept, modify, or reject and optionally tag reasons (eg, “no supporting evidence,” “wrong rubric mapping,” “overstrict,” and “language or cultural mismatch”). These rater actions are logged alongside time-stamped evidence links and model or prompt versions and summarized in dashboards tracking error modes, drift signals, and subgroup differences. In high-stakes settings, optimization should preferentially occur through governance-layer updates (persona cards, prompt sets, rubric anchors, and extraction rules) because they are auditable and reversible; model retraining or fine-tuning is treated as a higher-risk intervention requiring explicit approval, revalidation, and a rollback plan.

Complementary Strengths of Taiwan and Japan

Taiwan’s approach favors small-scope experiments that scale by evidence. Multidisciplinary task forces co-design cases, rubrics, and prompts; pilots start in practice environments to surface failure modes; mock OSCEs use A/B comparisons to quantify interrater agreement, time on task, and student workload. High-stakes use follows only after bias and error analyses are satisfactory. Explainability-by-design logs link every AI suggestion to specific utterances or events, and raters annotate accept, modify, or reject decisions. These habits align naturally with risk management frameworks that emphasize documentation, monitoring, and rollback capacity [4].

Illustrative Taiwan-Informed Implementation Pattern (an Example)

In an agile pilot cycle, a small multidisciplinary task force (nursing faculty, simulation or SP trainers, informatics staff, and a privacy and ethics representative) co-designs (1) a machine-readable rubric, (2) an AI-SP persona card with response boundaries, and (3) a constrained prompt set for evidence extraction. The team conducts short red teaming sessions to intentionally trigger unsafe or biased outputs, revises prompts or personas accordingly and then runs a limited practice pilot. In a subsequent mock OSCE, stations are A/B tested with and without AI assistance to quantify rater time per station, interrater agreement, frequency of rater overrides (accept, modify, or reject), and student workload indicators. Only stations meeting predefined gates progress to limited high-stakes use.

Japan contributes policy scaffolding and institutional coherence. National guidance on generative AI articulates transparency, fairness, and responsible use that carry into higher education [13]. The 2024 nursing model core curriculum provides outcomes and assessment blueprints that support machine-readable rubrics, blueprint-to-station traceability, and integration with institutional research dashboards. Such scaffolding complements cautious, phased adoption and supports the accumulation of reliability and validity evidence consistent with OSCE best practice [7,8] and broader frameworks for trustworthy AI [5,6]. Alignment with the Next Generation National Council Licensure Examination’s focus on clinical judgment strengthens the case for explicit reasoning processes and feedback [12].

Implementation Pathway and Practical Techniques

A staged pathway allows institutions to learn safely. Preparation includes encoding blueprints and rubrics in structured formats and creating AI-SP persona cards with response boundaries, affect, and cultural nuances. Faculty development favors minimal viable prompt sets for case generation, AI-SP control, and evidence extraction, paired with misuse-prevention checklists and short calibration workshops. Practice-environment pilots test persona stability, content safety, and evidence extraction quality. Mock OSCEs introduce AI-assisted stations and compare conditions with and without AI support to quantify benefits and harms in context. Limited high-stakes rollout is reserved for stations where behavioral anchors are clear and AI-extracted evidence is demonstrably reliable under human supervision.

Procurement and data governance underpin sustainability. Institutions should prefer tools that publish model cards and data sheets, expose application programming interfaces for log capture, support role-based access, and report subgroup performance [22,23]. Digital technology assessment criteria can be adapted for educational assessment to set minimum expectations for safety, security, interoperability, evidence, and transparency [24]. For cumulative improvement, traceability must be built into the system. Logs should record model

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versions, prompts, rater decisions, and time-stamped evidence to enable drift detection and recalibration.

Required manual interventions across the implementation pathway have 3 phases.

Phase 1 (practice setting) includes manually defining allowed prompts, approving rubrics and persona cards, running red-team tests, logging outputs, and reviewing failure cases on a fixed cadence (conducted by faculty).

Phase 2 (mock OSCE with A/B comparisons) includes manually assigning stations to either AI-assisted or standard conditions, conducting rater calibration, requiring raters to verify AI-extracted evidence, and collecting student and rater workload measures.

Phase 3 (limited high-stakes use) includes restricting deployment to stations with clear behavioral anchors, requiring a real-time kill switch and escalation route, implementing an appeal pathway supported by traceable logs, and scaling only if predefined reliability, equity, and workload gates are met.

A brief worked example for the assessment assistant follows. The system highlights a time-stamped utterance mapped to a rubric item; the rater verifies and clicks “accept.” For another item, the system suggests completion, but the rater observes no evidence and clicks “reject—no evidence.” Both actions are logged for audit and improvement.

Evaluation Strategy: Reliability, Validity, Equity, and Workload

Evaluation should rely on a concise, theory-informed set of indicators. Reliability includes interrater agreement, internal consistency where appropriate, and stability of AI-extracted evidence across sessions and subgroups. Validity evidence follows the inferences by Kane [11]—scoring, generalization, extrapolation, and decision—by linking rubric items to observable behaviors, checking generalization across variants, and examining decision consequences. Equity indicators track subgroup differences in scores, rater edits to AI suggestions, and the accessibility of feedback. Workload indicators include rater time per station, faculty preparation and calibration time, and student cognitive load. These indicators are reported at each deployment phase, with explicit gates for scaling. When subgroup gaps are detected, corrective actions target persona prompts, rubric anchors, or instructional supports and are followed by reevaluation, consistent with fairness-by-design practices [22,25].

A Taiwan-Japan Road Map and Shared Registry

A joint road map can speed regional learning and comparability. Taiwan’s experience points to colocated educational engineering task forces, short A/B cycles, and audit-ready logging before high-stakes use. Japan’s policy scaffolding points to a stronger blueprint-to-rubric alignment, integration of AI-supported OSCE data with institutional research dashboards, and continuity of AI literacy and ethics across the curriculum. Together, partners can harmonize rubric vocabularies and metadata across Chinese, Japanese, and English; build a shared, deidentified registry of OSCE logs and outcome indicators; and run faculty exchanges and peer review to refine standards iteratively. The registry focuses on reliability, validity, equity, and workload; it records model versions and prompts to enable cross-site comparability and accompanies each dataset with transparency artifacts documenting intended use and known limitations [22-24]. This approach answers international calls for trustworthy AI, risk management, and auditable evidence pipelines [1-6].

Position Within Assessment Theory and Practice

Our proposal aims to be compatible with established theory. The 5 AI roles address different parts of the evidentiary chain. The case generator and learning assistant support construct representation and learner preparation in line with blueprints, reducing construct underrepresentation [10,11]. AI-SP and assessment assistant emphasize consistent elicitation and capture of observable behaviors; human raters retain primacy in holistic judgments, which counters the tendency of automated signals to crowd out tacit expertise [9,11]. The learning analyst strengthens interpretation and use by providing timely, rubric-anchored feedback and surfacing patterns that inform teaching and remediation. In this way, AI can augment reliability and the feedback function of OSCEs while preserving the professional judgment central to programmatic assessment [9]. The approach also dovetails with licensure trends that foreground clinical judgment [12].

Ethical and Legal Considerations

Ethics and legality must be handled in practical terms. Defaults should be data minimization and deidentification. Only the information needed for assessment, feedback, and improvement should be collected; access should be granted by role; and logs for audit periods should be set by policy. Content safety and cultural sensitivity should be tested before deployment with red teaming; inappropriate outputs trigger prompt revision or model replacement. Transparency with students and faculty about what AI is used for, what purpose it serves, and what evidence is retained is essential. When using third-party models, they require disclosures consistent with model cards and data sheets and insist on contractual guarantees for security and incident response [22-24]. Treat equity as continuous work, not a one-off checklist, acknowledging the empirical record of algorithmic disparities in health contexts [25]. National guidance on AI in education provides a baseline to adapt locally [13,14].

This viewpoint did not involve human participants or identifiable data; therefore, informed consent and institutional review board approval were not required.

Cross-Border Legal and Data Governance (Taiwan’s Personal Data

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Protection Act and Japan's Act on the Protection of Personal Information)

If OSCE artifacts (audio, video, transcripts, and rater notes) are used for monitoring or a shared registry, cross-border data governance becomes central. Taiwan and Japan both maintain comprehensive personal data regimes—Taiwan's Personal Data Protection Act and Japan's Act on the Protection of Personal Information—with practical implications for purpose limitation, data minimization, security safeguards, retention, and accountability. Because OSCE logs can include direct identifiers (faces, voices, and names) and indirect identifiers (rare scenarios, time stamps, and free-text notes), the shared registry concept should default to the minimum necessary, deidentified derivatives (eg, rubric-level scores, time on task, interrater statistics, and error-mode tags) and model and prompt version metadata. Where richer logs are needed for audit or research, additional safeguards are required (role-based access controls, retention limits, documented purposes, standardized deidentification or pseudonymization aligned with each jurisdiction, and contractual incident response). Where cross-border transfer constraints are substantial, federated analytics (local computation with only aggregate sharing) is a practical alternative.

Limitations and Future Directions

This viewpoint is conceptual; it does not provide prospective evidence that AI-augmented OSCEs improve reliability, validity, equity, or learning outcomes. Multisite pilots with predefined gates and common indicators are needed to test the framework in practice. Second, several technical elements are still evolving, including standardized approaches to explainability for conversational interactions, subgroup performance reporting, and robust drift monitoring and rollback across model updates. Third, the generalizability of persona prompts, rubric encodings, and machine-readable blueprints across languages, institutions, and specialties remains uncertain; controlled A/B studies and qualitative work with faculty and students are required to identify where localization or standardization is appropriate. Fourth, implementing audit-ready logging, bias monitoring, and multilingual harmonization may pose workload and infrastructure challenges—especially in resource-constrained programs—and could shift effort from teaching to tooling unless processes are simplified and supported. Fifth, data governance and procurement constraints (eg, contractual access to logs, model cards, and version histories) may limit transparency when third-party vendors are involved; practical templates and sector-level expectations are needed to raise a common floor. Finally, legal and regulatory contexts differ across jurisdictions, and alignment with licensure or accreditation requirements may lag; institutions should adapt governance to local requirements with stakeholder input and contribute results to shared registries so that evidence accumulates over time.

Even with these caveats, converging guidance on trustworthy AI, programmatic assessment, and transparency offers a feasible path from cautious pilots to safe, equitable scale [1-6,9,11,24-26]. A Taiwan-Japan collaboration can generate deidentified shared evidence, reduce duplicated effort, and help the region articulate standards that are contextually grounded yet internationally interoperable.

Conclusions

AI can, with the right guardrails, make OSCEs more reliable, transparent, and feedback-rich while preserving human judgment. A 5-AI-role model integrated across pre-OSCE, peri-OSCE, and post-OSCE workflows—governed by human oversight, learning process transparency, ethics and safety, and traceability—provides a workable blueprint. Taiwan's agile pilots and explainability-by-design logging, together with Japan's policy scaffolding and blueprint-driven quality assurance, can form a credible Asia-Pacific reference model for trustworthy AI-augmented OSCE in nursing education. A shared registry and harmonized vocabularies would accelerate collective learning. The pathway outlined here is actionable now, accords with assessment theory and international AI governance, and invites empirical testing through cross-border collaboration.

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Data Availability

No datasets were generated or analyzed in this study. Materials such as figure and table templates are available from the corresponding author on reasonable request.

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Authors' Contributions

Conceptualization: AN, RS, LL, KK
Methodology: AN, RS, LL, KK
Writing—original draft: KK

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Writing—review and editing: RS, AN, LL, KK
KK, AN, RS, and LL contributed equally to this work. All authors approved the final manuscript.

Conflicts of Interest

None declared.

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Abbreviations

AI: artificial intelligence
AI-SP: artificial intelligence–augmented standardized patient
LLM: large language model
OSCE: objective structured clinical examination
SP: standardized patient

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Young People's Satisfaction With and Perceived Impact of a Multichannel Mental Health Helpline During and After COVID-19 Pandemic: Mixed Methods Analysis of Cross-Sectional Survey Data

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Abstract

Background: In the United Kingdom, there was an increased demand for young people's mental health helpline services during COVID-19 pandemic, when face-to-face services were often inaccessible. Despite this, there is scant research examining young people's experiences with these helplines during the pandemic and postpandemic periods.

Objective: Using a cross-sectional survey, this mixed methods study aims to examine young people's (aged 16-25+ years) experiences with the multichannel helpline provided by The Mix (Mental Health Innovations), the United Kingdom's leading online mental health support service for young people during and after the pandemic.

Methods: From February 2020 to October 2023, approximately 16,000 users aged 16-25+ years contacted The Mix's helpline. All users were sent an email by The Mix following helpline contact to answer their user survey. Of these, 796 participants aged 16-25+ years answered the survey, representing a response rate of 5%, with a survey completion rate of 65.3%. To address potential nonresponse bias and missing data concerns, a multiple imputation procedure using the Multiple Imputation by Chained Equations (MICE) package in R (R Core Team) provided a final imputed sample for both the pandemic (n=295) and postpandemic (n=501) periods. Open-ended survey responses from users were also explored. Of the 796 participants who responded to the survey, there were 1183 open-ended responses from 486 respondents. Of these, a total of 731 open-ended responses (approximately 60% of the total responses) were coded. The criteria for inclusion were applied by 2 independent coders. Excluded responses focused on single words (eg, "thanks"), irrelevant text, or duplicated entries, ensuring only responses containing substantive feedback were analyzed.

Results: During the pandemic, young people who contacted the helpline reported greater satisfaction after the first lockdown and a stronger perceived impact on their well-being after the first lockdown and during the second and third lockdowns, compared with those who contacted the helpline during the gradual easing period; phone users reported higher satisfaction than those using the contact form. Postpandemic, helpline users who identified as "other" in terms of their gender reported less satisfaction, while male users reported a greater impact on their well-being compared to female users. Qualitative analysis revealed how the participants felt supported by the helpline, such as "feeling heard" and "being empowered," and areas for improvement across service delivery, protocol, and technicalities.

Conclusions: The findings highlight the important role that helplines play in supporting young people's mental health, particularly in crises like the pandemic. This study underscores the need for service improvements to ensure young people continue to feel supported by helplines, highlighting key areas for improvement in service delivery, protocols, and technical infrastructure. Future research should explore channel preferences and minority experiences, often underrepresented in helpline studies.

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KEYWORDS

internet; online; adolescents; helpline; evaluation; qualitative; survey; quantitative; mental health; help-seeking

Introduction

Background

Globally, COVID-19 pandemic led to significant mental health declines. In the United Kingdom, 24% of the population reported experiencing worsening distress between initial and subsequent waves of the pandemic [1]. Lockdown measures particularly affected young people, who, despite lower health risks, experienced declining mental health [2], especially compared to other age groups [3]. Even before the pandemic, existing

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literature highlighted a growing concern, an absence of critical precrisis support and significant difficulties accessing traditional mental health services for this age group [4-6]. Delays in accessing professional care have been linked to adverse psychological outcomes, underscoring the importance of timely intervention [7]. The pandemic exacerbated these issues, disrupting established mental health services and straining service capacity [8,9], highlighting the need for systemic reform and alternative support options [10].

In response to the increased need and lack of accessible support, there was a steep rise in demand for young people's mental health helpline services during the pandemic [11]. A recent review [4] emphasized strong confidence in the evidence supporting the need for such crisis services staffed by trained professionals, especially those accessible via multiple platforms such as telephone, text, and email. Mental health helplines, which offer confidential, nonjudgmental, and often immediate support via telephone, web chat, and email, have been shown to be particularly valuable during a pandemic when face-to-face services and other supports are inaccessible [12]. Helplines are primarily staffed by trained volunteers equipped to provide emotional support without counseling and center around active listening and signposting to external support services [13]. The heavy reliance on helplines during crisis periods highlights their critical role as a timely accessible bridge to more comprehensive professional care.

Despite their increased use during the pandemic, there is scant research examining young people's experiences with mental health helplines during the pandemic and postpandemic periods. Existing research often relies on call metrics (eg, volume and duration) rather than user-reported outcomes like satisfaction and perceived impact [14]. Methodologically, most studies are either purely quantitative or focus narrowly on crisis calls, with reviews noting short-term or proximal endpoints, heterogeneous measures, and limited attention to young people's experiences [15]. This leaves a gap in understanding holistic user experience across nonphone channels (eg, chat and text). Such information can inform future service development and ensure helplines continue to meet the mental health needs of young people, especially during and after crisis periods.

To address these gaps, this current study examines cross-sectional survey data collected from 2020 to 2023 by The Mix (Mental Health Innovations), the United Kingdom's leading online support service for young people under 25 years. The Mix operates a volunteer-based helpline focused on active listening and signposting, accessible through phone, email, web chat, and contact form. During the pandemic, The Mix saw a significant surge in demand, prompting them to expand their volunteer base and extend helpline hours to manage the increased contacts [11].

Research Background

While randomized control trials are currently lacking, helplines seem to show benefits for young people seeking support for a range of issues, including depression and suicidality [16]. They may deescalate crises like self-harm and suicide [17], with one study in the United States demonstrating reduced psychological distress across demographic groups lasting up to 6 months after contact [17]. As community-based services appear more approachable than traditional professional services, helplines are well-positioned to mitigate the fear associated with seeking professional help, offering a valuable alternative [18]. Helplines' timely, confidential, and user-directed nature further aligns with features that encourage help-seeking behavior in young people at risk of suicide [18]. One study [19] found that young adults report digital emotional support through texting or video calling as effective as in-person support for regulating negative emotions. As digital platforms become the norm for young people seeking support, helplines have the potential to overcome stigma and accessibility issues surrounding traditional services [20,21].

Globally, helplines experienced a sharp increase in usage during the pandemic. For instance, a study on Malta's national mental health helpline reported a significant increase in calls, particularly during lockdown phases [22]. Samaritans UK reported an increased quantity and length of calls to the helpline, particularly between 2 AM and 6 AM, suggesting increased reliance on the service during lockdown periods [23]. A similar trend was observed in New Zealand, where young people were among the groups making more frequent contacts [24]. In Australia, Kids Helpline, which offers support via telephone, web chat, and email to children and young people, also saw an initial spike in demand, especially in the web chat modality, which remained the preferred mode of contact for young people throughout the pandemic [25]. The helpline recorded increases in contacts related to mental health, suicide, self-harm, and family relationship issues, with girls and adolescents aged 13 - 18 years being the most frequent users. These findings regarding the growing concerns among youth helpline users echo a helpline report noting heightened contacts relating to anxiety, depression, and self-harm during the pandemic that have persisted in the postpandemic period [26]. This sustained and evolving reliance on helplines, coupled with the necessity of rapid operational changes to meet the demand, highlights the critical need to assess the user experience to ensure service quality and sustainability, an area currently lacking robust evidence.

Beyond the quantity of contacts, a significant shift in communication channels has emerged, with web chat and text-based services becoming increasingly popular among young people. An analysis of Kids Helpline Australia usage from 2012 to 2018 revealed that while phone and email contacts declined, web chat usage rose sharply [27]. Similarly, a mixed methods study of web-based suicide prevention services for young people in the United Kingdom found that young people prefer text-based communication over verbal channels when seeking support [21]. Despite this trend, several studies note that certain modalities, such as text-based services, are less examined, potentially due to insufficient funding [28,29]. Therefore, investigating young people's experiences across nontelephone channels of delivery could provide valuable insight into their satisfaction with and perceived impact of the services. This line of inquiry is vital for optimizing resource allocation in the current digital service landscape.

Understanding the experiences of diverse helpline users is also crucial, as different groups present varying concerns and

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help-seeking behaviors. Research consistently shows that youth helpline users are predominantly female [26,27,30], a trend that mirrors patterns observed in general helplines [22]. During the pandemic, a German helpline reported a significant increase in calls, largely from female children and adolescents, who also experienced the most serious rise in serious mental health issues [31]. These trends underscore the importance of exploring whether satisfaction levels and perceived impact differ across genders among current helpline users, particularly between primary and underrepresented demographics.

Helpline services may require more nuanced tailoring to reach and support young people from diverse ethnic backgrounds. Although helplines are often considered beneficial for minority populations [14], a systematic review [28] identified a lack of evidence for youths in marginalized communities. This gap further underscores the need for more research exploring the helpline experiences of young people with diverse demographic characteristics, including age, gender, and ethnicity, to ensure equitable support.

Conceptual Frameworks

To ground this study conceptually, we draw upon two interrelated bodies of literature: (1) help-seeking behavior models and (2) service evaluation frameworks. Help-seeking models conceptualize support-seeking as a multistage process shaped by perceived need, stigma, and accessibility [32]. Helplines, by offering anonymity and low-threshold access, play a pivotal role in overcoming structural barriers to formal care, particularly at the accessibility stage. Accordingly, this investigation into demographic differences and channel preferences is framed by the need to understand how service design influences successful engagement across diverse groups. Service evaluation frameworks further emphasize the importance of user-reported outcomes over operational metrics alone [33]. Together, these frameworks provide a lens through which to examine not only who engages with helpline services and how, but also whether those engagements translate into meaningful support experiences across diverse populations and modalities.

This Study

Using cross-sectional survey data, this mixed methods study examines 2 datasets from The Mix's mental health helpline services, one collected during the pandemic and the other in the postpandemic period. The study focuses on young people aged 16-25+ years and addresses 3 main research questions:

- What was young people's satisfaction with the helpline services, and how did they perceive the services to impact their well-being during and after the pandemic?
- How did their satisfaction with and perceived impact of the helpline services vary by lockdown restrictions (pandemic dataset only), demographic characteristics (gender and ethnicity), and the channel through which support was accessed?
- Based on open-ended survey responses, how did young people describe feeling supported by the helpline, and what suggestions did they offer for improving the services?

Methods

Reporting Standards

This mixed methods study adheres to established reporting standards. Quantitative components were reported in accordance with the STROBE (Strengthening the Reporting of Observational Studies in Epidemiology) guidelines. Qualitative components were reported following the COREQ (Consolidated Criteria for Reporting Qualitative Research) checklist. Completed checklists are provided in Checklist 1 and Checklist 2.

Participants

From February 2020 to October 2023, approximately 16,000 users aged 16-25+ years contacted the helpline. All users were sent an email by The Mix following contact to answer their user survey. Of these, 796 participants aged 16-25+ years answered the survey, representing a response rate of 5%, which is typical for these large-scale service evaluations [34]. Of the 796 participants, 520 answered questions about their satisfaction and perceived impact of the helpline, representing a completion rate of 65.3%, which is consistent with similar service evaluations [34]. Of the 520 participants, 257 answered the survey during the pandemic period (February 2020-April 2022) and 263 (May 2022-October 2023) answered the survey during the postpandemic period. Chi-square tests comparing the predictors and covariates indicate that those in the noncomplete sample were more likely to use email and less likely to use phone helplines compared to those in the complete sample (χ^2_4=41.846; P<.001). There were no other significant differences between the noncomplete and complete samples.

To address potential nonresponse bias and missing data concerns, we conducted a multiple imputation procedure using the Multiple Imputation by Chained Equations (MICE) package in R (R Core Team) [35]. Separate imputation models were specified for the during-pandemic and postpandemic datasets, including key sociodemographic and survey variables (eg, gender, ethnicity, channel, age, and outcome measures). Likert-type variables were imputed using proportional odds logistic regression ("polr"), categorical variables using multinomial logistic regression ("polyreg"), and continuous outcomes using predictive mean matching ("pmm"). Convergence diagnostics (using trace plots) and sensitivity analyses (eg, increasing the number of imputations and varying imputation methods) were performed to assess the robustness of the imputed results. The consistency of descriptive statistics across imputations indicated that non-response bias was unlikely to substantially affect the observed patterns.

Visual inspection of the trace plots across all 20 iterations confirmed that the multiple imputation models for the pandemic and postpandemic datasets achieved satisfactory convergence. Each colored trajectory represents an independent imputation chain. For most imputed variables, the mean and SD lines fluctuated modestly during the initial iterations before stabilizing around consistent central values, indicating that the Markov chains reached a stationary distribution. No systematic upward or downward trends were observed after iteration 10, and the

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chains demonstrated strong mixing with substantial overlap, suggesting good between-chain convergence and independence across imputations. Combined with sensitivity checks, these findings support the robustness and reliability of the imputed results for subsequent regression analyses [36].

Using the imputed sample, Table 1 provides the characteristics of the pandemic (n=295) and postpandemic (n=501) samples. Table 1 shows a clear demographic skew in the help-seeking population, participants self-identified as predominantly "female" and "White". Age was concentrated in the 16 - 18 years and 19 - 21 years groups, with 22 - 24 years declining postpandemic and 25+ years remaining a small proportion. This mirrors established trends in youth helpline literature [26,27,30] and indicates that the current findings are generalizable to The Mix's majority user base. However, the underrepresentation of males and other groups (transgender, nonbinary, other, and prefer not to say), ethnic minorities (Asian, Black, Mixed, and Other), and older youth (25+ years) warrants caution in extrapolating results to these subgroups. In line with the help-seeking model, these distributional patterns may reflect differential barriers or preferences that shape who engages with standard helpline services.

Table . Participant characteristics of imputed pandemic and postpandemic samples.

Characteristics	Pandemic (N=295), n (%)	Postpandemic (N=501), n (%)
Age (years)		
16 - 18	105 (35.6)	190 (37.9)
19 - 21	72 (24.4)	170 (33.9)
22 - 24	97 (32.9)	100 (20)
25+	21 (7.1)	41 (8.2)
Sex		
Female	227 (76.9)	358 (71.5)
Male	54 (18.3)	103 (20.6)
Other	14 (4.7)	40 (8)
Ethnicity		
White	227 (76.9)	387 (77.2)
Minorities	68 (23.1)	114 (22.8)
Helpline channel		
Contact form	51 (17.3)	5 (1)
Email	154 (52.2)	192 (38.3)
Phone	39 (13.2)	26 (5.2)
Web chat	51 (17.3)	271 (54.1)

Procedure

From February 2020 to April 2022, survey invitations were sent a week following helpline contact. From May 2022 to October 2023, this was shortened to one day, with a reminder sent the following week if the survey was not completed. Participants completed the online survey on SmartSurvey (SmartSurvey is Smartline International Ltd).

Measures

Outcomes

The response scale changed from a 5-point (1=Strongly disagree; 2=Disagree; 3=Neutral; 4=Agree; 5=Strongly agree) to a 4-point scale (1=Strongly disagree; 2=Tend to disagree; 3=Tend to agree; 4=Strongly agree) from the pandemic to postpandemic periods. In both versions, "Not relevant" and "Don't know" options were also included. For this reason, the pandemic and postpandemic periods were examined separately in 2 different models; thus, each of their reliabilities is reported. Factor analysis confirmed a 2-factor model was an adequate fit to the data (Pandemic: comparative fit index [CFI]=0.97; Tucker-Lewis Index [TLI]=0.95; root mean square error of approximation [RMSEA]=0.13; standardized root mean square residual [SRMR]=0.04 and Postpandemic: CFI=0.98; TLI=0.96; RMSEA=0.10; SRMR=.04). Satisfaction was defined as participants' perceptions of service quality, while Impact was defined as the effectiveness of the service in positively influencing well-being or behavior.

Satisfaction

Cronbach alphas showed high reliability (α=.94 pandemic; .90 postpandemic). The mean of 3 questions was computed, assessing participants' satisfaction with the service. Questions included "I felt listened to," "I felt understood," and "I felt emotionally supported."

Perceived Impact on Well-being

Cronbach alphas showed high reliability (α=.93 pandemic; .93 postpandemic). The mean of 4 questions was computed, which assessed perceived changes in participants' well-being and behavior. Questions included "My wellbeing improved," "I feel

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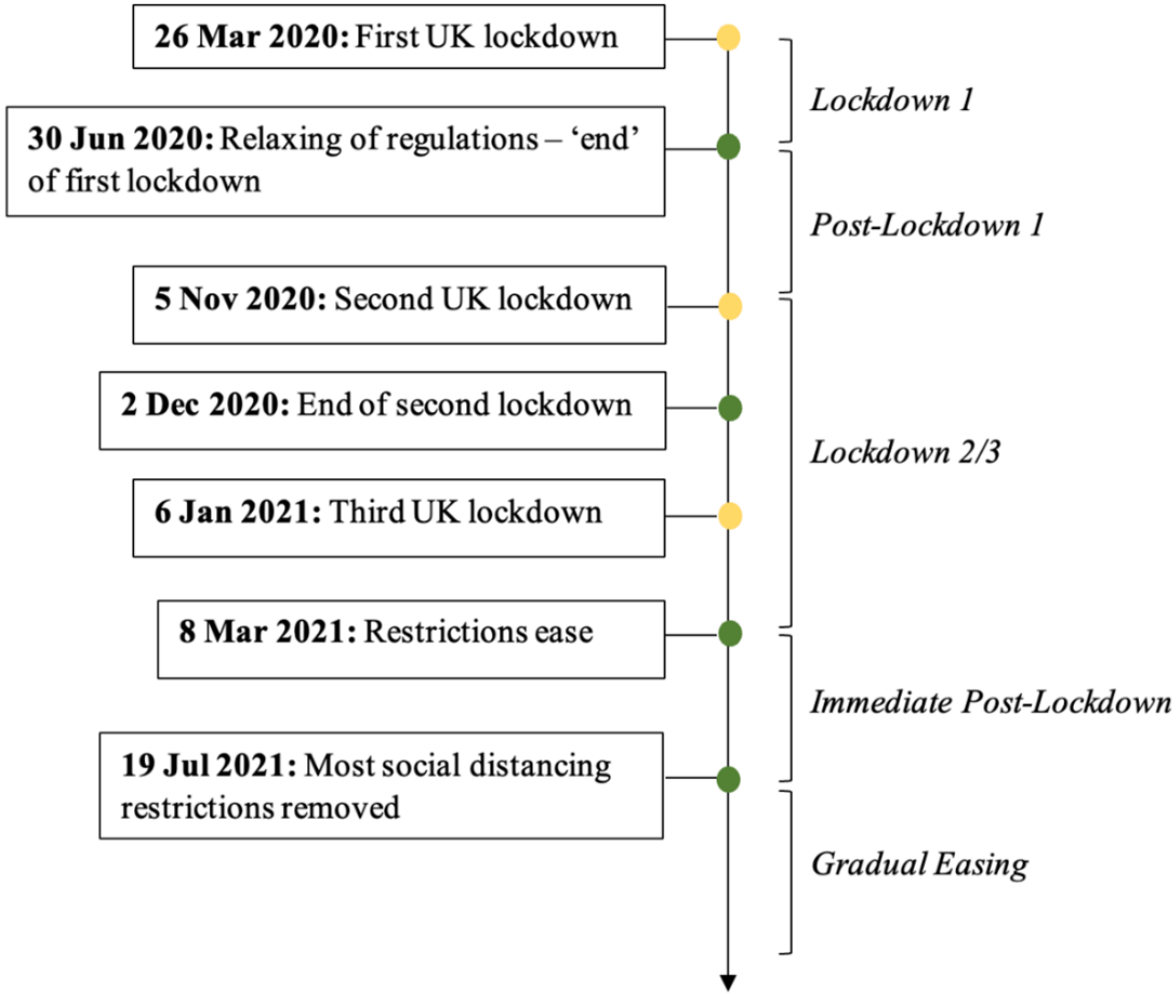
more able to cope with my situation or issue," "I feel more capable to make decisions," and "I formed/I will form a plan to make a positive change to my situation."

Predictors and Covariates

Time Period

The time and date of the helpline contact was recorded by The Mix. Using this information, 5 time periods were created to reflect the United Kingdom's COVID-19 pandemic restrictions from the Institute for Government (2022), including Lockdown 1 (March 2020-June 2020), Postlockdown 1 (June 2020-November 2020), Lockdown 2/3 (November 2020-March 2021), Immediate postlockdown (March 2021-July 2021), and gradual restriction easing (July 2021-April 2022, reference category) (see Figure 1). For the postpandemic model, the date was included as a continuous control variable (months since Lockdown 1). Consistent with this framework, we designated satisfaction and perceived impact as primary outcomes in a remote, multichannel environment where voice cues and interpersonal warmth may be diminished [33]. We additionally analyzed young people's open-ended responses to provide user-centered explanations of how service variables, such as channel delivery and time period, related to perceived outcomes.

Figure 1. Timeline of COVID-19 pandemic restrictions from March 2020 to July 2021 in the United Kingdom.



Age

Service users were asked their age during helpline contact by The Mix. Their responses were coded into 5 categories 16 - 18 years (reference category), 19 - 21 years, 22 - 24 years, 25+ years, and didn't ask/say.

Gender

Service users were asked their gender during helpline contact by The Mix. Their responses were coded into 4 categories: female (reference category), male, other, and didn't ask/say.

Ethnicity

Service users were asked their ethnicity during helpline contact by The Mix. Due to small numbers for the ethnic minorities (see Table 1), their responses were combined into a single group for analysis. There were 3 categories: White (reference category), ethnic minority, and didn't ask/say.

Helpline Channel

The helpline channel was recorded by The Mix. There were 4 helpline channels, including phone, web chat, email, and contact form (reference category).

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Overall Helpline Rating

Participants responded to the question, "How would you rate the helpline service overall?" (1=Very poor; 5=Excellent).

Open-Ended Questions

Qualitative data were obtained from three open-ended questions, "Please tell us how the service helped you," "What could we have done to support you even better?" and "How can we improve?"

Data Analysis

Quantitative Analysis

Statistical analysis was performed using R software (version 4.3.1; R Core Team). Multiple linear regression models were used to examine satisfaction and perceived impact across the fixed predictor of time, controlling for covariates. Due to the different response scales for the outcomes, models were run separately for the pandemic and postpandemic periods. Specifically, the Likert scale for satisfaction and perceived impact was modified from a 5−point scale (used in the pandemic period) to a 4−point scale (used in the postpandemic period) to simplify completion. Four regression models were constructed (2 outcomes x 2 datasets). The same reference group was selected for each categorical predictor across both datasets, including female (sex), White (ethnicity), and 16-18 years (age). For the Helpline Channel, the largest category differed between datasets, so Contact Form, the second largest in both, was chosen as the reference. For the pandemic dataset, the gradual easing phase was the reference. Interactions between time period and predictors and between demographic variables and channel use were explored in the regression models but were either nonsignificant or could not be examined due to insufficient sample sizes in each category and were therefore excluded from the final models.

Qualitative Analysis

Open-ended responses varied significantly in length and quality. To ensure meaningful thematic analysis, responses were first excluded if they met any of the following criteria (1) illogical, (2) overly vague, (3) "N/A" or "I don't know" response without elaboration. Additionally, responses solely discussing signposting were excluded as these were analyzed by another researcher on the project; our focus was the overall helpline service. Responses that indicated "no improvements necessary" (n=161) or "service did not help" (n=8) without further elaboration were also excluded, as our analysis centered on how participants felt helped and actionable insights for improvement. Of the 1183 qualitative responses, 452 responses were removed according to the exclusion criteria (40% of the total responses). In total, there were 731 responses from 486 out of 796 respondents, with approximately 60% of the sample providing at least one open-ended response.

Following the thematic analysis guidelines [29], an initial review of responses involved "active reading," where potential codes were noted. Inductive coding was then conducted in NVivo 14 (QSR International), focusing on what users found helpful or unhelpful about the service. Codes were organized into overarching themes and subthemes to ensure significance and distinctiveness. A codebook (in Section S2, Multimedia Appendix 1) was created and used for a final round of deductive coding in Microsoft Excel [32], with each response assigned up to four codes. There were disproportionately more responses from the postpandemic period (n=562) compared to the pandemic period (n=169).

Using the codebook, a second coder independently coded 20% of responses at random (n=152). Percent agreement, representing the proportion of cases where at least one code assigned matched between coders, was calculated at 87.6%. This prominent level of interrater reliability indicated consistent coding practice, enhancing the reliability of the study's findings.

Ethical Considerations

This study was approved by the University College London (UCL) Research Ethics Committee (reference 16583/003 on July 27, 2023). Participants were provided with informed consent before completing the online survey. Survey data were fully anonymized. As an incentive for participation, participants were entered into a lucky draw with the chance to win a £50 ($66.64) Amazon voucher.

Results

Quantitative Analysis

After imputation, in the pandemic sample, the mean of user satisfaction was 3.73 (SD 1.22) and the mean of perceived impact was 3.21 (SD 1.08), indicating responses between "neutral" and "agree"; in the postpandemic sample, the mean of user satisfaction was 3.31 (SD 0.87), indicating a response between "tend to agree" and "strongly agree", and the mean of perceived impact was 2.76 (SD 0.87), indicating a response close to "tend to agree".

Satisfaction and Perceived Impact During the Pandemic

Table 2 shows the statistical coefficients and significance for satisfaction with the helpline service during the pandemic period. Satisfaction was significantly greater during postlockdown 1 than during the gradual easing phase. Phone users reported higher satisfaction than contact form users, and higher overall helpline ratings were linked to greater satisfaction. The model explained 54.7% of the variance.

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Table . Regression model for user satisfaction of The Mix's mental health helplines during the COVID-19 pandemic.

Predictors	Estimate	SE	95% CI	*P* value
Intercept	0.44	0.27	–0.09 to 0.97	.10
Period				
Lockdown1	0.29	0.16	–0.03 to 0.62	.07
Postlockdown1	0.32	0.16	–0.00 to 0.64	.05
Lockdown 2/3	0.16	0.23	–0.31 to 0.64	.49
Immediate postlockdown	0.26	0.16	–0.06 to 0.58	.10
Sex				
Male	–0.11	0.14	–0.38 to 0.15	.40
Other	0.11	0.28	–0.45 to 0.68	.68
Ethnicity (minorities)	–0.07	0.12	–0.31 to 0.18	.58
Age (years)				
19-21	0.09	0.13	–0.16 to 0.34	.48
22-24	0.11	0.14	–0.17 to 0.40	.43
25+	0.28	0.19	–0.10 to 0.66	.15
Channel				
Email	0.06	0.14	–0.22 to 0.34	.69
Phone	0.44	0.19	0.06 to 0.83	.02
Web chat	0.22	0.20	–0.20 to 0.64	.29
Overall helpline rating	0.76	0.05	0.66 to 0.86	<.001
R^2 adjusted	0.547	—[a]	—	—

[a]Not applicable.

Table 3 shows the statistical coefficients and significance for perceived impact on well-being for the helpline service during the pandemic period. Perceived impact was significantly greater during postlockdown 1 and lockdowns 2/3 than during the gradual easing phase. Higher overall helpline ratings were also linked to greater perceived impact. The model explained 50.8% of variance.

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Table . Regression model for perceived impact on well-being of The Mix's mental health helplines during the COVID-19 pandemic.

Predictors	Estimate	SE	95% CI	*P* value
Intercept	0.39	0.24	–0.08 to 0.86	.10
Period				
Lockdown1	0.24	0.16	–0.08 to 0.55	.14
Postlockdown1	0.41	0.16	0.10 to 0.73	.01
Lockdown 2/3	0.46	0.18	0.10 to 0.81	.01
Immediate postlockdown	0.14	0.15	–0.16 to 0.43	.36
Gender				
Men	0.16	0.14	–0.11 to 0.43	.24
Other	0.31	0.27	–0.24 to 0.86	.25
Ethnicity (minorities)	–0.16	0.13	–0.43 to 0.11	.23
Age (years)				
19-21	0.02	0.13	–0.23 to 0.27	.87
22-24	0.19	0.12	–0.04 to 0.42	.11
25+	0.31	0.23	–0.17 to 0.79	.20
Channel				
Email	–0.02	0.15	–0.31 to 0.27	.89
Phone	0.01	0.21	–0.41 to 0.43	.95
Web chat	–0.28	0.19	–0.66 to 0.10	.14
Overall helpline rating	0.66	0.04	0.57 - 0.74	<.001
R^2 adjusted	0.508	—[a]	—	—

[a]Not applicable.

Satisfaction and Perceived Impact Postpandemic

Table 4 shows the statistical coefficients and significance for satisfaction with the helpline service postpandemic. Participants who identified as "other" in terms of their gender reported lower satisfaction than females. Overall helpline rating predicted greater satisfaction. The model explained 39.6% of variance.

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Table . Regression model for user satisfaction of The Mix's mental health helplines postpandemic.

Predictors	Estimate	SE	95% CI	*P* value
Intercept	2.01	0.48	1.03 - 2.99	<.001
Months since lockdown 1	–0.005	0.007	–0.02 to 0.01	.53
Sex				
Male	0.02	0.11	–0.21 to 0.24	.88
Other	–0.40	0.13	–0.67 to –0.13	.005
Ethnicity (minorities)	0.00	0.09	–0.19 to 0.19	.99
Age (years)				
19–21	–0.03	0.09	–0.21 to 0.15	.74
22–24	–0.11	0.11	–0.33 to 0.11	.32
25+	–0.13	0.18	–0.52 to 0.26	.48
Channel				
Contact form	–0.51	0.38	–1.28 to 0.26	.19
Email	–0.62	0.37	–1.36 to 0.12	.10
Phone	–0.39	0.47	–1.34 to 0.55	.41
Web chat	–0.38	0.38	–1.15 to 0.39	.32
Overall helpline rating	0.49	0.04	0.42 - 0.56	<.001
R^2 adjusted	0.398	—[a]	—	—

[a]Not applicable.

Table 5 shows the statistical coefficients and significance for perceived impact on well-being for the helpline service postpandemic. Participants who identified as male reported greater impact than females. Overall helpline rating predicted greater perceived impact. The model explained 41.6% of variance.

Table . Regression model for perceived impact on well-being of The Mix's mental health helplines post-pandemic.

Predictors	Estimate	SE	95% CI	*P* value
Intercept	0.62	0.40	–0.16 to 1.41	.12
Months since lockdown 1	0.003	0.01	–0.01 to 0.02	.65
Sex				
Male	0.23	0.08	0.07 - 0.40	.005
Other	–0.08	0.16	–0.42 to 0.25	.60
Ethnicity (minorities)	0.11	0.09	–0.08 to 0.30	.24
Age (years)				
19–21	0.04	0.08	–0.12 to 0.19	.65
22–24	–0.11	0.13	–0.41 to 0.18	.41
25+	0.13	0.12	–0.10 to 0.36	.27
Channel				
Contact form	–0.14	0.35	–0.85 to 0.56	.69
Email	–0.19	0.35	–0.89 to 0.50	.58
Phone	–0.08	0.43	–0.94 to 0.78	.85
Web chat	–0.01	0.35	–0.70 to 0.68	.98
Overall helpline rating	0.50	0.03	0.44 - 0.57	<.001
R^2 adjusted	0.416	—[a]	—	—

[a]Not applicable.

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Qualitative Analysis

Open-Ended Responses From Participants

There were 4 overarching themes, one theme focused on types of support and 3 themes focused on improvements involving service delivery, service protocol, and service technicalities. No differences in themes were noted between the pandemic and postpandemic periods. Table 6 provides a definition of each theme and subtheme, along with the number of times it was mentioned in the open-ended responses.

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Table . Thematic analysis of users' open-ended survey responses about The Mix's mental health helpline (N=731).

Theme	Theme definition	Subtheme	Subtheme definition	Frequency of mentions
Types of support (n=417)	Ways in which users felt helped (if they did) by the service.	• Felt heard • Someone to talk to • Better understanding of emotions and circumstances • Empowerment and direction • Timely support	• Felt listened to and supported without judgment • Felt less lonely or benefitted from talking through their issues with someone • Made sense of their emotions, or gained new perspective regarding their situation • Felt more confident, optimistic, and clear on how to seek help or move forward from their situation • Acute and timely support, practically (eg, emergency services), or emotionally (eg, calming down)	• 174 • 85 • 30 • 62 • 66
Service delivery (n=308)	Sentiments regarding the effectiveness of helpline delivery and execution by volunteers.	• Delivery and tone • Conversational elements • Rushing and rejection • Responsiveness	• Pace, tone, and phrases used by volunteers during conversation with users • Effectiveness of questions asked by volunteers and conversational practices (eg, rephrasing and repeating) • Sentiments of feeling pushed away, unheard, misunderstood, or excluded • How quickly, or whether, users received responses from volunteers (wait times)	• 73 • 38 • 99 • 98
Service protocol (n=105)	Sentiments regarding service protocol and standard practice by which the helpline is run.	• Lack of personal input and concrete support • Alternative support • Talk times	• Lack of personal opinions from volunteers and practical advice regarding solutions or action plans • Preference for longer-term follow-up support or face-to-face support • Preference for longer talk times and less restriction on chat duration	• 66 • 23 • 16

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Theme	Theme definition	Subtheme	Subtheme definition	Frequency of mentions
Service technicalities (n=80)	Sentiments regarding technical and administrative aspects of the service, including opening hours, IT matters, and advertisement.	• Opening hours • Platform functionality • Advertising	• Preference for keeping the helpline open for extended periods of time • Ensuring platforms are running without technical issues, and suggestions for improving platform functionality • Extending advertising of the service to wider audiences, and providing better/clearer information on how the service works	• 18 • 47 • 15

Types of Support

The most prevalent themes of support highlighted participants feeling heard and having someone to talk to.

Felt Heard

Participants reported feeling heard, supported, and cared for (“helped…knowing these people obviously care…[they] hear for us and support if I reach out…[this] comforted me”). Some highlighted the importance of patience and nonjudgmental attitudes of volunteers (“never felt judged or rushed”) and empathetic efforts (“counselors were trying their best to understand my situation”). This made them feel respected and validated (“felt…respected…[reassured] me that my feelings were valid”), creating a safe space for seeking comfort (“a space where I felt listened to and valued”).

Someone to Talk To

Many participants underscored the value of having someone to talk to, which made them feel less alone (“felt someone was with me when I’m alone”). They also noted the relief (“[got] things off my chest”) and perspective (“helped me to really take a step back and see more clearly”) gained from talking through their situation with a third party.

Better Understanding of Emotions and Circumstances

Some participants mentioned that talking to volunteers helped them “make sense of [their] feelings,” “see the situation more clearly,” and “understand [their] problems better.”

Empowerment and Direction

Participants occasionally mentioned feeling more optimistic (“I now have a positive outlook on life”) and hopeful (“a sense of hope and some pleasure towards the future”) after contacting the helpline. Some also expressed feeling clearer about their options (“[understood] what I could do next”) and empowered to act (“Helped me reach out to getting help”; “I felt less distressed and had a plan how to go forward”).

Timely Support

Several participants emphasized the timely intervention received, both practically (“They knew I was in danger of myself and got me immediate help from the police”) and emotionally (“[calmed] me down when I was feeling very distressed”; “Distracted me from my thoughts”). Notably, however, a few participants expressed intense dissatisfaction with contacting emergency services (“[Don’t] call the emergency services and panic my family”).

Service Delivery

The most common themes focused on responsiveness, along with participants’ experiences of feeling rushed or rejected by the service.

Delivery and Tone

A major concern was the robotic tone of volunteers. Some participants reported scripted and impersonal conversations (“[feels] like I’m speaking to a chat bot…always the same phrase”; “language seemed like…a generic template…difficult to feel understood”). Several participants suggested being “less formal,” being “a little more personal / [comforting],” and adding “some encouragement.” Participants who felt volunteers’ compassion felt heard and supported (“I felt emotionally supported…extremely thoughtful and compassionate”).

Conversational Elements

Some participants found conversations monotonous as volunteers frequently repeated what they said (“Perhaps not echo what I say back…[gets] a bit repetitive”). Additionally, some participants expressed preferences to be asked more questions, particularly regarding “roots/sources of problems, feelings or thoughts.”

Rushing and Rejection

Participants who felt rushed by volunteers felt unheard (“[could have] listened to what I was saying instead of trying to quickly end the chat”). One participant highlighted the need for improved volunteer training, as “it was all rushed and the workers “needed” to go…didn’t take me seriously.” A similar issue with signposting was raised, with some feeling unsupported (“didn’t really receive…support, just the links…without giving much more guidance”) and pushed away (“Not asked me to go somewhere else”).

Responsiveness

Participants frequently expressed frustration with slow response times (“reply time could be a bit quicker”) or receiving no response (“no one got back to me”). Email users seemed

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particularly dissatisfied, noting neglect of follow-up emails ("actually respond to my second email???"). However, a few participants reported prompt responses ("far quicker than I thought"), which were crucial for vulnerable individuals ("responses…was hasty, which was important in my state at the time").

Service Protocol

The most prominent theme centered on volunteers' limitations in offering personal input and practical support.

Lack of Personal Input and Concrete Support

A portion of participants expressed preferences for receiving input from volunteers ("Would've appreciated more input from the agent…repetition of my messages…made me feel worse"). Additionally, several participants suggested providing practical support in the form of grounding techniques and action plans ("[Teach] breathing exercises"; "More help with creating a plan of action").

Alternative Support

Some participants commented that follow-up checks ("Check in a few days after to see if things improved") and offline support ("an office people can go to") could be valuable improvements to current support.

Talk Times

A small subset of sentiments emerged postpandemic, expressing preferences for longer conversations ("Let people talk for longer") and frustrations with talk-time restrictions ("didn't even finish the conversation …time ran out which frustrated me").

Service Technicalities

The most prevalent theme related to platform functionality issues, along with suggestions for improvement.

Opening Hours

Several participants suggested extended opening hours would be useful ("have the web chat open longer on the weekends and during the week"), especially into the night ("Keep the lines open till 12").

Platform Functionality

Some participants encountered technical web chat issues ("[it] cut off"). Others highlighted that "the chat [was] offline even during open hours." Suggestions included providing pre-emptive notifications if the helpline was busy ("helpful…to have made it clear on the site that this might sometimes happen"). Other proposed improvements included implementing a "traffic light system" for waiting and providing "more specific" information about queue status.

Advertising

A few participants highlighted the need for clearer advertising regarding the services offered, suggesting to "mention on the website what to expect" and "the time period [given]." Additionally, there were suggestions for increased promotion to reach a wider audience ("more promotion…dug quite deep to find this...more people could use this").

Discussion

Principal Findings

Using cross-sectional survey data collected by The Mix from 2020 to 2023, this mixed methods study provides insights into how young people's experiences with the services varied according to lockdown restrictions (pandemic period only), their demographic characteristics, and the channel of delivery used to access the services. During the pandemic, young people's average responses ranged from "neutral" to "agree" regarding their satisfaction with the helpline service and their perception that it supported their well-being. In this period, young people reported greater satisfaction with the helpline postlockdown 1, and a stronger impact on their well-being postlockdown 1 and during lockdowns 2 and 3 compared with the period of gradually easing restrictions; phone users also reported higher satisfaction with the helpline compared to contact form users. Postpandemic, young people's average satisfaction with the helpline service exceeded the "tend to agree" threshold, while their perception that it supported their well-being was slightly below that level. In this period, helpline users who identified as "other" in terms of their gender reported lower satisfaction, while male users reported greater impact compared to female users. Thematic analyses offered deeper insight into ways in which participants felt supported and identified areas where participants felt there could be improvement.

Satisfaction and Perceived Impact During the Pandemic and Postpandemic

These findings—higher satisfaction after the first lockdown and greater perceived impact after the first, second, and third lockdowns compared with the gradual easing period—may reflect the additional measures The Mix implemented to meet increased demand. These measures included recruiting more volunteer counselors and extending the helpline's operational hours by 2 hours each day. As a result, The Mix's helpline saw a 14% increase in the number of contacts accepted since March 2020 [11], in line with evidence of pandemic-related surges in helpline demand across services [37]. This highlights the importance of helpline services being responsive to the greater mental health needs of young people during crisis periods.

This study also revealed differences in users' reported outcomes according to helpline channel. During the pandemic, phone users reported higher satisfaction than contact form users, potentially due to the nature of interaction. One helpline study [38] underscored the value of human connection in helpline support, where a volunteer's voice can convey warmth and reassurance, an element absent in contact forms. This verbal support could have been especially valuable during a time of heightened loneliness and social isolation for young people [13], especially as there was no difference in reported outcomes between channels during the postpandemic period.

In terms of demographic characteristics of the users, the sample remained predominantly female and White across periods. Postpandemic, there was a modest shift in gender composition, with the proportion of males increasing to 20.6% and those who

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identified as "other" in terms of their gender increasing by 8%. In postpandemic models, participants identifying as "other" reported lower satisfaction than females, while males reported greater perceived impact than females. The reasons explaining these statistical trends are unclear, however. Nevertheless, absolute numbers for some groups remain comparatively small—particularly minority ethnic youth (22.8% postpandemic) and the "other" gender category—limiting precision for subgroup and intersectional analyses; larger, targeted samples are needed to draw firmer conclusions, along with in-depth qualitative interviews to understand quantitative patterns.

While helplines have been recognized for their role in supporting minority groups, including Black and minority ethnic individuals, who are less likely to seek support through traditional avenues [15,39], our findings did not reveal any ethnic differences in satisfaction or perceived impact during the pandemic or postpandemic periods. This may be due to the small numbers of minority-ethnic respondents, which limited statistical power and widened confidence intervals, making modest differences hard to detect.

As expected, a strong relationship emerged between the young people's overall helpline rating and their reported satisfaction and perceived impact of the helpline during both the pandemic and postpandemic periods. When users had a positive overall experience, they reported higher satisfaction levels and felt the service had a greater impact on their mental well-being. This finding underscores the importance of understanding young people's experiences with the helpline, as these perceptions are key to supporting their mental health, in line with evidence that perceived helpfulness/satisfaction is associated with immediate reductions in distress and with the perceived effectiveness of crisis interventions [40]. Qualitative data offers further insight into these experiences. The next section explores key themes from young people's open-ended responses, linking these insights to the quantitative findings. It highlights their preferences for support and identifies opportunities to improve services.

Open-Ended Responses From Participants

Our thematic analysis highlighted multi-faceted benefits of the helpline for young people facing mental health challenges, aligning with previous findings [15]. Participants valued feeling heard and having someone to talk to and reported improved coping abilities and clarity about their emotions and circumstances. These benefits were described to alleviate loneliness, distract from unhealthy tendencies, and prompt further help-seeking behavior in the future with users of an eating-disorder helpline. Such support may have been particularly valuable in the context of social isolation during the pandemic, reflected in the quantitative findings showing higher perceived impact and a preference for the telephone helpline versus the contact form during this period. Additionally, while opinions on the involvement of emergency services were mixed, participants appreciated timely intervention by the helpline, ensuring participants were supported during emotional distress and kept safe from dangerous behaviors.

Nonetheless, participants identified several areas for improvement within the helpline service. Many emphasized the need to address variable service delivery standards, noting that some interactions felt robotic and impersonal, and they sometimes felt rushed and rejected by volunteers. This feedback aligns broader user perspectives on helpline services, which highlight the importance of a volunteer's engagement—especially through active listening—as crucial for user satisfaction and positive outcomes [41]. Participants' strong preference for a service that feels more personal and empathetic suggests that the higher satisfaction reported by phone users may stem from voice-based interactions, which likely conveyed more warmth and reassurance through vocal cues [42].

Concerns regarding service availability and responsiveness were also significant factors for young people seeking immediate support. Participants mentioned preferences for extended operating hours, aligning with research indicating user preferences for round-the-clock availability [43]. One suggested focusing on critical times, which could be after 11 PM when young people are more likely to seek help online [44,45]. Additionally, implementing a traffic light system on the website to indicate wait times was recommended, which could alleviate anxiety and frustration during busy periods by providing clearer estimates [46].

Young people also expressed the need for wider and clearer advertising to reach potential users. The volunteer-staffed nature of The Mix is central to its ability to provide low-threshold, nonclinical support. However, this model warrants critical evaluation in the context of outcomes. Future service evaluations should include operational metrics on volunteer retention and training consistency and link these directly to user-reported outcomes to ensure the model remains both scalable and high-quality.

Although the helpline was recognized as a valuable resource, participants noted it was not easily accessed or well-promoted. Transparency regarding the helpline's role was also emphasized, particularly the need to communicate that personal advice cannot be provided, as many were disappointed by the lack of advice provided during their experience. The idea of offering practical support was mentioned. For instance, a few participants suggested providing grounding techniques, which can be delivered by nontherapists [47]. Although mentioned less frequently, the exploration of follow-up and in-person support options could be valuable in addressing unmet needs for those seeking more comprehensive assistance.

Limitations

This study has several limitations, which must be considered in light of the findings. First, the sample was predominantly female and White, potentially underrepresenting males and minorities. Due to the small sample size, specific gender and ethnic groups were collated and not examined separately. Additionally, chi-square tests indicated differences in helpline channel usage between excluded and included participants, suggesting potential underrepresentation of email users, especially in the postpandemic sample. Survey representativeness is a common issue in online helpline research due to confidentiality, limiting sampling strategies [27]. Nevertheless, this study highlights the tendency to overlook

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underrepresented groups in helpline research, aligning with existing critiques [28], emphasizing the significant need for further research focused on these populations. Addressing this gap is crucial, as these groups are frequently described as having both the potential and the need to benefit from such services [15].

Another key limitation of this cross-sectional study is its reliance on a self-administered survey embedded within a service context, which yielded a low completion rate across the full user population. This introduces a substantial risk of non-response bias, potentially limiting the generalizability of our findings. Although we addressed missing data using MICE, we acknowledge that the absence of statistical weighting constrains our ability to fully account for differential response patterns.

Furthermore, the regression models were limited by the reliance on service data, which had several limitations, including the lack of psychometrically robust measures and volunteer bias. This also meant a lack of key clinical confounders (eg, prior mental health history, clinical severity, or specific contact reason) to include in the statistical models. Consequently, the findings should be viewed as exploratory associations. Finally, a major methodological constraint is the nonstandardized change in the Likert scale for satisfaction and impact (from a 5-point to a 4-point scale) between the two time periods; this difference precludes direct statistical comparison of mean scores across the pandemic and postpandemic periods.

In the qualitative component, the systematic exclusion of a large proportion of open-ended responses, while necessary to maintain the integrity of the thematic analysis, is a source of potential selection bias, which may restrict the diversity and trustworthiness of the qualitative themes. Similarly, qualitative data was unevenly distributed between pandemic and postpandemic periods, potentially underrepresenting pandemic-period sentiments. This uneven distribution made it difficult to map thematic insights to specific periods, limiting our understanding of the most relevant issues. Future research should involve in-depth interviews with purposefully sampled users to better understand their expectations and experiences with the helpline services and their suggestions for improvement.

Finally, the lack of prepandemic data limited our ability to compare helpline experiences across prepandemic, pandemic, and postpandemic periods. Such comparisons could have illuminated the pandemic's impact on helpline experiences and whether user satisfaction and impact returned to prepandemic levels or established a new normal. Finally, the reliance on self-report for both satisfaction and perceived impact means the observed correlation may be inflated due to shared method variance, warranting caution in their interpretation.

Conclusions

This study highlights the perceived positive impact of helplines in supporting young people's mental health, particularly during the pandemic, which saw surges in contacts surrounding anxiety, depression, and loneliness [26] alongside disrupted mental health services. During the pandemic, phone calls, offering a more personal connection, were linked to greater satisfaction than contact forms. These findings suggest a need for further research into channel preferences to align services with users' needs better and optimize resource allocation. Qualitative themes contextualized the quantitative patterns: young people highlighted timeliness, continuity, channel fit, and empathic, validating conversations as central to feeling helped, suggesting concrete targets for service improvement.

Key areas for improvement were identified, including service delivery, protocol, and technicalities. Based on the qualitative feedback regarding access difficulties during crises and the observed decline in postpandemic satisfaction, mental health helplines for young people should prioritize extending hours of operation for digital channels to ensure service continuity during nontraditional hours, alongside implementing a clearer queue system as suggested by young people. The frequent qualitative theme regarding the need for warmer and less scripted communication directly informs the need to enhance volunteer training in reflective listening and emotional validation, particularly for web chat modalities where nonverbal cues are absent. Addressing these areas is vital to ensuring helplines remain an accessible bridge to more comprehensive mental health support, thus improving overall experiences and enhancing satisfaction and perceived impact. Overall, the findings reinforce the value of helplines as interim support for young people awaiting professional care, offering critical, emotional, and informational support in times of need.

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Data Availability

Data sharing is not applicable to this article as no data sets were generated during this study. Rather, secondary data analysis was conducted via survey data provided by Mental Health Innovations.

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Conflicts of Interest

None declared.

Multimedia Appendix 1
Helpline feedback survey from The Mix.
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Checklist 1
Strengthening the Reporting of Observational Studies in Epidemiology checklist v4 combined Plos Medicine.
[PDF File, 925 KB - formative_v10i1e68507_app2.pdf]

Checklist 2
Consolidated Criteria for Reporting Qualitative Research checklist.
[PDF File, 379 KB - formative_v10i1e68507_app3.pdf]

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Abbreviations

COREQ: Consolidated Criteria for Reporting Qualitative Research
MICE: Multiple Imputation by Chained Equations
STROBE: Strengthening the Reporting of Observational Studies in Epidemiology

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Digital Health Communication and Vaccine Confidence in Mexico Using Aggregated Randomized Brand Lift Studies: Secondary Analysis

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Abstract

Background: Digital vaccination campaigns are increasingly used to address declining vaccine confidence, yet evidence from large-scale, real-world interventions in middle-income countries is limited. Meta's Brand Lift Studies (BLS), which use randomized test-control exposure, provide Bayesian estimates of attitudinal shifts resulting from digital content. Mexico, with over 88.6 million active internet users, provides a setting to evaluate the impact of targeted campaigns on vaccine attitudes.

Objective: This study evaluated the impact of 5 digital vaccination campaigns implemented by the Asociación Mexicana de Vacunología (@Vacunologia) on Facebook (Meta Platforms Inc) and Instagram (Meta Platforms Inc) in Mexico between 2021 and 2022 on key attitudinal constructs related to COVID-19 vaccine confidence.

Methods: This study used a retrospective ecological design. We analyzed aggregated BLS results for 5 campaigns targeting different audiences and vaccination themes. Measured outcomes included standard ad recall, perceived importance, perceived safety, perceived efficacy, and concerns about side effects. Statistical significance within the BLS framework was defined as an incremental lift of ≥2 percentage points with ≥90% posterior probability of replication—a threshold consistent with Meta's operational Bayesian approach. Exploratory comparisons across campaigns were conducted using 1-way ANOVA, unpaired 2-tailed *t* tests, and Fisher exact tests.

Results: Campaigns reached 84.9 million accounts and generated 179.4 million impressions with a total investment of US $215,600. All campaigns produced statistically significant improvements in at least one attitudinal outcome (Bayesian threshold ≥90%). Standard ad recall increased in 4 campaigns (ANOVA, $P<.001$), and concerns about side effects decreased in 2 campaigns (*t* test, $P=.049$; $P=.006$). Perceived safety, importance, and efficacy improved in selected audiences, with stronger effects observed among younger users and women (ANOVA, $P=.005$). No direct behavioral outcomes (eg, vaccination uptake) were measured; therefore, the findings reflect attitudinal rather than behavioral change. However, these constructs are recognized as proximal predictors of vaccine decision-making and constitute health-related outcomes.

Conclusions: Large-scale digital vaccination campaigns can meaningfully strengthen attitudinal determinants of vaccine confidence in a middle-income context. These social media advertising campaigns effectively increased standard ad recall and improved perceptions of vaccine importance and safety, particularly among younger audiences and women in urban areas. However, changes in efficacy perceptions and concerns about side effects were limited. The innovation and implications of this study lie in evaluating large-scale, real-world digital vaccine campaigns in Latin America using experimental BLS data. Findings

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highlight that audience segmentation yields stronger perceptual shifts, suggesting that tailored digital strategies can complement traditional public health communication. While the BLS does not measure behavioral end points, the observed attitudinal improvements represent foundational steps toward influencing vaccine-related behaviors. Future work should link digital attitudinal metrics with vaccination and epidemiological data to assess real-world health impact.

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KEYWORDS

COVID-19 vaccine; health behavior; health communication; social media; vaccination coverage; Mexico; health promotion; vaccine confidence; Bayesian analysis; digital health interventions; vaccine acceptance; public health messaging

Introduction

Vaccination is one of the greatest achievements of the 20th century, yet vaccine hesitancy and delayed uptake remain persistent public health challenges [1]. In March 2020, the World Health Organization (WHO) declared COVID-19 a pandemic, and the approval of the first vaccines in December 2020 was expected to mitigate its impact [2]. However, ensuring widespread acceptance required effective communication strategies to address doubts and misinformation.

During the pandemic, social media emerged as a critical channel for rapidly disseminating health information, enabling governments and organizations to reach large audiences with targeted messages [3]. Globally, more than 3.5 billion people use social media, spending an average of 3 hours per day on these platforms [4]. In Mexico, in 2021, there were 88.6 million internet users (75.6% penetration) of the population aged 6 years or older [5]. This makes Mexico a unique setting to evaluate the effectiveness of digital campaigns in shaping vaccine-related perceptions.

Evidence on digital health interventions suggests that campaigns with greater frequency, interactivity, and feedback are more effective in influencing attitudes and behaviors [4]. A Cochrane review of interventions to increase COVID-19 vaccine acceptance found heterogeneous strategies, with communication interventions being the most common, but highlighted gaps in studies from low- and middle-income countries (LMICs) [2]. Similarly, a meta-analysis of over 800 digital public health experiments showed that online advertising can shift beliefs and attitudes about COVID-19 and may represent a cost-effective approach to increasing vaccination rates [3].

Digital health communication on social media exerts a complex and multifaceted impact on vaccine confidence, with both positive and negative effects documented in the medical literature.

Large-scale randomized experiments of public health social media campaigns targeting COVID-19 vaccination have demonstrated that such interventions can modestly improve vaccine-related beliefs and knowledge, with measurable effects on self-reported attitudes and behaviors. For example, targeted social media advertising was shown to shift vaccine-related opinions and increase knowledge about vaccine access, with an estimated cost-effectiveness for influencing vaccination rates [3]. Systematic reviews of randomized controlled trials further support the potential for social media platforms to disseminate quality-assured information and increase vaccine uptake, but emphasize that the overall effect is variable and often nonsignificant, highlighting the need for careful moderation and integration with other communication strategies [6].

Conversely, observational and qualitative studies consistently report that social media is a major vector for the spread of vaccine misinformation and hesitancy. Thematic analyses of social media content and epidemiological survey responses reveal that social media interactions can perpetuate distrust in vaccine safety, skepticism about efficacy, and ideological isolation, particularly when algorithms amplify echo chambers and misinformation [7-9]. Heavy reliance on social media as a primary news source is associated with increased vaccine hesitancy, especially regarding beliefs that COVID-19 risks are exaggerated or that vaccines are unsafe [8,9]. The influence of social media is especially pronounced among individuals with lower news literacy, who are more susceptible to skepticism and hesitancy [9].

The impact of social media varies by platform and user characteristics. For instance, among mothers of adolescents, uncertainty about the veracity of social media messages is associated with increased human papillomavirus vaccine hesitancy, while Facebook (Meta Platforms Inc)-specific influence was negatively associated with hesitancy, suggesting that platform-specific dynamics and content moderation may play a role [10]. Additionally, unvaccinated individuals are more likely to report social media and messenger services as persuasive sources compared to vaccinated individuals, underscoring the importance of targeted science communication to counteract misinformation [11].

Social media analytics have also been shown to correlate with real-world vaccine uptake rates, suggesting that monitoring online sentiment can provide actionable insights for public health interventions, even if self-reported vaccine acceptance does not always align with actual behavior [12].

Despite the rapid expansion of digital communication during the COVID-19 pandemic, very few studies have evaluated the real-world impact of large-scale social media campaigns on vaccine perceptions in LMICs. Most existing evidence comes from high-income settings, leaving a gap in understanding how digital interventions perform in diverse populations with varying levels of vaccine hesitancy and information access. Mexico, with its high social media penetration and persistent challenges in vaccine confidence, represents a critical context to examine whether targeted digital campaigns can shift perceptions related to vaccination. This study addresses that gap by analyzing

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experimental Brand Lift data, offering empirical evidence from a region where such evaluations remain scarce.

This study addresses these gaps by evaluating 5 large-scale social media advertising campaigns conducted by the Asociación Mexicana de Vacunología (@Vacunologia) on Facebook and Instagram (Meta Platforms Inc) between 2021 and 2022. Using anonymized, aggregate-level data from Meta's Brand Lift Studies (BLS), we assess the campaigns' impact on standard ad recall and on perceptions of the importance, safety, efficacy, and side effects of COVID-19 vaccines. Importantly, this study does not measure actual vaccination uptake, but rather attitudinal and perceptual shifts that serve as precursors to behavior. By analyzing real-world campaigns in a middle-income country, this research contributes novel evidence on the role of digital media in public health communication in Latin America.

Decision-making regarding vaccines and other health topics is complex and influenced by multiple factors such as personal beliefs, experiences, and external influences. Effectively shifting attitudes toward vaccines requires sustained communication efforts across various levels—personal, community, and institutional.

Therefore, the objective of this study is to evaluate the effectiveness of 5 social media advertising campaigns on COVID-19 vaccination conducted in Mexico through Facebook and Instagram. Specifically, we aim to assess their impact on standard ad recall, perceived importance, safety, efficacy, and concerns about side effects, and to determine which audiences (by age and sex) were most responsive. Our working hypothesis is that targeted campaigns, particularly those directed at younger populations and women, would generate stronger positive shifts in vaccine-related perceptions compared to general population campaigns.

Methods

Research Design

We conducted a retrospective ecological analysis using anonymized, aggregated data from 5 BLS implemented by Meta on Facebook and Instagram. BLS are randomized ad-exposure experiments embedded within the social media platform, where users are automatically assigned to test (exposed) or control (unexposed) conditions. Because no individual-level longitudinal data, identifiers, or person-level outcomes are produced, this study does not constitute a retrospective cohort or case-control design. All analyses were performed using the aggregate outputs supplied by Meta.

Participants

All BLS results are aggregated and anonymized. BLS results for Meta are disaggregated by age and sex. Each audience member is likely to be presented with only 1 question in their newsfeed. This implies that all creative content should align with the BLS questions, as there is no control over which creative or question they will encounter. Facebook considers any Brand Lift result that shows a 2 percentage point or higher increase with at least a 90% probability of a Brand Lift to be statistically significant. Below are several questions to consider if a Brand Lift result greater than 2 percentage points is observed.

For the implementation of the BLS programs, an agreement was signed for the "Scaled Program Support" Program Participation between Facebook Inc and Asociación Mexicana de Vacunología.

The results provided by Facebook do not contain personal information about the users; they are only statistics about the BLS as presented in Tables 1-3, which were used to obtain the statistical results. The data were obtained by the BLS tools of Facebook Inc, in accordance with its privacy policies [13]. Table 1 summarizes problem statements, behavior change and communication goals, target audiences, survey questions, advertising objectives, campaign duration, and investment.

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Table . Characteristics of 5 Brand Lift Studies to promote COVID-19 vaccination in Mexico, 2021 - 2022.

Category	Campaign 1	Campaign 2	Campaign 3	Campaign 4	Campaign 5
Problem statement	• There are a large number of people in Mexico who are still undecided about getting a COVID-19 vaccine.	• According to recent data from the Data for Good survey, there are a large number of women in Mexico who are still undecided about getting a COVID-19 vaccine.	• There are people who travel in Mexico who are still undecided to take the COVID-19 vaccine booster.	• There are people in Mexico who have doubts about the effectiveness and safety of the COVID-19 vaccine booster.	• There are people in Mexico who have doubts about the COVID-19 vaccine booster if it works, especially to prevent serious diseases.
Behavior change goal	• Get the COVID-19 vaccine	• Get the COVID-19 vaccine	• Get the COVID-19 vaccine booster	• Get the COVID-19 vaccine booster	• Get the COVID-19 vaccine booster
Communications goal	• Decrease COVID-19 vaccine hesitancy in Mexico	• Increase confidence in vaccination	• Increase confidence in vaccination	• Increase confidence in vaccination	• Increase confidence in vaccination
Campaign target audience	• Age range: >18 • Gender: All • Geography: All of Mexico	• Age range: 18 - 44, • Gender: Women • Geography: Ciudad de México; Puebla; Guadalajara, Monterrey	• Age range: >18 • Gender: All • Geography: All of Mexico	• Age range: >18 • Gender: All • Geography: All of Mexico	• Age range: >18 • Gender: All • Geography: All of Mexico
Questions	• Recall: Do you recall seeing an ad for COVID-19 vaccines from @Vacunologia online or on a mobile device in the past 2 days? • Importance: How important do you feel a vaccine is to prevent COVID-19? • Safety: How safe do you think a COVID-19 vaccine is for people like you?	• Recall: Do you recall seeing an ad for COVID-19 vaccines from @Vacunologia online or on a mobile device in the past 2 days? • Side effects: How concerned are you about the potential side effects of a COVID-19 vaccine? • Safety: How safe do you think a COVID-19 vaccine is for people like you?	• Recall: Do you recall seeing an ad for COVID-19 vaccines from @Vacunologia online or on a mobile device in the past 2 days? • Safety: How safe do you think a COVID-19 vaccine is for people like you? • Importance booster: How important do you think the booster dose of the vaccine is to protect against COVID-19? • Efficacy: How effective do you think a COVID-19 vaccine booster is in protecting against COVID-19?	—[a]	—[a]
Campaign advertising objective	• Reach	• Page likes	• Reach	• Reach	• Reach
Duration	• June 6 to June 30, 2021	• September 10 to October 5, 2021	• June 16 to August 7, 2022	• June 16 to August 7, 2022	• June 16 to August 7, 2022

[a]These questions are also applicable to campaigns 4 and 5.

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Table . Results of 5 Brand Lift Studies evaluating COVID-19 vaccination campaigns on Facebook and Instagram in Mexico, 2021 - 2022.

BLS[a] metrics	1	2	3	4	5
Campaign advertising objective	Reach	Page likes	Reach	Reach	Reach
Duration (days)	22	25	54	54	54
Investment (US $)	14,800	14,920	58,708	58,708	68,493
Reach	18.3 million	1.9 million	21.5 million	21.4 million	21.6 million
Average frequency	2.4	7.7	1.7	1.7	1.7
Impressions	44.7 million	15 million	37.2 million	37.1 million	45.1 million
CPM[b] (US $)	0.3	0.9	1.5	1.5	1.4
Standard ad recall	2.1	11.6	3.8	2.6	−0.6
Importance	2.6	—[c]	2.7	1.4	3.2
Safety	0.3	2.4	−1.1	1.3	1.5
Side effects	—	−0.6	—	—	—
Efficacy	—	—	0.9	1.1	1

[a]BLS: Brand Lift Studies.

[b]Cost per thousand impressions.

[c]Not applicable.

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Table . Results of 5 Brand Lift Studies on COVID-19 vaccination campaigns in Mexico, 2021 - 2022, stratified by sex and age group.

Sex and age group	Female, 18 - 24	Male, 18 - 24	Female, 25 - 34	Male, 25 - 34	Female, 35 - 44	Male, 35 - 44	Female, 45 - 54	Male, 45 - 54	Female, 55 - 64	Male, 55 - 64	Female, ≥65	Male, ≥65
Campaign 1												
Standard ad recall	+1.3	+5.9[a]	+2.6	−2.0	−0.6	+5.9[b]	+2.5	+3.0	+3.0	−2.1	+3.8	+6.0[b]
Importance	+2.6[b]	+1.5	+5.3[a]	+4.0[a]	+3.0[b]	+2.5[b]	+0.0	+1.2	+0.6	−0.8	−0.5	+0.5
Safety	−1.0	−1.6	−0.7	+3.2[b]	+1.1	+0.2	−1.0	+1.1	−0.0	+0.3	+1.0	+0.2
Campaign 2												
Standard ad recall	+6.7[a]	—[c]	+13.1[a]	—	+12.7[a]	—	—	—	—	—	—	—
Side effects	−0.4	—	+0.3	—	−2.4	—	—	—	—	—	—	—
Safety	+3.4[a]	—	+2.5[b]	—	+1.5	—	—	—	—	—	—	—
Campaign 3												
Standard ad recall	+3.2[b]	+5.0[a]	+3.7[b]	+2.6	+5.1[b]	+3.9[b]	—	—	—	—	—	—
Safety	−1.3	−0.7	+1.4	−0.7	−4.0	−3.3	−2.6	+0.1	—	—	—	—
Importance	+5.0[a]	+0.8	+5.5[a]	−0.6	+0.9	+4.6[a]	+1.0	+1.4	—	—	—	—
Efficacy	+2.5[b]	+3.1[b]	+0.1	+1.9	−4.4	+0.1	+1.4	+0.8	—	—	—	—
Campaign 4												
Standard ad recall	+5.0[a]	−3.5	+5.6[a]	+2.4	+2.1	+3.5	+4.9	—	—	—	—	—
Safety	+1.2	−2.4	+5.1[a]	+3.2[b]	+0.1	−1.6	−0.4	+1.2	—	—	—	—
Importance	+3.3[a]	+3.4[b]	−0.7	+1.4	+1.7	−1.2	−0.3	+1.1	—	—	—	—
Efficacy	+0.1	+0.5	+3.8[a]	+3.1[b]	−3.8	+1.2	+1.3	−3.6	—	—	—	—
Campaign 5												
Standard ad recall	−1.2	+1.6	−1.9	−0.4	−0.2	−2.2	+2.2	+3.6	—	—	—	—
Safety	+4.9[a]	−2.7	+3.5[a]	−0.3	+1.1	+2.5	+0.8	+1.5	—	—	—	—
Importance	+4.9[a]	+1.0	+3.8[a]	+3.9[a]	+4.0[a]	+0.4	+3.4	+1.2	—	—	—	—
Efficacy	+1.3	+2.3	+0.5	+3.7[a]	−1.6	−2.3	−0.7	+1.7	—	—	—	—

[a]90% or greater chance that the increase is caused by Brand Lift.

[b]80% or greater chance that the increase is caused by Brand Lift.

[c]Not applicable.

The Asociación Mexicana de Vacunología A.C. accepted and approved the use of the results of the BLS performed for the realization of this study.

The Asociación Mexicana de Vacunología (@Vacunologia) participated in Facebook's 2021 and 2022 Scaled Workshop Social and Behavior Change Communication (SBCC) Program.

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As part of this program, the Asociación Mexicana de Vacunología received Facebook Ad Credits and support to conduct a public health campaign on Meta. The campaign characteristics are detailed in Table 1.

We analyzed information from 5 BLS conducted by the Asociación Mexicana de Vacunología on Facebook and Instagram (@Vacunologia). BLS are experimental tools developed by Meta to evaluate the impact of advertising campaigns independently of other marketing activities. They work by randomly dividing a representative sample of eligible users into 2 groups: a test group, which is exposed to the ads, and a control group, which is not. Both groups are then asked standardized poll questions, and the difference in responses indicates the incremental effect, or "lift," attributable to the campaign [14].

Randomization and audience segmentation are performed automatically by Meta's platform, using predefined targeting criteria such as age, sex, location, or interests. This design ensures internal validity and allows causal inference about the effect of ad exposure [15]. Lift is reported as the percentage point difference between the test and control groups, accompanied by a confidence estimate. Outcomes typically include awareness, recall, or perceptions related to the advertised content.

The study population consisted of adult Facebook and Instagram users in Mexico who were eligible to be exposed to the campaigns according to predefined targeting criteria (eg, all adults nationwide, or women aged 18 - 44 years in major cities). Randomization was performed automatically by Meta's BLS platform at the user ID level, assigning individuals to either the test group (with the opportunity to see the ads) or the control group (withheld from exposure). This design ensured balance between groups and minimized systematic differences at baseline. The only demographic variables available for analysis were age group and sex, which were provided in disaggregated form in the BLS reports. Because the data were anonymized and aggregated, no additional covariates were accessible.

Sampling Procedures

Overview

There are different types of lift tests: Conversion Lift (sales, leads, and engagement), Brand Lift (awareness and attitudes), and Experiments (custom questions on brand or campaign objectives) [16]. In our case, the BLS measured outcomes relevant to vaccination, such as standard ad recall, perceived importance, safety, efficacy, and concerns about side effects. These results—whether positive or negative—provide valuable insights into the effectiveness of digital communication strategies for vaccines.

In this study, the conversion rate was defined as the proportion of respondents in each group who provided a positive response to a BLS survey item. The expected conversion rate was estimated from the control group's responses, representing the baseline that would have been observed in the test group without ad exposure. Lift was calculated as the difference between the observed conversion rate in the test group and the expected rate from the control group, with ≥2 percentage points and ≥90% probability considered statistically significant.

Lift is widely used because it offers a standardized way to compare campaigns across contexts. Formally, it represents the relative change in outcomes among exposed users compared to the expected rate had they not been exposed. However, when baseline rates are very low, even small absolute differences can produce large lift values, which may overstate effectiveness. Despite this limitation, lift remains an informative indicator of advertising performance, particularly in digital public health interventions where direct behavioral outcomes (eg, vaccination uptake) are difficult to measure [17].

The BLS survey included 2 types of questions depending on the construct being evaluated. The recall question offered 3 response options: Yes, No, and I am not sure. In contrast, questions assessing perceived importance, safety, side effects, and efficacy were based on 5-point Likert-type scales. For example, the safety perception item included the options: Very safe, Somewhat safe, Slightly safe, Not safe, and I don't know. Depending on the specific construct, the term "safe" was replaced with "important," "effective," or the corresponding attribute. Changes in responses were categorized as either positive or negative shifts in perception, depending on whether the response moved toward or away from more favorable attitudes (eg, from "Somewhat safe" to "Very safe" vs from "Very safe" to "Not safe"). These directional changes were interpreted as proximal indicators of positive or negative behavior change, consistent with established frameworks in behavioral science.

Measures

The Meta reports use the Basic Bayesian Lift methodology, which provides estimates of confidence rather than *P* values. The Basic Bayesian results closely resemble frequentist results but offer confidence estimates. The observed difference between the control and test groups, not attributed to chance but instead attributed to a greater than 90% chance of Brand Lift being observed, is considered to have high confidence. If the ad were shown to a random sample of the target audience, there would be a 90% likelihood of observing the same lift from the control to the test group.

Several factors are taken into consideration when determining the chance of Brand Lift being observed, including the number of respondents answering the question (test group sample size), control response rate (control group sample size, often referred to as "base"), and the size of the lift (difference between control and test group scores). As the sample size increases for both groups, the scores become more stable. With more stable scores, smaller differences can be confidently declared as statistically significant.

The Bayesian statistical method is generally equivalent to frequentist statistical methods in most cases but offers a more conservative measure of confidence when there are known sources of bias or systematic errors. Therefore, observing any statistically significant positive shift (a "lift" of 2 percentage points or more) in vaccine attitudes as a result of an online

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campaign alone is a significant achievement and worthy of celebration.

In this study, we present the results provided by the Meta company. The outcomes measured were: (1) standard ad recall, (2) perceived importance of vaccination, (3) perceived safety, (4) perceived efficacy, and (5) concerns about side effects. These were assessed through BLS poll questions. No direct behavioral outcomes (eg, actual vaccination uptake) were available. Because Meta's BLS provide only aggregated, anonymized summary data, the dataset contained no item-level missing data. Each respondent is randomly assigned a single survey question, meaning that the number of observations varies across constructs and demographic subgroups by design. Therefore, the smaller n's observed in certain cells reflect the structure of the BLS survey, not missing or incomplete responses.

Analytic Strategy

Statistical analyses included 1-way ANOVA to compare mean scores across campaigns, unpaired *t* tests for sex differences, and Fisher exact tests to examine associations between campaign characteristics and the probability of achieving a Brand Lift (≥80% or ≥90% confidence). Bayesian confidence estimates from Meta's BLS are not equivalent to frequentist *P* values. Frequentist tests (ANOVA, *t* tests, and Fisher exact tests) were used only for comparisons derived from the summary metrics provided in Tables 2-7.

Table . Comparison of mean scores (with SDs) across 5 Brand Lift Studies of COVID-19 vaccination campaigns in Mexico, 2021 - 2022.

Outcomes	1, mean (SD)	2, mean (SD)	3, mean (SD)	4, mean (SD)	5, mean (SD)	*P* value[a]
Standard ad recall	2.4 (2.9)	10.8 (3.6)	3.9 (1.0)	2.9 (3.1)	0.2 (2.1)	<.001
Safety	0.2 (1.3)	2.5 (1.0)	−0.9 (1.5)	0.8 (2.5)	1.4 (2.3)	.049
Efficacy	—[b]	—[b]	0.7 (2.3)	0.3 (2.8)	0.6 (2.0)	.95
Importance	1.7 (1.9)	—[b]	2.3 (2.3)	1.1 (1.7)	2.8 (1.7)	.29
Side effects	—[b]	−0.8 (1.4)	—[b]	—[b]	—[b]	—[b]

[a]*P* value from 1-way ANOVA.

[b]Not applicable.

Table . Comparison of Brand Lift Studies results by age group for COVID-19 vaccination campaigns in Mexico, 2021 - 2022.

Age group (years), mean (SD)	18 - 24	25 - 34	35 - 44	45 - 54	55 - 64	≥65	*P* value[a]
Standard ad recall	2.7 (3.4)	2.9 (4.6)	3.4 (4.4)	3.2 (1.1)	0.5 (3.6)	4.9 (1.6)	.90
Safety	0.0 (2.6)	1.9 (2.1)	0.1 (1.7)	0.1 (1.4)	0.2 (0.2)	0.6 (0.6)	.34
Efficacy	1.6 (1.2)	2.2 (1.6)	−1.8 (2.2)	0.2 (2.0)	—[b]	—[b]	.005
Importance	2.8 (1.6)	2.8 (2.5)	2.0 (1.9)	1.1 (1.1)	−0.1 (1.0)	0.0 (0.7)	.10
Side effects	−0.4 (0.0)	0.3	−2.4	—[b]	—[b]	—[b]	—[b]

[a]*P* value from 1-way ANOVA.

[b]Not applicable.

Table . Comparison of Brand Lift Studies results by sex for COVID-19 vaccination campaigns in Mexico, 2021 - 2022.

Variable	Male, mean (SD)	Female, mean (SD)	*P* value[a]
Standard ad recall	2.2 (3.1)	3.7 (4.0)	.06
Safety	−0.1 (1.9)	1.1 (2.0)	.13
Efficacy	1.3 (1.7)	−0.2 (2.6)	.21
Importance	1.5 (1.8)	2.4 (2.1)	.21
Side effects	—[b]	−0.8 (1.4)	.18

[a]Unpaired *t* test.

[b]Not applicable.

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Table . Association between probability of behavior change (≥80% or ≥90% chance of Brand Lift) and campaign characteristics in 5 Brand Lift Studies of COVID-19 vaccination campaigns in Mexico, 2021 - 2022.

Probability of Brand Lift	BLS, n (%)					*P* value[a]
	1	2	3	4	5	
Standard ad recall of 90% or more						.006
Yes	1 (8.3)	3 (100)	1 (12.5)	2 (25)	0 (0)	
No	11 (91.7)	0 (0)	7 (87.5)	6 (75)	8 (100)	
Standard ad recall of 80% or more						.03
Yes	2 (16.7)	0 (0)	4 (50)	0 (0)	0 (0)	
No	10 (83.3)	3 (100)	4 (50)	8 (100)	8 (100)	
Importance of 90% or more						.31
Yes	2 (16.7)	0 (0)	3 (37.5)	1 (12.5)	4 (50)	
No	10 (83.3)	0 (0)	5 (62.5)	7 (87.5)	4 (50)	
Importance of 80% or more						.22
Yes	3 (25)	0 (0)	0 (0)	1 (12.5)	0 (0)	
No	9 (75)	0 (0)	8 (100)	7 (87.5)	8 (100)	
Safety of 90% or more						.15
Yes	0 (0)	1 (33.3)	0 (0)	1 (12.5)	2 (25)	
No	12 (100)	2 (66.7)	8 (100)	7 (87.5)	6 (75)	
Safety of 80% or more						.41
Yes	1 (8.3)	1 (33.3)	0 (0)	1 (12.5)	0 (0)	
No	11 (91.7)	2 (66.7)	8 (100)	7 (87.5)	8 (100)	
Efficacy of 90% or more						>.99
Yes	0 (0)	0 (0)	0 (0)	1 (12.5)	1 (12.5)	
No	0 (0)	0 (0)	8 (100)	7 (87.5)	7 (87.5)	
Efficacy of 80% or more						.75
Yes	0 (0)	0 (0)	2 (25)	1 (12.5)	0 (0)	
No	0 (0)	0 (0)	6 (75)	7 (87.5)	8 (100)	
Side effects of 90% or more						
Yes	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	
No	0 (0)	3 (100)	0 (0)	0 (0)	0 (0)	
Side effects of 80% or more						
Yes	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	
No	0 (0)	3 (100)	0 (0)	0 (0)	0 (0)	

[a]Fisher exact test.

Bayesian confidence estimates from Meta's BLS reflect the probability of observing the same incremental lift in a repeated randomized sample, and therefore should not be interpreted as frequentist measures of statistical significance.

Ethical Considerations

This study was based exclusively on secondary, anonymized, and aggregate data provided by Meta's BLS platform and did not involve any direct interaction or intervention with human participants. In accordance with national and international ethical guidelines, including the Declaration of Helsinki and the Council for International Organizations of Medical Sciences (CIOMS) International Ethical Guidelines, this type of research does not require formal review or approval by an institutional ethics committee. The Asociación Mexicana de Vacunología, as the coordinating institution, authorized the use of these data for academic and research purposes.

Because no individual-level data were accessed and no direct interaction with participants occurred, informed consent was not required. The original data collection by Meta was conducted under its own user agreements and privacy policies, which

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include provisions for the use of anonymized, aggregate data for research purposes. All data analyzed were anonymized and aggregated prior to researcher access. No personally identifiable information was available to the research team. Data were handled in accordance with Meta's privacy policies and the Asociación Mexicana de Vacunología's internal data protection standards.

No participants were recruited directly for this study, and therefore, no compensation was provided. No images or supplementary materials containing identifiable individuals are included in this paper.

Reporting Guidelines

This study adheres to the APA Journal Article Reporting Standards for Quantitative Research (JARS-Quant), which provide structured guidelines for reporting research design, participant characteristics, measures, and analytic procedures. We followed the recommendations outlined in the APA JARS-Quant Table 1 to organize the "Methods" section and ensure transparent and comprehensive reporting of quantitative analyses [18].

Results

Table 2 summarizes the results of the reports from the 5 BLS provided by the Meta company. Table 3 displays the results of the campaigns from the 5 BLS by sex and age group. It also indicates those that are likely to result in a change in behavior due to the campaign. Where we observe in black that the possibility of the increase being caused by the Brand Lift is 90% or greater and in gray 80% or greater.

The mean and SD are presented in the following table. A statistically significant difference was found in the mean of the standard ad recall (P<.001) and in the mean of the safety score (P=.049) between the campaigns as shown in Figures 1 and 2. The comparison of scores by BLS was conducted, and the mean and SD are presented in Table 4.

Figure 1. Incremental lift in standard ad recall across 5 Brand Lift Studies of COVID-19 vaccination campaigns conducted on Facebook and Instagram in Mexico, 2021 - 2022.

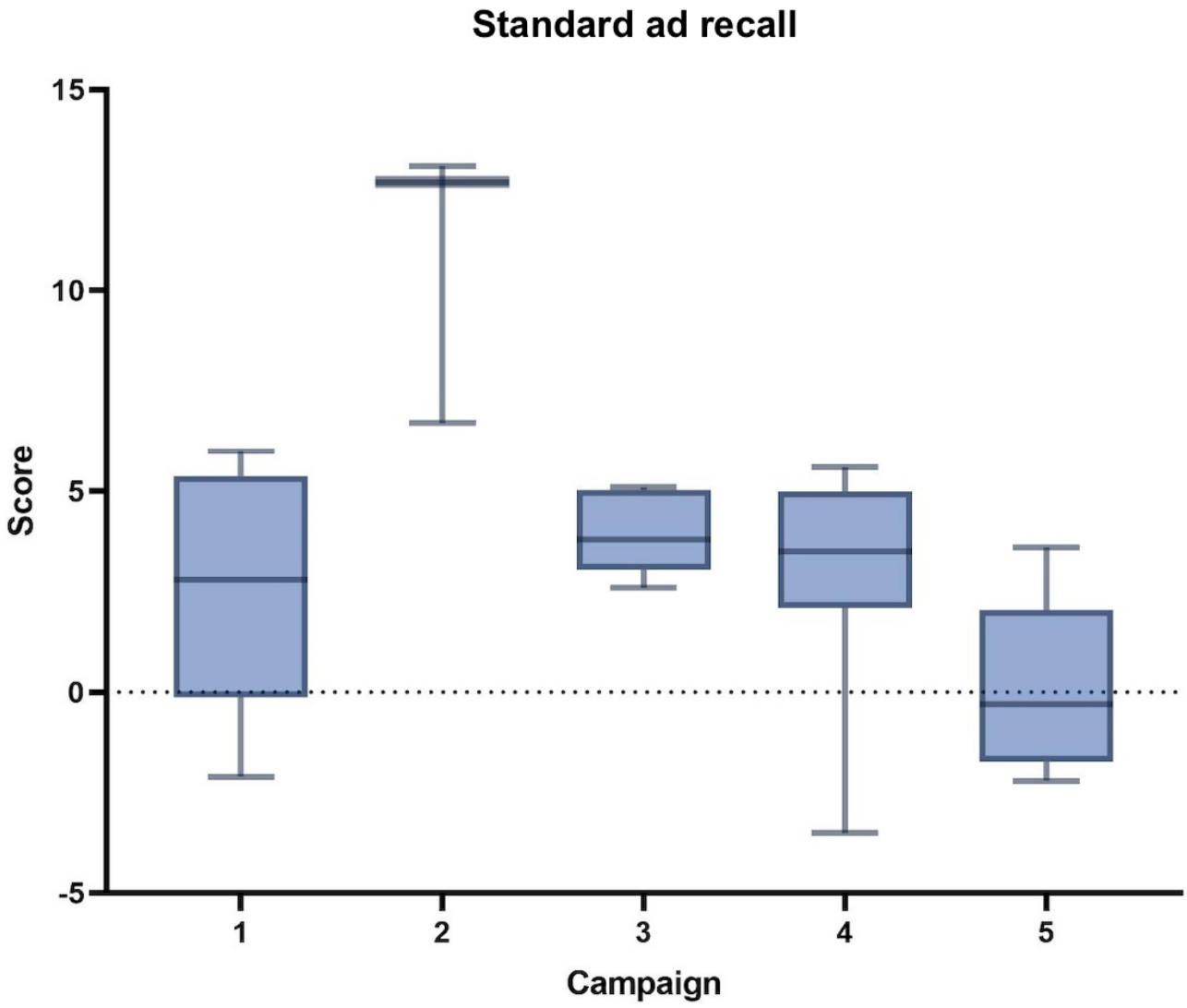

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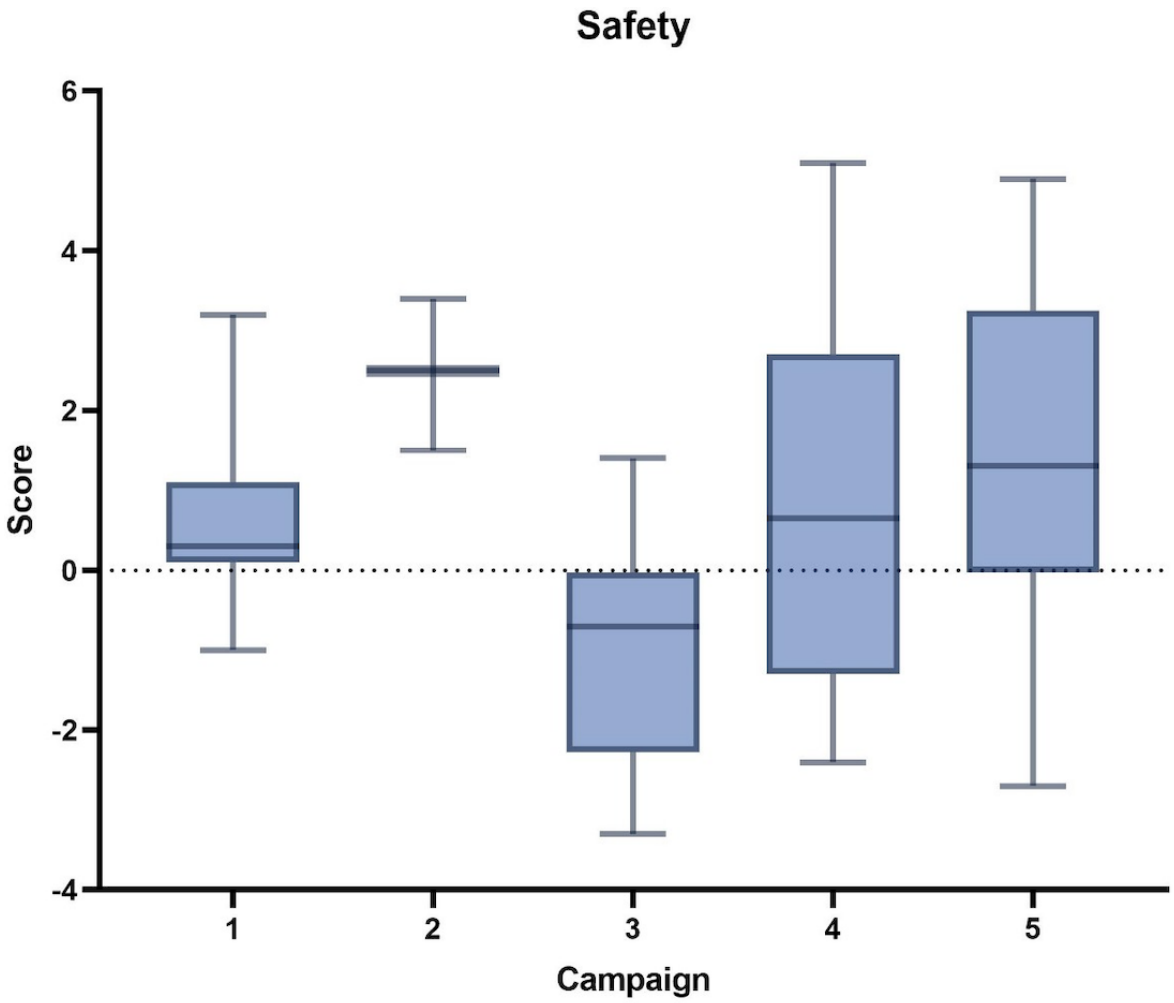
Figure 2. Incremental lift in perceived safety of COVID-19 vaccines across 5 Brand Lift Studies in Mexico, 2021 - 2022.



The comparison by age group was conducted, and the mean and SD are presented in Table 5. A statistically significant difference was found in the mean efficacy score (P=.005) between the age groups, as shown in Figure 3.

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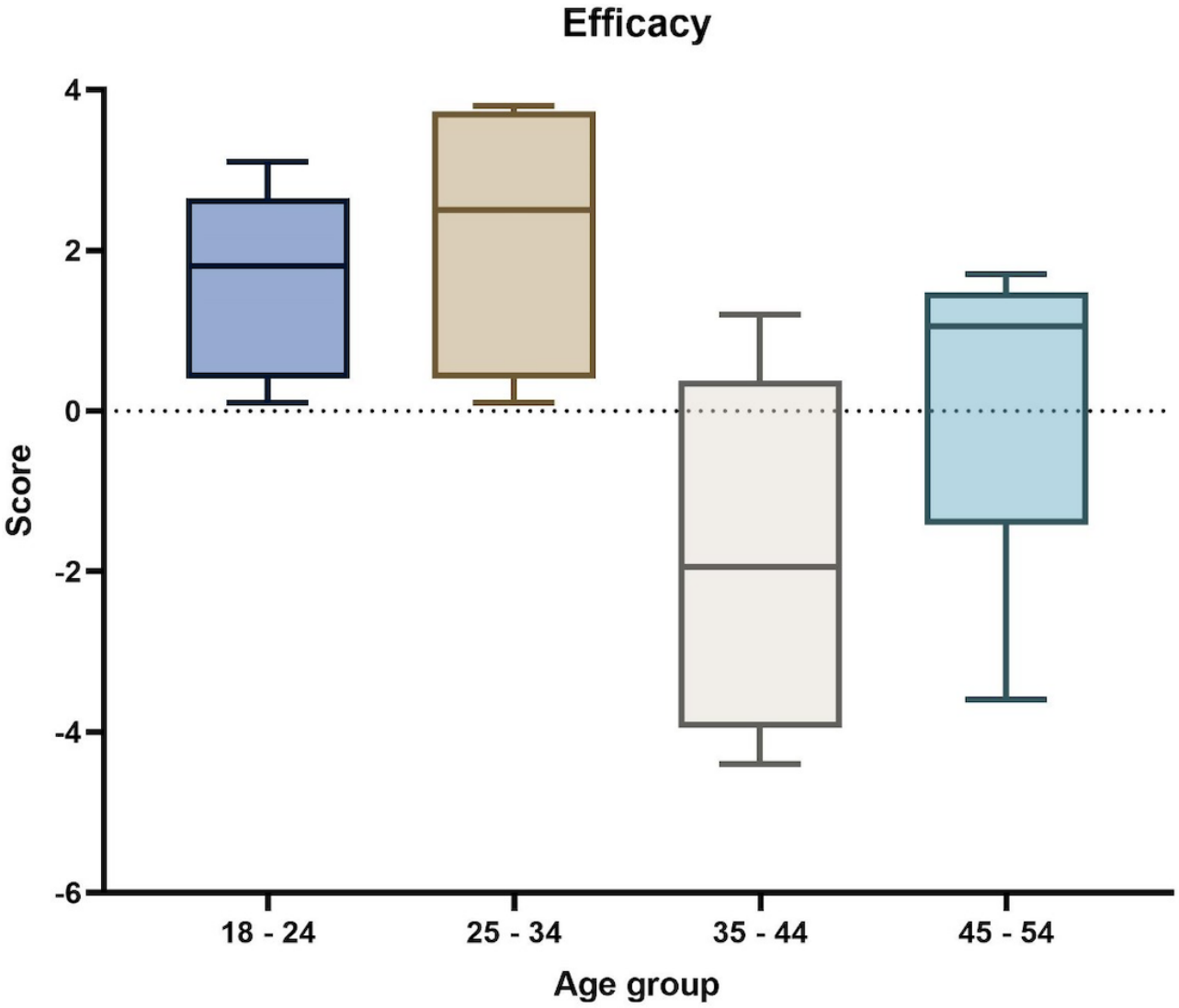
Figure 3. Incremental lift in perceived efficacy of COVID-19 vaccines by age group across 5 Brand Lift Studies in Mexico, 2021 - 2022.



The comparison by sex was conducted for each campaign, and the mean and SD are presented in Table 6. No statistically significant differences were found in the scores of any of the items between the sex groups (all $P \geq .06$).

An evaluation was conducted to assess the association between the probability of behavior change by the campaign. A statistically significant association was found between the probability of standard ad recall of 90% or more ($P=.006$) and 80% or more ($P=.03$) with the campaign; all the evaluations are presented in Table 7.

An evaluation was conducted to assess the association between the probability and age group. No statistically significant association was found between the probabilities of the items and the age groups ($P=.10$ or more); all the evaluations are presented in Table 8.

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Table . Association between probability of behavior change (≥80% or ≥90% chance of Brand Lift) and age group in 5 Brand Lift Studies of COVID-19 vaccination campaigns in Mexico, 2021 - 2022.

Probability of Brand Lift	Age group (years), n (%)						*P* value[a]
	18 - 24	25 - 34	35 - 44	45 - 54	55 - 64	65+	
Standard ad recall of 90% or more							.25
Yes	4 (44.4)	2 (22.2)	1 (11.1)	0 (0)	0 (0)	0 (0)	
No	5 (55.6)	7 (77.8)	8 (88.9)	8 (100)	2 (100)	2 (100)	
Standard ad recall of 80% or more							.30
Yes	1 (11.1)	1 (11.1)	3 (33.3)	0 (0)	0 (0)	1 (50)	
No	8 (88.9)	8 (88.9)	6 (66.7)	8 (100)	2 (100)	1 (50)	
Importance of 90% or more							.10
Yes	3 (37.5)	5 (62.5)	2 (25)	0 (0)	0 (0)	0 (0)	
No	5 (62.5)	3 (37.5)	6 (75)	8 (100)	2 (100)	2 (100)	
Importance of 80% or more							.43
Yes	2 (25)	0 (0)	2 (25)	0 (0)	0 (0)	0 (0)	
No	6 (75)	8 (100)	6 (75)	8 (100)	2 (100)	2 (100)	
Safety of 90% or more							.51
Yes	2 (22.2)	2 (22.2)	0 (0)	0 (0)	0 (0)	0 (0)	
No	7 (77.8)	7 (77.8)	9 (100)	8 (100)	2 (100)	2 (100)	
Safety of 80% or more							.18
Yes	0 (0)	3 (33.3)	0 (0)	0 (0)	0 (0)	0 (0)	
No	9 (100)	6 (66.7)	9 (100)	8 (100)	2 (100)	2 (100)	
Efficacy of 90% or more							.28
Yes	0 (0)	2 (33.3)	0 (0)	0 (0)	0 (0)	0 (0)	
No	6 (100)	4 (66.7)	6 (100)	6 (100)	0 (0)	0 (0)	
Efficacy of 80% or more							.57
Yes	2 (33.3)	1 (16.7)	0 (0)	0 (0)	0 (0)	0 (0)	
No	4 (66.7)	5 (83.3)	6 (100)	6 (100)	0 (0)	0 (0)	
Side effects of 90% or more							
Yes	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	
No	1 (100)	1 (100)	1 (100)	0 (0)	0 (0)	0 (0)	
Side effects of 80% or more							
Yes	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	
No	1 (100)	1 (100)	1 (100)	0 (0)	0 (0)	0 (0)	

[a]Fisher exact test.

An evaluation was conducted to assess the association between the probability and sex. No statistically significant association was found between the probabilities of the items and sex (*P*=.11 or more); all the evaluations are presented in Table 9.

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Table . Association between probability of behavior change (≥80% or ≥90% chance of Brand Lift) and sex in 5 Brand Lift Studies of COVID-19 vaccination campaigns in Mexico, 2021 - 2022.

Probability of Brand Lift	Sex		*P* value[a]
	Male, n (%)	Female, n (%)	
Standard ad recall of 90% or more			.42
Yes	2 (11.1)	5 (23.8)	
No	16 (88.9)	16 (76.2)	
Standard ad recall of 80% or more			>.99
Yes	3 (16.7)	3 (14.3)	
No	15 (83.3)	18 (85.7)	
Importance of 90% or more			.26
Yes	3 (16.7)	7 (38.9)	
No	15 (83.3)	11 (61.1)	
Importance of 80% or more			>.99
Yes	2 (11.1)	2 (11.1)	
No	16 (88.9)	16 (88.9)	
Safety of 90% or more			.11
Yes	0 (0)	4 (19)	
No	18 (100)	17 (81)	
Safety of 80% or more			.59
Yes	2 (11.1)	1 (4.8)	
No	16 (88.9)	20 (95.2)	
Efficacy of 90% or more			>.99
Yes	1 (8.3)	1 (8.3)	
No	11 (91.7)	11 (91.7)	
Efficacy of 80% or more			>.99
Yes	2 (11.1)	1 (8.3)	
No	10 (83.3)	11 (91.7)	
Side effects of 90% or more			
Yes	0	0 (0)	
No	0	3 (100)	
Side effects of 80% or more			
Yes	0	0 (0)	
No	0	3 (100)	

[a]Fisher exact test.

Discussion

Overview

To our knowledge, this is the first study to use experimental BLS data to evaluate vaccine communication in Mexico, providing a scalable model for assessing digital health interventions in other LMICs. This study evaluated the effectiveness of 5 large-scale social media advertising campaigns on COVID-19 vaccination in Mexico, using Meta's BLS to assess standard ad recall and perceptions of vaccine importance, safety, efficacy, and side effects. The findings demonstrate that digital campaigns can generate measurable shifts in awareness and attitudes, although the magnitude and consistency of these effects varied across campaigns and subgroups. These results partially confirm our hypothesis that targeted campaigns, particularly those directed at younger populations and women, would generate stronger positive perceptual shifts.

Principal Findings

Standard ad recall increased significantly in 4 of the 5 campaigns, with the women-focused campaign (aged 18 - 44 years in major cities) achieving the largest effect (+11.6 percentage points compared to control). Perceived importance

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of vaccination improved in 3 of the 4 campaigns where it was measured, with incremental lifts ranging from +1.4 to +3.2 points. Perceptions of safety showed modest but positive gains in 2 campaigns (up to +2.5 points), while efficacy perceptions improved only marginally (≤1.1 points). Concerns about side effects did not change significantly. These results indicate that recall and importance were the most responsive outcomes, whereas safety and efficacy perceptions were more resistant to change.

Differences Between Campaigns

Targeted campaigns produced stronger effects than general population campaigns. In particular, the women-focused campaign not only achieved the highest recall but also showed significant improvements in safety perceptions. In contrast, Campaign 5, which addressed doubts about booster effectiveness, did not produce significant changes in recall or perceptions. This suggests that audience segmentation and message framing are critical determinants of campaign success [3,4].

Subgroup Analysis

Younger audiences (18‐34 years) consistently exhibited stronger positive shifts in recall and importance compared to older groups. For example, in Campaign 3, recall increased by +5.0 points among men aged 18‐24 years, while no significant change was observed in older age groups. No consistent differences were observed by sex, except in the women-targeted campaign, where effects were concentrated among the intended audience. These findings align with prior evidence that younger, digitally native populations are more responsive to online health interventions [2,3].

Interpretation in Context

Our results are consistent with international evidence showing that digital advertising can shift health-related attitudes [3,4]. The stronger effects observed among younger audiences and in targeted campaigns suggest that segmentation strategies enhance the effectiveness of digital health communication [2]. However, the limited changes in perceptions of efficacy and side effects highlight the challenges of addressing entrenched concerns through short-format digital ads alone. These dimensions may require complementary strategies, such as longer-form educational content or integration with offline communication [9].

Limitations

This study has several limitations. First, outcomes were limited to recall and perceptions; no direct behavioral measures (eg, vaccination uptake) were available. Thus, while perceptual shifts are important precursors to behavior, they cannot be equated with actual vaccination. Although the BLS do not capture behavioral end points such as vaccination uptake, these attitudinal outcomes are therefore considered health-related because they influence individuals' likelihood of seeking vaccination and engaging with preventive health services.

Second, although randomization at the user ID level ensured balance between test and control groups, the data available to researchers were anonymized and aggregated, with only age group and sex provided in disaggregated form. As a result, we could not control for additional individual-level covariates (eg, prior exposure to vaccine information and baseline attitudes), which may have introduced residual confounding in subgroup analyses. Third, small sample sizes in some subgroups reflect the BLS survey design, where each respondent answers only 1 question, and should be interpreted with caution. Finally, the findings represent the digital population and may not generalize to individuals without internet or social media access. Our study includes a lack of individual participant data for conducting a cost-benefit evaluation and insufficient information on the number of vaccines administered in Mexico during the campaigns to assess their impact on the vaccination program. It is important to note that not all segments of the Mexican population use digital platforms. Therefore, the findings of this study primarily represent the digital population and may not be generalizable to those who are not connected to or active on social media platforms.

Implications

Despite these limitations, this study provides novel evidence on the role of social media in vaccine communication in a middle-income country. The results indicate that digital campaigns can effectively increase standard ad recall and improve perceptions of vaccine importance and safety, particularly when targeted to specific audiences. These findings reinforce that audience segmentation—especially toward younger adults and urban women—enhances the effectiveness of digital health messaging compared with broad, non-targeted approaches.

This study offers an innovative application of Meta's experimental BLS data to evaluate large-scale, real-world vaccination campaigns in Latin America—a setting where such experimental evidence remains scarce. By demonstrating that different demographic groups respond differently to campaign messages, the study provides practical insights for designing more efficient communication strategies.

These findings have several implications for public health practice. First, digital vaccination campaigns should prioritize precise audience segmentation to maximize impact while optimizing resources. Second, because BLS provide rapid, experiment-based feedback, they can be incorporated into real-time monitoring systems that allow authorities to adjust message framing, creative content, or targeting while campaigns are still active. Third, combining digital strategies with community-based interventions may help reinforce attitudinal changes and extend impact beyond online spaces.

For policymakers, this study illustrates how experimental digital metrics can complement traditional epidemiological surveillance. Future digital vaccination efforts in Mexico and other LMICs should integrate attitudinal indicators (eg, confidence and perceived safety) with real-world vaccination uptake from national immunization systems. Linking shifts in vaccine acceptance with the number of doses administered during campaign periods would provide a more robust measure of true impact and generate evidence to guide investment in digital public health interventions.

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Overall, this study contributes to the field by offering a replicable framework for measuring attitudinal effects of social media advertising using experimental causal methods seldom applied in LMIC settings. In practical terms, the findings demonstrate how digital platforms can complement traditional communication strategies by improving awareness and perceptions in key demographic groups, guiding authorities in resource allocation, message tailoring, and integration of digital analytics into broader vaccination efforts.

Conclusions

This study provides new evidence on the effectiveness of large-scale social media campaigns to influence vaccine-related perceptions in a Latin American middle-income country. Across 5 Meta BLS, digital advertising significantly increased standard ad recall and improved perceptions of vaccine importance and safety, particularly among younger adults and women in urban areas.

Our findings demonstrate that audience segmentation and message targeting enhance the impact of digital communication, suggesting that health authorities and organizations can use social media strategically to strengthen vaccine confidence. Although the study did not measure vaccination behavior directly, perceptual shifts represent important precursors to uptake and highlight the potential of digital platforms to complement traditional public health strategies.

This work contributes to the field by applying experimental BLS for LMICs data to evaluate real-world public health communication, where evidence on digital health interventions remains limited. These results can inform the design of future digital campaigns, guide resource allocation, and support the integration of digital analytics into broader immunization efforts. Future research should link digital engagement metrics with epidemiological data to assess downstream behavioral outcomes.

There is no doubt that there is still much work to be done, but it is of great importance for health specialists to continue collaborating and engaging audiences in digital media. By creating experts in the dissemination of medical information and generating behavioral changes, we can improve the health of the population. However, to identify the best strategies, it is essential to generate evidence to use as a basis for creating, designing, and evaluating successful campaigns that lead to real behavioral changes in health worldwide.

Acknowledgments

During the preparation of this work, the authors used generative artificial intelligence tools (ChatGPT and Grammarly) to improve language clarity and correct grammar. After using these tools, the authors carefully reviewed and edited the content as needed and take full responsibility for the final version of the manuscript.

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Data Availability

The datasets generated or analyzed during this study are available from the corresponding author on reasonable request.

Authors' Contributions

Conceptualization: BMC, RRF
Methodology: BMC, RRF, VMRR
Validation: RRF
Formal analysis: VMRR
Investigation: BMC, RRC, RMM
Resources: BMC
Data curation: RMM, LAFU
Writing – original draft: RRF
Writing – review & editing: RRF, RRC, VMRR, RMM, LAFU
Supervision: RRF, RRF, RRC
Project administration: RRF

Conflicts of Interest

The authors declare that they have no conflicts of interest, including financial, commercial, or institutional relationships, that could be perceived as influencing the design of the study, the collection, analysis, or interpretation of the data, or the writing and publication of this manuscript.

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Abbreviations

BLS: Brand Lift Studies
CIOMS: Council for International Organizations of Medical Sciences
LMIC: low- and middle-income country
SBCC: Social and Behavior Change Communication
WHO: World Health Organization

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Original Paper

Bayesian Spatial Analysis of Trends and Disparities in Telehealth Use During the COVID-19 Pandemic: Retrospective Observational Study

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Abstract

Background: Telehealth has emerged as an essential health care tool, particularly during the COVID-19 pandemic, when in-person medical services were significantly restricted. While telehealth adoption surged during the pandemic, disparities in its access and use have been observed, especially among vulnerable populations. Understanding these trends and identifying barriers is crucial for promoting equitable health care delivery.

Objective: This study aims to assess disparities in telehealth use across Virginia, focusing on demographic, socioeconomic, and geographic factors influencing access. Using spatial modeling, we evaluate the association between community-level characteristics and telehealth use. Our findings can highlight areas where telehealth remains underused, informing targeted interventions to improve equitable access.

Methods: A retrospective observational analysis was conducted from 2016 to 2021 using data from the Virginia All-Payer Claims Database (APCD) and demographic data from the American Community Survey. Annual telehealth use rates were calculated at the zip code tabulation area level during the study period. Demographic and socioeconomic variables, such as educational attainment, poverty, and broadband internet access, along with geographic factors, including population density and rurality, were incorporated. A Bayesian spatial regression with conditional autoregressive priors on zip code tabulation area–level random effects was used to assess the relationship between telehealth use and community-level characteristics. The deviance information criterion was used to select the final model. Results were presented as relative risks (RRs) with 95% credible intervals.

Results: The trends showed an increase in telehealth use during the pandemic, with rural areas showing the most notable rise in 2020 (41.2% of all the visits), up from 14.2% in 2016, representing a statistically significant upward trend (P<.001). However, by 2021, telehealth use shifted, with suburban areas leading (43.1% of the visits), while rural areas followed (37.7%), indicating evolving patterns of adoption over time. Some sociodemographic factors exhibited temporal shifts in their association with telehealth use. Disparities in telehealth use among older adults improved, as the adjusted RR increased from 0.74 in 2019 to 0.95 in 2020, though a slight decline was observed in 2021 (RR 0.92, 95% credible interval 0.89-0.96). Conversely, disparities among non-Hispanic Black populations widened, with adjusted RR declining from 0.96 in 2020 to 0.93 in 2021 (95% credible interval 0.90-0.97), signaling persistent disparities. Higher telehealth use was associated with better broadband access (adjusted RR 1.06, 95% credible interval 1.01-1.11) and increased population density (adjusted RR 1.07, 95% credible interval 1.02-1.12).

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Conclusions: Telehealth use surged in Virginia during the COVID-19 pandemic, particularly in rural areas. However, the findings indicate that disparities persist in the post–COVID-19 pandemic period, especially among minority population groups and older adults. Addressing these gaps requires targeted interventions, including expanding broadband infrastructure and improving telehealth literacy. These efforts are crucial to ensuring equitable access to telehealth services, especially for underserved communities.

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KEYWORDS

telehealth; COVID-19; health disparities; rural health; Bayesian analysis; telehealth use over time; Virginia

Introduction

Background

Telehealth has slowly gained popularity in recent years, becoming a vital tool during and after the COVID-19 pandemic [1]. Before the COVID-19 pandemic, telehealth was primarily used in hospital settings and for ambulatory purposes, particularly in outpatient care for mental health, although at a significantly lower rate than in-person care [2,3]. Its broader adoption had been limited by technological barriers, concerns about reimbursement, and questions regarding maintenance of care standards [4,5]. However, the COVID-19 pandemic acted as a catalyst, forcing health care systems worldwide to adopt telehealth to ensure continued access to health care during lockdowns and publicly mandated social distancing measures [6,7].

Prior Work

A major benefit of telehealth is its ability to increase access to care, particularly for populations with travel limitations or those in rural or underserved areas [8-10]. While clinicians recognize this benefit, they also note the challenges associated with telehealth, such as maintaining the quality of patient interactions, technical difficulties with internet connectivity, concerns over reimbursement structures, and the need for adequate training for both clinicians and patients [11].

Telehealth use in the United States increased substantially beginning in March 2020, peaking in April 2020, before gradually stabilizing [12,13]. National data indicate a significant increase in telehealth visits across all payer types during this period, with Medicare demonstrating the most substantial adoption growth [13]. This surge underscores the critical role of telehealth in maintaining health care access, particularly for high-risk populations, such as older adults, during the public health crisis. Recent studies report significant increases in telehealth use during the COVID-19 pandemic, followed by partial stabilization and variation according to payer type and geographic region [12,13]. Persistent inequities continue to harm rural and socioeconomically disadvantaged communities, where limited broadband, lack of appropriate devices, and gaps in digital literacy restrict access to services [8-11].

Usability and access barriers continue to limit effective patient engagement. However, interventions and solutions, such as simplified digital platforms, language interpretation services, and internet connectivity support, have demonstrated potential to mitigate these disparities [14,15]. In addition, audio-only telehealth encounters have improved convenience and sustained access for those lacking reliable video or broadband resources [16]. These findings highlight the importance of maintaining flexible telehealth modalities to ensure equitable health care.

Regional Context

In the Commonwealth of Virginia, telehealth adoption mirrored national trends but displayed noticeable disparities in use across different payer types and regions. Preliminary analyses reveal that Medicaid beneficiaries lag behind Medicare enrollees in terms of telehealth use, suggesting that barriers to access may be more pronounced among the Medicaid population [13,17]. Many of the previous studies rely on short observation windows concentrated in early 2020 and coarse geographic units. Community-level socioeconomic factors are inconsistently used, and spatial dependence is often not incorporated in a model, risking biased estimates and masking local disparities. Understanding these disparities and identifying factors influencing telehealth adoption in Virginia are essential for developing targeted interventions to ensure equitable health care access.

Objectives

The primary objective of this study is to evaluate telehealth use trends over time (particularly around the COVID-19 pandemic), identify demographic and socioeconomic factors contributing to disparities in access, and assess how geographic- and community-level characteristics influence telehealth adoption. In addition, this study aims to identify areas in Virginia where telehealth services remain underused, with the goal of informing future policy decisions and health care interventions.

Methods

Study Design and Data Sources

This retrospective observational study examined telehealth use in Virginia from 2016 to 2021, using 2 primary data sources. The first source was the Virginia All-Payer Claims Database (APCD), which provides comprehensive health care use data across all payer types, including private insurers, Medicare, and Medicaid. The APCD contains detailed information on health care services rendered, including telehealth visits. The second data source was the American Community Survey (ACS), which provides demographic and socioeconomic data at the zip code tabulation area (ZCTA) level. The ACS dataset included indicators of social determinants of health, such as educational attainment, poverty levels, broadband internet access, and population density. In addition, the Social Deprivation Index

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(SDI), developed by the Robert Graham Center, was used to assess the levels of social deprivation across communities [18].

Rationale for Study Setting

Virginia provides an analytically rich context for examining telehealth use because it captures a full spectrum of access environments—urban, suburban, and rural—including Northern Virginia and Appalachian localities. Documented broadband gaps, especially in rural communities, create meaningful variation in digital infrastructure that directly bears on telehealth use. Finally, this study leverages unique access to the Virginia APCD, which aggregates paid claims from commercial insurers, Medicaid, and Medicare, thereby enabling robust small-area inference that is not feasible in many other settings.

Study Population

The study population consisted of Virginia residents who used both in-person and telehealth services between January 1, 2016, and December 31, 2021. Individuals were included if they had at least 1 claim in the APCD throughout the study period and had a valid ZCTA identifier. Participants with non-Virginia ZCTA (ie, nonresidents), incomplete records, and individuals with missing or invalid ZCTA information were excluded. The inclusion of ZCTA-level data allowed for the geographic analysis of telehealth use patterns and the identification of community-level factors influencing use.

Variables and Measures

The primary outcome variable for this study was the telehealth use rate, defined as the proportion of unique patients per ZCTA who used telehealth services in a given year. This rate was computed for each year from 2016 to 2021 to observe temporal trends. Independent variables included demographic factors as well as socioeconomic indicators from the ACS, including educational attainment, broadband internet access, poverty status (measured as the proportion of the population below 200% of the federal poverty level), and population density. Patient-level usability metrics, such as task success and time to connect, were not directly measured in this study. Use differences were interpreted as population-level indicators reflecting convenience and access constraints.

For geographic factors, 2 approaches were used. First, rurality was classified using the ZCTA local assignments from the National Center for Education Statistics. This classification distinguishes between urban, suburban, and rural areas and is commonly applied in education and geographic research [19]. Second, for statistical modeling, population density was used as a continuous variable to account for geographic variation in telehealth use. The inclusion of broadband access as an independent variable was critical, as telehealth services rely heavily on reliable internet connectivity, especially in rural areas where broadband availability may be limited.

Covariate Selection and Multicollinearity Assessment

Candidate covariates were specified based on previous literature and conceptual relevance to this study's research questions. To minimize redundancy, variance inflation factors computed from an initial model using all candidate ZCTA-level predictors were examined. Variables with a variance inflation factor greater than 5.0 were considered collinear. In such cases, the variable demonstrating stronger construct validity and data completeness was retained. Some potential covariates, such as the Gini index, unemployment rate, the percentage of the population below 100% of the federal poverty level, and the percentage with a bachelor's degree or higher, were excluded from the final model due to multicollinearity. The final model included only nonredundant covariates.

Statistical Analysis

A Bayesian spatial regression model was used to estimate the relationship between telehealth use rates and community-level factors, accounting for spatial autocorrelation among ZCTAs. The Bayesian spatial model used a covariance structure proposed by Besag et al [20] to account for both spatially structured and unstructured variation across neighboring ZCTAs [20]. An adjacency matrix was created using queen contiguity [21], where contiguous ZCTAs were considered neighbors (ie, if they shared a common boundary). Spatial dependencies were given a conditional autoregressive prior, ensuring the model properly addressed spatial correlation in the data. The primary exposure variable was population density, while additional covariates included socioeconomic indicators, demographic characteristics, and health care access measures. These covariates were included in the fully adjusted model to assess their influence on telehealth use. Though telehealth data were summarized each year between 2016 and 2021, models were only built separately for the years 2019, 2020, and 2021. This decision reflected the substantial changes in telehealth patterns during these years, driven by evolving health care policies and patient behaviors, which make them the most relevant for understanding more recent use dynamics.

The number of telehealth visits per ZCTA was modeled using a Poisson distribution, with the log of the population size in each ZCTA included as an offset to account for differences in exposure. Both spatially structured and unstructured random effects were included to account for spatial heterogeneity and overdispersion. To efficiently estimate the posterior distributions of parameters and random effects, the integrated nested Laplace approximation (INLA) method was used, implemented through the *R-INLA* package [22]. This approach was favored for its computational efficiency and accuracy compared to the more time-intensive Markov chain Monte Carlo methods. Posterior distributions for each regression coefficient were approximated, and the relative risk (RR) with 95% credible intervals for each covariate was reported by exponentiating these mean estimates, facilitating statistical inference regarding the associations between telehealth use and community-level characteristics.

Model selection was guided by the deviance information criterion (DIC), with a lower DIC indicating better model fit. The models compared included the following:

- Model 1, namely, crude model, included only population density and accounted for unstructured (nonspatial) variation.
- Model 2, namely, crude spatial model, included only population density and accounted for both spatially structured correlation and unstructured (nonspatial) variation.

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- Model 3, namely, fully-adjusted model, incorporated all covariates and accounted for both spatially structured correlation and unstructured (nonspatial) variation.

Exceedance probabilities were also computed to identify ZCTAs with a high probability of telehealth use rates falling below a specific threshold, enhancing the spatial assessment of underuse [23]. Since 2019 was a pre–COVID-19 pandemic year, the telehealth use rate across Virginia was significantly lower, necessitating a 10% threshold to effectively identify underuse patterns in that year. By contrast, a 50% threshold was used for 2020 and 2021 to capture disparities in access as telehealth use increased during the pandemic. All statistical analyses were conducted in RStudio (version 1.3.1093; Posit, PBC).

Ethical Considerations

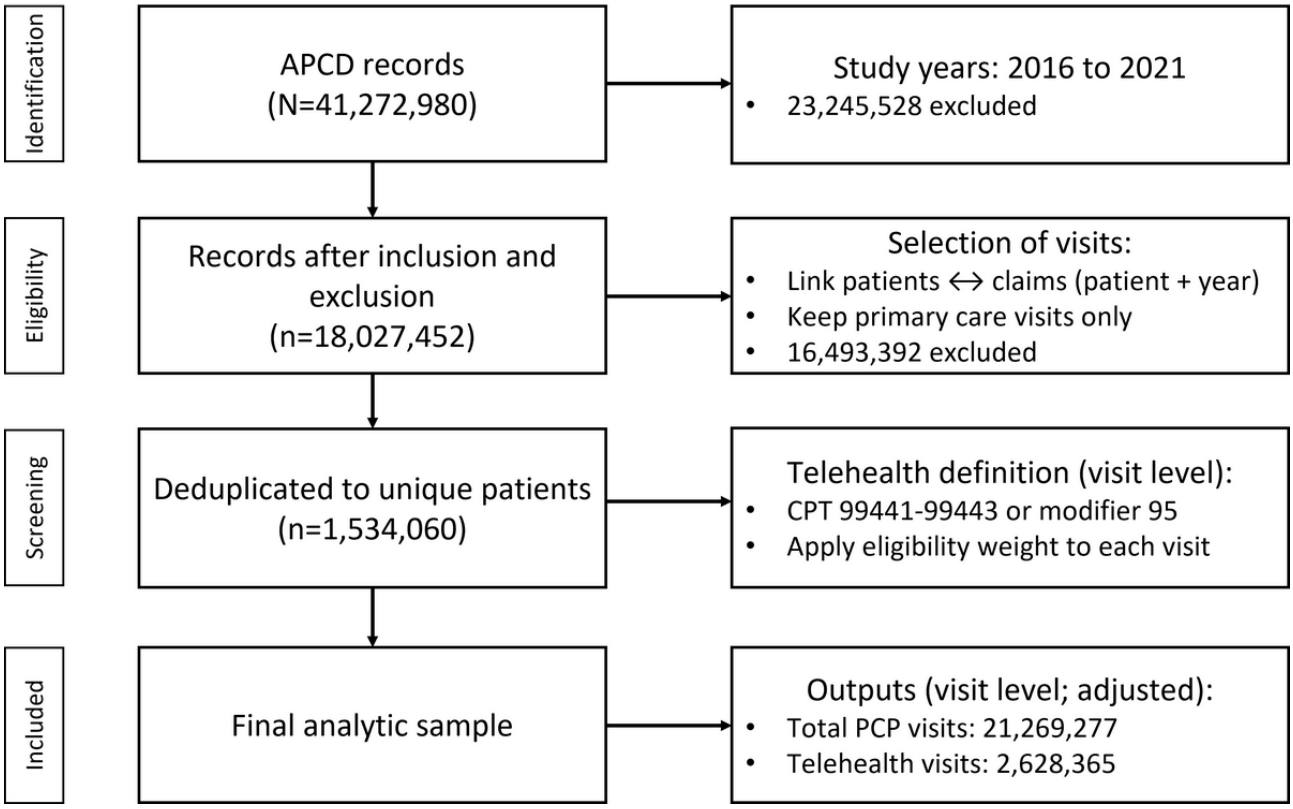
This study was reviewed by the Virginia Commonwealth University Institutional Review Board (IRB) and determined not to be human participant research. The original data collection was performed with IRB approval (HM20031637). The authors obtained permission to access and use the data. This study used only deidentified, aggregated data from the Virginia APCD and the ACS; therefore, it did not require additional IRB review. No identifiable patient information or sensitive personal data were used in this study, ensuring compliance with ethical standards for the use of deidentified data.

Results

Overview

The final analytic cohort comprised 1,534,060 unique patients. Figure 1 presents a sample selection flow diagram detailing the number of records at each stage of processing, from the initial APCD extraction through successive exclusions to the final analytic dataset.

Figure 1. APCD cohort selection (2016-2021) and visit-level telehealth counts in primary care. APCD: All-Payer Claims Database; CPT: Current Procedural Terminology; PCP: Primary Care Physician.



Temporal Variation in Telehealth Use

Our analysis of telehealth use rates from 2016 to 2021 revealed variations in adoption by rurality, year, and health care needs (Figure 2). In 2016, telehealth use was primarily concentrated in suburban or town areas, which accounted for 69% (2318/3359) of all telehealth visits. City areas followed with 16.6% (n=558) of the telehealth visits, while rural areas had the lowest telehealth use rate at 14.2% (n=478). These patterns persisted from 2016 to 2019. In early 2020, with the onset of the COVID-19 pandemic, telehealth use surged across all regions, with rural areas experiencing the most substantial increase, reaching 41.2% (644,404/1,564,817), representing a statistically significant upward trend (P<.001) (Figure 2).

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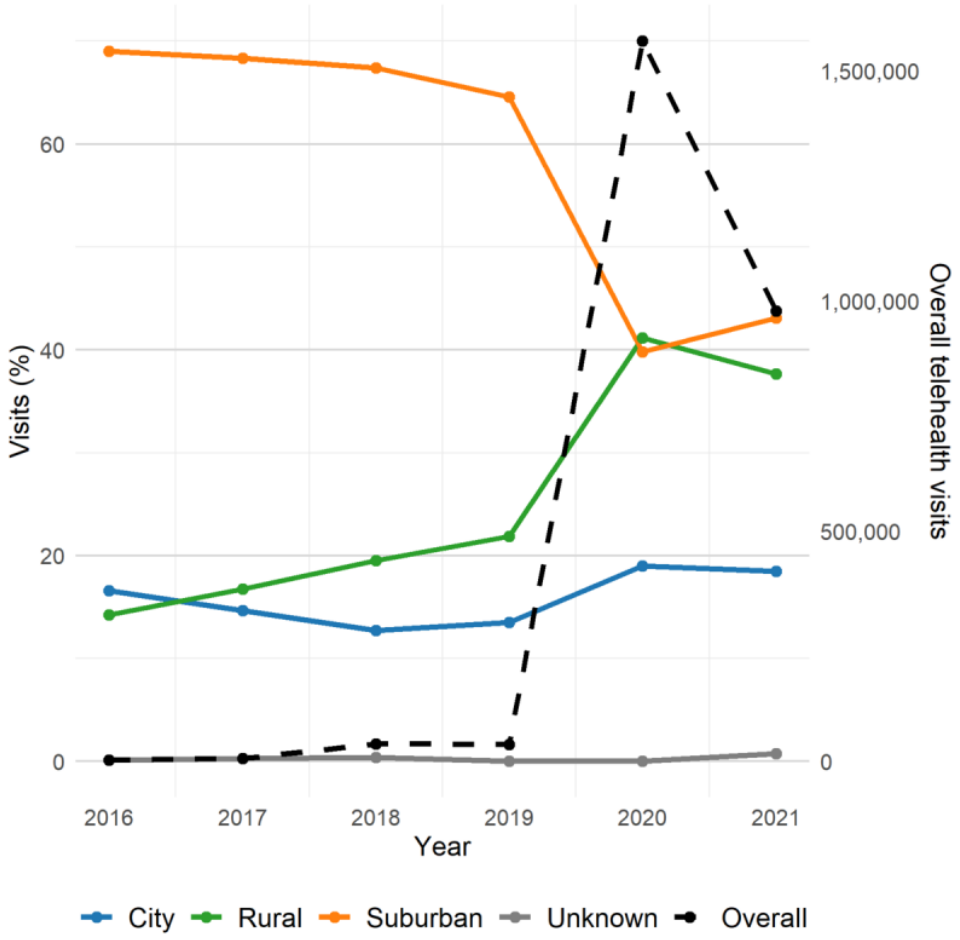
Figure 2. Temporal variation in telehealth use in primary care by rurality and year.



While suburban areas also saw significant growth—from 23,980 visits in 2019 to 622,947 in 2020—this increase is not proportionally reflected in Figure 2, as the figure displays percentages relative to total visits per year rather than absolute counts. A closer examination of the data indicated that rural areas exhibited the largest relative increase in use during the COVID-19 pandemic. In contrast, urban and suburban areas continued to experience growth, although at a slower pace than rural areas.

Despite a slight decline in telehealth use across all regions in 2021, use levels remained elevated compared to pre–COVID-19 pandemic years. In 2021, suburban areas accounted for 43.1% (421,564/978,207) of the telehealth visits, rural areas for 37.7% (n=368,343) of the telehealth visits, and city areas for 18.5% (n=180,754) of the telehealth visits. Although city areas had a smaller share of total visits, differences in telehealth adoption rates across geographic areas are further explored subsequently.

Bayesian Spatial Regression Findings

Model Comparison and Fit

The selection of the final model was based on the DIC, with lower values indicating better model fit:

- Model 1 included only population density and an unstructured (nonspatial) random effect (DIC=7956.42).
- Model 2 included only population density and both a spatially structured random effect and an unstructured random effect (DIC=7942.35).
- Model 3 included population density and all covariates, with both spatially structured and unstructured random effects (DIC=7939.77).

Community-Level Factors Affecting Telehealth Use

On the basis of the fully adjusted Bayesian spatial regression model, telehealth use was substantially associated with several community-level factors. As shown in Table 1, the proportion of individuals with disabilities was positively associated with higher telehealth use (adjusted RR 1.07, 95% credible interval 1.03-1.12). In addition, areas with higher population density were more likely to adopt telehealth (adjusted RR 1.07, 95% credible interval 1.02-1.12).

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Table 1. Telehealth use rate (2019-2021) associations—Bayesian spatial analysis.

Zip code tabulation area–level factors[a]	2019		2020		2021	
	CRR[b] (95% credible interval)[c]	ARR[d] (95% credible interval)[e]	CRR (95% credible interval)[c]	ARR (95% credible interval)[e]	CRR (95% credible interval)[c]	ARR (95% credible interval)[e]
Demographic (%)						
Hispanic	1.06 (0.96-1.16)	1.07 (0.95-1.22)	0.99 (0.97-1.01)	0.99 (0.98-1.02)	0.98 (0.95-1.02)	0.99 (0.96-1.02)
Non-Hispanic Black	0.96 (0.82-1.11)	0.97 (0.81-1.17)	0.94 (0.91-0.96)	0.96 (0.93-0.99)	0.93 (0.90-0.96)	0.93 (0.90-0.97)
Aged >65 y	0.84 (0.68-1.04)	0.74 (0.58-0.94)	0.97 (0.94-0.99)	0.95 (0.92-0.98)	0.95 (0.91-0.98)	0.92 (0.89-0.96)
Aged <5 y	1.08 (0.94-1.24)	1.13 (0.97-1.32)	1.01 (0.99-1.03)	1.01 (0.99-1.04)	1.03 (1.00-1.06)	1.04 (1.01-1.07)
Disability	1.22 (1.01-1.48)	1.61 (1.27-2.04)	1.00 (0.97-1.02)	1.03 (1.01-1.06)	1.00 (0.97-1.04)	1.07 (1.03-1.12)
Socioeconomic						
High school or less (%)	0.77 (0.63-0.94)	0.67 (0.51-0.87)	0.92 (0.89-0.95)	0.98 (0.94-1.02)	0.90 (0.86-0.94)	0.94 (0.89-0.99)
Below 200% federal poverty level (%)	0.97 (0.82-1.16)	0.84 (0.61-1.17)	0.95 (0.92-0.97)	0.99 (0.95-1.02)	0.96 (0.92-0.99)	1.01 (0.96-1.06)
Medicaid (%)	0.93 (0.80-1.07)	0.80 (0.63-1.01)	0.95 (0.93-0.97)	0.95 (0.93-0.98)	0.97 (0.94-0.99)	0.97 (0.93-1.01)
Social Deprivation Index	1.05 (0.94-1.18)	1.26 (1.03-1.55)	0.97 (0.95-0.99)	1.02 (0.99-1.06)	0.96 (0.93-0.99)	0.99 (0.95-1.03)
Access to care (%)						
No health insurance	1.03 (0.90-1.18)	1.01 (0.81-1.24)	0.96 (0.94-0.98)	0.97 (0.95-0.99)	0.97 (0.94-0.99)	0.97 (0.94-1.00)
Broadband internet	1.11 (0.82-1.51)	0.98 (0.69-1.39)	1.10 (1.05-1.15)	1.06 (1.01-1.11)	1.06 (0.99-1.14)	1.02 (0.95-1.09)
Geographic setting						
Population density	1.05 (0.92-1.21)	0.99 (0.85-1.14)	1.04 (1.01-1.07)	1.04 (1.01-1.07)	1.06 (1.01-1.11)	1.07 (1.02-1.12)

[a]All zip code tabulation area–level factors were standardized.

[b]CRR: crude relative risk.

[c]Univariate model included each variable and structured and unstructured random effects.

[d]ARR: adjusted relative risk.

[e]Included population density as the primary exposure variable with all other covariates and structured and unstructured random effects.

Disparities in Telehealth Access

The analysis also revealed several disparities in telehealth use. The proportion of non-Hispanic Black residents in a ZCTA was negatively associated with telehealth use (adjusted RR 0.93, 95% credible interval 0.90-0.97). Similarly, older populations (aged >65 y) were less likely to use telehealth (adjusted RR 0.92, 95% credible interval 0.89-0.96).

Trends in Telehealth Use From 2019 to 2021

As presented in Table 1, spatial regression models for 2019 to 2021 provided a broader context for understanding how telehealth use evolved before, during, and after the pandemic. In 2020, broadband internet access was associated with higher telehealth adoption (adjusted RR 1.06, 95% credible interval 1.01-1.11). The proportion of non-Hispanic Black residents and older adults remained negatively associated with telehealth use, a trend that persisted into 2021.

In 2019, before the COVID-19 pandemic, telehealth use was more strongly associated with the SDI and the proportion of individuals with disabilities. The SDI, an index of area-level social disadvantage (higher values indicate greater deprivation), was positively associated with telehealth use (adjusted RR 1.26, 95% credible interval 1.03-1.55). Similarly, areas with a higher proportion of individuals with disabilities were more likely to use telehealth (adjusted RR 1.61, 95% credible interval 1.27-2.04). However, this association diminished in subsequent years, with the adjusted RR declining to 1.03 in 2020 and 1.07 in 2021. However, disparities among non-Hispanic Black populations persisted, with adjusted RR values declining from 0.96 in 2020 to 0.93 in 2021.

Spatial Distribution of Telehealth Use

Geographic Disparities in Telehealth Use

Figure 3 illustrates the spatial distribution of telehealth use across Virginia, identifying several geographic areas with notably lower telehealth adoption. These regions included the Southwest, West Central, Southside, Valley, Hampton Roads, and Eastern regions, where ZCTAs exhibited telehealth use rates at least 50% lower than the state average.

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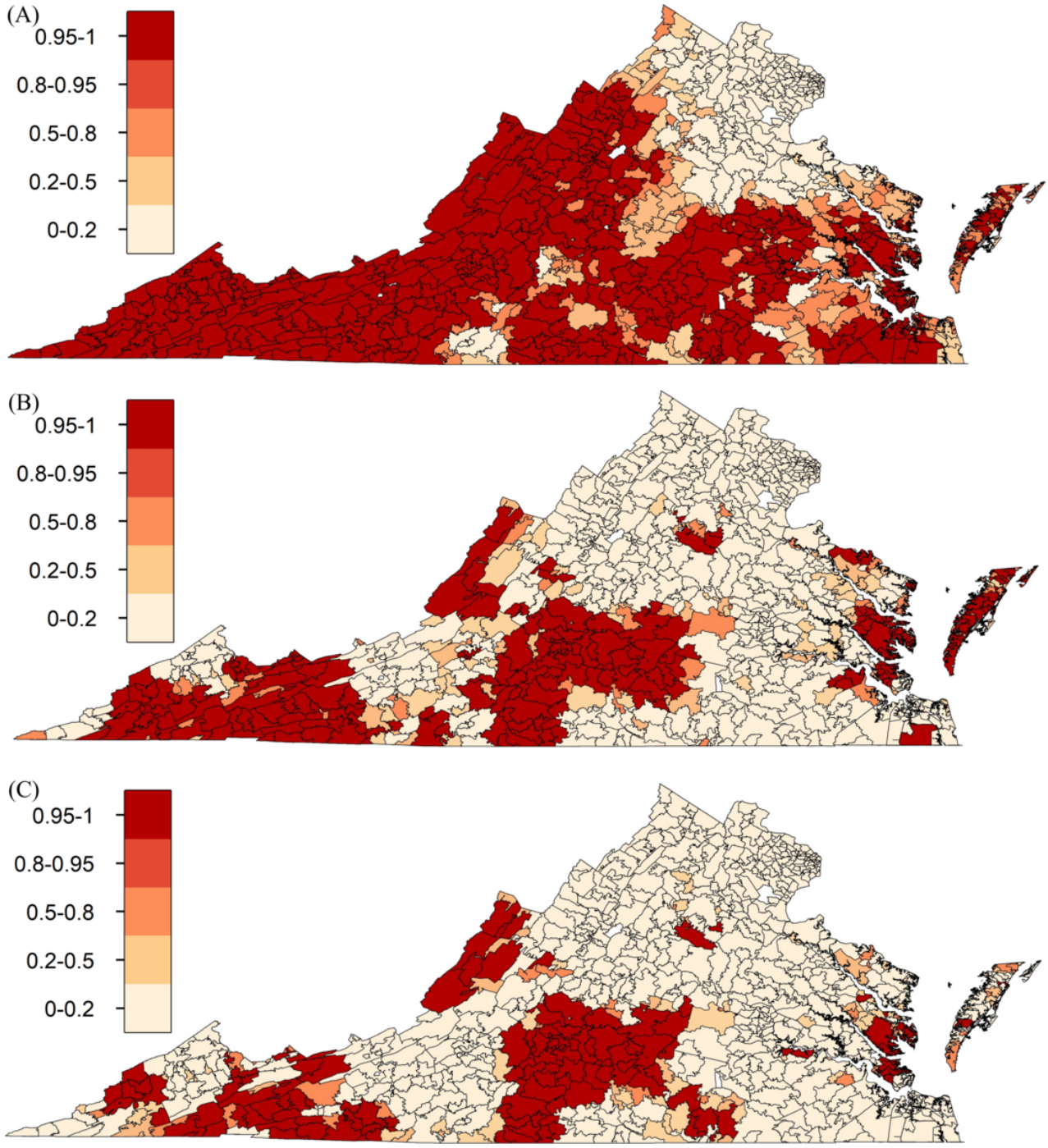
Figure 3. Probability of zip code tabulation areas (ZCTAs) exhibiting telehealth use rates below the Virginia average—10% in 2019 (A), 50% in 2020 (B), and 50% in 2021 (C).



Telehealth Use Disparities

Although Figure 3 illustrates ZCTAs with telehealth use rates below the Virginia average (10% in 2019 and 50% in 2020 and 2021), the analysis also identified some telehealth hot spots, mainly concentrated in Northern Virginia. Hot spots are defined as geographic clusters where telehealth use rates are significantly higher than the state average [24].

Telehealth Use by Medical Condition

Figure 4 presents a heat map of telehealth visits for the top 10 *International Classification of Diseases, 10th Revision* diagnoses in primary care from 2016 to 2021. The data indicated that primary hypertension (I10) consistently ranked as one of the most common conditions for telehealth visits, particularly during the COVID-19 pandemic. This was followed by hyperlipidemia (E78.5) and type 2 diabetes mellitus without complications (E11.9), both of which also saw increases in telehealth visits during the pandemic. Mental health conditions, particularly anxiety disorder (F41.9), saw the most pronounced increase in telehealth visits during the COVID-19 pandemic. COVID-19–specific *International Classification of Diseases, 10th Revision* codes (ie, U07.1, Z20.828, and Z20.822) rose to the top 10 in 2020 and 2021.

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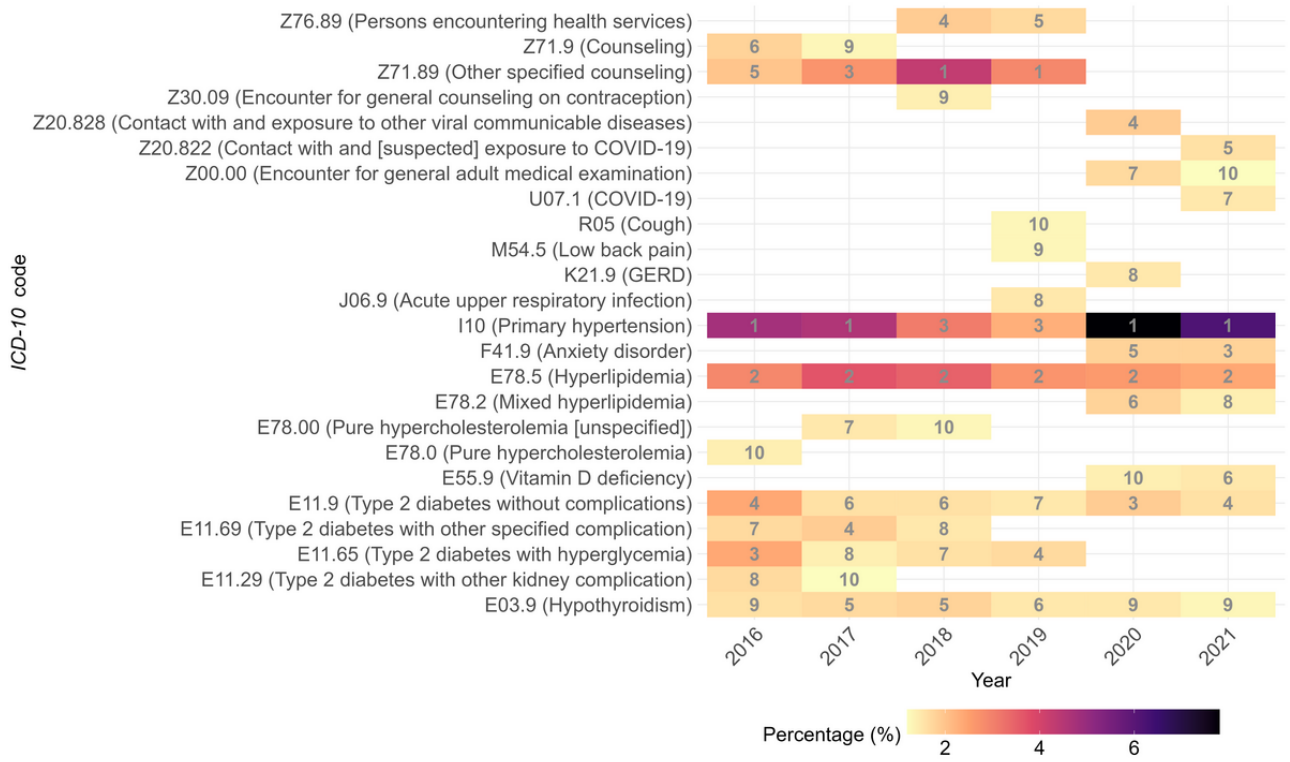
Figure 4. Heat map depicting telehealth visits for primary care's top 10 International Classification of Diseases, 10th Revision (ICD-10) diagnoses in primary care, arranged by year (the gray numbers within each cell indicate the respective annual rankings). GERD: gastroesophageal reflux disease.



Discussion

Principal Findings

This study provides a comprehensive analysis of telehealth use trends and disparities in Virginia during the COVID-19 pandemic. The findings reveal a significant increase in telehealth adoption starting in 2020, with use peaking during the height of the COVID-19 pandemic and remaining elevated compared to pre–COVID-19 pandemic levels. These results underscore the critical role telehealth played in maintaining health care access during a period of unprecedented disruption to traditional health care delivery [17]. The analysis identified key factors associated with telehealth use. Broadband internet access and population density were positively associated with higher telehealth use, highlighting the importance of digital infrastructure in facilitating access to telehealth services. However, broadband access did not exhibit a statistically significant association with telehealth use in either the pre–COVID-19 pandemic (2019) or post–COVID-19 pandemic (2021) periods.

Conversely, ZCTAs with higher proportions of the non-Hispanic Black residents, older adults, and Medicaid beneficiaries were negatively associated with telehealth use, highlighting disparities that may be driven by socioeconomic, technological, and systemic barriers. Telehealth has proven to be a valuable tool for expanding and broadening access to primary care services, particularly for managing chronic conditions, such as blood pressure monitoring and providing mental health care. Its integration into health care systems could improve access for populations with limited mobility or those residing in areas with health care provider shortages.

Comparison With Existing Literature

The findings of this study are consistent with national trends that have documented increased telehealth adoption during the COVID-19 pandemic [25]. Studies have shown that the shift to telehealth was driven by the need to maintain health care access while minimizing in-person contact, and its adoption was facilitated by short-term policy changes, such as expanded reimbursement for telehealth services [26,27]. The disparities identified in this study align with existing literature on the digital divide, which has highlighted the challenges faced by underserved populations, including racial and ethnic minority groups, in accessing telehealth services [25,28-30].

Reducing Telehealth Disparities Through Practice and Policy

Although telehealth is not suitable for every clinical condition, it is an essential tool for mitigating geographic and logistical barriers to health care access. Achieving equitable access requires coordinated efforts on infrastructure, financing, education, and inclusive design. Expanding broadband infrastructure and improving the affordability and reliability of internet service are crucial to equitable telehealth access. Targeted internet connectivity improvements in rural and low-income communities, coupled with public-private partnerships that establish telehealth access points in locations such as clinics, can improve availability and consistency of health care services [31,32]. These strategies are particularly important in areas where inadequate digital infrastructure

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overlaps with elevated rates of chronic disease and limited health care resources.

Equitable telehealth delivery depends on robust reimbursement and incentive policies. Payment parity policies for in-person and telehealth services can encourage broader adoption among health care providers, including those serving Medicaid enrollees and other low-income populations [30,33]. Enhanced funding for telehealth initiatives in medically underserved areas, particularly those characterized by poverty and lower educational attainment, is crucial for sustaining equitable service delivery [34].

Improving digital and telehealth literacy across populations with historically limited access is essential. Education and training programs that are accessible and tailored to older adults, racial and ethnic minority groups, and individuals with limited digital proficiency can reduce the digital divide [30,32,35]. Programs or initiatives that engage caregivers, community organizations, and peer-support networks can further increase user confidence in using telehealth platforms. Prioritizing inclusive design and accessibility is needed for equitable telehealth implementation. Telehealth platforms should incorporate features such as screen-reader compatibility, captioning, language interpretation services, and low-bandwidth modes to support users with disabilities or limited digital resources [29,35,36]. Device loan programs and mobile-friendly interfaces can increase participation among populations with limited access to technology.

Community engagement is critical for fostering trust and promoting digital inclusion and achieving digital equity. Collaborations with established local organizations can also facilitate outreach, raise awareness, and address cultural barriers, particularly among historically marginalized groups [34,36]. These partnerships can establish feedback mechanisms to ensure telehealth systems adapt to evolving community needs.

Ongoing monitoring of telehealth access and use across sociodemographic groups is necessary to identify persistent disparities. Analyzing telehealth use by race or ethnicity, age, rurality, and socioeconomic indicators enables stakeholders to detect and respond to inequities.

In addition, clinician preparedness and effective workflow integration are essential for sustaining telehealth services. Training health care providers to deliver equitable and culturally sensitive virtual care, supported by standardized workflows and integrated language interpretation services, may improve clinical quality and patient satisfaction [31,32,36].

Strengths and Limitations

One of the strengths of this study is the use of comprehensive health care use data from the Virginia APCD, which allowed a detailed analysis of temporal variation in telehealth use across multiple years. The application of Bayesian spatial modeling further strengthened the analysis by accounting for spatial dependencies and providing robust estimates of the associations between telehealth use and community-level factors. However, this study is not without limitations. The observational nature of the analysis limits the ability to draw causal inferences about the relationships between telehealth use and the independent variables. Thus, the findings may not be generalizable to other population groups or settings. In addition, the reliance on claims data may introduce misclassification bias, as not all telehealth visits may be accurately captured in the APCD. Furthermore, this study did not differentiate between video and audio-only telehealth encounters, which is an important consideration, as audio-only visits may help reduce disparities by addressing barriers, such as limited broadband access and digital literacy challenges.

Future Research Directions

Future research should focus on longitudinal studies to monitor post–COVID-19 pandemic telehealth trends and assess the long-term impact of telehealth on health care access and outcomes. Qualitative studies exploring the barriers to telehealth adoption, such as digital and telehealth literacy, technological access, and perceptions of care quality, would provide valuable insights into the challenges faced by underserved populations. Finally, intervention studies that test the effectiveness of targeted strategies to increase the telehealth adoption in underused areas would contribute to the development of more equitable health care delivery models.

Conclusions

This study provides a comprehensive understanding of telehealth use trends and disparities in Virginia during the COVID-19 pandemic. The findings highlight the significant increase in telehealth adoption during the COVID-19 pandemic as well as the persistent disparities in access among certain populations and areas. To ensure equitable telehealth delivery, targeted interventions, investments in broadband infrastructure, user-friendly digital platforms, and supportive policies are essential to ensure that telehealth remains a viable and equitable mode of health care delivery in the post–COVID-19 pandemic era.

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Data Availability

The datasets generated or analyzed during this study are not publicly available due to ethical restrictions and patient confidentiality but are available from the corresponding author on reasonable request.

Conflicts of Interest

None declared.

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Abbreviations

APCD: All-Payer Claims Database
ACS: American Community Survey
DIC: deviance information criterion
IRB: institutional review board
RR: relative risk
SDI: Social Deprivation Index
ZCTA: zip code tabulation area

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Original Paper

Cross-Cultural Differences in Public Discourse on COVID-19 Vaccination in the United States and South Korea: Cross-Sectional Analysis Using Natural Language Processing

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Abstract

Background: The COVID-19 vaccine was introduced as a crucial tool to combat the pandemic. However, concerns about its effectiveness, side effects, and misinformation spread remain. Prior research largely relied on survey-based approaches with limited populations. To address these limitations, social media offers a broader, more naturalistic lens into public discourse on COVID-19 vaccination. Accordingly, our study leverages social media data to identify factors shaping vaccine-related information needs, perceptions, and communication dynamics.

Objective: This study investigated public discourse about COVID-19 vaccines on community-driven question-and-answer sites in the United States (Quora; Quora, Inc) and South Korea (Naver Knowledge-iN; Naver Corp) to identify cross-national similarities and differences in vaccine-related information needs, sentiment patterns, and public perceptions over time.

Methods: We analyzed publicly available COVID-19 vaccine–related questions and answers posted between June 27, 2020, and June 27, 2021, on 2 community-driven question-and-answer platforms: Quora (United States) and Naver Knowledge-iN (South Korea). After preprocessing and sample-size matching, the dataset included 3952 question-answer pairs per platform, with one community-selected (most upvoted) answer analyzed per question. Natural language processing (NLP) techniques were applied for topic classification and sentiment analysis. Questions were categorized using a hybrid topic modeling approach combining Latent Dirichlet Allocation (LDA) and Top2Vec, identifying 5 topics on Quora and 7 topics on Naver Knowledge-iN. Answer sentiments were classified using an ensemble of Bidirectional Encoder Representations from Transformers (BERT; Google LLC)– and Efficiently Learning an Encoder that Classifies Token Replacements Accurately (ELECTRA; Google LLC)–based transformer models, and temporal sentiment trends were examined using monthly aggregation.

Results: Five shared information needs emerged, including effects of vaccines, variants, government policy, visiting overseas, and different vaccines, while South Korea uniquely exhibited vaccination appointments (711/3952, 18%) and school and education (513/3592, 13%). Negative sentiment predominated in US (Quora) answers across 4 of 5 topics, whereas positive sentiment exceeded 50% (498/790, 337/474, 367/592, 218/316, 348/553, 562/711, and 364/513) across all 7 topics on Naver Knowledge-iN. Temporally, US sentiment exhibited multiple positive-negative crossovers, whereas Korean sentiment stabilized toward positivity after February 2021, coinciding with the national vaccine rollout. Question-answer sentiment pairs showed contrasting interaction patterns, including negative-negative pairs dominated in the United States (eg, 504/978, 51.5% for different vaccines), while in South Korea, positive-positive and negative-positive pairs accounted for more than 63% (498/790, 337/474, 367/592, 218/316,

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348/553, 562/711, and 364/513) of interactions in 7 topics, with positive-positive pairs most prevalent in 6 of 7 topics, except for variants.

Conclusions: Public perceptions of COVID-19 vaccines and related information needs differ between the 2 countries, shaped by cultural context, trust in government, and information-seeking environments. Analysis of social question and answer data from the 2 countries reveals shared information needs but divergent sentiment patterns. These findings highlight the value of social media data for public health research and the need for culturally and platform-specific communication strategies.

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KEYWORDS

COVID-19 vaccine; natural language processing; topic detection; sentiment analysis; temporal dynamics; health communication

Introduction

Since the recognition of COVID-19 in December 2019, many efforts have been made to control it. Before the development and distribution of the COVID-19 vaccine, the World Health Organization (WHO) and the Centers for Disease Control and Prevention (CDC) recommended passive preventive measures like mask-wearing, hand hygiene, and social distancing [1,2]. The COVID-19 vaccine, released in 2020 [3], was anticipated to be a pivotal tool in ending the pandemic. However, the scientific evidence supporting its effectiveness remains limited, and concerns about potential side effects persist [4,5]. Furthermore, misinformation about the vaccine has fueled public uncertainty and apprehension [6-8], contributing to vaccine hesitancy [4,9-11].

These concerns were reflected in real-world vaccination uptake, which varied across populations and national contexts. Despite the availability of COVID-19 vaccines in both the United States and Korea, vaccination rates stalled at some point, with 68.7% fully vaccinated in the United States [12] and 85.6% in Korea [13] as of October 2022. Public perceptions and intentions toward vaccination varied significantly in both countries [14-17].

In the United States, numerous studies have focused on vaccine hesitancy, analyzing factors like sociodemographic characteristics [5,14,15,18,19]. Vaccination hesitancy was notably higher among those experiencing social injustices, including race and religious discrimination, with hesitancy rates at 68.9% for non-Hispanic Whites, 74% for African Americans, and 59.5% for Hispanics or Latinos [15]. Lower-income Americans showed less fear of COVID-19 and less trust in vaccines, while higher-income Whites were more willing to get vaccinated [18,20]. Political affiliations further highlighted disparities, with Republicans exhibiting the highest vaccine hesitancy [21,22]. Racial injustice exhibited higher vaccine hesitancy due to limited access to information and greater mistrust in the government [19,23].

Taken together, existing studies have primarily relied on self-reported online surveys to characterize vaccine hesitancy, emphasizing the roles of personal attributes, demographic characteristics, and political orientations, while offering limited insight into how concerns and information needs are expressed in natural settings [24,25]. However, many studies are limited by focusing on specific populations rather than the general public [26]. Survey data limitations can be mitigated by analyzing public opinions expressed on social media [27]. Social media is a natural setting for understanding public perceptions and information needs regarding the COVID-19 vaccine, potentially uncovering new factors influencing vaccine uptake [28].

To contextualize these vaccine-related discussions, social media serves as a central channel for exchanging health information, enabling users to share advice, knowledge, and experiences [27,29] while also playing a critical role in public health communication during health crises such as Hemagglutinin Type 1 and Neuraminidase Type 1 (H1N1), Middle East Respiratory Syndrome (MERS), and the COVID-19 pandemic [30,31].

During the COVID-19 pandemic, social media significantly impacted information sharing and vaccine hesitancy [32-35]. These studies underscore social media's role in shaping public perceptions and providing social and informational support, fostering a sense of connectedness during lockdowns [36,37].

Although social media offers many benefits, previous studies have suggested its potential risks associated with the spread of misinformation, which may cause severe consequences [33,38]. In the case of vaccine information, negative content has been widely disseminated through social media channels, contributing to vaccine hesitancy [39-41].

On Parler (Parler LLC), conservative-leaning hashtags like #NoCovidVaccine have supported negative vaccine perceptions [42]. YouTube's (Google LLC) user-generated content often includes misinformation due to limited regulations, and its recommendation systems promote conspiracy theories [43].

On Twitter (X Corp), sentiment toward vaccines varied by country; Switzerland had more positive tweets (11,621/16,268, 71.43%) than negative tweets, but the United States had only 10.48% positive tweets [44]. Only a small portion (< 10%, 9/107) of the most influential profiles engaging in the COVID-19 vaccine conversations originated from the medical professionals, indicating the need for public health stakeholders to address misinformation on social media [42,45].

Among these platforms, community-driven question and answer (Q&A) sites stand out as valuable online resources. Q&A sites like Quora (Quora, Inc) in the United States and Naver Knowledge-iN (Naver KiN; Naver Corporation) in South Korea (hereafter Korea) allow users to express their health information needs in natural language while fostering a sense of community [46]. During the COVID-19 pandemic, Q&A sites served as forums for discussing vaccines, offering valuable insights into

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public information needs. Understanding these needs and vaccine perceptions is crucial for creating effective vaccination campaigns [9,47]. To achieve this understanding, a strategic approach and the use of information and communication technology are essential [9].

Though not fully representative of Western and Eastern countries, the United States and Korea are frequently compared in health communication studies due to their distinct cultural traits, highlighting regional differences [48]. Throughout the COVID-19 pandemic, these countries exhibited disparities in vaccine-related aspects such as case proportions, quarantine regulations, and vaccine availability [49,50]. Nevertheless, there are few studies examining vaccine information needs and perceptions across multiple countries [51,52].

Consequently, we investigated the information needs, perceptions, and attitudes toward the COVID-19 vaccine expressed on social media by people in the United States and Korea. Our findings emphasize the complexity of public perceptions of vaccines and the critical need for targeted public health communication strategies. The unique information needs and varying sentiments across topics and Q&A pairs over time in both the United States and Korea illustrate the nuanced challenges faced by public health initiatives. Addressing those challenges through targeted, adaptive, and culturally aware communication efforts is essential for overcoming vaccine hesitancy, enhancing public trust, and ultimately achieving herd immunity against COVID-19.

Methods

Overview

This study conducted a cross-sectional analysis of vaccine-related questions and associated information needs on Quora and Naver KiN between June 2020 and June 2021. We followed the STROBE (Strengthening the Reporting of Observational Studies in Epidemiology; Multimedia Appendix 1) reporting guidelines. This study design is aligned with recent cross-sectional analyses of social media use for health-related issues [53].

To examine the perceptions and information needs of Q&A site users regarding the COVID-19 vaccine, we collected data from Q&A sites with representative US and Korean user bases. For this purpose, we chose Quora, a US platform hosting millions of questions and answers [54], and Naver KiN, the foremost social Q&A site in Korea [55]. Data were collected using Selenium (Software Freedom Conservancy, Inc), an open-source framework that allows automatic interaction with web browsers using Python 3.8.5 (Python Software Foundation) [56]. We set intervals during data collection to avoid overusing the service. For each question, we collected the URL, upload date, and answers. The data collection ran from June 27, 2020, to June 27, 2021, based on the upload dates for both websites, and the inclusion criteria were questions and answers pertinent to COVID-19 and any morphological form of the keyword “vaccine” (in Korean,백신), such as “vaccines” and words containing “vaccine.” By applying those criteria and excluding unanswered questions, we identified and subsequently removed questions falling outside our specified criteria.

As a result, after sampling the data, we collected 3952 sets of questions and answers from Quora and Naver KiN, as depicted in Figure 1. Rather than analyzing all the answers to the questions, we opted to examine only the most upvoted answers so that we could analyze the characteristics of the answers that users deemed most favorable [48]. Accordingly, only one answer for each question was used from an average of 27.4 and 2.7 answers detected on Quora and Naver KiN, respectively. All data and source code files can be found in the repository.

In this study, we used 2 major approaches to analyze the questions and answers (Figure 2), including topic categorization for questions based on Latent Dirichlet Allocation (LDA) [57] and Top2Vec [58], and sentiment analysis for answers using ensemble-bagging with Bidirectional Encoder Representations from Transformers (BERT) [59] and Efficiently Learning an Encoder that Classifies Token Replacement Accurately (ELECTRA) [60]. For answers, this study used the most upvoted answers to focus on the characteristics of answers that users deemed most favorable. These natural language processing (NLP) techniques have been shown to be effective for analyzing large-scale data [61].

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Figure 1. Data preprocessing. Data from Quora and Naver Knowledge-iN (Naver KiN) were collected between June 27, 2020, and June 27, 2021, using the keyword "Vaccine" (in Korean, 백신). After preprocessing, the Naver KiN data were randomly sampled to match the Quora sample size per platform (N= 3952).

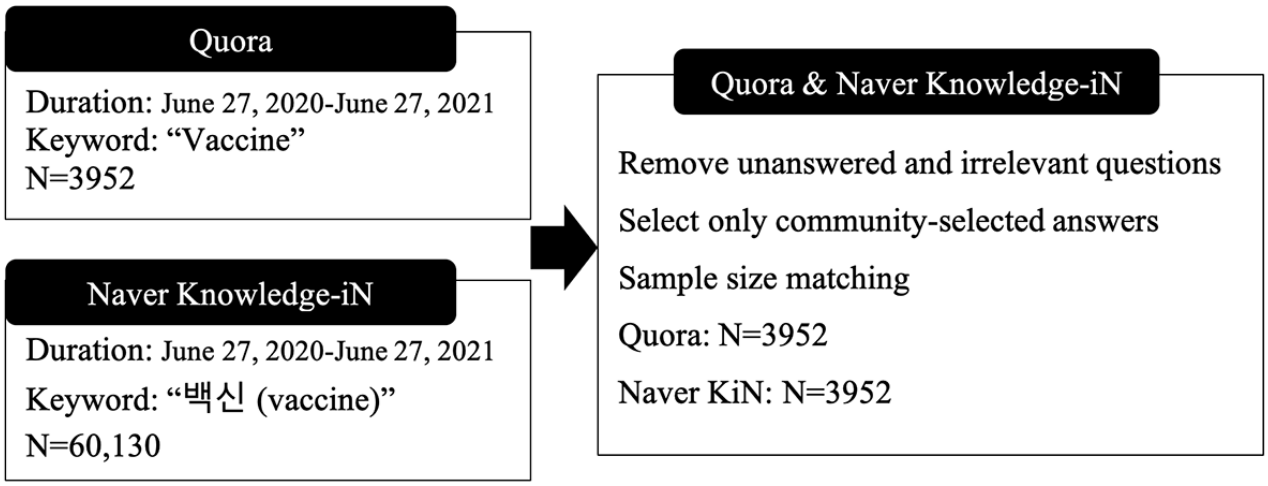
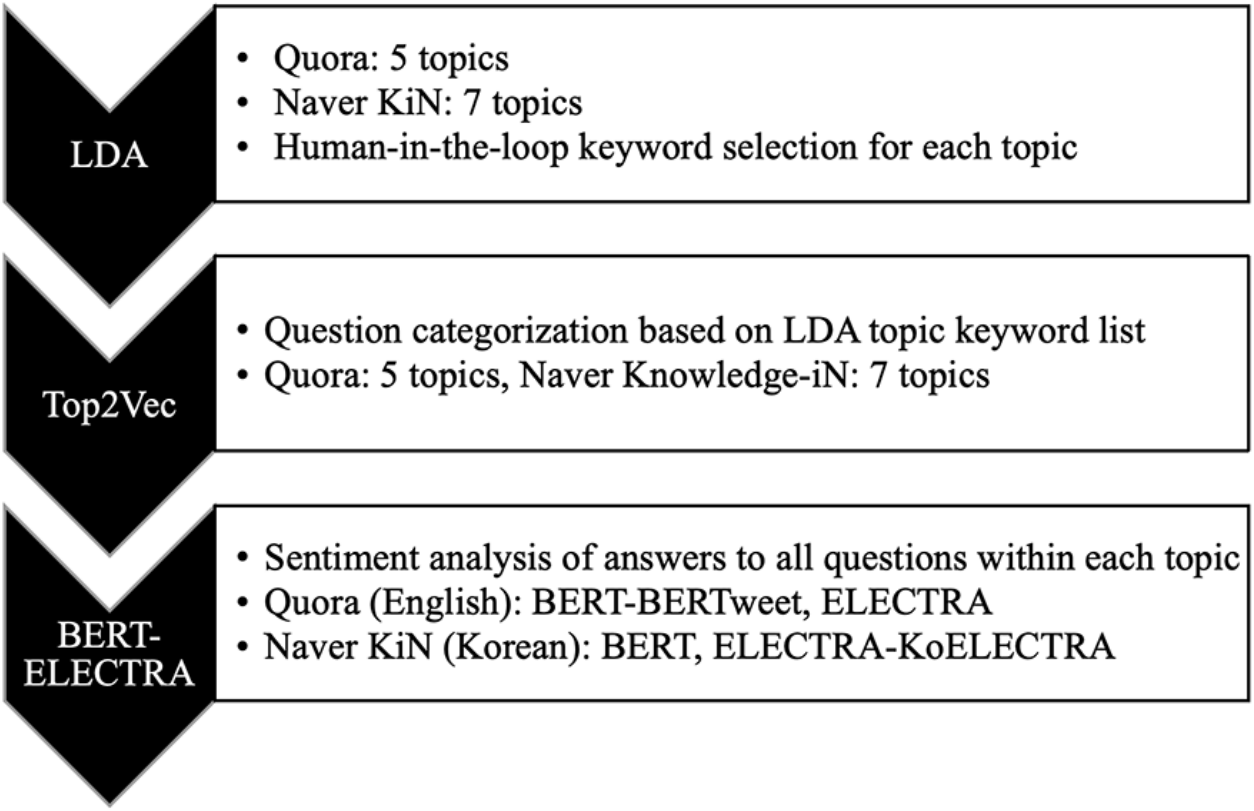


Figure 2. Overview of data analysis framework. Questions from Quora and Naver Knowledge-iN (Naver KiN) are grouped into topics using LDA and Top2Vec, with human-in-the-loop keyword selection. Sentiment analysis of answers within each topic is then performed using BERT- and ELECTRA-based models. BERT: Bidirectional Encoder Representations from Transformers; ELECTRA: Efficiently Learning an Encoder that Classifies Token Replacements Accurately; LDA: Latent Dirichlet Allocation.



Categorization of Questions: LDA and Top2Vec

In this study, we combined machine learning predictions with human-in-the-loop validation to categorize questions from Quora and Naver KiN. To this, we applied topic modeling to identify key topics across the documents, offering guidance for strengthening public health communication strategies [62]. Specifically, LDA was used to categorize the questions on Quora into 5 topics and those on Naver KiN into 7 topics. We initially extracted 50 topics, which is the optimal number of topics determined by the coherence score, and manually merged them into 5 topics for Quora and 7 topics for Naver KiN. Researchers (SY, SHJ, JC, and YJY) discussed and decided on each topic together. While merging topics, we discovered that Naver-KiN covered more topics than Quora.

LDA uses documents, words, and latent variables that represent the latent topics associated with word sequences. Although LDA

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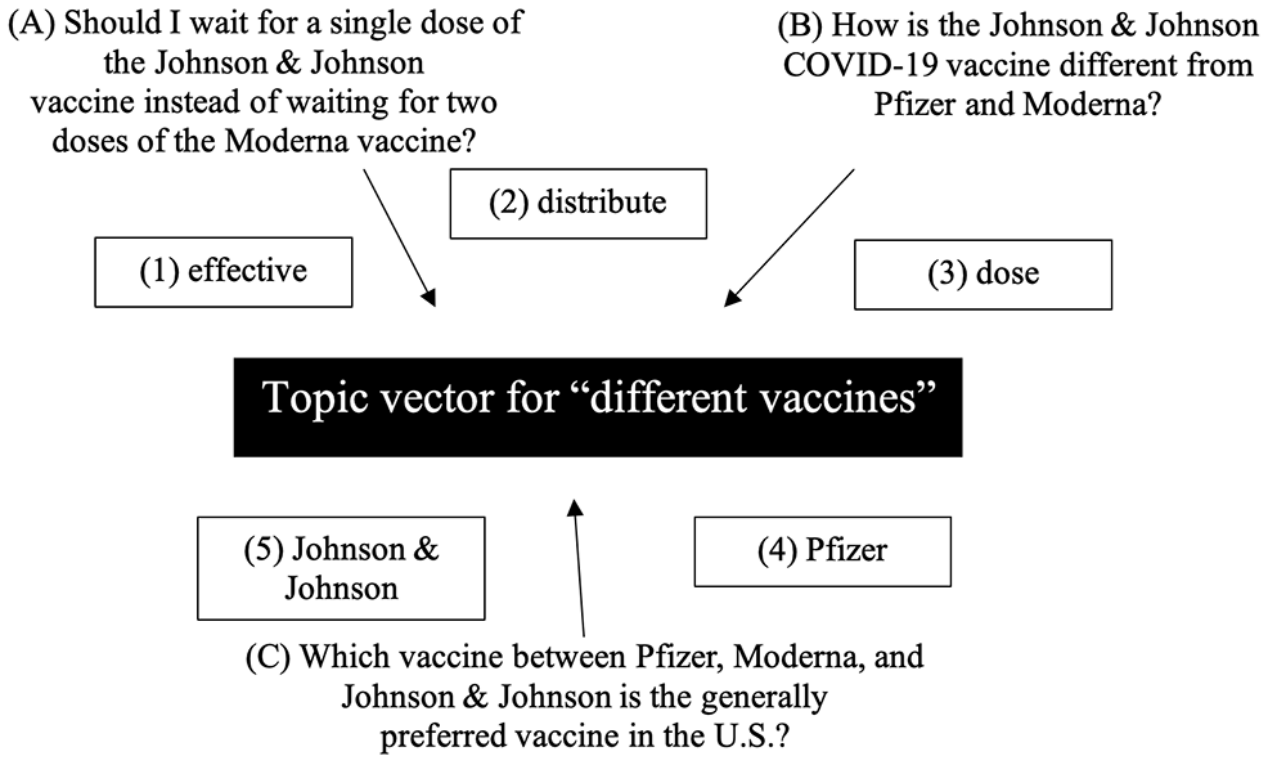
is effective in restricting the number of topics and offering keywords associated with each topic, it does not quantify the similarity between each keyword and its topic (it mainly uses document-word frequency when categorizing topics). That makes it challenging to determine which words are most relevant to the topic when relying solely on human decisions for keyword selection. To address this limitation, we incorporate Top2Vec, which preserves word semantics by representing words and documents in a shared embedding space and derives topic representations directly from these semantic structures.

Building on this motivation, we adopt a hybrid LDA-Top2Vec pipeline to combine probabilistic topic structure with semantic embedding-based topic modeling. While Top2Vec is often applied directly to raw documents, we instead use LDA to first identify topic-relevant keywords, which serve as a coarse topical filter. This step constrains the semantic space Top2Vec explores, enabling it to focus on semantically meaningful regions associated with each topic. As a result, this hybrid approach yields more interpretable and stable topic representations than applying Top2Vec alone to the full document corpus. While formal coherence scores were not used as a selection criterion, this hybrid approach was chosen to prioritize interpretability and topic stability.

Operationally, the LDA-extracted keywords were represented as word vectors, and the questions were represented as document vectors in the vector space. Figure 2 illustrates the process of question analysis using the mixed LDA and Top2Vec method. Figure 3 further visualizes a semantic space that consists of word vectors (enclosed numbers 1, 2, 3, 4, and 5) and document vectors (labeled A, B, and C). The centroid of the document vectors is a topic vector (black central square labeled topic vector for different vaccines). The word vectors in Figure 3 are the words with the closest semantic relationship to the topic vector, whereas the LDA keywords indicate the word distribution per topic solely by frequency. In other words, LDA delineates the statistical relationship among topics, but it fails to capture semantic information about those topics [63].

Figure 3. Illustration of topic vector construction for "different vaccines." The topic vector is defined as the centroid of the document (question) vectors (A, B, and C) and the associated keywords (1, 2, 3, 4, and 5). Keywords that are semantically closest to this centroid are used to characterize the topic.



Sentiment Analysis of the Answers: Transformer-Based Models

Because COVID-19 greatly affected the sentiments expressed on social media [64], we used a document-level sentiment analysis to extract and classify perceptions and attitudes toward the topics discussed in the documents [32,65]. This analysis served as an indicator of public perception regarding COVID-19 concerns [66]. We used 2 transformer-based models, BERT and ELECTRA, that are capable of fine-tuning with pretrained models. The pretraining and fine-tuning mechanism enhances each model's ability to effectively grasp the intricacies of downstream NLP tasks, such as sentiment analysis.

BERT is a widely used language model that uses pretrained data and a self-attention mechanism to generate contextualized vector outputs. It is applied to a range of downstream tasks, including sentiment analyses. BERT uses the masked language model; some tokens in the sentence are replaced with (MASK), and then the model is trained to regenerate the original tokens [59]. On the other hand, ELECTRA, which is another pretrained transformer model, uses a discriminator to predict the replaced tokens by generating token output instead of relying on a masked language model [60]. Both models have been widely used for

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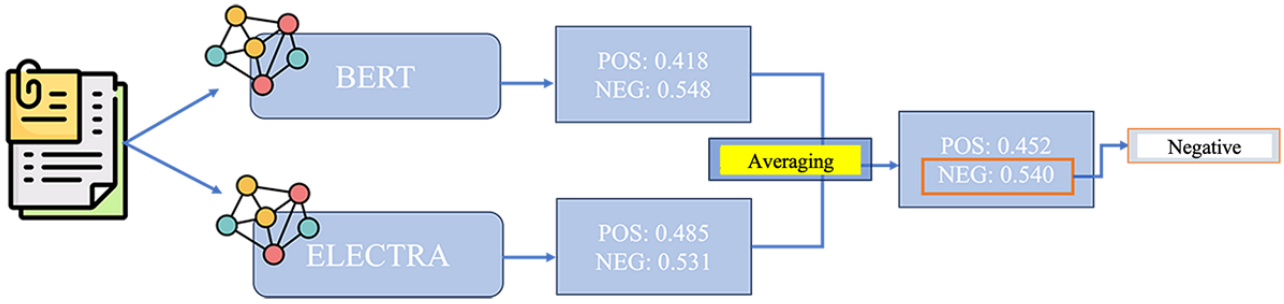
various NLP downstream tasks [67], and we used models fine-tuned for an English sentiment analysis and a Korean sentiment analysis.

For the English language model, both BERT-based [68] and ELECTRA-based [60] were specifically fine-tuned for a sentiment analysis using Twitter datasets. While Twitter and Quora have posts of different lengths (a Twitter post consists of 8 words on average and a Quora post consists of 40 words on average) [69], both Twitter and Quora texts are social media data originating from public interactions on a social media platform. They share similar traits, and the model fine-tuned on Twitter was effectively applied to the Quora dataset [70], and we conducted a sentiment analysis of Quora data with 66% (33/50) accuracy. For the Korean language model, both BERT-based [71] and ELECTRA-based [72] were fine-tuned using Naver KiN shopping reviews, Steam game reviews, and movie reviews. We evaluated the accuracy of these models for Naver KiN data and achieved 72% (36/50) accuracy in the sentiment analysis. This choice thus mirrored the strategy we used for the English model.

One limitation of using transformer models is the constraint of the input tensor size, which is restricted to a length of 128 tokens. This limitation can sometimes introduce biases because only the first 128 tokens are considered, potentially leading to inaccurate sentiment analysis results. For instance, the beginning of a post might convey a positive sentiment by starting with a greeting, for example, that is not representative of the main content of the post. To address that issue, we divided each post into chunks of 128 tokens, measured the sentiment of each chunk, and then averaged the sentiment values of all the chunks to determine the overall sentiment result.

To further enhance the validity of the sentiment analysis, we used an ensemble method called the bagging or bootstrap aggregating technique, which is known for its effectiveness in classification tasks. This method generates an ensemble classification output that outperforms the accuracy of a single prediction value [73,74]. We applied it to predict improved sentiment values for each answer using both BERT and ELECTRA. An overview of the process is provided in Figure 4. The outcomes from both models were the probabilities of positive and negative sentiments. Subsequently, we computed the average probabilities of positive and negative sentiments. Once we obtained the averaged positive and negative probabilities, we compared them and used the higher one.

Figure 4. Ensemble averaging for sentiment analysis. Positive and negative sentiment scores are independently predicted using BERT and ELECTRA. The corresponding scores are then averaged across models, and the sentiment label with the higher averaged score is selected as the final prediction. BERT: Bidirectional Encoder Representations from Transformers; ELECTRA: Efficiently Learning an Encoder that Classifies Token Replacements Accurately; Neg: negative; POS: positive.



Ethical Considerations

Ethical review was not required for this study because it exclusively used publicly available social media content shared in accordance with platform policies. As the data were publicly accessible, Institutional Review Board approval and a waiver of informed consent were not required [75,76]. This study did not use or infer individuals' identities but instead examined vaccine-related opinions at an aggregate level to provide an overall picture of public perceptions. To protect user privacy, all identifiable information was removed during preprocessing, and all questions and comments presented in this manuscript were paraphrased. The final aggregated dataset contains no personally identifiable information and cannot be traced back to individual users.

Results

Topic Analysis of Questions

Table 1 presents the topic modeling results for Quora, where 5 primary topics were identified. The most frequently discussed topic was different vaccines (978/3952, 25%), with users asking about characteristics and comparisons of various vaccine brands such as AstraZeneca (AstraZeneca plc) and Moderna (Moderna, Inc). This was followed by government policy (821/3952, 21%), where questions centered on administrative decisions and vaccine distribution, with keywords including "require," "Trump," and "supply." Variants (782/3952, 20%) included discussions focused on the severity of new COVID-19 strains and vaccine efficacy. The topic of visiting overseas (743/3952, 19%) comprised questions about travel eligibility based on vaccination status. The least frequent topic, effects of vaccine (626/3952, 16%), involved concerns about immunity, side effects, and infection risks.

Table 2 shows the topic modeling outcomes for Naver KiN, which yielded 7 topics. The most common was effects of vaccine (790/3952, 20%), marked by terms like "side effects" and "uptake," where users expressed hopes for effective vaccination and sought information on its impact. Vaccination appointments followed (711/3952, 18%), with users asking about eligibility and scheduling logistics. The variants topic (592/3952, 15%) reflected interest in vaccine efficacy against emerging strains. Government policy (553/3952, 14%) included questions about

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national vaccination strategies. School and education (513/3952, 13%) highlighted questions about children's school attendance in relation to family vaccination status. Visiting overseas (474/3952, 12%) addressed international travel feasibility amid varying vaccination policies. The least common topic was different vaccines (316/3952, 8%), where users asked about vaccine suitability for individual health conditions.

Table 1. Example question for each topic in Quora. For each topic identified in the Quora dataset, the table reports the proportion of questions assigned to the topic and provides an example question illustrating the topic content (N=3952).

Label	Topic proportion, n (%)	Example question
Different vaccines	978 (25)	"How come the other vaccines, including the Pfizer and Moderna vaccines, require 2 doses; however, the Johnson & Johnson COVID- 19 vaccine requires only one dose?"
Government policy	821 (21)	"On his tonight show, Sean Hannity credits Donald Trump with developing the COVID-19 vaccine rather than President Biden. Who in your opinion deserves the credit?"
Variant	782 (20)	"Does the delta variant of COVID-19 pose the highest threat to individuals who have not yet received vaccinations because it is more contagious, causes a more serious illness, and is not affected by the current vaccines?"
Visiting overseas	743 (19)	"Would you get vaccinated only to travel if many of the largest airlines in the world require verification of vaccination status in your passport and prevent unvaccinated people from traveling?"
Effects of vaccine	626 (16)	"Is it acceptable to state that you do not want the vaccine because everyone you know who has received the COVID-19 vaccine has become ill shortly after vaccination?"

Table 2. Example questions for each topic in Naver Knowledge-iN (Naver KiN). For each topic identified in the Naver KiN dataset, the table reports the proportion of questions assigned to the topic and provides an example question illustrating the topic content (N=3952).

Label	Topic proportion, n (%)	Example question
Effects of vaccine	790 (20)	"I heard that individuals under 18 years of age cannot be vaccinated but why? I also want to get vaccinated. COVID-19 will come to an end if everyone gets vaccinated quickly and becomes immune to the virus. I want to take off my mask and go somewhere."
Vaccine appointment	711 (18)	"Can civil defense corps members also get vaccinated? When are they eligible to get vaccinated? Tell me the vaccination schedule for both the 1st and 2nd dose."
Variant	592 (15)	"They say that COVID-19 vaccines are effective but is it too early to come to conclusions? For vaccines to be effective, antibodies should last for a long period. However, for COVID-19 vaccines, antibodies do not last even 1 year, indicating they are effective only for a short period of time. (…) Thus, is it too early to determine the effectiveness of the vaccines?"
Government policy	553 (14)	"I have recently taken interest in our government. I believe our government has responded well to the COVID-19 outbreak compared with other countries, and the delay in vaccine supply appears reasonable because vaccines are prioritized to countries that have not managed the virus well. (…) However, why are there so many negative comments regarding the government on Naver KiN? I am just wondering. Maybe I am wrong but I am leaving a comment because I want to know why people are so angry."
School and education	513 (13)	"My parents were vaccinated. Can I go to school?"
Visiting overseas	474 (12)	"How serious is the COVID-19 situation in Japan? Has Japan started vaccinations? Please tell me specifically about this situation. I am planning on traveling to Japan and was wondering whether it would be possible to go to Japan after COVID-19 comes to an end. I am planning my trip for next year. Will COVID-19 end in both countries by then?"
Different vaccines	316 (8)	"I am in my 20s and I have hypothyroidism. Are people with hypothyroidism considered chronically ill patients? When can people with chronic diseases get vaccinated? Which vaccine will I receive?"

Sentiment Analysis of Answers

A sentiment analysis was used to examine the answers given on both Quora and Naver KiN. Figure 5 illustrates the proportions of sentiments in Quora answers to questions from each topic. Across 4 of the topics—effects of vaccine, visiting overseas, variants, and different vaccines—the number of answers with negative sentiment exceeded the number of positive ones. However, within the topic of government policy, answers with positive sentiment were more prevalent than negative ones.

In Figure 5, positive versus negative sentiments were observed as follows: effects of vaccines (306/626, 48.79% vs 320/626, 51.12%), visiting overseas (335/743, 45.05% vs 408/743, 54.95%), variants (362/782, 46.29% vs 420/782, 53.71%), different vaccines (386/978, 39.47% vs 592/978, 60.53%), and government policy (437/821, 53.23% vs 384/821, 46.77%),

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where the first value represents positive sentiment and the second represents negative sentiment.

We analyzed sentiment outcomes on a monthly basis from June 2020 to June 2021, focusing on topic popularity over time (see Figure 6). While finer-grained temporal analyses are possible, we adopted monthly aggregation to reduce sparsity and short-term volatility and to emphasize broader discourse trends rather than reactions to specific events. Across all topics except different vaccines, positive-negative sentiment crossovers occurred at least 3 times. After May 2021, positive sentiment exceeded 50%, indicating its dominance across topics. Notably, only government policy consistently showed a surplus of positive sentiment over negative for 4 consecutive months after February 2021.

Figure 5. Sentiment proportions per topic in Quora.

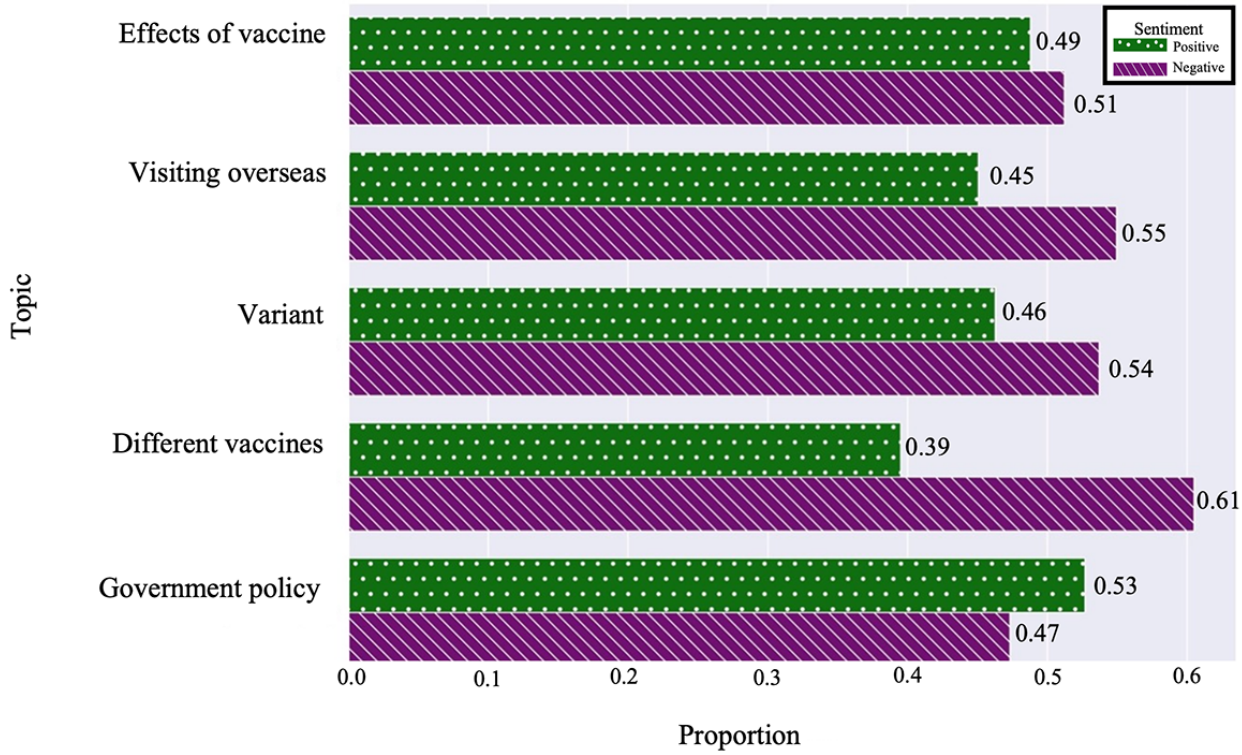

Figure 6. Temporal analysis of sentiments per topic in Quora. Due to limited data availability, 4 days at the end of June 2020 were merged into July 2020 for the analysis.

During this period, the vaccination rate increased by 15.3%, from 17.45% to 32.78% [52], coinciding with heightened public attention to vaccine rollout and access. Positive sentiment toward government policy appears to reflect evaluations of these concrete policy outcomes rather than a broader shift in institutional trust. In particular, the temporary increase in positive sentiment after February 2021 aligns with major administrative transitions and policy announcements, including changes in federal coordination, alongside continued public

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recognition of vaccine development efforts initiated under Trump, as reflected in the example in Table 1.

Prior research similarly suggests that during public health crises, shifts in public trust toward government are closely tied to public perception of policy responses and outcomes. Notably, policy-specific achievements (eg, visible progress in crisis management) are often associated with temporary increases in positive evaluations even amid persistent skepticism toward government institutions [77]. Thus, the observed temporal positivity in "government policy" sentiment likely captures situational approval of pandemic response measures rather than a reversal of widespread distrust in US governance.

The results of the sentiment analysis of answers to questions on Naver KiN are depicted in Figure 7. Across all 7 topics—different vaccines, government policy, schools and education, vaccine appointments, variants, effects of vaccines, and visiting overseas—positive sentiments were predominant over negative sentiments. This overarching trend is also highlighted in Figure 8, which shows that positive sentiment consistently exceeded 50% throughout the year except for the topic of different vaccines.

In Figure 7, the proportions of positive versus negative sentiment were as follows: effects of vaccines (498/790, 63.04% vs 292/790, 36.96%), visiting overseas (337/474, 71.10% vs 137/474, 28.90%), variants (367/592, 61.99% vs 225/592, 38.01%), different vaccines (218/316, 68.99% vs 98/316, 31.01%), government policy (348/553, 62.93% vs 205/553, 37.07%), vaccine appointment (562/711, 79.04% vs 149/711, 20.96%), and school and education (364/513, 70.96% vs 149/513, 29.04%).

For the topic of different vaccines, 4 positive-negative sentiment crossovers occurred between June 2020 and January 2021, often driven by concerns about side effects and individual health conditions. During this period, confirmed COVID-19 deaths per million rose sharply by 313% [52]. As shown in Table 2, a question regarding vaccine eligibility for individuals with chronic illnesses received a relevant response. After February 2021, coinciding with the launch of South Korea's vaccination program on February 26, positive sentiment prevailed, with no further crossovers observed [52].

Figure 7. Sentiment proportions per topic in Naver Knowledge-iN (Naver KiN).

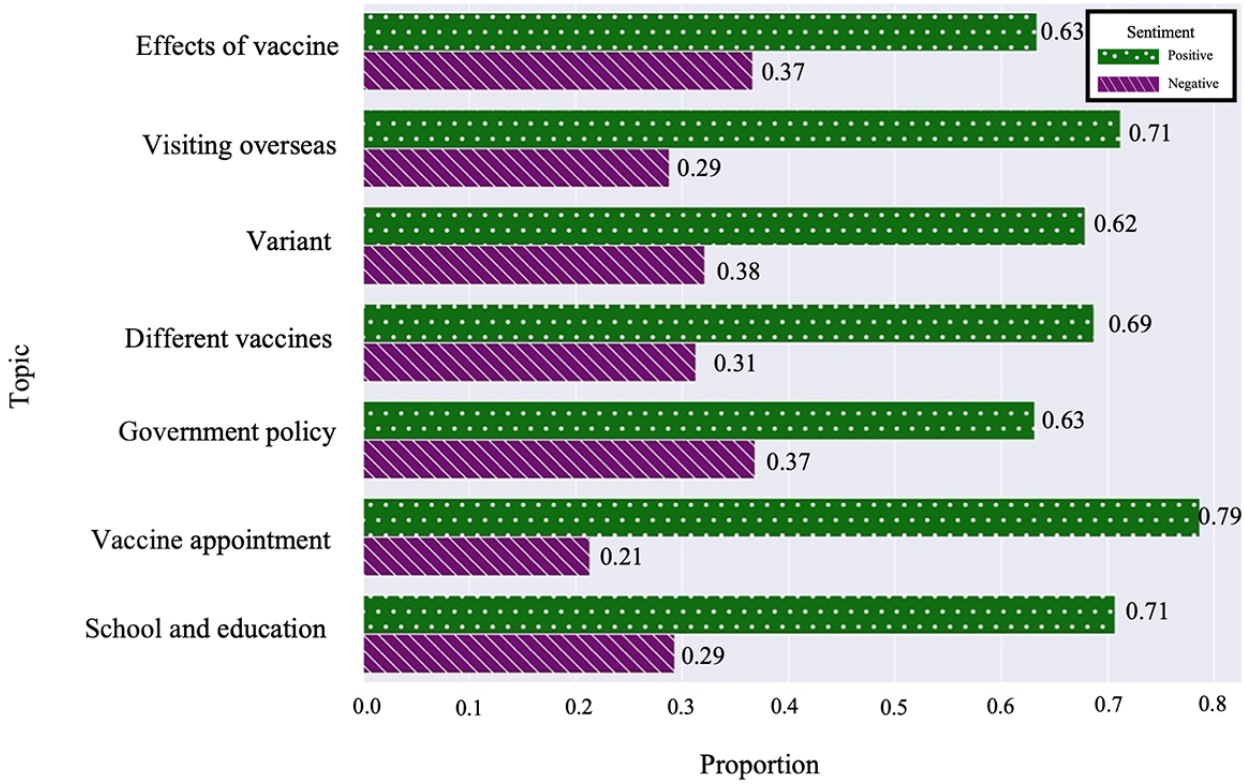

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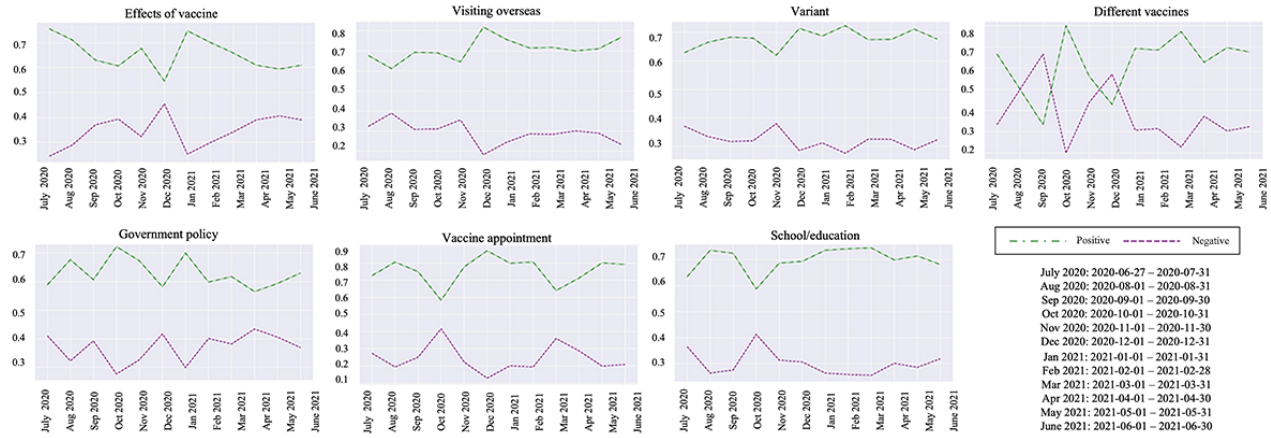
Figure 8. Temporal analysis of sentiment per topic in Naver KiN. Due to limited data availability, 4 days at the end of June 2020 were merged into July 2020 for the analysis.



Sentiment Analysis of Q&A Pairs

After analyzing the sentiments of the answers, we examined question–answer sentiment pairs within each topic to see if the question's sentiment might affect the answer. Table 3 shows the sentiments of question-answer pairs on Quora. In 4 topics—effects of vaccine, visiting overseas, variants, and different vaccines—the predominant sentiment pairs are negative-negative, followed by negative-positive, positive-positive, and positive-negative. For the topic of government policy, negative-positive sentiment pairs are as prevalent as negative-negative, with positive-positive and positive-negative following.

Table 4 illustrates the sentiment for question-answer pairs on Naver KiN. Across all topics, positive-positive and negative-positive pairs constituted more than 63% of the sentiment. For 6 topics—effects of vaccines, visiting overseas, different vaccines, government policy, vaccine appointments, and school and education—positive-positive pairs were the most prevalent, followed by negative-positive pairs. In contrast, for the topic of variants, negative-positive pairs were the most prevalent, followed by positive-positive pairs.

Table 3. Question-answer sentiment pairs for each topic on Quora.

Topic	Positive-positive, n (%)	Positive-negative, n (%)	Negative-positive, n (%)	Negative-negative, n (%)
Effects of vaccines (N=626)	101 (16.07)	49 (7.85)	205 (32.71)	271 (43.36)
Visiting overseas (N=743)	84 (11.3)	68 (9.11)	251 (33.75)	340 (45.84)
Variants (N=782)	123 (15.78)	91 (11.61)	239 (30.51)	329 (42.11)
Different vaccines (N=978)	114 (11.66)	88 (8.97)	272 (27.86)	504 (51.52)
Government policy (N=821)	123 (14.87)	73 (8.78)	314 (37.82)	311 (37.53)

Table 4. Question-answer sentiment pairs in each topic on Naver Knowledge-iN (Naver KiN).

Topic	Positive-positive, n (%)	Positive-negative, n (%)	Negative-positive, n (%)	Negative-negative, n (%)
Effects of vaccines (N=790)	279 (35.32)	187 (23.67)	219 (27.72)	105 (13.29)
Visiting overseas (N=474)	239 (50.42)	101 (21.31)	98 (20.68)	36 (7.59)
Variants (N=592)	178 (30.07)	102 (17.23)	189 (31.92)	123 (20.78)
Different vaccines (N=316)	125 (39.56)	49 (15.51)	93 (29.43)	49 (15.5)
Government policy (N=553)	177 (32.01)	90 (16.27)	171 (30.92)	115 (20.8)
Vaccine appointment (N=711)	374 (52.6)	110 (15.47)	188 (26.44)	39 (5.49)
School and education (N=513)	207 (40.35)	85 (16.57)	157 (30.61)	64 (12.47)

Discussion

Principal Findings

Social media provides valuable insights for policymakers developing health policies [27]. Our study pioneers exploring public discourse on vaccines in 2 countries using advanced NLP techniques, surpassing traditional survey-based methods. This approach reveals hidden aspects of vaccine perceptions beyond conventional demographics. We analyzed overall perceptions (via topic analysis) and communication within each topic (via sentiment analysis). In this discussion, we consider platform characteristics and acknowledge the study's limitations.

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Comparative Discourse on the COVID-19 Vaccine

The United States and Korea both have concerns about 5 topics, including effects of the vaccine, visiting overseas, variants, different vaccines, and government policy; however, Korea uniquely highlights vaccine appointments and school and education. Vaccine appointments became a significant issue in Korea due to delays in vaccine distribution [49], with the government implementing an age-based distribution policy to respect the cultural emphasis on older adults and their high risk of serious disease. Although prioritizing the older adults might have effectively reduced COVID-19–related mortality and morbidity within this age group, other vulnerable populations, such as prisoners and the homeless, experienced relative disadvantages. Therefore, the equitable distribution of vaccinations is a topic requiring open discussion.

Naver KiN also revealed a unique topic about school and education that did not appear on Quora. This topic highlights how deeply education is valued in Korean culture, which made vaccinating school-aged children and their parents crucial [78]. This contrasts with the United States, where, despite the CDC's recommendations [79], vaccine hesitancy remained a notable barrier among many parents [80]. Thus, the Naver KiN results underscore that cultural values and societal priorities, such as Korea's strong commitment to educational success, played a significant role in shaping public attitudes toward COVID-19 vaccination.

Based on those topics, we investigated the sentiments expressed in question-answer pairs and gleaned insights into the public perceptions of COVID-19 vaccines expressed on social Q&A sites in the United States and Korea. Our findings highlight distinct sentiment patterns reflective of the cultural and informational contexts of these countries. Quora and Naver KiN both have a similar tendency of consistency between a question's sentiment and the answers it receives (eg, positive [Q]-positive [A] or negative [Q]-negative [A]). However, users of the 2 platforms expressed different sentiments toward the COVID-19 vaccine.

The sentiment analysis of Quora data reveals that in the United States, negative sentiment was predominant in discussions about the effects of the vaccine, visiting overseas, variants, and different vaccines. In those topics, negative-negative (question-answer) pairs are the most common, indicating widespread skepticism and concern among users [15,25]. Unlike Quora, the majority of answers were positive in the Naver KiN data from Korea, with positive-positive (question-answer) and negative-positive pairs constituting more than 63% of the total. This difference may be attributed to varying levels of trust in the government between the 2 countries.

At the time we collected data from Naver and Quora, South Korea was effectively managing the pandemic, and public trust in the government was high, consistent with previous research showing high compliance with COVID-19 government policies [81]. As a result, both questions and answers were generally positive. The only topic that saw a higher occurrence of negative questions paired with answers with positive sentiment was related to variants, likely because the Korean government could not control the emergence of variants, leading to more negative sentiment. Even in discussions about variants, where there was more negative sentiment toward the question, the sentiment toward the answers remained largely positive, indicating resilience and hope [82,83]. In contrast, in the United States, the situation was markedly different. Public trust in the US government was lower, and adherence to COVID-19 policies was less consistent [81]. The skepticism and concerns expressed in the US discussions may have been driven by widespread dissatisfaction with how the pandemic was being handled, leading to a pervasive negative sentiment across various topics [81-83].

These contrasting attitudes suggest that the differences observed in the public discourse on the COVID-19 vaccine in the United States and South Korea may stem from cultural and situational factors rather than true variations in public perceptions. Given that the unique social context of each country shapes public discourse and sentiment, it can be inferred that communication strategies targeted to cultural contexts are required to address vaccine hesitancy. In the United States, public health campaigns should counter misinformation [32] and address specific safety concerns, engaging trusted community leaders and positive narratives about vaccination benefits. In Korea, on the other hand, maintaining positive public discourse through transparency and timely updates is crucial. The unique focus on vaccine appointments and education in Korean discussions highlights specific information needs that should be addressed.

Effects of the 2 Platforms on Sentiment

Platform-specific user dynamics also play a role in shaping public discourse [84,85], affecting the sentiments of each platform's answers. The presence of health care professionals on Naver KiN, who provide expert opinions, likely contributes to the positive sentiment and higher likelihood of their answers being perceived as trustworthy, in contrast to the diverse user base on Quora. Overall, understanding and leveraging these distinct sentiment patterns can help public health authorities craft more effective communication strategies to promote a positive and informed discourse about COVID-19 vaccination.

To select the responses for our analysis, we used a methodology intended to mirror the typical user experience on these platforms. Responses were chosen based on specific criteria designed to reflect a balance between popularity and relevance and, above all, to reflect which answers the users deemed most effective. This approach aligns with methodologies used in previous user-generated content analyses on platforms such as Quora and Naver KiN [48].

Limitations of This Study

This study has several limitations. First, there was a notable variance in the average length of answers between Quora and Naver KiN. This discrepancy might have introduced potential bias when comparing the answers. Future studies could mitigate this by standardizing the length of answers or selecting questions with a similar number of words for a more meaningful comparison. In addition, platform-specific user demographics may partially confound cross-cultural comparisons. Naver KiN serves as a dominant information-seeking platform in South Korea, characterized by large-scale daily participation and broad

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distribution of user expertise [48,86]. In contrast, Quora users in the United States tend to be younger and more educated [87]. These structural differences may shape how questions are shaped, how answers are evaluated, and how sentiment is expressed. As a result, the observed sentiment asymmetry between the 2 platforms may reflect platform participation norms and demographic composition, as well as national-level attitudes.

Second, although we used models already trained on our target social media outlets, Quora and Naver KiN, we applied both topic modeling and sentiment analysis models without fine-tuning them with our data. This may result in less optimal and lower-performing outputs from the experiments. To mitigate this limitation, fine-tuning each model should be performed to yield more reliable results in future studies.

Third, our analysis focuses on the most favorable answers associated with each question. This design choice may limit the generalizability of findings regarding public perception. By prioritizing community-validated information, often in the form of expert-driven responses, this analysis may also introduce a positive bias toward answers. Thus, the observed association between question sentiment and answer sentiment should be interpreted as reflecting how question framing relates to the community-validated information, rather than the full range of public perception, which may include greater uncertainty, disagreement, or negative affect.

Finally, we acknowledge as a limitation that no explicit bot-detection or automated content-authenticity filtering algorithm was applied. Given the highly politicized and time-sensitive nature of vaccine-related discourse during 2020-2021, bot-generated content may have contributed to the observed sentiment patterns. Although we partially mitigated this risk by excluding unanswered questions and constraining questions that include the keyword “vaccine” (in Korean, 백신), these measures did not guarantee the removal of automated or coordinated accounts. As such, some sentiment estimates may reflect amplified or artificial signals rather than purely user opinions.

Conclusions

This study has provided critical insights into the dynamics of vaccine discourse, underscoring the need for context-specific strategies for promoting vaccination. By melding state-of-the-art NLP technologies with a cross-cultural analysis, we have forged a path toward more informed, efficacious, and targeted efforts in public health communication, both in the ongoing battle against the COVID-19 pandemic and beyond. Above all, this study underscores the paramount importance of harnessing social media as a prolific source of public sentiment and information needs, particularly within the sphere of vaccine hesitancy. Analyzing public discourse on platforms such as Quora and Naver KiN provides researchers with an unfiltered view of individuals’ concerns and perceptions, offering insights invaluable for crafting responsive public health strategies.

Our findings reaffirm the profound effects of cultural and societal factors on public attitudes toward vaccines. The stark contrast observed between the United States and Korea in terms of vaccine perceptions underscores the need for culturally sensitive approaches in health communication and vaccination campaigns. This study advances the academic landscape by demonstrating the efficacy of NLP technologies for comprehending public perceptions and information needs related to vaccines. NLP methods transcend traditional survey methodologies, providing a more naturalistic perspective rooted in real-world discussions on community-driven social media platforms. Our innovative amalgamation of LDA, Top2Vec, and BERT- and ELECTRA-based sentiment analyses sets a pioneering benchmark for future research in this domain. This multifaceted approach augments our comprehension of the intricacies encircling vaccine discourse and can be adapted to explore analogous public health issues across diverse countries and cultures.

As for practical insights, our findings have implications for policymakers and health communication practitioners in both countries. The discernment of disparities in vaccine-related information needs and perceptions between the United States and Korea underscores the necessity of tailoring public health campaigns to the specific nuances of each nation’s context. Effectively addressing vaccine hesitancy—a complex interplay of safety concerns, access barriers, and misinformation—demands a nuanced, multifaceted approach. Our study underscores the need for policy interventions that take these underlying factors into account, while also recognizing the profound influence of cultural and societal values on vaccination decisions.

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During manuscript preparation, we used the generative artificial intelligence tool ChatGPT [88] exclusively to improve language clarity and readability. All content was reviewed and edited by the authors. The authors take full responsibility for the final manuscript.

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Data Availability

The data that support the findings of this study are openly available in GitHub repository.

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Authors' Contributions

SY, SHJ, JC, and YJY contributed to the conceptualization of the study. SY and JC contributed to data curation, methodology, and visualization. SY, SHJ, HK, JC, and YJY contributed to formal analysis and manuscript writing.

Conflicts of Interest

None declared.

Multimedia Appendix 1
STROBE checklist.
[PDF File (Adobe PDF File), 116 KB - formative_v10i1e84791_app1.pdf]

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Abbreviations

BERT: Bidirectional Encoder Representations from Transformers
CDC: Centers for Disease Control and Prevention
ELECTRA: Efficiently Learning an Encoder that Classifies Token Replacement Accurately
H1N1: Hemagglutinin Type 1 and Neuraminidase Type 1
LDA: Latent Dirichlet Allocation
MERS: Middle East Respiratory Syndrome
Naver KiN: Naver Knowledge-iN
NLP: natural language processing
Q&A: question and answer
STROBE: Strengthening the Reporting of Observational Studies in Epidemiology
WHO: World Health Organization

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Original Paper

The Influence of the COVID-19 Pandemic on Current Teaching Methods, Training, and Perception Among Romanian Surgery-Oriented Students: Cross-Sectional Study

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Abstract

Background: The COVID-19 pandemic prompted rapid changes in medical education, accelerating the adoption of online and distance learning methods as alternatives to traditional teaching. While these approaches offered logistical advantages, students worldwide reported significant limitations, particularly in terms of motivation, clinical exposure, and hands-on skill acquisition. Despite the increased use of digital teaching during the pandemic, core educational objectives and the mission of medical training remained unchanged, emphasizing the continued importance of practical experience.

Objective: This study aims to investigate the impact of the COVID-19 pandemic on current teaching methods in medical education and to explore students' perceptions of online learning, telemedicine, artificial intelligence, and other modern educational alternatives.

Methods: This observational, cross-sectional multicentric study surveyed a cohort of Romanian medical students using a self-developed 48-item online questionnaire distributed via social media. Data were collected over 6 weeks (February-March), yielding 451 responses, of which eligible participants included students in clinical years or preclinical students interested in surgical or orthopedic careers, with a heavy representation of the Medicine and Pharmacy University of Timisoara. Statistical analysis was performed using Microsoft Excel and JASP (University of Amsterdam; version 0.95.4).

Results: A total of 436 responses were analyzed, with students favoring online or hybrid formats for lectures but preferring on-site teaching for practical training. Reduced patient interaction and limited skill acquisition were the main drawbacks of online practical education. Acceptance of hybrid learning correlated with more positive perceptions of teaching methods and a lower perceived desire to cheat.

Conclusions: The COVID-19 pandemic brought significant changes to the way medicine is being taught in Romania, but it also brought a clearer picture for students and medical staff on how they want medical education to be done. Online cheating remains a significant challenge, but it is being tackled at the moment with different algorithms being tested.

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KEYWORDS

medical education; COVID-19 pandemic; medical students; medical training; post COVID-19 pandemic

Introduction

The COVID-19 pandemic represented a period of transition and adaptation of teaching techniques, particularly within medical schools. Furthermore, it acted as a catalyst for the implementation of innovative teaching methods, particularly through the widespread adoption of online learning, which served as an alternative to the traditional teaching approaches used before this period [1-3]. Beyond curriculum reorganization [2], this period also facilitated innovation in medical education by accelerating the implementation of distance learning approaches, including webinars, newly adopted digital platforms, and virtual reality–based instructional methods [4,5].

Despite the advantages associated with online teaching methods, such as increased time flexibility, improved time efficiency, enhanced comfort due to the absence of commuting, and reduced financial costs, students reported several perceived disadvantages, including decreased motivation for learning, loss of direct clinical contact with patients and health care staff, and a reduction in hands-on practical experience [6,7]. Both the advantages and disadvantages were consistently highlighted by medical students across different regions of the world and countries with varying levels of socioeconomic development, including the United Kingdom, Iran, Pakistan, Saudi Arabia, as well as countries in Asia and Europe [6,8-10]. Moreover, similar findings were reported in Romania, where the overall student perception of the impact of the COVID-19 pandemic was predominantly negative (78%) [11].

When comparing the prepandemic and pandemic periods retrospectively, it can be stated that the fundamental teaching methods used in medical education have largely remained unchanged, owing to the essential need for practical experience acquisition and the development of a solid theoretical knowledge base closely integrated with clinical practice [12]. Furthermore, the mission of medical education remains constant regardless of context and represents the cornerstone for the development of future generations of physicians [13]. At the same time, retrospective analysis indicates that the use of distance learning methods increased significantly during the COVID-19 pandemic compared with the prepandemic period. Stoehr et al [14] emphasized that the purpose of online education is to achieve educational objectives rather than to replace them.

Tabatabai [15] emphasized the critical importance of students' physical presence during training periods, highlighting the necessity of acquiring hands-on practical experience, as well as the limitations of virtual teaching methods in fostering practical competencies and clinical reasoning skills. Adaptability represents an indispensable quality for any future physician, as it requires creativity and the ability to respond to ever-evolving clinical contexts. In the postpandemic era, medical students must also acquire competencies related to telemedicine, as this modality has already become an integral component of health care delivery and is expected to expand substantially in the future [16].

In Romania, during the COVID-19 pandemic, the continuity of the educational process was ensured through distance learning modalities. Before this period, the use of telemedicine was limited. Following the pandemic, the adoption of online teaching methods increased significantly compared with the prepandemic era; however, their use has been reduced now that the pandemic period has passed.

The primary objective of this study is to analyze the effects of the COVID-19 pandemic on currently used teaching methods, particularly the use of online instructional approaches, and their impact on the training of future generations of surgical physicians, among a cohort of Romanian medical students. Additionally, this study aims to examine students' perceptions regarding the use of artificial intelligence (AI), telehealth, and other modern alternatives for acquiring theoretical knowledge and practical skills. In addition to existing literature, this study specifically targets surgery-oriented students, a subgroup with distinct educational needs related to hands-on training and clinical exposure. Furthermore, it evaluates postpandemic perceptions regarding emerging educational tools such as AI and telemedicine within a Romanian context, where digital integration in medical education was limited before the pandemic.

Methods

Overview

In this observational, cross-sectional, multicentric study, a Google Form composed of 48 total questions, including demographic information, nominal data, ordinal data represented by Likert-type scales, and binary variables, was sent to medical students in Romania. At the beginning of February, responses were collected from students from all universities in Romania. The students have been selected using nonprobabilistic convenience sampling, with the ones who received the link and wanted to take part in the study being selected as the cohort to be analyzed. Students from the following universities have been contacted: "Victor Babes" University of Medicine and Pharmacy Timisoara, "Iuliu Hatieganu" University of Medicine and Pharmacy Cluj, "Dunarea de Jos" University of Galati, "Carol Davila" University of Medicine and Pharmacy Bucharest, "Ovidius" University of Constanta, "Lucian Blaga" University of Sibiu, University of Oradea, University of Medicine and Pharmacy of Craiova, Transilvania University of Brasov, and "Vasile Goldis" University of Arad. The last 2 universities only had 2 students, so to maintain a systematic standard across the multicentric study, the minimum threshold of 3 responders per university was established. In doing so, 4 responses did not meet this inclusion criterion. The questionnaire was sent using WhatsApp (Meta) and Instagram (Meta) groups, directly related to medical students in the universities previously mentioned.

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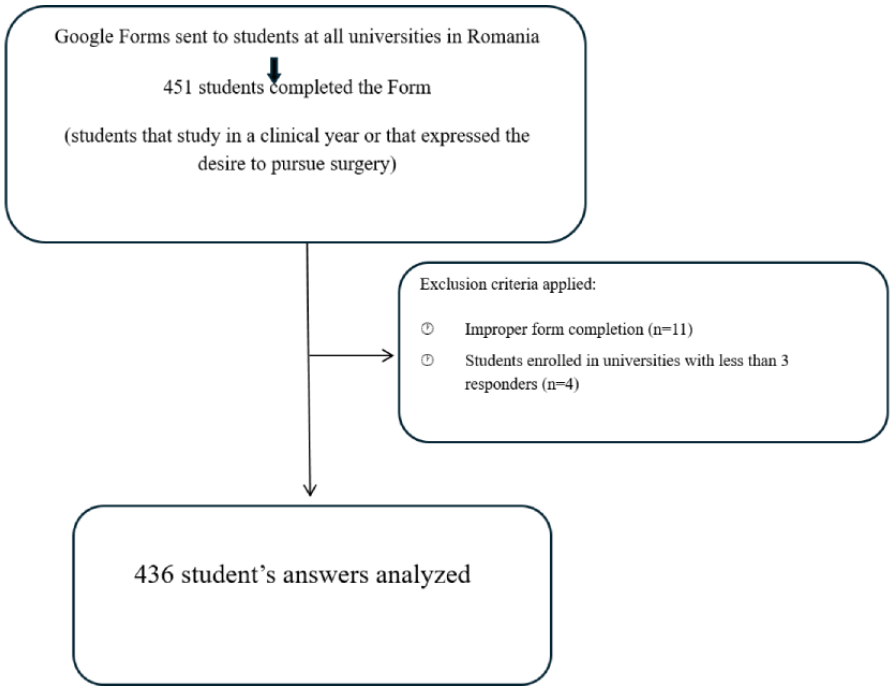
Response collection was made for a month and a half, until mid-March.

After closing the form, a total of 451 students from Romanian medical universities responded to the form. The criteria for completing the form were to be enrolled in one Romanian medical university, to attend 1 of the 4 clinical years (third to sixth years) and to be interested in following a surgical career. If the students were enrolled in one of the first two years, they could complete the form only if they expressed their desire to follow a career in a surgical field. The objective of the study was clearly indicated in the form description, so the completion of the survey was considered an implicit confirmation of their interest in surgery. After eliminating the responses of the students that did not fit the inclusion criteria (either they did not complete the form properly or they were enrolled in universities where only 3 or fewer students responded to the form), the statistical analyses were done. The study flowchart is presented in Figure 1.

Figure 1. Flowchart of participants' selection.



Data Collection and Form Design

A self-developed questionnaire has been developed, with no other similar form being available in Romania. The questionnaire was developed under the supervision of experts (the surgical professor and the medical education expert in the author list), after a comprehensive literature review of similar studies to identify the key domains relevant to medical education that need further exploration of the subject. It included data collected for the demographic assessment of the study (age, gender, and university), Likert-type questions (ranging from 1 to 5, where 1 is the lowest level possible and 5 the highest), and multiple-choice questions that assessed the opinion of the students regarding online and onsite teaching methods. Additionally, the questionnaire addressed students' perceived inclination toward cheating, the use of AI, and preferred examination methods. Before distributing the Google Forms, a small sample of 20 medical students from the Victor Babes University of Medicine and Pharmacy were selected to complete the form and evaluate the clarity and the technical functionality of the questionnaire. A test-retest procedure was performed after 1 week to evaluate response stability. Informed consent was obtained from all participants, with the first section of the Google Forms consisting of a general data protection regulation that needed the approval of the person completing the survey to advance to the other sections.

Statistical Analysis

Statistical analyses were performed using Microsoft Excel (2024) and JASP (University of Amsterdam; version 0.95.4). Categorical variables were expressed as frequencies and percentages, while continuous variables were described using median (IQR), depending on data distribution. Data normality was assessed using the Shapiro–Wilk test, kurtosis, and skewness, with P values <.05 being considered as the threshold for rejecting the null hypothesis, thereby categorizing the data as non-normally distributed. Since most variables were ordinal or non-normally distributed, nonparametric tests were applied (the Wilcoxon signed-rank test and Spearman rho). The Kruskal-Wallis test was used to assess the differences in perception based on study year. Correlations between ordinal variables were evaluated using Spearman ρ correlation coefficient, with values P<.05 being considered statistically relevant, and the strength of the correlation being evaluated based on the value of rho. The internal consistency of the questionnaire was assessed using Cronbach alpha. The alpha has been calculated demonstrating acceptable reliability with a coefficient of α=0.742.

Ethical Considerations

This study was conducted in accordance with the ethical principles outlined in the Declaration of Helsinki and adhered to the guidelines of the Committee on Publication Ethics. Ethical

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approval for this study was obtained from the Ethics Committee of the "Victor Babes" University of Medicine and Pharmacy Timisoara (approval number: 05/2020/03.02.2026_rev). Participation in the study was voluntary and anonymous. Before completing the questionnaire, all participants were provided with detailed information regarding the study objectives, data usage, and confidentiality. Informed consent was obtained electronically, as participants were required to agree to a consent statement before accessing the survey. No personally identifiable data were collected. All responses were anonymized and handled in accordance with the General Data Protection Regulation. Data were stored securely and used exclusively for research purposes. Participants were informed that they could withdraw from the study at any time before submission of the questionnaire, without any consequences. The Victor Babes University of Medicine and Pharmacy of Timisoara will be covering the publication costs for this research paper. This study did not receive any external funding.

Results

In the final analysis of the database, only 436 out of the 451 total responders' answers have been taken into consideration due to the exclusion criteria. Most of the students were female (340/436, 78%), and the most represented study year was the fourth year (115/436, 26.4%), closely followed by the fifth year students (101/436, 23.2%). With Romania having a 6-year medical school system, all study years have been well represented. Most students who answered the survey were enrolled in the "Victor Babes" University of Medicine and Pharmacy Timisoara (313/436, 71.8%; Table 1).

Table 2 showcases the descriptive statistics that were made on the Likert-type questions. The statistical analysis was made using the Shapiro-Wilk test, all calculations signaling a $P<.001$. The most notable finding was that students were willing to accept online teaching primarily for lectures, but in a hybrid manner, with a median of 4 compared to a median of 3 in the case of online-exclusive lectures. A hybrid way of teaching means that students would have lectures both onsite and online, based on the week and the decision of the professor. On the other hand, the responders consider that practical laboratories must be taught in an on-site fashion, not even the hybrid option being welcomed by students (median of 2 and IQR of 1-4). At the same time, students do not feel confident in the current ability of professors and medical teachers to use technology to its highest standard (median of 2 and IQR of 1-4).

Besides all of these, the desire to cheat is high in both online and onsite examinations. Online examination formats were perceived as offering more opportunities for academic dishonesty, which makes online testing a poor choice and should make professors be more alert about cheating opportunities. As can be seen, the desire of students to adopt more varied teaching methods is high, with a median of 5 (4-5).

The Wilcoxon signed-rank test revealed multiple statistically significant differences when performing the paired comparison. Online teaching looks to be a much better alternative for lectures rather than for practical training ($P<.001$; $r=0.817$). Students perceived much higher levels of academic dishonesty in an online format compared to in-person examinations ($P<.001$; $r=0.893$). Hybrid training seems to be much more accepted in the case of lectures rather than practical training ($P<.001$; $r=0.922$). The professor's technological adaptation was linked with online lectures' efficiency ($P<.001$; $r=0.626$) but not statistically significantly correlated with practical training's efficiency ($P=.43$; $r=0.051$; Table 3).

The practical side of medicine is essential to the development of future surgeons. It should be taught since medical school, with more practical methods being used. Figure 2 displays the advantages and disadvantages of online and in-person practical laboratories. For medical students in Romania, the time they spend at the university seems to be the most important factor in their choice of an online teaching method (231/436, 52.98%). On the other hand, we can see similar results between Figure 2 and Table 2, where the biggest disadvantage that students face when taking online practical laboratories is the lack of interaction with the patient (196/436, 44.95%) and the lack of practical abilities gained (123/436, 28.21%).

As can be seen in Table 4, most variables do not differ depending on study year. The Kruskal-Wallis test indicated that the study year has a minimal influence on student perception, with the effect size largely negligible. In this cohort, it seems that the students' attitude toward online teaching, teaching methods, AI, and technology use does not differ from one study year to another. This indicates a consistency of perception between students.

Figure 3 represents a heatmap of the correlations made between various parameters analyzed. The most powerful positive correlation is represented by the students who consider that online lectures and hybrid lectures represent a good alternative to traditional methods ($P<.001$, Spearman $\rho=0.652$). On the same note, students underline the importance of the teaching methods used, both in the hospital and in the lecture hall ($P<.001$, Spearman $\rho=0.639$). A strong correlation has also been observed between students who desire more varied teaching methods in general and those who desire more varied teaching methods for lectures ($P<.001$, Spearman $\rho=0.584$). The most pertinent negative correlation is between the students who consider online teaching a good alternative for practical laboratories and the desire to cheat online, even though this did not prove to be a statistically significant correlation. This might indicate, even though not statistically significant, that when students feel that they have more alternatives and are more involved in the educational process, their desire to cheat decreases ($P<.001$, Spearman $\rho=-0.304$).

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Table 1. Demographic description of the population (n=436).

Variables	Values
Sex, n (%)	
Male	94 (21.6)
Female	340 (78)
Other	1 (0.2)
I prefer not to mention	1 (0.2)
Year of study, n (%)	
1	55 (12.6)
2	57 (13.1)
3	56 (12.8)
4	115 (26.4)
5	101 (23.2)
6	52 (11.9)
University, n (%)	
UMFVBT[a]	313 (71.8)
UMFIHCJ[b]	30 (6.9)
UDJG[c]	28 (6.4)
UMFCD[d]	25 (5.7)
UOC[e]	24 (5.5)
ULBS[f]	9 (2.1)
UO[g]	4 (0.9)
UMFCV[h]	3 (0.7)

[a]UMFVBT: “Victor Babes” University of Medicine and Pharmacy Timisoara.
[b]UMFIHCJ: “Iuliu Hatieganu” University of Medicine and Pharmacy Cluj.
[c]UDJG: “Dunarea de Jos” University of Galati.
[d]UMFCD: “Carol Davila” University of Medicine and Pharmacy Bucharest.
[e]UOC: “Ovidius” University of Constanta.
[f]ULBS: “Lucian Blaga” University of Sibiu.
[g]UO: University of Oradea.
[h]UMFCV: University of Medicine and Pharmacy of Craiova.

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Table 2. Analysis of Likert-type questions regarding perception of online, hybrid, and onsite teaching methods.

Questions	Median (IQR)	Skewness	Kurtosis	*P* value[a]
Do you consider online teaching methods as an efficient alternative to lectures?	3 (1-5)	–0.21	–1.04	<.001
Do you consider online teaching methods as an efficient alternative for practical laboratories?	2 (1-4)	0.61	–0.77	<.001
Do you wish more varied methods were used in your lectures?	5 (4-5)	–1.40	1.40	<.001
Do you wish more varied methods were used in your practical laboratories?	5 (4-5)	–1.12	0.53	<.001
What level of desire do you consider exists when it comes to cheating in in-person exams?	3 (1-5)	0.17	–0.90	<.001
What level of desire do you consider exists when it comes to cheating in online exams?	5 (3-5)	–1.32	0.86	<.001
Would you agree to have hybrid lectures?	4 (2-5)	–0.618	–0.83	<.001
Would you agree to have hybrid practical laboratories?	2 (1-4)	0.518	–1	<.001
Do you wish to use more AI[b] tools in your medical training?	4 (2-5)	–0.547	–0.426	<.001
Do you consider the professors to be ready to use technology to the highest standard?	2 (1-4)	0.613	–0.352	<.001
Do you wish more varied methods were used in your medical education?	5 (4-5)	–1.20	0.70	<.001

[a]*P* value determined using the Shapiro-Wilk test was used to assess data normality.

[b]AI: artificial intelligence.

Table 3. Paired comparison of student attitudes regarding teaching modalities.

Comparison	W[a]	*P* value	Effect size (*r*)[b]
Online lectures vs online practical training	31536	<.001[c]	0.817
Cheating in person vs cheating online	2674	<.001[c]	0.893
Hybrid lectures vs hybrid practical training	1264	<.001[c]	0.922
Professor's technological adaptation vs online lectures	11306	<.001[c]	0.626
Professor's technological adaptations vs online practical training	21700	.43	0.051
Desire to use AI[d] vs cheating in person	12822	<.001[c]	0.432
Desire to use AI vs cheating online	44204	<.001[c]	0.609

[a]W: Wilcoxon signed rank statistic.

[b]*r*: rank-biserial correlation.

[c]Statistically significant values (*P*<.05).

[d]AI: artificial intelligence.

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Figure 2. Distribution of perceived advantages and disadvantages of online vs in-person teaching of practical laboratories.

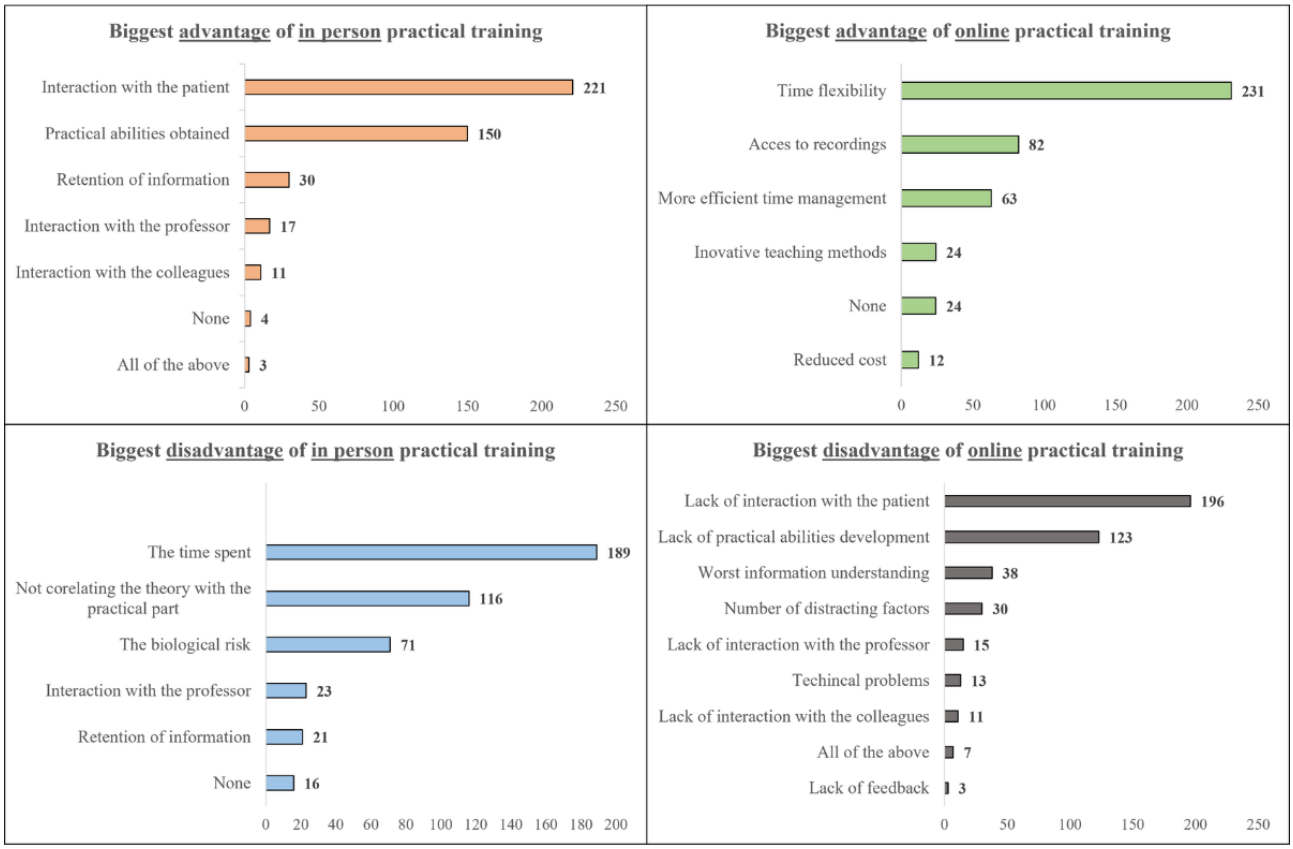

Table 4. Kruskal-Wallis test comparing students' perception based on study year.

Questions	H [a]	P value	Effect size (ε^2)[b]
Do you consider online teaching methods as an efficient alternative to lectures?	5.23	.39	0.001
Do you consider online teaching methods as an efficient alternative for practical laboratories?	5.68	.34	0.002
Do you wish more varied methods were used in your lectures?	7.15	.21	0.005
Do you wish more varied methods were used in your practical laboratories?	4.61	.47	0.000
What level of desire do you consider exists when it comes to cheating in in-person exams?	12.17	.03[c]	0.017
What level of desire do you consider exists when it comes to cheating in online exams?	4.29	.51	0.000
Would you agree to have hybrid lectures?	6.64	.25	0.004
Would you agree to have hybrid practical laboratories?	6.64	.25	0.004
Do you wish to use more AI[d] tools in your medical training?	10.48	.06	0.013
Do you consider the professors to be ready to use technology to the highest standard?	4.66	.46	0.000
Do you wish more varied methods were used in your medical education?	30.08	<.001[c]	0.058

[a]*H*: Kruskal-Wallis test statistic (factor: study year).

[b]ε^2: epsilon-squared size effect.

[c]Statistically significant (P<.05).

[d]AI: artificial intelligence.

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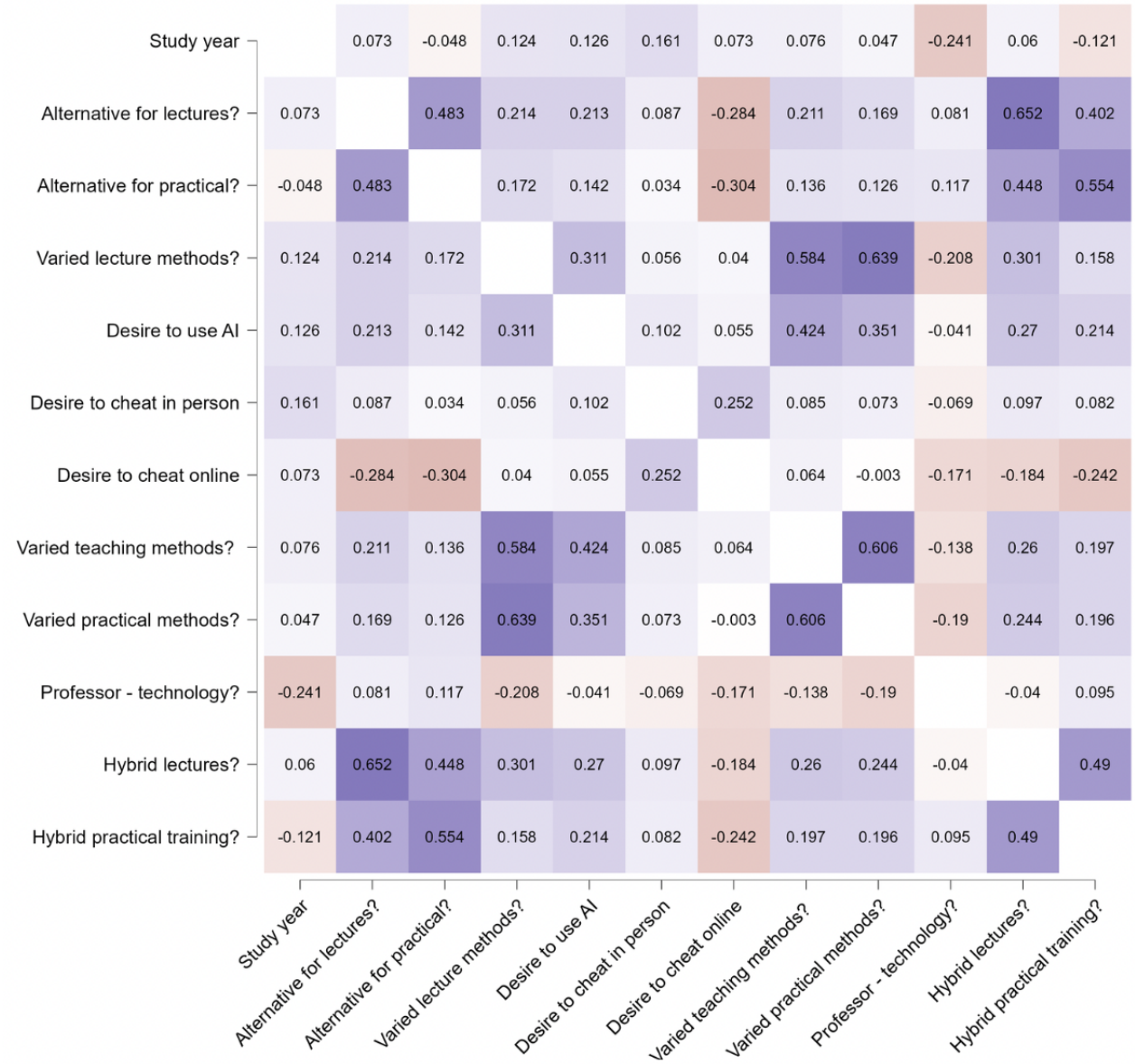
Figure 3. Heatmap of Likert-type data regarding perception of teaching methods, academic integrity, and technology use (Spearman ρ correlation). AI: artificial intelligence.



Discussion

Principal Findings

Unlike many studies conducted during the acute phase of the COVID-19 pandemic, this study evaluates postpandemic perceptions, offering insight into more stable student attitudes toward hybrid and digital education. Additionally, the focus on surgery-oriented students provides a more specific understanding of the limitations of online teaching in skill-dependent disciplines. The understanding of anatomy is essential for any surgeon. The use of AI is becoming more and more useful in the study of this subject, and many anatomists feel that in the future, there is a need to develop AI-related apps for the study of anatomy [17]. In our study, 65.6% (286/436) of the students declared that they use AI apps regularly. The most used AI apps are chatbots like ChatGPT (OpenAI) and Gemini (Google), with 80.3% (350/436) of students using such resources. Similar to the study cited, students showed a great desire to use more AI apps, with a median of 4 out of 5 (IQR 2-6).

AI is increasingly embedded in contemporary surgical practice. Current applications include image-guided navigation, intraoperative decision-support systems, robotic-assisted optimization, predictive modeling of postoperative outcomes, and automated image analysis [18]. In addition, machine learning algorithms are being developed to objectively assess surgical performance and provide structured feedback on technical skill acquisition [19]. Parallel to these clinical applications, AI is progressively influencing medical education. Large language models and AI-driven platforms support adaptive learning, rapid information synthesis, case-based self-assessment, and personalized feedback [20]. Evidence suggests that AI-assisted learning may enhance knowledge

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retention and clinical reasoning within competency-based frameworks [21,22]. Nevertheless, concerns persist regarding accuracy, overreliance, academic integrity, and potential impacts on critical thinking [23,24].

The substantial proportion of students in our cohort reporting regular AI use aligns with this global shift toward digitally augmented learning. Rather than replacing traditional instruction, AI appears to function as a complementary tool within blended educational models [25]. Consequently, the key challenge for medical schools is not whether to adopt AI, but how to integrate it responsibly while preserving academic rigor and ethical standards.

Bock et al [26] came to a very similar conclusion to ours when it comes to lectures and practical laboratories and the preferred method of teaching. In their study, 43.16% or respondents affirmed that they would prefer live lectures, where 49.5% of this cohort considered the online alternative an efficient one. On the other hand, a much higher percentage of students preferred online and prerecorded lectures in the study conducted by Watson et al [27]. Compared to the almost 50% ratios presented before, in this study, 74.04% (323/436) of students who were involved in this study considered pre-recorded lectures as extremely effective, showing much higher rates than in other studies.

One consistent finding of this study is the preference for in-person practical laboratories rather than online, as very few consider the hybrid approach to be effective. Teaching certain practical procedures can be done online, but only when practical kits are delivered to students or other physical materials are used [28,29]. In these 2 studies, practical suturing or dermatological kits were sent to students, but the teaching method was online, similar to during the COVID-19 pandemic, rather than fully online. Our study shows that this cohort of students prefers on-site practical laboratories. Only 22.5% (98/436) of the students thought online practical labs were effective for teaching an entire semester's curriculum, with the main drawback being the lack of patient interaction (196/436, 45%). It's evident that for the students involved in this study, acquiring practical skills must be done in person, with excellent results achieved through practical workshops in addition to the skills taught in medical school [30,31].

One major challenge that the online system encounters is the prevention of cheating in online exams. As Bilen et al [32] underline, cheating has to be expected in an online method of examination. That statement is backed by our study as well, with a median of 5 out of 5 on the Likert scale when asked about the desire to cheat online, compared to a median of 3 when considering in-person cheating. It was mentioned in Bilen et al's [32] work that there are methods that can be implemented to mitigate the desire to cheat online, with inspiration from online chess communities. Besides diminishing the desire to cheat, it is very important to positively influence students and offer them the proper means to be educated. As we discovered, when students feel that they are more involved in the teaching process and have better educational alternatives, their desire to cheat decreases (P<.001, Spearman ρ=–0.304). This association suggests that perceived teaching quality may be related to attitudes toward academic dishonesty; however, causal relationships cannot be inferred from this study design. Therefore, the pedagogical quality appears to be negatively correlated with academic dishonesty. Different methods are being tested to detect online cheating better, and maybe one day eliminate it, as seen in the study performed by Alsabhan [33], which achieved an accuracy of 92%.

The COVID-19 pandemic brought the need for new, more modern teaching methods. These changes have been welcomed by the students. The median for the desire for more varied teaching methods used was 5 (IQR 4-6). These modern methods can be implemented both in person and online. For example, simulation-based learning has been used as an online tool, which students perceived as a better method compared to problem-based learning for online use, with a high degree of commitment to the teaching process being showcased by the students [34]. Problem-based learning seems to be one of the modern teaching methods that can't be used in an online setting, as students consider it less engaging and deterring to the acquisition of clinical skills [35].

In Romania, as in many other countries, the COVID-19 pandemic led to an abrupt transition to fully online teaching across medical universities, reflecting the broader global shift toward emergency remote education [1,11]. Clinical rotations were suspended or significantly reduced, bedside teaching was replaced by virtual case discussions, and practical laboratory exposure was limited [8,36]. Assessment methods also shifted toward online examinations, frequently without standardized proctoring systems, raising concerns regarding academic integrity [32]. These structural changes appear to have had a lasting influence on students' perceptions of teaching efficiency. The strong preference observed in our study for in-person practical laboratories may reflect the perceived loss of hands-on clinical exposure during pandemic restrictions [37]. Similarly, while theoretical content can be delivered digitally with acceptable satisfaction levels, experiential and patient-centered learning remains difficult to replicate virtually [38].

Like any teaching method, both in-person and online teaching methods have their advantages and disadvantages. In our study, 33.9% (148/436) of students say that the biggest advantage of online teaching is time flexibility, but in an Indian research paper, the ability to divide into smaller work groups was considered the biggest advantage [39]. These differences come from the various teaching methods used, the structure of medical school in that country, and the perception of technology. Saverino et al [40] had very similar findings to ours, where the main advantages mentioned were the better usage of time that has been saved by not travelling to university and back home. Besides, the biggest disadvantage mentioned by students in the cited paper is the lack of interaction between them, where only 2.5% of the students we asked considered it the main disadvantage. The study conducted by the teaching methods used and the availability of curriculum resources seem to be the most important aspects that influence students' enthusiasm [41]. Moreover, students prefer a more interactive format of teaching rather than the old teaching methods used in medical school [42].

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Future research should focus on longitudinal evaluation of hybrid teaching models combining structured in-person clinical exposure with evidence-based digital supplementation [43]. Objective performance metrics, rather than perception-based outcomes alone, should be incorporated to assess competency acquisition in postpandemic curricula. Additionally, further investigation into regulated AI integration within medical curricula is warranted, including institutional policies addressing ethical use, academic integrity, and faculty development [23,25]. Multicenter studies with proportional institutional representation would improve generalizability and support the development of coordinated national educational strategies.

Study Limitations

This study presents a few limitations caused mainly by the subjective nature of the study. With students being asked from all medical universities in Romania, in any study year, differences in the method of teaching used will be seen, which brings bias about their past experiences. The vast majority of respondents were enrolled in one of the few universities mentioned, so the result may be influenced by this heavy lifting of one university. Despite the imbalance in university representation, this study offers one of the first multicentric perspectives on postpandemic medical education in Romania. The imbalance in university representation, combined with the use of social media for recruitment, limits the generalizability of the results. For future research, a more proportional representation of the universities in the Romanian educational system should be desired. Out of the total participants, 78% (340/436) are female, which can bring a degree of bias. Additionally, although the questionnaire demonstrated acceptable internal consistency and was pilot-tested, a full psychometric validation was not performed. Therefore, the findings should be interpreted within the context of an exploratory instrument. One other limitation is the distribution of the form, with students who are active on social platforms being favored.

Conclusions

This study suggests a shift in pedagogical methodology preferences among the surveyed medical students post COVID-19 pandemic. It indicates that even though there are more options for students to study (the online options), they do not consider them as efficient. The only efficient alternative might be for lectures, where students would agree to hybrid lectures. Furthermore, students wish for more varied teaching methods, which would enhance their involvement in the teaching process. Finally, online examinations represent a major limitation of online teaching, which, at the moment, is not a viable option, with high levels of cheating being involved.

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Data Availability

The dataset analyzed during this study is available from the corresponding author on reasonable request.

Authors' Contributions

Conceptualization: ID, DS
Data curation and formal analysis: BC, GM, ACZ
Investigation: ANC
Methodology: OAM, BND
Project administration: DS, RR, DIP
Resources: ID, DS, MS, VMC
Software, supervision, and validation: ID, OAM, BND
Visualization: ID, ANC, DIP
Writing – original draft: ID, BC, GM, MS, RR, ANC
Writing – review and editing: BND, OAM, DS, VMC

Conflicts of Interest

None declared.

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Abbreviations

AI: artificial intelligence

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Critical Limitations in Comparing ChatGPT and DeepSeek for Orthopedic Assessment

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KEYWORDS

ChatGPT; large language model; LLM; orthopedic; multiple-choice question; MCQ

We read with great interest the study by Anusitviwat et al [1], which compared the performance of ChatGPT and DeepSeek in orthopedic examinations. While the study provides timely insights into the utility of large language models (LLMs) in medical education, we identified specific methodological and terminological limitations that warrant clarification to ensure the validity and reproducibility of the findings.

Misinterpretation of Reliability Statistics

The authors state that the "interrater reliability between the two LLMs" was evaluated using the Cohen κ coefficient [1]. Mathematically, measuring the agreement between two independent raters (interrater) yields a single coefficient. However, the results report two separate values: κ of 0.81 for ChatGPT and κ of 0.78 for DeepSeek [1]. This finding, combined with the methodology stating that questions were input on "separate days" [1], indicates that the study actually measured intramodel consistency (test-retest reliability) rather than the agreement between the models. Labeling internal consistency as "interrater reliability" is terminologically inaccurate and misrepresents the statistical relationship between the two models.

Linguistic Ambiguity and Generalizability

The manuscript does not specify the language of the input multiple-choice questions (Thai or English) used in the assessments. This omission is critical, as the impact of input language on LLM performance is well-documented. For instance, Noda et al [2] demonstrated that GPT-4V's accuracy on the Japanese Otolaryngology Board Examination significantly improved from 24.7% (Japanese input) to 47.3% when translated into English. This finding underscores that models optimized for English exhibit distinct performance disparities in non-English languages. Without clarifying whether the assessments were administered in the local language or English, it is impossible to determine if the reported accuracy gap between ChatGPT (80.4%) and DeepSeek (74.2%) stems from medical reasoning capabilities or linguistic processing proficiency.

Reproducibility and Interface Transparency

The methodology reports the use of "Reason" and "DeepThink" functions but does not explicitly state whether the models were accessed via web-based user interfaces or application programming interfaces [1]. This distinction is vital for reproducibility. Web-based user interfaces are subject to opaque updates and lack the stability of controlled application programming interface environments. Without defining the access method and the specific prompt structures used, the experimental conditions cannot be replicated.

Risk of Data Contamination

The authors note that the multiple-choice questions "have been used in orthopedic examinations for more than 5 years." This longevity significantly increases the risk of data contamination, as older items likely exist in public repositories within LLM training corpora, potentially conflating memorization with reasoning. To ensure validity, recent benchmarks use private datasets (Busch et al [3]) or questions postdating the model's training cutoff (Noda et al [2]). The absence of such controls in this study undermines the internal validity of the comparison.

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Data Reporting Discrepancy

Finally, we noted a minor discrepancy in Table 2. In the "Pelvic and spine injury" category (n=19), the accuracy for the Reason function is listed as 16 (68.8%) [1]. Mathematically, 16 of 19 corresponds to approximately 84.2%, not 68.8%. We respectfully invite the authors to clarify this value to ensure the precision of the tabulated data.

Acknowledgments

Google Gemini was used for language editing.

Conflicts of Interest

None declared.

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Abbreviations

LLM: large language model

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Authors' Reply: Critical Limitations in Comparing ChatGPT and DeepSeek for Orthopedic Assessment

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KEYWORDS

ChatGPT; large language model; LLM; orthopedic; multiple-choice question; MCQ

We thank you for the useful and constructive comments [1] on our article "Comparing ChatGPT and DeepSeek for Assessment of Multiple-Choice Questions in Orthopedic Medical Education: Cross-Sectional Study" [2]. This reply aims to address the concerning points that were brought up in the letter to the editor.

Misinterpretation of Reliability Statistics

According to our study, we administered the multiple-choice questions (MCQs) for ChatGPT and DeepSeek on a separate day. All data from the two large language models (LLMs) were measured by two assessors. Although two assessors were used for each LLM, the reported Cohen κ coefficient values represent within-model interrater reliability, not interrater reliability between the two LLMs [3]. Therefore, describing these results as agreement between the two models is inaccurate.

Linguistic Ambiguity and Generalizability

All MCQs used in our study were administered in English. No Thai language inputs or translations were used. Therefore, the performance differences between the two models reflect the model performance on English language medical questions rather than variability due to language translation or non-English linguistic processing.

Reproducibility and Interface Transparency

All models in our study were accessed via web-based user interfaces (UIs), not application programming interfaces. We acknowledge that web-based UIs may be subject to updates and lack version control. However, the web-based version of ChatGPT is easy to access and requires no software installation. It also allows quick testing and exploration without technical or cost barriers, making it well-suited for nontechnical users and educational studies [4]. Therefore, we used the web-based UI in our study.

Risk of Data Contamination

Even though these MCQs have been used for more than 5 years, the MCQs used in our study are from private orthopedic examinations. Thus, we believe that these items would not appear in public sources. Future research using newly created MCQs may be better for assessing the capability or efficacy of LLMs.

Data Reporting Discrepancy

Upon re-examination, we confirm that the correct accuracy for the pelvic and spine injury category (n=19) using the Reason function is indeed 16 of 19, corresponding to approximately 84.2%. The value of 68.8% reported in Table 2 was a typographical error. This error has been corrected through a published corrigendum [5].

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Conflicts of Interest

None declared.

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Abbreviations

LLM: large language model
MCQ: multiple-choice question
UI: user interface

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Correction: Breath-Focused Mindfulness and Compassion Training in Parent-Child Dyads: Pilot Intervention Study

Satish Jaiswal[1], PhD; Jason Nan[1], PhD; Seth Dizon[1], BS; Jessica O Young[1], BS; Suzanna R Purpura[1], MS; James K Manchanda[1], BS; Dhakshin Ramanathan[2], MD, PhD; Dennis J Kuo[1], MS, MD; Jyoti Mishra[1], MBA, PhD

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Correction of: https://formative.jmir.org/2025/1/e69607

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Errors Identified

This corrigendum is being submitted for the article "Breath-Focused Mindfulness and Compassion Training in Parent-Child Dyads: Pilot Intervention Study" [1] in response to a PubPeer comment [2] regarding the neural data shared on Drayd. We found two major issues: (1) the duplications observed resulted from a batch processing script that erroneously plugged in repeat data, and (2) the subject IDs for pre- and postdata were misaligned when creating the final Dryad data Excel file.

Addressing Errors

The following steps were taken to address the errors:

- We reprocessed all child neural data individually instead of as a batch process. In this iteration, all child neural data were successfully individually processed. Final data are now unique for each child participant, except child subject PJ24 (one of the subjects flagged in the PubPeer comment [2]), which could not be processed as they did not have any meaningful on-task responses (child continuously held down response spacebar throughout task), hence had to be excluded.
- As part of our processing pipeline involves across-subject outlier cleaning (as explained in Multimedia Appendix 1 of the original paper [1]), all data values are now updated (ie, values that were previously processed correctly are also slightly updated, with a 98% correlation between previous and current processing).
- We have doubly ensured that subject IDs and data are correctly aligned in the updated final data.

Impact of the Errors on the Overall Findings

With the corrections made to the dataset, the overall conclusion of the study remains unchanged.

In the Neural Outcomes section, the statistics were changed from the following:

> *Across all participants, there was no significant change in FPN or CON source localized α activity (P>.4), but DMN activity was significantly reduced at postintervention relative to preintervention (signed rank test z=−2.48; d=−0.62; 95% CI −0.0096 to −0.0002; P=.01). In addition, there was no significant group difference in post- versus pre-DMN activity for children versus parents (rank sum test, P=.09; Figure 4). Group-specific post- versus prechanges in DMN activity showed significant reduction in DMN activity in children (signed rank test z=−2.56; d=−1.09; 95% CI −0.0015 to −0.0003; P=.01), but no change in parent (P>.5), suggesting that this neural outcome was exclusively driven by post- versus prechange in children.*

This section now reads:

> *Across all participants, there was no significant change in FPN or CON source localized α activity (P>.1), but DMN activity was significantly reduced at postintervention relative to preintervention (signed rank test z=−3.21; d=−0.53; 95% CI −0.0010 to −0.0003; P=.001; Figure 4). There was a significant group difference in post- versus pre-DMN activity for children versus parents (rank sum test, P=.002). Group-specific post- versus prechanges in DMN activity showed significant reduction in DMN activity in children (signed rank test z=−3.46; d=−0.98; 95% CI −0.0015 to −0.0005; P=.0005), but no change in parent (P>.5), suggesting that this neural outcome was exclusively driven by post- versus prechange in children.*

Additionally, these data updates are now reflected in the newly generated Figure 4D (attached here as Figure 1).

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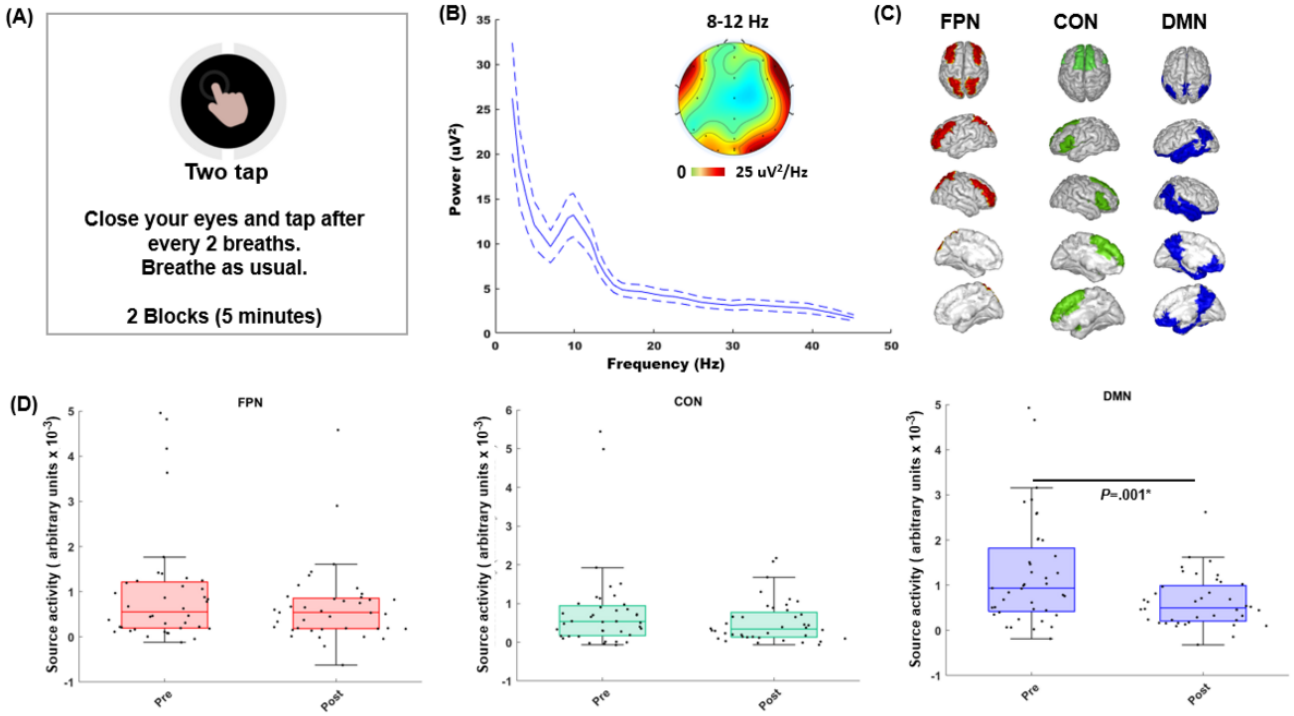
Figure 1. Cooperative compassion training–related neurophysiological changes evaluated on the attention-to-breath monitoring assessment. (A) Schematic of attention-to-breath task instructions. (B) Power frequency plot of scalp channel data across all participants and sessions showed peak processing in the α frequency band (8 - 12 Hz); dashed lines are 95% CIs. (C) Source-reconstructed electroencephalographic data were analyzed for 3 cognitive control networks: frontoparietal network (FPN), the cingulo-opercular network (CON), and the default mode network (DMN); regions of interest (ROIs) averaged within each network are highlighted. The identity of the ROIs within the 3 cognitive control networks is detailed in Multimedia Appendix 1. (D) Comparisons of the pre- to postintervention network changes across all participants are shown as swarm box plots. Box plots show median values with lower and upper quartiles as the bottom and top edges of the boxes, respectively. The whiskers denote the data range, and the scatter points show individual α source activity values.



The last statement in the abstract was updated from the following:

> *Cortical source imaging of electroencephalographic recordings was acquired simultaneous to an attention-to-breathing assessment that showed significant reduction in task-related default mode network activity (d=−0.62; 95% CI −0.0096 to −0.0002; P=.01).*

This sentence now reads:

> *Cortical source imaging of electroencephalographic recordings was acquired simultaneous to an attention-to-breathing assessment that showed significant reduction in task-related default mode network activity (d=−0.53; 95% CI −0.0010 to −0.0003; P=.001).*

The false discovery rate–corrected statistics are shown in Table 4 (attached here as Table 1), with changed values shown in italics.

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Table . Summary of post- versus prechanges in behavioral, cognitive, and neural outcome measures in parents and children[a].

Post versus preintervention outcomes	Cohen *d* effect size	Mean difference (95% CI)	fdr[b]-corrected *P* value
Child depression (self-reported)	–0.19	–3.57 (–8.89 to 1.74)	ns[c]
Child depression (parent-reported)	–0.20	–1.83 (–4.93 to 1.27)	ns
Parental stress	–0.41	–1.39 (–2.63 to –0.16)	.03
Parental anxiety	–0.47	–1.44 (–2.6 to –0.20)	.03
Parental depression	–0.50	–1.67 (–3.25 to –0.08)	.03
Children emotion bias cognitive processing (all faces)	*0.54*	*0.049 (.011 to .088)*	*.01*
Parent emotion bias cognitive processing (all faces)	*0.19*	*0.013 (-.006 to .031)*	*ns*
DMN[d] neural activity on attention-to-breath task (children and parents)	*–0.53*	*-0.0006 (-.0010 to -.0003)*	*.003*

[a]Children did not show any significant improvement in depressive symptoms, while parents showed significant improvement in stress, anxiety, and depression symptoms. Cognitively only children showed better emotion bias processing. Reduction in DMN neural activity was observed across all participants; there was no group interaction on this measure, but post-hoc tests showed this result to be driven by DMN neuroplasticity in children (see text).

[b]fdr: false discovery rate.

[c]ns: nonsignificant.

[d]DMN: default mode network.

The updated data files can be found on Dryad [3].

Lastly, we noted that in the previous corrected version, the correction in Table 1 regarding the age range of the children was only partially addressed. The age range for children was reported as:

5 - 12

This now reads:

5-15

An updated table is shown below (attached here as Table 2), with changes marked in italics

The corrections will appear in the online version of the paper on the JMIR Publications website, together with the publication of this correction notice. Because these were made after submission to PubMed, PubMed Central, and other full-text repositories, the corrected article has also been resubmitted to those repositories.

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Table . Summary of demographics and baseline mental health for parent-child dyad study participants[a].

Demographics and baseline mental health	Parents (n=24)	Children (n=24)
Age (y)		
Mean (SD)	44.5 (6.5)	9.5 (3.27)
Range	28-54	*5-15*
Gender, n (%)		
Male	4 (16.7)	10 (41.7)
Female	20 (83.3)	14 (58.3)
Race, n (%)		
Asian	8 (33.3)	5 (20.8)
Black/African American	0 (0)	0 (0)
Native American	0 (0)	0 (0)
Native Hawaiian or Other Pacific	0 (0)	0 (0)
White	14 (58.3)	11 (45.8)
More than 1 ethnicity	2 (8.3)	7 (29.2)
Other	0 (0)	1 (4.2)
Ethnicity, n (%)		
Hispanic or Latino	5 (20.8)	5 (20.8)
Not Hispanic or Latino	18 (75)	19 (79.2)
Unknown	1 (4.2)	0 (0)
Socioeconomic status		
Mean (SD)	6.5 (1.4)	—[b]
Range	4-8	—
Child Depression Index *T* scores		
Mean (SD)	54.08 (9.06)	57.96 (13.75)
Range	40-90	37-74
Parental Stress (DASS-21)		
Mean (SD)	4.91 (3.61)	—
Range	0-13	—
Parental Anxiety (GAD-7)		
Mean (SD)	4.39 (3.28)	—
Range	0-14	—
Parental Depression (PHQ-9)		
Mean (SD)	5.13 (3.52)	—
Range	0-13	—

[a]Parental stress was measured using the 7 stress items on the 21-item Depression Anxiety Stress Scale (DASS-21), anxiety was measured on the 7-item General Anxiety Disorder (GAD-7) scale, and depression was measured on the 9-item Patient Health Questionnaire scale (PHQ-9).

[b]Not applicable.

References

1. Jaiswal S, Nan J, Dizon S, et al. Breath-focused mindfulness and compassion training in parent-child dyads: pilot intervention study. JMIR Form Res 2025 Jul 17;9:e69607. [doi: 10.2196/69607] [Medline: 40674736]
2. Jaiswal S, Nan J, Dizon S, et al. Breath-focused mindfulness and compassion training in parent-child dyads: pilot intervention study. PubPeer. URL: https://pubpeer.com/publications/A3A0B6DC3D0240024423B217F3171E [accessed 2026-01-28]

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3. Jaiswal S, Nan J, Dizon S, et al. Data: breath-focused mindfulness and compassion training in parent-child dyads: a pilot intervention study. Dryad. URL: https://datadryad.org/dataset/doi:10.5061/dryad.9ghx3ffss [accessed 2026-01-28]

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Corrigenda and Addenda

Correction: The Mechanism of Online Health Information Seeking Switching to Online Medical Consultation: Cross-Sectional Study

Lijiang Zhang[1,2*], PhD; Jingjing Xia[1*], MS; Hui Chen[1*], MS; Yang Bai[3,4,5*], PhD; Jun Wang[4,5], PhD; Liuan Wang[6,7,8], PhD; Wenjie Ren[2*], PhD

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Related Article:

Correction of: https://formative.jmir.org/2025/1/e78397

(JMIR Form Res 2026;10:e94748) doi:10.2196/94748

In "The Mechanism of Online Health Information Seeking Switching to Online Medical Consultation: Cross-Sectional Study" [1], the authors noted one error.

The equal contribution designation has been added to the following authors:

Yang Bai, *Wenjie Ren*

The correction will appear in the online version of the paper on the JMIR Publications website, together with the publication of this correction notice. Because this was made after submission to PubMed, PubMed Central, and other full-text repositories, the corrected article has also been resubmitted to those repositories.

Reference

1. Zhang L, Xia J, Chen H, Bai Y, Wang J, Wang L, et al. The mechanism of online health information seeking switching to online medical consultation: cross-sectional study. JMIR Form Res 2025 Dec 03;9:e78397 [FREE Full text] [doi: 10.2196/78397] [Medline: 41337746]

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Correction: Transition From a Paper Diary to an Electronic Diary by Parents of Preschool Children With Food Allergies: Pilot Study

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Related Article:

Correction of: https://formative.jmir.org/2025/1/e73400/

Abstract

(JMIR Form Res 2026;10:e92855) doi:10.2196/92855

In "Transition From a Paper Diary to an Electronic Diary by Parents of Preschool Children With Food Allergies: Pilot Study" [1], the author made one correction.

In the Introduction section, the following sentence was revised:

> *The OITcontrol app (Mylan EPD) appears to be a valuable tool for monitoring treatment in children with FAs.*

This sentence now reads:

> *OITcontrol (University of Navarra, Pamplona, Spain) appears to be a valuable tool for monitoring treatment in children with FAs.*

The correction will appear in the online version of the paper on the JMIR Publications website, together with the publication of this correction notice. Because this was made after submission to PubMed, PubMed Central, and other full-text repositories, the corrected article has also been resubmitted to those repositories.

Reference

1. Kato Y. Transition from a paper diary to an electronic diary by parents of preschool children with food allergies: pilot study. JMIR Form Res 2025 Oct 21;9:e73400. [doi: 10.2196/73400] [Medline: 41118496]

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Correction: Comparing ChatGPT and DeepSeek for Assessment of Multiple-Choice Questions in Orthopedic Medical Education: Cross-Sectional Study

Chirathit Anusitviwat[1], MD; Sitthiphong Suwannaphisit[2], MD; Jongdee Bvonpanttarananon[1]; Boonsin Tangtrakulwanich[1], MD, PhD

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Related Article:

Correction of: https://formative.jmir.org/2025/1/e75607

Abstract

(JMIR Form Res 2026;10:e92549) doi:10.2196/92549

In "Comparing ChatGPT and DeepSeek for Assessment of Multiple-Choice Questions in Orthopedic Medical Education: Cross-Sectional Study" [1], a typographical error has been found.

In Table 2, the accuracy of the "Reason" function, reported as n (%) in the pelvic and spine injury category, was "16 (68.8%)." On re-examination, the correct accuracy for the pelvic and spine injury category using the "Reason" function was 16 out of 19, corresponding to 84.2%. Thus, the value reported in Table 2 has been revised from "16 (68.8)" to "16 (84.2)." The revised version of Table 2 is shown below (with change shown in italics).

Table . Comparison of accuracy between "Reason" (ChatGPT) and "DeepThink" (DeepSeek) functions across orthopedic multiple choice question (MCQ) categories (n=209).

MCQs in each category	Reason responses, n (%)	DeepThink responses, n (%)	*P* value
Upper limb injury (n=28)	25 (89.3)	25 (89.3)	>.99
Upper limb disease (n=21)	21 (100.0)	20 (95.2)	.32
Pelvic and spine injury (n=19)	*16 (84.2)*	14 (73.7)	.16
Lower limb injury (n=16)	11 (68.8)	9 (56.3)	.41
Lower limb disease (n=12)	11 (91.7)	10 (83.3)	.31
Back and neck problems (n=26)	22 (84.6)	22 (84.6)	>.99
Sprain and strain (n=8)	7 (87.5)	7 (87.5)	>.99
Pediatric and anomaly (n=20)	16 (80.0)	13 (65.0)	.18
Tumor and infection (n=14)	13 (92.9)	11 (78.6)	.16
Complication in orthopedics (n=11)	7 (63.6)	10 (90.9)	.08
Rehabilitation and physical therapy (n=34)	28 (82.4)	27 (79.4)	.56
Total (n=209)	177 (84.7)	168 (80.4)	.12

The correction will appear in the online version of the paper on the JMIR Publications website, together with the publication of this correction notice. Because this was made after submission to PubMed, PubMed Central, and other full-text repositories, the corrected article has also been resubmitted to those repositories.

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Reference

1. Anusitviwat C, Suwannaphisit S, Bvonpanttarananon J, Tangtrakulwanich B. Comparing ChatGPT and DeepSeek for assessment of multiple-choice questions in orthopedic medical education: cross-sectional study. JMIR Form Res 2025 Dec 19;9:e75607. [doi: 10.2196/75607] [Medline: 41418321]

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Correction: Personalized Diabetes Treatment Support Using Large Language Models Fine-Tuned on Electronic Health Records: Development and Evaluation Study

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Related Article:

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Abstract

(JMIR Form Res 2026;10:e93482) doi:10.2196/93482

In “Personalized Diabetes Treatment Support Using Large Language Models Fine-Tuned on Electronic Health Records: Development and Evaluation Study” [1], the authors noted one error.

In the author list, the first author’s name was changed from the following:

ShenYang He

The name now reads:

Shengyang He

The correction will appear in the online version of the paper on the JMIR Publications website, together with the publication of this correction notice. Because this was made after submission to PubMed, PubMed Central, and other full-text repositories, the corrected article has also been resubmitted to those repositories.

Reference

1. He S, Zhang Y, Li J. Personalized diabetes treatment support using large language models fine-tuned on electronic health records: development and evaluation study. JMIR Form Res 2026 Feb 9;10:e71541. [doi: 10.2196/71541] [Medline: 41662664]

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Correction: Promoting Sustained Real-Life Benefits of Virtual Reality–Based Interventions in People With Mental Health and Substance Use Disorders: Qualitative Study

Jan Aasen[1,2], MMHC; Fredrik Nilsson[3]; Torgeir Sørensen[2,4], Prof Dr; Marja Leonhardt[1,5], PhD

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Related Article:

Correction of: https://formative.jmir.org/2025/1/e57643

(JMIR Form Res 2026;10:e95127) doi:10.2196/95127

In "Promoting Sustained Real-Life Benefits of Virtual Reality–Based Interventions in People with Mental Health and Substance Use Disorders: Qualitative Study" [1], the authors noted one error.

Author JA's affiliations have been revised from the following:

[1]Research Centre for Substance Use Disorders and Mental Health Disorders (ROP-Forsk), Innlandet Hospital Trust, Hamar, Norway

The author's affiliations now read:

[1]Research Centre for Substance Use Disorders and Mental Health Disorders (ROP-Forsk), Innlandet Hospital Trust, Hamar, Norway

[2]Centre for Diaconia and Professional Practice, VID Specialized University, Oslo, Norway

The correction will appear in the online version of the paper on the JMIR Publications website, together with the publication of this correction notice. Because this was made after submission to PubMed, PubMed Central, and other full-text repositories, the corrected article has also been resubmitted to those repositories.

Reference

1. Aasen J, Nilsson F, Sørensen T, Leonhardt M. Promoting sustained real-life benefits of virtual reality-based interventions in people with mental health and substance use disorders: qualitative study. JMIR Form Res 2025 Aug 20;9:e57643. [doi: 10.2196/57643] [Medline: 40835410]

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Corrigenda and Addenda

Correction: Characterization of Post-Viral Infection Behaviors Among Patients With Long COVID: Prospective, Observational, Longitudinal Cohort Analyses of Fitbit Data and Patient-Reported Outcomes

Tianmai M Zhang[1,2], MA; Sydney P Sharp[1], MPH; John D Scott[3], MSc, MD; Douglas Taren[4], PhD; Jane C Samaniego[1], MS; Elizabeth R Unger[5], MD, PhD; Jeanne Bertolli[5], MPH, PhD; Jin-Mann S Lin[5], PhD; Christian B Ramers[1,6,7,8], MPH, MD; Job G Godino[1,9,10], PhD

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Related Article:

Correction of: https://formative.jmir.org/2025/1/e77644/

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In “Characterization of Post-Viral Infection Behaviors Among Patients With Long COVID: Prospective, Observational, Longitudinal Cohort Analyses of Fitbit Data and Patient-Reported Outcomes”, the authors made one correction.

In the abstract, the sentence on longitudinal results has been amended to replace “MVPA-inactive” with “MVPA-active” and “decreased” with “statistically less improvements.”

In the abstract, the following sentence was revised:

> *Longitudinal analysis found that MVPA-inactive patients showed a decreased ability to participate in social roles (estimated group difference=–4.21 T-score points over 3 months, 95% CI –6.64 to –1.78, P<.001) and a higher intensity of sleep symptoms (estimated group difference=2.06 severity score points over 3 months, 95% CI 0.40 to 3.71, P=.02) over time.*

The sentence now reads:

Longitudinal analysis found that MVPA-active patients had statistically less improvements in the ability to participate in social roles (estimated group difference=–4.21 T-score points over 3 months, 95% CI –6.64 to –1.78, P<.001) and the intensity of sleep symptoms (estimated group difference=2.06 severity score points over 3 months, 95% CI 0.40 to 3.71, P=.02) over time.

The correction will appear in the online version of the paper on the JMIR Publications website, together with the publication of this correction notice. Because this was made after submission to PubMed, PubMed Central, and other full-text repositories, the corrected article has also been resubmitted to those repositories.

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Identifying Undiagnosed High-Risk Suicidality Cases by Matching Patients With a Similar Comorbidity Burden: Retrospective Observational Study

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Abstract

Background: Suicide is the second leading cause of death for children and adolescents aged 6 to 18 years. Pediatric suicidality is underreported, which poses significant challenges for effective intervention and prevention strategies. Identifying populations at risk of suicidality can provide critical benefits in terms of study cohort selection, prevalence estimation, and clinical resource allocation.

Objective: This study sought to (1) measure the prevalence of mental health comorbidities in pediatric suicidality and (2) identify undiagnosed high-risk suicidality cases by matching them with patients with a similar mental health comorbidity burden.

Methods: Electronic health record data from a large academic pediatric hospital in Boston, Massachusetts, were analyzed for patients aged 6 to 18 years presenting to the emergency department between June 1, 2016, and June 1, 2022. Suicidality cases were defined using *International Classification of Diseases, 10th Revision* (*ICD-10*) codes for 3 suicidality subtypes: suicidal ideation, self-harm, and suicide attempt. Comorbidities of suicidality were calculated as the conditional probability of *ICD-10* code pairs. After multiple hypothesis corrections, statistically significant comorbidities and patient encounter demographics were input as covariates into a propensity score matching (PSM) model. The accuracy of the PSM model was validated against chart review by 2 independent subject matter experts.

Results: In total, 2.9% (2638/90,980) of emergency department encounters met an *ICD-10*–based case definition of suicidality during the study period. The prevalence of suicidality by subtype was 2.5% (2275/90,980) for ideation, 1.1% (1030/90,980) for self-harm, and 0.2% (177/90,980) for suicide attempt. Suicidality prevalence was more common for the female sex (1825/43,929, 4.2%) than for the male sex (813/47,045, 1.7%). Comorbidities of suicidality were statistically significant for 55 frequently co-occurring *ICD-10* codes. Nearly half of these comorbidities (26/55, 47.3%) were not present in the *Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition*, and nearly a quarter (12/55, 21.8%) consisted of *ICD-10* codes for accidental rather than intentional self-harm. Increased probability of suicidality was observed for patients with personality disorder (84/190, 44.2%), gender dysphoria (143/333, 42.9%), bipolar disorder (162/448, 36.2%), depression (1791/5426, 33%), and schizophrenia spectrum disorders (133/411, 32.4%). On the basis of gold-standard chart review, 53.4% of propensity-matched noncases were unrecognized cases of suicidality.

Conclusions: PSM using comorbidity profiles is an effective approach for identifying suicidality cases that lack *ICD-10* codes for suicidality.

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KEYWORDS

pediatrics; mental disorders; suicidal ideation; self-injurious behavior; propensity score; medical informatics; comorbidity; electronic health records; Diagnostic and Statistical Manual of Mental Disorders; DSM

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Introduction

Suicide is the second leading cause of death among children and adolescents aged 6 to 18 years in the United States [1], underscoring a major public health issue. The prevalence of cases of pediatric suicidal ideation, self-harm, and attempts in emergency departments (EDs) has dramatically increased [2-4]. However, many at-risk children and adolescents may never receive a formal diagnosis of suicidality (ie, due to variability in coding practices or stigma-related nondisclosure). Using *International Classification of Diseases, 10th Revision* (*ICD-10*)–based case definitions for prevalence estimation or cohort selection may lead to misclassifications or incomplete capture of cases [5-8], ultimately underestimating the true prevalence of suicidal behavior among children and adolescents. Additionally, the standard *Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition* (*DSM-5*) [9], which is used to guide hospital coding, may not comprehensively identify relevant psychiatric comorbidities.

Mental health comorbidity plays a crucial role in suicide risk [10-12]. Suicidality in youth arises from a complex interplay of emotional, cognitive, and environmental changes during development. Recent work shows that rapid neural and behavioral maturation during adolescence can increase vulnerability to suicidal thoughts and behaviors [13]. Psychopathological mechanisms such as impaired emotion regulation, heightened stress reactivity, and early exposure to adverse experiences further interact with these developmental processes to increase suicide risk [14]. Because of this critical interplay, understanding the relationship between certain comorbidity patterns and suicidality is valuable for identifying unrecognized suicidality or patients at risk of suicidality. The link between a higher comorbidity burden and increased suicide rates prompts the following question [10-12]: can we use information about a patient's comorbidity burden to identify patients at risk of suicidality who may be systematically undiagnosed in the electronic health record (EHR)?

Suicidality subtypes are generally diagnosed with respect to severity: ideation, self-harm, and attempt [15,16]. Self-harm, or nonsuicidal self-injury, exists on the same behavioral and psychological continuum as suicidal behaviors and remains one of the strongest predictors of future suicidal behavior [17,18]. The ability to systematically recognize comorbidity-driven risk patterns could facilitate earlier intervention and more accurate surveillance, resource allocation, and cohort identification for research.

Using a large dataset of ED visits from a major academic pediatric hospital, this retrospective study aimed to (1) measure the prevalence of mental health comorbidities in pediatric suicidality and (2) identify undiagnosed high-risk suicidality cases by matching patients with similar mental health comorbidity burden.

Methods

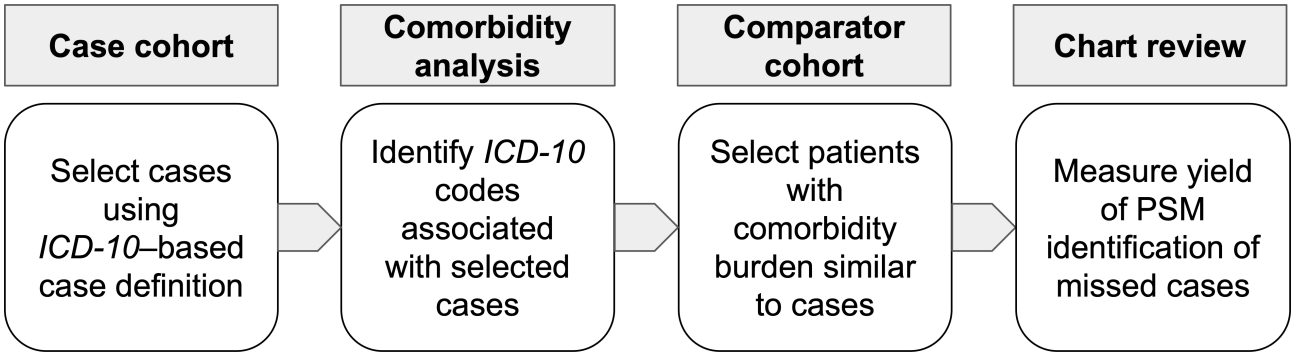
Overview

EHR data were extracted and analyzed for the study period (June 1, 2016, to June 1, 2022). The study population included all patients aged 6 to 18 years [15,19] who visited the ED during the study period, identified through the presence of an ED note. Patients were screened for suicide using the Ask Suicide-Screening Questions toolkit [20]. Patient EHR data were deidentified and loaded into Cumulus (Computational Health Informatics Program) [21], a platform for population health studies [22,23].

An *ICD-10*–based suicidality case definition [5] was used to select patient cohorts who matched suicidality criteria. Comorbidities in the suicidality population were reviewed as potential study variables for the *ICD-10*–based suicidality case definition. Statistically significant associated comorbidities were then used as input variables for a propensity score matching (PSM) model to select patients who did not match an *ICD-10*–based suicidality case definition [24]. The propensity-matched cohorts were compiled for chart review. The accuracy of the comorbidity-enriched PSM model was then compared to the interpretation of 2 subject matter experts (RX and AJM).

Figure 1 shows the sequence of case cohort selection, comorbidity analysis, comparator cohort matching, and chart review validation. First, cohorts were selected using an *ICD-10*–based suicidality case definition. Second, suicidality comorbidities were selected using conditional probabilities, tested for significance, and corrected for multiple hypothesis testing. Third, PSM was used to select patients similar to known suicidality cases. Fourth, manual chart review was used to assess the PSM model identification of suicidality cases missed by conventional *ICD-10*–based case selection.

Figure 1. Sequence of case cohort selection, comorbidity analysis, comparator cohort matching, and manual chart review. *ICD-10*: *International Classification of Diseases, 10th Revision*; PSM: propensity score matching.



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Ethical Considerations

This retrospective observational study was approved by the Boston Children's Hospital institutional review board (IRB-P00043211) with a waiver of ethics approval and informed consent. Patient data were deidentified before analysis.

Case Definition

Diagnosis of suicidality included 3 subtypes with increasing severity: ideation, self-harm, and attempt [6,24]. *ICD-10* codesets were compiled for each suicidality subtype [5]. Suicidal ideation is documented only for the present encounter (R45.851) as there are no *ICD-10* codes for history of suicidal ideation. Self-harm has 4 codes for personal history (R45.88, Z91.5, Z91.51, and Z91.52) and 1396 codes in total. Suicide attempt includes 4 codes: suicide attempt (T14.91), initial encounter (T14.91XA), subsequent encounter (T14.91XD), and sequela of suicide attempt (T14.91XS).

Study Variables

Study variables included the *ICD-10*–based suicidality case definition, *ICD-10*–based diagnosis codes for comorbid *DSM-5* disorders, patient demographics, encounter service date, health care use, and physician note types. Demographic variables included patient-reported race, sex assigned at birth, and age at ED visit, with age groups categorized as children (6 - 11 years) and adolescents (12 - 18 years). The encounter service date was used to determine the encounter sequence. Health care use provided a measure of the total number of patient visits and the number of clinical note types per patient. Each encounter was linked to clinical notes including the ED note and, optionally, psychiatric notes and discharge summary. The statistically significant codes resulting from the comorbidity analysis were added to the list of study variables (Multimedia Appendix 1).

Comorbidity Analysis

Conditional probability was used to quantify the relationships between additional *ICD-10* diagnoses and the *ICD-10*–based suicidality case definition. The conditional probability of suicidality *A* given the concurrent presence of a comorbid condition *B* in the same patient (equation 1) is denoted as follows:

$$(1) P(A|B)=P(A\cap B)P(B)$$

A denotes the suicidality *ICD-10* codeset. *B* denotes a particular *ICD-10* diagnosis not included in the suicidality codeset. *P(A ∩ B)* signifies the probability of suicidality *A* and diagnosis *B* occurring in the same patient, and *P(B)* denotes the independent probability of another *ICD-10* diagnosis code *B*. Expressed within the range of 0 to 1, a value of 0 signifies that the diagnosis pairs never co-occur, whereas a value of 1 indicates that the diagnosis pairs always co-occur. Conditional probabilities were calculated using equation 1 for all possible co-occurring *ICD-10* diagnosis codes stratified by age group, sex assigned at birth, and suicidality subtype (ideation, attempt, and self-harm). To increase the reproducibility and practical utility of the comorbidity model, only the 20 top-scoring co-occurring *ICD-10* codes were selected for each stratification. We then tested the statistical significance of these associations for each stratifier using a chi-square test for independence, with a Bonferroni correction applied to control for false discovery of multiple comparisons (SciPy; version 1.15.2). *ICD-10* codes occurring in fewer than 20 patient cases were omitted from the analysis to reduce the effect of rare events [25]. Conditional probabilities and *ICD-10* diagnosis pairs are further referred to as comorbidities even when not all *ICD-10* codes necessarily indicate a clinically recognized comorbid condition.

PSM Approach

PSM was used to match the case cohort to a comparator cohort covariates across all study variables, that is, patient demographics (age group, biological sex, and race), health care use codes, clinical note types, *DSM-5* categories, and significant *ICD-10* codes selected from the comorbidity analysis (Multimedia Appendix 1). The case cohort included every patient encounter with a suicidality diagnosis matching the case definition. The comparator cohort included every other patient encounter during the study period excluding patients matching the case definition. Case and comparator cohorts were compiled and ordered by encounter date, aggregating study variable observations up to the date of the encounter. To attain larger sample sizes and reduce variation in *ICD-10* billing practices, *ICD-10* codes were grouped using the *DSM-5, Text Revision* [9].

The study variables were compiled into a feature matrix [26] and analyzed using the *PsmPy* Python package [27]. A logistic regression model estimated propensity scores for suicidality using the feature matrix as input. Similarity between suicidality cases and patients without a suicidality diagnosis was measured using the PSM logit score (ie, the logarithmic transformation of the predicted probability and k-nearest neighbor).

The source code [28] for reproducing this work is freely available under an open-source Apache 2.0 License.

Results

Cohort Characteristics

During the study period, there were 59,866 patients aged 6 to 18 years with 90,980 ED encounters in total, of which 2638 (2.9%) encounters matched an *ICD-10*–based case definition of suicidality. Table 1 reports demographic characteristics for all ED encounters stratified for each suicidality subtype. Suicidality was significantly more common among female than male individuals across all suicidality subtypes ($P<.001$ via chi-square test).

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Table . Cohort characteristics.

Demographics	All ED[a] encounters (n=90,980), n (%)	ED encounters—patients with suicidality (n=2638), n (%)	Suicidality subtypes, n (%)		
			Ideation (n=2,275)	Self-harm (n=1030)	Attempt (n=177)
Aged 6-11 years	47,253 (51.9)	310 (11.8)	266 (11.7)	69 (6.7)	5 (2.8)
Aged 12-18 years	43,727 (48.1)	2328 (88.2)	2009 (88.3)	961 (93.3)	172 (97.2)
Male	47,045 (51.7)	813 (30.8)	707 (31.1)	222 (21.6)	37 (20.9)
Female	43,929 (48.3)	1825 (69.2)	1568 (68.9)	808 (78.4)	140 (79.1)

[a]ED: emergency department.

Table 2 shows the *ICD-10*–based prevalence of mental health conditions observed in all ED encounters according to *DSM-5* categories. Anxiety disorders were the most prevalent (9343/59,866, 15.6%), followed by attention-deficit/hyperactivity disorder (6250/59,866, 10.4%) and depressive disorders (5426/59,866, 9.1%). Notably, gender dysphoria (333/59,866, 0.6%), dissociative disorders (232/59,866, 0.4%), and personality disorders (190/59,866, 0.3%) were rare *DSM-5* categories.

Table . Prevalence of mental health conditions observed in all emergency department encounters (n=59,866) based on the *Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition*.

Disorder	Prevalence, n (%)
Anxiety disorders	9343 (15.6)
Attention-deficit/hyperactivity disorder	6250 (10.4)
Depressive disorders	5426 (9.1)
Trauma- and stressor-related disorders	5410 (9.0)
Sleep-wake disorders	4927 (8.2)
Disruptive, impulse control, and conduct disorders	3646 (6.1)
Communication disorders	2863 (4.8)
Autism spectrum disorder	2769 (4.6)
Intellectual disabilities	2728 (4.6)
Somatic symptom and related disorders	2614 (4.4)
Other neurodevelopmental disorders	2514 (4.2)
Elimination disorders	1955 (3.3)
Other mental disorders	1803 (3.0)
Medication-induced movement disorders and other adverse effects of medication	1304 (2.2)
Feeding and eating disorders	1256 (2.1)
Motor disorders	1086 (1.8)
Substance-related and addictive disorders	1010 (1.7)
Obsessive-compulsive and related disorders	933 (1.6)
Tic disorders	879 (1.5)
Specific learning disorder	738 (1.2)
Neurocognitive disorders	686 (1.1)
Bipolar disorder	448 (0.7)
Schizophrenia spectrum and other psychotic disorders	411 (0.7)
Gender dysphoria	333 (0.6)
Dissociative disorders	232 (0.4)
Personality disorders	190 (0.3)

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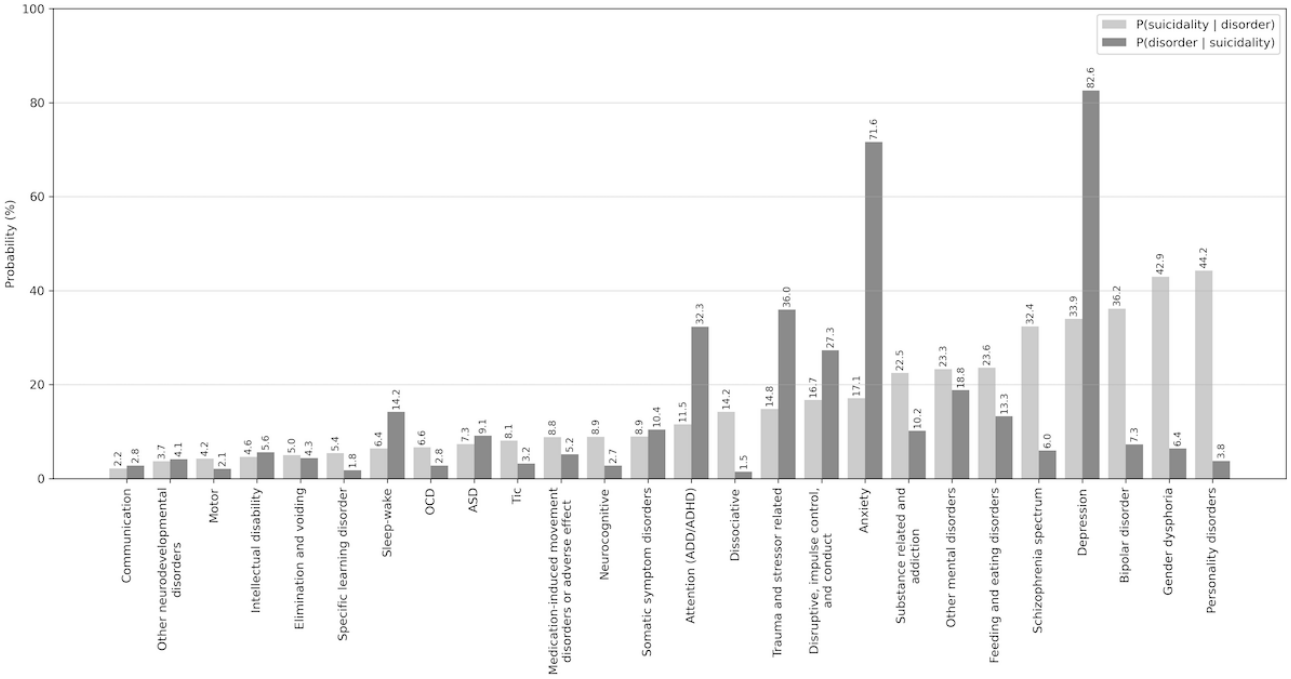
Comorbidity Analysis

Comorbidity analysis revealed that the conditional probability of suicidality was highest for the following *DSM-5* categories: personality disorders (84/190, 44.2%), gender dysphoria (143/333, 42.9%), bipolar disorder (162/448, 36.1%), depression (1842/5426, 33.9%), and schizophrenia spectrum disorders (133/411, 32.4%). Conversely, the probability of *DSM-5* category–given suicidality was highest for depression (1842/2230, 82.6%); anxiety (1597/2230, 71.6%); trauma- and stressor-related disorders (802/2230, 36.0%); attention-deficit disorder and attention-deficit/hyperactivity disorder (721/2230, 32.3%); and disruptive, impulse control, and conduct disorders (609/2230, 27.3%). Nearly half (1127/2230, 50.5%) of all patients with an *ICD-10* code for gender dysphoria (F64.8) also met the suicidality case definition. Figure 2 illustrates the conditional probabilities of suicidality and *DSM-5*–categorized mental health conditions. Detailed statistics for each *DSM-5* category can be found in Multimedia Appendix 2.

Figure 2. Conditional probabilities of suicidality and *Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition*–categorized mental health conditions. The light gray bars show the probability of suicidality given a specific disorder, whereas the dark gray bars show the probability of a disorder given that individuals also had a documented *International Classification of Diseases, 10th Revision*, code for suicidality. ADD: attention-deficit disorder; ADHD: attention-deficit/hyperactivity disorder; ASD: autism spectrum disorder; OCD: obsessive-compulsive disorder.



Of the 55 statistically significant *ICD-10* suicidality risk factors, nearly half (n=26, 47.3%) were not part of the *DSM-5* (Multimedia Appendix 1). Nearly a quarter (n=12, 21.8%) were for harm without documented self-harm intent, including "unintentional" drug poisoning and "accidental" lacerations of arms and legs. These *ICD-10* codes for unintentional poisoning or accidental injury were strongly associated with self-harm diagnosis. Female patients were significantly more likely (odds ratio 2.23, 95% CI 1.61 - 3.10; *P*<.001) than male patients to have *ICD-10* codes related to accidental (unintentional) or undetermined self-harm. Multimedia Appendix 3 provides a more detailed report on findings between subpopulations.

Mental health conditions such as F48.9 (nonpsychotic mental disorder, unspecified), F43.12 (posttraumatic stress disorder, chronic), and R44.0 (auditory hallucinations) were not found in *DSM-5* classifications [9], yet they were significant risk factors for suicidality within the study population. A full list of the top-scoring risk factors for suicidality is provided in Multimedia Appendix 4.

PSM Results

PSM was used to match cases with comparators sharing a similar comorbidity burden that may underreport cases using an *ICD-10*–based case selection. Figure 3 illustrates the distribution of propensity scores for suicidality cases and comparators before and after matching. Propensity scores closer to 0 indicate lower likelihood of suicidality, whereas scores closer to 1 represent a higher likelihood. Before matching, 70.4% (1571/2230) of suicidality cases (Figure 3) had a propensity score of ≥0.9. In contrast, only 1.9% (1051/56,725) of comparators had scores of ≥0.9 (Figure 3). After matching, the distribution of matched comparators (Fig. 4d) more closely resembled that of the cases. The number of comparators with propensity scores of <0.5 dropped from 94.7% (53,729/56,725) before matching to 12.2% (270/2230) after matching, demonstrating that PSM was effective in aligning the comparator group's comorbidity profile with that of the suicidality cases. Multimedia Appendix 5 provides more details on the PSM analysis.

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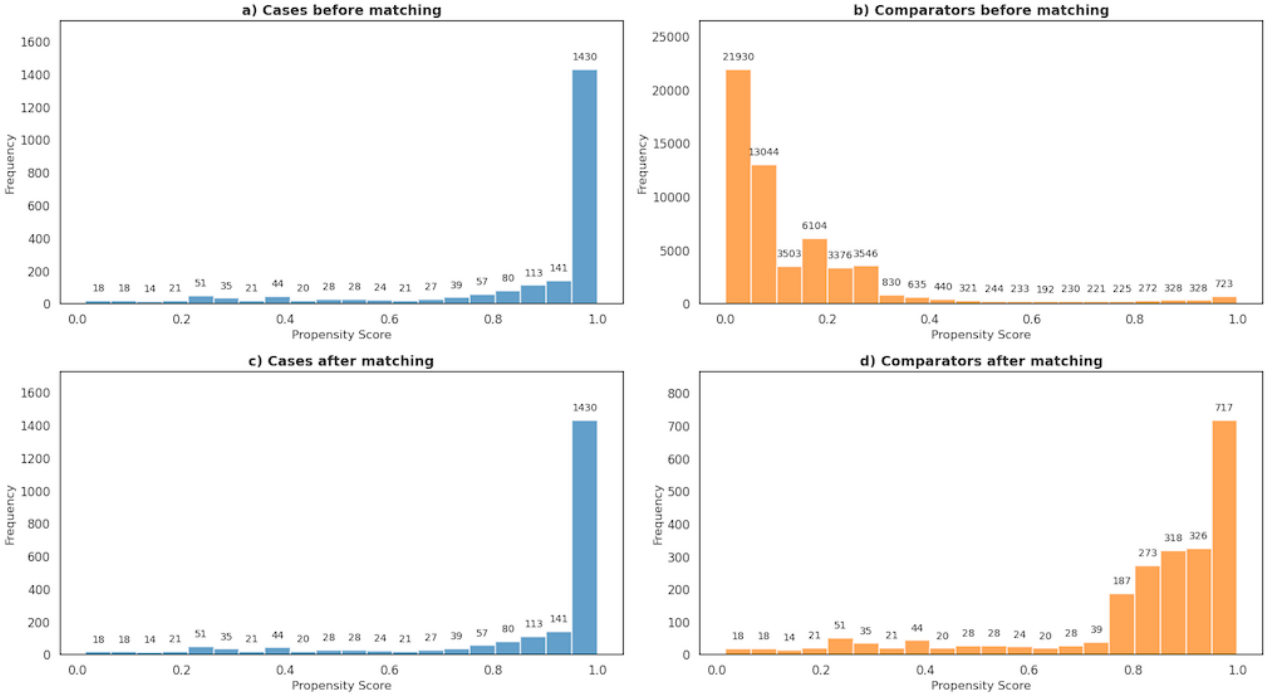
Figure 3. Distribution of propensity scores for suicidality cases and comparators before and after matching. The x-axis denotes propensity scores. The y-axis denotes the frequency, representing the size of the patient population.



Propensity-matched cohorts were selected for chart review (n=205 encounters) by subject matter experts [5]. Compared to the prevalence of suicidality in the overall study population (2638/90,980, 2.9%), the prevalence in a propensity-matched cohort was 22.3% (23/102) per human expert review. The difference in proportions of suicidality in the 2 populations was significant (P<.001; 2-proportion z test).

Discussion

Principal Findings

In this study, a patient-matching method using comorbidities as covariates identified a cohort of patients with high prevalence of suicidality despite lacking *ICD-10* codes for suicidality. This finding has several important implications. First, the PSM methodology could enable more accurate cohort identification for suicidality research; public health surveillance; and population-level analyses of suicidality risk, prevalence, and outcomes. Currently, the ability to identify suicidality cases relies heavily on *ICD-10* codes for suicidality, which are far from comprehensive and miss many cases [5-8]. Our established methodology incorporated both *DSM-5*–related codes and *ICD-10* codes not related to the *DSM-5*, expanding the range of comorbidity patterns associated with suicidality. Non–*DSM-5* codes, such as accidental poisoning or injury-related encounters, were statistically significant, indicating that relevant risk factors extend beyond formal psychiatric diagnoses. By demonstrating the utility of this broader, comorbidity-informed PSM approach to identify potential underdiagnosis and/or inadequate documentation of suicidality, this study advances methods for improving case ascertainment, including unrecognized cases of suicidality (ie, those that are not labeled with an *ICD-10* code for suicidality yet have demonstrated evidence of suicidal behavior).

These findings have important clinical implications as well. Mental illness and suicidality are a growing problem among youth in the United States. The ability to identify these cases accurately is essential both for clinicians to provide appropriate mental health care and reduce suicidality among those at risk, who may currently go unrecognized, and for researchers to study these problems and generate insights that can inform public health resource allocation and intervention development. This study identified comorbidity patterns that are associated with increased probability of suicidality. In patients with these phenotypes, additional screening may be warranted to assess for suicide risk. For instance, patients with multiple ED encounters for supposedly unintentional self-harm may be at increased risk of suicidality and require more in-depth psychiatric evaluation than the standard suicide screening measures used for all ED patients.

Suicide attempts were identified among preadolescent patients (<12 years), with a prevalence of 2.8% (5/177). The presence of suicide attempts in this younger age group underscores that suicidal behavior can emerge earlier in development than traditionally recognized. This observation is consistent with recent evidence reporting measurable rates of suicidal ideation and attempts in preadolescents [7,10] and emphasizes the need for early detection strategies and age-specific prevention efforts within pediatric clinical care. Notably, subclinical personality pathology in the developmental age (ie, personality disturbances) may amplify the effects of co-occurring psychiatric conditions, contributing additively to suicidality risk [29] and highlighting vulnerabilities that extend beyond what can be captured by categorical diagnostic frameworks such as the *ICD-10* and *DSM-5*. Similar to suicidality, personality pathology may be underrecognized in pediatric populations due to these diagnostic limitations.

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Moreover, while the objective of this study was to develop a method to identify unrecognized cases of existing suicidality rather than predict future risk of suicidality [30], it is feasible that the high-risk comorbidity patterns identified in this study are also associated with increased risk of future suicidality. Additional research is needed to understand how different comorbidity patterns predict suicidality risk and how such insights could be operationalized to improve care and outcomes. Future research could also examine how developmental processes interact with conditions such as personality pathology and gender dysphoria in shaping suicidality risk. These interactions may be more accurately captured through dimensional assessment frameworks that evaluate personality functioning and emotional regulation along a continuum rather than through categorical diagnoses [30].

Public health surveillance of pediatric suicidality using *ICD-10* codes is likely underreported. In the chart-reviewed sample, only approximately half (53.4%) of suicidality cases were identified using *ICD-10* codes. Recent pediatric suicidality studies have reinforced the need for computable phenotypes beyond a traditional *ICD-10*–based case definition of strict diagnostic criteria, namely, machine learning [7,31] and natural language processing [32,33] methods. While it was beyond the scope of this study to estimate the true and apparent prevalence [34] of suicidality, it may be possible to use large language models to provide a more accurate prevalence estimation [35].

Limitations

There were limitations in this retrospective observational study using EHR data. First, this study was conducted at a single large pediatric medical center in a northeastern urban area of the United States. Clinically relevant comorbidity profiles may vary by geography and urban vs rural settings. Second, this study focused on suicidality in ED encounters. *ICD-10* coding practices may vary across ED, inpatient, and ambulatory settings. Third, while PSM identified many instances of suicidality that were missed using *ICD-10* codes alone, it still might not identify all suicidality cases. Fourth, the effectiveness of PSM is highly dependent on the selected covariates [36]. Unmeasured or uncoded diagnoses could not be accounted for, potentially limiting the accuracy of matched comparisons. To maintain clinical interpretability and feasibility, we restricted the model to top-ranking comorbidities that a clinician could reasonably monitor in practice. However, other significant comorbidities not included in the model may also influence suicidality risk and affect matching accuracy. Further studies to test and refine the methodology may help increase the case detection yield.

Conclusions

This study provides a method for selecting case-matching cohorts with pediatric suicidality. Variables for the matched selection included significantly associated suicidality comorbidities and demographic variables in the study population. These findings suggest that pediatric suicidality may be highly underreported using an *ICD-10*–based case definition of suicidality.

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Authors' Contributions

Conceptualization: AJM (lead), LB (supporting), RX (supporting), KDM (supporting)
Data curation: LB
Formal analysis: LB (lead), AJM (supporting)
Funding acquisition: KDM
Methodology: AJM (lead), LB (equal), RX (equal)
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Conflicts of Interest

None declared.

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Multimedia Appendix 1
Significant suicidality risk factors.
[XLSX File, 41 KB - formative_v10i1e81499_app1.xlsx]

Multimedia Appendix 2
Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition, disorder prevalence and suicidality risk probabilities.
[XLSX File, 76 KB - formative_v10i1e81499_app2.xlsx]

Multimedia Appendix 3
Subpopulation findings.
[DOCX File, 14 KB - formative_v10i1e81499_app3.docx]

Multimedia Appendix 4
Top 20 *International Classification of Diseases, 10th Revision*, codes by sex, age, and suicidality subtype.
[XLSX File, 25 KB - formative_v10i1e81499_app4.xlsx]

Multimedia Appendix 5
Propensity score matching.
[DOCX File, 14 KB - formative_v10i1e81499_app5.docx]

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Abbreviations

***DSM-5*:** *Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition*
ED: emergency department

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EHR: electronic health record
***ICD-10*:** *International Classification of Diseases, 10th Revision*
PSM: propensity score matching

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Canadian Professional Association Resources on Diet and Tooth Decay: Website Content Analysis

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Abstract

Background: Tooth decay is an important public health concern affecting individuals of all ages. Dietary intake is critical to tooth decay prevention as both the types of foods and beverages consumed and how food and beverages are consumed (eg, frequency) can impact risk. Foods and beverages can both protect against and promote tooth decay.

Objective: This study aims to explore information targeted to the public on diet and tooth decay available from websites of professional organizations and regulatory bodies in Canada and the readability of this information.

Methods: Canadian websites of regulatory bodies and professional organizations for dietitians, oral health professionals, nurses, and physicians in Canada were thoroughly searched by 2 researchers (MF and JL) from June to August 2020 for information related to diet and tooth decay targeted to the public. Web pages were downloaded and underwent content analysis using NVivo software (version 12; QSR International). For each website, approximately 2 web pages focused on diet and tooth decay were selected to undergo readability testing.

Results: Overall, 213 web pages from 23 websites were found to contain information on diet and tooth decay. Of the 23 websites analyzed, 12 (52%) were from dental organizations, 7 (30%) from dental hygiene organizations, and only 1 (4%) from a dietitian organization. Messaging was present on numerous web pages focusing on diet and tooth decay and those that have other focuses (eg, oral hygiene tips for infants and children and general oral health tips). Messaging depth varied across all web pages, ranging from general advice (eg, consume a “healthy diet”) to specific recommendations (eg, amount of juice to consume per day). Many web pages targeted parents and school-aged children; fewer web pages targeted other age groups (eg, adolescents and older adults). Three major themes were identified: Foods, Beverages, and Behaviors to Limit; Foods, Beverages, and Behaviors to Choose; and Mixed and Other Unclear Messages. The most frequently discussed topic was sugar (mentioned in 67% of web pages). Sugar was often discussed in the context of limitation, infant feeding, and strategies for tooth-friendly consumption. The average Flesch-Kincaid grade level was 7.1 (SD 1.8), which exceeds the grade 6–level recommendation.

Conclusions: This analysis of web pages found that diet and tooth decay was heavily discussed throughout websites for Canadian health professional organizations, with many web pages targeting parents and school-aged children. The readability of many analyzed web pages was above the recommended grade 6 reading level. The development of comprehensive national guidelines related to diet and tooth decay would be helpful to ensure that consistent and clear messaging is available on this topic.

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KEYWORDS

diet; nutrition; tooth decay; internet; professional association; content analysis

Introduction

Oral diseases (eg, tooth decay, periodontal disease, edentulism, and oral cancer) are the most prevalent chronic diseases across the globe affecting 3.5 billion people [1]. More specifically, untreated tooth decay is the most common chronic disease worldwide with 2 billion people having untreated decay in their permanent teeth and 514 million children having untreated decay in their deciduous teeth [1,2]. In Canada, tooth decay is also a public health concern. The 2007-2009 Canadian Health Measures Survey, which is currently the most recent data available on the oral health status of the overall Canadian population, reported that tooth decay affected 57%, 59%, and 96% of Canadian children aged 6-11 years, children aged 12-19 years, and adults, respectively [3]. In addition, the prevalence of early childhood caries (ECC), which is defined as “the presence of one or more decayed (noncavitated or cavitated lesions), missing (due to caries) or filled tooth surfaces in any primary tooth in a preschool-age child, i.e., between birth and

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71 months of age" [4] in Canada has been reported to range from 0% to 98.5% with a higher prevalence being found in some communities (eg, indigenous communities and immigrant populations) [5]. Finding ways to decrease the burden of tooth decay is of public health importance.

Tooth decay is a complex and multifactorial condition [6] caused by the metabolism of dietary fermentable carbohydrates (eg, sucrose) in the mouth by bacteria (primarily *Streptococcus mutans*) leading to acid production which can cause tooth structure demineralization [7-9]. Untreated tooth decay in children can interfere with growth, sleeping, eating, and speech development; can cause poor self-esteem; and result in missed school days [4,10-12]. Tooth decay treatment varies, ranging from fluoride application in early stages to more invasive and expensive treatments including fillings, root canals, crowns, and extraction [8]. Tooth decay treatment is also the most common reason for day surgery in preschool-aged children in Canada [13]. Different approaches can be used to prevent tooth decay, including water fluoridation, topical fluorides, oral hygiene (eg, brushing and flossing), pit and fissure sealants, and optimizing dietary intake [14].

More specifically for dietary intake, the foods consumed can both cause and prevent tooth decay [9,15-20], making this relationship complex. For food constituents that cause tooth decay, a diet high in fermentable carbohydrates (eg, sugar) is associated with increased risk [15,21-23]. In addition, frequent consumption of fermentable carbohydrates (eg, sugar) is thought to be associated with more risk [23]. Because of a strong link between sugar and tooth decay, the World Health Organization recommends that intake of free sugars (ie, natural sugars within honey, syrups, fruit juices, and fruit concentrates, as well as simple sugars added to foods or beverages by a manufacturer or consumer) be less than 10% of total energy intake per day; furthermore, they suggest reducing free sugars to less than 5% of total energy due to the cariogenic effects [24]. In addition, the Canadian Pediatric Society recommends that juice should be limited to 125 milliliters per day for children [25]. Although sugar intakes are an important determinant of tooth decay, dietary factors and eating patterns can also have protective properties that minimize tooth decay risk. For example, consuming calcium-rich foods, such as cow's milk, cheese, and plain yogurt, promotes tooth enamel remineralization, which can assist in tooth decay prevention [26-28]. Furthermore, eating fresh fruit and vegetables, whole grains, and high-quality protein foods is recommended to help minimize tooth decay risk [15]. Consuming xylitol-based products (eg, sugar-free gum) is thought to also assist in prevention of tooth decay due to their ability to increase salivary output, decrease proliferation of cariogenic bacteria, and replace sugary foods in the diet [29,30]. Vitamin D deficiency has also been found to be associated with dental caries [31]. Because of the strong and complex relationship between diet and tooth decay, there is a need to ensure that the public has access to quality information on this topic from various channels.

Written information is commonly used to deliver health information and has been recommended to be used in combination with verbal information to improve patient-related outcomes [32]. This type of information can be delivered using various strategies, including paper-based resources available in clinic settings and online resources (eg, internet and social media). The readability, content, and trustworthiness of written information on various oral health topics have received some attention in the peer-reviewed literature [33-42]. However, studies on written information regarding diet and tooth decay have received less attention. Because providing counseling on diet and tooth decay has been found to be associated with numerous barriers [43], written information may be an important strategy to help disseminate information on this topic; therefore, research in this area is needed. For analyses of written content available on diet and tooth decay, a few previous content analysis studies on paper leaflets have been conducted in the United Kingdom and Australia. These studies found that the nutrition information was at times incomplete, confusing, and contradictory to other nutrition recommendations (eg, national guidelines) [44,45]. Information about written resources from online sources on this topic is limited.

The purpose of this study was to explore information targeted to the public on diet and tooth decay available from websites of professional organizations and regulatory bodies in Canada and the readability of this information. Professional organization and regulatory body resources were chosen as these organizations are known to produce numerous resources on health topics for the public that are easily and freely accessible and are often distributed using numerous channels including online (including social media), dental offices, health units, and schools.

Methods

This study followed the Standards for Reporting Qualitative Research (SRQR) checklist (Checklist 1) [46].

Ethical Considerations

This project was determined by the University of Saskatchewan Behavioral Research Ethics Board to meet the requirements for exemption status as per Article 2.2 of the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans—TCPS 2 (2018) [47]. No research participants were included as part of this study. Informed consent was not needed, because information was available in the public domain.

Data Collection

From June to August 2020, 2 researchers (MF and JL) thoroughly searched the websites of professional organizations and regulatory bodies for health professionals in Canada for all English language web pages that contained information related to diet and tooth decay targeted toward the public. MF was an undergraduate nutrition student at the time data were collected and analyzed, and JL is an academic dietitian and researcher with research interests in diet and oral health. JL has numerous years of research experience conducting qualitative research and mentored MF throughout the research process. The researchers (MF and JL) first attempted to locate all national and provincial professional association and regulatory body websites for the different health professions (eg, dentists, dental hygienists, dental therapists, dietitians, and physicians) using the Google search engine. Following identification of possible

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websites, each website was then thoroughly searched by the same 2 individuals for any information on diet and tooth decay; the websites were searched using multiple strategies including searching the terms “diet,” “nutrition,” “food,” “sugar,” “tooth decay,” “dental caries,” and so on, in the website search engine and also exploring website directories for possible web pages containing diet and tooth decay content. We did not limit the search to a specific domain or directory. Because information about diet and tooth decay was found in many places, a series of inclusion and exclusion criteria was developed to determine which web pages were eligible for inclusion.

All web pages from Canadian health professional associations and regulatory bodies with explicit information on diet and tooth decay were included except for curriculum-related materials and association magazines. We included all web pages with diet and tooth decay information (even if diet and tooth decay was not the focus) to ensure that all messaging related to this topic was captured from these websites. In addition, if an oral health professional organization web page had information about the relationship between diet and general oral health (eg, ‘tips for a healthy mouth’ and “good oral health”), these web pages were included. These web pages were included as many of the recommendations relevant to tooth decay were spoken about in broad terms. However, web pages from Canadian non–oral health professional associations and regulatory bodies (eg, dietitian and physician) were included only if they explicitly had content that linked diet to tooth decay. In addition, web pages targeted toward certain oral health conditions (eg, xerostomia, acid reflux, and dental erosion) were included if they explicitly connected the condition to tooth decay and discussed dietary information. Web pages on fluoride were included only if they discussed dietary fluoride sources (eg, fluoridated water and food sources). Finally, video content was included if the videos were made directly by the association or regulatory body themselves and contained information on diet and tooth decay. In addition, during the data collection phase, duplicate resources were found both within websites and between websites (eg, same resource in PDF format and on a web page). Therefore, if a web page provided a PDF containing duplicate information as on the web page, only the web page was selected. However, duplicate resources found across different websites or web pages were included in the dataset. Any discrepancies between the 2 searches (1 by MF and 1 by JL) were discussed and resolved.

Information about the website and web page characteristics was recorded by MF and verified by JL, including the title of the website and web page, name of organization, date of publication or last update, and URL. This information was organized using Microsoft Excel (Microsoft Inc). All included web pages were downloaded as PDF files. MF and JL met frequently through the data collection process to ensure that the search and data extraction processes were as thorough and accurate as possible.

Data Analysis

Readability Assessment

Two web pages that focused mainly on diet, excluding those specific to fluoride, were selected by MF and JL from each website for readability testing; visual elements such as images and graphics were not included as part of the readability assessment. The web pages focusing on fluoride were not chosen for this analysis as the usual content of these web pages was regarding fluoride varnishes and treatments in a dental office and not diet. If the website had only 1 relevant web page that was included in the dataset, then that single web page was included in the readability assessment. The WebFX Readability Test Tool [48] was used to assess the readability of the selected web pages using a variety of measures, including the Flesch-Kincaid Reading Ease (FKRE), Flesch-Kincaid Grade Level (FKGL), Gunning Fog Score (GFS), Simple Measure of Gobbledygook (SMOG) Index, Coleman Liau Index (CLI), and Automated Readability Index (ARI). This readability test tool has been used in other similar studies assessing the readability of written text [49,50].

FKRE scores are based on a 0 - 100 scale, in which a high score indicates a lower readability level; a score between 80 and 90 is equated to a grade 6 reading level [51]. FKGL, GFS, SMOG Index, CLI, and ARI scores all estimate the formal education-grade level needed to comprehend a passage of text [51]. The recommended reading level for the public is no higher than grade 6 [51,52]; therefore, a cutoff of 90.0 to 80.0 for the FKRE test and grade 6.0 reading level for the other measures was used to determine whether the web page met readability guidelines. The web pages were uploaded to the online tool through direct input by MF after excluding any text that was not in full-sentence format (eg, titles, headings, and bulleted lists).

Qualitative Analysis

The content of the web page messaging was analyzed using conventional qualitative content analysis [53]. Written data (as well as images) were coded inductively (without the use of preconceived categories) and organized into larger categories, subcategories, and themes by MF. NVivo software (version 12, QSR International) was used for data analysis. A second researcher with qualitative research experience (JL) read all included web pages and met numerous times with MF during the data analysis process to discuss code conceptualization and the themes that were being developed. These meetings helped to lead to new insights and better articulation of ideas and were important to promote trustworthiness regarding the findings [54]. Discrepancies between MF and JL were addressed through collaborative online discussions, where both researchers explained their reasoning and revisited the data together until they reached agreement. This approach helped ensure consistency and depth in the analysis.

In addition, as the analysis proceeded, we also recorded the number of web pages that provided information on key topic areas in the web pages including mentions of sugar or sweet or sugary or sugars, and so on, bottle and sippy cup use, avoiding dipping pacifiers in sweet substances to soothe an infant, snacking, Canada’s Food Guide, water, and cheese as a snack. These numbers were determined by MF and verified by JL.

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Results

Overview

In total, 23 Canadian health professional association or regulatory body websites were found to contain information on diet and tooth decay (or overall oral health as mentioned previously). Website characteristics are listed in Table 1. Most websites were from provincial dentist and dental hygienist organizations.

Table . Canadian professional association website characteristics that contain information on diet and tooth decay (n=23 websites).

	Values, n (%)
Website organization	
Dentist	12 (52)
Dental hygiene	7 (30)
Medical	2 (9)
Dental therapy	1 (4)
Dietitian	1 (4)
Organization level	
Provincial organization	17 (74)
National organization	6 (26)

Within these 23 websites, 213 web pages were collected, including 188 written resources, 11 videos, and 14 children's activities (eg, coloring sheets, word searches, and doorknob hangers) that contained diet and tooth decay information. Moving forward, these resources will all be described as web pages.

In total, 38 out of 213 (18%) web pages were focused directly on diet (eg, had diet- or food- or feeding-related words in the title), excluding those specific to fluoride. An additional 16 out of 213 (7.5%) included web pages focused on fluoride. Of note, many web pages targeted parents and school-aged children; fewer web pages targeted other age groups, including adolescents and older adults.

Web pages that focused mainly on diet and tooth decay had titles such as "Healthy Eating for Children," "Nutrition & Oral Health," and "Your Child's Diet." The remaining web pages with information on diet and tooth decay did not focus on this topic and instead had other focuses with small amounts of information about diet and tooth decay included. Examples of these non–diet-focused web pages were oral hygiene tips for infants and children, general oral health tips, information about specific dental conditions, oral health guides for caregivers of children and seniors, cannabis factsheets, dental hygienist factsheets, frequently asked questions pages, web pages targeted to retirees focused on dental health, and dental insurance resources.

Readability Analysis

Table 2 outlines readability measures for a sample of 37 diet-specific web pages. In total, only 5 web pages (14%) met the recommended 90.0 to 80.0 range for the FKRE test. Similarly, only 27%, 3%, 22%, and 19% of web pages met the grade 6.0 reading level cut-off for the FKGL, GFS, SMOG, and ARI tests, respectively. The CLI test found that all web pages scored higher than a grade 6.0 reading level.

Table . Readability test scores for Canadian professional association web pages that contain information on diet and tooth decay (n=37 web pages).

	Overall mean (SD)	Lowest score	Highest score
Flesch Kincaid Reading Ease	70.0 (10.9)	51.4	96.6
Flesch-Kincaid Grade Level	7.1 (1.8)	1.3	10.5
Gunning Fog Score	9.5 (1.9)	4.8	13.3
SMOG Index	6.9 (1.4)	3.9	9.8
Coleman Liau Index	11.5 (1.5)	8.1	13.8
Automated Readability Index	7.5 (2.1)	0.8	11.1

Content Analysis

Overview

Messaging depth varied across all web pages, ranging from general advice (eg, eat a "healthy diet" and "balanced diet") to specific recommendations (eg, specific number of meals and snacks to consume per day and amount of juice to drink per day). Three major themes were identified: Foods, Beverages, and Behaviors to Limit; Foods, Beverages, and Behaviors to Choose; and Mixed and Other Unclear Messages. These themes are described in detail in the paragraphs below.

Foods, Beverages, and Behaviors to Limit

Websites varied in their recommendations of which foods, beverages, and behaviors to limit. While some web pages stated

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that all foods can cause tooth decay (no matter what or how you eat), many web pages targeted (1) sugar, carbohydrates, and acid; (2) feeding children younger than 2 years; and (3) snacking and frequency of eating. These subthemes are described in more detail in the paragraphs below.

Sugar, Carbohydrates, and Acid

Sugar, carbohydrates, and acid were often discussed; however, sugar was the topic most mentioned. In total, 19 out of 23 (83%) websites and 142 out of 213 (67%) web pages mentioned the words "sugar" or "sweet" in any context. Some websites specified the type of sugar they were discussing (eg, natural and added) but most generally stated "sugar." Sugar was a central topic; therefore, it was embedded within many other themes and will be discussed throughout the "Results" section. The next three paragraphs will describe web page messaging surrounding (1) sugar amounts, (2) the language used to describe sugar and its relationship to tooth decay, and (3) the language used to recommend decreasing sugar consumption.

The overall message surrounding sugar was that it is linked to tooth decay and poor oral health and, therefore, intake amounts should be limited. No website quantified an amount of sugar that may cause tooth decay and poor oral health; however, most did generally state that a diet "high" in sugar or consuming "a lot" of sugar may put an individual at risk. One web page also noted that the amount of sweets eaten is not important; rather, it is the length of time that sweets remain in the mouth that negatively impacts teeth the most.

The language used to describe sugar and its relationship with tooth decay varied. While some web pages generally described sugar as a diet component to limit, others described sugar as "bad," "very harmful," and "can cause a lot of damage." Some web pages also included images to emphasize the latter message (eg, sugar as a cartoon pop can, candy bar, and sugar bug, chasing and attacking a scared cartoon tooth; sugar cubes with unhappy facial expressions). The language used to link sugar and tooth decay and poor oral health also varied in intensity. Some web pages acknowledged that sugar consumption may lead to, contribute to, or promote tooth decay and poor oral health, while others described sugar as being a direct cause. Several web pages described sugar as "feeding" the bacteria in the mouth. "Sugar bugs" were also mentioned in a few web pages directed toward children.

The language used to recommend decreasing sugar consumption varied. While some web pages vaguely stated that sugar was something to "be aware of" or "watch out for," others said to "limit" or "reduce" sugar with no quantification. One web page recommended that sugar be totally eliminated from the diet. Some web pages discussed avoiding "hidden sugars," at times listing other names for sugar (eg, maltose) and providing advice on reading nutrition labels to help identify and avoid such sugars. A few web pages also discussed limiting sugar intake as a method for decreasing dental care costs.

Alongside sugar, carbohydrates and acidic foods and beverages were also targeted as harmful dietary components that should be limited. A handful of web pages recommended generally limiting carbohydrates, with 1 web page describing carbohydrates as "decay-causing foods." Most websites recommended reducing intake of acidic foods and beverages due to their relationship to dental erosion and tooth decay. The language used to describe this relationship mirrored that of sugar, as web pages ranged from stating a general link to stating that acid is a direct cause of dental erosion and tooth decay. The call for limitation was also similar to that of sugar; however, no web pages advised the total elimination of acidic foods and beverages from the diet.

Beyond the general recommendation of limiting sugar, carbohydrate, and acid intake amounts described previously, some web pages targeted which dietary sources to limit. The top 5 sugary foods and beverages to limit across web pages were candy, dried fruit (eg, raisins and fruit leather), juice, soft drinks, and baked goods. Recommendations to limit carbonated beverages (eg, diet and nondiet soft drinks, alcohol, and carbonated water) were discussed in some web pages due to the high acid content; however, sugar was more often targeted than acid. The language used to describe these sugary and acidic foods and beverages varied in intensity across web pages. While some web pages did not use adjectives to describe these foods and beverages, others used adjectives in their descriptions (eg, "cavity-causing," "decay-causing," and "bad"). In addition, some web pages identified medicine (eg, cough syrup, and lozenges) as a common source of sugar that should be avoided.

Feeding Children Younger Than 2 Years

Foods, beverages, and behaviors to limit in children younger than 2 years was also a common topic. Bottle and sippy cup use was the most common topic and was discussed in 34 out of 213 (16%) web pages. The primary message identified was to limit constant sipping of juice, "milk" (ie, unspecified milk), and formula from a bottle and sippy cup, especially at naptime and bedtime. Some web pages also included breastfeeding limitations, advising that infants should not sleep at the breast. Some of these web pages further explained that sugars within nonwater liquids can cause ECC, especially if the infant has constant exposure through a bottle, sippy cup, or breast. Almost all these web pages recommended eliminating bottle and sippy cup use completely in between feedings.

Other infant feeding behaviors such as teething biscuits, dipping pacifiers in sweet substances, and sharing utensils were discussed. In total, 8 web pages recommended avoiding teething cookies, often describing them as "not a good choice" because they promote tooth decay due to their high sugar content. Similarly, 11 web pages recommended to avoid dipping pacifiers in sweet substances (eg, honey and corn syrup) to soothe an infant. Finally, some web pages recommended against sharing utensils with infants, as tooth decay–causing bacteria can be transmitted from the adult's mouth to the child.

Snacking and Frequency of Eating

Snacking messaging cut across almost all websites, primarily within web pages specific to parents and children, adolescents, and under the topics of stress and cannabis. Web pages largely discussed limiting sugary and starchy snacks, as well as limiting the frequency of snacking.

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In total, 38 web pages shared a common message of limiting snacking; however, such messaging varied. Some web pages remained general in their recommendation, advising readers to "limit snacking." Other web pages were more specific by recommending the limitation of sticky snacks and snacks high in sugar, carbohydrates, and acid. Many web pages directly targeted which snacks to limit between meals, most often targeting sticky and sweet foods (eg, candy, fruit leather, chips, and granola bars), carbonated and sugary beverages (eg, soft drinks, energy drinks, and juice), and sometimes fruit (eg, citrus fruits).

Snacking frequency was also commonly discussed; many web pages advised against "constant snacking," "grazing," and "frequent nibbling or sipping." Some of these web pages further explained that frequent snacking, as well as consuming snacks that stay in the mouth for a long time (eg, hard candy and breath mints), increases tooth exposure to sugar and acid. They explained that this exposure can increase the number and length of "acid attacks" within the mouth which can lead to tooth decay. Some web pages also noted that all foods may cause these acid attacks, including nutritious foods, and not just sugary snacks. Multiple web pages stated that "every time you eat" or "each time you eat or drink," acid attacks the teeth for at least 20 minutes. While some web pages described this process with a neutral tone, others used stronger language. For example, one web page stated that sugar will do more "damage" the longer and more often that the teeth are exposed.

Foods, Beverages, and Behaviors to Choose

All websites provided positive suggestions for which foods, beverages, and behaviors to choose to prevent tooth decay and promote general oral health. The main topics discussed across web pages were suggestions to eat a healthy diet, including specific foods, beverages, and micronutrients to choose; healthy snacking; and tooth-friendly eating and drinking. These subthemes will be described in detail in the paragraphs below.

Healthy Diet

Many web pages recommended enjoying a "well-balanced," "healthy," and "nutritious" diet or to eat foods that are "good for teeth," without further explanation as to what this recommendation would constitute. However, often these web pages referred the public to another web page within their website for more information on diet. In addition, 19 web pages recommended following Canada's Food Guide when eating, and some provided active links to the food guide itself, UnlockFood.ca (nutrition information for the public from Dietitians of Canada), and Dietitians of Canada. Of these web pages, one also included the Eat Well Plate as a visual aid. A few web pages stated that the public can consult with their oral health professional for nutritional counseling should more information be needed. Dietitians were referenced within 3 web pages as a profession that dental hygienists work with collaboratively.

When more information about a healthy diet was included, the main message across websites overall was that a healthy diet should contain a variety of foods from the different food groups to minimize tooth decay risk. Not all web pages outlined all 4 food groups (ie, vegetables and fruit, grain products, milk and alternatives, and meat and alternatives), as some left out certain groups, and the names of the food groups varied. However, most web pages explained what the food groups were (eg, dairy, fruits and vegetables, meat and alternatives, and whole grains), and sometimes they provided examples of foods within each group. Multiple web pages also recommended that 3 meals be consumed each day.

Specific Foods, Beverages, and Micronutrients to Choose

Although recommendations for a general healthy diet were often broad, web pages also commonly identified specific foods to choose and often discussed the importance of timing of these foods. Cheese was a food that was often highlighted. Cheese was commonly recommended as a healthy food to eat following a meal. Some web pages explained this recommendation, stating that cheese can play a protective role in cavity prevention as it can stimulate saliva flow and neutralize acids within the mouth. Multiple web pages also targeted apples and "juicy fruits and vegetables" as foods to eat after consuming sugary and sticky foods, if tooth brushing is not an option; these web pages sometimes stated that these foods can "clean your teeth." Finally, the most targeted beverage to choose when thirsty, excluding water (which is described later in this section), was cow's milk. Some web pages specified that milk should be unsweetened or low-fat.

Websites often discussed the importance of consuming specific micronutrients for optimal oral health. Fluoride was commonly mentioned. Almost all websites identified the benefits of fluoridated water in preventing tooth decay and advised the public to drink fluoridated water if possible. Some websites also mentioned that fluoride can be found in various foods; however, only 1 website provided specific examples (eg, ocean seafood and gelatin). Aside from fluoride, calcium was the most recommended micronutrient. Of the web pages that recommended calcium, only some provided examples of calcium-rich foods (eg, cheese, yogurt, and milk). Most web pages explained their recommendation for calcium, stating that calcium helps "rebuild your teeth," "make teeth hard," or "strengthen teeth." Finally, a small number of web pages recommended a multivitamin for individuals with allergies or restrictive diets (eg, gluten-free, vegetarian, and vegan) to ensure adequate nutrient intake, as they stated that vitamin deficiencies may cause increased risk of tooth decay. A couple of web pages also highlighted other micronutrients as being beneficial for oral health (eg, vitamin D, phosphorus, vitamin A, and vitamin C). In addition, a few web pages mentioned that anemia, iron deficiency, and vitamin D deficiency are more likely to occur in children with severe ECC.

Water

In total, 19 out of 23 (83%) websites specifically identified water as being the main beverage to choose in any context. Some web pages described water as providing "sugar-free hydration," and 1 web page stated that all foods and beverages can contribute to tooth decay except water. Web pages varied in their recommendations, ranging from general (eg, "drink water" and "choose water") to specific (eg, amount of water per day). Many web pages stated that water should be chosen

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to quench thirst, to have between and with meals, and to be kept readily available (eg, have a pitcher of water on the table or in the fridge, carry a reusable water bottle, and keep a glass of water handy at the bedside). Most web pages also suggested choosing water to replace sugar-containing beverages (eg, offer water instead of juice). Some web pages also recommended carbonated or sparkling water as a healthy alternative to other beverages.

Specific circumstances in which water would be beneficial to minimize the risk of tooth decay were also identified across web pages. First, water was recommended by many web pages to be used as a rinse after eating, drinking alcohol, eating sugary foods and beverages, or taking medicine sweetened with sugar. Some of these web pages further explained that water can help "rinse" or "wash" away any sugars and acids that may lead to tooth decay. Second, several web pages recommended that individuals experiencing dry mouth should drink or sip on water to avoid tooth decay. Third, many web pages stated that water is the only appropriate content for bottles and sippy cups, should a bottle or sippy cup be offered outside of mealtimes, as constant exposure to other beverages may cause tooth decay. Some web pages also recommended that non–water bottle contents (eg, milk and juice) be watered down gradually until only water remains.

Xylitol and Sugarless Gum, Mints, and Candy

Similar to using water as a rinse, xylitol and sugarless gum, mints, and candy were often recommended for tooth decay prevention. While some web pages advised that such items be chewed or sucked on immediately after eating, especially after eating sticky and sugary foods, others specified that individuals experiencing dry mouth would benefit as well. A few of these web pages further explained that xylitol and sugarless gum, mints, and candy stimulate saliva flow and help "wash away" sugar from teeth. Furthermore, some web pages stated that xylitol can neutralize the acids in the mouth that are produced after eating. One web page described xylitol as "one of nature's most powerful weapons against dental caries."

Of the web pages that recommended xylitol, 2 web pages discussed the amount of xylitol that should be consumed to effectively prevent tooth decay. One web page recommended consuming 5 - 10 grams of xylitol per day with no mention of frequency, while the other recommended 4 - 10 grams of xylitol 3 - 7 times a day for 3 - 7 minutes at a time. The latter web page noted that frequency is more important than quantity.

Healthy Snacking

Healthy snacking was a common topic among almost all websites. A variety of adjectives were used to describe healthy snacking including "healthy," "mouth-healthy," "dentally healthy," "safe," "tooth-friendly," and "smart" snacks. Healthy snacking messaging ranged across web pages from offering general recommendations (eg, "choose healthy snacks") to providing tangible examples. Most web pages provided a healthy snack suggestion as an alternative to a specific food to avoid (eg, snack on an apple instead of candy). The top 5 most mentioned snacks to choose for tooth decay prevention were cheese, nuts, apples, raw vegetables, and plain yogurt. Popcorn was also mentioned across multiple websites as a healthy snack. In total, 14 out of 23 (61%) websites and 36 out of 213 (17%) web pages recommended cheese as a snack. This recommendation was identified in numerous web page forms, including coloring sheets, healthy school snack and lunch ideas, and general "healthy snacking" lists. Every web page that outlined a healthy school snack and lunch recommended cheese (eg, "cheese," "cheddar cheese cubes," "cottage cheese," and "shredded Monterey Jack cheese"), with some web pages mentioning cheese numerous times. In addition, when apples were recommended as a snack, many web pages provided an image of an apple to coincide with the text (eg, cartoon apple and child eating an apple).

In addition to healthy snack ideas, some web pages also discussed healthy snacking behaviors to choose to minimize tooth decay risk. Recommendations varied in topic and depth, as some focused on making healthy snacks more available (eg, stock the pantry and fridge, keep healthy snacks on low shelves for children, and pack healthy snacks if leaving home) while others focused on the timing of snacks (eg, set specific snack times to avoid grazing, set a treat time, and schedule snacks in the midmorning and midafternoon). Numerous web pages quantified the number of healthy snacks to be offered per day, ranging from 1 to 3 times per day. However, other web pages were more general, such as one web page that generally advised "regular" snacks without further explanation as to what "regular" entailed. Some web pages also recommended that healthy snacks be chosen from at least 2 food groups, and 1 web page provided images of these snack combinations (eg, veggies and cheese and fruit and milk).

Tooth-Friendly Eating and Drinking

Rather than recommending the total elimination of cariogenic foods and beverages, many websites provided healthy suggestions for eating and drinking sugary foods and beverages to minimize tooth decay risk. If sugary foods or beverages were to be consumed, many web pages suggested enjoying them at mealtimes rather than between meals. Some of these web pages further explained that saliva levels are higher during mealtimes; therefore, sugar could be more easily washed away. Some web pages also mentioned that chocolate is a good alternative to sticky foods, such as chips and candy, because chocolate is easier to rinse away from teeth. In addition, a few web pages recommended eating carbohydrates as a part of a meal; however, no further explanation was provided.

Some web pages also identified fruit as a food to eat with a meal or as a dessert due to its acidity and sugar content. One web page recommended eating fruit over a small time if eaten as a snack (eg, have 10 strawberries or grapes at once rather than nibbling on one every few minutes). A handful of web pages also suggested choosing a piece of fruit over juice. If juice was to be consumed, web pages often quantified a daily maximum amount that varied across web pages, ranging from vague (eg, one serving per day) to specific amounts (125 mL [4 oz], half cup per day). When talking about juice, many web pages advised that juice be offered only as a part of a meal, not as a snack. Finally, 2 web pages recommended using a straw if consuming

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a sugary beverage and to drink them quickly to minimize contact with teeth.

Mixed and Other Unclear Messages

Minimal mixed messaging between and within web pages was found. In a few instances, some foods and beverages were subject to controversy, including recommendations of fruit as a snack between meals, dried fruit, milk in infant bottles, and carbonated or sparkling water. For each of these food and beverage items, there were mixed messages to consume and limit consumption. As mentioned previously, juice and dried fruit were also recommended as a snack in single instances, which is another mixed message. In addition, one web page recommended that sugar be totally eliminated from the diet; however, after providing tips for how to eliminate sugar, it stated in closing that sugar can be part of a healthy diet in moderation. Despite these few mixed messages, there was no widespread debate on these topics across web pages, as the majority shared consistent messaging.

In a few cases, some web page messaging was unclear. For example, sometimes foods were highlighted as healthy options to choose, but it was not clear as to what they actually were (eg, gelatin). Finally, as discussed previously, websites often did not quantify the amount of foods or beverages to consume (eg, "limit" sugar, eat sugar in "moderation," and "eat cheese"); therefore, it was unclear as to how much of a food or beverage was recommended.

Discussion

Principal Findings

To our knowledge, this is the first study that has examined consumer-based resources (primarily written) on diet and tooth decay from websites of professional organizations in Canada. Overall, we felt that there was an impressive number of web pages from these organizations that contained information on diet and tooth decay (213 web pages on 23 Canadian websites). Diet and tooth decay were also covered on web pages that focused on various topics, some of which were not expected to contain this information. The high frequency of this information suggests that professional organizations recognize a strong and important link between diet and tooth decay and general oral health in many different oral health contexts and are passionate about disseminating this message. This work also provides an inventory of how diet and tooth decay messaging is provided in written resources and may be useful for the development of resources on this topic in the future.

Overall, the diet and tooth decay messaging found on the web pages analyzed as part of this study aligns with studies conducted in other countries that have examined the content of diet and tooth decay information available to the general public. For example, messaging surrounding sugar was very common on the web pages analyzed as part of this study (ie, 67% of web pages mentioned "sugar" or "sweet" in any context) as well as other studies that have examined nutrition and oral health messaging in paper-based leaflets. For example, a study conducted in Australia by Arora et al [45] found that 20 of 43 leaflets recommended decreasing consumption of sugary and/or acidic foods and 23 of 43 leaflets recommended decreasing the consumption of sugary and/or acidic drinks. As well, a study conducted in the United Kingdom by Morgan et al [44] found that messaging surrounding sugar was also common; for example, they found that 27 of 30 leaflets recommended limiting consumption or reducing the frequency of sugary foods. As well, Long et al [55] found that 31 of 42 YouTube videos on nutrition and dental caries contained some type of message on sugar. Messaging surrounding water was also common in this study (19/23, 83% of websites) as well as the studies by Arora et al [45] and Morgan et al [44]. More specifically, Arora et al [45] found that 35 of 43 leaflets recommended water, and Morgan et al [44] found that 21 of 30 leaflets mentioned to drink only milk and water. However, Long et al [55] found that only 12 out of 42 YouTube videos on diet and tooth decay contained messaging on water. Finally, cheese as a snack was also a common recommendation in this study (61% of websites), which aligns with the studies also conducted by Arora et al [45] and Morgan et al [44]. Morgan et al [44] and Arora et al [45] found that 16 of 30 and 16 of 43 leaflets recommended cheese as a snack, respectively.

Although the large number of web pages available from Canadian health professional associations with information on diet and tooth decay is positive as it emphasizes the importance of this topic, the usefulness of this information may be limited in some cases. Web pages on topics separate from diet oftentimes included single, general recommendations related to diet (eg, "limit sugar" and "eat a healthy diet"). In this study, these statements commonly appeared on web pages with short lists of various oral health tips (eg, tooth brushing and flossing and tips for a healthy mouth). Similar results were found in related studies of nutrition and oral health resources performed in the United Kingdom and Australia as mentioned previously. These resources were oftentimes vague surrounding the amount, timing, and type of sugary foods and beverages to limit, and the Australian resources often did not explain what constitutes a healthy diet [44,45]. Although such information does link diet to tooth decay and overall oral health, the generality of such messaging may have narrow usefulness to the public and may limit their ability to follow recommendations.

More specifically, messages to "limit sugar" or to "limit sweets," without providing further information, assume that the public would know which sugary foods and beverages to limit and the amount in which those foods should be consumed. However, this assumption may not be true for everyone. Previous research has found a lack of knowledge among the public regarding sugar, including sugary foods and beverages [56-59]. In addition, although limiting sugar was discussed across almost every website, no website quantified a maximum daily amount recommended. The general language used by some web pages was difficult to quantify (eg, avoid having a diet "high" in sugar or "a lot" of sugar). Therefore, if referring to limitation, it may be effective for resources to provide the public with a recommended target maximum amount for daily sugar consumption. For example, a recommendation would be to consider using the World Health Organization's recommendation for free sugar intake (less than 10% of energy intake, with additional benefit of lowering to 5%, of total energy

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intake to prevent tooth decay) [24]. This quantification could be translated into practical terms for the public to understand (eg, 5% of total energy intake equals approximately 6 teaspoons of sugar [24]), which could be used in correspondence with visual aids which have been found to be helpful for nutrition education [60]. It may also be effective to demonstrate how many teaspoons of sugar are within specific food or beverage items (eg, soft drinks and candy).

In addition, the general recommendation to eat a "healthy," "well-balanced," and "nutritious" diet, with no follow-up information, assumes that the public would already understand what would constitute such a diet. This assumption was evident as oftentimes no further information (eg, food or beverage examples) coincided with this recommendation. Prior research has demonstrated that although the public oftentimes has a broad understanding of healthy eating and can acknowledge its importance, the application of such nutrition knowledge within daily life is difficult [61,62]. Numerous factors influence the discrepancy between knowledge and action in the context of healthy eating, one of which may include a lack of procedural knowledge ("knowing-how") in addition to declarative knowledge ("knowing-that") [62]. For example, while it is important to know that frequent and prolonged consumption of sugary beverages, such as soft drinks or fruit juice, may promote tooth decay (declarative), it is equally important to know that water is a healthy alternative to choose instead (procedural). Some web pages linked such messages; however, not all did. Therefore, a strategy for future resource development is to provide tangible examples of foods and beverages to choose so that the public can use their procedural knowledge. These food or beverage examples could be framed as alternatives to cariogenic foods or foods to pair with cariogenic foods.

Providing general healthy eating recommendations also assumes that the public would know and be able to find credible external resources to refer to for additional information on this topic. Some examples of credible resources include registered dietitians, other health professionals, regional health authorities, and federal and provincial government resources (eg, Public Health Agency of Canada and Canada's Food Guide). Although 19 web pages referred the public to Canada's Food Guide (and sometimes provided active links), prior research has demonstrated that Canadians largely have a relatively low reported use and low reported knowledge of Canada's Food Guide despite relatively high awareness of this document [63,64]. Therefore, despite the direct link, Canadians may still face the challenge of navigating and using this resource. Since most web pages did not provide direct referrals, it may be even more unlikely that the public would be able to refer to such resources due to the lack of knowledge suggested through previous research. Providing direct information about where the public can go for information is important as the use of potentially noncredible nutrition information is common.

Interprofessional collaboration is important as different professions have unique and specialized perspectives to help optimize the patient care and the health of populations. In this study, a need for improved collaboration between dental and dietetic professionals was identified. This collaboration could take on many forms, including referrals between the different providers and collaborating to develop resources and presentations for professionals and the public. Although 3 oral health web pages referenced dietitians as health care professionals that work collaboratively with dental hygienists, very few web pages referred the public to dietitians for assistance regarding eating to prevent tooth decay. Prior research and position statements have suggested that improved dietetic and dental collaboration is needed and can help improve oral health promotion, client-centered care, and disease prevention [15,65-67]. Depending on the patient, dental recommendations regarding eating could also differ from dietetic recommendations due to differences in professional perspectives; these differences have been reported previously [65,68,69]. For example, some websites in this study recommended eating no more than 3 meals and 2-3 snacks per day with only water in between meals. While this recommendation may be in congruence with the recommendation to minimize teeth exposure to foods and beverages other than water, this may oppose the common recommendation to eat intuitively. Intuitive Eating is a flexible style of eating that encourages an individual to intuitively gauge when to eat, what to eat, and when to stop eating largely through recognizing and following internal sensations of hunger and fullness [70]. As a result, the dental priority of minimizing teeth and food interaction may be incongruent with common dietetic recommendations of following a more flexible eating pattern. Therefore, it is important that all health professionals are familiar with the types of recommendations of their interprofessional colleagues and collaborate with one another to clarify and improve messaging to decrease confusion and promote better outcomes. More training on diet and oral health in health professional training programs is also a strategy that could be used to help address this issue [15,71].

Although mixed and unclear messaging was minimal across web pages, it was still present. Lack of clarity surrounding certain foods to choose and limit may form areas of potential confusion for the public. For example, it may be challenging for a parent to know whether dried fruit is a tooth-friendly snack for their child when one resource recommends limiting its consumption while another identifies it as a healthy snack. Furthermore, it may be challenging for the public to seek out recommended foods when it is not clear as to what these foods are (eg, gelatin). Therefore, as health care professionals and resource developers, it is important to clarify as much as possible what one's recommendations are as they could easily be misinterpreted by the public.

After analyzing the readability of the tested sample of web pages, we found that many web pages scored higher than a recommended grade 6 reading level. This finding aligns with other studies that also analyzed the readability of various online resources targeted toward the public, including those released by associations [34,35,72-75]. Providing written information that is accessible to individuals with lower literacy better allows for improved reading comprehension, thereby helping minimize health disparities, such as tooth decay.

Limitations

One limitation of this study was that the data were collected in 2020. However, most of the websites reviewed in the original

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study are still active and contain similar content; only some websites are no longer available or have removed the relevant resources. Among the active websites, many web pages analyzed in 2020 are still accessible at the same links with similar content. As well, in many cases, although the content analyzed in 2020 remained largely the same, it may have been moved to new locations due to website redesigns. Overall, we found that the content remained relatively consistent over time, suggesting that the findings from the original analysis would be similar should the data collection process be repeated today. In addition, no major changes in recommendations and evidence related to diet and tooth decay have emerged since these data were collected that would substantially change these messages. This study also serves as a valuable reference point for tracking changes over time. Another limitation of this study was that only a select sample of web pages was tested for readability due to the larger than expected dataset. A possibility exists that these selected web pages may not provide an accurate readability evaluation of the website's entire content on diet and tooth decay. In addition, the WebFX tool may not provide a perfect assessment of readability. We also did not contact the organizations to ensure that we had all their public web pages on diet and tooth decay. As well, since the information was present across the websites in numerous different types of places, it may be possible that not all web pages were found. However, 2 researchers independently and thoroughly searched the websites to ensure that all content was captured. We also included only English language web pages in this study, which could result in missing critical information that caters to non-English-speaking populations in Canada. In addition, we did not analyze social media content provided by these organizations which are also important means of conveying health information. By not including these elements, our assessment may be incomplete. As well, we did not examine differences in messaging between different types of organizations, which is an area for future research. Finally, because our study focuses on websites of professional organizations and regulatory bodies in Canada, it is not representative of the entire online landscape of diet and tooth decay resources available to Canadians. Future research could assess the content of other types of resources available on diet and tooth decay from different sources and organizations.

Conclusions

Overall, an abundance of information is available to the Canadian public on diet and tooth decay from professional associations and regulatory bodies. The dominant message across web pages was to limit sugar and to eat a healthy diet, although the explanation of this message varied in depth between web pages; as well, most of the information was targeted toward children and their parents. Of note, this information was found in many different forms under a wide variety of web page topics throughout the websites. Mixed messaging was present (eg, surrounding dried fruit) but was limited. In addition, the readability of web pages often exceeded the recommended grade 6 level, which is something to consider when creating future content on this topic. The development of national guidelines related to diet and tooth decay prevention would be helpful to ensure that consistent and clear messaging is available on this topic for health professionals and the public; this process will require extensive collaboration between experts from a variety of disciplines to ensure their applicability to the Canadian population. In addition, future research is needed to understand the perspectives of the public on resources for diet and tooth decay and how individuals interpret different types of messaging on this topic. Intervention studies could also be conducted to determine the impact of different types of messaging on knowledge, attitudes, practices, and oral health outcomes. These activities will all help to decrease the burden of tooth decay in Canada and beyond.

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Data Availability

The datasets generated and analyzed during this study are available from the corresponding author on reasonable request.

Conflicts of Interest

None declared.

Checklist 1
SRQR (Standards for Reporting Qualitative Research) checklist.
[PDF File, 143 KB - formative_v10i1e59474_app1.pdf]

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Abbreviations

ARI: Automated Readability Index
CLI: Coleman-Liau Index
ECC: early childhood caries
FKGL: Flesch-Kincaid grade level
FKRE: Flesch-Kincaid Reading Ease
GFS: Gunning Fog Score
SMOG: Simple Measure of Gobbledygook
SRQR: Standards for Reporting Qualitative Research

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Vitiligo in the Digital Spotlight: Retrospective Longitudinal Study in Germany

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Abstract

Background: Vitiligo is a chronic skin disease with a global prevalence of approximately 1% to 2%, characterized by depigmented macules. Little is known about the public interest and medical needs of patients with vitiligo in Germany. However, understanding this is critical for a patient-centered holistic therapeutic management of the disease.

Objective: This study aimed to analyze vitiligo-related web search behavior across Germany as a proxy for public awareness. A retrospective longitudinal study was conducted using Google Ads Keyword Planner to collect monthly search volume data for vitiligo-related terms from October 2019 to May 2023.

Methods: Keywords were identified in the 7 most spoken languages in Germany (German, Turkish, English, Arabic, Russian, and Polish). Seasonal and regional variations were analyzed, along with correlations with population density, dermatologist availability, and weather patterns.

Results: In total, 7,764,080 vitiligo-related searches were recorded. Most searches (n=5,808,360, 74.81%) addressed general information. Search volume peaked during the summer months and correlated positively with temperature and sunshine hours (P<.001). Notable regional differences were observed, with the highest search rates in Hamburg, Berlin, and Bremen. Rural areas showed higher search volume per 100,000 inhabitants than urban areas.

Conclusions: The findings suggest a strong public interest in vitiligo, particularly during periods of increased skin exposure. The high demand for treatment-related information further reflects the need for accessible, effective care. Web search behavior can offer real-time insights into public awareness and unmet needs, supporting earlier disease recognition, stigma reduction, and targeted educational strategies.

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KEYWORDS

vitiligo; chronic skin disease; pigmentary disorder; autoimmune skin disease; skin depigmentation; psychosocial burden; web search analysis; Google Ads Keyword Planner; digital epidemiology

Introduction

Vitiligo

Vitiligo is a chronic skin disease with a global prevalence of approximately 1% to 2% and is characterized by depigmented round to oval macules [1]. These lesions may expand over time and develop on various body areas. The pigmentation of the skin and hair is primarily determined by melanin, a pigment synthesized by melanocytes. In individuals with vitiligo, melanocytes undergo degeneration or lose their function, leading to gradual loss of pigment cells. The underlying mechanisms of this process are multifactorial, involving genetic predisposition, immune-mediated pathways, and environmental influences. Vitiligo is associated with a substantial psychosocial burden, often resulting in emotional distress and social stigmatization [2,3]. Furthermore, patients with vitiligo exhibit an increased prevalence of autoimmune comorbidities, allergic conditions, and other dermatological diseases [4]. Recent studies have also suggested broader systemic implications, potentially linking vitiligo to dysregulations in immune homeostasis. Additionally, mental health concerns are frequently observed among affected individuals, with evidence indicating a higher prevalence of depression in this patient population [5,6]. A holistic therapeutic management of vitiligo includes shared

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decision-making with defined therapeutic goals that also integrates comorbidities and the impact of the disease on the patient's quality of life. The currently available main therapeutic options are topical treatments (ruxolitinib, corticosteroids, and calcineurin inhibitors), systemic treatment (mainly oral corticosteroids), targeted and whole-body phototherapy surgical procedures (melanocyte transplantation), and depigmentation. Several new treatments are emerging [7,8]. Until now, a large proportion of patients with vitiligo appears to be unsatisfactorily treated, if not untreated [9,10]. Thus, seeking disease-related information beyond the typical medical settings, including on the internet, is common [11-14].

Internet Data Mining

Search engine analyses have proven to be an effective method for quantifying public interest in health-related issues based on search volume data [15]. Understanding public interest in vitiligo-related topics provides valuable insights into patient concerns and informational needs about a disease that still has many unmet needs [8]. Given the widespread use of digital resources for health information, analyzing search trends offers a unique opportunity to identify common patient concerns, unmet medical needs, and knowledge gaps in dermatology. In Germany, approximately 95% of the population has internet access [16], with 90.2% preferring Google as their primary search engine. Additionally, 59% of internet users report seeking health-related information online during the last 12 months [17]. This widespread use of digital resources provides a valuable opportunity to gain a comprehensive overview of public interest and information-seeking behavior in dermatology through search engine analyses.

Search engine data have been previously used to explore various dermatological conditions, offering insights into public awareness, seasonal trends, and treatment preferences. Comparable analyses of more prevalent conditions such as atopic dermatitis, psoriasis, and pollen allergies have shown strong correlations between search volumes and real-world epidemiologic indicators, supporting the validity of web-based search data as a proxy for population-level disease interest even in rarer conditions such as vitiligo [18-21]. Studies have shown that search volume patterns reflect shifts in awareness, evolving medical needs, and the influence of environmental factors on disease perception [18,22-25]. In the case of vitiligo, global search engine analyses have demonstrated both an annual increase in search volume and seasonal fluctuations in a few countries, with peak interest observed during the summer months [12,13]. Cultural and media events can also shape public interest. For example, following the death of Michael Jackson, who publicly disclosed his vitiligo diagnosis, there was a marked increase in online searches related to the condition [12,17,26]. Additionally, geographic variations have been noted, with countries such as the United States that have a larger proportion of individuals with darker skin types exhibiting significantly higher search frequencies for vitiligo-related topics [13]. Against the backdrop of international research and the established role of web search analyses in identifying public health interests, our study investigated how vitiligo is reflected in German web search behavior. The aim of this study was to analyze internet search data on vitiligo across all of Germany in the 6 most widely spoken languages to evaluate public interest in the condition and examine temporal and regional variations in search behavior. By identifying patterns in online search activity, this study sought to highlight seasonal trends, geographic disparities, and areas of unmet informational needs.

Methods

Study Design

This retrospective longitudinal study analyzed Google search volumes for vitiligo-related terms in Germany between October 2019 and May 2023. While initially designed for online marketing, Google Ads Keyword Planner has been widely adopted in scientific research for analyzing public health interests. It was selected as the primary data source because it provides absolute monthly search volumes rather than relative indexes, allowing for quantitative assessment of population-level search behavior. Previous research has established its reliability and reproducibility for epidemiologic and dermatologic investigations in Germany and internationally [18,22,23,27-29]. Google Ads Keyword Planner operates by aggregating anonymized queries entered into the Google search engine and estimating their average monthly search volumes using proprietary algorithms based on Google's advertising database. The tool identifies related search terms through semantic clustering and keyword co-occurrence analysis, providing quantitative data on search frequency stratified by geographic region, language, and time frame. Google Ads Keyword Planner was used to identify search terms (keywords) associated with vitiligo and extract the average monthly search volume. Search volume represents the number of user queries for specified terms. To ensure broad population coverage, the 6 most widely spoken languages in Germany (German, Turkish, English, Arabic, Russian, and Polish) were included. The analysis was performed using Google geotargeting, encompassing all 16 federal states and 1960 regional units across Germany. This analysis is based exclusively on data obtained from the Google search engine via Google Ads Keyword Planner. Searches on other engines (eg, Bing, Yahoo, or DuckDuckGo) were not included. This restriction was intentional as Google consistently accounts for more than 90% of all web searches in Germany [17], making it a highly representative proxy for overall internet search behavior in this context. For reasons of readability, the terms "internet search" or "web search" are occasionally used in the manuscript; however, all data reported are derived exclusively from the Google search engine.

This paper is based on a not yet published dissertation (C Gasteiger, unpublished data, 2025).

Ethical Considerations

As the data used in this study were publicly available and anonymized, no ethics approval or informed consent was required.

Categorization

Google Ads Keyword Planner was queried separately for each of the 6 most frequently spoken languages in Germany (German, English, Turkish, Arabic, Russian, and Polish) using the disease-related seed terms "vitiligo" and its direct translation

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or synonym in the respective language. For each language, the tool automatically generated a list of related keywords that users frequently entered in semantic or contextual relation to the seed term.

In an initial cleaning step, all duplicates and non–health-related entries were removed. The remaining keywords were categorized by 2 researchers (CG and AZ) according to thematic similarity and search intent. For the foreign languages (Turkish, Arabic, Russian, and Polish), machine translations (Google Translate) were first used to obtain English- and German-language equivalents. These translations were then verified and corrected by native speakers with a medical or linguistic background to ensure contextual accuracy and avoid cultural misinterpretations. To assess different areas of public interest, vitiligo-related keywords were categorized into 7 groups based on previous Google web search analyses and adapted to our dataset [12,13]: "general information," "symptoms," "affected body areas," "psychosocial aspects," "treatment options," "vitiligo experts," and "others." After harmonizing the categories across all 6 languages, the entire keyword list was independently reviewed by 2 board-certified dermatologists (CG and AZ) experienced in vitiligo and digital epidemiology. Both experts independently rated each keyword as relevant or irrelevant to vitiligo based on clinical plausibility. Disagreements were resolved through discussion until consensus was reached.

The total search volume was calculated and descriptively analyzed.

Keywords in Arabic, Russian, Polish, and Turkish were translated into German and English using Google Translate and Linguee (DeepL SE). To minimize translation bias, native speakers reviewed and refined the translations where necessary to ensure accuracy and contextual relevance. To assess regional and seasonal differences in search behavior, the monthly search volume was calculated and expressed as search volume per 100,000 inhabitants. Districts with fewer than 150 inhabitants per square kilometer were classified as rural, whereas those exceeding this threshold were defined as urban [30]. Population density information was obtained from official German sources [31]. Dermatologist density per 100,000 inhabitants was obtained from the German National Association of Statutory Health Insurance Physicians [32]. German weather data (sunshine hours, precipitation, and average temperature) were obtained from the European Climate Assessment & Dataset project and standardized in R (R Foundation for Statistical Computing) by subtracting the mean and dividing by the SD [33]. For the analysis of seasonal trends, monthly search volumes were grouped into the 4 European seasons: spring (March-May), summer (June-August), autumn (September-November), and winter (December-February).

Statistical Analysis

Statistical analyses were performed using Python (Python Software Foundation). Descriptive statistics were generated for all identified and categorized keywords. Seasonal variations in search volume were examined using the Kruskal-Wallis test, whereas regional differences between federal states were analyzed using the Friedman test. The Spearman correlation test was applied to assess associations between vitiligo-related search volumes and environmental as well as demographic factors, including weather conditions, dermatologist density, population density, pollen levels, and epidemiological data (COVID-19 and influenza cases). The significance threshold was set at $P<.05$. Nonparametric tests were chosen because the distribution of search volumes violated normality assumptions (Shapiro-Wilk test; $P<.001$). Therefore, the Kruskal-Wallis and Friedman tests were applied to account for nonnormally distributed and heteroscedastic data. To address potential temporal autocorrelation, the analyses were based on aggregated monthly data rather than daily values, reducing short-term dependency effects. Regional clustering was considered by comparing standardized search volumes per 100,000 inhabitants across federal states.

Results

Overview

During the study period, a total of 7,764,080 searches related to vitiligo were found in the 6 most common languages in Germany. The highest proportion of searches were in German, with 40.73% (n=3,162,260) of the queries, followed by English (n=2,428,440, 31.28%) and Turkish (n=1,667,580, 21.48%; Table 1 and Figure 1). Google Ads identified the most keywords in Arabic (n=1074), followed by English (n=823). Polish had the lowest number of keywords at only 22 (Table 1).

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Table . Comparison of the absolute and relative Google search volume of terms related to vitiligo in Germany from October 2019 to May 2023. Keywords are search terms entered by users into the Google search engine, representing real-world queries (n=7,764,080).

	Total	Arabic (n=367,460)	German (n=3,162,260)	English (n=2,428,440)	Polish (n=11,530)	Russian (n=126,810)	Turkish (n=1,667,580)
Number of keywords	2878	1074	284	823	22	265	410
Searches on “general information,” n (%)	5,808,360 (74.81)	142,700 (38.83)	2,241,480 (70.88)	1,730,200 (71.25)	7660 (66.44)	90,130 (71.07)	1,596,190 (95.72)
Searches on “symptoms,” n (%)	320,210 (4.12)	25,930 (7.06)	181,060 (5.73)	104,750 (4.31)	780 (6.76)	7500 (5.91)	190 (0.01)
Searches on “affected body areas,” n (%)	252,170 (3.25)	10,960 (2.98)	161,660 (5.11)	70,140 (2.89)	0 (0.00)	6650 (5.24)	2760 (0.17)
Searches on “psychosocial aspects,” n (%)	42,470 (0.55)	1350 (0.37)	13,590 (0.43)	21,700 (0.89)	1640 (14.22)	2840 (2.24)	1350 (0.08)
Searches on “treatment options,” n (%)	936,530 (12.06)	144,520 (39.33)	451,000 (14.26)	266,040 (10.96)	1450 (12.58)	19,460 (15.35)	54,060 (3.24)
Searches on “vitiligo experts,” n (%)	47,070 (0.61)	1690 (0.46)	35,450 (1.12)	7150 (0.29)	0 (0.00)	120 (0.09)	2660 (0.16)
Searches on “others,” n (%)	357,270 (4.60)	40,310 (10.97)	78,020 (2.47)	228,460 (9.41)	0 (0.00)	110 (0.09)	10,370 (0.62)

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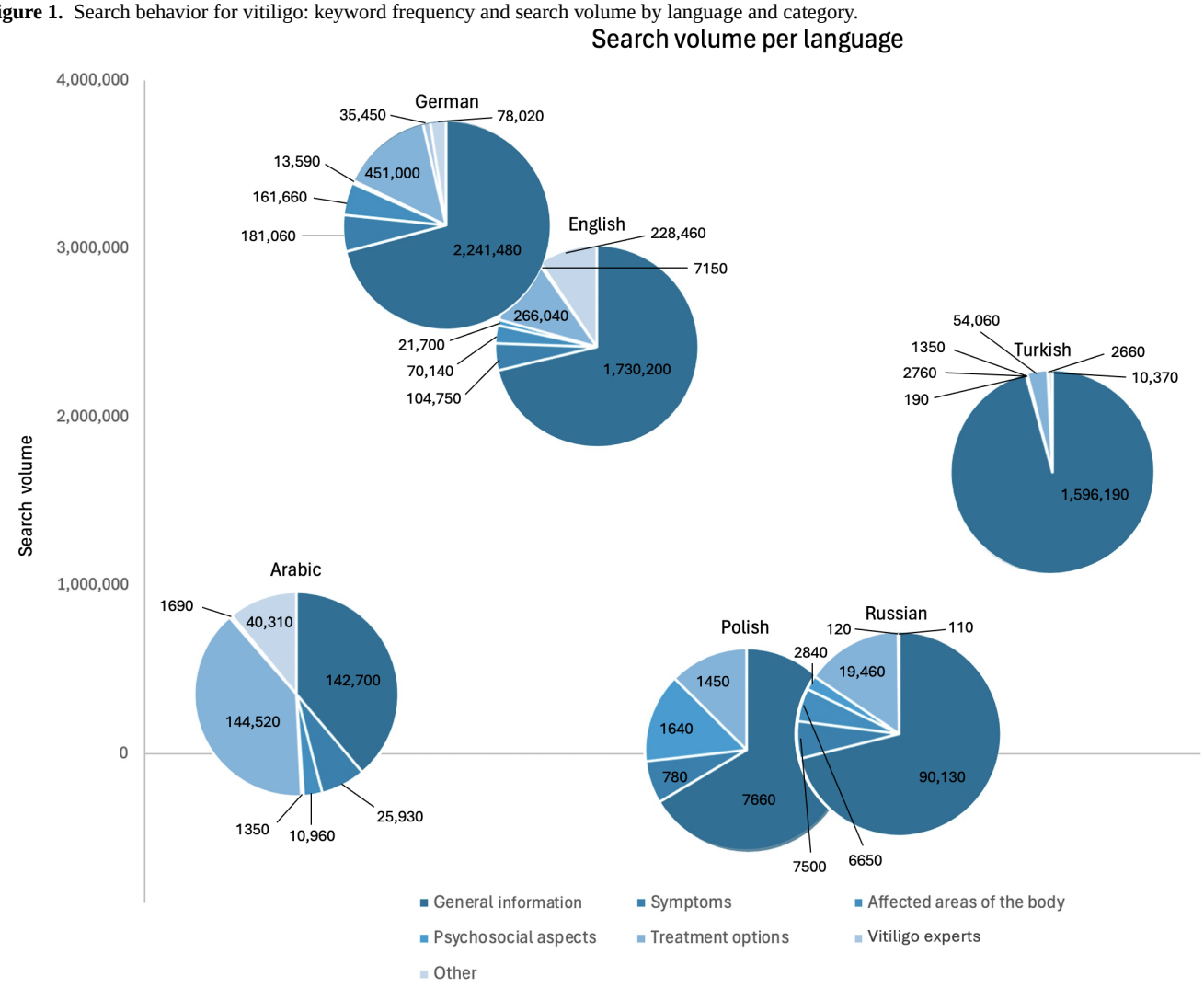
Figure 1. Search behavior for vitiligo: keyword frequency and search volume by language and category.



Search Categories

Vitiligo-related search queries were divided into 7 categories (Table 1). The category with the highest search volume in all languages except Arabic was “general information about vitiligo.” In Arabic, “treatment options” was the most frequently searched category, accounting for 39.33% (144,520/367,460) of all Arabic-language queries. Across all other languages, “treatment options” consistently ranked as the second most frequently searched category (German: 451,000/3,162,260, 14.26%; English: 266,040/2,428,440, 10.96%; Polish: 1450/11,530, 12.58%; Russian: 19,460/126,810, 15.35%; Turkish: 54,060/1,667,580, 3.24%).

In the “treatment options” category, 60.75% (568,929/936,530) of the searches referred to general treatment information (therapy). Searches related to “symptoms” accounted for 4.12% (320,210/7,764,080), whereas searches for “affected body areas” made up 3.25% (252,170/7,764,080). Among these, 41.17% (103,820/252,170) focused on the genitoanal region, and 31.76% (80,100/252,170) focused on the face. Searches related to “psychosocial aspects” accounted for only 0.55% (42,470/7,764,080) of all queries. Among Polish-language searches, “psychosocial aspects” represented a markedly higher proportion, accounting for 14.22% (1640/11,530) of all Polish-language queries (Figures 2 and 3).

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Figure 2. Categorization of the search terms of Google Ads Keyword Planner. SV: search volume.

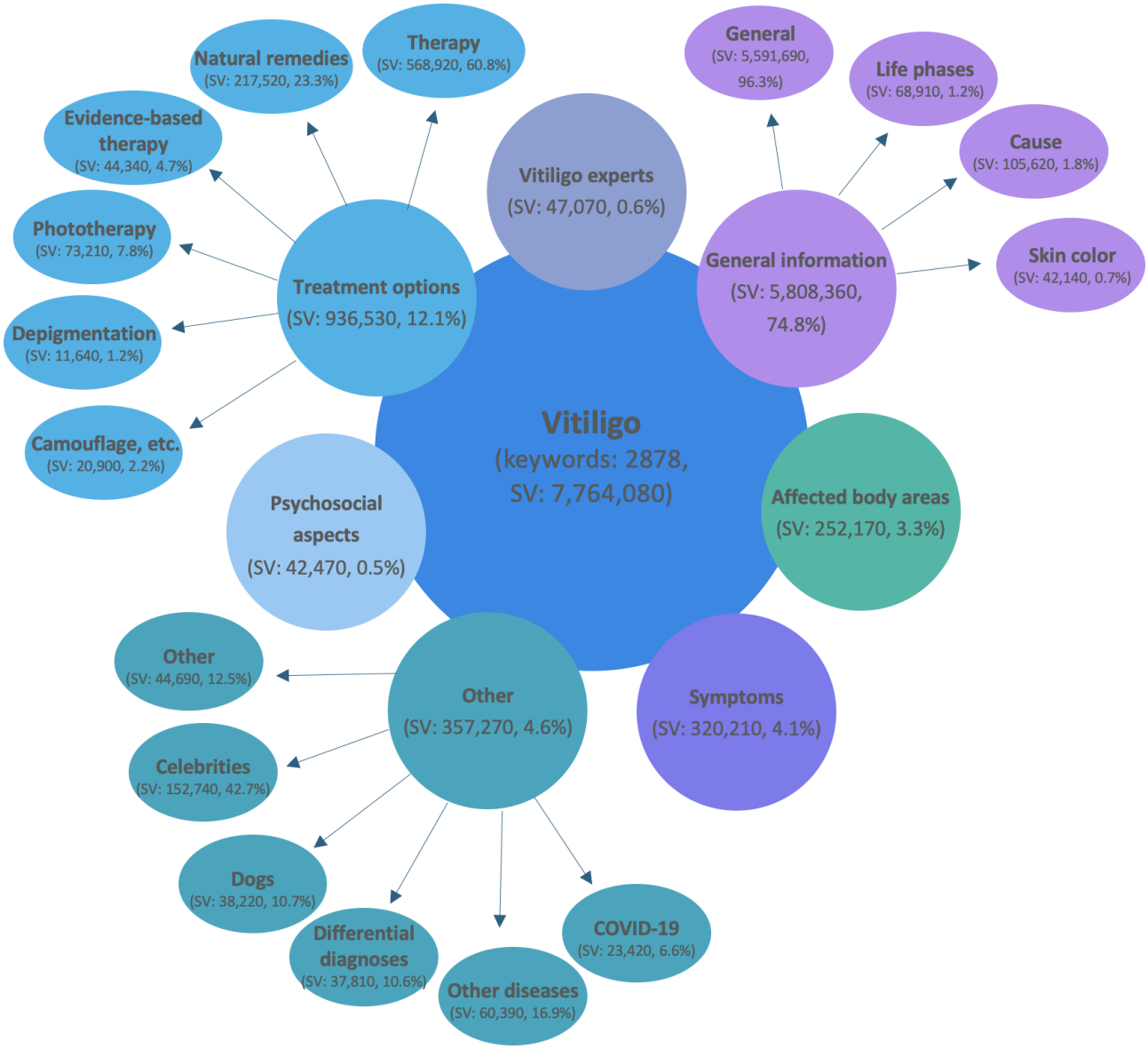

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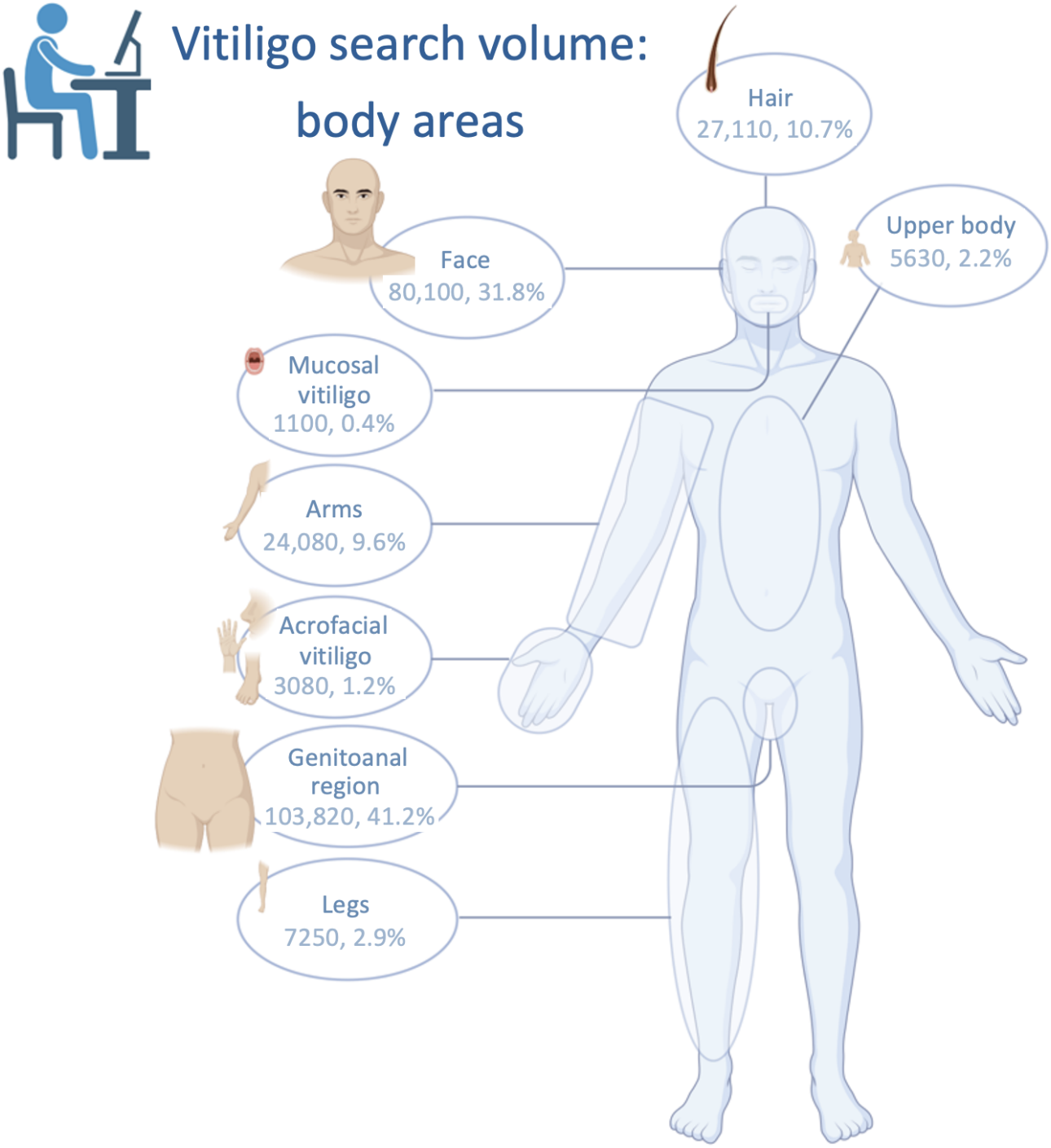
Figure 3. Vitiligo search volume in Germany grouped according to body localizations (created in BioRender).



Search Volume Over Time

The overall search volume per year increased during the study period. The lowest search volume was recorded in January 2020, and the highest search volume was recorded in June 2022 (Figure 4 [C Gasteiger, unpublished data, 2025]). Seasonal variations in search volume were evident, with significant differences in median search volumes across seasons (P<.001), showing peaks in spring and summer. This seasonal effect was observed in all 6 languages (Figure 4).

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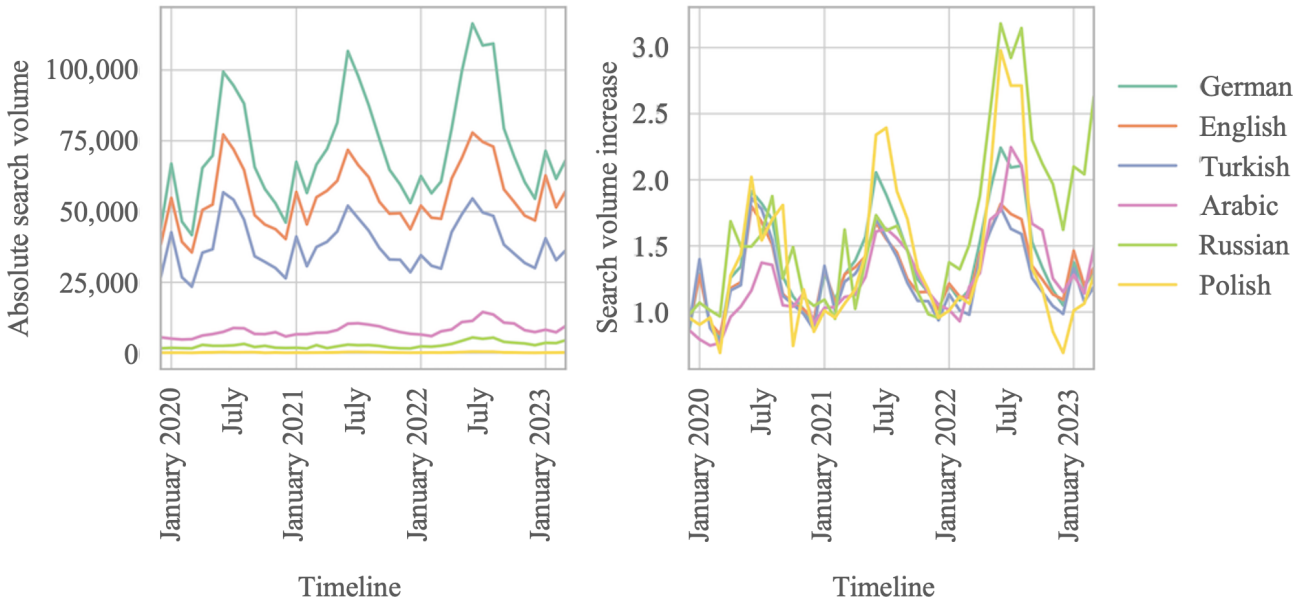
Figure 4. Seasonal search volume in Germany in 6 different languages (C Gasteiger, unpublished data, 2025).



All languages except Russian showed a steady annual increase in search volume between 2020 and 2022. The search volume in Russian declined by 282,445 searches in 2021 compared to 2020. In 2022, search queries in Russian increased by 653,421 from January onward compared to the previous year.

The seasonality of search volume suggests a possible connection with weather conditions. Sunlight hours (Spearman R=0.78; P<.001) and temperature (Spearman R=0.57; P<.001) showed a significant positive correlation with search volume. It is also known that sunlight hours and temperature are strongly positively correlated, reflecting their common seasonal variation. No correlation was found between search volume and precipitation levels (P=.28).

The analysis found no correlation between vitiligo-related search volume and COVID-19 or influenza cases in Germany. As expected, a seasonal pattern was observed for pollen levels, with peaks corresponding to the birch pollen season in the spring. The level of birch pollen exposure showed no measurable association with vitiligo-related search volume [34].

Geographical Distribution of Search Volumes

Search volumes per 100,000 inhabitants for vitiligo varied substantially across German federal states. The city-states Hamburg (16,758/7,764,080, 0.22%), Berlin (13,915/7,764,080, 0.18%), and Bremen (12,486/7,764,080, 0.16%) recorded the highest search volumes. The lowest search volume per 100,000 inhabitants was found in Saxony-Anhalt (5933/7,764,080, 0.08%; Figure 5).

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Figure 5. German federal state Google search volume of vitiligo-related terms per 100,000 inhabitants.

A significant positive correlation was observed between search volume per 100,000 inhabitants and the population density (P<.001), as well as the number of dermatologists per 100,000 inhabitants (P<.001). The density of dermatologists was also

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correlated with population density (P<.001). According to the regional typology of the Federal Statistical Office of Germany, search volumes were significantly higher in rural districts than in urban ones (Mann-Whitney U test; P=.02).

Discussion

Principal Findings

This study analyzed public interest in vitiligo using Google search data and identified notable seasonal and regional variations across Germany. Search volume peaked during the summer months and was significantly associated with temperature and sunshine hours. Additionally, rural areas showed higher search volume per 100,000 inhabitants than urban regions. As previous studies have shown, web search analysis is a valuable tool for monitoring disease trends and public interest in health-related topics [35-37]. Given that many patients with skin conditions search online before seeing a physician, these findings offer valuable insights for improving patient education and aligning clinical communication with common concerns.

A total of 7.76 million vitiligo-related searches were recorded between October 2019 and May 2023. Similar international analyses exist, although methodological differences limit comparability [12,13,26]. In line with previous studies on dermatological conditions in Germany [19-22,38,39], the most frequently searched category was “general information.” “Treatment options” ranked second, echoing trends from US data [10] and highlighting persistent demand for effective therapies. Our findings show that public awareness extends beyond general interest in vitiligo and is closely associated with concrete health-related concerns. While general awareness is reflected in the high volume of informational searches, the frequency of treatment- and symptom-related queries indicates an active demand for practical medical guidance. This high search volume focused on general information and treatment options, suggesting considerable uncertainty regarding disease mechanisms and therapeutic approaches. These patterns indicate substantial unmet informational needs, particularly with respect to comorbidities and evidence-based treatment pathways. This aligns with evidence from patient-centered research showing that more than half of individuals with vitiligo report having been told that no adequate treatment exists and a considerable proportion of dermatologists express skepticism regarding the effectiveness of currently available therapeutic options [10]. Dermatologists should recognize this demand and proactively address treatment-related questions during consultations [12]. Notably, “alternative medicine and home remedies” was the second most searched treatment-related subcategory—higher than in US studies [11]—mirroring findings from German psoriasis-related searches [21]. This aligns with a high prevalence of complementary and alternative medicine use in Germany, where up to 40% of individuals report using such therapies annually [40]. Conversely, the psychosocial aspects of vitiligo, though well documented in the literature [5,6,9], accounted for just 0.55% (42,470/7,764,080) of all queries—suggesting a potential disconnect between clinical focus and patient search behavior.

Language distribution revealed that 52.77% (2,428,440/4,601,820) of searches were in English, followed by Turkish, Arabic, Russian, and Polish. This does not reflect native speaker demographics in Germany, where Turkish is the most common non-German language. One explanation could be that health-literate individuals or medical professionals prefer English-language queries when seeking research-based information [41]. Interestingly, Russian-language search volume rose by 65% in 2022, likely related to migration dynamics following the onset of the Russian-Ukrainian war. Between 2022 and 2023, the number of Ukrainian residents in Germany increased 8-fold, whereas Russian nationals rose by 13.7% [30]. The high percentage of treatment-related searches in Arabic may reflect barriers to health care access or lower availability of language-appropriate medical resources. The relatively high interest in psychosocial aspects among Polish searches may point toward culturally mediated coping strategies. These findings underline the importance of multilingual and culturally tailored public health communication strategies [42,43].

Seasonal variation in search interest has been noted in prior global studies [10,11], with increased interest during the summer attributed to greater skin exposure and visibility. Analyses using other tools such as Google Trends likewise revealed seasonal patterns and search term distributions consistent with those in our findings, although these approaches are limited to relative search volumes rather than absolute numbers [12]. Our correlation analyses confirmed strong associations among search volume, temperature, and sunshine hours but not precipitation. Similar seasonal dynamics have been observed in other skin diseases; for example, Tizek et al [19] reported a winter peak in atopic dermatitis searches, which was attributed to seasonal symptom exacerbation.

Regionally, urban areas such as Hamburg, Berlin, and Bremen exhibited the highest search volume per capita, possibly due to younger populations and greater digital health literacy [19,23]. Interestingly, rural areas showed an even higher search volume per 100,000 inhabitants, perhaps reflecting more limited access to dermatologic care and longer wait times—pushing patients to seek digital information first.

These findings can inform public health strategies and clinical practice. Dermatologists and health authorities could develop multilingual digital education materials tailored to commonly searched topics. Seasonal peaks in search activity—particularly in the summer—present opportunities for targeted outreach or awareness campaigns. Addressing the popularity of alternative treatments with evidence-based education may also bridge gaps between public interest and clinical guidance.

Study Limitations

This study has several limitations. Google’s search volume estimates are derived from a proprietary algorithm that prioritizes frequently searched terms, possibly overrepresenting them. As vitiligo is a rare disease, the absolute search volumes were comparatively low, which may introduce random variation and potential bias in the data interpretation; therefore, the findings should be interpreted with caution, particularly when assessing regional or temporal fluctuations. Moreover, user demographics are not provided, preventing conclusions about

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specific population segments. As only Google was analyzed, with 95% of the market share in Germany [44], searches in other engines were excluded. As the study period (2019 - 2023) largely preceded the widespread use of artificial intelligence (AI)–based search systems (eg, ChatGPT), their impact on search patterns was considered negligible. As AI-driven search tools increasingly shape online information-seeking behavior, future studies should not rely on traditional web search data but adopt integrated approaches that also capture AI-mediated search activity. Internet use also varies by age; although 90% of Germans have internet access [14], older individuals may still be underrepresented. Additionally, web search data can be influenced by repeated queries from the same users or automated activity (bots), which cannot be fully excluded. In the statistical analyses, the assumption of data independence may be partly violated as temporal and spatial correlations can occur in Google search data. While monthly aggregation mitigated short-term autocorrelation, future studies could apply time-series modeling approaches (eg, autoregressive integrated moving average or mixed-effects regression) to better capture dynamic dependencies.

Study Strengths and Outlook

A major strength of this study is its inclusion of Germany's 6 most spoken languages, providing a broader, more inclusive picture of public interest. Most previous studies have focused only on English or the dominant national languages. Native speakers validated translated search terms, ensuring linguistic accuracy. Furthermore, the integration of external datasets—on weather, population, and health care access—allowed for robust contextual analysis.

Future research could apply qualitative methods to explore the motivations behind specific search behaviors and investigate how this correlates with clinical factors such as disease severity or treatment history. Analyzing social media platforms may also offer insights into community-level discussions and shared experiences related to vitiligo.

Conclusions

This study provides valuable insights into public interest in vitiligo through an analysis of Google search engine data in Germany. To promote inclusivity and representativeness, the 6 most widely spoken languages were included. As most of the searches focused on general information and general treatment options, this study suggests that, in addition to individuals diagnosed with vitiligo, many people may seek information online before consulting a physician. This highlights the potential to improve disease education by providing accessible and reliable online resources, such as government-funded websites with evidence-based information on vitiligo and treatment options, and the need for multilingual and culturally sensitive health information resources that acknowledge different approaches to disease management. The observed fluctuations in search activity may reflect variations in public awareness, perceived disease burden, and information-seeking behavior among individuals affected by or concerned about vitiligo. Higher search volumes could indicate periods of increased psychosocial stress, symptom exacerbation, or heightened media attention, whereas lower activity might correspond to times of reduced public discourse. Thus, such patterns can serve as a digital proxy for health-related interest and unmet informational needs in the general population. Understanding these dynamics may help clinicians and public health authorities identify temporal windows for targeted awareness campaigns and patient education. In general, monitoring online search trends can help evaluate the effectiveness of awareness campaigns and identify gaps in public knowledge. Clinical outcomes and qualitative research could further enhance our understanding of how online health information–seeking behavior relates to patient care and disease management.

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Data Availability

The datasets generated or analyzed during this study are not publicly available but are available from the corresponding author on reasonable request.

Conflicts of Interest

MB has received honoraria from Incyte Biosciences Germany GmbH for lectures on vitiligo. All other authors declare no other conflicts of interest.

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Abbreviations

AI: artificial intelligence

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Original Paper

Misinformation and Profitability of Hepatitis B Virus Claims on Instagram: Formative Cross-Sectional Study

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Abstract

Background: The internet is increasingly used to find health information, which often contains misinformation. Instagram is a likely source of health information online for many adults worldwide, given that there are more than 2 billion worldwide users. To date, no studies have documented the characteristics of hepatitis B virus (HBV) claims, information accuracy, engagement with, and profitability of HBV information on Instagram.

Objective: We aimed to document the characteristics, accuracy, engagement, and profitability of HBV misinformation on Instagram.

Methods: In this cross-sectional formative study, 2 research members searched for publicly available Instagram posts using the terms “hepatitis b” and “hep b” and manually extracted data from the most popular posts and user profiles for each term from December 2021 to January 2022 at varying times of the day and days of the week. We applied an existing and validated health misinformation codebook, adapted for this topic, to 103 posts for 58 variables, including post characteristics, types of HBV claims (eg, treatment, prevention, and cure), accuracy of information (misinformation vs accurate, coded by hepatology clinicians), engagement (number of likes), and profitability (yes or no). We calculated descriptive statistics and applied chi-square, Fisher exact, and *z* tests to compare posts with certain characteristics, claims, and engagement by accuracy and profitability in Stata (version 18.0) with significance set at an α of .05.

Results: Of the full sample, most posts had accurate (79/103, 76.7%) versus inaccurate (24/103, 23.3%) information about HBV. Among posts with claims about HBV treatment (18/103, 17.5%), there were more posts that had misinformation than accurate posts (55.6% vs 44.4%; χ^2_1=12.7; *P*<.001). Similarly, there were higher proportions of posts with misinformation compared to posts with accurate information about cures (n=12, 75% vs 25%; Fisher *P*<.001), natural remedies (n=13, 92.3% vs 7.7%; Fisher *P*<.001), symptoms (n=15, 60% vs 40%; χ^2_1=13.2; *P*<.001), and censorship conspiracies (n=9, 66.7% vs 33.3%; Fisher *P*=.005) related to HBV. Compared to posts with accurate information, posts with misinformation had more likes on average (mean 1459.2, SD 1458.8-1459.6 vs mean 941.8, SD 941.6-942.0; *z*=−517.4; *P*<.001). Significantly more posts with misinformation were for profit (39.5% vs 13.8%; χ^2_1=8.8; *P*=.003) than accurate posts.

Conclusions: HBV misinformation had more engagement than accurate information on Instagram and was more likely to be for-profit than accurate information. HBV misinformation may spread more easily than accurate information, meaning people searching for HBV on Instagram may encounter false, profit-driven claims that could affect health behaviors. Our focus on visual social media misinformation is innovative, as is our use of Instagram, an understudied platform. More research is needed to

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estimate the prevalence of HBV misinformation and its influence on health beliefs, behaviors, and outcomes. Improving media literacy may help reduce the influence of HBV misinformation online.

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KEYWORDS

misinformation; hepatitis B; Instagram; social media; vaccine

Introduction

The use of social media to seek and share health information has dramatically increased in the past few decades and was exacerbated by the growth of contemporary medical mistrust during the COVID-19 pandemic [1,2]. While social media improves access to health information and social support, health misinformation is widespread on these platforms [3-6]. Given the growing use of social media for health information seeking, public calls have been made for hepatologists to "lead and contribute" to online conversations to promote science-based information about liver disease on social media [7]. However, little research has been conducted to characterize the content and engagement of the public with online hepatology information, and this research is needed to guide clinicians and researchers on how to intervene and promote high-quality information online to modern health consumers.

Health misinformation has been defined as "any health-related claim of fact that is false based on current scientific consensus" [8]. Misinformation has been shown to disseminate faster than accurate information on social media [9], and health-related misinformation can have detrimental effects on patients, such as the promotion of unproven and ineffective medical treatments [10,11]. Exposure to misinformation on social media in other health contexts (eg, cancer) is associated with elevated patient distress, confusion about medical decision-making, and harm to interpersonal relationships [4,12,13]. Exaggerated beliefs that certain foods or food components can cure or cause disease, or have special health benefits, originate from the concept of "food faddism" [14,15]. Health misinformation often promotes food faddism through extreme dietary shifts, use of potentially harmful supplements, and opting for unproven alternative treatments, and these behaviors are known to contribute to treatment nonadherence and to increase mortality up to 5-fold for some diseases (eg, curable cancers) [11,16]. These patterns of misinformation suggest a pathway by which exposure to online misinformation about health has an eventual impact of patient health decisions and health outcomes. To establish a foundation for this novel research area, we studied hepatitis B misinformation on Instagram, a popular social media website that comprises visual and textual content.

We focused on hepatitis B because of its high worldwide prevalence and chronic nature. It is estimated that worldwide as many as 291 million people may be living with the hepatitis B virus (HBV) [17]. While most individuals who are infected with HBV are asymptomatic, up to 15% to 40% will develop chronic disease [18]. Chronic HBV infection can cause chronic hepatitis, cirrhosis, and hepatocellular carcinoma. Hepatocellular carcinoma is the fourth leading cancer-related cause of death worldwide, with 68% of cases occurring in sub-Saharan Africa [18-20]. While there is no cure for hepatitis B, treatment of the virus can reduce both morbidity and cancer risk and requires lifelong management [21]. The high prevalence and potential seriousness of HBV sequelae suggest that hepatitis B is a commonly discussed topic on the internet, but this has not been previously documented.

Furthermore, social media are a common source of social connection for patients with chronic, life-threatening, and stigmatized diseases such as cancer and HIV [22-24] and potentially HBV. Patients with chronic HBV infections experience clinically significant levels of anxiety, depression, and negative psychosocial (eg, incarceration, homelessness, and drug use) and community (eg, stigma)–level outcomes [25,26]. Social exclusion and the risk of psychological sequelae of a chronic HBV infection may increase patients' proclivity for online misinformation when they lack support from offline social networks [27]. Thus, patients with HBV are likely to turn to the internet to find information and support that they may otherwise not have access to offline. This pattern of simultaneous support and information seeking exists for patients with other diseases that have similar trajectories, such as cancer and HIV or AIDS [28].

Therefore, in this study, we aimed to document the characteristics and prevalence of HBV misinformation in Instagram posts, factors that may influence the impact these posts have on viewers, and engagement with HBV misinformation on Instagram. Instagram was the third most popular social media platform in the United States at the time of the study and has a wide global viewership estimated to be between 1.4 and 1.6 billion active users [29]. Instagram was selected for this study, given the paucity of research on visual and audio health misinformation, and Instagram is highly visual. We applied a deductive content analysis to classify the features of hepatitis B claims on Instagram using common search terms. This work was informed by a conceptual framework of online misinformation exposure, originally developed in an oncology setting [13]. Most studies of social media misinformation focus on vaccines, smoking and vaping products, or illicit drugs, with only 10% of studies about communicable diseases [30]. To our knowledge, this is the first study to evaluate the characteristics, prevalence, and reach of HBV misinformation and its association with profitability on social media.

Methods

Ethical Considerations

This study used publicly available social media data, which were considered exempt by the University of Arizona institutional review board. As no participants were recruited, no informed consent nor compensation was provided. We report

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analyses in aggregate, and all data are anonymized to eliminate the potential for reidentification of social media posts. No individual participants or users are identifiable in the paper or supplementary material. We followed the STROBE (Strengthening the Reporting of Observational Studies in Epidemiology) guidelines for reporting cross-sectional studies (Multimedia Appendix 1) [31].

Conceptual Framework

To situate this work within existing online misinformation research in other domains, we applied the Online Cancer Nutrition Misinformation (OnC-M) framework, a classification tool that identifies categories of misinformation, effect modifiers, and potential impacts of misinformation on patient behavior, decision-making, and health outcomes [13]. The OnC-M framework includes a codebook and definitions of health misinformation claims developed through a series of studies that provide important context for generating hypotheses about health misinformation online [13,32-37].

Instagram Platform

Instagram is a visual social media platform centered on content sharing through images and videos. Users share content, which can then be viewed and engaged with through likes and comments from their followers. Instagram is widely used in the United States, more commonly by female individuals than male individuals [29]. Our approach to collecting, coding, and analyzing data about hepatitis B–related claims on Instagram was informed by our prior studies of online health misinformation on Facebook, Instagram, Pinterest, and Twitter [13,35-37]. We adopted an existing codebook that was used in these prior studies to classify misinformation, which we modified to include hepatitis B content claims and began data collection.

Data Collection

In December 2021, we searched Instagram using key search terms “hepatitis b” and “hep b.” Search terms were intended to represent lay language used by social media users and were selected through consensus among the research team and community engagement feedback. To describe the most viewed content on Instagram, we collected the top 55 posts populated for each term. This procedure is standard, given that algorithmically the most popular and engaging posts (ie, most viewed and liked) are more likely to populate first [38]. Selected posts were captured with a screenshot, and the profiles of users who posted the content were subsequently coded for descriptive characteristics (eg, number of followers). Screenshots were taken to enhance data quality and completeness. We aimed for a sample of 100 posts, with oversampling each term to account for duplication; duplicates were removed, resulting in a final sample of 103 posts. Each row in the dataset represented a unique post, which was the unit of analysis. On completing data collection, the coding for each post was quality checked by ZCW and ELW (eg, live links, data completeness, and duplication).

Content Analysis

After finalizing the sample, each record was coded for 58 variables, which were chosen based on prior research [13,35-37], including characteristics of Instagram posts about HBV (graphics, creator expertise, creator status, target audience, world region, disclaimers, and mention of COVID-19), and content variables representing HBV-related claims (activism, treatment, natural treatment or cures, anecdotal experiences, prevention, cures, symptoms, censorship, and other). For each post, descriptive characteristics about the user and the post were manually coded from the Instagram platform and entered as variables into Microsoft Excel. We coded for 3 additional validity indicator variables that are known modifiers from the OnC-M framework, which in this study related to the quality of or truthfulness of HBV and nutrition-related claims. These 3 variables represented the inclusion of academic or government citations (yes or no), personal anecdotal experiences (yes or no), and the use of disclaimers to contextualize claims about hepatitis B (yes or no). Finally, given the previously discussed financial incentives for promoting unproven cures and treatments for diseases on social media, we coded an additional for-profit code to represent posts that were explicitly advertising or selling a product that claimed to treat or cure HBV. Variables were coded according to both the screenshots of posts and the poster’s Instagram user profile. Coding of the posts occurred through 2 cycles to establish reliability. Following standards for evaluating the accuracy of online health information, posts were evaluated for accuracy based on expert knowledge, including hepatology clinicians with technical and medical expertise, to identify the presence or absence of accurate information based on current standards of care, which was coded as accurate (score=0) versus misinformation (score=1). Examples of misinformation included false claims of HBV cures (“My herbal remedies can cure any kind of sickness and diseases...”) and HBV-related government conspiracies (“...expose the malfeasance, the coverups and the denials that run our health system”). In the first cycle, 10% of posts were inductively coded by 2 authors (ZCW and AG) to identify HBV-related claims. Areas of discrepant coding were reviewed, and decisions about new codes, refined definitions, and irrelevant content were made through coder consensus, with the input of a tiebreaker (ELW). The codebook was then applied to all the remaining posts. There were no missing data for which to account.

Statistical Analysis

We summarized each variable to describe the characteristics of Instagram posts about HBV and types of HBV claims. While this was a cross-sectional study with primarily descriptive aims, we performed limited secondary inferential analyses to examine selected associations for the purpose of hypothesis generation, a common goal of formative research [39,40]. We compared the proportion of claims associated with misinformation to the proportion of claims without misinformation using z tests. Finally, we evaluated the associations of claims with validity indicators (citations, anecdotes, and disclaimers) and profitability using chi-square and Fisher exact tests.

Results

Characteristics of Instagram Posts About HBV

Most HBV posts contained a mix of images and text (38/103, 36.9%) or an image alone (n=31, 30.1%; Table 1). A minority

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group of content creators claimed to have some kind of health expertise either in the post or on their Instagram profile (n=38, 36.9%). Similarly, a minority group of content creators claimed to be for-profit (n=38, 36.9%), meaning the majority claimed to be from not-for-profit sources (n=65, 63.1%). Most posts (n=52, 50.5%) did not specify a particular audience, but of those that did, the majority were targeting patients and caregivers of patients with HBV (n=32, 31.1%). While HBV infection is the most prevalent in sub-Saharan Africa, most HBV posts (n=40, 38.8%) in our sample originated from the Americas, followed by the Western Pacific region (n=20, 19.4%). Very few posts contained a health-related disclaimer (n=7, 6.8%), and 18.4% (n=19) of posts mentioned COVID-19.

Table 1. Characteristics of Instagram posts about hepatitis B (N=103).

Category	Posts, n (%)
Graphics	
Image only	31 (30.1)
Text only	10 (9.7)
Mix text and image	38 (36.9)
Video	8 (7.8)
Infographic	16 (15.5)
Creator expertise	
Health expertise	38 (36.9)
No health expertise	65 (63.1)
Creator status	
For profit	38 (36.9)
Not for-profit	65 (63.1)
Audience target[a]	
Prevention	21 (20.4)
Patients and caregivers	32 (31.1)
Health care providers	9 (8.7)
Other or not specified	52 (50.5)
Country or region	
Africa	16 (15.2)
Americas	40 (38.8)
Southeast Asia	15 (14.6)
European	7 (6.8)
Eastern Mediterranean	5 (4.9)
Western Pacific	20 (19.4)
Disclaimers	
Yes	7 (6.8)
No	96 (93.2)
Mentions COVID-19[b]	
Yes	19 (18.6)
No	84 (81.5)

[a]Multiple audiences could be selected to percentages to not equal 100%.

[b]Percentages shown among those posts promoting a product or service.

Characteristics of Instagram Profiles That Posted About HBV

A minority group of content creators claimed to have some kind of health expertise either in the post or on their Instagram profile (38/103, 36.9%). Similarly, a minority group of content creators claimed to be for-profit (38/103, 36.9%), meaning the majority claimed to be from not-for-profit sources (63.1%).

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Prevalence of and Engagement With HBV Claims and Misinformation on Instagram

The most common types of claims contained some kind of activism related to HBV (50/103, 48.5%; Table 2). These posts often included awareness of HBV causes and treatments, and there was no difference in misinformation prevalence among posts with claims about activism. However, for all the remaining claims, posts about treatment (55.6% vs 44.4%; χ^2_1=12.7; *P*<.001), cures (75% vs 25%; Fisher *P*<.001), natural remedies (92.3% vs 7.7%; Fisher *P*<.001), symptoms (60% vs 40%; χ^2_1=13.2; *P*<.001), and censorship (66.7% vs 33.3%; Fisher *P*=.005) contained significantly higher proportions of misinformation than accurate information. In contrast, there were significantly lower proportions of misinformation in posts about prevention (7.4% vs 92.6%; exact, *P*=.032) and other comments (39.4% vs 60.6%; χ^2_1=7.0; *P*=.008) than accurate information.

Table 2. Comparison of different types of claims by misinformation in posts about HBV on Instagram (N=103).

Claims category	Total (N=103), n (%)	Posts with each specific type of claims, n (%)	Posts without each specific type of claims, n (%)	*P* value[a]
Activism	50 (48.5)			.762
Misinformation		11 (22)	13 (24.5)	
No misinformation		39 (78)	40 (75.5)	
Prevention	27 (26.2)			*.032*[b]
Misinformation		2 (7.4)	22 (28.9)	
No misinformation		25 (92.6)	54 (71)	
Treatment	18 (17.5)			*<.001*
Misinformation		10 (55.6)	14 (16.5)	
No misinformation		8 (44.4)	71 (83.5)	
Cure	12 (11.6)			*<.001*
Misinformation		9 (75)	15 (16.5)	
No misinformation		3 (25)	76 (83.5)	
Natural remedies	13 (12.6)			*<.001*
Misinformation		12 (92.3)	12 (13.3)	
No misinformation		1 (7.7)	78 (86.7)	
Symptoms	15 (14.6)			*<.001*
Misinformation		9 (60)	15 (17)	
No misinformation		6 (40)	73 (83)	
Anecdote	10 (9.7)			*.036*
Misinformation		5 (50)	19 (20.4)	
No misinformation		5 (50)	74 (79.6)	
Censorship conspiracies	9 (8.7)			*.005*
Misinformation		6 (66.7)	18 (19.1)	
No misinformation		3 (33.3)	76 (80.9)	
Other	33 (32)			*.008*
Misinformation		13 (39.4)	11 (15.7)	
No misinformation		20 (60.6)	59 (84.3)	

[a]Fisher exact tests for variables with cells containing fewer than n=5; all other comparisons made with chi-square tests.

[b]Italics denotes statistical significance at *P*<.05.

Nearly a quarter of posts (24/103, 23.3%) contained misinformation about hepatitis B and hepatitis B treatment. Posts that contained HBV misinformation had higher engagement in the form of likes overall (1459.2 vs 941.8 engagements; *z*=−517.4; *P*<.001; Table 3). Content creators who shared misinformation about HBV had significantly fewer followers (24,075.7 vs 68,192.2 followers; *z*=44,116.5; *P*<.001) but were following significantly more accounts (1322.8 vs 910.7 accounts; *z*=−412.1; *P*<.001) than those who shared accurate information about HBV.

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Table 3. Comparison of engagement with posts on Instagram that contain misinformation about HBV (N=103).

Claims category	Misinformation (n=24)		No misinformation (n=79)		*P* value[a]
	Mean (SD)	95% CI	Mean (SD)	95% CI	
Likes	1459.2 (1)	1458.8-1459.6	941.8 (1)	941.6-942.0	<.001
Followers	24,075.7 (1)	24,075.3-24,076.1	68,192.2 (1)	68,192.0-68,192.4	<.001
Following	1322.8 (1)	1322.4-13,232	910.7 (1)	910.4-910.9	<.001

[a]z tests for comparing means.

Association of HBV Claims With Misinformation by Validity Indicators on Instagram

Validity indicators included variables representing the use of academic or government citations (yes or no), personal anecdotal experiences (yes or no), and the use of disclaimers to contextualize claims about hepatitis B (yes or no). When examined by misinformation status only, the use of anecdotes was marginally significantly different; 20.4% (19/103) of posts with anecdotes used misinformation compared to 79.6% of posts with anecdotes having accurate information (Fisher *P*=.036; Table 2).

Profitability of HBV Claims and Misinformation on Instagram

Significantly more misinformation posts were for-profit (39.5% vs 13.8%; χ^2_1=8.8; *P*=.003) compared to accurate posts (Table 4). Among posts with misinformation, 39.5% (15/24) were for-profit. The majority of censorship conspiracies, which were primarily about governments intentionally infecting and censoring citizens with HBV, were not profitable, 88.9% (8/9, Table 4). For-profit accounts were following a significantly higher number of accounts than those that were not for-profit (b=750.3, 95% CI 148.8-1351.8; *P*=.015; data not shown).

Table 4. Comparison of misinformation and censorship conspiracies by misinformation in posts about HBV on Instagram (N=103).

	Profitability	No profitability	*P* value[a]
Misinformation content			*.003*[b]
Misinformation	15 (39.5)	9 (13.8)	
No misinformation	23 (60.5)	56 (86.1)	
Censorship conspiracies			.284
Yes	1 (11.1)	8 (88.9)	
No	29 (30.9)	65 (69.1)	

[a]Fisher exact tests for variables with cells containing fewer than n=5; all other comparisons made with chi-square tests.

[b]Italics denotes statistical significance at *P*<.05.

Discussion

Principal Findings

The COVID-19 pandemic heightened public awareness of online misinformation, garnering the US Surgeon General's advisory in 2021 [41]. Since then, there has been a proliferation in research on the health impacts of social media use and how misinformation may influence patient health behaviors and health outcomes. Although medical misinformation is not a new health care issue, the internet has facilitated its more virulent dissemination [8]. Our results suggest this is the case for HBV misinformation on social media. Concerningly, 1 of 4 posts we sampled about HBV contained misinformation, and more than one-third of these posts were for monetary gain. A greater proportion of the accounts with misinformative posts were for profit. The typical motives are monetary gain, posing natural cures and false treatment options as opposed to promoting a patient's health interest. There is also a distinct lack of disclosures associated with profitability, which may bias information consumption among consumers. Disclosures are important indicators of potential bias that influence consumer information consumption. This formative research reveals the prevalence and types of misinformed claims about HBV on Instagram.

A notable finding in our formative study is the differential geographic distribution of content creators that shared HBV misinformation. While most posts were made by accounts originating in the Americas, most misinformation posts came from the African continent, suggesting that HBV misinformation differs by global region and may further disparities in information availability. Information inequality is the idea that individuals from impoverished backgrounds (eg, less educated and lower health literacy and incomes) access fewer information resources and thus experience unequal access to high-quality information [42]. Information inequality in action may predispose individuals from low socioeconomic backgrounds to pernicious and misleading online health misinformation. While the differential regional impact of online HBV misinformation was beyond the scope of this study, we recommend this as a priority for future research in this area, given the association of health literacy with poorer health outcomes in more rural and remote areas [43,44].

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These findings suggest potential clinical relevance for patient education, online health information seeking, and shared decision-making in the management of acute and chronic HBV. For patients who experience symptomatic or chronic HBV, there are regimens to ameliorate or treat lifelong disease [45]. However, the efficacy and availability of these regimens may be unknown to patients. Online information about HBV is unregulated, and nearly a quarter (24/103, 23%) of the posts in our study had misinformation, although this was only a snapshot in time and cannot be generalized to the prevalence of HBV on Instagram over time. Many misinformed posts contained conspiracy theories (30%) on Instagram. Social media disseminated misinformation is a potential barrier to prevention or initiation and sustained management of HBV that deserves ongoing attention in clinical and research agendas.

The majority of HBV information we evaluated on Instagram did not contain misinformation, and these accounts had significantly more followers than accounts proliferating misinformation. However, accounts that spread misinformation had higher engagement and followed more accounts than accounts with accurate HBV information. Overall, the virality and reception of misinformation in our sample of HBV posts outweighed that of accurate posts. While we did not evaluate health outcomes in this study, the most concerning *potential* effects of misinformed Instagram posts about HBV are with potential harm from treatment avoidance, adverse effects, or medication interaction of HBV-related products. With 30% of Instagram posts that had misinformation containing conspiracy theories, medication nonadherence, missed follow-up appointments, and progression of chronic hepatitis B to cirrhosis are of potential concern. Misinformation has the potential to contribute to adverse health outcomes and it can also sow seeds of distrust in health institutions and health care professionals [46].

Formative methodological approaches to describing online HBV misinformation can extend to other gastrointestinal pathologies in future research. This study provides an initial overview of HBV misinformation on Instagram, providing a foundation for future work. Qualitative research examining the narratives, themes, and user interactions surrounding this content could yield deeper insight into how HBV misinformation is framed and spread online. Additional research on the impact of social media in HBV care can improve clinicians' readiness to respond effectively to patient concerns related to online misinformation. By documenting the initial prevalence of and engagement with online misinformation about HBV, we lay the groundwork for monitoring the potential differential and unequal impact of HBV misinformation among subpopulations of individuals with HBV. Still, barriers to conducting research on misinformation remain, such as limited funding opportunities [47].

Limitations

Our study is limited by the cross-sectional nature of data collection, small sample, and the inability to tie HBV misinformation directly to patient health outcomes. However, due to the need for contextual and descriptive analysis of HBV topics to inform hypothesis generation and the development of larger more complex intervention trials [39,40], this research is critically needed as we are aware of no other prior studies that have contextualized the topics of popular HBV content on Instagram. Further research applying more sophisticated classification tools on larger, more robust samples of social media posts about HBV would provide more generalizable estimates of HBV misinformation prevalence. This future research is needed to fully understand and address the downstream effects of HBV misinformation on health behaviors, health decision-making, and, ultimately, health outcomes. Given the dynamic nature of social media, our findings may not be generalizable to other periods. To enhance transferability and relevance of the findings, we conducted a small replication study in September 2025 (n=60 posts, 30 from each search term), which exhibited similar topics of misinformation and a nearly identical proportion of misinformation (33% of posts, compared to 30% in the original sample from December 2021). Additional engagement measures, such as aggregated comments or shares, were not available at the time of data collection, which limits a more detailed evaluation of user engagement.

Conclusions

Social media are increasingly used by patients to seek health information; however, the quality of HBV information online appears to be inconsistent based on our sample. In this formative study, HBV misinformation had more engagement than accurate information on Instagram, and HBV misinformation was more likely to be for-profit than accurate information. This suggests that HBV misinformation spreads more easily than accurate information, suggesting that people searching for HBV information on Instagram may be targeted with false, profit-driven claims about treating, or curing HBV. In turn, misleading marketing may influence health decisions in harmful ways. The primary innovation of our findings lies in the characterization of visual social media information and misinformation about HBV on Instagram, a platform that has been understudied in health misinformation research, given the unique visual format of information. More research is needed to estimate the broader prevalence of HBV misinformation and its influence on health beliefs, behaviors, and outcomes. Improving media literacy may help reduce the influence of misleading HBV information online. The issues illustrated in this formative study do not solely affect the field of hepatology. Online medical misinformation is a longstanding challenge, exacerbated by recent technological advances, that requires clinicians and researchers alike to recognize a paradigm shift in how patients access information about HBV and other gastrointestinal diseases. Our study marks the first platform-specific investigation into HBV misinformation, suggesting that HBV misinformation is present on Instagram, particularly within the context of conspiracy theories and from accounts designed for monetary gain. This descriptive information can inform hypothesis generation, future classification of more robust social media samples of HBV content, and future health communication interventions [39,40].

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Acknowledgments

We used the generative AI tool (GPT-4.1) [48] to summarize text, which was further reviewed and revised by the study group.

Data Availability

The datasets generated or analyzed during this study are available from the corresponding author on reasonable request.

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The University of Arizona Postdoctoral Research Development grant funded this research.

Authors' Contributions

Conceptualization: ZCW, ELW, JFG-O, RA
Data curation: ZCW, ELW, AG
Formal analysis: ZCW, ELW, AG
Funding acquisition: ZCW,
Methodology: ZCW, ELW
Project administration: ZCW, ELW
Writing – original draft: ZCW
Writing – review and editing: ZCW, ELW, AG, JFG-O, RA, CAT

Conflicts of Interest

ZCW previously received grant funding from Merck for a small portion of her salary to research HPV vaccine misinformation.

Multimedia Appendix 1
STROBE checklist.
[DOC File , 83 KB - formative_v10i1e71584_app1.doc]

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Abbreviations

HBV: hepatitis B virus
STROBE: Strengthening the Reporting of Observational Studies in Epidemiology
OnC-M: Online Cancer Nutrition Misinformation

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Medical Students and Clinicians' Perceptions of Social Media Direct-to-Consumer Advertising and Medication Requests

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Abstract

This study examines how medical students and clinicians report experiencing patient medication requests associated with prescription drug direct-to-consumer advertising on social media; survey data from 98 respondents indicate that those providing both in-person and virtual care encounter more frequent requests for medications advertised online, particularly branded glucagon-like peptide-1 (GLP-1) weight loss drugs.

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KEYWORDS

pharmaceutical advertising; social media; telehealth; GLP-1 agonists; glucagon-like peptide-1

Introduction

Digital media have become important to pharmaceutical marketing, transforming both the scale and tone of direct-to-consumer advertising (DTCA). A 2024 industry analysis suggested that pharmaceutical brands accounted for approximately 88% of digital advertising spending in the health care sector [1]. Emerging studies show that social media DTCA may influence patient expectations [2], which may contribute to requests for specific medications during clinical visits [3].

Robinson et al [4] conducted one of the few physician investigations of DTCA, finding that 88% of primary care physicians believed DTCA prompted patients to request specific medications, with 65% agreeing it increased time spent with patients. Two decades later, comparable studies remain scarce, likely due to the inherent challenges of accessing clinicians for research [5,6]. This study examines how medical students and clinicians perceive medication requests associated with social media DTCA across in-person and virtual care settings.

Methods

Ethical Considerations

The University of Colorado Boulder Institutional Review Board approved the study and granted a waiver of signed informed consent due to minimal risk and anonymous data collection (protocol number 25 - 0076). Participants were provided with an electronic consent statement prior to beginning the survey and indicated consent by proceeding. Participation was voluntary, and respondents could exit the survey at any time without penalty. As compensation, participants were entered into a raffle to win one of fifteen US $50 gift cards.

Survey Instrument

A cross-sectional online survey was distributed using snowball sampling among medical students and clinicians in Colorado and Missouri. Ninety-eight valid responses were included in the analysis: medical students (n=85), residents (n=5), physicians (n=6), and nurse practitioners (n=2). Respondents evaluated items measuring clinical practice type (in-person, virtual), attitudes toward DTCA, and patient medication requests (eg, glucagon-like peptide-1 [GLP-1], Wegovy). All survey items were measured using 5-point Likert-type scales. Survey items assessing DTCA attitudes were adapted from Robinson et al [4] for relevance to students and clinicians in digital contexts; formal validation in student populations has not been established. Medication request items were developed to assess the frequency of patient requests for specific drug categories commonly promoted on social media [7]. K-means clustering grouped respondents by reported clinical setting (in-person only vs in-person and virtual); clustering was based on self-reported

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frequency of clinical practice in virtual and in-person settings. Multiple linear regression examined whether DTCA attitude items predicted the frequency of self-reported medication requests associated with social media advertising.

Results

Two clusters emerged: (1) in-person only and (2) in-person and virtual respondents (Table 1). The hybrid group reported significantly more patient requests for medications seen on social media (mean 3.15, SD 0.79) than the in-person group (mean 2.64, SD 0.91; $F_{1,96}$=8.67, P=.006). The effect size was medium (η^2=0.085). Requests were highest for GLP-1 agonists (eg, semaglutide) and branded weight loss medications (eg, Wegovy, Zepbound), with similar differences observed for sodium-glucose cotransporter-2 (SGLT-2) inhibitors. Given the exploratory nature of the study, adjustments for multiple comparisons were not applied.

Table . Patient requests for specific medications by practice type.[a]

Medication category	In-person mean (SD)	Hybrid mean (SD)	*P* value[b]
GLP-1 (glucagon-like peptide-1) agonists (eg, semaglutide)	3.18 (1.21)	3.89 (0.87)	*P*=.001
Wegovy	2.33 (1.21)	3.26 (1.02)	*P*<.001
Zepbound	2.11 (1.25)	2.83 (1.17)	*P*=.004
SGLT-2 (sodium-glucose cotrans-porter-2) inhibitors	2.04 (0.97)	2.53 (0.87)	*P*=.011
Metformin	1.96 (0.93)	2.26 (0.90)	*P*=.099
Compounded semaglutide	2.34 (1.24)	2.77 (1.14)	*P*=.76

[a]Means reflect Likert scale responses.

[b]Two-group comparisons from one-way ANOVA.

In regression analyses, respondents who perceived that DTCA influences prescribing practices (β =.24, *P*=.035) and increases patient requests for specific medications (β=.35, *P*=.012) reported higher frequencies of medication requests associated with social media advertising. The overall model accounted for 27% of variance (R^2=.27).

Discussion

DTCA in Practice

These findings align with previous assertions that digital DTCA may influence medication requests, particularly in virtual settings [3]. DTCA may be associated with patients expressing preferences for branded medications prior to visits. Previsit preference formation may shape clinical discussions, particularly in shorter virtual visits [8,9].

DTCA on social media may influence patients' expectations entering clinical visits, potentially increasing the salience of DTCA prior to medical evaluation. The notable influence of GLP-1 drug promotions illustrates how digital DTCA may be associated with heightened visibility of specific drug classes online. Because the sample consisted primarily of medical students, these findings should be interpreted as reflecting student and early-career perceptions rather than established prescribing behavior. Treatment deliberation may increasingly be informed by online content. However, these interpretations are exploratory and warrant further investigation in samples of actively practicing clinicians.

Clinical and Public Health Implications

As digital pharmaceutical promotions become more ubiquitous, medical students and clinicians may benefit from structured approaches for navigating patient requests shaped by online content. Skills in digital health literacy and expectation management may become core competencies, particularly in virtual visits where time is constrained.

From a public health perspective, social media DTCA may also widen disparities in medication access and understanding. Algorithms differentially target content based on demographic and behavioral data, meaning that some patients may be disproportionately exposed to GLP-1 promotions while others remain unaware of treatment alternatives. Integrating digital health literacy into preventive care could help mitigate these inequities and support more informed patient expectations.

Limitations

Physician surveys are known to have comparatively low response rates in general, which means that even achieving small samples represents substantial field access and resource cost. The predominance of medical students in this sample limits the ability to generalize findings to actively prescribing clinicians. Findings should therefore be interpreted as exploratory.

Conclusion

Digital DTCA is increasingly visible in the informational environment that often precedes clinical visits. In this sample, respondents reporting clinical practice in both in-person and virtual settings described significantly more frequent patient requests for GLP-1 and other branded medications associated with social media DTCA. These patterns suggest that digital advertising may shape patient expectations entering clinical settings, particularly in virtual contexts. Given the primarily medical student sample, conclusions regarding prescribing behavior should be interpreted in that light. Clinicians will need skills in digital health literacy and expectation management to

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preserve evidence-based prescribing while communicating respectfully about drugs that patients discover online. Future research should examine how training programs and regulatory bodies can better equip clinicians for a landscape where social media platforms serve as de facto medication counselors.

Funding

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Conflicts of Interest

None declared.

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Abbreviations

DTCA: direct-to-consumer advertising
GLP-1: glucagon-like peptide-1
SGLT-2: sodium-glucose cotransporter-2 inhibitor

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Retrieval-Augmented Generation Versus GPT-4o for Patient-Facing Gynecological Cancer Information: Quality Evaluation

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Abstract

Retrieval-augmented generation improved overall quality scores for patient-facing gynecological cancer information mainly through better source attribution.

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KEYWORDS

gynecological neoplasms; patient education as topic; health literacy; large language models; retrieval-augmented generation; readability; GPT-4o

Introduction

Health literacy, which is the ability to obtain, process and understand basic health information, varies widely. Furthermore, situational stress influences the ability to comprehend health information [1]. High-quality accessible information underpins shared decision-making. Yet people with cancer frequently report information overload and unmet needs at diagnosis and during treatment [2]. Producing timely, personalized, and readable health-related materials is human-resource intensive, yields static documents, and can result in duplicated effort and variable quality [3]. Large language models (LLMs) may offer a solution through rapid generation and adaptation of text. However, LLMs may hallucinate, cite unverifiable sources, and produce materials misaligned with literacy needs [4]. Retrieval augmented generation (RAG) may address these issues as it grounds LLM outputs in verified information as opposed to proprietary LLMs that rely on training data alone [5].

Our objective was to compare base GPT-40 with GPT-4o enhanced with a tailored gynecological cancer knowledgebase (RAG GPT-4o) in order to determine whether RAG improves the quality of AI-generated patient-facing information.

Methods

Study Design

We compared two GPT-4o configurations to answer frequently asked gynecological cancer questions compiled from patient queries and service information resources. For the RAG GPT-4o intervention arm, a retrieval layer supplied passages from a curated UK knowledge base restricted to Macmillan Cancer Support [6] and The Eve Appeal [7] resources. The Base GPT-4o control arm generated answers without retrieval of external sources. RAG GPT-4o ran via an application programming interface (API); Base GPT-4o ran via the web interface.

We compiled 17 questions and generated two responses per question (Base GPT-4o via ChatGPT web interface; RAG GPT-4o via API), producing 34 outputs. Prompts were held constant across configurations. Paired model outputs for each question formed the unit of comparison. Seven expert raters, each, evaluated eight paired outputs, while an LLM-judge evaluated all 17 paired outputs. Application Programming Interface generation settings were recorded for reproducibility;

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equivalent sampling parameters could not be fixed in the web interface.

Recruitment

We recruited a convenience sample of clinical nurse specialists (CNSs) via professional networks. Participants were presented with paired outputs in random order and blinded to allocation. Each participant evaluated the same eight preselected question-answer pairs, the maximum feasible within one hour based on pilot testing, using the Quality Analysis of Medical AI (QAMAI) tool (six domains rated on 5-point Likert scales) [8]. Readability was assessed with the Linguistic Features Toolkit (LFTK), including Flesch Reading Ease (FRE), Flesch Kincaid Grade Level (FKGL), and total words [9]. An LLM-judge, implemented with RAG GPT-4o, also rated all paired outputs using the QAMAI tool. Prompt templates and model configuration details, including API settings, are provided.

Analysis

Two-tailed paired *t*-tests were used to compare Base and RAG scores when the within pair differences were approximately normally distributed; Wilcoxon signed-rank tests otherwise. Inter-rater agreement was assessed with intraclass correlation coefficients (ICCs 3,k); internal consistency with Cronbach α.

Ethical Considerations

This study was approved by the King's College London Minimal Risk Research Ethics Committee (MRSU 24/25 46882). Participants received a participant information sheet, provided written informed consent, and could withdraw at any time. Privacy and confidentiality were protected throughout. Participants received a £25 voucher for participation.

Results

Seven UK-based CNSs participated in the study (median post-registration experience 20 years; IQR 5 - 30). Data collection ran from March-May 2025. Participants rated quality of RAG GPT-4o answers higher than those generated by base GPT-4o with highest mean difference in the domain, *Provision of Sources and References* (Table 1). Inter-rater agreement for total QAMAI scores was moderate (ICC 0.65, 95% CI 0.31-0.86); internal consistency was good (Cronbach α=0.81). The LLM-judge rated the quality of RAG GPT-4o answers higher than those generated by base GPT-4o (*P*<.001), again driven by the QAMAI *Provision of Sources and References* domain (*P*=.01) (Figure 1).

Figure 1. Mean QAMAI (Quality Analysis of Medical Artificial Intelligence) item-level domain scores (1 to 5, higher scores indicate higher quality) for RAG GPT-4o (RAG) and Base GPT-4o (ChatGPT). Left panel (Expert ratings): domain means calculated from 7 expert raters who each scored 8 matched answer pairs. Right panel (LLM ratings): domain means calculated from a single LLM-judge that scored all 17 matched answer pairs once. LLM: large language model; RAG: retrieval augmented generation.

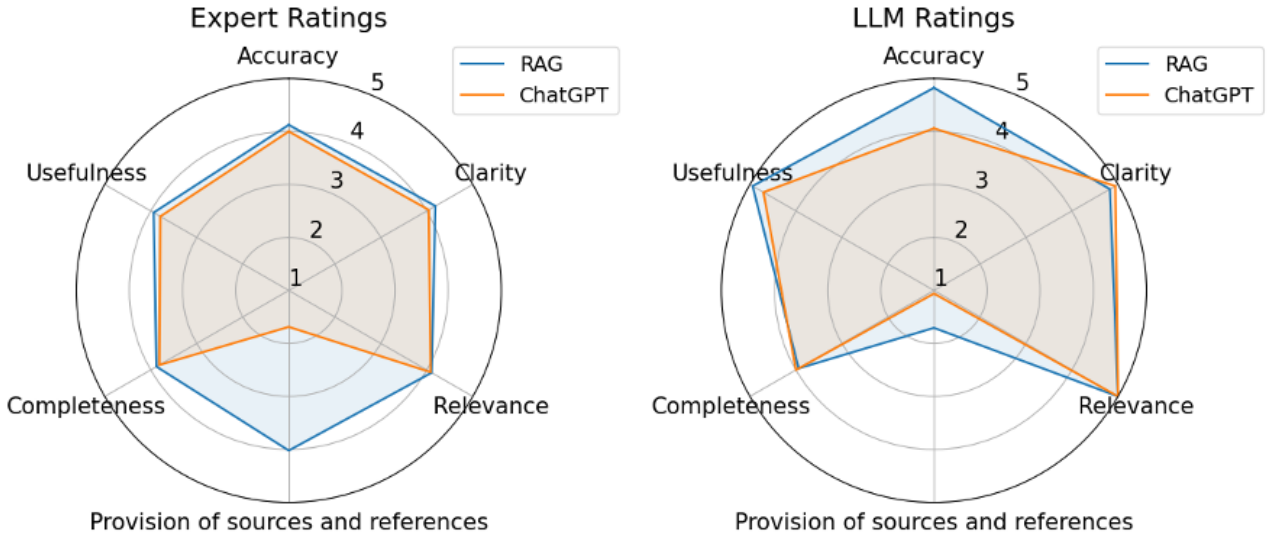

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Table . Paired analysis of QAMAI[a] and readability metrics.

QAMAI domain	RAG[b] GPT-4o, mean (SD)	Base GPT-4o, mean (SD)	Mean difference (95% CI)	*P* value
Participants: 8 question-answer pairs evaluated				
Accuracy	4.14 (0.75)	3.98 (0.75)	0.16 (−0.05 to 0.37)	.11
Clarity	4.16 (0.65)	4.02 (0.77)	0.14 (−0.01 to 0.30)	.06
Relevance	4.11 (0.73)	4.09 (0.67)	0.02 (−0.26 to 0.23)	.78
Completeness	3.88 (0.90)	3.84 (0.93)	0.04 (−0.16 to 0.23)	.58
Provision of Sources & References	3.98 (0.94)	1.80 (1.24)	2.18 (0.92 to 3.44)	.03
Usefulness	3.96 (0.69)	3.80 (0.64)	0.16 (−0.10 to 0.42)	.17
Total (max=30)	24.23 (3.60)	21.54 (3.46)	2.69 (0.77 to 4.62)	.01[c]
LLM-Judge: 17 question-answer pairs evaluated				
Accuracy	4.82 (0.39)	4.06 (0.24)	0.76 (0.53 to 0.99)	<.001
Clarity	4.82 (0.39)	4.94 (0.24)	−0.12 (−0.35 to 0.11)	.16
Relevance	5.00 (0)	5.00 (0)	NA[g]	NA[g]
Completeness	3.94 (0.24)	4.00 (0)	0.06 (−0.18 to 0.06)	.32
Provision of Sources & References	1.71 (0.77)	1.06 (0.24)	0.65 (0.25 to 1.05)	.01
Usefulness	4.94 (0.24)	4.71 (0.47)	0.23 (−0.03 to 0.49)	.10
Total (max=30)	25.24 (1.35)	23.76 (0.56)	1.48 (0.76 to 2.20)	<.001[c]
LFTK[d] Domain				
17 question-answer pairs evaluated				
FKGL[e]	7.2 (1.85)	6.2 (1.87)	1.00 (–0.1 to 2.2)	.08[c]
FRE[f]	67.9 (10.98)	75.2 (9.54)	−8.2 (–12.9 to –1.9)	.006[c]
Total words	370.8 (84.27)	308.5 (67.82)	62.3 (34.6 to 90.0)	<.001[c]

[a]QAMAI: Quality Analysis of Medical Artificial Intelligence.

[b]RAG: retrieval augmented generation.

[c]paired *t* test (otherwise Wilcoxon signed-rank)

[d]LFTK: linguistic features toolkit.

[e]FKGL: Flesch Kincaid Grade Level.

[f]FRE: Flesch Reading Ease.

[g]Not applicable.

RAG GPT-4o answers were longer (*P*<.001) and had a lower FRE score (*P*=.006), indicating more difficult-to-read text. FKGL did not differ significantly (Table 1).

Discussion

Overall, experts and the LLM-judge rated both configurations highly for accuracy, clarity, relevance, and readability. RAG GPT-4o achieved higher overall QAMAI scores than Base GPT-4o, driven mainly by better provision of sources and references rather than perceived gains in accuracy or clarity. Although the LLM-judge identified differences in source attribution, it appeared to weigh provenance less than expert raters or had difficulty applying QAMAI in this domain, consistent with other studies [10]. RAG GPT-4o outputs were longer and less easy to read.

Although overall QAMAI scores were high, this does not eliminate the risk of clinically important failure in patient-facing cancer information. Errors may present as confident hallucinated claims, omission of safety critical details such as red flag symptoms or treatment risks, or overgeneralization that fails to address question intent. Provenance related problems are also possible, including outdated guidance and references that do not support the accompanying statements. Within this small sample, ratings did not suggest prominent safety related concerns, but larger evaluations are needed to characterize the frequency and impact of these types of error, and to determine

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whether high rubric scores and source attribution are sufficient safeguards for deployment without clinical oversight.

Improved provenance is expected with RAG, but the marginal benefit observed here must be weighed against the overhead of curating and maintaining a knowledge base, monitoring retrieval quality, and updating content as guidance changes. Although transparent sourcing may support perceived credibility, acceptability and trust in patient-facing information are also shaped by readability, tone, length, and cognitive load. Future work should evaluate whether optimized RAG configurations, and patient centered presentation formats improve usability, comprehension, acceptability, and perceived trust without increasing cognitive burden.

These findings suggest LLMs can generate patient-facing information that clinicians may judge as accurate, relevant, and readable, and could reduce the time required to draft materials. In this study, RAG improved overall QAMAI scores primarily through source attribution rather than perceived improvements in accuracy or clarity. Because RAG outputs were longer and less easy to read, any gains in transparency should be balanced against potential impacts on comprehensibility and health literacy.

Study limitations include a small convenience sample, expert ratings restricted to eight of 17 questions, use of a single LLM and UK knowledge base, and interface asymmetry between API and web access. Because equivalent sampling parameters could not be fixed in the web interface, this comparison should be interpreted as pragmatic and exploratory.

Funding

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Data Availability

The datasets generated or analyzed during this study are available in the GitHub repository [11].

Conflicts of Interest

None declared.

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Abbreviations

API: application programming interface
CNS: clinical nurse specialist
FKGL: Flesch Kincaid Grade Level
FRE: Flesch Reading Ease
ICC: intraclass correlation coefficient

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LFTK: linguistic features toolkit
LLM: large language models
QAMAI: Quality Analysis of Medical Artificial Intelligence
RAG: retrieval augmented generation

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A Survey of Primary Care Clinician Experiences With Electronic Health Record–Based Clinical Decision Support to Improve HIV Pre-Exposure Prophylaxis Prescribing

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Abstract

A survey of primary care clinicians suggests that a clinical decision support tool to support sexual risk assessment and prescribing of HIV pre-exposure prophylaxis was appropriate and useful for identifying at-risk patients, but uptake was hindered by workflow and usability barriers, which underscores the importance of postimplementation clinician feedback to improve the use of clinical decision support tools.

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KEYWORDS

clinical decision support systems; HIV pre-exposure prophylaxis; PrEP prescribing; sexual history documentation; primary care clinicians; community health centers; electronic health records; implementation science; physician engagement

Introduction

Inadequate sexual history screening in US primary care limits identification of candidates for HIV pre-exposure prophylaxis (PrEP) and exacerbates inequities in PrEP uptake [1,2]. Many electronic health record (EHR) systems lack standardized prompts for documenting sexual risk, which contributes to missed opportunities for sexual health discussions and HIV prevention. This documentation gap is compounded by limited provider knowledge of PrEP and the absence of validated tools to guide prescribing decisions [3,4].

EHR-based clinical decision support (CDS) tools may address these gaps by facilitating sexual risk assessment and supporting PrEP prescribing [5]. Prior studies suggest that CDS tools are acceptable and feasible [6,7] and may improve PrEP prescribing [5]. Nevertheless, clinician experiences using CDS tools for sexual risk assessment and PrEP prescribing in primary care remain poorly understood. Clinician feedback about such CDS tools may inform efforts to optimize use of these tools. Therefore, we aimed to describe primary care clinicians' experiences using CDS tools implemented in urban community health clinics to support sexual risk assessment and PrEP prescribing.

Methods

Study Design

We followed the Checklist for Reporting of Survey Studies (CROSS) guidelines to structure this report. We surveyed primary care clinicians from 12 community health clinics at John Peter Smith Health Network (JPS), a publicly funded urban health system that serves as the health care safety net for Tarrant County, Texas. JPS implemented an EHR-based CDS tool comprising a sexual history questionnaire, a PrEP SmartSet, and a noninterruptive advisory alert (Multimedia Appendix 1). When clinicians complete the sexual history questionnaire during an outpatient visit, a noninterruptive PrEP advisory alert is triggered if documented responses indicate behavioral or sexual risk factors consistent with US Centers for Disease Control and Prevention PrEP eligibility criteria.

Survey Administration and Data Collection

We conducted a cross-sectional survey using a 12-item questionnaire to assess clinician awareness, use, perceptions, and perceived barriers and facilitators to the implementation of the CDS tool. Eligible participants included attending physicians, residents, nurse practitioners, physician assistants, and clinical pharmacists providing primary care at one of 12 JPS community health clinics. Survey items were adapted from

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prior CDS research and informed by the Consolidated Framework for Implementation Research (Multimedia Appendix 2). The anonymous web-based questionnaire (Research Electronic Data Capture) was distributed by email from July 8 to 29, 2024, and included 11 closed-ended items in Likert-scale format and one open-ended question to identify perceived implementation barriers and facilitators (Multimedia Appendix 3). The survey included core questions on tool awareness or use for all respondents and used branching (conditional) logic that prompted questions about tool perceptions only to respondents who reported awareness.

Statistical Analysis

We summarized scores for closed-ended responses using medians and interquartile ranges (IQRs) and summarized frequencies of agreement with each item, where agreement reflects "agree" or "strongly agree" and disagreement reflects "disagree" or "strongly disagree." Neutral responses were included in the denominator of these frequencies but not separately reported for easier contrast of extremes. We analyzed open-ended responses using conventional content analysis supported by a large language model (GPT-4 by ChatGPT) to identify recurring themes (Multimedia Appendix 4).

Ethical Considerations

The North Texas Regional Institutional Review Board approved this study (number 2023 - 151). This study followed the ethical standards of the responsible committee on human experimentation and the World Medical Association Declaration of Helsinki. All participants provided informed consent before participation. The survey was accessible only after consent was obtained. We collected responses anonymously and did not link any personally identifiable information to the survey data, ensuring privacy and confidentiality. Clinicians who completed the survey were entered into a draw for one of eight US $50 Walmart e-gift cards as compensation.

Results

Our study population comprised 33 clinicians (12% of 284 eligible). Participant characteristics are summarized in Multimedia Appendix 5. Most respondents were physicians (MD/DO, n=20, 61%), followed by nurse practitioners (n=10, 30%). The majority were older than 30 years (n=29, 88%), identified as female (n=23, 70%), and were non-Hispanic White (n=19, 58%).

Fewer than half of respondents (n=15, 45%) were aware of the updated sexual history questionnaire. Table 1 summarizes awareness, use, and perceptions of the CDS tool among respondents who reported awareness of the tool. Most clinicians who reported awareness or use of the tool agreed that the questionnaire was important to implement (n=10, 67%), helpful for identifying PrEP candidates (n=9, 60%), and appropriate for primary care (n=9, 60%). In contrast, clinicians reported concerns about increased patient interaction time (n=9, 60%) and workflow fit (n=7, 47%). Most clinicians agreed that the PrEP advisory alert was appropriate for primary care (n=12, 78%) and supported guideline-concordant care (n=11, 73%), although fewer reported that the alert fit within clinical workflows (n=6, 40%).

Qualitative analysis of open-ended responses from 10 clinicians identified 5 themes: workflow disruption and time burden, alert fatigue, discomfort with the sexual history questionnaire, limited understanding of CDS functionality, and perceived usefulness for identifying at-risk patients. Table 2 summarizes illustrative quotes from these themes.

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Table . Awareness, use, and perceptions of the CDS[a] tool among clinicians who completed both awareness and use questions (N=15).[b]

	Median (IQR)	Agreement[c], n (%)	Disagreement[c], n (%)
Clinician attitudes and perceptions of the sexual history questionnaire			
I like this tool	3.0 (2.0 - 4.0)	5 (33)	5 (33)
Suitable for my patients	4.0 (2.5 - 4.0)	8 (53)	4 (27)
The tool is easy to use	3.0 (2.5 - 4.0)	7 (47)	4 (27)
Trust evidence quality and validity	4.0 (3.0 - 4.0)	9 (60)	2 (13)
Good option to identify sexual risk factors	3.0 (3.0 - 4.0)	7 (47)	2 (13)
Facilitates sexual history-taking	3.0 (2.0 - 4.0)	6 (40)	6 (40)
Meets needs to provide resources to patients	3.0 (2.5 - 4.0)	5 (33)	4 (27)
Important to implement	4.0 (3.0 - 4.0)	10 (67)	1 (6.7)
Appropriate for primary care	4.0 (3.0 - 4.0)	9 (60)	3 (20)
Fits within workflow	3.0 (2.0 - 4.0)	5 (33)	7 (47)
Does not increase patient time	2.0 (1.0 - 3.0)	3 (20)	9 (60)
Easy to access and incorporate in workflow	3.0 (2.0 - 4.0)	6 (40)	5 (33)
Valuable for primary care	4.0 (3.0 - 4.0)	10 (67)	3 (20)
Helps identify PrEP[d] candidates	4.0 (3.0 - 4.0)	9 (60)	3 (20)
Clinician attitudes and perceptions of the PrEP advisory alert			
I like this alert	3.0 (3.0 - 4.0)	7 (47)	1 (6.7)
Suitable for my patients	3.0 (3.0 - 4.0)	7 (47)	2 (13)
Useful and actionable	3.0 (3.0 - 4.0)	7 (47)	3 (20)
Trust evidence quality and validity	3.0 (3.0 - 4.0)	7 (47)	3 (20)
Good for guideline-concordant care for PrEP	4.0 (3.5 - 4.0)	11 (73)	0 (0)
Facilitates PrEP assessment	3.5 (3.0 - 4.0)	7 (50)	2 (14)
Easy to access and incorporate in workflow	3.0 (2.5 - 4.0)	6 (40)	4 (27)
Appropriate for primary care	4.0 (4.0 - 4.0)	12 (79)	0 (0)
Fits within existing workflow	3.0 (2.5 - 4.0)	6 (40)	4 (27)
Does not increase patient time	2.0 (2.0 - 3.0)	2 (13)	8 (53)
Adds value to practice	4.0 (3.0 - 4.0)	8 (53)	3 (20)
Valuable for primary care	4.0 (3.0 - 4.0)	9 (64)	1 (6.7)
Helps identify PrEP candidates	4.0 (3.0 - 4.0)	8 (53)	0 (0)

[a]CDS: clinical decision support.

[b]Clinician level of awareness and use frequency of the sexual history questionnaire: n=6, 40% aware, no use; n=9, 60% aware, used at least once.

[c]Agreement reflects “agree” or “strongly agree.” Disagreement reflects “disagree” or “strongly disagree.” Neutral responses were included in the denominator but not separately reported.

[d]PrEP: pre-exposure prophylaxis.

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Table . Themes and illustrative quotes from clinician responses to open-ended questions regarding the use of the clinical decision support tool (sexual history questionnaire and PrEP[a] advisory alert).

Theme	Illustrative quotes (participant ID)
Concern about time and workflow	• The questionnaire is long; typical workflow is that MA [medical assistant] does questions, but then I do not see this information flagged for review if risks identified, so not sure if MA filling out correctly. (#3) • It does take some time to complete the advanced sexual history and can be cumbersome if patient has other medical issues to discuss. (#10) • Lack of time, patients and I both feel uncomfortable. I don't even know how to find the questionnaire and was not aware I should be using it. (#11)
Time and reducing alert fatigue as a facilitator	• If it doesn't increase time during visits. There are already so many screenings we are doing. Many of the patients have multiple comorbid conditions that take time to address. The language and cultural barrier all add up to long visit times. (#14) • Time. Along with all of the mandatory screening tools. I feel we 'screen' our patients to death. (#2) • It might be easy to think that a BPA [Best Practice Alert] is helpful, and it may be, but we are subjected to easily 3 to 5 BPAs that each add minutes to our workflow for each patient we see. Please help us reduce time spent with a computer rather than add to it. (#15)
Patient and provider comfort and appropriateness as a barrier	• There needs to be some sensitivity in how the questions are asked for refugee patients. I mostly work with refugees who are low risk. (#14) • For the right patient history on initial screen this would be useful—not on every patient. (#6) • This is not for every patient (#9) • This can [be a] very intrusive questionnaire (#2)
Training	• I have no experience prescribing PrEP and have not seen others do it. I feel uncomfortable with PreP. (#11) • Training on tool...to understand how it is triggered. (#3)
Perceived utility of tool	• The tool works well...if a patient is identified as being at risk for HIV based on the brief sexual screening, I use this tool. (#10) • I think it is a good tool; however, our patients complete many required screening tools every time they come to the office... (#11) • Useful for specific patients. (#6)

[a]PrEP: pre-exposure prophylaxis.

Discussion

Our findings suggest suboptimal awareness of the CDS tool among primary care clinicians, and uptake was limited even among clinicians who reported awareness. Clinicians who used the tool generally endorsed the value of the sexual history questionnaire and PrEP advisory alert but reported concerns regarding usability and workflow integration, particularly increased time burden during patient visits. Open-ended responses revealed workflow disruption, alert fatigue, discomfort with the sexual history questionnaire, and limited understanding of tool functionality.

Our findings should be considered in the context of a key limitation. Despite a structured reminder strategy, financial incentives, and peer-led outreach, only 12% of eligible clinicians completed the survey, and thus our findings are likely sensitive to selection bias. Low response proportions are a persistent challenge when using provider surveys and may reflect competing clinical demands or survey fatigue [8]. We were unable to apply quantitative approaches to explore the effects of this selection bias [9] because we lacked data about clinicians who did not respond to the survey. Nevertheless, we likely overestimated CDS tool awareness among our primary care clinicians, and responses among tool users likely reflect the perspectives of a highly select group of early adopters, which could overestimate favorable impressions of the CDS tool compared with the overall eligible population.

Despite the key limitation, our findings align with prior studies of CDS implementation in primary care [10] that report low awareness and barriers related to workflow integration, time constraints, alert fatigue, and limited stakeholder engagement. Clinicians in our study endorsed the potential value of the CDS tool for identifying patients who may benefit from PrEP, but perceived workflow burdens may limit adoption. These findings reinforce the importance of aligning CDS tools with clinical

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workflows and eliciting postimplementation clinician feedback to improve the use of CDS tools.

Acknowledgments

The authors did not use generative artificial intelligence in the writing of this research letter. Open-ended survey responses were analyzed using conventional content analysis supported by a large language model (GPT-4) to identify recurring themes.

Funding

This study received no external funding.

Data Availability

The datasets generated and analyzed during this study are available from the corresponding author on reasonable request.

Authors' Contributions

Conceptualization: AMA
Methodology: RPO, AMA, CTT, WL, JA, NL, EF
Investigation: AMA, CTT, WL
Data curation: AMA, WL, CTT, JA
Formal analysis: AMA, WL
Writing – original draft: AMA
Writing – review & editing: RPO, AMA, CTT, WL, JA, NL, EF
Supervision: RPO, AMA
Project administration: AMA

Conflicts of Interest

EF reports serving on an advisory board for Merck. The other authors declare no conflicts of interest.

Multimedia Appendix 1
Description of the clinical decision support intervention and screenshots of the sexual history questionnaire, pre-exposure prophylaxis advisory alert, and PrEP SmartSet in Epic.
[DOCX File, 1352 KB - formative_v10i1e89638_app1.docx]

Multimedia Appendix 2
Survey measures mapped to implementation constructs by Weiner et al [11] and the Consolidated Framework for Implementation Research (CFIR).
[DOCX File, 19 KB - formative_v10i1e89638_app2.docx]

Multimedia Appendix 3
Description of the survey instrument assessing clinician perceptions and use of the pre-exposure prophylaxis clinical decision support tool.
[DOCX File, 28 KB - formative_v10i1e89638_app3.docx]

Multimedia Appendix 4
ChatGPT input prompts used to support qualitative analysis.
[DOCX File, 17 KB - formative_v10i1e89638_app4.docx]

Multimedia Appendix 5
Characteristics of primary care clinicians who responded to a survey on an electronic health record–based clinical decision support tool for pre-exposure prophylaxis, stratified by awareness of the intervention.
[DOCX File, 19 KB - formative_v10i1e89638_app5.docx]

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Abbreviations

CDS: clinical decision support
CROSS: Checklist for Reporting of Survey Studies
EHR: electronic health record
IQR: interquartile range
JPS: John Peter Smith Health Network
PrEP: pre-exposure prophylaxis

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Development of a Novel Mobile App on Emergency Management Among Patients With Acute Ischemic Stroke at County-Level Hospitals in China

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Abstract

This retrospective study of 428 patients with acute ischemic stroke at a county-level hospital in China found that implementing the Xheart novel mobile app significantly reduced the median door-to-needle time from 52 to 38 minutes (*P*<.001) and was associated with lower National Institutes of Health Stroke Scale scores 24 hours after thrombolysis (*P*=.02), indicating the potential of mobile health technologies to improve the emergency management of patients with acute ischemic stroke in resource-constrained settings.

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KEYWORDS

acute ischemic stroke; mobile app; emergency management; door to needle time; county-level hospitals

Introduction

Stroke has become a main cause of death and disability-adjusted life-year loss in China [1], and ischemic stroke accounts for more than 80% of all incident strokes [2]. Shorter door-to-needle times (DNT) are associated with better acute ischemic stroke (AIS) outcomes, but guideline-recommended DNT (<60 min) is rarely achieved in county-level hospitals due to limited resources and fragmented communication [3,4]. Mobile technologies have the potential to shorten DNT and improve the prognosis of patients with AIS [5,6], but reports from resource-constrained settings are limited. We aimed to explore the effects of a new mobile app on the emergency management of patients with AIS in county-level areas in China.

Methods

Participants

This retrospective study was conducted at Xichang People's Hospital between March 1, 2019, and December 31, 2024. The participants included 428 patients who consecutively presented to the emergency department with AIS within 6 hours of its onset. The exclusion criteria were as follows: (1) stroke happened in the hospital; (2) another stroke etiology such as cerebral hemorrhage or nonvascular causes; (3) patients without complete medical records.

Mobile App

Xheart is a novel medical mobile app that has been freely available to 35 county-level hospitals in Sichuan since August 2020. The app comprises three core components: real-time information collection technology, real-time sharing of information technology, and process quality control management technology.

Data Analysis

The data were analyzed using SPSS (version 26.0; IBM Corp). The Shapiro-Wilk test was used to check for normal distribution. Differences in continuous variables were analyzed using the Mann-Whitney *U* test, and differences in categorical variables were compared using the χ^2 test. Univariable and multivariate linear regression analysis were conducted to assess associations between the new mobile app and the emergency management of patients with AIS. For all analyses, 2-sided *P* values <.05 were considered statistically significant.

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Ethical Considerations

This study was approved by the ethics committee of the Xichang People's Hospital (ID: 2025 - 50). The requirement for informed consent was waived and approved by the ethics committee. No compensation was provided to participants and all data were pseudonymized.

Results

Characteristics and time metrics of participants are shown in Table 1. All recorded time intervals were significantly shorter in the post-app group (all *P*<.001). Particularly noteworthy were the median reductions in critical time intervals: DNT was reduced by 26.9% (38 vs 52 min, *P*<.001). Table 2 shows the associations between the mobile app and time metrics and outcomes. Multivariate linear regression showed that after adjustment for gender, age, National Institutes of Health Stroke Scale (NIHSS) score on admission, and onset to door time, the associations between the mobile app and shorter door to blood sample time (B=−4.02, 95% CI −5.03 to −3.00; *P*<.001), door to computed tomography results time (B=−3.55, 95% CI −5.10 to −2.01; *P*<.001), DNT (B=−15.34, 95% CI −19.7 to −10.98; *P*<.001), and lower NIHSS 24 hours after thrombolysis (B=−1.73, 95% CI −3.19 to −0.26; *P*=.02) remained statistically significant.

Table . Characteristics, time metrics, and clinical outcomes of participants.

Variable	Pre-app group (n=52)	Post-app group (n=376)	Z-score/chi-square[a]	*P* value
Male, n (%)	27 (52.0)	252 (67.0)	4.59	.03
Age (y), mean (range)	68 (61-77)	68 (58-76)	−0.50	.62
Onset to door time, mean (range)	99 (52-145)	166 (127-229)	−6.90	<.001
Door to neurologist time, mean (range)	5 (3-8)	3 (1-5)	−3.62	<.001
Door to blood sample time, mean (range)	10 (9-13)	6 (5-8)	−9.24	<.001
Door to CT[b] time, mean (range)	11 (10-14)	9 (8-12)	−4.13	<.001
Door to CT results time, mean (range)	19 (17-21)	14 (12-17)	−6.75	<.001
DNT[c], mean (range)	52 (42-58)	38 (31-46)	−5.88	<.001
NIHSS[d] score on admission, mean (range)	9 (4-15)	4 (2-10)	−4.51	<.001
NIHSS score after thrombolysis, mean (range)	7 (4-15)	3 (1-9)	−4.90	<.001
NIHSS score 24 h after thrombolysis, mean (range)	5 (3-13)	2 (1-7)	−4.05	<.001
NIHSS score improvement after thrombolysis, mean (range)	0 (0-1)	0 (0-1)	−0.17	.87
NIHSS score improvement 24 h after thrombolysis, mean (range)	1 (0-4)	0 (0-2)	−1.77	.08

[a]All values are *z*-scores except the "Male" row (chi-square test, *df*=1).

[b]CT: computed tomography.

[c]DNT: door-to-needle time.

[d]NIHSS: National Institutes of Health Stroke Scale.

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Table . Associations between the mobile app and time metrics and outcomes. Multivariate model, adjusted for male gender, age, NIHSS[a] score on admission, and onset to door time.

Variable	Univariate model		Multivariate model	
	B (95% CI)	*P* value	B (95% CI)	*P* value
Door to blood sample time	−4.33 (−5.27 to −3.38)	<.001	−4.02 (−5.03 to −3.00)	<.001
Door to neurologist time	−1.16 (−2.34 to 0.02)	.05	−0.96 (−2.24 to 0.31)	.14
Door to CT[b] time	−1.46 (−2.65 to −0.28)	.02	−1.21 (−2.48 to 0.06)	.06
Door to CT results time	−3.68 (−5.13 to −2.24)	<.001	−3.55 (−5.10 to −2.01)	<.001
DNT[c]	−13.99 (−18.04 to −9.94)	<.001	−15.34 (−19.7 to −10.98)	<.001
NIHSS score after thrombolysis	−4.14 (−5.99 to −2.30)	<.001	−0.51 (−1.33 to 0.31)	.22
NIHSS score 24 h after thrombolysis	−4.66 (−6.67 to −2.66)	<.001	−1.73 (−3.19 to −0.26)	.02

[a]NIHSS: National Institutes of Health Stroke Scale.

[b]CT: computed tomography.

[c]DNT: door-to-needle time.

Discussion

Principal Findings

Our study found that after the introduction of the Xheart mobile app, median DNT decreased significantly from 52 to 38 minutes. The mobile app could improve the emergency management of patients with AIS by RFID-based time tracking, real-time information sharing, and process monitoring. Previous studies have demonstrated the effectiveness of mobile technologies in the emergency management of patients with AIS [5-7]. Our study is unique in focusing on resource-limited county-level settings in China. Integrating mobile health technologies with predictive models [8-10] could further optimize real-time risk assessment and patient stratification, offering a practical strategy to improve emergency management for patients with AIS in underserved areas.

Limitations

Limitations include retrospective single-center design, small pre-app sample size, and unmeasured confounding factors such as concurrent improvements in doctors' experiences. Besides, the lack of 90-day modified Rankin Scale data limits the assessment of clinical relevance.

Conclusions

These findings contribute to the potential of mobile health technologies to address critical treatment delays in resource-constrained settings. This novel mobile app can serve as a paradigm for advancing intelligent medical products, thereby facilitating the expansion of analogous apps to enhance system integration efficiency.

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Data Availability

All data are available from the corresponding author on reasonable request.

Conflicts of Interest

None declared.

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Abbreviations

AIS: acute ischemic stroke
DNT: door-to-needle time
NIHSS: National Institutes of Health Stroke Scale

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Examining Experiences With Menstruation and Glycemic Variability: Content Analysis on Reddit

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Abstract

Reddit users discussing diabetes report glycemic variability during menstruation and often turn to technology and health care for support; yet persistent gaps in provider guidance and awareness highlight the critical need for integrated care and future research at the intersection of menstrual health and diabetes management.

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KEYWORDS

social media; diabetes management; Reddit; menstruation; health education

Introduction

Research has demonstrated that women with diabetes experience fluctuations in glycemic control during various phases of their menstrual cycle; however, existing studies produce conflicting evidence regarding which specific phase contributes most significantly to heightened insulin resistance, ultimately leading to a variability in glycemic control and worsened quality of life due to diabetes than in men [1-3]. Social media research provides valuable insights into health-related experiences and attitudes, particularly for sensitive topics, such as menstruation [4,5]. Platforms like Reddit support anonymity and reduce social desirability bias, often yielding richer in-depth data than traditional surveys [6,7]. Since the early 2000s, engagement in Diabetes Online Communities (DOC) has continued to enable individuals with diabetes to share experiences and engage in peer advocacy [8,9]. This study aims to delve into Reddit DOC users' experiences with managing diabetes in conjunction with their menstrual cycles, seeking to identify unique perspectives and challenges that may be overlooked in traditional survey methodologies by using five popular diabetes subreddits.

Methods

Overview

This study was conducted by scraping posts from the five most populous diabetes-related subreddits with approximately 13,000 to 143,000 members. We used the ExtractoR tool (ExtractoR version 3.0.8.tar.gz , R version 4.4.1) to gather data and subsequently used Microsoft Excel for data analysis. Table 1 shows the inclusion criteria, keywords, and screening process during exploration of posts associated with diabetes-related subreddits.

Table . Screening of Reddit posts based on the inclusion criteria and keywords related to menstruation.

Inclusion criteria	Keywords	Screening and final sample
• Posts from five most popular subreddits of Diabetes (r/diabetes (143,000 members), r/type2diabetes (13,000 members), r/diabetes_t2 (46,000 members), r/diabetes_t1 (68,000 members), and r/Type1Diabetes (43,000 members) • Posts included if they contain menstruation-related "keywords" • Exclusion of any comments or links attached in the comment section • All posts before Jan 1, 2025. • Data extraction timeframe: Feb 1 through Feb 20, 2025	"menstruation" "menses" "Period" "Ovulation" "bleeding" "hormone" "hormones" "PCOS" "week before" "mother nature" "aunt flow" "cycle"	

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An initial codebook was developed by reviewing 20% of posts to provide a structured framework relevant to the study's aims. Codes were refined iteratively through team discussion with a distinct definition and organized into themes and subthemes. Two coders then independently applied the finalized codebook to the full dataset. Interrater reliability was assessed using Cohen's κ. Cohen's κ is a statistical measure of interrater reliability commonly used in content analysis and qualitative studies to assess the agreement between two raters on categorical data [10]. Cohen's κ value greater than 0.70 indicates acceptable reliability [10]. κ values are reported for each theme and subtheme in Table 2. Any κ values falling below the threshold of 0.70 were discussed and resolved with the assistance of a third coder, ensuring the accuracy of the coding process and strong interrater reliability.

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Table . Qualitative themes and example posts associated with diabetes management and menstruation from Reddit.

Code name	Definition	Number of posts	Example posts	Cohen's κ
Menstruation	Narratives regarding menstrual cycle, including symptoms, social and emotional experiences	27	1.1.“ *My periods are usually regular, but after my second [Trulicity] shot, my period came about a week early.*” 1.2. *“I'm on Mounjaro and Metformin, for both it's the second week and my period is late.*	0.72
1a. Emotional effects	Self-report or other's acknowledgment of emotional, psychological, or mental changes that happen during different phases of the menstrual cycle, including anger, sadness, irritability, relief of getting period, told by partner they are acting different, etc	9	1a.1. *“I feel so depressed everyday. I can't sleep, I have anxiety, and my self esteem is extremely low. At times I feel like I hate myself and I feel like I will never be the same after my diabetes diagnosis. ”* 1a.2. *“does anyone else experience PMS[a] even without a period? . I definitely experience PMS (slight bloating, much more sensitive to noises, and I'm much more irritable).*”	1.00
1b. Physical effects	Self-report of bodily sensations that happen during or around the time of menstruation. May include headache, cramps, change in appetite, nausea, breast tenderness etc Includes being tired, migraines, not being able to attend work/school, nausea, vomiting, unable to eat, eating disorders	14	1b.1.“ *Since starting insulin treatment, I've gained a considerable amount of weight., My period is now irregular every month and I have hot flashes and my acne has flared up.*” 1b.2.“*And my period is incredibly painful with really, really heavy flow.* *I feel weak overall, it was moderate/normal before.*”	0.87
1c. Irregular periods	Self-report of abnormal symptoms of period, such as longer period days, multiple periods in one month, longer menstrual cycle, abnormal spotting, heavy flow, no flow, too frequent or infrequent periods	12	1c.1.“*My periods starting becoming less frequent last year, and finally stopped altogether.*” 1c.2.“ *since starting insulin treatment,my period is now irregular every month and sometimes I don't get it at all.*” 1c.3.“*I originally found out I have diabetes because I hadn't gotten my period for almost three months,...*”	0.80
1d. Other hormonal comorbidities	Mentions being told by a health professional they have other medical conditions that coexist with menstruation and diabetes and impact hormonal health. Includes PCOS[b], Hashimoto's, thyroid disorders, but not cold, flu, stress, obesity	3	1d.1.“*I was diagnosed with Type 1 almost 30 years ago and with PCOS recently ,*	0.79

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Code name	Definition	Number of posts	Example posts	Cohen's κ
Management	Any mentions of strategies, routines, tools or behavior used to monitor, control, or adapt to the effects of menstruation on diabetes. Includes posts that mentions Hba_{1c} values, diet exercise, medications controlling glucose, trial and error, lived experiences. Does not include just symptoms and challenges without references to how they respond or manage them.	21	2.1."*Being 270+ for days now, been drinking honey to get better so it messes up with my glucose, too tired to go for walks.*" 2.2."*I only had a small smoothie this morning and no lunch. Dinner comes around (literally only a few things), and I take an extra 2 units [of insulin] than I would normally, and I'm STILL spiking"*	0.80
2a. Technology	Digital tools, apps, or platforms used to support the management of diabetes. Includes mentions of Insulin pumps (Tandum, Omnipod, Minimed, Medtronic 670G, 660G, 770G, 780G) Continuous Glucose Monitors (CGM, Dexcom, Libre, Freestyle Libre, Libre 6, Guardian, sensor), closed loop systems (usually with a Tandum and Omnipod (O5)), Automated Insulin Delivery Systems (AIDs) other key words include cannula, port, site, infusion set, wires, pump, charts showing glucose numbers, AI pancreas, telehealth, phone apps, frustrations with technology, social media support groups, smart insulin pens.	5	2a.1."*I have a CGM and recently got a pump which has made a huge difference, but I still struggle to manage my glucose levels.*" 2a.2."*[The user's daughter] is on the O5 (Omnipod 5) and we've already lowered her carb ratios, but, still, she goes low. "*	1.00

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Code name	Definition	Number of posts	Example posts	Cohen's κ
2b. Medical team	References to health care professionals or clinical teams, such as doctors, nurses, PC[c], DNP[d], who are involved in the management of diabetes and/or menstruation. This includes both negative and positive experiences or perceptions of while communicating with providers.	11	2b.1. *"My doctor just sent in the prescription. This was after monitoring sugars and trying to lose weight in order to conceive. "* 2b.2. *"Doc told me how proud he was of me for turning it around so fast in such a short time. "* 2b.3. *"Diagnosed type 2 diabetic and my doctor increased me from 1 pill of Metformin ER 750mg to 2 pills due to my A1C going up "* 2b.4.*"I did visit an endocrinologist once for my irregular periods, but they wanted to put me on birth control, which I wasnt comfortable with."* 2b.5.*" My previous OBGYN and pharmacist scared me out of the contraceptiove shot last year and were trying to push the Mirena IUD on me which I am not comfortable with. "*	1.00

[a]PMS: Pre-menstrual Syndrome.

[b]PCOS: Polycystic Ovary Syndrome.

[c]PC: Primary Care.

[d]DNP: Doctor of Nursing Practice.

Ethical Considerations

The University of Arkansas Institutional Review Board classified this study as nonhuman subjects research and exempt from review for involving secondary analysis of existing public data. No identifiable information, such as usernames, timestamps, or links, of participants in public subreddit groups was analyzed. Users' identities were further protected by shortening, masking highly identifiable details, and paraphrasing by substantial alteration of wording and structure of posts to minimize risks of reidentification. Data were stored on secure, access-restricted university servers. This study was supported by the University of Arkansas Honors College.

Results

Table 1 presents predefined keyword-based inclusion criteria that identified 35 unique posts regarding glycemic control and menstruation.

Theme 1: Menstruation

Among these 35 posts, 27 posts shared characteristics of the users' menstrual cycles and any alterations they noticed in their menstruation due to diabetes. Many users reported changes in their menstrual cycles following their diabetes diagnosis. Some experienced regular cycles for the first time, while others noted alterations in the frequency or characteristics of their periods, such as changes in flow and cycle length, as shown in example posts in Table 2. Four distinct subthemes emerged: emotional effects, physical effects, irregular periods, and other hormonal comorbidities, all showing strong interrater reliability.

Theme 2: Management Strategies

A total of 21 posts discussed management strategies, various routines, behaviors, and tools designed to mitigate the impact of menstruation on diabetes control. Many users reported engaging in physical activity or administering insulin when experiencing elevated blood sugar levels and adjusting their dietary habits according to their menstrual cycle phases. Table 2 shows two key subthemes: Technology and Medical Team, with strong interrater reliability.

Discussion

Most Reddit users discussed menstruation and diabetes management strategies, particularly blood glucose monitoring and control across menstrual cycle phases. Many described experiencing a range of physical and emotional symptoms while undergoing irregular, prolonged, or frequent periods. Although they did not specify the most challenging phase of the menstrual cycle for glucose control, they noted persistent elevation in blood glucose during a certain phase that affected their physical health (eg, bloating) and mental well-being (eg, irritability). These reports of emotional distress are consistent with prior

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research demonstrating that cyclical hormonal fluctuations can increase insulin resistance and glycemic variability, creating periods of unpredictability that place significant cognitive and emotional burdens on individuals managing diabetes [1-3].

Most users reported challenges of diabetes management during menstrual hormonal changes, along with the co-occurrence of other hormonal disorders, such as polycystic ovarian syndrome and thyroid disease. Furthermore, users shared diverse management strategies to address their diabetes, ranging from leveraging technology to seeking support from medical professionals. Some users' posts referenced consultations with medical professionals regarding diabetes and menstruation-related issues, but did not provide further details on the perceived benefits of these interactions. However, some users report insufficient guidance from health care providers on managing the intersection of diabetes and menstrual abnormalities, contributing to mental stress and reinforcing prior evidence that gaps in clinical guidance led to trial-and-error in diabetes management.

This study is one of a limited body of work that examines Reddit posts at the intersection of people's menstrual and diabetes management experiences, and some limitations are to be noted. Anonymous posts from Reddit users discussing menstruation and diabetes limit our ability to explore the gender identity and reproductive stages of the users, thereby restricting the generalizability of the results. Additionally, this study offers a snapshot of posts, eliminating the comments associated with them that were publicly available at the time of the analysis.

Our findings reveal a complex relationship between menstruation and diabetes management discussed by Reddit users, highlighting challenges in managing the intersecting hormonal conditions, which may imply a greater need for menstruation-informed care. Future studies should delve deeper into people's personal experiences relating to diabetes and menstruation, and how they can be supported with comprehensive health education to manage their health challenges associated with menstruation and diabetes management.

Acknowledgments

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The authors declare the use of generative AI in the research and writing process. According to the GAIDeT taxonomy (2025), the following tasks were delegated to GAI tools under full human supervision:

- Proofreading and editing

- Summarizing text to decide if they needed to be further investigated

- Adapting and adjusting emotional tone

The GAI tool used was ChatGPT version 5.

Responsibility for the final manuscript lies entirely with the authors.

GAI tools are not listed as authors and do not bear responsibility for the outcomes.

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Data Availability

The data used in this study were collected from publicly available Reddit posts using ExtractoR. Researchers can replicate the data by using the mentioned filter words.

Authors' Contributions

Conceptualization: KL, SB
Formal analysis: BN, HP, SB
Funding acquisition: KL, SB
Investigation: BN, HP
Methodology: BN, HP, SB
Supervision: KL
Writing - original draft: KL
Writing - review and editing: SB

Conflicts of Interest

None declared.

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Abbreviations

DOC: Diabetes Online Communities
PCOS: polycystic ovarian syndrome

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Engagement Patterns With #NaturalRemedies on TikTok: Formative Analysis

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Abstract

This research letter provides formative evidence from a cross-sectional analysis of 118 TikTok videos under #NaturalRemedies, identifying content formats and expertise cues associated with higher engagement, while also demonstrating the feasibility of using engagement metrics and thematic coding to analyze health narratives on emerging platforms such as TikTok.

(JMIR Form Res 2026;10:e83274) doi:10.2196/83274

KEYWORDS

natural remedies; TikTok; public health; alternative and integrative medicine; wellness industry; social media; influencers; health education; medical misinformation; patient trust; chronic illness; symptom management; self-care

Introduction

Social media platforms like TikTok are increasingly popular sources for public-health information and can shape health perceptions, decisions, and behaviors, especially via influencer-led health messaging [1]. TikTok's short-form, hyper-specific algorithmic design accelerates the dissemination of wellness content, raising concerns about creator credibility and misinformation [2,3]. Health content on TikTok and related platforms shows patterns in education-oriented videos and influencer and audience dynamics and often lacks evidence citation [4-6]. Mental health and COVID-19–related content on TikTok varies in credibility, health messaging strategies, and user engagement patterns [7-9]. Our formative analysis identified themes linked to engagement, informing future digital public-health interventions in #NaturalRemedies videos. Such videos represent a distinct subset of wellness content characterized by home-based practices, herbal or dietary interventions, and limited regulatory oversight, raising concerns about evidence quality, credibility, and potential misinformation [3,5,8]. A formative analysis can explore engagement patterns early on, with descriptive studies offering the opportunity to generate hypotheses and inform future digital health communication strategies.

Methods

Overview

On February 21, 2025, we captured the 120 most widely viewed content videos under the hashtag #NaturalRemedies after sorting by view count. Videos that were not in English (and missing subtitles), missing audio, duplicates, or misclassified were excluded, leaving 118. Sampling was conducted on one day to capture a consistent cross-section of #NaturalRemedies content. The specific date was selected based on the availability of the data collector. The sample size was consistent with prior TikTok content analyses [4,6] reporting that 120 videos was feasible for analysis; this aligns with typical TikTok content-analysis studies that examine the 100 to 200 top-ranked posts [4-7]. For each video, we extracted likes, comments, shares, and saves, coded sentiment (positive, neutral, negative), formats (tutorial, narrative), creator expertise (credentialed expert, scientist or medical professional, influencer), and themes (educational content, DIY, gut and skin health). These codes were drawn from prior content-analysis literature [5]; the full codebook is provided in Multimedia Appendix 1. A 10% subsample was double-coded (κ=1) for all variables. No discrepancies were reported.

Descriptive statistics summarized engagement, Mann-Whitney *U* tests compared theme-present versus theme-absent groups,

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and Spearman correlations explored associations. Analyses were conducted in R (version 2024.12.0+467; R Foundation for Statistical Computing). Because engagement data were nonnormally distributed (Shapiro-Wilk $P<.05$), nonparametric tests were used with a 2-tailed $\alpha=.05$. These methods align with prior social media health content analyses [4,6,10].

Ethical Considerations

Institutional review board approval was deemed unnecessary as the study did not involve human subjects.

Results

Descriptive statistics are summarized in Table S1 in Multimedia Appendix 1; inferential comparisons appear in Table S2 in Multimedia Appendix 1. Positive sentiment predominated (98/118) and corresponded with higher medians for likes and saves. Tutorials were associated with greater sharing and saving (shares: median 8310, IQR 3692-18,200 vs 5661, IQR 1981-10,100; $U=1194.5$; $P=.04$; saves: median 15,600, IQR 7795-30,900 vs 11,700, IQR 3578-21,500; $U=1204.5$; $P=.04$). Videos without DIY content received more likes (median 51,150, IQR 36,975-73,150 vs 35,150, IQR 18,775-64,87; $U=1070.5$; $P=.046$) and comments (median 973.5, IQR 429.5-1557 vs 469.5, IQR 157.25-907.5; $U=1152.5$; $P=.008$) than DIY videos.

Credentialed-expert videos ($\Sigma_n=118$; n=2) achieved the highest engagement (likes: median 120,200, IQR 100,050-140,350; $U=15.5$; $P=.04$), compared to the median like count of 39,000 (IQR 21,075-65,025) for nonexpert-created videos. Despite content categorized under "credentialed experts" representing approximately 1.69% ($\Sigma_n=118$; n=2) of the sample, 93.2% ($\Sigma_n=118$; n=110) of videos were coded as "educational content," and videos were marked as "not present" for "myth busting."

"Connection with nature" produced more comments when present (median 1321, IQR 744-1521 vs 477, IQR 184-909; $U=239.5$; $P=.01$). "Gut health" content showed higher shares when present (median 12,200, IQR 6211.5-20,750 vs 6106.5, IQR 391.75-13,950; $U=1076.5$; $P=.02$) and trended toward more comments and saves ($P=.07$ and $P=.06$), although this was not significant. Educational content approached significance for likes ($P=.10$). Personal-experience narratives differed in shares ($P=.03$), with lower medians when present in this sample. Furthermore, median like count for videos with the intent to sell a product was almost equivalent to those without such intent (respectively, 39,800, IQR 28,100-51,300 vs 39,900, IQR 20,850-66,750), despite the uneven distribution of videos with and without commercial intent ($\Sigma_n=118$; n=11 vs n=107).

Discussion

This formative analysis showed that engagement with natural-remedy content was shaped by sentiment, format, and expertise cues. Tutorials use a practical, action-oriented format, which was consistently associated with higher shares and saves, while DIY content underperformed. Rare appearances of credentialed experts corresponded with notably higher engagement, suggesting meaningful audience responsiveness to professional authority. Given that influencers and wellness enthusiasts produced almost all videos, health professionals thus have an important opportunity to increase their visibility in natural-remedy discussions on TikTok. Because natural remedies are often informal, experiential, and weakly regulated, understanding engagement patterns is especially relevant for assessing how health claims circulate on social media.

Our findings complement prior reports on influencer dynamics, education-oriented health videos and their credibility, and platform-specific engagement patterns [4,6,8,9]. Recent TikTok research has shown that users are highly responsive to content that is framed in an educational, structured, or professionally anchored manner, including studies of mental-health messaging and COVID-19 communications [7,8]. These results extend prior work by showing that similar engagement patterns apply to natural-remedy content, an area still under-studied despite its rapid growth. Elevated engagement with gut health and nature-linked themes reflects broader wellness trends across TikTok. The lack of myth-busting content, amid abundant educational videos, highlights persistent gaps in corrective, evidence-based messaging, mirroring earlier findings on wellness influencers, where evidence of citation and scientific grounding is often limited [1,3].

Tutorials requiring minimal user effort outperformed DIY formats, suggesting usability drives engagement. Expert-led or medically aligned videos also performed strongly, indicating viewer preference for legitimacy cues, mirroring findings from EduTok, naturopathic influencer behavior, and TikTok nutrition studies, which likewise emphasize credibility, structure, and clear visual demonstration [4,6,9].

Study limitations include the cross-sectional design, single-hashtag sampling, and absence of demographic data. Results from one day's algorithmic rankings may shift with platform trends and changing exposure patterns. View-count sorting may favor algorithmically boosted videos, though it captures the content most visible to users.

Overall, these results illustrate the feasibility of using social-media analytics to guide digital public-health communication and intervention design [10] and underscore the value of formative work in identifying emerging communication patterns. Given strong engagement with tutorials, expert-led messages, and wellness themes such as gut health, public-health practitioners may consider leveraging TikTok to disseminate evidence-based guidance. Future research should test messaging strategies, explore content accuracy, and examine how platform algorithms shape exposure to expert versus nonexpert information.

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Data Availability

The data supporting this study consist of publicly available TikTok videos under the hashtag #NaturalRemedies and are available on request.

Authors' Contributions

AM conceived and led the research project and drafted the manuscript. CHB provided research guidance and contributed to writing and critical revisions. KR-G conducted statistical analyses. CC and AG were responsible for data collection. VJ II wrote the methodology section. All authors reviewed and approved the final manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1
TikTok video differences in the median numbers of likes, comments, shares, and saves by theme, with descriptive statistics.
[XLSX File, 26 KB - formative_v10i1e83274_app1.xlsx]

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Social Media Listening in Congenital Ichthyosis: Quantitative and Qualitative Findings

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Abstract

This study analyzed social media posts from patients with congenital ichthyosis and their caregivers across Europe and found that users, primarily young women, discussed hygiene care, psychological impact, therapeutic challenges, and lack of disease awareness. This allowed for the identification of unmet needs and potential actions to improve patients' quality of life.

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KEYWORDS

social media; congenital ichthyosis; quality of life; unmet needs

Introduction

Congenital ichthyoses (CI), recently classified within the group of epidermal differentiation disorders, are chronic skin conditions characterized by anomalies such as scaling or skin thickening, often associated with erythroderma [1]. Quality of life is often impaired because of distressing symptoms, limited treatment efficacy, demanding skin care routines, social stigmatization, and a lack of awareness or education among both health care professionals and the general public [2,3]. Consequently, patients often turn to the internet to find answers, connect with other patients, seek support, and access information. In this study, we analyzed the role of the internet in the lives of patients with CI to better understand their experiences and needs, with the goal of improving patient care and management.

Methods

Study Design and Population

This observational, retrospective, real-world study used data collected from social media posts by patients with CI and their caregivers. The messages, written in the local languages, were geolocated in four European countries: France, Germany, the Netherlands, and Spain. This study covered the period from January 2014 through January 2024.

Data Extraction and Analysis

Data extraction and analysis methods are detailed in Multimedia Appendix 1. Briefly, data extraction was performed using the digital consumer intelligence platform Brandwatch to collect publicly available posts from public platforms and health-related forums (listed in Multimedia Appendix 2) using a list of CI-related keywords defined by the investigators (listed in Multimedia Appendix 3). Posts were cleaned by removing duplicates, irrelevant sources, nontarget languages, and messages that were too short or excessively long. A supervised machine-learning pipeline based on 2 sequential XGBoost classifiers was then applied to identify patient and caregiver experiences. Data analysis included manual extraction of demographic information when explicitly mentioned and identification of the main discussion themes using unsupervised topic modeling (biterm topic modeling), followed by human interpretation.

Ethical Considerations

This study used data exclusively from publicly accessible sources, thereby excluding private groups and web pages. Ethical approval was not required, as users implicitly consented to the reuse of their data by posting on public platforms, and

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all the results were presented without identifiable information. Sensitive details, including names, usernames or handles, geographic locations, and other personal data, were deleted. To ensure compliance with the General Data Protection Regulation, the names of treatments were anonymized and replaced with a generic [TREATMENT] placeholder in the messages.

Results

A total of 5175 messages were initially collected. After removing off-topic posts, 4302 messages from 2182 unique users remained. Following the application of the patient and caregiver classification algorithm, 201 messages from 169 users were identified. Of these users, 90 were patients and 79 were caregivers.

The characteristics of the users and their posts are reported in Table 1. Of the 169 users, 110 (65%) were women, with a mean age of 36 years (SD 6.1; range 21 - 57). Among the 43 identified social media networks (Multimedia Appendix 2), the most frequently used platforms were Twitter (31.3%, 63/201), Doctissimo (18.4%, 25/201), and Facebook (7.5%, 15/201). The 5 main discussion topics, in decreasing order of frequency, were hygiene care (31%, 63/201), psychological impact of the disease (18%, 37/201), disease characteristics (17%, 35/201), contact tracing (13%, 27/201), and treatments or lack of awareness of the disease (10%, 20/201). Content and examples of posts for each topic are provided in Table 2.

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Table . Characteristics of the users (N=169) and posts (N=201).

Characteristics	Values
Demographic data of the users, n (%)	
Users	
Patients	90 (53.3)
Caregivers	79 (46.7)
Gender	
Female	110 (65.1)
Male	27 (16)
Not mentioned	32 (18.9)
Age (y)	
18-19	0 (0)
20-29	27 (16)
30-39	105 (62.1)
40-49	30 (17.8)
50-59	3 (1.8)
60 and older	0 (0)
Not mentioned	4 (2.4)
Mean age (SD); range (y)	36 (6.1); 21 - 57
Characteristics of the posts, n (%)	
Topics of discussion	
Hygiene care	63 (31.3)
Psychological impact	37 (18.4)
Characteristics of the disease	35 (17.4)
Request for contact and discussions with ichthyosis patients or families	27 (13.4)
Information on available treatments and feedback	20 (10.0)
Other[a]	19 (9.5)
Social media platforms	
Twitter	63 (31.3)
Doctissimo	25 (12.4)
Facebook	15 (7.5)
Other[b]	98 (48.8)
Countries	
Germany	76 (37.8)
France	58 (28.9)
Spain	54 (26.9)
The Netherlands	13 (6.5)

[a]Includes doubts about the diagnosis and questions from parents about their child's case.

[b]The complete list of social media platforms analyzed is presented in Multimedia Appendix 2.

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Table . Description of the 5 main discussion topics and examples of posts

Topics of discussion	Examples of posts
Hygiene care	
• Description of their skin conditions and the type of ichthyosis they have. • Which skincare products (creams, lotions, soaps) improve their skin. • Their routines based on personal experience or dermatologist recommendations. • Experience with different products. • Seasonal influence.	• *I may have a solution that can work..., it depends on the type of ichthyosis you have. There's a cream that could help you,....* • *Our son suffers from ichthyosis. In winter, the skin is in really bad shape, but in summer we have it under control.*
Psychological impact	
• People's perception was a major concern of patients. • Patients felt burdened by how others looked at them outside their family circle. • Patients often had to explain their visibly different skin; this was especially difficult for adolescents and young adults, who struggled with feeling "different." • Caregivers, particularly parents, were also affected by others' reactions and questions. In some cases, these encounters felt like harassment and created a strong sense of injustice.	• *I've heard advice and comments all my life about my ichthyosis and I'm just sick of it.* • *Have you ever been reported to social services for lack of knowledge of this disease, on the pretext that your children are dirty? In my case, I have 2 children with ichthyosis and I feel harassed and tired of fighting against a steel wall...*
Characteristics of the disease	
• Physical burden was a key theme across many posts. • Patients and caregivers described skin lesion location, appearance, and symptoms, and functional issues such as the inability to perspire or difficulty regulating body temperature. • In some cases, skin lesions were highly visible and disruptive to daily life. • Caregivers often expressed a sense of helplessness in managing these symptoms.	• *My skin is dying with the cold + humidity and I'm in agony. Damn Ichthyosis.* • *I was scratching and bleeding because the itching was so much worse than anything else.*
Contact tracing	
• Need for connection and information. • Seeking advice from others due to unpreparedness of dealing with child's condition. • Dissatisfaction with medical advice led them to prefer peer feedback. • Created blogs to share experiences, bridge the information gap, and simply be heard. • Seeking emotional support from persons who understand and do not judge.	• *Hello, after much research we have been diagnosed with ichthyosis in our three-month-old adopted baby. Now, there are a lot of questions in the room, does anyone have any experience in this area?* • *I am the mother of a little boy who is 10 1/2 months old. He has Netherton syndrome and was hospitalized until 8 1/2 months....I would like to hear from parents who know about this disease and who can tell me about their daily lives..., parents who could give me advice, etc....to help my baby. Thank you to everyone.*
Treatments and lack of awareness of the disease	
• Through their experiences—both positive and negative—patients and caregivers shared opinions and reported on various treatments they have tried or been offered. • Many highlighted the general lack of awareness about the disease among those around them. • This lack of understanding was reported as a challenge in daily life, including interactions with family, friends, schools, and nurseries. • The main issue, from the patient and caregiver perspective, is the limited recognition of the condition by some health care professionals, which can strain the relationships between patients, caregivers, and doctors.	• *Hello my child has been suffering from second degree ichthyosis since birth and the only thing that is always suggested is cortisone....side effects are severe and unacceptable...but there is virtually no alternative for my child.* • *When my son went to nursery, one of the nursery nurses thought he had spots and tried to rub his legs. When she told me, I explained to her that it was ichthyosis and she had never heard of it.*

Discussion

This first European study on social media posts from users with CI and their caregivers found that users, predominantly young women on Twitter, primarily discussed hygiene care, therapeutic issues, psychological impact, and low disease awareness among the public and health care professionals.

Regarding the study population, we observed a predominance of young female users, consistent with the general tendency for women to seek health information online [4], and with the findings of Voillot et al [5] in atopic dermatitis (AD), suggesting both general and disease-specific trends.

Hygiene care and therapeutic issues were also key discussion topics for patients with AD, along with peer support [5]. In

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contrast, lack of disease awareness was specific to CI, a rare condition, and, together with the psychological impact, had already been highlighted in our 2012 focus group study [2]. Topics such as romantic relationships and sexual health, reported by van Veen [3] and a shared patient voices report [6], were absent in our study, either because patients did not raise them or because they were removed as sensitive information.

Inadequate management, linked to gaps in health care professionals' knowledge or interest and limited effective therapies, was expressed more strongly online, possibly due to the anonymity of social media. Unlike the 2012 qualitative study [2], no positive aspects of living with CI were reported, suggesting that social media mainly serves as a space to voice challenges rather than share positive experiences.

This study has several limitations, including the small number of posts due to the rarity of the disease, the exclusion of data from private groups and Instagram (Multimedia Appendix 1), and the possibility that it did not capture the needs and experiences of all patients, as those uncomfortable with the internet may not have participated.

In conclusion, this study highlights the needs of patients with CI that may guide improved management. Providing information, particularly through online tools developed in collaboration with patient associations, rare disease networks [7], or digital education programs such as our e-TPE (digital therapeutic patient education) is essential [8]. Public education also remains important and could be promoted through national society campaigns. The growing use of artificial intelligence, as recently explored in AD, is likely to transform how patients seek information [8-10]. Psychological support should be routinely offered to patients and caregivers, and research should continue to focus on developing new therapies. Collectively, these measures can help enhance patients' quality of life.

Funding

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Data Availability

All data generated or analyzed during this study are included in this published article and its supplementary information files.

Authors' Contributions

Conceptualization: JM-H (lead), KS (equal), AG (equal), ÁH-M (equal)
Formal analysis – JM
Funding acquisition: JM-H
Resources: JM
Supervision: JM-H
Validation: ÁH-M
Visualization: MS-F
Writing – original draft: JM-H (lead), CGT (equal)
Writing – review & editing: CGT (equal), JM-H (equal), MS-F (supporting), JM (supporting), KS (supporting), AG (supporting), ÁH-M (supporting)

Conflicts of Interest

MSF has been an investigator for Abbvie, AstraZeneca, COREvitas, Incyte, LEO Pharma, Novartis, and Sanofi Regeneron, and an expert for Abbvie, Almirall, BMS, Incyte, Krystal and Sanofi Regeneron. JM took part in drafting some parts of the manuscript/editing and is employed by Kap Code. KS received a research funding award from Berliner Dermatologische Gesellschaft (BDG), has been part of the Clinician Scientist Program from the Deutsche Dermatologische Gesellschaft (BDG) und Arbeitsgemeinschaft Dermatologische Forschung (ADF), has been a medical advisor for Nia Health GmbH and Thieme Referenz Dermatologie, has been part of the Dermatologisches Konsil from RG Ärztefortbildung, and received a support from ERN-skin for a guideline meeting. AHM has been a consultant for Sanofi, ViatriS, L'Oréal, LETI Pharma GmbH, Beiersdorf, and Alexion Pharma, and participated on a Data Safety Monitoring Board and Advisory Board for Sanofi, ViatriS, L'Oréal, and Galderma. JMH has been an investigator for Abbvie, Amryt Research Limited, Amgen, AstraZeneca, Celgène, COREvitas, Incyte, InMed Pharmaceuticals Inc, LEO Pharma, Lilly, Mayne, Novartis, Pierre Fabre, Pfizer, RHEACELL GmbH & Co KG, Sanofi, Scioderm Inc, Timber Pharmaceuticals, and Urgo, and an expert for Abbvie, Almirall, Incyte, Krystal, Pfizer, and Sanofi. The other authors have no conflict of interest to declare.

Multimedia Appendix 1
Supplementary methods.
[DOCX File, 19 KB - formative_v10i1e79761_app1.docx]

Multimedia Appendix 2
Social media used in the different countries.

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[DOCX File, 14 KB - formative_v10i1e79761_app2.docx]

Multimedia Appendix 3
Query used for extraction on Brandwatch.
[DOCX File, 14 KB - formative_v10i1e79761_app3.docx]

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Abbreviations

AD: atopic dermatitis
CI: congenital ichthyosis

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AI-Assisted Systematic Review: Humans Still Need to Review All Abstracts for Inclusion

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Abstract

Although a general purpose (GPT-5), and a fine-tuned (ASReviewLab) artificial intelligence were able to rank abstracts for likely inclusion in a variety of Cochrane systematic reviews, some actually included studies were not highly ranked, necessitating human review of all abstracts.

(JMIR Form Res 2026;10:e82896) doi:10.2196/82896

KEYWORDS

title and abstract screening; artificial intelligence; AI; large language model; LLM; machine learning; ChatGPT; GPT-5; ASReviewLab; systematic review

Introduction

Although systematic reviews (SRs) are the gold standard of evidence synthesis, they are time consuming, requiring evaluation of thousands of abstracts [1]. Artificial intelligence (AI) has the potential to identify and rank relevant studies for inclusion [2,3] but do they reliably rank all eligible abstracts high enough that only a subset of high-ranked abstracts require human review? We evaluated where studies actually included in published SRs fell within the "most likely for inclusion" rankings of a general-purpose AI (GPT-5), and an AI fine-tuned to identify SR-eligible studies (ASReviewLab)—assessing AI ranking reliability under worst-case constraints.

Methods

Overview

The most recently published 25 Cochrane SRs with ≥5 included studies were identified (as of May 5, 2025, from all subject areas), and their reported search strategies were replicated using the same databases, algorithms, and date ranges reported in each SR. We did not carry out gray literature searches, nor search databases with undefined algorithms, and limited abstracts to English. Deduplication and data export were completed using Covidence for each SR individually. Studies included in the published reviews were separated into "main results" publications and "supplementary studies" (eg, protocols, interim findings, subgroup analyses). Each publication record was separately ranked. We preidentified the AI tool as having "high-utility" if all eligible studies were placed/presented in the top 500, or top 15%, of AI-ranked abstracts (anticipated to shorten human review time by 85%).

For GPT-5 Thinking (version August 7, 2025), an AI prompt was iteratively developed to rank abstracts in order of likely inclusion. The prompt included 1) assessing whether the abstract reported on a randomized trial, 2) each SR's PICO (Patient/Population, Intervention, Comparison, and Outcome) criteria (setting, population, intervention, comparator, outcomes), and 3) an example of an included study (ie, the main results abstract for the trial with largest enrollment). An example of the final (best performing) prompt, used for all rankings, is provided in Multimedia Appendix 1.

For ASReviewLab (version 2.1.1), due to platform differences, PICO criteria could not be provided. Rather, per this AI's normal procedure of continually learning from human feedback, we provided it three included abstracts (those with highest enrollment), and subsequently labeled studies as included, or excluded, in the order ASReviewLab presented them. Given this interaction was time-consuming, we limited evaluation of ASReviewLab to the 10 most recent Cochrane SRs, and evaluated a maximum 500 studies for inclusion per SR.

Ethical Considerations

All studies were identified from previously published and publicly available SRs. Therefore, no research ethics approval was required. Ethical AI use was upheld through reporting of prompts and processes for replicability, and all AI outputs were evaluated by human reviewers for accuracy.

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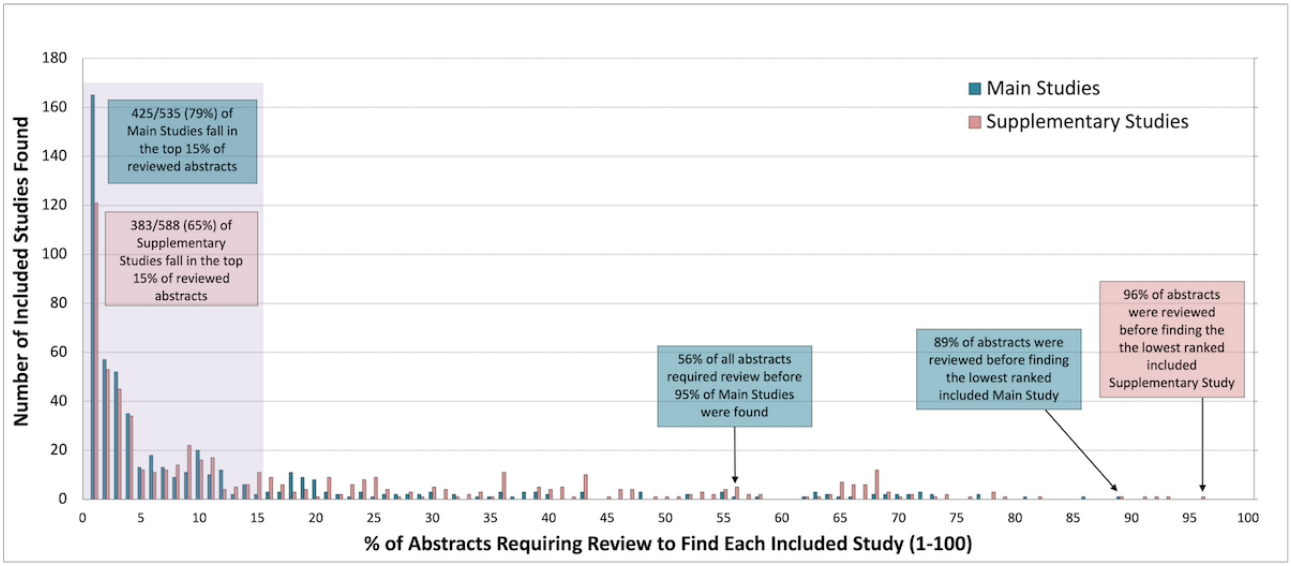
Results

Five SRs were excluded for having <5 included studies (ie, 25 of the 30 most recent SRs were eligible). The total number of abstracts requiring review ranged from 152 to 39,132 studies.

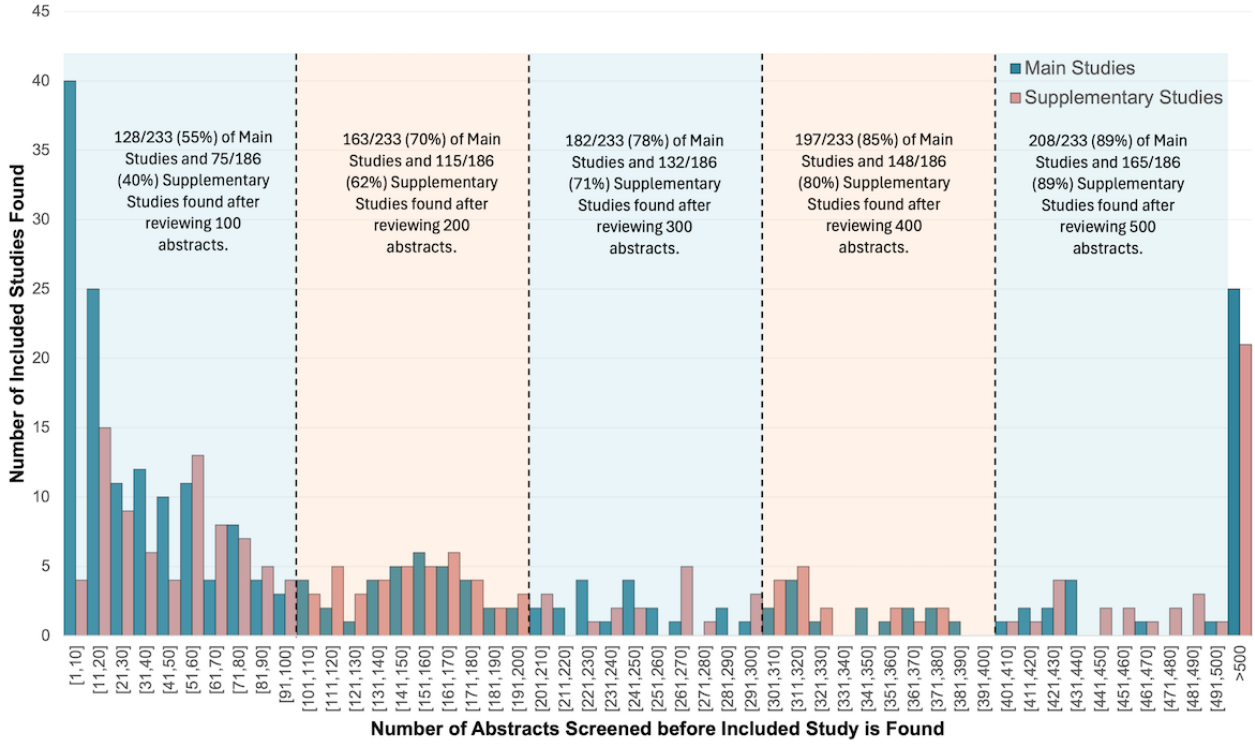
For GPT-5 Thinking, 144,120 abstracts were screened, of which 1123 were included studies—comprising 535 main results publications and 588 supplementary studies. Although 79.4% (n=425/535) of main results and 65.1% (n=383/588) of supplementary studies were within the highest-ranked 15% of abstracts, 89% (n=128,266/144,120) of abstracts were more highly ranked than the lowest-ranked main results publication, and 96% (n=138,355/144,120) of abstracts were more highly ranked than the lowest-ranked supplemental study (Figure 1).

Figure 1. GPT-5: % of abstracts requiring review to find each included study.



For ASReviewLab, 80,298 abstracts required review, of which 419 were included studies—comprising 233 main results publications and 186 supplementary studies. Although 89% of both main results (n=208/233) and supplementary studies (n=165/186) were identified in the first 500 AI-ranked abstracts, that left 11% (n=46/419) of included studies yet to be identified (Figure 2).

Figure 2. ASReviewLab: number of abstracts screened before included study is found.



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Discussion

Both AI tools ranked the majority of included studies within the first 500, or first 15% of abstracts. However, many included studies required substantially more abstracts to be reviewed before they were identified. For GPT-5, where it was possible to see where all abstracts were ranked, some included studies would have required 96% of abstracts to be reviewed before all included studies were found – making these tools unreliable, given ALL eligible studies need to be identified (ie, unacceptable tail risk).

Our findings are limited to the two AI tools utilized and to SRs with well formulated PICO questions, as is the norm for the Cochrane Collaboration. It is possible that better prompts could have been developed to improve GPT-5 performance. Had we reviewed more than 500 abstracts with ASReviewLab, we might also have found all included studies to lie within a still reasonable number of abstracts for humans to review in a timely manner – especially since reviewing more abstracts could have improved the AIs ability to recognize eligible studies. For GPT-5, there appeared to be no problem with prompt limits, domain variation, or publication types – as both main studies and supplementary studies had similar proportions of low-ranked included studies. Why some included studies received a low ranking is unclear.

Our findings align with other work suggesting AI models have potential to automate the SR process. However, the AI tools reported on here are not yet reliable enough to limit the number of abstracts human reviewers must evaluate if the goal is to find all eligible studies [4].

Our study is novel in providing a PICO-criteria-based prompt to GPT 5-Thinking, and in replicating abstract searches for multiple Cochrane reviews in order to identify all studies which should have been highly-ranked by AI tools. These Cochrane reviews additionally spanned many areas of medicine – from neonatal acupuncture to improving professional practice.

Unless performing a scoping review, where some relevant studies might be expected to be missed [5], the AI tools we examined are not yet sufficiently reliable at identifying eligible studies that lower-ranking studies do not require evaluation by a human reviewer. Doubtless this will change in time, as AI models evolve, for which further such evaluations of the ability to rank eligible studies would be worthwhile—including supplementary studies, and SRs of a non-medical nature, which pose different classification challenges.

Funding

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Conflicts of Interest

None declared.

Multimedia Appendix 1
Sample prompt to rank abstracts in order of most to least likely for inclusion.
[DOCX File, 25 KB - formative_v10i1e82896_app1.docx]

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Abbreviations

AI: artificial intelligence
PICO: Patient/Population, Intervention, Comparison, and Outcome
SR: systematic review

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Prospective Evaluation of Large Language Model Integration Into a Classical Hematology Case Conference

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Abstract

Prospective integration of large language model tools into a classical hematology challenging-cases conference was feasible, increased clinician familiarity and interest, and was perceived as diagnostically and educationally valuable.

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KEYWORDS

artificial intelligence; education; machine learning; large language model; classical hematology

Introduction

Artificial intelligence (AI) systems based on large language models (LLMs) are increasingly accessible to clinicians and trainees, yet their practical use in real-time case-based learning has not been systematically evaluated [1-3]. Classical hematology, with its diagnostic challenges and frequent reliance on critical thinking represents a relevant environment for early implementation. We conducted a prospective study to assess the integration of LLM tools into a classical hematology case conference and to evaluate user experience, perceived value, and key considerations for safe adoption.

Methods

Over eight consecutive sessions, two LLMs, ChatGPT and Open Evidence AI, were incorporated into the Yale Classical Hematology Case Conference (Figure 1). The use of two distinct LLM platforms was intentional; Open Evidence AI was selected because it provides guaranteed, source-linked medical references, while the inclusion of ChatGPT aimed to demonstrate that different LLM platforms can be leveraged to support case-based discussions in classical hematology. Importantly, no formal performance comparison between the two platforms was conducted in this initiative. Presenters prepared structured prompts summarizing clinical presentation, laboratory data, and specific questions relevant to differential diagnosis and management for each case. These prompts were used to generate outputs that included differential diagnoses, diagnostic algorithms, rationale for additional workup, evidence-based therapeutic recommendations, and citation-supported references.

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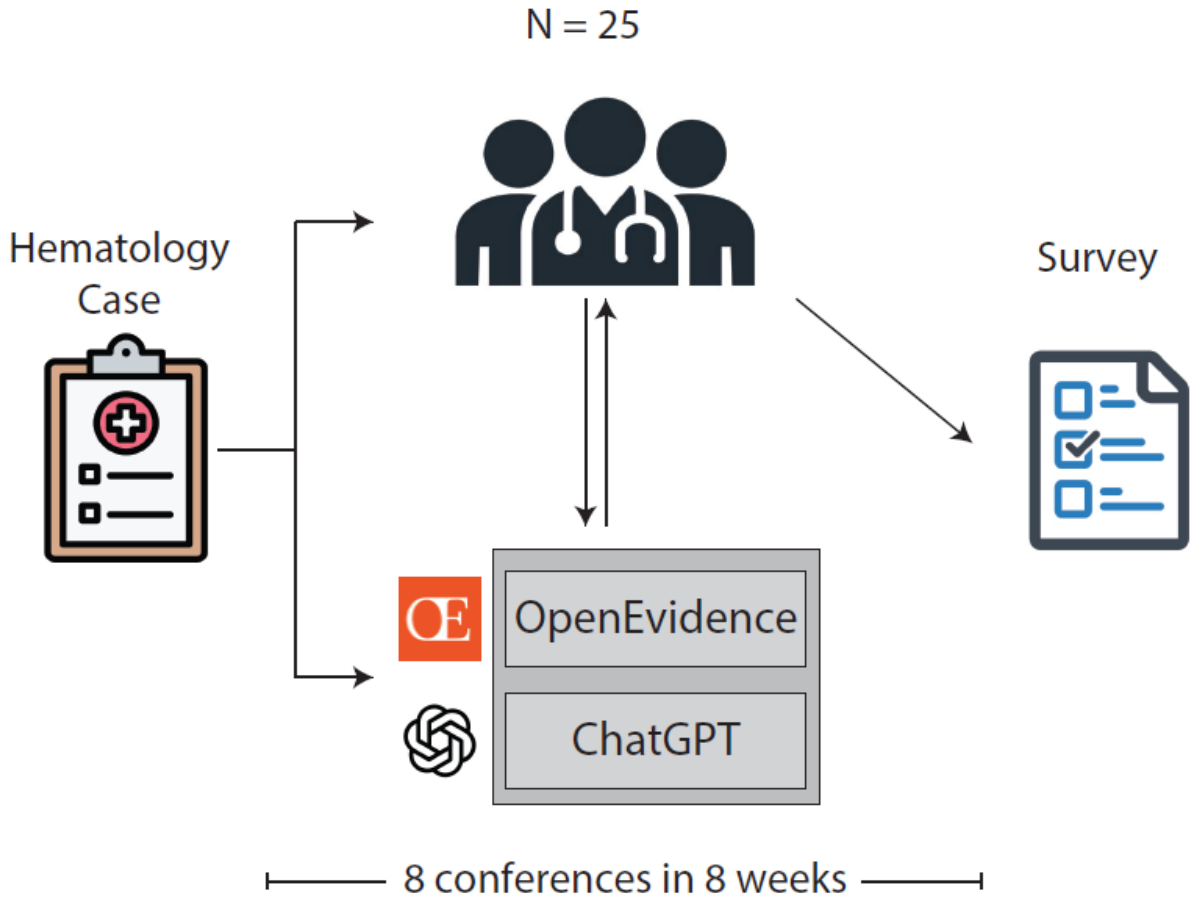
Figure 1. General scheme of large language models (LLMs) integration within the Classical Hematology Case Conference.



The AI-generated content was shown during case discussions and evaluated in parallel with expert clinical reasoning. This created a structured format in which faculty and trainees could critically evaluate LLM output, compare it with established approaches or recommendations, and examine areas of concordance and discordance.

Methods

Ethical Considerations

This prospective educational feasibility study involved an anonymous survey of conference participants without collection of identifiable private information. Participation was voluntary, and all data were analyzed and reported in aggregate to ensure confidentiality.

Results

Following the intervention, 25 attendees completed a structured questionnaire (Multimedia Appendix 1). Respondents were primarily faculty hematologists (n=16/25, 64%) and trainees (n=7, 28%), with a wide range of practice experience. Prior to the intervention, only 16% (n=4) reported being “very familiar” with AI in clinical hematology; after the intervention, 36% (n=9) reported “a lot of familiarity,” and none reported no familiarity. Similarly, the proportion using AI frequently or occasionally increased from 44% (n=11) preintervention to 68% (n=afterward. These findings suggest that even limited, structured exposure can influence clinician comfort with AI tools.

Participants generally perceived AI as valuable or somewhat valuable in the context of case discussion (n=21, 84%). The aspects rated highest were the generation of alternative diagnoses (80%) and the retrieval of relevant references (92%). These findings align with known capabilities of LLMs to rapidly provide relevant information, broaden diagnostic considerations, and provide literature support that may otherwise be time-consuming to compile during real-time discussions [4,5]. In classical hematology, where cases often involve complex presentations with broad differential diagnoses, these contributions offer notable educational benefits.

Participants also identified several limitations. The most frequently reported concern was that the quality and specificity of AI output depended significantly on the structure and clarity of the input (n=15, 60%). This finding underscores the need for standardized prompting frameworks, a known issue across clinical AI applications. Respondents also noted that AI-generated treatment suggestions were sometimes insufficiently tailored to the individual clinical scenario (52%) and that occasional incomplete or irrelevant outputs were generated for both diagnoses and management options (52%). These observations reinforce the importance of clinician oversight and illustrate the current inability of LLMs to independently interpret patient-specific detailed clinical scenarios [6].

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Importantly, nearly all respondents (n=23, 92%) believed that AI should function exclusively in an adjunctive capacity, supporting rather than replacing clinician judgment. Only one participant indicated that AI added little or no value to the case discussions. These perspectives mirror broader concerns in the medical community regarding reliability, safety, and the need for human supervision in clinical applications of AI [6,7].

Discussion

Our findings demonstrate that prospective integration of LLM tools into a classical hematology case conference is both feasible and acceptable to clinicians. The experience increased familiarity with AI systems, encouraged early adoption, and was perceived as valuable in enhancing diagnostic evaluation and reference retrieval. Importantly, the intervention created a structured environment for examining limitations of AI, including prompt dependency, generalization, and incomplete reasoning pathways, thus reinforcing the need for careful oversight and transparency.

This early experience suggests several considerations for future implementations. First, structured prompt templates may improve output reliability and consistency. Second, AI integration may be best positioned as an on-demand component rather than a continuous or self-supervised feature of case presentations. Third, further prospective studies should evaluate diagnostic accuracy, effects on clinical decision-making, potential biases, and implications for trainee education. Finally, developing practical guidelines for human-AI integration is essential as educational and clinical environments adopt these tools [8,9].

In summary, our prospective feasibility study provides early evidence that integrating LLM-based tools into clinical case conferences enhances educational value and increases clinician familiarity with AI. These findings support continued, supervised exploration of AI-assisted case-based learning within hematology and other medical specialties.

Acknowledgments

The authors declare the use of generative AI in the research and writing process. According to the GAIDeT taxonomy (2025), the following tasks were delegated to GAI tools under full human supervision: Proofreading and editing. Responsibility for the final manuscript lies entirely with the authors. GAI tools are not listed as authors and do not bear responsibility for the final outcomes.

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Authors' Contributions

TK conceived the study, designed the study protocol and survey, edited and distributed the survey, collected and analyzed the data, drafted the first version of the manuscript, and presented the clinical cases in a timely manner during the conference. AL contributed to study conception and design, survey development, facilitated survey implementation, assisted with data analysis and interpretation, contributed to drafting and revising the manuscript, and presented the large language model outputs to conference attendees. LVD contributed to study conception and design, survey development and implementation, data collection and interpretation, and contributed to drafting and revising the manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Structured questionnaire .
[PDF File, 522 KB - formative_v10i1e89939_app1.pdf]

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Abbreviations

AI: artificial intelligence
LLM: large language model

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Machine Learning–Based Audiovisual Phenotyping for Measuring Communication, Shared Decision-Making, and Trust

Shely Khaikin[1], BA; Vineet Tiruvadi[2,3], MD, PhD; Jeffrey Brooks[3], PhD; Alice Baird[3], PhD; Anne-Catherine Grela-Mpoko[1], BS, MPH; Lindsey Hoffman[1], BS; Jadyn Crossley[1]; Menachem Leasy[4], MD; Jaime Fineman[5], MD; Margot Savoy[6], MD; Laura Igarabuza[4], MD; Anuradha Paranjape[7], MD; Cheryl YS Foo[8], PhD; Michael L Birnbaum[9,10], MD; Yaara Zisman-Ilani[11,12,13], MA, PhD

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Abstract

Machine learning–based audiovisual phenotyping can reveal hidden discrepancies between patients' self-reported experiences and nonverbal expressions, offering a promising tool for objectively assessing communication quality and advancing health equity.

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KEYWORDS

audiovisual digital phenotyping; shared decision-making; AI; artificial intelligence; depression; primary care; natural language processing

Introduction

Although depression is highly prevalent, many patients do not engage with prescribed treatments, particularly racial and ethnic minority individuals in primary care settings where clinicians lack time and infrastructure for effective communication [1]. Shared decision-making (SDM) can enhance engagement [2], but SDM is not yet the norm [3]. Social desirability bias, power dynamics, and cultural norms may lead patients to report high SDM and trust [4] despite feeling otherwise.

Objective measurements may better capture true experiences. Current SDM assessments rely on subjective self-reports or observer ratings with no objective alternatives. Audiovisual digital phenotyping (ADP) is useful in monitoring depression [5,6] and could assess communication quality. This study evaluated multimodal ADP's usability for assessing health communication, SDM, and trust in depression care. We compared ADP outputs from audio, visual, and language modalities with validated patient-reported measures to identify patterns of discrepancies and alignments.

Methods

Study Design

Twenty-four participants were recruited from primary care practices. Eligible adults had a depressive disorder diagnosis (ICD-10-CM F33.xx) and a recent primary care visit.

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Participants completed recorded video interviews about patient-provider communication, decision-making experiences, and self-report measures: SDM-Q-9-Psy [7] (low to high SDM), CollaboRATE [8] (low to high provider engagement effort), and Trust scale [9] (low to high trust). Mean and sum scores were calculated; participants were categorized as having negative or positive communication experiences based on lower or higher scores, respectively.

From the interviews, two short video clips per participant were extracted: one reflecting positive communication experiences and one reflecting negative experiences. Verbal and nonverbal responses were analyzed with three on-premise Hume AI expression models capturing ADP [10,11]: (1) a facial expression model (FaceNet Inception-ResNet V1) capturing movement and nonverbal expression of the face; (2) a speech prosody model (Whisper-Small), assessing tone and vocal dynamics from audio; and (3) a natural language processing (NLP) model (BERT), identifying the emotionality of the spoken transcript. For each participant, the top three emotions per modality were extracted.

Alignment or discrepancy between self-report and ADP was assessed using face validity by comparing self-report scores with emotional outputs. Participants with positive experiences were matched to positive clips; those with negative experiences were matched to negative clips. Alignment required concordance between reported experience and extracted emotions (eg, negative emotions in negative clips for low scorers). Exploratory analyses examined clips with opposite experience types.

Ethical Considerations

This study was approved by the Temple University Institutional Review Board (Protocol #29435). Patients provided informed consent for participation. Participants received a US $20 gift card. Self-reported and ADP data were deidentified.

Results

Of the 24 participants who completed the study, data from 6 were analyzable after excluding cases with simultaneous on-screen appearances of participant and interviewer or poor video quality. The final sample included 3 women (50%), 5 Black participants (83%), and 4 unemployed participants (67%, Table 1). Because the six interviews lasted 48 (SD 13.1) minutes on average, we selected shorter clips for ADP analysis. Selected clip lengths were 14 - 58 seconds (mean 29.4, SD 12.7 seconds), each containing approximately 30 analyzable frames per second (about 840 - 3480 frames per participant for two clips). Categorization into low and high communication experience was conducted based on an SDM-Q-9-Psy score higher than 2.5 and a Trust score higher than 27.5, as most CollaboRATE scores were above average.

Table . Demographic characteristics and communication experiences.

Participant characteristics	P1	P2	P3	P4	P5	P6
Age (y)	24	56	58	58	68	39
Sex	Male	Female	Female	Male	Female	Male
Hispanic or Latino	No	No	No	No	Yes	No
Race	Black or African American	White or Caucasian	Black or African American and American Indian/Native American or Alaska Native	Black or African American	Black or African American and Other	Black or African American
Employment status	Employed	Unemployed	Unemployed	Unemployed	Unemployed	Unemployed
Decision made at the consultation	Referral to outpatient center	Refills, no new decisions were made	Referrals	Keep current medication	Stop therapy	Change in medications
SDM-Q-9-Psy, mean score (range 0 - 5)	1.11	1.89	3.00	4.56	5.00	5.00
CollaboRATE, mean score (range 0 - 9)	5.67	4.00	6.67	9.00	9.00	9.00
Trust in provider, sum score (range 0 - 55)	22	24	37	43	54	55

Four participants (P3-P6) reported positive communication experiences. However, for 3 (75%) participants, ADP analysis revealed discrepancies between self-reported positive experiences and the presence of negative (eg, distress or disappointment) or neutral (eg, confusion) emotion outputs in positive clips (Table 2). Disappointment, awkwardness, and annoyance were common negative emotions in negative clips by participants who reported positive overall experiences. These relationship-related emotions may reflect disappointment with specific aspects of the patient-provider communication. Among the ADP modalities, the greatest discrepancies between verbal content and ADP were observed in facial expression and NLP

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(in positive clips), whereas speech prosody aligned more closely with survey results in 2 participants (P4 and P6), with emotional outputs such as excitement and amusement (Table 2).

Table . Audiovisual digital phenotyping of emotional outputs.

Participant	Clip type and modality					
	Negative, mean (SD)			Positive, mean (SD)		
	FEa	SP[b]	NL[c]	FE	SP	NL
P1[d]	• Amusement: 0.41 (0.13) • Joy: 0.40 (0.16) • Satisfaction: 0.35 (0.11)	• Anxiety: 0.18 (0.19) • Confusion: 0.16 (0.17) • Calmness: 0.15 (0.14)	• Confusion: 0.32 (0.22) • Anxiety: 0.22 (0.15) • Contemplation: 0.18 (0.16)	• Amusement: 0.50 (0.20) • Joy: 0.50 (0.23) • Satisfaction: 0.40 (0.11)	• Realization: 0.16 (0.15) • Amusement:0.12 (0.10) • Disgust: 0.12 (0.12)	• Excitement: 0.27 (0.23) • Enthusiasm: 0.24 (0.07) • Interest: 0.21 (0.13)
P2[d]	• Calmness: 0.41 (0.17) • Tiredness: 0.36 (0.16) • Boredom: 0.32 (0.08)	• Awkwardness: 0.20 (0.14) • Sadness: 0.17 (0.19) • Realization: 0.14 (0.11)	• Annoyance: 0.31 (0.18) • Disappointment: 0.24 (0.14) • Pain: 0.16 (0.18)	• Confusion: 0.35 (0.13) • Concentration: 0.33 (0.15) • Calmness: 0.31 (0.15)	• Disappointment: 0.29 (0.30) • Confusion: 0.25 (0.14) • Realization: 0.21 (0.13)	• Disapproval: 0.31 (0.25) • Disgust: 0.24 (0.34) • Annoyance: 0.20 (0.13)
P3[e]	• Confusion: 0.49 (0.14) • Doubt: 0.33 (0.09) • Distress: 0.28 (0.08)	• Realization: 0.27 (0.17) • Distress: 0.19 (0.15) • Awkwardness: 0.17 (0.05)	• Annoyance: 0.36 (0.18) • Disappointment: 0.32 (0.17) • Sadness: 0.22 (0.19)	• Confusion: 0.43 (0.11) • Concentration: 0.34 (0.12) • Calmness: 0.32 (0.13)	• Distress: 0.21 (0.28) • Disappointment: 0.19 (0.16) • Realization: 0.16 (0.09)	• Annoyance: 0.16 (0.06) • Anxiety: 0.14 (0.13) • Disappointment: 0.13 (0.12)
P4[e]	• Confusion: 0.40 (0.15) • Disappointment: 0.33 (0.05) • Sadness: 0.33 (0.08)	• Awkwardness: 0.18 (0.11) • Realization: 0.17 (0.11) • Calmness: 0.12 (0.16)	• Awkwardness: 0.50 (0.10) • Anxiety: 0.23 (0.17) • Annoyance: 0.19 (0.11)	• Pain: 0.56 (0.19) • Sadness: 0.50 (0.10) • Distress: 0.46 (0.09)	• Determination: 0.19 (0.19) • Excitement: 0.16 (0.25) • Amusement: 0.15 (0.19)	• Awkwardness: 0.31 (0.07) • Realization: 0.20 (0.03) • Doubt: 0.18 (0.12)
P5[e]	• Confusion: 0.35 (0.11) • Distress: 0.29 (0.08) • Pain: 0.27 (0.18)	• Realization: 0.12 (0.13) • Amusement: 0.12 (0.14) • Sadness: 0.11 (0.22)	• Sadness: 0.43 (0.31) • Disappointment: 0.23 (0.14) • Annoyance: 0.20 (0.21)	• Confusion: 0.39 (0.11) • Distress: 0.30 (0.06) • Disappointment: 0.30 (0.08)	• Realization: 0.14 (0.06) • Contemplation: 0.12 (0.09) • Awkwardness: 0.12 (0.07)	• Disappointment: 0.16 (0.16) • Realization: 0.16 (0.06) • Contemplation: 0.14 (0.04)
P6[e]	• Interest: 0.42 (0.05) • Amusement: 0.39 (0.13) • Concentration: 0.33 (0.09)	• Anger: 0.19 (0.23) • Contemplation: 0.17 (0.11) • Disgust: 0.13 (0.12)	• Contemplation: 0.18 (0.14) • Emphatic pain: 0.15 (0.18) • Sympathy: 0.12 (0.13)	• Confusion: 0.48 (0.04) • Concentration: 0.44 (0.05) • Doubt: 0.37 (0.04)	• Realization: 0.21 (0.11) • Amusement: 0.13 (0.07) • Positive surprise: 0.13 (0.13)	• Gratitude: 0.43 (0.28) • Relief: 0.23 (0.14) • Satisfaction: 0.20 (0.10)

[a]FE: facial expression (FaceNet Inception-ResNet V1).

[b]SP: speech prosody (Whisper-Small).

[c]NL: natural language (BERT).

[d]Low SDM-Q-9-Psy score.

[e]High SDM-Q-9-Psy score.

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Two participants (P1 and P2) reported negative communication experiences on surveys. In their negative clips, NLP and prosody reflected these experience (eg, anxiety), while facial expressions showed mixed patterns: P1 displayed positive emotions (eg, amusement) and P2 displayed neutral emotions (eg, calmness). In positive clips, P1 showed predominantly positive emotions across all modalities, whereas P2 displayed a mix of neutral and negative emotions (eg, confusion) across all modalities, indicating a discrepancy with the positive clip classification but alignment with P2's overall negative self-reported communication experience. Notably, P1 exhibited similar facial expressions across positive and negative clips.

Discussion

This pilot study demonstrated the usability of multimodal ADP for evaluating patient-provider communication, SDM, trust, and engagement, with prosody showing the strongest alignment with self-reported experiences and facial expression showing the weakest alignment. Discrepancies between self-reports and nonverbal expressions may help explain high rates of service disengagement and treatment nonadherence among patients, whose nonverbal communication cues may be clinically overlooked despite reported trust and engagement [12]. Nonverbal expressions aligned with self-reports for negative experiences but contradicted self-reports for positive experiences, highlighting the need for providers to be mindful of social desirability bias and patient-provider power imbalances.

To protect privacy, analyses used on-premises technology, which offers fewer advantages than cloud-based artificial intelligence (AI) models. This created challenges with simultaneous on-screen appearances, poor lighting, and nonstandard camera angles, resulting in a reduced sample size for comparing ADP with SDM and trust measures. Despite constraints, ADP provided hundreds of thousands of analyzable frames per clip, offering extensive repeated measurements. Postappointment data collection was another limitation.

Technologically, facial expression sensitivity in depression requires optimization, as limited facial expression may affect provider responses and ADP emotion extraction. Future research should address how to implement commercial AI tools while respecting ethical requirements when handling protected health information [13]. Additional considerations for on-premises AI studies should ensure sufficient computing capacity to support analyses.

Given our predominantly Black patient sample, findings highlight providers' need to recognize how social desirability bias, power dynamics, and cultural norms may lead patients to report positive experiences despite feeling disengaged. This demonstrates multimodal ADP's promise for objectively assessing communication quality and advancing health equity.

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Artificial intelligence (AI) tools were used solely for copy editing, grammar checking, and spelling corrections during manuscript preparation. No generative content was created by AI.

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Data Availability

Deidentified data supporting the findings of this study are available from the corresponding author upon reasonable request, subject to approval by the Temple University Institutional Review Board.

Authors' Contributions

Conceptualization: YZ-I
Analysis: SK
Funding acquisition: YZ-I
Methodology & Resources: SK, VT, JB, AB, YZ-I
Project administration: SK, ACG-M, LH, JC, AP
Supervision: YZ-I
Writing – original draft: SK, YZ-I
Writing – review & editing: all authors

Conflicts of Interest

VT, JB, and AB have worked for Hume AI. The remaining authors declare no competing interests.

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Abbreviations

ADP: audiovisual digital phenotyping
AI: artificial intelligence
NLP: natural language processing
SDM: shared decision-making

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Transportation as a Barrier to Health Care Access Among Patients With Knee Arthritis: Cross-Sectional Study

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Abstract

This study uses the 2011-2017 National Health Interview Survey (NHIS) data to demonstrate that sociodemographic factors are associated with transportation delays among individuals with knee osteoarthritis.

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KEYWORDS

knee; arthritis; transportation delays; access to care; structural barriers

Introduction

In the United States, knee pain, often secondary to various forms of arthritis, is responsible for 5% of all primary care visits [1]. In accessing health care, transportation has often been cited as an impediment to proper care across various diseases and health conditions [2]. While there are studies that document decreased access to health care with respect to transportation barriers [2,3], to the best of our knowledge, there are none that explore this relationship among those diagnosed with knee arthritis.

Methods

Study Design

This retrospective study was conducted using data from the 2011 - 2017 National Health Interview Survey (NHIS). The NHIS is administered in-person annually and is a cross-sectional survey of noninstitutionalized adults in the United States [4]. Knee arthritis was defined by answers to questions pertaining to self-reported physician-diagnosed knee arthritis as well as self-reported knee pain. Among respondents who were told "by a doctor or other health professional that [they had] some form of arthritis, rheumatoid arthritis, gout, lupus, or fibromyalgia," knee arthritis was defined by those who indicated that they experienced "symptoms of pain, aching, or stiffness in or around a joint." (Multimedia Appendix 1). Adults who agreed to the statement, "Have you delayed getting care for any of the following reasons…In the past 12 months…You didn't have transportation" met the criteria for experiencing barriers to health care due to transportation delays (Multimedia Appendix 1).

Sociodemographic variables were used as covariates. Univariable and multivariable logistic regressions were conducted using R Studio (version 1.4.1106; R Foundation for Statistical Computing), α=0.05. Weighted analysis generated nationally representative results. Participants were excluded from this study if questions regarding knee arthritis or transportation delays were unanswered or if key sociodemographic factors were missing.

Ethical Considerations

Per National Institute of Health (NIH) guidelines, this research does not meet the definition of human subjects research as this data is publicly available, anonymized, and not obtained for the purposes of this study; therefore, institutional review board approval was not required for this secondary analysis [5].

Results

A total of 72,930,571 weighted respondents answered the question for knee arthritis on the 2011 - 2017 survey (mean age, 53.8, SE 0.10) years. Of the weighted respondents, 62.1% (n=45,258,537; mean age 53.9, SE: 0.12) years indicated that they experienced knee arthritis. Within the knee arthritis cohort, 3.8% (n=1,723,968) of participants noted transportation delays in medical care. Univariable and multivariable logistic regression analyses were performed to assess the effect of various sociodemographic variables on transportation delays for individuals with knee arthritis (Table 1).

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Table . Univariable and multivariable regression analysis of sociodemographic factors and transportation delays among those with knee arthritis.

Variables	Unadjusted odds ratio (95% CI)	Adjusted odds ratio (95% CI)
Sex		
Male	1.00 (Reference)	1.00 (Reference)
Female	*1.69 (1.49 - 1.92)*[a]	*1.47 (1.29 - 1.67)*[a]
Education		
less than High school	1.00 (Reference)	1.00 (Reference)
High school or GED[b]	*0.49 (0.42 - 0.57)*[a]	*0.84 (0.71 - 0.99)*[a]
College or more	*0.33 (0.29 - 0.37)*[a]	0.85 (0.73 - 1.00)
Region		
Midwest	1.00 (Reference)	1.00 (Reference)
Northeast	0.90 (0.72 - 1.12)	0.90 (0.72 - 1.12)
South	1.23 (1.03 - 1.46)	0.97 (0.81 - 1.15)
West	1.13 (0.92 - 1.38)	1.19 (0.96 - 1.46)
Age (y)		
17 - 44	1.00 (Reference)	1.00 (Reference)
45 - 64	0.98 (0.86 - 1.12)	*0.82 (0.70 - 0.95)*[a]
>65	*0.73 (0.62 - 0.85)*[a]	*0.59 (0.49 - 0.72)*[a]
Race		
White	1.00 (Reference)	1.00 (Reference)
Hispanic	*1.62 (1.34 - 1.96)*[a]	0.86 (0.70 - 1.07)
Black	*2.28 (1.97 - 2.64)*[a]	*1.21 (1.04 - 1.42)*[a]
Asian	*0.65 (0.45 - 0.94)*[a]	*0.50 (0.33 - 0.76)*[a]
Other	*2.84 (2.20 - 3.67)*[a]	*1.59 (1.22 - 2.09)*[a]
Income		
>200%	1.00 (Reference)	1.00 (Reference)
100% - 200%	*4.63 (3.90 - 5.50)*[a]	*2.47 (2.02 - 3.02)*[a]
<100%	*10.31 (8.77 - 12.11)*[a]	*3.81 (3.07 - 4.74)*[a]
Insurance		
Private	1.00 (Reference)	1.00 (Reference)
Public	*9.75 (8.26 - 11.51)*[a]	*2.87 (2.31 - 3.57)*[a]
No insurance	*4.35 (3.50 - 5.41)*[a]	*1.83 (1.44 - 2.32)*[a]
Other	*3.88 (3.25 - 4.64)*[a]	*2.39 (1.95 - 2.94)*[a]
Health status		
Bad health	1.00 (Reference)	1.00 (Reference)
Good health	*0.19 (0.17 - 0.22)*[a]	*0.37 (0.32 - 0.42)*[a]

[a]Italicized aOR values denote that results that are statistically significant.

[b]GED: General Educational Development.

Multivariable logistic regression analysis found that Black individuals (adjusted odds ratio [aOR] 1.21; 95% CI 1.04 - 1.42), individuals who were 100% - 200% above the federal poverty level (aOR, 2.47; 95% CI 2.02 - 3.02), and those<100% of the federal poverty level (aOR, 3.81; 95% CI 3.07 - 4.74) were associated with greater odds of encountering transportation delays. Those who were on public insurance (aOR, 2.87; 95% CI 2.31 - 3.57), those with no insurance (aOR,

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1.83; 95% CI 1.44 - 2.32), and those with other insurance (aOR, 2.39; 95% CI 1.95 - 2.94) were also more likely to experience transportation delays.

Discussion

Principal Findings

Black individuals were associated with increased odds of transportation delays. Studies highlight that residential segregation along racial lines impact Black individuals' ability to access health care [6]. A retrospective 20-year period study has found that among Black individuals in the United States, a high level of residential segregation coupled with a high density of low-income residents increased the odds of urban hospital closures [7]. Thus, it is plausible that hospital closures and other such factors associated with residential segregation may place these communities further away from medical facilities, which could further exacerbate access to reliable and efficient transportation.

Our study revealed that individuals with an annual income of 100% - 200% above the federal poverty level as well as individuals<100% the federal poverty level experience increased odds of transportation delays. This may reflect difficulties with car ownership among lower-income individuals, as previous analyses have shown that among cancer patients, lacking a private vehicle decreases treatment odds [8]. Additionally, individuals with public insurance plans and individuals with no insurance were more likely to experience transportation delays in our study. This may be attributable to the increased costs of travel experienced by those with public or no insurance. In a study observing travel distance among those in need of HIV medical care, it was found that those with no insurance traveled further than those with public insurance [9]. In fact, a key policy recommendation for reducing transportation barriers in accessing healthcare includes insurance coverage that is inclusive of transportation [10].

Strengths and Limitations

Strengths of this study are its usage of a nationally representative sample and a large sample size. Limitations include biases with self-reported data, additional confounders not included in this model, and the cross-sectional nature of the data, which prohibits casual inferences.

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Data Availability

The supporting data are openly available at IPUMS NHIS [4].

Authors' Contributions

EY – Conceptualization, Data Curation, Formal Analysis, Methodology, Software, Validation, Visualization, Writing – original draft, Writing – reviewing and editing
JC – Formal Analysis, Supervision, Validation, Writing – reviewing and editing

Conflicts of Interest

JC is an education consultant for Arthrex, receives compensation for medical instruction and educational lectures only, and reports personal fees from Arthrex.

Multimedia Appendix 1
Definition of knee arthritis and transportation delays.
[DOCX File, 14 KB - formative_v10i1e91207_app1.docx]

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Abbreviations

NHIS: National Health Interview Survey
GED: General Education Development
aOR: Adjusted Odds Ratio

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Caffeine Consumption Patterns Among Medical Students: Survey Study

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Abstract

This cross-sectional survey of a California medical school found that caffeine consumption increases across medical training, with third-year students consuming more caffeine, particularly from coffee, energy drinks, and over-the-counter stimulants, than first- and second-year students, and higher intake being associated with elevated modified CAGE scores, suggesting stress-related stimulant use.

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KEYWORDS

medical education; stress; caffeine; cross-sectional survey; student

Introduction

Medical students frequently use caffeine to maintain alertness, particularly during periods of high academic demand. Prior research shows that nearly 90% of adults in the United States consume caffeine regularly, with elevated use reported among students in rigorous training programs [1-3]. However, little is known about the patterns and potentially problematic caffeine-related behaviors across different stages of medical training. This study assessed caffeine intake and exploratory indicators of problematic caffeine behaviors among first-, second-, and third-year medical students using a cross-sectional design.

Methods

Study Design and Participants

A cross-sectional survey was administered to first-year medical students (M1), second-year medical students (M2), and third-year medical students (M3) at a single California medical school in 2024. An email was sent to all these students, and 121 students among all three classes opted to complete the survey. The inclusion criteria were that the participant was to be 18 years of age or older and to be able to provide consent for participation. All 121 participants met the criteria, and no responses were excluded. The final sample included 54 M1s, 45 M2s, and 22 M3s.

Ethical Considerations

This study received ethical approval from the California University of Science and Medicine Institutional Review Board (approval: HS-2024 - 51) on July 11, 2024. Informed consent for primary data collection and secondary analyses of the research data was obtained from all individual participants included in the study. Participants were entered into a raffle where they could win one of twenty US $20 gift cards. Participant privacy was protected by de-identiying all information obtained by preventing the collection of direct identifiers such as email addresses and instead using a study ID for the raffle.

Survey Instrument

The survey collected demographic characteristics and self-reported use of coffee, tea, energy drinks, sodas, and over-the-counter caffeine preparations (Multimedia Appendix 1). Participants were asked about only standardized serving sizes and not how much caffeine each serving contained.

To explore maladaptive caffeine-related behaviors, we adapted the four-item CAGE questionnaire to caffeine use. This tool has not been validated for caffeine; therefore, it was used only for exploratory screening.

Outcome Measures

The primary outcomes included (1) the daily caffeine intake (mg/day), (2) the proportion of participants consuming ≥400 mg/day, a widely accepted upper safe limit for adults [4]; and (3) the endorsement of ≥1 adapted CAGE item that was obtained using the descriptive data only.

Statistical Analysis

Descriptive statistics are reported as mean (SD) or median (IQR). Group differences across training years were evaluated using ANOVA or Kruskal-Wallis tests as appropriate. Analyses

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were descriptive and not adjusted for confounding variables such as sleep, stress, or baseline stimulant use.

Results

Participant Characteristics

Table 1 presents the sample characteristics. The cohort included 61.2% (74/121) female medical students, with a mean age of 24.1 (SD 1.7) years.

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Table . Table 1. Demographics and reported caffeinated substance intake of 121 medical students in 2025.

Demographics	First-year medical students	Second-year medical students	Third-year medical students	Male students	Female students
Which school year are you? n (%)	54 (44.6)	45 (37.2)	22 (18.2)	—[a]	—
What gender do you identify as? n (%)	—	—	—	47 (38.8)	74 (61.2)
Weekly servings of caffeine products[b], mean (SD)					
Coffee	5.8 (4.93)	5.36 (4.94)	8.67 (4.13)	6.8 (5.8)	5.7 (4.31)
Tea	3.04 (4.1)	3 (3.91)	2.67 (3.57)	2.78 (3.83)	3.07 (3.98)
Soft drinks	1.92 (4.27)	1.33 (2.81)	0.72 (1.02)	1.95 (4.04)	1.23 (2.93)
Chocolate	2.02 (2.51)	1.24 (1.41)	3 (4.63)	1.53 (2.18)	2.09 (2.96)
Energy drinks	0.61 (1.81)	0.74 (1.67)	0.61 (1.09)	0.75 (2.01)	0.61 (1.41)
Over-the-counter caffeine	0.06 (0.43)	0.02 (0.15)	0.11 (0.32)	0 (0)	0.09 (0.41)
Weekly caffeine consumption (mg), mean (SD)					
Coffee	421.7 (378.6)	398 (388.2)	635.2 (313.2)	495.9 (446.9)	420 (333.4)
Tea	139.7 (192.9)	154.9 (213.1)	122.3 (171.6)	134.8 (190.7)	147.3 (200.7)
Soft drinks	77.9 (181.2)	54.3 (119.3)	29.9 (42.4)	81.8 (179)	48.8 (118)
Chocolate	40.5 (57.9)	29.7 (45.3)	76.3 (119.1)	35.8 (55.6)	46 (75.8)
Energy drinks	96 (294.1)	100.7 (232.7)	98.1 (179.3)	118.3 (323.7)	86.5 (203.1)
Over-the-Counter caffeine	3.98 (27.86)	4.76 (30.86)	7.22 (21.02)	0 (0)	7.61 (34.83)
Total caffeine	779.9 (756)	742.4 (492.4)	968.9 (493.8)	866.5 (854.8)	756.2 (443.7)
Modified CAGE[c], mean (SD)					
Have you ever felt you needed to cut down on your caffeine intake?	0.45 (0.5)	0.29 (0.46)	0.39 (0.5)	0.45 (0.5)	0.33 (0.48)
Have people annoyed you by criticizing your caffeine intake?	0.18 (0.39)	0.14 (0.35)	0.11 (0.32)	0.13 (0.34)	0.17 (0.38)
Have you ever felt guilty about your caffeine intake?	0.2 (0.41)	0.19 (0.4)	0.11 (0.32)	0.2 (0.41)	0.17 (0.38)
Have you ever felt you needed to consume caffeine first thing in the morning to steady your nerves or to get rid of a headache?	0.31 (0.47)	0.31 (0.47)	0.5 (0.51)	0.23 (0.42)	0.41 (0.5)
Total modified CAGE score	1.14 (1.26)	0.93 (1.18)	1.11 (1.08)	1 (1.09)	1.09 (1.26)

[a]not applicable.

[b]The caffeine content per serving for each individual item and its source can be seen in Multimedia Appendix 2.

[c]The modified CAGE is a proprietary version of the CAGE questionnaire used in studying alcohol use, but has been modified to replace alcohol with caffeine in each question.

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Daily Caffeine Intake

The mean daily caffeine intake was 114.3 (SD 625.7) mg/day. Intake generally increased by training year (M1: 111.4 mg/day; M2: 106.1 mg/day; M3: 138.4 mg/day), although the differences were not statistically significant (P=.09). 1/121 of participants consumed ≥400 mg/day of caffeine.

Caffeine Sources

Coffee was the primary source of caffeine (96/121), followed by tea (85/121), sodas (51/121), and energy drinks (33/121). Over-the-counter caffeine products were used by 5/121.

Adapted CAGE Indicators

63/121 endorsed ≥1 adapted CAGE item. The most common was “felt the need to cut down” (42/121 or 35%). Because the CAGE-caffeine tool is unvalidated, these findings are interpreted only as exploratory descriptors and not diagnostic indicators.

Discussion

Principal Findings

In this single-institution cross-sectional study, medical students reported moderate caffeine intake, with one student exceeding the daily upper limit of 400 mg recommended for adults. Caffeine intake increased across training years, although the differences did not reach statistical significance. These findings are consistent with prior research showing rising caffeine use with progressing academic demands [3].

Limitations

A key limitation is the lack of validated screening tools for problematic caffeine use. Our adapted CAGE-caffeine items were included only to explore behavioral tendencies; they cannot indicate caffeine use disorder or dependence. Future work should employ validated caffeine behavior instruments or include psychometric testing. Other limitations include potential recall bias, the absence of important confounders such as sleep and stress, restricted generalizability due to the single-site sample, and potential self-selection bias. The potential for winning gift cards could have potentially attenuated some self-selection bias by providing a generalized incentive for participation. Despite these limitations, the study provides descriptive data on caffeine use patterns in medical training and highlights the need for validated tools to assess maladaptive caffeine behaviors.

Conclusion

Medical students commonly consume caffeine, with a minority exceeding recommended daily limits. Exploratory findings suggest some students may wish to reduce intake. Future studies should incorporate validated instruments and longitudinal designs to better evaluate changes over time.

Acknowledgments

The authors declare that they did not use generative artificial intelligence in the writing of this research letter.

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Data Availability

The data used to support our conclusions were not acquired from a public repository. The raw data and statistical analyses can be accessed at the link [5]. This work is licensed under a Creative Commons Attribution 4.0 International (CC BY 4.0) License.

Authors' Contributions

BP - Conceptualization, Funding Acquisition, Investigation, Methodology, Project Administration, Supervision, Writing - Original Draft, Writing - original draft, Writing - review and editing
JS - Conceptualization, Formal Analysis, Project Administration, Supervision, Visualization, Writing - original draft, Writing - review and editing
SY - Funding Acquisition, Investigation, Methodology, Project Administration
AL - Conceptualization, Methodology, Visualization, Writing - original draft, Writing - review and editing
AR - Conceptualization, Writing - review and editing
BN - Conceptualization, Writing - review and editing
EL - Conceptualization, Writing - review and editing
JH - Conceptualization, Writing - review and editing
RC - Conceptualization, Writing - review and editing
DW - Project Administration, Supervision, Validation

Conflicts of Interest

None declared.

Multimedia Appendix 1

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Survey used in study containing questions asking about caffeinated substance usage and the modified CAGE questions.
[PDF File, 150 KB - formative_v10i1e79077_app1.pdf]

Multimedia Appendix 2
Documentation of caffeine values used in data analysis.
[DOCX File, 2488 KB - formative_v10i1e79077_app2.docx]

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Abbreviations

M1: first-year medical student
M2: second-year medical student
M3: third-year medical student

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Characterizing the Multidimensional Relationship Between Spirituality and Obsessive-Compulsive Disorder: Thematic Analysis

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Abstract

To elucidate the complex relationship between spirituality and obsessive-compulsive disorder (OCD), we performed a qualitative analysis of messages (n=225) referencing spiritualities in r/OCD, a public online peer support forum for people with OCD with over 250,000 users; two central themes emerged: (1) influence of spirituality on OCD symptom manifestation and (2) impact of OCD on relationship with spirituality.

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KEYWORDS

spirituality; obsessive-compulsive disorder; OCD; qualitative; religion; coping

Introduction

The impact of spiritualities, defined as beliefs in transcendent forces, on experiences of obsessive-compulsive disorder (OCD) is nuanced and heterogeneous. Some quantitative research has found mixed or no correlation between spiritualities and OCD outcomes [1], while other research has linked religion to greater severity of OCD symptoms, particularly in the form of scrupulosity [2]. These discrepancies likely reflect the influence of complex underlying mechanisms, which are difficult to capture given the lack of validated quantitative metrics that specifically measure the relationship between spirituality and OCD.

Qualitative self-report from spiritual people with OCD may yield unique insights into this nuanced relationship. However, existing qualitative research remains restricted by small sample sizes (eg, due to OCD stigma) and deductive methodologies that limit analysis to a specific religion. Reddit's r/OCD forum, with over 250,000 members and 100 - 200 new daily posts, offers a large volume of naturally occurring qualitative data [3].

To investigate how people with OCD describe the role of spirituality in their illness narratives, an exploratory study was conducted analyzing posts from r/OCD that referenced faith in any context. This study hypothesizes that most users will report that spiritual beliefs aggravate obsessions related to moral transgressions, while not impacting or potentially alleviating obsessions with other themes—as spiritual explanations may reduce uncertainty—explaining prior mixed results.

Methods

Study Methodology

All new threads added to the subreddit within a 4-week period at the start of the study (August-September 2023; n=3543 threads) were downloaded manually. During the analysis protocol described in Table 1, codes on spiritualities and OCD organically emerged. The first and second author collaboratively identified messages that substantively mentioned both OCD and spiritualities (n=225), and the protocol described in Table 1 was repeated with only these messages.

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Table . The table outlines the six-phase process of thematic analysis as applied to posts from an obsessive-compulsive disorder peer support forum. The phases follow Braun and Clarke's methodology [4,5], including familiarization, code generation, theme development, and writing.

Phase	Steps taken during each phase
1. Familiarization with the dataset	The first and second authors read all eligible posts. Reflective memos were created during reading to note early impressions, possible codes, and interpretive tensions.
2. Coding of the dataset	The first and second authors developed an initial working codebook after a review of the dataset. Then, they independently coded half of the dataset. Discrepancies were resolved through discussion until consensus was reached. Data saturation was achieved after three-quarters of the dataset was coded, with no new concepts emerging from the data.
3. Generation of initial themes	After the dataset was coded, the first and second authors reviewed each other's work for internal consistency. During this process, the codebook was finalized. Then, codes were reviewed, grouped, and clustered into provisional themes.
4. Revision of themes	Themes were revised, collapsed, or separated until they demonstrated internal coherence and external heterogeneity [4,5]. The remaining themes were cross-checked against the raw data and full dataset to ensure representativeness and sufficiency.
5. Development of subthemes	Codes within each theme were organized into subthemes, following a similar process to what is outlined in phases 3 and 4.
6. Written analysis	This manuscript reports on the meaning of themes and subthemes, including illustrative quotes for each concept. Connections between these results and existing literature and religious coping were identified. All written analysis is contextualized within Braun and Clarke's guidance to present themes as active constructions of meaning [4,5].

An inductive and reflexive approach to thematic analysis was adapted; codes were generated without preexisting frameworks while acknowledging coder subjectivity. A discrete meaning unit, such as a sentence or short paragraph, was treated as the coding unit; a single post could contain multiple coded instances if multiple distinct ideas were expressed.

Throughout the process, the two coders—who were not spiritual but were raised in Buddhist and Christian contexts, respectively—actively reflected on how personal experiences influenced their interpretation. As Buddhism is a nontheistic Eastern religion that centers self-cultivation, while Christianity is a theistic Western religion that is highly institutionalized, the coders aimed to minimize bias through leveraging the differing perspectives conferred by their respective religious backgrounds.

Ethical Considerations

This study (protocol ID 2000036062) received a Not Human Subjects Research Determination from the Yale Institutional Review Board.

Results

Among 3543 threads, 225 messages from 147 unique threads discussed religiosity; 22 codes were used in a total of 302 instances. Two themes emerged, broadly reflecting how OCD affects spiritualities and how spiritualities affect OCD, with the latter representing the majority of instances (Table 2).

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Table . Themes and subthemes resulting from thematic analysis. Counts report the number of coded instances.

Theme and subtheme		Description
Influence of spiritualities on OCD[a] symptom manifestation (212/302)		
	Spiritual obsessions (143/212)	Users endorsed obsessions related to their faith, endorsing fears like committing blasphemy, going to hell, and being possessed by the devil.
	Religious compulsions (52/212)	Users performed faith-based rituals—most commonly, atonement-based compulsions like praying, confessing, and repenting to higher powers—to cope with obsessions with spiritual or nonspiritual themes.
	Symptom improvements attributed to faith (17/212)	Users reported that their faith helped them overcome OCD symptoms, such as by helping them persist through treatments or resist performing compulsions.
Impact of OCD on relationship with spiritualities (92/302)		
	Loss of faith due to OCD (22/92)	Continued suffering associated with OCD caused users to lose faith in the existence of higher powers (eg, struggles with theodicy) or in religious institutions that failed to support them.
	Persistent faith despite OCD (70/92)	Users described unwavering faith despite OCD, broadly citing divine providence and omniscience; some specifically suggested that higher powers would be understanding of and/or alleviate their OCD.

[a]OCD: obsessive-compulsive disorder.

Discussion

Through analyzing a peer support forum, this study identified a bidirectional relationship between spiritualities and OCD. Most messages described how spiritualities influenced OCD. Aligned with initial hypotheses, most messages included reports of faith-themed moral obsessions and compulsions, while some messages reported that faith helped the user overcome OCD, though it was not captured whether these users were also experiencing moral obsessions. Unexpectedly, other messages discussed OCD's influence on spirituality. These messages primarily emphasized the individual's persistent faith, though some messages suggested loss of faith due to OCD experiences.

Messages describing spiritual obsessions reflected rigid moral frameworks and thought-action fusion that is commonly observed with scrupulosity [6]. Meanwhile, users who benefited from spirituality reported that faith in higher powers encouraged them to accept uncertainty, a behavior that aligns with clinical advice for OCD. While prior studies suggested that faith may provide comfort and decrease anxiety, the specific mechanism has yet to be investigated among people with OCD [7]. Potential determinants of whether spiritualities are a source of support or fear should be further studied.

Additionally, organized religion was infrequently mentioned, contradicting prior reports that faith communities play significant roles in the mental health benefits associated with spirituality [8]. As this study primarily captures personal rather than social facets of spiritualities, future studies should investigate how peers, communities, and institutions may moderate this relationship. Altogether, qualitative studies in a larger corpus of data from the forum may help clinicians better address each individual's complex and unique relationship with their faith and potentially modify harmful relationships [9].

This study is limited in its ability to fully engage with literature on spiritualities and OCD due to space constraints. Additionally, Reddit users are predominantly English-speaking, Western, and male [10]; accordingly, this dataset appears to disproportionately represent Judeo-Christian concepts of God. Future studies should determine whether findings accurately capture experiences of those who endorse other religious or spiritual frameworks (eg, Eastern or secular spirituality). As this study is observational, further investigation is necessary to determine whether relationships between spiritualities and OCD may be correlational, even when users report them to be causative. Finally, it is not possible to confirm if users have OCD or honestly represent their experiences; posts may be intentionally or unintentionally tailored toward certain narratives.

Despite limitations, observing how people with OCD choose to report their relationship with spiritualities offers a unique perspective into the true role of spirituality in their lives. Subthemes like "symptom improvements attributed to faith" and "persistent faith despite OCD" may partially result from users' desire to be viewed as unwaveringly faithful, even if they experience doubts. Through conducting qualitative interviews with forum users, further studies may help elucidate why users conceptualize and/or publicly discuss their faith in a certain manner. These findings may inform the development of more effective therapeutic frameworks that better cohere with how each individual views their relationship with their spirituality—for example, exposure and response prevention

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therapy that incorporates religiosity exposures should be designed to not minimize one's commitment to their faith or offend the sanctity of one's faith.

Acknowledgments

No artificial intelligence tools were used to prepare this manuscript.

Conflicts of Interest

CP has consulted (past 3 years) for Freedom Biosciences, Biohaven Pharmaceuticals, Transcend Therapeutics, UCB BioPharma, Ceruvia Therapeutics, Mind Therapeutics, and Lucid/care. He has done sponsored research with Biohaven, Freedom, and Transcend. He holds equity in Alco Therapeutics, Mind Therapeutics, and Lucid/care, as well as pending patents on antibodies implicated in neuroinflammation, on psychedelic drug mechanisms and combinations, and on certain novel drugs and combinations for the treatment of OCD and related conditions. All other authors declare no conflicts of interest.

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Abbreviations

OCD: obsessive-compulsive disorder

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Association Between Availability of Fruits and Vegetables in Neighborhood Food Stores and Weight Among Residents of Low-Income Urban Public Housing: Cross-Sectional Study

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Abstract

This cross-sectional study examined the presence of food stores and availability of fruits and vegetables in food stores with weight among urban public housing residents. While there was no association between average number of fruits or vegetables in food stores and weight, there were positive associations between number of convenience stores and weight and between number of general merchandise stores and weight.

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KEYWORDS

food environment; fruits; vegetables; low-income; weight

Introduction

Though food environments are recognized as determinants of socioeconomic diet–related health disparities, there is less evidence delineating specific elements of food environments that contribute to bodyweight [1]. Previous literature is limited by variability in measurement approaches and a lack of capturing multiple food retail environments [1]. Among adults, a systematic review or meta-analysis assessing impact of food environments on obesity included only two studies with general merchandise stores as part of their analyses [1]. Furthermore, much research about general merchandise stores focuses on rural areas and children or adolescent populations, prompting evaluation among adults in urban areas [2,3]. This study's objective was to examine associations between two measures of food access: (1) presence of food stores (overall and by store types) and (2) availability of fruits and vegetables with weight at study enrollment among residents of urban public housing developments participating in a clinical trial for weight management [4].

Methods

Design

This is a cross-sectional analysis of baseline data from a clinical trial (Table 1) [1,4] along with neighborhood food store audit data collected by research personnel.

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Table . Description of the Path to Health Behavioral Clinical Trial for Weight Management (Recruitment period: 2021-2024; ClinicalTrials.gov #NCT04852042) [4]

Randomized groups	• Participants were randomized to: º Assessment only control (Control); º mHealth weight management intervention (Text messaging program and weight monitoring via digital scale) (mHealth only); º mHealth intervention plus motivational interviewing-based behavioral counseling delivered by a community health worker (mHealth+CHW)
Primary objective	• To evaluate if the mHealth+CHW intervention demonstrates efficacy for weight loss • Primary hypothesis: Both mHealth+CHW and mHealth only will outperform assessment only control and mHealth+CHW will outperform mHealth only in terms of weight loss at 12 months.
Eligibility criteria	• Trial inclusion criteria were: age >=18 years old; residents of Boston public housing; BMI >=27.0, and read/write English or Spanish (full criteria available [4]).
Study setting	• Our study setting consisted of family-designated housing developments (n=17) in the City of Boston managed by the Boston Housing Authority (n=9) or private property management companies (n=8) which receive subsidies for renting to low-income households.
Baseline characteristics	• Among 286 participants, 83.2% were female, 70.6% were Hispanic, 63.6% with up to high school education, with mean age of 53.6 (SD 14) years and mean weight of 188.1 (SD 42.9) pounds.

Measures

Weight

Research personnel measured participant (n=286) weight via scale during in-person, in-home baseline study visits [4].

Food Store Audit Instrument

Pairs of research personnel conducted in-store audits using the Food Environment Audit for Diverse Neighborhoods to identify food availability [5].

Data Analysis

Food access measures (number of food stores; total count of available fruits and vegetables or audited food store) were assigned to individual participants in the clinical trial, based on their public housing development of residence. We used separate generalized linear models examining associations between each access metric and participant weight at baseline. Specifically, we used generalized estimating equations to account for clustering of participants within housing developments (adjusted for resident age, gender, Hispanic ethnicity, and education). The model coefficient represents the difference in weight at baseline enrollment with a one-unit increase in count (ie, one additional store, or one additional fruit and vegetable available). Additional models adjusting for height were conducted (Multimedia Appendix 1). See Table 2 footnotes for details.

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Table . Descriptive information and associations between food access measures (number of food stores and availability of fruits and vegetables) and baseline weight (n=286 participants).

Descriptive information	Values
Total number of food stores within 1 mile, mean (SD)	23.6 (13.9)
Supermarkets/other grocery stores	11.1 (7.1)
General merchandise/dollar stores	2.5 (1.7)
Convenience stores	10.1 (6.5)
Fruits (fresh, frozen, canned, juice), vegetables (fresh, frozen, canned, juice), and beans (canned, dried) available in all audited food stores (n=31)	
At least one type of fruits & vegetables available, n (%)	30 (96.8)
10 or more types of fruits & vegetables available, n (%)	24 (77.4)
Number of fruits & vegetables, mean (SD)	32.6 (39.2)
Number of stores within 1 mile, unadjusted difference in weight (95% CI)	0.34 (-0.06, 0.73)
Supermarkets/other grocery stores	0.03 (-1.06, 1.12)
General merchandise/dollar stores[a]	3.11 (0.45, 5.76)
Convenience stores	1.12 (0.34, 1.91)
Number of stores[a] within 1 mile, adjusted[b] difference in weight (95% CI)	0.33 (−0.05, 0.71)
Supermarkets/other grocery stores	0.25 (−0.51, 1.01)
General merchandise/dollar stores[a]	3.08 (1.31, 4.85)
Convenience stores	0.87 (0.02, 1.72)
Number of fruits and vegetables,[c] unadjusted difference in weight (95% CI)	0.09 (-0.36, 0.53)
Supermarkets/other grocery stores	0.02 (-0.13, 0.17)
General merchandise/dollar stores[d]	0.05 (-0.38, 0.49)
Convenience stores	0.58 (-0.88, 1.41)
Number of fruits and vegetables[c] (Adjusted[b] difference in weight (95% CI)	0.08 (−0.26, 0.41)
Supermarkets/other grocery stores	0.02 (−0.11, 0.14)
General merchandise/dollar stores[d]	0.10 (−0.22, 0.41)
Convenience stores	0.30 (−0.40, 1.00)

[a]*Identification of Food Stores*: We used a commercial database called Data Axle Reference Solutions which contained location and business data on all U.S. businesses. Addresses for public housing developments and food stores were geocoded. ArcGIS Pro version 3.0 was used to model walking distance for one mile around public housing developments where participants lived. We chose one mile in order to capture a wide range of available food stores [6]. We identified three food store types using the North American Industry Classification Codes [NAICS], specifically including stores coded as: grocery stores (NAICS: 445110) retailing canned and frozen foods, fresh fruits and vegetables, and fresh and prepared meats, fish, and poultry; convenience stores (NAICS: 445120) retailing a limited line of goods including milk, bread, soda, and snacks; and all other general merchandise stores (NAICS: 452319) retailing general merchandise including dry goods as well as other merchandise such as apparel, housewares, and home furnishings. These food stores were categorized according to NAICS criteria. Our data manager used a random number generator to select one store to be audited from each food store category corresponding to each public housing development included in the Path to Health trial. We also measured food access via the total number of stores (and number within each food store category) within the walking buffer. Prior to conducting the audits, research staff conducted a spot check that actual store matched the expected store. In the audit, fruits and vegetables were counted as present or not present, instead of the actual number of individual fruits and vegetables.

[b]Separate generalized linear models adjusted for resident age, gender, Hispanic ethnicity, and education accounting for clustering within housing developments.

[c]Data represents food audits at eleven food store locations: Three groups of two public housing developments and one group of four public housing developments located within one mile of each other were combined into a single audit location due to proximity and overlapping identification of food stores. This process resulted in eleven unique food audit locations. From 11 audit locations (which corresponded to 17 housing developments), we audited 31 food stores (2 housing developments did not have a general merchandise store available for auditing). The total count of unique fruits, vegetables, and bean types available was created for each audited store and then these counts were averaged within each audit location.

[d]n=236 participants, due to the exclusion of two housing developments that did not have a general merchandise store available for auditing.

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Ethical Considerations

Boston University Medical Campus Institutional Review Board approved this analysis (H-41590). The original written consent process covered this analysis without additional consent. Privacy was ensured by deidentifying data with code numbers. Participants were paid US $50 for completing baseline assessment activities.

Results

There was no association between overall number of food stores and baseline weight nor between average number of fruits and vegetables in audited food store locations and baseline weight (adjusted difference in weight: 0.33, [95% CI −0.05,0.71 and 0.08, 95% CI: −0.26, 0.41 pounds, respectively). When food store type was examined, there were positive associations between number of convenience stores and baseline weight and between number of general merchandise stores and baseline weight (adjusted difference in weight: 0.87, 95% CI: 0.02, 1.72 and 3.08, 95% CI: 1.31, 4.85 pounds, respectively) (Table 2). Additional adjustment for height resulted in associations in a similar direction, with a small attenuation in magnitude (Multimedia Appendix 1).

Discussion

The number of convenience stores and general merchandise stores within a one-mile walking distance radius of public housing developments were associated with higher baseline weight, after adjusting for potential confounding factors. Unlike findings from systematic reviews or meta-analyses [1], we did not observe associations with number of grocery stores and baseline weight or availability of fruits and vegetables at audited food stores and baseline weight. Weight status is multifactorial and therefore, auditing a larger variety of foods may have been necessary to observe an association with weight. Others also noted lack of associations between new grocery stores and healthful eating among public housing residents [7]. Overall, neighborhood environment deprivation factors like lack of safe physical activity areas can all contribute to adverse health behaviors and outcomes.

Dollar stores are the fastest growing food retail type by share of household expenditure in the United States [3], raising concerns about nutrition and health-related outcomes [8] and impact on local businesses, staffing shortages, and overall cleanliness [9]. Municipalities have taken policy actions to address concerns including: moratoriums (prohibit new store openings for specified period) and conditional use ordinances (require local government to assess how proposed store aligns with certain conditions) [9]. Obtaining perspectives from key constituents and forming partnerships (eg, community members or policy makers workshops) can lead to creation of fair policies for equitable benefit [10].

This study benefited from a standardized validated audit data collection instrument and included diverse food stores. Limitations included: lack of consideration for sales volume; audits represented snapshots of food available that particular day or season; and inclusion of clinical trial participants potentially limited generalizability.

Our study suggests cross-sectional relationships between presence of convenience stores and general merchandise stores and higher weight among residents that were overweight or with obesity living in nearby public housing developments; findings may inform design of community-level food store policies.

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Data Availability

The datasets generated or analyzed during this study are available from the corresponding author on reasonable request.

Authors' Contributions

Conceptualization: LQ
Data curation: AF (lead), LR (supporting), KL (supporting), ZP (supporting)
Formal analysis: LR (lead), AF (supporting)
Funding acquisition: LQ (lead)
Methodology: ZX (lead), BB (equal), KL (supporting), ZP (supporting)
Project administration: JM (lead)
Supervision: LQ (lead)
Writing – original draft: RL (lead), LQ (equal)

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Writing – review & editing: LQ (lead), RL (equal), AF (supporting), LR (supporting), JM (supporting), KL (supporting), ZP (supporting), JK (supporting), ZX (supporting), BB (supporting)

Conflicts of Interest

None declared.

Multimedia Appendix 1
Descriptive information and associations between food access measures (number of food stores and availability of fruits and vegetables) and baseline weight.
[DOCX File, 68 KB - formative_v10i1e81581_app1.docx]

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Research Letter

Identifying Patient Sentiment in Atopic Dermatitis Treatment: Large Language Model Approach

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Abstract

This study demonstrates that GPT-4o outperforms traditional natural language processing methods in accurately analyzing patient sentiment toward atopic dermatitis treatments on Reddit, enabling more nuanced and reliable extraction of real-world patient perspectives from large-scale social media data.

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KEYWORDS

atopic dermatitis; eczema; large language model; social media; dupilumab; upadacitinib; abrocitinib; tralokinumab

Introduction

Atopic dermatitis (AD) treatment has broadened since 2017, with several new, targeted, highly efficacious systemic therapies. Patients' personal experiences with these novel therapies are largely unknown and unreported. Reddit is a rich source of patient perspectives on dermatology [1]. Previous studies have used traditional natural language processing (NLP) methods to extract meaningful information from unstructured social media data [2], but more relevant findings could potentially be extracted by applying large language models (LLMs) to such language data, including large-scale Reddit datasets, because tailored prompts can extract more specific and nuanced insights.

Methods

Overview

We used the Pushshift Reddit dataset to access all Reddit comments (n=8,543,388) posted prior to January 1, 2024, on various dermatology-related subreddits (Multimedia Appendix 1, Table S1). We analyzed all comments containing the generic or brand name of four AD therapies as of January 1, 2024: dupilumab, upadacitinib, abrocitinib, and tralokinumab. This resulted in 27,272 comments. Our novel approach applied OpenAI's developer application programming interface (API) to access GPT-4o [3], OpenAI's cutting-edge LLM, for sentiment analysis to determine whether comments indicated positive, neutral, or negative impressions of the medications. The GPT-4o API was configured with a temperature setting of 0.0 to ensure consistent and deterministic responses across all analyses, eliminating variability in sentiment classification. The complete prompt used for the GPT-4o sentiment analysis is provided in Multimedia Appendix 2.

Model Comparison

We compared 3 automated tools against manual sentiment analysis to identify the most accurate tool. Two dermatologists (JY and Hadley Johnson, MD) independently reviewed 100 randomly selected comments (25 comments for each medication) and reached concordance for 84 of 100 sentiments (κ=0.75, concordance=0.84). The dermatologists classified the comments as positive, neutral, or negative based on their overall expressed sentiment toward the medication without predefined annotation guidelines. Disagreements typically occurred for comments containing ambiguous treatment responses, mixed sentiments about medication efficacy, or informational discussions rather than clear personal sentiment expressions. The 84 comments were used as our reference standard for testing GPT-4o and two traditional NLP sentiment analysis methods: Valence Aware

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Dictionary and Sentiment Reasoner (VADER) [4], a lexicon-based tool specifically attuned to social media text, and distilbert-base-uncased-finetuned-sst-2-english (DistilBERT), a model pre-finetuned on the Stanford Sentiment Treebank for Sentiment Analysis [5]. The DistilBERT model was accessed through the Hugging Face Transformers library using its high-level pipeline interface. VADER and DistilBERT were used with default parameters. These models were selected as commonly used general-purpose sentiment analysis tools.

LLM Application

We applied GPT-4o to evaluate the sentiment of the posts as positive, neutral, or negative. This resulted in 28,889 total analyses, as some comments listed more than one medication. CIs were calculated for the proportion of positive comments and the proportion of negative comments using a binomial proportion CI.

Based on the high κ statistic (κ=0.73) of the LLM for predicting sentiment, we used GPT-4o to analyze sentiment in the full set of 27,272 comments mentioning the medications (Multimedia Appendix 3, Figure S1).

Ethical Considerations

This study analyzed publicly available, deidentified Reddit comments and does not constitute human subjects research as it involved secondary analysis of existing public data that cannot be linked to identifiable individuals.

Results

GPT-4o demonstrated superior performance across standard classification metrics (Table 1), with precision of 0.87, recall of 0.82, F_1-score of 0.82 (support-weighted across classes), and accuracy of 0.82, compared to VADER (precision: 0.42; recall: 0.38; F_1-score: 0.37; accuracy: 0.38) and DistilBERT (precision: 0.58; recall: 0.56; F_1-score: 0.56; accuracy: 0.56). The medications with the highest proportion of comments in the full dataset tagged as positive by GPT-4o (Figure 1) were upadacitinib (673/2107, 31.9%) and dupilumab (7724/25,926, 29.8%). Abrocitinib had a smaller percentage of negative sentiments than other medications (Figure 1). Dupilumab and upadacitinib had a high percentage of positive sentiment, which may suggest that many individuals are satisfied with the efficacy and safety of these medications.

Examples from the dataset illustrate the range of patient experiences. Positive comments expressed enthusiasm about treatment options, such as one patient's response to abrocitinib approval: "Just saw it was just approved! Calling my dermo on Monday!" Negative sentiment reflected disappointment with treatment outcomes, as seen in one dupilumab user's comment: "I thought Dupixent would provide relief too, but I'm still itchy and inflamed." Neutral comments predominantly involved informational exchanges, such as questions about accessing treatment and questions about clinical trial participation.

Table 1. In the initial subset of 84 manually evaluated comments, the large language model–based approach showed a remarkably stronger correlation with human judgment (κ=0.73) than distilbert-base-uncased-finetuned-sst-2-english (DistilBERT; κ=0.33) or Valence Aware Dictionary and Sentiment Reasoner (VADER; κ=0.06).

Model agreement with dermatologist judgment	GPT-4o	VADER	DistilBERT
Positive comments (n=26), n (%)	24 (92)	16 (62)	15 (58)
Neutral comments (n=41), n (%)	28 (68)	13 (32)	21 (51)
Negative comments (n=17), n (%)	17 (100)	3 (18)	11 (65)

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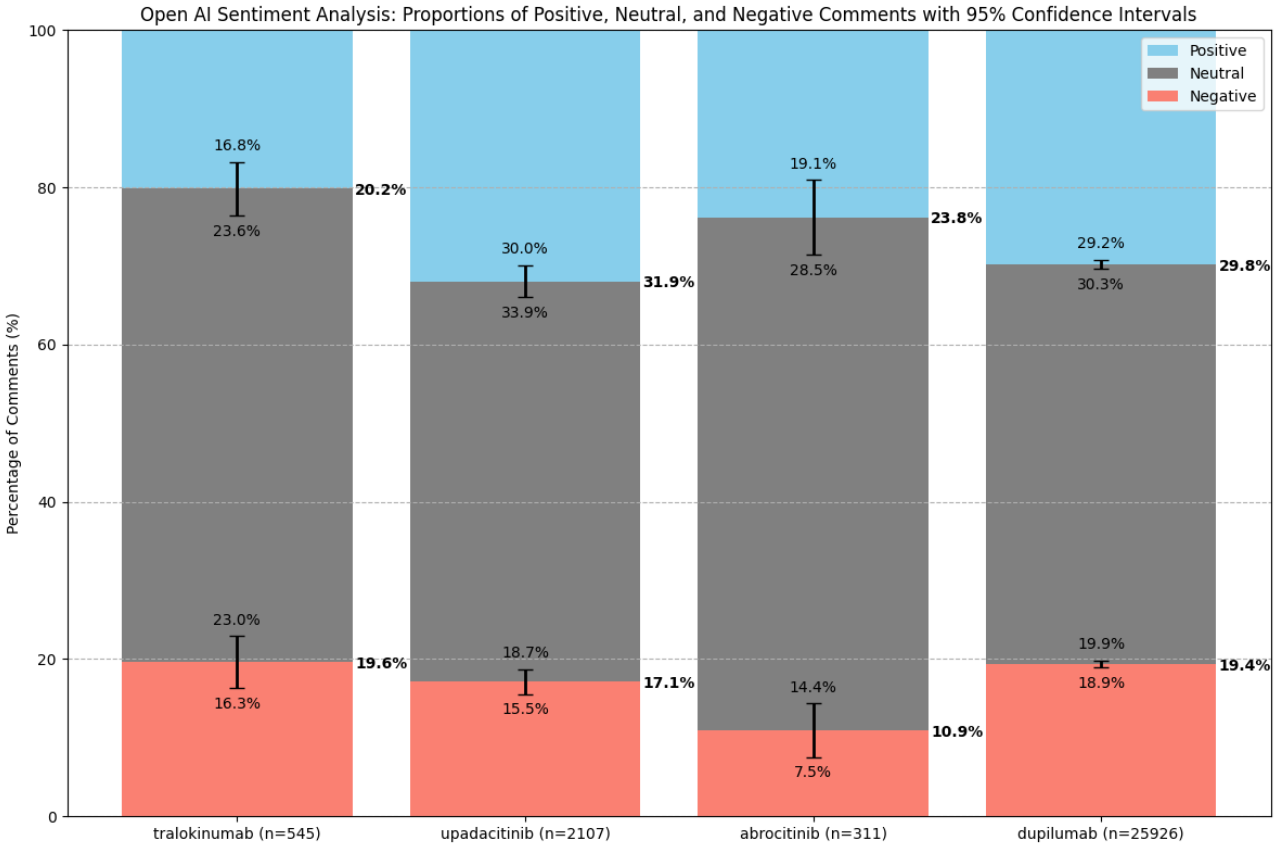
Figure 1. Bar chart showing the proportion of positive, neutral, and negative comments for each therapy, as identified by GPT-4o. CIs were calculated for the positive and negative bars using binomial proportion CIs.



Discussion

GPT-4o showed substantially better agreement with clinician judgment than traditional NLP methods when classifying patient sentiment in Reddit comments about AD treatments. The superior performance across all metrics establishes the feasibility of applying LLMs to extract patient perspectives from unstructured social media data. However, it is important to note that we excluded comments when the annotators disagreed to ensure a clear reference standard. This approach potentially biased the validation set toward straightforward sentiment examples and likely inflated the reported performance metrics, as the models were not tested on ambiguous, mixed-emotion, or context-dependent language, which is common in real patient discussions. Simple task-specific prompts applied to LLMs may yield more detailed insights than traditional NLP methods. LLMs offer advantages through basic zero-shot prompts that can be adapted for specific tasks like drug-specific sentiment analysis in medical discussions, whereas general-purpose sentiment analysis tools may struggle with medical terminology and context without additional training or customization. However, LLM-based approaches also have limitations, including computational costs and the need for careful prompt design to ensure reliable results. The predominance of neutral sentiment across all medications shows that many comments serve informational or question-asking purposes rather than expressing clear sentiment. Clinically, the observed higher positive sentiment for upadacitinib and dupilumab in our dataset may reflect patient satisfaction with these treatments, while the lower negative sentiment observed with abrocitinib could indicate fewer patient-reported concerns. Similar approaches could illuminate real-world perspectives on treatments for psoriasis and other chronic skin conditions where multiple therapeutic options exist. While our findings provide initial insights for AD treatment discussions, they also suggest potential broader applications for analyzing patient perspectives across medical fields. Future studies should expand beyond simple sentiment categorization to capture more nuanced patient experiences, including mixed sentiments, specific concerns about side effects, cost considerations, and conditional satisfaction with treatment. Additionally, future research should explore temporal trends in sentiment as medications gain market share and correlate social media sentiment with real-world evidence databases and patient registries.

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Conflicts of Interest

JY has served as a consultant, on the advisory board, or as an investigator, for the following: Abbvie, Arcutis, Astria, Dermavant, Hypothesis, Incyte, iRhythm, Johnson & Johnson, Kiehl's/L'Oreal, Leo, Lilly, National Eczema Association, O'Glacee, Pfizer, Sanofi, Smartpractice, Sol-Gel, and Soteri Skin. He also receives an honorarium from UptoDate.

Multimedia Appendix 1
List of dermatology subreddits used in the study and the total number of comments in each subreddit prior to January 1, 2024.
[DOCX File , 14 KB - formative_v10i1e78054_app1.docx]

Multimedia Appendix 2
Prompt used by GPT-4o to generate results.
[DOCX File , 13 KB - formative_v10i1e78054_app2.docx]

Multimedia Appendix 3
Flow chart displaying the system workflow for the study.
[PNG File , 132 KB - formative_v10i1e78054_app3.png]

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Abbreviations

AD: atopic dermatitis
API: application programming interface
DistilBERT: distilbert-base-uncased-finetuned-sst-2-english
LLM: large language model
NLP: natural language processing
VADER: Valence Aware Dictionary and Sentiment Reasoner

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Research Letter

Evaluating Spanish Translations of Emergency Department Discharge Instructions by a Large Language Model: Tool Validation and Reliability Study

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Abstract

When given a sample of 100 emergency department discharge instructions, Claude Sonnet, a large language model, produced accurate Spanish translations as evaluated by Spanish-speaking physicians and medical interpreters.

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KEYWORDS

artificial intelligence; machine learning; machine translation; language; disparities

Introduction

Language-concordant emergency department (ED) discharge instructions are an essential component of equitable care for patients who prefer a language other than English [1-4]. ED discharge instructions are often complex, combining standardized templates with personalized clinician-written text. In most cases, patients who prefer a language other than English still receive instructions in English [5]. When translation is attempted, clinicians will often informally rely on tools such as Google Translate that are not auditable, are generally not institutionally approved for clinical use, and have known performance limitations for long or technically detailed documents [6-8].

Large language models (LLMs) offer a promising auditable and institutionally governable approach to addressing this equity gap [6,9]. Because reproducibility in patient-care processes requires controlled models rather than open chat interfaces such as ChatGPT (OpenAI), institutions will need to deploy translation LLMs directly [6]. To our knowledge, no formative pilot studies have evaluated LLMs for translating ED discharge instructions. We therefore conducted a feasibility study using real ED discharge instructions to assess LLM translation performance in preparation for clinical implementation.

Methods

Study Design

This was a single-center feasibility study at an urban academic medical center. We iteratively developed a translation prompt using Claude Sonnet (version 3.5; Anthropic) accessed via protected health information (PHI)–compliant Amazon Web Services (Amazon), testing each version on batches of 10 to 20 randomly sampled free-text discharge instructions provided to ED patients between July 1 and December 31, 2024. Claude Sonnet 3.5 was selected as it balances cost, performance, and speed and was available in our PHI-compliant environment.

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Following prompt development, a team of independent evaluators (2 native Spanish-speaking physicians and 2 certified medical interpreters) reviewed a translated set of 100 randomly sampled free-text discharge instructions. We used a rubric adapted from prior studies consisting of a 5-point Likert scale across 5 domains (Multimedia Appendix 1) designed so that items rated a 3 or lower would be deemed substandard or unacceptable for use in a clinical setting [9]. Scores of 3 or lower in any domain required written explanation and were escalated for further review.

Our primary outcome was the proportion of discharge instructions that scored a 3 or lower in any one domain. The secondary outcome was the mean Likert score for each of the 5 domains stratified by reviewer type (interpreter vs physician). Descriptive analyses were performed in Python (version 3.11).

Ethical Considerations

This study was approved by the Beth Israel Deaconess Institutional Review Board (2024P000315). All abstracted data were deidentified.

Results

Of the 100 samples translated using the designed prompt (Multimedia Appendix 2), the mean Likert score ratings across samples by domain were as follows: 5.0 (95% CI 5.0-5.0) for completeness, 4.8 (95% CI 4.8-4.8) for fluency, 4.9 (95% CI 4.9-4.9) for meaning, 5.0 (95% CI 5.0-5.0) for severity, and 4.9 (95% CI 4.9-4.9) overall (Table 1; example translations are provided in Multimedia Appendices 3 and 4). One sample was given a score of 3 by a single reviewer in the domains of meaning and overall quality because the term “concussion” was translated as *conmoción cerebral* (full redacted translation in Multimedia Appendix 3). On adjudication, the translation was deemed clinically acceptable because the term *conmoción cerebral* is one of several translations of the term “concussion,” along with *concusión*.

Table 1. Interpreter and physician evaluator scores for Spanish translations (N=100).

Domain	Mean interpreter scores (95% CI)	Mean physician scores (95% CI)
Completeness	5.0 (5.0-5.0)	5.0 (5.0-5.0)
Fluency	4.8 (4.7-4.9)	4.8 (4.7-4.9)
Meaning	5.0 (5.0-5.0)	4.9 (4.9-4.9)
Severity	5.0 (5.0-5.0)	5.0 (5.0-5.0)
Overall	5.0 (5.0-5.0)	4.9 (4.9-4.9)

Discussion

In this feasibility pilot study, we found that Claude Sonnet produced clinically acceptable Spanish translations of ED discharge instructions. The one case flagged for further review reflected regional differences in Spanish vocabulary, an observation suggesting that future LLM prompts may incorporate patient nationality or dialects to improve comprehensibility.

Our results are in alignment with prior work on standardized discharge instructions as well as free-text instructions from pediatric settings [9,10]. Free-text instructions have the potential for grammatical errors, dictation and typographical errors, missing information, formatting issues, and use of overly complicated medical terminology that might compromise translation quality. A recent study (n=20) in the pediatric setting showed comparable quality between interpreter translation and the GPT-4o model from OpenAI [10]. Our study did not directly compare the LLM outputs to interpreter outputs, but instead included interpreters as reviewers.

Our single-center results may not apply to institutions that have different discharge instruction processes or lack access to PHI-compliant LLMs. Moreover, our study was limited to Spanish. Further testing will be needed to establish the safety of LLM translation before live implementation.

Acknowledgments

We would like to thank Shari Gold-Gomez, Ana Torres, Natalia Chilcote, and Marie Rodriguez for their contributions to this study. RCLB was affiliated with the Department of Pediatrics at Beth Israel Deaconess Medical Center at the time of the study and is currently affiliated with the Department of Pediatrics at Stanford University School of Medicine. DAI and ABM were affiliated with the Department of Medicine at Beth Israel Deaconess Medical Center at the time of the study. DAI is currently affiliated with the Department of Medicine at the University of California, San Francisco. ABM is currently affiliated with the Department of Medicine at Boston Medical Center.

Data Availability

The datasets generated or analyzed during this study are available from the corresponding author on reasonable request.

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Authors' Contributions

Conceptualization: ADH (lead), JACT (equal), RCLB (supporting)
Data curation: ADH
Formal analysis: ADH
Funding acquisition: ADH (lead), JACT (equal)
Investigation: DAI (lead), ABM (equal)
Methodology: ADH (lead), JACT (equal), AG (supporting), RCLB (supporting)
Project administration: ADH (lead), JACT (equal)
Resources: LAN (lead), RO (supporting)
Software: TF (lead), PA (supporting)
Supervision: ADH (lead), JACT (equal)
Writing—original draft: JACT
Writing—review and editing: JACT (lead), ADH (supporting)

Conflicts of Interest

None declared.

Multimedia Appendix 1
Interpretation rating guide.
[DOCX File , 17 KB - formative_v10i1e79676_app1.docx]

Multimedia Appendix 2
Large language model prompt.
[DOCX File , 15 KB - formative_v10i1e79676_app2.docx]

Multimedia Appendix 3
Translation with low score.
[DOCX File , 18 KB - formative_v10i1e79676_app3.docx]

Multimedia Appendix 4
Sample translation.
[DOCX File , 16 KB - formative_v10i1e79676_app4.docx]

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Abbreviations

ED: emergency department
LLM: large language model
PHI: protected health information

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Research Letter

Development and Validation of a Protein Electrophoresis Classification Algorithm: Tabular Data-Based Alternative

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Abstract

Serum protein electrophoresis (SPE) is routinely interpreted through visual assessment of electropherogram images by medical laboratory scientists. We introduce an efficient tabular data–based machine learning approach that directly leverages numerical SPE profiles, offering a robust and interpretable alternative to image-based deep learning methods.

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KEYWORDS

machine learning; CatBoost; serum protein electrophoresis; convolutional neural network; tabular data analysis; clinical informatics; diagnostic interpretation; computational efficiency

Introduction

Serum protein electrophoresis (SPE) is a key technique for separating and quantifying major serum protein fractions. Recent studies [1-3] have used convolutional neural networks (CNNs) to classify SPE results. Although these models have shown good performance, they primarily replicate the visual interpretation performed by medical laboratory scientists (MLS). Yet electropherograms are inherently numerical curves—that is, tabular data. This raises a simple question: why analyze an image when the analytical signal already exists as a numerical table?

Although image-based CNNs remain the dominant approach, we explicitly reframe SPE classification as a purely tabular learning problem concerning numerical SPE profiles. We evaluate this perspective by comparing our approach to the CNN-based study of Lee et al [1] by using the same dataset [4] and identical training-test splits, without additional data cleaning or hyperparameter tuning.

Methods

Input data were obtained by extracting numerical profiles from electropherograms and gel images as illustrated in Figure 1. Each image underwent grayscale conversion, cropping of the analytical region, interpolation into 150 point profiles, and min-max normalization. We computed SPE fractions by using local-minima detection (albumin, α-1, α-2, β, γ) and included demographic and biochemical variables from the dataset (sex, age, serum protein, serum albumin).

The 6 pathological categories defined in the reference dataset [4] were acute phase protein increase (74 cases), monoclonal gammopathy (264 cases), polyclonal gammopathy (244 cases), hypoproteinemia (249 cases), nephrotic syndrome (165 cases), and normal profiles (293 cases). Each case corresponds to a specific distribution pattern of proteins. These SPEs were collected in [1] between January 2018 and July 2019.

As recently emphasized [5,6], tree-based gradient boosting models remain the strongest performers for tabular data, often surpassing deep learning. After converting SPE images into numerical matrices, we reconfirmed this by evaluating XGBoost (extreme gradient boosting), TabPFN (tabular foundation

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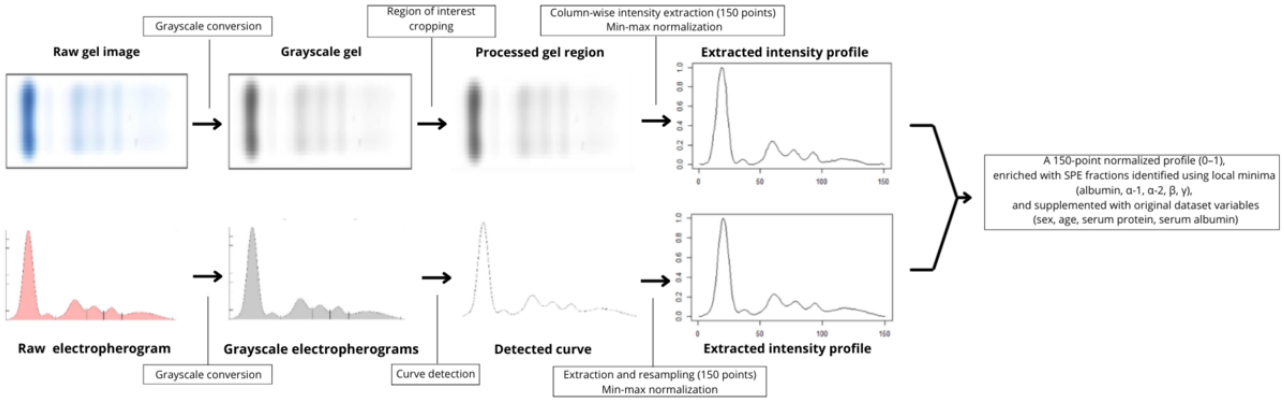
model), and CatBoost (categorical boosting). Without any hyperparameter optimization, CatBoost consistently produced the best results, especially on the gel-extracted data.

All results were obtained with the default CatBoost parameters from R implementation [7] running on R software (version 4.4.3; R Foundation for Statistical Computing) [8]. To enable a fair comparison to the CNN baseline in [1], we used the exact same training and test splits as in [1]: specifically, 10% of the cases were reserved for testing. However, the distribution of these cases differed between gel and electropherogram representations. Each experiment was repeated with 100 different seeds to estimate CIs for all performance metrics.

Figure 1. Preprocessing steps showing the tabular data extraction for both types of serum protein electrophoresis images.



Results

In total, 1289 SPE cases were available, each providing a gel and an electropherogram. However, the image quality varied substantially across samples: gel image heights ranged from 29 to 556 pixels (mean 81.9, SD 48.1) and widths from 96 to 876 pixels (mean 275, SD 129); electropherogram images heights ranged from 98 to 704 pixels (mean 410.7, SD 183.1) and widths from 250 to 1075 pixels (mean 649.6, SD 288.3) (Table 1).

Among the 20 polyclonal gammopathy cases in the gel test set, the sensitivity reported by [1] is 0.800, whereas our approach achieves a mean sensitivity of 0.941, with a 95% CI of 0.937-0.945 across 100 repeated runs. Except for monoclonal gammopathies where we, by contrast with [1], removed the unusual spike delimitation in our preprocessing step, the CatBoost-based tabular approach outperformed the CNN baseline across most categories. Weighted sensitivity, specificity, and F_1-scores were improved when using tabular data rather than images.

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Table 1. Sensitivities, specificities, and F1-scores for protein electropherograms and gels, comparing the original model with the average performance of our model over 100 repeated runs, stratified by pathology, with weighted averages computed over the entire dataset.

	Sens[a] Ref[b] Electro[c]	Sens CatBoost[d] Electro	Spec[e] Ref Electro	Spec CatBoost Electro	F_1-score Ref Electro	F_1-score CatBoost Electro	Sens Ref Gel	Sens CatBoost Gel	Spec Ref Gel	Spec CatBoost Gel	F_1-score Ref Gel	F_1-score CatBoost Gel
Acute phase protein (n[f]=5 or 9)	*0.600* [g]	0.594 (0.587-0.601)	0.951	*0.990* (0.990-0.991)	0.429	*0.648* (0.640-0.655)	0.222	*0.441* (0.437-0.445)	0.882	*0.993* (0.992-0.994)	0.160	*0.576* (0.571-0.582)
Monoclonal gammopathy (n=29 or 24)	*0.862* [h]	0.690 (0.689-0.691)	*1.000* [h]	0.984 (0.983-0.986)	*0.926* [h]	0.792 (0.790-0.794)	*0.792*	0.658 (0.650-0.665)	0.981	*0.998* (0.997-0.999)	*0.844*	0.788 (0.783-0.793)
Polyclonal gammopathy (n=22 or 20)	0.818	*1.000* (1.000-1.000)	*0.981*	0.978 (0.977-0.979)	0.857	*0.950* (0.947-0.953)	0.800	*0.941* (0.937-0.945)	0.917	*0.983* (0.982-0.984)	0.711	*0.925* (0.923-0.928)
Hypoproteinemia (n=26 or 25)	0.846	*0.878* (0.874-0.881)	0.853	*0.974* (0.973-0.975)	0.698	*0.887* (0.884-0.889)	0.520	*0.831* (0.827-0.834)	0.893	*0.898* (0.896-0.899)	0.531	*0.738* (0.735-0.740)
Nephrotic syndrome (n=16 or 21)	0.687	*0.853* (0.845-0.861)	*0.991*	0.0.954 (0.953-0.955)	*0.786*	0.783 (0.778-0.788)	0.238	*0.699* (0.692-0.706)	*0.972*	0.944 (0.942-0.945)	0.345	*0.704* (0.698-0.709)
Normal (n=30 or 29)	0.667	*0.920* (0.914-0.925)	*0.949*	0.939 (0.939-0.939)	0.727	*0.868* (0.865-0.870)	0.759	*0.935* (0.932-0.937)	0.879	*0.925* (0.923-0.927)	0.698	*0.854* (0.851-0.856)
Weighted scores	0.773	*0.852* (0.850-0.854)	0.952	*0.967* (0.966-0.967)	0.784	*0.849* (0.848-0.851)	0.602	*0.790* (0.788-0.792)	0.922	*0.950* (0.950-0.951)	0.599	*0.786* (0.784-0.788)

[a]Sens: sensitivity.

[b]Ref: reference.

[c]Electro: electropherogram.

[d]CatBoost: categorical boosting.

[e]Spec: specificity.

[f]The values of n correspond to the number of test samples for electropherograms and gels, respectively. Values in parentheses report the 95% CIs of our model.

[g]Italicized values indicate the best-performing model for each metric and category.

[h]Denotes the use of unusual spike delimitation on all electropherograms of monoclonal gammopathies.

Discussion

The main limitation appears in the monoclonal gammopathy class [9] on electropherograms, for which CNNs in [1] report higher performance. A plausible explanation lies in the structure of the original dataset: in [4], electropherograms corresponding to monoclonal gammopathies systematically contain manually drawn spike delimitations added by MLS during routine interpretation. These annotations are specific to this class and may therefore serve as highly discriminative visual cues for the convolutional model, artificially boosting its performance. In contrast, this dataset bias is removed from our tabular dataset using our preprocessing pipeline. It removes all such manual markings to retain a purely signal-based representation, thereby eliminating visual hints that CNN may have leveraged in the original setting. Despite this bias, our framework achieves stable and homogeneous performance across all pathological categories and does not show a specific degradation for monoclonal gammopathies.

Our CatBoost results were obtained using the default parameters, without any form of tuning. This choice was intentional: it demonstrates that even an entirely nonoptimized tabular model already outperforms the CNN baseline on most categories, even on a dataset with several low quality images. Consequently, additional improvements are highly plausible. More extensive hyperparameter optimization such as tuning tree depth, learning rate, and boosting iterations could further enhance performance. Likewise, hybrid approaches that enrich numerical profiles with peak-shape descriptors or selectively integrate localized image-based features may help address the specific challenges posed by narrow M-spikes in monoclonal gammopathies.

Reframing SPE classification as a tabular learning task leads to immediate performance improvements, even before any optimization. Beyond accuracy, this approach offers several practical advantages. First, the approach is computationally efficient: CatBoost trains rapidly on a standard laptop and requires no graphics processing unit, and it integrates easily into routine workflows. Second, this approach is readily generalizable, especially with modern SPE analyzers that already store raw numerical curves internally. It means the classification

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model can be applied directly to these exported values without any image-processing pipeline. Finally, tree-based models offer greater interpretability, allowing laboratories to analyze feature importance and understand which parts of the curve contribute to the classification—a key requirement for clinical use. Moreover, unsurprisingly, this framework is image type agnostic: when exchanging the train-test split for electropherogram and gel, performance remains consistent. This confirms that the improvement comes from the change in data structure rather than from the image source itself.

In summary, transitioning from image-based deep learning to tabular data-based machine learning increases performance and improves robustness, interpretability, reproducibility, and ease of deployment. This redefinition of the SPE classification problem, unconventional for practitioners yet natural for computational systems, provides a compelling alternative to CNN-based approaches and a promising basis for clinically reliable automation.

Acknowledgments

Generative artificial intelligence tools were used to assist in the development and refinement of the computational code employed in this study. Specifically, ChatGPT (OpenAI) was used under full human supervision during several nondecisional stages of the coding process (Multimedia Appendix 1).

Funding

PF-T is a partner in B2A, and the other authors are employed by B2A.

Data Availability

All data used in this study are publicly accessible through the Harvard Dataverse repository, as released by Lee [4].

Conflicts of Interest

None declared.

Multimedia Appendix 1
Use of generative artificial intelligence for code development.
[DOCX File , 15 KB - formative_v10i1e83124_app1.docx]

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Abbreviations

CatBoost: categorical boosting
CNN: convolutional neural network
MLS: medical laboratory scientists
SPE: serum protein electrophoresis

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TabPFN: tabular foundation model
XGBoost: extreme gradient boosting

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Research Letter

Feasibility and Acceptability of Just Breathe, A Novel Handheld Mindful Breathing Device, for Postpartum Stress: Pilot, Single-Arm Pre-Post Study

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Abstract

Among newly postpartum people, the novel Just Breathe guided breathing device showed high user satisfaction scores and self-perceived reductions in stress, although the Cohen d effect on heart rate variability and stress or anxiety symptoms as measured by validated psychometric scales was minimal.

(JMIR Form Res 2026;10:e85321) doi:10.2196/85321

KEYWORDS

postpartum stress; postpartum anxiety; heart rate variability; digital health; mindful breathing

Introduction

Over 1 in 5 birthing people are diagnosed with perinatal mood or anxiety disorders, and many who do not meet diagnostic thresholds for these conditions experience stress or anxiety that negatively impacts infant bonding or decrease breastfeeding rates [1-3]. Mindful breathing can improve mood and stress symptoms and increase heart rate variability (HRV) [4]. Defined as the beat-to-beat variability in heart rate, HRV is inversely associated with symptoms of depression and stress and can be assessed using wrist monitors [5]. A novel device, Just Breathe, incorporates airflow-guided cues that optimize adherence to evidence-based mindful breathing patterns shown to reduce stress symptoms [6]. Just Breathe is lifted to the user's slightly opened lips, and it directs gentle airflow into the mouth to prompt inhalation and on the upper lip to cue exhalation over a 3-minute cycle (Figure S1 in Multimedia Appendix 1); it is yet to be examined in clinical settings. Our primary aim was to assess Just Breathe's feasibility, acceptability, and perceived effectiveness among newly postpartum people. Our secondary, exploratory aim was to explore its effects on HRV, anxiety symptoms, and perceived stress.

Methods

Participants were recruited at a tertiary care women's hospital. Eligible patients were English-speaking, ≥18 years old, and admitted to the postpartum unit during their childbirth hospitalization. Patients were excluded if incarcerated or if their infant required neonatal intensive care unit (NICU) admission. After providing consent, participants completed demographic surveys and the Perceived Stress Scale-4 (PSS-4) [7] and Generalized Anxiety Disorder-7 (GAD-7) [8] scale to assess for symptoms of stress and anxiety, respectively. A research

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staff member applied a Kairos Biostrap wrist monitor, a commercially available high-grade wearable that uses infrared photoplethysmography to assess HRV, measured in root mean square of successive differences. The wrist strap monitor was connected to a smartphone app, Vital Science, which summarizes HRV during the 3-minute cycle. After the participant rested in her hospital bed or chair for 5 minutes without interruption, one Vital Science cycle was conducted before Just Breathe use, and one Vital Science cycle was conducted while the participant used Just Breathe for 3 minutes. Participants were provided a Just Breathe device and encouraged to use it at least 3 times for up to 24 hours. The day after consent, a research staff member repeated the same procedures to assess HRV.

Participants then completed PSS-4, GAD-7, system usability scale (SUS; assesses patient experience with ease of use), Client Satisfaction Questionnaire (CSQ; assesses patient satisfaction with device), and the Decisional Regret Scale (assesses regret after making a health-related decision). To preserve validity and reliability of the surveys while ensuring they pertained to Just Breathe, SUS and CSQ were minimally modified by replacing the words “system” and “service,” respectively, with the words “Just Breathe device.” Descriptive statistics (means, SD, and percentages) compared initial and final HRV assessments and psychometric survey results. For HRV, GAD-7, and PSS-4, effect sizes for pre-post changes were calculated using paired Cohen *d*. Hypothesis testing was not performed due to the sample size. This study was approved by the institutional review board at Women and Infant Hospital of Rhode Island before study initiation (WIH 24-0049; approved on October 14, 2024). Informed consent was obtained, all data were de-identified, and participants could opt out per their preference. Those who completed the study received a US $5 gift card.

Results

Among 46 consented participants, 40 completed all survey measures and were included. Participants were racially, ethnically, and socioeconomically diverse: 48% (19/40) were non-White or Hispanic and 40% (16/40) had federal health insurance. Among the 40 study participants, 83% (n=33) were mostly or very satisfied with Just Breathe, and most (n=30, 75%) believed the device met their needs. In terms of perceived effectiveness, 88% (n=35) felt that Just Breathe helped improve their symptoms of stress or anxiety, and 85% (n=34) would recommend the device to a friend who was pregnant or newly delivered (Table 1).

Regarding exploratory analyses on psychometric outcomes (Table 2), although Just Breathe use was associated with a 25% increase in mean HRV, Cohen *d* analyses suggested a minimal effect of Just Breathe on HRV, GAD-7 scores, and PSS-4 scores.

Table 1. Participant outcomes: patient-reported questions (N=40).

Question	Value, n (%)
How satisfied are you with the amount of information Just Breathe provided?	
Dissatisfied/indifferent	7 (17)
Mostly/very satisfied	33 (83)
To what extent has Just Breathe met your needs?	
Only a few/no needs met	10 (25)
Most/all needs met	30 (75)
Did Just Breathe help you to deal more effectively with symptoms of stress or anxiety? Answer: Yes	35 (88)
If a friend were pregnant or newly delivered, would you recommend Just Breathe? Answer: Yes	34 (85)
If you were able to, would you use Just Breathe again? Answer: Yes	29 (73)

Table 2. Participants’ psychometric outcomes (N=40).

Measure	Before Just Breathe, mean (SD)	After Just Breathe, mean (SD)	Change pre/post Just Breathe[a] (%)	Paired Cohen *d*
Heart rate variability (ms)	36.0 (19)	39 (18)	26	0.21
Perceived Stress Score-4	7.9 (2.3)	7.4 (2.5)	–8	–0.18
Generalized Anxiety Disorder-7	4.3 (3.7)	4.7 (3.8)	0.4	0.21

[a]For the pre/post change, no absolute value could be calculated, as only the change in mean (SD) was evaluated.

Discussion

Among newly postpartum people, Just Breathe was feasible and acceptable as a stress- and anxiety-reduction intervention, with high satisfaction ratings and strong user perception of benefit. Our exploratory analyses showed a minimal effect on HRV or psychometric outcomes after using Just Breathe for less than 24 hours. This could be because the device had no measurable effect or due to study methodology. Specifically, the study occurred in the early postpartum period over a 24-hour time period. Postpartum hospitalization is characterized by nursing- and infant-derived sleep interruption, delivery-related

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pain, and hormonal fluctuations that may increase stress and anxiety, thereby reducing Just Breathe's effect. Prior studies that demonstrated an association between mindful breathing and improved postpartum mood or stress symptoms required participants to use mindful breathing for up to 8 weeks [9,10]. Thus, the lack of a strong signal in our psychometric outcomes may be due to a short study period within a backdrop of profound physiologic and psychologic adjustments. This study's strengths include using both physiological and psychological measures, high participant retention, and inclusion of a racially, ethnically, and socioeconomically diverse study population. Limitations include the single-arm design, small sample size, short study duration, and exclusion of non-English speaking people and those whose infants were in the NICU, who are at higher rates of having stress or anxiety symptoms. Just Breathe is a novel device that is acceptable and viewed as effective. We did not assess the frequency that participants used Just Breathe between enrollment and study conclusion, which can be considered a major limitation that precludes the analysis of a dose-response relationship, thereby limiting the conclusions that could be drawn on Just Breathe's effect. In conclusion, a randomized controlled trial using Just Breathe as a study intervention for weeks, if not months, is needed to more accurately determine whether this promising device can improve perinatal physiologic regulation and symptoms of stress and anxiety after childbirth.

Acknowledgments

Artificial intelligence was not used in any capacity to generate or edit this manuscript.

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Conflicts of Interest

AKL served as a paid consultant for Sonio AI in 2024. The company that created Just Breathe provided 10 free Just Breathe devices, one Kairos Biostrap wrist monitor, and access to the Vital Science smartphone app for this study but was not otherwise engaged with the research. Specifically, the design, analysis, or reporting of study findings all occurred independently with the investigative team without any input from any technology company.

Authors' Contributions

Conceptualization: AKL (lead), NKA (equal), MHB (supporting)
Data curation: SDN (lead), JLR (equal)
Formal analysis: TLJ (lead)
Funding acquisition: n/a
Investigation: SKS (lead), LS (equal), KB (supporting), JRL (supporting)
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Supervision: AKL (lead), NKA (equal)
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Visualization: TLJ (lead), KB (supporting)
Writing – original draft: SKS (lead), AKL (equal)
Writing – review & editing: NKA (lead), MHB (equal), SDN (supporting), LS (supporting), TLJ (supporting), JLR (supporting), CFW (supporting), KB (supporting)

Multimedia Appendix 1
Diagram of the Just Breathe device mouthpiece and airflow haptic system.
[DOCX File , 293 KB - formative_v10i1e85321_app1.docx]

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Abbreviations

CSQ: Client Satisfaction Questionnaire
GAD-7: Generalized Anxiety Disorder-7
HRV: heart rate variability
NICU: neonatal intensive care unit
PSS-4: Perceived Stress Scale-4
SUS: system usability scale

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Research Letter

Exploring Feature Priorities and User Needs in Developing Virtual Study Assistants

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Abstract

This formative research explored health science researchers' perspectives on the development of an artificial intelligence–based virtual study assistant and identified 8 potential features and their priorities.

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KEYWORDS

virtual study assistant; user preference; user need; user-centered design; generative artificial intelligence

Introduction

With the proliferation of generative artificial intelligence (GenAI) tools in recent years, many research teams are exploring their potential applications in the health care field, including medical education, information provision, and disease diagnosis [1,2]. For example, GenAI tools have been used to support health care research training [3]. One underexplored application of GenAI is an AI-based virtual study assistant (VSA), which we define as a conversational and agentic technology capable of supporting participant-facing tasks in clinical research, such as screening, providing information, and facilitating consent. The purposes of this formative research were to (1) explore health science researchers' perspectives on the development of an AI-based VSA and (2) identify potential features and their priorities for future AI-based VSA prototype development.

Methods

Study Design

Participants were recruited from the University of Washington (UW) and consisted of research investigators and study staff with at least 2 years of experience in human subjects research. A snowball approach was used for recruitment. The individuals first completed a questionnaire (Multimedia Appendix 1) collecting information on their research experience and prior experience with GenAI. One-hour focus groups were conducted to identify a list of potential features for AI-based VSA guided by semistructured questions (Multimedia Appendix 2) about key features and participants' perceptions related to their use. In the final stage, participants completed follow-up surveys (Multimedia Appendix 3) to assess feature acceptability and preference across studies of varying risk levels.

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Quantitative data were analyzed using Microsoft Excel. Descriptive statistics, including frequency and mean (SD), were calculated. Thematic analysis was used to identify potential features in the qualitative interview data [4]. Two researchers coded the transcripts and identified themes. The prioritization of preferred features was evaluated using Borda Count, a ranking-based scoring method.

Ethical Considerations

This study was deemed exempt by the University of Washington Institutional Review Board (#21197) since it involved only minimal risk interviews and surveys. Informed consent was obtained from all participants, and data were recorded without identifiable information. All participants received a $10 gift card for completing the survey and a $25 gift card for participating in the focus group.

Results

A total of 14 respondents completed the pre–focus group survey. Among them, 10 took part in focus groups (n=5 per group). The others could not attend due to scheduling conflicts. Following the focus groups, a follow-up survey was distributed to all pre–focus group survey respondents, and 11 completed it. Focus group participants mostly included faculty members (n=6) or student research assistants (n=3). Participant demographics and work experience are presented in Table 1.

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Table 1. Demographics and research experience by study activity (with overlapping participants).

Characteristics	Pre–focus group survey (n=14), n	Focus group (n=10), n	Follow-up survey (n=11), n
Gender			
Female	11	8	9
Male	2	1	1
Nonbinary	1	1	1
Race			
Asian	2	1	2
Black or African American	1	1	0
White	9	7	7
More than one racial group	1	1	1
Prefer not to answer	1	0	1
Ethnicity			
Hispanic or Latino	1	0	1
Not Hispanic or Latino	13	10	10
Job title			
Research scientist/principal investigator	8	5	5
Interventionist	1	1	1
Research coordinator/assistant/consultant	4	3	4
Other	1	1	1
Education			
Bachelor's degree or other 4-year college degree	1	1	1
Master’s degree	6	5	6
Doctoral degree	7	4	4
Work experience			
2-3 years	3	2	3
5-6 years	1	1	1
6-7 years	1	1	0
7-8 years	2	1	2
9-10 years	3	1	3
10 years	4	4	2
Types of human subjects studies[a]			
Interventional studies such as clinical trials	9	6	8
Dissemination and implementation trials	5	4	4
Observational studies with biospecimens or behavioral testing	7	6	5
Observational studies with surveys only	9	5	7
Qualitative studies	12	8	10
Secondary data analyses, electronic medical record studies, or similar	4	3	2
Remote study experience			
Yes	10	7	8
No	4	3	3
Risk category experience[a]			
More than minimal risk (full institutional review board review)	—[b]	—	5

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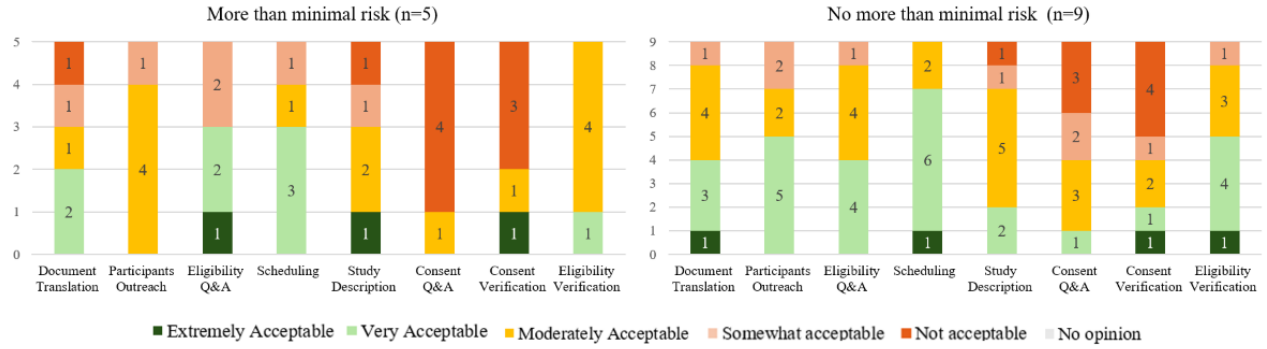
Characteristics	Pre–focus group survey (n=14), n	Focus group (n=10), n	Follow-up survey (n=11), n
No more than minimal risk and exempt	—	—	9

[a]Multiple responses were allowed.

[b]Not applicable.

Eight potential features for the AI-based VSA were identified from focus group responses, presented in order of most acceptable to least: (1) translating study documents into other languages, (2) contacting a potential participant to gauge their interest, (3) asking and answering questions about eligibility for the study, (4) scheduling participant interactions, (5) describing the study to participants, (6) answering participant questions about the consent form or study participation, (7) verifying participant understanding of consent, and (8) verifying eligibility. Most features were generally considered acceptable. However, those related to answering participant questions about the consent form or study participation, as well as consent verification, received lower levels of acceptance, particularly in studies involving more than minimal risk (Figure 1).

Figure 1. Acceptability of artificial intelligence–based virtual study assistant features among participants completing follow-up survey, by risk level of human subjects research. Q&A: questions and answers.



Discussion

Our findings reveal promising directions for the development of AI-based VSA for human subjects research. Among the potential features, translating study documents into other languages was rated as the most preferred. Features related to participant outreach and eligibility-related questions also ranked relatively high, indicating preferences for tools that reduce administrative burden and improve participant communication. One previous study [5] explored the use of GenAI for translating medical or public health–related documents in the health care sector. Specifically, postediting machine translation was on average 14% faster than translating from the beginning. Only a small proportion of outputs (11%-16%) required no human edits. Approximately half of the words needed to be edited [5]. These findings revealed both the potential and the limitations of such tools in this domain. Future research regarding VSA development could explore the linguistic and cultural considerations. There is limited research on using GenAI for participant outreach and scheduling; however, if such features were to be designed, considerations regarding data privacy and management would be necessary. Furthermore, these features entail agentic abilities beyond conversation, such as cross-checking participant and staff schedules and creating calendar appointments, which may involve greater potential for error than conversation alone. Some specific features such as consent verification or addressing questions regarding the consent form may require careful implementation and oversight, given the crucial ethical implications of informed consent. These options generated the highest rates of “not acceptable” responses, particularly among respondents conducting research in the “more than minimal risk” category.

This study identified potential features and offered preliminary observations regarding the development of a prototype. Limitations include the small, single institution sample, which may reduce the generalizability of findings, and the administration of a follow-up survey to all participants, that is, those who attended focus groups and those who did not, as responses from attendees may be biased by having attended a focus group. More formative work may be required to further validate and refine these findings, including engaging diverse potential participant populations and conducting iterative prototype development and usability assessments.

Acknowledgments

We are grateful to all the participants who took part in this study. No generative artificial intelligence was used in writing this manuscript.

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Conflicts of Interest

None declared.

Multimedia Appendix 1
Pre–focus group survey.
[PDF File (Adobe PDF File), 50 KB - formative_v10i1e86945_app1.pdf]

Multimedia Appendix 2
Semistructured questions.
[PDF File (Adobe PDF File), 83 KB - formative_v10i1e86945_app2.pdf]

Multimedia Appendix 3
Follow-up survey.
[PDF File (Adobe PDF File), 72 KB - formative_v10i1e86945_app3.pdf]

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Abbreviations

AI-based VSA: artificial intelligence–based virtual study assistant
GenAI: generative artificial intelligence
UW: University of Washington

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Research Letter

Prediction of Prefecture-Level Subjective Well-Being in Japan by Using Google Trends and Socioeconomic Data: Machine Learning Model Development and Validation Study

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Abstract

Incorporating prespecified Google Trends indicators into leakage-controlled stacked-ensemble models improved a 2025 holdout prediction of subjective well-being by using 2022-2025 data from Japan's 47 prefectures, reducing the mean squared error from 0.0050 to 0.0045.

(JMIR Form Res 2026;10:e88696) doi:10.2196/88696

KEYWORDS

infodemiology; infoveillance; subjective well-being; Google Trends; Japan; machine learning; stacked ensemble; forecasting; socioeconomic factors; digital trace

Introduction

Subjective well-being (SWB) increasingly complements traditional economic indicators in evidence-based policymaking. Although Japan's Digital Agency has published annual prefecture-level SWB aggregates (0-10 scale) since 2022 [1], the low reporting frequency limits real-time monitoring and timely policy intervention. Infodemiology involves the study of online information patterns, while infoveillance applies these patterns for health and social monitoring [2]. Notably, the Google Trends search activity can be leveraged as a demand-side infoveillance signal for evaluating prefecture-level SWB.

Google Trends signals have been linked to well-being and SWB nowcasting [3,4], but these data streams can exhibit high volatility at finer geographic scales [5]. Digital-trace SWB studies have also leveraged social media streams (eg, Twitter) [6]. In Japan, prefecture-level keyword queries are often limited by inadequate information [7]; we hypothesized that prespecified indicators using standardized categories and topic IDs can be implemented to improve reproducibility.

Herein, we extend prior digital-trace SWB nowcasting work by focusing on subnational (prefecture-level) prediction in Japan by using prespecified Google Trends category/topic identifiers to improve reproducibility and by evaluating performance under a strict temporal holdout year (2025). This study aims to evaluate whether prespecified Google Trends indicators provide incremental predictive value for prefecture-level evaluative SWB in Japan beyond socioeconomic and temporal predictors by using leakage-controlled stacked-ensemble modeling and strict 2025 holdout validation.

Methods

This study uses publicly available, aggregated, nonidentifiable prefecture-level indicators; therefore, ethical review was not required.

We analyzed a prefecture-year panel (47 prefectures, 2022-2025) of published prefecture-year mean evaluative SWB (0-10) from the Digital Agency's opt-in online survey [1] with leakage-controlled walk-forward stacked-ensemble modeling and a strict 2025 holdout (training 2022-2024, n=141 prefecture-years; holdout 2025, n=47).

Predictors were evaluated in three nested stages: stage 1 included socioeconomic indicators [8], stage 2 added temporal controls, and stage 3 incorporated Google Trends features. All variables are listed in Table S1 of Multimedia Appendix 1.

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Model specification and validation reporting items aligned with TRIPOD+AI (Transparent Reporting of a Multivariable Prediction Model for Individual Prognosis Or Diagnosis with Artificial Intelligence) are summarized in Table S2 of Multimedia Appendix 1.

We prespecified 25 Google Trends category/topic series by mapping OECD (Organization for Economic Co-operation and Development) well-being domains [9] to Google Trends categories and topic IDs and retrieving indices via PyTrends (Table S3 in Multimedia Appendix 1).

Trends were summarized using principal component analysis (>90% variance), and the outcomes and descriptive comparability summaries are presented in Tables S4 and S5 of Multimedia Appendix 1.

For interpretability, we ranked raw series by association with the first Trends component (principal component 1) and refit ElasticNet and extreme gradient boosting (XGBoost) by using the top 8 series.

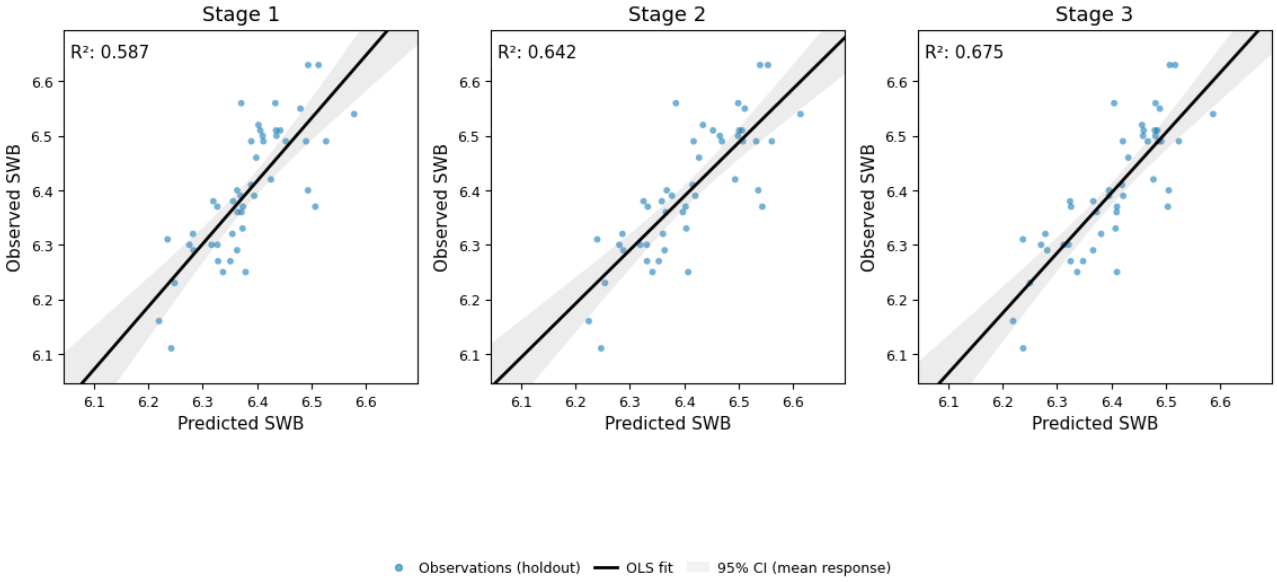
For validation, walk-forward stacking (2022→2023, 2022-2023→2024) was employed with within-window preprocessing and tuning to avoid leakage; we report adjusted R^2 and mean squared error (MSE) with 95% bootstrap CIs for 2025 (B=4000), following TRIPOD+AI guidance [10].

Algorithm S1 (Multimedia Appendix 2) and the analysis repository (Multimedia Appendix 3) support the replication.

Results

On the 2025 holdout, the adjusted R^2 increased from 0.587 (stage 1) to 0.642 (stage 2) and 0.675 (stage 3), and the MSE decreased from 0.0050 to 0.0045 (Figure 1). The bootstrap 95% CIs for the adjusted R^2 overlapped.

Figure 1. Observed vs predicted 2025 prefectural subjective well-being (SWB) at stages 1-3. OLS: ordinary least squares.



Sensitivity refits using the 8 principal component 1–aligned raw series did not improve performance compared with the principal component analysis–based Trends specification (Table S6 in Multimedia Appendix 1).

Calibration yielded a slope of 1.10 (95% CI 0.88-1.33) and an intercept of −0.67 (95% CI −2.12 to 0.78) (Figure 2). Furthermore, the prefecture-level MSE ranged from 0.000003 to 0.0257 (median 0.0022, n=47), with no strong regional bias (Figure S1 in Multimedia Appendix 4).

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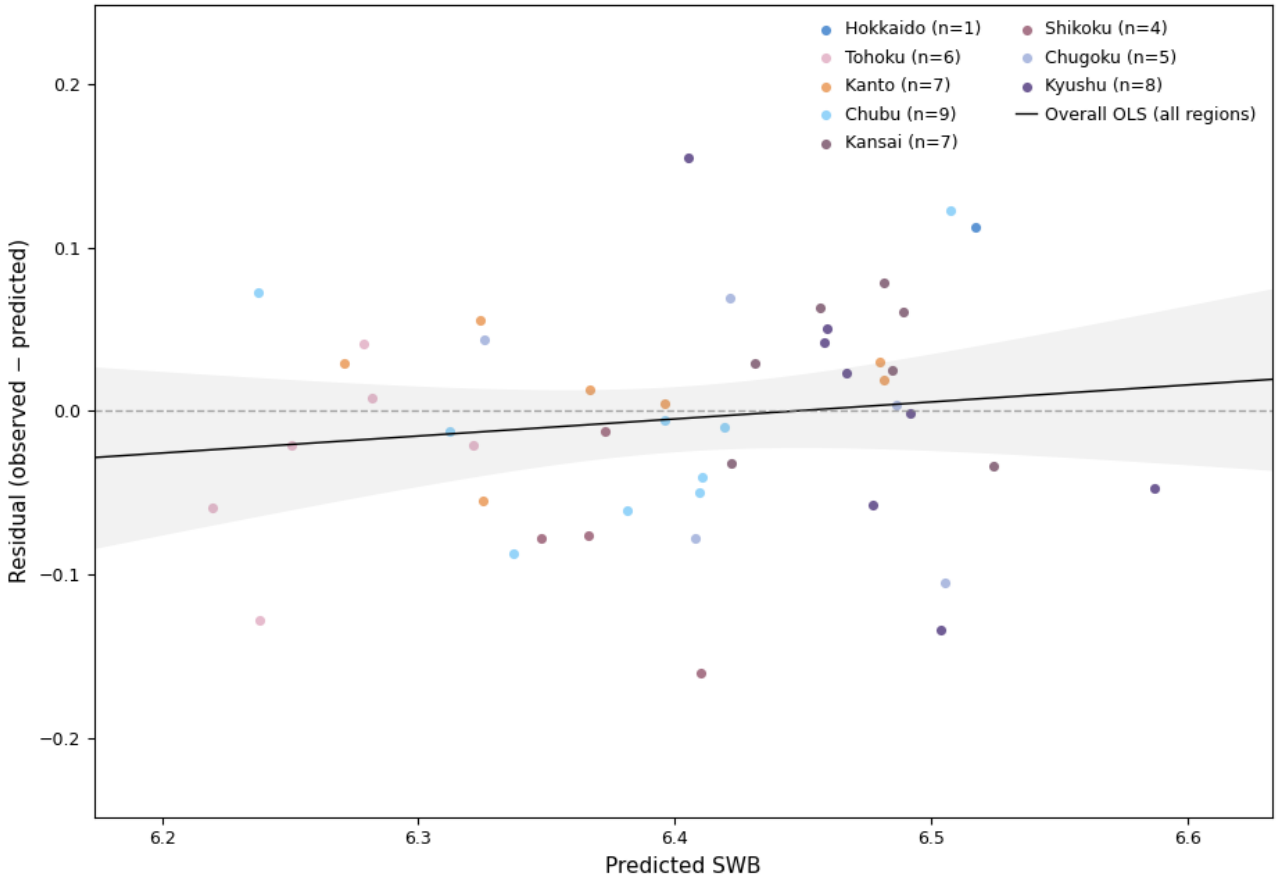
Figure 2. Residuals vs predicted 2025 subjective well-being (SWB) for the final model, by region. OLS: ordinary least squares.



Discussion

Adding prespecified Google Trends components to socioeconomic and temporal predictors modestly improved the strict 2025 holdout prediction (adjusted R^2=0.642-0.675, MSE=0.0050-0.0045). This result demonstrates the incremental value of search-derived indicators as an exploratory signal for prefecture-level SWB infoveillance [2].

Compared with national SWB nowcasting using Google Trends [4], subnational prediction with annual outcomes may be limited by lower signal-to-noise ratios. Standardized categories and topic IDs were exploited to improve reproducibility and reduce sparsity relative to keyword queries [7]. The dominant component reflected a broad lifestyle/mobility/consumption factor, and the ranked categories are provided in Table S6 of Multimedia Appendix 1 for hypothesis-driven follow-up. Note that these outputs should be treated as a cautious predeployment screening signal rather than a ranking or policy decision tool.

Limitations include the short panel (4 years), the ecological outcome, and reliance on a nonprobability opt-in survey with limited publicly disclosed quality-control details and uncertain year-to-year comparability (Tables S4 and S5 in Multimedia Appendix 1). Because only aggregated prefecture-year means are publicly available, we could not independently assess instrument reliability or test measurement invariance across years. Google Trends indices are normalized and may be sampled, and unmeasured time-varying factors may confound associations. Accordingly, findings should not be interpreted as causal.

Under leakage-controlled temporal validation, Google Trends signals added modest predictive value for prefecture-level evaluative SWB in Japan. Future work should test higher-frequency outcomes, lagged designs, and external validation to clarify when such signals are the most informative.

Acknowledgments

We used generative artificial intelligence tools under full human supervision for code optimization.

Data Availability

All data are publicly available (Digital Agency [1], e-Stat [8], Google Trends); the code and materials are described in Multimedia Appendix 4.

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Authors' Contributions

Conceptualization, data curation, formal analysis: KK, SK
Visualization, writing – original draft: KK
Methodology, software, validation: KK, HH
Writing – review and editing: HH, SK
Supervision: SK
All authors approved the final manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Detailed variable definitions, TRIPOD-AI reporting checklist, Google Trends identifiers, subjective well-being outcome transparency documentation, year-to-year comparability summaries, and sensitivity analyses.
[PDF File (Adobe PDF File), 536 KB - formative_v10i1e88696_app1.pdf]

Multimedia Appendix 2
Algorithm S1 (walk-forward stacking pseudocode): step-by-step pseudocode for the leakage-controlled walk-forward training and evaluation pipeline, including preprocessing, feature engineering, and stacked-ensemble integration for predicting prefectural subjective well-being.
[PDF File (Adobe PDF File), 135 KB - formative_v10i1e88696_app2.pdf]

Multimedia Appendix 3
Full analysis repository (code and project root): this archive contains the full project root, including source code, configuration files, and the analysis pipeline used to reproduce the walk-forward stacked-ensemble models for prefectural subjective well-being prediction.
[ZIP File (Zip Archive), 484 KB - formative_v10i1e88696_app3.zip]

Multimedia Appendix 4
Prefecture-level mean squared error for 2025 holdout.
[PNG File , 57 KB - formative_v10i1e88696_app4.png]

Multimedia Appendix 5
TRIPOD-AI–oriented reporting checklist. This checklist maps key aspects of the study (data sources, predictors, outcomes, model evaluation, robustness, fairness, reproducibility, and intended use) to TRIPOD-AI items to support transparent reporting of the prediction model.
[PDF File (Adobe PDF File), 100 KB - formative_v10i1e88696_app5.pdf]

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Abbreviations

MSE: mean squared error
OECD: Organization for Economic Co-operation and Development
SWB: subjective well-being
TRIPOD+AI: Transparent Reporting of a Multivariable Prediction Model for Individual Prognosis Or Diagnosis with Artificial Intelligence
XGBoost: extreme gradient boosting

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Integrating Mobile Text Messaging Pre-Exposure Prophylaxis Navigation Services Into a Home HIV and Sexually Transmitted Infection Self-Testing Program in the United States: Formative Work and Pilot Implementation Study

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Abstract

Background: HIV testing is the gateway to the HIV prevention continuum and offers an important opportunity to provide HIV prevention services. TakeMeHome.org is an online program that enables state and local health departments to offer free in-home HIV and sexually transmitted infection self-testing. As few TakeMeHome users have used pre-exposure prophylaxis (PrEP), there is an opportunity to link TakeMeHome users to PrEP information and services.

Objective: The aim of this study is to develop an implementation strategy to link HIV or sexually transmitted infection self-testers from online orders to PrEP services via direct digital linkage to a novel SMS text messaging navigation program.

Methods: PrEPmate is an evidence-based bidirectional text-messaging platform that has demonstrated increased PrEP retention and adherence. We developed a novel program to link TakeMeHome testers to mobile SMS text messaging PrEP navigation via PrEPmate. We conducted focus groups among TakeMeHome users to elicit preferences for linkage from TakeMeHome to PrEPmate. Based on these focus groups, we revised the content and functionality of this linkage intervention. In October 2023, we launched a pilot implementation study in 2 US Ending the HIV Epidemic jurisdictions: Sacramento, California, and Tarrant, Texas.

Results: Thirteen TakeMeHome users participated in 4 focus groups (mean age 31.5 years; n=4, 31% Latinx, n=2, 15% Black; n=9, 69% never used PrEP). When shown wireframes of the TakeMeHome or PrEPmate linkage, most thought they were easy to navigate and user-friendly. They liked the privacy of connecting with a PrEP navigator using SMS text messaging. Participants recommended providing a clear description of PrEP and PrEPmate services and indicating that PrEP is low or no cost on the TakeMeHome website. On the PrEPmate landing page, they recommended adding language on confidentiality and the partnership with TakeMeHome to show that both services are connected. Once enrolled, they recommended weekly or biweekly check-ins to assist with PrEP navigation. Overall, 92% (12/13) of focus group participants were likely to use PrEPmate to learn more about PrEP and/or link to PrEP services. From October 2023 to May 2024, among 537 individuals who ordered test kits and were not on PrEP, 169 (31%) were linked to the PrEPmate page, and 86 (16%) enrolled in PrEPmate. PrEP navigation was provided via SMS text messaging or phone, with 46 (53%) receiving PrEP education and 26 (30%) in various stages of starting PrEP. In exit interviews, participants found the intervention easy to use and appreciated being connected with an experienced PrEP navigator who helped them access PrEP.

Conclusions: Through user-centered design, we successfully developed a program to link TakeMeHome testers to PrEP navigation via PrEPmate, with high feasibility and acceptability of the intervention and a substantial number of clients starting PrEP. The next steps will involve evaluating the effectiveness of this program on a larger scale and, if successful, expanding PrEPmate navigation to all Ending the HIV Epidemic jurisdictions using TakeMeHome.

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(JMIR Form Res 2026;10:e83733) doi:10.2196/83733

KEYWORDS

pre-exposure prophylaxis; PrEP; HIV testing; mobile health; mHealth; HIV prevention; HIV; navigation; technology; formative; development; mobile technology; text-messaging; SMS text messaging; self-test

Introduction

HIV testing is the gateway to the HIV prevention and care continua, enabling timely diagnosis, linkage to antiretroviral therapy and HIV care, and offering effective HIV prevention strategies, including pre-exposure prophylaxis (PrEP) [1]. Despite the Centers for Disease Control and Prevention (CDC) recommendation that all persons aged 13 to 64 years receive an HIV test [2], testing coverage remains suboptimal, with only 36% of adults younger than 65 years in the United States having ever been tested for HIV, and lower testing rates among adolescents and young adults [3,4]. Web-based and mobile intervention models of HIV testing have demonstrated promise in reaching populations at risk for HIV and sexually transmitted infections (STIs), including those never tested and those in high HIV seroincidence populations, the priority population for rollout of PrEP [5,6]. Digital platforms can provide tailored education, testing reminders, testing locators, and home delivery of HIV and STI test kits [7].

Developed by Building Healthy Online Communities (BHOC) and in collaboration with the National Alliance of State and Territorial AIDS Directors and Emory University as a public-private partnership, TakeMeHome.org is an online program enabling state and local health departments to offer free in-home HIV and STI testing [8]. TakeMeHome has partnerships with several dating apps to provide in-kind links to resources and free messaging. Launched in March 2020, the TakeMeHome program has distributed more than 70,000 HIV self-testing kits in 29 jurisdictions across 20 states, with 31% of testers reporting testing for the first time [9]. In 2023, a national version of this program, Together TakeMeHome, was launched, and in the initial year's rollout of online access to HIV testing, of nearly 220,000 persons requesting test kits, 55% were persons from the CDC's priority populations, 24% had never had an HIV test, and another 25% had not tested in the last year [10].

While linkage to HIV care and antiretroviral therapy is generally high after HIV self-testing, rates of linkage to HIV prevention services in this setting remain low. In a recent systematic review and meta-analysis, rates of confirmatory testing, ART initiation, and HIV care were 92%, 89%, and 84%, respectively, after a reactive HIV self-test; however, linkage to PrEP after a negative HIV self-test result was low at 9%, with even lower rates (4%) observed among key populations [11]. Similarly, while TakeMeHome.org provides a novel national strategy to increase HIV and STI testing among priority populations in the United States, there is a missed opportunity to engage these individuals in PrEP services. Only 8% of TakeMeHome users and 7% of Together TakeMeHome users were currently on PrEP [9,10]. Multilevel barriers to PrEP uptake include lack of awareness of PrEP, stigma and discrimination, medical mistrust, concerns about side effects and/or PrEP effectiveness, limited access to PrEP providers, transportation barriers, and the cost and complexity of insurance coverage [12-14]. As prior digital HIV prevention tools have relied on a more passive referral of clients to PrEP services, a digital health strategy that integrates self-testing with direct PrEP navigation and linkage via SMS text messaging is a novel approach that could help address a number of these barriers and increase PrEP uptake among priority populations using home HIV and STI testing services. In this study, we conducted qualitative formative work to develop a novel program for linking TakeMeHome testers to mobile SMS text messaging PrEP navigation via PrEPmate, a CDC-endorsed bidirectional text-messaging platform that previously increased PrEP retention in care and adherence among young sexual minority men and has subsequently been tailored for transgender and Spanish-speaking populations [15]. PrEPmate was originally designed to provide weekly check-in messages to facilitate communication between the clinic and patients, help triage those who need additional assistance, and provide daily pill reminders for taking PrEP. We used a user-centered design approach in which end users are meaningfully involved in application development to ensure that our tools are functional, usable, and customized to meet their needs [14,16]. We then assessed the feasibility, acceptability, and preliminary effectiveness of this intervention to increase PrEP uptake among TakeMeHome users in Sacramento, California, and Tarrant County, Texas, both Ending the HIV Epidemic (EHE) priority jurisdictions in the United States with a large volume of HIV and STI testing via TakeMeHome and interest and capacity to participate. This implementation study is focused on the stages of developing or adapting a solution and piloting and evidence generation.

Methods

Study Objectives

The main objectives of this study and the overall aim of the implementation were to develop and refine the TakeMeHome to PrEPmate linkage program via focus groups and evaluate the feasibility, acceptability, and preliminary effectiveness of this novel approach via a pilot implementation study. The target population for this program includes individuals testing via the TakeMeHome.org program who are not taking PrEP but could benefit from it.

Focus Groups for Developing the TakeMeHome to PrEPmate Linkage

We conducted 4 focus groups with TakeMeHome users recruited from Sacramento, CA, and Tarrant County, TX. Eligible participants for the focus groups were individuals who had used the TakeMeHome.org testing service within the past 12 months in the 2 participating jurisdictions, were HIV-uninfected by self-report, and were currently or previously on PrEP or interested in starting or learning more about PrEP. Recruitment

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included sending an Institutional Review Board–approved recruitment email asking individuals if they would be interested in participating in a 90-minute focus group conducted virtually, with a link to complete a secure contact information form. A convenience sample of eligible participants was consented online using an information sheet prior to the initiation of the focus group. Focus groups were conducted using a Health Insurance Portability and Accountability Act–compliant videoconferencing program (Zoom). Using a discussion guide, we elicited participants' experiences with accessing PrEP; gathered feedback on questions to be added to TakeMeHome.org to identify individuals not currently on PrEP but interested in learning more about this prevention approach; reviewed PrEP educational materials to be incorporated into TakeMeHome.org; explored the optimal strategy to facilitate successful linkage between TakeMeHome.org and PrEPmate; and assessed preferences for PrEP navigation and initiation within PrEPmate. Participants were shown wireframes of the TakeMeHome and PrEPmate screens and provided feedback on these images. Upon completion of the focus group, participants completed a brief online survey via Qualtrics to collect sociodemographic information and assess potential interest in PrEPmate. Focus groups were led by 2 research staff members trained in qualitative methods and user-centered design principles and fluent in English or Spanish. Groups lasted 90 minutes and were audio-recorded and professionally transcribed and translated (for Spanish focus groups) verbatim.

Guided by user-centered design principles [17], we used rapid qualitative methods to analyze the focus group data [18]. After each focus group, key findings from the discussion were summarized in a debrief note drafted and reviewed by 2 research team members who attended the group. Data captured in this template were based on the interview guide, agreed upon via consensus of the investigator team, and focused on information needed to develop the linkage between TakeMeHome and PrEPmate. Upon receipt of transcripts from the focus groups, members of the team reviewed the transcripts and captured additional details to ensure completeness of the debrief reports. These data were used to refine this linkage before the initiation of the pilot study. For publication of this manuscript, we developed a coding matrix based on the interview and debriefing guides that was agreed upon by the research team. Coding was conducted by 2 members of the research team who reviewed each other's work and came to consensus with input from the research team. Relevant quotes were extracted from the primary transcripts for each of the codes.

Development of the TakeMeHome to PrEPmate Linkage Intervention and Description of the Intervention

With input from the qualitative data, BHOC developers built out the new flow and added screens prompting users who were not on PrEP to learn more and, if interested, click to get connected to the PrEPmate landing page, which provided information about the program and allowed users to sign up for the service. After enrolling in the program, a PrEP navigator reached out to the client and provided text- or phone-based support to answer questions and facilitate access to PrEP. The system was designed so that all TakeMeHome users indicating interest in PrEP would be offered the linkage to PrEPmate during the pilot study period. PrEPmate is a cloud-based, software-as-a-service solution [19] hosted on Health Insurance Portability and Accountability Act–compliant servers that meet global standards for privacy, security, and redundancy, and a business associate agreement has been established to ensure confidentiality and privacy of data. Development of this linkage intervention was funded via a Gilead Sciences NOVA (Novel Research to Advance HIV Prevention) grant provided to the Bridge HIV research team at the San Francisco Department of Public Health. The budget for this study covered the costs of conducting focus groups and the pilot study, technical development of the TakeMeHome or PrEPmate linkage by BHOC, and recruiting participants into the study. BHOC (developer of TakeMeHome) and WelTel (which supports the PrEPmate platform) are both sustainable programs funded through government and public health grants, pharmaceutical and foundation funding, and other partnerships. TakeMeHome's business model is based on health departments' and community-based organizations' funding covering the cost of the kits, shipping, and basic site operations for their constituents, which are identified by geographic area.

Pilot Study to Assess the Feasibility and Acceptability of the TakeMeHome to PrEPmate Linkage

After finalizing the TakeMeHome to PrEPmate linkage, we assessed the feasibility and acceptability of this novel PrEP uptake strategy in a pilot study conducted during a 9-month period (October 2023 to May 2024). Individuals linked to PrEPmate via TakeMeHome.org as part of standard-of-care services were sent an Institutional Review Board–approved recruitment text message invitation approximately 1 month after enrolling in PrEPmate to participate in a 10 to 15 minutes study survey and a 60 to 90 minutes exit interview (among a subset of participants) to evaluate the PrEPmate linkage and navigation process. Interested participants were consented online using an information sheet and directed to complete the online survey. The survey collected information about participant sociodemographics, mobile phone ownership, prior PrEP knowledge and use, and whether they were successfully linked to PrEP services. Acceptability and patient satisfaction were assessed using the System Usability Scale (SUS) and Client Satisfaction Questionnaire-8 (CSQ-8), 2 validated tools assessing usability and acceptability with demonstrated high internal consistency across several studies [20,21]. The SUS is a 10-item scale that measures a system's usability on a scale of 0 to 100, with a score greater than 80.3 consistent with an "excellent" rating and scores 68 to 80.3 consistent with a "good rating" [22]. The CSQ-8 is an 8-item scale that measures client satisfaction on a scale of 8 to 32, with scores above 26 considered high [23]. We compared sociodemographics of PrEPmate survey completers with available data from overall TakeMeHome users from the 2 jurisdictions during the same time period using Fisher exact test.

We also conducted exit interviews with randomly selected participants who completed a survey to elicit feedback on their experience being linked from TakeMeHome.org to PrEPmate and receiving telenavigation services via PrEPmate and any

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recommendations to improve their experience with these services. Exit interviews were conducted remotely via Zoom using a semistructured interview guide. Interviews lasted 60 to 90 minutes and were audio-recorded and transcribed. Exit interviews and text message content were analyzed using methods similar to those described for the focus groups above.

Feasibility was assessed descriptively via deidentified data in reports generated from TakeMeHome.org and PrEPmate, including monthly counts of the number of kit orders per month, the number of individuals not on PrEP, the number of individuals who clicked over from TakeMeHome to the PrEPmate landing page, and the number who enrolled in PrEPmate. PrEP outcomes (those in the process of starting or who had started PrEP) were assessed via navigator reviews of clinic records.

Ethical Considerations

All study procedures were approved by the University of California San Francisco Institutional Review Board (UCSF IRB 22-37766). Focus group participants were provided with an information sheet in English or Spanish describing study procedures and the risks and benefits of study participation. Pilot study participants were provided with an information sheet describing the study survey and exit interview procedures. Focus group transcripts were transcribed in a way that removed any identifying information. Survey data for both phases contained only deidentified data and were coded by a subject number. A business associate agreement was established with both developers to ensure confidentiality and security of data. Prior to enrolling in PrEPmate, participants were provided a data privacy policy statement explaining the use and safe storage of their data. Data collected via PrEPmate are stored in Health Insurance Portability and Accountability Act–compliant cloud-based servers and are owned by the research team at the San Francisco Department of Public Health. Focus group participants were paid US $75 for completing the focus group; pilot participants were paid US $70 for completing the survey and US $120 for completing the exit interview. As the use of TakeMeHome and PrEPmate was considered part of the standard of care, participants were not paid for signing up for these services, but only for the completion of the study survey and/or interview.

Results

Findings From Focus Groups

Participant Characteristics

From March to May 2023, we contacted 29 TakeMeHome users, of whom 7 were ineligible and conducted 4 focus groups with 13 TakeMeHome users (response rate 65%), with 7 (54%) participants from California, 5 (38%) from Texas, and 1 (8%) from another state. The median age was 31 years; 4 (31%) identified as Latinx, 2 (15%) Black, 6 (39%) white, and 2 (14%) Asian. Overall, 11 (85%) were cisgender male, 1 (8%) genderqueer, and 1 (8%) cisgender female; 11 (85%) were insured and 9 (69%) had a primary care provider; 2 (15%) were currently on PrEP, 2 (15%) had previously used PrEP, and 9 (69%) had never used PrEP.

Privacy and Confidentiality and Ease of Use as Motivators for Engagement

Participants in Texas reported stigma around PrEP and being part of the gay community as barriers to accessing PrEP services. When asked about barriers to getting on PrEP, one participant in Texas said,

> *I'd say the stigma. You don't want to be like the gay person that's going to get the HIV drugs and all the things that come with that…I live in Ft. Worth now…it's just if you go to the wrong place, you're going to be looked at the wrong way, and it's a little intimidating sometimes.*

When shown wireframes of linkage pages (Figure 1), most thought they were easy to navigate and user-friendly, and they liked the privacy of connecting with a PrEP navigator using SMS text messaging. One participant in Texas said,

> *I think it's very easy to navigate. If I were on this website and I were trying to find PrEP, I would definitely feel like it was very user friendly and very easy to navigate, just going through it. You know, I like that you can sign up for, like, a text, text communication. Because, I mean, everybody nowadays texts.*

Need for a Clear Description of PrEPmate and Its Connection to TakeMeHome

On the TakeMeHome PrEP page, participants recommended a clear description of PrEPmate services, with 1 participant in Texas saying,

> *I guess just informing that there is this text-based service where you can chat with live navigators to ask your questions in a completely confidential manner. Just knowledge that there are actual live experts on the subject that you can access through the privacy of text message at your convenience 24/7, to ask literally any question you can think of about this.*

On the PrEPmate landing page, participants recommended adding language on confidentiality and the partnership with TakeMeHome to show both services are connected. One participant in Texas remarked,

> *And also having on the website, maybe like, "Supported by TakeMeHome." So, there's that connection. And there's another trusted organization. So, it's like if that organization's supporting that, and I'm trusting that, then it's probably legitimate.*

Similarly, another participant said,

> *Making a more direct link to TakeMeHome, as a service that you're already familiar with, and then PrEPmate. So, kind of bridging that gap between the relationship.*

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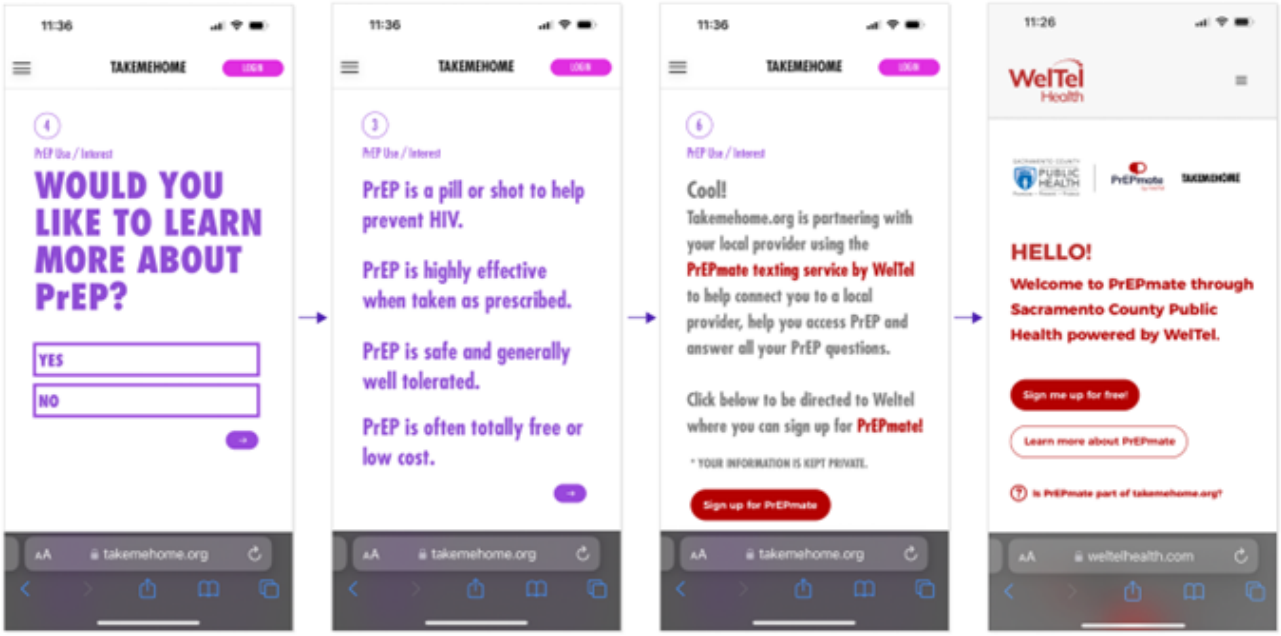
Figure 1. Screenshots of TakeMeHome to PrEPmate linkage pages. PrEP: pre-exposure prophylaxis.



Need for Clear Cost and Insurance Information for PrEP

Participants agreed that it would be important to have information about the cost of PrEP and whether it can be accessed at low or no cost. One participant in Texas noted,

> *I think, for me, medication, if the costs, it kind of scared you away without insurance.*

Another participant in Texas said,

> *Cost is the big thing. So, if we put here that, you know, PrEP is usually free or low cost, it would be more enticing to people to go ahead and learn more and continue on with this process.*

Desire for Immediate Human Connection (Live Navigator)

Several participants highlighted the importance of speaking with a live person knowledgeable about HIV prevention to answer their questions about PrEP. One participant in Texas said,

> *I definitely feel like having someone, either, like, a live person or chat feature… having that person who's very knowledgeable—someone who's professional, someone who knows about it—to be able to chat with. I feel like that is something that, you know, I really enjoy. You know, getting that information and getting all my questions answered, more importantly.*

They also suggested minimizing the number of questions prior to enrolling in PrEPmate, as this may contribute to drop-off, and 1 participant even suggested providing a direct link to PrEPmate first, and then having PrEP navigators ask the triage questions. A participant in Texas said,

> *It seems to me like you would want to funnel everybody directly into the text service, period. And then once you got them, and you got them in the text service, then you ask them the triage questions through the text service.*

Suggestions for Follow-Up Frequency, Language and Tone of Messages, and Laboratory Reminders

For ongoing navigation, participants recommended weekly or biweekly check-ins to assist with PrEP navigation. They recommended follow-up texts using casual language, with an example being

> *Hey, I haven't heard from you in a while. You've got whatever navigators here that can answer all your questions in private. Just reach out anytime if you have any questions. We're here to help.*

One participant commented on the challenges with completing blood work for PrEP follow-up visits and said it would be helpful if PrEP navigators could send text message reminders regarding when labs are due and help make those appointments. One participant in Texas said,

> *I think that would be a great idea. Because that's part of my problem, is time flies by and then I won't get a refill and it's because I didn't get my labs done. And now it's like, oh, everything comes to a stop. But if I had maybe text reminders, like, "Hey, your labs are due in 2 weeks." "Hey, your labs are due in a week," that would really help me not get in those really bad binds, for sure.*

In the postinterview survey, 92% (12/13) of participants reported they were likely to use PrEPmate to learn more about PrEP and/or link to PrEP services. Based on these findings, refinements were made to the TakeMeHome and PrEPmate sites prior to testing in the pilot study (Textbox 1).

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Textbox 1. Refinements made to TakeMeHome and PrEPmate based on feedback from focus groups.

TakeMeHome

- Added clear description of PrEPmate services
- Added information that PrEP is available at low or no cost
- Reduced number of screens required to be completed prior to linkage to PrEPmate
- Incorporated colors of the PrEPmate page (red font) into the final screen to promote consistency

PrEPmate

- Added logos of TakeMeHome, local health department or clinic, and PrEPmate, and a description of how sites are related
- Added information about privacy and confidentiality, including a link to the PrEPmate privacy policy
- Reduced number of questions and data elements collected as part of onboarding
- Used personalized, conversational language in initial welcome text messages to clients

Findings From Pilot Study

From October 2023 to May 2024, we conducted a pilot of the TakeMeHome or PrEPmate linkage in Tarrant County, Texas, and Sacramento, California, 2 EHE jurisdictions using TakeMeHome. Overall, 86 individuals enrolled in PrEPmate, and 31 (36%) completed the follow-up study survey.

The TakeMeHome to PrEPmate cascade by month is shown in Figure 2. Among 537 individuals who ordered test kits and were not on PrEP, 169 (31%) were linked to the PrEPmate page, and 86 (16%) enrolled in PrEPmate (median age 30 years, 402, 75% were interested in PrEP). PrEP navigation was provided via a local navigator through the PrEPmate platform. Among those enrolled, 46 (53%) were provided PrEP education, 7 (8%) were working on getting on PrEP, 5 (6%) had a scheduled PrEP appointment, and 14 (16%) had started PrEP (Figure 3).

Figure 2. TakeMeHome to PrEPmate cascade. PrEP: pre-exposure prophylaxis.

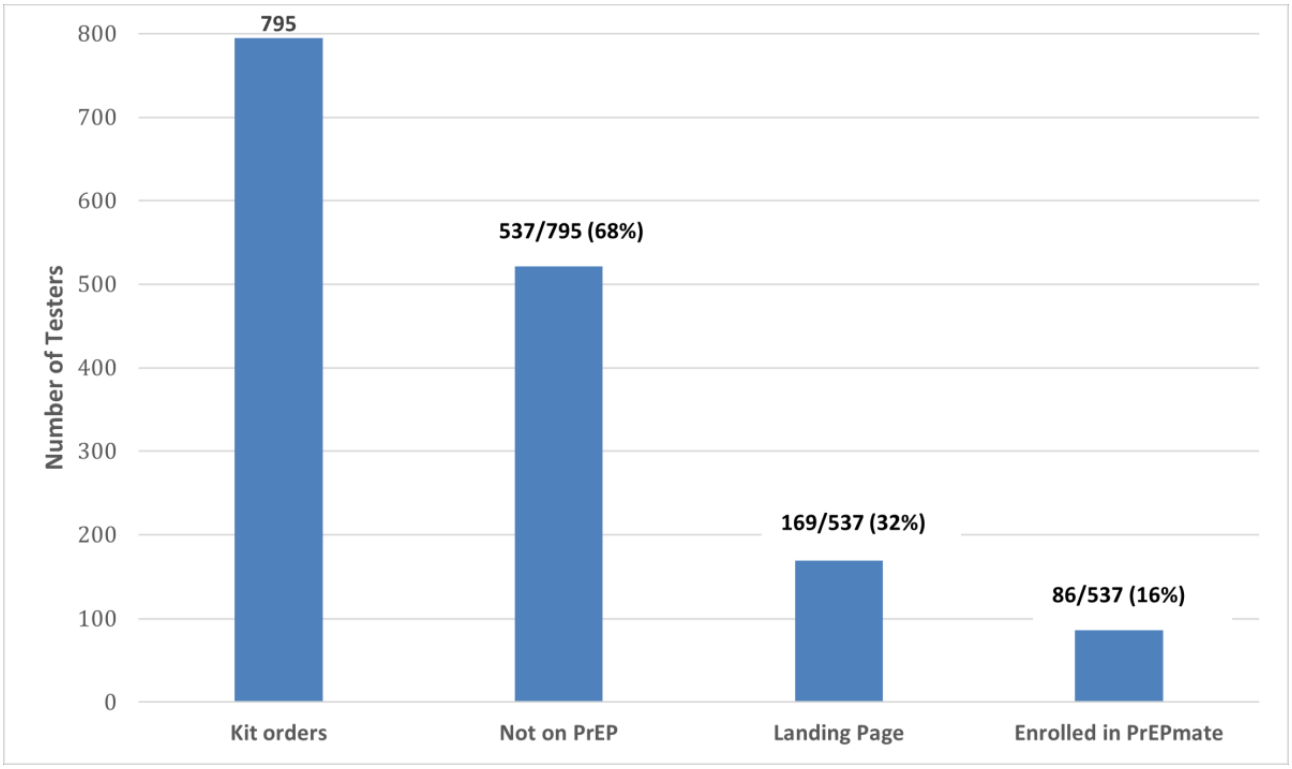

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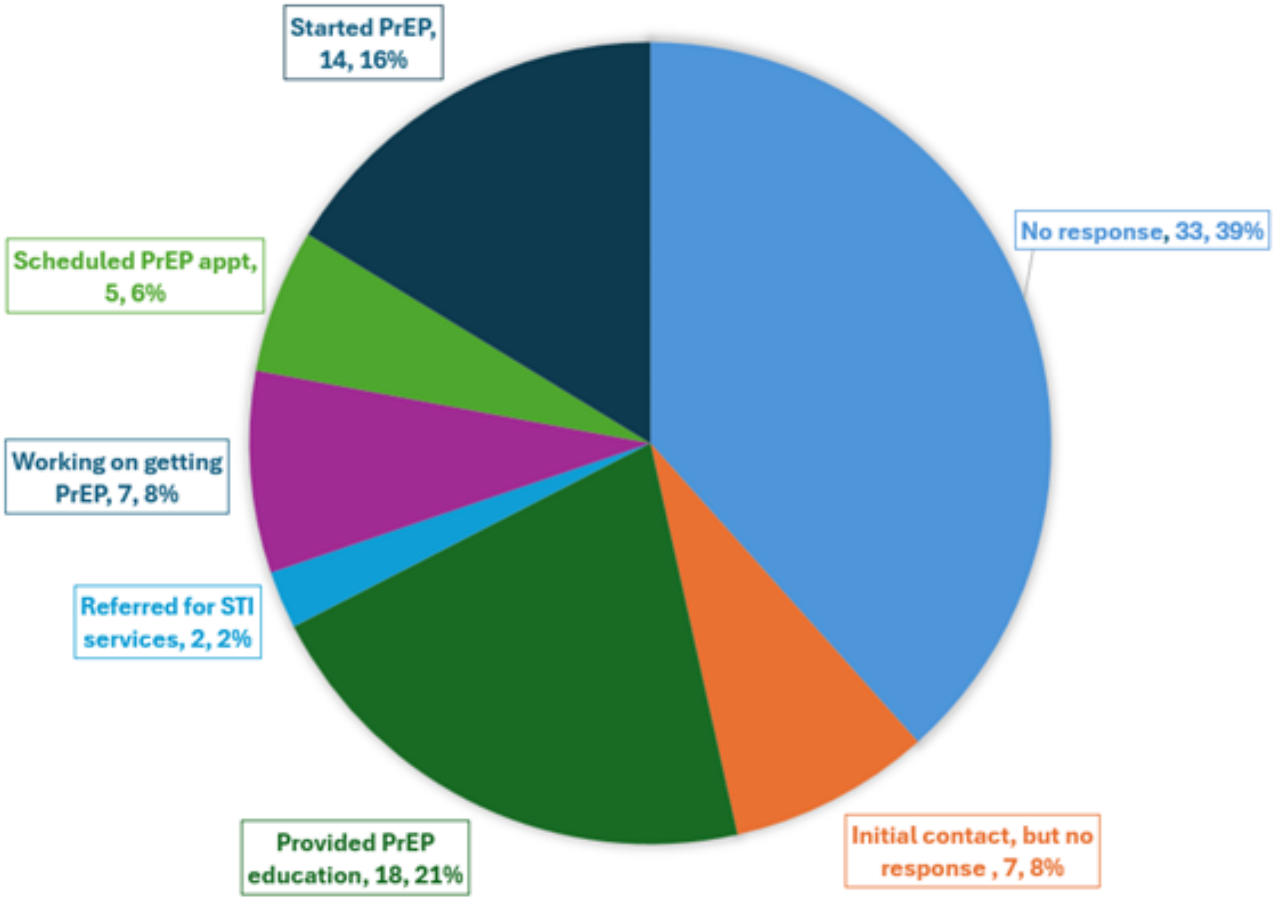
Figure 3. Pre-exposure prophylaxis (PrEP) outcomes for individuals enrolled in PrEPmate (N=86). STI: sexually transmitted infection.



Demographic characteristics of the 31 participants who completed the 1-month survey are shown in Table 1. The median age was 34 years; 22 (71%) participants were from California; and 17 (55%) identified as a man, 11 (35%) as a woman, and 3 (10%) as a transgender woman. Approximately one-third (10, 32%) identified as Hispanic/Latino/a/x, and 5 (16%) African American. The median number of sex partners in the last 3 months was 3. Overall, 25 (81%) had health insurance and 17 (55%) had a primary care provider; 20 (65%) had previously heard of PrEP, and 7 (23%) had previously used PrEP (but not currently). Participants who enrolled in PrEPmate and completed the 1-month survey were similar to overall TakeMeHome testers from the 2 jurisdictions with respect to age, race and ethnicity, gender identity, and reported sexual activity (see Multimedia Appendix 1). Among the 31 survey participants, 10 (32%) started PrEP as a result of PrEPmate, and an additional 14 (45%) were in the process of getting on PrEP. Among the 21 who had not yet started PrEP, most 16 (75%) were very or somewhat interested in taking PrEP.

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Table . Sociodemographic characteristics, pre-exposure prophylaxis interest, and uptake among focus group and survey participants in Sacramento, California, and Tarrant County, Texas.

Characteristic	Focus group (N=13)	Survey (N=31)
Age (y), median (IQR)	31 (24-37)	33.7 (25-41)
Location, n (%)		
California	7 (54)	22 (71)
Texas	5 (38)	9 (29)
Another state (Oregon)	1 (8)	0 (0)
Gender identity, n (%)		
Man	11 (85)	17 (55)
Woman	1 (8)	11 (35)
Transgender woman/genderqueer	1 (8)	3 (10)
Sexual orientation, n (%)		
Gay	__[a]	14 (45)
Bisexual	—	6 (32)
Straight	—	6 (19)
Hispanic or Latino/a/x	4 (31)	10 (32)
Race, n (%)		
Black/African American	2 (15)	5 (16)
White	6 (46)	16 (52)
Asian	2 (15)	3 (10)
Hispanic/Latino only	3 (23)	6 (19)
American Indian/Alaskan Native	0 (0)	1 (3)
Highest education, n (%)		
Never graduated high school	—	1 (3)
High school or GED[b]	—	14 (45)
Some college	—	11 (35)
College graduate	—	4 (13)
Any postgraduate studies	—	1 (3)
Sex partners in past 3 months, median (IQR)	—	3 (2-4)
Has health insurance, n (%)	11 (85)	25 (81)
Private	—	10 (32)
Medicaid/Medical	—	12 (39)
Not sure	—	3 (10)
Has primary care provider, n (%)	9 (69)	17 (55)
Prior knowledge of PrEP[c], n (%)	—	20 (65)
Prior use of PrEP (not current), n (%)	2 (15)	7 (23)
Started PrEP via PrEPmate, n (%)	—	10 (32)
In process of getting on PrEP via PrEPmate, n (%)	—	14 (45)
Interest in taking PrEP[d], n (%)		
Very interested	—	12 (39)
Somewhat interested	—	5 (16)
A little interested	—	3 (10)

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Characteristic	Focus group (N=13)	Survey (N=31)
Not interested at all	—	1 (3)

[a]Data not available for focus groups.

[b]GED: General Educational Development.

[c]PrEP: pre-exposure prophylaxis.

[d]Among 21 participants who did not already start PrEP at time of survey.

Regarding acceptability, the mean and median SUS scores were 68.8 and 70 (IQR 55‐83) out of 100, falling in the "good" range, and the mean and median Client Satisfaction Scores were 28 and 30 (IQR 25‐31) out of 32, indicating high satisfaction (above 26). Most participants (24/31, 77%) reported that PrEPmate helped them get access to PrEP, 31 (100%) would recommend PrEPmate to a friend, and 29 out of 31 (94%) were mostly to extremely satisfied with PrEPmate.

During the study, there was a mean and median of 5.9 and 3 outcoming messages and 5.3 and 2 incoming messages per client enrolled in PrEPmate. In a thematic analysis of text message conversations, key navigation services provided via PrEPmate included answering questions about PrEP, STIs, doxycycline postexposure prophylaxis, and other health concerns; providing information about the local PrEP clinic and the process for getting on PrEP; answering questions about insurance coverage and cost; assisting patients with getting on a patient assistance program; setting up a time for a phone call to discuss PrEP; scheduling and rescheduling PrEP appointments; and arranging transportation to the clinic. In some cases, navigators assisted clients with accessing PrEP via alternate sources (eg, online PrEP delivery program). For those who started PrEP, PrEPmate messages provided an opportunity to check in about adherence and served as a reminder to take PrEP.

Exit Interviews

Ease of Use and Convenience of Texting

Nine participants completed follow-up exit interviews approximately 1 month after enrollment. Most participants found TakeMeHome and PrEPmate straightforward and easy to use, had no issues with answering questions or learning about PrEP, and found the language easy to understand. One participant in California said,

> *I didn't find it hard. I didn't have to search too hard for information. It was easily accessible. And it was understandable, as well. It wasn't something that I had to Google and try to figure out. It was right there, very self-explanatory.*

In general, participants did not have issues being directed to another site, and most individuals did not feel like this was a trick or spam or click bait, although 1 participant wanted confirmation that their kit order had gone through before being redirected to the PrEPmate site. They appreciated being connected to a local lesbian, gay, bisexual, transgender, and queer resource and getting assistance through this agency.

One participant in California said about the messages from PrEPmate,

> *Very nice, easy to read, no big words. Me, dumb-dumb, can understand. I also think that it wasn't, like, flooding my inbox…It wasn't, like, spam messages. It felt like real information, and it felt like it was written by a person.*

When asked what he liked about PrEPmate, another participant in Texas said,

> *Well, I just liked it because it was more of—it was very motherly. It was like checking up on me.*

Positive Experiences With the Humanized, Responsive Navigator

Participants found PrEPmate easy to use and helped them with various aspects of getting on PrEP. They especially appreciated being connected to a navigator who was able to answer their questions and set up a PrEP intake appointment. A participant in California said,

> *The overall experience of the PrEPmate navigator, I would say it would be like a 10 out of 10. They do explain, and they do break down how it works. And they do what you understand how to use it and what day or time, you can schedule your appointment with them. They can help you. They're very helpful, too, because they will let you know how to use it and stuff like that.*

Another participant in Texas said,

> *I think it's helped a lot because it helped me book my appointments and helped check up on me. And it lets me ask questions and stuff when I'm curious about how it works.*

Participants found that staff responded to text messages in a timely manner, and also appreciated the frequency of check-ins, which maintained their interest in getting started on PrEP. When asked about the frequency of check-ins, one participant in California remarked,

> *Actually, I felt good about it because it helped me not forget. Honestly, if it took weeks for you guys to get back, it would have faded away, and I would have lost interest in the program. So it was perfect actually. It kept me engaged.*

This participant appreciated the ability to get her questions answered and set up an appointment quickly, saying

> *They made sure every step of the way, do you have any questions? "Hey, I just wanted to just see how everything is going." It's very—what's the word—consistent, and they really cared… And I was able to do everything straight from my phone. Yeah,*

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> *I didn't have to sit in a long line or wait at a long doctor's office.*

Recommendations to Improve Functionality and User Experience

As the overall system usability rating was "good," participants did have some recommendations for improvements. One participant suggested providing more information about PrEP and where it can be accessed before signing up for PrEPmate. Two participants had concerns about being transferred to a different site before ensuring their testing kit order was confirmed and wanted that task to be completed before being transferred to PrEPmate. While most participants understood that the PrEPmate messages were coming from a real person, 1 participant initially thought the messages were coming from a robot or artificial intelligence. To improve PrEPmate, they suggested,

> *I would make it feel more like a human because I didn't know it was a human, to be honest…I would say probably add a name or an emoji or whatever, something that a robot (wouldn't) do.*

Another participant in Texas suggested that having an app with additional functionality (including the ability to order PrEP delivery and track shipments) would be helpful. A participant in California found the hours of the PrEP clinic restrictive and recommended that PrEP facilities have available appointments after 5 PM or on weekends. Finally, 1 participant in California thought it would be helpful for the system to gather some information about insurance to provide better insurance navigation. She said,

> *If there was a feature that was like, "Okay, if you tap on it, you'd be able to link your medical insurance information…" If I could find my insurance company, and then, boom, log in or create an account. And then, boom, you guys have all my insurance information.*

Discussion

Principal Findings

This study describes findings from formative focus groups and a pilot study to develop and refine a novel strategy to link home HIV and STI testers using TakeMeHome to PrEP services via an SMS text messaging–based navigation program, PrEPmate. Key findings from the formative phase included having a clear description of PrEPmate services on the TakeMeHome site and stating that PrEP is available at low or no cost; having information about the partnership between TakeMeHome and PrEPmate and confidentiality of the text-messaging system on the PrEPmate landing page; and having weekly or biweekly text message check-ins regarding PrEP navigation using casual, conversational language. The majority of the recommendations from the focus groups were incorporated into the intervention prior to pilot testing. In a 1-month pilot of the finalized linkage and navigation program, nearly one-third of participants enrolled in PrEPmate began using PrEP, and there was high acceptability of this program assessed via survey and exit interviews. Our quantitative assessments included the SUS, which measured ease of use, and the CSQ-8, which measured the helpfulness of and satisfaction with the program.

Home HIV and STI testing offers a number of benefits, including increased privacy, convenience, and the ability to reach populations who have not previously tested [24-26], and integrating HIV and STI self-testing with low-barrier HIV prevention services can help close the "testing-to-prevention" gap. While a number of online HIV and STI testing programs designed to support HIV and STI testing have demonstrated increases in testing rates [5,10,27], these programs either do not have information about PrEP or only passively provide information about these prevention services. In the Adolescent Trials Network studies of 2 mobile apps designed to support HIV testing and PrEP uptake, the MyChoices and LYNX apps demonstrated an increase in HIV and STI testing rates, but no significant increase in PrEP uptake, suggesting that different modalities and a more active approach may be needed to successfully link home HIV and STI testers to PrEP services [28]. While mobile apps require downloading from an app store, TakeMeHome is a website available via one click from a dating app, reducing the initial barrier to engagement. Additionally, the text messaging component of PrEPmate offers an interactive method of weekly follow-up via text message to facilitate ongoing navigation and linkage to a PrEP provider.

A number of text-messaging interventions have been shown to increase PrEP retention in care and adherence [29]. The individualized Texting for Adherence Building intervention increased the likelihood of having near-perfect adherence among stimulant-using men who have sex with men (MSM) in the United States [30], and the PrEPmate intervention increased PrEP retention in care and adherence among young MSM [15]. This study extends the use of text-messaging to support PrEP linkage and navigation, earlier steps in the PrEP continuum. Text messaging interventions are inexpensive, widely available, and scalable, and they offer the ability to provide timely reminders and check-ins, deliver personalized messaging and support, and address stigma by using affirming language and offering a private way to receive support and information without going into a clinic [31-33]. One of our key findings is the usefulness of providing remote access to a PrEP navigator via PrEPmate. PrEP navigators can provide PrEP education and support, assist with insurance and medication access, connect clients with PrEP providers, and facilitate appointment scheduling and reminders, and several studies have demonstrated the positive impact of PrEP navigation on PrEP uptake [34-36]. In the THRIVE PrEP demonstration project, MSM who used navigation were 17 times more likely to link to PrEP compared with MSM who did not use navigation [35]. Additionally, a brief patient navigation intervention increased PrEP prescriptions, PrEP retention in care, and persistence among Black MSM in the Southern United States [33]. In our study, participants found the navigator to be especially helpful in answering their questions, getting a PrEP appointment scheduled, addressing cost and coverage issues, and following up to ensure successful linkage to the clinic. Nearly half of participants enrolled in PrEPmate who completed the survey were African American or Latinx, and 10% were transgender, which reflected the demographics of TakeMeHome testers in

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these jurisdictions. This model was able to effectively reach populations disproportionately affected by HIV.

Several digital health interventions have recently been tested to increase PrEP uptake and can serve as a benchmark for this study. In the HealthMindr PrEP study of a mobile HIV prevention smartphone app among MSM, 24% of eligible screening participants enrolled in the study, and among those assigned to the intervention arm, 32% reported starting PrEP over a 12-month follow-up period [37]. Similarly, in a randomized controlled trial of the Mobile Messaging for Men (M-cubed) app in MSM, 40% of eligible screening participants enrolled in the study, and among those in the intervention arm, 19% started PrEP [38]. In our pilot study, 16% of TakeMeHome testers who reported an HIV-negative HIV status enrolled in PrEPmate, and of those, 30% were in the process of starting PrEP. While our pilot study had a shorter follow-up duration and was not a fully powered randomized controlled trial, our preliminary data suggest that enrollment and PrEP uptake rates for PrEPmate are within a similar range to other recent trials of digital PrEP linkage interventions.

The positive findings from this pilot study support additional evaluation of the PrEPmate navigation program across a larger number of EHE jurisdictions currently using TakeMeHome and more diverse populations to fully evaluate the effectiveness of this intervention on PrEP uptake and persistence across a range of settings. While local PrEP navigators were used in this pilot study, future studies could investigate the use of a central PrEP navigator to provide support across multiple sites. This approach could be useful in locations without PrEP navigators available and increase efficiency and scalability of the intervention, although information on local PrEP clinics and providers will need to be collected and updated on a regular basis, and insurance navigation and scheduling clients for new PrEP intake appointments may be more challenging when done via a central navigator. Future studies should also evaluate the potential for integrating this intervention into existing public health infrastructure, such as local health departments or community-based organizations and clinics, as well as the cost and cost-effectiveness of different models of implementation. Resources needed to sustain SMS text messaging navigation, including staffing (eg, local or central PrEP navigators), training materials and staff, and the secure interactive SMS text messaging platform supporting PrEPmate, can be further explored in these studies. As a number of health departments and local jurisdictions are already implementing TakeMeHome and have PrEP navigators on staff, this workforce could be leveraged to support the integration of PrEPmate into existing programs. Finally, future studies could investigate the use of automated analytics and artificial intelligence or machine learning to identify individuals testing through TakeMeHome and most in need of navigation support.

This study had several limitations. First, the number of participants enrolled in the focus groups and pilot study was small and consisted of nonrepresentative convenience samples, and therefore, it was not designed to evaluate the efficacy of the intervention. Also, due to the short duration of the pilot, the final PrEP status of some participants was not available, and we were not able to evaluate PrEP persistence for those who initiated PrEP, as other efficacy studies have followed all participants for 12 months. Another limitation is that the demographics and analytics available from TakeMeHome were incomplete, and we were unable to assess how many participants completed the PrEP questions on the TakeMeHome website and made it to the final page prior to being directed to the PrEPmate landing page; these data would have allowed comparisons between individuals enrolling in PrEPmate versus those who did not and provided more granularity into the drop-off at each stage and whether additional revisions to the TakeMeHome PrEP pages would be useful. Social desirability may have impacted participant responses in the focus groups and technical pilot; however, we used computer-assisted self-interview to assess usability and acceptability, paradata metrics from TakeMeHome and PrEPmate to objectively assess feasibility, and participants in focus groups and exit interviews were encouraged to provide honest feedback that would help us best improve the linkage intervention. Due to the pilot nature of this study, we did not collect data on time spent by navigators or the cost and cost-effectiveness of the intervention; it is recommended that future studies assess these implementation outcomes. Additionally, there may be potential selection bias among digitally engaged users of TakeMeHome. Finally, for both phases of this study, participants were only enrolled from Sacramento and Tarrant counties, potentially limiting the generalizability of the findings, although both regions are in high priority EHE jurisdictions. Despite these limitations, our study had several strengths, including the user-centered approach incorporating input from our participants into the final design of the intervention, and the mixed methods approach to evaluate feasibility and acceptability in our pilot study.

Conclusions

Through user-centered design, we developed a novel SMS text messaging PrEP navigation program to link TakeMeHome home HIV and STI testers to local PrEP services. Preliminary testing in a pilot study demonstrated high feasibility and acceptability of the program and substantial uptake of PrEP among clients enrolled in PrEPmate and supports further evaluation of this program across additional EHE sites in the United States.

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We would like to thank all the study participants for their helpful insights and feedback in this study. The authors declare the use of generative artificial intelligence (GAI) in the research and writing process. According to the GAIDeT taxonomy (2025), the following tasks were delegated to GAI tools under full human supervision: literature search and systematization. The GAI tool used was ChatGPT (OpenAI; GPT-5.2). Responsibility for the final manuscript lies entirely with the authors. GAI tools are not listed as authors and do not bear responsibility for the final outcomes. Declaration submitted by: AL.

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Data Availability

Survey data for the pilot study will be uploaded to the Dryad Repository. Focus group transcripts will be made available upon request.

Authors' Contributions

AL wrote the manuscript. C-DA conducted qualitative interviews. JM provided study coordination. JV refined the intervention design. K Lafferty, SQ, ND, K Lopez, DJ, and AF assisted with data collection at the sites. SB and HS assisted with study design and analysis of data. DG conducted all statistical analyses. JH led revisions to the TakeMeHome intervention. All authors reviewed the final manuscript.

Conflicts of Interest

AL has received funding for investigator-sponsored research studies from Gilead Sciences and Viiv Healthcare and has led studies in which study drug has been donated by Gilead Sciences. SB has received funding for research studies from GSK and Merck. JH has received funding from Gilead Sciences.

Multimedia Appendix 1
Sociodemographic and behavioral characteristics of overall TakeMeHome users vs PrEPmate survey completers in Tarrant County, TX, and Sacramento County, CA.
[DOCX File, 15 KB - formative_v10i1e83733_app1.docx]

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Abbreviations

BHOC: Building Healthy Online Communities
CDC: Centers for Disease Control and Prevention
CSQ-8: Client Satisfaction Questionnaire-8
EHE: ending the HIV epidemic
MSM: men who have sex with men
PrEP: pre-exposure prophylaxis
STI: sexually transmitted infection
SUS: System Usability Scale

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Digital Infrastructure for Antimicrobial Susceptibility Testing and Surveillance: A CLSI and EUCAST-Based Model for Resource-Limited Settings

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Abstract

Background: Antimicrobial resistance (AMR) poses a significant global health threat, requiring effective antimicrobial susceptibility testing (AST) and surveillance systems. At the University Teaching Hospital of Butare (CHUB) in Rwanda, a baseline Laboratory Assessment of Antibiotic Resistance Testing Capacity (LAARC) identified critical gaps in the Laboratory Information System (LIS), including low capture rates for culture observation (60%) and AST data (25%), no standardization of AST panels (0%), and limited cumulative antibiogram generation (17%). Existing AMR surveillance platforms, such as the Information System for Monitoring Antimicrobial Resistance by the World Health Organization (WHO) Collaborating Center for Surveillance of Resistance to Antimicrobial Agents (WHONET), and the District Health Information System, operate as standalone systems separate from clinical workflows, which limits their real-time clinical utility.

Objective: This study aimed to develop an enhanced, web-based LIS integrated within routine clinical care to improve AST reliability, enable real-time AMR surveillance at CHUB, and provide a scalable model for subnational and national surveillance networks in resource-limited settings, supporting antimicrobial stewardship.

Methods: We developed an enhanced LIS using the OpenClinic GA, the current open-source hospital information system at CHUB, integrating Clinical and Laboratory Standards Institute (CLSI) and European Committee on Antimicrobial Susceptibility Testing (EUCAST) guidelines, and leveraging metadata from the AMR for R package, WHONET resources, and EUCAST Expert Rules. An agile development approach was used, incorporating a custom database schema, Java-based application programming interfaces (APIs), and web-based user interfaces. The system was designed to support minimum inhibitory concentration (MIC) and disk diffusion (DD) methods, automate result interpretation with color-coded outputs, WHO Access, Watch, Reserve (AWaRe)–based cascade reporting, and enable data export to WHONET for global surveillance.

Results: The enhanced LIS improved AST data capture and standardization, providing reliable, automated result interpretation and real-time AMR surveillance capabilities. The system's web-based architecture enables scalability through centralized deployment, allowing multiple facilities simultaneous access. Unlike standalone surveillance tools, the enhanced LIS integrates AST within electronic medical records, maintaining clinical information continuity from specimen registration through result reporting. The system supports immediate clinical decision through AWaRe–based cascade reporting, and automated resistance phenotype detection, followed by standardized WHONET-compatible exports for public health surveillance.

Conclusions: This scalable, LIS model demonstrates the feasibility of implementing standards-based AMR informatics in resource-limited settings. By embedding surveillance within clinical workflows rather than treating it as a separate downstream activity, the system maximizes data quality and clinical relevance while minimizing staff burden. The centralized web-based architecture provides inherent scalability from facility to national levels, eliminating data fragmentation and ensuring metadata consistency across networks. Long-term sustainability requires continuous user training, designated personnel for metadata maintenance, local IT capacity building, and funding mechanisms beyond donor dependency. This model provides a practical

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roadmap for national digital stewardship programs, supporting both immediate patient care and long-term public health surveillance goals.

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KEYWORDS

antimicrobial susceptibility testing; CLSI; EUCAST; Laboratory Information System; antimicrobial stewardship; resource-limited settings; openClinic GA; University Teaching Hospital of Butare; WHONet

Introduction

Antimicrobial Resistance (AMR) Surveillance Challenges in Resource-Limited Settings

Antimicrobial Resistance (AMR) is a global health emergency, with the World Health Organization (WHO) estimating 10 million annual deaths by 2050 if unchecked [1]. Effective antimicrobial susceptibility testing (AST) and robust surveillance systems are fundamental to combating AMR. AST guides appropriate therapy at the patient level, while surveillance aggregates resistance data to monitor trends and inform evidence-based treatment guidelines [2,3]. Resource-limited settings, particularly in Sub-Saharan Africa, face significant barriers to implementing reliable AST and surveillance infrastructure, including inadequate laboratory information systems, inconsistent adoption of standardized guidelines (Clinical and Laboratory Standards Institute [CLSI] and European Committee on Antimicrobial Susceptibility Testing [EUCAST]),[4] limited access to quality-assured testing protocols, and fragmented data management that impairs interoperability with national and global surveillance networks [5-8], undermine antimicrobial stewardship efforts and exacerbate AMR.

Baseline Deficiencies at the University Teaching Hospital of Butare

The University Teaching Hospital of Butare (CHUB), a tertiary referral center in Rwanda, exemplifies these challenges. CHUB's LIS (Laboratory Information System), built on the OpenClinic GA open-source hospital information system [9], exhibited critical deficiencies in microbiology services. A baseline Laboratory Assessment of Antibiotic Resistance Testing Capacity (LAARC) [10], identified critical deficiencies: 60% capture rate for culture observation, 25% for AST data, 0% standardization of AST panels, and 17% generation of cumulative antibiograms, reflecting systemic issues in resource-limited settings. The assessment revealed several qualitative deficiencies in the LIS that compromised bacteriology services at CHUB (Table 1) [11], which reflect systemic issues, where LIS platforms lack specialized microbiology functionality necessary for standards-compliant AST and surveillance.

Table . Qualitative LIS[a] deficiencies identified by the LAARC baseline assessment.

Deficiency	Impact
Does not record AST[b] method: Minimum Inhibitory Concentration (MIC) or Disk Diffusion (DD)	Hinders traceability of test methods
Cannot hide individual antibiotic results	Prevents cascade/selective reporting [12]
Only Susceptible, Intermediate, or Resistant (S/I/R) interpretations entered	Limits data granularity for analysis
Lacks automated interpretation	Manual processes, increasing error risk
EUCAST[c] Expert Rules not integrated	Limits clinical decision support
Inconsistent antibiotic panels	Results in data unsuitable for reliable cumulative antibiogram generation
Original results deleted during corrections	Compromises audit trails

[a]LIS: Laboratory Information System.

[b]AST: antimicrobial susceptibility testing.

[c]EUCAST: European Committee on Antimicrobial Susceptibility Testing.

Study Rationale and Objectives

Addressing the revealed gaps requires an enhanced LIS that integrates international AST standards, automates result interpretation, standardizes testing panels, and enables seamless data export to surveillance networks. This study aimed to develop such a system at CHUB leveraging the OpenClinic GA platform and integrating CLSI and EUCAST guidelines [2,3], incorporating metadata from the AMR for R package [13], and from the Information System for Monitoring Antimicrobial Resistance by World Health Organization (WHO) Collaborating Center for Surveillance of Resistance to Antimicrobial Agents (WHONET) [6,14,15], as well as EUCAST Expert Rules and expected phenotypes [16].

The enhanced LIS was designed to resolve all LAARC-identified deficiencies, standardize AST processes, enable real-time AMR surveillance, and facilitate data interoperability with the WHO Global Antimicrobial Resistance Surveillance System (GLASS) and national platforms. By building on OpenClinic GA's established infrastructure, the

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system provides a scalable, open-source model tailored to resource-limited settings, improving data quality, supporting evidence-based antimicrobial stewardship, and contributing to global AMR monitoring efforts. This approach offers a replicable blueprint for tertiary hospitals and reference laboratories in Sub-Saharan Africa and similar contexts, demonstrating how standards-based digital infrastructure can address critical surveillance gaps with minimal resource requirements and sustainable, locally adaptable solutions.

Methods

Study Design and Setting

This technical implementation study was conducted at CHUB, a key microbiology center in Rwanda, from January 2024 to June 2025. The study focused on upgrading the CHUB LIS, built on the OpenClinic GA open-source hospital information system [9], to address LAARC-identified deficiencies, leveraging metadata from the AMR for the R package and EUCAST Expert Rules.

System Development Approach

An agile methodology facilitated iterative development, incorporating feedback from laboratory staff, clinicians, and public health experts. Requirements targeted improved data capture, AST panel standardization, antibiogram generation, and interoperability with global surveillance systems, extending the capabilities of the OpenClinic GA platform. The agile approach was chosen based on its proven effectiveness in developing health information systems in low-resource settings [17,18].

Data Analysis and Metadata Integration

Metadata from the AMR for R package, including microbial taxonomy, antimicrobial profiles, and clinical breakpoints, were analyzed to standardize AST processes. EUCAST Expert Rules and expected phenotypes guided automated interpretations and dynamic testing panel generation. Nine metadata files, all in tab separated values (TSV) format, were integrated, each mapped to specific database tables within the OpenClinic GA system (Table 2).

Table . Integrated metadata files for LIS enhancement. The integration of these metadata files was based on their reliability and global compatibility [6,19-21].

File content	Purpose	Key fields
Clinical breakpoints	Stores CLSI/EUCAST[ab] breakpoint data defining S/R thresholds	Guideline, test method, pathogen, antimicrobial, breakpoint values
Microorganisms	Provides taxonomic and characteristic data for microbial identification	Pathogen identifier, kingdom, genus, species, prevalence, clinical codes (SNOMED[c])
Antimicrobials	Details antimicrobial agents with Access, Watch, Reserve (AWaRe) classifications	Antibiotic name, class, potency, administration routes, standardized codes (WHONET[d])
Antimicrobial screening rules	Defines screening rules for specific pathogens	Antimicrobial, target pathogen, screening criteria
Testable Antimicrobials	Lists antimicrobials with standardized AST[e] breakpoints	Group, name, abbreviation, AWaRe classification
Expected Phenotypes	Incorporates EUCAST Expert Rules for expected phenotypes	Antimicrobial, pathogen, phenotype (susceptible/resistant)
Site-Sample Mapping	Maps clinical sites to sample types	Site, specimen type (eg, Respiratory → Sputum)
WHONET Specimen Mapping	Standardizes specimen codes for WHONET interoperability	Local codes, WHONET specimen type codes
AWaRe Classification	Classifies antibiotics into AWaRe categories	Antibiotic name, AWaRe category

[a]CLSI: Clinical and Laboratory Standards Institute.

[b]EUCAST: European Committee on Antimicrobial Susceptibility Testing.

[c]SNOMED: Systematized Nomenclature of Medicine.

[d]WHONET: World Health Organization (WHO) Collaborating Center for Surveillance of Resistance to Antimicrobial Agents.

[e]AST: antimicrobial susceptibility testing.

System Architecture and Functionalities

The LIS was developed by extending the OpenClinic GA open-source web-based hospital information system, incorporating a custom database schema, Java-based APIs, and a web-based interface, optimized for resource-limited settings. The system comprises five key user interfaces, each designed for usability and compliance with CLSI, EUCAST, and WHO GLASS standards (Figure 1).

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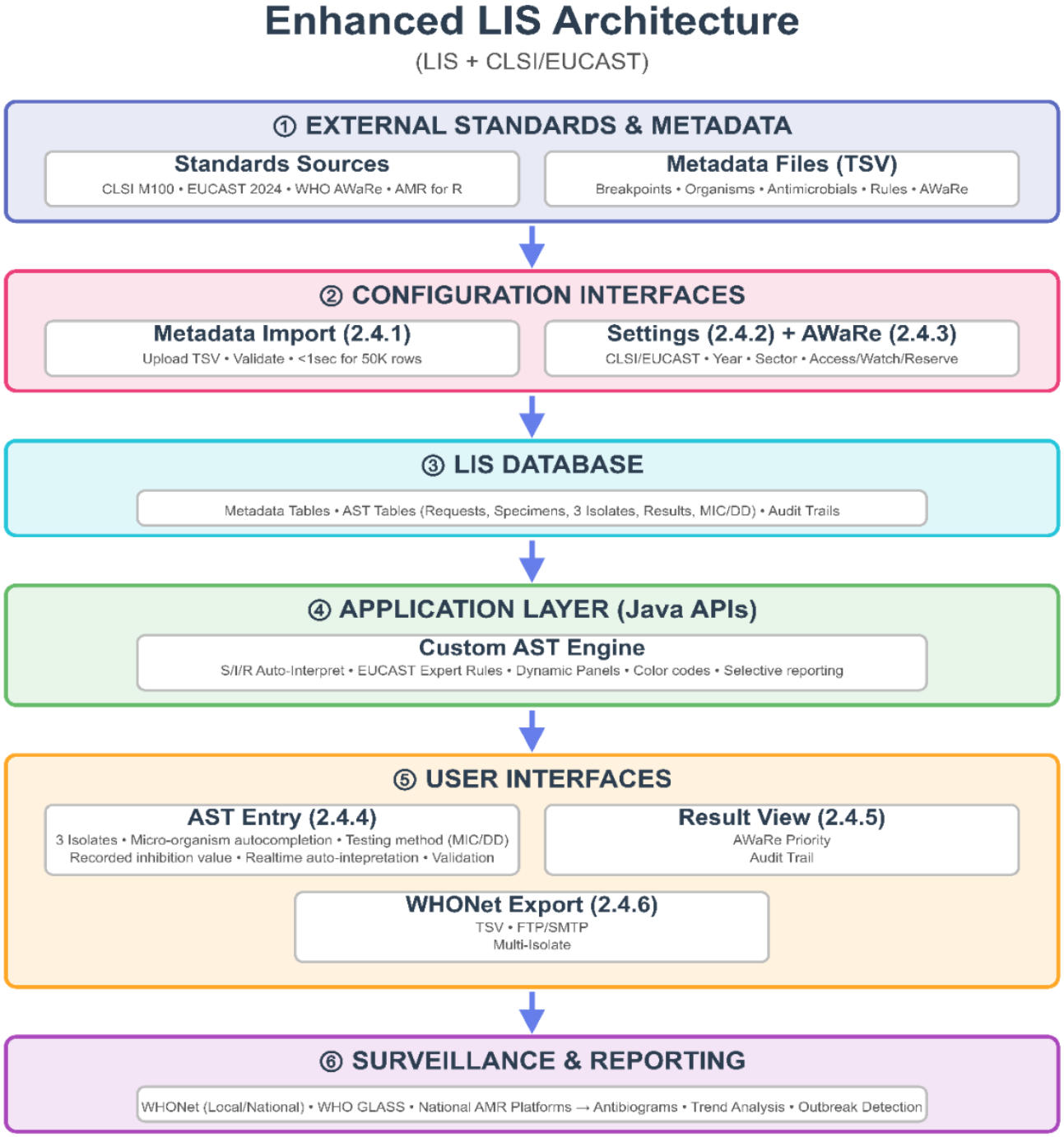
Figure 1. High-level schematic representation of the enhanced LIS architecture and end-to-end data flow. Circled numbers (①-⑥) denote the six architectural layers of the system. Numbers in parentheses refer to subsections in section 2.4 (system architecture and functionalities) where detailed technical descriptions are provided. AST: antimicrobial susceptibility testing; API: application programming interface; AWaRe: Access, Watch, Reserve; CLSI: Clinical and Laboratory Standards Institute; DD: disk diffusion; EUCAST: European Committee on Antimicrobial Susceptibility Testing; LIS: Laboratory Information System; MIC: Minimum Inhibitory Concentration; TSV: Tab Separated Values; WHONET: World Health Organization Collaborating Center for Surveillance of Resistance to Antimicrobial Agents.



Metadata Import Interface

A web-based tool simplifies the import and update of metadata files within the OpenClinic GA. Users select a file type from a dropdown menu, upload TSV files, and optionally clear existing data. The system validates file headers, provides real-time feedback on errors (eg, invalid format), and deletes temporary files to optimize storage. This interface leverages OpenClinic GA's robust file-handling capabilities to ensure efficient data management by enabling nontechnical users to update metadata with minimal training (Figure 2).

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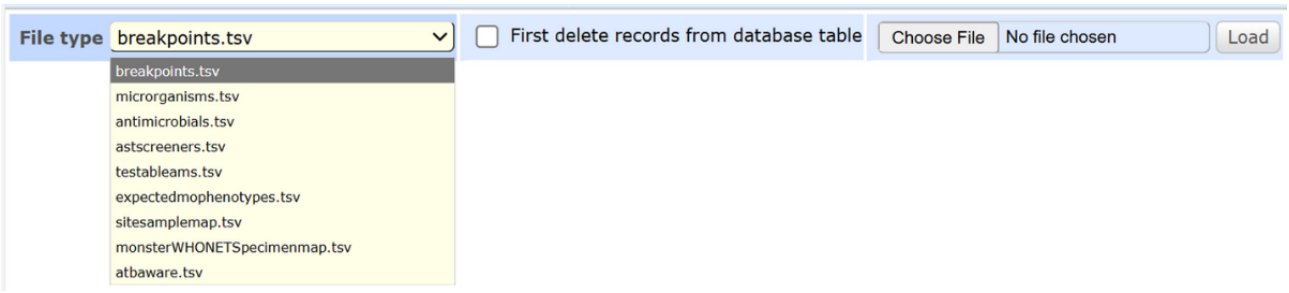
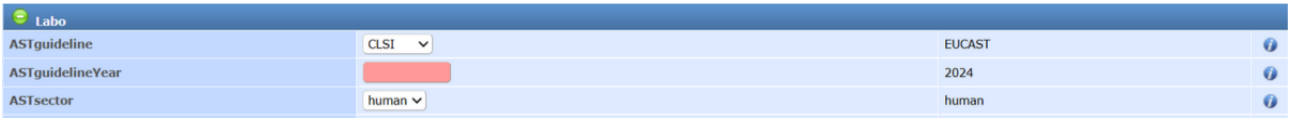
Figure 2. Screenshot of the metadata import interface, showing the dropdown menu for selecting file types, the file upload button, and the feedback panel for validation status.



Configuration Interface

A web-based tool allows users to configure the AST guideline (EUCAST/CLSI), guideline year, and sector (human or animal) to adapt the system to local needs (Figure 3).

Figure 3. Screenshot of the configuration interface, displaying dropdown menus for selecting AST guideline (CLSI/EUCAST), guideline year, and sector (human/animal), with multilingual support options. AST: antimicrobial susceptibility testing; CLSI: Clinical and Laboratory Standards Institute; EUCAST: European Committee on Antimicrobial Susceptibility Testing.



AWaRe Classification Management Interface

A dedicated tool manages the AWaRe classification of testable antibiotics. It displays a sortable table of antibiotics with their group, name, abbreviation, and AWaRe status or Not Available. Users update classifications via dropdown menus, with changes tracked client-side using JavaScript and submitted asynchronously to the server for database updates (Figure 4).

Figure 4. Screenshot of the AWaRe classification management interface, showing a sortable table of antibiotics with dropdown menus for updating AWaRe status and real-time feedback indicators. AST: antimicrobial susceptibility testing; AWaRe: Access, Watch, Reserve.

AST Result Entry Interface

Integrated into worklist management, this modal dialog supports manual entry and validation for up to three isolates per specimen, aligning with CLSI/EUCAST recommendations. Key features include: standardized pathogen identification via WHONET/EUCAST/CLSI taxonomy with autocompletion; dynamic antibiotic panels that expand based on whether to include screened antibiotics and/or those with expected phenotypes; real-time color-coded validation (green=Susceptible, yellow=Intermediate, red=Resistant) for inhibition zones or MIC values; icons indicating related antimicrobials and administration-route-dependent interpretations; alerts for invalid inputs, and incomplete method specification (Figure 5).

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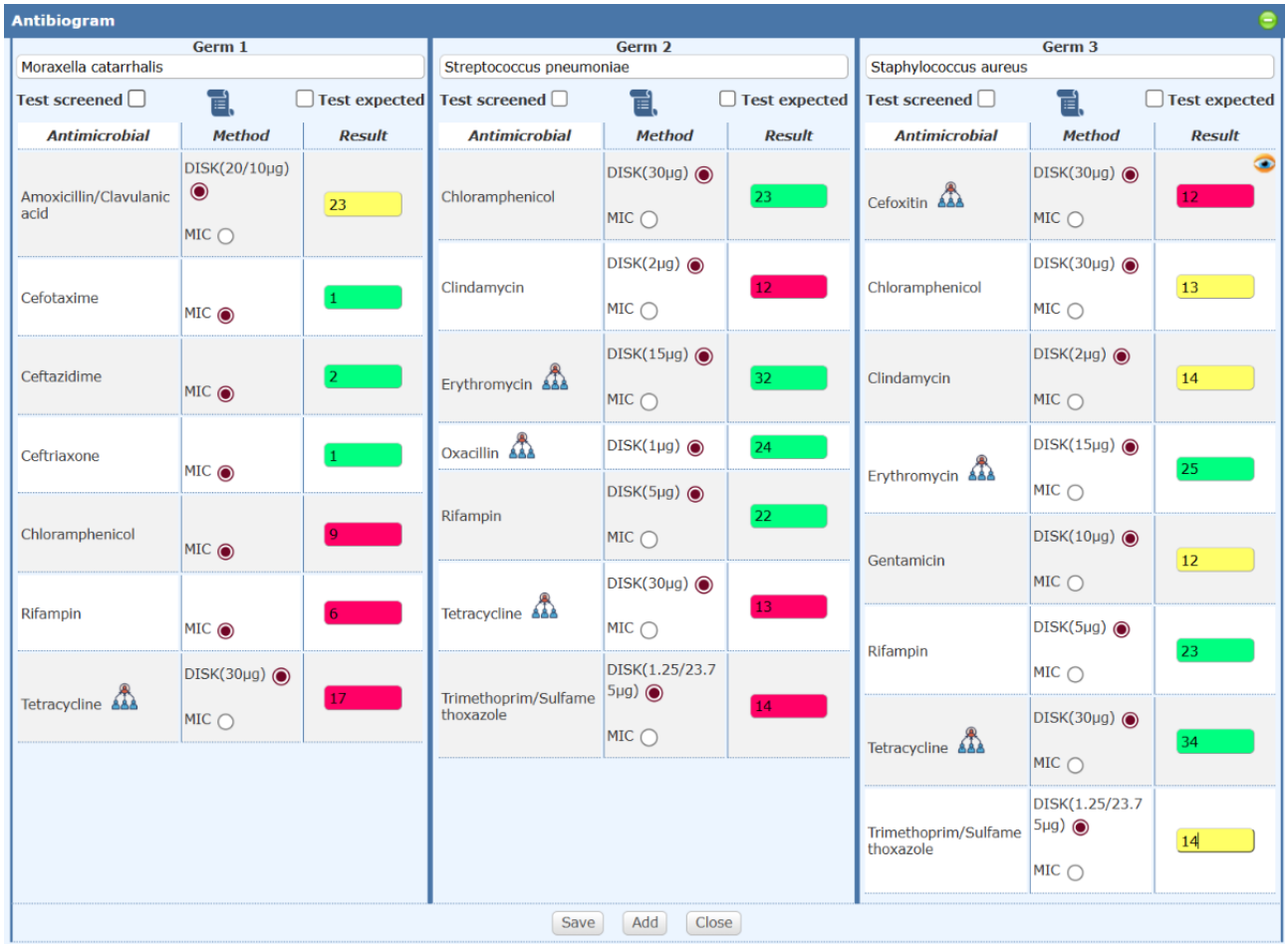
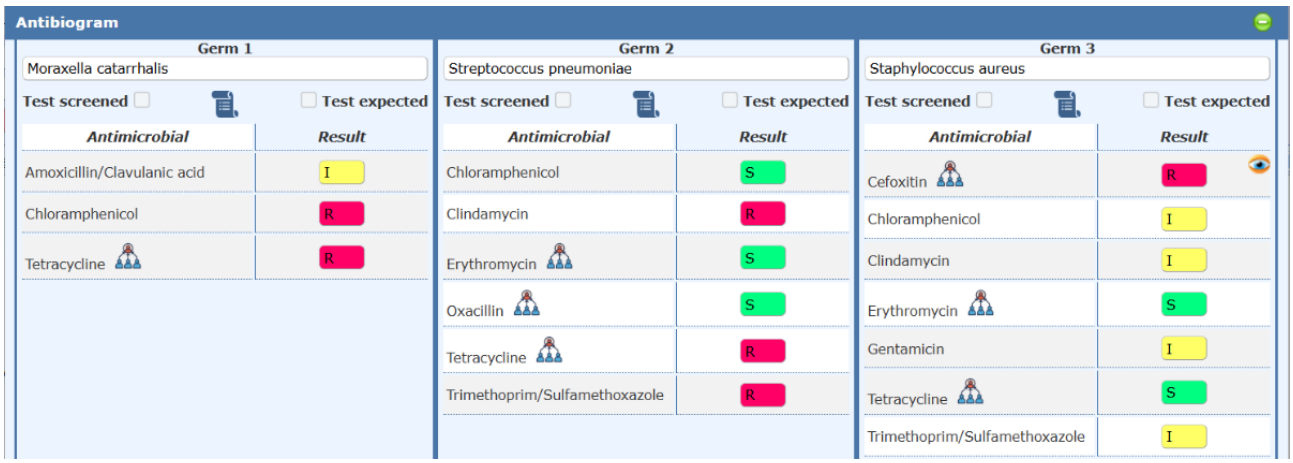
Figure 5. Screenshot of the AST result entry interface, showing the modal dialog with isolate panels, dynamic antimicrobial table, color-coded result fields, and autocompletion for pathogen identification. MIC: minimum inhibitory concentration.



AST Result View Form

Integrated into laboratory results view, this interface displays finalized AST results for clinicians, infection control staff, and surveillance teams, aligning with CLSI, EUCAST guidelines [12,22-24]. Results appear in modal dialogs grouped by patient and request time, showing up to three isolates with organism names, antimicrobials, S/I/R interpretations, and phenotype indicators. AWaRe–based selective display prioritizes Access antibiotics when susceptible or intermediate, then Watch, then Reserve. Read-only format ensures data integrity; edit history icons track corrections with timestamps and user details. Any pathogen isolated triggers red danger icons in the laboratory results overview that corresponds to automated SMS notifications at result validation sent to the patient informing result availability and to the requesting clinician alerting to urgently review results and take clinical action (Figure 6).

Figure 6. Screenshot of the AST result view form, showing the modal dialog with a grouped results table, color-coded isolate data, AWaRe-filtered antibiotic display, and tooltips for phenotypic comments. AST: antimicrobial susceptibility testing; AWaRe: Access, Watch, Reserve.



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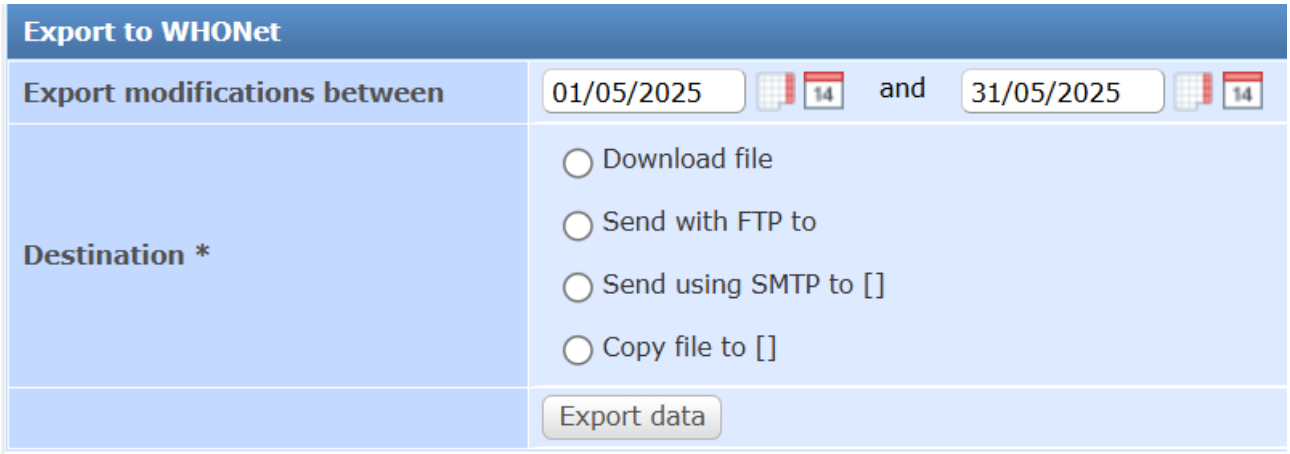
WHONET Export Interface

This interface enables seamless export of AST results to WHONET for global AMR surveillance, complying with WHONET's data formatting requirements. A web form with calendar widgets allows date range selection and export destination choice (download, FTP, SMTP, or directory). The system queries finalized AST records within the selected range, supporting multi-isolate reporting with patient demographics (ID, sex, age, WHO/CLSI age categories), specimen type (WHONET-mapped), pathogen identification, test method, antimicrobial codes, result values, S/I/R interpretations, guideline, sector, and workflow timestamps. Output generates TSV files matching WHONET import specifications, with legacy CSV support (Figure 7) [25,26].

Figure 7. Screenshot of the WHONET export interface, displaying the web form with calendar widgets for date range selection, a dropdown for export destination, and feedback on export status. WHONET: World Health Organization Collaborating Center for Surveillance of Resistance to Antimicrobial Agents.



Ease of Integration and Interoperability

The enhanced LIS incorporates interoperability features tailored for resource-limited settings, supporting structured data formats (TSV, CSV, JSON, HL7, FHIR) for direct mapping of organism codes, test results, and interpretations. Plug-and-play API endpoints enable the LIS to integrate with other systems with minimal development effort. Direct export to WHONET, WHO GLASS, and national platforms includes automated local-to-surveillance code mapping.

User Verification, Training and Deployment

Structured user verification and training were conducted before hospital-wide go-live. A dedicated User Acceptance testing was carried out by a team composed of the Laboratory Quality Manager, Microbiology Section Lead, and Information Communication Technology (ICT) staff under the supervision of the Head of Pathology. Nineteen detailed test cases covering system configuration, metadata import, AST result entry (disk diffusion and MIC), dynamic panel generation, EUCAST Expert Rules application, AWaRe–based cascade reporting, audit trails, WHONET export, data integrity, performance, and multilingual support were executed on 10 prospective samples, as per the laboratory standard operating procedure on user verification of LIS. All 19 test cases passed (100 % pass rate). Minor adjustments, mainly related to character encoding compatibility, were applied iteratively.

The six bacteriology laboratory staff received a full day of hands-on training. A 30-minute hospital-wide flash presentation of the new AST reporting features was delivered during clinical grand rounds, and finally, a 5-minute video tutorial covering the entire workflow was produced and disseminated via the hospital's official WhatsApp groups

The enhanced AST module fully replaced the legacy entry workflow for all new microbiology requests. For backward compatibility and data integrity, the previous (legacy) AST entry and viewing functionality was not removed or disabled. All AST results entered before enhancement remain fully accessible, searchable, and viewable in their original format without any modification or migration issues.

Ethical Considerations

The project received ethical approval from the CHUB Research-Ethics Committee (REC/UTHB/91/2023 renew, October 20th, 2024); individual informed consent was waived as the study was a quality-improvement intervention using routine clinical data. Patient confidentiality and data protection fully comply with hospital policy through role-based user authentication, display of patient identifiers and clinical information only to authorized clinical users, secure hosting within the hospital's firewalled data center with twice daily backups, and complete removal of identifiers from all shared data and aggregate datasets.

Results

The enhanced LIS, built on OpenClinic GA, significantly improved CHUB's bacteriology services, addressing LAARC-identified deficiencies (Multimedia Appendix 1). The system resolved qualitative gaps identified in the baseline LAARC audit, as detailed below.

Resolution of Qualitative Deficiencies

The enhanced LIS addressed the qualitative deficiencies identified in the LAARC audit (Section 1.4), all fully resolved. The following Table 3 summarizes the resolution status, referencing relevant system functionalities:

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Table . Resolution status of LAARC qualitative deficiencies.

LAARC deficiency	Status	Evidence and notes
Does not record AST method	Fully Resolved	Captures MIC/DD methods in the AST Result Entry Interface (Section 2.4.4) and includes them in WHONET exports (Section 2.4.5).
Cannot suppress antibiotic results for cascade reporting	Fully Resolved	AST Result View Form (Section 2.4.6) implements AWaRe-based cascade reporting.
Only S/I/R entered, not inhibition zone	Fully Resolved	AST Result Entry Interface (Section 2.4.4) captures inhibition zones/MIC values with automated S/I/R interpretation.
Cannot automatically interpret zone sizes	Fully Resolved	Automates S/I/R interpretation using CLSI/EUCAST breakpoints (Section 2.4.4).
Expert rules not integrated	Fully Resolved	Integrates EUCAST Expert Rules for phenotypic predictions (Sections 2.3, 2.4.4, 2.4.6).
Inconsistent antibiotic panels	Fully Resolved	Achieves 100% panel standardization (Section 3) via metadata-driven panels (Section 2.3) and AWaRe Classification Management Interface (Section 2.4.3).
Original results deleted during corrections	Fully Resolved	Tracks corrections via edit history icons in the AST Result View Form (Section 2.4.6), logging edited results with timestamps, reason and user details.

[a]LAARC: Laboratory Assessment of Antibiotic Resistance Testing Capacity.

[b]AST: antimicrobial susceptibility testing.

[c]MIC: minimum inhibitory concentration.

[d]DD: disk diffusion.

[e]WHONET: World Health Organization (WHO) Collaborating Center for Surveillance of Resistance to Antimicrobial Agents.

[f]AWaRe: Access, Watch, Reserve.

[g]S/I/R: Susceptible, Intermediate, or Resistant.

[h]CLSI: Clinical and Laboratory Standards Institute.

[i]EUCAST: European Committee on Antimicrobial Susceptibility Testing.

Key Functionalities

The system offers comprehensive AST functionality supporting both MIC and DD methods with automated interpretation based on the selected guideline. Results are displayed using color-coded outputs: green for Susceptible, yellow for Intermediate, red for Resistant, and pink for out-of-range values. The system provides real-time notifications for critical isolates to ensure timely clinical intervention.

Dynamic testing panels automatically adjust based on breakpoints, local antimicrobial stock availability, and clinical context, incorporating EUCAST Expert Rules and expected phenotypes. The cascade reporting feature prioritizes WHO AWaRe “Access” antibiotics, thereby reducing inappropriate use of “Watch” and “Reserve” categories.

For surveillance purposes, data export aligns with WHONET variable definitions, enabling seamless integration with WHO GLASS and national surveillance systems through robust interoperability features. The web-based interfaces, including the AST Result View Form, require minimal training and incorporate real-time feedback and tooltips to enhance usability for nontechnical staff.

Discussion

The enhanced LIS, built upon the OpenClinic GA open-source hospital information system, addresses critical gaps in CHUB’s microbiology services, offering a robust, standards-compliant solution for AST and surveillance in resource-limited settings. By integrating CLSI and EUCAST guidelines with metadata from the AMR for R package and EUCAST Expert Rules, the system ensures reliable AST results and real-time surveillance capabilities. The agile development approach, coupled with stakeholder engagement, resulted in a user-friendly system accessible to laboratory staff with minimal technical expertise.

The metadata-driven design, particularly the use of WHO AWaRe classifications and EUCAST Expert Rules, optimizes antimicrobial testing and supports stewardship by prioritizing “Access” antibiotics and flagging critical resistance mechanisms. The WHONET export interface enhances interoperability with global surveillance networks, contributing to AMR monitoring and policy development [1].

Comparison With Existing AMR Surveillance Platforms

The enhanced LIS offers distinct advantages over other popular AMR surveillance platforms by providing comprehensive, integrated laboratory workflow management within a clinical

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care context. Unlike WHONET, which operates as a standalone desktop on Windows environments and focuses exclusively on bacteriology data [27,28], the enhanced LIS is fully web-based, supports comprehensive clinical laboratory operations across all departments (hematology, biochemistry, immunology, microbiology) and accessible from any device with a standard browser, enabling real-time data entry, validation, and clinical decision support at the point of care. Integrated within the electronic medical record system, the enhanced LIS maintains continuity of clinical information flow from specimen registration through result reporting, directly supporting antimicrobial stewardship through features such as AWaRe-based cascade reporting, automated resistance phenotype detection via EUCAST Expert Rules, and critical alerts that prompt immediate clinical review. While District Health Information System (DHIS2) excels at aggregate health program reporting across multiple domains [29,30], the enhanced LIS provides specimen-level granularity essential for individual patient management, combining automated CLSI/EUCAST-based AST interpretation and quality-assured data validation within a single platform. This integrated approach ensures data serves dual purposes: immediate clinical utility for patient care and antimicrobial stewardship at the facility level, followed by standardized WHONET-compatible exports for public health surveillance at subnational, national, and global levels [6,15]. By embedding AMR surveillance capabilities within routine clinical workflows rather than treating surveillance as a separate downstream activity, the enhanced LIS maximizes data quality, clinical relevance, and public health impact while minimizing the burden on laboratory staff.

Scalability to Subnational and National AMR Surveillance Networks

The web-based architecture of the enhanced LIS provides inherent scalability for subnational and national AMR surveillance networks through centralized deployment models. The system can be hosted on centralized servers, enabling simultaneous access by multiple testing facilities through standard web browsers without requiring local software installation or high-specification hardware at peripheral sites. This approach ensures real-time data visibility across the network: facility-level users enter AST results through the web interface, while supervisory-level surveillance teams access aggregated data from the same system. From any supervisory level, the WHONET export interface generates standardized data files compliant with WHO GLASS requirements, enabling seamless reporting to global surveillance networks. The centralized model eliminates data fragmentation common in resource-limited settings, reduces infrastructure costs by avoiding multiple server deployments, and ensures metadata consistency (breakpoints, antimicrobial panels, AWaRe classifications) across all participating facilities.

Sustainability Considerations

Long-term sustainability of the enhanced LIS requires attention to three critical areas. First, continuous user training programs must be established to maintain laboratory staff competency in system use, AST interpretation, and data quality assurance. Second, metadata updates require sustainable mechanisms, including periodic review of CLSI/EUCAST guideline updates, AMR for R package datasets, WHONET resources and taxonomies, local antimicrobial availability changes, and emerging resistance patterns, with designated personnel responsible for metadata maintenance and validation. Third, ongoing technical support requires a multifaceted approach: capacity building for local information technology staff to handle routine troubleshooting, system upgrades, and eventually instrument integration; and sustainable funding mechanisms beyond donor-dependent models to ensure long-term system functionality and relevance.

Limitations and Future Directions

This study primarily describes the technical development and the qualitative resolution of LIS deficiencies identified in the baseline LAARC audit. Quantitative evaluation of key performance indicators was intentionally deferred to allow sufficient post-implementation observation time. Additional limitations include dependency on manual metadata updates and import, which may be challenging in resource-limited settings. Ongoing training is required to sustain system adoption and ensure data quality. Future enhancements could include automatic metadata updates, mobile app integration, and machine learning for predictive resistance modeling, which have shown promise in other AMR surveillance systems [23,31,32].

Conclusion

The enhanced LIS, built on OpenClinic GA and leveraging CLSI, EUCAST, and AMR for R metadata, demonstrates the feasibility of implementing standards-based AMR informatics in resource-limited settings. By significantly improving AST reliability, integrating clinical decision support, and enabling seamless integration with global surveillance networks, this model provides a practical roadmap for national digital stewardship programs. The system's scalability from facility to national levels, combined with its open-source foundation and standards-compliant architecture, offers a replicable blueprint for addressing AMR challenges, supporting both immediate patient care and long-term public health surveillance goals. Widespread adoption of such standards-based digital surveillance systems could significantly contribute to reducing AMR burden through earlier detection of resistance trends and evidence-based policy interventions.

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We thank the CHUB laboratory staff, clinicians, and public health experts for their invaluable feedback. The authors declare the use of Generative Artificial Intelligence (GAI) in the development of code for the LIS and manuscript writing process. According to the GAIDeT taxonomy (2025), the following tasks were delegated to GAI tools under full human supervision: code generation,

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code optimization, proofreading and editing, summarizing text, and reformatting. The GAI tools used were Grok 3, Gemini 3, GitHub Copilot, and Claude 4. Responsibility for the final manuscript lies entirely with the authors, and GAI tools are not listed as authors and do not bear responsibility for the outcomes [33].

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Data Availability

Metadata files, system documentation, and deidentified sample data are available at https://archive.org/download/metadata_LIS_CLISI_EUCAST/lmetadata_LIS_CLISI_EUCAST.zip under a Creative Commons Attribution 4.0 International License.

Authors' Contributions

• DM (Senior Consultant Pathologist, CHUB): Conceptualized the study, developed the model, served as principal investigator, and manuscript writing.
• ATT (Microbiologist, UR): Co-principal investigator, led the Research team, and contributed to manuscript drafting.
• GJD (IT expert, CHUB): Led user acceptance test and integration of new functionalities on production.
• MIB (Microbiologist, UR): Led the Diagnostic Stewardship team, contributed to metadata integration, and reviewed the manuscript.
• BJD (Laboratory Scientist, CHUB): Trained staff on microbiology processes, contributed to system testing, and reviewed the manuscript.
• KMF (Ear Nose and Throat Surgeon, CHUB): Served as General Secretary, coordinated administrative tasks, and reviewed the manuscript.
• II (Laboratory Scientist, CHUB): Facilitated training on Quality Management Systems (QMS) and contributed to system validation.
• RAl (Biochemist, UR): Coordinated events and public outreach, and reviewed the manuscript.
• ARO (Microbiologist, UR): Managed cumulative antibiogram generation and contributed to data analysis.
• BI (Finance Manager, CHUB): Handled financial and administrative logistics, and reviewed the manuscript.
• ASA (Microbiologist, UR): Managed AMR isolate biobanking and contributed to system testing.
• AAA (Pharmacologist, UR): Led the Clinical Stewardship team, contributed to antimicrobial stewardship strategies, and reviewed the manuscript.
• ME (Internist, CHUB): Managed data collection and analysis, and reviewed the manuscript.
• BA (Pharmacist, CHUB): Served as AMS and AMR surveillance liaison, and contributed to system integration.
• MF (Ophthalmologist, CHUB): Facilitated concept note writing and reviewed the manuscript.
• HS (Internist, CHUB): Managed clinical treatment guidelines and contributed to manuscript review.
• FH (Public Health Specialist, CHUB): Served as secretary for the Clinical Stewardship team and reviewed the manuscript.
• JPS (Microbiologist, UR): Trained staff on antimicrobial stewardship and contributed to system testing.
• RN (Pharmacist, CHUB): Monitored antibiotic prescriptions and reviewed the manuscript.
• NMJ (Anesthesiologist, CHUB): Coordinated project teams, facilitated stakeholder engagement, and reviewed the manuscript.
• TT (Anesthesiologist, CHUB): Oversee project implementation, and reviewed the manuscript.
• CN (General surgeon, CHUB): Led administrative logistics, oversee stakeholder engagement, and reviewed the manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Demo of new AST (antimicrobial susceptibility testing) reporting.
[MP4 File, 11375 KB - formative_v10i1e82727_app1.mp4]

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Abbreviations

AMR: antimicrobial resistance
API: application programming interfaces
AST: antimicrobial susceptibility testing
AWaRe: Access, Watch, Reserve
CHUB: University Teaching Hospital of Butare
CLSI: Clinical and Laboratory Standards Institute
DD: disk diffusion
EUCAST: European Committee on Antimicrobial Susceptibility Testing
GLASS: Global Antimicrobial Resistance Surveillance System
LAARC: Laboratory Assessment of Antibiotic Resistance Testing Capacity
LIS: Laboratory Information System
MIC: minimum inhibitory concentration
TSV: tab separated values
WHO: World Health Organization
WHONET: World Health Organization Collaborating Center for Surveillance of Resistance to Antimicrobial Agents

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Expression of Concern: Data Mining–Based Model for Computer-Aided Diagnosis of Autism and Gelotophobia: Mixed Methods Deep Learning Approach

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